BONE RESPONSE TO STAINLESS STEEL AND TITANIUM BONE PLATES

An Experimental Study On Animals

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ABSTRACT

Various types of metallic implants have been used in the form of screws, bone plates and compression plates to achieve rigid internal fixation. In the present study, bone response to imported titanium bone plates and indigenously manufactured stainless steel bone plates, has been evaluated in dogs.

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Introduction

Miniplate osteosynthesis plays an important role in the management of maxillofacial trauma, in orthognathic reconstructive surgery and in access osteotomies. The first use of bone plates in maxillofacial surgery was reported by Winter in 1945 [1]. The advantages of bone plates as evaluated by Roberts [1] include precise reduction and rigid fixation of fractured ends. Also the need for intermaxillary fixation is either reduced or completely omitted. On account of these factors bone plates have a special role in the management of fractures in children, mentally retarded and epileptic patients. In addition there is no danger of airway obstruction during recovery from general anaesthesia. It also prevents the possibility of temporo mandibular joint (TMJ) ankylosis in cases of concomitant condylar injury. They also have a special role to play in access osteotomies.

Various factors are to be taken into consideration while selecting an implant material. These include physical and chemical properties, the nature of host tissue, the

interface reaction between the bone and implant, cost effectiveness, availability, and choice of the operator.

Two different types of bio materials are commonly used in clinical practice, namely titanium and stainless steel. The titanium bone plates are imported from different countries. These bone plates are not only expensive but also require complicated instrument system. At present the stainless steel bone plates are manufactured indigenously. These bone plates are not only economical but also easily available. The present study was undertaken with the aim of comparing the bone response to these two different biomaterials in terms of healing following surgical fracture and histological changes in bone around the screw.

Material and methods

The animal models chosen were six mixed breed dogs with average built, weight and age. Both males and females were included. The animals were arranged in two different groups, that is, Group A and Group B, of three each and the study was conducted on the tibia of these dogs.

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Four-hole pure titanium bone plates of 1 mm thickness were selected. The length of the screws was 7 mm with a core and thread diameter of 1.6 mm and 2 mm respectively. These were manufactured by Martian Lorenz of Germany.

Four-hole stainless steel bone plates with intermediate bar of 0.9 mm thickness were selected. The length of the screws was 8 mm with core and thread diameter of 2 mm and 2.5 mm respectively. These plates were manufactured by AK Instruments of Bombay from AISI 316L grade stainless steel.

The dogs were starved on the day of operation. They were premedicated with 50 mg of chlorpromazine and 30 mg pentazocine by intramuscular injection 30 minutes before surgery. The dogs were anaesthetised with 500 mg of intravenous thiopental sodium. The operative site over right hind-leg was shaved, scrubbed and draped. The site of incision was infiltrated with 2% lignocaine with 1 : 80,000 epinephrine. An incision of about 6 cms length was made on the proximal end of the tibia. Tibia was exposed subperiosteally and a surgical fracture was created using a surgical fissure burr (Fig 1). Normal saline was used as coolant through-out the procedure. Both the fragments were approximated and immobilized with bone plates and screws. In group A, titanium bone plates and screws were used to immobilise the fracture whereas stainless steel bone plates and screws were used in group B (Fig 2). The wound was irrigated, hemostasis achieved and 500 mg of ampicillin powder placed in the operative site, and the incision closed in layers.

Post operatively the dogs were given 500 mg ampicillin and 80 mg gentamicin intramuscularly every day for 5 days. Sutures were removed on the 7th post operative day. The animals were maintained on a standard diet throughout the evaluation period. The dogs were observed for healing of the fracture clinically and radiologically. The parameters used were - absence of any infection and discharge from the operated site; the time

Fig. 1 Exposure of tibia and creation of surgical fracture

Fig. 2 Bone plates and screws

when full function of the leg was established without any noticeable limp; and the amount of callus formation as evidenced by inspection and palpation. Radiological evaluation of callus formation, remodelling and osteolysis around the screw was done at intervals of 4, 8, 12 and 16 weeks.

One dog from each group was sacrificed at the end of 8th, 12th and 16th week, by giving an overdose of thiopental sodium. The fracture site was exposed and the bone plates were removed. The segment of bone containing the screw holes was removed and preserved in 10% formalin. The segments were decalcified and embedded in paraffin wax. Finally 5 micron thick sections were cut, stained with haematoxylin and eosin stains, and then mounted.

Results

Clinically, full functional recovery was seen, on an average in 21 days in 'titanium'

TABLE 1

Periodic evaluation of clinical parameters in Group A (Titanium Group) and Group B (Stainless Steel Group).

	4th Week		8th Week		12th Week		16th Week	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Soft tissue swelling	Moderate	Severe	Moderate	Severe	Mild	Moderate	Nil	Mild
Mobility of fragment	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Callus formation	Moderate	Severe	Moderate	Severe	Mild	Moderate	Not palpable	Mild
Residual deformity	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

TABLE 2

Depicts progressive radiological findings of the bone response in Group A (Titanium Group) and Group B (Stainless Steel Group)

	4th Week		8th Week		12th Week		16th Week	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Callus formation	Mild	Severe	Mild	Severe	Mild	Moderate	Nil	Moderate
Periosteal reaction	Mild	Severe	Mild	Moderate	Mild	Moderate	Nil	Mild
Soft tissue swelling	Mild	Moderate	Nil	Moderate	Nil	Moderate	Nil	Mild
Radiological union	In progress	In progress	In progress	In progress	Complete	In progress	Complete	Complete
Osteolysis around the implant	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent

group and in 22 days in 'stainless steel' group. The clinico-radiological response of bone to stainless steel and titanium bone plates are illustrated in Table 1 and 2.

The 8th week gross specimen of titanium implant showed moderate amount of callus formation, whereas there was minimal amount of callus formation seen in the 12th and 16th week specimens. All the 3 specimens (8th, 12th and 16th week) revealed that the titanium implant was firmly adherent to the underlying bone with complete healing of the fracture. There was no evidence of corrosion of the implant (Fig 3). The gross specimen of 8th week stainless steel showed extensive callus formation with only a small portion of the implant being visible. The bone healing was complete with no evidence of corrosion of the implant. In comparison the 12th and 16th week specimens revealed moderate amount of callus formation with complete healing of the fractured bone. However, there seemed to be distortion of the implant without any evidence of corrosion (Fig 4).

Fig. 3 Titanium implant 16th week post-operative.

The histopathological examination of the 8th week titanium implant showed areas of haemorrhage, mild cellular reaction, necrotic bone pieces and deposition of osteoid. The 12th and 16th week specimens depicted areas of old haemorrhage, stellate cells and osteoid formation and signs of osteointegration (Fig 5). The histopathological findings of the 8th week stainless steel implant were similar

Fig. 4 Stainless steel implant 16th week post-operative.

Fig. 5 Titanium implant - histopathology of fracture site 16th week post-operative.

Fig. 6 Stainless steel implant - histopathology of fracture site 16th week post-operative.

to as observed in the 8th week titanium implant, whereas the 12th and 16th week specimen showed a predominantly fibroblastic reaction, endothelial proliferation and giant cell reaction. Presence of a fibrous capsule was evident (Fig 6).

Discussion

The titanium and stainless steel implant materials, are being routinely used in maxillofacial and other allied fields of surgery.

Using animal models it is possible to carry out histopathological evaluation of bone response. Tibia of dogs is relatively easy to access. Moreover the tibia and mandible are subjected to similar functional stress and show similar reparative response [2].

The skin incision in both the groups healed by primary intention and the limb returned to full function in about 3 weeks, though the amount of callus formation and soft tissue swelling was comparatively less in group 'A'.

Radiologically, there was no evidence of any osteolysis around implants in either group, which contrasts with the findings of Venable *et al* [3] who found evidence of osteolysis and necrosis around stainless steel implants which was attributed to electrolysis of implant material.

Linder and Lundskog [4] observed that the bone around the titanium screws was dense, which could be one of the reasons for difficulty in removing the titanium screws being firmly adherent, whereas removal of stainless steel implants was much easier.

On clinical examination, there was no evidence of corrosion of either titanium or stainless steel implants, which is in conformity with the findings of Black [5], Lewelyn and Sugar [6].

The presence of haemorrhage and osseous necrosis in 8th week histopathological specimen of both implants could be due to bone dust splinters and haemorrhage that might have been forced into adjacent marrow spaces during insertion of metallic screws. Similar observations have been reported by Southan and Selwyn [7].

The presence of fibrous capsule and foreign body type of giant cells was very significant in 12th week post-operative, histopathological specimen of stainless steel implants. According to Collins [8], implanted objects though histologically inert, never

become incorporated into bone. They are always surrounded by fibrous capsule.

As compared to stainless steel, 12th week specimen of titanium implant was surrounded by osteoid tissue, undifferentiated mesenchymal cells and monocytic infiltration. This could be due to osseointegration property of titanium. According to Branemark [9] osseointegration is a unique property seen with titanium implant wherein there is a direct contact at the light microscope level between living bone tissue and implant.

At the end of 16th week the area around titanium implant showed mature lamellar bone while stainless steel implant was surrounded by scanty mineralised osteoid tissue with persistence of giant cells. This view has been supported by Black [5]. The need for removal of stainless steel bone plates has been the subject of discussion for long. Cawood [10] recommends the removal of bone plates after 12 weeks to avoid interference of plate with function, as they prevent transmission of functional stress to the area, leading to osteoporosis and weakening.

Kennedy [11] also emphasises the removal of bone plates due to stress shielding effect. However the subject remains controversial. Due to the absence of any untoward response of bony tissue to titanium implants, the removal subsequent to their use can be safely avoided.

The indigenously manufactured AISI 326L grade stainless steel bone plates used in present study did show radiological and histopathological adverse tissue reactions to some extent. However, the absence of corrosion of implant, osteolysis in the surrounding bone, coupled with satisfactory bone healing confirms its biocompatibility. These

plates being economically viable and easily available can be recommended without hesitation to be routinely used in maxillofacial surgical procedures as a suitable alternative to the costlier titanium plates. However, it must be stressed that a long term clinical use of stainless steel bone plates on a larger number of patients in various anatomical situations if meticulously evaluated clinico-radiologically, will help in arriving at a definite conclusion.

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