Biomechanical characteristics of allogeneic cortical bone pins designed for fracture fixation

J. M. Liptak¹, M. R. Edwards¹, S. P. James², W. S. Dernell¹, R. J. Scott¹, A. M. Bachand³, S. J. Withrow¹

¹Department of Clinical Sciences, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, Colorado, USA
²Department of Mechanical Engineering, College of Engineering, Colorado State University, Fort Collins, Colorado, USA
³Department of Environmental and Radiological Health Sciences, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, Colorado, USA

Summary

The biomechanical characteristics of 1.2 mm diameter allogeneic cortical bone pins harvested from the canine tibia were evaluated and compared to 1.1 mm diameter stainless steel pins and 1.3 mm diameter polydioxanone (PDS) pins using impact testing and four-point bending. The biomechanical performance of allogeneic cortical bone pins using impact testing was uniform with no significant differences between sites, side, and gender. In four-point bending, cortical bone pins harvested from the left tibia (204.8 ± 77.4 N/mm) were significantly stiffer than the right tibia (123.7 ± 54.4 N/mm, P = 0.0001). The site of bone pin harvest also had a significant effect on stiffness, but this was dependent on interactions with gender and side. Site C in male dogs had the highest mean stiffness in the left tibia (224.4 ± 40.4 N/mm), but lowest stiffness in the right tibia (84.9 ± 24.2 N/mm). Site A in female dogs had the highest mean stiffness in the left tibia (344.9 ± 117.4 N/mm), but lowest stiffness in the right tibia (60.8 ± 3.7 N/mm). The raw and adjusted bending properties of 1.2 mm cortical bone pins were significantly better than 1.3 mm PDS pins, but significantly worse than 1.1 mm stainless steel pins (P < 0.0001). In conclusion, cortical bone pins may be suitable as an implant for fracture fixation based on initial biomechanical comparison to stainless steel and PDS pins used in clinical practice.

Keywords

Allogeneic, cortical bone, stainless steel, polydioxanone, pins, biomechanics, dog

Introduction

Surgical steel and titanium are frequently used to construct fracture-fixation devices such as intramedullary pins, interlocking nails, and bone plates and screws. However, complications associated with these implants, such as migration, infection, soft tissue tethering, and stress-shielding-induced osteoporosis, often necessitate a second surgery for implant retrieval or revision (1–3). Biodegradable fixation devices have been investigated in an effort to reduce this complication rate and need for further surgery. Other theoretical advantages of biodegradable implants include: progressive transfer of weight-bearing load to healing bone during implant degradation and better assessment of fracture alignment and bone healing because biodegradable implants are radiolucent (2, 4–6). Pins, rods and screws manufactured from synthetic polymers, such as polydioxanone, polyactic acid and polyglactin, have been used as biodegradable fixation devices in a variety of fracture types and osteotomies (4, 6–16). However, complications are common and include unpredictable resorption, inadequate fixation, and foreign body reactions associated with breakdown products (1, 4–6, 8, 9, 16–18). Autogenous and allogeneic cortical bone are commonly used in orthopaedic surgery. Cortical bone has a number of inherent advantages as a biocompatible fixation device, including predictable incorporation characteristics and osteogenic, osteoinductive, and osteoconductive capabilities (19–24). Autogenous cortical bone pegs have been used with good to excellent results in people for digital reimplantation (25) and the fixation of osteochondral fragments resulting from osteochondritis dissecans lesions (8, 18, 26–29) and intra-articular fractures (21). Disadvantages associated with the use of autogenous cortical bone include: donor site morbidity, poor uniformity in the size and shape of the bone pegs, limited availability of autogenous bone, and increased surgery time (18, 20, 26–28).

Cortical bone allografts have been used to reconstruct diaphyseal bone following fracture, nonunion, and bone tumour resection (2, 30–35). The healing and incorporation of cortical allografts has been well described (20, 22, 24, 34). Theoretically, pins constructed from cortical bone allografts should have similar healing characteristics to massive cortical allografts. Furthermore, pins milled from allogeneic cortical bone have been used with encouraging results for fixation of experimental and clinical osteo-tomies, fractures, and arthrodeses (19–36). As a fixation material, cortical allografts possess a number of advantages over synthetic polymers and autogenous cortical bone. Cadaveric cortical bone is readily available, pins can be constructed from cortical bone with uniform diameter, shape, and size, and biocompatibility and resorption characteristics may be more reliable and consistent than synthetic polymers (19, 25, 36). However, the biomechanical characteristics of cortical bone pins have not been established. The quality of cortical bone is determined by a number of different factors, including the inherent forces to which that bone is exposed (27, 37–39). Pins constructed from different re-
gions of the same bone may have different biomechanical characteristics.

The purpose of the present study was to evaluate allogeneic cortical bone pins as a fracture fixation device. Our three specific aims were: 1) to examine the biomechanical uniformity of cortical bone pins from different regions of the same bone using impact testing; 2) to compare the bending properties of 1.2 mm cortical bone pins and the clinically comparable 1.3 mm polydioxanone (PDS) pins\(^a\) and 1.1 mm stainless steel pins\(^b\) using four-point bending; and 3) to determine the relationship of impact and bending testing to donor site, side, and gender in cortical bone pins. We hypothesized that allogeneic cortical bone pins would have bending properties similar or superior to PDS pins, but inferior to stainless steel pins, and that site, side, and gender would influence these properties.

### Materials and methods

#### Bone pin production

Left and right tibiae were harvested from the cadavers of three male and three female retired, racing Greyhounds between one and four years of age. The paired tibiae were labeled for identification, wrapped in saline-soaked gauze, sealed in cellophane, and frozen at \(-80^\circ\text{C}\).

Five sites were identified in each of the canine tibiae where pins could be reliably produced (Fig. 1). The tibia was used for the production of canine cortical bone pins as the proximal and distal aspects of the canine tibia are straight with adequate cortical thickness to allow the fabrication of 1.2 mm diameter pins. Due to either bone shape or inadequate cortical thickness, pins of this diameter could not be reliably constructed from canine femora, humeri, or radii. The pins were milled using a modified 1.2 mm hollow-end drill\(^c\) mounted in an industrial drill-press operated at 460 revolutions per minute and advanced at a rate of 0.5 mm/sec with a constant irrigation of 0.9% sodium chloride (Fig. 2). This cortical bone pin milling procedure was based on the personal experience of the designers of the hollow-end drill. Fifty-one cortical bone pins were manufactured from the six pairs of canine tibiae.

The cortical bone pins were labeled to identify the donor, side, and harvest site, and were returned immediately to storage in sealed cellophane bags at \(-80^\circ\text{C}\). Bone pins were thawed to room temperature by soaking them in physiological saline at 37°C for four hours prior to testing. A single 6 mm segment was removed from the proximal aspect of each of the 51 cortical pins.

---

\(^{a}\) Orthosorb\(^\text{\textregistered}\), Johnson & Johnson Orthopedics, Raynham, MA, USA.

\(^{b}\) K-wires, Kirschner Medical Company, Timonium, MD, USA.

\(^{c}\) Holland RP and Stutts DS, University of Missouri-Rolla, MI, USA.
Bone pins and subjected to impact testing. Eleven 1.3 mm PDS pins, 12 1.1 mm stainless steel pins, and the remaining segments of the 1.2 mm cortical bone pins were tested in 4-point bending.

**Impact testing**

Impact testing was used as a relatively simple method to examine the biomechanical uniformity of the cortical bone pins and was performed using a pendulum device (Fig. 3). The final angle of the pendulum of known mass was recorded following a control run (no pin) and a test run (pin in place). The pendulum was raised to the same height prior to release for each test. The test and control pendulum angles were then used in a modified mass-gravity-height equation to calculate the energy required to fracture the pin. Energy imparted to the pin decreased the final height, and, therefore, the final angle of the pendulum relative to the control value. The purpose of the control run was to determine the amount of energy lost to overcome friction in the system. This value remained constant and negligible throughout the entire testing period. The energy imparted to the pin was calculated using the following equation:

\[ E_I = U_C - U_f = MxGx(L/2)x([\sin(B) - \sin(A)] \)

where \( E_I \) is the impact energy in Joules, \( U_C \) is the final potential energy of the system following the control swing, \( U_f \) is the final potential energy of the system following fracture of the sample, \( M \) is the mass of the pendulum in kilograms, \( L \) is the length of the pendulum in meters, \( G \) is the acceleration due to gravity in \( \text{ms}^{-2} \), \( A \) is the final angle of the pendulum after the control swing, and \( B \) is the final angle of the pendulum after the test swing.

**Four-point bending**

Four-point bending was selected as the most clinically relevant loading test to compare the structural properties of cortical bone pins to commercially-available fracture fixation pins which may be used in the same clinical setting. This test was used to measure the structural stiffness, maximum load, ultimate bending moment, and flexural elastic modulus of cortical bone, stainless steel, and PDS pins. Four-point bending was selected in preference to three-point bending as the constant bending moment in the test section is more sensitive to the presence of material defects. These are unlikely in stainless steel and PDS pins, but are expected in biological materials such as cortical bone. Pins were placed in a specially designed jig (Fig. 4) and tested to failure in 4-point bending. Load was applied using a modified linear distraction device\(^d\) at a constant rate of 0.35 \( \text{mm/sec} \). Displacement was defined as the distance traveled by the centre contact points of the bending jig. Analogue force and displacement data were digitized and stored by a computer software system\(^e\). The maximum load, defined as the load at failure, was recorded for each pin. Structural stiffness was calculated from the slope of the initial linear portion of the load-deformation curve (23, 37).

**Adjusted bending properties**

The bending properties of these pins were then adjusted to calculate ultimate bending moment and elastic modulus so that, independent of geometry, different pin materials (i.e. cortical bone, PDS, and stainless steel) could be compared. The ultimate bending moment of the cortical bone pins was calculated using the following formula:

\[ M = \left( \frac{F_{\text{max}} \times 2}{9} \right) \]

where \( M \) is the ultimate bending moment, \( F_{\text{max}} \) is the maximum load, and 9 represents the distance in mm from the load point to

---

\(^d\) Unislide\® model #B2S09P40J, Velmex Inc, East Bloomfield, NY, USA.

\(^e\) Labtech Acquire™, Wilmington, MA, USA.
nearest support (Fig. 4) (40). The bending structural stiffness for all of the pins was calculated using the following formula:

\[ EI_e = s^2 \times (L + 2 \times c) \times F/y/12 \]

where \( EI_e \) is bending structural stiffness, \( s \) is the span from the load point to the nearest support, \( L \) is the total span (and is equivalent to \( c + 2 \times s \)), \( c \) is the centre span (Fig. 4), and \( F/y \) is the slope of the elastic portion of the load-displacement curve (40). The elastic modulus for each pin was calculated using the following formula:

\[ E = EI_e / (\pi \times D^4/64) \]

where \( E \) is the elastic modulus and \( D \) is the diameter of the pin.

**Statistical analysis**

The mean and standard deviation (SD) for the five biomechanical parameters (stiffness, maximum load, impact energy, bending structural stiffness, and elastic modulus) were calculated for cortical bone pins, PDS pins, and stainless steel pins. One-way analysis of variance (ANOVA) and Tukey’s test were used in order to compare the means of the three pin types using statistical software. Multiway ANOVA was used to determine whether impact energy and bending properties depended on gender, side (left or right), site, or donor. All parametric assumptions were tested and there were no violations which necessitated data transformation. A \( P \)-value <0.05 was considered significant.

**Results**

**Impact testing**

The mean ± SD impact energy for all of the tested cortical bone pins was 26,275 ± 8,557 J. Cortical bone pins milled from different regions of the tibia were mechanically uniform. The weakest (n=25) (25,719 ± 6,675 J) and strongest (n=25) cortical bone pins (26,831 ± 10,211 J) were compared and significant differences were not detected.

**Four-point bending**

The 1.2 mm allogeneic cortical bone pins performed significantly better than 1.3 mm PDS pins, but significantly worse than 1.1 mm stainless steel pins (Table 1). The biomechanical performance of stainless steel pins was significantly better than cortical bone pins and PDS pins in all examined and adjusted bending properties (\( P<0.0001 \)). The cortical bone pins failed by fracture between the two central loading points in the area of constant bending moment. The PDS and stainless steel pins failed because of excessive deformation rather than fracture as the loading points bent the PDS and stainless steel pins beyond the support points.

**Effect of donor species, gender, bone, and site**

The raw and adjusted bending properties of cortical bone pins depended on side, site, and gender. Statistically significant and select non-significant results are included in Table 2. In dogs, one-way ANOVA showed left tibiae (204.8 ± 77.4 N/mm) were significantly stiffer than right tibiae (123.7 ±...
A significant interaction between gender, side, and site was demonstrated with multi-way ANOVA. In male dogs, site C had the lowest mean stiffness in right tibiae (84.9 ± 24.2 N/mm), but the highest mean stiffness in left tibiae (224.4 ± 40.4 N/mm). In female dogs, site A had the lowest mean stiffness in right tibiae (60.8 ± 3.7 N/mm), but the highest mean stiffness in left tibiae (344.9 ± 117.4 N/mm). Similarly, the results of data adjusted for pin diameter showed bending structural stiffness and elastic modulus were significantly greater in left (60,143.0 ± 15,970.8 N/mm², 356,905.0 ± 156,903.1 N/mm², respectively) than right tibiae (36,328.5 ± 22,730.8 N/mm², 258.7 ± 11.0 N/mm², respectively). Site C had the lowest mean bending structural stiffness and elastic modulus in right tibiae (24,921.9 N/mm² and 244,842.3 N/mm², respectively), but highest in left tibiae (101,283.0 N/mm² and 995,042.7 N/mm², respectively) in female dogs. Due to high variability between individual maximum load, impact energy, and ultimate bending moment results, clear patterns could not be established with respect to gender, side or site, although mean maximum load tended to be lower at site B in females and site C in males.

**Discussion**

The purpose of this study was to evaluate the stiffness and strength of allogeneic cortical bone pins and to compare these properties to commercially-available pins in order to determine the suitability of cortical bone pins as a fracture fixation device. Stainless steel and PDS pins have successfully been used for fracture fixation in people (4, 6–16). However, cortical bone pins may be advantageous due to a reduced complication rate, progressive transfer of weight-bearing load to healing bone, and better postoper-

<table>
<thead>
<tr>
<th>Biomechanical properties</th>
<th>Canine bone</th>
<th>PDS</th>
<th>Stainless steel</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness (N/mm)</td>
<td>165.1 ± 78.1</td>
<td>16.9 ± 9.4</td>
<td>402.3 ± 93.4</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Maximum load (N)</td>
<td>10.2 ± 2.0</td>
<td>2.2 ± 0.2</td>
<td>57.5 ± 2.4</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Bending structural stiffness (N/mm²)</td>
<td>48,479 ± 22,918</td>
<td>4,969 ± 2,752</td>
<td>118,129 ± 27,438</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Ultimate bending moment (N/mm)</td>
<td>46.1 ± 9.1</td>
<td>9.9 ± 0.9</td>
<td>258.7 ± 11.0</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Elastic modulus (N/mm²)</td>
<td>476,274 ± 225,156</td>
<td>69,146 ± 38,296</td>
<td>1,643,671 ± 381,782</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

**Table 2**

Biomechanical parameter | Comparison | P-value |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness (N/mm)</td>
<td>Gender¹</td>
<td>0.42</td>
</tr>
<tr>
<td></td>
<td>Donor¹</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Side¹</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td></td>
<td>Site¹</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>Gender-side-site¹</td>
<td>0.02*</td>
</tr>
<tr>
<td></td>
<td>Gender-side-site-bone¹</td>
<td>-</td>
</tr>
<tr>
<td>Maximum load (N)</td>
<td>Gender¹</td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>Donor¹</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>Side¹</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Site¹</td>
<td>0.05*</td>
</tr>
<tr>
<td></td>
<td>Gender-site¹</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Donor-site¹</td>
<td>0.05*</td>
</tr>
<tr>
<td>Impact energy (J)</td>
<td>Gender¹</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>Donor¹</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>Side¹</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Site¹</td>
<td>0.20</td>
</tr>
<tr>
<td>Bending structural stiffness (N/mm²)</td>
<td>Gender¹</td>
<td>0.42</td>
</tr>
<tr>
<td></td>
<td>Donor¹</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Side¹</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td></td>
<td>Site¹</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>Gender-side-site¹</td>
<td>0.02*</td>
</tr>
<tr>
<td>Ultimate bending moment (N/mm)</td>
<td>Gender¹</td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>Donor¹</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Side¹</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Site¹</td>
<td>0.05*</td>
</tr>
<tr>
<td></td>
<td>Donor-site¹</td>
<td>0.05*</td>
</tr>
<tr>
<td></td>
<td>Gender-side-site¹</td>
<td>-</td>
</tr>
<tr>
<td>Elastic modulus (N/mm²)</td>
<td>Donor¹</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Side¹</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td></td>
<td>Site¹</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>Gender-side-site¹</td>
<td>0.02*</td>
</tr>
</tbody>
</table>

¹one-way ANOVA results; ²multi-way ANOVA results; *significant result.
ative assessment of fracture alignment and bone healing. The biomechanical uniformity of cortical bone pins milled from cadaveric canine bone was evaluated by impact testing. Four-point bending was used to compare the structural and material properties of cortical bone, stainless steel, and PDS pins. Pin diameters were not equal, due to commercial design, and presented a limitation in comparing cortical bone pins to stainless steel and PDS pins. However, these comparisons were considered clinically appropriate as 1.1 mm stainless steel, 1.2 mm cortical bone, and 1.3 mm PDS pins would all be intended for use in the same clinical situations. In order to account for these differences in pin diameter, ultimate strength design principles were employed to allow a direct comparison of the biomechanical properties of cortical bone pins, stainless steel pins, and PDS pins independent of their diameter (40).

Impact testing provides a rapid and inexpensive method of comparing the biomechanical uniformity of a large number of cortical bone pins. Impact energy reflects bone pin strength and ductility and is analogous to the energy under a stress-strain tensile curve. Impact testing demonstrated that canine allogeneic cortical bone pins had uniform biomechanical characteristics with minimal and insignificant differences between the weakest and strongest pins.

Four-point bending allows comparison of the structural characteristics of devices with different geometry and to make a comparison of the material characteristics of implants with identical geometry (23, 37, 38, 41). The aim of four-point bending in the present study was to compare the biomechanical characteristics of two commercially available and clinically proven fracture fixation devices (stainless steel pins and PDS pins) to a novel fracture fixation device (allogeneic cortical bone pins) designed for similar applications. Cortical bone pins milled from the left tibia were significantly stiffer than those milled from right tibia. In the present study, tibiae were harvested from recently retired racing Greyhounds. In North America, Greyhounds race in a counter-clockwise direction resulting in higher loads being transmitted through left-sided limbs and the subsequent alteration of the structural and material properties of bone on this side (42, 43). Adaptive remodeling has also been reported in other species with increased humeral cortical thickness in the dominant arm of professional tennis players (44), increased stiffness of the third carpal bone in exercising horses (45), and enhanced bone density in the distal femora of human athletes (46). Hence, adaptive remodeling provides the most plausible explanation for the difference in stiffness between cortical bone pins milled from left and right canine tibiae. Age was not examined as a co-variable in the present study because the biomechanical properties of cortical bone pins procured from young to middle-aged mature Greyhounds (one to four years old) were expected to be similar. However, increasing age does adversely affect the biomechanical performance and healing characteristics of bone in dogs and humans (47–49).

The biomechanical characteristics of cortical bone pins were significantly better than PDS pins, but were inferior to stainless steel pins. These results support the findings of other studies in which the elastic modulus and tensile strength of cortical bone (16–28 Gpa and 0.09–0.12 Gpa), which is species and site dependent, is between that of poly-lactide (3–5 Gpa and 0.06 Gpa) and stainless steel (200 Gpa and 0.80 Gpa) (50). The biomechanical characteristics of an implant suitable for use as a fracture fixation device have not been defined. However, data from present and previous studies supports the use of cortical bone pins as a fracture fixation device as the strength and stiffness of cortical bone pins is intermediary to PDS pins and stainless steel pins, both of which have been used successfully in clinical practice for fixation of osteotomies, fractures, and arthrodeses (4–12, 14, 15, 51). In addition to experimental studies (36), allogeneic cortical bone pins have also been used with good results for primary fixation of first metatarsal distal chevron osteotomies and digital arthrodeses in people (19).

Allogeneic cortical bone pins appear to be suitable for the use as a biocompatible fracture fixation device based on historical descriptions of biological behaviour (20, 22, 24, 34, 52), the successful use in the clinical setting in human medicine, and the uniform and comparable biomechanical characteristics demonstrated in the present study. On the basis of our results, cortical bone pins for fracture fixation should be milled from site A (males) or site C (females) of the left tibia of Greyhound dogs. The effect of sterilization techniques on the healing characteristics and biomechanical performance of cortical bone pins requires further evaluation.

Acknowledgements

The authors would like to acknowledge Drs. Peter Schwarz and Rodney Straw from the Department of Clinical Sciences, Colorado State University, Fort Collins, CO, USA; Drs. Ronald Holland and Daniel Stutts from the Department of Mechanical and Aerospace Engineering, University of Missouri-Rolla, Rolla, MO, USA; and Dr. David Strege from the Department of Orthopedic Surgery, St Louis University School of Medicine, St Louis, MO, USA, for their assistance and technical expertise.

References