DensiProbe Spine: First Clinical Experience with Intraoperative Measurement of Bone Quality

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Introduction
Poor bone quality due to osteoporosis is an increasing problem in dorsal transpedicular instrumentation of the aging spine. As the number of patients and indications are increasing, complications as screw loosening, cut-out, migration and loss of reduction are more and more observed [1,2]. These complications can be avoided to a large degree by choosing appropriate implant design and length of the instrumentation as well as by augmentation of the screw anchorage using bone cement. However, these techniques are often costly and time consuming and bear, in the case of cementation, the risk of cement leakage with possible pulmonary embolisms or neurological complications. Furthermore in most cases no information of the quality of the bone is available at surgery. Therefore, there is a need for a diagnostic device that can intraoperatively support the surgeon’s decision on the appropriate treatment.

The measurement device called DensiProbe Spine consists of a modified pedicle probe and an electronic system to measure the peak torque to break-away of trabecular bone in the vertebral body at the site of the pedicle screw tip. Previous reported in vitro validation of the DensiProbe Spine tool was performed on ten human cadaver lumbar vertebrae. A highly significant (r = 0.90; p = 0.002) correlation between peak torque measured by DensiProbe Spine and regional bone mineral density (BMD) measured by micro-CT was found. A significant result was also found when correlating bone strength using DensiProbe with maximum loads to cut-out of the pedicle screw in a biomechanical test setup (r = 0.959, p = 0.003) [3]. The objective of this pilot study with 30 patients is to investigate safety, handling and feasibility of the newly developed DensiProbe Spine measurement device under clinical conditions.

Methods
30 patients, undergoing dorsal, multilevel, transpedicular instrumentation of the lumbar and thoracic spine, were selected for this prospective monocentric case series. Exclusion criteria were scoliosis of over 10 degrees, tumours, infections, life threatening conditions, and drug or alcohol abuse. All patients underwent areal BMD measurement by DXA of the lumbar spine, radius, femur, and tibia. The DensiProbe device was used on one side for each instrumented level, and a transpedicular bone biopsy of the contralateral side was collected. Apparent BMD measurements were performed by micro-CT (uCT40, Scanco Medical, X-ray tube operated at 55 kVp, 145 µA, with an isotropic resolution of 15µm). All break-away torque measurements were performed by one surgeon who was blinded to the BMD and peak torque data. Subjective impression of bone strength was reported and cement augmentation of the screws performed when indicated. Radiographs to detect screw loosening were performed intraoperatively between day 1-3, and after 2 months postoperative.

Results
The data analyses have currently been completed for 30 patients. In all patients the handling of the DensiProbe was feasible and unproblematic. No adverse events related to the measurement occurred. Operation time was prolonged by 1.5 minutes per level, but mainly due to the collection of the bone biopsy. In one patient implant migration was reported, and in eight cases the screws were augmented with cement. Clinical follow up is not completed yet. A significant correlation (R=0.427) between apparent BMD and break-away torque was found (Figure 1).

Discussion
First clinical experience with DensiProbe Spine shows that intraoperative measurement of bone quality is safe and feasible. The results of peak torque measurement correlate to local bone density and (in vitro) to pedicle screw migration. A larger multicenter study is planned to evaluate the predictive value of this tool, and to define a range where cementation is indicated.

Significance
Osteoporosis is a major burden for our society and a relevant and difficult problem to treat in spinal surgery. Intraoperative measurement of bone quality allows the surgeon to apply adequate treatments and could help to reduce complications and costs.

References