

# Using bioabsorbable fixation systems in the treatment of pediatric skull deformities leads to good outcomes and low morbidity

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## Abstract

**Background** Bioabsorbable fixation systems have been widely employed in pediatric patients for cranial reconstruction, obviating the complications of hardware migration and imaging artifact occurring with metallic implants. Recent concern over complications unique to

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bioabsorbable materials, such as inflammatory reaction and incomplete resorption, necessitates additional conclusive studies to further validate their use in pediatric neurosurgery and craniofacial surgery. Likewise, long-term follow-up in this clinical cohort has not previously been described.

**Methods** We included consecutive pediatric patients under the age of 2, from Lucile Packard Children's Hospital, who underwent cranial vault reconstruction with the use of a bioabsorbable fixation system between 2003 and 2010. Hospital records were queried for patient characteristics, intraoperative data, and postoperative complications.

**Results** Ninety-five patients with the following preoperative pathologies were analyzed: craniosynostosis (87), cloverleaf skull (5), frontonasal dysplasia (1), and frontonasal encephalocele (2). Median age was 6 months (range 1–24 months). Average case duration was 204 minutes (range 40–392 min), with median of 154 mL blood loss (range 30–500 mL). Ninety-three percent of patients had 1–4 plates implanted with 48 % receiving three plates. The median number of screws used was 59 (range 0–130). The median length of hospital stay was 4 days (range 2–127 days) with an average follow-up of 22 months (five postoperative visits). The complications related to hardware implantation included swelling (1 %) and broken hardware (1 %), the latter of which required reoperation.

**Discussion** The bioabsorbable fixation systems for cranial vault reconstruction in children less than 2 years of age is safe with tolerable morbidity rates.

**Keywords** Bioabsorbable · Craniosynostosis · Pediatric neurosurgery · Pediatric skull deformities · Resorbable plates

## Introduction

Bioabsorbable fixation systems have been widely employed for use in pediatric patients for cranial reconstruction since 1997, obviating the complications of hardware migration and imaging artifact occurring with metallic implants. Recent concern over complications unique to bioabsorbable materials, such as inflammatory reaction and incomplete resorption [3, 8, 10, 14, 15], necessitates additional conclusive studies to further validate their use in pediatric craniofacial surgery. Here, we present a retrospective analysis of children younger than 2 years of age who underwent craniofacial procedures with a bioabsorbable plating system.

## Methods

This was a HIPPA-compliant, IRB-approved research protocol, accessing password and firewall-protected patient databases. Hospital records from Lucile Packard Children's Hospital (LPCH) were retrospectively queried on consecutive pediatric patients who underwent cranial vault reconstruction with a bioabsorbable plating system (RapidSorb® Synthes CMF, West Chester, PA, L-lactide-co-glycolide) between 2003 and 2010. At our institution, this is the predominant system employed; therefore, to remove any potential variability between industrial product formulation, only patients with this specific bioabsorbable fixation system were included. Inclusion criteria included age less than 2 years, diagnosis of a skull or facial deformity requiring combined neurosurgery and plastic surgical intervention, and intraoperative use of bioabsorbable plates. Hospital records were queried for patient demographics, preoperative diagnoses, intraoperative data, and postoperative complications.

Funding was provided in part by an industry sponsored indirect educational grant to Stanford University to fund aspects of this study. The Synthes company administration and representatives had no contact with the study staff regarding the study design or results. Furthermore, the outcome of this study was not discussed with industry prior to data analysis or manuscript production. Ethical considerations of this educational grant were weighed heavily and ultimately approved by the Dean of the Stanford University School of Medicine.

## Results

Ninety-five patients with the following preoperative pathologies were analyzed: craniosynostosis ( $n=87$ ), cloverleaf skull ( $n=5$ ), frontonasal dysplasia ( $n=1$ ), and frontonasal encephalocele ( $n=2$ ). Median age was 6 months (range 1–24 months), with 83 % of patients less than 12 months of age. Forty-six

percent of patients were female ( $n=44$ ) and 54 % were male ( $n=51$ ). Demographic information as documented by self-report from patients' families was collected and included an ethnic distribution of: White, non-Hispanic (55 %), Hispanic (29 %), Black (2 %), Asian (13 %), and Native American (1 %). Sixty percent of patients had private insurance, 39 % had Medi-Cal, and one patient was without insurance.

Table 1 details the diagnoses included in the study, including the suture involved and the relative frequency of any associated syndrome. Three cases were identified as reoperations. Comorbidities were found in 22 % of patients ( $n=21$ ) with each detailed by system in Table 2. Eleven patients had preoperative developmental delay.

Average case duration was 204 min (range 40–392 min), with median of 154 mL blood loss (range 30–500 mL). Postoperatively, the threshold to receive a transfusion was a hematocrit of 22. Ninety-three percent of patients received a blood transfusion either intra- or postoperatively, with a median transfused volume of 150 mL (range 0–1,000 mL). Ninety-three percent of patients had one to four plates implanted with 48 % receiving three plates (Table 3). The median number of screws used was 59 (range 0–130).

**Table 1** Diagnosis, syndromes, and involved sutures

	Patients	
	Cases	(%)
Diagnosis		
Craniosynostosis	87	(92)
Frontonasal dysplasia	1	(1.1)
Frontonasal encephalocele	2	(2.1)
Kleeblattschädel	5	(5.3)
Total	95	(100)
Suture involvement <sup>a</sup>		
Unilateral coronal	28	(29)
Bilateral coronal	12	(13)
Lamboid	7	(7.4)
Sagittal	10	(11)
Multiple	6	(6.3)
Total	87	(91)
Syndrome <sup>b</sup>		
Apert	3	(3.2)
Crouzon	2	(2.1)
Downs	1	(1.1)
Muenke	1	(1.1)
Pfeiffer	1	(1.1)
Saethre–Chotzen	3	(3.2)
Sotos	1	(1.1)
Total	12	(13)

<sup>a</sup> Craniosynostosis cases only

<sup>b</sup> Where a known syndrome was diagnosed in addition to craniosynostosis

**Table 2** Medical comorbidities by system in 21 patients

System and disease	Cases	(%)
Cardiovascular	4	(4.2)
Endocrine	1	(1.1)
Gastrointestinal	3	(3.2)
Genetic	2	(2.1)
Neurologic	10	(11)
Prematurity	2	(2.1)
Pulmonary	5	(5.3)
Renal	1	(1.1)
Torticollis	3	(3.2)
Total	32	

The median length of hospital stay was 4 days (range 2–127 days). The average follow-up was 22 months (range 0.5–74; median 17) and the patients had an average of five postoperative visits (range 1–10, median 5). Overall, 91 % of all cases had no complications. Postoperative complications related to surgery included pneumonia (1 %) and superficial wound infection (3 %). Complications related to the hardware included one broken strut plate (1 %) and one patient with swelling at the site of the plate 7 months after surgery with complete resolution at 11 months (1 %). The wound infections were superficial and required only outpatient antibiotic treatment for resolution. Three patients were preoperatively determined to require a staged reconstruction for their cranial deformity. Two cases of unanticipated reoperations included one for persistent facial and cranial deformity several months after surgery and one for broken hardware on postoperative day 1.

## Discussion

Surgical correction of cranial and facial deformities in children requires the unique consideration of the child's growing skull while maintaining acceptable stability to enable osteogenesis.

**Table 3** Distribution of the number of plates installed per patient

Number of plates	Patients	
	Cases	(%)
1	8	(8.4)
2	20	(21.1)
3	46	(48.4)
4	14	(14.7)
5	6	(6.3)
– <sup>a</sup>	–	–
9	1	(1.1)

<sup>a</sup> No patients required six, seven, or eight plates

Resorbable plates and screws attempt to avoid the problems with metal fixation systems, including erosion into the dura and brain parenchyma, imaging artifact, and restriction of bone growth. Multiple studies have documented the use of these products in the repair of craniosynostosis and other pediatric cranial deformities (Table 4).

Resorbable fixation systems in cranial surgery have been found to provide stable cranial fixation, which allow for normal expansion of the cranial vault, while avoiding problems with migration or increased complication rates compared to metal alternatives [1, 7–9, 12, 14, 15, 17]. Complications with bioavailable fixation systems include inadequate resorption, osteolysis, inflammatory foreign body reaction, plate extrusion, and infection [3, 8, 10, 14, 15]. Recently, the use of these materials has expanded to include combination with hydroxyapatite cement for more extensive reconstruction procedures [4, 11, 16], reconstruction after trauma [6], and reconstruction of the orbit [2]. Animal studies have shown negligible involvement of the dura and brain parenchyma directly underlying the bioabsorbable materials [5]. Histologic examination of resorbable plates has showed fibrous encapsulation of the plates, with a foreign body macrophage and giant cell reaction and calcification [5, 13, 14].

Recent concerns, particularly in regard to the inflammatory reaction, necessitated further evaluation of the risks and benefits of resorbable fixation systems in young children [3]. To decrease variability in age, surgeon, and implants, we elected to study children under the age of 2, where the same resorbable system was utilized, operated on by our combined pediatric neurosurgery and plastic surgery team at LPCH. As with previous studies, over 90 % of patients had an excellent outcome with only one case of inflammation or broken hardware. Inflammation typically occurs within the first 12 months after implantation [3] which was accounted for with our mean follow-up time of 22 months. Another factor that can influence the outcome is comorbidities. Despite having 22 % of the patients in this cohort with other comorbidities (Table 2), the overall surgical and bioabsorbable material-related complications were not higher than in other published series. The unanticipated return to the operating room due to a broken plate was evident on postoperative day 1. The underlying cause of this plate fracture is unclear.

Our cohort has the advantages of a predefined age group, consistency in surgeons and implant product, a variety of sutures and syndromes involved, and extended follow-up. Our standard postoperative follow-up schedule includes visits at 1, 3, 6, and 12 months and the average in this series was five postoperative visits. Over 80 % of patients in this series have at least 12 months of follow-up, substantially decreasing the risk of a missed event. A limitation of this study is the retrospective, case series design; however, given

**Table 4** Literature review of resorbable fixation use in pediatric skull deformities

Primary author	Year	Implant	No. of patients in study	Age (mean, range; months)	Diagnoses included	Mean length of follow-up (months)	Complications (n, %)
Eppley	1997	LactoSorb <sup>a</sup>	100	9, 6–12	Craniosynostosis	15, 6–24	0, 0
Goldstein	1997	LactoSorb	8	38, 6–120	Craniosynostosis and encephalocele	4.5	1, 12.5
Kumar	1997	LactoSorb	22	76, 5–228	Craniosynostosis and congenital craniofacial lesions	0.5–4	1, 4.5
Tharanon	1998	LactoSorb	33	–, 4–144	Craniosynostosis, Hydrocephalus and congenital craniofacial lesions	12	1, 3.0
Aria	2000	Fixsorb <sup>b</sup>	3	–, 2–10	Craniosynostosis	16–18	0, 0
Kurpad	2000	LactoSorb	51	36, 1–120	Craniosynostosis and encephalocele	24	2, 3.9
Imola	2001	LactoSorb	55	17, 5–78	Craniosynostosis, craniofacial syndromes, and acquired disorders	6–36	4, 7.0
Burstein	2002	LactoSorb	21	53, 0.2–180	Craniofacial syndromes	24	2, 9.5
Cohen	2002	MacroPore <sup>c</sup>	5	–, 3–8	Sagittal synostosis	3–12	0, 0
Eppley	2004	LactoSorb	1883	–, <24	Frontal synostosis and occipital deformation	–	25, 1.3
Burstein	2006	LactoSorb	60	7, 4–15	Craniosynostosis	24	8, 13
Greenburg	2006	RapidSorb <sup>d</sup> , Bone Cement <sup>a, d</sup>	50	6, 0.25–24	Metopic synostosis	144	1, 2
Serlo	2007	PLGA <sup>e</sup>	10	14, 7–35	Craniosynostosis	42	1, 10
Sanger	2007	Craniosorb <sup>f</sup> , Biosorb PDX <sup>g</sup> , LactoSorb	52	8, 2–49	Craniosynostosis	17	3, 5.8
Ahmad	2008	LactoSorb	146	15, 2–192	Craniosynostosis	12	5, 3.4
Aldana	2008	Sonic Welding <sup>h</sup>	28	66, 2–216	Craniosynostosis, tumor, and traumatic injury	11.5	1, 3.6
Arnaud	2009	Sonic Welding <sup>h</sup>	20	16, 3–30	Craniosynostosis and congenital craniofacial defect	>30	1, 5
Munoz-Casado	2009	LactoSorb	216	6, 4–24	Craniosynostosis	6–60	7, 3.2
Guzman	2011	RabidSorb	70	6.5, 1–27	Craniosynostosis	15	2, 2.9

– unavailable

<sup>a</sup> Lorenz Surgical, BioMet, Jacksonville, FL

<sup>b</sup> Fixsorb-MX; Takiron Co., Ltd., Osaka, Japan

<sup>c</sup> MacroPore, Inc., San Diego, CA

<sup>d</sup> Synthes Inc, Paoli, PA

<sup>e</sup> Biosorb PDX or Inion CPS baby, Tampere, Finland

<sup>f</sup> Codman-Johnson & Johnson, Raynham, MA

<sup>g</sup> Bionx Implants Inc, Blue Bell, PA

<sup>h</sup> SonicWeld Rx, KLS Martin L.P.

the low number of patients and good outcome with resorbable plates, a randomized, prospective clinical trial is impractical. Overall, in comparison to prior studies of resorbable plates, our cohort confirms bioavailable fixation systems to be safe and effective for the treatment of craniofacial deformities in children.

## Conclusion

The bioabsorbable fixation system for cranial vault reconstruction in children less than 2 years of age is safe with very low morbidity rates. In our cohort, the risk of inflammation related to bioabsorbable fixation system was 1 %. It is

important to disclose to families the risks and benefits of using these systems, as summarized in our review.

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**Conflict of interest** Dr. H. Peter Lorenz is a consultant for Synthes Corporation. His work with Synthes does not involve any of the Synthes' materials or devices described in the article. All other authors have no personal, financial or institutional interest in any of the drugs, materials, or devices described in this article.

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