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**Research Paper** 

## Pullout strength of cancellous screws in human femoral heads depends on applied insertion torque, trabecular bone microarchitecture and areal bone mineral density



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#### ABSTRACT

For cancellous bone screws, the respective roles of the applied insertion torque ( $T_{Insert}$ ) and of the quality of the host bone (microarchitecture, areal bone mineral density (aBMD)), in contributing to the mechanical holding strength of the bone-screw construct ( $F_{Pullout}$ ), are still unclear. During orthopaedic surgery screws are tightened, typically manually, until adequate compression is attained, depending on surgeons' manual feel. This corresponds to a subjective insertion torque control, and can lead to variable levels of tightening, including screw stripping. The aim of this study, performed on cancellous screws inserted in human femoral heads, was to investigate which, among the measurements of aBMD, bone microarchitecture, and the applied  $T_{Insert}$ , has the strongest correlation with  $F_{Pullout}$ .

Forty six femoral heads were obtained, over which microarchitecture and aBMD were evaluated using micro-computed tomography and dual X-ray absorptiometry. Using an automated micro-mechanical test device, a cancellous screw was inserted in the femoral heads at  $T_{\text{Insert}}$  set to 55% to 99% of the predicted stripping torque beyond screw head contact, after which  $F_{\text{Pullout}}$  was measured.

 $F_{Pullout}$  exhibited strongest correlations with  $T_{Insert}$  (R=0.88, p<0.001), followed by structure model index (SMI, R=-0.81, p<0.001), bone volume fraction (BV/TV, R=0.73, p<0.001) and aBMD (R=0.66, p<0.01). Combinations of  $T_{Insert}$  with microarchitectural parameters and/or aBMD did not improve the prediction of  $F_{Pullout}$ .

These results indicate that, for cancellous screws,  $F_{Pullout}$  depends most strongly on the applied  $T_{Insert}$ , followed by microarchitecture and aBMD of the host bone. In trabecular bone, screw tightening increases the holding strength of the screw-bone construct.

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#### 1. Introduction

In orthopaedic surgery, fractured bones are stabilised by the use of implants, most commonly bone screws. Clinically, the bone screw is inserted and tightened, typically manually, until adequate compression is attained to provide adequate stability at the fracture site, as per the surgeons' subjective manual feel. This corresponds to a subjective insertion torque, which can lead to variable levels of tightening torque close to the screw's thread stripping failure limit, or even beyond it, resulting in compromised mechanical strength of the bone-screw construct (Cleek et al., 2007; Cordey et al., 1980; Siddiqui et al., 2005). The mechanical strength of the bone-screw construct on the other hand is typically assessed by a pullout test, performed through destructive laboratory testing where a tensile force is applied until the screw is stripped from the bone (giving pullout strength,  $F_{Pullout}$ ).

Bone quality, as assessed by bone density and microarchitecture, appears to play a major role in determining the pullout strength of bone screws (Basler et al., 2013; Martinez et al., 2001; Mueller et al., 2013; Okuyama et al., 2001; Reitman et al., 2004; Seebeck et al., 2004; Soshi et al., 1991; Thiele et al., 2007; Wirth et al., 2011) along with other factors relating to screw geometry, material, size and insertion technique (e.g. tapping versus non-tapping and size of pilot hole) (Battula et al., 2006; Frandsen et al., 1984; Johnson et al., 2004; Muller et al., 1992; Oktenoglu et al., 2001; Ramaswamy et al., 2010; Seller et al., 2007; Tingart et al., 2006). Previous investigations led to inconsistent conclusions regarding the order of importance of areal bone mineral density (aBMD, measured by Dual X-ray Absorptiometry (DXA)) and the applied insertion torque (T<sub>Insert</sub>), in predicting F<sub>Pullout</sub> (Reitman et al., 2004; Ryken et al., 1995). Those studies did not evaluate the bone microarchitecture, and the applied T<sub>Insert</sub> reported was limited in range, either surrounding the surgeon's perceived manual 'optimal' torque (Reitman et al., 2004) or ultimate tightening torque (before stripping) (Ryken et al., 1995) which might have already weakened the construct (Cleek et al., 2007). These limitations might also explain their inconsistent findings on the order of importance of aBMD and T<sub>Insert</sub> in predicting F<sub>Pullout</sub>. Also, those studies evaluated unicortical and bicortical screws in human cervical spines, which do not apply to cancellous screws and to other anatomical sites, such as human femoral heads (Helgason et al., 2008; Keaveny et al., 2001).

Variations in bone quality as measured by mechanical properties, mineral density and microarchitecture, exist between- and within-patients (Bouxsein, 2003; Hernandez and Keaveny, 2006; Keaveny et al., 2001; Perilli et al., 2008; van der Meulen et al., 2001; van Rietbergen et al., 2002), and these variations were found to influence the stability of the bone-screw construct during pullout and push-in testing in the laboratory (Mueller et al., 2013; Poukalova et al., 2010; Ruffoni et al., 2012; Yakacki et al., 2010). However, the influence of  $T_{\text{Insert}}$  on  $F_{\text{Pullout}}$  was not examined in those studies. In fact, in a recent study performed in human humeri, the authors concluded that the relationship between applied screw insertion torque and pullout strength still remains undetermined (Tankard et al., 2013).

Despite the body of published scientific literature, it is still unknown whether higher TInsert values applied during cancellous screw insertion do correspond with higher pullout strength values - that is, whether tightening does indeed improve the mechanical stability of the screw-bone construct - nor how this relates to the quality of the underlying bone, in terms of its micro-architecture and density. According to our study using an automated micro-mechanical screw-insertion device on human femoral heads (Ab-Lazid et al., 2014), the T<sub>Insert</sub> measured at the first sign of screw head contact (T<sub>Plateau</sub>) is influenced by the microarchitecture and aBMD of the host bone. In particular, bone specimens having a more plate-like trabecular microarchitecture and higher density (higher bone volume fraction and aBMD) exhibited higher T<sub>Plateau</sub>, compared to those with a more rod-like structure and lower density (Ab-Lazid et al., 2014; Reynolds et al., 2013). It could be reasonable to expect, that these specimens also exhibit higher pullout strength, for similar amounts of applied insertion torque. However, to the best of our knowledge, this has not been studied before, particularly over a wide range of applied T<sub>Insert</sub> values.

Thus, the aim of this study was to determine which, among measurements of aBMD, bone microarchitecture, and applied  $T_{\text{Insert}}$  has the strongest correlation with the  $F_{\text{Pullout}}$ .

#### 2. Material and methods

#### 2.1. Human bone samples

Forty-six femoral heads obtained from hip replacement surgery (donors' age mean (SD) [min, max]=78.2 (9.6) years [51, 92] years; 17 females, and 29 males) which were part of a previous study were used (Ab-Lazid et al., 2014). All tests were performed according to approved Human Research Ethics guidelines. The femoral head specimens were excised at the femoral neck with their soft tissues removed. Specimens were kept moistened in gauze with saline solution and stored at -20 °C until time of testing. Prior to testing, specimens were thawed overnight in a refrigerator.

#### 2.2. aBMD measurement with DXA

The excised femoral heads were scanned in-vitro with a DXA scanner (GE Lunar Prodigy, Madison, WI, USA) for the measurement of aBMD by an expert radiologist as described previously (Ab-Lazid et al., 2014; Kiebzak et al., 1999). A polyoxymethylene board (Delrin<sup>®</sup>) (DuPont, Wilmington, Delaware, USA) was used to simulate soft tissue and GE enCORE software (version 13.60, GE Healthcare Lunar, Madison, Wisconsin, USA) was utilised for the evaluation of bone mineral content (BMC, measured in g) and bone area (measured in cm<sup>2</sup>), from which aBMD was calculated (g/cm<sup>2</sup>). The bone area was defined as a region of interest with size and shape adapted via software to the morphology of the femoral heads within the DXA image (Ab-Lazid et al., 2014).

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