Original Article

Broken Orthopaedic Implant: An Experience at PIMS

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Objective: **To determine the causes of broken implants which are being used locally for fixation of different fractures.**

Study Design: **Case series study.**

Place and Duration: **This study was conducted at the Department of Orthopaedic Surgery, Pakistan Institute of Medical Sciences (PIMS) from May 2, 2006 to April 30, 2009.**

Materials and Methods: **The study included adult patients of either gender, reporting to the O.P.D. of Orthopaedic Surgery, with complaint of pain, deformity and loss of function after open reduction and internal fixation or external fixation of either limb.**

Results: **Out of thirty nine patients, 35 were males and 4 were females. They presented with broken dynamic compression plates, interlocking nails, K-nails, rush nails and Schanz screws.**

Conclusion: **The most important cause of implant breakage is its quality. Orthopaedic implants, either nails or plates when used for fracture fixation, act as weight sharing or weight bearing implants and are exposed to tremendous stress till the fracture unites. Quality of the implants should not be compromised and strict adherence to surgical principles should be ensured.**

Key Words: ***Broken implants. Open reduction and internal fixation.***

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Introduction

The main objective of the treatment of the fractured bones is that the bone should heal in such position that the function and cosmesis of the limb is not compromised. Generally, the methods of definitive treatment are conservative and operative. Most of the time, the end result of the conservative method is joint stiffness, soft tissue atrophy, osteoporosis and chronic oedema of the limb. To address these problems, open reduction and internal fixation was the break through in the history of fracture management when used in 1886. Later on, in 1970, Lane used plates and screws which were ordinary steel made but the problem was metallic corrosion, loosening, breaking of implants and chronic inflammation. [1-3] Significant developments have been taking place to provide suitable biomaterials from metals/ alloys, ceramics bio-glasses, and polymers with minimal reaction and rejection by body. [4-6]

The most dramatic innovation in the internal fixation was development of a system of rigid fixation with plates and screws by the A O / ASIF group. [7, 8] Their objective has been to make the fracture fixation so stable that immediately after the operation patient can do active exercises of muscles and joint. They have been able to address the problems related to conservative treatment. Metals were found as material of choice for implant manufacturing because they offer high stiffness, strength, good ductility and good biocompatibility. To achieve this aim along with innovation in the techniques of application of implants, the special emphasis was on the improvement of metallurgy of the implants to avoid problems faced with use of ordinary steel made implants. [9] Apart from metals, ceramics, titanium, titanium alloys, polymers carbon composites and degradable materials are being used for different implants and prosthesis. [10]

The present study was undertaken to determine the causes of broken implants which are being used locally for the fixation of different fractures.

Materials and Methods

This study was conducted at out patients Department (OPD) of Orthopaedic Surgery, P.I.M.S Islamabad from May 2, 2006 to April 30, 2009. Detailed clinical history was obtained from every patient with emphasis on mechanism of previous injury, initial management, definitive management, place of surgery, date of surgery, post operative management, and mechanism of recent injury (if any). An effort was made to collect the pre-operative and post-operative

radiographs of the patient to asses the configuration of the fracture, type of implants used and method of fixation of the fracture. Fresh x-rays were done to see the status of bone, level of breaking of implant, loosening, nonunion, and obviously for planning of revision surgery. While performing revision surgery findings like erosions / scratches, welded area over the implants and corrosion including rusting around the broken implants were noted. The special stress was to know whether the implant is locally made or imported one.

Results

Out of the 39 patients of broken implants, 35 (90%) were the male while 04 (10%) patients were females. Mean age of the patients was 39.5 years with range 23 to 56 years.

Most of our patients were in fourth decade of their life. Out of 39 implants retrieved from the patients, 37 (95%) were locally made and only 2 (5%) were imported. These foreign made implants included an intramedullary interlocking nail of femur and a broad based Dynamic Compression Plate (DCP). Local made implants were with out any manufacturing mark on them, the head of screws were deformed and many showed rust around the implants due to corrosion.

Majority of the patients presented with broken dynamic compression plates which were used to fix the fractures of long bones, the distribution of different types of broken implants is shown in Table No I.

We identified the causes of breakage / failure of these implants which are shown in Table No II. We were able to find even more than 1 cause of broken implants in some patients. There were also few cases (n=4) in which we were not able to find any specific cause of breaking of implants but all these implants were locally made.

All the implants were thoroughly examined after their removal. Faulty implants had the findings shown in Figure I.

Table I: Distribution of implants removed from patients (n=39)

Name of Implants	No. of Broken implants
Broad Base DCP	12
Narrow Base DCP	10
Dynamic Hip Screw (DHS)	03
Dynamic Compression Screw (DCS)	01
Angled blade plate	01
Recon plates	03
Small Fragment DCP	02
I / M nails	05
Schanz screws	01
Rush nail	01

Table II: Causes of broken implants (n=39)

Cause of Broken Implant	No. of Broken implants
Inappropriate surgery	13
Improper postoperative care	10
Faulty implant	21
No cause found	4

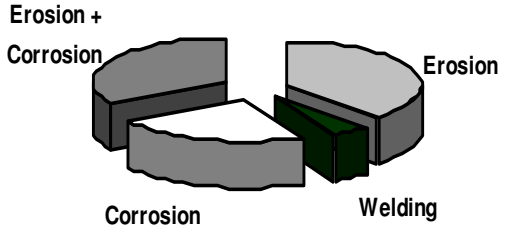

Figure I: Findings of the faulty implants

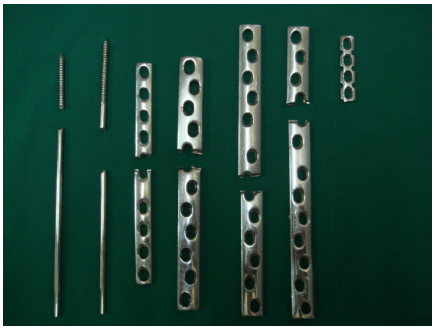

Figure II: Broken Schanz screws, dynamic compression plates and reconstruction plate.

Figure III: Broken reconstruction plate in a patient with humerus fracture

Figure IV: DCP broken for fixation of humerus shaft fracture.

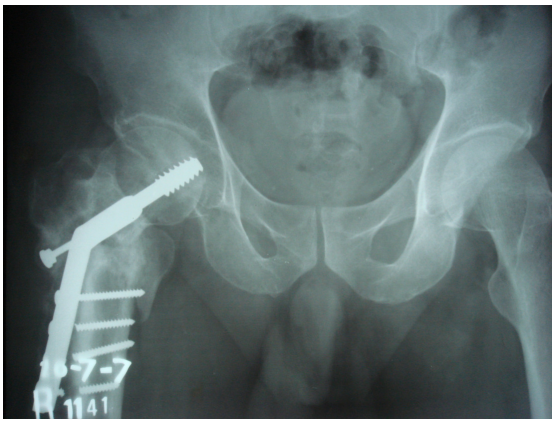

Figure V: X ray of a patient with intertrochanteric fracture and broken implants (DHS)

A 36 year old male, who had fracture shaft of right tibia and was fixed with inter locking nail presented with complaint of pain after 3 months of surgery. He was walking with help of crutches and putting weight on operated leg for last 2 months. X-ray right leg revealed non-union with broken nail at the site of fracture. On revision surgery it was found that ordinary K-nail was converted into an inter locking nail by drilling hole in its proximal and distal ends. This operation was performed in a private hospital in the periphery of Rawalpindi / Islamabad.

Another young man who had open fracture left femur stabilized with local made external fixator with two Schanz screws on each side of the fracture presented with broken Schanz screws without knowing what happened.

A 50 year old male who had fracture shaft of left femur was fixed with intramedullary nail about 20 years before and he was walking on non-united fracture and ended up with breaking of implant from one of the proximal interlocking holes.

A 30 year old man presented with a broken rush-nail which was used to fix fracture shaft of humerus about 3 years before (Figure No VI).

Analytic study of a locally made broken implant is indicated in Table III.

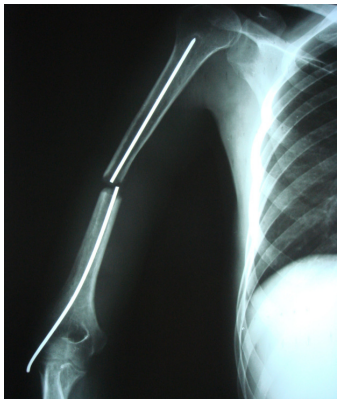

Figure VI: A broken rush nail in humerus

Table III: Metal analysis of an implant removed from our patient

METAL (CONTENTS)	PERCENTAGE
Chromium	18%
Nickel	8%
Molybdenum	0.4%
Manganese	2%
Carbon	major content

Discussion

Implants used for osteosynthesis restore bone stiffness temporarily by acting as either weight bearing or weight sharing till the fracture union restores bones stiffness permanently. Implants material used for internal fixation must conform to certain basic requirements like reliable function and minimal side effects. Orthopaedic implants are artificial mechanical devices, when mounted to the skeletal system of the human body are exposed not only to the stress of muscular forces of the limbs but exposed to living cells, tissues and biological fluids which are not only dynamic but a hostile environment for the survival of the implant.[11] So, the orthpaedic implants must conform to some special requirements like good fatigue resistance and ductility so as to maintain strength after having been adopted to the bone surface. Moreover, the stress relaxation by the implant should be minimum to maintain

compression and the material should not degrade in an uncontrolled way. Metals SS 316L have a long history of use in orthopaedic surgery because of their properties of stiffness, which prevents buckling at the fracture site; strength which resists deformation of implant under repeated load; ductility for the degree of plastic deformation it tolerates before rupture; corrosion resistance and biocompatibility. [12, 13] The composition of standard metals internationally recommended for orthopaedic implants is shown in Table No IV. [14] However, analytic study of the locally made broken implant (Reconstruction plate) removed of one of our patients showed composition of the metal revealed in Table III.

Table IV: Recommended composition of orthopaedic implants

METAL (CONTENTS)	PERCENTAGE
Chromium	17-20%
Nickel	12-14%
Molybdenum	2-4%
Manganese	2%
Carbon	0.03%

This analysis done at AAS lab of central analytic facility division of Pakistan Institute of Nuclear Science and Technology (PINSTECH) clearly indicates that the locally made implants are substandard in quality and can not conform to the required properties of implants. Apart from quality of the implant, the important aspect of the implant use is selection of implant and technique of application in different fractures according to recommended principles of AO and ASIF group e.g. when a broad base dynamic compression plate is used in fracture shaft long bones, at least 8 cortices should purchase on either side of the transverse fracture and there should be no fracture gap at fracture site where as in spiral and oblique fractures the principal of the lag screw should be applied. [15-17] In this study, it was found that inadequate number of cortices have been purchased, there was distraction at fracture site, screws were placed through the fracture site or a vacant hole was at the level of fracture site and the size of screws was either too short or to long. Similarly, in interlocking nails the set principles were not followed. Instead of using gold standard intra-medullary interlocking nails, ordinary K-nails were used. As mentioned in results, in one of our patients, K-nail was converted into interlocking nail by making hole in proximal and distal part of the nail.

In every failure of an orthopaedic implant, the patient is made to experience the physical and psychological trauma of repeated surgery, besides the severe pain experienced during the process of rejection of the device. The removal of the failed implant causes great expense and hardship to the patient. These revision surgeries are mostly very difficult, demanding and time consuming.[18] Complication rates are much higher as compared to the primary surgeries. 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 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.

To improve the overall situation regarding these broken implants in a country like Pakistan, we suggest certain measures that are necessary on individual and government level. 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 counselling 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 the rehabilitation phase specially about weight bearing after orthopaedic surgery of lower limbs. We can't deny the fact that most of our population can't afford imported and branded high quality orthopaedic implants. For these patients, quality of the local made implants should be raised to international standards. Orthopaedic surgeons should discourage use of substandard implants. Strict legislation is desired regarding implant manufacturing and distribution. All this manufacturing should be monitored and controlled by a body working under umbrella of Health Ministry and Government of Pakistan.

Conclusion

The most important cause of implant breakage is its quality. Orthopaedic implants, either nails or plates when used for fracture fixation, act as weight sharing or weight bearing implants and are exposed to tremendous stress till the fracture unites. Quality of the implants should not be compromised and strict adherence to surgical principles should be ensured.

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