Bone Ingrowth into Highly Porous Trabecular Metal™ Material: Evaluation of Canine and Human Models

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1 Background

Highly porous Trabecular Metal™ (TM) Material has been applied to dental and orthopedic implants to augment conventional osseointegration with additional bone ingrowth into the biomaterial. Two studies, one conducted in canines and the other in humans, were performed to evaluate bone ingrowth into TM during 2 to 12 weeks of submerged healing.

2 Methods

Canine Model: This arm of the study was approved by the Institutional Animal Care and Use Committee of The Ohio State University. Eight healthy 1-year-old male coonhound dogs were assigned to 1 of 4 groups (2 dogs per group) designated for implant removal after 2, 4, 8 or 12 weeks. The dogs were anesthetized and the mandible, maxilla and zygoma were exposed bilaterally to allow access to the teeth. Implants were inserted into the maxillary and mandibular alveolar bone. After implantation, the surgical site was closed with absorbable sutures. The dogs were weighed and measured every week. At the time of sacrifice, the dogs were anesthetized with the same protocol used for the surgery. The maxilla and mandible were harvested from each animal and processed for histomorphometric analysis. The bone ingrowth into the implant was measured by planimetry using histological sections stained with hematoxylin and eosin (H&E).

Human Model: This arm of the study was approved by the institutional review board of the University of León, Spain. Subjects were performed at the University of León and histological processing and analyses were performed at the Universidad de Alcalá, Spain. Healthy subjects (n=23) with existing implants and an edentulous space at least 7 mm in width were enrolled in the study. One or more 3 mm x 5 mm TM cylinders were placed between or distal to the dental implants in each patient. Subjects were assigned to 1 of 4 groups (6 cylinders per group) designated for cylinder explantation after 2, 3, 6 or 12 weeks of submerged healing. Osteotomies were prepared, cylinders were placed flush with the mandibular or maxillary ridge, and soft tissue closure was achieved. No barrier membranes were used. At the designated retrieval times, cylinders were explanted with 5.0 mm trephines, and marked to indicate orientation at placement. Specimens were 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

There were no complications during healing in either model. Bone ingrowth was significantly higher at week 12 than at weeks 2, 4 and 8 (p<0.024). BSE/EDX images and plots showed high intensities of calcium and phosphorus, the major components of bone mineral, inside the biomaterial as early as 2 weeks post-implantation (Fig. 1). In humans (Fig. 2), slides stained with hematoxylin and eosin, toluidine blue and Masson’s trichrome at 2 weeks showed prolific blood vessel formation and tissue inference inside TM. At 3 weeks, osteoblasts and new bone formation were observed inside the porous biomaterial. From 3 to 12 weeks, progressive bone formation was observed in contact with the surfaces and inside the inner pores of TM.

4 Discussion

Viable new bone formation was observed within the pores of TM after 2 weeks in canines and 3 weeks in humans, respectively. It was postulated that TM may allow active osteogenic and angiogenic cells to migrate deep into the inner pores and possibly contribute to bone formation. In the canine transcutaneous model, newly formed bone was observed inside TM at 2 weeks. The human model was the first study to document the process of new bone formation inside Trabecular Metal Material at the histological level. Both study models exhibited progressive osseointegration and bone ingrowth into the porous cylinders; however, healing was significantly faster in dogs as compared to humans.

5 Conclusion

In both canine and human models, TM exhibited progressive osseointegration and formation of new bone and blood vessels inside the material’s pores, a process termed osseoconformation. At 2 weeks in humans, porous cylinders of TM exhibited newly formed blood vessels, cells and tissue infusion, which subsequently led to new bone formation starting at 3 weeks.

6 References


*Trabecular Metal™ is a trademark of Zimmer Holdings, Inc.

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