

BONEWELDING® TECHNOLOGY

An innovative method for immediate anchorage of implants in bone

The insertion of implants into bone is always a critical part for immediate implant stability in the previously surgically prepared implant bed. In addition, implant insertion can be very tedious and time consuming, especially in craniofacial surgery where mini-screws are often used in large numbers. Last but not least, implant removal may be a problem such that it is desirable to have resorbable implants strong enough to withstand biomechanical forces on one hand and undergoing slow resorption over time on the other. BoneWelding Technology offers these requirements either by fully resorbable implants alone or by combinations of metal implants and polylactide polymer coatings for immediate stabilisation within the trabecular bone. Insertion of implants is achieved by ultrasound that liquefies the surface of the polylactide and thus allows rapid implantation and anchorage within the prepared bone bed. As soon as the ultrasound is stopped, the polymer hardens and immediate stabilisation is granted through the polylactide polymer that penetrated the trabecular space while liquid (Fig. 1).

This technology has advantages for many applications. Biocompatibility and safety were tested in several preclinical studies in sheep in the author's laboratory. In a first study in tibiae of sheep it was shown that no adverse inflammatory reactions of the surrounding tissue occurred after BoneWelding¹ (Fig. 2). The second study (to be published) confirmed the safety of the BoneWelding Technology and demonstrated the superior immediate stabilisation of dental implants within the bone (Fig. 3).

Osteosynthesis of the jaw in pigs revealed a normal histological pattern for bone healing after osteotomy and no interference due

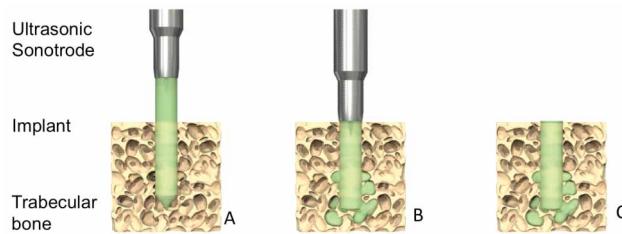


Fig. 1 Visualisation of the BoneWelding process: A) An active ultrasonic sonotrode drives the thermoplastic implant into the bone; B) Shearing forces at the contact face between bone trabeculae and polymer cause the polymer to liquefy and penetrate into the porous intertrabecular space; and C) The polymer cools rapidly, resulting in a stable joint to the bone after only a few seconds

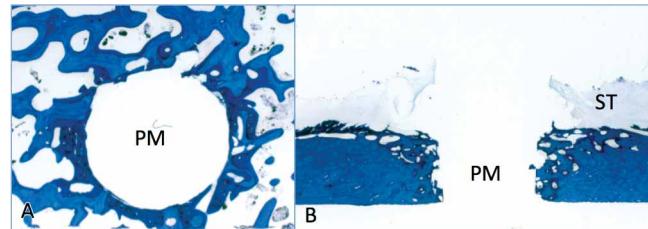


Fig. 2 Histological section after a polymer pin (PM) inserted into bone with BoneWelding Technology at A) a transverse and B) longitudinal section. New bone formation is visible (dark blue) close to the implant and soft tissue (ST) covering the implant (B)

to the type of fixation.² BoneWelding Technology was also successfully used for fixation of a release system for bone morphogenetic protein in the proximal tibia³ in sheep. Furthermore, specialised implants were developed for the immediate improved anchorage of tendon transplants within the bone tunnel during replacement of anterior cruciate ligament procedures⁴ (Fig. 4), where the squeezed tendon transplants were compared to those anchored by standard titanium interference screws. Polymer implants were specially designed for use in the spine in combination with polymer plates, where in preclinical studies in sheep it was demonstrated that BoneWelding Technology led to a locking screw mechanism when the polymer pins were inserted into the plate.

Despite the bulk aspect of the polymer, no adverse reaction in the adjacent tissues was noticed. In contrast, nearby vessels of the

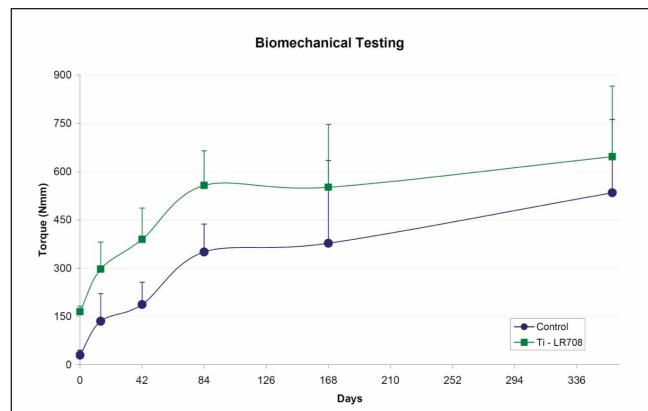


Fig. 3 Biomechanical torque test showed better implant stability throughout the implantation period of 336 days. The blue line indicates torque values of controls without polymer and bone welding, the green line represents values of implants inserted with BoneWelding Technology

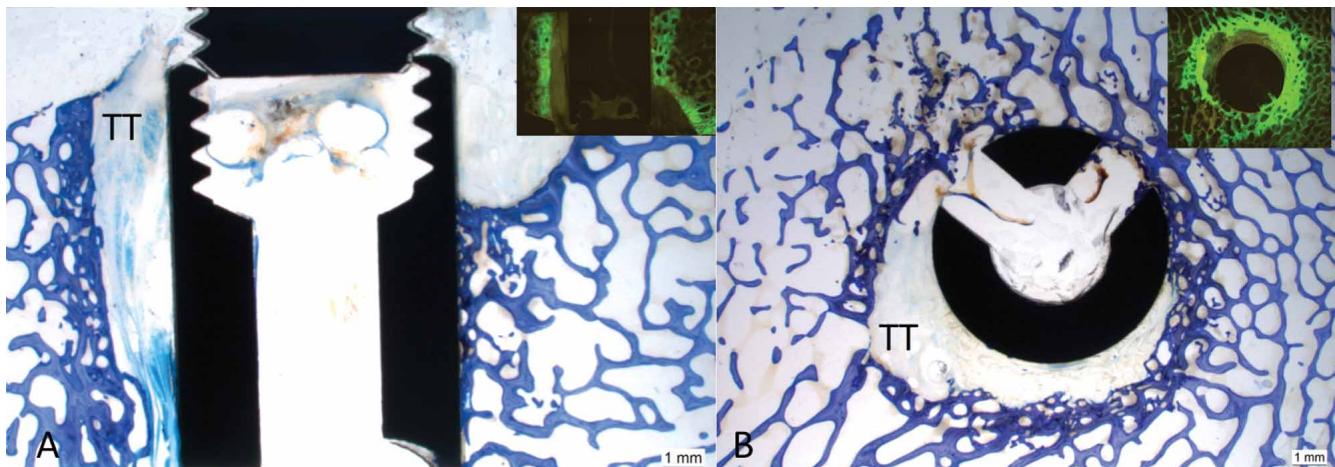


Fig. 4 Histological section after fixation of a tendon transplant with BoneWelding Technology for anterior cruciate ligament repair. New bone formation is visible (dark blue) close to the implant and tendon transplant (TT). The longitudinal (A) and transverse sections (B) are complemented with fluorescence section where bone deposition after three months is demonstrated

vertebral sinus or nerves were untouched and not affected in any way⁵ (Fig. 5). Clinically, the BoneWelding Technology has been widely used since 2005 to replace conventional titanium or polylactide screws in craniomaxillofacial surgery (SonicWeld Rx®, KLS Martin, Tuttlingen, Germany).

In summary, BoneWelding Technology is an innovative and highly attractive tool for applications in craniomaxillary, dental, orthopaedic, spinal and traumatological surgical procedures.

References

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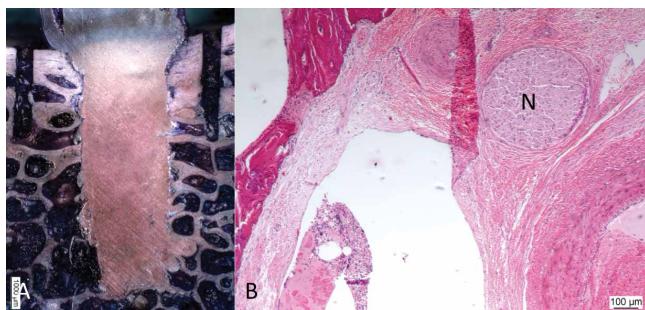


Fig. 5 A split macroscopic section of a polymer pin inserted into a vertebral body shows the penetration of the polymer into the trabecular bone during the ultrasonic insertion procedure (A). The HE section (B) demonstrates that the nerves (N) are not affected by the ultrasonic liquefaction and infiltration process

Osseointegration:

Implant stability is tightly connected to overall osseointegration of the implant, which in turn is dependent again on immediate stability after implant insertion. The surgical procedure itself causes trauma and bone resorption of the implant bed which, in combination with micromotion due to instability, can lead to the formation of an interface membrane between implant and bone. If immediate stability is provided bone inflammation will quickly subside and primary osseointegration is achieved.

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