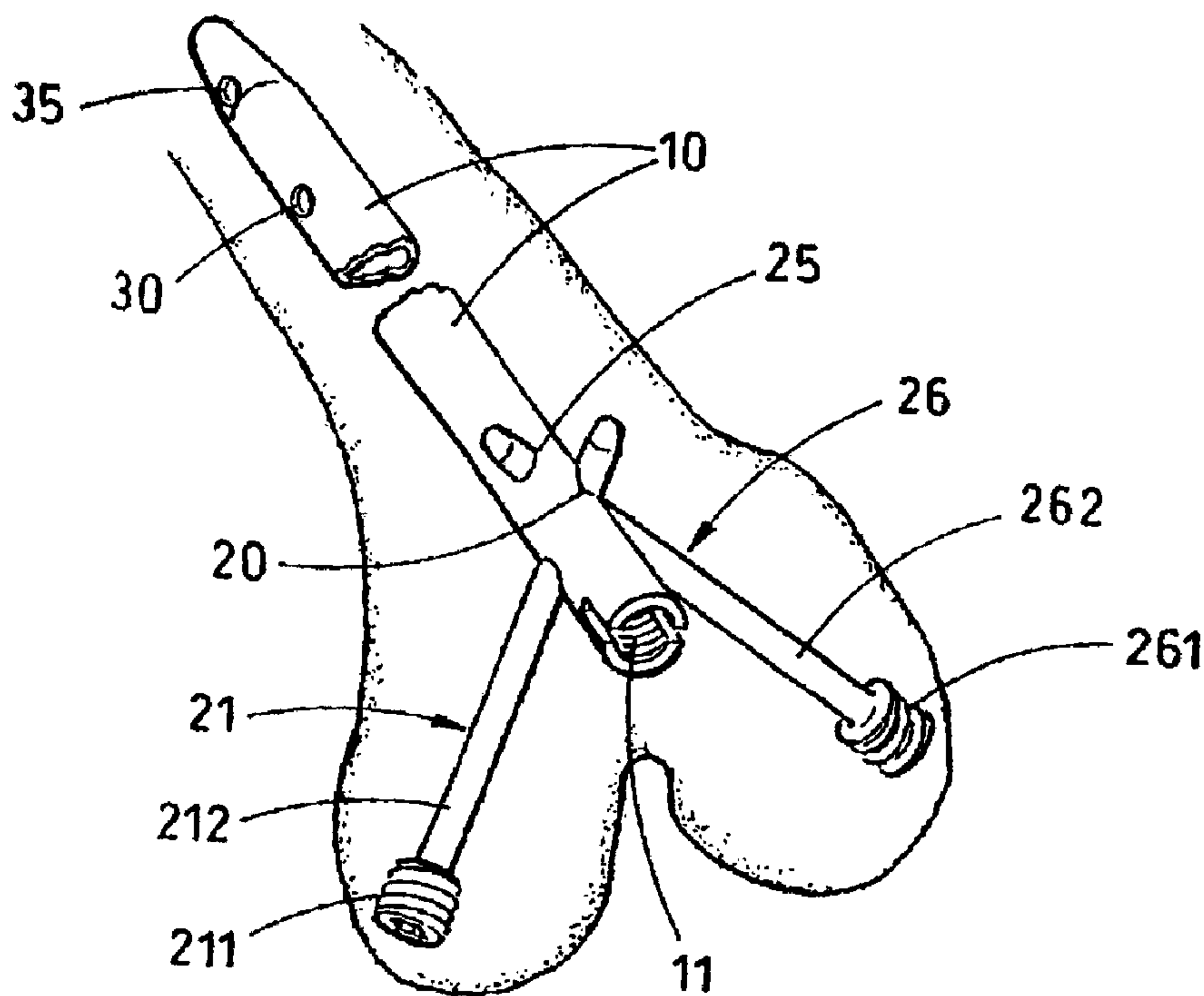




(86) Date de dépôt PCT/PCT Filing Date: 1995/06/09
 (87) Date publication PCT/PCT Publication Date: 1995/12/21
 (45) Date de délivrance/Issue Date: 2007/05/01
 (85) Entrée phase nationale/National Entry: 1996/11/27
 (86) N° demande PCT/PCT Application No.: GB 1995/001355
 (87) N° publication PCT/PCT Publication No.: 1995/034248
 (30) Priorité/Priority: 1994/06/10 (GB9411693.6)

(51) Cl.Int./Int.Cl. *A61B 17/72* (2006.01)
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(54) Titre : CLOU INTRAMEDULLAIRE
 (54) Title: INTRAMEDULLARY NAIL



(57) Abrégé/Abstract:

This invention relates to a surgical intramedullary nail (10), for stabilisation of condylar and supracondylar fractures of the femur. It incorporates a Cruciate arrangement of two obliquely crossing locking bolts (21 and 26) such that each condyle of the femur is gripped by an individual bolt. By this means both femoral condyles are stabilised with respect to the shaft of the femur. The bolts are oriented so that each passes through the main extra-articular mass of each condyle. Further predrilled holes are provided (30, 35) for insertion of proximal locking bolts to stabilise the nail with respect to the shaft of the femur. The nail is intended for retrograde insertion from distal to proximal into the intramedullary canal of the femur. Insertion of the locking bolts may be facilitated by the use of a temporary jig which is attached securely to the distal end of the nail (11). Nails of similar design can be used for stabilisation of equivalent fractures of the humerus.



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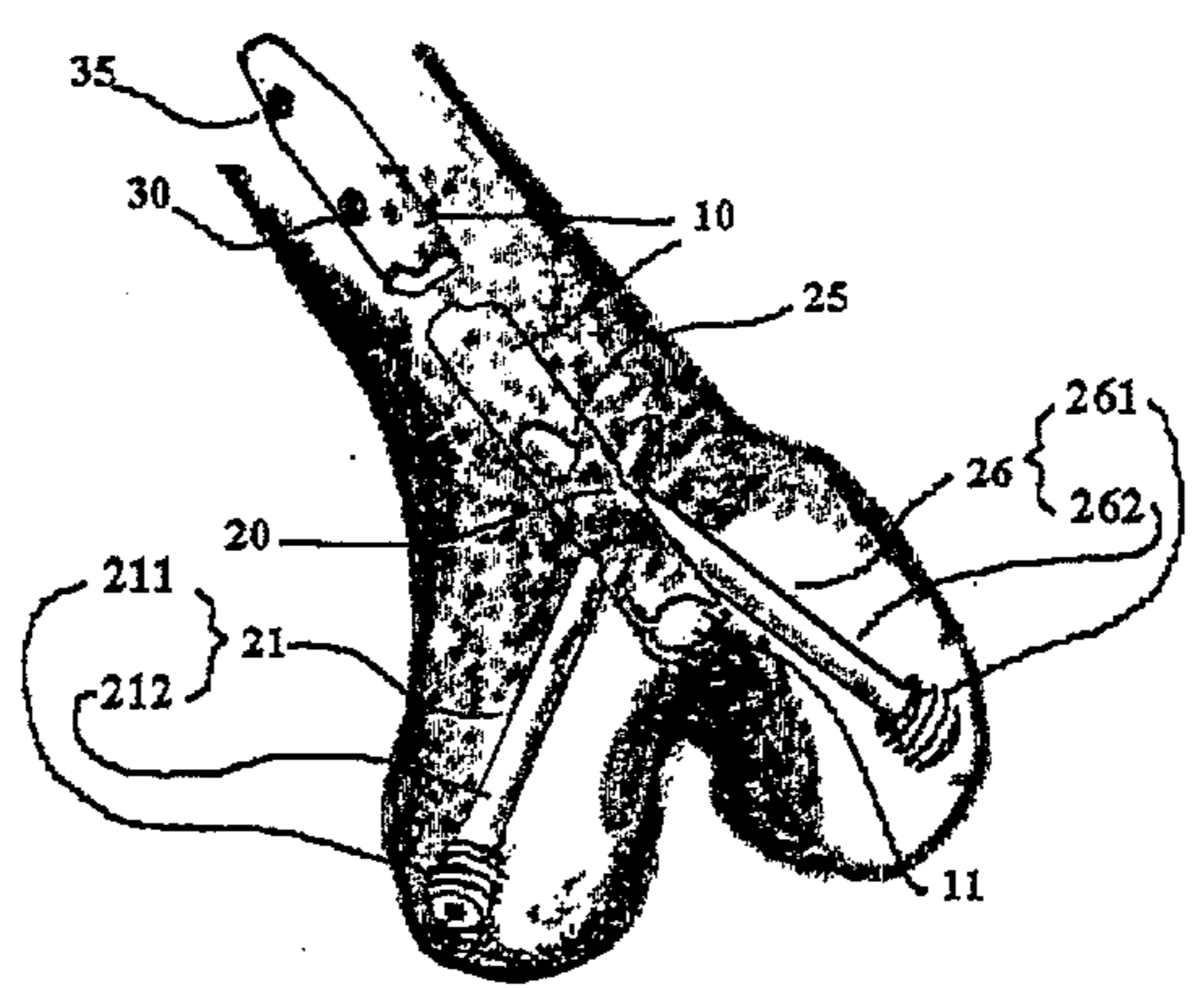
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/72	A1	(11) International Publication Number: WO 95/34248 (43) International Publication Date: 21 December 1995 (21.12.95)
<p>(21) International Application Number: PCT/GB95/01355</p> <p>(22) International Filing Date: 9 June 1995 (09.06.95)</p> <p>(30) Priority Data: 9411693.6 10 June 1994 (10.06.94) GB</p> <p>(71)(72) Applicant and Inventor: MATTHEWS, Michael, Gordon [GB/GB]; Orchard Farm, Little Kingshill, Great Missenden, Buckinghamshire HP16 0EB (GB).</p> <p>(74) Agent: WOODCRAFT, David, Charles; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).</p>	<p>(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p style="text-align: center; font-size: 2em;">2191427</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: INTRAMEDULLARY NAIL



(57) Abstract

This invention relates to a surgical intramedullary nail (10), for stabilisation of condylar and supracondylar fractures of the femur. It incorporates a Cruciate arrangement of two obliquely crossing locking bolts (21 and 26) such that each condyle of the femur is gripped by an individual bolt. By this means both femoral condyles are stabilised with respect to the shaft of the femur. The bolts are oriented so that each passes through the main extra-articular mass of each condyle. Further predrilled holes are provided (30, 35) for insertion of proximal locking bolts to stabilise the nail with respect to the shaft of the femur. The nail is intended for retrograde insertion from distal to proximal into the intramedullary canal of the femur. Insertion of the locking bolts may be facilitated by the use of a temporary jig which is attached securely to the distal end of the nail (11). Nails of similar design can be used for stabilisation of equivalent fractures of the humerus.

INTRAMEDULLARY NAIL

This invention relates to surgical intramedullary nails for stabilising condylar and supracondylar fractures, particularly of the distal femur or humerus.

The use of inert metal rods or tubes inserted into the intramedullary cavity of long bones in order to stabilise fractures is well established in orthopaedic and veterinary practice. These rods or tubes are usually referred to as "nails".

Fractures in the middle third of a long bone may be effectively stabilised with a simple intramedullary nail.

The effectiveness of this method may be increased by the use of cross bolts or screws passing through pre-drilled holes in the nail, so as to achieve better hold on the proximal and distal bone fragments.

Nails with cross bolts have become known as "locking" or "locked" nails. These nails have broadened the use of the method to fractures extending well into the proximal or distal ends.

The insertion of the cross bolts/screws may be facilitated by the use of a guide jig which attaches temporarily to the end of the intramedullary nail, but this is not invariable and many systems require at least some of the cross bolts/screws to be inserted freehand.

In cases where the fracture is in the vicinity of the condylar region of the femur or humerus, difficulties may be encountered in stabilising the distal condylar fragments in relation to the shaft of the bone.

The present invention comprises an intramedullary surgical nail designed for retrograde or reversed insertion into the distal end of the femur or humerus. It incorporates a unique staggered/crossed or "Cruciate" configuration of holes, so that two distal locking bolts may be inserted. This arrangement permits the

locking bolts to cross and overlap so that each condyle may be gripped by an individual bolt. Both condyles are thereby stabilised in relation to the shaft of the bone, along which the intramedullary nail passes.

The nails may also incorporate further pre-formed holes at their proximal ends so that further cross bolts may be inserted to improve the fixation of the nail with respect to the more proximal femoral or humeral shaft. Such further holes are usually arranged so that when cross bolts are inserted, they extend at right angles to the nail.

The invention thus provides according to an aspect, for a surgical intramedullary nail and locking bolt assembly for stabilizing fractures of the condyles and supracondylar region of a femur or humerus. The assembly comprises a nail in the form of a rod or tube having a longitudinal axis and adapted for insertion into an intramedullary canal through a distal end of the femur or humerus, the nail having first and second distal locking holes. The assembly also comprises first and second distal locking bolts for insertion into the first and second distal locking holes. The first and second distal locking holes are staggered and angled with respect to the longitudinal axis such that the distal locking bolts when inserted into the holes extend in a divergent manner from the nail and permit each condyle to be gripped by a respective one of the first and second locking bolts so as to stabilize the condyles with respect to the nail.

According to another aspect, the invention provides for a jig for facilitating the retrograde insertion of a surgical intramedullary nail into a femur or humerus from distal to proximal, the nail having a longitudinal axis, a proximal end and a distal end, the distal end having preformed holes which are staggered and angled with respect to the longitudinal axis such that distal locking bolts inserted into the holes extend in a divergent manner from the nail and permit each condyle to be gripped by a respective bolt. The jig comprises a frame having guide arms adapted to extend on either side of a knee or elbow. The frame includes means for attachment to the distal end of the nail in a predetermined angular relationship therewith. And the guide arms have guide means for guiding the introduction of the locking bolts into the condyles and into the preformed holes.

According to yet another aspect, the invention provides for a surgical intramedullary nail for stabilising fractures of the condyles or supracondylar region of a femur, the nail

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comprising a rod or tube adapted for insertion into a distal end of the femur, the nail having first and second distal locking holes which are so positioned and angled with respect to the nail, that cross bolts inserted into the distal holes extend into and grip the condyles. The distal locking bolts are positioned with respect to the nail so that a distal end of the nail is recessed beneath an articular surface of a femoral intercondylar groove, whereby the distal end of the nail is kept clear of the patella.

The invention also provides for the use of the surgical intramedullary nail and locking bolt assembly in the stabilisation of condylar or supracondylar fracture, the nail being further adapted for insertion of the locking bolts through non articular surfaces of the condyles and into the holes in the nail.

Features of the femoral and humeral nails in accordance with the invention and a jig for introducing the nails and locking bolts are illustrated in the accompanying drawings:-

Figure 1 is a perspective view of the nail 10, showing its location in the distal end of a femur after insertion, and with locking bolts 21, 26 in position passing through pre-drilled holes 20, 25. Free holes 30, 35 for insertion of proximal locking bolts are also shown.

Figure 2 is a similar view of the nail shown in Figure 1, but without the femur shown.

Alternative patterns of distal locking bolts are shown in Figures 1 and 2.

In Figure 1, locking bolts are shown with smooth shanks 212, 262 which are an easy sliding fit in predrilled holes in the nail 20, 25. These locking bolts have coarse threads 211, 261 which grip the bone of the femoral condyles.

In Figure 2, locking bolts of an alternative design are shown which have fully threaded shanks 214, 264. The threaded shanks are received in correspondingly threaded holes in the nail 10.

The head of all bolts 211, 261 and 213, 263 incorporate slots or sockets to accommodate an appropriate insertion wrench or screwdriver.

Figure 3 is an axial view of the nail 10 and distal locking bolts 21,26 of Figure 1 showing how the cross bolts are inserted to pass through the non-articular surfaces of the condyles (shown cross-hatched), while gripping the major mass of cancellous bone in each condyle 60,65.

Figures 4 and 5 show lateral views of the nail 10 and distal locking bolts 21,26.

Figure 5 shows how the nail is to be positioned in the femur so that the distal end of the nail lies recessed below the articular surface of the intercondylar groove 61 of the femur so that it does not foul the tracking of the patella. In this position, due to the obliquity of the cross bolts, these pass through the major mass of the cancellous bone of each condyle 60,65.

Intramedullary surgical nails in accordance with the invention are introduced into the femur through the knee. After surgically exposing the distal femur, an entry point is made in the intercondylar groove in line with the axis of the intramedullary canal. A guide wire or rod may be passed into the femoral intramedullary canal in order to assist the introduction of the nail into the canal. The nail may be of hollow section or "cannulated" so that it may be passed over the guide wire.

It is intended that insertion of the locking bolts will be facilitated by the use of a removable jig. This will be attached to the distal end of the nail which incorporates guide slots and a threaded axial hole 11, shown in Figures 1, 2, 4 and 5, for secure attachment to the jig, in the appropriate position to align the cross bolts with respect to the preformed holes in the nail. Typically, the attachment of the jig to the distal end of the nail will also be cannulated so that the jig may also pass over any guide wire used to introduce the nail into the femur.

Figure 6 shows a perspective view of a typical jig for facilitating introduction of the nail and locking screws. The jig comprises parts 51, 52 and 53, securing bolt 50 and guide tubes 54, 55, 56 and 57.

The jig is employed as follows:

An extension piece 51 is attached to the distal end of the nail fitting rigidly to slots and threaded axial hole 11 in the nail 10. The distal locking guide 52 attaches rigidly to the extension piece 51. This may be achieved using a jig securing bolt 50 which may be cannulated and engages in threads in extension piece 51. The distal locking guide 52 has predrilled guide holes through which guide tubes 54 and 55 may be passed. When the nail 10, extension piece 51 and distal locking guide 52 are rigidly coupled in this manner, the guide tubes 54,55 line up precisely with the predrilled distal holes in the nail 20,25. This permits drilling through the guide tubes to form holes through the femoral condyles in the correct position to pass through the existing predrilled distal holes 20,25 in the nail 10, and for subsequent insertion of the distal locking bolts 21 and 26.

The proximal locking guide arm 53 may be similarly attached to the extension piece 51. This incorporates predrilled guide holes through which guide tubes 56,57 may similarly be passed to align with the proximal predrilled holes 30,35 in the nail. Appropriately placed holes in the femoral shaft may be drilled and the proximal locking bolts inserted. The proximal locking guide arm 53 may be mounted either to the right as shown in Figure 6 or to the left, so that the proximal cross bolts can be introduced from the lateral side for left and right femurs respectively.

Following insertion of the nail and all locking bolts, all components of the jig as above are disconnected and removed.

Typically, the nails may be manufactured in varying lengths and diameters from a biologically inert material which is sterilisable and has appropriate mechanical strength and stiffness, such as stainless steel. For the femoral nail, typical lengths are 250 to 360 mm. The section of the nail is typically tubular with an outer diameter of approximately 12 to 16 mm. The nail may be slightly bent to suit the curvature of the long bone. Distal cross bolts may be typically 6 to 11 mm outer diameter and approximately 75 to 85 mm long. Cross bolts may be part or fully threaded.

Typical approximate linear dimensions (mm) and angular configuration (degrees) of the distal locking bolts in relation to a 14 mm diameter femoral nail are shown in Figures 7a-d.

Figure 7a shows an axial view of a femoral nail similar to that shown in Figure 3.

Figure 7b is a lateral view of the distal end of the femoral nail and distal locking bolts and in a similar projection to that shown in Figures 4 and 5.

Figures 7c and 7d are projections taken on the lines A-A and B-B, as shown in Figure 7a, showing distal locking bolts 21 and 26 respectively.

Figure 8 is a perspective view of a humeral nail 100, showing its position in the distal end of the humerus with distal locking bolts 210,260 in position, passing through predrilled holes 200,250. Free holes 300,350 are provided for insertion of proximal locking bolts.

CLAIMS:

1. A surgical intramedullary nail and locking bolt assembly for stabilizing fractures of the condyles and supracondylar region of a femur or humerus, said assembly comprising:
a nail in the form of a rod or tube having a longitudinal axis and adapted for insertion into an intramedullary canal through a distal end of the femur or humerus, said nail having first and second distal locking holes; and
first and second distal locking bolts for insertion into the first and second distal locking holes,
the first and second distal locking holes being staggered and angled with respect to said longitudinal axis such that the distal locking bolts when inserted into said holes extend in a divergent manner from said nail and permit each condyle to be gripped by a respective one of the first and second locking bolts so as to stabilize the condyles with respect to the nail.
2. A nail and locking bolt assembly as claimed in claim 1, wherein the distal locking bolts are positionable so as to pass through a non-articular portion of the condyles, while gripping the mass of cancellous bone in each condyle.
3. A nail and locking bolt assembly as claimed in claim 1 or 2 designed for retrograde insertion into the femur or humerus from distal to proximal, and incorporating a means of attachment of a temporary jig to facilitate drilling of pilot holes and subsequent insertion of said first and second locking bolts.
4. A nail and locking bolt assembly as claimed in any one of claims 1 to 3, wherein the distal locking holes are positioned at a distal end of the nail, and wherein said distal end of the nail comprises a threaded axial hole.
5. A nail and locking bolt assembly as claimed in any one of claims 1 to 4, wherein said nail has one or more preformed proximal holes extending transversely through a proximal region of the nail to stabilize the nail with respect to the shaft of the femur or humerus.

6. A jig for facilitating the retrograde insertion of a surgical intramedullary nail into a femur or humerus from distal to proximal, said nail having a longitudinal axis, a proximal end and a distal end, the distal end having preformed holes which are staggered and angled with respect to the longitudinal axis such that distal locking bolts inserted into said holes extend in a divergent manner from said nail and permit each condyle to be gripped by a respective bolt, said jig comprising:

a frame having guide arms adapted to extend on either side of a knee or elbow;
said frame including means for attachment to the distal end of the nail in a pre-determined angular relationship therewith; and

said guide arms having guide means for guiding the introduction of said locking bolts into said condyles and into said preformed holes.

7. A jig as claimed in claim 6, wherein said frame further comprises a reversible guide arm for the introduction of said first and second locking bolts from the lateral side for both right and left femora into preformed proximal holes in the nail.

8. Use of the surgical intramedullary nail and locking bolt assembly as claimed in claim 1, in the stabilisation of condylar or supracondylar fracture, the nail being further adapted for insertion of the locking bolts through non articular surfaces of the condyles and into the holes in the nail.

9. Use as claimed in claim 8, wherein said locking bolts comprise shanks dimensioned at one end to fit into said holes in the nail and being formed at the other end with threads for engaging and gripping the condyles.

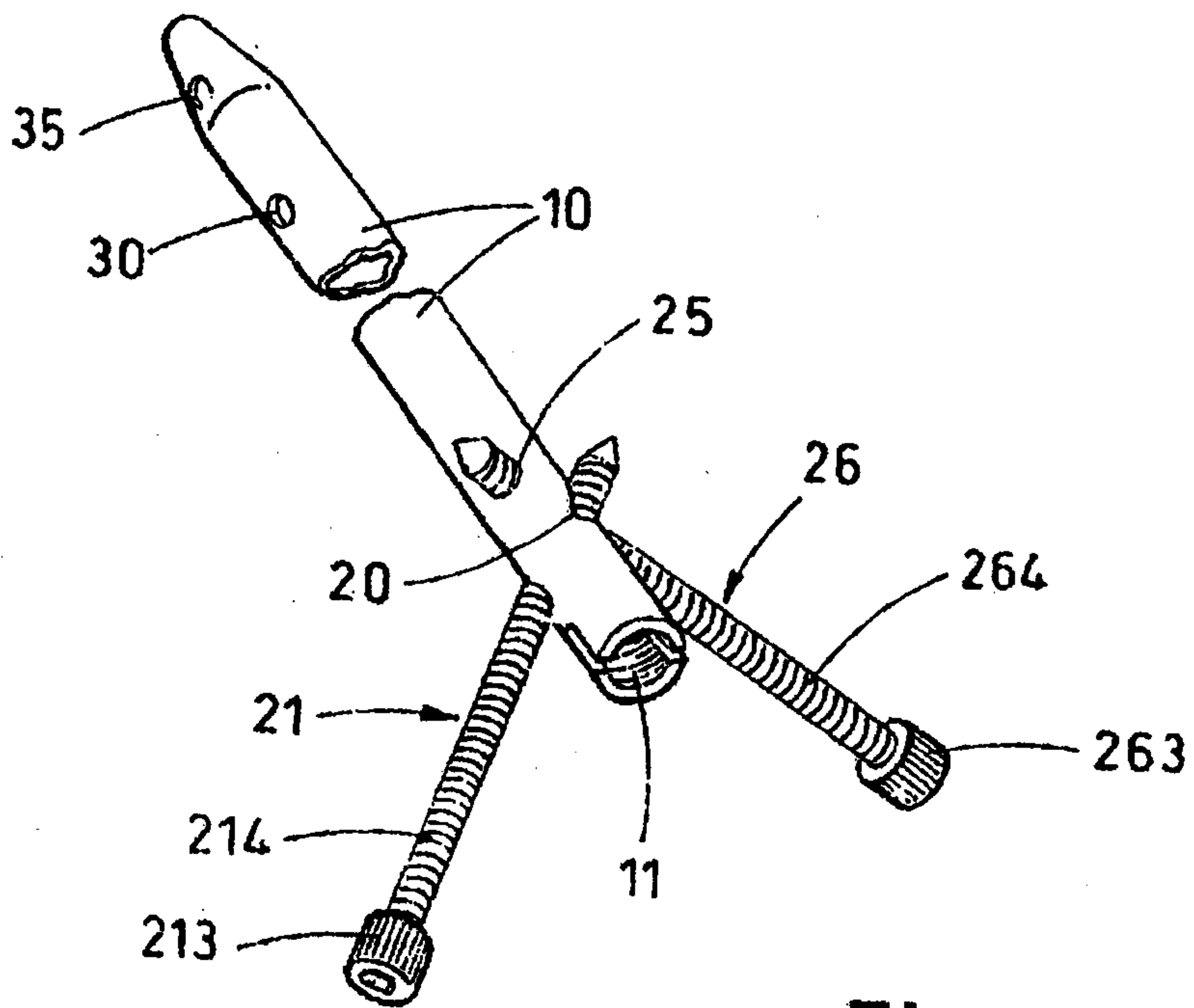
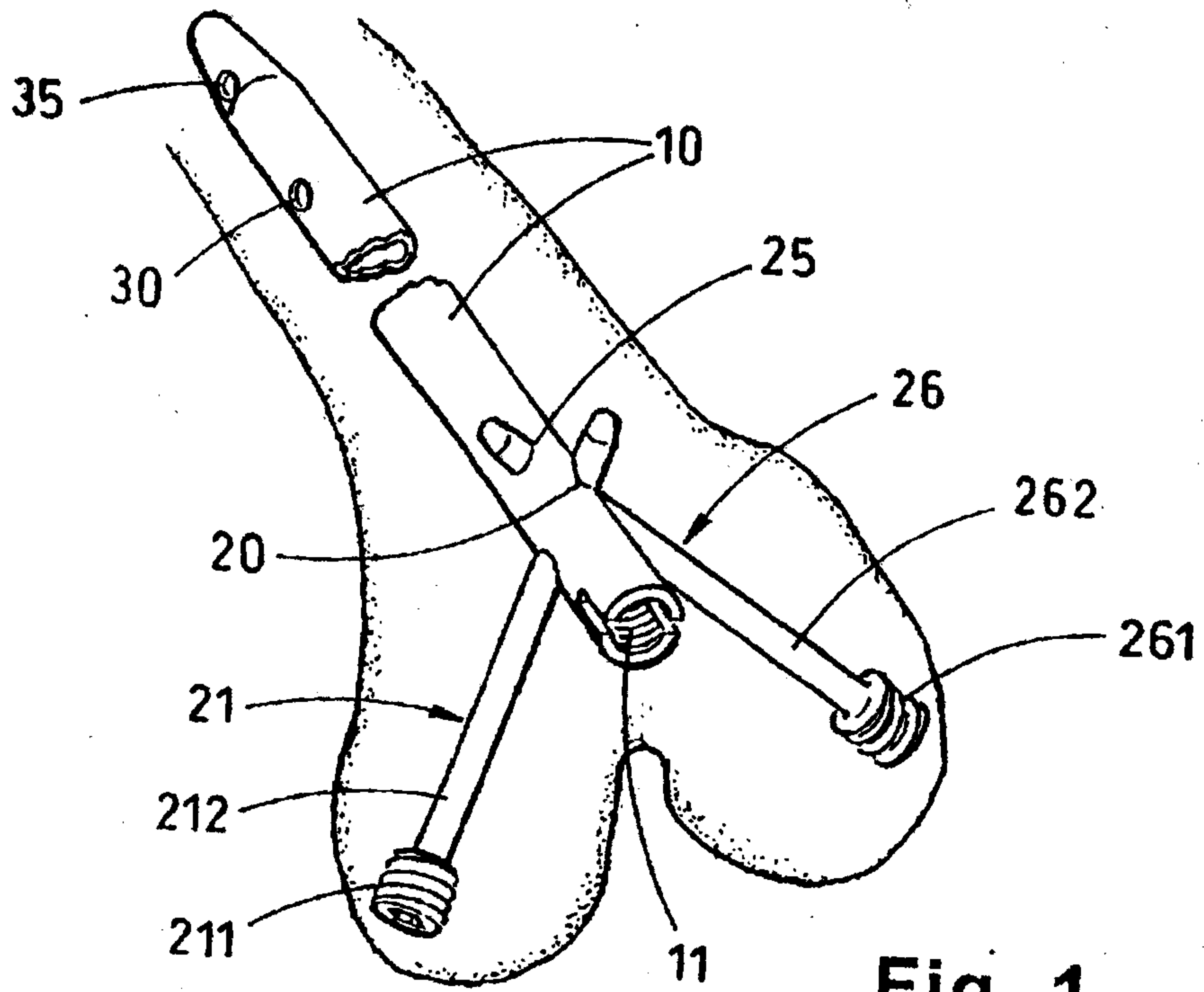
10. Use as claimed in claim 8 or 9, wherein the nail is also adapted for proximal insertion of the locking bolts into the femur or humerus and into proximal holes in the nail.

11. Use of the jig as claimed in claim 6 in the retrograde insertion of a surgical intramedullary nail into the femur or humerus from distal to proximal.

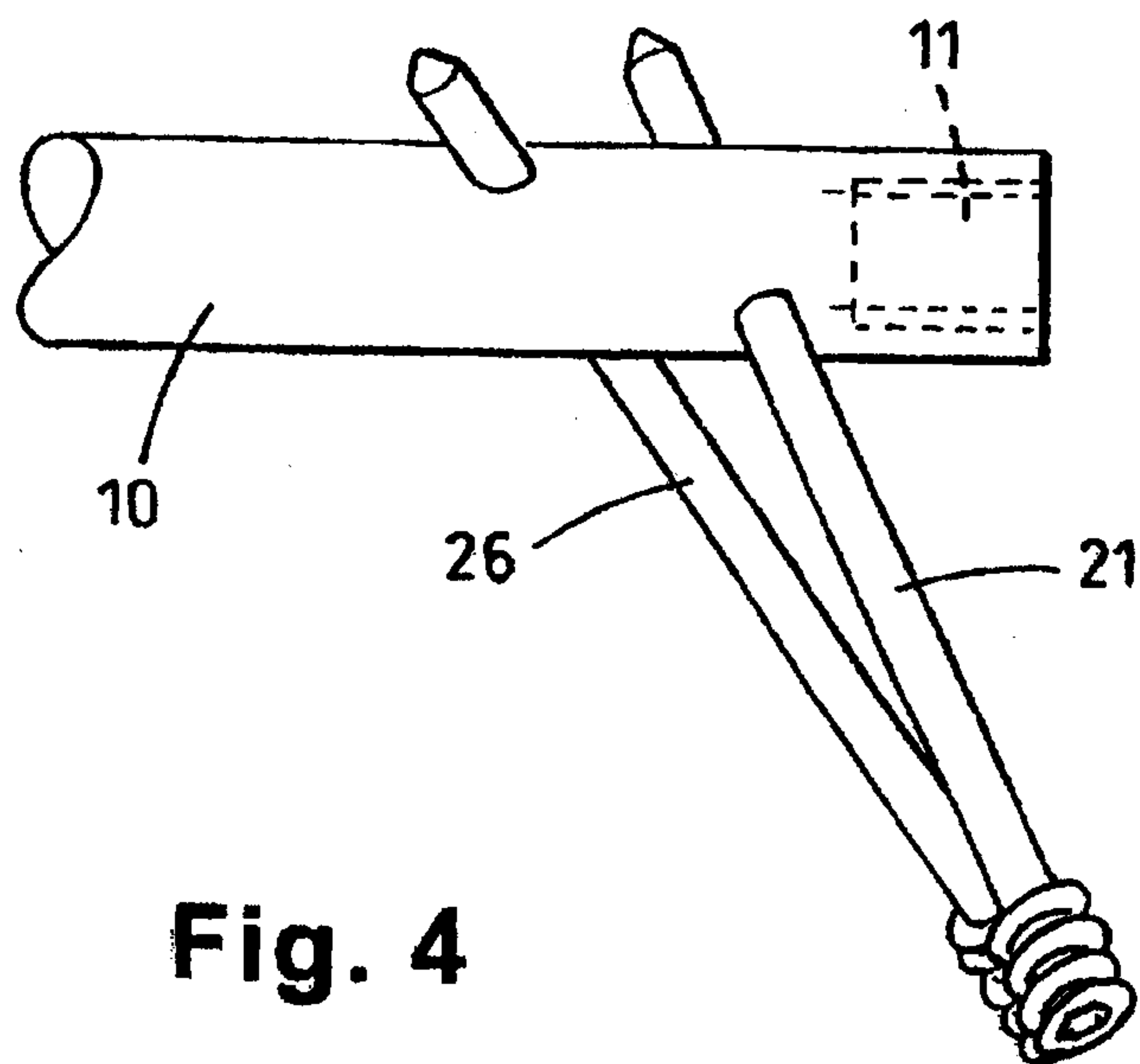
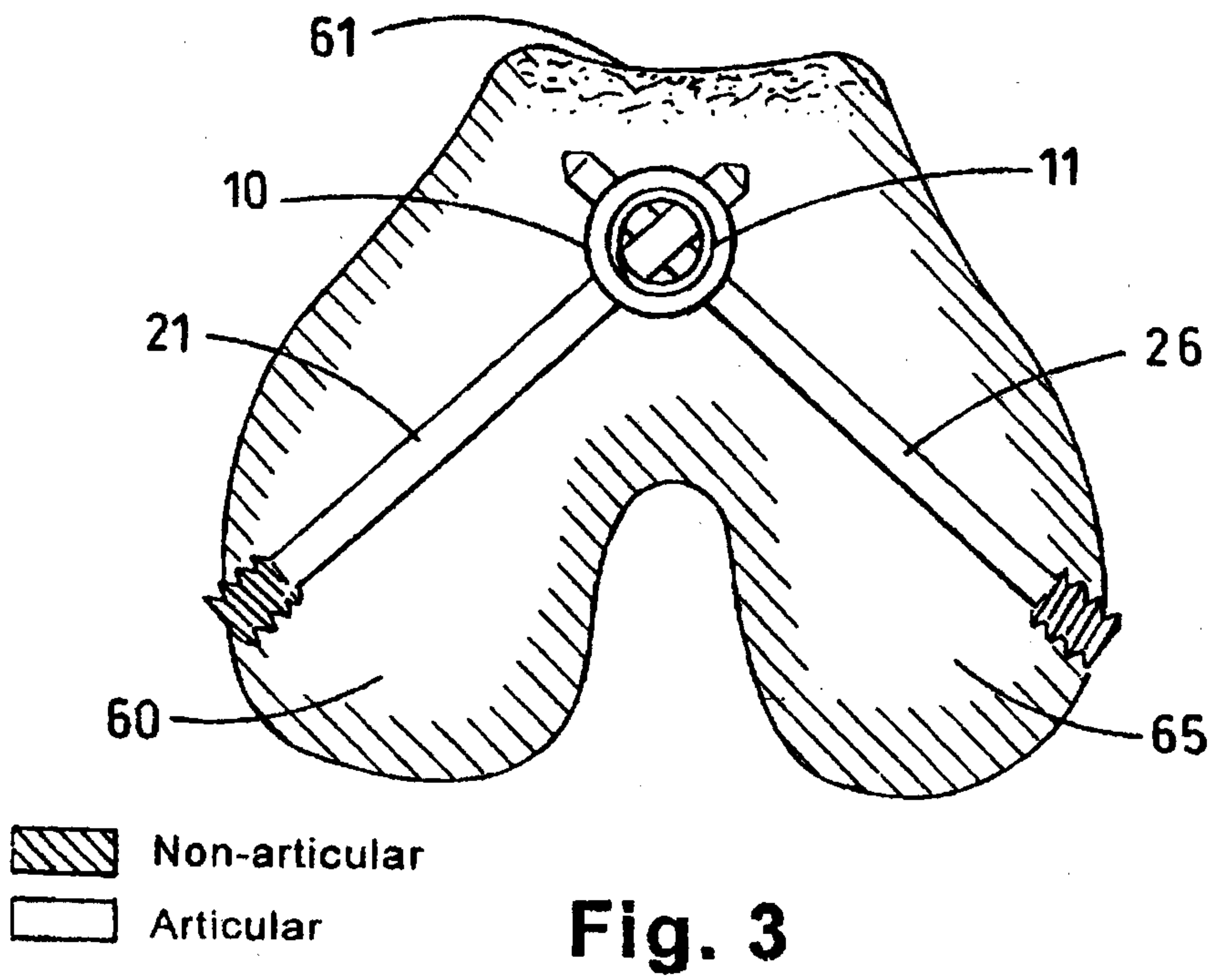
12. Use as claimed in claim 11, wherein the frame of the jig further comprises a reversible guide arm for the introduction of locking bolts from the lateral side for both right and left femora into preformed proximal holes in the nail.

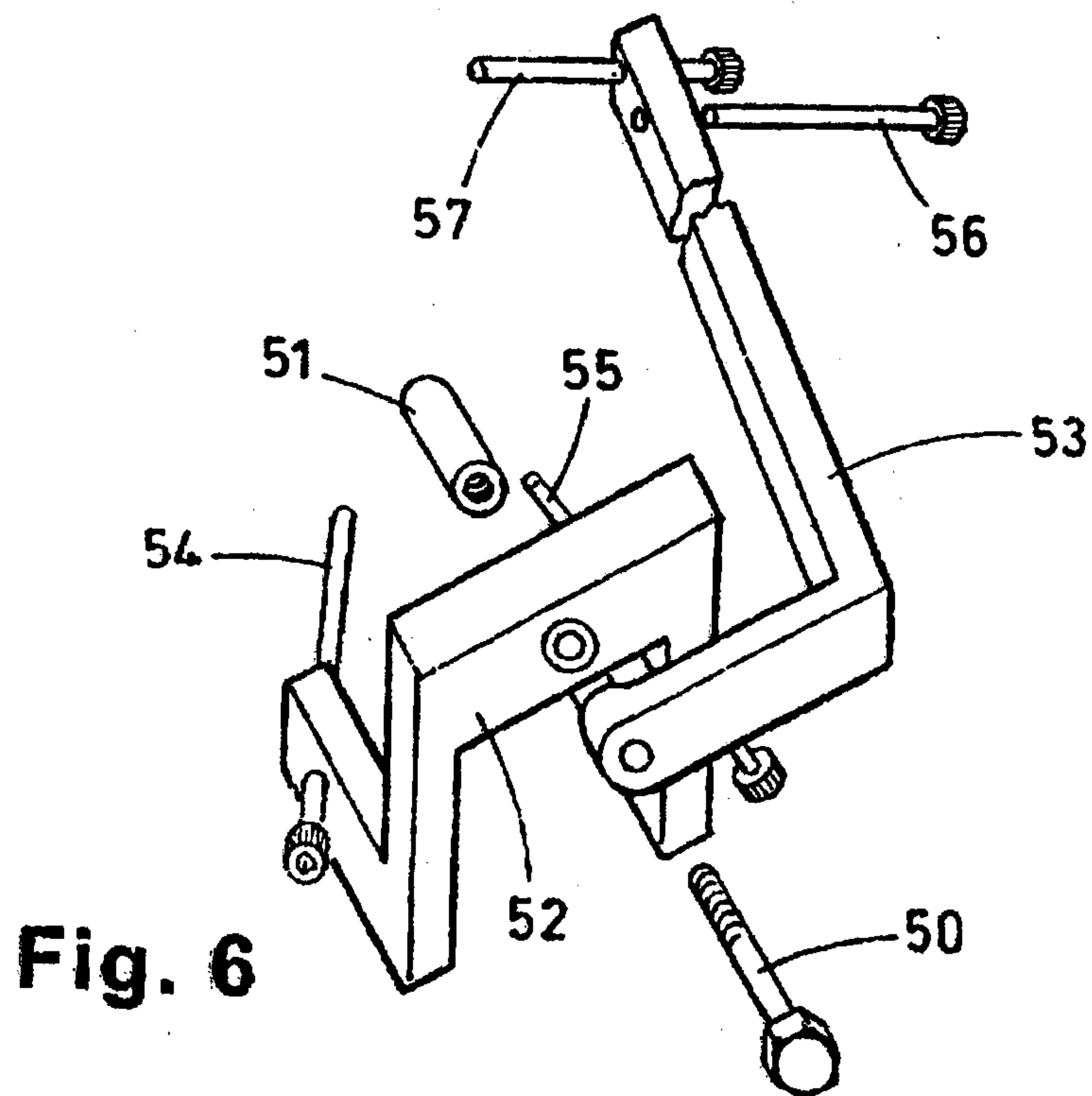
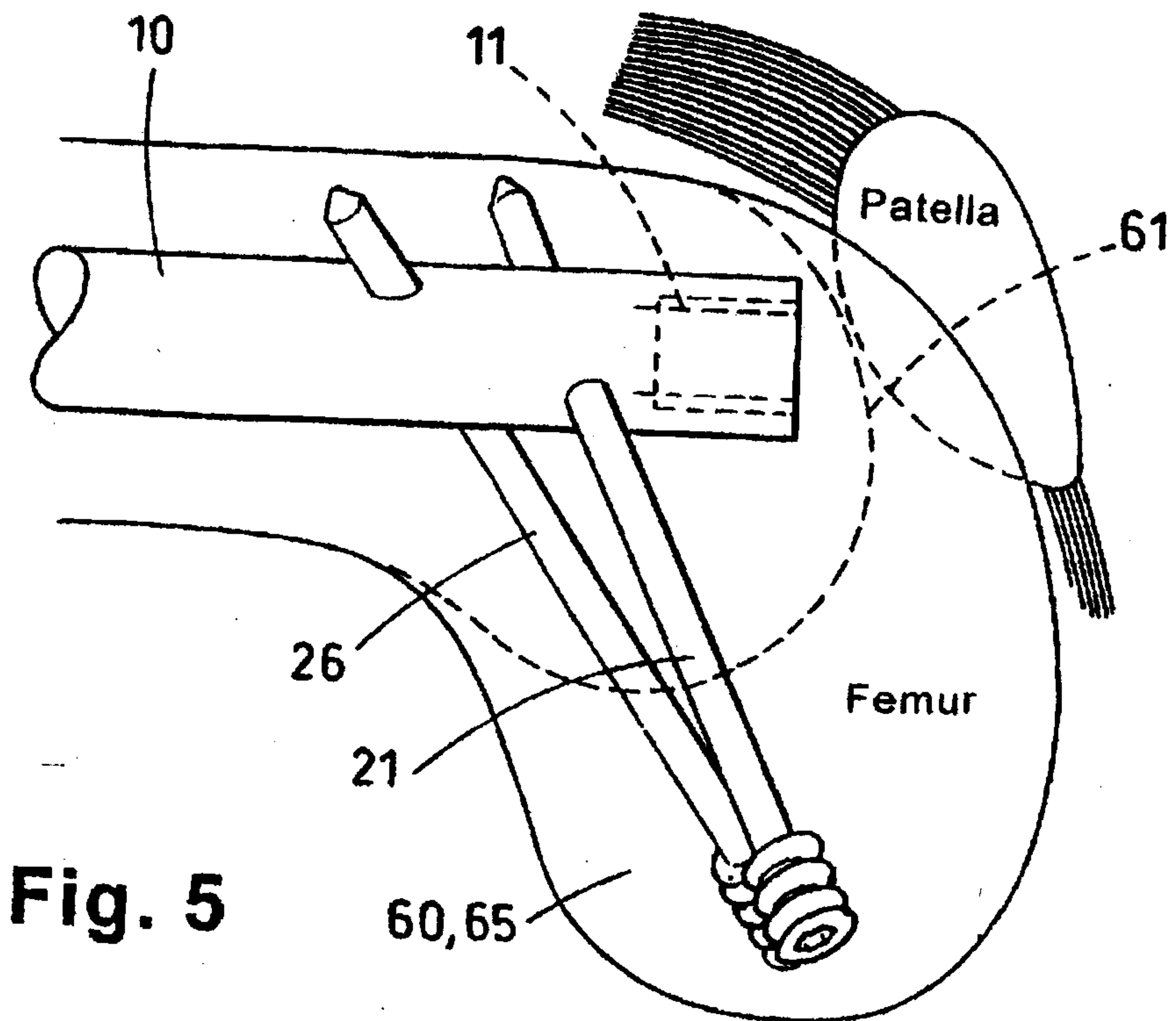
13. A surgical intramedullary nail for stabilising fractures of the condyles or supra-condylar region of a femur, said nail comprising a rod or tube adapted for insertion into a distal end of the femur, said nail having first and second distal locking holes which are so positioned and angled with respect to the nail, that cross bolts inserted into said distal holes extend into and grip the condyles, wherein distal locking bolts are positioned with respect to the nail so that a distal end of the nail is recessed beneath an articular surface of a femoral intercondylar groove, whereby the distal end of the nail is kept clear of the patella.

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2/5





4/5

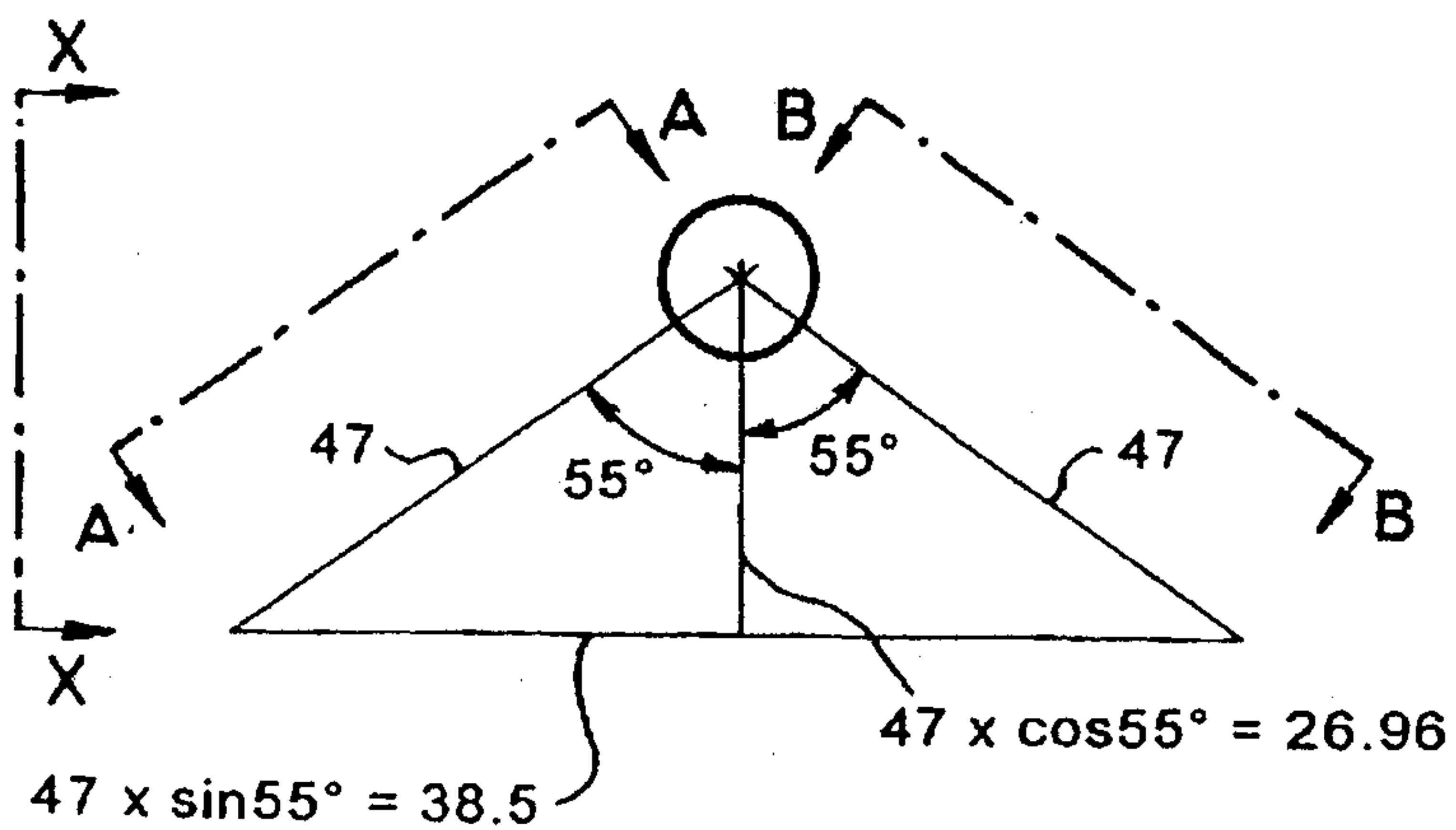


Fig. 7a

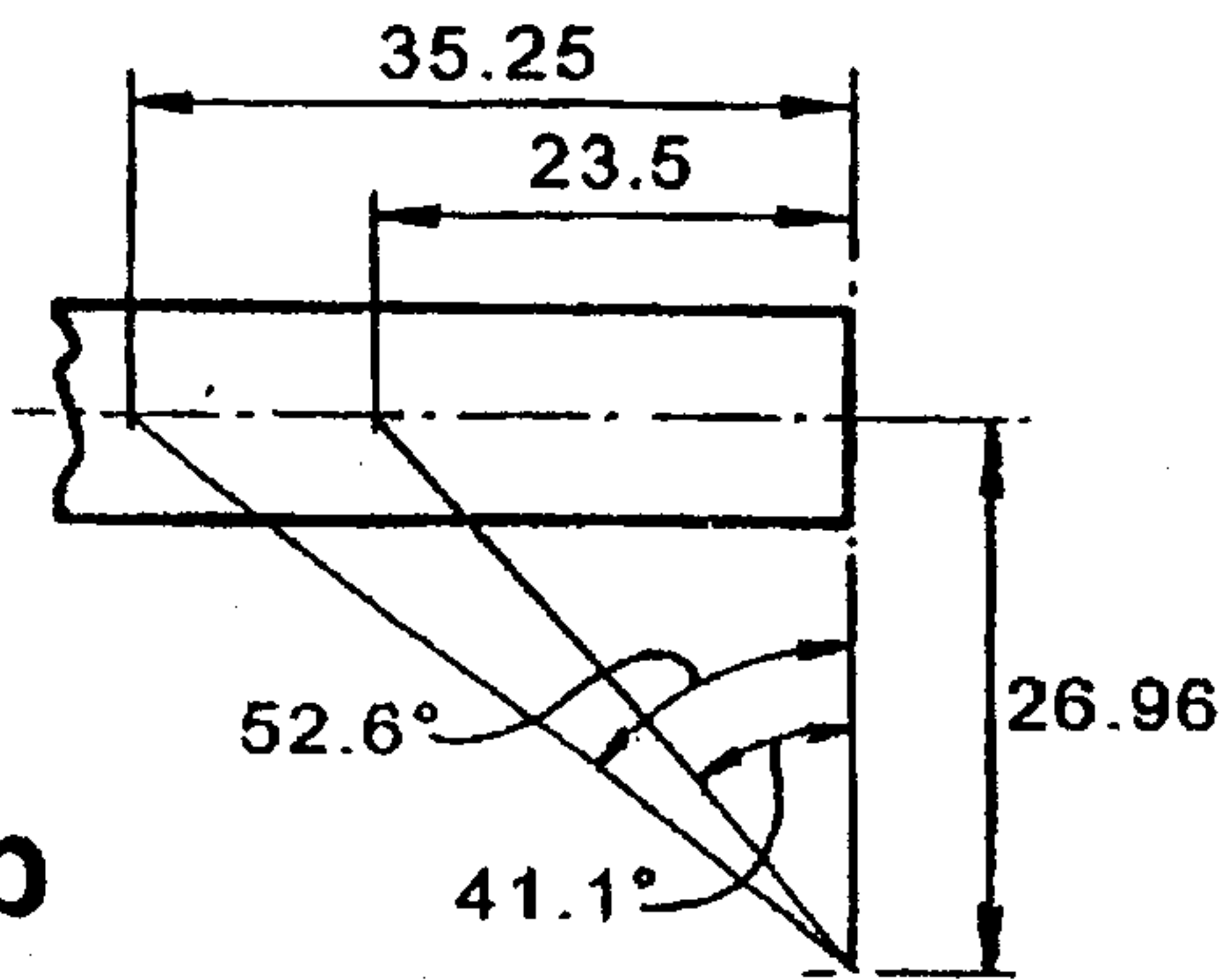


Fig. 7b

View on XX

Linear dimensions in mm
Angular dimensions in degrees

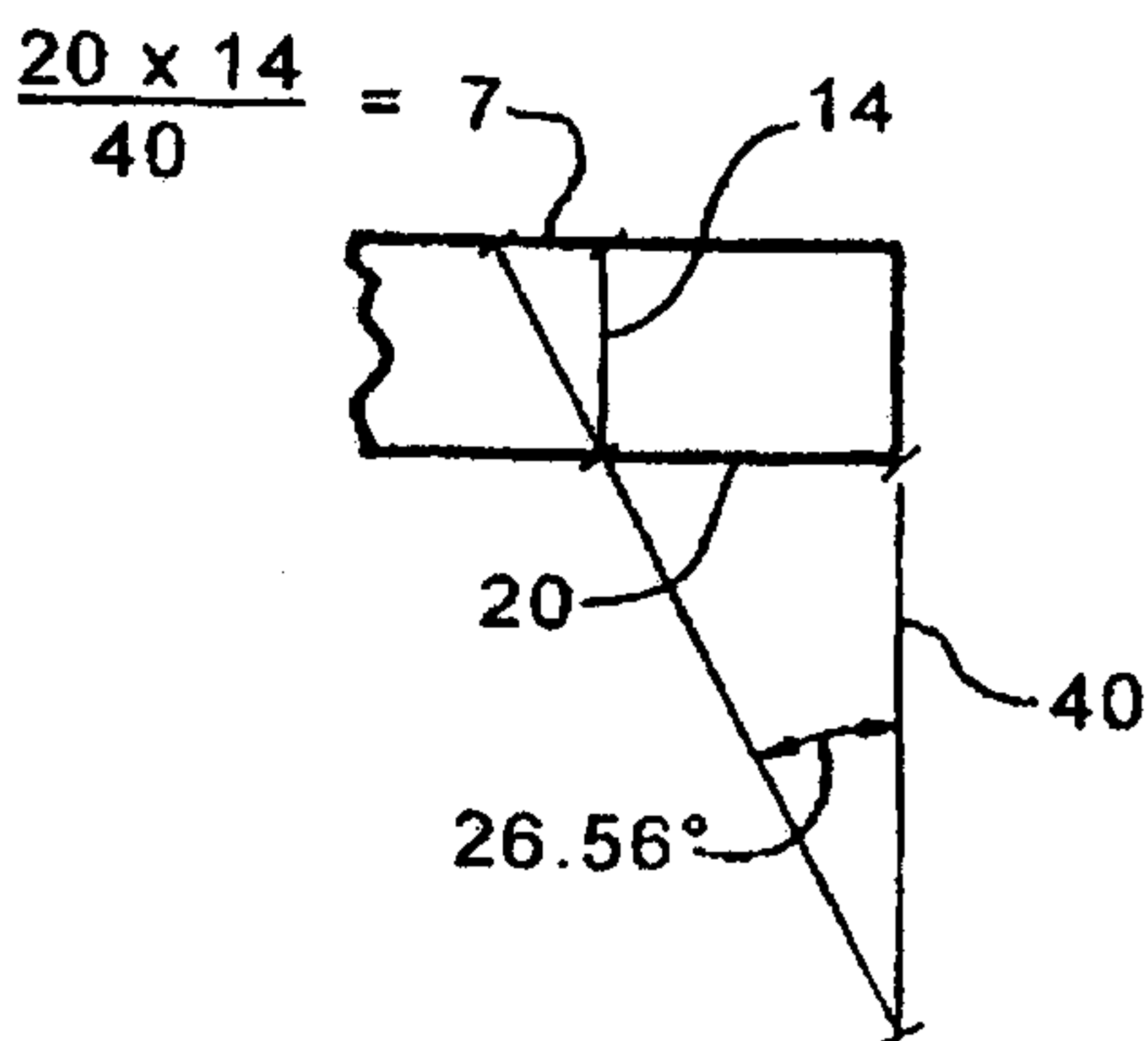


Fig. 7c

View on AA

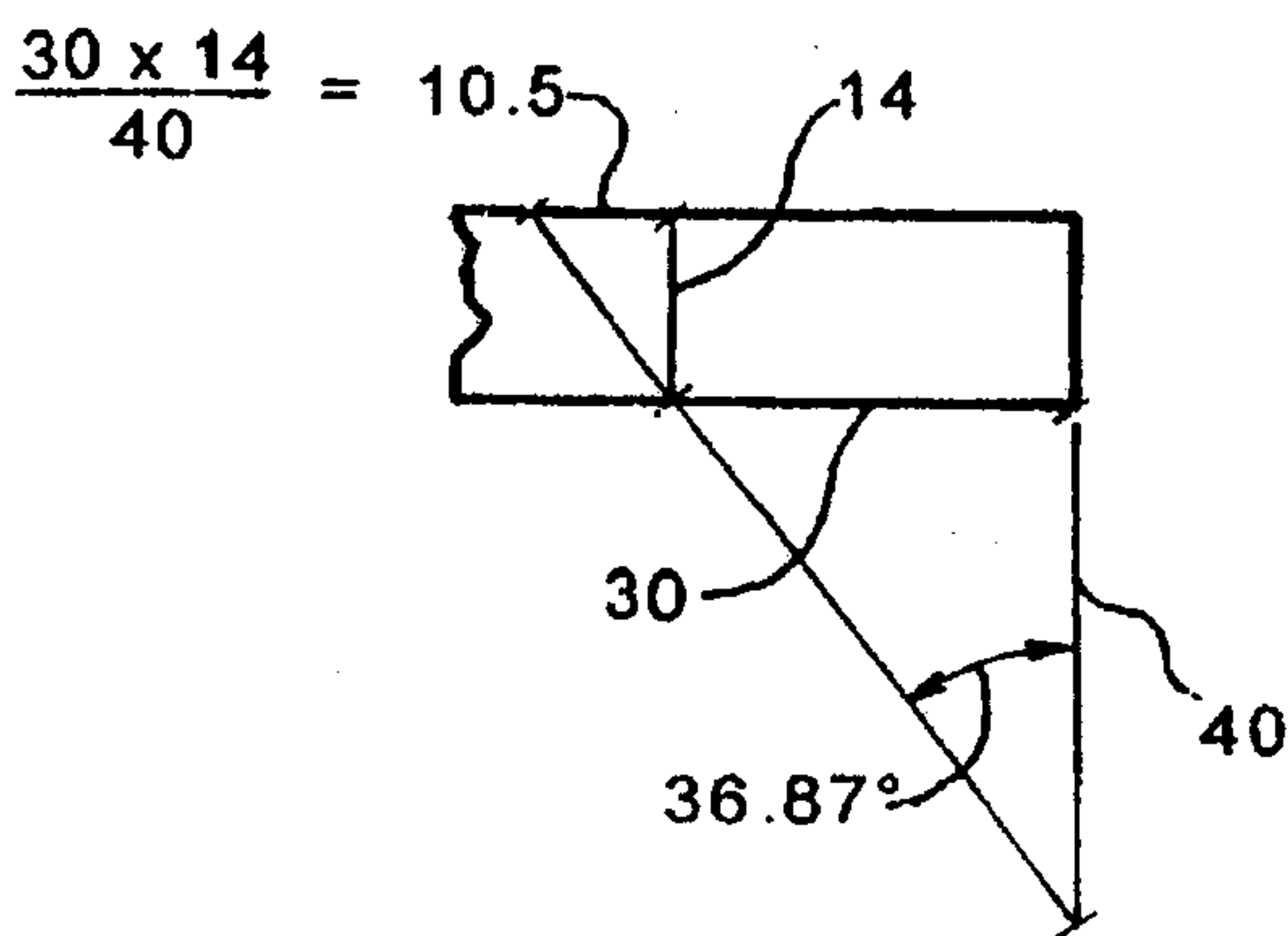


Fig. 7d

View on BB

5/5

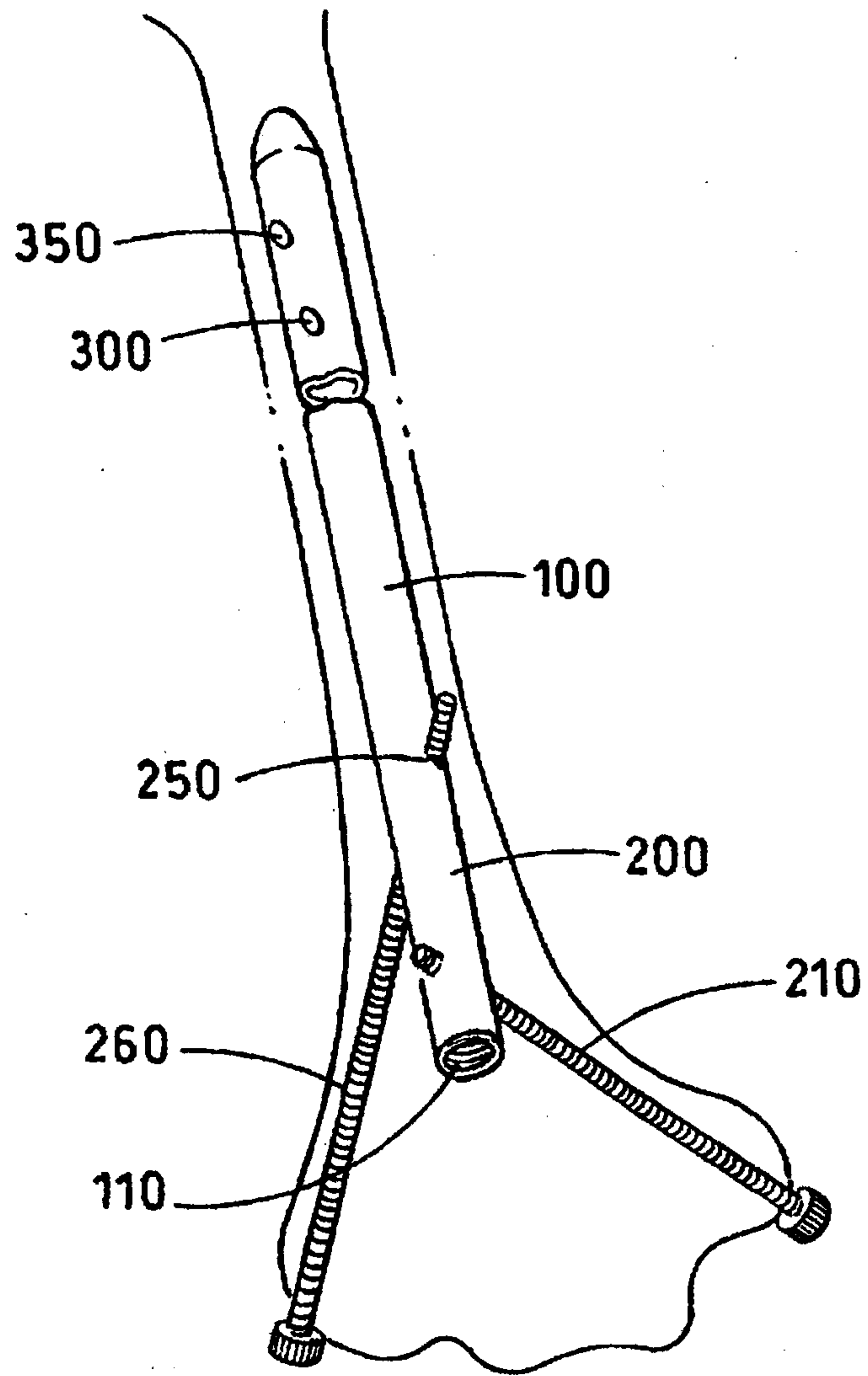


Fig. 8

