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Results of spectral analysis of extracted broken implants after osteosynthesis of long bones

V.V. Lozhkin, V.I. Zorya

A.I. Evdokimov Moscow State University Medical and Dental, Moscow, Russian Federation

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Introduction Along with expansion of the types of metal implants and indications to osteosynthesis with their application, contemporary operative traumatology continues to meet with such a complication as metal fixator breakage. The frequent cause of fixator failure is an incorrect osteosynthesis or an improperly chosen implant. Quite often, the cause of the complication remains unknown. The purpose of our study was to establish the need for spectral analysis in assessing the cases of metal fixator collapse after osteosynthesis of long bones as well as to determine the rate of the composition defects of the implants used for osteosynthesis of limb bones. **Methods** We performed a spectral analysis of 16 broken implants extracted from 15 patients operated on in Semashko Hospital, State Hospital No. 17 and State Hospital No. 68. The group included metal implants for both intra- and extramedullary osteosynthesis. **Results** Of the 16 implants studied, five (31.25 %) complied completely with the requirements of the standard, two stainless steel and three titanium metal implants among them; eleven implants (68.75 %) did not meet the international standards. **Discussion** In a number of cases (for example, with stainless steel implants) the deviations were significant; variability of the alloys was also noted in titanium implants. Because these deviations in composition may play a role in the destruction of metal fixators, we believe that such a study as spectrography should be recommended for the analysis of cases of implant breakage.

Keywords: osteosynthesis, complications, implant breakage

INTRODUCTION

According to foreign and domestic literature, implants used for osteosynthesis of different limb segments break in 4 to 7.2 % of cases, and this rate does not trend to decrease despite the improvement of osteosynthesis techniques and the quality of implants. This is primarily due to the growing number of injuries in the population, as well as due to the expansion of indications for surgical treatment.

Studies on failed implants are quite rare. We analyzed the reports in the journals on this type of studies.

B. Gervais and co-authors reported that the study of 130 femoral fractures treated with the LCP plate revealed complications in 27 cases, which in turn led to a re-operation in 18 cases. Non-union was the most common among the complications followed by implant fixation loosening and breakage [1].

The LCP plate for distal femur, analyzed by them, is 242 mm long and has 10 holes. The plate was proximally fixed by three locking and two cortical screws. The failure of the implant happened after a fall of the patient that occurred less than two years postoperatively. The implant and two screws, one cortical and one locking, broke.

Chemical and microstructural composition of the plate and its mechanical properties were studied. The analysis of the plate failure site revealed a fatigue breakage of the implant (extended for 85 % on one side of the hole and up to 30 % on the other). Scanning microscopy confirmed these data and detected changes in the structure of the implant characteristics due to a fatigue stress. Similar conclusions were made in regard to broken screws.

According to the authors' calculations, the plate withstood 1,642,500 stress cycles since the surgical intervention. Based on the absence of pronounced defects in the plate, the authors concluded that the reasons of the fatigue were excessive patient's physical loading on the leg, as well as a bridge-like fixation, as a result of which a large number of plate holes in the fracture zone was not used and was a concentration of stresses. The fall of the patient was, from the authors' point of view, only the final stage. The implant would have withstood excessive loads if there were no fatigue damage.

J.B. Marcomini and colleagues conducted an analysis of the LCP steel plate, mounted to an 83-year-old patient with an oblique fracture of the femoral diaphysis. The first plate was removed four months after osteosynthesis due to loosening, the second one after six months because of implant breakage [2].

The authors also analysed the chemical and microstructural composition of the plates and performed fractography.

They found that the chemical composition of the plate did not comply with the current standards of

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alloys for orthopedic implants due to almost a two-fold excess in the phosphorus content. In addition, the cold technology of plate manufacture results in an increased brittleness of the implant.

Thus, the main cause of this implant breakage was a violation of both the manufacturing technology and chemical composition of the plate.

C.R.F. Azevedo analyzed the breakage case of a titanium millimeter reconstructive plate with 13 holes.

The plate was studied for changes in chemical composition; microscopy and fractography were also performed. Chemical deviations from the standard ISO 5832-2 were not detected. Microstructural analysis showed traces of corrosion that indicated changes in the contact points of the plate with the body fluids.

The author concludes that the cause of the break were the changes due to metal corrosion and subsequent fatigue stress. Probable cause of the fatigue failure, as the author opines, was either an initial unstable fixation of the fracture due to surgical technique, or the resulting resorption of bone tissue at the site of the screws insertion [3].

L. Guerra-Fuentes and co-authors analyzed the case of breakage of a blade plate for osteosynthesis of fractures in the distal femur. The plate broke after four months in a 53-year-old patient.

The chemical composition complied with ASTM F-138-00 standard for stainless steel plates.

Fractography showed the fatigue character of the break with the final failure due to stresses. The micrography confirmed these assumptions. The collapse of the implant was associated by the author with fretting and prolonged cyclic loads caused by a non-ideal fitting of the plate over the surface of the bone. Concomitant osteoporosis promoted fixation instability and implant failure [4].

H. Amel-Farzad and co-authors investigated the case of a DCS plate failure, also used in the distal femur. The broken plate was removed from the patient two years after osteosynthesis with the fracture united. Presumably, the plate broke in the first few months before the final consolidation of the fracture.

Even by a visual examination, the authors found traces of corrosion which was facilitated by sulfide inclusions, detected by metallography. The chemical analysis of the plate composition revealed significant differences from the recommended standard for the manufacture of medical steel implants. The authors consider this to be the main cause of the implant failure. They described the mechanism of the breakage as a consistent process of metal corrosion. Compliance with the standards of chemical composition, in their opinion, prevents destruction [5].

N. Thapa and colleagues investigated a broken compression plate with 10 holes supplied with both locking and cortical screws using metallographic and fractographic analysis. The main cause of the failure was metal fatigue and corrosion. Fixator's failure started with corrosion in the area of metallic inclusions, and then continued due to corrosion and stress forces. The plate withstood about 2,035 load cycles after the start of the process. Unfortunately, there are no clinical data on the patient in the analysis [6].

Table 1 provides an overview of the methods used by researchers for analyzing broken metal fixators.

Almost all researchers used chemical analysis, but the authors of only two studies made a conclusion about the effect of the chemical composition on the implant failure.

The purpose of our study was to establish the need for spectral analysis in assessing the cases of metal fixator failure after osteosynthesis of limb long bones, as well as to determine the rate of violation of composition in manufacturing implants used for osteosynthesis of limb bones.

Taking into account the literature data, spectral analysis should be an integral part of the assessment of implant breakage (collapse).

Table 1

Overview of the study methods used for analyzing metal fixator failures

Author	Chemical analysis	Fractography	Mechanical analysis
Benjamin Gervais	+	+	+
J.B. Marcomini	+	+	+
C.R.F. Azevedo	+	+	–
L. Guerra-Fuentes	+	+	–
H. Amel-Farzad	+	+	+
Nirajan Thapa	+	+	+

MATERIAL AND METHODS

This study is part of the thesis on the topic "Failures of metal fixators in the osteosynthesis of long limb bones". Considering the diversity of implants used for osteosynthesis and a large number of suppliers (European, Asian and domestic), we decided to analyze the alloy composition of those implants that were extracted from the patients treated in three hospitals (Semashko hospital, hospitals No. 68 and

No. 17). There were 15 patients and 16 implants. Patients were hospitalized in trauma departments both as emergency cases or were referred in a planned manner. Two implants were intramedullary locking nails and the rest were metal fixators for extramedullary osteosynthesis.

The study was conducted at NTL "Pribor" using X-ray fluorescence spectrography. This method allows for determination of the elemental content in the crystal matrices of the object under investigation and is widely used in the metal science to determine the composition of alloys. The study was carried out with the Innov-x Alpha 2000 analyzer.

All implants for the study were delivered as two fragments that underwent appropriate treatment after extraction during the re-osteosynthesis/extraction of the metal fixator. Measurements were made at a minimum of four points: away from the cleavage site and directly at the site of the implant fracture to eliminate deviations in the measurements. According to the results of the study, all implants were divided into three large groups: made from medical stainless steel (7 samples, 44 %), titanium (3 samples, 19 %), doped titanium implants (6 samples, 37 %).

Further, we checked the compliance of the established alloy composition with the Russian State standards (GOSTs) in force. At the moment, there are three standards for these groups of implants in the Russian Federation that are based on the recommendations of the international ISO group. These are GOST R ISO 5832-1: 2010 (stainless steel), GOST R ISO 5832-2: 2014 (unalloyed titanium) and GOST R ISO 5832-3: 2014 (doped titanium). In addition, we checked the conformity of steel implants to GOST for a standard alloy, often used for the production of internal implants. It is an alloy of 316L stainless steel. GOSTs adopted on the basis of the documents of the International Association for Standardization, in general, meet international standards. There are deviations in GOST ISO 5832-1. In Russia, the 2010 standard is in effect, whereas the Association adopted the standard from 2016.

These standards define both the chemical composition of the alloys used for the manufacture of surgical implants and the physical properties of these implants.

RESULTS

Our data of the spectral analysis for three different groups of implants, we divided and compared with the relevant standards studied (Tables 2, 3, 4).

Table 2

Spectral analysis results for stainless steel implants

Plate	Measurement	Fe	Cu	Ni	Mo	Cr	Mn
1	1.1	69.53	0.22	10.46	0.16	18.27	0.62
	1.2	69.67	0.2	10.66	0.15	17.98	0.63
	1.3	69.40	0.25	10.48	0.15	18.23	0.67
	1.4	69.31	0.2	10.76	0.16	18.18	0.68
2	2.1	68.78	0.22	11.74	0.13	17.28	1.2
	2.2	68.99	ND	12.07	0.12	17.17	1.03
	2.3	68.67	0.18	11.91	0.12	17.32	1.19
	2.4	68.66	0.23	12.02	0.13	17.16	1.12
3	3.1	70.71	0.18	10.57	0.14	17.26	0.30
	3.2	70.79	ND	10.7	0.14	17.40	0.19
	3.3	70.67	0.16	10.44	0.15	17.30	0.34
	3.4	70.78	0.16	11.15	0.15	16.65	0.31
4	4.1	68.56	0.12	10.53	0.11	19.06	0.70
	4.2	68.91	ND	10.57	0.10	18.86	0.66
	4.3	68.62	ND	10.63	0.11	18.96	0.73
	4.4	68.86	ND	10.65	0.12	18.75	0.68
5	5.1	62.34	ND	15.08	2.88	17.96	1.75
	5.2	62.12	ND	15.45	2.82	17.85	1.76
	5.3	62.40	0.1	14.83	2.86	17.95	1.79
	5.4	61.79	ND	16.41	2.71	17.44	1.65
6	6.1	67.48	0.34	11.37	2.72	16.70	1.39
	6.2	66.44	0	12.03	2.46	16.80	1.36
	6.3	67.40	0.31	11.29	2.61	16.84	1.38
	6.4	67.53	0	11.76	2.8	16.37	1.54
7	7.1	70.55	0.42	9.68	0.33	17.12	1.52
	7.2	71.21	0	9.62	0.93	16.51	1.34
	7.3	70.51	0.34	9.68	0.34	17.37	1.45
	7.4.	69.38	0	9.89	0.66	17.20	1.6
GOST	ISO 5832-1:2010	Base	not more than 0.5	13.0–15.0	2.25–3.0	17.0–19.0	not more than 1.0
GOST	316L	Base	no regulation	10.0–15.0	2.2–2.8	16.8–18.3	1.0–2.0

Table 3

Spectral analysis results of failed non-alloyed titanium implants

Plate	Measurement	Ti	Fe
1	1.1	99.96	0.04
	1.2	99.93	0.07
	1.3	99.96	0.04
	1.4	99.94	0.06
2	2.1	99.70	0.30
	2.2	99.45	0.55*
	2.3	99.69	0.31
	2.4	99.51	0.49*
3	3.1	100.00	0
	3.2	100.00	0
	3.3	100.00	0
	3.4	99.54	0.46*
GOST	–	remaining part	not less than 0.1 and not more than 0.4

Table 4

Результаты спектрального анализа разрушенных легированных титановых имплантов

Plate	Measurement	Ti	Fe	V	Sn	Mo	Ni	Nb	Mn	Zr	Al
1	1.1	96.26	0.08	ND	3.23	ND	ND	ND	ND	ND	ND
	1.2	97.25	0.20	ND	2.52	ND	ND	ND	ND	ND	ND
	1.3	96.57	0.10	ND	3.29	ND	ND	ND	ND	ND	ND
	1.4	96.40	0.12	ND	3.46	ND	ND	ND	ND	ND	ND
2	2.1	95.33	0.24	4.27	ND	0.05	0.06	0.07	ND	ND	ND
	2.2	95.35	0.21	4.26	ND	0.05	0.05	0.08	ND	ND	ND
	2.3	95.24	0.21	4.38	ND	0.04	0.07	0.07	ND	ND	ND
	2.4	95.36	0.18	4.29	ND	0.05	0.06	0.07	ND	ND	ND
3	3.1	95.51	0.20	4.26	ND	0.01	0.03	ND	ND	ND	ND
	3.2	95.44	0.20	4.27	ND	0.01	0.02	ND	ND	ND	ND
	3.3	95.44	0.20	4.32	ND	0.01	0.03	ND	ND	ND	ND
	3.4	95.43	0.21	4.32	ND	0.01	0.03	ND	ND	ND	ND
4	4.1	99.03	0.11	ND	ND	ND	0.02	ND	0.84	ND	ND
	4.2	99.06	0.07	ND	ND	ND	0.02	ND	0.85	ND	ND
	4.3	98.93	0.09	ND	ND	ND	0.02	ND	0.97	ND	ND
	4.4	98.93	0.12	ND	ND	ND	0.02	ND	0.93	ND	ND
5	5.1	95.67	0.21	4.12	ND	ND	ND	ND	ND	ND	ND
	5.2	95.17	0.35	4.48	ND	ND	ND	ND	ND	ND	ND
	5.3	95.44	0.26	4.29	ND	ND	ND	ND	ND	ND	ND
	5.4	95.29	0.30	4.41	ND	ND	ND	ND	ND	ND	ND
6	6.1	94.52	0.09	1.44	ND	3.87	0.03	ND	ND	0.06	ND
	6.2	94.59	0.12	1.51	ND	3.71	0.03	ND	ND	0.06	ND
	6.3	94.38	0.12	1.57	ND	3.88	0	ND	ND	0.06	ND
	6.4	94.76	0.10	1.42	ND	3.67	0	ND	ND	0.05	ND
GOST		Base		Max 0,3		from 3.5 to 4.5		no regulation		from 5.5 to 6.75	

DISCUSSION

There was a great variability in the proportions of the regulated elements in steel implants. None of the seven implants met the nickel content requirement when checked for compliance with GOST ISO 5832-1: 2010; there was either its excess or a lack in the composition of the alloy down to 4 pp. In the five samples tested, there was a sharp shortage of molybdenum while a complete compliance with the standards was revealed in the other two tested. Manganum content exceeded the standards by almost one and a half time in four samples. Deviations in the chromium content against the above-described changes could be considered insignificant. However, in one case, three of the four measurements revealed a decrease in its content.

The results of compliance with GOST for 316 L steel found that two implants (sample No. 5 and No. 6) consisted of this steel type. In the remaining samples, there was a shortage of one alloy element, molybdenum, which is an anti-corrosion element.

Thus, of the seven steel implants, only two fixators met the standards by their composition.

The group of titanium implants, as can be seen from Table 3, fully complied with ISO standards. A high-strength titanium alloy must be used to produce medical products according to current standards.

As Table 4 with the results of the study of doped titanium implants shows, the normal content of these two elements was revealed. However, regulated vanadium was absent at all in two of the six samples. In one case, it was half as much as needed, and in the remaining three cases the norms were met. Aluminum was found in none of the implants. This is an element that takes the second place by the mass fraction in the composition of this group of metal fixators. Instead of aluminum, we found as many as six elements, the presence of which in the alloy for medical implants is not regulated.

Given the absence of aluminum in the alloys, it can be recognized that only one of the implants studied corresponded to the standards (implant No. 5). Two more implants contained various impurities, but their total proportion was small (up to 0.15 p.p.). The remaining three implants were made from other alloys, did not contain vanadium as a doping component, and also contained impurities in large quantities (> 1 p.p.). It should be noted that combinations of alloys with these added elements are encountered in production and are permissible, but their use for the manufacture of medical implants is not regulated.

CONCLUSIONS

Of the 16 implants studied, five (two steel and three titanium metal fixators, 31.25 %) fully met the standards; the remaining eleven did not meet the existing international standards (68.75 %). In a number of cases (for example, with steel implants), the deviations were significant. The variability of alloys was noted in the group of titanium implants. Due to the fact that these deviations may play a role in the metal fixator failure, we believe that such a study as spectrography should be recommended for analysis of cases of implant failure.

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Information about the authors:

1. Vladislav V. Lozhkin, M.D.,
A.I. Evdokimov Moscow State University Medical and Dental, Moscow, Russian Federation;
Email: evgenvladislav@gmail.com
2. Vasilii I. Zorya, M.D., Ph.D., Professor
A.I. Evdokimov Moscow State University Medical and Dental, Moscow, Russian Federation