DESIGN AND MANUFACTURING OF BONE ANALOG MODELS FOR THE MECHANICAL EVALUATION OF CUSTOM MEDICAL IMPLANTS

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Abstract

The performance of orthopedic implants is often evaluated using cadaveric bone specimens. The high inter-specimen variability of cadaveric bone properties requires large sample sizes to obtain statistical significance. With recent focus on custom implants manufactured using direct metal freeform fabrication techniques, the need for a customized bone analog model is recognized. Data for bone geometry and internal structure were obtained from computed-tomography imaging. Traditional rapid prototyping techniques are then used to generate the rapid tooling from which composite bones that mimic the properties of the real bone can be duplicated. This work focused on the manufacturing process of bone analog models.

1.0 Introduction

Additive manufacturing techniques that facilitate the direct fabrication of metal components such as electron beam melting (EBM) or selective laser sintering (SLS), are poised to revolutionize orthopedic implant and medical device manufacturing. Three-dimensional geometry data obtained with medical imaging systems such as computed tomography (CT) or magnetic resonance imaging (MRI) facilitate the design of custom implants and constructs that conform to a given individual's anatomy[9]. These custom implants are directly fabricated using the EBM or SLS processes, and may incorporate features to optimize healing and long term success by precisely controlling mechanical properties, material properties, surface topography, and implant structure. Because custom implants can be made to conform to the individual patients anatomy, orthopedic procedures can be carried out with little or no modification to the underlying bone structure thereby optimizing the bone-implant interface[11]. The additive nature of EBM and SLS also facilitates the generation of engineered lattice structures which can be optimized both for bone fixation, and for the transfer of mechanical loads through the implant and into the healthy bone tissue, thus minimizing stress shielding and bone resorption[1,9].

Despite the clear advantages of utilizing custom implants fabricated using direct additive manufacturing techniques, there is still a great deal of difficulty associated with the mechanical testing and evaluation of such implants. Traditionally, the pre-clinical biomechanical testing of orthopedic implants is carried out *in vitro* using materials testing equipment. Testing is typically comparative in nature, and cadaveric bones are often used as a substrate because they are available as matched pairs[15]. Furthermore, the size, shape, and properties of cadaveric bones typically allow an acceptable approximation of *in vivo* situations.

However, the high cost and lack of availability of cadaveric bones coupled with biological degradation and the potential transmission of infectious diseases, complicates the use of cadaveric specimens for the mechanical evaluation of orthopedic implants [6,23]. Although there is a general symmetry between right and left pairs of bones from the same cadaveric specimen, the high interspecimen variability between cadaveric specimens necessitates the use of large sample sizes to detect small differences between different implants or surgical methods[21]. In one study, the interspecimen variability of the mechanical properties of cadaveric specimens reached 100% of the mean[2]. Further, paired comparisons using cadaveric specimens are limited to the evaluation of a single independent parameter between the two groups, therefore, the sample size problem is greatly exacerbated when it may be desirable to test the differences between more than two configurations of an implant.

To overcome these disadvantages, materials such as wood[18], plastic[8], and polyurethane foam[16] are sometimes used to model the mechanical properties of both cancellous and cortical bone. These models can reduce variability in testing (and therefore the required sample size) but lack realistic bone geometry. Bone models that replicate the shape of average human long bones are now commercially available, the latest iteration of which utilizes discontinuous short-fiber reinforced resin molded around a foam core[13]. Although data regarding the formulation of the fiber reinforced composites are lacking in the literature, these models have demonstrated some mechanical properties that model natural human bones and at the same time exhibit comparatively low interspecimen variability[2,13]. The geometry of these bones is derived directly from a cadaveric specimen representing the average size and weight of a human male[12].

While a standardized analog bone model has many advantages, particularly when comparing data across multiple studies, this approach neglects the patient-specific geometry of custom implants fabricated with additive manufacturing technologies, making the meaningful evaluation of such implants impossible. In order to evaluate the *in vitro* performance of custom implants, patient-specific bone analog models are required that are both geometrically and mechanically accurate. This paper addresses these issues and presents; (1) the development of materials that can model the intensive material properties of cortical and cancellous bone, (2) the development and manufacture of patient-specific bone analog models of a canine radius utilizing CT data, rapid prototyping, and a rapid tooling, and (3) an examination of the potential for the direct fabrication of custom bone analog models using rapid prototyping techniques.

2.0 Development of Bone Analog Materials

Bone provides basic structural support for the body. Its internal architecture is organized in hierarchical fashion from constituent molecules to distinctive tissue types. At the lowest level bone can be thought of as a composite material made up of three primary components; the fibrous protein type I collagen, which acts as an organic matrix; a mineral phase called carbonated hydroxyapatite, and water[24]. At the next level these components can be organized into groups of osteons that, combined, form the bulk of the dense outer shell of the bone called cortical bone, or into the less dense packets of lamellae that form cancellous bone[3]. The combination and organization of these components give rise to the unique material properties exhibited by bone.

On the highest, macroscopic level, the long bones of the appendicular skeleton consist of a long hollow central shaft called the diaphysis, with two wider portions on each end called the epiphyses. The illustration in Figure 1 shows a simplified schematic cross section of a canine radius. The primary component of the diaphyseal portion of the bone is cortical bone, while the epiphyses contain a higher portion of cancellous bone surrounded by a thin cortical shell. Bone is also graduated, with compositions and configurations that differ from one geometric region to another; in particular, the transition from the cortical outer shell to the spongy, inner, cancellous bone is of particular interest to this study[19].

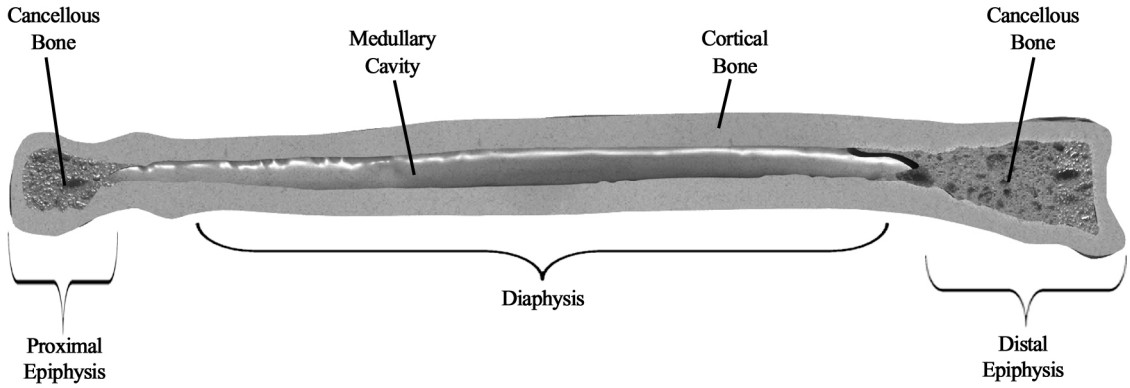

Figure 1: Schematic cross section illustrating some of the macroscopic components of a canine radius.

Although there is a large body of literature dedicated to the study of the mechanical properties of the low level constituents of bone, such as osteons or lamellae, most research on bone material properties has focused on cortical and cancellous bone[17]. Therefore in the development of analog materials to model bone, this study focuses on these two components.

2.1 Cortical Bone Analog Development

The reported values for the mechanical properties of cortical bone in the literature vary significantly; this is in part due to the natural variability of the material, as well as the variability testing methods from one study to another. In some studies whole bones were tested, typically in three or four point bending[19]. Other methods involve resting small sections of cortical bone were tested in tension, compression or indentation. In general the reported values for the modulus of elasticity of cortical bone for several mammalian species range from about 7 GPa to 34 GPa (1015 ksi to 4931 ksi)

During the selection of a material to model the cortical bone, similarity to real cortical bone, availability, ease of preparation, ease of manufacturing, and the ability to vary the properties to match patient-specific data were considered. The mechanical properties of a host bone have been successfully estimated from quantitative computed tomography scans[5,20]. Although it was not investigated in this study it may also be useful to match the properties of unhealthy or osteoporotic bone. For these reasons a fiberglass reinforced thermosetting epoxy resin was chosen for this study.

This material is easily mixed and injection molded, and the properties can be varied by adjusting the fiber content, matrix material, fiber material, fiber length, etc. In addition, epoxy-fiberglass mixtures have been used to replicate human cortical bone in several studies[12,13,23]. No data are present in the literature regarding the formulation of these materials. A mathematical model was used to determine the possible range of mechanical properties attainable through this method (given the constraints on processing and manufacturing), as well as to predict the modulus of elasticity of the cortical bone analog material.

Several mathematical models have been developed for the estimation of the tensile modulus of elasticity for discontinuous fiber composites, but the Cox model is widely used and regarded to be the simplest[26]. This model averages the elastic constants of the material over all possible fiber orientations[4]. This is represented in Equation 1 as a modified version of the rule of mixtures.

Equation 1:

$$E_c = \chi_1 \chi_2 \phi_f E_f + \phi_m E_m$$

Where, E_c, E_f, and E_m are the tensile elastic moduli of the composite, the fiber and the matrix respectively. ϕ_f and ϕ_m are the fiber volume fraction and the matrix volume fraction. The variable χ_1 represents the fiber orientation efficiency factor which is equal to 1 for axially aligned discontinuous fibers and 1/5 for randomly oriented fibers[12]. Details for the determination of the fiber orientation efficiency factor are discussed in several sources[4,7]. The variable χ_2 represents the fiber length correction factor as is given by Equation 2 – 4 below; as the fibers become longer this value approaches 1.

Equation 2:

$$\chi_2 = 1 - \frac{\tanh(na)}{na}$$

Equation 3:

$$n = \sqrt{1 - \frac{2G_m}{E_f \ln(\sqrt{\frac{\pi}{4\phi_f}})}}; G_m = \frac{E_m}{2(1+\nu_m)}$$

Where: G_m is the shear modulus of the matrix, and ν_m is the Poisson ratio of the matrix.

Equation 4:

$$a = L / d$$

Where a is the aspect ration of the fiber, L is the length of the fiber and d is the diameter of the fiber. As demonstrated by Gibson[7], the fiber orientation factor has a much greater impact on the mechanical properties of the composite than does the fiber length. Therefore the case of axially aligned discontinuous fibers provides a reasonable upper bound for the modulus of the composite.

The rule mixtures can also be applied to determine a reasonable lower bound for the composite modulus by considering the case of transversely aligned fibers (in which both the fiber and the matrix are under the same isostress condition) as given in Equation 5.

Equation 5:

$$E_{ct} = \frac{E_m E_f}{E_f \phi_m + E_m \phi_f}$$

This set of equations provides an upper and lower bound on the tensile modulus of a discontinuous fiber composite. For the cortical bone analog, epoxy resin and hardener (Fiberglast Corporation, Series 2000 and 2060 respectively) mixed in a 100:23 ratio (by weight) was used as the matrix material. The average modulus of elasticity of the cured resin was 3.091 GPa (448.3 ksi). The fibers used were 793µm (0.0313 inch) in length S-glass fibers with a diameter of 20µm (0.007 inch). The average modulus of elasticity of the glass fibers was 89 GPa (12908 ksi). Inserting these values into the mathematical models, Figure 2 shows a plot of the predicted tensile modulus of the cortical bone analog versus fiber volume fraction for various conditions of fiber alignment.

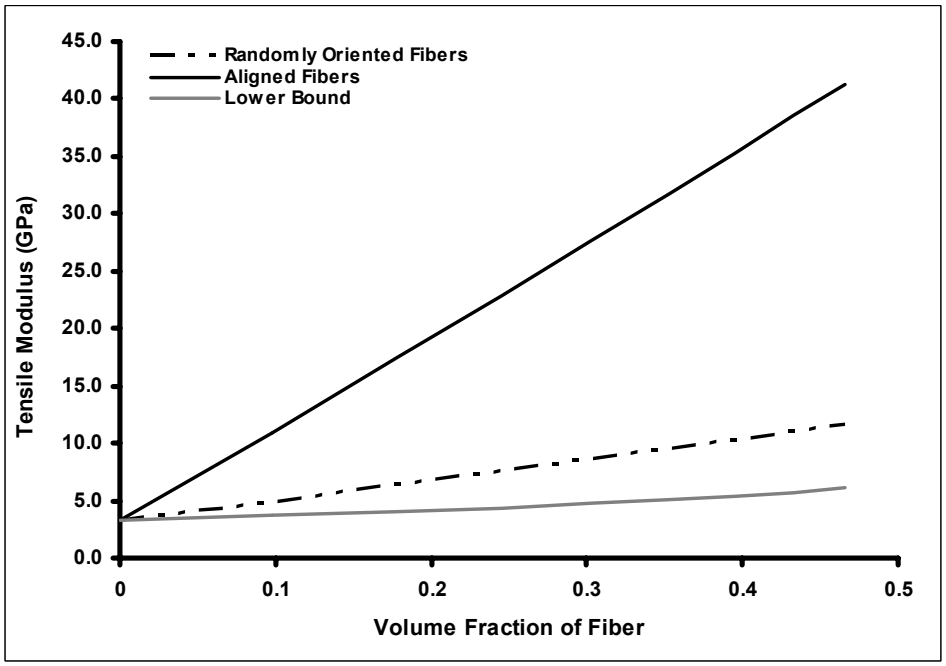

Figure 2: Plot illustrating the relationship between the volume fraction of fiber and the predicted tensile modulus for various conditions of fiber alignment (using 20µm diameter, 793µm long fibers).

In order to test the properties of the cortical bone analog material, tensile specimens were prepared in accordance with ASTM standard D638-08. A silicone rubber mold (Smooth-on Moldmax 30^{TM}) was used to fabricate the samples to the required dimensions. The epoxy resin and hardener were mixed with the glass fibers under vacuum for 10 minutes and then injected into the silicone rubber mold. After injection, the mold was placed in a pressure chamber at 482.6 kPa (70 psi) for a period of one hour, until the epoxy cured. The samples were then post cured in a convection oven at 75°C (167°F).

Twenty-eight tensile specimens were prepared with four different fiber loading conditions; 0%, 33% , 50% , and 60% fraction by weight (0%, 18%, 30%, and 39% by volume). Tensile testing was carried out on each of the formulations using an ATS 1620C testing machine with square, serrated grips, (Applied Test Systems, Butler, Pa.). An extensometer with a gauge length of 50.8 mm (2.0 inches) (Epsilon Technologies Corp, Jackson, WY) was affixed to the narrow section of the samples, and testing was carried out at a loading rate of 1.27 mm/min (0.05 in/min). The modulus of elasticity of each sample was calculated from the linear portion of the stress-strain plot.

The results were compared within groups for all loading regimens using paired t-tests after confirmation of normal distribution using the Shapiro-Wilk test for normality. The mean and standard deviation were calculated. Means were compared between groups using 2-tailed Student's t-tests (α=0.05). The results are shown in Table 1.

Table 1: Results of the tensile testing of the cortical bone analog material.

	Modulus of Elasticity (GPa)		
Fiber Volume Fraction	Average	Standard Deviation	95% Confidence Interval
0.0	3.091	0.271	2.839 - 3.342
0.18	5.954	0.410	5.574 - 6.333
0.30	7.890	0.854	7.100 – 8.681
0.39	10.607	1.331	9.377 – 11.83

All of the samples with glass fiber had a significantly higher modulus of elasticity compared to the samples made without any fiber ($p<0.001$). The samples with a fiber volume fraction of 0.30 had a modulus of elasticity that was significantly higher than the samples with a fiber volume fraction of 0.18 ($p<0.001$). The samples with a fiber volume fraction of 0.39 differed statistically from the samples with a fiber volume fraction of 0.30 ($p<0.001$). The high viscosity in the samples with 0.39 fiber volume caused some difficulty when mixing, degassing and filling the mold which may have led to some the higher standard deviation. In general, the measured tensile moduli fell within the expected range of cadaveric properties.

2.2 Cancellous Bone Analog Development

Cancellous bone is commonly found in the epiphysis of long bones. The structure of cancellous bone is very similar to that of open celled foam, and unlike the cortical bone analog, there is widespread documentation in the literature regarding material formulations for cancellous bone analog materials. Typically, rigid polyurethane foam materials are used as a model for cancellous bone. ASTM F1839 provides the specifications for preparing polyurethane samples for use in testing orthopedic devices. This material is easily mixed and poured/injected into molds, cures quickly, and exhibits material properties with much less variability compared to cancellous bone specimens obtained from cadavers[22]. By varying the ratio of isocyanate to resin in the mixture, Szivek showed that the mechanical properties of polyurethane foams could be adjusted to match the mechanical properties of a wide range of cancellous bone materials.

The tensile elastic modulus of cancellous bone varies depending upon the location in the body, the presence of disease, age, etc. In a book reviewing of multiple studies on the mechanical properties of bone, Yuehuei and Draughn found that the tensile modulus of elasticity of cancellous bone ranged from 69 MPa to 349 MPa (10 ksi to 50.6 ksi). Tensile testing on a polyurethane cancellous bone analog material was carried out in accordance with ASTM D638-08. Polyurethane foam (16lb/ft^3, U.S. Composites, West Palm Beach, FL) was used to prepare the cancellous tensile specimens, it was mixed in a ratio of 1:1 (by volume) and poured into the same silicone rubber mold that was used to fabricate the cortical bone tensile specimens The polyurethane cured for 1 hour at 21°C (70°F). Moisture in the air may affect the properties of the foam during curing, therefore the relative humidity was recorded at 42%. Tensile testing was carried out at a loading rate of 1.27 mm/min (0.05 in/min). The average tensile modulus of elasticity was 305MPa (44.3 ksi) with standard deviation of 30.06 Mpa (4.36 ksi).

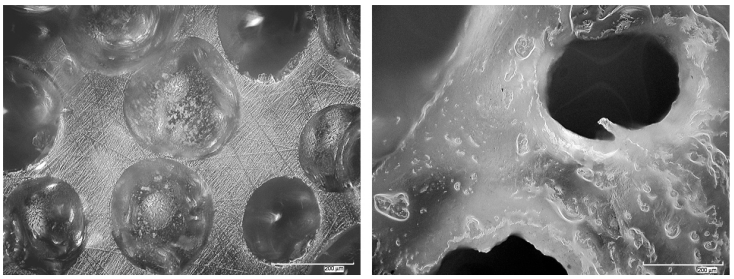

Figure 3: Images showing the microstructure of the polyurethane cancellous bone analog (left) and cancellous bone sectioned from the distal epiphysis of a canine radius (right). Scale bar indicates 200µm.

3.0 Design and Manufacture of a Patient-Specific Bone Analog Model

In the previous sections the materials have been developed that mimic some of the intensive mechanical properties of cortical and cancellous bone. This section describes rapid prototyping, and rapid tooling methods used to combine these materials into a patient specific geometry that also mimics the extensive mechanical properties of the whole bone of a given patient. The mechanical properties of the whole analog models of canine radii were compared to a group of cadaver bone in a separate experiment[14].

3.1 Design and Fabrication of Rapid Tooling for Bone Analog Models

Nine adult dogs weighing more than 30 kg (66.14 lbs) were collected after euthanasia. The dogs were euthanatized at a local animal shelter for reasons unrelated to this study. Age, breed, gender, and method of euthanasia were recorded. The thoracic limbs were disarticulated at the glenohumeral joint, wrapped in saline solution (0.9% NaCl) moistened gauze, sealed in a plastic bag, and frozen at -20°C (-4°F). The limbs were later thawed at room temperature and computed tomography imaging was performed using a helical CT (Siemens SOMATOM Sensation 16-slice configuration, Siemens Medical Solutions, Malvern, Penn) with 512 x 512 resolution and 0° gantry tilt. The CT images were retro-reconstructed into 1 mm (.039 inch) slices with a pixel size of 0.727 mm (0.029 inch). Materialise Mimics software (Mimics version 12.1, Materialise, Belgium) was used to isolate and reconstruct the three-dimensional geometry each specimen. Built in NURBS algorithms were used to generate a closed surface model for the cancellous and cortical regions of the bone (the cancellous portion has been extended to include the medullary canal for ease of manufacture).

These models were then imported into Solidworks 2009 3-D CAD modeling software in order to design the mold and mold parting lines, add geometric features for mold filling, venting, as well as features that facilitate the three dimensional alignment of the cancellous bone analog insert within the cortical bone mold. The models were then converted into stereolithography (.stl) format and fabricated in plastic using rapid prototyping technology (Objet Alaris 30). From the physical models, polyurethane rubber molds were fabricated. For each mold, the plastic model was placed into an adjustable acrylic plastic mold box, the parting line was marked on the models. The models were then coated with mold release agent (Ease-release 200, Smooth-on Inc.). Room temperature vulcanizing rubber (Reoflex 60, Smooth-on Inc.) was mixed in a 1:1 ratio (by weight) and degassed in a vacuum chamber, and then poured into each half of the mold and allowed to cure overnight. Figure 4 shows several images from the process. The rubber used for the molds was a relatively high durometer (60 Shore A) in order to minimize mold deformation during injection molding, yet still provide some flexibility to facilitate the demolding of parts with slight undercuts. Molds were post cured for 4 hours at 75ºC (167ºF). A clamp was fabricated using stainless steel strapping in order to hold the molds halves closed during injection/filling.

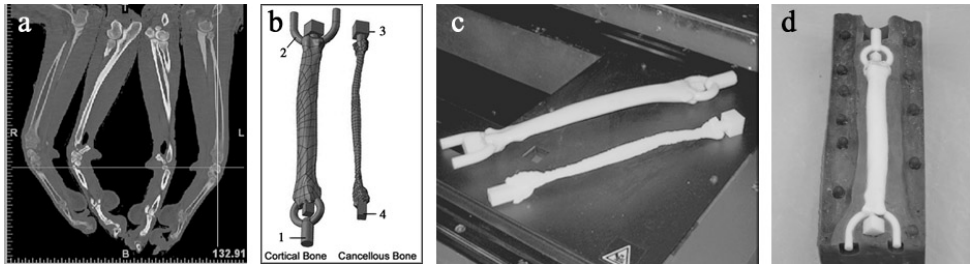

Figure 4: Images showing: a screenshot of CT data (a); images of the cortical and cancellous bone 3-D models with the filling sprue (1), air vents (2) and 3-D geometric locating features (3,4) (b); finished plastic models of the cortical and cancellous models (c); and polyurethane rubber mold (d).

3.2 Fabrication of Bone Analog Models

To fabricate the cancellous bone inserts, the mold halves were coated with mold release agent and then closed together using the custom clamps. Ten milliliters (0.610 in^3) of the 16 lb/in^3 density polyurethane were combined and mixed for 30 seconds, and then poured into the cancellous insert mold. Initial testing indicated that the polyurethane material would deform and break when subjected to the forces from injection molding the fiberglass cortical bone analog. For this reason, a 3.175 mm (0.125 inch) brass rod was placed in the cancellous bone mold, oriented axially. This rod was easily removed from the final bone analog, and leaving the medullary canal hollow. The mold was capped, and the polyurethane mixture was allowed to cure for 25 minutes at 21ºC (70ºF) and 42% relative humidity. After curing, the models were removed from the mold and rinsed with acetone solution to remove the mold release agent. To prevent the open pockets on the surface of the foam models from creating bubbles in the final product, the surface was coated with a thin layer of epoxy resin (Loctite 5 min epoxy, Henkel, Düsseldorf, Germany). In preliminary tests it was noted that the exothermic curing process of the epoxy/fiberglass generated enough heat to break down the polyurethane material, creating large bubbles. Therefore, the surface of the cancellous bone insert was coated with a layer of high temperature ceramic coating (VHT Ceramic Coating, Sherwin-Williams) that eliminated the formation of bubbles. The coating was allowed to dry for one hour.

Mold release agent was then used to coat the surfaces of the cortical bone mold. Using the built-in geometric locating features, the cancellous insert was precisely located within the cortical bone mold, the mold was closed using the aforementioned clamps. 200 g (0.441 lbs) of epoxy resin and short fiber glass in the ratios described in section 2 were mixed under vacuum using a custom-built mixer within a vacuum chamber for 10 minutes. While still under vacuum, the epoxy-fiberglass mixture was drawn into a 60 cc (3.66 in^3) syringe. The mold and syringe were then loaded into a custom-built injection molding machine that introduced the resin into the mold with a pressure of 68.94 kPa (10 psi). Figure 5 illustrates this process.

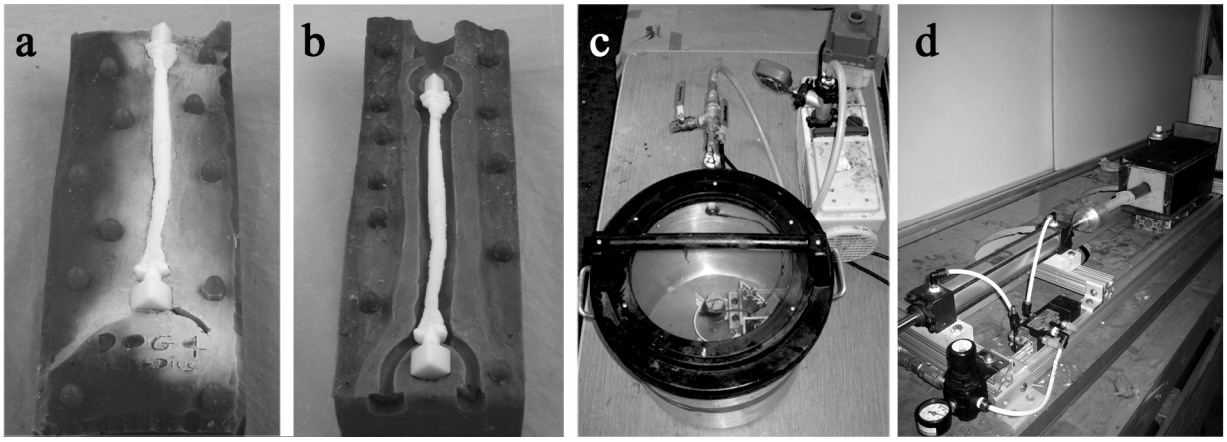

Figure 5: Photographs showing several steps of analog bone fabrication process; molding of the polyurethane cancellous bone analog insert (a), placement of the ceramic coated cancellous bone analog insert within the cortical bone analog mold (b) mixing of the epoxy-fiberglass mixture under vacuum(c), and injection of epoxy-fiberglass mixture into the cortical bone analog mold (d).

Immediately after mold filling had occurred (verified visually by the presence of the epoxy-fiberglass mixture in the mold air vents), the mold was placed inside of a custom-built pressure vessel at 482.6 kPa (70 psi) for one hour until the epoxy cured. This reduced the volume of any bubbles that formed either as a result of the epoxy curing process, or from the interaction between the epoxy and the polyurethane cancellous bone analog insert. The samples were then post cured in a convection oven at 75ºC (167ºF) for one hour before being removed from the mold.

One of the key parameters for the prediction of the modulus of elasticity of the short fiber composite bone analog is the orientation of the fibers within the composite. To evaluate the fiber orientation within the composite bone analogs, special bone samples were fabricated in which the epoxy matrix was dyed dark blue (Smooth-on Inc.). Cross sections were cut from the bone analog models which were progressively ground and then polished (120-2000 grit paper) using standard methods (ASTM E2015-04). The microstructure of the composite was then digitally photographed at a 350x magnification. Labview^{TM} software was used to threshold and filter noisy data points. Labview's built-in ellipse fitting algorithm was used to maculate the orientation, the center, the major axis (a) and the minor axis (b) for each fiber cross-section. From this a two-parameter fiber orientation distribution $\psi = [\Phi, \theta]$ was measured; where θ is the in-plane fiber orientation and, Φ is the out-of-plane fiber orientation ($\cos^{-1}$ b/a).

Despite the ambiguity of the in-plane orientation (i.e θ or θ+π) a close estimate of fiber orientation can be obtained[26]. The analysis indicates that the fibers are randomly oriented in plane, but are relatively aligned with the longitudinal axis of the bone (out-of-plane). This is a relatively common effect seen in short-fiber reinforced injection moldings. Figure 6 shows a photograph of several completed bone analog models, the microstructure of the cortical bone analog, and histograms showing the in-plane and out-of-plane fiber orientations.

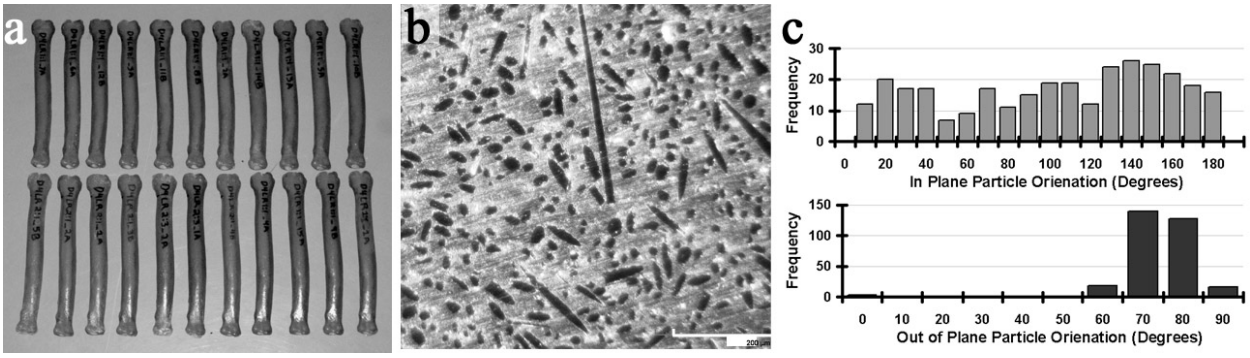

Figure 6: Photograph of several custom analog radii prepared for mechanical testing (a), the microstructure of the analog bone model (b) and histograms showing the in-plane and out-of-plane fiber orientations (c).

4.0 Preliminary Evaluation of the Potential for Direct Fabrication of Patient-Specific Analog Bone Models Using Additive Manufacturing Methods

In the previous sections, computed tomography, 3-D modeling, additive manufacturing and rapid tooling were utilized to quickly manufacture replicas of a patient-specific bone analog model with intensive mechanical properties similar to that of the original bone. The mechanical properties of these models have less variability than cadaveric specimens. However, the process requires a significant investment in time and effort (which translates into cost). This includes the scanning of the patient, design of the mold in a CAD system, fabrication of the cortical and cancellous mold plugs, fabrication of the mold, and then finally the fabrication of the analog bone models. One potential solution would be to fabricate the analog bone models directly from CT data using a new form of additive manufacturing that incorporates a fiber reinforced material similar to the epoxy resin used in this study. Several studies have examined the addition of fiber reinforcements to traditional additive manufacturing materials to improve the mechanical properties[26]. As an initial examination of this possibility, seven tensile specimens of each fiber fraction used in section 2 of this study; 0%, 33% , 50% , and 60% fraction by weight (0%, 18%, 30%, and 39% by volume) were prepared. The matrix material used was DSM Somos Watershed 11120 ultraviolet curing resin (DSM Somos Elgin, Il). This material has a tensile modulus of elasticity 2.59 Gpa (376.2 ksi). The resin and fiber were mixed under vacuum for 10 minutes and then poured into an open silicone rubber mold with the same geometry as the tensile specimens in section 2 (conforming to ASTM D638-08). The mold was placed into an ultraviolet chamber (PCA250 3D Systems) and cured for 12 hours, after which the samples were flipped and then cured for another 12 hours. In addition samples of the same geometry were fabricated with the same resin (0% fiber) but using the stereolithography process (SLA 250, 3D Systems Rock Hill, SC). The samples with 39% fiber volume fraction did not cure properly, and were therefore excluded from the test.

Tensile testing was carried out with the same methodology and equipment as previously described. The loading rate was 1.27 mm/min (0.05 in/min). The modulus of elasticity of each sample was calculated from the linear portion of the stress-strain plot. After confirmation of normal distribution using the Shapiro-Wilk test for normality, the mean and standard deviation were calculated for each test and reported. Means were then compared between groups using 2-tailed Student's t-tests. The results are shown in Table 2.

Table 2: Results of the tensile testing of the cortical bone analog material.

	Modulus of Elasticity (GPa)		
Fiber Volume Fraction	**Average**	**Standard Deviation**	**95% Confidence Interval**
0.0	2.594	0.089	2.372 – 2.816
0.0 (SLA fabricated)	2.752	0.054	2.617 – 2.886
0.18	3.845	0.270	3.174 – 4.516
0.30	6.116	0.128	5.797 – 6.435
0.39	NA	NA	NA

There was no significant difference between the 0% fiber tensile specimens made using the SLA additive manufacturing process and the 0% fiber tensile samples cured in the mold ($p=0.059$). The samples with 30% fiber (by volume) had a higher modulus than any of the other groups ($p<0.001$), the 18% fiber samples (by volume) had a modulus of elasticity that was greater than the 0% fiber samples ($p<0.001$) and less than the 30% fiber samples ($p<0.001$). The modulus of elasticity of the cortical bone analog samples made with UV curing resin and fiberglass were compared to that of the cortical bone analog made from epoxy resin and fiberglass. With the exception of the 39% (by weight) fiber, which was excluded from testing, the samples made with the epoxy and fiberglass had a higher modulus of elasticity compared to the samples made using UV resin and fiberglass ($p<0.001$).

5.0 Discussion and Conclusions

This paper has described a new platform upon which the mechanical properties of custom biomedical implants can be evaluated. The cortical bone and cancellous bone analog materials described herein have been shown to exhibit a tensile modulus of elasticity, a key intensive material property, within the expected range of cadaveric specimens and with a significant reduction in variability. This is advantageous on several levels, particularly because it allows the reduction in the required sample size while also providing the ability to evaluate multiple implant parameters simultaneously. Computed tomography combined with traditional, plastic-based, additive manufacturing facilitates the fabrication of rapid tooling for patient-specific bone geometries which will support the mechanical testing and evaluation of custom implants and devices.

The development of a short-fiber reinforced composite cortical bone analog material has also been translated to matrix materials typically used in rapid prototyping processes with promising results. This indicated that with the appropriate equipment modifications, the direct fabrication of custom, patient-specific bone analog models is possible.

6.0 References

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