An Investigation into The Effect of a Soft Tissue Stabilising Mesh Within Elastomeric Liners for Lower Limb Prosthetics

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Thesis to obtain the Master of Science Degree in Bioengineering and Nanosystems
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Abstract - *A suspension prosthetic liner, is a prosthetic component that functions as an interface between the skin of a lower residual limb and a rigid prosthetic socket. The ultimate purpose of a liner is to improve amputee safety and comfort. Although prosthetic liners for lower-limb amputees are broadly commercially available, no academic studies have been found that evaluate the effect of different configurations of imbedded reinforcement structures within the matrix of liners, preventing pistoning occurrence. The aim of this investigation is to create tools to produce a liner that provides prosthesis suspension, by reducing pistoning and subsequently avoid deep tissue injury and to guarantee acceptable levels of comfort for the patient, by allowing an easy insertion and use of the liner. In this work, after a commercial liner's development analysis study and a scientific literature review, a set of design goals was created to achieve such a liner and matrix reinforcement. A finite element model (FEM) was created with two main goals: proving the necessity of a reinforcement within the matrix, evaluating where the main areas of stress in the reinforcement mesh configuration are present and what was it' effect on the liner pistoning occurrence (longitudinal displacement). To compare the reinforcement mesh configuration produced in this project with the state of the art commercial liners, utilising mechanical tests mimicking the conditions of the swing phase of the gait cycle, the effect of the liners when stump volume variations occur, and if the liners were resilient enough to maintain contact with the stump while its volume varied, during swing phase conditions has also been investigated. The "Majicast" prototype liners, produced in this project, showed a state of the art response to the test conditions.*

Key words: Reinforcement mesh; Matrix; Liner; Pistoning; Deep Tissue Injury; Finite Element Model;

1. Introduction

1.1. Motivation

The purpose of a prosthetic device is to replace the normal functions of the missing body part. It generally, consists of a socket that surrounds the residual limb, a terminal device, and an apparatus to connect and adjust the position of the socket relative to the terminal device. [1] The load supporting structure of the human body is the skeleto-muscular system, and so a prosthesis is intended to behave like an extension of this system. When a prosthetic device is used, after a lower limb amputation, all external loads are transferred from the socket prosthesis to the skeleton through the residual soft tissue. This load transfer is problematic, as the soft tissues are not designed to transfer these loading conditions. To achieve enhanced performance with minimal discomfort and no soft tissue damage, it is necessary to guarantee an adequate fit between the prosthesis and the residual limb. Therefore, the study of prosthetic liners is fundamental.

A suspension or locking prosthetic liner, is a prosthetic component that functions as an interface between the skin of a lower residual limb and a rigid prosthetic socket. The ultimate purpose of a liner is to improve amputee safety and comfort. Although prosthetic liners for lower-limb amputees are broadly commercial available, no academic studies have been found that evaluate the effect of different configurations of imbedded reinforcement structures within the matrix of liners, preventing pistoning occurrence. The investigation has mostly been developed on the study of the single material properties, without considering the stump/socket interface has a whole system. This work strives to fill this gap.

1.2. Literature Review

Prosthetic liners have been developed in order to allow a good fit between the prosthesis and the residual limb. The study of a good prosthetic fit has been deeply conducted by (A. Buis, 2006). To achieve a definition of good fit, one needs to know what affect the fitting of a prosthesis. For this, two points of view can be taken into care: the medical and the biomechanical/engineering one.

On the medical point of view, the danger exists when the tissue is under pressure. It can be at the cellular level, due to the restricted O_2 and nutrients supply, caused by restricted blood flow, or it can be at the tissue level, with abrasion and tissue inflammation, due to heat development. Through the study of (Reswick, 1976) it is known that nowhere in the stump should the local pressure be higher than 20 mmHg, for a long duration of time. This is possible if the high pressures of the stance phase of gait are released during the swing phase.

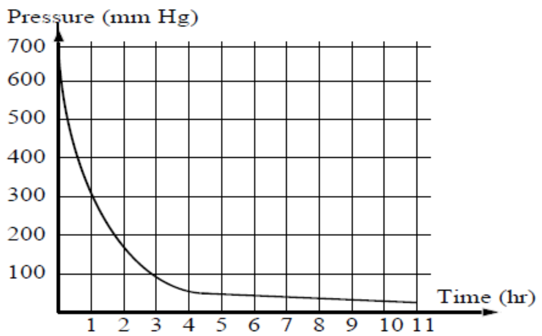

Figure 1: Reswick-Rogers diagram (1972), "safe" pressure below the curve. Adapted from (Reswick, 1976).

On the engineering point of view, the concern for a good fit is related to a criterion defined by (A. Buis, 2006) as coupling stiffness. It is a mechanical quality criterion accessed by the minimum relative movement between the two parts (prosthesis and stump), and it can be defined as the unit of load per unit of movement. There are two relative movements of the socket/liner system: Longitudinal (called pistoning), occurring between full body weight and swing phase, and transverse or rotational movement. An enhanced coupling stiffness according to (A. Buis, 2006) allows for:

- An increase in patient's comfort, and pressure symptoms prevention at the stump surface.
- Increase proprioception;
- Reduced pistoning, that way decreasing the risk for sores, eczema or ischemic problems, and also reduce the risk that the foot touches the ground during the swing phase.

To achieve the enhanced coupling stiffness, the socket/liner system must apply pressure and shear stresses to the stump surface. This way, the criteria for a good fit would be: as stiff a coupling as possible, with no tissue damage. For this to happen, the stresses allowing a stable coupling can't overstress the soft tissues, especially at pressure peaks, that are not only dangerous due to blood flow restriction, but also due to the shear stresses that they create within the soft tissue when pressure gradients are present (figure 2).

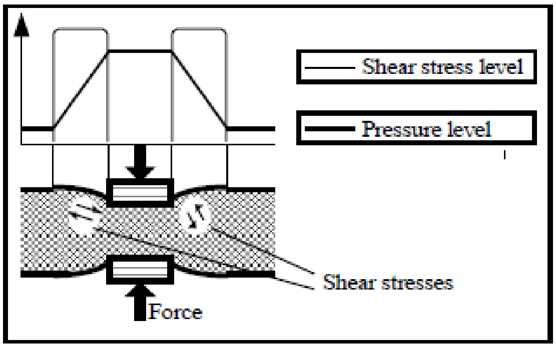

Figure 2: Representation Adapted from [1]. The graphic represents the pressure level and the shear stresses that result from a pressure gradient. This shear stresses within the soft tissue are especially likely to occur at bony prominences.

How does load transmission occur at the soft tissues is a question quickly raised after following this rationale. The load transmission can be drastically simplified if the soft tissues are considered to have a linear elastic stress-strain behavior. Although simple, it can be a good starting model for deformation and pressure distribution on living tissue, as it may remain sufficiently valid if it is considered only the short-term loads during the gait cycle. Using the elastic behavior model, surface matching liners were developed aiming to achieve local pressure distribution at full load, with moderate pressure gradients even at bony prominences. Silicone and other elastomers were used at this basis as the matrix of liners, due to their values of compressive stiffness (Sanders JE, 2004).

However, the concept of surface matching of an elastomeric liner is at risk if pistoning occurs, which is more likely to happen if the stump volume changes, daily, or even on a long-term basis (Sanders, 2005). To avoid pistoning, several liners have an embedded reinforcement mesh within its matrix, in order to create an anisotropic behaviour for the liner mechanical response (Bo Klasson, 1987)

1.3. Objectives and main contributions

The aim of this work is to investigate the use of an embedded fabric mesh within an elastomeric matrix of a liner. The objective of this investigation is to allow the production of a liner that provides a good prosthesis suspension, by reducing pistoning, avoids deep tissue injury, through a good pressure distribution, and reaches acceptable levels of comfort for the patient, by allowing an easy insertion and use of the liner.

To achieve the mentioned objectives, there is the need to study how a fabric mesh embedded within a liner, achieves a solution that fulfils a "surface matching" concept.

With this said, the main goals to look for in a liner and in this project are:

- Full contact with the stump, capable of avoiding pistoning and maintain the surface matching concept.
- To avoid pistoning, the liner's matrix must have an anisotropic behaviour. The liner can't stretch in a longitudinal direction, but it must stretch radially, to allow the donning of different stump sizes.
- Local pressure distribution around bony prominences, using an elastomeric material, that avoids peak pressure due to its viscoelastic behaviour akin to soft tissue behaviour (soft tissue, in reality, behaves more as a viscoelastic than elastically).
- A constant volume material, even while deforming, to minimize the effect of stump volume variations.

This thesis provides the following contributions to achieve the previously mention goals:

- A computational model was developed. It predicts the behaviour of a silicone prosthetic liner under longitudinal stretch, mimicking the tension that the prosthetic device exerts in a liner during the swing phase of the gait cycle. This model justifies the need for an embedded fabric mesh within elastomeric liners;
- The development of a computational model that compares an imbedded reinforcement mesh within a silicone matrix with the absence of it, enabling prediction of the soft tissue stabilization effect that a liner has.
- The development and creation of an imbedded fabric mesh within an elastomeric liner, creating an anisotropic composite able to control pistoning.
- Creation and development of a residual limb physical model, capable of being used to compare the effectiveness of different liners and their effect to avoid pistoning.
- Development of a liner's testing methodology, that compares the effectiveness (regarding pistoning decrease) of different liners in a realistic model.

2. Methodology

As previously stated in introduction, two FEM were created. One with the purpose of modelling the stump with a silicone liner without a reinforcement mesh embedded, inserted. To apply a force in a realistic way a steel plate was bonded to the bottom of the liner, but this was considered a rigid body, which, will therefore, not be analysed by the software.

The second model consists only in the silicone liner with a reinforcement fabric mesh embedded within it.

A mechanical method that identifies which of the prosthetic liners tested show the smallest longitudinal stretching capacity was also developed. In order to verify the one that will reduce pistoning the most and its effect in soft tissue control.

2.1. Methodology–1st model–non-reinforced

- To define the model geometry and dimensions;
- Define the material properties;
- Create the FE mesh of the model;
- Specify the boundary conditions and the loads applied;
- Run the model conditions;
- Analyse and improve the model.

This entire 1st model analysis was made using ANSYS software. The liner dimensions were based on dimensions of regular commercial liners[1].

The geometry sketch is represented in figure 3.

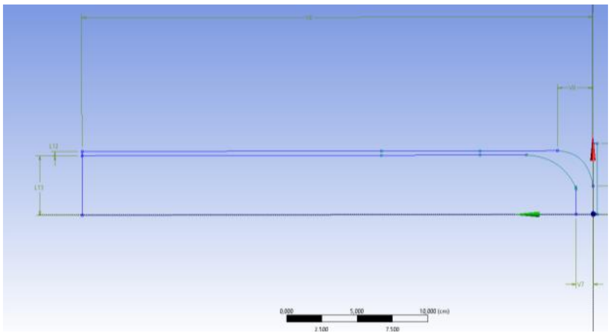

Figure 3: Model sketch with dimensions shown:
- *Liner's dimensions: Thickness at top=3mm, Total height = 36,2 cm; Contact between liner and plate radius =2 cm, Thickness at the bottom =1,19 cm;*
- *Inside core dimensions: Cylindrical part radius = 4,2 cm;*
- *Steel plate radius = 5cm*

The material properties defined in this study, for the soft tissue and liner were adopted from the literature.

The soft tissue properties were adapted from (M. B. Silver-Thorn, et al., 1996), considering a linear isotropic elasticity, being the values used similar to the ones observed in other studies (Lin, 2004) and stated in table 1.

For the silicone properties, two material models were evaluated. A hyperelastic and a linear elastic one. The behaviour of these two models was compared with the real behaviour of a non-reinforced silicone liner under similar characteristics. The model with a closer behaviour to the real liner was the linear elastic model for silicone. This means the silicone is still at the linear range of the stress-strain curve for the load applied in this simulation. This way, the linear silicone properties were used in both reinforced and non-reinforced models. These properties are shown in table 2.

Table 1: Soft tissue linear elastic properties (M. B. Silver-Thorn, et al., 1996).

Property	Value	Units
Density	1,1	g/cm^3
Isotropic Elasticity		
Young's Modulus	3E+05	Pa
Poisson's Ratio	0,45	
Bulk Modulus	1E+06	Pa
Shear Modulus	1,0345E+05	Pa

Table 2: Silicone material properties for the linear model. Young's modulus and Poisson's ratio retrieved from (Lin, 2004).

Property	Value	Unit
Density[2]	2,3	$Kg\ m^{-3}$
Isotropic Elasticity		
Young's modulus	4E+05	Pa
Poisson's Ratio	0,45	

[1] https://www.willowwoodco.com/products-services/liners/transtibial/alpha-classic-liners/#tab-2 consulted on 15/04/2018

[2] Adopted from: https://www.azom.com/properties.aspx?ArticleID=920 consulted on 4/04/2018

Bulk Modulus	1,333E+06	Pa
Shear modulus	1,3793E+05	Pa

For the first model, the boundary conditions applied were a fixed support at the top surface of the liner and soft tissue, and a remote force of 49N applied and the central point of the rigid steel plate. This force wants to mimic the maximum real force that a prosthetic device of a certain weight, exerts at a liner's pin during the swing phase. For this, a simple pendulum model was created. This pendulum mimics the below knee rotation occurring during the swing phase, using the knee flexion angle (θ=60º from (Stephen J.Piazza, 1996).

The variables for this calculation were the angle, the mass of the prostheses (in this case 3,5 Kg, an average value between a heavy and light prostheses (Selles RW, 1999)), the distance between the knee and the centre of mass of a regular shank (approximately 15 cm). Considering conservation of energy in this pendulum movement, as the velocities are low and air resistance can be neglected, the maximum tension that a bulb of 3,5 Kg exerts on the string was calculated to be:

$$T = \frac{mv^2}{l} + mg\cos\theta = 49N \qquad (1)$$

Another boundary condition on the first model were the contacts, one between the liner and the soft tissue, and another with a bonded contact between the liner and the steel plate. The fist is a frictional contact, with a coefficient of friction of 0,6, adapted from (M.ZhanG, 1999). As this analysis is a static structural one, the coefficient of friction used by Ansys is a static one based on Coulomb's law for friction.

To create the best FE mesh, a mesh sensitivity analysis was performed, this means that the mesh size was optimized in such a way that no difference in results in comparison with denser meshes are observed. This way optimizing processing times and having minimal adjustments. The mesh had 32.360 elements and 52.455 nodes. A mesh quality analysis was also made, to choose the size function that would create the better-quality mesh.

2.2. Methodology–2nd model–reinforced

What was done at this second stage of the finite element analysis, was a comparison between the deformation of a reinforced and a non-reinforced silicone liner, during the swing phase of gait cycle. Abaqus and Ansys were both used in this stage. Abaqus for the creation of the reinforced model, and Ansys for the creation of the non-reinforced model. In both software's the mesh (the computational one) and geometry, the boundary conditions, the silicone's properties and the analysis conditions were the same. The only difference was the full liner's length reinforcement fabric mesh assigned in Abaqus with polyester material properties and not assigned in Ansys.

A code capable of generating a mesh with a specific configuration of elements was created in FreeCAD by the University of Strathclyde and used in this work. This way, the methodology in this stage was different from the first stage model. Instead of creating a geometry and asking the software to do the meshing later of that geometry, here a geometry was created from an initial mesh. Ansys showed some limitations due to this change in methodology, this way, Abaqus was also used in this simulation.

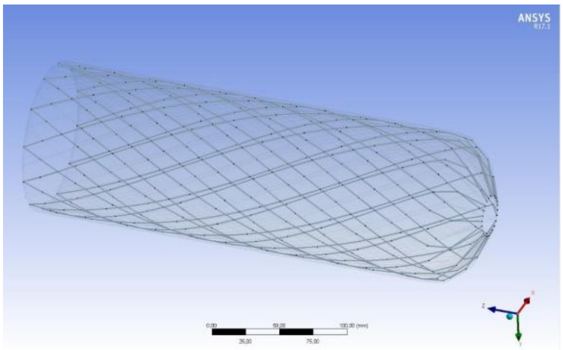

Figure 4: Beam elements representation in ANSYS.

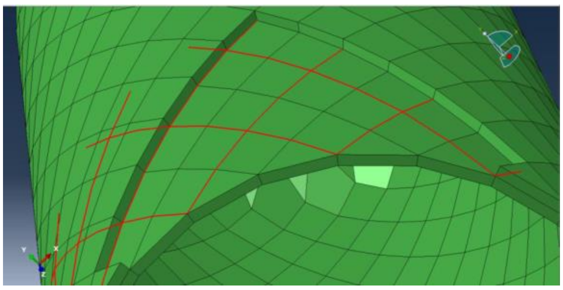

Figure 5: Highlighted in red are the beam elements. The inner layer is shown, to understand the disposition of the beams with the matrix, and that they are coincident with some solid elements' edges. Representation in ABAQUS

The material properties assigned for the silicone were the same as in the first model. There was not a soft tissue insert in this stage. Polyester fibres were the material used for the reinforcement mesh. The properties for the model were retrieved from the university of Michigan material's science department[3] and present in the following table.

Table 3: Polyester fibres material properties. Linear elastic model.

Property	Value	Unit
Density	1540	Kg
Isotropic Elasticity		
Young's modulus	2,5E+09	Pa
Poisson's Ratio	0,33	

The boundary conditions applied both in the reinforced and non-reinforced liner are a fixed support at the top of the liner, and a force applied as "general surface traction" in ABAQUS, and in ANSYS through a force vector applied uniformly to the entire surface, with the surface in both software being the smaller circumference at the bottom of the liner.

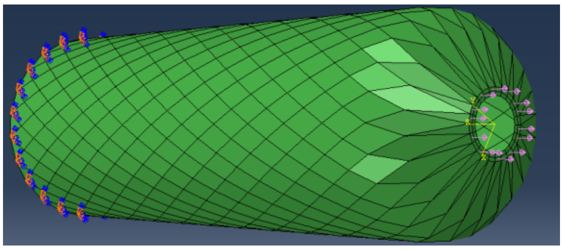

Figure 6: Boundary conditions in Abaqus. The top surface is fixed, and the distal end opening as an applied force in the same conditions as reported in Ansys.

3 http://www.mse.mtu.edu/~drjohn/my4150/props.html - retrieved 13/09/2018

2.3. Methodology – Liner's mechanical tests

The materials consisted in in a model of a transtibial stump and a prosthetic liner sample. The stump model consists in a bone replica, covered with a soft tissue model. The soft tissue model was constructed using silicone foam that covered the bone and mimics soft tissue properties. Inside it has a cavity that was filled with a bag, where water can be drained in or out, to simulate the stump volume variations during the day. The cavity was then fulfilled with silicone RTV6166 (from Silicone Solutions Ltd), that mimics the mechanical behavior of soft biological tissue, due to a similar stiffness and viscous behavior (Valtorta, 2007) and has been used in previous studies for soft tissue testing (Ottensmeyer, 2002) (Kalanovic, 2003). Finally, the stump model was covered with a silicone membrane, with the thickness of half a liner. This membrane didn't allow air to get between the liner and the stump during the mechanical tests, this way mimicking the behavior when a liner is donned into a residual limb, where the atmospheric pressure keeps the liner in place without air between the liner and the stump.

Five liners were tested. Two produced at the University of Strathclyde, called Majicast liners (one with a full-length reinforcement mesh and the other without reinforcement), and different three reinforced liners from "Össur hf", Iceross "comfort", "original" and "clear".

Thirty dynamic and load controlled tests were conducted, mimicking the swing phase of gait cycle and small stump volume variations. Description of such tests present in table 4.

Table 4: Tests description.

Test conditions	Non-reinforced Majicast liner	Reinforced Majicast liner	Iceross Clear	Iceross Original	Iceross Comfort
10 mL mark on the syringe	• Dynamic load-controlled tests: Triangular function: 49N max, 0N min, 2 Hz, 30 cycles; • Results: Load and displacement were retrieved at an acquisition rate of 100Hz and 3 graphics were constructed: Displacement vs time; Load vs time and Displacement vs load; • 2 tests for each volume change;				
15 mL mark on the syringe					
20 mL mark on the syringe					

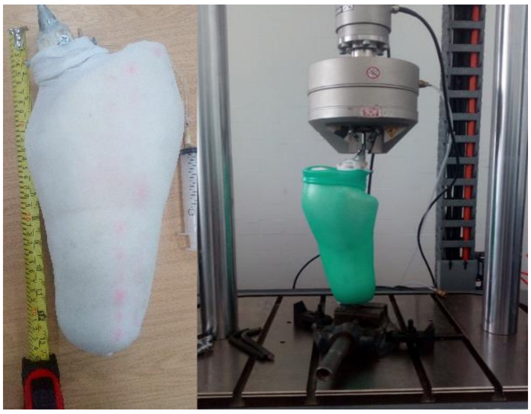

Figure 7: Image from the left - Stump model, showing the syringe controlling the volume. Image from the right – Experimental set up with liner inserted in the stump and the Instron Machine attached.

3. Results

3.1. 1st FE model–non-reinforced

The main result of the FEM is the deformation pattern prediction. For the 1st FEM, the non-reinforced one with soft tissue inserted in the cavity, the maximum deformation of the liner occurred at the bottom of the liner, with a deformation of 3,13cm for the liner. Another important result from this model, is the deformation that the soft tissue suffers when pistoning (separation of the liner from the stump) occurs, with a value of 7mm.

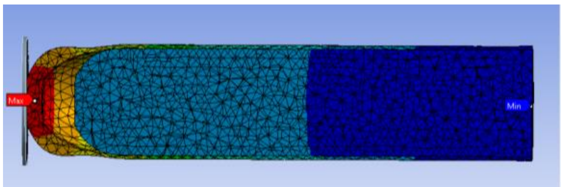

Figure 8: Pattern of deformation in the soft tissue. The maximum value of deformation in the soft tissue is of 7mm

3.2. 2nd FE model – reinforced

For this model, it is important to compare the deformation results between the reinforced and non-reinforced liner, under the same boundary conditions. The reinforced liner demonstrated a deformation of 3 cm, while the non-reinforced liner suffered a deformation of 6,7 cm. With both having the highest deformation at the tip of the liner.

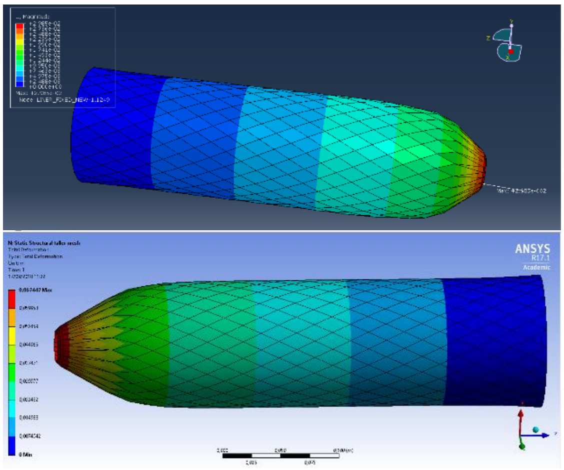

Figure 9: Deformation representation. Top image representing the reinforced liner deformation (3cm) and the bottom image the non-reinforced liner deformation (6,7 cm)

3.3. Mechanical liners tests results

The average maximum amplitude of displacement is the criterion chosen to evaluate the pistoning tests of the 5 different liners. This resulted in three displacement groups:

- In group I: the non-reinforced Majicast liner and the Iceross comfort liner, with an amplitude of displacement with a range between 7,4mm and 13,1mm.
- Group II: with the Iceross clear and original, with a range between 5,2-7,2 mm
- Group III - with a range between 4,1 and 2,9 mm, where only the Reinforced Majicast liner enters.

4. Discussion

4.1. 1st FE model–non-reinforced

These results demonstrate how the pistoning effect of a liner affects the model of a limb. Although the soft tissue model is not sufficiently exact to quantify this effect, it gives some clues of what happens during pistoning, and how the action of a stabilizing mesh fabric imbedded within the silicone matrix is necessary for soft tissue control. In this model it is seen that the concept of surface matching is lost, which will cause the loss of an even pressure distribution, by other words, will cause boundary pressure gradients along the stump and bony prominences, and that will be problematic at full load, during the stance phase of gait. This pressure gradients will cause shear stress within the soft tissue, compromising the quality of the coupling. It is also seen in this model, that the biggest soft tissue deformation during pistoning occurs at the distal end of the stump. This might cause scar stretching, which should always be avoided.

Comparing the experimental results from the liner's mechanical tests, specifically, the results taken from the non-reinforced Majicast liner, with the deformation from the linear model, it is observed that the deformation from the FEM is essentially 3 times higher than the real deformation. An explanation for this is the fact that friction is not the main factor responsible for suspension of elastomeric liners. Instead, the correct insertion (donning) of the liner, pushes out the air between the liner and the stump, creating a negative pressure in the region, allowing the atmospheric pressure to apply pressure on the exterior surface of the liner, maintaining suspension.

So, to a certain degree, this study reflects how the effect of a stabilizing mesh is important to avoid pistoning during swing, as the silicone matrix by itself is not capable of such a thing.

4.2. 2nd FE model – non-reinforced VS reinforced

Comparing both models deformations:

- Reinforced linear elastic silicone liner – Deformation of 3 cm at the distal end;
- Non-reinforced linear elastic silicone liner – Deformation of 6,7 cm;

It is observed that the reinforcement reduces by more than half, the deformation of the liner. It is also seen that the region of highest deformation is the conic region at the bottom of the liner. This suggests that this reinforcement configuration will not require a full-length reinforcement. This is beneficial because a full-length liner is less flexible, and for transtibial amputees, it might constrain the knee movement.

Considering the result of this model and comparing it to the experiment with the full length reinforced Majicast liner, a major difference is observed, from 3 cm of deformation at the computational model and 3mm of deformation in the experimental model. This computational model doesn't include the friction between the soft tissue and the liner, or does it consider the negative pressure that the liner suffers when donned correctly. However, it already has a deformation of 3 cm, equal to the deformation a non-reinforced computational model liner suffers when friction is considered.

Further work necessary to confirm that this reinforcement mesh configuration is good enough to avoid pistoning would be to create a model where soft tissue is inserted but also, where the atmospheric pressure exerted at the liner is applied to the model. Also, further work would be to construct a liner with the same reinforcement mesh configuration but only reinforcing the first 25mm. This would confirm that this configuration is competitive with the present state of the art commercial reinforced liner configurations.

4.3. Mechanical liners tests

It is surprising that Iceross comfort is in the same range of values that the non-reinforced Majicast liner. This because Iceross comfort has an embedded fabric mesh at its distal end, with the purpose of avoiding pistoning (longitudinal displacement), while the Majicast liner doesn't have a fabric mesh embedded and is just composed by the silicone matrix, not having an anisotropic behaviour within its material allowing the liner to stretch longitudinally. The reason for this behaviour from Iceross Comfort is probably due to a higher silicone concentration in order to increase comfort in comparison with other Iceross liners.

In group II are the other two commercial liners studied: Iceross clear and original. The main difference between these two liners is the presence of a covering nylon fabric on the outside of the "Original" liner. The two fabric reinforcements present within the silicone matrix are the same for both liners (the mesh has the same configuration and density), covering only the distal area of the liner. The fact that both liners present the same behaviour leads to the conclusion that the nylon fabric cover of the surface of the liner doesn't have any especial effect on the longitudinal displacement control. Instead, it seems to have only an aesthetic and ergonomic function.

Group III only has the reinforced Majicast liner. This liner shows a stiffer behaviour over all liners tested, showing not only the smaller displacement, but also the smallest force offset. This can be explained by the full-length fabric reinforcement imbedded within the silicone. This fact shows the possibility for a better soft tissue control during swing. Further tests are required to analyse the pressure distribution during stance phase and the bending of the knee.

5. Conclusion and future developments

In this work, a small step for the development of a new elastomeric liner was made. It is already known that an elastomeric liner locally distributes the pressure around bony prominences, as far as the surface matching concept is acquired, due to the mechanical properties of elastomeric materials. This thesis brings a study on the main aspect that distinguishes elastomeric liners: its reinforcement.

With the FEM created with the isotropic linear elastic silicone, and absence of a reinforcement, it was possible to observe the loss of surface matching due to pistoning occurrence, but also, the observation that soft tissue also suffers stretching during pistoning, which might be dangerous if the tissues around the scar are stretched until breakdown. This is especially dangerous in low income countries, (target of this work) where concerns are raised due to improper surgery (S Harkins, 2013).

The study developed with the FEM containing the reinforcement mesh configuration, allowed us to evaluate the clear improvement on pistoning control (less than half of the displacement observed in the model without reinforcement). This result shows that the configuration proposed by the University of Strathclyde is effective.

The mechanical tests resulted in some new discoveries. The first one is the fact that the non-reinforced Majicast liner shows the same pistoning control as the Iceross Comfort liner. It shows that the medical grade silicone used by the University of Strathclyde creates a matrix capable of avoiding longitudinal stretch to a certain extent. The other main discovery is the fact that the reinforced Majicast liner shows a higher pistoning control than Iceross Clear and Iceross Original. This is positive, because it justifies the mesh configuration used for the reinforcement. Also, connecting this liner with the reinforced FEM liner created, it is seen that the main stresses are sustained at the distal end, and the reinforcement along the liner is ineffective as it supports a small stress. If, in future work, a testing of a half-length reinforced liner is made, with the same mesh configuration, it is expected that this configuration allows a pistoning control as good as the state of the art liners, once the reinforcement on the top half of the liner is ineffective.

It is still necessary, however, to test the capacity for radial displacement of the reinforced liner. Two movements that the liner needs to do, both in a full-length and half-length reinforced liner, are the knee bending movement and the donning of the liner by an amputee. This should be done in the near future.

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