Abstract: An external bone fixator device is provided for the treatment of a bone fracture in a patient body, in particular for the treatment of a multi-fragmentary fracture of the proximal humerus which is effective and minimally invasive for the patient. The device comprises a support structure configured for being arranged outside of said patient body, a group of fixing elements connected to said support structure and configured for being stuck in said bone for anchoring said external bone fixator device thereto; the fixing elements of said group extend along respective longitudinal axes which are transversely arranged to one another. In a version, two or more fixing elements lie in a plurality of mutually transversal planes thus defining a multiplanar stability system. Methods for the treatment of bone fractures are also proposed.
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
**External bone fixator system**

The invention relates to an external bone fixator system for the treatment of bone fractures. In particular, the invention relates to an external bone fixator device and a method which enable, with a new tridimensional and multiplanar approach, to treat a bone fracture, especially a multi-fragmentary fracture of the proximal humerus, with a great effectiveness and in a very minimal invasive way for the patient.

In the field of the orthopaedic surgical procedures, it is often required to secure two or more fragments of a fractured bone in a relatively fixed relationship to each other in order to ensure a correct merging of the fragments and thus a properly regeneration of the bone.

Different types of bone fixator devices are known for securing the bone fragments. For this purpose, a type of external bone fixator device is known comprising a first arm and a second arm which are mutually connected at an end through a pivotal joint. The device further includes a first group of pins or rods and a second group of pins or rods which transversely project from the first arm and from the second arm respectively and which are intended to be fitted to a first fractured bone portion and to a second fractured bone portion respectively.

The rods have threaded ends for engaging with the relative portions of the fractured bone. The rods of the first group of rods, and, analogously, the rods of the second group of rods, extend parallel to one other and have respective longitudinal axes so arranged as to define a single plane in the space.

A drawback of the external bone fixator device above disclosed is that it is not able to provide an adequate positional stability and thus to reliably ensure a correct and precise position of the fractured bone fragments. Such a fixator device proves to be rather ineffective and unreliable especially when three, four or more fragments
of the humerus proximal head are to be treated.
In particular, the stability of the device only depends on the capability of the rods to keep itself firmly anchored to the bone fragments. In other words, such a stability depends on the static mechanical adherence of the threaded portions of the rods which are stuck into the bone matrix. The known device so configured, with the spatial arrangement of the rods of the first group being all parallel to one other, and with the spatial arrangement of the rods of the second group being all parallel to one other, turns out to be not very reliable, stable and precise, especially when the device is subject to even minimal stress deriving from movements of the patient.

Therefore, the effectiveness of the device in the treatment of the fracture evidently is not assured at all, particularly when elderly patients are involved, whose osteal structures show rather deteriorated mechanical properties, or when patients suffering from osteoporotic pathology are involved.

Another type of bone fixator device is known which comprises a plurality of pin elements, or so called "Kirschner wires" or "K-wires", which are intended to be stuck in the bone fragments, and a plate element having coupling holes suitable for being traversed by the pin elements. The pin elements are thus kept in a relative fixed position by the plate element. The plate element, in order to properly work, need to be placed subcutaneously, and is configured for being arranged near or in contact with the surface of the humerus shaft. Evidently the use of such a device implies a treatment of the fracture which is very uncomfortable and invasive for the patient. Furthermore, a high risk of infection for the patient is associated when this device is used.

The use of simple K-wires to stabilize the proximal humerus fractures is certainly attractive for its mini-
invasiveness and for the lower risk of ischemic necrosis but is unreliable as it exposes to the risk of several re-interventions, and of the loss of the reduction due to the low stability of the K-wires during the active movements of the shoulder. Especially in elderly patients with 3 or 4 fragments fractures minimal osteosynthesis with K-wires, eventually associated with cannulated screw, in the 25% of cases undergoes an early loss of reduction. In order to minimize the risk of early loss of the reduction, the surgeon is used to delay the resumption of active movements with the consequence of articular stiffness and a risk of treatment failure.

It would be desirable to improve the known bone fixator devices and to provide an external bone fixator device and a method for the treatment of a bone fracture which enable all the above mentioned drawbacks to be overcame.

An object of the invention is also to prevent any risks of avascular necrosis of one or several fragments, and the risk of postoperative stiffness for impairment or adhesions of the rotator cuff and general risk of infection, which often arise from the prior art treatments and devices.

In a first aspect of the invention, there is provided an external bone fixator device as defined in claim 1.

In a second aspect of the invention, there is provided a method for the treatment of a bone fracture in a patient body, as defined in claim 13.

In a third aspect of the invention, there is provided a method for the treatment of a fracture in a humerus of a patient body, as defined in claim 19.

Characteristics and advantages of the invention will result from the description and from claims.

The invention can be better understood and implemented with reference to the attached drawings that illustrate some embodiments thereof by way of non-limiting example, in which:
Figure 1 is a schematic perspective view of an external bone fixator device according to the invention in a possible configuration;

Figure 2 is a schematic frontal view of the external bone fixator device in a further possible configuration;

Figures 3 to 7 schematically show portions of the external bone fixator device;

Figure 8 is perspective view of the external bone fixator device in a functioning configuration;

Figure 9 is a diagram showing a plurality of directions of interaction between the device and the bone to be treated, according to a tridimensional and multiplanar approach;

Figure 10 is a further diagram showing a tridimensional and multiplanar interaction between the invention device and the bone;

Figure 11 shows the external bone fixator device in use on a patient arm whose humerus is to be fixed;

Figure 12 shows a centring mask element intended to cooperate with the external bone fixator device.

With reference to the attached Figures, an external bone fixator device 1 according to the invention is shown, which can be used for the treatment of bone fractures, especially multi-fragmentary fracture of the proximal humerus, in an effective and minimally invasive way for the patient.

Owing to the invention a new tridimensional approach is possible for the treatment of bone fractures, in particular of multifragmentary fractures of the humerus head, which proves to be more reliable and effective compared with the prior art techniques which usually involve monoaxial systems or a plurality of mutually parallel K-wires which are kept in a stationary position by a percutaneous plate.

This is possible owing to the external bone fixator device 1 according to the invention, which is a multi planar
device working through suitable pin or rod elements which can be positioned in several and mutually different angular positions, differently to the prior art devices. In particular the pin elements can be set in at least three different orthogonal positions thus achieving an extraordinary tridimensional angular stability for the device which keeps itself firmly anchored to a bone.

As it will be disclosed in detail later on, the functioning principle of the invention device takes advantage of a multiplanar interlacement of pin or rod elements, in particular of so called "Kirschner wires", and of an external percutaneous fixation methodology. In particular, the invention device includes some technical features which represent an improvement of a "Ilizarov" type apparatus, but with the difference that a tridimensional angular stability is achieved, owing to the specific technical features and configuration described in the following.

The external bone fixator device according to the invention, as shown in Figures 1, 2, 8, 10, 11, comprises a support structure provided with a first arm element and a second arm element, which are mutually connected. In particular the first arm element, which can be simply a threaded rod, and the second arm element are pivotally connected to one other. More precisely, the device comprises a threaded coupling between the first arm element and the second arm element. Anyway, instead of the threaded coupling above disclosed, other equivalent types of connection can be provided for linking the first arm element and the second arm element.

In the version here disclosed and shown in the Figures, the first arm element comprises a threaded portion which is at least partially received in a threaded cavity obtained in the second arm element. The first arm element and the second arm element, in particular, are coaxially aligned along a first longitudinal axis A1, and
can be mutually moved, by screwing the first arm element 3 in the second arm element 4, so as to change a first dimension D1 of the device 1. By doing so, the device 1 can be advantageously adapted to the patient arm 20 to be treated.

There is provided a locking nut 8 which enables relative movement of the first arm element 3 and the second arm element 4 to be prevented once they have been set in a desired mutual position. In an alternative version of the device 1, as shown in Figure 11, locking of the first arm element 3 and second arm element 4 can be ensured by other equivalent solution, like a further locking nut 9 placed at an end 10 of the second arm element 4, as shown in Figure 11.

The external bone fixator device 1 further comprises an anchoring support portion 11 whose function is to connect the support structure 2 to the patient arm 20, thus anchoring the device 1 to the bone 30 to be healed.

The anchoring support portion 11 is adjustably connected to a first end 14 of the support structure 2, in particular it is connected to the second arm element 4. In the version of Figure 1 and 2, the anchoring support portion 11 is a part distinct from the second arm element 4, but connected thereto. In the version of Figure 11, the anchoring support portion 11 is defined by the second arm element 4 itself.

Anyway, the anchoring support portion 11, as better shown in Figure 1, 2, or 11, comprises a through cavity 12 which is shaped for housing one or more anchoring pins or screws 13, which are intended to be stuck in a healthy zone 31 of the bone 30 to be treated, in order to anchor the device 1 to the patient arm 20. Particularly, but in a not limitative way, the device 1 includes a pair of anchoring pins 13 which are intended to be arranged transversely to first longitudinal axis A1, in particular, but in a not limitative way, parallel to one other each
along a second longitudinal axis A2. The anchoring pins 13 may have a diameter of about 2.5 mm to 4 mm and may be of any suitable material. In particular, the anchoring pins 13 may be made of carbon fibre which is a light and strong material and advantageously is also radio-translucent, thus improving the x-ray visibility and thus favouring the surgery operations.

The anchoring support portion 11 is provided with one or more holes which receive locking screw 36 for locking the anchoring pins 13.

The external bone fixator device 1 further comprises, at a second end 15 opposite the first end 14, a bracket element 16, which is mounted on the support structure 2 in an adjustable relative position. In particular, the bracket element 16 extends, with a second dimension D2, substantially orthogonally to the first longitudinal axis A1, and can be rotated thereabout, as shown by the rotation arrows R1, to be adjusted in a desired angular position. On the bracket element 16 a first connecting hole 18 is obtained for receiving a threaded portion of the support structure 2. The threaded portion engages with a fixing nut 19 in order to firmly connect the bracket element 16 to the support structure 2.

The first arm element 3 and the second arm element 4, as already discussed, can be rotated relative to one other, so as to adjust the distance between the bracket element 16 and the anchoring support portion 11, thus acting as spacer elements.

In the version shown in Figure 2, the external bone fixator device 1 comprises a further bracket element 23 which is configured analogously to the bracket element 16. In a non limitative way, the further bracket element 23 has a width dimension which is lesser than the width dimension, or second dimension D2, of the bracket element 16. The further bracket element 23 is placed in an intermediate region between the first end 14 and the
second end 15, and it is mounted on the support structure 2 in an adjustable relative position. In particular, the further bracket element 23 extends substantially orthogonally to the first longitudinal axis A1, and can be rotated thereabout, as shown by the further rotation arrows R2, to be adjusted in a desired angular position. On the further bracket element 23 a second connecting hole 24 is obtained for receiving a further threaded portion of the support structure 2 which engages with further fixing nuts 25 in order to firmly connect the further bracket element 23 to the support structure 2.

The external bone fixator device 1 comprises on or more fixing elements 17 which are configured for being stuck in fracture fragments 22 of the bone 30 in order to keep such fracture fragments 22 in a relative fixed relationship to each other. The fixing elements 17 have an oblong shape, and in particular are rod-shaped or pin-shaped and may have a threaded end 35 for interacting with the bone matrix. The fixing elements 17 have a minimal diameter, for example of 2 mm.

In particular, the fixing elements 17 can be configured as so called "Kirschner wires". In particular the fixing elements may comprise Kirschner wires 17 having a diameter of about 1.2 mm to 4 mm, in particular of 1.6 mm to 2.6 mm, depending on the material which the K-wires 17 are made of, in such a way as to ensure the desired stiffness for the device 1. Obviously, a greater diameter and a large number for the K-wires 17 can be chosen according to the dimensions of the patient arm to be treated. In other words, a suitable number of K-wires 17 greater than three can be chosen according to the dimensions or conditions of the patient arm to be treated. Anyway, the fixing elements 17 may comprise other equivalent elements.

The fixing elements 17 are connected to the structure support 2 through the bracket element 16 and/or the
In particular, the external bone fixator device 1 comprises one or more block elements 26, each being configured for housing one or more fixing elements 17. Suitable through openings 27, shown in Figures 3, 4, 5, are obtained in the block elements 26 for receiving the fixing elements 17. Each fixing element 17 can be placed in a desired position relative to the respective block element 26. In particular, each fixing element 17 can be tilted in a desired position with respect to the block element 26 and can be so arranged as to project therefrom by a suitable amount and towards a desired direction. Suitable clamping elements 28 are provided for firmly tightening the fixing elements 17 to the block elements 26.

Each block element 26 is provided with a threaded protrusion 29 which is shaped for engaging with suitable nuts and linking openings 32 provided on the bracket element 16 and the further bracket element 23.

The linking openings 32 may have several shapes. In the version of the device 1 disclosed in connection with Figures 1 to 7, the linking openings 32 comprises slot openings 21 obtained on the bracket element 16, and further slot openings 33 obtained on the further bracket element 23. In particular, the bracket elements 16 and 23 and the slot openings 21 and 33 have curved shape. The slot openings 21 and the further slot openings 33 so configured enable the block elements 26 to be fixed in any desired position along the bracket element 16 and/or the further bracket element 23.

In alternative or in addition to the slot openings 21, the linking openings 32 may comprise a plurality of linking holes 34 distributed along the bracket element (s), as visible in the version shown in Figure 8 or 11. In this case, the block elements 26 can be placed at any desired position corresponding to a specific linking hole 34. This enable to freely chose the best position for the fixing
elements 17 according to the extent and geometry of the fracture of the bone 30 involved.

Owing to the above disclosed structural configuration of the external bone fixator device 1, the fixing elements 17 can be arranged in any desired and adequate position, and can be so oriented as to extend along respective longitudinal axes which are anyhow arranged to one other, i.e. which are anyhow transversely oriented with respect to one other.

As schematically shown in Figure 9, the fixing elements 17 can be set so as to extend along respectively freely chosen directions d1, d2, ..., dn, thus lying and defining a plurality of mutually transversal planes P1, P2, P3, ..., Pn.

In the device 1 according to the invention, the fixing elements 17, or "K-wires", once inserted in the humeral head, without having a surgical exposition as it occurs in the prior art, are firmly blocked through specific elements (half-ring shaped bracket(s), bolts or nuts, spacer elements, etc.) having a low thickness (3 cm max).

With reference to Figure 12, a centring mask element 50 is shown which is intended to be used in connection with the external bone fixator device 1 of the invention. The centring mask element 50 enables correct positioning, centering and enhanced stabilization of the fixing elements 17 to be achieved.

The centring mask element 50 comprises a plate body 51 in which a plurality of distributed centring through holes 52 are obtained, through which the fixing elements 17 may extend. The centring mask element 50 comprises connecting portions, such as clamping protrusions 53 for mechanically connection to the bracket elements 16. The plate body 51, in particular, may have a curved shape, so as to match the bracket elements 16.

The centring mask element 50 can be made from any suitable material being radio-translucent and having good mechanical properties. In particular, the centring mask
element 50 is made from Polyether ether ketone (PEEK), which is a light material having excellent mechanical resistance properties and is radio-translucent thus improving the x-ray visibility.

The device 1 so configured proves to be extremely stable and sufficiently stiff for a limb that is not under loading during movements.

In particular, the invention device 1 enables a great angular stability of the external fixation to be achieved, with a sufficient rigidity to permit the immobility of the fracture fragments 22.

The stability of the device 1, differently from the prior art devices, is ensured by the angular spatial arrangement of the fixing elements 17, regardless of the capability of the latter to keep itself firmly anchored to the bone fragments, i.e. regardless of the static mechanical adherence of the threaded ends of the fixing elements 17 which are stuck into the bone matrix. The fixing elements 17, being positioned spatially at angles different from one other, enable a multi-fragments fracture to be successfully treated.

The effectiveness of the external bone fixator device 1 in the treatment of the fracture, even having 3 or more fragments, is evidently assured also when elderly patients are involved whose osteal structures show rather deteriorated mechanical properties, for example due to osteoporotic pathology.

The external bone fixator device 1 enables to successfully deal with the problem of the porosity in osteoporotic patients, owing to the k-wires 17 arranged in a divergent trapezoidal configuration, (in at least three distinct angular relative positions) and provided with a suitable elastic modulus.
Differently from the prior art devices, the device 1 according to the invention enable to treat the fracture by noticeably limiting the invasive percutaneous access, thus reducing any infection risk, such as avascular necrosis. Surgical exposure of the fracture of the humeral diaphysis is avoided.

Furthermore, owing to the device 1 of the invention, there is no need for leaving any metallic implants in the fracture zone.

The fixing elements 17 are left in contact with the fracture fragments 22 only for a period which is sufficient for ensuring the natural recovery of the fracture, thus with no risk of secondary loosening.

The device 1 enables to avoid impairment of the rotator cuff and subacromial bag, thus reducing the risk of scarring and enabling immediate active movements of the shoulder.

Furthermore, the device 1 enables involvement of the proximal third of the arm only, in particular under the circumflex nerve and above the radial nerve, which are potential sites of surgical lesion.

Fractures with four or more fragments of the classification of Neer, corresponding to the type C fractures in the "Arbeitsgemeinschaft fur Osteosynthesefragen (AO) classification", especially in elderly osteoporotic patients, can be treated in the prior art with the ORIF (open reduction internal fixation) technique that implies use of a plate (LCP-PH) connected to k-wires.

The device and the method according to the invention enable to achieve better functional results in proximal humerus type C fractures without the risks of ORIF, this system being considerable an improvement of a "hybrid" synthesis based on a closed reduction and percutaneous angular stability external fixation, with a sufficient rigidity to permit the immobility of the fragments
fracture. The device and the method according to the invention allow the full active and passive mobility of the shoulder immediately after its application.

The method according to the invention takes the advantage of three different approaches of fractures treatment: the temporary percutaneous fixation with K-wire, the fixation with angular stability design and the Ilizarov external fixation method.

The study relies on the hypothesis that the reduction of proximal humerus fractures obtained by means of minimally invasive intervention and completed with a strong stabilization similar to the technique of Ilizarov can lead to optimal functional results not inferior to those obtained with the traditional ORIF, but without exposing to the risks that the latter entails.

In the following, functioning of the device and a method for the treatment of a fracture will be disclosed, with particular reference to the version of Figures 8 and 11. The following steps are performed:

a) With the patient supine and with the availability of an x-ray amplifier, two anchoring pins 13 having a diameter of 3 mm are first mounted on the lateral humeral in the region of the transition between the proximal and middle third. Afterwards, an anchoring support portion 11, or second arm element 4, which can be for example a nut with many (2-4) holes, is mounted to fix anchoring pins 13 with a stable mechanical bond given by locking screws 36. The anchoring support portion 11 is assembled on the first arm element 3, or threaded rod, having a diameter of 5 mm and length about 10 cm placed parallel to the longitudinal axis of the humeral diaphysis;

b) In this phase of the reduction, the "firmly anchored" threaded rod drives the humeral diaphysis in the right position (Joystick technique) in order to obtain the reduction with the humeral head;

c) A fixing element or K-wire 17, having diameter of 2 mm
is obliquely introduced in the ephyseal greatest proximal fragments of humeral head. This constitutes the first transient synthesis that will be removed after the entire system has been completed;

d) Now at least four threaded K-wires 17 with diameter of 2 mm are placed with trapezoidal configuration with different angle in order to configure an angled stability system, as schematically shown in Figure 9. After lowering the humeral greater tuberosity with an external manipulation or with a mini-invasive access to position this anatomical structure in the most functionally appropriate position, one or two of the K-wires 17 are driven into it;

e) The K-wires 17 inserted into the humeral head and greater tuberosity fragments are connected between them and the threaded road or first arm element 3 using a bracket element 16, such as half ring element. The K-wires 17 are fixed to the bracket element 16 with the block elements 26 and clamping elements 28 (such as screws and nuts) above discussed and should be placed on different levels according to a trapezoidal scheme in order to obtain the angular stability, as shown in Figure 9. It's before and during fixation of the K-wires 17 to the bracket element 16 (and possibly to the further bracket element 23, which take place under x-ray control, that the reductive manoeuvres aimed to rebuild the epiphysis in the most functional position is performed;

a correct and firm positioning of the K-wires 17 can be easily achieved owing to the centring mask element 50 used in connection with the external bone fixator device 1;

f) A final x-ray control is performed to make sure the stability of the synthesis during the movements and to exclude incidental insertion of the K-wires 17 in the joint space.

Active free movements of the shoulder, from the first post-operative day until the pain threshold are allowed.
Advantageously, after an x-ray control, the removal of all components of the external bone fixator device 1 can be performed after a month without hospitalization in local anesthesia.

Trial and survey have been performed which involved 74 patients, 58 females and 16 males, with a mean age of 68 years ± 22 ranging from 24 to 87 years. The classification of fractures according to AO consisted of: 11 patients with fracture CI, 12 with fractures C2 and 7 with fractures type B2. The surgery was performed for the majority of patients under local anesthesia, the average time surgery was 35 minutes. In only 8 patients a minimal invasive access to reduce the humeral great tuberosity was performed. All the patients were operated without dissection of the rotator cuff.

All the patients left the surgery room without any means of immobilization of the shoulder. The medication of the external fixation apparatus occurred every 10 days and was removed after 4 weeks with local anesthesia. Clinical control was planned to be performed at 2, 6, 12 months afterwards and x-ray control after 4 weeks and 2 months.

At the moment, among the 74 cases above reported, only 60 have performed the control of 6 months from the date of injury, and the results are as follows:

- no loss of the reduction achieved and stabilized with external fixation (the bone has been totally stabilized);
- no migration of K-wires, owing to the angular stability configuration above disclosed;
- 4 weeks after fracture and after removal of external fixator: the articular range has an active abduction to 90° and a passive one about 100°, with no pain nor stiffness;
- active movements resumed after two months in most cases. At 6 months the majority of patients with
fractures of type B and C I showed almost complete functional recovery, patients with fractures type C 2 showed minimal functional limitation to extreme ranges but no pain;

- Good quality of life without pain in the normal range of movements for all the patients;
- one of the patients developed a humeral head necrosis.

The invention above described successfully fulfils the purposes intended for it. In particular, an external bone fixator device 1 has been provided which enables a treatment of bone fractures, especially multi-fragmentary fracture of the proximal humerus, in an effective and minimally invasive way for the patient. The invention device 1 is defined by structurally simple components which inevitably lead to low production costs and to easier maintenance. From the above description it is clear that the device 1 according to the invention is as effective as cheap and simple to be produced and to be used. The K wires 17 and the anchoring pins 17 are the only components which are disposable, whereas the remaining components of the device 1 can be reutilized. The external bone fixator device 1 may undergo a number of modifications and variants, all coming within the scope of the inventive concept. Moreover, all details may be replaced by other technically equivalent elements without thereby departing from the scope of the invention. The material to be used may be of any type according to the needs and the state of the art, provided they comply with the specific use. In particular the device 1 can be manufactured by using very light materials such as carbon fibre, which is more comfortable per the patient and advantageously, is also radio-translucent, thus improving the x-ray visibility and thus favouring the bone reduction surgical operations. The device 1 can be made from
Polyether ether ketone (PEEK), which is a light material having excellent mechanical resistance properties and is radio-translucent thus improving the x-ray visibility.
CLAIMS

1. External bone fixator device for the treatment of a bone fracture in a patient body, comprising:
   - a support structure configured for being arranged outside of said patient body;
   - a group of fixing elements connected to said support structure and configured for being stuck in fracture fragments of the bone for keeping said fragments in a relative fixed relationship to each other;
   - one or more anchoring elements connected to said support structure and configured for being stuck in said bone for anchoring said external bone fixator device thereto,

   characterised in that the fixing elements of said group extend along respective longitudinal axes which are transversely arranged to one other.

2. External bone fixator device according to claim 1, wherein two or more fixing elements lie in a plurality of mutually transversal planes thus defining a multiplanar stability system.

3. External bone fixator device according to claim 1 or 2, wherein said fixing elements comprise "Kirschner wires".

4. External bone fixator device according to any one of claims 1 to 3, wherein said support structure comprises an anchoring support portion housing said anchoring elements in an adjustably way by apposite locking nuts or screw, and an arm element connected to said anchoring support.

5. External bone fixator device according to any one of claims 1 to 4, wherein a screwing coupling is provided between said arm element and said anchoring support portion for enabling relative extension adjustment thereof.

6. External bone fixator device according to claim 4 or
wherein said anchoring support portion and said arm element extend along a longitudinal axis intended to be placed, in use, substantially parallel to a further longitudinal axis of a humeral diaphysis.

7. External bone fixator device according to any one of claims 1 to 6, further comprising one or more bracket elements for supporting said fixing elements, said bracket element (s) being adjustably mounted on said support structure.

8. External bone fixator device according to claim 7 as appended to claim 6, wherein said bracket element (s) extend(s) substantially transversely to said longitudinal axis and can be angularly positioned about said longitudinal axis.

9. External bone fixator device according to claim 7 or 8, wherein said bracket element (s) is/are half-ring shaped.

10. External bone fixator device according to any one of claims 7 to 9, wherein said fixing elements are mounted on said bracket element (s) through block elements, said bracket element (s) and said block elements being configured for mutually coupling in several relative positions thus enabling the position and orientation of the fixing elements to be spatially set in a desired way.

11. External bone fixator device according to claim 10, wherein said fixing elements are removably fixable to said block elements through apposite further locking nuts or screws.

12. External bone fixator device according to any one of preceding claims, wherein said fixing elements have a diameter comprised in a range from about 1.6 mm to about 2.5 mm.

13. External bone fixator device according to any one of preceding claims, wherein said fixing elements have a diameter comprised in a range from about 2 mm to about
14. External bone fixator device according to claim 7 or to any one of claims 8 to 13 as appended to claim 7, further comprising a centring mask element configured to be connected to said bracket elements and arranged for enabling correct positioning, centring and enhanced stabilization of said fixing elements, said centring mask element having a curved plate body in which a plurality of distributed centring through holes are obtained for said fixing elements, and comprising clamping protrusions for mechanically connection to said bracket elements, said centring mask element being made from radio-translucent material such as Polyether ether ketone (PEEK).

15. Use of the external bone fixator device according to any one of claims 1 to 11 for the treatment of a humerus fracture.

16. Method for the treatment of a bone fracture in a patient body, comprising the steps of:
   a) exerting a simultaneous plurality of fixing actions on fragments of said bone fracture along respective longitudinal directions which are transversely arranged to one other, and
   b) keeping said plurality of fixing actions in a mutual stable condition through a support action exerted from the outside of said patient body.

17. Method according to claim 16, wherein two or more of said plurality of fixing actions are exerted along respective directions lying in a plurality of mutually transversal planes.

18. Method according to claim 16 or 17, wherein said step b) comprises mounting anchoring pins on a healthy portion of said bone distinct from a fractured portion of said bone, firmly coupling the anchoring pins to an anchoring support portion, and further coupling an arm...
element firmly to the anchoring support portion, so that the arm element results placed substantially parallel to the longitudinal axis of the bone;

19. Method according to claim 18, further comprising driving, through said arm element, the healthy portion in the right position in order to obtain the reduction with the fractured portion, introducing a fixing element obliquely in the fracture fragments of the bone, placing further fixing elements with trapezoidal configuration with different angle in order to define an angular stability configuration, connecting the fixing elements mutually and with the arm element through a bracket element and performing reductive manoeuvres so as to rebuild the epiphysis in the most functional position.

20. Method according to any one of claims 16 to 19, wherein step a) is carried out with the patient supine with the aid of an x-ray amplifier, and wherein two anchoring pins are mounted which have a diameter of 3 mm.

21. Method according to any one of claims 16 to 20, further comprising performing a final x-ray control to make sure the stability of the synthesis during the movements and to exclude incidental insertion of fixing elements in a joint space of the fracture fragments.

22. Method for the treatment of a fracture in a humerus of a patient body, comprising the steps of:

i) mounting anchoring pins on the lateral humeral bone in the region of the transition between the proximal and middle third of the bone, firmly coupling the anchoring pins to an anchoring support portion, and further coupling an arm element firmly to the anchoring support portion, so that the arm element results placed substantially parallel to the longitudinal axis
of the humeral diaphysis;
ii) driving, through the arm element, the humeral
diaphysis in the right position in order to
obtain the reduction with the humeral head;
iii) introducing a fixing element obliquely in the
ephyseal greatest proximal fragments of humeral
head;
iv) placing further fixing elements with trapezoidal
configuration with different angles in order to
define an angular stability configuration;
v) connecting the fixing elements mutually and with
the arm element through a bracket element and
performing reductive manoeuvres so as to rebuild
the epiphysis in the most functional position.

23. Method according to claim 22, wherein step i) is
performed with the patient supine with the aid of an
x-ray amplifier, and wherein two anchoring pins are
mounted which have a diameter of 3 mm.

24. Method according to claim 22 or 23, wherein said step
iii) comprises introducing a "Kirschner wire" having a
diameter of about 2 mm.

25. Method according to any one of claims 22 to 24,
wherein said step iv) comprises placing further
"Kirschner wires" having a diameter of about 2 mm, and
after lowering the humeral greater tuberosity with an
external manipulation or with a mini-invasive access
to position this anatomical structure in the most
functionally appropriate position, one or two of the
"Kirschner wires" are driven into it.

26. Method according to any one of claims 22 to 25
comprising performing a final x-ray control to make
sure the stability of the synthesis during the
movements and to exclude incidental insertion of
fixing elements in a joint space of the fracture
fragments.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61B17/64

According to International Patent Classification (IPC) and both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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<td>US 4 127 119 A (KRONNER RICHARD F) 28 November 1978 (1978-11-28) figures 1,5,6,17 col umn 3, l ines 40-65 col umn 7, l ines 34-60</td>
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<td>US 5 591 169 A (BENOIST LOUIS [US]) 7 January 1997 (1997-01-07) figures 6,7,13,15 col umn 3, l ines 3-23</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
  * **A** document defining the general state of the art which is not considered to be of particular relevance
  * **E** earlier document but published on or after the international filing date
  * **L** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another invention or other special reason (as specified)
  * **O** document referring to an oral disclosure, use, exhibition or other means
  * **P** document published prior to the international filing date but later than the priority date claimed

**Date of the actual completion of the international search**

20 March 2012

**Date of mailing of the international search report**

29/03/2012

**Name and mailing address of the ISA**

European Patent Office, P.B. 5018 Patentliaan 2 NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer

Fourcade, Olivier

Form PCT/ISA/210 (second sheet) (April 2005)
### Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 15-26 because they relate to subject matter not required to be searched by this Authority, namely:

   see FURTHER INFORMATION sheet PCT/ISA/210

2. **□** Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **□** Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. **□** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **□** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. **□** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. **□** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.
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<td>wo 01/51119 AI (AMEI TECHNOLOGIES INC [US]) 19 July 2001 (2001-07-19) figures 1,2b page 11, lines 19-27 page 13, lines 23-31</td>
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)
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Claims 15-26 relate to subject-matter considered to be covered by the provisions of Rule 39.1(iv) PCT (Method for treatment of the human or animal body by surgery). Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims which are also not searched.