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A surrogate long-bone model with osteoporotic material properties for biomechanical testing of fracture implants

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Abstract

In vitro comparative testing of fracture fixation implants is limited by the highly variable material properties of cadaveric bone. Bone surrogate specimens are often employed to avoid this confounding variable. Although validated surrogate models of normal bone (NB) exist, no validated bone model simulating weak, osteoporotic bone (OPB) is available. This study presents an osteoporotic long-bone model designed to match the lower cumulative range of mechanical properties found in large series of cadaveric femora reported in the literature. Five key structural properties were identified from the literature: torsional rigidity and strength, bending rigidity and strength, and screw pull-out strength. An OPB surrogate was designed to meet the low range for each of these parameters, and was mechanically tested. For comparison, the same parameters were determined for surrogates of NB. The OPB surrogate had a torsional rigidity and torsional strength within the lower 2% and 16%, respectively, of the literature based cumulative range reported for cadaveric femurs. Its bending rigidity and bending strength was within the lower 11% and 8% of the literature-based range, respectively. Its pull-out strength was within the lower 2% to 16% of the literature based range. With all five structural properties being within the lower 16% of the cumulative range reported for native femurs, the OPB surrogate reflected the diminished structural properties seen in osteoporotic femora. In comparison, surrogates of NB demonstrated structural properties within 23–118% of the literature-based range. These results support the need and utility of the OPB surrogate for comparative testing of implants for fixation of femoral shaft fractures in OPB.

Keywords: Osteoporosis; Surrogate; Bone; Femur; Mechanical properties

1. Introduction

Implant evaluation using clinical data are confounded by multiple patient- and fracture-specific factors, making it difficult to draw meaningful conclusions despite the inclusion of large patient numbers (Audige et al., 2003; Chinoy and Parker, 1999; Leung and Chow, 2003). Biomechanical testing of implants therefore plays a vital role in the evaluation of any new implant technology. Paired cadaveric testing under simulated loading conditions is an accepted standard for biomechanical testing of fracture implants (Davenport et al., 1988; Koval et al., 1997). Unfortunately, cadaveric specimens are not uniform, resulting in the use of specimens with vastly heterogeneous bone quality and strength (Cristofolini et al., 1996; Heiner and Brown, 2001; Marti et al., 2001). Due to this heterogeneity, paired cadaver studies often require a large sample population to obtain a satisfactory significance and power for statistical comparisons. Furthermore, paired testing regimes necessarily limit studies to the exploration of a single independent parameter between two experimental groups.

With constraints regarding availability, handling and reproducibility of cadaveric specimens, bone surrogate models have been introduced for mechanical testing of fracture fixation implants. Several studies confirm that currently available bone surrogates possess mechanical properties adequate to evaluate the performance of implants in normal bone (NB) (Agneskirchner et al.,

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2006; Cristofolini et al., 1996; Heiner and Brown, 2001; Peindl et al., 2004). However, as our population ages, the mechanical performance of fracture implants in osteoporotic bone (OPB) is of increasing interest (Schneider et al., 2005). No validated bone surrogate specimen exists simulating weak bone, making the mechanical evaluation of implant performance in OPB difficult at best.

The goal of this study was to develop and validate a mechanical surrogate model for osteoporotic diaphyseal bone. We hypothesized that the model could replicate five mechanical characteristics (torsional rigidity and strength, bending rigidity and strength, and screw pull-out strength) within the lower quartile of the range of corresponding values reported for human cadaveric femora.

2. Methods

2.1. Literature analysis

A meta-analysis of biomechanical studies on structural properties of human cadaveric femora was conducted. Published results corresponding to the five outcome parameters of torsional rigidity and strength, bending rigidity and strength, and screw pull-out strength were extracted. Bending and torsional rigidity were chosen as outcome measures of specimen stiffness to account for geometric variations between test setups utilized in published studies. For each outcome parameter, the lower 25th percentile of the published cumulative range was set as a target range for structural properties of the OPB surrogate. Furthermore, the coefficient of variation (COV, standard deviation/average) reported in the literature was extracted for comparison to COV values obtained on bone surrogates.

2.2. Osteoporotic surrogate

OPB surrogates consisting of a cylindrical cortex shell filled with a trabecular core were designed to fulfill two requirements: first, their geometry should be representative of the osteoporotic femoral diaphysis. Second, their structural properties should remain within the lower 25% of cadaveric femora. Theoretical calculations of structural properties along with experimental validations were performed for a range of surrogate materials and geometries to derive a design configuration that fulfilled both the geometric and structural requirements. The final OPB configuration utilized a cortex shell material identical to that used in commercially available 3rd-generation composite bone surrogates (Pacific Research Laboratories, Inc., Vashon, WA) (Fig. 1a). This material has a tensile modulus of 12.4 GPa and a tensile strength of 90 MPa (Cristofolini et al., 1996; Heiner and Brown, 2001), which correspond to those reported for human cortical bone (Bayraktar et al., 2004; Burstein et al., 1976; Lotz et al., 1991; McCalden et al., 1993; Reilly et al., 1974). The cortex shell was 160 mm long, had a 27 mm outer diameter and a shell thickness of 2 mm (Fig. 1b). The 27 mm outer diameter was representative of the human femoral shaft, reported to be in the range of 21–38 mm (Cristofolini et al., 1996; Noble et al., 1995; Rubin et al., 1992). The 2 mm shell thickness represented the low range of cortex thickness (1.6–12 mm) (Cristofolini et al., 1996; Noble et al., 1995; Rubin et al., 1992) to account for osteoporosis-induced cortex thinning (Noble et al., 1995; Parfitt, 1984). The core was machined from solid rigid polyurethane foam (Pacific Research Laboratories, Inc., Vashon, WA) of 10 pcf ($0.16\,g/cm^3$) nominal density. This material has an elastic modulus of 57–77 MPa and a yield strength of 2.2 MPa, falling in the range of human cancellous bone (Brown et al., 2002; Linde et al., 1989; McCalden et al., 1997; Reilly et al., 1974). Furthermore, it was the lowest grade of surrogate foam recommended by ASTM standard F1839 for modeling of trabecular bone to reflect osteoporosis-induced trabecular thinning and to account for the partial absence of trabecular bone in the diaphyseal canal of native bone (ASTM, 2002). Cores were press fitted and rigidly bonded to the entire inside of the cortex shells using cyanoacrylate glue.

2.3. Structural property testing

OPB surrogates were tested to failure in torsion, three-point bending, and screw pull-out for comparison to structural data of human femora published in the literature (Fig. 2). Both ends of the bone surrogates were potted in polymethyl-methacrylate (PMMA) squares. Specimens were transferred to a biaxial material test system (Instron 8874, Canton, MA) for testing. In each of the three test modes, three OPB surrogates were tested. For comparison

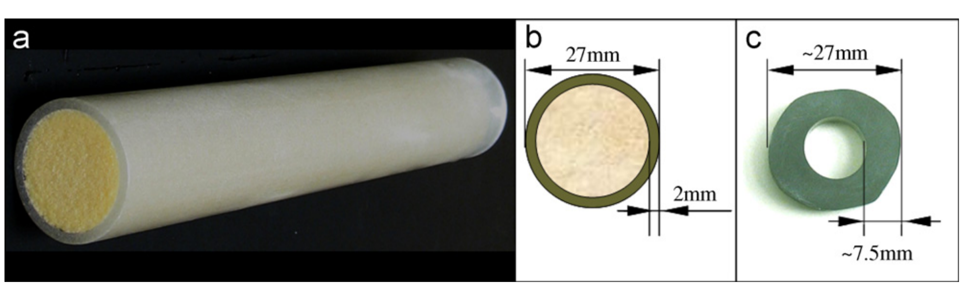

Fig. 1. (a) Osteoporotic bone (OPB) surrogate composed of a short e-glass fiber reinforced epoxy cortex and a polyurethane foam core, (b) cross-sectional geometry of OPB, and (c) normal bone surrogate in diaphyseal region.

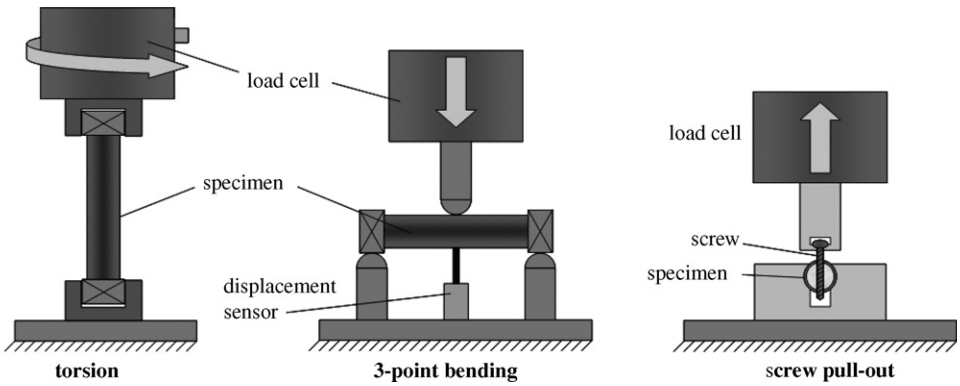

Fig. 2. Test configurations for structural property evaluation of bone surrogates in torsion, bending, and screw pull-out.

to NB surrogates, all tests were repeated on 3rd-generation composite femora (#3303 Pacific Research Laboratories, Inc., Vashon, WA).

2.4. Torsional tests

For torsional tests, one end of the OPB surrogates was rigidly affixed to the Instron base and the other end was mounted on the biaxial load cell, which was connected to the rotary actuator. For torsional testing of NB surrogates, the condylar and trochanteric regions were potted in PMMA and mounted to the Instron base and load cell, respectively. Care was taken to align the diaphyseal axis with the rotation axis of the actuator to avoid off-center loading. The specimens were loaded in torsion to failure at a constant rotational velocity of 1°/s. Torsional rigidity was calculated by multiplying the unsupported specimen length with the slope of the torsion versus rotation curve during the initial 10% of the rotation excursion. Torsional strength was determined as the maximum torque prior to specimen fracture.

2.5. Bending tests

Bending tests were performed in a custom-designed three-point-bending apparatus. The lower supports were spaced 140 mm and the upper indenter was centered between the lower supports. The contact cylinders had a diameter of 25 mm. For NB surrogates, bending was applied in anterior direction that increased the native antecurvature of the diaphysis. Flexural rigidity R_F was determined by loading at a constant rate of 0.1 mm/s. For accurate flexural rigidity assessment free of possible indentation artifacts at the loading cylinders, a displacement sensor (LVDT, LD 400-5, Omega, Stamford, CT) was centered below the specimen to measure specimen deflection. Flexural rigidity was calculated by the equation $EI = Fl^3/48d$, where E is the elastic modulus, I the second moment of area, F the applied force, l the distance between the lower supports, and d the center deflection measured with the LVDT sensor. After removal of the displacement sensor, each of the specimens was loaded to failure in bending at 0.1 mm/s. Bending strength was determined as the maximum bending moment ($M_B = Fl/4$) before specimen fracture.

2.6. Screw pull-out

The screw pull-out force was determined for 4.5 mm diameter self-tapping screws of 35 mm length (Synthes, West Chester, PA). This screw size was chosen to allow for direct result comparison with previous studies on cadaveric specimens, which also used 4.5 mm bone screws (Bolliger Neto et al., 1999; Stromsoe et al., 1993). According to the manufacturer's recommendation, screw holes were predrilled at 3.2 mm diameter. Specimens were transferred into custom-made holders for OPB and NB surrogates mounted to the base of the Instron machine. Pull-out tests were conducted in load control at a rate of 100 N/s. Pull-out strength was determined as the maximum load recorded during each pull-out test.

3. Results

The final configuration of the OPB surrogate yielded theoretical values for torsional rigidity, torsional strength, bending rigidity, and bending strength of 1.38 $Nm^2/^\circ$, 120 Nm, 123 Nm^2, and 91.4 Nm, respectively. In absence of a closed-form solution, no theoretical screw-pullout strength could be calculated.

The mean age of the cadaveric femora included in the meta-analysis was 63.2 years. Values for the five structural parameters are summarized in Table 1, including the values for native bone extracted from the literature and the results from the current study for both the OPB and NB surrogates. The torsional rigidity of the OPB surrogates was in the lower 2nd percentile of the cumulative range of three previous studies on human cadaveric femora (Cristofolini et al., 1996; Martens et al., 1980; Mensch et al., 1976) (Fig. 3a). Torsional strength was in the lower 16th percentile of the cumulative range of three previous studies (Hubbard, 1973; Martens et al., 1980;

Table 1
Summary of results for the five structural properties (torsional rigidity and strength, bending rigidity and strength, screw pull-out strength), shown for the cumulative literature ranges of human femora (native), osteoporotic bone (OPB) surrogates, and normal bone (NB) surrogates

		Native				OPB surrogate		NB surrogate	
		Average ± STDEV	Range	COV [%]	References	Average	COV [%]	Average	COV [%]
Torsion	Rigidity [$Nm^2/°$]	2.9 ± 1.1	1.0–6.9	32–4	[10, 21, 25]	1.2	1.7	2.4	11
	Strength [Nm]	147 ± 64	42–316	29–73	[15, 21, 25]	87	13	365	5
Bending	Rigidity [Nm^2]	275 ± 171	37–664	23–109	[10, 12, 33]	103	8	228	1.8
	Strength [Nm]	318 ± 170	52–605	21–44	[12, 33]	96	9	278	6
Screw pull-out	Strength [kN]	4.3 ± 1.9	0.6–8.4	4–54	[6, 34, 35]	1.8	1.5	7.6	2.3

For native femora, average values and standard deviation were calculated cumulatively for all data, while the coefficients of variation reflect those of individual studies.

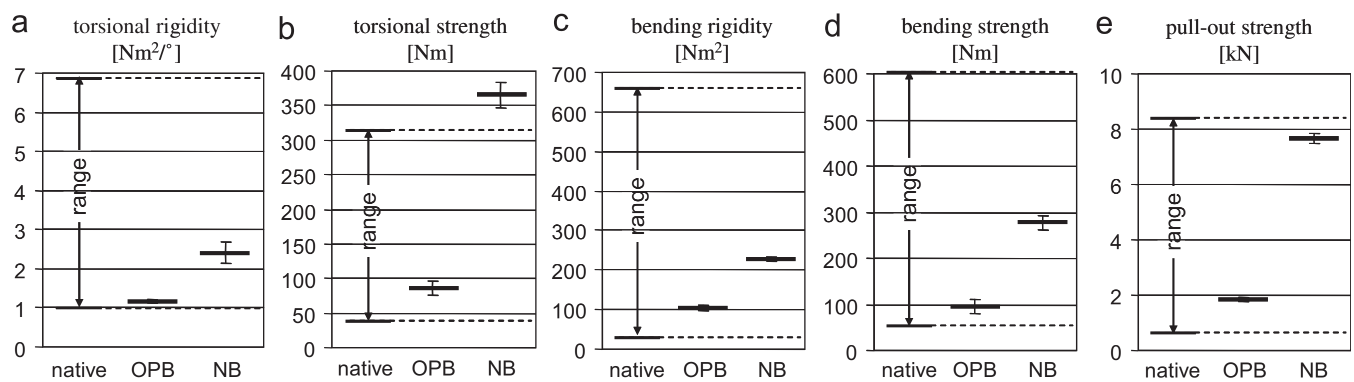

Fig. 3. Five structural properties for cadaveric femora (native, cumulative literature range), osteoporotic bone (OPB) surrogates, and normal bone (NB) surrogates: (a) torsional rigidity, (b) torsional strength, (c) bending rigidity, (d) bending strength, and (e) screw pull-out strength.

Mensch et al., 1976) (Fig. 3b). For NB surrogates, the torsional rigidity and torsional strength corresponded to the 23rd and 118th percentile, respectively, of the cumulative literature range. In torsion, all bone surrogates exhibited spiral fracture patterns characteristic for torsion-induced fractures in diaphyseal bone (Fig. 4).

The bending rigidity of the OPB surrogates fell within the lower 11th percentile of the cumulative literature range (Cristofolini et al., 1996; Funk et al., 2004; Stromsoe et al., 1995) (Fig. 3c). The bending strength of the OPB surrogates was in the lower 8th percentile of values from previous studies (Funk et al., 2004; Stromsoe et al., 1995) (Fig. 3d). For NB surrogates, the bending rigidity and strength were in the 31st and 41st percentile, respectively, of the cumulative literature range. In bending, all OPB surrogates exhibited transverse fracture patterns characteristic of bending-induced fractures in diaphyseal bone (Fig. 5).

The pull-out strength for the OPB surrogate fell within the lower 16th percentile of the cumulative literature data (Bolliger Neto et al., 1999; Stromsoe et al., 1993; Yerby et al., 2001) (Fig. 3e). The pull-out strength of NB surrogates fell within the 90th percentile of the cumulative literature range.

The COV observed in all five outcome parameters was 2–10 times lower for surrogate specimens as compared to COV values reported in the literature for cadaveric specimens.

4. Discussion

The mechanical and geometric heterogeneity of cadaveric bone confounds biomechanical testing of fracture implants. Cadaveric bone strength is extremely variable, with up to a seven-fold range between the highest and lowest reported values for whole femora (Hubbard, 1973). Differences in specimen age and the degree of osteoporosis partially account for the variability in mechanical properties across cadaveric specimens. Additionally, there are relatively large differences in cortex thickness within a single bone and across specimens (Bolliger Neto et al., 1999; Cristofolini et al., 1996; Noble et al., 1995; Rubin et al., 1992).

This variability in geometric and material properties of cadaveric specimens often requires prohibitively large sample sizes to detect statistically significant differences in implant performance. Bone surrogate specimens hold the advantage of known mechanical characteristics with

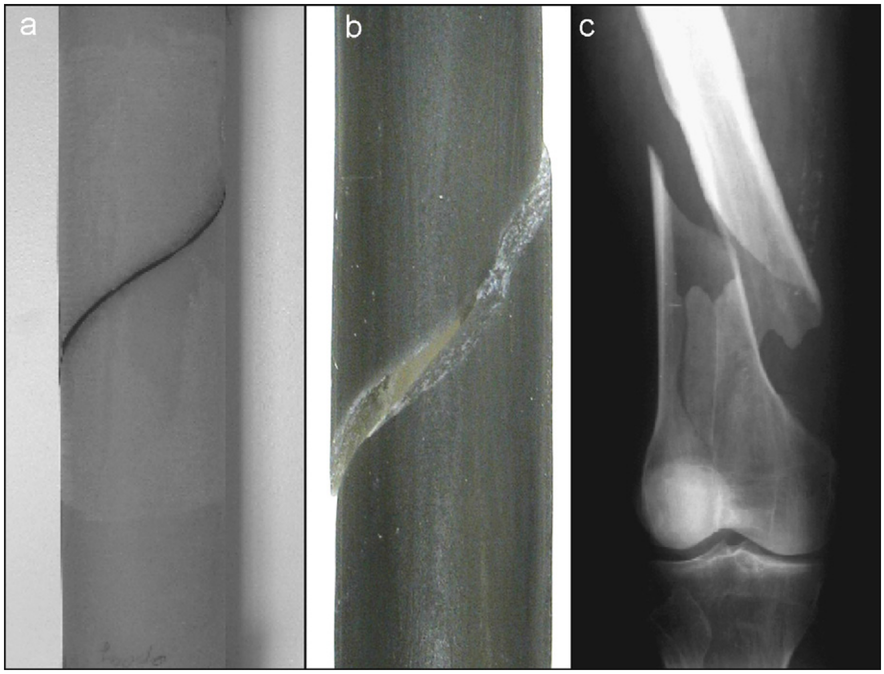

Fig. 4. (a) Torsion failure in the osteoporotic bone surrogate, (b) normal bone surrogate, and (c) in a femur shown on a clinical radiograph-depicting spiral fractures typical for torsional injuries.

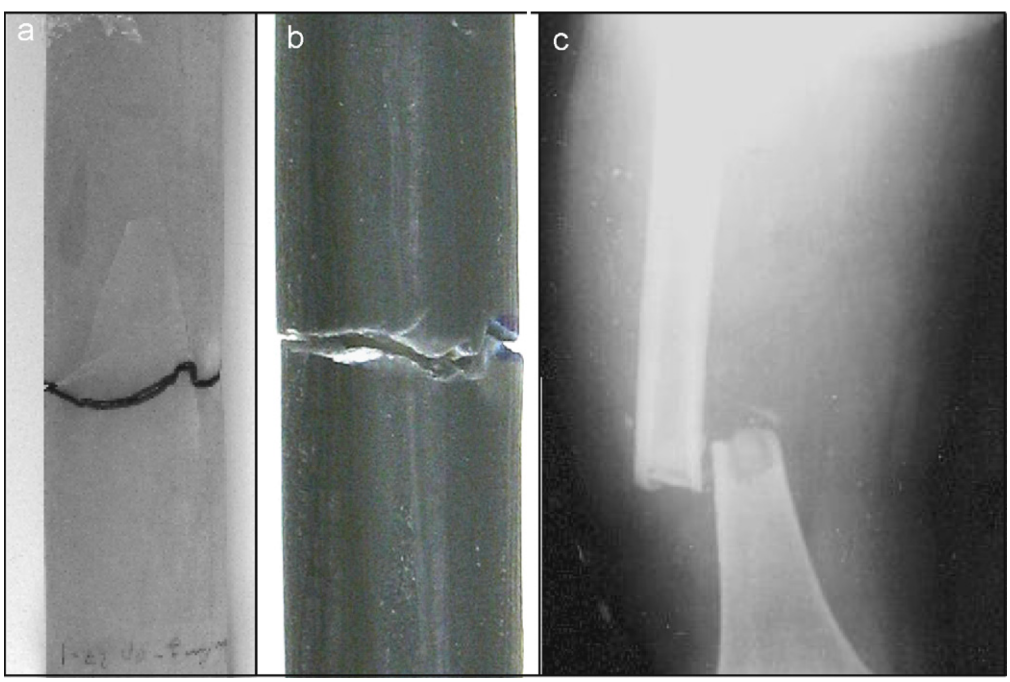

Fig. 5. (a) Bending failure of osteoporotic bone surrogate, (b) normal bone surrogate, and (c) in a femur shown on a clinical radiograph depicting transverse fractures typical for bending-induced injuries.

small standard deviations, allowing statistically valid comparisons with much smaller sample sizes. It is widely accepted that fracture fixation performance and failure mechanisms differ in strong bone and weak bone (Battula et al., 2006; Gardner et al., 2006; Schneider et al., 2005; Seebeck et al., 2005). Although validated strong bone surrogates exist (Cristofolini et al., 1996; Heiner and Brown, 2001), there is no such surrogate for weak bone. Recently, attempts have been made to study fixation strength in OPB (Battula et al., 2006; Gardner et al., 2006), emphasizing the fact that behavior of fracture implants in weak, OPB represents an increasingly important question (Schneider et al., 2005). The development of a weak bone surrogate model therefore seems vitally important.

Among the key parameters classically used to describe the mechanical properties of diaphyseal bone are torsional rigidity and strength, bending rigidity and strength, and screw pull-out strength. Previous studies have employed these parameters to evaluate the mechanical properties of large series of intact human femora (Cristofolini et al., 1996; Funk et al., 2004; Martens et al., 1986, 1980; Mensch et al., 1976; Seebeck et al., 2005; Stromsoe et al., 1993, 1995; Yerby et al., 2001). We pooled the individual data from these studies to develop a cumulative range of mechanical properties for human femoral bone. The use of these literature-based values allowed the comparison of our bone surrogate with mechanical properties obtained from series of cadaver bones much larger than we could generate in isolation. While differences in study techniques and specimen population exist in the reference studies, the validity of their results is confirmed by their overlapping data ranges and standard deviations.

Structural properties of the OPB surrogate initially were calculated from constitutive and geometric data. Mechanical testing demonstrated reasonable correlation to these theoretical results. Bending rigidity, bending strength, torsional rigidity, and torsional strength yielded theoretical values of 123 Nm^2, 91.4 Nm, 1.38 $Nm^2/°$, and 120Nm), and physical test results of 103 Nm^2, 96 Nm, 1.15 $Nm^2/°$, and 86.5 Nm, respectively.

Bending rigidity and strength were assessed using three-point bending tests to allow a direct comparison to literature values. While some authors used four-point bending, no difference could be found in a direct comparison of data from a four-point and a three-point bending study (Funk et al., 2004; Martens et al., 1986). The literature values for bending rigidity were inversely correlated to specimen age, with the studies drawing from younger donors having more than double the rigidity values as compared to the studies with the older population (Funk et al., 2004; Martens et al., 1986; Stromsoe et al., 1995).

Screw pull-out strength was difficult to determine from the literature, given the multiple factors that can affect this value. In addition to bone quality, differences in specimen type (femur versus tibia), bone sample region (diaphysis versus metaphysis), screw diameter, thread type, pre-drilling, and tapping all affect pull-out strength. Therefore, the OPB surrogate data were only compared to those studies which used femoral diaphyseal bone to determine the pull-out strength with a similar screw type and dimensions (Bolliger Neto et al., 1999; Stromsoe et al., 1993; Yerby et al., 2001). Screw insertion torque was not extracted from the literature due to the extensive number of variables that make a proper comparison with large, validated series nearly impossible. Nevertheless, peak torque during screw insertion was experimentally determined in three OPB surrogates (0.95 ± 0.11 Nm) and three NB surrogates (2.64 ± 0.52 Nm).

When considering the utility of a surrogate for mechanical testing, both the absolute mechanical values and the standard deviations of these values are important. In all cases, the COV was between 2 and 10 times lower for the surrogate specimens relative to literature-based values obtained in cadaveric specimens. This high reproducibility increases the sensitivity to detect true differences between test constructs.

For all five structural tests, the OPB surrogate yielded structural parameters within the lower 2–16% of the cumulative range of corresponding values reported for human cadaveric femora. The combination of proper geometry, high reproducibility, and the five structural characteristics that correlate to the osteoporotic femoral diaphysis underscores the utility of the bone surrogate for mechanical testing. OPB and NB surrogates delivered a comparably high reproducibility with COV values remaining below 15% for all outcome parameters. However, the NB surrogates were considerably stronger than OPB surrogates and yielded structural parameters corresponding to 23–118% of those reported for native femurs. The most pronounced differences were observed in torsional strength and screw pull-out strength, both of which were over four times higher in NB surrogates as compared to OPB surrogates. This suggests that OPB surrogates will enable more realistic evaluation of implants for diaphyseal fracture fixation in OPB than would be possible with NB surrogates.

As is the case for any bone surrogate, one must recognize the limitations of the OPB model prior to drawing conclusions regarding data obtained from it. Although the OPB surrogate lies in the weak bone range for five key mechanical characteristics of bone, there are other mechanical behaviors that were not evaluated. Crack propagation and fatigue under dynamic loading were not quantified since comparable values for these properties are not readily available in the literature. However, the fracture patterns in OPB surrogates closely correlated with those seen clinically. Furthermore, the OPB surrogate was not designed to mimic the frictional properties of native bone. Therefore, the OPB surrogate may be best suited for testing of implants that are rigidly fixed to the bone, such as osteosynthesis plates and screws, and may not properly reflect fixation constraints of implants that primarily rely on intramedullary interface friction.

In general, the use of surrogate models does not allow a direct implant performance correlation to the clinical setting. Next to geometric and constitutive differences, surrogate models cannot account for time-dependent changes of bone *in vivo*, including remodeling and osteolysis. However, for evaluation of implant performance in the early post-operative phase the relative relationships between implants should remain intact, but with a much tighter standard deviation due to greater reproducibility with highly uniform specimens. While implant evaluation on bone surrogates cannot provide a comprehensive assessment of clinical performance, bone surrogates are well suited for relative comparison between implant types under various loading conditions. After such time- and cost-efficient bone surrogate testing over a wide parameter range, key findings should be validated on a small number of paired cadaveric specimens.

In conclusion, we developed the first bone surrogate model that matches diaphyseal bone geometry and material properties in line with weak cadaveric femora, as published in the literature for five important bone property descriptors. Therefore, this model has great potential to serve as a test medium for fracture implants requiring the simulation of osteoporotic diaphyseal bone.

Conflict of interest

There is no conflict of interest.

Acknowledgments

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