Failed Osteosynthesis: Responsible factors, management and Its Outcome

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ABSTRACT

Objective: To examine the factors responsible for implant failures and the management outcomes in our practice
Methods: The data of patients with failed osteosynthesis from January 2018 to December 2020 was analyzed. Information on socio-demographics, main presenting complaint, patients' clinical features, indications for osteosynthesis, duration from surgery, bone involved, imaging features, type of implant used, factors responsible for implant failures, assessment of the challenges of Management and Management outcomes were retrieved from the patients' case files at medical record department of the hospitals. Data was subjected to analysis with SPSS software. Patient with incomplete documentations were excluded. The inclusion criteria include all patients diagnosed with failed osteosynthesis, who were able to provide history or had reliable informant(s) to provide history and those with detailed medical reports from other hospitals where the osteosynthesis was done.
Results: Fifty-three patients studied, out of which 46 (86.8%) males and 7 (13.2%) females in the age group of 7-69 years with a mean age of 37.5 years. Fresh fracture was the highest (58.5%) indication for the surgery that failed. The other indications were malunion (20.8%), non-union (14%) and pathological fracture (7.5%). All the patients had operation with 32.1% of them had implant removal alone because revision was not necessary, 24.5% had revision alone while the rest (43.4%) had exchanged implant with a biologically and biomechanically more superior implants. The study revealed that many (85%) had satisfactory results as revision surgery.
Conclusion: The study revealed non-compliance with post-operative protocols as the commonest causes (28.3%) of failed implants followed by re-trauma (17%) and non-union (17%) respectively while femur is the commonest (45.3%) bone with failed implant. Many (65%) of the patients presented with combination of symptoms which necessitated revision osteosynthesis with a superior implant. Even though, the management of these patients were challenging but many (85%) had satisfactory results. Orthopaedic surgeons are encouraged to review the principles to individualized the patient's management protocols and risk of implant failure with adequate measure to prevent

Key words: Failed osteosynthesis, responsible factors, implants, challenges, management outcome

INTRODUCTION

Osteosynthesis can be defined as a surgical procedure that stabilizes and joins the ends of fractured fragments together by mechanical devices such as metal plates, screws, pins, wires or intra-medullary nails (Moy et al., 2005; Peivandi et al., 2013). Osteosynthesis refers particularly to internal fixation of a fracture by such means, as opposed to external fixation of a fracture by a splint or cast.

The modern practice of facture care as influence by socioeconomic demands of patients and relative has being satisfactorily achieved by early anatomical fracture union and maximal functions of the patient as result of appropriate implants use (Moy et al., 2005). The role of the implant in fracture care is to keep the fracture fragments together until union is achieved and strong enough for normal function required by the activity of daily living (Moy et al., 2005; Peivandi et al., 2013; Buckley et al., 2017). The success of osteosynthesis is dependents on a multiple and spectrum of factors such from the implant metallurgical characteristics, patient's level of co-operation with the quality of bone or fracture type and pattern and also the surgeon's skills, choice and methods of osteosynthesis. It is of surgical interest to research into risk factors or causes of implants failure to serve as basic measures to prevent failed osteosynthesis. The attention has been on the development of implants which are cheaper, durable, stronger, bio-compatible, acceptable and easy to use by the surgeons. Failed osteosynthesis is said to have occurred when the implants fail to achieve its functions expected by its manufacturers or the health care providers (Moy et al., 2005). Orthopaedic implant failure may occur before healing strength is strong enough to withstand normal physiological demands of the fractured bone.

After the initial resuscitation and stabilization of a patient with fracture then the treatment of the fracture comes next (Peivandi et al., 2013). This consists of reduction/manipulation of fracture fragments to improve the position of the fragments, followed by splintage until they unite meanwhile joint movement and function must be maintained as much as possible. Fracture healing is promoted by physiological loading of the bone by encouraging muscle activity and early partial or full weight-bearing (Moy et al., 2005; Peivandi et al., 2013). These three objectives of fracture reduction, stabilization and functional maintenance are easily and better achieved by osteosynthesis ((Moy et al., 2005; Peivandi et al., 2013; Buckley et al., 2017). Stable fixation of fractures is a necessity for the immediate mobilization of patient after surgery and to actively exercise the joints and muscles. The orthopaedic implants have been in use for osteosynthesis worldwide for over a century to achieve these purposes (Moy et al., 2005; Buckley et al., 2017).

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The Foundation's Association for the Study of Internal Fixation focused and promoted principles of fracture fixation with implants in the form of plates and screws (Moy et al., 2005; Buckley et al., 2017)

Mechanically, failure of implants is categorized into: plastic, brittle, fatigue failure or loosening. It is called plastic failure when the device fails to sustain its original configuration and this leads to the eventual clinical failure (Sharma et al., 2006; Navarro et al., 2008). When the implant has primary defect in its design or metallurgy and leads to clinical failure, it is known as brittle failure while in fatigue failure, there is repetitive loading which eventually weaken the device and leads to clinical implant failure (Sharma et al., 2006; Navarro et al., 2008). Loosening occurs when there is weakness in the bone and eventually screw became loose or reverses the primary position (Sharma et al., 2006; Navarro et al., 2008). Therefore, mechanical failure of implants may be as a result of spectrum of risk factors such screws holding strength of the bone and physical strength of the plate and screws. Hence, orthopaedic surgeons should consider the importance of maintaining implant strength till the healing strength takes over the weakness caused by fracture (Sharma et al., 2006; Navarro et al., 2008).

The biomechanical characteristics of orthopaedic implants depend on material properties and structural properties as well as implant positioning. The development of the modern orthopaedic implants is currently targeting a device with more strength, biocompatibility, cost effectiveness, durability and safety with ease of positioning or anatomical friendly (Moy et al., 2005; Buckley et al., 2017). It paramount that biomechanical properties must include safety, resistance to corrosion, erosion, and adaptation to biological milieu (Navarro et al., 2008).

Failed osteosynthesis or failed Implant can be defined as the failure of the implant/ prosthesis to fulfil its purpose by the manufacturer or the surgeons due to biomechanical reasons (Chen et al., 2014; Buckley et al., 2017). Implant can also be

said to have failed when there is a need to remove the implant prematurely due to its unmet function. So, orthopaedic implants fail due to stress shielding as result of implant faulty placement, bone resorption or bone weakening/ osteoporosis as a result of reduced physiological bone loading (Chen et al., 2014; Buckley et al., 2017).

The management of patients with failed osteosynthesis could be highly challenging with likely huge socio-economic and psychological consequences on the patients, hospital facilities and caregivers especially the surgeons with higher risks of morbidity and even mortality (Liu et al., 2020; Müller & Frosch, 2021). The Revision surgery for failed implant is usually more difficult, technically more demanding and time-consuming than the initial surgery (Liu et al., 2020; Müller & Frosch, 2021).

The objective of this study was to examine the factors responsible for failed osteosynthesis as well as the challenges and management outcome of patient with failed osteosynthesis.

MATERIALS AND METHODS

Prior to the commencement of the study, Ethical clearance was obtained from the Hospital Research and Ethical committee. This was two-year prospective study of patients who had failed implants from January 2018 to December 2020.

The Information on socio-demographics, main presenting complaint, patients' clinical features, indications for osteosynthesis, duration from surgery, bone involved, imaging features, types of implants used, factors responsible for implant failures, type of implant failure, assessment of the challenges of Management and Management outcomes were retrieved from the patients' case files at medical record department of the hospitals.

Patients with incomplete case file documentations were excluded from the study. The inclusion criteria were: All patients diagnosed with failed osteosynthesis, Patients who were able to provide history, Patients who had reliable informant(s) to provide history and those with detailed medical reports from other hospitals where the osteosynthesis was done.

A questionnaire was employed to retrieve the information needed from patients' case notes and other details such as presenting complaint, current patient's clinical status, previous and current imaging findings, current treatment offered when indicated and intra-operative findings on implants and bone were also noted. The general outcome of the treatment was assessed at 6 months by subjective patient's self- assessment using Likert scale.

The data was subjected to analysis using IBM SPSS version 22.0 in form of descriptive statistical analysis, frequency, charts, tables and percentage were used for the categorical and ordinal variables. Mean, median, range and standard deviation were used for the continuous variables

RESULTS

Out of the 86 patients, 53 patients met the study criteria were studied. Majority of the patients were males 46 (86.8%). The age range of the patients was 7-69 years with a mean age of 37.5 years. Of all the cases, 22.6% had initial osteosynthesis in the study centre while the remaining 77.4% of the cases self-presented or were referred from other facilities for expert care at the study centre.

The commonest indication for the initial osteosynthesis was fresh non-pathological fracture (41.5%) followed by malunion (30.2%) (Figure 1)

Most patients (65.3%) presented with combinations of symptoms (Figure 2).

Non-compliance with post-operative protocols was the commonest) cause of failed osteosynthesis (28.3%. Femur was the commonest bone with failed implant (45.3%) (Table 1)

Five-point seven percent (5.7%) of the patient presented with advanced stage of fracture healing, hence cast was used. The majority (67.9%) of patient required similar but superior implants. Of which 26.3% had exchanged implant with a biologically and biomechanically more superior implants such as conventional Broad Dynamic Compression Plates (BDCP) replaced with Limited Contact- Broad Dynamic Compression Plates (LC-BDCP), Anatomical Locking Compression Plates, Locked Intramedullary Nailing or external fixation where appropriately indicated (Figure 3).

Bone grafts were utilized in more than two thirds (68.4%) of the patients (Figure 4). Using subjective self- assessment, patients rated their management outcomes as excellent (20.8%) and good (43.4%) (Figure 5).

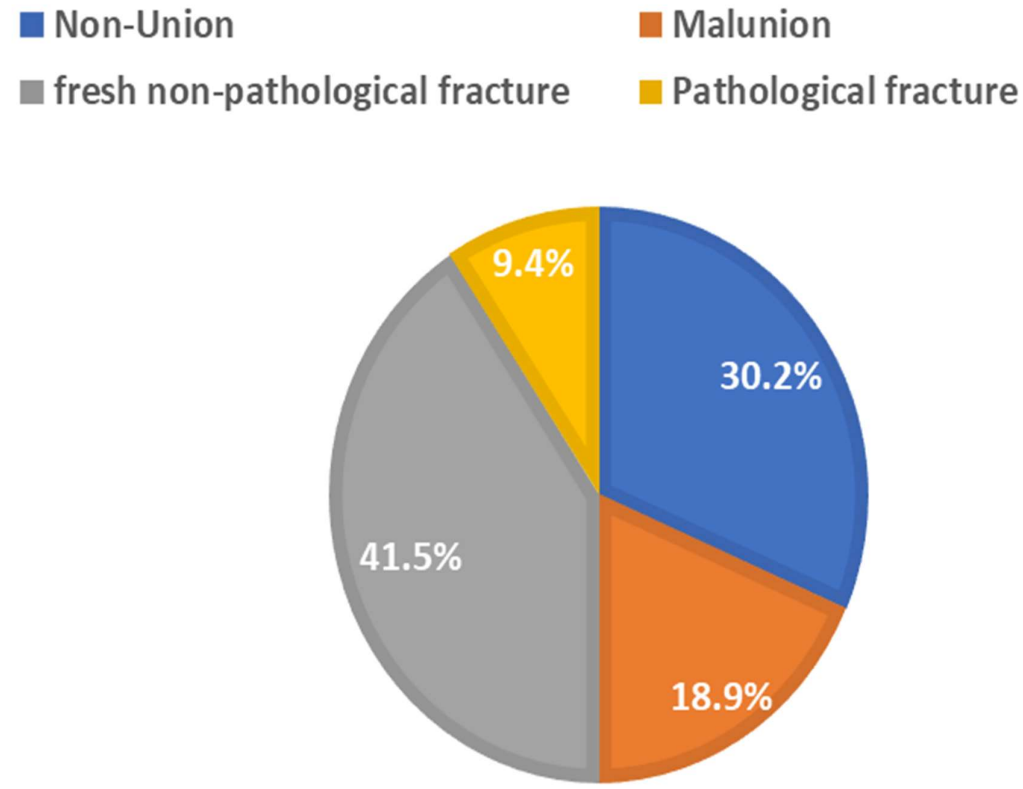

Figure 1: Indications for the initial Osteosynthesis

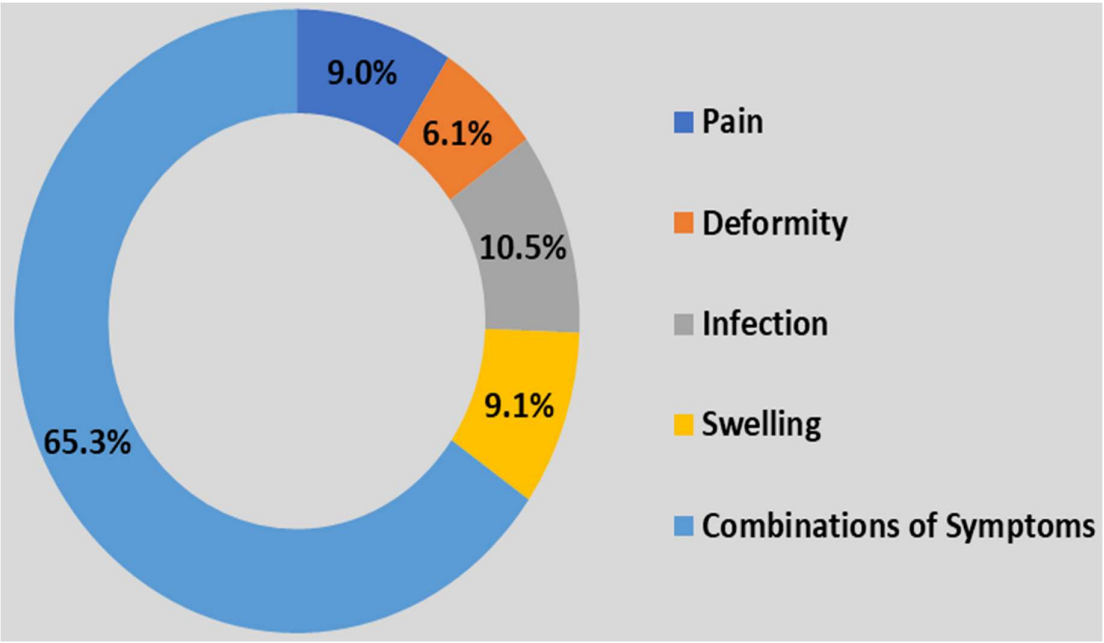

Figure 2: Major complaints at presentation for implant failure

Table 1: Causes of failed implants and bones involved

Causes/Risk factors	Bones					Total n (%)
	Radius/ Ulna	Humerus	Femur	Tibia/ Fibula	Clavicle	
Infection	1	1	1	1	0	4 (7.5)
Mal-positioned implant	1	1	3	0	0	5 (9.4)
Re-trauma	1	1	5	2	0	9 (17.0)
Non-compliance	2	4	6	2	1	15 (28.3)
Non-union	0	2	4	2	1	9 (17.0)
Iatrogenic by physiotherapy	0	1	1	1	0	3 (5.7)
Wrong choice of implant	0	1	2	0	0	3 (5.7)
Weight lifting/Sport	1	1	0	0	0	2 (3.8)
Unknown	0	1	2	0	0	3 (5.7)
Total n ((%))	6 (11.3)	13 (24.5)	24 (45.3)	8 (15.1)	2 (3.8)	53 (100.0)

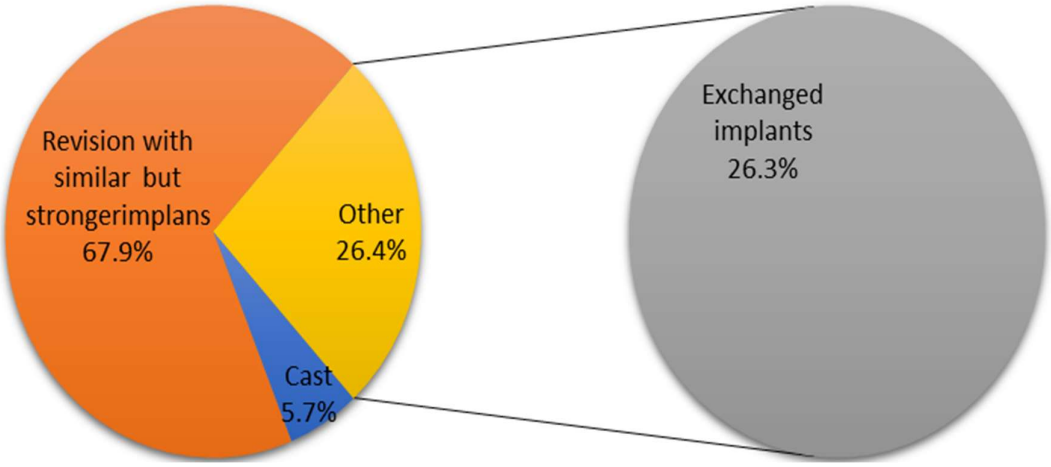

Figure 3: Methods of fracture stabilizations following removal of the failed implant

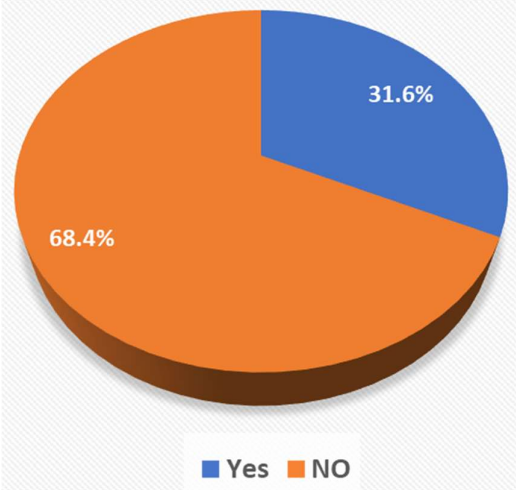

Figure 4: Utilization of bone grafts

Figure 5: Management outcomes by subjective patient's self- assessment using Likert scale

DISCUSSION

Fifty-three patients were studied out of which 46 (86.8%) males and 7 (13.2%) females in the age group of 7-69 years with a mean age of 37.5 years. This higher frequency of male gender and age distribution are likely to be due to the fact that males have higher incidence of injuries that lead to the initial fracture that was operated and also likely with higher risks of implant failure due to their higher activity levels. Of all the cases studied, 22.6% had initial osteosynthesis in the study centre while the remaining 77.4% of the cases self-presented or were referred from other facilities for expert care. This pattern may be as a result of better level of skills and specialists at the study centre unlike the variable skills that are available at many private and smaller government hospitals around the study centre where there is absence or paucity of consultant orthopaedic surgeons and the surgeries were not done most of the time by specialists. The presenting complaints varied among patients and this study revealed 65.3% with combinations of two or more of the following: pain, swelling deformity and infection. This could be explained partly that most of the implant failures were preceded by trauma and this usually leads to pain. Also, the failed implants may also cause angulations which may present as deformity, swelling and pain. The implant failure may also result from infection which may either stop the progress of healing, weaken bone architecture and eventually this may lead to pain, deformity or swelling. This pattern of permutations as combination of symptoms has been similarly reported in studies (Sharma et al., 2006; Zimmerli, 2014).

Non-compliance or partial compliance to post operative instructions among males may be contributory. This frequency is in keeping with many studies because male and younger ones are more involved in musculoskeletal injuries (Zimmerli, 2014).

The commonest indication for the initial osteosynthesis was fresh non-pathological fracture (58.5%). This was also as noted in the study of fractures (Zimmerli, 2014; Buckley et al., 2017). In all the patients, 32.1% of them had implant removal alone because union has been achieved this likely due to the adequacy of the initial osteosynthesis as well as duration of fixation before implant failure occurs. However, 24.5% had re-do surgery with implant stabilization after corrective osteotomies and bone grafting in other to correct the associated deformities, freshened the ends of the fragments and also to encourage faster union. The rest (43.4%) had exchanged implant with a biologically and biomechanically more superior implants such as conventional Broad Dynamic Compression Plates replaced with Limited Contact- Broad Dynamic Compression Plates, Anatomical Locking Compression Plates, Locked intra-medullary Nails or External Fixators where appropriately indicated. The fracture union achieved are likely due to the strength of the implants that were able to hold the fragment together during healing as well as neo-biology created by freshened fracture ends as well as bone grafting that encourage better healing process and also due to more cooperation from the patients after the second surgery by obeying diligently post operative instruction (World Health Organization, 2013).

In all the factors responsible for implant failures noted in the study, non-compliance with post-operative instruction such as earlier weight bearing was the commonest followed by re-fracture and non-union respectively. The use of the limbs prior to fracture union possesses a lot of force on the implants either by load shearing (intra-medullary device) and load shielding (plating devices).

The risk of implant failure due to patient poor post-operative compliance, re-trauma and non-union were also documented in previous studies (World Health Organization, 2013; Zimmerli, 2014; Buckley et al., 2017). The outcome of the treatment was satisfactory in 85.0% of the cases by patient's self-assessment using Likert Scale. This might be partly due to the fact that the revision was done by a specialist with better experience and in a teaching hospital with better facilities compare to many of the centers around the study centre. The satisfactory outcome might also be due to the better surgical decision regarding the revision surgery with better and superior implants use. There are similar studies with varying degree of management outcome in the literatures. Sharma et al. in india and Onuoha et al. in Nigeria reported similar satisfactory outcome respectively in their different studies (Sharma et al., 2006; Onuoha et al., 2019)

CONCLUSION

The study showed that fresh fracture as the commonest (41%) indication for the initial osteosynthesis with non-compliance with post-operative protocols as the commonest causes (28.3%) of failed osteosynthesis Majority (65%) of the patient with implant failure presented with combination of symptoms (pain, swelling, deformity, features of infection). Majority (68%) had revision osteosynthesis but with a superior implants and bone grafting was used in 68% of the revised cases. The treatments were challenging but many (85%) of the cases coming out with satisfactory results.

Orthopedic Surgeons are encouraged to individualized the management protocols of patients and risk of implant failure should be part of pre-operative, intra-operative and post-operative consideration as well as adequate measure to prevent it should be well discussed with the patients and relatives

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