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Compressive Properties of a Synthetic Bone Substitute for Vertebral Cancellous Bone

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Abstract**—**Transpedicular screw fixation in spinal fractures, degenerative changes, or deformities is a well-established procedure. However, important rate of fixation failure due to screw bending, loosening, or pullout are still reported particularly in weak bone stock in osteoporosis. To overcome the problem, mechanism of failure has to be fully investigated in vitro. Post-mortem human subjects are less accessible and animal cadavers comprise limitations due to different geometry and mechanical properties. Therefore, the development of a synthetic model mimicking the realistic human vertebra is highly demanded. A bone surrogate, composed of Polyurethane (PU) foam analogous to cancellous bone porous structure, was tested for 3 different densities in this study. The mechanical properties were investigated under uniaxial compression test by minimizing the end artifacts on specimens. The results indicated that PU foam of 0.32 g.cm^{-3} density has comparable mechanical properties to human cancellous bone in terms of young's modulus and yield strength. Therefore, the obtained information can be considered as primary step for developing a realistic cancellous bone of human vertebral body. Further evaluations are also recommended for other density groups.

Keywords**—**Cancellous bone, Pedicle screw, Polyurethane foam, Synthetic bone

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I. INTRODUCTION

TRANSPEDICULAR fixation in spine surgery is advantageous owing to three column fixation [1]. However, screw failure is still a concern arising from bending or breakage, loosening, pullout or migration at insufficient strenght screw-bone interface [2]-[4].As an example, rates of failure due to loosening or decreased fixation strength at screw-bone interface are reported to be 0.8% to 17% [5]-[7]. Therefore, a large number of studies paid a special attention to the biomechanics of pedicle screw, insertion techniques, pedicle morphometry, and bone quality [3],[7]-[9]. Human cadaveric vertebral models capture the morphology and heterogeneous mechanical bone properties but are difficult to obtain and are generally limited to elderly bone. Animal models are readily available and have less variability compared to human vertebrae. However, the results may be different than human models [10]. Aerssens*et al.*[11]have compared bone density, composition and mechanical properties between the human vertebral bone and different animal species. They suggest that human vertebral density and ultimate stress are lower than those for animal species while the relationship between maximum stress and density of each animal are different from the other species. The discrepancy of results in animals due to lack of morphological and geometrical information and restrictions to access to human cadavers reveals the necessity of having a synthetic bone model akin to the realistic one for in vitro applications. The consistency of bone surrogates can reduce variance and eliminate some of the confounding variables to better isolate the important parameters affecting biomechanical properties of the bone.Current American Society for Testing and Materials (ASTM) standards recommend the use of polyurethane (PU) foam blocks as bone surrogates for testing orthopedic devices and instruments [12]. There are number of studies that introduce synthetic vertebral models for various biomechanical analyses. The model used by Au *et al*. [13] mimics geometrical properties of human lumbar vertebra for testing interbody device subsidence. This model consists of cortices, endplates, and polyurethane foam as the cancellous bone. Another model was applied by McLain *et al*.[14]for assessing the effect of vertebral bone quality on pedicle screw bending moment. Several studies [15]-[17] have examined application of PU foams for cancellous bone substitute material under compression and shear. However, none of these studies have fully reported fracture characteristics of PU foamsin comparison to human vertebral cancellous bone in terms of foam's stiffness, young's modulus, yield stress and strain, energy to yield (elastic toughness) and ultimate strength and strain. Moreover, since there are several commercially available PU foams, it is not always practical to formulate particular compositions of PU foam. The vertebral cancellous tissue is found inside thin cortical shell and consists of a network of interconnecting trabeculae of minerals with perforations through which blood vessels pass. This lattice-like tissue provides support and strength to the bone, whilst being light weight and absorbs energy during compressive loading. Bone quality is dependent upon structural (micro-architecture), material (mineralization) and mechanical properties of the bone that contribute to fracture risk [18], [19]. Determination of compressive properties of the human vertebrae has been the subject of biomechanical research from early days. There is a definite relationship between the strength and relative osseous tissue of vertebra such that a small loss of osseous tissue causes considerable loss in the vertebral bone strength [20]. This is due to honeycomb arrangement and load carrying capacity of vertical and horizontal trabeculae that form the central part of vertebra. The main objective of this study is to characterize the mechanical behavior of PU foams of various densities as cancellous bone surrogate. Therefore, specimens of PU foams are preparedand their efficiency are mechanically tested using the same method applied for human cadaveric vertebra by Morgan*et al.*[21]. The resultsare then compared to those reported for humancadaveric vertebrae.

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II. METHOD

A. PU specimen preparation

Nine specimens were prepared from cellular rigid Polyurethane Foam Blocks of different densities with dimensions 4×6.5×4cm^3 (Sawbones® Vashon Island, WA). The range of densities was chosen from 0.16 g.cm^{-3}, 0.20 g.cm^{-3}, and 0.32 g.cm^{-3} to model cancellous bone of low, medium and normal densities. Cylindrical specimens with average diameter of 6 ± 0.15mm were extracted to be parallel to the foam rise direction using diamond coring drill from each block of various PU densities. The average specimens' length of 22 ± 1.90 mm was measured by a digital caliper. This specimen size was chosen to be consistent with porcine cadaveric samples tested previously [22].

B. Testing procedure

The compressive properties were evaluated according to gold standard (ASTM D1621-00) in compression loading until failure. A mechanical test machine (Mini-Bionix 859, MTS Corp., Eden Prairie, MN) with a load cell of maximum capacity of 2500N was used to perform these tests. The samples were embedded in aluminum endcaps of 5mm depth by cyanoacrylate glue (Prism 401, Loctite, Newington, CT, USA) and gripped in the load frame in order to minimize the end artifacts according to Keaveny*et al.* [23]. The length of specimen between the endcaps was measured by digital caliper. Therefore, the effective gauge length is an average of the specimen's initial length and the one measured between the endcaps [24].

An axial compressive load was applied in quasi-static load condition at room temperature through an unconstrained testing procedure. This test was done without preload or preconditioning to the specimens. The compressive load was applied at strain rate of 0.5% for specimen's effective gauge length until 13% displacement was obtained according to ASTM standards [21], [25].

The stiffness was calculated as the slope of the initial linear portionof the force-displacement curve. The yield strength was calculated by dividing the load (at yield) by the cross sectional area of cylindrical PU foam specimen at 0.2% offset criterion. The elastic modulus was calculated for 0 to 0.2% strains in elastic region of stress-strain curve [21]. The ultimate strength and corresponded ultimate strain were obtained from the maximum point on stress-strain curve. The elastic toughness (energy absorbed to yield) was calculated by integrating the polynomial equation of the engineering stress-strain curve between the limits of zero and the strain point at which the yield strength is determined [26].

III. RESULTS

Fig. 1 demonstrates a typical stress-strain curve for High density PU foam which was destructively tested. The young's modulus is therefore determined by the slope of the curve. Similar curves were obtained for the two other PU foam densities.

A summary of average values obtained in this study for stiffness, young's modulus, yield strength, yield strain, ultimate strength, ultimate strain and elastic toughness are given in Table I. All values were acquired for cylindrical specimens.

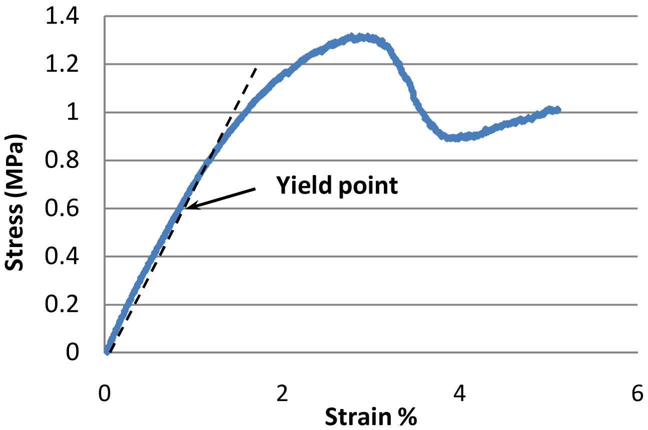

Fig. 1 Stress-strain curve for cellular rigid PU foam specimen of 0.32g.cm^{-3} density that was applied to model normal human cancellous bone.The yield point is obtained by drawing a line parallel to slope of elastic part of the curve at 0.2%strain

TABLE I
COMPRESSIVE MATERIAL PROPERTIES OF PU FOAM SPECIMENS OF VARIOUS DENSITIES

Material property	ρ= 0.32 g.cm^{-3}	ρ= 0.20 g.cm^{-3}	ρ= 0.16 g.cm^{-3}
Stiffness (N/mm)	527 (515-540)	132 (116-150)	29.5 (27-31.5)
E (MPa)	80 (70-95)	18 (16-21)	4(3.8-4.3)
σ_y(MPa)	0.8 (0.7-0.95)	0.44(0.4-0.5)	0.13 (0.12-0.14)
σ_{ult} (MPa)	1.32 (1.2-1.460	0.61(0.55-0.68)	0.37 (0.31-0.41)
ε_y(%)	1.02(0.85-1.26)	2.78(2.33-3.51)	3.31 (3.02-3.68)
ε_{ult} (%)	2.8 (2.5-3)	16.4 (15-17.2)	12.4 (10-15.2)
ElasticToughness (kJ.m^{-3})	2.4×10^{-3} (2-2.27×10^{-3})	1.1×10^{-3} (1.0-1.15 ×10^{-3})	2.3×10^{-3} (2-2.5 ×10^{-3})

TABLE II
MECHANICAL PROPERTIES HUMAN VERTEBRAL BONE ACHIEVED BY SEVERAL AUTHORS

Mechanicalproperty	Kopperdahl et al. [27]		Keaveny et al. [23]	Morgan et al. [21]
ρ (g.cm^{-3})	0.17 ± 0.04		0.14 ± 0.06	0.18 ± 0.05
E (MPa)	291±113[a]	90-536[b]	165±110	344 ±148
σ_y(MPa)	1.92±0.84	0.56-3.71	-	2.02±0.92
σ_{ult} (MPa)	2.23±0.95	0.70-4.33	-	-
ε_y(%)	0.81±0.06	0.75-0.95	-	0.77±0.06
ε_{ult} (%)	1.45±0.3	0.96-2.30	-	-

[a] Mean values (± S.D.)
[b] Range of values obtained

Table II, presents the mechanical properties measured for human vertebral bone by various authors. Thereby, the values given in Table II can be compared directly to those achieved in this study for PU foams of different densities in Table I.

IV. DISCUSSION

Evaluation of bone's mechanical behavior leads to several advantages including comprehension of interaction between bony tissue and the orthopedic implants and also the fracture risk. Cellular rigid PU foam specimens of three different density group in this study were chosen to be in consistent with ASTM standard [12] and their compressive properties were compared to human vertebral cancellous bone [21], [23],[27] using the same methods.

According to Table II, the range of values for yield strength reported from Kopperdahl*et al.* is between 0.56 to 3.71 MPa [27].The density reported by [27] is assigned into a range of 0.17± 0.04 g.cm^{-3}forboth male and female human lumbar spine between ages of 32 to 65 yearswhich is correlated tothe lowest and mid-level densities applied in this study (see Table I). Yield strength results for 0.16 g.cm^{-3} and 0.20 g.cm^{-3} densities are lower than the range reported for human by Kopperdahl*et al.* (see Table II), respectively.

It is observed from Table I that the yield strains for 0.20 g.cm^{-3} and 0.16 g.cm^{-3} densities are greater than reported rangefor human vertebral bone (0.75-0.95%).The minimum and maximum values measured for the young's modulus in compression for humans are 90 and 536 MPa[27]. Some authors also evaluated the modulus of elasticity of the porcine vertebral bone model. For instance, Lin *et al.*[28]reported a mean modulus of elasticity of 520.6 ± 144.75 MPa while Teo*et al.*[29] and the study by [22] obtained an average of 229 ± 138 MPa and 883±332 MPa respectively.

On the other hand, it is evident that Young's modulus is a function of yield stress and yield strain. The young's moduli obtained in this study for PU samples of 0.20 g.cm^{-3} and 0.16 g.cm^{-3} densities aresignificantly lower than human vertebral bone's modulus range. This is resulted from the lower yield stress and higher yield strain measured for PU foams. This is justified by the lower strength value need for PU foam to yield while showing a large strain.

A study by Li and Aspden [30] reports the young's modulus and yield strength values for normal human cancellous bone of 40-460 MPa and 0.4-9.0 MPa respectively. Considering the highest density group examined in this study, the values for yield stress and young's modulus (see Table I) are within the range reported by Li and Aspden [30] for femoralcancellous bone. This proves the efficiency of 0.32 g.cm-3 density asa bone surrogate but dependent to anatomical site for biomechanical studies.

The interpretation of results demonstrated in Table II for energy absorbed to yield or elastic toughness indicates that that they fall into the range of 0.21-1.76 kJ.m^3. This indicates that the values measured for all PU foams of various density groups are significantly lower than expected range of elastic toughness for human bone. This behavior of PU foam specimens are justified as the brittleness of uniform PU foam comparing to human bone as an inhomogeneous natural composite material.

Human cancellous bone properties reported by Kopperdahl*et al.*[27] represent an ultimate stress to be in range of 0.7 to 4.33 MPa while for the 0.32 g.cm^{-3} and 0.20 g.cm^{-3} PU foam specimens ultimate strength is 1.32MPa and 0.61 MPa respectively. This reveals that for higher density specimens the ultimate strength of the material is within expected range for human vertebral bone.Dissimilarity in properties of cellular rigid PU foams and the realistic heterogeneous bone model may need extra effort for material reconsideration. Use of additives and/or reinforcement can be considered to enhance the performance of whole surrogate.

Moreover, discrepancy of experimental results to those in literature may result from uncertainties in measuring the specimens' dimensions by a digital caliper with absolute uncertainty of ± 0.01 mm. Applying the load cell measuring the compressive force on the samples with maximum capacity of 2500N and the uncertainty of ± 1%, it is higher than the maximum force needed for sample failure. This may affect the accuracy of measured results; however, it may improve by reconsidering the test with a lower scale load cell.

V.CONCLUSION

This study presented cellular rigid PU foams of three different ranges of densities. The samples were examined to verify the compressive mechanical properties of PU foams if they are appropriate models analogous to the range of normal and osteoporotic human cancellous bone. Although PUs of different densities in this study exhibited differentfunctionality as compared to vertebral cancellous bone, the similarity in results obtained from 0.32 g.cm^{-3}provide encouraging information as a preliminary step for further investigations and development of a new innovative surrogate model.Other foam densities are recommended to be tested and evaluated to mimic other density ranges of human cancellous bone. Furthermore, other mechanical examinations need to be conducted for verification of synthetic model for shear, fatigue and viscoelastic properties.

NOMENCLATURE

E	Young's modulus
σ_y	Yield strength
σ_{ult}	Ultimate strength
ε_y	Yield strain
ε_{ult}	Ultimate strain
ρ	Density

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