COMPARISON OF LOCAL AND IMPORTED OSTEOSYNTHETIC MANDIBULAR BONE PLATES IN TERMS OF MICRO HARDNESS IN MODIFIED SIMULATED BODY FLUID AT PERIODIC INTERVALS

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ABSTRACT

Objective: To determine the micro hardness of novel Pakistani manufactured osteosynthetic titanium bone mini plates (MPP) and imported osteosynthetic titanium bone mini plates (MPG) in body like conditions.

Study Design: Descriptive study.

Place and Duration of Study: This study was carried out at School of Chemical and Material Engineering, NUST from March to May 2013.

Material and Methods: Microvicker hardness tester was used for assessment of micro hardness of two types of plates. The hardness was checked before conditioning and after conditioning at (six different places) on interval of 1, 7,14,21,28 and 40 days in modified simulated body fluid with ph 7.4 and temperature 37°C.

Results: Result showed that hardness of MPG was higher than MPP and after conditioning in simulated body fluid at all time periods, hardness of both types of plates was increased.

Conclusion: It can be concluded from this study that micro hardness of imported plates is more than local plates so recommendations should be sent to manufacturers of local industry of Pakistan to improve the hardness of local plates so that they can meet international standards.

Keywords: Bone plates, Hardness, Simulated body fluids.

INTRODUCTION

In recent years the incidence of trauma involving maxillofacial region is increasing at faster rate because of number of reasons such as science progress, large number of vehicles, armed wars and urban life style. The fixation of mandibular fractures is most frequently achieved by utilizing bone plates and screws because they offer a number of advantages over the other methods used for fracture fixation such as fixation beneath periosteum to maintain enough blood supply, multiple points for fixation, inhibition of rotational movements of fractured fragments, maintaining dimensions of face, rapid healing of fractures and the patient does not need to undergo intermaxillary fixation for weeks^{1,2}.

In Pakistan the osteofixation plates used for maxillofacial surgeries are either imported

from abroad or manufactured in local industry. The bone plates imported from other countries such as Germany are used more commonly than locally manufactured plates because extensive research has been done on these plates and attempts are frequently made to improve their quality³⁻⁶. But unfortunately no research till date has been done to analyze the local plates, although maxillofacial surgeons do use them some times but there is no specific authentication regarding them. The mechanical properties especially hardness is the basic requirement of these plates due to fact that they may fracture if these lack sufficient hardness. In this study hardness was assessed in modified simulated body fluid (mSBF) at specific time intervals in order to have similar conditions of clinical use.

The basic aim of this study was to determine and compare hardness of locally manufactured and imported commercially pure titanium bone plates.

MATERIAL AND METHODS

Bone plates

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Detail of bone plates used in this study is given in table-1. The dimension for each sample were 6x3x1mm.

Modified simulated body fluid

Modified simulated body fluid (mSBF) was prepared according to the standard method

Table-1: Type of bone plates used in this study.

Each sample was suspended separately with silk in a 250 ml capacity beaker filled m-SBF.

It was made sure that each specimen would not touch bottom of beaker so that all the surfaces were exposed to mSBF. The temperature of beakers was maintained

Serial No	Commercial name	Center	Malleable	
01	Mini plate Germany (MPG)	Narrow	Yes	
02	Mini plate Pakistan (MPP)	Narrow	Yes	
Table-2: Composition of modified simulated body fluid.				
Compounds		Reagents	Amount	
Sodium Chloride		NaCl	5.403g	
Sodium Bicarbonate		NaHCO ₃	0.504g	
Sodium carbonate		Na ₂ CO ₃	0.426g	
Potassium Chloride		KCl	0.225g	
Potassium DiHydrogen Phosphate		NaH ₂ PO ₄ .3H ₂ O	0.230g	
Magnesium Chloride hexahydrate		MgCl ₂ .6H ₂ O	0.311g	
Sodium hydroxide		0.2 M-NaOH	100ml	
Calcium Chloride		CaCl ₂	0.293g	
Sodium sulphate		Na ₂ SO ₄	0.072g	
Sodium hydroxide		1.0 M – NaOH	15ml	
2-(4-(2-hydroxyethyl)-1-piperazinyl)		HEPES	17.892g	
ethanesulfonic acid			-	

described by Oyane et al⁷, by dissolving reagent in deionised water as shown in table 2, which is almost equal to the composition of human blood plasma, except HCO₃. All the reagents and compounds were supplied by inorganic chemistry laboratory of NUST.

Microvicker hardness tester

Micro hardness of bone plates was checked through 402 MVD micro hardness tester (Wolpert Shingai).

This machine provides most accurate micro hardness details of metallurgical equipment. The accuracy of this hardness tester conforms to ISO 6507 and ASTM E384& E92. Load control is automatic and has built in printer for data output.

MATERIAL AND METHODS

All the apparatus used in this study was washed thoroughly with distilled water and acetone. All specimens were tied with silk wire. Silk was used in sterilized form. It was cut into pieces of similar length with sterilized scissor. constant at 37°C in water bath (digital constant temperature tank HH-4 China).

Hardness of these plates was examined through microvicker hardness tester (402 MVD, Wolpert, Shanghai) fitted with pyramidal shape diamond indentor. The indentations were made on bone plates at six different places. Test load applied was 50g with load duration of 5 seconds and test load selection mode was dial. Total magnification used for measurement in this study was 400X. The operating temperature was 38°C and power supply was 110-220V AC, 60/50Hz.

RESULTS

The mean values for hardness of MPG and MPP are 195.42 and 149.05 (Table-3).

DISCUSSION

Generally the fixation of mandibular fractures is most frequently achieved by utilizing bone plates and screws because these plates have several advantages over other treatment options i.e. intermaxillary fixation with wires or arch bars, external pin fixation and lag screws etc. The advantages of utilizing bone plates are easy plate adaptability, good surgical outcomes with fewer chances of complications, small diameter of screw, adequate load-sharing rigid fixation for noncomminuted and parasymphyseal and symphyseal mandible fractures.

Currently two brands (local and imported from Germany) of titanium bone plates are used in Pakistan. The present study aimed to evaluate the behavior of these two brands in terms of hardness. In this study the hardness of local brand of bone plates are compared with an international brand of bone plates. The hardness is basically the measure of resistance to any indentation. It is very important property of medical devices and implants used inside human body as any type of effects on hardness of plates whether positive or negative alters the original mechanical properties and this leads toward fragility of plates.

The results of study showed that hardness of MPG higher than MPP (Table-3). It means they are more resistant to cracks and fractures which may occur during fixation and other movements and are less fragile. In 1986 Champy et al reported the mechanical characteristics of osteosynthetic titanium miniplates in which hardness was 120-180 HN (Hardness Number), while in this study hardness of both the plates comes in this range so these findings confirm the study of Champy et al⁹.

The hardness after conditioning increased (Table-3). This marked increase in hardness seems to be most probably because of rapid deposition of different ions on the bone plates during immersion in modified simulated body fluid. After that there is less increase in hardness of bone plates due to slow deposition of ions especially calcium, phosphate and chloride. Balakrishnan et al in 2008 observed same ionic deposition on the titanium bone plates after conditioning in modified simulated body fluid¹⁰.

These findings are in correlation with results of study by Tuncer et al¹¹. They compared hardness of used and original titanium bone plates in dogs. They found out that hardness was increased when they were

Table-3: Mean Hardness values of MPG and MPP.

Serial No	MPG	MPP
1	193.3VH	137.2 VH
2	209.1 VH	162.5 VH
3	197 VH	146.8 VH
4	196.1 VH	155.5 VH
5	191.6 VH	148.06 VH
6	189.6 VH	145.5 VH
7	191.3 VH	147.8 VH

left for more time inside animal body. This shows that the period in tissue positively influences the hardness of plates.

While in another study done by Matthew et al vicker hardness test was performed of mini plates which were retrieved after 4 and 12 weeks of operative treatment¹². But they haven't found any significant change in micro hardness of mini bone plates even after 12 weeks of surgery.

The less hardness of local plates when compared with imported bone plates may be due to deficient anodization layer (reduced amount of Titanium oxides on surface) on its surface which makes it more prone to corrosion attack so it seems this may be responsible for its less hardness.

CONCLUSION

Conclusion drawn from this study is that imported bone plates are harder than locally manufactured bone plates. So recommendations should be given to local industry to improve quality of bone plates.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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