# Mechanical properties of Ossedensification drilling as compared to Regular drilling

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**Statement of Purpose:** Treatment of skeletal anomalies through the surgical fixation of implants into bone has positively influenced the well-being of patients and continues to be the basis of orthopedic rehabilitation. Surgical fixation is dependent on the principle concept of osseointegration, the anchorage of bone around the implant. Osseointegration is broken up into two scopes, *primary stability* and *secondary stability*. Primary stability, the initial interlocking between bone and implant, can be measured through insertion torque of the implant into the osteotomy. Furthermore, mechanical properties such as pullout strength also demonstrate the anchoring strength of implants. Secondary stability, characterized by the amount of bone growth through the healing chambers of the implant and its contact with the device, can be measured through histological analysis in analyzing bone area fraction occupancy (BAFO) and bone implant contact (BIC) that occurs in the healing chambers. Osseointegration is dependent on multiple factors of the implant, such as macrogeometry, host bone quality, and drilling techniques. Previous research has proven the efficacy of multi-step drilling and higher drilling speeds (~700 rpm) in providing adequate osseointegration, however there is a scarcity in literature regarding non-subtractive drilling techniques. Therefore, we chose to explore the novel approach of osseodensification in implant insertion.

**Methods:** Utilizing a translational animal model, 64 implants were installed in the cervical spine of 8 adult sheep (n=8/animal) bilaterally, with each pedicle screw measuring 4.5mm in diameter x 45mm length. The animals were separated into two time points, with four animals being *in-vivo* for 12 weeks and four animals were *in-vivo* for 6 weeks. The left side of each cervical vertebra underwent the traditional subtractive drilling, while the right side had implants installed through osseodensification drilling. The animals were then sacrificed by overdose of anesthetic, and the vertebrae with devices were removed en bloc. In order to measure pullout strength, mechanical testing of all implants was performed using a universal testing machine (Instron Series 5560 Norwood, MA) with a cross-head speed of 1.00 mm/sec. For histological analysis, the implant blocks were dehydrated in a series of ethanol solutions and embedded in a methyl methacrylate-based resin. After being embedded, these blocks were sliced into sections using a diamond saw (Isomet, 2000, Buehler Ltd., Lake Bluff, IL, USA). The samples were polished on a grinding machine (Metaserv 3000, Buehler, Lake Bluff, IL, USA) and then stained in Stevenel's blue and Van Gieson picro fuchsin, respectively. The samples were prepared for histologically analysis through software (ImageJ, NIH, Bethesda, MD). The results of the biomechanical testing were recorded and analyzed as mean values with the corresponding 95% confidence interval values (mean ± CI). Pull-out strength were compared using several factors of time *in vivo* (6- and 12-weeks) as well as surgical drilling method -Regular (R), and Osseodensification (OD). All statistical analyses were completed with IBM SPSS (v23, IBM Corp., Armonk, NY).

**Results:** Mechanical pullout strength collapsed across all time points delineated no significant difference in outcomes between vertebrae. However, when comparing mechanical stability between osseodensification and regular drilling at 6-weeks, there was significantly greater pullout strength for the OD group versus the R group. The OD group measured ~ 390 N, meanwhile the R group only measured approximately ~300 N. Furthermore, at the 12-week time point similar results were seen as the OD group had pullout strength of ~320 N and the R group had ~230 N. Overall, when comparing the data irrespective of vertebrae and time point, the OD group had significantly greater pullout strength, ~350 N than that of the R drilling group ~250 N. All results were significant with $p<0.05$. In addition, Figure 1a and 1b demonstrate the initial histological evidence of increased bone growth in the OD group versus R group.

**Conclusions:** Mechanical pullout testing demonstrated that OD drilling provides better implant anchoring and stability compared with the R group. The trend that pullout strength was greater at 6 weeks than that at 12-weeks can be explained by the further development of secondary stability at the 12-week time point. Hence, it is evident that implant biomechanics are improved with OD both in primary and secondary stability.

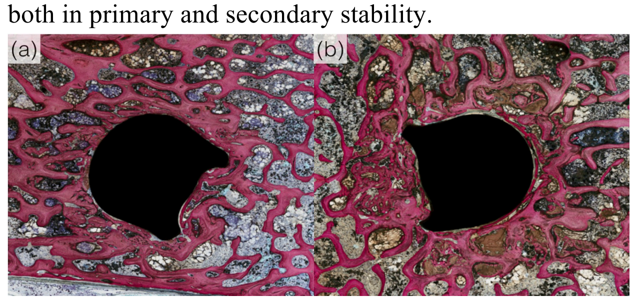


*Figure 1: Transverse histological sections of (a) regular (R) and (b) OD drilling protocols*