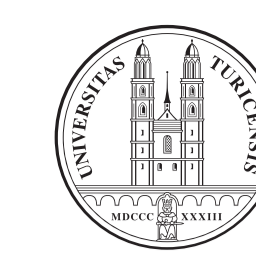


An Experimental *in vivo* Analysis of the Bone Response to Ultrasonically Inserted Pins (BoneWelding® Technology) in the Sheep Spine



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Introduction

- The BoneWelding® Technology is an innovative insertion method for bonding bioresorbable polymer implants into bone. By employing ultrasonic energy, the thermoplastic polymer is molded into the pores of the host bone forming a strong and uniform bond with the adjacent bone. (Fig 1).
- The method provides enhanced stability [1,2] and can lead to less implant failure.
- It has already replaced screwed osteosynthesis systems in the cranio-maxillofacial surgery [4,5,6] and also reduced the duration of surgery [3].
- The aim of this study was to investigate the suitability of the BoneWelding® Technology for spinal applications in a double exposure setup.

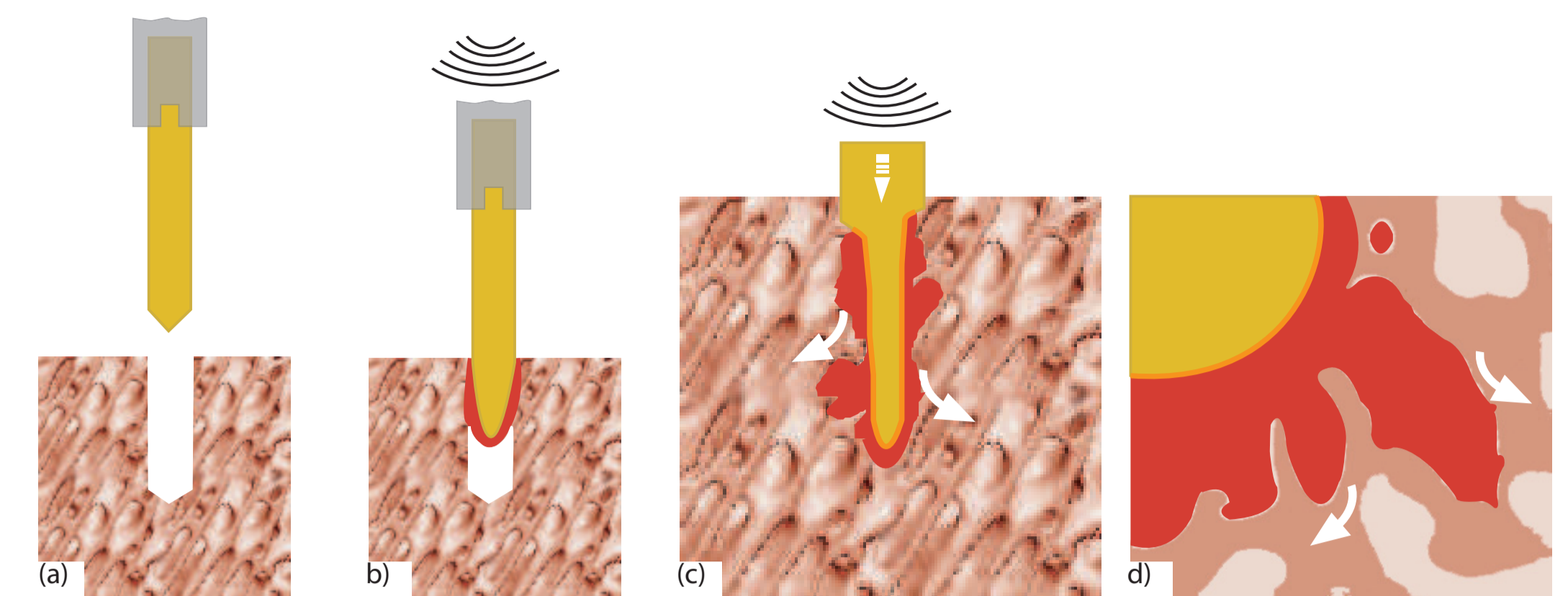


Fig. 1: Schematic drawing of the BoneWelding® Technology
a) Bioresorbable thermoplastic pin attached to the ultrasound- device
b) Ultrasonic power molds the outer edge of the pin
c) The liquefied part of the pin penetrates the pores of the host bone
d) Seconds after stopping the ultrasonic energy the polymer solidifies.

Study Design

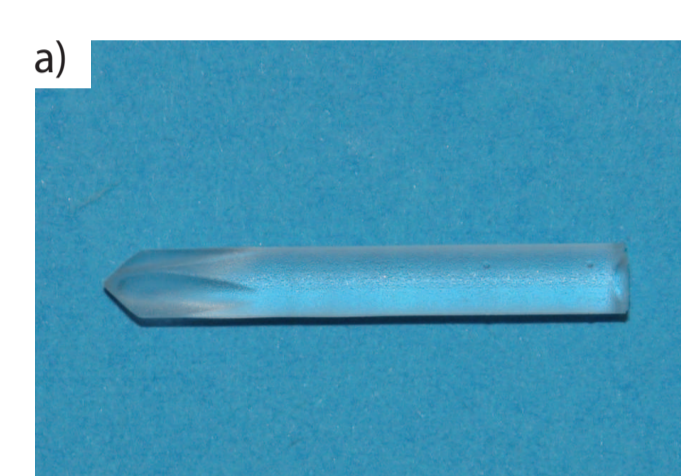
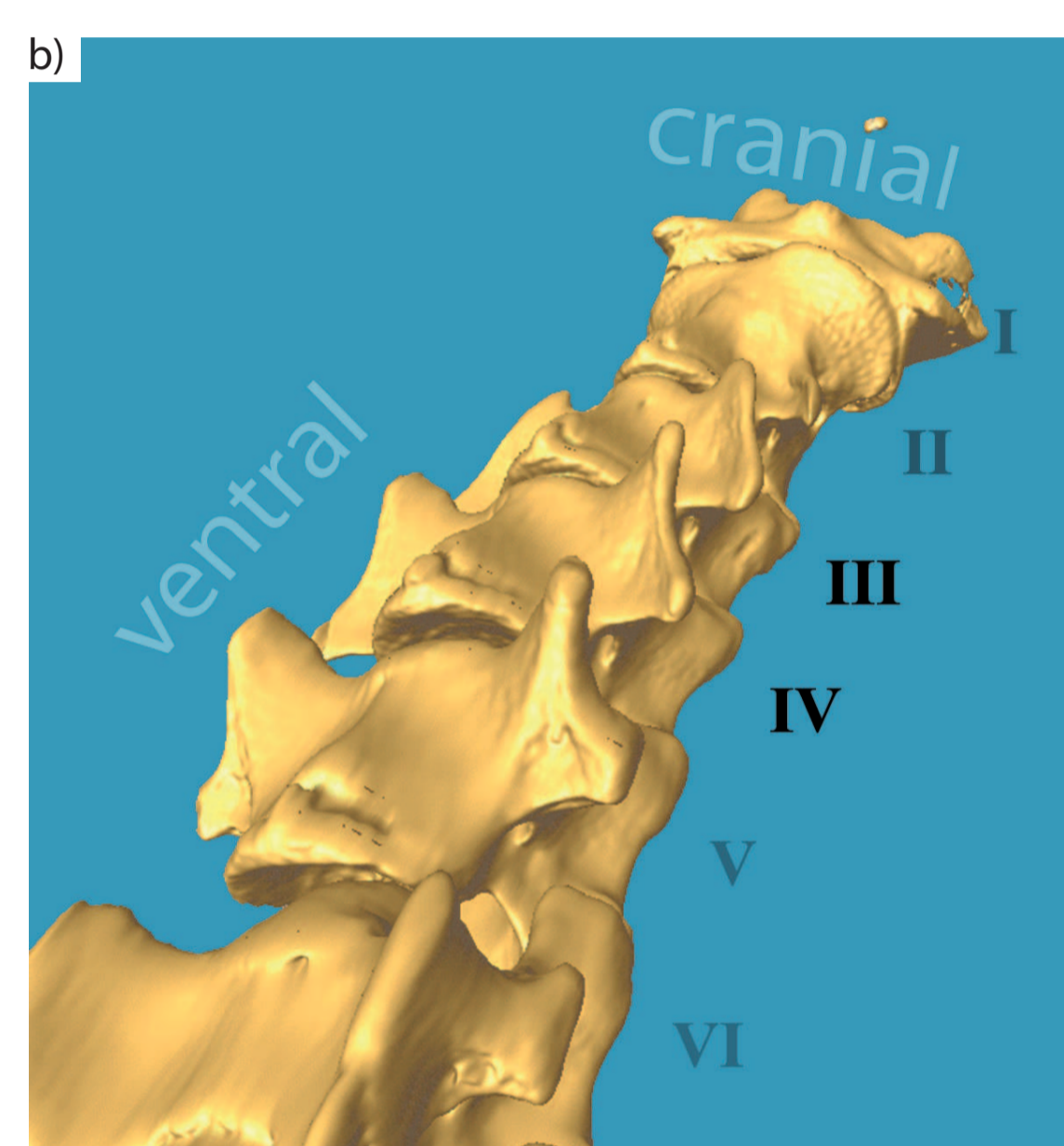


Fig. 2:
a) The implant with a conical apex. The diameter was 3.5 mm and 25 mm long (10 mm inserted).
b) The sheep cervical spine in a ventro-lateral view. Level III and IV were used for implant insertion.



- Polylactide pins (PLDLLA 70/30) (Fig. 2a) were inserted (n=24).
- Three sheep were used in a cervical spine model (Fig. 2a, 3).
- A converging insertion (Fig. 3) aimed to create a maximum stress at the pins' apices.
- Samples were evaluated by macroscopical, radiographical, and histological investigations for host tissue response.
- Cellular and morphological parameters were assessed after an observation period of two months.

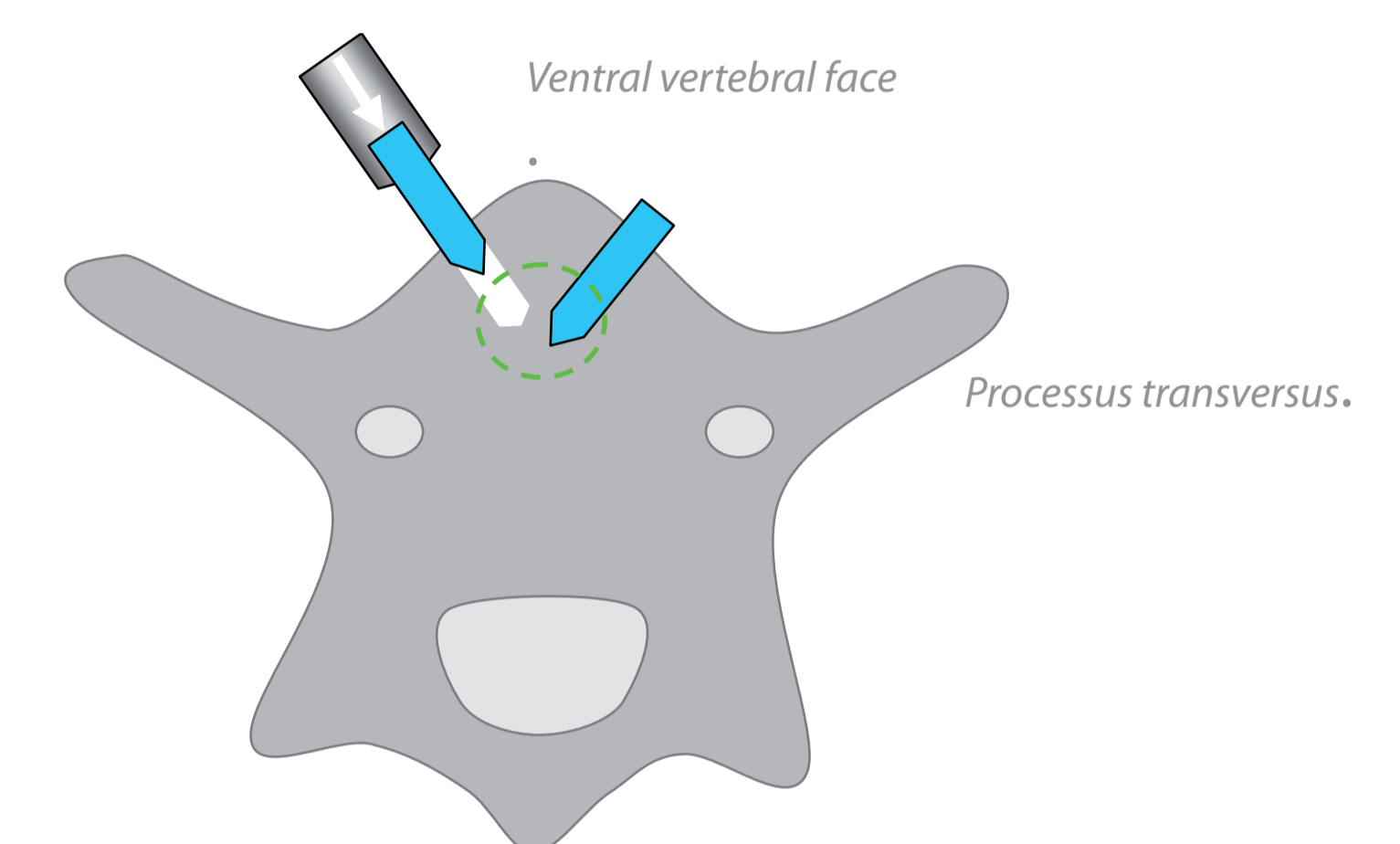


Fig. 3: Converging pin pairs were inserted into the cervical spine using an anterior approach. The angle between 2 pins is 70 degrees. Double impact is achieved at the apices of 2 converging pins (green circle).

Histology and Histomorphometry

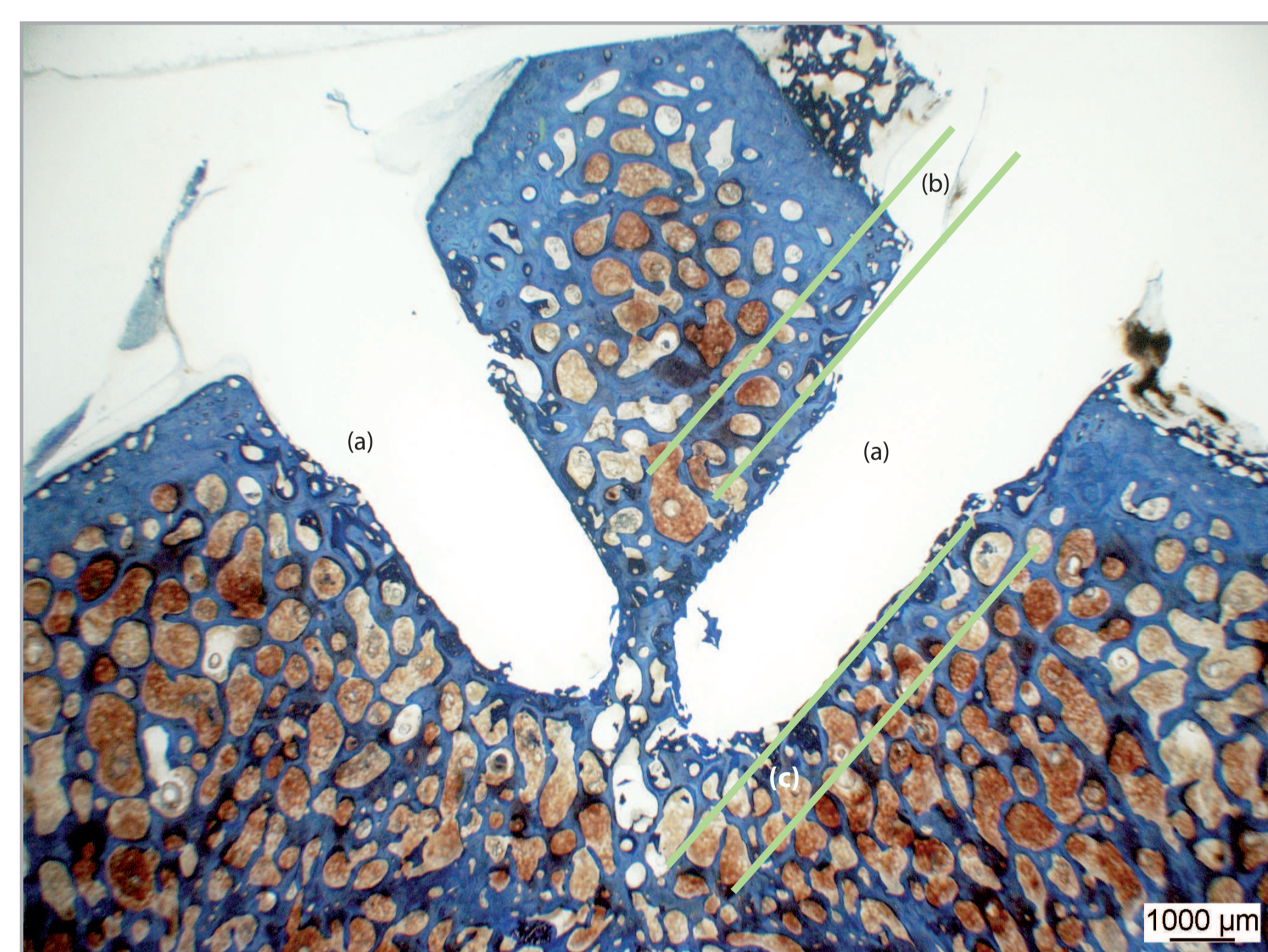


Fig. 4: Overview picture of converging implants (a). Samples were cut longitudinally through the pin pairs. The width of the remodeling area (green lines) was measured in the cortical (b) and cancellous bone (c). Toluidine Blue staining.

- Undecalcified bone samples were embedded in pMMA and cut longitudinally in sections of 5µm and 200µm through the implant pairs.
- Qualitative histological evaluation was performed with the HE or Toluidine Blue stained samples (Fig. 4,5).
- Assessment of the cellular response of the host tissue was done according to ISO 10993.
- Quantitative histomorphometrical evaluation was achieved by measurement of the width of the remodeled bone around the implant (Fig. 5).

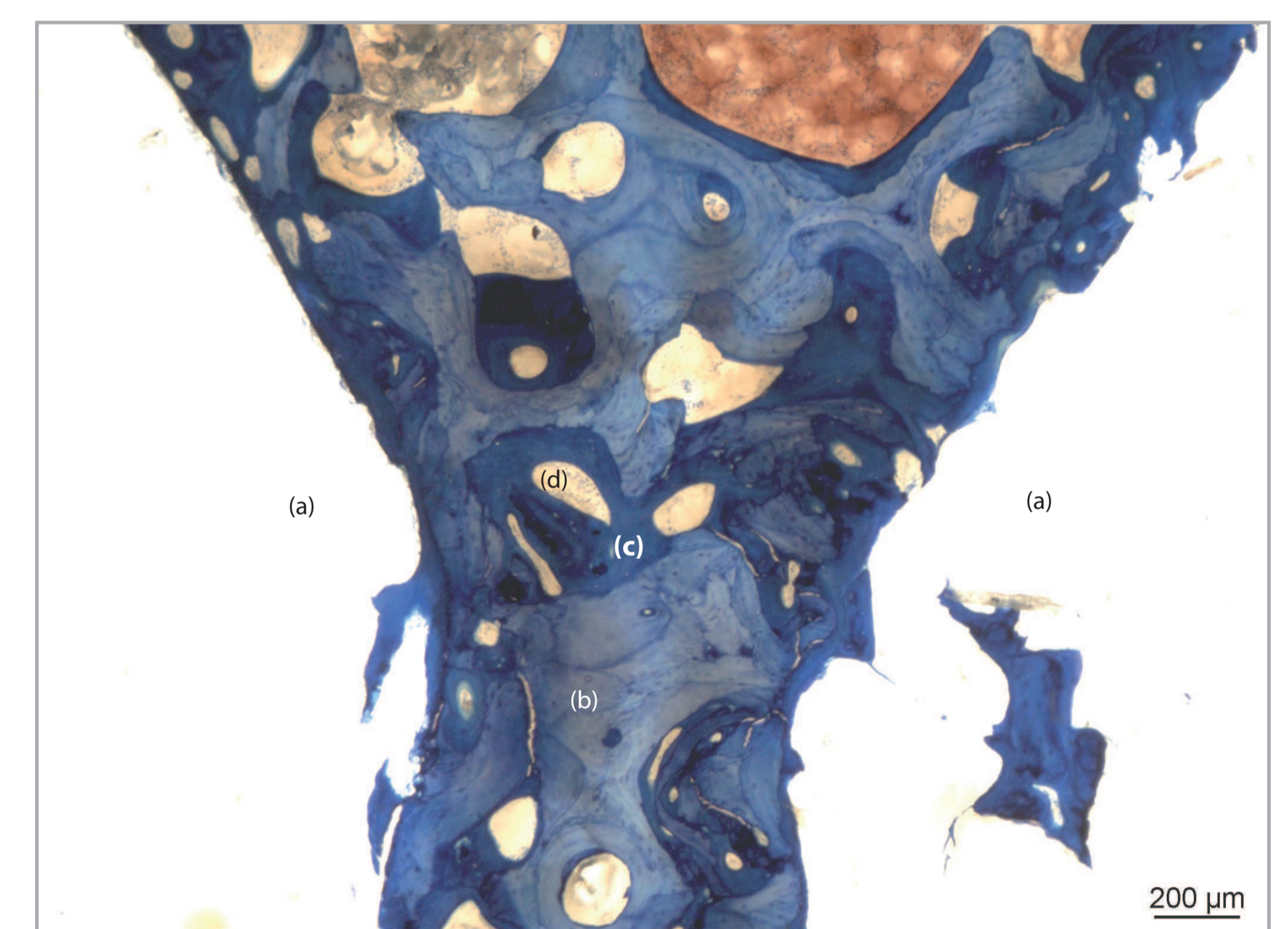


Fig. 5: Focus on the apical region. Inbetween the distal parts of the implants (a), old (b) and new bone formation (c) and vital bone marrow (d) was found.

Results

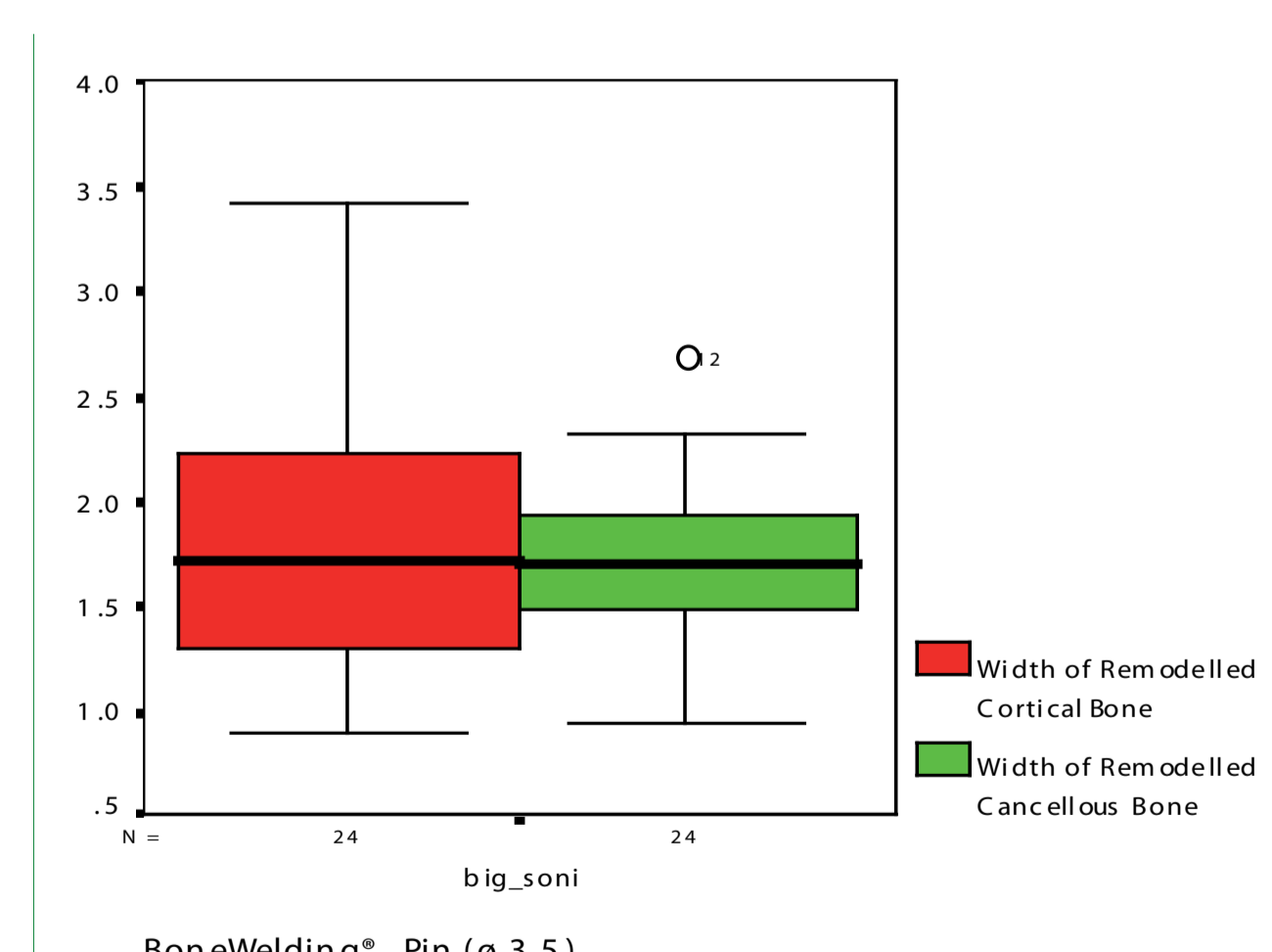


Fig. 6: Remodeling distance. Measured width of the remodeled cortical (red) and cancellous (green) bone in mm. New bone in the cortical area was formed around the pin to a width of 1,3- 2,3 mm and 1,5-1,9 mm in the cancellous bone.

- Insertion of the PLA pins went successful using the BoneWelding® Technology .
- Histology showed remodeled bone around the implant.
- Bone response at the apices of two pins was similar as alongside the pin.
- The zone of the remodeled bone had an average width of 1,7 mm (Fig. 6).
- Assessment on the cellular level also showed no adverse reaction (Fig. 7).

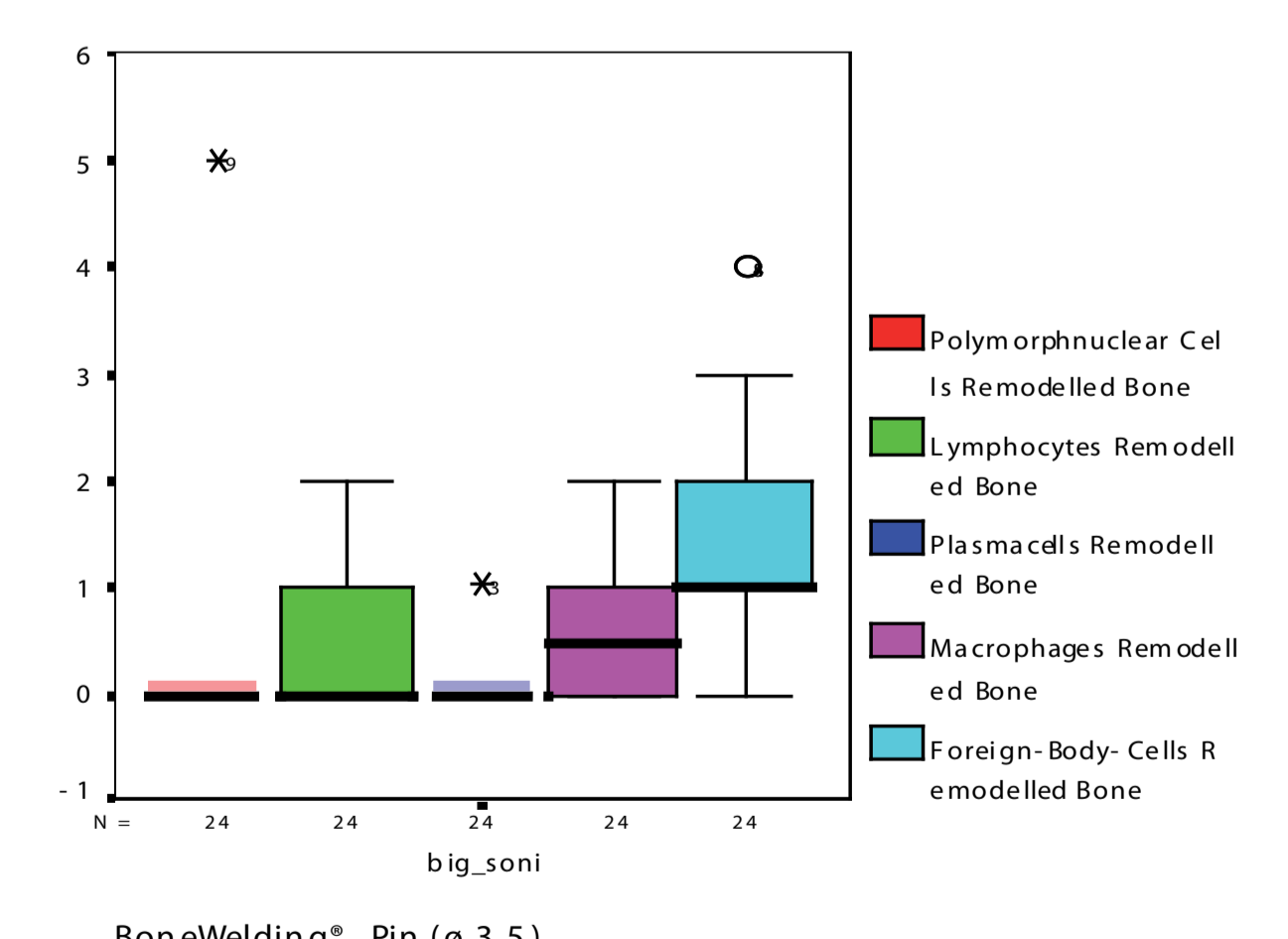


Fig. 7: Cellular Response. Box Plots of the inflammatory cells in the remodeled bone. The cells around the implant were counted and scored (0 = 0 cells; 1= 1-5 cells; 2= 6-10 cells; 3= 11-15 cells; 4=many; 5= crowded)

Discussion and Conclusions

- Bone remodeling around the implant was within the normal healing process.
- No adverse reaction was found - even in the region of high exposure.
- The suitability of the BoneWelding® Technology for spinal applications was demonstrated in this study.

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