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Comparison of Resorbable Plating Systems: Complications During Degradation

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Abstract

Introduction—Several bioresorbable plating systems have become standard in pediatric craniosynostosis reconstruction. A comparison of these systems is needed to aid surgeons in the preoperative planning process. We aim to evaluate one institution's experience using Resorb X® by KLS Martin and Delta Resorbable Fixation System by Stryker (Stryker Craniomaxillofacial, Kalamazoo, MI).

Methods—A sample of patients with single-suture nonsyndromic craniosynostosis treated at St. Louis Children's Hospital between 2007 and 2014 using either Resorb-X or Delta bioresorbable plating systems were reviewed. Only patients with pre-operative, immediate and long-term 3D photographic images or computed tomography scans were included. A comparison of plating system outcomes was performed to determine the need for clinic and emergency room visits, imaging obtained, and incidence of subsequent surgical procedures due to complications.

Results—Forty-six patients (24 Resorb-X and 22 Delta) underwent open repair with bioabsorbable plating for single suture craniosynostosis. The mean age at each imaging time point was similar between the two plating systems ($p>0.717$). Deformity-specific measures for sagittal (cranial index), metopic (inter-frontotemporale) and unicoronal (frontal asymmetry) synostosis were equivalent between the systems at all time points ($0.05<p<0.904$). A single Delta patient developed bilateral scalp cellulitis and abscesses and subsequently required operative intervention and antibiotics.

Conclusion—Bioabsorbable plating for craniosynostosis in children is effective and has low morbidity. In our experience, we did not find a difference between the outcomes and safety profiles between Resorb-X and Delta.

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INTRODUCTION

The standard of care for patients with craniosynostosis is surgical remodeling of the cranial vault with either endoscopic or open techniques (1, 2). For open procedures, cranial vault remodeling involves extensive contouring and precise placement of bone segments that benefit from fixation to form a stable construct.

The introduction of permanent metallic plating systems revolutionized the field of craniomaxillofacial fixation by allowing for stable constructs (3). These fixation systems were found to be problematic in the pediatric population, particularly in cranial vault reconstruction in patients with craniosynostosis. These permanent plates resulted in growth restriction in animal models (4). In addition, transcranial migration was a potential complication in humans, resulting in dural injury (5, 6). Resorbable plating systems were therefore developed to circumvent these potential complications. The safety and effectiveness of resorbable fixation has been documented in the literature, and it has now become the most popular method of fixation of the craniofacial skeleton in the pediatric population (7, 8). Unfortunately, complications during the resorption process have been described, mainly attributed to the variety and composition of the resorbable polymers (9). Such complications lead to increased cost of care due to added clinic or emergency room visits, imaging, and in some cases, additional surgical procedures (Figure 1) (10).

Multiple resorbable plating systems have recently become available. A comparison of these systems is needed to aid surgeons in the preoperative planning process. We aim to evaluate one institution's experience using two different plating systems: Resorb X® by KLS Martin and the Delta Resorbable Fixation System (Stryker Craniomaxillofacial, Kalamazoo, MI). A comparison of resorbable plating system outcomes will be performed to determine the need for clinic and emergency room visits, imaging obtained, and incidence of subsequent surgical procedures due to complications associated with these resorbable plates. Anthropometric outcomes amongst these two resorbable systems are analyzed as well, as they are critical elements of successful reconstruction.

METHODS

This study was approved by the Institutional Review Board at Washington University School of Medicine. A sample with nonsyndromic single suture sagittal, metopic, or unicoronal craniosynostosis treated at St. Louis Children's Hospital using either Resorb-X or Delta bioresorbable plating systems were reviewed retrospectively and prospectively. Patients with pre-operative, peri-operative (2–4 weeks postoperative) and long-term (1 year) 3D photographic or computed tomography (CT) images were included.

Patients with single suture craniosynostosis treated with Resorb-X fixation system acted as the comparison group 1, while the nonsyndromic patients with single suture craniosynostosis treated with bioresorbable Delta fixation acted as the comparison group 2. This small sample of patients was selected based on availability of data at our institution. A fully powered study was not feasible at our single institution; if the true difference in complication rates is 5%, an adequately powered study would require evaluation of over 450

control and 450 cases (Type I error = 0.05). We used Fisher's exact test to evaluate this hypothesis (11).

Patients meeting inclusion criteria were reviewed using the electronic medical record and images in the St. Louis craniofacial archive. Additional events related to hardware beyond standard of postoperative care were identified. These were telephone calls, clinic/emergency room visits, additional imaging, and additional operations.

Adverse events associated with surgical treatment and implanted fixation devices were tracked for each test group/plating system. These events included: *inflammation*, defined as focal swelling not previously present in location of hardware; and *infection*, defined as redness or purulence around hardware requiring medical or operative treatment.

Head Shape Analysis

A single individual (GBS) analyzed 3D photographs with Vultus software (3dMD, Atlanta, Georgia). The same operator used Analyze 12.0 (Mayo Clinic, Rochester, Minnesota) for analysis of CT data. Head shape analysis was performed akin to previously published methods evaluating calvarial outcomes in patients with craniosynostosis (12, 13). Computed tomography data was adjusted to exhibit the soft tissue (skin) surface. Both 3D photos and reconstructed CT data were oriented to the Frankfort Horizontal. For scans of patients with unicoronal synostosis, the renderings were further oriented to establish the two apex corneae in the same coronal plane. For all types of synostosis, head circumference was the maximum circumference measured in an axial plane, roughly at the level of the glabella-opisthocranium. Specific measurements for each type of synostosis were obtained as follows.

Sagittal craniosynostosis: Cephalic index (CI) was based on landmarks placed at the glabella, opisthocranium, and euryons.

Unicoronal craniosynostosis: Frontal asymmetry was defined as the sum of the differences between the synostotic and non-synostotic sides in asymmetry in the coronal plane at the height of the orbitale superior (OS), the height of the orbitale superior plus 1/6 the distance to the vertex, and the height of the orbitale superior plus 1/3 the distance to the vertex (Figure 2).

Metopic craniosynostosis: Interfrontal distance (ft-ft) was defined as the lateral distance between the two frontotemporale.

The analysis techniques for frontal asymmetry and ft-ft were confirmed to have excellent reliability on different patient cohorts (unpublished data).

Head shape analysis was performed at two time points: early postoperative period (1–5 weeks) and late postoperative period (1 year).

Statistical analysis

Differences in mean values of continuous variables between the groups were assessed using Student's t-test. Differences in proportions of discrete variables such as imaging modality

were assessed using Fisher's Exact testing. Holm-Bonferroni correction was applied to account for multiple comparisons between the plating groups.

RESULTS

A total of 46 subjects (24 Resorb-X and 22 Delta) underwent open repair with bioabsorbable plating for single suture craniosynostosis (Table 1). The mean preoperative, perioperative and postoperative age at which the patients underwent imaging and operative times were similar between the two plating systems ($p = 0.493$). Deformity-specific measures: cranial index (sagittal), inter-frontotemporale (ft-ft; metopic) and frontal asymmetry (unicoronal) were assessed (Table 2). The measures were equivalent between both groups at all the time points ($0.05 < p < 0.904$). The patients who received the Resorb-X plating system were identical to the patients who received the Delta plating system in nearly every facet, except for peri-operative change in head circumference ($p = 0.031$), post-operative change in head circumference (0.017), and proportion of peri-operative imaging modality ($p = 0.001$). However, only peri-operative imaging modality remains significant after Holm-Bonferroni correction ($p < 0.003$). In the peri-operative period, a greater proportion in the Resorb-X group underwent 3D photography, while a greater proportion of subjects in the Delta group underwent CT scans. However, both groups had a similar proportion of CT scans at the 1-year postoperative time point.

Table 3 summarizes the number of unanticipated phone calls, clinic appointments and interventions associated with each plating system that were beyond those typical of an open craniosynostosis repair. In review of phone records, 2 patients in the Resorb-X group (both for swelling) and 1 from the Delta group (1 bump) made additional calls for concern of post-operative swelling or contour irregularities on the scalp. All of the phone calls resulted in a followup clinic visit for a wound check. Specifically, four patients in the Resorb-X group (1 bump, 1 fullness, 1 fluid collection, 1 swelling) and 2 in the Delta cohort (1 scalp abscess followup, 1 bump after a fall) scheduled additional clinic visits. None of those patients who made additional phone calls or clinic visits underwent any additional diagnostic or surgical intervention. The most notable complication was in a single Delta patient who developed bilateral scalp cellulitis and abscesses. The patient presented to the emergency room within 2 weeks postoperatively and subsequently required operative incision and drainage of abscess and antibiotics. There was no indication that the plating system and bone was involved.

DISCUSSION

Clinical outcomes are multifactorial and contingent on technique as well as implant design and deformity being treated. Unfortunately, complications during the resorption process have been described which potentially lead to increased cost of care (10).

Craniofacial reconstruction in the pediatric population has gone through considerable evolution in the past few decades. Bioabsorbable fixation systems have become available and well-accepted by surgeons for cranial vault remodeling (14). These have been particularly useful in children where the calvaria are softer and more suited to less-rigid fixation material. Theoretically, the polymers used are in a common non-inflammatory

pathway for dissolution and the site of fixation is rendered less prone to inflammatory complications in granulomatous depositions. Generally, enough integrity is achieved after 3 months of fixation such that continued fixation is not required (8). Depending on the ratio of polymers, the resorption time for bioresorbable plates is generally much longer, from 12–36 months. It should be noted that the degradation characteristics of these materials were experimentally determined in vitro – either in phosphate-buffered saline at pH 7.4 and 37 degrees Celsius or in vivo using animal models (15, 16) – although neither method accurately replicates the clinical environment.

Our study examined the outcomes from the Resorb-X and Delta plating systems. Resorb-X by KLS-Martin (17) is a polymerization of 50:50 racemic mixture of L- and D-lactides leads to the synthesis of poly-DL-lactide (PDLLA), which is completely amorphous and transparent. Once heated up to 65–70 degrees Celsius (149–158 degrees F), they easily adapt to any anatomical structure. After cooling down, they regain their original rigidity and stability. Resorb-X retains approximately 80% strength at 2 months and 55% at 6 months. In contrast, Delta Polymer by Stryker (18) is a copolymer composition of poly L-lactide (PLLA), poly D-lactide (PDLA) and polyglycolide (PGA) in a ratio of 85:5:10. The plates maintain 78% and 50% of their initial strength at 2 and 6 months, respectively. Resorption rate has been reported to be between 18 and 36 months. The plates are hydrolyzed into lactic and glycolic acids and subsequently metabolized into glucose, carbon dioxide and water. These systems can be used in both adult and pediatric patients but are not intended for plating of the mandible and/or full load bearing procedures. A comparison of these systems is useful to aid surgeons in the planning process.

The literature is continually expanding with studies on outcomes of resorbable plating systems. The current study did not find a difference in head shape analyses between the patients who received ResorbX versus Delta plates (Table 2). Ahmad et al. evaluated the application of bioabsorbable fixation system (LactoSorb: L-lactic and glycolic acids) in craniofacial reconstructions of 146 cases of cranial vault reconstruction (8). Postoperative evaluation with clinical examination and CT scans revealed 6 patients with palpable plates, 2 patients with palpable screws, and 5 patients with surgical site infection. From our institutional experience, we had one post-operative infection that resolved uneventfully with operative drainage and intravenous antibiotics. So far, patient counseling during clinic visits and close observation have been adequate for our patients with inflammatory nodules and palpable plates – as it is known to take up to 3 years for the plates to fully disappear.

Likewise, Goodrich et al. reported excellent outcomes, with no major complications and no return to the operating room in posterior cranial vault reconstruction (sagittal and lambdoid synostosis) using ResorbX (KLS Martin LLP, Jacksonville FL, USA) (19). Wood et al reported on the use of ResorbX to treat 134 consecutive cases of primary craniosynostosis (20). The authors followed patients for an average of 18 months, which they suggest is the interval for complete resorption in pediatric patients. Interestingly, the authors also reported palpable and visible masses associated with the implants over time. Tatum reported that some patients with craniosynostosis developed scalp fluid collections in the 6–18 month range (21). He suspected that these findings were related to the hydrolysis and break down of the plates. Pietrzak suggested that observations like the ones we document in this study

are important as an indirect means to follow the degradation of the plates in patients (16). The extent of degradation can be precisely determined by biopsy of the plate; however, this is not feasible or indicated.

A study of this design has a number of limitations. Notably, our conclusions are based on the experiences at a single institution. It is underpowered to make definitive recommendations regarding clinical equivalence or non-inferiority. Multi-institution collaboration and longer period of follow-up may strengthen the conclusions. Only one patient from the Delta group required operative intervention for infection. The advent of this infection was within 2 weeks postoperative and upon drainage was found to not involve the plate. While our nurse coordinators followed each patient closely, there are possible phone calls that were not documented. A majority of the patients were imaged preoperatively and postoperatively with 3D photography. This modality does not show abnormalities with the plates or subclinical complications. Furthermore, compiling head shape analysis data from two modalities (CT and 3D photographs) introduces the prospects of additional error and measurement bias. However, previous research has shown that the bias of these measurements (e.g. CI) between CT and 3D photography is limited and unlikely to have a significant impact on the findings (12). Lastly, Dvoracek et al have asserted that measures such as traditional cranial index are widely used but are imperfect surrogates of disease severity (22).

CONCLUSION

Bioabsorbable plating for craniosynostosis in children is effective and has low morbidity. No difference in outcomes and complications were found in our experience with Resorb-X by KLS-Martin and Delta by Stryker.

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Figure 1.
Palpable nodules around hardware 14 months post-reconstruction with Resorb-X.

Figure 2. Unicoronal measurement of asymmetry. Measurements are soft tissue on 3D CT reconstruction measuring coronal retrusion or protrusion relative to the apex cornea. The asymmetry is the sum of these measures at the orbitale superior and points 1/6 and 1/3 of the axial distance from exocanthia to vertex.

Table 1

Patient characteristics

	Resorb-X N (%)	Delta N (%)	P-value
CRANIOSYNOSTOSIS			
Sagittal	8 (33.3)	8 (36.4)	
Metopic	8 (33.3)	9 (40.9)	
Unicoronal	8 (33.3)	5 (22.7)	
Total	24 (100)	22 (100)	
Operative Time (minutes)	260	274	0.493
AGE (months ± SD)			
Pre-Op image	14.3 ± 13.3	12.8 ± 17.2	0.737
Peri-Op image	17.6 ± 13.0	16.0 ± 16.8	0.717
Post-Op image	29.8 ± 13.5	28.7 ± 17.0	0.820
Pre-Op Imaging Modality			0.538
CT	7	9	
3D Photo	17	13	
Peri-Op Imaging Modality			*0.001
CT	3	14	
3D Photo	21	8	
Post-Op Imaging Modality			0.369
CT	7	9	
3D Photo	17	12	

Table 2

Measurements for each synostosis.

SAGITTAL			
Pre-Op CI (%) (Confidence Intervals)	70.6 ± 2.8 (65.1 – 76.1)	69.1 ± 3.1 (63.1 – 74.1)	0.324
Peri-Op CI (%)	77.8 ± 3.8 (70.4–85.2)	76.8 ± 3.8 (69.4–84.2)	0.618
Post-Op CI (%)	74.3 ± 3.3 (67.8–80.8)	75.2 ± 4.2 (66.9–83.5)	0.636
Peri-Op CI (%)	7.2 ± 1.7 (3.9–10.5)	7.8 ± 2.8 (2.3–13.3)	0.648
Post-Op CI (%)	–3.5 ± 3.5 (–10.4–3.4)	–1.7 ± 1.2 (–4.1–0.7)	0.188
Total CI (%)	3.7 ± 2.8 (–1.8–9.2)	6.1 ± 3.1 (0.1–12.1)	0.123
METOPIC			
Pre-Op Ft-Ft (mm)	84.2 ± 13.3 (58.2–110.2)	78.3 ± 10.6 (57.5–99.1)	0.322
Peri-Op Ft-Ft (mm)	99.3 ± 10.9 (77.9–120.7)	103.7 ± 12.2 (79.8–127.6)	0.481
Post-Op Ft-Ft (mm)	100.2 ± 9.0 (82.6–117.8)	112.2 ± 51.0 (12.2–212.2)	0.521
Peri-Op Ft-Ft (mm)	15.1 ± 14.4 (–13.1–43.3)	26.5 ± 12.5 (2.0–51.0)	0.128
Post-Op Ft-Ft (mm)	0.9 ± 7.0 (–11.9–13.7)	10.4 ± 48.1 (–83.9–104.7)	0.588
Total Ft-Ft (mm)	16.0 ± 15.5 (–14.4–46.4)	35.1 ± 50.3 (–63.5–133.7)	0.323
UNICORONAL			
Pre-Op Frontal asymmetry (mm)	6.0 ± 2.4 (1.3–10.7)	7.6 ± 1.6 (4.5–10.7)	0.224
Peri-Op Frontal Asymmetry (mm)	2.2 ± 1.2 (–0.2–4.6)	0.9 ± 1.5 (–2.0–3.8)	0.123
Post-Op Frontal Asymmetry (mm)	2.1 ± 1.6 (–1.0–5.2)	3.5 ± 1.0 (1.5–5.5)	0.074
Peri-Op Frontal Asymmetry (mm)	3.8 ± 2.2 (–0.5–8.1)	6.5 ± 1.2 (4.1–8.9)	0.054
Post-Op Frontal Asymmetry (mm)	± 1.8 (–3.4–3.6)	–2.0 ± 2.4 (–6.7–2.7)	0.123
Total Frontal Asymmetry (mm)	4.0 ± 2.4 (–0.7–8.7)	4.1 ± 2.5 (–0.8–9.0)	0.904
ALL SUBJECTS			
Pre-Op Head Circumference (mm)	466.4 ± 54.8 (359.0–573.8)	432.6 ± 110.9 (215.2–650.0)	0.191
Peri-Op Head Circumference (mm)	491.3 ± 31.5 (429.6–553.0)	506.2 ± 51.1 (406.0–606.4)	0.277
Post-Op Head Circumference (mm)	509.3 ± 29.6 (451.3–567.3)	453.6 ± 160.8 (140.0–767.2)	0.142
Peri-Op Head Circumference (mm)	25.1 ± 38.7 (–50.8–101.0)	49.7 ± 29.3 (–7.7–107.1)	*0.031

Post-Op	Head Circumference (mm)	18.1 ± 19.2 (-19.5–55.7)	0.2 ± 26.3 (-51.3–51.7)	*0.017
Total	Head Circumference (mm)	42.8 ± 37.1 (-29.9–115.5)	52.2 ± 30.0 (-6.6–111.0)	0.385

Peri-operative is the difference in the measure between the first post-operative scan and the pre-operative scan. Post-operative is the difference in the measure between the one-year post-operative scan and first post-operative scan. Total is the difference in the measure between the one-year post-operative scan and pre-operative scan.

* p-values < 0.003 are statistically significant after Holm-Bonferroni correction.

Table 3

Complications

	Resorb-X N (%)	Delta N (%)
Phone call(s)		
1	–	1 (4.5)
2	1 (4.2)	–
3	1 (4.2)	–
Clinic visit(s)		
1	3 (12.5)	1 (4.5)
2	1 (4.2)	1 (4.5)
Emergency Room visit(s)		
1	–	1 (4.5)
Additional CT	1 (4.2)	–
Additional Operation	–	1 (4.5)
Inflammation Bump	1 (4.2)	1 (4.5)
Antibiotics	–	1 (4.5)