Clinical Notes
Outcome Analysis for Correction of Single Suture Craniosynostosis Using Resorbable Fixation

Albert Losken, MD
J. Kerwin Williams, MD
Fernando D. Burstein, MD
Steven R. Cohen, MD
Roger Hudgins, MD
William Boydston, MD, PhD
Andrew Reisner, MD
Catherine Simms, RN

Atlanta, Georgia

A retrospective review was performed on 63 patients at Childrens Healthcare of Atlanta at Scottish Rite who underwent correction of single-suture craniosynostosis using a resorbable fixation system. Included in the series were 24 patients with metopic synostosis, 15 with sagittal synostosis, and 24 with unicoronal synostosis. The average age at operation was 22.7 months (range: 2.8 months–18 years), and mean follow-up time was 30.7 months (range: 7.1–10 years). Reoperation equal to or exceeding the magnitude of the original procedure occurred in 4.76% of the patients. This was comparable to the reoperation rate observed at our institution using traditional fixation systems. Minor complications related to the use of resorbable plates were also identified, and the final outcome for single-suture synostosis was favorable. Results suggest that resorbable plates and screws are as effective as titanium-based systems in the treatment of single-suture synostosis.

Key Words: Craniosynostosis, single suture, resorbable fixation, titanium

Effective management of craniosynostosis involves extensive cranial remodeling within the first year of life. Microplating systems have become an integral part of pediatric craniofacial reconstruction, given their ability to provide structural integrity and support. Titanium plating systems have traditionally been used for rigid fixation because they are easy to apply, effective, and generally well tolerated. However, concerns about growth restriction, transcranial migration of the hardware, and the occasional infection or plate exposure have led to the search for alternative methods of fixation.

Technical advances in plating systems have stimulated an evolutionary interest in the use of resorbable polymer plates and screws for craniofacial surgery. Since its introduction, rigid fixation using resorbable polymers has been used by many surgeons. The ability of these plates to maintain sufficient rigidity until skeletal healing is complete has made them an attractive alternative for pediatric skeletal fixation. The ideal resorbable fixation system should not interfere with healing, should provide adequate stability throughout the process of bone healing, and should not cause any local or systemic side effects. During the past 2 decades it has become apparent in the literature that surgeons have been using this system with encouraging early results.

Most of the initial applications were used in areas of minimal weight bearing; however, several reviews have discussed the use of resorbable fixation devices in areas of higher stress, as in facial fractures and mandibular advancements. Likewise, we have used a resorbable plating system (Lactosorb,
Lorenz Surgical Inc.) for the correction of single-suture synostosis. Specifically, these resorbable plates and screws have been used to stabilize advancements of the frontal bone and/or the orbital bar.

This report reviews our experience with the use of Lactosorb plates and screws for the reconstruction of single suture craniosynostosis. Comparisons were made to historic controls from a series previously reported at this institution. The evaluation of results and outcome analysis focused on indications, reoperation rate, and complications. Additionally, cost analysis was completed for both systems.

**Patients and Methods**

All patients who underwent correction of single-suture synostosis between September 1996 and March 2000 were identified. They were seen by a multidisciplinary group at the Center for Craniofacial Surgery at Children's Hospital of Atlanta Scottish Rite, and underwent corrective surgery by a team of craniofacial surgeons and neurosurgeons. A retrospective review of 63 consecutive patients who underwent correction of their deformity with Lactosorb plates and screws was compiled. Our protocols for managing these patients are shown in Table 1. The Lactosorb resorbable craniomaxillofacial fixation system (Walter Lorenz Co., Jacksonville, FL) was used. This system is made of a patented copolymer of poly-L-lactic acid and polyglycolic acid. Data points were queried with regard to patient demographics, indications, operative intervention, and postoperative course. Outcome measures included postoperative complications, reoperation rate, recurrence, and outpatient follow-up. Reoperation was defined as total if it equaled or exceeded the magnitude of the original procedure, or partial if it did not. Partial reoperations included minor recontouring with or without hardware removal. Patients were followed either directly through clinic visits or indirectly through personal communication. Complications were recorded and noted as either unrelated to aesthetic outcome, or those requiring reoperation. A cost analysis was also performed per hospitalization for the Lactosorb patients. A formal statistical analysis was not performed, given the size of each group in our series.

**Results**

**Demographics**

Sixty-three patients underwent correction of a single-suture synostosis using the Lactosorb system, and were included in the series. There were 46 males (73%) and 17 females (27%), and the mean age at the time of operation was 22.7 months (range, 2.8 months–18 years). The diagnosis in the patient population included 24 patients with metopic synostosis (38%), 15 patients with sagittal synostosis (24%), and 24 with unicoronal synostosis (38%). Average length of stay was 3.2 days (range, 2–6 days) All patients in this series required a bifrontal craniotomy with cranial vault remodeling via a coronal incision (Figs 1 and 2). Early sagittal synostosis requiring strip craniectomies were not included in this review. All plates and screws were from the Lactosorb (Lorenz/Biomet, Warsaw, IL) 1.5-mm set. The average number of mesh panels used per patient was 1.5, with an average of 13 screws per patient. Mean follow-up time was 30.7 months (range, 7.1 months–10 years).

**Complications**

Six patients (9%) had no postoperative data and were lost to follow-up. Nine patients (14%) experienced general complications while in the hospital, unrelated to the Lactosorb plating system. The complications included intraoperative blood loss, airway difficulties, chemosis, dural compromise, and Jackson-Pratt (JP) drain malfunctions. Palpable hardware was noted in the early postoperative period in seven patients (four metopic, two sagittal, one coronal), and one patient with metopic synostosis had an area of redness in the area of the plate, which resolved with antibiotic therapy. Patients with palpable hardware were also managed conservatively, and had complete resolution by 6 to 9 months postoperatively. Three patients with metopic synostosis and one patient with sagittal synostosis did require a partial reoperation with minor recontouring for bony irregularities, and had their hardware removed at the same time. These patients were not included in the total reoperative group.

**Total Reoperation Rate**

Three patients (4.76%) required a total secondary reconstruction (Table 2). The indications for reoperation and procedures performed can be found in

<table>
<thead>
<tr>
<th>Table 1. Treatment Protocol for Isolated Synostosis</th>
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<tbody>
<tr>
<td><strong>Isolated Synostosis</strong></td>
</tr>
<tr>
<td>Sagittal synostosis (&gt;7 weeks, severe deformity)</td>
</tr>
<tr>
<td>Unicoronal and metopic synostosis</td>
</tr>
</tbody>
</table>

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Table 2. These reoperation rates were compared with historical control data previously presented from our institution using titanium plates and screws. Average interval time to reoperation was 2.4 years (range, 12 months–5.3 years).

**Cost**

The mean cost for initial hospitalization was $22,646 (range, $11,271–$47,951). Average charge for the Lactosorb implants was $6,663 (range, $3,007–$12,880), accounting for 29% of the total cost. Patients requiring reoperations had an additional cost, averaging $7,926 (range, $2,689–$18,091). Lactosorb accounted for 20% of the secondary reoperation costs. The mean hospitalization cost of $22,646 for Lactosorb patients was compared with a mean hospitalization cost of $24,846 for patients with titanium plates (data collected between November 1996 and November 1999).
DISCUSSION

Clinical concerns exist regarding the permanent nature of metallic plates and screws in the pediatric craniofacial skeleton, including growth restrictions, implant migration, palpability, interference with radiographic imaging, and long-term local and systemic effects of a permanent foreign body.\textsuperscript{13-16} Recent trends in pediatric craniofacial surgery have suggested that resorbable plating systems are becoming the method of choice for skeletal fixation of the craniofacial skeleton. Although current management of single-suture craniosynostosis at our institution has remained relatively stable, the type of fixation device has changed. This report demonstrates our experience in the use of resorbable plates and screws for calvarial reconstruction and frontal bone fixation in children with isolated metopic, sagittal, or coronal suture synostosis. The pediatric craniofacial skeleton provides an ideal setting for the use of resorbable plates and screws, especially for total remodeling of the face and cranial bones. The rapid healing process of osteotomies in infants and children contributes to the requirement for a short period of skeletal stability.

Initial concerns about adequate plate fixation and stability have been addressed experimentally, and supported clinically.\textsuperscript{2,9-11,16-22} Our findings support the idea that there was no sacrifice in rigidity or strength with the use of absorbable plates for the management of single-suture synostosis. Furthermore, given the ease in construction of multiple plates from a Lactosorb panel, one could argue that increased stability was created because more plates could be used, improving positioning of the bony segments (Fig 2). Ease of construction and plate manipulation anecdotally also contributed to faster operating times.

Our approach to children with isolated cranio-

Table 2. Complications Requiring Total Reoperations

<table>
<thead>
<tr>
<th>Suture</th>
<th>Secondary Procedures</th>
<th>Indications</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sagittal</td>
<td>1</td>
<td>Skull irregularity, contour defect</td>
<td>orbital/cranial reconstruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uniconoral</td>
<td>1</td>
<td>Temporal contour irregularity, asymm.</td>
<td>orbital/cranial reconstruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metopic</td>
<td>1</td>
<td>Bitemporal pinching, palpable hardware</td>
<td>orbital/cranial reconstruction</td>
</tr>
</tbody>
</table>

Table 3. Comparative Data on Total Reoperation Rates

<table>
<thead>
<tr>
<th></th>
<th>Historic Control (8 wu 34 Months)</th>
<th>Lactosorb (8 wu 30 months)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td># of Patients</td>
<td>Reoperation rate (%)</td>
</tr>
<tr>
<td>Metopic</td>
<td>39</td>
<td>2.86</td>
</tr>
<tr>
<td>Sagittal-vault</td>
<td>31</td>
<td>6.45</td>
</tr>
<tr>
<td>Uniconoral</td>
<td>18</td>
<td>5.56</td>
</tr>
</tbody>
</table>

synostosis is comparable to treatment modalities at other institutions.\textsuperscript{1,23-25} It includes frontoorbital remodeling with a floating forehead at 4 to 6 months for isolated synostoses other than sagittal synostosis. Sagittal synostoses with mild deformities were treated with strip cranietomies, and were not included in our series. Total cranial vault remodeling was reserved for severe deformities at ages greater than 7 weeks. Patients with syndromic-related craniosynostoses were not included in this review. Also excluded were reoperations for midface deformities (monoblock or LeFort III advancements) and orthognathic procedures.

Criteria for total reoperations were consistent with Whitaker's classification of clinical results after a craniofacial procedure.\textsuperscript{1} Category IV (C-IV) required duplication of the previous procedure. With the type of skeletal fixation devices used as the only difference, the reoperation rates for sagittal and uniconoral synostosis using Lactosorb were comparable to those previously reported at our institution for titanium plates and screws.\textsuperscript{15} These results were also consistent with previously reported reoperation rates in the literature. Whitaker had a reoperation rate of 3% for asymmetric, isolated lesions.\textsuperscript{7} Wall et al. demonstrated a reoperation rate of 5.1%, and McCarthy et al. showed one of 6.7% for single-suture synostosis using traditional fixation systems.\textsuperscript{26,27} Reoperation rates for metopic suture synostosis in a larger series were previously calculated at our institution to be 8.7% and more recently 2.86%.\textsuperscript{12,28}

Reoperation rates represent an important outcome measure for craniofacial surgery, allowing fairly accurate comparisons between institutions or differing techniques. Our analysis was limited to clinical outcomes including complications, reoperation rate, and cost analysis. The results indicate that resorbable plates are safe and effective for calvarial reconstruction of patients with single-suture synostosis requiring fixation of stress-bearing advancements. Results, outcome, and reoperation rates were comparable to those for traditional fixation, without
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the undesirable consequences of permanent titanium plates and screws. With the continued success of biodegradable plates and screws in the pediatric population, it has surpassed metallic devices as the plating system of choice and is quite rapidly becoming the standard of care for reconstruction of the infant calvarium.

REFERENCES