Solid Freeform Fabrication of Soft Tissue Simulators for Needle Injection

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Abstract

Medical training and surgical planning are becoming important applications for Solid Freeform Fabrication (SFF). To date, the vast majority of these training applications have relied on the production of stiff materials to replicate bones. Others have used soft materials to replicate soft tissues without regard for replicating the mechanical properties of the tissues. Varying the Young's Modulus of a printed object using various propriety materials and processes, we were able to replicate the injection force profile of a sharp hypodermic needle stick using blunted needles safer for training usage. The composite structures and needle pairs have a puncture force of 2.8 Newtons at a depth of 9 - 15mm, within the reported range for human skin. This will provide a safer training alternative in the use of hypodermic needles without the need for training on humans or animals.

1. Introduction:

3D printing and rapid prototyping has been applied to the field of medical training and simulation by several groups over the last twenty-five years. Researchers have used every commercially available technology from FDM (Patamianos, et al. 1998), to SLA (Kai, et al. 1998), to 3DP (Jacobs, et al. 2008), SLS (Suzuki, et al. 2004), and Polyjet (Kim, Hansgen and Carroll 2008). The majority of these processes, produce structures with rigid mechanical properties. The human body, by contrast, is mostly a water based structure with very compliant tissues. Mechanically, only bones should be considered a rigid construct for the purpose of simulation. This has limited focus on applications of 3D printing technologies to visualization of anatomical data (Jacobs, et al. 2008) or surgical planning for operations involving boney constructs. (Patamianos, et al. 1998) (Petzold, Zeilhofer and Kalender 1999) (Suzuki, et al. 2004) (Kai, et al. 1998) (Gibson, et al. 2006) (Sanghera, et al. 2001)

A few attempts to use soft materials for medical modeling have used the Polyjet and Fab@Home systems. (Lipton, et al. 2009) (Abdel-Sayed, Kalejs and von Segesser 2009) (Kalejs and von Segesser 2009) (Kim, Hansgen and Carroll 2008). While the Polyjet system allows for compliant materials, it has serious limitations as a platform for fabricating medical training simulators. According to Kim, et al. "Although the printing material used in this technology [Polyjet] results in models that are highly flexible, with capability to be realistically manipulated (i.e. performing transseptal punctures with standard Brockenbrough needles), it remains limited in its reduced tensile strength and long term durability" (Kim, Hansgen and Carroll 2008). This must be contrasted with the success of items printed on a Fab@Home system. According to Drs. Kalejs and von Segesser, "We have successfully started to use this type of model [printed on Fab@Home] in in-vitro valved stents testing integrating the aortic root in an artificial circulatory loop." (Kalejs and von Segesser 2009). Other attempts to make soft structures have relied on printing molds and casting materials into the molds to make the final geometry. (Bruyere, et al. 2008) (Sanghera, et al. 2001). While these have allowed for the production of training devices, they are limited in the construct they can produce since it would be impossible to produce structures with complex internal geometries though casting.

Efforts to apply 3D printing to medical training have focused on the collection of anatomical data from MRI or CT scans. (Gibson, et al. 2006). The anatomical data has been used to collect only geometric data and produced STL files as a result. This causes the vast majority of the information about the tissue constructs to be lost or not collected: No information about the relative density, mechanical properties or internal structures are used in the generation of these teaching models.

Efforts to apply 3D printing to medical training have also nearly exclusively focused on surgical training while the vast majority of healthcare workers are not surgeons. According to the Bureau of Labor Statistics, there were 239,100 emergency medical technicians and only 41,030 surgeons in the United States. (Bureau of Labor statistics 2014). This does not include the large number of US military personnel who are combat medics, who also require specialized training in medical procedures. Combat medics in particular carry a bag which contains: IV starting kits, Intra-osseous fluid kits, tourniquets, blood clotting agents, chest decompression kits, chest seals, nasopharyngeal airway devices, cricothyrotomy kits, hypodermic needles and epi-pens. Such medical practitioners clearly need to be trained on needle sticks much more than they need 3D visualizations of anatomy or laparoscopic procedures.

2. Background

The current state of the art needle stick training simulators are cast structures of silicones/hydrogels or foam structures wrapped in a "skin." There has been no empirical study that we are aware of that verifies the accuracy with which these traditional simulators can replicate the force profile produced upon injection of human tissue. Often, such simulators merely rely on testimonials for verification of their fidelity to the haptic feedback of tissue. However, the literature is clear in documenting that various tissue types have distinct needle puncture profiles whose differences are very appreciably felt by clinicians. According to Schneider et al., the forces acting on a needle when puncturing skin can be broken into three phases. The first phase is the puncture phase: the needle comes in contact with the skin and the force on the needle increases with distance until a peak force is reached. At that point, the second phase is reached. The skin is punctured and the force decreases with distance as the skin releases the elastic energy built up before puncture. Once the force reaches plateau, a third phase begins. In this phase, the drag forces on the needle dominate and the force on the needle rises again with distance. (Schneider, Peck and Melvin 1978). This process repeats as the needle passes layers of tissue inside the body as demonstrated by Brett et al. (Brett, et al. 1997). Additionally, the depth of the puncture, drag force, and needle puncture force vary between tissue types. Schneider et al. demonstrate that for human buttocks, a puncture force of 2.1 to 3.2 Newtons can be expected, while Brett et al. showed that a puncture force of up to 17 Newtons can be expected for penetrating the supraspinous ligaments. Indeed, with such a wide range of force profile producible by various human tissues, it is important that simulators are validated for accuracy using empirical data about their force profile upon puncture.

3. Methods

To make an accurate simulator, we determined a composite structure was necessary mimicking the layered, multi-tissue composition of the human body. Schneider et al. demonstrated that the subcutaneous tissues under the skin directly affected the needle puncture force profile. As result, we determined that a two layer system was required: A top layer to simulate the epidermis and a base layer to simulate the subcutaneous tissue. We identified four key variables which will control the needle puncture force and depth: the Young's Modulus of the base layer, the Young's Modulus of the top layer, the thickness of the top layer, and the sharpness of the needle.

Variables

* stiffness of top layer E_1
* thickness of top layer L
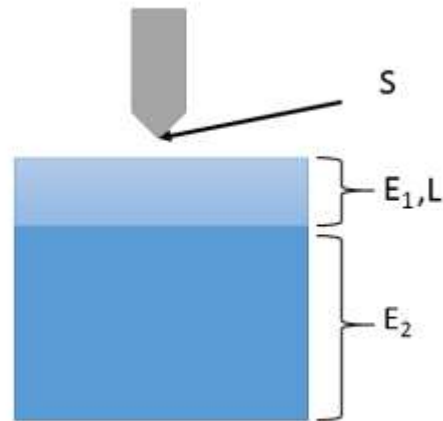* stiffness of base layer E_2
* sharpness of needle S

Figure 1: The idealized model for a tissue simulant has four key variables. The stiffness of the top, The stiffness of bottom, the thickness of the skin simulant, and the sharpness of the needle.

We used samples provided to us by Seraph Robotics, Inc. The samples were produced using proprietary materials and processes on a Fab@Home Model 3 3D printer, which the company manufactures. The constructs will be referenced as constructs 29, 39, 60 and S. Each construct has a unique Young's Modulus listed in Table 1. These constructs were combined into a series of sample blocks listed in Table 2. For needles, we selected a 1mm diameter, 30mm long sharp tip needle which was designed for hypodermic injections, a blunted version of the same needle with the sharp tip removed, and a 0.5 mm diameter, 15 mm long blunted tip needle from Nordson EFD.

Construct	Elastic Modulus in Tension (MPA)
S	0.608
29	0.380
39	0.077
60	0.010

Table 1: Young's Modulus of the constructs provided by Seraph Robotics for testing

We modified the Freeloader design developed by John Amend for use as a testing apparatus (Amend and Lipson 2011). We added a twenty Newton capacity, compressive load cell and modified the cross head to load a standard 10CC Becton Dickenson syringe. The luer lock needed was fitted to the syringe to allow for penetration testing. Penetration tests were conducted by aligning the needle to the surface of the sample. The needle then advanced into the sample at a consistent rate of 60mm/min, the same rate used in Brett et al. The software we wrote for the system then recorded the position of the head and the force on the load cell to provide force vs displacement curves for the system.

Sample	Base Layer Construct	Top Layer Construct	Top Layer Thickness (mm)
Test 1	60	S	5
Test 2	60	S	10
Test 3	60	29	5
Test 4	60	29	10
Test 5	39	S	5
Test 6	39	S	10
Test 7	39	29	5

Table 2: Samples were produced using the following constructs and thicknesses. They were tested using all three needle types. (Note that the Base Layer Thickness is not important to the calculations as it can be regarded as infinite long, so long as it is standardized to be greater than the length of the needle).

A   b   C

Figure 2: A freeloader system (a) was modified to include a 10CC BD syringe (b) and a compression load cell (c) to allow for materials testing.

4. Results

The initial results of the testing indicated that the sharp needle fractured the surface skin of the samples with little to no resistance. As seen in Figure 3, the force vs displacement curves did show one or two regions with a definable slope. This is most likely due to differences in the drag forces felt on the needle during puncture. The regions selected by the peak force detection algorithm are most likely noise generated by lack of homogeneity in the printed samples.
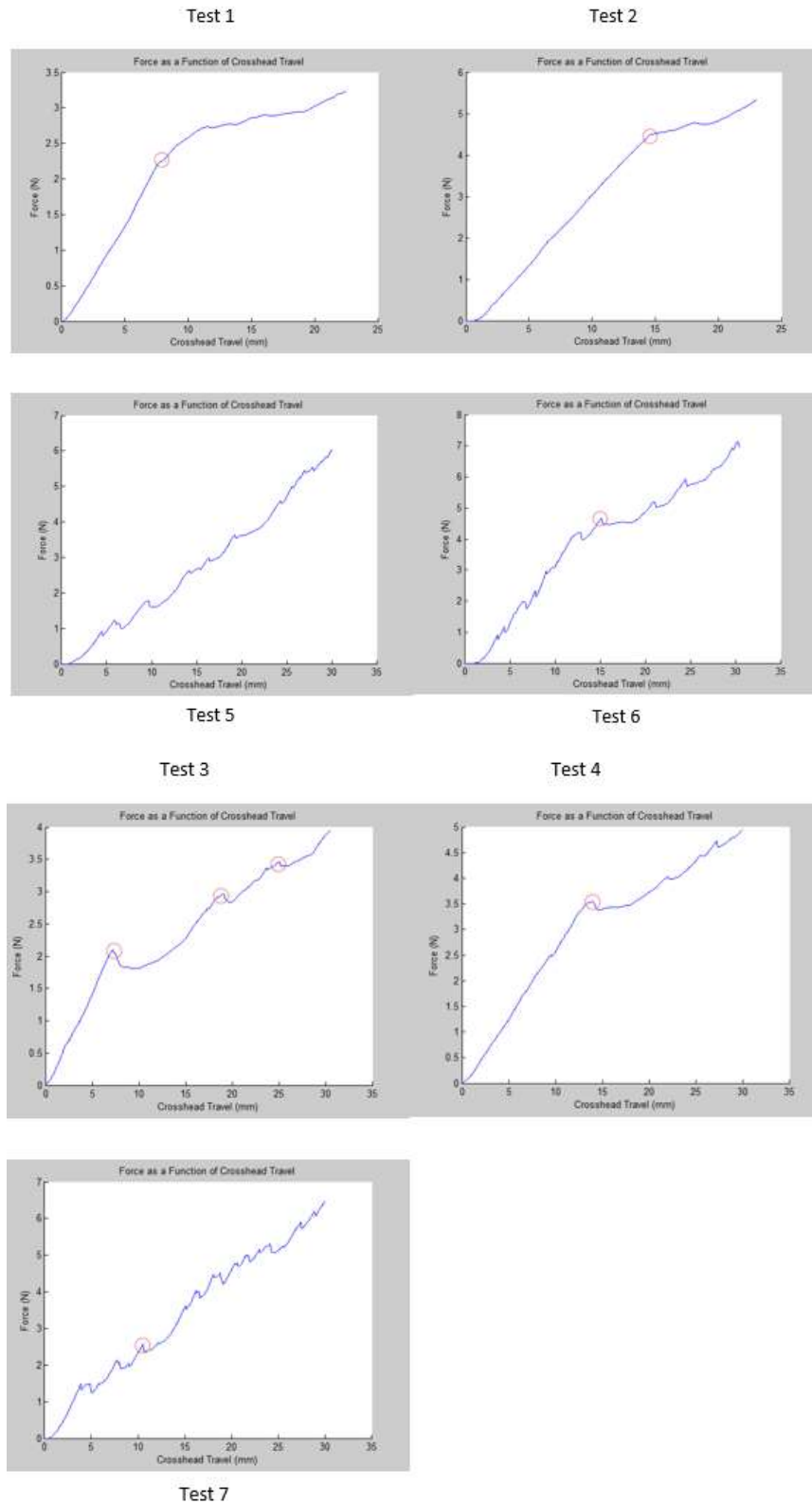
Test 1

Test 2

Test 5

Test 6

Test 3

Test 4

Test 7

Figure 3: The test samples provided little resistance to the hypodermic needles. As a result, the material was quickly pierced and drag forces dominated.
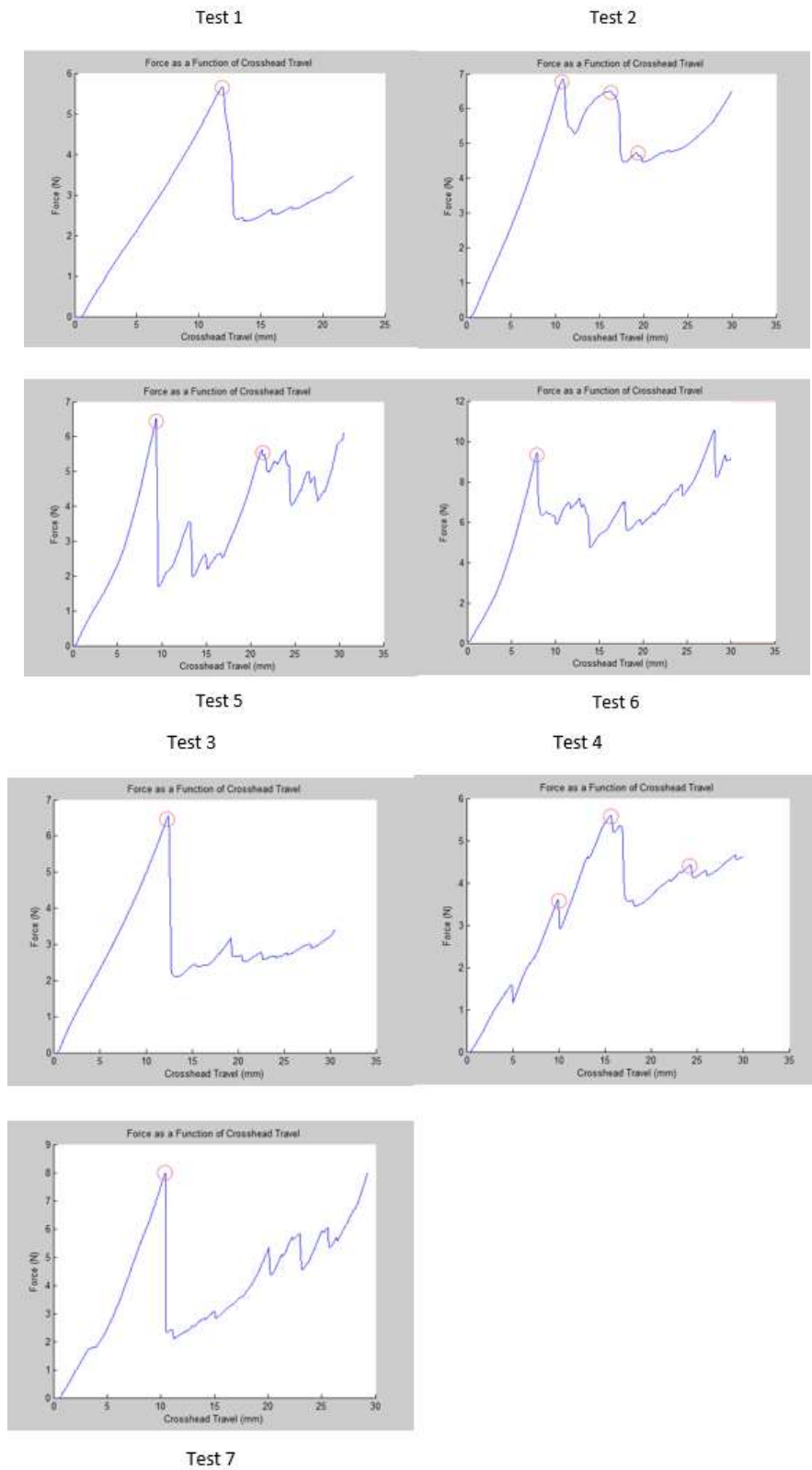
Figure 4: Samples run using the blunted 1mm needle showed a properly shaped needle injection curve, but had puncture forces higher than the target 3 Newtons for human buttocks.
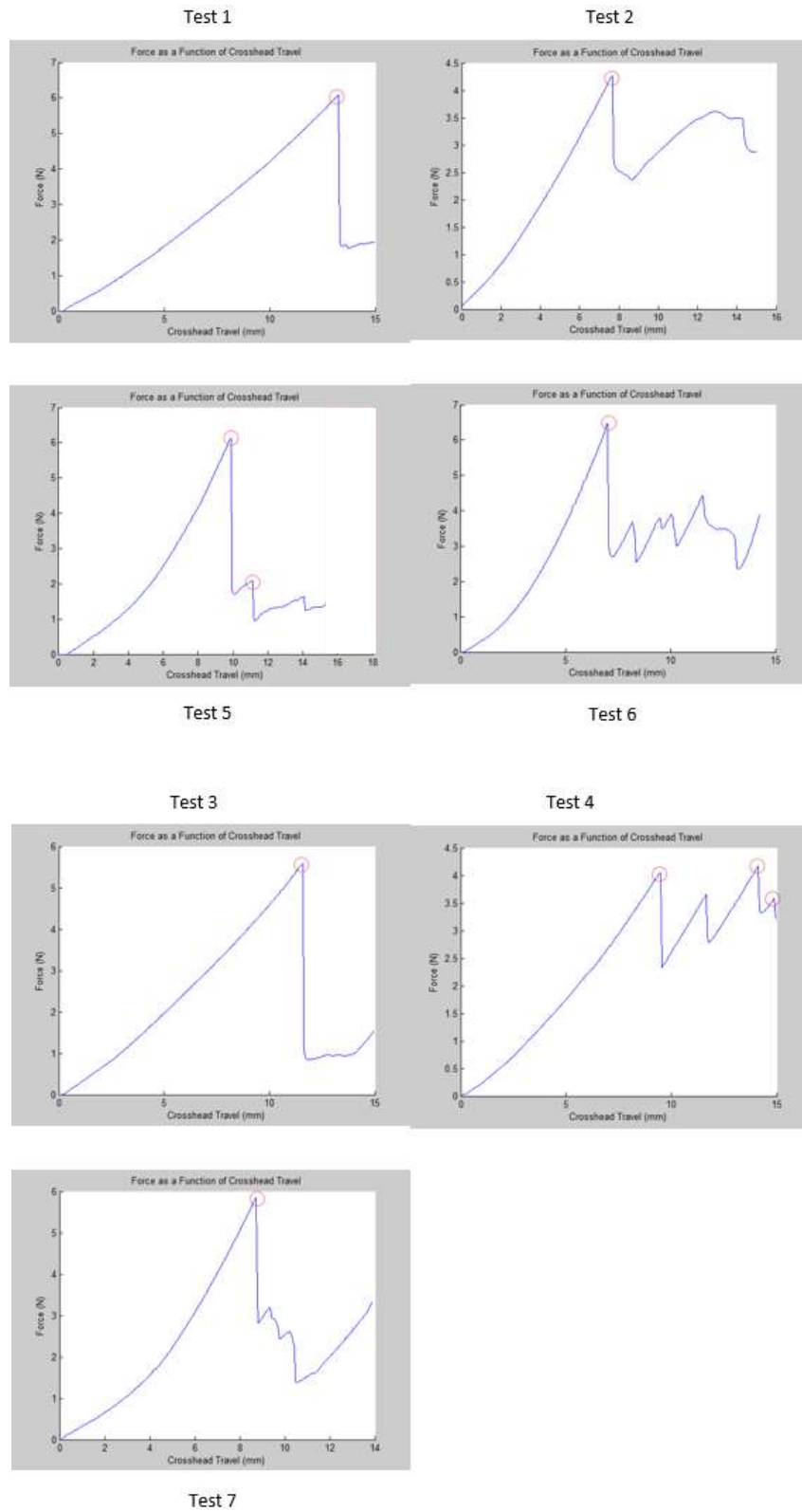
Test 1

Test 2

Test 5

Test 6

Test 3

Test 4

Test 7

Figure 5: The 0.5mm diameter needle consistently generated a properly shaped curve, but produced a puncture force that was too high (4-7 Newtons) when a 5 or 10mm thickness top layer was used.

The blunted 1mm tip proved to have the characteristic curve shape of needle puncture that is described in the literature. The system had its force rise towards a maximum, fall sharply, and rise again. Test samples 1, 3, 4, 5, 6, and 7 all showed a strong peak. All of the peaks were between 7 and 15 millimeters of depth, but were at a force of 6 to 8 Newtons. This was significantly higher than the target force of two to three Newtons described by Schneider et al.

The blunted 0.5mm diameter needle data showed the correct curve shape across all samples; however, the needle was not long enough to collect data on the drag dominated regions for test sample 1 and 2. The puncture force was between 4 and 6.5 Newtons for all samples with a depth ranging between six and ten millimeters.

From these results, we determined that the overall thickness of the skin was too great, and we needed to lower the force required to puncture the membrane with a blunted needle while maintaining the depth of puncture. We determined we wanted to optimize the system for a 1mm diameter needle since it provides the correct length and is most similar to the needles used in medical procedures. A new sample was generated by Seraph Robotics with a 1.6mm thick top layer of "S" construct and a base layer of construct 60. The resulting material was tested as described above. The data for the test is shown in Figure 6. This sample has a peak force of 2.8 Newtons at a depth of 12 mm. This is perfectly in line with the target puncture force of 2.1 to 3.2 Newtons at a depth of 9 - 15mm described by Schneider et al.
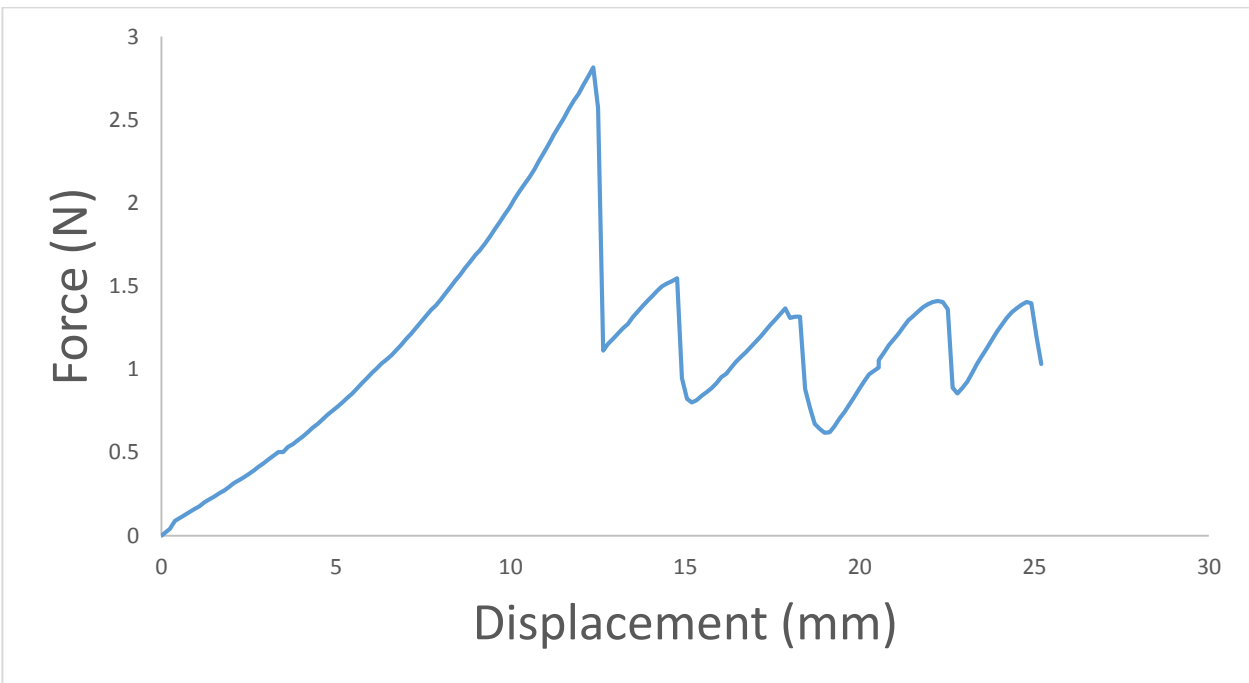

Figure 6: The force vs displacement profile of a 1.0mm blunted tip through a 1.6mm top layer of S construct with a construct 60 base layer matches the requirements set forth in literature. It has a puncture depth of 12.4mm and a puncture force of 2.8 Newtons.

5. Discussion and Future work

The novel simulator described herein using a blunted needle and composite printed structure can generate the ideal force profile for a human injection. The use of a blunt needle enhances the safety of the simulator for use as a teaching tool. As hypodermic needles are a controlled item in the United States due to their potential use in the administration of illegal narcotics, the use of a blunted needle will allow users to train without obtaining a hypodermic needle permit.

Further tests should be done to collect data on the puncture force relative to layer thickness and the other parameters of the system. Additionally, puncture force and depth should be correlated with other needle tip diameters to allow for the production of a truly parameterized sample design system. This will allow for the creation of an injection trainer which can replicate a specifiable force displacement curve associated with various other parts of the anatomy.

6. Conclusions:

With thousands of new non-surgical healthcare professionals being trained each year, there is a clear need for medical simulators which can adequately train users in basic needle injection by correctly simulating the haptic feedback one would get from puncturing human tissue. The Seraph Robotics technology investigated provides a pathway for creating not only geometrically complex simulators, but also tissue simulation that accurately replicates the puncture profiles of various tissues. Controlling mechanical properties and dimensions of simulators is critical to accurately replicating the injection properties of tissues, as clearly demonstrated by the varied puncture profiles documented in the literature.

Indeed, this technology can not only better serve surgeons in their early training, but also serve as a useful and inexpensive tool for more complex and accurate training simulators for use by non-surgical professionals such as EMTs, nurses, and combat medics. Needle injection is an important part of medical training of these professionals. This works represents the first attempts to truly accurately replicate the mechanical properties of tissues using 3D printed simulants, and has resulted in the first empirically verified soft tissue specific 3D printed needle injection simulation system.

7. Acknowledgements

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