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(54) **A medical device for the operative treatment of a proximal humerus fracture.**

(57) The invention provides an implantable medical device for treatment of a proximal humerus fracture, comprising:
- a base element to be anchored in the medullar cavity of the humeral shaft,
- a support element to be fixed with respect to the base element, wherein the support element is configured to support one or more bone fragments,
wherein the medical device comprises positioning means configured to position the support element with respect to the base element in a range of rotational positions and axial positions, and
wherein the medical device comprises fixation means to fixate the support element, within the range of rotational positions and axial positions, in a desired rotational and axial position with respect to the base element.

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Title: A medical device for the operative treatment of a proximal humerus fracture

The present invention relates to a medical device for the operative treatment of a proximal humerus fracture.

Proximal fractures of the humerus are fractures often related to osteoporosis, which occurs frequently in elder people. A proximal fracture of the humerus results in two or more fractured bone fragments. These bone fragments may comprise the humeral head, the humeral shaft, and the greater or lesser tuberosity.

If the bone fragments of the broken humerus are still properly positioned after the fracture, the patient may be successfully treated without surgery. If the bone fragments are dislocated, the position of the bone fragments is often unfavourable so that non-operative treatment would lead to incorrectly or no growing together of the bone fragments.

In those cases the results are generally quite poor and lead to permanent stiffness, pain and limitation of shoulder movements and possibly invalidity of a person. Subsequent interventions to this problem generally do not provide further improvement. Re-operations for bone fractures of a humerus fracture which are not or incorrectly grown together, rarely lead to good results.

A proper reconstruction of the humerus, wherein the bone fragments are relocated to and fixed substantially in their original positions is an important aspect in the treatment of humerus fractures. A fracture in a good position gives a significantly better result than a fracture healing in a bad position.

Various techniques for surgical treatment are used, such as pin- or plate osteosynthesis, K-wire osteosynthesis, screw fixation, suture techniques (cerclage) and treatment by placement of a shoulder prosthesis. Although these techniques are used successfully in some cases, relatively high rates of complications and problems are described in literature. In the existing fixation techniques is frequently seen that the surgery is not sufficient.

Reasons for a low success rate of operation results are for example the weak bone of the humerus in older people, the weak structure of the humerus in general (not weight-bearing joint), the disruption of the vascularization (blood flow) of the humeral head due to the fracture and the difficult surgical technique.

In view of the problems encountered in the known techniques for reconstruction of the humerus in the treatment of a humeral fracture, there is a need to provide new

techniques for reconstruction of the humerus, which make proper and reliable reconstruction of the humerus possible.

The aim of the present invention is to provide an implantable medical device for treatment of a proximal humerus fracture, which provides flexibility during the reconstruction of the humerus of a patient. This flexibility makes a more efficient treatment of a proximal fracture of the humerus possible, in particular when the humerus is broken in three or more bone fragments.

The invention provides an implantable medical device for treatment of a proximal humerus fracture, comprising:

- a base element to be anchored in the medullar cavity of the humeral shaft,
- a support element to be fixed with respect to the base element, wherein the support element is configured to support one or more bone fragments,

characterized in that

the medical device comprises positioning means configured to position the support element with respect to the base element in a range of rotational positions and axial positions, and in that

the medical device comprises fixation means to fixate the support element, within the range of rotational positions and axial positions, in a desired rotational and axial position with respect to the base element.

The medical device of the invention makes an efficient and reliable reconstruction of the fractured humerus possible, in particular in complex fractures where the proximal end of the humerus is fractured in three or more bone parts.

The base element can be anchored in the medullar cavity of the humeral shaft. The medullar cavity of the humeral shaft may usually provide a good support for anchoring of the medical device.

When the base element is anchored in the medullar cavity at a fixed position, the positioning means, i.e. a positioning device, make it possible that the support element which is used for supporting one or more further bone fragments, in particular the greater and lesser tuberosity and/or the humeral head, can still be moved in a range of positions in both rotational and axial directions. In any of these rotational and axial positions the support element can be fixed to the base element by the fixation means, i.e. fixation device, resulting in a fixed position of the support element with respect to the humeral shaft.

With this construction, the positioning of the support element with respect to the humerus is made, within the range of rotational and axial positions, independent of the anchoring of the medical device in the medullar cavity of the humerus. The position of the support element can be selected on the basis of the desired positions of the further bone

parts, such as the greater and lesser tuberosity and/or the humeral head after reconstruction of the humerus.

Once the support element is fixed in the desired position with respect to the base element and the humeral shaft in which the base element is anchored, the one or more bone fragments may be supported by the support element. The one or more bone parts may also be secured to the support element. Any suitable technique may be used to fix the bone parts to the support element, for example suture techniques, in particular cerclage.

After reconstruction, the medical device itself provides support to the bone fragments, and the bone fragments may be attached to the support element.

Because the interior of the proximal humerus is filled with the medical device it is prevented that the possibly thin and porous bone fragments will damage or break during or after fixation of the bone fragments on the medical device.

In an embodiment, the base element is configured to be easily removable, if necessary, for example when it is desired to replace the medical device in a next operation with an alternative prosthesis.

In an embodiment, the positioning means comprise a cylindrical opening in one of the base element and the support element, and a cylindrical extension at the other of the base element and the support element.

In such embodiment, the inner diameter of the cylindrical opening may substantially correspond or be smaller than the outer diameter of the cylindrical extension so that the cylindrical extension can be at least partially arranged in the cylindrical opening.

The combination of a cylindrical opening and a cylindrical extension, which are telescopically arranged with respect to each other, provide a relative simple and reliable mechanism creating a range of rotational and axial positions providing a large range of freedom of movement to position the support element with respect to the base element.

The cylindrical shapes of extension and opening make relative rotation over the whole circumference possible, while the extent of overlapping of the extension and the opening defines the axial range of movement of the support element with respect to the base element. The relative rotation of the cylindrical opening and the cylindrical extension may be limited by one or more rotation limiting elements to a part of the circumference, i.e. smaller than 360 degrees, for instance by rotation stops. The axial range may also be limited by stops or other elements.

In an embodiment, the positioning means comprise at the distal end of the support element a tube-shaped part defining a cylindrical opening, and at the proximal end of the base element a cylindrical extension, wherein an outer diameter of the cylindrical extension substantially corresponds to an inner diameter of the cylindrical opening.

The cylindrical opening of the support element preferably is a through opening, such that the proximal part of the cylindrical extension can be reached from the proximal side of the support element through the cylindrical opening. The outer diameter of the cylindrical extension and the inner diameter of the cylindrical opening are preferably selected such that the base element will hold the support element when no other force is exerted on the support element, while at the same time the support element can be moved with respect to the base element with a little force.

The friction between the cylindrical extension and the cylindrical opening is preferably kept at a low level so that relative positioning of the support element with respect to the base element can be done with high accuracy. The friction may also be reduced by providing materials having a low friction on or in the respective surfaces of the cylindrical extension and the cylindrical opening.

In an embodiment, the fixation means comprise a fixation element to be placed in the proximal end of the base element, which fixation element is configured to increase the outer diameter of the cylindrical extension when placed in the proximal end of the base element.

When the diameter of the cylindrical extension can be increased by placing a fixation element in the cylindrical extension, the cylindrical extension can be clamped in the cylindrical opening. This fixation of the support element with respect to the base element is performed when the support element is positioned in a desired position with respect to the base element and humeral shaft during reconstruction of the humerus.

Such clamping device may for example be obtained by providing a cylindrical extension having two diametrically opposed extension parts extending in the axial direction which are movably radially outwards by the fixation element, wherein preferably the fixation element is a screw element having an outer screw thread, and wherein the two extension parts having an inner screw thread to cooperate with the outer screw thread.

It is remarked that the fixation element may also be used to adjust a friction during positioning between cylindrical extension and cylindrical opening in agreement with the wishes of the surgeon.

In an embodiment, a distal end of the base element comprises one or more anchor elements extending in radial direction over a limited part of the circumference of the base element to anchor the base element in the medullar cavity of the humerus. By providing one or more anchor elements extending in radial direction over a limited part of the circumference a proper anchoring of the base element in the medullar cavity may be obtained. At the same a substantial part of the circumference of the base element is not blocked by the one or more anchor element. These parts of the medullar cavity that are not blocked form longitudinal channels in the medullar cavity. These longitudinal channels are

advantageous as they enable blood to flow in longitudinal direction past the medical device. Blood flow is of high importance for the healing of the bone fragments of the humerus.

The term over a limited part of the circumference means in this application that the one or more anchor elements do not extend radially over the complete circumference therewith blocking the medullar cavity. Furthermore, the limited part of the circumference may be divided over a plurality of sub-parts divided over the circumference of the base element.

In addition, or as an alternative, the base element may comprise one or more through going channels which run between proximally of the one or more anchor element and distally of the one or more anchor elements to allow a blood flow past the one or more anchor elements. The one or more through going channels may for example be provided in the one or more anchor elements and/or in a main body of the base element.

In an embodiment, the one or more anchor elements comprise at least three fins divided over the circumference of the base element and extending in a plane perpendicular to a tangential direction. The fins may be at or near the distal end of the base element. The radial dimensions of the fins are selected such that the fins provide a proper anchoring of the base element in the medullar cavity.

The fins are preferably stiff but thin so that the fins block the medullar cavity in axial direction as little as possible.

Before anchoring of the base element in the medullar cavity, the radial extent of the fins may be adapted to the required radial extent of the fins for proper anchoring of the base element in the medullar cavity, without requiring excessive force to bring the base element in the medullar cavity or having the risk of damaging the anchor fins or bone. The fins may for instance be clipped or cut to the desired radial dimensions.

In an embodiment, the base element at least between the one or more anchor elements tapers in the distal direction. By tapering of the base element in the distal direction between the anchor elements, the cross section of the medullar cavity which is not occupied by the base element may be increased, therewith creating more space for a blood flow between a distal end and a proximal end of the one or more anchor elements.

In an embodiment, the support element comprises a cage for fixation of one or more bone fragments. The support element may be used for support for and fixation of the one or more bone parts in the respective desired locations. A cage provides a relative large volume with several possibilities to attach the one or more bone parts to the cage. The cage may for example be formed as an open construction having struts for attachment of loops or use of K-wires or other attachments devices or suture material for the fixation of one or more bone fragments.

Any other means for support and/or fixation of the one or more bone parts may also be provided.

In an embodiment, the cage is formed to substantially fill the interior of a proximal end of a humerus to be treated. The cage preferably fills substantially the interior of the proximal end of the humerus, so that when the one or more bone parts are placed against the cage for support and fixation, the one or more bone parts are properly positioned for a successful reconstruction of the humerus.

In an embodiment, the medical device, preferably the cage, defines a humeral head support plane to support the humeral head. To properly position, during reconstruction of the humerus, the humeral head with respect to the support element, a support plane is formed for supporting the humeral head. This support plane is angled with respect to the longitudinal axis of the medical device with an angle substantially corresponding to an angle in which the humeral head should be located with respect to the longitudinal axis of the humeral shaft. This angle substantially corresponds to the angle of the anatomical neck of the humerus.

It is remarked that the humeral head support plane may also be defined by any other suitable part of the medical device of the invention

The humeral head positioning element may for example be arranged on the humeral head support plane or may be an integral part of the support element.

In an embodiment, the medical device comprises one or more protrusions which project from the support plane, the protrusions being configured to at least partially penetrate the humeral head. One or more, for example three, protrusions projecting from the humeral head support plane may be provided to at least partially penetrate into the bone structure of the humeral head to provide or improve a connection between the humeral head and the medical device. The one or more protrusions may have any suitable shape.

In such embodiment, the one or more protrusions may for example be formed on one or more struts of a cage element.

The protrusions may be pointed or sharpened to facilitate penetration of the bone structure of the humeral head.

Further protrusions may be provided to penetrate other bone fragments of the fractured humerus.

In an embodiment, the medical device comprises a humeral head positioning element configured to be at least partially arranged in the humeral head for positioning of the humeral head with respect to the support element. For further support of the humeral head, a humeral head positioning element may be provided which may provide internal support to the humeral head.

In an embodiment, the medical device could be made of biodegradable material.

After reconstruction of a humerus using the medical device of the invention, the medical device is enclosed by the humerus and will remain therein. After the bone fragments are healed to a single bone structure, the medical device may no longer be required in the humerus. By forming the medical device from a biodegradable material, the medical device can be degraded or decomposed after a certain period of time so that no body foreign material remains. It may be desirable to use a hybrid type of device in which parts are made of biodegradable material and parts are made of non-biodegradable material. IN an embodiment, it may for example be possible that the base element is made of a non-biodegradable material, for example a metal, while the other parts are made of biodegradable material. Such embodiment provides the possibility to use the base element to support, when desired, a new support element. In such embodiment, a screw element to be screwed in the base element may also be of non-biodegradable material such that the screw element, when desired, can reliably be removed from the base element. Any other suitable combination of biodegradable and non-biodegradable parts may also be applied.

In an alternative embodiment, it may be desirable that the medical device remains in the humerus to provide permanent support to the bone structure of the proximal humerus end from the interior.

The medical device may also comprise a material which stimulates bone growth, so that the presence of the material of the medical device improves healing of the bone.

The present invention also relates to a method to treat a proximal humerus fracture, comprising the steps of:

providing an implantable medical, comprising:

- a base element to be anchored in the medullar cavity of the humeral shaft,
- a support element to be fixed with respect to the base element, wherein the support element comprises a cage for fixation of one or more bone fragments,

wherein the medical device comprises positioning means configured to position the support element with respect to the base element in a range of rotational positions and axial positions, and wherein the medical device comprises fixation means to fixate the support element, within the range of rotational positions and axial positions, in a desired rotational and axial position with respect to the base element,

- anchoring a distal end of the base element in the medullar cavity of the humerus,
- positioning by means of the positioning means the support element, within the range of rotational and axial positions, in a desired position with respect to the base element,
- fixing by means of the fixation means the support element with respect to the base element, and
- reconstructing the humerus by fixing one or more fractured bone fragments of the fractured humerus to the support element.

An embodiment of an implantable medical device according to the invention will now be described in further detail, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows, in perspective view, an embodiment of a disassembled medical device according to the invention; and

Figures 2-5 show the build-up of the medical device of Figure 1 during treatment of a proximal humerus fracture.

Figure 1 shows an embodiment of an implantable medical device according to the invention in disassembled and perspective view. The medical device is configured for treatment of a proximal humerus fracture and comprises a base element 1 to be anchored in the medullar cavity of a humeral shaft of a humerus to be treated and a support element 2 configured to support one or more bone fragments of the humerus.

The base element 1 comprises a base element body forming a cylindrical extension 3 at its proximal end. The distal end of the base element 1 comprises five anchor fins 4 divided over the circumference of the base element. The anchor fins 4 extend in radial direction and are configured to anchor the base element 1 in the bone of the humeral shaft surrounding the medullar cavity of the humeral shaft.

The anchor fins 4 are thin walled but stiff elements which provide for proper anchoring of the base element 1 in the medullar cavity. The anchor fins are arranged over a limited part of the circumference of the base element 1, and the anchor fins 4 will only partly enter into the bone of the humeral shaft so that space will remain between the base element body and the inner wall of the humeral shaft.

This space is advantageous for blood flow past the base element in longitudinal direction which is important for proper healing of the humerus. In addition, or as an alternative, blood may also flow between a distal end and a proximal end of the base element through one or more internal channels in the base element.

The proximal end of the cylindrical extension 3 comprises two diametrically opposed extension parts 5 extending in the axial direction which are movably radially outwards by a screw element 6, having an outer screw thread, which cooperates with an inner screw thread arranged on the inner sides of the extension parts 5.

The support element 2 comprises at its distal end a cylindrical tube 7 having an inner diameter which substantially corresponds with the outer diameter of the cylindrical extension 3. The outer diameter of the cylindrical extension 3 is slightly smaller than the inner diameter of the cylindrical tune 7, when the screw element 6 is not screwed between the extension

parts 5. However, when the screw element 6 is screwed between the extension parts 5, the extension parts 5 will be moved away from each other, therewith increasing the diameter of the cylindrical extension 3 to a diameter larger than the inner diameter of the cylindrical tube 7. In alternative embodiments, more than two extension parts 5 may be provided

The cylindrical tube 7 can be placed about the cylindrical extension 3 in a telescopic manner. The cylindrical tube 7 can be moved with respect to the cylindrical extension over a range of rotational and axial positions, while the screw element 6 makes it possible to fixate the support element 2 with respect to the base element 1 in any of these positions within this range.

This gives the surgeon performing a reconstruction of the proximal humerus the possibility to adjust the position of the support element 2 within a range of rotational and axial positions after the base element 1 has been anchored in the medullar cavity by the anchor fins 4. Once the surgeon has positioned the support element 2 in the desired position, the support element 2 may be fixed in this position by screwing the screw element 6 into the base element 1 between the extension parts 5. A screw tool 40 (Figure 4) is provided for rotating the screw element 6. The support element 2 comprises a longitudinal channel so that the screw element 6 can be reached from the proximal end of the medical device.

The proximal end of the support element 2 comprises a cage 8 formed by struts 9 as an open construction.

The cage 8 is formed to substantially fill the interior cavity of the proximal end of the humerus, so that the one or more bone parts can be placed against the support surfaces of the cage 8 for support and fixation, therewith also placing the one ore more bone parts in the desired position for a proper reconstruction of the humerus.

The struts 9 can advantageously be used for attachment of loops of K-wires or other attachments devices or suture material for the fixation of one or more bone fragments to the cage 8.

The cage 8 forms support surfaces for the bone parts such as the greater and lesser tuberosities and the humeral head.

The cage 8 for example defines a humeral head support plane 10 to support the humeral head. This support plane 10 is angled with respect to the longitudinal axis of the medical device with an angle substantially corresponding to an angle in which the humeral head should be located with respect to the longitudinal axis of the humeral shaft.

On the humeral head support plane 10 three pointed protrusions 11 are provided. The protrusions 11 are formed on the strut elements 9 of the cage 8. The protrusions 11 project from the humeral head support plane 10 and are provided to at least partially penetrate the bone structure of the humeral head to improve the connection between the

cage 8 and the humeral head. Other protrusions may also be provided at any suitable location, for instance to at least partially penetrate other bone fragments of a fractured humerus.

As an alternative, or in addition, a humeral head positioning element may be provided. The humeral head positioning element may be placed in the humeral head for further support in the positioning of the humeral head with respect to the cage 8. Usually, the humeral head comprises a cavity having internal dimensions. It has been found that it may be advantageous to provide a humeral head positioning element being substantially smaller than this internal dimensions. This provides some freedom to reposition the humeral head at the end of the reconstruction, since the position of the humeral head is not completely dictated by the cage 8 and the humeral head positioning element provided thereon.

The elements of the medical device may be made from any suitable material, such as for example biocompatible plastics material. The medical device may be made of biodegradable material, so that after the reconstructed humerus has healed, the material of the medical device may degrade or decompose. However, the medical device may also be configured to remain within the humerus for permanent support of the proximal end of the humerus from the interior. Support from the interior has the advantage that the presence of the medical device does not hamper functioning of other parts of the body, such as ligaments or muscles.

It is desirable that the base element 1 is removable from the medullar cavity when required, for example in the case of a prosthesis replacement in the future. The anchor fins 4 provide such removable medical device.

The medical device of the invention makes an efficient and reliable reconstruction of a fractured humerus possible, in particular in complex fractures where the proximal end of the humerus is fractured in three or more bone parts. These bone parts typically comprise the humeral shaft, the humeral head and one or both of the greater and lesser tuberosities.

The different steps for placing the medical device in a proper position in the humerus will now be discussed.

As a first step, the base element 1 is anchored in the medullar cavity of the humeral shaft. This anchoring is performed by forcing from the proximal side the base element 1 into the medullar cavity, while the anchor fins 4 at least partly penetrate into the bone of the humeral shaft.

Figure 2 shows a hammer 50 and a rod element 55 with which the base element 1 can be hammered into the medullar cavity in the direction indicated by an arrow. The rod element 55 comprises longitudinal ribs the ends of which can be positioned into slots of the

base element 1 to properly engage the rod element 55 and the base element 1 during anchoring of the base element 1.

Before actual anchoring of the base element 1 in the medullar cavity, the radial extent of the anchor fins 4 may be adapted, for example by clipping or cutting, to adapt the anchor fins 4 to the required diameter for proper anchoring of the base element 1 in the medullar cavity, without requiring excessive force.

When the base element 1 is properly anchored in the humeral shaft, the cylindrical tube 7 of the support element 2 may be placed over the cylindrical extension 3 of the base element 3 in a telescopic arrangement as shown in Figure 3.

The telescopic arrangement of cylindrical tube 7 and cylindrical extension 3 provide a range of rotational and axial positions in which the support element 2 can be positioned with respect to the base element 1. The freedom of movement of the support element 2 with respect to the base element 1 is indicated in Figure 3 by arrows A in longitudinal direction and B in rotation direction . The desired position of the support element 2 is the position in which the cage 8 provides the best start position for reconstruction of the humerus.

When the support element 2 is positioned in this desired position, the support element 2 can be fixated with respect to the base element 1 by screwing the screw element 6 with screw tool 40 into the base element 1 between the extension parts 5, as shown in Figure 4. In practice, the screw element 6 may already be partly brought into the base element 1, so that the screw element 6 can directly be screwed further into the base element 1 without the need of aligning the outer screw thread of the screw element 6 with the inner screw thread of the extension parts 5. This pre-placement, may be advantageous as the aligning may have the consequence that the support element 2 is moved out of the desired position by manipulation of the screw element in the support element 2.

It is remarked that the presence of the screw element 6 in the base element 1 can also be used to set a friction level between the cylindrical tube 7 and the cylindrical extension 3, which is regarded by the surgeon as pleasant during positioning of the support element 2 with respect to the base element 1.

After the support element 2 is fixated, the position of the cage 8 can be checked. When required, the support element 8 may be repositioned by unscrewing the screw element 6 so that the support element 2 and the base element 1 are again movable with respect to each other.

Figure 5 shows the medical device after fixation of the base element 1 and the support element 2 with respect to each other and after removal of the screw tool 40.

When the surgeon has determined that the support element 2 and therewith the cage 8 is positioned in a proper start position for reconstruction of the humerus, the reconstruction

can be started. When desired a humeral head positioning element can be arranged on and when desired attached to the humeral head support plane 10.

During reconstruction the one or more fractured bone fragments of the fractured humerus can be fixed to the cage 8. The struts 9 of the cage 8 provide a plurality of attachment locations for attachment materials such as K-wires or suture material. The medical device, in particular the cage 8, provides a proper support for repositioning and fixation of the bone parts. The humerus head may be supported by the humerus head support plane 10, where it is placed on the protrusions 11. The protrusions 11 may at least partially penetrate the bone structure of the humerus head to improve the connection between the humerus head and the medical device.

After the reconstruction of the humerus has been finished, the arm of the patient can be fixated so that the humerus may heal.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

CONCLUSIES

1. Implanteerbare medische inrichting voor behandeling van een proximale humerus fractuur, omvattende:
- een basiselement dat te verankeren is in de medullaire holte van de humerusschacht,
- een steunelement dat vast te zetten is ten opzichte van het basiselement, waarbij het steunelement is geconfigureerd om een of meer botfragmenten te ondersteunen,
met het kenmerk,
dat de medische inrichting positioneringsmiddelen omvat die zijn geconfigureerd om het steunelement in een gebied van rotatieposities en axiale posities te positioneren ten opzichte van het basiselement, en
dat de medische inrichting vastzetmiddelen omvat om het steunelement, binnen het gebied van rotatieposities en axiale posities, vast te zetten ten opzichte van het basiselement in een gewenste rotatiepositie en axiale positie.

2. Medische inrichting volgens conclusie 1, waarbij de positioneringsmiddelen een cilindrische opening omvatten in een van het basiselement en het steunelement, en een cilindrische verlenging aan de andere van het basiselement en het steunelement.

3. Medische inrichting volgens conclusie 1 of 2, waarbij de positioneringsmiddelen aan het distale einde van het steunelement een buisvormig deel omvatten dat een cilindrische opening definieert, en aan het proximale uiteinde van het basiselement een cilindrische verlenging, waarbij een buitendiameter van de cilindrische verlenging in hoofdzaak overeen komt met een binnendiameter van de cilindrische opening.

4. Medische inrichting volgens een van de conclusies 1-3, waarbij de vastzetmiddelen een vastzetelement omvatten dat te plaatsen is in het proximale uiteinde van het basiselement, waarbij het vastzetelement is geconfigureerd om, wanneer geplaatst in de proximale einde van het basiselement, de buitendiameter van de cilindrische verlenging toe te laten nemen.

5. Medische inrichting volgens conclusie 4, waarbij de cilindrische verlenging twee diametraal tegenover elkaar liggende verlengstukken omvat die zich in axiale richting uitstrekken en radiaal buitenwaarts beweegbaar zijn door middel van het vastzetelement.

6. Medische inrichting volgens conclusie 5, waarbij het vastzetelement een schroefelement met een uitwendige schroefdraad is, en waarbij de twee verlengstukken een inwendige schroefdraad hebben voor samenwerking met de uitwendige schroefdraad.

7. Medische inrichting volgens een van de voorgaande conclusies, waarbij een distaal uiteinde van het basiselement een of meer ankerelementen omvat die zich in radiale richting uitstrekken om het basiselement te verankeren in de medullaire holte van de humerus.

8. Medische inrichting volgens conclusie 7, waarbij de een of meer ankerelementen ten minste drie vinnen omvatten verdeeld over de omtrek van het basiselement en die zich uitstrekken in een vlak loodrecht op een tangentiële richting.

9. Medische inrichting volgens conclusie 7 of 8, waarbij het basiselement ten minste tussen de een of meer ankerelementen in de distale richting taps toeloopt.

10. Medische inrichting volgens een van de voorgaande conclusies, waarbij het steunelement een kooi omvat voor het bevestigen van de een of meer botfragmenten.

11. Medische inrichting volgens conclusie 10, waarbij de kooi is gevormd om het inwendige van een proximaal uiteinde van een te behandelen humerus in hoofdzaak te vullen.

12. Medische inrichting volgens conclusie 10 of conclusie 11, waarbij de kooi is uitgevoerd als een open constructie met stijlen voor de bevestiging van lussen of het gebruik van K-wires of andere bevestigingsinrichtingen voor de een of meer botfragmenten.

13. Medische inrichting volgens een van de voorgaande conclusies, waarbij de medische inrichting een steunvlak definieert om een humeruskop van de humerus te ondersteunen.

14. Medische inrichting volgens conclusie 13, waarbij de medische inrichting een of meer uitsteeksels omvat die uitsteken vanaf het steunvlak, waarbij de uitsteeksels zijn geconfigureerd om de humeruskop ten minste gedeeltelijk te penetreren.

15. Medische inrichting volgens een van de voorgaande conclusies, waarbij de medische inrichting is gemaakt van biologisch afbreekbaar materiaal.

FIGURE 1

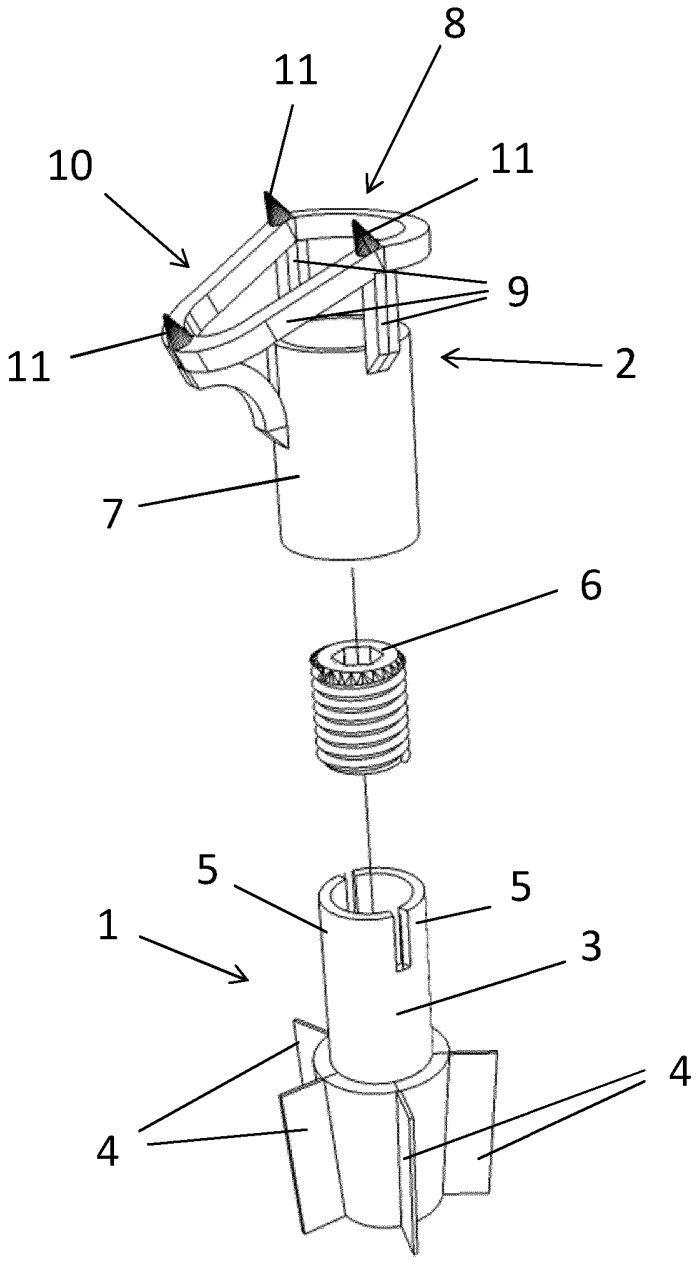


FIGURE 2

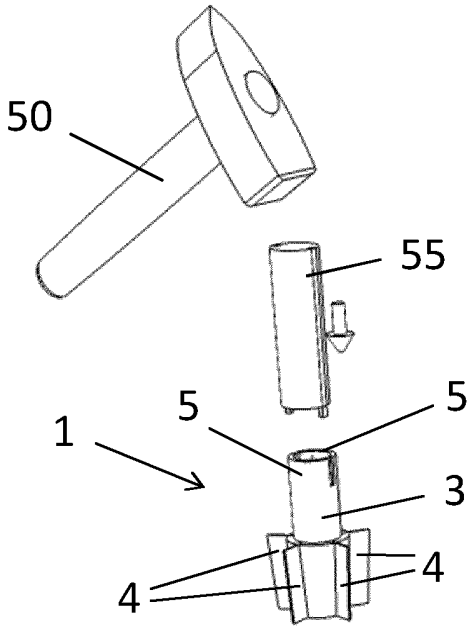


FIGURE 3

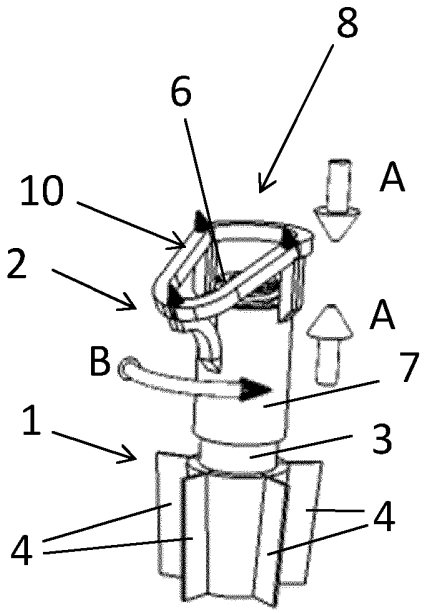


FIGURE 4

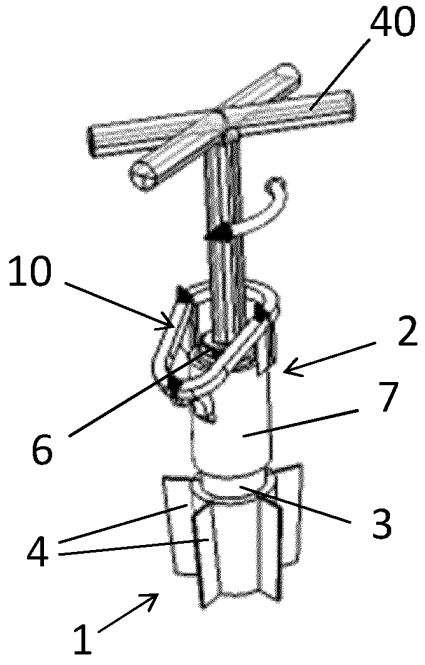
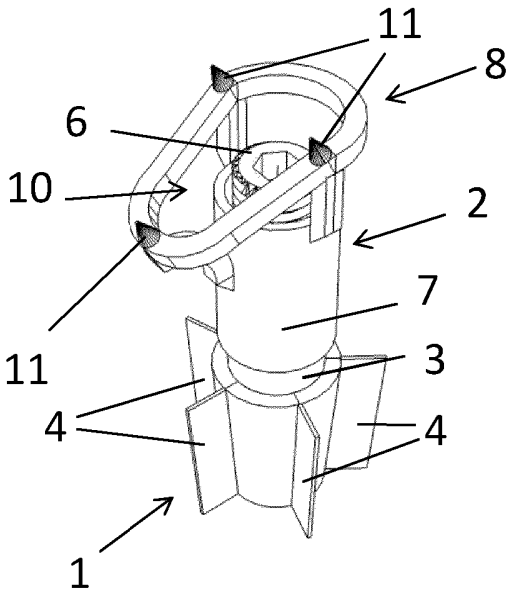


FIGURE 5



SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	P31169NL00/MVM
Nederlands aanvraag nr. **2009592**	Indieningsdatum **09-10-2012**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Visser**	
Datum van het verzoek voor een onderzoek van internationaal type **17-11-2012**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN59154**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

A61F2/30;A61F2/40;A61F2/46

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**A61F;A61B**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III. ☐ **GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES** (opmerkingen op aanvullingsblad)

IV. ☐ **GEBREK AAN EENHEID VAN UITVINDING** (opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2009592

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61F2/30 A61F2/40 A61F2/46
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61F A61B

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	EP 2 431 008 A1 (TORNIER INC [US]) 21 maart 2012 (2012-03-21) * alineas [0013], [0014], [0015]; figuren 4-6 *	1-3,7-9
X	US 2005/125067 A1 (SWEENEY PATRICK J [US]) 9 juni 2005 (2005-06-09)	1-6,13
Y	* alineas [0030] - [0032]; figuren 2,3 *	10-15
Y	DE 10 2009 050044 A1 (AAP IMPLANTATE AG [DE]) 7 april 2011 (2011-04-07) * samenvatting; figuren 2,3 *	10-12
Y	FR 2 726 994 A1 (CAFFINIERE JEAN YVES DE [FR]) 24 mei 1996 (1996-05-24) * conclusie 1; figuren 1,2 *	10-14

-/--

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
2 mei 2013	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Louka, Maria

1

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2009592

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
Y	US 2005/187550 A1 (GRUSIN N K [US] GRUSIN N KELLEY [US]) 25 augustus 2005 (2005-08-25) * alinea [0023] * -----	15

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2009592

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
EP 2431008 A1	21-03-2012	EP 2431008 A1	21-03-2012
		US 2012071985 A1	22-03-2012
US 2005125067 A1	09-06-2005	EP 1696836 A2	06-09-2006
		US 2005125067 A1	09-06-2005
		WO 2005060452 A2	07-07-2005
DE 102009050044 A1	07-04-2011	DE 102009050044 A1	07-04-2011
		WO 2011041999 A1	14-04-2011
FR 2726994 A1	24-05-1996	GEEN	
US 2005187550 A1	25-08-2005	AT 540628 T	15-01-2012
		AU 2004294998 A1	16-06-2005
		CA 2548469 A1	16-06-2005
		EP 1691700 A1	23-08-2006
		ES 2379877 T3	04-05-2012
		JP 4823917 B2	24-11-2011
		JP 2007512875 A	24-05-2007
		US 2005187550 A1	25-08-2005
		WO 2005053552 A1	16-06-2005

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN59154	09.10.2012		NL2009592

International Patent Classification (IPC)
INV. A61F2/30 A61F2/40 A61F2/46

Applicant
Visser

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☐ Box No. VIII Certain observations on the application

	Examiner
	Louka, Maria

Application number

WRITTEN OPINION

NL2009592

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	5, 6, 9-12, 14, 15
	No:	Claims	1-4, 7, 8, 13
Inventive step	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VII Certain defects in the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 EP 2 431 008 A1 (TORNIER INC [US]) 21 maart 2012 (2012-03-21)

D2 US 2005/125067 A1 (SWEENEY PATRICK J [US]) 9 juni 2005 (2005-06-09)

D3 DE 10 2009 050044 A1 (AAP IMPLANTATE AG [DE]) 7 april 2011 (2011-04-07)

D4 FR 2 726 994 A1 (CAFFINIERE JEAN YVES DE [FR]) 24 mei 1996 (1996-05-24)

Lack of novelty

The present application does not meet the criteria of patentability, because the subject-matter of claims 1-4,7,8,13 is not new.

D1 discloses an implantable medical device (see fig. 4) for treatment of a proximal humerus fracture (see § 2) comprising:

a base element (40) to be anchored in the medullar cavity of the humeral shaft,

a support element (42) to be fixed with respect to the base element, wherein the support element is configured to support one or more bone fragments,

characterized in that

the medical device comprises positioning means (tubular section (72) with bore (82)) configured to position the support element with respect to the base element in a range of rotational positions and axial positions, and in that

the medical device comprises fixation means to fixate the support element, within the range of rotational positions and axial positions, in a desired rotational and axial position with respect to the base element (see § 13).

D1 further discloses the additional features of claims 2 and 3 (see fig. 4), 7 and 8 (see figs. 5, 6, § 15).

D2 is also disclosing an implant as specified in claim 1 (see fig. 2, base element (18), support element (16), fixation means (22)) and the additional features of claims 2-4 (see fig. 2, § 30-32) and 13 (see fig. 3, support surface (16)).

Lack of inventive step

The present application does not meet the criteria of patentability, because the subject-matter of claims 5, 6, 9-12, 14, 15 does not involve an inventive step.

The additional features of claims 5 and 9 appear to be common design praxis in modular implants or implants with prongs.

The additional features of claim 6 are well-known securing means, see e.g. D2, screw 22, fig. 2.

The additional features of claims 10-12 have already been employed for the same purpose in a similar shoulder prosthesis (see D3, cage (1)). It would be obvious to the person skilled in the art, namely when the same result (internal filling of the proximal humerus) is to be achieved, to apply these features with corresponding effect to an implant according to D1, thereby arriving at an implant according to claims 10-12.

The additional features of claims 10-14 are also considered well-known in the art, see e.g. D4, support with protrusions (I).

Finally the biodegradable material is a well-known option, see e.g. D5, § 23 and as such lacking inventive step.

Re Item VII

Certain defects in the application

The features of claims 1-15 are not provided with reference signs placed in parentheses.