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First Clinical Trials of Using Knee Stabilisers with Adaptable Kinematics for Functional Treatment of Periarticular Fractures – Experimental Research and Computer Simulation

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Abstract

This paper presents an orthopedic stabiliser to be used for the treatment of periarticular fractures of the knee joint. The design of the device is documented by experimental research of the knee joint kinematics. Experimental and simulation research suggest the use of a four-bar linkage mechanism. This research has also made it possible to define the range of adjustment to adapt the stabiliser kinematics to the individual properties of the patients. A sensitivity analysis points to the fact that the stabiliser must be positioned very precisely during installation. The stage of prototype construction was preceded by the design of a virtual model in CAD system.

The stabiliser makes it possible to move the lower leg relative to the thigh throughout the treatment. Stabiliser tests that have been made on artificial models of knee joint have proved correctness of its working. This paper also presents results of first clinical stabiliser trials.

I. INTRODUCTION

The inseparable side effect of continually developing motorization is the larger number of traffic accidents. Those usually result in trauma to organs responsible for movement, and this is one of the driving forces behind the search for new methods to treat such cases. The process of constructing stabilizers which aid this treatment is preceded by modelling and stimulation. The movements occurring in the knee joint have a complex character and they can't be approximated by a movement in a simple hinge joint. While treating the periarticular fracture the task of the stabilizer is to imitate the physiological movement in the articulated knee joint. This is the basis of functional treatment which is a new method in dealing with periarticular fractures using external osteosyntesis. Recently, there has been some fast-paced development of new orthopedic designs of external joint stabilisers. The new designs are aimed at meeting the following clinical requirements:

- functional treatment must be possible: the natural movements of human joints must be imitated in treating periarticular fractures, and micro-movement must be possible within the fracture (taking place in a particular direction, and within a precisely determined range),
- biologically friendly materials must be used, and the stabiliser must be easy to install,
- stabiliser must be "firmly" set onto the bone material, resistance to osteolysis must be ensured,
- easy bone repositioning must be provided,
- it must be possible to attach manipulators so as to assist the repositioning process,
- a measuring system must be installed to assist the synostosis process, e.g. using neuron networks.

Each of these requirements and their clinical importance has been thoroughly analyzed in a number of studies [1],[2]. This paper focuses on the issue of functional treatment of periarticular fractures of the knee joint. This treatment allows for bone movement within the affected knee joint as early as possible. For this purpose, the kinematics of the knee joint and of the stabiliser joint must be closely matched.

The list of publications on the knee joint is rather extensive. In studies [3]-[5], the knee joint dynamics are analysed, taking into account the geometry of the bone, as well as the spatial configuration and the non-linear characteristics of the joint ligaments. Studies [6]-[8] analyzed the forces and stresses generated in the knee joint. Studies of knee joint dynamics and their analysis can also be found in papers [9]-[12] and in the book [13]. The authors of this papers believe that the concepts contained in these studies carry important theoretical content, however they provide no clear indication of possible practical application. To the best of the authors' knowledge, there is no stabilizer with adaptable kinematics that is available for treating periarticular fractures of the knee joint. Therefore, we believe that the subject of this paper is novel in its nature.

II. EXPERIMENTAL RESEARCH. ANALYSIS OF RESULTS

In the process of designing a knee joint stabiliser for treating periarticular fractures, some of the preliminary research was experimental in nature. The difficulty in designing such a device lies in the fact that the stabiliser must closely follow the joint's natural kinematics. This depends not only on the geometry of the various joint surfaces, but also on the workings of the ligament system

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[7],[14] (mainly of the cruciate and lateral ligaments). To the authors' best knowledge, no literature on kinematics is available to provide sufficient background for imitating the natural knee joint kinematics in stabiliser design. Therefore, it was necessary to undertake experimental research.

The purpose of the research was to provide a description of the tibial bone movement relative to the femoral bone. The research relied on the roentgenography technique to make observations of X-ray images of the joint at different angles of flexure. It was assumed that a 2-D analysis of the joint movements would be sufficient to solve the problem.

Modern X-ray imaging equipment with low levels of radiation was used in the observations. This equipment provides real time X-ray imaging of joint movement, and makes it possible to create documentation in the form of individual images. For each patient, a package of 30 digital images was made to create a graphic record of the knee joint movement (Fig. 2.1).

Fig. 2.1 X-ray images for experimental research in knee joint kinematics.

The examination involved a group of 20 patients of both genders at different ages and with a different bone structure. The results of the analysis made it possible to estimate the scope of variations in knee joint kinematics for the general population.

To find the relative movement of the bone, WiseImage 5 software was used. The purpose of the research was to map the movement of the tibia and the femoral bone by analysing a succession of images within a stationary system of co-ordinates

Then, elementary transformation was used to map the movement of the tibial bone relative to the femoral bone expressed in the related local system. This movement was described as the movement of certain point positioned on the tibial bone as a function of the angle of joint flexure. In the next step, using the description of the relative bone movement, an algorithm was created to automatically generate the trajectories for any selected point positioned within the tibia. Using the optimisation procedures, we looked for a position of new point which traces a trajectory closest to the arch (Fig. 2.2a). The decisive variables in the task of optimisation were the position of the points p' and A, and the length of the segment (radius) AB. As a limiting condition it was assumed that $y_A = y_B$. The objective function was the minimum of the sum of the squares of the distances between the trajectory of point p' and the arch traces by point B. By treating point A as the centre of rotation for point B, the optimisation task was aimed at finding a position of points A and p' for which the objective function would reach the minimum.

As a result, we could observe certain characteristics which were shared by all patients. If the tibia is analysed as a solid, then point p` makes a circular motion, but also the tibia rotates around that point (Fig. 2.2b). This rotation is referred to as polar rotation. By analysing the joint movements in different patients, we arrived at different lengths of AB within the range of 60-100mm.

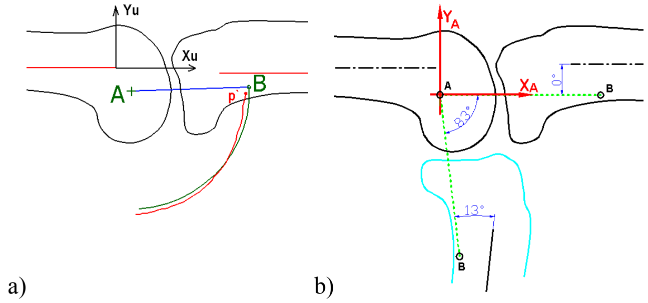


Fig. 2.2 Diagram of the knee joint movement.

This way we were able to determine the kinematics of the knee joint for all the patients as a double joint with two centres of rotation: A – on the femoral bone, and B – on the tibial bone, whose segments rotate at the angles of α_A and α_B which are uniquely related to each other in each individual person. The sum of angles $\alpha_A + \alpha_B = \alpha$ (Fig. 2.4) is the total flexure angle of the lower leg relative to the femoral bone. Fig. 2.3 presents sample charateristics of the changes to the angle of polar rotation α_B as a function of the joint flexure angle α (for four cases).

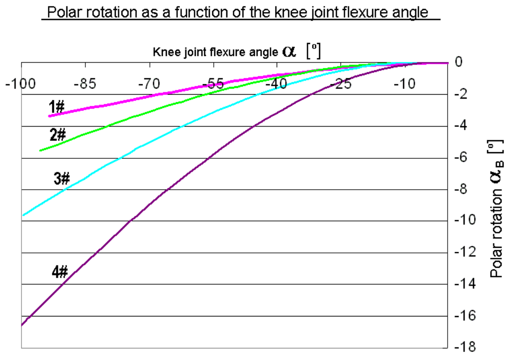


Fig. 2.3 Polar rotation as a function of the knee joint flexure angle, (i#: i=1,2,3,4 – cases numbers).

The inter-relation of these movements can be realised using the variable-parameter four-bar linkage mechanism (Fig. 2.5). The mechanism is simple and allows for a number of regulating options to change its kinematics.

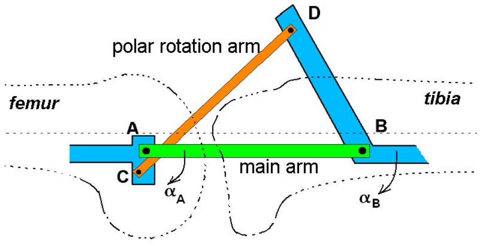


Fig.2.4 Diagram of the four-bar linkage mechanism.

In this context, it was necessary to find how joints C and D are positioned so that the four-bar linkage mechanism can correctly reflect the polar rotation motion for each patient. For that purpose, the position of the arm of polar rotation was optimised. Assumed as the objective function was the minimum of the sum of the squares of the difference of the values of the studied polar rotation $\alpha_{BK\,i}$ and of the rotation necessitated by the mechanism $\alpha_{B\,M\,i}$.

The decisive variables were the positions of points C and D. As a result of this procedure, the optimum ranges of change to the position of those points were found. Fig. 2.5 shows the diagram of changes to the position of the joints.

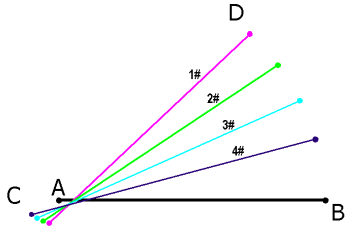


Fig.2.5 Diagram of changes to the positions of joints C, D (i#: cases numbers)

Based on this analysis, the variable-parameter four-bar linkage mechanism has been suggested to imitate the kinematics of the knee joint. By changing the length of arm AB and by regulating the position of joints C and D we can adapt the kinematics of the mechanism to the patient's individual characteristics.

III. SIMULATION STUDY, ANALYSIS OF PARAMETER SENSITIVITY

Simulation studies were carried out using the 2-D Working Model system of MSC software. The system allows for easy kinematics simulation of complex 2-D mechanisms. To begin with, a 2-D model of the knee joint was created whose movement was defined using the results of experimental research (Fig. 3.1). The next step was to build a model of the four-bar linkage mechanism by using the results of the optimisation tasks as discussed above. This simulation confirmed that the kinematics of the model was correct.

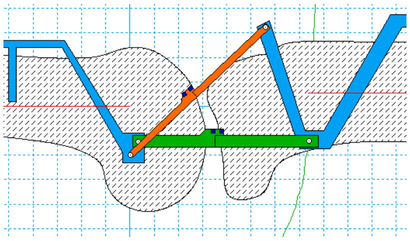


Fig. 3.1 Model for verifying the synthesised results for parameter settings.

In the next stage of the study, the position of the mechanism model was changed relative to the knee joint. The aim of this study was to check the impact of the mechanism positioning inaccuracies on the correct functioning of the stabiliser. This is to be fitted in the particular conditions present in the operating room, and currently there exists no navigation tool to facilitate the positioning of the mechanism.

The bones are practically rigid, the meniscus – a cartilage positioned between the bones – is slightly susceptible to compression, however it is rather thin and therefore its compressibility is low, so the possible extent of bone convergence in the knee joint is low.

In view of these differences it was necessary to carry out an analysis of parameter sensitivity. For the purposes of this paper, the authors understand the term of "parameter sensitivity" as the calculation of the characteristics of the change of the sum of the squares of the distance between the knee joint trajectory and the mechanism trajectory. The parameter is the distance from the right position stated in two directions. The calculated sum of the squares of the distances between the knee joint trajectory and the mechanism trajectory are presented in diagram 3.2.

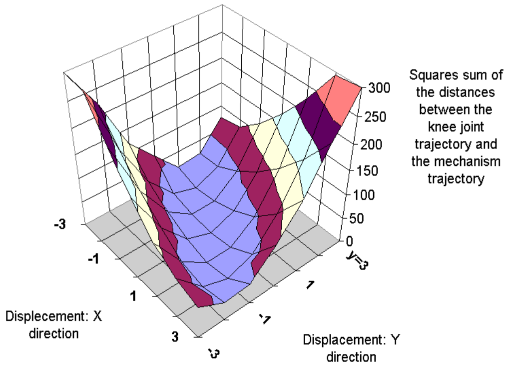


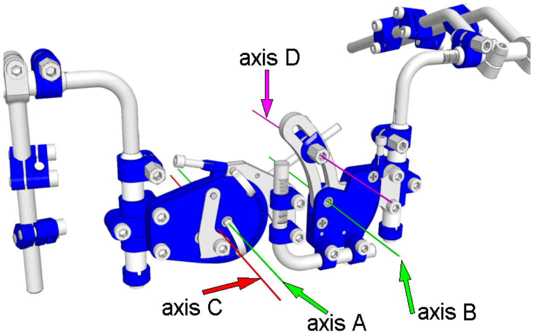
Diagram 3.2 Parameter sensitivity of stabiliser positioning.

The results of the analysis show that finding the right joint position in the mechanism has a crucial impact on the functioning of the stabiliser. The slight compressibility of the joint provides some chance of approximating certain movements and of allowing some slight load on the bone in accordance with normal physiological movement, however these values are small.

IV. CONCEPT FOR A CONSTRUCTION SOLUTION

The stage of prototype construction was preceded by the design of a virtual model (Fig. 4.1). The Catia system was used for that purpose. Modelling and simulation techniques made it possible to eliminate the errors which always occur at this stage.

The stabiliser makes it possible to move the lower leg relative to the thigh throughout the treatment. This movement is closely similar to the natural physiological movement, so the union of the fractured bone can be restored without interruption, and the postulate of functional treatment is realised. Moreover, this makes it possible to make adjustments which can bring the movements guided by the stabiliser in line with the natural, physiological movements of the joint, with a degree of inaccuracy which can be compensated for by the natural compressibility of the joint.



Fot. 4.1 Virtual Catia model of knee joint stabiliser.

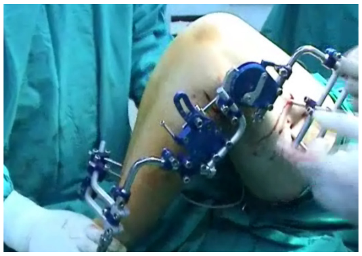
The physiological movement is realised by active joints which make movement possible within a limited, adjustable range. It is possible to block the stabiliser in any selected position without changing the selected range. The range of movement can be changed by settings of 10° each. The range of joint flexure is $\alpha \geq 130^o$, i.e. α_A=100º for the main joint A, and $\alpha_B \geq 30^o$ for the polar rotation of joint B. The value of the polar reflection depends on the individual characteristics of the knee, and therefore the actual range of joint flexure may vary from patient to patient.

All elements of the stabiliser are symmetrical and may only be used in this configuration. During fracture treatment, the stabiliser should only transmit loads resulting from the flexing of muscles and ligaments, the weight of the part of the leg below the fracture, and of accidental loads. The stabiliser is not suitable for transmitting the load caused by the weight of the body resting on the leg while walking. This results from the distribution of forces within the joint according to position [15]. Stabiliser tested on the artificial models of knee joint agreed with the theory.

V. First Clinical Trials

The stabilizer for the functional treatment was used for the first time in the Clinic of Orthopaedics and Rehabilitation of the Warsaw Medical School. The stabilizer was used in the treatment of three patients with periarticular fractures of knee joint. The results achieved were much better than in treatments of this type of fractures using the classic methods. During the time of treatment the range of physiological movement of knee joint was increased gradually up to the 90 degree bending angle. Implementation of functional treatment shortened the time of periarticular fracture treatment up to 8 weeks, and also it restored the full function of the knee joint.

Fot. 5.1 First clinical stabiliser trials.



Fot. 5.2 First clinical stabiliser trials.

Conclusions

The paper presents a concept of an orthopedic stabiliser solution to be used for treating periarticular fractures of the knee joint. The design of the device is documented by experimental research of the knee joint kinematics. Experimental and simulation research suggest the use of a four-bar linkage mechanism. Experimental research has also made it possible to define the range of adjustment to adapt the stabiliser kinematics to the individual properties of the patients. A sensitivity analysis points to the fact that the stabiliser must be positioned very precisely during installation.

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