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# Experimental investigations for mechanical joint strength following ultrasonically welded pin osteosynthesis

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**Abstract** The purpose of this study was to determine whether fixation of cranial bone segments using ultrasonically welded pin osteosynthesis showed differences in mechanical stability as compared to fixation of cranial bone segments using screw osteosynthesis. Right and left cranial bone segments from each of 16 young sheep were obtained by craniotomy and re-fixed: on the right with a mesh plate and pins, and on the left with a mesh plate and screws. All osteosynthesis materials consisted of PDLLA, fully amorphous polyactid. A total of 167 cranial bone / mesh plate segments from 16 animals were investigated; 84 segments were pin-fixed and 83 segments were screw-fixed. The implantation time of the re-fixed segments ranged from 1 day to 196 days. The mechanical methods chosen for simulation of stress on the bone segment bonds were two bending tests (horizontal and vertical directions) and a tensile test. The values obtained in the mechanical tests indicate differences in the bond strength between the pin- and screw- fixation methods over the length of in vivo implantation time. The mechanical stability of the ultrasonically welded pin osteosynthesis bonds over the screw osteosynthesis bonds proved to be statistically significant. The implication of these findings should also be relevant in the field of medicine.

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## Introduction

Resorbable osteosynthesis systems offer advantages over osteosynthesis systems that require a second surgery for the removal of the system bonding fixatives (i.e., titanium screws) after bone fusion has taken place [1–3]. The fixation of resorbable craniofacial osteosynthesis plates is normally done with screws [4–6], and the surgical procedure using screws requires a high degree of precision and experience; furthermore, it is time-consuming. The use of a resorbable pin as a fixative with a resorbable mesh plate, instead of the resorbable screw fixative, is less complicated and the pin can be ultrasonically welded into place in less time than the screw osteosynthesis technique. The device used to place the pins was the SonicWeld Rx® Co. KLS, Tuttlingen, Germany [7]. This osteosynthesis system employs a bone welding technique whereby an ultrasonic handpiece gently taps the pin into the bone preparation. The transmission of the sound wave into the pin implant causes the implant to vibrate into a forced resonance mode. During the insertion, the surface amplitude of the implant induces an immediate liquefaction of the polymer surface at the contact points between implant and the hard tissue. Since the polymer behaves as a structurally viscous material, its viscosity is further reduced by the high shear rates applied, thus facilitating the local infiltration of the polymer into the open, e.g. intertrabecular, space. Once the insertion process is completed, the liquefied portion of the polymer freezes immediately and forms an interdigitating composite interphase with the hard tissue. The

**Fig. 1** Section of an ultrasonically welded resorbable pin fixed in the bone (left side) and a resorbable screw manually fixed in the bone (right side), stereo microscopic picture, 8× magnification

conventional technique of screw placement requires that the screw be manually turned into the bone preparation.

The focus of this investigation was to evaluate the bond strengths of pin-fixed and the screw-fixed osteosynthesis systems. The tests were carried out to determine the differences in mechanical behavior between the innovative ultrasonically welded pin bonding osteosynthesis system and the screw osteosynthesis system (Fig. 1) at different implantation times in vivo.

The strength of the force required for destruction of the bonds, when the two systems were subjected to bending and tensile force, was measured.

## Materials and methods

A total of 16 sheep (4 months old) underwent right and left cranial resection in sterile surgical conditions. The right and left bone segments were re-fixed with resorbable mesh plates (Resorb-X® mesh plate 0.6/51.2 × 51.2 mm, Co. KLS Martin, Tuttlingen, Germany) that overlapped the cranial resection area completely. On the right cranium the mesh plate was re-fixed with 20 resorbable screws (1.6 × 5 mm Resorb-X®, Co. KLS Martin, Tuttlingen, Germany). On the left cranium the mesh plate was re-fixed with 20 ultrasonically welded resorbable pins (1.6 × 5 mm, Resorb-X®, Co. KLS Martin, Tuttlingen, Germany).

The test animals were sacrificed at fixed time intervals during the 196-day period to allow for absorption of the bonding materials and osteogenesis to occur (Table 1). The influence of time on the mechanical properties of the bond would be assessed. After sacrificing the animals, the pin- and screw-fixed mesh plate-cranial bone segments were removed and immediately placed in saline solution (0.9%) at 37 °C to preserve the microbiological environment. The storage time was limited to less than 3 h. A lathe-cutting instrument (EXAKT, Co. Walter Messner, Oststeinbek, Germany) was used to separate the osseous-integrated mesh plate into uniform-sized samples (14.7 mm × 4.7 mm). For mechanical investigations at least six pin-fixed and six screw-fixed samples per animal were tested. The test samples varied in thickness dependant on the area of the cranium where they were located. For this reason 50% of the samples from sheep 3, 4, and 5 were deemed unsuitable for testing. Animal 8 died during the test period; no samples from it were tested. A total number of 167 samples from 16 animals were investigated in mechanical tests; 84 samples were pin-fixed and 83, screw-fixed.

**Table 1** Implantation times of the tested osteosynthesis bondings in vivo († see text)

| Implantation time (d) | Number of sheep |
|---|---|
| 0–2 | 4 |
| 9–11 | 3 |
| 32–34 | 3 |
| 193–196 | 3 |

Two types of stress affect craniofacial sites post-operatively, tensile stress and bending stress. The mechanical test methods for simulation of the bending stress were designed to apply force input in the vertical (Fig. 2a) and the horizontal (Fig. 2b) direction. A tensile stress test was also included in the mechanical simulation (Fig. 3). The mechanical tests were carried out with the universal strength test apparatus, TIRAtest 2720 (Manufacturer: Co. TIRA WPM Leipzig, Schalkau, Germany).

During the testing the samples were kept moist with a constant aerosol spray mist of 0.9% saline at 37 °C to prevent changes in the samples due to loss of body specific

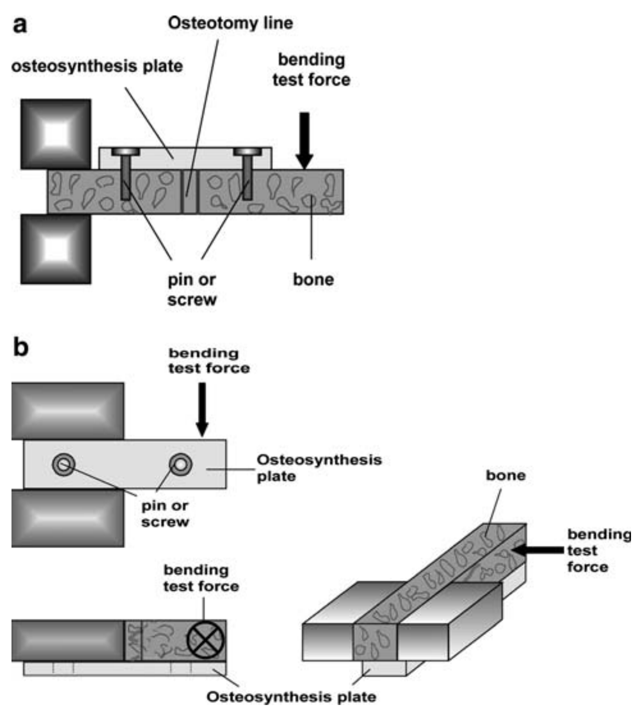


**Fig. 2** (**a**) Diagram of the experimental set-up of the bending test with force input perpendicular to the mesh plate surface (bending test A) (**b**) Diagram of the experimental set-up of the bending test with force input parallel to the mesh plate surface (bending test B)

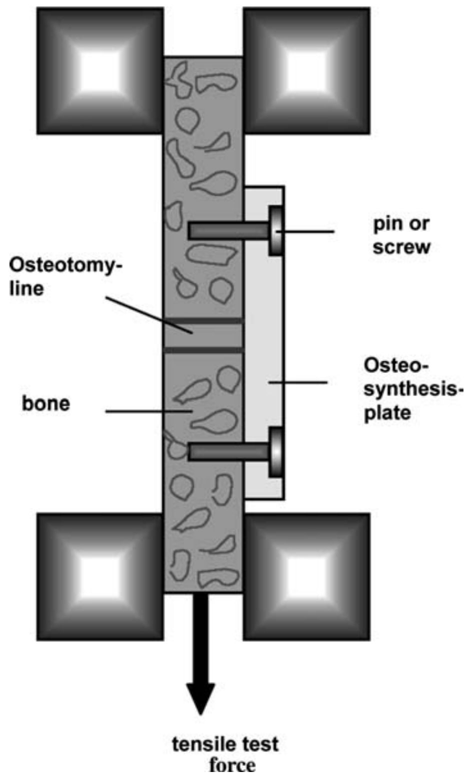


**Fig. 3** Diagram of the experimental set-up of the tensile test

conditions. The spray mist was produced by a humidifier with a thermostat, type VH2 (Manufacturer: Co. Draeger, Luebeck, Germany). The clamps used in the tensile test were the clamps, ESV 2233.

Bending stresses in implanted osteosynthesis systems can occur perpendicular and parallel to the mesh plate, causing different areas of tensile and pressure stress in the cross section of the bond. In order to simulate these stresses, two different variations of force input were applied in the bending test, (Fig. 2a, b). The goal of the test investigation was to determine the strength of force that would cause the failure of the bond system of the pin–mesh plate–bone segment or screw–mesh plate–bone segment. The displacement forces of the bone segments samples were measured by bending tests carried out parallel to the mesh area (Fig. 2b). The occurrence of tensile stresses in the bone tissue (Fig. 3) was also simulated. In connection with tensile stress is the effect of shearing forces at the pins or the screws. Stress parameter is a continuously increasing tensile force that is evenly distributed over the cross section of the sample. The maximum force that caused the failure of the system pin—or screw—mesh plate bond was determined in the tensile test.

The statistical evaluation was done by means of linear models of variance analysis with an independent factor (implantation time) and two repeated-measures factors (fixation and test direction). The analysis was carried out under consideration of all interactions of second order.

For the repeat measurements identical correlations of the measuring values were assumed (compound symmetry). Contrasts were derived from the estimated model parameter and Tukey-adjusted examined. The analyses were carried out by the SAS procedure MIXED.

## Results

The values of the maximum force needed to fracture the test sample (Table 2) are grouped according to the following criteria:

- The designation of the sheep from which the sample was taken
- The test method (bending test A, bending test B, tensile test)
- The fixture system (ultrasonically welded pin or manual screw)
- The implantation time in vivo.

The time interval of the implants in vivo was assigned into five groups:

Zero to two days, 9–11 days, 32–34 days, 95–96 days, 193–196 days. The measuring values from the time interval of 95–96 days were not included in further evaluations

**Table 2** Results of the variance analytical hypothesis tests

| Factor | Factor steps | *P*-value |
|---|---|---|
| Implantation time | 1 = 0–2 days | 0.0105 |
| | 2 = 9–11 days | |
| | 3 = 32–34 days | |
| | 4 = 193–196 days | |
| Fixture | 1 = Pin | 0.0114 |
| | 2 = Screw | |
| Test direction | 1 = Tensile | 0.3093 |
| | 2 = Bending vertical | |
| | 3 = Bending horizontal | |
| Implantation time × test direction (different effect of the implantation time with the 3 force input directions) | (Interaction) | 0.7772 |
| Fixture × test direction (different effect of the fixture type with the 3 force input directions) | (Interaction) | 0.4434 |
| Fixture × implantation time (different effect of implantation time with both fixture types) | (Interaction) | 0.1498 |

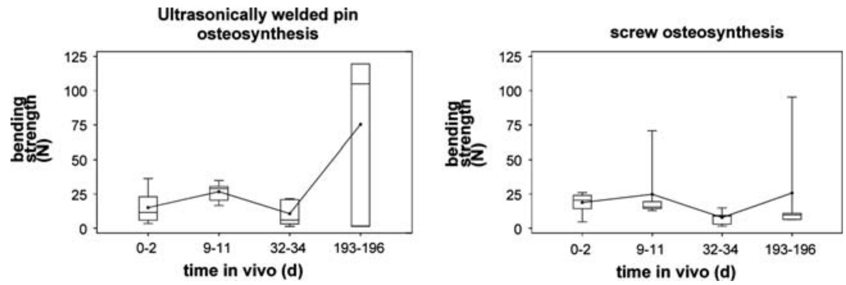


**Fig. 4** Bending test A

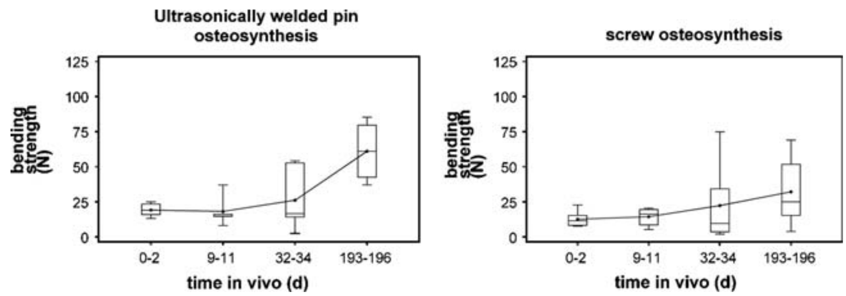


**Fig. 5** Bending test B (2 values above 125 N, for the time frame 0–2 days and 193–196 days, are not represented in the pin-related diagram)

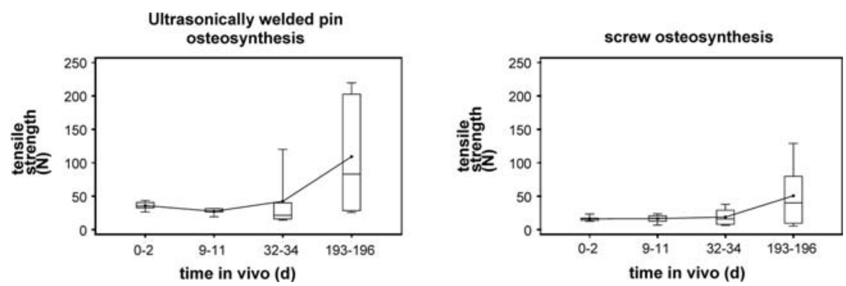


**Fig. 6** Tensile test

because of the low number of samples available. The ossification filling the division between the bone surfaces (osteotomy line) and the fragmentation of osteosynthesis material occurred by degree, dependent on the length of implantation time in vivo [8].

The measure of the force that caused fracture of the osteosynthesis-bone segment in each time interval was tabulated. The graphical representation of the values, according to the fixing system and the implantation time, can be seen in Figs. 4, 5 and 6.

Ultrasonically welded pin osteosynthesis bondings show higher stability values under bending stress when force input is vertical to the mesh plate surface (Fig. 2a). In the bending test with force input parallel to the mesh surface (Fig. 2b), the bonding elements were also tested for rotation. The superiority of the ultrasonically welded pin osteosynthesis bondings are clearly shown especially in the immediate post-operative phase (Fig. 5). An initial higher level of stability in the ultrasonically welded pin osteosynthesis bondings was also detected in the tensile test (Fig. 3). This advantage remained during the entire test period. The value spread increases because of the onset of re-ossification (Fig. 6).

In animal tests the superiority of ultrasonically welded pin osteosynthesis bonding over the screw osteosynthesis with regard to mechanical stress resistance in the craniofacial area could be proven statistically. The statistical significance tests confirm that the measured values depend on the type of fixation of the osteosynthesis system (i.e., pin or screw), as well as on the implantation time in vivo. This statistical significance applies independent of the test direction (Table 2).

## Discussion

The evaluation of the mechanical investigations proves the superiority of the ultrasonically welded pin osteosynthesis bondings over the screw osteosynthesis bondings:

- Independent of the implantation time of the system in vivo (exception: bending test A, indwelling time 0–2 days).
- Independent of the force input direction tested: bending stress, in vertical and horizontal directions, and axially effective tensile stress.

The highest significance, in terms of practical application, can be given to the results of the bending test A (Fig. 4), because of the effect external force input has on the bonds during the healing process. Bending test B (Fig. 5) shows the relative lack of influence that horizontal force input has on the bond systems due to the large apposition areas that hinder horizontal bending. The results of the tensile tests (Fig. 6) must be especially pointed out. In the early stage of healing (0–2 days) the ultrasonically welded pin bonds showed a higher level of stability when compared to the screw bonds, as the two bond types were subjected to tensile force. The slight decrease of the bond strength in the time frame 9–11 days shows the beginning of the degradation process of the resorbable pin material. The following periods 32–34 days and 193–196 days indicate the formation of the bone and the level of healing. These aspects have not been proven histologically.

## Conclusions

The evaluation of the mechanical investigations proves with statistical evidence the superiority of ultrasonically welded pin osteosynthesis bonding over screw osteosynthesis bonding under these test conditions. The use of ultrasonically welded pin ostesosynthesis in human craniofacial reconstruction also appears relevant.

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