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ORIGINAL ARTICLE

A CLINICO-METALLURGICAL STUDY OF IMPLANT BREAKAGE IN DIAPHYSEAL FRACTURES OF HUMERUS, TREATED BY PRIMARY 316L SS DCP FIXATION

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ABSTRACT: Implant breakage is a catastrophic event for the patient and for the surgeon. Hence our aim was to assess the reasons for plate breakage in humeral diaphyseal fractures treated by 316 L SS DCP.A total of ten cases in Govt. medical college Trivandrum during period of June 2011 to November 2013, who were treated initially by plating of humerus presented with plate breakage were studied. Factors like weight bearing, osteoporosis and infection the usual confounding factors in any study does not feature in our study as only diaphyseal humeral fractures fixed with stainless steel DCP were studied and all patients were young. Pre and post-operative X-rays were evaluated by two surgeons to assess fracture and quality of fixation. Removed failed plates and controls were sent for metallurgical analysis. Presence of far cortex commination and empty screw hole (70%) at fracture site were the commonest clinical cause and corrosion especially pitting (90%) was the commonest metallurgic cause of plate breakage. When more than two clinical and metallurgical factors coincided implants failed within two years denoting a cumulative effect.
KEYWORDS: Metallurgical, implant failure, 316 L stainless steel, Humerus.

INTRODUCTION: A biomaterial is defined as 'any synthetic material that is used to replace or restore function of a body tissue and is continuously or intermittently in contact with body fluids.[1] The ability to replace or augment diseased body parts totally or partially, has improved the quality of life for millions of people over the quarter of a century. Implant materials and devices are needed for a number of reasons, such as replacing tissue that has become damaged or destroyed by disease or trauma. Such devices include plates, nails, artificial hips, knees or elbows etc. Internal fixation is advocated for all diaphyseal fractures, to adequately stabilize the fractures and to allow for early mobilization.[2]

We use 4.5 system DCP with cortical screws either as compression or as neutralization plate for the diaphyseal fractures of humerus.[3] Austenitic stainless steel [316 L] is the material of choice for most of the internal fixation devices.[4] The strength and low cost of the material are advantageous. Different manufacturers have their trade name for the standard alloy but must conform to the standards.[4] Several national and international organizations developed implantable materials.[5]

Implant failure especially when it occurs before fracture union is a catastrophy both functionally and financially for the patient as it warrants a repeat surgery and more loss of working days. For the surgeon, redo surgery is often more prolonged and complicated with more chances of failure and infection often necessitating bone grafts. Hence we undertook this study to analyse reasons for increased implant breakage in humerus. This is more relevant especially in a developing country like India where most of the orthopedic surgeons are forced to use the locally made implants

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for their patients rather than going for standard fixation hardwares due to economic restraints and availability.

AIM AND OBJECTIVES: The aim of the study was to assess the clinical, radiological and metallurgical factors influencing implant breakage in diaphyseal fractures of humerus treated by 316 L Stainless Steel primary Dynamic Compression Plate [DCP] fixation.

PATIENTS AND METHODS: This was a descriptive study during the period July 2011 to Nov 2013 done at Government medical college Thiruvananthapuram with 10 cases of humerus diaphyseal fractures. Only primary DCP failures of humerus and 316 L stainless steel implants were included irrespective of gender.

Secondary trauma, periarticular fractures, pathological fractures, infected implants and age more than 50 were excluded. Metullurgical study conducted at Sree Chithira Thirunal Institute for Medical Sciences and Technology [SCTIMST], Engineering & Biomedical technology wing, Poojappura, Thiruvananthapuram.

All cases were clinically analysed with patient's socioeconomic factors, fracture pattern and types, co morbidities, site of fracture. Initial fracture was analysed as location of fracture, whether open or closed and simple or comminuted. All were plated by anterolateral approach with plate on lateral side for humerus. All patients had immobilization for 4 weeks with U-slab. All patients had comparable postoperative period care. The eldest patient was 44 years of age, with no evidence of osteoporosis. Hence osteoporosis is not a confounding variable in this study.

In the cases studied fractures were assessed radiologically by two independent consultants, fractures assessed for type, combination, fixation quality, plate and screw adequacy were duly noted. Metallurgical study was based on "Retrieval and analysis of surgical implants by international standards ISO 12891."[6]

Three sets of orthopedic implant samples including fixation plates and associated screws were send for examination. These included a set of ten samples (Code CRY) which were retrieved after structural dysfunction (specifically fatigue fracture) after implantation in patients, a set of two samples (Code RSN), which were unused reference samples and a set of four samples which were used but without any structural dysfunction (Code RSU).

To remove the protein, samples were boiled in water for three hours. Components were boiled separately in order to prevent rubbing. After boiling, the components were dipped in diluted 3M Rapid Multi Enzymatic Cleaner.2% solution was used for soaking overnight. All the components were further cleaned in ultrasonic cleaner with 2% 3M rapid multi enzyme cleaner. All components were dried in a drier at a temperature of 60^{0} C for three hours. After drying all the components were packed in separate polythene covers for avoiding rubbing.

The micro hardness measurements were carried out on the same system used for the evaluation of coating adhesion studies (Micro–Combi Tester, M/s. CSM Instruments, USA). The areas of corrosion in metallic implants were identified and estimated using the digital microscope at magnifications 20X and 50X. The areas estimated were normalized against the years of implantation and the spread of corrosion with duration of implantation was estimated. The surface roughness of samples was measured by profilometry technique.

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The surface profile was obtained using Talysurf CLI 1000 (Taylor Hobson, UK) with the software Talymap Gold (version 4.1).Surface analysis showed three values-Ra, Rp and Rq. Of which Ra value is used to assess the pitting corrosion and Ra/Rp value shows crevice and intergranular corrosion.[6]

RESULTS: The eldest patient was 44 years of age, with no evidence of osteoporosis. Five patients (50%) were manual laborers, two (20%) students, two (20%) housewife and one (10%) having office job. Among the ten cases, failure occurred in 9 patients less than two years (90%) and one patient (10%) more than two years of putting implant. Three out of ten had open fractures (30%). None were primarily or secondarily grafted. The commonest recurring variable in preoperative evaluation radiologically was comminution of far cortex (70%) [Fig 1]. Another common recurring variable was leaving a free hole of DCP at fracture site (70%) [Fig 1].

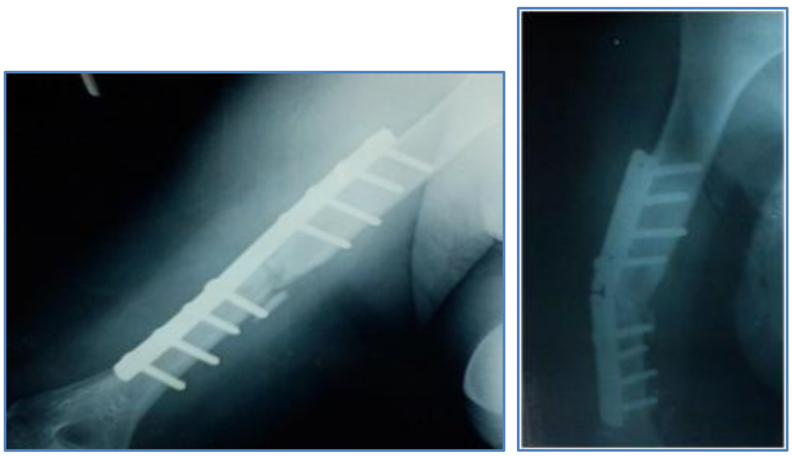

Fig. 1

As in the above figure [Fig 1], all cases except one fixation was found adequate with 4.5 narrow DCP with 8 screws (4 proximal and 4 distal to fracture. In all situations failure occurred near the initial fracture and the screw hole close to the fracture failed. The most common metallurgical change observed was corrosion mainly pitting corrosion(90%)especially at screw holes [Fig 2] which corroborated well with surface profilometric study (Ra value).

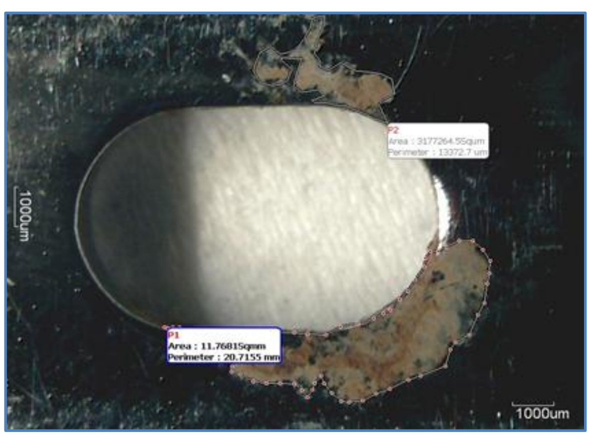

Fig. 2

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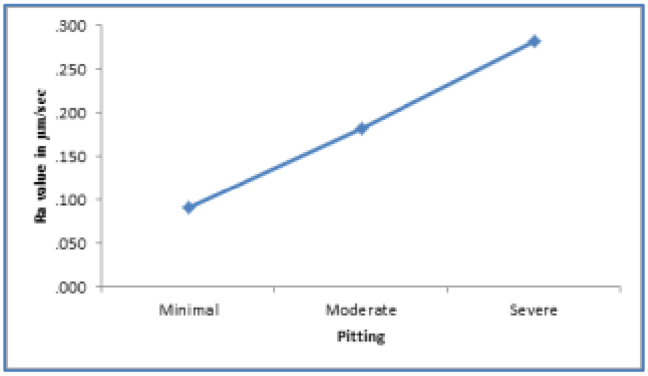

Fig. 3

Pitting corrosion	Frequency	Percent
Minimal	1	10.0
Moderate	6	60.0
Severe	3	30.0
Total	**10**	**100.0**

TABLE 1

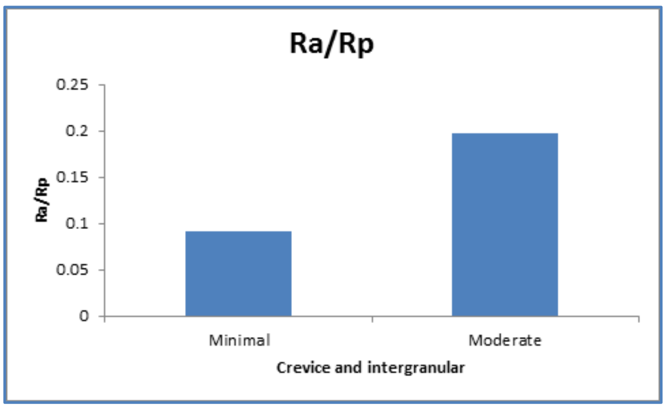

Fig. 4

Crevice and intergranular corrosion	Frequency	Percent
Minimal	7	70.0
Moderate	3	30.0
Severe	0	0
Total	**10**	**100.0**

TABLE 2

Ra and Ra/Rp values showed high values in some reference samples also.

Microhardness assessment [Fig5] showed significantly (P value -0.001) increased Vickers hardness values on used samples than unused. As the hardness increases implant becomes more brittle.[7] Infact used but unfailed reference samples (RSU) showed more hardness values than failed study samples (CRY).

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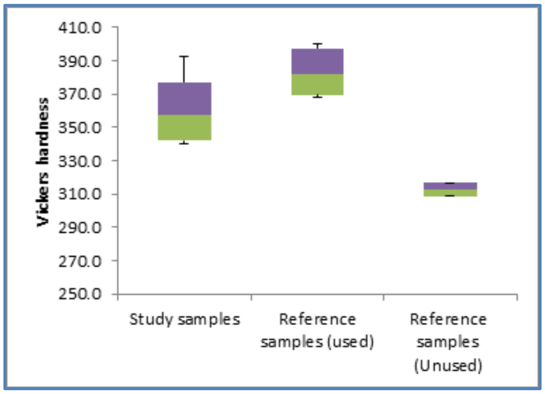

Fig. 5

FIG. 5: Box plot diagram describing Micro hardness evaluation among the three categories. Lower and upper end of the whiskers of the box plot represents the minimum and maximum hardness respectively. Lower border of the box (green coloured) represents the 25th percentile and the upper border of the box (purple coloured) represents 75th percentile. The middle line (line of separation of the two coloured box) represents the median hardnes in vickers.

DISCUSSION: The metallurgical analysis done at Sree Chithira Thirunal Institute for Medical Sciences and Technology [SCTIMST] does not show gross deviation in the quality of implants from accepted standards, to a level that it alone lead to failure. Commonest metallurgical change in comparison with reference implants, was corrosion, which was present in 90% of retrieved failed implants. The ratio of the Ra to Rp (crevice and inter granular corrosion) continues to be less than 1:6 (minimal) for majority (70%) of the explanted samples, which did not substantially changed during the course of implantation indicating that the corrosion of the metal surface due to pitting (Ra value) is the dominant factor (90% retrieved samples).

This study confirms that more than 90% of failure of stainless steel implants is due to pitting and crevice corrosion[8] and pitting corrosion shows only mild improvement with ion implantation, a usual method to increase corrosion resistance in stainless steel implants.[7] The corrosion was localized to screw holes and all implant breakage (100%) in this study occurred through holes which showed linear correlation. Moderate corrosion in some reference samples showed that along with metallurgical changes, biological factors (initial fracture pattern and quality of fixation) also contributed to failure. Microhardness assessment showed significantly increased Vickers hardness values on used samples than unused, infact used but unfailed reference samples (RSU) showed more hardness than failed study samples (CRY).

This might be due to the effect of work hardening[9] occurring in plate in vivo for longer period of bone consolidation compared to failed implants. The eldest patient was 44 years of age, with no evidence of osteoporosis. Hence osteoporosis is not a confounding variable in this study. The commonest recurring variable in preoperative evaluation clinically and radiologically was comminution of far cortex (70%), the next common variable was open wound (30%) and diabetes mellitus (20%). All these variables are present together in one case (10%). Implant failure in 100% cases occurred through screw holes which correlate well with corrosion studies. An empty screw hole is the culprit in majority (70%).Co morbidities like diabetes mellitus did not show a linear correlation with implant failure.

CONCLUSION: The humerus is the bone in which tension and compression sides were poorly defined.[10] This may be the reason for high degree of plate failures in humerus. Presence of far cortex comminution[11] in the absence of bone grafting was the commonest clinical cause of implant failure. Presence of an empty screw hole at fracture site increases the chance of implant failure. Commonest metallurgical cause attributable to implant breakage was corrosion especially pitting followed by crevice type. When more than two clinico-radiological and metallurgical factors coincided implants failed within two years denoting a cumulative effect (90% cases).

REMARKS AND RECOMMENDATIONS: Though sample size is limited, the study comprises only of humeral diaphyseal fractures in non-osteoporotic bone treated by Dynamic Compression Plate thus making it significant. It is advisable not to leave a screw hole vacant adjacent to the fracture site wherever possible. The threshold for primary bone grafting[12] by clinicians in presence of comminution should be low. Training of junior surgeons and theatre sisters in proper handling[13,14] of implants should be emphasized. Corrosion is prevented metallurgic ally by passivation[13,14]which creates a corrosion resistant oxide coating. Proper analysis of procurement of raw material, manufacturing techniques and design of orthopedic implants by manufacturers should be scrutinized on a regular basis to ensure adherence to accepted standards

FUTURE DIRECTIONS: Larger multicentric continuation study is recommended. It is advisable to keep a confidential registry of all implant failures at least at regional level with emphasis on type of implant, fracture characteristics, etc. All broken implants should be sent for metallurgical analysis

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