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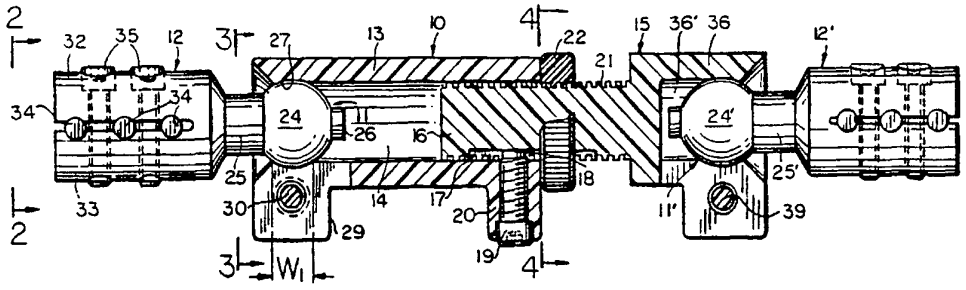
(54) Title: DISPOSABLE EXTERNAL FIXATOR



(57) Abstract

A disposable, single-use external-fixator construction features maximum utilization of plastics material or materials. An elongate outer-body member (13) has a cylindrical bore (14), and an elongate inner-body member (15) has a cylindrical body (16). Selectively operable clamping means (19) is provided for securing the body members to each other to retain an adjusted overall body length between axially projecting ends of the body members. A separate bone-screw clamp (12, 12') is connected to each of the respective axially projecting ends of the body members. The connection of at least one of the bone-screw clamps to its body-member end includes a ball-joint (24, 24') with provision (30, 39) for releasably securing an adjusted orientation of the ball-joint connected bone-screw clamp with respect to its body member end. Provision (21, 22) is also made for selective distraction adjustments to be made in the adjusted overall body length between the respective bone-screw clamps. And all or substantially all of the indicated components are preferably of plastics material, for such low-cost purposes as to enable economic disposal of the fixator after a single use.

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DISPOSABLE EXTERNAL FIXATOR

BACKGROUND OF THE INVENTION

This invention relates to a bone fixator of the external type having a pair of spaced clamps for bone pins or screws which are anchored to fractured bone parts, wherein connecting means between the clamps comprises longitudinally telescoping inner and outer body parts and at least one universal joint, and wherein means are provided (1) for securing the telescoping parts in adjusted position to set the spacing between the clamps and (2) for securing each universal joint to set the angle between an involved clamp and adjacent body structure.

The means to secure an adjusted relation of the telescoping body parts may be a set-screw in a threaded hole in the outer telescopic body parts, bearing against (e.g., in a longitudinal groove in) the inner telescopic body part, and the angle-securing means may be a lock-nut or screw carried by or forming part of the socket and bearing on the ball. In existing bone fixators, these securing means require the telescopic body parts and the universal joint to be made of metal, for durability and effectiveness of the screw-threads. Such construction requires expensive machined parts, but the expense is only justifiable if the fixator is re-used after effective cleaning and sterilization. However, such usage is not usual nowadays because of the risk of AIDS or other infection. Disposal of a fixator after a single use is therefore now the common practice.

It is also known for a fixator to be formed subs of plastics material (except for clamping screws for the bone pins or screws). In such fixators, provision is made for introducing hardenable filler between the telescoping body parts and into the universal joint to secure the telescopic parts and the universal joint in adjusted position, once the filler sets. However, this securing arrangement has its disadvantages, namely: (1) the need to prepare the filler mix and difficulties in

introducing it, especially under less than ideal conditions, such as in a military field hospital; (2) the difficulty of controlling the setting time of the filler, especially in hot climates; and (3) the inability at any stage in the healing process to release the telescopic parts to allow "dynamic" knitting of the fractured bone parts to take place.

BRIEF STATEMENT OF THE INVENTION

It is an object of the invention to provide an external fixator construction of such low manufacturing cost as to be practical for single-use, i.e., expendable after use in the repair of a single fracture.

It is a specific object to meet the above object with features of adjustability, both in respect of universal joint articulation between spaced locations of bone-screw anchorage to a fractured bone and in respect of length adjustment between such spaced locations.

Another specific object is to meet the above objects with structure that is at least somewhat transparent to x-radiation, thus not impeding x-ray analysis of a bone fracture in the course of or after setting the adjustments of the fixator.

Still another specific object is to achieve the above objects with structure that does not require use of a hardenable filler.

The invention in its presently preferred embodiment achieves these objects in a construction involving an elongate outer-body member having a cylindrical bore, and an elongate inner-body member having a cylindrical body portion that is telescopically guided in the cylindrical bore. Selectively operable clamping means is provided for securing the body members to each other to retain an adjusted overall body length between axially projecting ends of the body members. A separate bone-screw clamp is connected to each of the respective axially projecting ends of the body members. The connection of at least one of the bone-screw clamps to its body-member end includes a universal joint with provision for releasably securing an adjusted orientation of the joint connected bone-screw clamp with respect to its body-member end. Provision is also made for selective distraction adjustments to be

made in the adjusted overall body length between the respective bone-screw clamps, and all or substantially all of the indicated components are preferably of plastics material, for such low-cost purposes as to enable economic disposal of the fixator after a single use.

DESCRIPTION OF THE DRAWINGS

The invention will be described in detail in conjunction with the accompanying drawings, in which:

Fig. 1 is a view, partly in side elevation and partly in longitudinal section of the presently preferred embodiment of an external fixator of the invention;

Fig. 2 is an end view of bone-screw clamp structure at the left end of Fig. 1, the viewing aspect being indicated at 2-2 in Fig. 1;

Fig. 3 is an end view of outer-body structure shown in Fig. 1, the viewing aspect being indicated at 3-3 in Fig. 1;

Fig. 4 is a section taken at 4-4 in Fig. 1; and

Fig. 5 is a fragmentary view similar to Fig. 1, but showing an alternative bone-screw clamp for optional substitution for one of the bone-screw clamps of Fig. 1.

DETAILED DESCRIPTION

In Fig. 1, an adjustably extensible fixator body 10 is shown with independent ball-joint/universal connections 11, 11' of separate bone-screw or bone-pin clamps 12, 12' to its respective ends. The fixator body 10 comprises an outer-body member 13 having a cylindrical bore 14, and an inner-body member 15 has a cylindrical body portion 16 which is telescopically guided in and by the cylindrical bore 14.

It is preferred that the telescoping relation between the indicated parts of body members 13, 15 shall be solely longitudinal and without relative rotation. To this end, a keyed relationship is provided by a longitudinal groove 17 in the cylindrical body portion 16 of member 15 and by a key element 18 carried by outer-body member 13. As shown, the key element 18 is the short cylindrical end of a clamp bolt 19, which is threadedly engaged to a tapped local radial bore in body member 13; a local boss formation 20 of body member 13 enables substantial threaded engagement for bolt 19, which is configured at its outer end for tool actuation, as for example for Allen-head wrench torquing to jam bolt end 18 securely against the bottom of groove 17.

The outer surface of the cylindrical body portion 16 may be threaded, as suggested at 21. Preferably, the particular threads are of sufficient pitch to define a helical land between successive turns of the threads, this cylindrical land being to a cylindrical diameter which establishes a free-running but close-clearance relation with the cylindrical bore 14. Suitably, the threads 21 may be of rectangular section, in the style generally referred to as square-threaded. An annular nut 22 has a bore with threads which engage the threads 21. Nut 22 may have a cylindrical periphery with knurls to facilitate finger adjustment of nut 22 against the adjacent end face of outer-body member 13, whereby to be able to make an increment of distracting displacement between the respective bone-screw clamps 12, 12', when bolt 19 is released from clamped engagement to the bottom of groove 17. This release will be understood to require only slight retraction of bolt 19, so that the keyed relation between body members 13, 15 can remain, even while effecting the distracting displacement.

As shown, the bone-screw clamps are duplicates of each other, and the ball 24 of each ball joint is integrally formed with bone-screw clamp structure, being offset therefrom via a neck or stem 25 of less-than-ball diameter. The ball center is on the central axis of stem 25, the latter being on the central longitudinal axis of the involved bone-screw clamp. On the same central axis of stem 25, a small angle-limiting stop projection 26 is another integral formation of the ball 25, being diametrically opposite stem 25. Projection 26 will be understood to interfere with the bore 14 and thus to limit the range of angular orientation achievable through ball-joint action.

The socket element of each ball joint is exemplified by discussion in connection with ball 24 and its connection to outer-body member 13. This connection relies on the diameter of ball 24 exceeding the diameter of cylindrical bore 14. As shown, a circumferential ball-seating groove 27 having the spherical radius of ball 24 is provided near the outwardly extending end of body member 13, and bore 14 flares outwardly beyond this spherical ball-seating groove 27; the axial width of groove 27 is indicated at W_1. And a radial slot 28, of width W_2 (see Fig. 3) extends axially

inward, well beyond groove 27, to provide a degree of stiffly compliant transient deformability for the outer end of body member 13, in the course of assembling ball 24 to its spherical seat (groove 27). Once thus assembled, a clamp is provided to retain the ball-joint assembly to body member 13.

As further seen in Fig. 3, a local enlargement 29 of body member 13 is in the form of a cylinder that is at eccentric offset δ from the central body axis of the fixator. This offset places maximum body material at both sides of the confronting faces of slot 28, so that substantial material exists for accommodation of a single clamp bolt 30, in a single bore 31 transverse to the slot 28. Bolt 30 is seen in Fig. 3 to be of headed variety, passing freely through the bore 31 on one side of slot 28 and having substantial threaded engagement to a tapped remaining half of the bore, on the other side of slot 28. On the unthreaded end, a counterbore 31' enables the bolt head to develop a well-seated reference for drawing together the adjacent faces of slot 28, for clamping a ball-joint angular setting of its bone-screw clamp 12, or for flexing the ball-joint orientation as may be needed. In all cases, the stop projection 26 of ball 24 provides an assured angular limit of ball-joint orientation, and whether or not clamped by bolt 30, there is no danger of the stop projection 26 being the cause of inadvertent dislodgement of the ball from its socket.

The bone-screw clamp 12 is seen to comprise two half-shell elements 32, 33, having confronting otherwise-flat surfaces that are transversely grooved for reception of longitudinally spaced bone screws or bone pins 34. One (33) of these half-shell elements is integrally formed with ball 24 and its connecting stem 25, and clamp bolts 35, in bores transverse to the longitudinal axis and normal to the confronting faces of the half-shell elements 32, 33 are seated in counterbores of one half shell (33) and are thread-engaged to tapped regions of these bores in the other half shell (32).

As previously indicated, the bone-screw clamp 12' at the other end of the fixator of Fig. 1 may be a duplicate of that which has been described in connection with bone-screw

clamp 12. The only difference is that the axially outward end of inner body member 15 is enlarged at 36 to define an axially outwardly open cylindrical bore 36' having the diameter of bore 14. The enlargement at 36 may further include an eccentrically offset enlargement 37 (of the nature described at 29) to provide clamping action across a longitudinal slot, one radial face 38 of which is exposed in the sectional view of **Fig. 1**. A clamp bolt 39, threaded into the body of enlargement 37 on one side of this slot, and counterbore-seated into the body of enlargement 37 on the opposite side of this slot, may achieve the same universally adjustable range of bone-screw clamp (12') orientation as has been described for the bone-screw clamp 12.

Fig. 5 shows optional application of different bone-screw clamp structure 40, in replacement of one of the bone-screw clamps of **Fig. 1**. The ball 24" of the bone-screw clamp structure 40 may be integrally connected by stem 24" to one (41) of the half-shell formations (41, 42) of the clamp 40, but in **Fig. 5**, the central axis of this connection is perpendicular to the elongation axis of the clamp 40; in fact, the stem axis of stem 25" is preferably perpendicular to the plane of the confronting faces of the respective half-shell formations. Thus, in **Fig. 5**, the alignment of plural bone screws 43 may be perpendicular to the central axis of ball-24" connection to half-shell formation 41. And, again, bolts 44 acting between adjacent bone screws 43 provide the basis for clamping to bone screws.

Fig. 5 serves further to illustrate that for any and all of the bone-screw clamp locations referred to thus far, the respective half-shell formations 41, 42 may be integral parts of a single structure that is interconnected by a sufficiently compliant end connection 45; compliant incremental spreading of the half shells away from each other is all that is needed for reception or removal of one or more bone screws 43.

The described invention will be seen to accomplish all stated objectives, and further economies of plastics use may be realized if one is willing to eliminate certain structural arrangements of the described (preferred) embodiment. Thus, the use of a single universal-joint-connected

bone-screw clamp may be deemed to serve certain purposes, in which case the other bone-screw clamp may be directly connected to one of the body members; for example, the stem 25' associated with bone-screw clamp 12' in Fig. 1 may be an integral formation with the cylindrical body portion 16 of inner-body member 25, in which case the enlargement 35, its ball-seating groove, and clamp bolt 39 are not needed. Also, in the event that a distraction feature is not needed, the cylindrical outer surface 21 need not be threaded, and there need be no nut 22.

While clamp bolts at 19, 30, 35 and 39 may of course be standard metal parts, it is preferred that these all be of plastics material of sufficient strength to serve all fixator purposes. In that event, the entire fixator may realize not only the economies of plastics, including molded-plastics construction, but the fixator as a whole becomes at least somewhat transparent to x-radiation, thus assuring maximum freedom of viewing aspect, for x-ray observation of a fixator-retained fracture. The particular plastics material selected for the described parts may be selected from commercially available material as long as the molded product is in each case sufficiently rigid, as may be obtained, for example, from use of P.E.S., or glass-filled nylon, or carbon-fiber-filled nylon.

CLAIMS:

1. An external fixator, comprising an elongate outer-body member having a cylindrical bore, an elongate inner-body member having a cylindrical body portion telescopically guided in said cylindrical bore, selectively operable clamping means for securing said body members to retain an adjusted overall body length between axially projecting ends of said body members, and a separate bone-screw clamp connected to each of the respective axially projecting ends of said body members, the connection of at least one of said bone-screw clamps to its body-member end including a universal joint with means for releasably securing an adjusted orientation of said at least one bone-screw clamp with respect to its body member; said body members and said bone-screw clamps and said universal-joint connection being of plastics material.

2. The external fixator of claim 1, in which the connection of the other of said bone-screw clamps to the other of said body members includes a universal joint with means for releasably securing an adjusted orientation thereof.

3. The external fixator of claim 1, in which said members have longitudinally keying engagement, against their relative rotation.

4. The external fixator of claim 3, in which said keying engagement consists of an elongate groove in the cylindrical body portion of said inner-body member, and a key element carried by said outer-body member and projecting radially inward into keying relation with said groove.

5. The external fixator of claim 4, in which said key element has threaded engagement in a tapped local bore of

said outer-body member, said key element having a distal end projecting into the keying relation with said groove.

6. The external fixator of claim 5, in which said key element has an externally accessible tool-engageable formation for driving said key element into radially inward jamming engagement with said groove, thereby constituting with said groove said means for securing said body members for an adjusted overall fixator-body length.

7. The external fixator of claim 1, in which the cylindrical body portion of said inner-body member has external threads, and a distraction nut threadedly engaged to said external threads and interposed axially between said outer-body member and the bone-screw clamp that is connected to the axially projecting end of said inner-body member, said distraction nut being of plastics material.

8. The external fixator of claim 7, in which said nut has a generally cylindrical external surface with finger-engageable knurl formations.

9. The external fixator of claim 7, in which the external threads of said cylindrical body portion are of generally rectangular section, said threads having a pitch which is at least approximately twice the sectional width of said threads, there being a cylindrical land between axially successive thread portions, said cylindrical land being of cylindrical radius for axially distributed running-clearance support of said inner-body member in its telescopically guided relation with the cylindrical bore of said outer-body member.

10. The external fixator of claim 1, in which said one bone-screw clamp comprises two elongate half-shell elements having separably confronting faces that are characterized by axially-spaced transverse grooves for bone-screw or bone-pin reception, and threaded means carried by one of said half-shell elements and engageable with the other half-shell element for removably clamping said half-shell elements against one or more bone screws or bone pins in said

grooves, the connection of said one bone-screw clamp to its body member being to one of said half-shell elements.

11. The external fixator of claim 10, wherein the connection of said at least one bone-screw clamp to said one half-shell element is to one longitudinal end of said one half-shell element.

12. The external fixator of claim 11, wherein the connection of said one bone-screw clamp to said one half-shell element is integral with said one half-shell element and is such that said separably confronting faces determine a geometric plane which includes the ball center of a ball-joint connection constituting said universal joint.

13. The external fixator of claim 2, in which said at least one bone-screw clamp is ball-joint connected to said outer-body member and said outer-body member has a longitudinal slot at the axially projecting end thereof and in which the bore diameter of said outer-body element is less than the ball diameter of said ball-joint connection, said outer-body bore having a circumferential spherical groove centered on the axis of said outer-body bore and axially intermediate axial limits of said longitudinal slot, the spherical radius of said groove being substantially one half said ball diameter, and releasable clamping means for selectively narrowing said slot to circumferentially compress said circumferential groove into a frictionally locked engagement with the ball of said ball joint.

14. The external fixator of claim 13, in which the ball of said ball joint integrally includes, on a single diametric axis through the ball center, a proximally projecting neck connection to said one bone-screw clamp and a distally projecting stop formation having interference with the cylindrical bore to determine an angular limit of ball-joint orientation of said one ball-joint clamp.

15. The external fixator of claim 13, in which said releasable clamping means comprises a headed bolt received in a bolt-receiving bore through said outer body member on

an alignment that (i) is perpendicular to a geometric axial plane which includes the longitudinal slot and (ii) is fully contained by material of said outer-body member; said bolt-receiving bore having a counterbore for bolt-head seating on one side of said slot and having threads for bolt engagement on the other side of said slot.

16. The external fixator of claim 1, in which a tubular formation characterizes the axially projecting end of said inner-body member and in which said at least one bone-screw clamp is ball-joint connected to the tubular formation of said inner-body member, said tubular formation having a longitudinal slot open to said axially projecting end, the bore diameter of said tubular formation being less than the ball diameter of said ball-joint connection, said tubular formation having a circumferential spherical groove centered on the longitudinal axis of said inner-body member and axially intermediate axial limits of said longitudinal slot, the spherical radius of said groove being substantially one half said ball diameter, and releasable clamping means for selectively narrowing said slot to circumferentially compress said circumferential groove into a frictionally locked engagement with the ball of said ball joint.

17. The external fixator of claim 16, in which the ball of said ball joint integrally includes, on a single diametric axis through the ball center, a proximally projecting neck connection to said one bone-screw clamp and a distally projecting stop formation having interference with the cylindrical bore to determine an angular limit of ball-joint orientation of said one ball-joint clamp.

18. The external fixator of claim 16, in which said releasable clamping means comprises a headed bolt received in a bolt-receiving bore through said tubular formation on an alignment that (i) is perpendicular to a geometric axial plane which includes the longitudinal slot and (ii) is fully contained by material of said tubular formation, said bolt-receiving bore having a counterbore for bolt-head seating on

one side of said slot and having threads for bolt engagement on the other side of said slot.

19. The external fixator of claim 1, in which said one of bone-screw clamp comprises a unitary clamp body consisting of two elongate half-shell elements integrally and compliantly connected to each other at a single longitudinal end, said half-shell elements having compliantly separable confronting faces that are characterized by axially-spaced transverse grooves for bone-screw or bone-pin reception, and threaded means carried by one of said half-shell elements and engageable with the other half-shell element for removably clamping said half-shell elements against one or more bone screws or bone pins in said grooves.

20. The external-fixator of claim 19, in which the connection of said one bone-screw clamp to its body member is to one of said half-shell elements.

21. The external-fixator of claim 20, wherein the connection of said one bone-screw clamp to said one half-shell element is integral with said one half-shell element and is such that said confronting faces determine a geometric plane which is at radial offset from the ball center of a ball-joint connection constituting said universal joint.

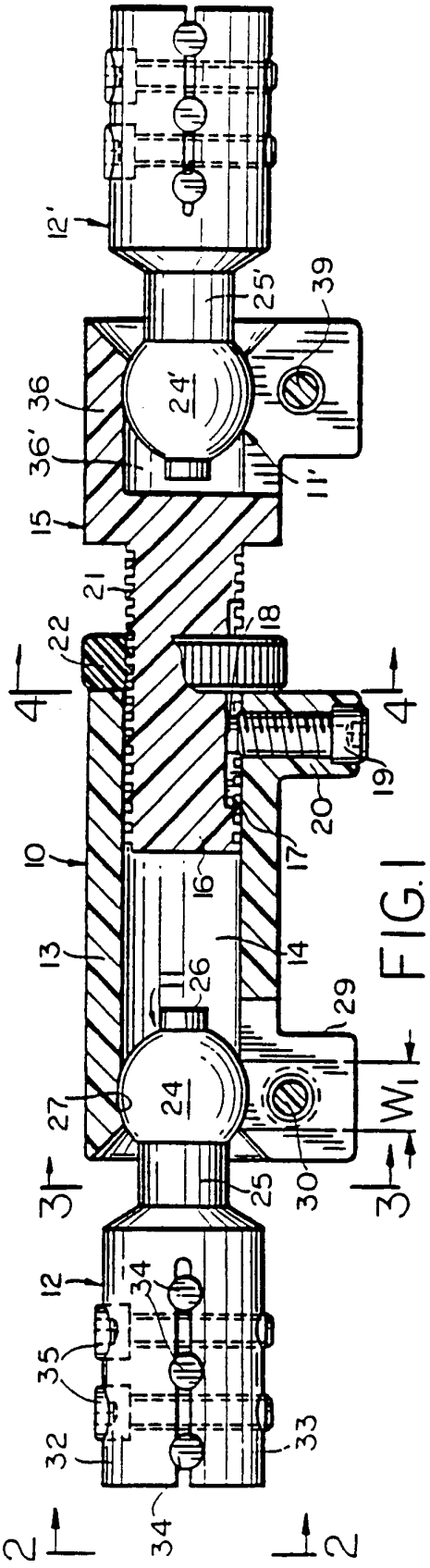
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FIG. 1

FIG.2

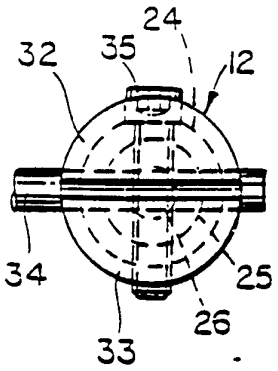

FIG.3

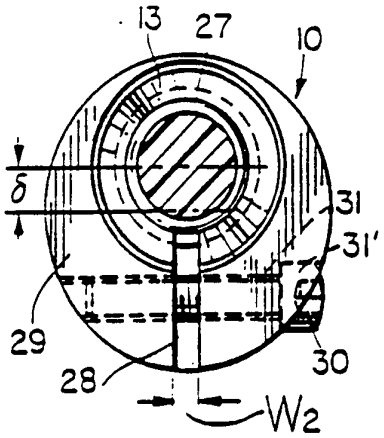

FIG 4

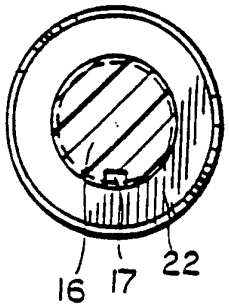

FIG.5