Ultrasound assisted osseous fixation of degradable polymer implants

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INTRODUCTION: Ultrasound assisted osseous fixation of degradable polymer based implants **(**BoneWelding® technology) is an innovative, new method for bonding dental or orthopaedic implants directly to bone. This process employs ultrasonic energy to liquefy a polymeric interface between implants and the host bone. Polymer penetrates the pores of the surrounding bone, rapidly solidifies and forms a strong and uniform microscopic inter-digitation interface between implant and bone. The project combined in vivo and in vitro experimental studies with computer simulations to fully characterize the ultrasonic fixation process.

METHODS: Quasi-static and dynamic biomechanical testing in a variety of bone analog materials (Sawbone, solid rigid and cellular rigid 7.5 to 20pcf) was used to fully characterize the mechanical performance of the inter-digitation interface. For testing, injection molded polymer dowels (length 25mm, Ø 3.5mm, PLDLA 70/30) were used, insertion was achieved using ultrasonic power at 20kHz and with an amplitude of about 50µm. Titanium cancellous bone screws (Ø 3.5mm) were used as reference, details are given elsewhere [1]. A large animal (sheep), *in vivo* study was conducted to evaluate short and long term (2 – 6 months, 3 sheep per time point, implantation in distal femur and proximal tibia) biological response to the process and implant materials.

RESULTS: The microscopic inter-digitation interface was found to be stronger than the surrounding host material – failure always occurred in the bone analog material. Consequently, substantially superior mechanical performance of the ultrasonically inserted dowels in comparison to conventional bone screws was demonstrated (Figure 1). This has also been confirmed in highly osseo-porotic human bone (proximal humerus) [2] .

In the *in vivo* study no inflammation or excessive fibrous tissue formation was observed. No bone necrosis was found in the interface zone. Active bone remodeling was seen around the implant. A decreased rate of bone resorption immediately adjacent to the implant in comparison to control sites distant from the implant was observed.

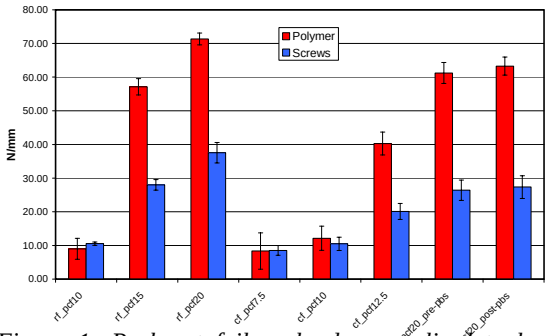

Figure 1: Push-out failure load, normalized to bone depth. Ultrasonically inserted dowels consistently outperformed conventional metallic screws.

Micro finite element computer models were developed to compare the local mechanics of load transfer through the microscopic inter-digitation interface and conventional bone screws. Peak bone stresses were lower for the ultrasonically inserted implants. Conventional screws produced point loading of individual trabeculae with significantly higher stress levels.

DISCUSSION & CONCLUSIONS: Ultrasound assisted fixation of polymeric implants has shown to be a biocompatible and mechanically superior fixation technique if compared to anchorage capacity of cancellous bone screws. These findings have has also been confirmed in highly osseo-porotic human bone (proximal humerus) comparing the ultrasonically inserted polymeric implant with a titanium suture anchor [2]. Furthermore, the ultrasound specific torque-free axial insertion process will allow non-circular implant cross-sections that will display distinct mechanical advantages. In 2005, the technology has been clinical introduced for maxillo-facial surgery.

REFERENCES: [1]S.Ferguson et al (2006), *J Biomed Mater Res Part B: Appl Biomater* **77B**: 13–20. [2]D.C.Meyer et al (2006) *Clin Orthop Relat Res*.**442**:143-8

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