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The choice of osteosynthesis technology for unstable clavicle fractures

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Background Review of the effectiveness of different methods used to repair clavicle injury allows for identifying rational aspects of treatment factors that would directly reflect key pathogenetic mechanisms. A greater part of surgical treatment options have been reported to lead to faster recovery of the patients' structural and functional stereotypes in majority of the cases. **Purpose** Improve outcomes of surgical treatment of middle-third clavicle fractures. **Material and methods** Experimental bench tests of various osteosynthesis technologies using original interlocking intramedullary nail for clavicle fracture and a clinical study of 104 patients with middle-third clavicle fractures were carried out. Original IM nail was applied to repair clavicle fracture in index group (n = 48) and the fractures were plated in control group (n = 56). The DASH questionnaire was used to evaluate results of surgical intervention at 3, 6 and 12 months. **Results** Original IM nail and plate with angular stability showed comparable characteristics in stability. Original compression interlocking intramedullary nail offered to treat middle-third clavicle fractures showed improvements in outcomes of the patients. **Discussion** The algorithm developed for diagnosis, treatment and rehabilitation of clavicle fractures showed better results of treatment providing easier social reintegration into everyday life. Clinical findings demonstrated significantly improved DASH scores and lower complications rate in index group (p = 0.038).

Keywords: clavicle, middle third, fracture, osteosynthesis, bench test, intramedullary nail, plate

INTRODUCTION

Clavicle fractures are relatively common injuries representing 2.6-4% of all fractures. The midshaft portion is the most frequently fractured area of the clavicle, and midshaft fractures account for 69-82% of all clavicle fractures [1, 2, 3, 4]. Clavicle fractures most often occur in young active individuals [5, 6].

Review of the effectiveness of different methods used to repair clavicle injury allows for identifying rational aspects of treatment factors that would directly reflect key pathogenetic mechanisms. A greater part of surgical treatment options have been reported to lead to faster recovery of the patients' structural and functional stereotypes in majority of the cases. However, complications and poor outcomes can develop due to different reasons including fracture pattern, benefits of osteosynthesis technology used and optimality of rehabilitation programme [7, 8, 9].

Intramedullary fixation is an accepted method of treating diaphyseal fractures of different segments to provide stable bone fixation. Intramedullary pin plays a role of internal bar aligned with the axis of the fractured bone with minimally disturbed vascularity at the fracture site providing good conditions for osteoreparation and minimizing risk of hardware migration with the possibility of early functional rehabilitation [10, 11]. There is a need of comparative analysis of the effectiveness of different technologies of osteosynthesis used to repair clavicle fractures. The main aim of the study was to improve outcomes of surgical treatment of middle-third clavicle fractures.

MATERIAL AND METHODS

The study included experimental bench tests of different technologies of osteosynthesis and clinical review of two groups of patients. Six groups of experimental specimens of middle-third clavicle fractures simulated with similar mechanism on biomodels and synthesised with different implants randomising technology of osteosynthesis and a group with intact bone were investigated. Biomodels were comparable by anthropometry, age and gender. A bone-implant-bone specimen was identified for the test using technique of random sampling. Conditions for bench tests of bone-implant-bone system were relevant by injury mechanogenesis. Instron 1185 universal testing frame was used. Specimen ends were fixed with epoxide composition in a metal cup 15 mm high and 42 mm in diameter. Specimens were

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deformed from the bottom to the top at the rate of 2 mm/minute with acromion end at the bottom and sternum on top. Each system was gradually loaded along the axis of the limb to complete destruction at the rate of 2 mm/minute.

The tests were performed for the next specimens:

1) a specimen with intact clavicle;

2) a specimen with 1.2 mm reconstruction plate and six screws;

3) a specimen with 2.3 mm reconstruction plate and six screws;

4) a specimen with interlocking IM nail of original design (patent of invention № 2281786 dtd 25.03.2005, № 2345730 dtd 10.02.2009);

5) a specimen with LCP plate and six screws with three interlocking screws;

6) a specimen with thick 3.5 × 4.5 mm Bogdanov's IM nail;

7) a specimen with 2 × 3 mm Bogdanov's IM nail.

Analog-to-digital converter was used to document tests automatically recording time, speed, loading force and cinematography. Maximal values of load resistance, length of effective load resistance, critical points of the system failure, magnitude of decline in interfragmental stability and pattern of stress decrease were measured.

Clinical study included 104 patients with middle-third clavicle fractures treated at Ufa hospital № 13 and central regional hospital of Tuimazy between 2009 and 2017. There were 82 male patients. The mean age was 32.3 years. Clavicle fracture was fixed with intramedullary nail of original design in patients of index group (n=48) and plated in control group (n=56). Both groups were comparable by gender, age and severity of injury.

Outcome measures comprised orthopaedic status and functional condition with the Disabilities of the Arm Shoulder and Hand (DASH) score. Radiography of the broken segment was performed pre-, postoperatively, at 3, 6 and 12 months after the surgery.

Statistical data analysis was performed using Statistica 7.0 computer program. Quantitative assessment included mean, standard deviation, median, lower, upper quartile, minimum, maximum, range. Kolmogorov-Smirnov test was used when distribution was different from the norm with criteria chosen to compare groups. Mann-Whitney test was employed to compare groups' mean of the variable which normal distribution was denied. $P < 0.05$ was considered statistically significant.

The study was conducted in accordance with the Declaration of Helsinki and ethical guidelines for clinical studies and was approved by the institutional review board of Federal State Budget Educational Institution of Higher Education Bashkir State Medical University of the RF Ministry of Health. Written informed consent was obtained from all patients.

An implant of original design for intraosseous osteosynthesis represents a compression interlocking nail of circular cross-section (1) threaded (2) at one end and flatly extended (3) with screw hole (4) at the other end. The device has two detachable parts including square metal plate (5) with a screw hole (6). Holes in the tube have two diameters at the end and at the base (**Fig. 1**).

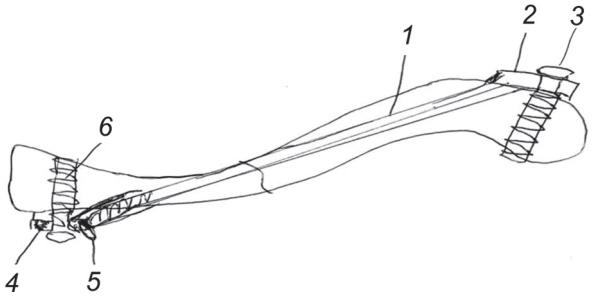

Fig. 1 Intramedullary nail of original design

Threaded end of the nail is made as a truncated cylinder. Bilateral upright truncation is provided at the flat extension. The detachable plate with a tube of two diameters, a less diameter hole at the end of the tube are meant for truncated cylinder with minimal access to threaded end to avoid mobility between nail and plate.

Osteosynthesis with the nail of original design was less invasive in most of the cases. An incision of 2.5 to 3 cm was produced at the clavicle sternum end, the bone was reduced in a closed manner and 6 mm canal arranged to introduce the nail along the axis of the central and peripheral fragments with flat extension settled on the bone and threaded end being in the hole on the posterior surface of the clavicle. Extension end of the nail can be reshaped for better contact with the bone if needed. The plate with the tube was attached to the threaded end on the posterior surface of the clavicle providing contact between the plate and the bone. The plate could be reshaped for better contact with the bone. A nut is attached to the threaded end of the nail to ensure bone compression. Then the nail is anteroposteriorly locked at the flat

extension on the sternum end with standard 2.5 mm screws and posteroanteriorly at the plate with the tube. With accurate reduction and reliable fixation provided the wounds were sutured by layers.

RESULTS

Bench tests of bone-implant-bone system and intact bone showed maximal mechanical strength in intact specimens destroyed with a load of 2600 N on average. Maximal values of load resistance with standard technologies applied with certified implants were as follows (**Fig. 2**):

Group 2 (2.5 mm reconstruction plate) – 1520 N;
Group 3 (4 mm reconstruction plate) – 1730 N;
Group 4 (IM nail of original design) – 2450 N;
Group 5 (LCP plate) – 2480 N;
Group 6 (2 × 3 mm Bogdanov's nail) – 1010 N;
Group 7 (3.5 × 4.5 Bogdanov's nail) – 1260 N.

The utmost temporary resistance was detected in specimens fixed with LCP plate that remained stable for 817 seconds of the experiment. Less temporary resistance was observed in specimens fixed with reconstruction plate and IM nail of original design. The lowest values showed specimens fixed with Bogdanov's IM nail.

Evaluation of baseline stability characteristics of bone-implant-bone system with use of explored technologies of osteosynthesis of middle-third clavicle fractures showed critical points of failure and aspects to improve functional quality of implant.

Comparative analysis of maximal values of axial load resistance revealed comparable measures between plating and IM nailing. Maximal timing resistance exhibited specimens with LCP plate with the measure exceeding that of other specimens by 3.4 times.

Outcomes of clinical study showed significant advantages in index group (Me = 21.5, Q1 = 18, Q3 = 27) as compared to the control group (Me = 24.0, Q1 = 19, Q3 = 28.25) on DASH score (p = 0.038) at 12 months after surgery (**Fig. 3**).

Clinical instance. A 43-year-old male patient, an engine driver, sustained a closed middle-third clavicle fracture resulting and injury at home. The fracture was fixed with interlocking IM nail of original design after 3 days of injury. No external immobilisation was provided. Exercise therapy started after 3 postoperative days. The patient could return to his job after 2 months of injury. Ha had 23.8 points on DASH score at 1 year after surgery.

Control group showed high rate of fixator migration. Other complications were comparable in both groups.

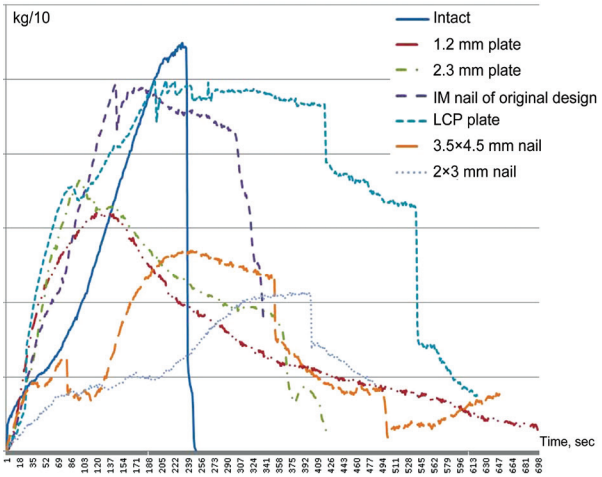

Fig. 2 Mechanical strength of bone-implant-bone system during fixation of middle-third clavicle fracture

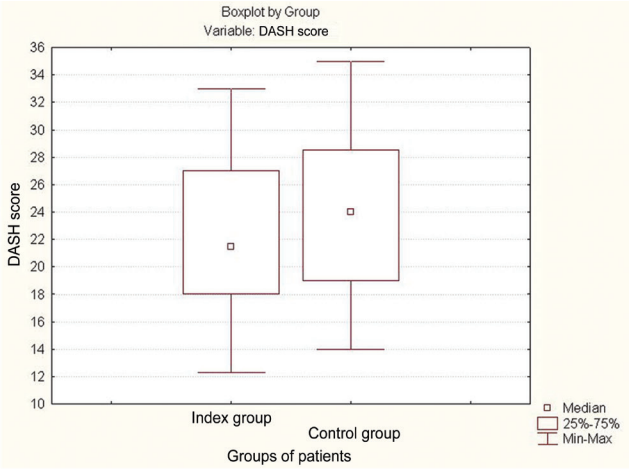

Fig. 3 Comparative analysis of functional condition of upper limb on DASH score at 1 year after surgery in index and control groups

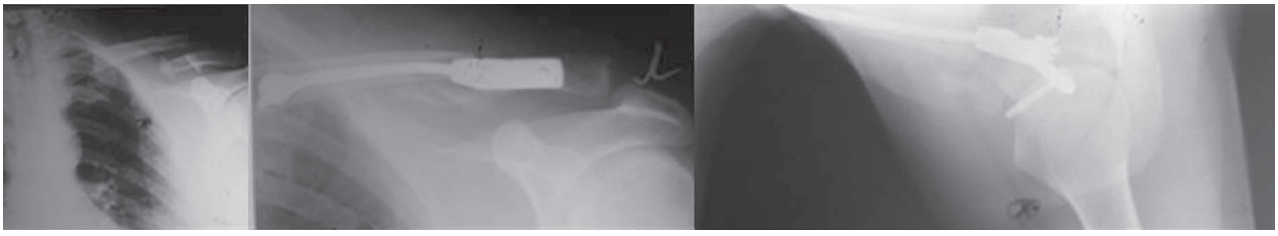

Fig. 4 Radiograph of the fracture site on admission and after operative treatment

Table 1

Complications of clavicle osteosynthesis

Type of fixator applied	Fixator migration	Broken fixator	Delayed consolidation	Total number of complications
Index group (n = 48)	0	0	1 (2.08 %)	1 (2.08 %)
Control group (n = 56)	5 (8.93 %)	1 (1.79 %)	1 (1.79 %)	7 (12.5 %)

DISCUSSION

Comparative analysis of the effectiveness of different technologies of osteosynthesis is traditionally based on clinical studies. Despite multiple publication in the field, advances in trauma and orthopaedics the optimal treatment of clavicle fracture is controversial [3, 4, 5, 6]. Biomechanical tests performed did not indicate to evident advantages of one of the technologies [12]. The study showed possibilities with different techniques from other side and allowed for evaluation of the functional properties of the constructs and mechanical characteristics. This aids the proper choice of the technology of osteosynthesis.

Bench tests of bone-implant-bone system applied to clavicle showed that none of the technologies could reach mechanical strength of intact bone. Axial load tests indicated to simultaneous stress decrease in intact specimens and gradual stress decrease in bone-implant-bone systems.

Patients with clavicle fractures are to be comprehensively evaluated considering impaired upper limb girdle as one of the key kinematic unit of the skeleton. The choice of technique to repair clavicle fracture requires differentiated approach to benefits of the technology of surgical treatment to be used.

The technology offered to treat middle-third clavicle fractures using original compression interlocking IM nail allowed us to improve outcomes in this cohort of patients. Algorithm of diagnosis, treatment and rehabilitation devised for patients with clavicle fractures has shown to optimise results of the treatment providing the social reintegration.

CONCLUSION

1. The construct offered can be recommended as the method of choice to fix clavicle fracture demonstrating higher mechanical characteristics as compared to other systems being comparable with plate with angular stability.

2. Long-term outcomes of middle-third clavicle fractures showed effectiveness of standard techniques of osteosynthesis. However, there is a certain complication rate observed in the form of nonunions and contractures.

3. Intraosseous osteosynthesis with compression interlocking IM nail designed to fix middle-third clavicle fractures (patent on invention № 2281786 dtd 25.03.2005, № 2345730 dtd 10.02.2009) has shown to be more efficacious in functional recovery of patients by DASH score and complication rate as compared to plating.

4. Knowledge of implants' functional qualities allows for prognosis of the survival and appropriate choice of osteosynthesis technology and can be the key factor for efficacious surgical treatment and functional rehabilitation.

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