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Ultrasound melted polymer sleeve for improved screw anchorage in trabecular bone—A novel screw augmentation technique

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ABSTRACT

Background: Screw anchorage in osteoporotic bone is still limited and makes treatment of osteoporotic fractures challenging for surgeons. Conventional screws fail in poor bone quality due to loosening at the screw–bone interface. A new technology should help to improve this interface. In a novel constant amelioration process technique, a polymer sleeve is melted by ultrasound in the predrilled screw hole prior to screw insertion. The purpose of this study was to investigate in vitro the effect of the constant amelioration process platform technology on primary screw anchorage.

Methods: Fresh frozen femoral heads ($n = 6$) and vertebrae ($n = 6$) were used to measure the maximum screw insertion torque of reference and constant amelioration process augmented screws. Specimens were cut in cranio-caudal direction, and the screws (reference and constant amelioration process) were implanted in predrilled holes in the trabecular structure on both sides of the cross section. This allowed the pairwise comparison of insertion torque for constant amelioration process and reference screws (femoral heads $n = 18$, vertebrae $n = 12$). Prior to screw insertion, a micro-CT scan was made to ensure comparable bone quality at the screw placement location.

Findings: The mean insertion torque for the constant amelioration process augmented screws in both, the femoral heads (44.2 Ncm, SD 14.7) and the vertebral bodies (13.5 Ncm, SD 6.3) was significantly higher than for the reference screws of the femoral heads (31.7 Ncm, SD 9.6, $p < 0.001$) and the vertebral bodies (7.1 Ncm, SD 4.5, $p < 0.001$).

Interpretation: The interconnection of the melted polymer sleeve with the surrounding trabecular bone in the constant amelioration process technique resulted in a higher screw insertion torque and can improve screw anchorage in osteoporotic trabecular bone.

1. Introduction

Due to demographic changes, the proportion of geriatric trauma patients and osteoporotic fractures is continuously increasing (Bleibler et al., 2013; Burge et al., 2007). Over the last decade, research and implant development focused on novel implant designs for the treatment of osteoporotic fractures. However, screw anchorage in trabecular bone of reduced bone quality is still limited. Insufficient screw anchorage causes reduced load bearing capability of the screw increasing the risk of osteosynthesis failure.

Screw anchorage in trabecular bone, such as pedicle screws, can be reinforced by cement injection into the adjacent bone around the screw. Biomechanical studies showed increased load bearing capability of screws with cement augmentation in comparison with non-augmented screws (Bostelmann et al., 2014; Bullmann et al., 2010). Cement augmentation of screws is already performed in clinical practice and investigated in experimental studies for several anatomic regions, e.g., spine (Bostelmann et al., 2014; Bullmann et al., 2010), proximal humerus (Roderer et al., 2013; Unger et al., 2012), hip (Erhart et al., 2011; Sermon et al., 2012), distal femur (Wahnert et al., 2013), and proximal tibia (Goetzen et al., 2014). However, this technique has potential disadvantages such as the additional surgical time caused by cement preparation, the excessive heating during curing of polymethylmethacrylat (PMMA) cement leading to bone necrosis, and the risk of cement leakage out of the bone into the

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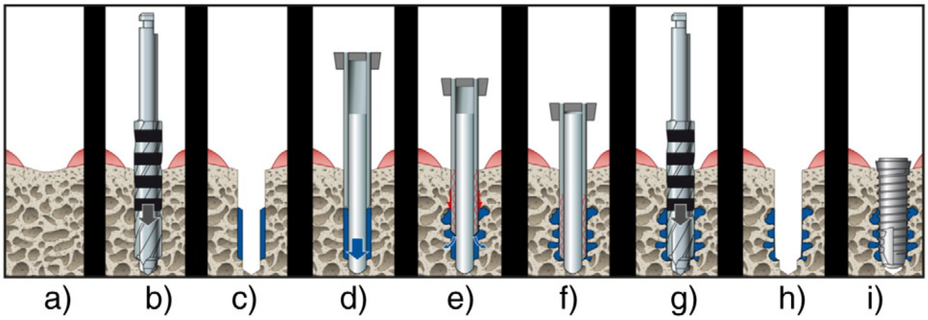

Fig. 1. The application of the CAP technique to improve screw anchorage includes the following steps: predrilling with 4.3 mm (b), insertion of polymer sleeve (c), attachment of the ultrasound applicator with core guidance into sleeve (d), melting of polymer sleeve by ultrasound (e + f), extraction of ultrasound applicator and re-drilling of borehole with melted sleeve (g), reinforced borehole for screw (h), and screw insertion (i).

surrounding structures (Breusch and Kuhn, 2003; Ciapetti et al., 2000; Jung et al., 2010; Stanczyk and van Rietbergen, 2004).

A novel method for screw augmentation represents the constant amelioration process technique (CAP). A polymer sleeve consisting of poly-L-DL-lactide copolymers (PLLAA) gets melted within the borehole by ultrasound. The melted polymer penetrates the trabecular bone cavities, following a rapid solidification. A conventional screw can then be inserted into the reinforced borehole (Fig. 1). The melted polymer within the borehole increases the overall contact surface area between screw and bone. This method can considerably save operating time in comparison with cement screw augmentation due to the fast melting and re-solidification of the polymer sleeve and no need of cement preparation. Stubinger et al. (2014) showed in an in vivo sheep model that the CAP technique significantly improved primary stability regarding insertion torque in sheep pelvic bone. However, the cancellous bone of the sheep has more densely packed bone trabeculae, lower porosity, and higher bone mass compared to human cancellous bone (Wang et al., 2010). It is still unknown if the beneficial effect on screw anchorage of the CAP screw augmentation technique is also present in human trabecular bone with reduced bone quality.

The aim of the present study was to investigate the effect of an ultrasound melted polymer sleeve on the screw insertion torque in human trabecular bone.

2. Methods

2.1. Specimens

In order to obtain trabecular bone densities of different anatomical regions six femoral heads (mean age 74.7 years, SD 9.1) and six vertebral bodies (mean age 79.3 years, SD 6.3) were used for testing. The bodies were donated by people who had given their informed consent for their use for scientific and educational purposes prior to death (McHanwell et al., 2008; Riederer et al., 2012). Specimens were stored at −20 °C and thawed at room temperature 12 h before testing. Specimens were cut in cranio-caudal direction in order to get comparable trabecular bone stock for a paired comparison of the augmented (CAP) and non-augmented reference (Ref) screw. Femoral heads were cut in the frontal plane through the axis of the femoral neck. Vertebrae were cut in the sagittal plane through the spinal process. Glass balls (2 mm diameter) were glued to the corresponding sites of both cut cross sections serving as landmarks. The location of screw insertion in the cross section was determined by a template aligned to the landmarks. Screws were implanted in both sides of the cut cross sections at the corresponding positions in order to allow a paired comparison (Fig. 2) of CAP and reference screws. In the femoral heads, three screws were placed in each side of the cross sections while only two screws could be placed in each side of the cross section of the vertebrae. This resulted in a total number of 18 paired tests at the femoral head and 12 at the vertebral body with a total of 30 screws with (CAP) and without CAP (Ref) augmentation.

2.2. Screw implantation

The same screws were implanted for both groups (SPI Element 5 mm diameter, 9 mm length, Thommen Medical AG, Switzerland). A borehole was drilled with a core diameter of 4.3 mm and a minimum depth of 9 mm prior to screw insertion.

For the CAP technique, a polymer sleeve (outer diameter 4.3 mm, 0.3 mm thickness, 5 mm height) consisting of 70:30 PLA (70% L-lactide and 30% DL-lactide (Resomer LR708, Böhringer Ingelheim, Germany) was inserted in the borehole (Fig. 3). A commercially available ultrasound applicator was used (Branson E-150, Branson Ultrasonics SA, Carouge, Switzerland; 20 kHz, amplitude of max. 60 μm = 150 W, set at 50%) and attached to the polymere sleeve. The polymer sleeve was melted by ultrasound and disseminated in the trabecular cavities by pushing the outer casing of the ultrasound applicator into the borehole. The borehole was re-drilled with the 4.3 mm drill, and the screw was inserted in the reinforced borehole (Fig. 1). For the reference screw group, screws were inserted immediately after initial borehole drilling. During screw insertion, the torque was measured with a torque measurement device (Chiropro 980, Bien-Air, Switzerland), and maximum values were recorded.

2.3. Micro-computed tomography

All specimens were scanned with a micro-CT (vivaCT 40, Scanco Medical) prior to testing. The following scan parameters were used: energy 70 kV, intensity 114 μA, image matrix of 1024 × 1024 pixels per slice, and integration time 200 ms. Total scanning time per sample

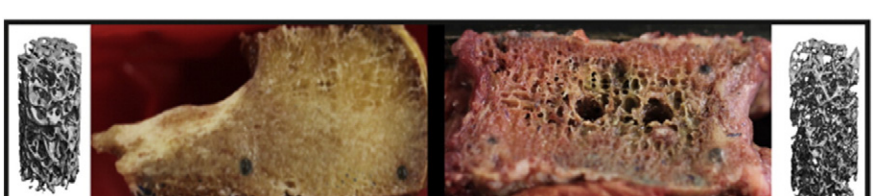

Fig. 2. Exemplary 3D reconstruction of micro-CT scans and the screw placement location in the femoral head (left) and in the vertebra (right).