



## Design of a surrogate for evaluation of methods to predict bone bending stiffness

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### ABSTRACT

The high incidence of osteoporosis and related fractures demands for the use and development of methods capable of detecting changes in bone mechanical properties. The most common clinical and laboratory methods used to detect changes in bone mechanical properties, such as stiffness, strength, or flexural rigidity, include: mechanical testing, medical imaging, medical image-based analytical calculations, and medical image-based finite element analysis. However, the innate complexity of bone makes validation of the results from each method difficult. The current study presents the design, fabrication, and functional testing of a bi-material and computed tomography scan compatible bone-surrogate which provides consistent reproducible mechanical properties for methodological evaluation of experimental, analytical, and computational bone bending stiffness prediction methods.

### 1. Introduction

In 2014, the National Osteoporosis Foundation reported that over half of the total adult population of the United States over the age of 50 suffered from osteoporosis or low bone mass (Wright et al., 2014). Osteoporotic related fracture is associated with an increased risk of patient morbidity. Despite the severe consequences of osteoporotic related fracture, many patients go undiagnosed until their first fracture.

Due to the limited availability and restrictions associated with the use of human specimens in biomechanics research, many studies use animal models in preclinical studies. Animal models, both large and small, are commonly used to investigate the effect of osteoporosis (Dias et al., 2018; Heiss et al., 2017), fracture healing (Decker et al., 2014), orthopaedic implants (Pearce et al., 2007), diet (Aiyangar et al., 2010; Crenshaw et al., 1981), etc. on the biomechanics of bone. Large animal models such as the sheep, goat, and pig, combined, make up roughly 18% of animal studies focused on bone fracture and 19% on osteoporosis (Martini et al., 2001). Large animal models are particularly relevant for the understanding of human bone because of their more comparable sized skeletons and bone metabolism as opposed to small animal models like the mouse or rat.

The most common clinical and laboratory methods used to detect changes in bone mechanical properties, such as stiffness, strength, or flexural rigidity, include: mechanical testing, medical imaging, medical image-based analytical calculations, and medical image-based finite element analysis. Although the majority of these methods can be used

to measure bone mechanical properties, the innate complexity of bone makes validation of bone stiffness prediction methods difficult (Cristofolini et al., 1996; Heiner, 2008). Therefore, a common surrogate is needed to quantify methodological errors across imaging, testing, analytical, and finite element (FE) methods. The objective of this study was to design and fabricate a bi-material surrogate which is computed tomography (CT) scan-compatible in order to provide consistent reproducible mechanical properties for methodological evaluation of experimental, analytical, and computational bone bending stiffness prediction methods. To meet this objective the following steps were taken:

1. Concept Design: Define geometric parameters.
2. Configuration Design: Design custom components and select and test off-the-shelf materials for surrogate.
3. Fabricate and evaluate functional bone surrogate prototype

### 2. Materials and methods

#### 2.1. Bone surrogate concept design

A porcine femur was used to determine the product design specifications (PDS) of the bone surrogate; however, the PDS could easily be adapted to generate a bone surrogate for a long bone from a different animal model. Functional and size requirements were set such that the total envelope of the surrogate should not exceed 40 mm x 30 mm

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**Nomenclature**

AC	acetyl copolymer
$a$	length of the moment arm from the upper to lower support, 12.7 mm
$b_b$	width of the four-point bending test specimens, mm
$CSA_c$	cross-sectional area of the compression test specimens, $\text{mm}^2$
$CSA_t$	cross-sectional area of the tensile test specimens, $\text{mm}^2$
CT	computed tomography
$D$	support diameter, 0.5 mm
DICOM	Digital Imaging and Communications in Medicine
$E_b$	elastic bending modulus, MPa; $\left(\frac{a(3Lx - 3x^2 - a^2)K_b}{12I}\right)$
$E_c$	elastic compressive modulus, MPa; $\left(K_c \frac{h_c}{CSA_c}\right)$
$E_t$	elastic tensile modulus, MPa; $\left(K_t \frac{L_t}{CSA_t}\right)$
$EL_{eff}$	effective flexural rigidity, $\text{Nmm}^2$ ; $\left(\frac{a(3Lx - 3x^2 - a^2)K_s}{12}\right)$
$EL_{eff,adj}$	adjusted effective flexural rigidity, $\text{Nmm}^2$ ; $\left(\frac{a(3Lx - 3x^2 - a^2)K_s}{12}\right)$
$EL_{Goal}$	target flexural rigidity, $1-2 \times 10^8 \text{ Nmm}^2$
$EL_x$	flexural rigidity about the x-axis, $\text{Nmm}^2$ ; $\left(E_{b,AC} \left[ \frac{wh^3}{12} + \left(\frac{E_{b,HDPU}}{E_{b,AC}} - 1\right) \left(\frac{\pi r^4}{4}\right) \right]\right)$
$EL_y$	flexural rigidity about the y-axis, $\text{Nmm}^2$ ; $\left(E_{b,AC} \left[ \frac{w^3h}{12} + \left(\frac{E_{b,HDPU}}{E_{b,AC}} - 1\right) \left(\frac{\pi r^4}{4}\right) \right]\right)$
$E_1$	elastic modulus of the steel support (compressive), MPa
$E_2$	elastic modulus of the AC shell (compressive), MPa
$F$	force, N

$\bar{F}$	applied force per unit length, N/mm
FE	finite element
HDPU	high density polyurethane foam
HU	Hounsfield unit
$h$	height, mm
$h_b$	height of the four-point bending test specimens, mm
$h_c$	height of the compression test specimens, mm
$I$	second moment of area about the bending axis, $\text{mm}^4$ ; $\left(\frac{b_b h_b^3}{12}\right)$
$K$	stiffness, N/mm; $\left(\frac{F}{\delta}\right)$
$L$	length of the lower support span, 50.8 mm
$L_t$	gauge length of the tensile test specimens, $\sim 50$ mm
$m$	sample mass, g
PDS	product design specifications
$R$	radius, mm
$V$	sample volume, $\text{cm}^3$
$w$	width, mm
$x$	position at which displacements were measured, mm
$y$	local deformation, mm; $\left(\bar{F} \left(\frac{1-v_1}{\pi E_1} + \frac{1-v_2}{\pi E_2}\right) \left[1 + \ln \left\{ \frac{8 \left(\frac{w}{2}\right)^2}{\left(\frac{1-v_1}{\pi E_1} + \frac{1-v_2}{\pi E_2}\right) \bar{F} D} \right\} \right]\right)$
$\delta$	displacement, mm
$\delta_{adj}$	adjusted displacement, mm; $(\delta - 2y)$
$\rho$	density, $\text{g/cm}^3$ ; $\left(\frac{m}{V}\right)$
$\nu_1$	Poisson's ratio of the steel supports
$\nu_2$	Poisson's ratio of the AC shell

x 150 mm in width ( $w$ ), height ( $h$ ), or length in order to mimic porcine femur geometry (Crenshaw et al., 1981). The geometric features of the surrogate should be simple to fabricate using standard machine shop equipment. Reported values of porcine femur flexural rigidity under four-point bending test conditions vary widely due to differences in diet, age, and sex (Aiyangar et al., 2010; Crenshaw et al., 1981). Therefore, the final dimensions of the bi-material surrogate should yield a flexural rigidity between 1 and  $2 \times 10^8 \text{ Nmm}^2$  ( $EL_{Goal}$ ) to represent the stiffest four-point bending flexural rigidity found within the literature (Aiyangar et al., 2010). For comparison, the flexural rigidity of a sheep femur has been reported as  $1 \times 10^8 \text{ Nmm}^2$  (Bramer et al., 1998), near the low end of the range found for the pig femur, while the flexural rigidity of the human femur has been reported to range from 2.7 to  $3.7 \times 10^8 \text{ Nmm}^2$  depending on the direction of the applied bending moment (Cristofolini et al., 1996; Heiner, 2008).

The surrogate materials should be selected from readily available homogeneous stock materials. The two materials selected should have different densities in order to act as density calibration phantoms for medical image-based analysis methods. Both materials should be durable, sterilizable, and non-metallic in order for the surrogate to withstand repeated handling and to be permitted in clinical CT scanners. All selected materials must be non-toxic to prevent release of dangerous byproducts during the machining process.

## 2.2. Bone surrogate configuration design

To reflect the natural geometry of a porcine femur diaphysis, the surrogate was designed with a stiff outer shell and a more compliant inner core. A rectangular shell cross section was selected to provide distinct  $h$  and  $w$  dimensions, and to resist rotation during bending mechanical testing. A cylindrical core was selected for ease of machining. Based on the above PDS, stock acetyl co-polymer (AC) and 40 lb/ft<sup>3</sup>, Grade 40, high-density polyurethane foam (HDPU) were

selected for the shell and core, respectively.

Material testing blanks of AC and HDPU were machined according to ASTM D638-14, ASTM D1621-10, ASTM D790-10, and ASTM D1622/D1622M-14 to determine the tensile, compressive, flexural, and density properties of both materials, respectively (ASTM Standard D, 1621-10, 2010; ASTM Standard D, 1621-10/D, 1622M-14, 2014; ASTM Standard, D638-14, 2014; ASTM Standard, D790-10, 2010). All tests were performed at room temperature in air.

Five tension test specimens with initial 50 mm gauge length ( $L_t$ ) were machined from stock AC and HDPU. Average cross-sectional area ( $CSA_t$ ) of the AC and HDPU tension test specimens were  $78.5 \pm 6.78 \text{ mm}$  and  $87.1 \pm 1.74 \text{ mm}$  (95% confidence interval (CI)), respectively. Each tension test specimen was clamped into a MTS Sintech 10/GL testing machine (MTS, Eden Prairie, MN) using self-aligning tension grips such that the distance between grips was 115 mm. A quasi-static displacement (5.0 mm/min) was applied to each specimen until failure, the moment of rupture of the test specimen. Force ( $F_t$ ) and extension data ( $\delta_t$ ) were directly measured from the MTS testing system load cell and crosshead, respectively. Tensile stiffness ( $K_t$ ) was calculated using linear regression to determine the slope within the linear region of the  $F_t$  vs  $\delta_t$  curve, represented by Eq. (1). Elastic tensile modulus for the AC ( $E_{t,AC}$ ) and HDPU ( $E_{t,HDPU}$ ) were computed using Eq. (2).

$$K = \frac{F}{\delta} \quad (1)$$

$$E_t = K_t \frac{L_t}{CSA_t} \quad (2)$$

Five compression test specimens with initial height ( $h_c$ )  $50.8 \pm 0.026 \text{ mm}$  and  $25.2 \pm 0.396 \text{ mm}$  (95% CI) were machined from stock AC and HDPU, respectively. Average cross-sectional area ( $CSA_c$ ) of the AC and HDPU compression test specimens were  $162 \pm 0.891 \text{ mm}$  and  $2580 \pm 1.87 \text{ mm}$  (95% CI), respectively. Each

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