

Original Article

Exploring the Reasons for Orthopedic Implant Failure in Traumatic Fractures of the Lower Limb

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Abstract

Background: A damaged orthopedic implant in the body can cause problems for the patient and disrupt the therapeutic process. This study investigates various factors for orthopedic implant failures in patients with traumatic lower limb fractures who referred to a trauma center in Mashhad, Iran.

Methods: This was a prospective study of 23 patients referred to Kamyab University Hospital with failed orthopedic implants in 2009. We included any patient with an orthopedic device previously implanted secondary to a traumatic lower limb fracture who later presented to Kamyab University Hospital because of a failed implant.

For all patients, a thorough history was taken and the necessary investigations that included radiographic studies were performed. We investigated the quality of the failed devices by chemical analysis, metal hardness testing and metallography. The results were statistically analyzed.

Results: The mean age of the patients was 33 ± 19 years. There were 19 (82.5%) male and 4 (17.4%) female patients. In 14 (60.9%) cases, there were failed femoral implants and 9 (39.1%) cases had failed implants for tibial fractures. We compared the implants against ASTM standards. According to chemical analysis, all internally produced devices and one of the leading international brands were within the expected standard. However, in 3 cases chemical analysis showed a deviation from the standards. These were manufactured by "miscellaneous" companies. In one (4.3%) case the device failure was iatrogenic, in 14 (60.9%) it was due to faulty implants and in 8 (34.8%) cases, the patients were non-compliant with instructions. Hardness testing was satisfactory in all cases and metallographic studies showed good quality for the leading international brands, satisfactory quality for the internally produced devices and poor quality for the miscellaneous devices.

Conclusion: The implants classified as miscellaneous were of poor quality. Thus, we cannot recommend their use in orthopedic surgeries. We recommend using credible, known brands.

Keywords: Implants failure, traumatic fractures, orthopedic implants

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Introduction

Orthopedic implants are devices produced to replace bones or support broken bones. The use of metal devices for immobilization is one of the greatest achievements in orthopedic history. Orthopedic devices such as joint prostheses and internal fixators are the most commonly used implants in medicine. These implants are constructed of a variety of metals. Due to the considerable increase in human life expectancy, orthopedic implants should be developed to have longer life spans. In addition the increasing number of traffic accidents necessitates the use of high quality implants. Therefore, the biomechanical properties of corrosion/erosion resistance and adaptation to biological environments are particularly important. Metals such as cobalt chrome alloy, stainless steel, titanium and their alloys are used for implants as they have good biological adaptation, corrosion/erosion resistance, mechanical hardness and are cost-effective. Successful

implants are dependent upon various factors, all of which should be investigated thoroughly.

Implant failures cause new complications for patients, lengthen the healing process and increase cost. An implant failure often leads to a re-fracture, thus complicating the healing process. On occasion there is the need for additional, often more complicated repeat surgeries. These complications show the importance of exploring the causes of this problem.

Implant failures can result from an intrinsic device fault or external factors such as the surgical process, patient non-compliance with implant instructions and the degree of union.¹ Different quality implants are manufactured at various companies. According to a study in Argentina in 2007, the quality of many implants produced in Argentina is not as high as those manufactured in European countries, North America and Brazil.²

Only a small percentage of implants fail. Because of the increase use of implants it is important to investigate the outcome of their use according to their impact on patients and the financial impact on the national health system.

The aim of this study was to understand the underlying reasons for orthopedic implant failure in patients with traumatic lower limb fractures who were seen at a tertiary hospital in Mashhad, Iran. The intent of this research was to determine the reasons for implant failures and reduce the likelihood of reoccurrence.

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Patients and Methods

This prospective study consisted of 23 patients referred to Shahid Kamyab University Hospital in 2009 due to implant failure. The inclusion criterion was any patient with an orthopedic implant inserted secondary to a traumatic lower limb fracture who was later admitted to this hospital because of implant failure. There were 15 cases of nail failure from which 14 were cracked, as follows: femoral interlock (n = 8), femoral cuntscher (n = 1) and unreamed tibia nail (UTN, n = 5). In addition there was one case of a bent UTN. There were 5 cases of cracked plates (2 femoral and 3 tibial). A bent femoral DCS (dynamic condylar screw) plate was observed in 2 cases and 1 case presented with a cracked femoral DHS (dynamic hip screw). In 4 cases the primary fracture was an open fracture; the remainder sustained closed fractures. All cases, except for one, referred for first-time implant failure. This case, a 76-year-old male, referred following the third UTN failure, then he was treated with an LCP plate.

All patients had thorough histories taken by three orthopedic specialists and the necessary investigations that included physical examinations and radiographic studies were performed. During the preliminary examination, patients were asked for correct post-operative activities including, time of beginning of range of motion and weight bearing.

Amongst this, the most important factor was not doing heavy work with the operated limb before certainty was reached that bone healing had occurred. Also the patients were asked for possible history of trauma.

The possibility of infection was also determined. Of patients with closed tibial primary fractures, there were two cases (one UTN and one plate) that had superficial infections. In the first case, implant failure was secondary to the implant itself. The second case was the result of patient non-compliance.

The second surgery and implants removal, analyses were carry out on the broken implant and also the available radiographs in the patients history pertaining to before and after the original operation to determined if they had been any pitfall in complying with orthopedic instructions.

We classified the implants into the following three groups according to the manufacturer recorded on each patient's case notes: 1) active national manufacturer, 2) leading international manufacturer, and 3) miscellaneous manufacturers that included companies from developing Asian countries and those with unknown marks. For all cases we investigated the quality of the implants. At this stage, samples from different sections of the implants were taken for chemical and mechanical analyses in addition to microscopic studies.

Chemical analysis

The use of appropriate implant material in medicine is necessary as this material must be suitable for body conditions such as PH, moisture, temperature, etc.

Therefore the choice of an appropriate implant material is of utmost importance for which a quantometer with one percent precision is needed. Spectrometric analysis determines the percentage of different alloying elements.

In this research chemical analyses were performed at a laboratory accredited by the Institute of Standard and Industrial Research of Iran (ISIRI), located at Jihad Daneshgah, Sharif University. We determined the samples' alloying elements and their percentages.

In addition we have investigated the alloy inclusions which are defined as unwanted elements that deteriorate the essential alloying elements and cannot be eliminated because it is technically implausible or too expensive. We aim to compare the chemical properties against universal standards. The desirable alloying elements and their percentages determine the chemical properties, physical properties and corrosion resistance. Alloy inclusions should be kept to a minimum in orthopedic implants otherwise they damage these chemical and physical properties and corrosion resistance.

Microscopic and macroscopic hardness testing

Hardness testing is used to determine the quality of the elements and is defined as the resistance against plastic deformation or indentation. It is not a defined physical standard but rather, a numerical value that is derived from methods such as Vickers hardness testing or Brinell hardness testing. In this study we have performed Vickers hardness testing at the macroscopic and microscopic scales with the intent to determine compliance of the implant hardness with the standards.

Metallography

Microscopic investigations determined the microscopic structure of the alloys. The aim was to explore the microscopic roots of the mechanical properties and corrosion of the alloys (Figure 1).

Following all investigations we used SPSS version 17 for statistical analyses. Findings were shown with frequency tables. We used ANOVA and the chi square test for statistical analyses. Chemical analysis quantitatively showed the weight percentage of each element whereas mechanical analysis and microscopic findings were reported qualitatively.

Results

Totally, we analyzed implant failures in 23 patients (mean age: 33 ± 19 years; range: 15 – 76 years). Of cases, there were 19 (82.6%) males and 4 (17.4%) females. A total of 14 (60.9%) presented with failed femoral implants and 9 (39.1%) had failed tibial implants. Causes for failure were iatrogenic (1, 4.3%), implant related (14, 60.9%), and patient non-compliance with post-operative instructions (8, 34.8%). On average it took 6.7 ± 4.7 months (range: 3–24 months) for the implants to become damaged. For non-compliant cases the mean time was 4.5 months. Mean time to failure for the iatrogenic group was 9 months and for those with faulty implants, it was 7.8 months. The numbers of implants according to manufacturer are shown in Table 1.

Table 1. The numbers of implants according to manufacturer.

Group	Frequency n (%)
Iranian manufacturer	10 (43.5%)
International manufacturer	1 (4.2%)
Miscellaneous manufacturers	12 (52.3%)

The cause for orthopedic implant failure according to manufacturer group is shown in Table 2.

In this study we used chemical analysis, microscopic and macroscopic hardness testing, and metallography to study the faulty implants. Implants from the various manufacturers were classified according to quality, as good, average or low, according to these results.

Table 2. The distribution of the cause for orthopedic implant failure according to manufacturer group.

Group	Cause			
	Iatrogenic <i>n</i> (%)	Non-compliant <i>n</i> (%)	Faulty implant <i>n</i> (%)	Total <i>n</i> (%)
Iranian manufacturer	1 (10%)	4 (40%)	5 (50%)	10 (100%)
International manufacturer	0	0	1 (100%)	1 (100%)
Miscellaneous manufacturers	0	4 (33.3%)	8 (66.7%)	12 (100%)

Table 3. The chemical compositions of the implants (weight percentage of each element) compared against the recommended alloy with standard 316L.

Alloy	Chemical composition (weight percentage of each element)									
	C	Si	Mn	Cr	Ni	Mo	V	Cu	S	P
316L (standard)	<0.030	<0.75	<0.75	17–19	13–15	2.25–3.00	—	<0.50	<0.010	<0.025
Iranian manufacturer	0.029	0.57	0.57	17.15	13.91	2.30	—	0.06	0.009	0.022
International manufacturer	0.025	0.32	0.32	1.85	13.27	2.56	—	0.03	0.007	0.019
Miscellaneous manufacturers	0.121	0.35	0.35	9.90	1.45	0.11	0.01	1.45	0.008	0.028

Bold figures show chemicals that did not meet standard requirements.

Table 3 compares the chemical compositions of the implants (weight percentage of each element) against the recommended alloy with standard 316L.

All implants produced by the Iranian and international manufacturers met the standard requirements. However in three implants produced by miscellaneous manufacturers, the standard requirements were not met. In one of these three cases there was considerable deviation from the set standards. The remaining implants were within the standard range.

Microscopic and macroscopic hardness testing

The results of these tests were satisfactory in all cases. Hardness testing was performed on numerous parts of the implants, for which all met the standard range of 280–290 HV.

Metallography

In this microscopic investigation, photographs of microscopic structures from various samples were taken. Alloy inclusions in implants from the Iranian manufacturer were not of expected quality (average quality from a metallographic point of view). The international manufacturer's implants in terms of alloy inclusions were of good quality. In implants from miscellaneous manufacturers there were a number of dangerous faults such as cracks, holes, and stress corrosion cracking, which supported the chemical analysis results (poor quality).

There was no statistical significance between the chemical quality of the implants ($P = 0.5$) and metallographic quality ($P = 0.7$) with the cause of implant failure noted by the orthopedic specialists.

Discussion

Shahid Kamyab Hospital, a level one trauma center, performs an average of 2640 orthopedic implant surgeries annually. In 2009, 30% of the implants that were used in traumatic lower limb fractures were obtained from an Iranian manufacturer, 20% were from miscellaneous manufacturers and 50% were a leading brand produced by an international manufacturer. Thus, in 0.63% of the implants from the Iranian group, 1.51% of the implants from the miscellaneous group and 0.075% from the international group there were faults that caused implant failures.

The most common cause for implant failure was a faulty im-

plant. Of implant failures, 4% were iatrogenic, 34.8% were due to non-compliance with post-operative instructions and 60.9% were the result of poor quality implants. In a study by Sharma, the most common reason for failure was a traumatic event before complete healing of the fracture. In that study, plate failures were more common than nail failures in lower limb long bone fractures.³ In the current study nail failures comprised the majority of the implant failures. This difference in results was possibly related to the difference in implants between the studies. In the current study, 15 (65.2%) nails and 8 (34.8%) plates were analyzed whereas Sharma analyzed 11 (27%) nail and 30 (73%) plates.

Different studies on implant failure^{3–6} and on the chemical composition of the implants^{7,8} have been performed. In each study different techniques were used to determine the cause of implant failure and implant quality. According to laboratory results from a study by Azevedo in Brazil have shown that most implants did not meet ISO standards. In most, there was evidence of implant fracture secondary to corrosion. Additionally, some impurities showed a defected production process which was responsible for the failure.²

In this study, we performed chemical analyses, hardness testing and metallographic studies. The results from chemical analyses showed that all implants produced by the Iranian and leading international manufacturers met the required standards. In three cases the implants did not meet the set standards; all three belonged to the miscellaneous group. One of the three implants that had considerably poor laboratory results was labelled as a leading international brand, however due to its poor quality this label was probably imitation. A leading manufacturer has high standards in their production; most likely they would not produce a poor quality device. There are numerous imitation implants labelled with leading trademarks, yet they have unacceptable quality.

As mentioned earlier, the implants produced by developing Asian countries and those with unknown trademarks were classified as miscellaneous. Similar trademarks were used for different samples that were of various shapes and sizes; all were labelled with a very poor quality and were most likely imitation. Statistically they had very poor quality. The extent of deviation from the set standards according to chemical analysis was adequate to label these implants as insufficient and dangerous. Nevertheless, we performed additional investigations such as hardness testing and metallographic studies on these implants.

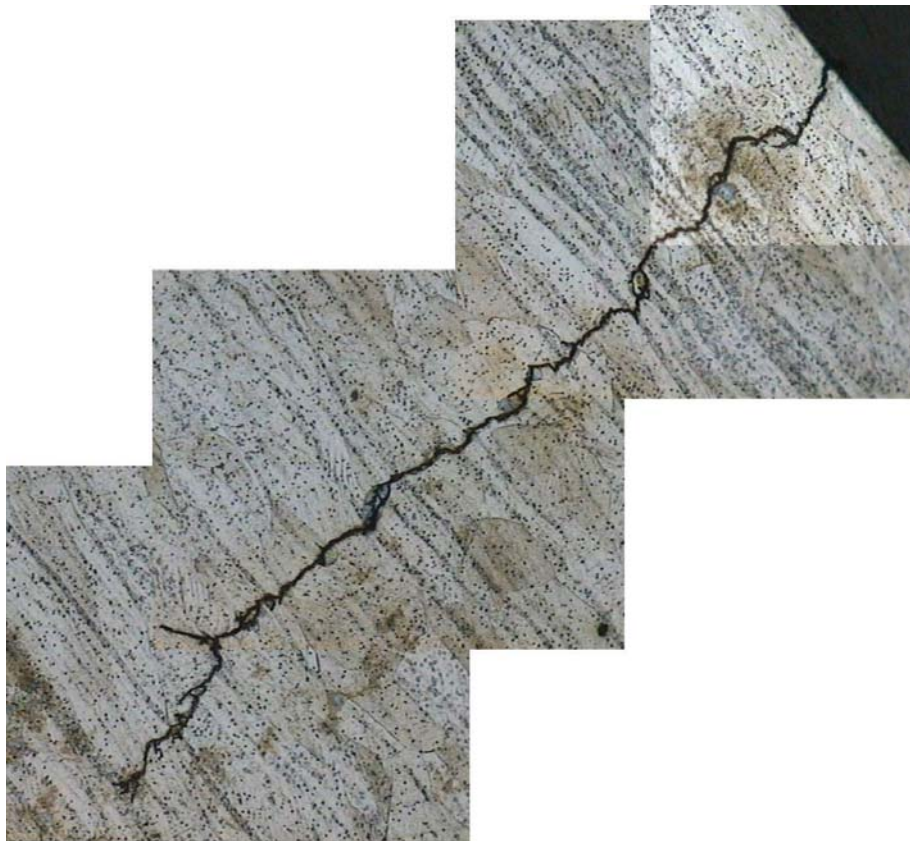


Figure 1. In this figure we can see the progression of crack in the implant of miscellaneous companies.

All implants according to hardness testing were within the standard range of 280–290 HV. Thus the observed failures were not due to hardness. However there were other reasons for the failures that could be attributed to other properties of the metals such as corrosion resistance, alloy purity, type, amount, shape and alloy inclusions or the degree of compliance with the post-operative instructions.

Metallographically, the implants produced by a leading international manufacturer were excellent and those manufactured by the Iranian company were slightly lower than the expected standard. It was possible that implants differed from other implants in terms of purity and alloy inclusions. Possibly the imported metal bars were not of good quality, however this was out of the scope of this research. Metallographically, the implant produced by the miscellaneous group was disappointingly poor.

The implantation of a device in the body can cause infection which may occur during surgery or later by hematogenous spread. An infected implant usually causes inflammation, leading to implant failure and multiple surgeries which in turn increases morbidity. In a study by Sharma, there was one (2.4%) implant failure associated with evidence of a deep infection that led to additional surgery and removal of the implant.³ In our study there were 2 (8.69%) cases of superficial infection in the injured area. Because the infections were superficial, there were other reasons for the implant failure (one case was the implant itself, the other was due to patient non-compliance). Therefore we did not consider the infections as the sources for these implant failures.

The surgical technique is an important factor in determining the success of an implant. In our study the one case of iatrogenic failure was in a 21-year-old male whose implanted femoral nail was shorter than the necessary length, such that one end of the nail was

not sufficiently far from the fracture. Subsequently the nail was under tremendous stress and fractured. There were three cases of implant failure in a study by Barbosa; he concluded that surgical and design errors were the most important cause of implant failure.⁴

In our study the implant quality appeared to be lower in those with faulty implants compared to those whose implants failed due to iatrogenic failure and non-compliance. However there was no statistical significance between implant quality in terms of chemical analysis ($P = 0.5$) and metallographic studies ($P = 0.7$) when compared with the reasons identified by orthopedic specialists. Perhaps due to the small number of samples, there was no statistical significance, which was one of this study's limitations. In addition, we were unable to generalize the results as our research was undertaken in one referral center. Another limitation was the lack of a comparison control group to better identify the different causes for implant failures.

Conclusion

Implants failed in 0.63% of implants produced by an Iranian manufacturer and in 1.51% of implants produced by miscellaneous manufacturers. In terms of quantitative tests and metallographic studies the implants from miscellaneous manufacturers were far short of expected standards and are not fit for purpose. All Iranian manufactured implants were better and safer than implants from the miscellaneous group. Considering the high numbers (20%) of implants produced by the miscellaneous group, we have recommended replacing them with credible, certified implants.

Conflict of interest

The authors and the sponsors in this research have no ties or relationships of any kind with the companies that produced the implants. Implant failure is both legally and scientifically important to be studied and new products from Iranian manufacturers must be tested in clinical trials.

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