

An Audit of Implant Failure in Orthopedic Surgery

Sanallah, Muhammad Inam

ABSTRACT

Objective: To determine the causes of orthopedic implants failure, which is being used in our setup for fixation of different fractures.

Materials and Methods: The study was conducted at Orthopedic and Spine surgery unit of Hayatabad Medical Complex (HMC) Peshawar from November 2007 to May 2014. A total of 62 patients were retrospectively identified and included in the study. The inclusion criteria was adult patients of both gender under 45 years of age, who presented to our unit with complaints of pain, deformity or inability to bear weight after fixation of fracture of either limb. Exclusion criteria were age above 45 years, pathological fractures, diabetes mellitus, recent significant trauma, radiologically osteoporotic bones of any cause and infected implants. Type of fracture and implant used whether proper or not and adherence to AO trauma surgery principles were also assessed.

Results: A total of 62 patients admitted with broken (failed) implants. There were 55 male and 7 female with a mean age of 38 years (18 to 45 years). They presented with failed DCP, ILN, Dynamic Hip Screw, Dynamic compression screw, IM nail, Schanz screws, Austin moor prosthesis and AO cannulated screws

Conclusion: The most important causes of implant breakage are combination of biological and metallurgical. Commonest metallurgical cause attributable to implant failure was corrosion. Biological causes include selection of implant, surgical techniques, post operative care and fracture geometry.

Key Words: Broken implants, corrosion, implant failure

INTRODUCTION

Orthopedic fractures are basically divided into open and close fractures. Generally fractures are either treated by conservative or operative methods. Both have advantages and disadvantages over each other. Conservative method has the disadvantages of joint stiffness, non-union, mal union, pressure sores, regional osteopenia and disuse atrophy of the limb. On the other hand reduction and internal fixation provide immediate stability and postoperative mobility or at least active and passive exercise of the operated limb and avoids all the complications of conservative treatment. Operative method has the disadvantages of blood loss, neurovascular injury, infection, non-union and implant failure¹. Failure of orthopedic implants before union of fracture seems to be more common in our country.

Causes of orthopedic implant failure (breakage) are related to quality of implant, surgeon's experience and adherence to AO principles, selection of proper type of implant for particular fracture type and post op care particularly weight bearing in lower limbs surgery^{2,3}. Patients with implant failure usually present with pain and deformity of the operated limb, it may or may not be related with a recent trauma⁴. Patients admitted with failed implant face psychological stress and financial burden because they have already lost many working days and spend more on the primary surgery. For orthopaedic surgeon these revision surgeries become challenging because the tissue planes are scared and retrieval of broken implants are always a difficult job^{5,6}. Chances of neurovascular injury infection and fixation failure are more. Orthopedic implants include plates, nails, screws, wires and joint prosthesis^{7,8}. If the composition of these implants is substandard, chances of their failure are more^{9,10}. Previous studies have demonstrated that quality of implant is the main cause of implant failure^{11,12}. Other studies have shown that early weight bearing may be the main cause of early implant failure¹³. In our study we have focused on metallurgic as well as on biological causes i.e., pattern of fracture, type and size of implant, adherence to AO trauma

Senior Registrar Department of Orthopedic and Spine Surgery Hayatabad Medical Complex Peshawar KPK

Correspondence: Muhammad Inam

Email: dr_mohammadinam@yahoo.co.uk

surgery principles and post op weight bearing. We are of the opinion that when two or more than two causes coincide together implant fail early. Hence this study was designed to find out the causes of orthopedic implant failure.

MATERIALS AND METHODS

This study was conducted at Orthopedic and Spine Surgery unit Hayatabad Medical Complex (HMC) Peshawar. The inclusion criteria was adult patients of both gender under 45 years of age, who presented to our unit with complaints of pain, deformity or inability to bear weight after fixation of fracture of either limb. Exclusion criteria were age above 45 years, pathological fractures, diabetes mellitus, recent significant trauma, radiologically osteoporotic bones of any cause and infected implants. Initially 158 cases presented with complaints of pain, deformity or inability to bear weight after fixation of fracture of either limb were studied, 51 patients had infected implants, 23 patients were either above 45 years age or had evidence of osteoporosis, 13 patients had incomplete documentation and 9 had incomplete x-rays either pre operative or post operative. All these patients were excluded from the study. 62 patients were included and studied in detail with emphasis on mechanism of initial trauma, whether open or close fracture, type of initial treatment or fixation, co-morbid, associated injuries or fractures, type of surgery and implant used, time between trauma and surgery, any pre operative or post operative complication, pre operative and post operative radiographs, post op care specially weight bearing in lower limbs surgery, and recent event which led to implant failure. Pre and post operative x rays were studied for type of fracture and type of implant used whether proper or not and adherence to AO trauma surgery principles were also assessed. For DCP in upper limb surgery at least 4 cortices above and below should be engaged, in lower limbs 8 cortices above and below should be engaged with appropriate size screws. In interlocking nail maximum reaming should be done according to medullary cavity size and one or one and half size smaller nail than last reamer should be used. In addition proximal and distal locking should be done with 2 screws each. Similarly in external fixation 2 schanz screws should be applied above and below for upper limb fracture and 3 schanz screws above and below for a lower limb fracture. In DCS and DHS at least 6 to 8 cortices should be engaged depending upon the

fracture pattern. At least 3 AO screws should be used for fixation of femoral neck fracture). Recent x-rays were studied for level of implant failure, screws failure, non-union or mal union and for planning retrieval of broken implants. In revision surgeries effort was made to assess the size of implant and screws and its appropriateness, any signs of corrosion, erosion or any welding of implants and any signs of infection.

RESULTS

Out of the 62 patients of broken implants, 55 (88%) were the male while 07 (12%) patients were female. Mean age of the patients was 38 years (18 to 45). Most of our patients were in third decade of their life. Most of the broken implants removed from the patients, were locally made and only 2 were imported. These foreign made implants included 2 intramedullary interlocking nails. Local implants were having no manufacturing company mark on them most of screws were deformed and many showed corrosion. Distribution of these failed implants is shown in (Table 1). We identified combination of causes of breakage / failure of these implants which are shown in (Table No 2). There were few cases in which there was no apparent cause of breaking of implants but all these implants were locally made.

All the failed implants were broadly divided into 7 groups. There were 14 (22%) failed DCP (dynamic compression plate) implants including broad base DCPs, narrow base DCPs and small fragment DCPs, main cause of failure in this group was metallurgic (78%), inappropriate surgery and opposite cortex comminution were the biological causes. Most of the DCPs failed at or near fracture site. Failed Intramedullary interlocking nails were 13 (21%). Most of the initial fractures were comminuted or had distraction at fracture site in which case the whole weight was taken by the implant and chances of failure increased. Moreover in many cases smaller ILNs both in length and width were used. Often a vacant distal locking hole was present. Distal and proximal locking screws were either too short or too small and diameter of the screws was small from the standard imported implants. The proximal broken point was actually a welded area, which failed under stress. Fracture site had little comminution. In this case diameter of the nail was 9 and one distal locking hole was left vacant. In revision surgery 13 sizes nail was used and both the distal holes were locked so there was combination of

metallurgic and biological causes for implant failure. Failed intramedullary nail (IMN) implants were 5 (08%). All were locally made implants, 3 were broken and 2 were bended. Broken dynamic hip screws (DHS) were 12(19%). In 11 (92%) cases there was single cause and that was quality of implant. In one case there was breach of basic AO principles. In dynamic compression screw (DCS) group there were 8 (13%) failed implants, Faulty implant, inappropriate surgery and early weight bearing was the combination of causes.

Failed schanz screws were 5 (08%). All had erosion or corrosion as the metallurgic cause and in all cases there were inadequate number of cortices engaged which exposed the low quality screws to high stress and they ultimately failed. Austin Moor prosthesis and AO cannulated screws (for neck of femur fracture fixation) were 3 (5%) and 2 (3%) respectively. In this group the reason of failure was low quality of the implant.

Table 1: Distribution of failed implants (n=62)

Name of Implants	No. of Broken Implants
DCP	14 (22%)
ILN nails	13 (21%)
Dynamic Hip Screw (DHS)	12 (19%)
Dynamic compression screw(DCS)	08 (13%)
IMN nail	05 (08%)
Schanz screws	05 (08%)
Austin moor prosthesis	03 (05%)
AO cannulated screws	02 (03%)

Table 2: Major Causes of broken implants (n=07)

Name of Implants	Causes
DHS group	Faulty implant (92% of the cases) plus inappropriate surgery
DCS group	Faulty implant (75% of the cases) plus inappropriate surgery and early weight bearing
ILN group	Faulty implant (77% of the cases) plus inappropriate surgery and early weight bearing
DCP group	Faulty implants (78%) plus inappropriate surgery and opposite cortex comminution
IMN group	Faulty implant (100%) plus inappropriate surgery
Schanz screws group	Faulty implant (100%) plus inappropriate surgery
Austin moor prosthesis and AO cannulated screws group	Faulty implant (100%)

DISCUSSION

Orthopedics implants are being used since last century^{14,15}. When used in fracture management they act as weight bearing or weight sharing devices. Chances of implant failure in weight bearing implants are more as compared with weight sharing devices as some of the body weight being taken by own bone in later¹⁶. Metals SS 316L are most commonly used in orthopedic surgery because of their properties of stiffness, strength, ductility, corrosion resistance and

biocompatibility^{17,18}. In this study we found that implant failure is the outcome of combination of causes like quality of implant, selection of implant, quality of fixation, geometry of fracture and post operative care (protective weight bearing). 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. Local implants used in our country are not of international standard and they fail early as shown by our results i.e., only 2 imported failed in our

study. Apart from quality of the implant, second important aspect is selection of implant for particular fracture type and technique of application according to recommended principles of AO trauma group, for example, while fixing long bones diaphyseal fracture with a broad base DCP (dynamic compression plate) eight cortices should be engaged both proximally and distally. In addition technique of compression at fracture site should be used so that there should be no gap at fracture site. This technique may not be applicable in oblique and spiral fractures and another technique of lag screw can be used. In this study, it was found that improper size of plates and screws were used in most of the cases. The principles were not followed. In interlocking nails group again the principles were not followed. Most of the nails and locking screws selected were smaller in size. Inadequate numbers of proximal and distal locking screws were used and postoperative care was not proper. Patients admitted with failed implant face psychological stress and financial burden because they have already lost many working days and spend more on the primary surgery. For orthopedic surgeon these revision surgeries become challenging because the tissue planes are scared and retrieval of broken implants are always a difficult job. Chances of neurovascular injury infection and fixation failure are more. Therefore, it is highly desirable to keep the number of failures to a minimum. Hence, the determination of the mechanism that caused failure of an implant is not only important but also necessary to explore the event or sequence of events, which caused the particular mechanism(s) to become operative. Furthermore, failure investigation will help to improve the total performance of implant devices, besides revealing the details of the mode and origin of the failure mechanism. As a basic rule, none of the well-defined surgical principles is to be violated while treating any surgical patient. The successful treatment is the one in which patient is rehabilitated till his returning to normal life. Thorough counseling of the patient is obligatory before commencement of any treatment. It is the responsibility of the surgeon to execute the desired postoperative care. Patient must be educated about the dos and don'ts of a local or a branded high quality orthopedic implant and should be given a choice to select one. In addition clear instructions regarding postoperative weight bearing should be given to the patients. Orthopedic

surgeons should discourage use of substandard or used (second hand) implants.

CONCLUSION

The most important causes of implant breakage are combination of biological and metallurgical. Commonest metallurgical cause attributable to implant failure was corrosion. Biological causes include selection of implant, surgical techniques, post operative care and fracture geometry. When more than one biological and metallurgical factor coincided, implants failed within two years denoting a cumulative effect.

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