Clinical Biomechanics 52 (2018) 95–99

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Short communication

Local bone quality measurements correlates with maximum screw torque at the femoral diaphysis

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ARTICLE INFO

Keywords:
Reference point indentation
Bone quality
Screw stability
Screw maximum stripping torque

ABSTRACT

Background: Successful fracture fixation depends critically on the stability of the screw-bone interface. Maximum achievable screw torque reflects the competence of this interface, but it cannot be quantified prior to screw stripping. Typically, the surgeon relies on the patients' bone mineral density and radiographs, along with experience and tactile feedback to assess whether sufficient compression can be generated by the screw and bone. However, the local bone quality would also critically influence the strength of the bone-screw interface. We investigated whether Reference Point Indentation can provide quantitative local bone quality measures that can inform subsequent screw-bone competence.
Methods: We examined the associations between the maximum screw torque that can be achieved using 3.5 mm, 4.5 mm, and 6.5 mm diameter stainless steel screws at the distal femoral metaphysis and mid-diaphysis from 20 cadavers, with the femoral neck bone mineral density and the local measures of bone quality using Reference Point Indentation.
Findings: Indentation Distance Increase, a measure of bone's resistance to microfracture, correlated with the maximum screw stripping torque for the 3.5 mm ($p < 0.01$; $R = 0.56$) and 4.5 mm diameter stainless steel screws ($p < 0.01$; $R = 0.57$) at the femoral diaphysis. At the femoral metaphysis, femoral neck bone mineral density significantly correlated with the maximum screw stripping torque achieved by the 3.5 mm ($p < 0.01$; $R = 0.61$), 4.5 mm ($p < 0.01$; $R = 0.51$), and 6.5 mm diameter stainless steel screws ($p < 0.01$; $R = 0.56$).
Interpretation: Reference Point Indentation can provide localized measurements of bone quality that may better inform surgeons of the competence of the bone-implant interface and improve effectiveness of fixation strategies particularly in patients with compromised bone quality.

1. Introduction

Annually, there are > 2 million fragility fracture cases whose costs approach 20 billion dollars United States (Braithwaite et al., 2003; Ensrud, 2013). Fractures of the femur can occur proximally at the femoral head or distally at the metaphysis (Amin et al., 2014; Court-Brown and Caesar, 2006). The surgical options for treating distal femur fractures include intramedullary nailing and fixed-angle plates with a combination of non-locking and locking screws (Ehlinger et al., 2013). Locking plate systems are well-suited for fragile bone as it provides increased stability in axial compression and torsion (Fulkerson et al., 2006) by avoiding screw-bone interface loosening. The compressive force that is applied to plate-bone interface is proportional to the torque that was applied to the screw head (Hughes and Jordan, 1972). The screw will strip and loosen from its applied site when the applied torque exceeds the competence of the screw-bone interface (Dinah et al., 2011). A number of factors including the appropriate pilot hole, the design of the screw, and the pitch, influences the maximum generated torque prior to stripping. Although maximum screw stripping torque does not directly predict pull-out strength (POS) (Ricci et al., 2010), the stripping of the screw remains a clinically important factor because it reduces the POS by > 80% (Collinge et al., 2006).

Thread stripping occurs approximately 10% of the time during insertion of nonlocked screws (Dinah et al., 2011). Upon screw stripping, the screw can be exchanged for another of a larger diameter; a new hole can be drilled elsewhere; or the hole can be augmented (Wall et al.,

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https://doi.org/10.1016/j.clinbiomech.2018.01.016
Received 26 July 2017; Accepted 19 January 2018

2010). Exchanging the stripped screw for a larger diameter screw did not significantly alter POS, packing the stripped hole with bone graft also did not alter POS, while packing the hole with acrylic bone cement increased POS but can be a more time-consuming process (Collinge et al., 2006; Renner et al., 2004; Tankard et al., 2013). Despite this ability to remedy a stripped screw, the ability to assess the likelihood of such an event has significant clinical utility.

Bone Mineral Density (BMD) is the current gold standard for quantifying bone mass and is used in predicting bone strength (Abraham et al., 2015; Amin et al., 2014), and likewise can be used for estimating the stability of screw insertion (Brand et al., 2000). Despite BMD's clinical utility, bone matrix quality plays a critical role in mechanical performance. Although there are a number of non-invasive approaches to measure bone material properties in vivo, including ultrasound microscopy and FTIR, they are currently developmental stages of clinical translation (Rho et al., 1993). Another promising method of measuring bone matrix quality is via reference point indentation (RPI), which enables the user to directly measure the bone's matrix material properties through minimally invasive indentation (Guerri-Fernandez et al., 2013). In particular, cyclic RPI works through applying a test probe to an accessible bone surface that creates micrometer scale indents to measure the bone's resistance to penetration (Diez-Perez et al., 2016). RPI-measurements have been successful in differentiating populations with bone fragility when there is otherwise no detectable difference in BMD (Farr et al., 2014; Guerri-Fernandez et al., 2013; Rasoulian et al., 2013). The RPI approach enables minimal specimen preparation along with rapid clinical deployment. In the surgical setting, the region of interest may already be exposed, providing an opportunity to quantitatively assess local bone quality. We thus hypothesized that these RPI-derived local bone quality is predictive of the mechanical competence of the eventual screw-bone interface. Thus, the objective of this study is to compare the utility RPI and BMD towards predicting maximum screw torque from several screw sizes applied to both the femoral metaphysis and diaphysis.

2. Methods

20 right lower extremities from fresh frozen female cadavers (mean: 74 years, range 55–95 years) were used in this study. Femoral Neck (FN)-BMD were measured from the proximal femurs immersed in a 15-cm-deep water bath to mimic soft-tissue during the DeXA scan (GE Lunar DPX-L, Madison, WI, USA) (Roberts et al., 2010). Localized measures of bone quality were obtained by an in situ Reference Point Indentation (RPI) system (BioDent 1000; Active Life Scientific, Santa Barbara, CA, USA) mounted on a stand and applied to the respective skeletal sites prior to screw insertion. The system consists of a reference probe that rests on the bone surface and initiates and propagates a microcrack approximately 50 to 100 μm through repeated indentations (Abraham et al., 2015, 2016; Diez-Perez et al., 2010; Guerri-Fernandez et al., 2013). Indentations were performed using the BP2 probe for 20 cycles with a peak force of 10 N. Indentation Distance Increase – IDI – was computed as the difference in indentation depth between the first and 20th cycle. To ensure the sharpness of the probes, a new probe was used for every 3 bones.

The distal femurs were clamped to a vice, and pilot holes were predrilled at the distal femoral mid-diaphysis and metaphysis. All screws were instrumented from the lateral side of the femur. Holes were instrumented with 3.5 mm (2.5 mm pilot) cortical, 4.5 mm (3.2 mm pilot) cortical, and 6.5 mm (3.2 mm pilot) stainless steel cancellous bone screws (Synthes, Paoli, PA) in the metaphysis and 3.5 mm (2.5 mm pilot) cortical and 4.5 mm (3.2 mm pilot) cortical screws in the diaphysis (Fig. 1). Choice of screw placement was based on typical clinical fixation strategies (smaller fragment interfragmentary compression, larger cancellous fragment compression, lag screws through a plate, and fixation of the plate to the bone surface). In the metaphysis, each femur was instrumented with an anterior 3.5 mm cortical screw under the subchondral zone of the trochlea, a distal 6.5 mm cancellous screw in the central/distal metaphysis, and a 4.5 mm cortical screw just proximal to the level of the trochlea in the anterior 1/3 of the femur. The 3.5 and 4.5 cortical screws in the diaphysis were placed 2 cm apart in the anterior half of the femur, with the 3.5 screw always distal to the 4.5 screw. All screws were long enough to ensure that the threads were visible beyond the far cortex. The screws were inserted manually using a torque measuring digital screwdriver. A single operator inserted each screw to minimize variation and error. The screws were tightened until either the screw stripped or until the screw head had begun to penetrate the cortical surface, and the maximum torque was determined from the digitally recorded history of the screw advancement.

Pearson's correlations were used to assess the relationships between BMD and bone quality (IDI) with screw insertion torque. Student's *t*-test was used to analyze the relationship of screw size and insertion location with insertion torque.

3. Results

The mean Femoral Neck Bone Mineral Density (FN-BMD) was 0.27 g/cm^2 (range: 0.15–0.52). 16 samples had a t-score > 2.5 standard deviations below the mean. The mean IDI across all screw insertion sites for this cohort was 12.3 (range 5–24), confirming that there is a wide range of bone quality. As expected, the cortical bone site of the diaphysis demonstrated higher maximum screw torque suggesting higher screw compression compared with the cancellous bone site ($p < 0.001$; paired *t*-test; Table 1). Pearson's correlation analyses showed that IDI measured at the site of screw insertion was a significant predictor of maximum screw stripping torque for both the 3.5 mm ($p < 0.01$; $R = -0.57$; MSE = 0.82 N/mm) and 4.5 mm OD stainless steel screws ($p < 0.01$; $R = -0.61$; MSE = 0.10 N/mm) at the femoral diaphysis (Table 2; Fig. 2).

BMD did not predict maximum screw stripping torque at the cortical bone sites. At the femoral metaphysis, BMD significantly correlated with the 3.5 mm ($p < 0.01$; $R = 0.61$; MSE = 0.18 N/mm), 4.5 mm OD stainless steel screws ($p < 0.01$; $R = 0.51$; MSE = 0.33 N/mm), and 6.5 mm OD stainless steel screws ($p < 0.01$; $R = 0.56$; MSE = 0.19 N/mm) maximum screw torques (Table 2; Fig. 3).

4. Discussion

Our results suggest that measuring the local bone quality at the site of the screw insertion may provide an estimate of the maximum achievable screw torque and subsequent screw purchase. This has the potential to predict the success or failure of application of standard cortical screws to achieve interfragmentary screw compression or plate-bone friction in the femoral diaphysis in elderly patients. With this information, surgeons may be able to adjust their operative strategy to achieve appropriate stability with minimal morbidity.

The measurement of bone mineral density has excellent utility in discriminating between diseased populations (Hui et al., 1988; Kanis, 2002; Licata, 2009; Roberts et al., 2010); however, its utility decreases within osteopenic populations and patients with metabolic disorders (Gregson et al., 2013; Guerri-Fernandez et al., 2013). Indeed in the current study, BMD better predicts maximum screw torque at the metaphysis. The high BMD reflects a dense and connected cancellous bone network which provides the screw with more material to compress upon insertion (Fig. 3). These IDI measurements may also be aversely affected by the repeatability bias resulting from the thin cortical shell at this site (Coutts et al., 2015). Yet in cortical rich regions, the thickness predicts pull-out strength (POS) only in some studies (Thiele et al., 2007) but not in others (Dinah et al., 2011). Similar to cases of disparate fracture incidence and BMD (Farr et al., 2014; Guerri-Fernandez et al., 2013), local bone tissue quality may also be important for achieving high screw-bone torque. RPI provides the opportunity to make in situ measurements of bone quality in order to locally assess the