Resorbable Implants in Maxillofacial Surgery: A Reality Check

Suresh Menon · Col SK Roy Choudhury

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Abstract

Background Stability is the main feature of fixation techniques in fracture management modalities, in vogue today. One of the most significant landmarks in the armamentarium of maxillofacial fracture management has been the introduction of rigid internal fixation (RIF). The biomaterials used in RIF have seen a gradual change from Stainless steel to titanium due to the evidence based advantages of the latter. However, the inherent problems with metallic implants led to the introduction of resorbable polymers in RIF.

Materials and Method This article evaluates the efficacy of these polymers in fixation of bone segments as compared to titanium fixation implants in 40 patients of zygomatic complex fractures. The study compared the clinical efficacy, technique, cost and time factors in the use of these two biomaterials.

Results The results showed very little difference after the use of these two biomaterials in spite of the increased time, technique sensitivity and cost of the resorbable system.

Conclusion The argument for use of the resorbable fixation implants as a better alternative to titanium in maxillofacial fracture management seems overstated considering the insignificant differences in the results obtained but

significant differences in the time taken and economics of the two biomaterials. The resorbable system should ideally be restricted for use in pediatric craniofacial surgery.

Keywords Zygomatic complex · Resorbable system · Osteosynthesis

Introduction

The main function of a dynamic tissue like bone is to carry load and support and protect organs. The transmission of normal forces through the bone is disrupted in fractures and osteotomies. Treatment of fractures essentially aims at achieving a situation as close to the pre fracture situation as possible. Absolute stability is the main feature of fixation techniques in vogue today which makes the environment conducive to direct bone healing. The management of craniofacial fractures using osteosynthesis and rigid internal fixation (RIF) has undergone tremendous changes in the last 4–5 decades.

The concept of monocortical miniplate fixation has gained popularity as a RIF method due to its numerous advantages. RIF with metals is a reliable method of achieving osteosynthesis while at the same time allowing the patient passive or even functional loading of the fracture region.

Titanium has fulfilled most requisites that a biomaterial should possess and has been the most frequently used material for these implants. However, the stress shielding effect on the bone and possible interference with the growth of the region may necessitate their removal.

This led to the introduction of resorbable polymers in RIF. The biggest advantage of these according to certain workers was the fact that they degrade slowly in the body

S. Menon (✉)
Department of Oral & Maxillofacial Surgery, Vydehi Institute of Dental Sciences, 82 # EPIP Area, Whitefield, Bangalore 560066, India
e-mail: psurmenon@gmail.com

C. S. R. Choudhury
Military Dental Centre, BEG, Kirkee, Pune, India

Fig. 1 Titanium plate fixation at frontozygomatic region

Fig. 2 Titanium plate fixation at zygomatic buttress

[1] thus staying only long enough to stabilise the bone till union takes place.

Materials and Method

This study was carried out at Army Dental Centre, Research and Referral, New Delhi.

A total of 40 patients diagnosed with zygomatic complex fractures were included in the study, 20 for fixation with titanium devices and 20 with resorbable devices alternatively. A homogeneous patient material was secured by strict inclusion and exclusion criteria. Patients with associated maxillary fractures or grossly comminuted fractures were not part of the study. All procedures were carried out by the authors.

The age range was 20–51 years with an average of 31 years. The sample included 7 females and 33 male

patients. Surgical armamentarium consisting of Titanium rigid fixation devices included

1. Titanium miniplate 4 hole/L plate of German origin (Leibinger)
2. Mini screws 2.0 mm diameter/6 mm length—self tapping
3. Titanium drill bit 1.6 mm diameter.
4. Screw holding screw driver

The resorbable system was also manufactured by the same company from Germany (Delta System from Leibinger) and consisted of:

1. 2.2 mm resorbable four hole straight plates with a thickness of 1.4 mm.
2. 2.2 mm resorbable screws/6 mm length—non self tapping
3. Titanium drill bit 1.8 mm diameter.
4. 2.2 mm bone tap
5. 2.2 mm Screw driver blade with handle.
6. Water bath for heating plates

All patients were operated under general anaesthesia with naso endotracheal intubation.

Procedure

The modality of rigid fixation in these fractures was 2 point fixation at the fronto zygomatic and the zygomatic buttress region. The frontozygomatic suture was approached by the lateral eyebrow incision and the buttress by a vestibular intraoral incision. Fixation of these sites were performed using either titanium (Figs. 1, 2) or the resorbable system four hole plates with a minimum of two screws on either side of the fracture (Figs. 3, 4). In the resorbable system the additional procedure performed was use of a tap after drilling prior to screw insertion. Haemostasis was achieved and watertight closure obtained.

Results

20 patients (17 male and 3 female) were managed for zygomatic complex fractures using resorbable system. The age of the patients ranged from 20 to 41 years with a mean age of 30.5 years.

Another 20 patients (16 male and 4 female) were managed for zygomatic complex fractures using titanium rigid fixation system. The age of the patients ranged from 21 to 51 years with a mean age of 31.3 years. 17 of the resorbable group sustained injuries due to road traffic accidents (RTA), two due to a fall and 1 due to physical assault. In the titanium group, 17 sustained injuries due to

RTA and 3 due to a fall. The indications for surgical intervention were:

- (i) Restricted mouth opening in 18 patients
- (ii) Paraesthesia/anaesthesia of infraorbital nerve in 22 patients
- (iii) Flattening of cheek prominence in 18 patients
- (iv) Diplopia in 5 patients in superior gaze.

The average number of days when surgical intervention was undertaken after the injury was 6 days for both groups.

There was screw breakage in the frontozygomatic region in 4 of the resorbable group during the screw tightening procedure. However, the new hole was drilled through the remnant of the screw in the hole and a new screw fixed. In the titanium group there were 4 cases in which screws during tightening became loose and emergency screws had to be used.

The average operative time with the resorbable system was longer than the titanium system by 25 min (Table 1). The cases were postoperatively reviewed clinically and radiologically after 3, 6 and 12 months. All cases showed adequate reduction of fracture segments and good healing. Post operative radiographs revealed only signs of the screw holes in the resorbable group that disappeared at the end of 6 months.

In 3 patients treated with titanium plates, there was dehiscence of the plate from the zygomatic buttress region that resolved with constant irrigation and dressing of the site uneventfully.

In all 40 cases, the signs and symptoms disappeared after surgery. Infra orbital paraesthesia/anaesthesia persisted in 3 patients of the resorbable group for 3 months and in 2 patients of the titanium group for about 10 weeks post operatively.

Discussion

The management of maxillofacial fractures aims to achieve a final function and structure that mimics the prefracture situation. The lack of rigidity and directional control in wire osteosynthesis led to its replacement by RIF. The

Table 1 Perioperative handling of systems

System	Titanium	Resorbable
Working time	1 hr 15 Min	1 hr 40 Min
Contourability	Good	Good
Adaptability	Satisfactory	Good
Reduction	Good	Good
Screw fixation	Good	Good
Operative complications	Loose screw	Screw breakage

Fig. 3 Resorbable plate fixation at frontozygomatic region

Fig. 4 Resorbable plate fixation at zygomatic buttress

concept of RIF transformed maxillofacial fracture management culminating in the advent of monocortical miniplates.

An ideal implant in the treatment of facial fractures must have adequate strength and versatility. It should be non-toxic to allow bony healing, not interfere with imaging, function while the bone heals, and resorb once the task has been accomplished [2]. In the past biomaterials used in fixation techniques were of a transient nature, with the hardware removal being undertaken within a short interval after completion of healing. Improvement in material sciences has led to the use of materials that have excellent characteristics of biocompatibility and can be left in situ indefinitely.

The three basic classes of biomaterials used are metals, ceramics and polymers. RIF to date have relied on metallic components exclusively due to their high strength and contourability. The excellent properties of corrosion resistance, biocompatibility and osseointegration led to the

acceptance of titanium as the metal of choice in all internal devices in contemporary maxillofacial surgery.

One of the biggest arguments against titanium has been 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 on the metal [3, 4]. There have also been reports of titanium deposits being seen in the adjacent lymph nodes [5–7].

Another aspect of metal RIF has been the effect on growth of the bone involved. The proponents of the resorbable system showed that the confining nature of metallic implants would affect growth of the bone concerned [8].

While this is theoretically possible, no evidence has been shown to substantiate the fact that there has been a recordable inhibition of growth in the bones of the maxillofacial region.

Another significant factor considered in cranial bones was the possibility of migration of the implant to the subcranial region as bone deposition occurs in the calvarium. This could result in the implant ending up adjoining the dura [9].

Among the other complications attributed to metal implants is the probable loosening or corrosion of the metallic implants leading to inflammatory reactions, visibility, palpability and cold sensitivity.

It is these facts that led to an interest in replacing metallic implants with a biomaterial that could provide stabilisation during healing and which would gradually disappear to allow normal growth and/or remodeling [10].

The advent of polymers in RIF was aimed at negating all these disadvantages—real or theoretical of metal implants. Resorbable polymers have been in vogue in biomedical application for decades in sutures. The materials included polyglycolic acid (Dexon) and a copolymer of Polyglycolic acid (92%) with Polylactic acid (8%) (Vicryl). The biggest advantage of these materials is their degradation completely in 12–24 months [11].

The resorbable system manufactured by a leading company from Germany that was used in this study 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 characteristics from Glycolide.

One fact that needs to be stated is that the disappearance of the resorbable implant is not always an uneventful process but may be accompanied by local fluid accumulation and sinus tract formation [12].

Since the success of an implant in fracture management hinges on the resistance to stress and stability provided during the healing phase, innumerable studies have compared these characteristics of titanium and resorbable system.

Most have shown comparable results, very similar to our study in terms of final results [13]. Wittwer reported that biodegradable materials and titanium fixation were not significantly different with respect to fracture healing and postoperative complications [14]. The limitations of the resorbable system in zygomatic complex fractures have been stated by Wittwer G et al. [15] wherein they saw insufficient fracture stabilization, especially at the infraorbital rim and the zygomaticomaxillary crest/anterior sinus wall resulting in a switch to titanium osteosynthesis. The biodegradable screw design is possibly too bulky for these particular bony structures. In contrast stability of mandibular angle fractures with titanium miniplates under simulated chewing forces was significantly higher than with the resorbable system in another study [16]. The titanium system also exhibited greater resistance to deformation from a vertical load than did the resorbable plate groups in the study by P Ricalde et al. [17].

A similar study in orthognathic surgery, however, showed a greater stability with titanium fixation. A greater degree of postoperative open bite and a trend toward relapse were observed in patients' cases in which an absorbable fixation plate was used [18]. Most of the surgeons preferring the resorbable system base their views on the premise that titanium implants need to be removed after the healing phase. This is a controversial opinion with a divided house. There is agreement that symptomatic plates should be removed, but there is no consensus among maxillofacial surgeons on the need for routine removal of asymptomatic plates [19]. Some authors recommend routine removal of the implants [20, 21]. Others recommend retention unless clinically indicated for removal [22, 23].

The consensus statement issued at the end of the 3rd Strasbourg Osteosynthesis Group meeting at Volendam, the Netherlands in Nov. 1991 states that the removal of a nonfunctioning plate is desirable 'provided that the procedure does not cause undue risk to the patient.

Ward Booth P [24] has assessed the risk factors in plate removal and surmised that for most patients there is less risk in leaving symptom-less plates in situ than removing them. Further evidence of the acceptability of titanium is provided by Haug RH, [25] who reported that there was no association between tumour formation or allergic reactions and commercially pure titanium.

In a long term study, Langford RJ and Frame JW found no evidence to support the routine removal of titanium miniplates due to corrosion up to 13 years after insertion [26]. Rosenberg A and co workers have also shown that the amount of titanium deposition from miniplates was small and pigmentation was asymptomatic. There was no relation between complications and pigmentation. It is their opinion that changes in soft tissues near titanium miniplates should not be interpreted as an indication to remove the plates.

Table 2 Cost of the accessories in Indian rupees for 2 point fixation in zygomatic complex fracture

S No	Item	Resorbable implants	Titanium German make
1	Water bath	116000.00	–
2	Screw driver	65800.00	3894.00
3	Bone tap	40100.00	–
4	Drill bit	3020.00	1106.00
5	4 hole plate	12100.00	900.00
6	6 mm screw	13400.00	1038.00

Their study included 1,247 plates in a 10 year period showing barely 3% rate of plate removal [27]. On the flip side the duration of implant fixation in the resorbable system was 25 min longer than the titanium system for each case due to the softening process, adaptation of the plate and the use of the bone tap before screw insertion. The cost factor was very significant in the comparative study. The cost of the resorbable screw was 13 times costlier, resorbable plate was 11 times costlier and the drill bit 3 times costlier than the titanium implants (Table 2). The added expense for the non expendable accessories would substantially add to the cost of the treatment.

Conclusion

The rigid fixation of bones in fractures requires ideal properties for these implant materials.

Polymer based resorbable system has been found to have properties simulating the titanium system in most occasions where tension forces were not a factor determining 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.

In view of these findings, it would not be justified to routinely use the resorbable system in maxillofacial fracture management. The resorbable system should ideally be restricted to pediatric craniofacial surgery.

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Conflict of interest None.

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