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Bio-Degradable Versus Titanium Fixation in Oral and Maxillofacial Surgeries-A Review Article

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Abstract:- Recent researches have recognised limitations of titanium plates and screws fixation post othognathic surgeries. Though widely used and considered as the 'gold standard' for rigid fixation; it has its own demerits like, interference with radiological investigations, barrier in growth and healing, secondary surgery for patient's need in removal of the plates and screws post healing. Although resorb able fixation systems appear advantageous over metal systems; its stability, biodegradation and foreign body reactions are a matter of concern and further investigation.

➢ *Purpose*:-
The purpose of this study was to determine whether bioresorbable fixation system is superior to titanium fixation system in orthognathic surgeries.

Keywords:- *Orthognathic surgery; Bioabsorbable plate; Biodegradation; Titanium plate; skeletal stability.*

I. INTRODUCTION

The field of oral and maxillofacial surgery has witnessed a remarkable evolution in terms of fixation and stability post-surgery in the last 2-3 centuries. From bandages to internal fixations, from implants to plating; the primary goal has always been restoration and healing of the fractured bone to provide stability, form, function and early mobilization post- surgery. Minimizing infection, malunion, soft tissue breakdown, and technical challenges should be included in the overall management of fractures. Most mandibular fractures have been treated by closed reduction with maxillomandibular fixation, open reduction with nonrigid fixation, and open reduction with rigid internal fixation [(1, 2, 3)].

The recent trends focus more on creating a fixation system which is stable, cheap, and durable and has no foreign body reactions. The invention of biodegradable fixation system is what can be termed as the Paradigm shift in the field of faciomaxillary surgery. Although, there have been many studies showing the success of biodegradable plates and screws in various other sites of the body (especially in pediatric patients where the anatomy is unfavourable); there use in maxillofacial region still remains controversial [(2)].

A rigid fixation system should be easy to place, does not require an extensive training protocol, should be of adequate strength, should not fracture and should be biocompatible.

Orthognathic surgery aims for predictable, fast, anatomical, safe and painless functional union of bones with efficient healing [(2, 3)]. Many researches and controversies have been done to find out the ideal material for osteosynthesis for undisturbed bone healing with minimal limitations. The ideal material should have a good load bearing and load sharing property, should be easy to manipulate and remove if necessary and should be cost effective [(1, 2, 3)].

In today's world bio degradeable fixation system is being used extensively in many fields such as, orthopaedics, reconstructive surgeries, neurology, gynaecology and cardiothoracic surgeries. They are favoured because of their compatibility with diagnostic aids and radiation therapies. There are no current evidences to establish the superiority of either fixation systems on a clinical and histopathological evaluation as an ideal material for osteo synthesis.

The biodegradable fixation system consists of an amorphous injection-molded copolymer of L-lactide/ D-lactide/trimethylene carbonate (Fig 1). The initial tensile strength is 452.0 +/-7.8 N). These plates resorb slowly, maintaining 70% of their initial strength at 9 to 14 weeks, with 42% bulk resorption by 40 weeks, and are completely resorbed by 2 to 4 years (in vitro data performed by Inion for the US Food and Drug Administration). The mechanism for resorption is hydrolysis. These plates can be bent to match the curve of the bone, but they cannot be bent to change vertical orientation, for example, to create a c-shaped arc from a straight plate. They can rotate around the central axis [(4)].

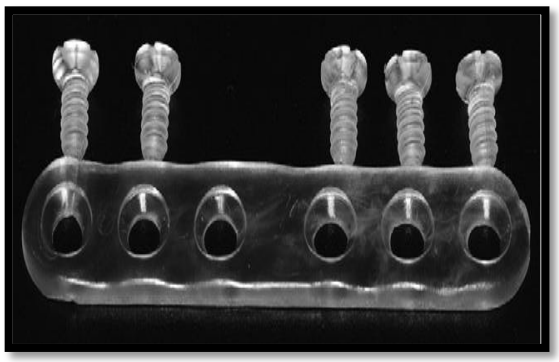

Fig 1:- A typical resorbable plate and resorbable screws used in this study.

Laughlin et al. Resorbable Plates for Mandibular Fractures. J Oral Maxillofac Surg 2007

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II. MATERIALS AND METHODS

A review and electronic search of several databases were performed. 50 articles including 3937 subjects in total were evaluated in this study.

III. INCLUSION

Patients with maxillofacial trauma, Lefort osteotomies, BSSO (bilateral saggital split osteotomy) and zygoma fractures. Patients with ASA I and II.

IV. EXCLUSION

Heavily comminuted fracture compromised medical status (ASA III and IV), psychiatric disorders, cleft lip and palate surgeries and those not determined suitable by the operating maxillofacial surgeons.

V. RESULTS

None of the studies showed evidences of allergies, infections, inadequate fixation in the long term followup. The biodegradeable plates were bulkier as compared to the titanium plates to provide stability, but became unnoticeable gradually as they disintegrated. Both showed similar stability and fixation.

VI. DISCUSSION

The major difference in the titanium and biodegradable fixation system is that, the titanium plates and screws do not resorb. In many countries the removal of the plates is a compulsion once the fractured sements are stabilised, whereas most of the cases for removal of the plates were because of the following criterias: Infection, malunion, non-union, foreign body reaction or patients' need. The removal needs general anaesthesia, re-surgeries and added medical care and cost. This disadvantage is overcome with the use of biodegradable fixation systems. But because of its known lesser shear strength, the material is made bulkier and hence it is palpable immediately after the surgery, but in a considerable amount of time it becomes less palpable as it heals and resorbs. The second concern is of the cost effectiveness. The titanium fixation systems are readily available and hence cheap, forming the primary choice of most of the surgeons, as compared to the biodegradable ones which are costlier and less readily available. The biodegradable screws are available in multiple packs; once a pack is used the remaining unused screws are thrown away and hence have more wastage unlike titanium which has none. Moreover, the biodegradable screws are prone for more breakage and loosening in heavy loading areas, where the masticatory efficiency (load) is more. The titanium systems offer a relatively easier application and adaptability during the surgeries unlike the biodegradable ones which need tapping, prebending and adapting of the plates and screws after being heated at a special temperature or they become stiff and warp if worked on without heating [1, 2, 3, 4].

Various studies have been conducted and literatures reviewed; to test the hypothesis if biodegradable fixation system is superior to titanium ones or can be used as an ideal material for osteosynthesis.

103 patients were evaluated in 2 rounds of trials. The first group was given titanium fixation and stability and the second was given biodegradable fixation and stability. In the 1st trial, patients experienced mild discomfort in both the groups, but showed no significant statistical difference in clinical examination. The mean scores for satisfaction for both the groups were 7.43-8.63 (0-10 range). In the 2nd trial, each group had a plate exposure postoperatively (between 3-9 months) due to infection, loose screws and wound dehiscence (titanium=3/196, biodegradable=3/165). Due to a high risk of bias and very limited data for primary outcome it was statistically insignificant [5].

A Pubmed systemic search of 577 studies was done in 2014. 22 studies met the inclusion criteria (8 randomised control trials, 10 controlle clinical trials and 4 retrospective studies). 130 patients were undertaken for bsso (bilateral saggital split ostetomy), 86 for bimaxillary surgeries and 844 patients for the evaluation of strength of various materials used for stability and fixation.

Surgeries	Total number of patients	Patients with titanium fixation- A	Patients with biodegradable fixation- B	Outcome
BSSO	130	65	65	No statistical significance
Bimaxillary surgeries	86	44	42	Good vertical and occlusal results in A
Material related study (wound dehiscence, infection, breakage)	844	491	353	Group A was better as group B had 143 screw head breakage. But results were not statistically significant (P=0.10).

Table 1. Results in Group A and Group B

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Due to a difference in the type of fixation devices used and various intra operative techniques used, no significant decision could be made [6].

A randomised controlled trial of 230 injured and orthognathic patients was conducted between 2006- 2009. Randomisation was done and patients were divided into 2 groups. Patients underwent BSSO, in the control group fixation was done with titanium plates and screws whereas the patients in the test group were given the biodegradable fixation. No significant difference in relapse was seen postoperatively in either of the groups [7].

Ballon.et.al conducted a non-randomised controlled trial of 84 patients. 42 patients in each group were treated with titanium fixation system and biodegradable fixation systems respectively. Both the groups gave similar post-operative results and hence it was concluded that biodegradable fixation systems should not be discouraged on mere fracture or palpability and more research should be done in the respective fields [8].

3D image analysis of bio cortical screws fix in was done in mandibular condylar regions to check for post-operative stability. 25 patients were given biocortical screws and 5 patients were given titanium screws. Pre and post-operative (6 months) images were recorded and analysed. Stable error was 0.16mm in all the analyses. No significant difference in total spatial changes in the condyle were seen, except in the lateral-medial direction of condylar centre (P=0.042) for bio cortical screws [9].

A randomised control trial was done to determine the switch over of patients with biodegradable fixation to titanium fixation intra operatively in 230 patients. 117 patients were given biodegradable fixation system while 113 patients received titanium fixation. 25 patients having biodegradable plates and screws were switched over to titanium intra operatively. Unfortunately, due to inconsistency in the number of operations and the surgeon's personal preferences a subjective learning curve could not be objectified. No significant predictor variables could aid in deciding one better than the other [10].

Choi.et.at (2011), studied the post-surgical relapse of 20 patients with maxillary surgeries stabilised with biodegradable fixation. No intra or post-surgical switch or removal was recorded in any patients [10].

Paeng.et.al (2012), evaluated 25 patients treated with mandibular setback to check for skeletal stability of titanium and biodegradable fixations. Monocortical screws were replaced with bicortical screws. No intra operative or post-operative switch or removal was done. Both the groups showed similar skeletal stability [10, 11].

Name and Year	Surgeries	Total number of patients	Patients with titanium fixation A	Patients with biodegradable fixation B	Results	Significance and conclusion
Izumi Yoshioka.et. al [12]. 2012	BSSO	200 (67 men and 133 women)	90	110	8.2% (9 cases) fracture and breakage of screws in B. 3.3% (3 cases) fracture and breakage in A	Biodegradable fixation system is a reliable alternative for titanium but is recommended in areas of minimal loading
Izumi Yoshioka.et. al [13]. 2012	BSSO	169 (62 men and 107 women)	-	169 Multiple logistic regression analysis used to find the factor with dependent variable: breakage of biodegradable plate fixation system.	Asymmetry and open bite due to breakage of screws in biodegradable plates and screws. P=0.02	Recommended to be used in areas of minimal loading and masticatory forces.
Alexander Ballon.et.al [4]. February 2012	Orthognathic surgery	100	50	50	Lesser strength against compressive forces seen in group B (less resistant to forces of the	Can be used in all the situations like titanium fixation except in cases of maxillary elongation and mandibular setback.

					tongue). The group A showed more strength and stability.	
Jun-Young Paeng .et.al [14]. 2010	Mandibular setback surgeries	50	25 (control=4 screws)	25 (test=5 biocortical screws)	Mean follow up 17.8 months. Average stback=6.9mm. No complications in any group. 1 case reported with infection, cured with antibiotics.	Biocortical screws are less stable vertically as compared to titanium. But small sample size and hence statistically insignificant.
Philipp Stockmann.et.al [15]. 2010	Jaw disproportion correction surgeries	66	33	33	34 patients (54%) reported for follow up till the end of the study. No foreign body reactions, no significant difference in terms of osteosynthesis for the 8 years.	Equally effective. Biodegradable fixation is a good alternative for titanium for osteosynthesis.
Krushna Bhatt.et.al [16]. 2010	Orthognathic surgery	40	21 (20 men, 1 woman)	19 (18 men, 1 woman)	Group A 0 % non-union, need of alternative treatment and postoperative swelling,7.7% malocclusion, 2% chronic pain, 5.2% infection, 7.7% inability to chew food, reoperation 31% Group B 4.7% non-union, 0% need of alternative treatment 8.3%postoperative swelling,11.1% malocclusion, 37.5% chronic pain, 0% infection, 11.1% inability to chew food.	Same outcomes in both the groups. Small sample size was inconclusive of any significant finding. Established that no need of re-operation in case of group B.
Hyo-Bin Lee.et.al [17]. 2010	Manibular fractures	91 (65 males and 26 females)	46	44	Overall complication rate was 4.41%. 4.26% (2 cases of infection was	Results showed that rate of morbidity are very low with the use of biodegradable plates. Suggested that both

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					reported in group B) 1% (1 case of infection and 1 case of plate fracture was reported in group A)	should be used equally as they have potential for successful use in fixation of mandibular fractures.
L. K. Cheung.et.al [18]. 2008	Lefort I osteotomy	40	20	20	Maxilla was comparatively more mobile in group B as compared to group A. Upward displacement of anterior maxilla and downward displacement of posterior maxilla was seen in group B. No post-operative complications were noted. Biodegradable plates were more palpable initially but decreased with time.	No greater morbidity was reported when either of the two fixation systems was used and reviewed 1 year post operatively.
Robert M. Laughlin.et. al [19]. 2007	Mandibular fractures	50	-	50 (body, symphysis, angle and ramus)	After clinical and radiological evaluation, 6% sites (3 cases) showed signs of infection. 12 screw heads fractured were replaced immediately.	The need for secondary surgery can be totally avoided with the use of biodegradable plate and screw fixation system.
Fabio Costa.et.al [20]. 2006	Class III skeletal cases-BSSO setback.	22	12	10	Group A showed no positive findings. Group B showed significant correlations between maxillary advancement and relapse.	No difference in post-operative skeletal and dental stability was seen.
Koichiro Ueki.et.al [21]. 2006	Lefort I (saggital and vertical split osteotomy)	47	24 (saggital split ramus osteotomy)	23 (vertical split osteotomy)	Group A ($P<0.05$) showed anterior displacement. Group B ($P<0.05$) showed difference in vertical component.	Slight vertical disimpaction may be suggested in group B but on long term follow up, normal occlusion was clinically apparent. Hence, no significant findings.
Lim Kwong	Maxillofa	60	30	30	Group A	No statistical difference

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Cheung.et.al [22]. 2004	cial osteotomies	(177 osteotomies)	(196 titanium plates and 784 screws)	(165 plates and 658 screws)	Infection=1.53% (Wound dehiscence and loose screws) Plate removal=1.53%. Group B Infection=1.82% (Wound dehiscence and loose screws) Plate removal=3.63%	in subjective clinical parameters such as discomfort, stability, palpability and overall satisfaction.
Young-Wook Park [23]. Sep 2002	Mandibular fracture management and fixation	22	-	22 (14 male, 8 female) Mean age=26.3 years.	Follow up period averaged upto=49.1 weeks. Mucosal dehiscence over devices was seen in 2 patients. In 1 patient the material was switched over to titanium.	Mucosal healing and consolidation was normal in all the patients. Hence, biodegradable plates can be used as a reliable alternative for titanium.
Carlo Ferretti.et.al [24]. 2002	BSSO	40	20	20	1 year follow up showed no clinical and radiological evidence of wound infection or dehiscence.	No long term stability problems. No statistical difference was noted in either of the two fixation systems. Biodegradable was suggested as a good and reliable alternative for titanium.
Richard C. Edwards.et.al [25]. 2001	BSSO, Mandibular symphysis osteotomy, Lefort osteotomy	12 BSSO=8, Mandibular symphysis osteotomy=2, Lefort osteotomy=2.	-	12 BSSO= 1 patient underwent biopsy for histological evaluation of screw fixation site. Lefort osteotomy= 2 patients underwent visual exploration of operated site.	All 48 screw holes showed radio locency initially, followed by trabecular bone filling.	Complete bone healing with no communication, infection, residual polymer and no bone defects was seen.

Table 2. Summary of studies and articles on biodegradable and titanium fixation system

VII. CONCLUSION

With the recent advancements, biodegradable fixation systems come very close to being called as the ideal material for fixation and osteosynthesis. In the last few decades these plates were primarily used for orthopaedic and pediatric patients but now its use and contribution in the field of oral and maxillofacial surgery is remarkable. It is an attractive alternative for various kinds of craniofacial reconstructive procedures as well. The results of this review article support the hypothesis that biodegradable fixation devices have similar skeletal stability as titanium fixation when used for trauma and orthognathic surgeries. This study also brings in to notice that biodegradable screws showed higher chances of breakage and war page as compared to the titanium screws. Stability of fixation , length of time

required for the degradation and the possibility of foreign body reactions still remain as a matter of primary concern, hence more detailed and further studies will be required in this field to prove the superiority of biodegrade able fixation system over titanium.

To summarise the review paper, several factors need to be considered and evaluated before any fixation is declared superior than the other and it is the patient and the surgeon that should direct the choice of the fixation systems.

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