Hip Region Soft Tissue Analysis Whitepaper

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Hip fractures as a result of falls are a serious problem among the elderly. Approximately 20% of older adults hospitalised as a result of a hip fracture die within a year of their accident.

A hip protector is a device that locates over the hip of its user and supported in an undergarment. Its purpose is to reduce the force on the hip that the user suffers during a fall; either by directly absorbing the force of the impact, or by shunting the energy of the fall into the soft tissues around the hip.

The International Hip Protection Research Group (IHPRG) has released guidelines on biomechanical testing of hip protectors; however the model they suggest for approximating soft tissue during testing is a simple layer of foam. It is possible that a more anatomically accurate tissue model would produce more precise and useful force attenuation results.

This project set out to develop a more anatomically accurate model of the hip region that better represents the human anatomy and improve hip protector test results.

Physiological research underpinned the study by identifying the key mechanical characteristics of biological components to be represented in artificial materials.

Preliminarily finite element analysis (FEA) was used to computationally investigate how energy is transferred to the soft tissue region in the event of a fall and what is the mechanical effect on the hip region. FEA is now recognised by the FDA as a method to prove mechanical efficacy in medical device design. This study was used to explore the use of FEA in proving biomechanical performance.

An artificial soft tissue model was developed for use on impact test apparatus. The biofidelity characteristics of the artificial model were closely matched to human soft tissue. The developed model was impact tested and evaluated against the current polyethylene foam model and shows that hip protector force attenuation performance is closely linked to the soft tissue model used within the test apparatus.

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Product Development

Introduction

Hip fractures as a result of falls are a serious problem among the elderly. 90% of hip fractures are attributed to falls, approximately 20% of older adults hospitalised as a result of a hip fracture die within a year of their accident and approximately 50% suffer a serious decline in independence and mobility (Robinovitch SN, 2009).

A hip protector is a specialised form of undergarment with integrated protective pads that sits over the hip bone of the wearer. In the event of a sideways fall onto the hip the impact energy is reduced to the vulnerable greater trochanter (the bony protrusion of the hip bone). Fall energy is directly absorbed by the protective pad or shunted into the soft tissues surrounding the hip.

The International Hip Protection Research Group (IHPRG) is a group of falls and biomechanical experts who focus on the development of hip protector testing protocols. The IHPRG has released guidelines on biomechanical testing of hip protectors (Robinovitch SN, 2009); however the specification for the surrogate hip region is largely under developed and debate remains around an accurate artificial representation of a human hip. The IHPRG recognises the importance of the accuracy of the anatomy, surface geometry and soft tissue stiffness as key components that influence the distribution of force to the femur (Robinovitch SN, 2009). They also acknowledge that sufficient knowledge is lacking in hip region geometry and the mechanical characteristics of the surrounding soft tissues to develop an accurate specification (Robinovitch SN, 2009).

The Surgical Dressing Manufacturers Association (SDMA) in the UK is seeking to create a British standard for biomechanical testing of hip protectors. Currently in draft form, the EN standard recommends high-density polyurethane foam shaped to the upper lateral thigh, with a 6mm layer of silicone elastomer layer to simulate soft tissues and skin (Evans, S., 2011). However, it is expected that this may move to a silicone model (Evans, S., 2012) similar to the BFU Swiss Test Method for hip protector testing (Derler, S., 2010).

This lack of specificity results in different impact attenuation performance of the same hip protector between different test apparatus. This raises questions over the compliance requirements for hip protectors.

This study was undertaken by Locus Research and supported by Callaghan Innovation under the Tertiary Innovation Fellowship (TIF). Matthew Davison of the Auckland Bioengineering Institute was supervised by Jonathan Jones of Locus Research.

Aim

The study set out to develop a more anatomically accurate soft tissue hip region model to improve the accuracy of in-vitro testing of hip protector devices and correlation to real world user application of the devices.

Finite Element Analysis (FEA) software was used to computationally investigate how fall energy is transferred through the hip region. FEA is a mathematical technique for solving very complex physical problems.

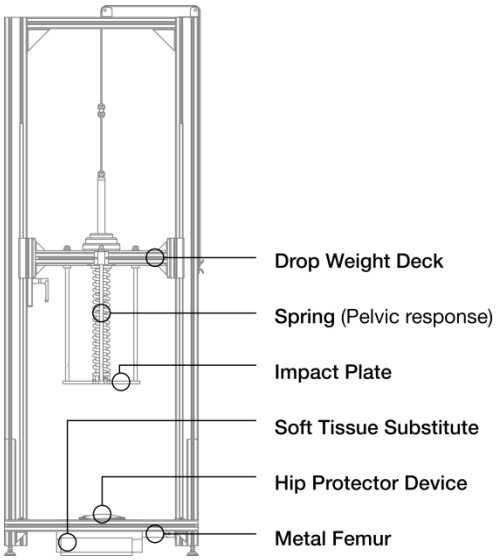
Delloch Ltd has developed and three hip protector variants and tested them on test apparatus built according to the IHPRG guidelines. These devices were used as the test samples within this study.

This study aims to advance this area of research and provide a more accurate artificial representation of a hip region for use in impact testing.

Current Impact Test Apparatus

Figure 1 shows an IHPRG compliant test apparatus used to impact test hip protectors. The test apparatus represents the impact energy experienced by the hip in the event of a fall.

Figure 1: Current Test Apparatus & Tissue Model



A hip protector device is shown located on the foam substitute hip region. The foam represents the soft tissue surrounding the femur. The steel

surrogate femur is seen protruding horizontally from the soft tissue model to the right. The greater trochanter (not shown) is positioned within the foam model directly beneath the hip protector.

The weight deck positioned above the hip protector is dropped directly onto the device. A piezoelectric force-voltage sensor above the impact plate measures and records impact force. Attenuated force is measured by another sensor at the neck of femur where hip fracture most commonly occurs.

The soft tissue model is based on the recommendations of the IHPRG. It is constructed from four layers of 5mm closed cell polyethylene (PE) foam (20mm total thickness). This study will explore material options that behave more closely to the soft tissues of the hip region.

All the tests were carried out on the test apparatus to the IHPRG guidelines shown in Table 1.

Table 1: IHPRG guidelines

Parameter	*Recommended Value*
Effective drop mass	28 kg
Effective pelvic stiffness	47 kN/m
Drop height	0.5 m

Process & Methodology

The study consists of three main parts:

1. **Physiological Research and Analysis**
   Identify the key bio-components in the human hip region and their mechanical characteristics. Build a digital FEA model of the hip region and run computational impact analysis to investigate the energy transfer through the hip region in the event of a fall.

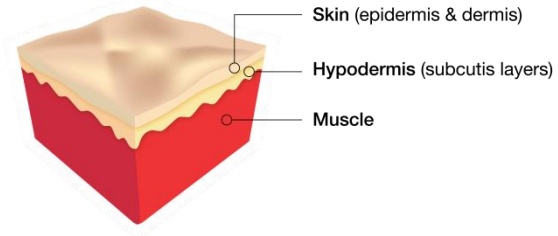
2. **Soft Tissue Model Specification**
   Develop the specification for an anatomically correct physical hip region model including materials, material grades, and material processing techniques, surface geometry and test protocol.

3. **Physical Model Build and Test**
   Build the physical model to the defined specification. Impact test a range of hip protector devices and compare against the results on the existing soft tissue model.

Physiological Research

Although the actual anatomical distribution of the tissues in the hip region is very complex, it can be broadly approximated with three tissue layers. These layers are the skin, the hypodermis (a fatty layer immediately underneath the skin) and muscle shown Figure 2.

Figure 2: Soft Tissue Layers of the Human Hip.



Skin Layer

The skin is the largest organ on the body. It serves many purposes, including protecting the body from minor impacts, and aiding healing afterwards.

Skin is a complex organ made of many different layers. However the mechanical behaviour of the skin is dominated by the largest layer; which is called the dermis (Geerligs, 2009).

Skin is anisotropic; being stiffer in the direction of the skin's structural fibres. The direction of the structural fibres in the skin is called the Langer lines or, alternatively, the Relaxed Skin Tension Lines. The Langer lines overlaying the hip region move overwhelming from the front of the body to the back. Therefore any model that takes anisotropy into account must place the direction of maximum stiffness along these lines.

Skin Hypodermis

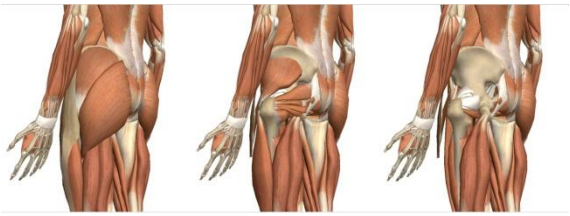
The hypodermis is technically part of the skin. It is the layer that lies between the dermis and the muscle, and it is made up mostly of fat cells. One of the purposes of the hypodermis is to insulate the body against mechanical shocks, and for this reason it is far less stiff than the tissue around it (Geerligs, 2009).

Muscle Tissue

Skeletal muscle is the tissue responsible for human body movement. It makes up the bulk of the tissue surrounding the hip, and for this reason may be the most important soft tissue in determining the mechanical response of the hip during a fall. Although many muscles are present in the hip region, as shown in Figure 3, no evidence was found in literature of them having different mechanical properties from each other, therefore they can be treated as a single layer of muscle.

Muscles are stiffest in the direction of the muscle fibres, which in the hip run mostly down the leg. This is 90 degrees different from the direction of the structural fibres in the skin.

Figure 3: Muscles of the Hip Region (Zygote media group, 2012)



Muscle has high water content, and is largely incompressible; combined with the fact that it cannot easily move in the way that skin and particularly fat can, this means that impact force that reaches the muscle will be quickly transferred down to the bone.

Bone Tissue

Bone is the final tissue present in the approximation of the hip region. Bone is far stiffer than the tissues of the region, resulting in some researchers (Derler, 2005) using metal to approximate it. This method is also recommended by the IHPRG and within the SDMA draft standard.

Mechanical Characterisation

Advanced understanding of the mechanical properties of the bio-components in the hip region was required. Artificial materials can then be matched to these characteristics to form a more accurate tissue model.

It is important that the artificial materials used mirror the response during impact of the soft tissues. This response can be qualified through their movement, compression and elasticity.

The following mechanical characteristics have been identified as important to the mechanical character of the region:

- Incompressibility;
- Young's modulus;
- Shear modulus;
- Bulk modulus;
- Anisotropy;
- Viscoelasticity;
- Nonlinear stiffness.

Incompressibility

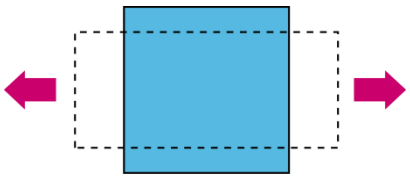
A material is said to be incompressible if applying force to it does not cause its volume to change in any way. An effective example of an incompressible material is water.

Young's Modulus

Moduli (singular modulus) is a property of a material that determines how it reacts to being stressed in a certain way.

The stiffness of a material is given by its Young's modulus, it is one half the amount of stress required to force the material to twice its original length, assuming the material doesn't break in the process.

Figure 4: Young's Modulus

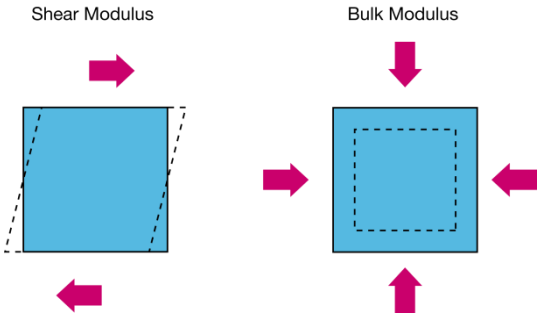


Shear & Bulk Modulus

Shear and bulk modulus also represent the response of the material to an applied stress. They differ from Young's modulus in that while Young's modulus deals with axial stress, shear and bulk deal with shear and pressure forces respectively, as shown in Figure 5.

It was decided that the modelled biological materials would be simplified by assuming that they were incompressible. This meant that the bulk modulus of the materials would be theoretically infinite, and practically much higher than any other parameter, and that the shear modulus would always be equal to one third of the Young's modulus.

Figure 5: Shear Modulus & Bulk Modulus

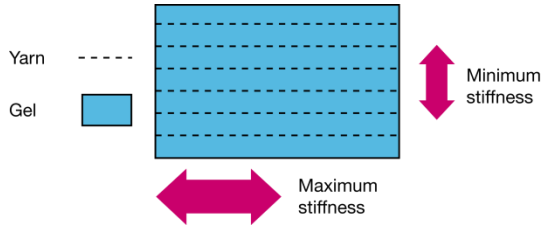


Anisotropy

Anisotropy is the property of having a different mechanical response depending on the direction the material is being stressed. Due to their complex microstructures, biological materials tend to be anisotropic. An example of a simplified anisotropic material is shown in Figure 6. In this material wool

yarn is set inside a gel block, it can be easily seen that the resulting material will be far stiffer when pulled in the direction to the wool fibres.

Figure 6: A Simplified Anisotropic Material



Skin is anisotropic; being stiffer in the direction of the skin's structural fibres. The direction of the structural fibres in the skin is called the Langer lines or cleavage lines. The Langer lines overlaying the hip region move overwhelming from the front of the body to the back and correspond to the alignment of collagen fibres within the dermis layer (Davide Brunelli).

Viscoelasticity

Viscoelasticity is a property of materials that have both the properties of an elastic solid, and a viscous fluid. The result is that the physical properties of the material are affected by the rate at which it is stretched; generally behaving stiffer the faster it is stretched.

Viscoelasticity is a common property in biological material, and since the project involves impact forces; and therefore very high stretch rates, it's a significant factor.

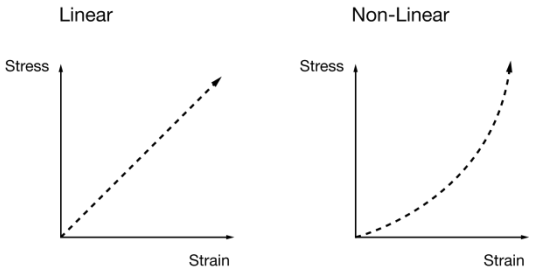
Viscoelasticity was not included in the model generated in this study for reasons of simplicity; however it is recommended to be explored in later and more complex generations of the FE model.

Nonlinear Stiffness

Stiffness is defined as the amount of stress necessary to stretch the material by a certain amount (the strain). Stiffness in most engineering materials, such as steel, is linear; this means that increasing the stretch by a certain amount requires the same increase in stress each time.

Nonlinear stiffness is a property of most biological tissues due to their complex microstructure. In nonlinear stiffness the material becomes increasingly difficult to stretch the further it is stretched.

Figure 7: Linear & Non-Linear Stiffness



Characteristics of Biological Components

Literature research was carried out to determine the mechanical properties of human tissue. On several occasions many different values were given from different literature articles and sources for the same property; this is a reflection of the complexity of biological tissue. Where non-conclusive median values were derived.

The values resulting from the research that were taken forward in the project are given in Table 2.

Table 2: Results of Physiological Research

Thickness	*Density*	*Young's modulus*
Skin		
2.1 ± 0.3 mm (Jarkko T. livarinen, 2011)	1.1 g/cm^3 (S W Ohl, 2009)	210 kPa (Jarkko T. livarinen, 2011)
Hypodermis		
2.1 ± 2.3 mm (Jarkko T. livarinen, 2011)	0.95 g/cm^3 (S W Ohl, 2009)	5.6 kPa (S W Ohl, 2009)
Muscle		
48mm (Blaž Mavčič, 2009)	1.06 g/cm^3 (Urbanchek, 2001)	150 kPa (F.A Bandak, 2001)

Hyperelastic Equations

Hyperelastic constructive equations define the relationship between stress and strain in a material. They were initially created to model rubbers at very large strains and they have turned out to model biological tissue very effectively.

Two hyperelastic models were used to analyse the biological components within the software: Mooney-Rivlin equation, and the Ogden equation. These material models were specifically developed to model hyperelastic materials such as rubbers and biological components (Ogden (hyperelastic model), 2013).

FEMAP has pre-programmed Mooney-Rivlin and Ogden equations. The Mooney-Rivlin coefficients for muscle are shown in Table 3.

Table 3: Mooney-Rivlin Equation Coefficients of Muscle

Coefficient 01	*Coefficient 10*
0.01 MPa (Jia Zhiheng)	0.03 MPa (Jia Zhiheng)

Skin and hypodermis were both modelled using the Ogden equation. The Ogden equation can model very large strains more accurately than Mooney-Rivlin, handling up to 700% strain where the Mooney-Rivlin equation can only handle up to 200% (Sharcnet, 2010). Skin and hypodermis coefficients are shown in Table 4.

Table 4: The Ogden Coefficients used to Model Skin & Hypodermis

μ	α
Hypodermis	
0.01 MPa (C.W.J. OOMENSa, 2003)	5 (C.W.J. OOMENSa, 2003)
Skin	
0.11 MPa (Roxhed, 2007)	9 (Roxhed, 2007)

FEA Models

What is FEA?

Finite element modelling is the process of dividing complex problems into many small sub-functions and solving each in relation to each other. This is typically used to analyse the stress and strain distribution through a part before it is manufactured. The use cycle can be simulated within the software allowing for part optimisation based on how the part performs under stress. The practise in this study is called finite element analysis (FEA).

FEA was used in this study to develop schematic understanding of how impact forces are transmitted into the hip's soft tissues. Unlike isotropic materials such as polymers and metals that have predictable performance characteristics, biological materials are inherently variable. It was recognised that modelling biological materials and components at a finite element level is complex due to variable characteristics such as hydration, muscle growth, muscle fibre types, fat volumes and location on the body.

The first iteration of the FE model presented in this study was simplified with a view to increase complexity in future models. The preliminarily model is based on the biomaterial characteristics derived from the physiological research.

The finite element analysis (FEA) used in this project was done with the commercial computational software FEMAP with NX NASTRAN. The NX NASTRAN engine was required for dynamic transient analysis functionality.

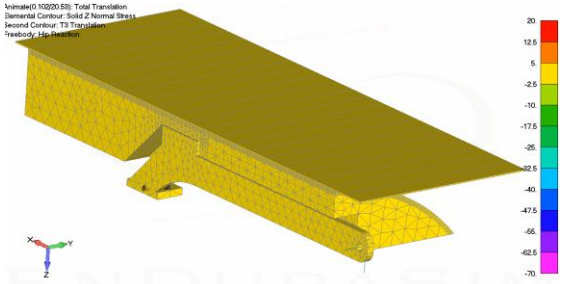
Model Design

A CAD model was built in Solid Edge that represented the simplified form of a section of the hip region. The geometry was derived from the circumference of outer thigh about the hip of a study into the anthropometry of elderly woman (Jarosz, 1999). The anthropometric data is derived from the 70-79 years age bracket of elderly women to match the demographic where the highest incidence of hip fracture occur (Kanis JA., 2006).

The model was constructed from the three core bio-component materials: muscle, hypodermis and skin. The three components were modelled as hyperelastic materials. To mirror the physical test rig, the model was stressed by dropping a massed plate in the FEA software. The femur was modelled as steel to mimic the physical test apparatus and IHPRG guidelines.

To reduce computational effort (computer time to analyse) the model was cut in half and symmetry parameters added.

Figure 8: Finite Element Model



FEA Outcomes

Computational impact analysis was carried out on the virtual model. The bases of the models were fixed in place and plate suspended above. The plates were weighted with a mass of 28Kg, and were given an impact velocity 3.4 m/s. The impact plate was modelled larger than the hip region to simulate the floor on impact.

A number of insights can be derived from this preliminary analysis.

Peak Stress

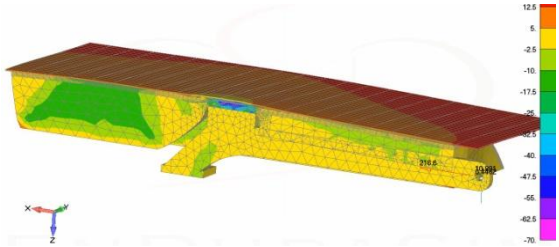
Figure 9 shows the stresses in the soft tissue and femur at the point of peak force. The soft tissues directly above the protruding greater trochanter show the highest stress as expected under compression between the impact plate and steel

femur. This illustrates the need to protect the greater trochanter from transfer of fall energy.

It should be noted that the volume of tissue above the length of the proximal femur extending to the right of the greater trochanter in Figure 9 (towards the knee) is not related to the bone in this model. Had this been in place the stresses in this tissue would be seen to be higher than currently shown under compression between the plate and the bone. This is important to understand further as the transfer of force away from the trochanter by a hip protector should also avoid the proximal femur.

The large volume of muscle to the left of the trochanter show relatively low levels of stress and a preferred area to shunt fall energy.

Figure 9: Peak Stress



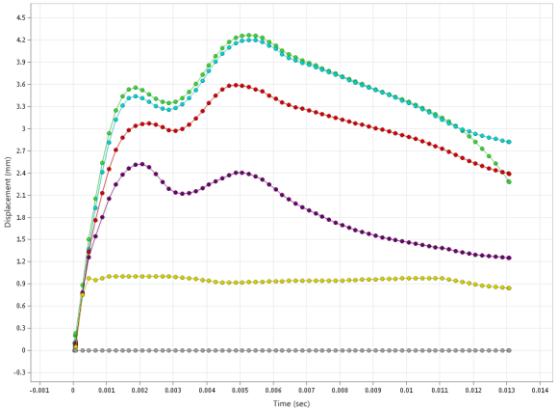
Component Compression

Displacement data recorded from six locations is shown in Figure 11 for the different bio components. Compression ratios of the different materials calculated from the data are show in Figure 10.

Figure 10: Compression

	Muscle	*Fat*	*Skin*
Thickness (mm)	8	2	2
Compression (mm)	1.6	1.2	0.9
Compression %	20%	60%	45%

Figure 11: Displacement



The hypodermis (fat) layer is shown to compress more than the stiffer skin and muscle layers. This correlates with the understanding that fat serves to protect from impact trauma and a compressible material absorbs and dissipates impact energy.

Rotational Force through the Femoral Head

Stress forces through the femur are shown in Figure 12: Femur Stresses. In the computational model the flat plate is constrained from movement. Torsion forces are shown propagating from the inside corner of the femur by contoured colouring. The deflection is magnified by 1000 times for illustrative purposes.

Figure 12: Femur Stresses

This can be used to demonstrate the in vivo effects on the femoral neck as the femoral head is considered constrained by the pelvis. This highlights the weakest point of the proximal femur as the femoral neck strengthening the argument to transfer force away from the region.

Moderate levels of stress are shown in the proximal femur through bending. Significant force applied to this region during a fall could result in a subtrochanteric fracture breaking the femoral shaft below the lesser trochanter.

Future Improvements to the FE Model

Many areas of the FEM could be iterated and advanced to improve the biofidelity of the model.

Advanced Characteristics

Introduction of the complex characteristics of biological components such as anisotropy and viscoelasticity would advance the biofidelity of the computational models. These would however require more research and potentially in-vivo measurements to gather the necessary mechanical characteristics of biological soft tissues. This would also require additional computational power for analysis.

Impact Plate
The thin impact plate deflected on impact absorbing a significant amount of fall energy. An improvement of the model would replicate the test apparatus with a rigid 10mm thickness aluminium plate. This would ensure a more appropriate transfer of energy into the soft tissues in the model.

Addition of Pads into the FEM
When the model is refined and calibrated to soft tissue characteristics CAD modelled hip protector devices can be introduced into the model to understand the force dissipation from the pad into the soft tissues. This could validate preferred pad geometries.

Further FEA Opportunities for Hip Protection Research

Finite element analysis can be used to analyse a range of physical conditions. The following are examples of how further FE analysis can be applied to hip protector research.

Pressure Sore Prevention
Pressure sores are a particular problem with the elderly. They are caused when pressure is applied to the tissue in such a way that the blood flow into that tissue is obstructed. Without a supply of oxygen the tissue begins to die.

The soft tissue FEA model developed in this study could be adapted to the problem of pressure sore prevention. Instead of dynamic analysis this would be a static analysis with the hip protector being forced down into the soft tissue.

Literature research is required to determine the risk stresses for pressure ulcers. Pressure onto the soft tissues can be evaluated through FEA and compared against physical testing with pressure measurement equipment.

Thermal Analysis
Compliance is a very important part of hip protector effectiveness. High thermal output on the skin has been recognised as a potential conformance issue (Man, B., 2008). This can be caused by heat generated under the pad.

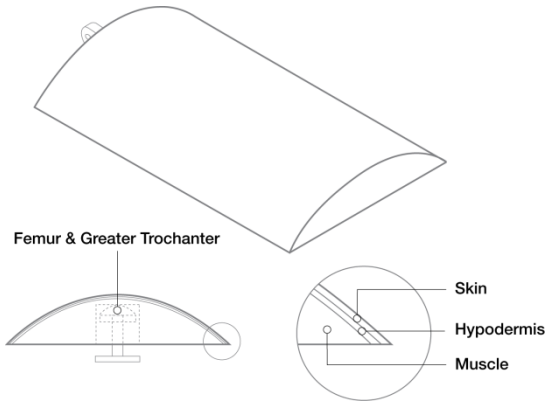
The soft tissue model produced from this project could be adapted for thermal analysis. It would involve applying initial heat conditions, heat production rates, and cooling effects at the skin surface across the different layers of the tissue. Adding the hip protector model to the computational model will allow for accurate monitoring of heat in under the hip protector. Vents or thermal regulation methods could then be better understood.

Heat would be generated in the soft tissue model and be allowed to diffuse upwards. A cooling effect would be applied to the top layer of skin, allowing heat to be removed, but not to the skin under the hip protector. The heat under hip protector would rise until it reached steady state with the ability of heat to transfer though the material of the hip protector.

Physical Model

The design used in the FEM was developed into a physical model to be used for impact testing hip protector devices. Two layers of different materials, both 2mm, represent skin and the hypodermis overlaying a solid muscle component.

Figure 13: Physical Soft Tissue Model



Material Selection

A range of artificial materials were assessed for suitability to accurately simulate the characteristics of the soft tissues. PVA-C, PVC, silicone, gelatine, agarose and Zerdine were considered. Silicone was selected due to its high stability, non-linear stress/strain characteristic and viscoelasticity.

Silicone is a very soft and flexible rubber, which exhibits many similar properties to human tissue. Silicone is very strong and tear resistant, and exhibits viscoelasticity in the same way that human tissue does. These properties have led many researchers to make use of it in their biomechanical research (Derler, 2005).

Silicone is available in several different formulations, of which the most robust, and therefore useful for impact testing is platinum or addition cured silicone. Silicone is also available in various shore hardness providing the opportunity to simulate varying Young's modulus characteristics.

Two part silicone must be mixed thoroughly before use. During this mixing, the silicone will chemically

react and rapidly cure into rubber (within minutes). The pour into the mould must occur before the silicone cures. This 'pour-time' is a documented property of the silicone grade.

Silicone Grades

Different silicone formulations are given by their hardness. The hardness of materials like silicone rubber is measured on a Shore durometer scale, which is determined by how far a spring loaded point can be pushed into the material (A. W. Mix, 2011). There are 12 recognised Shore durometer scales; which correspond to different shape and size points.

Mix and Giacomin created formulas to translate Shore hardness to Young's modulus (A. W. Mix, 2011). Since this study was interested in values of Young's modulus between a few kPa for hypodermis, and a few hundred kPa for skin and muscle, appropriate hardness of silicone was ~5-10 on the Shore OO scale, and ~10-20 on the Shore A scale, respectively.

Polytek PlatSil™ 71-11 for the skin and muscle, and Polytek PlatSil™ Gel-OO for the hypodermis were used in this model.

Model Construction

MDF moulds were designed and manufactured to create the silicone soft tissue model shown in Figure 14.

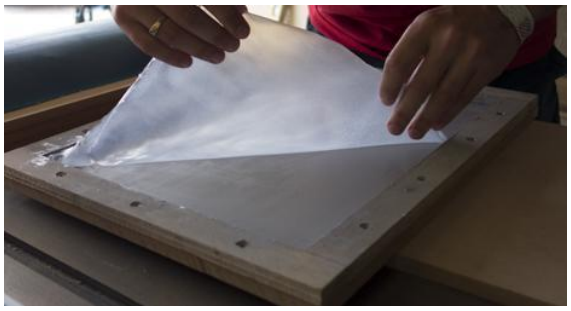
Figure 14: Silicone moulds

The curvature required for the muscle component mould was derived from the anthropometric study of elderly woman. The curvature was outputted from CAD and CNC machined for accuracy. 3mm MDF was bent over the radius and fixed with screws to form a trough for the liquid silicone.

During mixing, silicone is prone to forming air bubbles that remain trapped in the solid state after curing. In this application the trapped air bubbles could change the physical characteristics of the silicone during impact so the 'bombs away' technique was used to expel air bubbles during the pour. In this technique a small hole is pierced in the bottom of the mixing container, and the silicone is poured from height. Since silicone is very viscous the falling silicone stretches into a thin stream and the air bubbles are forced out. It was difficult however to ensure that the entire model was bubble free as the silicone cured quicker than the pore procedure could allow introducing small bubbles in the final stages to the underside of the silicone furthest away from the impact zone. Utilising a vacuum during production could be trialled in future phases to remove air from the model.

A flat, rectangular timber mould was used for the skin and hypodermis layers. The muscle and skin layers cured overnight whereas the softer hypodermis layer required only one hour.

Figure 15: Hypodermis layer being removed



The three layers were combined and placed on MDF spacers to form the physical soft tissue model, as shown in Figure 16. It was found that if the rough face (mould side) and smooth face (air side) of the silicone layers interfaced, the surface bond was sufficiently high friction to not require adhering. This was a benefit because silicone is difficult to adhere to.

Figure 16: Silicone physical model

Results

Impact testing under the industry agreed protocol (Table 5) was carried out on the silicone model to evaluate the performance against the PE foam variant and how hip protector performance is affected by the soft tissue substitute.

Table 5: IHPRG guidelines

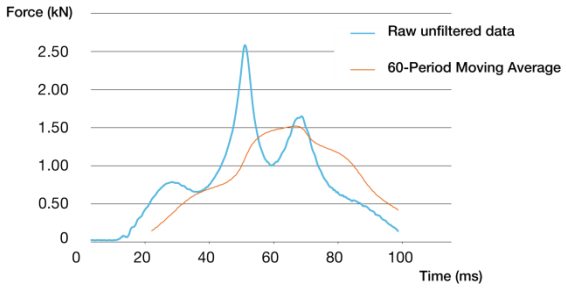
Parameter	*Recommended Value*
Effective drop mass	28 kg
Effective pelvic stiffness	47 kN/m
Drop height	0.5 m

A peak force calibration test was used to ensure the instrumentation was reading accurately. This involves removing the soft tissue dropping the impact deck directly onto the surrogate steel femur.

Unpadded Impact Test Results

Both foam and silicone soft tissues were impacted under normal test conditions. Recorded forces from the attenuated force sensor positioned beneath the metal femur are shown in Table 6. These values are the average of three test cases per model. A low pass filter is applied to the data to smooth and extrapolate a peak attenuated force result. This is calculated from a 60 period moving average calculation shown as a trendline on the graph in Figure 17. This is required to smooth the large resonance peaks experienced by the data acquisition apparatus during testing.

Figure 17: Example Attenuated Force Graph



The impact force generated at the impact sensor when impacted directly onto the metal femur is 3.348kN.

Table 6: Unpadded Impact Test Results

	Foam	*Silicone*
Attenuated Force	2.510 kN	2.041kN
% Force reduction	25.0%	39.1%

A range of studies have recommended the force attenuation performance of the soft tissue layer alone. In one study Parkkari et al suggest 20% force reduction from the soft tissue model (Jari Parkkari M.D, 1995), in another study they used a soft tissue model that attenuated closer to 15% (P Kannus, 1999). Robinovitch et al conducted impact testing on the soft tissue from cadavers and recorded the force to attenuate by 71N/mm with an average of 24mm of soft tissue over the greater trochanter (Robinovitch SN et al, 1995). This would equate close to 50% reduction in force when impacted at 3.5kN. Van Schoor et al tested hip protectors on apparatus with ½ inch and 1 inch soft tissue thicknesses that attenuated 18% and 49% of impact force respectively (N.M. van Schoor et al, 2006).

Although only 8mm thick over the surrogate greater trochanter the silicone model attenuated 39.1% whereas the PE model with 20mm foam thickness attenuated 25.0% unpadded. This illustrates that silicone hardens and absorbs impact energy to a greater degree than PE foam.

Padded Impact Testing

Two Delloch hip protector products were impact tested on both soft tissue models for comparison.

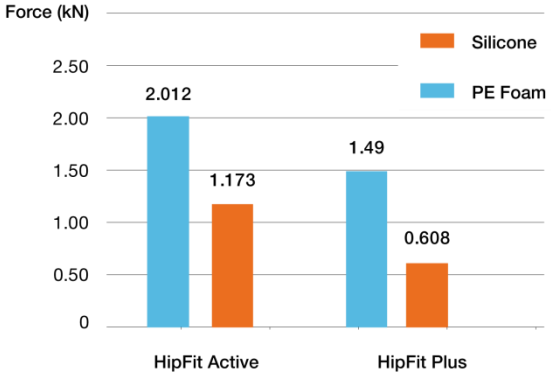
HipFit Active is a soft-shell pad with a dual density closed cell foam construction where the thick inner layer is a low density PE and the thin outer layer is a high density PE.

HipFit Plus is a hard-shell pad with reinforced glass filled nylon outer and low density PE foam inner. The averaged results of three impacts are shown in Table 7:

Table 7: Impact Testing with Delloch Hip Protectors

	HipFit Active	*HipFit Plus*
Foam	2.012kN	1.490kN
Silicone	1.173kN	0.608kN
Difference	0.84kN	0.88kN

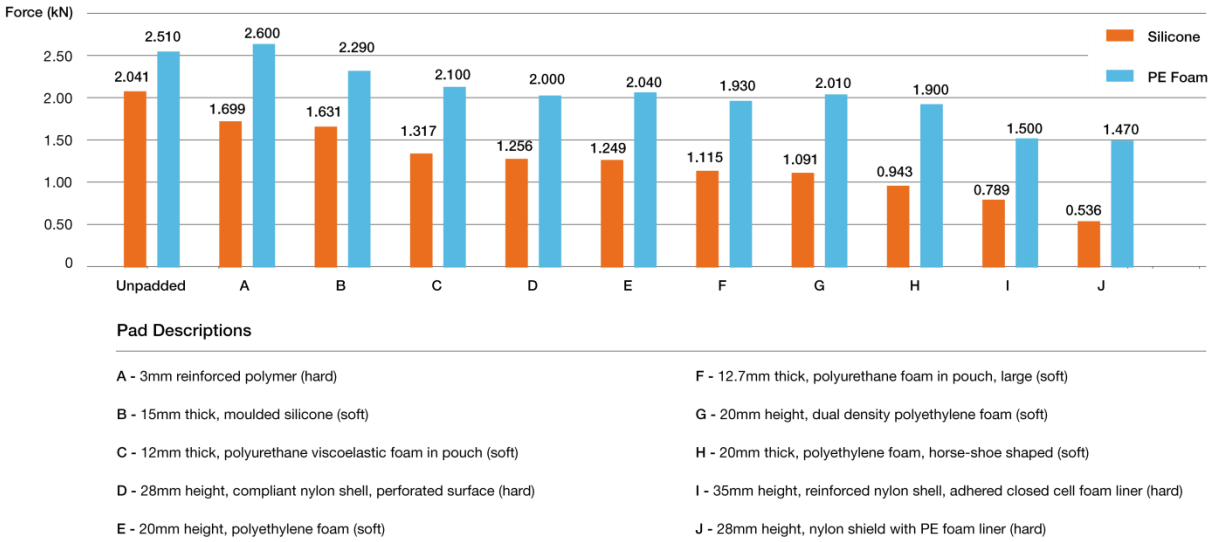
Figure 18: Impact Testing Results



Both hip protector devices attenuated significantly more force when tested on the silicone tissue model.

The decrease in force read by the attenuating sensor (increased force attenuation through the model) was very similar across both devices at 0.86±0.02kN. To understand if this difference is linear across despite the hip protector pad construction, further testing was completed on a range of hip protector devices.

Figure 19: Impact Testing Results



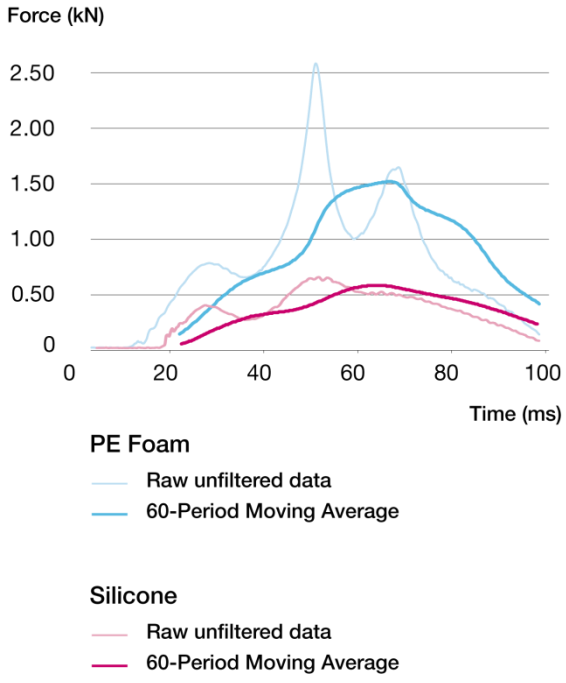
The results show that impact forces recorded at the attenuated sensor are significantly lower across all hip protector configurations. The difference between attenuated force results from the two models across the range of hip protectors is not however linear – a consistent % drop is not evident. The largest difference between the two models was pad 8 at 64% and the least is pad 4 at 29%, median 40%, S.D. 12%. This shows that hip protector performance results are closely linked to the soft tissue model of the test apparatus.

Hip protectors with a rigid hard-shell or soft-shell with an open cavity about the greater trochanter attenuate more relative force on the silicone model than the foam. This is likely because both configuration styles do not directly transfer fall energy into the femoral neck by shielding the greater trochanter with an empty cavity.

Model Resonance

The raw (non-smoothed) data acquired from the attenuation sensor for the same pad on the two different tissue models is shown in Figure 20.

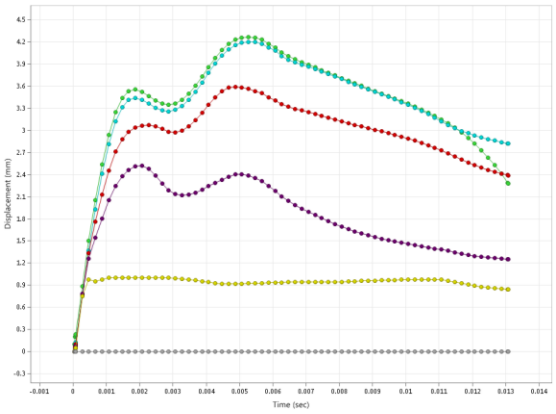
Figure 20: Attenuated Sensor Readout



The noticeable difference between the two materials is the extreme resonance peaks seen on the foam model compared to the silicone. This illustrates how silicone provides a significant mechanical damping effect compared to the foam.

The displacement curves derived from the FEM show similar curves patterns to the physical silicone impact results. See Figure **11**. These peaks are generated from the initial strike of the impact plate followed by the compression of the spring and force from the weights creating the second peak. The foam model produces a third harmonic not seen in the silicone. Derler selected silicone for the Swiss hip protector standard due to its ability to dampen and disperse load in a similar fashion to soft tissue (Derler, 2005).

Figure 21: FEM Displacement



The effect of the filtering on the foam model is dramatic by smoothing the three large force peaks. The silicone is less affected by filtering illustrated by a more closely aligned trendline. This suggests the filtered data gathered from the silicone model is more accurate and better suited to this test regime than foam.

The time to reach the peak force is seen to occur at the same point on both material models.

Discussion

Hip Fracture Threshold

Testing on the silicone model significantly improves the force attenuation performance of all hip protector devices tested due to increased impact energy absorption within the surrogate tissue material. This means that devices that are considered to be inadequate in protecting from hip fracture on other tissue models are now within the acceptable limits. There is no consensus for a performance threshold for hip protectors to meet and the IHPRG recommend clinical trials are conducted to evaluate the efficacy of hip protectors before committing to a performance target (Robinovitch SN, 2009). Guidance is given by the IHPRG for femoral strength at 2.966kN (Robinovitch SN, 2009). It is recommended that a lower threshold is used to recalibrate the soft tissue and account for the additional energy absorption; this could be 1.5kN.

Biofidelity

At a qualitative level the silicone used in the model feels more lifelike in response (to the touch). Many literature sources also state silicone to behave closely to soft tissues under mechanical stress. This is an important factor and could be further substantiated by in-vivo testing of soft tissues in the hip region. Indentation tests could be used to further qualify stress/strain characteristics of the surrounding tissues.

Model Life & Production Costs

Compared to sheet PE foam silicone is an expensive material. The silicone model also requires mould production as described and additional material costs for processing. The silicone model cost ~ NZ$400 to produce compared to ~NZ$50 for the PE foam equivalent. However, the PE foam sheet is pierced by the metal greater trochanter on impact and requires replacement after each test case. The sheet closest the greater trochanter is moved laterally before each test to ensure undamaged foam is in the impact zone.

Longitudinal impact testing of the unpadded silicone model is required to evaluate the durability with repeat impact testing.

Variation in foam mechanical characteristics is experienced from different foam supply chains. Although documented as PE, some foam supply can be a blend of PE and ethylene vinyl acetate (EVA). EVA foam is known to be softer than PE at the same density. Due to this, a variation in blend ratios could affect overall foam softness and resulting force attenuation characteristics of the foam.

BioFEA Practice

At present it is only possible to test designs for hip protectors after they have been physically made. This makes it uneconomical to test minor alterations in design that might occur to the designers. By making use of the soft tissue FEA model it should be possible to test new designs for hip protectors and rapidly explore the effectiveness of new design possibilities in a cost effective manner.

Summary

The soft tissue model has proven to affect the performance characteristic outcomes of hip protectors. The increased energy absorption characteristic of silicone compared to PE foam is not linear when tested with hip protector devices.

Device constructions with cavities over the greater trochanter attenuate more relative force on silicone than PE foam. This is expected to be due to the non-linear stress/strain characteristics of the material.

It is recommended that the silicone soft tissue model is adopted for use in impact testing of hip protector devices. The research has proven the mechanical characteristics better represent those of soft tissues. It is also recommended that a lower performance threshold or increased impact velocity and force is used to account for the additional energy absorbed by the silicone.

Until an international standard is agreed for a hip fracture threshold or an absolute performance target for hip protectors, impact testing should remain as comparative where devices are assessed against each other and within the boundaries of expert panel recommendations.

Through this study finite element analysis has proven to be a powerful tool to investigate complex theory before high cost physical testing is required. Within hip protector device development FEA can be employed to test and analyse a range of factors but the underlying soft tissue mechanics should be resolved first to ensure accuracy. Further research and consensus is required to develop a specification for accurate biological material testing.

FEA & the FDA

The US Food and Drug Administration (FDA) recognise FEA as a viable test method for proving medical device performance (Stephen J. Mraz, 2009). This is an important development for medical devices research as it allows more accurate test beds through advanced computational modelling. This study has illustrated the potential for FEA in the field of hip protection and falls research. The study has also highlighted the complexities of simulating biology components and the appropriate test environment and conditions within the FE package. Within FEA variables are vast and open to interpretation. This will be an area where the FDA will require standardised approaches to ensure consistency across medical device developers (Erdemir. A., 2012).

It is possible that hip region soft tissues cannot be accurately simulated by artificial physical materials to the degree that can be achieved computational in FEA. The gap between physical representation and simulated models is likely to grow significantly as research develops further understanding and capability in this area.

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Bibliography

A. W. Mix, A. J. (2011). Standardized Polymer Durometry. *Journal of Testing and Evaluation* , 1–10.

Ainsworth, R. (2012, July 20). *Seeing what can't be seen in a triple point of argon system*. Retrieved December 18, 2012, from Fluke Calibration: http://us.flukecal.com/blog/seeing-what-cant-be-seen-triple-point-argon-system

Blaž Mavčič, M. K.-I. (2009, May/June). *Repeatability of biomechanical computations based on*. Retrieved December 11, 2012, from https://www.mf.uni-lj.si/dokumenti/8de0968510fcb9b982e6dd3667c83a94.pdf

C.W.J. OOMENSa, *. O. (2003). Can Loaded Interface Characteristics Influence Strain Distributions in Muscle Adjacent to Bony Prominences? *Computer Methods in Biomechanics and Biomedical Engineering,* , 171–180.

Davide Brunelli. (n.d.). *Langer Lines of the Skin*. Retrieved February 09, 2013, from Med Art: http://www.med-ars.it/galleries/langer.htm

Derler, S. (2005). Anatomical hip model for the mechanical testing of hip protectors. *Medical Engineering & Physics* , 475–485.

Derler, S. (2010). Test regulations R 0407 / Hip protectors. *Test regulations (Swiss Council for Accident Prevention bfu) for the acquisition of a bfu safety symbol for hip protectors* . Switzerland: BFU.

Erdemir. A., e. a. (2012). Considerations for Reporting Finite Element Analysis Studies in Biomechanics. *J Biomech* , 625–633.

Evans, S. (2011). Hip Protectors used as Medical Devices – Performance requirements and test methods. *British Standards* . Not published.

Evans, S. (2012, December 4). Soft Tissue Analysis. *Email to Jonathan Jones* .

F.A Bandak, R. T. (2001). On the development of an osseo-ligamentous finite element model of the human ankle joint. *International Journal of Solids and Structures* , 1681–1697.

Feamax. (2012). *FEAmax Price Schedule*. Retrieved Feburary 21, 2013, from Feamax: http://www.feamax.com/cost.html
Geerligs, M. (2009). *Skin layer mechanics.* Eindhoven: Koninklijke Philips Electronics.

Jari Parkkari M.D. (1995, October). Energy-shunting external hip protector attenuates the peak femoral impact force below the theoretical fracture threshold: An in vitro biomechanical study under falling conditions of thel elderly. *Journal of Bone and Mineral Research* , pp. 1437–1442.

Jarkko T. Iivarinen, R. K. (2011). Experimental and computational analysis of soft tissue stiffness in forearm using a manual indentation device. *Medical Engineering & Physics* , 1245–1253.

Jarosz, E. (1999). Anthropometry of elderly women in Poland: dimensions for design. *International Journal of Industrial Ergonomics* , 203–213.

Jia Zhiheng, D. Z. *A Novel Finite Element Method based Biomechanical Model for HIT-Robot Assisted Orthopedic Surgery System.* Robotics Institute, Harbin Institute of Technology, Harbin, China.

Kanis JA., J. O. (2006). An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporosis international* , 1726-33.

Kurowski, P. M. (2008, July 10). *FE Update: Expecting Too Much from FEA*. Retrieved December 19, 2012, from Machine Design: http://machinedesign.com/article/fe-update-expecting-too-much-from-fea-0710

Laing AC, T. I. (2006). Effect of compliant flooring on impact force during falls on the hip. *Journal of orthopedic research* , 1405-1411.
Man, B. (2008). *Hip Protectors for Hip Fracture Elderly People.*

N.M. van Schoor et al. (2006). Biomechanical comparison of hard and soft hip protectors and the influence of soft tissue. *Bone* , pp. 401 – 407.
Ogden (hyperelastic model). (2013, February 2). Retrieved March 14, 2013, from Wikipedia: http://en.wikipedia.org/wiki/Ogden_(hyperelastic_model)
P Kannus. (1999, August). Comparison of force attenuation properties of four different hip protectors under simulated falling conditions in the elderly: an in vitro biomechanical study. *The Bone Journal* , pp. 229-235.

Polytek. (2012, November 15). *PlatSil 71-Series RTV Silicone Rubbers.* Retrieved Feburary 21, 2013, from Polytek development corp: http://www.polytek.com/images/Technical%20Bulletins/platsil71.pdf

Polytek. (2012, November 16). *PlatSil Gels.* Retrieved Feburary 21, 2013, from Polytek development Corp: http://www.polytek.com/images/Technical%20Bulletins/PlatSilGel-2012.pdf

Robinovitch SN et al. (1995). Force attenuation in trochanteric soft tissues during impact from a fall. *J Orthop Res* , pp. 956–962.

Robinovitch SN, E. S. (2009). Hip protectors: recommendations for biomechanical testing--an international consensus statement . *Osteoporosis international* , 1977-88.

Roxhed, N. (2007). *A Fully Integrated Microneedle-based Transdermal Drug Delivery System.* Stockholm, Sweden: KTH—Royal Institute of Technology.

S W Ohl, E. K. (2009). The dynamics of a non-equilibrium bubble near. *PHYSICS IN MEDICINE AND BIOLOGY* , 6313–6336.

Sharcnet. (2010). *Hyperelasticity*. Retrieved 01 30, 2013, from https://www.sharcnet.ca/Software/Fluent13/help/wb_sim/ds_non_linear.html

Smooth-On, Inc. (2011). *How long will a casting, mask or sculpture made out of silicone rubber last?* Retrieved Feburary 21, 2013, from Smooth-On: http://www.smooth-on.com/faq_display.php?faq_id=107

Stephen J. Mraz. (2009, November 17). *FEA for the FDA*. Retrieved March 12, 2013, from Machine Design: http://machinedesign.com/article/fea-on-new-and-redesigned-medical-components-can-save-time-and-money-during-fda-approval-111

Urbanchek, M. P. (2001). Specific force deficit in skeletal muscles of old rats is partially explained by the existence of denervated muscle fibers. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences* , B191-B197.

Zygote media group. (2012). *Zygote body*. Retrieved Janurary 17, 2013, from Zygote body: http://www.zygotebody.com/#nav=2.18,85.86,213.56