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A NEW TYPE OF EXTERNAL FIXATION

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The paper presents some problems related to external osteosynthesis. Design of the new generation of external fixators should use modelling, computer simulation and clinical postulates. New generation of external fixators has been equipped with the measuring system of the bone healing process. Some of the important problems connected with the mechatronical and clinical aspects of the external fixator design and clinical application are presented.

1. Introduction

External fixation is a very effective, simple and versatile method in the treatment of fractured bones, that uses percutaneous pins to join the bone to a rigid external frame, which is ussually made of metal or plastic. It was used to stabilize open fractures in order to keep the bone fragments in place during treatment of the soft tissues.

This fixation is based on the principle of "load transfer". The forces, normally transmitted through the fracture site, are bypassed through the fixator frame and bone interface at the initial stage of treatment, Fig. 1. The moment when the fracture callus begins to consolidate, more load will be transmitted by the bone fragments. Then, at the end of the healing process of the bone fragments, all forces are transmitted by the bone [1, 2, 6, 7, 9]. The advantages of the external fixation can be formulated as follows:

- the preserption of the postulate of functional treatment, i.e. reflecting the motions of human joints in the case of healing periarthric fractures, ensuring micro-movements within the fracture interstice (in a strictly defined direction and of a strictly defined value),

- the application of biocompatible materials,
- simple installation of the fixator,
- secure fastening of the fixator in the osseous material and resistance to the osteolysis phenomena,
- possibility of a simple reposition of the bone,
- possibility of attaching manipulators for aiding the reposition process,
- installation of a measuring system for aiding evaluation of the bone union forming.

New generation external fixators satisfied many of these postulates [3, 5]. We list here the most important of them:

- The capability of generation of micro-movements during the treatment process called dynamically performer treatment. The structure intended to achieve this goal is the dynamisation chamber.
- Postulate of the elimination of influence of the osteouses. This is connected with wharmful appropriate construction of the external fixators and snitook choice of the configuration of the bone screws in the fragments of the treatment bone and bearing frame.
- Unilateral external fixators are very stiff, light and made of bioactive materials.

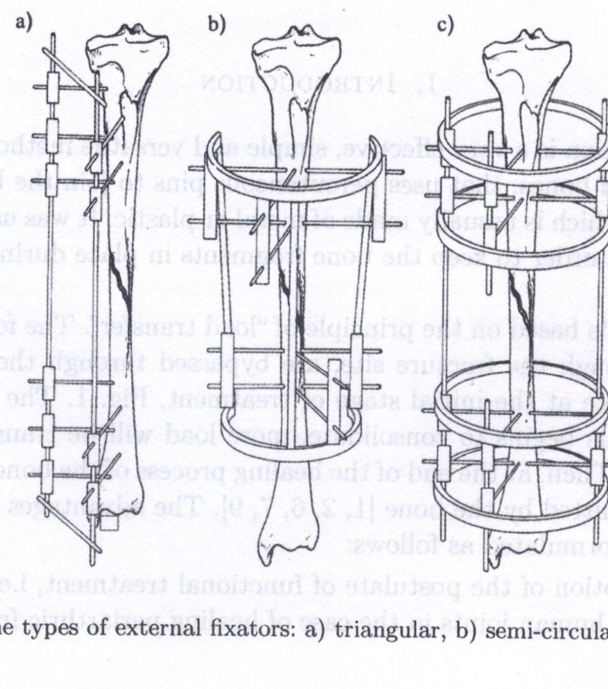


FIG. 1. Some types of external fixators: a) triangular, b) semi-circular, c) circular.

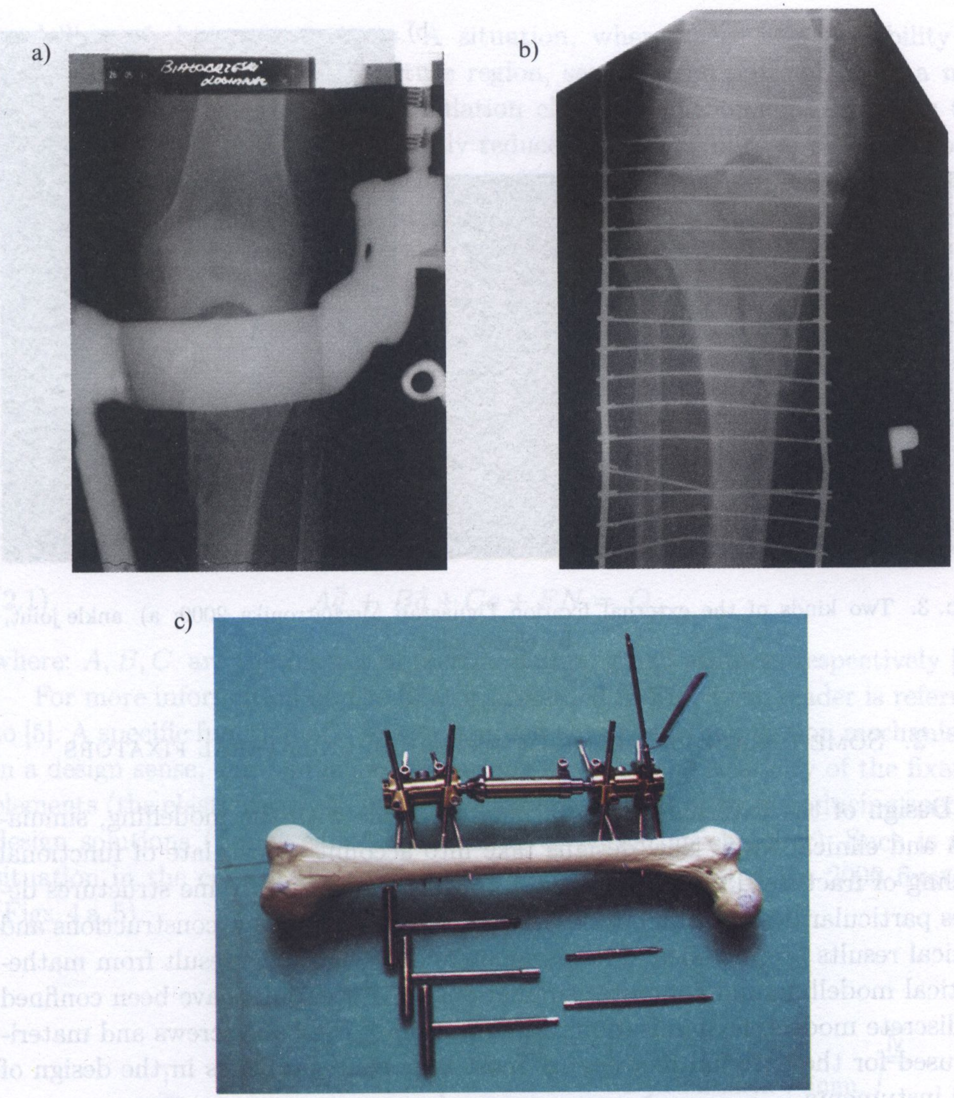
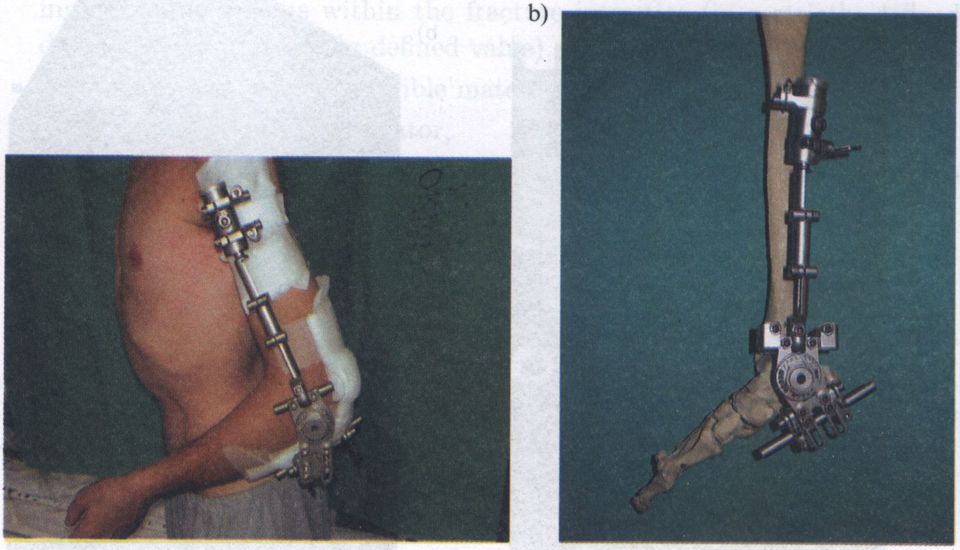


FIG. 2. Two methods of the external fixation: a) Dynastab DK, b) healing rail, c) Dynastab Mechatronika 2000 (long bones).

Application of mechanical models only for the analysis of the external fixator-bone system seems to be insufficient – the clinical research is also very important. This paper presents selected problems of the design of external unilateral fixators.

Special emphasis was put on relations between clinical investigation and the applied analytical and simulation apparatus. The tests with a new generation of external fixators were performed. The results of clinical tests are also reported. Some findings obtained in environment of a clinic are also presented here.



b)

a)

Fig. 3. Two kinds of the external fixation Dynastab Mechatronika 2000: a) ankle joint, b) elbow joint.

2. Some design problems of external unilateral fixators

Design of the external unilateral fixators deals with the modelling, simulation and clinical tests. New designs take into account a postulate of functional healing of fractures [3, 5]. A variety of bone screw bearing frame structures defines particular designs of fixators. The description of the new constructions and clinical results are included. The parameters of new designs result from mathematical modelling and computer simulations. Investigations have been confined to discrete models. Dynamisation, configuration of the bone screws and materials used for the external fixators are most important problems in the design of this instuments.

2.1. Dynamisation: a functional treatment postulate

The dynamisation is the realisation of the postulate that mint motion stimulates the bone union processes, however these micro-movements should be under control. In the case when the stresses between the bone fragments are too high, they may cause the so-called “mortar effect” and lead to necrotic changes. On the other hand, if the fixation is too rigid and the motion is impossible, it may cause the cortex layer to disappear or its decalcification, since the bone is “protected” against natural stress on stimulating a continuous remodelling of the osseous tissue. A situation, where there is a possibility of only axial movement in the fracture region, seems to be optimal. Such a motion, caused among others by stimulation electrical phenomena, decreases the time of treatment. It also significantly reduces the probability of complications. A feature of the fixator consists in ensuring micro-movements [1, 3, 5] of the bone fragments (and therefore stress interactions) in a strictly defined direction and range. The papers [3, 5] and the author's own clinical tests, permit to claim that this feature is of great importance in the process of healing of fractures. Our external fixator is characterised by high rigidity and the micro-movement values are adjustable only by the dynamisation chamber. A nominal model of the system is shown in Fig. 4b. This model was prepared to analyse the bone fragments micro-movements in dynamic conditions [5]. The dynamical equations of the model are described by the Lagrange equations. The general form of the equations of motion for the MOUFB System is expressed by [5]:

$$A\ddot{q} + B\dot{q} + Cq + FN = Q_w \tag{2.1}$$

where: A, B, C are the matrix of inertia, damping and stiffness respectively [5].

For more information on the fixator presented in Fig. 4 the reader is referred to [5]. A specific function of a fixator equiped with the dynamisation mechanism, in a design sense, can be realised in various ways: by the elasticity of the fixator elements (the elasticity of the frame or the bone screws) or by introducing special design solutions (the so-called dynamising or actuating chamber). Such is the situation in the case of the series of the Dynastab Mechatronika 2000 fixators (Figs. 4 a, 5).

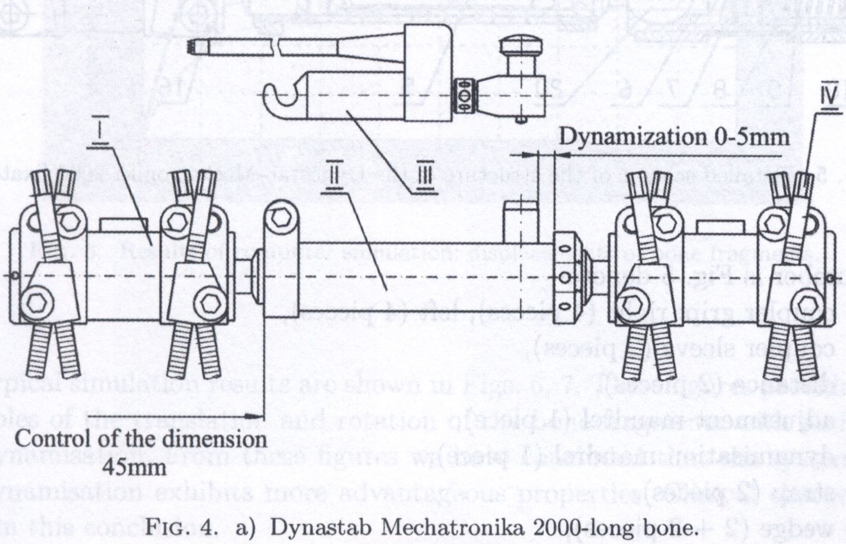


FIG. 4. a) Dynastab Mechatronika 2000-long bone.

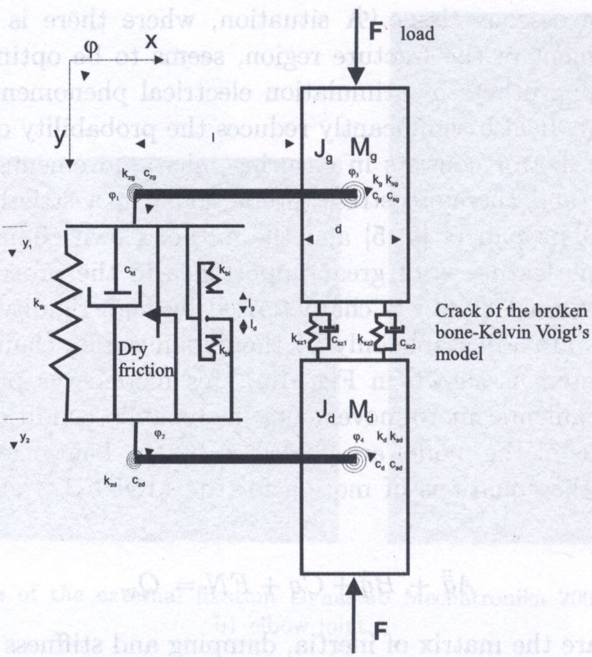


FIG. 4. b) Nominal model of the MOUFB System.

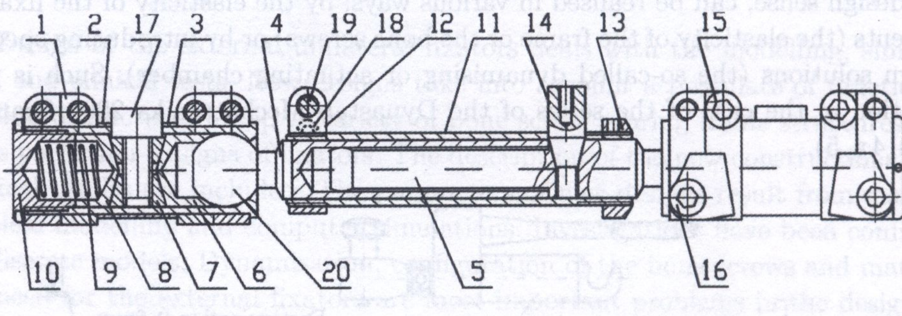


FIG. 5. Detailed scheme of the structure of the Dynastab-Mechatronika 2000 fixator.

The number is Fig. 5 denote:

1 – coupler grip: right (4 pieces), left (4 pieces),
2 – coupler sleeve (2 pieces),
3 – distance (2 pieces),
4 – adjustment mandrel (1 piece),
5 – dynamisation mandrel (1 piece),
6 – strap (2 pieces),
7 – wedge (2 + 2 pieces),

8 – stop (2 pieces),
9 – spring (2 pieces),
10 – stopper (2 pieces),
11 – shank sleeve (1 piece),
12 – shank grip (1 piece),
13 – dynamisation nut (1 piece),
14 – driver (1 piece),
15 – M 6 × 22 screw of the coupler grip (8 pieces),
16 – M 6 × 12 screw fastening the bone implants (8 pieces),
17 – M8 × 18 screw of the blockage of the ball-and-socket joint (2 pieces),
18 – locating screw of the shank (1 piece),
19 – M6 × 15 screw of the shank grip (1 piece),
20 – ball-and-socket joint.

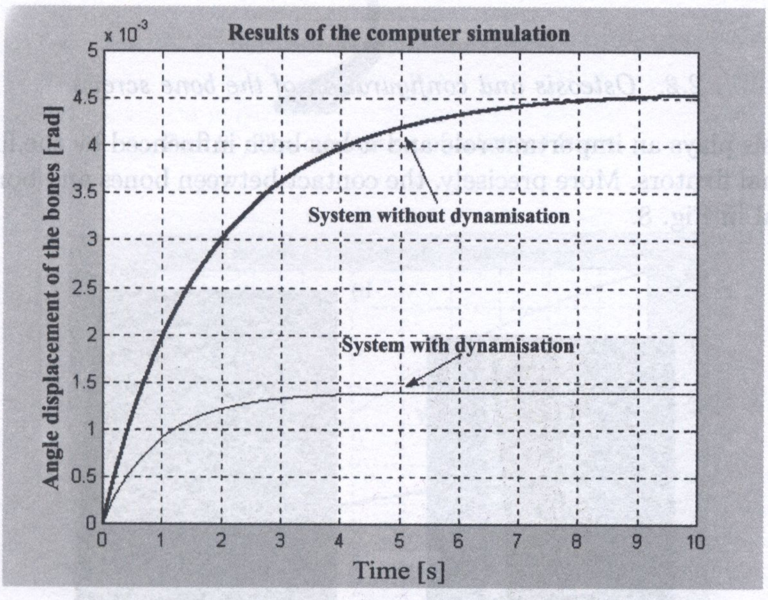


FIG. 6. Results of computer simulation: displacements of bone fragments.

Typical simulation results are shown in Figs. 6, 7. These figures provide some examples of the translation and rotation of the bone fragments with and without dynamisation. From these figures we have concluded that the system with the dynamisation exhibits more advantageous properties. Clinical observations confirm this conclusion.

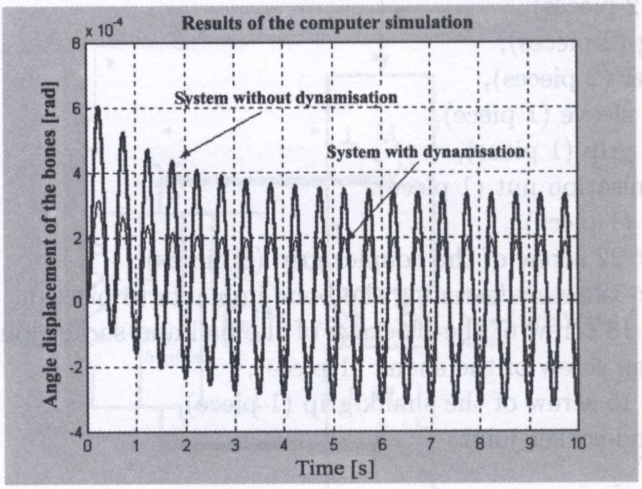


FIG. 7. Results of computer simulation: angle displacements of bone's fragments.

2.2. Osteosis and configuration of the bone screws

Osteosis plays an important role and it has been influenced by the fixation of the external fixators. More precisely, the contact between bones and bone screws is essential in Fig. 8.

a)

b)

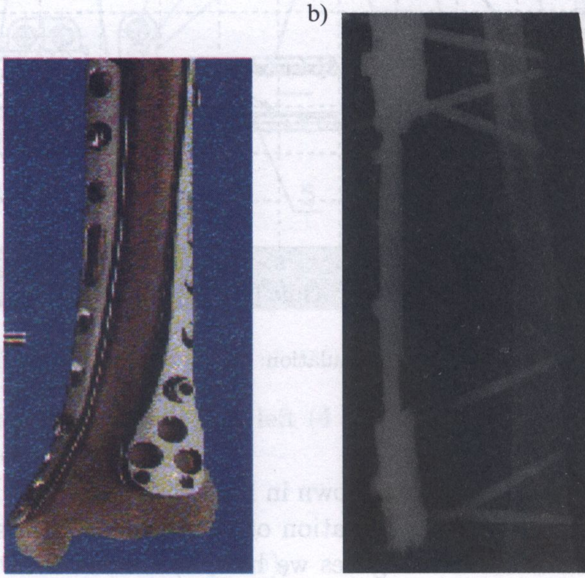


FIG. 8. Two kinds of fixation: a) plate fixator installed on the bone, b) external fixator Dynastab Mechatronika 2000 – long bone.

Mechanical properties of the MOUFB System are lowered by this process. The osteosis may lead to the destabilisation of broken bones. Configuration of bone screws and their spatial configurations can help to characterise mechanical properties of the MOUFB System. The scheme of the loading is presented in Fig. 9. Typical simulation results are shown in Fig. 10.

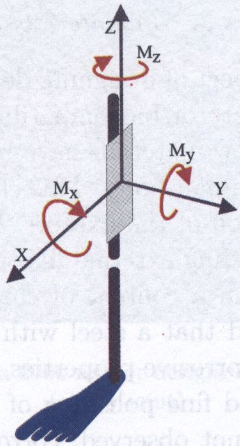


FIG. 9. The orientation of reference frame.

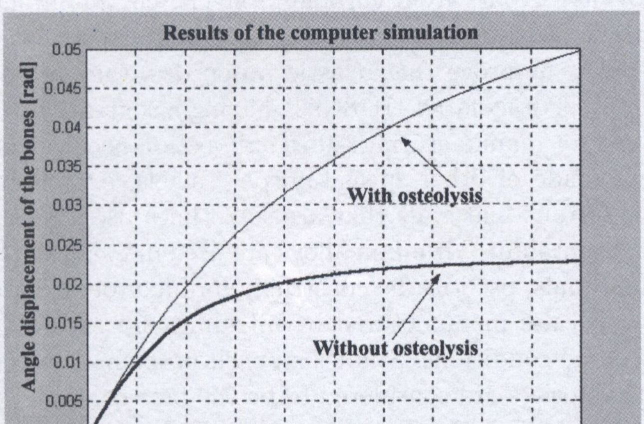


FIG. 10. Results of computer simulation: angle displacements of bone's fragments.

A positive effect of "spatial tent" configuration of bone screws upon the system rigidity with respect to the linear configuration (where α and β are equal to zero), is evident. The following data were assumed as an optimal system:

α=20 degrees, β_1=17 degrees, β_2=-17 degrees (the angles of arial configuration of the bone screws in the bones). The limitations imposed on the values of angles resulted from clinical observations and a significant increase in the tangential stresses in the contact areas occur with the increase in the values of angle β, [3, 5].

2.3. *Biomaterials*

Another very important aspect of designing devices for fixation of bone fragments is satisfying the postulate of biocompatibility [8] of the materials they are made of. Recently, many new materials have been introduced that interpenetrate with the tissue of the human body. This challenging issue requires some modifications in the construction of the fixators. In recent years, the basic material for surgical devices, including external fixators, were stainless alloy steels. These are chromium steels with a content of chromium exceeding 12%. However, it should be kept in mind that a steel with a content of chromium from 12% to 14% features high anticorrosive properties provided that: an appropriate heat treatment (hardening) and fine polishing of the surfaces were performed. If any of the above factors is not observed, corrosive stains on an instrument designated as N or STAINLESS will occur [8]. In the Polish standard PN-ISO 5832-1 appropriations of particular grades of stainless steels used for surgical devices are provided. Apart from chromium steels, chromium-nickel steels are applied. This grade of steel, contrary to the chromium steels, is not to be hardened but in order to improve their elastic properties, they are cold-rolled and cold-forged. The steel designated 1H18N9T, having a content of titanium smaller than 1.5%, is used for manufacturing tubes of injection needles. Sometimes, surgical devices are made of other special-purpose steels, e.g. chromium-wolfram steel HW5. Non-ferrous materials that are sometimes used for surgical devices are platinum and tantalum. Titanium alloys are used in medical devices too. The future of new materials, used in the construction of fixators is based on the new surface layers which are manufactured by nitriding and carbonitriding process under glow discharge conditions. Studies on such problems are continued [8].

Currently, composites are considered to be the best constructional materials in the osteosynthesis. They combine, in an advantageous way, a very good biological compatibility of the ceramics with tissues, its corrosion resistance with optimal strength of the metallic core [8], that transmits the loads. The first applications of the carbon materials for fixation of bones were started in 1980. In Poland, the results of a work on application of the carbon-carbon composite for plate joints were presented in 1993. The author of [8] elaborated and experimentally tested a fixator of a new design having variable elasticity. It was made of carbon composite elements. The results obtained by him confirmed usability and

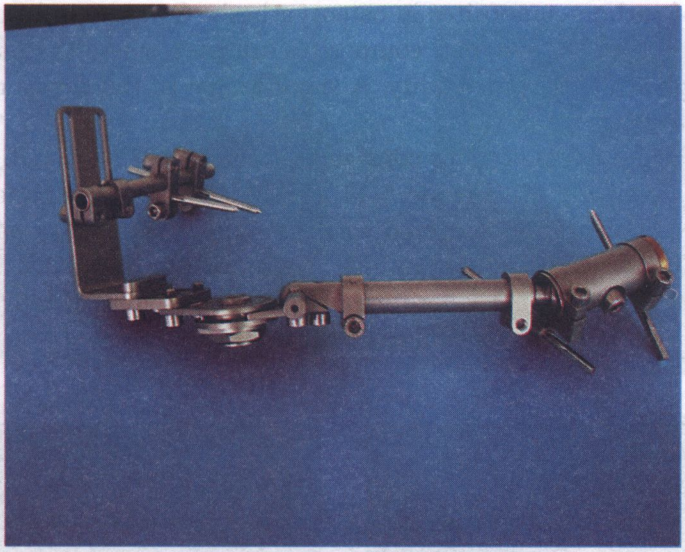


FIG. 11. Dynastab Mechatronika 2000 fixator designed for healing periarthric fractures (elbow joint).

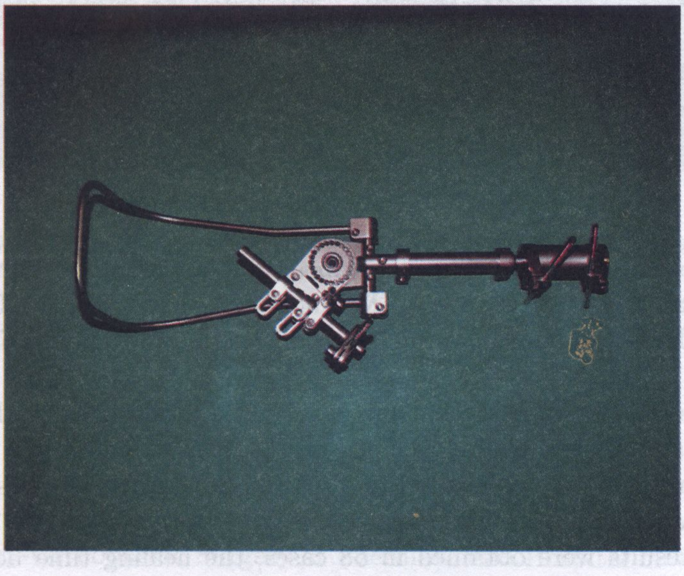


FIG. 12. Dynastab Mechatronika 2000 fixator designed for healing periarthric fractures (ankle joint).

advantages of carbon composites in osteosynthesis. Owing to advantageous mechanical properties, the polymer composites are used where the material needs to feature high strength and rigidity. A small weight of the device must be kept at the same time.

Finally, the materials used for constructing the fixator Dynastab DK and Dynastab Mechatronika 2000 (Fig. 3c, 5, 11, 12, 13) should be mentioned. The bone screws are made of titanium covered with titanium nitride. The majority of the outer elements is also made of titanium. There was no case (even though there were over 100 installations) where inflammatory reactions would be observed, what proves a good biocompatibility of the material.

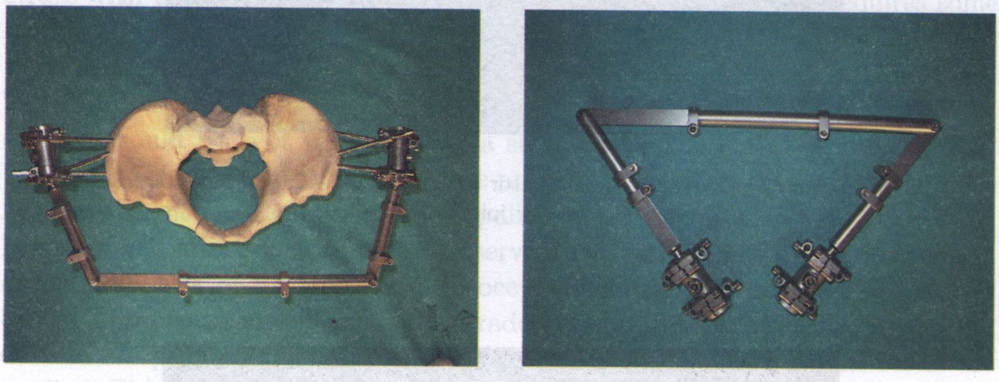


FIG. 13. Dynastab Mechatronika 2000 fixator designed for another healing periarthric fractures.

3. Clinical verification

Experimental verification was performed at the Institute of Micromechanics and Photonics (Fig. 14), Faculty of Mechatronics of the Warsaw University of Technology. Next the clinical verification followed at the Czerniakowski Hospital Warsaw.

The Type DYNASTAB Mechatronika 2000 Fixator designed for healing long-bone shaft fractures had been developed on the basis of the results presented in this paper, and it was implemented to about 60 bone fracture cases (compound fractures of thigh and lower-limb long-bones).

Positive results were obtained in 58 cases, the healing time being reduced by a factor of 18% in average when compared to conventional methods. The authors viewpoint is that this resulted, to a great extent, due to the fact that the postulate of functional treatment of fractures was satisfied. Clinical pictures are presented in Figs. 3a, 15. Substantial concurrence of results can be observed.

a) b)

FIG. 14. Experimental equipment to analyse the force of influence on the fixator – bone system.

a) b)

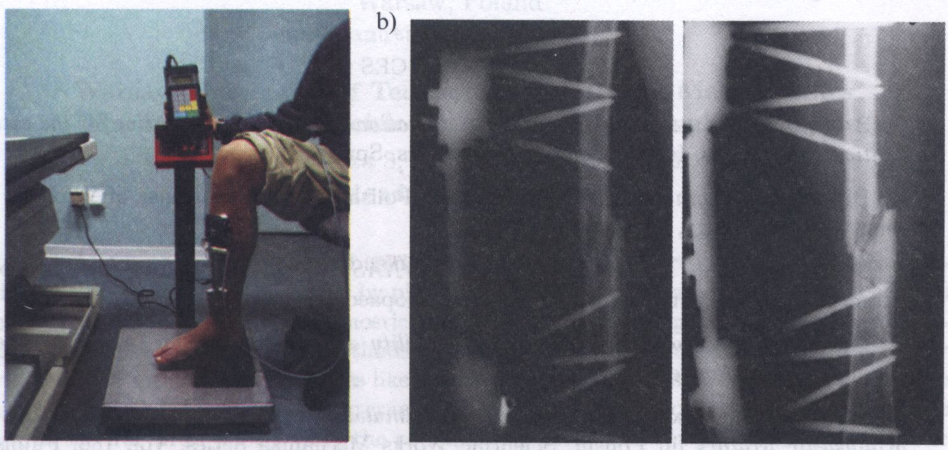


FIG. 15. a) A patient in the process of determining the bone-union measures (the load F_z is read on the electronic-balance display; the value of the load carried by the bearing frame in the fixator is measured by a strain gauge system and stored in the computer). b) X-ray picture of fractured bone with the DYNASTAB DK Fixator installed; the characteristic spatial configuration of bone screws can be seen.

4. CONCLUDING REMARKS

The described fixators are applied and verified in the clinical practice (the Ward of Injury-Orthopaedic Surgery at Czerniakowski Hospital in Warsaw). To recapitulate the clinical observations, one can formulate the following conclusions:

- Functional external fixators shorten the time of fracture treatment by ca 18%.

- Application of fixators with dynamisation system decidedly decreases the number of complications in the treatment.
- In the case of this method of healing with spatial configuration of bone screws in the bones and bearing frame, the time of rehabilitation after removal of the fixator is much shorter when compared to other methods, e.g. plaster dressing, Zespol fixators).
- External fixators should feature high rigidity and small weight what results in requirements for the applied materials.

More and more operational methods and treatment systems have been invented as well as many kinds of materials of new generation (e.g. used in space flights) having properties perfectly fitting the application in the external fixation. Designing a fixator with active dynamisation is the task for the future (the work has already been started).

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