Setbacks of Bio-Resorbable Plates and Screws in the Management of Condylar Fractures: Our Experience

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Abstract

Purpose Fractures of the condyle can be managed by open or by closed reduction. This study was designed to mention the complications of the bio-resorbable material we had experienced while using them in the management of condylar fractures.

Methods Fifteen (11 men and four women) patients with subcondylar fractures were included in the study. Resorbable poly-L-lactide plates and screws were used for the fracture fixation. Patients were followed up clinically and radiographically for a period of 2 years.

Results Seven patients had a satisfactory reduction following the placement of bio-resorbable plates. Three patients had developed a swelling in the pre-auricular region, extending till the angle. Two patients had a screw breakage whereby leading to malunion and three other patients had bone resorption, at the fractured site that was appreciated radiographically.

Conclusion In spite of the advantages of these materials, certain complications have been experienced in our study with regard to the resorption and degradation of the material which has been mentioned and explained in our article.

Keywords Condylar fractures · Bio-resorbable plates and screws · Poly-L-lactide · Retromandibular approach

Introduction

The incidence of condylar fractures amongst all the mandibular fractures is as high as 25–35%. Out of which 50% are condylar fractures and are associated with other mandibular fractures [1, 2]. Condylar fractures can be managed by open or closed method, depending on characteristics of the fracture pattern and the dislocation of the condylar head [3, 4]. Experience has shown that the open reduction and the internal fixation allow a good anatomic repositioning of the fractured fragments of condyle thereby restoring early function [4, 5]. Numerous techniques including the use of Kirschner wires, lag screws and mini plates have been described [4, 6]. Metal plates and screws are frequently used in the field of oral and maxillofacial surgery. Despite good fracture reduction and healing, atrophy that is caused because of the metallic components necessitates a second surgery to remove the metallic implants [4, 7]. Considerable progress has been made in the development of bio-degradable fixation devices both in the field of maxillofacial surgery, [7, 8] and orthopedics for the last 10 years. The three most commonly used materials are polyglycolide (PGA), polylactide (PLA) [7, 8] and polydioxone (PDX). Use of these materials started with sutures, but now has progressed to biodegradable pins, plates,

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screws, tacks and membranes [8]. Use of these biodegradable devices could eventually obviate the necessity and cost of the second surgery for the removal of the internal fixation material. In our cases we have used resorbable Poly-L-lactide plates and screws for the fixation of mandibular condylar fractures.

Materials and Methods

Fifteen patients (11 men and 4 women) with age ranging from 20 to 29 years were treated for left (nine patients) and right sub-condylar fractures (six patients). Open reduction and internal fixation of the sub-condylar fractures with the other concomitant fractures were carried out under G.A. Rigid fixation was carried out using bioresorbable 2.5 mm, four holed plate with gap and 8 mm screws Inion CPS system, Tamepre, Finland. The resorbable plates and screws that were used consisted of an amorphous injection molded co-polymer of L-lactide/D-lactide/trimethylene carbonate. Retromandibular approach was used in all the cases. These plates were placed in a water bath at 55°C for 1–2 min following which plating was carried out at the fractured site. Post-operatively, intermaxillary fixation was considered for the first 2 weeks. Patients were advised to take soft and liquid diet after the removal of IMF for about 2 months. Post-operatively patients were evaluated for a period of 24 months with a regular periodic follow up of 15 days, 1, 3, 6, 12, 18, and 24 months. Pre-operatively and post-operatively, the patients were evaluated clinically and radiographically. Post-operative complications like marginal mandibular weakness, sialoceles related to the surgical site, foreign body reaction, condylar exarticulation, malocclusion, mouth opening, loss of fixation due to plate fractures and screw loosening and restricted mandible movements that were related to the fracture reduction and fixation were evaluated.

Results

Seven patients had satisfactory healing of the fractured segments by the end of 24 months, with no deviation of mandible and 38–40 mm of mouth opening. Six patients had a mouth opening of 30–35 mm. Complications that occurred post-operatively were screw breakage (Photograph 1) in two patients that resulted in malunion of fractured segments (Photograph 2, 3) that was recorded in sixth month of post-operative follow up period, thus resulting in mal-occlusion in terms of crossbite on the ipsilateral side in two patients. Bone resorption around the screw holes was evident radiologically in three patients (Photograph 3). Three patients had developed a swelling at the end of

Photograph 1 Screw breakage

Photograph 2 Mal-union of fractured segment

1 year and the other two patients after 2 years post-operatively (Photograph 4) (Table 1). The swellings were seen predominantly in the preauricular and over the angle region of the mandible. All the three patients had similar clinical findings.

Photograph 3 Bone resorption around the screw holes

The inspectory findings revealed a well defined swelling restricted to the site of implantation and was accompanied with limited mouth opening. The overlying skin was erythematous, with no discharge evident. Palpatory findings revealed that the swelling was soft to firm in consistency and tender with increase in local temperature.

Ultrasonography revealed a well defined partially organizing abscess of 4.2×3.5 cm, (Photograph 5) that was seen predominantly over the angle region with 30 ml of collection approximately. The lesion was extending along the ramus and inferiorly to the body of mandible. Surgical exploration and biopsy in one patient revealed a chronic granulomatous tissue eliciting a foreign body reaction. Only a few polymorphonuclear leukocytes were present, mostly located in the peripheral part of the mass, remnants of PLLA material was found in the specimen. The PLLA material was also seen in the extracellular spaces between the collagen fibers.

Discussion

In condylar fractures, the fractures above the insertion of the lateral pterygoid into the neck will cause little displacement of condylar head due to lack of muscle pull, but

Photograph 4 Swelling

Table 1 Post-operative complications

S.No	Complication	Number of patients
1	Screw breakage	2
2	Malunion of fractured segments and malocclusion	3
3	Bone resorption around the screw holes	3
4	Swelling in the pre-auricular and ramal region	2

fracture below the muscle insertion will lead to the displacement of the condylar head medially and forward [9]. Management of the condylar fractures has been controversial. But as proved in previous studies, the problems resulting from treatment by closed reduction are not only early dysfunction but also the arthritic changes that can occur 10–15 years following the closed reduction [10–12]. Moreover it was found that bioresorbable osteosynthesis is capable of withstanding the masticatory loads that is 1.5 times the amount of the load measured at the operated site, which leads to the confusion that they do withstand the forces of mastication and provide adequate fixation that needs to be achieved. Moreover, bending modulus of the PLLA plate being (5 GPA) and Champy plate (5–7 GPA) that were found to be close to each other signifying that PLLA plates have appropriate stiffness to reduce the risk of displacement at the fractured site [13–17]. The initial tensile strength is 452.0 ± 7.8 N of the Inion CPS 2.5, four holed plate, as reported by the manufacturer. These plates

Photograph 5 Ultrasonography

are easily adaptable along the contour of the bone. They can rotate around the central axis. Resorbable plates undergo a phase of degradation process. After implantation, there is an inflammatory response by the body leading to hydrolytic degradation that causes overall reduction of the molecular weight and eventual loss of strength of the implant. As this process continues the macrophages phagocytose the fragments and the implant loses its mass. The rate of resorption is approximately $5.3 \mu\text{m}$ per day. Thus a resorbable implant loses its mechanical strength long before the clinically observed reduction of the implant mass [13, 14].

The tensile strength of this plate material is $452 \pm 7.8 \text{ N}$, which is much lower than the loading force of $135\text{--}300 \text{ N/mm}^2$ and maximum torsional forces of 920 N/mm^2 . Initial immobilization of 14 days is necessary to avoid the excessive loading on the plate. Due to the high value of impact resilience (47 kg/m^2) of the material and its microporosities allows the osteosynthesis area to absorb considerable energy when exposed to dynamic stresses in the body [14–17] resulting in decrease of strength in the load bearing of the osteosynthesis area of the healing fractures segment and henceforth all our patients were placed on IMF for a period of 15 days in the immediate post-operative period.

These plates have been reported to resorb slowly, maintaining 70% of their initial strength at 9–14 weeks, with 42% bulk resorption by 40 weeks and are completely resorbed by 2–5 years. The mechanism of resorption is by

hydrolysis and product formed is taken up by macrophages and finally eliminated through Krebs's cycle. PGA is rapidly resorbed, while PLA is hydrophobic and can take up to 5 years to disappear completely. It contains polylactic acid in its L-isomer form (PLLA) which forms degradation resistant crystals and PGA, which absorbs very quickly due to the microporosities of the material, (50–100 nm) leading to hydrolysis at a greater surface resulting in rapid degradation of the material. Thus, these plates lose their strength in 1 month, leading to an inflammatory reaction, sterile abscess formation which increases the osmotic pressure in the sub-cutaneous tissues and subsequent development of the fibrous tissue. It was also proved in one of the studies that the combination of change in quality, degradation characteristics, associated morphological alterations of the implanted material and the characteristics of the tissue in which the material is implanted are responsible for the clinical reaction [4, 7, 8, 13, 14, 17–20]. As mentioned in the literature, we had experienced the same clinical presentation in two of our patients.

The strength of PLLA is $178 \pm 2 \text{ N}$ which is very low, compared to the stress on the plate and screws in the fractures site. This leads to screw loosening and resorption [21–25]. Another possible reason for resorption of screw holes may be due to the development of the osteolytic changes due to increased intraosseous pressure caused by liquid polymer debris of resorbable materials retained within the channel. So, minimum number of the screws must be used to minimize the breakdown product [4, 20, 22]. As mentioned in the literature we have experienced bone loss around the screws in three of our patients.

Intraoperative handling of bioresorbable plates and screws has shown that there have been two instances of breakage of the screws in the region of the head and shaft interface. This breakage could be due to the manufacturing weak spots within the screw dimension, as experienced by various authors [4, 14, 17, 19]. Screw breakage at the interface of head and shaft was seen in 2 of our patients (Photograph 1) that could either be attributed to the manufacturing defect or to the intra-operative handling of the plates and screws.

The usage of bioresorbable osteosynthesis is very technique sensitive and could lead to failure at screw bone interface due to improper handling. Overdrilling of the bone to a diameter not compatible with the screws or improper bone tapping when carried out would lead to decrease in screw stability. The repeated insertions of the drill or bone tap would lead to changes in the angulations of the drill and also disrupt the screw threads, eventually causing loosening of the screws.

Overheating of the drilling process needs to be avoided to minimize the bone destruction which could lead to osteonecrosis causing excessive screw resorption [25]. On

regular follow up in 10 of our cases, radiological evaluation revealed distinct radiolucent spots at the region of the screw placement. This visibility of drill holes would take a protracted period of time to disappear [4, 16, 18].

Conclusion

Biomaterials are being used with increased frequency of tissue substitution. The major barriers in the use of biomaterials are the possibility of bacterial adhesion to the biomaterials, that causes biomaterial centred infections' and lack of soft tissue integration or biocompatibility with biomaterial surfaces. When looking for suitable biomaterials one should critically evaluate the scientific papers regarding the use of the product. To conclude, the quantity, the degradation characteristics and associated changes in the morphology of the implanted materials as well as the characteristics of the tissue in which the materials are implanted, are the entities that might influence the nature of the adverse tissue reaction.

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