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[1] into the biomaterial. Two studies, one conducted in canines[2] and the other in humans,[3] 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 of healing. During the first surgical stage, 4 mandibular premolars were extracted bilaterally using an atraumatic technique to preserve the alveolar sockets. Wound sites were sutured closed and left to heal for 3 months. During the second surgical phrase, 3 threaded and tapered dental implants with a midsection of TM were implanted in interalveolar margins between the mandibular extraction sites of each dog. Newly formed bone tissue was labeled by intravenously injecting calcein (12.5 mg/kg) into the dogs. For the 2-week group, dogs were injected once at day 5. For the 4-, 8- and 12-week groups, injections were administered twice, on day 11 and 4 days before euthanization. Immediately after euthanization, mandibles were dissected and block sections were retrieved for histomorphometric analysis and scanning electron microscopy (BSE/EDX) inspection. Goldner's trichrome (GT) was use to distinguish between mature bone (blue-green) and osteoid material (bright orange).

Human Model: This arm of the study was approved by the institutional review board of the University of León, Spain. Surgeries 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 (hemotoxylin-eosin), osteoid tissue (Masson trichrome) and markers of developing and existing trabecular bone (toluidine blue).

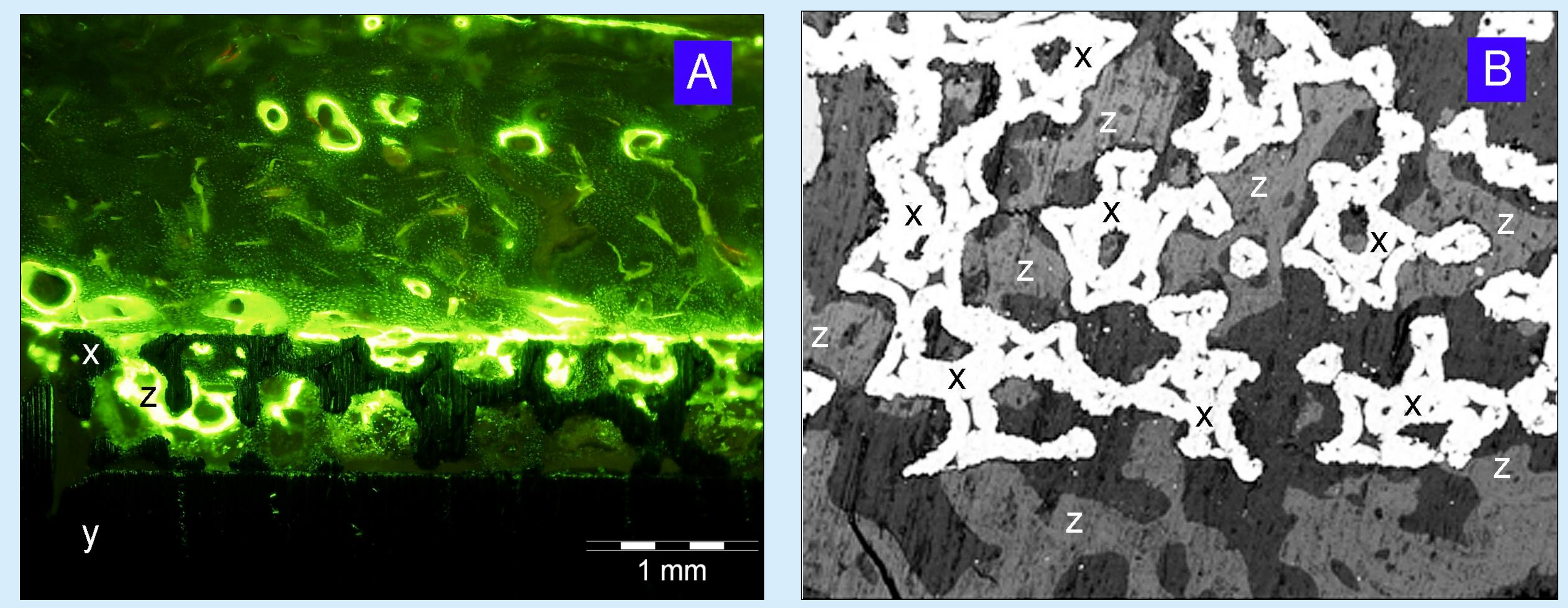

Figure 1. Canine Model: Bone ingrowth (z) into the porous tantalum material (x) above the titanium substrate (y) of the implant at 2 weeks (Calcein) (A); backscattered imaging shows new bone ingrowth (z) into the porous material (x) at 12 weeks (B).

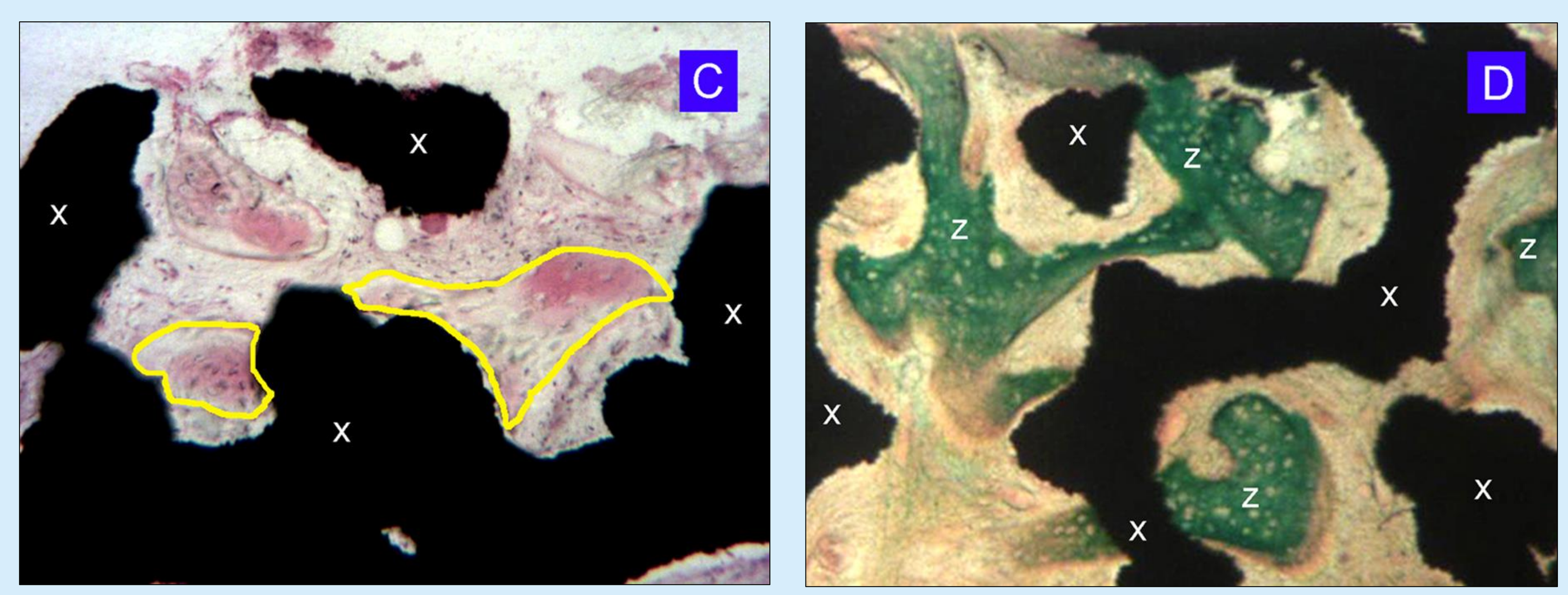

Figure 2. Human Model: Newly formed bony trabeculae partially surrounded by a front of osteoblasts (inside yellow lines) in a peripheral pore at 3 weeks (Masson's trichrome) (C); bone trabeculae with osteoid tissue (z) along the edges inside the porous material at 12 weeks (Masson's trichrome) (D).

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 eosine, toludine blue and Masson's trichrome at 2 weeks showed prolific blood vessel formation and tissue infusion 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 transcortical 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 osseoincorporation.[3] 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

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