



Osseoincorporation of Porous Tantalum Cylinders Implanted in Human Subjects: 12-Week Interim Results

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1 Background

Osseoincorporation is implant anchorage via a combination of bone-to-implant contact with an implant surface (bone ongrowth) and bone ingrowth into a highly porous implant surface. An ongoing clinical study is currently evaluating the osseoincorporation of Trabecular Metal[®] (TM) cylinders after early healing in the human jaw.

2 Methods

This clinical study was approved by the institutional review board of the University of Leon, Spain. Surgeries were performed at the University of Leon and histological processing and analyses were performed at the University of Alcalá, Spain. Healthy subjects (n=23) with available bone of at least 7mm in width to accommodate 1 or more 3x5mm porous tantalum cylinders between or distal to preexisting dental implants were enrolled in the study. Subjects were assigned to 1 of 4 groups (6 cylinders per group) designated for cylinder explantation at 2, 3, 6 or 12 weeks. After preparation of osteotomies, cylinders were placed flush with the mandibular or maxillary ridge and covered by the soft tissues without a barrier membrane. At the designated retrieval time, cylinders were explanted with 5.0mm trephines, marked to indicate orientation at placement, buffered in 10% formaldehyde, histologically processed and slides were stained to identify cells (hematoxylin-eosin), osteoid tissue (Masson trichrome) and markers of developing and existing trabecular bone (toluidine blue).

3 Results

New bone formation was observed inside the pores (ingrowth) and in direct contact with the external surfaces (ongrowth) of all samples at 12 weeks. The mean percentage of bone ingrowth into the cylinders, as measured longitudinally from the outside surface of the cylinders, varied according to the depth of measurement: at a depth of 0.5mm (measurement field = ~0.5x5mm), mean bone fill was 22.7%; at a depth of 1 mm (measurement field = ~1x5mm), mean bone fill was 16.8%. The average volume of new bone formation inside the entire 3x5mm cylinders

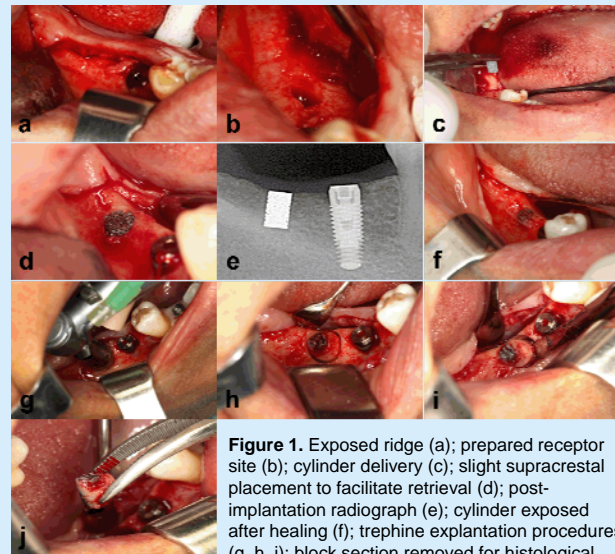
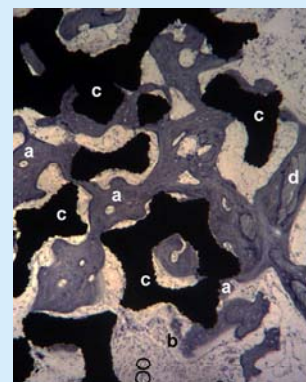


Figure 1. Exposed ridge (a); prepared receptor site (b); cylinder delivery (c); slight supracrestal placement to facilitate retrieval (d); post-implantation radiograph (e); cylinder exposed after healing (f); trephine explantation procedures (g, h, i); block section removed for histological processing (j).

Figure 2. Osseoincorporation at the histologic level shows ongrowth and ingrowth of new bone (a) with osteoid (b) and blood vessels (O) inside a porous tantalum test cylinder (c) explanted from the maxillary right cuspid area of a human subject after 12 weeks of healing. Note the old bone fragment (d) encapsulated by new bone. As measured longitudinally from the outside surface of the cylinders, the mean percentages of bone ingrowth in this sample were 43.0% at a depth of 0.5mm, 34.2% at a depth of 1mm, and 27.8% in all areas combined after 12 weeks of healing (toluidine blue).



was 14.4%. Very little osteoclastic activity or bone resorption was observed, but bone was still maturing, especially inside the material. Mucosal epithelium penetrated one sample, but overall the presence of mesenchymal cells, bone formation activity and intense angiogenesis in all samples indicated good tissue response with developing osseoincorporation. Newly formed trabeculae with osteoid borders surrounded by osteoblasts were evident inside and on the surfaces of the vast majority of samples. Bone ingrowth into the samples primarily occurred along the lingual, buccal or palatal surfaces. Except for 1 sample with poor tissue formation inside the pores and some evidence of foreign body reaction, implants exhibited good bone response, with the formation of bone trabeculae alternating with vascularized tissue inside the samples.

4 Discussion

The earliest evidence of osseointegration (bone ongrowth) reportedly occurs after a few weeks of early healing, and then progressively forms on the implant surface over a period of months or years.¹ In contrast, bone ingrowth was not only observable, but also quantifiable after 12 weeks of early healing. The presence of maturing and developing bone both inside and outside the porous material demonstrated that osseoincorporation was a progressive process. Further studies with longer follow-up times will help to document the rate of bone ingrowth into TM cylinders.

5 Conclusion

Twelve (12) weeks after placement, ingrowth of bone trabeculae and blood vessels inside highly porous TM cylinders was observed.

6 References

[1] Albrektsson T, Berglund T, Lindhe J. Osseointegration: Historic Background and Current Concepts. In Lindhe J, Karring T, Lang NP (eds.). *Clinical Periodontology and Implant Dentistry*. Oxford: Blackwell Munksgaard, 2003:815.

^{*} Trabecular Metal[™] Material is a trademark of Zimmer Holdings, Inc.

