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Mechanical analysis of cranial distractor attachment with three different resorbable fixation systems

M. Savolainen [a, *], A. Ritvanen [b], E. Tukiainen [a], J. Leikola [a]

[a] Department of Plastic Surgery, Helsinki University Central Hospital, P.O. Box 266, 00290, HUS, Finland
[b] Department of Electrical Engineering and Automation, School of Electrical Engineering, Aalto University, P.O. Box 13000, 00076, Aalto, Finland

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ABSTRACT

Distraction osteogenesis (DO) has become increasingly popular to correct craniosynostosis. Disadvantages of DO include the secondary operation needed for device removal and titanium screw related dura injury. To reduce invasiveness of the secondary device removal operation and to overcome titanium-related problems, fixation of the cranial distractor with resorbable materials is a potential alternative. New resorbable fixation methods, such as ultrasound-activated pins (UAPs) or heat-activated pins (HAPs), allow faster attachment on thinner bone than conventional resorbable screws (CRSs) since tapping is not required. However, resorbable materials are designed to be attached with a resorbable plate, not with a titanium distractor.

We evaluated the suitability of CRSs, HAPs and UAPs for the cranial distractor fixation in a laboratory setting with a mechanical testing machine. Fracture tests were conducted in two directions with respect to the longitudinal axis; vertical *i.e.* axial pull-out strength, and horizontal *i.e.* shear strength. Mean maximum pull-out strength for CRS, HAP and UAP was 48.9 N, 32.5 N and 14.7 N, respectively. Mean maximum shear strength for CRS, HAP and UAP was 40.8 N, 77.9 N and 38.9 N, respectively. According to our in vitro tests, the cranial distractor attachment with four CRSs or six HAPs per footplate would provide sufficient fixation stability.

1. Introduction

Distraction osteogenesis (DO) has become increasingly popular to correct craniosynostosis. Advantages of posterior calvarial vault distraction osteogenesis (PCVO) relative to one-stage calvarial vault reconstruction (CVR) include a shorter, less invasive operation, good shape maintenance, greater potential for intracranial volume advancement and lower overall morbidity (Imai et al., 2002; Steinbacher et al., 2011; Lao and Denny, 2010; Kim et al., 2008). Gradual advancement ensures better soft tissue adaptation and better wound healing. DO represents a more physiological treatment than CVR since bone segment vascularity remains intact, no dead space is left between the dura and bone segments and no ossification defects remain (Nonaka et al., 2003; Lao and Denny, 2010). DO also provides cost savings (Ong et al., 2014).

A disadvantage of DO is the need for a second operation for device removal. In many cases, DO should be performed in early infancy to release increased intracranial pressure. However, the calvarium in early infancy may be too thin for distractors to be fixed with titanium screws (Steinbacher et al., 2011). The titanium screws might also injure the dura through thin bone (Nowinski et al., 2012).

To reduce the invasiveness of the secondary device removal operation, resorbable mandibular distractors were introduced. The same device has been used in PCVO (Maurice and Gachiani, 2014). The stability of the mandibular device in the calvarial region is questionable since resisting force in PCVO is reported to be higher than in mandibular DO and force-related complications, such as distractor breakage and footplate loosening, are commonly seen (Ritvanen et al., 2017; Imai et al., 2002; Nonaka et al., 2003; Steinbacher et al., 2011; White et al., 2008; Derderian et al., 2015; Nowinski et al., 2012).

The evolution of cranial distractors (Cranial vault distractor, KLS Martin, Germany) has resulted in increased strength of the device and positioning hooks on footplates being added that gain support on the bone edge and reduce the stress from screw fixation. In

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* Corresponding author. Department of Plastic Surgery, Töölö Hospital, P.O. Box 266, FI-00290, HUS, Finland. Fax: +358 94 718 7217.
E-mail address: savolainen_mikko@yahoo.com (M. Savolainen).

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general, the attachment of a cranial distractor with resorbable materials is a potential option. New innovative resorbable fixation methods, such as ultrasound-activated pins (UAPs) and heat-activated pins (HAPs), allow attachment on thinner bone than with conventional resorbable screws (CRSs) since tapping is not required (Eckelt et al., 2007). Resorbable materials might also reduce the risk of titanium fixation-related dura injury through the thin bone.

Arnaud and Renier (2009) described fixation of cranial distractors with UAPs in monoblock DO. However, resorbable materials are designed to be attached with resorbable plates. UAPs fuse with the resorbable plate, increasing fixation strength (Pilling et al., 2007). Mechanical properties of resorbable fixation systems when attached via titanium distractor on bone remain unclear.

We designed a laboratory setting to evaluate the mechanical properties of three different resorbable fixation systems (CRS, HAP and UAP) when attached via titanium on bone. The aim was to find a safe resorbable fixation method to attach the distractor in calvarial DO.

2. Materials and methods

The porcine rib was chosen to most closely resemble the paediatric calvarial bone. The ribs were cut into 4 cm pieces from the same proximal area to provide homogeneous bone (Fig. 1). All soft tissue, including the periosteum, was meticulously dissected. The bones were split under the ventral cortex. The bone blocks were ground to a thickness of 4 mm to resemble the thickness of the paediatric calvarium (Fig. 1). The grinding was carefully orientated so that the ventral cortex and the dorsal surface were parallel (Fig. 1).

The universal testing machine (e3000LT, Instron, USA) was used to characterize the mechanical properties of resorbable fixation connected via a titanium plate to the bone. Two custom-made test set-ups were used to measure pull-out (Fig. 2-1) and shear (Fig. 2-2) strength on the testing machine.

We used 12 CRS (1.5 × 6 mm, Inion CPS™, Inion, Finland), 24:70:6 Poly (DL-Lactide-co-trimethylene carbonate); 12 HAP (1.5 × 6 mm, Inion CMF RapidTack™, Inion, Finland), 17:78.5:4.5 Poly (DL-Lactide-co-trimethylene carbonate); and 12 UAP (1.6 × 5 mm, Sonic Weld, KLS Martin, Germany), 50:50 poly (DL-lactide). We used in both shear and pull-out set-ups 6 CRSs, 6 HAPs and 6 UAPs. The screws and pins were connected to bone via the titanium plate (2.3 mm Smart Shape plate, KLS Martin, Germany). In the pull-out set-up, titanium plates were bent from both sides of the hole, where resorbable material was inserted at an angle of 90° (Figs. 2-1 and 3-2).

The screws and pins were individually fixed with the titanium plate on the outermost point, i.e. tangential to the concave-shaped rib, as in clinical situations with dedicated tools. Fixation was done by a person familiar with all of the fixation devices and according to manufacturers' instructions.

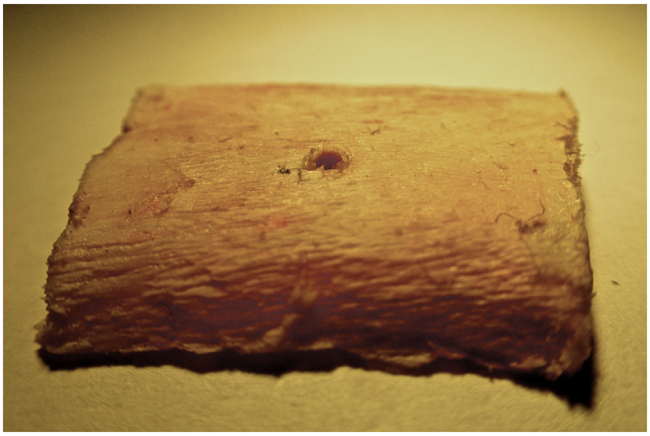

Fig. 1. Porcine rib prepared for the test set-up.

Tapping for the CRSs was accomplished with the dedicated self-tapping thread 1.5 × 8 mm. The screws were inserted to the bone through the titanium plate with the dedicated screw driver. The holes for the HAPs were drilled by the dedicated thread 1.6 × 8 mm. The HAPs were inserted to the bone through the titanium plate, and heat activation with a dedicated tool was performed until the pin was attached. Holes were drilled for UAPs with the 1.0 × 4 mm thread. The UAPs were inserted into the drilled hole through the titanium plate. Ultrasound activation by a sonotrode was provided until the pin had reached the bottom of the hole.

All test samples were set in an incubation bath (NaCl 0.9%, 26 °C) for 20 h. After the incubation, the test samples were kept inside moist paper at room temperature (26 °C) for 30 min to 3 h before testing.

The titanium plate and the bone were connected to a testing machine with the designed pull-out (Fig. 2-1) and shear (Fig. 2-2) set-ups. The fixation was always orientated so that the force generated by the testing machine was conducted at a 90° angle to the fixation. The bone segments were firmly fixed to the testing set-ups, paying special attention to the tensile force direction to remove any backlash in the set-up. The testing machine conducted force to the fixation at a speed of 0.05 mm/s until breakage. The force conducted by the testing machine and the displacement was recorded at an amplitude of 50 Hz.

The maximum force (N) and displacement (mm) for each test were recorded. Also elongation (mm) at the break was recorded. The energy (mJ) needed to break the fixations was calculated from the force displacement curve for each test. Energy needed to reach maximum force was used, rather than total energy in the tests, as after the force required reaching further displacement starts to decrease, the fixation can be considered to have failed.

2.1. Statistical methods

Means and standard deviations were determined for each test group. Two-tailed Student's *t*-test was used to calculate statistical significance between the groups (*p*-value). A *p*-value of 0.05 was considered statistically significant. Excel software (Excel, Microsoft, USA) was used for data processing.

3. Results

Thirty-five fracture tests were performed: 12 for CRS, 12 for HAP and 11 for UAP. The results are presented in Table 1. One UAP pull-out test was abandoned due to test sample breakage before testing. One HAP pull-out test was abandoned because of technical failure. Thus, five pull-out tests were included in the study for HAP and UAP.

3.1. Pull-out test

The mean maximum strength was for CRSs 48.9 N (SD 8.4, Range 37.8–60.0), for HAPs 32.5 N (SD 16.2 Range 18.3–53.0) and for UAPs 14.5 N (SD 7.5, Range 5.6–24.0). The results between CRSs and UAPs were statistically significant (*p*-0.000006).

The mean energy needed to break the fixation was for CRSs 9.0 mJ (SD 3.4, Range 4.9–12.9), for HAPs 21.7 mJ (SD 36.5, Range 1.7–86.3) and for UAPs 1.3 mJ (SD 0.8, Range 0.5–2.2). The results between CRSs and UAPs were statistically significant (*p*-0.002).

The mean elongation at the break was for CRSs 0.03 mm (SD 0.09, Range 0.2–0.4), for HAPs 0.7 mm (SD 0.8, Range 0.2–2.2) and for UAPs 0.2 mm (SD 0.1, Range 0.09–0.4). The results were not statistically significant between the groups.

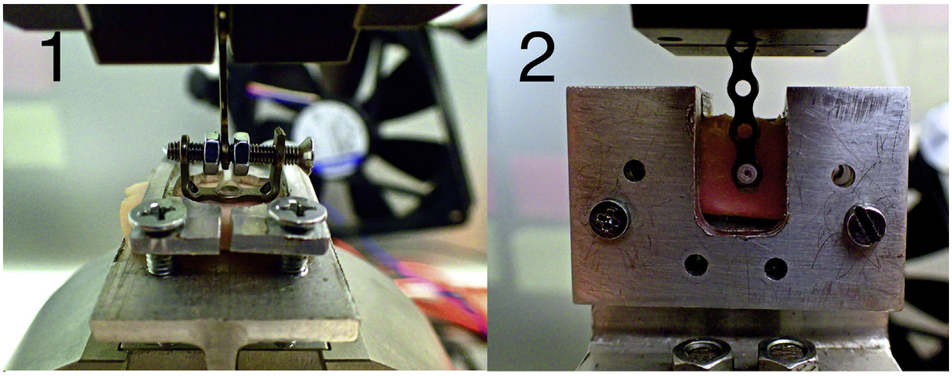

Fig. 2. Custom-made test set-ups. 2-1 pull-out set-up. 2-2 shear set-up.

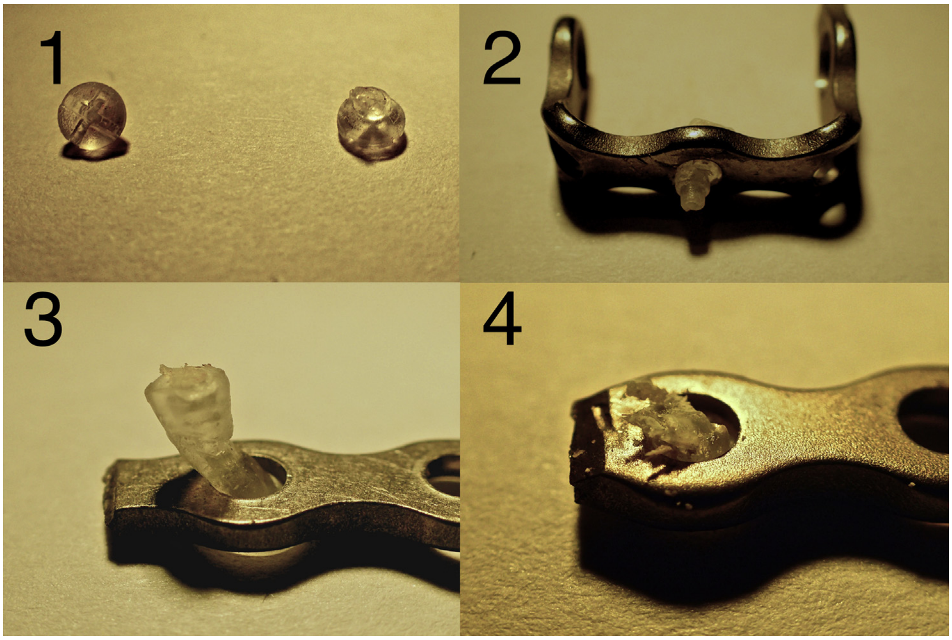

Fig. 3. CRS, UAP and HAP samples after break test. 3-1 broken CRS head after pull-out and shear test. 3-2 broken UAP head after pull-out test. 3-3 HAP after shear test. 3-4 broken UAP after shear test.

Table 1
The fracture test results for conventional resorbabla screws (CRS), heat activated pins (HAP) and ultrasound activated pins (UAP).

Pull-out Test	Mean strength (N)	Energy to break (mJ)	Elongation at break (mm)
CRS	48.9 (SD 8.4, n = 6)	9.0 (SD 3.4)	0.3 (SD 0.09)
HAP	32.5 (SD 16.2, n = 5)	21.7 (36.5)	0.7 (SD 0.8)
UAP	14.7 (SD 7.5, n = 5)	1.3 (SD 0.8)	0.2 (SD 0.1)
Shear Test	**Mean strength (N)**	**Energy to break (mJ)**	**Elongation at break (mm)**
CRS	40.8 (SD 6.0, n = 6)	31.8 (SD 8.2)	1.3 (SD 0.3)
HAP	77.9 (SD 18.3, n = 6)	141.3 (SD 91.5)	2.3 (SD 0.1)
UAP	38.9 (SD 14.9, n = 6)	20.3 (SD 12.9)	0.7 (SD 0.3)

Five CRS shafts broke underneath the titanium plate and one screw pulled out from the bone without breakage (Fig. 3-1). The CRS fracture surfaces showed characteristics of tough fractures with plastic deformation.

Five HAPs were pulled out without breakage but with slight plastic deformation. Four UAPs broke underneath the titanium plate (Fig. 3-2) and one was pulled out without breakage. The UAP fracture surfaces showed characteristics of tough fractures with plastic deformation.

3.2. *Shear test*

The mean maximum strength was for CRSs 40.8 N (SD 6.0, Range 31.7–47.1), for HAPs 77.9 N (SD 18.3, Range 52.0–95.4) and for UAPs 38.9 (SD 14.9, Range 17.8–58.1). The results were statistically significant between HAPs and CRSs (p-0.0031) and between HAPs and UAPs (p-0.0031).

The mean energy needed to break the fixation was for CRSs 31.8 mJ (SD 8.2, Range 14.8–41.2), for HAPs 141.3 mJ (SD 91.5, Range

42.6–251.1) and for UAPs 20.3 mJ (SD 12.9, Range 6.2–42.7). The results were statistically significant between HAPs and CRSs and UAPs (*p*-0.03) and between UAPs and HAPs (*p*-0.04).

The mean elongation at the break was for CRSs 1.3 mm (SD 0.3, Range 0.7–1.6), for HAPs 2.3 mm (SD 1.0, Range 0.9–3.4 N) and for UAPs 0.7 mm (SD 0.3, Range 0.4–1.0). The results were statistically significant between CRSs and UAPs (*p*-0.008) and between HAPs and UAPs (*p*-0.01).

Six CRS shafts broke underneath the titanium plate (Fig. 3-1). The CRS fracture surfaces showed characteristics of tough fractures with plastic deformation. Six HAPs were pulled out from the bone without breakage but with plastic deformation (Fig. 3-3). Six UAPs broke underneath the titanium plate (Fig. 3-4). The UAP fracture surfaces showed characteristics of tough fractures with plastic deformation.

3.3. *Case report*

A seven-month-old girl with Crouzon syndrome and bilateral coronal synostosis was treated with PCVO at Helsinki University Hospital. A bicoronal zic-zac incision was made to access calvaria. Bicoronal osteotomy and horizontal osteotomy above the inion were performed to create a maximal free floating posterior bone flap. Four cranial distractors were positioned between the osteotomy lines (Fig. 4). Distraction vectors were orientated parallel antero-posteriorly. Footplate positioning hooks were carefully orientated to gain support from the bone edges. Each footplate was attached with four conventional resorbable screws (1.5 mm, Rapidsorb, Synthes, USA), 85:15 poly (L-lactide-co-glycolide). Distractors were activated and a 2 mm gap was left between the osteotomy lines. A latency period of 5 days was used. The distraction rate was 1.2 mm once daily, and a total distraction distance of 20 mm was achieved. Distractors were removed in a second operation after a 1-month stabilization phase. Bicoronal incision was performed on the old scar. The distractors could be removed by bending the device from the distractor arms. Secondary fronto-orbital advancement was performed at the age of 15 months. No complications occurred during the treatment.

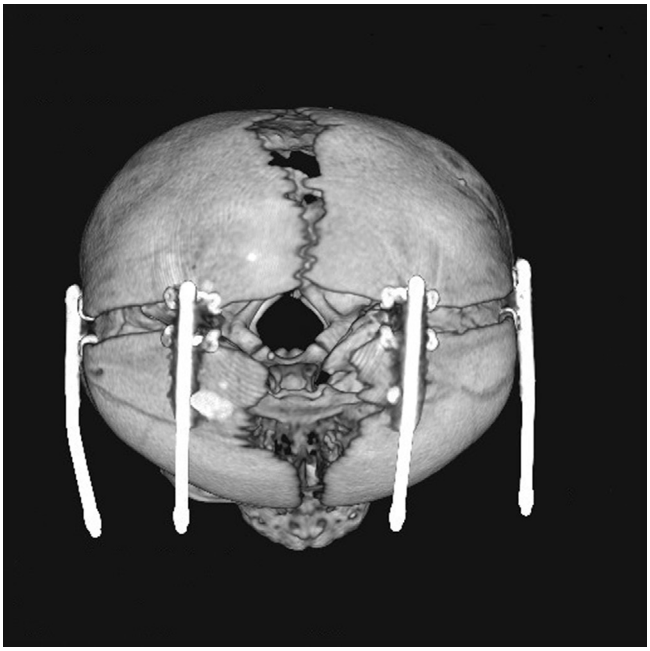

Fig. 4. Four cranial distractors of a PCVO patient were attached with conventional resorbable screws.

4. Discussion

This study explores the mechanical properties of three different resorbable fixation systems connected via titanium to bone. The peak force recorded in PCVO was 74 N for patients younger than 13 months (Ritvanen et al., 2017). Thus, footplate fixation with four CRSs and six HAPs provide 200% of the required fixation strength in the pull-out and shear directions. Our earlier study showed that the CRS in clinical use has comparable strength to the tested CRS (Savolainen et al., 2015). Attachment of the cranial distractor with four CRSs per footplate provided sufficient fixation strength in our PCVO clinical case.

Force is directed perpendicularly with respect to the distraction vectors and is conducted via shear strength to the fixation material. The cranial distractor positioning hooks can reduce the shear stress from the fixation by supporting the bone edges. In any case, torque force can be conducted to the fixation. Both shear and pull-out fixation strengths are relevant in calvarial DO.

The UAPs are designed to fuse with the resorbable plate, increasing the strength of the fixation (Pilling et al., 2007). The weakest and narrowest point of the UAPs is the neck; fusion with the resorbable plate is likely to increase the strength of the weakest point (Savolainen et al., 2015). The UAP fixation with the resorbable plate as designed probably explains the earlier observed high stability (Pilling et al., 2007). However, attaching the cranial distractor with UAPs has already been found successful in a clinical setting (Arnaud and Renier, 2009). The aim of this study was to provide further information about cranial distractor attachment in a laboratory setting. An in vitro model cannot fully match in vivo conditions. Therefore more research is needed in order to reach a final conclusion about cranial distractor attachment with different resorbable fixation systems.

The energy needed to break the fixation illustrates the toughness of the material. Tougher material allows more elongation, providing a more stable fixation on the concave-shaped calvarium. Tougher material is also more stable due to shock absorption. Traumas have been reported to cause footplate loosening (Steinbacher et al., 2011). Thus, toughness is an important factor when mechanical properties of a fixation material are evaluated.

High toughness was observed for HAPs, especially in the shear direction. HAPs are produced by a self-reinforcement technique. Implants produced by this technique exhibit high orientation of polymer fibres, increasing the strength along their long axis (Törmälä, 1992). Higher toughness makes HAPs a potential option for distractor fixation.

Most CRSs and UAPs broke at the shaft underneath the titanium plates, indicating that the material–bone interface is not a limiting factor for fixation strength. The higher variation in the fixation strength for HAPs than for CRSs or UAPs can be explained by pin-bone interface stability since HAPs were pulled out from the bone without material breakage (Fig. 3-3). The device needed to heat, i.e. activate, the HAPs is a prototype of the product coming to market. Thus, these results might not be entirely accurate for the upcoming product.

A drawback of DO is the second operation needed to remove the distractors (Derderian and Seaward, 2012). To address this issue, resorbable mandibular distractors were introduced, which can be removed through the exit hole of the distractor arm. The same device was used in PCVO (Maurice and Gachiani, 2014). The resisting force in calvarial DO is higher than in mandibular DO (Ritvanen et al., 2017). Thus, the mandibular device stability is questionable since distractor breakage and footplate loosening are commonly seen in calvarial DO (Imai et al., 2002; Nonaka et al., 2003; Steinbacher et al., 2011; White et al., 2008; Derderian et al., 2015; Nowinski et al., 2012; Ong et al., 2014). Fixation of a more stable cranial distractor with resorbable materials can thus be a better option.

The CRSs and HAPs lose about 52–70% of their strength between 12 and 26 weeks after the implantation (Nieminen et al., 2007). However, the self-reinforcement of HAPs can increase degradation time (Tormala, 1992). The UAPs should provide strength of 80% and 55% two and six months after implantation, respectively (Nguyen et al., 2017). The resorption profile of all tested materials should provide sufficient strength for the consolidation, distraction and stabilization phases. The weakening of the material could allow removal of the cranial distractor through the distractor arm exit after the stabilization phase (2–5 months after implantation), although no data are available on the actual resorption rate of these materials in clinical situations. In our case report, bending from the distractor arms could fracture the distractor fixation in the device removal operation. That indicates that the cranial distractor fixed with resorbable material could be removed through the distractor arm exit. However, the removal operation was easier and less invasive in our case than with titanium fixation.

The paediatric calvarium is often too thin for footplate attachment using conventional screws. Thus, PCVO is usually performed on patients older than 6 months when the bone is thicker (Nonaka et al., 2003; Steinbacher et al., 2011). In some cases, resolving an ICH is necessary before the age of 6 months. Fixation can be done on the thinner bone with HAPs since tapping is not required (Eckelt et al., 2007). Another benefit lies in the use of resorbable fixation screws or pins, which can reduce the risk of a fixation-related dura injury through the thin bone.

No data are yet available about the resisting force in PCVO for patients older than 13 months. The resisting force might be higher for these patients due to a thicker callus and scalp. This assumption is supported by distractor breakage being observed especially in older patients (Ong et al., 2014). Also missing are data on resisting forces for other types of calvarial DO besides PCVO. In monoblock DO, the resisting force is probably similar to that in PCVO according to Newton's third law. Suitability of resorbable distractor fixation for patients older than 13 months and for other types of calvarial DO remains unclear.

The same fixation stability cannot be achieved with resorbable materials as with titanium. Thus, any additional stress from the fixation should be avoided. An earlier study showed that performing distraction in a more gradual manner would decrease the distraction force (Ritvanen et al., 2017). Accurate vector positioning is imperative to avoid conflicting distraction vectors and torque forces from the attachment and to maintain the cranial distractors position hook support from the bone edges.

Continuous force monitoring during DO would allow adjusting the distraction rate to avoid fixation or device breakage. Moreover, a desynchronous force increase between the distractors could be a sign of conflicting distraction vectors or another device-related problem. Some of these complications might be avoided if the problem was recognized sufficiently early.

Earlier studies on resorbable materials have used red oak wood, sheep bone and polymethylmethacrylate as ground material for fixation (Pilling et al., 2007; Buijs et al., 2009). Porcine rib is softer than the human cadaveric mandible (Bredbenner and Haug, 2000). The paediatric neurocranium is characterized as a soft and viscoelastic structure (Margulies and Thibault, 2000). We therefore consider porcine rib to have the closest substitutional biomechanical and structural properties to the paediatric neurocranium. Natural bone could represent a better material–bone interface than synthetic materials.

We do not know the actual resorption rate of the tested materials in a clinical situation. Thus, the fixation stability and the possibility of removing the distracters through the distractor arm exit warrant further research. In addition, the suitability of resorbable distractor fixation for older patients (>13 months) and for types of calvarial DO other than PCVO or monoblock remains to be elucidated. Clinical studies are needed to provide answers for these questions.

5. Conclusions

According to our in vitro tests, attaching a cranial of distractor with four CRSs or six HAPs per footplate can provide sufficient stability in PCVO and monoblock DO. The resorbable fixation reduces invasiveness of the secondary device removal operation and might reduce the titanium fixation-related dura injury. Fixation with HAPs allows fixation on thinner bone since tapping is not required.

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Declaration of interests

No conflicts of interest.

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