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Research Article

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Expandable Screws Can Increase Fixation Strength But Can They Be Removed? An in-vivo Sheep Study Demonstrating Removal Of A Novel Expandable Screw

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Abstract

Screw fixation failures remain clinically challenging especially hip fracture fixation in osteoporotic bone. Prior studies have shown that expandable orthopaedic screw devices can improve biomechanical fixation in bone, but concerns over their removability remains. A novel expandable screw implant has been developed that optimizes both implant fixation and removability. The present study investigated the implant removability in an animal model.

A specially manufactured expandable screw implant was surgically implanted in 5 sheep for 4 months. The distal femur were extracted with the implants in-situ after euthanasia. The bone samples were scanned using micro-CT and the retraction torque of the expandable screw wings were measured to assess ease of removability.

Analysis of the micro-CT images verified that bone had not grown inside the expandable screw mechanism and all expandable screw samples were removed without complication. The mean peak torque to fully retract the screws ready for removal was 0.86 Nm (0.59-1.30 Nm) and the mean peak removal torque for the retracted screws was 7.98 Nm (1.70-15.40 Nm).

This large animal study result shows the feasibility of an expandable screw concept with a novel gapless design, to improve screw fixation strength mechanically, without compromising on the implant removability.

Keywords: Expandable Screw, Hip Fracture, Orthopaedic, Ovine, Trauma

1. Introduction

Hip fracture is one of the most common Emergency Department presentations for the elderly, with an annual incidence of 14.2M globally [1]. Implant cut-out failure rate reported in the literature for gold standard neck screw or blade system are between 1.2% and 7.8%, with lower bone density, unstable fracture types and larger implant tip-to-apex distance identified as risk factors for failure [2-11]. Given the large number of cases globally, this presents a large health and economic burden due to revision surgery, potential loss of independence and increased mortality rate. Recent advances in implant designs such as the X-Bolt and bone cement augmentation such as the DePuy Synthes TFNA aim to improve patient outcomes, especially in osteoporotic bone [12,13]. Bone cement augmentation has shown 0% cut-out rate in published clinical trials, and a recent Randomized Controlled Trial of the X-Bolt expandable fixation device compared to a gold standard lag screw showed a very low cut-out rate of 0.8% [15-17]. However, in both cases potential difficulty in removing the implant after long term implantation remains a clinical concern, especially in the X-Bolt clinical trial where 4 implants in 401 patients had to be revised due to cut-out failure. To date, no information demonstrating the removability of expandable devices has been reported, which could hinder surgeon's adoption of expandable devices due to the risk of difficult removal.

There have been previous attempts to improve fixation strength through expanding type devices such as the Brooker-Wills Nail and the Alta Dome Plunger from Howmedica [18,19]. However, all of these expanding devices risk bone in-growth into the expanding mechanism, jamming the mechanism open and preventing removal [20,21]. To obviate this issue, a new removable and expandable (REX) screw has been developed with design features to prevent bone growing into the expanding mechanism [14]. This is achieved by minimizing the internal gaps into the expanding mechanism to prevent ingrowth. Previous studies have investigated how well bone can grow into holes and porous surfaces to improve fixation and indicated that a hole size of greater than 140 µm is potentially a threshold for bone ingrowth [22-25]. However, no studies have investigated the maximum allowable gap size that would prevent bone ingrowth.

The REX Screw is designed to increase fixation strength and resistance to screw migration (especially in osteoporotic bone) by increasing the surface area in contact with bone by deploying the expander wings. A previous study demonstrated that the F- REX Screw for proximal femur fracture fixation had significantly improved performance compared to a standard screw in a synthetic bone model under cyclic testing [14].

This study investigated whether a designed gap size of 40 µm is sufficiently small to prevent viable bone ingrowth, and to validate the ease of removability and medium-term safety of the REX Screw in an in-vivo animal model.

2. Materials and Methods

2.1. In Vivo Model

Animal ethics approval was granted for the study through the Murdoch University Animal Ethics Committee in Western Australia (Permit No. R3122/19). Bilateral surgery around the femoral condyle was conducted from a medial approach in five healthy sheep to implant ten expandable screw samples. To allow for sufficient bone ingrowth the screw remained in situ for four months before the animal was sacrificed. See Supplemental Digital Content 1, which provides detailed information on the animals and their management preand post-surgery [26].

2.2. Expandable Screw Implant

The expandable screw was specifically designed for the animal study to have the same diameter as a human sized proximal femoral hip screw (10.4 mm) but with a shorter length (32 mm) to fit within the sheep femoral condyle. The screws were conventionally manufactured out of Titanium Grade 5 (Ti6Al4V) material and surface treated with anodization type 2. The screw has an internal expandable part consisting of two expandable wings coupled to a rod, which can be deployed outwards symmetrically by screwing an expander bolt along the internal channel of the screw to advance the rod (Figure 1). The expandable wings can be retracted by engaging and pulling the expander rod backwards which pulls the wings back and inwards, to allow the screw to be removed from the bone.

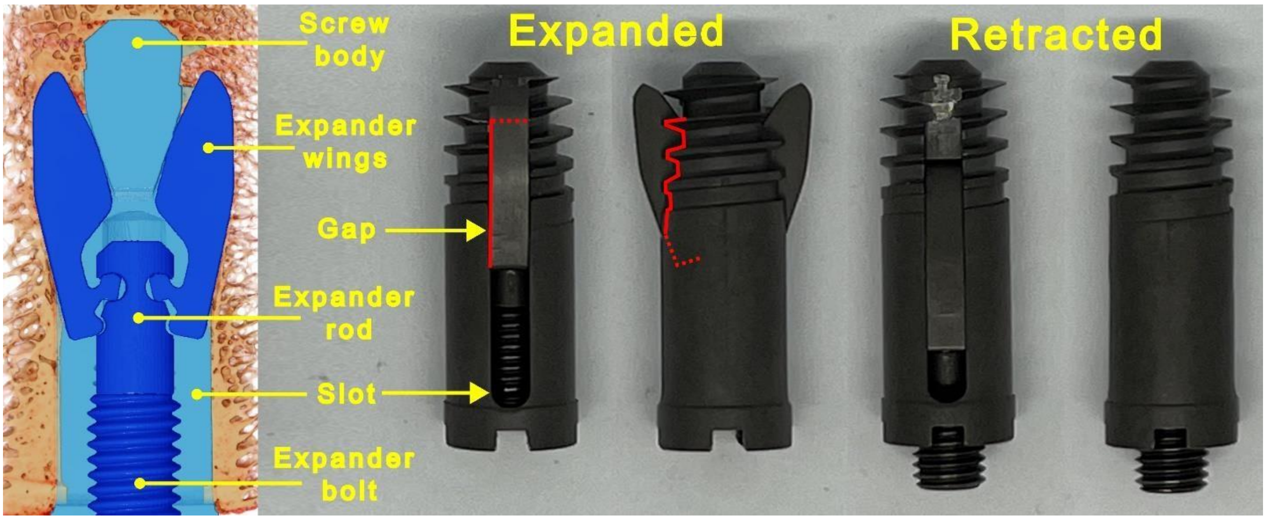

Figure 1: The shortened expandable screw; micro-CT cross section visualisation (left), when wings are expanded (middle) highlighting the gap into the expander mechanism in red and when wings retracted (right)

The expandable screw was manufactured with a 40 µm clearance at the critical location for bone in-growth into the internal mechanism (the gap between the wings and the slot of the screw body). All expandable screw parts and instrumentation for the surgery were steam sterilized (134°C for 4 mins).

2.3. Surgical Procedure

The surgery was conducted by an Orthopedic surgeon with the assistance of an Orthopedic Veterinary surgeon and Veterinary researcher. The distal femur condyle was exposed by a medial incision with the sheep in a supine position. A guide wire was used to confirm the screw trajectory through intraoperative X-ray imaging. A modified surgical bone drill was then inserted over the guide wire and a 32 mm deep hole was created for the expandable screw with saline irrigation throughout the drilling. The expandable screw implant was screwed in using a conventional screwdriver and then the expander wings deployed by turning the expander bolt using a torque limiting orthopedic screwdriver up to the designed expansion torque of 1.5 Nm. Once the wings were expanded in the bone, the fascia was tightly sutured over the defect and the wound was closed with absorbable sutures.

At the end of the 4-month implantation period, the sheep were euthanized with an overdose of intravenous pentobarbitone and the femurs were harvested. The distal portion was removed en-bloc and soft tissues were cleaned off each specimen which were stored at -20ºC before analysis.

2.4. Micro-Computer Tomographic Scanning

The bone specimens were scanned using high resolution micro-Computerized Tomography (micro-CT) with the Zeiss VersaXRM-520 at the Center for Microscopy, Characterisation and Analysis (CMCA) at the University of Western Australia (UWA).

The samples were scanned when the screw was fully expanded (Figure 2 left) and after the screw wings were fully retracted (Figure 2 right). Prior to micro-CT scanning and/or mechanical testing, the femoral condyle bone samples were thawed. To mitigate decay, samples were re-frozen and stored at -20ºC with each sample limited to five freeze thaw cycles. Detailed information on micro-CT scanning parameters can be found in the Supplemental Digital Content 2 and an animated 3D reconstruction of the micro-CT images can be found in Supplemental Digital Content 3.

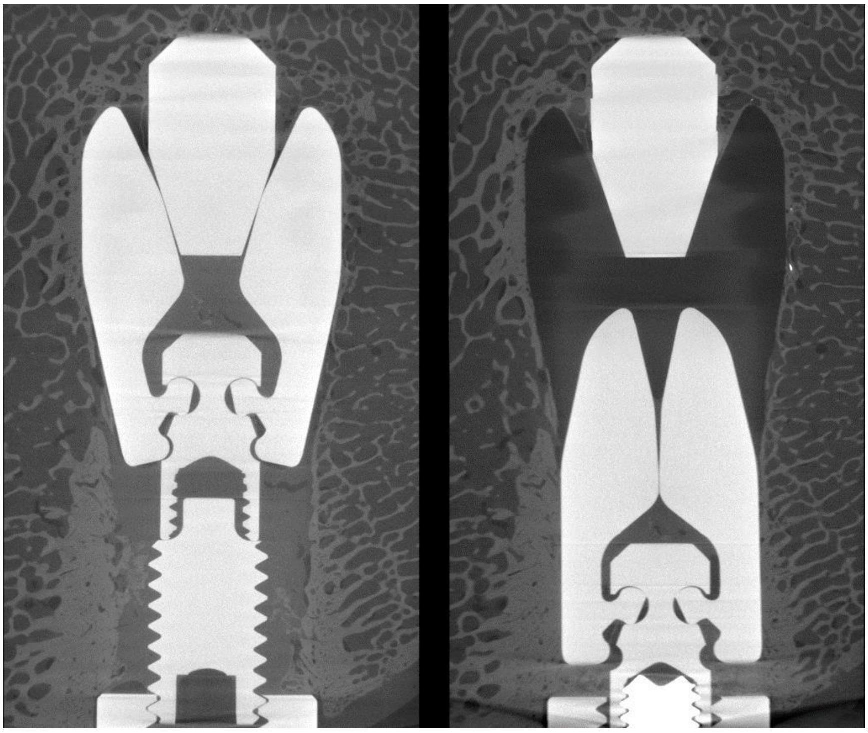

Figure 2: Micro-CT images of harvested bone samples. REX Screw wings expanded (left), REX Screw wings retracted (right)

2.5. Biological Ingrowth Analysis

The presence of biological material in the central screw mechanism was assessed by visual inspection of the micro-CT images. Bone formation in the slot was also inspected
to assess any impact, it may have on the removability of the screw and verify bone ingrowth.

2.6. Mechanical Evaluation

Once the expander bolt was removed, the REX screw removal instrument was attached. The removal instrument consists of an M4 screw that engages with the thread in the expander rod, and a nut on the M4 screw that abuts the top of the outer screw. Turning the nut retracts the M4 screw, which pulls back the expander rod and thus the wings connected to it until the wings are back in the original position and inside the slot. An Instron 8874 mechanical testing machine (Instron, High Wycombe, UK) at Royal Perth Hospital, Centre for Implant Technology and Retrieval Analysis (RPH-CITRA) was used to measure the torque required to retract the wings with the removal instrument.

The nut was rotated at 10 degrees/sec and angular rotation and torque values were recorded at 10 Hz. The pitch of the thread was used to calculate the linear movement from the measured rotation. After the wings were fully retracted, the screws were removed from the bone using a screwdriver adapted to fit a high precision electronic digital display torquemeter (WRG3-135) to simulate a manual removal procedure in surgery. Maximum torque was recorded at 90º intervals for the first 360º of rotation and then every 180º until the torque was below the sensitivity of the torquemeter (1.35 Nm).

3. Results

3.1. Surgery And Recovery

No adverse events were recorded during the surgery. All expandable screw samples were implanted and expanded to a torque of 1.5 Nm. There were no post-operative complications, and all sheep were able to stand or walk around the pen within two hours after surgery. Post-surgery X-ray showed acceptable screw positioning and expansion of the wings as shown in Figure 3 below. There were no recorded adverse events in the 4 months study period until the sheep were euthanized.

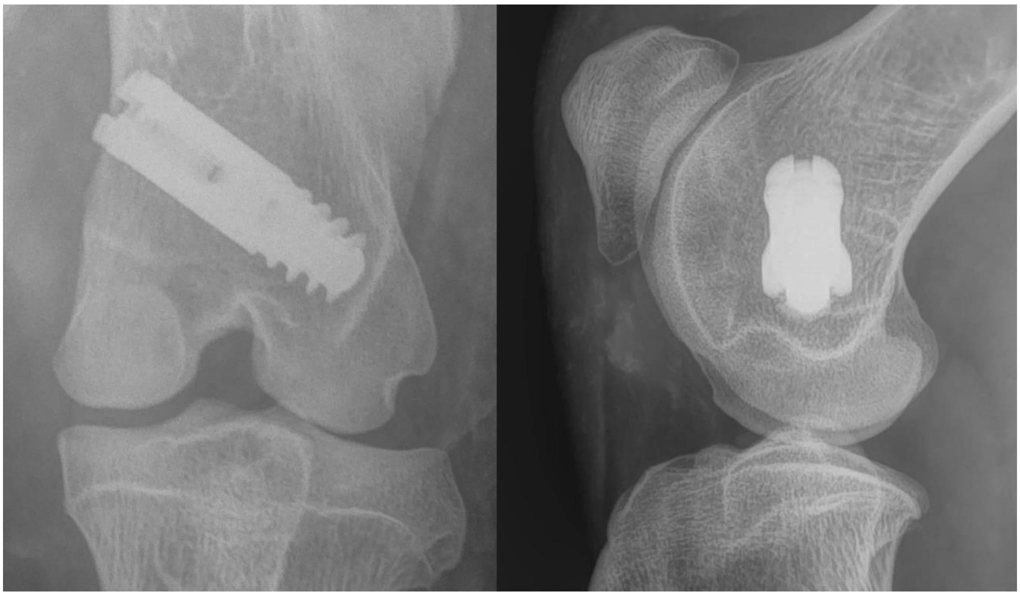

Figure 3: X-ray taken 10 days post-operatively, Anterior/Posterior view (left), Lateral view (right)

When harvesting the sheep femora, no adverse reaction was observed in the bone or tissue surrounding the implant. No inflammation or evidence of significant seroma was observed in any sample.

3.2. Bone Ingrowth Analysis

As anticipated, bone ingrowth into the external slot of the screw was observed on the micro-CT images as shown in Figure 4. An unstructured non-calcified material with a density lower than bone was also observed inside the mechanism of the screw. A similar material was also observed in the cavity bounded by the expander rod and expander bolt, which have conformal anodized surfaces under compression. Further analysis on the gap size of the slot/wing interface is provided as Supplemental Digital Content 4.

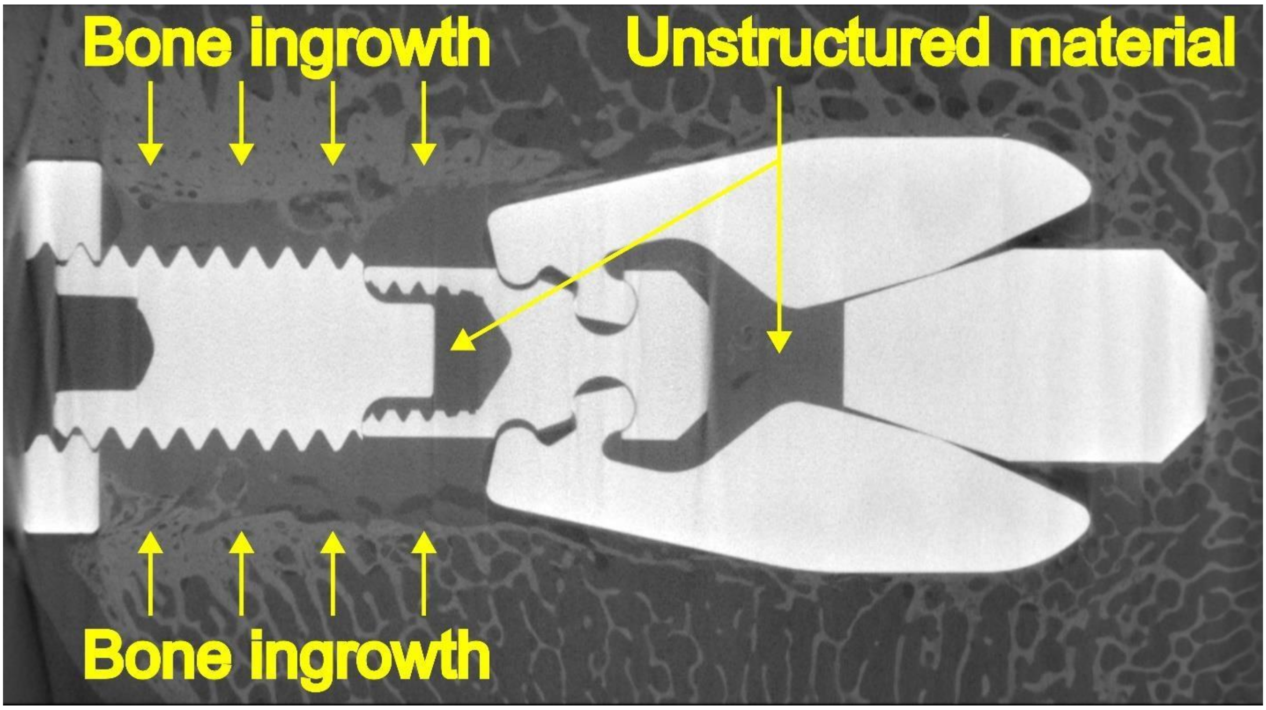

Figure 4: Qualitative bone ingrowth analysis of REX Screw sample

3.3. Mechanical Testing

In all samples, the wings were successfully retracted without complications. The mean peak torque to fully retract the screw was 0.864 Nm (0.586-1.30 Nm). Figure 5 shows the traces of the wing retraction torque from the starting expanded position (0%) to the final retracted position (100%). The retraction torque typically had two distinct stages. The first stage is where the wings initially move back and separate from the surrounding bone, thus breaking the osseointegration bond along the surface of the wings. The second stage is where the wings are retracted until they are fully inside the screw outer diameter, allowing for the screw to be removed. Throughout the second stage of retraction, the torque increases as bone material is accumulated behind the wings and compressed.

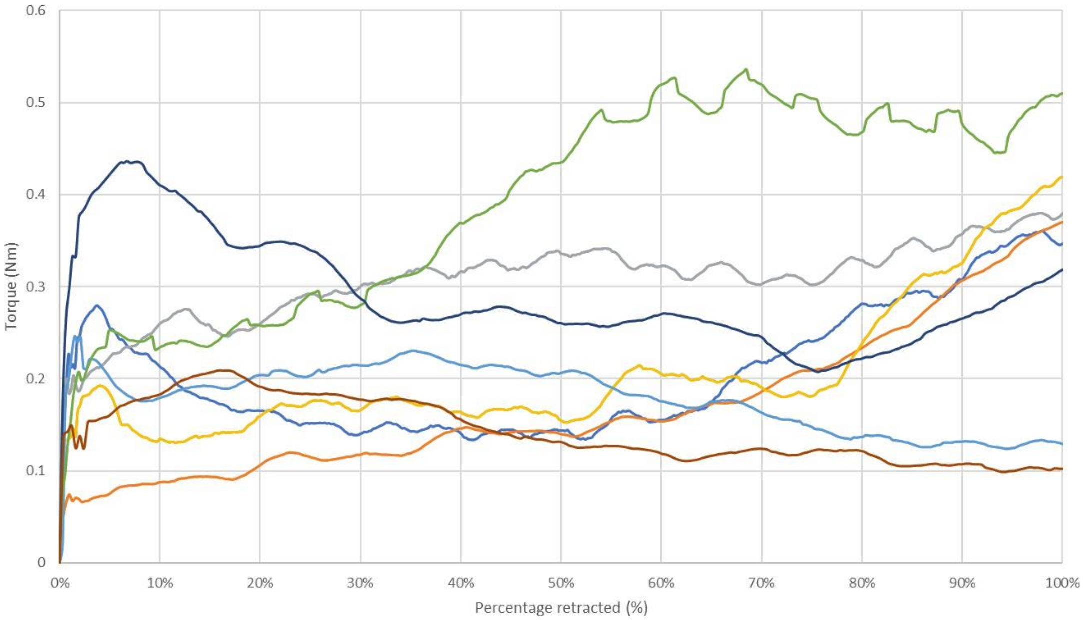

Figure 5: Expander wings retraction torque from expanded (0% retracted) to fully retracted (100% retracted)

Once the wings were retracted, all screws were successfully removed using the digital torque screwdriver with an average peak removal torque of 8.55 Nm (1.70-15.40 Nm) which occurred in the first quarter turn of the screw in each case. The removal torque then progressively decreased before complete removal from the bone.

4. Discussion

This study demonstrated that a gap size of 40 µm was small enough to prevent bone ingrowth and also validated both ease of removal and medium-term safety of the REX Screw in an in-vivo ovine animal model. The present study using the sheep femoral condyle allowed implantation of a standard diameter expandable femoral lag screw while having sufficient cancellous bone volume for implant expansion. A medial approach was selected as it allowed the surgeries to be performed bilaterally without repositioning the sheep during surgery, minimizing surgical time and risk of infection for the sheep. The femoral condyle of sheep and the use of a bilateral model have been used previously by several other studies investigating screw osseointegration [28-30]. The fact that we used an unloaded bone model, without the presence of a fracture, is likely to affect the bone osseointegration and potentially the screw removal torque. However, based on previous studies, an unloaded model typically creates a more favorable condition for bone ingrowth and so therefore a more conservative model for the purpose of this study [22].

Assessment of medium-term safety and removability of the REX Screw in an animal model requires sufficient time for the implant to osseointegrate to the surrounding bone, which occurred within 4 months in comparable studies [26, 28-30]. This duration is clinically relevant to the context of implant removal after complete fracture healing (typically between 6-12 weeks) and well advanced into the re- modelling phase, where immature bone (plus remnant traces of cartilage and fibrous repair tissue at the defect site) is replaced with mature bone [31]. However, implants may need to be removed many years after implantation, e.g. after the patient has developed osteoporosis and requires a hip replacement.

During the surgery it was necessary to apply high force on the drill-bit (designed for human hip fracture surgery) to create the screw hole due to the denser sheep bone. Future animal studies could use drills that are designed for denser bone. Despite this, the surgical procedure for implantation was uncomplicated and clinically relevant, being exactly the same as a typical hip screw insertion method with only one additional step; screwing the TORX screwdriver to expand the wings.

Future studies could also use a control screw to investigate the difference in removal torque compared to a standard screw or use a mechanical testing machine to measure screw removal torque to increase the consistency of the removal torque. This study did not use a control screw and measured removal torque using a digital display torquemeter screwdriver controlled by hand as we were primarily interested in the retraction torque and ensuring the screw could be retracted reliably and removed by using a handheld screwdriver. Once the screw was retracted, the screw removal torque was not anticipated to significantly differ to that of a conventional screw.

In the present study the REX Screw design was shortened for implantation into the sheep distal femur which could only accommodate a maximum length of 32 mm (compared to 80-130 mm for human femoral neck screws). The diameter of the screw was maintained at 10.4 mm in order to minimize design changes to the expander mechanism to maintain clinical relevance. To accommodate the reduction in overall length, the wings expansion size was reduced and the expansion angle was increased. Future studies could investigate scaling down the entire screw to maintain the expansion profile. However, this may be less clinically representative as the expansion mechanism geometry would not be the same and would result in overall lower removal forces, indicating that the current study model was conservative.

The gap between the side of the wings and the screw outer slot, which we determined was the largest gap, is due to the machining tolerance of both parts. The samples were made using tolerances that were anticipated to be achievable with orthopedic implant mass manufacturing processes.

Based on size alone bone cells may be able to penetrate very small gaps (down to 15 µm), however without stress stimulus and other biological requirements such as blood flow, mineralised bone structure would not form [32]. The lower density material observed inside the expanding mechanism is thought to be unstructured collagen. On a macro level, this material was observed to be soft and jelly-like and easily compressed inside the mechanism during unexpansion. It did not present a barrier to wing retraction and removability which is consistent with our mechanical testing results. The bone that grew into the slot appears to be dense cortical-like bone with minimal trabeculae structures.

Damage to the bone surrounding the expanded wings during retraction could be a clinical concern. However, as indicated in Figure 6, the interface between the wings and the bone was left intact after wing retraction, demonstrating negligible bone disruption during retraction.

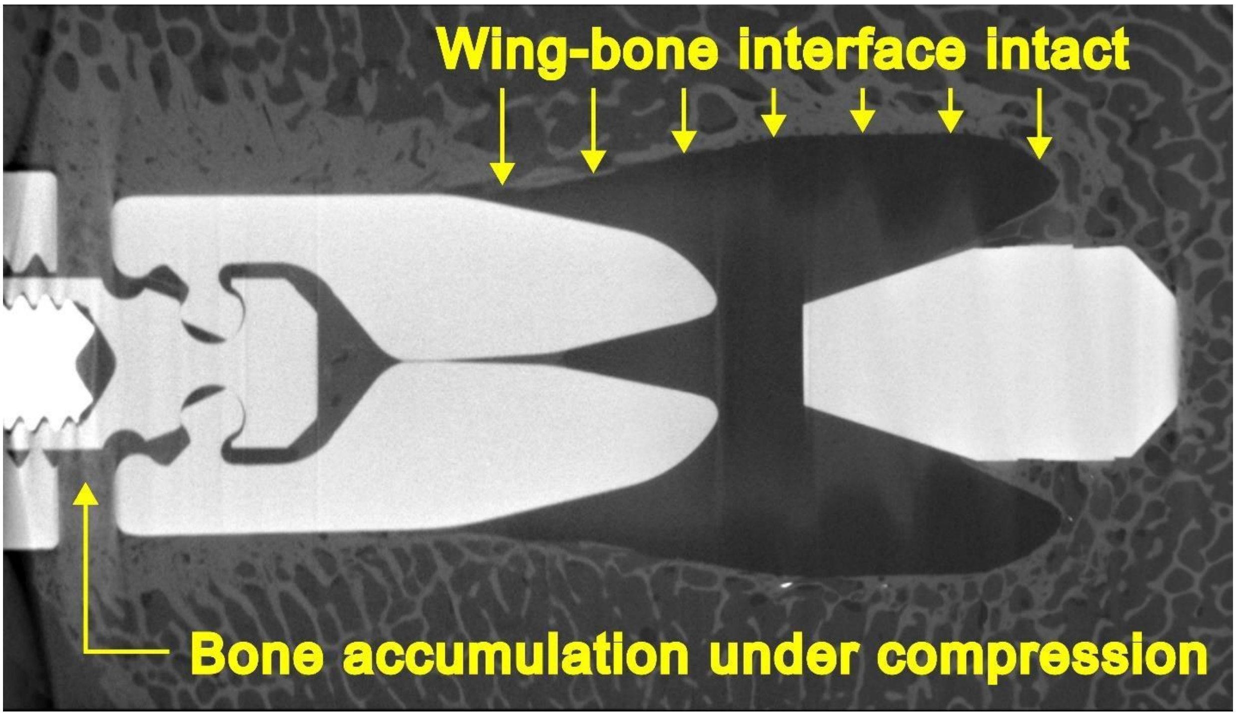

Figure 6: During retraction of the wings bone accumulated behind the wings and was then compressed whilst the wing-bone interface was left intact, demonstrating negligible bone disruption

As shown in Figure 5, during the first stage of retraction, a potential osseointegration peak torque was observed in most samples, however this torque was less than 0.5 Nm in all samples indicating minimal osseointegration force on the surface of the wings. The fact that some samples did not show a distinct osseointegration peak could be that the gentle hand tightening to secure the samples onto the removal jig was sufficient to overcome the osssointegration force, prior to the torque measurement recording.

During the second retraction stage the torque typically increased throughout unexpansion due to the bone accumulation behind the screw arms being compressed as the back of the wings approached the end of the slot. However, the peak torque was still relatively low (significantly less than 1 Nm in all samples) compared to torques seen in other orthopedic surgeries. For example, manufacturer recommendation for locking screws tightening torque is up to 4 Nm [33].

Although the torque required to retract the wings was minimal, the torque required to remove the screw after the wings are retracted is still substantial, demonstrating strong osseointegration on the screw thread and confirming that the sheep model is an aggressive bone ingrowth model. Table 1 outlines previous studies and compares the removal torque to surface area ratios reported in the literature to the results from the present study.

	Animal model	Implantation time (weeks)	Diameter (mm)	Length (mm)	Surface area (mm^2)	Average peak removal torque (Nm)	Removal torque/ surface area ratio ($x10^{-3}$)
Present study	Sheep femur	16	10.4	30	980	8.55	8.70
Marin et al. (2008) [34]	Dog tibia	4	4	10	126	1.36	10.8
Pearce et al. (2008) [35]	Sheep tibia	6	3.5	10	110	1.22	11.1
Cheng et al. (2010) [36]	Rabbit tibia	8	3	10	94	0.23	2.44
de Lima Fernandez et al. (2007) [37]	Rabbit tibia	9	3.75	5.5	65	0.33	5.09

Table 1: Comparison of removal torque to screw surface area ratios reported in previous studies

Although there have been no previous removal torque studies with such a large diameter screw, the removal torque to surface area ratio was similar to previous studies using smaller diameter screws. In addition, previous studies have typically been investigating the effects of various surface treatments to improve osseointegration which explains why some of these ratios are higher than the present study.

5. Conclusion

This study demonstrated that the designed wing to slot clearance of 40 µm, achievable in orthopedic implant manufacturing, were sufficient to avoid mineralized bone ingrowth into the expansion mechanism of the REX expandable screw. After being implanted in sheep for 4 months, the wings of the expandable screw samples required very low torque to retract and the retracted screws were removed without complication or visible damage to the bone. The highest torque was observed during the screw removal, which was comparable to conventional screws. This study demonstrates a promising path for expandable screws to increasing fixation strength without compromising removability.

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Declaration of Interest Statement: Matthew Oldakowski, Intan Oldakowska and Markus Kuster are inventors of the REX Screw technology. Philip Procter is a consultant to REX Ortho Pty Ltd. For the remaining authors no conflict of interest are declared.

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Supplemental Digital Content 1

Animal management

The sheep were selected from the Murdoch University farm flock for the experiment. The sheep were large skeletally mature (approximately 3 years old) Merino ewes with a mean weight of 63.8kg ± 13.7kg. This was both to ensure that no growth plates were present in the femoral condyle and that the femur would be as large as possible to cater for the equivalent screw diameter to a human hip screw design. All experiments were conducted in accordance with the animal research guidelines, Australian Code for the Care and Use of Animals for Scientific Purposes, 2013 (the Animal Code) and the Animal Welfare Act, 2002 (WA), and all efforts were made to minimize animal suffering.

All efforts were made to maximize animal welfare and provide a comfortable environment during the peri-operative and post-operative period. The sheep were acclimatized for 2 days in straw-bedded pens at the Murdoch University Animal Hospital, Perth, Australia.

Prior to surgery, the sheep were premedicated with buprenorphine (0.02 mg/kg) and acepromazine (0.03 mg/kg) by intramuscular administration, 30-45 minutes prior to catheter placement in the cephalic vein. Induction was performed using intravenous administration of diazepam (0.25 mg/kg) and ketamine (5 mg/kg), to effect. Once adequate depth was achieved, an endotracheal tube was inserted and attached to a rebreathing breathing system. Anaesthesia was maintained with isoflurane (2-3%) delivered in oxygen. All sheep were mechanically ventilated using volume controlled ventilation with an initial tidal volume of 10mL/kg and respiratory frequency of 12 breathes per minute. Tidal volume and respiratory frequency were adjusted as required to maintain end-tidal carbon dioxide tension of 35-45 mmHg. Routine monitoring included clinical assessment of depth of anaesthesia, pulse oximetry, capnography, electrocardiography, invasive

arterial blood pressure and oesophageal temperature. In addition to the buprenorphine administered prior to anaesthesia, intra-operative analgesia was provided using an ultrasound-guided femoral nerve block (bupivacaine 1 mg/kg) performed at the femoral triangle After anaesthesia, the sheep were transferred to a small recovery pen, to restrict movement, and positioned in sternal recumbency with the head elevated. The endotracheal tube was removed when the sheep were actively swallowing. Sheep were continuously monitored until standing, so assistance could be provided if necessary.

The sheep were returned to the pens postoperatively and continuously monitored until they were able to stand easily to prevent injury. The sheep were provided with a high-fiber diet and were housed together as a flock to reduce stress.

Postoperative analgesia was provided using meloxicam 1 mg/kg administered subcutaneously at end of surgery and repeated 48 hours after the first dose. Buprenorphine was also provided at 0.02 mg/kg by intramuscular injection every 12 hours for 3 days, starting 12 hours after premedication. A broad-spectrum antibiotic (amoxycillin 7 mg/kg and clavulanic acid 1.75 mg/kg) was continued daily for three days postoperatively.

All sheep were clinically examined daily for the first 10 days for signs of surgical site infection, lameness or other concerning behavior. Ten days after surgery, external sutures were removed from the surgical site and X-rays of the femurs were taken to confirm the screw placement. After this review, the sheep were returned to pasture in a small paddock on the Murdoch University on-campus farm. The sheep were visually inspected daily throughout the study period, with more thorough examination including clinical examination, palpation of implant site, and pain score assessments weekly for 2 weeks and then monthly for the remainder of the study period.

Supplemental Digital Content 2

Micro-CT scanning protocol

For X-ray micro-computed tomography (X-ray µCT) each sample was wrapped in plastic film and mounted onto custom 3D printed supports adapted in each case for scanning the device in the expanded, retracted and removed state. A small notch was cut into one surface of each bone in order to position the sample in a similar orientation for each repeat scan. Scanning was undertaken on samples brought to 28oC at 140kV and 10W using a Versa 520 XRM (Zeiss, Pleasanton, CA, USA). An HE4 beam filter was used to mitigate beam hardening and increase contrast. Source-sample and sample-detector distances were set to -63 and 150 mm, respectively, which together with the 0.4X objective and 2x camera binning, resulted in a final pixel resolution of 20.4 µm. Suitable image intensity was achieved with an exposure of 5 s and a total of 1001 projections were collected through 360° for each tomography. In order to capture the full length of the implant at this pixel resolution, vertical stitch mode was used to capture two tomograms with a minimum overlap of 21% and a default cone angle of 12 degrees.

Reconstruction of projection data was conducted using XRM Reconstructor (Zeiss, Pleasanton, CA, USA), which performs centre shift and beam hardening corrections automatically upon scan completion using default parameters. The two reconstructed tomograms were automatically stitched by the software.

Supplemental Digital Content 3.wmv

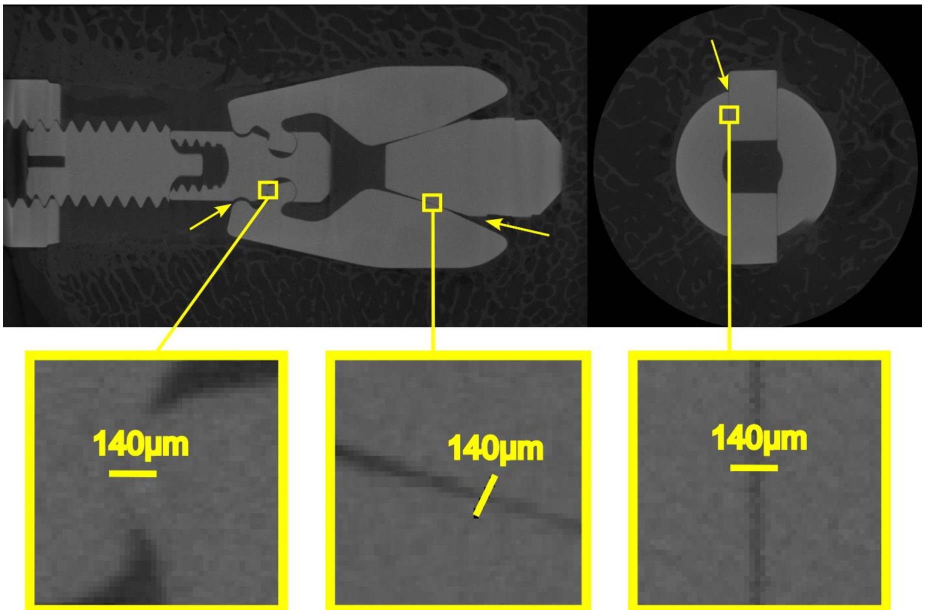
https://www.opastpublishers.com/assets/videos/supplement-digital-content.wmv

Supplemental Digital Content 4

Screw gap analysis

The processed micro-CT image stacks of each expanded sheep screw sample (SDC 4 Figure) were visually analyzed to identify the largest gap that could allow bone to grow into the central screw mechanism. The identified gaps were further analyzed to verify that they were below the threshold of 140µm.

There are three locations where the REX screw parts interface and there is the potential for gaps into the expanding mechanism where bone ingrowth may occur, the expander rod joint interface (SDC 4 Figure left inset), the tip of the wings where they interface with the screw inner (SDC 4 Figure middle inset) and between the side of the expander wings and the outer screw slot (SDC 4 Figure right inset). Inspection of the gap size in the micro-CT images determined that the largest gap is between the side of the expander wings and the outer screw slot is much less than the 140µm reported to prevent bone ingrowth (22).



SDC 4 Figure: Locations of gaps into the expanding screw where bone ingrowth could occur (indicated with arrows)

Accurately measuring the gap size within the screw was challenging due to the pixel size of the images relative to the gap size. Scanning the samples with a higher resolution would be able to give a more accurate measurement of the gap size, however the current pixel size (approximately 20μm) was sufficient to demonstrate that the gap size was substantially less than the theoretical threshold for bone ingrowth of 140μm (22).