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P.F. Muzichenko

BIOCONSTRUCTION IN TRAUMATOLOGY

Constructional design for skeletal fixation, structures testing, clinical application and analysis of economic benefits of implementation

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In the pages of his book the author shares his experience of inventor and creator of the new system for the situated on bone stable - functional osteosynthesis "METOST". On the most parts of this system components the author received a patent for an invention. Over the past 20 - 30 years, the stable - functional osteosynthesis of long tubular bones is confidently taking the leading place, as well in our country as abroad. However, the fixatives that are used for this purpose are not ideal and need to be improved. Each step and every element of the METOST system has been subjected to comprehensive analysis, mechanical and mathematical modeling and testing on experimental animals. Only after that, the author started using METOST system in the clinic on patients and achieved excellent results, having operated over 1,500 patients and reducing the percentage of errors and complications to - 1,5%. This work could be used as a handbook for master classes for creative doctors who have dedicated their efforts to improving the methods of patients treatment. The monograph could be useful for all operating traumatologists - orthopedists, as well experienced doctors, as young aimed to succes - inventors.

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Foreword

Dear colleagues!

After having a look at this monograph and reading it, you will scarcely get full and irrefragable answers to the questions regarding engineering issues of our practice. Nevertheless, we were trying to convey the basic principles of development and approaches to new structures testing related to osteosynthesis.

A stretch of inventor's imagination in the field of traumatology and orthopedics is caused by a lack of an "ideal" fixation structure for damaged bones, both in production materials selection, and in design features.

Traumatology-Orthopedics science is the closest one to mechanics, as "metal - bone" system is exposed to variable dynamical loads, and works under the laws of motion. While working on original design, an orthopedist-traumatologist should be thoroughly enlightened upon mechanics, namely in the field of machine elements, or better yet, work in collaboration with design engineers.

I sincerely wish you a fruitful work.

About the author

Muzichenko Pyotr Fyodorovich - holder of Habilitation degree in Medicine (habilitational thesis defended at the CITO in 1994, nostrification in Ukraine - in 2004), professor of Operative Surgery and Topographic Anatomy Department of Bogomolets National Medical University, Honored Inventor of Ukraine.

My work is dedicated to my wonderful PARENTS-

Muzichenko Fedor Stepanovych
and Muzichenko Praskovia Grigorievna

"If you were alive, my dear, you would never feel ashamed for the work I have dedicated the best part of my life to"

CONTENT

INTRODUCTION

Developed countries face the trend towards a significant increase in injuries number during recent decades. The material losses of society incurred by injuries are huge, primarily due to the fact that fractures result in long-term loss of ability to work, and appear a major cause of disability among young and middle-aged persons. Therefore, injuries are one of the most important issues that should be considered not only at medical but also at social terms /K.S. Ternovoy, I.V. Schumatsa 1978, A.E. Romanenko 1982/.

Significant progress was made in treatment of injuries and their consequences within the last decades. Alongside with conservative method, which is a primary one for the last 25-30 years, there has been a marvelous progress in development of surgical methods for fracture treatment. The dominant value in surgical treatment of fractures, both in our country and abroad, is a stable-functional osteosynthesis that provides a rigid fixation of bone fragments, that permits to stop using plaster immobilization in postoperative period, allows for early movement in the adjacent joints, and reduces the terms of treatment due to the combination of fracture consolidation period with a period of rehabilitation.

Modern stable and functional metal osteosynthesis using submersible structures certainly is not “the last word in traumatology and orthopedics”, however, it has some essential advantages compared to osteosynthesis devices, which do not provide sufficient stability, that requires plaster bandaging for a long period before fracture consolidation, resulting in "fracture disease" development /V.N. Levents, V.V. Plyatsko, Ihedzhirika Kevin, 1983; U.Y. Bogdanovich, V.A. Zakirov, 1984; L.N. Ankin, 1985; G.I. Gertsen, P.F. Muzichenko, Y.P. Tsap, 1986; S.S. Tkachenko, 1987; M. Allgower, Ph. Spigel, 1979; M.E. Muller, M. Allgower, R. Schneider, H. Willengger, 1979; K. Welz, 1982 /.

It should be noted that in the late 80s - early 90s production of external fixing devices for stable functional osteosynthesis was not arranged in our country, and therefore, traumatologists in their daily work had to use "AO-type plates and screws", which were manufactured in makeshift conditions and made a certain effect on the treatment of fractures. /By B.L. Goldman, N.A. Litvinova, B.V. Kornilova, V.V. Evsyukov, A.N. Orlov 1987 /. External fixing devices manufactured in this period by domestic industries did not ensure conditions required for a stable functional osteosynthesis. As a result of using such bone fixators, the percentage of mistakes and complications varies within 8.5 - 16.9% /G.S. Yumashev, 1966; V.M. Volkov, O.N. Gudushauri, O.A. Ushakova, 1965; M.M. Rozhinsky, G.I. Kononov, V.V. Kozlov, 1981; Y.A. Zakirov, 1984; K.A. Palgov, 1985; K.S. Ternovoy, M.I. Sinilo, 1987; M.E. Miller, M. Allgower. R. Schneider, H. Willengger, 1979 /.

These data emphasize the importance of improving the results of surgical treatment of long bones fractures, and that has brought us to the expediency of this study.

It was necessary to develop an extra-cortical osteosynthesis structure competitive with AO system (Arbeitsgemeinshaft für Osteosynthesefragen), which was successfully applied in all western countries in this period. Recent 20-30 years have been fruitful enough in this regard but basically, as it has been already said, these remarks refer to our Western counterparts. Whilst we were facing complete chaos among traumatology scientists and medical practitioners in our country, each traumatologist involved in implants development kept own design "in the pocket." All strength characteristics tests were made on the principle “as far as doctors had a dip in Theory of Strength of Materials manual", or other textbook on mechanics. “Techies” - consultants and trauma physicians far from always used to "speak the same language." This “lack of coordination” in development issue, testing process and application of metal structures does not improve the results of fractures treatment. In our country, the demand has come to fruition for Traumatologists and Orthopedists Association to TAKE A FIRM HOLD of controlling and development of unified regulations for osteosynthesis fixators assessment, as well as industry standards for implant designers, testing methods, and indications or precautions in a clinical setting.

Experience gained in the course of sources exploration resulted in elaboration of development program for fixation kit of original design, and accessory instruments required for osteosynthesis, their comprehensive study including mechanical and mathematical modeling, bench testing, experimental studies using trial animals, and clinical application. Besides, on the basis of this research work I have drafted and defended my thesis work performed at the Chair of Traumatology and Orthopedics №1 of the Kyiv institute of advanced training of the doctors run by the head of the Chair, **holder of Habilitation degree in Medicine, professor Vitaly Nikolaevich Levents.**

That is what we want to personally thank V.N. Levents and professors and employees of the department headed by him.

Bench tests of fixation device, as well as mechanical and mathematical modeling of external fixation using a new design of fixing plates were carried out at the structural fatigue department / head of the department - Professor M.E.Garf / the Institute of Mechanics of NAS of Ukraine headed by the Senior Fellow, Ph.D. in Engineering Science V.E. Pavlovskiy. Thus we enclose our deep gratitude, yet to our most regret - posthumously.

Not preserved and non-macerated cadaveric bones of lower limbs /femorotibial/ have been used for this study, because the lower limb bones are supporting bones exposed to the highest loads, and also due to availability of cyclic loads modeling, similar to the loads experienced by damaged bone and fixation device connecting bone fragments in the process of walking.

Experimental studies were carried out at Testing Department of the Kyiv Institute of Advanced Training of the Doctors. Modeling of transverse fracture followed by fixation with channel-shaped (flat topped) compression plate with an eccentric mechanism for compression was made with the use of femur of 12 random bred dogs. Description of histological specimens and analysis of osteanagenesis distinctions were performed at the Pathomorphology department / Chief of the department - professor V.I.Stetsula /the Kiev Research Institute of Orthopaedics headed by senior research scientist, holder of Habilitation degree in Medicine Nikolai Fyodorovich Morozov, and we bring him our deep gratitude therefore. The clinical part of the work is based on the results analysis of stable - functional osteosynthesis of upper and lower limbs long bones in 65 patients operated within the traumatology clinical units of the Kyiv Institute of Advanced Training of the Doctors / clinical hospitals №7,15,28, Kyiv Regional Hospital / Kiev Medical Institute / clinical hospital №15, Moscow / 2nd Moskow Medical Institute / clinical hospital №4 / Vyshgorod, Baryshevka, Brovary, Bila Tserkva, Boyarka / Armenian SSR / Kafanska CRH / etc., where the author had come for osteosynthesis surgeries using "METOST" fixation kit.

By order of the Ministry of Health of the USSR, national clinical trials of "METOST" fixation kit were carried out at the N.N. Priorov Central Research Institute of Traumatology and Orthopaedics clinical units under the supervision of public health leader of soviet trauma surgeons, holder of Habilitation degree in Medicine, professor A.V. Kaplan, and holder of Habilitation degree in Medicine, professor D.I. Cherkes-Zadeh, the Sklifasovsky Federal Research Institute of Emergency Medicine headed by the holder of Habilitation degree in Medicine, professor A.V. Ohotskiy and at the 2nd Moscow Medical Institute headed by the Chief Traumatologist and Orthopedist of the Ministry of Health of the USSR, holder of Habilitation degree in Medicine, professor A.I. Kuzmenko. Performance tests were carried out in Leonov All-Union Scientific Research Institute for Testing of Medical Equipment. We express our deep gratitude TO ALL OF THEM - THE OUTSTANDING TRAUMATOLOGISTS AND ORTHOPAEDISTS.

On the basis of mathematical, medical, mechanical, biological studies and bench tests we have developed a new design of channel-shaped compresses plate providing limited contact with the bone and enhanced mechanical features, in comparison with analogues. Interfragmental dynamic compression was insured by eccentric mechanism compression. Five standard sizes of osteosynthesis plates for long bones and a set of accessory instruments required during the surgical intervention process - benders of original design for fixator modeling, screwdrivers with a screwholder, bone taps and surgical drills equipped with drill stop, etc.- were developed for each segment. In addition, we developed an original technique for osteosynthesis using our fixation devices – that is why we have joined the whole set of instruments and methods of their application in a single system - "METOST" /metalosteosynthesis/.

Proceeding from modern structures requirements, a series of mechanical and mathematical studies for stable functional osteosynthesis were carried out on the basis of Institutes of the National Academy of Sciences of Ukraine; and experimental studies with the use of animals have proven advantages of our designs in comparison with analogues, and high efficiency of "METOST" plate, which provides primary bone fusion. Indications and contraindications for osteosynthesis with plates of "METOST" fixation kit are specified.

A series of fixation kits and accessory instruments are protected by Ukrainian Patents: -№ 93926 – bulletin №4.-1993; № 93927- bulletin №4 -1993; patent of Ukraine number 24478 and copyright certificates for inventions a/c №120811, a/c №4871788, a/c №1233519, a/c №1761127, a/c №1734766, a/c №1638349, a/c №1776391, a/c № 1417869, a/c № 1706595, a/c № 1761158, a/c № 1695907, a/c № 1799569, a/c № 1748805, a/c № 134794, a/c № 1765243, a/c № 1653750, a/c № 93926, a/c № 93927. The positive decision on granting a/c № 4680064/30 - 14/054504 /, № 4926675/30 - 14/030362 /; № 4824434/14/02504.

In the second half of the 80s, the author managed to launch "METOST" Medical and Technical Association combining the efforts of scientists of the Institute of Mechanics, Institute for Problems in Casting, the Institute of Theoretical Thermodynamics, Institute of Electrodynamics of National Academy of Sciences of Ukraine, and three Institutes of Traumatology and Orthopaedics - Kiev Research Institute of Traumatology and Orthopedics, Kharkov Research Institute of Traumatology and Orthopedics, Central Research Institute of Traumatology and Orthopaedics, and manufacturing plant named after G.I.Petrovskiy in Kiev - a production enterprise integrated in MIC of Ukraine. The designs developed at "METOST" Medical and Technical Association - "METOST" fixation systems – were batch-produced at the G.I.Petrovskiy factory and sold across the whole USSR and later - the CIS countries.

The research results are currently used in the training programs of the Department of Traumatology, Orthopaedics and Burn Disease of P.L. Shupyk National Medical Academy of Postgraduate Education, Bogomolets National Medical University, Kyiv Institute of Traumatology, and Orthopaedics of NAMS of Ukraine and others.

Materials of the work were reflected in information circular "Stable-functional osteosynthesis of shaft fractures using "METOST" fixation kit / Kyiv, 1988 / approved by the Ministry of Health of Ukrainian SSR.

"METOST" fixation kits are introduced in traumatology clinic units of the P.L. Shupyk National Medical Academy of Postgraduate Education / clinical hospital №7,15,28, Kyiv Regional Hospital / Bogomolets National Medical University / clinical hospital № 25 /, the Kiev Research Institute of Orthopedics / clinical hospital №12 / Central Research Institute of Traumatology - Orthopaedics / clinical hospital № 15, Moscow / 2nd Moscow Medical Institute / hospital №4 / Baku Institute of Traumatology - Orthopaedics, as well as in many institutions of practical healthcare of the Ukrainian SSR, the RSFSR, the Belorussian SSR, the Armenian SSR, and this fact is confirmed by the acts of the implementation of these institutions.

The main provisions of our study were reported and discussed at the conferences of young scientists of the Kyiv state institute of advanced training in 1982, 1983, 1986, All-Union Scientific and Technical Meeting in Kazan in 1984, at the 5th Congress of the Orthopaedic and Traumatology of Baltic republics in 1986, at the 10th Congress of Orthopaedic and Traumatology of Ukraine in 1987, at the meeting of the orthopedists and traumatologists association of Kyiv and Kyiv region in 1986.

In 1986 "METOST" fixation kit was presented at the Exhibition of National Economic Achievements of - the author was awarded the Golden medal; in 1987 - at the Exhibition of Economic Achievements of the Ukrainian SSR - the author was given a diploma of the 1st degree, also at Leipzig, Plovdiv, Warsaw, Paris exhibitions.

In 1985 the author was given a diploma of the Ukrainian Republican Council of Trade Unions; in 1984 the author was granted a certificate of appreciation of the City Council of All-Union Society of Inventors and Rationalizers in Kyiv; in 1985, on behalf of Presidium of the Central Council of All-Union Society of Inventors and Rationalizers the author was conferred a decoration on "Excellence in invention and rationalization." In 1985 the author was awarded the diploma of the Central Komsomol Committee, and granted the title of Laureate of the Exhibition of Scientific-Technical Creativity of Youth.

On 03.07.1992 according to the Decree of the President of Ukraine, Muzichenko P.F. was awarded the honorary title "Honored Rationalizer of Ukraine" for development and organization of "METOST" system serial production.

SECTION I. LITERATURE REVIEW

I.I. The main stages of osteosynthesis fixation devices design and development

The history of metal bone fixators application for osteosynthesis purposes passed over 200 years of different metal alloys testing, development and improvement of structures for fixation of bones in cases of fractures. For the first time the White metalosteosynthesis was made (1760), Lappeod, Siere (1775) (cit. ex N.A.Oborin, 1952).

In Russia metalosteosynthesis was first effected in 1805 by E.O.Muhin (cit. ex A.V.Vorontsov, 1973) using the metal wire. Internal fixation of humerus on the subject of dysarthrosis was made using nickel-plated peg by K.K.Reyer in 1875. In the following years, the similar operations on the bones were carried out by N.V. Sklifasovskiy (1885), V.I.Kusmin (1892), A.F.Perimov (1895), N.I.Sevrikov (1908), N.K.Spikarniy (1913), P.G.Gertsen (1916).

Extramedullary metalosteosynthesis (external fixation) was first implemented by Hansman (1866), W.A.Lane (1892), and E.Lambotte (1892).

Copper, aluminum, iron, silver, gold, and platinum were used for fixators manufacturing. This wide range of applied metal alloys can be explained primarily by the surgeons' desire to reduce the frequency of suppurative complications in pre-antiseptic period (Mitanin N.K., 1966; Dubrov Y.G., 1972; Gertsen G.I., Muzichenko P.F., Tsap Y. P., 1986; H.S.Levert ,1829; E. Hey- Groves, 1913; K.Schober, P.F.Matzen, 1980, etc.).

W.A.Lane (1913) believed that most of complications emerge from infection, as a result of a "dirty surgery", but the purulency prevention measures offered by him had no significant impact on the total number of complications. Severe complications after metalosteosynthesis surgery interventions in the form of suppurations, sepsis, osteomyelitis, formation of false joints, fixator corrosion forced the major of surgeons to abandon the "bloody fragment reposition" and select conservative therapies in the late XIX and early XX century.

Introduction of aseptic principles and aseptics into surgical practice permitted many surgeons to come back to the osteosynthesis problem, while exercising judgment in interpreting various metal implant materials (D.Lister, 1875; N.V.Sklifasovsky, 1885; W.A.Lane, 1892; brothers A. and E. Lambotte 1892; V.N.Kuzmin, 1893; A.F.Perimov,1895 etc.). The first successful bone fusion with a metal wire was carried out by D.Lister under antiseptics in 1883.

Intramedullary osteosynthesis experiment using metal rods coated with various alloys (gold, silver, platinum, nickel) was performed by E.W.Hey-Groves in 1912 at the 41 th conference of German Surgical Society (1913). Up to the 30s of this century, carbon steel, nickel plated, cadmium, silver and gold mainly were used for manufacture of implants required for osteosynthesis performance.

A significant milestone in the development of orthopedics and traumatology was introduction of 18/8 stainless steel in 1926 (C.Y.Venabl, W.Y.Stuck, 1947), and X18P9T stainless steel in 1936, (manufacture mark 3Ф-IT), which is used nowadays (Y.G.Dubrov, 1949; F.R.Bogdanov, 1967; I.G.Gertsen,
1951; N.K.Mitenin, 1967; M.M.Rozhinsky et al, 1981; T. Rae, 1981; O.Rohler, F.Strauman, 1975).

Discovery of antibiotics, appliance of antiseptics, and further development of anesthesiology contributed to the expansion of metalosteosynthesis clinical use that resulted in possibility to apply metal structures to bone fusion, not only in case of subcutaneous fractures but also in compound limb bone fractures.(N.V.Novikov, 1963; F.R.Bogdanov 1968; D.D.Bitchuk 1985; H.Zimmerman, 1967; P.W.Brown, 1973).

A great contribution to evolution of intramedullary fixation with metal components was made by Y.Kuntscher (1940, 1962, 1964, 1970), who scrupulously developed the rodding method including preliminary reaming of medullar conduct; Y.G.Dubrov (1946), offered a round rod of stainless steel; F.R. Bogdanov developed the retrograde method for rod insertion, and proposed an oval-shaped rod in 1947.

Subsequently, on the basis of F.R. Bogdanov proposal, a package of osteosynthesis fixation devices and accessory instruments were designed for of all segments of upper and lower limbs, which are currently produced by our domestic industry.

The process of improvement of external and intramedullary fixation structures, as well as the issue of bioindifferent material selection for fixators manufacturing and designing are integrally interlinked in Trauma-Orthopedics. Therefore, we have considered these two matters in parallel , as well as the history of their development.

The works of I.G.Gertsen (1951), V.F.Trubnikov (1958), K.M.Klimov (1958), I.L.Krupko (1965), K.M.Sivash, A.M.Berman, K.M. Zherepo, B.P.Moroz, Y.Y.Shapiro (1979), J.S.Paradopulus, D.D.Varonus (1983) proved the relative bioindifference of X18H9T stainless steel that in fact made no negative influence on regenerative process. They found that tubular bones are exposed to the following alterations in the process of intramedullary rodding when inserting stainless steel fixator:

1) A narrow resorption zone appears in the neighborhood with a metal implant within the first weeks;

2) A fibrous capsule surrounding the fixator arises from the 10-15th day. In some places of fibrous capsule we can observe osteoid and cartilaginous tissue.

Bone marrow recovers its structure in 2-2.5 months.

Improvement of materials for implants manufacturing and fixators design significantly depended on engineering level of the historical period, as well as on the experience accumulated by orthopedics-traumatology specialists in the field of implant orthopedics-traumatology. The efforts of researchers were directed at creating the most favorable conditions for reparative processes in the area of fractures and treatment outcomes improvements. Up to a certain time, osteosynthesis devices were developed through trial and error. And the number of complications and mistakes that accompanied the pioneers of metal osteosynthesis, was primarily determined by the fact that biological systems modeling is an extremely complicated issue, and fixation device designing was performed, as a rule, by orthopedic-trauma surgeons with no special technical education, or any background in the Theory of

Strength of Materials and descriptive geometry. The stress concentration in the structure, anelastic deformation limit, the nature and magnitude of fragments displacing forces and many other factors were rather disjointed, and it was not possible to analyze them from a technical point of view.

W.F.Lane plate (1892) can be an example of imperfect structure having a variety of stress concentrators; and for this reason it did not endure relocating loads of synergist muscles.

Subsequent fixation structures by Scherrard (1912), (1913), Scherman (1914) also had significant shortcomings, which were the cause for quite frequent complications arising in post-operative period.

To increase structural stiffness, and improve its mechanical features, M.J. Verbrugger used plates deformed at an obtuse angle. Fixing screws were inserted along intersecting lines to increase fixation strength.

The same principle was laid down in fixation structure designs developed by K.Townsed, C.Gilfillan (1943) and Eggers (1948), which were made in the form of a channel with its strengthening ribs facing the surrounding soft tissues, as well as in the fixator constituting two perpendicularly disposed plates proposed by Klimov in 1948. Split pins in the form of split nails were used to fix the tee girder (K.M. Klimov, 1949). The emergence of K.M.Klimova beam was a step forward on the way of creation of the "optimal" clamp for the osteosynthesis of bone fractures and surgical treatment of false joints (I.I.Talko, 1955; N.N.Priorov, 1959; I.Y.Krupko, A.V.Vorontsov, 1957). However, the created construction was not viceless: a skeletonization of bone fragments on a large area, an inability to create interfragmentary compression, the threat of a bedsore as a result of tibia osteosynthesis, a great difficulty in removing a fixator after fracture consolidation (I.D.Kinchaya, 1961, N.E. Kabardin, 1963).

A.V.Vorontsova (1956), B.A.Matveeva (1961) and S.S.Tkachenko (1963) were the modifications of K.M.Klimova beam. Moreover, the fixation of bone fragments in the mentioned fixation kits were performed with the help of screws, while in the

S.S.Tkachenko fixator, the eccentric mechanism was provided for the creation of interfragmentary compression on the bone fragments body.

The fixator to the original design was proposed by N.V.Novikov in 1956, who subsequently developed a set of fixators for the osteosynthesis of all limb segments and support tools, necessary in the case of osteosynthesis (N.V.Novikov, 1963). The attachment of fragments with the N.V.Novikov fixator was conducted through a relatively small cut on the soft tissues, but removing it was quite difficult (A.G.Kletsky, N.Y.Mitelman, 1958; I.I. Zhadenov, A.M.Kositsina, A.M.Novikov, E.G.Samoylova, 1977).

A common disadvantage of these fixators is the essence of overlaying a plaster immobilization during the postoperative period, since the displacement of fragments or the fracture of the fixator can happen in the places where adjacent joints joins with a fracture place, while being moved.

As a result of prolonged immobilization there develops a "fracture disease", which manifests itself in muscle wasting, osteoporosis, joint stiffness, chronic poor circulation (V.S.Katkovsky, 1967; L.N.Anкhin, S.A.Spasov, 1979, O.A. Zakirov 1984; M.E.Muller, M.Allgower, H.Willenegger, 1963, 1969, 1976).

As it follows from the already mentioned, osteosynthesis followed by plaster cast immobilization combines the disadvantages of conservative and surgical treatments, so the use of these bone fractures treatment methods and their consequences, in our view, is mistakable. Physical disability after osteosynthesis with the following by plaster immobilization, according to K.F.Krasnovoy, reaches 36-38% of the total amount of operated patients.

The works of F.R. Bohdanov, N.A.Kramarova (1960), K.M.Sivash (1963), Y.G.Dubrova (1965), Y.Charnley (1967), M.Allgower, R.Ehrsam, P.Matter, S.M.Perren (1970), G.Lavarde (1977) are given as a ways of theoretical justification to improve fracture healing, consisting of the exact adaptation of fragments, rigid fixation and interfragmentary compression. However, until now the domestic industry has not mastered the production of plate fixators for stable functional osteosynthesis.

1.2. Reparative regeneration and compression role in optimizing the conditions of fracture healing

By means of experimental-clinical studies to optimize the conditions for fracture healing it was found that reparative regeneration process may be controlled by acting on both internal factors, by maintaining bone tissue anatomical structures and vascular networks, and due to external factors - the exact adaptation of fragments, interfragmentary compression, rigid fixation (V.I.Stetsula, G.A.Ilizarov, Rzhavina, 1961; V.I.Stetsula, 1962; Y.G .Dubrov, 1965; G.I.Lavrischeva, 1969; S.S.Tkachenko, 1987; R.Danis, 1949; M.E.Muller, M.Allgower, H.Willenegger,1965, etc.).

There is a physiological regeneration, consisting of rebuilding of bone tissues, accompanied by partial or complete dissolving of bone structures and the creation of new ones, as well as of reparative regeneration that occurs when bones are damaged and flow through the proliferation of cambial layer of the periosteum endost cells, undifferentiated cells of the bone marrow and other marrow stroma. Depending on the conditions, established in the treatment of fractures, from precision resistance, rigidity and degree of reliability of fixing they distinguish three kinds of reparative bone regeneration – in the sort of primary, primary-delayed and secondary adhesion. The most perfect form of fusion is the fusion of bone fragments of the primary type, when the consolidation occurs due to the bone beams with minimal formation of periosteal callus. The bone fusion of the secondary type occurs due to the significant restructuring of the advanced periosteal callus, going through the desmal and enchondral stage. In the process of primary-delayed type the fusion occurs in the cases of excessive interfragmentary compression when intermedial fusion of fragments is proceeded by a resorption through the break (V.I.Stetsula, 1962; Y.G.Dubrov, 1965; G.I.Lavrischeva, 1969; S.S .Tkachenko 1987; M.E.Muller, M.Allgower, H.Willenegger, 1965).

The value of compression in optimizing conditions for fracture healing is now proven. However, an assessment of its role and value has been different over a number of decades.

The issue of compression osteosynthesis has been being discussed on the pages of scientific journals for about 100 years. In 1892 J.Wolf, W.Rouf formulated their law on compression, arguing that it promotes the formation of callus and the distraction, on the other hand, - impedes. Further studies of K.M.Sivash (1958, 1962, 1965), V.I.Stetsula, G.A. Ilizarov, V.P.Rzhavina (1960), I.D.Krupko together with (1965), F.R. Bohdanov together with (1960), Y.G.Dubrova (1965), A.A.Korzh, L.M.Belous, E.Y.Pankov (1968), M.Muller, M.Allgower, H.Willenegger (1965), the G .Carnley (1967), M.Allgower, R.Ehrsam, R.Ganz, P.Matter, S.Perren (1969) showed that compression does not affect the stimulating effect on the regeneration process, but creates a favorable environment for the fusion. The formation of callous occurs only at the expense of normal osteoblastic reaction in response to the bone damage.

However, there were no thoughts about the range of force compresses. Thus, according to F.R. Bohdanov (1967), B.I.Panchenko (1964), Z.Friendenberg, G.French (1952) the interfragmentary compression force should be equal to the force of muscle traction, which normally affects the bone intact. Its range differs for different segments of limbs and comprises: 5-7 kg / cm^2 - for the humerus; 5-7 kg / cm^2 - for the forearm bones; 15-25 kg / cm^2 - for a hip; 10-15 kg / cm^2 - for tibia.

In the experiments, tested on 100 animals, G.I.Lavrischeva and E.Y.Dubrov (1967) substantiated the need of interfragmentary compression to create the conditions of the primary fusion of the bone fragments. They indicated that due to the different structure of bone diaphyseal cortical bone portion and metaphysis, the compression range should be different. A large number of vessels in the spongy bone allow osteogenetic processes to occur at day 2-3 after fracture, providing that the close contact between the fragments of the damaged bone is present.

While the poverty of compact bone with vessels is reflected in the course of healing of diaphyseal fractures by the extension of reparative processes terms. The vessels in the fracture zone penetrate from the medullary space, periosteum and advanced bone and marrow channels. For the occurrence vascular net it the prior resorption of vascular channel walls for an additional time of 3-4 weeks is required, which is longer in comparison to the spongy bone.

It was also indicated that the optimum size of intermedial slit, which the callus is formed in, is 50-100 A, which corresponds to the size of the primary bone beam.

In the absence of the necessary diastase, that is under a closer interfragmentary contact between the fragments of compact bone, the fusion occurs with prior resorption of vascular channels wall fragments and their merger, because the vessels of the medullary space and periosteum can penetrate through the bone structures, emerging on them, but fail to that that through the fragments.

Thus, the excessive interfragmentary compression delays fracture consolidation. Moreover, the lack of necessary diastasis between the fragments results in the formation of narrow bone spikes, which cannot always provide sufficient bonding strength of the bone fragments.

Hence, in the experiment of G.I. Lavrischeva and E.Y. Dubrov it was proved that the interfragmentary compression should be well-defined and aimed to the creation of optimal diastase in the range of 50-100 A. Reducing the gap between the fragments of less than a specified size, which is possible under the excessive interfragmentary compression, is not only healthless, but also vice versa - is a brake of repairing processes.

Nowadays, this position is preserved by most of orthopedic traumatologists (V.M.Demyanov, 1967; G.A.Ilizarov 1976; L.N.Ankin, S.A.Spasov 1979; V.F.Trubnikov et al,. 1980; M.E.Muller, M.Allgower, H.Willenegger, 1979; D.G.Lawallen, E.Y.S.Chao, R.Kasman, P.G.Kelley, 1984; V.Heifemeyer, G.Hierhjlzer, 1985, etc.).

When a fixator for stable functioning of osteosynthesis is created, it should be considered that, in order to insure the rigidity of fixation, the unambiguous force acting in a strictly defined direction, must be neutralized, as the established system of "metal-bone" is under constant influence of variable dynamic loads.

V.I.Stetsula (1961, 1962, 1965) divided the acting forces on the broken (crossed) bone into two groups:

- forces that determine the stability of bone fragments, i.e., balanced thrust component of muscle and pressure of soft tissues, that surround bones;
- forces that combine fragments, i.e. unbalanced thrust component of muscle - the weight of the distal fragment and the effect of functional exercises.

The effectiveness of osteosynthesis depends on the ratio of these two groups of forces. In developing the fixator for a stable functional osteosynthesis one should give it such mechanical characteristics, that with the help of it one could not only lower, but also eliminate the biasing force synergist muscles, and neutralize the weight of the distal limbs and the action of functional loads.

When applying the interfragmentary compression one can counteract the unbalanced thrust component of the opposite muscle actions, i.e., under a segment axis for transverse and oblique fractures of the transverse or perpendicular to the fracture plane in the oblique fractures and helical.

Thus, as it follows from the above, when one creates a fixator for stable functional osteosynthesis, they must take into account that the system of "Silver", formed under osteosynthesis, is subjected to dynamic variable loads. The fixator, given this fact, must not only have good mechanical properties, but also a mechanism for interfragmentary compression with which it would create the optimal interfragmentary diastasis in the range from 50 to 100 A.

1.3. Stable-functional osteosynthesis with extramedullary plates

For many decades there had been a controversial on the role of interfragmentary compression when creating optimal conditions for the consolidation of the fracture, and only in the early twentieth century, the need for it was proven, and the optimal parameters for each segment of the upper and lower limbs were determined. In this section, we provide a retrospective analysis of search by much orthopedic trauma fixator optimal form, equipped with a specific mechanism for compression.

One of the most successful designs of plate retainer for compression osteosynthesis is the R.Danis plate (1949). Interfragmentary compression in the plate is created by a maximum screw-based screw, built in the end of a plate.

In the future, this design was improved by C.S.Venable (1951), T.Borcon and P.Harmann (1952), but the compress's effort was created by a similar compress unit, but it was located at a certain angle, relative to the plane of the fixator.

The plates, where the effect of contracting the muscles was used, worsened when walking by an axial load, were first proposed by K.Townsend, C.Gilfillen (1943).

In subsequent years, it was improved by G.W.Eggers (1948), S.S.Tkachenko (1978). And in S.S.Tkachenko's construction of combined two methods of convergence of fragments - one-stage, during the operation with the help of removable fixator and the so-called normal in the postoperative period, that was provided by the presence of elongated grooves in the plate to facilitate the convergence of the fragments and not impede the physiological compression by the reflex of tonic contraction of muscles and the effect of the dynamic compression in the axial load on time to the final support. The authors of the above-mentioned that fixators were designed for the early rehabilitation of patients who have 2-3 weeks of allowed dosage, and then - the full load.

Since 1963 they were employed, and in 1967 the plate was described by the record, suggested by V.M.Demyanov, interfragmentary compression, which is created by the sliding of the screw head in a truncated cone-plate hole. To create the desired force under the compression of holes on the plate in the form of a truncated cone, all are satisfied, and the alternately interfragmentary considerable pressure is developed, when using them. This principle is currently used by the SA Company (Switzerland, Germany), which produces these fixators.

In order to increase the stability of connected fragments and neutralize rotational biasing force in 1961, Hicks suggested pulling anti-rotation plate, thanks to semi-oval protrusions, fixing holes, is located on a larger area on the bone fragments.

The same aim of compression-detorsion plate was pursued by A.V. Kaplan and A.I. Antonov (1969). Due to the protrusions, that exist on the sides, it also prevents rotational displacement of the fragments, however, these protrusions are located only on one side of the plate and the fixing holes are on the plate itself (V.A. Kaplan, V.Y. Golyahovsky 1969; V.A. Kaplan , 1979).

However, the authors' idea went much further towards the improving of the fixator. With removable contractor, developed by them, one can create interfragmentary compression.

The authors have developed several sizes of fixator for osteosynthesis of all segments of the upper and lower extremities, which are produced and are now at the pilot plant of the Central Research Institute of Orthopaedics-Traumatology.

The original decision in creating a one-moment compression is of the suggestion of H.S. Rahimkulova (1959), who offered to use the eccentric mechanism, disposed in the lock body, for this purpose. The same principle is applied in the interfragmentary compression structures, proposed by L.I. Tsiporkin (1966) and S.S. Tkachenko (1968) and in the fixator, developed in Kharkov NIITO. Moreover, the HNIITO fixator has the shape of channel, whose ribs are facing towards the bone fragments. A similar form of fixator was given by E.E. Kobzev (1986), however the interfragmentary removable compression is achieved by the contractor.

The next group of fixators, with which one can create a permanent compression plate, includes Ulrich (1956), K.K. Nigmatulina (1980), B.D. Shevts, V.G. Zankovskii, V.N. Levents, E.N. Shergina (1975). These fixators are composed of a plurality of parts and assembled just before the operation itself, or in the manufacture of packs in a single housing. The common disadvantage of these fixators is their high susceptibility to corrosion as a result of the interaction of pairs of metals (L.N. Ankin, S.A. Spasov 1979; A.I. Gritsanov, Y.F. Stanchits, 1977; M.M. Rozhinsky, N.I. Kononov, V.V. Kozlov, 1981; E. Frank, H. Zitter, 1971; M. Allgower, Ph. Spigel, 1979; H.K. Vhthoff, M.A. Finnegen, 1984, etc.).

U.Y. Bogdanovich and Y.F. Zakirov (1984) proposed a classification of the bone fixing device, according to their functional purpose and compression method:

1. **The bone fixing device, performing the role of the tire** (W.A. Lane plate (1982), Sehermann (1912), V.A. Polyakova (1967), and others.).

II. **Extramedullary compress fixators:**

1) Fixators with an elastic compression (S.S.Tkachenko plate (1978), K.Townsed, C.Gilgillano (1943);

2) Plates with a mechanism for compression, located on the fixator body:

a) The plates with simultaneous compression (R.Danis plate (1949), H.S. Rahimkulova (1958), L.I. Tsiporkina (1966), S.S. Tkachenko (1968), etc.);

b) Fixators with a permanent compression (Ulrich plate (1966), K.K. Nigmatulina (1980), etc.);

3) The plates with the usage of removable contractor to create the interfragmentary compression (S.S. Tkachenko plate (1978), Kaplan-Antonova (1969), E.E. Kobzeva (1984), M.E. Muller (1969), etc.);

4) The plates with the simultaneous usage of the compression mechanism at the plate itself and a removable fixator (M.E. Muller plate (1970), L.N. Ankina (1977, 1982), and others.).

It has been experimentally proved that, under the creation of immobility for bone fragments - the consolidation of the fracture is of the direct type, which bypasses the stage and cartilage callus formation faster than with unstable osteosynthesis (F.R. Bogdanov, I.A. Kramarov, 1960; V.I. Stetsula, G.A. Ilizarov, G.N. Rzhavina, 1961; G.I. Lavrischeva, E.Y. Dubrov 1967 etc., A.A. Korzh, A.M. Belousov, EY. Pankow, 1968).

With the method of mathematical modeling, offered by U.Y. Bogdanovich, Y.A. Zakirov (1984), the optimum length of plate lock, which must be ½ - 1/5 of length of the segment, was calculated.

So, based on the experience of our predecessors in recent decades there loomed a position of modern stable functional osteosynthesis, which is carried out at the expense of accurate anatomical adaptation of fragments, sparing surgical technique, high stability of osteosynthesis, through the use of massive structures, dosage interfragmentary compression, which all together ensures elimination (neutralization) of all types of biasing forces acting on the system "metal-bone" and consolidation of the fracture on the direct type. Modern stable-functional osteosynthesis allows you to fully align the fracture consolidation period, with medical and social rehabilitation of victims, as movements in adjacent joints in this type of surgical treatment begins in 2-

3 days after surgery. Active movements help to restore blood circulation in the affected limb and reparative processes occurs at the optimal time (L.N. Ankin, S.A. Spasov 1979; A.A. Gumenyuk, 1982; V.N. Levenets, V.V. Plyatsko, Ihedzhirika Kevin, 1983; P.F. Muzychenko, V.N. Levenets, 1986; G.I. Gertsen, P.F. Muzychenko, Y.P. Tsap, 1986, S.S. Tkachenko, 1987; M.E. Muller, M. Allgower, H. Willenegger, 1963, 1965, 1969; H.K. Vhthoff, M.A. Finneggen, 1984).

For stable functional osteosynthesis plate the intramedullary structure (K.M. Sivash, 1954; V.P. Ohotsky 1964, etc.), external fixation devices (G.A. Ilizarov 1954; O.N. Guduschuari, 1960; V.K. Kalnberz 1975, etc.) are widely used (M.E. Muller).

The extramedullary stable-functional osteosynthesis is noteworthy by its high efficiency, comfort for the patient and simultaneous help without the need for further manipulation, and the lowest percentage of complications, which is 1.5% (with closed fractures) and 3.3% with open fractures of the total number of operated patients (F.G. Novikov, S.A. Spasov, L.N. Ankin, 1985; V.L. Goldman, N.A. Litvinova, B.M. Kornilov, V.V. Evsyukov, A.N. Orlov 1987; M. Allgower, R. Ehrsan, R. Janz, P. Maffer, S.M. Perren, 1964; M. Allgower, Ph. Spigel, 1979; R.R. Jacobs, 1980; J.W. Bownen, 1980; H.K. Vhthoff, M.A. Finngan, 1984).

When under stable-functional osteosynthesis with the usage of external fixators, the disability equals 2.2% (G.A. Ilizarov, 1975).

The leading role in the development of fixators for osteosynthesis, its improvement and widespread clinical application takes the Swiss-West German company AO (Arbeitsgemeinshaft für Osteosynthesefragen), which in their studies, based on the achievements of the world of orthopedics, traumatology, collect all the best for the operative treatment of fractures and their consequences. Leading specialists in orthopedics, traumatology - M.E. Muller, M. Allgower, H. Willenegger work in close contact with mechanical engineers, materials scientists, technologists.

Based on the experience in experimental studies and the results of clinical observations, they laid the foundation of standardization in orthopedics-traumatology with detailed elaboration of indications for osteosynthesis, recommendations on the use of certain fixators, depending on the location and type of fracture, etc.

The composition of the company's stock includes research laboratories, the documentation center for the manufacture of tools plant. Development tools, their production, product advertising, sales organizational issues are well thought out. In order to promote the principles of fracture treatment, the staff of the system JSC regularly holds courses, seminars, including off-site; send their experts to other hospitals, located anywhere in the world, regularly publish their work in the periodical press and publishes atlases and monographs.

The AO Company possesses the means for free education in the workplace cadets - state representatives, wishing to buy their products.

In our country, extrafocal Transosseous compression-distraction devices (G.A. Ilizarov, O.N. Gudushauri, M.V. Volkova-O.V. Oganesyana, V.K. Kalnberza) are produced and widely used in clinical practice.

However, the question of serial production of fixators for osteosynthesis and auxiliary instruments is still not adjusted (L.N. Ankin, 1985; V.V. Klyuchevsky, 1985; V.L. Goldman, N.A. Litvinova, B.M. Kornilov, V.V. Evsyukov, A.N. Orlov 1987; P.F. Muzychenko, V.N. Levenets 1986; P.F. Muzychenko, 1987). Created in small batches, locally, at the initiative of some departments of traumatology, the fixators of type AO cannot meet the needs, that arose in them. In addition, manufactured in semi-artisan conditions, these fixators do not hold water, because their quality is much lower in comparison with the samples of signature, which in a certain way affects the quality of surgical treatment of fractures (B.L. Goldman, N.A. Litvinova, B.M. Kornilov, V.V. Evsyukov, A.N. Orlov, 1987).

Thus, in a modern stable functional osteosynthesis one of the dominant places belongs to the method of fixation of bone fragments with massive bone fixing compress device. And the feasibility of organizing their production in our country is obvious.

With the awareness of the need and the importance of addressing the urgent issues, we have begun to carry out this research.

SECTION II. DEVELOPMENT AND TEST METHODS OF BONE FIXING DEVICES FOR OSTEOSYNTHESIS OF THE "METOST" SYSTEM AND ACCESSORY INSTRUMENTS

II.1. Theoretical justification of the use of channel-shaped fixing devices with permanent compression

The basic requirements for any design, including bone fixing devices, reside in the reliability of their operation, i.e. when it provides a reliable fixation, in particular, of bone fragments without being damaged by external forces in the process of operation, construction, being strong, rigid and stable.

The indestructibility of the structural element should be considered as the indestructibility under action of the forces (loads), applied to. The structural element is considered to be hard, if the load, applied to it, changes its size and shape very slightly, and these changes do not exceed the established standards.

The ability of a structure to keep its equilibrium shape taken at the time of its manufacturing in the process of operation is meant by its stability. When carrying out calculations on the strength, rigidity and stability of a structure as a whole, it is necessary to seek the combination of the reliability of the structure on the one hand, and its efficiency at the lowest material consumption, on the other.

The requirements for the increase of structure strength are sometimes related to the necessity to increase the transverse dimensions of its elements, while the efficiency requirements, on the contrary, necessitate reducing them (N.S. Ulitin, 1975). Besides, the method of increasing the strength of an element by increasing its transverse dimensions is not always appropriate, because it results in the structure heaviness and large consumption of material, which ultimately leads to the inability to use it because of the mismatch of the bone fixing device size to the bone diameter and the state of soft tissues.

In this study, the task is set - to develop a bone fixing device reliable in operation, with the most cost-effective cross-sectional dimensions, as well as to give it the most appropriate form, providing improved mechanical properties, weight reduction of plates, as well as the decrease in the degree of bone tissue degeneration at the site of direct contact of the plate with a bone.

Experimental studies have given us the opportunity to examine the mechanical properties and behavior of the created structure and its elements both, in the most simple and in the more complex operating conditions of its elements, and also, to carry out comparative tests with known analogue structures.

From the course on the strength of materials we know that the area of a rod section serves as the measure of stiffness of the rod at tension or compression. Therefore, in the case of equal cross-sectional area and equal rod material, its extension or compression strength does not depend on the shape and arrangement of section elements in relation to the axis and appears to be equal.

Quite different is the case in the process of torsion and bending. In cases of these deformations the internal forces are brought to the moment in relation to the center of gravity of the cross section.

Using the formula: $$\sigma_{max} = \frac{Mmax}{W}$$

Normal strains at bending are determined (max – maximum strain, W - moment resistance, Mmax – bending moment).

As can be seen from this formula, the greater the resisting moment is, the firmer is the rod, because strains in its cross section will be smaller.

Thus, the most efficient in terms of material savings are the sections in which the greater moment of resistances appear with the smaller area. The material of the rods next to the neutral axis experiences slight strain, that is why it is more advantageous in terms of saving the material to focus it further from the neutral axis, in the locations where it will experience more stress. That is why for metal beams, working equally in tension and compression cross-sections in the form of an I-beam or a channel are used most often. These beams, as compared with rectangular means with the equal area, have significantly greater moment resistances. In I-beams and channel bars the neutral axis is in the middle of their height, whereby the greatest tensile and compressive stress will be equal in value.

When selecting a cross-section type of beams and deciding on the most cost-effective design it is necessary to seek to ensure that at one and the same area it could be possible to obtain the greatest moment of resistance and inertia. The solution to this problem requires locating considerable part of the material farther of the neutral axis. In this regard, the best solution is to give the bone fixing device the shape of channel beam; thereby the mechanical characteristics of the fixing device will increase significantly.

The work, carried out by us, is a comprehensive clinical and experimental research on the creation and justification of a broad clinical application of a new design of bone fixing devices for extramedullary stable functional osteosynthesis of diaphyseal fractures of long bones, united in the "METOST" system.

The design of a bone fixing device, taken as a basis for the "METOST" system has been developed in joint authorship with Professor V.N. Levenz – the Head of the Traumatology, Orthopaedics and burn disease Department of the Kyiv State Extension Course Institute for Medical Practitioners, V.E. Pavlovsky – the Candidate of Technical Sciences, Senior Researcher of the department of structural fatigue at the Institute of Mechanics of the NAS of Ukraine Y.P. Tsap - the head of a group of department of new casting materials of the Institute of casting problems of the National Academy of Sciences of Ukraine. I express deep gratitude to the co-authors in the development of the original design of fixing devices and creation of "METOST" systems listed herein.

The methods we used in the process of developing and testing the new design were as follows:

1) Biomechanical bench tests using a non-macerative cadaver bones with the elements of mechanical and mathematical modeling of units and elements of the fixing device structure;

2) Experiment on 12 mongrel dogs with subsequent morphological study of the preparations;

3) Clinical and radiographic methods and statistical analysis of clinical material.

II.2. Design specifics and osteosynthesis technology using the suggested bone fixing device

As a result of the conducted work, a new design of extramedullary bone fixing device has been created which has a profile of a channel bar with three support points (Fig. I a, c). This profile provides the improved mechanical features of the structure, as well as minimizing the area of the formation of pressure sores in the case of prolonged contact of metal with bone tissue.

Interfragmentary compression is created by means of an eccentric mechanism, constructed in a form of a slotted eccentric washer, secured on the case of the bone fixing device (Fig.1 a, Fig. 2). Metalosteosynthesis by means of fixing device of new design is carried out in the following way: after accessing the damaged bone and bone fragments apposition, the bone fixing device is put so that the fracture line is between the two middle holes, and the eccentric mechanism is located above the proximal fragment (Fig. 2). However, a direct bone fixing device, put on the damaged bone, does not "fit into the shape of the segment" (Fig. 3). In order to reconstitute the shape of the bones correctly, it is necessary to model the bone fixing device using rod benders (efficiency suggestion No.37), as shown in Figure 4a and b. Then the modeled bone fixing device is again put on the bone fragments and, together with the latter, is gripped by a bone holding clamp. Securing of the bone fixing device is made first to distal fragment, using screws 4.3 mm through the previously made channels in the bone with diameter of 3.5 mm in the plane perpendicular to the longitudinal axis of the bone (Fig. 2a). Then, through the hole in eccentric washer, a screw is inserted for proximal fragment without tightening its "tight" and using a wrench (efficiency suggestion No.8) the eccentric is rotated around the displaced center in a clockwise direction, causing a coaptation of fragments (Fig. 2 b, a) .

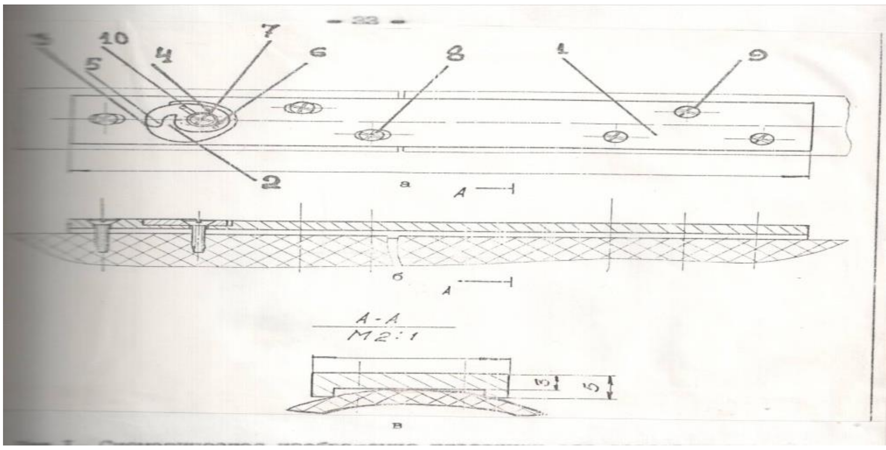


Fig.1. Schematic diagram of the plates for osteosynthesis of a new design when fitting them to the bone fragments. The horizontal projection (a) - 1 case of the bone fixing device, 2 - cross-section on the eccentric, 3 - point of application of a deforming force to the dissected eccentric 4 - recesses for compression wrench, 5 - the sector of circle to be subjected to strain, 7 - screw that secures the eccentric, 8 and 9 - screws securing the plate to the distal and proximal fragments. Channel-shaped plate contacts in 3 points with the bone fragments (c).

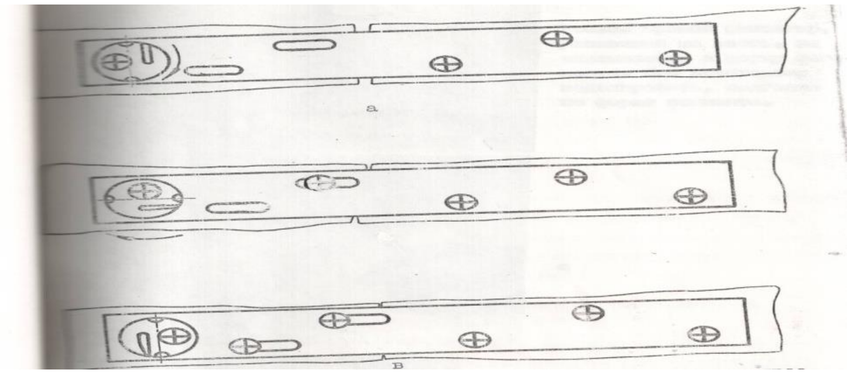


Fig. 2. The diagram of order of osteosynthesis using compression plate of new design. Plate is secured with screws to the distal (a) fragment. Then, screws are inserted through the proximal fragment (b) and by turning the eccentric clockwise, a coaptation of bone fragments takes place. Last step (c) - the introduction of the screws

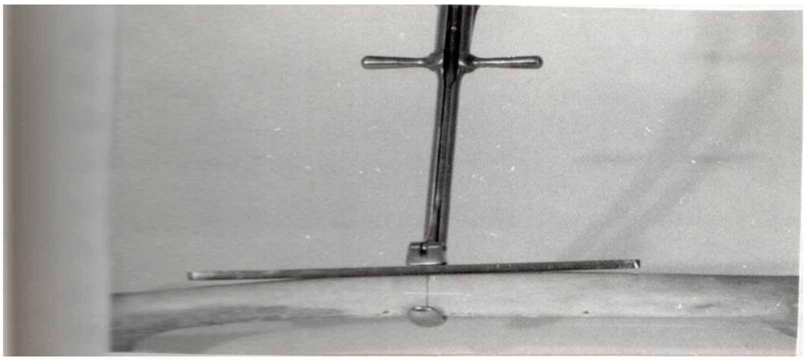
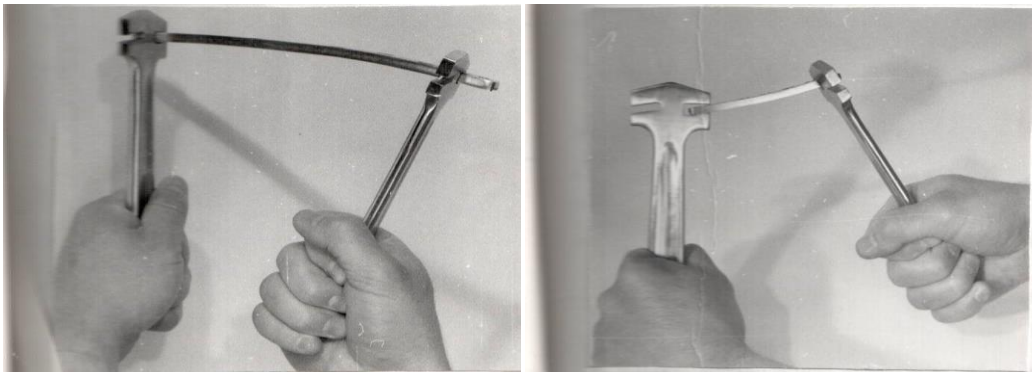


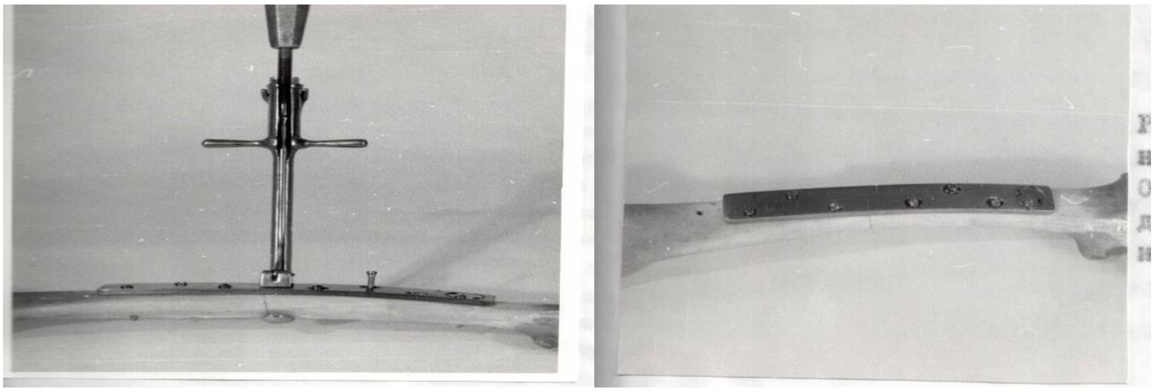
Figure 3. Direct bone fixing device laid on the bone does not fit into segment shape. It is necessary to model it by adjusting it to the shape of the segment



a *b*

Figure 4. Variants (a, b) of modeling bone fixing device depending on the shape of the segment.

Dissected eccentric, turned about its axis through an angle of 180°, it develops the maximum interfragmentary pressure, taking the strain by the small segment, which is deformed under the impact of this pressure within the limits of elastic deformation proving dynamic interfragmentary compression. The final step of osteosynthesis is the introduction of additional screws through the elongated holes in the proximal fragment (Fig. 2a). During the manipulation with the eccentric it is necessary to hold the bone fragments and the plate “softly” by means of bone holding forceps in order to prevent mutual displacement (Fig. 5,a). The plate is secured on the bone fragments. Fragments are compressed – there is no diastasis between the fragments (Fig. 5, b).



a *b*

Fig. 5,a. The plate is secured on the distal fragment with 3 screws, compressing unit performed the compression of bone fragments and an additional screw is introduced in the proximal fragment.

Fig. 5, b. The plate is secured on the bone fragments. Fragments are compressed – there is no diastasis between the fragments.

Therefore, meticulous and precise execution of all stages of the methods of osteosynthesis that we developed, using the new channel-shaped fixing device with eccentric mechanism, enables to accurately reconstruct the shape of the damaged segment, tightly pull together the fragments and fix them in this position.

II.3. Methods of bench tests of compressing unit

The purpose of the conducted tests is to define the reliability, i.e. strength and stability of the plate structure, suggested by us, as well as to prove the serviceability of the compression device in the form of dissected spring-elastic eccentric, suggested by us.

6 femoral bones of the dead bodies of people aged 25 to 50 years were prepared for testing. Femoral bones were sawed in the middle third, strictly perpendicularly to the longitudinal axis, thus, a transverse fracture was modeled. Fixation of bone fragments was made in the following manner: apposition of the bone fragments was made exactly on osteotomy line, the plate designed for testing, modeled according to the shape of the bone as it shown on Fig. 3, 4, 5.

Then it was secured by fixing screws, according to the method, described in the previous section and shown on the Fig. 1, 2, first on the distal fragment, after it was secured on the proximal fragment. In the following sequence: the eccentric was set to "0" - its small radius was facing the proximal direction, through the compression unit a screw was introduced, and it was not tightened "tight", leaving the possibility of free rotation around the displaced axis of the eccentric.

The last step was to insert additional screws through the elongated fixation holes. Wherein they were introduced in the middle of the elongated holes, keeping the possibility of free movement of the bone fragments together with the screw at the moment of creating interfragmentary compression. Interfragmentary compression was created when turning the eccentric about its axis in a clockwise direction.

Before testing the fixing device, strain gage sensors were secured on it and on the calibration bar, the system was formed according to the diagram shown on Fig. 6, as well as the elements of the assembled test complex: transsected femoral bone, the fragments of which were secured, using the tested plate. In the foreground there was a calibration bar, behind the tested plate, secured on the bone. In the background there was a device ID-70, by means of which the recording of these test was made. The parameters of the calibration bar: width – B=30 mm, height H= 6 mm, length from the loose end to firm embedding L=250 mm. With the purpose of calibration of the ID-70 device readings force P = 10 + 40 N was applied to the loose end of the beam, the beam was subjected to pure bending, on the scale of the device ID-70 the degree of deviation of the arrow at a given load was recorded.

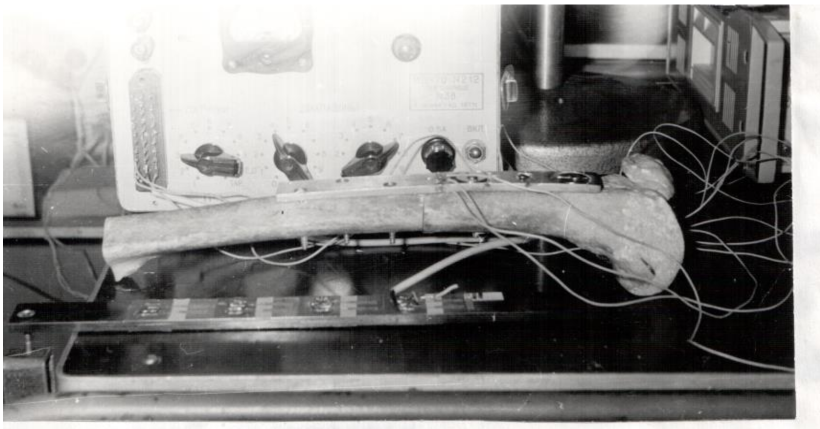


Рис.6. View of the assembled complex for testing the serviceability of the eccentric device

The arm of the plate was measured – distance from the osteotomy line to the nearest fixing screw – L = 15 mm. (tested plate and calibration beam were made of the similar steel grade X18H9T).

After securing the plates on the bone fragments, the eccentric was turned about clockwise with the help of a wrench 45°, 90°, 120°, 180° around the displaced rotation center.

At that the interfragmentary compression degree was registered on the scale of the ID-70 device.

The study of interfragmentary compression degree was justified by the following considerations: knowing the degree of deformation and elastic modulus of the material, from which the bone fixing device was made, it is possible, according to the Hooke's law, to determine the strain at the surface of the tested area of the device. It is known that in the case of development of the maximum force that occurs, when turning the eccentric clockwise, in the moment of creation of interfragmentary compression bending of plates occurs within the limits of elastic deformation (A.M. Turchin, 1961).

Fig.7. Taking instruments readings in the process of the studies

The bending degree of the plates is registered by the ID-70 device. The dependence of mechanical strain on deformation within the proportionality is expressed by the formula:

$$\sigma = E\text{Ę}_l = E\frac{\Delta l}{l} = E\frac{\Delta l}{R} = E\frac{\text{Ę}R}{R}$$

l - relative strain, measured by the transducer;

R - relative sensitivity of the transducer;

E - elasticity modulus of the material (for the grades of steel X18H9T, X18P10T it equals E = (2 + 2,2) x 10 kg/cm^2);

Ę - deformation of the fixing device.

Thus, carrying out this bench test enabled us to determine the value of interfragmentary pressure which can be developed using the eccentric mechanism, secured on the case of the suggested fixing device.

The results of the performed tests show that by using the dissected eccentric it is possible to create a compression force of 10 to 120 kg / cm^2, which is sufficient in the osteosynthesis of all segments of the upper and lower limbs.

The value of interfragmentary compression force in the process of osteosynthesis of a femoral bone should be 80 - 100 kg / cm², in the process of osteosynthesis of tibia - 60 - 80 kg / cm², of humerus - 40 - 60 kg / cm², forearm bones - 20 - 40 kg / cm².

II.4. Method of bending and torsion, comparative tests of sector-shaped fixing devices (type AO) with fixing devices of the "METOST" system

It is known from theoretical mechanics course, that the channel-shaped structures are more rigid in comparison with structures having cross-sectional shape in the form of a rectangle or circle sectors, provided that their cross sectional areas are equal.

However, for greater credibility and visibility, we have found it necessary to conduct comparative tests of sector-shaped fixing devices (type AO, made in accordance with the drawings by AO) with fixing devices from the set of the "METOST".

Due to the fact that under real-life conditions a fixing device, secured to bone fragments, preferably undergoes bending and torsion, we put the fixing device of the new design and a prototype (fixing device of AO type) to the tests of this kind.

For the tests of sector-shaped (Fig. 8, c) and channel shaped (see Fig. 8 a and b) fixing devices were made them of steel of the same grade H18R9E, according to AO drawings. The parameters of the fixing devices are indicated in Fig. 8. The tests were carried out in similar conditions and modes.

The bending was tested in these tests by means of hydraulic machine KM-50-1, torsion was tested by means of the universal rupturing unit G-100. The diagram of the tests is shown in Fig. 9. In the process of bending tests, the fixing devices were secured at both ends; dosage load was applied strictly in the middle of the plates. Wherein the loads were determined, which caused residual deformations in the structure, and then the bending under the impact of fixed bending moment was determined.

In the process of torsion tests of plates, one of the ends of the fixing device was secured firmly and to the opposite end rotation force was applied around the longitudinal axis of the fixing device. Wherein the loads were also determined, this caused permanent deformations in the structure and the rotation angle of the plates under the influence of constant torsion.

Thus, comparative bending and torsion tests enable to objectively evaluate the mechanical data of channel and sector-shaped fixing devices.

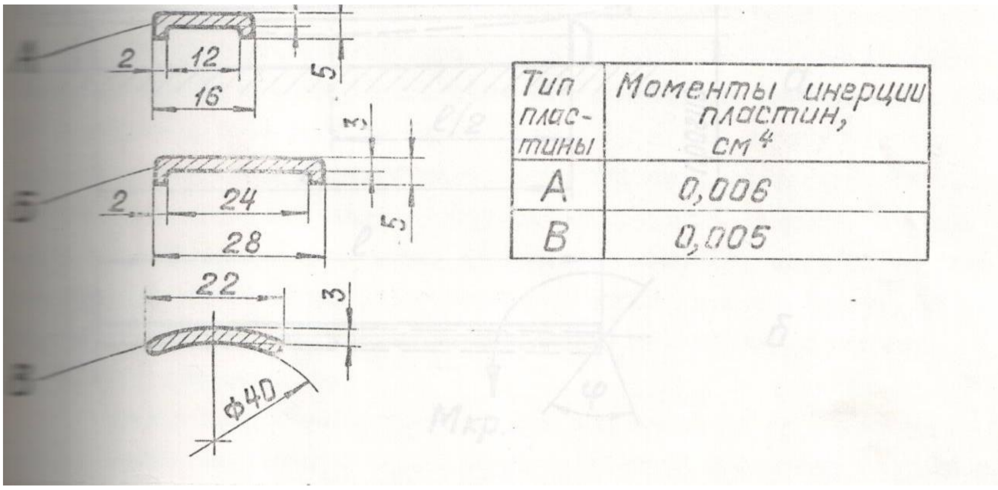


Figure 8. Parameters of the tested sector-shaped and channel plates.

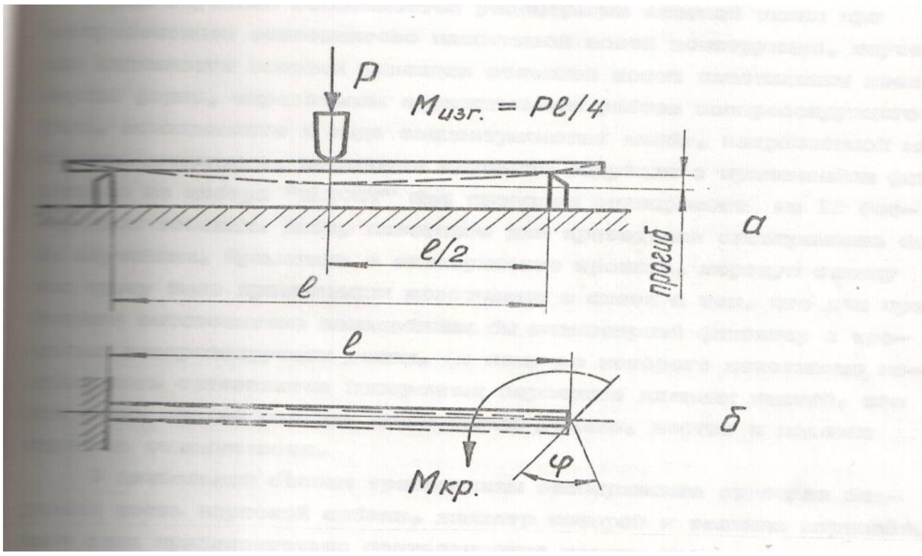


Figure 9. Diagram of bending and torsion tests of the fixing devices.

The parameters of the fixing devices that have been subjected to comparative tests are shown in Fig. 8. As can be seen, the size (cross-sectional area) of the plates A and B differ significantly from Plates C. The cross sectional area of channel plates A is somewhat smaller than the cross-sectional area of the plates B, but the visibility of the obvious advantages of channel structures wins in the process of comparison tests.

The significant difference of the parameters of plates of type A and B is due to the fact that at the initial stage of selection and optimization of parameters of fixing devices, we proceeded comprehensively in this question, in several ways: through mathematical calculations and bench tests, using cadaver bones, testing fixing devices by means of animal experiments, which means we approached gradually, step-by-step the real (optimal) parameters of the fixing devices and the variations of sizes, which are included in the set of the "METOST".

Analyzing the obtained data, it should be noted that the residual deformation of plates A and B under the impact of intersecting forces occurs at loads greater than in the case of plates B.

A comparison of numerical characteristics of the plates A and B, as the most similar in cross-sectional area, enables us to draw the conclusion about appropriateness of using type A plates, the moment of inertia of which is J = 0,006 cm. This characteristic is decisive in assessing the strength and stiffness of the parts.

Thus, in the process of comparative bending and torsion tests the advantages of the channel-shaped structures, compared with structures having cross-section shape in a form of a circle sector, were proven.

II.5. Calculation of vibration-reducing properties of the compression unitm performed in the idea of a dissected eccentric.

An eccentric mechanism, which is a slotted eccentric washer, secured to the case of the fixing device, is provided in the fixing devices of "METOST" set for creating interfragmentary compression. Compression of fragments is carried out after securing the fixing device on the distal fragment by turning the eccentric around the displaced center. The degree of interfragmentary compression depends on the value of eccentricity (the displacement value of rotation axis of eccentric washers from its true center). In the fixing devices of the “METOST” set, the eccentricity in the eccentric device is from 1.5 to 5 mm, the value of which depends on the dimensions of the limb segment and the fixing device by using which the osteosynthesis is made. The distance on which the fragments can be shifted during compression, is equal to twice the eccentricity, i.e. it is in the range from 10 mm to 3 mm, provided that the eccentric is turned about 180 ° around the displaced axis.

Compression force in the process of turning the eccentric 180° does not develop in a single-step way, but due to the presence of incomplete dissected sector of the eccentric washer, which serves as a spring bending within the limits of elastic deformation, and it creates the permanent compression for the period of consolidation of bone fragments.

As shown in the diagram (Fig. 10) on the sector L, the deformation occurs due to the force arising at the time of the full load of the washer, i.e. when it is turned about 180°. For the eccentric to work as a spring, i.e. the sector B is not subjected to plastic deformation, it is necessary to calculate the parameters of the eccentric, based on the load value, i.e. degree of interfragmental compression. For this purpose, we have determined the torsion: M = PL

Resisting moment: $W = \frac{Bh}{\sigma} = \frac{0,3 \times 0,16}{6} = 0,006$ см^2

The allowable strain that the B section can withstand, without losing the vibration-reducing properties: $\sigma = \frac{50 \times 0,4}{0,08} = 2500$ кг/см2

Thus, for the manufacture of an compression eccentric washer by means of which a force can be developed up to 100 kg / cm², when the eccentric parameters are: diameter 10 - 15 mm, thickness = 2.3 mm, the eccentricity - 2 mm, height H = 3.4 mm, the following material is required: for its production:

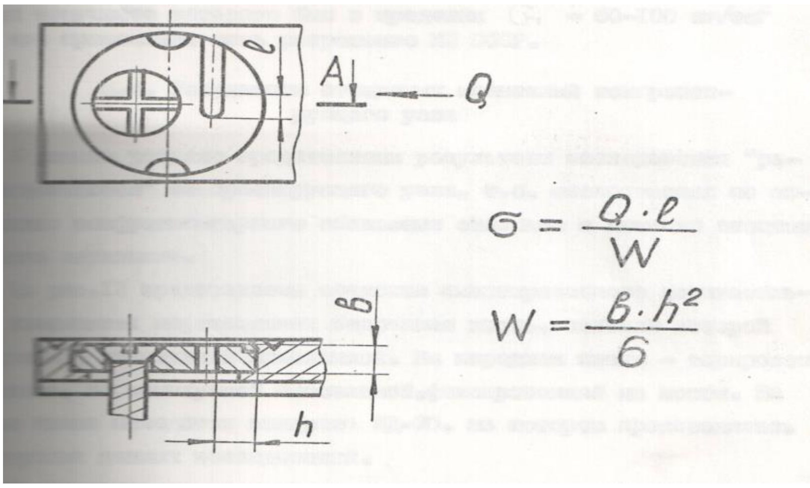


Figure 10. The scheme of calculating vibration-reducing properties of the eccentric

1) stainless steel 40X13, X18H9T;

2) titanium alloy: BT-5; BT-6.

Which means, for the manufacture of the eccentric, the material is required of the flow limit, which is in the range σ = 60-100 kg / cm² and its application has been permitted by the Ministry of Health of the USSR.

II.6. Results of calculation of the angular displacement degree of bone fragments at the time of rotation of the eccentric.

The extreme point of large radius strikes an arc of Archimedes, because the eccentric center is displaced by a certain amount.

Due to the fact that the eccentric, secured on the plate is a unitary structure and, at the time of turning it, the plates are shifted together with the bone fragment, to which the plate is secured with a fixing screw, introduced through compression assembly unit.

By elementary trigonometric calculation, the displacement angle of the proximal bone fragment was determined, along with the plate secured thereon as related to the proximal fragment. Fig. 11 is a diagram on which the calculation is made of the value of angular displacement of bone fragments, when turning the eccentric. In a right triangle, which can be constructed by taking half the length of the fixing device for one leg, the eccentricity value for the perpendicular leg, drawn to the first one, the angle between said legs we take as 90 °.

The calculation of the deflection angle is made according to the formula:

We should look up the value in the trigonometric table.

Thus, calculations made, show that the angular displacement may be in the range of 1°35 to 2°30, which can be neglected under real-life conditions.

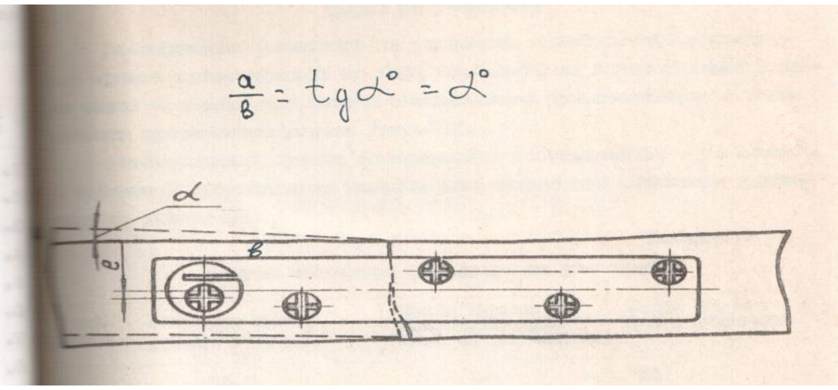


Figure 11. Diagram of calculation of deflection angle

II.7. Results of fatigue tests of the channel-shaped fixing device (III.6.)

The tests of fixing device for fatigue and building of fatigue curve were carried out according to GOST 25.503-79, using testing machine of low capacity by means of a special device with console application of force (Fig.12, 13, b). Fatigue point was established during the tests, which is 35 – 36 kg/mm².

Thus, the tests show high fatigue strength of the fixing device of our design, which provides sufficient reliability in its practical application. In Figure 13.a, the curve of fatigue of channel-shaped fixing device is shown.

The tests of sector-shaped fixing devices has not been carried out due to the fact that their moment of inertia and the resisting moment are lower than that of the channel-shaped fixing devices, the fact of which we had defined in the process of the comparative tests - Section 4 of Chapter II. These parameters define the lower fatigue values during fatigue tests. This fact is undeniable and requires no rechecking in the experiment.

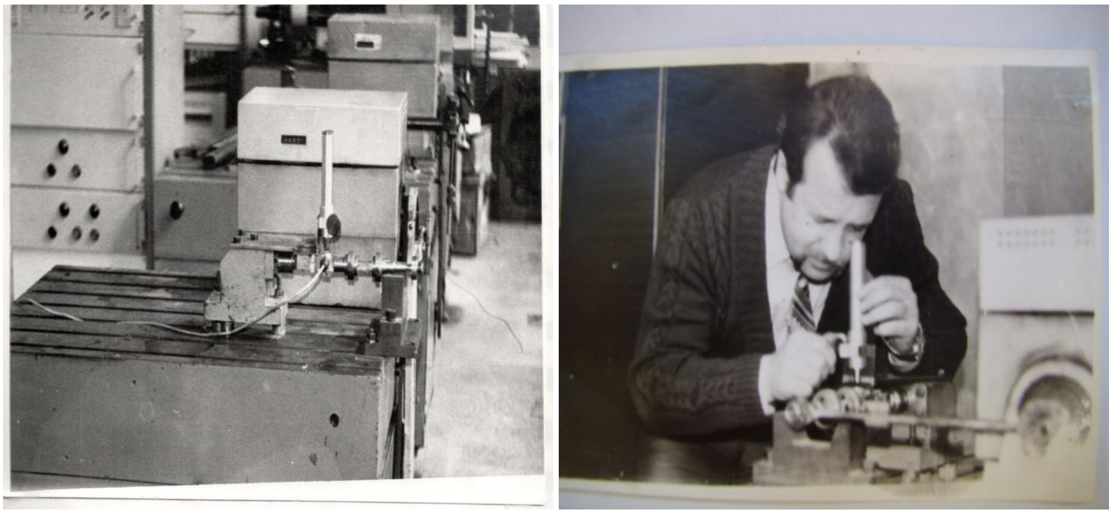
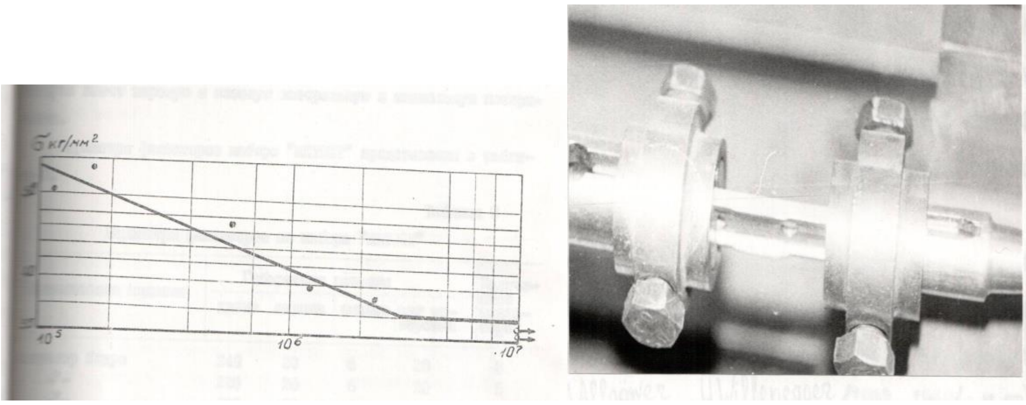


Рис. 12. The testing machine for fatigue strength tests. Recording of the testing machine indications.



a *b*

Fig. 13, a. Fatigue curve of channel-shaped fixing device

Fig. 13, b. Fixing device secured in the testing machine

II.8. Developing the "METOST" system.

Complex of tests and calculations, carried out in the previous sections on mechanical and mathematical modeling of extramedullary osteosynthesis, using channel-shaped compression plate, as well as determining the strength properties of the fixing device of new design, have enabled us to start developing a set of instruments for stable-functional osteosynthesis, called metalosteosynthesis by the "METOST".

The "METOST" set comprises 4 mini-kits – 3 fixing devices of typical sizes for osteosynthesis of humerus, femur and tibia each, as well as 2 typical sizes osteosynthesis of forearm bones; 2 typical sizes of fixing screws for each segment of upper and lower limbs – in total, 42 fixing devices and 278 screws, manufactured, according to OST 64-1-152-80 (diameter of screws 4.3 mm).

When defining the parameters of fixing devices we took as a basis the research of K.M. Klimov (1949), F.R. Bogdanov (1959), N.V. Novikov (1956), U.Y. Bogdanovich, Y.A. Zakirov (1984), M.E. Muller, V. Allgower, H. Willenegger (1963, 1969) and others in this field, who noted that the length of a fixing device must be proportional to the length of the bone segment. The ratio of the length of the segment and the fixing device should be in the range from 1/5 to 1/2.

We calculated the width of the fixing device in accordance with its ratio to bone diameter of the corresponding segment, so that when applying the bone fixing device, the bone circumference would fit into the channel profile, which would have three points of support, as the most stable variant of structures ratio.

An exception, in this respect, is that the fixing device, designed for osteosynthesis of the tibia, having 2 points of support, due to the anatomical structure of the tibia, which has a wide and flat lateral and medial surface.

In addition to fixing devices and fixing screws, the set of "METOST" includes: 1 screwdriver to tighten the screws (Ukraine Patent №1653750), 2 rod benders for modeling fixing devices (efficiency suggestion No. 37) and three wrenches for tightening the eccentric (efficiency suggestion No. 8).

Rod bender for modeling fixing devices consists of a handle and a head, intended for holding fixing devices. The rod bender head is meant for modeling fixing devices both, of our structure specifications, of channel shape, and of other extramedullary fixing devices which have sector shape.

Wrenches, for tightening the eccentric are open end wrenches the fork of which is inserted into the recess on the eccentric. Three typical sizes of wrenches in the set are intended due to the fact that on the plates of different sizes the eccentric device is made also in different sizes (three typical sizes with diameters 10, 12 and 17 mm).

Fig. 14,a shows the main components of the “METOST” set: three typical sizes of plates for osteosynthesis of humerus, femur and tibia each, two typical sizes for osteosynthesis of forearm bones, two typical sizes of fixing screws, rod bender for modeling fixing devices, a screwdriver, 3 wrenches for tightening the eccentric (Fig. 16, a) an advertising set (Fig. 14, b), which was demonstrated at the exhibitions in Exhibition of Economic Achievements of USSR and Exhibition of Economic Achievements of USSR (Ukrainian Soviet Socialistic Republic).

Fixing devices and fixing screws are made of titanium alloy BT-5, BT-6 or stainless steel X18H9T, and the accessory instruments are made of stainless steel X18H9T.

Thus, taking as a basis the channel-shaped fixing device, we created a set of instruments called "METOST" and intended for osteosynthesis of diaphyseal fractures of all segments of the upper and lower limbs.

The "METOST" set is equipped with accessory instruments, which significantly facilitate mastering the methods of osteosynthesis and its practical implementation.

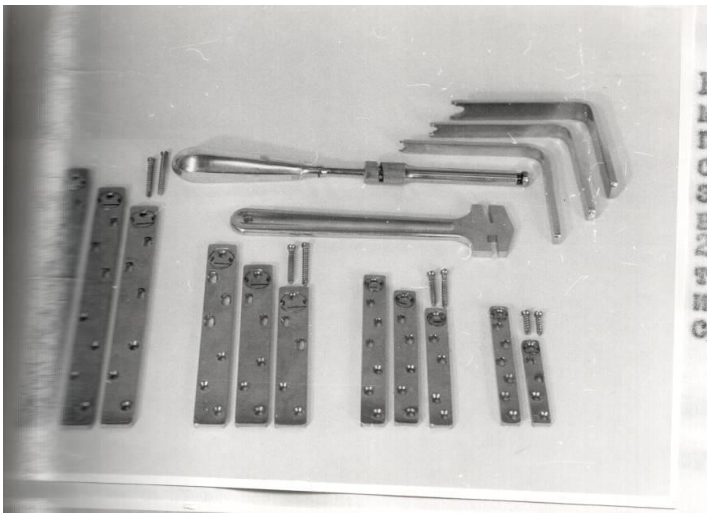


Fig.14, a. The main elements of the set "METOST": 3 typical sizes of plates for osteosynthesis of femur, tibial bone and shoulder, 2 typical sizes - for forearm bones, screws and accessory instruments - 3 wrenches for tightening the eccentric 1 rod bender for modeling the fixing device, 1 screwdriver.

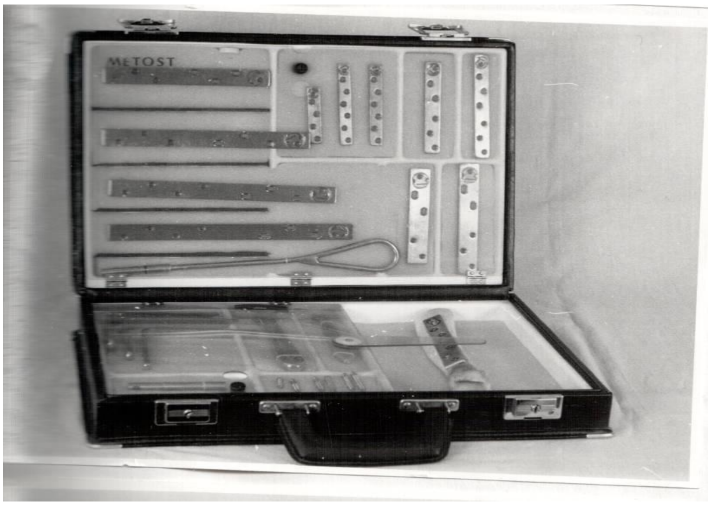


Fig.14, b. Advertising set of instruments for osteosynthesis "METOST" which was demonstrated at the exhibitions in Exhibition of Economic Achievements of USSR and Exhibition of Economic Achievements of USSR (Ukrainian Soviet Socialistic Republic).

III. STABLE FUNCTIONAL OSTEOSYNTHESIS WITH "METOST" COMPRESSING PLATE UNDER EXPERIMENTAL CONDITIONS

III. 1. Selection and rationale of experimental animal, fixator selection and experimental method.

The experiment was carried out on 12 mongrel dogs in order to investigate the features of osteoanagenesis in the process of compression osteosynthesis using the plate of our construction, reliability of bone fragment fixation using U-shaped plates, determination of operational efficiency of compression node in the eccentric node form fixed to the plate case, operational technique practising with "METOST" system fixation device. Selection of experimental animal was not accidental. It was practically impossible to set up the experiment on a rabbit, a guinea pig or a rat, due to the fact that miniature fixator with tiny compression node, by means of which modeling of long bones transverse fractures osteosynthesis is impossible, on account the difficulty of developing the required force and fixing the bone fragments in a rigid and reliable way, would be necessary for osteosynthesis.

Femur of an adult dog, diameter and thickness of the cortical layer of which approximately corresponded to the human bones of the forearm, was most compatible with the experimental requirements.

Bone fixing devices by means of which the osteosynthesis was carried out, were made of BT-6 titanium alloy. Depending on the length of the segment (femoral bone) of the experimental animal, the bone fixing devices of the following parameters were used: length - 70 mm, 100 mm, 115 mm, 120 mm, 130 mm; width - 10 mm or 12 mm; thickness, including reinforcement ribs - 5mm; eccentric diameter - 8 mm, 10 mm, with a eccentricity - 1.5 mm.

Fixing screws applied for the osteosynthesis were standard, in compliance with OST-64-1-152-80 (diameter of the screws was 4.3 mm). Length of the screws was 20 – 25 mm. Diameter of screw holes on fixing devices was 3.5 mm, number of holes in a fixing device depending on the length of the fixing device was from 4 to 7, the spacing between the holes on the fixing device was 15 mm.

Accessory instruments used in the experiment – benders for modeling the fixing devices, wrenches for tightening the eccentric, a screwdriver for drawing up the screws – were standard, included in the "METOST" set intended for osteosynthesis of all segments of upper and lower limbs.

Thus, we tried to approximate the conditions of the experiment on animals to the real conditions of the osteosynthesis of shaft fractures of long human bones.

III.2. Operational technique at experiment and method of the experimental animals examination.

For investigation the time course and characteristics of regeneration of experimental fractures (osteostomy) of femur in the course of osteosynthesis using compression U-shaped plate with an eccentric mechanism for creating interfragmentary compression 12 adult mongrel dogs in total with weight 10 to 23 kg were applied. Observation period was 15 days, 30 days, 60 days, 90 days.

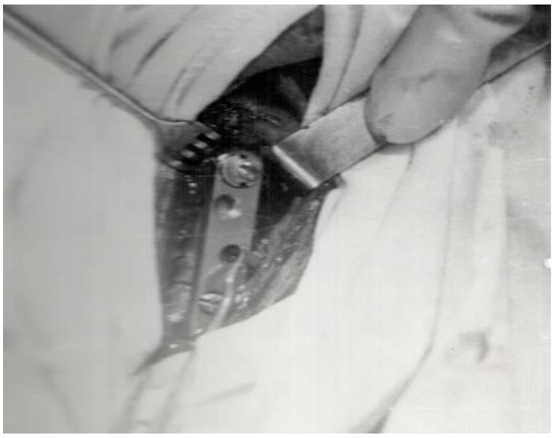
30-45 minutes before the surgery the intramuscular injections were administered to the animal: 2.0 – 50% of analgin, 1-2.0 of pipolphen, 1.0 of droperidol. Then, on the expiry of the 30-45 minutes after the premedication, intrapleural injection of 5.0 – 8.0 – 5% solution of thiopental sodium was administered, whereafter the surgical field was washed using soapy water, dried with sterile wipe and accurately shaved.

An animal was positioned on an operating table on the left side, forelegs and left hind leg were immobilized, and the right hind leg, being the subject of the experiment, was free. After iodinating the surgical field with 5% iodine tincture local anesthesia was made with 1% solution of novocaine 15-25 ml, the surgical field was additionally twice iodinated with 5% tincture of iodine and a longitudinal section of the soft tissue was made on the lateral line of the right thigh of 8-14 mm (depending on the length of the bone fixing device). At that, the skin, subcutaneous tissue, superficial fascia were dissected. Then partially "acutely", partially "bluntly" the femoral bone was reached through the intermuscular space (Figure 15,a). Gigli saw was introduced under the femur in its middle third and the femur was sawed strictly perpendicular to the longitudinal axis of the bone. Femur fragments were reduced, a fixing device was selected and modeled using benders corresponding to the bone shape. Then the bone fixing device was placed onto the bone fragments so that osteotomy line was located between two middle holes of the bone fixing device and the compression unit was placed on the proximal fragment. A bone holding clamp was used to fix the bone fragments together with the plate.

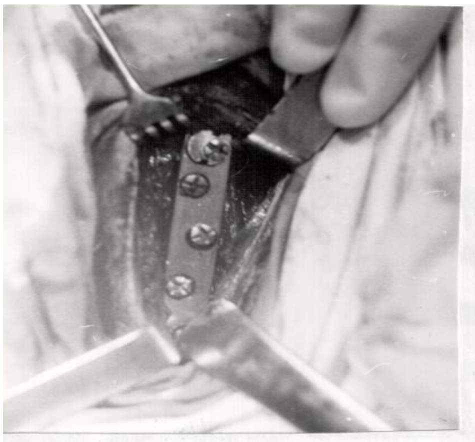
Bone canals were made using electric drilling machine through the holes of the plate above the distal fragment (the drill's diameter was 3.5 mm) and the plate was fixed by screws (Fig. 15,b). Then a fixing screw was introduced through eccentric device into the proximal fragment, wherein it was not completely tightened enabling to turn the eccentric with a wrench clockwise around the displaced center which helped to perform interfragmentary nailing up of fragments (Fig. 15,c). Then the screw was completely tightened up and the plate was fixed to the proximal fragment with additional screws (Fig.15,d). An important point is the necessity of "soft" holding of bone fragments together with the plate by the bone holding clamp during the whole procedure of plate securing and especially at the time of turning the eccentric, because dislocation of the fragments may happen at that moment.

a

b



c



d

Fig.15 Stages of surgery on experimental animals.

An access to the bone was performed in the way described above in Part 2, Section III. A field for osteotomy was prepared on the femoral bone (Fig.15,a), the bone fixing device was secured by fixing screws to the distal fragment of the bone subjected to the osteotomy (Fig.15,b), compression of the fragments was made using an eccentric mechanism (Fig.15,c), the proximal fragment was secured by two additional screws (Fig.15,d).

Reliability and stiffness of the osteosynthesis was checked after all the screws have been tightened. The cut was washed with antiseptics, dried, antibiotics were dispersed on it and the layer-by-layer seam was imposed. The post-surgical suture was iodinated using 5% tincture of iodine. Operated limbs of animals were not plastered.

Clinical monitoring of the animals was conducted daily for a week, and then once in 3-4 days. During the first 5 days the body temperature of the animals was measured, their behavior was under observation, attention was paid to their general state, reactions, appetite.

At the end of the observation period (15 days, 30 days, 60 days, 90 days) in turn, the corresponding term of the observation, a dog was driven out of the experiment by injecting lethal dose of 20% thiopental 10-20,0 and 100 mg of muscle relaxant into the pleural cavity or the lungs.

Roentgenography of the experimental femoral bone was made on the day of surgery, immediately after its completion and on the day of termination of the experiment. The femoral bone was disjointed of articulations, soft tissues were separated. Wherein the surgical place was examined, attention was paid to the presence of scars, nature of changes in the periosteum, nature of commissure (adnation) between fragments. Then the preparations were fixed in 10% formalin solution during 6-10 days. After that the preparations were placed in 5% solution of nitric acid for 4-7 days for decalcification. Then the preparations were sawed with a thin saw in the horizontal and the sagittal planes. Sawed out parts of bone tissue were embedded in photoxylin according to usual technique. Histological sections were stained using hematoxylin-eosin technique and Van Gieson's technique.

Thus, during the realization of the experiment on animals one of the objectives was to refine technique of osteosynthesis and methods of gypsum-free postoperative care. The control over effectiveness of the osteosynthesis, as well as over the reparative process was performed using clinical, roentgenological and morphological techniques, the results of which will be presented in the next section of this chapter.

III.3. Results of clinical, roentgenological and histological research of the experimental animals.

Observation period – 15 days.

The observation group consisted of three animals under the number 16, 17, 25.

The surgery – compression metal osteosynthesis with "METOST" system fixation device.

In terms of clinical examination to 15th day there was no difference between surgically operated dogs and not operated ones. On the second day after the surgery all animals stood up, were moving in the cage slightly loading the operated limb. The dog under the number 17 was a little less active but on the 3rd - 6th day all dogs were loading operated limbs almost to the full extent. The animals were active, have normal appetite.

Postoperative scar is slightly thickened, dense. No apparent signs of inflammation in the area of postoperative scar were observed.

In terms of radiology (Fig. 16,a; and Fig.17,a) the line of hip osteotomy of all dogs can be clearly defined. There is no diastasis between the fragments. The dog under the number 25 has an insignificant dislocation up to 2,5 mm along the width in sagital projection. Analyzing the dogs under numbers 16 and 17 (Fig. 17,a), their fragments fit in well, there are no dislocations. The dog under the number 16 has a metal fixing device that clamps the fragments with 4 screws, the length of the fixing device is 70 mm, length of the segment is 125 mm; examining the dog under the number 17 – the fragments of the injured bone are fixed with 4 screws, the length of the fixing device is 70 mm, length of the limb segment is 150 mm; the dog under number 25 – fixation – with 7 screws, the length of the fixing device is 130 mm, the length of the limb segment is 230 mm.

The bone fixing devices are tightly adjusted to the bone fragments, hold them stiffly. There are no clear signs of periosteal bone formation on radiographs.

Macroscopic investigation of the preparation: the plate fixing the bone fragments is covered with fibrous capsule (membrane). Consolidated bone fragments in the region of the former osteotomy can be seen (Fig. 18) after removing soft tissues and the plate. The periosteum in the area of adherence to the bone fixing device has normal color. It is absent on the line of direct contact of fixing device and the bone, in the "unloaded area" the periosteal appositions follow the inner shape of the fixing device which is U-shaped. From the opposite, in relation to the fixing device, cortical layer screws protrude for no more than 1-1.5 mm.

Microscopically all experimental dogs had comparatively dense contact of the fragments and good development of adhesion processes between them. All experimental dogs had fibro-reticular and partially close-meshed osteoid tissue invading here primarily from the side of the medullary cavity (Fig. 17, b, c) between the ends of the fragments on the side where the fixed plate was secured. Marginal areas of cortical fragments have no osteocytes and no signs of osteogenesis. However, there is moderate activation of osteogenic cell and tissue elements with formation of a thin layer of fibro-reticular and close-meshed osteoid tissue in the periosteal layer of bones in the osteotomy area. On the opposite side of the fixing plate between the bone fragments there is a more pronounced osteoblastic reaction with large growths of osteoid nature.

Along the entire length of the bone fragments in the area of adherence of the fixing plate in the outer cortical plate there are faint phenomena of osteoclastic resorption with formation of small surface gaps and somewhat dilated vascular channels (Fig. 16, b).

Medullary cavity in the osteotomy area along its entire length is unevenly filled with fibro-reticular and close-meshed spongy osteoid tissue abundant in vessels, expanding here from the proximal bone (Fig. 17, a). There are necrotized fragments of trabecula of bone, signs of former hemorrhage with hemosiderin and fibrin depositions in some places of the area. Necrosis of some elements of bone marrow, which gradually merges into the area of normal bone-marrow structures, can be seen in the medullary cavity, more distal of the osteotomy area. In addition, the dog under the number 17 had small areas of fibrous connective tissue of various extension with areas of chondrogenesis in the osteotomy area.

Almost all dogs had uniformly pronounced osteogenic reaction of newly formed close-meshed osteoid tissue in the area of channels made by fixing screws on its entire length; there are small periosteal appositions in the area of the fixing device localisation in the regions of partial loading (Fig. 17, b).

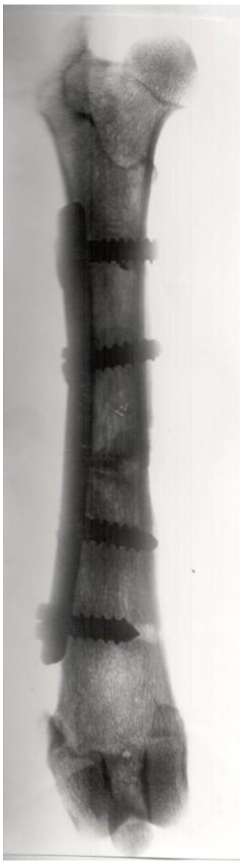
d b c a

Fig.16. ***Radiograph*** *of femur with a fixing device (a), dog No. 25, 15 days*

Histotopograph. *Osteotomy area with phenomena of endosteal and periosteal reaction on the side of the fixing device and on the opposite side of the fixing device.*

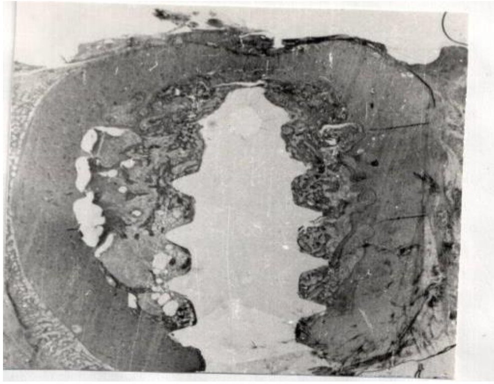
Microphoto *– formation of close-meshed osteoid tissue between the fragments and phenomena of resorption of the fragment's edge.*

*Hematoxylin-eosin, enlarg. 10x10***.**



a

b



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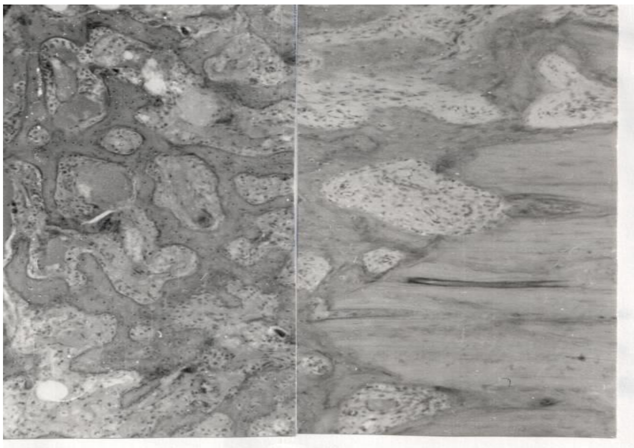


c d

*Fig. 17. **Radiograph** (a), dog No. 16, 15 days*

***Histograph** (b), the area of adherence of the U-shaped fixing device to the bone. Endosteal and periosteal reaction in the region of localization of the fixing screws.*

***Microphoto** - (b) endosteal bone growth on the place of osteotomy in the bone-marrow canal, (d) formation of close-meshed osteoid tissue between the fragments.*

Hematoxylin-eosin, enlarg. 10 x 10.

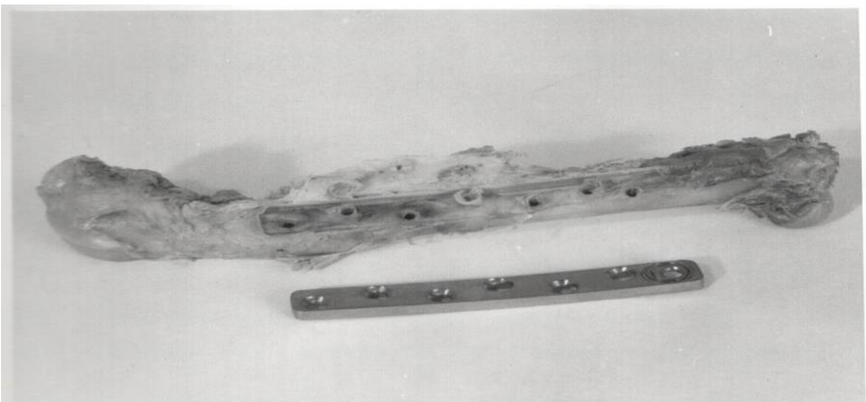


Fig. 18. Preparation of femur of an experimental animal.

Dog No. 17, 15 days. The bone fixing device is removed, there are periosteal appositions following the inner shape of the U-shaped fixing device in the region of former placement of the fixing device.

Observation period 1 month

This group with this observation period consisted of three dogs (number 11, 15, 3/23).

The surgery – compression metal osteosynthesis with "METOST" system fixation device.

In terms of clinical examination all the dogs stood up and were moving in the cabin loading their operated limbs partially after 2-3 days, they were moving not lamely in the cabin, treading on the operated limb after 5-9 days after surgery. It is necessary to note that the dog under the number 11 recovered after the surgery a little later than expected. However, all the dogs behaved their usual way to the 30th days from the beginning of the experiment. They didn’t differ from not operated animals in their outward appearance, were active, loaded the operated limb to the full extent and the right hip was fully covered by fur in the region of the surgical site.

In terms of radiology (Fig. 20, a) the dog under the number 3/23 had good apposition of fragments, no diastasis and no dislocation. The dog under the number 11 had a slight dislocation of fragments along the width to 1.5 mm. The length of the fixing device was 70 mm, the length of the limb segment was 110 mm. The bone fragments are fixed by 3 screws only, instead of 4. The introduced error during the surgery caused insufficient fixation stiffness of bone fragments and protracted adaptation period of the animal after the surgery.

The fragments of the dog under the number 15 were fixed with a plate 70 mm long, length of the segment of the operated limb was 150 mm, the plate was secured to the bone fragments with 4 screws.

Analyzing the dog under the number 3/23, its length of the limb segment was 155 mm, length of the fixing device used for the osteosynthesis was 70 mm, the plate was secured to the bone fragments with 5 screws.

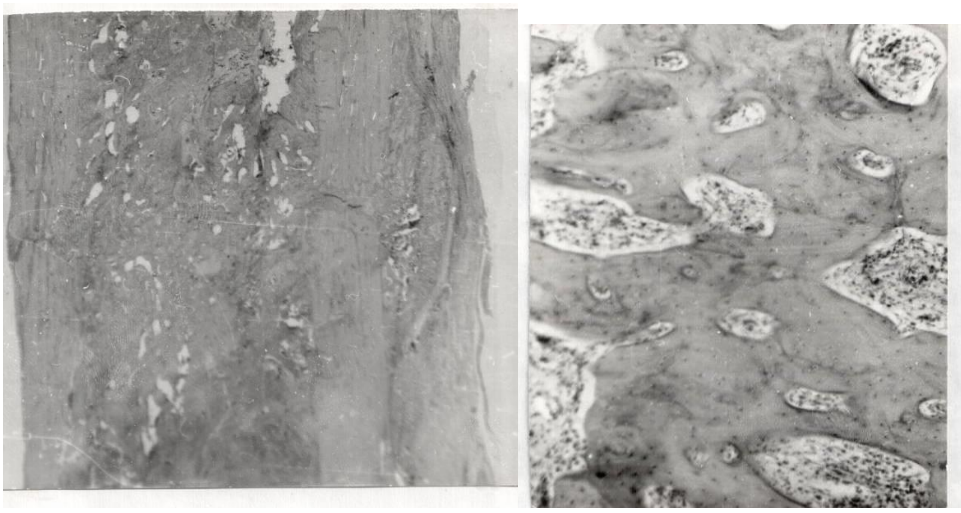
There is induration of structure of bone tissue on the osteotomy lines, the osteotomy line can be seen only slightly during the examining of the dog under the number 15. The almost complete recovery of the homogeneity of the bone structure of the medullary canal was registered. There is a slight reaction of periosteal coverage in the form of a small cloud around fixing screws.

Macroscopically - after removal of the fixing device there is thinning of the periosteal coverage in the fitting area of the former osteotomy and there is no periosteal coverage on the line of direct contact of the channel with the bone. Periosteal appositions follow the shape of the inner surface of the U-shaped plate.

Microscopically – in two observations with the dog under the number 15 and 3/23 (Fig. 19 b, 20 b) the ends of the fragments were well fitted in the course of the surgery, correctly put together and with the dog under the number 11 they were put together with a slight dislocation to 1.5 mm along the width and a somewhat broadened cleft remained between the fragments. But both in the cases of correct putting together the fragments and in the case when a small dislocation of them occurred, there was almost complete union of the fracture.

About the dog under the number 3/23, there is a stripe of a newly formed condensed spongy bone with restructuring phenomena (Fig. 20, d) in osteotomy area between the fragments of the compact bone on the side of the fixing plate. Bone fragments are tightly put together and compressed on the opposite side but their union took place on the outer side and on the side of the medullary canal, where there were endosteal and periosteal reactions along the entire length of the investigated regions both of the distal and of the proximal fragments as well as in the area around the fixing screws. There were no phenomena of periosteal reaction in the area of direct contact of the fixing device and the bone (in the load area).

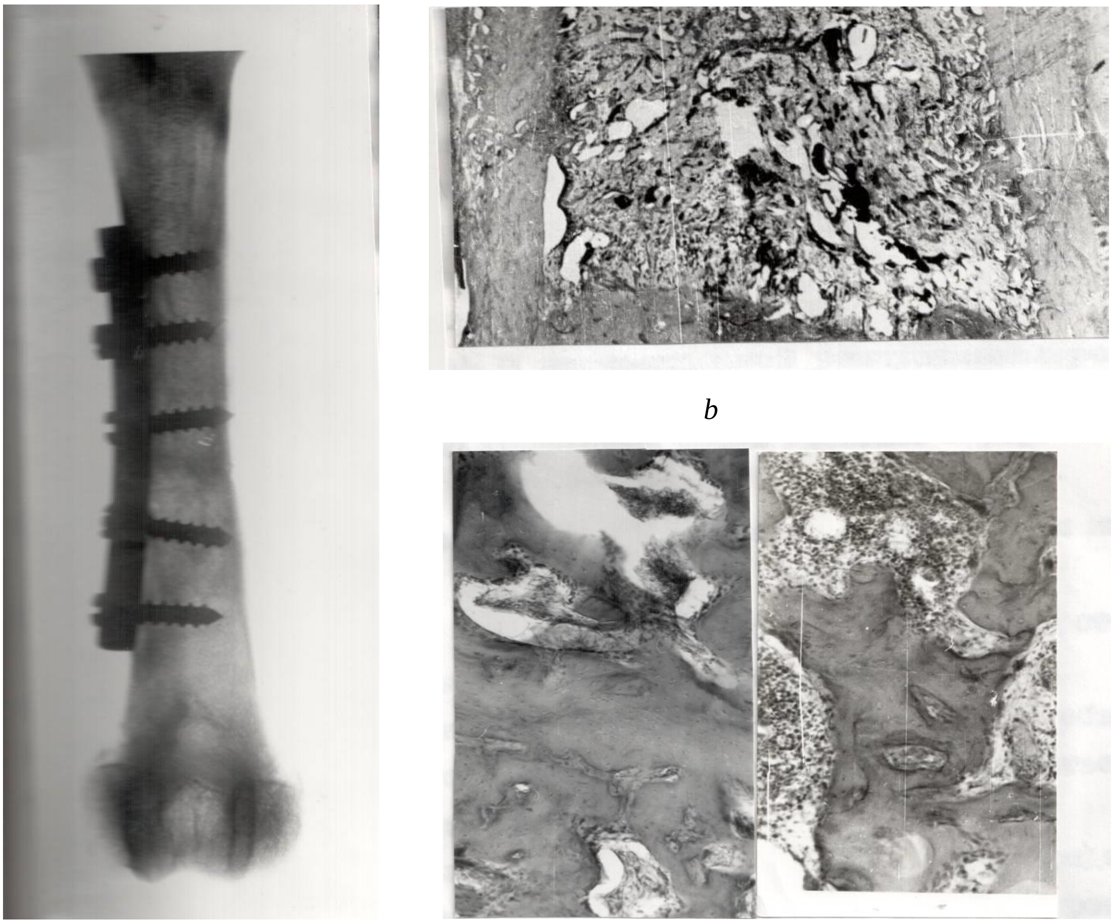
The processes of fragments' union of the dogs under the number 11 and 15 proceed with pronounced hyperplastic reparation reaction by way of formation of spaceous regions of periosteal and endosteal bone tissue / Fig.19, b/. A cleft between the fragments of the compact bone and in the area of medullary canal is mainly filled with condensed spongy tissue (Fig.19, c). The dog under the number 11 has the regions without trabecula of bone of fibrous connective tissue or fibrous cartilage that are present only in the form of isolated areas in the osteotomy area. Periosteal reaction is present on the entire circumference of bone fragments, whereas periosteal reaction is depressed in the area of direct contact of the plate with the bone and there is pronounced osteoclastic resorption of the outer common plate of compact bone here and rarefication of all layers with regions of spongeous bone formation. The processes of endosteal and periosteal reparative reaction with formation of regions with various density of spongy bone tissue, pronounced in varying degrees, taking place in the area of location of fixing screws.



b *c*

Fig. 19. Radiograph dog No. 15, 30 days.

Histotopograph (b), pronounced endosteal and periosteal reaction in the osteotomy area. No periosteal reaction on the side of securing the fixing plate in the area of its direct contact to the bone (c), a region of newly formed condensed spongy bone between the bone fragmen



b

a *d* *c*

Fig. 20. Radiograph (a), dog No. 3/23, 30 days.

Histotopograph (b) expanded region of endosteal bone formation in the osteotomy area. Microphoto (c) a region of condensed spongy bone in medullary canal, (d) a region of condensed spongy bone at the junction of fragments. Hematoxylin-eosin, enlarg. 10 x 10

Observation period 2 months

The group with this observation period includes the animals under the number 19, 1/21, 28, 29.

Surgery – compression metal osteosynthesis with "METOST" system fixation device.

In terms of clinical examination – after 2-months period all the animals didn’t differ from the not operated ones. Postoperative scar is soft, completely covered with fur. Movements in the adjacent articulations are in full range. The animal effortlessly moves in the cabin, can stand on both hind legs.

In terms of radiological examination (Fig. 22 a, 23 a) the good apposition of the fragments is defined. They are well-compressed, that is why only a slight trace of osteotomy line can be seen already on the radiographs made immediately after the surgery.

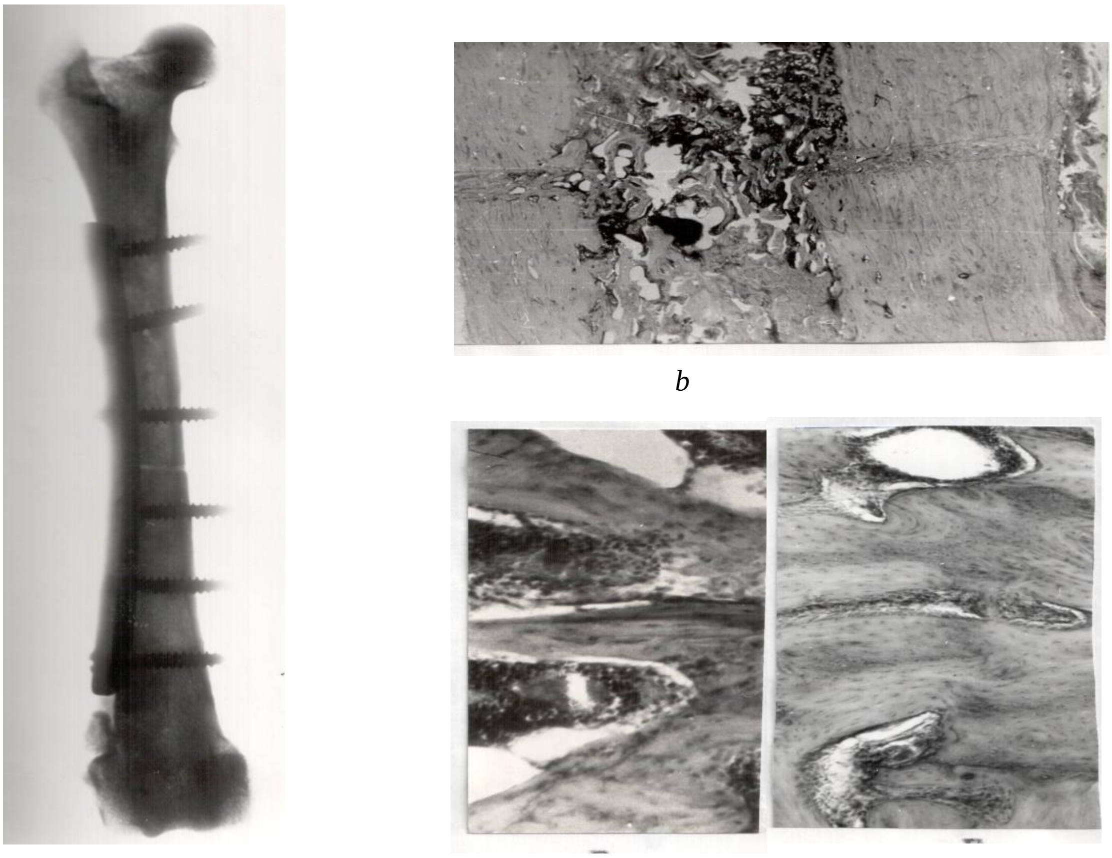
Only a slight trace of osteotomy line can be seen on the radiographs of the preparations of femoral bones which were obtained after butchering the animals. It is noted almost complete restoration of integrity and structure of the cortical plate. Integrated medullary cavity was restored.

The bone fragments of the dog under the number 19 are fixed with a plate 130 long using 7 screws, the length of the operated segment is 200 mm. The dog under the number 1/21: the length of the fixing device was 110 mm for 6 screws, the length of the operated segment was 180 mm. The dog under the number 28: length of the fixing device was 115 mm for 6 screws, length of the operated segment was 190 mm. The dog under the number 29: the bone fixing device was secured with 6 screws, length of the fixing device was 130 mm, length of the operated segment was 205 mm.

Macroscopic image of the preparation is analogous to the preparations with observation period of 1 month.

Microscopically – in all investigated cases (dogs under the number 19, 1/21, 28, 29) one-type union of bone fragments as formations of condensed spongy bone with the phenomena of osteonization can be observed in osteotomy area (Fig. 22 b, 23 b, c).

X-ray translucency and partial thinning of glomerular trabeculae of bone can be seen in the medullary canal (Fig. 22 c, 23 c). The height of periosteal appositions reduces significantly in all cases both in the osteotomy area and in the distance of it, they condense noticeably and get osteoid structure in some places.



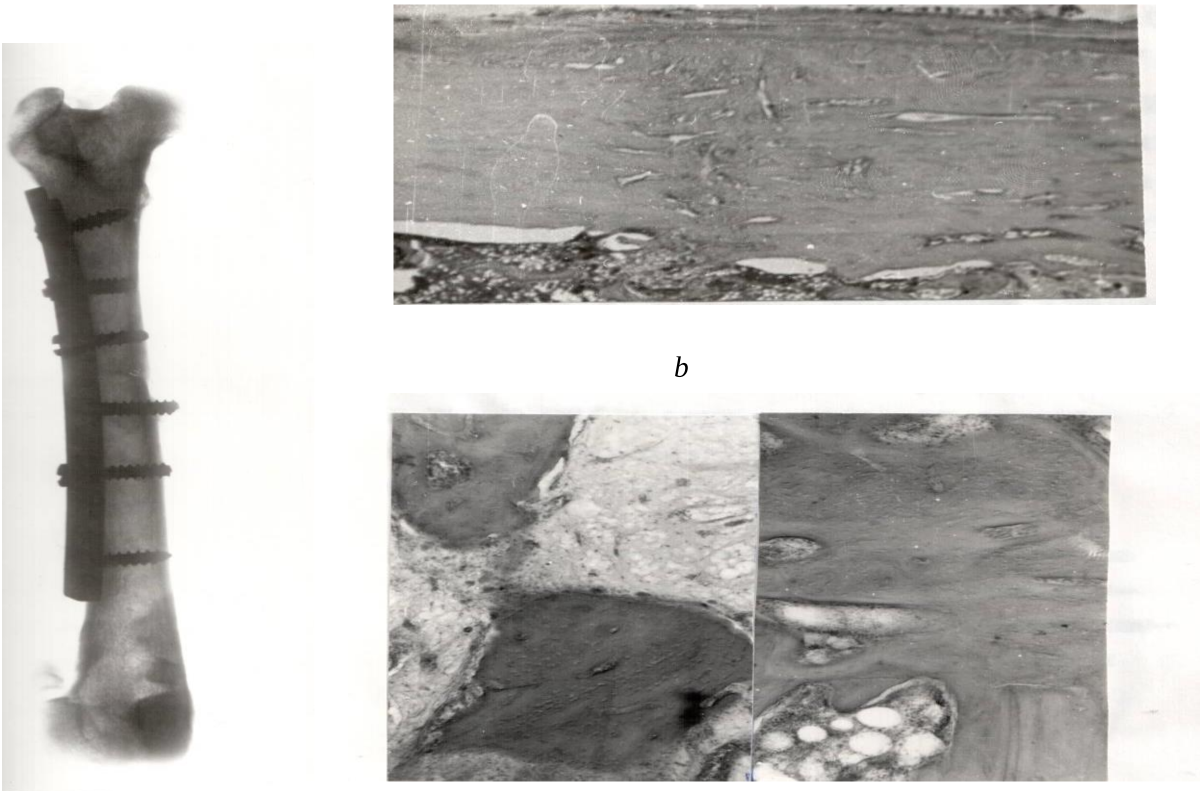
b

a c d

Fig. 21. Radiograph (a), dog No. 19, 60 days.

Histotopograph (b), in the osteotomy area formation of condensed bone tissue with phenomena of osteonization can be seen.

Microphoto (c), phenomena of bone loss in condensed areas of bone tissue, (d) condensation and restructuring of the newly-formed bone tissue in progress between the bone fragments. Hematoxylin-eosin, enlarg. 10 x 10.



a *c* *d*

Fig. 23. Radiograph (a), the dog No. 1/21, 60 days.

Histotopograph (b), some spacious resorption lacunae remain in the region of contact of the bone fixing device in the former osteotomy area.

Microphoto (c), osteoclastic resorption of trabeculae of bone in the area of endosteal regenerate, (d) a region of interfragmentary union with phenomena of restructuring. Hematoxylin-eosin, enlarg. 10 x 10.

Observation period 3 month

The group with this observation period includes three dogs (under the number 20, 2/22, 4/24).

The surgery – compression metal osteosynthesis with "METOST" system fixation device.

In terms of clinical examination - after 3-months period all the animals didn't differ from the not operated ones. Postoperative scar is soft, completely covered with fur. The animal moves easily on all its four legs. Motion activity of all animals was restored almost simultaneously. All the animals stood up already on the second day after the surgery, treading slightly at their operated legs. Full load started to be applied to it after 4-9 days after the surgery.

In terms of radiological examination (Fig. 23 a, 24 a) good fitting of the fragments can be seen, they are well-compressed, that is why only a slight trace of osteotomy line can be seen already on the radiographs made immediately after the surgery.

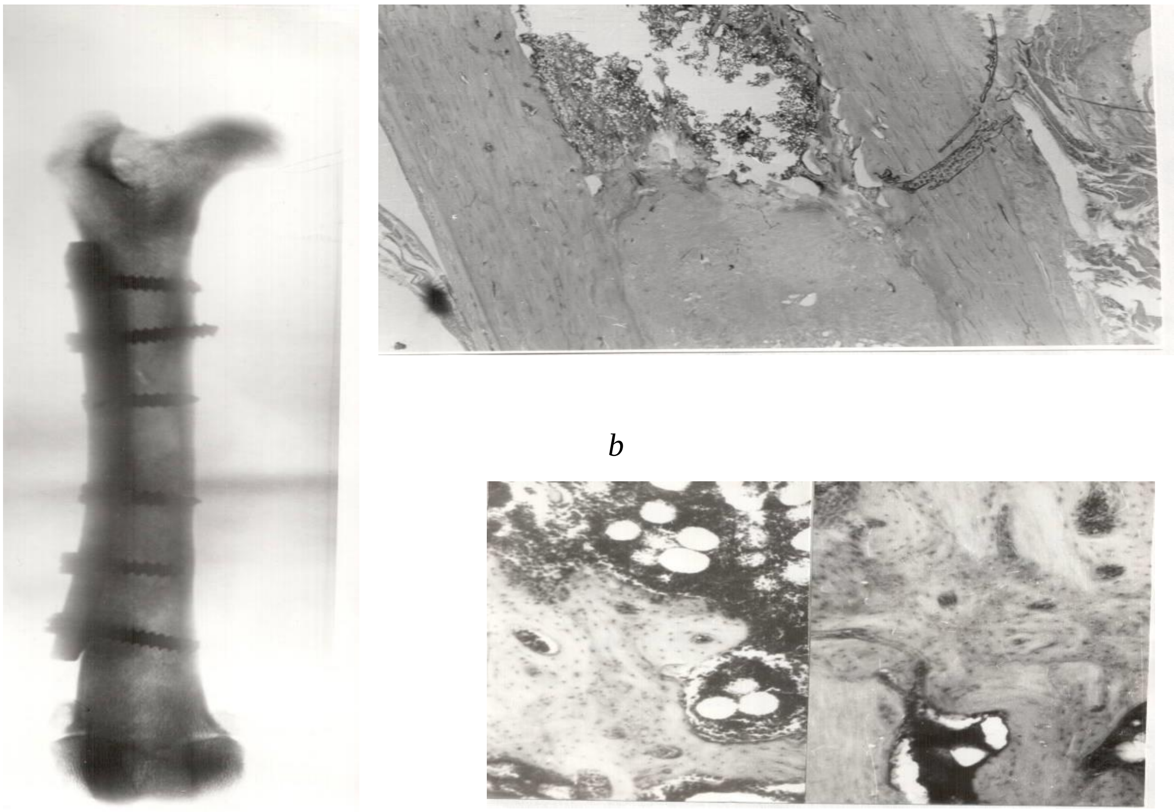
The bone fragments of the dog under the number 20 are secured to the plate with 6 screws, the length of the fixing device was 130 mm, the length of the operated segment was 190 mm.

The bone fragments of the dog under the number 2/22 are secured to the plate with 7 screws, the length of the plate was 100 mm, the length of the operated segment was 180 mm. The bone fragments of the dog under the number 4/24 are secured to the plate also with 7 screws, the length of the fixing device was 100 mm, the length of the operated segment was 180 mm.

On the radiographs of the preparations of femurs the osteotomy line cannot be seen. Almost complete restoration of integrity and structure of the cortical plates can be seen. Integrated medullary cavity was restored (Fig. 23, a, 24, a).

Macroscopically – the bone fixing device is covered with fibrous capsule. After removing the bone fixing device a bed of former placement of the bone fixing device reveals following the shape of a U-shaped plate, formed by periosteal appositions.

Microscopically in all cases (dogs under the number 20, 2/22, 4/24) complete union between the bone fragments can be seen in the area of the former osteotomy, in the form of bone tissue formation with phenomena of restructuring (Fig.24, c, 24, c). Almost complete assimilation of periosteal bone appositions can be seen (Fig. 24, d). Medullary canal is almost fully recovered and filled with adipoid and sanguiferous bone marrow. Isolated trabeculae of bone can be seen at some places in the former osteotomy area (Fig. 23 b, c, 24, b).



b

a c d

Fig. 23. Radiograph (a), the dog under the number 20, 90 days.

Histotopograph (b), complete bone union with almost complete restoration of the medullary canal.

Microphoto (c), phenomena of resorption of trabeculae of bone in the medullary canal, (d) traces of restructuring in the former osteotomy area. Hematoxylin-eosin, enlarg. 10 x 10.

The condensed bone of the former fragments still has traces of restructuring in the form of patchy osseous structure with distinct lines of adhesion, where a large number of dilated bone canals remained. Traces of former and continuing resorption processes can be seen in the area of contact with the fixing plate (Fig. 23 d, 24 c).

Conclusion. The conducted clinical, radiological and histological investigation of dogs undergoing experimental metal osteosynthesis after experimental osteotomy of the right femur in a midleg enabled us to obtain an idea of the nature of the postoperative care of the animals and describe the radiological and histological characteristics in the time course of reparative osteogenesis. It was clinically determined, that all experimental animals for 2-5 days after surgery stood up, they were active, limping slightly on the first few days, and after 4-7 days they fully loaded the operated limb. Postoperative wound of all animals healed in primary union.

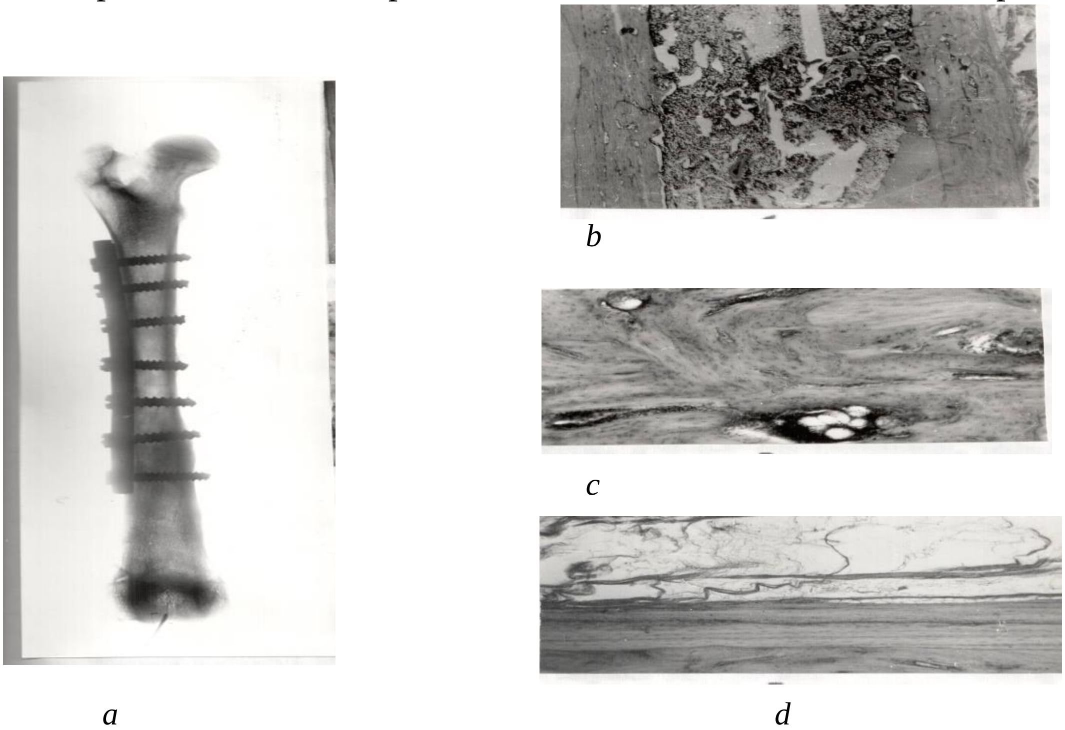


Fig. 24. Radiograph (a), the dog under the number 4/24, 90 days.

Histotopograph (b), almost complete restoration of the medullary canal in the former osteotomy area.

Microphoto (c), restored regions of condensed bone with residual effects of restructuring, (d) full assimilation of periosteal bone appositions. Hematoxylin-eosin, enlarge.

Radiologically all investigated dogs had correct apposition of the fragments and firm fixation of them by means of metal plate from 70 to 130 mm long and number of screws from 4 to 7. Only the dog under the number 25 had a slight dislocation of the fragments along the width to 2.5 mm.

Active process of consolidation of fragments could be seen in the course of radiological examination of the preparations after 15 days but no apparent signs of complete union were observed.

Only to the second term of observation period (1 month) consolidated structure of bone tissue was noted at the osteotomy line. Clearly pronounced endosteal and periosteal reaction could be seen in the osteotomy area and all over the fixing plate.

After 2 month, a light shadow of compacted bone could still be seen in the osteotomy area, almost complete recovery of the medullary canal could be seen. Clearness and height of periosteal appositions reduced significantly.

Full restoration of integrity and structure of the cortical bone, full restoration of integral medullary cavity could be seen in the osteotomy area after 3 months.

Reparative osteogenesis proceeded according to the type of direct osteogenesis with formation of close-meshed spongy bone tissue that could be well traced in the histological preparations on all stages of observation.

Reparative reaction in the osteotomy area occurred both on the side of medullary cavity and on the side of periosteal regions of bone fragments. The cleft between the fragments of the dog under the number 3/23 was filled with fibro-reticular, sometimes with fibrous connective tissue and partially with closed-meshed osteoid spongy tissue on the side of medullary cavity of the proximal fragment.

However, in areas directly adjoining of the plate to the bone, and in the area of passage of the fixing screws, pronounced osteoclastic resorption processes with bone loss in the condensed layer can be seen. On the whole, a firm union in the area between the fragments in the form of condensing glomerular spongy bone was formed, with small areas of fibrous and chondroid tissue.

In two month after the surgery further condensation of spongy bone took place in all the investigated cases in the osteotomy area between the former fragments of condensed bone, osteoid structures appeared. Similar changes occurred in the periosteal appositions which took the form of an uneven layer of condensed bone. Restructuring processes could be seen in the medullary cavity where the newly formed trabeculae of bone were X-ray luminous to the great extent, only isolated insulae of glomerular spongy bone resolved and remained.

Small foci of fibrous cartilage tissue could be seen in some of the observations in the former osteotomy area and along the medullary canal in the area of fixation of the fixing screws. Resorption lacunae persisted and even expanded in the fragments of compact bone directly underneath the plate, forming areas of spongy bones.

Three months after the surgery, all of the investigated dogs had complete union of the bone fragments with an almost complete recovery of the original bone structure and medullary cavity. Only in the former osteotomy area between the former fragments signs of bone restructuring showed in the form of its osteonization and formation of new bone canals. Medullary cavity was completely restored and periosteal bone appositions were almost completely assimilated. Wide resorption lacunae and dilated bone canals persisted under the fixing plate.

Thus, the data of the experimental investigations have shown that stable-functional osteosynthesis of femoral bone using the bone fixing device of our design, when it is made technically correct, enables to create optimal conditions for the formation of partial endosteal bony union after 15 days, with the further recovery of integrity of cortical layer and medullary cavity within 2-3 months.

The bone fixing device developed by us has U-shape with 2-3 support points, due to which periosteum is damaged only along the lines of direct contact in the area of contact of the bone fixing device to the bone fragments, creating optimal conditions for the processes of bone formation in the osteotomy area.

However, we have observed that prolonged exposure of metal bone fixing device on the bone leads to increased bone resorption processes in the cortex, to weakening of its mechanical properties and an increased risk of refracture.

Therefore, despite the fact that the bone fixing device has U-shape and provides more benign conditions at an early stage of reparative osteogenesis it is to be removed after bony union.

The conducted investigations demonstrate that compression unit located on the bone fixing device, makes it possible to create a tight contact between the fragments, to develop interfragmentary compression required to increase the stiffness of the "plate - screw - bone" system.

In addition, a bone fixing device of this design has sufficiently good mechanical properties that provide the conditions of reparative bone formation and consolidation of bone fragments according to direct type - direct osteogenesis.

SECTION IV. RESULTS OF STABLE FUNCTIONAL OSTEOSYNTHESIS AT SHAFT FRACTURES OF LONG BONES WITH “METOST” SYSTEM FIXATION DEVICE.

In the present section the summarized data of experiment of stable-functional metal osteosynthesis of shaft fractures of long bones using “METOST” system fixation device are presented. At the first stage of work the plates of the “METOST” set were approbated in the clinics of the Department of traumatology, orthopaedics and burn disease of the Kyiv institute of advanced training of the doctors, and then by order of the Ministry of Health of USSR clinical approbation of the “METOST” set was carried out in traumatology clinics of the Central Research Institute of Traumatology and Orthopaedics named after N.N. Priorov, the Scientific Research Institute of Emergency Care named after N.V. Sklifosovsky and the 2nd Moscow Medical Institute. The new set is also implemented in traumatology clinics of the Kyiv Institute of Advanced Training of the Doctors (clinical hospitals № 7, 15, 28, the Kyiv Regional Clinical Hospital), the Kyiv Medical Institute (clinical hospital №.25, the Kiev Railroad Hospital №1), the Kyiv Scientific Research Institute of Orthopedics (clinical hospital № 12) as well as the Baku Scientific Research Institute of Traumatology and Orthopedics, specialized divisions of central district hospitals of the Kyiv region (Vyshgorodskaya, Brovarskaya, Baryshevskaya, Bielotserkovskaya, Boyarskaya), Armenian SSR (Kafan Central District Hospital) and others where the author had to go to conduct surgeries.

As our experience shows, use of extramedullary bone fixing devices of U-shape with eccentric mechanism of our design creates real conditions for combining the fracture consolidation period with the period of limb function recovery, it enables to minimize the length of periods of medical and social rehabilitation of patients, to shorten the period of recovery of their performance, which ultimately provides a tangible economic effect.

The mechanical and mathematical modeling that have been carried out as well as the data obtained in the experiments on the animals enabled us to perfect methods of osteosynthesis and minimize the number of unsatisfactory outcomes in the cases of clinical application of the bone fixing devices of the “METOST” set. 1 165 patients with shaft fractures of the long bones were operated on for the period from 1984 to 1999.

IV.1. Indications and contraindications for osteosynthesis with bone fixation device taken from “METOST” kit.

We divided the indications for the osteosynthesis using bone fixing devices of the “METOST” set in two groups: direct and relative.

Direct indications for osteosynthesis are transverse and short oblique congruent shaft fractures of the long bones of the upper and lower extremities. In the cases of these types of fractures it is possible to create rather definite interfragmentary compression of the damaged bone by means of an eccentric device in the process of osteosynthesis of any given segment.

We classified also false joints of the shaft fracture of the long bones as direct indications, which we treated with success using our methods protected by the Patent of Ukraine No.27478//Bulletin.No.4,15.09.2000.

However, due to the fact that the accumulated experience of treating this type of pathology was small, 3 cases only, we have not detached it as a separate section.

Relative indications for osteosynthesis using bone fixing devices of the “METOST” set are: oblique, helical, multi-fragment fractures of the diaphysis segment and diaphyseal fractures of the clavicle, for the osteosynthesis of which we applied the bone fixing devices of 70 and 100 mm intended for the osteosynthesis of forearm bones.

In the cases of oblique, helical, multi-fragment fractures when the eccentric device is not used, the hole on the eccentric, according to its intended purpose, is used as a conventional fixing hole for securing the plate to the bone fragments.

We divided contraindications for osteosynthesis using bone fixing devices of the "METOST" set also into the direct ones, to which the double and multi-fragment fractures shaft fractures of long bones belong, involving ¼ and more of the segment's length, because bone fixing devices, by means of which it could be possible to fix the fractures of this type are not included into the set. Relative contraindications for osteosynthesis using bone fixing devices of the "METOST" set include: cases of multiple open reduction of fragments with fixing of all kinds of submersion structures, extensive dermal scarring, with adnation to the underlying tissues and bone.

We consider it necessary to focus on some issues of application of bone fixing devices of the "METOST" set: 3 typical sizes of bone fixing devices are provided in the set (except for arm bones for which 2 typical sizes are provided) and 2 typical sizes of fixing screws for each segment of upper and lower extremities (Fig.14,a).

Dimensions of the bone fixing devices and fixing screws are based on several factors: the length of the segment of the extremity and diameter of bone fragments and on the type and location of the fracture. In this connection, it is impractical to use bone fixing devices of the other mini-sets which are not intended for particular segments because a wrong choice of bone fixing devices of lesser dimensions, caused by traumatologist's desire to reduce the length of surgical cut and the further wish to decrease surgical injury for the patient, results in instability of the osteosynthesis, and often, in growing of a false joint.

As for the application of bone fixing devices with larger dimensions, as compared to our calculations, it results in increased injuring of the patient given in the course of the surgery, what is more, unreasonable one. Both in the first and in the second cases the circumference of bone fragments doesn't fit into the profile of U-shaped bone fixing device, increased number of fixing screws also influences the quality of fixation of bone fragments.

IV.2. Preoperative assessment and postoperative rehabilitation technique (V.2).

When an injured patient was admitted to a hospital, the fracture diagnosis was based on clinical and radiographic examination made according to common methods.

After the examination the patient was transferred to bandaging room where skeletal extension was applied in the cases of fractures of shin or thigh bones and in the cases of segments of the upper limb, as a rule, gypsum bandage or dressing in splints by the Central Institute of Traumatology and Orthopaedics were applied, after anaesthesia and reducing of the fragments.

The best period for surgery is 3rd - 10th day after the injury. During this time, the general condition of the patient improves, swelling of the damaged limb decreases and dislocation of the fragments is eliminated by means of skeletal extension of the lower limb.

With the purpose of preventing pyoinflammatory complications, the day before the surgery the skin of the injured limb is treated with 0.5% solution of ammonia, and then with 70% ethanol and wrapped up in a sterile drape or sheet.

On the day before the surgery a plan of the surgery was made, an appropriate bone fixing device and fixing screws were selected (a certain mini-set intended for osteosynthesis of a certain segment was submitted for sterilisation). When selecting a bone fixing device it is necessary to pay attention to the length of the segment of the limb which is the target of the surgical interference, the degree of development and strength of muscles, based on the data of clinical examination and radiographs.

Surgeries of the large segments were conducted, as a rule, applying endotracheal anesthesia, only for three patients in the course of surgery of the shin bone spinal anesthesia was applied and for two patients in the course of collar bone osteosynthesis local anesthesia was applied using 0.5% novocaine solution.

Removal of the bone fixing devices on the upper limb was made not earlier than after ½ of a year and on the lower limb after one year. The procedure of removal of the bone fixing device, as a rule, was not difficult, the plate could be easily taken out through surgical cut after unscrewing the fixing screws.

IV.2.I. The methodology of postoperative rehabilitation

Postoperatively, external plaster immobilization of the operated extremity in the majority cases of patients was not performed. Only within the first 4-15 days after surgery on the lower extremity segments was laid into the deep cast or Beller cast overnight. For upper extremity segments operations triangular bandage was used for the same period of time.

Drains were removed on the 2nd and 3rd day, the stitches were removed 10-12 days after surgery.

The basis of postoperative rehabilitation was the scheme proposed by S.Zhila (1966), which includes a set of measures for the rehabilitation of patients after metalosteosynthesis. This scheme was supplemented taking into account modern physiotherapy tools recommended for wide clinical use - laser therapy, magnetic therapy, baromassage, acupuncture, electrical stimulation, and others. (V.V. Chaplinsky, E.A. Yurmin, M.A. Yunko, O.P. Oleksa, D.V. Ruda, Y.E. Jackiewicz, 1981; I.S. Shepelev, N.A. Demetskaya, V.F. Pozharsky, 1980; K.S. Ternovoy, A.A. Kravchenko, A.F. Leschinsky, 1982; K.S. Ternovoy, 1983;. K.S.Ternovoy, 1985)

Since Day 1 after surgery laser-, magnet therapy, UHF were appointed for preventing festering, removal of edema and reduce of pain in the surgical wound. At the same time impulse movements in the muscles of the operated extremity were appointed.

Patients after surgery on the lower extremities bones were allowed to get out of bed on the 2nd -6th day after surgery, which depended on the age and the presence and severity of physical comorbidity and general condition.

Patients after surgery on the bones of the upper extremities were allowed to get out of bed on the 2nd - 3rd day. Sitting down in the bed was allowed on the second day after surgery for all patients.

After 5 - 10 days therapeutic exercises of the 2nd period, electrophoresis, total UV radiation were prescribed to prevent contractures in adjacent joints, recovery of movement in them, strengthening of operated extremity muscles. At first, for 2-3 days passive movements were carried out followed by active movements. By the time it coincided with the removal of sutures of surgical wounds and complete cessation of pain in the operating extremity.

To restore motion in the knee joint unit with the linkage system was used. The extremity was put on the sliding surface or on a mobile trolley.

For the development of the elbow movements a system with a rubber countertraction was used.

After 2-3 weeks after the surgery physical therapy sessions by the 3rd period were prescribed. In this case the patient was taught to "pass foot in the step", started walking up the stairs, taught self-sitting down on a chair.

Throughout the period of rehabilitation patients had massage of operated and symmetrical extremity.

The duration of hospital treatment after surgery of the lower extremity segments was ranged from 16 up to 46 days (in 87% of patients), depending on the patient's general condition. In cases of multiply injures postoperative treatment was delayed up to 3-4 months.

In case if surgical treatment of shaft fractures of the upper extremity segments duration of postoperative in-patient treatment was in the range between 15 and 35 days (95% of patients), and in cases of multiple trauma - 64 days. After skeletal fixation of the clavicle - 12-15 days

The vast number of patients (57 out of 65 patients, 87.7%) were discharged from the hospital without external immobilization; there were only 2 cases of combined damage of both lower extremity segments, 2 cases of combined hip fracture with comminuted fracture of the patella and 1 patient - comminuted fractures of both bones of the lower leg, where tibia fragments were fixed by plate designed for osteosynthesis of shoulder - external plaster immobilization for a period of 1.5 to 3.5 months was performed. In 3 cases of delayed consolidation of forearm bones splint plaster was put for 2.5 - 3.5 months.

Thus, in case of combined injury when both segments of one extremity are damaged over a large area, combined fracture of one segment of the lower extremity and patella, as well as in case of wrong selection of fixator, we recommend the immobilization for the entire period before the fracture consolidation.

For fractures with subsequent osteosynthesis with fixator from the set of "METOST" for long bones of the upper extremity total load was allowed in 1.5 - 2.5 months after operation.

For operations on lower extremity walking with crutches without load on operating extremity was recommended for 1 – 2 months, after which, depending on fracture localization and quality of fracture healing, walking with one crutch or a cane was allowed for 3.5 - 5.5 months. Full load was allowed after complete fracture healing.

Consolidation control over the process was carried out on the basis of clinical and radiological examinations every 1.5 - 2.5 months.

IV.3. Analysis of the results of the stable functional osteosynthesis of shaft fractures of long bones with fixation device taken from "METOST" kit.

Evaluating results of treatment of patients with "METOST" set for osteosynthesis we took into account 16 factors considering the following criteria:

1) duration of preoperative preparation,

2) duration of inpatient treatment,

3) duration of outpatient treatment;

4) fracture consolidation time;

5) recovery periods for support ability of lower extremity and immobilization;

6) duration of immobilization of upper extremity;

7) type of fracture;

8) fracture localization;

9) presence of pain;

10) type of consolidation and the recovery of the integrity of the cortical layer;

11) presence of extremity shortening;

12) degree of periosteal callus;

13) degree of recovery of function in adjacent joints;

14) presence of neurodystrophic disorders

15) presence of pyoinflammatory complications;

16) terms of rehabilitation

Efficiency of the patients recovery was appraised based on 6 tests:

1) No pain in the operated extremity, pain under load, constant pain;

2) Good bone fusion, delayed fusion, pseudoarthrosis;

3) Supporting the extremity, not supporting extremity;

4) Flexion the knee to an angle of 70 °, flexion to an angle of 90 °, flexion to an angle of 120 - 130;

5) Full extension, lack of full extension;

6) Wound healing by first intention, wound healing by the secondary intention, purulency surface, deep purulency.

Evaluating the results of the implementation we use three-point system: good, satisfactory, unsatisfactory.

Good results include the outcome of operative treatment, after which the criteria specified in paragraphs 1-6 with a positive clinical value were set

Satisfactory results include cases with treatment outcome in which no less than 2/3 of criteria specified in paragraphs 1-6 were met with a positive clinical value.

Unsatisfactory results include outcome of the operation, after which more than ½ points were confirmed by bad clinical criteria.

Radiological signs were also taken into account:

- recovery of uniform cortical layer.
- recovery of the medullary canal,
- extensive periosteal bone growths,
- slow fusion (in terms of the above signs).

Thus, to assess the resulting clinical experience of surgical treatment of fractures using a new fixator for 1,165 patients we developed criteria which allow to judge the appropriateness of the recommendations to use fixators of this design in clinical practice.

Dynamic clinical and radiological monitoring of patients after osteosynthesis of shaft fractures of long bones using set of fixators "METOST" revealed follows: out of 1165 patients who underwent osteosynthesis, treatment was finished by 752 (64.6%) patients with removal of fixator and patients started to work. 2 patients received disability status due to the fact that they had multiple injuries, one patient developed post-traumatic neuritis of the peroneal nerve, 4 patients are seniors due to age, 16 patient started to work with the presence of the fixator.

Total 1158 patients, that is 99,4%., start working Pain in the operated region of the wound ceased by after 3-4 weeks after the operation, shortening of the operated extremity was not identified among operated patients; damage of main nerve trunks of hip and forearm was not observed.

As an example of osteosynthesis due to direct indications we provide discharge summary and radiological images for a patient Av.VF, 39 years old, who was admitted to surgical department of Vyshgorod Central Clinical Hospital on 27.H.1987 due to cross fracture of left humerus in the middle third with displacement (Figure 25, a). On 4.XI.1987 metall osteosynthesis was performed with extramedullary compressing plate from "METOST" set (115 x 6). Radiographs on 4.XI.87 showed that fragments are well matched and compressed (Fig. 25a), with only slightly traced the line of fracture. Radiographs on 25/01/88, showed almost complete recovery of cortical layer and medullary cavity with a mild periosteal reaction (Figure 25 in.).

a

b

c

Fig.25. Radiography images of patient A. V.F. Fracture of the left humerus (a) in the middle third with displacement. Fragments are matched and fixed (b), Day after osteosynthesis. Periosteal layers are minor, there is recovery of the integrity of cortical layer and medullary cavity (c), follow-up period - 2 months and 20 days.

Clinical and X-ray analysis of the numerus osteosynthesis results found that the function of adjacent joints was completely restored in 8 patients within period from 1.5 to 3 months. One patient, who suffered multiple injuries - combined damage of both humeri showed restriction (within 10%) of movements in the shoulder joints.

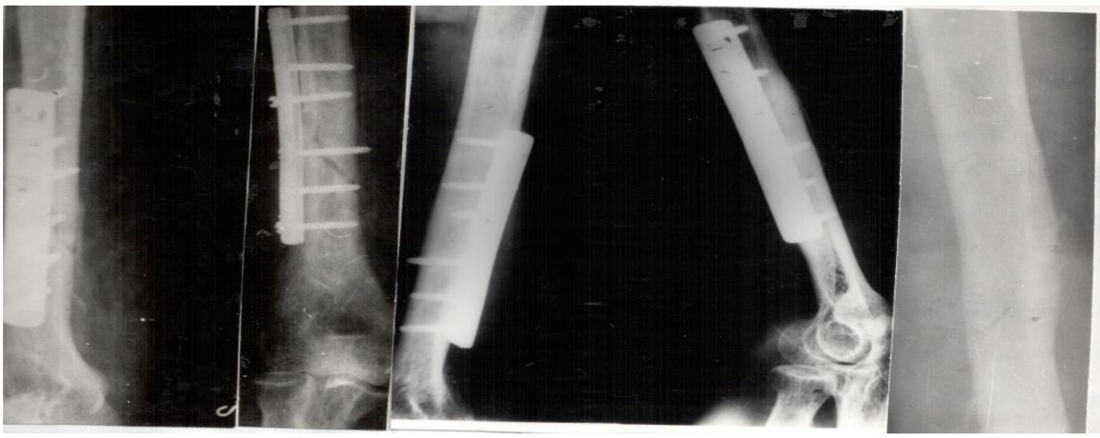
Dynamic X-ray examination of the patients revealed that apposition of all fragments during the operation was good. The following observation noted that 8 patients developed minor periosteal layers without affecting the function; one patient had more pronounced periosteal reaction that limits the function of up to 10%.

Three patients with a fracture of the humerus developed traumatic neuritis of the radial nerve, and in 2 of them the cause of the injury was injury itself and function recovered in 2.5 - 3 months after fixation. One patient developed neuritis of the radial nerve in the postoperative period, and the function was restored shortly after the fixator removal (fixator is removed in 4.5 months after neurodystrophic disorders).

We give the following example of osteosynthesis of oblique shaft fractures of the left humerus due to relative indications, complicated by radial nerve neuritis developing in the postoperative period:

The patient G. MN, 52 years old, was admitted to the surgical department of the Kiev region Vyshgorod Central Clinical Hospital in 24.IX.1986, due to oblique fracture of the left humerus in the midleg with dislocation (Figure 26, a). On 1.X.1986 under endotracheal anesthesia osteosynthesis with "METOST" fixator (115 x 6) was performed. Interfragmentary compression was not performed. The hole in the eccentric was used as typical fixation for screw introduction. Radiographs on 3.X.1986 - Fragments are well-matched, fixed by plate with screws (Figure 26, B), fracture line is clearly seen on the lateral projection. Radiographs on 20.XI.86 (1.5 months after osteosynthesis) - periosteal layering is minor, cortical bone under fixation and on the dorsal surface is almost completely recovered (Fig. 26, c). Along medial and ventral surfaces fracture line is clearly observed. Radiographs on 24.XII.86 - almost complete recovery of cortical integrity and medullary cavity (.Fig 28), follow-up period – 3 months.

a *b*



c *d* *e* *f*

Fig. 26. Radiography images of patient G. MN. Left shoulder fracture in the midleg (a). Fragments are fixed by plate with screws "METOST" (115 x 6), Day 3 after operation (b). Follow-up period

- 1.5 months. (c). Follow-up period - 3 months. (d). Follow-up period - 4 months. (d). View of the humerus after fixator removing (a), Follow-up period - 5 months.

Fracture zone shows signs of minor periosteal layers. Radiographs on 25/02/87 show complete recovery of integrity of cortical bone marrow cavity (4 month follow-up after osteosynthesis, the former is without signs of fracture and periosteal layers (Figure 26, d).

Due to the fact that the patient developed postoperative signs of neuritis of the radial nerve and conducted rehabilitation measures were ineffective, we have decided to remove fixator and, during operation, conduct revision of radial nerve. At operation, which was conducted on 02.25.87 - it was found that radial nerve was not damaged.

Soon after conducted intervention under the influence of rehabilitation treatment, including electrical stimulation, extremity function was completely recovered.

The following is as an example of osteosynthesis of forearm bones performed due to direct indications.

Patient Yu. AM, 32 years old, was admitted to traumatology department of Clinical hospital № 28 in Kyiv on 06.07.87 with transversal fracture of the left forearm radial bone in the middle third with displacement (Fig. 27a). On 06.07.87 osteosynthesis with fixator "METOST" (100 x 6) was performed. Radiographs dated 08.07.1987 show well-matched and compressed fragments (Figure 27, b.), follow-up period - 2 days. Radiographs obtained in 1.5 months after osteosynthesis (Figure 27 c) showed - only lateral surface contains fracture line, periosteal reaction is insignificant. After 3.5 months of follow-up (Figure 27 d) there is almost complete recovery of cortical integrity and bone marrow cavity. After follow-up of 4 months after osteosynthesis (Figure 27, e.) there is complete recovery of the integrity of cortical and medullary cavity, periosteal layers are not marked. On 15.12.1987 fixator was removed.

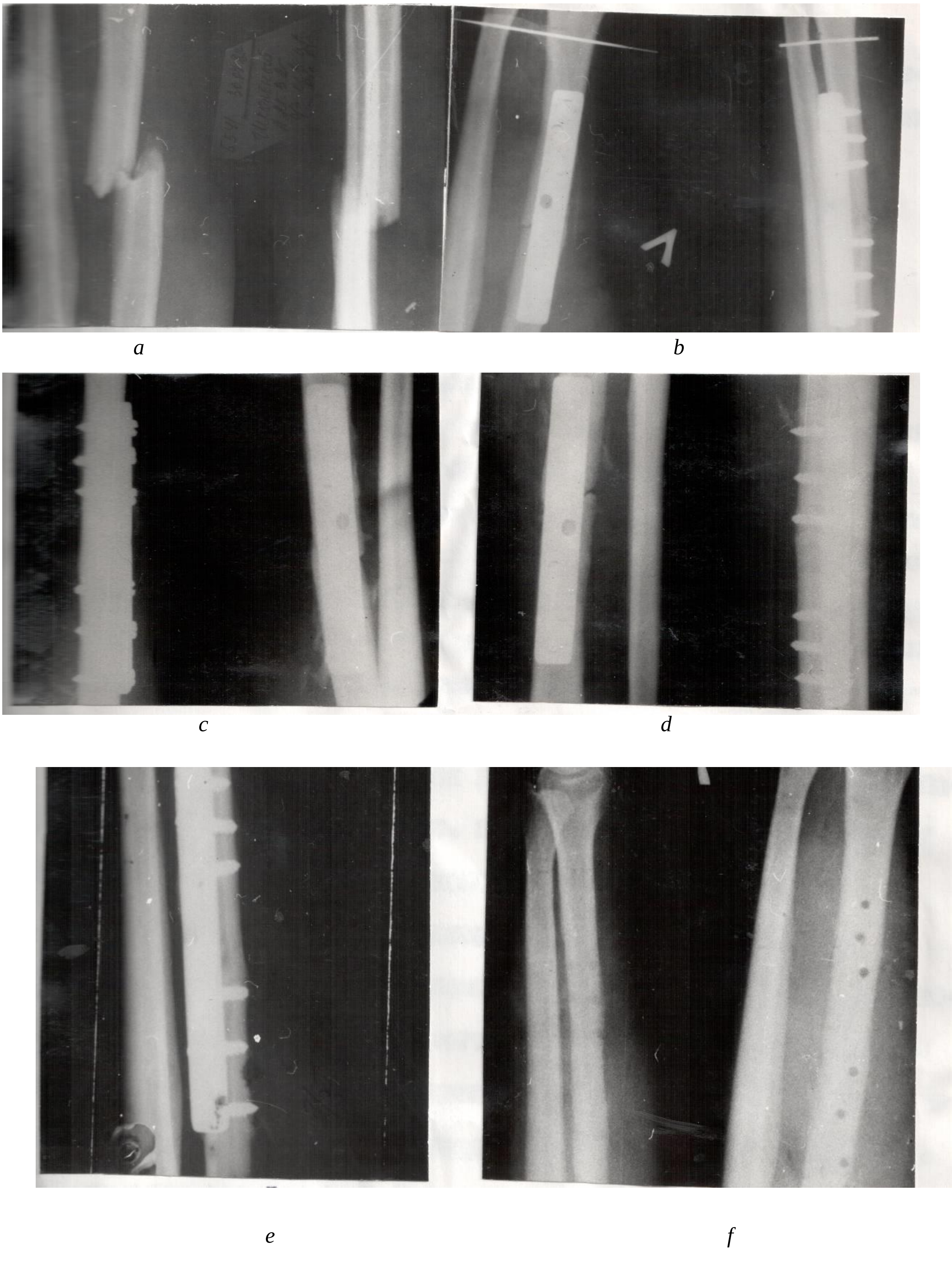


Fig. 27. Radiography images of patient Yu. AM. Fracture of the left forearm radius (a). Fragments are fixed with plate with screws (100 x 6) and Kirschner wires (b), follow-up period is 2 days. Follow-up period 2.5 months. (c). Follow-up period - 4 months. (d). Radius after removal of fixator (e). Fig. 27, f bone after fixator removing.

Long-term results were evaluated in all patients with a fracture of forearm. None of the patients showed postoperative pyoinflammatory complications. Duration of inpatient treatment was in the range from 15 to 27 days for isolated fractures of the radius and from 15 to 45 days for fracture of both bones of the forearm. The duration of the subsequent outpatient treatment, in most cases was within 2-5 months, with the exception of 3 cases with delayed fracture consolidation as a result of technical errors made during the operation, which will be discussed in section 5 of this chapter. One patient did not have consolidation. This case was referred as poor. For the last 4 observations with nonunion fractures and delayed union, within period from 2.5 to 4.5 months plaster immobilization was performed. These patients had moderately expressed neurodystrophic disorder which disappeared in 3 of them under the influence of rehabilitation therapy at the end of 1 - 1.5 months period after removal of immobilization.

The function in the adjacent joints was completely restored in the majority of patients within period from 1 to 1.5 months after osteosynthesis, and in cases of delayed consolidation - by the end of 4 - 5.5 months.

Dynamic X-ray examination of the patients revealed that in the majority of patients matching of fragments during operation is good. Subsequent X-ray data revealed that the bone fragments consolidation took place within period from 2 to 4.5 months, and in 3 cases of delayed consolidation within period from 5 to 7.5 months. Periosteal reaction in fracture zone in all cases was small, reflecting the robust, rigid fixation in brooms / bone system in cases of osteosynthesis using "METOST" fixators.

Employability was restored in most patients in the period from 2.5 to 7.5 months.

Long-term results were evaluated in all patients after osteosynthesis of the femur. Postoperative pyoinflammatory complications were not observed.

In the majority of cases osteosynthesis was performed in the first 2 - 3 days after admission. The length of hospital treatment was within 1 - 3 months. The duration of outpatient treatment was within 4.5 - 6 months. Only in cases of multiple trauma rehabilitation was prolonged on for up to 10 - 14 months.

Function in adjacent joints was completely restored in all patients within 3 to 4.5 months.

5 patients still had limitation of movement in the knee joint in the range of 10%, and 2 patients after multiple trauma still had flexion contracture (flexion up to 90 - 100 °).

X-rays performed at different periods of observation after conducted osteosynthesis found that fragments matching produced during the operation was good, fracture consolidation was observed in a period of 4 to 6 months. In most patients, periosteal callus was expressed slightly and did not affect extremity function.

Twelve patients had periosteal layers of significant size, mainly due ossified hematoma (Fig. 37).

Fixator in the femur is usually removed in one year, after the clinical and X-ray confirmed fracture consolidation. Employability was restored in most patients in the period from 4.5 to 7 months and in 2 patients rehabilitation was prolonged to 10-13 months due to multiple trauma.

As an example, we provide discharge summary of the patient B. GA, 20 years old, who was admitted to the surgical department of Vyshgorod Central Clinical Hospital on 07.10.86 due to transversal fracture of the left femur in the midleg (Fig. 28 a), a shock 1-2 degrees, multiple bruised wounds of the trunk and lower limbs, brain concussion.

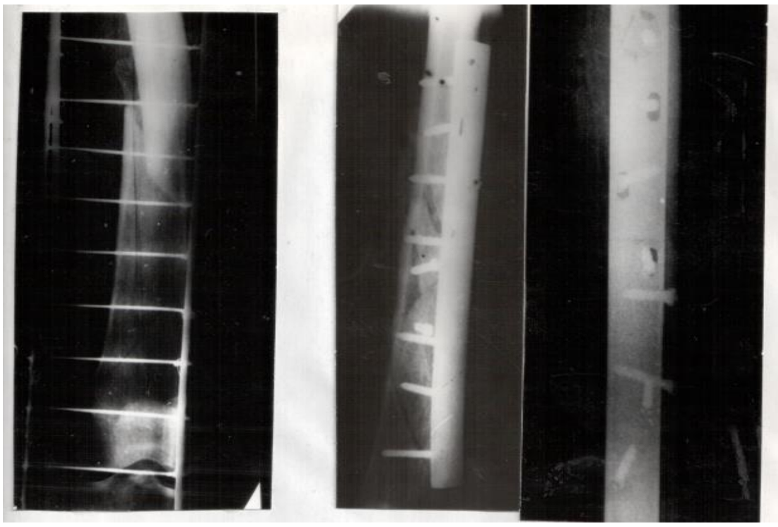
Fig. 30. Radiography images of patient B. GA show fracture of the left femur (a) in the midleg with displacement. Fragments are matched and fixed by plate with screws (b) - 4 days after osteosynthesis. Follow-up period -2 months after operation (c). Follow-up period - 4 months. (d). Femur after removal of fixator (e).

Metall osteosynthesis of left thigh was made by plate "METOST" (220 x 7) 24/10/86. Radiographs on 28.10.86 showed that fragments are well-matched and compressed; line of fracture (Figure 28, n) is only slightly traced. After follow-up of

2 months (Fig. 28, c) slight periosteal layers are noted; former fracture line is fuzzy. After follow-up of 4 months. (Figure 28, d) there is almost complete recovery of the integrity cortical layer and the medullary cavity, periosteal layers are moderate.

On 31/03/87 fixator was removed. Fig. 28 d - view of the femur after removal of fixator in 5.5 months after osteosynthesis. Bone fragments are consolidated, integrity of cortical and medullary cavity are completely restored, periosteal layering is minor. The patient returned to work in 6.5 months after osteosynthesis, only after removal of fixator since patient rehabilitation was delayed through the fault of a trauma clinic which supervised patient after discharge from the hospital.

As an example of the femur comminuted fracture and it osteosynthesis by fixator "METOST" the relative indication is the following observation: patient K. MP, 49 years old, female, was admitted to the surgical department of Vyshgorod Central Clinical Hospital on 10/02/86 due to comminuted fracture of the right femur at the border of middle and lower third (Figure 29, a).



a *b* *c*

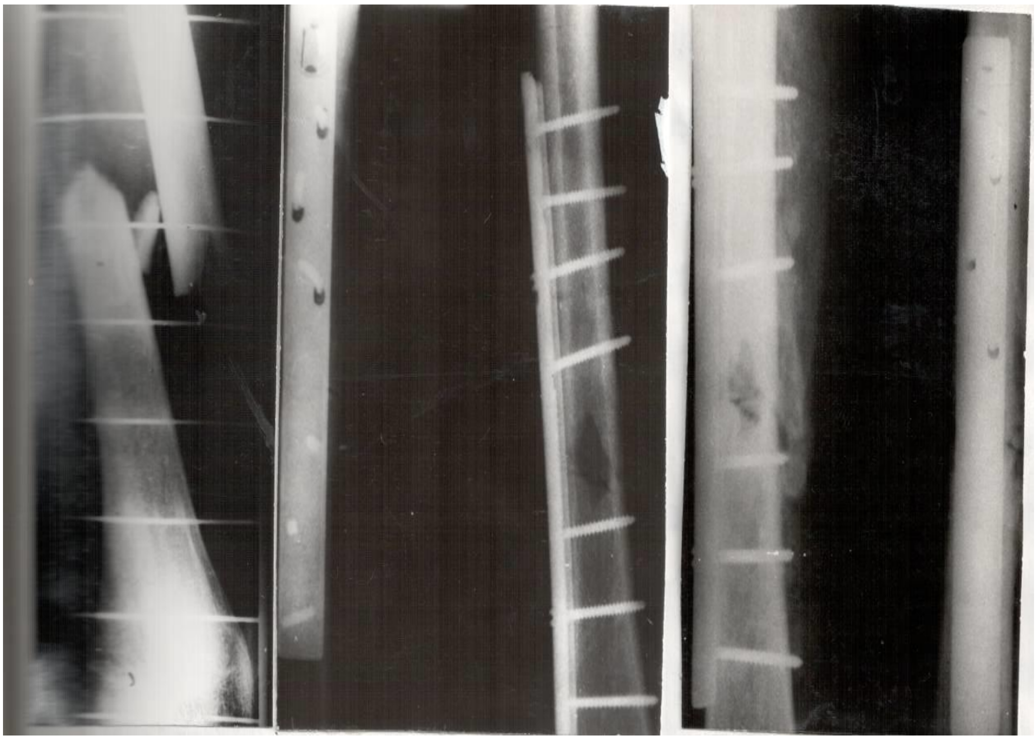
Fig.29. Radiography images of patient to K. MP - comminuted fracture of the right femur (a). Fixation of bone fragments with extramedullary plate and 2 additional screws (b). Fracture consolidation (c), slight periosteal layers.

14.10.86 - open reposition of bone fragments, osteosynthesis with "METOST" fixator (220 x 7), intermediate fragments are fixed with 2 additional screws introduced outside the plate. Radiography image on 23.12.86 – in 2.5 months after osteosynthesis (Figure 29, b) show almost no periosteal callus; fracture lines are clearly traced. Within follow-up period of 3.5 months there is good bone fusion

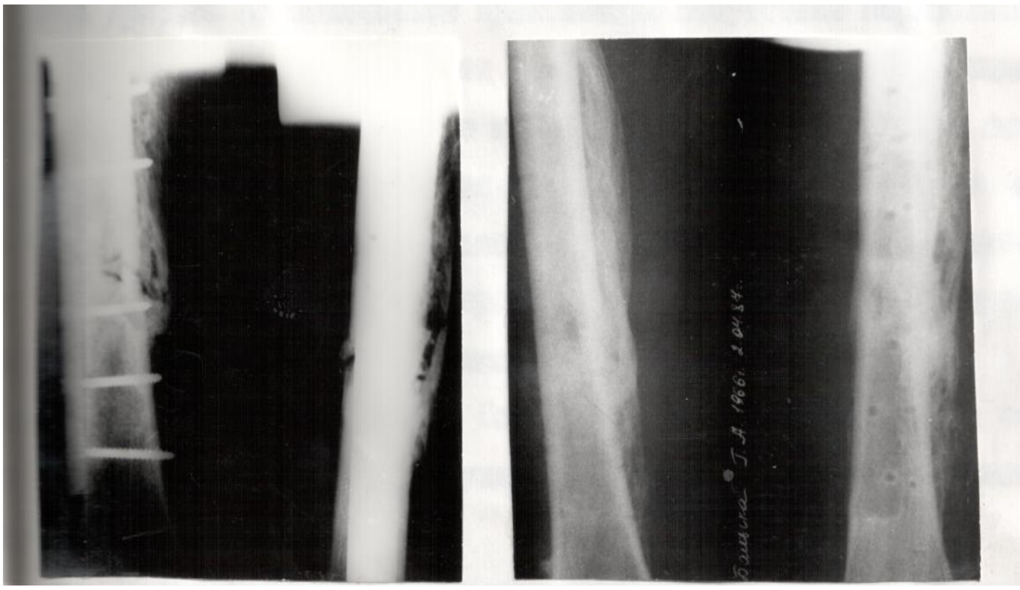
(Figure 29, c), the fracture line is slightly traced; there is almost complete recovery of cortical layer. Periosteal callus is moderately expressed.

Patient rehabilitation was successful: within 1.5 months patient moved with crutches, and then until the end of 3 months - using cane. Full load was allowed within 3 months after the operation. Knee joint function was completely recovered in 2.5 months.

As an example of osteosynthesis with "METOST" fixator for helical shaft femur fracture for relative indications we give discharge summary of patient to the B. MD, 62 years old, female, who was admitted to the surgical department of Vyshgorod Central Clinical Hospital on 09.08.87 due to helical right hip fracture in the lower third with dislocation (Figure 30, a).



a *b* *c*



d *e*

Fig. 30. Radiography images of patient B.MD. Helical fracture of the right femur with displacement (a). Fragments are fixed with plate and screws 7 x 220 and an additional screw outside the plate (b), period after osteosynthesis is 3.5 months. Follow-up period is 6.5 months. (c).

Osteosynthesis was performed on 21.08.87 with fixator "METOST" (220 x 7) and 2 additional screws introduced outside the plate. X-ray on 01.12.87 shows well-matched fragments, former fracture line is still observed, periosteal layers are minor (Figure 30, b.), follow-up period is 3.5 months. In 6.5 months there is complete recovery of integrity of cortical layer and medullary cavity (Fig. 30c), the line of the former fracture is slightly observed.

The patient walked with crutches for 2 months, followed by up to 3 months of cane use.

As can be seen from the presented example in case of properly produced osteosynthesis with fixators of new design, i.e. when osteosynthesis is performed for indication with correctly chosen fixator size, and operation was not associated with gross errors, the timing of consolidation for helical, comminuted and oblique fractures is optimal and the same as for transverse and oblique transverse fractures.

Long-term results were followed in patients after osteosynthesis of tibia.

Only one case was associated with superficial abscess of postoperative hematoma, which was managed within 4 weeks using complex medical treatment and physiotherapy.

Surgery was done usually in the first 2 - 3 days after admission, and only in exceptional cases surgery operation was postponed for a longer time.

Duration of hospital treatment - within 10 – 12 days.

Complications included: expressed neurodystrophic disorders in 3 patients and 1 posttraumatic neuritis of fibular nerve.

Function in the adjacent joints was completely restored in the majority of patients after 2.5 - 4 months; in 2 patients with the sights of neurodystrophic syndrome movement restored by the end of 5.5 - 6 months.

One patient had developing neuritis of fibular nerve, caused by trauma, received disability status; patient did not come for follow-up examination.

X-ray examination found that matching of fragments during the operation was good in all patients; in 1 patient comminuted tibia fracture was fixed by plate from mini-kit designed for shoulder fixation (short fixator), besides the fragments are poorly matched with angular (valgus) dislocation. Postoperatively plaster cast was applied for 2.5 months followed by deep plaster splint on the lower leg for a period of 1.5 months. As the result there was slow consolidation of the fracture till 8 months.

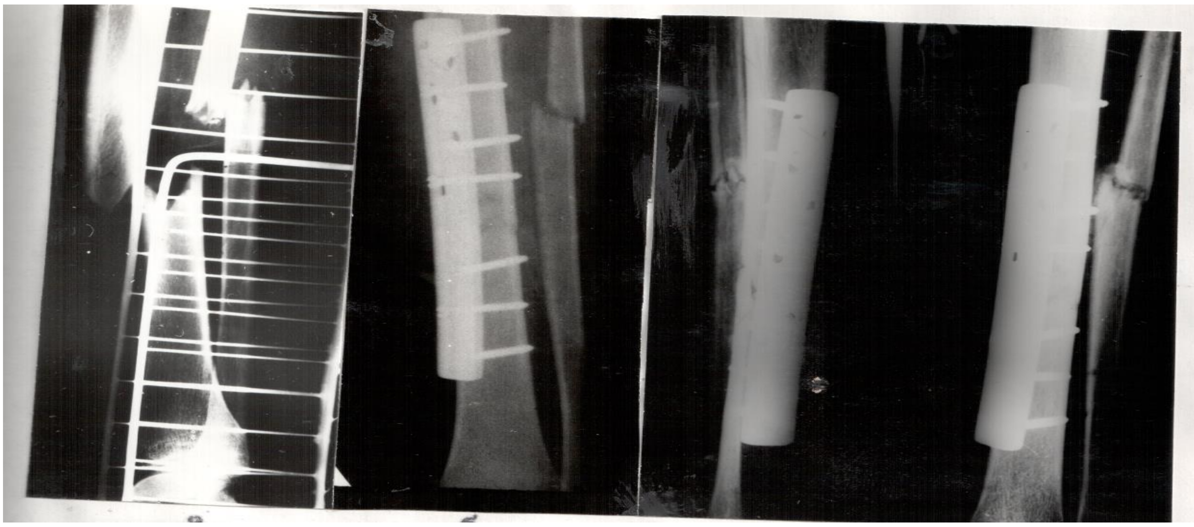
Fracture consolidation in most patients was observed within period of 3 to 4 months. Development of periosteal callus was negligible in all cases. Fixator was removed from the patient at the end of the year.

Employability was restored, removing fixator from 11 patients within period from 5 to 7 months; 3 patients returned for work with the presence of fixator, 1 patients after multiple trauma received disability status.

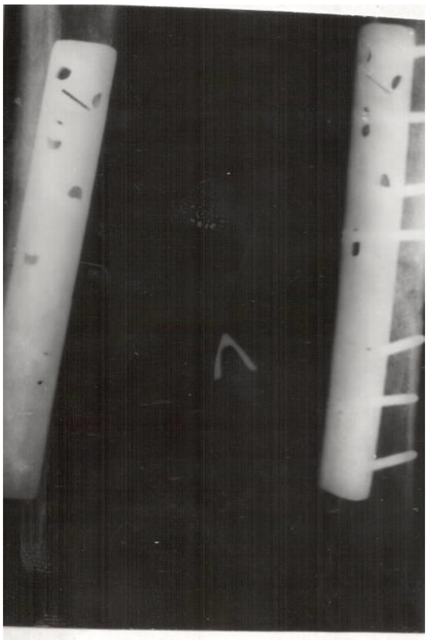
As an example of clinical use of a set of fixators "METOST" for osteosynthesis of the tibia on the direct indication, we provide the following observation.

The patient K. OV, 17 years old, male, was admitted to the surgical department of Vyshgorod Central Clinical Hospital on 19.10.86 due to transverse fracture of both bones of left shin in the midleg with dislocation (Fig. 31 a).

Vyshgorodsky CRH 19/10/86, on the occasion of the cross fracture of both bones of the left tibia in the midleg of the offset (Fig. 31 as well).

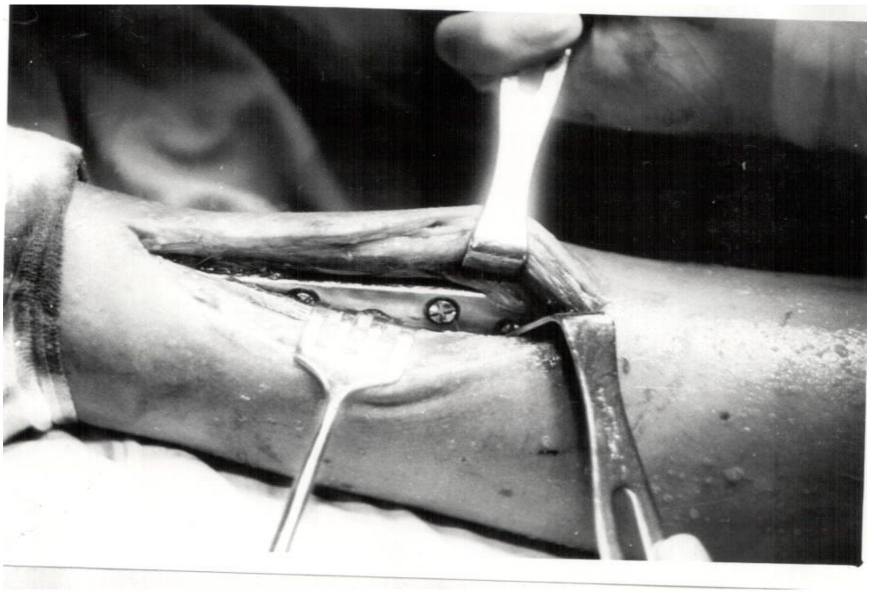


a *b* *c*



d *e*

Fig. 31. Radiography images of patient K. M.P. Fracture of both bones of the left shin (a). Fragments of tibia are fixed with plates with screws 140 x 7, (b) 1 month after osteosynthesis. Follow-up period - 2 months (c). Follow-up period - 3.5 months (d). Functional result (e).



a

b

Fig. 32. Surgery stage (a) removal of fixator. View of former fixator position on tibia. (b) resuming shape of channel iron.

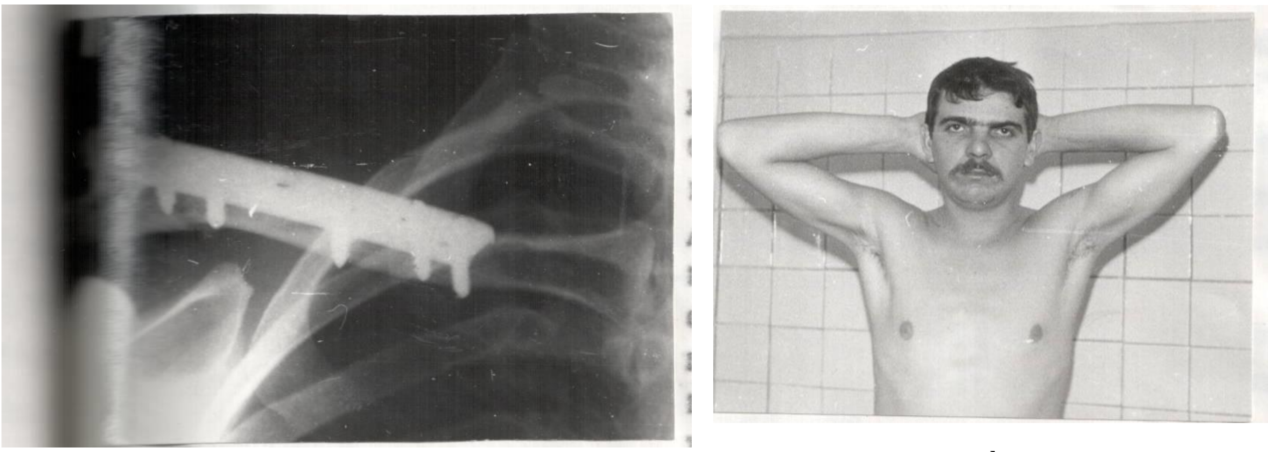
On 24.10.86 osteosynthesis of the tibia was performed by plate "METOST" (140 x 7). Radiography images on 28.11.86 conducted in 1 month after osteosynthesis fragments are well matched, periosteal layers are virtually absent (Fig. 31b). After follow-up of 2 months. (Fig. 31, c) there is almost complete recovery of integrated cortical layer and medullary cavity which complete restoration could be observed within period of 3.5 months. (Fig. 33 d).

On 19.03.1987 fixator was removed in 19 weeks after osteosynthesis. Fig. 31.f presented functional results.

Fig. 32 a shows moment of fixator removal from tibia, and in Fig. 32 b - view of bone after removal of fixator. This photo indicates that the periosteal layers are insignificant, they do not wall in fixator, and on the surface of direct contact they resume shape of channel iron.

For clavicle fracture when for one reason or another it is impossible to performed closed reduce and retain fragments, we used open reduction and osteosynthesis for relative indication, using fixator "METOST" with length 70 or 100 mm, width 12 mm, i.e from mini-kit intended for osteosynthesis of forearm bones.

Radiography images of Fig. 33 shows the results of osteosynthesis with fixator "METOST" (100 x 6) of right collarbone of patient D. NI, 27 years old, male, admitted on 09.18.86, in the surgical department of Vyshgorod Central clinical hospital where on 10.01.86 osteosynthesis was performed.



a *b*

Figure 33. Radiography images of patient D. NI. Period of follow-up is 3 months (a), the full restoration of the integrity of cortical layer and medullary cavity, no periosteal layers. Functional result (b).

Radiographs on 01.86 was conducted in 3 months after osteosynthesis (Figure 33 a), there is a complete fusion with restoration of the integrity of cortical layer and medullary cavity. Figure 33, b represents functional result.

Evaluating the positive outcomes of osteosynthesis for fractures of the clavicle, we, however, cannot recommend this operation for a wide clinical application, since proposed fixator is not designed for a bone with a large bend as clavicle has. For this reason, we classified the indications for osteosynthesis of clavicle with fixator "METOST" to relative.

IV.4 Results of the analysis of the operative treatment of shaft fractures of long bones with "METOST" system fixation device.

Careful evaluation of clinical data on the clinical and radiological features (16 tests) allowed us to obtain the following results of surgical treatment of shaft fractures with the use of fixators from "METOST" kit.

Good and satisfactory results were obtained in 1165 patients (98.5%).

Unsatisfactory results with non-consolidated fractures of the forearm bones amounted to 1.5%

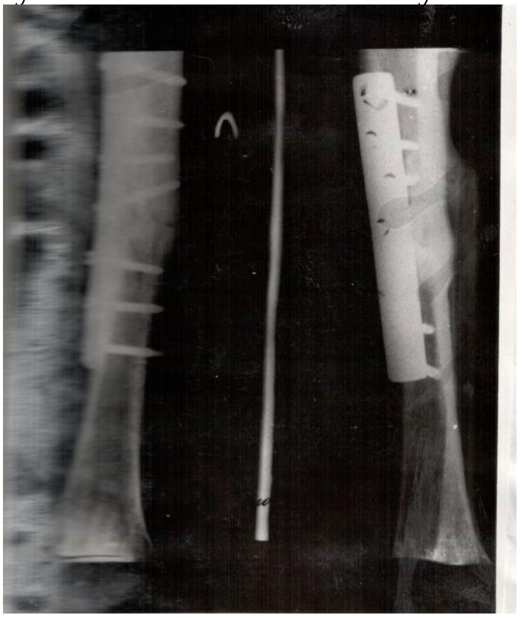
IV.5. Mistakes and complications of osteosynthesis using "METOST" system fixation device.

Osteosynthesis of shaft fractures of long bones with the use of fixators from "METOST" kit was associated with mistakes and complications that are caused by various objective and subjective reasons.

In order to facilitate the evaluation and analysis of the causes of mistakes and complications we have divided them into two **groups: 1) tactical, 2) technical.**

Total 1165 operations were associated with 2 complications: 1 superficial abscess in case of tibia osteosynthesis which was managed within 4 weeks. In 1 case soon after humerus osteosynthesis neuritis of the radial nerve developed. Signs of neuritis of the radial nerve disappeared after the removal of the fixator performed in 4.5 months.

Except noted complication there were 6 mistakes which were divided into tactical: in the two cases, the plate with inappropriate size was used in the tibia osteosynthesis: in 1 of 2 cases tibia was fixed with plate from mini-kit for humerus (Fig. 34 a). In this case fragments were not properly fixed by plate and valgus displacement was not eliminated. In this case, taking into account the mistakes of plaster free management of the patient in the postoperative period was unacceptable, since osteosynthesis did not reach required stability. Fracture consolidation was observed only in 8 months (Fig. 34b), but at this moment line of the former fracture was slightly traced. Complete restoration of the integrity of cortical layer and medullary cavity occurred only in 15 months after osteosynthesis (Fig. 34, c).



a

b

c

Fig. 34. Radiography images of patient D. MP Comminuted fracture of the left tibia is fixed by plate with screws 130 x 7 (a). The term – 12 days. Follow-up period – 8 months (b). Follow-up period - 15 months. (c) In all cases periosteal layers were minor.

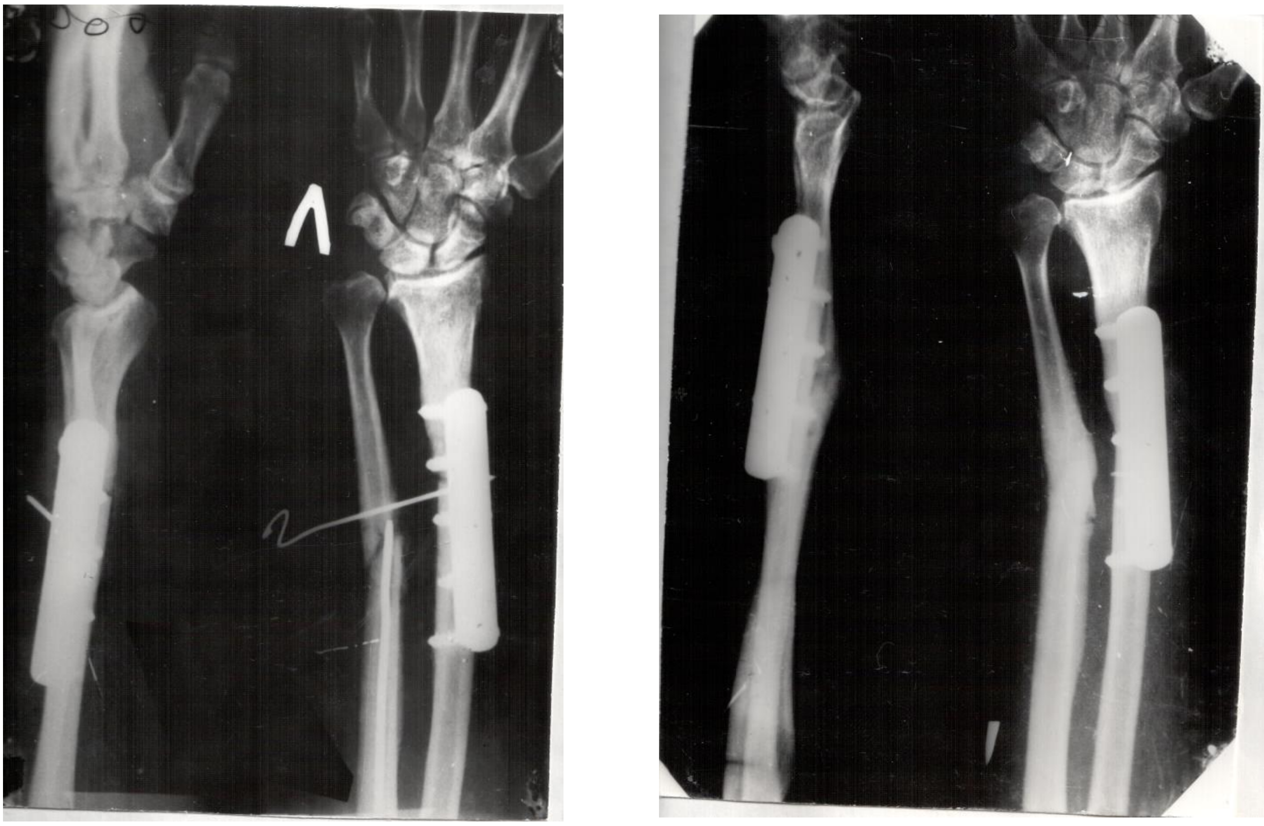
In the second of the 2 cases osteosynthesis of comminuted fracture of the tibia used plate from mini-kit designed for the femur resulting in greater patient trauma than was expected.

In two cases of fracture of both bones of the forearm fragments of ulna were fixed by F.R. Bohdanov's shaft and radius - by plate "METOST" that did not provide sufficient stability. There was a need for deep plaster split within 2.5 - 3.5 months. (Fig. 35, 36). The consolidation of the fracture occurred in patient M. YM in 9 months after osteosynthesis (Fig. 36b), and in the patient M in 11.5 months. (Fig. 35b). Thus, the combination of osteosynthesis with plates "METOST" and intramedullary fixators not providing sufficient stability eliminates the benefits of stable functional osteosynthesis, and, from our point of view is incorrect.

a *b*

Fig. 35. Radiography images of patient M. VV. The radius is synthesized by plate, radius - Bohdanov's shaft of right forearm (a),the term - 2.5 months after operation. Fragments of bones of the right forearm are consolidated (b), the term - 11.5 months after osteosynthesis.

Periosteal layers represented in following terms are minor.

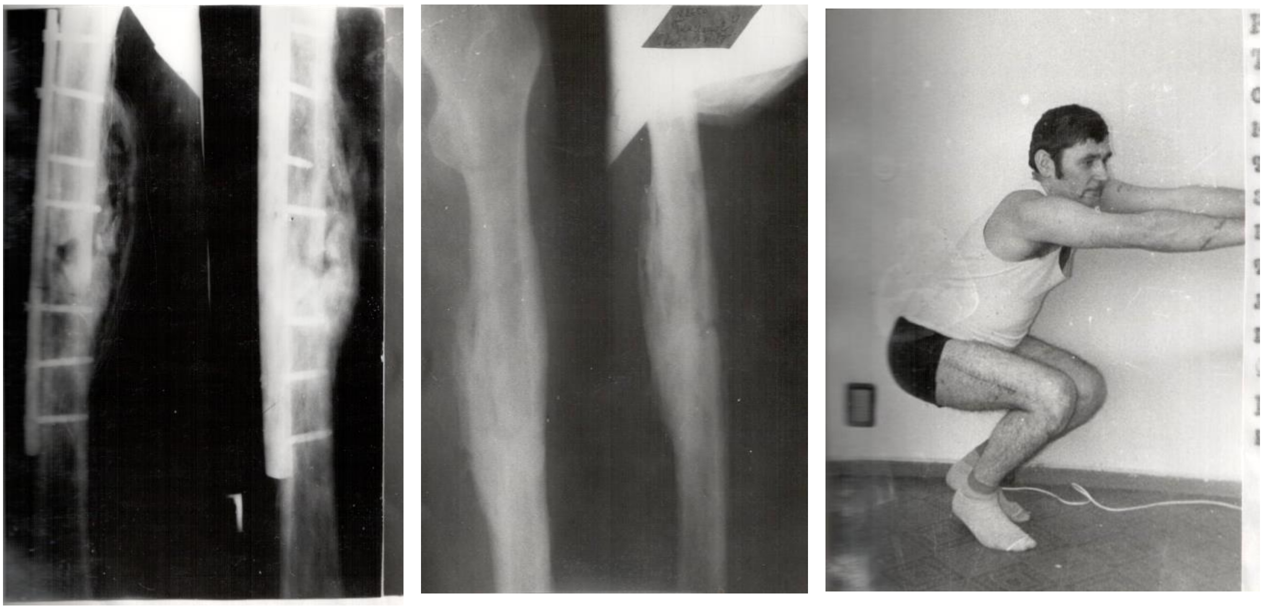


a *b*

Fig. 38. Radiography images of patient M. YM. Fragments of radius are fixed by plate; of the ulna – Bogdanov's shaft and distal fragments between themselves are a fixed by Kirschner wire. There is Day after operation. There is almost complete recovery of integrity of cortical layer and medullary cavity, periosteal reaction id minor (b), 9 months after osteosynthesis.

The technical mistakes included 2 cases: when the fixing screw was introduced in the vicinity of the line of fracture during osteosynthesis of the radius of the forearm. This was the reason for the delayed fracture consolidation.

Technical mistakes should also include rude attitude of the surgeon to the soft tissues and poorly conducted hemostasis during surgical intervention which caused the formation of a large hematoma in the fracture zone with subsequent ossification (Fig. 37). Rehabilitation of patients with and extensive hematoma was delayed because it compresses the soft tissue, contributes to "adhesion" of the surrounding muscles to callus.



a b c

Fig. 37. Radiography images of patient T. SU. Almost complete recovery of integrity of cortical layer and medullar cavity (a), paraosseously ossified hematoma of a large size decreased.

Functional outcome (c) of surgical treatment of the femur fracture.

Summing up this section - "mistakes and complications," based on the analysis of the results of the implementation of fixator system "METOST" in various hospitals, we can conclude that after a comprehensive testing and receipt approval of USSR Ministry of Health for industrial production and widespread clinical use, fixator system "METOST", as stated in the introductory part of our work, has successfully been used in specialized trauma and orthopedic departments of hospitals, at the research Institute of Traumatology, Orthopaedics and research centers in different regions of the USSR, and after the collapse of the Soviet Union -various CIS countries, where kits were supplied. Unfortunately, due to the broken connections with colleagues, for obvious reasons, we only partially managed to trace the long-term results of implementation of fixator system "METOST". But the analysis of material available to us for the processing showed that orthopedic and trauma specialist in the field are not sufficiently meticulous use our experience and do not always adhere to our developed methods and recommendations. And this is often the cause of higher percentage of unsatisfactory results of treatment of fractures than we have; and the reason for their failure are similar and repetitive, almost in all hospitals.

In this situation, the only way to improve the results of treatment of fractures is more rigid and demanding attitude towards working out of tactical skills at the departments of advanced training and frequent, at least once a year, thematic conferences with a mandatory "demo master classes." We allow ourselves to express our - "in case of adherence of all developed techniques osteosynthesis using fixators form "METOST" kit, the number of complications and mistakes can be minimized.

IV.6. Calculation of saving rate due to introduction of the “METOST” system fixation device to the clinical practice.

Calculation of the economic effects of the **introduction into the clinical practice fixators from "METOST" kit** was based on the method developed by E.N. Kulagina (1980).

The amount of economic loss is calculated as the sum of 3 values:

Y = Dp + B + L

Where -

Y - the value of national economic losses due to morbidity;

Dp - the value of the national income produced for 1 day per 1 employee;

B - the average amount of benefits at the expense of social insurance for 1 day of temporal disability;

L - the cost of treating of one patient per 1 calendar, day of temporal disability;

Economic benefit due to the reduction of treatment duration (Eef) is defined as the difference between the national economic losses at basic conditions (Ub) and the loss at design conditions (Ur): **Eef = Ub – Ur**

Total economic effect depends on the economic effect resulting from the reduction of terms of treatment by an average of 1 patient and the number of treated patients. To simplify the calculations we can base on the difference in days of temporary disability in the billing period compared with baseline. The calculation can be carried out initially per 1 patient, and then, if necessary, multiply the total number of patients under observation. The formula for the calculation in this case is the following:

E total = (D x Tr) + (B x Tr) + (L x Tc)

Where –

D - the value of national income produced for 1 day per 1 employee;

B - the average amount of benefits at the expense of social insurance for 1 day of temporal disability;

L - the cost of treating per one patient, based on the 1 calendar day of temporal disability;

Tr - reduction of duration of temporal disability in the billing period compared with the basic one per 1 employee in the working days.

Tk - reduction of duration of temporal disability in the billing period compared with the basic one per 1 employee in calendar days.

Since the working days are about ¾ of calendar days Tr value could be calculated according to the formula: **Tr = Tc x 0.75**

Value of ingredients - D, B, L - is taken from the data of official statistics and literature, and is presented in Table 18. During determination of the national economic losses from morbidity with temporary disability of employees of a particular enterprise calculating a new value under produced for 1 day of illness, it is justified to define it as a result of the shortfall in the incidence of net production (normative). For individual companies it is calculated on the basis of the report on labor - a form of 2m.
However, due to the fact that the surgical treatment of fractures with the use of fixators form "METOST" kit we were dealing with heterogeneous by nature classes of patient contingent and from a variety of companies and institutions, calculation of economic effect used the average data ONS, presented in Table 1.

For determining the value **Tk,** we took the parameters of treatment period of the patients due to long bone fractures as basic data from departmental instruction of the MH of USSR of 9.11.1987, drafted by the employees of the Kyiv and Kharkiv Scientific and Research Institutes of Ortopaedics and Traumatology. Basic data of medical and social rehabilitation and the calculated data obtained as a result of applying fixing devices from the "METOST" set for osteosynthesis are presented in Table 2.

Due to the fact that the osteosynthesis by means of the fixing devices of the "METOST" set was made in different medical institutions with different cost of a bed day, we used average values when calculating the economic benefit: - the cost of in-patient treatment 8 rubles; - Value **L** (cost of treatment of 1 patient per 1 calendar day of temporary incapacity) is an arithmetic average of in-patient and out-patient treatment cost– 4.5 rubles; - arithmetic average of **Tk** index**,** according to the data presented in Table 20, makes 40 days. The **Tr** value we calculate according to the formula:

Tr = Tk x 0,75 = 40 x 0,75 = 30 days

Arithmetic average of economic benefit of 1 patient treatment using fixing devices of the "METOST" set is determined according to a well-known formula:

E average = (D x Tr) + (B x Tr) + (L x Tk) = (17 x 30) + (6 x 30) + (4,5 x 40) = 870 rubles

According to the same formula we calculated the economic benefits that can be obtained by osteosynthesis in particular specific segment by means of fixing devices of the "METOST" set. The obtained calculation results are presented in Table 3.

Table 1

The data needed to calculate the economic effect of reducing the time of temporary disability of employees

Data	Data sources	Provisional data used for calculations
1. The cost of the national income produced by 1 working person for 1 working day	Data of the Central Statistics Administration of the USSR on the production of national income and the number of employees in the national economy	National income per 1 worker in the national economy of the USSR according to the Data of the CSA for 1982 amounts to 17 rubles.
2. Benefit by social security funds	Data of department of social insurance in the City Council of Trade Unions	The amount of the benefit is on the average 6 rubles
3. Cost of 1 bed day	Data of hospitals according to the category of medical institutions	It ranges from 6 to 10 rubles. (Sovietskoye zdravookhranenie (*Soviet public health*), issue 5, 1980)
4. The average cost of one visit to the doctor in the clinic and at home	Data of hospitals and literature sources according to the category of medical institutions	On the average it is 1 ruble, (Sovietskoye zdravookhranenie (*Soviet public health*), issue 2, 1977).

Table 2

The average time of treatment of long bone fractures at baseline and on targeted conditions as well as the value of Tк index

Localization of the fracture	Heavy manual operations			Light labor without physical effort		
	Baseline data	Estimated data	Value of Tk	Baseline data	Estimated data	Value of Tk
Thighbone	9 months 270 days	6,5 months 195 days	75 days	7,5 months 225 days	No patients	-
Both shin bones	8 months 240 days	6 months 180 days	60 days	6 months 180 days	5 months 150 days	80 days
Humerus	4,5-5 months 144 days	4 months 120 days	24 days	4-5 months 135 days	3 months 90 days	45 days
Brachium: - radial bone	3,0-4 months 105 days	3,5 months 105 days	-	2.5-3.5 months	No patients	-
- both bones	4,5-6 months 158 days	4,8 months 144 days	14 days	3-5 months 120 days	4 months 120 days	-
Collar bone	2,53 months 83 days	2,5 months 75 days	8 days	1,5-2 months 53 days	1,5 months 45 days	8 days

Thus, the calculations have demonstrated that average economic effect in cases of clinical application of fixing devices of the "METOST" set per 1 patient amounts to 870 rubles.

The greatest economic benefit obtained by osteosynthesis of bones of the lower limbs: the thighs osteosynthesis - 1626 rubles, and osteosynthesis of shin bones - 1305 rubles. The economic benefit obtained by osteosynthesis of bones of the upper limb and the collar bone is somewhat less.

To determine the total economic benefit, the amount of economic benefit obtained by the treatment of 1 patient must be multiplied by the number of operated patients. Due to the fact that no bony union was achieved with the 1st patient after osteosynthesis of forearm bones, we excluded the patient when calculating the total economic impact and the number of patients with good and satisfactory long-term results of treatment multiplied by the average economic benefit, which goes to the state as a result of applying the "METOST" bone fixing devices for stable-functional osteosynthesis of shaft fractures of upper and lower limb segments.

Table 3

Calculation results of economic benefit obtained in the course of osteosynthesis of shaft fractures of long bones using the fixing devices from the "METOST" set

Localization of the fracture	Heavy manual operations			Light labor without physical effort		
	Index value		Economic Effect	Index value		Economic Effect
	Tk	Tr		Tk	Tr	
1	2	3	4	5	6	7
Thighbone	75 days	56 days	1626 rubles	-	-	-
Both shin bones	60 days	45 days	1305 rubles	80 days	60 days	1740 rubles
Humerus	24 days	18 days	522 rubles	45 days	34 days	984 rubles
Brachium: - both bones	14 days	12 days	348 days	-	-	-
Collar bone	8 days	6 days	174 rubles	8 days	6 days	174 rubles

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CONCLUSION

Literature review carried out along with assessment of modern methods of treatment of fractures suggests that a definite success was achieved in solving this problem, the problem of regenerating anatomic integrity of bone tissue.

However, the existing significant percentage of unsatisfactory outcomes in the treatment of bone fractures is currently a reason for searching for improved treatment methods through creating new structures and improving well-known ones, along with the further study of the processes of regeneration and biochemical conditions of osteosynthesis.

The basis of the work done by us is creating and determining mechanical characteristics of new designs of compression extramedullary bone fixing devices and their components, experimental testing on animals as well as substantiation of broad clinical application, feasibility of mass industrial production.

Design features of the new bone fixing device are as follows:

1) Its U-shape that has 3 support points placed on a bone, which minimizes the area of the pressure sore formed upon prolonged contact of metal with bone tissue.

In addition, the structures made in the form of U-section have improved mechanical characteristics as compared to the bone fixing devices with profile shaped as a circle sector;

2) To generate compression, an eccentric mechanism is located on the case of a bone fixing device, in the form of a slotted eccentric washer, providing dynamic interfragmentary compression;

3) Availability of longitudinally elongated holes, of trapezoidal shape, enabling to create, if necessary, additional compression force.

In order to investigate the mechanical characteristics of a bone fixing device of the new design a complex of mechanical and mathematical and biomechanical studies was carried out that have resulted in the following data:

1) comparative tests on bending and torsion of a U-section bone fixing device to AO type bone fixing device having a profile shape in the form of a circle sector using the hydraulic machine KM-50-1, bending and torsion tests using universal unit for rupturing deformation T-100 showed that the bone fixing device of the new design has 1.5 times better strength characteristics;

2) vibration-reducing properties of a slotted eccentric washer are calculated so that its vibration-reducing component was deformed within the limits of elastic deformation, thus, providing dynamic interfragmentary compression;

3) as a result of benchmark tests of the eccentric mechanism using the ID-70 device it was determined that it is possible to generate force of interfragmentary relative pressure ranging from 10 to 104 kg / cm^2 by means of the eccentric which is quite sufficient when using this bone fixing device for osteosynthesis of all segments of the upper and lower extremities;

4) the degree of possible angular dislocation of the bone fragments, which may occur at the time of turning the eccentric, is in the range from 1º35 to 2º30, which is negligible in real-life conditions;

5) the fatigue tests of a new bone fixing device carried out on a low capacity testing machine showed very high fatigue strength of the bone fixing device which provides high reliability in real clinical conditions.

For refinement of dynamic and characteristics of bone tissue regeneration, for perfecting methods of osteosynthesis, we carried out an experiment on 12 mongrel dogs which were used to carry out modeling transverse fracture with subsequent fixation of fragments of osteotomised bone using compression plate of the new design. Upon the expiry of observation period (15 days, 30 days, 60 days, 90 days) an animal was taken out of the experiment, radiology of the operated segment was carried out and the preparations for pathomorphological study were made.

The clinical, radiological and histological study of the dogs subjected to metal osteosynthesis after experimental osteotomy of the right thigh bone in its middle third enabled us to get an idea of the nature of post-operative management of an animal and describe radiological and histological parameters in the time course of reparation osteogenesis. Clinically, it was found that all experimental animals after 2-5 days after surgery stood up, were active and, were limping slightly in the first few days, and they applied full load to the operated limb after 4-7 days. Postoperative wound healed in primary union with all animals.

In terms of radiology, all the dogs under the study had correct apposition of the bone fragments and firm fixation using metal plate from 70 to 130 mm long and number of screws from 4 to 7. Only a slight dislocation of the fragments of the dog under the number 25 could be seen along the width from 2.5 mm.

After radiological study of the preparation on the 15th day an extensive process of consolidation of fragments could be seen, but no distinct signs of complete union could be observed.

Only to the second observation period (1 month) consolidated structure of bone tissue could be seen on the osteotomy line. Clearly pronounced endosteal and periosteal reaction could be seen in the osteotomy area and along the entire fixing plate.

The traces of slightly pronounced shadow of compacted bone tissue could still be seen in the osteotomy area, an almost complete recovery of the medullary canal was beginning to show after 2 months. The definition and height of periosteal appositions noticeably decreased.

Complete recovery of integrity of cortical bone structure, complete restoration of a single medullary cavity could be seen in the osteotomy area after 3 month.

Reparative osteogenesis proceeded according to direct type, with formation of close-meshed spongy bone tissue which was clearly visible on the histological preparations in all observation periods.

The bone fixing device proposed by us and having a U-section shape contacts bone tissue in 3 points, and pressure sore does not appear under the plate in areas to which no load is applied, which creates conditions for periosteal bone formation in the area where the bone fixing device is located. However, prolonged location of a metal fixing device on a bone leads to an increase in resorption processes in the cortex, to loss of its mechanical properties and an increased risk of refracture. That is why the bone fixing device is to be removed after consolidation of the fracture. The studies also are an evidence of the fact that a compression component located at the fixing device enables to make a close contact between bone fragments, generate interfragmentary compression required for increase of stiffness of the "plate – screw – bone" system. In addition, a bone fixing device of this design has rather good mechanical properties, which provides conditions of reparative osteogenesis and consolidation of the fragments according to direct type.

In the source of the experiment on the animals osteosynthesis methods were perfected, sequence of procedures of osteosynthesis has been refined.

Data of the preclinical benchmark tests of the bone fixing devices, mathematical calculations as well as the results of the experiment on the animals enabled to develop a new set of instruments for osteosynthtesis of shaft fractures of long bone of upper and lower limbs which obtained the name "METOST" which means metal osteosynthesis. This set includes 42 bone fixing devices of various sizes, 3 wrenches for tightening up the eccentric, 278 screws, screwdriver and 2 rod benders for modeling of bone fixing devices according to the shape of the bone.

It should be pointed out that the length of the screw corresponds to the diameter of the bone on which the surgery is performed, the diameter of the screw is 4.3 mm.

Osteosynthesis method using the bone fixing devices of the "METOST" set is as follows:

Main components of the "METOST" set and their parameters

Product name	Overall dimensions				Quantity
	Length	Width	Height	Pitch of holes	
Fixing device for femoral bone	240 220 200	20 20 20	6 6 6	20 20 20	3 5 3
Fixing device for shin bone	160 140 120	20 20 20	5 5 5	20 20 20	3 5 3
Fixing device for humerus	130 115 110	15 15 15	5 5 5	20 20 20	4 4 2
Fixing device for brachium bones	100 70	12 12	3-5 3-5	15 15	5 5

- after accessing the damaged bone and apposition of the fragments, the bone fixing device is located so that the fracture line is between the two middle holes on the fixing device and eccentric is over the proximal fragment. The plate is secured to the distal fragment first, then a screw is introduced into the proximal fragment through the compression washer which faces proximal direction with its small radius. The joining of the fragments is achieved by turning the eccentric clockwise with the wrench. At the moment of procedures involving using plate and the eccentric, the bone holding clamp “softly” holds the bone fragments together with the plate. The final stage is fixing the plate to the proximal fragment with additional screws, inserted through the oblong holes.

Removing the lock, after the fracture union presents no particular difficulties. The plate could be quite easily removed through the surgical cut after removing the fixing screws.

As ordered by the MH of USSR, the state clinical tests of bone fixing devices of the "METOST" set were made in the clinics of the Central Research Institute of Traumatology and Orthopedics , N.V. Sklifosovskiy Scientific Research Institute of First Aid and the 2nd Moscow Medical Institute.

The "METOST" set is implemented in the traumatology clinics of the Kyiv institute of advanced training of the doctors (clinical hospitals № 7, 15, 28, the Kyiv clinical regional hospital), the Kyiv Medical Institute (clinical hospital № 25), the Kyiv Scientific Research Institute of Orthopedics (clinical hospital № 12), the Baku Scientific Research Institute of Orthopedics and Traumatology as well as in many practical health care institutions of the Ukrainian SSR, the RSFSR, the Byelorussian SSR, the Armenian SSR, as evidenced by extracts from case histories and acts of implementation.

For the period from 1984 to 1998 1,165 patients with shaft fractures of long bones were operated.

Direct indications to osteosynthesis using bone fixing devices of the "METOST" set are: transverse and short oblique fractures and false articulations of diaphysis of long bones.

Relative indications are: oblique, helical, multi-fragment fractures that do not exceed ¼ of segment length.

Direct contraindications to osteosynthesis using bone fixing devices of the "METOST" set are: multi-fragment fractures of diaphysis of long bones taking more than ¼ of segment length, open fractures with compression syndrome of adjacent soft tissues.

Relative contraindications are: cases of repeated reducing of fragments with fixation of the fragments using various submersible structures, extensive dermal scarring, fused with adjacent tissues and bone.

Prior to the operation a bone fixing device is selected from the corresponding mini-kit. The surgery is usually made under general anesthesia. Triangular bandage was applied after the surgery on the bones of the upper limb for a period of up to 15 days. In the cases of the surgeries on the lower extremities, however, the extremity is put into a deep plaster bandage or in Beller's splint for the same period. It was permitted to stand up after 2-5 days after the surgery. The length of in-patient treatment after the osteosynthesis of the bone of upper limb was from 3 to 12 days in 95% of the cases. And in the cases of osteosynthesis of the bone of lower limb it was from 10 to 26 days in 87% of the cases. Only in the cases of multiple trauma the in-patient treatment was protracted from 2 to 4 month.

The overwhelming majority of patients, constituting the above 87.7%, was discharged from hospital without external immobilization. The exceptions were 4 cases of combined damage of both segments of the lower limb and the patella, and 1 case when multi-fragment fractures of both bones of the shin, the tibia was fixed using a plate designed for osteosynthesis of humerus. External immobilization was made for these patients for a period of 1.5 to 3.5 months. Plaster splint was applied for 2.5 – 3.5 months in 3 cases of prolonged consolidation of forearm bones.

Terms of fracture consolidation were optimal in the majority of cases, with the exception of 3 cases of delayed consolidation of fractures of forearm bones in which tactical errors were made in the course of the surgery. Consolidation in these cases took place after 5- to 7-month period and in the 1st case of osteosynthesis of tibia due to comminuted fracture of both shin bones.

In the overwhelming number of cases the consolidation on the fracture site occurred without the expressed periosteal bone over-productions which shows quite stiff fixation of bone fragments, only 17 patients had moderately severe periosteal callus detected by radiological examination and not affecting the recovery of limb function. Limitation of movement in the adjacent joints was identified with the 1st patient.

Osteosynthesis methods using the bone fixing devices of the new design were perfected in the course of benchmark tests and in the experiment which enabled to reduce the share of unsatisfactory outcomes to 1.5%, the satisfactory outcomes work out 12.3%, the good outcomes work out 86.2%.

Mistakes and complications related to them observed in the course of clinical application of the "METOST" set were related to technical errors made in the course of the surgeries when in the process of osteosynthesis of thigh bone hemostasis was carried out poorly which resulted in formation of a large hematoma that had ossified subsequently as well as in the case when a fixing screw was inserted in close proximity to the fracture line which resulted in increased term of union of fragments.

In 4 cases tactical errors were made when in the course of osteosynthesis of multi-fragment fractures of both shin bones, the tibia was fixed with a plate designed for osteosynthesis of the humerus in one case, and for osteosynthesis of the hip in another case. As a result of wrong choice of bone fixing device no sufficient stability was achieved in the first case, and unreasonably large damage was made to the patient in the second case.

In 2 cases, in the course of osteosynthesis of forearm bones, radial bone was fixed with "METOST" plate, and the ulnar bone was fixed using Bogdanov's rod. This combination of fixing devices, in our view, is unacceptable, because in these cases no sufficient stability had been achieved, requiring applying plaster immobilization in the postoperative period.

Bone fixing devices were removed with 93.5% of patients after the periods from 4 to 20 months, three patients flatly refused to remove the fixing devices.

Calculation of economic benefit resulting from implementation of the "METOST" set was made according to the method developed by Kulagina E.N. and has demonstrated that using bone fixing devices of this design the state would receive average savings of about 1 thousand rubles (870 rubles) per patient.

FINDINGS

1. The extramedullary U-section compression plate with eccentric mechanism developed by us served as a basis in the process of creation of the new instrument set "METOST" for stable-functional osteosynthesis of shaft fractures of all segments of upper and lower extremities.

2. Bone fixing devices of the "METOST" set made in U-section shape have improved mechanical properties as compared to the fixing devices in the form of a circle sector and the eccentric mechanism pressed into the case of the bone fixing device provides dynamic interfragmentary compression.

3. Experimental investigations on the thigh bones of dogs have shown that stable-functional osteosynthesis using the "METOST" bone fixing devices enables to create optimum conditions for partial endosteal bony union already to 15 days with subsequent termination of the restructuring of bone regenerate during 2-3 months.

4. In the course of surgical treatment of shaft fractures of long bones, fixing devices of the "METOST" set can be used according to direct indication for transverse fractures and short oblique fractures with congruent fracture lines.

5. Subject to the indications and required technique of osteosynthesis using the "METOST" fixing devices sustained stabilization of bone fragments is achieved, the need for external immobilization is eliminated, the time of fracture healing and the time of recovery of functional activity of the limb is combined, it shortens the period of medical and social rehabilitation of patients and gives economic benefits. The economic benefit resulting from introduction of the "METOST" fixing devices is in the range from 174 rubles to 1,626 rubles per patient.

7. Positive results of stable-functional osteosynthesis of shaft fractures of long bones enables in 98.5 cases to recommend the "“METOST" set of instruments for stable-functional osteosynthesis of shaft fractures of long bones for broad applicability in the work of trauma and orthopedic surgeons.

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