Objective: To determine the long-term efficacy of resorbable plate fixation in pediatric patients undergoing craniofacial surgery for congenital anomalies, traumatic deformities, or skull base tumors.

Design: Retrospective case review.

Materials and Methods: Medical records of 57 consecutive cases using resorbable plates and screws for craniofacial fixation in patients younger than 18 years were analyzed.

Main Outcome Measures: The status of bone healing postoperatively (anatomical union, malunion, delayed union, or nonunion) and any complications or adverse effects (hardware visibility or palpability, plate extrusion, or infection) were noted.

Results: In midfacial and upper face procedures (54 patients) anatomical union and uncomplicated bone healing occurred in 52 (96%) of the patients. In this same group, complications (plate extrusion) occurred in 2 patients (3.7%) and were resolved using conservative treatment without untoward sequelae. These outcomes are comparable to results using metal osteosynthesis in similar situations. Costs of resorbable hardware are similar to existing metal fixation systems.

Conclusions: Our data support the use of bioresorbable plate fixation in pediatric craniofacial surgery as a means of avoiding the potential and well-documented problems with rigid metal fixation. Indications include fractures and segmental repositioning in low-stress non–load-bearing areas of the middle and upper craniofacial skeleton. Although there is an initial learning curve in using this technology, we believe the benefits are well worth the effort and represent a major advance in pediatric craniofacial surgery.

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A host of techniques and materials for fixation of the facial skeleton have emerged in the field of craniofacial surgery over the past several decades. During the last 20 years or more metal plates and screws have been widely favored as the method of choice to achieve stable internal fixation. While metal fixation has distinct advantages, several concerns have been raised when it is used in growing patients. Intracranial translocation of plates and screws can occur in up to 50% of pediatric cases using metal plates.1 Risk factors for internalization include long plates, placement over the temporal region, younger patient age, and syndromic craniofacial dysostosis. The intracranial presence of titanium plates has been shown to incite inflammatory responses in the adjacent dura and brain tissue, although no association with specific neurologic dysfunctions has been noted.22 Several experimental studies have demonstrated that rigid plate fixation may interfere with craniofacial growth in the pediatric skull, although this issue remains controversial.4-6 Stress shielding leading to bone atrophy has been debated, and problems with visibility, palpability, tenderness, and thermal sensitivity have been described.7,8 Additionally, metal hardware interferes with diagnostic imaging techniques. For these reasons, some investigators have suggested routine removal of metal fixation once stable osteosynthesis has been achieved.9-10

As an alternative to metal plate fixation in children, clinicians have recently taken a greater interest in biodegradable fixation techniques. Resorbable sutures have long been used to secure bone fragments; however, they have the same mechanical disadvantages as interosseous wires and cannot provide the necessary rigidity required in many situations. Early animal experiments in the development of...
MATERIALS AND METHODS

We have been using resorbable plate fixation since April 1997 for a variety of cranio-maxillofacial indications, and our cumulative experience provided the clinical material for this retrospective review. All pediatric patients in whom resorbable fixation of the cranio-maxillofacial skeleton was used between April 1, 1997, and March 30, 2000, were identified. Pediatric patients were defined as those younger than 18 years. The underlying diagnosis was noted in each case as well as the nature of the surgical procedure performed. The location, type, and size of plates used as well as the size and number of screws were noted. During the better part of the study, only one resorbable plating system (LactoSorb [PLA-PGA copolymer]; W. Lorenz Surgical Inc, Jacksonville, Fla) was available; hence, most of the surgical procedures were performed using this resorbable plating system.

Information concerning patient demographics, diagnoses, and surgical plan were obtained from preoperative clinical assessments, radiographic imaging studies, and photographs. Intraoperative data detailing the exact procedure performed and the plates and screws used were obtained from operative notes and intraoperative photographs. Observations regarding any intraoperative technical difficulties were recorded. Follow-up data included postoperative clinic notes, radiographic images, and photographs for all patients.

The critical outcome parameter assessed was the nature of the bony union achieved. Anatomical union was defined as union of the osseous segments in the desired position vs malunion where fragments shifted and healed in undesirable relationships postoperatively. Delayed union was defined as clinical and radiologic evidence of inadequate osseous healing at 6 weeks and, if the same was present at 3 months, this constituted nonunion. All early complications were noted with specific attention to extrusion and wound infection. If plates and screws were visible or palpable through the skin, this finding was noted as well as the eventual outcome of the palpable hardware.

Data were collated and analyzed to determine the efficacy and indications for using resorbable plating systems in different surgical settings as well as to define any precautions or special considerations.

Thus far, development of resorbable plates and screws has focused on polymers that are macromolecular chains composed of repeating subunits. Two poly-alpha-hydroxy acids, polyglycolic acid (PGA) and polylactic acid (PLA), are polymers that have been used in the manufacturing of resorbable suture for several years and have been the most widely used in manufacturing resorbable plates and screws. Other polymers include polyglyconate and polydioxanone. Polyglycolic acid is a hard crystalline polymer that resorbs rapidly and loses virtually all of its strength within 1 month. Polylactic acid is a semicrystalline structure with softer amorphous regions of random and loosely packed polymer chains interspersed between the orderly and more densely packed strong crystalline regions. Polylactic acid can exist in 2 different isomeric configurations: poly-L-lactic acid (PLLA) or poly-DL-lactic acid (PDLLA). Polyglycolic acid and PLA are biomolecules that occur naturally in the human body. The physical properties of the polymers discussed earlier are outlined in Table 1. Polyglycolic acid has the greatest flexural strength but undergoes the most rapid degradation with the majority of its strength lost by 6 weeks and complete volume loss by approximately 9 months. Poly-L-lactic acid is characterized by greater strength and much longer degradation times (up to 5-6 years) than PLLA. Alternatively, PDLLA is an amorphous polymer with a lower strength and more rapid degradation (approximately 1 year). Combining 2 or more of PGA, PLLA, or PDLLA homopolymer yields a copolymer with varying initial strength, rate of strength loss, biodegradation properties, and tissue tolerance depending on the ratios of the individual polymers used. The glass transition temperature represents the point above which the material is soft and flexible allowing manipulation into the desired shape and below which it transitions into a firm, rigid structure suitable to impart adequate strength and fixation. This point needs to be sufficiently greater than body temperature but cannot be so hot as to preclude practical use within a surgical setting.

Biodegradation of PGA and PLA occurs in 2 phases. During phase 1 (hydrolysis phase), water molecules are inserted into the long macromolecule cleaving it into shorter polymeric chains. As a result, the plate substrate looses structural integrity and fragments into microparticles. Subsequently, during phase 2 (metabolic phase), macrophages phagocytize the small polymer fragments eventually yielding the breakdown products of glycolic and lactic acid that are eventually metabolized by the liver into carbon dioxy-

<table>
<thead>
<tr>
<th>Monomer</th>
<th>Glass Transition Temperature, °C</th>
<th>Flexural Strength, MPA</th>
<th>Degradation Time, In Vivo</th>
<th>Degradation Time, Strength, Mass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyglycolic acid</td>
<td>25-40</td>
<td>320</td>
<td>4-6 wk</td>
<td>6-12 mo</td>
</tr>
<tr>
<td>Polylactic acid</td>
<td>60-65</td>
<td>190</td>
<td>6 mo</td>
<td>1-6 y</td>
</tr>
<tr>
<td>Polylactic acid</td>
<td>55-60</td>
<td>150</td>
<td>8-12 wk</td>
<td>12-16 mo</td>
</tr>
<tr>
<td>Polydioxanone</td>
<td>16</td>
<td>120</td>
<td>4-6 wk</td>
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A total of 55 patients were identified in whom 57 surgical interventions were performed where resorbable fixation of the craniomaxillofacial skeleton was used. The group consisted of 27 male and 28 female patients ranging in age from 5 months to 17 years. Congenital craniofacial anomalies were identified as the underlying diagnoses in 40 cases while acquired disorders accounted for the remaining 17 cases (Table 3). Of the 40 surgical cases with congenital craniofacial anomalies, 32 were primary interventions and the remaining 8 were revisions. In the primary surgery group the median age was 11 months (age range, 5-78 months; mean age, 17 months). In the patients undergoing revision surgery, procedures were performed to improve deformities in previously operated sites; the median age for this group was 10.5 years (age range, 3-14 years; mean age, 9.3 years). The group of 17 patients with acquired disorders consisted of 11 facial trauma repairs and 6 skull base tumors; the median age for this group was 13 years (age range, 1.5-17 years; mean age, 1 year).

In the 40 patients with congenital craniofacial anomalies, surgery consisted of either a single procedure or multiple procedures performed concurrently, so that a total of 75 separate procedures were performed overall as outlined in Table 4. The number of procedures per surgical intervention was as follows: 12 patients, 1 procedure; 23 patients, 2 procedures; 3 patients, 3 procedures; and 2 patients, 4 procedures. In the group of patients with acquired disorders a total of 18 craniofacial procedures...
were performed and consisted of either open reduction internal fixation of facial fractures or skull base approaches to tumors of the cranial base (Table 4).

A total of 408 plates and 1785 screws were used in this series, and most of these were from the LactoSorb system (390 plates). Smaller 1.5-mm hardware (393 plates) was used much more commonly than the 2.0-mm system. An average of 7.2 plates and 31.3 screws per case was used overall. However, in the cases of congenital craniofacial anomalies and skull base tumor nearly 4 times as much hardware was used than in the trauma patients as given in Table 5.

Resorbable plates were used as the sole type of bone fixation in the cases of trauma and skull base tumor (Figure 2). In the patients with congenital craniofacial anomaly, however, the resorbable plates were usually combined with suture fixation in 22 of the 40 cases and/or metal plate fixation in 15 of the 40 cases. Suture fixation was most commonly used for cranial vault remodeling in patients who were between the ages of 12 and 14 months (Figure 3 and Figure 4). During cranial vault reshaping and fronto-orbital advancement, bone segments are often recontoured out of the surgical field or are otherwise very accessible, thereby facilitating technical ease in the application of resorbable plates. Metal plates were added to resorbable plates for older patients, particularly in revision procedures, and at anatomical sites believed to be subjected to the greatest forces of relapse (Figure 5 and Figure 6). As our confidence with the mechanical stability using resorbable plates increased over time, the addition of metal plates became less frequent later in the study.

Table 4. Individual Procedures Performed in the Overall Group of 57 Craniofacial Surgical Interventions

<table>
<thead>
<tr>
<th>Acquired Disorders* (n = 18)</th>
<th>ORIF Facial Trauma, No. of Procedures</th>
<th>Skull Base Approaches, No. of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cranial vault remodeling, 37</td>
<td>CMZ Le Fort I osteotomy, 2</td>
<td>Frontal subfrontal, 4</td>
</tr>
<tr>
<td>Anterior, 30</td>
<td>Mandible, 3</td>
<td>Periorbital, 1</td>
</tr>
<tr>
<td>Posterior, 7</td>
<td></td>
<td>Le Fort I osteotomy, 2</td>
</tr>
<tr>
<td>Fronto-orbital advancement, 28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midface advancement, 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertelorism correction, 3</td>
<td></td>
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</tbody>
</table>

*ORIF indicates open reduction internal fixation; CMZ, orbitomaxillary zygomatic fracture.

Table 5. Number of Plates and Screws Used per Case in the Different Categories of Surgical Procedure

<table>
<thead>
<tr>
<th>Type of Case</th>
<th>Plates, Mean No. per Case</th>
<th>Screws, Mean No. per Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital craniofacial anomalies</td>
<td>8.6</td>
<td>37.9</td>
</tr>
<tr>
<td>Craniofacial trauma</td>
<td>2.1</td>
<td>9.1</td>
</tr>
<tr>
<td>Skull base tumor</td>
<td>7.6</td>
<td>28</td>
</tr>
</tbody>
</table>

Figure 2. A 22-month-old boy. A, Preoperative magnetic resonance image of a craniopharyngioma with a large suprasellar component. B, A frontotemporal-orbitozygomatic approach with 2 bone segments was used. C, Wide open access to the tumor was afforded. D, Following tumor removal the bone segments were repositioned using only resorbable plate fixation, and healing proceeded uneventfully.
Figure 3. A 9-month-old girl. A, View of nonsyndromic synostosis of the sagittal, metopic, and proximal coronal sutures leading to significant cranial deformity and elevated intracranial pressure. Lateral (B) and vertex (C) intraoperative views demonstrate frontal bossing, bitemporal bossing, and scaphocephaly. Total cranial vault remodeling was undertaken in addition to fronto-orbital advancement. Lateral (D) and vertex (E) views showing fixation with resorbable plates and sutures plus the use of interpositional bone grafts in selected locations. F, The immediate result demonstrates significant improvement in cranial form that has remained stable at 2 years of follow-up.
Bone grafting was used at key locations in 35 of the 40 congenital craniofacial anomaly procedures; but, in none of the cases of trauma and skull base tumor. Outcome was such that anatomical union was achieved in 52 (96%) of 54 cases involving the upper and middle craniofacial skeleton. Malunion occurred in 2 patients undergoing correction of craniofacial deformities. Analysis of the cases with malunion revealed that both were revision procedures, bone grafting was not used in either of them, and they underwent complex procedures with repositioning of 2 or more bony segments. Deterioration in the postoperative form occurred gradually over the postoperative course and there were no acute shifts in bony segment repositioning. The malunion was graded as mild in one case and moderate in the other.

Delayed union was encountered in 2 of 3 patients with mandibular fractures treated with open reduction internal fixation using resorbable plates. These patients were treated with the full understanding that current usage of resorbable plates in mandible fractures is investigational, and therefore they were to remain in an extended period of maxillomandibular fixation with gradual resumption of oral function after 3 to 4 weeks. Unfortunately, noncompliance was an issue in both youngsters and they removed their interdental fixation within the first postoperative week. One of these patients experienced plate extrusion and wound infection that required a second open reduction internal fixation using metal plate fixation. The other patient experienced mobility at the fracture site but went on to heal with prolonged maxillomandibular fixation.

**Figure 4.** A. Intraoperative vertex view of a 3-year-old boy who presented with sagittal synostosis. B. View after anteroposterior cranial vault remodeling was performed using several resorbable mesh panels for fixation in addition to sutures. C. Preoperative computed tomographic scan of an 18-month-old boy with bicoronal synostosis who underwent fronto-orbital advancement and anterior vault remodeling. D. Resorbable plates and mesh were used to contour the bandeau and stabilize the advancement as well as interpositional bone grafts.
Palpable and/or protuberant hardware was the most common adverse effect after surgery and occurred following 14 procedures (Figure 7A). Note that this group of patients includes patients with hardware that was palpable and not visible as well as those with visible hardware. All but 2 of these cases involved fronto-orbital advancement or cranial vault expansion in patients with congenital anomalies. In all cases the plates gradually decreased in prominence and became nonpalpable within 6 to 12 months. Direct evidence of plate resorption was evident in the 2 cases where planned secondary procedures were undertaken 6 months after the initial craniofacial surgery during which resorbable hardware was used (Figure 7B). Plate extrusion at the frontozygomatic region occurred in 2 (3.7%) of the 54 patients with upper and midfacial anomalies. Both patients were infants who underwent large fronto-orbital advancements and both extrusions resolved using conservative management.
without untoward effects. Infection occurred in 2 patients—1 patient with frontozygomatic extrusion and 1 patient with a mandibular fracture that developed plate extrusion and resulted in delayed union.

Several intraoperative observations were made as our experience evolved and are noteworthy. There was consensus among the principal investigators that usage of the resorbable plating systems was both labor intensive and technique sensitive. Specifically, a traditional drill, tap, and screw process needs to be performed with each screw placement making sure that the holes are not overdrilled and that the tap and screw paths coincide with the drill path. If the holes are not precisely drilled and tapped or the pathways are not coincident, then difficulties with thread damage or premature binding are inevitable during screw insertion. The process of plate adaptation can be time consuming in that it requires a warming device to heat the plates to a temperature where they become malleable enough to bend. The plates are then contoured to the desired shape by placing them in situ while still soft; however, the working time is short and more than one attempt is often necessary to achieve an acceptable adaptation. In situations with limited access, malleable metal templates are supplied as intermediaries to facilitate the process. As experience with the resorbable plates progressed, the amount of time and duplication of effort decreased so that eventually there was only a minor difference when compared with metal plating systems. Indeed, the mesh panels available in all of the resorbable systems proved to be very useful and in some ways preferable to metal plates. Once rendered malleable by heating above the glass transition temperature, the mesh panels are readily cut with heavy scissors into customized shapes and adapted to precisely conform over complex surfaces. Resorbable mesh also expedited the orientation and fixation of bone grafts (Figure 8).

**COMMENT**

Our data support the use of resorbable plate fixation in pediatric craniomaxillofacial surgery of the upper and...
middle facial skeleton. Bony healing, rates of anatomical union, and incidence of complications are comparable to results with the current standard metal plate fixation. Additionally, resorbable plates provide the added benefit of avoiding the potential problems with metal implants. Our long-term follow-up demonstrated excellent segmental stability and anatomical union in 52 (96%) of the 54 patients. Postoperative malunion occurred in 2 patients in which postoperative shift was contributed to by several other factors including prior surgery, soft tissue scarring, complex multiple part segmental repositioning, and failure to use interpositional bone grafts.

Other studies have also demonstrated favorable results with resorbable fixation in the craniofacial skeleton for both adult and pediatric applications (Table 6). Thranon et al reviewed 33 consecutive pediatric patients who underwent craniofacial surgery for congenital anomalies and tumor removal. LactoSorb fixation was used in all patients and follow-up ranged from 1 to 12 months. Early results demonstrated no cases of postoperative bony segment shift or loss of fixation. Notably, none of the cases involved secondary surgical intervention. In a larger study, Habal and Pietrzak27 reviewed their results using LactoSorb fixation in 163 patients (both pediatric and adult) with a variety of underlying diagnoses (96 congenital anomaly, 34 traumatic deformity, and 33 tumor removal). Follow-up ranged from 1 month to 3 years and no major complications with bone healing were noted in the case series. Patients undergoing reconstruction of congenital deformity or following tumor resection required 2 to 3 times more hardware elements than those undergoing traumatic repairs to achieve fixation, a finding noted in our study as well.

The lack of a significant inflammatory response or infection associated with resorbable plates in our study and in others is an important finding.26,27,31,32 To date the long-term studies have used exclusively LactoSorb that contains a higher concentration of PGA and resorbs faster (approximately 1 year) than some of the more recently released systems that have a higher PLA content. Polyglycolic acid degradation results in rapid increases in local glycolic acid concentration within a few weeks following implantation.20 This can be associated with transient short-term inflammatory responses and, on occasion, sterile sinus formation or bone osteolysis.33-35 The same phenomenon may explain the transient peri-implant edema noted by some craniofacial surgeons when using LactoSorb copolymer.27 Fibrous encapsulation and intermittent long-term inflammatory responses have been reported with monomeric polymers of PLGA and may be due to their protracted half-life and a low-grade foreign body reaction.20 Systems using copolymers of PLLA and PDLLA have recently become available for craniofacial application (Table 2) and it will be interesting to see what rate of foreign body reactions is associated with these plates over the long-term.

The most common adverse effect with resorbable plates relates to the higher rate of visible or palpable hard-
ware postoperatively. This results from the higher profile of resorbable plates necessary to offset the lower intrinsic strength of polymers and achieve mechanical properties comparable with titanium hardware. The thickness of polymeric plates averages 2 to 3 times the thickness of titanium hardware with comparable flexural strengths. The problem is further aggravated during large advancement and cranial expansion procedures that stretch the overlying soft tissue envelope and in extreme cases can contribute to plate extrusion. Other investigators\textsuperscript{26,27} have reported similar findings with hardware palpability and visibility, but because the problem resolves as the polymers resorb, this is not considered a true complication of bioresorbable fixation.

Some authors\textsuperscript{26,27} have resisted using resorbable fixation on the basis of uncertainty in their ability to provide adequate biomechanical strength of fixation. Existing studies\textsuperscript{20,38-40} have shown that the available resorbable plating systems (1.5- and 2.0-mm screw diameters) provide flexural and tensile strength comparable to the microplate titanium systems (1.0- to 1.3-mm-diameter screws). Interestingly, the polymeric plates have been shown to provide...

Figure 8. A 7-year-old girl with Pfeiffer syndrome. Preoperative view (A) and computed tomographic scan (B) demonstrating hypertelorism, exotropia, exophthalmos, and upper midfacial deficiency. The patient underwent a 2-stage anterior vault remodeling, fronto-orbital advancement, and 4-wall orbital repositioning for hypertelorism repair. C. Intraoperative view demonstrating use of resorbable mesh to stabilize bone grafts placed into gaps along the lateral orbital wall following orbital repositioning. D. Postoperative view of the same patient 2 years after surgery illustrating stable correction of hypertelorism and exophthalmos.
greater resistance to failure than micro and midface metallic plates when placed across interfragmentary gaps under compressive loads. This application is common to segmental advancements and cranial vault expansions for congenital anomaly correction. Other investigators have reported screw pull-out strengths comparable to titanium screws of equal diameter in the early period following insertion. Thus, resorbable plates and screws are considered to provide adequate rigidity and immobilization for routine osteosynthesis within the upper and middle facial skeleton. One must consider, however, that internal fixation in craniofacial surgery encompasses a wide range of applications where deformational forces can vary from low-stress passive applications to high-stress load-bearing areas. Factors that influence the amount of biomechanical strength necessary to achieve adequate stability include the forces of masticatory musculature, the degree of comminution or segmentation, the magnitude of segmental advancement or cranial vault expansion, and the amount of elastic recoil from the overlying soft tissue envelope. Therefore, it is prudent to consider each situation individually when determining the type, location, and amount of fixation necessary. For example, when dealing with zygomatic fractures, it would seem reasonable to assume that resorbable fixation at 2 or 3 points would be sufficient in an isolated, noncomminuted, minimally displaced, malar body fracture. Alternatively, a severely comminuted fracture involving the zygomatic arch and body, coexisting adjacent midfacial fractures, and disruption of multiple reference points presents an entirely different scenario. In this setting there is very little intrinsic structural strength remaining within the bony architecture, and the deformational forces acting on the fixation devices will be substantially greater than in the simple zygomatic fracture. Therefore, the internal fixation applied during reconstruction must provide a much more rigid and stable framework. Use of existing resorbable fixation technology in such a case may not be advisable.

Mandibular fractures present another situation in which available resorbable plates do not provide the necessary stability to resist masticatory forces. Our limited findings in which both patients resuming oral function within days of repair went on to delayed union would seem to support this belief. We are awaiting development of resorbable plates with greater flexural, torsional, and compressive strength suitable for open reduction internal fixation of lower jaw fractures.

In summary, bioreabsorbable fixation systems represent a major advance in cranio-maxillofacial surgery and have significant benefits in pediatric applications. The major advantages over existing metal plate fixation include avoidance of potential risks associated with intracranial migration, dural irritation, and growth restriction. Indications for available resorbable technology include a wide variety of procedures such as major reconstruction for congenital deformities, trauma, and skull base tumors involving non-load-bearing regions of the upper and middle third craniofacial skeleton.

Cases should be carefully selected, and points of fixation carrying a high risk for postoperative shift and relapse should be reinforced with interpositional bone grafts and perhaps fixed using more rigid metallic systems. Resorbable plates have not been approved for nor are they indicated for repair of lower jaw fractures with early return to oral function. Resorbable plate fixation of tooth-bearing bony segments can be problematic secondary to the increased risk of injury to tooth roots and dental buds when using the larger resorbable plates. This disadvantage may preclude their use in patients with mixed dentitions. The surgeon should be aware that resorbable plates are technically more challenging to work with, particularly early in the learning curve, and this needs to be weighed against their potential benefits. In terms of cost, the pricing of resorbable plates and screws is such that they are comparable to metallic fixation in most situations. The use of large mesh panels helps to contain costs with resorbable systems because several smaller customized pieces can be cost-effectively fashioned from a single large panel. The argument for resorbable plate fixation in adult craniofacial surgery is less compelling, primarily because the metal plate fixation it would be considered in lieu of, is easier to work with and presents a much smaller potential downside. Research is moving forward quickly in polymer chemistry, and future developments may well lead to the introduction of degradable systems that are easy to use, carry all the biomechanical advantages of metallic plates, are devoid of any adverse tissue reactions, and resolve soon after bone healing is complete. Until then, their use needs to be thoughtfully considered on an individual basis.

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