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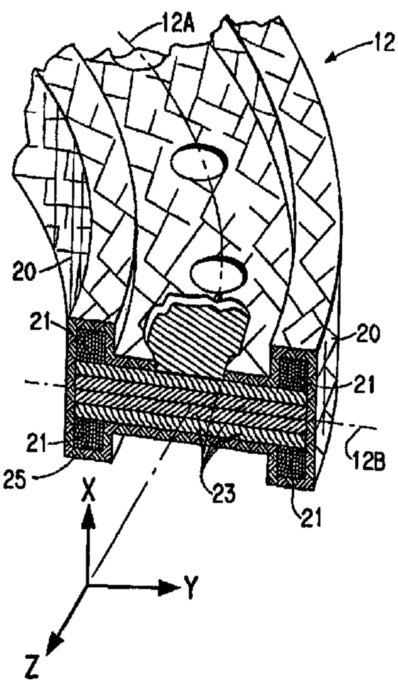
(54) Title: EXTERNAL FIXATION DEVICE WITH COMPOSITE RINGS

(57) Abstract

An improved external fixation device composed of a plurality of fixation rings, multiple tie rods, and pin holders which cooperate to immobilize a bone fracture. An improved composite fixation ring having a core of a resin matrix reinforced with fibers is covered with a braided sleeve with resin impregnating the sleeve and the core.



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TITLE

EXTERNAL FIXATION DEVICE

**Background of the Invention:**

The present invention relates to fiber-reinforced composite structures having improved performance under shear, bending, and torsional stresses and a process for making fiber-reinforced composite structures. The composite structures are useful in a wide range of applications. They are especially useful as external fixation devices.

External fixation methods for treating bone fractures are well-known in the art, including the use of a number of curved rings or curved partial rings that are spaced apart and structurally connected using a plurality of tie rods. Transversely extending pins or wires are attached to the rings and extended from the rings and into the bones so that the frame and transverse pins support and/or load the bone tissue in a desired manner. Such methods are described in Fischer U.S. Patent No. 4,308,863 and Jamison et al. U.S. Patent No. 5,062,844 as well as German Publication No. DE 3935134-A.

External fixation ring systems are commercially available and utilize either metal or composite rings. Composite rings that are transparent to x-rays are desirable as they do not interfere with evaluation of medical radiographs. In addition, composite rings are lighter than comparable metal rings, resulting in improved patient comfort.

The above-referenced Fischer Patent describes partial metal rings having an I-beam cross-section resulting in high strength with minimum weight. Although I-beam structures generally make efficient use of materials by using the flange sections to resist bending forces, they generally provide more limited resistance to torsional forces.

The above-referenced German Publication describes a solid plastic core reinforced by fibers on surface of core.





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In use, external fixation rings are subjected to shear, torsional, and bending forces. External fixation rings in the form of the fiber-reinforced composite structures of the current invention provide an improved balance of mechanical properties for improved performance under combined bending, shear, and torsional forces.

**Brief Description of the Drawings:**

Fig. 1 is a perspective view of an external fixation device installed on a fractured bone illustrating the external fixation rings of this invention.

Fig. 2 is an exploded perspective view partially in section of an external fixation ring of this invention.

Fig. 3 is a plan view of fixation rings of 240 degrees and 120 degrees angular lengths connected by connecting links.

Figs. 4A-4G illustrate a preferred process for making the fixation ring of this invention.

**Detailed Description of the Preferred Embodiment:**

The embodiment chosen for purposes of illustration is shown in Fig. 1 to include an external fixation device 10 composed of arcuate fixation rings 12 and 14, which are disposed about a fractured bone 16. The fixation rings 12 and 14 have an I-beam cross-section composed of a central web portion 18 and a pair of flanges 20. A plurality of holes 22 are formed and symmetrically spaced in the web portion. When installed upon fractured bone 16, a plurality of tie rods 24 pass through some of the holes 22 and are attached to rings 12 and 14 by fasteners 26 and 28. Pin holders 30 and 32 are fastened at various locations on rings 12 and 14 and mount pins 34 and 36, which pass through the bone 16.

As best shown in Fig. 2, a fixation ring 12 has a core (shown as core 13 in Fig. 4F) formed of unidirectional fibers 21 in the flanges 20 and a plurality of layers 23 of unidirectional fibers in the web and a braided sleeve 25 formed about the core 13. The sleeve 25 is bound to the core 13 by resin, which impregnates the fiber of the core and the sleeve. The ring has a circumferential axis designated 12A.

The unidirectional fibers 21 are aligned along the curved flanges 20, approximately parallel to the circumferential axis 12A of the web core. Use of unidirectional fibers in the flanges 20 of the core results in improved resistance to bending forces in the final composite. Preferably, the unidirectional fibers 21 are oriented between 0 and about ± 15 degrees relative to the circumferential axis of the core, 12A in Fig. 2.

The web portion of the core is preferably reinforced with fiber layers 23 oriented roughly parallel (between zero and about ± 15 degrees) to unidirectional fibers 21 and said layers 23 containing fibers oriented between approximately ± 45 degrees ± 15 degrees relative to a tangent to the circumferential axis of the core, more preferably, between approximately ± 45 degrees ± 5 degrees, most preferably, approximately ± 45 degrees. This provides optimum resistance to shear stresses, which are generally greatest in the interior of the core. Preferably, the fiber orientation in the interior of the core is symmetric about the cross-sectional center-line 12B and balanced in the positive and negative directions.

In order to improve the overall resistance of the composite ring to torsional forces and delamination within the core, a layer of fiber material is applied to the exterior surface of the inner core (e.g., braided sleeve 25). The fiber material is applied such that it conforms to the outer shape of the core and is oriented at between approximately ± 45 degrees ± 15





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degrees relative to the tangent of the circumferential axis through the centroid of the ring or core, more preferably, between approximately ± 45 degrees ± 5 degrees, most preferably, approximately ± 45 degrees. The term relative to the tangent of the circumferential axis through the centroid of the ring or core means that for a particular cross-section, when XYZ coordinate axes at the centroid of the cross-section are drawn and the cross-section lies in the X-Y plane and Z is perpendicular to the X-Y plane, Z is the tangent to the circumferential axis 12A in Fig. 2 for that cross-section. All angles (for that cross-section) are measured relative to the Z axis. For horizontal surfaces, the angles are measured in the Y-Z plane and for vertical surfaces, angles are measured in the X-Z plane.

A wide range of fibers and polymeric matrices may be used to form the composite rings of the current invention. For end-uses such as external fixation devices where high strength and stiffness are required, carbon-fiber reinforced epoxy resins are preferred. Other fibers including aramid, glass, or nylon may be also used. Preferably, continuous filament reinforcing fibers are used. Thermoset or thermoplastic matrices may be used, including polyester, nylon, or bismaleimide resins. Preferably, the composite device comprises approximately 30-70 vol% fiber and 70-30 vol% resin. More preferably, the composite comprises approximately 50-70 vol% fiber, most preferably, approximately 65 vol% fiber.

External fixation rings may be formed from the composite rings of the current invention in a variety of diameters, lengths, and cross-section dimensions. For rings having I-beam cross-sections, increasing the thickness of the flange in general increases the bending strength; shear strength may be increased by increasing the thickness of the web. The external fixation devices may be formed as partial rings, for example, as 120 degrees (1/3 ring), 240 degrees (2/3 ring), 180 degrees (1/2 ring), or full rings. External fixation rings generally include a plurality of holes 22 symmetrically spaced along the length of the arcuate frame. The apertures may be drilled into the part during final machining.

As shown in Fig. 3, partial ring segments 30 and 32 may be joined together by the use of connecting links 17. The connecting link 17 may include bosses (not shown) to engage the ring between the flange sections for rings having I-beams cross-sections. The link is attached to the ring using screws (not shown) through holes 22 at the ends of each ring section.

Figs. 4A-4G illustrate a process for forming an arcuate fiber-reinforced composite I-beam ring 12 according to the current invention. An arcuate fiber-reinforced resin I-beam core is formed, covered with a fiber material, and enclosed in a mold shaped to conform to the shape of the fiber-covered core. Resin is then injected into the closed mold under pressure to impregnate the fiber material and bond it to the core. Injecting resin under pressure into the unimpregnated fiber material surrounding the core results in isobaric conditions during injection and more uniform properties in the final part than would be achieved by applying prepreg material to the core and consolidating under heat and pressure with no resin injection.

Figs. 4A-4E illustrate steps in forming the arcuate fiber-reinforced composite core having an I-beam cross-section. Unidirectional fiber prepreg material (containing unidirectional fibers and resin) may be placed in grooves in each half of a mold, as shown in cross-section for one half of the mold in Fig. 4B. To facilitate lay-up of the unidirectional fibers 21, unidirectional fiber prepreg sheet material may be cut into strips 40 with the fibers running along the long dimension of each strip. The strips may then be folded along the direction of the unidirectional fibers

21 several times to provide unidirectional "noodles" 42. In Fig. 4A, the strips have been folded in half and then in thirds to form a noodle structure. The noodles are placed in grooves which run along the inner and outer edges of each side of the mold 30 and will ultimately form the flange section 20 of the core 13. Alternatively, layers of unidirectional tow that has been impregnated with resin may be laid into the groove. However, the use of prepreg sheet material assures more reproducible lay-up of fibers and better control of fiber orientation in the final part.

A convenient way to form the web portion of the core is to cut a plain weave prepreg fabric at 45 degrees to the fiber axes. Plain weave is preferred because there are equal amounts of fiber in the warp and fill directions. Other weaves may be used which do not contain balanced fiber ends in the warp and fill directions. The fiber ends in the + and - directions may then be balanced by flipping the fabric over in alternating layers or by cutting alternating layers at 90 degrees from each other in the original fabric. Alternatively, unidirectional fiber prepreg sheet may be used with alternating layers of fiber oriented at approximately 45 degrees in the + and - directions. Woven fabrics are generally more convenient when constructing parts having substantial thickness as they are generally available in greater thicknesses and contain more fiber ends than commercially available unidirectional ply materials. The undulations present in woven fabric can result in parts having higher toughness as the undulations may resist the propagation of cracks. However, the undulations may also reduce the strength and stiffness of the final part.

The cut-to-size rectangular prepreg strips or layers 23 are placed into each of the mold halves overlaying the unidirectional noodles at the inner and outer edges as shown in Fig. 4C. To facilitate working the fabric strips into the shape of curved molds, the mold may be warmed during placement of the fabric plies. To increase the thickness of the web, the layers could be also placed in between the noodles.

After lay-up of the noodles of unidirectional fibers 21 and fabric layers 23, the mold is closed as shown in Fig. 4D and heated under pressure to sufficient temperature and pressure to consolidate the core 13. The consolidated core 13 (Fig. 4E) is then removed from the mold, and may be machined to the appropriate dimensions and the surface sanded to remove excess resin and mold lines. Preferably, the surface is sanded to provide an even matted finish with no visible fiber fraying. This is conveniently done using a sandblaster, taking care not to oversand.

As shown in Fig. 4F, a fiber material is then applied to the outer surface of the prepared inner core. This may be done by pulling one or more ± 45 degrees braided sleeves 25 having a circumference that is approximately equal to that of the composite I-beam over the outer surface of the core. By using a braid having a circumference that is approximately equal to that of the core, the fibers in the braid will be oriented approximately ± 45 degrees relative to the tangent to the longitudinal axis of the core. The initial braid angle is preferably chosen such that the final braid angle in the composite part is approximately ± 45 degrees. Depending on the weight of braid used, a single braided sleeve may be used, or multiple sleeves may be applied to achieve the desired final part volume. In general, the number of filaments in the tow and the pick count should be chosen to reduce the number of undulations in the fabric for a desired weight. Braided fabrics are especially useful as the outer surface fiber material because they can be easily worked into and around complex shapes such as I-beams and eliminate seams in the outer covering fibrous material.

Alternatively, the fiber material may be applied to the inner core by overbraiding or overwinding the part with a tow of the desired fiber. Tow may be wound on the part, alternating layers of approximately + 45 degrees and - 45 degrees relative to the tangent of the arc of the core. This approach is more readily applied to simple shapes such as rectangular, square, or circular cross-sections.

After application of the fiber material to the outer surface of the inner core, the part is placed into an injection mold 45 (Fig. 4G) shaped to conform to the shape of the covered inner core. The mold is closed, heated, and resin injected under pressure to impregnate the braided preform to form a composite article.

Although composite structures having I-beam cross-sections are disclosed, it is to be understood that the advantages of this invention may be achieved using other cross-sections, such as rectangular and square. For example, in a curved flat ring, ± 45 degree ± 15 degree unidirectional sheet or woven fabric prepreg may be used to reinforce the interior of the ring and unidirectional sheet or tow may be used to reinforce the inner and outer edges of the core component of the ring. The fibrous materials may be a braided sleeve as described above. Alternately, flat rings may be overwound with layers of ± 45 degree ± 15 degree tow.

Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification, they are to be interpreted as specifying the presence of the stated features, integers, steps or components referred to, but not to preclude the presence or addition of one or more other feature, integer, step, component or group thereof.

The claims defining the invention are as follows:

1. An external fixation device for immobilizing a bone fracture that includes a plurality of external fixation rings, a plurality of pins anchored to the bone and clamped to the fixation rings and lockable adjustment rods interconnecting the fixation rings, the improvement comprising:

said fixation rings being a unitary composite structure that includes a core of a resin impregnated fiber matrix, a fiber material sleeve covering and bound to said core by resin impregnating said fiber material sleeve, the core including a curved I-beam cross-section having flanges and a web said core fibers including unidirectional fibers within said flanges and further including layers of material forming said web.

2. The external fixation device of claim 1, the fixation rings being unitary composite structures wherein the core fibers are oriented in transverse and non-transverse directions with respect to the longitudinal axis of the article.

3. The external fixation device of claim 1, wherein the fiber material sleeve covering said core is a braided sleeve.

4. The external fixation device of claim 2, wherein the fiber material sleeve covering said core is a braided sleeve.

5. The external fixation device of claim 1, wherein said layers of material include fibers, said fibers within said layer being oriented between about ±45 degrees ±15 degrees relative a tangent to the longitudinal axis of the core, the angles being balanced in the positive and negative directions.

6. The external fixation device of claim 5, wherein said fiber material coveting said core comprises braided or wound continuous filament tow

and wherein the braid or winding angles are between about ±45 degrees ±15 degrees relative to the tangent of the longitudinal axis through the centroid of the core.

7. The external fixation device of claim 1, wherein said fiber material are carbon fibers said resin material is epoxy resin.

Dated this 15th of July, 1999

**E.I. DU PONT DE NEMOURS AND COMPANY**
By their Patent Attorneys:
CALLINAN LAWRIE

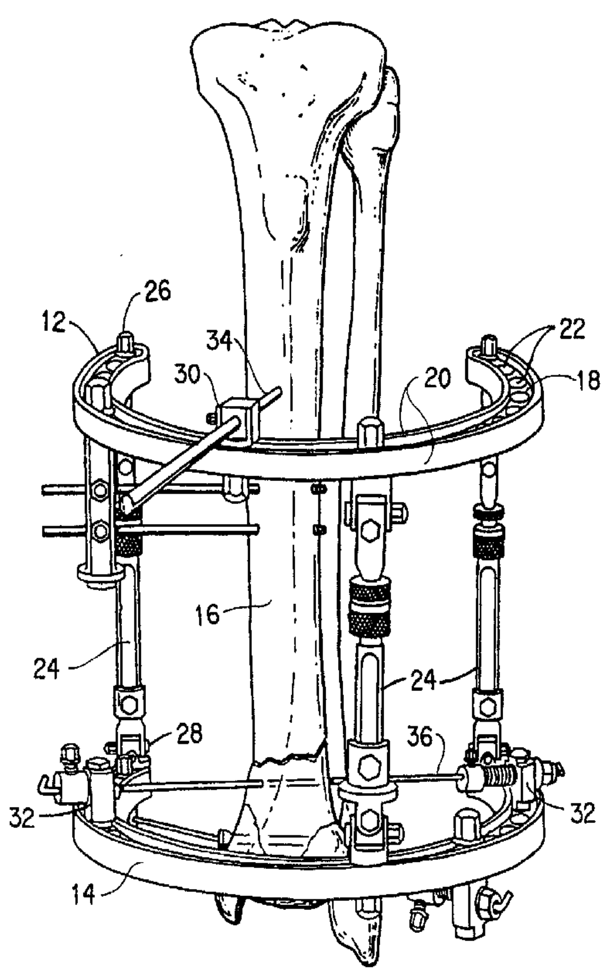


FIG.1

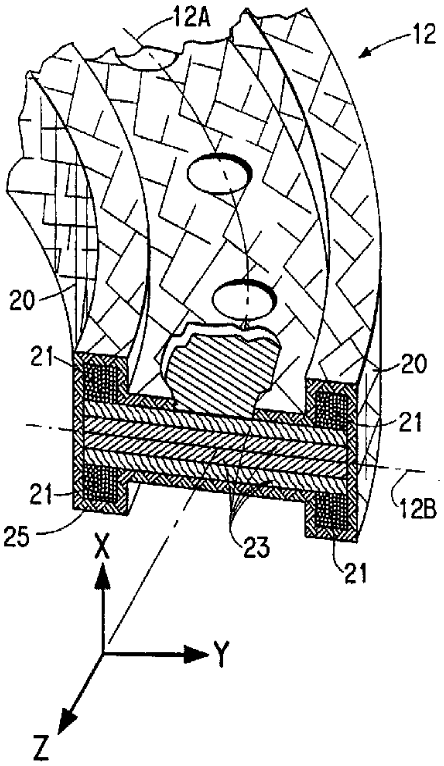


FIG.2

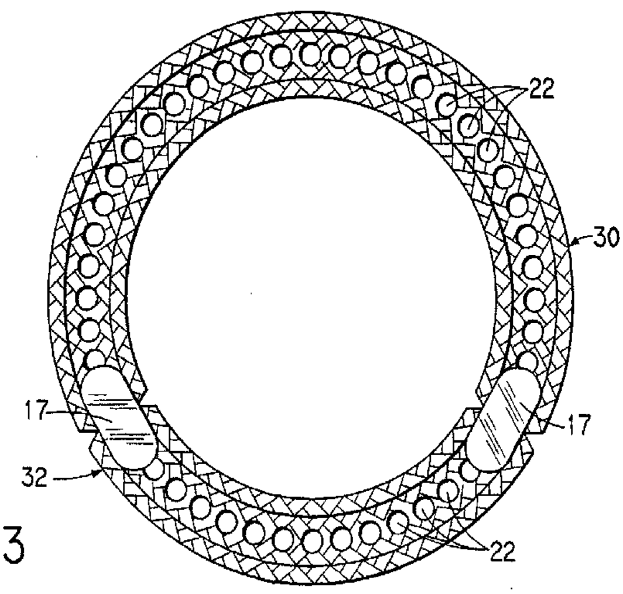


FIG.3

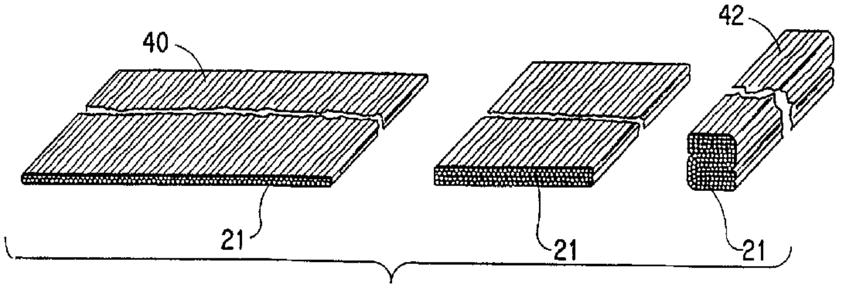


FIG.4A

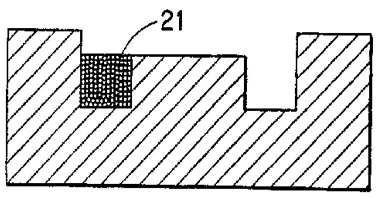


FIG.4B

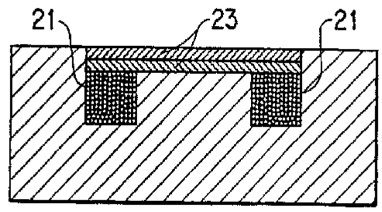


FIG.4C

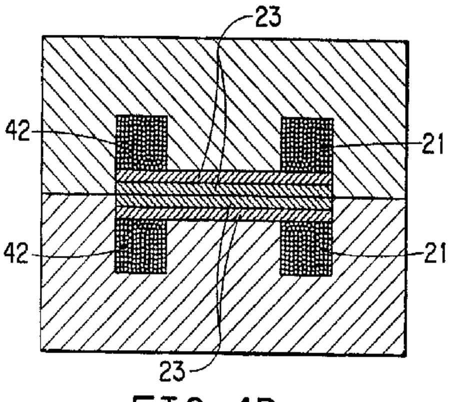


FIG.4D

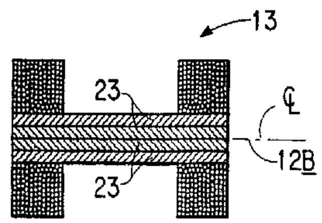


FIG.4E

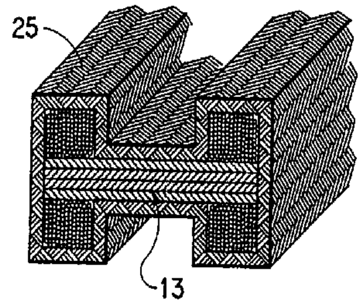


FIG.4F

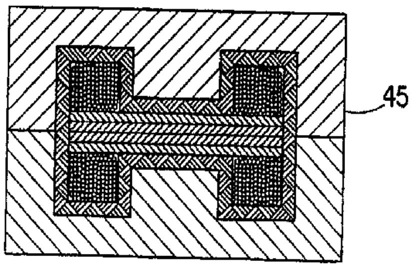


FIG.4G