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Telemetric and Holter measurement systems aiding lengthening of limbs with the use of external stabilizers

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This paper describes the use of Holter (marked HSP) and Telemetric (marked TSP) measurement systems used for monitoring of deformations in an Ilizarov-type stabilizer in clinical conditions. Measurement data is constantly transmitted to a stationary receiver unit via a radio link for TSP and via a periodic cable link for HSP. The article presents the use of the above-mentioned measurement systems supporting treatment by means of identifying problems and clinical difficulties, constructing biomechanical characteristics, it also aids the Clinical Control Program and other supporting applications.

Key words: biomechanics, long limb lengthening treatment support methods, Telemetric (TSP) and Holter (HSP) measurement systems, biomechanical characteristics

1. Introduction

This paper presents a short description and use of two control and measurement systems with data transmission and acquisition based on Holter and telemetric methods accordingly. Their work has decreased the number of complications during treatment and long-limb lengthening therapy. In order to set the rate of limb distraction properly, an analysis of deformation and distribution of forces for certain elements of the stabilizer is necessary. Such an analysis is conducted along with medical assessment of the lengthening therapy process [1], [3], [4].

The use of wireless measurement systems applied full time to monitor certain chosen parameters of the Ilizarov-type stabilizer allows constant observation of its functioning during treatment to assure its proper work. This, in turn, allows us to describe indirectly the phenomena, which occur during lengthening of the treated limb.

It is usually not recommended to intervene in the treatment, contrary to identifying all factors, which, in turn, leads to increase in effectiveness of treatment. This identification may apply to such phenomena and processes as proper setting issue, control and application of the stabilizer itself; it may also be a control tool for monitoring correctness of its work in clinical conditions. Moreover, it may be used to assess the treatment in its various stages and levels. Finally, measurement systems may be a basic source of information for purposes of data storage and predictions of treatment duration.

2. Material and methods

The Ilizarov-type stabilizers with the above-mentioned measurement systems were used in children aged 10–18, suffering from idiopathic lower leg discrepancy of 4–7 cm. Two different wireless measurement systems have been used to monitor constantly their working parameters [2], [5], [6]. Patients were subjected to single level limb lengthening, following a surgical procedure of corticotomy – making an incision on the bone and fracturing it without damaging the continuity of the medullary cavity.

Deformation of Kirshner's wires and telescopic rods was measured in periodic and daily cycles for different stages of treatment and stabilizer's work. Tensometric sensors were used to collect data. Novelty of those measurements was based mostly on the constant character of monitoring during the long treatment period in clinical conditions (figure 1). It is worth mentioning here that data transmission as well as communication with the measurement registration device are continuous for the radio link (telemetric registration type) for TSP, and periodical via cable link (Holter registration type) for HSP. Uniqueness of those measurement systems is constituted by the fact that the patient was allowed to move around and engage oneself into various physical activities virtually without a limit. In this case, "wireless" refers to lack of wires, physically connecting the patient to the receiver device in the surroundings. Of course, the sensors themselves have wires connecting them to the registration device.

Those innovatory measurement systems were designed, made and set working at the Cracow Technical University, Department of Experimental Mechanics and Biomechanics, in cooperation with domestic electronic companies. Because of limited space, those have not been dealt with in the article. Their description and technical data can be found in publications [2], [5], [6].

3. Clinical observation and analysis

Intensive cooperation of clinic staff such as doctors, ancillary personnel, patients themselves and their families allowed measurements in five full treatment cycles of clinical cases. Further on, the results were recognized and divided according to specific states of patient activity. Resulting data packages, diagrams and charts contain sequences of deformation changes ε_{PT}, ε_{DK}, and after further changes of distraction σ_{PT}, σ_{DK} [MPa] in telescopic rods and Kirschner wires. Some additional detailed descriptions of patient physical activities with indication of their times proved very helpful. Various stages of several months of treatment were described, and the following periods of patient activity were isolated: **motion (M)**: moving around the ward, walks; **sitting (St)**: meals, lessons, rehabilitation, free time; **lying down (L)**: resting, rehabilitation, falling asleep; **sleeping (Sl)**, **failure (F)**: fall, climbing stairs, impact.

Pictures of two patients undergoing treatment are shown in figure 1. It is worth mentioning that those two patients have two different measurement systems: Holter and Telemetric.

Taking account of the character and subject of the research presented, information on course of deformation/distraction changes for stages of lengthening and stabilization in subsequent stages of activity was not presented here.

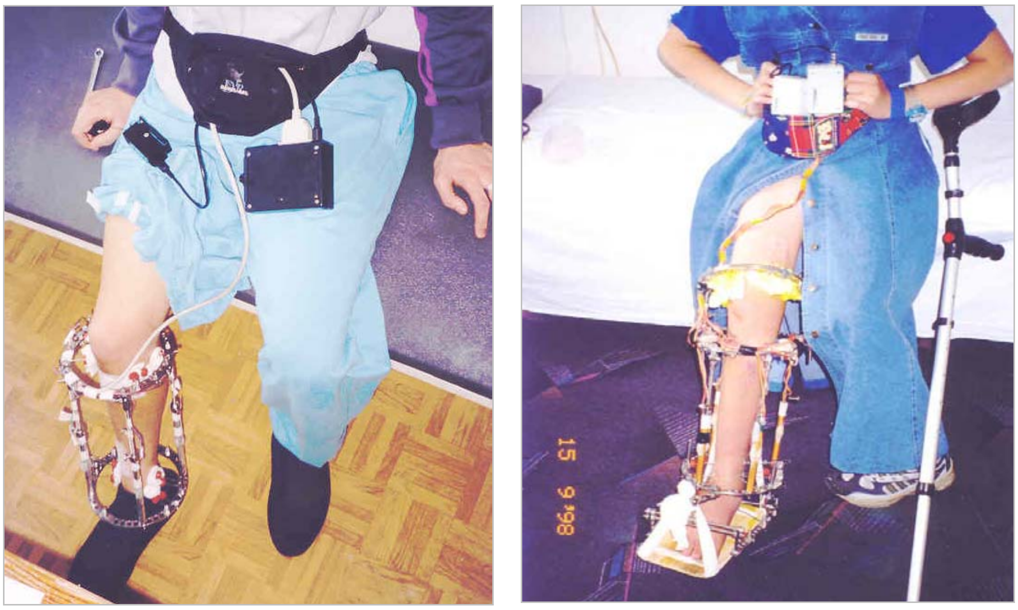

Fig. 1. Patients No. V and No. IV during clinical measurements with Telemetric (TSP) and Holter (HSP) measurement systems

Preliminary analysis conducted on the data with additional description of individual physical activities allows predetermining and forecasting the patient's state of motion.

It is also possible to observe a specific way the telescopic rods work, as well as the level of changes in deformation/distraction in relation to the type of rod. Some characteristic distraction levels appeared in individual rods: σ (PT1) > σ (PT2) > σ (PT3) > σ (PT4) for majority of clinical cases as well as lab simulations. Rods No. 1, 2 (PT1, PT2) are front rods, and rods No. 3, 4 (PT3, PT4) are back rods for the front view of the patient.

In the course of further analysis process, it becomes apparent that the gathered data cannot directly describe the condition of newly forming callus in the fracture crevice. This data is an easily available source of information, which may serve to control the appliance stability or correctness of desired and actual settings during the lengthening process.

As time passes, in the stabilization period one may observe a slow decline of deformation/distraction in majority of telescopic rods. There have also been cases where the structure got warped and courses oscillated around a certain average value, or even grew locally. Average levels of distraction are comparable in both stages of treatment: lengthening and stabilization. It is so because of very high initial levels, which formed in the point where the soft tissue reached its maximum length or because of lack of relaxation effects in time, for this period. Average values of distraction/deformation are fully described in [6]. Data and results presented there (see: appendix) are explained so clearly that they do not require any additional comment or interpretation. The influence of the building and mineralization of the new bone tissue in the distraction crevice on the general decrease of distraction/deformation levels in telescopic rods, due to the bone structure taking over support of some portion of weight, is a very interesting issue. Unfortunately, lack of means to assess the quantity of rebuilt bone tissue and as result – the change of its rigidity (*EA*, *EJ*) from zero up to that of a normal healthy bone make such evaluation or further interpretation of results virtually impossible. Therefore, this matter still awaits further identification as well as a quantitative and qualitative description.

Laboratory simulations would make an excellent complement of the clinical research, but in consideration of the major goal and range of this study they were disregarded further. Experimental research was conducted in parallel with development of numerical calculation models describing the complex design and behaviour of the entire biomechanical system consisting of the treated limb and the apparatus. Those models were used for comparative calculations, using the MES method, and for additional supplement of experimental methods, possible only using the numerical method.

4. Telemetric (TSP) and Holter (HSP) Measurement Systems in support of limb lengthening – discussion

As mentioned earlier, the main goal of the research was to provide the apparatus support to lengthening treatment. This is possible by constant monitoring of the stabilizer, using the above-mentioned measurement systems adapted to clinical practice. This in turn allows introduction of guidelines for initial settings and further control, or further research leading to the development of certain control programs, creation of biomechanical characteristics describing both operation of the stabilizer and settings of medical treatment parameters.

Basic goals achievable due to those measurement systems are as follows:

- control of initial settings and stabilizer configuration,
- support, optimization and forecasting of treatment stages,
- observation and monitoring of the lengthening process,
- identification and correctness of stabilizer operation.

In summary, examples of implementation of both systems in the form of their certain functions and applications may be presented.

4.1. Identification of problems and clinical difficulties

This is nothing but finding and registration of certain critical conditions like sudden uncontrolled changes of deformation levels in rods. This phenomenon may indicate a premature adhesion of fractured bone tissue, or that the corticotomy was not performed properly. Failure of the biomechanical system, mainly the stabilizer, was registered for patient number III. Measurements played a very important diagnostic part. This pathology is presented in figure 2a showing two parts of measurement files for the third day of distraction (left side of the graph), and the seventeenth day of distraction (graph right side).

A distinct difference is visible here for individual telescopic rods strongly compressed, stretched and squeezed as a result of large deformation of the stabilizer itself.

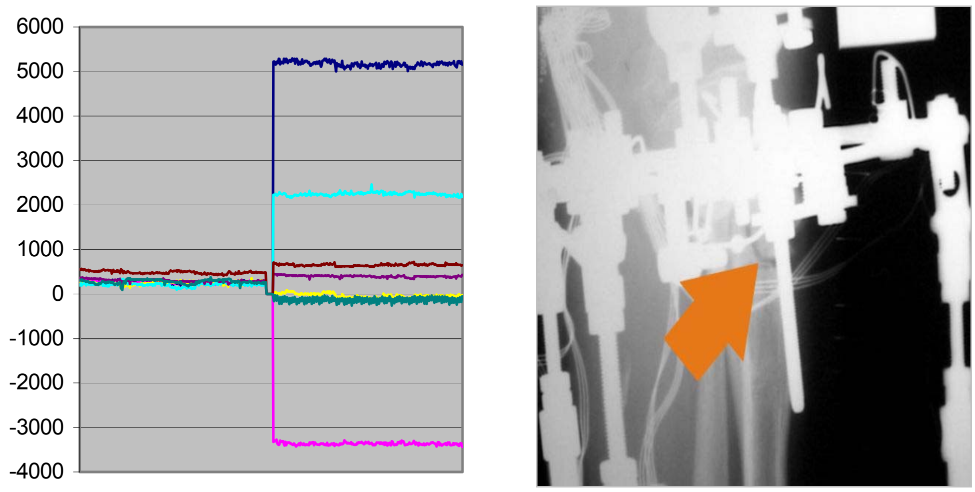

Fig. 2. Deformation ε_{PT} of telescopic rods with an incomplete corticotomy.
Caution: axis of ordinates is described by HSP receiver's own units used by the measurement system (a).
Radiograph showing the incomplete corticotomy side-view (patient No. III) (b)

Receiver damage or wrong course of treatment was suspected. This information was communicated to the doctors in charge of the patient. Those concerns were fully confirmed after an X-ray picture analysis on the 18th day of distraction (figure 2b). It turned out that the corticotomy procedure on the lengthened bone was not performed completely, that is, the bone was not fully cut through the compact layer on the back side of the extremity. Lack of growth of the not fully cut tibia is visible on the X-ray slide (see: arrow).

4.2. Control of treatment course

Among other top priorities was this of being able to create various biomechanical characteristics: population-based, experimental, clinical and other, describing limb lengthening in different ways. Owing to those characteristics there is a possibility of supporting the treatment process by optimization of settings for chosen parameters, characteristic of a given disease entity. This, in turn, assures significant acceleration of the treatment and improvement of treatment quality. There are some experimental characteristics shown in figure 3. They have been used for assessment and prediction of treatment. Those characteristics were built based on charts describing successive stages: lengthening (DYS) and stabilization (STA) of the limb.

Created characteristics were named: *rod-distraction* and *rod-stabilization*. These characteristics were developed based on experimental research conducted in clinical conditions and their creation was possible thanks to the above-mentioned measurement systems and constant measurements of telescopic rods' deformation during
a treatment period of several months.

Data collected from telescopic rod number 2 was used for computation of characteristics. Rod number 2 (PT2) was chosen as representative after an initial quantitative and qualitative analysis of resulting deformations.

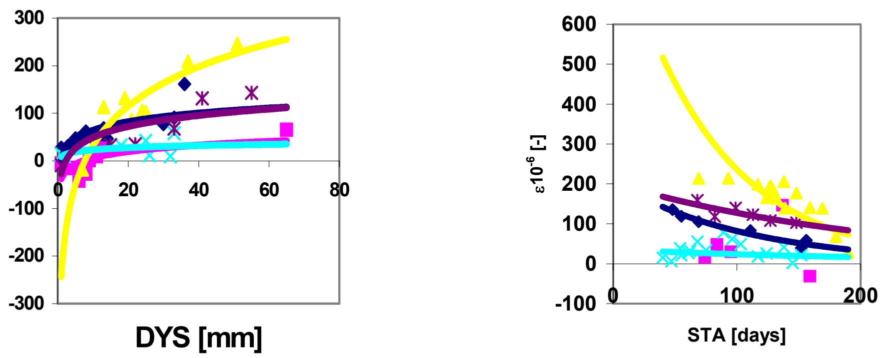

Fig. 3. Approximation functions of deformation change $\varepsilon_{PT}\cdot 10^{-6}$ in representative telescopic rod No. 2 (PT2) during: distraction *DYS* [mm] (a), stabilization *STA* [days] (all patients) (b)

Primary task of diagnostics based on rod-distraction characteristics (figure 3a) computed from the above-mentioned functions for distraction stage is estimation of correct functioning of the stabilizer in clinical lengthening treatment.

Rod-stabilization characteristic was computed based the on above-mentioned functions for distraction stage (figure 3b). It describes deformation state of a chosen rod. This description is meant to determine such a level of deformation in a chosen representative telescopic rod (or rods) which together with qualitative analysis of X-ray images at a given point of treatment allows a decision to be made whether or not the appliance should be dismantled. This is possible due to the deformation reduction in telescopic rods when a new bone tissue starts to carry the main load of body mass and muscle force. Upon achievement of minimum deformation level, the stabilizer may be removed. Of course, high levels of deformation registered in the final stage of stabilization may testify to the lack of bone adhesion.

In the next stage of the study, a non-dimensional, universal union quality index (W.J.Z.) is determined based on a set of various characteristics: experimental, population-based, clinical and other, which could be used to compare and verify the suitability of the process at each stage of treatment.

4.3. Develpment of a clinical control program

A Clinical Control Program may allows the medical staff to conduct and forecast the patient's treatment in a variety of medical and technical aspects of appliance settings, it may also be a diagnostic and prognostic tool in aiding decisions on treatment and removal of the device. Therefore one should conclude that such a system should be useful in a general system of treatment support. Databases containing identical or very similar clinical cases were developed based on data obtained from the Orthopedics and Rehabilitation Clinic of Jagiellonian University's Collegium Medium in Zakopane, such as limb contraction, patient's age, height and weight as well as distraction magnitude and stabilization period duration.

The data collected allowed us to derive approximation functions for distraction time, based on the contraction magnitude and stabilization period duration being dependent on patient's weight, height and age. Those characteristics are of course computed based on a certain considerable population containing also five cases examined with the aid of HSP and TSP measurement systems. "Mathcad2000" was used to compute approximation functions. The program also served for choosing the best interpolation function.

Based on the clinical database, the functions for duration of distraction and stabilization were computed (table 1).

Table 1. Approximation functions for distraction and stabilization

Distraction = $82.964 - 192.842 \frac{1}{(x+1)} + 0.234 \cdot x^2$	where x is contraction [cm]
Stabilization = $162.064 - 475.504 \frac{1}{(x+1)} + 0.018 \cdot x^2$	where x is age [years]
Stabilization = $135.587 - 833.299 \cdot 10^3 \cdot \frac{1}{(x+1)} - 5.442 \cdot 10^{-3} \cdot x^2$	where x is weight [kg]
Stabilization = $327.06 - 2.247 \cdot 10^4 \cdot \frac{1}{(x+1)} - 1.913 \cdot 10^{-3} \cdot x^2$	where x is height [cm]

Duration of distraction period is calculated based on one parameter, while that for stabilization is determined based on three different parameters. The program computes and displays an average stabilization duration value for identical weight 1/3 for particular above-mentioned variables. Of course, this relation can be modified at any given time. In figure 4, some exemplary data of a virtual patient was given, and based on this program, the time of distraction and stabilization was calculated. So, the expected distraction period was forecasted to be 48 days and stabilization period 135 days. Total time of hospitalization was183 days.

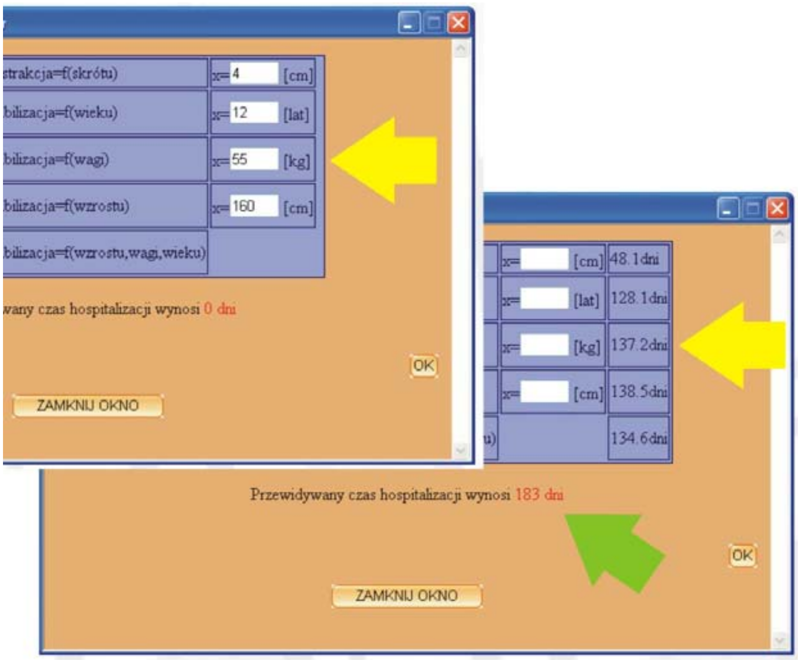

Fig. 4. View of individual windows of the program in the process of calculating the predicted distraction, stabilization and hospitalization times

The Clinical Control Program allows testing and verification as well as database supplementing. It is worth mentioning here that the program written in "Java" is commonly used to create web components and may be easily used locally. The central server of the clinic may contain main data and password-protected applications, accessible via all popular browsers like Explorer or Navigator. Due to such a setup, a doctor in any given location within the clinic has access to the program-database in the following ways: passively by creating reports and queries from the database, and actively by modification of the case studied. When both quantity and quality of the data studied are sufficient, a doctor has a chance to notice certain regularities in the processes observed and the possibility of creating universal statistical models. Such models allows comparison of patient's treatment results with a theoretical treatment course.

Owing to this program and other similar ones, a decision taken by doctor is additionally supported by impartial exact knowledge that results from mathematical and statistic analysis of a given clinical case. Finally, all this improves the treatment quality.

4.4. Verification of stabilizer operation and settings

The analysis of the stabilizer operation permits identification and elimination of faults related to improper assembly. Further, it enables choosing the appropriate appliance elements and settings. Based on the above analysis it is also possible to detect unsuitable course of distraction applied over the telescopic rods, which may result in sudden and unpredictable changes of rod deformation that can even lead to damage to a newly-formed bone tissue in the fracture crevice. The diagnostic function of measuring systems is visualized in result of previous disturbances in extremity lengthening process and it contributes to improvement of the stabilizer operation and its further settings.

As is well known, an optimal lengthening pace ranges from 0.25[%] to 0.50[%] of an initial segment length per day. Practically it is 1 [mm/day] which is divided into four doses, that is 4×0.25 [mm/day]. Such lengthening pace was set for patient No. I. Unfortunately, the patient, who following a proper training, adjusted the appliance by herself and made a mistake after thirty odd days of distraction. She started shortening of the telescopic rod No. 3 (PT3), maintaining the same pace, but the process itself was opposite to that desired and carried out earlier. Measurements (figure 5) followed immediately, but they differed considerably from those obtained previously.

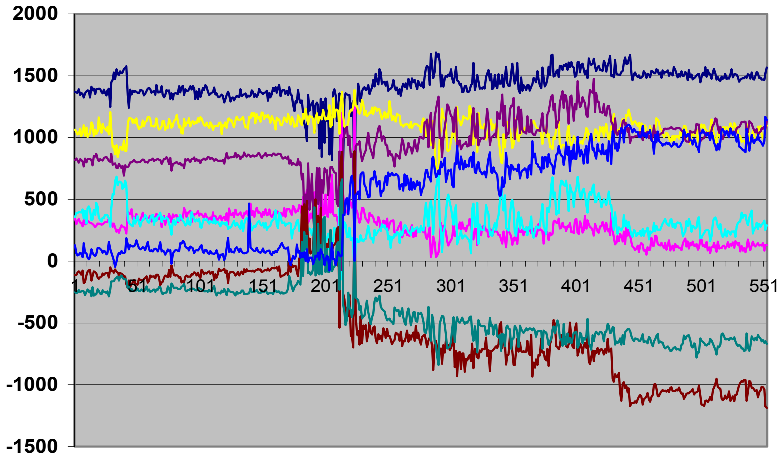

Fig. 5. Diagram showing erroneous distraction setting on one of the telescopic rods (patient No. I).
Caution: Both axes are described by HSP receiver's own units used by the measuring system

Therefore a sudden disturbance in the values measured is visible on the graph in the 1/3 of the curve, representing an increased deformation levels of telescopic rods. One of those rods is strongly extended (negative runs denoted by "minus"), it is probably the one with wrong distance settings (shortening). After interviewing the patient and explaining the reason for those anomalies, the problem was solved and all reverted to a previous state. In this process, some very valuable information was gained about clinical application of stabilizers, which would not be possible without a considerable aid of Holter (HSP) and Telemetric (TSP) measurement systems. Their use also enabled identification of actual condition and specification of indications and guidelines for further structural modifications. They can be itemized as follows:

• High levels of tension in wires were accompanied by a distinct bending of the stabilizing ring, which may be responsible for an unacceptable flexibility of the entire system. This in turn can lead to the damage to the area under treatment. It is necessary to improve rigidity of the rings, making them resistant to bending and twisting.

• It is advisable to introduce adjustment heads for initial precise setting of tension in the Kirschner wires. Uniformity of tension plays a key role in the treatment success in this method. A wide-range studies were carried out on modification of design of adjustment heads to achieve the precision of operation. This led to the development of a new solution filed for patenting in 2002 (RP nr P-357845).

• It would be advisable to change the conception of stabilizer design in such a way as to combine its two main functions: stabilization and lengthening. This will result in constructional simplification and improvement of appliance stability.

5. Conclusions

A wide-range, multistage research with the use of telemetric (TSP) and Holter (HSP) measurement systems showed that constant monitoring of motion of a biomechanical system consisting of the treated limb and the apparatus is possible, and such a monitoring is aimed at aiding the process of limb equalization.

The research conducted allowed us to identify various stages of treatment as well as various activity states of the patient, all helpful in assessment of treatment progress. In the case of experimental research conducted in laboratory conditions, it became possible to recognize and to assess the operation of Ilizarov stabilizer as a construction. The research demonstrated that there exists the possibility of changing the settings and adjusting precisely the elements responsible for the function of adjustable axial flexibility as well as overall effectiveness. The research enabled the development of experimental and population-based characteristics and development of the Clinical Control Program. Those characteristics made the control of the limb lengthening easier allowing a non-invasive evaluation of mineralization process and bone union advancement in order to settle the point of safe removal of the appliance, without exposing a patient to X-rays. The complementary Clinical Control Program prepared in a close connection with other medical diagnostic indicators during treatment is a tool of fast visualization and recognition of certain regularities in the treatment process as well as makes certain predictions about the date and quality of treatment possible. The population-based database allows certain optimization and assessment of the results obtained.

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