Biomechanical comparison of the pullout properties of external skeletal fixation pins in the tibiae of intact and ovariectomised ewes.

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Citation  
Biomechanical comparison of the pullout properties of external skeletal fixation pins in the tibiae of intact and ovariectomised ewes

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Summary
The pin-bone interface is the least stable component of the external skeletal fixator. Concerns exist regarding the ability to obtain adequate implant purchase in poor quality bone. Consequently, reduced bone quality has been viewed as a contra-indication for the use of external skeletal fixators. The aim of this study was to investigate the holding power of two different fixator pin designs in bone from entire and ovarioctomised sheep. Thirty-two aged ewes were divided into two groups. Group 1 were controls, and Group 2 were ovarioctomised (OVX). The ewes were sacrificed 12 months post-ovarioectomy and five pairs of tibiae were harvested from each group. The holding power of cortical and cancellous fixator pins was assessed at five standardised locations on each tibia. An increase in mean cortical thickness was noted in the OVX group. The holding power of cancellous fixator pins was superior to that of cortical pins, irrespective of whether or not ovarioectomy had been performed. Cancellous pins had an increased holding power in post ovarioctomised bone compared to control bone. Cortical pin performance was not affected by ovarioectomy. There was a lack of correlation between the incidence of insertional fractures of the far cortex and implant holding power. The results raise questions over the effectiveness of ovarioectomy in establishing osteopoenic bone suitable for assessing implant performance, hence further investigations are warranted.

Keywords
Implant, holding power, mechanical properties, cortical, cancellous

Introduction
The pin-bone interface is the least stable component of the external skeletal fixator (1). As such, it is most often the determining factor in fixator longevity and subsequent clinical success or failure (2). Resistance to acute axial extraction (pullout strength) is an indirect measurement of integrity of the pin-bone interface, and is often referred to as ‘holding power’ (3). Holding power is known to be influenced by the method of pin insertion (4), pin design (5) and bone density (6, 7).

Low mineral density and deteriorated micro-architecture of bone are not only major risk factors for fractures, they also contribute to orthopaedic complications in fracture stabilisation. The attainment of adequate implant purchase remains a challenge in poor quality bone (8–10). Historically, pin-fixation has been contra-indicated in the stabilisation of such pathological bone (6, 11–14) however, recent in vitro studies have demonstrated that reduced quality bone no longer needs to be viewed as a contra-indication for the use of external skeletal fixators (15, 16).

The aspects of major interest in orthopaedic surgery are bone fragility, efficacy of implant fixation and bone healing. Various osteopoenic animal models have been established and used to investigate implant performance (17–20). The sheep has been proposed as an effective model (21–25) because ovine bone remodels and heals similarly to human bone (26). Decreased bone mineral density (23) and a reduction in the mechanical properties (27) of ovine bone have been demonstrated post ovarioectomy. Increased bone turnover (26, 28), and reduced bone mass (29, 30) have also been reported. Biomechanical markers of bone formation like bone-specific alkaline phosphatase have been reported to increase in sheep after ovarioectomy, indicating an increase in bone turnover similar to the human postmenopausal condition (23).

The aim of this study was to investigate the effect of ovarioectomy on the holding power of threaded implants using an ovine osteoopenic model. This paper describes an in vitro assessment of threaded external skeletal fixator pins in tibiae harvested from ewes one-year post-ovarioectomy, and compares the findings to a control group of similarly managed entire ewes.

Materials and methods
Surgical procedure
Thirty-two aged ewes were included in this project. Sixteen underwent ovarioectomy (treatment group) while the remainder were maintained under similar conditions but did not have their ovaries removed (control group). Under Irish Government license, ovarioectomy was performed through a veno-
strength (28).

Bone although his did not translate into a significant reduction in compressive bone. Cortical bone turnover and cortical porosity were significantly increased in the OVX group, there was a non-significant reduction in the modulus and ultimate compressive strength of the OVX cancellous bone (30). The left and right tibiae were randomly collected from five ewes in the control group (CON) and five ewes from the group OVX. Within eight hours of euthanasia, the bones were stripped of their soft tissue attachments and dual energy X-ray absorptiometry (DEXA) was used to determine the bone mineral density (BMD) at specific points along each tibia. The bones were individually wrapped in saline (0.9% NaCl) soaked towels, packaged in double plastic bags, and stored at –20°C. The specimens were numbered and the investigators performing the biomechanical testing were blinded to the group (CON or OVX) from which each specimen originated. Five pairs of tibiae were thawed at room temperature 24 hours before pin insertion and mechanical pullout testing. All of the specimens were kept moist with saline at all times. Several thawing and refreezing sequences do not change the mechanical properties of bone (32).

Assessment of bone quality

A wide variety of histomorphological and biomechanical tests were carried out on cortical and cancellous bone samples collected from both the control and post-ovariectomy groups. Micro-computed tomography imaging was performed to generate data relating to the histomorphology and trabecular microarchitecture of the specimens. Static compression testing was carried out in order to obtain information about the specimens’ mechanical properties and epifluorescence microscopy was utilized to quantify the degree of bone turnover. The results demonstrated that the sheep in the ovariectomy group (OVX) had changes in their cortical and cancellous bone quality consistent with the onset of osteoporosis (28, 30, 31). While there was a non-significant reduction in cancellous bone mineral density in the OVX group, there was a significant reduction in the modulus and ultimate compressive strength of the OVX cancellous bone (30). Cortical bone turnover and cortical porosity were significantly increased in the OVX bone although this did not translate into a significant reduction in compressive bone strength (28).

Bone preparation

The left and right tibiae were randomly collected from five ewes in the control group (CON) and five ewes from the group OVX. Within eight hours of euthanasia, the bones were stripped of their soft tissue attachments and dual energy X-ray absorptiometry (DEXA) was used to determine the bone mineral density (BMD) at specific points along each tibia. The bones were individually wrapped in saline (0.9% NaCl) soaked towels, packaged in double plastic bags, and stored at –20°C. The specimens were numbered and the investigators performing the biomechanical testing were blinded to the group (CON or OVX) from which each specimen originated. Five pairs of tibiae were thawed at room temperature 24 hours before pin insertion and mechanical pullout testing. All of the specimens were kept moist with saline at all times. Several thawing and refreezing sequences do not change the mechanical properties of bone (32).

Pin selection

Commercially available stainless steel cortical and cancellous, bicortical, end-threaded, positive profile pins (Veterinary Instrumentation, Sheffield, UK) were inserted into one of five locations on each tibia. All of the pins were new and were used only once during the study (Table 1).

The toss of a coin was used to randomly select which pin design (cortical or cancellous) was inserted at each of the five designated sites on the left tibia of each pair of tibiae. The alternate pin type was then placed at the equivalent site on the contralateral (right) tibia.

Table 1

<table>
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<th>Specifications of each external fixator pin design</th>
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<td>Material</td>
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</tr>
<tr>
<td>Diameter (mm)</td>
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<td>Length (mm)</td>
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<td>Overall length (mm)</td>
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Prior to insertion of each pin a 3.1-mm pilot hole was drilled perpendicular to the longitudinal axis of the tibia in a medial-to-lateral direction using a high-speed (600 rpm) bench mounted drill (Model # HDP600B, SIP [Industrial Products] Ltd., Loughborough, UK). A new drill bit was used for every eighth hole drilled. All of the pins were placed by the same investigator (B. Keeley), in accordance with the manufacturer’s guidelines. Pin placement was performed using a slow-speed (<150 rpm) power drill (Hitachi Impact Drill DV18V, Hitachi Europe Ltd., Maidenhead, UK) and insertion was stopped once the entire tro-
The tip of the pin had penetrated the far cortex. A second investigator observed pin placement and noted when the correct pin insertion depth was achieved, allowing one continuous insertion process.

**Mechanical testing**

A stainless steel flat washer (R.A. Poole & Co. Ltd., Chessington, UK) (internal diameter 18 mm, external diameter 35 mm) was affixed to the medial surface of the bone at each pin insertion point using methyl methacrylate (Demotec 95, Demotec Siegfried Demel, Nidderau, Germany). Washers were placed at 90° to the long axis of the pin in order to ensure a planar bearing surface for pullout testing. A spirit level was used to guarantee that the washers were level and that care was taken to exclude methyl methacrylate from within the internal diameter of each washer. Biomechanical testing was performed on the same day as pin insertion. The test specimen was positioned in a test fixture from which a counter force was produced against the washer. Pins were axially extracted with a constant extraction speed of 5 mm/minute, as defined by The American Society for Testing and Materials (ASTM) guidelines, using a universal testing machine (Hounsfield THE 050KS Test Equipment, Salfords, UK). The tibia was repositioned for each pullout test to accomplish exact alignment of each pin at all five tibial locations. The results of all pin pullout tests were recorded on a personal computer, and the ultimate load required to cause specimen failure was determined from the load displacement curves recorded (QMat Professional, Tinius Olsen Ltd., Salfords, UK); the ultimate load being marked by a clear drop off in the curve.

**Radiography**

After testing, the pins were removed using a slow speed (<150 rpm) electric drill (Siroflex Ltd. Vailance Works, Leeds, UK). A craniocaudal radiographic projection of each tibia was performed using digital radiography (Kodak CR500, Kodak Limited, Hemel Hempstead, UK). A radio-opaque marker was placed next to each tibia to allow quantification of any radiographic magnification. At each diaphyseal insertion site the cortical bone thickness and bone diameter were measured using the Kodak CR500 software. Cortical thickness was defined as the sum total of the width of the near and far cortices in the central cross-section of each diaphyseal insertion site. Pin tract length alone was measured at the metaphyseal insertion sites, as accurate assessment of the cortical bone thickness at these locations was deemed impossible.

**Holding power**

The holding power was determined for each pin at each of the insertion sites (33). For the purposes of this article, holding power was defined as yield strength per millimetre of cortical bone thickness at the diaphyseal insertion sites or yield strength per millimetre of pin tract at the metaphyseal insertion sites.

**Mode of failure**

Mode of specimen failure was categorised using visual examination of the near and far cortices of each tibia during and after pullout testing and from post-testing radiographs. Mode of specimen failure was categorised as: pin slippage within the universal testing machine, bone failure, implant failure, or failure at the bone-implant interface (shearing of bone around the pin threads). Failure was defined as an acute reduction in the ability of the pin to resist axial extraction from the bone specimen, visualised as a clear drop off in the load displacement curve.
Statistical analysis

Pullout data were expressed as mean ± SD. Student’s t-test assuming equal sample variance was used to compare pin pullout data. P<0.05 was considered statistically significant.

Results

DEXA analysis

A significant difference in BMD was not noted between groups at any of the pin insertion sites. The mean global BMD was 0.93 ± 0.09 g/cm² and 1.00 ± 0.04 g/cm² for the CON and OVX groups, respectively.

Cortical thickness

Evaluation of the cortical bone thickness at the diaphyseal pin insertion sites revealed a large variation in morphology between the different bone specimens and at different implant insertion sites. The maximum cortical thickness in the diaphyseal segments varied between 4.4 mm and 8.4 mm in the CON group, and 5.4 mm and 8.8 mm in the OVX group. The mean cortical thickness was significantly greater in the OVX group at all three diaphyseal insertion sites. A significant difference in pin tract length (bone diameter) was not observed between the CON and OVX groups (Figs. 2 and 3).
Holding power

According to the axial extraction forces recorded, cortical and cancellous pins placed in the CON group behaved differently from those in the OVX group. Implant holding power was significantly greater at site 5 (p=0.016) in the OVX group compared to the CON group irrespective of pin design. The same strong trend was noted at site 2 (p=0.078). In OVX bone, cancellous pins had a greater holding power than cortical pins at insertion sites 2 (p=0.048), 3 (p=0.023) and 5 (p=0.039). An association between extraction force of cortical pins and bone quality was not observed.

Pin design

The 3.2/4.8 mm cancellous pin was superior (p<0.05) at insertion sites 3 and 5 compared to the 3.2/4.0 mm cortical pin, irrespective of bone quality. The same trend was also noted at insertion site 1 (p=0.071). Cancellous pins had a statistically significant (p<0.05) increased holding power in OVX bone at pin insertion site 5 (p=0.001), and the same trend was noted at pin site 2 (p=0.077) and site 4 (p=0.060). There was not a statistically significant difference between the holding powers of cortical or cancellous fixator pins in CON bone (Fig. 4).

Failure mode

In all pullout tests, bone failure occurred without implant breakage. Pin pullout testing of both pin types consistently resulted in bone shearing along a line parallel to the outer edge of the pin’s thread. In all diaphyseal regions, there was shearing of the pin-bone interface at the far cortex with generation of a butterfly fragment at the near cortex (Figs. 5 and 6).

Coincidental findings

An audible crack was heard during advancement of 33% of both cortical and cancellous pins through the far cortex. This sound corresponded to visually evident chip fractures.
adjacent to the exit holes of the enhanced threaded pins and was only heard during implant placement at the diaphyseal insertion sites (Table 2).

Discussion

For uneventful healing of long bone fractures treated by external fixation, certain conditions are required of the bone/implant construct, namely the preservation of the capacity of the bone to heal and of a mechanically sound fixation. Fatigue of the implant, implant loosening and bone resorption may jeopardise optimal maintenance of a stable fracture reduction. Implant loosening is the result of a complex process of both mechanical and biological events that are initiated by microstructural trauma which occurs during the insertion of threaded implants (34, 35). Static preloading and cyclic loading of the implant by the patient propagates micro-cracks causing further implant loosening (35). Biological alterations, owing to vascular and thermal insult during implant insertion, result in the death of peri-implant bone (34), which further compromises implant holding power and fracture stability.

This study compared pin thread variables (cortical and cancellous designs) at metaphyseal and diaphyseal locations of ovine tibiae. The tibia was selected because of the relative frequency of external skeletal fixation usage on this bone. The use of paired tibiae for comparative implant pullout testing was considered to be an appropriate comparison technique in order to assess biomechanical properties of the two pin designs.

All biomechanical tests ended in failure of the pin-bone interface; bone shearing as a cylinder with a diameter equal to the outer thread diameter of the corresponding pin. Occasionally, a small cone of bone fractured from the near cortex and remained attached to the pin thread. This was due to the shear strength of the portion of bone avulsed being less than or equal to the implant holding power at this site (3, 36). Implant holding power is dependent on the major diameter of the pin, as well as the pin’s minor diameter, thread depth (defined as the distance from the apex to the base of the thread), extent of cortical bone engaged by the thread, density and shearing strength of the bone and the size of the pilot hole drilled (12, 13, 37, 38). It has been reported that the major diameter of a threaded implant needs to be considered as the most important implant-related factor influencing pullout force; other factors such as thread design, pitch, and minor diameter having been shown to have a lesser effect on pullout forces (5, 36, 39). The difference in major diameter between pin designs tested could explain the improved performance of cancellous pins compared to cortical pins.

Cancellous pins have been specifically designed for use in the metaphyseal and epiphyseal regions of long bones, where the cancellous bone has thin trabeculae (40). In this study, there was a trend towards cancellous pins having a greater holding power at the distal metaphyseal insertion sites, compared to cortical pins. However, the cancellous pins performed significantly better than cortical pins when placed at the proximal metaphyseal site of OVX bone. This improved holding power can most likely be explained by the design characteristics of cancellous pins. The larger thread depth and pitch, and a larger ratio between the major and minor pin diameters (37) allows a greater volume of bone to reside between threads and increases pin to bone surface contact (41).

There was not a statistically significant (p<0.05) difference between the maximum holding power of the pin designs at the metaphyseal insertion sites in control bone, despite the difference in the thread diameter. It has been reported that in regions with a cortical thicknesses of less than 1.5 mm, cancellous density determined the ultimate pullout load, while in regions with cortices thicker than 1.5 mm, cortical thickness alone significantly influenced the holding capacity of an implant (42). At metaphyseal locations, Marti and Roe (1999) reported that there is only a small amount of thread-bone contact between the trabeculae and the pin, the primary site of engagement appearing to be the thin cortical shell (43). The influence of pitch and thread depth on the pullout strength of implants in thin cortical bone warrants further study.

Insertional trauma associated with the use of cancellous pins has been seen as a contraindication for their placement in diaphyseal bone (44) although the results of this in vitro study do not support this finding. The fracturing of the far cortex during implant insertion was noted in one third of all cases in this study, and was observed with both types of pin. This phenomenon has previously been reported following the use of enhanced threaded pins with and without the pre-drilling of a pilot hole prior to pin insertion (2, 33). A higher incidence of insertional fractures was noted when inserting cancellous pins at the mid diaphyseal insertion site, or when placing both cortical and cancellous pins in control bone. Although insertional torque was not measured in this study, it could be speculated that the greater major diameter of the cancellous pin resulted in increased insertional torque and a subsequent increased incidence of fractures of the far cortex. No correlation between the presence of mild to moderate fracturing of the far cortex and implant holding power was detected in this study.

Bone strength can be defined as the ability of a bone to endure the application of force without yielding or breaking. It reflects the integration of two main features: bone density and bone quality (The National Institutes of Health Consensus Statement, 2000). With the advent of dual energy X-ray absorptiometry (DEXA)
scanning, the relationship between bone density and bone failure has been extensively investigated, including studies that prove a direct relationship between bone density and bone strength (45). A universally accepted definition of bone quality does not exist. Several factors may be involved; the most important is probably the micro-architecture of bone. It seems reasonable to view bone quality as a set of characteristics unrelated to bone mineral density that influence bone strength (46). The quality of bone is determined by many factors, including trabecular and cortical microarchitecture, bone turnover, the degree of mineralization of the bone matrix, and the amount of microdamage present (46).

Previous studies have shown that bone density has a major influence on implant holding strength, with only minor improvements being reached following modification of thread shape, pitch, and depth (6, 7). In this study, ovariectomy did not affect cortical pin holding power when compared with control bone. Additionally, cancellous pins had an increased holding power in OVX bone. The increase in cortical bone thickness noted in the OVX group is the most likely explanation for this improved performance. The relationship between cortical thickness and the surface area of the pin-bone interface has been previously reported (3, 11, 35, 36, 38, 39). Cortical bone thickness has a direct effect on the force required to extract a pin from the pin-bone specimen (47), implant holding increasing linearly and rapidly with increased thickness of cortex engaged by the thread (39).

The inability to detect a difference in bone mineral density (BMD) and altered implant holding power between the two study groups raises questions concerning the efficacy of this osteopaenia model. The significant increase in diaphysial cortical thickness in the OVX group is one possible explanation for the inability of DEXA to differentiate between the two study groups. Bone remodelling secondary to reduced bone quality may have resulted in a compensatory increase in regional bone quantity. McNamara et al. (48) reported microtensile testing of individual trabeculae collected from the proximal tibia of control and ovariectomised rats. One of the group’s main findings was that the Young’s modulus and yield strength of the cancellous bone from the ovariectomised group was higher than that from the control bone. This suggests that the biological system is compensating for the lower bone mass post ovariectomy by increasing the strength and stiffness of the bone that does remain. This may be seen as a ‘Wolff’s law’ type adaptation where a homeostatic strain is maintained on the mechanosensitive cells by increasing the stiffness of the tissue when the amount of it has reduced. Adaptive bone remodelling seems to be a viable explanation for the increase in cortical bone thickness observed in this study, i.e. an increase in cortical bone thickness compensated for a decrease in cortical bone quality. The bone quantity value obtained using DEXA is based on a two-dimensional measurement of area and does not consider the volume of the bone. Consequently DEXA is unable to differentiate between thin cortices composed of dense bone and thicker cortices composed of low-density bone (49). It has been hypothesised that when using DEXA, quantitative changes in cancellous bone are being disguised by increases in cortical bone thickness (30).

Other possible explanations for the increase in cortical thickness should also be considered. Arens et al. (50) recently demonstrated that marked seasonal variations in BMD and biochemical markers of bone turnover occur in entire sheep, characterised by increasing bone mass in the summer and decreasing bone mass in the winter. Our study commenced and concluded during the summer months but it is conceivable that increased vitamin D production secondary to improved weather conditions prior to culling may have affected cortical thickness. It does, however, seem very unlikely that seasonal variations affected the OVX group and not the CON group. Campbell et al. (51) have previously reported significant differences in BMD in sheep. The increase detected in cortical thickness could potentially be explained by chance variation between populations.

It has been shown that short-term (one year) oestrogen depletion in the ewe can result in structurally significant changes in bone density within the cortical bone of the radial diaphysis (52). Kennedy et al. (28) analysed intracortical bone turnover, intracortical porosity and level of resorption of bone harvested from the left metatarsal of the ewes included in this study. Cortical bone turnover was significantly increased in the OVX group at six, nine and 12 months. Increased intracortical porosity and resorption was also demonstrated in the OVX group 12 months post-ovariectomy (p<0.05). Bone quality parameters were significantly altered in the metatarsal cortical bone and it would seem fair to assume that this deterioration in bone quality is generalised. Despite the detection of significant alterations in bone turnover parameters and porosity in Kennedy’s study, mechanical testing failed to recognise changes in the compressive strength of the ovine cortical bone 12 months post-ovariectomy. The findings in this study fail to support the theorem that OVX bone has a reduced strength. It may be more appropriate to view post-ovariectomy bone as simply different rather than of reduced strength.

It is also worth considering the argument that ovariectomised sheep may not be a good model for osteoporosis (20, 53). The requirements for an animal model simulating the behaviour of osteopaenia bone during fracture treatment are different from those for pharmacological testing (20). Most animal models simulating the osteoporotic condition have been used to test drugs that have been developed to treat osteoporosis. Bone fragility, efficacy of implant fixation and bone healing must all be taken into consideration in the field of orthopaedics and traumatology. It is generally accepted that bone fragility is reflected in decreased BMD and bone mechanical properties (20). We failed to demonstrate significant changes in BMD or ultimate compressive strength in the cortical bone of ovine tibiae 12 months post-ovariectomy.

This biomechanical study provides a comparison of the holding power, measured as pullout strength, of two commercially available fixation pin designs. Implant holding power is a relatively simple, reliable, repeatable in vitro test but it is not without its limitations as holding power is only one of the components that govern how pins maintain fracture stability clinically. More factors than biomechanical advantage deter-
mine the clinical success of a new fixation principle or a new implant. In particular, questions concerning the osseous response to pin implantation and loading must be addressed. An in vivo study would be necessary to determine how the differences in thermal and microstructural bone damage between the two pin types affect the long-term stability of the pin-bone interface.

Bone remodeling (resorption and formation) takes place throughout life and is orchestrated by a complex interplay of bone cells and factors that regulate the functions of the cells. The principle influences on the remodeling process are those derived from mechanical loading and hormonal signals. Caution must be expressed when extrapolating the results from this in vitro study to clinical cases of disuse osteopenia. An absence of a continued load-bearing stress is accompanied by a marked cortical thinning secondary to decreased bone formation, whereas oestrogen depletion is associated with increased bone remodeling with resorption exceeding formation causing increased porosity. Further studies using in vivo models are required in order to investigate the effect that these differing bone responses have on implant holding power.

Postmenopausal bone remodelling is a well-established and heavily investigated phenomenon. Ovine animal models are widely accepted as an effective means of studying reduced bone quality (20). The significant effect that bone remodelling had on the holding power of the external fixator pins tested in this study highlights the need for further study of hormone-related bone remodelling. Continued investigations are necessary in order to test the efficiency and appropriateness of animal models for investigation of pin performance in osteoporotic bone.

Acknowledgements
This project was funded by the Higher Education Authority (HRB), under the Programme for Research in Third Level Institutions (PRTLI) Cycle 3, and also by the Health Research Board of Ireland under Grant no. RP/2004/229. The authors thank Veterinary Instrumentation Ltd., Sheffield, UK, for donating the external skeletal fixator pins tested in this study. Thanks also go to Brian Cloak and the staff at the Lyons Research Facility, UCD for expert animal care and handling.

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Vet Comp Orthop Traumatol 5/2008