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# Lower limb phantom design and production for blood flow and pressure tests

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## Abstract

Phantoms are specifically designed objects that are utilized or imaged to evaluate, analyze and tune the performance of experimental devices. In this project, it is aimed to design a phantom that responds in a similar manner with how human blood circulation would act in specific flow and pressure tests such as pulse measurement.

Ballistic gelatin is a member of hydrogel family with 250 Bloom value which resembles human muscle tissue in terms of mechanical features. That's why we carried out a uniaxial compression test on our gelatin sample to analyze its similarity of human muscle tissue in terms of elastic modulus, stiffness and rupture strength. Test results indicated that our gelatin sample has approximate values with organic human muscle tissue. Designed model was X-rayed and the similarities of the model to human texture were compared. After producing of lower limb phantoms, we carried out a circulation test through them by the aid of a peristaltic pump to simulate the actual blood circulation of human body limbs. This designed phantom is made ready for available flow and pressure tests.

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## Introduction

Globally, imaging phantoms or simply phantoms are widely used in various disciplines such as MRI, Ultrasound, CT, PET imaging since they are enabling us to avoid the use of a living subject or cadaver. In addition to that, they are utilized for experimental purposes like needle-guidance for medical students or simulating some physiological features of human body such as blood flow. In this study, a phantom is designed to mimic the anatomy and physiology of lower limbs of human body.

In medical imaging sector, assessment of image quality is mainly done with phantoms to calibrate of imaging system. The purpose of using phantoms in imaging is to avoid the use of living subjects. Since medical imaging involves hazardous intake of x-rays, it is considered as unethical to experiment on living subjects. That is why, phantoms are heavily employed to solve this dilemma, plus they indicate consistent results compared to cadavers.

Phantom usage for educational purposes is also another subsection where novice sonographers, medical students are taught with phantoms. Since commercially available training models and cadavers are expensive, medical colleges tend to utilize phantoms for needle-guidance and incision practices (1).

Phantoms have the ability to provide performance results of well-defined task based applications. For instance, the ballistic gel based phantoms of the muscle tissue can give the same results under mechanical tests such as tension, compression shear tests so that actual biologic muscle tissue usage can be evaded. If there are other attributes being investigated rather than mechanical features, it can be also investigated through phantoms. In this case, blood flow rate, pulse determination can be examined on human circulation mimicking phantom models as we did in this study.

In this study, we have designed phantom limbs of lower extremity where they resemble the human limbs in terms of anatomy and physiology. We developed our model using ballistic gelatin, artificial bones and veins. The artificial bone can be produced by 3D printers to create the closest model to bone structure. The stages of preparation and modeling of the phantom will be elaborated in further sections of this report.

The essential purpose of this study: modeling limb phantoms, is to provide a human body simulant for a further research which will be also conducted in our university. This further research is about to develop a novel tourniquet which functions electronically and enables the user to stanch limb rupture easily. The model that has been designed in this study, will be used in that further research to estimate the tourniquet's real-time performance on actual human body.

## Materials and Methods

### Soft tissue simulant: Ballistic gelatin

Designing a phantom model a material must be use to simulate human viscosity. Some imaging phantom manufactured a clear tube which includes a specific fluid to calibrate image resolution and enhance image quality. However, if a phantom use a tourniquet application or a similar application, it should be manufactured some organic or ductile material. There are some studies about manufacturing phantoms with agar–silica gel's to simulate head structure (2). However agarose conductance can be vary quickly, after it is produced. Repeatedly material conductance has to be measure. In contrary to agarose based phantoms, gelatin commonly use in phantom design to simulate human tissue.

Gelatin is a protein substance that is extracted from the natural protein collagen which presents in skin, bones and tissues of mammalians. As a protein, collagen contains more amino acids that enables itself to be utilized in a diverse amount of applications.

Ballistic gelatin is an extensively used soft tissue simulant in terminal ballistic testing which enables us to assess the effects of a projectile to living tissue. This is where it differs from "casual gelatin". Its main area of usage is ballistics especially. However, it is also the basic building material for all types of experimental limb reconstructions. Fundamental requirements for a good simulant are;

- The experiments must be reproducible and must always produce the same results.
- It must be possible to observe the process.
- Bullet dynamics and the behavior of the medium must correspond very closely to the real-life situation of a bullet in biological tissue.
- The values of the physical parameters along the wound channel (deceleration, force, penetration depth and timing) must be close to those encountered in real life (3).

The validity of scientific reports, associated with the use of gelatin is usually questioned since there is no common ground for preparing ballistic gelatin. Some researchers use 10%, whereas some use 20% concentration in different temperatures. The conflict on concentration is trivial if the gelatin has been validated to give results that can be extrapolated to living tissue. It is also claimed that (4) water temperature and storage time affect the physical properties of gelatin as a tissue simulant.

Other than water temperature and storage time, there are different parameters that might also affect gelatin properties as well. To get reliable and reproducible results, every step of the production process and storage conditions shall remain constant. However, there is a controversy going on (5) which type of simulant should be used for ballistic testing. However, in this project, we did not mean enter this debate which is about what type of material should be used. We only followed the exact process of gelatin production (6). Supposedly, any sort of gelatin could be produced if only it simulates any kind of biological system virtually. Any real or simulated organs can be embedded (7). As a matter of fact, artificial veins and bones are used in this study.

### Preparation of ballistic gelatin

Ballistic gelatin (BG) is usually utilized in 10 or 20% nominal concentrations. The actual concentration should be adjusted, in other words, should be calibrated for every batch of gelatin powder to acquire precisely desired penetration and to compensate for possible manufacturing tolerances such as inhomogeneities in the mixture (6). Different concentrations of ballistic gelatin samples are produced (**Fig. 1**).


**Figure 1.** Test samples of different densities.

For the purposes of this study, ballistic gelatin batches are produced from 250 Bloom Gelatin Powder. The gelatin production process was done according to the (8) which corresponds to 10% concentration at 4 degrees Celsius. We have prepared different groups of batches for different purposes. Our first group of batches are meant to use in mechanical testing "uniaxial compression test" where we put gelatin mix into cylindrical molds with different concentrations.

On the other hand, the other batch which is from the same powder "250 Bloom Gelatin powder", is used in construction of limb phantom models. 200 grams of powder was mixed with 1800 grams of distilled water to obtain 10% concentrated gelatin. Half portion of water was heated to higher degrees whereas other portion stayed at cold temperatures (4 - 6°C).

After mixing hot water with cold water, 200 grams of gelatin powder poured into the same beaker (**Fig. 2**). The mixture was kept heated and stirred at 1400 rpm by the aid of a paramagnetic stirrer during the whole mixing process. Furthermore, a couple of cinnamon oil (anti-foaming agent) drops were added into the mixture so that lumps and inhomogeneities can be dissolved. Lastly, a fair amount of paraben was added into the mixture to elongate preservation time of the gelatin. Also, it acts as a microbial growth inhibitor (MGI) in the mixture since this is an organic structure it requires inhibition of microorganism reproduction. Final gelatin solution is poured into small specimens of cylinders and limb phantom models. These models and specimen samples were left to cool down in room temperature for 24 hours. After that, they were put in the refrigerator (4°C). The conserved solutions are solidified and became way stiffer after 48 hours of time span past.

**Figure 2.** Mixing process.

From the same gelatin batch, we have prepared calibration blocks with different concentrations for gunshot testing. As it is mentioned before, another way of understanding the BG mimicking capabilities of human muscle tissue is doing gunshot tests. The penetrations of pellets (Air gun bullets) are examined on various calibration blocks of ballistic gelatin. The penetration length of pellets allows us to equate different batches so that we can comprehend which concentration of gelatin is optimal for soft-tissue mimicking.

We appreciate the aids of Police Department of Ankara in the process of doing gunshot tests. All the gunshot tests on different calibration blocks were made at Police Department.

1 to 6, 1 to 8, 1 to 9, and 1 to 10 concentrated calibration blocks have undergone close range shooting. The bullets that are used in this test are air pistol pellets which are supposed to be in ballistic testing of gelatins. The air pistol that is used in the experiment can be seen in **Fig. 3**.

**Figure 3.** Air pistol which is used for gunshot tests.

Each calibration block has shot with air pistol at 4 times, different lengths of penetration were measured. The speed of the pellets was set to 154m/s with ±5 offset and the shooting is done in close distance. The purpose of doing several shots in the same calibration block is to eliminate the user errors in the shooting phase.

Comparably higher concentrated calibration blocks showed greater resistance against pellets progress. 1 to 6 ratio block of gelatin had the highest resistive and allowed pellets penetration by only 40.75±1.7 millimeters whereas 1 to 10 ratio gelatin block allowed 76.25±2.0 millimeters (**Table 1**).

**Table 1.** The penetration test results

| Gelatin Density | Average |
|---|---|
| **1:6** | 40,75±1.7 mm |
| **1:8** | 54.00±0.8 mm |
| **1:9** | 72.25±2.0 mm |
| **1:10** | 76.25±2.2 mm |

Ideal resemblance for human muscle tissue mimicking suggests that pellet penetration range should be 70±3 millimeters (9). Since the results, we have acquired in this section of the project reflects the fact ideal gelatin density would be %10, 1:9 ratio (**Fig. 4**).

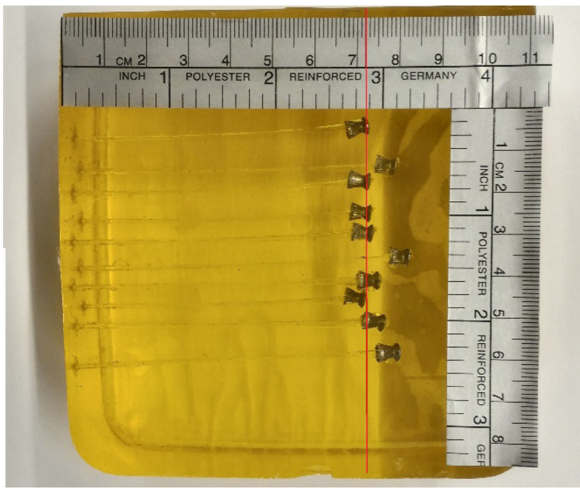


**Figure 4.** The gunshot test result for ideal gelatin density.

Compression testing is where a material experiences opposing forces push inwards upon the sample from opposite sides or is otherwise compressed, crushed, or flattened. Test specimen is usually placed in between two plates that distribute the applied force across the entire surface area of two opposite faces of the test sample and then the plates are pushed together by a universal test machine causing the sample to squeeze. A compressed sample is usually shortened in the direction of the applied forces and expands in the direction perpendicular to the force. A compression test is essentially the opposite of the more common tension test.

The main reason for doing a compression test is to assess the mechanical behavior or response of the material while it experiences a compressive load by measuring fundamental variables, such as strain, stress, and deformation. By testing a material in compression, the compressive strength, yield strength, ultimate strength, elastic limit, and the elastic modulus among other parameters may all be found. With the comprehension of these different parameters and the values associated with a specific material, it can be determined whether the material is suited for specific application you ask or if it will fail under the specified stresses.

As it is mentioned earlier, a compression test for a material involves at least two opposing forces directed towards each other applied to opposite face of the test sample so that the sample is compressed yet, there are many different variations to this test setup that associate any combination of different variables. The more commonly used compression tests involve forces applied to more than one axis of the specimen as well as the testing of the sample at elevated and lowered temperatures. Uniaxial, biaxial, triaxial, cold temperature, elevated temperature, fatigue and creep are all examples of different compression tests that may conducted on a material. However, the only example that is used in this study is uniaxial one which can be seen in **Fig. 5-(A)**.

Mostly all the materials can be subjected to compression testing where they have a compressive strength generally accepted to be high and a tensile strength (e.g. tensile test) that is of a lower value. Almost all materials can experience compressive forces in one way or another depending upon their application, but the most common materials are composites, concretes, metals, polymers etc. The material that is used in compression test in the project only involves gelatin which is an organic polymer. They tend to buckle up easily in higher strain rates which can be seen in **Fig. 5-(B)**.

In this study, several trials have been made to deduce the graphical values of (10) through quasistatic testing. In primary trials, test specimen failed way too early since we could not adjust the ideal length for the specimen (50 mm) (10). In addition to that, ambient temperature could not have kept in 4 degrees Celsius, even though the test conducted right after specimen came out from refrigerator. We needed some sort of specific chamber in pursuit of keeping the ambient at constant 4 degrees Celsius, however, due to some inadequacies, we could not perform that. That is why our sample is ended up with buckling too early and fracture eventually (**Fig. 5-(C)**).

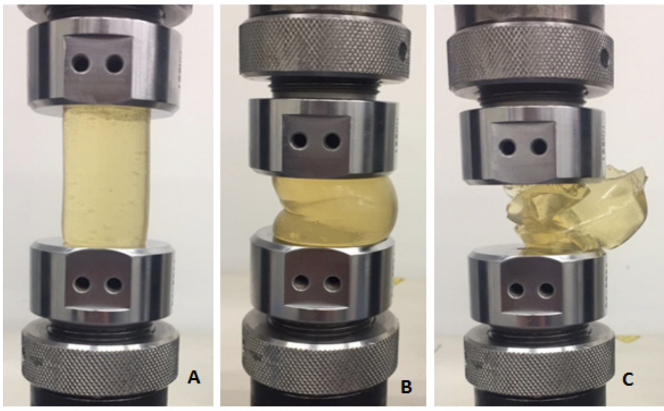


**Figure 5.** Uniaxial compressed gel material (A), Buckled up gelatin sample (B), Early fracture of gelatin sample (C).

### Mold material selection

As it is previously mentioned, in our study, skin muscle simulant was decided as ballistic gelatin in the form of 250 Bloom gelatin powder. The optimal concentration for gelatin was deduced as 10% due to the results of gunshot testing. Since 1:9 concentrated gelatin batch allowed 70±3 millimeters of penetration as it is in the ideal range (9).

After the material selection of muscle tissue simulant, it was followed by mold material selection. Since our phantom required specific shaping as in the anatomy of the leg limb, we were supposed to make a mold that replicates just like it. The aim of the mimicking lower limb is mainly due to the development of a new tourniquet where it suppresses the blood flow of the main artery. Because of that, we only sectioned the limb from the acetabulum to the end of the femur shaft where the main femoral artery lingers. The collateral arteries and capillaries were ignored during the design of the mold.

Materialization of mold was heavily debated. Our initial trials were with plaster molds so that it would enable easy formation. However, it ended up with failures where the plaster mold caused some errors. Since our mold is discontinuous from the bottom, the mold permits the freshly casted gelatin to drip from the bottom of it. In addition to that, surface roughness of the plaster did not adapt with the gelatin material. The adhesion of the gelatin molecule into polypropylene mold hindered the extraction of the frozen material after casting. Then, the mold was sharpened up in an orthopedics firm. Polypropylene mold was taken in the dimensions of the leg and the arm of one of the group members. The limb mold is given formation by the sizes of an average adult male. The circumference of the leg is 50 centimeters whereas the length of the whole limb is 45 centimeters.

### Modeling of mold

The discontinuous model of the phantom has initially caused problems such as disintegration of the bone structure to the gel as well as the artificial venular structure. The stabilization of the bone and vein could not have reached after the casting of the gelatin into the mold. Consequently, the integrated bone and artery structure glided after some timespan since it they were floating in a fluidic environment.

Another issue with the model was the dripping of the freshly casted gelatin on the bottom of the mold. Even though the mold was firstly stuck with epoxy adhesives, it still let some viscous gel to pour forth. That is why the whole model was redesigned in terms of cross-sections. Additionally, there is some support added from top to support the bone-vein integrated structure stabilization.

Add-on support and newly designed mold was envisioned in the computer aided program "Siemens NX". Using this program .step file can be imported and integrated your own assembling. A real human femur bone computer aid design data imported as a .step file. Then, the mold length and diameters, which changes from bottom to top because of their conic shape, have measured and designed a 3D body in this program as suit up the femur bone model. The mold has represented a cone in design assembly. Finally, a setup for mold has designed at this software with its real dimensions. The simulated version of the mold in the program can be seen in the figure below (Fig. 6).

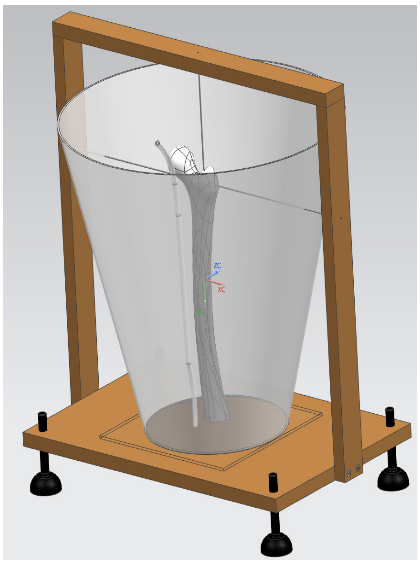

**Figure 6.** Virtual illustration of the mold.

The exactly same structure was constructed by wood materials and screws in our laboratory. The setup is shown in the **Fig. 7**.

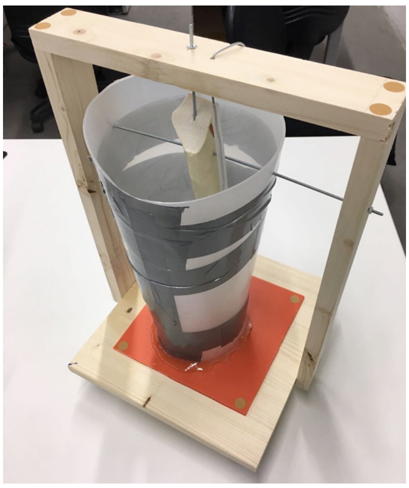

**Figure 7.** The phantom setup.

The casted gelatin material was poured into this supported mold, then preserved in that way in a refrigerator for 72 hours. After the thawing process ended, it is extracted from the mold outside by cutting it from end to end.

**Circulating Fluids Through Phantom**

Circulating the blood flow through our phantom model is our main priority during our project. This study is about working on a phantom model which mimics the blood flow of the femoral artery. That is why one of the major key points of our study is circulating blood through our phantom model.

Circulation process initiates as a peristaltic pump is connected to the outlets of the phantom model's artificial artery. This peristaltic pump siphons the liquid by you wish by the peristaltic movement and then it transmits the liquid through the artery in the phantom consequently creates the pressure in the artery. The amount of the pressure it will apply can be adjustable by the machine's user interface. The major principle of this act is to assess the circulation performance of a fluid through the artery in the model. If the desired values are reached, the designed phantom can be considered as a solid candidate for flow and pressure testing on a phantom media.

Peristaltic pumps are a type of pump in which peristaltic motion ratios provide fluid movement of the pressurized fluid created by synchronizing certain portions of the hose synchronously by the rotor connected to the electric motor. Our circulation platform can be seen in the **Fig. 8**.

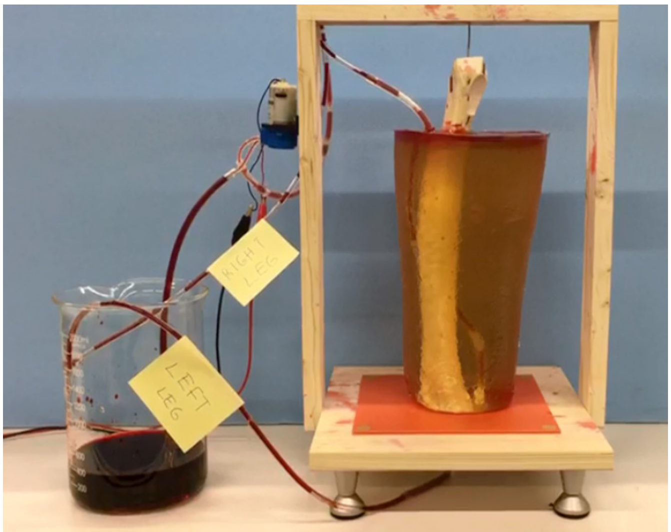


**Figure 8.** Blood circulation simulation.

This circulation movement siphons the liquid you want to put in it then transfers it through the phantom meanwhile it flushes out the liquid that is already in the phantom to the container back. That is how the amount of liquid will always be in balance due to this cycle. This system basically replicates the heart's behavior in a simple manner. The radius of the femoral artery is approximately 9.0 ± 0.8mm (11) for a 25-year-old male whereas the blood flow is 635.9 ± 223.1 ml/min (12). These values can fluctuate depending upon parameters like sex, exercising, room temperature, heart rate etc.

X-rays are a form of radiation called electromagnetic waves. It can help the view of your inside of your body without having to make any cutting process. The images show the parts of your body in different shades of black and white. This can help diagnosing, monitoring, and treatment in many medical conditions.

X-rays imaging can be used to examine most areas of the body. They're mainly used to look at the bones and joints, although they're sometimes used to detect problems affecting soft tissue, such as internal organs. However, due to its inefficacy to imaging soft tissue, there are other available technologies developed in the sector such as MR imaging and so on. The designed model of ours was taken to Gülhane Medical Military Academy for imaging it under X-ray and compared with a x-ray image which is belong a human limb in **Fig. 9 – (A)**. The phantom model was imaged in sagittal plane by using X-ray imaging technique. The resulted images can be seen in **Fig. 9 – (B)**. The main purpose of the X-ray filming is to analyze the phantom anatomy with the actual anatomy of the human body. Similarities and differences are evaluated in terms of anatomical aspects can be seen that figure. By the way, the venular structure is replaced with metal wires to get viewed under X-ray imaging. Obviously, since this is a basic X-ray imaging without DSA, the real vein would not appear that is why metal wire was replaced with vein substitute.

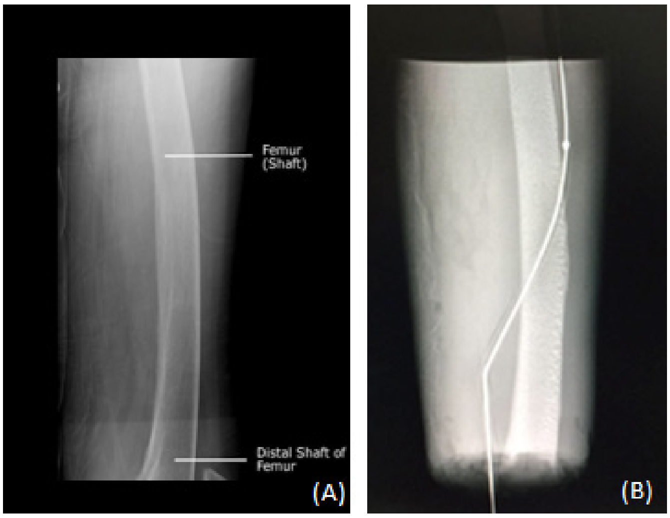


**Figure 9.** X-ray image of human limb (A) and Sagittal (B) view of phantom model under X-ray imaging.

## Results

In this project, several studies among the literature are surveyed and analyzed before the experiment begins. The preparation of mimicking-gel process is done accordingly to the highest cited articles in the scientific literature. It is observed that the closest similar way to mimic the human muscle tissue is to manufacture a phantom model with 10% ballistic hydrogel. Furthermore, several gel samples underwent mechanical tests to compare their mechanical features like stiffness, fracture point etc. It appears that 10% ballistic gelatin has nearest compressive strength with live muscle tissue. Other than mechanical tests, ballistic gunshot tests were conducted so that our samples can be compared with other ballistic gel products among the literature in terms of penetration allowance. It is analyzed that our samples have nearly the same density with muscle tissue since pellets could not penetrate the samples more than 70 millimeters in gunshot tests, which is the ideal range of pellet penetration for muscle tissue. The modeling of the mold is performed at the computer program Siemens NX and it is attempted to design actual anatomy of the human limbs. The location of the bones and main arteries is closely approximated. After the physical model casting is done, a circulation simulation is conducted through the phantom with a peristaltic pump externally. Lastly, the manufactured phantom model is imaged with X-ray screening so that similarities between phantom and human tissue can be defined anatomically. To sum up, we have developed a limb phantom which is nearly the same with human tissue in terms of mechanical characteristics that can be used in flow and pressure tests in further researches.

## Discussion

During our design phase, we had some technical issues ongoing. The primary failure we resulted with was, after casting of ballistic gelatin into a plaster mold, it let the viscose gel to drip out from the porous structure in it.

Secondly, another problem we have dealt with was the instability of our bone-vein substitute when it was put in the phantom model. The buoyant force of the fluidic material (freshly casted gel) pushed the substitute upwards during the freezing phase in the refrigerator. Consequently, after 72 hours of solidification, we acquired a slipped bone structure on top of the frozen gel.

In the end, we have changed the mold material with polypropylene and reinforced our model with a scaffold. That is how we managed the ideal conditions to shape up a limb phantom.

Uniaxial compression testing was conducted on gelatin test specimens several times. There are considerable number of different parameters that might cause these errors. The first one is, the strain rate was way too higher as it is supposed to be in (10).The second misconception of ours was preparing a lengthy test sample (50 millimeters in length), which ended up with early fracture than it was expected. After going over the articles we look up to, we decided to shorten up our test specimen in lengths. However, in our final trial, even though we cut the length of the specimen in half and adjusted the strain rate in desired values (1.5 mm/min) (10), we still could not get the ideal range of engineering stress/engineering strain. Our main presumption for these errors is the ambient temperature. Even though we preserved our test specimens in refrigerator (4 degrees Celsius), we could not keep the test specimens at 4 degrees Celsius during the testing process. In the article, we take as reference (10), the testing machine was sustained in 4 degrees Celsius by a cooling chamber. Due to some inadequacies, we could not provide that kind of a system for our assessment.

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## Conflict of interest statement

The authors declare there is no conflict of interest.

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