THE RESULTS OF TREATMENT OF FEMORAL DIAPHYSIS FRACTURES USING LOCKED INTRAMEDULLARY OSTEOSYNTHESIS AND EXTRAMEDULLARY OSTEOSYNTHESIS (RESULTS FOR 10 YEARS)

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ABSTRACT

Background. *Femoral diaphysis fractures are one of the most common and significant injuries to the bones of the limbs. Locked intramedullary osteosynthesis makes it possible to reduce the injury rate of the surgery and its length, as well as to carry out early rehabilitation of patients.*

The aim of the study. *To conduct a continuous retrospective single-purpose comparative study of the results of treatment of patients with femoral diaphysis fractures treated with locked intramedullary osteosynthesis and extramedullary osteosynthesis for 10 years. This study did not include patients with double femoral fractures treated by osteosynthesis using a combination of two implants – locked intramedullary implant and extramedullary implant.*

Material and methods. *We conducted a retrospective study of the results of treatment of patients from 2011 to 2020. During this period, we treated 794 patients aged from 16 to 77 years with femoral diaphysis fractures. The share of people of working age was 75 %. The patients were divided into two groups depending on the method of surgical treatment. Group 1 included 500 patients who had surgical treatment using locked intramedullary osteosynthesis. Group 2 included 294 patients who had surgical treatment using extramedullary osteosynthesis.*

Results. *In patients of group 1 treated with locked intramedullary osteosynthesis, good anatomical and functional treatment results were achieved in 70 % of cases; satisfactory treatment results – in 25.2 % of cases, unsatisfactory results – in 4.8 %. In the group 2, good results were achieved in 61.9 % of cases, satisfactory – in 29.6 %, unsatisfactory – in 8.5 %.*

Conclusion. *The obtained results of treatment of femoral diaphysis fractures show the undeniable advantage of using locked intramedullary osteosynthesis compared to extramedullary osteosynthesis.*

Key words: *femoral diaphysis fracture, extramedullary osteosynthesis, locked intramedullary osteosynthesis, complications of femoral osteosynthesis*

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РЕЗУЛЬТАТЫ ЛЕЧЕНИЯ ПЕРЕЛОМОВ ДИАФИЗА БЕДРЕННОЙ КОСТИ БЛОКИРУЕМЫМ ИНТРАМЕДУЛЛЯРНЫМ И НАКОСТНЫМ ОСТЕОСИНТЕЗОМ (ИТОГИ ЗА 10 ЛЕТ)

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РЕЗЮМЕ

Обоснование. *Переломы диафиза бедренной кости являются одними из наиболее распространённых и значимых повреждений костей конечностей. Блокируемый интрамедуллярный остеосинтез (БИОС) позволяет уменьшить травматичность операции и время её проведения, а также проводить раннюю реабилитацию пациентов.*

Цель исследования. *Провести сплошное ретроспективное одноцелевое сравнительное исследование результатов лечения пациентов с переломами диафиза бедренной кости, лечившихся способом блокируемого интрамедуллярного остеосинтеза (БИОС) и способом накостного остеосинтеза пластинами, за 10 лет. Не включены в данное исследование пациенты с двойными переломами бедренной кости с остеосинтезом сочетанием двух имплантов – БИОС и накостного.*

Материал и методы. *Нами проведено ретроспективное исследование результатов лечения пациентов с 2011 по 2020 г. В отделении за данный период было пролечено 794 пациента в возрасте от 16 до 77 лет с переломами диафиза бедренной кости. Доля лиц трудоспособного возраста составила 75 %. Пациенты были разделены на две группы в зависимости от применённого метода оперативного лечения. Первая группа – оперативное лечение методом интрамедуллярного блокируемого остеосинтеза (500 пациентов). Вторая группа – оперативное лечение методом накостного остеосинтеза пластинами (294 пациента).*

Результаты. *В первой группе пациентов, пролеченных методом БИОС, хорошие анатомо-функциональные результаты лечения были достигнуты в 70 % случаев; удовлетворительные результаты лечения – в 25,2 % случаев, неудовлетворительные результаты – в 4,8 %. Во второй группе хорошие результаты достигнуты в 61,9 % случаев, удовлетворительные – в 29,6 %, неудовлетворительные – в 8,5 %.*

Заключение. *Полученные результаты лечения переломов диафиза бедренной кости показывают неоспоримое преимущество применения блокируемого интрамедуллярного остеосинтеза по сравнению с накостным остеосинтезом.*

Ключевые слова: *перелом диафиза бедренной кости, накостный остеосинтез, блокируемый интрамедуллярный остеосинтез, осложнения остеосинтеза бедренной кости*

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INTRODUCTION

Femoral shaft fractures are among the most common and significant injuries of extremity bones. These fractures are particularly common in victims with multiple and combined trauma. The frequency of these injuries has remained high in recent years [1, 2]. Femoral shaft fractures comprise up to 20 % of femoral shaft injuries [3, 4]. The technically correct and timely surgical treatment of these fractures directly affects the quality of life and further ability of patients to work. The incidence of various complications can range from 5 % to 35 % [5, 6]. Many different techniques are available and used for surgical treatment, the priority of which has changed with the passage of time and advances in technology. Since the mid-20th century, the emphasis was mainly focused on the use of external osteosynthesis with external fixation devices, which, despite their effectiveness, remained rather inconvenient and labour-intensive to use, required constant care of spokes and rods, and brought discomfort and inconvenience to patients. At the end of the 20th century, the priority in the treatment of these fractures shifted towards immersion extra-cortical osteosynthesis with plates [7–10].

A less invasive and more functional in the postoperative period method of treatment of femoral shaft fractures with an intramedullary locking nail became actively used in the early XXI century and subsequently became the gold standard of treatment.

This technique used in surgical treatment significantly reduces injuries to soft tissues during surgical access and the surgical access itself, eliminates the need for external immobilisation, allows for stable strong fixation, reduces the operation time. Locked intramedullary osteosynthesis (LIOS) can provide early activation and rehabilitation measures from the first days after surgery, which significantly reduces the risk of complications in the postoperative period [11, 12].

THE AIM OF THE STUDY

To conduct a continuous retrospective single-targeted comparative study of the treatment results in patients with fractures of the femoral shaft treated by locked intramedullary osteosynthesis and extra-cortical osteosynthesis with plates over a period of 10 years. All surgeries during the years under study were performed by surgical teams of the traumatology department, formed from physicians with the highest and first qualification category.

The work was approved at the meeting of the Local Ethical Committee of the Izhevsk State Medical Academy (Minutes No. 763 dated October 24, 2022), was carried out in accordance with the ethical standards of the World Medical Association Declaration of Helsinki "Ethical Principles of Scientific Medical Research Involving Human Subjects" as amended in 2013 and "Rules of Clinical Practice in the Russian Federation" approved by the order of the Ministry of Health of Russia dated June 19, 2003 No. 266. All patients signed informed consent to undergo a surgery and to publish the findings without identifying themselves.

MATERIAL AND METHODS

In the traumatology department of the First Republican Clinical Hospital of the Ministry of Health of the Udmurt Republic, locked intramedullary osteosynthesis has been used since 2010 along with extra-cortical osteosynthesis. A comparative analysis of the patient outcomes with femoral shaft fractures (according to AO fracture classification: 32A, 32B, 32C) between 2011 and 2020 was performed.

The study excluded patients with double femur fracture who were being treated with two methods of operative treatment – locked intramedullary osteosynthesis and extra-cortical osteosynthesis [13].

Statistical processing of the research was carried out in two directions. Firstly, the hypothesis of the equality of samples of the analyzed signs (Pearson's Chi-squared test) and the hypothesis of the difference in the effectiveness of the treatment methods used (Student's T-test) were tested. All calculations were performed using a personal computer.

During this period, 794 patients aged 16 to 77 years with femoral shaft fractures were treated in the department. The proportion of working-age individuals was 75 per cent.

Open fractures were observed in 24 (3 %) patients, multisegmental fractures in 27 (3.4 %) patients, and pathological fractures (benign and malignant tumors) in 8 (1 %) patients.

Patients were divided into two groups depending on the surgical treatment method they underwent. The first group included patients whose surgical treatment was implemented by the method of locked intramedullary osteosynthesis – 500 patients. The second group included patients who underwent extra-cortical osteosynthesis with plates – 294 patients.

The number of patients treated in different years is summarised in Table 1.

The table reveals that at the beginning of the second decade of the 21st century, LIOS of the femoral shaft is gradually becoming the main method of surgical treatment being used. Extra-cortical osteosynthesis of femoral shaft fractures has been gradually phased out since 2014. By the end of the second decade, LIOS was already being used in 3/4 of patients in our department.

According to the type of fracture received, the patients were distributed as follows (Table 2).

In terms of fracture type, simple A1–A3 type fractures were predominant in both groups (± 56.8 %). The low number of compound fractures of the C1–C3 type (< 5 %) is to be mentioned (Table 3).

In terms of gender composition, males predominated in both groups.

The mean age of patients in the first group was 49.76 ± 20.36 years and in the second group it was 47.04 ± 16.6 years.

TABLE 1

NUMBER OF PATIENTS WITH FEMORAL SHAFT FRACTURES OVER A 10-YEAR PERIOD (LIOS AND EXTRA-CORTICAL OSTEOSYNTHESIS)

Surgical treatment method	Year										Total (patients)
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	
LIOS	15	50	44	36	40	47	50	65	77	76	500
Extra-cortical osteosynthesis using plates	49	43	44	39	32	27	18	16	13	13	294

TABLE 2

DISTRIBUTION OF PATIENTS BY FRACTURE TYPE

Fracture type according to AO classification	Patients who underwent LIOS treatment	Patients who underwent extra-cortical osteosynthesis treatment
A1–A3 type fractures	291 (58.2 %)	163 (55.4 %)
B1–B3 type fractures	189 (37.8 %)	125 (42.5 %)
C1–C3 type fractures	20 (4 %)	6 (2.1 %)
Total	500 (100 %)	294 (100 %)

TABLE 3

AGE AND SEX DISTRIBUTION OF PATIENTS

Age (years)	Patients who underwent LIOS treatment	Men	Women	Patients who underwent extra-cortical osteosynthesis treatment	Men	Women
16–18	10 (2 %)	5 (50 %)	5 (50 %)	8 (2.7 %)	5 (62.5 %)	3 (37.5 %)
19–45	172 (34.4 %)	95 (55.2 %)	77 (44.8 %)	115 (39.1 %)	63 (54.8 %)	52 (45.2 %)
46–60	180 (36 %)	94 (52.2 %)	86 (47.8 %)	105 (35.7 %)	59 (56.2 %)	46 (43.8 %)
61 years and older	138 (27.6 %)	71 (51.5 %)	67 (48.5 %)	66 (22.5 %)	37 (56 %)	29 (46 %)
Total	500 (100 %)	265 (53 %)	235 (47 %)	294 (100 %)	164 (57.3 %)	130 (42.7 %)

In terms of age and gender composition, the groups were comparable to each other, as statistical analysis revealed no statistically significant differences ($p > 0.05$).

Patients were admitted to the hospital both initially for emergency indications and by transfer from central district hospitals (CDH) for surgical treatment in the first few days after injury. During hospitalisation standard manipulations and examinations were performed in accordance with the accepted standards – in case of fractures of bones of the lower extremity, ultrasound examination (US) of the lower extremity vessels to exclude blood clots in the veins was obligatory included. Our initial assumption for lower extremity venous ultrasound is that according to the Caprini scale of individual risk assessment for venous thromboembolic complications, all our patients had moderate or high risk of venous thromboembolic complications (bed rest for more than 72 hours and severity of operative treatment) [14]. Prior to surgery, patients with lower extremity injuries were under skeletal traction, and either osteosynthesis with external fixation apparatus as a stage of preoperative preparation was performed as an emergency indication.

The surgeries were performed after the acute period subsided after the patients recovered from shock, in average on the days 5–10. In case of venous thrombosis in the veins of the lower extremity, treatment with anticoagulants followed by ultrasound control of the veins was performed.

Early rehabilitation was used in the postoperative period no matter the method of femoral osteosynthesis. Motion in the joints adjacent to the fracture were commenced from the first day after surgery. Axial load (walk-

TABLE 4

LUBOSHITZ – MATTIS – SCHWARTZBERG FEMORAL FRACTURE TREATMENT OUTCOME ASSESSMENT SYSTEM

Indicator	Score, points		
	4	3	2
Pain	none	with heavy physical activity	with light physical activity
Radiological signs of fracture consolidation	fusion at mid-physiological term	slow consolidation	false joint
Shortening (anatomical)	none	up to 2 cm	over 2 cm
Segment deformation	none	up to 10°	over 10°
Range of motion in adjacent joints	full	minor restrictions	pronounced restrictions
Thigh muscle atrophy	none	up to 2 cm	over 2 cm
Vascular disorders	none	hypostatic edema	edema and other disorders
Neurological disorders	none	nerve paresis	nerve paralysis
Infectious complications	none	soft tissue	osteomyelitis
Functional fitness of the extremity, ability to work	restored, no means of additional support required	use of a walking stick, orthopedic shoes	loss of extremity support; need to use crutches

ing) was allowed on the next day after surgery or after the oedema had subsided, with the use of unloading aids on the days 3–4 depending on the somatic and functional status of the patient and the method of osteosynthesis. In case of LIOS, partial loading up to 30 % of the patient's weight (lightly stepping in) is permissible on the second or third day, and in case of extra-cortical osteosynthesis – after two months. When discharged from the hospital, the recommendations in case of LIOS included the necessity of dynamisation 2 months after surgery, as timely dynamisation is a preventive measure for delayed consolidation and formation of a false joint [15, 16].

Treatment results and the anatomo-functional state of the extremity were assessed according to the Luboshitz – Mattis – Schwartzberg outcome scorecard [17–19], considering the degree to which the patient returned to the premorbid level of extremity function. A comprehensive assessment of the obtained treatment results was performed using the clinical parameters summarised in Table 4. Ten parameters characterising the adequacy of reparative osteogenesis and its X-ray image, as well as the result of patient rehabilitation were assessed during the study of anatomo-functional results. Each of these indicators was evaluated in points – 4, 3, 2. Treatment outcome was assessed by dividing the sum of the numerical expressions of all indicators by the number of indicators studied. The resulting mean numerical expression for the anatomo-functional outcome (index) corresponded to the defined treatment outcome. An anatomo-functional result was considered good if the treatment index was 3.5–4, satisfactory if the index was 2.6–3.4, and unsatisfactory if the index was 2.5 points or less (Table 4).

RESULTS

The results of surgical treatment were monitored in all patients in 8–12 months (Table 5).

In the first group of patients treated by LIOS method, good anatomo-functional results of treatment were achieved in 350 (70 %) patients, satisfactory in 126 (25.2 %) patients, and unsatisfactory in 24 (4.8 %) patients.

Complications in the form of non-union of the fracture and formation of a false joint were revealed in 23 (4.6 %) cases. These complications were mainly observed in the group of patients of working age, from 19 to 60 years old. The causes of these complications were: soft tissue interposition; insufficiently accurate repositioning; combined trauma in the patient; lack of load on the operated extremity; not performed or not timely performed dynamisation of the fracture area. According to literature data, infectious complications comprise up to 4 % [20]; according to our data, these complications occurred in 1.4 % of patients underwent surgery (7 patients) for open fractures and against the background of, as a rule, high-energy trauma. Conventional antibiotic therapy after necrectomy resulted in cure. This is associated with the fact that patients with a suspicion of the possibility of infectious complications after the performed operation were under constant dynamic observation.

Patients with signs of non-union formation underwent the following surgeries at an early stage (1.5 time periods from the proper average physiological fusion of a particular bone, i. e. after 5–6 months): rod replacement with a larger diameter with reaming of the medullary canal; open re-

TABLE 5

TREATMENT OUTCOMES OF PATIENTS IN BOTH GROUPS AND INCIDENCE OF COMPLICATIONS

Patient group	LIOS treatment method		Extra-cortical osteosynthesis treatment with plates	
	n	%	*n*	%
Treatment results				
Good	350	70 %	182	61.9 %
Satisfactory	126	25.2 %	87	29.6 %
Unsatisfactory	24	4.8 %	25	8.5 %
Total	500	100 %	294	100 %
Complications that have arisen				
False joint formation	23	4.6 %	26	8.8 %
Infectious complications	7	1.4 %	6	2 %
Implant migration and failure	11	2.2 %	10	3.4 %
Total	41	8.2 %	42	14.2 %

positioning with elimination of displacement and elimination of soft tissue interposition; Khakhutov bone grafting without removal of the blocked rod.

Complications in the form of migration and fracture of the locked rod and screws were observed in 11 (2.2 %) cases. These complications are associated with errors in surgical technique, failure to dynamise the fracture and excessive activity in the form of full early loading (failure to comply with the recommendations of the attending physician when the patient is discharged from hospital). Treatment in this case included removal of the broken structure and rheosteosynthesis with a larger diameter nail.

In the second group of patients treated by extra-cortical osteosynthesis with plates, good anatomo-functional treatment results were achieved in 182 (61.9 %) patients, satisfactory treatment results – in 87 (29.6 %) patients, unsatisfactory treatment results – in 25 (8.5 %) patients.

Non-unions and false joint formation were observed in 26 (8.8 %) patients. These complications were caused by: unstable and inaccurate fixation of bone fragments, interposition of soft tissues between the fragments; too early loading of the operated extremity; ineffective immobilisation [21, 22].

The following surgical procedures were performed to correct the non-union: repeated rheosteosynthesis with a plate after excision of scar tissue; plate removal; bone grafting according to Khakhutov; osteosynthesis with a lockable rod.

Infectious complications were observed in 6 (2 %) patients. Migration and breakdown of metal structures were observed in 10 (3.4 %) patients. These complications were caused by insufficiently stable fixation, excessive early loading of the operated extremity and inadequate immobilisation.

DISCUSSION

In summary, the ten-year experience of treatment of 794 patients with femoral shaft fractures has shown high efficacy of the applied treatment techniques. Generally, good and satisfactory anatomo-functional treatment results were achieved in 745 (93.8 %) patients. The risk of various types of complications was significantly lower with locked intramedullary osteosynthesis than with extra-cortical osteosynthesis with plates. The number of non-unions and false joint formations is 4.2 % lower, and the number of infectious complications is 0.8 % lower. As well, the interlocking nail is more resistant to loads and the risk of failure and migration of steel structures is lower by 2 % [23–25]. These results were proved by statistical analysis, in which the value of the Student's t-test was 2.50, that is, the differences were statistically significant ($p = 0.012664$). The Student's t-test critical value was 1.972 at a significance level of $\alpha = 0.05$.

Locked intramedullary osteosynthesis has become the gold standard for the treatment of diaphyseal femoral fractures for a number of reasons. The use of this method allows early loading of the operated extremity and does not require additional immobilisation, which is a key factor enabling early rehabilitation of patients, which is especially important for elderly and senile patients and those with comorbidities. The use of LIOS approach also reduces the risk of infectious complications and migration of metal structures. LIOS is obviously a less traumatic method of surgical treatment, requiring minimal operative access, minimising blood loss during surgery and, when used correctly and with the necessary experience, reducing operative time compared to extra-cortical osteosynthesis. All these factors make it possible to reduce the period of stay of pa-

tients in hospital and thereby increase the bed turnover and economic efficiency of the department.

CONCLUSION

The best results of femoral shaft fractures treatment were achieved using locked intramedullary osteosynthesis (95.2 %) compared to extra-cortical osteosynthesis with plates (91.5 %).

This method of surgical treatment is considered to be the "gold standard of treatment" for diaphyseal fractures of long tubular bones.

Notwithstanding its advantages and effectiveness, it is not always possible to apply this method of treatment due to various factors, and therefore an individual approach to the choice of surgical treatment method remains relevant.

Conflict of interest

The authors of the article declare no conflict of interest.

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