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COMPUTER MODELLING AND SIMULATION TECHNIQUES AS A TOOL FOR AIDING THE DESIGN OF ORTHOPAEDIC UNILATERAL EXTERNAL FIXATORS – FOCUSED ON INNOVATIVE SOLUTIONS

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The paper presents the methods of modelling and simulation of the bone-external fixator system for fracture healing of long bones. Special emphasis was put on relations between clinical assumptions and the applied analytical and simulation apparatus. Concepts of application of heuristic techniques based on artificial neural networks for studying the process of bone union are presented. Together with the results of the simulation studies, some results of the examinations performed under clinical conditions are presented.

1. Introduction

The external osteosynthesis is one of the methods of bone fractures healing. This method is especially recommended in the following cases:

• fractures, in which losing control of the soft tissues may cause serious complications, as abscesses, necrosis and vascular-nervous distempers,

• fractures, in which it is purposeful to apply compression or distraction of the bone fragments,

• fractures coexisting with heavy injuries of the entire system, in which the risk of operational anaesthesia reduces the appropriateness of internal fixation,

• fractures with a complicated abscess, spurious joint, retarded bone union or lack of the bone union,

• congenital or acquired cases of anatomic distempers of the system of motion organs,

• arthrosis.

One should recognise the following reasons as the basic advantages of the external fixation:

• possibility of immobilising the bone fragments outside the place of fracture or infection centre;

• simplicity of care and inspection of the injury;

• simplicity of installing most of the fixators;

• elimination of internal couplers made of metal;

• possibility of performing motion in the region of the broken limb (especially in cases meeting the postulate of functional healing), in the early stage.

The basic device applied in external osteosynthesis is an external fixator. Idea of design of the external fixators consists in inserting into the bone fragments elements (called implants or bone screws) which are coupled outside the limb by means of an element, called carrier (or frame of the fixator), after setting the fracture. Structures of the carrier and the implants, and their spatial locations determine variety of solutions of the external fixators (Fig. 1). From the point of view of the structure, one can divide them into clamp, frame and circular fixators. In [6] one can find a detailed description of various design solutions. The external fixation is based on the principle of "load transfer". Forces normally transmitted through the fracture site are bypassed through the fixator frame and bone screw/bone interface at the initial stage of treatment. As the fracture callus begins to consolidate, load will be transmitted by the bone fragments. When the

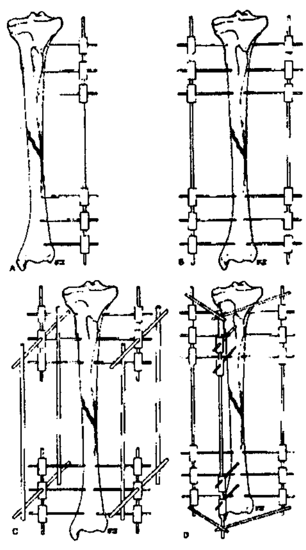


FIG. 1. Types of external fixators: A) unilateral, B) bilateral, C) quadrilateral, D) triangular.

fracture is healed, all forces are transmitted by the bone and the external fixator can be safely removed. However, such load-transfer characteristics depend on the rigidity and adjustability of the fixation device used. Considerations in the paper are limited to the unilateral external fixator designed for long bones healing. Specific results concern the structure of a Dynastab-DK fixators [1], which are shown in Fig. 2.

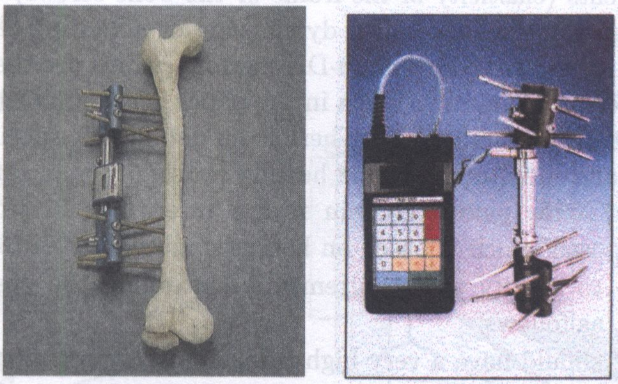


FIG. 2. Dynastab-DK fixator with the measuring circuit for healing fractures of long bones: a) version with on-board computer; b) modified version with external computer.

Contemporary designs of the external fixators realise the postulate of functional healing of the fractures.

This postulate has two meanings:

• in healing periarthric fractures, it consists in imitating physiological motion of the human joint,

• in healing long bones, it ensures performing micro-movements in strictly defined direction and strictly defined range.

Realisation of the first postulate makes it possible to cut down the time of healing and rehabilitation, and gives good prognoses, as far as restoring of the full efficiency after the treatment is concerned. Realisation of the second postulate stimulates the bone union processes, however these micro-movements should be under control. For if the pressure between the bone fragments is too high, it may cause the so-called "mortar effect" and lead to necrotic changes. On the other hand, if the stiffening is too rigid and motion is impossible, it may cause the cortex layer to disappear and its decalcification, since the bone is "protected" against the natural stress stimulating a continuos rebuilding of the osseous tissue. A situation, where there is only a possibility of axial movement in the fracture region, seems to be optimal. Such motion (by stimulation of electrical phenomena), cuts down the time of treatment. It significantly reduces also the probability of complications. Literature dealing with the external fixation, in the country [1, 2, 3, 4, 7, 8, 13] and abroad [5, 6], is very extensive. A feature of the fixator consisting in ensuring micro-movements of the bone fragments (and therefore force interactions) in a strictly defined direction and range is called *dynamisation.* The paper [6] and the author's own clinical tests, allow to formulate that this feature is of great importance in the process of healing the fractures. This feature, in a design sense, can be realised in various ways: by elasticity of the fixator elements (elasticity of the frame or the bone screws) or by introducing special design solutions (so-called dynamising or actuating chamber) – as it is in the case of series of the Dynastab-DK fixators (which are the subject of our studies). Another problem undertaken in the paper is the problem of monitoring and evaluation the bone treatment. There is no doubt that specifying an objective evaluation and monitoring of the healing process remain difficult. Manual examination and X-ray picture contain always an error of subjectivism. A new approach is proposed which is based on heuristic methods.

We propose to specify the requirements concerning the design of modern external fixator, as follows:

- the fixator should have a very high translation and rotation rigidity,
- the fixator should ensure adjustable diminishing of the rigidity in a strictly defined axial direction and strictly defined range (so, it should have a feature called earlier dynamisation),
- the fixator should ensure motion in the region of the joint of the broken limb,
- the fixator should have large compensatory possibilities, in order to reposition precisely the fracture,
- the fixator should be equipped with a measuring system for monitoring the treatment process, and should be linked with a computerised system analysing the measurement data, in order to aid the decisions of the orthopaedist and predict the treatment process.

All these requirements are met by the series of the Dynastab-DK fixators [1, 2, 3, 4]. Previous investigations dealing with external fixators are mainly focused on clinical observations, tests performed in laboratory-conditions and studies of simple mathematical models. The approach developed by us enables to intervene at the stage of designing the Dynastab-DK fixator for healing fractures of long bones.

2. Nominal model of external fixator – bone system

As it was mentioned before, the process of studying mechanical properties of the external fixator-bone system can be realised in an experimental or theoretical way, with application of computer simulation techniques. The theoretic studies require to create some abstract (idealised) model, called later a nominal model, and to describe its properties on this basis. Then the mathematical model is built. Only the mathematical model can be a basis for application of computer simulation techniques. In the field of mechanical phenomena, one of the main goals of the study was to determine the influence of the spatial configuration of the bone screws on the system rigidity. The nominal model of the system is presented in Fig. 3.

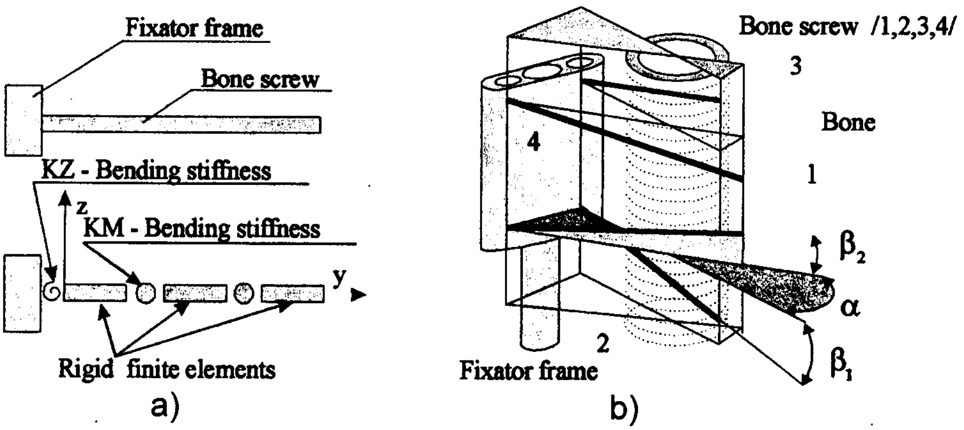


FIG. 3. a) Nominal model of the bone screws, b) Nominal model of the external fixator-bone system.

Three angles α, β_1 and β_2 determine spatial configuration of the bone screws. The ideal rigidity of the fixator frame as well as the bone material were assumed. From the practical point of view, this assumption is fully justified, since the frame is a pipe (in the case of the Dynastab fixators) having the external diameter of 20 mm, which can be dealt with as a non-deformable element, when loads act in a real way under clinical conditions.

While modelling the bone screws, the rigid finite element method [11] used to be applied. It consists in partition of the real systems, including the continuos systems, into non-deformable solids, called rigid finite elements. However, in contrast to [11], in our case one can take into account both the linear and nonlinear characteristics of *flexible* elements. In the nominal model of the external fixator-bone system, one may assume an elastic interaction of the bone screw with the substance of the bone fragment both in the tangential and normal directions in relation to the contact region – see Fig. 4.

Let us note that the strain of the fixator frame can also be analysed using the rigid finite element method.

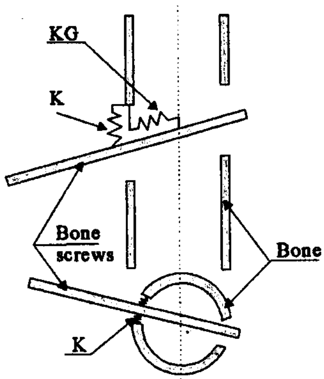


FIG. 4. Model of interaction between the bone screw and the bone.

On the basis of the given nominal models, motion equations were derived for the external fixator-bone system on the basis of the Langrangian equations of the second kind. The applied AGEM software (Automatic Generations of Equations of Motions) was prepared at the Warsaw University of Technology to derive the equations of motion. Values of the parameters are shown in Table 1.

Table 1.

No.	Designation	Value	Definition
1	KZ	1E5 Nm/rad	Stiffness of screw mounting in the bearing frame
2	K	Calculated	Bending rigidity between finite elements modelling the bone screw (see Fig. 3)
3	KG	1E6 N/m	Tangential rigidity in contact region (see Fig. 3)
4	K	1E5 N/m	Rigidity in contact region in normal direction (see Fig. 3)
5	E	2.0E11 N/m^2	Young's modulus of the materials, which the frame and screw bones are made of
6	d	0.006 m	Root diameter of bone screw
7	R	0.05	Distance between the point of mounting the screw in the fixator frame and the nearest point of contact between the screw and bone
8	D	0.03 m	Averaged diameter of bone
9	0.5 α	0 – 20 deg	Range of variations of the angle 0.5 α
10	β	±17 deg	Range of variations of the angles β_1 and β_2
11	β_2	0 deg	Constant value of the angle β_2 with various values of the angles β_1 and α
12	0.5 α	17 deg	Constant value of the angle 0.5 α with various values of the angles β_1 and β_2
13	F_x	300 N	Constant horizontal load
		0 – 300 N	Range of variations of the load (see Fig. 5)
14	F_y	300 N	Constant horizontal load
		0 – 300 N	Range of variations of the load (see Fig. 5)

15	F_z	500 N 0 – 500 N	Constant vertical load Range of variations of the load (see Fig. 5)
16	M_x	10 Nm 0 – 20 Nm	Constant loading torque Range of variations of the load (see Fig. 5)
17	M_y	10 Nm 0 – 20 Nm	Constant loading torque Range of variations of the load (see Fig. 8)
18	M_z	10 Nm 0 – 20 Nm	Constant loading torque Range of variations of the load (see Fig. 8)
19	M	50 kg	Reduced mass of the patient body above the fracture, analysed in dynamic studies
20	J_x, J_y, J_z	20,20,7 kgm^2	Reduced moment of inertia of the patient body above the fracture
21	Kr	8E6 N/m	Compression rigidity of the bearing frame of the fixator
22	Kd	0, 1E4 lub ∞ N/m	Axial rigidity of the dynamisation chamber
23	L	0, 0.002 m	Clearance in the dynamisation chamber

2.1. Examples of computer results

In this section we present some results of the computer simulation, obtained by application of the nominal models and the methods presented in the previous sections. The results correspond to the loads characterised in Fig. 5.

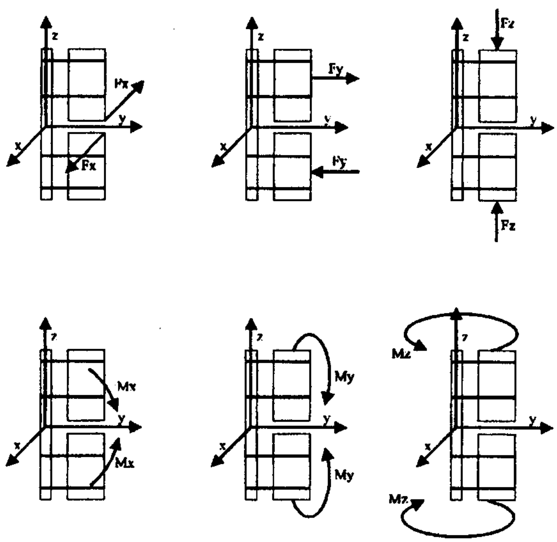


FIG. 5. Analysed types of loads in the external fixator-bone system.

We have presented comparative characteristics of a fixator with optimal spatial configuration of the bone screws (angle $\alpha = 20$ degrees, $\beta_1 1 = 17$ degrees, $\beta_2 = -17$ degrees – a thickened line in the charts) and a fixator with linear configuration of the bone screws, where α and β equal zero, and the distance between the bone screws in the vertical direction is 0.02 m (in the case of spatial configuration this is the distance between the bone screws 1, 2 and 3, 4 see Fig. 3).

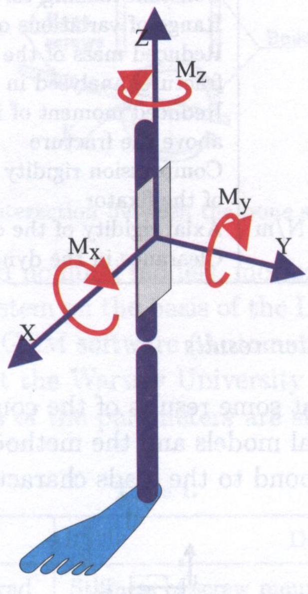


FIG. 6. Orientation of reference frame.

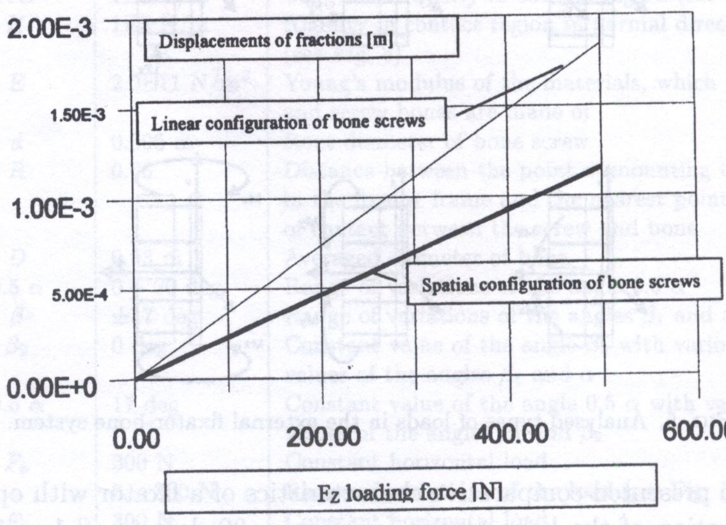


FIG. 7. Computer simulation – system loading by force F_Z.

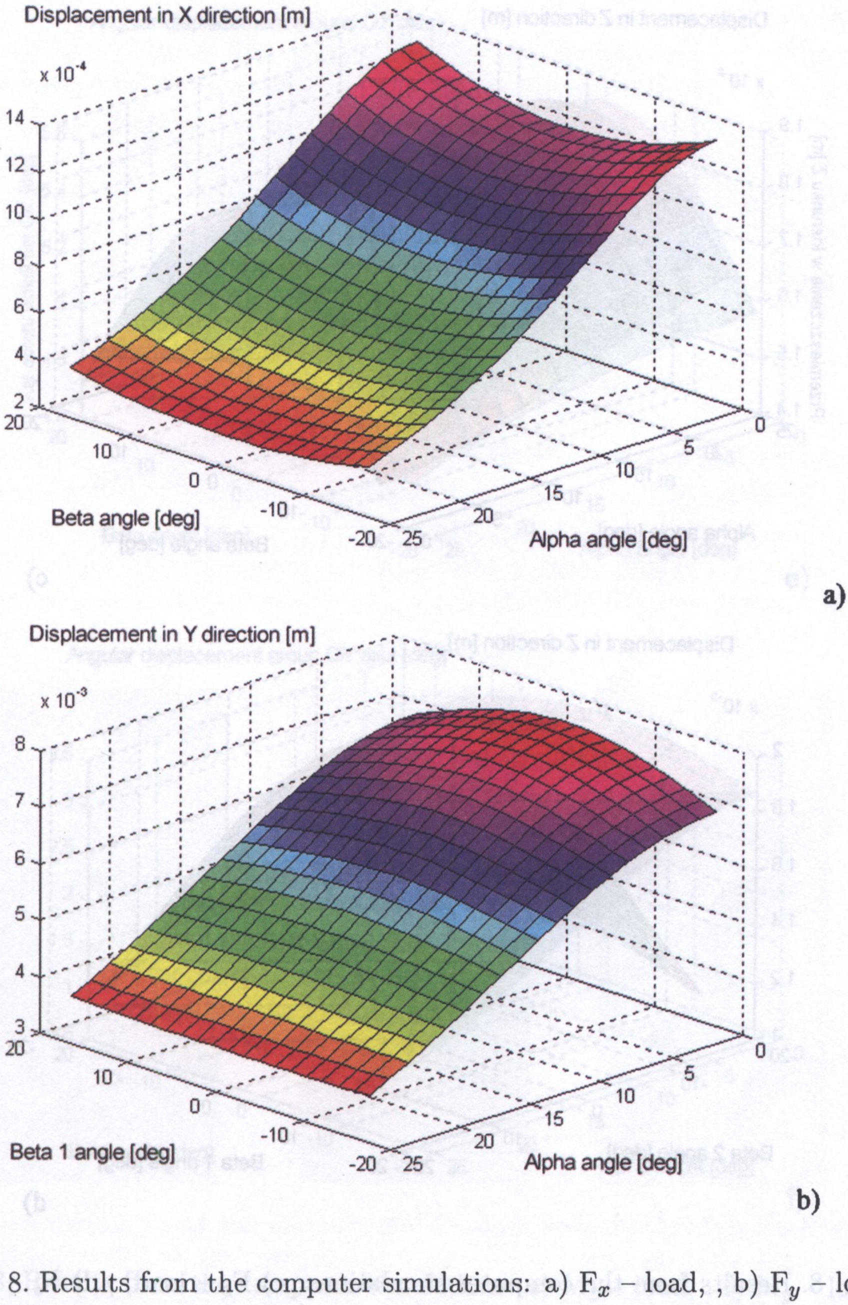


FIG. 8. Results from the computer simulations: a) F_x – load, , b) F_y – load.

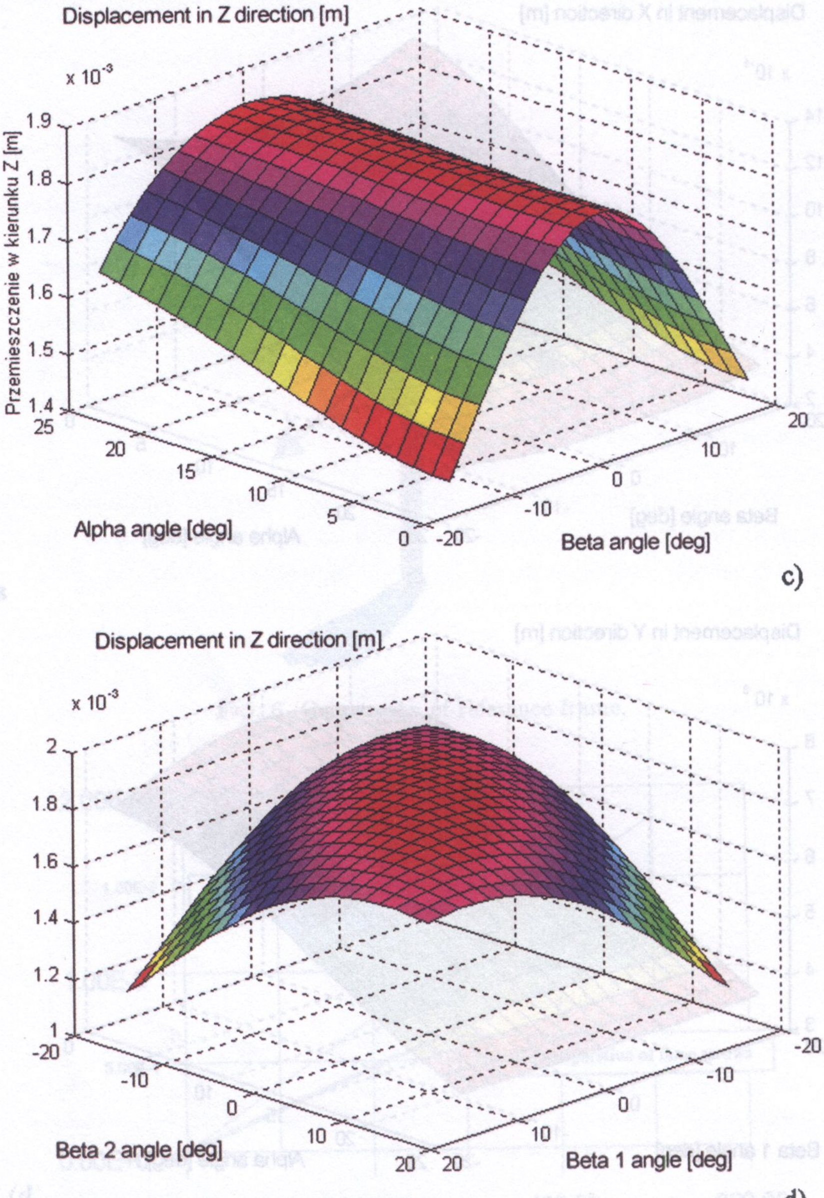
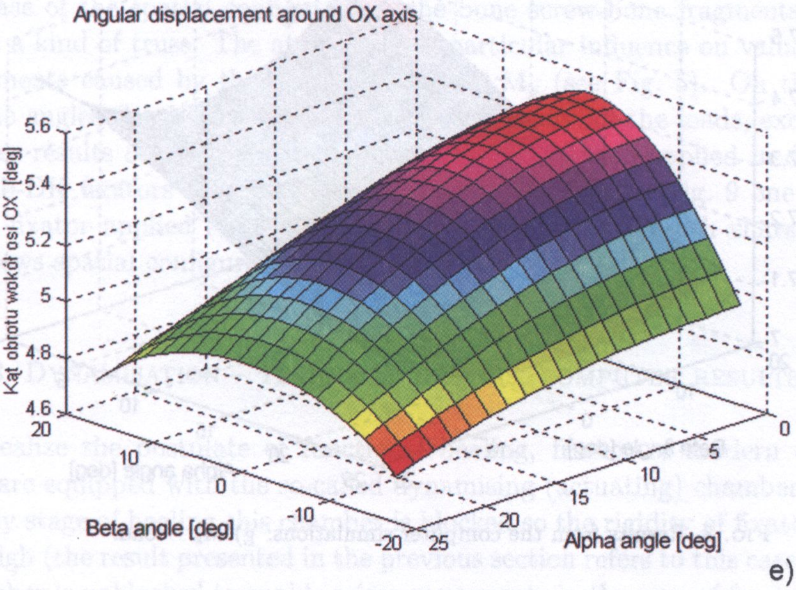


FIG. 8. Results from the computer simulations: c) F_z – load, , d) F_z – load.



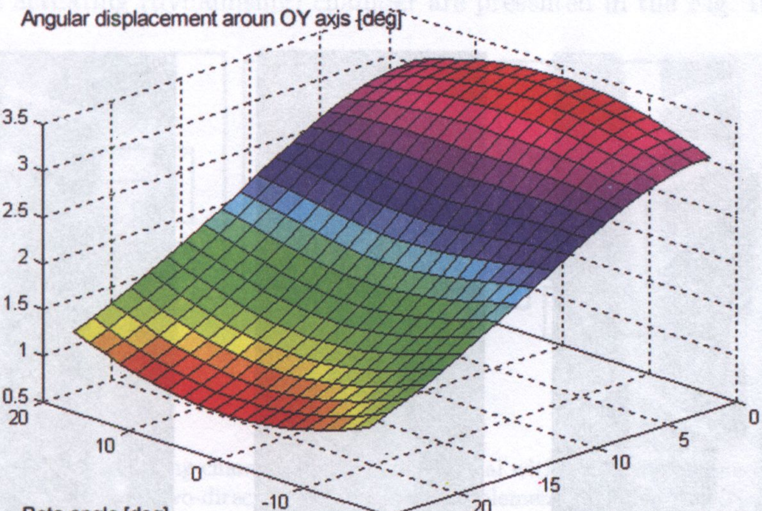


FIG. 8. Results from the computer simulations: e) M_x – load, , f) M_y – load.

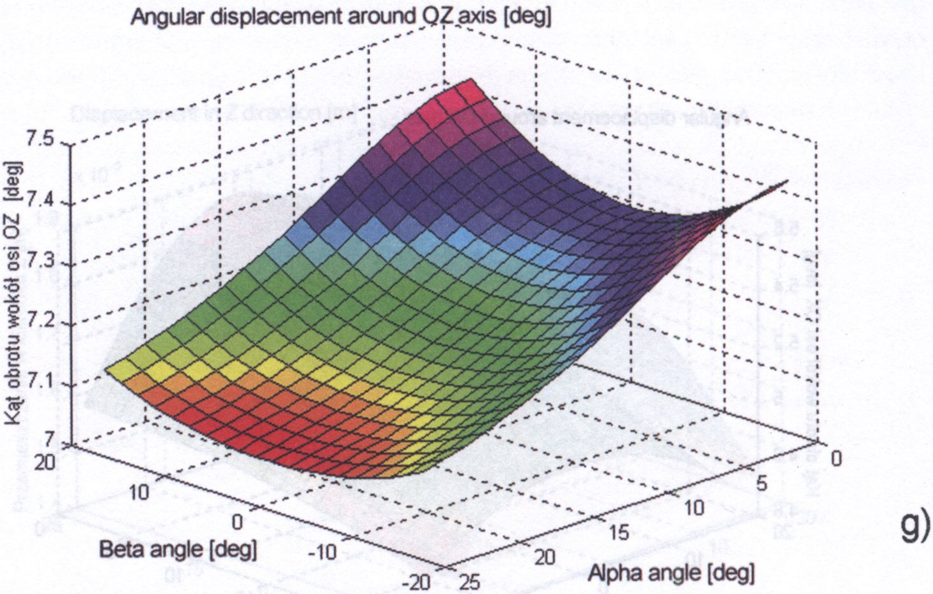


FIG. 8. Results from the computer simulations: g) M_z – load.

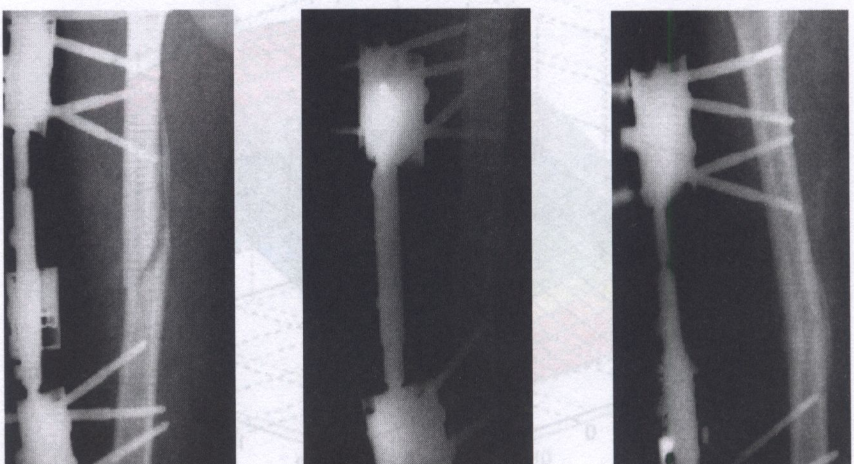


FIG. 9. Radiographs of aplications Dynastab-DK fixator for long bone fracture treatment (the X-ray pictures have been made available thanks to J. Deszczyński, the Czerniakowski Hospital in Warsaw, Poland).

We observe a positive influence of the spatial configuration of the bone screws on decreasing the displacements of the bone fragments, and therefore increasing the rigidity of the external fixator-bone system. This results from the fact that in the case of the spatial configuration, the bone screw-bone fragments system becomes a kind of truss. The angle α has a particular influence on values of the displacements caused by the loads F_x, F_y and M_y (see Fig. 5). On the other hand, the angles $\beta_{1,2}$ significantly influence practically all the loads, except M_z. Computer results obtained from computer simulation were applied in design of Dynastab-DK fixators and introduced to clinic practice. In Fig. 9 one can see external fixator applied for a long bone fracture treatment with characteristic bone screws spatial configuration.

3. Dynamisation – technical designs, computer results

To realize the postulate of functional healing, frames of modern external fixators are equipped with the so-called dynamising (actuating) chamber. In the very early stage of healing this chamber is blocked so the rigidity of fixator frame is very high (the result presented in the previous section refers to this case). Later the chamber is unblocked to enable micro-movements in the area of fracture. The concepts of actuating (dynamising) chamber are presented in the Fig. 10.

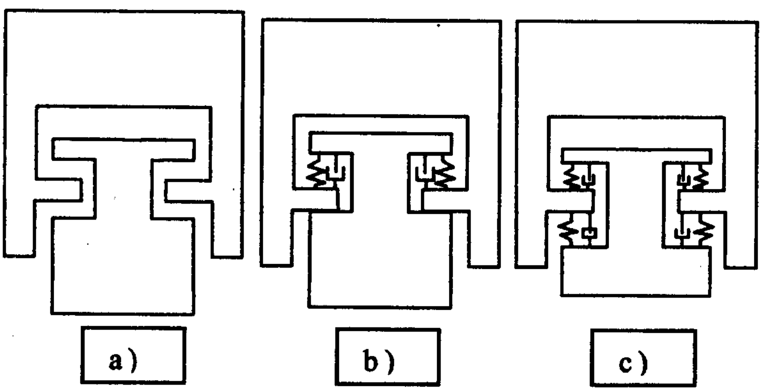


FIG. 10. Designs of dynamising chambers: a) two-directional with clearence, b) one-directional with flexible element, c) two-directional with flexible element (applied in Dynastab-DK fixators).

The Figures 11 and 12 present some computer results (which refer to case c in Fig. 10). They refer to vertical displacement of bone fractions and the vertical load 400 [N]. Total relative displacement of bone fraction is a sum of two components:

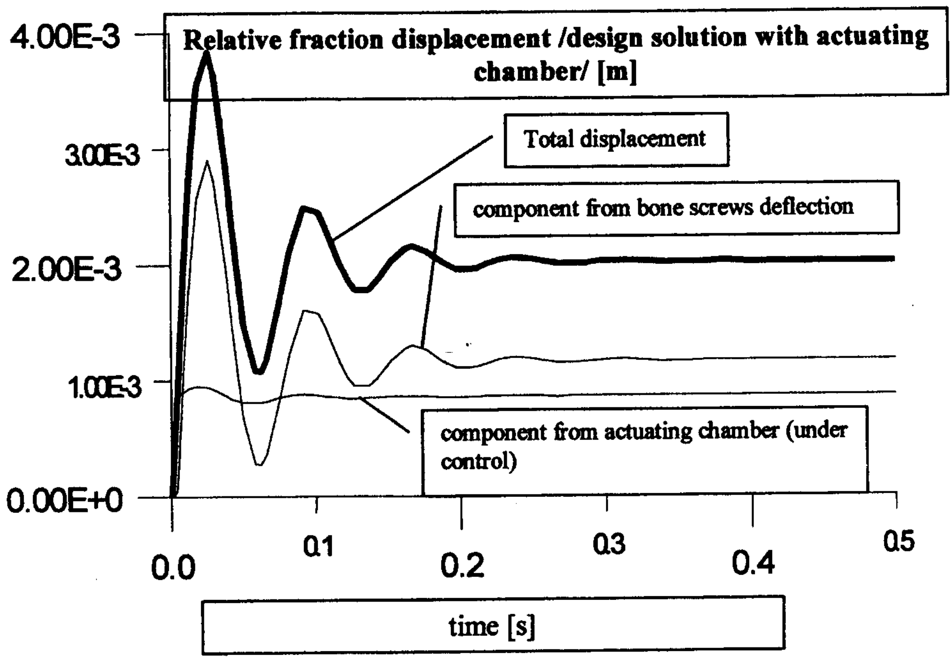


FIG. 11. Transient state (vertical load by weight of patient – 400 [N].

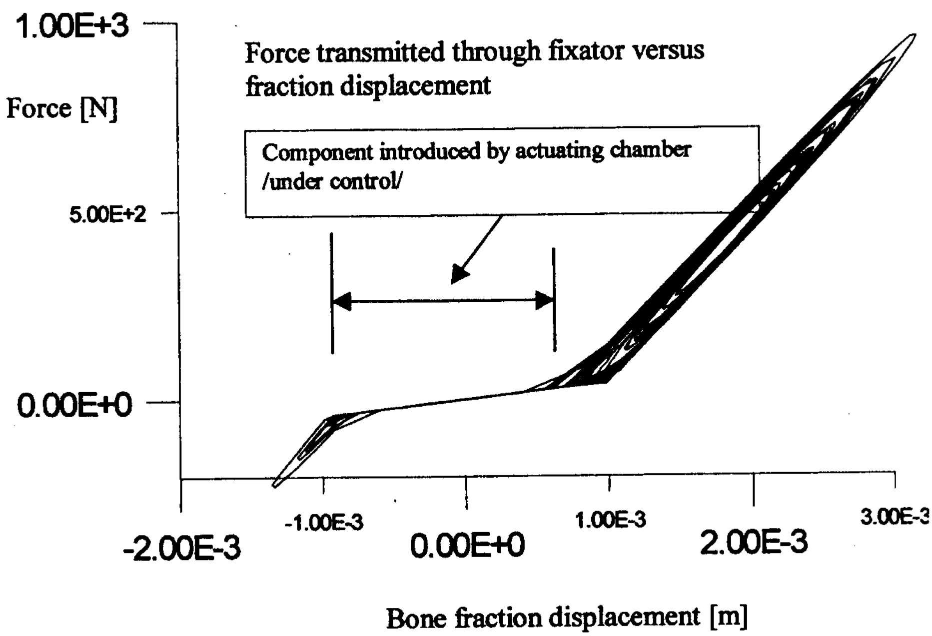


FIG. 12. Hysteresis caused by vertical load from – 50 to 1000 [N].

• component from bone screw deflection (this component should be minimized as this component is uncontrolled and as screws deflection cause also disadvantageous angular displacement);

• component from actuating chamber (by changing the clearance – see Fig. 10 – this component is under control during the healing period).

4. Concept of simulation and prediction of the bone union processes

One of the important problems in clinical practice is the problem of evaluating the bone union process. The methods which are mainly applied in clinical practice, are based on evaluation of X-ray pictures and manual examinations by an orthopaedist. These methods are commonly applied, however they have many disadvantages. The basic ones are relatively low precision of the evaluation and significant contribution of a subjective factor, connected with experience and practice of a doctor. Problems concerning a new method of evaluation, monitoring and prediction of the bone union process are the subject of analyses in this section In fact, the method is based on the data, which can be obtained from the measuring circuit of series the of Dynastab-DK external fixators. It is oriented toward applications in clinical practice. Its essence consists in measuring the interactions between the bone fragments in the case of various loading of the fractured limb. The measurement is performed by a microprocessor measuring circuit, equipped with semiconductor strain gauges. Analysis of the measurement data is performed by application of neural networks (mainly for simulation and prediction of the bone union process) having a multilayer structure. Let us introduce the so-called measure of bone union. An essence of the bone union measure consist in measuring the total load acting in the broken limb and then in measuring the load transmitted by the fixator bearing frame – F_1 and the bone being united – F_2. Knowing the above values, the measure of the bone union can be introduced as follows:

$$M = \frac{F_2}{F} = \frac{F_2}{F_1 + F_2}. \tag{4.1}$$

Let us note that this measure is a function of time. Its time-course determines the so-called bone union curve. Essence of this idea consists in monitoring the bone union curve and developing the methods, which on this basis will make it possible to determine the so-called standard bone union curve and to diagnose the healing process (deviations form the standard curve). Analysis of the standard curve in various cases will make it possible to study the influence of various factors on the bone union processes (therefore it is a significant research tool).

One more significant aspect of the problem should to be discussed. The loading of the fixator-bone system with an axial force is presented in Fig. 13. However, it should be noted that mechanical properties of the bone being united can be strongly nonlinear. Therefore measures of the bone union can prove to be different in the case of various values of a given load and in the case of various kinds of loads (forces acting in various directions and moments of force). So, it seems to be reasonable to introduce an n-element vector of the bone union measure and a vector of standard curves instead of a single measure:

$$M_i = \frac{F_{2i}}{F_i} = \frac{F_{2i}}{F_{1i} + F_{2i}}, \qquad i = 1...7. \tag{4.2}$$

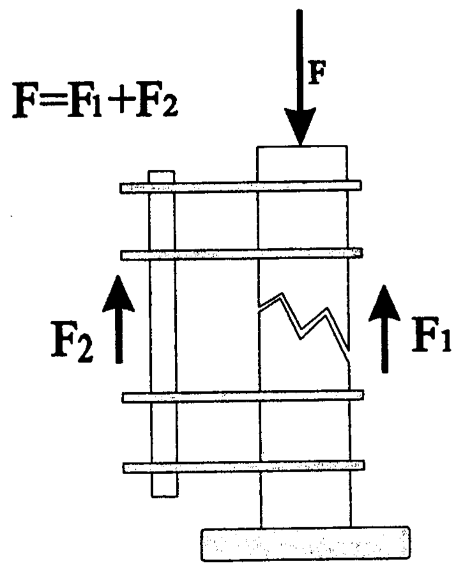


FIG. 13. Illustration of the concept of the measure of the bone union.

A positive result of healing cause a situation, when all the measures of the bone union equal zero, i.e. the whole load is transmitted by the limb.

It becomes a significant problem to choose a method of analysing the bone union curves, obtained by means of the measuring circuit of the Dynastab-DK fixators (the description of this system has not been included). It is a complicated microprocessor system based on semiconductor strain gauges. One of the interesting tasks is the prediction of the bone union curve, obtained on the basis of the data obtained from measurements performed in early stage of healing, in order to carry out e.g. corrections, if needed, or analysis of potential dangers. On the other hand, multiplicity of various cases (age of patients, kind of the fracture, other diseases, intensity of rehabilitation exercises, drugs taken, etc.)

cause hardships in selection of the computer simulation techniques. We have finally decided to apply the techniques based on artificial intelligence, and more precisely, artificial nonlinear and multilayer neural networks.

It was assumed that separate neural structure would be determined for each kind of fracture and additionally, for two sexes and kinds of addictions (smokers, non-smokers) of a person. Each structure built on the basis of a feed-forward type of neural network [10, 12] will have indeed a character of a recurrent neural network because of introduction of a feedback. Architecture of a neural predictor for prediction of the bone union curve is shown in Fig. 14.

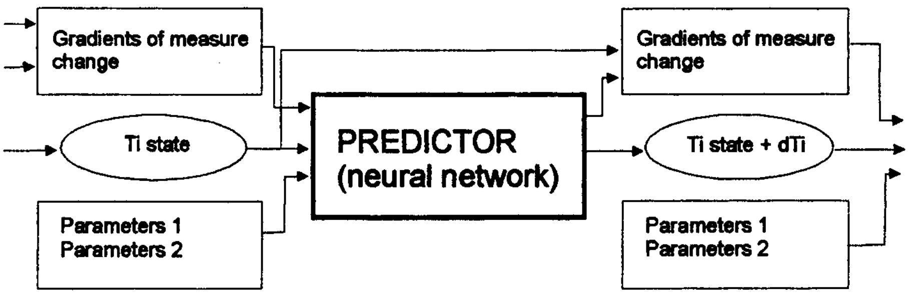


FIG. 14. Architecture of the system for prediction of bone union curves.

The present stage of healing (Ti STAGE) is determined by seven measures of the bone union being determined in the case of various loads, according to the measures (4.2) (these measures are obtained from the measuring circuit of the Dynastab -DK fixators or taken from the previous step of calculations in the process of computer simulation). Additionally, input quantities for the neural predictor are gradients of the above measures. Parameters denoted by number 1 in Fig. 14 determine values of the chosen analyses: level of Ca and P in blood serum, basic phosphates, intensity of rehabilitation exercises (measured with application of the fixator measuring circuit) and run of time from the moment of installing the fixator. The parameters denoted by number 2 determine the age of a patient, bone density, time of prediction dTi, operative technique applied (for instance fixation with a preliminary pressure). A structure of three-layer nonlinear neural network [10, 12] was applied for analyses. Results of clinical examinations and algorithm of reverse error propagation were applied as a method of training. The network (being a subject of continuous modifications during realisation of the grant) finally took a form of the above mentioned three-layer neural network including 617 neurones (the first layer includes 40 neurones realising transformation by means of hyperbolic tangent function, the second layer includes 570 neurones realising transformation by means of a logistic function, the third layer includes 7 neurones – because that is the number of the system outputs connected with 7 measures of the bone union – realising also transformation by means of a logistic function). The algorithm of backpropagation with a modified moment [12], mentioned before, was applied for training the neural network.

In spite of satisfactory results (they are mentioned in the next section), significant numerical problems occurred consisting in very long times of network training (what limited in a significant way the number of the neurones used). The training process was convergent well enough, i.e. the program reached the desired accuracy of training characterised by an error of 0.01.

4.1. Clinical and computer results

In the case of a fracture of tibia bone, the following kinds of loads for determination of seven measures of the bone union have been assumed:

1. M_1 contraction of tibialis-posterior muscle in a supine position.
2. M_2 active raising up of a limb by an angle of 30 degrees.
3. M_3 limb raised up passively, muscles relaxed.
4. M_4 contraction of muscles in a vertical position of the limb.
5. M_5 when laid on the sound side, limb abducted by an angle of 20 degrees.
6. M_6 load on an electronic weigher with a force of 100 N in a vertical position.
7. M_7 load on an electronic weigher with a force of 200 N in a vertical position.

FIG. 15. A patient in the course of healing a fracture of the tibia bone.

The data are used for prediction of evolution of the measures of bone union on the basis of the data achieved in measurements carried out in early stage of healing. Example results of a computer simulation are presented in Figs. 16 and 17. They are compared with a real variation of the values.

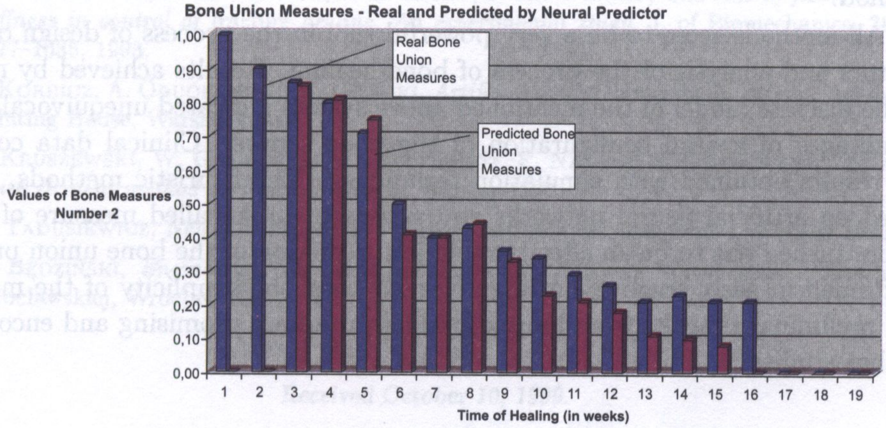


FIG. 16. Example results of prediction of bone union with application of neural network.

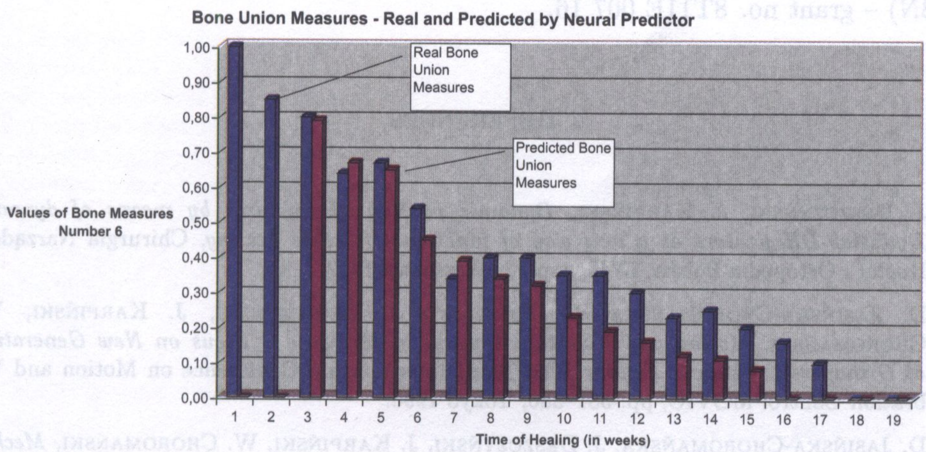


FIG. 17. Example results of prediction of bone union with application of neural network.

The first results achieved on the basis of a statistic test of 50 patients turned out to be very promising. Satisfactory agreement of the real values of bone union measures with the values achieved by prediction in early stage of the healing process can be observed.

5. Concluding remarks

The method proposed in the paper consists in

- modeling and simulation the fixator-bone system using discrete models,
- modeling of the bone union process with application of one of the heuristc method.

All methods seem to be a very powerful tool in the process of design of new fixators and analysis of the process of bone healing. Results achieved by means of the discrete model of the mentioned above system indicated unequivocally the advantages of spatial configuration of the bone screws. Clinical data confirm the results obtained with simulation techniques. The heuristic methods, being based on artificial neural networks and a concept of so-called measure of bone union, turned out to be an effective tool for prediction of the bone union process performed in early stage of healing. Nevertheless, the simplicity of the method and preliminary results from limited patient group are promising and encourage further studies.

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