University of Strathclyde
National Centre for Prosthetics and Orthotics

Evaluation of the Tracer CAD and T ring Prosthetic Shape Capture Systems

By

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A thesis submitted in accordance with the regulations governing the award of the Degree of Doctor of Philosophy in Prosthetics and Orthotics.

2009

This is to declare that this project is entirely my own work and has not previously been submitted to this or any other university.

Signature:……..

Anthony McGarry

Dedication

For Susie,

Fraser and Lewis.

and

also for my parents John and Margaret McGarry

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Abstract

The quality of prosthetic socket fit can affect the function of the final prosthesis and may be compromised by errors during the residual limb shape capture. Plaster of Paris and Computer Aided Design (CAD) systems are currently used with the residual limb exposed to different conditions. Limited measure of accuracy or repeatability of CAD systems exist when compared to plaster of Paris methods.

The thesis aims to evaluate the accuracy, repeatability and reliability of commonly used prosthetic CAD systems and compare results with traditional shape capture methods.

A survey established that the most commonly used CAD systems are the Tracer CAD and T ring systems which use the same software but different principles of operation.

Systems were evaluated using a series of models of known dimensions and volume. Each was measured by CAD systems and compared to a gold standard to evaluate accuracy and repeatability of diameter and volume measurement.

Reliability between users was also compared and found to be high when assessing all models using both CAD systems (ICC > 0.984).

Tracer CAD system repeatability was good (CV<5%) for diameter and volume measurements on solid models but less repeatable in areas of a manikin which were easily deformed (CV 9.66%). Less repeatability of T ring volume measurement was observed particularly at distal levels. Plaster of Paris casting was more repeatable than CAD systems. Poorer repeatability of volume measurement was observed at the distal end of deformable and shaped models (CV=8.97%).

Plaster casts showed the best accuracy of diameter measurement of all systems on non deformable models (<1mm) and similar accuracy of volume measurement compared to Tracer CAD. The T ring was the least accurate system. Errors were

largest on shaped and deformable models. Poorer accuracy was observed towards the distal end. Based on limited evidence, results indicate that methods of shape capture analysed do not show sufficient accuracy for prosthetic shape capture.

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Chapter 1

1 Introduction, aims and objectives

The primary focus of this thesis is concerned with methods of shape capture used at the trans-tibial level of amputation. Trans-tibial amputation is the most common level accounting for almost half of a total of 5000 new referrals to prosthetics service centres in the UK (NAS/DAB 2006/7).

Appropriate treatment for any patient with amputation involves the correct use of technology to capture the shape of the residuum and a sound knowledge of the interaction between the prosthetic device and the residual limb. It is accepted that the quality of fit of a prosthetic socket has an effect on the function of the final prosthesis (Datta 2000, Douglas et al. 2002) and can be compromised by errors during the capture of the residual limb shape (Radcliffe 1955, He et al. 1999, Johansson and Oberg 1998).

Scientific evidence to determine conditions necessary to provide an 'optimal socket prosthetic fit' is limited. Two fundamentally different socket designs exist side by side for the trans-tibial level of amputation; the patellar tendon bearing (PTB) and 'hydrostatic' sockets. Although both are routinely used in clinics, designs are based on conflicting and radically different rationales.

Traditionally, shape is captured by taking a plaster of Paris mould of the residual limb which is used for socket production. This may be taken by hand or with the limb exposed to a variety of different conditions, including the use of air or water pressure.

Whether the limb shape should be captured with a plaster of Paris (POP) cast or not, and whether the anatomical data should be obtained whilst weight bearing or

offloaded is also questionable. Conditions under which the residuum should be captured have been discussed by a number of researchers and clinicians who have attempted this in a variety of ways (Buis et al. 2003, Kristinsson 1983, Isherwood 1978, Murdoch 1968).

Depending on these conditions, an exact replica of the residuum may not fulfil criteria for optimal socket fit and the resulting shape captured will require modification. Material may be added to the shape captured over areas which, in the patient's limb are at risk of overloading, and removed from areas which are considered suitable for weight bearing (modification). Both the casting and modification procedures have been described as subjective, inconsistent, and performed on the basis of skill and judgement of the prosthetist (Kristinsson 1983, Convery et al. 2003). Errors associated with modification are not well understood or quantified. It has been suggested that plaster of Paris modifications present inherent difficulties in the quantification and recording of results used to produce comfortable sockets (Saunders et al. 1989). However, scientific evidence to support these statements or establish alternative methods is limited.

Researchers agree that the shape of the residual limb must be captured accurately and precisely although the degree to which this is required continues to be debated (Fernie and Holliday 1982, Lilja and Oberg 1997, Saunders 2003, Smith and Burgess 2001). It was hoped that the introduction of Computer Aided Design (CAD) techniques would minimise errors and that measurements produced would facilitate greater insight into the understanding of how to achieve optimal prosthetic socket fit (Lilja and Oberg 1995).

However, different CAD systems have been developed in different ways, and in isolation to other traditional shape capture concepts, instead of being used as a tool by which understanding of these concepts might be enhanced. The best method of shape capture using CAD has yet not been decided conclusively. Systems use both contact and non contact methods, and employ different modes of shape capture (mechanical digitisers; electromagnetic scanners; optical laser systems and digital

photography). Current systems do not permit the limb to be loaded whilst data is collected.

Lilja and Oberg (1995) stated that CAD systems required independent evaluation to ensure accuracy and improve understanding of how best to digitise shape. They believed this would allow identification of measurement errors before systems were introduced into patient care and also allow identification of future enhancements which may then be made to new systems. Despite this, systems have been introduced for clinical use without independent evaluation.

The repeatability and accuracy of prosthetic shape capture using different CAD systems has been reported in several papers (Hastings et al.1998, Johansson & Oberg 1998, Lilja & Oberg 1995, Oberg & Johansson 1993, Saunders et al. 2003, Vannah et al. 1997). However, socket fit is still poorly understood. No system has been directly compared to plaster of Paris and therefore the context in which these factors affect the final shape captured when compared to traditional plaster of Paris methods is still debated.

Prosthetic sockets shaped by traditional design have been compared to those made by CAD in several studies with varying success (Boone and Burgess 1989, Ellepolla and Sheredos 1993, Engsberg et al.1992, Holden and Fernie 1986, Oberg et al. 1993, Topper and Fernie 1990). CAD systems however have not fully replaced traditional methods of shape capture.

The scientific quality of literature in this area is limited. Different studies use different CAD systems which are difficult to compare. Most studies are limited in sample size, use convenience samples and different outcome measurements. No socket fit criteria were established in any of the studies identified which makes the 'success' of a socket from one study difficult to compare to other studies.

Studies often relied on subjective opinions of patients and prosthetists to compare the success of one socket fit to another made by a CAD process. Furthermore, as patients

and prosthetists were not always blinded to the treatment modality this may have influence on final results. As many studies predate 2000, most evaluate systems which have become outdated and no longer used.

The addition of the use of CAD systems seems only to have increased uncertainty in determining the best method of capturing the shape of the trans-tibial limb. As no agreement has been reached as to how shape should be captured, no consensus has been reached in determining the best method to use with CAD systems. This has resulted in development of different systems which employ different methods of shape capture for different socket designs.

The aims of this thesis are to evaluate the accuracy, repeatability and reliability of the most commonly used prosthetic CAD systems and compare results with traditional methods of shape capture using plaster of Paris.

A literature review was undertaken to establish the conditions which are most likely to produce an ideal fit of prosthetic socket. This thesis examines current trans-tibial socket design and identifies what exists in the way of prosthetic socket fit criteria.

The aim of the literature review also included investigation of current methods of prosthetic shape capture. Traditional and CAD methods of shape capture are examined including the conditions under which the trans-tibial residual limb is placed during each process.

To understand the extent of use of prosthetic CAD systems a survey of all UK limb centres was carried out. The success of each CAD system depends on how reliably and with what repeatability it achieves the required accuracy. Limited evidence exists on the extent to which errors of shape capture affect the fit of a prosthetic socket. Evaluation of CAD systems must therefore be compared to traditional plaster of Paris shape capture methods. This will place inaccuracy and lack of repeatability in capturing the final shape in the correct context.

Results are discussed and conclusions made as to the efficacy of each system. Recommendations are made for conditions required to produce the most accurate and repeatable method of shape capture based on socket fit criteria described in this thesis.

Chapter 2

2 Socket fit criteria and trans-tibial socket design

Traditionally trans-tibial shape has been captured by wrapping plaster of Paris impregnated bandage around the residual limb. Assessment of tissue consistency helps the prosthetist gauge the desired shape and volume of the final socket and determines how much plaster is removed from the shape captured. Buis (2003) believed that this process relied on artisan practice which he described as inaccurate and not repeatable. Many different methods of casting have been introduced to attempt to capture the shape more accurately and in a repeatable manner (Murdoch 1968, Gardner 1968, Kristinsson 1983). No consensus has been reached as to the best method of, or the conditions under which the limb should be placed during shape capture. Different principles of socket design exist side by side in the clinical arena, each with entirely different rationale.

In order to consider the success of any prosthetic shape capture system, including CAD, it is essential to specify the criteria which are desirable to promote optimal prosthetic socket fit.

This chapter will define socket fit criteria and describes socket designs currently used for the patient with trans-tibial amputation. Advantages and disadvantages with respect to errors of shape capture which may affect prosthetic fit are discussed.

2.1 What constitutes a good prosthetic fit?

To understand what constitutes a ‘good socket fit’ it is necessary to specify desired criteria required to ascertain this goal. However, very little scientific evidence exists in this area. One of the main bodies of work which identifies the contributing factors of optimal socket fit, is from an internal University of Strathclyde manual (Klasson 1995). Although this document has not been peer reviewed, it does provide a clear

and sensible rationale for the achievement of optimal socket fit. Klasson stated that a good fit is determined by:

- As stiff as possible a coupling between the skeleton and the prosthesis.
- No tissue damage
- Minimum discomfort

Biomechanical coupling elements exist between the soft tissues of the stump and the socket interface during static loading and throughout the gait cycle. To reduce detrimental shear stresses, internally and at the stump socket interface, the stiffness of this coupling is important to the success of the rehabilitation process. Stiff coupling will contribute to the static and dynamic stability of the prosthesis and reduce pistoning (Figure 2-1). Movement or displacement can actually happen in different areas: either between skin and the socket; between soft tissues; or soft tissues and bone, even when total contact is achieved. Reduction in pistoning between stump and socket may improve comfort, reduce pressure on sensitive areas and prevent the foot making contact with the floor during swing phase. It is suggested that higher stiffness increases proprioception which is important as prosthetic users experience limited feedback from the prosthetic foot (Kristinsson 1983, Buis et al. 2003.)

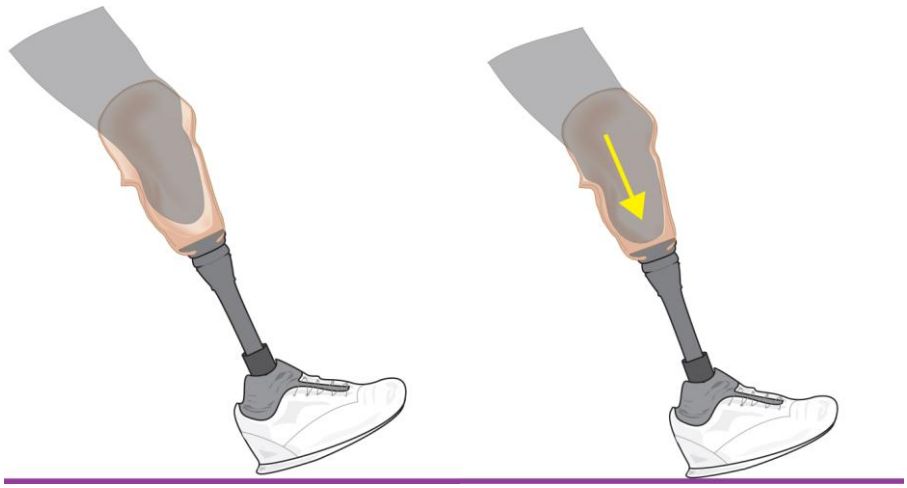

Figure 2-1 Residual limb position terminal swing and (Rt.) at initial contact (Pistoning).

It is important that the load, which is distributed over the total area, is at a level which is tolerable to the user. If the shape of the stump is not captured accurately or under the correct conditions, problems may occur at the stump / socket interface as high local pressures and prominences such as the head of the fibula may not be adequately accommodated within the prosthesis. The position of prominences such as the head of the fibula or the tibial crest will change relative to the socket at different points of the gait cycle and be subjected to excessive local pressures should accommodation not be made for these prominences (Figure 2-2, Figure 2-3).

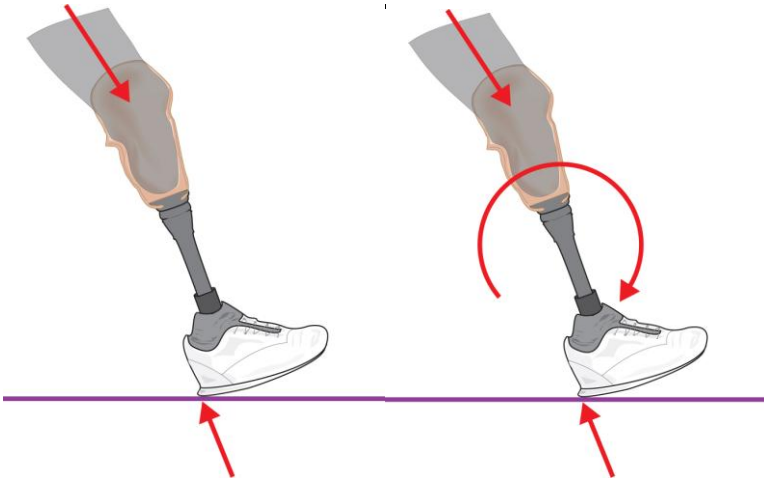

Figure 2-2 Misalignment of support and ground reaction forces causing coupling

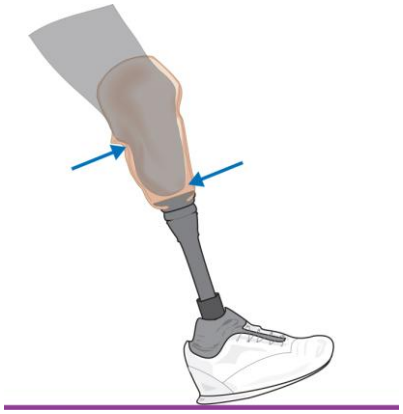

Figure 2-3 Resulting forces during loading response.

It is normal practice to influence the shape of the prosthetic socket by modifying the plaster positive cast on which it is formed. This is achieved by the addition of plaster on a positive stump model which results in local pressure relief in the socket wall.

However, if reliefs are excessive, the prosthetist will lose area for force transmission and increase pressure on the surrounding areas.

Pressure is equal to force applied per unit area of application. The amount of pressure (stress) applied determines the deformation of tissue in relation to thickness of the layer of tissue (strain).

As the load on an area of the residual limb increases, pressure increases and tissue thickness decreases. If the thickness of the soft tissues varies and the indentation or deformation is the same over the area, then the pressure will be higher at the thinner areas. Ideally, the socket shape is modified to allow for this. However, if a small error is made in the socket shape over thin soft tissue or a hard bony area then even greater pressure will result.

The distribution of pressure has been the subject of debate throughout the history of socket fitting. According to Klasson (1995), the ideal pressure distribution over a selected bony area of the stump is a uniform pressure distribution if the purpose is to make sure that local pressure peaks are avoided or minimised. Although a uniform pressure distribution may result over certain areas an even pressure distribution over the stump throughout the gait cycle is not possible since the forces and moments vary (Figure 2-2 and Figure 2-3.)

Buis et al. (2003) contended that it is ideal only to avoid peaks and that it may not necessarily be ideal for tissues to have a uniform pressure distribution. They were of the opinion that the ideal loading pattern would be able to accept the highest load applied without exceeding the tissue pressure tolerance level. Uneven pressure distribution strives to push the material from high pressure areas to low pressure areas prevented only by potentially damaging shear stresses. The uniform pressure distribution is desirable at the highest load during the gait cycle since it is logical that the risk for tissue damage is highest at peak loads. If this is achieved then theoretically there may be no requirement for relief over bony prominences.

This is only partly true as the assumption is made that dynamic and static situations are the same. During stance phase, much higher pressures may be acceptable if applied over a shorter time span

Figure 2-4 (Reswick and Rogers 1972) shows maximum tolerable pressure related to duration of application for porcine tissue.

This figure provides guidelines about pressure duration tolerance, although is intended to be used in connection with bed - sore prevention in healthy tissues and is of a static nature rather than cyclical loading. Values above the curvature of the graph are considered unsafe, whilst those below the curve are considered' safe'. This paper used the assumption that porcine tissue would exhibit similar properties to that of humans.

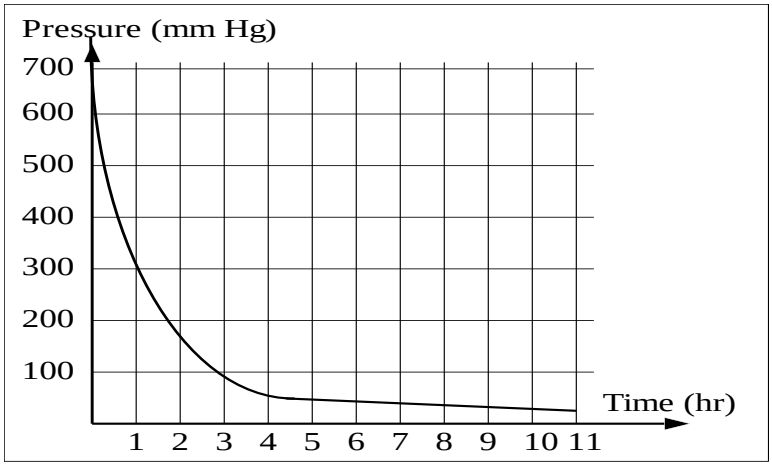

Figure 2-4 Safe pressure (Reswick & Rogers 1972)

The rationale for using interface pressures rather than shape replication to define a comfortable socket is based upon the behaviour of the soft tissue of the limb segment that remains after amputation (Krouskop et al. 1987). It may also be because it is easier to measure.

Interface pressure and shape are likely to be related. It is probably not possible to determine the final loaded shape of the stump unless we have a means of capturing the shape under normal loading conditions. If the shape cannot be captured in this

way then the only alternative is to substitute the missing information by modification of the original (unloaded) shape.

The trans-tibial residuum consists of non-homogeneous surfaces of different underlying shape and size which are subjected to different conditions as the load changes. This situation becomes even more complicated when the tissue stiffness is not constant either due to the stump shape or where stiffness gradients cause stress concentrations (Murphy 1954).

If the soft tissue layer over loaded bony areas is only 2mm thick, it would prove very difficult to design a surface matching that results in an even pressure distribution at peak loads. Small errors in socket shape may increase the local pressure considerably decreasing the surrounding pressure. Even pressure distribution is difficult to achieve using rudimentary tools in the plaster room. It is likely that errors would be introduced as modifications are difficult to quantify. The addition and removal of plaster is not improved by the use of computer programmes which incorporate a modification process as the result cannot be measured. Visualisation of the shape on a monitor does not enhance this process since the prosthetist experiences the same difficulty in knowing how much to add or remove from the original model.

2.2 Summary

In conclusion, the final shape of the socket must accurately resemble the shape of the residual limb under peak loading conditions. To do this the shape of the limb should ideally be captured when loaded. Reliefs are not desirable as these promote boundary shear stress in localised areas. Residual limb shape capture under different conditions requires the captured shape to be modified. However, this has the potential to introduce discrepancies in shape between the loaded stump and socket. Such a result would affect the stiffness of the coupling mechanism with the potential to introduce pistoning, excessive peak pressures and detrimental shear stresses. This could result in discomfort and potentially tissue damage to the residual limb.

2.3 Trans-tibial socket design

The socket of a trans-tibial prosthesis is important because the residual limb does not have the same weight-bearing capabilities as the normal foot. Therefore, the design and fit of a socket are important factors in the successful rehabilitation of a patient. However, many different opinions still exist regarding the weight-bearing characteristics that a prosthetic socket should possess (Fergason 1999).

As far back as 1954, Murphy reported on considerable confusion and lack of basic knowledge in the entire field of fitting a socket to a stump. He stated that some prosthetists and surgeons argued for uniform distribution of pressure over the stump while others believed in supporting high pressures in certain tolerant areas considered physiologically able to support weight. Relief of pressure is advocated correspondingly on other areas of greater sensitivity. Murphy stated that individual prosthetists differed as to the exact areas involved and the methods employed.

Over fifty years later, both concepts are still advocated and used in the clinical setting in the form of the Patellar tendon bearing (PTB) and the Total surface bearing (TSB)(also known as total surface volume matching (TVSM) or hydrostatic) socket designs.

Both socket designs have been extensively reported and are described in detail below.

2.4 Patellar tendon bearing socket design

The PTB socket design was first described by Radcliffe and Foort (1961), and was originally introduced in 1959. This socket design followed clinically evaluated methods including weight bearing on the medial and lateral tibial flares (usually with an open-ended socket), or partial support using a thigh corset, and was made possible with the advent of new casting and manufacturing materials.

The PTB concept used the design criterion that pressure should vary according to the pain threshold of different tissues in the residual limb (Radcliffe 1961, Murdoch 1968). Specific pressure-tolerant and intolerant areas of the residual limb were identified, and pressure tolerant areas loaded and sensitive areas relieved. Pressure sensitive areas tend to be bony and include the fibular head, tibial crest, tibial tubercle, cut end of tibia and fibula (Figure 2-5). These bony areas may not be able to tolerate high stresses (Radcliffe 1961).

The design followed the criterion that because the weight bearing capacity of the stump was somewhat limited, the prosthesis must be designed to place a major portion of the supporting loads on the structures around the knee joint. The areas which are adaptable to weight are the patellar tendon and the medial and lateral flares of the tibia. Because the flare surfaces are oblique to the floor, the total pressure on them must be greater than the vertical support component.

The amount of tissue loading in the final socket is determined during the casting and modification processes by the prosthetist. The shape is captured with the limb in an unsupported, unloaded position. In the PTB design the tips of the thumbs are used anteriorly to indent the plaster of Paris wrap cast on either side of the patellar tendon. The required counter pressure is achieved posteriorly by the second and third fingers which are used to form the popliteal indentation at this level. The PTB socket had its own specific alignment in 5 degrees initial flexion so that full advantage was taken of the patellar tendon as a weight bearing structure and to make full use of the remaining knee function. If supracondylar suspension was prescribed a proximal slab of plaster of Paris bandage could also be added and moulded to capture and define the proximal shape. The motion of the hamstring tendons must be accommodated in the shape of the posterior wall to prevent abrasion.

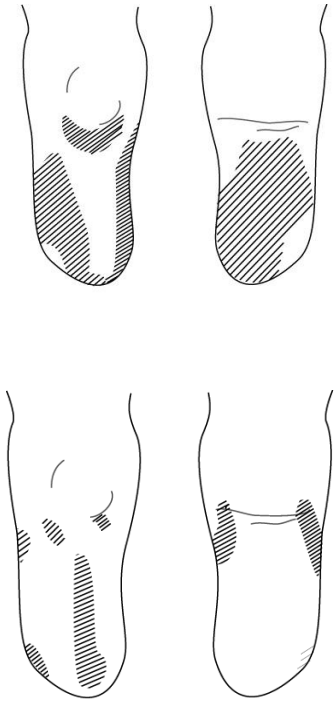

Figure 2-5 Pressure distribution of a PTB prosthesis

As the cast is taken in an unloaded position, an exact mould of the residuum does not fulfil criteria for optimal socket fit and requires modification. (Radcliffe 1961). Material is added to the positive plaster model over areas which are pressure intolerant and removed from areas which are loaded for weight bearing (Figure 2-5). Both the plaster casting and modification procedures are subjective and dependant on the skill and judgement of the prosthetist.

If the socket is to transfer the support and control forces to the skeleton the prosthetist must be conscious of the underlying skeletal shape. The prosthetist must also be aware of tissue consistency and the load bearing capabilities of the soft tissues overlying the skeleton if volume matching is to be achieved. The amount of plaster which is removed is dependent on the prosthetists assessment of the density of the stump tissues and on the quantity of tissue present. Judgement is required to assess the amount of plaster to be removed from the model and the size of the plaster build ups.

Another factor which affects the amount of shape modification is the deliberate deformation introduced during wrap casting. The success or otherwise of such pre-shaping will affect the amount of plaster removal required.

The prosthetist must also be concerned about the angle at which the cast is taken and that the cast is taken with the patient in a relaxed position, as both will affect the shape captured. Lilja et al. (1999) investigated the effect of muscle activity on stump volume. He found that a significant increase (up to 5%) in stump volume was recorded when patients contracted the stump muscles compared to that of the relaxed stump. This occurred regardless of whether a silicone liner was used and he considered that this would have a detrimental effect if a stiff coupling is to be achieved during gait.

Many prosthetists have tried to eliminate plaster modification from the process and attempted to get as close as possible to an even pressure distribution when they make the cast at the stump. Holmgren (Klasson 1995) went as far as to say that 'there was no truth in the plaster room.' He stated that if he failed to get the fit right, he would not modify it in the plaster room, (except for some reliefs,) but preferred to go back to the stump and make a new cast with a new pressure distribution.

Kristinsson (1993) argued that a trans-tibial socket, designed to transfer loads primarily to limited areas of the limb such as the patellar tendon and the medial flare, was in most cases both ineffective and uncomfortable. The most effective socket, in his view, was one that relied on the hydrostatic principle for load transfer.

However, the author presented expert opinion and this was not backed up with scientific evidence to substantiate the claims made that this design offered considerable improvement to the weight bearing capability and the interface between the prosthesis and the user. It should also be noted that in the years since it was first introduced, thousands of amputees have been fitted with, and benefited from the design of the PTB prosthesis.

Several researchers have reported on PTB stump / socket interface pressures using a limited number of individual transducers.

Hulshof (1995) tested whether the amount of distal end loading correlated to proximal variations in the socket design. He created six versions of the same socket using a CAD system. The shape and volume of these were altered at four socket locations using the rectification software. This allowed investigation of socket end pressures related to shape and volume.

Results from this study indicated that the traditional modifications at the patellar tendon, medial flare and lateral flare can reduce distal end pressure in the static position. However the reduction in distal end pressure was relatively small for an average rectification. In the over rectified model, the end pressure dropped considerably more, but it was thought that the skin condition of the patient in the patellar tendon area after the tests suggested that a rectification of this area of such severity would not be tolerated for a long time.

An overall impression of the stump / socket interface pressure distribution was not possible with the type of pressure transducer used in this study and Hulshof recommended further tests to determine the contribution of each individual rectification.

Hulshof did report a difference in distal end pressure in dynamic tests results but reports no clear evidence that the rectifications had a significant effect. This suggests that tests were not sensitive enough or that other mechanisms, (such as the alignment of the prosthesis,) play a more important role in providing dynamic support than the socket rectifications.

Convery and Buis (1998) investigated and described the distribution of the pressure patterns monitored during prosthetic stance phase gait of an amputee wearing a PTB socket. Force sensing resistors (FSR) were used to measure dynamic stump/socket interface pressures during the gait of a trans-tibial amputee. A total of 350 pressure

sensor cells were attached to the inner wall of a patellar tendon bearing (PTB) socket and pressures recorded during a single prosthetic stance phase.

A distinct pressure pattern was demonstrated. A ring of pressure at the patellar bar level in the PTB socket was noted with no major distal end pressure. Four areas of the socket that experienced pressures in excess of 100kPa were identified: patellar bar, proximal popliteal area, the posterior medial flare and the fibular head.

Limitations of this study were in the sample size and the authors concluded that a greater number of subjects must be investigated to confirm the effectiveness of different socket designs.

Inaccuracies have been reported using FSR technology (Cavanagh et al. 1992, Ferguson-Pell and Cardi, 1992). These are mainly due to drift, hysteresis, temperature sensitivity, and the loading rate and range.

As sensors are statically loaded they may deform causing drift and may exhibit hysteresis as they are loaded and unloaded causing errors in readings. The frequency of the rate of the load applied can result in aliasing if the system is not responsive enough and the load cells must exhibit the same behaviour when subject to different ranges of load.

The FSR was designed for use in footwear to measure plantar surface pressure in podiatry. This application may have resulted in bending of the force sensor as the foot rolled over resulting in errors of measurement. To combat this, Buis (1997) developed and validated a unique *in situ* equilibration and calibration protocol specific for prosthetic socket applications. Convery and Buis (1997) used this procedure and glued the pressure sensors to the socket and used a pressurised gel filled bag to equilibrate the sensors in situ. This overcame any errors produced by the curvature of the socket and showed reduced drift after a period of loading.

Kim et al. (2003) aimed to determine the effect of the patellar tendon on pressure distribution within the socket by varying the depth of the modification in this area in 2mm increments. Results ascertained that an increase in modification of the patellar depth did significantly affect pressures in certain other socket regions and that the patellar tendon could be used successfully to offload these areas. Higher loading of the patellar tendon could however cause discomfort and skin breakdown should it be excessive. The study was limited by a small sample size (n=5). The selection criteria for this study are vague and do not indicate the age or weight of the patient, the length or shape of the residuum, or cause of amputation which could have some effect on results obtained. No socket liners were used to allow the pressure sensors to measure forces as accurately as possible. However, pelite liners are normally used in this design of prosthesis. Similar measurement system problems (drift, hysteresis etc) also exist as with the previous study by Convery and Buis (1997).

Despite the limitations of the experimental design and measurement systems the study concluded that the optimal depth of the patellar bar varied from patient to patient as residual limbs were different and had different loading capabilities. A change in depth of the patellar tendon was found to have a significant effect on the load applied to other areas. The study did state that patients reported that sockets felt most comfortable when the bar was carved to a depth of 4mm; however this was based upon the subjective feedback of only five patients using four differing thicknesses of patellar bar spacers.

2.5 Total surface / volume matching (TSVM or 'Hydrostatic' sockets)

The TSVM socket design may be produced by hand casting but are generally created by pressurised casting techniques. This socket relies on the theory based upon Pascal's principle of fluid dynamics also known as hydrostatics. This principle states that pressure when applied to an enclosed fluid is transmitted undiminished and equally to every part of the fluid as well as to the walls of the container. As fluids and semi-fluids are relatively incompressible, under varying pressure they will remain at constant volume.

The stump is complex but for simplification is referred to as an elastic solid with low stiffness surrounding a piston. If the mass can be fitted into a containing vessel corresponding exactly to its volume the fitting can be expected to behave like a hydrostatic system when loaded. In the absence of motion, there is no shear stress and the internal state of pressure determined by the load itself. Therefore, the pressure at a point is the same in all directions and the pressure designed to support the weight would be determined by the cross section of the socket opening.

The hydrostatic principle for load transfer is possible when the volume of the soft tissues in a residual limb can be contained in the same volume in a socket so that no fluid is lost or tissue displaced from this volume. A closed system may then be maintained and a hydrostatic system established.

However, these theories have limitations in being applied to hydrostatic weight-bearing in sockets as they assume that gravitational forces are negligible. Most importantly they also assume a closed system when the residual limb is not a closed fluid system. It should also be noted that Pascal's principle assumes a fluid at rest. Fluid in the residual limb is not at rest and therefore shear stresses will not be zero. Because of these limitations, these sockets are referred to as 'quasi-hydrostatic'.

In the total surface / volume matching design (TVSM), thick walled polymer sleeves with varying degrees of thickness are normally used, consisting of a gel-like silicone or polyurethane with 'flow' characteristics. Sleeves are initially selected by circumferential measurement of the distal stump. Once rolled snugly onto the stump they claim to offer a more even pressure distribution within the prosthetic socket and are especially suited to pronounced bony prominences or scars (Kristinsson 1993).

A literature review of the possible advantages of silicone liners was conducted by Baars and Geertzen (2005). The aim of this review was to examine the evidence to support claimed advantages of silicone liners i.e. improved suspension, skin protection and improved cosmetic appearance. Five papers were reviewed from an initial total of 132 articles. Results indicated low evidence in support of silicone

liners in trans-tibial prostheses due to the poor quality of study design. However, the review did state that suspension was improved when wearing a silicone liner as this part of the literature was judged to be of good design, although based on patient's opinions.

Walking patterns were also thought to be improved as this was shown in all studies, with less dependence on walking aids and increased outdoor walking recorded. Skin problems, such as increased perspiration, abrasion, itching and irritation however, were not generally solved by, and sometimes caused by the liner (Cluitmans et al. 1994; Datta et al. 1996; Hachisuka et al. 1998).

Other contra indications for the use of silicone may include cognition impairment as the donning and doffing of liners does require a level of thought, understanding and care to ensure correct function and minimise possibility of damage. Poor hygiene may also contraindicate the use of silicone liners which, due to their close proximity to skin tissue, can promote heat with associated sweat and infection implications.

'Hydrostatic' sockets may include small rectifications on the anterior distal tibia, fibular head, and the tibial crest. The sockets produced are notably different in shape than the traditional PTB socket. One major difference is that hydrostatic sockets are not indented proximally in the patellar tendon region and in the posterior popliteal region of the socket. Another difference was that while the PTB socket biomechanics were developed with respect to each phase of the gait cycle, the hydrostatic socket simply assumed that pressure at one point would be transferred by the fluid principle to other accommodating soft tissues.

If a cast is taken by hand it will be necessary to modify the cast to simulate the static loaded stump shape. A hand casting procedure involves taking the best cast that a prosthetist can by hand, and reducing and deforming the shape at rectification. During rectification, when a prosthetist removes material, the aim is a reduced volume which will displace the stump and the liner towards the opening. When the socket is loaded it reaches equilibrium with little further tissue displacement (if there

are any reliefs or air gaps in the socket then the material will attempt to fill them when under pressure). Modification of the cast shape has the potential to introduce error as discussed previously.

It is thought that the most uniform spread of pressures is resultant from pressure casting (Buis et al.2003, Kristinsson 1993). Pressures applied displace tissues relative to the bony structures (equivalent to the reduction of a hand cast) and ensure no air spaces in the socket. When body weight is transmitted into a socket an equilibrium point is achieved. A good fitting is one that reaches equilibrium with little vertical movement or pistoning. To explain this further the weight is transferred from the body and soft tissues via the skeleton. The rigid socket applies the opposing force; any soft material between these two rigid components will attempt to equalize the pressure over the whole system.

One of the uncertainties of pressure casting in general has been the pressure magnitude and duration required in order to create a good socket fit. Gardner (1968) recommended an applied pressure of 13kpa. whilst Kristinsson (1993) proposed pressure levels of 23 to 34 kpa, commenting that applying pressures of less than 23kpa often resulted in a slack fit. No experimental evidence exists to suggest the ideal pressure under which a shape should be captured. As stump tissue is not compressible, this implies that tissue fluid will migrate from the stump with the application of constant pressure (Krouskop et al. 1987).

An attempt at pressure casting was first described by Murphy (1954) and has since been developed by Wu et al. (2003, 2009) and evaluated by Thanh et al (2009), where an impression of a trans-tibial residuum was made using a ‘dilatency’ machine. This involved placing the stump in a canister with sand placed in an annular space in-between the stump and the container. A rubber sock sealed between the stump and the canister and the space was evacuated until the beads reached the desired firmness. The patient was weight bearing as the canister was evacuated and so an accurate weight bearing impression was obtained. The patient was asked to

withdraw from the container while the vacuum was maintained. This gave an accurate impression which could be filled with plaster.

Additionally the machine had “knurled wheels” which could be tightened to apply pressure to the posterior aspect of the stump. Rectification techniques also allowed felt pads of the desired shape and thickness to be added prior to shape capture to allow relief of certain areas.

As this medium was sand it may not represent a true weight bearing situation and if so would only represent a vacuum capture of the limb in a partially loaded situation. This device did not represent a controlled uniform distribution of the pressure that a liquid medium can supply. The danger in this socket is that as the person pushes into the socket a ring of tension may be applied proximally as the pressurised sand displaces the surface tissue of the stump. Furthermore, the ability for the prosthetist to make shape adjustments using knurled wheels or rectification pads undermines the repeatability of the process and could introduce potential errors.

Wu (2009) presented a technical description of the CIR casting system in which the sand medium was replaced by lightweight polystyrene beads. This system was primarily designed to save costs, (no plaster is required), and waste in the developing world.

Thanh et al (2009) report on preliminary experiences when using the CIR system in a pilot series of ten patients. The series compares the quality of fit to the original sand casting mechanism but does not define criteria on which ‘a good fit’ was based. Results do seem encouraging with a significant reduction in circumferential measurements when compared to sand casting. However, the reduction was compared to the original sand casting technique which was reported to require between two to five stump socks. The study also reports on findings of only one prosthetist. As modification of the captured shape is required it is possible that a larger variety of sockets could be produced by different prosthetists.

The Dundee socket was first introduced by Murdoch (1968). Work on this concept commenced when difficulties were being experienced in producing consistency in sockets for trans-tibial patients using the PTB concept. This was blamed on three areas:

1. Inadequate training of prosthetists in the PTB technique
2. The persistence of cast rectification in central factories rather than by the prosthetists
3. The system of prosthetic manufacture including socket fabrication in centralised factories.

The purpose of the programme was to determine whether a socket could be produced which would eliminate the hand as a deforming factor. Murdoch (1968) argued that as the prosthetist makes patellar bar and popliteal indentations that he is squeezing the AP dimension, thus creating a narrow AP and subsequently a wide ML, since the tissue must move somewhere. He stated that prosthetists hands varied considerably in size and dexterity which placed doubt over the consistency of the casting method. This results in loose contact over the condyles when viewed in the coronal plane. The prosthetist may then attempt to rectify out this error created during the casting process.

For the Dundee socket, a hydrostatic concept was introduced. This was also called the “no hands” concept as the prosthetist should not be able to influence the design of the socket shape.

Water was contained in a stainless steel tank in the form of a truncated cone with a circular opening at the proximal end to allow the patient to enter. Water was allowed to enter and exit via a narrow hose from a tap. Air was allowed to exit from the top of the tank. Plaster of Paris was wrapped around the stump. Water was run into the tank still allowing the stump and lower thigh to enter and the patient stood with weight equally distributed between the amputated and sound side (stump loaded to approx 2 psi.) The stump was separated by a double nylon sheath from the water. Water was added as required until the patient was evenly balanced and the amputated

limb immersed in the tank to a point about 3” above the knee level. The patient was also asked to flex the knee to approx 10 degrees flexion which was sufficient to bring the hamstrings into hard relief.

The aim of this concept was to apply a uniform pressure around the residual limb. This concept was developed to remove factors such as human error in the shape capture process and to produce a cast which truly represented the shape of the residuum under load.

This said, the socket, although used in walking trials, did have a rubber patellar tendon bearing bar added, something which goes against the principles of a total surface matching and volume matching design. This was to allow the optimum loading of the patellar tendon bar and correct positioning of the patient within the socket. Plaster was also added to the positive mould over the distal tibia to allow pressure relief over this area.

It is not clear why Murdoch and the prosthetic team did not persist with this socket design but instead reverted to the PTB socket. With the exception of the patellar tendon bar modification, the ‘Dundee socket’ was based on sound rationale which attempted to improve the repeatability of the quality of fit of sockets at a time when PTB sockets were first introduced. The quality of PTB sockets at this time was detrimentally affected by the fact that the casts taken were modified by technical staff in centralised locations who had never met the patient, something which is now considered to be poor practice. One can only speculate that problems were solved by training of prosthetists in correct procedures for casting and modification of the PTB design. However, this does not address Murdoch’s concerns about repeatability and uncontrolled deformation of casts by different prosthetists.

In 1968, Gardner invented a pneumatic shape capture system for trans-tibial casting. Gardner worked on the theory that higher pressures should be concentrated in tolerant areas with gradually reduced pressures applied to the surrounding areas tapering to controlled lower uniform pressure over the remainder of the stump. The

system involved a pressure sleeve cone with an inner and outer wall. Air was introduced into the chamber by a small hand pump. When this happened, the outer sleeve varied only slightly in dimension whereas the inner sleeve moved more freely. The casting forms consisted of two resilient sections of moulded latex. One form was shaped to concentrate force over the anterior proximal portion of the stump in the patellar tendon area. The contour of that side of the stump was convex forming a transverse ridge over the patellar tendon bar. The posterior portion was convex and slightly wider and thicker in its centre so that if placed between the hamstrings, it flattened the popliteal area whilst relieving the hamstrings. No attempt was made to control the amount of flexion although the person was cast in relaxed attitude. The inflated pressure sleeve was said to control flexion.

Prior to casting, it was necessary to make a distal end cap in plaster of Paris. A pressure of 2 psi. was maintained. Rectification involved a wash of plaster over the fibular head and anterior tibial crest from the tibial tubercle to the distal end. The distal tibia was routinely built up with plaster of Paris to avoid socket contact at this point.

Whilst an adequate technical description of equipment and methods of casting are given, no clinical trial has been published using this equipment making evaluation of this method difficult.

Other pressure casting methods were described between 1969 and 1996. Isherwood (1978) described a controlled hydraulic pressure distribution casting technique in which individually placed pockets, shaped for particular areas within a socket simulator, were inflated with water. This was coupled with pre fabricated foam relief pads placed over pressure sensitive areas, thereby loading the residuum in pre determined, specific areas, in a measurable and consequently repeatable manner.

Adjustment in load distribution with the patient weight bearing was possible. This was achieved via a hydraulic end pad and five additional syringes connected to the individually inflated bags. Each bag was inflated to an initial pressure of 9-10 psi

with the patient bearing 50% of his weight into the system. Results were based on prosthetist and patient interaction.

Advantages of the system were in the patient interaction and the feedback the prosthetist received into socket design during the simulation stage as well as minimal rectification of the positive model (Tanner 2008).

Disadvantages of this technique were that it relied on the individual skill of the prosthetist combined with patient feedback in the same manner as a hand cast. This was considered a time consuming process that took prosthetists some time to learn and perfect. It called into question the possibilities of increased or insufficient loading of stump areas and whether this would always promote the optimal socket. The lack of quantification suggests that repeatability of results may also be difficult. No scientific studies have been carried out to examine the success or efficacy of this method and only anecdotal results are reported.

Kristinsson (1993) proposed that the socket, designed to transfer loads to the limited areas of the stump such as the patellar tendon and the medial flare and condyles of the tibia, remained ineffective and uncomfortable. He argued that reliefs added during rectification of the positive model of the patient's residuum allowed the patients stump to swell into spaces created in the final socket. He believed that this meant the stump was constantly changing and that volume was less likely to stabilise and stated that the creation of true total contact via a hydrostatic socket would promote volume stabilisation in the stump. If the volume is stable, then this should allow the use of the same prosthesis for a longer time span.

He developed a pressure casting concept by using air as a medium in the Icelandic Roll On Silicone Socket (ICEROSS) system. The socket shape was defined by casting plaster wrap over the residual limb over the ICEROSS silicone liner and applying pressure over the cast using an air pressure chamber with the patient in a seated non-weight-bearing state. Kristinsson (2002) described a pressurised casting instrument which consisted of an acrylic cylinder with an attached silicone bag,

pressure relief and a proximal sealing ring. Modifications are incorporated through addition of padding over bony areas of the residual limb during the socket manufacture process.

The 'ICEROSS' design was intended to protect bony areas particularly at the distal end of the residual limb. Scars also require protection as if the elasticity of the skin is reduced, shear forces may increase. Scars can be quite stiff structures if shear is applied especially if adhered or tethered to underlying bone. Silicone liners may assist in the reduction of shear force in these areas and have excellent properties which allow containment and protection of the residual limb (Cluitmans et al. 1994, Datta et al. 1996, Hachisuka et al. 1998.)

Cluitmans et al. (1994) and Datta et al. (1996) both surveyed patient's views of the ICEROSS concept using self developed questionnaires.

Cluitmans et al. (1994) surveyed 43 patients, 26 of whom were provided with ICEROSS sockets. He stated that the improved suspension was clearly the most significant advantage of the roll on liner with results beneficial to improved patient function. Survey results however, were retrospective and based on the subjective clinical assessment of each user which was considered to be the most important factor in determining the prosthetic success. He concluded that the high level of patient satisfaction expressed by patients resulted in prosthetists considering the ICEROSS socket to be a standard prescription for a person with trans-tibial amputation.

However, in a case series of 54 patients, Datta et al. (1996) contradicted this finding when he concluded that there was no convincing clinical evidence to suggest that significant gains could be achieved by considering ICEROSS as a standard prescription for all trans-tibial amputees. He considered that if prescribed appropriately with the correct technical expertise then the ICEROSS design could provide considerable benefits to the patient.

Results of both studies may depend on the way in which questions were posed to patients, and the method by which sockets were produced. There are disadvantages associated with both PTB and hydrostatic socket design and therefore a 'standard prescription' may not be as important as consideration of the individual patient's prosthetic requirements.

Hachisuka et al. (1998) investigated the qualitative advantages, disadvantages and clinical implications of total surface / volume matching design in a case series of thirty two amputees asked to provide their opinion on a list of 13 aspects of the socket. Results were statistically analysed with seventy-five per cent satisfied with the socket provided. Advantages of the socket design were comfort, ease to swing, pain, piston movement, tightness, skin irritation, appearance and durability which were thought by three quarters of the users to be good. Disadvantages reported included donning, perspiration, odour and staining.

Hydrostatic sockets aim to produce an even distribution of pressure over the entire residual limb. This design is truly total contact and aims to achieve an interface design that uniformly delivers a minimum skin pressure. Convery and Buis (1999) found, in a single case study, that a hydrostatic socket produced considerably fewer pressure peaks than a PTB socket during the gait cycle. In addition, the quasi hydrostatic design promoted elongation of the tissue, promoting stiffness of the residuum, whilst protecting the distal tibia.

Narita et al (1997) used cineradiography and X rays to measure the suspension effect of the TSB design compared to that of the PTB design by measuring the distance from the tibia to a reference point on the prosthetic socket. The study used nine trans-tibial amputees all of whom had previously worn PTB prostheses.

They stated that the TSB design produced an increase in range of motion as a result of the relationship between the anterior and posterior walls of the socket which also increased the flexion angle of the limb during swing. Due to the high coefficient of friction between ICEROSS and residual limb in the hydrostatic prosthesis, there is

also a decrease in piston action at initial contact. Patients also reported that the limb felt lighter and that balance was improved and that this was due to the positive suspension effect of the silicone liner as well as improved stability in the stance phase compared to the PTB design.

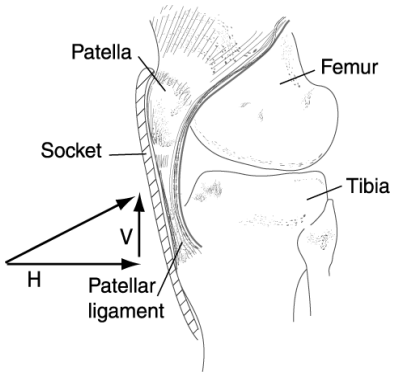

Figure 2-6 Total surface /volume matching

Convery and Buis (1999) investigated socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of one person with trans-tibial amputation when wearing a hydro cast socket. The dynamic pressure distributions were compared to those within a hand cast socket reported by Convery and Buis (1998). Results demonstrated significant differences in pressure magnitude and pressure distributions were noted for the hand cast and hydro cast sockets. However, although both prostheses were considered satisfactory by the prosthetist and patient at the time of the trial it may be argued that should higher pressures and pressure gradients be evident within the socket then the patient is likely to be placed at greater risk of shear pressure which could lead to tissue breakdown.

Pressure gradients within the hydro cast socket were less than those of the hand cast PTB sockets. The proximal ring of high pressure in the hand cast PTB socket was replaced with a more distal pressure in the hydro cast socket.

Convery and Buis (1999) assumed that the weight transfer force applied by the same stationary patient was approximately common to both sockets although they noted

the limitation in this study that the alignment was not identical in both sockets which they concede may have influence on the pressure data.

They concluded that:

- Dynamic pressure levels were lower and more evenly distributed in the hydro cast socket.
- A ring of pressure at the PTB level in hand cast sockets was noted with no major distal end pressure.
- The pressure gradient was less pronounced with the hydro cast socket and more distal pressure was noted.
- Higher localised pressures were noted on the hand cast socket as compared with the hydro cast socket.

A major limitation in this study was that it was a case study (involving one patient.) Problems associated with the pressure transducers are still apparent. Additional studies are required to confirm the differences between prostheses incorporating hand cast and hydro cast sockets and are being investigated currently by Dumbleton et al. (2009 (paper in press)) who attempted to measure the success of the socket in terms of satisfaction and activity. These were thought to be related to the comfort of the socket which is dependant on the interface pressure between socket and residual limb.

Results showed similar distributions of interface pressures regardless of the casting concept used. The impact the design of the socket had on the user's activity was similar. Buis (2007) also noted that the activity of the person with trans-tibial amputation was remarkably similar to that of the normal population.

Goh et al. (2004) generally agreed with findings in the study by Convery and Buis (1999) in a study of four patients with PTB and sockets made using a hydro casting mechanism (p cast). Results of this study showed a consistent ring of proximal pressure for one user of the PTB, whilst another consistently showed high distal pressure using the p cast socket. Results were based on a small sample and may have

been affected by alignment of different prostheses which was carried out to the 'satisfaction' of one experienced prosthetist and the subject. Differences between the hydro cast socket and PTB socket alignments were not recorded and may have affected the pressures within sockets. Each socket was also suspended by the means of a leather 'cuff' suspension. Due to the differences in the shape of each socket it would prove extremely difficult to ensure that the suspensions were placed in exactly the same position on each socket. If a cuff suspension is inaccurately positioned then pistoning will occur resulting in higher shear stresses.

Yigiter et al (2002) assessed a limited number (n=20) of unilateral amputees supplied with PTB and TSB socket designs and found statistically significant differences between the two socket types in favour of the TSB design. Using strict patient selection criteria patients were fitted with both PTB and TSB designs of sockets and trained in their use. The ability of patients to perform a series of tests was then assessed. Assessment included weight bearing on the amputated side, time to perform ambulatory activities, volume and suspension of the socket, prosthetic weight bearing and temporal distance characteristic of gait and balance. It was found that weight acceptance on the amputated side was improved to a more normal level with the TSB prosthesis and that other temporal distance characteristics showed improvement using this design

2.6 Summary

It may be argued that one design is not suitable for all persons with trans-tibial amputation. As every person with amputation has different needs, they and will require a socket designed to meet personal specific requirements. There is a lack of scientific evidence to suggest which socket design is most appropriate.

Socket fit criteria have been determined. To promote stiff coupling and minimise pistoning the shape of the limb should be captured when loaded. Capture of the unloaded shape will require modification which has the potential to introduce discrepancies in shape between the loaded stump shape and socket. This may cause

pistoning, peak pressures and potentially detrimental shear stresses resulting in discomfort and possibly damage to the residual limb.

The cast for the PTB socket design is taken with the limb in an unloaded position, is deformed by the prosthetist, and then modified subjectively by the individual prosthetist who takes each cast. Although studies were limited in design and sample size, literature indicates that hand casting is less repeatable than pressure casting (Buis et al. 2003) and modifications are subject to discrepancies between prosthetists (Convery et al. 2003).

If a cast is taken in an unloaded position, it may be possible, through cast modification, to produce a socket that promotes a stiff coupling from an unloaded stump. This requires considerable skill on the part of the prosthetist but is subjective, unquantified and difficult to replicate from cast to cast. This process may also depend on the patient's ability to become accustomed to a less than optimal fit.

Although the evidence is limited, it suggests that the design of the PTB socket and the conditions under which the shape is captured may make stiff coupling less likely than pressure casting. Therefore sockets created in this way may not always satisfy the agreed socket fit criteria. To promote stiff coupling it could be argued that 'hydrostatic' sockets should be used for the management of trans-tibial amputation and must be captured under conditions most likely to reflect the shape of the statically loaded limb.

Whether the final shape should be captured by a casting concept utilising water or air as a loading mechanism has not yet been established. It is therefore difficult to state which is the best method of shape capture or whether each will obtain the same final shape.

One of the main advantages of using a hydro tank is that the extent to which the stump is pressurised is determined by the patients load (Murdoch 1964). Pressure casting using an air medium has also been shown to be successful but is taken in a

seated position which may suggest that it is less likely to reflect the shape of the loaded limb when standing.

Regardless of the method used to pressurise the residual limb, it is undesirable to modify the captured shape in any way as this has the potential to introduce inconsistency in shape and volume in final sockets produced and could detrimentally affect the stiff coupling mechanism.

'Hydrostatic' sockets aim to produce a more even distribution of pressure over the entire residual limb. This design is truly total contact and aims to achieve an interface design that uniformly delivers a minimum skin pressure. Although limited in design and number of papers, literature suggests that hydrostatic sockets produce considerably fewer pressure peaks than PTB during the gait cycle (Hachisuka et al. 1998). In addition, the design promotes elongation of the tissue, promoting stiffness of the residuum, whilst protecting the distal tibia (Convery and Buis 1998), and improves weight acceptance on the amputated side to a more normal level (Yigiter et al. 2000).

Chapter 3

3 Methods of shape capture

The method by which the shape of the residual limb is captured is a central aspect in determining prosthetic fit, with the resulting socket depending on the accuracy and repeatability in the way the data is required (He et al. 1999). In the case of the person with trans-tibial amputation, shape capture has been reported by numerous authors using a variety of different methods.

The following sections provide details of methods of shape capture used historically until the present day. Advantages and disadvantages of each method are discussed.

3.1 Tracings and measurements

In traditional socket design, a prosthetist was able to manufacture a prosthetic socket from a tracing of the coronal and sagittal views of the lower extremity on a sheet of paper (Murphy 1954). This required the pencil to be held vertically for accurate shape capture and a guide was useful for this purpose. Both the stump and the contra lateral limb were traced up to the level of the pelvis and landmarks noted on the tracing. A number of circumference and diameter measurements were taken and these were used in conjunction with specially made templates to create the prosthetic socket. Prostheses of this type were generally made of metal and leather. Sockets were not total contact design and required a trial and error fitting technique.

Murphy (1954) reported that the most common type of prosthesis used at trans-tibial level in the 1950s was carved from a willow wood block which formed the outside of the shank. This method depended very much on the skill of the prosthetist and the ability to make adjustments on a trial and error basis with simple carving tools. The prosthetist would begin by hollowing a general shape using patterns to specific measurements used on a tracing. He would then carve the socket with whatever

corrections he felt necessary, and with limited information and reduced visibility would carve a negative replica of the stump inside a cylinder.

A satisfactory fit was only ever obtained by the best of prosthetists after successive trials (Murphy 1954). One advantage of this socket design was the ability to make adjustments by removal of the wood material. However, the entire success of the socket depended on the skill and experience of the prosthetist and the system lacked quantification.

Measurements used in the creation of a prosthesis typically include the length and circumferences of the residual limb which are measured with a measuring tape. Depending on whether the tape is held loosely or tightly against the body and on the angulation of the tape, these measurements can differ.

Without a consistent measurement system, it is difficult to know whether consistent outcomes were achieved. This makes assessment of residual limb changes over time especially challenging and affects accuracy, repeatability and reliability of measures if a patient is seen by different clinicians.

3.2 Alginate casting

Murphy (1954) described a method of casting with alginate which provides shape capture with exceptional detail.

However, one of the problems of this method of shape capture is that alginate shrinks rapidly as it dries. Although Murphy recommended that the plaster cast is poured as soon as possible, material shrinkage may be difficult to identify on the complex shape unless severe, and therefore errors may be introduced. In addition it was not possible to load the stump through this medium and therefore a weight bearing cast is not possible (Schuch 1987).

If materials are to be used in a wet state, shrinkage should not occur as the materials dry. If this happens, then the prosthetist will have to compensate for any shrinkage during cast rectification, otherwise sockets will not be of the correct volume.

3.3 Plaster casts

Plaster of Paris is a fine white powder, calcium sulphate hemi hydrate ($CaSO_4\ 5H_2O$) and is produced by heating gypsum to about 150 °C. The chemical reaction that occurs when the dry plaster powder is mixed with water is exothermic in nature and forms to fully hydrated calcium sulphate (gypsum), a white solid.

Plaster of Paris bandage is made from a specially woven cloth, uniformly impregnated with plaster of Paris. Once immersed in water at a temperature of 20ºC. for 2-3 seconds the plaster will set in approximately 3-4 minutes.

The introduction of plaster of Paris impregnated bandages in the 1950's transformed the way in which the shape of the residual limb was captured. This method allowed the shape to be captured in its entirety allowing total contact sockets to be produced for the first time. This is by far the most commonly used method of shape capture although the conditions under which it should be used are still debated.

Although widely used the accuracy of this method of shape capture in prosthetics applications is unclear. Further experiments are required to assess the accuracy and the repeatability of this mode of shape capture.

The simplest method of use is to wrap the plaster impregnated bandage by hand. This allows the prosthetist to contour into pressure tolerant areas and around pressure sensitive areas. In this way areas which will ultimately provide load bearing within the socket may be 'pre-loaded'.

During hand casting there is a risk for the uncontrolled deformation of the soft tissues, leading later to poor socket fit (Murdoch 1968). The plaster casting material can be stretched loosely or tightly, and the prosthetists hands can apply varying

levels of pressure. The prosthetist must be conscious of over emphasising the triangular shape of the stump anteriorly. Many prosthesis are not successful and this may be in part due to the shape captured which may in turn affect the fit of the prosthetic socket (Murdoch 1968).

Once the residual limb cast has been wrapped by hand it may then be pressurised by air or by water to change the shape of the cast to create a 'hydrostatic' socket. The mechanisms and the theory of this socket design have been described (chapter 2.)

Some socket designs advocate the application of a vacuum over the hand cast residuum to improve the accuracy and repeatability of the shape captured. Plaster of Paris is wrapped over the residual limb and a plastic sheath is applied over the plaster wrap. Air is then removed from the sheath to form a vacuum over the plaster wrap. This differs from application of pressure since the vacuum does not alter the shape of the residual limb but replicates it. As this cast is taken with the in an limb unloaded state, undesirable subjective modifications to the positive cast are required as well as the introduction of thick polyurethane sleeves which exhibit flow characteristics for high to low stress areas.

Vacuum sockets are used generally with a vacuum suspension system which consists of a one way valve at the distal end of the socket and a proximal sleeve. As the patient dons the socket, he expels air from the distal socket and a vacuum suspension is achieved via the proximal sleeve. Claims have been made to suggest that the vacuum suspension creates a stiffer coupling and therefore reduced pistoning.

Board et al (2001) argued that daily volume loss of the stump leads to a poor fit of the prosthetic socket and made sockets by applying a vacuum over a plaster cast mould of the residual limb. In order to combat pistoning a total surface bearing socket was produced and a vacuum system attached. The effect was when the liner was held tightly by the vacuum, the volume loss of the stump reduced from 6.5% wearing a non vacuum suspension to 3.7 % over a 30 minute walk. X-rays revealed that the limb and tibia pistoned by 4mm and 7mm less respectively under vacuum

conditions. Board observed that a combination of reduced pistoning and maintenance of volume allowed the patient to walk with a more symmetrical gait.

Beil et al. (2002) came to similar conclusions as vacuum assisted suspension provided lower positive pressures during stance as well as higher negative pressures during swing phase in a study of nine trans-tibial patients which they believed reduced volume fluctuation when wearing a prosthesis.

3.4 Direct manufacture of the socket over the residuum

When the socket is manufactured directly over the patient's residuum without the interim plaster cast or modification process, this is known as direct manufacture.

If direct manufacture is used, materials will have to become more affordable, and more adjustable than are presently available. Carlsson (1997) outlined the ICEX direct socket fabrication technique on silicone sockets. The ICEX concept utilises a carbon fibre weaved material that is rolled onto the patients residuum over a silicone liner and shape formed using pressure in the Icecast equipment just as the plaster cast would be.

A positive advantage may be that a socket can be created instantly, removing the errors introduced by human application or shrinkage in application of materials such as plaster of Paris. The fact that the socket is pressure cast means that there is no rectification process, and that the patient can see exactly how the socket is produced.

Datta (2004) however stated that although the time to manufacture the ICEX socket was considerably shorter than that of the PTB design, the cost to produce the ICEX was significantly higher. Disadvantages may also include that as the material is thermosetting, it is difficult to adjust once cured should the need arise for small socket modifications.

Direct manufacture is a positive method of capturing a shape. Current materials used are expensive. If an error occurs in the shape capture process, high stump socket

interface pressures may result. As materials are not adjustable the prosthetist must begin again. It may also be argued that although it is possible to successfully manufacture a pressure cast socket over the residuum directly, this does not assist in understanding what a good socket fit is as no data is collected from one socket to another, and is lost on destruction of the socket and so no comparison can be made.

Sockets made by direct manufacture could be digitised, but this would rely on investment in a suitable digitiser and in direct manufacture technology which would be expensive.

3.5 CAD systems

The idea of Computer Aided Design (CAD) systems appeared in the late 1960`s and the first system appears to date to 1983 (Marincek 2004).

Marincek described CAD as 'Anatomical shapes converted to mathematical equations using data points assessed in measurements.'

Marincek (2004) compared the time for cast and cast modification using traditional methods to the CAPOD system. He concluded that the CAPOD system saved on average 106 minutes and also claimed that CAD systems may present a more effective method in prosthetics for better and faster treatment.

Unfortunately this study, although comparing the faster time required for each treatment, did not address the important aspect of the quality of the final sockets produced. No evidence was presented to suggest that better sockets were produced although this was the opinion of the author based on anecdotal evidence (Marincek 2004). Faster treatment does not necessarily mean more effective or better treatment and can in fact have the opposite effect. The socket design (either PTB or hydro cast) is not stated. However the fact that the cast required modification suggests that they were most likely of PTB design and hence would be unlikely to promote the best mechanism for stiff coupling (Pg 46).

Many papers (Michael 1989, Steele 1994, Sewell et al. 2000, Ross 2004) agree that in the future CAD/CAM systems will probably replace the classical prosthetic and orthotic manufacture using plaster and that the development of the technology has brought many advantages like repeatability of the process and a comprehensive database that can be accessed remotely.

Other papers consider CAD/CAM to be only a tool to help the prosthetist but which will not replace the need for skill in evaluation and individual design of prosthetic sockets (Sewell 2000, Fergason and Smith 1999).

Although literature continually states that CAD systems offer the advantage of repeatability, this has not been proven. The conception that CAD systems offer a more repeatable method of shape capture than traditional methods has been perpetuated in literature by experts expressing their opinion based on anecdotal evidence of what they see happening in clinics. These opinions appear to have been accepted as true, and yet minimal scientific evidence exists to show this to be the case.

As with traditional methods of shape capture CAD scanners use a variety of methods by which the shape can be captured. CAD scanners may be hand held and may or may not involve contact with the surface that they scan.

An explanation of the different methods employed by current CAD systems is given with respect to commercial availability. Greater detail of research pertaining to the use of CAD systems in prosthetics is contained in the next chapter.

3.5.1 Mechanical digitisers

Mechanical digitisers can be used to reconstruct the shape of a surface, for example the inside of a cast. A mechanical arm rotates around the inner surface of the cast, and mechanical or electromagnetic sensors monitor tip location which may be mapped on screen once the entire surface has been scanned.

Saunders et al. (2003) reported the best radial resolution of commercial mechanical digitisers to be around 0.4mm. Although this may appear to be very accurate the digitiser is only as accurate as the cast which it measures. This system was a mechanical digitiser used for scanning existing shapes and was not used to capture shape directly from the patient's residuum. It was therefore, only as accurate and repeatable as the cast taken.

Saunders et al. (2003) stated that this system was accurate enough for research purposes. However as socket fitting criteria have not yet been established and we do not know what constitutes a good or a poor fit of prosthetic socket; it is questionable what level of accuracy is required.

It is claimed that residual limb volume changes as low as 5% can detrimentally affect the socket fit (Fernie et al. 1982, Lilja and Oberg 1997). With a 90mm diameter residual limb and a uniform expansion, this volume corresponds to a radial alteration of 1mm. If different casts from different time points are to be compared, e.g. if 2 socket designs with subtle changes are to be compared then a resolution of less than 0.5mm is necessary. A system with this accuracy would allow the location and magnitude of local changes to be determined. If research demonstrated that these subtle socket modifications significantly affect socket fit and performance, then use of more accurate digitisers in clinical practice would be warranted. Use of highly consistent casting procedures would also be suggested (Saunders et al. 2003).

3.5.2 Electromagnetic scanning systems

Data may be captured using a hand held electromagnetic probe containing a magnet (or coils) within. The probe moves within a specific field determined by the orientation of a transmitter, and as it moves over the shape, the magnet acts as an antenna within the magnetic field which gives a 3D positional reference. Probes may be mechanically passed around the shape or hand held.

Tracking of the probe works by determination of the location, orientation, and positioning information relative to a coordinate system and requires coordinates for

the origin and the receiver. Electromagnetic trackers use the attenuation of oriented electromagnetic signals to determine the absolute position and orientation of a tracker relative to a source. The source contains three orthogonal coils that are pulsed in rotation, one after another. Each pulse transmits an electromagnetic signal that is detected by a sensor. The sensor also contains three orthogonal coils, which measure the strength of the signal from the current source coil.

By using the known pulse strength at the source and the known attenuation of the strength with distance, these nine values can be used to calculate position and orientation of the sensor coils. The source and the sensor are connected to a box, which contains a microcomputer and electronics associated with the pulses.

Commercially available systems which use this method of shape capture are the *Tracer CAD* by *Ohio Willow Wood*, and *Bio sculptor systems* by *Bio Sculptor Corporation.*

These systems use a hand held electromagnetic probe containing a Fastrak 3-D motion tracking and digitising system which is passed over whilst in continuous contact with the residual limb to capture or "trace" the shape and record it on computer. A transmitter mounted on a tripod sends an electromagnetic signal that is picked up by the probe and by a sensor that is strapped to the patient's limb. Proximal, distal, anterior, medial and lateral landmarks are added to establish the position of the residual limb in relation to the sensor. The clinician then moves the probe over the surface of the limb and a control unit determines the spatial location and orientation of the coils within the probe and conveys this information to the software. A cloud of data points is then established and plotted as a 3 dimensional representation of the stump shape on a 2 dimensional screen. Further landmarks may then be added in positions determined by the prosthetist. Addition of a landmark during shape capture will be added directly to the surface of the model.

Such systems may be portable because a positioning mechanism for the probe is not always required. However the lack of a positioning mechanism may make it more

difficult to guarantee the data points are recorded in a geometrically regular manner. The result is that some areas of the shape might be under sampled.

Compared with other systems hand held digitisers have an inherently higher incidence of signal noise associated with them. The signal noise could result from the transducer itself, the shaking of the operator's hand or subject motion during sampling. Systems may also experience signal noise from metal objects placed in close proximity of the scanning system.

Since the residual limb has to be digitised point by point with the hand held digitiser, the scanning time may also be of concern particularly if the patient has difficulty in maintaining knee extension, or has reduced cognitive ability. Since the sensor strapped to the patients residuum is positioned above the level of the knee so as not to interfere with the trace, change in flexion of the knee will result in a change in distance between landmarks added. This system may therefore be unsuitable for those who cannot maintain knee extension for a long enough time (approximately 3-4 minutes), or those who cannot comprehend the importance of doing so, for example, children.

The electromagnetic system design used by Tracer CAD and Bio sculptor allow an interactive experience that is well-suited for clinicians who do not want to relinquish the tactile process of taking and modifying a cast. Not only does the Tracer Pen allow the clinician to touch the patient's limb, but it also allows the practitioner to make modifications directly on the limb. For example, a prosthetist can press the Tracer Pen into the patella tendon area of the limb and instantly see a patella tendon bar appear on the model on the computer screen.

It could be argued that such systems allow prosthetists to use the same intuitive hand skills as when casting with plaster of Paris. Ross (2004) was of the opinion was that the contact method employed by Tracer CAD had similarities to the contact methods that the prosthetist would use to capture the shape traditionally with plaster of Paris and that this may offer some advantages.

Ross believed that data capture did not entirely remove the hand skills of the prosthetist but that it might offer development of these skills. He advocated shape capture which he believed allowed deformation of soft tissue in a similar manner that the prosthetist would do during a casting process with plaster of Paris bandage.

The amount of pressure applied to the residual limb as the shape is traced may allow the prosthetist to deform the stump in a way which is similar to plaster casting. The probe allows the prosthetist to perform 'hands-on' compressions and modifications to the patient's residual limb while observing effects by viewing an image of the limb on the computer screen. This allows the patient to be involved in the modification process, allowing greater communication opportunity between practitioner and the patient.

Although Ross (2004) provided expert opinion, it was based on anecdotal clinical experience. No scientific evidence exists to substantiate the opinion that deformation by an electromagnetic probe gives a similar deformation to that of a plaster cast where the prosthetist deforms the cast by hand. While both methods deform the residual limb, deformation of a residual limb with both hands may not resemble that of deformation with a small plastic probe.

Unfortunately such modifications to the shape captured are uncontrolled and unquantified regardless of whether the prosthetist uses his hands or a probe. Use of systems in such a way only replaces the potential for errors in shape capture associated with traditional plaster of Paris casting with those of electromagnetic scanning as any deformation of the shape will not be easily repeated or quantified.

Geometric readings may be affected by the indentation if the probe needs to contact limb tissues. It is difficult for the prosthetist to maintain a consistent pressure on the tissue surface during contact scanning. Error will not always be detected by the prosthetist as it is difficult to visualise how a scan relates to the stump dimension. It may also be argued that once examination has taken place, the prosthetist should not

make contact with the patient's residuum when acquiring data as this will affect repeatability of each scan.

The best way in which to acquire data is still debated. Contacting methods may seem less alien to prosthetists and patients, but may introduce dimensional errors due to deformation of the soft tissues, while non contacting shape capture may enable measurement of greater precision, Lilja and Oberg (1995).

While opinions vary, if the shape capture of the patient is enhanced or altered by the practitioner this may mean that every practitioner could capture different shapes. Although this method replaces the plaster of Paris cast directly, it may not offer any advantage to the patient over the conventional method of data capture in advancing the understanding of socket fit (Pratt 1999).

Opinion on the state of CAD/CAM systems was sought by Ross (2004) who described two CAD systems for prosthetic sockets in the UK - Tracer CAD and Electronic Test Socket (ETS). He interviewed five prosthetists based at various centres who were asked to describe their experiences with Tracer CAD, and comment on the advantages and disadvantages of the system.

The limitation of this paper is that it is based purely on a limited number of experts' personal opinions and not on any scientific evidence. Evidence presented consists of subjective commentary and caution should be exercised in accepting argument based on subjective opinion. Nevertheless, this is a useful document in providing a snap shot of prosthetists perceptions of shape capture methods used by systems currently in clinical use.

Boender (Ross 2004) outlined several difficulties with this mode of electromagnetic scanning used by the Tracer CAD system. Boender's opinion agreed that CAD is a clean method of stump imaging but advocated use of the system with simple 'routine' models and not complex models, contrary to the commentary by Kelly (Ross 2004). He warned against the pressure of the trace directly onto the soft

compliant tissue of the stump and stated that models may be undersized if trace pressure is too great. This does seem to be a reasonable conclusion but is again contrary to original statements by Ross that sockets produced required the addition of two or three socks to enable adequate fit. Boender was also concerned that any error may not always be detected by the operator as it is difficult to understand how a scan relates to the stump dimension.

Boender believed that Tracer CAD was very good at dealing with cylindrical shapes yet not so accurate when it came to small radiuses or the presence of horizontal or flared socket brims. He suggested that a more reliable solution was to take a plaster of Paris cast and to scan this in afterward.

One must ask why it might not be easier to substitute one method for the other. It could be that prosthetists know intuitively how to modify a plaster of Paris cast from its starting position. If this starting position is different from a trace then a different modification process would be required.

If there is a requirement to modify the model in a different way then this goes someway to saying that taking a plaster of Paris cast is different from taking a trace. This would mean that prosthetists are starting in a different position when it comes to modification and explains somewhat the remarks by Kelly (Ross 2004) regarding why scanning of total surface / volume matching sockets was not preferred to pressure casting. This may also provide the reason why sockets produced by Ross were on the whole, too large.

So far, electromagnetic scanners have been used to collect data with the residual limb in an unloaded position and it would be impracticable (although not impossible) to use these systems as their design does not allow the use of pressurised equipment to facilitate conditions of a hydro cast design.
The Tracer CAD and Bio sculptor systems do allow scanning of the inside of a negative cast when taken. This allows hydro casting or pressure casting equipment to

be used but would entail the use of a plaster of Paris wrap cast rather than obtaining the shape capture of the stump directly, thus risking further error.

3.5.3 Optical laser systems

An optical laser system projects a laser beam onto a mould while digital cameras record the shape of the curve of the light when it contacts the shape.

The scanner works by casting a fan of laser light over the object, while a camera fixed to a wand at a known angle views the laser to record a cross-sectional profile of the object. These systems acquire three dimensional surface measurements by sweeping a handheld laser scanning wand over an object, (in a manner similar to spray painting,) and are designed to scan non-reflective, opaque objects. The embedded positional receiver is used to determine the position and orientation of the wand, enabling the computer to reconstruct the full three-dimensional surface of the object. Moveable objects may be scanned by attaching a second receiver to the object. Reconstruction algorithms may then used to establish the shape on screen and the finished scan is processed to combine any overlapping sweeps.

Systems are normally hand held, lightweight and portable and non contact in nature and may be used to scan shapes directly with a level of accuracy of up to 1mm (Saunders et al. 2003).

Examples of such commonly used systems are the CAPOD system by Ossur, the Canfit by Vorum Technology, and the OMEGA Scanner by Ohio Willow Wood.

The Omega Scanner is hand-held and manufacturers claim accuracy to +/- 0.5mm
The CAPOD system uses the same method of capture (a scanner which consists of a video camera and a laser-light source) but is mounted to a rotatable frame to measure the limb. The patient’s residual limb is placed in the centre of the frame and a plane of laser light is directed toward the central axis of the rotatable frame which intersects with the limb to form a line contour on the limb's surface.

To measure the limb's shape, the frame containing the video camera and a laser light source is rotated around the limb. The computer controlled images of the stump-shape dependent line contour are taken at 3.6° intervals. Coordinates of the contour image are stored for processing. The planar coordinates are then transformed into three-dimensional (3-D) position coordinates to obtain the complete shape of the limb.

Houston et al (1995) assessed a prototype of the VA-Cyberware lower limb prosthetics-orthotics optical laser. They believed that significant portions of the prosthetics CAD/CAM process still remained largely subjective and need to be further quantified and improved. When modified plaster wrap casts are used, the casts and measurements for CAD systems input are subject to intra and inter prosthetist variations and errors just as in prosthetics practice. Errors were frequently introduced when the surface landmarks were displaced due to tissue movement during the casting process.

This scanner also positioned the residual limb within an electronically controlled optical laser system. This consists of two scanners which are passed vertically from the proximal to the distal aspect of the limb, incrementally sampling horizontal cross sectional data over the length of the body segment. Houston reports up to +/- 0.5mm consistency between scans which take approximately 2 seconds.

An evaluation of the CAPOD system for reliability and validity in foot measures was described by Brodtkorb et al. (2006). They compared measurements taken by a scanner to those taken by clinician. Results showed that the CAPOD scanner was accurate and valid and also showed a significant difference between measures taken by hand and those taken by scan. This was potentially due to the fact that measures were taken in a loaded scenario and scans were not loaded which may account for some of the differences between measures.

Optical laser systems however, do not attempt to capture shape under pressurised conditions. Most limbs will be scanned in an unsupported standing or seated

position. Further modification of such a shape captured, regardless of the accuracy obtained would be required to ensure that an optimal socket fit was obtained.

3.5.4 Digital photography systems

The T-ring is a non contact optical scanner, using four digital imagers and four projectors placed within an octagonal ring with an extended fixed structure (distal rod) to control the distance from the ring to the stump end. The octagonal ring is positioned perpendicular to the central axis of the residual limb with the distal rod in contact with the centre of the distal end of the stump. The prosthetist then presses a button to collect an instantaneous picture of the residuum. The system is capable of shape capture in 1/100th of a second and is commercially available from Ohio Willow Wood (OWW). Striped or white socks are necessary for the T-ring to capture prosthetic limb shapes. OWW claim that the system is accurate to + /-1.0 mm but also state that the T-Ring is ideal for cases where there are no particularly intricate anatomical details that need to be captured, or for when the patient is incapable of holding the limb steady for more than a few seconds.

Since the photographs do not reach the end of the cast, the distal end is mathematically closed by the CAD software. OMEGA state that interpolation of data may constitute up to 5-10% of the model length. Unfortunately, the generated shape may not necessarily conform to the subject if the distal aspect is not positioned properly. The CAD end cap may then be too flat, and as a result, produce a socket that is too short. The ability of the prosthetist to position a ring parallel to the central axis of the residuum is also questionable although the effects of mis-positioning have never been analysed.

When used for trans-femoral amputation, the scanner captures the distal part of the residual limb instantaneously, (extrapolating the distal end,) while a brim is used for the proximal part. The T-ring can also be used for trans-tibial amputation.

Electronic Test Socket (ETS) is designed and sold by Otto Bock, and the system is available at most Otto Bock prosthetic service centres (Ross 2004). This CAD/CAM

system is based on measurements and 2D digital images, and is available for both trans-femoral and trans-tibial use.

ETS used on trans-tibial amputated limbs is based around measurements, in addition to a 2D digital image. The residual limb is dressed with a stump sock, and landmarks and a calibration measurement tool are added. Measurements are taken in relation to a calibration device positioned on the tibial crest, and digital photographs are taken from the front and side. The software generates a 3D socket from the photographs and the measurements, and the shape can then be modified.

It seems unclear how a three dimensional shape can be extrapolated from a photograph taken in the sagittal plane. Such a photograph cannot possibly visualise the shape of the residuum on the medial aspect of the residual limb and must rely on computer software to extrapolate shape to fill in missing data. This does not provide an accurate representation of residuum on the medial aspect and relies on the ability of the patient to tolerate a socket which may be of less than ideal fit.

Digital photography systems available for use in prosthetics again rely on photographs of the residuum in an unloaded state.

3.5.5 Generation of shapes from templates and measurements

CAD sockets design procedures have been developed whereby a trans-femoral socket shape can be created based on anthropometric measures taken from an amputee (Torres Moreno et al. 1992). Trans-femoral applications of the Electronic Test Socket (ETS) and Tracer CAD systems involve the selection of appropriate predetermined templates which can be adjusted to measurements of individual patients taken in the traditional manner by prosthetists.

Advantages of this method appear to be in the time saving for the production of sockets which may be centrally fabricated. Disadvantages include the need for correct selection of shaped template and repeatability of measurements carried out in the traditional method by prosthetists.

Measurements used typically include the length and circumferences of the residual limb which are measured with a measuring tape. Depending on whether the tape is held loosely or tightly against the body, or whether the tape is held at a slight angle, these measurements can differ. Different prosthetists can measure the same patient, one immediately after the other, and obtain different sets of numbers. Without a consistent measurement system, it is difficult to achieve consistent outcomes.

3.6 Ultrasound, Computerised Tomography scans (CT) and Magnetic Resonance Imaging (MRI)

An understanding of the biomechanical interaction between the residual limb and prosthetic socket, and development of quantitative measures to predict the quality of fit of the socket are important for optimal socket design. The interaction may be modelled using finite element analysis (FEA). Finite element (FE) modelling requires information on the internal and external geometry of the residual limb. To date, the display of internal structures of the residual limb and the biomechanical effects on the tissue, when fitting a socket has been neglected in CAD systems.

The finite element method relies on the break down of complex shapes into small elements. These are analysed individually, to give approximate solutions to problems for which traditional mathematical solutions cannot be obtained.

Finite element analysis is used in lower limb prosthetics to predict the stress distribution in the residual limb under different loading conditions and socket configurations. The use of FE methods for modelling the trans-tibial residuum has been reviewed by Zhang et al. (1998).

Current FE modelling assumes that soft tissue is homogenous. However, fat, muscle, and inter muscular fascia have different properties and also behave differently and interact with one another when loaded. In addition muscle bundle fibres contract independently. Therefore the inclusion of the internal soft tissue geometry of the residual limb may enhance biomechanical modelling provided the respective material properties are known. Knowledge about loads experienced by the residuum during

ambulation is also essential for FE modelling; the simplification of these loads in practice is another shortcoming of biomechanical modelling.

Ultimately a model incorporating details of residual limb musculature, soft tissue interface characteristics, and complex loading conditions would be desirable. FE modelling requires input in the form of tissue boundary contours. The methods for obtaining these can be manual to fully automated. The automatic extraction of muscle contours, which would enhance model accuracy, has been successful only in proximal images of the limbs.

In order to predict how the unloaded residual limb is affected by the prosthetic socket it is necessary to measure the limb under both loaded and unloaded conditions. An ultrasound transducer placed directly on the limb would indent the tissues of the limb and the acquired images would not reflect the natural shape of the limb. Placing the transducer directly on a prosthetic socket enclosing the limb may create an acoustic problem between the socket and the transducer and degrade images of the limb due to the curvature of the socket. Scanning through a water bath may eliminate indentation problems.

Zhang et al. (1998) argue that as a first step in the direction of a more complete depiction of the residuum in CAD systems, display of the internal structure would be useful, giving the prosthetist an opportunity to visualise the bone and manipulate the limb model accordingly. Accurate geometry of the residuum is also required for the generation of the finite element mesh. Generic literature based shape information that may be scaled for particular individuals may be used, particularly for bone where surface shape methods fail to specify bone.

Volumetric imaging methods such as CT, MRI and ultrasound provide both internal and external geometry and allow a more complete representation of the stump.
X-ray measurements have not been used to create a socket shape but rather to compare and contrast suspension capability in different socket designs. Narita et al. (1997) compared the suspension effect and stability of a total surface / volume

matching ICEROSS prosthetic socket to that of a patellar tendon bearing (PTB) trans-tibial design. The suspension effect was measured as the difference in distance between the tibia and the socket in both the non weight bearing and weight bearing positions in both types of prosthesis. Results showed that the suspension effect of total surface / volume matching prosthesis using ICEROSS liner was superior using both evaluation positions.

CT has been used for volumetric analysis and visualisation of soft tissue deformations in response to socket fitting and load application as well as for assessment of socket fit and provides excellent bone resolution.

The use of CT as a potential method of shape capture was investigated by Faulkner and Walsh (1989) with the hope that data could be used to reconstruct 3-dimensional images of tissue and bone to design a custom fitted prosthetic socket without touching the amputated stump.

This study concluded that because of the complexity of this technique and high costs it did not lend itself for use with prosthetic CAD/CAM systems.

MRI has been identified as the most promising imaging modality (Douglas et al. 1998, Buis et al. 2006) for obtaining geometric data for FE analysis due to its ability to differentiate between soft tissue layers.

One major advantage of MRI over ultrasound is the ability to show anatomical landmarks such as bone. Bone is a strong reflector of ultrasound and its shape is therefore not well determined. Spatial compounding of ultrasound images allows more complete bone visualisation when different view angles are used.

However CT and MRI have disadvantages, particularly CT scans where the patient is exposed to potentially harmful ionising radiation. Both systems are expensive. In addition to the initial capital cost of scanners, additional facilities are required.

Another drawback is that both systems require the patient to lie supine during scanning. This alters the natural shape of the stump under gravity. It is particularly disadvantageous when loading conditions of the limb are examined, since it removes loading from the limb in addition to altering its geometry.

The use of ultrasound has advantages over MRI and CT as it provides a relatively low cost solution and is not ionising in nature. Ultrasound images, however, may not always show complete tissue boundaries which are often incomplete and occluded by noise and artefacts. Disadvantages of ultrasound may be in the time it takes to produce a scan of a residual limb (12- 15 minutes) which is much longer than optical scanners. Compensation for involuntary movement during this time is required which could compromise the accuracy of the final scan. However overlapping of images obtained in the compound scan could compensate for motion artefacts.
Ultrasound is of two main types:
1) B scans
2) Ultrasound Computed Tomography (UCT)

A single pulse of ultrasound passed into a series of tissues will give rise to a series of spots of different brightness (B) which correspond to the amplitude of the reflection from different layers. These are known as B scans

B scans show characteristics of low contrast, granular appearance, and partial views of ultrasound images necessitating considerable processing after image acquisition in order that useful prosthetic images are produced. B scans are characterised by several artefacts that hinder clear visualisation of anatomical features including speckle due to coherent wave interference, spurious echoes known as clutter, shadows caused by strong reflections such as bone, and anatomical boundaries which are blurred and have non uniform intensities due to varying surface curvatures and orientation.
Averaging B scans reduces speckle and noise and enhances contrast. The variety of scanning angles ensures that boundaries become more uniform, that shadows are filled in, and that more complete information is shown on strong reflectors in the compound image. For individual B scans to be placed correctly in a compound

image, image matching or registration must take place. Acquiring images at known positions with respect to one another would ensure accurate matching. Alternatively, feature based matching algorithms may be used to orientate images whose relative positions are not known but which represent the same anatomy. The use of external markers to indicate common points in images of the same anatomical area is also common (Zhang et al. 1998).

Approaches to 3 dimensional ultrasound were outlined by Fenster et al. (2001). Systems generally combine a series of 2D images obtained by a 1D transducer arrays and may make use of image compounding to improve the quality of the image.

Morimoto et al. (1995) designed a mechanical scanner for acquisition of scans radially and along the length of the residuum. The ultrasound transducer was attached to a window in a cylindrical scanning water tank and rotated in a plane around the limb which was immersed in the water filled tank. Scans were taken at predetermined angular intervals around the limb. The system was under computer control and images were acquired in two modes; with the transducer in vertical and horizontal planes. Douglas (2002) described a similar methodology for use at trans-femoral level. Both researchers concluded that involuntary patient movement during scanning and difficulty in accessing all areas of the residuum (particularly at trans-femoral level), presented severe limitations of this method.

Accurate compounding of ultra sound images of the residuum depends upon accurate knowledge of the position of scans with respect to one another. Small errors in system calibration (determining the centre of rotation and positioning the angular intervals), as well as movement of the transducer with respect to the water bath and movement of the object from its position in space during ultrasound scanning are possible sources of mis-registration in image compounding. Patients may have difficulty holding the residuum still while the B scans are being taken

Ultrasound has however been shown to hold promise for visualising the trans-tibial residuum when the limb is restrained

He et al (1999) incorporated trans-tibial ultrasound images into a visualisation tool that included a CAD surface model derived from vertical mode scanned images and horizontal and vertical slices of the limb. This tool was not evaluated to determine reliability and is not being used routinely in clinical practice in prosthetics.

Traditionally ultrasound applications in the medical field have involved scanning an organ or fetus through direct contact of the transducer with the body. Scanning methods that place the transducer in direct contact with the limb have not been used due to concerns about indentation of the soft tissue of the residuum. Insertion of the limb in a water bath for scanning places the limb at a greater distance from the transducer. This makes the ultrasound signal weaker, resulting in a lower quality image than direct scanning.

Mechanical localisers have been used to position the transducer with respect to the limb for scanning. Scanning with the transducer in direct contact with the limb not only eliminates the water bath but allows the use of freehand methods which eliminate the need for elaborate mechanisms to place the transducer in predetermined locations. Theoretically ultrasound scanning of the residual limb could then become as effortless as ultrasound in routine medical practice.

The accuracy of the skin and bone contours and of limb volumes using B scans must be assessed, and it must be determined whether CAD FE modelling is tolerant to the errors inherent in ultrasound systems. All three groups involved in imaging the residual limb found resolutions of 1mm or less in each dimension of the reconstructed image when imaging test objects in the absence of motion artefacts that usually degrade the image quality when human subjects are examined. Using current scanner and transducer technology, 1mm may be regarded as the practical limit of resolution that could be attained with the scanning configuration improved to reduce patient motion to a minimum.

UCT has not been used to obtain limb structure in lower limb prosthetics but is capable of capturing shape and position of the limbs being scanned. 360 degree UCT

systems could be used in cases where access permits use e.g. trans-tibial limbs. A 360 degree system would eliminate the artefacts that appear in the compound image as a result of patient motion between scans in an axial plane.

Fenster et al. (2001) recommend future research into ultrasound imaging of residual limbs. They suggest redesign of the way that patient motion is controlled, as well as a longer ultrasound beam path through a water bath which does not degrade image quality.

Such a system was investigated by He et al. (1999) who tested 3-D imaging of residual limbs using ultrasound. This system employs two separate ultrasound scans and combined them. A horizontal scan showed internal structure and a vertical scan displayed skin external structure.

The accuracy of volumetric measurement based on the method was tested using a cylindrical model and custom-made limb model. Results demonstrated the feasibility of using ultrasound to perform limb measurement for prosthetic CAD applications.

He et al. (1999) demonstrated significant time reduction, (less than 10 minutes) during the scanning process when compared to MRI or CT scans. It is expected that this processing time will reduce as computers become more powerful making this potentially a practical method of data capture.

They also reported improved resolution and accuracy when using the system in measuring external geometry. (144 points per circumference, 28 points per cm in longitudinal direction). Such a high resolution may not actually be required, but may help to extract an accurate and smooth skin boundary from the vertical image.

Ultrasound is an inexpensive and easy to use imaging modality and has the potential to become a standard procedure in the assessment of trans-tibial residual limbs. Ultrasound is not however incorporated into everyday prosthetic practice. MRI and

CT scans are also are not used routinely possibly due to potentially harmful radiation and cost.

3.6.1 Display of internal structures

Brncick (2000) reviewed the history and development of CAD-CAM and presented recommendations to improve system effectiveness in the field of prosthetics and orthotics. Brncick had a more positive outlook on what CAD has to offer stating that the clinician and the clients they serve have a lot to gain from further research in this field. He stated importantly, in agreement with Sewell et al. (2000) that if focus is made on how one can improve prostheses, one can expect great things from the methodology of CAD/CAM.

The question he wishes to answer is not whether the prosthetist achieves satisfactory results but why satisfactory results are satisfactory. Brncick believed that the use of CAD would give the necessary information needed to predict what the socket shape should be to produce a specific pressure distribution within the socket. He is hopeful that should technology be used in the correct manner, the information it yields will perhaps provide clues to why some prostheses fit well and some do not.

Much of today's research on CAD and prosthetic socket design now centres on finite element analysis (FEA). An attempt to create an integrated CAD-FEA prosthesis was made by Goh et al (2005). The aim was to provide a more objective assessment and clearer understanding of socket fit and improve the chance of a successful first fitting prior to prosthetic manufacture.

With the integration of finite element techniques, local stress and strain can be calculated in the amputation stump and prosthetic socket although this is difficult to achieve through the entire gait cycle. Once practicalities of experimental measurement systems are overcome the socket can be optimised and simulations can be performed before the final socket is made for the patient (Oberg et al. 1993).

However more work needs to be done for this to have a practical application in the clinical setting, for example translating interface pressures to more clinically relevant pain or discomfort of the person with amputation.

The most important advantages in using FEA are that information on stress, strain and motion anywhere within the model can be predicted and it is convenient for a parametric analysis for optimal design

The main concern is development of an appropriate model rather than the performance of the calculation. If the model is not a valid representation of the real situation then results will be misleading hence the development of a FEA model for stump/ socket interface need to be carefully monitored, critically assessed and validated.

Zhang et al (1998) argued that as a first step in the direction of a more complete depiction of the residuum in CAD systems, display of the internal structure would be useful, giving the prosthetist an opportunity to visualise the bone and manipulate the limb model accordingly. Accurate geometry of the residuum is also required for the generation of the finite element mesh. Generic literature based shape information that may be scaled for particular individuals may be used, particularly for bone since surface shape methods fail to specify bone.

Summary

Shape capture of the internal and external dimensions of the residual limb may be obtained using imaging methods such as CT, MRI and ultrasound. MRI appears to offer the most promising method of obtaining data for FE analysis as it has the ability to differentiate between soft tissues layers and show anatomical landmarks such as bone. However CT and MRI are not without disadvantages; systems are expensive, require the patient to lie supine during scanning; and expose patients to potentially harmful ionising radiation.

Ultrasound is not used in clinical prosthetic practice. It is inexpensive and easy to use and has the potential for everyday use in the shape capture of trans-tibial residual limbs.

Spatial compounding of ultrasound images allows more complete bone visualisation when different view angles are used, (since bone is a strong reflector of ultrasound). Fenster et al. (2001) recommended future research in ultrasound imaging of residual limbs. A redesign of the method by which patient motion is controlled, as well as a longer ultrasound beam path through a water bath which does not degrade image quality was suggested.

He et al (1999) demonstrated the feasibility of ultrasound to obtain 3-D imaging of residual limbs using a system that combined horizontal and vertical scans to show internal and external residual limb structure. Results identified a possible method of shape capture of the future although this tool was not evaluated to determine reliability and is not being used routinely in clinical practice in prosthetics.

The use of ultrasound technology of appropriate frequency could offer advantages in prosthetic application due to the fact that the limb is immersed and could be loaded in a water tank. Internal structures could be visualised whilst the limb was held in this medium which could theoretically improve understanding and promote developments in FEA in relation to what constitutes ‘good’ prosthetic socket fit. Future research is required in this area to develop a CAD system which could interpret ultrasound results for a hydro cast socket without the need for plaster of Paris.

Chapter 4

4 Computer aided design in prosthetics

'*It is important to investigate all possibilities to ensure that improvements in future systems are identified and made possible and to identify potential errors, as these may be more dangerous than known ones*' (Lilja and Oberg 1995).

4.1 Introduction

It is thought that James Foort, an engineer from the University of British Columbia, introduced the first concept of CAD/CAM for prosthetics over forty years ago (Brncick 2000). It was not until the 1980's when affordable and reliable computer technology became available, that CAD/CAM was introduced in prosthetics (Sewell et al. 2000). At this time, CAD/CAM was regarded as the technology of the future because of its many advantages (Otto 2001c) and it was hoped that it would facilitate revolutionary methods of prosthetic socket production (Sewell et al. 2000).

A new mindset for the production of prosthetic limbs was required for CAD use. Most prosthetists were not used to using computers at all, and CAD/CAM technology was an advanced way of using a computer. For these reasons CAD/CAM was not embraced in the beginning as systems required significant investment in terms of finance and training (Sewell et al. 2000).

Although practices invested in CAD/CAM systems and were motivated to use them, some were not prepared for all of the changes to their practice that were required. This made it easy for practitioners to fall back to familiar traditional techniques. Additionally, many prosthetists may have been concerned that CAD systems would allow other allied health professionals the ability to work with patients with amputation, and technicians feared they may be replaced by computer aided manufacture (Brncick 2000).

For these reasons, some researchers believed that CAD/CAM may have been prematurely introduced into prosthetic practice and might have benefited from a period of sustained development away from clinical practice.

Boone (2001) stated that CAD/CAM has not been the force for change that was originally envisioned. He agreed with Sewell et al. (2000) in stating that the initial introduction of CAD was ahead of its time and that initially technology was relatively rudimentary. The result was that those who took on CAD/CAM systems quite early were not prepared for the fundamental changes in their practice to make CAD/CAM advantageous over manual methods. The long term result was that these operators drifted back to traditional methods of shape capture.

Boone (2001) argued that it was not that prosthetists were unwilling to change, but that when people are uncertain, it is human nature to fall back on tried and true methods. Furthermore he argued that CAD software limitations have not held the development of CAD systems back as much as limitations in clinicians understanding how to use the tools in the way that they need to.

He stated a lack of clinical effort to apply CAD because systems did not inform the user how much to take off or add to a model, but only facilitated the process. Practitioners who already knew how to do this by hand were not committed to learning how to use new on screen tools less familiar to them than the plaster tools in their hands.

Contoyannis (Boone 2001) reinforced Boone's argument that there was an inflated expectation as to how CAD might have been used, both in terms of giving guidelines of what is considered a good fit and indication of modifications required to achieve this goal.

Boone (2001) argued that CAD/CAM needs a more robust and consistent level of supplier support and that clinics must also consider how much effort is required to allow the use of CAD/CAM efficiently rather than falling back on familiar means.

Steele (2001) reinforced the argument of sustained effort to make systems work when he stated that sporadic use of CAD does not give the user enough experience to be successful and that continued perseverance is necessary.

Benveniste (2001) stated that perseverance was not the problem but that the fundamental problem with CAD has been the accuracy of systems in capturing an appropriate and accurate image.

Literature presents a mixed view regarding whether CAD technology is being appropriately and advantageously used in prosthetics to achieve better understanding of socket fit.

Brncick (2000) stated that computerisation is here to stay and will continue to influence the field of prosthetics if used with a focus on prosthetic fitting techniques. Brodtkorb et al. (2006) argue that CAD/CAM was introduced more than two decades ago into the field of orthotics and prosthetics and that this new method of shape capture has not lived up to the expectations of twenty years ago expressed by Klasson (1985) and other contributors to the special issue of Prosthetics and Orthotics International (1985).

Sewell et al. (2000) investigated developments in trans-tibial prosthetic socket fitting process and reviewed literature on past and present research. He found that current research was focused on achieving a better understanding of prosthetic socket fit by quantification of normal stresses at the stump socket interface. Although convinced that advances in socket fitting techniques had been made, Sewell stated that what was not clear was the actual extent to which advances in CAD technology had contributed to these advances.

They stated little evidence that current CAD systems offered any significant advantages over conventional techniques and argued that while CAD was being used as a very effective tool in the capture of trans-tibial shape, it was still being used in a very artisan fashion rather than in a more scientific way. CAD systems have been

largely used to collect stump dimensions to facilitate easier and more efficient socket fabrication rather than to improve the fundamental understanding of socket fit.

They concluded that CAD systems have simply imitated the traditional plaster and rectification process that can be undertaken manually. The prosthetist has little additional information available to assist in the shaping of the socket than he had previously. Goh et al. (2005) concur that although CAD has been used in prosthetics since the 1980s it does not introduce any new principle into socket design.

The change from traditional casting methods to a computerised method of shape capture and on screen modification appears to be difficult for the practitioner. Traditional methods do allow the prosthetist to achieve a reasonably successful outcome. CAD techniques tend to involve steep learning curves in order to ensure a similar quality of socket fit. During this time sockets deemed unsuccessful are inevitable as the prosthetist endeavours to become accustomed to the new method of design. If the CAD system is based upon traditional method such as Sewell and Goh suggest, and the prosthetist does not have more information available to assist in the understanding of the socket fit, it is perhaps less surprising that CAD systems have not been employed with greater enthusiasm throughout the prosthetic industry.

Steele (1994) conducted a survey of prosthetic limb centres in the USA. He stated that when introduced into clinics, CAD/CAM was difficult to understand and intimidating. This resulted in a resistance to change on its introduction. Perhaps it was not the lack of understanding of the prosthetists but a lack of understanding by the developers of the CAD systems as to what it was that the market demanded?

Sewell et al. (2000) suggests that as a ‘good’ socket fit could not be guaranteed with traditional or CAD / CAM techniques, CAD / CAM have not fulfilled its potential. He stated that there is no proof that CAD/CAM systems resulted in more comfortable sockets, but they could aid in reproducing a socket that the patient has found to be comfortable in the past. It is debatable whether the stump is likely to remain the same. In any case reproduction of a model can already be achieved by filling the

socket with plaster of Paris. Although this is more time consuming, it does offers a cheaper alternative.

Ross (2004) found results difficult to quantify and reported no two prosthetists getting the same results when CAD systems were utilised. He concluded that the main advantage in CAD appears to be time saving. However, although time may be saved in the initial scan, Ross reported that 2 -3 check sockets were required for each limb which may result in extra time spent from shape capture to delivery over traditional methods. Ross' paper, however, like many others discussing CAD, is based on expert opinion gained from clinical experience and not scientific evidence.

Green (2003) sought expert opinion on recent developments in prosthetic socket design, materials, and fabrication, including the use of CAD/CAM techniques and silicone liners. Opinions varied but consensus was given on the requirement for ongoing development of socket design, materials and fabrication.

Experts felt that the CAD process was not still entirely equal to that of the results of an experienced prosthetist in all circumstances. He reported that Uellendahl believed that even with current technology, hand made sockets were still best. Additionally, good results were still possible with CAD but in the hands of an experienced prosthetist. He believed that handmade sockets still have the advantage in comfort and quality of fit (Green 2003).

Klasson (1995) believed that CAD development only highlighted the problem of current socket technology. This mainly deals with the procedures involved (like casting, rectification, modelling, selection of materials, manufacturing etc). He believed that to a lesser extent it dealt with specifying and evaluating the final result in terms that can be used for analysis and development.

Other experts believe that CAD systems can only improve and offer the opportunity to quantify how sockets fit. CAD may not currently guarantee good results because prosthetists need to develop a better understanding of what constitutes an optimal

socket fit. Development of systems which assist analysis and improve the fitting process are required to continually refine the processes and improve the outcomes (Green 2003).

Traditional plaster of Paris shape capture techniques do not guarantee an appropriate shape and volume match of the residuum. This is because these tools are rudimentary and lack accuracy. Additionally when it comes to measuring and calculating the socket fit, traditional techniques do not provide the required information. Techniques that offer solutions and enable the prosthetist to quantify the procedure and results are required. The desire to answer the more challenging questions about what makes a socket successful are key to improving understanding and the method by which the shape is captured.

4.1.1 On screen modification

Sewell et al. (2000) stated that on screen rectification is more efficient in the long term; but is initially more time consuming and relied on the skills of the prosthetist to relate the on screen image manipulation to traditional cast rectification.

Ross and Kelly (Ross 2004) agree that on screen rectification possibly saves time, and also allows the patient to become involved or have an input into the design process. Ross argues that this may mean that patients are more compliant in accepting the final result as the process of rectification becomes transparent to the user.

Lemaire (1996) adopted a different approach in an attempt to minimise errors during rectification. He argued that prosthetists did not understand the optimal method of designing a comfortable functional socket and were reliant on hand-sculpting techniques. He averaged a series of modifications made manually by seven prosthetists and used the averaged values as templates in a commercial CAD/CAM system. Lemaire believed that CAD/CAM used in this way would limit errors of rectification as it provided a controlled mechanism for shape modification. He

pointed out difficulties in visualisation of modifications on a 2 dimensional screen as opposed to hand sculpting modifications on a physical plaster cast and stated that this adaptation process took time and was not easy for the prosthetist using trial and error (Lemaire 1996, Lemaire et al.1999).

By customising rectification, modifications were made using an averaged modification pattern with the aim that that this process would improve the efficiency and effectiveness of moving from traditional to computer socket design.

Lemaire argued that averaging a series of modifications produced an acceptable and functional design. However, the modifications varied in size and shape which meant that different rectifications could be made by the individual prosthetist which Lemaire attributes to 'a certain tolerance within which a prosthetist can work.'

Lemaire appeared to be attempting to create a standard rectification package to minimise individual rectifications by individual prosthetists. This did not take into account the variety of different shapes, tissue consistency of different residual limbs. Furthermore, by producing a 'range' of modifications, he was not applying modification consistently but allowed individual preferences of prosthetists to be used. Socket design is not based upon any socket fitting criteria and rectification shapes based upon a small sample of rectifications.

Yildirim and Ostanger (1998) demonstrated the use of rectification maps as a means by which different methods of fitting prostheses could be compared. The rectification map showed the build up or reduction compared to the original surface shape captured and could be coded by colour to assist in visualisation of the amount of change. This can at a glance recognise differences in rectification and hence loading strategies used at specified areas on the stump surface. Sidles et al. (1989) believed that maps could be used regardless of the method of shape capture and that the difference between the shape captured and the final modified shape may be described by a rectification map.

Regardless of claims made by Lemaire (1996), Lemaire et al. (1999), Yildirim et al. (1998), and Sidles et al. (1989) as to the best method of modification, it must be beneficial to minimise any form of modification to the final shape captured by capturing the residual shape of the limb to be closer to that of the loaded shape. Provision of maps or rectification patches must lead to differing socket designs and reduces understanding of what constitutes an optimal fit.

Klasson`s opinion (1995) was that it was not possible to achieve an even pressure distribution by modifying the cast in the plaster room. Many prosthetists have tried to depart from the plaster room modelling concept and try to get close to an even pressure distribution when the cast is taken, leaving only very little for reshaping of the plaster positive.

The repeatability of traditional patellar-tendon-bearing cast rectification between two experienced prosthetists and between the rectified casts of each individual prosthetist has been investigated (Convery et al. 2003).

Each prosthetist was given five previously duplicated plaster cast models to rectify by hand based on their interpretation of basic rectification guidelines. The re-measured rectified plaster model data were compared to unrectified data. The amount of modification by each prosthetist was then calculated and compared at 1800 locations on each plaster model. In modified areas, the mean difference between prosthetists was quantified as 2mm and the standard deviation about the mean was +/-1mm for each prosthetist. The maximum variation by one prosthetist was recorded over the fibular head where a standard deviation of 4.3 mm was recorded. This pilot study demonstrated the variation between rectifications performed by two prosthetists and in an individual's rectification. The sample size is small (n=2) and further research is required to prove whether this represents typical variation. Although Sewell et al. (2000) are partially correct in identifying the best method of shape capture, the way in which the stump is loaded whilst the data capture is achieved is vital in the way that this affects the shape captured. This should minimise or negate the requirement for rectification (either on screen or in the plaster room,)

which can only serve as a potential for serious error in production of a prosthetic socket.

Kristinsson (1993) tested the results of the casting and rectification procedure carried out by prosthetists. Although excellent, these were never similar and not repeatable. He believed results would be more similar if the modelling process was performed under full load bearing. Kristinsson believed that this is beyond casting and 'free surface scanning' CAD techniques.

He discussed the latest methods of fitting a prosthetic socket and the level of skill required from the prosthetist. Interestingly Kristinsson stated that although CAD/CAM may be the answer, more research should be directed towards understanding the complex interaction between socket and skeleton. In any case Kristinsson did not accept the current state of CAD as a toolbox because in his view all systems seemed to have inherited the PTB concept or relied on the topography of the hanging limb or a cast. He did not consider that CAD has anything else to offer besides documentation and ease of fabrication but hoped this would change in the future as the systems evolved.

4.1.2 Model axis

Klasson, (1985) pointed out that the ability to reproduce a prosthetic socket will be a key feature of the future of CAD systems in prosthetics. However, Brncick, (2000) stated that prosthetists have not yet been able to quantify how a socket fits, and are therefore unable to classify the very fundamental concepts of what constitutes a good fitting socket.

One of the claimed advantages for the use of CAD is the fact that a socket may be made in a repeatable fashion. However advocates of this argument would state that while it may be possible to carve the same model twice, difficulty exists in comparison of models due to the fact that a socket axis cannot be identified. This

means that it is difficult to compare like with like socket shapes or to analyse changes in stump shape and volume between different scans.

Further research is required to develop a central axis socket locator. This might allow optical non contact systems to be placed at the correct angle as a central axis would be identified. At present the author is collaborating on a pilot study to establish methods by which this could be realistically and practically achieved for routine use in prosthetic practice.

Manual socket axis location has been previously attempted. Zahedi (1986) reported a mechanical tool, the Szulc Socket Axis Locator (SSAL) (Figure 4-1, Figure 4-2 and Figure 4-3). The tool is made up of two independently operating units located on a central axis. These units operate like an umbrella, with the four legs of each unit moving outwards whilst under the control of a compression spring. A key system stops these units rotating. The way in which this device operates cause it to self align when placed in a socket therefore allowing the centre axis of the device to be used as the centre axis of the socket. Testing of the tool shows some inaccuracies as it has a very small negligible centre line offset of 0.75mm (Zahedi 1986).

Figure 4-1 Szulc socket axis locator within the prosthetic socket

Figure 4-2 Szulc socket axis locator

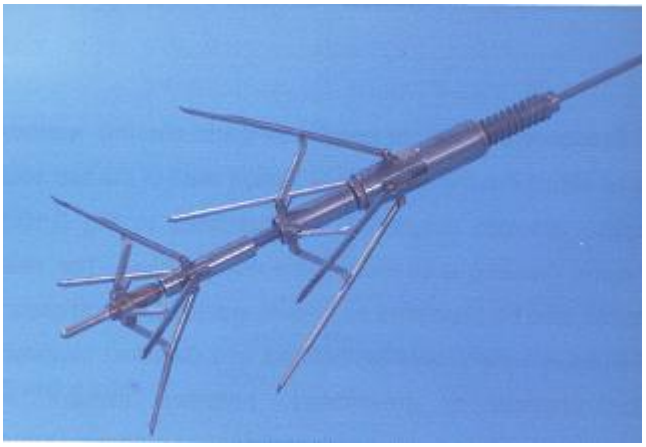

Figure 4-3 Szulc socket axis locator inside the prosthetic socket

However, there are some issues with the functionality of this tool. Because the legs of the units are constantly trying to move outwards and because they are made from metal, it is common for them to interfere with the cast and therefore not define the true central axis of the socket. The process also requires careful positioning and placement of the tool and therefore the accuracy is dependent on operator skill.

Lemaire (1994) outlined the use of a CAD based axis locator which worked through creation of a line of best fit through the centroid. Cross sectional areas were then recalculated once the model was realigned allowing comparison of models.

A further attempt at socket axis location was made by Boone and Burgess (1989) in development of the Seattle Shape maker software. Prosthetists made a plaster cast of the patient's residuum and the Seattle Shape maker then traced the shape of the cast, taking measurements approximately every 6 millimetres. These measurements were automatically entered into the computer, which displayed the shape graphically on its screen.

Another example of socket axis location was developed using magnetic resonance imaging (MRI) technology to determine the bone data for use as a reference grid. Buis et al. (2006) performed a study of the reliability of using MRI scans as a feasible method of obtaining a reference grid for trans-tibial prosthetic sockets. The main concern was that the materials used in casting prosthetic limbs, such as plaster of Paris and silicone, would interfere with MRI data and distort the images. However it was found that these materials did not have any interfering impact on the scanned image and so using MRI technology to locate a lower limb socket axis could be considered as accurate. This would be excellent for research purposes but may not be practical for clinical use.

The ability to view multiple shapes on screen, perform measurements, obtain total and sectional statistics and compare two images would allow the user to compare and examine the effect of intervention in a qualitative and quantitative manner. Identification of an accurate three dimensional axis would allow more of the potential of CAD systems to be released and may enhance the understanding of prosthetic socket fit since different volumes, and modifications could be compared directly as one link in the chain in facilitation of the understanding of socket inaccuracies.

4.1.3 Clinical research trials

Brodtkorb (2006) stated that because of the diversity among the different CAD systems, results for one system can rarely be directly interpreted as valid for other systems. He called for individual evaluation of the performance of each new system

taken into practice to assure the accuracy needed for making an impression. He felt this was increasingly important given the rising demand for the evidence of cost effectiveness when introducing new technology to health care. These demands for assessment have for centuries been the norm when introducing new drugs, whereas the medical devices have to a great extent until now been spared this scrutiny.

Throughout the literature there have been reports of many evaluations and trials of different systems. These are difficult to analyse consistently since most are of small sample size, each uses a different CAD system or method of shape capture, and it is unclear or not stated in many articles whether the mode of treatment is known for each patient or prosthetist involved. Additionally, bias may be present in several studies. Results vary widely depending on systems used and are not based upon socket fitting criteria that determine requirements for a 'good' prosthetic fit. Many of the evaluations report on successful trial fittings of patients using a CAD system proving more successful than sockets made with traditional hand casting methods while others report the contrary.

Results of the pilot phase of a clinical evaluation of computer aided design of trans-tibial prosthesis sockets were reported by Holden and Fernie (1986). For a small sample of ten trans-tibial amputees, conventional sockets were compared with CAD sockets. Patients were blinded to the socket production method. Six prosthetists, of high, medium and low experience from three different centres were randomly asked to create for each patient a socket by CAD or by conventional means. Three of the ten patients preferred CAD sockets and one preferred the conventional socket. Six of the patients preferred sockets produced by conventional means.

Boone and Burgess (1989) presented a CAD system named automated fabrication of mobility aids (AFMA). This system was produced to demonstrate a principle that a cast can be remotely digitised and rectified routinely and remotely to produce a satisfactory socket. This study goal was to prove that a computer system for prosthetic socket design and manufacture could be used as a workable method in prosthetic clinics and used CAD in fitting final trans-tibial prostheses for normal use

by patients. The efficiency of the CAD fitting process in terms of the number of socket iterations necessary to produce a fit satisfactory upon clinical examination and for extended use by the amputee was measured and electronic modification of prosthetic sockets held in a computer database. Limbs were digitised from a group of 13 patients with amputation meeting selected criteria. Casts were taken of individuals and sent to a remote base for scanning and rectification. A standard rectification was built into the design software, modifications to accommodate individual subject variations were not made to the first socket. Once fitted, individual modifications could then be suggested by the prosthetist fitting the device. Results showed that the AFMA techniques were adequate to provide a clinically satisfactory fit in 85% (11 of 13) of the population studied. The number of iterations of socket designs needed, as modifications were required to provide an adequately fitting prosthesis averaged 2.89. (This does not include the initial standard rectification.)

While this study appears to state that it is quite possible to use CAD/CAM routinely in clinics, CAD is still not used routinely in clinics almost twenty years later.

Limitations of this study may be in the small population sample which may not be representative of the entire prosthetic population. It is also unclear as to whether the patients were blind to treatment and results may be subject to some bias as patient feedback was at least part of deciding if a socket was successful. Satisfactory fittings were those that the prosthetist deemed suitable for delivery for permanent use by the prosthetist and patient which may have influenced results.

Different prosthetists may have given an entirely different result in this experiment. Prosthetists were aware of the treatment offered and the success of a fit was based at least partially on a subjective decision made by the prosthetist responsible for fitting. This may have influenced the outcome of this study.

A numerical method for fabricating prosthetic sockets for trans-tibial amputees was developed by Engsberg et al. (1992) who fitted fifteen patients; all of whom stated that the computer designed socket fitted better than their conventionally made socket.

Once again however, there may be bias in this result since it is unknown whether all prosthetists and patients were blind to which socket they were fitting.

An evaluation of the (AMFA) CAD system in the manufacture of trans-tibial prostheses was reported by Ellepolla and Sheredos (1993). A plaster of Paris cast was taken by hand of the patient's stump. Each cast was then digitised by a mechanical digitiser (shape maker CAD software). Diagnostic sockets were then produced on a model of the residual limb and fitted. Prosthetists were then allowed to make a maximum of 6 diagnostic sockets to optimise socket fit.

Interestingly one of the important goals of this study was to verify the claim that the VA Seattle prosthesis could be delivered to the patient sooner. The results indicate that the prosthesis delivery time did not improve because although the CAD allowed for quicker fabrication of sockets and assembly, up to six check sockets were produced. The progress of patients fitted with these prostheses was followed for a period of 6 months and subjects reported that they were both comfortable and preferable to their former prostheses. This study concluded that, in order to optimise the advantages of computerised design and manufacture, prosthetists should undergo a complete training programme in the use of the CAD system.

Oberg et al (1993) conducted a clinical trial comparing the CAPOD system and conventionally produced sockets. The population sample was once again relatively small (n=22). Results analysed subjective experience, prosthetist judgment and that of a physiotherapist, social variables and objective gait parameters. No difference was found between the fit of the sockets although the conventionally manufactured sockets tended to fit with more socks. The patient was unaware of which socket he was wearing although it was impossible to make the prosthetist unaware of which socket he was fitting which may have introduced inevitable bias. The study concluded that the quality of socket fit using the CAPOD system was at least the same as conventional methods.

Andrews (2000) reported that results of an audit undertaken in Bristol, UK have shown that CAD (Tracer CAD) is equally effective at creating comfortable sockets as traditional methods but that it saves time which can be re deployed. The audit related to the first six months of Tracer CAD use in the Bristol prosthetic centre and was of retrospective design based on clinical notes. The aims of the audit were to assess the number and type of sockets that had been made and to evaluate failures of the system. Results concluded that this CAD system required substantial ongoing training but has wide clinical applications. It did require more diagnostic sockets although this was expected to reduce as prosthetists became more experienced with the system. Positive aspects were that the system saved time, and fewer socket adjustments were recorded, although the number of patient visits remained the same.

Another optical scanner the CANFIT system was evaluated by Topper and Fernie (1990). Again, this study aimed to compare trans-tibial sockets designed using CANFIT with sockets made using plaster of Paris casts. A sample of 48 persons with trans-tibial amputation was fitted with sockets produced by the CANFIT system and by conventional methods. Sockets produced by CAD/CAM were initially preferred by 50% of the first 20 subjects. The authors concluded that the CANFIT system was found, in a controlled single-blind trial, to be capable of fitting patients with trans-tibial amputation as well as could be achieved with conventional methods (Topper and Fernie 1990).

Possible advantages of CAD systems were identified by Lilja and Oberg (1995) as an even quality of prosthetic sockets; time saving; lower cost. Despite this potential these researchers identified that the use of CAD/CAM techniques was rare in daily prosthetic and orthotic practice at the time. They predicted an increase in the use of CAD but offered a cautionary note to consider possible errors of measurement. They considered identification of potential errors to be essential as this would facilitate corrective measures. Volumetric measurements were carried out using a water immersion / displacement technique, and compared on cylindrical and amputation residual limb models using an optical non contacting (CAPOD) system. Results indicated that the system was accurate in determining the volume of simple models

but over compensated for shaped or more complex models with a systematic error of +2.5% for all models tested. The authors argue that once this error is known, it can be easily corrected for. They did not evaluate variations due to soft tissue deformation.

The accuracy and precision of volumetric measures by two different techniques of shape capture have also been analysed. (Johansson and Oberg 1998). This study analysed the Seattle Shape Maker (electromechanical contact scanning) and the CAPOD (optical non contacting medium) system using three types of reference objects of known dimensions and volume. Each model volume was measured using the Archimedes water displacement method which was considered to be free from error but which conceivably may have been affected by immersion beyond the trim line of the model. Results indicated that although both systems contained systematic errors when measuring, they both had sufficient precision for routine clinical use in prosthetics and orthotics. However the systematic error and random error on the contact method was larger than with the optical method of shape capture. As both systems work with different scanning techniques it is logical to assume that an increased number of steps in a process increases the risk of errors. The fact that the plaster of Paris wrap cast is the starting point for Seattle shape maker may introduce errors in shape and volume of the residual limb model and this must be remembered when systems are compared.

4.1.4 The use of CAD as an educational tool

Literature is full of different educational courses in instruction of prosthetists on CAD/CAM principles and techniques (Lemaire 1993, 1994).

Ross (2004) reports a steep learning curve when prosthetists endeavour to learn to use the Tracer CAD system. Andrews (2000) also agrees that Tracer CAD requires a lot of training in early days of use. This is because different prosthetists are able to produce a variety of sockets using the system. Ross reports that it was not uncommon for a socket to be produced that required addition of two or three socks to optimise fit. He attributed this to how hard the prosthetist presses with the pen against the

residuum and hypothesises that this will vary from prosthetist to prosthetist in a similar way to a casting technique.

Boender (Ross 2004) stated that Tracer CAD had good potential as a teaching tool. This is because a model may be viewed and saved at various stages of modification. Boender pointed out however that working on CAD systems tended to be much more private and that this might reduce the cross fertilization of ideas during rectification between prosthetists

Zahedi (1996) stated that the population of people with amputation in developing nations has increased due to advances in medicine and increases in road traffic accidents and land mine injuries. He identified a shortage of trained operators which could limit the application of CAD in developing world. It is thought that the ratio of prosthetists to amputees is approximately 1:300 in the developed world. In developing countries the ratio of prosthetists to amputee is continually growing and is thought to be one to thousands (Day 1998).

Jones (1993) wrote philosophically about prosthetic and orthotic technological developments that combine the efficiencies of rapid measurement and manufacturing technologies. He asked how to allow the prosthetist to gain efficiency and effectiveness in use of the computer based system without the computer getting in the way. He also asked how to allow a computer based system to evolve as the knowledge of the user developed.

Fernie et al. (1984) developed a method of overlaying cross sectional images of a cast modified by students over the unmodified cast cross section. This allowed students to view modifications made on sockets they had produced successfully or otherwise for demonstration patients. Sixteen students participated in 96 prosthetic fittings. The overlaid pictures allowed lecturers and students to discuss possible socket errors and potential solutions in relation to the experience during socket fitting. Prosthetic fitting problems do not always manifest immediately and can take several days to materialize. Students of prosthetics only try out sockets on patients

for a limited time and therefore Fernie et al. (1984) believed that the data provided a more thorough critique of a students modified cast than was possible with only a brief trial on the patient. Whilst this may offer a visual method of differing modifications in a teaching situation, the axis of the models may differ and so may be misleading if overlaid incorrectly.

Jones (1993) argued that new prosthetists must first focus on the fine details and technicalities of the tools and then, with practice and experience, these details can become second nature. Only then was it possible to concentrate fully on the creative aims of the task. Ideally tools such as CAD should allow the user to free up the mind from the minor details and be more creative. The user could then be considered to be operating at a higher level in which the underlying form and essential expertise of a task can be considered. He stated that if the underlying philosophy is acceptable then the sockets will tend to be too.

4.1.5 Summary

The use of CAD in prosthetics appears to offer an opportunity to increase understanding of the conditions required to promote optimal socket fit. Unfortunately, literature available to support this is limited. Many papers present commentaries and expert opinion about a variety of systems, and many systems which have been evaluated are no longer used.

Whilst expert opinions are useful, they appear to have promoted certain conceptions about CAD relating to accuracy and repeatability of systems. The statement that CAD systems are more accurate and repeatable than traditional plaster of Paris methods is based mainly on opinions and clinical experience, and is not backed by scientific evidence. Other research relates to clinical trials of CAD systems and the quality of this research is limited in design. Many of the outcome measurements are ambiguous and based upon the qualitative estimations of the socket fit or patient's feedback rather than quantative measurements.

There is a lack of consensus on how best to capture the shape of a residual limb. When one looks at the methods available, the prosthetist must choose between several different combinations of shape capture and socket design. This is confused by ambiguous and subjective prescription criteria. Consensus must be reached on these important factors and research undertaken to identify which methods offer the best accuracy and repeatability of shape capture of the trans-tibial residual limb under the conditions most likely to promote good socket fit.

The real breakthrough in CAD development will occur when the concept of applying the desired pressure distribution to simulate the socket on the stump is achieved using CAD in conjunction with some form of pressurising device. This will offer a direct method for shaping instead of an iterative process.

Accurate, repeatable and consistent capture of a residual shape removes inaccuracies of different prosthetists. If it is possible to capture the shape and volume of a residual limb so that the stiffest path is achieved, rectification of the cast should not be required. Rectification will only decrease the scientific validity of the socket design and introduce errors and inaccuracies.

There are no CAD systems currently available which allow integration with pressure casting systems. Many CAD systems which are currently in use are without independent evaluation. Independent evaluation is important to ensure that inaccuracies are understood and so that improvements may be made to future systems. The type of CAD systems and the extent to which these are in use in prosthetic clinics is unclear.

If CAD is to be used in conjunction with pressure casting, we must agree on the best method of shape capture and this should be affordable, consistent, and easy to use. The method used must also be at least as accurate, repeatable, and reliable as traditional plaster of Paris methods. (A result is *repeatable* when, each time the clinician measures the same patient using the same equipment, the measurements are the same. *Reliability* is the extent to which the same measurements of individuals

obtained under different conditions yield similar results, for example, changing the day or person doing the measuring.)

The importance of using accurate measurements is vital. If the process begins with inaccurate data, then there the chance that the final socket will fit properly will be reduced. (*Accuracy* is how close the measured value is to the actual value.)

Contacting methods may seem less alien to prosthetists and patients, but may introduce dimensional errors due to deformation of the soft tissues, while non contacting shape capture may enable measurement of greater repeatability. The use of CAD will remove the possibility of material shrinkage and will also allow the prosthetist to view measurements on screen this will hopefully allow a greater understanding of how a socket should fit.

If we are to evaluate systems individually it is important to identify the systems which are used. Once identified, the accuracy and repeatability of measurements taken by such systems must be independently evaluated to identify errors of measurement.

The following chapter consists of a survey of CAD use in the UK and provides information regarding the methods and frequency by which CAD data is collected and the perceptions of clinical staff within the UK.

Once systems are identified, independent evaluation and comparison of the most common systems will be carried out.

Chapter 5

5 An Investigation into prosthetic CAD use in the UK

Provision of artificial limbs is divided into regional centres and each centre is responsible for deciding the manner in which prosthetic treatment and rehabilitation are delivered to the referred patient. Currently, the extent to which different prosthetic CAD systems are used in clinics in the UK is unknown.

Steele (1994) conducted a survey of clinical CAD/CAM use in the USA. He ascertained which systems were being used; how they were used; and provided a useful summary of clinicians opinions about systems available at the time. This study is now out of date and new systems are available and in use in the UK. A new survey based on the survey by Steele (1994) was prepared to investigate the extent to which different CAD systems are used in prosthetic clinics and useful to understand the opinions of clinicians on these systems. Results of the investigation are discussed in this section.

5.1 Methodology

A postal survey entitled ‘An Investigation into Prosthetic CAD/CAM use in the UK’ was sent to one participant in every prosthetic centre in the UK (Appendix 1). Each participant was identified as a Prosthetist. Due to the limited number of prosthetic centres in the UK (n=43) all centres were sent a questionnaire. All respondents were required to comply with conditions of ethical approval sent separately by post (Appendix 2).

No potential risks or special considerations were identified. No payment was made. Questions were designed to give an overall picture of the systems in use; what categories of patients they are being used for and why? How prosthetists were trained; and what effect this has on use was also obtained from results. Opinions of

prosthetic CAD specialists were also requested as these may provide further insight and answers to the above questions.

The survey used in this study was an adapted version of the earlier survey by Steele (1994). The adapted version underwent internal critical content analysis by an expert group. Questions were added, deleted and terms anglicised by the group. The final survey differed notably from the earlier publication by Steele (1994) as only two of the original questions asked remained unchanged. A further eleven questions were adapted, and nine were entirely new.

The survey consisted of 22 questions with regard to CAD/CAM use (type of use and frequency). A balance of open and closed questions were asked to ensure that the questionairre was not too time consuming for the respondent to complete. This also enabled management and facilitated meaningful synthesis of data whilst allowing the respondent to reflect and express opinions and feelings on important CAD issues.

Prosthetic centres using CAD/CAM were asked to answer all questions. Prosthetic centres who do not use CAD/CAM were asked to answer only 7 questions of the same survey.

Participants were asked to return the completed survey in a pre paid envelope. A reminder letter was sent to those who did not reply within two weeks. Surveys returned without consent form were not entered into the data analysis and were disregarded in compliance with ethical requirements.

Analysis of data was conducted at the National Centre for Prosthetics and Orthotics (NCPO). Surveys were coded to ensure anonymity. Each code referred to a prosthetic limb centre. The code was cross referenced to the prosthetic centre on a separate document which was held in a locked filing cabinet. Confidentiality, anonymity, and data protection were ensured at all times.

5.2 The Pilot

In accordance with University regulations, Departmental Ethical Committee (DEC) approval was granted for the Pilot study.

The main aim of the pilot study was to assess whether questions could be misinterpreted by the participant and to avoid ambiguity or misunderstanding.

For this pilot a convenience sample of five external experts was used (11.6% of final survey population). These experts were excluded from the final survey. Experts were asked to complete the survey in the normal manner.

5.3 Pilot Results

Four out of the five pilot surveys were returned. Participants noted two questions in particular which required clarification, and each of these questions involved was changed as shown in Appendix 3.

A final questionnaire was created which was approved by the Departmental Ethical Committee.

The survey and consent form were then sent to a prosthetist in all limb centres in the UK. A participant's information sheet (Appendix 4) and consent form were also supplied. Subjects were asked to return the completed survey in a pre paid envelope within two weeks. A reminder letter was sent to those who failed to reply within two weeks.

5.4 Results

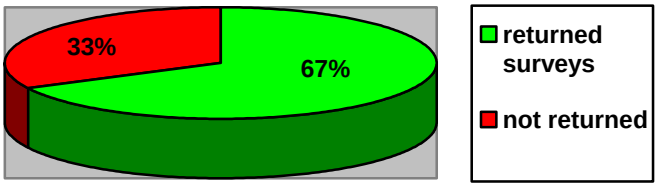

Figure 5-1 Survey response rate

29 of the original 43 surveys were returned (response rate 67%) (Figure 5-1). The prosthetists (n =162 full time equivalent) employed at these centres were responsible for the management of approximately 43225 patients with amputation.

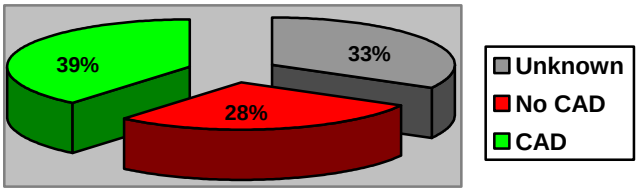

Figure 5-2 Percentage of all UK centres who have a CAD system

Of completed surveys, 58.6% of centres used CAD (n =17) and 41.4% did not use CAD (n=12). (Figure 5-3). Of all prosthetics centres, including those who did not respond, 39% of centres used CAD (Figure 5-2).

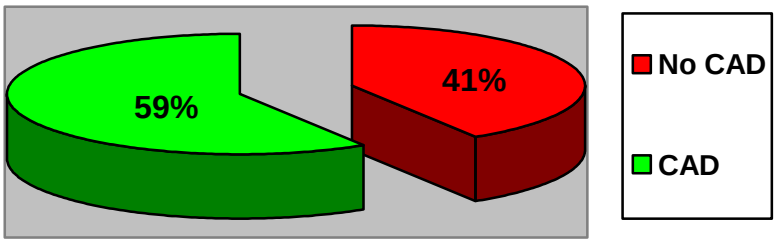

Figure 5-3 Percentage of centres who have a CAD system (completed surveys)

Different CAD systems were employed in different centres. The most common, Tracer CAD was used in 76.5% (n= 13) of centres (Table 1).

Table 1 CAD systems used in UK centres

	Percentage of centres using CAD (n=17)	Percentage of all centres responding to survey (n=29)
Tracer CAD	35 (n=6)	21
Tracer CAD & T ring	29 (n=5)	17
ETS	18 (n=3)	10
Tracer CAD & ETS	12 (n=2)	7
Bio sculptor	6 (n=1)	3

A further centre was in the process of introducing Tracer CAD and T ring but was awaiting training and was not counted in the table above. The length of time centres had used a CAD system at the time of the survey is illustrated in Figure 5-4.

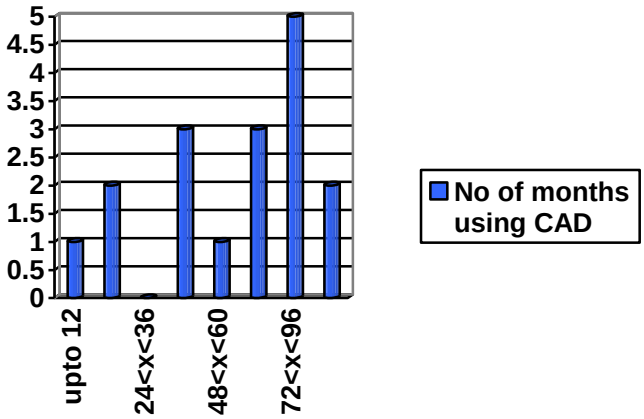

Figure 5-4 No of months using CAD.

Of those using a CAD system, only 41% (n=7) had evaluated other systems (Figure 5-5). This was surprising since systems are expensive and so further analysis was performed to analyse figures by the commercial company providing the prosthetic contract at each centre (Table 2 & Table 3).

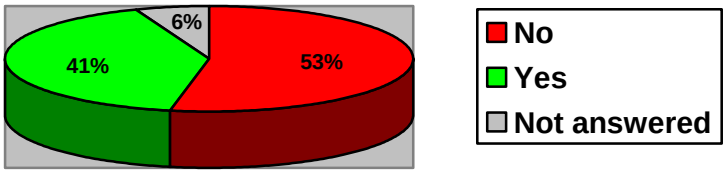

Figure 5-5 Evaluation of other systems

Table 2 Contractors using Tracer CAD

Limb centre contractor	Tracer CAD	Evaluation of other systems took place prior to system introduction.
Opcare	6/13 limb centres	1/6 limb centres
Blatchfords	3/13 limb centres	2/3 limb centres
RSLSteeper	2/13 limb centres	2/2 limb centres
Otto bock	1/13 limb centres	0/1 limb centres
NHS	1/13 limb centres	0/1 limb centres

Note: Opcare is a sister company to OrthoEurope, who have sole distribution rights for Tracer CAD in the UK.

Table 3 Contractors using Otto bock ETS

Limb centre contractor	ETS	Evaluation of other systems took place prior to purchase.
Opcare	0/5 limb centres	
Blatchfords	1/5 limb centres	1/1 limb centres
RSLSteeper	0/5 limb centres	
Otto bock	4/5 limb centres	0/4 limb centres
NHS	0/5 limb centres	

Due to the very small numbers of centres using Bio sculptor system (n=1) and the problems with integration of a suitable carver for use with this system at this centre, this system was discounted from further analysis.

The ratio of prosthetists employed at each centre to the number of patients was compared (Table 4) and illustrated (Figure 5-6).

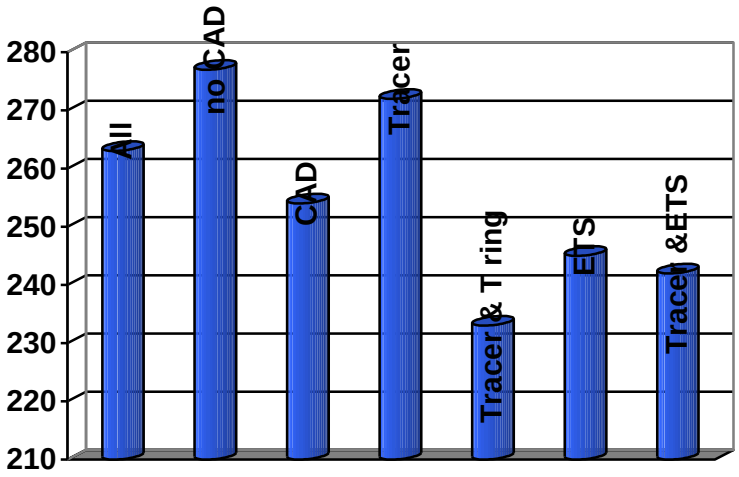

Figure 5-6 Mean ratio of patients to prosthetists

Table 4 Ratio of patients to prosthetists

	Mean	Max	Min	SD
All centres (n=29)	263	454	150	70
Centres not using CAD (n=12)	278	454	150	92
Centres using CAD (n=17)	253	356	183	52
Centres using Tracer CAD (n=6)	272	325	217	38
Centres using Tracer CAD & T ring (n=5)	233	283	183	43
Centres using ETS (n=3)	245	333	185	78
Centres using Tracer CAD and ETS (n=2)	242	250	234	11

Prosthetists were asked what in their opinion were the clinical benefits associated with CAD/CAM systems and were encouraged to give more than one answer (Table 5).

Table 5 Prosthetist opinion on the benefits of CAD/CAM

Time saving	20
Accuracy and repeatability	15
Data storage	15
Controlled modification	12
Less plaster mess / dust	9
Patient involvement in socket design	7
Duplication of sockets	5
More dignity for trans-femoral patients	3
Portability	2
Quality	1
Cost efficiency	1

Most centres using a CAD system (n=13) were satisfied or very satisfied when asked about their level of satisfaction with the system (Table 6) and with the level of support (n=11) from the CAD supplier (Table 7).

Table 6 Satisfaction with the CAD system (percentage)

	Very satisfied	Satisfied	No opinion	Dissatisfied	Very dissatisfied
Tracer CAD	17	66	17	0	0
Tracer CAD & T ring	20	60	20	0	0
Tracer CAD & ETS	0	100 ETS 50 Tracer	0	50	0
ETS	33	33	33	0	0

Table 7 Level of support from CAD supplier (Percentage)

	Very satisfied	Satisfied	No opinion	Dissatisfied	Very dissatisfied
Tracer CAD	17	50	0	33	0
Tracer CAD & T ring	0	80	20	0	0
Tracer CAD & ETS	50	0	0	50	0
ETS	0	67	33	0	0

However, only 78.5% of all prosthetists who had access to CAD systems used them. An additional 63.4% do not have access to a CAD system which means that overall 47% of all prosthetists surveyed used CAD on a regular basis.

Table 8 displays the categories of patients by level of amputation on which each system was used. The ETS system was almost exclusively used on capture trans-femoral shape whereas the Tracer CAD and T ring systems were also used to capture trans-tibial shape.

Table 8 Categories of patients on which systems were used

	TF	TT	KD	Other
Tracer CAD	58	35	6	1
Tracer CAD & T ring	54	38	4	4
Tracer CAD & ETS	80	20	0	0
ETS	99	0	1	0

The mean number of patients supplied with a new socket created by CAD over all centres surveyed was 24%. This ranged widely between 1% and 80% of all sockets delivered at different centres (Figure 5-7). It took between 0-2 diagnostic check sockets to produce a satisfactory socket for both trans-femoral (mean 0.88) and trans-tibial (mean 0.77) levels of amputation regardless of the CAD system used.

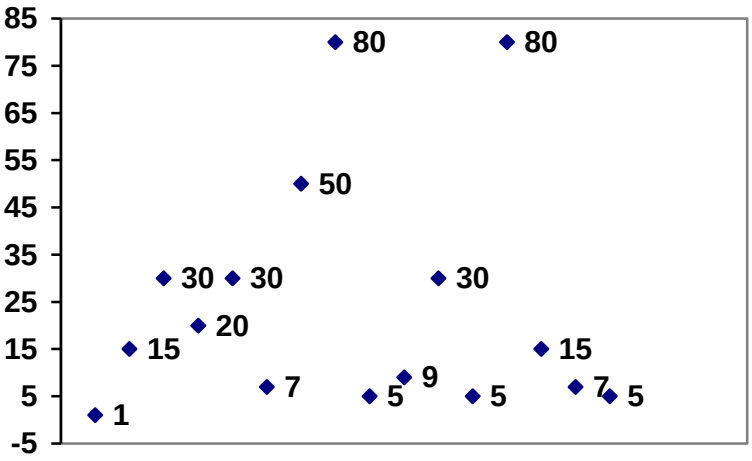

Figure 5-7 Mean percentage of patients supplied with a CAD socket at each centre (%)

The way in which the prosthetic socket for the limb was manufactured including carving of the final shape was also of interest and this is shown in Figure 5-8 & Figure 5-9.

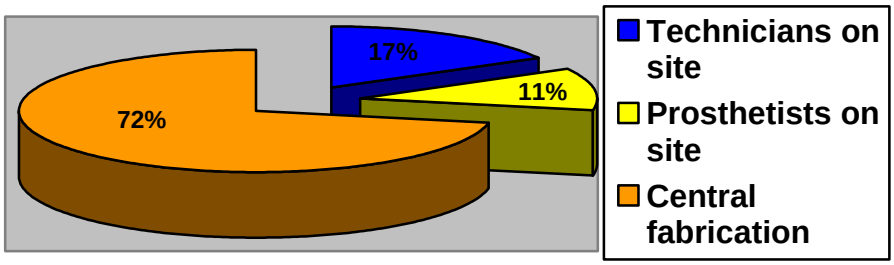

Figure 5-8 Who provides carving?

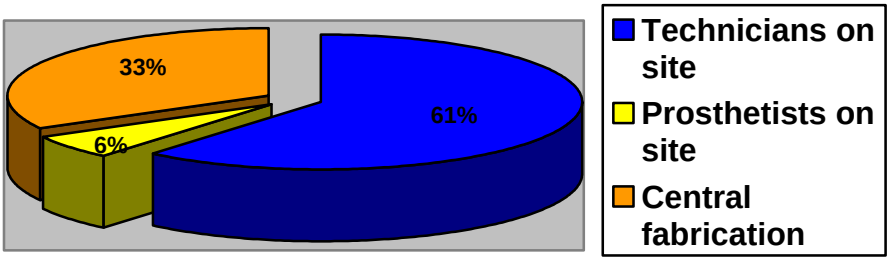

Figure 5-9 Who provides manufacture?

Prosthetists were also asked to reflect on how to make the CAD learning process easier and more efficient (Table 9).

Table 9 What would you change to make the learning process easier?

CAD training should be more structured	17% (n=6)
Software should be more fully explained	11% (n=4)
Better distributors tutorials	22% (n=8)
Better distributors manuals	17% (n=6)
More time spent with a CAD specialist	19% (n=7)
More reliable hardware	8% (n=3)
No changes	3% (n=1)
Desire to try other systems	3%(n=1)

A variety of different training strategies exist and these are detailed in Table 10.

Table 10 Method of training

One prosthetist learned the package and taught others	20%
A professional from the distributor instructed the prosthetists	32%
No formal training	8%
A group of prosthetists learned the package and taught others	32%
Other	8%

26% of limb centres (n=7) were considering purchase of a new CAD system (Figure 5-10). The reasons for purchase are displayed in Table 11

Figure 5-10 Percentage of centres considering purchase of a CAD system

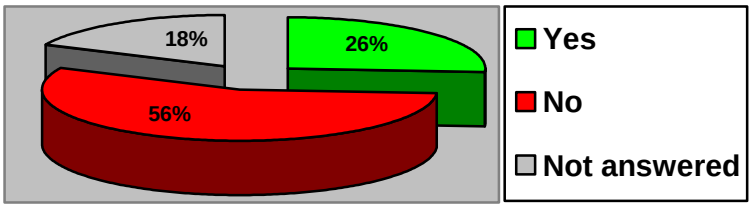

Table 11 Reasons to consider purchase of a new CAD system

YES	n=7
Centre does not have a CAD system	3
Extension of current system (ETS)	2
Replacing previous system	2

NO	n=15
No funding available	7
Already have a system	4
Happy with current data capturer	3
No reason stated	1

Prosthetists were asked what advice would be given to a prosthetic unit currently in the process of evaluating and implementing a CAD system.

Table 12 What to consider when implementing a CAD system

Training	25
Ensure system is easy and accurate in use	18
Review other systems	12
Consider methods of carving and manufacture	10
Select system that best reflects patient requirements	9
Consider cost of system	9
Consider accuracy of system	6
Use system frequently	4
Ensure that staff wish to use system before purchasing	4
Consider how system will be introduced	4
Use check sockets	3

5.5 Discussion of survey results

The survey of CAD use in the UK has indicated that different systems are being used in different ways or not at all in some clinical practices (Figure 5-2 & Figure 5-3). Different methods of shape capture are currently used in different clinics to a greater or lesser extent (Table 1 & Figure 5-7). The Tracer CAD and T ring measurement systems are among the most commonly used and employ the same software package. Different limb centres use different CAD systems in their clinics (Table 1). Some do not offer CAD as a method of shape capture at all. There is no evidence however, to suggest that using CAD offers superior treatment to traditional methods.

The length of time CAD systems had been used varied from centre to centre depending on when each system was introduced and varied from 11 to 110 months (mean 59.71 months). The numbers of centres in each category were too low to allow analysis of any effect of the length of use on the amount of system use at each centre (Figure 5-4).

Of those using a CAD system, only 41% (n=7) had evaluated another system (Figure 5-5). In some regions, prosthetic services are supplied by a private contractor or prosthetic company who have contracts for the maintenance and supply of artificial limbs. Some of these companies also supply CAD systems. Results show that all centres where the main contractor is Otto Bock have employed the use of their own ETS system without evaluation of another system (Table 3). 46% of all Tracer CAD and 100% of T ring use is in centres where the main contractor is Opcare, a sister company to the main distributor of Tracer CAD in Europe, Ortho Europe. Other CAD systems were only evaluated in one Opcare centre (Table 2).

In contrast, where the contractor differed from the supplier of the CAD system, other CAD systems were evaluated in 63% of centres (Table 2 & Table 3). However it is not known what criteria were used to assess systems and if these differed in each case.

Results show that introduction of CAD systems is influenced when the contractor providing the prosthetic service to the NHS is either Opcare (Ortho Europe) or Otto Bock who are the main distributors of current prosthetic CAD systems. These companies appear to favour the systems which they own or distribute.

Results indicate that there is a wide range of prosthetist to patient ratios at centres regardless of whether a CAD system is used or not. The maximum number of patients seen by a prosthetist was 454 (number of prosthetists 5.5) and the lowest was 150 patients (number of prosthetists 2) (Table 4).

Many variables may affect how many patients each prosthetist can manage at each centre. This may include different prosthetist responsibilities from centre to centre and the amount of administrative / managerial support available. For example smaller centres that require fewer than two but more than one prosthetist, may employ a second prosthetist to ensure holiday cover and continuity of treatment for patients. One prosthetist at each centre will have managerial responsibilities and so the impact on the number of patients seen by each prosthetist will be higher at smaller centres.

Survey results show that the mean number of patients seen by each prosthetist is lower in centres using CAD (mean 254 patients) than in centres not using CAD (mean 277 patients) (Figure 5-6 & Table 4). This result was unexpected since 69% (n=20) of prosthetists stipulated that one of the main clinical benefits to CAD/CAM was time saving (Table 5).

The sample size is small, and the overall number of patients treated by each individual prosthetist varies, but there is no evidence that CAD systems allow fewer prosthetists to be employed due to time saving they produce.

This finding appears to be supported by Andrews (2000) in an audit of initial use of Tracer CAD in the first six months of clinical use. He stated that although the system saved time, the number of patient visits remained the same. If time is saved by each

prosthetist in data capture, this time may be spent in consultation with patients or in performing other duties which may facilitate a better quality of patient care.

However, although out with the scope of this research, it would be interesting to investigate the individual roles of prosthetists at different centres to examine in more detail why such a discrepancy exists between the numbers of patients seen by prosthetists at different centres.

Prosthetists expressed the opinion that a clinical benefit of CAD was system accuracy and repeatability (Table 5). Manufacturers claim that the accuracy of the Tracer CAD system is within +/- 0.5mm and T ring +/- 1.0mm. However, no evidence exists in literature to suggest that the Tracer CAD / T ring or ETS systems have been proven more accurate or that results are more precise than traditional methods. Prosthetists may base this judgement on the fact that more measurements appear on screen making modification seem more controlled than traditional plaster casts where the original shape is lost when modified. To assess the accuracy and repeatability of systems independent tests are required.

One advantage may be in data storage (Table 5). Note keeping is essential in modern practice and CAD systems offer a capability to store patients' notes within computer files. However it would be interesting to ascertain whether this facility is used in all limb centres employing CAD or if another separate electronic system is used for this purpose.

Data storage is thought useful for storing or creating electronic shapes of prosthetic sockets to enable duplication. However the same result could be achieved using traditional methods although this presents storage problems. The additional expense of a CAD system simply to solve this is not justifiable. Additionally, the shape of the patients residuum is likely to change over a period of time and prosthetic sockets made from existing 'casts' (whether physical or electronic) will not reflect these changes. Using old casts is not best practice since undesirable socket pressures could result if changes in stump shape are not captured.

Arguably the best advantage of CAD systems may be the lack of plaster mess and dust from the workplace. This is beneficial to both patient and practitioner. Patients with more proximal levels of amputation (e.g. trans-femoral level) will not require to be wrapped with wet plaster of Paris bandage and therefore CAD may afford a greater degree of privacy and dignity to these patients (Table 5).

Only 7% (n=2) rated system portability as an important factor although most systems are designed for use in several different locations (Table 5). Current practice does not require systems to be portable and as a result this should not be considered fundamental in the design of new systems. The sample size however is very small and further research is required in this area.

Most centres (n=13) were satisfied or very satisfied when asked about their level of satisfaction with the system (Table 6) and with the level of support (n=11) from the CAD supplier (Table 7). However results may be biased by the fact that many of those using systems are employed by the companies who provide them. Only one centre expressed dissatisfaction with a CAD system and three others were neither satisfied nor unsatisfied with all systems. In all cases the supplier of the system was different from the contractor providing prosthetic service

Three centres expressed dissatisfaction with the level of support provided by the CAD supplier. In two cases the prosthetic limb service contractor differed from the supplier of the system which was Tracer CAD. In the other case the prosthetic service contactor had changed and was introducing the ETS system but had previously used Tracer CAD and was also unsatisfied with the level of support from the Tracer CAD distributor (Table 7).

The mean percentage of patients supplied with a new socket created by CAD over all centres surveyed was 24% (range 1% to 80%) (Figure 5-7). Over 98% of all patients provided with a socket using CAD had trans-femoral (58%); trans-tibial (31%), or knee disarticulation (9%) amputation. Each system was used differently with the ETS system being used predominantly on trans-femoral patients (Table 8).

The ETS system may be sold as a trans-femoral system only or as a complete system with specialist equipment required to capture the shape of the trans-tibial residuum. Some centres may be using only the trans-femoral version which would explain the difference in amputation levels on which both systems are used. This may also explain why fewer patients are provided with sockets at centres employing ETS (mean 10.75%, range 1 to 30%) than at centres using Tracer CAD (mean 28%, range 5 to 80%) (Figure 5-7).

Carving of blanks is usually provided by a central fabrication unit (72%) which may possibly be due to the expense of specialised carving machines (Figure 5-8). On site technicians (61%) still provide the majority of manufacture of the final prosthesis (Figure 5-9). Although prosthetist numbers appear unaffected by the introduction of CAD, it would be interesting to examine the number of technicians employed at centres using CAD compared to those not using CAD to ascertain whether the number of technicians had reduced.

When asked to reflect on how the learning process could be made easier and more efficient 39% stated that distributors should produce better manuals and tutorials for their software package and hardware, 19% stated that more time should be spent with a CAD/CAM experienced prosthetist, and 17% stated that the initial CAD/CAM training approach used at each centre should be more structured (Table 9).

Different training and implementation plans on the introduction of CAD at different centres may explain why some prosthetists do not use systems even though they have access to do so (Table 10). Poor training and support from CAD suppliers is likely to result in poor results which could easily affect whether or not a system remains in use. Responses from the survey indicate that the initial attitude of the prosthetist towards CAD, and the training, time to learn, and support they are given appear to affect the method and the frequency of system use.

In most cases training was given by a professional from a CAD/CAM distributor who instructed a prosthetist or a select group of prosthetists how to use the CAD

system. These prosthetists having learned the package then taught other prosthetists. In 8% of centres (n=2) no formal training was given and prosthetists were required to learn the package on their own (Table 10).

Prosthetists were asked what advice they would give to a prosthetic centre when evaluating a system prior to purchase (Table 11).

The initial and ongoing costs and compatibility of CAM carvers was considered to be important (10%) as was the ease of use and accuracy of the system (18%). Prosthetic centres should also consider the type of patient on which they planned to use each system (9%). Systems were believed to be successful only when fit for the purpose intended and detailed planning before purchase should consider the type of patient on which the systems would be used

One in four responses stated the importance that prosthetists be given enough time and training to learn each system. (25%) Centres using CAD systems believed that the aim should be to have one expert or experienced user who could support and assist other staff, whilst others believed that the support of managers was important to ensure successful use.

Consideration of the best methods of implementation and choice of system was important as seven limb centres were considering purchase of a new system. Reasons for purchase included that the centre did not have a CAD system, or wished to update or extend the current system in use. The main reason why systems are not being purchased appears to be lack of available funds (Table 11).

5.6 Survey limitations

A limitation of the survey design was in response to question 2. From the way in which the question was asked it was not clear if all centres that used Tracer CAD also used the T ring. Further investigation has determined that five limb centres where Ortho Europe is the main contractor use the T ring as well as the Tracer CAD measurement systems. Because these systems operate the same software, respondents

did not separately answer each survey question twice and have considered the combined effect of the Tracer and the T ring as one combined CAD system.

5.7 Summary

CAD systems are already in use in UK prosthetic centres. Different CAD systems are employed, the main systems being the Tracer CAD / T ring systems.

Systems may provide some advantages such as note keeping and lack of plaster mess which may be beneficial for both the prosthetist and patients. Socket shape duplication does not justify the use of a CAD system. Using a previously recorded shape should be considered poor practice as it can not be guaranteed that a patients shape will not change over a period of time.

The main advantage of CAD expressed by prosthetists was time saving. Time saved by CAD systems does not show an increase in patient to prosthetist ratio.

The second main advantage of CAD expressed by prosthetists was that data recorded by CAD systems was repeatable and accurate. No evidence exists to support this opinion. Systems are expensive, lack independent evaluation and are commercially based.

As Tracer CAD / T ring measurement systems are the most commonly used systems the possible misperception of prosthetists justifies an independent evaluation of both systems for reliability, repeatability and accuracy.

Over a decade ago, it was recommended that training should be more robust and consistent in order to optimise the potential of CAD (Boone and Burgess 1989, Ellepolla and Sheredos 1993, Steele 1994). Despite this, very little seems to have changed. Results appear to show that training is patchy, inconsistent and variable between different prosthetic centres. A structured, planned approach is required to introduce, educate and train individuals as they develop their use with CAD systems.

This will ensure appropriate use and understanding of systems and avoid repetition of mistakes made by individuals in different centres.

Prior to education and training, an accurate and precise system must be identified. Ideally this should happen prior to system introduction to clinical use. However, as systems are already in use and the Tracer CAD and T ring among the most commonly used, an independent evaluation of the systems reliability, repeatability and accuracy is required.

Chapter 6

6 Evaluation of the Tracer CAD and T ring systems: Methodology

6.1 Overview of experimentation

The aim of experiments described in this chapter is to assess the accuracy, repeatability and reliability of the Tracer CAD and T Ring systems and compare to the traditional method of shape capture using plaster of Paris.

Four 'hard' models were prepared. The first was an accurately machined nylon cylinder with a flat end; the second, a larger cylindrical model with a domed end; the third a truncated cone; and the fourth, a trans-tibial plaster of Paris cast. Each model was accurately measured so that results from CAD systems could be compared to a 'gold standard.'

Diameter measurements were selected and measured at four specific levels on each model using a comparator measuring device accurate to 10 microns (model 1) or a programmable CNC milling machine (Deckel™) and a displacement tool (Mitutoyo, series 543 1DF Dynamic Indicator™), both with an accuracy of five microns (0.005mm)(model 2-5). The volume of each model was calculated in the corresponding intervals between each level and verified using water displacement technique.

Experiments were conducted to allow individual analysis of causational factors of error such as different users and the effect of shape of the model. As the initial models were hard, they represent only some of the errors that are possible during shape capture of the residual limb. Ideally it would also be preferable to conduct system tests on patients as residual limbs are deformable.

However, measurement of residual limbs presents some difficulty as a reference grid to identify the axis of the stump would have to be established to ensure direct comparison. Failure to establish a reference grid would result in serious errors of measurement beyond which each system could be tested.

No method of obtaining such a reference grid has been established. Therefore, it was not feasible to evaluate the systems in vivo. The use of residual limbs in system testing would also present difficulty in assessment of the source of error since the unsupported residual limb could change in shape and volume over time.

To overcome these difficulties and assess the effect of deformation of tissue during shape capture, a manikin in the shape of a trans-tibial residual limb was created (model 5). This was measured and landmarks positioned allowing diameters and volumes to be determined as the 'gold standard'.

The repeatability, accuracy and reliability of the Tracer CAD and T ring systems were then assessed on all models (1-5) by repeated scans taken by four users, and the results compared and discussed.

To place results in clinical context the repeatability and accuracy of plaster of Paris wrap casting was assessed on three of the models: the cylindrical model with domed end (model 2); the trans-tibial model (model 4); and the deformable manikin (model 5). An overview of the entire experimental process is outlined below (Table 13).

		Method of shape capture			
Model	Description	Gold standard	Tracer CAD	T ring	Plaster of Paris
1	Hard cylinder	•	•	•	
2	(Larger) hard cylinder with domed end	•	•	•	•
3	Hard truncated cone	•	•	•	
4	Hard (Trans-tibial) shaped model	•	•	•	•
5	Deformable (Trans-tibial) shaped model	•	•	•	•

Table 13 Overview of experimental process

Mean and maximum values of diameters and volumes measured by Tracer CAD, T Ring, and plaster of Paris are compared to means of Gold Standard to examine the accuracy of each system. The coefficient of variation of all diameter and volume measurements is compared to show the repeatability of each method. Inter class correlation is used to compare reliability of measurement of each system by each user.

Results are displayed as error bar plots of each level of diameter and volume measurement by each system. These plots illustrate the mean value +/- two times the standard error for each repeated measure. This allows accuracy and repeatability to be compared to the gold standard.

Significance of results is determined using statistical analysis. Results are then compared to those obtained using plaster of Paris to show if CAD systems are at least as repeatable and as accurate as traditional methods. Results are discussed with reference to shape capture method and conclusions for future system clinical use determined. Statistical testing was set at 5% level of significance.

To clarify how the Tracer CAD and T Ring systems are used routinely in clinics, a detailed description of each system and how they operate is described initially.

6.2 The Tracer CAD system

The Tracer CAD system uses an electromagnetic contact scanner; (previously described.) The accuracy of the Tracer CAD shape capture is claimed by the manufacturer to be+/- 0.5mm.

During normal clinical use the patient is seated in a chair, which should be of non metallic construction, and the residual limb covered in a stockinette which is secured using clamps. The stockinette assists in 'firming up' soft tissues and allows the Tracer probe to glide over the surface of the residuum. The outline of bony landmarks may be added to the stockinette in the traditional manner using an indelible pencil to assist in identification of areas using the probe.

A transmitter cube is positioned on the lateral aspect of the stump with the anterior surface of the transmitter turned toward the stump and slightly toward the operator to ensure that the limb is entirely within the transmitter field of 'vision'. Clearance should be provided to ensure that the operator may scan the limb without interfering with the transmitter during the trace process.

The patient sensor is then attached via a Velcro strap as low as possible on the patient's thigh. The strap should be positioned so that no movement is allowed between patient and sensor and to allow the tracing procedure to extend proximally enough.

Disturbance of the sensor during tracing produces erroneous results. If the relationship between the sensor and the patient is changed, then the system will no longer be able to determine the coordinates of the limb.

A probe, (approximately 8cm in length and 2.5 cm wide), connected to a control unit is switched on and is self calibrating after 20 seconds (the probe must be kept at least one foot away from the transmitter).

The probe consisted of a pointed end, used for identification of landmarks, s button or switch which is depressed to click onto these landmarks. A flattened edge along the length of the probe is used to in contact with the residuum to capture shape whilst a round edge may be used in conjunction with the switch to smooth the shape captured.

A suitable software tracing ‘sequence’ is selected by the user which guided the clinician through the process of shape capture. The probe is then switched on to start the process.

The prosthetist must then identify what he considers to be the distal; medial; anterior; and lateral aspects of the limb. This is carried out with the limb in extension so that the distance between the distal end and the sensor does not alter.

Unfortunately these landmarks are not easy to mark consistently on an irregular residual limb. Ohio Willow Wood recommend careful placement of these landmarks at the same level to avoid the model being off centred or tilted.

The most proximal level of the trace is then indicated by pointing the probe at the most proximal level and by clicking the button on the probe. This position should not be placed too high to ensure that the sensor position may be disturbed making the proximal trace difficult.

The Tracer probe is then clicked to advance to tracing mode when held by the rounded sides; the flat side is placed in contact with the surface of the patient’s limb. The probe is then moved lightly over the surface of the limb using overlapping strokes as if painting.

During tracing, a field of blue dots on the model shows areas about to be updated. A field of red dots indicates that the user is tracing too quickly and that some data may not be captured. A small white square in the top left corner of the screen indicates that there has been a change to the model which has not yet been updated.

A red ‘pie’ graphic with white indications is placed at the most distal level that has not been traced completely. The white indicators show the orientation of the missing data. The user must continue to trace until all of the data is inputted.

The trace is dependant on the pressure applied by the user. If the prosthetist presses harder, more deformation of tissue will result. This is called ‘active tracing’ which the manufacturer claims mimics the shaping a prosthetist produces by hand using traditional plaster of Paris methods.

Landmarks may then be added to identify specific points on the cloud data. The system automatically generates antero-postero (AP) diameters and medio-lateral (ML) diameters at each landmark level. Volumes are also automatically generated using cloud data between the level of the landmark and the end of the traced object.

Once captured, the shape may then be smoothed and modified using a series of available software tools. The final model is then carved for manufacture using a CNC milling machine.

The aim of this study was to investigate only the scanning process. Only the shape capture was assessed. No smoothing or modification of models took place.

Positioning of distal, medial, anterior, lateral and proximal landmarks was marked on each model prior to the tracing process. Each prosthetist then had an exact point to ‘click’ on using the Tracer probe to identify landmarks. This was to be sure that the Tracer CAD model was traced in the best possible manner and that the best results would be obtained. (This differs from the clinical set up as these landmarks are added by eye which may reduce repeatability and accuracy of results further.)

6.3 The T Ring system

The T-ring is a hand held non contact optical scanner which utilises 8 digital cameras to reconstruct the shape of the residuum (Figure 6-1). In order to extrapolate the shape of the model, the T ring uses a sock which allows residual limb contour to be identified. The ring is placed over the residual limb until the distal spacer makes contact with the distal end (Figure 6-2). The T ring is then held along the axis of the centre of the residuum and a button pressed to capture shape instantly. Since the system does not use a distal camera, the distal shape of the cast is extrapolated using a mathematical algorithm from the circumferential pictures taken. Software uses the information that is captured in combination with mathematics that is based on the T-Ring's calibration files stored in the individual cameras. This depends upon correct positioning of a distal spacer by each prosthetist which must make contact with the centre of the distal end of the residuum.

In order to identify landmarks, prosthetists are asked to palpate through the sock and add a black marker dot.

Lilja and Oberg (1995) thought that non contacting optical scanning would enable measurement of a greater precision as prosthetists would be unable to deform soft tissue. However, a disadvantage of using this method may be that the prosthetist does not palpate the limb while capturing the shape. This differs to traditional practice where the prosthetist gains a sense of tissue consistency during the shape capture process. The prosthetist may lose this feedback as he no longer needs to touch the residuum to capture the shape (Ross 2004). However there is no reason why the prosthetist should not carry out a separate physical examination before capturing shape data.

The Tracer Pen is adversely affected by metal and magnetic fields, whereas the T-Ring is entirely optical and immune to metal and magnetic fields that are often found in a clinical setting, e.g. hospital beds, MRI machines, etc. The T ring however may be adversely affected by different intensities of light which can cause surface

reflections and shadows which may affect the detail of the shape captured by the digital cameras.

As a sock is pulled over the object scanned, measurement error will also be introduced since the thickness of the sock will be added to the scanned shape. If the thickness of the sock is known, compensation for increase in diameter and volume measurement can be made during the modification process. However, as a sock is pulled over a deformable residual limb with varying tissue characteristics it deforms the limb. The deformation may not be repeatable making compensation more difficult.

It is debatable how easily the prosthetist can position the T ring and landmarks to ensure repeatable shape capture or how accurate the algorithm to fill in ‘missing’ data actually is.

The effect on results was also compared when variables were introduced such as changing the angle of the T ring relative to the axis of the model and by purposefully placing the distal probe in an incorrect position. These are two variables thought to be likely in the clinical situation.

Figure 6-1 The T ring system

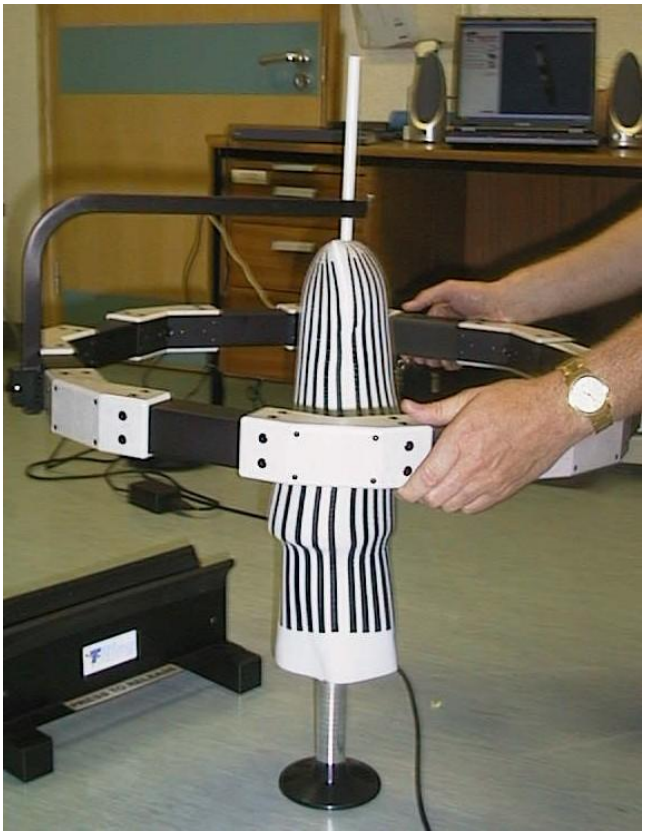

Figure 6-2 Distal spacer contacting residual limb

6.4 Methodology

Five models were created including a deformable manikin. The following sections describe each of the models in turn and how they were measured by the digital indicator (gold standard) and the Tracer CAD and T Ring systems. Following this, the technique for plaster of Paris casting is described including the use of a water tank to determine plaster model volume.

6.4.1 Models

6.4.1.1 Model 1 Cylindrical model with flat distal end

For ease of calculation of true diameters and volumes, a solid cylinder was manufactured in natural Nylon material type 6.6 (Figure 6-3). The dimensions of each model were considered to be the mean value of the gold standard measurement system shown in Table 14.

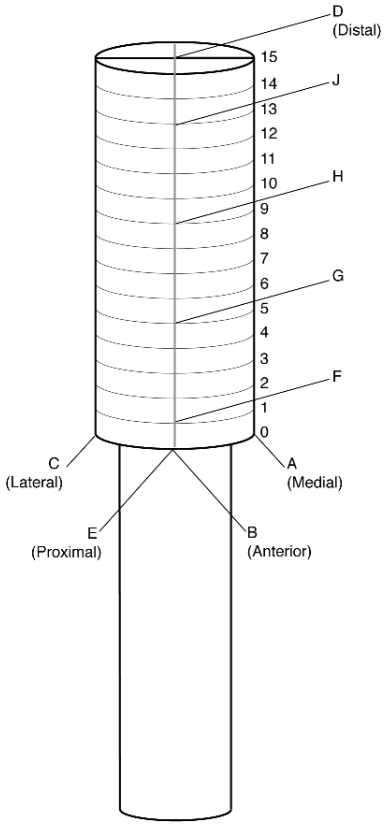

Figure 6-3 Illustration of model 1: cylinder

Table 14 Model 1 dimensions

Model 1	AP (mm)	ML (mm)	Volume (mm^3)	
F	58.08	58.08	F-G	105.94
G	58.06	58.06	G-H	105.87
H	58.04	58.04	H-J	105.83
J	58.04	58.04	J-End	50.02

6.4.1.2 Model 2: Cylinder with domed end

A solid cylinder with a spherical end was manufactured in natural Nylon 6.6 as illustrated (Figure 6-4). This model was larger in size than model 1 and had a domed end to facilitate assessment of the effect of volume capture of the distal end of the model. The model was constructed with a central hexagonal proximal mandrel which determined the model axis. Model dimensions are shown in Table 15.

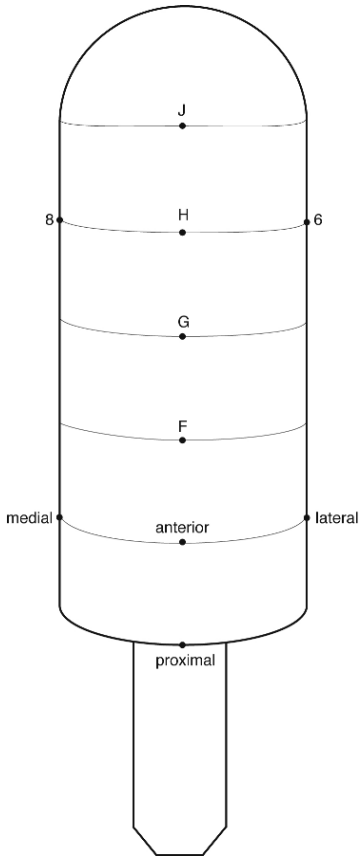

Figure 6-4 Illustration of model 2: cylinder with domed end

Table 15 Model 2 dimensions

Model 2	AP (mm)	ML (mm)	Volume (mm^3)	
F	99.94	100.29	F-G	319.74
G	100.10	100.19	G-H	310.38
H	99.60	99.85	H-J	314.67
J	99.61	99.59	J-End	262.72

6.4.1.3 Model 3: Truncated cone

For ease of calculation of true diameters and volumes, a solid truncated cone was manufactured in natural Nylon material type 6.6 (Figure 6-5). Model dimensions are shown in Table 16.

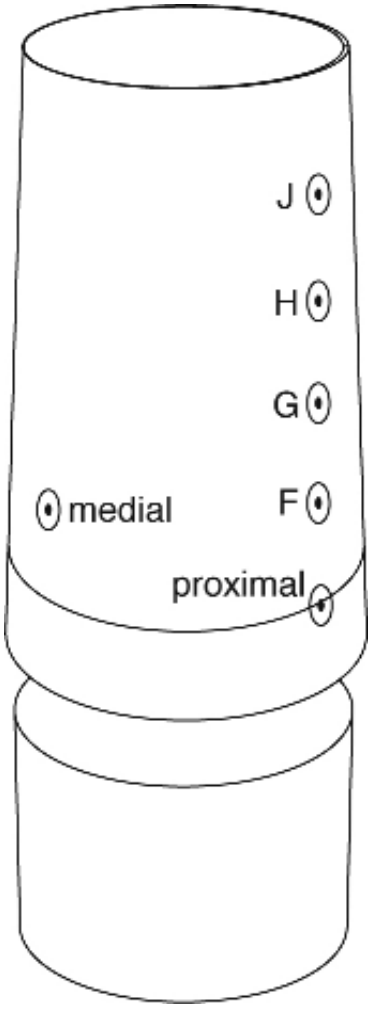

Figure 6-5 Illustration of model 3: truncated cone

Table 16 Model 3 dimensions

Model 3	AP (mm)	ML (mm)	Volume (mm^3)	
F	71.97	72.04	F-G	77.00
G	68.04	68.04	G-H	68.53
H	64.04	64.04	H-J	60.48
J	60.04	60.04	J-End	52.94

6.4.1.4 Model 4: Shaped trans-tibial model

Accurate dimensional capture of the residuum is an important process in the production of a prosthetic socket. Residual limbs are irregular in shape therefore it is important to assess if shape has an effect on the accuracy of data collected when using Tracer CAD.

A plaster of Paris cast replicating the dimensions of a rectified trans-tibial stump was produced (Figure 6-6). A hexagonal mandrel pole was used to ensure that alignment could be reproduced as demonstrated by Convery et al. (2003). Model dimensions are shown in Table 17.

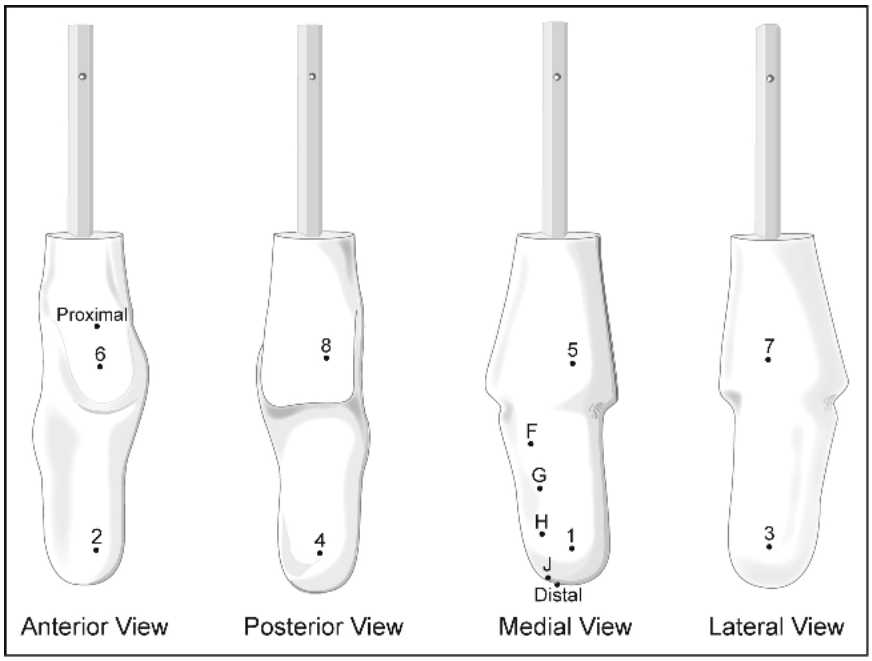

Figure 6-6 Illustration of trans-tibial model showing landmark position

Table 17 Model 4 dimensions

Model 4	AP (mm)	ML (mm)	Volume (mm^3)	
F	105.49	103.49	F-G	382.47
G	95.42	86.78	G-H	321.16
H	97.15	87.09	H-J	292.46
J	75.35	70.95	J-End	41.66

6.4.1.5 Model 5: TT deformable manikin

Ideally a patient would be used to test and compare the shape capture methods. The objective of this being to explore the effect of tissue compliance on CAD sensing particularly as one system relies on a contact method of shape capture. As a method of obtaining a central axis on the residual limb has not been established, accurate comparison of results on a patient is not possible. Additionally as volume changes in the stump could occur it would be difficult to determine whether the error was caused by changes in residual limb volume or by shape capture systems.

To enable the effect of tissue deformation in shape capture an alternative approach has been adopted to assess the Tracer CAD and T ring systems using a deformable manikin (Figure 6-7, Figure 6-14). Model dimensions are shown in Table 18.

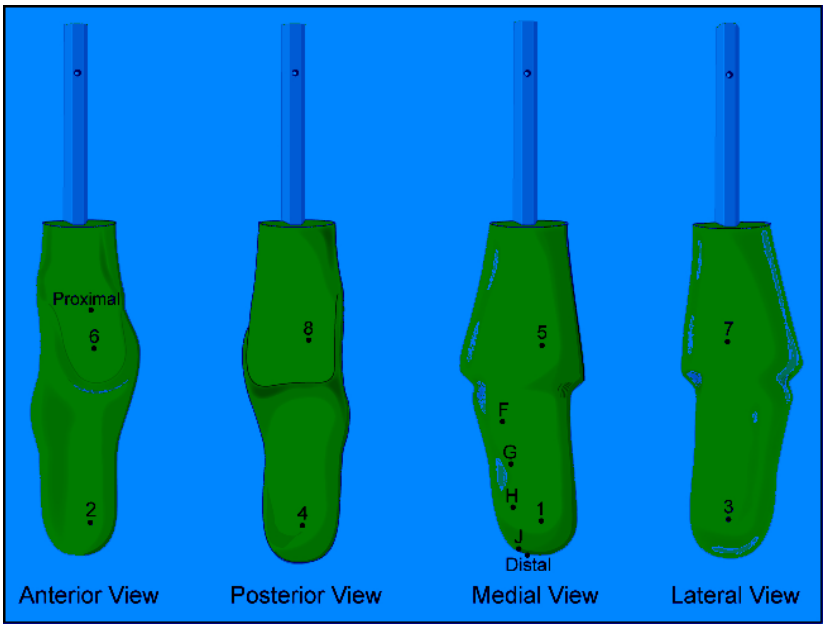

Figure 6-7 Illustration of trans-tibial manikin showing landmark position

Table 18 Model 5 dimensions

Model 5	AP (mm)	ML (mm)	Volume (mm^3)	
F	104.63	103.56	F-G	362.29
G	95.13	86.12	G-H	323.66
H	96.58	86.43	H-J	297.17
J	74.55	70.77	J-End	43.76

The manikin created was deformable and made with medical grade 2-part silicone rubber (RTV6166 General Electric co.) which has proven success in tissue simulation whilst allowing a constant volume to be maintained (Kerdok AE et al 2001).

The manikin was a complex structure which was developed as far as possible to simulate the properties of a residual limb.

A *northplex* former was draped over model 4. Once draped, the model and former were placed into the copying jig and a hexagonal mandrel post bonded distally. The former was carefully removed from the model and bivalved so that it could be mechanically fitted together.

To provide an outer 'skin' to the model, layers of silicone were built up around the inside of the plastic former. This was done using Otto Bock silicone (617H44 silicone gel shore hardness 5^0) which was swilled around the plastic former in several layers until the thickness of silicone was approximately 3-4 mm thick (Figure 6-8).

Figure 6-8 Outer silicone 'skin' of model

An anatomical functional model of a Right knee joint was used to simulate the shape, size and location of the bony structure within the model (Adam, Rouilly model ME43).This corresponded to the size of the former from model 4.

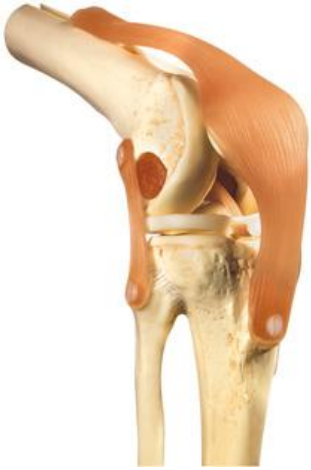

Figure 6-9 Skeletal manikin structure

A ‘muscle’ was added to the posterior aspect of the bony model to represent the deformable nature of musculature (namely gastrocnemius) and fixed in position to the insertions and origins of this muscle to mimic a residual limb. The ‘muscle’ was then placed in a polypropylene net to try to simulate the muscle fibres and consisted of a condom filled with hydroscopic granules mixed with water. The muscle allowed a constant volume to be obtained but was more deformable than the silicone which surrounded it (Figure 6-10).

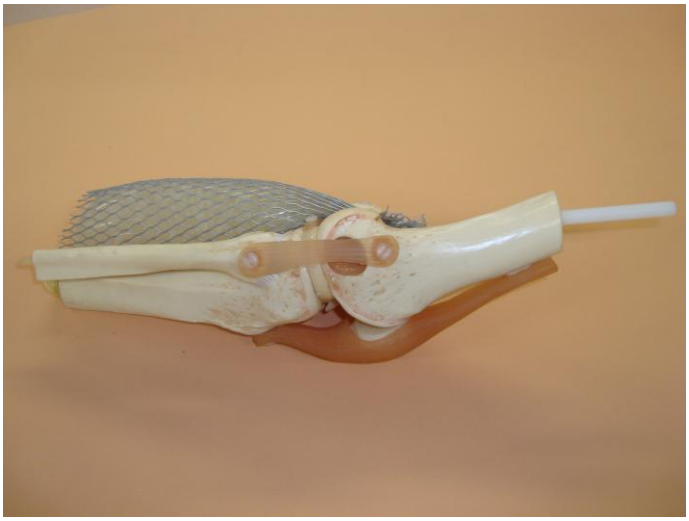

Figure 6-10 Skeleton of manikin with 'muscle' attached

The anatomical knee joint was fixed in 5 degrees flexion and bonded to a wooden top plate with hexagonal mandrel post attached (Figure 6-11).

Figure 6-11 Attachment of proximal plate and alignment post

The former was then repositioned within the copying jig and the top plate to the proximal end of the plastic former which then contained the bony model and muscle (Figure 6-12). This left a void which was filled by injecting the 2-part silicone rubber, (RTV6166 General Electric co.), through a hole in the top plate.

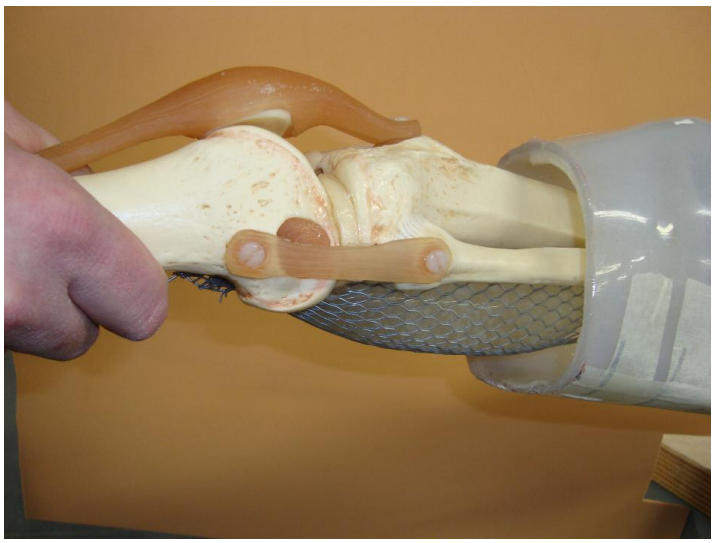

Figure 6-12 Placement of the skeletal structure into the former

Once cured the manikin was removed from the bivalved plastic former (Figure 6-13).

Volumetric measures were taken and diameters were used from the mean value of the casts produced from filling the plastic former.

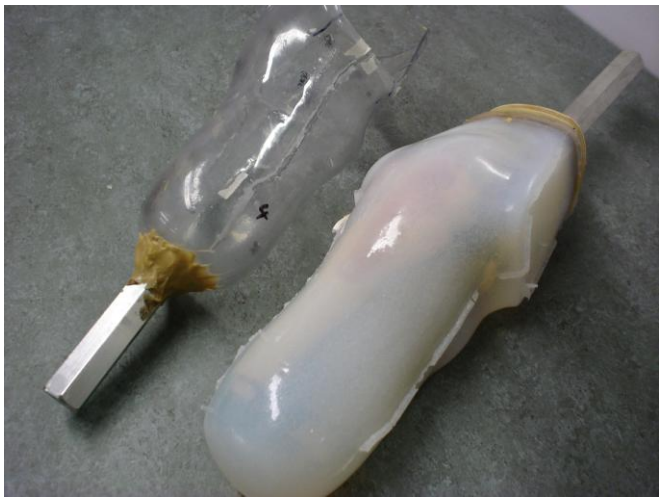

Figure 6-13 Manikin removed from former

Figure 6-14 Deformable manikin

6.4.2 Gold standard measurement

Model 1 was given to the Metrology Laboratory, Department of Design, Manufacture, and Engineering Management in the University of Strathclyde for accurate placement of datum lines and reference points to allow the model to be measured. All measurements were repeated ten times.

Three longitudinal datum lines, (A, B, and C,) were marked at 90 degree intervals around the circumference to be used as lateral, (A), anterior, (B) and medial, (C) reference lines. Sixteen regular 10mm intervals were accurately measured and marked onto the model, (point 0-15). The diameter of the cylinder was measured on each of these intervals from point 1 to point 14 on datum lines A and B. As both points 0 and 15 lay on the edge of the model, both were discounted to avoid possible error.

The volume of the shape was then determinable between any two points between 1 and 14 on the model (Figure 6-3. This was completed by the metrology laboratory using a comparator measuring device accurate to 10 microns. The comparator was routinely calibrated at regular stages throughout the measuring procedure to ensure accuracy.

The distal, (D), and proximal, (E), landmarks were also precisely indicated. Four further reference points, (F, G, H, J,) were also marked precisely to enable comparison of data at these levels. These points were identified as follows:

F	Intersection of the 10mm line (1) and anterior line B
G	Intersection of the 50mm line (5) and anterior line B
H	Intersection of the 90mm line (9) and anterior line B
J	Intersection of the 130mm line (13) and anterior line B

The ML diameters and the AP diameters were re-measured to check that the model was truly cylindrical. Diameter measurements were taken at the levels of F, G, H, and J in both AP and ML planes using an electronic digital calliper with resolution and accuracy as follows:

Measuring range	0 - 300mm	Resolution	0.01mm
Measuring range	300 - 500mm	Accuracy	0.05mm

No difference was noted between AP and ML dimensions.

All other models were held vertically in a Deckel CNC machine for accurate placement of datum lines and reference points to allow the model to be measured (Figure 6-15).

Figure 6-15 Model 2 in Deckel measurement system

Each model was placed into the Deckel CNC machine for accurate placement of datum lines and reference points to allow measurement (model 2 and 4 shown as examples Figure 6-15, Figure 6-16). To facilitate orientation of the model using Tracer CAD, landmarks were precisely marked using a Deckel CNC milling machine.

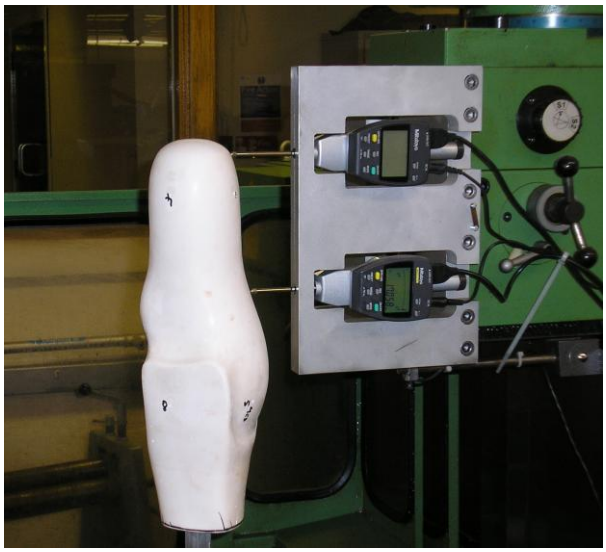

Figure 6-16 Placement of reference marks by CNC milling machine (Deckel) and a displacement tool, (Mitutoyo, series 543 1DF dynamic Indicator and data acquisition software) (model 4)

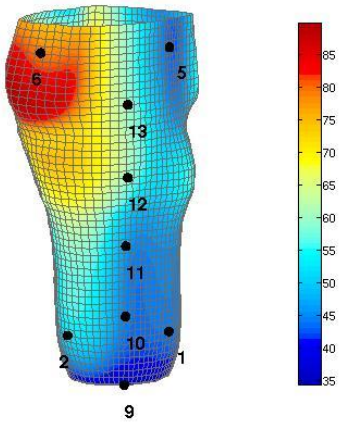

Figure 6-17 Measured data plotted and landmarks positioned (model 4)

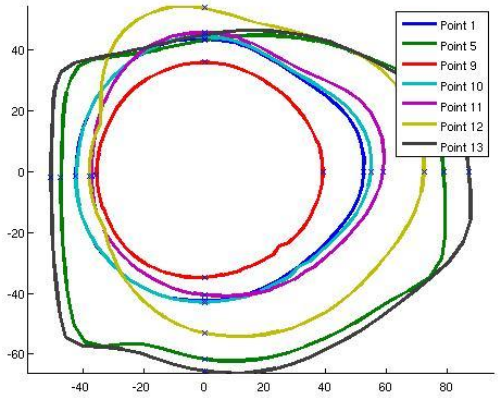

Figure 6-18 Transverse sections of data plotted at individual landmark levels (model 4)

Four datum lines (A, B, C, and D) were marked along the length of each model from the distal end to the proximal edge, at 90^0 intervals to be used as anterior (A), medial (B), posterior (C) and lateral (D) reference lines. Four circumferential lines were accurately measured and marked at regular intervals on each model (levels F, G, H and J,) (Figure 6-15). The diameter of the shape was measured on each of these intervals from level F to level J on their intersection with the Datum lines A, and B (Figure 6-4, Figure 6-5, Figure 6-6).

These diameters are denoted as follows

1A to 1C = AP dimension at level J
1B to 1D = ML dimension at level J
2A to 2C = AP dimension at level H
2B to 2D = ML dimension at level H
3A to 3C = AP dimension at level G
3B to 3D = ML dimension at level G
4A to 4C = AP dimension at level F
4B to 4D = ML dimension at level F

The distal and proximal landmarks were precisely indicated on the model. The diameters and circumferences of the shape were measured three times on each of these intervals using a programmable data acquisition system. The data acquisition system included a programmable CNC milling machine (Deckel™) and a displacement tool (Mitutoyo, series 543 1DF Dynamic Indicator™), both with an accuracy of five microns (0.005mm).

All measurements were repeated three times. The coordinates of data were then plotted and landmarks positioned to calculate AP, ML diameters, circumferences and volumes between levels (Figure 6-17, Figure 6-18).The mean value of measures taken by the dynamic indicator measurement system was calculated. The volume of the shape was then determinable between any two circumferential lines between levels F and the end of the model.

6.4.3 Volume determined by water displacement

As well as the mathematical calculations from gold standard scans, water displacement technique was also used to ascertain the volume of all models.

A water tank was built to dimensions suitable for water submersion of the largest model. The tank was filled with deionised water. At the water level there was a spout through which any displaced water was released. The displaced water was collected

and weighed on a precision balance. Temperature and atmospheric pressure were recorded in order to have control over any undesirable alterations (Figure 6-19).

Figure 6-19 Volume measurement by water displacement

A mechanism that allowed controlled descent of each model into the tank was constructed. A holding pin was screwed into the proximal end of the mandrel of each model and fixed to the holding mechanism above the water tank.

Each model was then fully submerged to displace its entire volume. Once water was fully displaced, a mark was placed on the arm of the lowering rig to indicate the level. This was repeated three times before any volume measurements were taken to ensure placement of the initial mark on the arm of the lowering jig was in the same place. Once this line was established, datum lines corresponding to the distance between the proximal end of the model and each landmark were added (Figure 6-20)

Figure 6-20 Scale applied to lowering jig

The tank was filled to the highest level and water allowed to run until it stopped. The precision balance was then zeroed and each model lowed into the tank to the corresponding level on the arm of the lowering mechanism (Figure 6-21).

Figure 6-21 Volume determination by water displacement

The weight of the displaced water was recorded and from this the volume of the immersed object was calculated. (The density of de-ionized water at 22° C is 0 .997770 kg/dm'). Five repeated measurements were performed on each object.

Due to the capillary forces (forces of surface tension and adhesive forces acting on the test object) generated using the water immersion technique, the surface is curved near the test object. This could introduce a small error of measurement but was considered small enough to be discarded in the further calculations (Lilja and Oberg 1995).

6.4.4 Tracer CAD measurement

Each model was then set up for measurement using Tracer CAD.

Figure 6-22 Vice constructed in wood

As metals in close proximity may have an adverse effect on measurements, a vice was constructed in wood to hold the model, receiver and the transmitter firmly in the desired positions to eliminate error due to the relative movement of these items during the procedure (Figure 6-22). The room was a large clinical area and all metal objects were removed as far as was practical, to reduce the chance of interference. Medial, anterior and lateral reference points were identified using the intersection of the 40mm point and lines A, B, and C respectively. The distal landmark was marked on the model at the intersection of datum line B with the 0mm circumferential line. Each model was then scanned using the Tracer CAD system a total of 120 times (30 times by each of four prosthetists) and volume & diameters at levels F to J were indicated and recorded. Each user was required to work through a sequence of events

to allow scanning to be completed in a similar method to the way in which the system is used clinically.

Each trace began with identification of landmarks using the probe. This involved touching the model (at the appropriate numbered landmark) with the probe and clicking the button. Initially to set up the axis of the model, the proximal, distal, medial, anterior and lateral landmarks were indicted. The user then traced the model using the flat side of the probe (Figure 6-23). Once cloud data was established, the level of measurement was obtained by indicating each landmark F-J. To do this, each user was required to touch the model with the pointed end of the probe and click the probe button.

Figure 6-23 Tracer CAD scanning using flat side of probe (model 3)

Although this sequence of events replicates the clinical method, it should be expected that identification of axis and landmarks should be more accurate in the experimental method. This is because the landmarks on the model have been added by the dynamic indicator rather than by eye in the clinical situation. This means that the user has a definite landmark 'target' to aim for rather than estimating the position of each landmark as in the clinical situation.

All tracings were carried out following a strict protocol to minimise the possibility of error. Prosthetists were instructed how to carry out each trace and were allowed to practice tracing before these were recorded.

6.4.5 T ring measurement

Once all users had completed tracings, a T ring sock was added to each model. Each model was then moved to the vice constructed in wood designed to hold the model, firmly in the desired position to eliminate error due to movement during the procedure (Figure 6-22). Models 1-5 were then scanned 30 times by four users of the T-Ring. Lights were dimmed to ensure no differential of intensity of light which may affect the shape captured. Volume, circumferences & diameters at levels were indicated and recorded at the same levels. All scans were taken sequentially without moving the model or removing the T ring sock to minimise the possibility of error. This process was deemed to be similar to that of the use of the T ring in normal clinical use.

Figure 6-24 T ring scanning (model 3)

To investigate the effect of angulation of the T ring, and misplacement of the distal spacer, model 2 and 4 were placed vertically and the T-Ring clamped in a horizontal position on the CNC milling machine. These models were then scanned by the T-ring a total of thirty times. Volume, circumferences & diameters at levels were indicated and recorded. All scans were taken sequentially without moving the T-Ring or model to minimise the possibility of error. The angle of the T ring was then changed, using an angular adjustment on the Deckel CNC milling machine, by 2^0, 4^0, and $6^{0.}$ All measurements were repeated (n=30) for each of these three orientations.

6.4.6 Plaster of Paris measurement

The shape of models 2, 4 and 5 were also captured using plaster of Paris.

Landmarks (F-J) were highlighted on the original model using indelible pencil. The model was placed in a vice and wrapped with 150mm plaster of Paris bandage (Gypsona) (Figure 6-25). Each wrap cast used three rolls of plaster bandage applied in a similar manner as a prosthetist would apply bandage to a residual limb. The use of indelible ink meant that landmarks transferred automatically to the plaster wrap from the model surface. No intermediate stockinette was used although a very small amount of lubrication oil was applied to the model to ensure that the cast could be removed.

Figure 6-25 Plaster of Paris casting model 2

The initial cast was left to dry for ten minutes and was then fixed in a proximal vice in a copying jig specifically designed to allow duplication of the alignment of each cast (Figure 6-26).

Use of the copying jig allowed the negative plaster mould to be removed from the model and filled without alteration to the angle or length of the mandrel post. The copying accuracy of this jig was previously validated and was considered to produce reliable copying results (Convery et al. 2003).

The copying jig consisted of a proximal and distal vice which were perfectly aligned such that if a long length of mandrel post was placed in the proximal vice, it would run through the centre of the distal vice. The fact that each mandrel post was hexagonal meant that the rotation of the model could also be controlled. The vice also contained two end stops such that the distance between the top of the proximal vice and the bottom of the distal vice was fixed. This prevented any length discrepancies between the end of the mandrel pole and the end of each final model which is important to ensure coordinates are matched when measuring each cast in the gold standard measurement system.

Figure 6-26 Cast duplication jig

Once the cast was positioned in the proximal vice, a length of hexagonal post was placed in the distal vice. This had an additional T bar added to prevent rotation. The distal mandrel post was then bonded to the distal end of the cast and additionally wrapped in plaster of Paris to prevent any possibility of movement (Figure 6-27).

Figure 6-27 Fixation of distal hexagonal alignment post

The entire model with distal mandrel post attached was removed from the jig and placed in a vice (Figure 6-28). The negative plaster mould was then removed from the model (Figure 6-29).

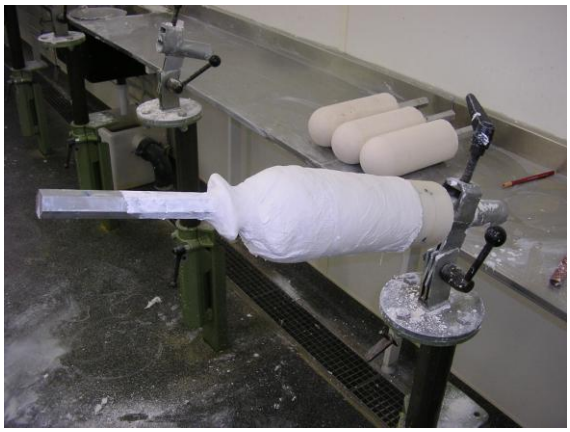

Figure 6-28 Removal of negative cast from model 2

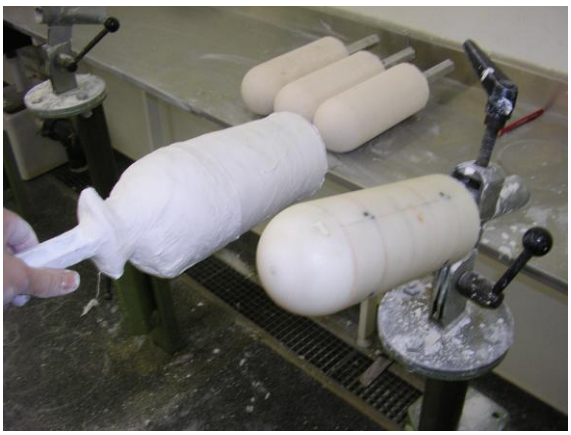

Figure 6-29 Removal of negative cast from model 2

The negative mould with distal mandrel post was then reinserted into the distal vice of the copying jig in the same angle of rotation as before the model was removed. A new mandrel post was positioned in the proximal vice and the cast filled with plaster (Figure 6-30).

Figure 6-30 Repositioning of negative cast of model 2 ready for filling

The quantity of Plaster of Paris was mixed with water according to manufacturers guidelines (www.bpbformula.com). Quantities of water in relation to Plaster were weighed prior to mixing to ensure no difference between casts. The negative mould was then carefully cut and removed from the positive mould. This entire procedure was repeated four times to create four plaster of Paris casts of the model.

The original model was then placed in the gold standard measurement system and the coordinates of points F-J located and recorded (Figure 6-31).

Figure 6-31 Model 2 location of landmark coordinates

Each plaster of Paris model was then placed in the programmable CNC milling machine (Deckel^{TM}) and measured starting from the coordinate of the original landmark. This ensured that the same points on each model were measured. AP and ML diameters were recorded at each level. Measurements were repeated three times and the mean value calculated (Figure 6-32).

Figure 6-32 Plaster of Paris cast measurement

Following determination of diameters, the volume of each model was calculated using the water displacement technique. This is described in full in the previous section (Pg 141).

A shaped cast was then assessed. The accuracy and repeatability of plaster of Paris shape capture may be affected by the shape of the model. It is important to assess this as the shape of a residual limb is not cylindrical. The complex shape and material of model 4 presented some challenges in how best to create a plaster of Paris cast. This was because after a cast is taken over a plaster model, a residue of plaster is left on the model which is not possible to remove without risk of alteration to the model shape. This could introduce changes from cast to cast if the same plaster model was used.

It was also extremely difficult to remove the plaster negative from the positive plaster model without damage to the model and / or the cast. The negative cast could be removed by cutting the cast off, however this involved cutting directly onto the positive model causing damage to the model thus changing the dimensions. Addition of a cutting strip would eliminate damage but introduces changes to the negative cast dimensions.

In clinical practice the trans-tibial casting procedure does not include cast cutting and therefore the above experiment was not considered to be a good representation of this process.

A new trans-tibial model was prepared to allow removal of the model from a plaster cast without damage to the cast or model (Figure 6-35). The new model was made of a hard foam material, in sections and contained a central core and was created from the original former user to create the shaped trans-tibial model (model 4) (Figure 6-36). Removal of the core allowed sections to be removed from the cast and reassembled avoiding the need to cut off the plaster negative cast. The model material was sealed allowing it to be easily cleaned without damage to avoid build up of plaster residue.

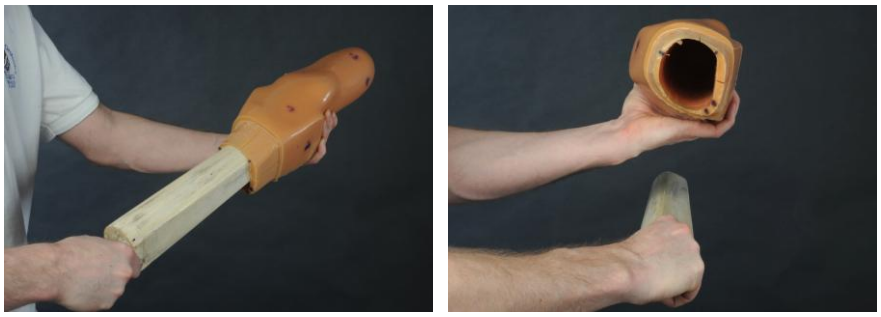

Figure 6-33 Removal of central core

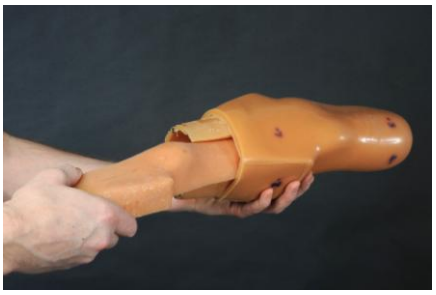

Figure 6-34 Removal of inner sections

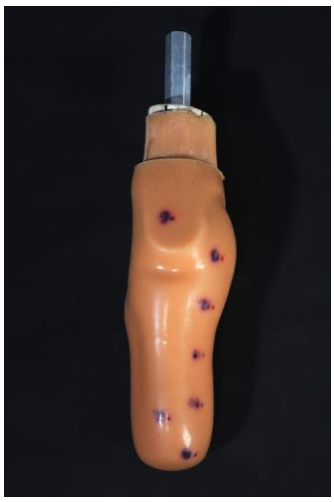

Figure 6-35 Shaped removable model

Figure 6-36 Shaped TT model; model former; Shaped removable model and manikin

To manufacture the removable model (model 4B) an orthoplex drape was created over model 4 and the model and socket placed in the transfer jig.

With the hexagonal mandrel post of model 4 held in the proximal vice, a distal hexagonal mandrel post was bonded to the distal end of the draped model. Landmarks were transferred though the transparent material and screw attachments added to each side of the drape which was bivalved to allow model 4B to be

removed. The plaster of Paris was then chipped out. The addition of the distal hexagonal post ensured that the alignment of the central axis of the cast did not alter.

A large tapered mandrel with hexagonal post within was then manufactured to fill a large central portion of the cast. Stiff foam was then poured and swilled around the inside of the drape to create a wall thickness of approximately 5mm and thus duplicating the dimensions of the drape. The material was cured and lubricated so that no further foam could bond to it. The partially duplicated drape with distal mandrel attached was placed back into the transfer jig. The large tapered mandrel (with hexagonal post within) was placed in the upper vice and lowered into the socket. Stiff foam material was then poured into the remaining void between the outer and the mandrel and allowed to cure.

Once cured, the entire model and mandrel was removed from the bivalved drape. The tapered mandrel was removed allowing the inner to be removed from the outer section.

To facilitate easy removal of the inner from the outer the inner was then cut into three sections to allow easy removal and assembly (Figure 6-35).

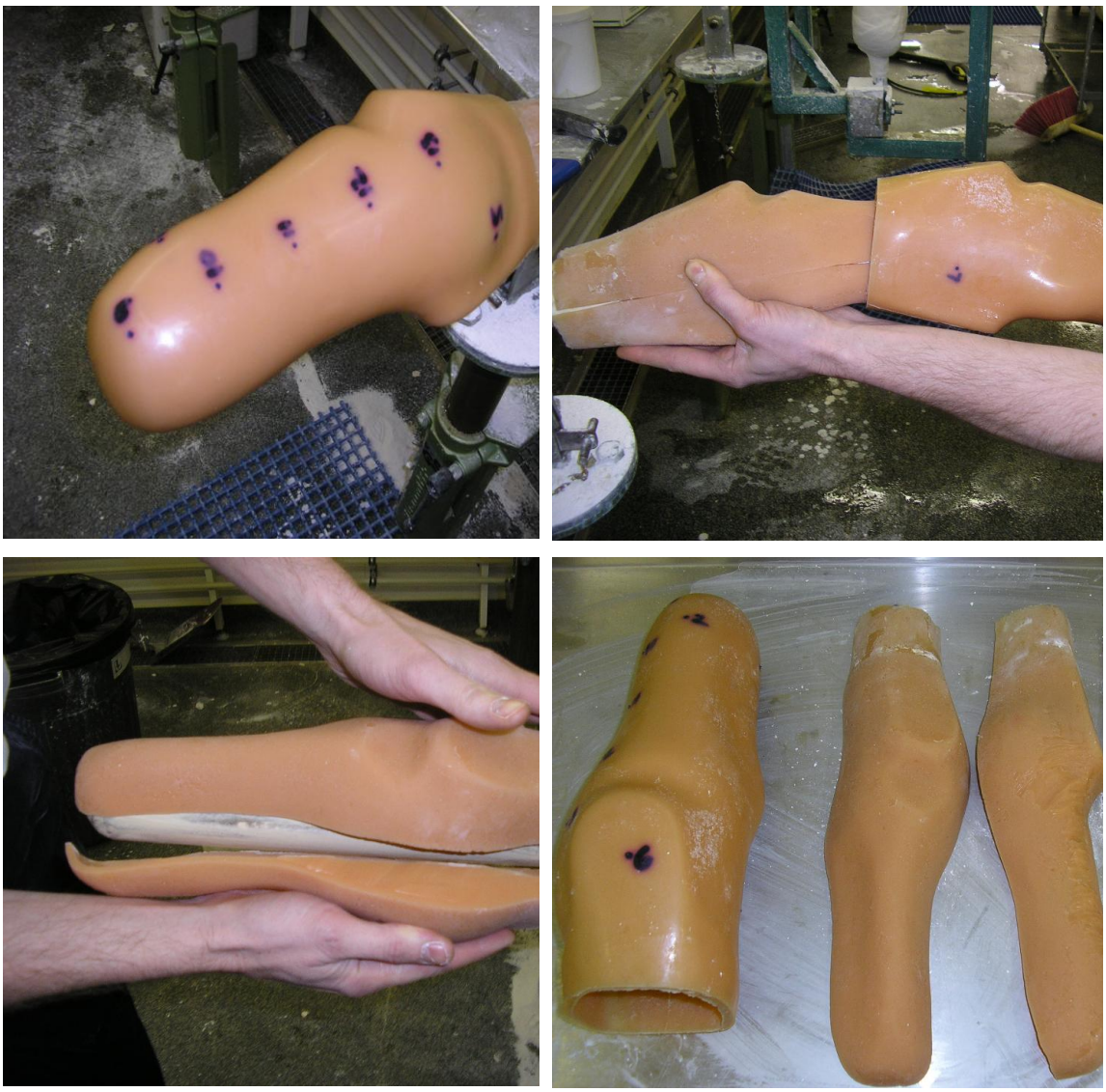

Figure 6-37 Removable model

Figure 6-38 Measurement of removable model

The new model (model 4B) was then measured by the dynamic indicator (accurate to 0.005mm) and diameters at each level F- J recorded (Figure 6-38). These were compared to the model from which it was created (model 4). Due to the copying process, inevitably some minor changes in measurement occurred. To ensure best interpretation of results, plaster of Paris measurements were compared to model 4B whilst those obtained by Tracer CAD and Tring were compared to model 4 (Figure 6-39).

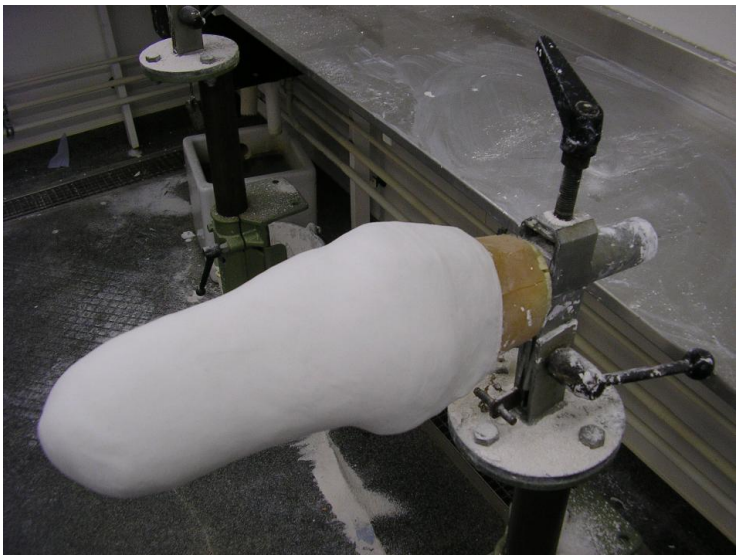

Figure 6-39 Plaster of Paris shape capture model 4B

The model was then cast four times using plaster of Paris. Once cast, each model was placed in the specially constructed copying jig to ensure that the mandrel post was positioned in the same place each time so that the angle of the model did not change (Figure 6-40, Figure 6-41).

Figure 6-40 Positioning of cast model 4B in duplication jig

Figure 6-41 Placement of distal hexagonal alignment post

The removable model was then removed from the negative mould in sections, allowing the negative cast with distal mandrel to be re inserted into the copying jig (Figure 6-42, Figure 6-43). Once filled (Figure 6-44), each plaster cast was removed and placed in the gold standard dynamic indicator measurement system to determine diameters and allow comparison with Tracer CAD and T ring systems.

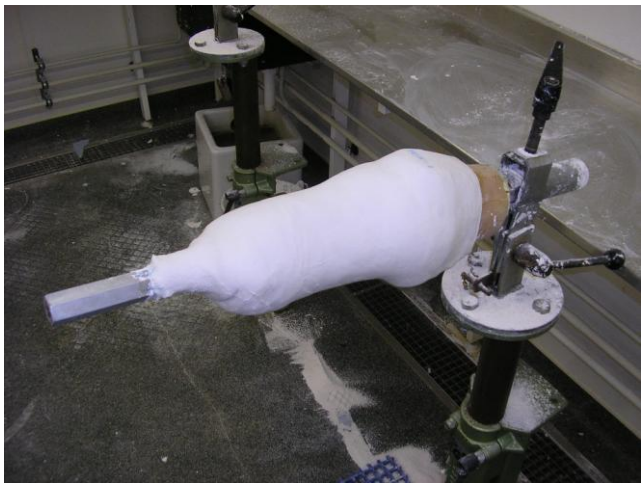

Figure 6-42 Negative cast of model 4 prior to removal

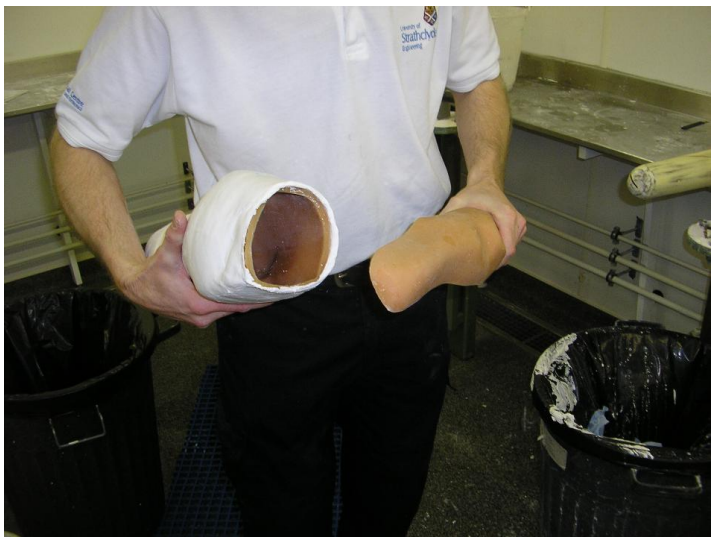

Figure 6-43 Removal of model from negative plaster cast

Figure 6-44 Filling of negative cast in the duplication jig

The major concern about determining the accuracy and repeatability of plaster of Paris in this experiment was that a positive model was required to obtain

measurement. This introduced an additional step and potential additional errors in the filling process beyond which CAD systems are tested.

To validate the accuracy of the copying procedure and examine what errors may be introduced during the filling procedure the original former was placed within the jig and filled three times using plaster of Paris (Figure 6-45). Errors are displayed on volume graphs in the results section and are discussed.

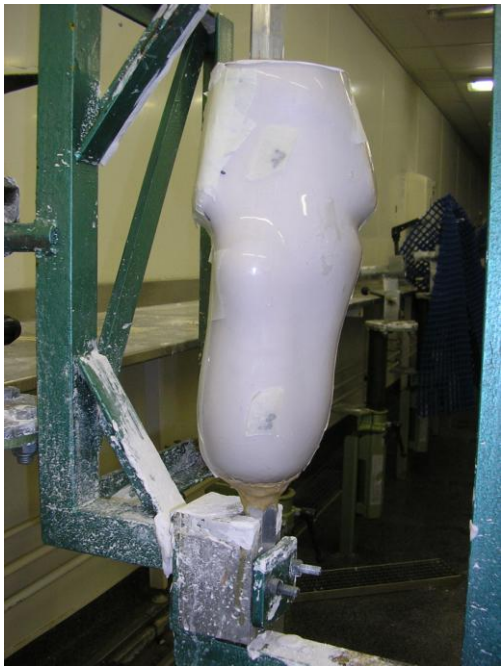

Figure 6-45 Validation of the copying procedure

Removal of the plaster of Paris negative mould from the manikin was straightforward due to the deformation of the model. Use of a manikin allowed a central axis to be established and landmarks positioned ensuring accurate comparison of results.

To ensure it returned to its original shape following deformation, digital photographs of the manikin were taken from a camera mounted on a tripod after each plaster cast and every 5th Tracer CAD and T ring scan. A scale was added to the manikin shape prior to photography. Photographs were imputed into Adobe Photoshop (CS3 extended edition) which allowed photographs to be converted and measured to scale

at each landmark position. No difference was observed in the measurement of landmarks on photographs taken at different times during shape capture, concluding that the manikin returned to its original shape following measurement.

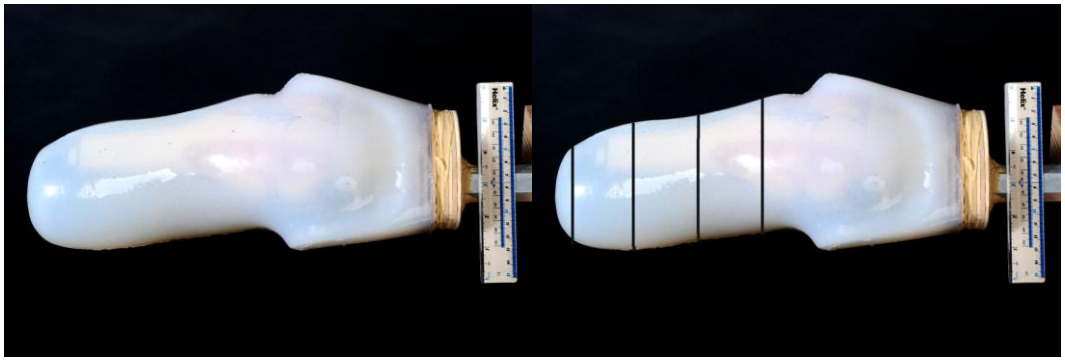

Figure 6-46 Checking manikin dimensions between casts/scans levels FGHJ

It is important to note that the manikin represents a deformable shape which happened to be of dimensions similar to that of a trans-tibial stump. It does not attempt to replicate all residual limbs as the tissue consistency of stumps differs from patient to patient. Creation of a manikin permits the effect of deformation on CAD sensing to be assessed, particularly as one system relies on a contact method of shape capture. This facilitates greater clinical inference from results.

6.4.7 Additional experiments to determine cause of errors: Bending effect

As models were clamped at the distal end it was thought that it may be possible, using the Tracer CAD pen to cause a bending effect on the model.

If distal pressure is applied this will result in an increasing bending moment on the model. To examine the effect of bending and shifting of the model, a further experiment was conducted. The model was placed in the wooden vice (Figure 6-22), and the dynamic indicator placed touching the model on the lateral distal model as shown, 500mm above the level of the wooden vice (Figure 6-47). Each of the original four users was asked to simulate how they would trace the model a total of twenty times each. This allowed the deflection of the model to be measured (Table 23). If the same force is applied distally it would cause greater discrepancy than

proximally if bending is the mechanism involved. Users were not given feedback on the deflection they caused during each trace while they were carrying out the scans.

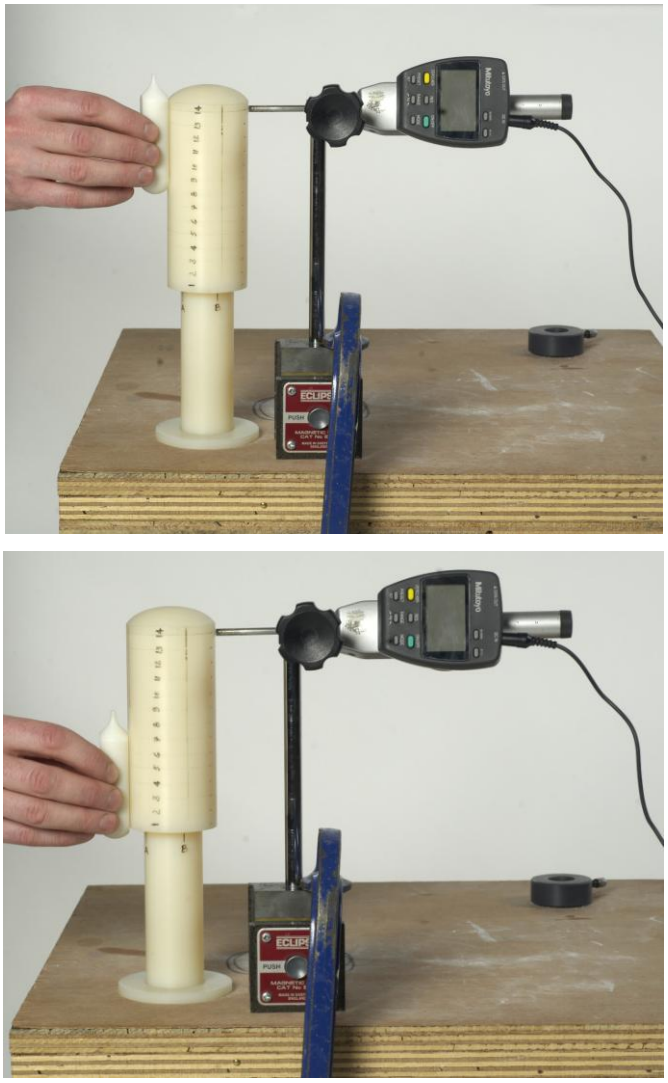

Figure 6-47 Experiment to examine the effect of bending of the model.

Results of all experiments are reported in the next section and discussed in chapter 8.

Chapter 7

7 Results

7.1 Summary statistics

Summary statistics, mean value and (standard deviation) are presented for diameter and volume measurement at by each system at each level on each model. The number of times each model was scanned is also shown in italics.

Table 19 Summary statistics: mean AP diameter values (mm)

Level	System	Model				
		1	2	3	4	5
F	Gold std.	58.08 (0.01) *n=10*	99.94 (<0.01) *n=3*	71.97 (0.06) *n=3*	105.49 (<0.01) *n=3*	104.63 (0.17) *n=30*
	Tracer CAD	57.70 (0.24) *n=15*	99.52 (0.32) *n=30*	71.51 (0.46) *n=30*	107.19 (0.98) *n=30*	103.95 (2.01) *n=30*
	T ring	58.83 (0.65) *n=30*	100.35 (0.63) *n=30*	75.01 (0.59) *n=30*	107.88 (1.64) *n=30*	110.30 (2.01) *n=30*
G	Gold std.	58.06 (<0.01)	100.10 (<0.01)	68.04 (<0.01)	95.42 (<0.01)	95.13 (0.93)
	Tracer CAD	57.46 (0.24)	99.52 (0.35)	68.40 (0.48)	97.97 (0.40)	96.44 (1.86)
	T ring	60.05 (0.88)	100.28 (0.71)	71.72 (0.64)	97.94 (0.71)	100.53 (1.20)
H	Gold std.	58.04 (<0.01)	99.60 (<0.01)	64.04 (<0.01)	97.15 (<0.01)	96.58 (0.13)
	Tracer CAD	57.44 (0.21)	99.43 (0.36)	65.36 (0.44)	98.86 (1.23)	97.02 (2.40)
	T ring	59.63 (0.89)	100.09 (0.75)	68.48 (0.95)	97.63 (0.36)	96.95 (3.76)
J	Gold std.	58.04 (0.01)	99.61 (<0.01)	60.04 (<0.01)	75.35 (<0.01)	74.55 (0.20)
	Tracer CAD	57.35 (0.24)	99.31 (0.61)	62.43 (0.44)	75.73 (0.75)	73.14 (2.58)
	T ring	54.56 (1.53)	99.26 (0.5)	64.67 (2.04)	73.11 (4.83)	58.52 (4.43)

Summary statistics list the mean diameter and volume results measured by each system on each model at each level. For example, the AP diameter of model 4 at level G obtained by Tracer CAD was 97.97mm (Table 19).

Table 20 Summary statistics: mean ML diameter values (mm)

Level	System	Model				
		1	2	3	4	5
F	Gold std.	58.08 (0.01) *n=10*	100.29 (<0.01) *n=3*	72.04 (<0.01) *n=3*	103.49 (<0.01) *n=3*	103.56 (0.19) *n=3*
	Tracer CAD	58.06 (0.21) *n=15*	99.49 (0.33) *n=30*	71.83 (0.38) *n=30*	107.75 (0.61) *n=30*	105.07 (1.42) *n=30*
	T ring	58.73 (0.60) *n=30*	100.61 (0.74) *n=30*	75.53 (0.49) *n=30*	107.40 (0.49) *n=30*	100.88 (2.41) *n=30*
G	Gold std.	58.06 (<0.01)	100.19 (<0.01)	68.04 (<0.01)	86.78 (<0.01)	86.12 (0.12)
	Tracer CAD	57.82 (0.27)	99.36 (0.39)	68.68 (0.41)	88.24 (0.61)	82.63 (1.63)
	T ring	61.39 (0.90)	100.92 (0.71)	72.52 (0.60)	90.88 (1.63)	87.47 (1.29)
H	Gold std.	58.04 (<0.01)	99.85 (<0.01)	64.04 (<0.01)	87.09 (<0.01)	86.43 (0.11)
	Tracer CAD	57.72 (0.25)	99.20 (0.46)	65.59 (0.36)	88.53 (0.37)	80.59 (1.52)
	T ring	61.01 (1.10)	100.80 (0.69)	69.64 (0.89)	89.85 (1.35)	87.79 (2.96)
J	Gold std.	58.04 (0.01)	99.59 (<0.01)	60.04 (<0.01)	70.95 (<0.01)	70.77 (0.09)
	Tracer CAD	57.70 (0.19)	99.05 (0.71)	62.64 (0.31)	72.58 (0.63)	67.18 (2.14)
	T ring	56.23 (2.16)	99.92 (0.48)	66.29 (2.08)	70.95 (4.45)	57.30 (5.14)

Note: 'n' data is the same for levels F, G, H and J and therefore not repeated.

Table 21 Summary statistics: mean Volume values (mm^3)

Level	System	Model				
		1	2	3	4	5
F	Gold std.	105.94 (0.01) *n=10*	319.74 (<0.01) *n=3*	77.00 (0.06) *n=3*	382.47 (0.92) *n=3*	362.29 (2.28) *n=3*
	Tracer CAD	105.66 (1.89) *n=15*	317.77 (5.17) *n=30*	77.38 (2.36) *n=30*	389.84 (6.94) *n=30*	357.07 (12.49) *n=30*
	T ring	113.11 (3.75) *n=30*	328.65 (7.26) *n=30*	83.83 (5.03) *n=30*	395.73 (10.07) *n=30*	379.69 (12.74) *n=30*
G	Gold std.	105.87 (<0.01)	310.38 (<0.01)	68.53 (<0.01)	321.16 (0.64)	323.66 (1.18)
	Tracer CAD	103.80 (1.90)	313.58 (7.12)	71.95 (2.20)	320.44 (8.97)	296.44 (12.27)
	T ring	115.70 (4.03)	332.04 (13.41)	75.93 (3.62)	337.27 (10.35)	341.03 (11.23)
H	Gold std.	105.83 (<0.01)	314.67 (<0.01)	60.48 (<0.01)	292.46 (0.94)	297.17 (3.66)
	Tracer CAD	105.93 (1.68)	315.31 (6.94)	65.97 (2.02)	269.63 (5.80)	227.61 (11.46)
	T ring	107.65 (4.06)	321.72 (14.29)	68.49 (3.31)	271.86 (16.18)	258.19 (23.98)
J	Gold std.	50.02 (0.01)	262.72 (<0.01)	52.94 (<0.01)	41.66 (0.73)	43.76 (1.54)
	Tracer CAD	51.35 (1.82)	257.24 (6.74)	66.16 (1.81)	90.71 (3.04)	75.37 (7.28)
	T ring	33.85 (3.01)	251.10 (14.36)	59.56 (9.45)	82.75 (22.00)	38.89 (7.92)

7.2 Accuracy results

The importance of using accurate measurements is vital. If the process begins with inaccurate data, then there the chance that the final socket will fit properly will be reduced. Accuracy is how close the measured value is to the actual value which in this thesis is considered to be the mean value of the gold standard measurement.

Statistical significance of results and interactions causational of errors were analysed using three factor balanced parametric analysis of variance for each measurement (*General linear model, Minitab 15*).

Three different factors thought to have possible effect on the accuracy obtained by each system were tested; the shape captured (the model); the method of shape capture (the system used); and the level of capture (level F, G, H and J).

Each of the six hypotheses that were appropriate for testing for AP, ML and volume results obtained are presented. The two hypotheses that relate specifically to the effect of the intervention (model-system and system-level) are highlighted in bold.

H_0: There is no model effect H_1: There is a model effect	H_0: There is no system effect H_1: There is a system effect
H_0: There is no level effect H_1: There is a level effect	**H_0: There is no model-system interaction** **H_1: There is a model-system interaction**
H_0: There is no model-level interaction H_1: There is a model- level interaction	**H_0: There is no system-level interaction** **H_1: There is a system-level interaction**

Table 22 summarises the significance ($p<0.05$) or otherwise of each of these hypotheses when each of the six factors was analysed. Significant p-values are highlighted in yellow.

Table 22 Summary of significant results

Dimension	Model factor (Models 1-5)	System factor (Gold std, Tracer Cad, T ring)	Level factor (levels F-J)	Model*system	Model*level	System*level
AP	<0.001	0.528	<0.001	0.584	<0.001	0.039
ML	<0.001	0.163	<0.001	0.023	<0.001	0.045
Volume	<0.001	0.238	<0.001	0.688	<0.001	0.012

Results indicated a significant effect for both the model ($p<0.001$) and level of measurement ($p<0.001$) as well as the interaction between model and level ($p<0.001$) (Table 22).

A significant effect was seen with the model-level interaction for diameter and volumes measured (Table 22). This was expected as the physical dimensions, (diameters and volumes), of all models were not the same i.e. the models were significantly different. For example at level G, the AP diameter of model 4 was less than the AP diameter on model 2, but the converse is true at level F. This explains why such a significant result was obtained. (Figure 7-1).

More importantly, there was significant effect for system-level interaction (AP $p = 0.039$, ML $p =0.045$, Volume $p=0.012$) (Table 22).

Even though a significant effect was not observed for model-system interaction for AP diameter and volume diameter, plots are also analysed to allow visual comparison to the gold standard measurement.

Residual plots did not however show normal distribution and despite several attempts, a transformation was not forthcoming. Despite this, analysis of variance is known to be a robust method of analysis (Howell 1997, Rutherford 2001) and results are displayed on interaction plots (Figure 7-1 to Figure 7-7). Plots are presented for AP and ML diameter and volume measurement. For clarity, graphs are interpreted in greater detail in this section.

AP diameter

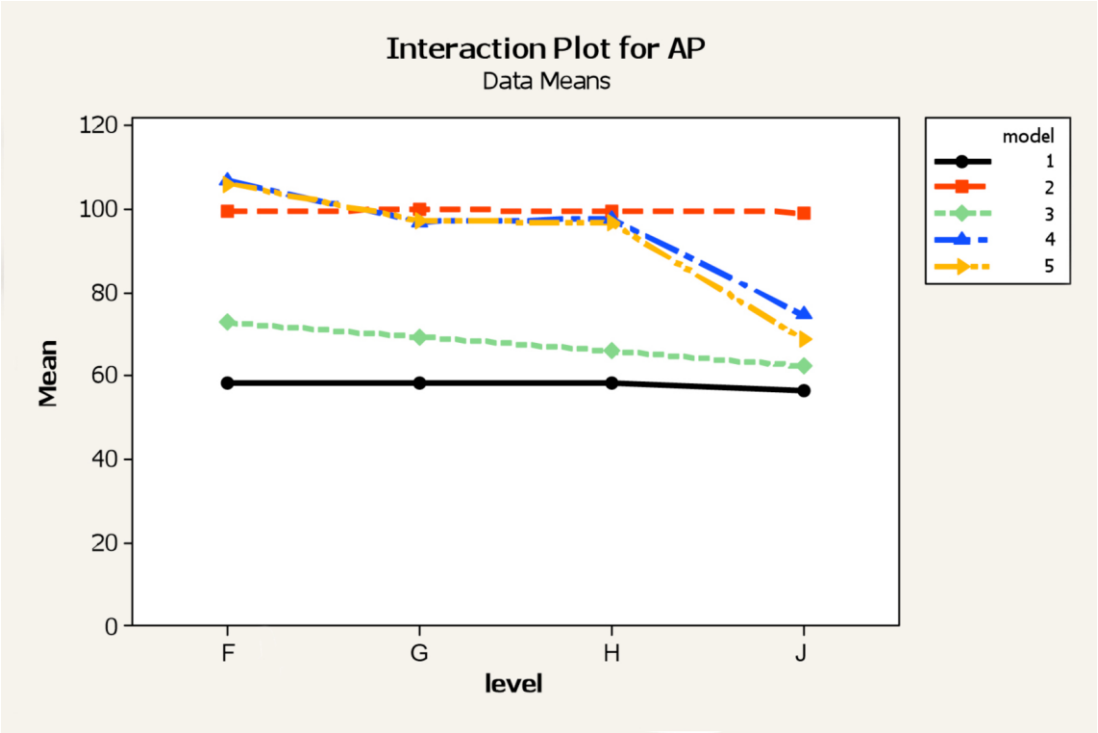

Figure 7-1 Interaction plot AP model*level

Interaction plots provide useful insight into the accuracy obtained by each system at each level of measurement. For example Figure 7-1 illustrates a model-level interaction plot for AP diameters. Each line of the graph illustrates the measurements for each model (1-5), at each level (F-J). Whilst not of particular interest given that models are different and shapes differ, this analysis does confirm that for models 1, 2 and 3 AP dimension varies little across levels F-J. Not surprisingly, given the shape of models 4 and 5 the AP diameter varies considerably at different levels measured (Table 22).

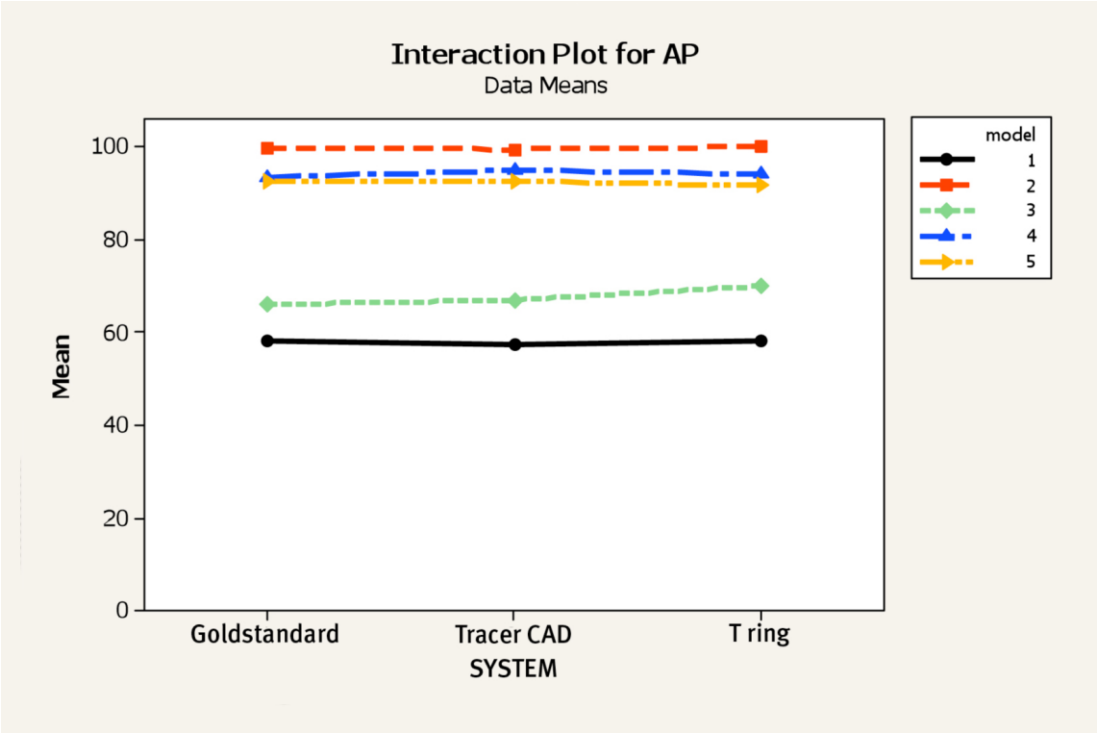

Figure 7-2 Interaction plot AP model*system

No significant effect was seen with the model-system interaction for AP diameters measured (p=0.584). (Table 22) (Figure 7-2).

Analysis of the AP model-system interaction plot showed good accuracy of both Tracer CAD and T ring systems when recording AP diameter measurement of simple cylindrical models. Good agreement between measurements of the gold standard and CAD systems was seen on models 1 and 2.

The Tracer CAD system showed good accuracy when measuring the AP diameter of model 3. However, the T ring system tended to overestimate the AP diameter relative to the gold standard.

Both systems, (and in particular the Tracer CAD system), tended to overestimate the AP diameter of model 4 (non deformable shaped trans-tibial cast), but appear to show good accuracy in recording the diameters of model 5.

The interaction system-level plot of measurement of all models shows a distinct pattern in the accuracy of AP diameter data collected by each system (Figure 7-3). The Tracer CAD system showed good accuracy at all levels of measurement when compared to the gold standard. The T ring system however had a tendency to overestimate values at proximal levels but underestimated the distal AP diameter considerably at level J (Table 22).

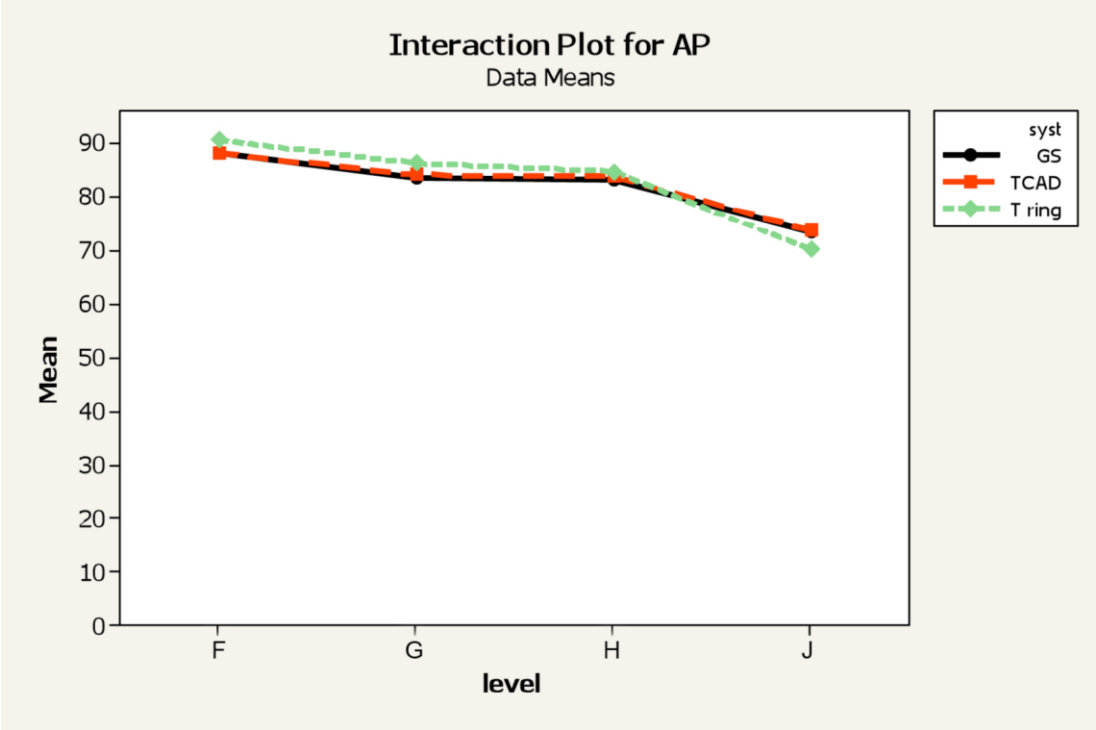

Figure 7-3 Interaction plot AP system*level

ML diameter

Significant effect was observed with the model-system interaction for ML diameters measured (p=0.023). (Table 22)).

Good diameter accuracy was observed on simple cylindrical models (models 1 and 2). However both systems, (and in particular the T ring system), had a tendency to overestimate values on more complex non deformable models (Models 3 and 4) (Figure 7-4).

CAD system ML mean diameters at all levels were notably less than those obtained by the gold standard on the deformable model (model 5).

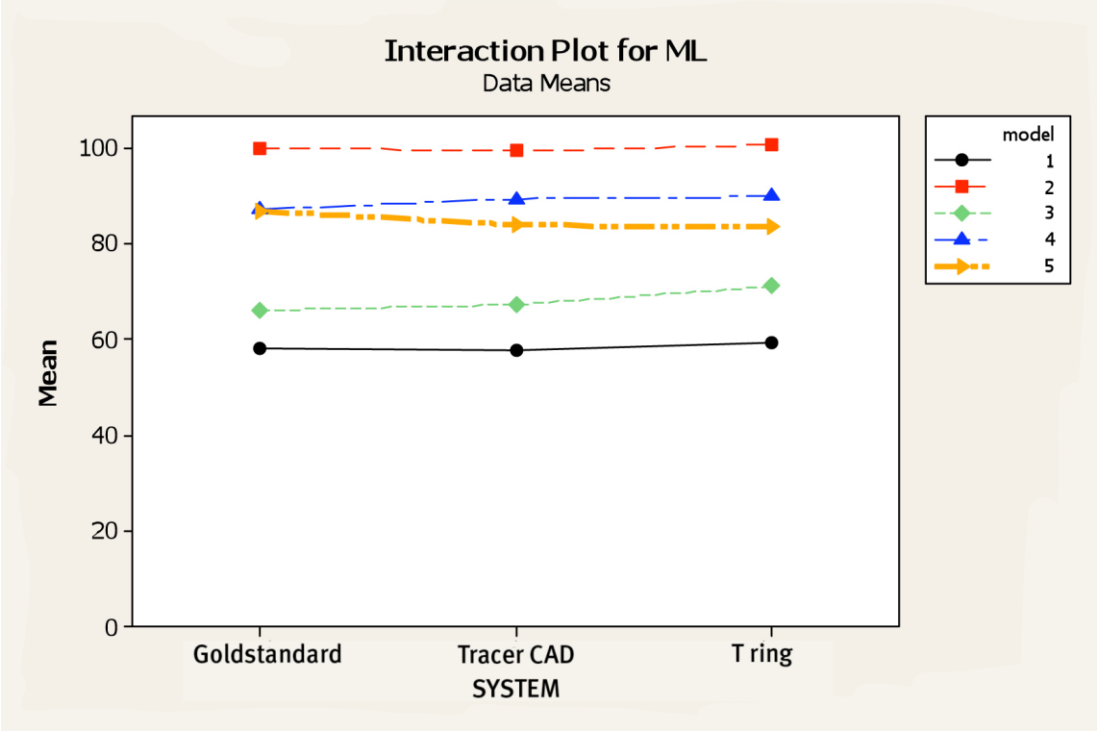

Figure 7-4 Interaction plot ML model*system

Significant interaction was noted on ML dimensions captured by systems on all models (p= 0.045) (Table 22). Closer examination of the interaction plot and statistics summary (Figure 7-5, Table 20) indicates an overestimation of the mean ML value by the T ring at levels G and H, and underestimation of ML diameter at level J. Slight underestimation of the ML diameter by the Tracer CAD system is also evident at levels G and H

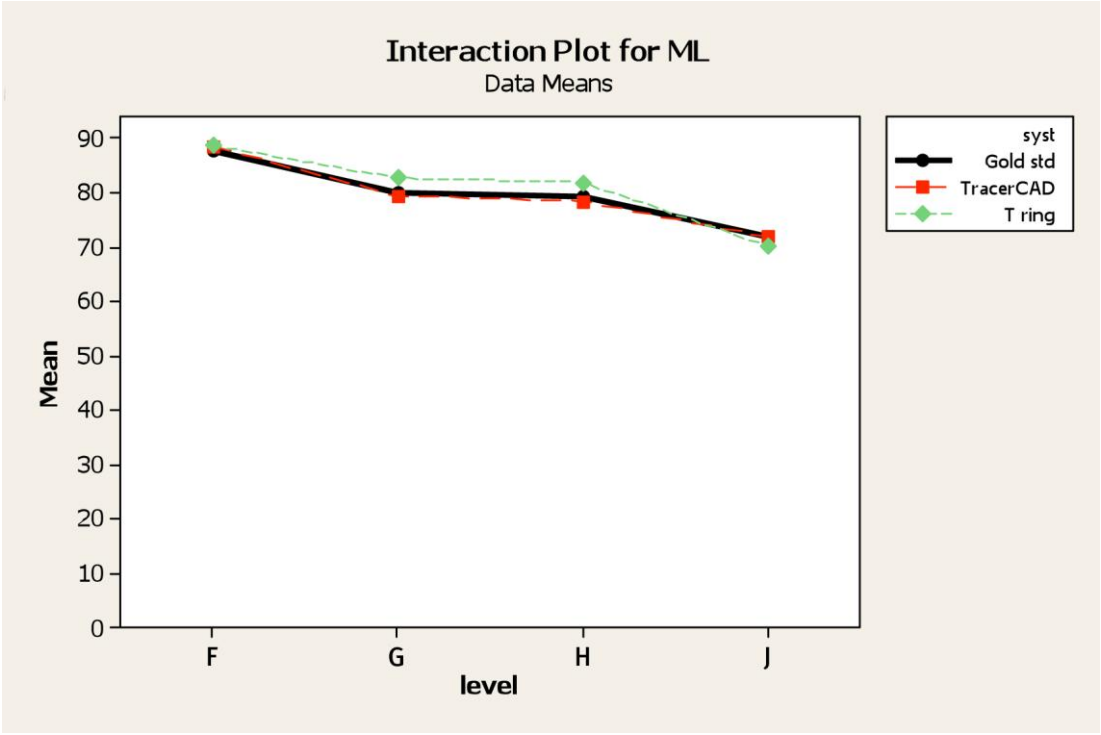

Figure 7-5 Interaction plot ML system*level

Volume

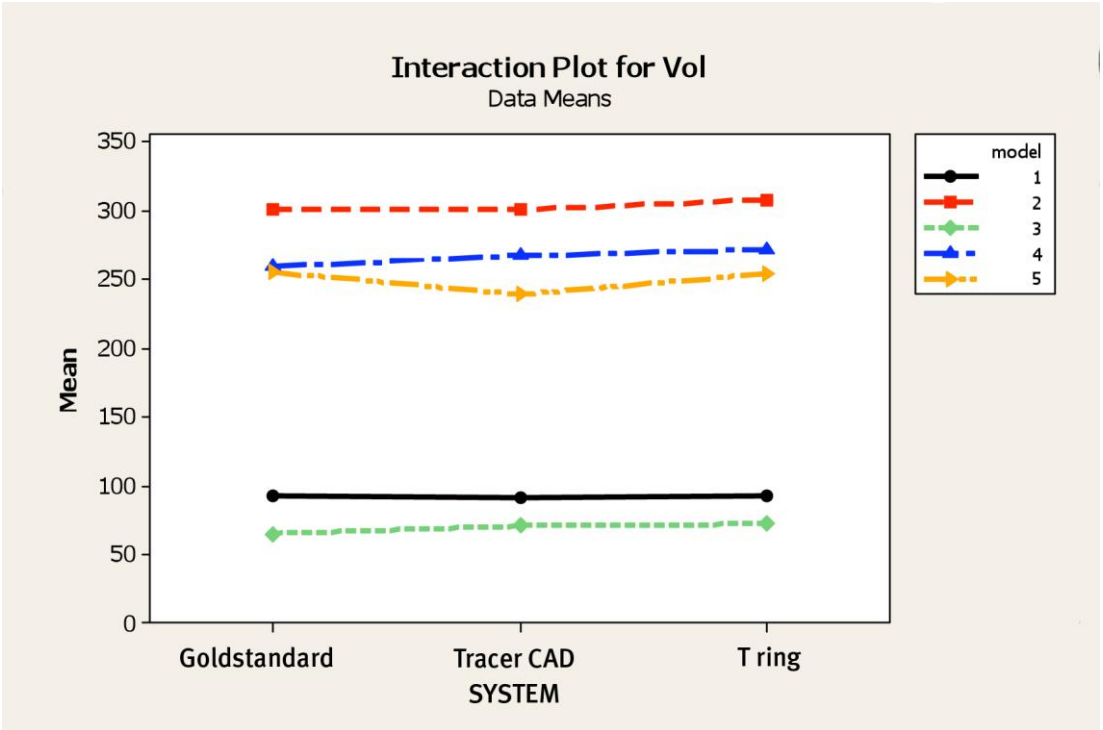

Figure 7-6 Interaction plot volume model*system

No significant effect was seen with the model-system interaction for volumes measured (p=0.688). (Table 22) Figure 7-6).

Analysis of a model-system interaction plot showed good accuracy of both Tracer CAD and T ring systems when recording volume measurement of simple conical and cylindrical models. Good agreement between measurements of the gold standard and CAD systems was seen on model 1 and 2, although a slight overestimation of measurement was evident by the T ring on the latter model (Figure 7-6).

Model 3 again illustrates good accuracy of both systems in recording volume measurement although both systems tended to show an overestimation (Figure 7-6).

More complex models showed less volume accuracy. Both systems tended to overestimate the volume of model 4 the solid trans-tibial cast (Figure 7-6).

In contrast, the volume of model 5, the deformable manikin, was underestimated by the contact system (Tracer CAD).

As the shape of model 3, 4 and 5 are thought to be more like those experienced in the clinical situation, (a residual limb will never be totally cylindrical,) the reduced accuracy of diameter and volume capture is of concern since the prosthetic socket would contain greater errors of measurement.

The deformability of model 5 when using the contact system may also present difficulties in the clinical setting since underestimation of volume could cause detrimental results to the prosthetic socket fit.

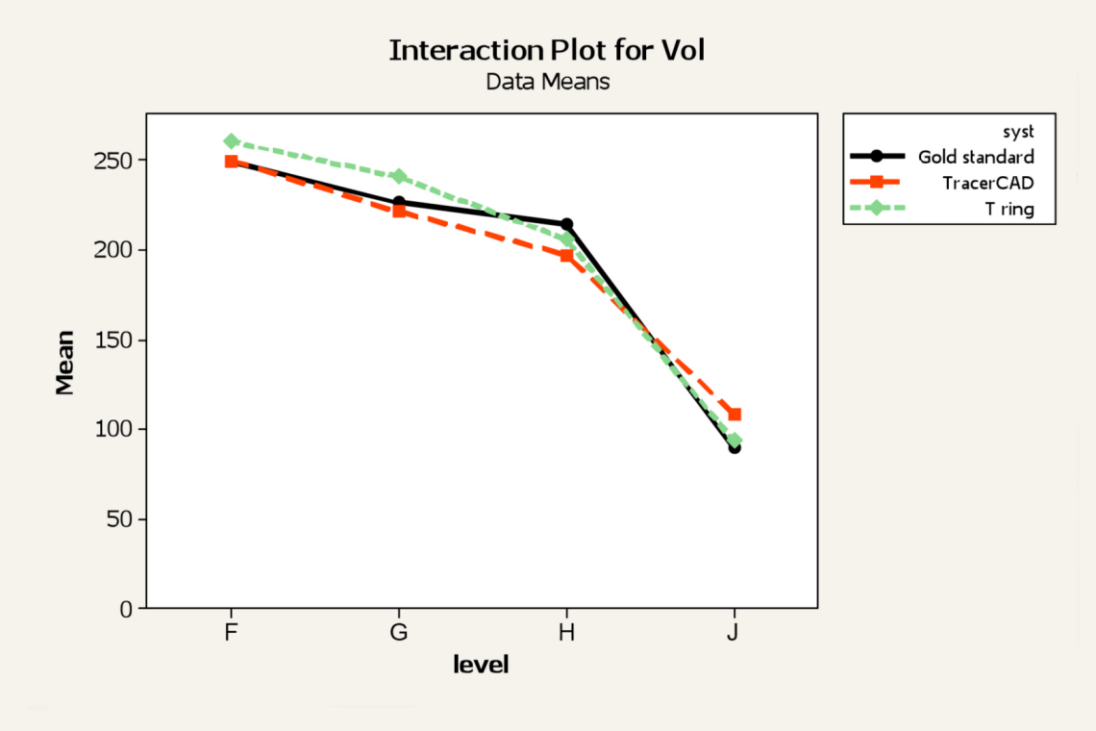

Figure 7-7 Interaction plot Volume system*level

A significant effect for system-level interaction was observed for volume measurement (p= 0.012) (Table 22). The interaction system level plot of volume measurement of all models shows a pattern in the accuracy of data collected by each system at each level (Figure 7-7).

The Tracer CAD system showed best volume accuracy at the most proximal level of measurement (F) when compared to the gold standard. The system did however show poor accuracy and underestimated the volume of models overall at level G and H. Overestimation of the volume was apparent at the distal end.

The T ring system again had a tendency to overestimate values at proximal levels but underestimated volume at level H. Better accuracy was observed at the distal volume level J-end (Table 16).

Interaction plots illustrate the overall effect of system, model and level interaction. Analysis indicates significant effect for system level interaction when measuring AP, ML and volume of models and also indicates significant effect for ML diameter

model system interaction. This analysis only informs part of the story since model system interaction does not show at what level the errors are most likely, and the system level interaction combines all models. As prosthetists in the clinical situation would only trace the patient's residuum once, measurement errors in individual traces could be inadvertently used to produce the final prosthetic socket. Individual tests, (and not the mean of repeated tests,) must also therefore be considered.

To examine the effects illustrated in interaction plots in greater depth, diameter and volume results were plotted for each model at each level of measurement for each measurement system. Due to the extent of of graphs generated, only graphs discussed in the text are contained in the results section. All other graphs are contained in appendix 5.

Each plot illustrates a simple error bar summary of separate variables and plots the method of shape capture against the mean +/- 2 times the standard error from the mean value. Each measurement system is colour coded and labelled on the x axis. A line corresponding to the mean value of the gold standard measurement has also been added for ease of interpretation. The mean value of the gold standard measurement is also labelled on the right hand side of the graph.

When standard error bars overlap no significant difference between the two means exists. However if two standard error bars do not overlap the converse is not necessarily true and does not necessarily mean that the difference between the two means is significant.

A large standard error (relative to the sample mean) indicates increased variability between means of different samples and so the samples the effect of the measurement system may introduce a systematic variation. A small SE indicates that most sample means are similar to the population mean.

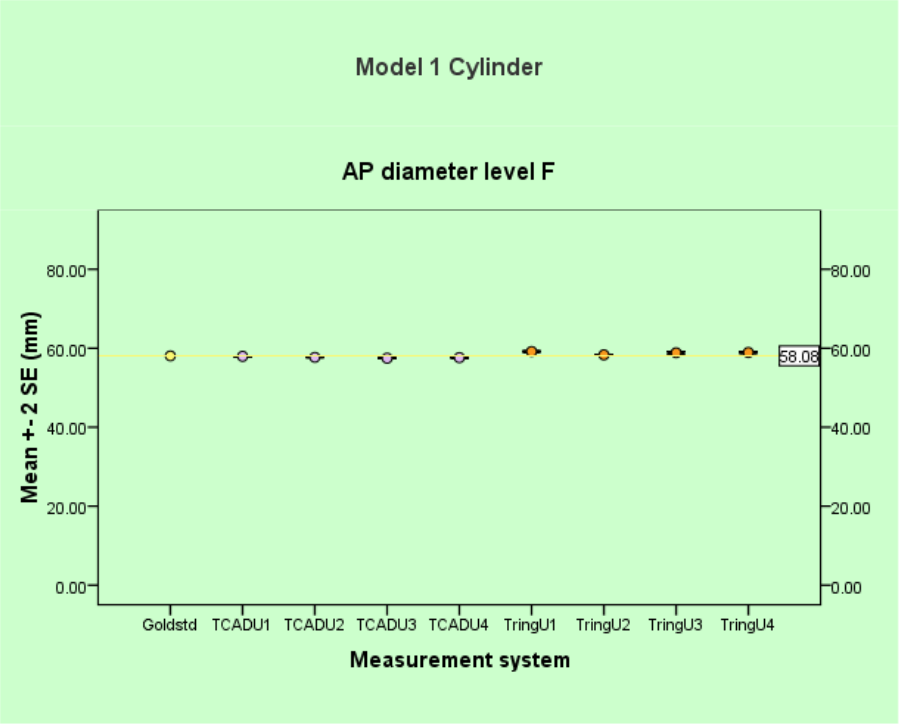

Figure 7-8 AP diameter level F Accuracy and repeatability of systems (model 1)

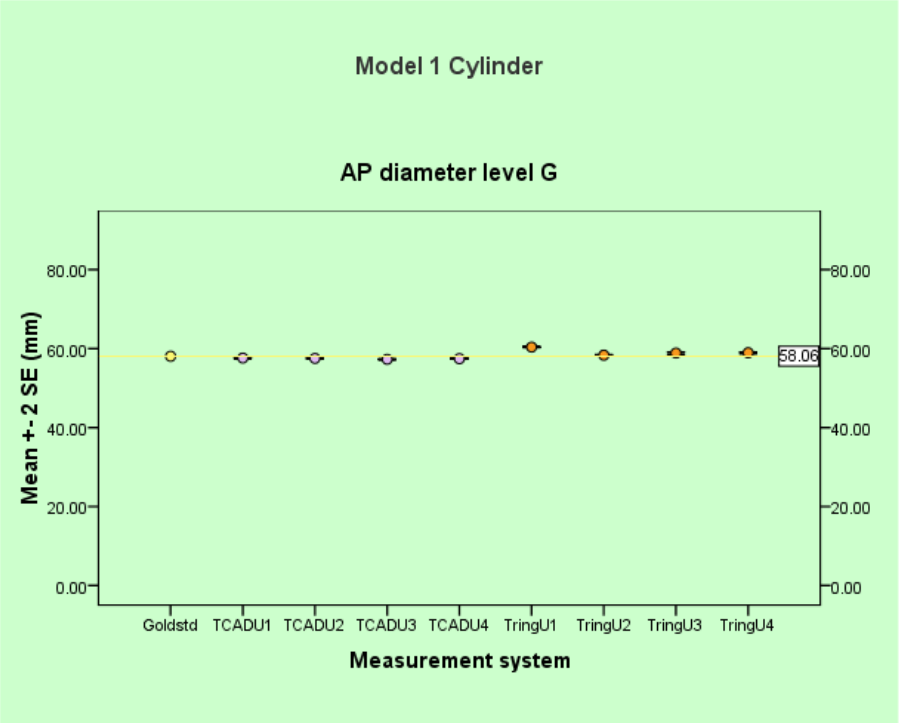

Figure 7-9 AP diameter level G Accuracy and repeatability of systems (model 1)

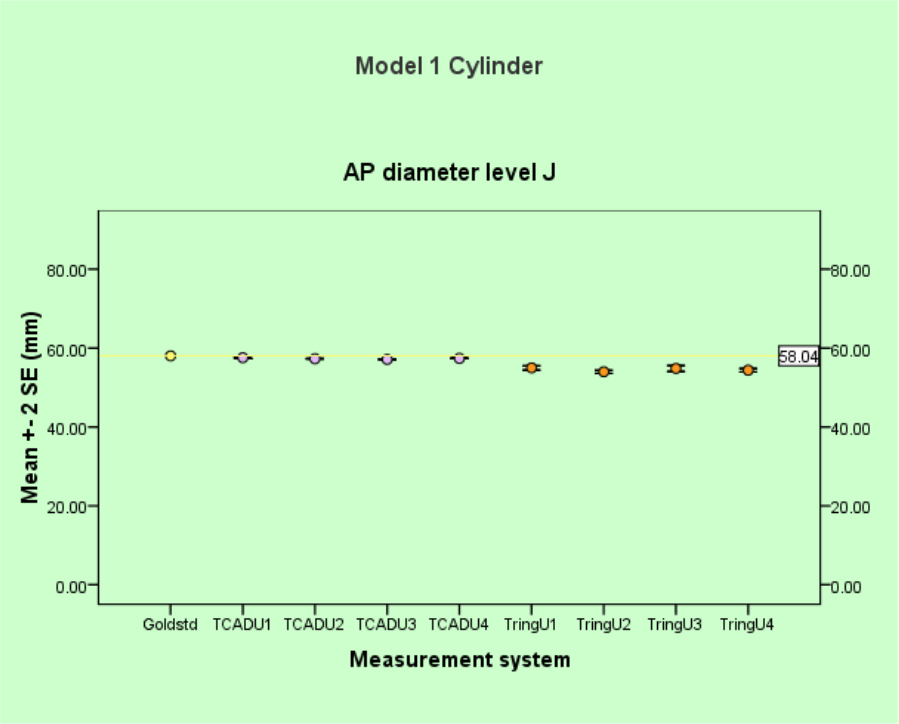

Figure 7-10 AP diameter level J Accuracy and repeatability of systems (model 1)

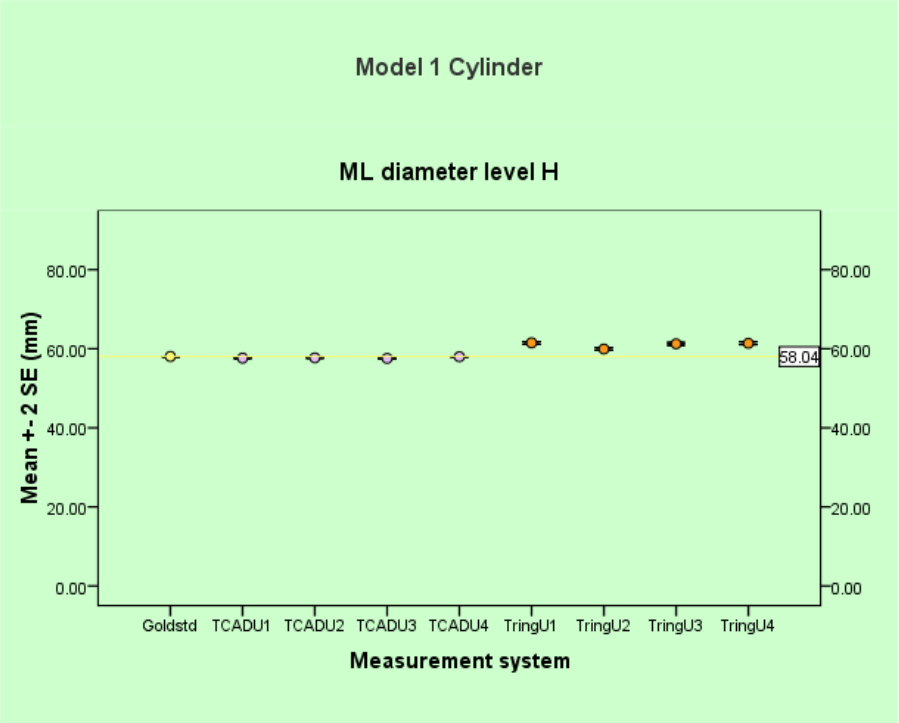

Figure 7-11 ML diameter level H. Accuracy and repeatability of systems (model 1)

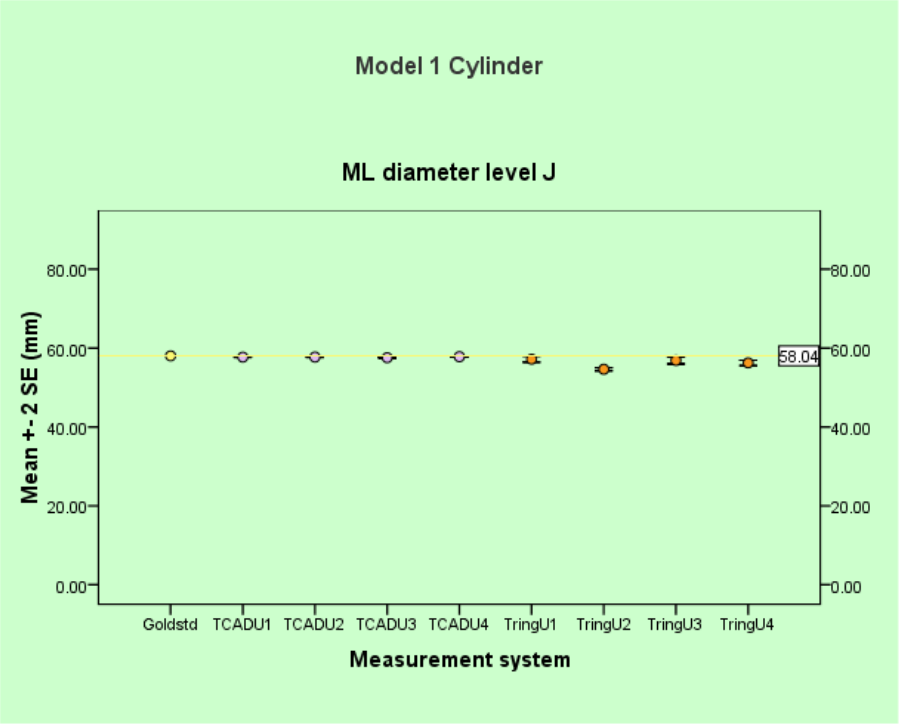

Figure 7-12 ML diameter level J. Accuracy and repeatability of systems (model 1)

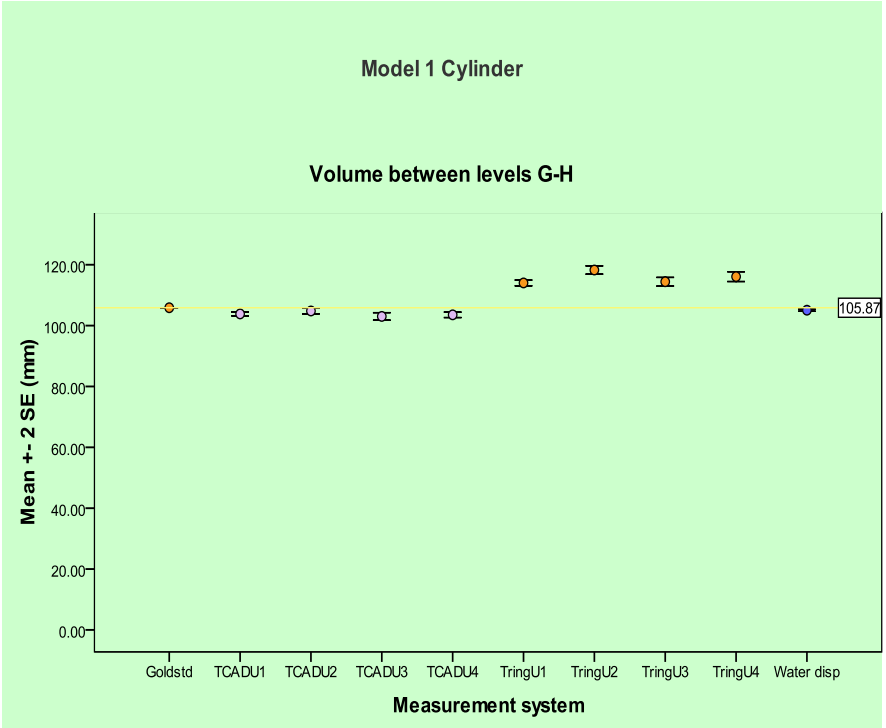

Figure 7-13 Volume level G-H. Accuracy and repeatability of systems (model 1)

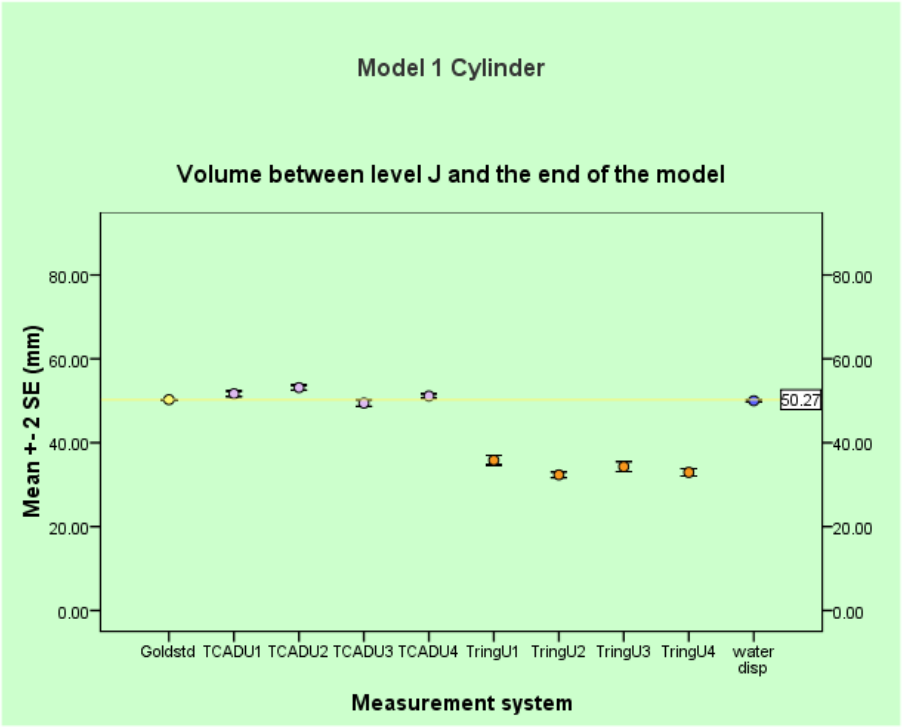

Figure 7-14 Volume level J- model end. Accuracy and repeatability of systems (model 1)

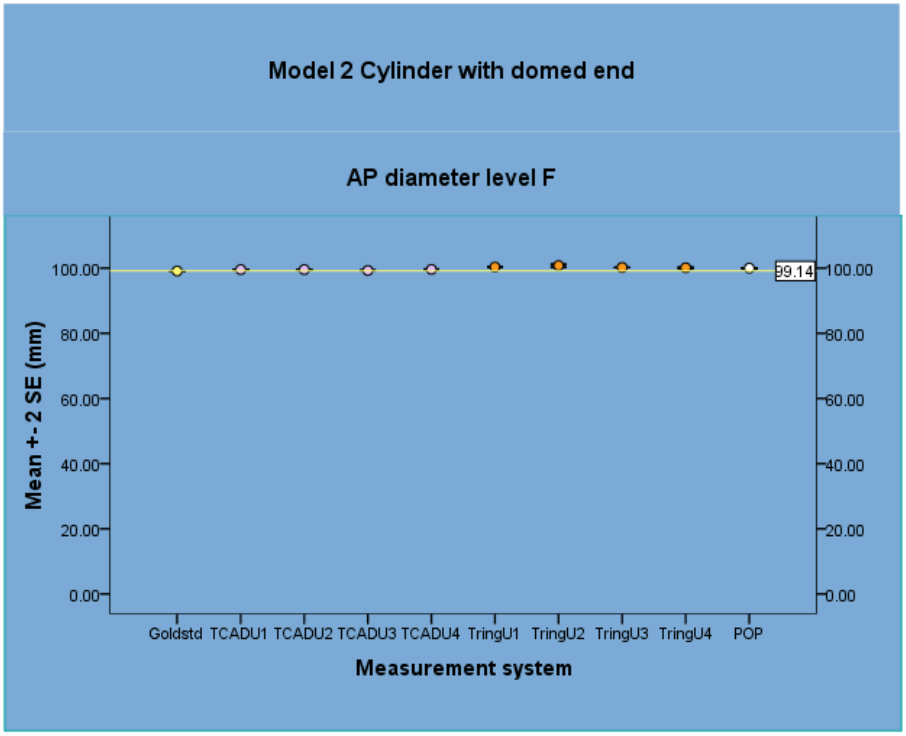

Figure 7-15 AP diameter level F Accuracy and repeatability of systems (model 2)

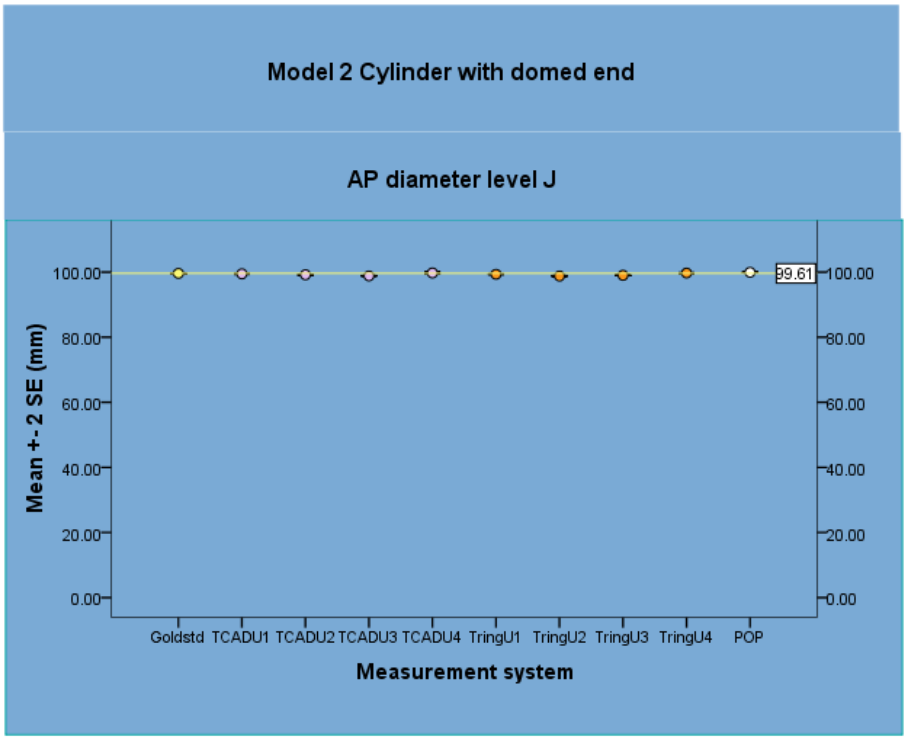

Figure 7-16 AP diameter level J Accuracy and repeatability of systems (model 2)

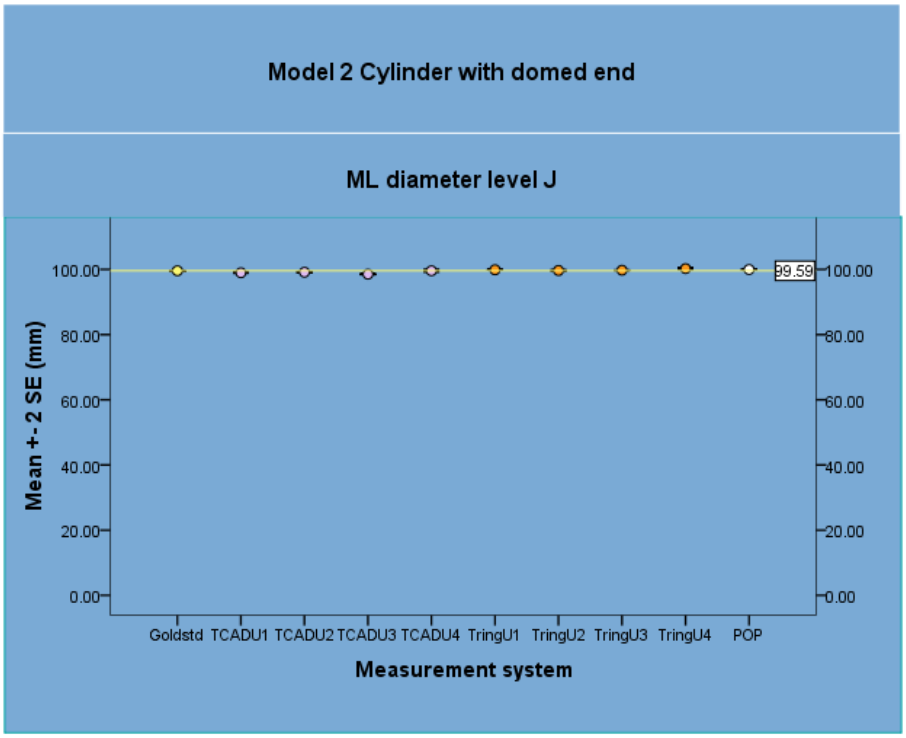

Figure 7-17 ML diameter level J. Accuracy and repeatability of systems (model 2)

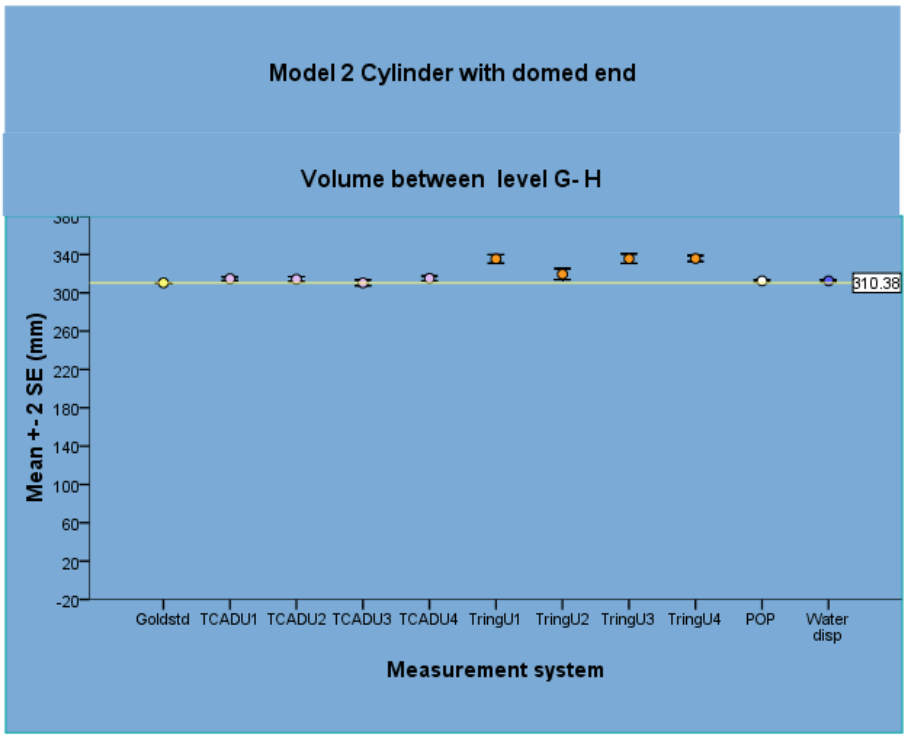

Figure 7-18 Volume between level G-H. Accuracy and repeatability of systems (model 2)

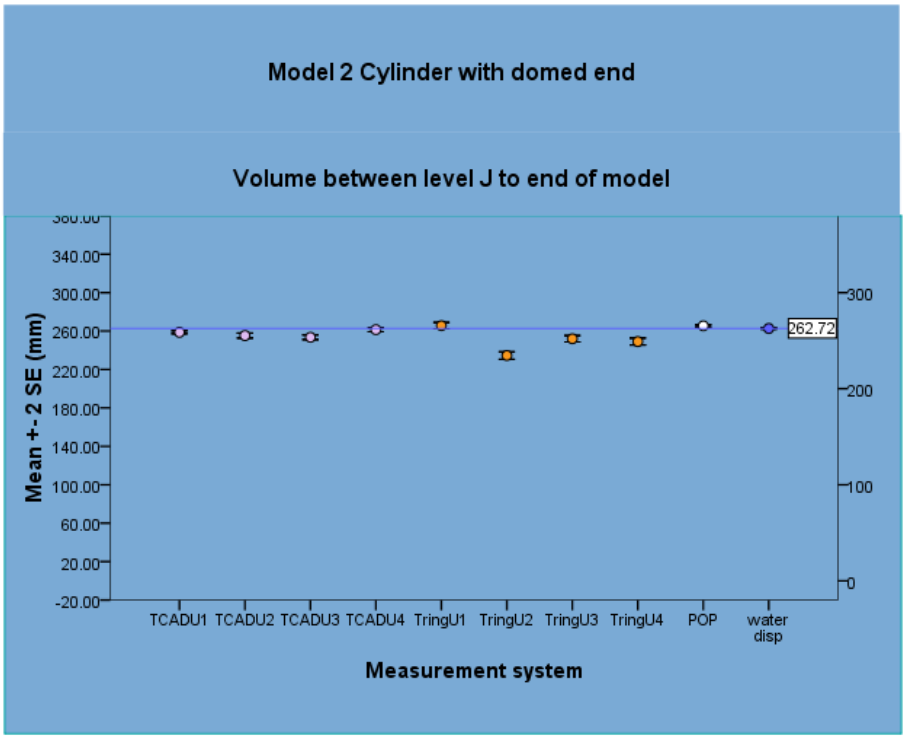

Figure 7-19 Volume between level J- model end. Accuracy & repeatability of systems (model 2)

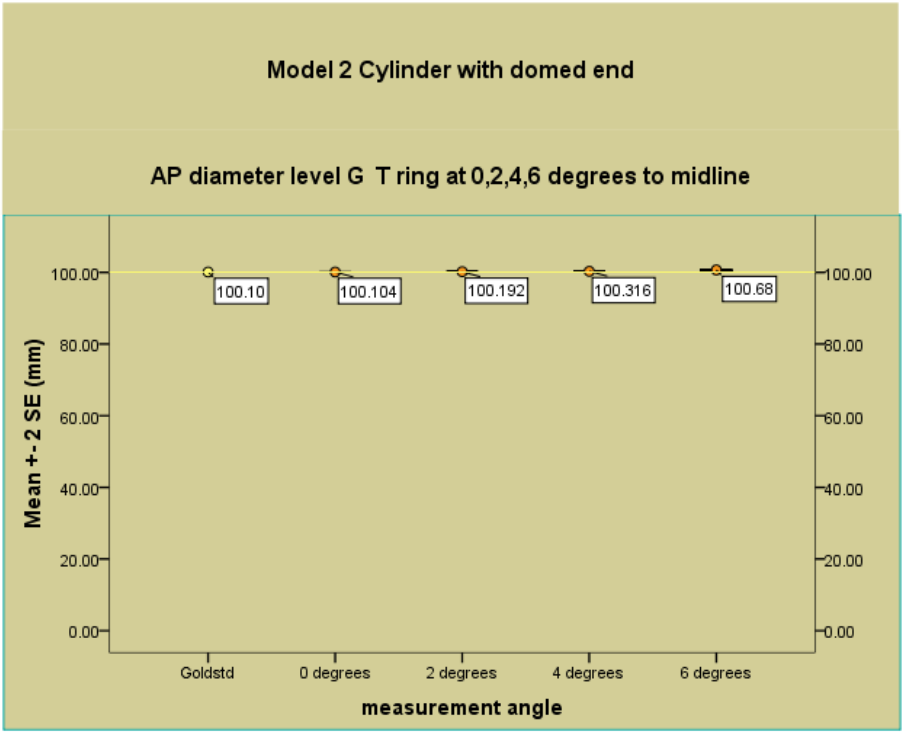

Figure 7-20 AP diameter level G. T ring held at specific angles (model 2)

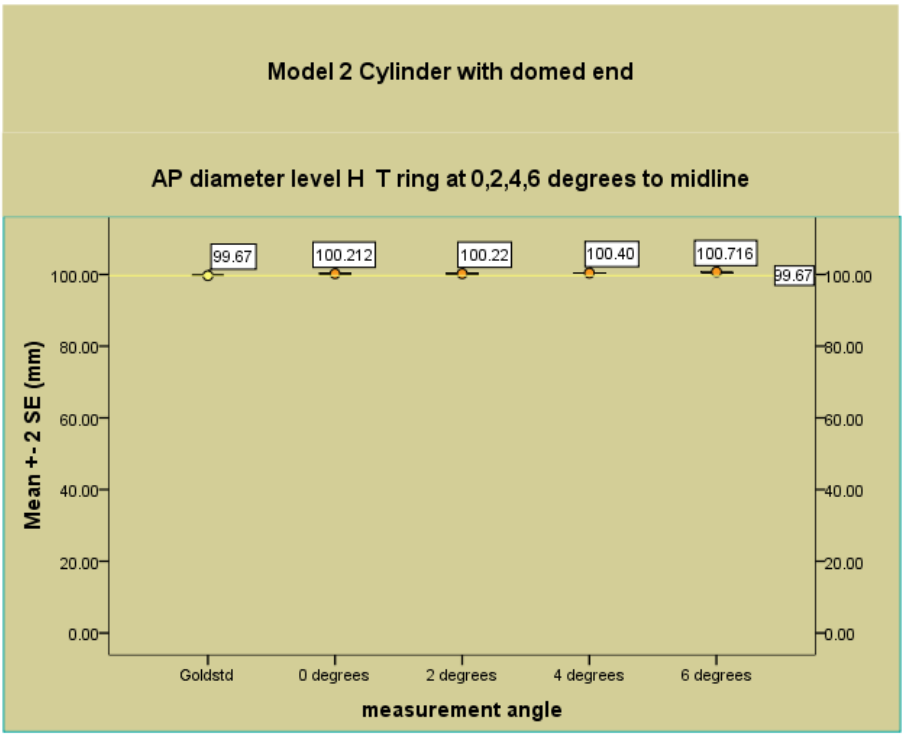

Figure 7-21 AP diameter level H. T ring held at specific angles (model 2)

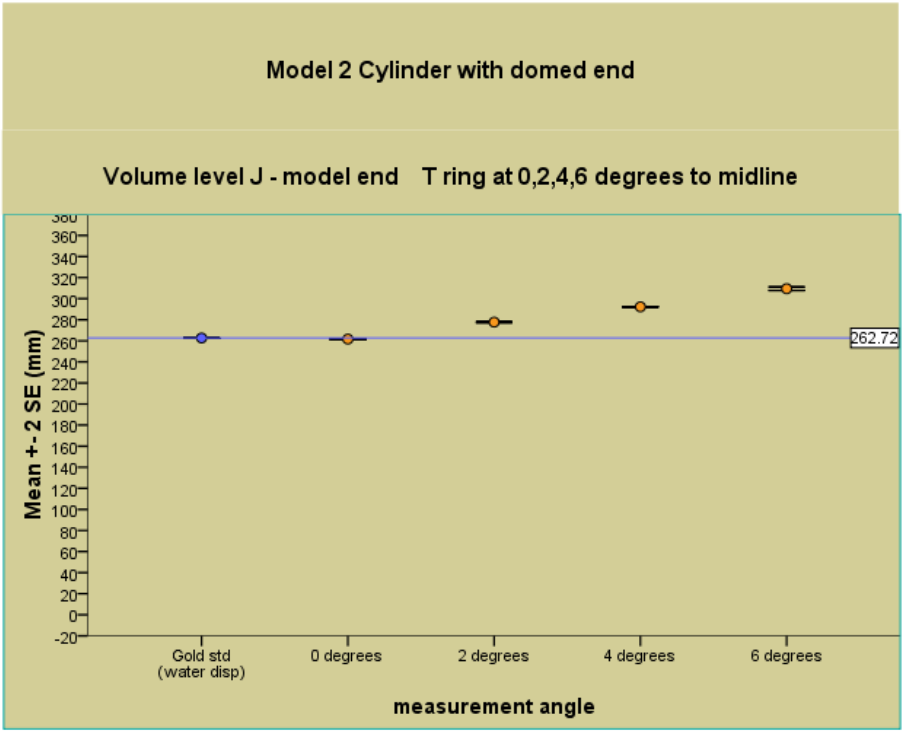

Figure 7-22 Volume level J-model end. T ring held at specific angles (model 2)

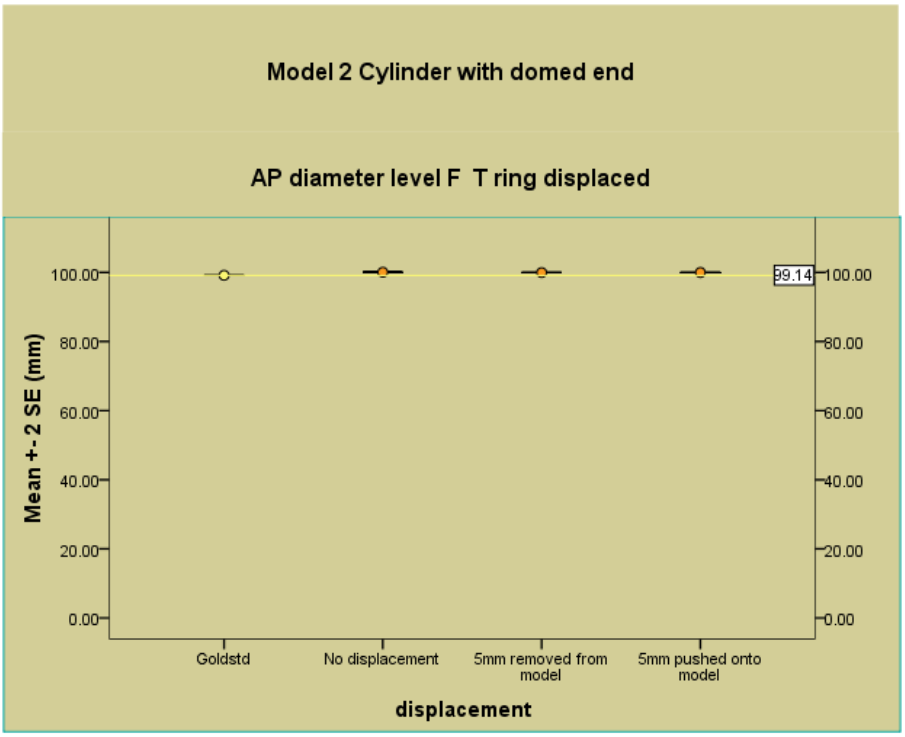

Figure 7-23 AP diameter level F. T ring deliberately misplaced (model 2)

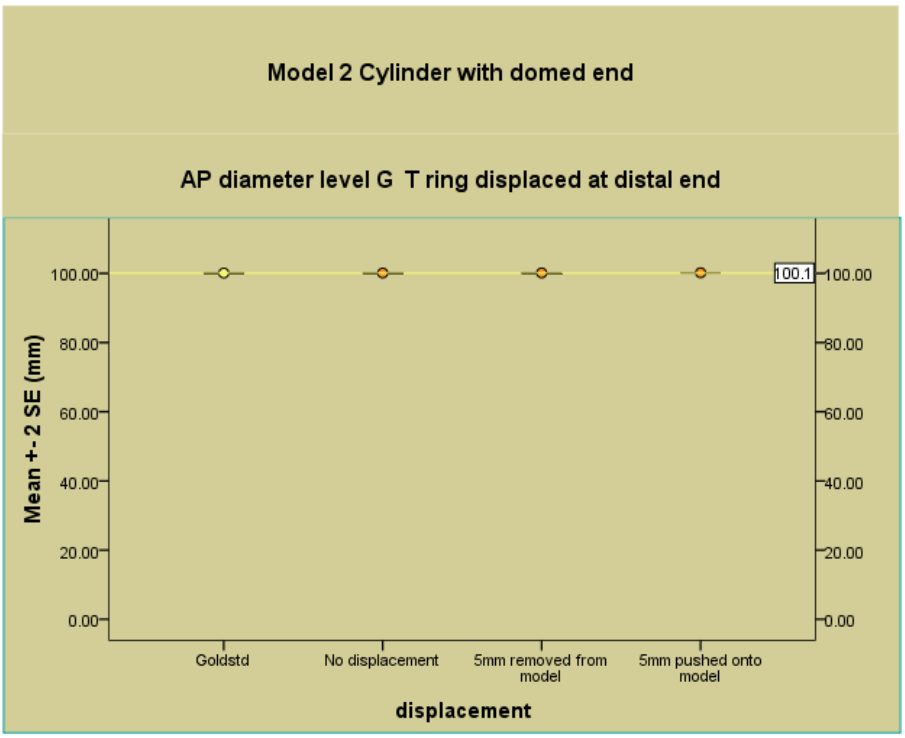

Figure 7-24 AP diameter level G. T ring deliberately misplaced (model 2)

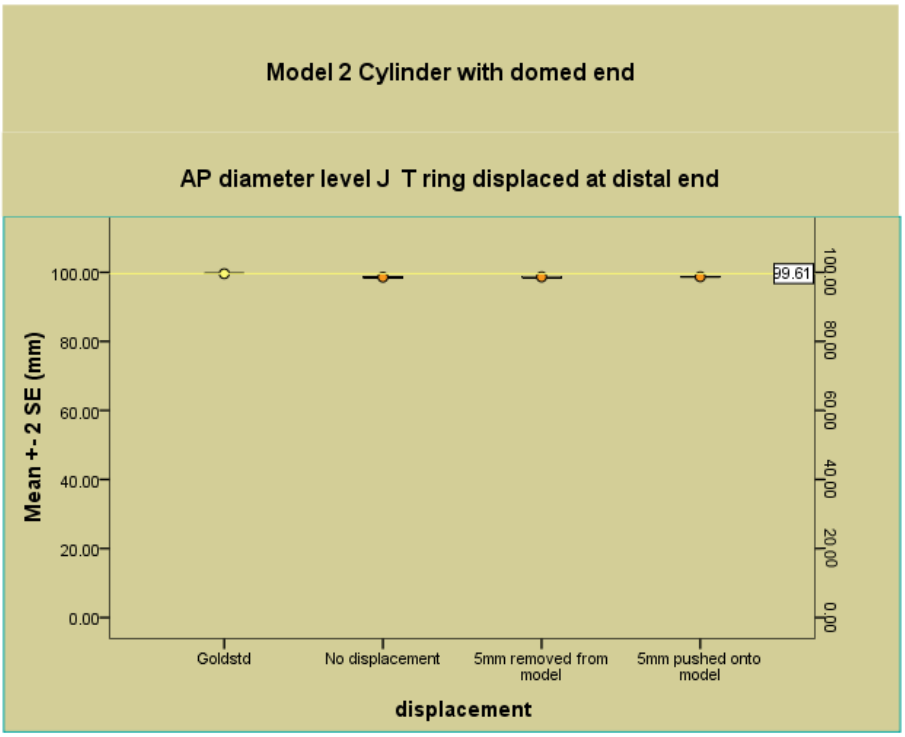

Figure 7-25 AP diameter level J. T ring deliberately misplaced (model 2)

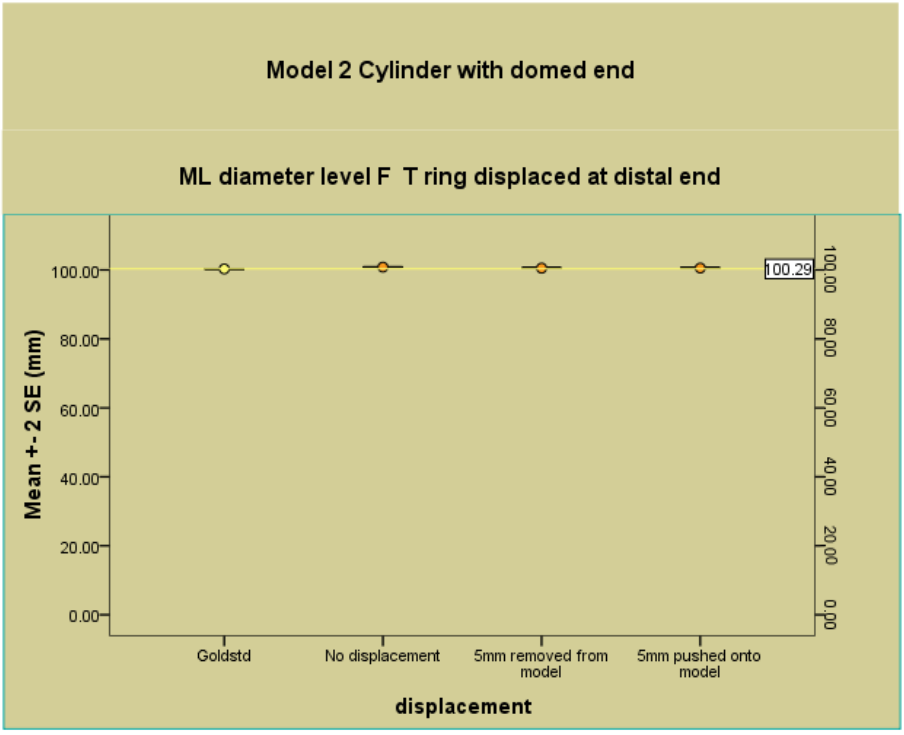

Figure 7-26 ML diameter level F. T ring deliberately misplaced (model 2)

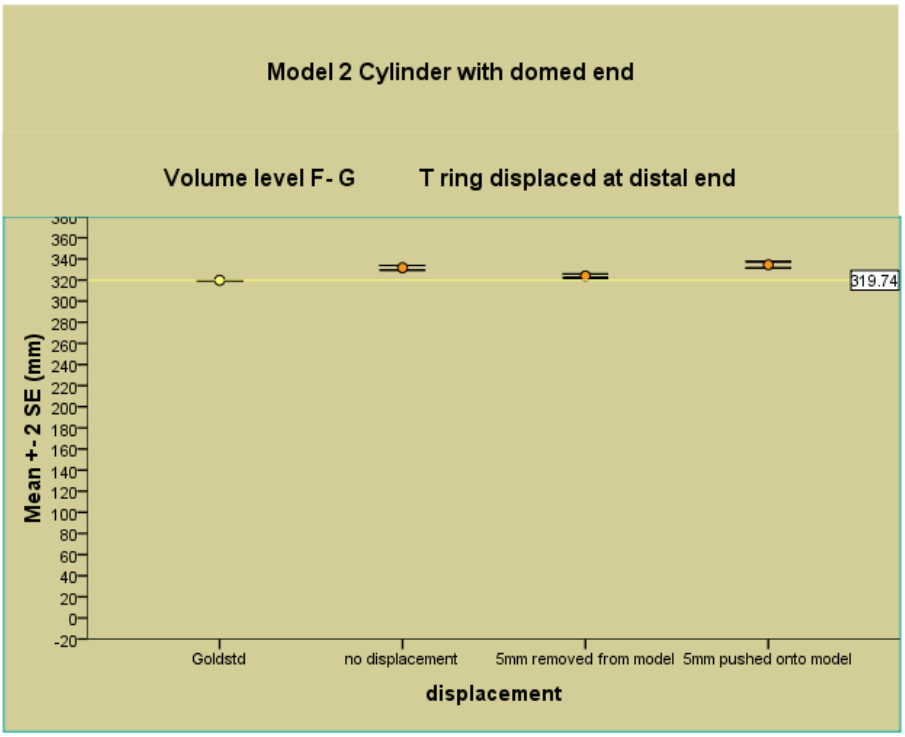

Figure 7-27 Volume level F-G. T ring deliberately misplaced (model 2)

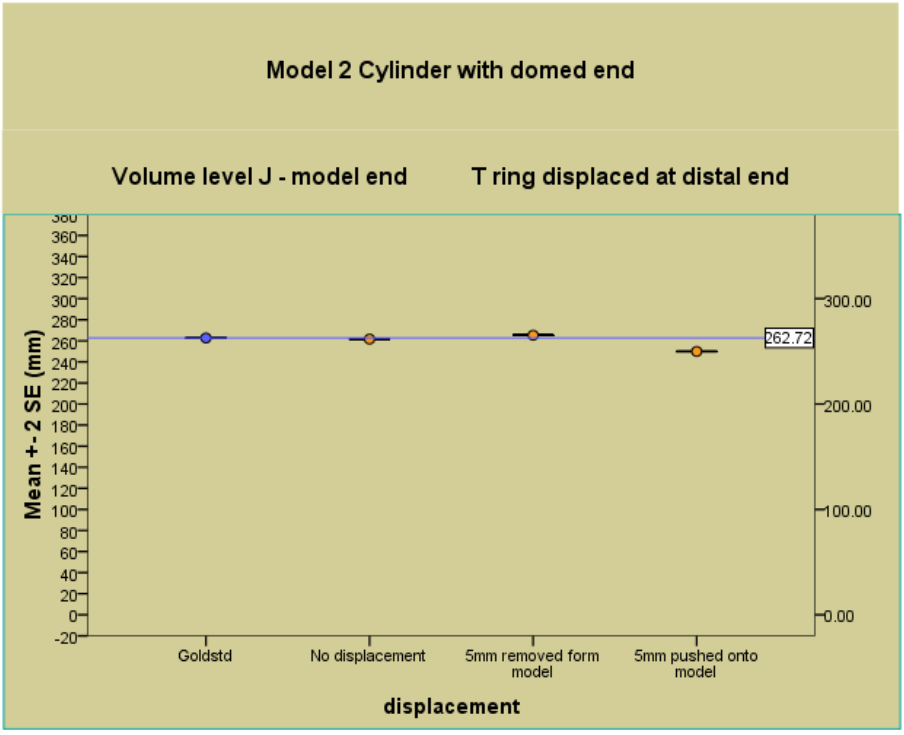

Figure 7-28 Volume level J- model end. T ring deliberately misplaced (model 2)

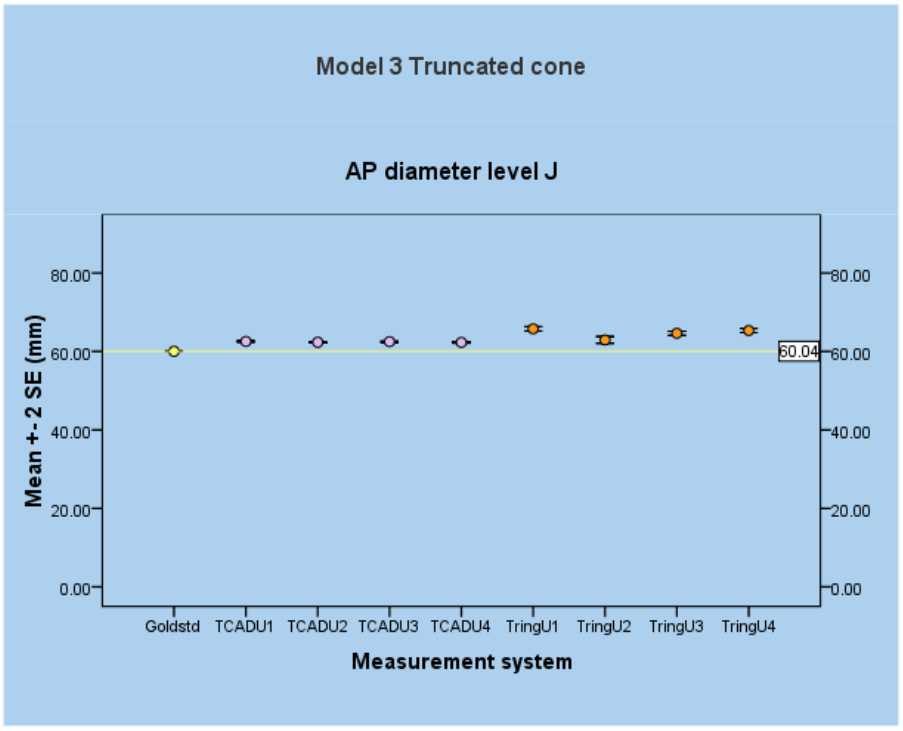

Figure 7-29 AP diameter level J. Accuracy and repeatability of systems (model 3)

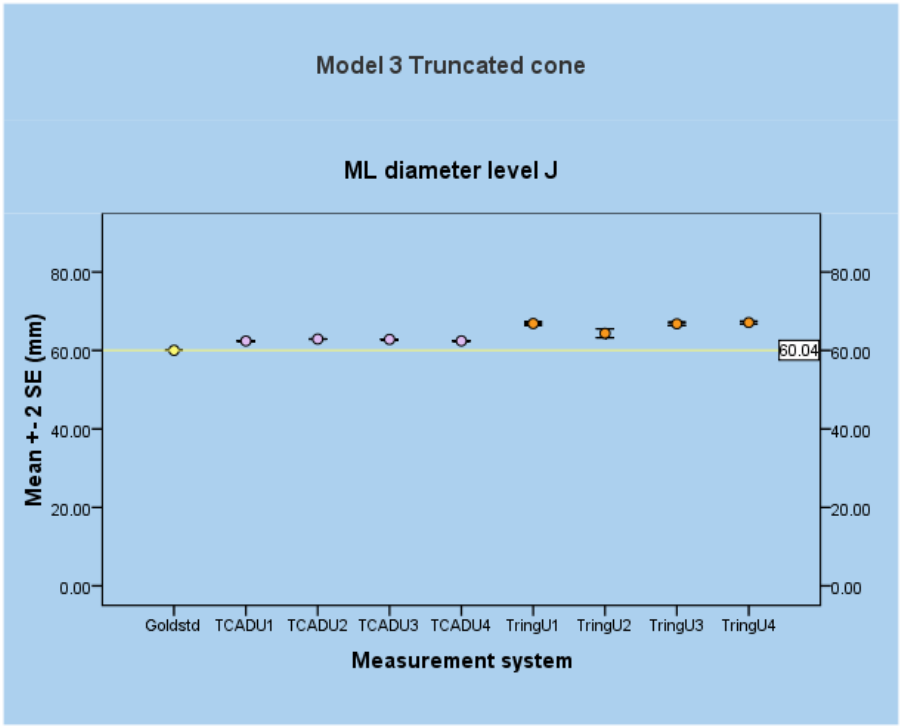

Figure 7-30 ML diameter level J. Accuracy and repeatability of systems (model 3)

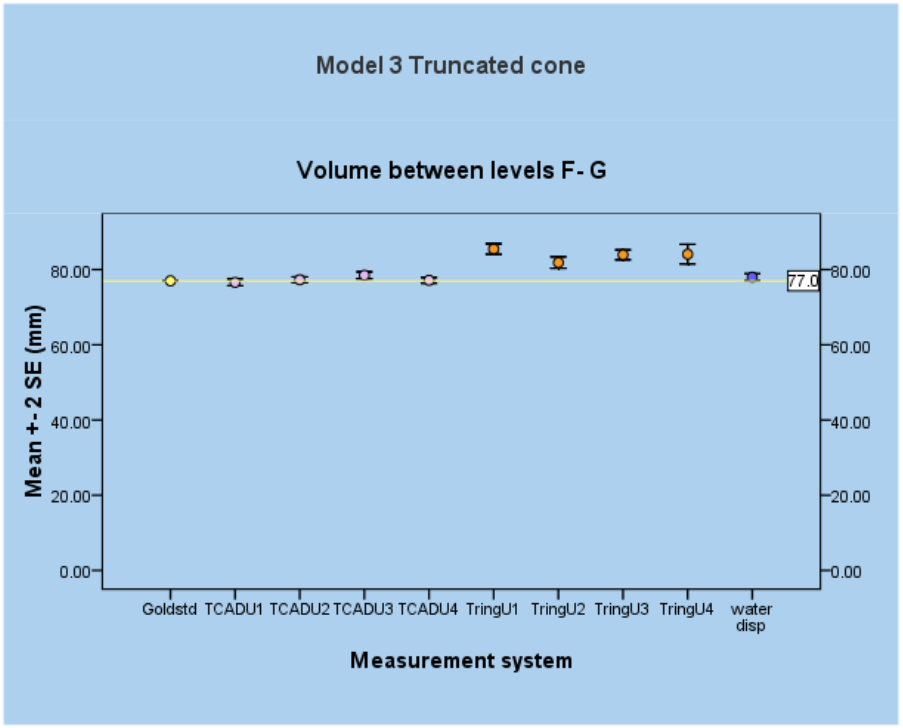

Figure 7-31 Volume level F-G. Accuracy and repeatability of systems (model 3)

7.2.1 Results of bending moment experiment

Table 23 Deflection of model at the distal end (mm)

	User 1		User 2		User 3		User 4	
	Distal	Proximal	Distal	Proximal	Distal	Proximal	Distal	Proximal
Min	0	0	0.02	0.007	0.006	0.003	0.002	0
Max	0.011	0.011	0.042	0.024	0.034	0.015	0.019	0.012
Mean	0.0042	0.0024	0.0299	0.0142	0.0191	0.0084	0.0112	0.0052
SD	0.003	0.003	0.007	0.004	0.007	0.004	0.005	0.004

7.2.2 Validation of volume determined by water displacement

In addition to model volume measurement by the gold standard, volume measures were calculated using water displacement. Results showed water displacement volume measurement to be accurate as no statistical difference between volumes calculated by water displacement and the mean of the gold standard at any level on any model. An example is shown in Figure 7-32.

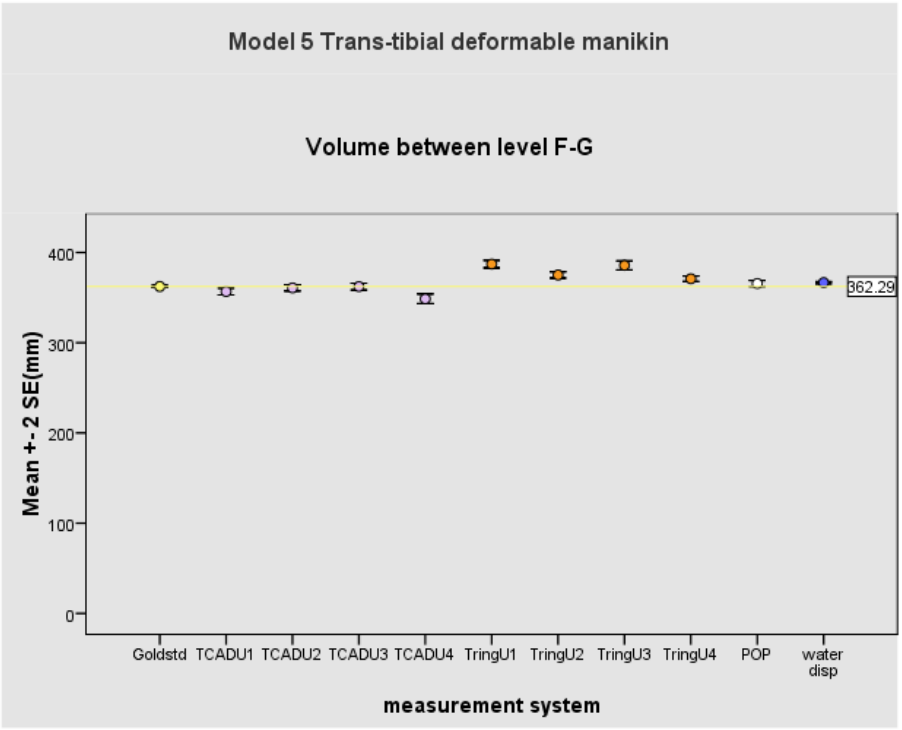

Figure 7-32 Validation of the water displacement technique for determining volume (model 5)

The maximum difference between any mean volume by water displacement to the gold standard mean was -7.38mm^3 (-2.46% of total volume). This was not significantly different ($p > 0.05$).

Table 24 Volume determination by water displacement. Coefficient of variation (%)

	Vol F-G	Vol G-H	Vol H-J	Vol J-end
Model 1	0.22	0.36	0.28	0.61
Model 2	0.33	1.00	0.42	0.29
Model 3	1.30	0.94	1.37	1.69
Model 4	0.24	0.20	0.32	1.75
Model 5	0.37	0.35	0.39	2.24

The coefficient of variation (CV) of volumetric determination by water displacement was also calculated at all levels on all models. The level of repeatability of volume measurement using water displacement was found to be less than 1% on models 1 and 2, and less than 2.5% on models of more complex shape, (models 3, 4, and 5)(0.93% <CV<2.24%) (Table 24). Variation of measurement had a tendency to be largest when the volume between the most distal landmark and the model end was measured (CV max (model 4) = 1.75%.

As accuracy and good repeatability was shown (model 1 CV < 0.61%, model 3 CV <1.75%) this method was accepted as being suitable for determination of model volumes. Since the gold standard measurement system was unable to determine the volume between the most distal landmark and the end of irregular (trans-tibial) models, water displacement was used to calculate the distal volume (between landmark J and the model end) of Model 4 and 5 (Figure 7-33).

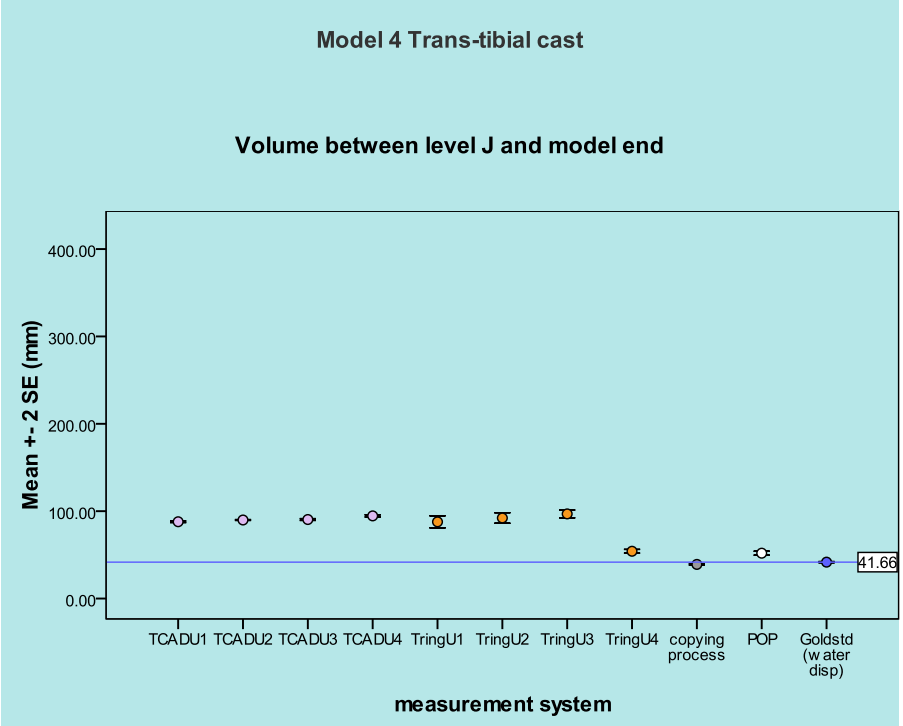

Figure 7-33 Distal end volume calculated by water immersion technique

Standard error bars continued

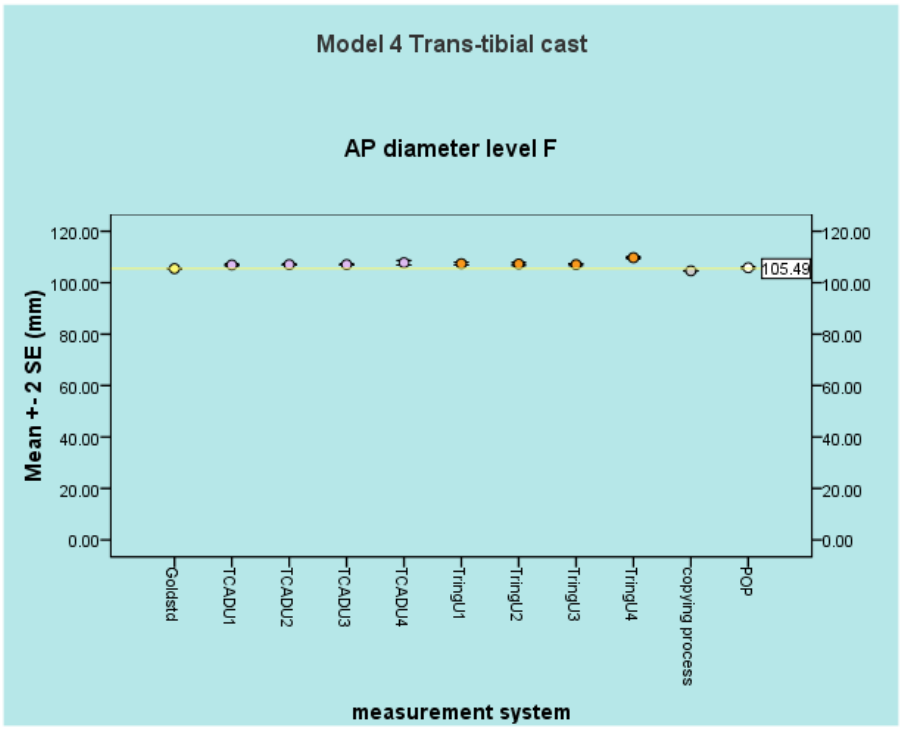

Figure 7-34 AP diameter level F. Accuracy and repeatability of systems (model 4)

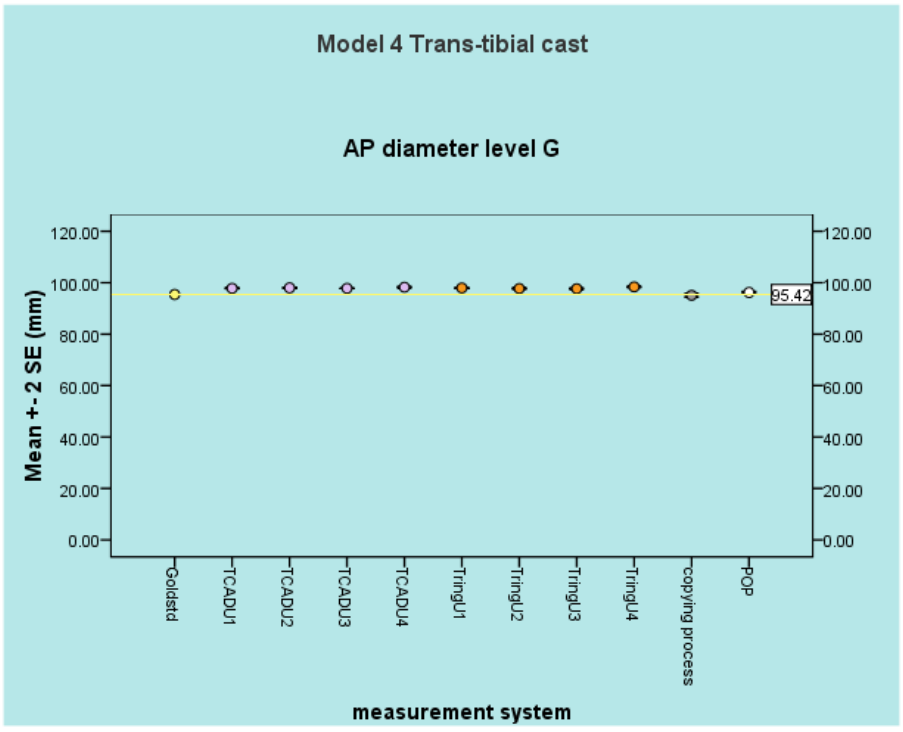

Figure 7-35 AP diameter level G. Accuracy and repeatability of systems (model 4)

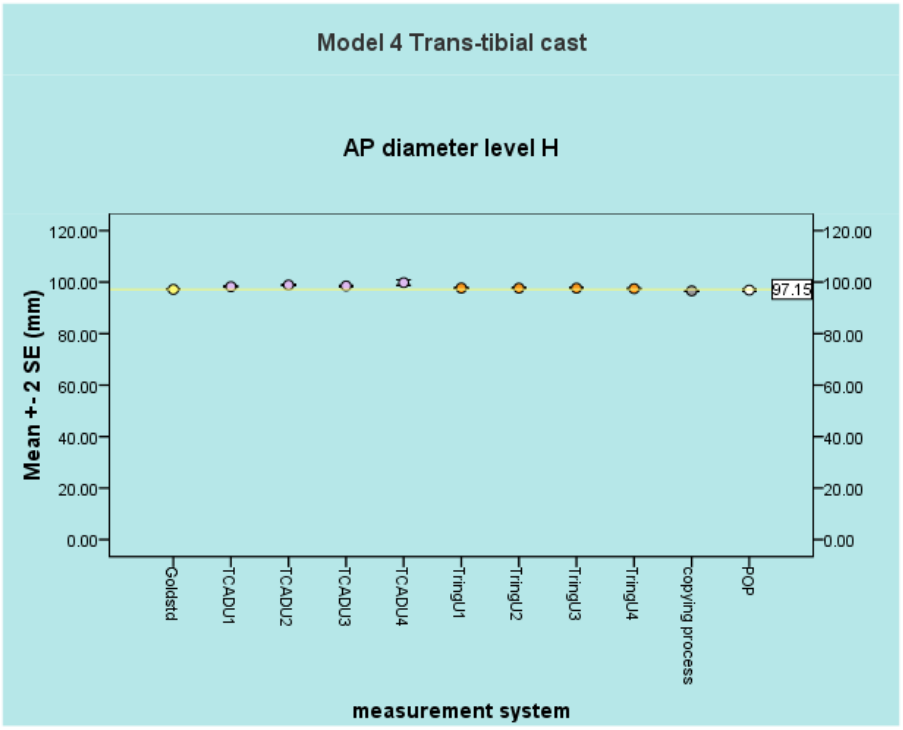

Figure 7-36 AP diameter level H. Accuracy and repeatability of systems (model 4)

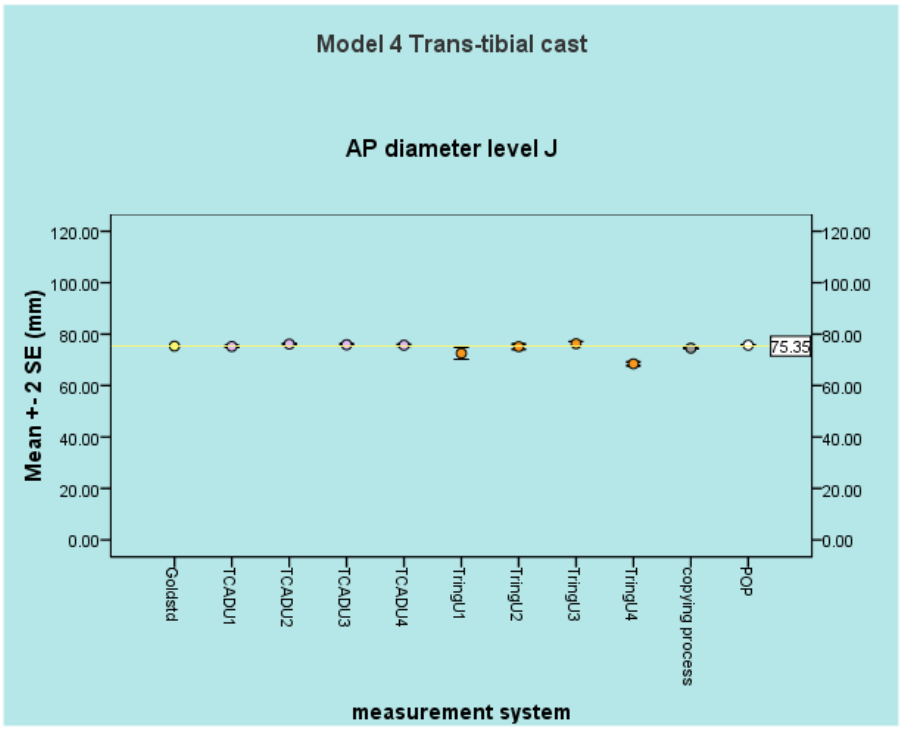

Figure 7-37 AP diameter level J. Accuracy and repeatability of systems (model 4)

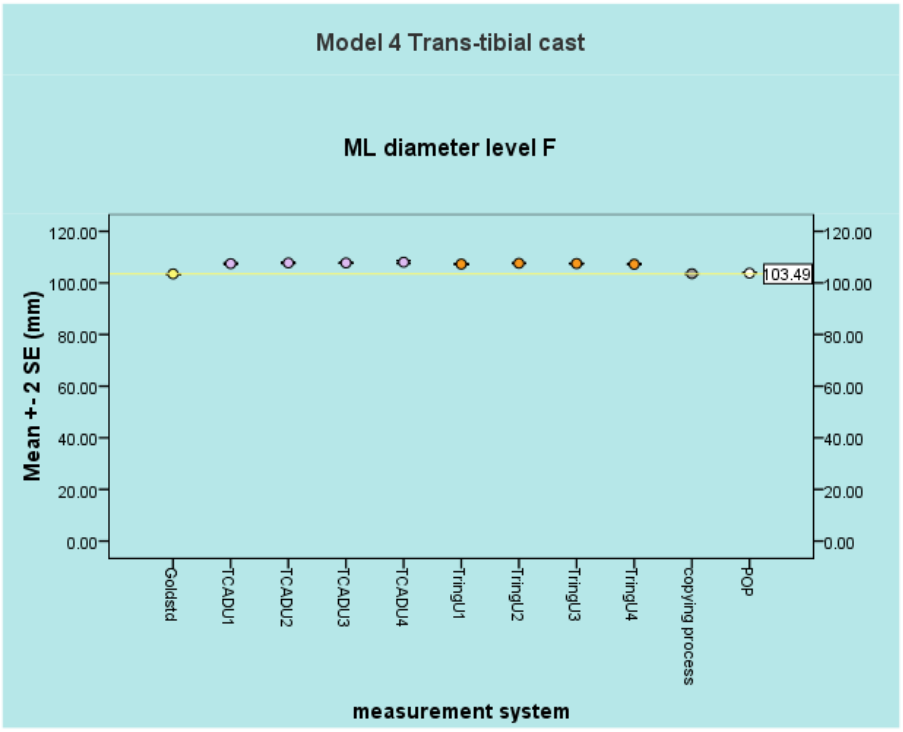

Figure 7-38 ML diameter level F. Accuracy and repeatability of systems (model 4)

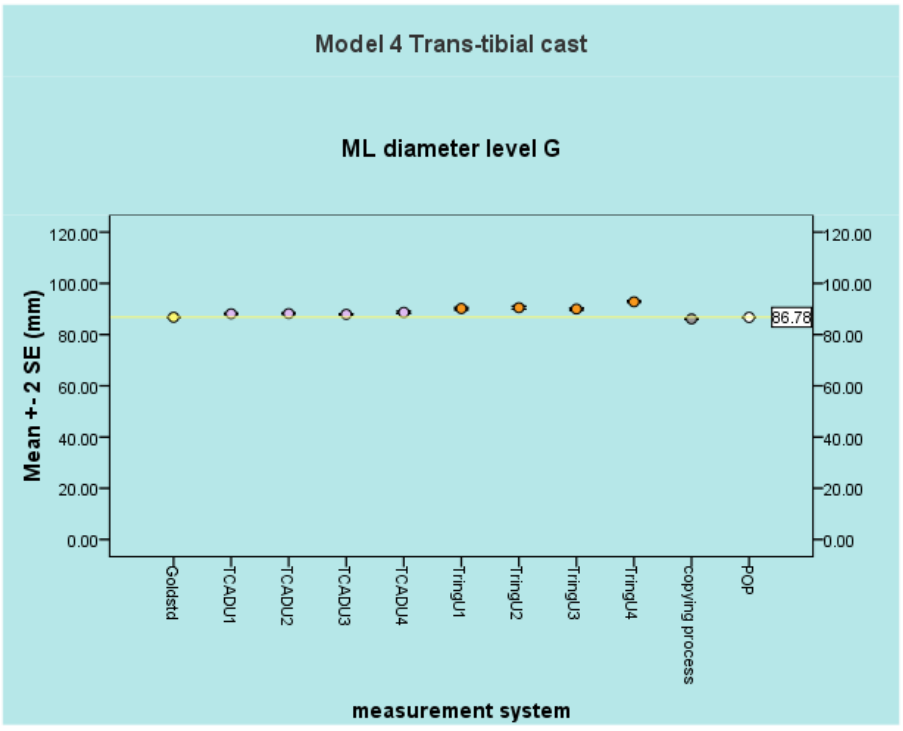

Figure 7-39 ML diameter level G. Accuracy and repeatability of systems (model 4)

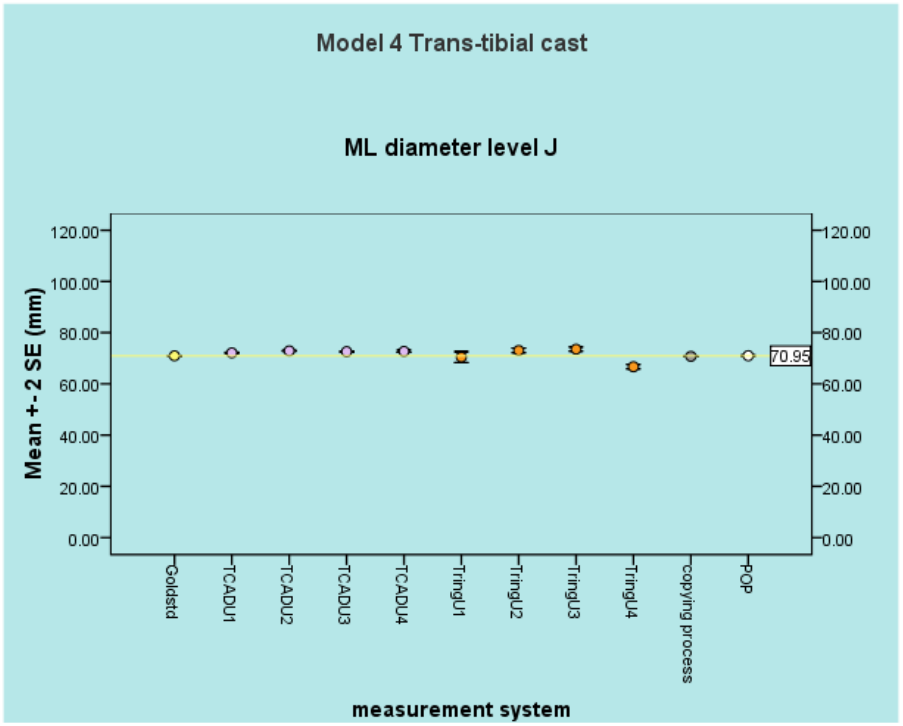

Figure 7-40 ML diameter level J. Accuracy and repeatability of systems (model 4)

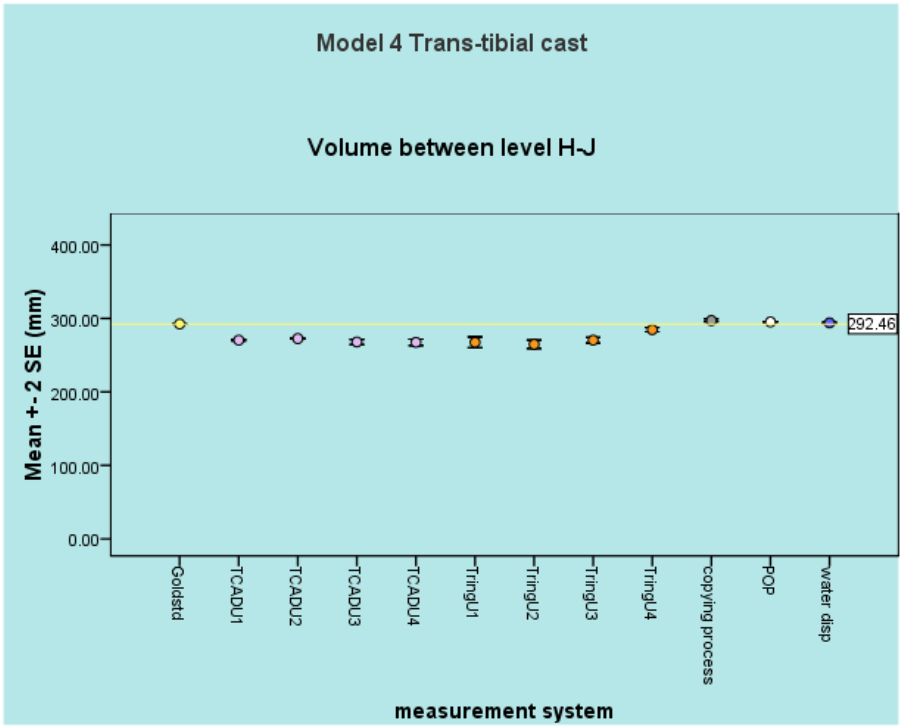

Figure 7-41 Volume level H-J. Accuracy and repeatability of systems (model 4)

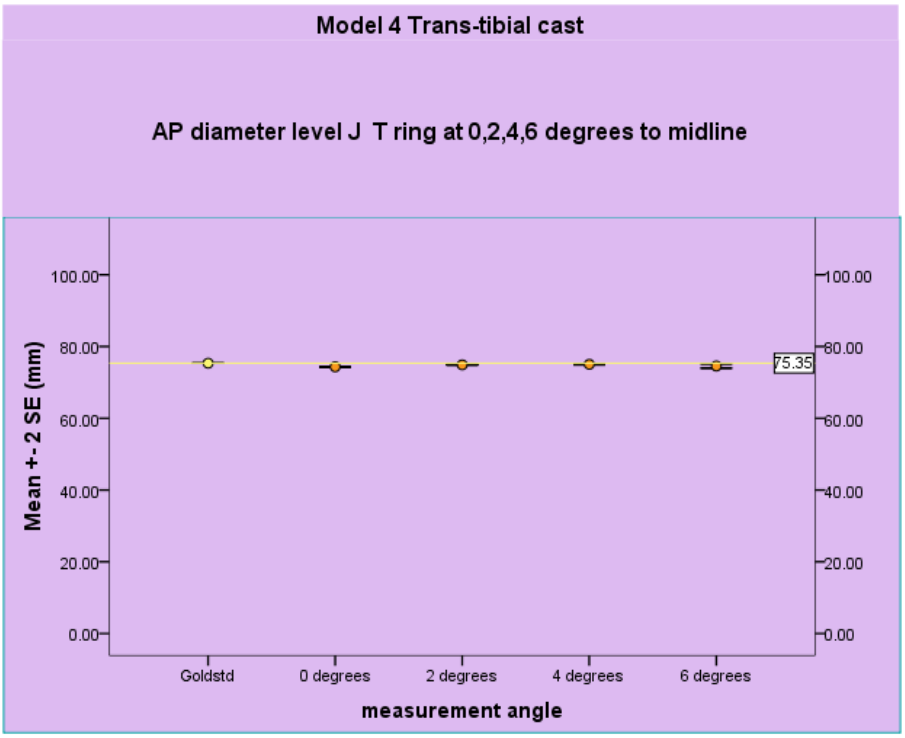

Figure 7-42 AP diameter level J. T ring held at specific levels (model 4)

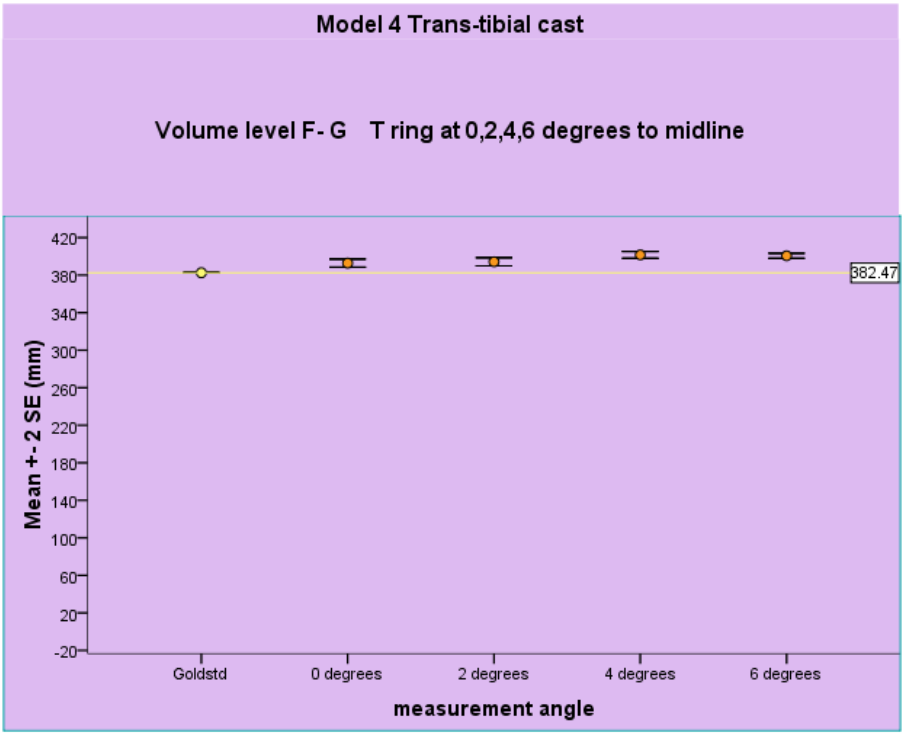

Figure 7-43 Volume level F-G. T ring held at specific levels (model 4)

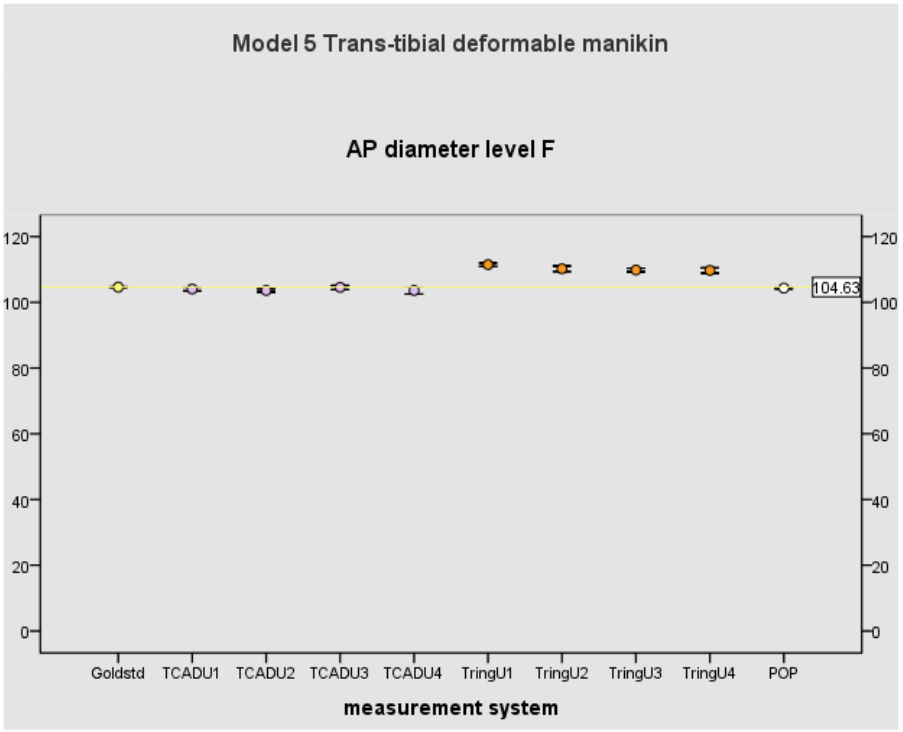

Figure 7-44 AP diameter level F. Accuracy and repeatability of systems (model 5)

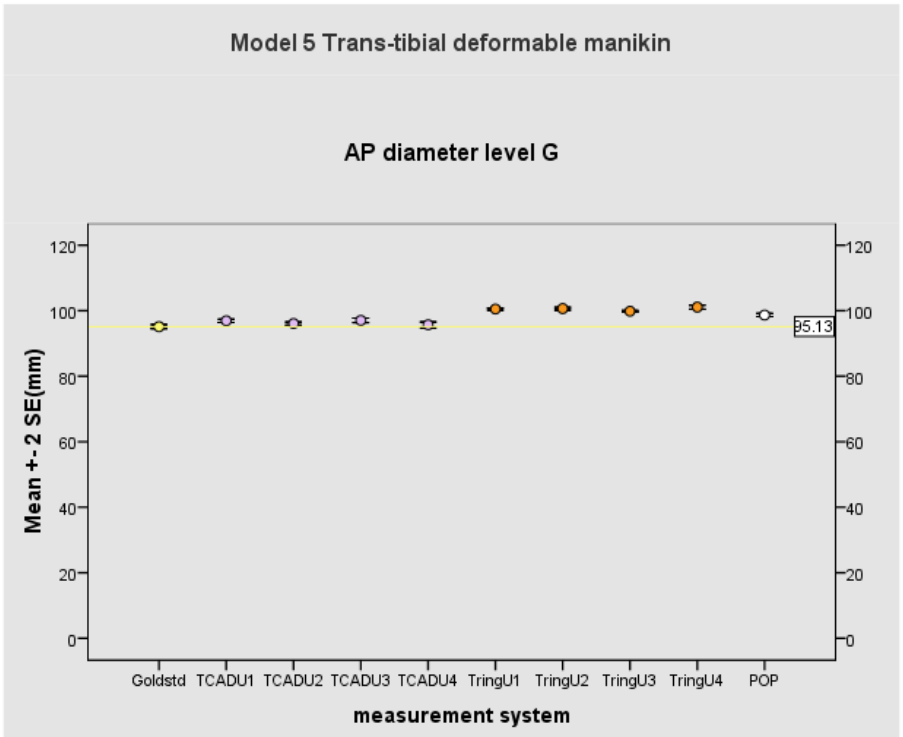

Figure 7-45 AP diameter level G. Accuracy and repeatability of systems (model 5)

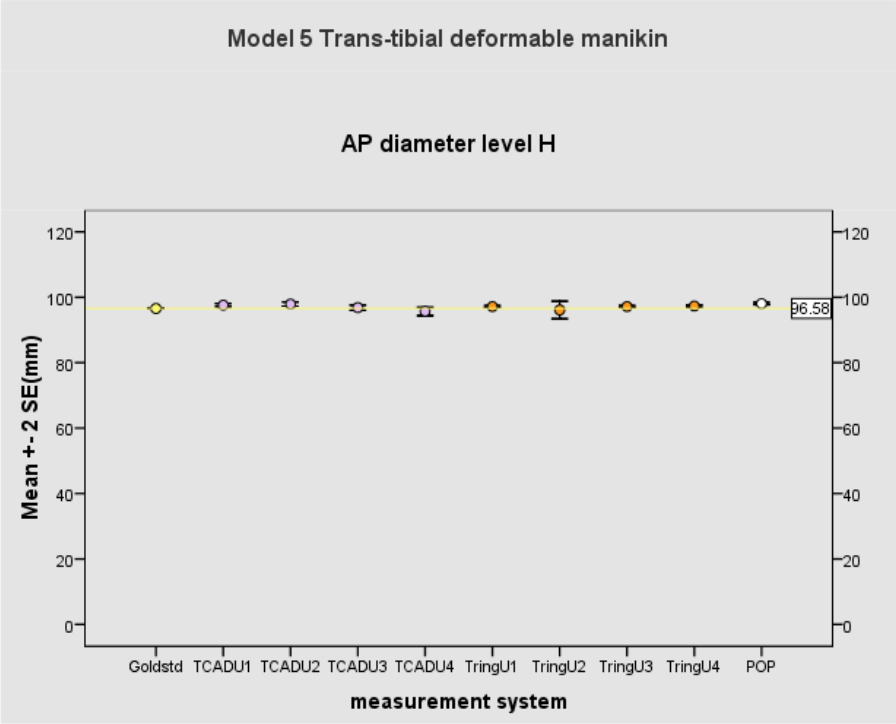

Figure 7-46 AP diameter level H. Accuracy and repeatability of systems (model 5)

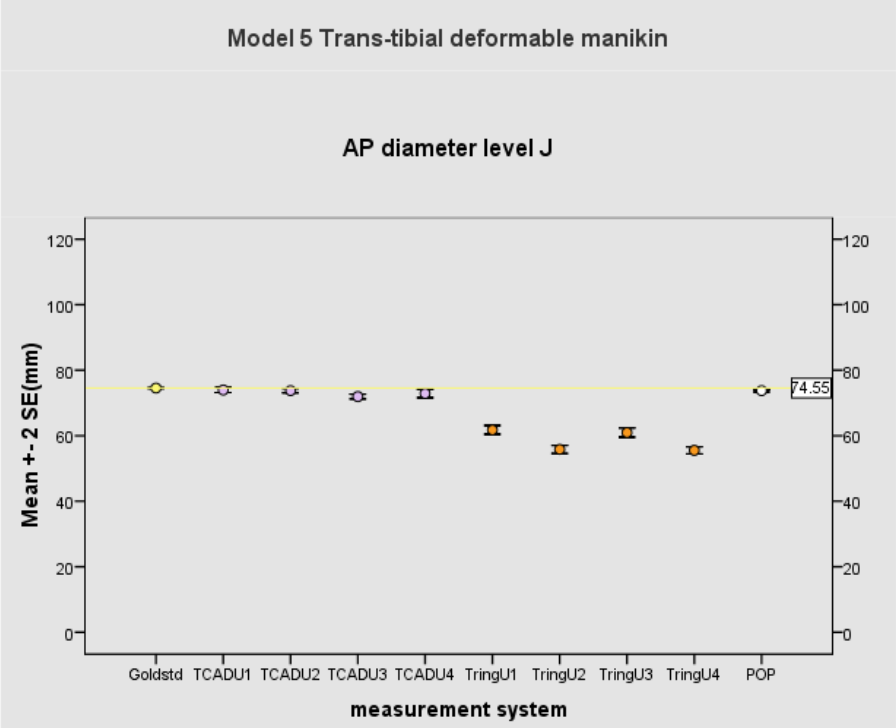

Figure 7-47 AP diameter level J. Accuracy and repeatability of systems (model 5)

Figure 7-48 ML diameter level F. Accuracy and repeatability of systems (model 5)

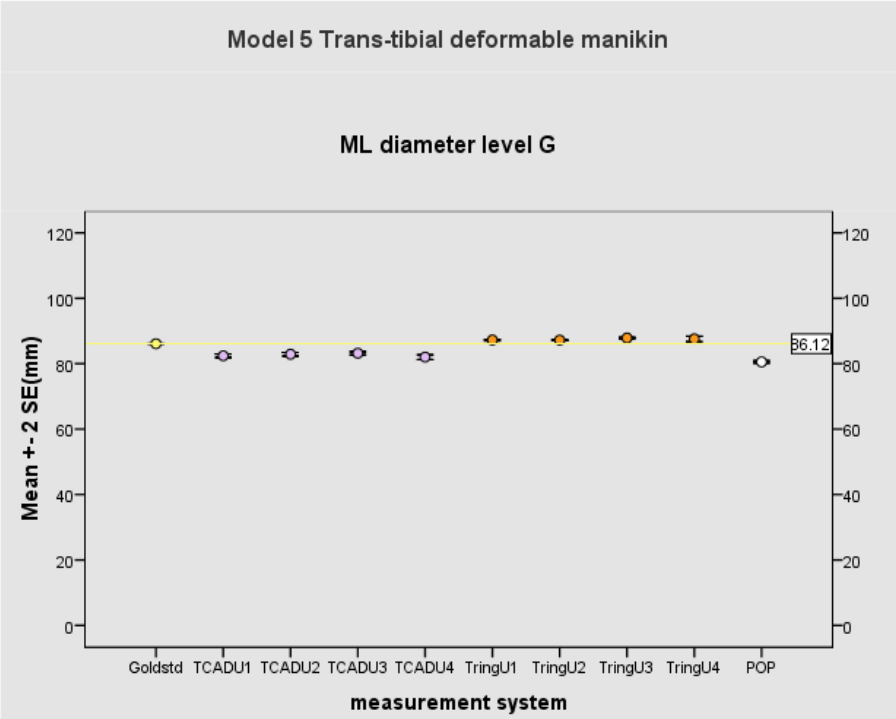

Figure 7-49 ML diameter level G. Accuracy and repeatability of systems (model 5)

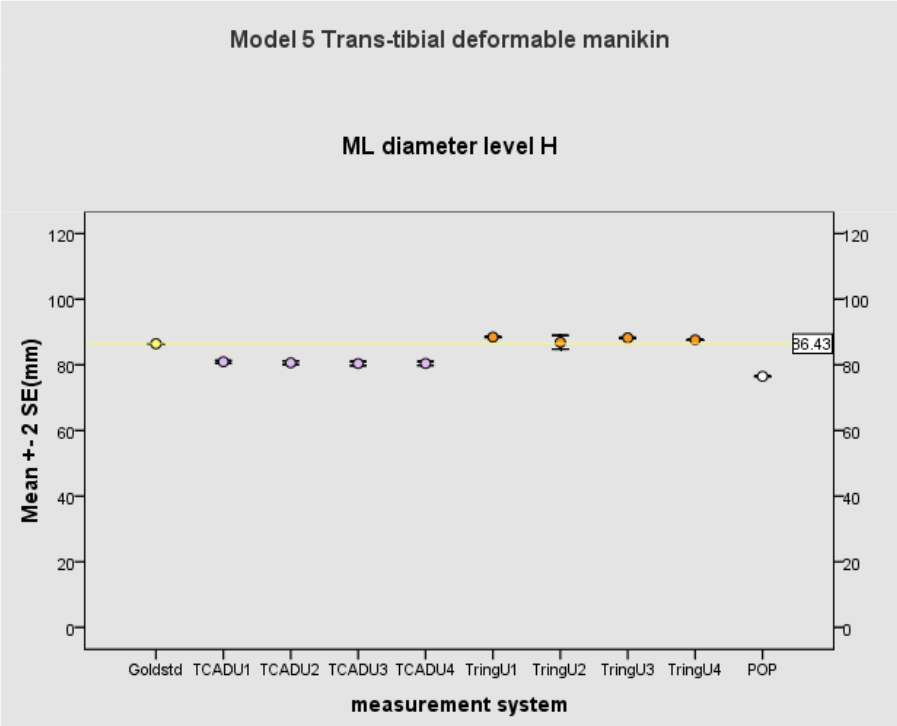

Figure 7-50 ML diameter level H. Accuracy and repeatability of systems (model 5)

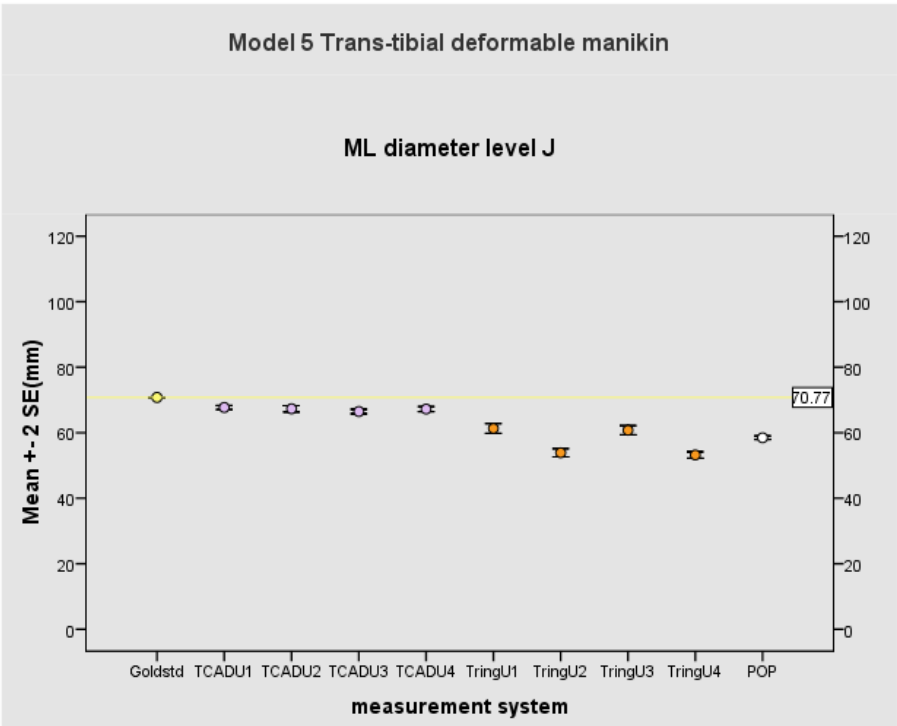

Figure 7-51 ML diameter level J. Accuracy and repeatability of systems (model 5)

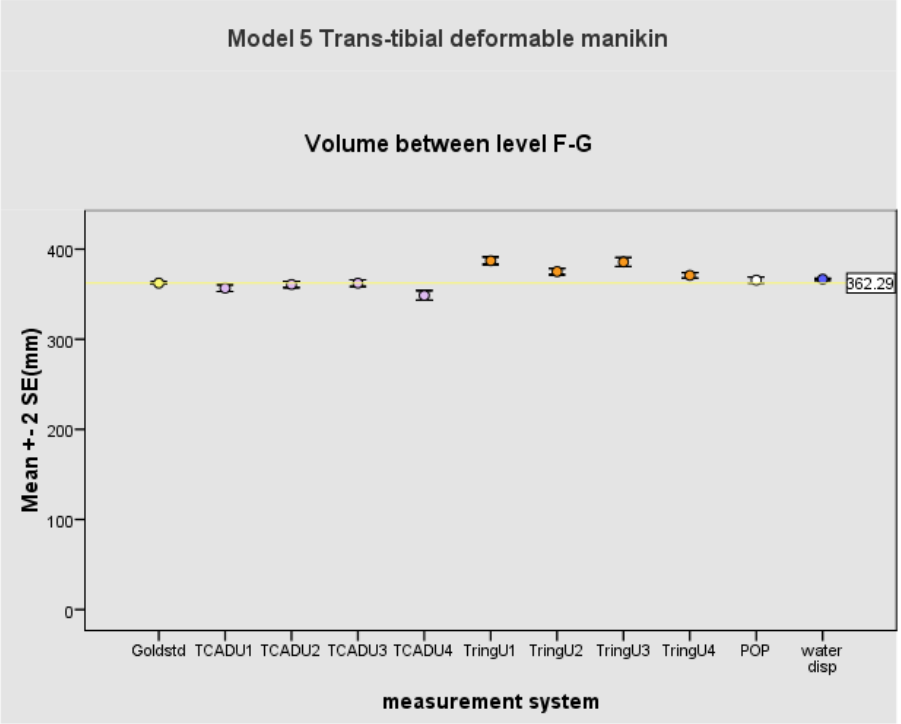

Figure 7-52 Volume level F-G. Accuracy and repeatability of systems (model 5)

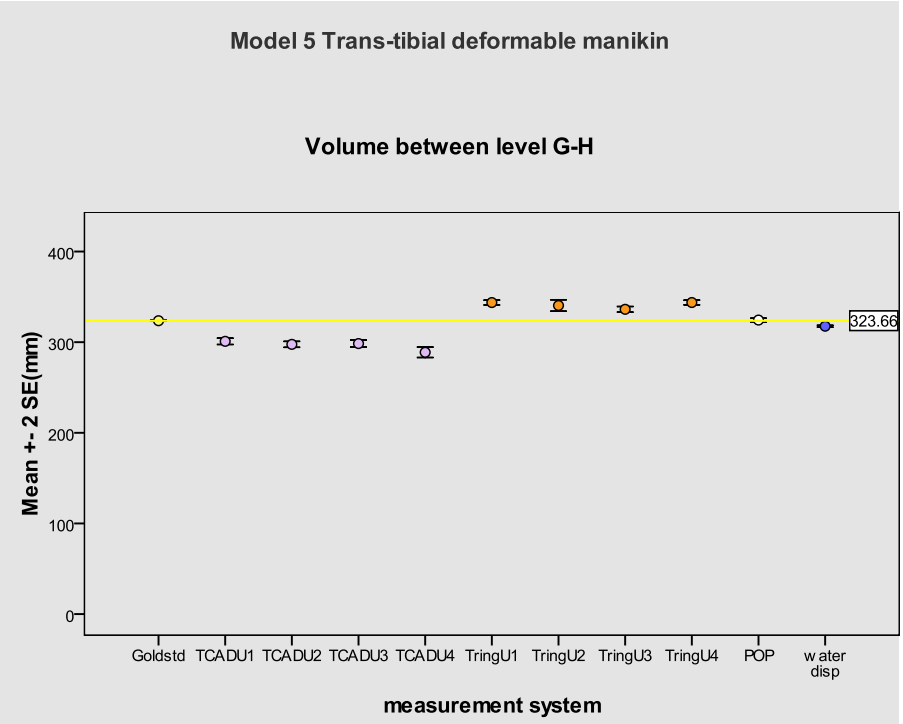

Figure 7-53 Volume level G-H. Accuracy and repeatability of systems (model 5)

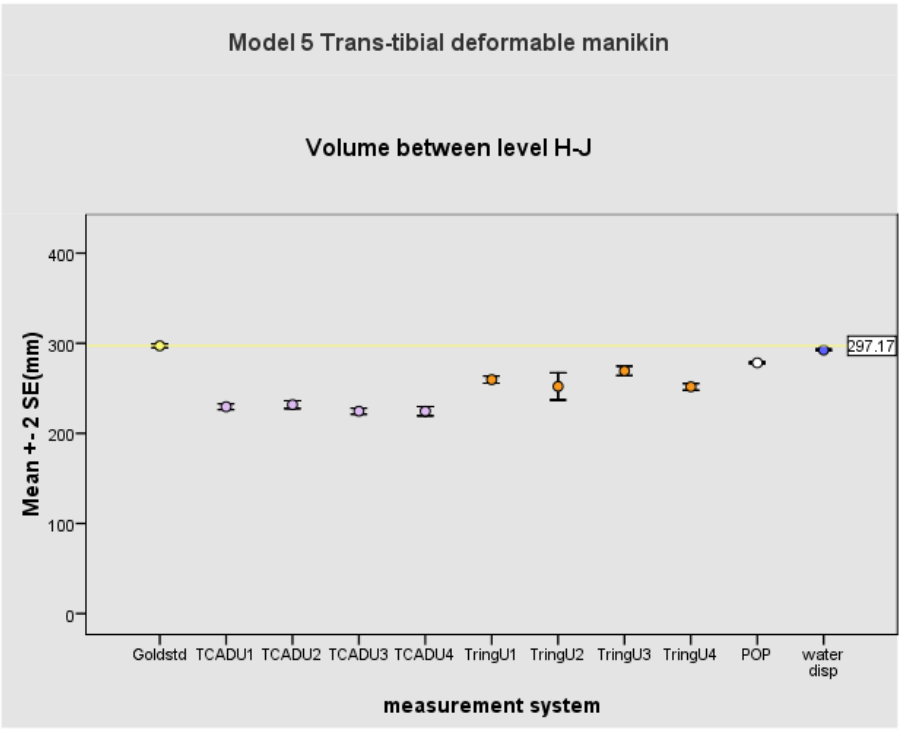

Figure 7-54 Volume level H-J. Accuracy and repeatability of systems (model 5)

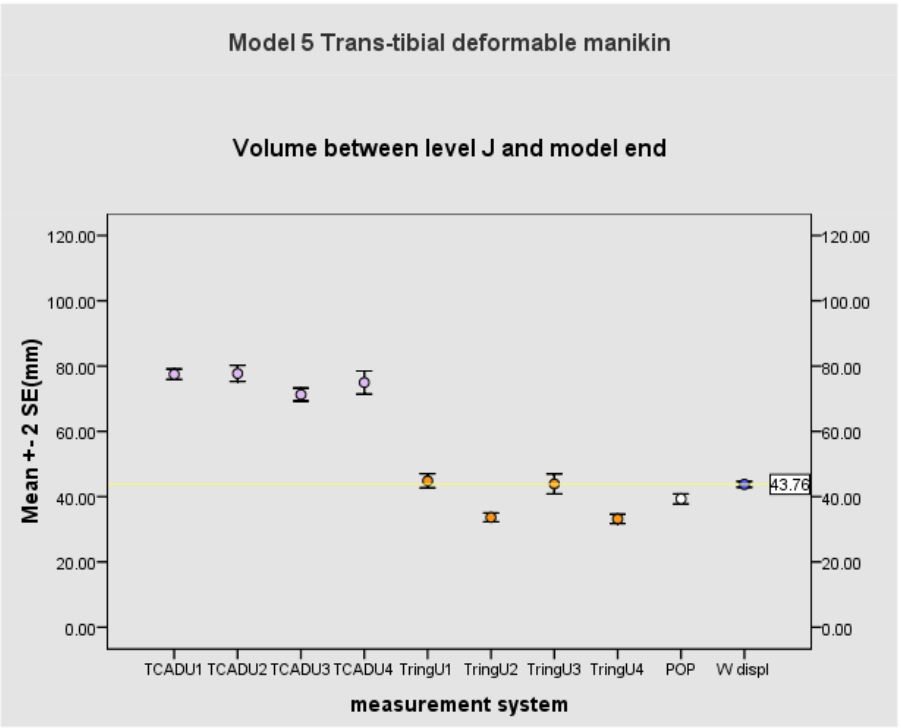

Figure 7-55 Volume level J-end. Accuracy and repeatability of systems (model 5)

For ease of interpretation, all results obtained are summarised in a simplified table (Table 25).

Note: Accuracy (diameter) <1mm Saunders (2003), Accuracy (volume) <5% (Lilja and Oberg 1997, Fernie and Holliday 1982).

*accuracy is displayed as the mean of repeated measures. Individual measurements did not always provide adequate accuracy.

Table 25 Accuracy summary table

MEANS	Tracer CAD			T Ring			Plaster of Paris		
Model 1	AP	ML	Volume	AP	ML	Volume			
F	**Y**	**Y**	**Y**	**Y**	**Y**	**6.33%**			
G	**Y**	**Y**	**Y**	**1.99**	**3.33**	**8.5%N**			
H	**Y**	**Y**	**Y**	**1.59**	**2.97**	**Y**			
J	**Y**	**Y**	**5.71%**	**3.48**	**-1.81**	**-32.32%**			
Model 2	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**
F	**Y**	**Y**	**Y**	**1.36**	**Y**	**Y**	**Y**	**Y**	**Y**
G	**Y**	**Y**	**Y**	**Y**	**Y**	**6.97%**	**Y**	**Y**	**Y**
H	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
J	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**
Model 3	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**			
F	**Y**	**Y**	**Y**	**3.04**	**3.49**	**8.87%**			
G	**Y**	**Y**	**Y**	**2.47**	**4.48**	**10.8%**			
H	**1.32**	**1.55**	**9.07%**	**Y**	**5.6**	**13.2%**			
J	**2.39**	**2.6**	**24.9%**	**-2.24**	**6.25**	**12.5%**			
Model 4	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**
F	**1.7**	**4.26**	**Y**	**2.39**	**3.39**	**Y**	**Y**	**Y**	**Y**
G	**2.55**	**1.46**	**Y**	**2.52**	**4.1**	**N (5%)**	**Y**	**Y**	**Y**
H	**1.71**	**1.44**	**-7.8%**	**Y**	**2.76**	**-7.04%**	**Y**	**Y**	**Y**
J	**Y**	**1.63**	**117.73%**	**-2.24**		**98.6%**	**Y**	**Y**	**24.6%**
Model 5	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**	**AP**	**ML**	**Volume**
F	**Y**	**1.51**	**Y**	**5.67**	**-2.68**	**Y**	**Y**	**-3.77**	**Y**
G	**1.31**	**-3.49**	**-8.41%**	**5.4**	**1.35**	**5.36%**	**3.5**	**-5.58**	**Y**
H	**Y**	**-5.84**	**-23.4%**	**Y**	**1.36**	**-13.1%**	**1.48**	**-9.59**	**-6.36%**
J	**-1.41**	**-3.59**	**72.23%**	**-16.03**	**-13.47**	**-11.1%**	**Y**	**-12.29**	**-10.12%**

To ensure reliability of findings it is advisable to examine results using two approaches. In addition to error bars, graphs of the difference in measurement versus the average difference in measurement for each system were also plotted (AP, ML and volume dimensions). These plots illustrate the limits of agreement between measures a lower and upper limit (mean +/-2SD) (Bland and Altman 2005). The mean value of the difference in measurement was also calculated and displayed (Figure 7-56 to Figure 7-61). Each model (1-5) is labelled on each graph by level (F-J). In a more formal systematic way, graphs should confirm what is already implied in the more descriptive approach using error bar graphs. All graphs are discussed in the next section.

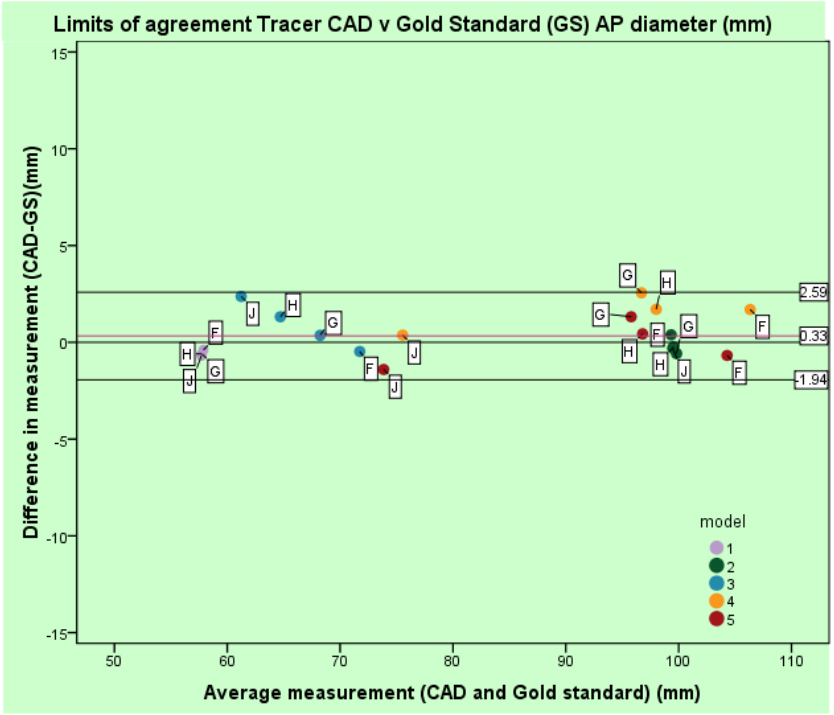

Figure 7-56 Limits of agreement Tracer CAD v gold standard AP diameter

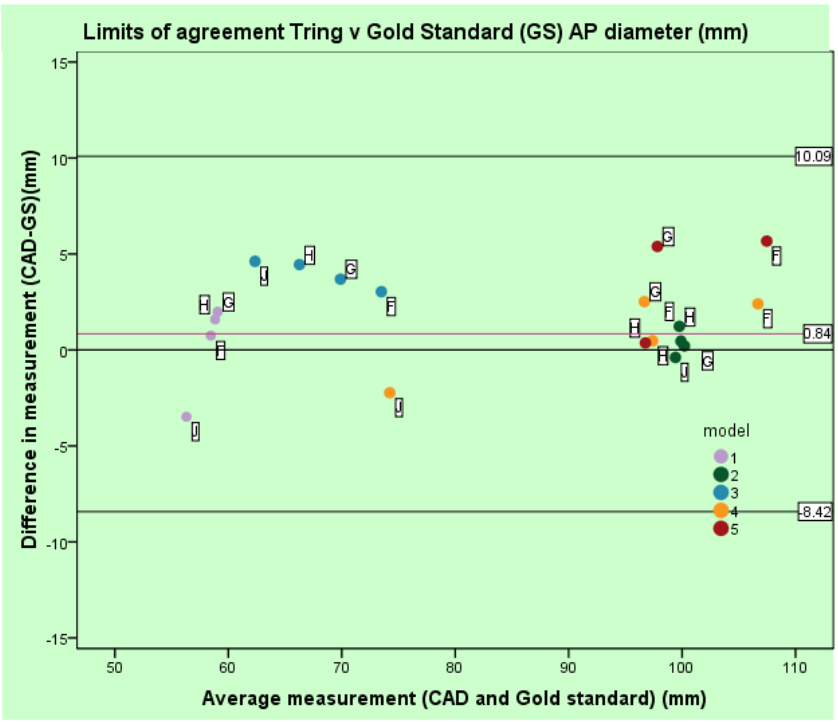

Figure 7-57 Limits of agreement T ring and gold standard AP diameter

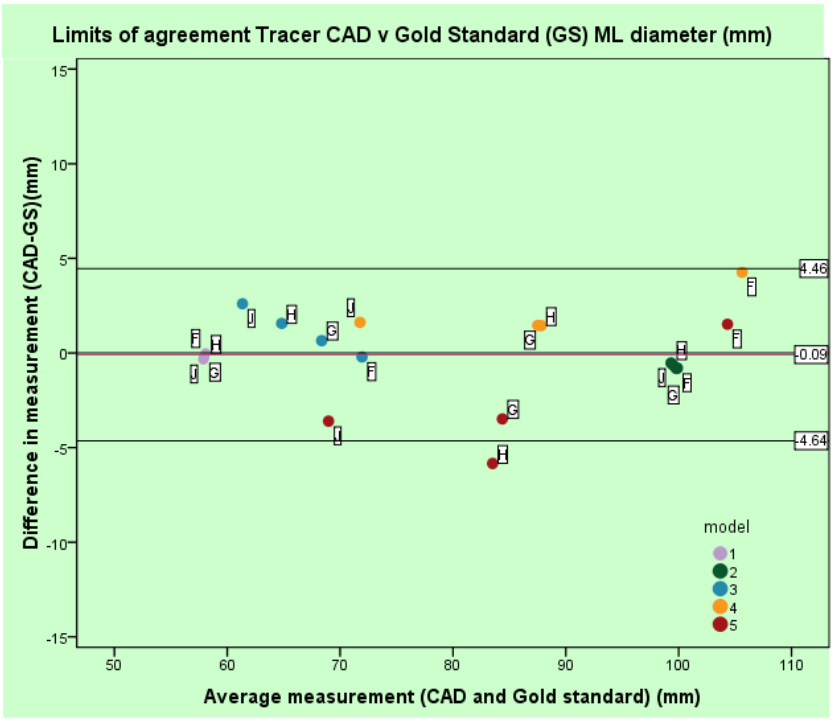

Figure 7-58 Limits of agreement Tracer CAD v gold standard ML diameter

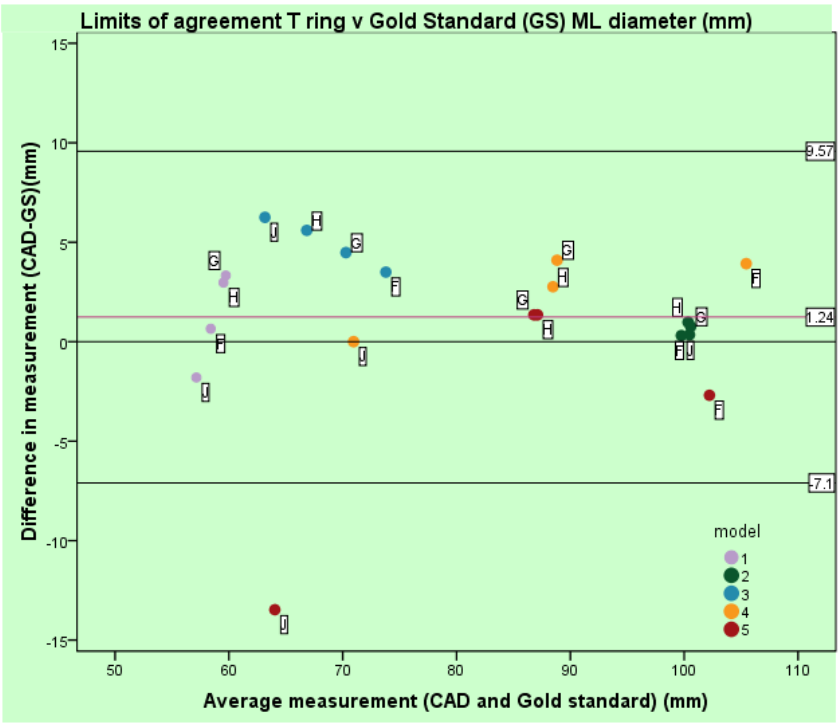

Figure 7-59 Limits of agreement T ring v gold standard ML diameter

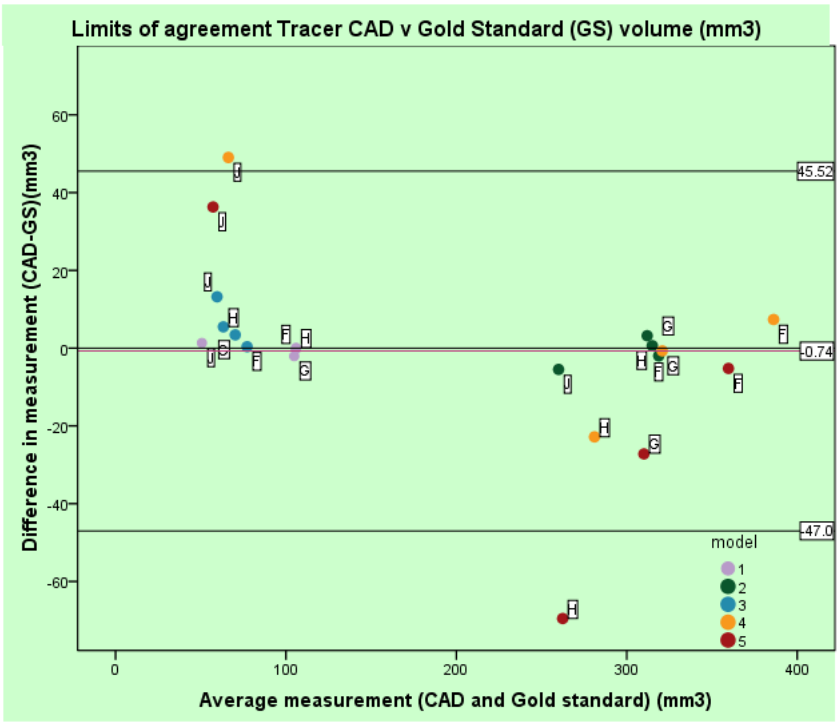

Figure 7-60 Limits of agreement Tracer CAD v gold standard volume

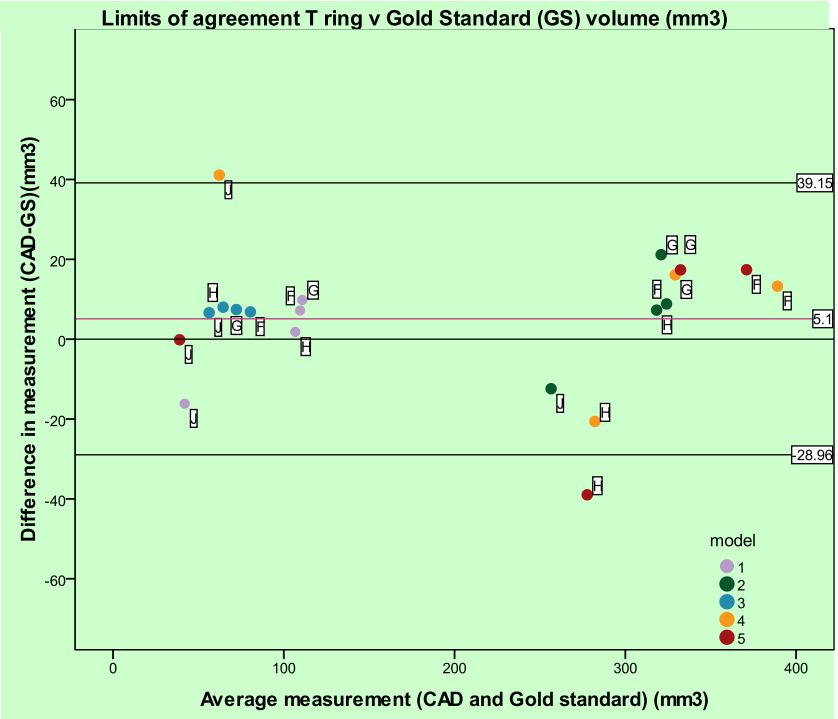

Figure 7-61 Limits of agreement T ring v gold standard volume

7.3 Repeatability Results

A result is repeatable when, each time the clinician measures the same patient using the same equipment, the measurements are the same. The coefficient of variation (CV) of all diameter and volume measurements was used to compare the repeatability of each method. The coefficient of variation is the standard deviation divided by the mean; and is used to summarise the amount of variation as a percentage or proportion of the mean.Limitations of the usefulness of his technique arise when the mean value is near zero as the coefficient of variation becomes sensitive to small changes in the mean.

A summary table of the coefficient of variation is provided for each method of shape capture (Table 26). This allows repeatability of a particular shape capture method to be examined over models 1- 5 at all levels of measurement. The lower the value obtained, the more repeatable the method (Stokes 1985). Commonly a CV of less than 5% is deemed to show acceptable repeatability (Campbell et al. 2007). Measurements where good repeatability was not achieved are highlighted (Table 20). In addition repeatability of landmark identification is also presented (Table 27).

Table 26 Coefficient of variation models 1-5 (%)

CV %	Model 1		Model 2			Model 3		Model 4			Model 5		
	Tracer CAD	Tring	Tracer CAD	Tring	Plaster of Paris	Tracer CAD	Tring	Tracer CAD	Tring	Plaster of Paris	Tracer CAD	Tring	Plaster of Paris
APF	0.42	1.11	0.32	0.62	0.07	0.64	0.79	0.91	1.52	0.4	1.94	1.82	0.35
MLF	0.36	1.02	0.33	0.73	0.04	0.52	0.65	0.57	0.46	0.28	1.35	2.39	0.9
Vol F-G	1.79	3.32	1.63	2.21	0.79	3.05	5.99	0.73	2.55	0.84	3.5	3.35	2.05
APG	0.41	1.46	0.35	0.71	0.12	0.71	0.9	0.41	0.73	0.62	1.92	1.19	0.61
MLG	0.47	1.47	0.39	0.7	0.1	0.6	0.82	0.69	1.8	0.43	1.97	1.47	0.8
Vol G-H	1.83	3.48	2.27	4.04	0.8	3.06	4.76	1.23	3.08	0.56	4.14	3.29	1.38
APH	0.36	1.49	0.36	0.75	0.12	0.68	1.39	1.25	0.37	0.63	2.47	3.87	0.57
MLH	0.43	1.8	0.46	0.68	0.06	0.55	1.28	0.42	1.51	0.19	1.89	3.38	0.88
Vol H-J	1.59	3.77	2.2	4.44	0.57	3.06	4.83	1.61	5.97	0.51	5.03	9.29	0.78
APJ	0.43	2.8	0.62	0.51	0.11	0.7	3.16	0.99	6.62	0.33	3.53	7.57	0.4
MLJ	0.33	3.84	0.71	0.48	0.05	0.5	3.14	0.86	6.29	0.62	3.18	8.97	1.62
Vol J-e	3.54	8.88	2.62	5.72	0.97	2.74	15.86	3.35	26.68	8.39	9.66	20.37	8.79

Table 27 Repeatability (COV) of landmark identification by CAD systems (%)

Tracer CAD	Model 1	Model 2	Model 3	Model 4	Model 5
F	0.79	0.41	0.58	0.39	0.86
G	1.01	0.54	0.85	0.67	1.28
H	1.66	0.81	1.16	1.19	2.30
J	4.84	1.53	2.71	3.74	11.13
T ring	Model 1	Model 2	Model 3	Model 4	Model 5
F	0.54	1.90	2.72	1.03	4.28
G	1.01	2.51	3.24	1.58	6.07
H	1.66	3.48	4.73	2.72	8.30
J	6.34	7.35	9.41	17.53	18.05

7.4 Reliability Results

Reliability is the extent to which the same measurements of individuals obtained under different conditions yield similar results, for example, changing the day or person doing the measuring. Inter class correlations were calculated for all models for each user between each system and the gold standard measurement systems at each level of measurement. Results are shown in tables. Measurements showing good reliability are considered to be greater than 0.7 (Evers 2001).

Table 28 Inter class correlations for all models (Reliability of individual users)

	ICC Gold standard vs. Tracer CAD				ICC Gold standard vs. Tring			
AP	TCADU1	TCADU2	TCADU3	TCADU4	TringU1	TringU2	TringU3	TringU4
F	0.999	0.999	0.999	0.999	0.987	0.991	0.991	0.989
G	0.997	0.998	0.997	0.998	0.985	0.987	0.987	0.982
H	0.999	0.998	0.999	0.998	0.993	0.995	0.994	0.994
J	0.997	0.997	0.995	0.997	0.925	0.879	0.925	0.855
ML	TCADU1	TCADU2	TCADU3	TCADU4	TringU1	TringU2	TringU3	TringU4
F	0.995	0.994	0.995	0.995	0.993	0.991	0.993	0.988
G	0.989	0.990	0.990	0.989	0.982	0.985	0.981	0.972
H	0.988	0.986	0.986	0.986	0.980	0.987	0.982	0.977
J	0.994	0.991	0.989	0.992	0.951	0.897	0.945	0.877
Volume	TCADU1	TCADU2	TCADU3	TCADU4	TringU1	TringU2	TringU3	TringU4
F-G	1.000	1.000	1.000	0.998	0.996	0.998	0.996	0.997
G-H	0.996	0.995	0.996	0.992	0.992	0.995	0.994	0.990
H-J	0.961	0.964	0.954	0.955	0.984	0.976	0.990	0.982
J-end	0.955	0.951	0.956	0.950	0.973	0.955	0.960	0.991

The reliability of individual users was demonstrated to be high when assessing all models using tracer CAD and T ring systems (Table 28).

Table 29 Interclass correlation (users)

	ICC Gold standard vs. Tracer CAD			ICC Gold standard vs. Tring		
	AP	ML	Volume	AP	ML	Volume
F	1.000	1.000	0.999	0.999	0.999	0.999
G	1.000	1.000	0.999	1.000	0.998	0.999
H	0.999	1.000	0.999	0.999	0.998	0.996
J	0.999	1.000	0.999	0.985	0.980	0.984

The probability that diameter and volume measurements obtained by different users were alike was confirmed by interclass correlation of users at each level of measurement (Table 29). Results show good correlation (ICC > 0.7) between users in measurement of diameters and volumes at each level on each model using either system (Evers 2001). Results of different users were therefore combined to allow a balanced analysis of variance (*SPSS statistics 17*).

Chapter 8

8 Discussion

8.1 Introduction

Since data acquisition is the first step necessary of any shape capture process, with the consequent socket design depending upon the data acquired, the reliability, repeatability and accuracy of data acquisition is crucial to the final product. If errors are not identified they may jeopardise the measurements in clinical practice as well as in research.

The following discussion evaluates the repeatability and accuracy of the Tracer CAD and T ring systems on a sample of models (n=5). Each model was designed to isolate and introduce potential sources of error in a controlled way. The shape of three of the models (model 2, 4 and 5), was also captured in the traditional way using plaster of Paris.

8.2 Repeatability of measurements

To assess the repeatability of measurement, the coefficient of variation (CV) of all diameter and volume measurements of each method was compared. Coefficient of variation less than 5% is considered to show good repeatability **(**Campbell et al. 2007). Repeatability results are summarised by model, system and level of measurement (Table 26).

8.2.1 Model 1 Cylinder

Initial tests involved the use of the Tracer CAD and T ring systems on a cylindrical model with a flat end (Figure 6-3).

Gold standard measurements were completed by the metrology laboratory using a comparator measuring device. The mean value of diameters and volumes are

considered to be the 'true' diameters to an accuracy of 0.01mm and were used as the gold standard measurement (GSM). Diameter and volume measurements taken by this method showed good repeatability (CV<0.01%).

Tracer CAD

The Tracer CAD system showed good repeatability of all AP and ML diameters (CV < 0.43%). This did not appear to be affected by the level at which the measurement was taken (Table 30).

Table 30 Maximum and minimum coefficient of variation (%) Model 1

CV	AP	ML	Volume
Tracer CAD	0.36 (F,G) -0.43 (J)	0.33 (J) -0.47 (G)	1.59 (H-J) -3.54 (J-end)
T ring	1.11 (F) – 2.80 (J)	1.02 (F) -3.84 (J)	3.32 (F-G)-8.88 (J-end)

Good repeatability of volume measurements was also observed (CV < 3.54%) on model 1. Less repeatability of volume measurement was seen at the distal volume measured (J- end of model) where CV=3.54%, than at proximal levels (F-G, G-H and H-J) where CV< 2% (Table 26).

Identification of landmarks by users of the Tracer CAD system was repeatable at all levels (CV <5%) (Table 27). However although acceptable, placement of the distal landmark (level J), was less repeatable than that of proximal landmarks.

Repeatability of diameter measurement was not affected adversely by incorrect landmark identification (as this was repeatable). However, even if landmark identification had been variable, it would be unlikely to affect diameters measured on a cylindrical model (since these are virtually the same at all levels).

Repeatability of volume measurement on a cylindrical model is more likely to be affected by incorrect landmark identification since the volume is calculated between landmarks. Volume will become smaller should the landmarks be indicated closer together and larger should they be placed further apart.

Although repeatability (CV) of volume measurement was good (less than 5% at all levels), least repeatability of volume measurement was observed at level J. This corresponds to where landmark identification varied most and shows that less repeatable identification of landmarks may affect repeatability of volume measurement on a cylindrical model.

T ring

Diameter and volume measurements taken by the T ring system showed greater variation of measurement at all levels than the Tracer CAD system (Table 30). The system showed good repeatability of diameter measurement at all levels (CV<4%) although variation tended to increase toward the distal end of the model (Table 30).

Repeatability of volume measurement tended to decrease with more distal measurement. Measurement repeatability at the distal end was poor (CV 8.88% level J –model end) (Table 26, Table 30).

Repeatability of T ring landmark identification was similar to that of the Tracer CAD system on model 1 at levels F-H (Table 27). However, although good at proximal levels repeatability of T ring landmark identification was poor distally at level J (CV 6.34%). Again, as the model is cylindrical, diameter measurements are unlikely to be affected. However, repeatability of distal volume measurement was poor at this level demonstrating that landmark variation will have affect on the volume measured)(Table 26, Table 30).

Summary for Model 1

Tracer CAD:	Good repeatability of all diameters measured (CV<1%).
	Good repeatability of all volumes measured (CV<5%).
T ring:	Good repeatability of all diameters measured (CV<5%).
	Poor repeatability of distal end volume measurement (CV 8.88%).

8.2.2 Model 2 Cylinder with domed end

Both the Tracer CAD and the T ring systems showed good repeatability of diameter measurement on model 2 (CV<1%) (Table 20).

Table 31 Maximum and minimum coefficient of variation (%) Model 2

CV	AP	ML	Volume
Tracer CAD	0.32 (F) -0.62 (J)	0.33 (J) -0.71 (F)	1.63 (F-G) -2.62(J-end)
T ring	0.51 (J) – 0.75 (H)	0.48 (J) -0.73 (F)	2.21 (F-G)-5.72 (J-end)
Plaster of Paris	0.07(F) -0.12(G)	0.04(F)-0.1(G)	0.57(H-J)-0.97(J-end)

(* Note: for convenience levels of measurement are denoted in superscript)

Tracer CAD

Repeatability of AP and ML diameter measurement by Tracer CAD on model 2 was slightly less than on model 1 (Table 31, Table 30, Table 27). Repeatability in all cases was good.

Tracer CAD showed good repeatability of volume measurement at all levels. Repeatability of measurement tended to decrease towards the distal end (CV 1.63(F-G) CV 2.62. (J-end)[1] This pattern was similar in model 1 where increased variation of measurement was also noted toward the distal end. Repeatability of landmark identification (Table 27) was good, but variation was highest at the distal end (level J). This may have had some effect on the repeatability of volume measurement at the distal end. Repeatability of Tracer CAD volume measurement was good at all levels (1.63 (F) -2.62 (J) (Table 25) and compared favourably to those on model 1 (1.59 (H-J) -3.54 (J-end) (Table 30)).

1 The level at which the error was measured is denoted in superscript for reference.

T ring

T ring showed good repeatability of diameter measurement on model 2. This compared favourably to repeatability of diameters on model 1(M2 AP CV <0.75 ML CV <0.73; M1 AP CV <2.80, ML <3.84%) (Table 30, Table 27)

T ring volume measurements also tended to become more variable towards the distal end. Proximal measurements showed good repeatability (CV 2.21$^{(F-G)}$ -4.44% $^{(H-J)}$**),** however poor repeatability of measurement was again observed at the distal volume (CV 5.72 %$^{(J- End)}$). Although poor, this compared favourably to the distal volume measurement on model 1 (CV 8.88 %$^{(J- End)}$).

Once again, repeatability of volume capture corresponds to the locations at which repeatability of landmark identification was good (levels F, G, and H) (Table 27). Repeatability of landmark identification was poor at level J (7.35%) and may be a cause of reduced repeatability of T ring distal end volume measurement (5.72%) (Table 26).

Plaster of Paris

Diameter and volume capture by plaster of Paris casts showed the least variation of all three systems. Variation of measurement was minimal (<1%) and showed good repeatability AP CV 0.07 – 0.12%; ML CV 0.04- 0.1%, volume CV 0.57-0.97% (Table 20, Table 25).

Summary for model 2

Plaster of Paris:	Good repeatability of all diameters measured (CV<1%).
	Good repeatability of all volumes measured (CV<1%)
Tracer CAD:	Good repeatability of all diameters measured (CV<1%).
	Good repeatability of all volumes measured (CV<5%).
T ring:	Good repeatability of all diameters measured (CV<5%).
	Good repeatability of proximal volumes measured $^{(F\text{-}G,\ G\text{-}H,\ H\text{-}J)}$ (CV<5%).
	Poor repeatability of distal end volume measurement (CV 5.72%).

8.2.3 Model 3 Truncated cone

Table 32 Maximum and minimum coefficient of variation (%) Model 3

CV	AP	ML	Volume
Tracer CAD	$0.64^{(F,G)}$ -$0.71^{(J)}$	$0.5^{(J)}$ -$0.6^{(G)}$	$2.74^{(H\text{-}J)}$ -$3.06^{(J\text{-}end)}$
T ring	$0.79^{(F)}$ – $3.16^{(J)}$	$0.65^{(F)}$ -$3.14^{(J)}$	$4.76^{(F\text{-}G)}$-$15.86^{(J\text{-}end)}$

Tracer CAD

The Tracer CAD system once again showed good repeatability of diameter measurement on model 3. Repeatability of AP diameter measurements was slightly worse than those on models 1 and 2 although the difference was minimal. ML diameter repeatability on model 3 was similar to that of model 2 but worse than model 1 (again minimal) (Table 26).

Repeatability of Tracer CAD volume measurements on model 3 was good (Table 32) and compared similarly to results obtained on model 1 (Table 30), but less favourably when compared to results on model 2 (Table 25). Users of the Tracer CAD system also showed repeatability when identifying landmarks on this model. This goes some way to showing that if landmarks are positioned in a repeatable way

then measurements will be repeatedly taken at the same level, increasing repeatability of diameter and volume measurements. This does not mean that results will be accurate however, as measurements may be repeatedly taken in the wrong place.

T ring

Repeatability of T ring diameter measurements was good although not as good as the Tracer CAD system on this model (Table 32).

T ring volume repeatability was poor at the two levels; the proximal level (CV 5.99$^{(F-G)}$ and once again as in all other models so far, the distal level (CV 15.86 %$^{(J\text{-}end)}$) (Table 32). Identification of landmarks by the T ring system was more variable than the Tracer CAD system affecting repeatability of volume measurements. Repeatability of the distal landmark (J) identification was shown to be poor (Table 27), and corresponded to increased variation in AP and ML diameters measured (AP CV 3.16%, ML CV 3.14%), and poor repeatability of distal end volume measurement (CV 15.86%).

Summary for model 3

Tracer CAD:	Good repeatability of all diameters measured (CV<1%).
	Good repeatability of all volumes measured (CV<5%).
T ring:	Good repeatability of all diameters measured (CV<5%).
	Poor repeatability of proximal volume measured $^{(F-G)}$ (CV<5%).
	Poor repeatability of distal end volume measurement (CV 5.72% $^{(J\text{-}end)}$).

8.2.4 Model 4 Trans-tibial cast

Table 33 Maximum and minimum coefficient of variation (%) Model 4

CV	AP	ML	Volume
Tracer CAD	$0.41^{(G)} – 1.25^{(H)}$	$0.42^{(H)}$ -$0.86^{(J)}$	$0.73^{(F-G)}$ –$3.35^{(J-end)}$
T ring	$0.37^{(H)} – 6.62^{(J)}$	$0.46^{(F)} – 6.29^{(J)}$	$2.55^{(F-G)}$-$26.68^{(J-end)}$
Plaster of Paris	$0.40^{(F)}$ -$0.63^{(H)}$	$0.19^{(H)}$-$0.62^{(J)}$	$0.51^{(H-J)}$-$8.39^{(J-end)}$

Tracer CAD

Of the two CAD systems, Tracer CAD showed better repeatability overall than the T ring on the shaped trans-tibial model. Tracer CAD showed good repeatability of diameter and volume measurement at all levels (CV<5%). Repeatability of landmark position was also good (Table 26, Table 27).

Tracer CAD AP diameter measurement was much less repeatable on the shaped model (CV $0.41^{(G)}$ - $1.25^{(H)}$**)** than on the cylindrical and conical models 1-3 (almost double that of variation on model 2.) (Table 33).

Repeatability of ML diameter measurement also reduced on this model (CV $0.42^{(H)}$ - $0.86^{(J)}$**)** when compared to the previous cylindrical and conical models measured (Table 33, Table 27).Tracer CAD showed good volume measurement repeatability on the shaped model 4 ($0.73^{(F-G)}$ -$3.35^{(J-end)}$**).** Variation of volume repeatability on the shaped model 4, although good, was greater than on model 2 ($1.63^{(F-G)}$ -$2.62^{(J-end)}$**)** and model 3 ($2.74^{(F-G)}$ – $3.06^{(J-end)}$**)**.

T ring

The T ring system showed much poorer repeatability of measurement than Tracer CAD system on the shaped trans-tibial model. Not all diameter results showed adequate repeatability (CV<5%). In general, repeatability of measurements had a tendency to reduce towards the distal end.

AP diameter repeatability on model 4 was much less favourable ($0.37^{(H)}$ -$6.62^{(J\text{-}end)}$**)** than repeatability of measures on models 1-3 (M1 AP CV $1.11^{(F)}$ - $2.80^{(J)}$, M2 ML CV $0.51^{(F)}$-$0.75^{(G)}$, M3 AP CV $0.79^{(F)}$-$3.16^{(J)}$) (Table 33). T ring AP diameter measurement repeatability was poor at distal landmark J (CV 6.62%) (Table 27)

For the T ring, repeatability of ML diameters also compared less favourably to previous cylindrical and conical models and was poor at the distal landmark J (CV 6.29%).

Repeatability of volume measurements made by the T ring system also decreased towards the distal end of the shaped model and was poor at distal levels volume H-J (CV 5.97%) and particularly poor at the most distal level J –model end (CV 26.68%).

This may in part be due to poor repeatability of the identification of landmark J (Table 27). Since the model was of complex shape, poor identification of this landmark would affect repeatability of diameters measured at this level. The position of this landmark also determines the level at which diameters H-J and J-model end are taken. Measurements have been shown to be less repeatable at these levels (Table 26).

Plaster of Paris

Plaster of Paris showed good repeatability of AP (0.40(F)-0.63(H)) and ML (0.19(H)-0.62(J)) dimensional measurements (Table 33). Of the three shape capture methods, this system showed best repeatability of diameter measurement. Repeatability, (although still good,) compared less favourably to that obtained by plaster of Paris casting on a simple cylindrical shape (Model 2 AP CV 0.07-0.12%, ML0.04-0.1% (Table 26)).

Repeatability of plaster of Paris volume capture on the shaped model was similar to that obtained on model 2 at proximal levels (model 4 Vol CV 0.51- 0.84%. Shape capture using plaster of Paris was variable at the distal end of the shaped model and

was unsatisfactory (CV 8.38%). This means that repeatability of plaster of Paris measurement on the shaped model (0.51(H-J)-8.39(J-end)) compares less favourably to plaster of Paris repeatability on a cylindrical model which was good (0.57(H-J)-0.97(J-end)) (Table 31, Table 27).

Although Tracer CAD showed less repeatability of measurement at most levels than plaster of Paris it is still the preferred system at this stage since repeatability of measurement is below 5% at the distal landmark.

Summary for model 4

Tracer CAD:	Good repeatability of all diameters measured (CV<5%).
	Good repeatability of all volumes measured (CV<5%).
Plaster of Paris:	Good repeatability of all diameters measured (CV<1%).
	Good repeatability of volumes (F-G, G-H, H-J) measured (CV<1%).
	Poor repeatability of distal end volume measurement (CV 8.39%).
T ring:	Poor repeatability of distal diameters (H, J) measured (CV 6.62%).
	Poor repeatability of distal end volume measurements (H-J, J- end) (CV 26.68%).

8.2.5 Model 5 Trans-tibial deformable manikin

Table 34 Maximum and minimum coefficient of variation (%) Model 5

CV	AP	ML	Volume
Tracer CAD	1.92 $^{(G)}$ – 3.53 $^{(J)}$	1.35 $^{(F)}$ -3.18 $^{(J)}$	3.50$^{(F-G)}$ –9.66$^{(J\text{-end})}$
T ring	1.19 $^{(G)}$ – 7.57 $^{(J)}$	1.47 $^{(G)}$ – 8.97 $^{(J)}$	3.29$^{(G-H)}$-20.37$^{(Jed)}$
Plaster of Paris	0.35$^{(F)}$ -0.61$^{(J)}$	0.9$^{(F)}$- 1.62$^{(J)}$	0.78$^{(G-H)}$-8.79$^{(J\text{-end})}$

Tracer CAD

All diameter measurements showed good repeatability (1.92 $^{(G)}$ – 3.53 $^{(J)}$) (Table 34). However, repeatability of diameter measurement compared less favourably on a deformable manikin than on any other model measured (Table 35). This was somewhat expected due to the contact method of shape capture which would affect repeatability of measurement on a deformable shape.

Table 35 Tracer CAD AP and ML diameter repeatability (models 1-5)

Model	AP diameter Coefficient of variation	ML diameter Coefficient of variation
1	**0.36 $^{(F,G)}$ -0.43 $^{(J)}$**	**0.33 $^{(J)}$ -0.47 $^{(G)}$**
2	**0.32 $^{(F)}$ -0.62 $^{(J)}$**	**0.33 $^{(J)}$ -0.71 $^{(F)}$**
3	**0.64 $^{(F,G)}$ -0.71 $^{(J)}$**	**0.5 $^{(J)}$ -0.6 $^{(G)(J)}$**
4	**0.41 $^{(G)}$ – 1.25 $^{(H)}$**	**0.42 $^{(H)}$ -0.86 $^{(J)}$**
5	**1.92 $^{(G)}$ – 3.53 $^{(J)}$**	**1.35 $^{(F)}$ -3.18 $^{(J)}$**

Results suggest that diameter measurement repeatability of the Tracer CAD system becomes worse with increasing complexity of shape and on a model with deformable characteristics. Deformable characteristics appear to have the greatest effect on repeatability of measurement using this system. At best (AP CV 1.92, ML CV 1.35%) repeatability was less than the largest coefficient of variation of all other models (AP CV 1.25$^{(\text{model 4 H})}$, ML CV 1.35 %$^{(\text{ model 4 J})}$) (Table 35).

Tracer CAD volume measurement repeatability was reduced when compared to repeatability of measurement on model 4 at all levels. Poor repeatability of measurement was observed at volume H-J (CV 5.03%) and at the distal volume J-model end (CV 9.66%).

For the very first time on any model, Tracer CAD recorded results with poor repeatability (CV> 5%). Distal volumes were particularly poor due to the increased deformation in this area. Less repeatability of measurement may be due to the contact nature of the Tracer CAD system. This would be expected to deform the manikin resulting in less repeatability of measurement.

Greater variation in landmark identification was observed on the deformable shaped model than on other models (1-4) (Table 27). Repeatability of the distal landmark (J) identification was poor and may affect repeatability of diameters measured at this level since the model is irregular. AP and ML repeatability was less than other models (CV 3.53% and 3.18% respectively). The position of this landmark also determines the level at which diameters H-J and J-model end are taken. Volume measurements were less repeatable at these levels (Table 26).

However, as in previous models, the Tracer CAD system showed better repeatability of measurement than the T ring system (Table 34). This was somewhat surprising as it was thought that less repeatability would be observed when scanning a deformable model with a contact method of shape capture.

T ring

Proximal diameter T ring measurements showed good repeatability (Levels F, G, and H, CV<5%). Poor repeatability of diameter measurement was observed again at the distal landmark J (AP CV 7.57%, ML CV 8.97%). Diameter measurement repeatability compared less favourably to all other models measured and was poor at the distal landmark level J (Table 36).

Table 36 T ring AP and ML diameter repeatability (models 1-5)

Model	AP diameter Coefficient of variation	ML diameter Coefficient of variation
1	1.11 (F) – 2.80 (J)	1.02 (F) -3.84 (J)
2	0.51 (J) – 0.75 (H)	0.48 (J) -0.73 (F)
3	0.79 (F) – 3.16 (J)	0.65 (F) -3.14 (J)
4	0.37 (H) – 6.62 (J)	0.46 (F) – 6.29 (J)
5	1.19 (G) – 7.57 (J)	1.47 (G) – 8.97 (J)

Results suggest that repeatability of T ring system measurement is adversely affected by the shape of the model and by the deformability of the model. Results do not show as clear a definition between models 4 and 5 as observed using the Tracer CAD system. This is thought to be due to the contact nature of the Tracer CAD probe to achieve shape capture. The repeatability of results between model 4 and model 5, however, is still reduced when using the T ring system. This is thought to be caused by the distal spacer of the T ring which must make contact with the soft end of the deformable model. Failure to position the spacer in the correct orientation or with the same pressure on the distal end will result in increased variation. All of these factors are thought to have affected the repeatability of landmark identification which was shown to be poor in all cases (Table 26, Table 27).

T ring volume measurement showed poor repeatability at the distal volumes (CV $9.29^{(H-J)}$ and $20.37^{(J\text{-}end)}$). Measurement repeatability compared less favourably to cylindrical and conical models (1-3) but was similar to that of model 4.

Table 37 T ring volume repeatability (models 1-5)

Model	Volume Coefficient of variation
1	3.32 (F-G)-8.88 (J-end)
2	2.21 (F-G)-5.72 (J-end)
3	$4.76^{(F-G)}$-$15.86^{(J\text{-}end)}$
4	$2.55^{(F-G)}$-$26.68^{(J\text{-}end)}$
5	$3.29^{(G-H)}$-$20.37^{(J\ end)}$

Poor repeatability of distal end volume capture by the T ring was observed on all models. The variability of results appears to increase with increasing complexity of shape. Results are inconclusive as to whether repeatability of volume shape capture

is affected by deformable model characteristics. To prove this conclusively, a further cylindrical model with deformable characteristics would be required.

Plaster of Paris

AP and ML diameter repeatability on the deformable manikin using plaster of Paris was good at all levels measured. Repeatability of measurement using plaster of Paris compares favourably to the repeatability of both CAD systems on the deformable manikin **(**Table 34, Table 38 Table 58**).**

Table 38 Plaster of Paris AP and ML repeatability (model 5)

Model	AP diameter Coefficient of variation	ML diameter Coefficient of variation
Plaster of Paris	0.35 (F) – 0.61 (J)	0.9 (F) -1.62 (J)
Tracer CAD	1.92 (G) – 3.53 (J)	1.35 (F) -3.18 (J)
T ring	1.19 (G) – 7.57 (J)	1.47 (G) -8.97 (J)

Variation of plaster of Paris measurement did increase slightly, however, on the shaped, deformable model when compared to Plaster of Paris shape capture on models 2 and 4 (Table 39). Good repeatability of diameter measurement was still observed, but results suggest that diameter measurement repeatability may be affected by the shape or the deformability of the model cast by plaster of Paris.

Table 39 Plaster of Paris AP and ML diameter repeatability (models 1-5)

Model	AP diameter Coefficient of variation (%)	ML diameter Coefficient of variation (%)
2	0.07(F) -0.12(G)	0.04(F)-0.1(G)
4	0.40(F) -0.63(H)	0.19(H)-0.62(J)
5	0.35(F) -0.61(J)	0.9(F)- 1.62(J)

Repeatability of distal end volume measurement by plaster of Paris on the deformable shaped model was still poor (CV 8.97%) and comparable to that shown on model 4 (Table 40). Repeatability of measurement, although poor at the distal volume was still much better than either the Tracer CAD or T ring systems at all levels (Table 34).

Table 40 Plaster of Paris volume repeatability (models 1-5)

Model	AP diameter Coefficient of variation (%)
2	$0.57^{(H\text{-}J)}$-$0.97^{(J\text{-}end)}$
4	$0.51^{(H\text{-}J)}$-$8.39^{(J\text{-}end)}$
5	$0.78^{(G\text{-}H)}$-$8.97^{(J\text{-}end)}$

Summary for model 5

Plaster of Paris: Good repeatability of all diameters measured (CV<5%).
Good repeatability of volumes $^{(F\text{-}G,\ G\text{-}H,\ H\text{-}J)}$ measured (CV<5%).
Poor repeatability of distal end volume measurement (CV 8.97%).

Tracer CAD: Good repeatability of all diameters measured (CV<5%).
Poor repeatability of distal volumes $^{(H\text{-}J,\ J\text{-}end)}$ measured (CV 9.66%).

T ring: Poor repeatability of distal diameters $^{(H,\ J)}$ measured (CV 8.97%).
Poor repeatability of distal end volume measurements $^{(H\text{-}J,\ J\text{-}end)}$ (CV 20.37%)

8.3 Accuracy of measurements

The dimensions of each model (1-5) were measured repeatedly using a comparator measuring device accurate to 10 microns (n=10) (model 1), or data acquisition system (programmable CNC milling machine (Deckel™) and a displacement tool (Mitutoyo, series 543 1DF Dynamic Indicator™), both with an accuracy of five microns (0.005mm) (n=3) (model 2-5)).

The mean value of AP and ML diameter measurements at four levels (F,G,H and J) and the corresponding volumes between levels (F-G, G-H, H-J and J- model end), were then used as a gold standard measurement on all models. These measures are considered to be an accurate representation of the dimensions of all models and are referred to as the 'gold standard mean' (GSM) measurement or 'true' value.

The mean value of repeated measurements (n=30) by 4 users of the Tracer CAD and T ring systems of each model was compared to the gold standard mean value at each level.

Statistical significance of results and interactions causational of errors were analysed using three factor balanced parametric analysis of variance for each measurement (*General linear model, Minitab 15*).

Interaction plots illustrate the overall effect of system, model and level interaction. Analysis indicates significant effect for system level interaction when measuring AP, ML and volume of models and also indicates significant effect for ML diameter model system interaction. This analysis only informs part of the story since model system interaction does not show at what level the errors are most likely, and the system level interaction combines all models. As prosthetists in the clinical situation would only trace the patient's residuum once, measurement errors in individual traces could be inadvertently used to produce the final prosthetic socket. Individual tests, (and not the mean of repeated tests), must also therefore be considered.

The level at which errors in diameter and volume measurement become clinically significant is also important. In other words, what level of error will be detrimental to socket fit? Literature pertaining to this subject has already been reported (Pg 21). The quality of evidence relating to socket fit criteria was found to be limited in quantity, generally poor in design and without consensus. The magnitude of errors thought to cause detriment to socket fit were therefore based on best available publications but should be interpreted with caution.

Fernie and Holliday (1982) evaluated residual limb volume fluctuations of new and mature amputees in order to predict the most appropriate time to fit a prosthesis. A water displacement measurement system was used to measure cross-sectional area of residual limbs. Data was obtained and a large sample size of participants was used (n=49). They estimated a maximum increase for maintenance of acceptable fit of a trans-tibial prosthesis was approximately 5%. This was based upon experiences with patients where patients who had experienced an increase between 3-5% in socket volume had difficulty in donning their prosthetic sockets. The study recognised that 5% was an approximation since stump measurement does not uniformly affect all levels, is difficult to measure, and is linked to weight gain or loss of each patient. Fernie and Holliday (1982) and Lilja and Oberg (1997) also demonstrated that the volume of one terry sock used to compensate for differences between residual limb and socket volumes is about 5% of the typical residual limb volume.

Saunders (2003) calculated that a uniform expansion to produce a 5% increase in volume on a limb with 90mm diameter would mean a radial alteration of 1mm.

Diameter error greater than 1mm (Saunders 2003) and volume errors greater than 5% (Fernie and Holliday 1982, Lilja and Oberg 1997) are considered to be clinically significant. A system is considered to provide accurate clinical measurement if measurements are within 1mm of the gold standard diameter, or 5% of the gold standard volume measured.

Because scientific data was limited, both CAD systems were compared to shape capture using plaster of Paris on three models (as described Pg 147). This was to investigate if they were at least as accurate and repeatable as traditional methods.

Results are displayed (Pg 177) to show error bar plots of each level of diameter and volume measurement by each system (*SPSS statistics 17*). These plots illustrate the mean value and the standard error (SE) of each repeated measure. This allows accuracy and repeatability to be compared to the gold standard at each level by each user of each system.
To ensure reliability of findings, results were also plotted to illustrate the limits of agreement between each CAD system and the gold standard measurement.

8.3.1 Model 1 Cylinder

To determine the accuracy of each system by each user comparisons of AP and ML gold standard diameters and volumes were made to the Tracer CAD and T ring at each of the reference points F, G, H, and J. The corresponding volume was determined and compared by each system at levels F-G, G-H, H-J and J to the end of the model.

Results using the mean value obtained from repeated measures using Tracer CAD on a simple cylindrical shape, showed good diameter measurement accuracy (difference <1mm compared to the gold standard).

AP mean diameters of repeated measurements by the Tracer CAD system accuracy were within 1mm, and did not significantly differ to the gold standard (maximum difference -0.91mm $^{(J)2}$ Figure 7-10). Tracer CAD ML diameters also showed no significant difference to the gold standard value at any level and exhibited accuracy of measurement to within 0.5mm (maximum difference -0.48mm$^{(J)}$Figure 7-12). Comparison of mean diameters of Tracer CAD measurements showed greater accuracy to the gold standard than mean values of T ring diameter measurements. No

[2] The level at which the error was measured is denoted in superscript for reference.

significant difference to the gold standard in diameter measurement was recorded by any Tracer CAD user at any level. (Figure 7-8, Figure 7-9, Figure 7-10, Figure 7-11, Figure 7-12).

Measurements taken by the Tracer CAD system did have a tendency to underestimate the gold standard value and the discrepancy appeared to increase slightly with measurements at distal landmarks.

Diameters recorded by all users of Tracer CAD at all levels, however, all underestimated the mean value (maximum difference =-0.93mm level J user 3.) (Figure 7-10) Differences in measurement between Tracer CAD and the gold standard had a tendency to increase as the user moved distally (Table 41). Such errors may suggest bending of the model (discussed on Pg 242).

Table 41 Maximum mean difference between Tracer CAD and the gold standard (mm)

Level	Maximum AP difference between means (all users)	Maximum ML difference between means (all users)
F	-0.59 mm	-0.17 mm
G	-0.77 mm	-0.40 mm
H	-0.78 mm	-0.47 mm
J	-0.91 mm	-0.48 mm

Individual scans showed greater AP diameter error when compared to the true value (maximum difference -1.48mm $^{(J\ user\ 3)}$). Although the greatest individual error in diameter measurement was observed at the distal end, all other levels of measurement showed maximum individual differences were greater than 1mm. Individual error on ML diameters showed good accuracy and was always within 1mm (max difference -0.98mm$^{(G\ user\ 3)}$).

Tracer CAD volume differences in measurement were observed up to 2.87mm$^{3\ (level\ J\text{-}model\ end).}$ (Figure 7-14). Mean volume measurement was good at proximal levels F, G and H (maximum difference -2.68 %$^{(\ level\ G\text{-}H)}$ (Figure 7-13), but poor at the distal end

(2.87mm^{3} or 5.71%). Individual tracing showed maximum difference between volume measurement to be poor at three levels (-5.22%^{F}, -7.35%^{G}, 8.33%^{H}).

Less accuracy of volumes measured, particularly at the distal end coincide with less repeatability of measurement. One cause of variation in volume measurement has been shown to be landmark identification which was most variable at this level. Less repeatability in landmark identification is shown to have detrimental effect on the repeatability and accuracy of volume measurement (Table 26, Table 27, Figure 7-14).

Results may also be explained by the pressure applied by each user due to the contact methodology of the tracing mechanism. This was examined in a subsequent experiment to determine the bending, shifting effect on each model (Section 6.4.7).

Manual tracing of the model may result in greater pressure being applied than optimally preferred. This may also result in a smaller volume being recorded, as both ML or/and AP diameters may be affected. This experiment was carried out using a hard model that would be difficult to deflect or change shape by exerting pressure. Changes in user pressure may have greater affect on measurements of a deformable shape since this would be susceptible to deformation when force is applied. This may affect the volume measured. It might be expected that volume measurement would always be underestimated when AP and ML diameter measurement is underestimated. While this is possible, it is not always the case. Figure 8-1 shows a hypothetical transverse section of model 1. The solid line represents the actual gold standard dimension and the dotted line that of the hypothetical data gathered by the Tracer CAD system. Whilst the AP and ML diameters appear to have been correctly measured, diameters in other planes have not. The model in this example overestimates the posterior diameters (except in the AP and ML planes), and is likely to overestimate the volume. The opposite is true in the anterior portion of this example. It is feasible that although diameter dimensions are correct, volumes could be over or underestimated depending on the accuracy of data in between the AP and ML planes. Therefore accuracy of diameter measurement does not necessarily mean

accurate volume measurement. This scenario is thought even more likely in the more complex deformable model 5.

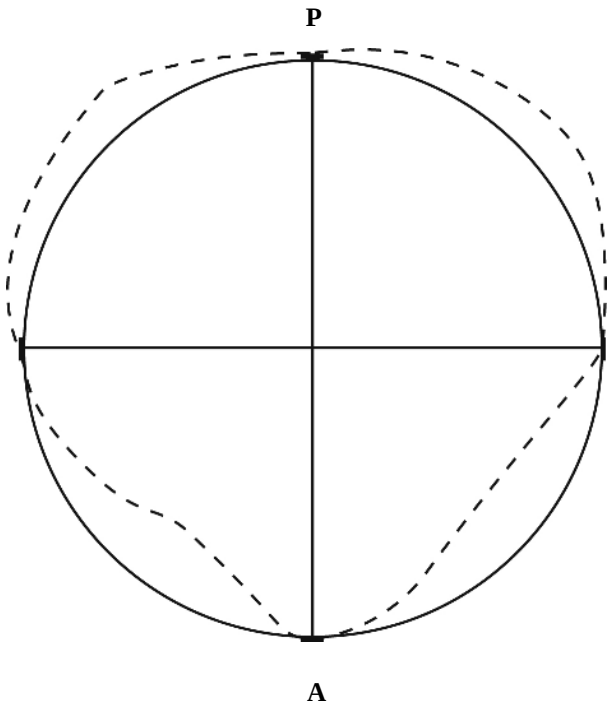

Figure 8-1 Transverse section of model

The largest volume differences in individual tracings were much higher than the mean percentage difference. Individual discrepancies are relevant since each patient is measured only once. In the clinical situation, measurement of stump volume is important in determining the correct volume of the socket. If incorrect, this could lead to a socket which is either too loose or tight. If volume measurement is inconsistent, determining the optimum volume and therefore ideal fit of the prosthesis, when using Tracer CAD is made more difficult.

As illustrated by interaction plots (Figure 7-3) the T ring showed less accuracy than the Tracer CAD system when measuring the cylinder and had a tendency to overestimate the 'true' gold standard mean. Many levels were considered likely to differ significantly from the gold standard.

Mean AP T ring diameter accuracy was poor at the distal end (1.1mm ^{F} >4.03mm ^{J} (Figure 7-10)).

AP diameters at levels F, G, and H, all T ring users overestimated the mean value of the gold standard (Maximum difference between means User 1 = 2.32mm level G User 1. (Figure 7-9)) Significant differences in measurement were probable at level G in which the mean value was overestimated. Individual measurements showed greater inaccuracy (-7.78mm).

Mean ML accuracy was good at level F (0.73mm) but poor at all other levels, and greatest at the distal end (-3.41mm [J])(Figure 7-8, Figure 7-10).The maximum difference in ML individual T ring scans of all users was -9.48mm. These error values correspond to those illustrated ML diameter system level interaction plot for all models (Figure 7-5).

All ML measures by all T ring users overestimated the mean value of the gold standard at levels F, G and H. Significant differences in measurement may be likely at level G (all users), Level H (User 1, 3 & 4) (Maximum difference between ring and GSM level G User 4 = 3.6mm) (Figure 7-11).

One explanation for the over estimation of diameters measured may be due to the addition of a sock which is necessary when using the T ring. Addition of a sock, however thin would have the effect of increasing diameters measured and would have effect on increasing the volume of the model.

However, in contrast to other levels, diameter results obtained using T ring tended to underestimate the true diameter at level J. Significant difference in measurement was likely by user 2 (Max diff= -3.41mm) (Figure 7-12, Figure 7-5).

T ring volume measurement was inaccurate. Poor accuracy was observed at proximal levels (12.41mm^3, 11.72%) but was most apparent at distal levels where a mean difference of -17.93mm^3 was observed. Individual scans again showed even greater discrepancies in measurement. Greatest inaccuracies were measured at the distal landmark (Level J) and correspond to gross under sizing of the model in this region. Poor accuracy corresponded to poor repeatability of landmark identification affecting

the actual volume measured ((Table 26, Table 27, Figure 7-14).Error values are aligned to those illustrated in volume system level interaction plots (Figure 7-7).

Overall, accuracy of T ring measurements was disappointing and better results were expected since the model was not of intricate shape. The reasons why this might be the case are discussed in greater detail with reference to model 2 and 3.

8.3.2 Model 2 Cylinder with domed end

Model 2 was a simple cylindrical model manufactured in a hard nylon material (Figure 6-4). The model was measured using Tracer CAD and T ring systems and additionally wrapped with plaster of Paris.

Initially this model was scanned with the T ring held horizontally over the vertically held model in a Deckel CNC milling machine. A spirit level and laser line were used and checked by two prosthetists to ensure the T ring was initially horizontal. This allowed the cylindrical shape to be captured using the T ring whilst eliminating any 'error' caused by the human interaction of the operator holding the scanner.

To assess the accuracy of scans, the T Ring and dynamic indicator mean: AP, ML mean diameters and volumes were then compared (Figure 7-23, Figure 7-26, Figure 7-27) (maximum difference between gold standard mean and T ring mean AP 0.998mm, ML 0.56mm, Volume 11.28mm^3 (3.56%).

From results, it appears that the T ring system has a tendency to overestimate the true value of the gold standard volume measured. In this scenario this was not caused by human interaction with the system since the system was left, horizontally, in place on the model between scans. Addition of the sock required for T ring scans would cause increase in diameter and volume measurement. The only other interaction with the system is the button pressed by the user to complete a scan. It is feasible that the action of pressing this button could have some effect on the angle of the

T ring, and thus affect repeatability and accuracy of scans taken. Variation in measurement must in some part be explained by surface reflection and shadows caused by the effect of light on the scanned surface. If the intensity of light is not constant then shadows can occur which may affect the accuracy of dimensional measurements on the model. However, prior to scanning, lights were dimmed to a level thought to minimise the effect of shadows on the model. The model is also a cylinder and is likely to produce fewer shadows than a complex shape such as a trans-tibial shape.

It is unlikely that the T ring, due to its size and weight, would be held by the operator in a perfectly level position. Even if this were possible, this may not correspond to the central axis of the residual limb shape which is clinically not possible to locate (although it was possible in this experiment).

The largest discrepancy of measurement was the most proximal volume. (Figure 7-27)

Table 42 Maximum mean volume difference between Tracer CAD and T ring and the gold standard

Volume	Difference between T ring mean and GSM (mm^3)	Percentage difference between T ring mean and GSM (%)
F-G	11.28	3.56
G-H	7.8	2.51
H-J	2.6	0.8
J- model end	1.1	-0.4

To assess what these errors mean in a clinical sense, errors were equated to the number of additional socks required as specified by Fernie and Holliday (1982) and Lilja and Oberg (1997). A 3.56% difference, (volume F-G, Table 42) would equal an increase in approximately over half a thickness of one sock at this level. As volume variation between T ring and dynamic indicator measurements do not consistently

affect each of the differing levels, addition of a sock at one level would have potential to cause excessive loading at another level (for example volume J-model end which is already underestimated). This could result in potentially high pressures and inadequate socket fit in the distal aspect of the residual limb.

Discrepancies in measurement may also be caused due to manual identification of landmarks. If landmarks are indicated incorrectly, then measurement error would result as the volume is derived from the diameters and the lengths between known points. It is unlikely that the landmark position would affect diameter measurement on this model since the SD was less than 1mm and the model was cylindrical. However landmark identification does have potential to influence volumetric calculation. Landmarks were marked precisely using the Deckel CNC milling machine and under these conditions the T ring exhibited a high level of accuracy.

However, although the T ring does identify landmarks indicated on each model, indication of landmarks in the clinical setting must be identified and positioned manually by the prosthetist. This means that landmark identification will be subject to potential errors of incorrect location and will be dependant upon the expertise and skill of the individual clinician.

In the above conditions the T ring was held perpendicular to the central axis with the distal probe in contact with the distal end. However, since the T ring is used in a hand held manner, and the trans-tibial shape is complex and not cylindrical, it may be argued that these conditions, although optimal, are unlikely to occur in the clinical situation.

To investigate the effect of angular displacement measurements were repeated with different orientations of T ring inclined at 2^0,$4^0$and 6^0 relative to its initial position and the results compared to those taken at 0^0.

Although significant difference was not observed between any AP or ML T ring diameters and the gold standard mean value, the discrepancy between measures and

the gold standard mean increased as the angle was made larger. (Figure 7-20, Figure 7-23, Table 43).

Table 43 T ring compared to gold standard when held at different angles: Mean volume difference (mm^3)

	0^0	2^0	4^0	6^0
Volume F-G	-0.91	15.39	29.9	45.93
Volume G-H	-15.24	-15.04	17.55	-15.88
Volume H-J	9.11	26.37	39.82	58.13
Volume J-End	20.08	39.13	52.33	69.04

Results showed decreasing volumetric accuracy as the angle between the T ring and the model increased. This was most evident at the distal end of the model where the 'missing' data is extrapolated (Figure 7-22).

In the clinical situation the T ring is held by the prosthetist who attempts to simulate conditions where the ring is held at 90 degrees to the stump axis. The patient is asked to extend the knee and hold the limb in extension. The hand held nature of this process may result in the photograph being taken at an angle other than 90 degrees relative to the central axis. This would have an important effect on the accuracy and repeatability of data collected and would also affect the final fit of the socket, particularly in the distal region.

If a measure is not taken truly at 90^0 to the central axis of the model then elliptical circumferences and unequal diameters will be recorded. in a cylindrical model. This results in greater values recorded. However, this may not be the case in the more complex model where smaller or larger diameters and circumferences may result due to complexity of shape. This means that angular displacement may cause error that is not easily recognised in the clinical situation.

Reduction in repeatability may also be caused by the effect of increased shadows on one side of the model should it be angled away from the light source.

Angular displacement in these tests was thought to be relatively small compared to the clinical setting ($0\text{-}6^0$). Realistically the angle at which the T ring is held in relation to the residual limb may be much larger in the clinical situation due to the hand held design of the T ring system and this will depend on each individual clinician. If the angle at which the scan is taken deviates further then the accuracy of the scan may decrease further and could cause potentially larger errors than those recorded in this experiment. These inaccuracies may not always be easily identified on a complex residual limb shape.

The effect of mis-positioning of the distal probe was also examined. The cylindrical model was positioned vertically in the Deckel CNC milling machine. The T ring was then held horizontally in the system, and the distal probe held in contact with the distal end of the model. The probe was then removed 5mm from the distal end and scans taken. Once these scans were completed the T ring was then pushed 5mm onto the distal end. For each of these settings the model was scanned thirty times.

Removal or pushing of the probe from the model by 5mm created the effect of elongation or shortening of the model and had an adverse effect on the volumes recorded at the distal end (Figure 7-28).

Results showed that removal of the probe from the distal aspect of the model resulted in extrapolation of the cylindrical model which could be seen visually on screen. This was easily seen as the model was cylindrical but may not be so obvious when used on a more complex model with irregular distal shape. No significant difference was observed in any diameter measurement although this may not be the case on a more complex shape.

Volumes were compared and were specifically affected at the distal end where, as expected, as much smaller volume was measured for the pushed situation and a larger volume recorded for the pulled situation (Figure 7-28). Mean volumes increased by up to 5% at the distal end (Vol. J- end) and 3.11% at the next level (Vol.

H-J). Other volumes on the model remained relatively unaffected compared to those under normal conditions.

Incorrect placement of the distal end spacer is thought likely in the clinical situation as the system is applied by different users. Model 2 was not deformable and it is expected that results may be more variable due to the deformable nature and less regular shape of the distal aspect of a residual limb. If such results as those obtained were used in the clinical setting, undesirable distal space and loss of total contact (distal spacer removed from the model) or excessive pressure (distal spacer pushed onto the model) would be likely within the prosthetic socket

The model was then scanned a number of times using the T ring and Tracer CAD systems in the same way in which they are used in the clinical setting. Results of these scans were compared to Plaster of Paris casting. Each user held the T ring scanner by hand and was reminded to attempt to ensure that the T ring was level as possible in each plane during each scan.

Plots showed that no statistical difference was likely between either CAD system mean AP or ML diameters or the gold standard mean at any level of measurement (maximum difference between Tracer CAD mean and Gold standard = -1.08mm (ML diameter J user 3). Maximum difference between T ring mean and Gold standard mean = 1.69mm AP diameter F user 2) (Figure 7-15, Figure 7-17). In general, Tracer CAD diameters tended to underestimate the gold standard mean whilst T ring overestimated these values.

Volume measurement for the T ring system by all users at all levels was overestimated compared to the gold standard mean and this was likely to be significant (Maximum difference between T ring mean and Gold standard mean = 25.37mm^3 level G user 4) (Figure 7-18).

The Tracer CAD and T ring systems showed significant differences to be probable between volume calculations between the most distal marker and the end of the

model (J to end) (User 2 and 3 underestimation of the mean gold standard value) (Figure 7-19).

Inaccuracies in measurement at the distal end volume coincide with less repeatability of landmark identification at level J. Less repeatability in landmark identification is a factor affecting repeatability and accuracy of volume measurement (Table 26, Table 27, Figure 7-14).

Although standard error graphs indicated no statistical difference to gold standard AP or ML diameter measurements, Mean Tracer CAD and T ring diameter measurements did vary from the true value by more than 1mm (Maximum error : Tracer CAD -1.08mm^{G} T ring 1.64mm^{F}). This is below the accuracy required for sockets in clinical use (Saunders 2003).

Additionally, the graphs compare the *mean* values of all diameter and volume measurements recorded by different users of the Tracer CAD and the T ring systems. As the prosthetist will only measure the model once, it is likely that a much larger error will be produced. It is doubtful that the prosthetist will record the mean value of measurements since clinically he only takes one measure of the patient.

This was shown in individual tests of the experiment where individual scans measured much greater differences between diameters and volumes when compared to the gold standard mean (Maximum difference between Tracer CAD mean and Gold standard mean: AP = -1.8mm (U3 level 11), ML= -2.49mm (U3 level 11), volume= -21.62mm^3 (-8.23%) (U3 vol. 9-model end); Maximum difference between T ring mean and Gold standard mean AP= 3.96mm (U2 level 12), ML=4.65mm (U2 level 10), volume = -54.13mm^3 (U2 level J-end). In these situations, both systems Tracer CAD would be unsuitable for clinical use.

The T ring system significantly overestimated the values of the volume measurement at all levels except at the distal level where the volume was underestimated. Tracer CAD users tended to underestimate the distal volume. Errors were considered to be

clinically significant. T ring overestimation of volume would result in a socket that is too large. Errors in shape capture at the distal end could cause high or low pressure gradients on distal stump tissue likely to cause skin breakdown.

Compared to both CAD systems, plaster of Paris casting showed much better accuracy and when casting a non deformable model of simple cylindrical shape (maximum error plaster of Paris mean AP= 0.88 mm^{F} (Figure 7-16) ML = 0.39mm^{J}, volume = -4.68mm^{3} (1.46%^{F}). This was even though the casting process involved a number of additional steps such as cast filling and copying procedure which may contribute to the errors and variation of measurement recorded.

Plaster of Paris casting showed best repeatability and accuracy of any systems tested and would be an acceptable method of capturing the shape of a cylinder with a domed end.

A cylinder with domed end, of course is not the shape of a residual limb, and further testing of systems required to assess whether errors become greater under these circumstances.

8.3.3 Model 3 Truncated cone

AP and ML diameters recorded by Tracer CAD and T ring followed a similar pattern on model 3. To avoid repetition, both AP and ML diameters are analysed collectively for this model.

Tracer CAD diameter measurements were more accurate than T ring measurements at all levels. Standard error plots indicate that statistical difference between the gold standard mean and Tracer CAD measurements is unlikely at the two most proximal diameter measurement (F and G), but was likely at the most distal level by all users. Adequate clinical accuracy was observed at levels F and G (<1mm) when compared to gold standard values. However results became less accurate at distal landmarks (maximum difference between Tracer CAD mean and gold standard mean AP=

2.51mm level 1 ML= 2.86 level 1) (Figure 7-29, Figure 7-30). The maximum diameter error (2.86mm) on model 3, was much greater than the maximum inaccuracy recorded on model 1(-0.93mm).

Maximum inaccuracies of Tracer CAD mean and individual tracings occur at the most distal diameter measured. The differences in mean measurements between Tracer CAD and the gold standard had a tendency to increase as the user moved distally even as the diameter of the model became smaller and may be in some part due to pressure exerted by the user as the distal end is traced (Figure 7-29, Figure 7-30).

Table 44 Mean difference between Tracer CAD and the gold standard

Level	Gold standard	Maximum difference between means (all users) AP	Maximum difference between means (all users) ML
F	71.04 mm	-0.66 mm	-0.57 mm
G	68.04 mm	0.54 mm	1.06 mm
H	64.04 mm	1.56 mm	1.98 mm
J	60.04 mm	2.51 mm	2.86 mm

At the most proximal landmark (F) Tracer CAD volumes (of all users) were not significantly different to the gold standard mean value (Max diff User 3 =1.48mm^3). All users of the T ring recorded volumes that significantly overestimated the true value at this level (Max diff User 1 = 8.47mm^3) (Figure 7-31).

At all other levels users of both systems showed likelihood of significant overestimation the value of the gold standard mean value at this level. Tracer CAD generally showed better accuracy, but still significant difference (maximum difference User 2 13.47 mm^3) compared to the T ring mean value (maximum difference User 4 12.67 mm^3).

Bending moment experimentation

In a similar manner to results of model 1, errors recorded by the Tracer CAD system had a tendency to increase as the user moved distally.

As the Tracer CAD system depends on a contact method of shape capture, any force applied by the probe will cause a bending moment. To ascertain the extent of this error, four practitioners were asked to scan the same cylindrical model using the Tracer CAD pen in an additional experiment.

All users caused some bending and shifting of the model which was higher toward the distal end. This indicates that some bending occurred and is responsible for part of the overall error recorded during tracings (Table 23).

Different users recorded different deflection of the model and this must be due to the pressure applied by that user during each trace. The maximum deflection was caused by User 2 (mean 0.03mm).

Bending and displacement of the model does occur, however, the amount of deflection was minute and was considered to account for only a very small part of overall error in measurement.

(Model 3 continued)

Results from individual measurements of both systems showed much less accuracy (maximum AP error: Tracer CAD = 3.86mm, T ring= -8.84mm. Maximum ML error: Tracer CAD = 4.6mm, T ring= -10.24mm). All maximum errors observed (both systems) were recorded at distal landmark J.

All diameters recorded by the T ring systems at the distal landmark J showed likelihood of significant overestimation of the gold standard mean value and compared less favourably to the Tracer CAD system (Tracer CAD max AP mean

diff= 2.51mm (ML= 2.86mm), T ring max AP mean diff= 5.73mm (ML=7.08mm) (Figure 7-29,Figure 7-30)).

The accuracy of T ring volume measurement over the entire model was poor and showed significant overestimation of the mean value at all levels (minimum overestimation 8.47 mm^3 (11%) maximum overestimation 12.67 mm^3 (24%). Individual measurements indicated a higher level of error.

In summary, the Tracer CAD system showed better accuracy of diameter measurement at all levels compared to the T ring system. Standard error plots indicated that significant difference of measurements at the three most proximal levels (F, G, and H) was unlikely. However, although no statistical difference was shown, the difference between the means may be clinically significant as a maximum difference between means of 1.98mm [ML H] was recorded. Results became significantly less accurate towards the distal end (Max error 2.86mm [ML J)] and much worse on individual tracings.

T ring measurements overestimated the gold standard significantly. Inaccuracy of measures increased toward the distal end of the model scanned and coincided with lack of repeatability of landmark identification. As volumes are derived from the distance between landmarks, lack of landmark repeatability will affect the position of measurement. Diameters measured on a truncated cone will vary if taken at a higher or lower level, and resulting volume accuracy may be affected (Table 26, Table 27).

Of concern was the distal end volume and diameters recorded with results obtained with much less repeatability. This was of particular concern since it was expected that much less error would be experienced by the non contact system (T ring) on simple models.

The addition of a sock necessary for T ring scanning may contribute to overestimation of model size. However, in a solid model, a sock would add a

uniform thickness which would be expected to increase diameters and volumes uniformly at each level measured. This was the case.

A further cause of this may be due to the operating mechanism of the T ring system. The ring is placed over the residual limb until the distal spacer makes contact with the distal end. The T ring is then held along the axis of the centre of the residuum and a button pressed to capture shape instantly. Since the system does not use a distal camera, the distal shape of the cast is extrapolated from the circumferential pictures taken. The position of the distal spacer is determined by each prosthetist. This must make contact with the centre of the distal end of the residuum and be aligned to the centre axis of the model.

The centre of the distal end of a small model is difficult to locate accurately and precisely when positioning a cumbersome (and relatively heavy) measurement system such as the T ring. In addition there is no way to ascertain the true central axis of the model, which must be followed in all planes.

Because the T-Ring's cameras can only see so far up and down the model, it cannot see the distal end. The T-Ring uses information it can and can not physically see to build the model. The software uses the information that is captured in combination with a mathematical extrapolation template in the T-Ring's calibration files stored in the individual cameras. This template is cylindrical tapering to a domed end and fills in missing data between the lowest level of the photograph and the distal end spacer. This could be acceptable if; the missing data is minimal; the placement of the distal end spacer is correct; the angle of the system is neutrally aligned to the centre axis, and if the radius between the lowest circumferential edge of the photographic data and the distal spacer equates to that of the model or stump being scanned. The T ring template expects the end of the model to taper to a point (in the same way as a residual limb). However, Model 1 and 3 were cylinder and cone with a flat end. Therefore as the T ring tried to extrapolate the distal end to be of domed shape it inaccurately recorded the distal diameters and volume.

This was evident when scanning due to the shape on screen shape produced which did not closely resemble models 1 or 3 at the distal end. However, this should not affect the proximal measures (which were overestimated) and appear to show a systematic error of measurement which in some cases was significant.

Residual limbs are not generally of cylindrical or conical shape and do not have flat ends. These models perhaps presented a less than ideal model to test the T ring system. However, tests highlight an important point about the mechanism by which the distal end shape is extrapolated. Models 1 and 3 are entirely different from the mathematical model used by the T ring system to extrapolate the distal end. This meant that errors were easy to recognise as the user could see that the correct shape had not been captured. However, inaccuracies will still result where the contour of the end shape differs slightly when compared to the T ring mathematical model. Such errors may not always be obvious to the clinician, and could cause potentially unacceptable errors in the creation of a prosthetic socket, particularly at the sensitive distal end.

It seems unlikely that extrapolated data can reflect the variety of individual unknown different shapes of the distal residual limb. Shape capture is especially important in this area as the distal end of the stump is sensitive and prone to skin breakdown.

The T ring system is not truly a ‘non contact’ system but relies on correct positioning of a distal end spacer in contact with the residual limb/ model. The position of this spacer appears to be crucial as incorrect placement of this or the angle at which the T ring is held will have effect of shortening or lengthening the model captured and altering the measurements taken (as shown on model 2).

As residual limbs are not generally of this shape (i.e. do not have a flat distal end) it may not matter clinically. However, results of this experiment indicate that T ring did not measure a simple cylindrical shape with a flat end with suitable diameter (<1mm) or volume (<5%) accuracy at all levels.

8.3.4 Model 4 Trans-tibial model

Once results had been analysed on cylindrical and conical models, the experiment was repeated on a trans-tibial plaster model to analyse whether the shape of the model had any effect on shape capture using the Tracer CAD or T ring systems. The effect of angular displacement was also considered using the T ring.

All results were compared to Plaster of Paris casting. This process is fully described on page 153. This involved an extra stage in manufacture similar to that of carving a model from a CAD file. The procedure included duplication of alignment, and careful filling of model with correct ratios of plaster. The filling process was thought to have potential to cause error and so was analysed for repeatability and accuracy in which a model former was filled in the duplication jig three times.

Duplication of casts following the methodology described when using the duplication jig was extremely accurate and repeatable (Figure 7-34) Maximum AP diameter difference between the copying process and the GSM was -0.86mm (ML 0.23mm). Most measurements underestimated the gold standard mean but graphs did not indicate significant difference.
Responses to the survey carried out in this thesis (Pg 97) stated that an important and useful feature of the Tracer CAD was the ability to duplicate sockets. However, although more time consuming than the Tracer CAD process, results indicate that plaster of Paris provides good accuracy for socket duplication and could be considered as a much cheaper alternative.

It is important to note that the errors contained within this cast filling method, although small, form part of the error stipulated for plaster of Paris casting. If this extra stage could have been omitted, the minimal error may have been even smaller. If on screen models were carved and then measured, it is likely that they would exhibit greater errors in measurement since an additional source of error has been introduced (the carver.)

Plaster of Paris casting showed no significant difference to the gold standard mean for either ML or AP diameter measurement. (Maximum means difference 0.8mm AP level G)(Figure 7-35). Coefficient of variation of plaster of Paris measurement was also below 1% for all diameter measurements (CV<0.63%) and was not affected by the level of measurement.

This shows that the accuracy and repeatability of diameter dimensions is very high using traditional method of Plaster of Paris. The accuracy and repeatability of this process also includes production of the positive model which was even more impressive. Mean differences in diameters recorded were always less than 1mm. Differences in casting by individuals may possibly show greater variation. However due to time and cost constraints within this project, this was not measured.

As plaster is applied in a wet stage, it allows exact contour of shape if correctly applied. As the model was not deformable, very few errors resulted. If filled with the correct ratio of plaster to water, (not always weighed in prosthetic clinics), and appropriately sealed, plaster of Paris has appropriate accuracy and repeatability to be used as a method of casting hard shaped objects.

Plaster of Paris volume measurement did show errors at the distal level of measurement. Graphs indicate significant over estimation occurred at the distal end of the cast (10.35mm3 or 24.6%) (Figure 7-33). Less repeatability of measurement was also observed at this level than at all other landmark levels (CV 8.39%). The variation in plaster of Paris shape capture corresponds to where the greatest variation in the copying (or filling) process occurred and may be due to inaccuracies in positive model production rather than in the wrap casting itself.

In the clinical situation, this could present some difficulties since overestimation of the distal volume would result in lack of support or tissue contact at the distal end. Lack of total contact at the stump socket interface is likely to reduce surface are over which the weight can be spread and has potential to cause distal oedema.

Tracer CAD diameters were analysed for measurement accuracy and repeatability at each landmark level on the same trans-tibial model **(**Figure 7-35).

Tracer CAD AP diameter measurement showed no significant inaccuracy at any level although the maximum difference at 3 levels (F,G,H) was greater than 2mm(Maximum difference 2.83mm[G].)(Figure 7-34, Figure 7-35, Figure 7-36).

Results from individual tracings showed that dimensions on the trans-tibial model varied by a maximum of 3.28mm. AP dimensional measurement repeatability for the more complex shape of the trans-tibial cast (CV= 1.25%) was poorer than that of a simple cylindrical model (0.62%) and the truncated cone (0.7%).

Only one Tracer CAD ML mean diameter differed from the dynamic indicator ML mean diameter significantly (maximum of 4.54mm (U3 1evel F))(Figure 7-38). All other measurements were not significantly different although all overestimated the gold standard measurement (Figure 7-39). On individual tracings this range increased to a maximum of 5.22mm.

Differences between Tracer CAD diameters have increased notably more on the more detailed TT model and repeatability of measurement reduced. Repeatability of shape capture was poorest at dimension level H. This corresponds to concavity seen in the medial and lateral tibial flares and also extreme convexity at the fibular head. This may be caused by a bridging effect of the Tracer CAD probe on the hard model over the more complex shape or may be due to the pressure applied by the user. As the probe is of fixed rectangular dimensions and is flat in shape, any areas where the concave curvature of the model is less than the length or width of the probe make it very difficult to ensure that contours have been accurately followed. As the model is non deformable, it is difficult to push the probe into these areas, leaving the area bridged by the Tracer CAD scan. As some users will perform this task more easily than others, increased variation is caused between scans.

Additionally, extreme convexities, such as the fibular head or the anterior tibial distal end, (ironically the most sensitive areas of the stump and prone to breakdown), may be underestimated as the operator traces round the highest point of the curve.

This model is not deformable, and therefore bridging can occur, however deformation of tissue adjacent to concavities on deformable models will also lead to decreased repeatability and errors. If contact methods are to be used, perhaps the probe should be shaped in a way that overcomes this problem.

Inaccuracies in the Tracer CAD AP and ML measurements would result in the on screen model having a different shape to the actual model, since diameters at levels measured are different. On a simple cylindrical model, errors in the diameter measurement cause the cross section of the digital model to be elliptical or irregular in shape. Discrepancies may be less easily identified and corrected on more complex shapes such as the stump.

However, such distortion may result in sockets which do not match the underlying shape of the stump, which could affect the pressure distribution at the stump socket interface. If the affected socket fit is compromised, this may undermine user confidence and perhaps explain one reason why some prosthetists revert to the original plaster of Paris cast method for shape capture of the residuum.

In the clinical situation, a patient would be scanned once, rather than take the mean value of thirty traces, and therefore the individual peak value could be the one which is utilised to make a prosthetic socket. Comparison shows that increased accuracy may be obtained by retracing the model a number of times which assists in eliminating any spurious errors made in individual traces. Allowing the user to sample multiple inputs of data and averaging results may have the effect of excluding outlying results and eliminate the possibility of these being used in the manufacture of the final socket shape.

On the trans-tibial shaped model the mean Tracer CAD volume differed by up to a maximum of -24.95mm3 (-8.4% U4 vol. H-J) (Figure 7-41). Repeatability of measurement (0.73<CV< 3.35%) was also poorer than that of previous models (model 2 CV 2.62%, model 3 3.06%) and is thought to be caused by a combination of compounding errors previously described. As for other models, variation of measurement was much greater at the distal end than at other levels.

To illustrate the clinical relevance and complexity of incorrect volume capture, an example is given of two individual traces (Table 45). The approximate number of socks required based on approximately 5% volume per sock is also indicated.

Table 45 Example of clinical relevance of two individual traces (mm^3)

	Tracer CAD		Gold standard	Percentage difference		Approx socks required	
	Trace 17	Trace 21	Mean	Trace 17	Trace 21	Trace 17	Trace 21
Vol. J-end	258.29	275.53	292.46	-11.68	-5.79	-2.33	-1.15
Vol. H-J	335.14	317.66	321.16	4.35	-1.09	0.87	-0.21
Vol. G-H	393.83	390.89	382.47	2.97	2.20	0.59	0.44
Vol. F-G	540.62	544.85	539.13	0.28	1.06	0.05	0.21

This table illustrates the complexity of volume variation at each level. Clinically this would be difficult to identify, and compensate for given that the percentage difference is not constant over the entire model. Both individual tracings also illustrate that the model appears to have the largest difference in volume at the most distal part of the cast. More consistent results are shown on the more proximal volumes; however, sockets manufactured using either trace may prove to be too tight distally causing discomfort to the user, resulting in unsuccessful fitting of the prosthesis. Again, all tests were carried out on a hard model. Logically one might expect increased error from tissue deformation when tracing a prosthetic residual limb.

Manual tracing of the model may result in greater pressure being applied than optimally preferred. This may also result in an incorrect volume being recorded, as both ML and AP diameters may be affected.

The repeatability and accuracy of the T ring scanning technique was tested on at the shaped trans-tibial model of determinable volume. Scans were taken with the T ring clamped at various angles to each model and then by a number of users holding the scanner by hand.

The trans-tibial model was initially held vertically (0 degrees) in the Deckel CNC milling machine with the T ring held horizontally, and then at 2^0, 4^0, $6^0$to the central axis.

The maximum difference between mean T ring AP and ML diameters and the gold standard mean did not always appear to increase when the angle was increased between the T ring and the central axis of the model. In most graphs a fairly random pattern resulted (Figure 7-42) which is explained by the irregularity of the model itself. The model if tilted has a capacity to measure a larger diameter or a lower diameter depending on the shape of that part of the model. This experiment shows how difficult it is to understand and visualise when an error has occurred. Volume measurement was also affected since the volume is measured with respect to the central axis. If tilted from this axis, it is possible that a volume will be larger or smaller depending on the shape of the model at that part.

When the T ring system was hand held, users showed maximum difference to the mean AP diameter of -2.79mm (U1 level J) (Figure 7-37), and for ML diameters was 2.63mm (U4 level J) (Figure 7-40). No significant difference to the gold standard mean was observed at any level of AP diameter measurement. However T ring mean values had a tendency to overestimate the gold standard measurement at three levels (maximum overestimation = $2.55mm^G$) (Figure 7-39). This may be due in part to the addition of a sock necessary for scanning with the T ring.

Such differences were much greater than those recorded by Tracer CAD or Plaster of Paris measurement. Differences of up to 1mm are thought to be clinically significant and so measurement errors of this magnitude are thought likely to cause detriment to the prosthetic socket fit.

This is particularly important since the measurements overestimate the mean value in the three proximal levels yet underestimate the distal diameter. This is likely to cause high pressure on the distal end of a residual limb and could cause socket discomfort or worse, tissue damage.

ML T ring diameters showed likely statistical overestimation of the GSM at all levels. The maximum difference between mean values was 4.1mm overestimation at level F (Figure 7-38).

T ring volume measurement showed the greatest variation of all systems at all levels. Measurement repeatability was poor (2.55 %< CV 26.68%) and as expected, worst at the distal end. The coefficient of variation was greater in the hand held situation (Table 47) than when the T ring was held horizontally (Table 46). This is thought to be caused by the human interaction of the system and the user. As all other things remain the same between the two experiments, it can be assumed that the human interaction, either the angle at which the T ring is placed, or the pressure the user exerts on the distal end must cause the variation in results.

Table 46 Coefficient of variation T ring model hand held

CV	Vol F-G	Vol G-H	Vol H-J	Vol J-end
User 1	2.52	3.24	7.49	21.57
User 2	2.58	2.68	5.99	17.85
User 3	2.70	2.80	3.97	12.61
User 4	2.23	2.01	2.75	10.91

Table 47 Coefficient of variation T ring model held in Deckel at various angles

CV	Vol F-G	Vol G-H	Vol H-J	Vol J-end
0 degrees	2.67	2.61	0.26	1.09
2 degrees	2.63	2.58	0.22	0.69
4 degrees	2.18	0.26	1.62	5.19
6 degrees	1.55	0.16	1.48	4.47

Although the prosthetist will try to align the T ring perpendicular to the central axis of the limb this is difficult to do since both the residuum and the T ring can move independently. If the T ring was held mechanically in a static jig this could minimise error caused by the prosthetist inadvertently angling the T ring when scanning. This could in theory allow the prosthetist to concentrate on control of the positioning of the residual limb within the system.

The axis of the residual limb could be found by calculating the centroid of the residual limb. The centroid could theoretically be located at a number of levels and a line positioned through these points and assumed to be the central axis of the residuum. Only when the T ring is exactly at 90 degrees to this imaginary axis in all planes could a true representation of the residual limb be gained without introduction of angular error. So far a practical method of determining this axis for use in a clinical situation has not been determined. It is not possible to do this in a satisfactory manner using human hand eye coordination.

Future research on systems could also test the ideal contact pressure on the distal end of the residuum to ensure that deformity of tissue does not take place, or use a different non contact method of shape capture. This may perhaps involve the use of a distal camera to capture the important distal end rather than extrapolating this important shape.

To date, no reliable, practical method of location of the socket axis exists. This requires future research and could prove vital to the success of non contact systems as well as defining the ultimate best relationship for positioning of the foot relative to the socket. Until this can be achieved by a practical reliable method, inaccuracies

caused by angular or distal probe mis-positioning will cause inaccuracies in measurement.

8.3.5 Model 5 Trans-tibial deformable manikin

Three systems of shape capture were tested on the deformable manikin (model 5): Tracer CAD, T ring and plaster of Paris and compared to the gold standard (accuracy 0.05mm). Measurements were recorded at 4 predetermined levels on the model (F, G, H and J.) Volumes were measured between levels (F-G, G-H, and H-J), and from the level J to the end of the model.

Minimal difference was observed at proximal landmark levels F, G, or H, between the mean AP Tracer CAD diameters by all users Significant difference in diameter measurement was likely at the most distal landmark (level J) where Tracer CAD underestimated the gold standard mean value (Figure 7-47)(Maximum difference = -2.6mm (level J)). This corresponds to where repeatability of landmark identification and hence volume measurement was poorest (Table 26, Table 27).

Significant differences between the mean ML Tracer CAD diameters were likely at all levels. Overestimation of the mean value was seen by one user at level F, (2.27mm) (Figure 7-48). Significant underestimation by all users of the Tracer CAD system was likely at all other ML diameters recorded. (Max difference = -6.04mm (level H) (Figure 7-50)

Differences recorded on individual tracings were much higher than mean values (Individual maximum difference to gold standard mean AP =9.15mm (APJ) ML=-8.07mm (MLJ). Maximum diameter differences by all users were always recorded at the distal most deformable level.

The Tracer CAD volume measurement underestimated the value of the gold standard mean volume at all levels. Underestimation of the mean value was observed by one user at level F (maximum difference -13.65mm^3) (Figure 7-52). All users of the

Tracer CAD system significantly underestimated the gold standard value at all other levels of measurement.

Likelihood of significant differences in Tracer CAD diameter measurement can be explained by method of shape capture which depends upon a contact method using a plastic probe traced over the surface of the model.

The manikin model was deformable but has been demonstrated to return to its original shape following deformation (Pg 132). The model was easily deformed and so represented a residual limb with soft tissue consistency. Users of the Tracer CAD who all had similar experience in using the system, stated that tracing the manikin was more difficult than models 1-4 which were not deformable. A slight increase in pressure tended to reduce the size of the on screen model. If this was judged not to represent the manikin shape, the participant was free at any time to begin again. Several traces were abandoned and retraced.

Tracings were only restarted when the user observed what they considered to be an obvious error. However, when small discrepancies are made on either side of the model they may accumulate to show inaccuracy of measurement of the scale shown with this model. This may not be obvious to the system operator. Users of each system were asked to repeat tracings a total of thirty times. It is feasible that fatigue during the tracing process could affect the quality of tracings.

The manikin is of fixed volume. If deformation occurs, the volume should theoretically stay much the same but the shape may be different as the deformed material will be pushed to another area within the manikin. An illustration of this effect is shown in Figure 8-2. Even if the shape is deflected during plaster casting; the volume should be captured as the deflected shape will bulge to adjacent areas.

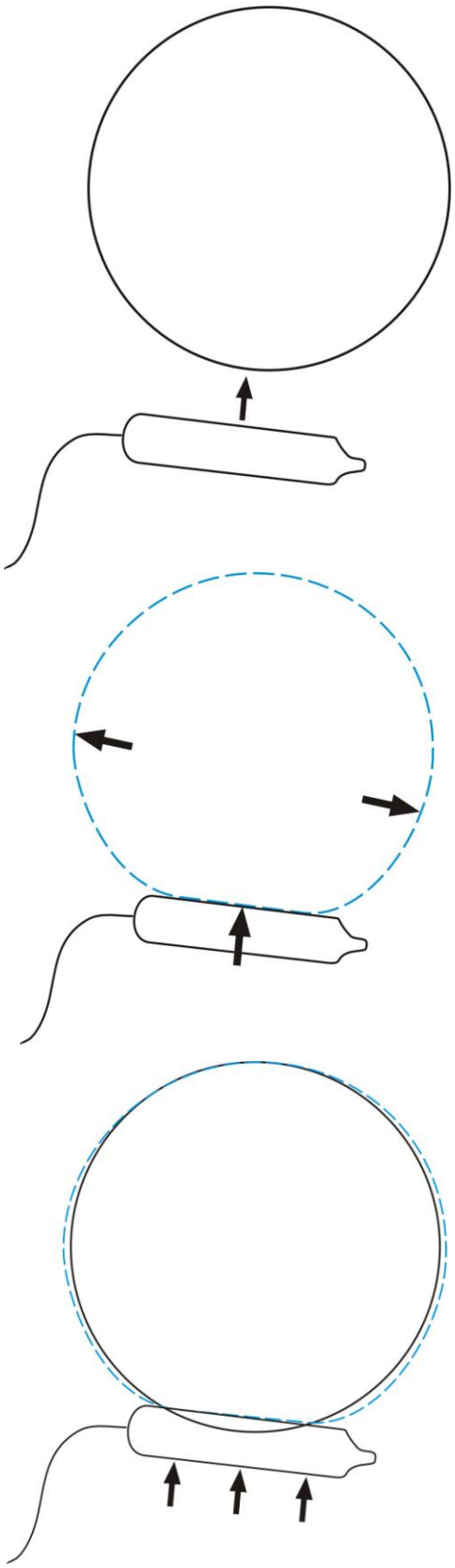

Figure 8-2 Transverse section of deformable model

Unlike traditional systems, deformation of material pushed to another area by the Tracer CAD probe is not captured. Because the shape is virtually captured, it is possible for the deformed material to have returned to its original position by the time other areas of the model are traced. This means that a corresponding oversize caused by deformation of material into other areas will not necessarily occur. This means that shape and volume dimensions will be underestimated by Tracer CAD, but captured by plaster of Paris (although the shape may be incorrect). From results obtained by the Tracer CAD system on model 5, this has caused significant underestimation of volume measurements.

Standard error plots indicated significant differences in all ML measures which underestimated the mean value. This may be due to the position of the model which caused the user to exert slightly more error on each side of each model rather than on the anterior and posterior aspects.

AP and ML diameters significantly differed from the mean value at the distal end (level J) (Figure 7-47, Figure 7-51). Greatest inaccuracy of measurement was recorded at these levels. Repeatability of diameter measurement also deteriorated towards the distal end where the model was more deformable. This was where the bony structure of the model was deepest and where the model was most deformable. Less difference was seen at the proximal level where the bony structure was more superficial and therefore the model less deformable.

In summation, Tracer CAD AP values did not differ from the gold standard mean measure at levels F, G and H, but underestimated the gold standard diameter at the distal end (level J) where least repeatability of measurement was demonstrated. The model was most deformable at the distal end and most at risk from deformation by the contact tracing method. Although not significantly different, measurement errors up to 1.93mm were observed at levels F, G and H. Errors of this magnitude would be clinically significant as they would cause variation in prosthetic socket shape which could lead to tissue breakdown. Less accuracy was seen in individual Tracer CAD scans.

The Tracer CAD volume measurement underestimated the value of the gold standard mean volume at all proximal levels (Figure 7-52, Figure 7-53, Figure 7-54,)

T ring

AP diameters at proximal levels were significantly overestimated by the T ring system (Maximum difference 6.83mm level F) (Figure 7-44). Best accuracy was achieved at level H where the mean difference was 0.75mm (Figure 7-46).

Greater inaccuracy was seen when comparing individual scans with the gold standard mean value (maximum difference =-19.35mm U2 AP9.) Maximum differences in T ring diameter measurement always occurred at the distal end (landmark 9). This compares less favourably to the Tracer CAD individual scans where the maximum difference in measurement was 9.15mm.)

Repeatability of measurement decreased dramatically at the distal end (CV 7.57%) to a level which affected accuracy of measurement. Accuracy of measurement comparing the mean values of the T ring to the gold standard showed poor accuracy of shape capture at the distal end.

In general ML dimensions showed better accuracy than AP measurements. However, ML measurement significantly undersized the model at two landmark levels (level F (max difference = -4.68mm) and level J (max difference = -17.56mm) (Figure 7-48, Figure 7-51). Differences between individual scans and the gold standard mean value became much larger, this is important as the patient is only scanned once in the clinical situation. (Max ML difference = -17.47mm U2 ML J). Maximum differences between tracings of all users always occurred at the distal end.

Accuracy and repeatability of measurement at the distal end was extremely poor and in conjunction with undersized AP diameter measurements would cause significant under sizing of the model at this level.

Should a socket be made using AP and ML diameters with the above errors, it is likely that a prosthetic socket of incorrect shape, loose at the proximal levels and very tight at the distal level, will result.

This creates problems in prosthetic fit as the patient will lack support in the pressure tolerant proximal regions causing potential overloading of tissues at the distal end. As the socket is not the correct shape due to over sizing and under sizing of diameters, uniform loading cannot be guaranteed. This is coupled with the fact that distal end would be very tight, so tight in fact that the person will not be able to fully enter the socket. If the person were able to don this socket, it would cause distal end pressure from a highly supported area to one that is not in total contact with the distal end. It is likely that such a socket could not be tolerated for any length of time to allow a walking trial in such an ill-fitting design.

The T ring volume measurement falls into a similar pattern as that of the one described by diameter measurement.

All volumes determined by the T ring system differed significantly from the mean. Proximal volumes (F-G and G-H) were significantly overestimated (Maximum difference between T ring mean and gold standard mean 24.83 mm3 or6.85% level F U1)(Figure 7-52).

Significant underestimation of volumes occurred at the two distal volumes measured (volumes H-J and J - model end). (Maximum difference between T ring mean and Gold standard mean -45.51 mm3 or -15.31% level 10 U4) (Figure 7-54, Figure 7-55)
Of all systems, T ring showed the least accuracy and repeatability of measurement which would cause differences in the shape and volume captured. This was significant in many areas of the model and would caused detriment to the socket fit.
Landmark identification was variable and may have affected the measurements recorded Table 26, Table 27). From tests on the manikin, measurements taken by the T ring system are variable and lack the accuracy required to capture the shape and volume of a trans-tibial manikin.

In addition to landmark positioning, the action of pulling the tight T ring sock over the deformable manikin may affect distal diameters and volumes measured. As the sock is pulled proximally it seems likely that that material would deform proximally. This would cause smaller diameter and volume measurement, whilst increasing proximal diameters and volume. It is also possible that as the model deforms that landmarks are displaced proximally. The action of pulling a sock over a manikin with different deformable properties at different levels would not cause a systematic error that could be easily compensated for. Residual limbs with varying tissue stiffness characteristics would respond differently and so deformation would be difficult to predict.

Plaster of Paris diameter measurements showed differences of up to 12.29mm (ML level J) (Figure 7-51). All ML diameters were significantly underestimated and this is thought to be caused by the wrapping action of the plaster of Paris bandage. This would cause significant changes in shape of the model as the AP and ML diameters are affected. Inaccuracy in diameter measurement tended to increase with distal measurements. (Figure 7-48, Figure 7-49, Figure 7-50, Figure 7-51). This corresponds to the areas in which the model becomes more deformable due to the position of the hard skeletal structure within, (less deformable at level F, most deformable at level J).

Volume measurements were significantly affected at only one level (level H where volume was significantly underestimated (Figure 7-54)

Repeatability of plaster of Paris casting was also worse than when compared to model 4 and 2. It was within acceptable standards for shape capture and showed repeatability of diameter measurement to within 1% (Table 26). The repeatability of volume measurements was poor again at the distal end and showed increased variability when compared to model 4.

8.4 Limits of agreement

To assess agreement between the CAD and the gold standard, results were also plotted to illustrate the limits of agreement between each CAD system and the gold standard measurement (Bland and Altman. 1986). Agreement of diameter and volume measurement between each CAD system was assessed and compared.

Tracer CAD AP Diameter

The limits of agreement between the Tracer CAD system and the gold standard were -1.94mm to 2.59mm with mean value of 0.33mm (Figure 7-56). In theory the mean value should not differ from the zero value since differences in measurement should be zero if systems show agreement. As the mean value was slightly above zero, this suggests that for all models, the Tracer CAD system slightly overestimated the AP gold standard diameter.

Required clinical accuracy of systems was defined by Sanders et al. (2003) to be within +/-1mm of the gold standard measurement.

The Tracer CAD system demonstrated suitable accuracy on simple cylindrical models 1 and 2 as measurement error was within +/-1mm of the gold standard. Tracer CAD system measurements underestimated the AP dimension of both cylindrical models in all measurements taken except the proximal diameter (level F) of model 2. This may be due to the contact nature of the Tracer CAD system which when pressed onto the model would cause a bending moment. The extent to which bending or shifting of the model affects diameters measured has been discussed (Pg 217) although the above graph illustrates that this may be minimal.

Model 3 appears to show increasing overestimation in measurement as the measurement is taken more distally. Results became more inaccurate at distal levels G, H and J. The shape of this model is conical and therefore the incorrect positioning of landmarks would have serious effect on the dimensions measured as a much larger measurement would be recorded.

Accuracy is reduced in more complex models (4 and 5) and does not meet requirements specified in the creation of prosthetic sockets. Shaped models (model 4) show much less accuracy of measurement than cylindrical models (model 1 and 2).

AP measurements recorded on model 5, which was the same shape as model 4 but was deformable, were all of lower value. This illustrates that AP dimensional capture on a deformable model is reduced by the contact method of shape capture.

Tracer CAD illustrated sufficient accuracy in the measurement of AP diameters of models 1 and 2. Less agreement was shown between measurements taken on more complex models.

T ring AP Diameter

The limits of agreement between the T ring system and the gold standard were -8.42mm to 10.09mm with mean value of 0.84mm (Figure 7-57). The T ring system showed much less agreement (in excess of 18mm) with the gold standard AP dimension than the Tracer CAD system (within 5mm). The mean value for all models was 0.84mm. This suggests that the T ring system had a tendency to overestimate the AP gold standard diameter and that the error was greater than that of the Tracer CAD system. Agreement was poor on all models but particularly at distal levels J. A particularly high discrepancy was observed on model 5 (the deformable manikin) at level J.

Tracer CAD ML Diameter

The mean value of all measurements (-0.09mm) appear to illustrate good agreement to the gold standard. As this was slightly below zero, it suggests that for all models, the Tracer CAD system slightly underestimated the ML gold standard diameter. The limits of agreement between the Tracer CAD system and the gold standard were -4.64mm to 4.46mm (Figure 7-58).

Results followed a similar pattern to that of AP Tracer CAD measurements when compared to the gold standard. The Tracer CAD system demonstrated suitable accuracy on simple cylindrical models 1 and 2 as measurement error was within +/- 1mm of the gold standard. Tracer CAD system measurements underestimated the ML dimension of both cylindrical models in all measurements taken except the proximal diameter (level F) of model 1.

Model 3 appeared to show increasing overestimation in ML measurement as the measurement is taken more distally. Results became more inaccurate at distal levels G, H and J.

Accuracy was reduced in more complex models (4 and 5). Shaped models (model 4) show much less accuracy of measurement than cylindrical models (model 1 and 2).

ML measurements recorded on model 5, were all of lower value. This illustrates that diameter measurement on a deformable model was reduced by the contact method of shape capture.

Tracer CAD illustrated sufficient accuracy in the measurement of AP and ML diameters of models 1 and 2. Less agreement was shown between measurements taken on more complex models.

T ring ML Diameter

The mean value for the difference in ML diameter measurement between the T ring and the gold standard for all models was 1.24mm. This suggests that the T ring system had a tendency to overestimate the ML gold standard diameter and that the error was greater than that of the Tracer CAD system (-0.09mm). The limits of agreement between the T ring system and the gold standard were -7.1mm to 9.57mm (Figure 7-59). The T ring system showed much less agreement (in excess of 16mm) with the gold standard ML dimension than the Tracer CAD system (within 9mm).

Good agreement between measurements was observed on model 2 regardless of the level at which the measurement was taken. Agreement was poor on all other models but particularly at distal levels J. A particularly high discrepancy was observed on model 5 (the deformable manikin) at level J.

Tracer CAD Volume

The limits of agreement between the Tracer CAD system volume measurement and the gold standard were -47.0mm^3 to 45.52mm^3. The mean value of -0.74mm^3 suggests overall agreement with slight underestimation of the volume measured (Figure 7-60).

However, the plot indicates that agreement between volumes measured is less for the irregular trans-tibial shaped models (4 and 5) than for those of cylindrical shape.

Model 4 is shown to overestimate proximal and distal volumes whilst underestimating intermediate volumes (G and H). Measurements are not within the 5% difference specified by Fernie and Holliday (1982) and could cause problems in prosthetic fit. The addition of socks has also been discussed as a method of accommodation of errors during the shape capture process. This would not be possible should a system overestimate proximally and distally, whilst underestimating at levels in between.

In a similar way to diameter measurement, the difference in volume measurement of model 5 appears to be of a more negative value at all levels (F-J) when compared to model 4. Since the only difference between models is that model 5 is deformable, it is likely that this has been caused by the contact method of the Tracer CAD system.

T ring Volume

The limits of agreement between the T ring system volume measurement and the gold standard were -28.96mm^3 to 39.15mm^3.Overall the T ring system showed

slightly better agreement (within 70mm^3) with the gold standard volume measurement than the Tracer CAD system (in excess of 90mm^3). However the mean value of 5.1mm^3 suggests overall overestimation of the volume measured by the T ring system (Figure 7-61). This was much greater than differences recorded in volume measurements on the same models by the Tracer CAD system (-0.74mm^3).

Poor agreement is shown for volume measurement of all models particularly in models 4 and 5 at distal levels.

In summary, plots of the limits of agreement between systems confirm what has already been implied by previous analysis. On the sample of models measured, the Tracer CAD system showed better diameter and volume agreement with the gold standard than the T ring system which was poor. Tracer CAD diameters and volumes showed better agreement with the gold standard on simple cylindrical models 1 and 2). Agreement was poorer on models of irregular shape and was affected by the deformable properties of the model.

8.5 Summary

The aims of this thesis were to evaluate the reliability, repeatability, and accuracy, and of the most commonly used prosthetic CAD systems and compare results with traditional methods of shape capture using plaster of Paris. Two methods of shape capture using CAD were evaluated on models of known dimensions: contact (Tracer CAD) and non contact systems (T ring) and compared on three models to plaster of Paris shape capture.

The probability that diameter and volume measurements obtained by users were alike was shown to be high. The reliability between users when assessing all models using both Tracer CAD and T ring systems was demonstrated to be high (ICC > 0.999 Tracer CAD and ICC > 0.984 T ring) (**Error! Reference source not found.**). (Evers 2007). The reliability of the Tracer CAD and T ring systems is adequate for clinical use.

Repeatability of systems was analysed using the coefficient of variation and compared to that of plaster of Paris. Measurements were shown to be affected by variation in landmark identification. The T ring system did not exhibit suitable repeatability in identifying the distal landmark J on any model. Variation in landmark identification using either system increased on complex deformable models (Table 27).

The Tracer CAD system showed good repeatability of diameter measurements on cylindrical and conical models (CV<1%). Greater variation was seen when recording more complex shapes such as the hard trans-tibial model (model 4) or deformable manikin (model 5) although repeatability was still considered to be good (CV<5%). All volume measurements on *non deformable* models also were of good repeatability (CV<5%).

However, variation in volume measurements increased on the deformable manikin (CV 9.66%). Less repeatability in measurement by Tracer CAD corresponded to the most deformable distal aspect of the manikin. Repeatability of shape capture using

the contact method was reduced in areas of the residual limb that are most deformable. In the clinical setting, there is more possibility that this would occur distally, greater soft tissue/ muscle bulk tends to be located at the distal end of the residual limb. Less repeatability in these areas could cause clinically significant errors of shape capture with detriment to the socket fit.

Accuracy of each dimension was analysed using a three factor parametric analysis of variance (general linear model.), and was examined in detail by plotting standard error bars. Results were also confirmed by plotting the limits of agreement of CAD systems with the gold standard.

The Tracer CAD system showed good accuracy at all proximal levels of AP diameter measurement when compared to the gold standard. Poorer accuracy was observed with distal Tracer CAD AP measurement on more complex models (model 4 and 5). Results are thought to be caused by variation of landmark identification (model 5) Table 27), bridging of the contact probe over complex shapes (model 4), and deformation of the model (model 5).

Good ML diameter accuracy was observed on simple cylindrical models. However the Tracer CAD system had a tendency to overestimate ML measurements on more complex non deformable models (models 3 and 4). Underestimation of the gold standard ML mean diameters of all levels was notable on the deformable model by each system.

Analysis of a model system interaction plot showed good accuracy of the Tracer CAD system when recording volume measurement of simple conical and cylindrical models (models 1, and 2). More complex models showed less volume accuracy. The system tended to overestimate the volume of models 3 and 4. In contrast, the volume of model 5 which was a deformable manikin was underestimated by the contact system (Tracer CAD).

On these models the Tracer CAD system showed best volume accuracy at the most proximal level of measurement when compared to the gold standard. The system did however show poor accuracy and underestimated the volume of models overall at level G and H. Overestimation of the volume by Tracer CAD was apparent at the distal end.

As the shapes of models 4 and 5 are thought to be more like those experienced in the clinical situation, the reduced accuracy of diameter and volume capture is of concern since the prosthetic socket would contain greater errors of measurement. The deformability of model 5 when using the contact system may also present difficulties in the clinical setting since underestimation of volume could cause detrimental results to the prosthetic socket fit.

To summarise, Tracer CAD measurements showed less accuracy when the shape was complex. Less accuracy and repeatability of (volume) measurement was observed when the shape was complex and deformable.

Repeatability of the T ring was less than that of the Tracer CAD system. Diameter measurements on cylindrical and conical models showed good repeatability (CV<5%). However, repeatability of diameter measurement on models of greater complexity (models 4 and 5) was poor. This was particularly notable at more distal levels.

Repeatability of volume measurement was poor on all models, particularly at the distal end. Lack of repeatability, particularly in the distal aspect is thought to be caused by the mechanism by which the scan is taken. T ring is not truly a ‘non contact system’ but relies upon the correct placement of a distal spacer in contact with the stump. Incorrect placement is likely to have effect on the repeatability of results obtained. Due to the nature of T ring scanning, not all data of the object is captured. The system relies on software to interpolate missing data in each scan. Repeatability is reduced by this mechanism, the distal shape of the model, the angle at which the T ring is held and the position of the distal end spacer.

Results indicate that the accuracy of T ring AP diameter measurement on all models at all levels was much poorer than the Tracer CAD system. The T ring system had a tendency to overestimate values at proximal levels (F, G and H) but underestimated the distal AP diameter considerably at level J.

T ring ML diameter accuracy was observed on simple cylindrical models, (models 1 & 2). However the system had a tendency to overestimate values on more complex non deformable models, (models 3 and 4). Underestimation relative to the gold standard ML mean diameters of all levels was notable on the deformable model (model 5).

The T ring system had a tendency to overestimate volumes at proximal levels but underestimated volume at level H.

The repeatability of plaster of Paris wrap casting was examined on three of the models (model 2, 4, and 5).

Good repeatability of diameter and volume measurement was observed on the cylindrical model using plaster of Paris. (CV<1%)

Plaster of Paris showed good repeatability of diameter shape capture on the shaped trans-tibial cast (CV<1%) but less repeatability on diameter capture when the model was deformable. Repeatability of all diameters of all models, however, was good (model 5 CV <5%). Repeatability of proximal volume measures was also good when the model was shaped and not deformable (model 4 < 1%), and deformable (model 5 CV <5%).

However, repeatability of plaster of Paris distal end volume shape capture compared less favourably on the shaped trans-tibial model (CV= 8.39%) and trans-tibial manikin (8.97%). Results of plaster wrapping technique were based on a limited number of repetitions by one clinician and involved an extra stage in manufacture

than CAD results since each cast was filled with plaster creating a positive mould. Although results should be interpreted with caution, they suggest less repeatability of plaster of Paris shape capture at the distal end.

Plaster of Paris wrap casting showed the best accuracy of AP and ML diameter measurement of all systems. Accuracy of mean measurements taken by plaster of Paris were within 1mm of the gold standard on all hard (non deformable) models (models 1-4).

Accuracy of Plaster of Paris diameter shape capture was however poorer on the deformable manikin than Tracer CAD measurements taken at corresponding levels. Results indicate this to be caused by unintentional deformation applied to the manikin when wrapping the plaster of Paris. As this is the model with most similarities to the residual limb, it is highly likely that a similar effect would occur in the clinical situation.

Plaster of Paris showed accuracy to within 5% of volumes measured on the simple cylindrical model with the domed end (model 2). Accuracy of the most distal volume measured on more complex shaped models (model 4) and the deformable model (model 5) showed decreased accuracy. Due to the limitations of the plaster of Paris experimental method, results should be interpreted with caution. However, plaster of Paris volume measurement showed similar accuracy of volume measurement to the Tracer CAD systems. Results of plaster wrapping technique also involved an extra stage in manufacture than CAD results since each cast was filled with plaster creating a positive mould. This in itself could contribute to the errors shown.

Tracer CAD and plaster of Paris errors increased on the shaped model and further on the deformable manikin. Poor accuracy of shape capture was observed by both systems particularly toward the distal end.

The amount of accuracy required to capture the shape of a residual limb is still debated as evidence is limited in quantity and design. Only three publications

identified required accuracy. Saunders et al. (2003) identified the required accuracy as 1mm diameter measurement, Fernie and Holliday. (1982) and Lilja and Oberg (1997) identified 5% volume error as being detrimental to socket fit.

Based on these calculations, results indicate that none of the three systems are accurate enough for prosthetic shape capture, although acceptable results were obtained for Tracer CAD and plaster of Paris on a simple cylindrical model. However, results based on this evidence must be interpreted with caution as literature pertaining to the accuracy and repeatability required is limited, and the factors which contribute to an optimal fit of socket, poorly understood.

All systems analysed in this thesis are already in use in residual limb shape capture in prosthetic clinics. This may be made possible by modification of casts which is always normally required to some extent in the clinical setting. Although modification may be undesirable, plaster of Paris casting showed slightly better repeatability of measurement than Tracer CAD. This means that errors using Plaster of Paris may be more easily compensated for as they are more repeatable. Prosthetists may be compensating for errors in a routine way, perhaps without full understanding of the cause or magnitude of complex errors. This would account for a variety of different fitting successes between sockets.

Plaster of Paris casting of the manikin was carried out in a similar manner to how a cast would be applied in the clinic. However, no deformation was intentionally applied. This means that only plaster of Paris as a shape capture medium was assessed. Intentional deformation such as that applied during creation of a patellar tendon bearing cast is likely to cause different errors to occur and would have some effect on repeatability of casting (Buis et al. 2003).

Additionally, plaster of Paris may offer different repeatability when subjected to pressure (Buis et al. 2003). This may offer repeatability but would change the dimensions of the stump or manikin shape. This is desirable in the clinical sense but would produce inaccurate measurements compared to the gold standard. In effect, the

shape that was captured was not necessarily the shape that would produce ideal socket fit.

Both CAD systems show inaccuracy and lack of repeatability, particularly towards the distal end of the model. However, should the unloaded shape be captured, modification of this shape would be required. Limited studies suggest that modification of shape by different users is not repeatable (Convery et al. 2003) and only has potential to increase inaccuracies further. If modification of the shape is to be minimised, limited studies suggest that shape should be captured under pressure of water. No CAD system offers this possibility. Therefore the CAD systems being used in this thesis are trying to capture the shape of the stump under conditions less likely to fulfil socket fitting criteria (Pg 26). This shape, which is incorrect is also captured with less accuracy than is required for clinical use, and is not repeatable, particularly using the T ring system.

Klasson (1985) was surprised that the concept of applying the desired pressure distribution by means of some pressurising device when scanning the surface was not applied when the CAD/CAM projects started. This method may offer a direct method for shaping, has been shown to be more repeatable than hand casting (Buis et al. 2003), and may reduce the requirement for rectification which is subject to error (Convery et al. 2003).

Kristinsson (1993) stated that although CAD/CAM may be the answer, more research should be directed towards understanding the complex interaction between socket and skeleton. Kristinsson did not agree with the way in which CAD systems were being used. He perceived that systems had inherited the PTB concept and relied on the shape of the unsupported limb. He did not consider that CAD has anything else to offer besides documentation and ease of fabrication but hoped this would change in the future as the systems evolved.

Future systems could be developed to allow CAD to take advantage of advances in ‘non computerised’ shape capture. The link between shape capture to promote stiff

coupling and hydrostatic concept using pressure or hydro casting and CAD has not been established in any system commercially available.

Future research could examine systems which practically combine the theories of CAD and pressure casting. Shape capture of loaded stumps is desirable in the long term to avoid the requirement for shape modification which has potential to introduce increased error and greater variability of shape.

Ping et al. (1999) argue that since getting hold of data is the necessary first stage of any CAD/CAM process, with the resulting socket depending upon the data acquired, the accuracy and precision of the way we acquire the data is central to the final socket production. Development of systems such as ultrasound which allow internal structures to be visualised and overlaid onto the external structure may be beneficial. If the residuum was held in a specially designed pressurised hydro casting chamber, such systems could eliminate human interaction and provide an accurate, practical, inexpensive and repeatable method of shape capture. So far, no practical method of such a system is available.

Whatever system is identified it must be evaluated prior to use. Systems should offer accuracy, repeatability of shape capture of the pressurised residual limb. A structured education and training schedule should be implemented based on socket fit criteria by educators to ensure appropriate understanding and use. The prosthetics and orthotics industry must take advantage of new technology but also be aware of the shortcomings and advantages of each method of shape capture.

Most systems, whether contact or non contact, pay little or no attention to the angle at which the limb is placed when scanned. The opportunity has not been taken to combine other methods such as pressure, vacuum or hydro casting with CAD systems, thus eliminating plaster of Paris from the process.

Many studies have blamed prosthetists for not engaging with systems or falling back to more conventional methods of shape capture. This may be true in some cases, but

perhaps with just cause. Systems are inaccurate with variable results. Systems are produced commercially and ‘borrow’ technology used from other industries without real consideration to the underlying challenges in prosthetics. CAD systems appear to have developed without consideration of the state under which the residuum is held. CAD shape capture has ignored the advances made in traditional capture through application of pressure. This means that the shape captured represents the unloaded residuum, which may not be conducive to providing conditions for optimal fit.

Further research could investigate the efficacy of the different methods of shape capture and clarify which method is most appropriate. Furthermore, the use of CAD with the limb exposed to ideal conditions could alter the way in which future CAD systems are used.

Chapter 9

9 Limitations of study and Future research

Experimentation was conducted on five models with different characteristics to determine the accuracy and repeatability of two commonly used prosthetic CAD systems.

Given the number of models (n=5) this presents a limited sample size. Measurements were repeated on the same models and were not independently sampled. A larger sample size of test objects may have given different results as these may represent the population differently. Although a larger sample size would have been preferable, this was not possible due to the time constraints of the researcher, the commitment of other staff who scanned casts and the expense of producing and measuring models.

The manikin created represented only one deformable shape. Many different types of residual limbs exist with stiffer and less stiff properties. The manikin represented the residual limb of only one patient. The results obtained are only applicable to the manikin used. Different results may have been collected from manikins with different properties of stiffness.

Plaster of Paris shape capture was carried out on only three of the five models. Each plaster cast was repeated a limited number of times (n=4). This was due to the time consuming process required to fill and measure each model. Three models were selected that were considered to best represent and isolate errors that may occur during shape capture using this medium. To facilitate measurement, the plaster of Paris cast was filled with plaster. This represented an additional production stage and perhaps placed this technique at a disadvantage to CAD systems. Despite this, plaster of Paris casting compared favourably to the T ring method, and at least as good, if not better than the Tracer Cad system.

Ideally, further study is required to assess the accuracy, repeatability and reliability of shape capture systems used on actual patients. This type of study would have to overcome some considerable difficulties such as location of a central axis and controlling volume fluctuations, but if successful could provide useful clinical information in relation to data capture. Such information would be useful in identifying potential sources of error in the creation of prosthetic sockets.

Chapter 10

10 Conclusions

The aims of this thesis were to evaluate the accuracy, repeatability and reliability of the most commonly used prosthetic CAD systems and compare results with traditional methods of shape capture using plaster of Paris.

A survey showed that CAD systems are not available in all prosthetic limb centres. Centres that do employ CAD used different systems. The most commonly used systems are the Tracer CAD and T ring systems which use the same software but different methods of shape capture. Use of systems varied from centre to centre. (1-80% of all new sockets made). This appears to be affected by the type of system available, the amputation level, and the training of each prosthetist.

CAD has been introduced to different centres using a variety of different training methods. Opinions of prosthetists indicate that the initial attitude of the prosthetist towards CAD, the training received, time to learn, and support they are given, as well as the system design appear to affect the way in which the system is used.

The perception of the majority of prosthetists surveyed was that the main clinical benefits of CAD/CAM were time saving, accuracy and repeatability. However, the mean number of patients seen by each prosthetist is greater in centres not using CAD systems and up to three diagnostic socket fittings were required using CAD systems.

No evidence existed in literature to suggest that the Tracer CAD or T ring systems were more accurate or repeatable than traditional plaster methods. This is in part due to the fact that the accuracy required making a well fitting socket remains poorly understood as well as limited available literature in this area.

The Tracer CAD and T Ring systems of shape capture were evaluated on models of known dimensions. Systems were considered reliable when inter class correlation

was greater than 0.7(Evers 2007). Repeatability was assessed using the coefficient of variation (CV) and deemed to be acceptable when CV < 5%.

The accuracy of diameter and volume measurement is important in shape capture of the residual limb since this can affect the shape and size of the resulting prosthetic socket fit. Limited evidence suggests that diameter error greater than 1mm or a volume error greater than 5% may compromise prosthetic socket fit. Systems were considered to be accurate when measuring within this range. Due to the lack of scientific evidence as to the accuracy required, systems were also compared on three models to the traditional method of shape capture, plaster of Paris

The reliability between users was demonstrated to be high when assessing all models using both Tracer CAD and T ring systems (Interclass correlation > 0.999 Tracer CAD and ICC > 0.984 T ring). The probability was high that diameter and volume measurements obtained by users were alike (Evers 2007). The reliability of the Tracer CAD and T ring systems is adequate for clinical use.

Tracer CAD

The Tracer CAD system showed good repeatability of diameter measurements on all models (CV<5%). Diameter and volume measurement repeatability tended to reduce on models of tapered or complex shapes when compared to cylinders scanned but were repeatable on non deformable models. Tracer CAD volume measurement was not repeatable at the distal end of the deformable manikin (CV 9.66%). The most variable volume measurements by the contact method of shape capture, (Tracer CAD) corresponded to the most deformable distal aspect of the manikin.

Repeatability of shape capture using the contact method is likely to be reduced in areas of the residual limb that are most deformable. This is likely to be at the distal end and would in some cases be clinically significant and was thought to be caused by the contact nature including variation in landmark identification of this method of shape capture

The Tracer CAD system showed adequate accuracy in the shape capture of all diameter measurements on cylindrical shapes (<1mm). The Tracer CAD system was not accurate in distal diameter measurement of the truncated cone. This may have been caused by inaccurate landmark positioning or a bending effect on the model caused by the contact nature of the shape capture method. Poorer accuracy was observed with distal Tracer CAD diameter measurement on more complex models (model 4 and 5). Results indicate this to be caused by incorrect landmark identification, bending of the model, bridging of the contact probe over complex shapes (model 4), and deformation of the model (model 5).

T ring

Repeatability of shape capture by the T ring was less than the Tracer CAD system. Repeatability of landmark identification was poor at distal levels on all models.

Diameter measurements on cylindrical and conical models showed good repeatability (CV<5%). However, repeatability of diameter measurement on models of greater complexity (models 4 and 5) was poor.

Repeatability of volume measurement was poor on all models, (CV>5%), particularly at the distal end. Lack of repeatability, particularly in the distal aspect is thought to be caused by the mechanism by which the scan is taken. T ring is not truly a ‘non contact system’ but relies upon the correct placement of a distal spacer in contact with the stump. Incorrect placement is likely to have effect on the repeatability of results obtained. Due to the nature of T ring scanning, not all data of the object is captured. The system relies on software to interpolate missing data in each scan. Repeatability is reduced by this mechanism, the distal shape of the model, the angle at which the T ring is held and the position of the distal end spacer.

The T ring system was the least accurate of the three methods employed and did not show adequate accuracy of diameter or volume measurement at all levels on any model. Measurement accuracy was reduced by the shape of the distal end of the

model, the angle at which the T ring was held, the position of the distal spacer, and the complexity of shape of the model.

Plaster of Paris

The repeatability of plaster of Paris wrap casting was examined on three of the models (model 2, 4, and 5).

Good repeatability of diameter and volume measurement was observed on the cylindrical model using plaster of Paris. (CV<1%) Plaster of Paris also showed good repeatability of diameter shape capture on the shaped trans-tibial cast (CV<1%) but less repeatability on diameter capture when the model was deformable. Repeatability of all diameters of all models, however, was good (model 5 CV <5%).

Repeatability of proximal volume measures was also good when the model was shaped and not deformable (model 4 < 1%), and good when deformable (model 5 CV <5%).

However, repeatability of plaster of Paris distal end volume shape capture compared less favourably on the shaped trans-tibial model (CV= 8.39%) and trans-tibial manikin (8.97%). Results of plaster wrapping technique were based on a limited number of repetitions by one clinician and involved an extra stage in manufacture than CAD results since each cast was filled with plaster creating a positive mould. This in itself could contribute to the errors shown. Although results should be interpreted with caution, they suggest less repeatability of plaster of Paris shape capture at the distal end.

Plaster of Paris wrap casting showed the best accuracy of AP and ML diameter measurement of all systems. Accuracy of mean measurements taken by plaster of Paris were within 1mm of the gold standard on all hard (non deformable) models (models 2 & 4).

Accuracy of Plaster of Paris diameter shape capture was however poor (>1mm) on the deformable manikin. Results indicate this to be caused by unintentional deformation applied to the manikin when wrapping the plaster of Paris. As this is the model with most similarities to the residual limb, it is highly likely that a similar effect would occur in the clinical situation.

Plaster of Paris showed accuracy to within 5% of volumes measured on the simple cylindrical model with the domed end (model 2). Accuracy of the most distal volume measured on more complex shaped models (model 4) and the deformable model (model 5) showed decreased accuracy. Due to the limitations of the plaster of Paris experimental method, results should be interpreted with caution. However, plaster of Paris volume measurement showed similar accuracy of volume measurement to the Tracer CAD systems. Results of plaster wrapping technique also involved an extra stage in manufacture than CAD results since each cast was filled with plaster creating a positive mould.

In summary, results indicate that repeatability of shape capture of cylindrical models was good by Tracer CAD and plaster of Paris. Tracer CAD and Plaster of Paris also showed good repeatability of shape capture on shaped and deformable trans-tibial models. However plaster of Paris showed higher variation in capture of distal end volume of both shaped and deformable models, and Tracer CAD less repeatability at the distal end of the deformable manikin. The T ring system showed poor repeatability in capturing trans-tibial shaped models and manikins.

The amount of accuracy required to capture the shape of a residual limb is still debated as evidence is very limited. Based on available publications (Saunders et al. 2003, Fernie et al. 1984 and Lilja and Oberg 1997), results indicate that none of the three systems are accurate enough for prosthetic shape capture, although acceptable results were obtained for Tracer CAD and plaster of Paris on a simple cylindrical model.

Tracer CAD and plaster of Paris errors increased on the shaped model and further on the deformable manikin. Poor accuracy of shape capture was observed by both systems particularly toward the distal end.

Modification of casts is always normally required to some extent. Although much of the error is randomly caused, Plaster of Paris casting showed greater repeatability of measurement than the Tracer CAD system. This means that errors using Plaster of Paris may be more easily compensated for as they are more repeatable. Prosthetists may be compensating for errors in a routine way, perhaps without full understanding of the cause or magnitude of complex errors. This would account for a variety of different fitting ‘successes’ between sockets.

Future research in the development of systems such as ultrasound which allow internal structures to be visualised and overlaid onto the external structure may be beneficial. Whatever system is identified it must be evaluated prior to use. Systems should offer accuracy, repeatability of shape capture of the residual limb. Further research could investigate the efficacy of the different methods of shape capture and clarify which method is most appropriate. Furthermore, the use of CAD with the limb exposed to ideal conditions could alter the way in which future CAD systems are used.

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info@murray-foundation.org.uk

ISD Online - Amputee Statistical Database for the United Kingdom

Appendices Appendix 1 survey

The National Centre for Prosthetics and Orthotics
WHO Collaborating Centre for Research and Training in Prosthetics Orthotics and Orthopaedic Technology

University of Strathclyde Glasgow

AN INVESTIGATION INTO PROSTHETIC CAD CAM USE IN THE UK

1 In total, approximately how many prosthetic patients attend your prosthetic centre? (Please include satellite clinics)

2 How many prosthetists are employed in your limb centre?

3. Do you use CAD CAM at your prosthetic centre? YES / NO
If you answer NO, please answer questions 19, 20, 21, and 22 only

4. What CAD CAM software are you currently using?

5. Approximately how many months have you been using your CAD CAM system?

6. Please indicate your level of satisfaction or dissatisfaction with the CAD CAM system

a. Very satisfied
b. Satisfied
c. Neither satisfied or dissatisfied
d. Dissatisfied
e. Very dissatisfied

7. Estimate what percentage of the total number of patients at your centre have sockets delivered using CAD CAM?

8. Estimate by percentage, the distribution of CAD CAM use over the following levels of amputation.

Partial foot	
Ankle disarticulation	
Trans-tibial	
Knee disarticulation	
Trans-femoral	
Hip disarticulation	
Upper limb	
TOTAL	100%

9. How many prosthetists in your centre use the CAD CAM system?

10. How were prosthetists trained to use the system? (Please tick all that apply.)

a. One prosthetist was required to learn the package and teach others
b. A professional from a CAD CAM distributor instructed the prosthetists.
c. Prosthetists were required to learn the package on their own without any formal training.
d. Initially a select group of prosthetists learned the package and then taught other prosthetists.
e. Other. (Please state)

11. Were all the prosthetists allowed to commence learning and using the CAD CAM system at the same time? YES NO

12. On average, using CAD CAM, how many diagnostic sockets does it take to get an appropriate fitting:

trans-tibial socket?

trans-femoral socket?

13. Who provides carving? (Please tick box)

a. Technicians only (on site)
b. Prosthetists only (on site)
c. Both (on site)
d. Central fabrication
e. Other (Please state)

14. Who manufactures the socket?

a. Technicians only (on site)
b. Prosthetists only (on site)
c. Both (on site)
d. Central fabrication
e. Other (Please state)

15. Looking back, what would you change that would make the learning process easier and more efficient?

(Please tick all that apply)

a. The initial CAD CAM training approach used at a centre should be more structured.
b. CAD CAM software should be explained more fully.
c. Distributors should produce better tutorials for their software package and hardware.
d. Distributors should produce better printed manuals for their software package and hardware.
e. More time should be spent with a CAD CAM experienced prosthetist/orthotist.
f. Distributors need to make the hardware more user friendly.
g. Distributors need to make the hardware more reliable
h. The prosthetic centre should be more selective in the patient it chooses initially for CAD CAM.
i. Other (Please state)

16. Did you evaluate other CAD CAM software packages? YES NO

If yes, which packages?

17. Please indicate your level of satisfaction or dissatisfaction with the CAD system support received from the vendor.

a. Very satisfied
b. Satisfied
c. Neither satisfied or dissatisfied
d. Dissatisfied
e. Very dissatisfied

18. Do you have any additional comments about CAD CAM in prosthetic use?

19. Are you considering purchasing a system in the future? YES /NO

20. If you are not considering the purchase of a prosthetic CAD system, please state reasons in order of perceived priority.

21. Please list up to five pieces of advice that you would give a prosthetic unit currently in the process of evaluating and implementing a CAD CAM system?

22. In your opinion, list the five main clinical benefits of CAD CAM in order of perceived priority.

Please return in the stamped addressed envelope supplied

Thank you for completing this survey

Appendix 2 Consent form

Consent Form

An Investigation into Prosthetic CAD/CAM use in the UK

NAME….....**.....**

To be completed by the Person filling out the questionnaire

. Have you read the Participant Information Sheet?
Yes No

. Have you had an opportunity to ask questions and discuss this study?
Yes No

. Have you received satisfactory answers to all your questions?
Yes No

. Have you received enough information about the study?
Yes No

Who have you spoken to?
Dr/Mr/Ms_____

Do you understand that you are free to withdraw from the study –?

. at any time
. without having to give a reason
Yes No

Do you agree to take part in this study?
Yes No

Signed…..**.....** Date…..
.

Name in Block
Letters…..

Code: XX0000

Appendix 3 Amendments to pilot study

Q11 Did you allow all of the prosthetists to commence learning and using the CAD/CAM system at the same time?

Changed to:

Q11 Were all of the prosthetists allowed to commence learning and using the CAD/CAM system at the same time?

Q12 On average, using CAD/CAM, how many diagnostic sockets does it take to get an appropriately fitting socket?

Changed to:

Q12 On average, using CAD/CAM, how many diagnostic sockets does it take to get an appropriately fitting trans-tibial socket?
trans-femoral socket?

Appendix 4 Participant information sheet

Researcher:	Tony McGarry, Principle Investigator Tel: 0141 548 3396 E mail: anthony.mcgarry@strath.ac.uk
Research supervisors	Dr Brendan Mc Hugh Dr Arjan Buis Tel: 0141 548 3693
Department	The National Centre for Prosthetics and Orthotics.

Title of Project	An Investigation into Prosthetic CAD/CAM use in the UK.

This document will give some background information on the project, what it aims to achieve, who it will be engaging with and what involvement will mean. Please take the time to read the following information carefully and discuss with others if you wish. Please contact us if there is anything that is not clear or if you would like further information.

The purpose of the survey is to evaluate the use of CAD/CAM systems in prosthetic clinics in the UK. We hope to find out what systems are currently being used, how many participants have access to this technology, and how many prosthetic sockets have been manufactured using this technique. We also wish to identify areas in which this technology has not proved successful to identify possible improvements for the future.

You have been chosen to take part in a research study that will examine the use of CAD/CAM systems in Prosthetic Centres in the UK. We wish you to complete the survey whether you use a prosthetic CAD/CAM system or not since we wish to build an accurate representation of CAD/CAM use on all patients in the UK. If you are

using a CAD system please complete all survey questions. If you are not using a CAD system, please fill out questions 1-3 and 19-22 only.

The survey will be sent to a prosthetist in every limb centre in the UK. This will allow statistical analysis on important aspects of CAD use in the UK. Subjects will be asked to return the completed survey in a pre paid envelope within two weeks of receipt.

You are not required to participate in this study. The decision to do so is yours. If you decide to take part in the study and then change your mind, you are free to withdraw from the study at any time, and without giving a reason. If you decide to take part, please return the completed questionnaire and the signed consent form in the pre paid envelope.

Surveys will be coded to allow a reminder letter to be sent to those who have not replied. Each code will refer to a prosthetic limb centre. The code will be cross referenced to the prosthetic centre on a separate piece of paper which will be held in a locked filing cabinet. Confidentiality, anonymity, and data protection will be adhered to at all times.

The data that we receive will be analysed and published in a peer reviewed journal, and will form part of a PhD thesis. When we have finished writing up the project findings and any associated journal articles, all raw data will be destroyed.
This project has been reviewed and approved by the Departmental Ethics Committee of The National Centre for Prosthetics and Orthotics, University of Strathclyde. If you have any concerns about the study or how it is being conducted, please do not hesitate to contact us.
Many thanks if you do decide to take part.
Tony McGarry Brendan McHugh Arjan Buis

Appendix 5 Error bar plots

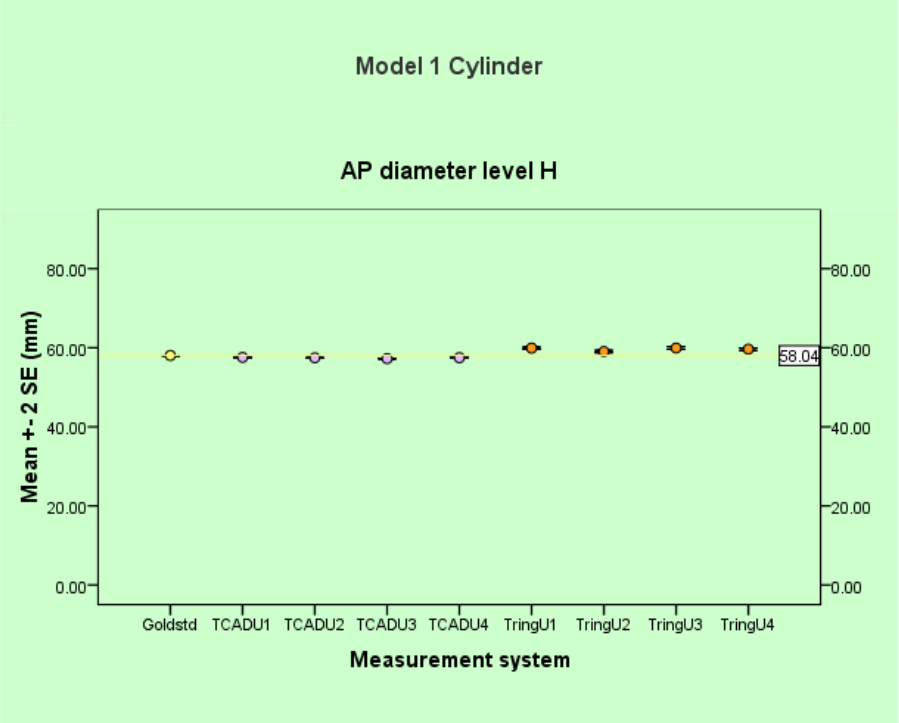

Figure 0-1 AP diameter level H Accuracy and repeatability of systems (model 1)

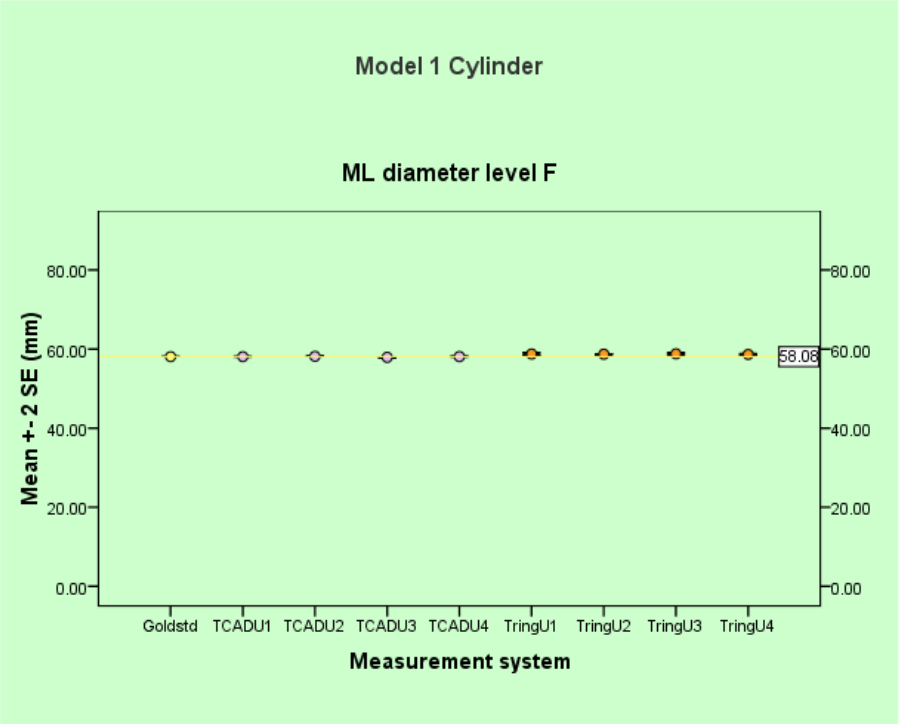

Figure 0-2 ML diameter level F. Accuracy and repeatability of systems (model 1)

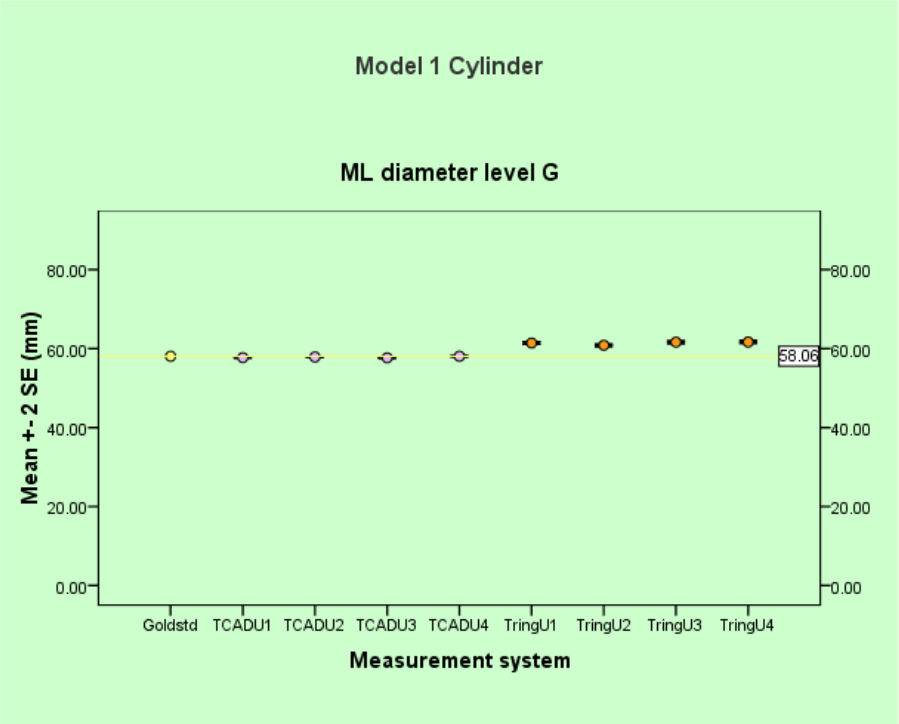

Figure 0-3 ML diameter level G. Accuracy and repeatability of systems (model 1)

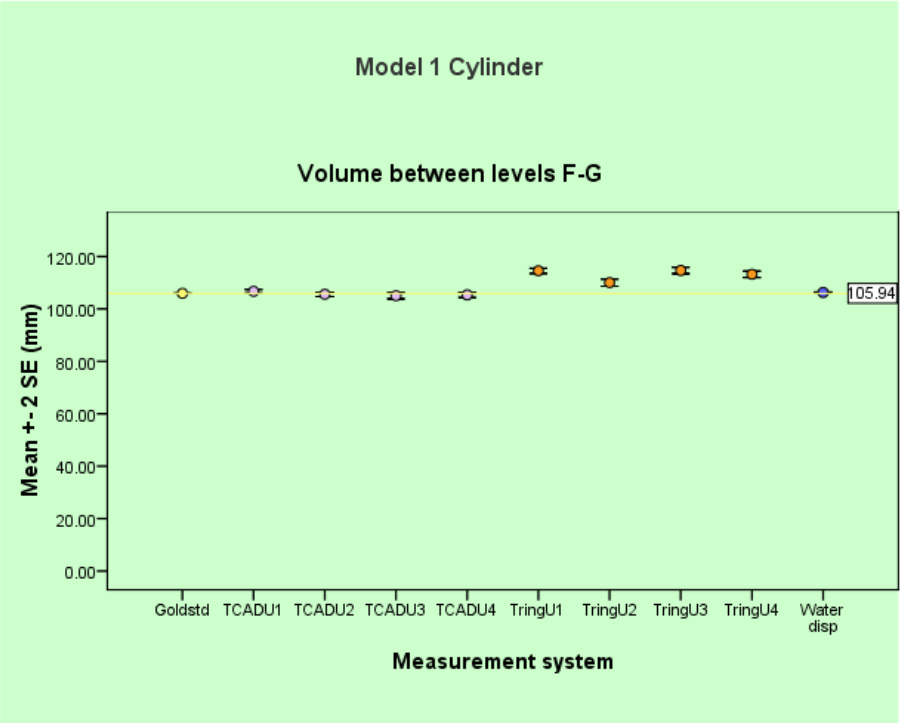

Figure 0-4 Volume between levels F-G. Accuracy and repeatability of systems (model 1)

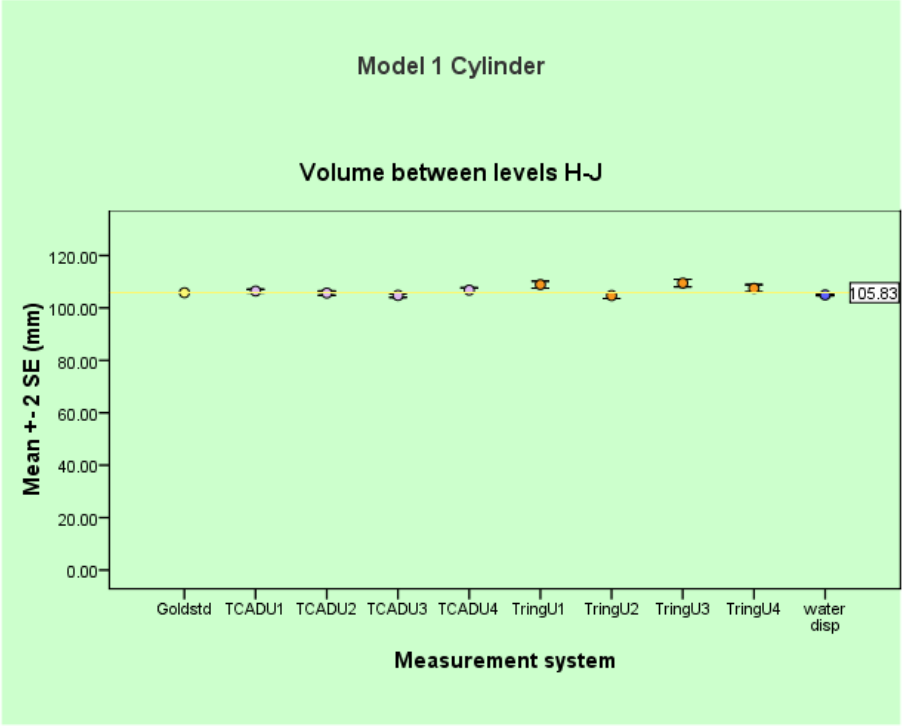

Figure 0-5 Volume level H-J. Accuracy and repeatability of systems (model 1)

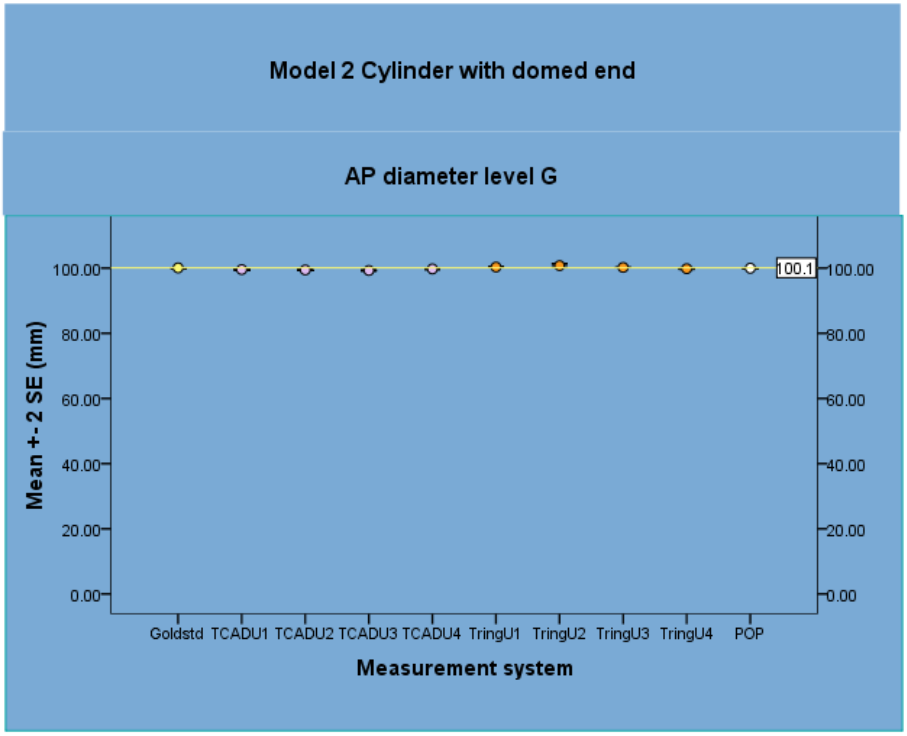

Figure 0-6 AP diameter level G Accuracy and repeatability of systems (model 2)

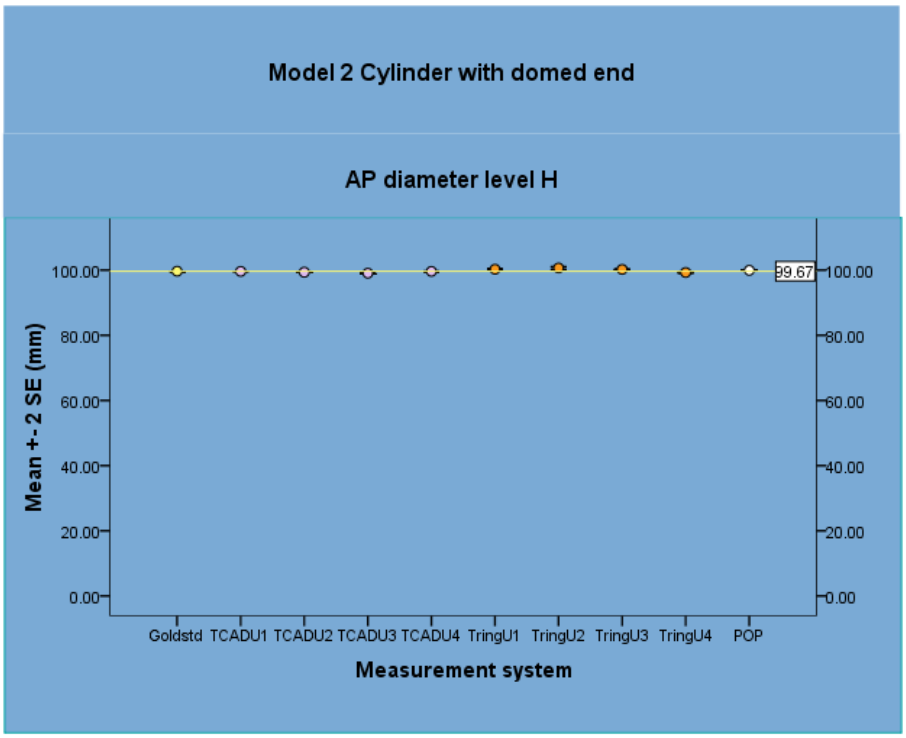

Figure 0-7 AP diameter level H Accuracy and repeatability of systems (model 2)

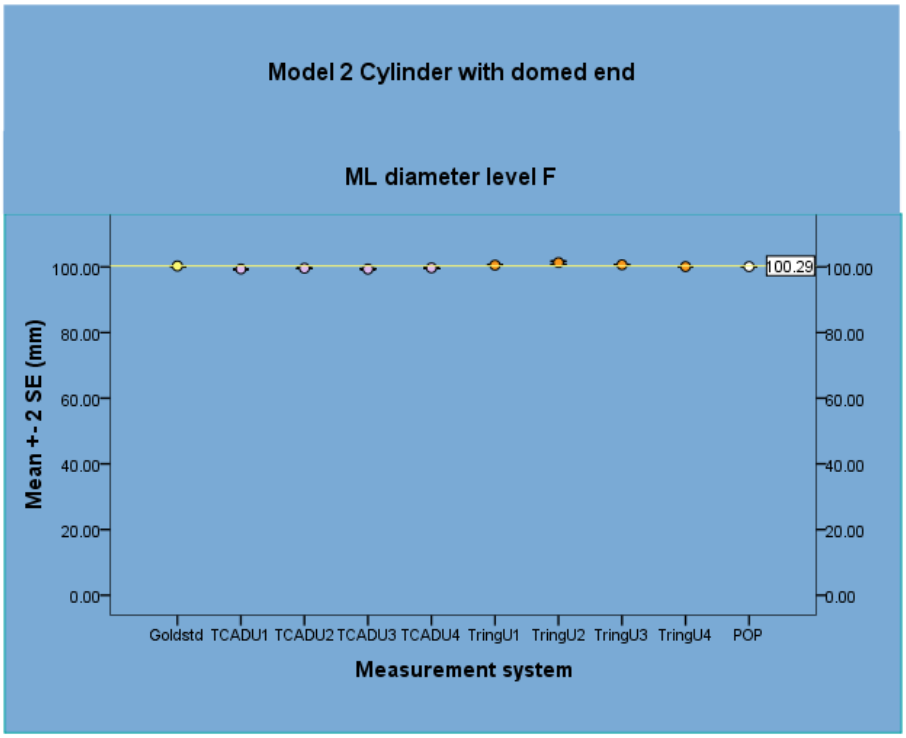

Figure 0-8 ML diameter level F. Accuracy and repeatability of systems (model 2)

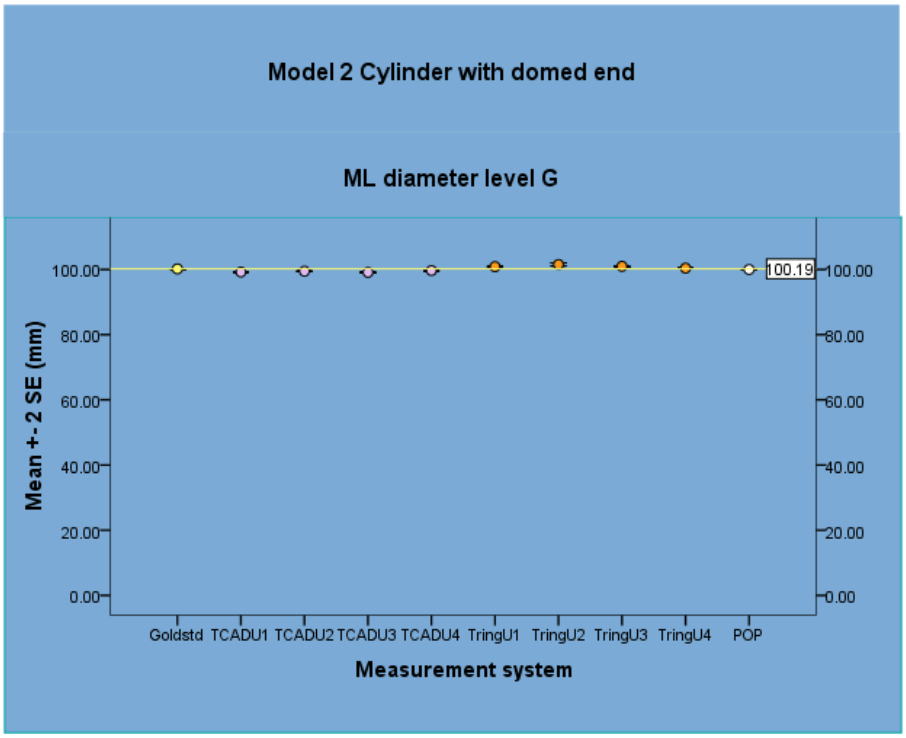

Figure 0-9 ML diameter level G. Accuracy and repeatability of systems (model 2)

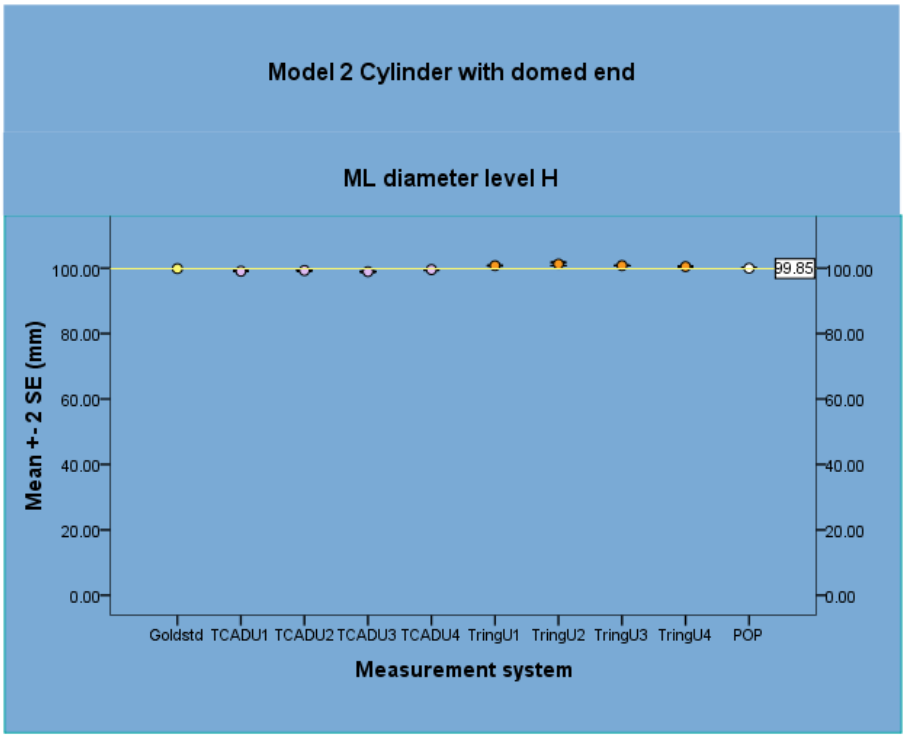

Figure 0-10 ML diameter level H. Accuracy and repeatability of systems (model 2)

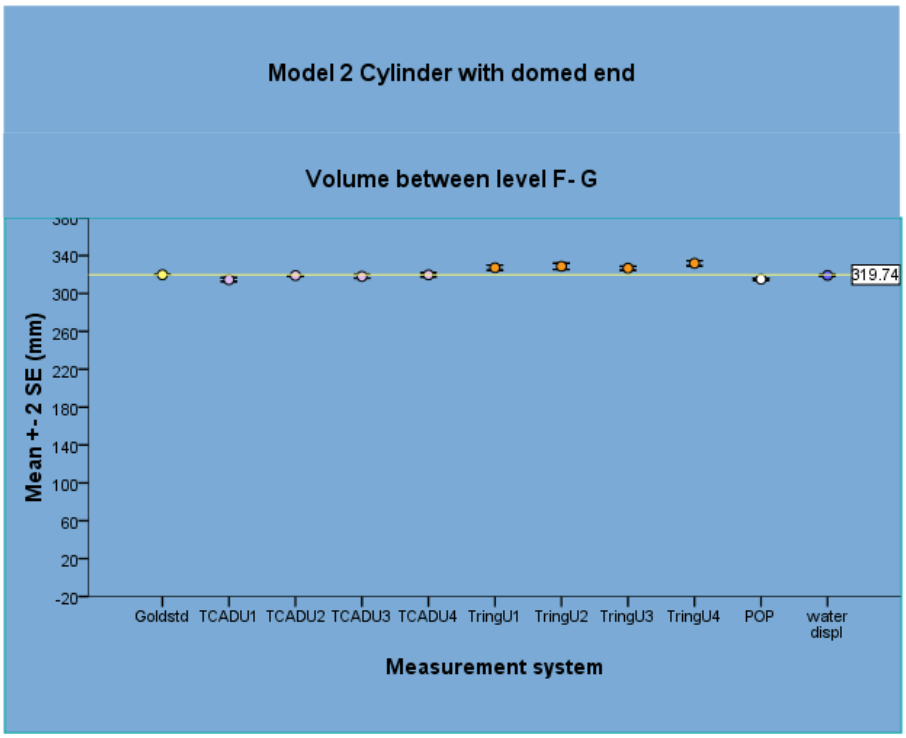

Figure 0-11 Volume between level F-G. Accuracy and repeatability of systems (model 2)

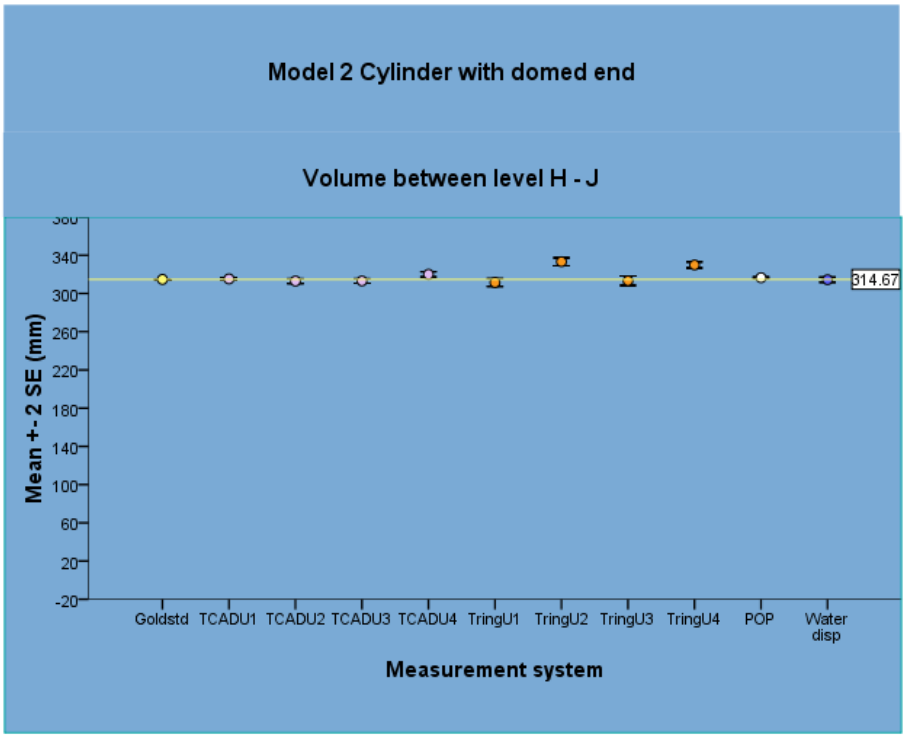

Figure 0-12 Volume between level H-J. Accuracy and repeatability of systems (model 2)

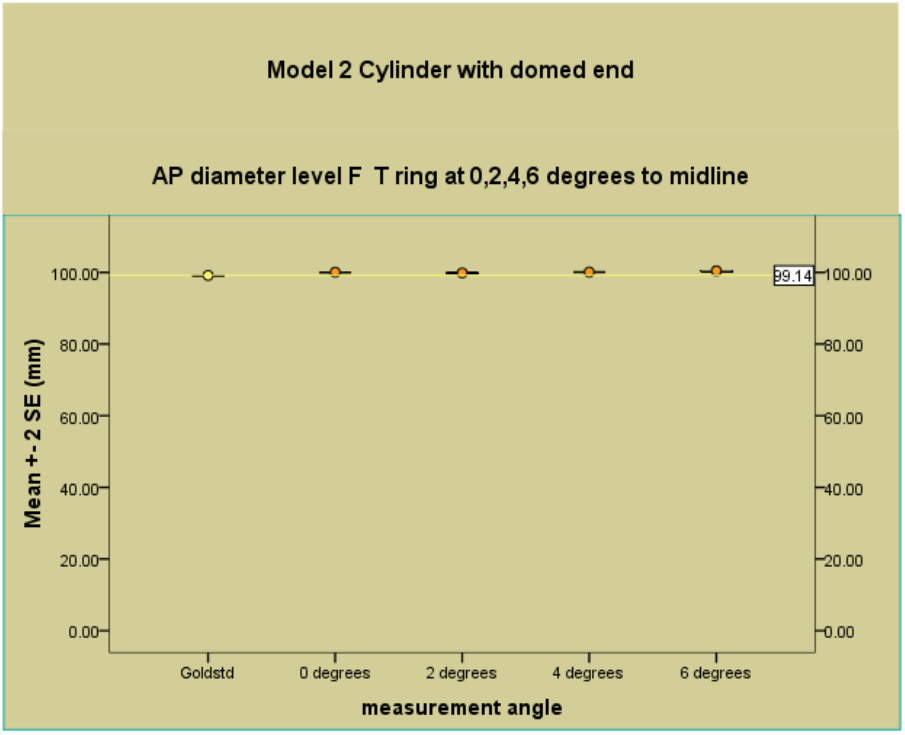

Figure 0-13 AP diameter level F. T ring held at specific angles (model 2)

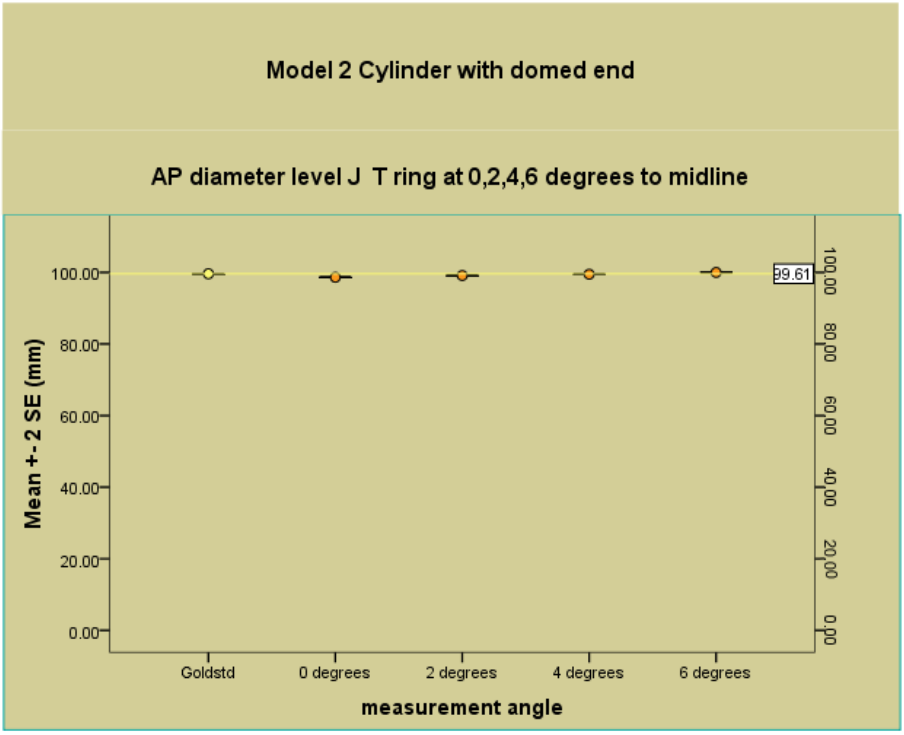

Figure 0-14 AP diameter level J. T ring held at specific angles (model 2)

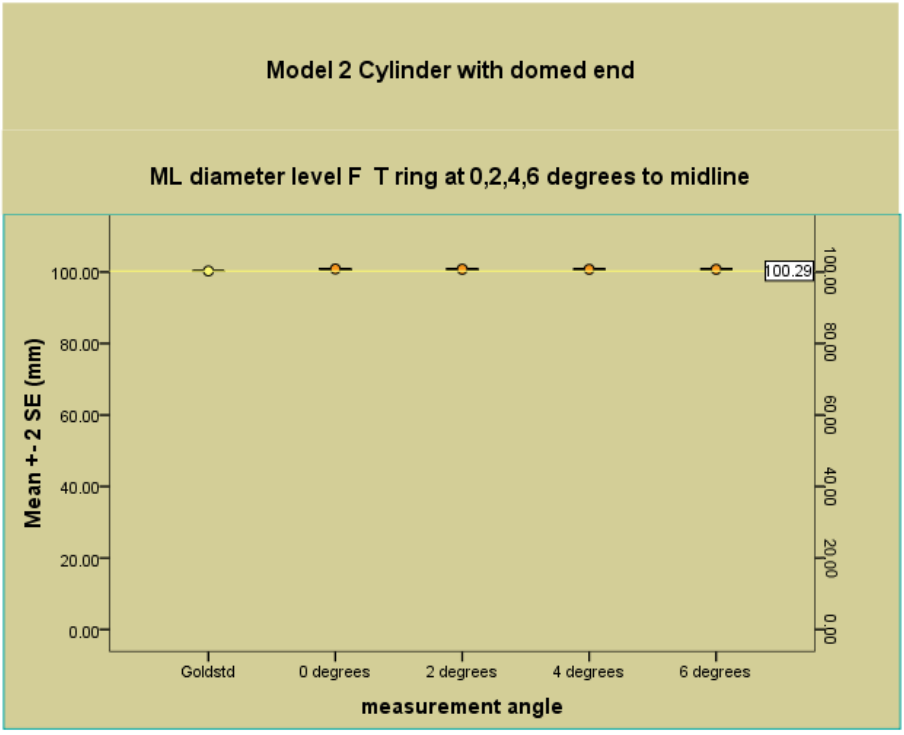

Figure 0-15 ML diameter level F. T ring held at specific angles (model 2)

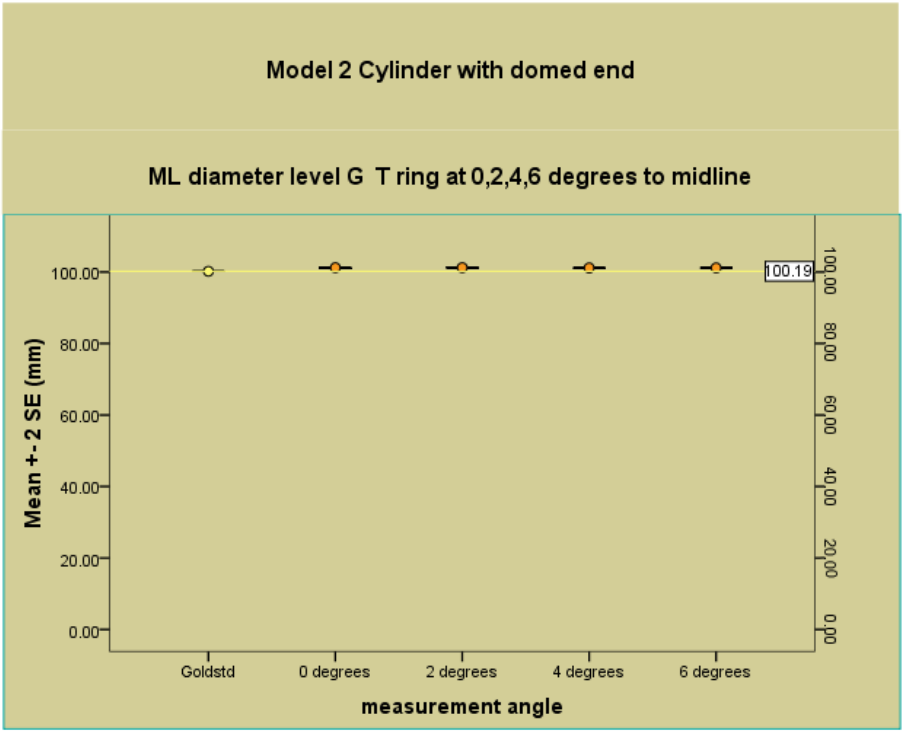

Figure 0-16 ML diameter level G. T ring held at specific angles (model 2)

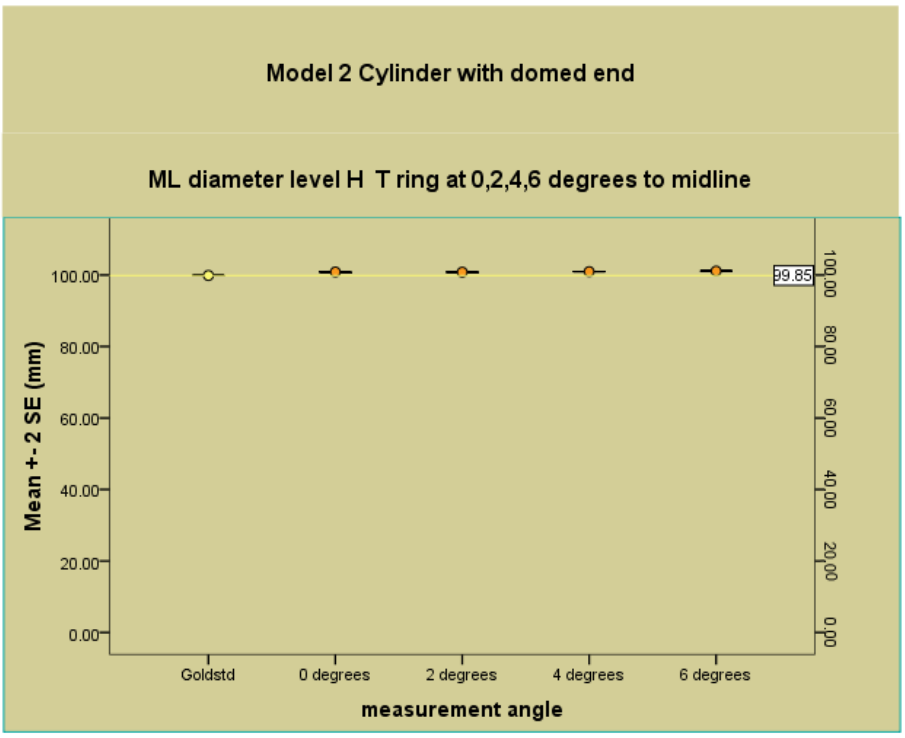

Figure 0-17 ML diameter level H. T ring held at specific angles (model 2)

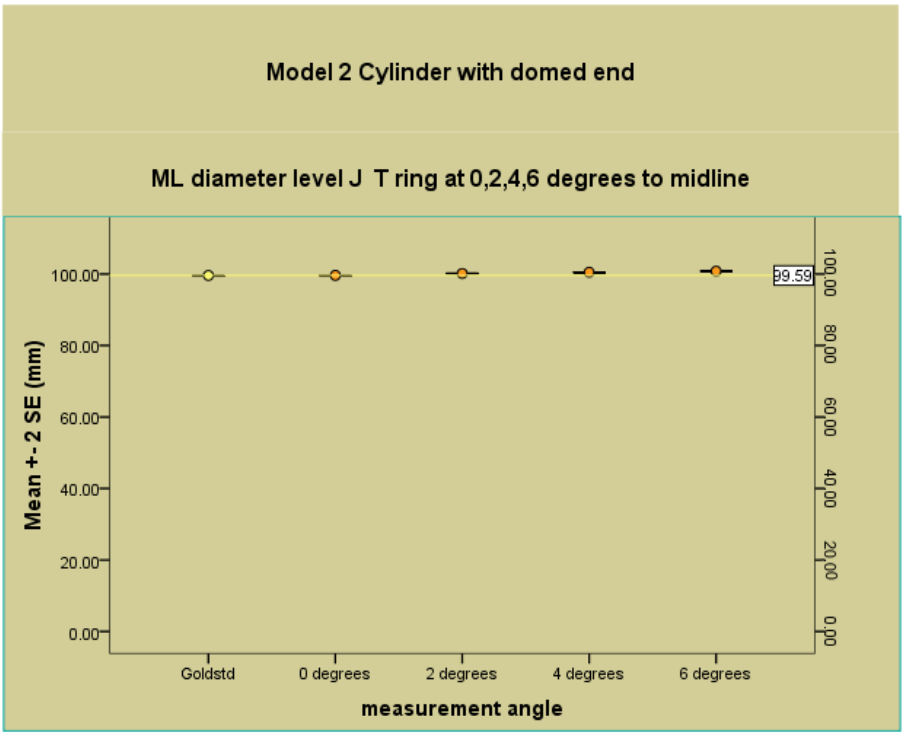

Figure 0-18 ML diameter level J. T ring held at specific angles (model 2)

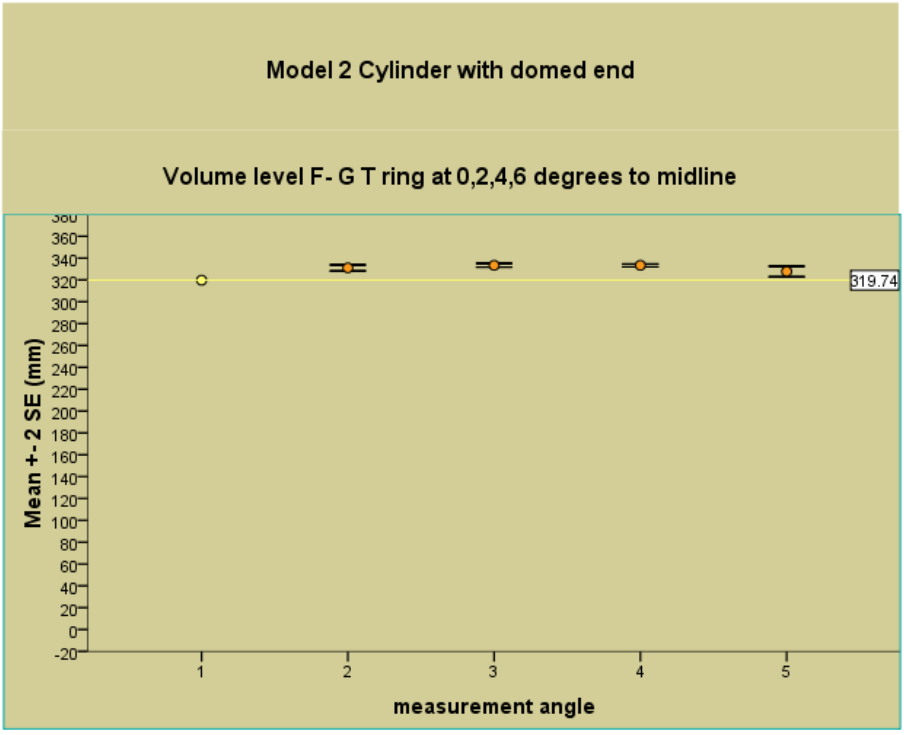

Figure 0-19 Volume level F-G. T ring held at specific angles (model 2)

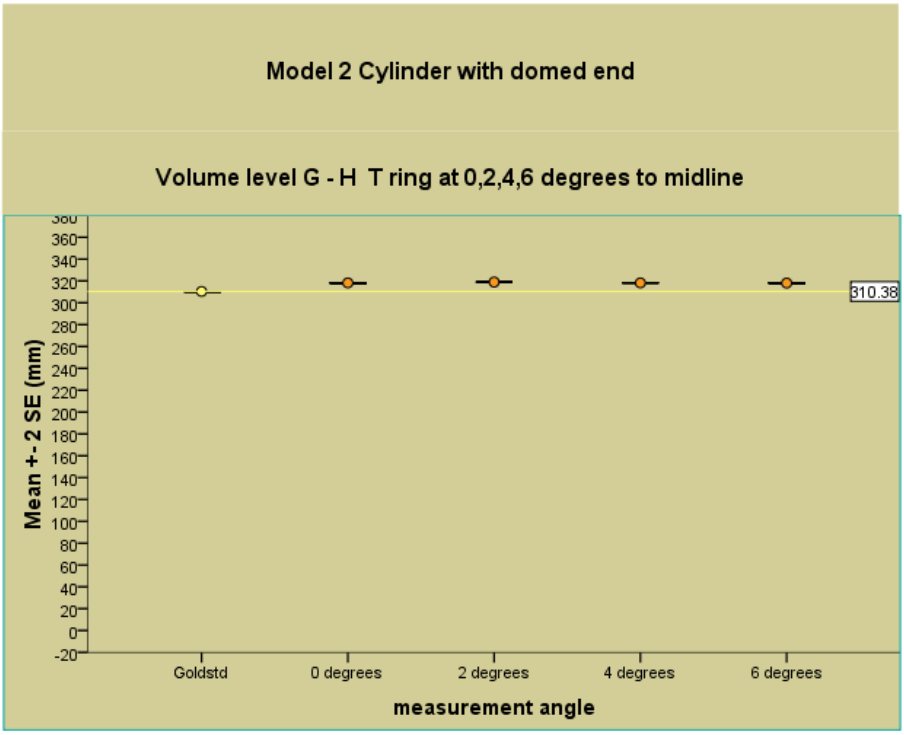

Figure 0-20 Volume level G-H. T ring held at specific angles (model 2)

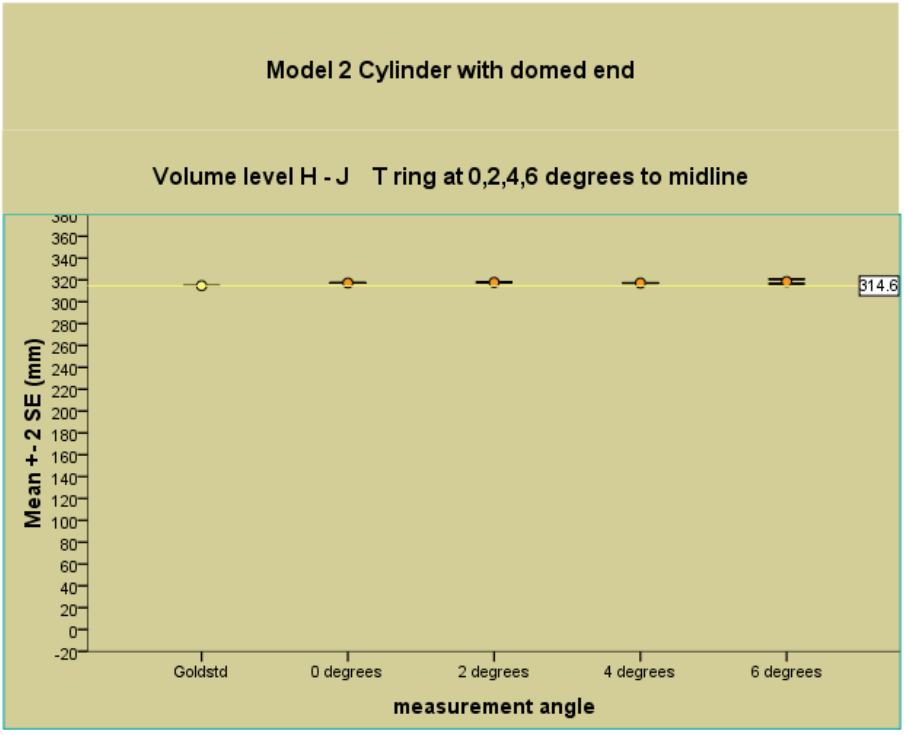

Figure 0-21 Volume level H-J. T ring held at specific angles (model 2)

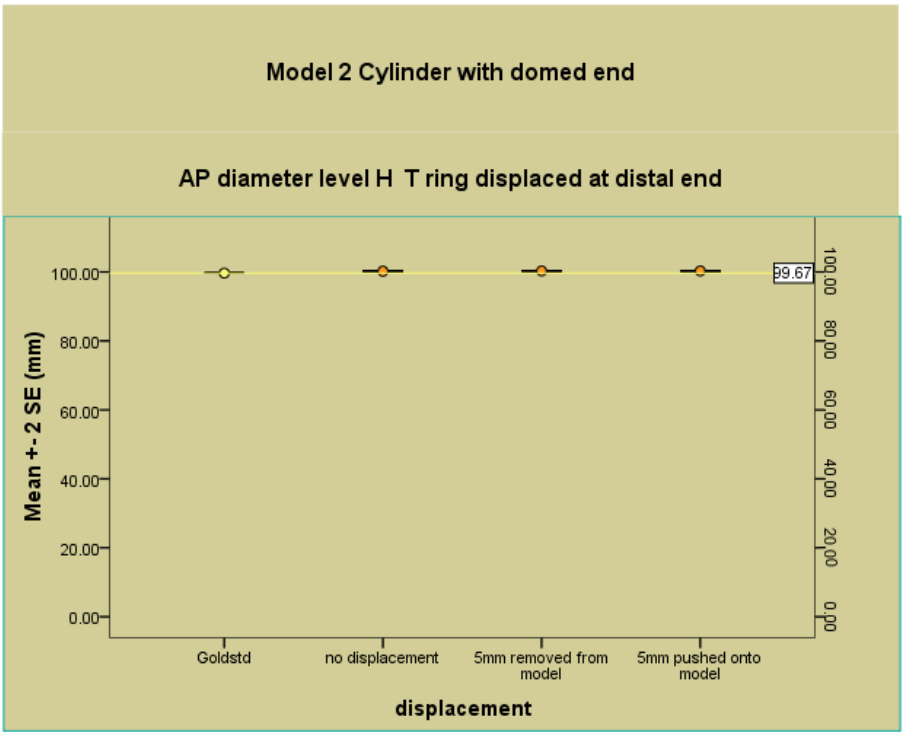

Figure 0-22 AP diameter level H. T ring deliberately misplaced (model 2)

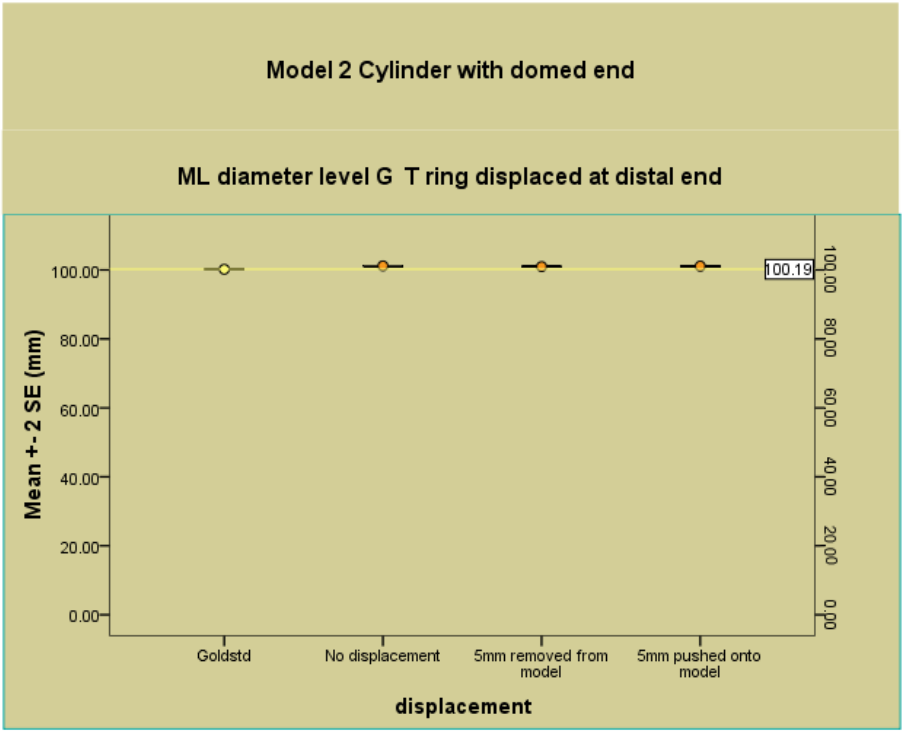

Figure 0-23 ML diameter level G. T ring deliberately misplaced (model 2)

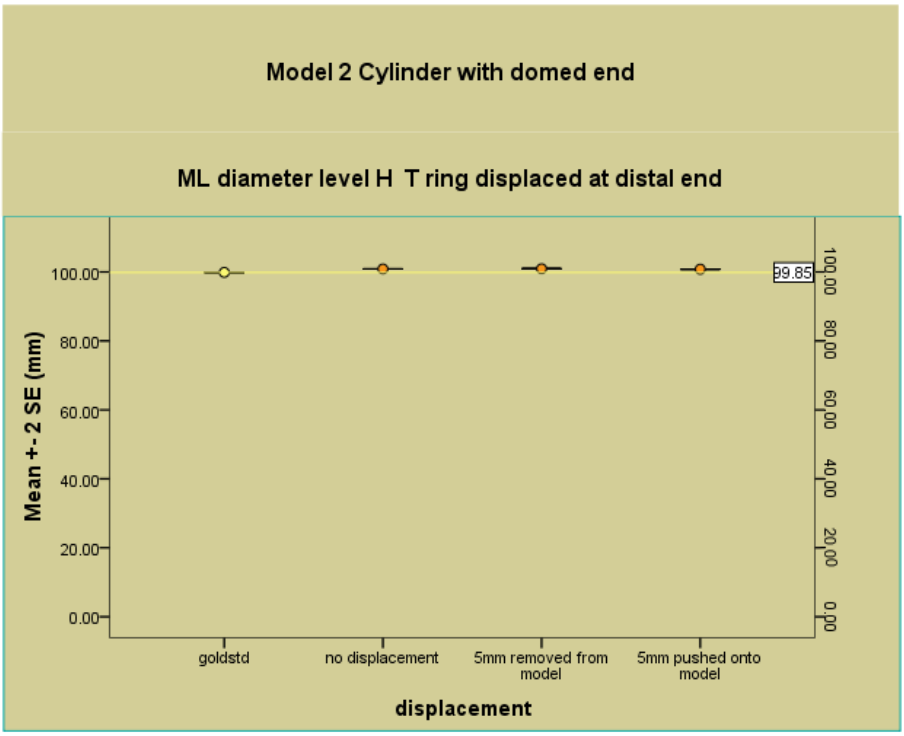

Figure 0-24 ML diameter level 10. T ring deliberately misplaced (model 2)

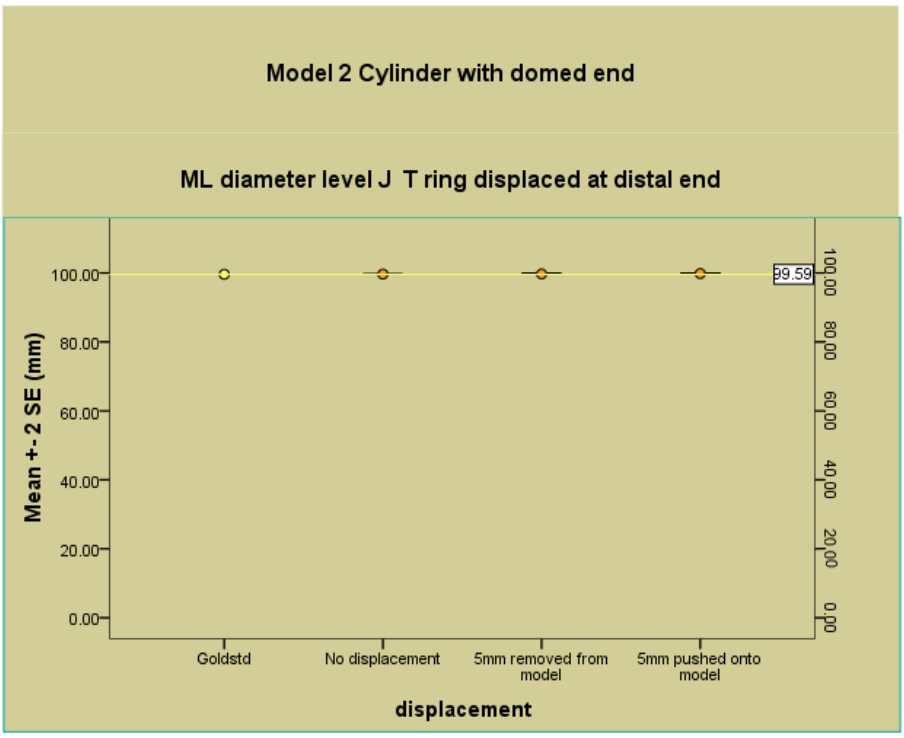

Figure 0-25 ML diameter level 9. T ring deliberately misplaced (model 2)

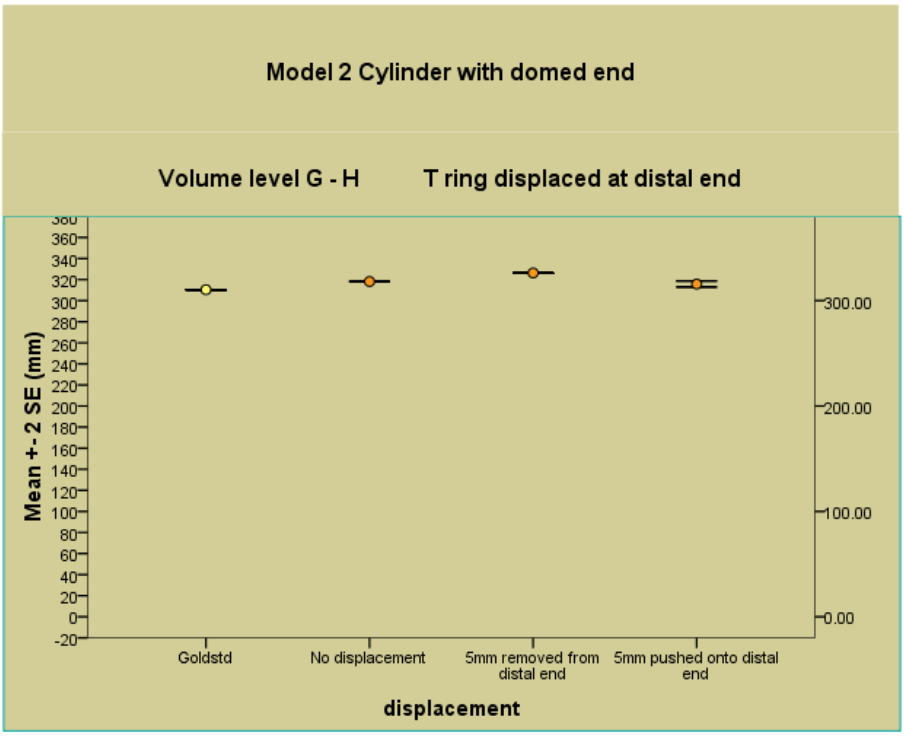

Figure 0-26 Volume level G-H. T ring deliberately misplaced (model 2)

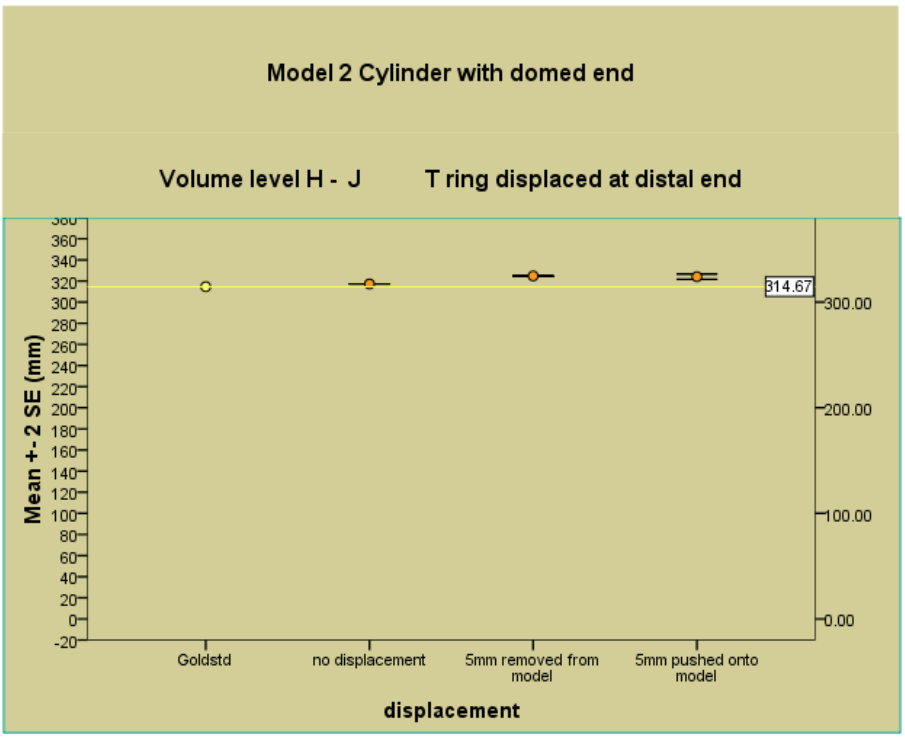

Figure 0-27 Volume level H-J. T ring deliberately misplaced (model 2)

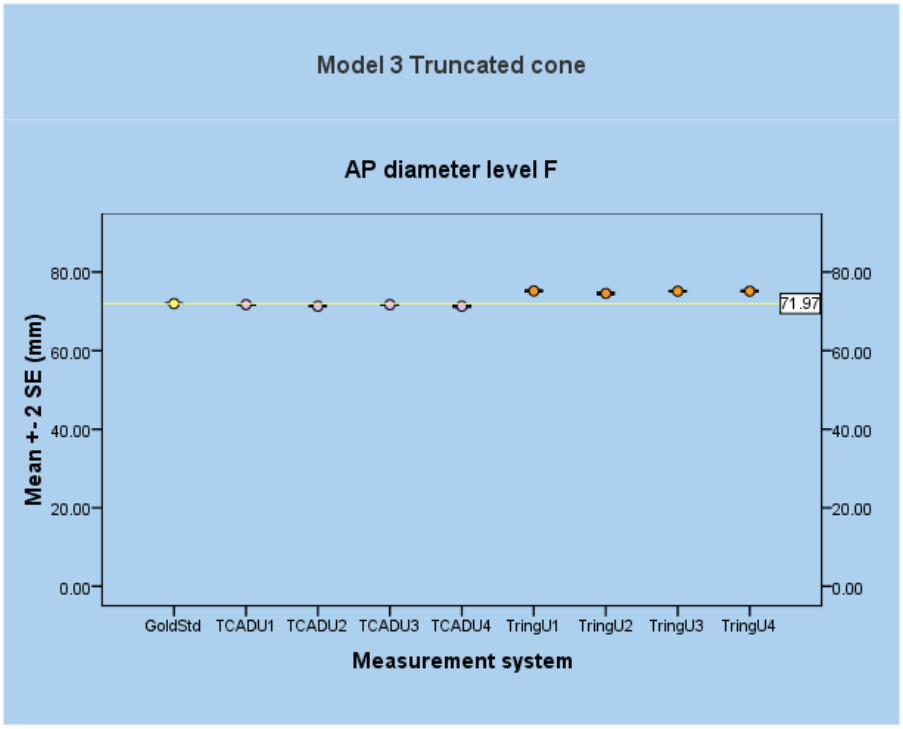

Figure 0-28 AP diameter level F. Accuracy and repeatability of systems (model 3)

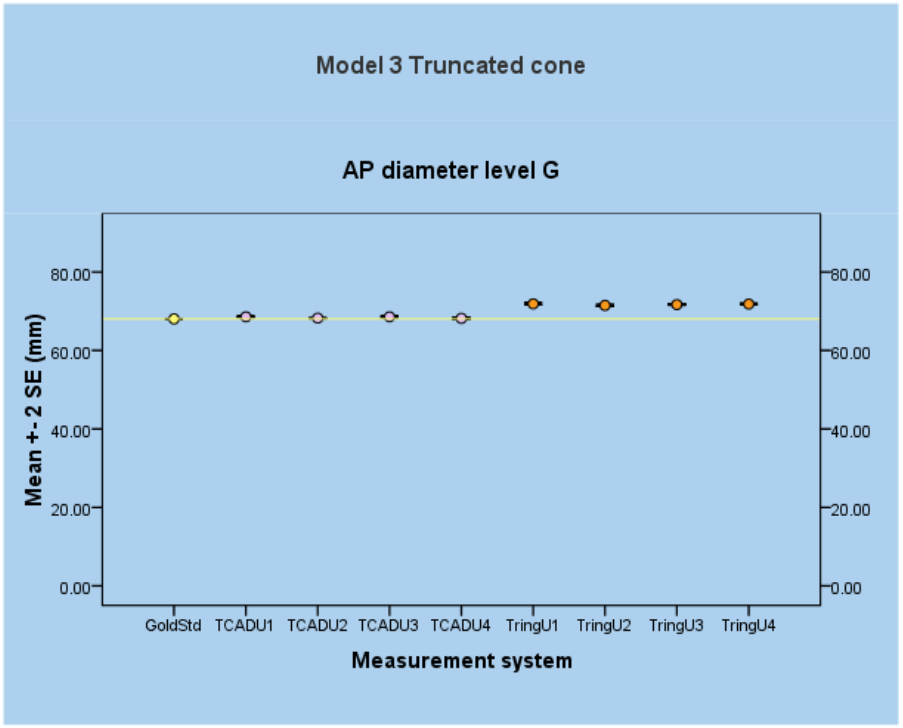

Figure 0-29 AP diameter level G. Accuracy and repeatability of systems (model 3)

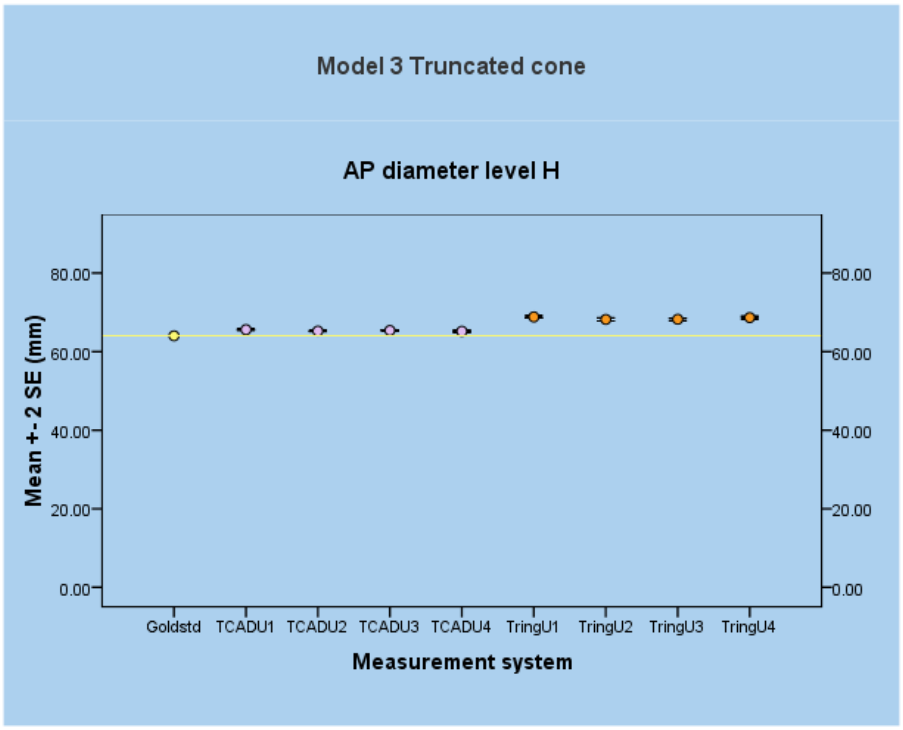

Figure 0-30 AP diameter level H. Accuracy and repeatability of systems (model 3)

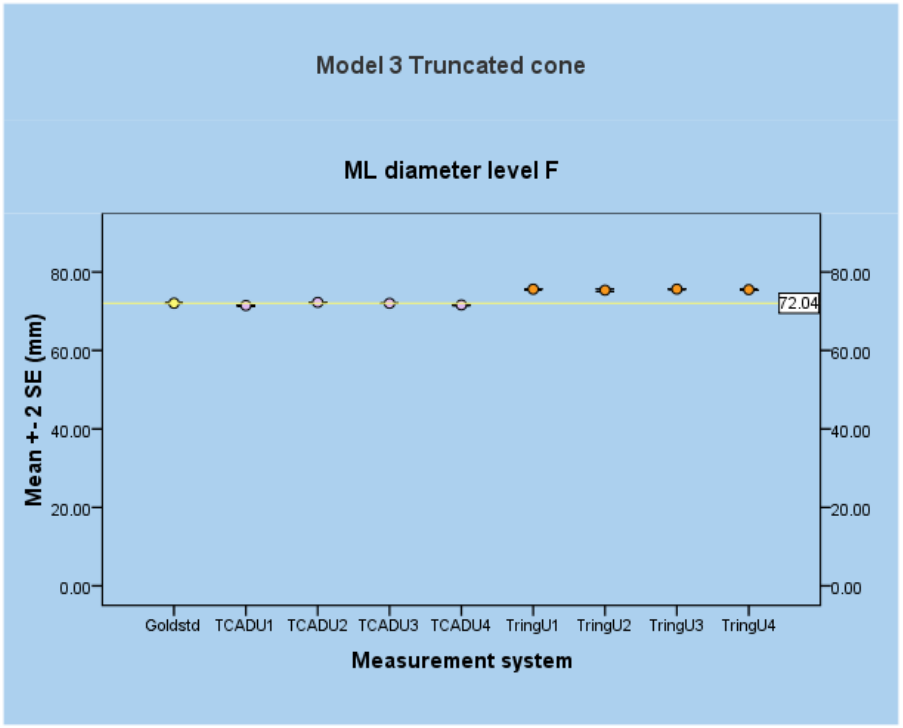

Figure 0-31 ML diameter level F. Accuracy and repeatability of systems (model 3)

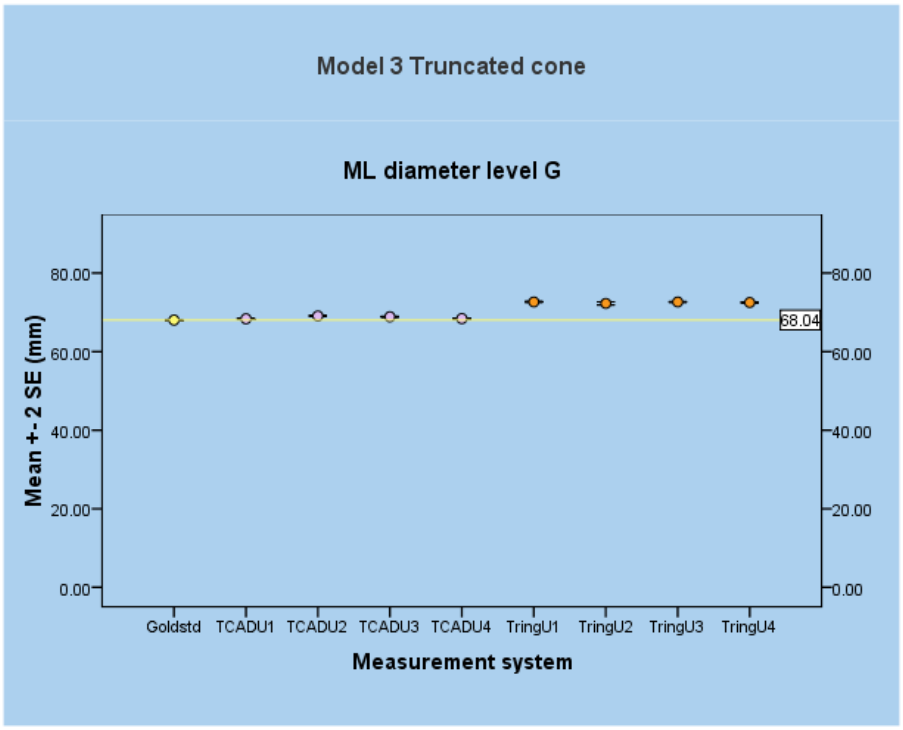

Figure 0-32 ML diameter level G. Accuracy and repeatability of systems (model 3)

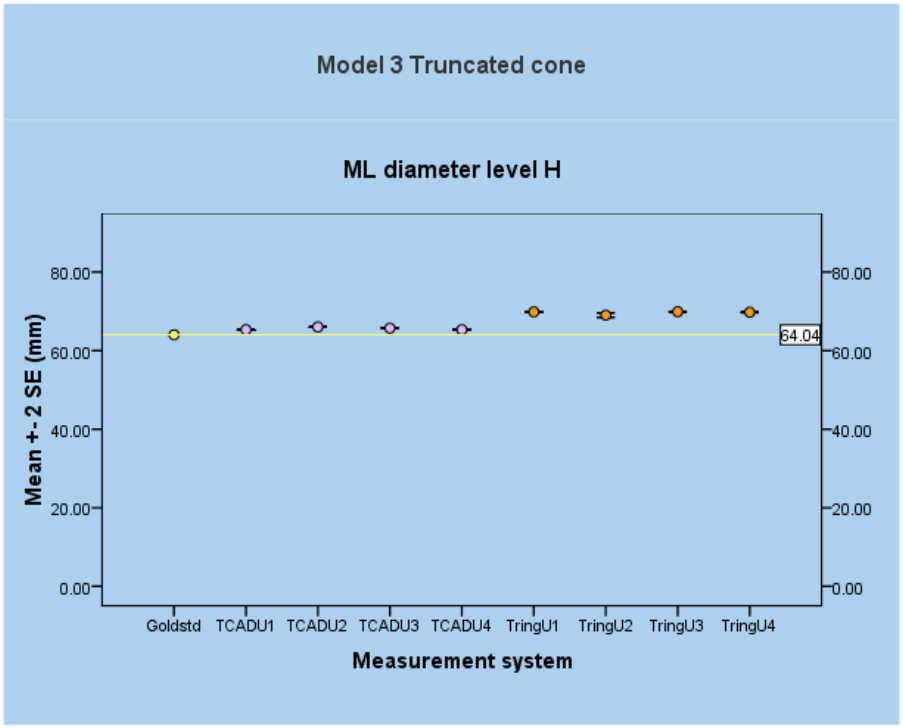

Figure 0-33 ML diameter level H. Accuracy and repeatability of systems (model 3)

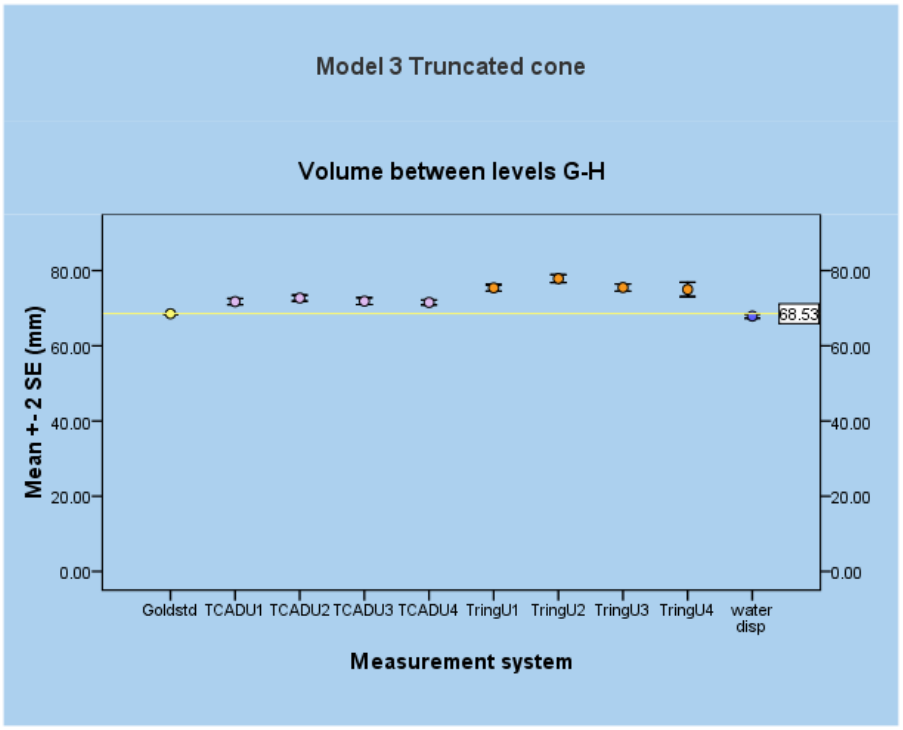

Figure 0-34 Volume level G-H. Accuracy and repeatability of systems (model 3)

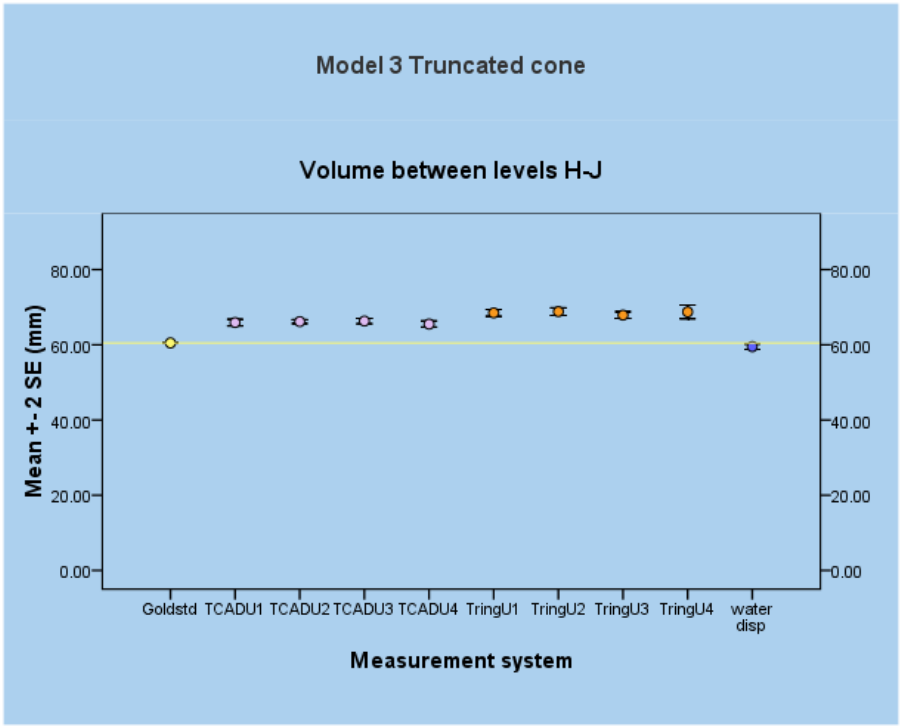

Figure 0-35 Volume level H-J. Accuracy and repeatability of systems (model 3)

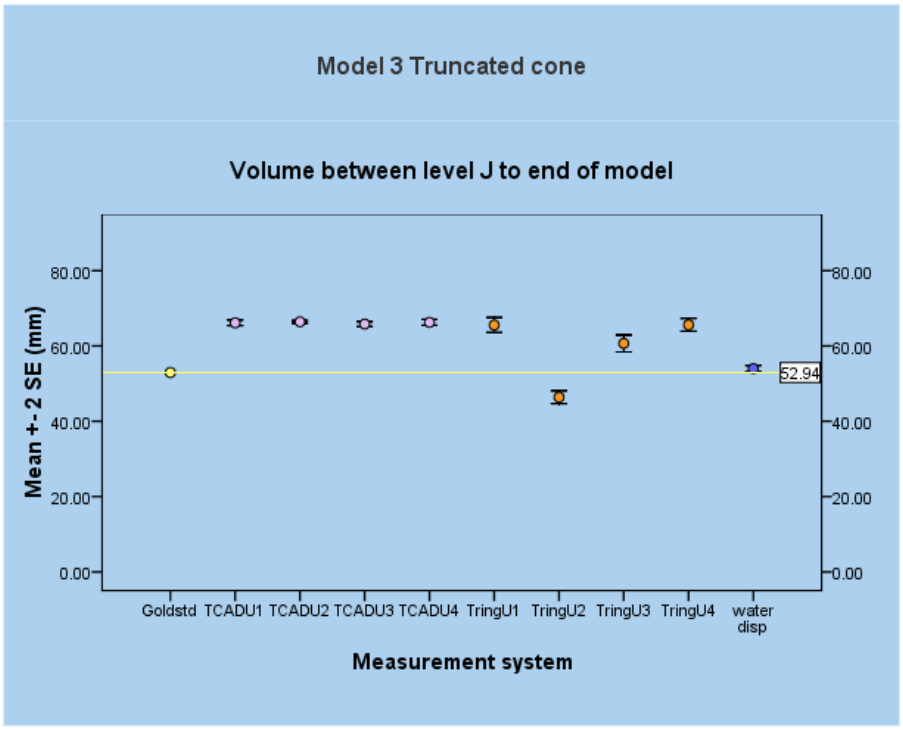

Figure 0-36 Volume level J – model end. Accuracy and repeatability of systems (model 3)

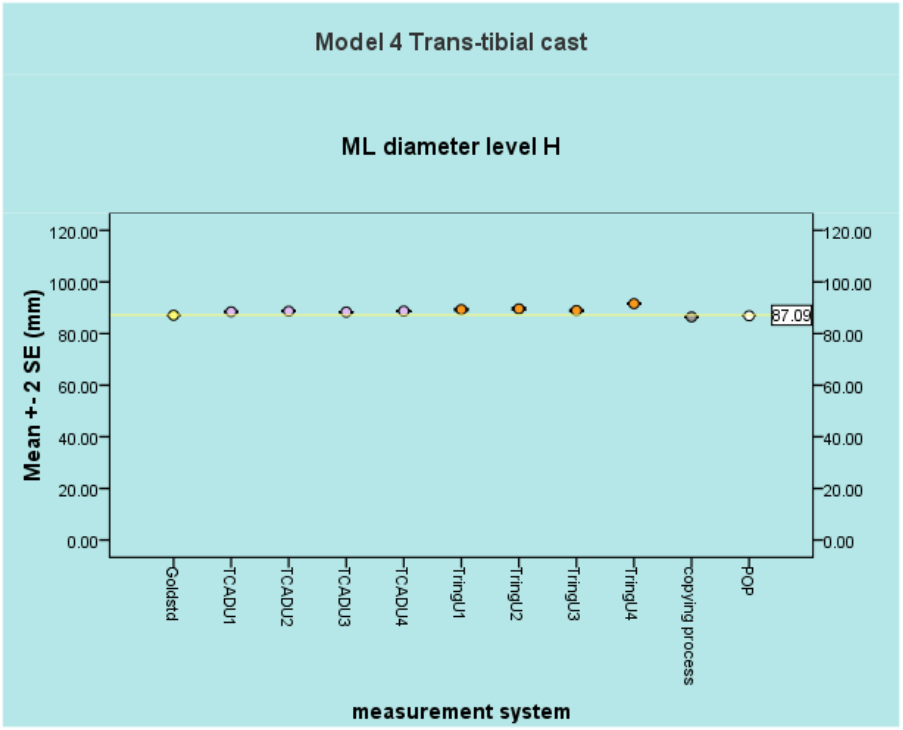

Figure 0-37 ML diameter level H. Accuracy and repeatability of systems (model 4)

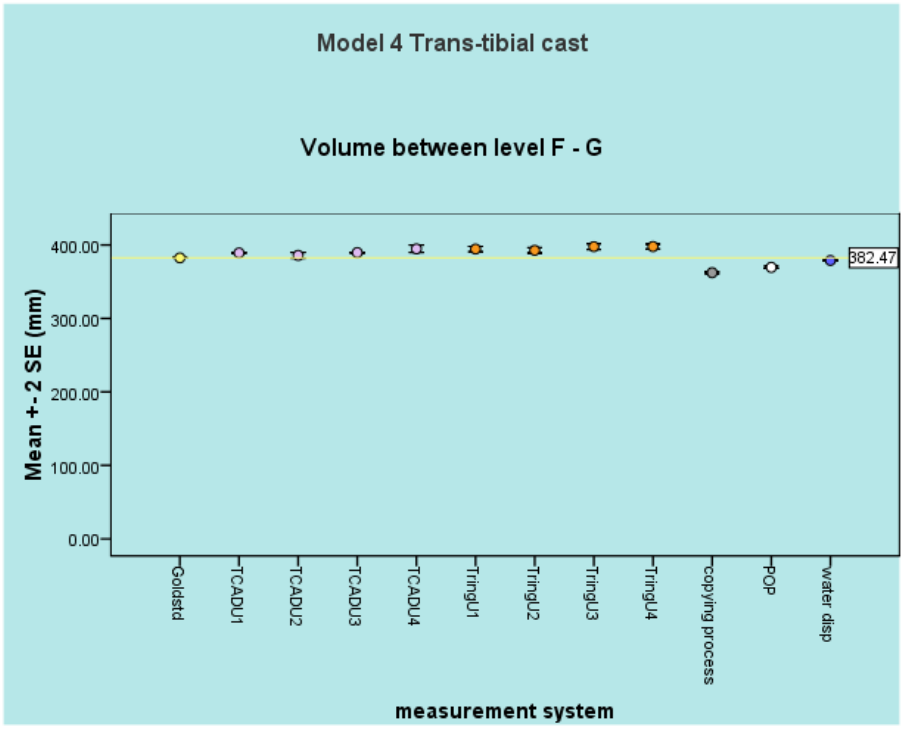

Figure 0-38 Volume level F-G. Accuracy and repeatability of systems (model 4)

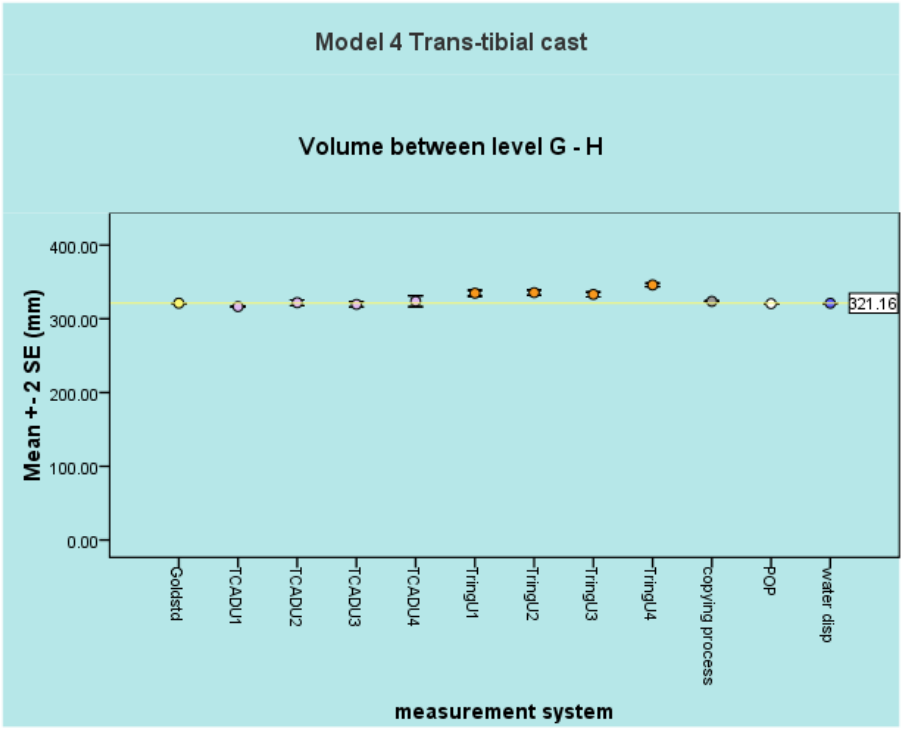

Figure 0-39 Volume level G-H. Accuracy and repeatability of systems (model 4)

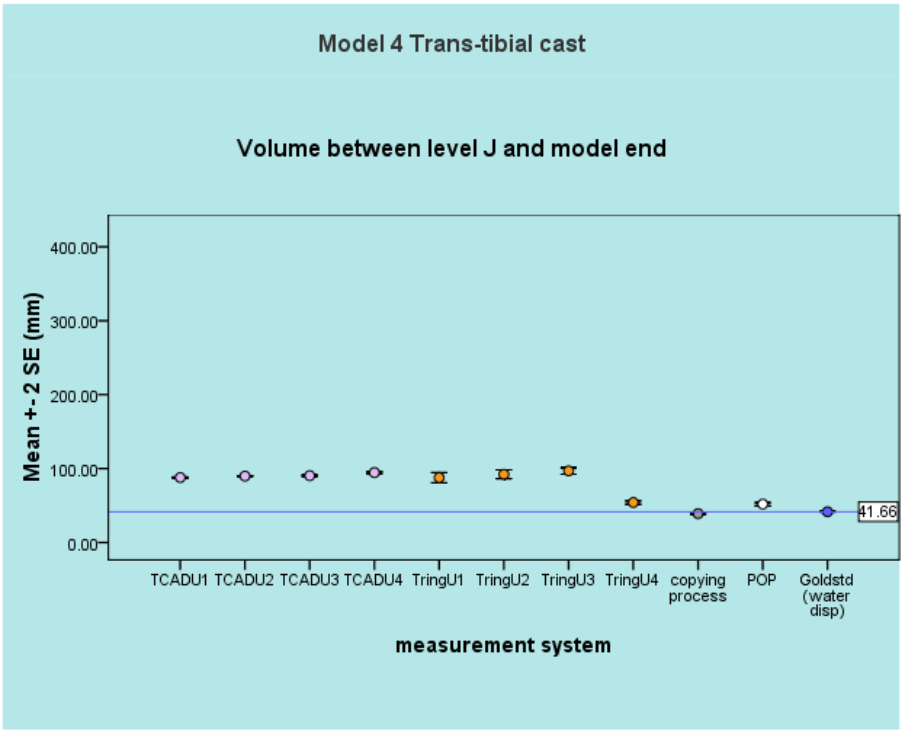

Figure 0-40 Volume level J- model end. Accuracy and repeatability of systems (model 4)

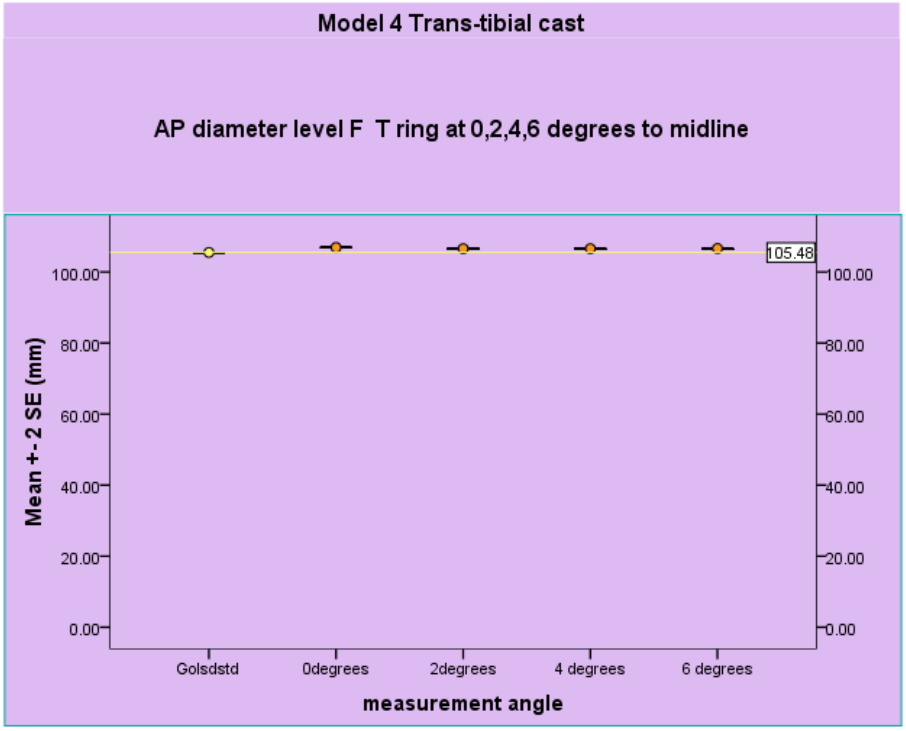

Figure 0-41 AP diameter level F. T ring held at specific levels (model 4)

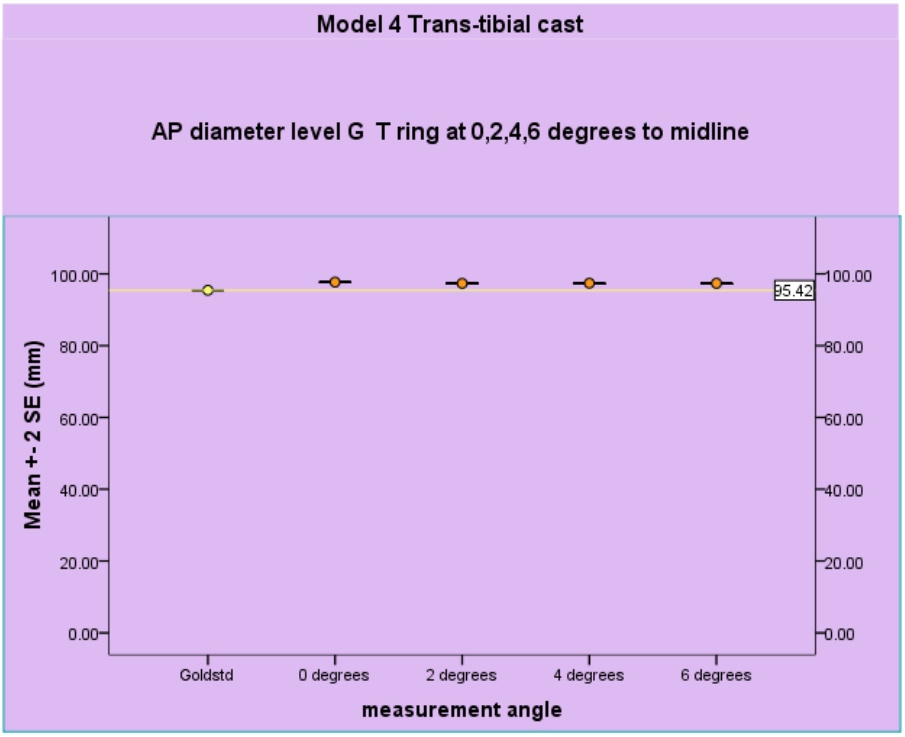

Figure 0-42 AP diameter level G. T ring held at specific levels (model 4)

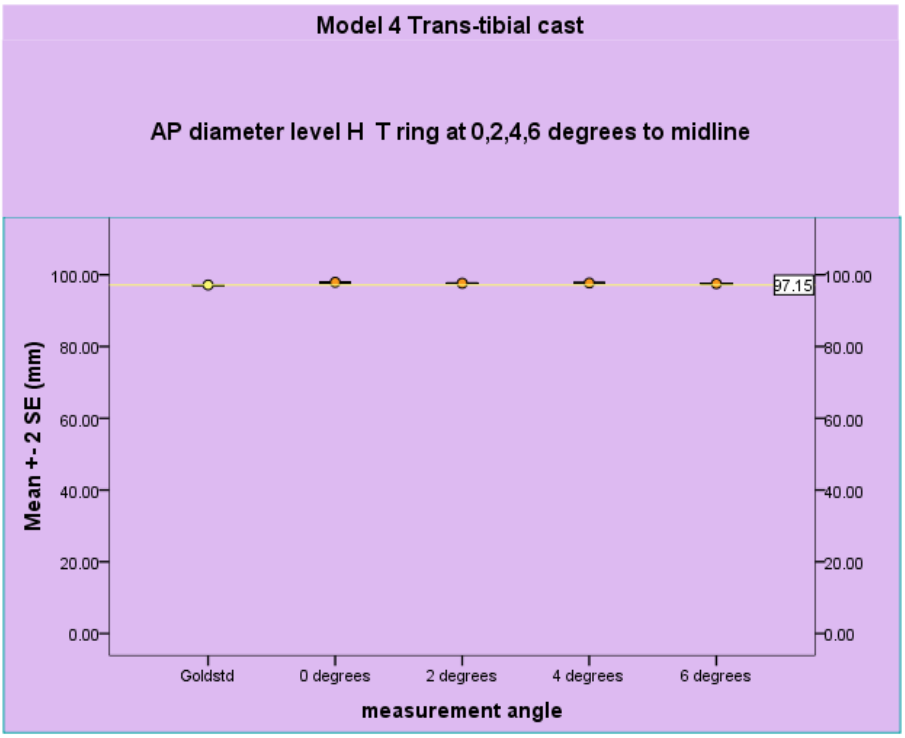

Figure 0-43 AP diameter level H. T ring held at specific levels (model 4)

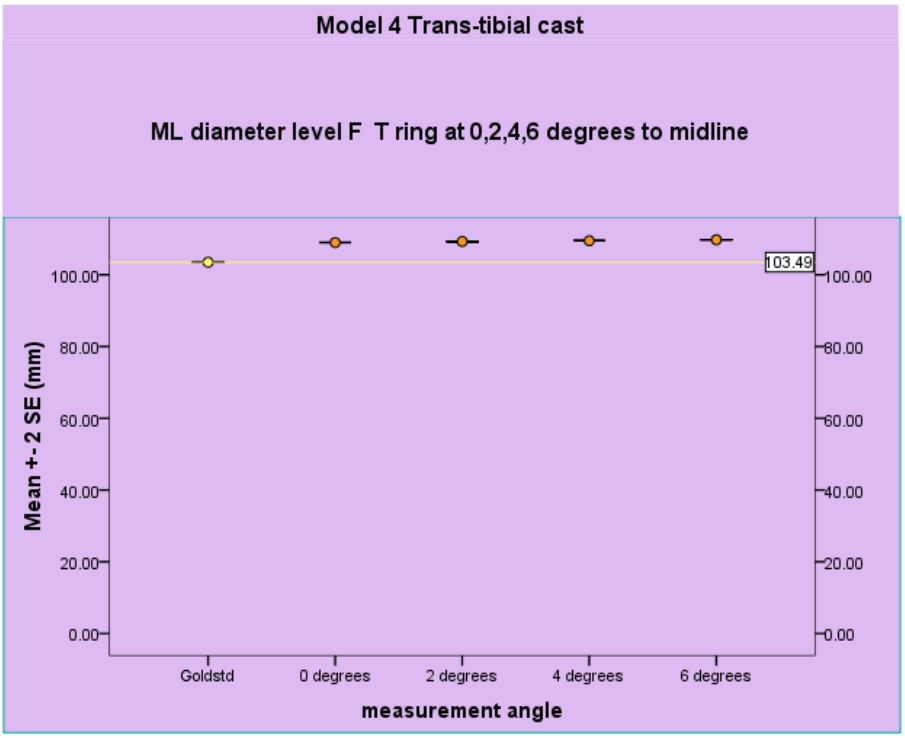

Figure 0-44 ML diameter level F. T ring held at specific levels (model 4)

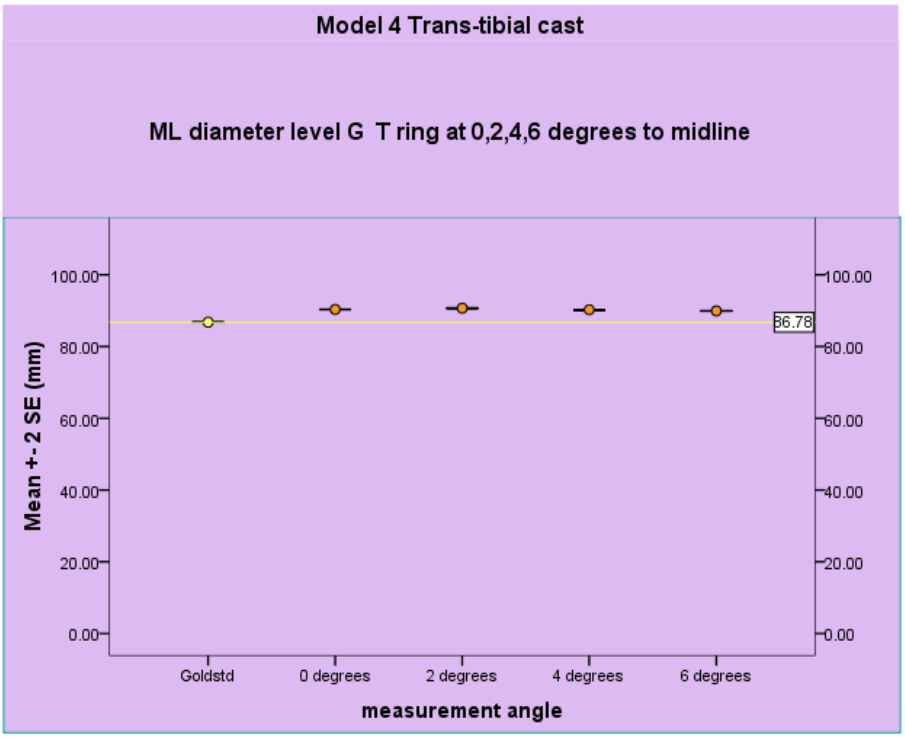

Figure 0-45 ML diameter level G. T ring held at specific levels (model 4)

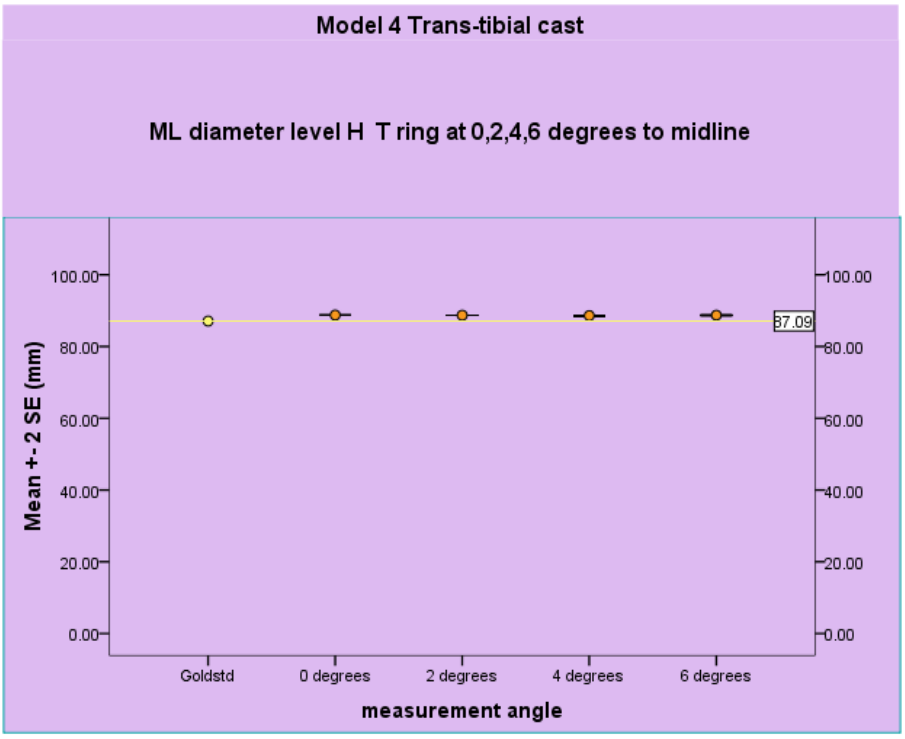

Figure 0-46 ML diameter level H. T ring held at specific levels (model 4)

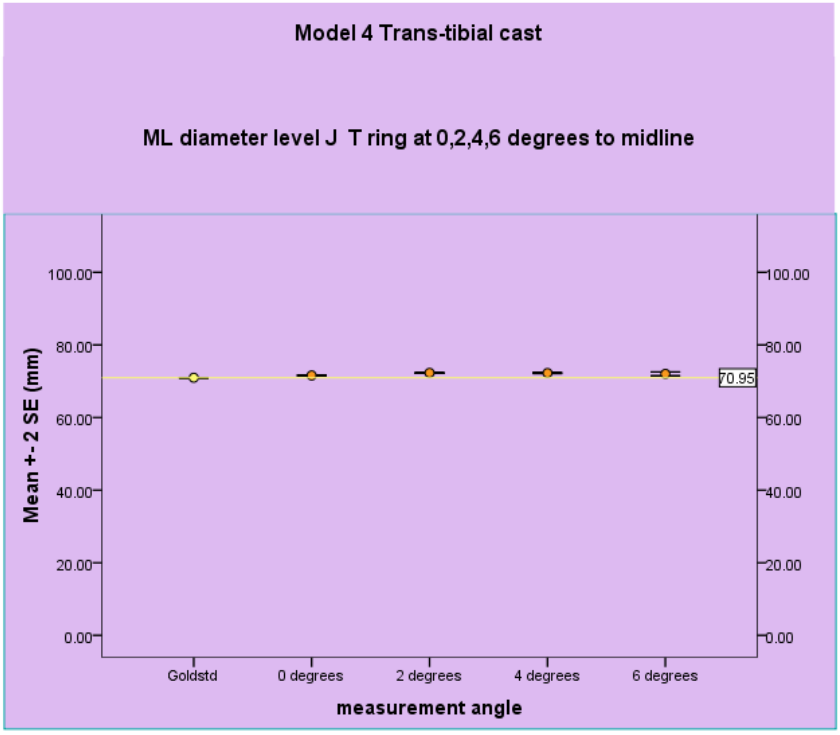

Figure 0-47 ML diameter level J. T ring held at specific levels (model 4)

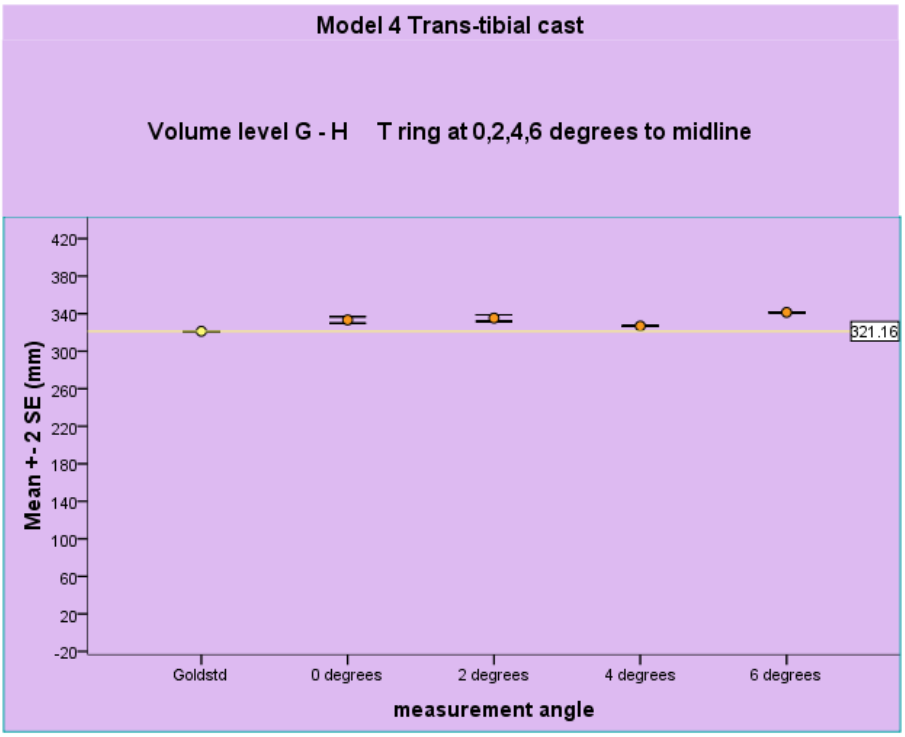

Figure 0-48 Volume level G-H. T ring held at specific levels (model 4)

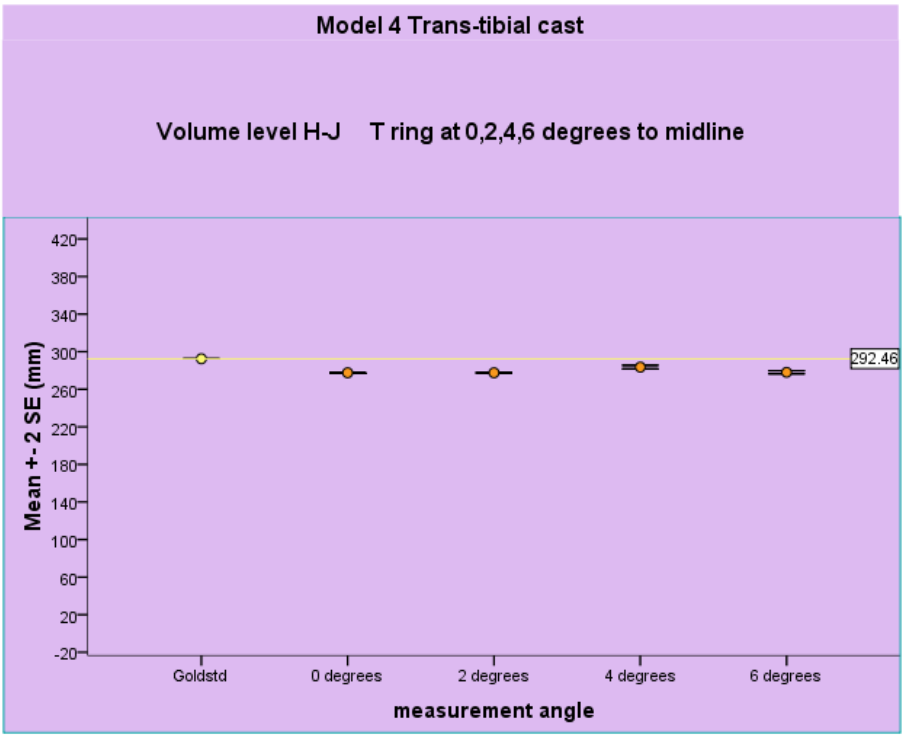

Figure 0-49 Volume level 10. T ring held at specific levels (model 4)

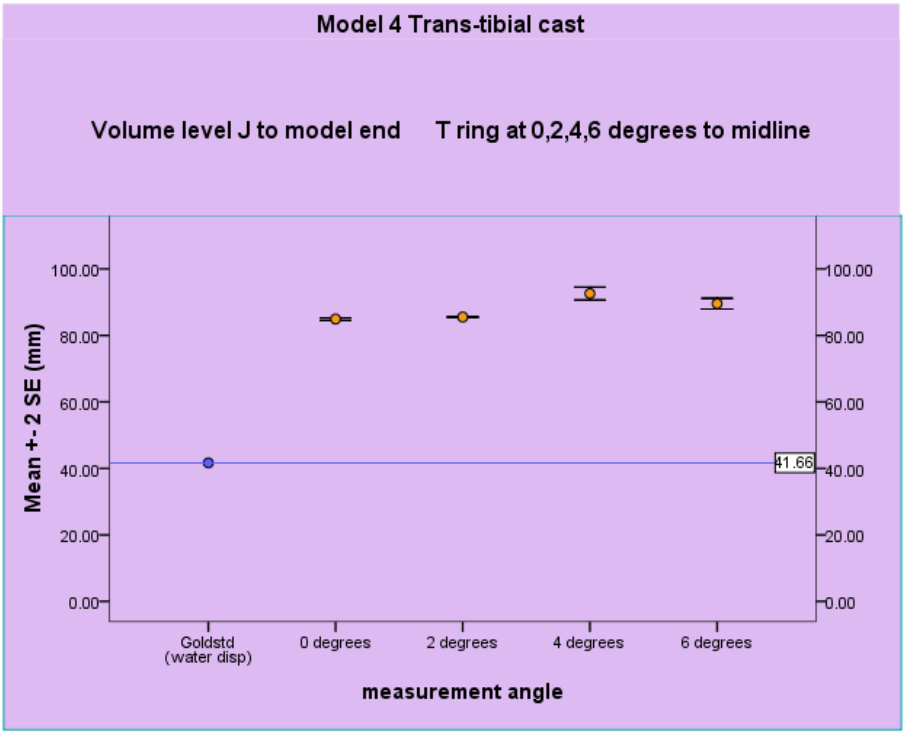

Figure 0-50 Volume level J-model end. T ring held at specific levels (model 4)

Appendix 6 Publications

McGarry T, McHugh B. (2005). Evaluation of a contemporary CAD/CAM system. *Prosthet Orthot Int*, 29, 221-229.

McGarry T, McHugh B. (2007). Comparison of the results of four users of a contemporary CAD system. *Prosthet Orthot Int*, 31, 27-35

McGarry T, Dixon MT, Greig RJ, Hamilton DRL, Sexton S, Smart H (2008) Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly: a systematic review. *Dev Med Child Neurol*, 50, 1-9.

McGarry T, McHugh B, Buis A, McKay G (2008) The effect of shape on a contemporary CAD system. *Prosthet Orthot Int*, 32, 145-154.

Appendix 7 Presentations

2004

University of Strathclyde research forum poster presentation

Evaluation of a contemporary CAD/CAM system. (Poster)

2005

ISPO World Conference 2005, Hong Kong, China:

Evaluation of a contemporary CAD/CAM system.

2006

CAPO annual conference 2006, Quebec, Canada:

Computer Aided Design and Manufacture of the Pelvic Section of a Reciprocating Gait Orthosis

2007

BAPO Conference 2007: CAD technology in prosthetics (chair)

University of Strathclyde research forum: The effect of shape on a contemporary CAD system.

ISPO World Conference 2007, Vancouver, Canada:

Comparison of the results of four users of a contemporary CAD system.

The effect of shape on a contemporary CAD system. (Poster)

Computer Aided Design and Manufacture of the Pelvic Section of a Reciprocating Gait Orthosis

2008

University of Strathclyde Faculty of Engineering research presentation day: Evaluation of a non contact optical CAD system. McGarry T, McHugh B, Buis A, McKay G.

Merit awarded for the best oral presentation in the rehabilitation and biomechanics session.

BAPO Conference 2008: Discussion forum: Shape capture in prosthetics (chair)
Including a presentation entitled 'An Investigation into prosthetic CAD use in the UK.' Mc Garry T, Buis A, Murray K.

5th Regional Central European ISPO Conference, Sept 2008 Porto rose, Slovenia: The evaluation of an optical CAD system used in prosthetic shape capture. McGarry T, McHugh B, Buis A, McKay G.