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The value of ultrasound-assisted pinned resorbable osteosynthesis for cranial vault remodelling in craniosynostosis

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ABSTRACT

Resorbable osteosynthesis is a widespread tool in craniofacial surgery, however only a limited number of studies have focused on ultrasound-assisted pinned resorbable systems in the treatment of craniosynostosis.

Thirty-eight children with various types of craniosynostosis including scaphocephaly, trigonocephaly, anterior and posterior plagiocephaly were treated using the Sonic Welding resorbable osteosynthesis system. All patients were evaluated for operation time, stability of the surgical results, rate of local infections and visibility or palpability of the osteosynthesis material in the follow-up ranging from 15 to 21 month.

Mean operation time was not significantly higher compared to conventional osteosynthesis material and all remodelled cranial vaults showed immediate stability. Only one patient showed signs of an inflammatory skin reaction, which recovered spontaneously. The number of palpable or visible plates, respectively, increased during the first months with a maximum at 12 months (34 (89%) plates palpable, 26 (68%) plates visible). After this time point, the number decreased continuously until the end of the follow-up period at 21 months when 3 (20%) plates were palpable, 0 (0%) plates were visible).

Ultrasound-assisted pinned resorbable systems seem to be a promising tool in craniofacial surgery providing a timesaving and stable osteosynthesis. An initial swelling of the plates during the first 12 months before the complete degradation might result in a palpable and visible bulge.

1. Introduction

In the surgical correction of craniosynostosis, bone fixation using osteosynthesis is an element step (Arnaud and Renier, 2009). Historically, various techniques have been used for rigid fixation including simple metallic wires, metallic plates and screws or titanium meshes (Arnaud and Renier, 2009). The most common problems of metallic osteosynthesis are the temperature-induced pain, interference with imaging modalities, the risk of intracranial migration into the growing skull and the disadvantage of removing the material in a second surgical procedure. To avoid this second operation, biodegradable osteosynthesis materials have been introduced and their use has been well documented over the past 10–20 years in the maxillo-facial literature (Becker et al., 1999; Eckelt et al., 2007; Imola et al., 2001; Obwegeser, 1998). Some disadvantages of biodegradable osteosynthesis materials have been published, varying from less stabilisation to more difficult handling (Landes and Kriener, 2003; Maurer et al., 2002; Yerit et al., 2002). In particular there are reports of, an increase in operation time due to the extra need for tapping the screw hole and an increased risk of screw fractures, when the screws are not applied accurately in an orthograde direction (Eckelt et al., 2007).

A promising approach in the field of biodegradable osteosynthesis materials has been introduced with the Sonic Welding System developed by KLS Martin/Germany, which is based on ultrasound-assisted pinned resorbable systems. The pins (Resorb-X, KLS Martin, Tuttlingen, Germany) are made of poly D-lactide (50%) and L-lactide acid (50%) (PDLLA) and are inserted after conventional hole drilling with the aid of ultrasound to weld with the bone in order to fix plate or mesh. Typical thread cutting becomes redundant which results in reduction of operation time and minimizes the risk of a possible screw head fracture (Eckelt et al., 2007).

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The aim of the present study was to evaluate the use of the Sonic Welding System in the surgical treatment of various types of craniosynostosis with respect to operation time, stability of the surgical results, rate of local infections and visibility or palpability of the osteosynthesis material in the follow-up.

2. Materials and methods

The study was based on a retrospective design using a standardized measurement protocol, examined and approved by the local Ethics Committee (Ethics number S-237/2009). The study was carried out according to the Declaration of Helsinki and written informed consent was obtained from the parents. We included all children with craniosynostosis who were treated with primary cranial vault remodelling between October 2010 and October 2011 in our department. Resorbable plates and pins (SonicWeld/Resorb-X, KLS Martin, Tuttlingen, Germany) were used in all cases according to the manufacture's protocol. In brief, an ultrasonic sonotrode unit is used to bond a pin (SonicPin Rx) to the Resorb-X plates (KLS Martin, Tuttlingen, Germany). A variety of plates and meshes are available for this system. We preferred linear mesh-plates (diameter 0.8 mm, length 11 × 126 mm), which can be adapted to the desired size intraoperatively. The number of plates and pins used for each patient were placed by a standardized protocol adapted to each specific type of craniosynostosis: In Sagittal synostosis with frontal bossing, four two-hole plates were used to fix the 180 degree rotated frontal segment to the orbital bone (Fig. 1A). In Metopic synostosis, Unilateral and bilateral coronal synostosis, an eight- or twelve-hole plate with four pins were applied to the area of the tongue and groove technique (Fig. 1A and B) and four two-hole plates to fix the frontal segment to the orbital bone, similar to the procedure applied to scaphocephaly (Fig. 1B). For posterior expansion in lambdoid synostosis, three plates were used to stabilize the unilateral occipital advancement: one plate at the non-advanced side and two plates located at the tongue and grooves of the advanced side (Fig. 1D). In some cases, additional resorbable sutures (PDS 2/0; Ethicon) were used in combination with the resorbable plates. Intraoperatively, photo documentation of the placed resorbable material was performed in all cases. The mean operation time in 14 cases of trigonocephaly and in 18 cases of scaphocephaly was compared to our older collective of 50 patients with metopic synostosis and 96 patients with sagittal synostosis where conventional titanium plates had been used.

Minimum follow-up was 15, maximum 21 months. Standardized post-operative clinical examination was performed 3, 6, 9, 12, 15, 18 and 21 months after surgery. Clinical evaluation was performed by the senior author and attending maxillo-facial surgeons. Beside standardized anthropometic measurements, all patients were examined for signs of local infection at the incision site in the follow-up examination. In addition the stability of the remodelled cranial vault and the palpability and/or the visibility of the osteosynthesis material were observed. Plate palpability was defined as the ability to locate plates in a tactile fashion. Plate visibility was defined as notable irregularity in the area of plate location.

Student *t*-test was used to compare continuous variables and *p*-values < 0.05 were considered as significant. All statistical analyses were performed using SPSS for Windows version 12.0 (SPSS, Chicago, USA).

3. Results

Over the 1-year period, 38 patients conforming to our study criteria were included. The overall male to female ratio was 3.4 to 1 (31 male, 9 female). The distribution and the surgical treatment

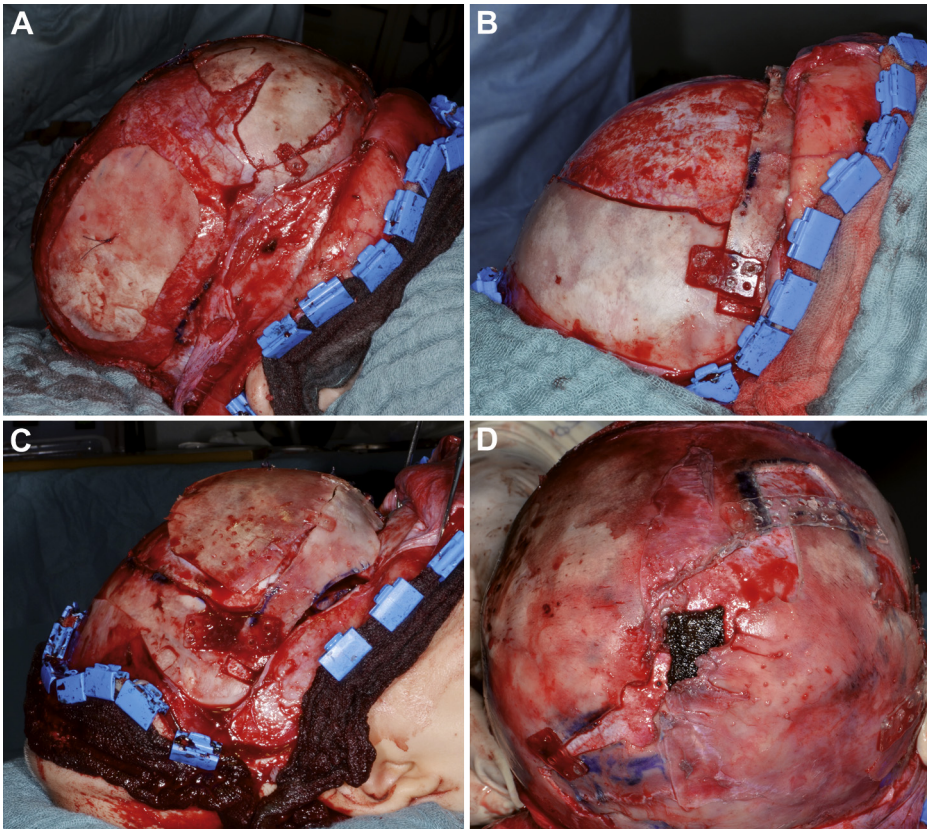

Fig. 1. Representative intraoperative views of standardized placement of resorbable plates. (A) pi-procedure in Sagittal synostosis with frontal bossing, (B) and (C) fronto-orbital advancement in metopic synostosis, (D) posterior expansion in lambdoid synostosis.