

## Bio-degradable osteosynthesis system in treatment of mandibular parasymphysis fractures

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**Abstract:** *Background:* Rigid internal fixation using metal compression plates, miniplates, micro plates etc are established system in treatment of facio-maxillary trauma. Most of the time results are satisfactory and are in vague. Until recently, unfortunately these well established treatments have certain inherent disadvantages like foreign body sensation, tissue reaction, secondary infection, galvanic current reaction etc. Bio-resorbable plating system has been used in the present study in selected patients and results have found to offer better advantages than routine metal plates. *Objective:* This study aims to demonstrate the biocompatibility and benefits of bioresorbable plating system with surrounding soft tissue and bone. *Methods:* The present study uses bioresorbable polyL lactic acid (PLLA) plating system to treat the mandibular fractures. These plates were assessed for biodegradability using ultrasonographic aid for period of 1 year. *Results and Conclusion:* We found at end of 1 year thickness of plate changed markedly with decrease in size of plates and screws with fading of bur holes. Hence these materials are satisfactory in treatment of maxillofacial fractures offering better advantage than conventional metal plating system

**Keywords:** Maxillofacial trauma, Mandibular fractures, Bioresorbable plates, Ultrasonography

### Introduction

Internal fixation of maxillofacial fracture is indicated after open reduction. Since 1970 fixation devices have developed to achieve adequate strength, rigidity as well as biocompatibility with satisfactory bone healing at fracture site. Titanium bone plates are currently used extensively for fixation of facial fractures in form of compression plates, micro plates and miniplates and these several disadvantages persists including palpability, hardware loosening, temperature sensitivity, fretting corrosion, interference with radiographic imaging and subsequently need for a second surgery for removal of implant.

In order to overcome some of the problems a new class of materials namely bioresorbable polymers have been developed for the use in internal fixation of maxillofacial injuries. These materials are in use since early eighties as the fields of bio-resorbable materials have matured, many devices have become available to maxillofacial surgeon including pin, suture materials, plates etc. These

materials undergo resorption, thereby achieving the advantage of titanium fixation without the associated long term problems. These bio-resorbable polymer plates have been chosen to treat selected number of patients with vertical undisplaced fractures of mandible in the parasymphysis region and evaluated our own observations regarding biodegradability of plates and screws by ultrasonographic aid.

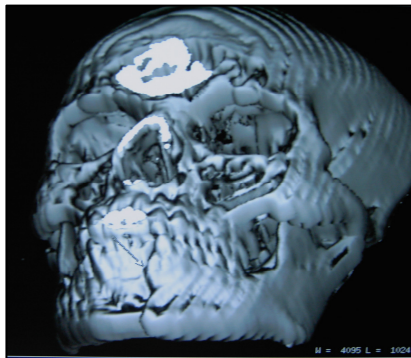
### Aims and objective:

1. The purpose of the present study is to highlight the possible benefits of bio-resorbable plate and screw fixation system in mandibular parasymphysis fracture.
2. To demonstrate biocompatibility of bio-resorbable plating system with surrounding soft tissue and bone.
3. The purpose of this study is also to investigate the use of ultrasound for detection and monitoring the degradation process of bio-resorbable plating system for period of twelve months.

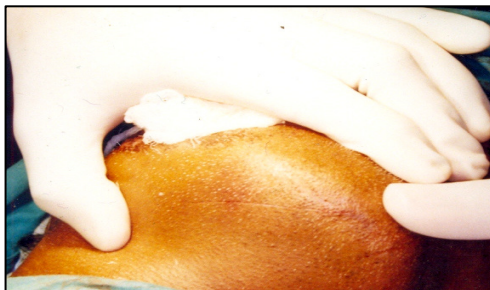
**Material and Methods**

The bio-degradable materials used nowadays for fracture fixation are high molecules weight polymers. The bio-degradable material used in the present study is the poly-L lactic acid (PLLA). It has ideal strength properties for internal fixation of fracture (bending strength, is up to 240 mega Pascal). This is hydrophobic, highly crystalline, resorption time is long, and during degradation it forms crystals which take considerable time to resorb [1]. The other bio-resorbable materials are polydioxanone (PDS), poly lactic acid (PLA), poly glycolic acid (PGA) etc. These plating materials are well tolerated by living tissue; mild inflammatory reactions are seen around the implants. Local swelling, sinus formation have been reported in human beings [2].

Ten patients reporting to department of oral and maxillofacial surgery requiring open reduction and internal fixation were selected. A four holed plate with 2.5 mm of thickness were used for fracture reduction. The vertical fracture in the body of mandible at parasymphysis region, single, comminuted, compound fractures was selected in patient age ranging from 20-45 years. (Fig -1)

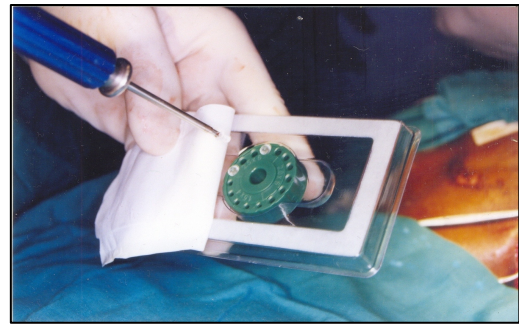


**Fig-1:** CT scan 3D reconstruction images of fracture parasymphysis of the mandible

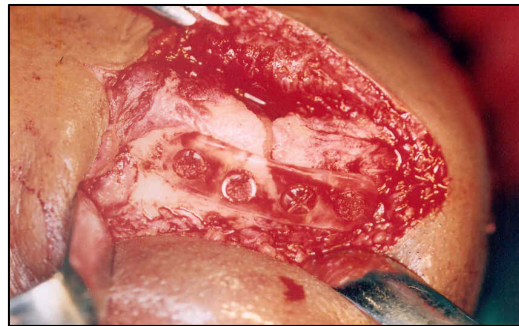


**Fig-2:** Submandibular incision

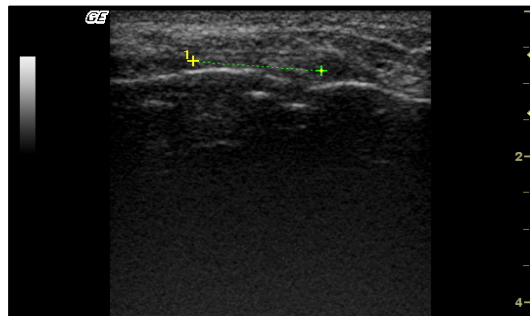
Risdon’s incision (submandibular incision) (Fig- 2) was taken for all the patient to expose the fracture site followed by 8mm screw application on 4 holed extended miniplate. (Fig -3, Fig- 4) Post operative healing and fracture stability was achieved in the entire patients except in one case where the implant related fluctuant swelling was seen at end of 4 months. Later swelling was subsided by antibiotic regimen, healing of bone was undisturbed. Ultrasound with 5 MHz linear probe was used at implanted site of plate fixation at interval of 2 month 4 month 8 month and 12month to assess the bio-degradability.



**Fig-3:** Loading of the screw before application

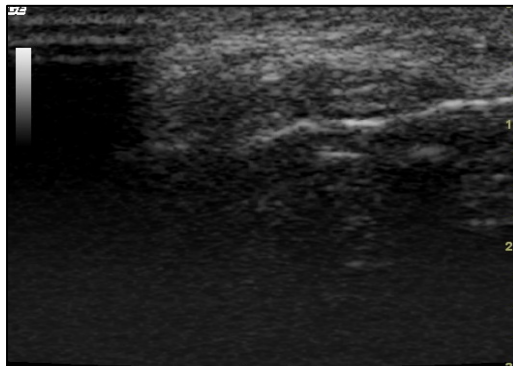


**Fig-4:** Adaptation of 4 holed miniplates at fractured site



**Fig-5:** USG views of plates and screws in mandibular parasymphysis region after two months of insertion

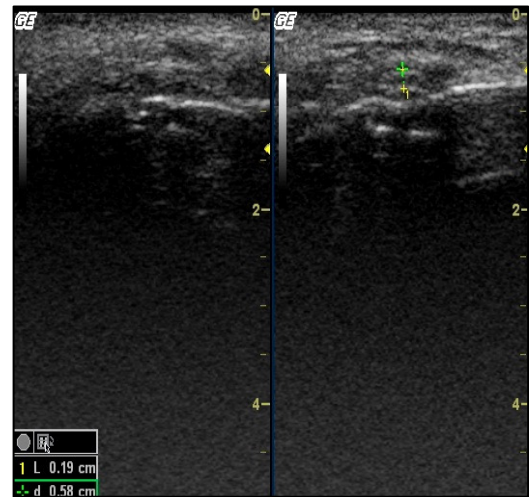
At the end of 2 months (Fig-5) no significant ultrasonographic feature were noted. At the end of 4 months (Fig-6) ultrasonographically outer border of plate was precisely limited as a hyperechoic periphery in comparison to hypoechoic centre. No change in the diameter of bur holes in bone was seen, echoes were much appreciable at this stage. No implant related infection, swelling seen. Degradation started with water in take, producing increase in the distance between the hyperechoic outer borders with breaking in the lines, further at the end of 8 months (Fig-7) maximum of volume was reached, and hypoechoic structure was seen at the site of the plate. Bur holes were fading, plates and screws appeared less echoic compared to the fourth month scan. Healing of the bone was satisfactory at this period with out any complications. At the end of 1 year length (Fig-8) thickness of plate changed markedly with decrease in the size of plate, screws and bur holes and region appeared less echoic.



**Fig-6:** USG views of plates and screws in mandibular parasymphysis region after four months of insertion



**Fig-7:** USG views of plates and screws in mandibular parasymphysis region after eight months of insertion



**Fig-8:** USG views of plates and screws in mandibular parasymphysis region after twelve months of insertion

### Results and Discussion

Treatment methods in maxillofacial fracture have evolved over centuries. Bridle wires, gold wires, splints, head cap, arch bars, head frames etc have been tried and used. The treatment of maxillofacial fracture took the greatest step ahead in middle of 20<sup>th</sup> century with advent of plates and screws [3]. Advantage with these plates and screws are easy to use, allow precise anatomic repositioning, less relapse and in case of mandibular fracture with rigid internal fixation there is no need for maxillomandibular fixation, allowing early return to masticatory function. Stainless steel plates was one of earliest materials used which is resistant to corrosion, but it does corrode and may cause hypersensitivity in patients known to be sensitive to any of its components [3].

Vitallium, titanium evolved later which also showed the corrosion product in distant organs like lungs, liver etc [4]. They also produced star burst or streak artifacts on standard CT scan [5]. To overcome these problems search for better alternative was ignited by the pioneering work by Kulkarni R.K. et al [6]. They studied the synthesis, characterization, tissue reactivity and in vivo degradation of polylactic acid and found no inflammatory reaction to tissue implant. The material was slow degrading and eliminated possibly by carbon dioxide through the

respiration. This study spurred the interest in using biodegradable materials in the maxillofacial surgical field [6].

In the present study biodegradable plates used for treatment of mandibular symphysis fractures were 4 holed 2.5 mm plates for all cases to ensure uniform results. Only parasymphysis fracture were treated and fractures at other sites of the body of mandible were not treated due to fact that interfragmentary contacts plays an important role during the post-operative stability [7] and hence these fractures were a contraindication for resorbable plates. The undisplaced favorable fractures at the parasymphysis region were plated with resorbable 2.5mm plates and screws. Healing was uneventful in all cases throughout the follow up period of 1 year, in only one case swelling around plate after 6 months was noted which was relieved by antibiotics and anti-inflammatory drugs. Swelling may be explained by a combination of factors such as disintegration of PLLA into small particles on increased osmotic pressure caused by these fragments and low mechanical resistance against pressure of subcutaneous tissue compared with bone which leads to noticeable swelling [8]. In the present study, screws breakage and distortion of screw head was noted, similar to findings noted by many authors [9]. When screw breakage occurred there was no need to relocate the plates to second position, as is the case with broken metal screw, instead holes are drilled through the broken screw itself [9]. Bahr W [10] showed by light microscopy that highest mechanical stress was at transition from screw head to screw shaft, there by making it weaker part of screw. Tendency to tighten a 'A little more' to ensure stable fixation may place these screws closer to failure range and in advertent application of excessive torque can

lead to shearing off of the screw head [11]. These however occurred in our initial cases probably due to the complexity of handling the material and initial learning curve required as material is highly technique sensitive [12]. No such complications occurred during later cases because the material is highly technique sensitive and with practice placement of plates and screws became easier and quicker reducing the operating time.

As these plates are not radiopaque the disappearance of the plates cannot be verified radio-graphically, hence disappearance of bur holes and assessment of degradation by ultrasonography may be taken as an indication of total degradation of plates. It is observed from the present study that bio-resorbable system proved efficient and ideal in treating the maxillofacial fractures.

### Conclusion

With the advent of biodegradable plating system it is hoped that one day it will eventually replace conventional metal plates and screws. Hence we would say that these materials are satisfactory in treatment of maxillofacial fractures offering better advantage, however proper case selection is essential criteria to make these plates successful. Once the cost factor of bioresorbable plating system is taken care these will become useful over the metal plating system. Ultrasonographic aid has proved an essential diagnostic aid in assessing the biodegradation process of plates and screws in mandibular fracture over a period of 1 year in the present study.

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