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Local Bone Quality Measurements Correlates with Maximum Screw Torque at the Femoral Diaphysis

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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 3.5mm, 4.5mm, and 6.5mm 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 3.5mm ($p<0.01$; $R=0.56$) and 4.5mm 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 3.5mm ($p<0.01$; $R=0.61$), 4.5mm ($p<0.01$; $R=0.51$), and 6.5mm diameter stainless steel screws ($p<0.01$; $R=0.56$).

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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.

Keywords

Reference Point Indentation; bone quality; screw stability; screw maximum stripping torque

1. Introduction

Annually, there are more than 2 million fragility fracture cases whose costs approach 20 billion dollars United States (Ensrud; Braithwaite). Fractures of the femur can occur proximally at the femoral head or distally at the metaphysis (Court-Brown and Caesar; Amin Achenbach, Atkinson). 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, Ducrot and Adam). Locking plate systems are well-suited for fragile bone as it provides increased stability in axial compression and torsion (Fulkerson, Koval and Preston) 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). The screw will strip and loosen from its applied site when the applied torque exceeds the competence of the screw-bone interface (Dinah, Mears and Knight). 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, Tornetta and Petteys), the stripping of the screw remains a clinically important factor because it reduces the POS by more than 80% (Collinge, Hartigan and Lautenschlager).

Thread stripping occurs approximately 10% of the time during insertion of nonlocked screws (Dinah, Mears and Knight). 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, Soin and Knight). 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, Hartigan and Lautenschlager; Renner, Lim and Kim; Tankard, Mears and Marsland). 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 (Amin, Achenbach, Atkinson; Abraham, Agarwalla, Yadavalli 2015), and likewise can be used for estimating the stability of screw insertion (Brand, Pienkowski, Steenlage). 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, Ashman, Turner; Donnelly). 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 (Guerra-Fernandez, Nogues and Quesada Gomez). 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, Guerra, Nogues, Abraham, Agarwalla, Yadavalli 2016). RPI-measurements have been successful in differentiating populations with bone fragility when there is otherwise no detectable difference in BMD (Rasoulzadeh, Raeisi Nafaji and M; Guerra-Fernandez, Nogues and Quesada Gomez; Farr, Drake, Amin). 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, Thrall and J). 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 (Guerra-Fernandez, Nogues and Quesada Gomez; Abraham, Agarwalla, Yadavalli 2015, 2016; Diez-Perez, Bouxsein, Eriksen). 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 pre-drilled at the distal femoral mid-diaphysis and metaphysis. All screws were instrumented from the lateral side of the femur. Holes were instrumented with 3.5mm (2.5mm pilot) cortical, 4.5mm (3.2 mm pilot) cortical, and 6.5mm (3.2 mm pilot) stainless steel cancellous bone screws (Synthes, Paoli, PA) in the metaphysis and 3.5mm (2.5 mm pilot) cortical and 4.5mm (3.2 mm pilot) cortical screws in the diaphysis (Figure 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 3.5mm cortical screw under the subchondral zone of the trochlea, a distal 6.5mm cancellous screw in the central/distal metaphysis, and a 4.5mm 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 2cm 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 0.27g/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 I). 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 3.5mm ($p<0.01$; $R=-0.57$; $\text{MSE}=0.82\text{N/mm}$) and 4.5mm OD stainless steel screws ($p<0.01$; $R=-0.61$; $\text{MSE}=0.10\text{N/mm}$) at the femoral diaphysis (Table II; Figure 2).

BMD did not predict maximum screw stripping torque at the cortical bone sites. At the femoral metaphysis, BMD significantly correlated with the 3.5mm ($p<0.01$; $R=0.61$; $\text{MSE}=0.18\text{N/mm}$), 4.5mm OD stainless steel screws ($p<0.01$; $R=0.51$; $\text{MSE}=0.33\text{N/mm}$), and 6.5mm OD stainless steel screws ($p<0.01$; $R=0.56$; $\text{MSE}=0.19\text{N/mm}$) maximum screw torques (Table II; Figure 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 (Licata; Hui, Slemenda and Johnston; Roberts, Thrall and J; Kanis); however, its utility decreases within osteopenic populations and patients with metabolic disorders (Gregson, Hardcastle and Cooper; Guerri-Fernandez, Nogues and Quesada Gomez). 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 (Figure 3). These IDI measurements may also be adversely affected by the repeatability bias resulting from the thin cortical shell at this site (Coutts, Jenkins, Dunlop). Yet in cortical rich regions, the thickness

predicts pull-out strength (POS) only in some studies (Thiele, Eckhardt and Linke) but not in others (Dinah, Mears and Knight). Similar to cases of disparate fracture incidence and BMD (Guerra-Fernandez, Nogues, Quesada; Farr, Drake, Amin), 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 competence of the bone tissue. Despite the direct contact of the probe with the bone tissue, no complications have been reported from this measurement in humans (Diez-Perez, A., Güerri, R., Nogues; Furst, J. R., Bandeira, L. C., Fan; Mellibovsky, L., Prieto-Alhambra, D., Mellibovsky, F; Nilsson, Sundh, Johansson). Indentation Distance Increase–(IDI)–measures the resistance of the bone tissue against microfractures as indicated by the penetration of a sharp probe applied at a given load. IDI correlates with fracture toughness (Diez-Perez, Guerra, Nogues), tissue-level bending toughness (Uppuganti, Granke, Manhardt) and whole bone strength (Abraham, Agarwalla, Yadavalli 2015) and toughness (Gallant, Brown, Organ). A low IDI suggests that the bone has a high resistance towards crack propagation (i.e. good bone quality), while a high IDI suggests a crack is propagated easily (i.e. poor bone quality). Although other parameters can be measured using cyclic RPI (Abraham, Agarwalla, Yadavalli 2016), clinical studies have found IDI to be the most effective parameter in discriminating diseased populations (Diez-Perez, Guerra, Nogues; Farr, Drake, Amin; Furst, Bandiera, Fan; Guerra-Fernandez, Nogues, Quesada; Mellibovsky, Prieto-Alhambra, Mellibovsky; Nilsson, Sundh, Johansson). Accordingly, the low IDI bone produced higher maximum screw torques than those with high IDI in both the 3.5 and 4.5 mm OD screws (Figure 2). However, as bone quality can vary significantly with age, and our study cohort contained more elderly samples. The prediction error for maximum torque is approximately 5% for the 3.5 mm screw and 15% for the 4.5 mm screw, and this may be due to the inability of the mounted cyclic RPI system to engage the bone surface in a perpendicular manner. Impact RPI, a subsequent iteration of the cyclic RPI technology, enables the operator to hand-hold the smaller indentation system to better engage in the contours of the bone surface (Bridges, Randall, Hansma) and may improve these prediction errors. Nevertheless, our results here suggest that *in situ* measurements of bone quality may inform bone's ability to interact with fixation instrumentation in the elderly population.

6. Conclusion

In this study we examined the ability of BMD and Reference Point Indentation (RPI) to predict maximum screw torque at the femoral metaphysis and diaphysis. The results suggest that BMD is the best predictor for maximum screw torque at the metaphysis, and RPI provided the best predictor of maximum screw torque in the diaphysis.

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Highlights

- There is a need for assessing the stability of the bone-screw interface
- Bone mineral density correlates with screw stripping torque at the femoral metaphysis
- Reference point indentation correlates with screw stripping torque at the femoral diaphysis
- Understanding local bone quality may allow more personalized and effective fixation strategies

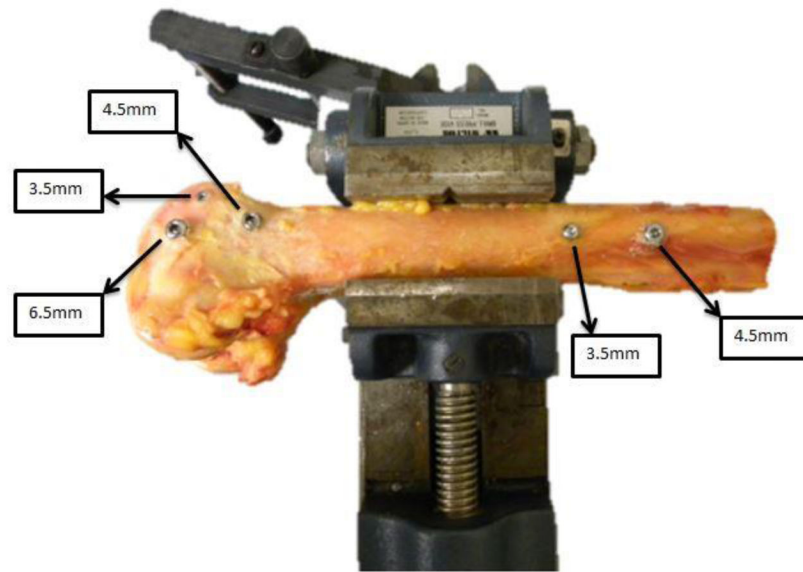


Figure 1.

Schematic of where the stainless screws were placed on the lateral side of the femur. Each femur received three screws on the distal metaphysis and two screws on the mid-diaphysis for a total of five screws. Maximum screw stripping torque was digitally recorded for each of these sites. Reference point indentation was also performed at these same sites prior to screw application.

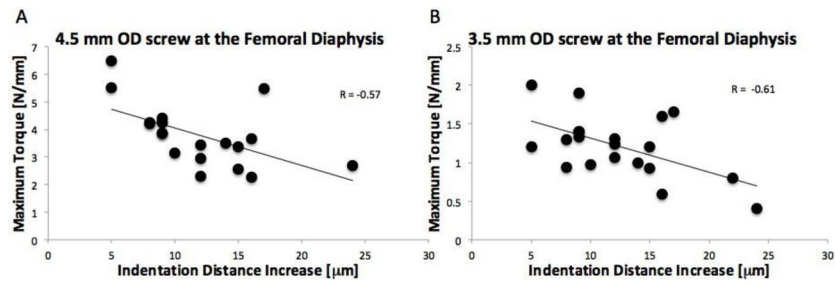


Figure 2.

Indentation distance increase (IDI), a measurement of bone quality, correlated with the maximum screw torque achieved at the femoral middiaphysis in both the (A) 4.5mm OD screw ($p < 0.01$; Pearson's correlation; $R = -0.57$; $MSE = 0.82$ N/mm) and (B) the 3.5 mm OD screws ($p < 0.01$; Pearson's correlation; $R = -0.61$; $MSE = 0.10$ N/mm). Specifically, the more resistant the bone is to indentation, the more torque it can sustain.

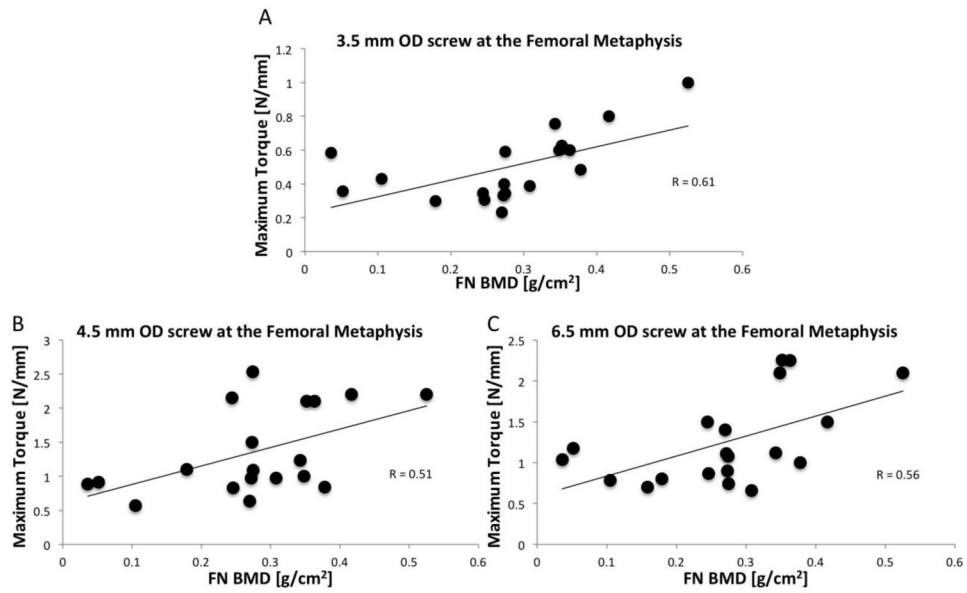


Figure 3. Femoral Neck BMD correlated with the maximum screw torque achieved in the (A) 3.5 mm OD screw ($p < 0.01$; Pearson's correlation; $\text{MSE} = 0.18 \text{ N/mm}$), (B) 4.5 mm OD screw ($p < 0.01$; Pearson's correlation; $\text{MSE} = 0.33 \text{ N/mm}$), and (C) 6.5 mm OD screw ($p < 0.01$; Pearson's correlation; $\text{MSE} = 0.19 \text{ N/mm}$). A higher BMD was associated with a higher maximum screw torque.

Table I

The stainless steel screws demonstrated higher maximum screw stripping torque at the cortical bone site compared to the cancellous bone site *($p < 0.001$; paired t-test).

	Maximum torque achieved [N/mm]	
	Femoral diaphysis	Femoral metaphysis
3.5 mm OD screw	1.20 (0.40)*	0.50 (0.20)
4.5 mm OD screw	3.8 (1.1)*	1.40 (0.63)
6.5 mm OD screw	--	1.25 (0.53)

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Table II

Pearson's correlation analyses show that the BMD does not predict maximum torque at the cortical bone site. IDI was a significant predictor of maximum torque for both the 3.5mm and 4.5mm OD stainless steel screws at the femoral diaphysis. At the femoral metaphysis, BMD significantly correlated with the maximum screw stripping torque for all three screws. In contrast, IDI did not predict maximum screw stripping torque for any of the screws at the metaphysis.

	Correlations with maximum screw stripping torque			
	Femoral diaphysis		Femoral metaphysis	
	vs BMD	vs IDI	vs BMD	vs IDI
3.5 mm OD screw	NS	p < 0.01 R = -0.56	p < 0.01 R = 0.61	NS
4.5 mm OD screw	NS	p < 0.01 R = -0.57	p < 0.01 R = 0.51	NS
6.5 mm OD screw	--	--	p < 0.01 R = 0.56	NS