



Study Confirms
3D Printed Tissue
Can Mimic the
Properties of
Porcine Liver,
Epicardium and
Aorta Tissue



Introduction

Anatomical 3D printing has mainly been used for training, education and surgical planning purposes because previous materials have been unable to mimic the mechanical and material properties of tissue.

However, there are new Digital Anatomy (DA) materials on the market that mimic the material configurations of soft organ, subcutaneous tissue and myocardium. These new DA materials, developed by Stratasys, promise to mimic the mechanical performance of biological tissue and allow for lower cost and quicker development of models.

The use of 3D anatomical models promise to be beneficial because it doesn't require regulatory ethical requirements (or a facility to handle the biohazards and sterilization) and offers longevity and reduced cost compared to ex-vivo and in-vivo cadaveric animal testing. In addition, 3D technologies also address constraints of conventional manufacturing that require fabrication processes like molding and casting, which is not ideal for the creation of patient-specific models because of high tooling costs and process time.

Study Confirms 3D Printed Tissue Can Mimic the Properties of Porcine Liver, Epicardium and Aorta Tissue



Objective

The study focused on comparing porcine tissue with the mechanical properties of DA Soft Organ (SO), the lubricity of DA myocardium (very stiff, extremely stiff and highly contractile) and the tactile capabilities of DA Subcutaneous Tissue (ST).

Scientists and engineers from Medtronic, a global leader in medical device manufacturing, conducted an independent third-party comparison of the DA materials to porcine tissue. The following summarizes the findings and presents implications for future work in material development.

Methods

The stiffness and lubricity of 3D models was compared to those of porcine tissue. To mimic the conditions during in-vivo procedures, tests were developed to evaluate lubricity/friction, qualitative cutting, stiffness and puncture testing and tunneling (subcutaneous tissue) for comparison between porcine tissue and DA materials.

The mechanical properties of porcine tissue (liver, aorta and epicardium) were compared to those from a wide spectrum of 3D DA material blends. Porcine tissue was chosen as the baseline for comparison because of its similarity to human tissue, availability, and the precedent for its use in pre-clinical testing. All samples were printed on the Stratasys J750 Digital AnatomyTM 3D printer.





Key findings

Stiffness Testing

Porcine livers were dissected and assessed for stiffness from 1 to 3 N. From those samples, two representative values for thickness were used as the size for the DA liver cube samples. Two iterations of the porcine and DA liver configurations were tested.

The statistics for Iteration 1 – Liver 2 are displayed in Table 1, which shows the lower standard deviation, which equates to higher repeatability of DA SO liver in comparison to the porcine liver tissue.

Success:

- The experimental DA SO liver configurations have the capability to match the stiffness of liver tissue.
- The stiffness of 3D printed parts is more consistent than porcine tissue, which can be highly variable between samples.

| Sample Type | Mean [N/mm] | Standard Deviation | Standard Error of the Mean (SEM) |
|----------------------------------|-------------|-----------------------|----------------------------------|
| Iteration 1 – Liver 2 | 0.695 | 0.025 | 0.010 |
| Shell: 0.4 mm Thickness: 15 mm | | | |
| Iteration 1 – Liver 2 | 0.570 | 0.033 | 0.014 |
| Shell: 0.4 mm Thickness: 25 mm | | | |
| Iteration 1 – Liver 2 | 0.914 | 0.020 | 0.008 |
| Shell: 1.0 mm Thickness: 15 mm | | | |
| Iteration 1 – Liver 2 | 0.743 | 0.033 | 0.003 |
| Shell: 1.0 mm Thickness: 25 mm | | | |
| Porcine Liver Tissue | 1.144 | 0.455 | 0.038 |

Key findings

Lubricity (epicardium and aorta)

Porcine heart tissue samples were attached to a tribometer and tested with a 0.25 in diameter steel ball with an applied axial force along the tissue surface of 0.75 N at a velocity of 0.5 mm/s for a distance of 30 mm. The output was a coefficient of friction vs. time curve which was analyzed for a stabilized window of time. DA myocardium was also attached to the base of the tribometer and tested with a 0.25 in diameter steel ball probe with the following lubricant conditions: none (dry), DI water, mineral oil, and dish soap.

All of the DA printed materials were close in value to the porcine aorta when tested with a lubricant layer of soap, with Agilus being slightly higher in value than the DA materials. DA myocardium had values which encompassed the lower to upper quartile of the porcine epicardium and Agilus was very close to porcine epicardium under these conditions.

Figures 1-5 shows how the various printed configurations compare with the porcine tissue values.

Success:

 By combining the ability to modify the coefficient friction with tissue realistic values, DA materials can allow for more appropriate bench testing boundary conditions prior to utilizing animal or cadaver models.

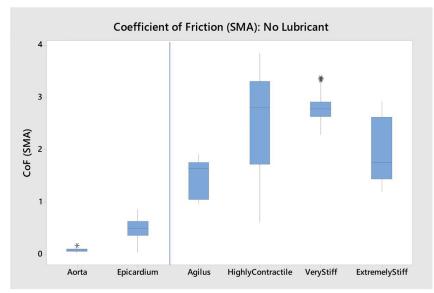


Figure 1

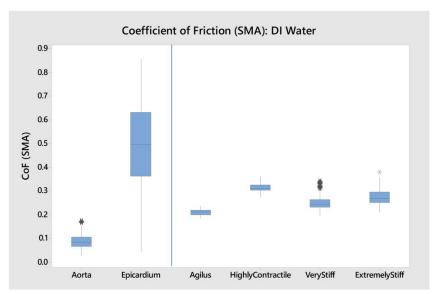


Figure 2

Tunneling and Puncture (Subcutaneous)

Cutting, puncture and tunneling of DA ST (fat and muscle) were evaluated qualitatively by pre-clinical implant specialists. They found the puncture and tunneling to be close to real tissue behavior for many of the DA ST configurations, however, cutting was not. According to the specialists, too much force was needed to create an initial incision and there was also too much drag in the cutting motion.

Success:

 DA materials can be used to design anatomical models for qualitative benchtop testing, implant procedure testing and planning because of its ability to mimic mechanical properties and the qualitative hepatics of tissue.

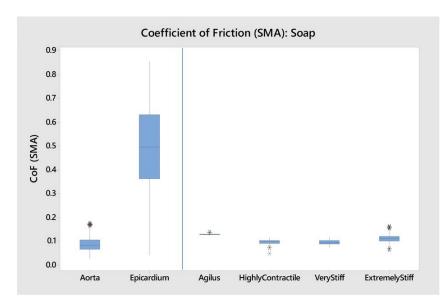


Figure 3

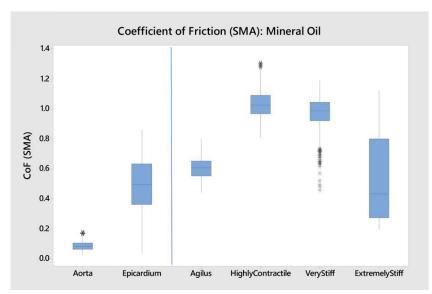


Figure 4

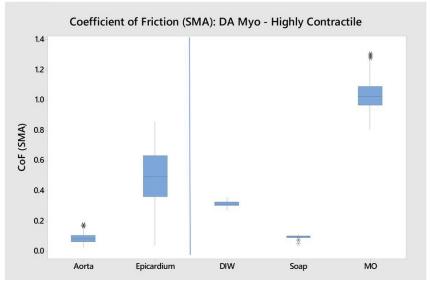


Figure 5

Summary

In summary, the new DA materials developed by Stratasys mimic the mechanical performance of biological tissue including soft organs, subcutaneous tissue and myocardium. Results from this study showed:

- DA SO liver configurations displayed the capability to match the stiffness of liver tissue and were more consistent between samples.
- The lubricity of DA materials with surface treatments were similar to porcine epicardium and aorta.
- Puncture and tunneling of DA materials also behaved comparable to real tissue, however, qualitative cutting had limited performance.

Despite a few shortcomings, the DA materials from Stratasys perform more like real tissue than any other commercial 3D printed materials on the market today. These promising results suggest that in addition to being a tool for surgery, training and education, anatomical models made with DA materials can add new value as a research tool and could reduce preliminary animal testing and usage of cadaver models.

Read the full study results here: PolyJet 3D Printing of Tissue Mimicking Materials: <u>An Investigation of Characteristic Properties of 3D Printed Synthetic Tissue</u>

Learn more about <u>Digital Anatomy™ Material</u>

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Creating biomechanically accurate bone models.





Creating biomechanically accurate bone models.

To create realistic synthetic musculoskeletal models for medical device development, physician training, surgical demonstration and procedural planning, synthetic bones must replicate the density properties and mechanical behavior of human bone.

The J750 Digital Anatomy™ printer gives clinicians and engineers the power to create the most lifelike anatomical models available. Combinations of unique materials that vary in softness, flexibility and density, and more than 100 clinically-validated preset anatomy options, help to mimic human bone like never before.



THE POWER TO CREATE

Accurate cortical and cancellous bones: Testing screw pull out force and driving torque

In 2020, researchers at the Computational Mechanics and Experimental Biomechanics Lab evaluated the characteristics of bone models 3D printed on the J750 Digital Anatomy printer and how accurately they replicate screw pull out force and driving torque.

Method

3D printed models of cortical and cancellous bone were created using Digital Anatomy printer software. Pilot holes were drilled into each model, and tapped with the appropriate tap. The most commonly-used cortical and cancellous screws were inserted to the ASTM standard depth for testing bone substitutes.

Pullout tests were performed until the screw was released from the bone model, and measured to compare force and displacement. Driving torque and pullout measurements were then compared to values found in literature and to ASTM standards.

Results

Screw pull out force during screw insertion corresponded to those found in literature for the cortex of a cadaver bone, demonstrating that the 3D printed model accurately replicates cortex thickness.

Conclusion

Orthopedic screws have a similar haptic response in human bone and 3D printed bone models.

The J750 Digital Anatomy printer allows clinicians and engineers to control density properties of bone models with physician-tested anatomical presets. 3D printed models accurately mimic bone density characteristics and behave like native bone when force is applied such as drilling, reaming, or sawing.



THE POWER TO CREATE

Accurate lumbar spine models: Testing mechanical performance

In 2020, researchers from the Technion Institute of Technology Materials Science and Engineering Laboratory performed mechanical lab tests to measure the mechanical accuracy of 3D printed synthetic spine models compared to cadaver spine.

Method

Using Digital Anatomy printer software, researchers constructed four lumbar spine models using 3D printed lumbar vertebrae (S1-L3), ligaments, sacrum, facet joints, and intervertebral discs. Each model was created using unique pre-set material combinations that varied in flexibility, stiffness and density to mimic a range of native musculoskeletal characteristics.

Mechanical tests were performed to simulate the natural axes of movement of the human spine as force is applied: disc compression, extension, flexion, lateral bending, and axial tension. Force values were then compared to those found in literature for human cadaver lumbar spines.

Results

Mechanical disc compression, displacement, and elasticity values for the 3D printed model corresponded to those found in literature for cadaver lumbar spines, demonstrating that the synthetic model accurately replicates biomechanical behavior of human bone.

Conclusion

3D printed L3-S1 models accurately represent the range of motion of human and cadaver spines.

Digital Anatomy printer technology uniquely allows clinicians and engineers to control the range of lumbar disc stiffness to accurately mimic the disease pathologies and anatomy variations of the human spine.



/hite Paner

Unlock the power to mimic native bone structures.

- Highly-realistic, low-risk training
- · High repeatability between samples
- Clinically-relevant benchtop testing
- Most consistent, accurate representation of bone
- Cost reduction of up to 70%

Learn more about the J750 Digital Anatomy printer, materials and software at **Stratasys.com**.

Questions? Contact us at **medical@stratasys.com**.



References

Dahan, Gal et al., "Screw Pull-Out and Driving Torque Experiments," Computational Mechanics and Experimental Biomechanics Lab, Final Report (2020).

ASTM F1839 – 08, Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments, *ASTM International*, West Conshohocken, PA, USA, (2016).

Barak, Yaron, "Biomechanical Evaluation of a Printed Digital Anatomy Lumbar (L3-S1 Spine Model), *Technion Institute of Technology Materials Science and Engineering Laboratory*, Final Report (2020).

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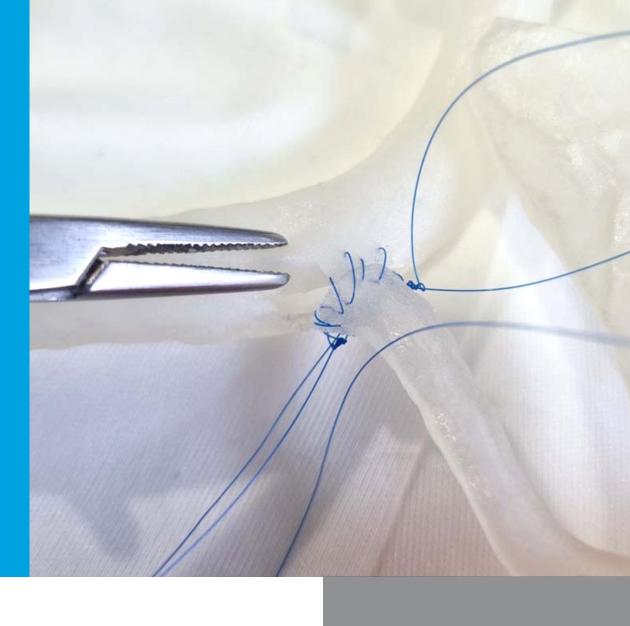
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Biomechanical
Tests Confirm the
Potential for 3D
Printing Suturable
Vascular Models with
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Anatomy Printer



Biomechanical Tests Confirm the Potential for 3D Printing Suturable Vascular Models with the Stratasys Digital Anatomy™ Printer

To create the most realistic, patient-specific simulation for surgical training, vascular models must mimic how native tissue responds to pressure, punctures, and stitches. Experiencing the behavior of biological blood vessels during anastomosis is a crucial part of preparing surgeons to treat patients safely and confidently, and materials must be chosen carefully to produce the most accurate anatomical models.

In 2021, researchers at the University of Pavia in Pavia, Italy evaluated the performance of blood vessel models printed on the Digital Anatomy Printer, comparing different material combinations to porcine tissue samples. Their research resulted in a new printing preset for suturable vascular models that mimics vessels' mechanical response during suturing.

Method

In order to create the material mixture for blood vessel suturability, the researchers printed 37 different presets. Mechanical tests were performed to validate the compliance of the 3D printed models compared to fresh porcine tissue samples including single stich, puncture, tensile and suturing. The single stich test is shown in Figure 1 and the tensile test is shown in Figure 2. Researchers thoroughly tested these combinations by performing 10 repetitions for each material and mechanical test type. Of the 37 samples, 6 showed the most accurate results compared to the real porcine tissue.

Figure 1: Comparison between single stitch mechanical tests performed on porcine aorta (up) and on a 3DP material (down).

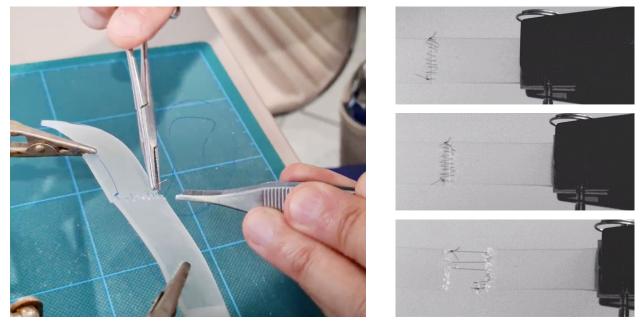


Figure 2: Uniaxial tensile test performed on a 3D printed sample sutured by an expert surgeon in order to mimic the surgical suture on a medium caliper arterial vessel.

The Results

The following table (Figure 3) presents the selected material in comparison to porcine tissue in the different tests – puncture and single stich.

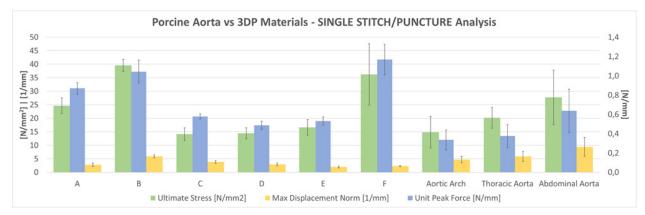


Figure 3: Overall results of puncture and single stich tests on the pool of 6 selected materials compared with porcine aorta tracts (namely aortic arch, thoracic aorta and abdominal aorta)

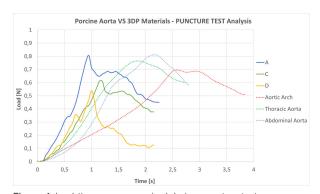


Figure 4: load-time curves acquired during puncture tests: Comparison between 3DP materials and different porcine aorta tracts on one representative curve per material (not normalized)

| | | | Puncture Tests |
|--------------------|----------------|----------|---------------------------|
| Materials | Thickness [mm] | #Samples | Unit Peak Force [N/mm] |
| А | 1 | 5 | 0,87 ± 0,06 |
| С | 1 | 4 | 0,58 ± 0,03 |
| D | 1 | 5 | 0,49 ± 0,04 |
| AORTIC ARCH | 2,2 ± 0,26 | 2 | 0,34 ± 0,10 |
| THORACIC AORTA | 2,18 ± 0,19 | 3 | 0,38 ± 0,12 |
| ABDOMINAL AORTA | 1,46 ± 0,19 | 3 | 0,64 ± 0,22 |

Table 1: Normalized puncture tests' results: comparison between 3DP materials and different porcine aorta tracts

Figure 4 above represents the load-time curves, in which values are not normalized according to the sample thickness. Table 1 shows the normalized values for the same test.

The values measured demonstrate repeatable results between the 3D printed models, while in the tissue samples, the standard deviation is much higher. The selected presets accurately resemble the measured values from the porcine vessels.

Two material combinations were identified as the most promising solutions for simulating and practicing surgical techniques on blood vessels. These materials could simulate the flexibility and softness of both minor and thicker vessels.

The Conclusion

Suturable vessel wall 3D models printed with the Stratasys Digital Anatomy Printer can provide surgeons and researchers biomechanically accurate blood vessel models for realistic treatment planning and training. Stratasys developed new software presets based on this research allowing clinicians to control the range of thickness and flexibility to mimic disease states and variations of human blood vessels on medical 3D printed models.

Unlock the power to simulate suturable blood vessels.

- Highly-realistic, low-risk training
- High repeatability between samples
- Physiological response of native vascular tissue
- Standardize surgical skills and delivery of care
- Tested material combinations create realistic models

View the complete study findings at the following link: Quantitative Assessment of 3D Printed Blood Vessels Produced with J750™ Digital Anatomy™ for Suture Simulation

Learn more about the Digital Anatomy™ Printer, materials and software at https://www.stratasys.com/3d- printers/j750-digital-anatomy.

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