Evaluation of the Etiologies of Implant Fracture in Patients With Fractures of the Implants of Lower Limbs’ Long Bones

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ABSTRACT

Background: Orthopedics implants are important tools for treatment of bone fractures. Despite available recommendations for designing and making the implants, there are multiple cases of fracture of these implants in the body. Hence, in this study the frequency of failure of implants in long bones of lower extremities was evaluated.

Methods and Materials: In this cross-sectional study, two types of fractured implants in the body were analyzed and underwent metalogical, mechanical, and modeling and stress-bending analysis.

Results: The results revealed that the main cause of fractures was decreased mechanical resistance due to inappropriate chemical composition (especially decreased percentages of Nickel and Molybdenum).

Conclusions: It may be concluded that following the standard chemical composition and use of optimal making method are the most important works for prevention of failure of implants.

Key words: Implant, SEM, Optical Metallography, Quantometry.

1. INTRODUCTION

Fracture of long bones would require the time for healing ranging from several weeks to months. Since the introduction of antibiotics, direct bone surgeries and fixation with metals have changed to a conventional method (1). Use of internal fixators has increased the rate of bone fracture treatment and decreased the time interval for normal life. This matter is not acceptable by majority of patients and may result in mental and somatic problems.

Regarding the increased use of internal fixators in recent years and diversity of available products, the failure of these tools has also increase. It may be seen as different forms including major deformity, mechanical fracture, corrosion, and avulsion from the bone (2). Also different factors are contributing for failure including inappropriate material and make-up, inappropriate fixator selection and surgical technique, and lack of consideration of optimal weighting by patient (2, 3). The failure before treatment completion is an important complex complication leading to numerous problems and Reoperation leading to costs and injuries (1).

Two different types of alloys including stainless steel 316 and pure titanium are two optimal materials for making the internal fixators introduced in ASTM and ISO standards (4-6). Regarding to optimal technique and fixator would result in higher tolerability and better healing (7). Since the failure rate has increased, this study was performed to determine the etiologies of implant fracture in patients with fractures of the implants of lower limbs’ long bones for better programming to reduce the rate of failure of fixators.

2. METHODS AND MATERIALS

In this cross-sectional study, two types of fractured implants in the
body were analyzed and underwent metallogical, me-
chanical, and modeling and stress-bending analysis
among 11 subjects among 21 total sample size attend-
ing to a referral academic hospital in 2013 and 2014 who had Reoperation for femoral and tibial bones repair. Back-
ground diseases such as osteoporosis, osteopenia, ma-
lignancy, diabetes mellitus, high-energy trauma, and the
fixator types other than stainless steel and titanium were
the exclusion criteria.

At first the fixators underwent quantometry to deter-
mine the weight percent of each one. This stage was per-
formed by Spark Emission Spectrophotometer (Made
in Germany) in environmental situations by standard
of ASTM E406-81 and the results were compared with
ISO-5832-1 amounts. Then optic metallography was
performed by Optical Microscope. Determination of size
of particles in microstructure of metal, cycle of thermal
operation, production procedure and type of superficial
operation, microstructural cracks, and type of impuri-
ity in cross-section were the objectives in this study. The
used chemical to determine the border of particles was,
CuCl2, HCl, and alcohol. The experiment was performed
in two sections of far and near. The photographs were in
1000×, 500×, 250×, and 100× views. The third matalo-
logical test was electron microscope evaluation in which
the cross-section was assessed by scanning electron mi-
croscope (SEM) to determine the fracture cause by eval-
uation of borders and lines and cracks and corrosions.

The goal of mechanical assessment was determination
of mechanical tolerance of implant; the hardness of sam-
pies was measured and altered to stretch tolerance by
experimental data. The hardness was measured by Mac-
rophardness Tester by Wicker’s method. For alteration of
hardness to stretch tolerance, reference data were used
(11). The results were compared with stretch stress of
implants in ISO5832 standard. By considering the large
predicted stresses in DHS plaque, it underwent stress-
strain analysis. For geometric modeling the Solidwork
software was used and the model was completely made
according to real sample. Stress analysis was performed
by element method via ANSYS software. The borderline
conditions were prepared with fixation of screws loca-
tion and insertion of external forces to femoral head.
Regarding difference of inserted forces on implants ac-
cording to patients’ activity, the reference data were used
from study by Bergmann et al (8) was used. The locks
were in holes for linkage of the screw and bone.

2.4. Stress Analysis

Regarding complexity of loading of DHS implants and
uncertainty about the stresses by segment method the
stress-strain analysis was performed. For determination
of type of loading and locking on the segments the data
from study by Bergmann et al (8) was used. The locks
were in holes for linkage of the screw and bone.

Final data analysis was performed by SPSS software
(version 18.0). The percent for categorical and the mean
and standard deviation were reported for numeric vari-
ables.

3. RESULTS

Results of our investigation are shown in Tables 1-6.

| Demographics | Fz | Fx | Fy |
|--------------|----|----|----|
| Slow walking | 1751 | 411 | 274 |
| Normal walking | 1682 | 411 | 280 |
| Fast walking | 1820 | 411 | 290 |
| Up stairs | 1751 | 480 | 480 |
| Down stairs | 1888 | 411 | 274 |
| Standing up | 1340 | 411 | 68 |
| Sitting down | 1477 | 754 | 411 |
| Standing up 2-1-2 | 1408 | 274 | 70 |
| Knee bend | 1408 | 685 | 40 |

Table 1. The Forces on femoral head in three orientations
The samples were 11 cases after exclusion of 20 ones. 73% were male and 27% were female. The mean age was 35.8 ± 8.2 years (ranging from 21 to 52). The mean weight was 71.6 ± 5.4 kg and the mean BMI was 20.6 ± 1.22 kg/m² (Tables 1 and 2).

Chemical composition
The chemical composition is showed in Table 3. Except samples 2, 8, and 10, the other samples were not in congruence with standard. The most incongruence rates were related to Ni and Mo. Also in some samples, the phosphorous and sulfur were more than standards.

Metalogical Microstructure
For all except the sample number 5, the size of particles was fine and in standard level. In samples 2, 8, 10, and 11, there was no Delta-Ferrit phase but the other samples had some amounts especially samples number 5, 7, and 9. The impurity particles were low in majority of samples but it was high in samples number 8, 9, 10, and 11.

Hardness and stretch tolerance
Sample number 5 had stretch tolerance very lower than standard. Also the stretch tolerance of samples numbers 2, 8, and 10 had most stretch tolerance and far from standard (Table 4).

Stress analysis
The most stress was in second hole exactly in location of fracture showing 1.2 gigapascal. It means a stretch tolerance of 640 megapascal. As shown in Table 5, down stairs results in most stress which is more than twice the allowed limit.

4. DISCUSSION
The main causes of failure are mentioned in Table 6. About the chemical composition the phosphorus and sulfur were the elements with most impurity. Also the percent of chromium and nickel was out of standard limits (17-19 for chromium and 13-15 for nickel). Regarding the important role of these elements in corrosion and mechanical tolerance this may be contributing for implant failure (13-19). In optic metallographic evaluation, the dense points of carbide particles were seen on the surface of implant that would result in crack and subsequent stress fractures.

In implant hardness test, the mean wicker’s number was 193 showing a stretch resistance of 640 megapascal which is smaller than standard. The maximal stress in the piece was in location of fracture showing 1100 megapascal which is more than 640 megapascal for stretch tolerance. It shows the effect of bad chemical composition and low mechanical tolerance in presence of implant failure.
In metallographic results, high density of aplacements and bigeminies was seen in microstructure of some particles. So the austenite would change to martensite structure. This composition is predisposed to corrosion due high energy despite high mechanical tolerance. The cause of failure may be the hardness in manufacturing process (probably due to cold method) and subsequent corrosive failure. The severe corrosion was seen in cross-section of fracture which was accompanied with fine and gross cracks. It shows the failure due to corrosion.

However low small sample size may result in low probability for utilization of the results about the failure of implants some conclusions may be said. Majority (nine out of eleven) of samples had failure due to incongruence with standards. Some samples were made from alloys with chemical composition not in accordance with standards resulting in lowered corrosive and mechanical tolerance and modeling. Also some samples had inappropriate manufacturing method leading to large particles and disturbing phases, or cold method effects. Despite partial increase in mechanical tolerance, significant reduction may be seen in corrosive and modeling tolerance. Regarding the increased rate of internal fixators use, exact supervision on alloys and manufacturing processes and checking for immune status and function would prevent further problems.

Application condition is another cause of failure in some samples (three out of eleven) and even it was the main failure cause in two cases (despite standard status of implant). The weight-loading conditions should be respected in patients under internal fixation for fractures. The tolerance of high stress forces on implants during some operations such as up staring is difficult and proper weight-loading and optimal physical activity should be learned to the patients. Also before increasing the loading weight, the fracture repair status and callus formation process should be evaluated radiographically for higher confidence about tolerance to mechanical loads. Many samples (six out of eleven) were locking plate. These implants are usually used with space from bone periosteum leading to higher bending stresses. For this reason the surgeons should be more cautious about fixation and use of these implants. Sudden stresses are also important and may lead to sudden fractures or fatigue fractures. So, more caution should be performed by patients. The corrosion was also another important factor for failure of internal fixators and was seen in five out of 11 samples in current study. The duration of presence of implants in patient’s body is an important factor for corrosion. Delayed removal would result in lack of sufficient mechanical load for callus maturation and bone regeneration in fracture region. Also corrosive complications would result in decreased mechanical tolerance of implants leading to higher probability of fractures. Hence paying attention to proper definite time of implant removal is an issue of importance.

## 5. CONCLUSIONS

It may be concluded that following the standard chemical composition and use of optimal making method are the most important works for prevention of failure of implants. However further studies with larger sample size is required to obtain more definite applicable results.

### CONFLICT OF INTEREST: NONE DECLARED.

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