

“Evaluation of Mandibular Bone Segment Changes with Functional Loading After Fixation of Symphysis And Parasymphysis Fracture Using Bioresorbable Bone Plates”

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Abstract: The primary goal of fracture management is restoration of healing of the fractured bone, resulting in restoration of form and function. Even though titanium plating system is well established in treatment for mandibular fracture there are certain inherent disadvantages. In order to overcome these drawbacks Resorbable polymers were evolved for usage in Rigid Internal Fixation. Resorbable materials have been used as fixation materials in craniomaxillofacial surgery and orthognathic surgery. In contrast to titanium plating systems, resorbable plating systems have not been used on larger scale for the fixation of mandibular fractures.

Objectives : This study aims to access the efficacy, stability and rigidity of bioresorbable poly-L-lactide (PLLA) system for mandibular symphysis and parasymphysis fracture osteosynthesis.

To evaluate the displacement occurring in the mandibular bony segments with functional loading after fixation.

To evaluate and compare the complications associated with the use of bioresorbable miniplates and titanium plating system.

Study Design : This in VIVO study was carried out on 15 adult patients with isolated undisplaced anterior mandibular symphysis and parasymphyseal fractures, which were treated by means of open reduction and internal fixation using bioresorbable plates and screws.

Material And Methods: The present study used bioresorbable polyL lactic acid (PLLA) plating system to treat mandibular fractures. These plates were assessed for efficacy and interfragmentary displacement by subjecting them to functional loading following bone segments fixation using gnathodyanometer followed by 3D CT aid over a period of 1- 2 year.

Result And Conclusion: The stability of the resorbable fixation was found to be comparable to metallic fixation though the armamentarium and procedure of fixation of resorbable system was more demanding and technique sensitive. The resorbable system is good system for rigid internal fixation in specific conditions where muscular and stress forces are not a demanding factor in fracture fragment displacement.

Keywords: Symphysis and parasymphysis fractures, Undisplaced, Isolated, Bioresorbable plates, bite force, 3D CT

I. Introduction

Mandibular fractures are among the most common injuries to the facial skeleton. The primary goal of management in such cases is the realignment of fracture segments and restoration of which aids healing of fractured segments. Multiple surgical modalities have been devised over time. These include treatment by closed reduction with maxillomandibular fixation, open reduction with non-rigid fixation , and open reduction with rigid internal fixation. All of these modalities carry certain advantages and disadvantages .Titanium plates have been used for over two decades to achieve internal rigid fixation of mandibular fractures because of their bio—inert behaviour , unmatched strength , ease of application and less frequency of reported complications . Titanium plates may however, require removal in circumstances like growing patients associated infection or on patient preference etc ¹⁰. With the introduction of biodegradable materials in the field of medicine, a new treatment modality was introduced as a substitute for titanium plates. These plates are available in different materials like polyglycolic acid or poly-lactic acid, with varying properties . They have less strength as comparable to metallic plates but provide a major advantage ; they get resorbed approximately in a year ^{11,12}. This gives an advantage over conventional metal plate; they do not require subsequent removal and thus a secondary surgery is avoided.¹³ Although restorable plates for rigid craniomaxillofacial fixation were introduced couple of decades ago, they are still not used on a large scale. They can be ideal for young patients in which growth is occurring at a fast pace as metallic plates are thought to restrict the growth.

The aim of this study is to assess the efficacy, stability and rigidity of bioresorbable poly-L-lactide (PLLA) system for mandibular symphysis and parasymphysis fracture osteosynthesis.

Aims And Objectives

- To assess the efficacy of bioresorbable plates for the treatment of fracture of mandibular symphysis and parasymphysis
- To evaluate the displacement occurring in the mandibular bony segment with functional loading after fixation.
- To evaluate and compare the complications associated with the use of bioresorbable mini plates and titanium plating system.

II. Material And Methods

The bio-degradable materials used nowadays for fracture fixation are high molecular weight polymers. The bio-degradable material used in present study is poly-L-lactic acid (PLLA). It has ideal strength properties for internal fixation of fracture (bending strength, is upto 240Mpa). This is hydrophobic, highly crystalline, resorption time is long, and during degradation it forms crystals which take considerable time to resorb⁹. The other bioresorbable materials are polydioxanone (PDS), polylactic acid (PLA), polyglycolic acid (PGA) etc. These planting materials are well tolerated by living tissues; mild inflammatory reactions are seen around the implants. Local swelling, sinus formation have been reported in human beings².

This prospective in vivo study was conducted in department of oral and maxillofacial surgery at H.K.E'S S Nijalingappa Institute of dental sciences and research, Gulbarga between the period of 2012-2014. Fifteen patients who had isolated symphysis and parasymphysis fracture, were treated by open reduction and plate fixation using resorbable plating system.

The criteria governing the selection were as follows

Inclusion criteria

1. Adult patients with isolated fracture of symphysis and parasymphysis region of the mandible.
2. Patient should be available for periodic review.
3. Fracture without or with minimal displacement indicated for open reduction and internal plate fixation

Exclusion criteria

1. Malunited cases
2. Patient with bone loss and those with pathologic abnormalities of bone
3. Multiple fracture of body, condyle and angle of mandible.

III. Study Design

Fifteen patients who fulfilled the above criteria were selected for the study. A standard proforma was used to collect necessary information regarding each case. Pre-operative assessment with photographs and 3D CT. Reconstructive view with detailed case history was recorded in all the cases. Preoperative and post operative photographic and radiographic investigations (3D CT Skull Reconstructive view) were taken in all the cases. Complete case history was taken, neurological evaluation was done to rule out head injury and cervical spine injury especially fresh cases reporting immediately after trauma. General physical examination was done to ascertain the absence of any associated injury to the abdomen, genitourinary tract or long bones. General physical examination was done to ascertain the absence of any associated injury to the thorax; abdomen; genitourinary tract or long bones. Local examination was carried out to check for the presence of following variables such as edema, hematoma, infection, tenderness, trismus, step deformity and paresthesia. All standard investigations required for general anesthesia were carried out.

IV. Surgical Protocol

The patient was taken to operation theatre and was scrubbed and draped as per routine. Surgical approach for all the fractures was through intraoral approach. First the site was cleaned using 5% betadine solution and then infiltrated with 2% xylocaine with 1:80000 adrenaline. Erich's arch bar is placed mandatorily in all cases. The lip was then retracted and an incision was taken beginning on the vestibule area, 5mm from the junction of the attached mucosa. The mucoperiosteal flap was then raised with the periosteal elevator and the fracture site was exposed. The segments were manipulated and satisfactorily reduced, occlusion was established and IMF was done. The biodegradable plates are activated by immersion in a thermostat at 55 degree and can be moulded easily to the desired shape. The biodegradable plates were adapted and held with plate holding forceps to make bur holes for the screws. The fractured fragments were then fixed using 4-holed biodegradable mini plates by cortical screws of 9mm and 11mm were used. Care was taken to avoid the roots of the teeth, mental nerve and the inferior alveolar nerve.

Once adequate fixation was achieved, the area was irrigated with betadine and saline and after adequate hemostasis the wound was closed with 3-0 vicryl adhesive pressure bandage was given extraorally and intermaxillary fixation was done. IMF was released on the 5-7 days postoperatively. Bite force was applied at 3D CT was taken to check displacement of fractured segments following which IMF was redone for a duration of 2 weeks. Patients were followed and observed for displacement on 14 and 21 days postoperatively as well for complications such as soft tissue infection, plate dehiscence, non union or malunion of fractures, osteomyelitis, malocclusion, dental injury and iatrogenic nerve injury

V. Results

The sample comprised of 15 adult male patients. The average age of sample was 20-40 years with the minimum of 27 years and maximum of 48 years sustaining simple isolated linear undisplaced symphysis and parasymphysis fracture. Of total sample 80% of patients gave a history of RTA and the remaining 20% gave history of self fall. 10 out of 15 patients were reported with right (6) and left (4) parasymphysis fracture and the remaining sustained symphysis fracture. In all 15 (100%) cases PRE OP 3D CT were done and fracture type in all the cases were UNDISPLACED. The entire sample was presented with soft tissue injury, edema, trismus where as infection, parasthesia and step deformity were absent in all. The normal surgical approach for all the 15 (100%) cases is intraoral. In all cases, the self reinforced fixation system was used and it provided satisfactory stability to enable bone healing during the initial phase. The average BITE FORCE measured in all 15 cases on the 3rd postoperative day is 56.13 ± 17.16 N, this was found to increase in the further follow up. The postoperative follow up was not endangered by displacement, infection, exposition of implant material, diastasis, or non union there by suggestive of healing being uneventful in all patients. During the follow up, no evidence of malocclusion or growth restrictions was observed.

VI. Discussion

The aim of the fracture treatment is to obtain a final function that is as close to the pre function situation as possible. Prior to the introduction of rigid internal fixation (RIF), stainless steel wires were used to fix the fracture segment. The disadvantage of which was that it was not rigid and a 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 which culminated in RIF devices like plates and screws. The concept of RIF of maxillofacial fractures lead to the development of monocortical miniplates osteosynthesis.

Metal plate-screw systems are fixation materials that have been used for the long time commonly in plastic and orthopedic surgery. Metal plate screw system enable adequate fixation in the bone healing process. However titanium plating has some disadvantages, including palpability, thermal sensitivity, image interference, transcranial migration in pediatric cases, growth inhibition when laced across growth sutures and the need for secondary hardware removal surgery, this led to the evolution of resorbable plating system which in contrast do not have to be removed.

Biodegradable osteosynthesis material are known for their advantage over metal osteosynthesis due to their disappearance over time, which obviates any desire for implant removal and minimize the risk of complications for remaining hardware. In a study conducted by Moberg et al where the occurrence of corrosion with the use of metallic implants to stabilize jaw fracture were studied. It was found that cobalt, chromium, nickel, molybdenum, aluminium and titanium were found in the hard and/or soft tissue near the implants in higher concentrations. This type of metal release from plates can be avoided with biodegradable implant systems and used in jaw fracture management, recent reports on the use of BioSorbFXs for elective surgery such as for mandibular and maxillary osteotomies and cranioplasties (Haers and Sailer, 1998⁸; Haers et al., 1998; Serlo et al., 2000 and 2001; Turvey et al., 2002) have been promising reports with the follow up time well beyond the biodegradation period (Suuronen et al., 1999 and 2000; Laine et al., 2004) showed excellent long term results. In 2002, Yerit et al. (2002) and Kim and Kim (2002) reported excellent result with BioSorbFXs plates and screws for fixation of mandibular fracture in 22 and 49 patients respectively. Their findings were encouraging for the use of this material in our study.

In this study KLS MARTIN Resorb X plates and screws were used in the treatment of undisplaced fractures of the mandibular symphysis and parasymphysis. Before being used, a plate is softened in a water bath and then it is contoured to the desired shape of the site where it is inserted; which makes the adaptation of biodegradable self reinforced plates uncomplicated as compared to metallic system. We used 2mm resorbable plates and screws and found to be successful without any case of plate exposure, in contrast to a study conducted by Wood G D who used 2.5mm plate and noted plate exposure in 28% of cases. There was no clinical evidence of implant related inflammatory reactions. This can be compared to the findings of Cutright D E et al⁴, Boss R. R. M et al⁵, Cordewener et al, Enislidis et al, Haers P.E et al, Thoma K et al, Al-Sukhun J et al, Bell et al, Wittwer G et al)

Bite force can be defined as the forces applied by the masticatory muscles in dental occlusion. Bite force is one indicator of the functional state of the masticatory system that results from the action of elevator muscles modified by the craniomandibular biomechanics. Most widely accepted recording device is strain gauge force transducer. So in this study we have used strain gauge device to measure the bite force. Strain gauges are simple and accurate readings can be recorded than other extensive equipments like pressure sensitive devices. It has been shown in many studies that the bite force remains significantly less in the fractured site than those observed in non injured individuals even after 4 weeks following surgery. The reason for this reduced bite force values observed is because of pain, protective mechanism known as muscle splinting that occurs following fractures of bones. Neuromuscular adaptation is considered to be the most important contributing factor for the observed reduction in bite forces.

The bite forces recorded in this study unilaterally ranges from 30N to 120N. the average BITE FORCE in all 15 cases on 5-7th post operative day is 56.13 ± 17.16 , this is found to increase in the further follow up. Similar to the results attained in a study done by K.L. Gerlach⁷ who obtained 31% at the end of 1st post operative week. Following which 3D CT was taken to check for displacement. In the previous studies clinical evaluation was used to check displacement there by not giving any accurate result as the technique was more vague and unpredictable unlike the bite force which gives more precise results. Hence being first of its kind as no literature exists which states the usage of bite force to measure post operative displacement of bioresorbable plating system.

In our study, post operatively occlusion was stable in all cases with 3 to 6 months of follow up. The skeletal stability was adequate in all our cases which correlates with the study done by Yeri et al, author who treated 22 mandibular fractures and found that, the treatment goals of immobilization, fixation and stabilization were fulfilled. The skeletal study was comparable with actual standards and sufficient for the time needed for mandibular healing. There by we conclude that biodegradable SR-PLLA implants have the potential for the successful use in the fixation of mandibular fractures.

VII. Conclusion

The mechanical properties of the PLLA plates and screws applied for undisplaced symphysis and parasymphysis fracture fixation are comparable with those of metal fixation systems. The treatment goal of immobilization, fixation, and stabilization were found to be fulfilled. A total of 15 patients had sustained simple isolated undisplaced linear symphysis and parasymphysis fracture which was treated with bioresorbable plates. The in-vivo performance of these plates was then confirmed by checking for any displacement on 3D CT by subjecting the patient to bite force post operatively, as bite force and 3D CT scan are reliable measures to assess the displacement and level of rigidity achieved after fixation in mandibular fractures specially when the displacement is clinically not evident.

By this study we have made an attempt that the resorbable plating system have the potential for successful usage in mandibular fracture, as no much literature exists regarding the usage of these plates in mandibular fracture. Finally we can conclude that the bioresorbable plates can be used in simple mandibular fracture with interfragmentary contact, with the similar duration of MMF as that needed for metal osteosynthesis. Hence confirming the potential for its successful use in simple linear undisplaced symphysis and parasymphysis fracture.

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