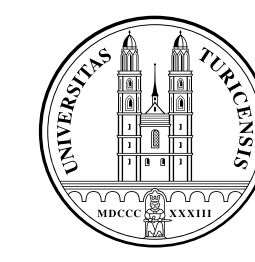


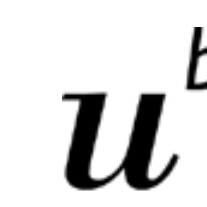
A novel concept of anchoring permanent implants into bone

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Introduction

- The BoneWelding® Technology is a patented innovative method for bonding implants directly to bone
- The process employs ultrasonic energy to mold a polymeric interface between implants and the host bone
- Polymer penetrates the pores of the surrounding bone, rapidly solidifies and forms a uniform bond between implant and bone (Fig. 1), which was proven to be stronger than screws of the same dimension in vitro [1, 2] and in vivo [3, 4]
- The use of the BoneWelding® Technology process already replaced screwed osteosynthesis systems in the craniomaxillofacial surgery [5-7].

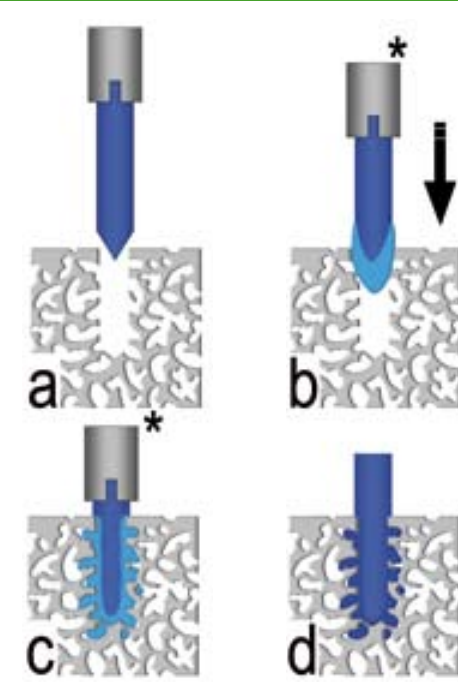


Fig. 1: Schematic drawing of the BoneWelding® Technology

Project Goals

- Implant design employing the BoneWelding® Technology for permanent implants
- Validation of the hybrid concept for primary and secondary stability (Fig. 2)
- Characterization of the mechanical quality of the resulting interface
- Histological analysis of the osseointegration process
- Comparing the influence of polymer degradation speed
- Establishing the novel animal model for screening studies

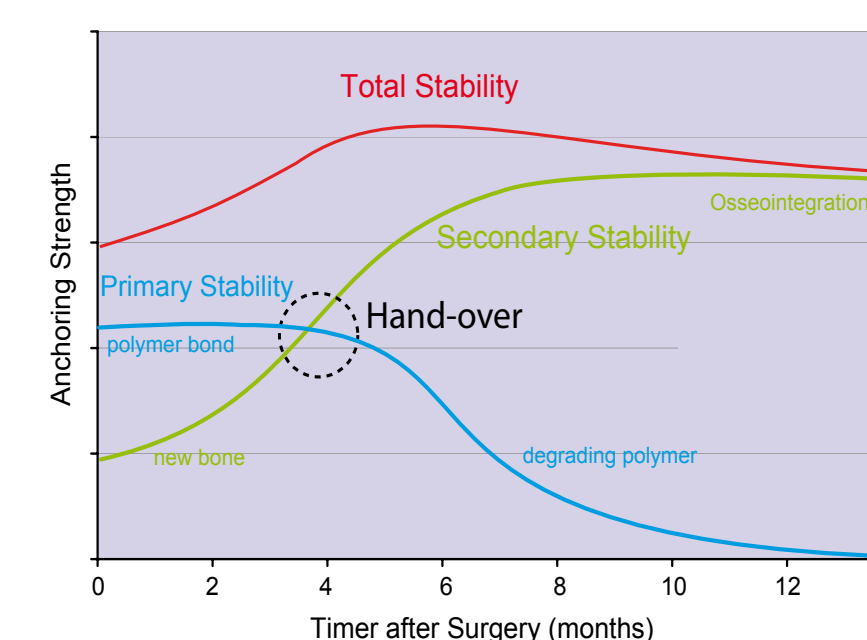


Fig. 2: The hybrid implant concept of primary and secondary stability.

Study Design

- A hybrid implant was designed for this study, consisting of a cylindrical titanium pin (∅ 2.8 mm) partially coated with a bioresorbable polylactide (LR708 or R 208, Boehringer, Germany) (Fig. 3)
- 16 Sheep were used as large animal osseointegration model.
- Implants were inserted in the iliac bone (Fig. 4, 5). Each side provides space for 10 samples.
- The study covers observation periods of 2 weeks, 6 weeks, 3 months, 6 months and 12 months.
- Samples were evaluated with biomechanical, histological and histomorphometrical methods



Fig. 3:
Left: Test implant with titanium core and two polymer (PLA) stripes (yellow)
Right: Control implant type without polymer parts

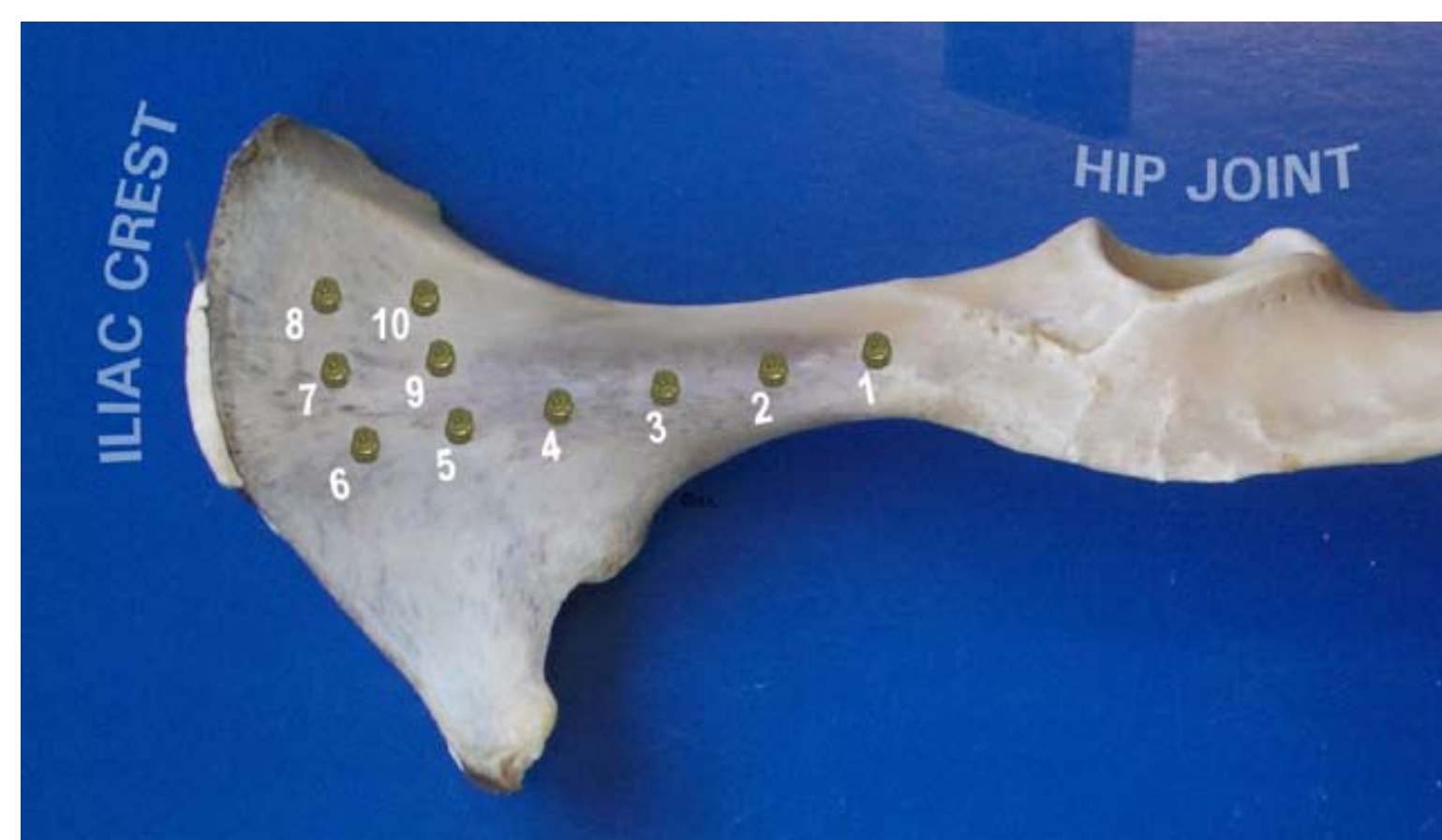


Fig. 4: The sheep pelvis is a novel model, which provides space for 10 implants in predominantly cancellous bone. Minimal distance between implants was 10 mm. These properties reduce animal number and costs for screening studies.

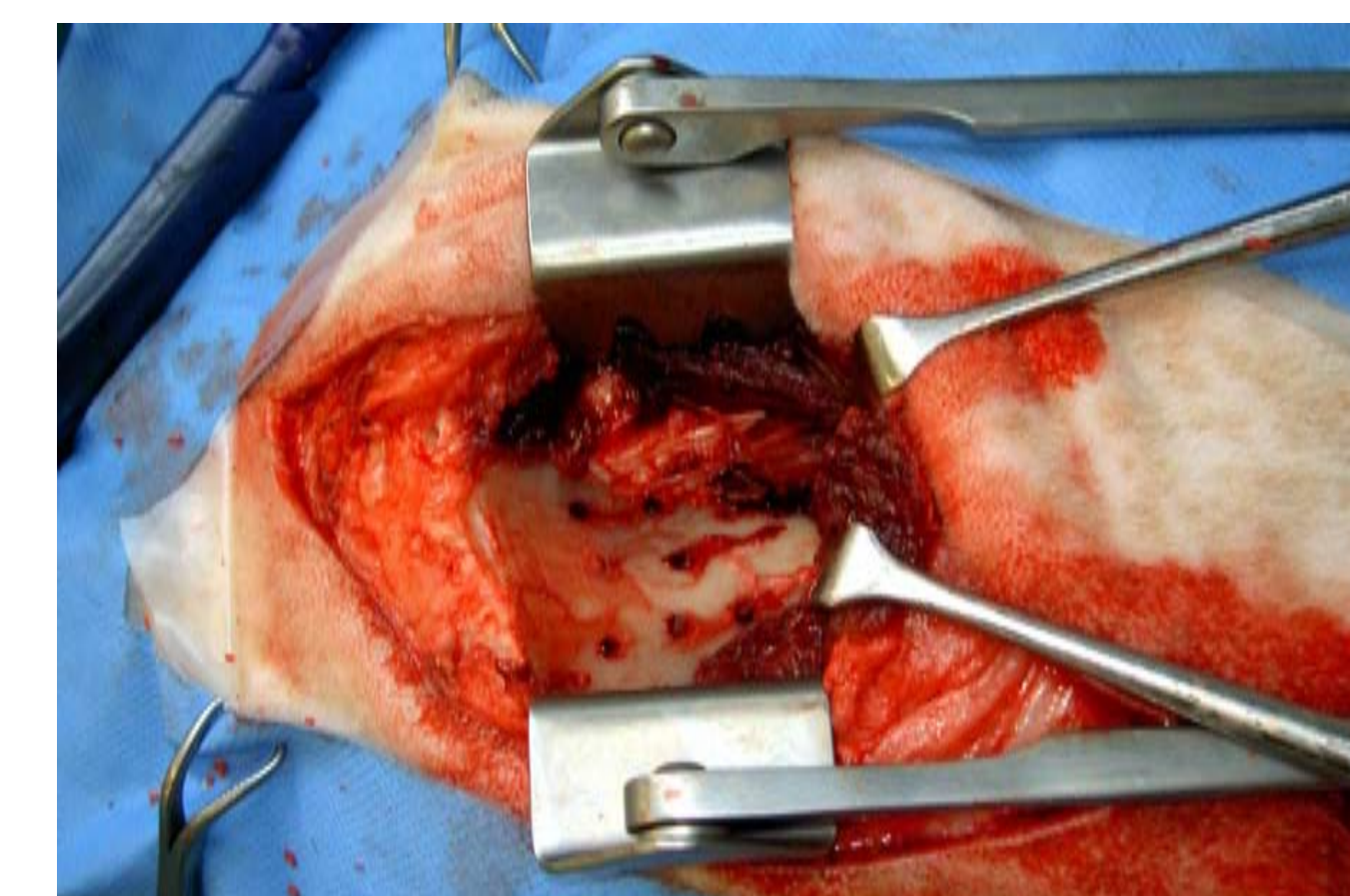


Fig. 5: The access to the pelvic bone was performed from dorso-laterally by a standard surgical procedure. The tendinous insertion of the muscle was cut at the cranial crest and the muscle body was bluntly removed to expose the shaft of the iliac bone. Cavities were pre-drilled before implant insertion.

Biomechanical Testing



Fig. 6: Setup of mechanical testing. MTS testing machine and a fixed sample

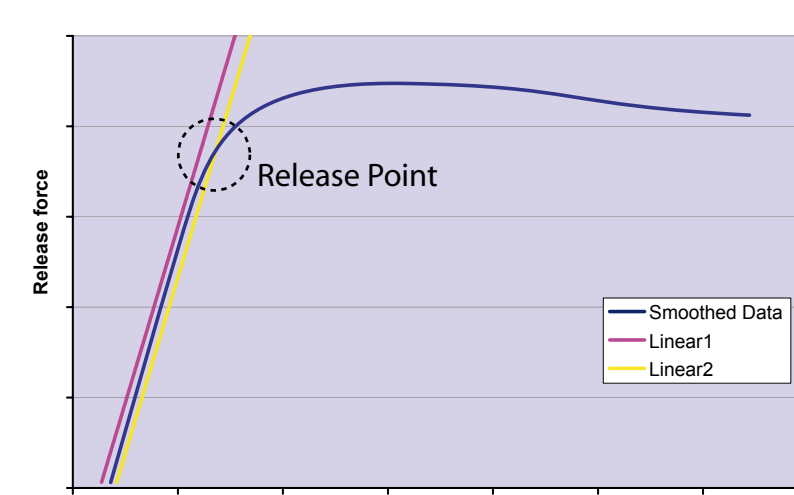


Fig. 7: Typical torque release force curve and release force calculation with shifted regression lines.

- The samples were embedded into a plaster socket which was then aligned exactly in the axis of the implant holder with a special metal alloy (MCP 47 Alloy)(Fig. 6). Biomechanical tests were performed on the MTS 858 Mini Bionix. The implants were turned for a total angle of 30° (rotation speed 90°/minute) at a temperature of 29°C. Torque release force was calculated (Fig. 7) subsequently.

Results

- A clearly increasing anchoring strength could be demonstrated for all implant types (Fig. 8).
- Polymer coated implants were performing better than the control type without polymer part.
- Polymer degradation did not lead to an overall decreased implant stability.

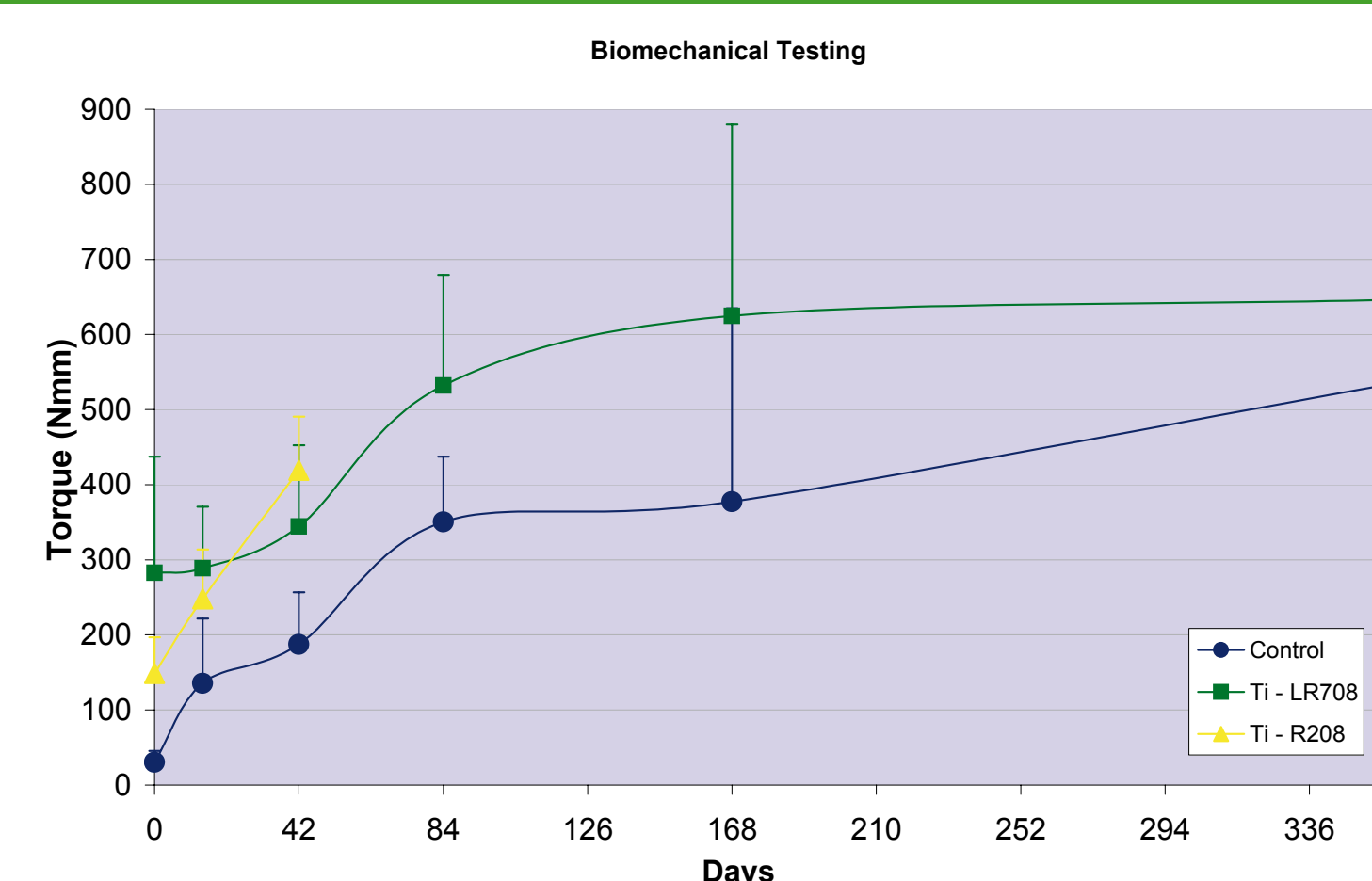


Fig. 8: Torque release force with time of hybrid implant types (Ti-xxx) and control implants. The polymer part of type 'Ti-R208' was already resorbed at 12 months.

Histology and Histomorphometry

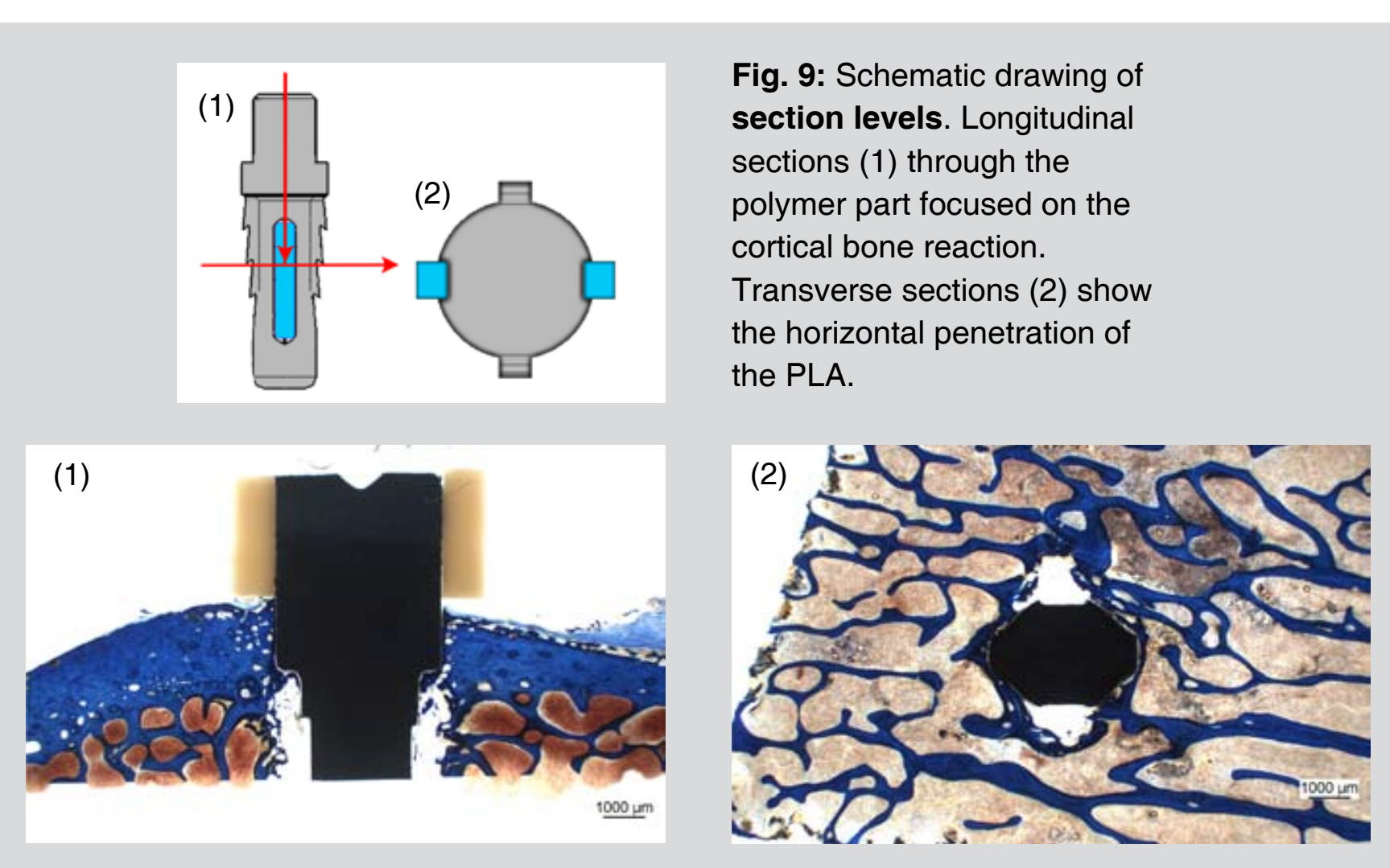


Fig. 9: Schematic drawing of section levels. Longitudinal sections (1) through the polymer part focused on the cortical bone reaction. Transverse sections (2) show the horizontal penetration of the PLA.

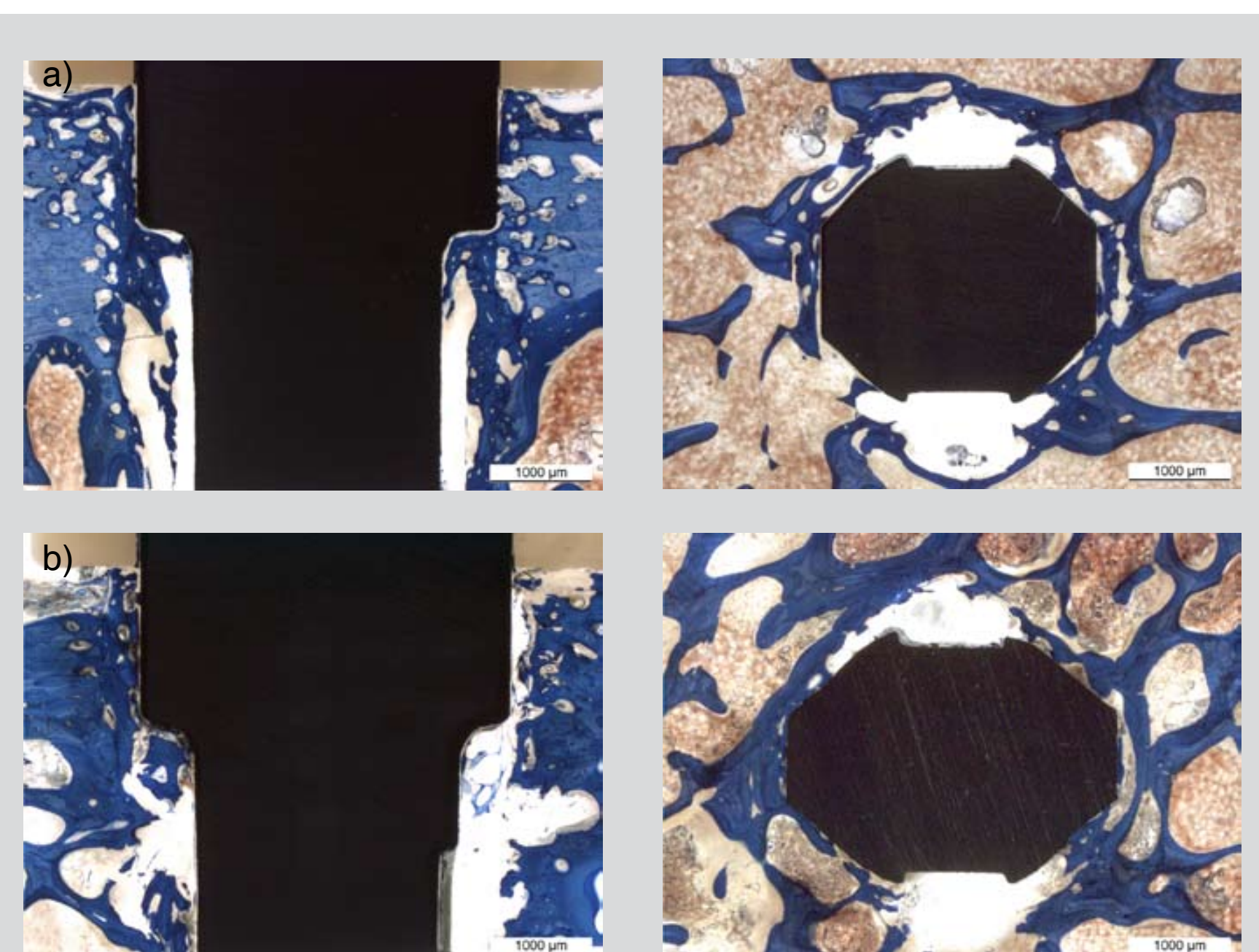


Fig. 10: Histology: Exemplary pictures of bone response at 6 weeks (a) and 6 months (b). Polymer material (white) was either covered by bone (blue) or lined by cells of the bone marrow (brownish). New bone was stained darker by the toluidine blue dye.

- Undecalcified bone samples were embedded in to pMMA resin. Ground sections (200 µm) were cut longitudinal and transverse to the implant axis (Fig. 9)
- Qualitative histological evaluation was performed after Toluidine blue staining.
- New bone of the remodeling and early osseointegration phase was in vivo stained with a sequence of fluorochromes (Table 1).
- Direct bone-implant contact (BIC) was measured semiquantitatively (Fig. 12).
- Digital pictures were taken and processed in Adobe Photoshop® (Fig. 14) for area measurement in Leica QWin® (Leica Microsystems, Germany)

Results

- Implants equipped with polymer showed excellent biocompatibility at all observation periods.
- New bone was built up continually, enclosing the implants without soft tissue capsule (Fig. 10). After 6 months, the new bone was already remodeled into lamellar bone that was clearly visible around the implant (Fig. 11).
- The percentage of bone-implant-contact was also increasing steadily, even faster for the polymer coated implants (Fig. 13).
- Bone mass development was following the dynamics of healthy bone healing (Fig. 15).

weeks	2	4	6	8	10	12	14	24	52
acute									
remodeling		*	**	***	***	***	***	***	***
osseointegration									
Fluorochromes:									

Table 1: Scheme of in vivo fluorochrome staining and histological evaluation at the end of the observation periods.

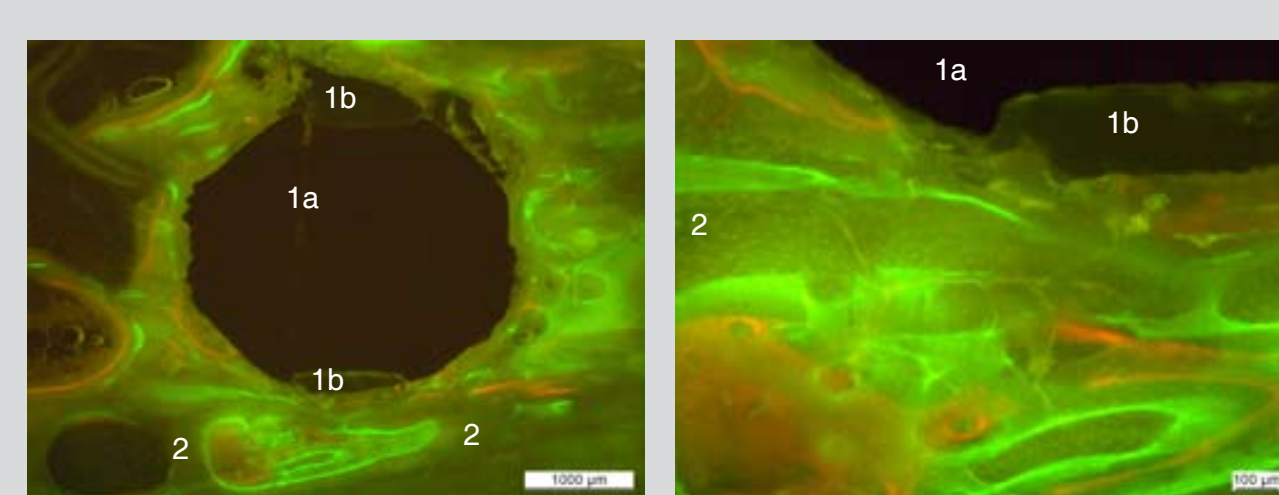


Fig. 11: Evaluation of the remodeling activity with fluorochrome labeled bone. Transverse section at 6 months: New bone was built up at the implant (1a: titanium core, 1b: polymer) mainly within the first 6 weeks (bright green), followed by less new bone thereafter (orange band). Only few old bone (2) outside a 1 mm perimeter was remodeled.

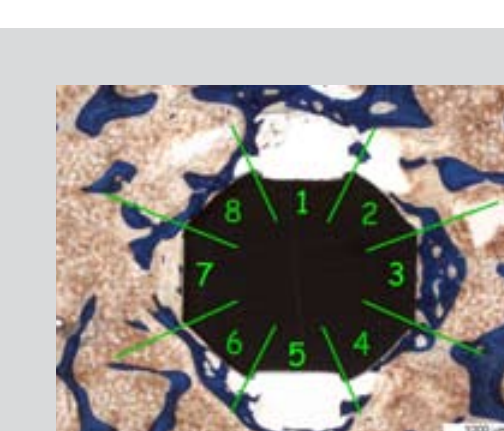


Fig. 12: The total implant surface was divided into 8 sectors for bone-implant contact measurement (BIC). BIC was estimated in 10% steps.

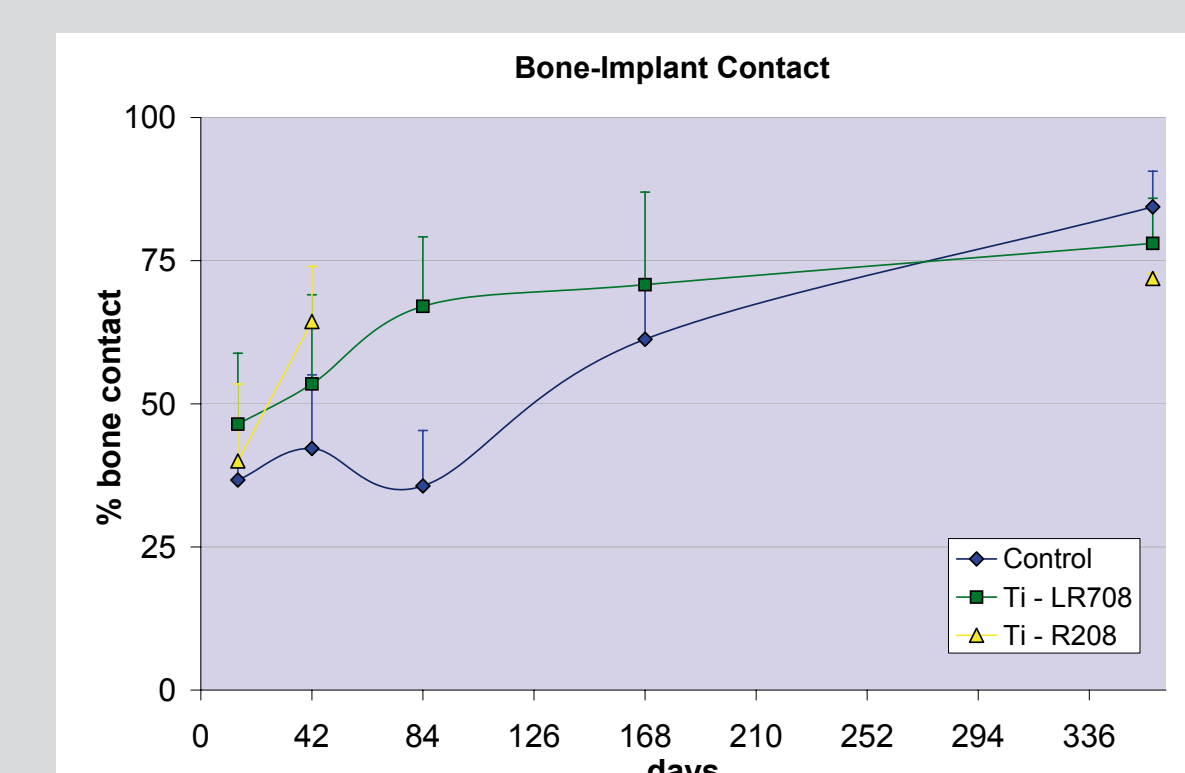


Fig. 13: Bone-implant contact (BIC) with time of hybrid implant types (Ti-xxx) and control implants. BIC was higher for the polymer coated implants during the osseointegration phase.

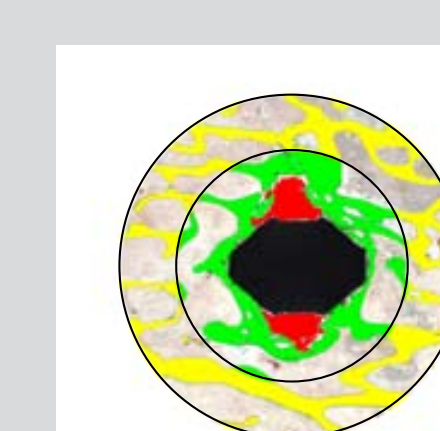


Fig. 14: Bone area was measured in an inner and outer sector and calculated as percentage to the total sector area. Differences (x= inner sector / outer sector) between both sectors give the percentage of bone resorption or new bone formation at the implant.

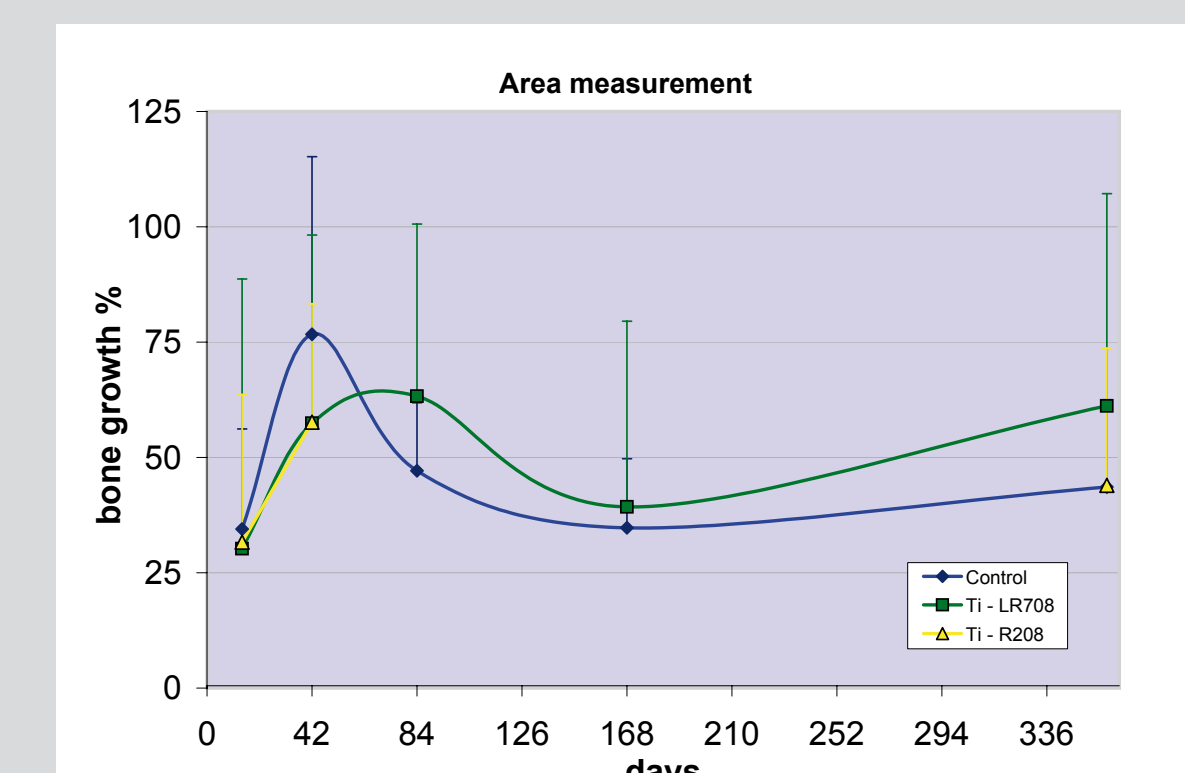


Fig. 15: Bone area differences at the implant with time of hybrid implant types and control implants. Bone area was increasing fast in the early phase, but came down in the osseointegration phase. The results show normal changes of bone mass during osseointegration.

Discussion and Conclusions

- It was shown, that the BoneWelding® Technology is suitable to anchor permanent implants into bone.
- The hybrid concept of a biodegradable part for primary stability and a non-degradable part for long-term stability resulted in improved osseointegration.
- The sheep pelvis model was suitable for preclinical implant testing.

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