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ABSTRACT

Objective: The level to which bone screws are tightened is determined subjectively by the operating surgeon. It is likely that the tactile feedback that surgeons rely on is based on localised tissue yielding, which may predispose the screw-bone interface to failure. The purpose of this study was to measure, for the first time, the ratio between yield torque (T_{yield}) and stripping torque (T_{max}) during screw insertion into cancellous bone, and to compare these torques to clinical levels of tightening reported in the literature. Additionally, a rotational limit was investigated as a potential end-point for screw insertion in cancellous bone.

Methods: A 6.5 mm outer diameter commercial cancellous bone screw was inserted into human femoral head specimens (n=89). Screws were inserted to failure, whilst recording insertion torque, compression under the screw head, and rotation angle.

Results: The median, interquartile ranges (IQR) and coefficient of variation were calculated for each of the following parameters: T_{yield}, T_{max}, T_{yield} / T_{max}, slope, $T_{plateau}$ and rotation angle. The median ratio of T_{yield} / T_{max} and rotation angle were 85.45% and 96.5°, respectively. Coefficient of variation was greatest for rotation angle compared to the ratio of T_{yield} / T_{max} (0.37 versus 0.12).

Conclusions: The detection of yield may be a more precise method than rotation angle in cancellous bone; however bone-screw constructs that exhibit a T_{yield} close to T_{max} may be more susceptible to stripping during insertion. Future work that can identify factors that influence the ratio of T_{yield} / T_{max} may help to reduce the incidence of screw stripping.

1 INTRODUCTION

Whether used alone, or with plates, bone screws are the most common implant device. Mechanically, the purpose of a screw is to transform a rotational force into axial motion or force (1). Lag screws, in particular, are used to provide compression across fracture fragments; the threaded portion of the screw is placed distal to the fracture line, and compression is achieved once head contact occurs and the screw is restricted in axial translation by the bone surface or plate that it is positioned against. The screws are then tightened until adequate compression is achieved at the fracture site. Surgeons perform this by manually tightening to what they subjectively perceive to be the ‘optimal’ torque depending on the quality of the host material (2, 3). A surgeon’s ability to accurately gauge the appropriate level of tightening torque depends heavily on experience (4), since there is no quantification as to what this torque should be. Average clinical tightening torque levels lie within the range of 84 – 88% of stripping torque (T_{max}), (5, 6); where T_{max} of screws in cancellous bone lies in the range of 1-3 Nm, depending on screw geometry, bone strength and anatomical location (7-11). An adequate tightening torque is necessary to achieve sufficient compression and primary stability of the fixation; however tightening beyond this can result in micro-failure of the peri-implant bone that may lead to screw loosening. In osteoporotic bone, over-tightening can lead to complete failure of the surrounding material and immediate loss of fixation due to the weakened bone structure (12). In patients over the age of 50, the incidence of screw stripping during internal fixation of displaced lateral malleolar fractures was reported to be as high as 38% (13), with another study reporting an incidence of 45.4% in synthetic cancellous bone specimens (14). These consequences demonstrate the need for an improved method of screw insertion into cancellous bone to avoid over-tightening and inadvertent stripping.

In cortical bone, Thakkar et al. (2014) suggested the use of the "Turn-of-the-nut" method, that uses a rotational limit (15), and is commonly used in building construction (16). However their results revealed that the strength of the bone-screw construct is compromised at a lower rotational angle than hypothesised, and that the optimum rotation angle is likely between 90 and 180° degrees. We sought to identify whether a rotational limit is applicable for screw insertion into cancellous bone. Furthermore, we wanted to address the overarching question: "what is the mechanism that signals to the surgeon that adequate tightening has been achieved?". It seems likely that the tactile feedback the surgeons are detecting is the onset of tissue yielding in the peri-implant bone (17).

Therefore the goals of this study were two-fold; first to determine the yield/stripping torque ratio, with the hypothesis that this is coincident with current clinically reported stopping/stripping torque ratios; and second to determine whether a rotational limit existed, that would reduce the incidence of stripping, whilst maximising compression, during screw insertion into cancellous bone.

2 MATERIALS & METHODS

2.1 Screws

A partially threaded stainless steel 6.5 mm outer diameter (OD) cancellous lag screw, with a 16mm thread length, 4.4mm inner diameter (ID) and 2.7mm pitch (Mathys, Australia) was used(Figure 1).

2.2 Bone samples

Twenty-four excised human femoral heads (mean (SD) age = 72.8 (12.85) years, 17 female, 7 male) were used (18). Specimens were retrieved from patients undergoing hemi- or full-arthroplasty for osteoporosis or osteoarthritis. The excised heads were cut at the femoral neck, and bone specimens were extracted from the central portion with parallel cuts. Specimen slice thicknesses were either 20mm or 25mm in width.

All specimens were individually wrapped in saline soaked gauze and stored at -20°C until the time of testing. Specimen donors had given their consent for use in the research and ethical approval was obtained from relevant institutions for use in the project.

2.3 Screw insertion tests

A table-top test rig was used for testing (18), which comprised a torque transducer to monitor insertion torque, a load cell to monitor compression under the screw head and a rotary encoder for monitoring screw rotation. All signals were digitally recorded at a sample rate of 500Hz. For each insertion, bone specimens were secured in a self-centring four-jaw chuck. Consistent with surgical guidelines, 4.5mm pilot holes were drilled in each specimen before being transferred to the test rig (19). Screws were continually inserted at a rate of 60rpm until failure occurred.

Failure was defined as achieving the maximum torque with the slope of the torque versus rotation curve being negative.

2.4 Data analysis

The torque and compression versus rotation angle curves were analysed using a custom written program (Matlab, MA, USA). The point of screw head contact was defined once the slope of the compression trace exceeded a threshold of 10N/°. Plateau torque was defined as the average torque over the 60 of rotation prior to head contact, and stripping torque was defined as the maximum torque (T_{max}). Yield torque (T_{yield}) was determined from the torque vs rotation plots as follows: a moving average filter with a span of 5 samples was applied to the torque versus rotation angle curve reduce signal noise. The 'linear' region of the curve was defined as the region of the curve between the tenth and fiftieth percentiles of plateau torque to stripping torque. A line was constructed parallel to the slope, but offset by 0.2° (Figure 2). T_{yield} was defined as the torque at which the constructed line intersected the smoothed torque-rotation curve. The rotation angles between head contact, T_{yield} and T_{max} were also measured from the curve.

Shapiro-Wilks tests for normality showed the data were not normally distributed, consequently non-parametric analyses were performed. The median and interquartile ranges (IQR) were calculated for each of the following parameters: T_{yield}, T_{max}, T_{yield} / T_{max}, slope, $T_{plateau}$, rotation angle between head contact and T_{max} ($ROT_{HC\text{-}Tmax}$) and head contact and T_{yield} ($ROT_{HC\text{-}Tyield}$). The coefficient of variance (COV) is reported as both (standard deviation / mean) and (IQR / median) was also determined. All statistical analysis was performed in SPSS (v20, SPSS, Inc, Chicago, Il) with $p < 0.05$ considered significant.

3 RESULTS

A total of 89 insertions were performed in the femoral head bone, with nine of the tests excluded from the analysis due to errors associated with the torque recordings, resulting in analysis of 80 tests. A typical torque versus rotation angle trace is shown in Figure 2. The median (IQR) and coefficient of variation for T_{yield}, T_{max}, ratio of T_{yield} / T_{max}, slope, and $ROT_{HC\text{-}Tmax}$ and $ROT_{HC\text{-}Tyield}$ are listed in Table 1. The median ratio of T_{yield} / T_{max} was 85.42 %, which is consistent with clinical tightening torque levels. The coefficient of variation was greatest for the slope and rotation angle between head contact and T_{yield} ($ROT_{HC\text{-}Tyield}$). Peak compression and torque occurred at a rotation angle of 80° past head contact, however by this point just over 33% of screws had also stripped.

4 DISCUSSION

Prevention of over-tightening during screw insertion relies on the surgeon's ability to accurately detect the onset of the tightening phase, both visually and by the feel of the rapid increase in torque (20). The stripping torque of a screw is determined by the material and geometric properties of the surrounding bone (21), which can vary greatly within and between patients (22). Consequently this is difficult to ascertain prior to surgery and methods that have relied on torque limiting devices have had little success in orthopaedics because the quality of bone exhibits large individual and topographic variations (23).

The first goal of this study was to quantify the ratio between T_{yield} and T_{max}, with the hypothesis that this was consistent with tightening torque levels observed clinically. Only two other studies have looked at the ratio of clinical tightening torque to T_{max}; Cordey et al. (1980) reported that on average surgeons tightened to within a mean (SD) of 84% (± 13%) of T_{max} in human cancellous tibial bone and 88% (± 18%) in human cancellous femoral bone (5). These results are consistent with more recent findings by Tsujii et al (2013), who reported mean stopping/stripping torque ratios of 84.5% (± 9.7%) in human cancellous femoral bone. This study has demonstrated that the median ratio of T_{yield} / T_{max} is consistent with the clinical ratios of tightening torque / T_{max} reported in the literature (Table 1). Furthermore the coefficient of variance of this ratio is similar across all studies (0.15, 0.11, 0.12, for Cordey et al, Tsuji et al and this study respectively). This supports the theory that the tactile feedback the surgeons use to detect that adequate tightening has been achieved is consistent with the onset of localised yielding of the peri-implant tissue.

Only three (3.8%) specimens exhibited a ratio of T_{yield} / T_{max} less than or equal to 70%. Interestingly, 27/80 tests (33.8%) exhibited a T_{yield} greater than or equal to 90% T_{max}. However by 90% of T_{max}, , surgeons are very close to stripping torque and if they are waiting for the tactile feedback, (that occurs past 90% of T_{max} in 30% of cases), then it is not surprising that stripping occurs with a similar frequency (i.e. around 30% of cases (13)). Specimens with a high ratio of T_{yield} / T_{max} are most likely at a greater risk of stripping during insertion.

With the goal of reducing the incidence of screw stripping during insertion in cortical bone, Thakkar et al. (2014) investigated the implementation of a rotational limit termed “turn-of-the-nut” (15). Their results showed that the rotation angle between head contact and stripping torque was much lower than initially assumed and that rotation past 180° resulted in a minimal increase in screw tension, with a large increase in the number of stripped screws. There did however appear to be little variation in rotation angle to peak compression across specimens, suggesting that in cortical bone this may provide an alternative end-point with a reduction in the incidence of stripped screws.

We sought to establish whether this was also the case for screw insertion in cancellous bone. Our results indicate that in cancellous bone the rotation angle between head contact and stripping is significantly lower than that of cortical bone (96.5° vs 286°), and that there was a large variation in rotation angle to stripping (COV = 0.37). Since cortical bone is stiffer than cancellous bone, a larger rotational angle to stripping may seem surprising. However one contributing factor to this could be the definition of head contact; Thakkar et al (2014) defined head contact as the rotation angle at which insertion torque increased beyond baseline, with baseline torque defined as the average of the peak torques measured while the self-tapping screws were cutting threads into the bone (15). Since in this study compression under the screw head was measured as a representation of the resultant axial force, and this doesn't occur until after head contact, a threshold on the slope of the compression trace was used to define head contact. This is a more robust method, as it is independent of any noise present in the torque trace due to the heterogeneous nature of the material the screw is being inserted into, particularly in cancellous bone. Additionally, the high porosity of cancellous bone may mean that micro-damage to only a small number of surrounding trabeculae will result in overall failure of the bone-screw construct.

By applying a rotation angle of 90° past head contact, just over 20% of specimens had stripped and by 180°, all but one of the screws had stripped. This suggests that if rotation angle was to be used as an end point, a significantly lower rotation angle would be necessary in cancellous bone compared to cortical bone. In this cohort of data, to eliminate screw stripping, a rotational limit of 30° would be necessary. However the median peak compression occurred at a rotation angle of 80°, and since some specimens exhibited a rotation angle at T_{max} as high as 200°, setting a rotational limit so low may result in less than optimal compression; while stripping may be reduced, the incidence of non-union may increase due to inadequate compression achieved at the fracture site.

Whilst a large variation in rotation angle between head contact and T_{yield}, (i.e. the current point of clinical tightening) was observed (COV = 0.54); a much smaller variance was seen in the ratio of T_{yield} / T_{max} (COV = 0.12). This suggests that the current method of screw tightening (which attempts to detect yield) is likely a more reliable method than rotational angle, in cancellous bone. The issue with this however, is in specimens that exhibit yield torques very close to T_{max}.

Theoretically, an insertion torque closer to T_{max} will result in a more stable construct, since axial compression increases with increasing torque. However numerous studies have found only a moderate relationship between stopping torque and holding strength as measured by pull-out force (24, 25). A previous study found that in ovine tibial cortical bone, peak pull-out strength occurred at 70% of T_{max} (17). However a more recent study, in human humeral cortical bone, reported no significant difference in pull-out strength of screws tightened to 50, 70 or 90% T_{max} (26). Both of these studies suggest that little is gained in tightening past 70% of T_{max}, however both were performed in diaphyseal bone, which is primarily cortical. The effects on pull-out strength by tightening to various levels of T_{max} in cancellous bone have not been reported. It is possible, that tightening to a lower ratio of T_{insert} / T_{yield} will still provide adequate compression and stability, whilst minimising the incidence of screw stripping, however this has yet to be investigated in cancellous bone.

It is important to note the limitations of the study. Firstly, only one anatomic location was considered. Since bone volume fraction, elastic modulus and apparent strength are known to vary with anatomic location (22), the relationship between T_{yield} and T_{max} may also differ. Secondly, we did not measure clinical tightening torque as such, but compared our data to the clinical data reported in the literature. However both studies considered also used human femoral cancellous bone and the reported ranges of measured stripping torques is comparable to that seen in this study (0.5 – 5.5 Nm and 1 – 5.9 Nm, Tsuiji et al (2014) and Cordey et al (1980), respectively).

Despite these limitations, this is the first study that experimentally confirms that current reported clinical levels of tightening torque are coincident with the onset of tissue yield. Perhaps the most important finding clinically, is that in some specimens the onset of tissue yielding, which appears to provide the sensory signal to stop, occurs very close to T_{max}. Whilst it is necessary to provide adequate tightening to achieve primary stability of the fixation, specimens with a high ratio of T_{yield} / T_{max} may be at an increased risk of screw stripping. However under-tightening may have equally deleterious results; if sufficient torque is not achieved, inadequate reduction may occur, leading to fragment misalignment, fixation failure and possible non-union (27). A *priori* knowledge of the relationship between T_{yield} and T_{max} would be highly beneficial for surgeons, specifically in light of recent literature that demonstrates T_{max} can be predicted from the plateau torque prior to head contact (18). Further investigations should look to identify factors that may influence the ratio of T_{yield} / T_{max}, and any differences between healthy and diseased bone.

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FIGURE CAPTIONS

Figure 1: Partially threaded 6.5 mm outer diameter, stainless steel cancellous lag screw (Mathys, Australia).

Figure 2: Typical output of the torque versus rotation angle recorded during insertion. The dotted line represents the 0.2 degree offset that was used to determine T_{yield}.

TABLE CAPTIONS

Table 1: Results for analysis of torque versus rotation data curves for screw insertion into femoral head cancellous bone (n = 80).

Table 2: Compression and insertion torque at 20 degree increments of rotation angle past head contact. The percentage of screws stripped for each time point is also listed.

FIGURES

Figure 1: Partially threaded 6.5 mm outer diameter, stainless steel cancellous lag screw (Mathys, Australia).

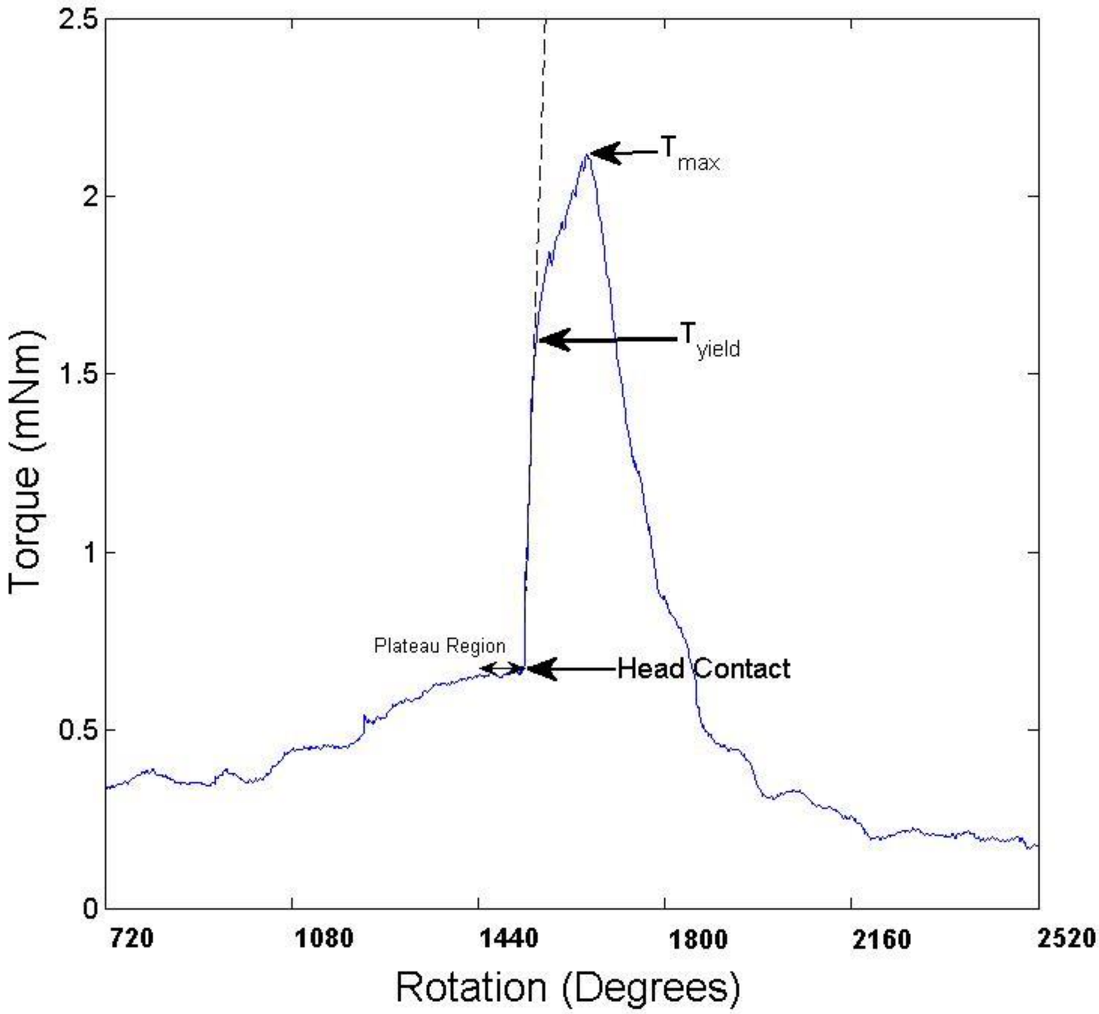

Figure 2: Typical output of the torque versus rotation angle recorded during insertion. The dotted line represents the 0.2 degree offset that was used to determine T_{yield}.