INTRODUCTION:
The outcome of distal radius fracture fixation can be affected by local bone mineral density (BMD) [1,2]. BMD is commonly assessed preoperatively using dual-energy X-ray absorptiometry (DEXA). However, DEXA scans provide global BMD values and cannot accurately predict variations in BMD within a local anatomical site [3]; furthermore, patients frequently present without a preoperative DEXA scan due to instability. Therefore, intraoperative BMD assessment would be clinically ideal. We developed a simple sensor system that would be appropriate for assessing local BMD intraoperatively, consisting of a “smart” Weber clamp that was instrumented with a single uniaxial strain gage to provide real-time feedback for local BMD.

The goal of this study is to evaluate the efficacy of the instrumented Weber clamp in assessing local BMD in the distal radius. Specific aims include: 1) to validate the “smart” Weber clamp for inter and intra-user repeatability and reliability and 2) to compare Weber clamp bone strength measures to clinical DEXA measurements in the distal radius.

METHODS:
The Weber clamp was instrumented with a single uniaxial strain gage (Vishay Micromeasurements, Raleigh, NC) and calibrated using a uniaxial load cell (Vishay) (Figure 1, left). For instrument validation, the “smart” Weber clamp was tested on composite biomechanical test cylinders (Synbone) and assessed for inter and intra-user variability. Eight users tested the instrument, 4 surgeons and 4 engineers; 2 of each set were considered to be experienced in device usage and 2 were considered to be novice. Each punctured the cortical layer of the test cylinder 20 times and the puncture force was recorded.

RESULTS:
The average intra-user variance was 2.5±1.2N (12.9±3.9%) with a range from 1.4N to 5.1N (8.7% to 20.8%). There was a significant difference in puncture strength for surgeons vs. engineers (21.9±4.7 N vs. 16.0±4.1 N, p=0.0001). There was no difference between skill levels within each professional category; however, there was a slightly higher puncture force for novice vs. expert surgeons (p=0.06).

Figure 2. Locations on distal radius tested with Weber clamp.

The force needed to puncture the bone was quantified. The clamp induced only a small region (10 mm2) of damage to the bone. The force needed to penetrate the cortex at each point was measured at 8 locations on the radius (Figure 2): Locations 1-3 were in metaphyseal bone corresponding to the UD region, while locations 4-6 were in diaphyseal bone corresponding to the MID region. Regions 7 (styloid) and 8 (Lister’s tuberosity) were considered to be in the UD.

Figure 3. Average Weber clamp strength values across professional category and skill level.

Strength values measured in the MID region using the Weber clamp strongly correlated with MID-DEXA BMD measurements (adj. R2=0.74, p<0.001). Furthermore, average Weber clamp strength measurements in this region successfully differentiated between normal and osteoporotic donors as classified using TOTAL T-score (p<0.05 ANOVA). Average Weber clamp strength measures across all sites (1-8) modestly correlated with TOTAL T-score (adj. R2=0.37). Similarly, strength measurements in the UD region modestly correlated with UD T-score (adj. R2=0.39).

DISCUSSION:
The results of our study indicate that the “smart” Weber clamp predicts bone strength well in the mid-region of the distal radius. Strength measurements in this region are able to distinguish between normal and osteoporotic donors, as diagnosed by a standard distal radius DEXA scan. Conversely, the Weber clamp is not a good predictor of local bone quality in the ultra-distal region, possibly due to the thin cortex in this region [4].

The difference between surgeons and engineers in device validation may be explained by a difference in how surgeons and engineers feel the cortex has been breached. This may be a result of educational background. A standard definition of fracture point may be obtained by controlling for puncture depth.

Future work will focus on increasing the sample size as well as varying tip geometry and other design modifications to control puncture depth. The results of this study are promising for the continued development of this technology as an intraoperative BMD assessment tool.

REFERENCES: