Biomechanical Tests Confirm the Potential for 3D Printing Synthetic Myocardium With the Stratasys J750 Digital Anatomy Printer

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White Paper

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Introduction

Cardiac applications of 3D printed patient-specific models (PSMs) include surgical training, complex procedural planning, and the creation or refinement of cardiac devices. As structural heart interventions become increasingly complex, the ability to effectively model patient-specific geometry, as well as the interaction of devices within and around that geometry, becomes even more valuable to advance surgical interventions.

Until now, the focus of PolyJet™ 3D printing technology and other traditional anatomical modeling methods has been on achieving precise external anatomical geometry and appearance. The next frontier in 3D printed PSMs is the simulation of the biomechanical properties of human tissue.

Objective

To replicate the physiological response of native cardiac tissue including vessel walls, chamber walls, and valve leaflets, Stratasys studied the mechanical behavior of each structure in collaboration with medical device manufacturers, world-class research institutions, hospitals and medical personnel. Findings from these studies were used to develop software and materials to simulate those properties. Scientists and engineers from Medtronic, a global leader in medical device manufacturing, conducted an independent third-party comparison of the Digital Anatomy myocardium materials to porcine cardiac tissue. The following summarizes the findings and presents implications for future work in material development.

Methods

The mechanical properties of porcine myocardium were compared to those from a wide spectrum of 3D printed myocardium material blends (Table 1). Porcine myocardium was chosen as the baseline for comparison because of its similarity to human tissue, availability, and the precedent for its use in cardiac device preclinical testing. All samples were printed on the Stratasys J750™ Digital Anatomy™ 3D printer.

Table 1 - Digital Anatomy Myocardium Material Properties

Material	Biomechanical Property	Description
Myocardium 1	Highly Contractile	Softest infill wrapped in 0.4 mm Agilus™*
Myocardium 2	Moderately Stiff	Second softest infill wrapped in 0.4 mm Agilus
Myocardium 3	Stiffened	Second stiffest infill wrapped in 0.4 mm Agilus
Myocardium 4	Very stiff	Stiffest infill wrapped in 0.4 mm Agilus
Myocardium 5	Extremely Stiff	Softest infill wrapped in 0.6 mm Agilus

*Agilus is a soft, flexible PolyJet 3D printing material.

Key Findings

Compliance

The Digital Anatomy material properties were either within the same range of compliance as the porcine myocardium or stiffer. At anatomically relevant thicknesses, stiffness values of printed Digital Anatomy samples corresponded to most of the chambers of the porcine heart (Figure 1).

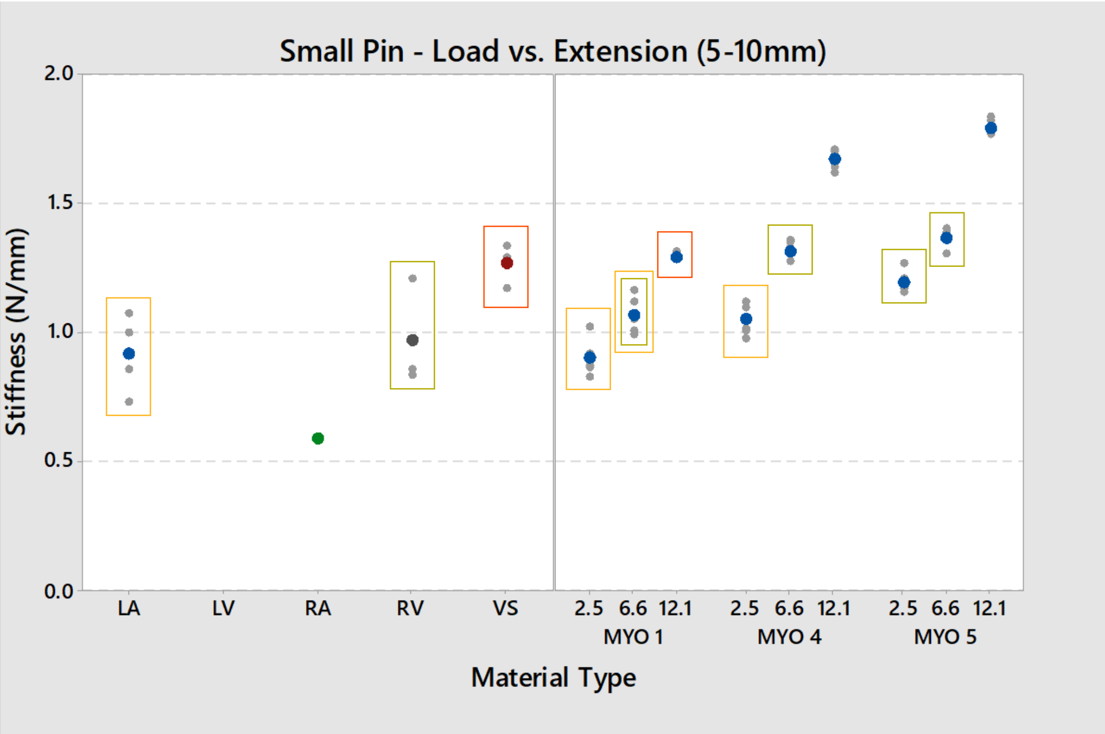

Figure 1 - At anatomically relevant thicknesses, stiffness values of printed Digital Anatomy samples corresponded to most of the chambers of the porcine heart.

Compliance Variability

Porcine myocardium showed considerable variability in compliance from chamber to chamber and within each chamber (Figure 2). In contrast, the Digital Anatomy samples were highly consistent (Figure 3).

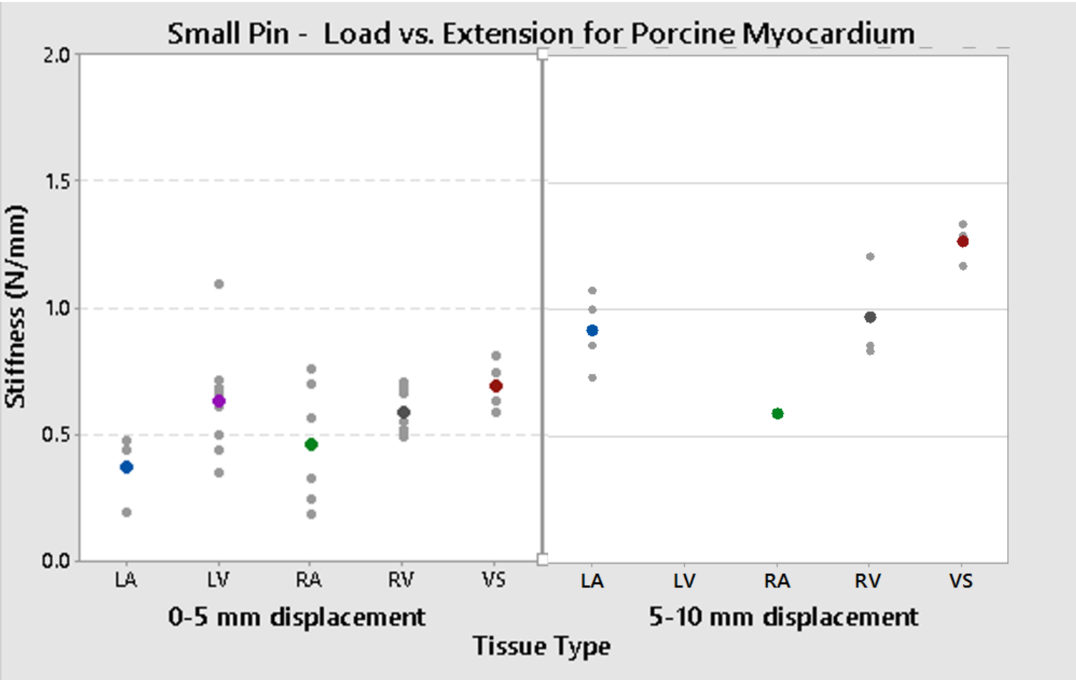

Figure 2 - The porcine tissue had significant variability between samples.

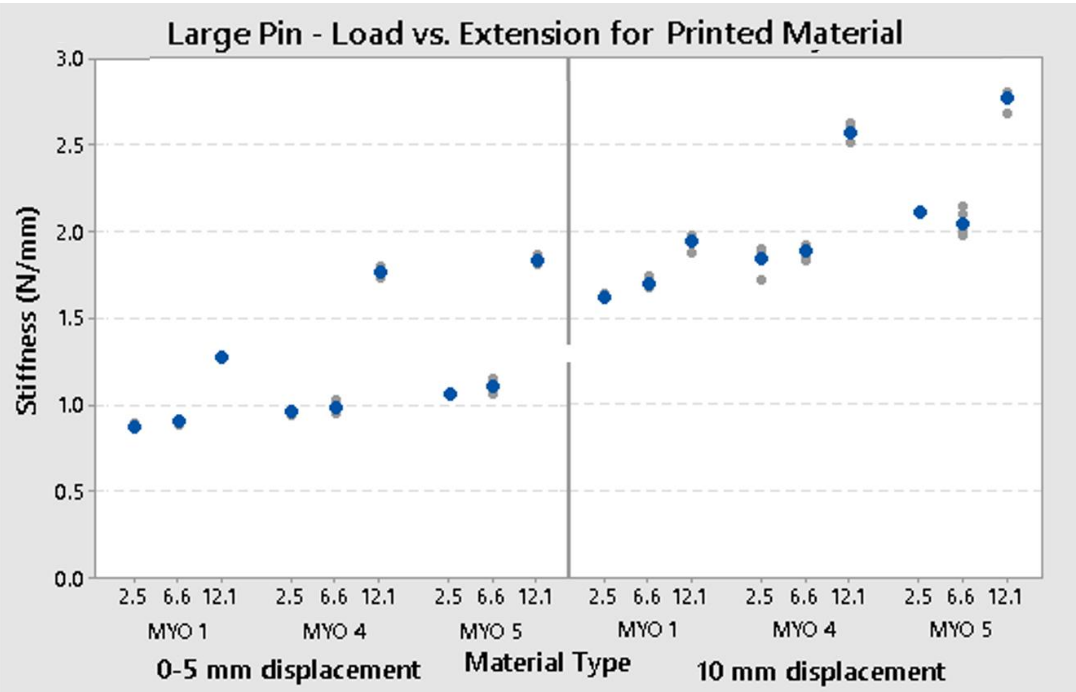

Figure 3 - Digital Anatomy printed materials showed very little variability.

Elasticity

Elasticity was measured for each of the printed samples to determine each material's flexural and tensile behavior. The moduli of the printed materials ranged from 0.262 to 0.536 MPa with Agilus being the least flexible, compared with the digital myocardial material blends. Furthermore, the standard deviation for each material type tested was small, providing a high degree of confidence the printed samples would behave in the same way every time (Table 2).

Table 2 - Analogue of Young's Modulus Values for Printed Materials

Material	Modulus (N/m2)
Agilus	0.536 ± 0.009
Myocardium A	0.262 ± 0.004
Myocardium 1	0.294 ± 0.003
Myocardium 2	0.310 ± 0.003
Myocardium 3	0.327 ± 0.005
Myocardium 4	0.342 ± 0.007
Myocardium B	0.334 ± 0.010

Puncture Testing

Both Digital Anatomy and porcine myocardium had similar failure mechanisms. Both saw an initial peak force as the first tough layer was punctured; endocardium for the tissue and the first Agilus layer for the Digital Anatomy samples.

Suture Testing

The sutures cut through the printed material more easily than porcine tissue. However, this is also given the specific suture setup used to prevent preliminary tearing of printed samples. If standard suture techniques were used it would've resulted in the printed material failing prior to testing. Regardless, the tissue and printed myocardium both showed delamination prior to failure.

Conclusion

Digital Anatomy 3D printed materials have great potential in fabricating patient-specific myocardium with accurate mechanical properties associated with gender, age, ethnicity, and other physiological and pathological characteristics. The results of this study suggest that the fabrication of patient-specific tissue-mimicking heart models with both geometrical and mechanical accuracy is possible with the Stratasys J750 Digital Anatomy printer, software and material. Specifically, the Digital Anatomy material shows promise in its ability to replicate porcine tissue compliance consistently with minimal variation. This is a major advantage given the wide variability of porcine compliance in samples tested from the same area of the heart.

When developing new devices and understanding their functionality, repeatability between samples and times of testing is very important to minimize confounding variables. The Digital Anatomy printed myocardium shows high repeatability in stiffness value within the same sample tested multiple times, as well as between samples. This presents a significant advantage to medical device manufacturers seeking bench testing models to produce reliable and consistent results with minimal variability. It therefore lends itself to applications in product development where repeatability and reliability are of paramount importance.

Table 3 - Summary of Printed Myocardium Comparison to Porcine Tissue

Biomechanical Testing Demonstrated Various Degrees of Success
Similar compliance to real tissue
Similar failure modes to real tissue
High repeatability of results
Ability to target stiffness values
Much closer to real tissue than other currently available 3D printing materials
Opportunities for Improvement
Increase toughness to accommodate realistic suturing
Reduce stickiness to facilitate accurate cutting and suturing

Future work will be directed at improving the suturing and cutting properties of the Digital Anatomy material blends to more closely match the compliance of native tissue. Stratasys will continue to collaborate with leading medical device companies, hospitals, and research institutions to compare the digital anatomy materials to native tissue and bone. The data received from these organizations will be used to perfect new anatomical applications that more closely match the biomechanical properties of human anatomy in healthy and diseased states. The goal is to ultimately eliminate or at least minimize the need for cadaver and animal models.

View the complete study findings at the following link: "PolyJet 3D printing of tissue-mimicking materials: how well can 3D printed synthetic myocardium replicate mechanical properties of organic myocardium?"

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