Early Integration and Mechanical Stability of Tantalum Porous Implants in an Ovine Trabecular Bone Model

Jin Whan Lee, PhD, Hai Bo Wen, PhD, Jeffrey Bassett, BS

Zimmer Dental, Carlsbad, CA

1 Introduction

A recent study of the tantalum (Ta) porous implants evaluated bone ingrowth and implant stability in canine healed extraction sites.[1] However, continuous research is necessary to verify the benefits of bone ingrowth on implant stability during early healing in animal models and human patients. The objective of this study was to evaluate the early integration and mechanical stability of Ta porous implants in an ovine trabecular bone model.

2 Methods

Thirty-six Ta porous implants (4.1 mmD × 10 mmL) were placed bilaterally in femoral condyles of 6 ovine subjects (Figure 1). Implant stability was assessed by resonance frequency analysis and measured according to the unit's proprietary implant stability quotient (ISQ) values. Measurements were performed at implant placement (as a baseline), and following euthanasia after 3 or 6 weeks of healing. Insertion torque values (ITV) were measured using a calibrated torque limiting device during implant placement. After euthanasia at 3 or 6 weeks post-implantation, removal torque values (RTV) were measured. Implants were retrieved *en bloc* after 3 and 6 weeks. Specimen blocks were fixed in 10% formalin, dehydrated in ethanol, infiltrated, and embedded in PMMA for non-decalcified histology processing. Sections were cut, ground (≈50 µm thick), polished, and stained with toluidine blue and basic fuchsin. The stained slides were examined using a microscope. The mean percentage of bone in contact with implant (%BIC) was calculated using Scion® Image Analysis software by considering the entire length of implant surface in direct contact with mineralized bone tissue. The region of interest (ROI) for bone area measurement was defined as the area encompassing intra-thread regions along the entire length of the implant. The amount of bone within the ROI was measured by calculating the percentage of surface area inside the ROI occupied by bone. Data were analyzed statistically by paired t-test ($p<0.05$).

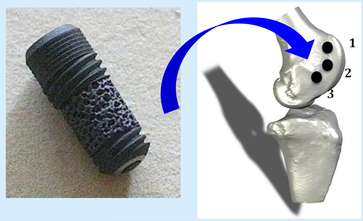

Figure 1. Ta porous implants tested in the study were placed in femoral condyle sites identified as proximal (L1, R1), middle (L2, R2) and caudal (L3, R3). L and R were the left and right legs, respectively.

3 Results

There were no implant failures and all implants harvested at 3 and 6 weeks exhibited no adverse tissue responses. Mean ISQ values were 67 at placement, 68 at 3 weeks, and 70 at 6 weeks (Figure 2). ISQ measurements revealed no decrease in stability at any time. The change between 0 and 3 weeks was 0.72±6.4. The change between 0 and 6 weeks was 2.9±6.8. Maximum torque values were 47 Ncm at placement, 102 Ncm at 3 weeks, and 150 Ncm at 6 weeks (Figure 3). Mean torque values increased by 122% from the baseline to 3 weeks, and the corresponding values increased by 213% from 0 to 6 weeks. Nominal ISQ values didn't exhibit any statistical differences ($p>0.05$), nor did the change in ISQ ($p>0.05$). However, a statistically significant difference was observed in each group for torque comparison ($p<0.05$).

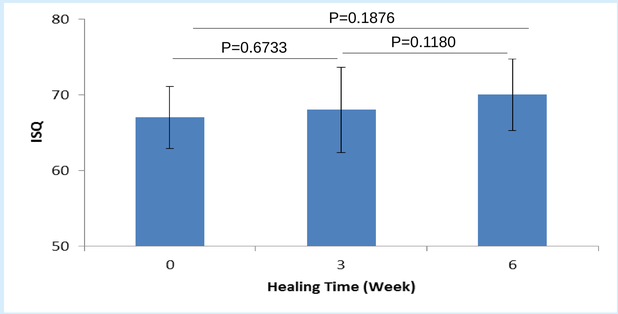

Figure 2. ISQ values at placement, 3 and 6 weeks for Ta porous implants placed in femoral condyle sites. No significant differences were observed during healing ($p>0.05$).

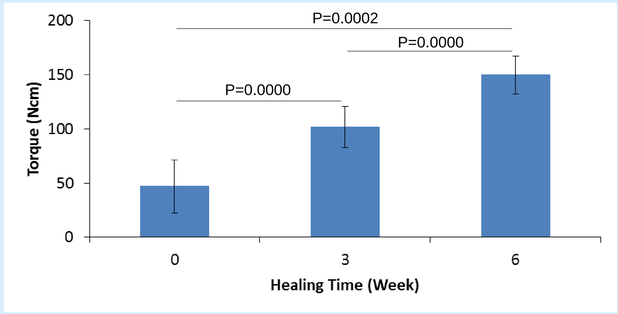

Figure 3. Maximum torque values at placement, 3 and 6 weeks. RTV at 3 and 6 weeks were significantly higher than ITV at implant placement ($p<0.05$). From 3 weeks to 6 weeks of healing, RTV increased significantly ($p<0.05$).

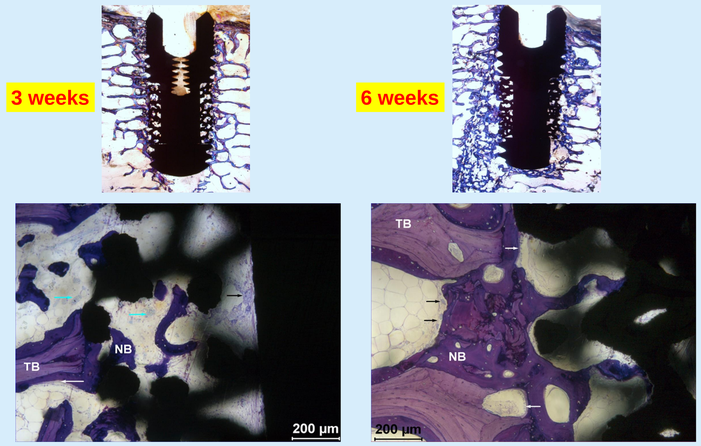

Figure 4. Representative histologic images for Ta porous implants at 3 and 6 weeks (toluidine blue and basic fuchsin stains. 1.25x, 100x mag respectively) *TB*: original trabecular bone, *NB*: new bone, *white arrow*: osteoblasts/osteoid, *black arrow*: osteoclast, *aqua arrow*: blood vessel

Noteworthy at 3 weeks was the presence of osteogenic tissue along with the infiltration of blood vessels within the porous spaces and at the interface. In the corresponding porous regions after 6 weeks, bone ingrowth into the deep internal pores was significant (Figure 4). The new bone observed at 6 weeks presented lamellar arrangement and different-sized medullar spaces, showing mature bone trabeculae. Also, at the Ti alloy-based threaded regions at 3 weeks, a thin layer of newly mineralized bone formation was apposed. Newly formed osteogenic tissue and preexisting old bone were also directly apposed to the threaded surface. In the threaded regions after 6 weeks, the new trabecular bone appeared thicker and bone density increased. The %BIC in the threaded regions was 67% after 3 weeks and then remained unchanged. The majority of the pores were filled with active bone formation (28.5%) whereas a very small portion of the pores were filled with old bone fragments (1.3%) at both 3 and 6 weeks. No significant difference in the amount of new bone was observed between 3 and 6 weeks ($p>0.05$).

4 Discussion

Both ISQ and torque values are often considered good indicators for determining implant stability. However, the data analysis obtained from two testing methods does not confirm a correlation.[2] In contrast to the findings of the previous study, the present data analysis showed a moderate correlation between ISQ and torque value (Pearson correlation: 0.620, p value: 0.006). In the present ovine femoral condyle model, mean ISQ values did not show a pivotal dip in stability during the first 3 weeks of healing and values maintained until 6 weeks. Interestingly, similar findings of no dip in stability values were observed in the distal femurs of rabbits,[3] but contradictory results were found in the mandibles of dogs.[1] Dissimilar physiology and anatomy of intrinsic bone might have influenced the differences in ISQ values. Histologic and histomorphometric assessments demonstrated that bone ingrowth (≈30%) was evident within the Ta porous shell during the early healing phase. A comparable new bone ingrowth (~23% at 3 weeks) within the same Ta porous shell was reported in the canine transcortical model.[4]

5 Significance

In the ovine trabecular bone model, Ta porous implants demonstrated that mean ISQ data revealed a steady rise with non-dipping behavior while mechanical torque data showed a statistically significant increase. In addition, histologic evidence of bone apposition as well as bone ingrowth was observed after 3 and 6 weeks of early healing.

6 References

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