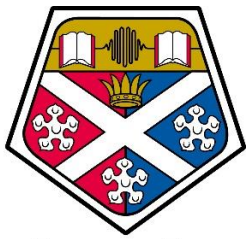

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Soft Tissue Control During Hydrostatic Shape Capture for Trans-Tibial Prosthetic Provision

By

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Submitted in part fulfillment of the requirements for MSc Biomedical Engineering

2015

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:

ABSTRACT

Current methods of prosthetic socket design are inadequate. A socket that fits well should demonstrate minimal longitudinal displacement from mid-stance through swing phase of the gait cycle and minimal rotational and transverse movements. To eliminate these issues, the socket should match the surface and volume of the residuum. Of the various methods for creating a prosthetic socket, hydrocasting is the only one which offers volume- and surface-matching under load bearing conditions that are analogous to the stance phase of the gait cycle. However the uniform pressure forces the soft tissue of the stump to redistribute causing the residuum to be shorter and wider. The socket produced from this design method will not demonstrate volume- and surface-matching during swing; this mismatch causes longitudinal displacement, a phenomenon known as pistoning. A Chinese finger trap weave prototype and a polyethylene cylindrical mesh prototype embedded in silicone were developed and tested for radial grip, forces measured on analogue limb, and proximal-to-distal displacement. 3-D CAD models of the weave and mesh were built and tested for radial grip and displacement using an FEA plugin. The data from the empirical grip test was invalid for technical errors. The weave alone was the most successful prototype in empirical displacement testing; this prototype experienced the largest and most consistent displacement in relation to applied tension. The 3-D CAD models were completed, but could not be tested due to time constraints. Future work will include experimenting with different embedding materials; 3-D CAD models will be modified and simulated.

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LITERATURE REVIEW

NEED & GOAL

Over a billion people worldwide, around 15% of the global population, are classed as disabled as of 2011.[1] 80% of this population live in low-income countries, less than 3% of whom have access to essential rehabilitation services.[2] Countries are classified as low-income if their citizens earn less than 2USD per day.[3] It is estimated more than 30 million people with disabilities from these areas require a prosthesis. Due to environmental and financial considerations, primary health concerns must take precedence over rehabilitation services leaving these patients' needs unfulfilled. Lower life expectancy in these countries results in a higher proportion of paediatric patients compared with more developed countries. This high prevalence of paediatric patients increases the demand on limited resources due to their constant growth and continually changing activity levels.[2]

Causes for amputation are region specific and therefore are unique to each country. Epidemiology ranges from disease such as polio, malaria, or diabetes to traumatic injuries such as landmines, accidents, or other war-related injuries.[2] Prosthetic design and implementation must consider each countries culture, terrain, and climate before attempting to provide aid. Educating and training residents from the local population in prosthetic socket casting protocols will make the industry sustainable. Expatriates cannot remain to run the facilities

permanently and the local population will need to maintain and operate the clinics.[2]

Rural populations find that limited access and the incredibly high costs of custom prosthetics from trained prosthetists are insurmountable obstacles.[2; 4] Current efforts involve “recycling” limbs from developed countries to be used in low-income countries; however, these devices do not fit the new owners appropriately which leads to disuse of the prosthetic and continued disability. The impact on families from taking care of a disabled family member can be debilitating because the caregivers are forced to give up work to stay home with the amputee.[2] The loss of this income can force the family deeper into poverty. A sound fitting socket would eliminate the issues associated with an ill-fitted limb and therefore allow a more normal life for the amputee and the caregiver.[1; 2; 4]

A socket is said to fit well if it complies with certain parameters. Firstly, a prosthetic sockets requires an accurate evaluation of the residuum including geometry and soft tissue mechanical properties. The socket should be characterized by a close-fit which distributes the biomechanical stresses appropriately without negatively affecting blood flow. The socket should contain and protect the residuum while transmitting load from the ground to the skeletal system.[5]

HAND CAST METHOD

Sockets are traditionally hand cast by trained prosthetists using the following protocol. First the residuum is carefully measured. Plaster of Paris is then wetted

and wrapped directly on the residuum using chalk and bandages. During cast application, pressures must be exerted on certain load points to alter the distribution.[5] The negative cast of the residuum is removed from the patient and used to create a positive plaster model of the residuum. The measurements of the residuum are compared to those of the model and rectifications for pressure redistribution are made as necessary. A test socket is created by fitting thermoforming plastics around the modified model. After the patient approves all changes made to the test socket a final socket is created.[5]

The hand casting method is widely employed as the current gold standard within the field of prosthetics, but the process is fallible and costly. This method falls prey to human error throughout the casting and fabrication processes. Two sockets by the same prosthetist are never the same, and significant inter- and intra-prosthetist variation is highly probable. A prosthetist's inexperience or inadequate training amplifies errors; for example female casts are produced with linear tension lines due to inconsistent plaster wrap application.[6] Another drawback to hand casting is time consumption and expense, traits placing it out of reach for lower income patients.

Thigh-Corset Suspension

Socket design and suspension methods in early prosthetic work did not allow for direct socket and residuum weight bearing.[7] Initially weight was transferred to the thigh through side joints and a leather corset that laced up the anterior thigh thus securing the open-ended socket to the residuum.[7; 8] This design stabilizes

unstable knees against extreme mediolateral motion, dislocation, and hyperextension.[8] Due to the suspension system, the prosthesis migrates downward during swing resulting in skin irritation and pain within the soft-tissue. Patients complained of oedema and verrucous hyperplasia, both of which were attributed to the open-ended socket design.[7; 8]

Patellar Tendon Bearing Sockets

To improve upon the thigh-corset design, Charles Radcliffe of University of California Berkeley developed the patellar-tendon bearing (PTB) socket design; this design attempted to accommodate pressure intolerant areas around the residuum with respect to the biomechanics of gait and ground reaction force.[8] The PTB socket uses supracondylar suspension, meaning that the cast has indentations above the femoral condyles rather than thigh corset suspension; such suspension saves the thigh muscles from atrophy and allowing the knee a more normal movement.[8] This type of socket requires a highly skilled prosthetist to produce an acceptable hand cast. A poor fitting socket will result in residuum deterioration, excessive shrinking, and oedema.[8] Due to the nature of hand casting, sockets can never be replicated and are susceptible to human error.

PTB sockets must fit the criteria developed as explained by Foort *et al*.[8] The distal end must contact the socket without weight bearing to prevent oedema. Pressure must be carried on weight tolerant areas: patella tendon, medial tibial flare, residual pretibial anterior compartment musculature, gastrocnemius muscle belly, and fibular shaft. These areas have been identified as tolerant to pressures and

biomechanics of socket/residuum interaction throughout gait. Pressure intolerant areas should be avoided to prevent discomfort; these areas include the tibial crest, tibial tubercle, lateral proximal tibia, distal fibula, fibular head, patella, and hamstring tendons.

The biomechanics assumed by Radcliffe *et al* have been evaluated a number of times by Goh *et al*. The results from these evaluations have continually shown an anterior/posterior pressure profile that is inconsistent with Radcliffe's predictions and also dissimilar between the participants of the studies.[6; 9; 10] Inconsistencies could be from poor fit, poor design, or a combination.

Modifications for pressure relief often result in a volume mismatch between the socket and the residuum which causes increased patient discomfort. Overemphasis on applying pressure on the patellar-tendon bar causes a severe increase in pressure in the popliteal region.[8] Constriction from this error affects circulations, causes oedema, and results in distal residuum deterioration. Fibular modifications are meant to provide mediolateral stability, but instead they create constriction mid-residuum; the resulting sensation resembles socket contact by the distal end or soft tissue pulling against the bone.[8] Constriction causes oedema and distal residuum deterioration if the situation is unrectified.

Total Surface Bearing Sockets

Total Surface Bearing Sockets (TSB) were designed around 1985 as an improvement to PTB.[7] The TSB method employs hand casting, but it adheres to the concept of all areas being capable of tolerating pressure; pressure is neither

directed toward pressure-tolerant areas nor away from pressure-intolerant areas.[11] TSB relies on anatomical accuracy at the interface so weight may be borne over the entire surface of the residuum.[11] This style is costly, requiring significant skill and multiple rectifications to produce a perfect cast.

In 1986, ICEROSS (Icelandic Roll-On Silicon Socket) was introduced by Össur Kristinsson to reduce need for a perfect cast, improve the skin-socket interface, and improve the suspension system.[12] ICEROSS and other gel liners contain the entire volume of the residuum within an equal volume of socket to help prevent pistoning during gait; this is accomplished by keeping residuum in contact with the socket throughout the gait cycle.[7; 12] The gel interface allows for a certain margin of error in regards to socket fit; the gel liner provides padding at the distal end of the residuum, stabilizes the soft tissue, stretches the skin and protects the skin from friction.[7; 12] The compression from the liner and the protection it provides contribute to improved comfort and alleviation of many dermatological issues experienced by prosthetic users.[10; 12] Additionally liners provide alternatives to supracondylar suspension; these include a distal pin and lock, lanyard and Velcro, air expulsion valves for suction suspension, and vacuum suspension.[11; 12]

Computer-Aided Design & Modelling

Computer-aided design/computer-aided modelling (CAD/CAM) was first introduced to the prosthetic industry in the 1980s as a novel method of rectification and socket design.[13] Today it is geared for central fabrication where the digital model is sent away for outside fabrication with a turnaround time of 24-48 hours.[13]

The process involves either a surface scan of the residual limb or digitized plaster cast of the residuum; then the obtained limb shape is modified using available software. A positive model of the modified limb is carved using a computer-driven milling machine. This use of technology does not replace the need for skilled evaluation of the socket design, individual modification, or limb alignment; however, it can allow for rapid design of test sockets, is more cost effective to incorporate changes, and does not require a new cast for every change.[7; 13]

The digitized residuum is rectified using software packages that identify pressure tolerant and intolerant areas across a range of residuum sizes and shapes. Prosthetists can apply a template to the digitization that modifies the model residuum based on areas identified in the template.[13] Refinements or custom built templates may be saved and used multiple times across any number of patients. CAD/CAM software is successful in orthoses, particularly spinal orthoses.[13] This method has been used successfully in Hanoi, Vietnam as a solution to the challenges faced by low-income amputees.[13]

There is no gold standard for the digitization method due to the low number of studies investigating the various parameters.[5; 7; 13] Existing research does not examine how the limb should be prepared for digitization. The limb has been moulded into a desired shape before casting in some studies but unmoulded in others.[5; 7; 13] Another important variable that should be considered is the status of the limb, weight-bearing or non-weight-bearing, during digitization.[5; 7; 13] In addition to the inherent lack of continuity, the cost of acquiring, replacing, and

upgrading the software and equipment is high; software life-expectancy can also be uncertain, adding to financial burden.[13]

PRESSURE CASTING

Pressure casting assumes the hydrostatic principle which states soft tissue behaves as a fluid and follows Pascal's principle. Pascal's principle purports that a confined fluid will transmit external pressure uniformly in all directions perpendicular to the containers surface.[10; 14] When volume- and surface-matching are achieved, a more uniform pressure distribution with lower and fewer peak pressures throughout the socket is attainable.

A pressure cast socket can be achieved using air pressure, sand pressure, or water pressure. Often the need for a test socket can be avoided, drastically improving production time and cost. Equal pressures applied to the limb during casting lead to an almost perfect cast of the residuum with minimal or no rectifications necessary. The uniform pressure also eliminates inter-prosthetist variance.[10] Theoretically the pressure cast socket will match residual limb volume leading to improved blood circulation, sensory feedback, and proprioception.[14]

Issues with pressure casting vary depending upon the technique used, but many assumptions must be made for all techniques. Casting is most commonly done with the limb at rest and not under load, however this does not translate well into the patients' everyday life. The hydrostatic pressure principle is not evident during standing or gait due to the changing muscle tone and nonhomogeneous nature of

soft tissue effect the volume of the residuum.[10] Also, the fluid within the residuum is not at rest, therefore the shear forces cannot be assumed to be zero as Pascal's principle requires.[6] Factors such as those mentioned above should be controlled to create a successful pressure cast socket.

CIR/Sandcasting

The following protocol for sandcasting was developed by Wu *et al* [15] in the early 2000s as a possible solution to need in low-income countries. Prior to casting the residuum is placed in an elastic sock with cotton padding over bony prominences. The residuum is then placed in a plastic bag inside the sandcasting container. Pressurized air is pumped through an inlet and sand filter giving fluid-like properties to the sand and allowing for positioning of the residuum with minimal distortion. Next the container is tightly packed with sand up to the femoral condyles. The plastic bag surrounding the residuum is pulled over the rim of the container and sealed with a rubber band to allow the pump evacuation of air. The solid mould is ready within minutes and is immediately usable as a test socket. Post-production modifications for comfort can be made to the negative sand mould. With the residuum removed, sand is poured into the plastic bag inside the negative mould and a mandrel is placed in the centre. The same plastic bag is folded up and sealed via tape to the mandrel. A hose is then attached to the mandrel and air evacuated; the first vacuum hose is then disconnected which loosens the negative mould and allows the positive mould to be removed from the container.[15] Fabrication follows traditional methods.[15] Improvements to the

system replace the sand with polystyrene beads and the air compressor is no longer required.[16]

This method is low-cost and uses low-maintenance equipment.[15] Additionally plaster of Paris is replaced with sand to allow for rapid forming of negative and positive moulds of the residuum.[15] Sandcasting inevitably has limited use in low-income countries as this method requires a trained prosthetist as well as a ready and consistent source of electrical power.[4] The procedure is complicated and time consuming and the results from the preliminary study showed that the socket cast was too wide 35% of the time.[16]

Pneumatic Casting

Pneumatic casting was developed by Össur Kristinsson to complement the ICEROSS liner.[17] Silicone pads can be inserted into the liner prior to casting to protect bony prominences and sensitive areas.[10; 17] Plaster of Paris is wrapped around the liner with uniform pressure from firm hands.[12; 17] An air bladder is then rolled over the residuum and pressurized which forces the membrane into compressive contact with the casting medium.[17] This pressurization tends to push the soft tissue proximally without the application of external tension. A tension connector, usually a pin at the distal end, attaches the liner to the pressure casting device to prevent proximal movement.[17] The air pressure is released decreasing the pressure and freeing the residual limb from the casting device after which the cast is removed.[17]

This method requires constant and reliable access to electricity and a trained prosthetist.[12; 17] Additionally, the pneumatic system requires a silicone or gel liner, the cost of which pushes this technique out of the reach of patients in low-income countries. Another point to consider is the medium chosen for pressurization, air is compressible and thus the cast may not fit as desired.

Hydrocasting

The hydrocasting pressure casting technique was first introduced with the Dundee socket in 1965.[10] Fluid is known to be incompressible which makes it an ideal candidate as a pressure casting medium. The even pressure provided by the fluid medium creates a socket with high volume- and surface-matching; however, this is only the case in static situations.[10; 18] Hydrocasting can be almost hands-free thereby removing inter-prosthetist variance and exhibiting high levels of repeatability.[7]

Manucharian *et al* in 2011 investigated the comfort level trend differences between PTB sockets and hydrocast sockets. The hydrocast socket was found to be more comfortable; however, the pressure profiles from the study did not match Radcliffe's predicted pressure profiles.[18] This is likely due to the inherent difficulty of volume- and surface-matching in a dynamic situation.

Goh *et al* have continually not found the expected uniform pressure distribution.[6; 9; 10] The anteroposterior pressure profile was inconsistent between all subjects and was poorly correlated to Radcliffe's predictions. The mediolateral pressure profiles were consistently close to Radcliffe's predictions. There was a

consistently high pressure in the patellar region halfway through the gait cycle mimicking PTB pressure profile without the PT indentation.[6; 9; 10]

COMPUTER AIDED DESIGN & FINITE ELEMENT ANALYSIS

Krouskop *et al* proposed the use of finite element analysis (FEA) as a mechanism to aid the design of sockets for trans-femoral amputees in the late 1980s.[19] The first trans-tibial FE model was developed by Steege *et al* in 1987 which was used to predict pressure between the residuum and the prosthetic socket.[20; 21] Despite CAD and FEA developments, there are still concerns regarding the accuracy and relevance of the results obtained; inaccurate models produce results with relatively little real-world applications.

Every CAD-FEA model contains assumptions and simplifications due to the inherent complexities of prosthetics design. Arguably setting boundary conditions for slip and friction is the most problematic issue due to the material properties of soft tissue.[22] Furthermore information is lost when transferring a CAD model into a FEA program, affecting accuracy and precision; the CAD model is meshed within the FEA program, and any changes to the model can alter both the mesh and simulated results.[22] Additionally residuums are three-dimensional with patient-specific geometries; exact loading conditions can also be difficult to quantify.[22]

INTRODUCTION

Hydrocasting is a viable solution to the problem faced by amputees everywhere, especially those in low-income countries. The system is cost-effective to implement, requires no test socket, removes the human influence inherent in hand casting, and can be made without an expensive liner.

PROBLEMS

The largest obstacle to a liner-less socket with hydrocasting is the nature of the residuum's soft tissue. Evenly distributed pressure around the residual limb from the water causes the soft tissue to deform and migrate proximally. This migration of soft tissue leads to a cast that is wider than required thus volume- and surface-matching no longer occurs when the residuum is unloaded. During the gait cycle, the weight of the prosthesis pulls downward on the residuum causing longitudinal displacement, also known as pistoning. Pistoning can lead to pain and discomfort from soft tissue damage.

AIMS

The aim of this project is to design a component to fit within the parameters of the Majicast® hydrocasting system that will eliminate slack (soft tissue migration) by controlling the soft tissue during residuum shape capture. A successful component will radially grip the residuum during shape capture and displace the soft tissue proximal to distal.

DESIGN: CHINESE FINGER TRAPS AND COMMERCIAL NETTING

Chinese finger traps, although originally a children's toy, are currently used in the medical community to help set Colles' fractures, Bennett's fractures, and to provide tension for healing joints.[23; 24] "Closed reduction of forearm and hand fractures can be performed with Chinese finger traps. These are applied individually to the fingers and the limb is suspended, with gravity providing countertraction to disimpact the fracture by ligamentotaxis. The fracture fragments are manipulated once length is restored. Chinese finger traps are a valuable tool that can maintain traction while a cast is applied and can also be useful during fracture fixation."[24] It is possible that an enlarged version of such a device may be repurposed to remove slack from soft tissue in the residuum; the term assigned to such a device in this project is a slack elimination device (SED).

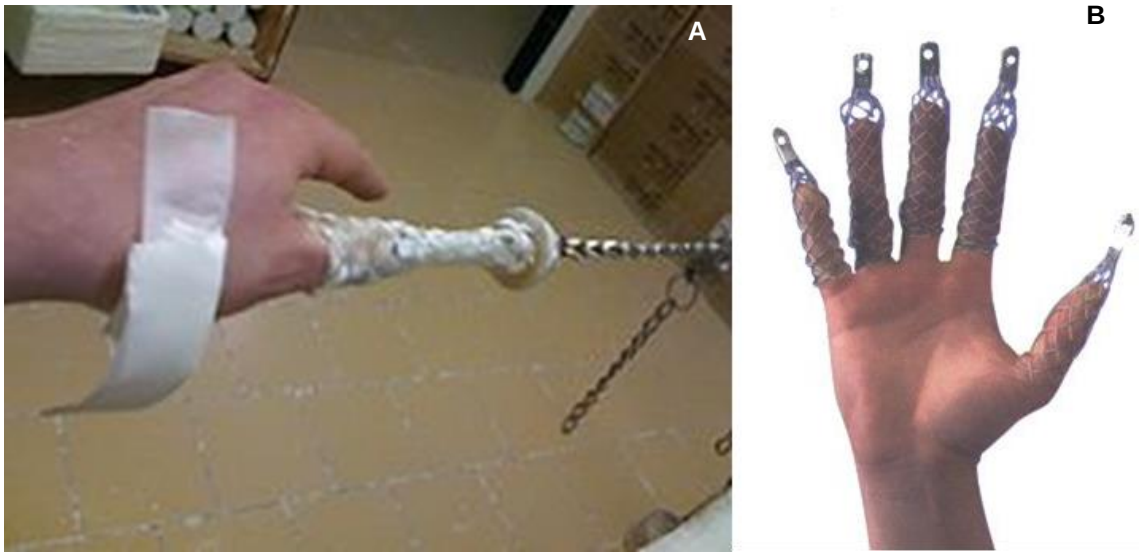

Figure 1: Finger traps used for Bennet's fracture (A) and Colles' fracture (B)

An alternative to a finger trap style weave is protective netting such as the kind used around dive tanks. The material has elastic behaviour and with a similar geometrical pattern to that achieved by the cuff weave. There is no indication that this material has previously been repurposed in the manner proposed.

HYPOTHESES

The first hypothesis is that applying tension to the distal end of the SED while securing the proximal end will result in radial compression of the residuum and proximal-to-distal longitudinal displacement. A prototype of each model will be created and tested. Residuum radial grip and longitudinal displacement will be measured and images captured using equipment to be detailed below.

The second hypothesis of this project is that developed CAD-FEA models will acceptably simulate empirical test results. A CAD model of the weave and mesh design will be developed and tested within SolidWorks®.

MATERIALS & METHODOLOGY

PRODUCT DESIGN SPECIFICATIONS AND DESIGN MATRICES

The SED is a component of the Majicast® system, but it was beneficial to analyse it as a stand-alone product during certain design phases. Product design specifications (PDS) are an integral part of creating a marketable device as the level of detail encourages research and foresight with sections such as performance, local constraints, environment, testing, weight, cost, maintenance, ergonomics, and safety (Appendix I). The parameters created within these sections are later used in concept development.

The first section of PDS refers to the products performance, or what it is meant to do; for example the SED must fit within the Majicast® system. The SED must relax against the interior walls of Majicast® while not in use and also must decrease in diameter when tension is applied in superior to inferior direction. This device must cause a minimum 2 cm longitudinal displacement of the residuum's soft tissue proximal to distal and withstand up to 20 N of force. Ideally the device should provide a uniform grip around the residual limb. The SED should be easy to install, maintain, and replace.

Another important section covers the environment the device will be working in such as the forces applied to it or exposure to moisture, severe temperatures, or pressure. The SED must be attached to the lip of the Majicast® superiorly and to the piston at the inferior end. When in use the device will be submerged in water under high pressure with an additional 20 N pulling proximal to distal. The device

will be exposed to air and high water pressure cyclically throughout its life. The device must withstand high room temperatures of tropical and subtropical climates. The unit must withstand pressures from 101 kPa when not in use to high hydrostatic pressure depending on the patients' anthropometrics. The device must not corrode with water exposure or from wear at couplings, intersections, or attachment sites. The unit must be durable and easy to clean.

Many other sections were smaller or needed to be considered as a component rather than a product. Other important considerations included cost, ease of use, safety for prosthetists and patients, and the expected life span of the product. As designs are considered and expanded upon, changes to the specifications improve the overall quality of the delivered product.

A detailed PDS is essential for a successful product and is the basis for all future decision making. Any ideas that could fulfil the requirements of the PDS are put into a table called a design matrix. A design matrix has desired features down the y-axis and concept designs along the x-axis (Appendix II). A datum is often used as a measure against which to compare the new concepts. A +1 is given if the concept design is better than that datum, -1 if the concept design is worse than the datum, and 0 if the concept design is considered the same. The design matrix for the SED included features such as material behaviour, maintenance level, displacement of soft tissue, produces radial grip, and cost. The concept with the highest score is the better design; however, the scores can also be used to help

improve the poorer designs. The matrix points out flaws which can often be rectified through a change in design.

Another type of design matrix can be used if the previous method is not specific enough. Concept designs are again on the x-axis and desired features down the y-axis. The concepts are then ranked against one another and assigning a score (Appendix II). The desired features can be more specific and therefore are capable of producing a more accurate depiction of the concept designs. Design improvements are easily spotted in a matrix such as this. The results of these two design matrices indicated two slack elimination designs were viable for testing: the Chinese finger trap (weave method) and the protective mesh.

PROTOTYPES

Loom Description

The woven prototypes were created over a cylindrical loom 330 mm in height and a 180 mm diameter. Screws were placed evenly (28 mm apart) around the top and bottom circumferences 12.7 mm from the edge.

Material Selection

The purpose of the component dictates the material selection process. To achieve slack elimination, the material must be flexible, inelastic, water resistant, and less than 12.7 mm wide. A prototype was considered to be of testable quality if the weave displaces longitudinally less than 5 mm and produces a radial grip around forearm when pulled inferiorly and clamped superiorly. Concept prototypes were

first created with 12.7 mm cotton bias tape. 12.7 mm Polyester ribbon, 6 mm satin ribbon, 3 mm wax cotton string, and 1 mm wax cotton string were all woven into the desired pattern. Manual inspection of the 6 prototypes showed the wax cotton weaves achieve most closely the desired results.

Material	Width (mm)	Number of Strands	Notes:
Polyester cotton bias tape	12.7	28	Strands are flat. Width too great for 28 strands, weave too tight for movement
Cotton bias tape	12.7	14	Strands are flat. Proof of concept
Polyester ribbon	12.7	14	Strands are flat. Less strands would be better
Satin Ribbon	6.00	28	Strands are flat. Friction too great.
Wax coated cotton string	3.00	28	Strands are round. Maintains shape, appears to grip skin, appears to cause displacement
Wax coated cotton string	1.50	28	Strands are round. Maintains shape, appears to grip skin, appears to cause displacement

Table 1: Description of weave materials and prototypes

Weave Method

The material was purchased uncut at 42 m long and then cut into 1.5 m-long strips (28 per prototype). The first strand was secured with the centre of the strand over the screw at the top labelled “1”. The right-side strand was secured down with a washer and placed inside the centre of the loom to keep it out of the way. The left-side strand was wrapped 360 degrees counter-clockwise around the loom and secured around the screw labelled “1” on the bottom of the loom. This was repeated for the remaining 27 strands. The right-side strand from screw “1” was released from the washer and wrapped around to the right in the clockwise

direction passing over and under the counter-clockwise strands as it encountered them and finally secured to the left-side strand at the screw labelled “1” at the bottom. This process was repeated for the remaining 27 strands.

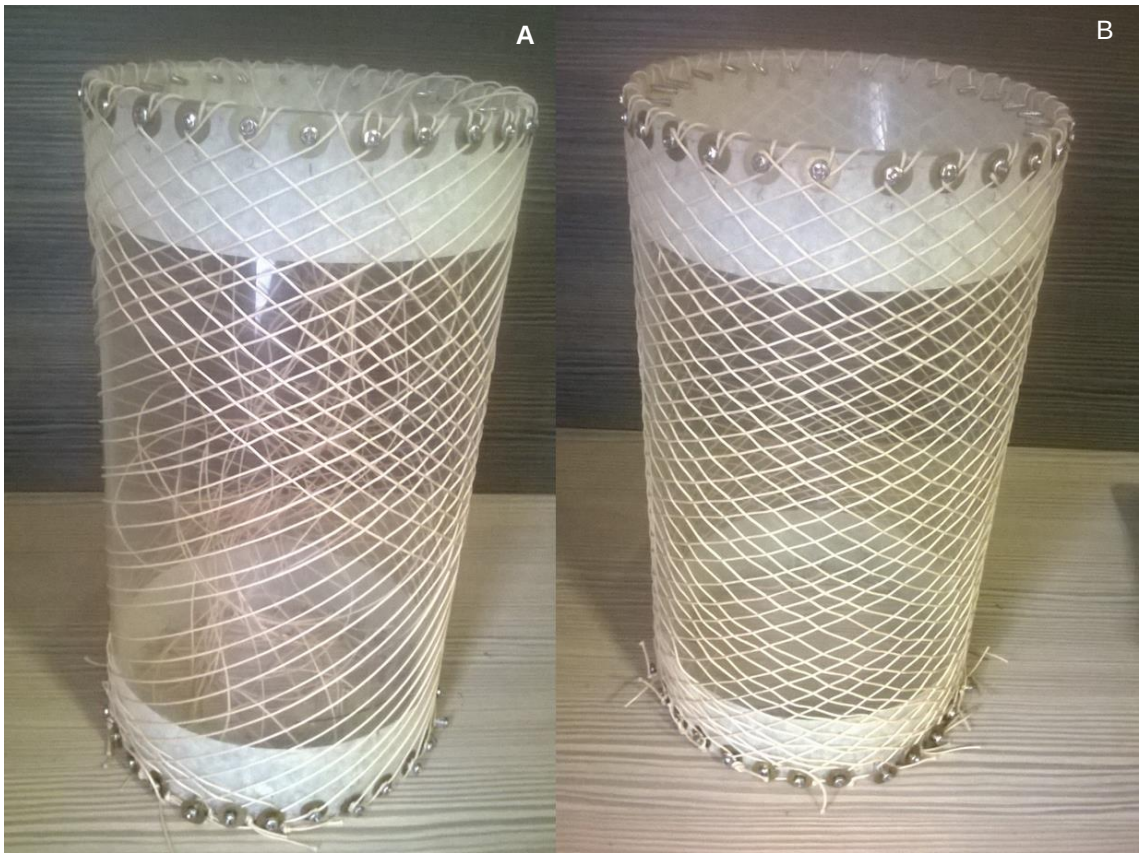

Figure 2: Partially complete thin wax cotton prototype (A) and completed prototype pre-removal (B)

Mesh Selection

Due to the specifications of the hydrocasting system, the mesh was selected based on the material listed and the diameter range provided. The standard protective netting was chosen for testing because it had a diameter range from 100 mm to 200 mm and is made of polyethylene. Gas cylinder mesh was chosen because it had a diameter range from 100 mm to 200 mm and is made of low-

density polyethylene (LDPE) mesh. The protective netting was quickly eliminated as it does not grip when pulled upon but rather pulls away from the contours of the limb. The gas cylinder mesh, however, performed as desired under the same basic manual inspection.

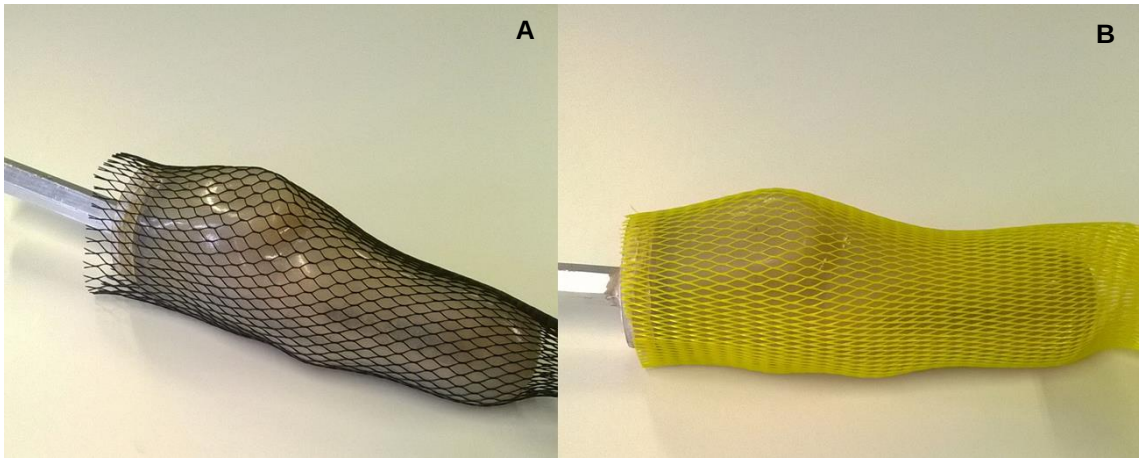

Figure 3: Gas cylinder mesh (A) and standard protective netting (B) on original model residuum

Embedding in Silicone Membrane

The SED must be incorporated into a membrane to comply with Majicast® specifications, so the mesh was embedded within silicone. First a fabric wick was wrapped under the mould to allow the vacuum to function. Thin nylon was then pulled over the mould and vacuum pipe to aid airflow to the vacuum. A damp PVA bag was pulled over the nylon and sealed at both ends; the inner vacuum was then switch on. Another thin nylon was pulled to cover the bottom half of the mould after which a third thin nylon was pulled over the entire mould. The mesh device was then rolled onto the mould. A full length of nylon was pulled over the mesh, another layer of nylon was then added to the bottom half of the mould, and a final length of thin nylon was added to cover the entire mould. A second damp PVA

bag was placed over the mould and secured at the base. The PVA bags were left to dry for 15 minutes. The silicone was mixed, taking care to allow as few air bubbles as possible, at a 10:1 ratio, for this mould 430 g of silicone A to 43 g of silicone B were used (Appendix III).

Due to the high cost of silicone, only the mesh device was embedded for this experiment. The weave design was tested alone; additionally the weave design was tested under a silicone sleeve and over a silicone sleeve to simulate an embedded weave.

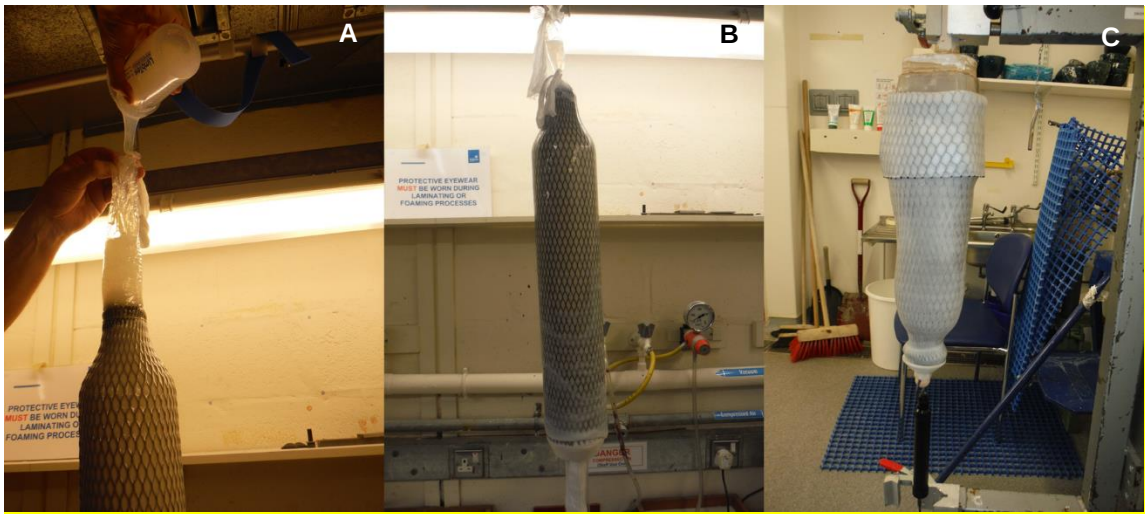

Figure 4: Pouring silicone (A), silicone curing (B), final prototype on original model residuum (C)

PROTOTYPE TESTING

Radial Grip Protocol

The purpose of radial grip testing is to see if the changing geometry of the device will create an equal radial grip around the residuum. The materials for this test included: an analogue limb, two prosthetic modification clamps, the embedded

mesh, the weave and liner, a spring balance, a timer, and F-Socket pressure sensors from Tekscan® with their accompanying software. The analogue residuum was clamped horizontally and pressure sensors were applied on the anterior, medial, and lateral surfaces of the limb.

The posterior surface was not included as the residuum was too small to accommodate four sensors. The device to be tested was rolled over the limb from distal to proximal. The top of the spring balance was attached to the distal end of the device while the bottom end was attached to a thick nylon strand that was run through a neighbouring clamp. The sensors were equilibrated at rest and calibrated with 1kg for each device test. Testing began with 63.77 N (6.5 kg) on the spring balance, of applied tension. Every 20 seconds the tension applied was released by 4.91 N (0.5 kg). Once 0 N had been held for 20 seconds, tension was reapplied at a rate of roughly 4.91 N every 10 seconds. Tekscan® software only allows for a maximum recording time of 350 seconds so the reapplication of tension did not always follow the test guidelines as it was deemed more important to regain the original tension of 63.77 N.

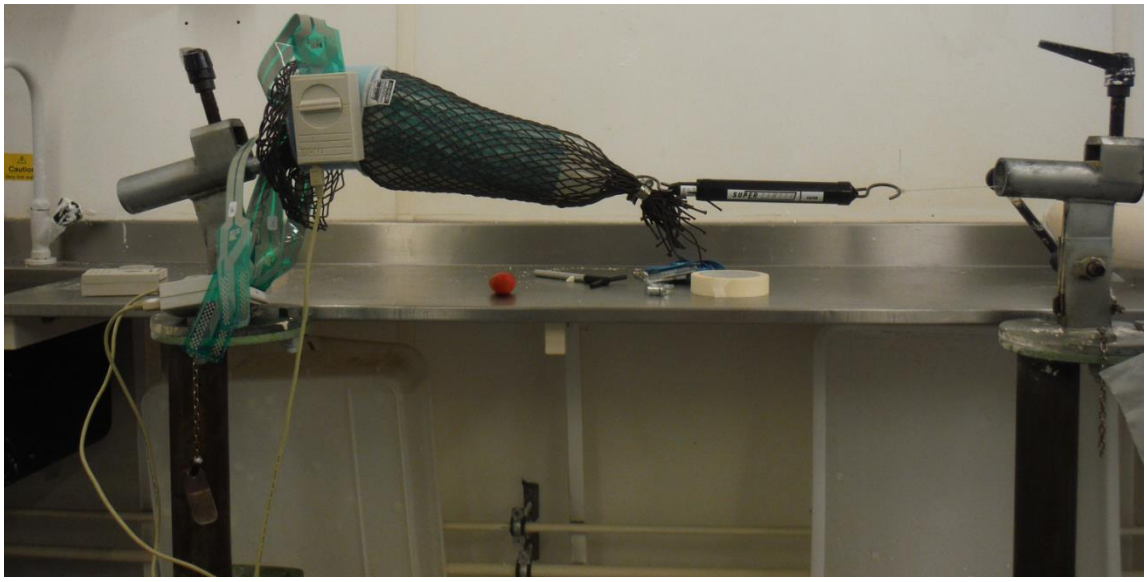

Figure 5: Testing set up for radial grip

Displacement Protocol

The purpose of the displacement test was to determine if the changing geometry of the device was capable of displacing the soft tissue from proximal to distal, how much displacement occurred, and if the devices were capable of the same amount of displacement. Materials for this test included: two coloured markers, the weave and a liner, a spring balance, a camera and tripod, the same clamp system as stated above, a timer, and an analogue residuum. The residuum was first marked every centimetre from proximal to distal and then clamped into the suspension system.

The camera was positioned so the marks on the residuum were clearly visible through the viewfinder, then the datum photograph was taken. The device to be tested was rolled over the limb from distal to proximal. The top of the spring

balance was attached to the distal end of the device while the bottom end was attached as mentioned in the grip protocol above.

The device was pulled to 39.24 N (4 kg) on the spring balance, and a photograph was taken. The force applied was increased by 4.91 N (0.5 kg), until 88.29 N (9 kg), was reached. Test A was of the weave alone for proof of concept. Test B involved a silicone sleeve rolled over the weave to simulate being embedded in a silicone membrane for Majicast®. Test C was of the weave over a silicone sleeve to simulate being outside of a silicone membrane for Majicast®.

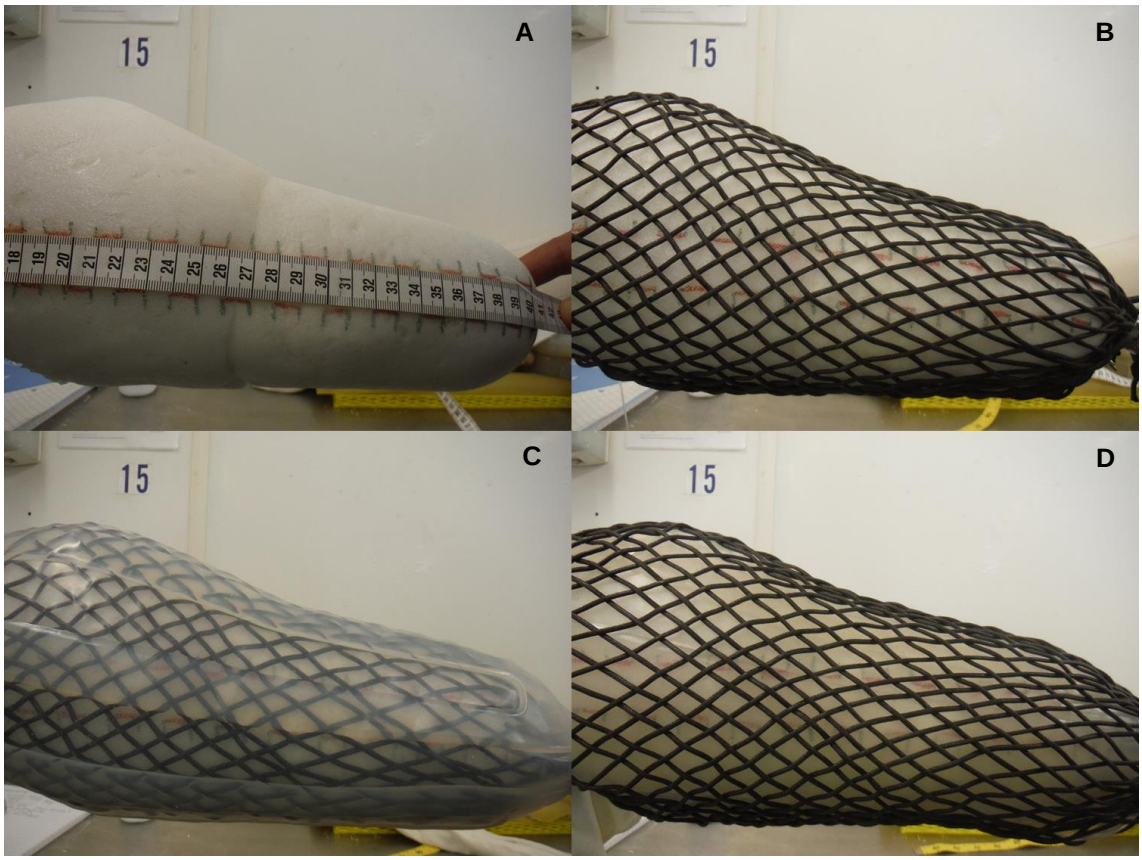

Figure 6: Datum – new residuum (A), Test A – weave alone (B), Test B – sleeve over weave (C), Test C – weave over sleeve (D)

Analysis Protocol

The grip strength data was converted from an .asg file to a workbook in Excel® 2013. The data was reduced from 35033 data points to 352 using the protocol detailed in Appendix V.[25] The data was then plotted to show the relationship between the force measured against the residuum and elapsed time.

The displacement data was obtained by analysing the photographs taken during testing using ImageJ® version 1.49. The datum photograph was used to divide the analogue residuum into thirds, a proximal third, middle third, and distal third. To calibrate ImageJ®, the centre of the desired third was found and one centimetre is marked on the image. The scale was then set so that the number of pixels marked on the image equalled 10000 μm globally. Then the desired third was measured for change in length from applied force. The data was collected and imported into Excel® 2013. The process was repeated for each third of the analogue limb and for every displacement test.

The displacement results were plotted in Excel® 2013 to demonstrate the relationship between applied force and measured displacement. The data was also evaluated using Minitab®16 to complete a One-Way ANOVA (unstacked) for analysis of variance as well as individual statistics and confidence intervals. Force-displacement relationships and statistical analysis provide valuable information regarding test validity.

CAD-FEA

Computer Aided Design (CAD) modelling can be a useful tool in the design process. A successful model will indicate potential issues with the design that had previously been unconsidered. Data from simulations can also indicate the range in which experimental data should lie. A Chinese weave and protective mesh were modelled in SolidWorks®.

Weave Protocol

The weave has 28 strands in each direction plaiting over and under each other in a helical pattern. Half of the strands run clockwise around the central axis while the other half run counter-clockwise. Due to the interwoven nature of the part, the helical path of the strands changes in diameter, creating a wave pattern for each strand to avoid intersection. The strands will extend down the axis in the z-direction with the necessary diameter changes pre-determined by x and y coordinates. As a strand spirals around the centre, it crosses each oppositely-woven strand twice. One revolution is defined by 28 points each with an x, y, and z value. These values can be determined using basic trigonometry in Excel® 2013.

The protocol is as follows:

1. Determine the desired internal diameter of the part (180 mm)
2. Determine the middle diameter by adding the radius of the strand to the internal diameter (181.25 mm)
3. Determine the outer diameter by adding 1.5 times the radius of the strand to the internal diameter (181.88 mm)
4. Determine the angular increment between each crossing point by dividing 2π rad by the number of strands ($\frac{\pi}{14}$ rad)

5. Multiply cos($\frac{\pi}{14}$) by the middle and outer radii alternately to determine x values
6. Multiply sin($\frac{\pi}{14}$) by the middle and outer radii alternately to determine y values
7. Z values begin at zero and increase in increments of 1/28th of the helix pitch (11.79 mm)

Now the x, y, and z coordinates have been determined; they can be formatted and imported into SolidWorks® as follows:

1. Save the Excel® file as a .csv file (comma separated variable)
2. Change the files extension to .txt format
3. In SolidWorks® select “Curve Through XYZ Points”
4. Select the .txt file

There is now a single helical strand. To build the complete model the protocol is as follows:

1. Draw a circle to the desired diameter of the part (180 mm)
2. Draw a central axis in the z-axis for construction (330 mm)
3. Select “Sketch” and select a plane
    a. Draw a circle with the desired diameter of the strand (1 mm)
    b. Hold the CRTL key and select the strand and the centre of the small circle
    c. Select “Pin”
4. Select “Swept Boss/Base”
    a. Select the central axis
    b. Select the strand
5. Mirror the single strand
6. Select Body-Move/Copy and move the new strand 1 z-increment in the – z direction
7. Select Body-Move/Copy and rotate the mirrored body $\frac{\pi}{14}$ rad
8. Select “Circle Pattern”

a. Select the original strand
b. Select the central axis
c. Select equal spacing and designate desired number of strands

9. Select “Circle Pattern”
    a. Select the mirrored strand
    b. Select the central axis
    c. Select equal spacing and designate desired number of strands

The SolidWorks® weave model is now complete. A copy of the original Excel® file can be found in Appendix VI.

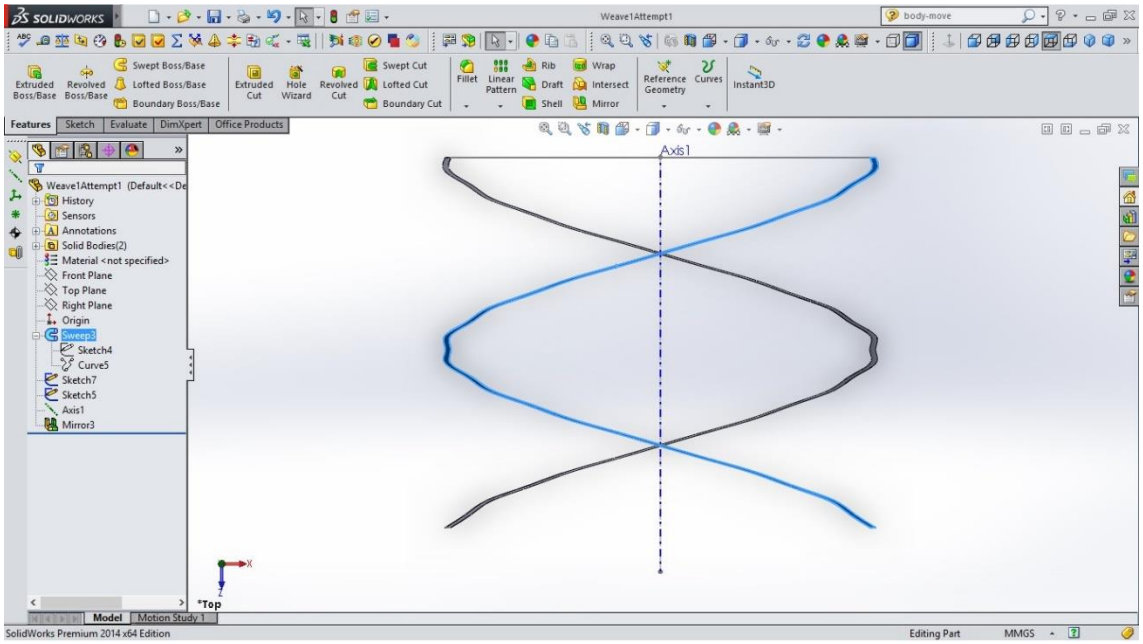

Figure 7: The mirrored helical strand (grey) and the original strand (blue)

Gas Cylinder Mesh Protocol

The protective mesh was made of interconnected hexagons. The protocol is as follows:

1. Draw a circle to the desired diameter of the part (180 mm)
2. Draw a central axis for construction (330 mm)
3. Create a plane 90 mm from the axis on the edge of the circle

4. Select “Extrude” and select the new plane
    a. Sketch a hexagon with an internal circle diameter of 10 mm
5. Select “Extruded Cut” and select the surface of the hexagon
    a. Sketch a hexagon with an internal circle diameter of 8 mm
    b. Select “Through All”
6. Select “Circle Pattern”
    a. Select the hexagon and central axis
    b. Select equal spacing and designate desired number of hexagons
7. Select “Linear Pattern”
    a. Select the circle pattern from the features dropdown tree

The mesh model is now complete.

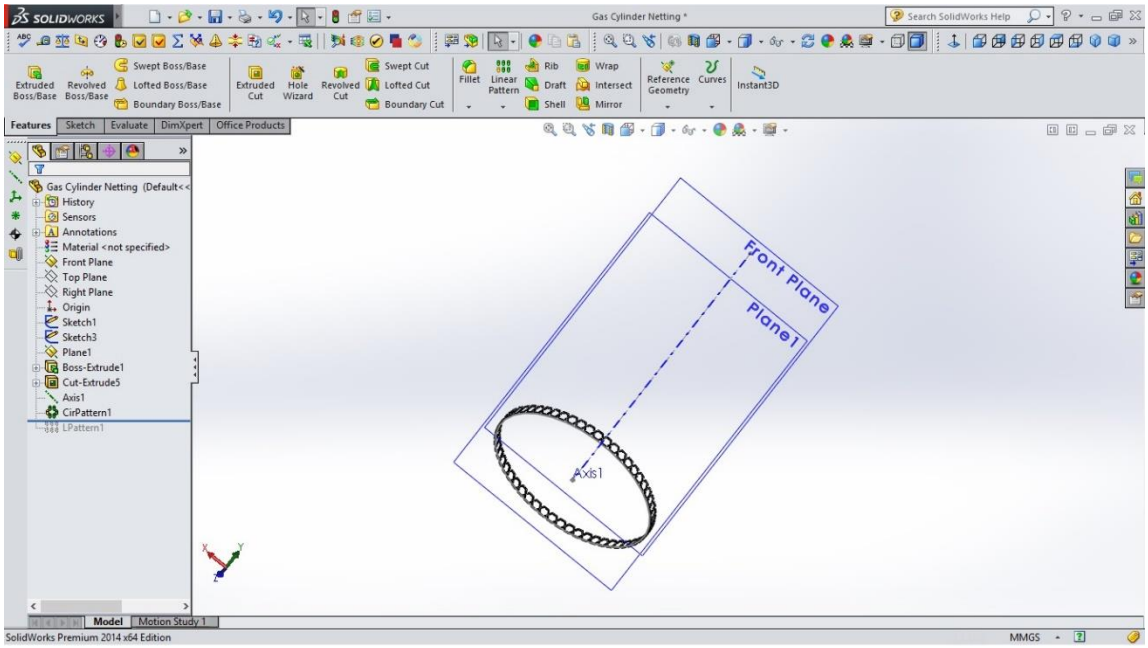

Figure 8: The model after circle patterning of hexagon

RESULTS

COMPLETED WEAVES

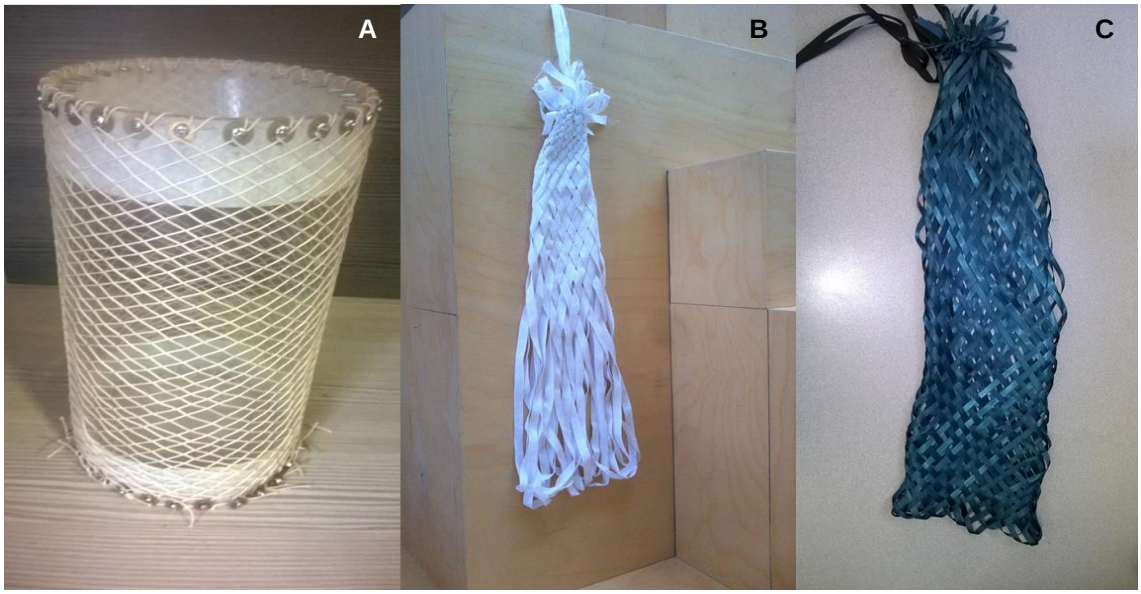

Figure 9: Examples of completed weaves: thin wax cotton prototype (A), cotton bias tape (B), satin ribbon (C)

EMBEDDED MESH

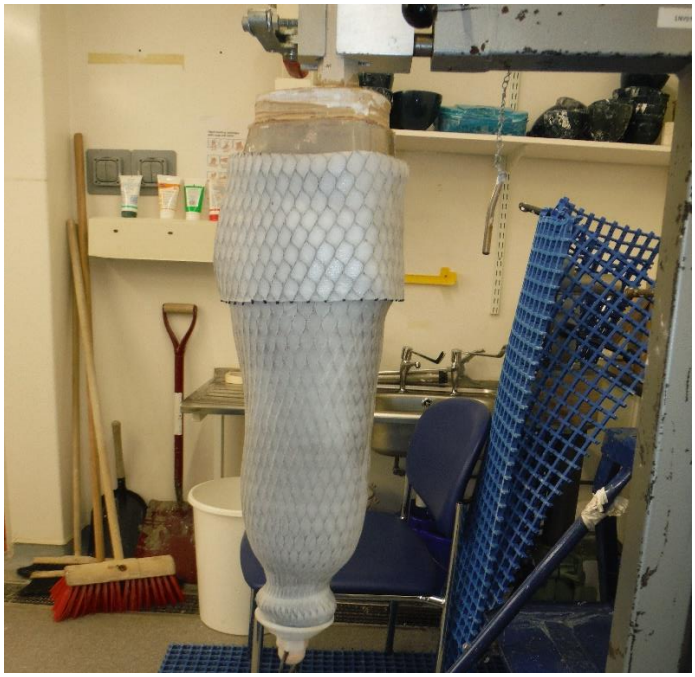

Figure 10: Mesh embedded in cured silicone over original residuum

RADIAL GRIP

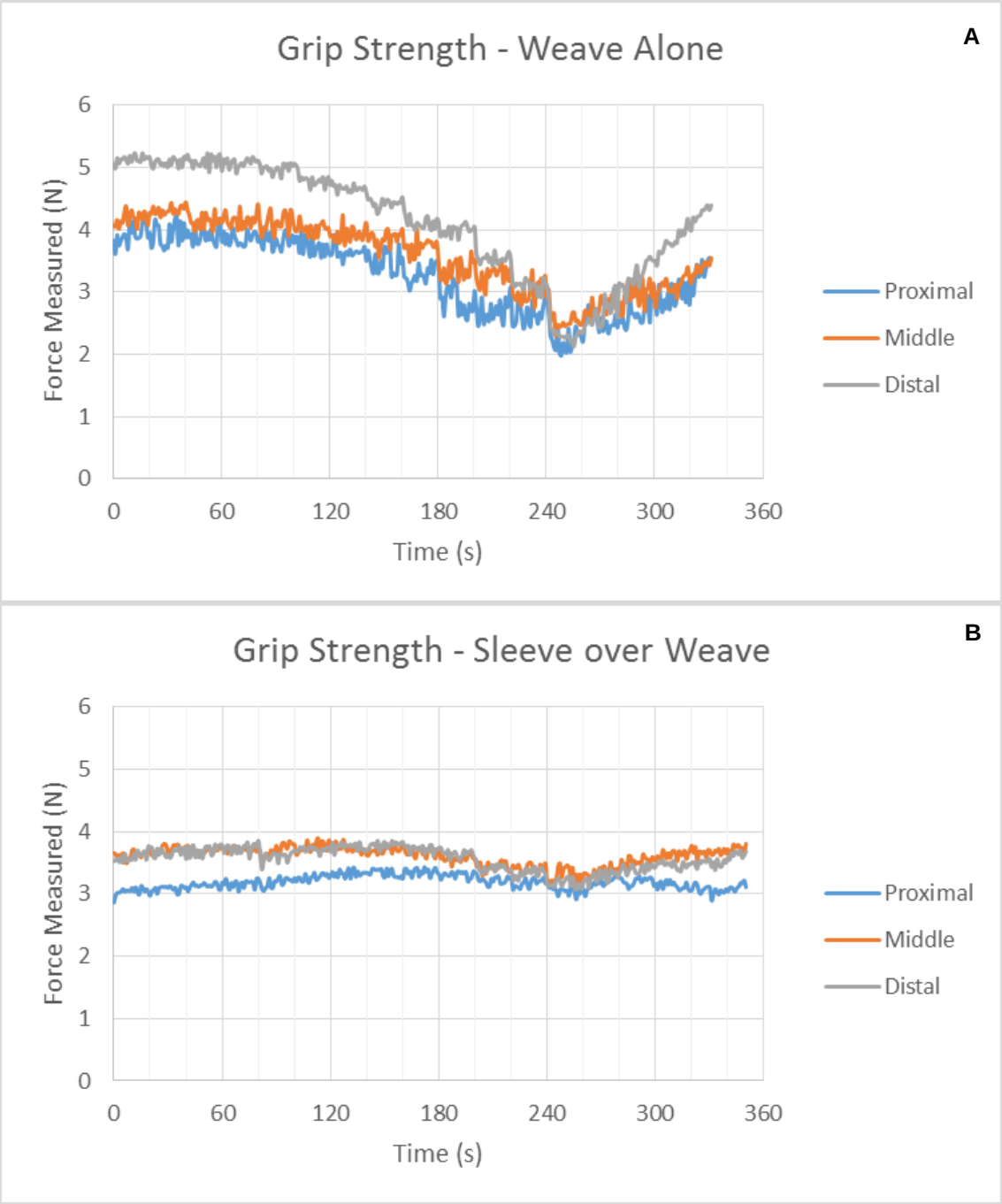

Figure 11: Grip strength refers to the amount of force the device applied over the residuum. This graph depicts the relationship between the release of tension over time (s) and the force (N) the device applies over the residuum.

DISPLACEMENT

Graphs

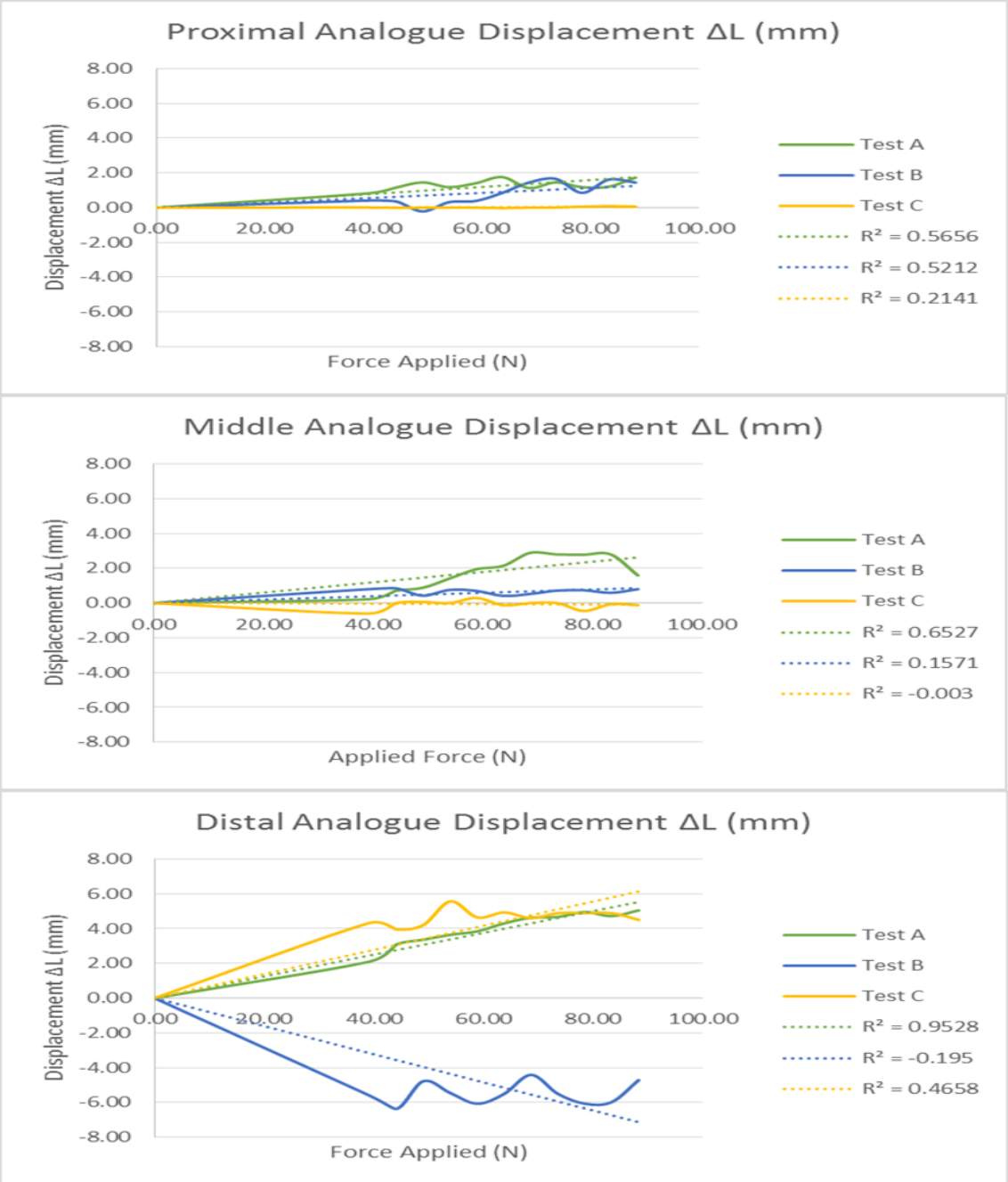

Figure 12: The relationship between the force (N) applied and the displacement (mm) experienced by the analogue residuum. Test A (weave alone) Test B (sleeve over weave) Test C (weave over sleeve).

Analysis of Variance

P=0 at α=0.05 for the proximal, middle, and distal thirds of the residuum. The pooled standard deviation value for the proximal sections was S=0.46 and the pooled correlation was R^2=55.30%. For the middle sections it was found that S=0.64 and R^2=58.68%. The distal sections had values of S=1.53 and R^2=89.48%.

Individual Statistics and Confidence Intervals

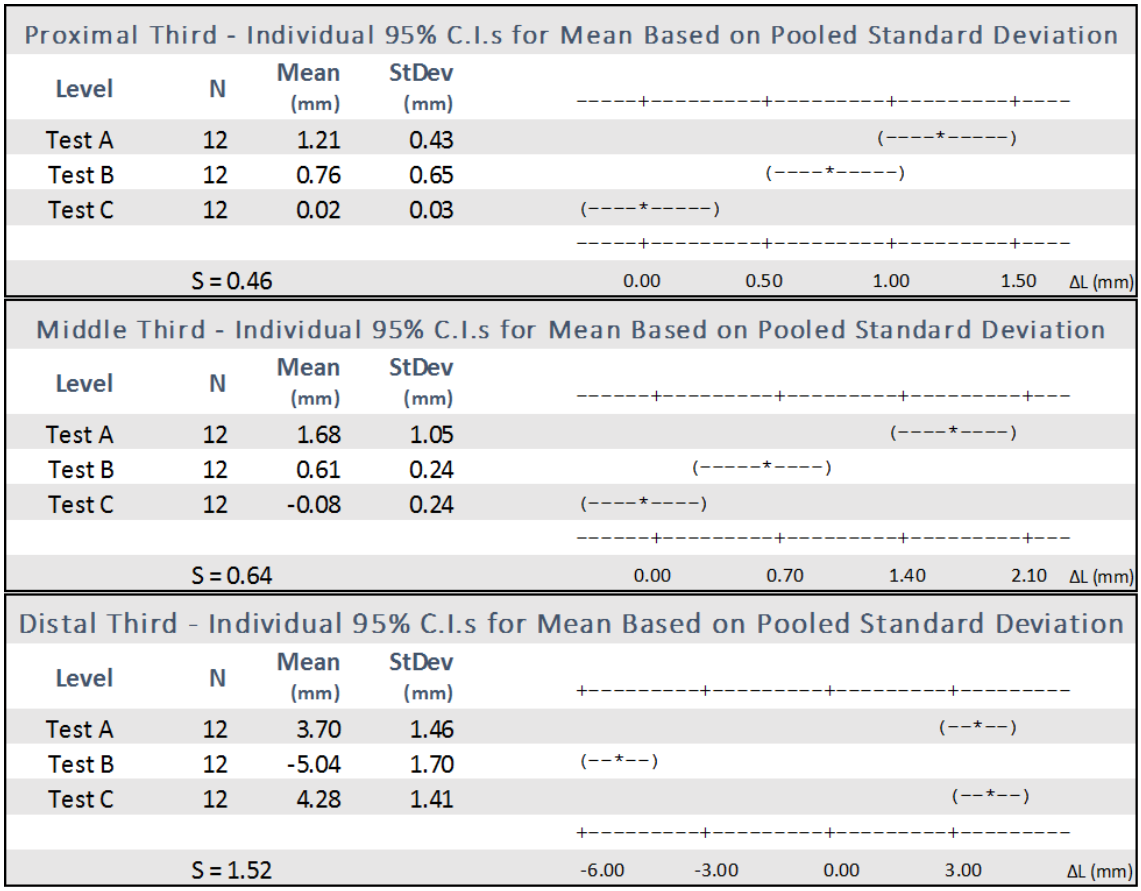

*Figure 13: N=number of data points, StDev=individual standard deviation, S=pooled standard deviation, * indicates the mean, (-----) envelops the 95% confidence interval for the mean of the population.*

CAD-FEA

There were insufficient time and limited resources (online tutorials only) to allow mastery of SolidWorks® for this project. The complicated process of weave-building was successfully achieved and the woven model built for testing; construction of a model consisting of the meshed material is still in progress. Attempts at simulation currently return “unknown errors” messages. Exporting the files to different FEA simulators and attempting to learn those additional programs was not feasible given time constraints; such undertakings will be pursued in the future.

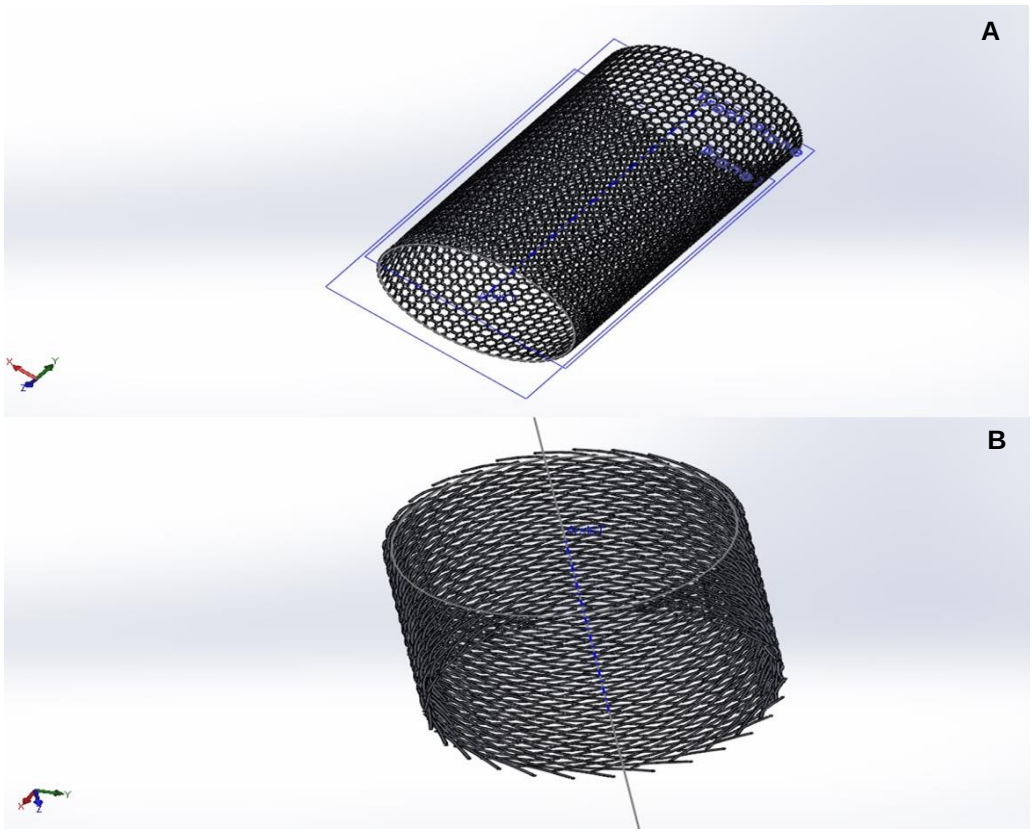

Figure 14: Mesh model (A) and weave model (B)

DISCUSSION

RADIAL GRIP

The radial grip for both the weave alone and weave with silicone sleeve showed a linear decrease in experienced force as the tension was released. Both devices also showed a linear increase in experienced force upon tension reapplication. Ideally grip strength, or the force experienced by the analogue residuum, will be the same down all three sections of the limb and uniformly distributed over the surface. Figure 11A shows the three segments of the residuum (proximal, middle, and distal) experience a similar force, rarely experiencing more than 1 N of difference. Figure 11B shows the sleeve over the weave exerts the most uniform grip with a maximum range of 0.5 N of force separating the three anatomical sections. There were many issues with the Tekscan® equipment, therefore it is necessary to comment on the validity of the data obtained; a further discussion of this can be found in the Conclusions section below.

DISPLACEMENT

Graphs

Test A (weave alone) displayed an increasing positive correlation across the three sections of the analogue limb. The distal third displayed the strong correlation (R^2=95.28%) while the proximal third displayed the weakest correlation for this device (R^2=56.56%). The correlation increases in strength from proximal to distal.

This agrees with residuum anatomy as there tends to be more soft tissue in the more distal regions.

Test B (silicone sleeve over the weave) experienced the strongest positive correlation at the proximal section (R^2= 59.32%). The correlation for the middle and distal sections for this device were poor, (R^2=15.71% and R^2=19.50% respectively). This indicates the weave under a silicone sleeve is not able to grip and properly displace the soft tissue. A hypothesized reason for the displacement experienced at the proximal end is the increased diameter of the knee joint which limits radial contraction of sleeve.

Test C (weave over the silicone) showed no correlation between applied tension and displacement. The strongest correlation for this device was in the distal third, however this was a negative correlation; such a relationship indicates the device made the residuum compress and applied tension had no visible effect. As the other data values from Test C are very close to zero, it can be assumed the device had no significant effect on analogue residuum.

Analysis of Variance

The p-value for the proximal third of the residuum was found to be P=0 at α=0.05 indicating at least one of the means of the three tests was significantly different. The pooled standard deviation was S=0.4612 and the pooled correlation was R^2=55.30%. This indicates a mediocre data fit, as an ideal model aims to keep a low S value with a high R^2 value. The p-value for the middle third was also P=0 at α=0.05 indicating the mean of at least one of the three tests was significantly

different. For the middle section S=0.636 and R^2=58.68% which indicates a slightly better model fit to the data than seen proximally. The p-value for the distal limb was P=0 at α=0.05 indicating that at least one of the means is significantly different. S=1.527 and R^2= 89.48% indicating that the model fits the data well.

Individual Statistics and Confidence Intervals

Proximal Third

Test A has the largest mean displacement (1.21 mm ± 0.46 mm) and Test C has the smallest (0.02 mm ± 0.65 mm). Regarding the confidence intervals, none of the tests overlap with Test C indicating the population means are different. Test A and Test B overlap suggesting the population means may not be significantly different. The pooled standard deviation is 0.46 mm.

Middle Third

Test A has the largest mean displacement (1.68 mm ± 1.05 mm) and Test C has the smallest (-0.08 mm ± 0.24 mm). The standard deviation for Test A is 0.81 mm larger than the standard deviations for the other tests. The confidence interval for Test A does not overlap the confidence intervals for the other tests indicating the population mean is significantly different from Test B and Test C. Test B and C slightly overlap indicating their population means may not differ significantly. The pooled standard deviation is 0.64 mm.

Distal Third

Test C has the highest positive mean (4.28 mm ± 1.41 mm) while Test A has the smallest positive mean (3.70 mm ± 1.46 mm). Test B has a negative mean (-5.04 mm ± 1.70 mm) indicating device shrinkage. Test A and C have 95% confidence

intervals with a large overlap indicating the population means are not significantly different. Test B has a significantly different population mean. The pooled standard deviation is 1.5 mm.

CAD-FEA Future Work

No model is currently ready for testing, although the weave construction is complete; simulations will not run due to reasons previously mentioned. Proper alignment and configuration to attain mating within shapes of the hexagonal mesh has not yet been determined. To accurately model the gas cylinder mesh, hexagons should pass under one another so they appear as diamonds when relaxed and as hexagons when stretched. In the current mesh model (Figure 14A) the hexagons sit directly against one another so small diamonds form between them. Although this is not the intended pattern, the mesh construct may still provide information about other possible design solutions.

Initially the models will be tested on a cylinder to check for any obvious errors before testing on a more geometrically accurate residuum. The pressure exerted by the models on the cylinder can be tested in SolidWorks® with an FEA plugin. Models will then be exported to ANSYS® where they must be converted to the correct format and have the appropriate mesh applied. A cylinder with the material properties of soft tissue will be used check for any obvious errors before testing on a more geometrically accurate residuum.

CONCLUSION

The displacement data indicated the weave was a successful concept meriting further investigation. The additional statistics indicated the results were valid and statistically significant, although many limitations must be considered. Among the difficulties encountered the following were the most impactful limitations: there was limited silicone (one device was embedded) with incorrect viscosity, an unideal analogue limb was used, the Tekscan® software was outdated, many F-socket sensors were damaged, and only 1 of the 8 sensor boxes was functional. Due to issues with the Tekscan® equipment and software, the grip data could not be validated and was unusable.

Human error exists in the measuring of displacement using ImageJ®. It is up to the observer to determine the beginning and end of the desired segment and to accurately and precisely place markers on each image. Reliability of measurements would improve by including one or two additional measurements by different people, but they will require proper instruction in the system beforehand.

The embedded mesh was deemed unfit for testing after it destroyed the original analogue residuum during donning. The silicone ordered (Appendix III) was meant to have a very low viscosity (similar to the consistency of olive oil) to facilitate the embedding process; however the tested silicone had a much higher viscosity (similar to molasses) which significantly impacted the ability to control

pouring and embedding. Once this silicone cured, it was too stiff to allow any changes to geometry.

The primary concern is the analogue residuum designated for testing was irreparably damaged when attempting to don the embedded mesh device prior to any tests being run. This forced the use of another analogue residuum which was smaller and less malleable than the original (see Appendix IV for material specifications). The new analogue could not adequately imitate the displacement seen in real residual limbs. A new analogue residuum needs to be built to adequately imitate behaviour of residual limb soft tissue.

Silicone with a lower viscosity should be attempted next to allow for real-world displacement. It is also possible to create similar membranes using latex. Multiple mesh devices should be cast, one in thin silicone and one in latex, and then tested using protocols described above. If these allow change in geometry, the weave prototypes should also be embedded in silicone or latex (corresponding to casting of mesh device) and tested using protocols above.

SolidWorks® modelling and simulations were abandoned in favour of attaining empirical data. Tasks were reprioritised so some usable data was assured for this project within the limited time. SolidWorks® design and simulation will be continued beyond this juncture.

The weave appears to be a successful concept because it displayed significant displacement in empirical testing. The mesh prototype will be retested with

appropriate materials; although currently there is no data on this prototype. The weave model was successfully built in SolidWorks® while the mesh model is still in development. Meshing and simulation of both models has yet to be completed pending further education in SolidWorks® and finite element analysis. Continued investigation in the laboratory and on the computer will lead to an improved understanding of the behaviour and control of residuum soft tissue. The application of this learning will lead to an inexpensive and practical device complying with Majicast® specifications.

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APPENDIX I

Product Design Specification
Slack Elimination Component

Performance

1.1 To fit within the Majicast system
1.2 Must be able to expand to the interior wall of Majicast
1.3 Must decrease in diameter when tension applied to distal end
1.4 Must cause minimum 2cm longitudinal displacement of soft tissue through casting medium
1.5 Must present uniform radial grip around residuum
1.6 Must be easy to install
1.7 Must be easy to maintain and repair
1.8 Must be easy to replace
1.9 Must be able to withstand 20N of force
1.10 Operating conditions (see 'Environment')

Environment

2.1 Normal use: Component will be attached to a membrane proximally and to a piston distally
    2.1.1 When in use, the component will be surrounded by water in high pressure with 20N of force pulling distally.
    2.1.2 Component will be submerged in water and exposed to air cyclically
2.2 Temperature: The unit must withstand "room temperature" in tropical/subtropical climates
2.3 Pressure change: The unit must withstand pressure changes from 101kPa (storage) to high hydrostatic pressure (in use, depends on patient anthropometrics)
2.4 Corrosion resistance: Must not corrode with water exposure or from wear at couplings/intersections and/or at attachment site
2.5 Abuse: The part must withstand misuse, difficult fittings (larger patients), and rough handling
2.6 Dust and Dirt: Part must be easily cleaned as to not affect casting quality

Life in Service

A minimum of 30 years is required due to location and local economy, but, if possible, a longer life in service would be preferred.

Maintenance

Our competitors either do not include a slack elimination component, or the component is part of the socket suspension system. To keep within targeted production costs and to achieve an ideally maintenance-free component, the design should comply with the following:

4.1 Be completely maintenance free excepting cleaning to remove dirt and debris and to check for component failure
4.2 Where screws, washers, and other such supplies are used, UK/EU standards must be complied with (see 'Standards and Specifications')
4.3 Any parts needing cleaning or lubrication must be accessible within one minute
4.4 The part should be easily removable for replacement at the end of its life

Target Product Cost

Our aim is to produce an effective slack elimination component of a hydrostatic prosthetic socket casting system that will be affordable for prosthetic practices in low-income countries. The retail cost of present devices is _____. Allowing for overheads and the possibility of unforeseen events, the target cost for manufacture should be between ____ and ____ per completed and packaged device.

Competition

Össur is the only company with a slack elimination system as part of the socket casting process. This system requires a silicon liner (ICEROSS).

Packing

If the component is to be created at a different location from Majicast and therefore must be assembled into Majicast by the customer, then the following should be considered for the final packaging of the device (see 'Materials').

7.1 Size must be kept to a minimum
7.2 Cost must be kept to a minimum
7.3 Package used must be attractive to the customer (shape and colors used)
7.4 Weight must be kept to a minimum
7.5 Should prevent corrosion if applicable
7.6 Must be water proof
7.7 Should prevent damage
7.8 Must be easily removed by customer
7.9 Assembly and fitting instructions should accompany the package
7.10 Company logo must be on the package

Shipping/Transport

If the component is to be created at a different location from Majicast and therefore must be assembled into Majicast by the customer, then the following should be considered for the final packaging of the device.

8.1 Packages will be stored for transport in boxes with at least 10 per box
8.2 ISO containers will be used to carry the boxes
8.3 Transport will be by air or sea then road or rail

Quantity

Meta-analysis of limb loss and prosthetic need in developing and low-income countries indicates a substantial need for quality, cost-efficient, hands-free casting systems. The current methods for casting in these conditions are inadequate, produce ill-fitting sockets, or are too expensive. However, once in place, they should not need replacing for 30 years.

Manufacturing Facility

There are no constraints on manufacturing facility. To reduce cost, it would be advisable to manufacture the component in the same facility as the Majicast so that they can be assembled there thus removing the need to package and ship the component separately from the device.

Size

11.1 Length not to be greater than 33cm (length of Majicast)
11.2 Breadth not to expand past 18cm in diameter

Weight

12.1 The weight of the component should be minimal while maintaining strength as a principal factor

Aesthetics

13.1 Robust image must be projected to the customer
13.2 Attractive appearance, should “go” with the rest of the device

Materials

14.1 The use of existing materials is preferable; developing new materials is unnecessary
14.2 Must be easily used in production
14.3 Chosen material must withstand the necessary environmental conditions (see ‘Environment’)
14.4 Must not oxidize in any way

14.5 Should be lightweight; however, strength should not be sacrificed for weight reduction
14.6 Resistant to wear and tear
14.7 Chosen finish should not react with skin or anything else it might contact in normal use
14.8 Materials should not be poisonous
14.9 Materials must be flexible
14.10 Materials must be able to relax to original shape after use
14.11 Materials must not be made of elastic

Product Life Span

This should be as long as possible so that the initial investment may be recovered. Each market will be analyzed separately, and production will continue until the “product life cycle curve” levels out. The product life span depends on favorable market reception.

Standards/Specifications

I would need to have access to the Majicast Product Design Specifications in order to complete this. The slack elimination component is just that, a component, therefore it needs to fit within the PDS for Majicast and the standards and specifications for the whole device.

Ergonomics

I cannot specify this until I know how the part fits into the Majicast device.

Customer

The customer will either be prosthetists working in low-income countries or organizations in low-income countries that are developing a prosthetic center.

Quality and Reliability

The device and this component must comply with MRHA standards for quality and reliability.

Shelf Life Storage

20.1 Warehouse storage: devices will be stored in their individual packaging. Depending on the final size of the device, they will be stored in boxes with a minimum of 10 per box.
20.2 There may be a shelf-life on the material as the part materials are uncertain at this time.

Processes

There are no limitations on processes as there are no limitations on manufacturing facilities

Time-Scale

22.1 Specification formulation
22.2 Concept evaluation
22.3 Evaluation of concepts
22.4 Design process complete
22.5 Process setting complete
22.6 Commence manufacturing

Testing

23.1 Batch inspection for the final product. A batch test of 1 in 40 will be carried out

Safety

Device must comply with all relevant parts of the MHRA

Company Constraints

Unknown

Market Constraints

Unknown

Patents

To the author's knowledge, there are no existing patents for this type of component

Political and Social Implications

Unknown

APPENDIX II

Design Matrices

	Concepts					
Features	ICEROSS	MDWCWE	SDWCWE	MeshSE	SDWCW	MDWCW
Inelastic material		0	0	0	1	1
Flexible material		-1	-1	-1	1	1
Elastic behavior of part	d	0	0	0	1	1
Maintenance level	a	0	0	0	0	0
Easily cleaned	t	0	0	0	0	0
Uniform radial grip	u	-1	-1	1	1	1
Distal diplaces soft tissue	m	-1	-1	-1	-1	-1
Manufacturability		-1	-1	1	-1	-1
Cost		0	0	0	1	1
Score:		-4	-4	0	3	3

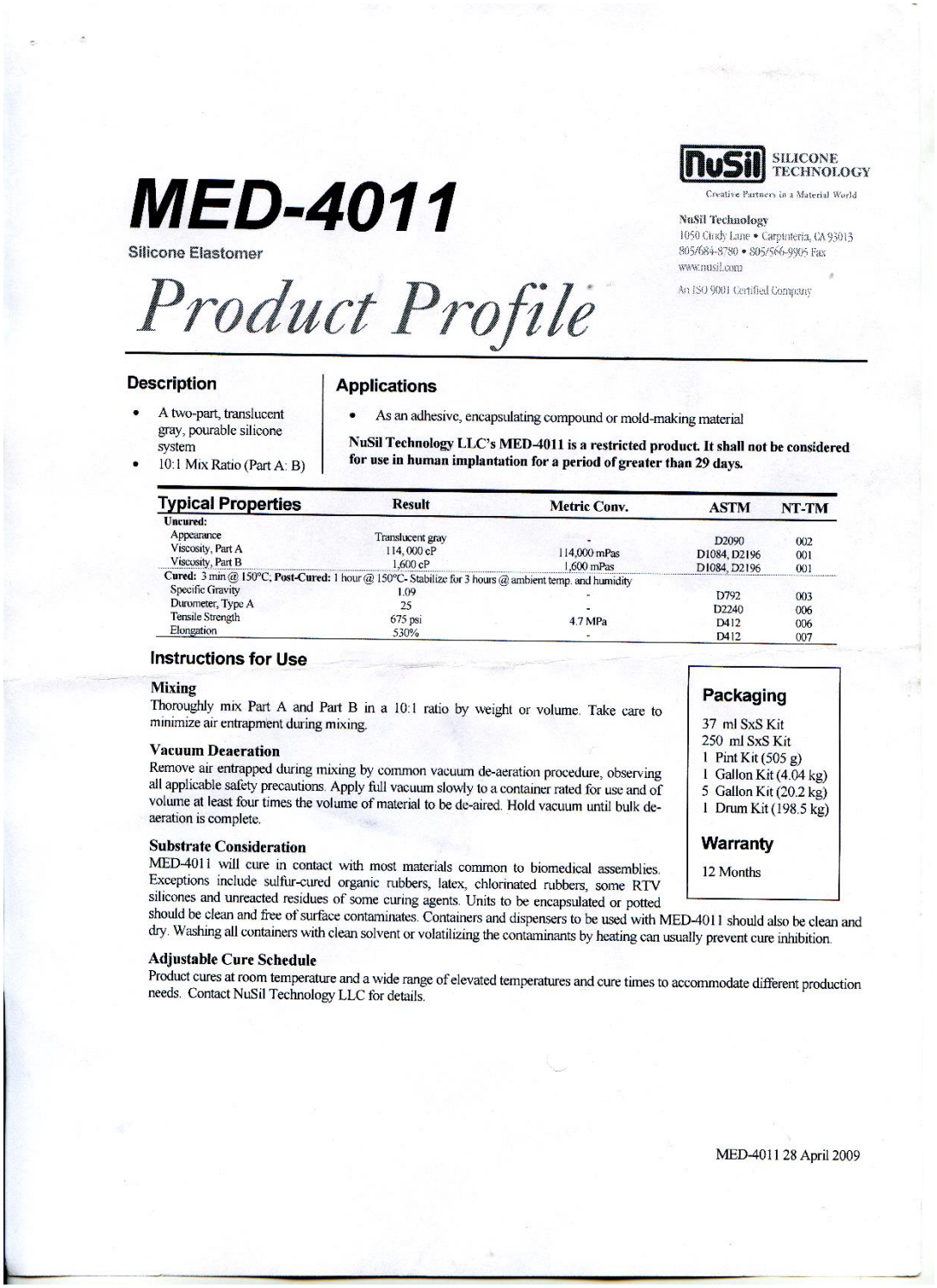
ICEROSS = Ossur's Icelandic Roll On Silicone Sleeve
SDWCWE = single density wax cotton weave embedded in silicon
MDWCWE = multi-density wax cotton weave embeded in silicon
MeshSE = mesh embeded in silicon
SDWCW = single density wax cotton weave outside membrane
MDWCW = multi-density wax cotton weave outside membrane

	Concepts					
Features	ICEROSS	MDWCWE	SDWCWE	MeshSE	SDWCW	MDWCW
Inelastic material	6	5	4	3	1	1
Flexible material	1	1	1	6	1	1
Elastic behavior of part	2	2	2	2	1	1
Maintenance level	1	1	1	1	1	1
Easily cleaned	1	1	1	1	2	2
Uniform radial grip	1	3	3	3	2	1
Distal diplaces soft tissue	1	3	3	3	2	1
Manufacturability	1	6	5	2	5	6
Cost	6	2	2	3	1	1
Easily installed/replaced	0	1	1	1	1	1
Water resistant	0	1	1	1	2	2
High fatigue resistance	0	3	2	1	4	5
Wear resistant	0	4	3	2	5	6
Reusable	0	1	1	1	1	1
Score:	20	34	30	30	29	30

Ranking System
0 = n/a
1 = best
6=worst

APPENDIX III

Silicone Used to Embed Mesh Prototype



MED-4011

Silicone Elastomer

Product Profile

NuSil SILICONE TECHNOLOGY
Creative Partners in a Material World

NuSil Technology
1050 Cindy Lane • Carpinteria, CA 93013
805/684-8780 • 805/566-9905 Fax
www.nusil.com
An ISO 9001 Certified Company

Description

- A two-part, translucent gray, pourable silicone system
- 10:1 Mix Ratio (Part A: B)

Applications

- As an adhesive, encapsulating compound or mold-making material

NuSil Technology LLC's MED-4011 is a restricted product. It shall not be considered for use in human implantation for a period of greater than 29 days.

Typical Properties	Result	Metric Conv.	ASTM	NT-TM
Uncured:				
Appearance	Translucent gray	-	D2090	002
Viscosity, Part A	114, 000 cP	114,000 mPas	D1084, D2196	001
Viscosity, Part B	1,600 cP	1,600 mPas	D1084, D2196	001
Cured: 3 min @ 150°C; **Post-Cured:** 1 hour @ 150°C- Stabilize for 3 hours @ ambient temp. and humidity				
Specific Gravity	1.09	-	D792	003
Durometer, Type A	25	-	D2240	006
Tensile Strength	675 psi	4.7 MPa	D412	006
Elongation	530%	-	D412	007

Instructions for Use

Mixing
Thoroughly mix Part A and Part B in a 10:1 ratio by weight or volume. Take care to minimize air entrapment during mixing.

Vacuum Deaeration
Remove air entrapped during mixing by common vacuum de-aeration procedure, observing all applicable safety precautions. Apply full vacuum slowly to a container rated for use and of volume at least four times the volume of material to be de-aired. Hold vacuum until bulk de-aeration is complete.

Substrate Consideration
MED-4011 will cure in contact with most materials common to biomedical assemblies. Exceptions include sulfur-cured organic rubbers, latex, chlorinated rubbers, some RTV silicones and unreacted residues of some curing agents. Units to be encapsulated or potted should be clean and free of surface contaminates. Containers and dispensers to be used with MED-4011 should also be clean and dry. Washing all containers with clean solvent or volatilizing the contaminants by heating can usually prevent cure inhibition.

Adjustable Cure Schedule
Product cures at room temperature and a wide range of elevated temperatures and cure times to accommodate different production needs. Contact NuSil Technology LLC for details.

Packaging

37 ml SxS Kit
250 ml SxS Kit
1 Pint Kit (505 g)
1 Gallon Kit (4.04 kg)
5 Gallon Kit (20.2 kg)
1 Drum Kit (198.5 kg)

Warranty

12 Months

MED-4011 28 April 2009

FDA Master Access File

A Master Access File for MED-4011 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master Access File must contact NuSil Technology LLC.

Warnings About Product Safety

NuSil Technology LLC believes the information and the data contained herein are accurate and reliable. However, the user is responsible to determine the material's suitability and safety of use. NuSil Technology LLC cannot know each application's specific requirements and hereby notifies the user that it has not tested or determined this material's suitability or safety for use in any application. The user is responsible to adequately test and determine the safety and suitability for their application and NuSil Technology LLC makes no warranty concerning fitness for any use or purpose. NuSil Technology LLC has completed no testing to establish safety of use in any medical application.

NuSil Technology LLC has tested this material only to determine if the product meets the applicable specifications. (Please contact NuSil Technology LLC for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology LLC products in a particular application, review the latest Material Safety Data Sheet and contact NuSil Technology LLC with any questions about product safety information.

Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other materials mentioned in the text, obtain available product safety information and take the necessary steps to ensure safety of use.

Specifications

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please contact NuSil Technology LLC for assistance and recommendations in establishing particular specifications.

Patent Warning

NuSil Technology LLC disclaims any expressed or implied warranty against the infringement of any patent. NuSil Technology LLC does not warrant the use or sale of the products described herein will not infringe the claims of any United States' or other country's patents covering the product itself, its use in combination with other products or its use in the operation of any process.

Warranty Information

NuSil Technology LLC's warranty period is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology LLC provides a specific written warranty of fitness for a particular use, NuSil Technology LLC's sole warranty is that the product will meet NuSil Technology LLC's then current specification. NuSil Technology LLC specifically disclaims any other expressed or implied warranty, including warranties of merchantability and fitness for use. The exclusive remedy and NuSil Technology LLC's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. NuSil Technology LLC expressly disclaims any liability for incidental or consequential damages.

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1050 Cindy Lane
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805/684-8780
805/566-9905 Fax
www.nusil.com

STANDARD MATERIAL CERTIFICATION
(SMC)

Customer: **POLYMER SYSTEMS TECHNOLOGY LTD**
UNIT 2,NETWORK 4,CRESSEX BUSINESS
PARK, LINCOLN RD. HIGH WYCOMBE
BUCKINGHAMSHIRE, HP12 3RF
UNITED KINGDOM

Customer Purchase Order Number: **307470**

Nusil Technology Material No.: **MED-4011 SILICONE ELASTOMER**

Nusil Technology Lot No.: **68925**

Quantity Shipped: **2 x PINT 2PRT**

Warranted To: 14-Oct-15 when stored below 40°C in original, unopened containers.

Properties	Units	Test Method	Specification Limits	Test Results
UNCURED: PART A				
Viscosity - Rotational, (V2) Spindle 6, 5 rpm	cP	TM001	70000 - 150000	96,000 (96,000 mPas)
UNCURED: PART B				
Viscosity - Rotational, Spindle 3, 20 rpm	cP	TM001	5000 Maximum	1,275 (1,275 mPas)
UNCURED:				
Appearance, Physical State: Liquid		TM002	Pass/Fail	Pass
Appearance, Color: Gray		TM002	Pass/Fail	Pass
Appearance, Miscellaneous: Free of particulate		TM002	Pass/Fail	Pass
Appearance, Light Transmittance: Translucent		TM002	Pass/Fail	Pass
Viscosity - Rotational, Spindle 6, 5 rpm	cP	TM001	40000 - 75000	57,000 (57,000 mPas)
Viscosity - Rotational, Spindle 6, 5 rpm, Test @ 2 +/- 0.25 hours after catalyzation @ ambient temperature and humidity	cP	TM001	70000 - 150000	86,000 (86,000 mPas)
Particulate Analysis, less than 100 microns forming a visible pattern	#/1 sq in	TM060	0 Maximum	0
Particulate Analysis, 100 - 199 microns	#/1 sq in	TM060	4 Maximum	0
Particulate Analysis, 200 - 299 microns	#/16 sq in	TM060	3 Maximum	0
Particulate Analysis, 300 - 399 microns	#/16 sq in	TM060	1 Maximum	0

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www.nusil.com

STANDARD MATERIAL CERTIFICATION
(SMC)

Nusil Technology Material No.: **MED-4011 SILICONE ELASTOMER**
Nusil Technology Lot No.: **68925**

Properties	Units	Test Method	Specification Limits	Test Results
Particulate Analysis, 400 microns or larger	#/16 sq in	TM060	0 Maximum	0
Particulate Analysis, Macroscopic reflective particulates	#/16 sq in	TM060	0 Maximum	0
CURED: 3 +/- 0.5 minutes @ 150 +/- 5°C **Mix Ratio: 10:1 Part A:Part B** **POST CURED: 60 +/- 5 minutes @ 150 +/- 5°C in oven. Stabilize for 3 hours minimum @ ambient temperature and humidity.**				
Specific Gravity		TM003	1.07 - 1.13	1.09
Durometer, Type "A" scale		TM006	25 - 35	27
Tensile Properties of Elastomers, Tensile Strength	psi	TM007	550 Minimum	703 (4,847.19 kPa)
Tensile Properties of Elastomers, Elongation	%	TM007	350 Minimum	554
Tissue Culture (Cytotoxicity Testing)		TM061	Pass/Fail	Pass
Elemental Analysis of Trace Metals, Method A - As, Ca	ppm	TM131	100 Maximum	Pass
Elemental Analysis of Trace Metals, Method A - Fe, Ti	ppm	TM131	50 Maximum	Pass
Elemental Analysis of Trace Metals, Method A - Ba, Cd, Zn	ppm	TM131	30 Maximum	Pass
Elemental Analysis of Trace Metals, Method A - Ag, Bi, Co, Cr, Cu, Ge, Mn, Mo, Ni, Pb, Sb, Sn, Tl, V, Zr	ppm	TM131	10 Maximum	Pass

X

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www.nusil.com

STANDARD MATERIAL CERTIFICATION
(SMC)

Nusil Technology Material No.: **MED-4011 SILICONE ELASTOMER**

Nusil Technology Lot No.: **68925**

This is a restricted product. It shall not be considered for use in human implantation for a period greater than 29 days.
NuSil Technology has tested this lot of material only to determine if it is in compliance with current specification requirements. It is the sole responsibility of each purchaser to ensure that any use of these materials is safe and complies with all applicable laws and regulations. It is the user's responsibility to adequately test and determine the safety and suitability for their applications and NuSil Technology makes no warranty concerning fitness for any use or purpose.

Quality Assurance: Brenda Middleton

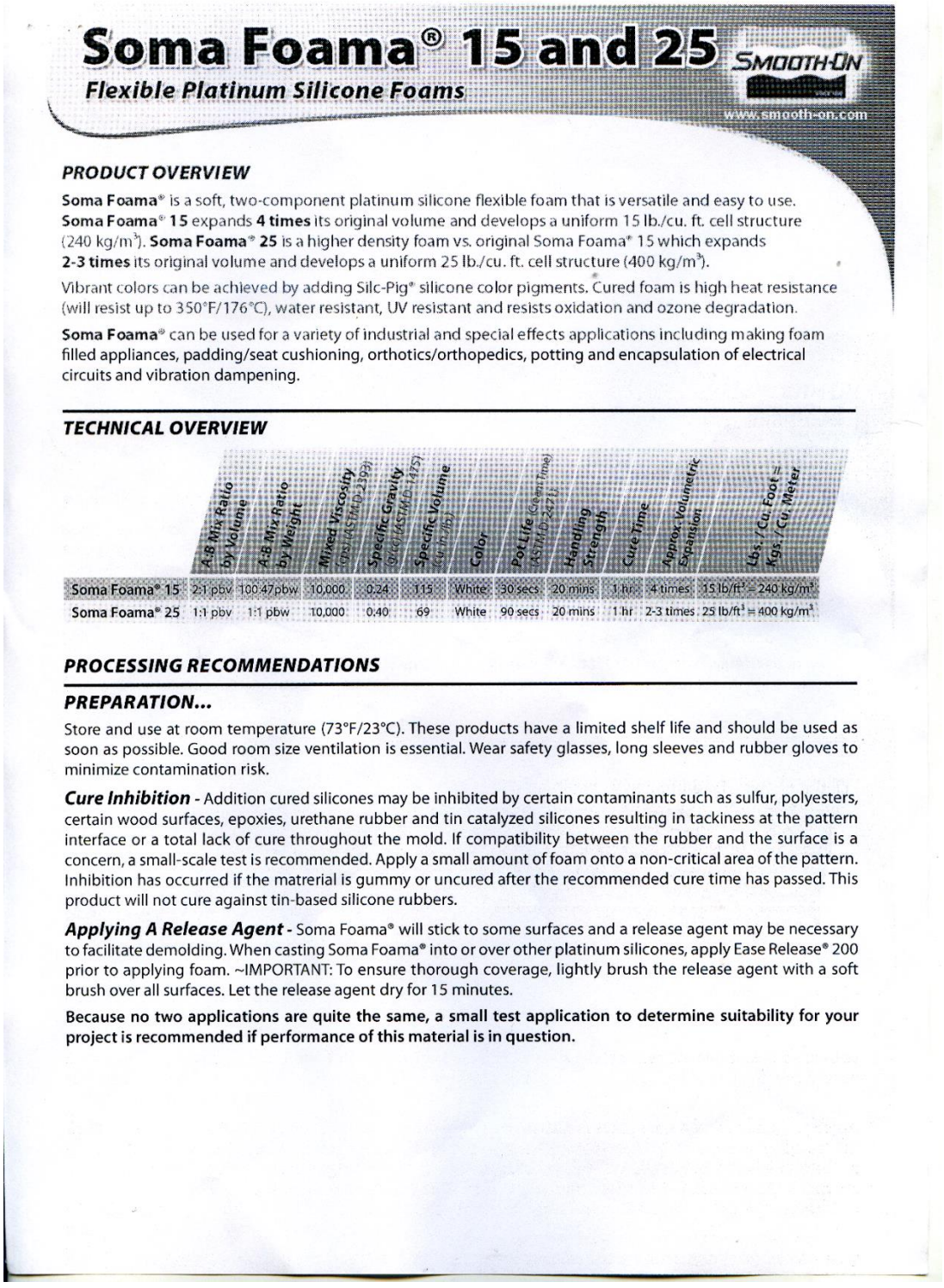
Date of Shipment: 14-Oct-14

Cage Code: **5U206**

Country of Origin: **United States of America**

APPENDIX IV

Material Data for New Analogue Residuum



Soma Foama® 15 and 25

SMOOTH-ON

www.smooth-on.com

Flexible Platinum Silicone Foams

PRODUCT OVERVIEW

Soma Foama® is a soft, two-component platinum silicone flexible foam that is versatile and easy to use. **Soma Foama® 15** expands **4 times** its original volume and develops a uniform 15 lb./cu. ft. cell structure (240 kg/m³). **Soma Foama® 25** is a higher density foam vs. original Soma Foama® 15 which expands **2-3 times** its original volume and develops a uniform 25 lb./cu. ft. cell structure (400 kg/m³).

Vibrant colors can be achieved by adding Silc-Pig® silicone color pigments. Cured foam is high heat resistance (will resist up to 350°F/176°C), water resistant, UV resistant and resists oxidation and ozone degradation.

Soma Foama® can be used for a variety of industrial and special effects applications including making foam filled appliances, padding/seat cushioning, orthotics/orthopedics, potting and encapsulation of electrical circuits and vibration dampening.

TECHNICAL OVERVIEW

	A:B Mix Ratio by Volume	A:B Mix Ratio by Weight	Mixed Viscosity (cps) (ASTM D 2393)	Specific Gravity (g/cc) (ASTM D 1475)	Specific Volume (cu in/lb)	Color	Pot Life (gel time) (ASTM D 2471)	Handling Strength	Cure Time	Approx. Volumetric Expansion	Lbs. / Cu. Foot = Kgs. / Cu. Meter
Soma Foama® 15	2:1 pbv	100:47pbw	10,000	0.24	115	White	30 secs	20 mins	1 hr.	4 times	15 lb/ft³ = 240 kg/m³
Soma Foama® 25	1:1 pbv	1:1 pbw	10,000	0.40	69	White	90 secs	20 mins	1 hr	2-3 times	25 lb/ft³ = 400 kg/m³

PROCESSING RECOMMENDATIONS

PREPARATION...

Store and use at room temperature (73°F/23°C). These products have a limited shelf life and should be used as soon as possible. Good room size ventilation is essential. Wear safety glasses, long sleeves and rubber gloves to minimize contamination risk.

Cure Inhibition - Addition cured silicones may be inhibited by certain contaminants such as sulfur, polyesters, certain wood surfaces, epoxies, urethane rubber and tin catalyzed silicones resulting in tackiness at the pattern interface or a total lack of cure throughout the mold. If compatibility between the rubber and the surface is a concern, a small-scale test is recommended. Apply a small amount of foam onto a non-critical area of the pattern. Inhibition has occurred if the matrerial is gummy or uncured after the recommended cure time has passed. This product will not cure against tin-based silicone rubbers.

Applying A Release Agent - Soma Foama® will stick to some surfaces and a release agent may be necessary to facilitate demolding. When casting Soma Foama® into or over other platinum silicones, apply Ease Release® 200 prior to applying foam. ~IMPORTANT: To ensure thorough coverage, lightly brush the release agent with a soft brush over all surfaces. Let the release agent dry for 15 minutes.

Because no two applications are quite the same, a small test application to determine suitability for your project is recommended if performance of this material is in question.

Safety First!

The Material Safety Data Sheet (MSDS) for this or any Smooth-On product should be read prior to use and is available upon request from Smooth-On. All Smooth-On products are safe to use if directions are read and followed carefully.

Be careful.

Use only with adequate ventilation. Contact with skin and eyes may cause irritation. Flush eyes with soap and water for 15 minutes and seek immediate medical attention. Remove from skin with waterless hand cleaner followed by soap and water.

Warning - a small amount of Hydrogen gas is released as part of the A:B reaction. Use only with adequate ventilation and do not breath fumes. Also do not smoke or have other ignition sources in proximity to this product during mixing and pouring.

Important: The information contained in this bulletin is considered accurate. However, no warranty is expressed or implied regarding the accuracy of the data, the results to be obtained from the use thereof, or that any such use will not infringe upon a patent. User shall determine the suitability of the product for the intended application and assume all risk and liability whatsoever in connection therewith.

MEASURING & MIXING...

Mixing - Mixing can be done by hand or using a drill and a mixer attachment, such as a "squirrel" mixer. After dispensing required amounts of Parts A and B into mixing container, mix thoroughly for 30 seconds. Stir quickly and deliberately, making sure you scrape the sides and bottom of the mixing container several times. Be careful not to splash material out of the container. Remember, foam cures quickly. Do not delay between mixing and pouring. Elevated temperatures will result in a reduced pot life and cure time.

POURING, CURING & PERFORMANCE...

Warning - A small amount of Hydrogen gas is released as part of the A:B reaction. Use only with adequate ventilation and do not breathe fumes. Also do not smoke or have other ignition sources in proximity to this product during mixing and pouring.

Pouring - For best results, pour your mixture in a single spot at the lowest point of the containment field and let the mixture seek its own level.

Handling Strength is 20 minutes with full cure in 1 hour at room temperature. Foam color will darken over time. Adding Silc-Pig® silicone pigments will help stabilize color of cured foam. **To adhere Soma Foama® to other platinum silicones**, best adhesion is realized when poured against newly cured platinum silicone rubber.

Results May Vary: This material is subject to variables such as high or low environmental temperatures. A small test to determine how material performs for your application is recommended.

Improve Surface Finish and Minimize Voids With Back Pressure
Use a board that will completely cover the mold opening. Using a ¾" (2 cm) drill bit, drill 3 holes in the board spaced a few inches / cm apart. Make sure that, when the board is placed over the mold opening, the holes are over the mold cavity and rising foam will be able to make it through. Apply Ease Release® 200 thoroughly too both sides of the board and into the drilled holes. Mix and pour foam into mold cavity and place board over mold opening. Hold board firmly in place. As foam rises in the mold cavity, some foam will grow out of the drilled holes. After the foam stops growing, you can let go of the board. Do not demold for at least 20 minutes.

Demold - After 20 minutes, cut excess material that came through holes. Gently remove board and casting.

SMOOTH-ON

Call Us Anytime With Questions About Your Application
Toll-free: **(800) 762-0744** Fax: **(610) 252-6200**

The new **www.smooth-on.com** is loaded with information about mold making, casting and more.

030612-JR

APPENDIX V

DOWN SAMPLING DATA IN EXCEL

Excel has a limit of 32000 elements in a series to be plotted in a graph, and plots of this size can swell the size of output files. To reduce the file size and still maintain the original data trend, down sample the data in a 1-for-2, 1-for-3, 1-for-4 etc manner. This can be done easily using the index function and the drag-and-fill operation. The index function in excel allows elements in a block of data to be referenced by their position in the block, versus an absolute reference.

Generic form **=INDEX(array,row_num,column_num)**

For this example **=INDEX($B$6:$B$65536,(ROW(C6)-6)*2+1,1)**

$B$6:$B$65536 This defines the array from which the down sampling draws. $B$6 is now index (1,1) of the array. The use of the *"$B$6"* form versus *"B6"* prevents excel from incrementing the numbers when the functionis copied.

(ROW(C6)-6)*2+1

- ***Row(C6)*** This uses the current row position as the step index, it returns the value "6" for the first element defined in this example.
- ***-6*** This subtracts out the starting offset of the index function to return "0" for this row, "1" for the next row and so on.
- ****2*** This defines the step function to return every second sample. The functions return ***(6-6)*2 = 0***, ***(7-6)*2 = 2*** and so on. Use 3 for a 1-for-3 down sample etc.
- ***+1*** The first element of the array defined in the function (Top left corner) has an index of (1,1) so the +1 adjusts for this for the previous part of the equation which returns 0 for the first row.

1 The simply means use column number 1 of the defined array.

Once the function is typed in, simply select the cell and drag the fill-handle to select at least N/2 cells below it (N is the number of original samples) to copy the formula. As can be seen from the graphs below of column B (The original data) and column C (The down sampled data), the curve of the source data is maintained with 1/2 of the information.

APPENDIX VI

SolidWorks® Excel® Data for Weave Construction

0	x	y	z		Pi	3.141593		
1	181.875	0	0		Angle in Rad	0.224397		
2	176.7058	40.33148	11.78571		Z Increment	11.78571		
3	163.8641	78.91179	23.57143		Strand Dia	2.5	Radius	1.25
4	141.7078	113.0065	35.35714		Internal Dia	180	Radius	90
5	113.3986	142.1945	47.14286		Middle Dia	181.25		
6	78.64346	163.2996	58.92857		Outer Dia	181.875		
7	40.47365	177.3144	70.71429					
8	0.003163	181.25	82.5					
9	-40.4675	177.3158	94.28571					
10	-78.6378	163.3024	106.0714					
11	-113.394	142.1984	117.8571					
12	-141.704	113.0114	129.6429					
13	-163.861	78.91751	141.4286					
14	-176.704	40.33765	153.2143					
15	-181.875	0.006349	165					
16	-176.707	-40.3253	176.7857					
17	-163.867	-78.9061	188.5714					
18	-141.712	-113.002	200.3571					
19	-113.404	-142.191	212.1429					
20	-78.6492	-163.297	223.9286					
21	-40.4798	-177.313	235.7143					
22	-0.00949	-181.25	247.5					
23	40.46127	-177.317	259.2857					
24	78.63206	-163.305	271.0714					
25	113.3887	-142.202	282.8571					
26	141.6999	-113.016	294.6429					
27	163.8586	-78.9232	306.4286					
28	176.703	-40.3438	318.2143					