QUANTIFYING THE MECHANICAL PROPERTIES OF THE HUMAN PREPUCE IN COMPRESSION

by

Tricia Evangelista

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Advisory Committee:
Michael Peterson, PhD, Professor: Mechanical Engineering (Advisor)
Robert Causey, DVM, PhD, Associate Professor: Animal and Veterinary Sciences
James Gallagher, PhD, Associate Professor Emeritus: Sociology
Peter Millard, MD, PhD, General Physician Concentrating in Infectious Diseases
Xudong Zheng, PhD, Assistant Professor: Mechanical Engineering
Abstract

Millions of people worldwide contract HIV each year. Preventative techniques are being developed to stop the spread of this virus. To that point, studies show that a male is 60% less likely to contract HIV from a female partner if he is circumcised. The standard procedure is not suitable for providing the large quantities of circumcisions that are needed in areas such as Sub-Saharan Africa, where the majority of new cases occur. However, some aspects of the current surgical procedure are convenient, mainly the reduced likelihood of related bleeding and the minimal time requirement per circumcision. This thesis is supporting the development of a surgical device which maintains these aspects of the standard procedure, but can be produced on a large scale in order to be used as a disposable tool.

This thesis serves as a pilot study on the mechanical properties of human prepuce (or foreskin) in compression, which are required to allow better understanding of the current procedure. Testing provides an approximate compressive yield strength of 50 kPa. The pressure exerted by a surgical device can be optimized using this information.
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**Introduction**

Human immuno-deficiency virus (HIV) is a blood-borne virus that affects millions of people each year. The majority of worldwide infections have occurred in sub-Saharan Africa, where 25.4 million individuals were HIV-positive in 2006. As shown in Figure 1, this is 18 million more than the area with the next highest amount of infections (South-Southeast Asia) [1]. Because of these high infection-rates, steps are being taken to reduce the spread of HIV in sub-Saharan Africa.

![Figure 1: Global HIV prevalence and distribution for 2006 shows Sub-Saharan Africa has the highest prevalence](source)


Since a vaccine is not expected to be ready for decades, prevention methods thus far have focused mainly on controlling the spread of the disease. To that point, male circumcision

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has come up as a method to slow the spread of HIV. This is thought to be because the innermost layer of the foreskin is largely comprised of langerhan cells. These cells present foreign bodies to the immune system, which is detrimental if these cells come in contact with HIV. Removing this portion of skin has been shown to decrease a man’s chances of contracting HIV from a female partner by 60%. This is considerable because heterosexual intercourse is the most prevalent way to contract the virus [1]. Based on this, circumcision as a method of HIV prevention has the “potential to avert up to 174,000 new infections each year” [2]. Yet, less than 30% of males in Africa are circumcised. In order to provide the number of circumcisions necessary to reduce the spread of HIV, a safe, reliable, and quick procedure must be developed.

The standard circumcision procedure in America involves a specialized device which assists in controlling the amount of prepuce (foreskin) to be removed as well as facilitating hemostasis. Of these, a popular device is the Gomco clamp, shown in Figure 2. The device works by exerting a crushing force on the foreskin at the junction of the bell and baseplate. After a period of time, a hemostatic seal has formed which causes the skin to stick together temporarily even if the device were removed. At this point, the skin is cut away, the device removed, and medical grade glue is applied to maintain the contact supplied by the hemostatic sea. Sutures are usually unnecessary [3] [4]. The Gomco clamp provides a simple, safe method for circumcision, and allows for a minimal amount of equipment, making it an ideal device to be used for the purpose of providing large quantities of the procedure in sub-Saharan Africa.
There is, however, one key aspect of the Gomco clamp and similar devices that prevent it from being used widespread in areas such as sub-Saharan Africa: sterilization. The areas of sub-Saharan Africa which are most affected by the spread of HIV are comprised mainly of developing countries [1]. Generally, these countries lack the technical capabilities to provide adequate sterilization. The possibility of improper sterilization increases the chance of spreading blood borne pathogens. So, a device which is meant to be reused after sterilization does not comply with the necessary quality standards for this situation [5]. Without knowing whether or not a patient is already HIV-positive, reusing a device that has been improperly sterilized could increase the spread of infection instead of preventing it.

For this reason, a device is being designed which maintain the effective method employed by the Gomco clamp, but meets quality standards associated with donating medical equipment to necessary for this application. The World Health Organization recommends that these standards be met by employing devices that are impossible to use
more than once, eliminating the possibility of improper sanitation and reuse [5]. Also, since HIV is a blood-borne virus, efforts to minimize the exposure of sharp edges mean that surgeons are less likely to come in contact with contaminated blood.

**Problem Statement**

Cost is an important factor considered when designing a disposable surgical device. In order to be truly effective in curbing the spread of HIV, a large quantity of these devices must be produced. A constant supply must be maintained in order to be able to offer the procedure on a large scale. It is imperative to keep the cost of manufacturing the device low to attain these goals. However, making the device incapable of being used more than once while also minimizing exposed sharp edges makes for a complicated design, which increases the manufacturing costs. The best way to create a cost-effective design is to optimize the material utilization in the formation of the device.

Using less material decreases the forces that the device can withstand without bending out of shape and becoming ineffective. After optimizing the design for cost, the device must still be effective. For that reason, the minimum required pressure that is needed between the bell and base plate must be known. This report will:

- Approximate the yield stress of human prepuce using an acceptable animal model
- Discuss the required pressure of ring between the bell and baseplate of the Gomco clamp (and comparably shaped circumcision clamps) necessary to cause a hemostatic seal using this yield stress
- Discuss how the experimental values affect potential clamp designs
Modeling Human Skin

Mechanical properties are typically found through experiment. Different types of materials are studied in different ways. So, it is necessary to first decide what type of material skin can be treated as during an experiment.

Skin is a complex organ comprised of different layers with different properties within each layer. However, for mechanical studies, the skin is often modeled as a composite comprised of a matrix and fibers. This idealized model allows the properties of skin to be consolidated into two or three separate parts, with a layer of blood vessels (generally not analyzed with the skin) at the bottom. This is in contrast with attempting to define properties of the individual layers. There are two common composite models used when studying the mechanical properties of skin. The first, described by Hara [6], treats individual skin cells as particle fibers within an “extracellular matrix”. Since actual skin cells are different sizes throughout the different layers of the skin, the composite model is understood to be irregularly packed. Particles are more densely packed at the surface, where the actual skin layer is comprised entirely of skin cells. Figure 3, below, illustrates this concept.

Figure 3: Composite structure to model skin as described by Hara showing distribution of skin cells
The second, more popular, composite model of skin describes all the skin cells as a single unit which is understood as the matrix. The fibers then become strings of collagen (known as a “collagen fiber matrix”) running at the bottom of the composite. The ultimate tensile strength of skin is “positively correlated with the mass-average diameter of the collagen fibrils” [7]. This is a popular model because collagen tends to resist most of mechanical loading applied to actual skin. Skin in areas that are meant to take on more mechanical stress are found to have more collagen fibers than skin in areas that are not and are thus better equipped to resist ulcers and other skin damage.

Blood vessels and elastin fibrils cannot be ignored as part of the composite model. The internal pressure of the blood vessels must be overcome in order to prevent bleeding in order to experience ischemia, which is one of the desired results of the circumcision tool. Elastin fibrils act similarly to collagen fibrils when it comes to the strength of the skin, but add elasticity to the tissue. The level of elasticity added by these fibrils affect how the material can be treated during an experiment. To maintain the simplicity of the composite model, the blood vessels will be analyzed as part of the layer with the collagen fibers. Using this simplified model, skin can be tested as a mechanical material.

The skin cell particles and the collagen fibers have different properties, both of which need to be taken into account when attempting to determine a minimum pressure which causes damage to skin. The composite model used in calculations will be a combination of both the described skin model composites. An illustration of such a composite is shown in Figure 4.
Animal Model for Skin

Many animals have been used for the purpose of learning about human skin. However, skin is a diverse organ whose properties change depending on the area of the body which it covers. Because of this diversity, one must be careful to select an animal model whose properties resemble the characteristic of the type of skin which is being studied.

A clear candidate for modelling the human foreskin is porcine intestine. Certain layers of porcine intestine, specifically those remaining once outer mucosal and muscular layers are removed, have been found to be “suitable for in vitro as well as in vivo support of epithelial cells” [8]. Lindberg’s experiment used these parts of the porcine intestine to grow a new generation of human skin. That is, the intestine does not simply accept the human foreskin, which is a phenomenon that can be seen in similar types of experiments using other animal tissues where the tissue is allowed to live alongside the host tissue [9]. Porcine intestine allows more foreskin cells to grow. This can happen because the two types of tissue act sufficiently alike and have remarkably similar properties [8]. Growing foreskin is useful in the case of burn victims, but in the case of studying the material properties of foreskin, simply using the animal intestine will provide similar results to
those which may be found if human samples were obtained. “Bung” is a layman’s term referring to the end of the porcine intestine, ending in the anus [10]. This area has the foreskin-like properties contained by the rest of the intestine, with the added benefit of properties contained by outer skin, as opposed to inner tissue. These properties make this part of the intestine essentially identical to the skin found in the foreskin and thus an ideal portion to be used as an experimental sample.

**Hypothesis**

Gaeton [11] conducted an experiment in the dorsal skin of Sprague-Dawley rats meant to find pressure and time combinations that produce ulcer. Figure 5 shows a linear correlation between the two pressure and time combinations that produced ulcers from this research.

![Figure 5: Pressure against time relationship for instances where skin damage occurred, data from Gaeton and Vistnes [11]](image)
From these two points a relationship between time and pressure required to cause permanent damage to skin can be derived. This can be used to find pressures for any desired time. Figure 5 gives this relationship as:

\[ P = -0.021t + 44.769 \]  \hspace{1cm} (1)

A limiting pressure can be found which results in a stress state such that the skin cell matrix experiences a stress above its yield point, and capillaries (in the same area as the collagen fibers) experience a stress greater than their internal pressure. Since the outermost layer is mostly skin cells (more than the skin cell matrix), this limiting pressure will greatly exceed the yield strength of skin cells which is accepted to be 44.6 kPa, as found from Equation 1. At this pressure, the contact surfaces of the skin will deform to create a temporary seal and the blood flow to the attached skin will be cut off.

**Testing**

Certain aspects of foreskin and comparable tissue add difficulty to the development of experiments meant to study them. Because studies on the mechanical properties of foreskin are limited, it is necessary to understand similar processes to those involved in clamp circumcision must be studied to begin with. One such phenomenon is bed sores. Bed sores are defined as the breakdown of tissue as a result of abnormal mechanical loading on the tissue. Sufficient loading can cause an injury that damages the entire thickness of the skin. Eventually, if a load is applied for enough time, the injury will become irreversible and necrosis, the premature death of cells, and ischemia, a restriction of blood supply to tissues, will occur [7]. The similarities between bed sores, which are
the topic of numerous studies, and the concept of the hemostatic seal caused by the intended method of circumcision, which has not been studied as in-depth, help create a theoretical model.

In the case of circumcision via tissue breakdown, the negative effects of bedsores are part of the intended result. Ideally, a pressure and time combination can be found which causes necrosis and ischemia to a point where adequate bleeding as a result of the procedure is minimized. Relatively low pressures can be used in this situation, but must be applied for a correspondingly large amount of time [11] in order to overcome the reparative abilities of the skin [7]. The circumcision process involving the Gomco clamp is most effective when the patient does not have to wait a long time for the device to have full effect. For this reason, time must be the limiting factor and a pressure must be found to correspond with the desired time of five to ten minutes.

**Technique for Testing Skin**

A material property known as yield stress gives the load which, when applied to a sample and then removed, a material will not return to its original shape. In other words, this stress overcomes the elastic abilities of the material. Usually, this property is found experimentally by loading a sample with known initial dimensions. Different loads and the corresponding deflection are recorded and converted into stresses and strains respectively. The resulting curve typically looks like the one shown in Figure 6. The first part of the curve shows a linear correlation between stress and strain, but after a certain point the strain starts to increase exponentially with changes in stress. This point is taken to be the yield strength.
Skin is regarded as a visco-elastic material, which cannot be treated the same as most materials. This is because a visco-elastic material will initially resist a stress, but if left in a stress state for any amount of time it will relax into a new shape [12]. Thus, experimental curves could be found that follow the same shape as most materials, but resulting yield stress would be inaccurate due to the visco-elastic material’s ability to adjust to new shapes. Thus, a stress-strain curve “does not give an indication of the purely elastic constants” such as the yield stress of skin [13].

In the case of conducting a circumcision using a clamp, the yield stress is useful to know because it will give the point at which the elastic properties of skin can be overcome. Thus it will likely a temporary seal, since it will not immediately return to its original
shape, but it will not yet be considered a completely damaged crush injury, which would not heal into useful skin.

The process is conducted as follows:

First, apply a load to the sample and allow it to relax with the crosshead stopped. Then partially unload the sample and stop again, so that the sample exhibits the recovery effect. Now repeat this process for smaller changes in load until a point is reached by successive approximation or “bracketing,” at which the load does not change in either direction when the crosshead is stationary. As a result of the well-known “memory” effect of visco-elastic materials, by which the sample remembers all its past conditioning, a form of dynamic equilibrium has been established such that the relaxation is exactly balanced by the recovery, and temporarily only the elastic properties remain. [13]

The specimen experiences this cycle over small displacements about the point of “no relaxation”, and then the slope of the graph obtained by charting change in height as a function of load is taken to be the modulus of elasticity [13].
Materials List

Universal Testing Instrument
Intron Model 10-13-1M-(B)8
Configured with Compression Load Cell Attachments
Max Compressive Load: 200 lbs

Transducer
Trans-Tek Model 0244-0000
Measurement Range: ± .05 - ± 3.0 in.

Erick Magna Holder
Cullen-Legois MFG Model 200B

Multimeter
Hewlett-Packard Model 34401A
Max Voltage: 1000 V

Quad Power Supply
Elenco-Presicion Model XP-580
Voltage Range: 2-20 V
**Strain Gage**

Measurements Group  
Model P3500  
Gage Factor: 1.7-2.5

**Porcine Anal Tissue**

Approximately 2.54 cm x 2.54 cm squares

*Figure 7: Concept of experiment equipment setup*
Test Procedure

The equipment was set up as shown in the concept drawing in Error! Reference source not found.. The linear variable differential transformer (LVDT) was attached to the Universal Testing Instrument (mechanical testing machine) in such a way that it measured changes in the distance between the upper and lower compression load cells. This setup is shown in Figure 8. Lab set up with LVDT hookups labeled. The LVDT was powered with 10 V using the quad power supply with its variable resistance being measured as changes in voltage by the multimeter. This setup is shown in Figure 9. The strain indicator was set up to measure the load applied to the lower compression load cell in a full bridge configuration.

Figure 8: LVDT attachment to mechanical testing machine with LVDT wires labeled
Samples of the porcine intestine were prepared. It is important to include only tissue from the very end of the large intestine, just inside the anal tissue. This is where the intestine is most similar to that of human foreskin. The dimensions of the sample were recorded (length, width, and original thickness) before testing the sample. In the time between preparing the sample and testing the sample the tissue relaxes into a shape that is not the same as when it was cut.

Samples were then tested. A sample was placed at the center of the lower compression load cell. The upper compression load cell was lowered onto the sample to supply a lower limit load. Generally, the lower limit for the test was applied at a distance between the two compression load cells that compressed the tissue to half its original thickness. In some cases it was necessary to hold the corner of a sample in place while the upper compression load cell was being lowered to ensure that the sample did not move during the procedure. The sample was allowed to rest for five minutes. The upper load cell was then raised in order to partially unload the sample and was left in the upper position for

Figure 9: Lab set up with LVDT hookups labeled
two minutes. This cycle of loading, resting, unloading, and resting was repeated, with less unloading each time (using the same lower limit for each iteration) until the load at the upper position was sufficiently close to the rested load at the lower position. The load was then slowly lowered from this upper position to the lower position as points loads were recorded against position with no rest.

**Data Reduction**

Before testing occurred, the LVDT and strain indicator readouts were calibrated by using the equipment to measure known values and plotting the outputs. These calibration curves are shown in Appendix A. From these curves, it is found that:

\[ \delta = -0.3044L + 2.7967 \]  \hspace{1cm} (2)

\[ F = 0.1107S \]  \hspace{1cm} (3)

Where:

- \( \delta \) is the distance in centimeters between the bottom compression load and the top compression load
- \( L \) is the LVDT output
- \( F \) is the force on the sample in Newtons
- \( S \) is the strain indicator output

In order to obtain the material property of compressive yield strength, a curve of stress against strain must be obtained. The curve was obtained using the initial dimensions of the sample combined with the test results. The required stress and actual strain measurements are found using Equations 4 and 5.

\[ \varepsilon = \ln \left( \frac{\delta}{\delta_0} \right) \]  \hspace{1cm} (4)
\[ \sigma = \frac{F}{A} \]  

(5)

Where:

- \( \varepsilon \) is actual strain
- \( \delta \) is the previously-established distance (Eq. 2)
- \( \delta_0 \) is the original thickness of the sample
- \( \sigma \) is stress
- \( F \) is the previously-established force (Eq. 3)
- \( A \) is the original top-face area of the sample

The stresses and strains for the recorded values were plotted and a line of best fit was calculated. The slope of this line was taken to be the yield stress, which corresponds to the pressure at which the skin will begin to sustain damage.

**Results and Discussion**

From the data reduction, the yield stress of the samples ranged from 30 kPa to 50 kPa for the four samples tested. The resulting curves are given in Appendix B. Many factors may have contributed to the differences in these experimental findings. Firstly, only two samples were obtained from each specimen. So, for the test, two different pigs were involved. Both samples from the same specimen came to have the same yield strength (two samples at \( \sim 30 \) kPa and two at \( \sim 50 \) kPa). From one mammal to another, there are many differences that cause changes in skin properties. Among these is moisture content, which is widely accepted as a contributing factor to the strength properties of skin [7]. The value of approximately 45 kPa, which was obtained from an experiment done on
living tissue, falls comfortably within the range found here. This is evidence that this is an acceptable range to base a pressure on for the intended design.

Given that the area around the ring that contacts the skin is 1.4 cm$^2$, and using the higher end yield strength of 50 kPa, the minimum force exerted by the bell that is necessary to cause lasting damage to the double-layer of skin clamped between the pieces is 14.04 N (3.14 lb).

**Application of Findings**

This force is much less than the 2,580 N (580 lb) that the Gomco clamp is capable of exerting [4]. It is now necessary to comment on alignment between the angle of the base plate and the bell. In order for a force of 14.04 N to be effective, these parts need to line up perfectly. Using the much larger force compensates for misalignments in the shapes of these two parts, allowing for a more even pressure distribution despite differences in contact area. This is a necessary practice since slight misalignment is expected in any manufacturing process.

What the findings in this report show is that there is the possibility that a force which is less than 2,580 N, but still significantly higher than the discussed yield strength, may allow for an effective clamp. Using a lower force is ideal because the base plate could be designed with a smaller thickness and still resist deflection. A thinner base plate would require less material, ultimately saving money.
This study has produced results that suggest the possibility of an effective circumcision device that utilizes lower forces than those employed by the Gomco clamp.

**Moving Forward**

In order to fully support the theory that the Gomo clamp can be optimized to use less force, a more comprehensive study must be conducted. Such an experiment would study the way that misalignments between the base plate and the bell affect a device’s ability to provide a ring of equal pressure so that a hemostatic seal can form. From there, a minimum stress can be found which overcomes the effects of misalignment. Using this stress information, the design of a disposable clamp can be optimized.
Works Cited


Appendix A: Calibration Curves

LVDT Calibration

height = -0.3044(\text{readout}) + 2.7967

\[ R^2 = 1 \]

![LVDT Calibration Graph](image)

Strain Indicator Calibration

Force = 0.1107(\text{readout})

\[ R^2 = 0.9999 \]

![Strain Indicator Calibration Graph](image)
Appendix B: Experimental Curves

**Test 1**

\[ y = -30752x - 20893 \]

\[ R^2 = 0.965 \]

**Test 2**

\[ y = -29676x - 23007 \]

\[ R^2 = 0.9841 \]
Test 3

\[ y = -49513x - 30197 \]

\[ R^2 = 0.9554 \]

Test 4

\[ y = -45946x - 31508 \]

\[ R^2 = 0.9852 \]
Author’s Biography

Tricia Evangelista was born in Portland, Maine in 1992 and grew up in Old Orchard Beach. She attended the Old Orchard Beach School System before pursuing a bachelor’s degree in Mechanical Engineering from the University of Maine. While at UMaine, Tricia became involved in the Society of Women Engineers and Pi Tau Sigma MEE Honors Society. As part of these groups, she worked to promote interest in career fields pertaining to science, technology, engineering, and math. Tricia has accepted a job with offer from the Naval Sea Systems Command as a Combat Systems Integration Engineer.

Outside of academics, Tricia takes part in the performing arts. She performed with dance clubs at UMaine as well as with a dance studio in her hometown throughout her college career. Additionally, she can play a wide variety of musical instruments and is more than happy to volunteer with the concert band at Old Orchard Beach High School while she is home.