

Resorbable plate-screw systems: Clinical applications

Eriyebilen plak vida sistemleri; klinik uygulamaları

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BACKGROUND

OBJECTIVE

To evaluate the results we obtained from 37 patients referred to our clinics with resorbable plate-screw systems which have been claimed as biodegradable fixation materials and used in craniofacial, maxillofacial and orthopedic reconstructive procedures owing to their advantages such as biocompatibility, adequate biomechanical resistance, longer dwelling time, elimination through physiological routes without causing any foreign body reaction and/or significant sequelae.

METHODS

Resorbable plate-screw systems used in 37 patients between 2000-2003 for various craniofacial reconstructive procedures were evaluated as for their efficacy, and biocompatibility.

RESULTS

Adequate fixation was obtained in all patients, excluding one case operated for mandibula fracture whose reconstruction was completed with titanium plate-screw system. No serious complication was seen except a granuloma and sinus formation on subciliary incision in one patient.

CONCLUSION

Owing to their improved polylactic acid/polyglycolic acid ratio resorbable plate-screw systems which contain varying compositions of polylactic acid and polyglycolic acid copolymers are ideal fixation materials used favourably in maxillofacial, craniofacial and orthopedic reconstructive surgery in that they make effective fixation and have further advantages such as biocompatibility, adequate biomechanical resistance against distraction and compression forces in the early postoperative period, longer dwelling time and elimination from the body through physiological routes without causing any foreign body reaction or significant sequelae.

Key Words: Craniofacial surgery, absorbable resorbable plate-screw

AMAÇ

Amacımız kliniğimize sevk edilen 37 hastada biyolojik yolla degradasyona uğradığı ileri sürülen ve biyouyumluluğu, yeterli biyomekanik dirence, daha uzun kalış süresi ve herhangi bir yabancı cisim reaksiyonu ve/veya önemli sekellere neden olmaksızın fizyolojik yollardan eliminasyonu gibi avantajlara sahip olması nedeniyle kraniyofasiyal, maksillofasiyal ve ortopedik rekonstrüktif girişimlerde kullanılan eriyebilen plak-vida sistemlerine ilişkin sonuçlarımızı değerlendirmektir.

GEREÇ VE YÖNTEM

İki bin -2003 yılları arasında toplam 37 hastada muhtelif amaçlı kraniyofasiyal rekonstrüktif girişimde kullanılan eriyebilen plak-vida sistemleri retrospektif olarak etkinlik ve biyouyumluluk açısından değerlendirildi.

BULGULAR

Tüm hastalarda yeterli fiksasyon sağlanmış, mandibula fraktürü nedeniyle opere edilen bir hastada intraoperatif olarak yetersiz fiksasyon kararı verilerek titanyum plak vida sistemi ile rekonstrüksiyon tamamlanmıştır. Bir hastada subsilyer insizyonda granülom ve sinüs oluşumu dışında ciddi bir komplikasyon gözlenmemiştir.

TARTIŞMA

Eski fiksasyon materyallerine göre polilaktik/poliglikolik asit oranları iyileştirilmiş değişik oranlarda polilaktik asit ve poliglikolik asit kopolimerleri içeren eriyebilen plak vida sistemleri sağladıkları efektif fiksasyon ve biyouyumluluk, erken postoperatif dönemde çekme ve kompresyon kuvvetlerine karşı yeterli biyomekanik direnç, daha uzun kalış süresi herhangi bir yabancı cisim reaksiyonu veya önemli sekellere neden olmaksızın vücuttan fizyolojik yollarla atılmaları gibi ek avantajlara sahip olmaları nedeniyle maksillofasiyal, kraniyofasiyal ortopedik rekonstrüktif cerrahide gelecekte de kullanılacak ideal fiksasyon sistemleridir.

Anahtar Sözcükler: Kraniyofasiyal cerrahi, eriyebilen plak-vida

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INTRODUCTION

Various bone fixation materials have been used in maxillofacial and orthopaedic surgery. In addition to conventional techniques such as fixation with suture materials and wires, metal-plating systems have been widely used. Recently, “resorbable plate-screw systems” have attracted attention as an efficient fixation system, and started to be used more commonly for various indications.^[1]

Resorbable plating systems were first used approximately two decades ago as hemostatic vascular clips or surgical suture material.^[2] They are polymeres consisting of varying compositions of polylactic acid and polyglycolic acid copolymers.^[3] In the early period of their evolution, many problems were encountered such as foreign body reactions, and persistence in the body for longer periods than desired as they contained high molecular weight polylactic acids.^[4,5] Through the rapid development of polymer technology and regulation of polylactic acid/polyglycolic acid ratios, almost ideal fixation materials have been obtained at present. Current materials are completely biocompatible, and have adequate biomechanical resistance and can be eliminated from the body without causing any foreign body reaction.^[6-9] The alterations in the polylactic acid/polyglycolic acid ratio also changed the dwelling time in the body and the rate of biomechanical resistance.^[10]

Resorbable plate-screw systems can be completely excreted through physiological routes. Since the material is composed of essentially alpha-hydroxy acid polymers, breakdown occurs through hydrolyzation and end products are carbon dioxide and water.^[2,11] The degradation of polylactic acid polymers is quite slow owing to their hydrophobic

semicrystalline structure. Conversely, polyglycolic acid polymers have a rapid degradation process due to their highly amorphous structure and increased hydrolytic activities.^[12]

Here we present a wide variety of clinical applications of biodegradable fixation materials used for the last three years for various indications including traumatic, postsurgical and congenital cranio-maxillofacial reconstructive procedures.

MATERIAL AND METHODS

In our clinic, two different resorbable plate-screw systems (Bionix, Bisorb, FL, USA and W. Lorenz Lactosorb FL, USA) were used for the reconstruction of 37 patients with congenital craniofacial anomalies (n = 9), maxillofacial trauma (n = 25) and traumatic cranial bone defects (n= 3) between 2000-2003. The sites of the maxillofacial trauma cases are as follows: 4 frontal sinus, 3 maxilla, 10 isolated orbital floor, 1 mandible, and 7 orbito-zygomatic fractures.

Resorbable plate screw systems consist of plates of various shape, length and thickness and screws at corresponding sizes and weights. There are also auxiliary materials that aid their placement such as drills, taps, screw drivers, heat bags and heat pens. Plates at varying sizes according to the application site and the indication offer rich reconstruction alternatives. Likewise, screws have various sizes such as 1.5, 2 and 2.4 mm. in thickness.

First of all the plates at the form and size suitable for the reconstruction planned are selected. Afterwards appropriate plate and screw is chosen and an indicated hole size is opened with a drill and enlarged with a tap. The final procedure is screwing it to the system with special screw drivers. During

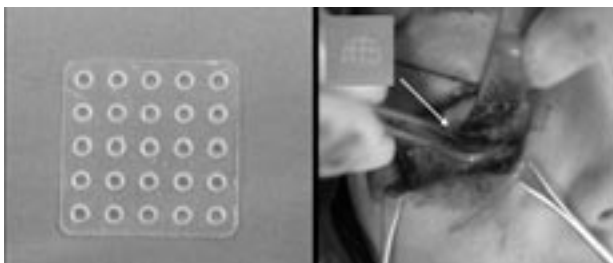


Figure 1: Biodegradable mesh plate. (left) Infraorbital rim fracture fixated with resorbable plate and insertion of the pre-prepared mesh plate over the orbital floor. (right)

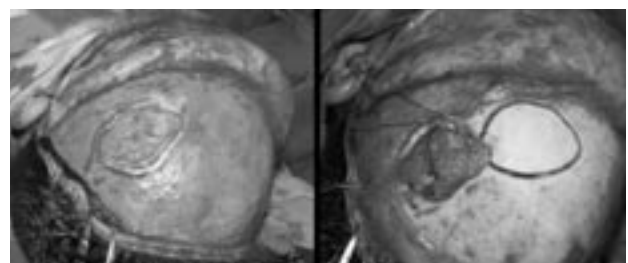


Figure 2: Exposure of the cranial bone defect on left parietal region of the skull. (left) Preparation of the full thickness bone graft next to the bone defect. (right)

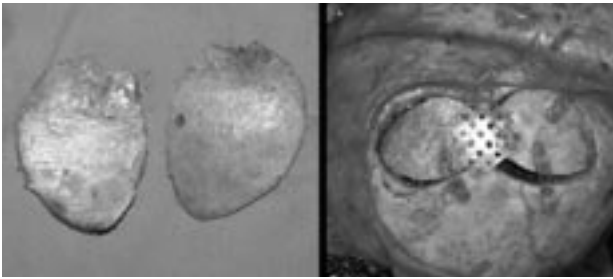


Figure 3: Splitting of the bone graft to separate inner and outer tables. (left) Outer table left was used to close the donor site and inner table to reconstruct the cranial defect. Both grafts were fixated with three biodegradable plates and one mesh plate to the cranium and each other. (right)

this procedure, care should be taken in manipulating the material, as they are more sensitive and fragile than metal plate and screws.

Beside fractures of various sites on maxillofacial region, orbital floor fractures were also treated with resorbable systems. Absorbable mesh plates were used to span the orbital floor defect rather than conventional plates and screws.

Although resorbable plate-screw systems display changes according to the type of the material used, they may be shaped in hot or cold setting to be fit to our application surface. Heating procedure is carried out by special heating bags or pens. Four cases whose fractures were reconstructed by means of resorbable plate screw systems in our clinic are presented:

CASE I

A twelve year-old female patient who had a motor vehicle accident was seen in the emergency room. Maxillofacial examination and radiological evaluation revealed right orbitozygomatic and orbital floor fracture. Open reduction and internal rigid fixation with resorbable system were planned. Subciliary and lateral brow incisions were used to reach the fracture sites. Following reduction of the displaced fractures at inferior orbital rim and zygomatico-frontal junction, 2 mm resorbable plates were used for fixation. Then soft tissues, herniating through orbital floor fracture into the maxillary sinus were released and orbital floor defect was isolated. A resorbable mesh was easily cut and shaped to fit the orbital floor and gently inserted to support the



Figure 4: Thirteen month-old boy with bicoronal cranial synostosis. Note the defects in frontal and supraorbital regions. (upper left) Following frontal craniotomy, frontal bone and supraorbital bar were advanced. All bony structures were fixated with biodegradable plates. (lower right, left) Good frontal and supraorbital contours were obtained at the end of the procedure. (upper right)

orbital contents. (Figure 1) No complication was seen during postoperative follow up period. Besides, her excellent facial contour, she had no diplopia, enophthalmos and gaze restriction.

CASE II

A 32 years old male patient was complaining about unpleasant appearance of a depression on the left parietal region of his head. A cranial bone defect with a diameter of 6 cm was detected on his computerized tomography. It was due to a previous neurosurgical intervention following a motor vehicle accident. The cranial defect was reconstructed with an autogenous calvarial split thickness bone graft. Cranium and the bony defect were exposed with bicoronal approach. (Figure 2) Full thickness bone graft with an identical size was harvested from just medial to the original bone defect. (Figure 2, right) Outer and the inner tables of the bone graft was separated by splitting. (Figure 3) Inner table was used to reconstruct the defect and outer table was returned to the donor site. Finally both bony structures were fixated with three resorbable plates to the cranium and a mesh plate to each other. (Figure 3) No complications were seen in two years of follow-up period and the patient was satisfied with the result.

CASE III

A 24 year-old female patient referred to the emergency department with maxillofacial trauma after a motor vehicle accident. Physical and radiological examinations revealed a frontoorbital fracture. When it was explored through a bicoronal scalp incision, displaced fracture line was observed in the frontoorbital region that was affecting only the anterior wall of the frontal sinus and the nasofrontal duct was intact. Following the reduction of the fractured segment into its proper anatomic position, reconstruction was completed using absorbable mesh plate and 2 mm. screws. No complication was seen in the postoperative clinical and radiological controls. The late which was minimally palpable in the frontal region at the early period, was no longer palpable at the end of one year.

CASE IV

A thirteen month-old boy was referred to our clinic with bicoronal cranial synostosis. (Figure 4) A frontal craniotomy extended to the fused coronal sutures was performed and the supraorbital bar is was removed. Following frontal advancement of the supraorbital bar and frontal bone all the bony segments were fixated with biodegradable plate-screws. (Figure 4, lower) Postoperative shape of the cranial vault was satisfactory and no early or late postoperative complications were seen. (Figure 4)

RESULTS

No infection, local-systemic allergic reaction or inadequate fixation were observed in any of the patients. When plates were placed under thin soft tissue and skin areas such as frontal region, they were palpable in the early postoperative period and they became gradually unnoticeable starting from the postoperative eight month.

In one single patient that was due to a mandibular fracture resorbable plating systems failed to provide adequate fixation intraoperatively and they were replaced with metal plates and screws. In another patient, who is operated for zygomatico-orbital fracture presented with a granuloma and sinus formation at subciliary site on postoperative sixth month. She was reoperated and sinus tract, granulation tissues and resorbable plate-screws

which were partially degraded and lost their original shapes were removed. She had no complaints on her postoperative follow up.

DISCUSSION

Metal plate-screw systems are fixation materials that have been used for a long time commonly in plastic and orthopedic surgery. Metal plate screw systems enable adequate fixation in bone healing process. Yet, their effects such as limiting bone growth especially in pediatric age group have prompted investigators to look for alternative fixation materials in the reconstruction of trauma and craniofacial anomalies.^[13] Ideal fixation materials should have adequate biomechanical resistance against distraction and compression forces in the early postoperative course as well as making bone healing possible without causing foreign body reaction in the later period.^[2,14,15]

Another disadvantage of metal plate-screw systems is that they may undergo "intracranial migration".^[16,18] There are some case reports in the literature, where metal plate-screws progressed as far as dura mater and cause neurological seizures and necessitated their removal with reoperation. Furthermore, metal plate-screws might lead to destruction and osteoporosis in the surrounding bone tissue.^[19]

Metal plate screws used in regions where dermis and subcutaneous tissue are relatively thin, such as forehead. These regions may be conspicuous and felt by inspection and palpation.^[20] Most of the patients present with subjective complaints such as, a sense of cold and pain on their face. These cosmetic problems and discomforting complaints necessitate a second operation for the removal of plate screw systems.

In addition, metal plate systems may be displaced or cause artifacts on radiograms, being influenced by the magnetic field produced during MRI.^[2,21] Moreover, they have heating problems during radiotherapy.

Resorbable plate-screw systems can not be imaged radiologically. Therefore, intraoperative photographs should be taken in order to follow up the patients postoperatively in a proper way and to prevent medicolegal problems. As the placement of

material requires a certain learning curve, operation times are longer initially. Also their unpractical packaging systems which every individual package contains single plate or screw limit their easy use during operation. However getting more experienced, operation time shortens and become comparable with the same kind of procedures that are performed with other metal systems.

This material which has resistance against distraction and compression forces is comparable with that of metal plate-screw systems in the early era of the reconstruction. They are completely removed in 12-18 months without producing any foreign body reaction.^[2,22,23] Bone healing was also comparable with metal plate screw in clinical and radiological examinations. Similar results have been obtained in animal studies and their histological examinations^[24,29] Because of their self removal after a period of time, resorbable fixation system is an excellent alternative among pediatric patient group. Complete resorption of the plates and screws at the fracture site by biodegradation let the craniomaxillofacial bones continue their physiological growing.

Although successful applications of biodegradable systems on various sites of craniofacial anatomy are well known, fixation of weight bearing bones such as mandibles with resorbable plate-screws remains controversial. There are few studies on using biodegradable fixation materials for mandibular fractures. These systems were reported to be reliable for mandibular fractures and fixation procedures following orthognatic osteotomies of both maxilla and mandible.^[30,31] As we had an intraoperative problem in fixation of a mandibular fracture with biodegradable plates, we beleive that further investigations should be done on this subject.

Orbital floor is one of the most commonly affected anatomic regions in maxillofacial fractures. Although various materials were used to reconstruct the defect, resorbable plate systems became our first choice for the selected patients. Absorbable mesh plates were used to span the orbital floor defects. Easy shaping and application are advantages of this material.^[32] In the postoperative period, fibrous healing tissue is formed in order to provide the anatomic integrity while the mesh was degrading. We used autogenous and cadaver originated bone grafts for orbital floor fractures in the past.^[33] Long lasting

proptosis and ocular distopia, time consuming preparation and shaping were the disadvantages of these bony materials. Easy shaping with scissors and hand and perfect compatibility to the orbital floor made resorbable meshes a superior choice among others.

At present, the most important problem with resorbable plating systems is their higher cost than their metal counterparts. Compared to metal plate-screw systems, plate or screw systems are much more expensive (2.5 and 3 times respectively) in Turkey. However, their advantages such as low infection rates and minimization of the need for secondary operations make them an attractive option. With newer and cost-effective systems we believe that they will be preferred more frequently among other options.

CONCLUSION

With developing technology and research, bioresorbable fixation materials come close to ideal. In the beginning they were served as a choice for the pediatric patients but nowadays they have become standard materials in most of the centers. As a conclusion, resorbable plate-screw system is an attractive alternative for various kinds of craniofacial reconstructive procedures.

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