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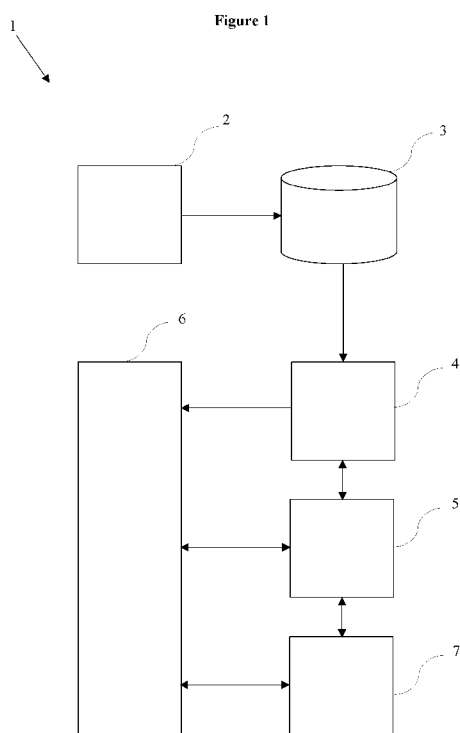
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(54) Title: A SYSTEM FOR BONE FRACTURE AND CORRECTION TREATMENT



(57) Abstract: The present invention relates to a system (1) which is all about attempts to adapt the bones to anatomical alignment by providing prescriptions of measurement, analysis, planning, surgery, fixation and correction for use in the treatment of disordered bones with the aid of an external fixation device and calculates the amount of correction by controlling the bones' correction steps.

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A SYSTEM FOR BONE FRACTURE AND CORRECTION TREATMENT

Technical Field

10 The invention relates to a system for use in the treatment of disordered bones with the aid of an external fixation device, providing recipes for measurement, analysis, planning, surgery, fixation, and correction, to adapt the bones to anatomical alignment, and to calculate the amount of correction by controlling the level of bones.

15 Previous Technique

'Ilizarov Circular External Fixator" system developed by Ilizarov was first used in the treatment of bones in the 1950s. With the help of the trays used in this system, gradual bone alignment disorders have been started to be corrected. The aim is to measure
20 misalignment in the bones and to correct this disorder with the fixation material attached to the bone for the amount of the detected disorder. For this, the necessary amount of correction should be calculated and the gradual malfunction of the bones should be corrected gradually. In the present system, vertical axis movements are provided by 3 or 4 grooved rods which are connected between the tables for 6-axis
25 motion required for bone correction, while correction is performed by connecting additional apparatus for angulation, translation and rotation according to the bone's motion point (CORA). In this system, measurements and calculations are performed manually.

30 Then, in the early 1990s, again with the help of trays, this time again when using the connected arms of the hexapod array, but also with the X-ray films to measure the array defect and the measurement of the computer using the software to correct the hexapod system to correct the distortion. It is used as a prescription for how to use the handheld device.

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5 Owing to the hexapod arrangement of the 6 rods, the ends of which are articulated,
there is no need for additional parts for 6-axis trimming movements. However, the
angular positioning of the arms according to the hexapod arrangement according to
the amount of correction necessitates longer arm requirements and associated arm
change in high amount movements. In addition to the manual measurements in the
10 system, the angular arrangement of the legs causes very small measurement errors to
cause large deviations in the process. In this system, correction motion center (CORA)
is determined manually by measurements and drawings in the user description, which
makes repeated revisions in the system inevitable in case of possible errors. In this
system, the main difference from the previous one is that the calculations are made
15 with the help of computers.

Finally, in the previous technique, octopod systems with eight arms and a trapezoidal
edge and then a movement mechanism in vertical lines on square ground and
navigation software for measurement are used. This system works with cylindrical
20 arrays as before.

There are ball joints or hinged joints at both ends of the grooved bars used in existing
software supported systems and the joints move with the movement of the bars.
Consequently, transportation in all existing systems; depending on the compression
25 of the joints. On the other hand, in some conventional ring systems, locking joints are
used at the end of the grooved rods and the joints are locked in the end position of the
frame so that load can be transported with fewer rods.

In the software, the measurement and calculation works on bringing the axes to the
30 desired position.

In the present systems used today, frames are prepared as cylindrical. Because in non-
cylindrical structures, additional angles and lengths are entered into the circuit for
calculation. This makes calculation and control difficult.

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5 Due to the abundance of human factor in the existing systems and the need for
experience due to the arrangement of the devices over time, even small errors require
revision, this situation increases the use of x-rays, increases the cost, and results
damage on health of people and the environment due to radiation exposure to the
patient and the environment
10
Therefore, there is a need for a system that can overcome the problems above before
the surgery and provide the movement of the bone fragments on the 6 axis and adapt
them to the anatomical order required and ensure that the movement of the bone
fragments can be visualized while the bones are corrected on the 6 axis and can be
15 used with less rods.

Brief Description of the Invention

The object of this invention is to treat deformity treatment which provides correction
20 prescriptions and simulations for use in adjusting the fractured bone fragments caused
or formed by fractures due to primary or secondary causes to the anatomical alignment
required, and by following the movement of the bone fragments while finalizing the
bone fragments to enable the analysis of the correction.

25 Detailed Description of the Invention

A system for the treatment of bone fracture and correction realized in order to attain
the aim of the present invention is illustrated in the attached figure.

30 **Figure 1** - Is the schematic view of a system used in the treatment of bone fractures
and correction.

Parts shown in the figure are numbered one by one and the corresponding numbers
are given below.

35

1. System

- 5 2. Interface
- 3. Database
- 4. Dimension calculation unit
- 5. Unit of analysis
- 6. Display element
- 10 7. Application unit

A system according to the invention for the treatment of deformity (1),
 -at least one interface (2) in which personal information of the person(s) undergoing deformation treatment is entered,
 15 - at least one database (3) in which X-ray films containing a coin and the coin information and dimensions used in the films are stored, with personal information entered on the face (2) and the person / persons to be treated,
 - at least one dimension calculation unit (4), which calculates the actual dimensions on the x-ray films of the person (s) using the coin and dimension information on the
 20 database (3),
 - at least one analysis (5) unit that determines the type and amount of deformity by performing navigation operations on the films, measuring and analyzing deformities and providing correction information to the user as a result of the analysis (5),
 -at least one display element (6) in which the results obtained by the analysis unit (5)
 25 are shown.
 -data base (2), the person to be treated and the parameters of appropriate type depending on the information in the frame and the frame to be used in fixation and implantation of fixation material included in the proposal, if necessary, contained in the proposal osteotomy, deformity validation remediation planning for a prescription
 30 (RX), which determines the information during the period of treatment dynamization (dynamization) that you would need based on the information it receives from the user the device will change when used in the treatment of fixation used in determining part of, it contains at least one application module (7) that shares information with the user about when to lock the joints at the end of the rod.

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- 5 In the preferred embodiment of the present invention, the user information such as name, surname, gender, age of the patient to be treated is entered via the interface (2). On the interface (2), status information such as extremity, indication, clinical rotation, limb outer diameter, and proposed surgery date are entered. The information entered via the interface (2) is recorded in the database (3) for use.
- 10 The system (1) of the present invention is defined in the database (3) by the dimensions of the coin information of each country. Thanks to the coin types stored in the database (3), the coin information found in the extremity film during pre-op x-ray shooting is calculated by using the size calculation unit (4) to calculate the actual
- 15 dimensions of the images on the film. For this purpose, it is expected from the user to enter the country and coin information via the interface (2). The dimension calculation unit (4) receives the measurement information of the coins from the database (3) using the country and currency information entered via the interface (2).
- 20 In the preferred embodiment of the present invention, the size calculation unit (4) uses the coin information contained in the database (2) and the coin information contained and specified by the user on the shot film. The user defines the coin information on the film by punctuation and markings and the information defined is used in the dimension calculation unit (4). The dimension calculation unit (4) calculates the
- 25 actual dimensions in the film, which is preferably x-ray, by analyzing the information recorded in the database (2) by the user-defined information on the film.
- In the system (1) of the present invention, the analysis unit (5) performs the measurement and analysis of the deformity of the person to be treated according to
- 30 the defined angles and measurements and decides the types and amounts of the deformity using the navigation calculations made by the dimension calculation unit (4). The analysis unit (5) informs the user of the results obtained or the existing x-rays presented to the user or the display element (6), which is simulated according to the deformity measurements defined by the user, on the display element 6, preferably a
- 35 screen. The user can use the data obtained by the analysis unit (5) directly or by making changes on it.

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In the preferred embodiment of the system (1) according to the invention, the application unit (7) offers two different options, robotics and analog. The application unit (7) allows the user to modify the data presented in the analog unit, the robotic unit. In this way, the user can apply any recipe in the real transaction after virtual transactions.

In the preferred embodiment of the present invention, the application unit (7) first proposes to the user in robotic mode a frame of the type and parameters suitable for the patient to be treated. The application unit (7) provides arm and ring information in the type information. The application unit (7) provides position, limb and frame ratio, bone and frame ratio, and deformity ring and connection ratio in the fixation parameters.

The application unit (7) prescribes at what stage of the treatment the insertion or removal of the arm and insertion or removal of the ring part, the change in the portion of the ring to be modified. The application unit (7) also prescribes when the frame is to be used as a full-ring, partial-ring, hybrid or single-sided fixator type, or when and how to switch from one to another. The application unit (7) also prescribes when the joints at the ends of the rods will be locked and released, depending on the insertion or removal of parts in the frame. The application unit (7) prescribes when the tilted arms are to be compressed or released for dynamization and when the joints at the ends of the arms are fixed and released.

In the robotic mode, the application unit (7) also gives recommendations for fixation materials and implantation of the frame to be used during the fixation of the bone. The application unit (7) provides the user with frame connection and implantation data, while providing material information such as screws, pins and clamps to be used during the fixing process.

In the preferred embodiment of the invention, the administration unit (7) proposes an osteotomy in the most suitable location, shape and method according to the deformity

5 analysis, if necessary for treatment. The application unit (7) also provides connection and positioning information for the osteotomy apparatus to be suitable and combined with any fixation device such as "Adam Frame", the manner of attachment of the apparatus to the fixation device and the positioning of the osteotomy prescription to be applied. The application unit (7) provides the user with osteotomy type, method,
10 location, and osteotomy guide connection information to the frame.

The application unit (7) also proposes correction recipe to the user by planning the deformity correction according to the Paley principles. The application unit (7) manages the frame position by determining the days and amounts of movement of the
15 arms. In this way, correction of deformity is provided.

In the system (1) of the present invention, the application unit (7) adds to the information of correcting the amount and dates of the arm change for the self-locking operation with the arms of the frame, depending on the period of dynamization of the treatment received by the user. The application unit (7) makes additions to the recipe
20 information depending on the rigid or dynamic fixation information received from the user. In the application unit (7) the user can switch between as many rigid and dynamic as he wants. The application unit (7) preferably asks the user to specify the pass information in a calendar.

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In the preferred embodiment of this invention, the fixation device used in conjunction with the system (1) is Adam Frame with a modular ring and a locked articulated arm structure. The application unit (7) determines the whole frame or with which parts it will replace for the correction period in the fixation device. The application unit (7)
30 also determines the complete or partial replacement schedule and part subtraction or addition within the fixation device after the correction period. The application unit (7) determines the periods of insertion or removal of the ring to be made in the frame, the insertion or removal of the arm, the locking periods of the joints at the arm ends.

35 In the system (1) of the present invention, fixation, osteotomy, verification and changeover processes are performed. The application unit (7) shows the frame change

- 5 according to the correction plan on the display element (6) as a frame simulation on the patient's film. The application unit (7) also shows the exchange of representative bone fragments according to the correction plan on the patient's film (x-ray) in the imaging element (6) at the desired time intervals, preferably day by day. The application unit (7) can display simulations on the display element (6) in two-dimensional (2D) and / or three-dimensional (3D). The application unit (7) shows the simulations on the patient's films (x-ray) and / or the limb picture. In another preferred embodiment, the application unit (7) shows the simulation with the bone and the frame it forms on the display element (6).
- 10
- 15 The system (1) according to the invention also allows the correction plans generated by the application unit (7) to be printed out. In the system (1) according to the invention used in the treatment of deformity, necessary preparations are made by using frame, fixation parts and osteotomia guide parts depending on the correction prescriptions created by the application unit (7). After the operation, correction prescription determined by the application unit (7) is applied or post-up measurement, analysis and planning operations are performed by using x-ray films. When the correction is finished in the system (1), the control unit and the dimension calculation unit (4) recalculate and the analysis unit (5) accepts the correction if the amount of deformity in the imaging element (6) is zero or a predetermined, acceptable limit. If
- 20
- 25 the amount of deformity is not within the determined limits, the analysis unit (5) triggers the application unit (7) to generate a correction recipe. Since the correction plan is made according to Paley principles, the correction result is also measured according to these criteria.
- 30
- 35 In the system (1) of the present invention, the application unit (7) performs measurement and analysis of deformity on control films and monitors their simulations. The application unit 7 comparatively simulates the pre-op and post-op control results in the simulation and reports the results. The application unit (7) prepares a report according to the result. Application unit (7) in the report; pre-op deformity measurement results, control x-ray measurements and results, pre-op x rays

5 and final control x-rays, comparison pictures, and, if available, the revised correction recipe.

It is possible to develop a wide variety of embodiments of a system (1) used in the treatment of bone fractures and correction according to the invention, the invention
10 being not limited to the examples described herein, but essentially as set forth in the claims.

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CLAIMS

1. Used in the treatment of deformity,
- at least one interface (2) in which the personal information of the person (s) undergoing deformation treatment is **entered**
 - 10 - at least one database (3) in which X-ray films containing a coin and the coin information and dimensions used in the films are stored with personal information **entered** on the face (2) and the person (s) to be treated.
 - at least one dimension calculation unit (4), which calculates the actual dimensions on the x-ray films of the person (s) using the coin and dimension information on the
 - 15 database (3),
 - at least one analysis unit that determines the type and amount of deformity by performing navigation operations on the films, measuring and analyzing deformities and providing correction information to the user as a result of the analysis (5)
 - at least one display element (6) in which the results obtained by the analysis unit (5)
 - 20 are shown; and
 - depending on the information of the person to be treated in the database (2), propose the fixation material and prescription information for correction planning, proposing fixation material and implantation to be used for fixing the frame and frame in appropriate types and parameters, proposing osteotomy if necessary for treatment.
 - 25 **characterized** by a system (1) characterized by at least one application module (7), which determines the period during which treatment will be required (dynamization) in accordance with the information received from the user, and shares the information about when the parts used in the treatment will change within the fixation device frame.
 - 30
- The system (1) as in Claim 1, characterized by the interface (2) on which patient information such as name, surname, gender, age of the patient to be treated is entered.
3. With the interface (2) in which case information such as extremity, indication,
- 35 clinical rotation, limb outer diameter, and proposed surgery date are entered A system (1) as claimed in claim 1 or 2.

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4. A system (1) as in any one of the above claims, **characterized** in that the database (3) of each country is defined by the size of the coin information.

5. The dimension calculator as claimed in claim 4, **characterized** in that the coin variants stored in the database (3) calculate the actual dimensions of the images on the film using the coin information contained in the extremity film during pre-op x-ray shooting, a system (1).

6. A system (1) according to any one of the preceding claims, **characterized** by a size calculation unit (4), which calculates the actual dimensions in the film, preferably x-ray, by analyzing the information defined on the film by the user and the information stored in the database (2).

7. A system (1) as in any one of the above claims, **characterized** by the analysis unit (5) which performs the measurement and analysis of the deformity of the person to be treated according to the defined angles and measurements and decides the types and amounts of the deformity using the navigation calculations made by the dimension calculation unit (4).

8. The results obtained or the current x-rays presented to the user or the deformity simulated according to the user-defined deformity measurements on the screen presented to the user; A system (1) as in any one of the above claims, **characterized** by the analysis unit (5) which notifies the user via the display element (6), which is preferably a screen.

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9. A system (1) according to any one of the preceding claims, **characterized** in that the application unit (7) provides two different options: robotics and analogue.

10. A system (1) as in Claim 9, **characterized** in the application unit (7) allows the user to modify the data presented in the analog unit in the robotic unit.

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- 5 11. A system (1) according to claim 9, **characterized** in that in robotic mode, the application unit (7) first proposes a frame of type and parameters suitable for the patient to be treated.
12. A system (1) as in Claim 11, **characterized** by the application unit (7)
10 providing arm and ring information in the type information.
13. A system (1) according to claim 11, **characterized** in that the fixation parameters information includes the application unit (7) which provides position, limb and frame ratio, bone and frame ratio and deformity ring and connection ratio.
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14. A system (1) according to any one of claims 11 to 13, **characterized** in that in the robotic mode, the application unit (7) recommends fixation materials and implantation of the frame to be used during the fixation of the bone.
- 20 15. A system (1) according to any one of claims 11 to 14, **characterized** by the application unit (7) providing material information such as screws, pins and clamps to be used during the fixing process while providing the frame connection and implantation data to the user.
- 25 16. A system (1) according to any one of the preceding claims, **characterized** by the application unit (7) which proposes osteotomy in the most appropriate location, shape and method according to the deformity analysis, if necessary for treatment.
17. A system (1) according to claim 16, **characterized** in that the osteotomy
30 apparatus suitable and combined with any fixation device is provided with the application unit (7), which provides connection and positioning information for the fixation of the apparatus to the fixation device and the positioning to which the osteotomy prescription is to be applied.

- 5 18. A system (1) as in Claim 16 or 17, **characterized** by the application unit (7) providing the user with the osteotomy type, method, location, and osteotomy guide connection information to the frame.
- 10 19. A system (1) according to any one of the preceding claims, **characterized** by the application unit (7) which proposes correction recipe to the user by planning deformity correction according to the Paley principles.
- 15 20. A system (1) as in Claim 19, **characterized** by the application unit (7) which manages the frame position by determining the days and amounts of movement of the arms.
- 20 21. A system (1) as in any one of the claims above , **characterized** by the application unit (7), which shows the frame change according to the correction plan on the imaging element (6) as a frame simulation on the patient's film (x-ray).
22. A system (1) according to claim 21, **characterized** in that the exchange of representative bone fragments according to the correction plan is on the patient's film (x-ray) of the imaging element (6) at the desired time slots, preferably day by day.
- 25 23. A system (1) as in Claim 21 or 22, characterized by the application unit (7) on the display element (6) showing simulations in two-dimensional (2D) and / or three-dimensional (3D).
- 30 24. A system (1) according to any one of claims 21 to 23, **characterized** in that the application unit (7) shows the simulations on the patient's films (x-ray) and / or the limb picture.
- 35 25. A system (1) according to any one of Claims 21 to 24, **characterized** by the application unit (7), which simulates the display of the simulation on the display element (6) with the bone and the frame it creates.

5 26. A system (1) according to any one of the preceding claims, **characterized** in that at which stage of the treatment the arm insertion or removal and insertion or removal of the ring part, the application unit (7) prescribes the change in the portion of the ring to be changed.

10 27. A system (1) as in any one of the above claims, **characterized** by the application unit (7), which prescribes when and how the frame is to be used as a full-ring, partial-ring, hybrid or unilateral fixator type, or when switching from one to the other.

15 28. A system (1) as in any one of the above claims, **characterized** by the application unit (7) which prescribes when the joints at the ends of the arms (rods) are locked and released, depending on the insertion or removal of parts in the frame.

20 29. A system (1) according to any one of the preceding claims, **characterized** by the application unit (7) which prescribes when the tilted arms are to be compressed or released for dynamization and when the joints at the arm ends are fixed and released.

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Figure 1

