Title: HIP FRACTURE DEVICE WITH BARREL AND END CAP FOR LOAD CONTROL

Abstract: A hip fracture device providing distance limited dynamization, load controlled dynamization and combinations of both dynamization methods by varying components. The hip fracture device includes a plate having a head portion and a shaft portion. A barrel projects from the head portion of the plate and a screw is inserted in the barrel. A friction pin is slidably connected with the screw, and an end cap is fixed to the head portion of the plate. The friction pin is fixedly connected with the end cap. The screw slides over the friction pin and toward the end cap when a load is applied on the fracture device. The load required for further sliding of the screw over the friction pin increases incrementally as the screw slides towards the end cap.
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
Hip fracture device with barrel and end cap for load control

DESCRIPTION

Cross-reference to related application

This application claims the benefit of the filing date of United States Provisional Patent Application No. 60/925,399 filed April 19, 2007, the disclosure of which is hereby incorporated herein by reference.

Field of The Invention

The present invention relates generally to an apparatus and method for the treatment of fractures of the proximal femur including the neck of the femur and the intertrochantric region.

Brief Description of the Prior Art

Referring to FIG.1, the femur 1, otherwise known as the thigh bone, generally comprises an elongate shaft extending from the hip to the knee. The proximal end of the shaft 3 includes a head 5, a neck 7, a greater trochanter 8 and a lesser trochanter 9. Internal fixation of femoral fractures in general is one of the most common orthopedic surgical procedures. Fractures of the proximal portion of the femur (hip fractures) generally include femoral neck fractures and intertrochanteric fractures.

Fractures of the femur which extend into the neck of the bone are often treated with screws that thread into the femoral head and extend generally parallel to the femoral neck axis A-A to a plate on the lateral side of the shaft 3.

A conventional fracture fixation system for femoral neck fracture is disclosed in U. S. Patent No. 3,107,666 (the '666 Patent). The fracture fixation system of the '666 Patent has a sleeve and a nail that is inserted in the sleeve. A plastic ring is disposed between the sleeve and the nail. The plastic ring frictionally engages the internal cylindrical surface of the sleeve and the external surface of the nail. The friction
creates resistance to relative movement between the sleeve and the nail. However, upon the force acting on the system exceeding a threshold, relative movement between nail and sleeve is permitted.

Other conventional screw and plate systems typically apply a static compressive force across the fracture. It has been found that allowing the screw to travel along its axis in response to loading by the patient further encourages the growth of strong bone to heal the fracture. Screws of this type, known as dynamic compression screws, must provide axial movement while preventing angular rotation or lateral movement across the fracture. One shortcoming of dynamic compression screws is that unless the travel is appropriately limited, the neck of the femur may be undesirably shortened. Therefore, it is desirable to adjustably control the extent of axial movement (distance limited dynamization) and to adjustably provide a force that resists travel (load controlled dynamization). It is especially advantageous if the resisting force increases with the extent of travel.

As used herein, when referring to bones or other parts of the body, the term "proximal" means closer to the heart and the term "distal" means more distant from the heart. The term "inferior" means toward the feet and the term "superior" means towards the head. The term "anterior" means towards the front part of the body or the face and the term "posterior" means towards the back of the body. The term "medial" means toward the midline of the body and the term "lateral" means away from the midline of the body.

Summary of the invention

The present invention fills the need described above by providing hip fracture devices allowing distance limited dynamization, load controlled dynamization and
the combination of the distance limited dynamization and load controlled
dynamization and methods of using these devices.

The hip fracture device has a plate and screw assembly. By replacement of modular components in the screw assembly the extent of axial travel and the force resisting travel may be adjusted interoperatively.

In one aspect of the present invention, the hip fracture device uses a fixed barrel and modular end caps to variably limit the extent of axial travel of the screw within the barrel while restraining the screw to be coaxial with the barrel.

In another aspect of the invention, a friction pin mounted to an end cap progressively engages a bore in the screw to provide load controlled dynamization.

In another aspect of the invention, the hip fracture device includes a plate having a head portion and a shaft portion. A barrel projects from the head portion of the plate and a screw is inserted in the barrel. A friction pin is slidably connected with the screw, and an end cap is fixed to the head portion of the plate. The friction pin is fixedly connected with the end cap. The screw slides over the friction pin and toward the end cap when a load is applied on the fracture device. The load required for further sliding of the screw over the friction pin increases incrementally as the screw slides towards the end cap.

Another aspect of the invention is a method of repairing a fracture between the head and neck of a femur. The method includes the steps of affixing a plate having a head portion and a shaft portion on the femur, the plate having openings in the head portion and the shaft portion. A barrel is inserted in the opening in the head portion and a screw is inserted in the barrel. An end cap is inserted in the opening having the barrel inserted therein, and a friction pin is inserted between the end cap and the screw. The screw can slide over the friction pin and towards the end cap, and the
load required for further sliding of the screw over the friction pin increases incrementally as the screw slides towards the end cap.

In another aspect, the invention provides a kit for repairing a fracture between the head and neck. The kit includes at least one plate, the plate having a head portion and a shaft portion, and openings formed in the head portion and the shaft portion. The kit also includes at least one barrel configured for insertion in the opening in the head portion, and at least two screws each having a central bore, each bore having a different diameter. Also included are at least two friction pins, each pin having an external diameter that matches the diameter of one of the central bore in one of the screw, and at least two end caps, each end cap having a first bore that matches the diameter of one of the friction pins.

**Brief description of the drawings**

Figure 1 is a frontal elevation view of a hip fracture device implanted in a proximal femur.

Figure 2 shows another embodiment of a bone plate that may be used with the hip fracture device of Figure 1.

Figure 3 is a close up view of a portion of Figure 1.

Figure 4 is a sectional lateral view as shown in Figure 1 with the end cap removed.

Figures 5 is a view as in Figure 3 showing an end cap with a long shaft.

Figures 6 is a view as in Figure 3 showing an end cap with a short shaft.
Figures 7 is a view as in Figure 3 showing a friction pin placed between an end cap and a hip screw.

Figure 8 is a view as in Figure 3 showing the friction pin engaged in the end cap and the hip screw with the hip screw at the farthest distance from the end cap.

Figure 9 is a view as in Figure 3 showing the friction pin engaged in the end cap and the hip screw having moved axially towards the end cap.

Figure 10 shows the hip screw after it has moved further axially towards the end cap as compared to the position shown in Figure 9.

Figure 11 shows the hip screw after it has moved farthest axially towards the end cap such that the top of the hip screw is touching the end cap and cannot move any further.

**Detailed description of the preferred embodiments**

Referring to Figure 1, a hip fracture device 21 includes a locking plate 11 and one of more (preferably three) screw assemblies 31. The hip fracture device 21 may be used for fixing bone fractures, particularly femoral neck fractures including Gaarden III/IV type fractures.

The locking plate 11 generally conforms to the lateral portion of the proximal femur 1 and is attached to the femur by at least one cortical interlocking screw 15 passing through holes 13 in the subtrochanteric shaft region 3 of the femur 1. The interlocking screws 15 serve to attach the plate 11 to the femur 1. The plate 11 also has one or more stepped bores 17 for each screw assembly 31. The major diameter of the stepped bore 17 incorporates a screw thread for fastening the screw assembly 31. The minor diameter of the stepped bore 17 creates a shoulder 19 at the junction.
of the major and minor diameters. Each stepped bore 17 is aligned with the axis of each of the screw assemblies 31. Figure 2 shows a plate HA. Plate HA is a variation of design of plate 11, and includes a slot 13A. Plate 11A may be used in place of plate 11. A guide wire may be inserted through slot 13A and into the femur 1. The guide wire may be used to position the plate 11A in a desired alignment on the surface of the femur 1. The compression screw embodiments disclosed hereafter may be used with the bone plate 11A.

The screw assemblies 31 incorporate a hip screw 33, a barrel 41, an end cap 51 and an friction pin 61. The friction pin may also be referred to as a spring pin. At least one screw assembly 31, in conjunction with the plate 11, provides angular stability in the indicated direction to counteract the moment created on the femoral neck 7 by the normal force F resulting from loads on the femoral head 5. The screw assembly 31 also provides angular stability in all other directions. Rotational stability about the head axis A-A is achieved if more than one screw assembly 31 is connected to the plate 11. Typically the hip screw assemblies 31 are oriented parallel to the femoral neck axis A-A as shown.

Hip screw 33 is typically cannulated with a bore 37. Non-cannulated versions may have a blind bore 37 at the distal end. The screw 33 has a central shaft 34 defining a minor external diameter and an external flange 38 defining a major external diameter at the distal end of the screw. Formed internal to flange 38 are rotational features such as a hex socket 39. Threads 35, suitable for anchoring to bone, are formed at the proximal end of the screw 33 and engage the cancellous bone of the femoral head 5.

Referring to FIG. 3, barrel 41 is generally cylindrical in shape with an external diameter 43 corresponding to the minor diameter of the stepped bore 17 in plate 11. The barrel 41 has a sliding fit in the stepped bore 17 and rests on the shoulder 19.
Located at the distal end of barrel 41 is an external flange 49 that is a sliding fit with the major diameter of stepped bore 17 and engages shoulder 19 to prevent movement of the barrel 41 in the proximal direction along the screw assembly axis. The barrel 41 has a stepped bore 45 with major diameter 46 and minor diameter 47. The minor diameter 47 creates a shoulder 48 at the junction of the major diameter 46 and minor diameter 47. The minor diameter 47 is a sliding fit with central shaft 34 of the screw 33 and the shoulder 48 engages the external flange 38 to limit movement of the screw 33 in the proximal direction along the screw assembly axis.

A head 52 is formed in a distal portion of the end cap 51. The head 52 has a major diameter 53 and external machine threads formed on the major diameter 53 for fastening with the mating threads of the bore 17 of the plate 11. Formed internal to head 52 are rotational features such as a hex socket 59. The proximal region of the end cap 51 is a shaft 55 with a minor diameter 56 providing a slip fit with major diameter 46 of the barrel 41. The shaft 55 has a proximal end 58 which may abut the end of the flange 38 to limit movement of the screw 33 in the distal direction along the screw assembly axis. The end 58 has a blind bore 57.

The friction pin 61 is provided for load controlled dynamization. The friction pin 61 is typically a roll pin with a slot 67 (FIG. 4) that, when present, is press fit in bore 57 and is also a sliding interference fit with the bore 37 of the screw 33. The bore 57 is sized to firmly retain the friction pin. The bore 37 is sized to provide a controlled factional resistance to resist movement of the screw 33 in the distal direction along the screw assembly axis as will be further described in conjunction with FIGS. 8-11.

All the various diameters and bores of the screw assembly 31 are concentric about the axis of the assembly as depicted in FIG. 4, which does not show the end caps 51 or the hex socket 39. The various concentric sliding fits allow the screw 33 to move only along its axis, that is, parallel to the axis A-A.
Assembly of the device 21 on femur 1 proceeds as follows. First, the plate 11 is fixed at the proximal femur 1 at the lateral region of the shaft 3. The femur 1 is prepared by drilling holes sized for insertion of the screw 31 and the barrel 41. The barrel 41 is then inserted into the bore 17 of the plate 11 until its final position where the flange 49 is seated against the shoulder 19 formed between the major and minor diameters of the bore 17. The screw 33 is then inserted into the barrel 41 and turned into the bone until the screw flange 38 is seated against the barrel shoulder 48. By turning several additional turns of the compression screw 33 a femoral head fragment that includes the femoral head 5 is pulled against the distal fracture surface of the femur 1 and the fracture is initially compressed.

By selecting from a kit of various configurations of end caps 51 and friction pins 61, the extent and force required for dynamization can be adjusted by the surgeon at this point in the operation. Should the surgeon desire static locking of the fragment in order to strictly limit travel and prevent shortening of the femoral neck, an end cap 51a with a longer shaft 56a is used to prevent distal motion of the screw 33 as shown in FIG. 5. Here the end cap 51a is in contact with the end of screw 33 and therefore no axial movement of the femoral head fragment is allowed. FIG. 6 shows how caps 51 with various lengths of shaft 56 may be used to allow distance limited sliding of the screw 33. In Figure 6, there is a space between the end of the end cap 56 and the opposing end of the screw 33. Therefore, the screw 33 and consequently the femoral head fragment can move axially towards the cap end 56. The maximum travel in this case is equal to the space between the end of the end cap 56 and the opposing end of the screw 33. This distance limited sliding of the femoral head fragment allows for fragment opposition and postoperative dynamic fracture site compression by weight bearing while limiting excessive femoral neck shortening.

As shown in FIG. 7, when friction pin 61 is added, the screw assembly 31 provides load controlled sliding of the screw 33. This sliding allows femoral head fragment
opposition and postoperative dynamic fracture site compression by weight bearing while limiting the load on the fracture site, limiting the travel based on the load, and preventing stress induced resorption of the bone. The initial friction created by the friction pin 61 and the bore 37 can be varied by selecting from a kit of pins with varying diameters according to the patient’s weight, bone structure and the type of fracture. Thus, a heavier patient with larger bones may be fitted with a pin that creates more friction.

The hip fracture device 21 shown in Figure 7 provides load controlled sliding of the femoral head fragment in order to allow for fragment apposition and postoperative dynamic fracture site compression by weight bearing while limiting the load on the fracture site and preventing stress induced resorption of the bone. The control mechanism provides increasing resistance with increasing sliding distance. This is caused by the progressively greater length of the friction pin 61 engaged by the bore 37 during sliding as depicted in FIGS. 8-11. Sliding of screw 33 stops when either the resistance becomes equal to the body weight induced force or when the distance limit is reached.

When multiple screw assemblies 31 are used, the installation steps are repeated and the resistance may be varied by using the friction pins in some or all of the assemblies. Typically, the distance limits are the same for all the assemblies.

In use, the plate 11 is fixed to the bone by inserting cortical screws 15 through holes 13 and into the subtrochanteric shaft region. Using methods known to one skilled in the art, one or more stepped holes are drilled from the lateral side of femur into the femoral head portion. The holes are sized to accept screw 33 and barrel 41. Next, a barrel 41 is inserted in a hole 13 and a screw 33 is inserted in the barrel. If more than one screws are to be used, the process may be repeated at this time or later. Next, the screw 33 is rotated in the femoral head fragment thereby attaching it to the fragment.
The rotation is continued after the screw 33 has bottomed on the shoulder 48 resulting in closing of the fracture gap. The screw may be rotated further to apply initial compression to the fracture site. Next, the end cap 51a (Figure 5) is inserted in the hole 13 and screwed in place. The end cap 51a may be of such length that its proximal end rests on the end of the screw 33 to prevent any axial movement of screw 33. If the end cap is of a shorter length, the screw 33 would be allowed to slide back in axial direction. The sliding movement would be stopped when the screw 33 touches the end cap 56.

Alternatively, as shown in Figure 8, one end of the friction pin 61 is inserted in the bore 37 of the screw 33 and the other end is inserted in the bore 57 of end cap 51, thereby clamping the friction pin 61 between the end cap 51 and screw 33. Upon application of load, for example, by putting body weight on the hip and thus device 21, the friction pin 61 may be pushed further into the bore 37. As the friction pin 61 is pushed further in the bore 37, as seen in Figure 9 and 10, increasingly greater load is required for axial movement of the screw 33 towards cap 51. Once the screw 33 touches the end cap 51, as seen in Figure 11, any further axial travel of the screw 33 is prevented.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention.
CLAIMS

1. A hip fracture device comprising:
   a plate (11), the plate having a head portion and a shaft portion (3);
   a barrel (41) projecting from the head portion of the plate;
   a screw (33) inserted in the barrel;
   a friction pin (61) slidably connected with the screw; and
   an end cap (51) fixed to the head portion of the plate, wherein the friction pin
   is fixedly connected with the end cap, and the screw slides over the friction pin and
   toward the end cap when a load is applied on the fracture device.

2. The device of claim 1, wherein the load required for further sliding of the
   screw over the friction pin increases incrementally as the screw slides towards the
   end cap.

3. The device of any of claims 1 and 2, wherein the friction pin comprises:
   a tubular body (65); and
   a slit (67) formed in the tubular body.

4. The device of any of claims 1 to 3, wherein the end cap comprises:
   a head (52); and
   a shaft (55) projecting from the head, the shaft having a blind bore (57) sized
to form a press fit with the external surface of the friction pin.

5. The device of claim 4, further comprising:
   first threads (53) formed on the head (52); and
   second threads (53) formed in a bore (17) in the head portion of the plate
   (11), the first and the second threads configured to mate, thereby fixing the end cap
   (51) to the plate (11).
6. The device of any of claims 4 and 5, wherein the maximum length of travel of the screw (33) toward the end cap (51) is inversely proportional to the length of the shaft (55) projecting from the head (52).

7. The device of any of claims 4 to 6, wherein the screw further comprises a flange (38) and the barrel (41) comprises a shoulder, and the flange rests against the shoulder when the screw is at the farthest distance possible from the end cap.

8. The device of any of claims 1 to 7, wherein rotating the screw (33) when the flange (38) is resting against the shoulder pulls a femoral head fragment towards a femur to close a gap between them.

9. The device of any of claims 1 to 8, further comprising:
   a second and a third barrel (41) projecting from the head of the plate (11);
   a second screw (33) inserted in the second barrel and a third screw (33) inserted in the third barrel;
   a second friction pin (61) slidably connected with the second screw and a third friction pin (61) slidably connected with the third screw; and
   a second and a third end caps (51) fixed to the head portion of the plate (11), wherein the second friction pin is fixedly connected with the second end cap and the third friction pin is fixedly connected with the third end cap, and the second and the third screws slide over the second and the third friction pins respectively and toward the end cap when a load is applied on the fracture device.

10. The device of claim 9, wherein the load required for further sliding of the screw (33), the second screw (33) and the third screw (33) over the friction pin (61), the second friction pin (61) and the third friction pin (61) respectively increases incrementally as the screws slide towards the respective end caps (51).
11. The device of any of claims 9 and 10, wherein the friction pin (61) is of different diameter as compared to the second friction pin (61) and the third friction pin (61).

12. A method of applying a hip fracture device for repairing a fracture between the head and neck of a femur comprising:

   affixing a plate having a head portion and a shaft portion, the plate having openings in the head portion and the shaft portion;
   inserting a barrel in the opening in the head portion;
   inserting a screw in the barrel;
   inserting an end cap in the opening having the barrel inserted therein;
   inserting a friction pin between the end cap and the screw, such that the screw can slide over the friction pin and towards the end cap, and the load required for further sliding of the screw over the friction pin increases incrementally as the screw slides towards the end cap.

13. The method of claim 12, wherein affixing comprises affixing on the femur.

14. The method of any of claims 12 and 13, further comprising:

   changing the load required for axial movement of the screw towards the end cap by selecting a friction pin of different size.

15. The method of any of claims 12 to 14, further comprising:

   inserting a second barrel in a second opening in the head portion;
   inserting a screw in the second barrel;
   inserting a second end cap in the second opening; and
   inserting a second friction pin between the end cap and the screw.
16. The method of claim 15, wherein the second friction pin is the same size as the friction pin.

17. The method of claim 15, wherein the second friction pin is a different size from the friction pin.

18. The method of claim 15, wherein the first and the second pin are same length.

19. A kit for repairing a fracture between the head and neck of a femur comprising:

   at least one plate (11), the plate having a head portion and a shaft portion (3), and openings (13, 17) formed in the head portion and the shaft portion (3);

   at least one barrel (41) configured for insertion in the opening in the head portion;

   at least two screws (33) each having a central bore (37), each bore having a different diameter;

   at least two friction pins (61), each pin having an external diameter that matches the diameter of one of the central bore (37) in one of the screw; and

   at least two end caps (51), each end cap having a first bore (57) that matches the diameter of one of the friction pins.
**INTERNATIONAL SEARCH REPORT**

**International application No:**

PCT/EP2008/002892

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### A. CLASSIFICATION OF SUBJECT MATTER

**INV.** A61B17/74 A61B17/86

**ADD.** A61B17/00

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According to International Patent Classification (IPC) or to 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

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

**EPO-Internal, WPI Data**

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### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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**X** Further documents are listed in the continuation of Box C

**X** See patent family annex

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### Date of the actual completion of the international search

21 August 2008

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Date of mailing of the international search report

03/09/2008

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Name and mailing address of the ISA/

European Patent Office, P B 5818 Patentlaan 2

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Fax (+31-70) 340-3016

Authorized officer

Cuiper, Ralf

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INTERNATIONAL SEARCH REPORT

Box No. II 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. [ ] Claims Nos.: 12-18
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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).

Box No. III 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.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)
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