EFFICACY OF INDIGENOUSLY MANUFACTURED TITANIUM BONE PLATES AND SCREWS IN MAXILLOFACIAL SURGERY

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ABSTRACT

Titanium plates and screws (implants) developed indigenously by DRDO were used to manage 20 patients with maxillofacial fractures. Efficacy of these implants was evaluated clinically and radiographically so that these can be put into use on routine basis. In 18 patients recovery was uneventful. Extended maxillomandibular fixation was employed for 3 to 7 days only depending on the degree and displacement of fractures and; mobilisation of jaw was allowed fully from 7th post operative day onwards. 2 patients developed discharging sinus at the fractured mandibular angle region which was due to impacted mandibular third molar in the line of fracture. This healed completely after extraction of offending tooth and appropriate medication. There was no occlusal or nerve disturbances, wound dehiscence or rejection of the bone implant. Radiographical evaluation at various intervals showed good alignment, approximation and sound healing of fractured fragments, with complete osteointegration.

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Key Words: Biocompatibility; Maxillofacial fractures; Osteointegration; Titanium bone plates and screws; Titanium implants.

Introduction

The concept of management of maxillofacial injuries has undergone remarkable transformation with bone plate and screw osteosynthesis. This technique provides three dimensional stability to bone fragments, minimises the need of extended maxillomandibular fixation, restores early function and return to employability.

Bone plates and screws are manufactured from stainless steel (316 L), vitallium and Titanium [1]. Stainless steel possesses structural, mechanical and physical characteristics but has risks of a compromised biological response resulting in infection with persistent sinus and wound dehiscence where as vitallium bone plates and screws used in maxillofacial regions do not have adequate fatigue resistance, strength and exhibit low resistance to corrosion, moreover these plates cannot be adapted with ease along the anatomical bony contours.

The application of Titanium plates and screws in maxillofacial surgery has gained world wide acceptance because of its higher strength, resistance to corrosion, being lighter in weight and most importantly its biocompatibility and osteointegration properties, Titanium bone plates and screws are available in pure form or as an alloy with aluminium and vanadium to increase strength and osteointegration. Titanium has

got properties of combining with Oxygen to form inert Titanium dioxide which is stable and is responsible to prevent corrosion and play important role in osteointegration. Keeping in view the advantages of Titanium implants, DRDO has undertaken a project to manufacture Titanium bone plates and screws indigenously which possesses all the properties of a similar imported system. To assess the feasibility, efficacy and acceptance of these plates and screws (manufactured by DRDO) a study was conducted in the department of Dental Surgery AFMC Pune, taking various parameters into consideration. This system has been found to be biocompatible with satisfactory results.

Material and Methods

20 patients with compound fractures involving more than one site with grossly displaced fractures and occlusal disharmony were included in this study. Medically compromised patients with chronic respiratory obstruction, neuropsychotic disorders, epileptics, chronic alcoholics, patients with spine and head injuries, perforated chest and abdomen wound and associated limb injuries were excluded.

The kit supplied by DRDO has straight plates of 6,8,12, 16 holes length, and bar 'L' and 'X' type plates having 6 holes. The width of these plates is of 3 mm and diameter of each hole is of 2 mm. Length of screws supplied is in range of 6 mm, 8 mm, 10 mm and 12 mm. These are pretapped screws with 'V' thread type angulated at 60° having core diameter of 1.8 mm and thread diameter 2 mm. The screw head is conical with uniform slot with 0.1 mm undercut and diameter of screw head is 2.3 mm for 6 and 8 mm length screws and 2.5 mm for 10 and 12 mm length screws.

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The kit also contains Titanium tweezer and Titanium screw driver.

The methods employed for managing the selected patients were as per the normal oral surgical procedures which included proper history, clinical and radiographical evaluation. All patients were intubated under General Anaesthesia and fracture sites were approached either extra orally or intra orally depending upon their site. On exposure of fracture site all fracture fragments were thoroughly cleaned of granulation tissue, immobilised, rigidly fixed and stabilised with DRDO titanium mini bone plates and occlusion was checked. Haemostasis was achieved and wound sutured in layers after placement of vacuum suction drain. Patients were placed on Maxillomandibular fixation for 3 to 7 days followed by active jaw movement and function.

Results

A total of 23 fractures were treated with a majority of fractures occurring on left side (Fig 1). Peak incidence was in the 20-30 years age group with range of 18 to 55 years. (Fig 2)

Road traffic accidents accounted for 60% of the injuries while physical violence, fall to the ground during PT/Drill and organised sports were responsible for 25%, 10% and 5% of fractures (Table 1). Distribution of the plates placed is depicted in Table 2.

TABLE 1

Classification according to aetiology

Aetiology	Number of patients	Percent
Road traffic accidents	12	60
Fall	2	10
Physical Violence	5	25
Sports	1	5

TABLE 2

Distribution of plates placed

Position of plates	Number	Screws
Angle of mandible	13	43
Mandibular parasymphysis	18	52
Mandibular subcondylar	2	8
Frontozygomatic suture	5	18
Infraorbital region	2	4
Buttress		
Total	42 plates	134 screws

Two cases developed infection who had compound fracture with tooth in line of fracture, which was corrected by extraction of offending tooth. Occlusal disturbances in two patients were cor-

TABLE 3

Incidence of complications

Complications	Post Op	1 week	4 weeks	8 weeks	3 months	6 months to 1 year
Infection	2	1	—	—	—	—
Occlusal disturbance	2	—	—	—	—	—
Wound dehiscence	—	—	—	—	—	—
Nerve disturbances	1	1	1	1	1	—
Failure	—	—	—	—	—	—

Fig. 1 : Distribution of fractures according to site

Fig. 2 : Age distribution

rected by spot grinding and removal of premature contacts. Mental nerve sensory disturbance observed in one patient, returned to normal within three months post operatively (Table 3).

During radiographic evaluation after 12 weeks, in addition to alignment, approximation and healing of bone at an advanced stage there was no stress shield effect in the implant bone interface. The radiographic evaluation after six months to one year showed complete integration of screws within the bone (Figs 3-5).

Fig. 3 : CP Titanium pretapped screws of 8mm, 10mm, 12mm & 14mm length.

Discussion

The application of bone plates and screws in the management of maxillofacial trauma has gained widespread acceptance. Treatment with wire osteosynthesis has got several disadvantages like inadequate rigidity, lack of three dimensional control, insufficient contact area and cannot prevent telescoping of bony fragments. [2-5].

These factors contribute in healing of the bone by secondary intention with excessive endosteal and periosteal callus formation and requires prolonged immobilisation by maxillomandibular fixation which takes time in remodelling, laying of lamellar bone and is prone to infection [6]. The disadvantages can be minimised if bone fragments are brought in close anatomical alignment, immobilised and stabilised rigidly by bone plates and screws.

The plate and screw system designed in stainless steel, although accepted by the human body, has several drawbacks such as high rate of infection, pain, wound dehiscence, persistent sinus, plate exposure and high susceptibility to corrosion (89% to 97%) it also exhibits increased non metallic inclusion content, lacks homogeneity due to larger grain sizes [7], and possesses porosity which provides undesirable areas of stress concentration and also carries the danger of localised metallosis necessitating removal of plates [8]. Vitallium, the chrome-cobalt-molybdenum alloy has good metallic characteristics such as high yield strength, high tensile strength and stability in biological environment. However, it has inferior resistance to corrosion, less biocompatibility, high rigidity and difficulty is experienced in moulding the plate to the anatomic shape of bone [9].

Bone plates and screws manufactured of Titanium, have got high biocompatibility, excellent osteointegra-

Fig. 4 : Per operative photograph showing fracture mandible parasymphysis (Rt).

Fig. 5 : Post operative photograph showing fracture fragments rigidly fixed and stabilised with titanium bone plates and screws.

tion, low thermal conductivity, malleability and ease in adaptation to anatomical bony contours. It has got high corrosion resistance due to superficial stable Titanium-di-oxide layer of 2-20 nm thickness and produce low magnitude of artifacts in radiographs vis-a-vis stainless steel and vitallium.

Titanium alloys has got Aluminium 6% and vanadium 4%, both these materials act as phase condition stabilizer, former is an alpha phase condition stabilizer which increases the strength and decreases the weight of the alloy, whereas latter is a beta phase stabilizer which is responsible for stress, corrosion and cracking resistance.

Titanium and its alloys possesses high strength, low density and low modulus of elasticity $16.5 (\text{psi} \times 10^6)$ which is closer to bone vis-a-vis stainless steel and Vitallium having 85 and 35 ($\text{psi} \times 10^6$) respectively [10].

Large amount of Titanium can be placed in the biological tissues without producing toxic effects as the

rate of dissolution of Titanium and accumulation in tissues is in the range of 50 ppm which is not harmful. However, if Titanium comes into intimate contact with dissimilar metal during insertion into the biological environment, galvanic ions are liberated with galvanic potential and this may cause corrosion [11].

The unique advantage of Titanium and its alloys is that they possess mechanical properties specific for bone plate and screw. A plate is made with lower elasticity, better deformability and lower hardness so that it is accurately adapted to the anatomical contour of bone. The screws are so fabricated that it has a high elasticity, low deformability, high tensile strength and low breaking factor.

The DRDO manufactured indigenous Titanium bone plates are of the specification of American society of Testing and material B 348 Grade I quality. This material has been subjected to Haemolysis test, mast cell degranulation tests, mucous membrane irritation tests and subcutaneous reaction tests with encouraging and successful in-vitro-studies. In order to evaluate their efficacy in human body, a total of 42 plates and 134 screws were employed in the management of 19 mandibular and 5 zygomaticomaxillary complex fractures with successful results.

It has been observed in our study that immobilisation and three dimensional stability offered by indigenous Titanium bone plates is adequate to allow early mobilisation of jaws and reduce the period of extended maxillomandibular fixation [12-15]. The healing pattern was uneventful both clinically and radiographically with complete osteointegration of the system with host bed. There was no adverse reaction, wound dehiscence or rejection of bone plates.

However, the gray area at present with this system is lack of tensile strength in screws because some of them got damaged, distorted and fractured as they were unable to withstand the force of rotation and torque when screw driver was applied to tighten. Further clinical trials, scientific evaluation and modification of plate and screws to enhance their strength is

contemplated before putting them to use in the Armed Forces.

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