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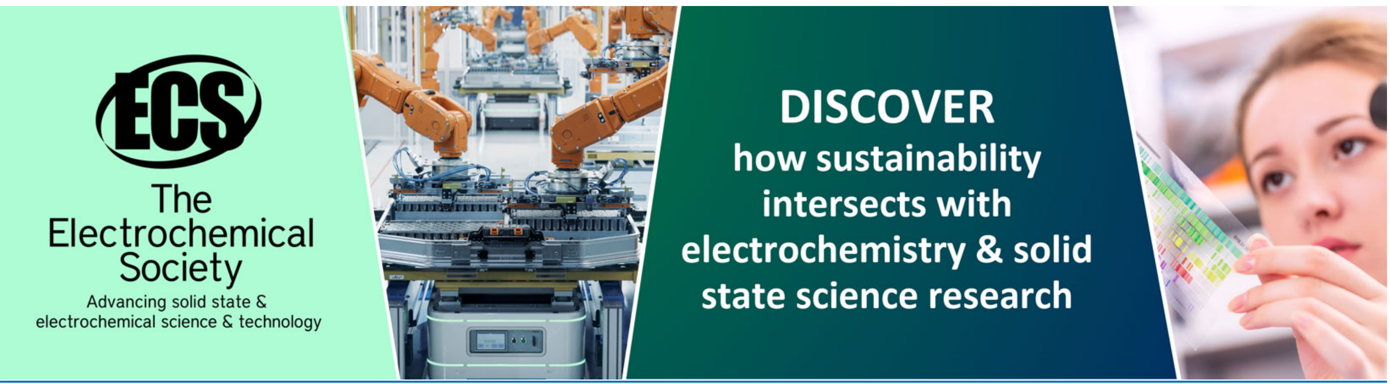

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Influence of bone morphological properties on a new expandable orthopaedic fastener

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Abstract. Previous studies have demonstrated that bone morphological properties are a significant determinant of orthopaedic fastener fixation strength. The authors previously tested a new design of unthreaded expandable fastener (UEF) prototype against screws and demonstrated a significant increase in pull-out strength. However the effect of bone morphology on the pull-out strength of the UEF and expandable fasteners in general is unknown. This study assessed the correlation between failure force and maximum force against five microstructural parameters. The failure force of the UEF was correlated to the trabecular bone volume fraction, as with screws. Unlike screws, however, the maximum force of the UEF has an inverse relationship with cortical volume. No correlation was found between failure force and the Structural Model Index (SMI). Additionally the critical volume of interest (VOI) for the UEF is around the bottom of the fastener where the expansion occurs, whereas for the screw a full height VOI is critical. Furthermore, we observed that screw mechanical performance may be affected more by bone morphological parameters that are associated with poorer quality bone. Therefore the UEF may perform better than screws in low quality osteoporotic bone.

1. Introduction

Orthopaedic screws have long been used to affix orthopaedic implants to bone in order to stabilise fractures and fuse joints. However screw loosening and pull-out are still significant problems [1, 2]. In order to address these problems, the authors are developing a new design of expandable fastener to provide superior fixation strength and reduce the incidence of loosening.

Pull-out strength is a critical measurement of the performance of orthopaedic fasteners. Low fastener pull-out strength can lead to screw loosening in–vivo, causing injury and potentially requiring revision surgery. Often the cause of this failure is low quality bone due to osteoporosis [1, 2]. In a previous study [3], the authors have demonstrated a 41% higher failure strength for a new design of unthreaded expandable fastener (UEF) prototype compared to conventional orthopaedic screws of equivalent length and diameter in a non-osteoporotic ovine bone model. King and Cebon have also demonstrated favourable results for expandable fasteners in osteoporotic bone but not in normal bone, indicating that expandable fasteners may perform better relative to screws in poor quality bone [4].

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Many ex–vivo studies have investigated the correlation between Bone Mineral Density (BMD) and screw pull-out force with varied success [5]. More recently researchers have begun to assess the effects of trabecular bone morphology on screw pull-out strength. In 2010, Poukalova *et al*. investigated how the trabecular bone structure immediately adjacent to screws affected their pull-out strength and demonstrated significant correlations with some microstructural properties [6]. Ab-Lazid *et al*. investigated the effect of bone microstructure, using a volume of interest (VOI) centred on the screw and demonstrated a strong relationship between most microstructural properties [7]. The diameter of the VOI for their study was taken from the deformed area during pull-out loading in the FEA study by Wirth *et al*. [8].

This paper aimed to quantify the effects of bone quality on the pull-out strength of a new design of UEF and compare this to standard orthopaedic screws. Furthermore the study investigated the VOIs in which the bone properties are most critical, allowing future studies to use the most appropriate VOI.

2. Method

The pull-out testing data and CT scans analysed in this study were taken from a previous study by the authors [3]. Briefly, experimental square unthreaded expandable fasteners were manufactured using a Realizer SLM100 machine from a low–modulus pure–beta titanium alloy Ti2448 (Ti-24Nb-4Zr-8Sn, all in wt%). The parts were produced using a standard contour and vector fill scanning strategy, with the direction of the fill vectors rotated 90° between layers. The laser power was 120W for the contour and 175W for the fill, while the scan speed, scan spacing, beam compensation and layer thickness were 1000 mm/s, 100 μm, 60 μm and 50 μm, respectively. The particle size of the powder was 45 μm.

The expandable fasteners were 10mm long, 4mm wide and expanded to approximately 6.2mm. The most critical novel design feature of the UEF is the expansion sides having dedicated bending sections that have a thin rectangular profile with minimal area moment of inertia. This allows a much larger expansion than currently available expandable fasteners with purely elastic expansion (see figure 1). An ISO 5835 cancellous orthopaedic screw was also tested for comparison purposes. The screws were self-tapping and had a 4 mm outer diameter, were 40 mm long, had a pitch of 1.9 mm and thread depth of 0.5 mm (see figure 1). Both the fasteners and screws were inserted at 10mm depth and tested in pull-out using an ovine vertebral body.

The bones were CT scanned using the Skyscan 1176 micro-CT scanner at the Centre for Microscopy, Characterisation and Analysis, at the University of Western Australia. Scanning was performed after the pilot holes were created at 18 microns resolution, using a rotation step of 0.5°, 2 frame averaging, a source voltage of 80 kV, an exposure time of 285 ms and Cu+Al filter. A 3D median filter was applied to remove noise and cortical segmentation was performed using a modified method based on the work of Buie *et al*. [9]. Pull-out testing was performed using an Instron 8874 with a quasi-static 5mm/minute loading rate and failure force and maximum force were recorded. Failure force was defined as the highest force before significant non-linearity in the force-displacement curve and maximum force was defined as the highest force anytime during the pull-out test.

Bone property measurements were calculated from CT scans of the bone samples in the VOI created by centring a cylinder on the fastener location, with varying diameters and heights measured from the bottom of the fastener (figure 2). We created VOIs from 6mm to 16mm diameter in 2mm increments and from 2mm height to 10mm height in 2mm increments.

Bone properties were calculated using FIJI [10], an open source image analysis program and the BoneJ [11] plugins. Trabecular volume (Tb.V) and cortical volume (Cor.V) were calculated by voxel counting. The trabecular bone volume fraction (Tb.V/TV) was calculated as the quotient of the trabecular bone volume and total bone volume, where the total bone volume was calculated by applying a 15 iteration 3D voxel dilation/erosion to create a solid bone volume. Trabecular length (Tb.L) was calculated using a 3D skeletonisation procedure [12]. Trabecular Bone surface area (Tb.SA) was calculated by creating a surface mesh using the marching cubes algorithm and summing the area of the triangles making up the mesh [13]. Structural Model Index (SMI) was calculated using the voxel dilation method [14]. All calculations were performed at 35 microns resolution.

Correlation analysis of sample bone properties to failure force and maximum force were performed based on paired Pearson coefficients with a high degree of correlation defined as $r>0.6$ or $r<-0.6$. The probability of significance of the correlation was calculated using a two-tailed test with a correlation having $p<0.05$ considered to have a high probability of significance.

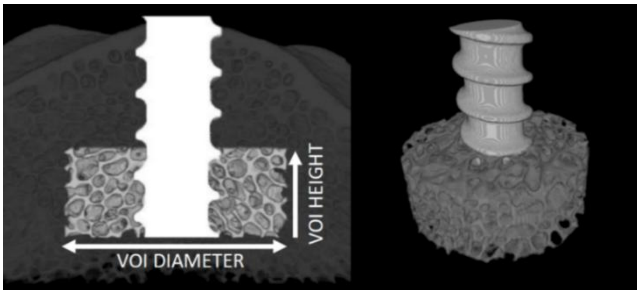

Figure 1. (left) Tested UEF prototype and screw [3].

Figure 2. (right) VOI defined by the VOI diameter and VOI height.

3. Results

Table 1 reports the correlation coefficients (r-values) and the corresponding probability of its significance (p-values) for the relationships between mechanical performance and the bone morphological properties. Only at the VOI diameter and height combination with the lowest p-value is reported to highlight the critical VOI for the screws and expandable fasteners. For screws, the maximum force is equal to the failure force.

Table 1. Correlation between mechanical performance and bone morphology.

		Tb.V/TV	Tb.L	SMI	Tb.SA	Cor.V
EF - Failure Force	r-value	0.740	0.870	-0.471	0.769	-0.538
	p-value	0.018	0.002	0.201	0.015	0.135
	VOI Diameter (mm)	8	14	10	14	8
	VOI Height (mm)	2	2	4	2	-
EF - Maximum Force	r-value	0.526	0.765	-0.343	0.838	-0.857
	p-value	0.146	0.016	0.366	0.005	0.003
	VOI Diameter (mm)	8	16	10	16	14
	VOI Height (mm)	2	2	4	2	-
Screw – Failure/ Maximum Force	r-value	0.710	0.414	-0.685	0.580	0.222
	p-value	0.032	0.268	0.042	0.102	0.566
	VOI Diameter (mm)	8	6	8	6	16
	VOI Height (mm)	10	10	10	10	-

Trabecular bone volume fraction demonstrated a high degree of positive correlation with failure force for the screw over all full height VOI diameters (figure 3). The highest correlation ($r=0.710$) with a high probability of significance ($p=0.032$) was demonstrated at full (10mm) height and 8mm diameter. For the UEFs a high degree of positive correlation was only demonstrated for failure force over a small range of VOI diameters (6-8mm) and VOI heights (2-4mm). The highest correlation ($r=0.740$) was found at 2mm height and 8mm diameter, and is considered to have a high probability of significance ($p=0.018$).

Cortical volume demonstrated a high degree of negative correlation with maximum force for the UEFs over all VOIs tested. The highest correlation ($r=-0.857$) with a high probability of significance ($p=0.003$) was found for a 16mm diameter VOI for cortical volume (figure 4). This relationship was negative, indicating a higher pull-out strength for thinner cortices. Only a weak correlation was found between the cortical volume of the screw set and the failure force.

Trabecular length demonstrated a high degree of positive correlation (r=0.870) with UEF failure force (p=0.002) and trabecular bone surface area also demonstrated a high degree of positive correlation (r=0.838) with UEF maximum force (p=0.005). Both correlations having a high probability of significance. A weak correlation was demonstrated between screw failure force and trabecular bone surface area. SMI demonstrated a high degree of negative correlation with screw failure force for VOIs between 6mm and 10mm diameter with a full height VOI, however no significant correlation was found for the UEFs.

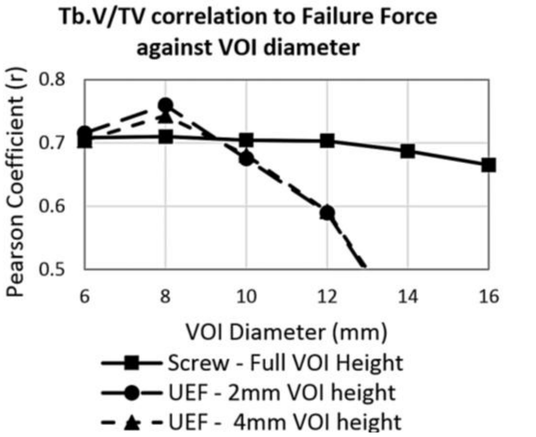

Figure 3. Correlation coefficient between Tb.V/TV and failure force against VOI diameter.

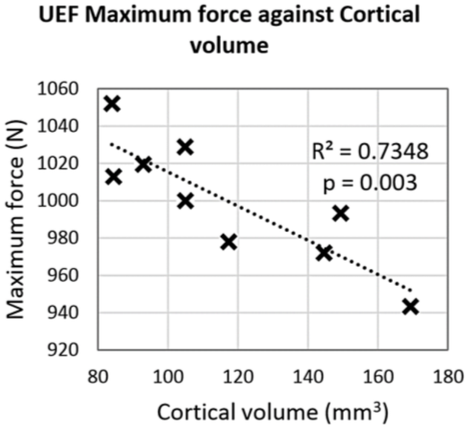

Figure 4. Correlation between UEF maximum force and cortical volume.

4. Discussion and conclusion

Correlation of fastener performance to bone properties was found to vary with the VOI over which the bone properties are measured. By taking an arbitrary VOI or else by including the entire bone volume a significant relationship can be obscured, which may explain some previous inconclusive attempts to correlate bone properties to pull-out strength.

Previous studies reported on the significance of correlations between pull-out force and up to nine microstructural properties without correcting for multiple comparisons [6, 7]. In this study, not correcting for multiple comparisons would be problematic as we were making multiple comparisons across different VOIs to determine the effect of VOI size in addition to multiple microstructural properties. Consequently we have reported p-values and r-values without commenting on significance.

It was found that the critical VOI for screws covered the entire length of the screw with the highest correlation at 8mm diameter, reducing in degree of correlation in both directions (figure 3). This relationship (critical VOI twice the diameter of the screw) is similar to the deformed area calculated with FEA by Wirth *et al*. [8] and the experimental set up of Ab-Lazid *et al*. [7].

Trabecular bone volume fraction, trabecular length and trabecular surface area only demonstrated a high degree of correlation with UEF failure load when only the bone around the bottom of the fastener is considered in isolation. The authors hypothesise that this is because the UEF fails due to slipping and so only the bone that contributes to increased pressure at the expansion zone is critical. This hypothesis would indicate that the expandable fasteners will be less sensitive to fastener length.

These results confirm previous studies with trabecular SMI and trabecular bone volume fraction being the most highly correlated parameters. Some deviation is inevitable, as previous studies use the epiphysis of human long bones where the current study used ovine vertebral bone. Contrary to epiphysis of human long bones where the current study used ovine vertebral body bone. Contrary to previous studies in long bones [6, 7] no correlation between cortical volume and screw failure force was found. The authors hypothesise that this was because, in the vertebral body, the cortex was thinner and the trabecular bone denser than in the epiphysis of the long bones and therefore the influence of the cortical properties was reduced.

Osteoporotic bone can be characterised by a reduction in bone volume fraction, cortical thinning, and a deterioration of plate-like trabeculae into rod-like trabeculae [15]. Compared to screws, UEFs demonstrated a similar dependence on trabecular bone volume fraction but no relation to SMI and an inverse relationship with cortical thickness, indicating potential suitability for osteoporotic bone.

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