

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



WIPO | PCT

**(43) International Publication Date
18 February 2016 (18.02.2016)**

(10) International Publication Number



0) International Publication Number
WO 2016/024149 A1

(51) **International Patent Classification:**
A61B 17/00 (2006.01) *A61F 2/00* (2006.01)
B25C 1/00 (2006.01)

(21) **International Application Number:**
PCT/IB2014/065204

(22) **International Filing Date:**
10 October 2014 (10.10.2014)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
2601/MUM/2014 12 August 2014 (12.08.2014) IN

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(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

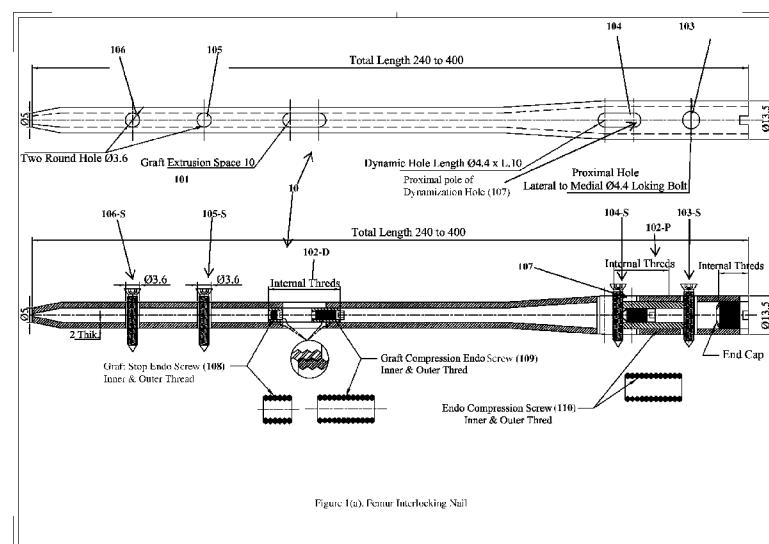
(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published: _____ with international search report (Art. 21(3))

Published:

— with international search report (Art. 21(3))

(54) Title: INTERLOCKING NAIL



(57) Abstract: The invention relates to an interlocking nail (10) for fixation of transverse and short spiral fractures of, long bone, particularly shaft of the femur, tibia and humerus, having Graft extrusion space/slot (101) for holding stem cells graft and 4 or 5 holes for putting interlocking bolts from lateral to medial direction. Constant compression achieved (irrespective of weight bearing cycle) at the fracture site by tightening of the Endo-Compression Screws (108, 109 and 110) results in stimulation of stem cells and reduction in bone gap, thus enhances bone healing and union manifolds.

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INTERLOCKING NAIL

This application claims priority benefit of Indian Patent Application No. 2601/MUM/2014 filed on August 12, 2014.

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FIELD OF INVENTION

[0001] This invention relates to an interlocking nail for fixation of transverse and short spiral fractures of, long bone, particularly shaft of the femur, tibia and humerus with the mechanism provided in the invention to augment the bone healing 10 and union manifolds. The disclosed interlocking nail specification could also be used for fractures of the radius and ulna.

BACKGROUND OF ART

[0002] Indian Patent Application 1088/MUMNP/2005 provides a 15 intramedullary nail for the fixation of fractures of the proximal femur, with a femur neck screw, installable with a proximal femur nail, into the intramedullary area, by a diagonal bore, running to the longitudinal axis of the femur nail, from the side of the femur nail, and a locking element with at least one branch parallel to the axis of the femur neck screw. The connection between the locking element and a groove in the 20 bore of the femur nail forms a twisting lock of the femur neck screw and allows for the axial movement of the femur neck screw in the bore of the femur nail.

[0003] Indian Patent Application No. 3544/DELNP/2005 provides an 25 intramedullary nail that has a distal end suitable for insertion in the medullary space. The intramedullary nail has several cross holes with a hole axis, each of which defines a virtual drill cylinder with a cylinder axis corresponding to the hole axis of the defining cross hole. The drill cylinders of at least two cross hole penetrate each other. The cylinder axis of the two mutually penetrating drill cylinders do not have any common intersection point on the longitudinal axis, resulting in improved 30 mechanical strength without any need for the size of the cross section of the medullary nail to be increased.

5 [0004] Indian Patent Application No. 3986/DELNP/2012 provides systems, devices and methods for limiting compression of a fracture imposed by a lag screw of a fixation system that includes a fixation device, a lag screw and a compression screw. The disclosed devices, systems and methods prevent over-compression of a fracture by a lag screw caused by over rotation of the compression screw.

10 [0005] Indian Patent Application No. 4467/DELNP/2007 provides an intramedullary nail having overall length L ranging from 200 to 500 mm; a first curved section having a length $G_1 = L$ and a radius of curvature R_1 and a second curved section having a length $G_2 = G_1$, and a radius of curvature $R_2 < R_1$ which is arranged between the proximal end part and the first curved section. The tangents in the two end points of a center section comprising the two curved sections form a total angle gamma between 9° and 12° .

15 [0006] Indian Patent Application No. 2825/DELNP/2006 provides an intramedullary nail suitable for being inserted into the medullary canal. The distal half of the nail provided with three transverse bores is suitable for receiving locking screws. The distal half, along the central axis has a proximal transverse bore having a bore axis, a central transverse bore having a bore axis, and a distal transverse bore having a bore axis. The bore axis of the central transverse bore extends between the proximal transverse bore and the distal transverse bore, is spaced at a shortest distance "a" from the bore axis (15) of the proximal transverse bore (5), and at a shortest distance "b" from the bore axis (17) of the distal transverse bore (7). In addition, the condition $a > b$ is applicable.

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30 [0007] Indian Patent Application No. 1567/DELNP/2006 provides an intramedullary pin for the tibia fractures, intended for the introduction into the medulla. The intramedullary pin has an overall length of L in the range of 200 to 500 mm and a curved section (4) with the length of $G < L$. The curved section with the length of G, has a curvature radius R in the range of 300-1300 mm and the L/R ratio is in the range of 0.2-0.8.

5 [0008] Indian Patent Application 3656/DELNP/2006 provides an intramedullary nail designed in particular for the tibia and has three distinct locking sections with at least one through-hole each for receiving locking screws. The said three locking sections are separated from each other by two distinct intermediate sections having less through-holes (8) per length unit than each of the locking sections (5, 6, 7).

10 15 [0009] The intra-medullary nails mentioned above for fixation of fractures are inserted in the medullary space. However, none of the prior art discusses about the improved and enhanced healing of the bone irrespective of the weight bearing cycle. The present invention relates to increasing bone healing due to the continuous compression caused by the Endo-Compression Screw that is inbuilt in the interlocking system. Additionally, none of the prior arts suggest the use of auto graft (i.e cancellous bone graft) in the interlocking nail obtained from medullary cavity of bone which is being operated.

SUMMARY OF THE INVENTION

20 25 [0010] The invention relates to an interlocking nail for fixation of transverse and short spiral fractures of, long bone particularly shaft of femur, tibia and humerus, having slot for holding pluripotent mesenchymal stem cells derived from auto-graft particularly cancellous bone graft. The interlocking nail has 4 or 5 holes for putting interlocking bolts from lateral to medial direction or from medial to lateral direction or in anterio-posterior direction, depending on orientation of interlocking hole. Constant compression at the fracture site is achieved (irrespective of weight bearing cycle) by tightening of the Endo Compression Screw at the proximal end of the interlocking nail resulting in the stimulation of mesenchymal stem cells due to compression as well as reduction in gap at fracture site, thus enhances bone healing and union manifolds.

30 [0011] Accordingly the principal object of the invention to introduce an interlocking nail for fixation of transverse and short spiral fractures of, the long bone.

5 [0012] Another object of the invention to provide a slot in the interlocking nail for holding mesenchymal stem cells graft, preferably from *cancellous bone graft* which helps in the enhanced healing and fixation of fracture. The said graft is obtained from medullary cavity of bone which is being operated. This particular slot should match with fracture site.

10 [0013] It is another object of the invention to provide a Graft Stop-Endo Screw inside the nail for holding the cancellous bone graft at the fracture site and Graft Compression Endo screw for compressing the bone graft thus allowing bone graft cell compression as well as cell migration across the fracture site.

15 [0014] It is another object of the invention to provide long graft extrusion space which threads internally to allow egress of graft cells maximum at fracture site via movement of Graft Endo-Compression screw and same could be modified as per the requirement.

20 [0015] It is another object of the invention to maintain the strength of the nail bone construct by providing hole in the graft extrusion space from medial to lateral direction (i.e. side to side) not from front to back (anterior to posterior).

25 [0016] It is another object of the invention to thread Graft Extrusion Space, 10mm above margin of the graft and 5mm below this space. The space of 10 mm allows the movement of the stem cells from auto-graft for bone healing from inside the nail.

30 [0017] A further object of the invention to achieve a static compression with tightening of the Endo Compression Screw, at fracture site irrespective of weight bearing cycle resulting in enhanced bone healing due to stimulation of stem cells, particularly pluripotent mesenchymal stem cells that divide into the osteoblast to form new bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The present invention may be better understood and its numerous objects, features and advantages made apparent to those skilled in the art, by referring to the accompanying drawings:

5 Fig 1 (a) and (b) illustrates the schematic diagram of the Interlocking Nail;

(a)Anterio-posterior and Lateral view of femur interlocking nail.

(b)Anterio-posterior and Lateral view of tibial interlocking nail.

Fig 2 showing the cancellous autograft inside the nail with Graft Stop-Endo Screw

10 holding graft at the fracture site;

Fig 3 showing introduction of Graft Compression Endo Screw;

Fig 4 showing migration of bone graft across fracture site due to the tightening of

15 Graft Compression Endo Screw;

Fig 5 showing introduction of 2nd proximal screw in proximal end of dyanamisation hole;

20 Fig 6 showing introduction of Endo Compression Screw and reduction of gap at the fracture site by tightening of screw;

Fig 7 showing introduction of remaining screw and final reduction of gap at the fracture site.

25

Note:

(1)The whole mechanism of action in the presenting interlocking nail is demonstrated with fixation of transverse fracture of shaft the femur only in stepwise manner.

30 (2)The same internal mechanism is used for interlocking nail for the tibia ,the humerus and radius and ulna bone.

DESCRIPTION OF THE INVENTION

[0019] The detailed description of the appended drawings is intended as a description of the currently preferred embodiments of the present invention, and it is not intended to represent the only form in which the present invention may be practiced. This is to be understood that the same or equivalent functions may be accomplished by different embodiments that are intended to be encompassed within the spirit and scope of the present invention.

[0020] The present invention relates to an interlocking nail (10) for fixation of transverse and short spiral fractures of long bone particularly shaft of the femur, tibia and humerus. The disclosed interlocking nail specification could also be used for fractures of the radius and ulna.

[0021] In accordance with an embodiment of the present invention, the interlocking nail (10) is a hollow cylinder having an outer diameter ranging from 8 to 15 mm and length ranging from 260-400 mm. The length of the interlocking nail (10) is not limited to the aforesaid range, but may vary depending upon the length of the bone. The thickness of interlocking nail (10) is as per international protocol for nail. However for better understanding and for description we are using the thickness of the interlocking nail (10) as 2 mm.

[0022] The shape of the interlocking nail (10) depends upon the bone type. For instance, [ref. fig 1 (b)] in fixing the fracture of tibia, interlocking nail (10-b) is curved in its proximal part at an angle of 110⁰ to accommodate the proximal angle of the bone. Similarly, in case of femur fractures, interlocking nail is slightly curved/bent anteriorly.

[0023] The graft extrusion space or slot(101) of 10 mm, for holding stem cells graft (plurio-potent mesenchymal stem), preferably from *cancellous bone graft (autograft)*, which helps in the enhanced healing and fixation of fracture is introduced in the interlocking nail (10). A preoperative analysis is done in order to assess the exact location of the fracture and to determine the configuration of fracture. The position of the slot (101) for egress/extrusion of stem cells could be

modified as per the preoperative analysis of fracture and interlocking nail (10) is chosen with a slot (101) which matches with the fracture site.

5 [0024] The length of the graft extrusion space (101) is about 10 mm, which is from medial to lateral direction i.e. from side to side. The whole part of the graft extrusion space (101) is threaded internally. The internal thread (102-D) begins from 10 mm above margin of graft extrusion space (101) and 5 mm below the said space (101). The slight space between the nail surface and bone surface allows the movement of the stem cells for the bone healing from inside the nail, to the fracture 10 site and along the endo-osteal surface.

15 [0025] In the standard interlocking nail (10) for long bone fracture, 4 or 5 holes are present for fixing interlocking bolts from lateral to medial direction or from medial to lateral direction or in anterio-posterior direction, depending on orientation of interlocking hole . These holes are oriented along the line perpendicular to central axis of nail and on opposing surface, across whole thickness at the corresponding level. Two holes are present at proximal part (103 and 104) and two holes (105 and 106) are present at distal part of nail (10). However, the number of holes and angle of screw insertion could be modified as per requirement.

20

25 [0026] Unlike the second proximal hole (104), first proximal hole (103) is same as found in other available interlocking nails. The second proximal hole (104) in the interlocking nail (10) would be of 10 mm in length and quadra-angular in shape with curved margin. Screw is inserted in the most proximal part, i.e. in upper end of dynamization hole (107). As already discussed internal thread (102-P) starts about 5 mm above the second proximal hole (104) and covering 3/4th of internal surface of hole.

30 [0027] This internal threading (102-D) leads to compression of bone graft between Graft Stop Endo Screw (108) and Graft Compression Endo Screw (109) which would create constant static compression, thus stimulating pluripotent stem cell for bone formation and bone healing.

[0028] The Graft Stop-Endo Screw (108) is introduced inside nail (10), after putting all interlocking bolts (105-S and 106-S) in distal holes (105 and 106) of the nail (10). The Graft Stop-Endo Screw (108) inside the nail (10) holds the cancellous bone graft, approximately 3 mm, below the level of the fracture line. The Graft 5 Compression Endo Screw (109) is then inserted inside the nail, at desired level. With the tightening of the Graft Compression Endo Screw (109), the graft is compressed between two endo screws (108 and 109), results in the migration of cells from the space provided in nail at the fracture site. These cells also cross the fracture site and come to lie under peri-osteum. Some cells migrate along the endo-osteal surface both 10 in proximal and distal direction across the fracture site. Compression of graft would also stimulate plurio-potent stem cell to divide into osteoblast that will further enhance fracture healing.

[0029] Even after fastening of the screw in the typical standard interlocking nail a slight gap is left at the fracture site ranging from 2-5 mm, which in turn delays bone formation and healing. In order to overcome such limitation of standard interlocking nails, the present invention has devised Endo-Compression Screws (110) inside nail (10). After the lower proximal screw (104-S) is tightened, the compression screw (110) is inserted from the proximal end of the nail (10). The 15 fracture is continuously compressed with tightening of the Endo Compression Screw (110), resulting in the movement at fracture site which is along the axis of nail (10). In turn maximum compression is achieved at the fracture site, irrespective of weight bearing cycle, results in enhanced bone healing. In addition to this, constant compression at fracture site enhances bone healing, due to stimulation of stem cells, 20 particularly plurio-potent mesenchymal stem cell to divide into osteoblast that will further enhance healing.

[0030] Further both the Graft Endo Screws used are solid screws that cover most of the length of Graft Extrusion Space; therefore the concerned space in the 30 question would be reduced in size. Thus strength of the nail would not be compromised significantly in any way.

CLAIMS

- 1) An interlocking nail (10) for the fixation of transverse and short spiral fractures of long bone particularly shaft of the femur, tibia and humerus comprising:
 - 5 a. holes for fixing interlocking bolts;
 - b. graft extrusion space /slot (101) for holding stem cells graft;
 - c. space for inserting endo-screws (108, 109 and 110);wherein the said holes ranges from 4-5.
- 10 2) The interlocking nail (10) as claimed in claim 1, wherein said interlocking nail (10) is a hollow cylinder having an outer diameter ranging from 8 to 13 mm and length ranging from 260-400 mm.
- 15 3) The interlocking nail (10) as claimed in claim 1, wherein said interlocking nail (10) is used for fixation of fractures of radius and ulna, more particularly transverse and short spiral fractures of long bone shaft of the femur, tibia and humerus.
- 20 4) The interlocking nail (10) as claimed in claim 1, wherein said holes (103, 104, 105 and 106) are oriented along the line perpendicular to central axis of nail and on opposing surface, across whole thickness at the corresponding level.
- 25 5) The interlocking nail (10) as claimed in claim 1, wherein both proximal part (103 and 104) and distal part (105 and 106) have two holes.
- 6) The interlocking nail (10) as claimed in claim 1, wherein said graft extrusion space /slot (101) holds stem cells graft, preferably from *cancellous bone graft (autograft)*, which enhances healing and fixation of fracture, manifolds.
- 30 7) The interlocking nail (10) as claimed in claim 10, wherein the stem cell graft is obtained from medullary cavity of bone which is being operated.

- 8) The interlocking nail (10) as claimed in claim 1, wherein said graft extrusion space (101) is approximately 10 mm in length from medial to lateral direction i.e. from side to side.
- 5 9) The interlocking nail (10) as claimed in claim 1, wherein said graft extrusion space (101) is threaded internally from 10 mm above and 5 mm below the margin of graft extrusion space (101).
- 10 10) The interlocking nail (10) as claimed in claim 8, wherein said internal threading (102-D) leads to compression of bone graft between Graft Stop-Endo Compression Screw (108) and Graft Compression Screw (109).
- 11) The interlocking nail (10) as claimed in claim 9, wherein said Endo Compression Screws (108 and109) create constant static compression on the autograft.
- 15 12) The interlocking nail (10) as claimed in claim 10, wherein said compression of the Endo Compression Screws (108 and109) stimulates pluripotent stem cell for bone formation and bone healing.
- 20 13) The interlocking nail (10) as claimed in claim 1, wherein Endo-Compression Screw (110) is inserted from the proximal end of the nail (10) creating compression with tightening of the Endo Compression Screw (110), resulting in the movement at fracture site along the axis of nail (10).
- 25 14) The interlocking nail (10) as claimed in claim 12, wherein said compression is achieved at the fracture site, irrespective of weight bearing cycle results in enhanced bone healing.

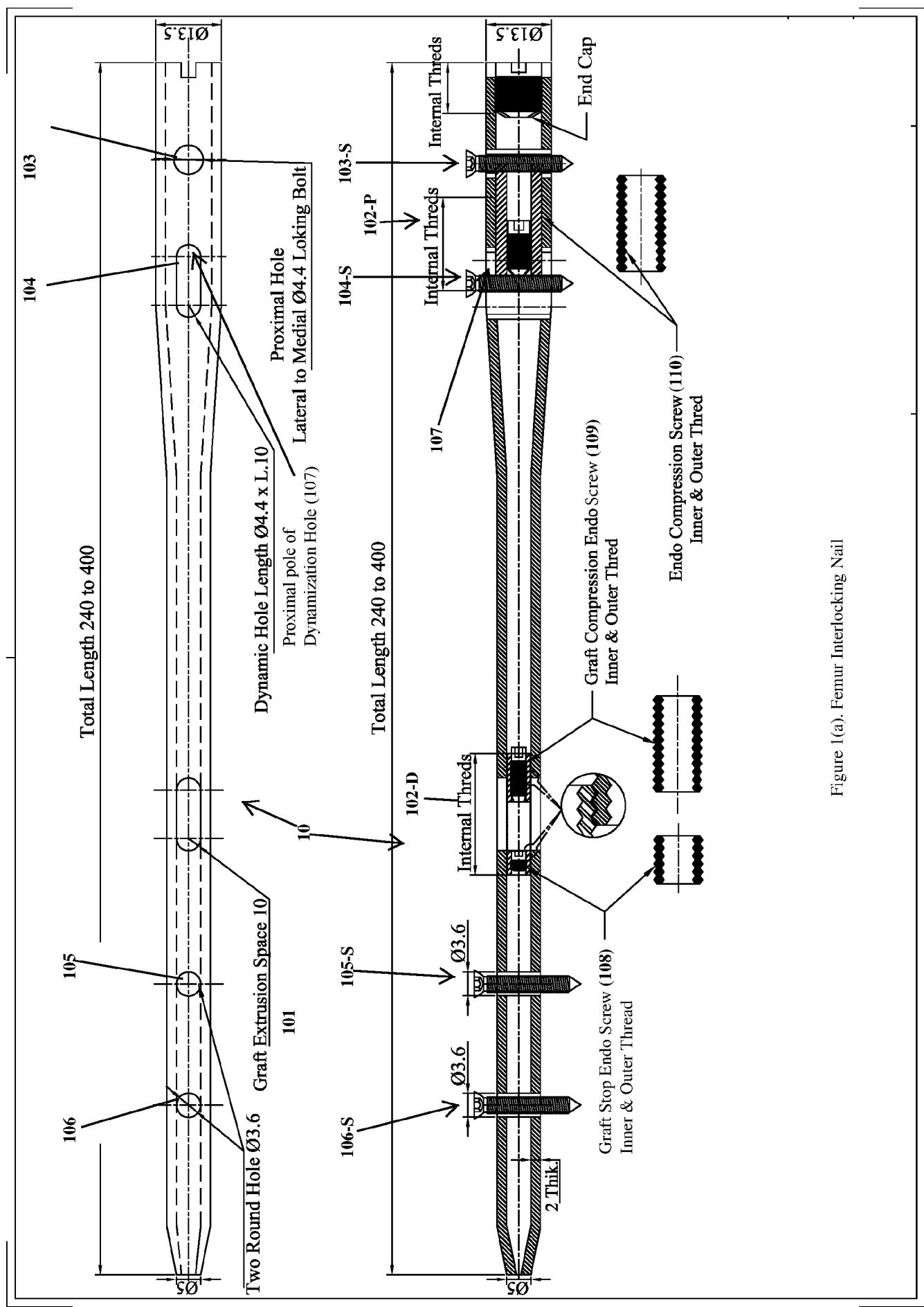


Figure 1(a). Femur Interlocking Nail

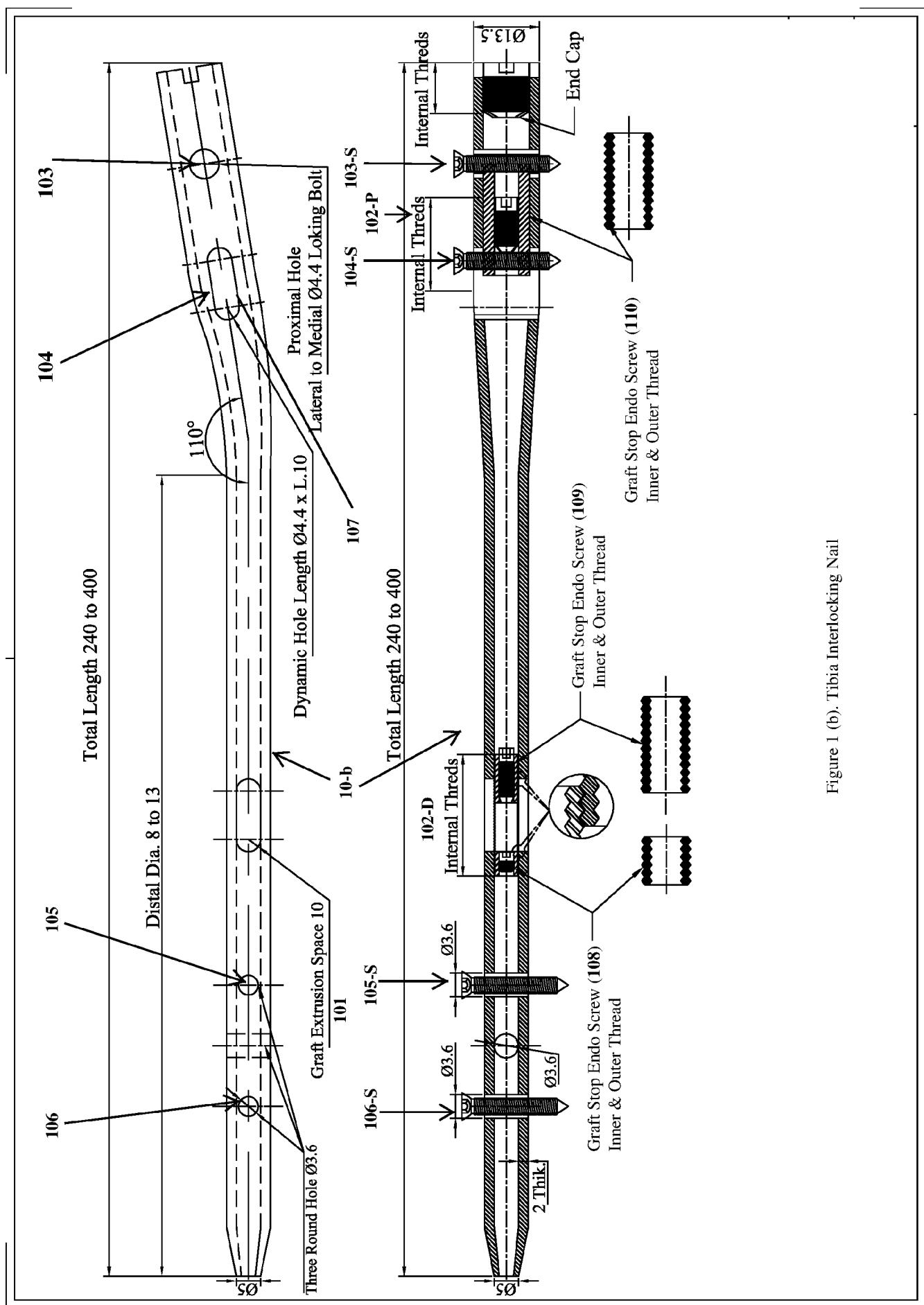
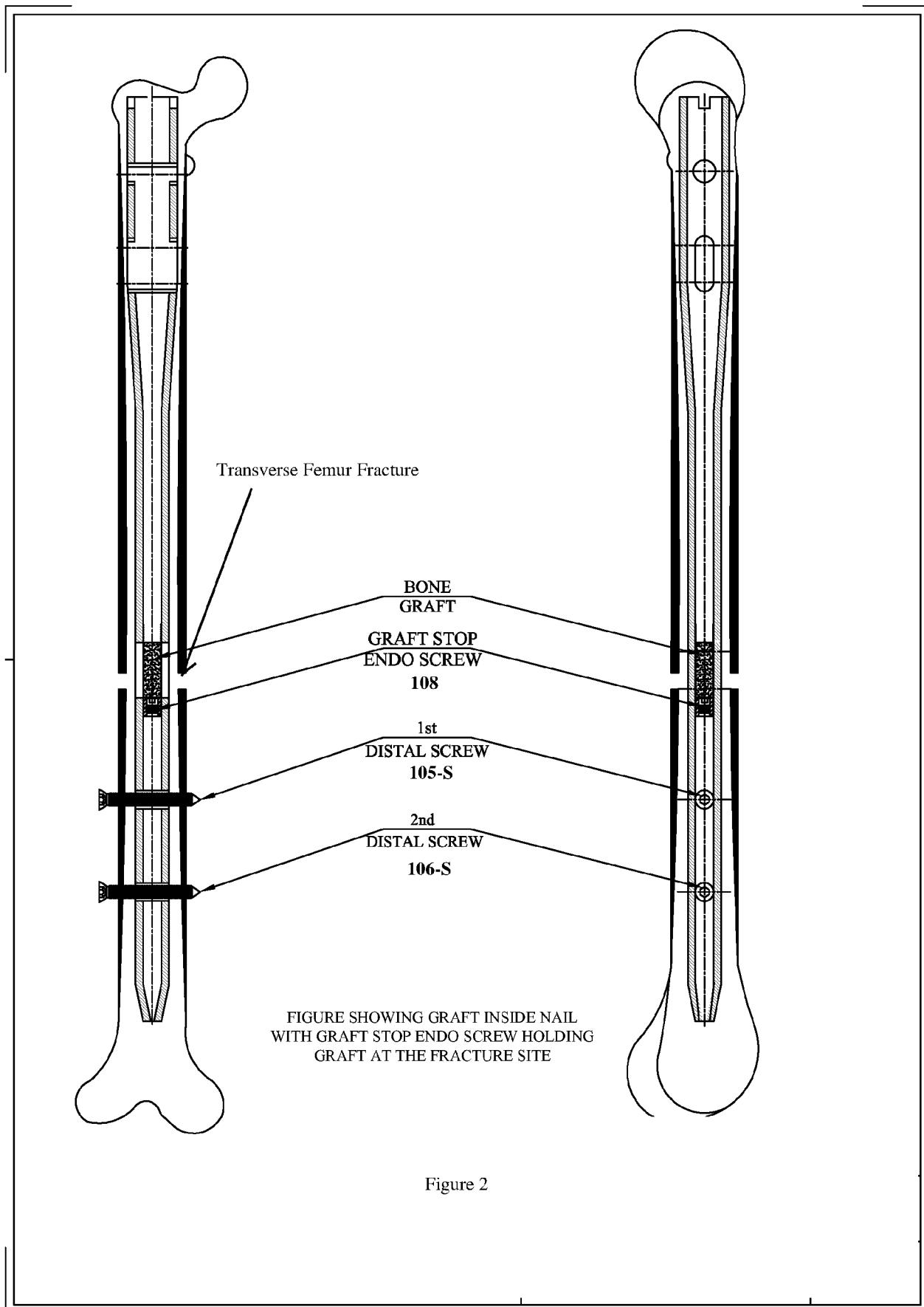


Figure 1 (b). Tibia Interlocking Nail



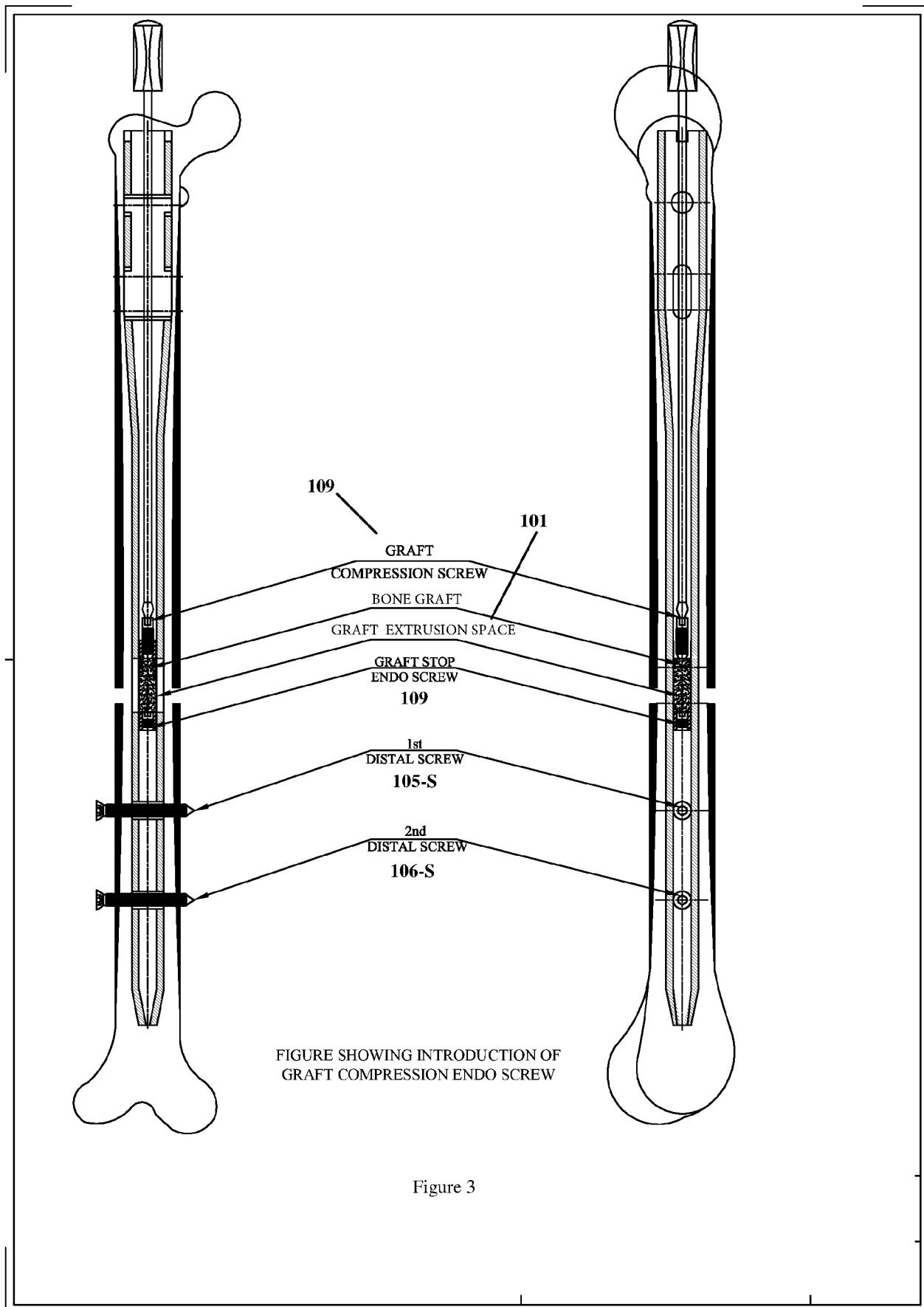


Figure 3

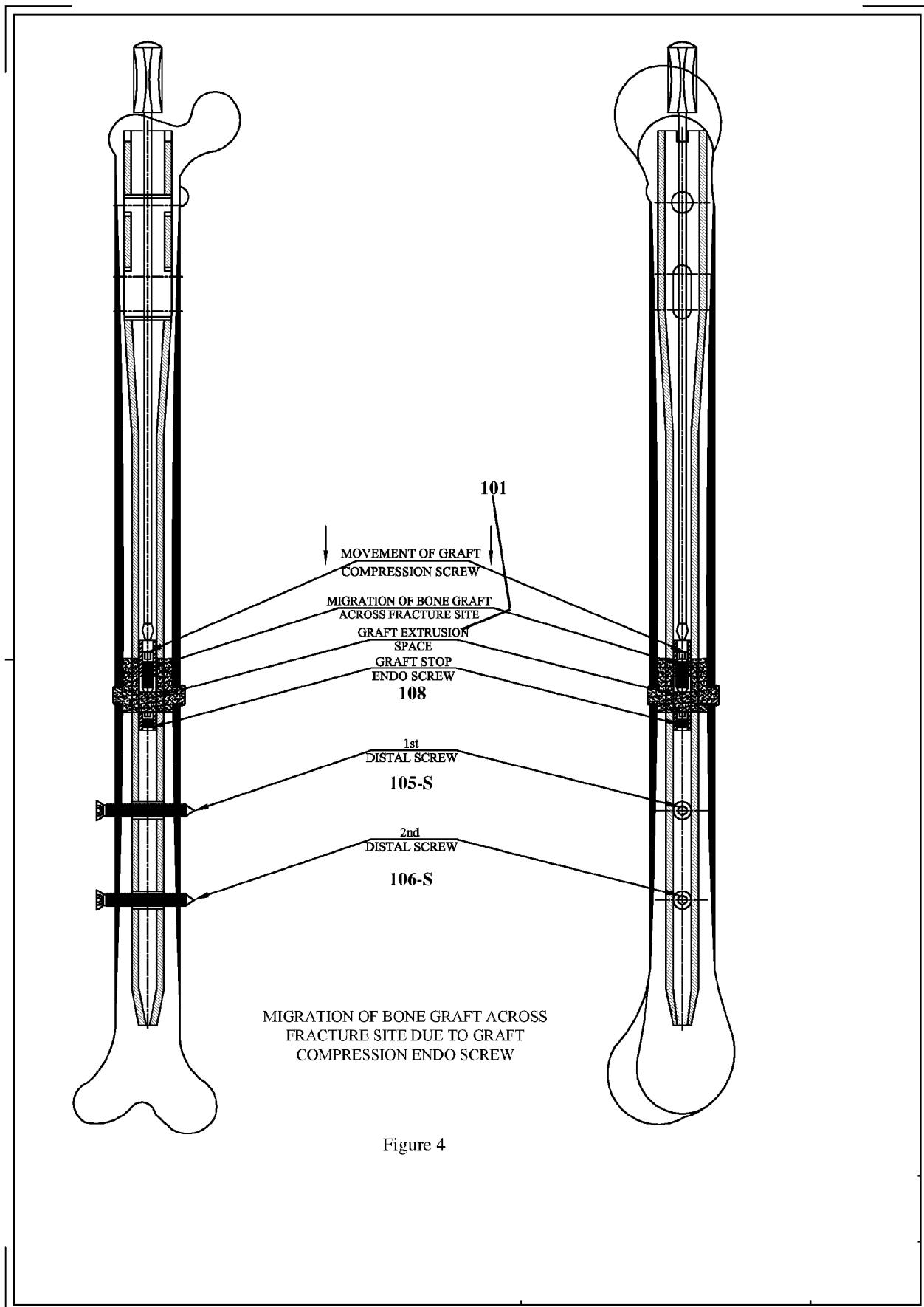


Figure 4

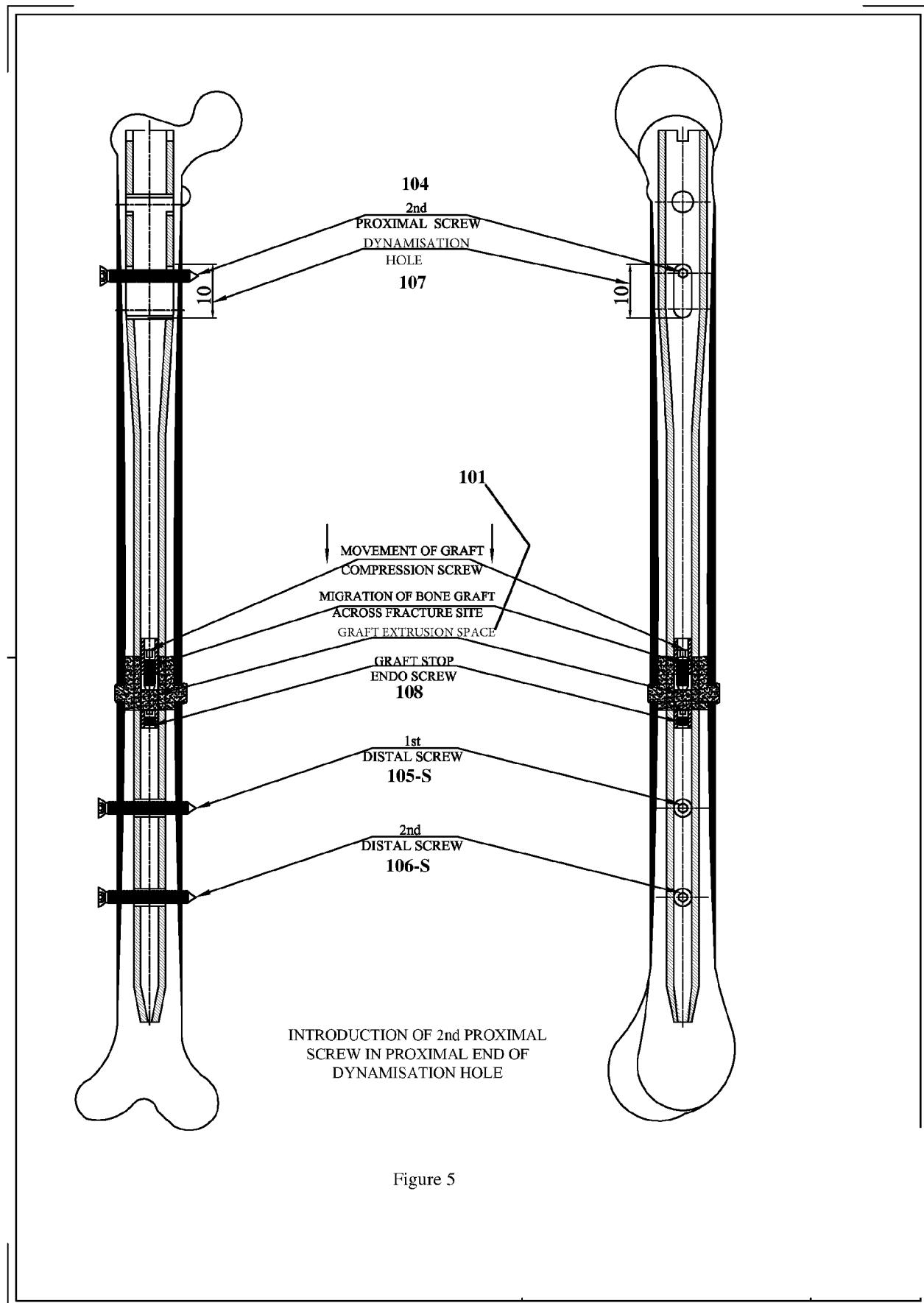


Figure 5

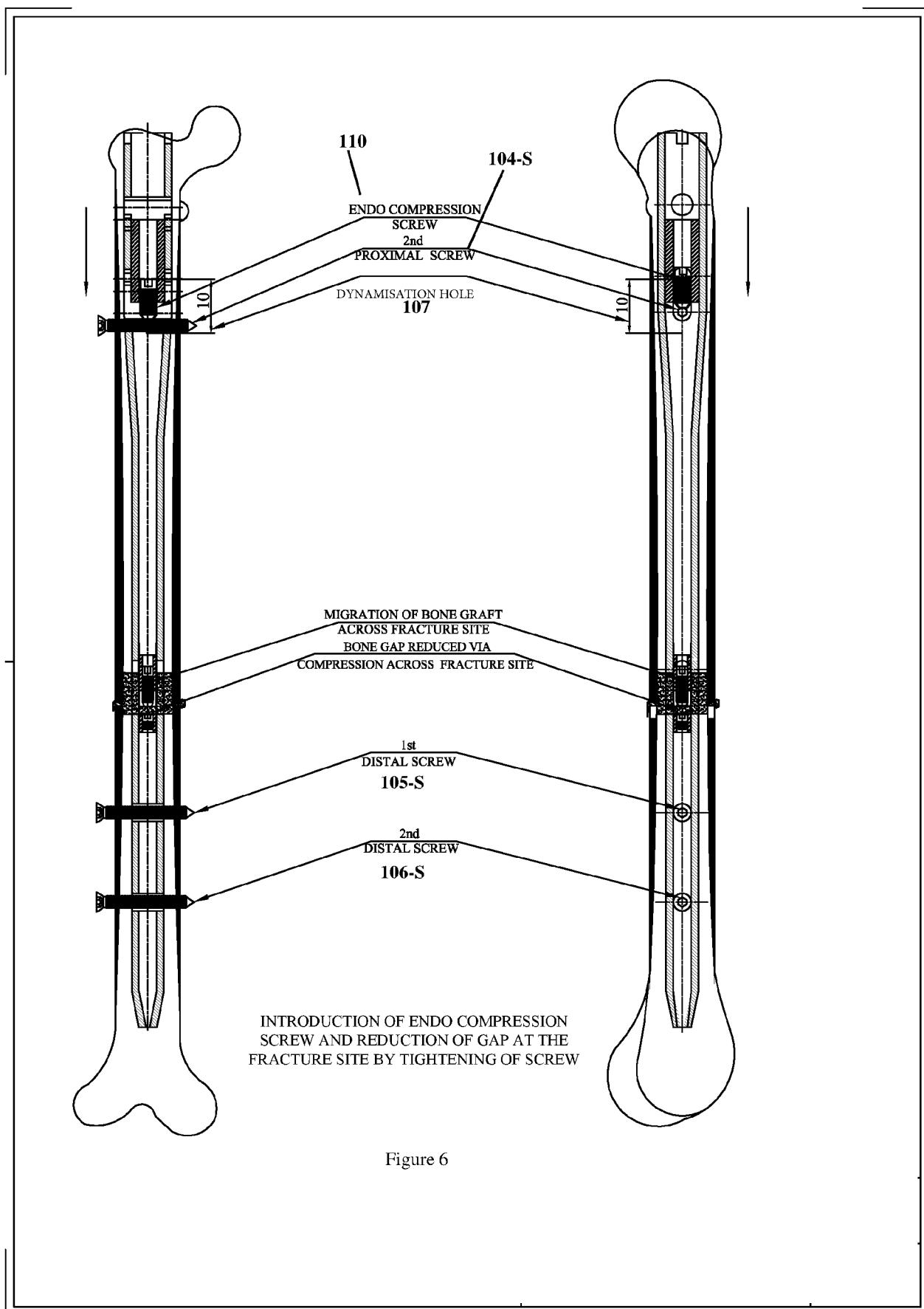


Figure 6

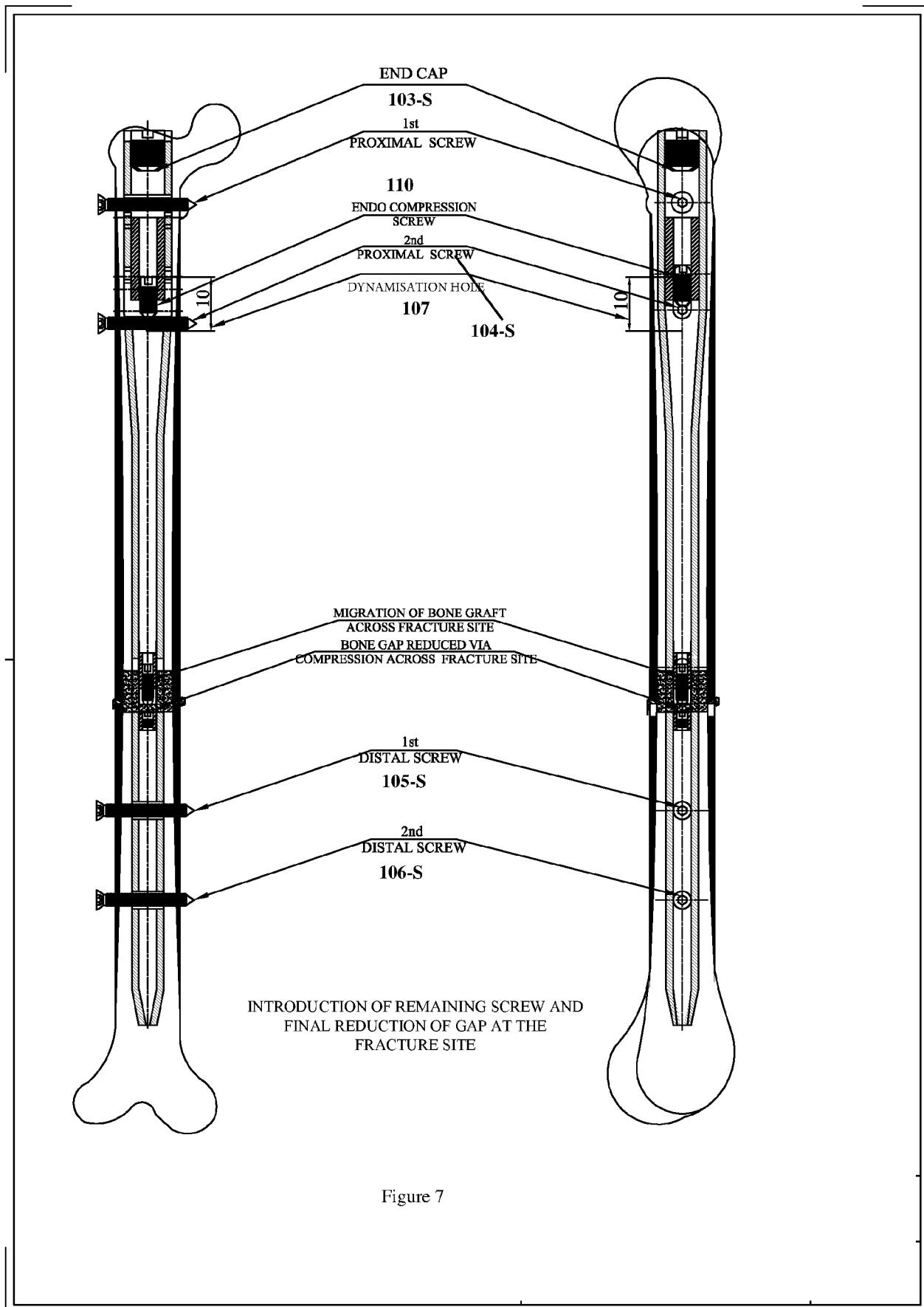


Figure 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2014/065204

A. CLASSIFICATION OF SUBJECT MATTER
A61B17/00, B25C1/00, A61F2/00 Version=2014.01

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, A61F and B25C.

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 practicable, search terms used)

DATABASES: QUESTEL, IPO INTERNAL.

SEARCH TERMS: INTERLOCKING, INTRAMEDULLARY, NAIL, SHAFT, BONE, FRACTURE.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | WO 1995015732 A1 (Richard D Coutts) 15-06-1995 Abstract, Figs 1-28 and Pages 1-49. ----- | 1-14 |
| Y | US 20070123873 A1 (Czartoski Timothy J et al.,) 31-05-2007 Abstract, Figs 1-35 and Pages 1-13. ----- | 1-14 |
| Y | EP 0493570 A1 (British Technology Group Limited) 8-07-1992 whole document. ----- | 1-14 |
| Y | US 8591513 B2 (DePuy Synthes Products, LLC) 26-11-2013 Abstract, Fig 13C and columns 15-18. | 1-14 |



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INTERNATIONAL SEARCH REPORT
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International application No.

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| Citation | Pub.Date | Family | Pub.Date |
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