Comparison of the Primary Stability and Seating Force of Two Uncemented Cup Designs Used for Total Hip Replacement

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Declaration of authenticity and author's rights

'This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.'

Signed: Date:

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Abstract

The primary stability of uncemented press-fit acetabular cups is critical for osseointegration and implant longevity. Cup design is fundamental in achieving an initial (primary) stability between the acetabular component and the reamed cavity, thereby minimising micromotion and promoting long term bone ingrowth. Different cup designs are commercially available but the choice of geometry is controversial. A study was undertaken to compare the primary stability of two commercially available cup designs in-vitro; these cups are produced by the same manufacturer and differ only in geometry – one being purely Hemispheric and the other being peripherally enhanced (peripheral self-locking - PSL).
The cups were seated in reamed polyethylene bone substrate of low ($0.22g/cm^3$) and high ($0.45g/cm^3$) density, mimicking two qualities of bone (softer and harder).

The primary stability of each design was investigated by recording the peak failure load during uniaxial pull-out and tangential lever-out tests.

Potential between-cup differences in peak seating force, pull-out force and lever-out moment were evaluated for each test using independent samples t-tests ($p<0.05$).

There was no statistically significant difference in seating force or pull-out and lever-out stability between the PSL and Hemispheric designs in the low density substrate.

In the high density substrate, the Hemispheric design required a significantly lower seating force than the PSL ($p=0.016$). Once seated, there was no statistically significant difference in pull-out and lever-out stability between the cup designs in the high density substrate.

The high density substrate represents the harder bone of younger patients where uncemented cups are mainly used anyway. If translated clinically, the findings of the study are crucial because high seating forces during cup insertion may result in bony fracture or implant malposition. On this basis, the Hemispheric cup geometry would seem preferable.

Contents

1 Introduction

Total hip arthroplasty is a procedure performed in a substantial number of patients every year in the UK. According to data from the National Joint Registry regarding England and Wales, 55352 primary total hip arthroplasties took place in 2006 (4th Annual Report, National Joint Registry database). It was estimated that by the year 2026, the number would increase by approximately 40% to 77500, based on projected demographic changes associated with an ageing population (Birrell *et al*. 1999). However, over 70,000 hip procedures were undertaken in 2009 (National Joint Registry, 2009) suggesting that such approximations have substantially underestimated the growing need for hip surgery in the UK over the past decade. In Scotland, 6312 hip replacements were recorded in 2007/2008 (Scottish Arthroplasty project, Annual Report 2009).

1.1 Background

Total hip arthroplasty is the treatment of choice for patients who suffer from degenerative or inflammatory arthritis with destruction of the articular surface. These patients have typically been treated conservatively (analgesia, physiotherapy, loss of weight) for a period of time but have reached a point where their quality of life and ability to perform activities of daily living are significantly impaired despite conservative management. The general principle in total hip arthroplasty is to provide two artificial bearing surfaces to replace the damaged articular cartilage, prevent bone–to–bone contact and minimise pain. The surgeon aims to restore as much of the normal anatomy and mechanical function as possible. The ultimate target is to improve the patient's quality of life by relieving pain and enhancing mobility.

Polymethylmethacrylate (self-curing acrylic cement) has been used over the last few decades as the fixation material of choice for total hip arthroplasty. There is good evidence to support the use of fixation with cement, especially for the femoral component of the total hip arthroplasty, where for many it still remains the gold

standard (Mulroy and Harris, 1990; Keisu and Lindgren, 1996; Wroblewski *et al.* 2007). There is concern, however, that cement is associated with high rates of aseptic loosening when used for the fixation of the acetabular component of the total hip arthroplasty (Schmalzried *et al.* 1992; Kay *et al*. 1995; Rorabeck *et al.* 1996; Chen *et al.* 1998). This problem is accentuated in younger patients, who have a higher level of physical activity and a greater life expectancy (Kay *et al.* 1995). Consequently, an alternative method of fixation has become increasingly popular, especially in younger patients. This method employs uncemented prostheses and is based on the principle of biological fixation.

Uncemented components require excellent initial implant stability to allow for bone ingrowth and remodelling and to ensure the long-term durability of the prosthesis. Initial stability is usually achieved by the principle of press-fit, where an oversized component is inserted into an undersized cavity reamed within bone. The residual compressive forces help to hold the implant in place and prevent micromotion at the bone-component interface (Figure 1) (Cameron *et al.* 1973; Pilliar *et al.* 1986; Morscher and Masar, 1988; Søballe *et al.* 1992).

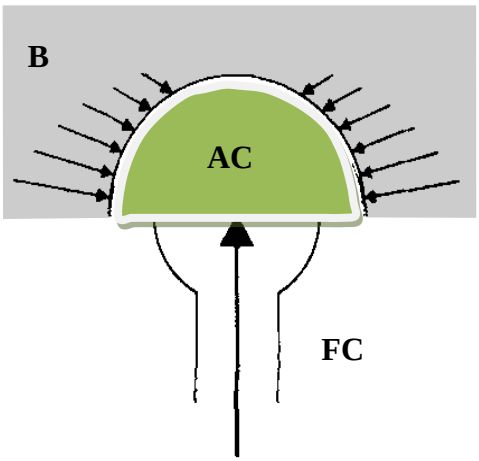

Figure 1: A schematic representation of the residual compressive forces within the acetabular bone (B) which act on the oversized cup (AC) during press-fit and which aid initial stability. The femoral component (FC) and the direction of loading are also shown (adapted from Morscher and Masar, 1988).

The short and medium-term clinical results for uncemented hip arthroplasty are satisfactory overall. The revision rates are low and there has been success in achieving significant improvement in quality of life postoperatively (Harris *et al.* 1988; Morscher *et al.* 1989; Incavo *et al.* 1996; Rorabeck *et al.* 1996; Cruz-Pardos and Garcia-Cimprelo, 2001; Ha *et al.* 2007; Reina *et al.* 2007).

The most common uncemented cup design used to achieve the press-fit effect has been the Hemispheric, in which the cup is essentially a hemisphere except for the dome which is flat, and the very outer aspect of the periphery where it doesn't extend to be a perfect hemisphere. This cup is inserted oversized into a reamed acetabular cavity. There have been clinical concerns regarding the generation of excessive periprosthetic strains with this design, which may be associated with periprosthetic fractures, as well as polar gaps, that could serve as routes for wear particles or obviate bony ingrowth (Curtis *et al.* 1992; Kwong *et al.* 1994; MacKenzie *et al.* 1994; Sharkey *et al.* 1999).

Other designs have, therefore, been introduced commercially. One of the most widely available is the peripherally enhanced design such as the Peripheral Self-Locking (PSL) cup, where the cup is essentially a Hemispheric design with an enhanced (wider) peripheral dimension (Figure 2). In contrast to the Hemispheric cup, the peripherally enhanced cup is typically inserted into a cavity that is reamed line-to-line or even over-reamed with respect to its core diameter. The overall press-fit effect, therefore, is provided entirely by the enhanced periphery.

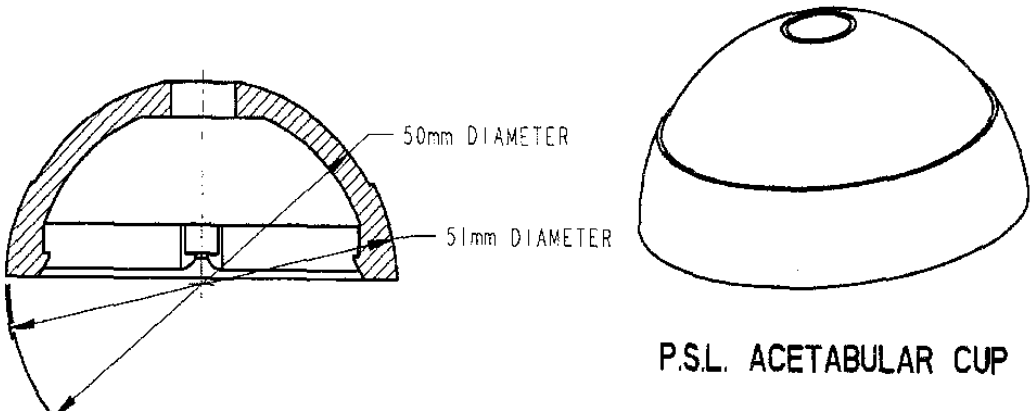

Figure 2: An illustration of the cross-section as well as the outer appearance of the Peripheral Self-Locking (PSL) cup, showing the enhanced rim structure (Van Flandern *et al*. 1998). The acetabular cavity is reamed line-to-line or even over-reamed with respect to the core diameter of the cup.

Few studies have provided clinical data on the survivorship of peripherally enhanced cups. Although all studies report overall satisfactory results (Önsten *et al.* 1996; Van Flandern *et al.* 1998; Torga Spak and Stuchin , 2005), empirical evidence for the potential benefits of a peripherally enhanced design over a purely hemispheric cup, such as a better distribution of periacetabular strains, decreased polar gaps and improved initial stability, is lacking (Kim, Brown *et al.* 1995).

1.2 Project rationale

The choice of cup designs in uncemented hip arthroplasty remains controversial. While both hemispheric and peripherally enhanced cups are commercially available and widely used in the clinical setting, the choice often comes down to the surgeon's personal preference.

Primary stability is an important factor for implant longevity. However, few studies have considered the effect of cup geometry on the primary stability of acetabular components. Of the few studies undertaken, the majority have compared cup designs from different manufacturers, with differences not only in geometry but also in parameters such as surface finish and material. Any difference in primary stability could not, therefore, be attributed solely to differences in cup geometry.

In the absence of long-term clinical studies, this study sought to evaluate the primary in vitro stability of two cup designs, the Hemispheric and the Peripheral Self-Locking cups (Trident, Stryker Ltd., UK). These widely used cups differ only in their geometry. Synthetic bone substrate and a materials testing machine were used to measure the peak pull-out forces and lever-out moments for each design following cup insertion as measures of primary stability (Adler *et al.* 1992; Ries, Harbaugh *et al.* 1997; Kuhn *et al.* 1999; Macdonald *et al.* 1999a; Olory *et al.* 2004; Wetzel *et al.* 2005).

1.3 Research questions

This project used an in vitro model to evaluate the primary stability achieved by two designs of uncemented cups. In doing so, the research aims to address the following questions:

RQ1. ***Are there any differences in the peak forces and moments required to produce failure in pull-out and lever-out tests between the Hemispheric and the Peripheral-Self Locking cup designs?***

In addition, the behaviour of the cups is assessed in terms of the force required to achieve satisfactory seating in the synthetic bone substrate. Seating forces are an important clinical parameter; too high, and the components may be difficult for the operating surgeon to insert and may precipitate periprosthetic fractures. The project, therefore, also addresses the following question:

RQ2. ***Does cup geometry affect the force required to seat the acetabular component?***

As it has already been mentioned, there is a paucity of research and hard scientific facts relating to the effects of cup geometry on primary stability - in particular relating to the Hemispheric and PSL cup designs used at our local practice. There is even less research on the influence (if any) of cup design on seating forces. The research questions addressed in this study have arisen from our own experience at our local Orthopaedic Practice at the Golden Jubilee NHS Hospital , as well as from further surgical anecdotal evidence arising through discussions and interaction with other Orthopaedic Surgeons.

To address the research questions, the following steps were required:

- Design and manufacture of a test rig to facilitate the pull-out and lever-out failure tests
- Identification of a suitable synthetic bone substrate, including an evaluation of its structural properties
- Development of a clinically relevant method of substrate reaming and cup insertion which could be accurately reproduced during the testing
- Standardisation of a protocol to achieve pull-out and lever-out failure and quantify primary in vitro stability by the measurement of peak forces and moment.

2 Literature Review

2.1 Total Hip Arthroplasty – a background

2.1.1 Potential problems

Failure of total hip arthroplasty may occur with time due to the expected wear of the prosthetic articulating surfaces e.g. polyethylene, and due to chemical changes that may affect the fixation material such as cement (Orthoteers).

Another important proposed mechanism of late implant failure is aseptic loosening and bone resorption – 'osteolysis'. Particles that are generated from the contact between the articulating surfaces, such as polyethylene on metal, accumulate in gaps between the cement and bone and activate the immune system. The resultant inflammatory reaction leads to further bone resorption (osteolysis), more and greater potential space for circulating particles to accumulate and eventually gross loosening of the components (Schmalzried *et al*. 1992). (Figure 3)

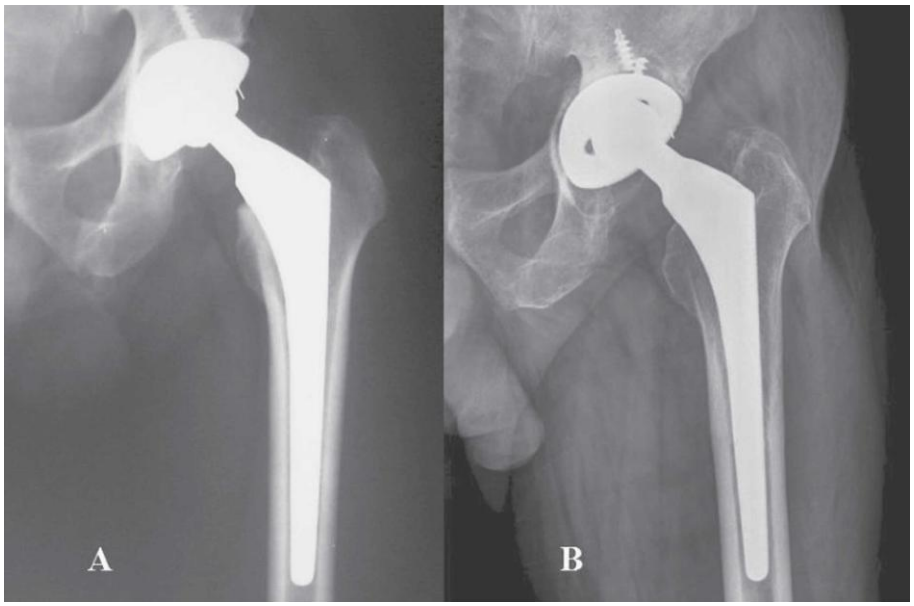

Figure 3: Serial radiographs from the same patient showing in (A) a well fixed cup post-operatively whereas in (B) after 8 years there is cup migration and areas of osteolysis and progressive radiolucencies (Kim *et al*. 2006).

Failure may also occur prematurely if implant fixation is otherwise compromised. There are many mechanisms responsible for this such as infection, malalignment of the components due to the surgical technique that may cause recurrent dislocation or premature asymmetrical wear, as well as trauma such as periprosthetic fractures that may compromise the fixation.

Revision surgery is more demanding as there is often significant bone loss compared to the situation encountered at the first procedure and the patient is invariably older and more frail. Not surprisingly, therefore, revision arthroplasty has a higher rate of complications including dislocation, infection and the need for reoperation, than primary procedures (Orthoteers). Given the difficulties of revision surgery, as well as the substantial number of arthroplasties performed (section1), it is obvious that improved implant longevity would have important benefits not only for the individual patient, but also on a purely financial basis.

2.1.2 Cement – the earliest form of fixation

The polymer polymethylmethacrylate –'cement'- has been used over the last few decades as the fixation material of choice for total hip arthroplasties. It has been described as 'a load-transferring space-filling material that allows secure fixation of the components without the need for accurate matching in shape between component and cavity' (Orthoteers).

There is good evidence to support the use of cement as the fixation material for the femoral component of the total hip arthroplasty, where, for many, it still remains the gold standard (Mulroy and Harris, 1990; Keisu and Lindgren, 1996; Wroblewski *et al*. 2007). However, the use of cement is not without problems. Adverse effects such as allergic reactions, localised tissue necrosis, age-related degradation and even adverse reactions seen in the staff who handle cement, have been reported in the literature (Jones and Hungerford, 1987).

Of particular concern is the performance of cement when used for the fixation of the acetabular cup, especially in the younger patients who have a higher level of physical activity and a greater life expectancy. In such patients, significant rates of aseptic loosening and revision surgery have been demonstrated at 15 years post primary intervention (Schmalzried *et al*. 1992; Kay *et al.* 1995).

2.1.3 Uncemented hip arthroplasty

As the problem of aseptic loosening in cemented acetabular cups became apparent, an alternative form of fixation, via press-fit, was conceived. Instead of using cement for fixation, the main principle with uncemented hip arthroplasty is to establish a biological bond between the bone and the prosthesis in the form of bony growth into or onto the surface of the prosthetic material. This bond eventually becomes strong enough to ensure satisfactory long-term stability. There are various factors considered important for achieving satisfactory bony ingrowth and for ensuring a good clinical outcome in uncemented hip arthroplasty, including:

1. The preservation of the subchondral bone of the pelvis, situated beneath the articular cartilage and superior to the acetabular cancellous bone, during surgical reaming. The subchondral layer is thought to transmit a major part of the bearing load from the hip joint to the rim and cortical shell of the ileum (Jacob *et al.* 1976).
2. The coating of the cementless components. Porous coated surfaces provide microscopic gaps which are needed for bony ingrowth (Morscher and Masar, 1988). While pore size is critical for the success of the prosthesis (Bobyn *et al.* 1980), the choice of coating material for the cup surface is also important. Hydroxyapatite has been commonly used to this purpose as a bone conductive surface (Søballe *et al.* 1992).
3. The surface finish of the cup which affects the friction between cup and bone is also of importance. A combination of coarse and fine wire mesh layers has been

used extensively to provide a 'rough' surface cup finish which has been shown to be advantageous for initial stability (Markel *et al.* 2002, Schreiner *et al*. 2007) (Figure 4).

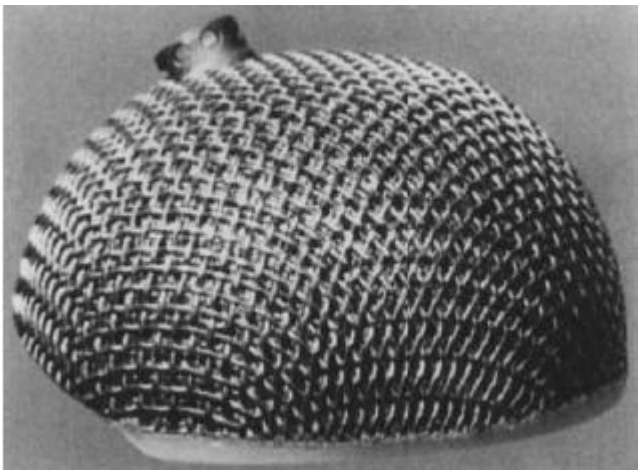

Figure 4: An illustration of the 'rough' wire mesh surface finish of an uncemented acetabular cup (Morscher and Masar, 1988).

4. Of particular importance in achieving satisfactory bony ingrowth, is the initial or primary stability of the acetabular cup following component insertion, which determines the extent of micromovement of the prosthesis relative to the bone. In vitro studies assessing various degrees of micromovement across osteotomies have demonstrated an adverse effect of micromovement on bone growth (Cameron *et al.* 1973; Pilliar *et al.* 1986). Further in vitro research has also examined micromovement in the context of titanium and hydroxyapatite-coated implants and demonstrated that mechanically stable constructs exhibited bony ingrowth compared to fibrous ingrowth in unstable conditions, leading most authors to advocate that a satisfactory endpoint requires ingrowth of bone rather than fibrous tissue (Søballe *et al*. 1992).

The choice of the immediate post-operative regime may compromise the initial stability achieved. Many surgeons advocate a partial weight-bearing regime or

avoidance of certain high risk activities(Burke *et al.* 1991; Spears *et al.* 2000; Bellini *et al*. 2007).

One of the most important factors affecting initial stability is the actual surgical technique used to achieve good fixation of the components in the bone cavity. The press-fit technique is most frequently used to establish satisfactory initial stability during the insertion of components in uncemented arthroplasties.

2.2 Press-fit

Morscher and Masar (1988) described their experience in designing and using an acetabular press-fit cup and provided an excellent comprehensive account of the basic principles underlying the technique. The acetabular cavity is under-reamed by the surgeon with respect to the cup to be used; the oversized cup which has a flattened dome is then inserted into the cavity with sequential impacts of the surgical mallet, until it 'bottoms out' and no further advance is seen. In the process, the periacetabular bone expands to accommodate the oversized cup and results in a residual compressive force which improves cup stability (Morscher and Masar, 1988). These peripheral compressive forces augment the friction between the cup and the bone preventing cup displacement and providing fixation (Widmer *et al*, 2002)(Figure 1).

While various studies have emphasised the importance of these peripheral residual compressive forces for initial stability (Kuhn *et al.* 1999; Olory *et al.* 2004), residual compressive forces are largely related to the extent of bone under-reaming (i.e. cup oversizing). Provided the cup can be adequately seated, the greater the oversizing of the component the greater the peripheral forces generated. The term interference value is used to quantify this under-reaming / oversizing. There is some consensus as to what constitutes optimal interference but recommended values are not absolute and also depend on the quality of bone. Clinically a balance has to be struck between under-reaming/oversizing – which creates greater residual compressive force but also

increases the risk of incomplete cup seating or acetabular fracture. Incomplete seating is especially common in more dense bone– and while more liberal tolerance values make cup seating easier , they also result in lower residual compressive force (Curtis *et al.* 1992; Ries and Harbaugh, 1997).

Reaming accuracy may affect the interference value achieved and therefore the peripheral compressive forces generated and the initial stability. Reamers / reaming techniques that lead to larger cavities than intended may lead to loss of the press-fit effect and therefore be detrimental to the initial stability (Macdonald *et al*. 1999b).

2.3 Mechanical in vitro testing for initial stability

Assessing and comparing initial press-fit stability of different cup designs in vivo is extremely difficult to perform. In vitro studies have been described where mechanical testing is used to compare the initial stability of different cups in different conditions, using synthetic bone analogue or cadaveric bone as the substrate. Mechanical tests have assessed initial stability of press-fit cups by evaluating the peak loads necessary to produce failure in various modes or by comparing micromotion under various conditions.

Most studies have assessed peak forces / moments causing failure in **torsion** (rotatory stability), **lever-out** (tangential stability) and **pull-out** as indirect measures of initial stability.

Adler *et al* (1992) assessed the initial stability of press-fit acetabular cups with respect to cup design, surface structure and surgical preparation. Polyethylene foam cubes as well as bovine bone were used as substrates. Two different densities of polyethylene were prepared to simulate two qualities of cancellous bone. Various degrees of press-fit were assessed as well as cavity sizes and defects. **Tangential stability** as well as **rotatory stability** of the cups were assessed by the application and quantification of lever-out moments and torques to failure.

Ries, Harbaugh *et al* (1997) assessed the effect of acetabular cup geometry on strain distribution and press-fit stability. A finite element model was created to investigate strain distribution. Mechanical testing was also carried out. Aluminium models of the cups were manufactured and then inserted into appropriately reamed foam cavities. **Pull-out** and **lever-out** tests were then conducted and the peak forces and moments were considered as measures of initial stability.

Kuhn *et al* (1999) assessed the effect of various degrees of under-reaming on the stability of six different types of titanium uncemented press-fit cups. PVC foam blocks were used as substrates and following insertion the cups were removed with **lever-out** tests.

Macdonald *et al* (1999a) used three types of substrates. Polyurethane foam was used to model cancellous bone and glass-fibre reinforced epoxide was used to model acetabular cortical bone. Cadaveric acetabular bone was also used. The cups were inserted into appropriately reamed cavities, generally with a 2mm oversize. The initial stability was assessed by measuring the peak loads to failure for **pull-out**, **lever-out** and axial **torque**. The authors justified their choice of modes of testing by relating these to conditions that may exist in vivo - resistance to axial torque as assessed in vitro may be related to the ability to resist failure in rotation in vivo; resistance to lever-out in vitro may be related to the ability to resist lever-out due to impingement or articulation forces in vivo; resistance to pull-out in vitro may be related to the ability to resist the mechanism of pistoning in the acetabulum in vivo which may cause loosening.

Olory *et al* (2004) used polyurethane resin blocks as synthetic bone analogue. Cementless acetabular cups were impacted into the reamed cavities. Eleven types of cups were tested. Primary stability was assessed by quantifying the maximum force needed to **pull-out** the cups.

Wetzel *et al* (2005) assessed the in vitro stability of five different uncemented hemispherical press-fit cups by inserting them into polyurethane foam blocks and then performing mechanical **lever-out** tests.

Schreiner *et al* (2007) assessed the influence of different surface treatments on the in vitro primary stability of cementless acetabular cups. The basic cup design was a hemispherical press-fit geometry; different surface finishes were applied. Polyurethane foam was used as the synthetic bone analogue. Mechanical **lever-out** tests were performed to test stability.

What follows is a summary of the key studies that assessed initial in vitro stability of uncemented acetabular cups through mechanical testing, and the modes employed (**Table 1**).

Study	Pull-out	Lever-out	Torsion
Adler *et al.* (1992)	✖	✓	✓
Hadjari *et al.*(1994)	✓	✖	✓
Ries, Harbaugh *et al.* (1997)	✓	✓	✖
Kuhn *et al.* (1999)	✖	✓	✖
Macdonald *et al.* (1999)	✓	✓	✓
Olory *et al.* (2004)	✓	✖	✖
Wetzel *et al.* (2005)	✖	✓	✖
Schreiner *et al.* (2007)	✖	✓	✖

Table 1: A summary of the key studies that assessed initial in vitro stability of uncemented acetabular cups through mechanical testing.

2.4 Geometry of cups

A number of different cup designs have been used over the years. The two cups featured in this study possess two of the most common geometries used – a purely hemispherical and a peripheral self-locking (enhanced periphery) design.

2.4.1 Hemispherical cups

These cups have an almost purely hemispherical shape (except for the flattened dome and very outer part of periphery where they don't fully extend to become perfect hemispheres) and are inserted with various degrees of oversizing to achieve good initial stability in the reamed acetabular cavity through the press-fit mechanism. The advantages of this design relate to the surgical preparation of the acetabulum for cup insertion. As this design approaches the real shape of the acetabulum, not a lot of bone has to be removed during surgery, making any future revision surgery less challenging, protecting the medial wall of the acetabulum better and facilitating the preservation of the subchondral layer. However, precision is needed for the preparation of the cavity (Morscher and Masar, 1988).

Clinical experience and research have identified potential problems with this hemispherical design, such as excessive periacetabular strains and polar gaps.

Curtis *et al* (1992) tested the torsional stability of press-fit cups using human cadaveric bone. The hemispherical cups were inserted with various degrees of under-reaming and the authors observed cases of pelvic fractures when some cups were inserted 4mm oversized.

MacKenzie *et al* (1994) investigated the areas of contact as well as the gaps between cup and bone in press-fit hemispherical components inserted in under-reamed cadaveric acetabular bone. The use of pressensor film and epoxy moulds demonstrated that for over sized components, contact between the cup and acetabular bone extensively involved the peripheral aspect of the cup with minimal polar contact. Large polar gaps were often demonstrated, with some gaps greater than

1mm, the maximum distance allowable before osteocyte infiltration is significantly impaired.

While the main concern regarding the presence of gaps is that they act as a reservoir for wear particles which may then activate the immune system and set off the process of osteolysis and aseptic loosening, which eventually may lead to failure , gaps also influence bony ingrowth and therefore long-term stability of the implant. Sandborn *et al* (1988) investigated the effect that gaps between bone and prosthesis may have on the rate and quality of bony ingrowth. Canine femoral models were used. Growth was seen even with gaps as big as 2.0mm, but in comparison to the models where the gaps were 0.5mm or less, the rate of bone growth, the degree of maturity and the mineralisation were impaired. Similarly, Cook *et al* (1988) performed histological and radiographical analysis on 36 porous-coated total hip components, both femoral stems and acetabular cups, that had been retrieved from patients. One of the main observations was that any bony ingrowth tended to occur where the implant made direct contact with the endosteal cortical surface.

Such problems associated with purely hemispherical cups prompted further research for alternative geometries.

2.4.2 Peripheral self-locking cups

This design consists of a core hemispherical shape with an enhanced peripheral structure. Such cups are generally described as dual radius cups, enhanced periphery cups or peripheral self-locking (PSL) cups (Figure 5, Figure 6).

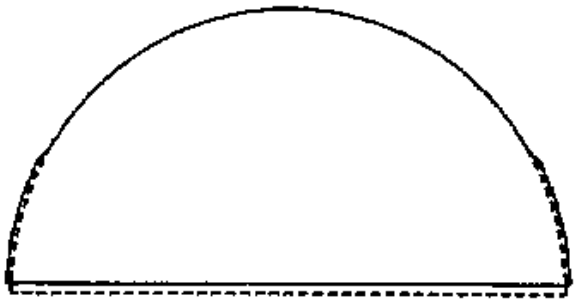

Figure 5: An illustration of a Peripheral Self-Locking design; the dashed line represents a hemisphere, the solid line represents the non-hemispheric geometry. The wider peripheral dimension can be seen in this model (Ries, Harbaugh et al, 1997).

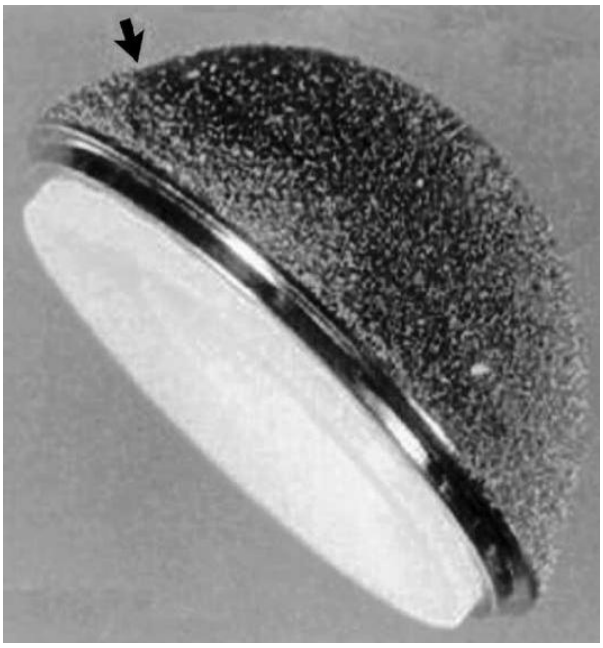

Figure 6: The titanium porous-coated acetabular cup (part of the Interseal acetabular component system); the arrow demonstrates the beginning of the enhanced periphery which offers an additional 2mm press-fit at the rim (Torga Spak and Stuchin, 2005).

The differences in geometry are meant to address some of the challenges observed with the purely hemispherical cups.

The importance of the compressive peripheral forces generated through press-fit between the periacetabular bone and the cup for initial stability has been emphasised (section 2.2). For this type of cup, reaming of the acetabulum typically employs the same diameter reamer as the hemispherical core diameter of the cup (line-to-line). The oversized periphery in these designs, therefore, is meant to ensure the generation of these forces as in an oversized purely hemispherical cup.

As the rest of the cup is hemispherical and designed to have the same diameter as the reamed cavity, the theoretical advantages over a hemispherical cup include better contact with the acetabular cavity, smaller polar gaps, a more uniform distribution of stresses and a lower incidence of periprosthetic fractures during cup insertion (Kim, Callaghan *et al.* 1995; Ries, Harbaugh *et al*. 1997).

Kim, Brown *et al* (1995) compared the seating of hemispherical and dual radius components in press-fit acetabular fixation. The dual radius cups possessed a peripheral enhancement of 1.3mm. Cadaveric models were used to recreate conditions of line-to-line hemispheric and dual radius cup fixation as well as oversized (by 1mm and 2mm) hemispheric and dual radius cup fixation. Dental impression material was used to assess the contact between cups and substrates. The results confirmed the preferential peripheral engagement of the press-fit cups, with both dual radius as well as oversized hemispherical cups showing better peripheral contact than line-to-line hemispherical cups. In addition, the line-to-line dual radius cup showed better peripheral contact than the 2mm oversized hemispherical cup. However, the polar contact shown by the line-to-line dual radius cup was only slightly greater than that achieved with the 2mm oversized hemispherical cup, and was not as good as the polar contact seen between the bone and the line-to-line hemispherical cup.

2.4.3 Geometry and initial stability

Except for its potential importance in the issues highlighted above (incidence of periprosthetic fractures, polar gaps, etc), cup geometry may be an important factor in terms of the initial (primary) stability achieved in the press-fit situation.

Various authors have tried to assess the primary stability of different press-fit cup geometries, but their research demonstrates certain limitations and results are mostly equivocal:

Adler *et al* (1992) performed a variety of mechanical tests in order to characterise the primary stability of press-fit cups. Eight cups were used (six commercially available and two modified ones) that did not include the exact cups that we focused on; the cups were all manufactured from different companies. They possessed various geometries, such as pure hemispheric, 'low profile' and enhanced periphery. The calculated coating area as well as hole-surface pattern also varied – any differences in primary stability could not therefore be attributed solely to geometry. Initial in vitro stability was assessed with tangential and rotatory failure testing. Two different techniques of cup insertion were used for the tests; manual impaction and impaction by the Instron, based on the forces generated during manual impaction.

The authors concluded that the most important factor for stability was 'the ability of the cups to engage around the outer periphery'; thus, the greatest initial stability was demonstrated by the hemispheric and enhanced cups over the 'low profile' designs that actually lack a complete rim. However, the study did not focus on assessing (any) differences in the insertion forces required for the different cup designs.

Ries, Harbaugh *et al* (1997) compared cup geometries in terms of strain distribution and press-fit stability. Various geometries were assessed – including oversized hemispheres, elliptical shapes, low profile and peripherally enhanced / dual radius designs. Finite element analysis was used to assess the magnitude and distribution of acetabular strains during cup insertion. For the mechanical testing, aluminium

models of the various cups were produced, to ensure that any differences in the results could be attributed to geometry. Pull-out and lever-out failure on a synthetic substrate was achieved as measure of primary stability. The stability results were taken into the context of the acetabular strain associated with each cup design, to identify the optimal geometry combining satisfactory stability and acceptable strains. Even though the oversized hemispheric cup geometry (press-fit 2mm) demonstrated superior lever-out stability, the results overall suggested that a non-hemispheric cup with a gradual transition from hemisphere at the dome to larger peripheral dimension may be advantageous in terms of combining satisfactory stability and acceptable strains. However, as with previous research, the study did not quantify any differences in insertion forces between the various cup designs.

Kuhn *et al* (1999) used an in vitro lever-out model to investigate primary stability as well as insertion forces for different hemispherical acetabular cups at different press-fit degrees. While insertion forces as well as primary stability, as expressed by lever-out failure values, increased with increasing press-fit values from 1mm to 2mm, no conclusions regarding cup geometry could be made as the cups differed on other parameters such as surface coating.

Macdonald *et al* (1999a) employed 3 modes of in vitro failure to assess primary stability, stating that these may be relevant to the way prostheses fail in vivo:

-failure in rotation

-lever-out failure (impingement or articulation forces in vivo)

-axial pull-out (pistoning in vivo).

Polyurethane foam, glass-fibre reinforced epoxide as well as cadaveric acetabula were used as the substrate materials. Four acetabular cups were tested; three were manufactured by different companies and employed different coating materials (sintered bead coating as opposed to compressed wire coating), while the fourth cup was an experimental cup with a solid surface grit-blasted finish and an enhanced peripheral rim. A universal materials testing machine was used for insertion of the

cups as well as to produce failure in the required mode. The stability, as expressed by the failure forces, moments and torques, increased with oversizing. Surprisingly, acetabular fractures were observed in some cases with a nominal press-fit of greater than 1mm. The experimental cup was significantly more secure in all substrates and most -but not all- modes of testing than the other cups. However, as with previous research, insertion forces for each cup design were not monitored.

Olory *et al* (2004) tested a large number (11) of different cups. Although various geometries were assessed, the cups differed in numerous respects – e.g. cups with screws and fins were also included. As such, any difference in initial stability could not be attributed solely to cup geometry. Impaction of the cup was done manually without any effort to assess the insertion forces, and the degree of (nominal) press-fit varied between cups; only one pull-out test was performed for every cup. Although an oversized (1mm press-fit) hemispheric design achieved marginally better results compared to the other ten designs, the findings were not statistically significant.

Schreiner *et al* (2007) performed an in vitro study with polyurethane foam as the bone analogue; lever-out failure was taken as a measure of primary stability, and insertion forces ranged up to 6000N. The emphasis, however, was placed on the influence of different cup surface treatments on the primary stability, with no alteration made to the geometry of the cups tested. Thus, a hemispherical press-fit cup design with a flattened pole was used. Smooth surfaces demonstrated significantly less stability than the rough surfaces.

2.4.4 Conclusion

In summary, there has not been a satisfactory volume of research assessing the impact of cup geometry on primary stability in vitro. Most studies have compared cups that differ in more than one parameter, so any observed differences could not be attributed only to geometry. Very little data exists on the insertion forces generated in vitro and on any impact that cup geometry may have on these forces.

The results are mostly inconclusive in relation to the difference the actual cup geometry makes.

3 Materials and Methods

This study compared the primary stability achieved in vitro by two commercially available press-fit uncemented acetabular cups. The stability was evaluated during pull-out and lever-out failure testing in two densities of synthetic bone substrate.

It had initially been decided to include failure in torsion as one of the modes of testing for the primary stability.

Despite multiple trials and amendments to the test rig, it proved impossible to achieve a satisfactory reproducible method of testing in vitro failure of the cup designs in this mode.

Given the limitations in terms of time, it was therefore decided to abandon the plan to include torsion and to proceed with only pull-out and lever-out failure testing as means of assessing in vitro primary stability for the purposes of this study.

3.1 Equipment

3.1.1 Acetabular cups

Two acetabular cup geometries (Trident, Stryker Ltd., UK) were evaluated: A Hemispheric (H) cup design and a Peripheral Self-Locking (PSL) cup design, which consisted of a hemispherical design with a 1.8mm enhanced peripheral structure (Figure 7). For testing, size 52 cups (nominally 52mm in diameter) were used. These had a threaded polar hole (Ø 7mm) for coupling with the cup introducer. Both cups were manufactured from a titanium alloy (6Al-4V ELI) with a porous-coated hydroxyapatite-treated surface.

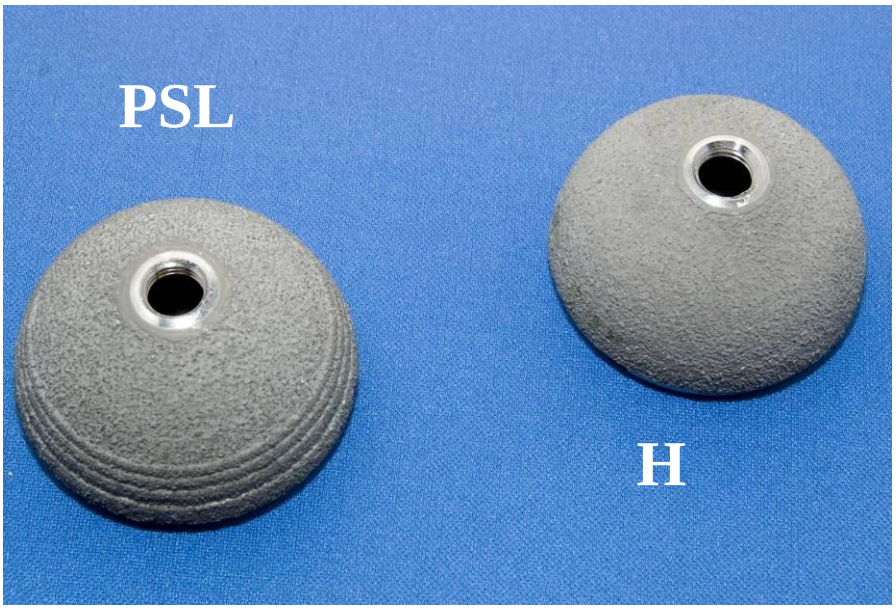

Figure 7: Illustration of the two cup designs tested. The Peripheral Self-Locking (PSL) cup with the peripheral enhancement is seen on the left and the Hemispherical cup (H) is seen on the right.

In terms of cup size, a nominal diameter of 52mm represents a commonly used size for arthroplasties in average-built adult patients (personal communication, Mr M Sarungi, Consultant Orthopaedic Surgeon).

For each design, four cups were available for testing, with a new cup used to test each density of bone substrate (0.22 g/cm^3 and 0.45 g/cm^3) and mode of failure (pull-out and lever-out).

3.1.2 Synthetic bone substrate

Polyethylene foam (Pedilin foam, Otto Bock, Austria) was used as a synthetic bone substrate (Adler *et al.* 1992; Litsky and Pophal, 1994; Pitto *et al.* 1997). The foam was prepared in cylinders of 1.5m in length, in accordance with the manufacturers' guidelines and in densities of 0.22g/cm^3 and 0.45g/cm^3. The selected densities mimic qualities of soft and hard cancellous bone respectively (Adler *et al*. 1992). Cylindrical blocks of radius 51mm and height 50mm were subsequently prepared from the initial cylinders.

To evaluate the modulus of elasticity of the substrate, uniaxial compression tests were performed on cylindrical subsamples of foam (Ø15.9mm, height 10.5mm) using a materials testing machine (Instron 5800R, Instron, UK). Ten samples of each density (0.22g/cm^3 and 0.45g/cm^3) were positioned between compression platens and loaded at a rate of 2.5mm/s (24%/s). Force and crosshead displacement were recorded and, along with measures of specimen length and cross–sectional area, were used to calculate stress and strain. The tangential modulus of elasticity was subsequently estimated by calculating the gradient of the most linear section of stress strain curve. The mean modulus of elasticity for low and high density samples was 77 ± 12 MPa and 211 ± 8 MPa, respectively. These results are within the range of values reported for cancellous bone (Li and Aspden, 1997).

3.1.3 Materials Testing Machine

A mechanical uniaxial materials testing machine (Instron 5800R, Instron, UK) was used to evaluate the press-fit stability of the two acetabular cup designs. The materials testing machine possessed a fixed upper crosshead and a moving lower crosshead. A 10kN load cell with an accuracy of 0.1% full scale (i.e. 10N) was incorporated within the fixed upper crosshead. The maximum displacement rate of the machine was 1000 mm/min with an accuracy of displacement of 10µm. Waverunner and Wavemaker Editor software (Instron, UK) were used to operate the materials testing machine under displacement control.

Acetabular cups were mounted in the Instron using a brass rod assembly (175mm length, Ø 19mm) attached by a polar screw thread (Ø 7mm). The proximal end of the assembly was secured to the load cell via a locating pin and locking nut (Figure 8). The assembly incorporated a universal joint attachment, 108mm superior to the upper surface of the acetabular cup, which was used for conducting lever-out tests (section 3.3.3.2).

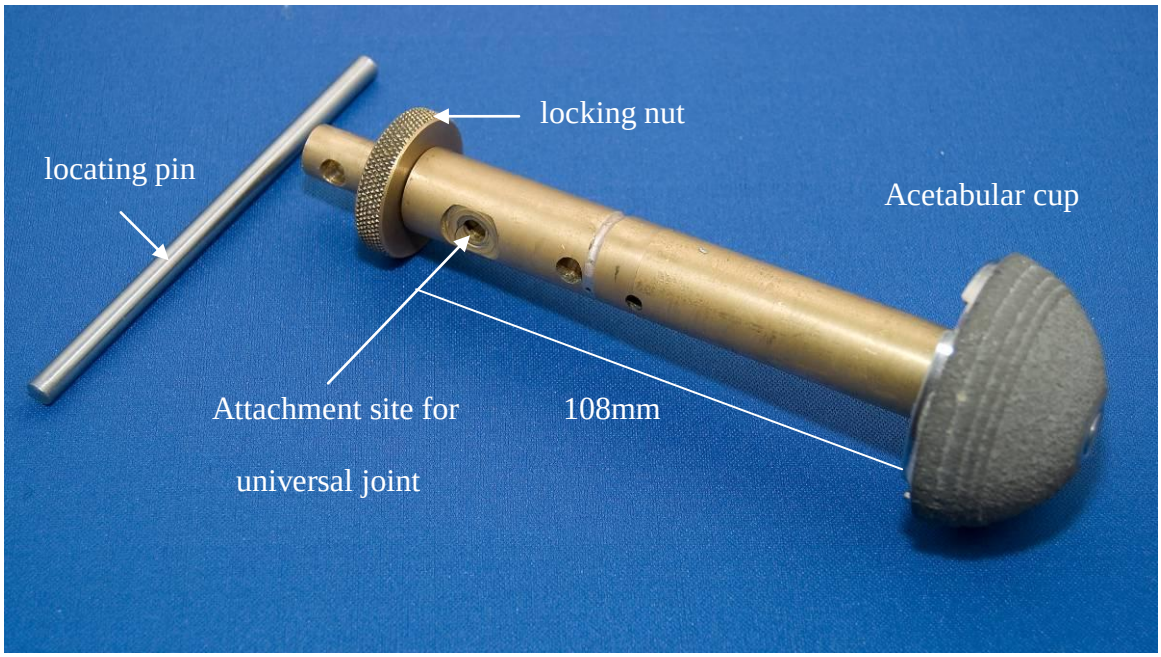

Figure 8: Illustration of the brass rod connecting assembly used to secure the cup to the load cell.

3.1.4 Test Rig

The press-fit stability of the acetabular cup designs was tested within a custom-made, aluminium test rig which was mounted on the lower crosshead of the materials testing machine (Figure 9, Figure 10). The test rig consisted of a large base plate (390mm x 330mm), a smaller square plate (120mm x 120mm) for mounting the bone substrate block and a height–adjustable low friction pulley system for lever-out testing. The bone substrate was firmly secured to the mounting plate via four 6mm screwed studs and two adjustable toggle clamps.

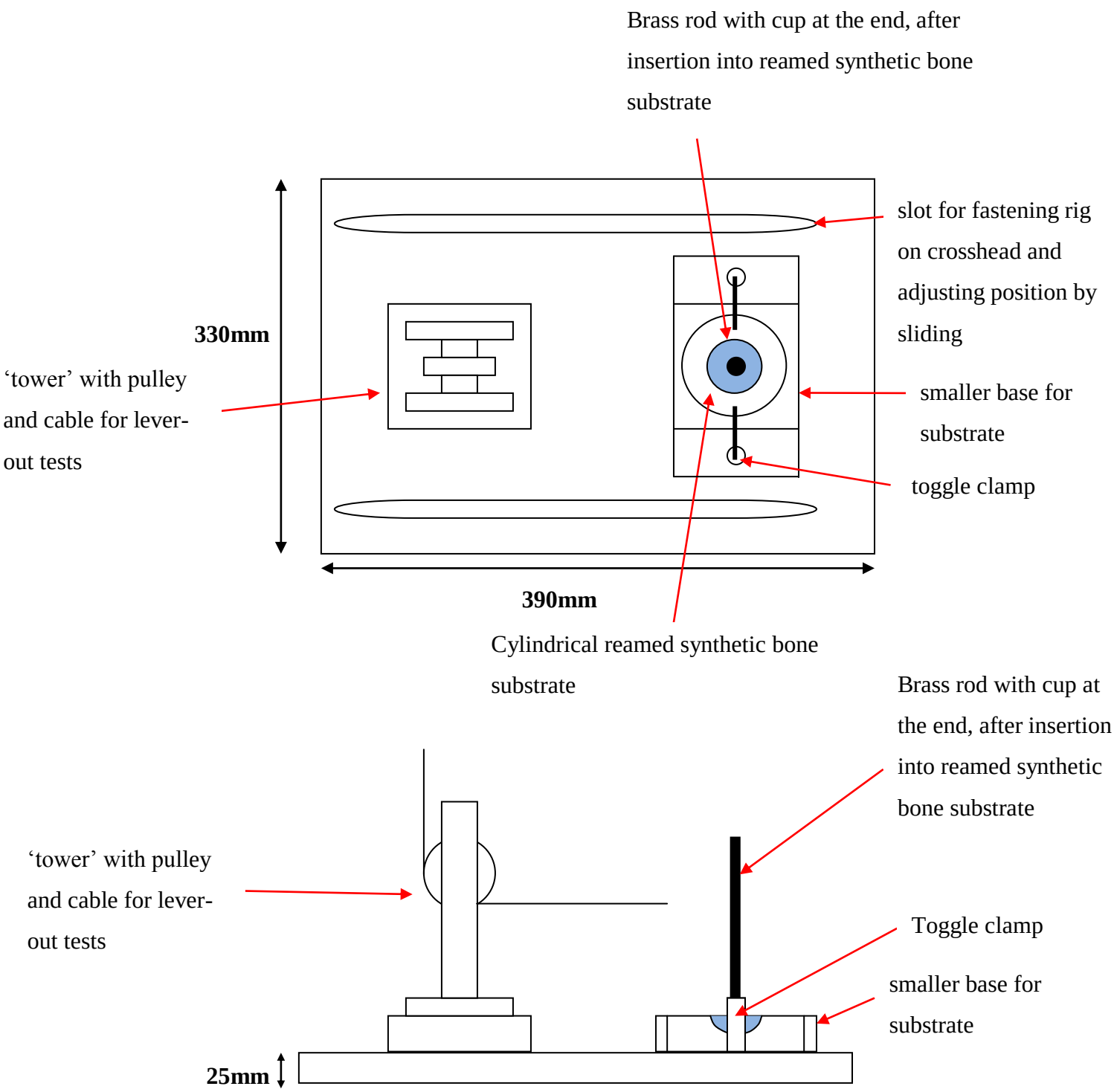

Figure 9: Illustration of the rig used for the testing of the press-fit stability of the Hemispheric and Peripheral Self-Locking cup (shown after cup insertion).

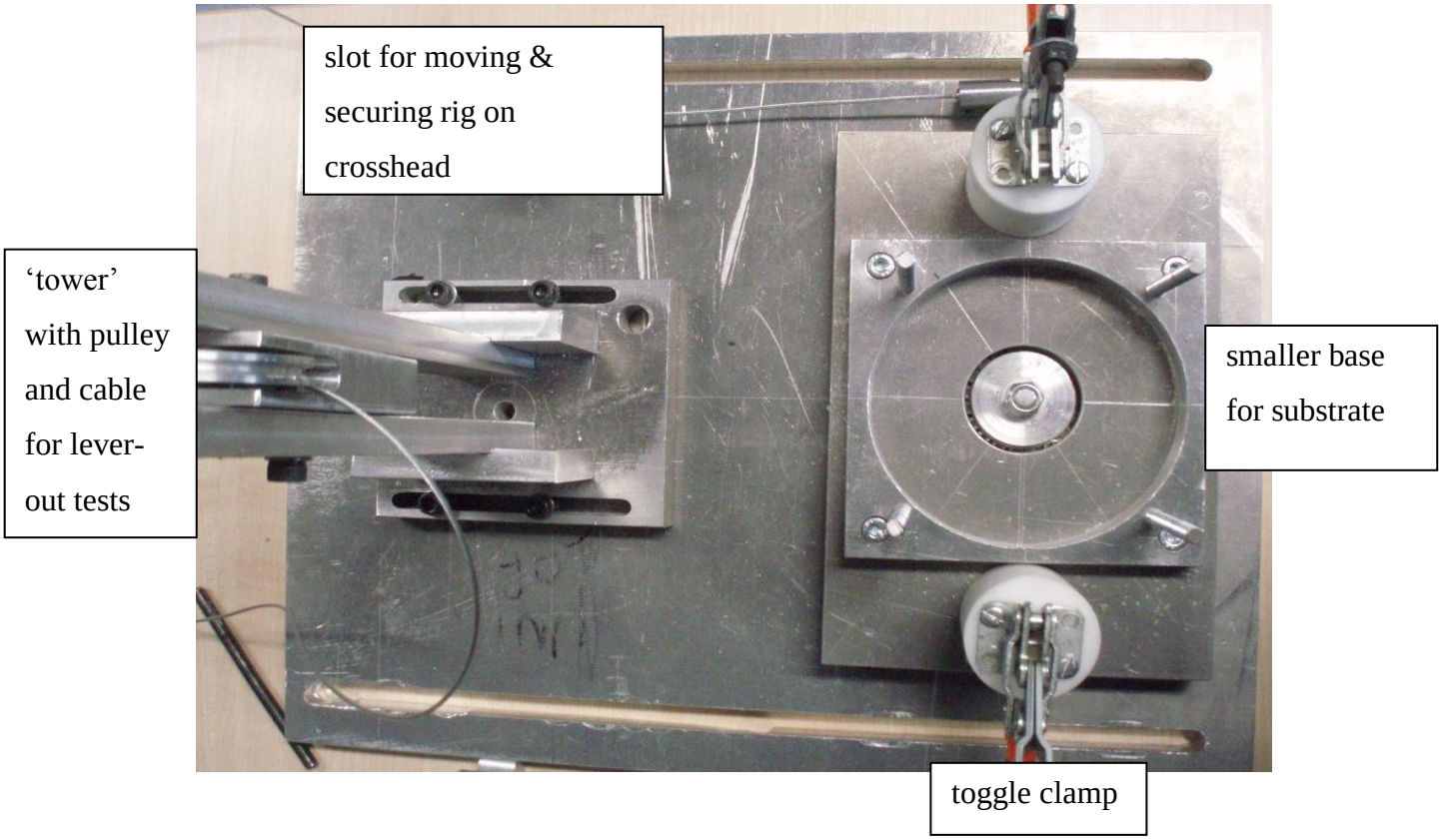

Figure 10: Illustration of the custom-made test rig used to evaluate the in vitro primary stability of the two acetabular cup designs.

3.2 Pilot Studies

3.2.1 Substrate Density

During pilot testing, unexpected discrepancies were observed in the force required to satisfactorily seat the acetabular cups, when using the same mode of seating, the same cup design and the same nominal substrate density. For example, to seat a 52mm Hemispheric acetabular cup satisfactorily (as confirmed visually) in 2 blocks of low density substrate, originating from the same cylindrical tube and reamed with the same reamer, forces of 1993N and 4042N were generated (nominal press-fit of 2mm). Similar discrepancies were observed for the high density substrate. Closer inspection of the substrate revealed that for a nominal given density, there was an appreciable difference in the weight of samples despite their similar dimensions.

Such disparity in substrate density may account for the variation in force required to successfully seat the same cup design into different substrate blocks.

Aims

The aim of this pilot study, therefore, was to assess variation in substrate density arising during the manufacturing process.

Methods

Polyethylene foam was prepared in cylinders, 102 mm in diameter and 1.5 m in length, as per the instructions of the manufacturing company (Pedilin foam, Otto Bock, Austria). The manufacturing process involved a two-part mixture which was left to cure, upright in the cylindrical tube. Once set, smaller cylindrical test blocks of radius 51mm and height 50mm were prepared from the initial cylinders.

Four cylindrical blocks were produced from the same cylindrical tube (nominal density 0.45 g/cm^3) and their position within the manufacturing tube (i.e. top / middle / bottom) recorded. In addition, further two blocks originating from the top and bottom of a manufacturing tube of nominal density 0.22 g/cm^3 were evaluated. Four cubic subsamples from the bottom surface of each block were acquired. The dimensions of each cubic subsample were measured to the nearest 0.01mm with a Vernier Calliper and the mass determined to the nearest 0.0001g with electronic scales. The density was subsequently calculated (mass / volume) for each of the four subsamples, and the average calculated and used to represent the density of each block.

Results

Table 2 demonstrates the variation in substrate density during the manufacturing process. Blocks located at the bottom of the manufacturing tube possessed higher densities than those located at the upper surface of the tube.

Table 2: Variation in substrate density and the effect of test block position within the manufacturing tube during curing.

Nominal density (g/cm^3)	Position in the manufacturing tube	Average measured density (g/cm^3)	Difference from nominal density (g/cm3)
0.45			
	top	0.43	-0.02
	upper half	0.44	-0.01
	lower half	0.44	-0.01
	bottom	0.45	0.05
0.22			
	top	0.22	-0.00
	bottom	0.23	0.01

Conclusions

Despite the small number of blocks tested, the results suggested that there was variation in the substrate density between blocks produced from the same manufacturing tube and that there was an association with the position of the block in the tube during curing. These findings were more marked in the higher density substrate (nominal density 0.45 g/cm^3). As a result, density was determined for each block and subsequently used as a covariate in later statistical analysis when found to correlate with the parameters of interest (section 3.4). In addition, the uppermost and bottom-most sections of the manufacturing tubes were discarded before producing the substrate blocks, in order to avoid extreme variations in density.

3.2.2 Reaming methods – cavity size

In the operating theatre, preparation of the acetabular cavities prior to cup insertion is achieved by reaming with conventional debris-retaining reamers provided by the manufacturers. The size of the reamers (expressed in their diameter in mm) is chosen depending on the size of the cup to be used and the degree of press-fit that the surgeon aims to achieve.

During reaming, the surgeon introduces the reamer into the acetabulum and reams until the destroyed cartilage is removed and cancellous bone is exposed in the acetabular cavity and the reamer edge is sufficiently covered around the acetabular rim. The accuracy of reaming in terms of width and depth of the resultant cavity is critical in uncemented arthroplasty; if there is excessive movement during reaming, the reamed acetabular cavity will be larger (wider) than intended, minimising the press-fit effect and leading to the generation of smaller peripheral compressive forces and unacceptable primary stability. If the reamer is not fully introduced into the acetabulum, the resulting reamed cavity will be too shallow. If the operating surgeon attempts to fully seat a cup into such a cavity, excessive periprosthetic strains may result in periprosthetic fractures. Alternatively, if the cup can be seated into the shallow cavity, not all of its outer coated periphery will interact with the substrate and this will lead to decreased press-fit effect. The aim of this pilot study was to determine a method of reaming bone substrate that was reliable and clinically relevant.

Aim

To establish a technique for reaming bone substrate cavities in vitro and to evaluate the accuracy and repeatability of reaming.

Methods

Substrate blocks were reamed in the workshop at the Bioengineering Unit of the University of Strathclyde using a standardised protocol. Commercially available cutting reamer edges were provided by the manufacturer (Figure 11).

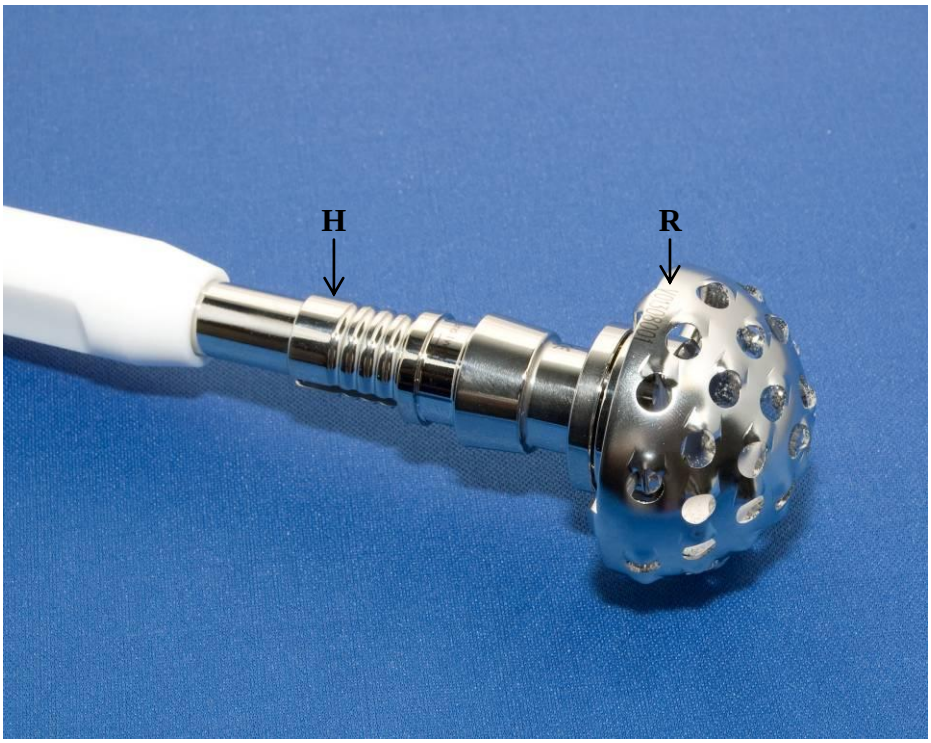

Figure 11: Illustration of the cutting reamer edge (R) mounted on the reamer handle (H).

A 50mm acetabular hemispherical cutting reamer edge was mounted on the reamer handle, which was secured to the tailstock of a lathe (Colchester Master 2500). The metal steady of the lathe was used to maintain centralisation and prevent undue movement of the cutting reamer edge (Figure 12). Once the bone substrate was centralised and fixed, the cutting edge of the reamer was manually advanced while the specimen rotated at 98 rpm to approximate the reaming speed used in the operating theatre (personal communication, Mr M Sarungi, Consultant Orthopaedic Surgeon).

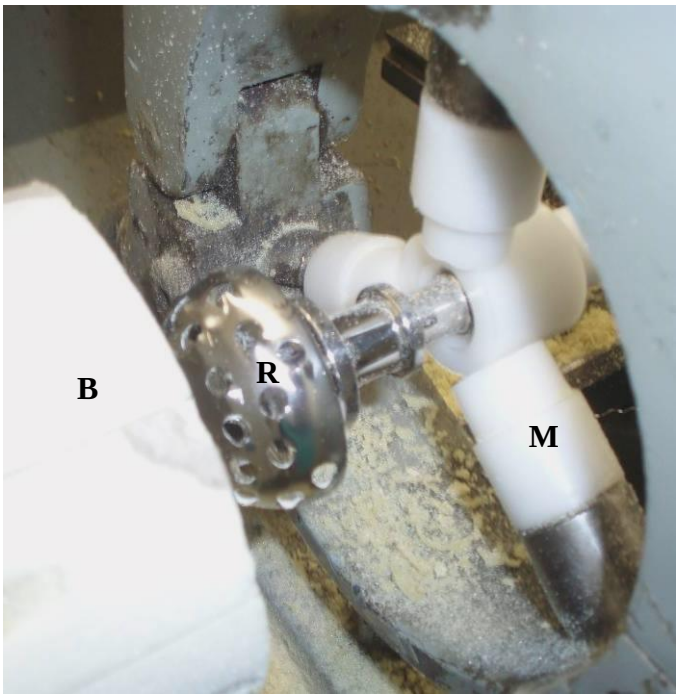

Figure 12: Illustration of the method used to centralise the reamer and limit undue movement. The cutting reamer (R) edge was mounted within a centralising mechanism (M) on the metal steady of the lathe and was advanced toward the bone substrate (B), which was rotating at 98 rpm.

A single operator (GA) performed all reaming. The tailstock handle of the lathe machine was used to manually introduce the reamer into the substrate block. The handle was calibrated in 0.1mm increments, with a complete revolution corresponding to a depth of 2.5mm (25 increments). .Five substrate blocks of nominal density 0.22 g/cm^3 and 5 substrate blocks of nominal density 0.45 g/cm^3 were reamed to a desired depth of 25mm. A standard depth gauge (resolution 0.1mm) was subsequently used to measure the depth of the cavity, while an optical Mitutoyo vision measuring machine (resolution of 2μm) was used to measure the diameter of the reamed cavities. Measurements were made in triplicate for each block and the average depth and diameter calculated. The bias and limits of agreement were used to investigate the magnitude of error in the reamed depth and width of substrate blocks.

Results

A summary of the errors involved in reaming is shown in Table 3. An average depth of 25.0 ± 0.3mm was achieved with reaming. The upper and lower limits of agreement for depth measurements were ±0.5mm, indicating that 95% of reamed cavities would fall between 24.5mm and 25.5mm.

The average diameter of the cavities was 48.7 ± 0.2 mm when a 50 mm proprietary reamer was employed. There was a systematic bias in diameter of -1.3mm, with 95% of reamed cavities having diameters between 48.4mm and 49.1mm.

Table 3: Errors in the diameter and depth of cavities created with a 50mm proprietary reamer in bone substrate. An a priori depth 25mm was used.

Block Number	Reamed Depth (mm)	Depth Error (mm)	Reamed Diameter (mm)	Diametral Error (mm)
1	25.5	0.5	48.64	-1.36
2	25.2	0.2	48.65	-1.35
3	24.9	-0.1	48.52	-1.48
4	25.2	0.2	48.62	-1.38
5	25.2	0.2	48.70	-1.30
6	24.8	-0.2	48.80	-1.20
7	24.9	-0.1	48.63	-1.37
8	24.7	-0.3	49.20	-0.80
9	24.7	-0.3	48.70	-1.30
10	24.8	-0.2	48.70	-1.30

Conclusions

The standardised reaming technique employed in the current study resulted in as average a cavity depth identical to that decided a priori. However, the upper and lower limits of agreement for depth measurements were 24.5mm and 25.5mm, indicating that blocks may be under– or over–reamed in terms of depth by 0.5mm. Based on the assumption that under-reaming for cavity depth would have a greater impact on the seating of acetabular cups than over-reaming, it was decided that an a

priori reaming depth of 26.5mm would be used for all subsequent tests in which a 52mm cup was to be employed (section 3.3.1). This depth would give each 52mm cup the opportunity to fully engage its coated periphery with the substrate (as cup diameter is 26mm). A cavity depth between 26mm and 27mm, therefore, was deemed acceptable for testing.

Although the reaming method employed in the current study resulted in cavities that were of appropriate depth, the technique resulted in cavity diameters that were substantially undersized (1.3 mm) than that expected for a 50mm proprietary reamer. Discrepancies between nominal reamer diameter and that of resultant cavities have been previously reported when handheld reaming was undertaken (Macdonald *et al.* 1999). However, in contrast to the current study, the diameter of the reamed cavities was noted to be greater than that of the proprietary cutter (Macdonald *et al.* 1999b). The reaming protocol used in the current study, however, did not employ a handheld reaming technique. Rather, cavities were reamed using a lathe in an attempt to minimise potential errors and produce cavities of precise dimensions. While it is possible that manufacturers may deliberately undersize reamers to account for the potential movement arising during manual reaming, the resultant discrepancy in diameter (1.3mm) noted in the current study would result in a substantial increase in press-fit parameters; if translated to the in vivo situation, this might have important clinical repercussions e.g. leading to generation of excessive periprosthetic forces during seating and increasing the risk of periprosthetic fractures, as already mentioned in this section.

Whilst we decided to accept this situation for the purposes of the study, future research evaluating the dimensions of cavities produced with manual reaming, would seem clinically relevant and appropriate.

3.2.3 Cup seating

In vivo, the insertion of the press-fit cup takes place manually. Following reaming, the surgeon introduces the cup into the cavity and impacts it using a mallet on the cup introducer, until the cup is deemed to be fully seated. Satisfactory insertion is confirmed visually by the periphery of the cup being flush with the outer surface of the acetabular cavity and also by the change in auditory pitch during the impact, once the cup is firmly seated in the cavity. It is not possible to exactly reproduce these conditions in vitro. The forces involved in satisfactory insertion of cups into acetabular cavities in vivo, are not precisely known.

Aims

To establish a repeatable method of cup insertion which would result in satisfactory seating.

Methods

Cups were seated using a uniaxial materials testing machine. Two approaches to seating were evaluated. Cup insertion under load control and cup insertion under displacement control.

Seating under Load Control

Based on previous work, the initial approach to seating cups was to use a given load, initially in the range of 2000N to 5000N (Adler *et al.* 1992; Baleani *et al.* 2001). For this approach, the Instron was used under load control and the various gains (PIDL) were established to gain a steady feedback control loop with the polyethylene foam.

Twelve reamed substrate blocks were used (8 with nominal density of 0.22 g/cm^3 and 4 with nominal density of 0.45 g/cm^3). A Hemispheric cup and a Peripheral Self-Locking cup were then inserted into the reamed cavities under load control. The

quality of cup seating was assessed visually and the peak force during the seating process was recorded and compared to the desired seating force.

Seating under Displacement Control

In the second approach to cup seating, the reamed depth of each substrate cavity was measured with a depth gauge (resolution 0.01mm). The uniaxial materials testing machine was then operated in displacement control i.e. a specific displacement, equal to the measured reamed depth, was requested. In theory, this would result in 'bottoming out' of the cup during insertion, and would be more representative of the intraoperative technique.

Eight reamed substrate cavities (4 of nominal density 0.22 g/cm^3 and 4 of nominal density 0.45 g/cm^3) were used. A Hemispheric cup and a Peripheral Self-Locking cup were inserted into the reamed cavities under displacement control. The quality of seating was assessed visually and the displacement during the seating process was recorded and compared to the desired value.

Results

The load control approach resulted in highly variable seating forces and consequently, the quality of seating, as confirmed visually, varied markedly (Table 4).

Insertion of the acetabular cups under displacement control, in contrast, consistently resulted in satisfactory visually confirmed seating of the cups (Table 5). The displacement produced exactly matched in each case the displacement requested from the machine.

Table 4: Insertion forces and quality of seating achieved with Hemispheric (H) and Peripheral-Self Locking (PSL) cups inserted via a materials testing machine operated under load control.

Substrate density (g/cm^3)	Cup Design	Nominal press-fit (mm)	Insertion force requested (N)	Seating force achieved (N)	Difference (%)	Quality of cup seating
0.22	PSL	1.8	2000	1513	-24	Incomplete
0.22	PSL	1.8	3000	2138	-29	Incomplete
0.22	PSL	1.8	4000	2929	-27	Satisfactory
0.22	PSL	1.8	4000	2551	-36	Satisfactory
0.22	H	2.0	3000	1795	-40	Incomplete
0.22	H	2.0	4000	1993	-50	Incomplete
0.22	H	2.0	4000	2470	-38	Incomplete
0.22	H	2.0	4000	4042	1	Satisfactory
0.45	PSL	1.8	6000	4800	-20	Incomplete
0.45	PSL	1.8	7000	5408	-23	Satisfactory
0.45	PSL	1.8	7000	5628	-20	Satisfactory
0.45	PSL	1.8	7000	6139	-12	Satisfactory

Table 5: Insertion forces and quality of seating achieved with Hemispheric (H) and Peripheral Self-Locking (PSL) cups inserted via a materials testing machine operated under displacement control.

Substrate density (g/cm^3)	Cup Design	Nominal press-fit (mm)	Reamed Depth (mm)	Displacement achieved (mm)	Seating force achieved (N)	Quality of cup seating
0.22	H	2.0	24.61	24.61	2211	Satisfactory
0.22	H	2.0	24.77	24.77	2760	Satisfactory
0.22	H	2.0	24.88	24.88	2367	Satisfactory
0.22	H	2.0	24.90	24.90	2173	Satisfactory
0.45	PSL	1.8	25.83	25.83	4510	Incomplete
0.45	PSL	1.8	26.05	26.05	5183	Satisfactory
0.45	PSL	1.8	26.20	26.20	3756	Satisfactory
0.45	PSL	1.8	26.60	26.60	3792	Satisfactory

Conclusions

The uniaxial materials testing machine was able to insert each cup to the depth measured during reaming on each occasion during pilot trials, when operated under displacement control. This method resulted in satisfactory seating as confirmed visually, with only the inner sleeve of the cup visible after insertion. This technique of cup insertion was therefore employed for future tests (section 3.3.2).

3.2.4 Press-fit parameters

The degree of press-fit is an important parameter in achieving satisfactory primary stability of the acetabular cup and biological fixation. For press-fit cup sizes of 52mm, a nominal press-fit value of 2 mm is the one most typically used in vivo, although smaller degrees of press-fit (such as 1mm) can also be employed when insertion proves difficult (Ries and Harbaugh, 1997; Kuhn *et al*. 1999; personal communication, Mr M Sarungi, Consultant Orthopaedic Surgeon). However, the exact forces required to seat acetabular cups using such parameters are unknown.

Aim

The aim of this pilot study, therefore, was to assess whether nominal press-fit values typically employed intraoperatively can be used in vitro given the 10kN limit of the load cell of the uniaxial materials testing machine.

Methods

Substrate blocks were prepared and reamed using the methods previously outlined (section 3.2.2). For low (0.22 gm/cm^3) and high (0.45 gm/cm^3) density substrates, cavities were initially reamed "line-to-line" for the Peripheral Self-Locking cup, resulting in a nominal press-fit of 1.8mm, and 2mm under-reamed in terms of core diameter for the Hemispheric cup, resulting in a nominal press-fit of 2mm. These nominal press-fit values are as recommended by the manufacturer (personal communication, Mr M Sarungi, Consultant Orthopaedic Surgeon). Six substrate

cavities of nominal density 0.22 gm/cm^3 and six substrate cavities of nominal density 0.45 gm/cm^3 were used. A Hemispheric cup and a Peripheral Self-Locking cup were inserted into the cavities under displacement control (section 3.2.3) and the quality of seating was assessed visually. The seating force generated was also recorded for each cup.

Results

Satisfactory seating of both cup designs was achieved with the nominal press-fit employed in the low density substrate. Seating forces were consistently below the upper 10kN limit of the load cell (Table 6). In high density substrate, however, satisfactory seating of the Peripheral Self-Locking design was not possible within the limits of the load cell (10kN) when a nominal 1.8mm press-fit was employed. Satisfactory seating was only possible when forces exceeded the rated capacity of the Instron load cell (Table 6).

However, satisfactory seating of the cups was achieved in high density substrate and within the capacity of the load cell, by using a smaller nominal press-fit value (Table 6). Similar degrees of press-fit have been employed for high density bone substrate in other studies (Adler *et al*. 1992).

Table 6: Force required to seat Hemispheric (H) and Peripheral Self-Locking (PSL) cups during pilot testing with various press-fits. Note the capacity limit of the Instron was 10kN.

Substrate density (g/cm^3)	Cup	Nominal press-fit	Seating force(N)	Quality of seating
0.22	H	2.0	2260	Satisfactory
	H	2.0	2211	Satisfactory
	H	2.0	2760	Satisfactory
	PSL	1.8	5183	Satisfactory
	PSL	1.8	3756	Satisfactory
	PSL	1.8	4510	Satisfactory
0.45	PSL	1.8	11800	Satisfactory
	PSL	1.8	12144	Satisfactory
	PSL	1.8	10568	Satisfactory
	PSL	0.8	6800	Satisfactory
	PSL	0.8	7700	Satisfactory
	PSL	0.8	7319	Satisfactory

Conclusions

In the current pilot study, an average force of approximately 3.5kN was required to satisfactorily seat both the Hemispheric and Peripheral Self-Locking designs in the low density substrate when press-fit values typically used in surgery (nominal press-fit of 2.0 mm and 1.8 mm, respectively) were employed.

In the high density substrate, however, satisfactory seating of the Peripheral Self-Locking design with the same press-fit value required a 3-fold greater force. While previous research has shown that an average force of approximately 3.7kN is typically required to seat acetabular cups in human bone, seating forces were shown to range from 1.0 kN to 8.9 kN when typical surgical press-fits were used (Fritsche *et al*. 2008).

In the current study, forces in excess of 10kN were noted with typical surgical press-fits. Such a magnitude of force would be likely to result in acetabular fractures (Kim, Callaghan *et al.* 1995) and consequently the press-fit values for seating Hemispheric and Peripheral Self-Locking cups in the high density substrate were reduced by under-reaming by 1mm for the Hemispheric cup and over-reaming by 1mm for the Peripheral Self-Locking cup (in terms of core diameter), giving nominal press-fit values of 1.0 and 0.8 mm respectively. Other studies employing high density artificial bone have made similar observations, reporting that similar modification in the degrees of press-fit was necessary to seat the acetabular components (Adler *et al*. 1992; Fritsche *et al* 2008).

Although suggestive that high density bone substrate may have a limited ecological validity, an alternative explanation underlying the relatively high force required to satisfactorily seat the cups in high density bone substrate in the current pilot study, may lie with the actual size of the cavity milled by the reamer. As demonstrated in section 3.2.2, the proprietary reamers used in the current study produced systematically undersized cavities. Based on pilot work (section 3.2.2), when using a 50mm reamer for a 52mm Hemispheric cup (nominal press-fit 2mm), the effective press-fit would be approximately 3.3 mm. This could account for the very high insertion forces required under these press-fit values for the high density bone substrate.

3.3 Testing Protocol

3.3.1 Preparation of the substrate cavities

Reaming was undertaken using a standardised set-up established during pilot testing (section 3.2.2). In brief, a modified lathe was used to introduce an appropriately sized commercially available hemispherical cutting reamer to the bone substrate. In light of the error associated with reaming during pilot work (section 3.2.2), cavities were reamed to a depth of 26.5mm to ensure that the 52mm cups (vertical depth 26mm) could be fully seated (Figure 13). In all cases, the upper edge of the reamer was visually flush with the surface of the bone substrate, as would be the case during surgery. All reaming was undertaken by a single operator (GA) and consistently produced cavities with no obvious visual ridging. Once completed, the depth of the cavity was measured to the nearest 0.01mm using a depth gauge and a digital calliper (Figure 14). Two measurements were performed and the average depth calculated.

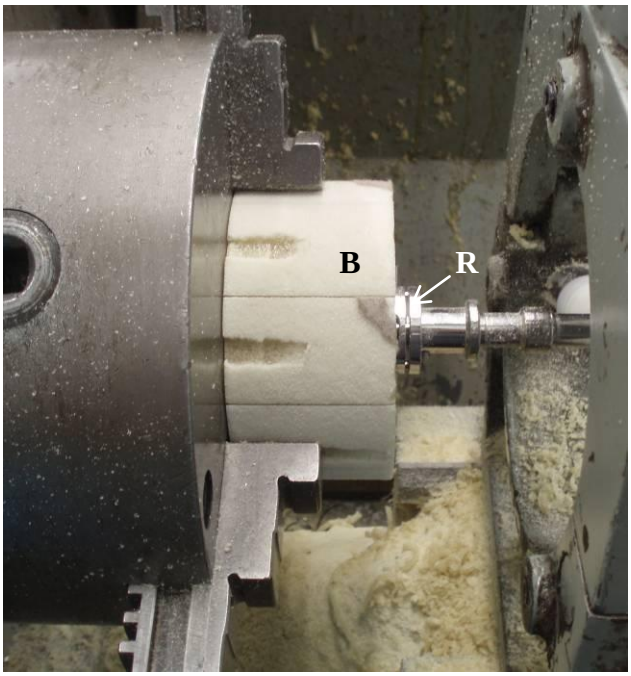

Figure 13: Cavities were reamed at the centre of the bone substrate to a depth of 26.5mm. The cutting reamer edge (R) was manually advanced to form a central cavity within the bone substrate (B).

Figure 14: Illustration of the measurement of the depth of the reamed cavity to be tested, using a depth gauge.

For the low density bone substrate, the cavities were reamed nominally "line-to-line" for the 52mm Peripheral Self-Locking cup (with a 52mm reamer) and nominally 2mm under-reamed (in terms of core diameter) for the 52mm Hemispheric cup (with a 50mm reamer) (section 3.2.4). The press-fit, therefore, would be provided by the enhanced periphery in the case of the Peripheral Self-Locking cup (nominal press-fit 1.8mm) and by the 2mm oversizing in the case of the Hemispheric cup (nominal press-fit of 2mm) (Ries and Harbaugh, 1997; Kuhn *et al*. 1999).

As shown in the pilot studies, in high density substrate, satisfactory seating of the Peripheral Self-Locking design was not possible within the limits of the load cell (10kN) when a nominal 1.8mm press-fit was employed. Satisfactory seating was only possible when forces exceeded the rated capacity of the Instron load cell. This led to an adjustment of the reaming parameters for the high density substrate (section 3.2.4). In the high density substrate, a 53mm reamer was used for the 52mm Peripheral Self-Locking cup (nominal press-fit of 0.8 mm) and a 51mm reamer for the 52mm Hemispheric cup (nominal press-fit of 1mm).

A summary of the reaming properties used for high and low density substrate is provided in Table 7.

Table 7: Reaming variables used to evaluate the press-fit stability of Hemispheric (H) and Peripheral Self-Locking (PSL) acetabular cup designs in high (0.45 g/cm^3) and low (0.22 g/cm^3) density bone substrate.

Nominal density (g/cm^3)	**52mm PSL cup**	**52mm H cup**
0.22		
Reaming diameter (mm)	52	50
Nominal press-fit (mm)	1.8	2
Reaming depth (mm)	26.5	26.5
0.45		
Reaming diameter (mm)	53	51
Nominal press-fit (mm)	0.8	1
Reaming depth (mm)	26.5	26.5

3.3.2 Cup seating

Cups were seated using the materials testing machine operated under displacement control. Each cup was displaced according to the measured depth of the reamed cavity (section 3.2.3) at a crosshead speed of 2.5 mm/s. The maximum force required during insertion was recorded on the Waverunner control panel which was then recorded manually on the test sheet (Appendix I – test protocol).

For the purposes of the current study, the cup was considered to be seated when:

1. The cup had been displaced by a distance equal to the measured reamed cavity depth, and

2. Visual inspection confirmed the entire hydroxyapatite-coated area of the cup was engaged within the bone substrate, such that only the inner cup sleeve was visible (Figure 15).

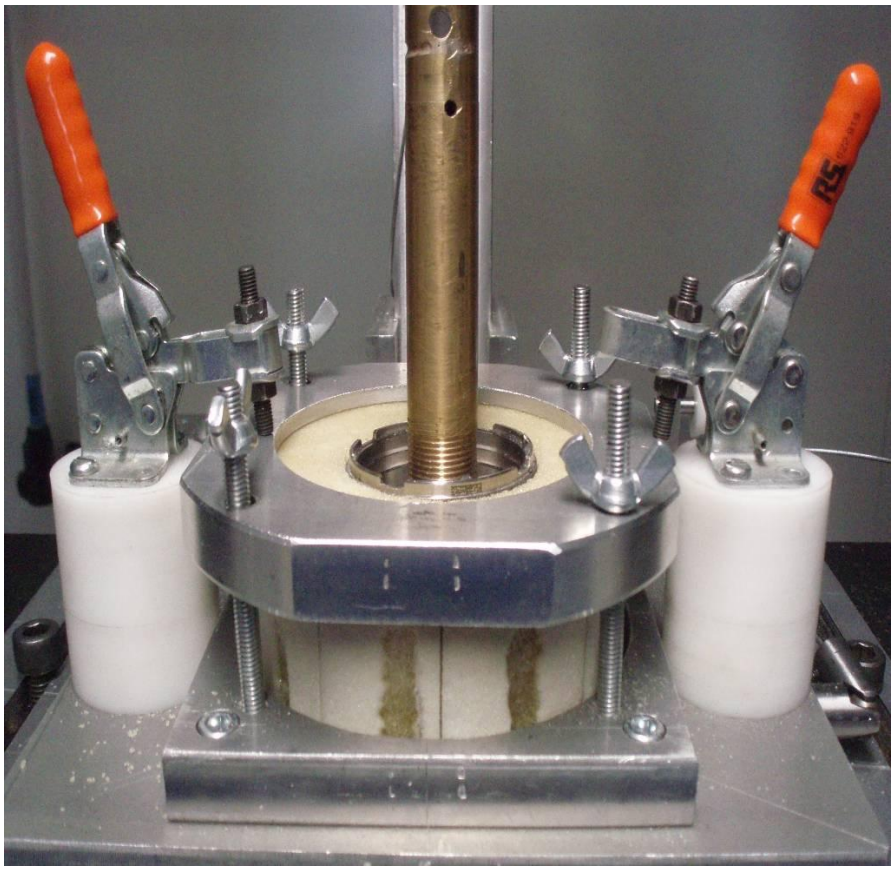

Figure 15: Illustration of the typical appearances following cup insertion into the reamed cavity. Note that only the rim of the inner sleeve was visible when the cup was seated, with the entire hydroxyapatite coated area of the cup engaged within the substrate.

3.3.3 Failure testing

Following seating, the stability of the acetabular cup was assessed by undertaking one of two failure tests; a pull–out or a lever–out test. The tests are widely used and thought to represent clinical modes of failure (Adler *et al.* 1992; Hadjari *et al.* 1994; Ries, Harbaugh *et al.*1997; Kuhn *et al.* 1999; Macdonald *et al.* 1999a; Olory *et al.* 2004; Wetzel *et al.* 2005; Schreiner *et al.* 2007). The order of failure testing was randomised for each substrate density.

3.3.3.1 Pull–out tests

Following seating, the cup was distracted from the reamed cavity at a rate of 2mm/s. Force and displacement data were recorded at 1kHz. Ten repetitions were performed for each cup design in both high and low density bone substrate, resulting in a total of 40 pull-out tests. At the end of each test, the cup was inspected for evidence of gross deformation or other damage. A new substrate block was used for each repetition and a new Peripheral Self-Locking or Hemispheric cup was used when the density of the substrate was altered.

3.3.3.2 Lever-out tests

Following seating of the acetabular cup, the brass rod was disconnected from the load cell and the test rig, including the entire substrate-cup-brass rod assembly was lowered. The distance from the upper surface of the bone substrate to the rim of the inner sleeve of the cup (subsequently referred to as 'seating height') was measured twice, to the nearest 0.01mm using a digital calliper, and the average was taken. Seating height was used to adjust the effective moment arm for the lever-out test (Figure 16). A steel cable was then attached to the load cell and connected, via an adjustable pulley system, to the universal joint of the brass rod. The test rig was then realigned to ensure an axial load was placed on the load cell and the height of the pulley carefully adjusted to ensure a horizontal axis between the pulley and brass rod under nominal 'no load'. The lower crosshead was then displaced inferiorly at the rate of 10mm/sec (Adler *et al*. 1992), resulting in lever-out failure. Force and displacement data were recorded at 1kHz.

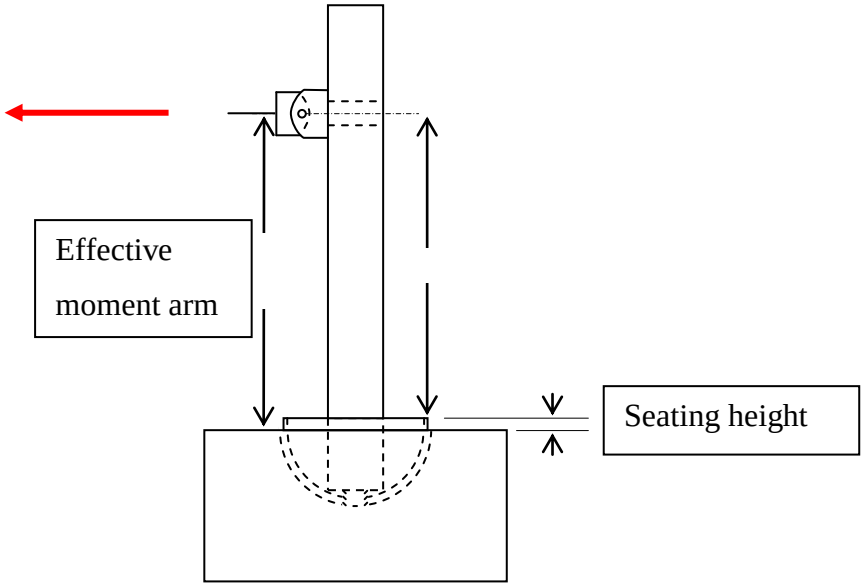

Figure 16: Illustration of the seating height measurement. Seating height was defined as the distance of the inner sleeve from the surface of the bone substrate.

Ten repetitions were performed for each cup design in both high and low density bone substrate, resulting in a total of 40 lever-out tests. As for the pull-out tests, at the end of each test, the cup was inspected for evidence of gross deformation or other damage. A new foam block was used for each repetition and a new Peripheral Self-Locking or Hemispheric cup was used when the density of the bone substrate was altered.

3.4 Data Reduction and Statistical Analysis

For each test, time, force and displacement data were stored as comma separated files. For pull-out tests, the pull-out force was also expressed as a percentage of the seating force, while for lever-out tests, the moment arm for each test was defined as the distance between the centre of the universal joint and the surface of the bone substrate and was calculated by adding the seating height to the known distance of the cup to the universal joint. The peak lever-out moment was calculated by multiplying the peak lever-out force by the respective moment arm.

All data were compiled into Microsoft Excel worksheets and analysed using the statistical software package SPSS 16.0 for Windows. Underlying assumptions of normality and of equality variance were assessed using the Kolmogorov-Smirnoff test and Levene's test, respectively (Statistics Solutions, Testing of Assumptions).

Since data were normally distributed, parameter means and standard deviations are presented. As press–fit parameters differed between high and low density bone substrate, separate analyses were conducted for tests performed in each bone substrate.

Correlation analysis (bivariate two-tailed Pearson correlation coefficient) was performed to assess the relation between substrate density and seating forces as well as pull-out and lever-out moments. Substrate density was taken as a covariate if found to correlate with these parameters. Between-cup differences in peak seating force, pull-out force and lever-out moment for each test were evaluated using independent samples t-tests or analysis of covariance (when density was taken as a covariate). In all tests, statistical significance was taken at $p<0.05$.

4 Results

4.1 Summary of tests

Excluding pilot work, a total of 84 tests were performed. Data from four tests were excluded from analysis due to incorrect implementation of the set protocol. On two occasions the holding rod was not securely fastened to the Instron load cell resulting in off-axis seating, while an incorrect reaming depth calculation took place on one occasion. In one case the Instron crosshead was moved in the wrong direction during pull-out testing resulting in over seating of the cup.

The remaining 80 tests were conducted according to the standardised protocol (Appendix I – test protocol).

In all cases the cup was inserted to the measured reaming depth and visual observation confirmed satisfactory seating (i.e. the coated area of the cup was completely engaged within the substrate). During pull-out and lever-out tests, complete failure was achieved in all cases (i.e. complete disengaging of the cup from the substrate). Thus, for each nominal density (0.22 g/cm^3 and 0.45 g/cm^3), 20 seating tests were performed for each cup, with 10 failure tests conducted for each mode of failure (Table 8).

Table 8: Number of tests performed for each cup in high and low density substrate.

	Hemispheric		**Peripheral Self-Locking**	
	Low density (0.22gm/cm^3)	High density (0.45gm/cm^3)	Low density (0.22gm/cm^3)	High density (0.45gm/cm^3)
Pull-out	10	10	10	10
Lever-out	10	10	10	10

4.2 Low density substrate

There was no statistically significant difference in the substrate density used to test the 2 cup designs (Table 9) .

4.2.1 Seating forces

The mean peak seating force for the Peripheral Self-Locking cup was 14% higher than for the Hemispheric cup. This difference was not statistically significant (p=0.104, Table 9). Substrate density was not significantly correlated with seating force.

Table 9: Mean (SD) substrate density and peak seating forces for Peripheral Self-Locking (PSL) and Hemispheric (H) cups in low density substrate.

	PSL	**H**	**p value**
Sample size	20	20	
Substrate density (g/cm^3)	0.228(0.01)	0.227(0.01)	0.605
Peak seating force (N)	4649(1114)	4078(1055)	0.104

4.2.2 Pull-out tests

The mean pull-out force for the Peripheral Self-Locking cup was 5.8% greater than for the Hemispheric cup. This difference was not statistically significant (p=0.171, Table 10). Substrate density was not significantly correlated with pull-out force.

Table 10: Mean (SD) pull-out forces for Peripheral Self-Locking (PSL) and Hemispheric (H) cups in low density bone substrate.

	PSL	H	p value
Sample size	10	10	
Peak pull-out force (N)	707 (50)	668 (72)	0.171
Pull-out force/seating force (%)	16.58 (1.80)	17.50 (2.15)	0.315

4.2.3 Lever-out tests

The mean lever-out moment for the Peripheral Self-Locking cup was 12.5% greater than for the Hemispheric cup. This difference was not statistically significant (p=0.087, Table 11). Substrate density was not significantly correlated with lever-out moments.

Table 11: Mean (SD) peak lever-out forces and moments for Peripheral Self-Locking (PSL) and Hemispheric (H) cups in low density bone substrate.

	PSL	H	p value
Sample size	10	10	
Peak lever-out force (N)	148 (19)	131 (22)	0.082
Peak lever-out moment (Nm)	16.2 (2.0)	14.4 (2.5)	0.087

4.3 High density substrate

There was no statistically significant difference in the substrate density used to test the 2 cup designs (Table 12).

4.3.1 Seating force

The mean peak seating force for the Peripheral Self-Locking cup was 25 % higher than for the Hemispheric cup. This difference was statistically significant (p=0.006, Table 12). In contrast to findings in low density substrate, substrate density was significantly correlated with seating force and was taken as covariate in the statistical analysis.

Table 12: Mean (SD) peak seating forces for Peripheral Self-Locking (PSL) and Hemispheric (H) cups in high density substrate.

	PSL	**H**	**p value**
Sample size	20	20	
Substrate density (g/cm^3)	0.467 (0.042)	0.463 (0.048)	0.803
Peak seating force (N)	7858 (2383)	6264 (1535)	0.006*

* Indicates statistically significant difference ($p<0.05$)

4.3.2 Pull-out tests

The mean pull-out force for the Peripheral Self-Locking cup was 8% less than for the Hemispheric cup. This difference was not statistically significant (p=0.154, Table 13). Substrate density was significantly correlated with pull-out force and was subsequently taken as covariate in the statistical analysis.

The stability ratio of pull-out force to seating force was significantly lower for the Peripheral Self-Locking cup compared to the Hemispheric cup (22% to 29%, p=0.000, Table 13).

Table 13: Mean (SD) pull-out forces for Peripheral Self-Locking (PSL) and Hemispheric (H) cups in high density bone substrate.

	PSL	**H**	**p value**
Sample size	10	10	
Peak pull-out force (N)	1424 (338)	1553 (429)	0.154
Pull-out force/seating force (%)	22.37 (2.11)	29.34 (2.44)	<0.001*

* Indicates statistically significant difference (p<0.05)

4.3.3 Lever-out tests

The mean lever-out moment for the Peripheral Self-Locking cup was 7% greater than for the Hemispheric cup. This difference was not statistically significant (p=0.574, Table 14). Substrate density correlated with the lever-out moment and was taken as covariate for statistical analysis.

Table 14: Mean (SD) peak lever-out forces and moments for Peripheral Self-Locking (PSL) and Hemispheric (H) cups in high density bone substrate.

	PSL	**H**	**p value**
Sample size	10	10	
Peak lever-out force (N)	370 (67)	342 (56)	0.325
Peak lever-out moment (Nm)	39.8 (7.0)	37.2 (5.4)	0.574

The raw data of the results are given at the end of the thesis (Appendix II – the raw data).

5 Discussion

The current study aimed to evaluate the primary stability of two acetabular cup designs in vitro and assess the behaviour of the cups in terms of the force required to achieve satisfactory seating in the synthetic bone substrate. Therefore the following research questions were addressed:

RQ1. ***Are there any differences in the peak force and moment required to produce failure in pull-out and lever-out tests between the Hemispheric and the Peripheral-Self Locking cup designs?***

RQ2. ***Does cup geometry affect the force required to seat the acetabular component?***

A synthetic bone substrate (polyethylene foam) was milled using a commercially available reamer and a materials testing machine was used to measure the peak pull-out forces and lever-out moments for each design following cup insertion. These forces and moments were used as measures of primary stability.

5.1 Preparation of the substrate cavities

The principal manufacturers' recommendation for the degree of press-fit in uncemented hip arthroplasty was to aim for a 2mm under-ream in terms of core diameter for the Hemispheric cup (nominal press-fit 2mm) and a line-to-line ream for the Peripheral Self-Locking cup (nominal press-fit 1.8mm) (personal communication, Mr M Sarungi, Consultant Orthopaedic Surgeon ref OP technique from Stryker). The pilot studies demonstrated that full seating of both cups required forces in excess of 10kN when high density substrate was used (section 3.2.4). The degree of under-reaming, therefore, was changed for the high density substrate to ensure satisfactory seating within the safety limit of the material testing machine. A 1mm under-ream was used for the Hemispheric cup (nominal press-fit 1mm) and a

1mm *over-ream* was used for the Peripheral Self-Locking cup (nominal press-fit 0.8mm).

There is anecdotal evidence to suggest that surgeons find it physically difficult to insert these cups in younger patients when following the original manufacturers' recommendation for reaming. Following our findings, the manufacturers have changed the relevant sections in the official surgical technique booklets to include the degree of under/over-reaming we have used for the high density substrate (personal communication, Mr M Sarungi, Consultant Orthopaedic Surgeon). The pilot study evaluating reaming properties provided results that may, in part, explain these high insertion forces. The reamer provided by the manufacturer resulted in cavity diameters that were substantially undersized (e.g. by 1.3 mm, when a 50mm reamer was used) than expected.

In other studies where handheld reaming was employed, the diameter of the reamed cavities was noted to be *greater* than that of the proprietary cutter (Macdonald *et al.* 1999b). The reaming protocol used in the current study employed a lathe in an attempt to minimise potential errors and to produce cavities of precise dimensions, and in this respect was an artificial situation compared to the in vivo conditions. It is possible that manufacturers may have deliberately undersized reamers to account for the potential movement arising during manual reaming. This would aim to prevent over-reaming in terms of core diameter and therefore help to maintain the press-fit effect and initial stability. In any case, the actual press-fit effect generated in our pilot studies is greater by 1.3mm than the nominal one. This would be associated with higher insertion forces, especially in the denser substrate.

5.2 Cup seating

The pilot studies demonstrated that a cup seating technique employing displacement control mode rather than a load control mode for the uniaxial materials testing machine gave more reproducible results in our setting.

The two cups behaved differently in terms of seating forces. In the current study there was no statistically significant difference in the seating force required to satisfactorily insert each cup design in low density substrate. In high density substrate, however, the Hemispheric cup required a 20% lower seating force ($p<0.05$) yet achieved the same level of primary stability as the Peripheral Self-Locking cup.

The exact force needed to insert a cup satisfactorily in an appropriately reamed acetabular cavity in vivo is currently not known. The seating forces generated in this study, therefore, can only be compared to corresponding values estimated from other in vitro studies. The majority of studies have not reported information about the magnitude of the force required to seat the acetabular component, nor described the exact method of seating or defined the adequacy of seating. Of the few studies that have quantified seating forces with similar press-fit values (0mm up to 2mm) and substrate densities (0.2 g/cm^3 and 0.5 g/cm^3), two have reported a range of 1500N – 5000N with a variety of uncemented cups that included purely hemispheric as well as peripherally-enhanced designs (Adler *et al.* 1992, Baleani *et al.* 2001). The range of seating forces generated in the current study (4078N – 7858N) is higher. There are at least two possible explanations for the apparent discrepancy. Firstly, while the cited studies have employed similar substrates (polyethylene foam and polyurethane foam) and comparable press-fits, certain cup designs were reported to be incompletely seated with the forces used (Adler *et al.* 1992). In comparison, satisfactory seating was achieved in all tests in this study, although higher forces were required. Secondly, the current study observed a discrepancy between the expected and actual width of the cavities reamed with commercially available reamers. The cavities produced in the current study were smaller than expected for the nominal size of

reamer used (section3.2.2). Thus, the effective press-fit used in the current study was likely to be approximately 1.3mm greater than the nominal press-fit. Adler *et al* and Baleani *et al* do not mention a similar issue; theoretically at least, a cavity under-reamed by 2mm in terms of core diameter in our setting would be smaller than a similarly under-reamed cavity in these two studies therefore for a satisfactorily seated cup, the forces generated would be higher in this study.

These observations may have important clinical implications.

Overall, the results are favourable for the Hemispheric cup: the same primary stability could be achieved with less force required during insertion. When the operating surgeon tries to achieve higher seating forces, as in the case of the Peripheral Self-Locking cup, there is a higher risk of acetabular fracture during insertion.

The findings of the current study also emphasise the importance of substrate density in seating of the implant. As expected, the high density substrate is associated with higher insertion forces (range 6264 – 7858N) compared to the low density substrate (range 4078 – 4649N). If this is translated clinically, it would be more difficult to seat an uncemented cup in a younger patient's reamed acetabular cavity, as their bone density is higher (Wheeless Textbook of Orthopaedics). As uncemented arthroplasties are procedures that are generally favoured for younger patients, it becomes apparent that extra vigilance is required during cup insertion to avoid acetabular fractures. If the guidelines for an under-ream of 2mm for the Hemispheric cup or line-to-line for the Peripheral Self-Locking cup are followed, the required seating forces could be too high. This may lead to incomplete seating, component malposition or acetabular fractures; any of these represents a significant adverse event for the patient.

5.3 Failure testing

The two cup designs behaved similarly during failure testing and did not demonstrate a statistically significant difference in the primary stability achieved in vitro as assessed by the peak forces and moments occurring during pull-out and lever-out testing. This was true for both high and low density substrates.

The magnitude of pull-out forces in our series (668N – 1553 N) is comparable to the range of failure values (680N – 2009 N) reported in the literature (Ries, Harbaugh *et al.* 1997; Macdonald *et al.* 1999a). Similarly, the magnitude of the lever-out moments resulting in failure in the current study (14.4Nm - 39.8 Nm) is within the wide range (5Nm – 50.8 Nm) reported in the literature (Adler *et al.* 1992; Ries, Harbaugh *et al.* 1997; Kuhn *et al.* 1999; Macdonald *et al.* 1999a; Olory *et al.* 2004; Wetzel *et al.* 2005).

Few studies have compared the primary stability of different cup designs in vitro (Ries, Harbaugh *et al.* 1997; Macdonald *et al.* 1999a). One study concluded that a non-hemispheric cup with a *gradual* transition from a hemisphere at the dome to a larger peripheral dimension provided the optimum balance in terms of peripheral strains, implant stability and acetabular deformation (Ries, Harbaugh *et al.* 1997). Another study concluded that an experimental cup (full hemispheric form with a rim of cylindrical section with enhanced fixation) was superior to the other cups tested (which included hemispheric designs as well as more conventional enhanced periphery designs) in lever-out and pull-out stability but not rotational failure (Macdonald *et al.* 1999a). The findings of the current study, however, suggest that there is no significant difference in the primary pull-out and lever out stability of Hemispheric and PSL designs.

Long term clinical evidence comparing the survivorship of these 2 cups (and therefore indirectly assessing primary stability achieved in vivo) is required.

5.4 Limitations

There are several limitations in this study which should be taken into consideration. Firstly, this study evaluated the primary stability of the designs by evaluating failure during pull-out and lever out testing. The clinical importance of failure by pull-out and lever-out mechanisms is questionable. While authors have proposed scenarios by which pull-out and lever-out failure could be relevant to situations *in vivo* (Macdonald *et al.* 1999a), others consider failure by torsion as a more clinically relevant predictor of in vivo primary stability and outcome (Adler *et al.* 1992; Baleani *et al.* 2001; Hadjari *et al.* 1994; Macdonald *et al.* 1999a). The current study did not assess torsional stability (section 3).

Inclusion of a low friction bearing within the experimental apparatus, however, would allow for such tests to be undertaken and is recommended for future studies.

While pilot work confirmed that the modulus of elasticity of the low and high density synthetic substrate was within the range of values reported for cancellous bone (section 3.1.2), it is unlikely the substrate would have an identical viscoelastic response as bone during cup insertion in vivo. Moreover, stability was assessed immediately after cup insertion, and the effect of bone remodelling that would occur in vivo is not taken into consideration here.

The degrees of press-fit quoted in the current study represent nominal values. As observed during pilot testing, it is likely that nominal press-fits are lower than those actually tested, due to undersizing of reaming components (section 3.2.2). It is recommended that future research establish accurate diameters/profiles of cups and reamed cavities. Techniques, such as laser scanning, which was not available for this research, may provide one avenue for such work.

The number of tests performed (10 repetitions for each cup design for each mode of failure in each of the substrate densities) represents a small sample size and as such it adversely affects the statistical power of the study.

Nonetheless, this in vitro study, in which primary stability of two cup designs was evaluated during pull-out and lever-out testing, represents an important first step in evaluating the effect of cup geometry on implant performance. While the findings of the current investigation suggest that a hemispheric design may be preferable to a peripheral self-locking design due to its lower seating force in high density bone substrate, further research incorporating long-term clinical data is required to fully appreciate the benefit of the two acetabular cup designs.

6 Conclusions

This study has produced results that may have important clinical relevance and has also highlighted issues for further consideration.

6.1 Project aims and findings

The following project aims were achieved in order to address the research questions:

- A test rig was successfully designed and manufactured to facilitate the pull-out and lever-out failure tests.
- A suitable synthetic bone substrate was identified and its properties assessed to confirm that it was an appropriate analogue for bone.
- A reproducible method of substrate reaming and cup insertion was developed.
- A standardised protocol was used to quantify insertion forces and measure pull-out and lever-out forces and moments required to disengage the cup from the substrate. These were used to define primary in-vitro stability.

The research questions were answered through the tests performed:

- There was no significant difference in the in vitro primary stability of the Hemispheric cup and the Peripheral Self-Locking cup, as assessed by pull-out and lever-out tests, in either low density or high density substrate.
- In the low density substrate, seating forces for both cup geometries were found to be similar.
- In the high density substrate, the seating force required to fully insert the Peripheral Self-Locking cup was found to be significantly higher than for the Hemispheric cup.

In addition, the following observations were also made:

- For the reamers that were employed in the current study, the diameter of the reamed cavities was consistently less than that expected.
- It was not possible to insert either cup geometry into the high density substrate using the manufacturers' original recommendations for press-fit; these parameters had to be revised.

6.2 Clinical relevance

These results may have the following clinical relevance:

- In higher density bone, the Hemispheric cup may be favourable to the Peripheral Self-Locking cup design as, in our setting, it achieved the same in-vitro stability but required less insertion force.
- Since uncemented hip arthroplasty is generally favoured in younger patients who have higher density bone, the implication of these results (clinical and financial) may be significant.
- The disparity between actual and expected diameter of reamed cavities in this study may be due to deliberate undersizing of the components by the manufacturers to avoid over-reaming. It may partly explain why it was not possible to insert either cup into the high density substrate using the manufacturers' original recommendations for reaming. Anecdotal clinical evidence supports this finding.

6.3 Future work

Future work should address the following issues in order to achieve a greater correlation with what really happens in vivo:

- A more accurate and representative substrate could be validated and used to assess the parameters tested here; actual human bone could be a choice if varying material density was accounted for.
- Any subsequent work should include a greater sample size to the one used for this study (i.e. more tests) as a way of boosting statistical significance and limiting the inherent sampling error.
- Work could be directed in quantifying the actual insertion forces used in the operating theatre and reproduce them more realistically in vitro, e.g. insertion forces applied in short impulses to mimic the 'hammering' technique in the operating theatre.
- A mode of failure testing should be used that is more clinically relevant to the complex processes that happen in vivo e.g. a combination of torsion and lever-out.
- Further investigation into the discrepancies between actual and expected reamed cavity profiles should be considered.

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8 Appendix I – test protocol

Date:

Test: pull-out / lever-out

Substrate:0.22 g/cm^3 or 0.45g/cm^3

Batch number/date made: Block number:

Type of cup: PSL / hemispheric Cup serial number:

Confirm rig complete with lever-out equipment if necessary ☐

If Waverunner not running open Waverunner. ☐

Check display readouts correct (track extension, track load, max load, min load, max ext) ☐

Filename:…….…… e.g. PSL/P1/22/1/12-4-8

cup type, PSL or H

*test, P1 for push-in and **P2 for pull-out**, L1 for push-in and L2 for lever-out*

22 for soft, 45 for hard –

block number

date

Confirm cup as 52mm☐

Reamed with: 50mm(hemi,soft foam) 51mm(hemi,hard foam)

52mm(PSL,soft foam) 53mm(PSL,hard foam)

Depth of cavity: ……mm (A) (aiming for 26.5mm when reaming)

Width of cavity:……..mm

Attached brass connector bar and cup to load cell ☐

Calibrate load cell ☐

Confirm in extension control ☐

Place rig on instron surface, with block in situ ☐

Drive cup to foam edge, to contact load up to -5N ☐

Reset gauge length ☐

Drive Xhead up to centralise cup to contact load of <10N ☐

Pin out and tighten collar if lever – out to follow ☐
☐

Secure rig with screws then clamp foam block into place ☐

Current displacement ……. mm (B)

Calculate relative displacement still required (A-B)
=……..……..……mm (C)

Calculate duration (C/2.5) in seconds=……sec

Rate:2.5 mm/sec

Check block loop set to finish at end of test ☐

Open Wavemaker Editor and "push in file"; Set file name for output……..……

Check data collection is 0.1 kHz ☐

Save file and start Waverunner ☐

Check load cell limits enabled @ –8000N ☐

Run test ☐

Impaction: peak force reached:…….……N

Maximum displacement achieved……..mm

Quality of seating as seen:……

THEN, IF PULL-OUT:

Filename:……..……..e.g. PSL/P1/22/1/12-4-8

cup type, PSL or H

*test, P1 for push-in and **P2 for pull-out**, L1 for push-in and L2 for lever-out*

22 for soft, 45 for hard –

block number

date

Open Wavemaker Editor with "pull out file" ☐

Check block loop set to finish at end of test ☐

Check waveform is relative ramp of (positive) displacement of 5mm at 2mm/sec for 2.5sec ☐

Set file name for output ……

Check data collection is 1 kHz ☐

Save file and start Waverunner ☐

Starting load ……N

Check load cell limits enabled @ +8000N ☐

Run test ☐

Stop test when cup has pulled out ☐

peak force:……N

OR, IF LEVER-OUT:

Filename:……..……..e.g. PSL/P1/22/1/12-4-8

cup type, PSL or H

*test, P1 for push-in and P2 for pull-out, L1 for push-in and **L2 for lever-out***

22 for soft, 45 for hard –

block number *date*

Basic lever arm =……m A

Can rod be disconnected from load cell YES / NO

If NO (due to high residual loads) reduce load, then disconnect rod ☐

Drive X head down ☐

Connect pulley cable to brass rod and load cell ☐

Align rig and pulley to achieve axes vertical to load cell, horizontal to rod ☐

Secure rig with screws ☐

Measure distance from foam surface to cup edge:……mm.…… m B

Open Wavemaker Editor with "lever out file" ☐

Check block loop set to finish at end of test ☐

Check waveform is relative ramp of (positive) displacement of 25 mm at 10mm/s ☐

Set file name for output ……

Check data collection is 1 kHz ☐

Save file and start Waverunner ☐

Check load cell limits enabled @ +8000N ☐

Run test ☐

peak force:…….N

Lever arm = A + B

Lever-out moment: force * lever-arm=……*……..=…….Nm

9 Appendix II – the raw data

9.1 Low density Pull-out

PSL Push in N	Hemispheric Push in N	PSL Pull out N	Hemispheric Pull out N
4021.1	3626.677	721.986	595.8
4407.813	2939.885	690.829	578.908
4363.2	3350	729.57	659.5
3857.93	3092.8	702.76	614.978
3979.456	3581.93	654.6	619
4151.1	4131.678	696.799	679.361
4133.425	3964.544	705.191	687.684
4065.314	5530.338	730.611	819.664
3681.991	3743.684	626.351	729.994
6799.516	4984.075	813.884	693.141

9.2 Low density Lever-out

PSL Push N	Hemispheric Push N	PSL Lever N	Hemispheric Lever N
3910.675	2706.939	139.297	95.035
4879	2384.3	159.062	87.955
3166.448	4465.342	129.172	129.483
3193.369	3351.953	110.333	132.25
4886.383	5066.641	150.737	158.502
6850.203	3879.58	163.962	145.165
6289.331	6743.157	167.685	140.781
5802.748	4723.032	157.249	133.513
5970.426	4993.415	163.696	144.596
4574.253	4290.638	134.107	138.561

9.3 High density Pull-out

PSL Push in N	Hemispheric Push in N	PSL Pull out N	Hemispheric Pull out N
5130.952	4153.696	1268.258	1039.348
5571.448	4168.997	1201.317	1056.362
4806.258	4529.487	962.443	1412.93
4752.237	3897.067	1161.827	1082.115
5955.106	4341.479	1093.556	1339.989
7936.197	5399.995	1910.585	1619.893
9186.423	6860.299	1923.909	2043.569
6821.263	6229.463	1528.167	1912.209
6423.589	6942.807	1522.305	2195.168
7101.271	5875.868	1666.533	1827.593

9.4 High density Lever-out

PSL Push N	Hemispheric Push N	PSL Lever N	Hemispheric Lever N
5764.808	6105.224	197.56	259.893
8229.237	7208.728	359.629	266.291
9752.529	7032.605	386.07	271.786
9448.1	9200.549	405.688	352.803
9696.269	6569.716	392.728	389.526
9567.698	8054.048	347.522	405.892
13756	6576.219	445.193	359.752
7653.469	7967.479	382.844	390.685
7826.504	8524.137	370.735	378.091
11783.96	5646.867	409.988	345.845