

Abstract

"Optimization of trans-articular fixation of complex ankle fractures with displacement of fragments and dislocation of the foot»

Thesis for the Degree of Doctor of Philosophy (PhD)

6D110100 – Medicine specialty

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Relevance of the study:

Currently, there is a high level of injuries in adults associated with employment and transport injuries. Damage to the lower extremities has been observed in a significant proportion of cases. The severity of the injury and its complex nature is determined by the impact of a large force, in particular transport injuries, and there is a need to improve the treatment and prevention of complications. Ankle fractures with dislocation of bone fragments with subluxation or dislocation of the foot, as well as damage to the capsule-binding apparatus of the ankle joint, according to literature data, account for 6% to 32% of all injuries of the musculoskeletal system and 40.0-69.7% of the number of fractures of the Shin bones (Korzun O. A., 2012; Grear B. J., 2016).

According to some data, the frequency of adverse results of conservative treatment can reach 63%, and operative treatment-39%. The average duration of disability remains high (3.5-6 months or more). Treatment outcomes associated with persistent disability of patients have 2.0-2.8% frequency. The reason for such frequent negative results is the difficulty of maintaining the fragments and the foot in the reported position for the entire period of fusion of fragments (Harris AP et al., 2015).

Thus, the treatment of complex closed ankle fractures with dislocated fragments and dislocated feet still needs research to improve the results of treatment.

Purpose of the study:

Improvement of treatment results in patients with complex ankle fractures with subluxation or dislocation of the foot, using the developed device for repositioning and trans-articular fixation of the foot (TFF) to the tibia.

Objectives of the study:

1. To conduct a retrospective analysis of the results of traditional methods of treatment used in clinical practice in patients with complex ankle fractures with subluxation or dislocation of the foot for the period from 2006 to 2014 in the Department of Traumatology and Orthopedics of "SemeyEmergency Hospital" using archival materials.

2. To develop a device for repositioning bone fractures of the ankle with subluxation of the foot and TFF wire to the tibia and to implement it in clinical health care practice.

3. To study the quality of life of patients in a comparative aspect, in the process of their treatment, using traditional and proposed methods of treatment.

4. To study the cost assessment of the treatment results of the proposed and traditional methods of treatment and conduct a comparative analysis of them.

Study design: a cross-sectional retrospective study, a prospective non-randomized clinical study.

Materials and methods of the study

The study was conducted in 2015-2019 by studying the results of the treatment of 650 patients with foot dislocations and complex ankle fractures in the Department of Polytrauma and orthosurgery of the Semey Emergency Hospital. An archival retrospective study was conducted on 508 patients with plantar slip and displaced ankle fractures. We studied the original medical histories in the archives during treatment in 2006-2014, and the results of treatment of 142 patients in 2015-2019. studied prospectively.

In total, the study included data from 142 patients with closed ankle fractures, with subluxation or dislocation of the foot. Among 142 patients who underwent trans-articular fixation of the foot to the tibia, there were 87 men (61.3%) and 55 women (38.7%) aged 19 to 75 years (average age 46.1 ± 2.5 years). The main study group included 97 patients who used the developed device during treatment. In the comparison group, there were 45 people (31.7%) who carried out fixing spokes without using a device, and repositioning was carried out manually by A.V. Kaplan (1979).

Criteria for inclusion: age over 18 years; presence of an ankle fracture with dislocated fragments and subluxation or dislocation of the foot; treatment of fractures using trans-articular fixation of the foot; availability of informed consent to the use of appropriate treatment methods and anonymous use of the data obtained for scientific research.

Exclusion criteria: incomplete examination and lack of data from a long-term follow-up period; refusal to participate in the study.

Research methods: General clinical; radiological; clinical and functional questionnaire AOFAS; quality of life analysis (General questionnaire SF-36, specialized Russian questionnaire for determining the quality of life of patients with lower limb injuries FAOS); economic analysis (cost-effectiveness).

Statistical methods: The SPSS application package version 20 has been used to process statistics data. For graphics, the packages of SPSS, version 20 and Microsoft Excel 2010 were used.

When analyzing quantitative data, a check was carried out for the correctness of the distribution of the characteristics in the sample, with a visual assessment and the use of the Shapiro-Wilk test. If the distribution of a characteristic was different from normal, medians (Me) and interquartile ranges (Q1; Q3) were used as the central measure. Parametric analysis of continuous values-student; nonparametric analysis of continuous values-Mann-Whitney

If the distribution of the characteristic was normal, the mean value was expressed as the arithmetic mean - M (mean) with a description of the 95% confidence interval (95% CI) or standard deviation (SD). If the distribution of symptoms differed from normal, the median (Me), quartiles (Q1, Q3) and interquartile range (IQR) were used as the central value.

To compare frequency indicators, Pearson's χ^2 test was used. If the number of any subgroups was less than 10, then a two-sided Fisher's exact test was used. A statistical significance level of $p=0.05$ was accepted to reject the null hypothesis.

The scientific novelty of the study thesis:

- for the First time, a comprehensive analysis of the clinical effectiveness of the developed "Device for eliminating subluxation of the foot, diastasis of the tibia-fibular syndesmosis, displacement of ankle fragments and trans-articular fixation of the foot to the tibia" was carried out (RF Patent no. 2690613, June 2019).

For the first time, using the proposed device, a comparative analysis of the life quality of treated patients was carried out.

For the first time in the comparative aspect, the economic efficiency of the proposed device was studied, with the determination of the cost indicators of inpatient treatment of these patients.

The scientific novelty of the proposed device allowed for the treatment of complex ankle fractures with subluxation or dislocation of the foot with a rupture of the tibia-fibular syndesmosis to conduct minimally invasive, low-cost closed osteosynthesis and improve the results of their treatment, in particular:

- reduce the incidence of complications in patients in the study group by 68.9% ($p=0.004$);

- improve the functional results of treatment by 19.1% ($p=0.03$), compared with the analogical data of patients in the comparison group;

- inflammation of the tissues around the wires and ankle arthritis reduced by 3 times, secondary dislocations of ankle fragments and foot subluxations reduced by 12.8% ($p<0.01$), traumatic injuries of articular cartilage reduced by 33.3% ($p=0.048$), absence of bends and fractures of spokes and spoke osteomyelitis reduced by 11.1% ($p<0.01$), good indicators in patients of the main group increased by 19.1% ($p=0.02$), satisfactory results decreased by 13.3% ($p<0.01$), and unsatisfactory results were absent at all, observed in the comparison group in 4.4% ($p=0.03$) of patients.

- using the developed device, the cost of inpatient treatment for one patient decreased by 14.9% ($p<0.01$), that is, by 44339 ± 1498 tenge ($p<0.01$).

The practical significance of the thesis study:

The usage in clinical practice of "Device for the elimination of subluxation of the foot, diastasis of the tibiofibularsyndesmosis, displacement of ankle fragments and trans-articular fixation of the foot to the tibia" (RF Patent No. 2690613, June 2019) for the treatment of severe injuries of the ankle joint revealed the following practically significant moments:

- perform a closed (without cutting the covering tissues) minimally invasive osteosynthesis operation of complex ankle fractures with dislocation of fragments, with subluxation of the foot and rupture of tibiofibularsyndesmosis;

- perform a reposition of complex ankle fractures with foot subluxation and diastasis of the tibiofibularsyndesmosis, with high accuracy up to a millimeter by

the parameters of the healthy leg, removed before reposition by the device using a millimeter scale (13) on the frame (1) of the device (Fig. 9, section 2.4.1);

- repositioned and fixed positions of ankle fragments with foot subluxation and rupture of the tibiofibular syndesmosis in the device allow x-ray examinations in main group patients without the risk of secondary displacement, even without TFS to the tibia, which we did not observe in comparison group after manual reposition, requiring forced spokes due to 100% secondary displacement of them without fixing the foot to the tibia;

- if residual phenomena of ankle fragments displacement, foot subluxation or rupture of the tibiofibular syndesmosis are detected, the device allows to complete their reposition more quickly and without additional injuries for the elements of the Ankle joint, due to the lack of fixing spokes, which can't be done in patients of the comparison group, without removing the fixing spokes held before;

- reduced trauma surgery closed osteosynthesis, as the spokes when TFF are conducted only once and objective evidence based on x-ray no residual phenomena of displacement of fragments ankles, subluxation of the foot and tear of TFF and the lack of deflection of the sharp ends of the spokes they are also a less traumatic operative reception and eliminates the need for their remake;

- The biomechanically justified triangular and parallel arrangement of spokes in the bones of the foot and lower leg increases the mechanical holding forces, in contrast to the method of conducting spokes in patients of the comparison group.

The above-mentioned practically significant features of the device allowed to reduce the frequency of complications observed among patients of the comparison group during their treatment, thereby improving the results of treatment of patients of the study group, reducing the cost of treatment, improving the quality of life of patients during their treatment in the long-term follow-up, save material costs of health authorities and time of medical staff when providing urgent urgent care.

Conclusions:

1. In a retrospective analysis of the results of treatment of 508 patients with complex ankle fractures with subluxation of the foot and rupture of tibiofibular syndesmosis (TFS), conservative treatment was performed in 60 (11.8%) patients. Various complications during their treatment were found in 17 patients (28.3%, $p < 0.01$). Surgical treatment was performed in 100 (19.7%) patients, including 21 patients (21.0%) with complications ($p < 0.01$). Among 348 (68.5%) patients who used manual repositioning and TFS to the tibia with spokes followed by a plaster cast, complications were found in 59 patients (16.9%) ($p < 0.01$). Among the patients of the last group, the most common were secondary foot subluxations (17.0% - $p < 0.01$), dislocation of fragments (6.3% - $p = 0.03$), osteoarthritis (13.5% - $p < 0.01$), bending of the spokes and fractures (6.9% - $p < 0.01$), delayed consolidation of fractures (8.9% - $p = 0.03$), and GSS contractures (4.3% - $p = 0.02$).

The causes of these complications were repeated repeated wires due to the forced repeated manual reposition (2-3 times), re-examination of incorrectly performed spokes caused additional trauma to the tissues of the foot, SCS and lower leg. In addition, when the plaster cast was loosened, they did not strengthen or shift, which contributed to the appearance of negative consequences of treatment.

2. Despite these shortcomings, traumatologists and orthopedists of the Semey Ambulance Hospital preferred closed osteosynthesis with TFS to the tibia with wires (68.5%) when providing urgent care than conservative and open surgical methods. In the treatment of patients with malleolar fractures, subluxation or dislocation of the foot and with a gap of TFS offered by the device in patients of the study group compared with the comparison group showed that artrose-arthritis in the main group compared to the comparison group were 3 times lower (at 5.2%, $p=0,07$ and 15.6%, $p=0,07$), the defeat of the cartilage of the joints based on CT or 33.3%, ($p=0.048$) lower secondary displacement of fragments ankles and feet, bend and broken spokes by 12.8% ($P<0.01$) rarely met, and inflammation of the soft tissues around the spokes has decreased in 3 times, spoke of osteomyelitis did not exist. Therefore, there were 19.1% more good results of treatment in the main group ($p=0.03$), and 14.7% less satisfactory results ($p<0.01$). There were no unsatisfactory results in the main group. The duration of treatment among patients with complications in the comparative group compared to the main group was 10.1 ± 0.7 ($p=0.04$) days (by 11.0%, $p=0.03$).

3. In the treatment of patients using the "device", according to questionnaires FAOS and SF-36 quality of life of patients in the main group compared with the results of the comparison group after 1 year showed that the amount of activity in daily life by 2.7 ± 0.1 ($p<0.01$), the scale of sports and recreation by 6.7 ± 0.2 ($p<0.01$), pain by 12.8 ± 0.1 ($p<0.01$), and the scale of symptoms by 7.7 ± 0.1 ($p<0.01$) were better, and had a high degree of confidence.

4. Due to the decrease in the frequency of complications among the main group of patients treated in the hospital using the device, the average cost of treatment per patient was lower by 44339 ± 1498 tenge ($p<0.01$), i.e. by 14.9% ($p<0.01$).

When comparing the functional results of two AOFAS-treated groups, the "cost-effectiveness" indicator in the main group was lower by 1.27 thousand tenge/point compared to the data of the comparison group, or better by 26.14% ($p<0.01$).

The main provisions submitted for protection:

The provision of emergency care to patients with complex ankle fractures with subluxation of the foot and rupture of the tibiofibularsyndesmosis:

- after repositioning displacement of ankle fragments, foot subluxation and tear of the tibiofibularsyndesmosis manually by the "eye" and the "hands" of the doctor, and TFF to the tibia wires are very common residual displacement of ankle fragments or foot subluxation, or TFS tear, if these offsets we are not able to resolve at a fixed condition of the foot to the leg, then we need to pull out the

needles, and repeat all over again, to reposition and TFS to the tibia wires, sometimes it must be done internally 2-3-4... repeated operations of the spokes lead to secondary, traumatic damage to the tissues of the foot and lower leg, muscles, tendons, blood vessels, nerves, cartilage coverings of the talocalcaneal joints and ankle joint, which, in combination, reduce the indicators of treatment results, unsatisfactory indicators appear, treatment costs increase multiple times and the operation time increases;

- when using the devices offered by us, the disadvantages of the traditional method of repositioning and TFF to the tibia by wires are eliminated, since in this case the traumatology doctor can reposition the device, to objectively monitor the accuracy of the repositioning of x-ray studies without the wires, to incorporate if necessary, and after education only once, correctly, to produce TFF for tibia without risk of deviation;

- reduce the frequency of treatment complications both during surgery and in the postoperative period;

- eliminate the deviation of the sharp ends of the spokes outside the bones into the soft tissues of the foot and lower leg with the threat of their damage, with their location in a triangular shape, parallel to each other based on a biomechanical reasonable calculation, which allows:

- improve the good and reduce the satisfactory results of their treatment, eliminate the unsatisfactory indicators;

- improve the quality of life of patients during their treatment in the long-term follow-up period;

- reduce the cost of their treatment, to reduce the time of performing surgical reception of closed minimally invasive osteosynthesis.

Information about publications:

17 works have been published on the topic of the dissertation, of which 5 articles have been published in journals recommended by the Committee on Control in the field of education and science of the MES of Kazakhstan; 3 articles in indexed publications in the Tomson Reuters database (patentref) and Scopus (2); 9 abstracts in the materials of the international scientific conferences;

Patents received:

- "Device for the trans-articular carrying of spokes through the foot to tibia" (certificate no. 55201, 2006; Nur-Sultan and pre-Patent no. 19661, 2006; Committee on Intellectual Property Rights of the Ministry of Justice of the Republic of Kazakhstan;

- "Device for eliminating subluxation of the foot, diastasis of TFS, displacement of ankle fragments and trans-articular fixation of the foot to the tibia" (RF Patent no. 2690613, 04. 06.2019 G., bull. No. 16, 2019 of the Federal Service for Intellectual Property of the Russian Federation, Moscow-is equated as an article with an impact factor (if) based on the Tomson Reuters database).

Scope and structure of the dissertation:

The dissertation consists of an introduction, 3 sections of research, a general conclusion, a conclusion and practical recommendations, and a list of the literatures, including 218 titles.

The text is typed in computer form 143 pages, the text is made of 14 tables, 57 figures and diagrams.