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# Ultrasound aided pin fixation of biodegradable osteosynthetic materials in cranioplasty for infants with craniosynostosis

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*SUMMARY.* Aim: **Biodegradable osteosynthesis materials are often used for fixation of bone fragments when repairing craniosynostoses. When compared with titanium plates they have the disadvantage of difficult handling and time-consuming thread cutting. A new method of using resorbable pins inserted with the aid of ultrasound (bone welding) and not requiring thread cutting was applied in patients for the first time.** Method: **In eight patients with craniosynostoses, the biodegradable material Resorb-X® was fixed with resorbable pins inserted with the aid of ultrasound. The patients were followed up for 12 months.** Results: **Pin fixation was stable in all cases. The time required for applying the osteosynthesis materials was reduced by about 50% since handling of the material was easier and no thread cutting was required.** Conclusions: **Due to fixation in cortical as well as cancellous bone ultrasound aided fixation using resorbable osteosynthesis materials is more stable than screw fixation. The time required for application is considerably shortened as no thread cutting is required.** © **2007 European Association for Cranio-Maxillofacial Surgery**

***Keywords:*** **craniosynostoses; resorbable materials; bone welding**

## INTRODUCTION

According to present theory, craniosynostoses develop from premature fusion of cranial sutures due to hereditary disturbances of the chondroblasts' dividing capacity in the cartilage of the skull base. Reduced ventral growth of the chondrocranium slows down drifting of intramembranous (desmal) ossification centres and promotes premature ossification of adjacent membranous sutures. This impedes growth of the cranial vault vertically to the affected suture which is mostly compensated by increased growth in another direction. The consequences are characteristic deformations of the skull, i.e. trigonocephalus, plagiocephalus, oxycephalus, brachycephalus and scaphocephalus (*Virchow*, 1851; *Mühling*, 1995; *Alden* et al., 1999).

Apart from the obvious cranial malformation, a craniosynostosis produces risks at early infant age due to high intracranial pressure resulting from the rapid but constrained growth of the brain. There is a disproportion between cranial volume available and space required by the growing brain (*Renier* et al., 2000). Therefore, early surgical intervention is usually advised. Surgical correction such as frontoorbital advancement (Fig. 1) is preferably performed early (within the first year of life), since the rate of complications increases with age, as has been shown in several studies. With increasing age, thickness and mineralization of cranial bones increase entailing a decrease in malleability and reossification potential of the vault. As a consequence, surgery becomes more complicated and sophisticated and requires more time, which in turn means a higher rate of possible complications. (*Whitaker* et al., 1979; *Poole*, 1988; *Siegel* and *Israele*, 1989; *Jones* et al., 1992; *Faberowski* et al., 2000).

The severity of the growth disturbance and the morphological appearance determine the extent to which the frontoorbital segment is advanced and how the frontal bone cover is formed and incorporated. Over-correction is the rule because of the expected growth. Rigid fixation of the fragments is required to make sure that the surgical result is maintained (*Mühling*, 1995; *Alden* et al., 1999). Whilst initially wire sutures were favoured, titanium miniplates were mostly used later (*Mühlbauer* and *Anderl*, 1983). Since the appositional growth of cranial bone causes relative migration of the osteosynthesis material in a centripetal direction (*Stelnicki* and *Hoffmann*, 1998; *Kosaka* et al., 2003), it should be removed 3–6 months postoperatively. In order to avoid this second operation, biodegradable osteosynthesis materials are now used more frequently (*Obwegeser*, 1998; *Becker* et al., 1999; *Imola* et al., 2001). However, biodegradable osteosynthesis materials have been shown to have the disadvantage of being less stable and more difficult to use (*Maurer* et al., 2002; *Yerit* et al., 2002; *Landes* et al., 2003). Resorbable plates fixed by screws produce stable results only when the screws are applied most accurately in an orthograde direction.



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Minor inaccuracies readily produce fracture of the material. Cutting the threads is important and considerably prolongs the duration of the operation. Self-cutting screw systems (e.g. TACKER™; Inion Ltd. Tampere, Finland) are an alternative but are still screws and have the disadvantage of the risk of fracturing due to torsional forces exerted on the junction between the head and neck of the screw (*Haers*, 2005).

The SonicWeld® system developed by KLS Martin (Tuttlingen, Germany) in which the osteosynthesis materials are fixed by inserting resorbable pins with the aid of ultrasound, was applied in patients with craniosynostosis following successful application in animal experiments (*Eckelt* et al., 2005). It was the aim of the present study to evaluate the findings regarding surgical technique, stability of osteosynthesis and individual biocompatibility.

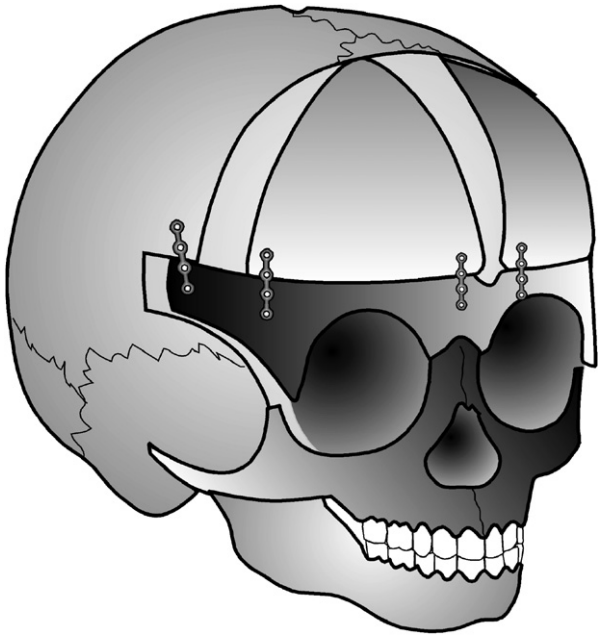

**Fig. 1** – Frontoorbital advancement.

## MATERIAL AND METHODS

### SonicWeld® system

The new method of fixing biodegradable osteosynthesis materials is based on ultrasound aided pin osteosynthesis. Pins (2.1 × 4 mm, Resorb-X®, KLS Martin, Tuttlingen, Germany) made of poly D-lactide (50%), L-lactide (50%) acid (PDLLA) are inserted with the aid of ultrasound following conventional hole drilling (∅ 1.6 mm) and melted to weld with the bone in order to fix plate or mesh (thickness 1.0 mm). No time-consuming thread cutting is required nor is a manual screw driver required to insert the screw, nor is there any screw head fracture.

In conventional fixation by means of a screw, its stability in the surrounding bone is based on the interlinkage of the profiles of screw and thread cut into the drilled hole. In contrast, the pin inserted by using ultrasound obtains its stability by filling the cavities in the trabecular bone structure opening by the hole drilling, and by fusion with the osteosynthesis material (Fig. 2). In addition there is welding of the pins to the meshplate.

### Clinical results

In eight patients, resorbable pins were used to fix the osteosynthesis material. Follow-ups were performed regularly – immediately following surgery, 4 weeks, 3,

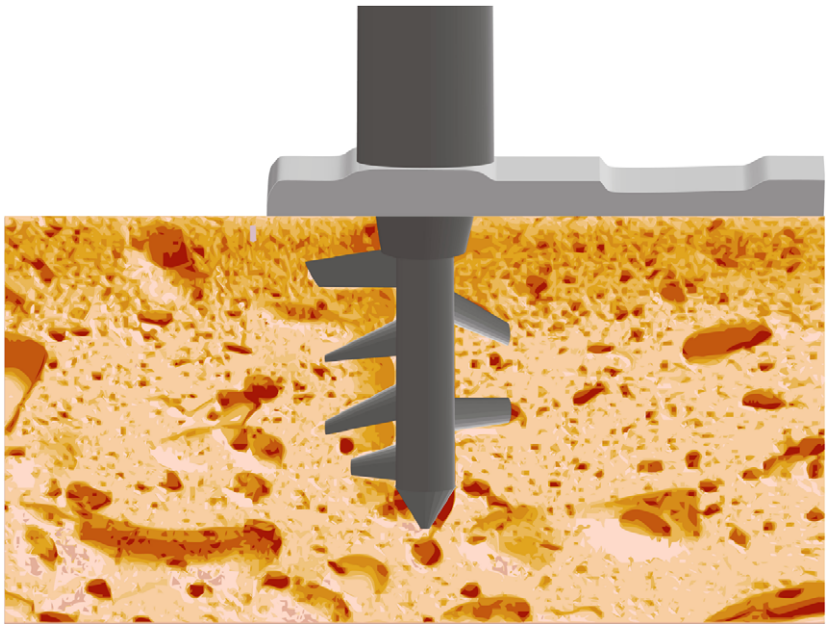

**Fig. 2** – Bone welding – resorbable osteosynthesis pin fuses with osteosynthesis plate and enters the trabecular bone.

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6 and 12 months postoperatively – to evaluate stability of the osteosynthesis and soft tissue reaction to the resorbable material. In only one case was re-operation necessary since the bony support of the fragments was insufficient and the 1 mm-thick mesh was not sufficiently stable to resist the significant pressure developing from replacing the galea-periosteum flap following frontoorbital advancement. In that case, the bony fragments in the region of the coronal suture were re-fixed with titanium miniplates. In all other seven cases, the stability of the osteosynthesis was excellent. In the follow-up 1 week postoperatively, minor swelling was observed in the region of the osteosynthesis material which slowly disappeared in the following 4 weeks. Three, 6 and 12 months postoperatively healing was normal.

### Surgical technique

Surgery was performed mostly at the age of 12 months, in two cases at the age of 4 years, since those patients presented late at that age. In six cases, the diagnosis was trigonocephalus, whilst plagiocephalus and brachycephalus had one case of each. The typical technique for frontoorbital advancement was applied using a bicoronal incision adapted to the particular type of craniosynostosis. Following advancement of the frontoorbital complex and refiguration of the cranium to repair the particular malformation, the fragments were fixed with a 1.0 mm Resorb-X® mesh which had been heated in water to increase its pliability and cut into smaller segments to fit the required location. The mesh was adapted to the bones while still warm and fixed in the new configuration without any problems. Then holes with a diameter of 1.6 mm were drilled and the resorbable pins (diameter 2.1 mm, length 4 mm) inserted using a special applicator and with the aid of ultrasound (capacity 20 W). In contrast to fixation by conventional screws, no thread cutting was required and no fracturing of the screw head occurred as there was no high torsional load as observed with other systems in many previous occasions. Also intraoperative handling was much easier than with conventional screw fixation. In particular, the first fixation of the mobile fragments was much easier and quicker as no thread cutting was needed. As had been demonstrated in earlier animal experiments (*Eckelt et al., 2005*) the time required for fixing the osteosynthesis material could be reduced by 50% (by using 80 to 100 pins) per patient, thus considerably reducing also the total time required for craniosynostosis surgery. Using the 1 mm mesh, a very good three-dimensional stability of the repositioned bone fragments was obtained already (intraoperatively). This may also be due to the fusion of the pins to the mesh. However, it was most important that the bone fragments also supported each other and that this mutual support was stable enough to ensure resistance to the pressure resulting from the replaced skin flap (Fig. 3).

## DISCUSSION

Clinical application of the new method of fixing resorbable SonicWeld Rx® materials revealed that this produced the same stability as the conventional resorbable osteosynthesis fixation by means of screws. In particular, the 1 mm thick resorbable mesh produced excellent stability intraoperatively. Easy adaptation of the warmed Resorb-X® mesh and fixation by means of pins rendered osteosynthesis much easier than had been the case earlier with conventional screws and allowed optimal configuration of the cranial vault. As has been shown in animal experiments, it was possible to reduce the time required for applying the osteosynthesis materials by 50%. Since the pins were not exposed to torsional forces, the material did not fracture.

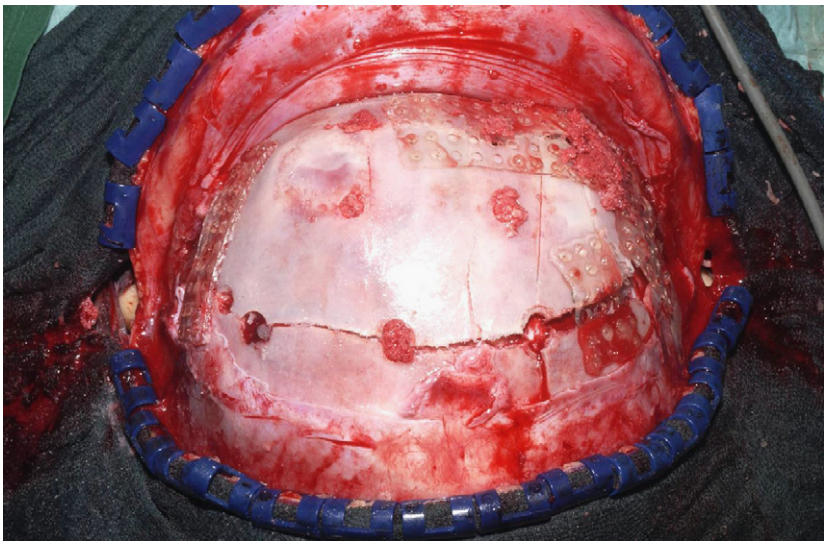

**Fig. 3 –** Plagiocephalus – fixation of fragments using resorbable osteosynthesis material and pin fixation.

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## CONCLUSION

Osteosynthesis with resorbable materials, i.e. Resorb-X®, proved advantageous for the patient when compared with conventional titanium plates. There was sufficient stability and good bio-compatibility. A second operation for plate removal was not required.

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