Original Article

Evaluation of Bioresorbable vis-à-vis Titanium Plates and Screws for Craniofacial Fractures and Osteotomies

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Abstract

Background: Rigid internal fixation with metals is a reliable method of achieving osteosynthesis while allowing the patient passive or even functional loading of the fracture or osteotomised bone segments. The disadvantages with metals have led to the introduction of resorbable polymers in rigid internal fixation.

Methods: This study was conducted to evaluate the efficacy of these polymers as compared to titanium in fixation of bone segments fixation in 40 patients of zygomatic complex fractures and craniosynostosis management. The cases were followed up for one year.

Result: The stability of the fixation was found to be comparable to metallic fixation though the armamentarium and procedure of fixation of resorbable system was more demanding and the technique sensitive.

Conclusion: The resorbable system is a good system for rigid internal fixation in specific conditions where muscular and stress forces are not a determining factor in fragment displacement.

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Key Words : Zygomatic complex; Resorbable system; Osteosynthesis

Introduction

The aim of fracture management is to obtain a bone function as close to the pre fracture state as possible. Absolute stability is the main criteria of fixation which aids in direct bone healing. In the last three decades, management of craniofacial fractures by means of osteosynthesis and rigid internal fixation (RIF) has undergone a vast development.

The concept of monocortical miniplate fixation developed in 1970s, gained popularity as a RIF method. RIF with metals is a reliable method of achieving osteosynthesis which allows simultaneous passive or even functional loading of the fracture or osteotomised bone segments. Though titanium has fulfilled most qualities of the biomaterial requisites, it has a lot of inherent disadvantages. The elastic modulus of titanium is five times that of bone. This stiffness can cause a stress shielding effect on the bone leading to osteoporosis under the plate. It could interfere with the growth of the region, migrate intracranially if placed on the calvarial bone necessitating its removal.

Resorbable polymers have been used for biomedical applications especially in surgical sutures for a long time. The disadvantages of titanium led to their application in RIF. Their biggest advantages were the fact that they degrade slowly in the body [1] thus staying only long enough to stabilise the bone till union takes place. Since their modulus of elasticity simulates bone, stress shielding effect is not a feature. Due to slow resorption they transfer stresses slowly to bone preventing osteoporosis. These polymers can be broken down naturally by the metabolic system.

Material and Methods

A total of 40 patients were included in the study, 20 for fixation with titanium devices and 20 with resorbable devices. In both groups, 19 patients had zygomatic complex fractures and one had craniosynostosis. The procedures were carried out by the same surgical team.

The titanium rigid fixation devices included : Leibinger titanium miniplate 4 hole/L plate, Leibinger mini screws 2.0 mm diameter/6 mm length – self tapping, 1.6 mm titanium drill bit and screw holding Leibinger screw driver.

Delta system devices consisted of : 2.2 mm resorbable 4 hole straight plates with 1.4 mm, 2.2 mm thickness resorbable screws/6 mm length – non self tapping, 1.8 mm diameter titanium drill bit, 2.2 mm bone tap, 2.2 mm screw driver blade with handle and water bath for heating plates.

Clinical and radiological evaluation for zygomatic complex fractures was done. The craniosynostosis was confirmed after clinical and radiological evaluation using computed tomography (CT) with 3D reconstruction. All patients were

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operated under general anaesthesia with naso endotracheal intubation. Zygomatic complex fractures were managed with rigid fixation using a minimum of two point fixation at the fronto zygomatic suture line and the zygomatic buttress region. Fixation was done using titanium or the Delta System 4 hole plates with a minimum of two screws on either side of the fracture. In the resorbable system, the need to use a tap after drilling prior to screw insertion was done additionally. Haemostasis was achieved and wound closed with vicryl and silk.

The cranium was approached using a bicoronal incision for craniosynostosis and predetermined osteotomy was performed. The frontal bone was removed and the segments moved to the predetermined position to relieve the pressure on the cranial contents. The bones were then fixed rigidly in new position by either titanium or resorbable plate system.

All the patients were followed up clinically and radiologically for one year to assess bone union.

Results

Nineteen patients were managed for zygomatic complex fractures by Delta System. The age of the patients ranged between 20 to 41 years with a mean age of 30.5 years. Another 19 patients (15 male and 4 female) were managed for zygomatic complex fractures by Titanium rigid fixation system. The age of the patients ranged from 21 - 51 years with a mean age of 31.3 years. One six year old child was treated for craniosynostosis with resorbable system and another of seven years with titanium fixation devices.

Sixteen patients of the resorbable group sustained injuries due to road traffic accidents (RTA), two after a fall and one after physical assault. In the titanium group, 17 sustained injuries due to RTA and two due to fall. The criteria for surgical correction were (i) Restricted mouth opening;six in resorbable group and 12 in titanium group (ii) Paraesthesia/anaesthesia of infraorbital nerve ; 12 in resorbable group and 10 in titanium group (iii) Flattening of cheek prominence; nine each in resorbable and titanium group (iv) Diplopia; three in resorbable group and two in titanium group. The average gap from the date of injury to surgical intervention was 6 days for both groups.

All thirty eight patients underwent open reduction and RIF. There was intraoperative screw breakage in four of the resorbable group during the screw tightening. All these were in the thick frontozygomatic region. In the titanium group there were four cases in which screws during tightening became loose and emergency screws had to be used in these places. All the complications mentioned in this group occurred in the zygomatic buttress region in contrast to the resorbable group. The average operative time was longer with the resorbable system than the titanium system (Table 1). Post operatively review of the cases was done clinically and radiologically at three,six and twelve months. All cases had adequate reduction of fracture segments with good healing without any segment mobility. Post operative radiographs revealed only signs of the screw holes in the resorbable group that disappeared at the end of 6 months.

Table 1

Perioperative handling of systems

System	Titanium	Resorbable
Working time	1hour 15 minutes	1hour 40minutes
Contourability	Good	Good
Adaptibility	Satisfactory	Good
Reduction	Good	Good
Screw fixation	Good	Good
Operative complications	Loose screw	Screw breakage

In three patients treated with titanium plates, there was dehiscence of the plate from the zygomatic buttress region that resolved with constant irrigation of the site uneventfully. There was local reaction to titanium plate that resulted in its removal after three weeks in one case. In two cases the titanium devices had to be removed after a month due to loose screws causing local inflammatory reaction in the buttress region. There were no complications in any of the 19 cases treated by resorbable material. Both craniosynostosis cases had an uneventful recovery.

In all 38 cases of zygomatic complex fractures, the signs and symptoms disappeared after surgery. Infra orbital paraesthesia/anaesthesia persisted in three patients of the resorbable group for three months and in two patients of the titanium group for about 10 weeks post operatively.

The most important finding in the post operative review was the palpability of the plates in 17 of the titanium group in the zygomatic buttress region and 15 of the same group in the frontozygomatic region after one year. In the resorbable group, plates were palpable in the frontozygomatic region in seven patients at the end of six months and none were palpable at the end of one year.

Discussion

The aim of fracture treatment is to obtain a final function that is as close to the prefracture situation as possible. Prior to introduction of rigid internal fixation (RIF), stainless steel wires were used to fix the fracture segments. The disadvantage of which was that it was not rigid and the lack of directional control with wire osteosynthesis was another deterrent factor.

The search for a more rigid means of fixation that would permit patient simultaneous passive or even functional loading of the fractured bones culminated in RIF devices like plates and screws. The concept of RIF of maxillofacial fractures led to the development of monocortical miniplates osteosynthesis. This consisted of plates that are malleable and miniaturised for maxillofacial reconstruction.

The rarity of solid compact bone in the midface is an important factor. It is located at the frontozygomatic suture, infraorbital margin and zygomatic buttress. This has proved beneficial in its use for RIF for zygomatic complex fractures. Open reduction and RIF in at least two fracture sites has been the cornerstone of zygomatic

complex fracture management. The frontozygomatic suture and zygomatic buttress have been the most favoured sites of RIF in terms of stability, aesthetics and prevention of rotation of the fracture segments in either vertical or horizontal axis.

Improvement in material sciences has led to the use of materials that have excellent biocompatibility and can be left in situ indefinitely. The three classes of biomaterials used are metals, ceramics and polymers. RIF has relied on metallic components exclusively due to their high strength and contourability.Corrosion resistance, biocompatibility and osseo integration have led to the acceptance of titanium as the metal of choice for internal devices in maxillofacial surgery.

Long term studies on the effects of metal osteosynthesis have shown the presence of metal ions in the vicinity of the site, leading to speculation that metal is gradually leached out by the action of body fluids [2,3]. There is definite proof of growth alteration due to rigid nature of the metallic device but its significance on overall growth has not been conclusively proved. The loosening or corrosion of the metallic implants may also cause inflammatory reaction. Visibility, palpability and cold sensitivity are other potential problems of metallic RIF. These factors led to a search for biomaterial that could provide stabilisation during healing and it should gradually disappear to allow normal growth and remodeling [4].

The advent of polymers in RIF was aimed at negating these disadvantages of metal implants. Resorbable polymers have been used in sutures for decades. The advantage of these materials is their complete degradation in 12 to 24 months [5].

The resorbable system used in this study was the Delta System manufactured by Stryker Leibinger of Germany. This system is a composition of Poly L Lactide/ D Lactide / Glycolide with a molecular ratio of 85/5/10. This tripolymer is a combination deriving the desirable properties of strength from Poly L Lactide, contourability from Poly D Lactide and absorption characteristic from Glycolide.

The problem encountered in the titanium system was the palpability of plates in all 19 patients at the end of one year. Other minor complications were dehiscence in three, loose screw in one and local reaction in one patient necessitating removal of the plates in the last two patients.

At the end of one year, fracture healing was satisfactory in all the cases irrespective of the system used. Serial radiographs showed screw holes in the resorbable system that disappeared within six months.

We achieved satisfactory results in all patients. The biggest advantage with the resorbable system was the ability to soften the plate and adapt it to the bony contours perfectly. On the other hand, the malleability of the titanium plate not withstanding, it was not easy to adapt the plate to the curvature especially the buttress region. The bends in the plate are areas of stress concentration in metal. The loosening of titanium screws necessitated use of emergency screws while in the resorbable system, use in the thick zygomaticofrontal region led to breakage due to use of excess force, but there was no necessity to retrieve the broken screws as a new hole could be drilled through the broken ones, as reported by other workers also [6].

However the disadvantage of the resorbable system include cost, large number of armamentarium and inability to withstand torsional and muscular forces thus preventing its use in mandible.

To conclude, polymer based resorbable system have the properties simulating the titanium system in most occasions where tension forces do not determine the stability of the reduced bone segments. Bone healing was found to be satisfactory in both systems with no statistical difference in quality of healing. It is recommended that this device should be used in young children where growth retardation needs to be prevented.

Conflicts of Interest

None identified

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