Temperature Characterization of Ultrasonically Inserted Polymer Implants (BoneWelding® Technology) in the Sheep Vertebral Body – an *in-vitro* and *in-vivo* Study.

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Introduction

- The BoneWelding® Technology has proven to be biocompatible and suitable for bonding resorbable thermoplastic polymer implants directly to bone [1, 2].
- The implantation method employs ultrasonic energy to infiltrate the polymer into the pores of the host bone and forms a strong and uniform bond between implant and bone (Fig 1).
- Even though the insertion takes only about a second to complete, a local temperature increase is part of the process.
- The present study aimed to clarify the local thermal effect of the insertion and to compare *in-vitro* and *in-vivo* temperature measurement.

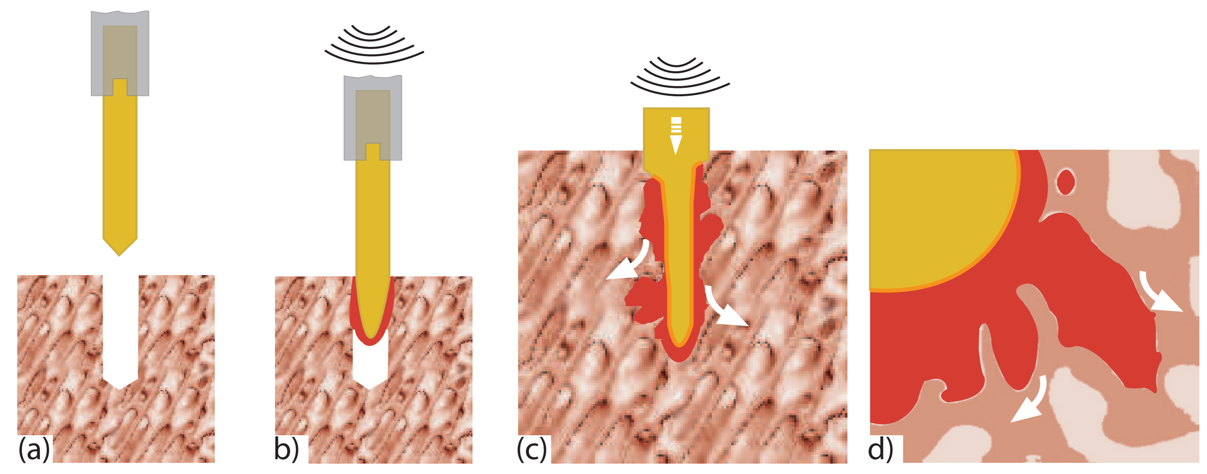

Fig. 1: Schematic drawing of the BoneWelding® Technology: An active ultrasonic sonotrode drives the thermoplastic element into the bone (a). Shearing forces at the contact face of the polymer cause it to liquefy and penetrate into the pore space (b-c). The polymer cools rapidly, resulting in a stable joint after only a few seconds (d).

Study Design

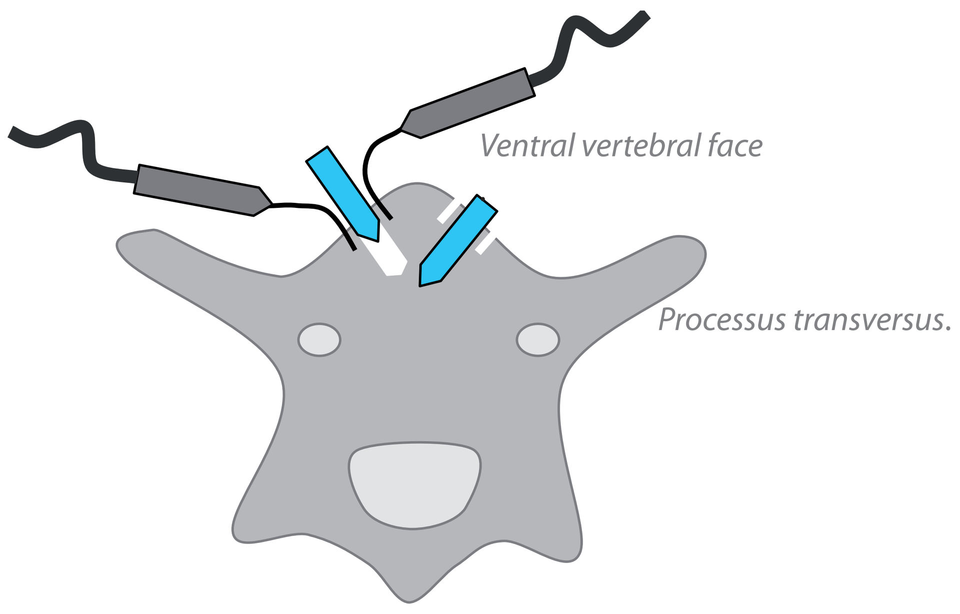

Fig. 3: Test setup in the vertebral body. An anterior approach was used to insert pin pairs into the ventral face of the vertebral body. .

- Implants were made from Poly-Lactide (Fig. 2)
- A sheep cervical spine model was used.
- Cavities were prepared in the vertebral body after predrilling and cortex opening (Fig 3).
- The setup was applied for
  - *in-vitro* measurements in cadaver bone and
  - *in-vivo* measurements in one deeply anaesthetized animal (Fig. 4).

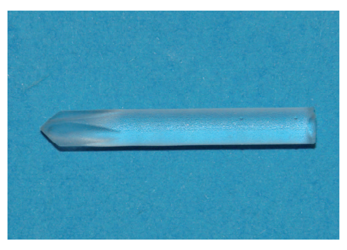

Fig. 2: The implant is a polylactide pin (PLDLLA 70/30) with a conical apex. Diameter of 3.5 mm and length of 25mm - 10 mm deep inserted into the bone.

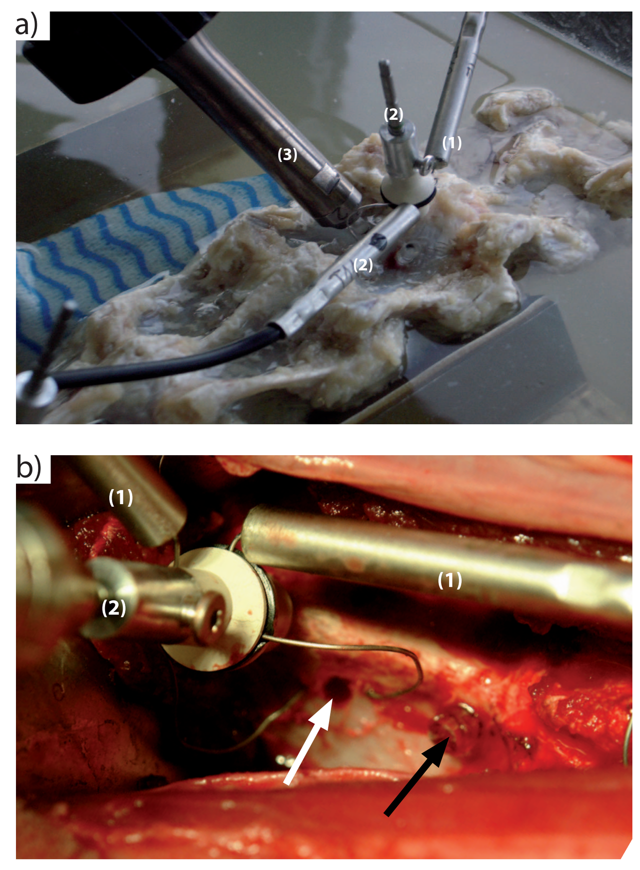

Fig. 4:
a) *In-vitro* measurement. The sample was submerged in a waterbath at 37°C. The thermocouples (1) were clamped in a holding device (2), such that the sonotrode (3) did not touch during insertion.
b) Similar *in-vivo* measurement. A predrilled cavity (white arrow) and a already inserted pin (black arrow) are visible.

Temperature measurement

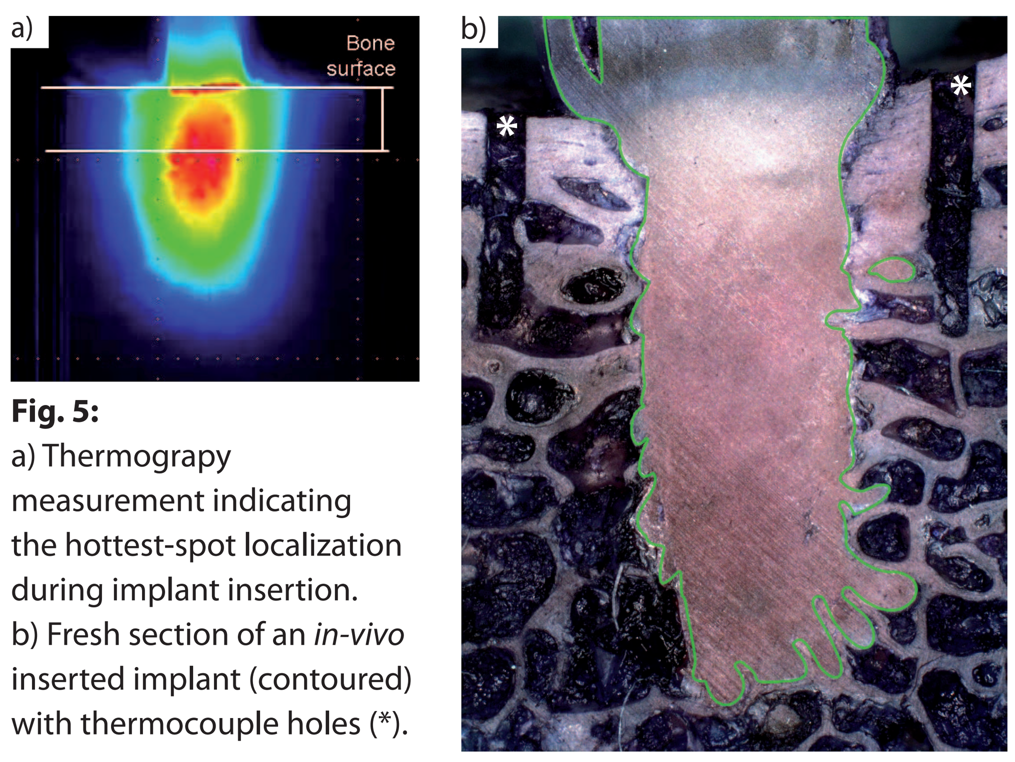

Fig. 5:
a) Thermograpy measurement indicating the hottest-spot localization during implant insertion.
b) Fresh section of an *in-vivo* inserted implant (contoured) with thermocouple holes (*).

- Temperature changes were measured in a distance of 1mm from the implantation site during insertion, referenced by a thermocouple in 20 mm distance.
- Thermography camera testing was previously done to determine the hottest spot during implant insertion (Fig. 5a).
- Local temperature was recorded with thermocouples in the maximal exposure area (Fig. 5b)
- Temperature curves were plotted and median values were calculated (Fig. 6).

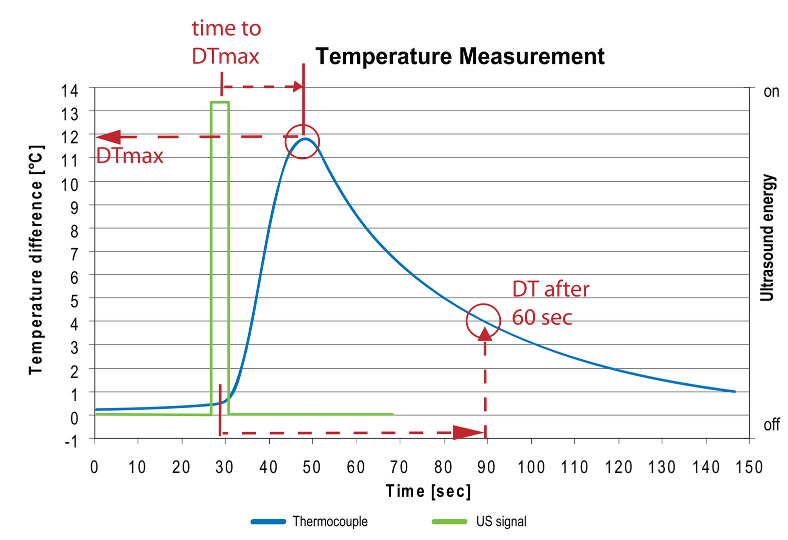

Fig. 6 : Typical temperature curve, analysed for maximal temperature difference (DTmax), temperature difference after 60 seconds (DT-60) and time to the maximal temperature (t-DTmax) after insertion.

Results

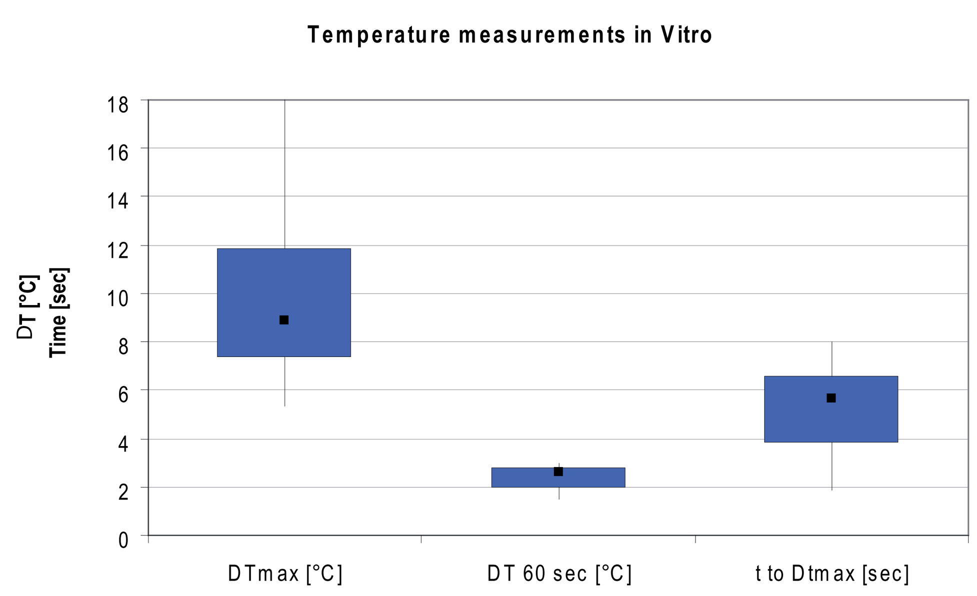

Fig. 7: Temperature changes recorded ***in-vitro.***
Box plots of temperature changes during insertion

- According to the thermography films, the hottest spot was in depth of 3 mm below the surface (Fig. 5a).
- The thermocouple records in cadaver bone showed, 'DTmax' was 9 °C, 'DT-60' was 2.6 °C and 't-DTmax' 5.6 sec (Fig. 7), whereas
- values in vivo were 11 °C 'DTmax', 2.4 °C 'DT-60' and 5.2 sec 't-DTmax' (Fig. 8).

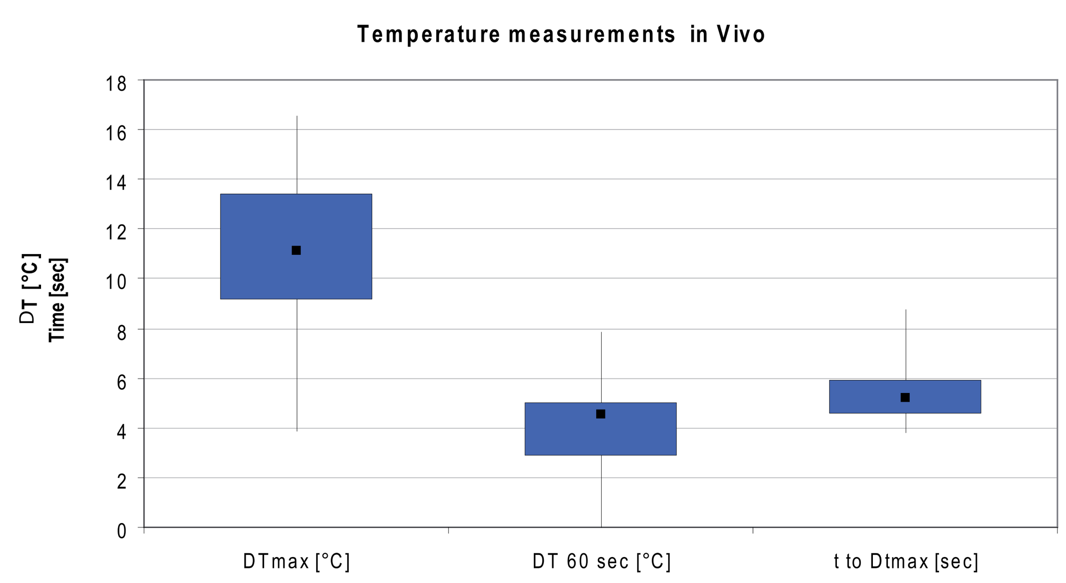

Fig. 8: Temperature changes recorded ***in-vivo.***
Box plots of temperature changes during insertion

Discussion and Conclusions

- The main temperature increase was observed at the primary contact point of the implant, underneath the bone surface.
- The temperature curves and calculated medians were nearly similar in vitro as in vivo.
- Compared to the literature [3], temperature increase and exposure time was considered to be not critical for bone tissue healing.
- This was supported by uneventful bone response after 2 months healing period in the identical sheep model (please see special poster SP 3 of D. Heidenreich et al.).

References

[1] Mai, R., et al., Bone welding--a histological evaluation in the jaw. Ann Anat, 2007. 189(4): p. 350-5.
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