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Comparison between different absorbable plating systems in craniofacial surgery-an original research

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***Abstract*---**Aim: The purpose of this in vitro present research was to evaluate different absorbable plating systems in different craniofacial surgeries. Methodology: A sample of patients with single-suture nonsyndromic craniosynostosis treated using either Resorb-X or Delta bioresorbable plating systems were reviewed. Only patients with preoperative, immediate, and long-term 3-dimensional 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 2 plating systems ($P>0.717$). Deformity specific measures for sagittal (cranial index), metopic (inter fronto temporale), 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 as well as craniofacial surgeries are effective and has low morbidity.

***Keywords*---**Bioresorbable plating, Cranio-Maxillofacial Surgery, cranial vault remodelling.

Introduction

Resorbable materials have been used as fixation materials in craniomaxillofacial surgery.[1] In contrast to titanium plating systems, resorbable plating systems have not been used on a large scale for the fixation of mandibular fractures or for bony free flap fixation. The introduction of permanent metallic plating systems revolutionized the field of craniomaxillofacial fixation by allowing for stable constructs.[2] 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 animalmodels.[3] In addition, transcranial migration was a potential complication in humans, resulting in dural injury.[4,5] 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.[6,7] Unfortunately, complications during the resorption process have been described, mainly attributed to the variety and composition of the resorbable polymers.[8] Such complications lead to increased cost of care due to added clinic or emergency room visits, imaging, and in some patients, additional surgical procedures.[10]Nevertheless, the onset and popularity of the combination of polylactic and polyglycolic acids has shown these new materials are being frequently used. There is no doubt left about the usefulness in paediatric applications, but there is still controversy on its use in maxillofacial surgery of adult patients.[11] When using titanium plates, sometimes it is necessary

to perform a second operation for the removal of these screws. All the disadvantages inherent to metallic materials such as palpation, sensitivity, migration, possible bone resorption, allergies, and growth delays in children have led to the development of resorbable materials. However, biodegradable materials cause inflammation, it is then necessary to allow for a phase that will enable resorption without causing toxic reactions. Resorbable bicortical screws have been used in craniofacial surgeries, and several studies prove the security and effectiveness reached when using these materials in mandibular osteotomies.[12]Yerit et al. in 2005 performed the largest single trial of poly- L/D-lactide resorbable plates in sixty-six consecutive patients with mandibular fractures (22 female, 44 male; mean age, 23.9 years). A total of 89 fractures at various sites of the mandible were included in the study. It was found that the self-reinforcement technique provided sufficient mechanical stability of the implants for primary healing of these high-load mandibular bone areas. Postoperative complications were transient and limited to wound dehiscence and localized wound infection (two patients). In some patients, hyperaesthesia (three patients) or slight pain (10 patients) was reported at the 1-year recall examination, but implant-related serious adverse tissue reactions were not observed during the follow-up (mean, 24.4 months; range 6.4 to 44.3 months). This suggested that resorbable plates have a place in the mainstream of mandibular fractures.[10,11]Multiple resorbable plating systems have recently become available. A comparison of these systems is needed to aid surgeons in the preoperative planning process.

Aim of the present study

The purpose of this in vitro present research was to evaluate different absorbable plating systems in different craniofacial surgeries.

Methodology

A sample with nonsyndromic single suture sagittal, metopic, or unicoronal craniosynostosis Treated using either Resorb- X or Delta bioresorbable plating systems was reviewed retrospectively and prospectively. Patients with preoperative, perioperative (2–4 weeks postoperative), and long-term (1 year) 3-dimensional 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.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. A single individual (GBS) analyzed 3-dimensional photographs with Vultus software (3dMD, Atlanta, GA). The same operator used Analyze 12.0 (Mayo Clinic, Rochester, MN) for analysis of CT data. The analysis techniques for frontal asymmetry and ft–ft were confirmed to have excellent reliability on different patient cohorts.Head shape analysis was performed at 2 time points: early

postoperative period (1–5 weeks) and late postoperative period (1 year). Differences in mean values of continuous variables between the groups were assessed using Student t-test. Differences in proportions of discrete variables such as imaging modality were assessed using Fisher exact testing.

Results

A total of 46 subjects (24 Resorb-X and 22 Delta) underwent open repair with bioabsorbable plating for single suture craniosynostosis. The mean preoperative, perioperative, and postoperative age at which the patients underwent imaging and operative times were similar between the 2 plating systems ($P \geq 0.493$). Deformity specific measures: cranial index (sagittal), interfrontotemporale (ft–ft; metopic), and frontal asymmetry (unicoronal) were assessed. 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. In the perioperative period, a greater proportion in the Resorb-X group underwent 3-dimensional 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. The most notable complication was in a single Delta patient who developed bilateral scalp cellulitis and abscesses. (Table 1).

Table 1
Patient Characteristics

	Resorb-X, N (%)	Delta, N (%)	P
Preop imaging modality CT 3D photo	3 21	14 8	0.001
Postop imaging modality CT 3D photo	7 17	9 12	0.369

Discussion

There have been two high quality review articles with regard to the use of biodegradable/ resorbable plates. The first article, reviewed twenty-two articles detailing 19 studies, including 1 randomized controlled trial. These studies included fixation of mandibular fractures at various locations or fixation of bilateral sagittal split osteotomies. Overall, a total of 326 patients treated with resorbable plates and screws and 112 patients treated with resorbable screws alone were analysed. Analysis of these studies indicates that several material types are used in resorbable mandibular implants, including poly-L-lactic acid (PLLA) and 70% poly-L-lactic acid/30% poly-D,L-lactic acid (PLLA 70/PDLLA 30), coming from at least 10 different manufacturers. Mean follow-up ranged from 3 to 348 weeks. Based on the reported data, of 14 to 15 infections, 2 foreign body reactions, 7 malocclusions, 8 malunions, and 8 to 10 premature removals in the plate group and 1 foreign body reaction and 2 malocclusions in the screws-only group were found.[14]The Cochrane Review, reviewed 53 potentially eligible studies. The review illustrated that there are no published randomised controlled clinical

trials relevant to this review question. It concluded that there is currently insufficient evidence for the effectiveness of resorbable fixation systems compared with conventional titanium systems for facial fractures. The review found that, based on the results of the aborted trials, do not suggest that resorbable plates are as effective as titanium plates. It was suggested that, in the future, the results of ongoing clinical trials may provide high level reliable evidence for assisting clinicians and patients for decision making. There are complications with titanium plate and screw fixation of vascularised free bone graft/ bony free flap reconstruction of the mandible.[15]Knott et al. reviewed 290 titanium plates used to fixate free flap defects of the mandible. They found that 14.8% of all plates needed removal because of hardware related complications. Fourteen of these plates required removal because of plate extrusion or osteoradionecrosis. Predictors of success or failure associated with plate removal were previous treatment with hyperbaric oxygen (P<.001), radiation therapy (P<.001), and cancer recurrence (P=.03) were statistically significant predictors of Locking Mandibular Reconstruction Plate (LMRP) relatedcomplications at univariate analysis. At multivariate analysis, previous treatment with hyperbaric oxygen (P<.046) remained a statistically significant predictor of LMRP-related complications. LMRPs are highly effective for fixation of vascularized bone grafts, with a highincidence of bone-graft healing and a low incidence of complications related to lose screws. Nevertheless, there remains a 15% incidence of hardware-related complications, most related to hardware extrusion.[16]Whilst previous treatment with hyperbaric oxygen is a statistically significant predictor of LMRP-related complications, treatment with hyperbaric oxygen is time consuming, expensive and can be difficult for patients with multiple co-morbidities. Bayram et al. compared the fixation reliability and stability of titanium and resorbable plates and screws by simulating chewing forces. Sheep hemimandibles were mounted with a fixation device in a servohydraulic testing unit for compressive testing. Displacement values under 20, 60, 100, 120, 150, and 200 N; maximum displacements; and maximum forces that the model could resist before breakagewere noted. Significant differences were found between resorbable and titanium plates and screws at all forces (P<.05). However no statistically significant differences in the breaking force and maximum displacement values (displacement values at the breaking forces) between the groups. This is interesting as it suggests that until there is osseo-integration, it is the functional use of the mandible that leads to the failure of the resorbable plate.[17]A study of 54 patients with a mean postoperative follow up of 63 months were reviewed retrospectively.[18] In addition, each patient completed a 12-item scaled questionnaire to assess perception of pain, speech, mastication and deglutition on recipient site. This showed that Mastication Functional scores on mastication were low for both sexes.In oncological reconstruction of the mandible, patients are frequently fed via a Percutaneous Endoscopic Gastrostomy or with Nasogastric tube. Initially this is to allow the soft tissue element of the reconstruction to heal, however if the soft tissue reconstruction involves the swallowing mechanism, it may be to prevent aspiration. It may be continued or commenced, due to the complications of post operative radiotherapy, to allow the patient to undertake appropriate calorific intake. Most commonly patients are managing with a diet which requires little mastication. This shows that in the healing period of the reconstruction, very few patients are eating a normal diet compared to patients with a fractured mandible. Post operative radiotherapy takes place normally 4 to

6 weeks after surgery and lasts normally for 6 weeks. This means that when function is being fully restored, the mandible will have fully osseo-integrated with the free flap. Therefore, in oncological reconstruction of the mandible, the significant differences between resorbable and titanium plates in compression[17] are irrelevant as the mandible is not placed under the same functional stresses.Our study examined the outcomes from the Resorb-X and Delta plating systems. Resorb-X retains approximately 80% strength at 2 months and 55% at 6 months. In contrast, Delta Polymer, 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.

Conclusion

Bioabsorbable plating for craniosynostosis in children as well as craniofacial surgeries are effective and has low morbidity.

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