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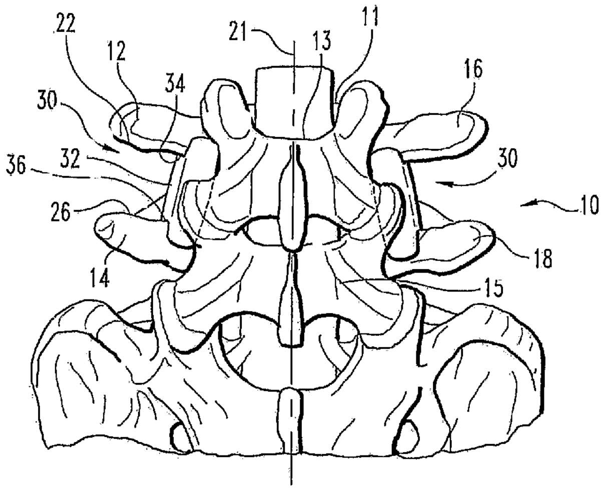
(54) **Title:** IMPLANTS AND METHODS FOR INTER-TRANSVERSE PROCESS DYNAMIC STABILIZATION OF A SPINAL MOTION SEGMENT



(57) **Abstract:** An implant assembly (30, 130) for stabilizing a spinal motion segment includes a flexible spacer member (32, 132) positionable between adjacent transverse processes.

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IMPLANTS AND METHODS FOR INTER-TRANSVERSE PROCESS DYNAMIC STABILIZATION OF A SPINAL MOTION SEGMENT

BACKGROUND

Implants can be positioned between adjacent spinous processes to provide resistance to vertebral movement as a result of extension of the spinal column. These implants can provide a shock absorber or bumper that dynamically limits spinal extension. The implants can be secured to the adjacent spinous processes with looped cables or straps that extend completely about the spinous processes and implant to maintain positioning of the implant between the spinous processes while also limiting spinal flexion. While spinous process implants provide dynamic stabilization along the spinal midline, dynamic stabilization at uni-lateral or bi-lateral locations of the posterior vertebral elements is not achieved with such implants.

SUMMARY

There is provided spinal implants, implant assemblies and implants that provide uni-lateral or bi-lateral dynamic stabilization of a spinal motion segment through the posterior vertebral elements.

According to one aspect, a spinal implant includes a spacer member extending between opposite upper and lower ends. The upper and lower ends each include a pair of arms and a recessed surface between the pair of arms. The arms are structured to receive a respective adjacent one of upper and lower transverse processes of a spinal motion segment. The spacer member includes a compressible body sized and shaped to extend between the upper and lower transverse processes to dynamically limit movement of the upper and lower transverse processes toward one another upon extension of the spinal motion segment.

According to another aspect, a spinal implant system includes a first spacer member extending between opposite upper and lower ends structured to receive a respective adjacent one of upper and lower transverse processes of a spinal motion segment at a first side of the spinal midline. The system further includes a second spacer member extending between opposite upper and lower ends structured to receive a respective adjacent one of upper and lower transverse processes of a spinal motion

segment at a second side of the spinal midline. Each of the spacer members includes a compressible body sized and shaped to extend between the upper and lower transverse processes to dynamically limit movement of the upper and lower transverse processes toward one another upon extension of the spinal motion segment.

According to a further aspect, a method for stabilizing a spinal motion segment comprises: positioning a spacer member between adjacent upper and lower transverse processes of the spinal motion segment, the spacer member including an upper end contacting an inferior surface of the upper transverse process and a lower end contacting a superior surface of the lower transverse process; and dynamically stabilizing the spinal motion segment with the spacer member resiliently compressing between the transverse processes in response to extension of the spinal motion segment.

These and other aspects will be discussed further below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevation view of a posterior portion of a spinal column motion segment with implant assemblies engaged thereto.

FIG. 2 is a lateral view of the spinal column motion segment of Fig. 1.

FIG. 3 is an elevation view of another embodiment implant assembly.

FIG. 4 is an elevation view of another embodiment implant assembly.

FIG. 5 is an elevation view of another embodiment implant assembly.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

Implants are positionable between adjacent transverse processes of a spinal motion segment to dynamically stabilize and limit spinal extension and/or flexion. The implant includes a spacer member received between the transverse processes that is compressible to allow extension motion of the motion segment while maintaining a distraction force between the transverse processes.

In one implant system, spacer members are positioned bi-laterally relative to a spinal motion segment in order to provide bi-lateral stabilization. In another implant system, uni-lateral stabilization is provided by the implant system. In still other systems, multi-level vertebral stabilization is contemplated for either uni-lateral or bi-lateral systems. The implant systems may be employed either alone or in combination with other implants, such as rods, plates, tethers, interbody fusion devices, interbody spacers, artificial discs, annulus repair system, or staples, for example.

In a further form, one or more engaging members in the form of a tether couples the implant to one or more posterior vertebral elements or implants. The engaging members can be engaged to the spacer member, or extend through the spacer member. The engaging members can be engaged to the posterior elements in a configuration that limits spinal flexion. Alternatively or additionally, the engaging members can be engaged to the posterior elements in a manner that prevents the spacer member from being displaced from its implantation location between the transverse processes.

In Fig. 1 there is shown a spinal column segment 10 including an upper vertebra 11, a lower vertebra 15 and a spinal disc 13 therebetween along a central axis 21 of the spinal column. The vertebrae 11, 15 and disc 13 comprise a spinal motion segment, it being understood that a spinal motion segment may include multiple vertebral levels. Upper vertebra 11 includes a first upper transverse process 12 and a second upper transverse process 16. Lower vertebra 15 includes a first lower transverse process 14 and a second lower transverse process 18. The transverse processes 12, 14, 16, 18 comprise posterior elements of the vertebrae of the spinal motion segment along with the spinous processes 17, 19, facets, pedicles and other posterior structures of each vertebrae 11, 15.

A spinal implant 30 is positioned in engagement with the posterior vertebral elements to provide dynamic spinal stabilization. Spinal implant 30 includes a spacer member 32 extending between and contacting adjacent surfaces of transverse processes 12, 14 to limit movement of the spinous processes toward one another as a result of extension of the spinal motion segment. For example, spacer member 32 can include an upper end 34 in contact with inferior surface 22 of transverse process 12, and a lower end 36 in contact with superior surface 26 of transverse process 14. Spacer member 32 can include a body structured to resiliently compress in response to extension of the spinal extension, providing resistance to the extension forces and limiting movement of the transverse processes 12, 14 toward one another as spacer member 32 is compressed.

Fig. 1 further shows a second spinal implant 30 on the other side of central axis 21 of the spinal column. The second spacer member 32 can be structured like the other implant 30, and is configured to extend between and contact adjacent surfaces of transverse processes 16, 18 to limit movement of the spinous processes toward one another as a result of extension of the spinal motion segment. The implants 30 work bi-laterally to provide bi-lateral stabilization of spinal column segment 10. Additional implants 30 may be provided at one or more additional vertebral levels for multi-level stabilization procedures. It is further contemplated that implants 30 may be employed to uni-laterally stabilize one or more vertebral levels. The spinal implants, either alone or in combination, can function to distract the spinal space and/or the spinal foramen to relieve nerve root pressure, decompress spinal elements. The implants provide overall stability while maintaining motion capabilities of the spinal motion segment.

As further shown in Fig. 2, spacer member 32 includes a pair of upper arms 42 and a pair of lower arms 44. Upper arms 42 define a concavely curved upper surface 35 therebetween, and lower arms 44 define a concavely curved lower surface 37 therebetween. The concavely curved surfaces 35, 37 can conform generally to or be conformable to the surface of the transverse process against the surface is positioned. Arms 42, 44 extend along opposite sides of and receiver the respective transverse process 12, 14 to resist dislodgement of spacer member 32 from its positioning between transverse processes 12, 14.

In its implanted orientation, spacer member 32 includes an anteriorly oriented surface 46 and a posteriorly oriented surface 48. Anteriorly oriented surface 46 can include a concave curvature to fit over the exiting nerve root 28 and prevent or avoid any impingement thereof. Posteriorly oriented surface 48 can be convexly curved as illustrated, or can include a concave curvature, or it can be linear in form.

In addition, each of the arm pairs 42, 44 includes a posterior arm 42a, 44a and an anterior arm 42b, 44b. In the illustrated embodiment, posterior arms 42a, 44a have a thickness that is less than the thickness of the anterior arms 42b, 44b. The reduced thickness limits the amount of spacer material in the area where nerve root 28 exits the spinal foramen, increasing the space available for nerve root 28 to pass.

In a further embodiment, it is contemplated that stiffening members can be provided to enhance or increase the stiffness of spacer member 32. For example, as shown in Fig. 3, a stiffening member 50 is shown in the form of a band that extends about and contacts the perimeter of spacer member 32 in a direction transverse to central axis 33. Multiple stiffening members 50 can be provided about spacer member 32 to allow the stiffness profile of spacer member 32 to be increased or decreased by adding or removing stiffening members 50. In another embodiment, stiffening member 50 includes a width that extends along a substantial portion of the length of spacer member 32.

In Fig. 3 there is shown one embodiment shape for spacer member 32 in the medial-lateral direction when in its implantation orientation. Fig. 4 shows one embodiment of spacer member 32 positionable along the left hand side of the spinal column and in an elevation view looking the posterior to anterior direction. Spacer member 32 extends between upper end 34 and lower end 36, and arms 42 are provided at upper end 34 and arms 44 are provided at lower end 36 as discussed above. A central axis 33 divides spacer member 32 into a right hand or medial side and a left hand or lateral side. Spacer member 32 includes a medial surface 52 extending along the medial side and a lateral surface 54 extending along the lateral side. Adjacent lower end 36, medial surface 52 is offset laterally toward or to one side of central axis 33 along lower arms 44. Medial surface 52 extends transversely to central axis 33 from lower arms 44 to upper arms 42 at upper end 34. Along upper arms 42, medial surface 52 is offset medially of central axis 33 and also offset medially with respect to the portion of medial surface 52 along lower arms 44.

The offsetting medial surface 52 is shaped to facilitate placement of spacer member 32 along or against the bony structure and shapes at the junctions of the transverse process and pedicle. By allowing placement of spacer member 32 as close as possible to the junction of the transverse process with the pedicle, the moment arm on the transverse process is minimized. In another embodiment, spacer member 32 is made with material properties that deform to allow conformance upon contact of spacer member 32 with the bony structure. In still other embodiments, the medial and lateral surfaces can be parallel to one another.

Referring now to Fig. 5, there is shown an implant assembly 130. Implant assembly 130 includes a spacer member 132 having a body extending between an upper end 134 and a lower end 136. A first pair of arms 142 are provided adjacent upper end 134, and a second pair of arms 144 are provided adjacent lower end 136. Spacer member 132 is similar to spacer member 32 discussed above and is structured for positioning between and receiving adjacent upper and lower transverse processes of a spinal motion segment. However, implant assembly 130 include an engaging member 150 extending therefrom to attach spacer member 132 to posterior vertebral elements or implants of the spinal motion segment.

Spacer member 132 includes through-passages 148 extending between opposite sides thereof, which include the anterior and posterior sides of spacer member 132 in the illustrated embodiment. Passages 148 receive engaging member 150 therethrough. Engaging member 150 may comprise multiple engaging members, or a single engaging member looped through passages 148. Still other embodiments contemplate a single passage 148, or three or more passages 148, through which one or more engaging members 150 are positioned.

Engaging member 150 can be in the form of a tether, cord, wire, cable, suture, band, strap, belt, or other suitable structure for manipulation and securement to one or more posterior vertebral elements. Engaging member 150 may be wrapped or positioned around posterior vertebral elements and then maintained in position with a crimp or other suitable fastener. Furthermore, engaging member 150 can be coupled to spacer member 132 in any suitable manner. In one embodiment, engaging member 150 is movably coupled to spacer member 132. Engaging member 150 can be integrally formed with spacer member 132, or can be attached by a fastener, suture, anchor, cable, link, over-molding or other suitable connection. Spacer member 132 can be provided with ears, eyelets, recesses or other suitable structure to facilitate engagement of engaging member 150 to spacer member 132. Engaging member 150 may be employed in spinal stabilization procedures where it is desired to limit spinal flexion by, for example, wrapping engaging member 150 about the superior surface of the upper transverse process and the inferior surface of the lower transverse process. Engaging member may alternatively be employed as a retention mechanism to maintain spacer member 132 in position between the transverse processes.

With respect to the various embodiments described herein, the engaging member can be joined or fixed to the spacer member using various devices and/or techniques, or can be integrally formed with or form an extension of the spacer member. The spacer member can be joined or attached to the engaging member by, for example, sewing the engaging member to the spacer member, thermal welding or bonding, adhesive bonding, three dimensional weaving or braiding, screws, staples, pins, tacks or rivet fixation. Furthermore, the engaging member can be secured to the spacer member either before or after the spacing member is placed between the transverse processes. The engaging member can be engaged to other engaging members of other implant assemblies or to other implants engaged to the spinal column in the surgical procedure.

The spacer member can be fabricated from components that are flexible or exhibit at least some flexibility. Examples of such components include woven fabric tubing, woven and non-woven mesh, or braided or woven structures, sutures, tethers, cords, planar members, bands, wires, cables, or any other component capable of extending between and supporting the adjacent spinous processes. Additionally, the spacer member may be resilient and/or elastic so it can assume various shapes during and after insertion and attachment.

The spacer member can be made from any biocompatible material, material of synthetic or natural origin, and material of a resorbable or non-resorbable nature. Suitable examples of spacer member material include autograft, allograft or xenograft; tissue materials including soft tissues, connective tissues, demineralized bone matrix and combinations thereof; resorbable materials including polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, collagen, albumin, fibrinogen and combinations thereof; and non-resorbable materials including polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, poly-paraphenylene terephthalamide, polyetheretherketone, cellulose, and combinations thereof.

The engaging members described herein can be made from any one or combinations of biocompatible material, including synthetic or natural autograft, allograft or xenograft tissues, and can be resorbable or non-resorbable nature. Examples of tissue materials include hard tissues, connective tissues, demineralized bone matrix and combinations thereof. Further examples of resorbable materials are polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, and combinations thereof. Further examples of non-resorbable materials are carbon-reinforced polymer composites, shape-memory alloys, titanium, titanium alloys, cobalt chrome alloys, stainless steel, and combinations thereof.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A spinal implant, comprising:

a spacer member extending between opposite upper and lower ends, said upper and lower ends each including a pair of arms and a recessed surface between said pair of arms, said arms being structured to receive a respective adjacent one of upper and lower transverse processes of a spinal motion segment, said spacer member including a compressible body sized and shaped to extend between the upper and lower transverse processes to dynamically limit movement of the upper and lower transverse processes toward one another upon extension of the spinal motion segment.

2. The implant of claim 1, wherein said body includes a posterior surface and an anterior surface in an implantation orientation between the upper and lower transverse processes, said anterior and posterior surfaces extending between said first and second ends, wherein said anterior surface includes a concave curvature between said first and second ends.

3. The implant of claim 2, wherein said posterior surface is convexly curved between said first and second ends.

4. The implant of claim 1, further comprising at least one band extending about said body in contact therewith about a perimeter of said body, said at least one band compressing said body about said perimeter.

5. The implant of claim 1, wherein each of said arm pairs includes a posterior arm positionable along a posterior side of the transverse process and an anterior arm positionable along an anterior side of the transverse process.

6. The implant of claim 5, wherein in the implantation orientation said posterior arms each include a thickness in the anterior-posterior direction that is greater than a thickness of each of said anterior arms in the anterior-posterior direction.

7. The implant of claim 5, wherein said body extends along a central axis between said first and second ends, said arms at said upper end of said spacer member being offset in the medial direction from said arms at said lower end of said spacer member.

8. The implant of claim 1, further comprising at least one tether engaged to said body and extending therefrom, said tether being positionable about posterior elements of the spinal motion segment.

9. The implant of claim 8, wherein said body includes at least one bore extending therethrough between a posteriorly oriented side and an anteriorly oriented side of said body when positioned between the upper and lower transverse processes, said at least one tether extending through said at least one bore.

10. The implant of claim 9, further comprising a second bore through said body adjacent to and paralleling said first bore.

11. A spinal implant system, comprising:

a first spacer member extending between opposite upper and lower ends structured to receive a respective adjacent one of upper and lower transverse processes of a spinal motion segment at a first side of the spinal midline; and

a second spacer member extending between opposite upper and lower ends structured to receive a respective adjacent one of upper and lower transverse processes of a spinal motion segment at a second side of the spinal midline, wherein each of said spacer members includes a compressible body sized and shaped to extend between the upper and lower transverse processes to dynamically limit movement of the upper and lower transverse processes toward one another upon extension of the spinal motion segment.

12. The system of claim 11, further comprising an engaging member for each of said spacer members, each of said engaging members being in the form of a tether positionable about posterior elements of the spinal motion segment to secure said spacer member thereto.

13. The system of claim 11, wherein said body of each of said spacer members includes a posterior surface and an anterior surface in an implantation orientation between the upper and lower transverse processes, said anterior and posterior surfaces extending between said first and second ends, wherein said anterior surface includes a concave curvature between said first and second ends.

14. The system of claim 13, wherein for each of said spacer members said posterior surface is convexly curved between said first and second ends.

15. The system of claim 11, wherein for each of said spacer members said body includes a pair of upper arms defining a recessed surface therebetween for receiving the

upper transverse process and a pair of lower arms defining a recessed surface therebetween for receiving the lower transverse process.

16. The system of claim 15, wherein each of said pair of arms includes a posterior arm positionable along a posterior side of the transverse process and an anterior arm positionable along an anterior side of the transverse process.

17. The system of claim 16, wherein in the implantation orientation of each of said spacer members said posterior arms each include a thickness in the anterior-posterior direction that is greater than a thickness of each of said anterior arms in the anterior-posterior direction.

18. A method for stabilizing a spinal motion segment, comprising:

positioning a spacer member between adjacent upper and lower transverse processes of the spinal motion segment, the spacer member including an upper end contacting an inferior surface of the upper transverse process and a lower end contacting a superior surface of the lower transverse process; and

dynamically stabilizing the spinal motion segment with the spacer member resiliently compressing between the transverse processes in response to extension of the spinal motion segment.

19. The method of claim 18, further comprising positioning each of the upper and lower transverse processes between arms at each of the upper and lower ends of the spacer member.

20. The method of claim 18, further comprising engaging the spacer member to posterior vertebral elements of the spinal motion segment with a tether.

21. The method of claim 18, further comprising increasing a stiffness of the spacer member with a stiffening member extending about the body of the spacer member transversely to a central axis of the body.

22. The method of claim 18, further comprising maintaining clearance of a spinal foramen by concavely curving an anterior surface of the spacer member.

23. The method of claim 21, further comprising positioning a second spacer member between second adjacent upper and lower transverse processes of the spinal motion segment on a side of the spinal motion segment opposite the other spacer member, the second spacer member including an upper end contacting an inferior surface of the

second upper transverse process and a lower end contacting a superior surface of the second lower transverse process; and

dynamically stabilizing the spinal motion segment with the second spacer member resiliently compressing between the second transverse processes in response to extension of the spinal motion segment.

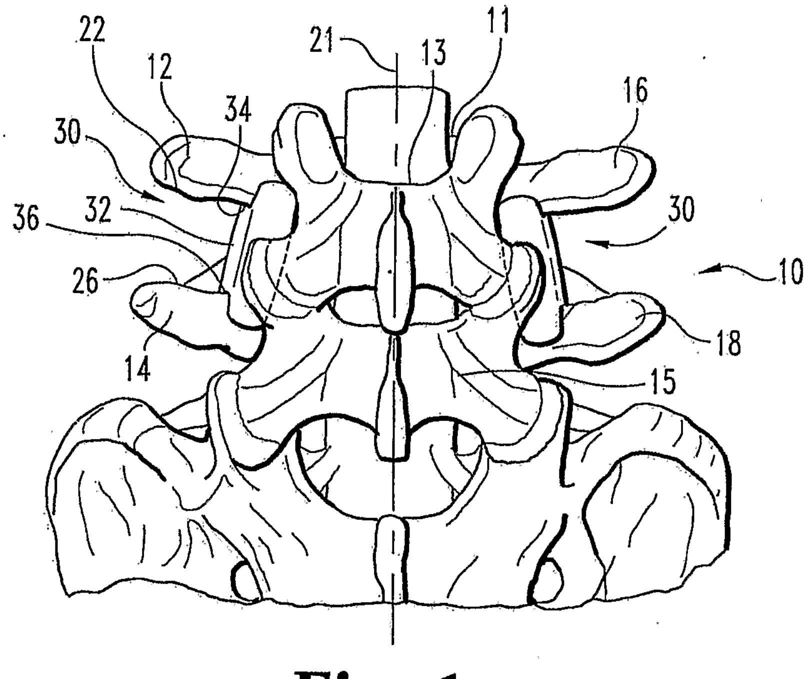

Fig. 1

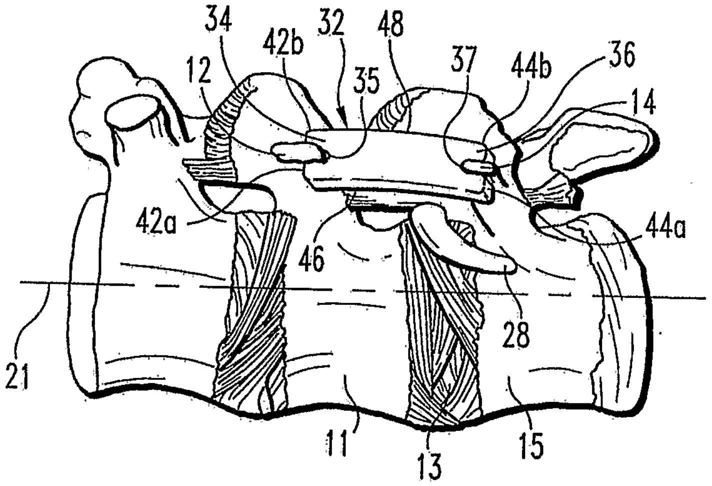

Fig. 2

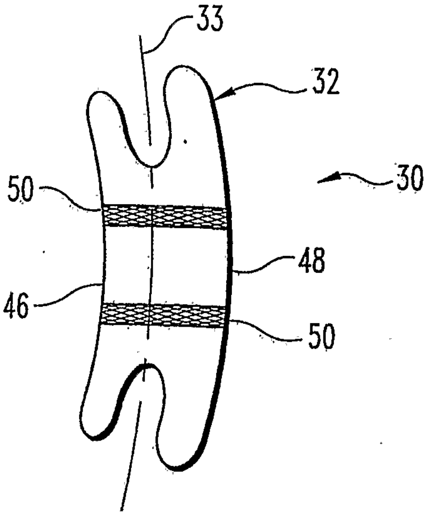

Fig. 3

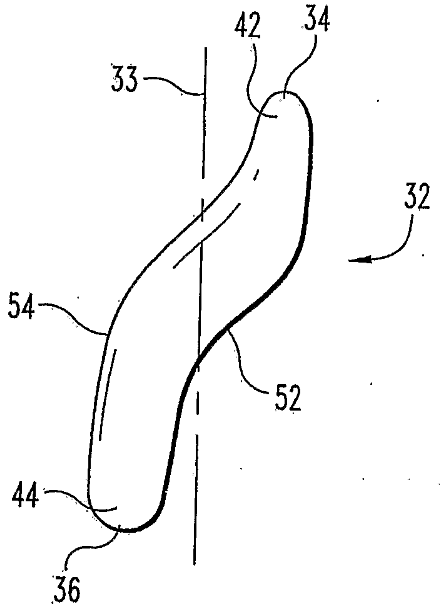

Fig. 4

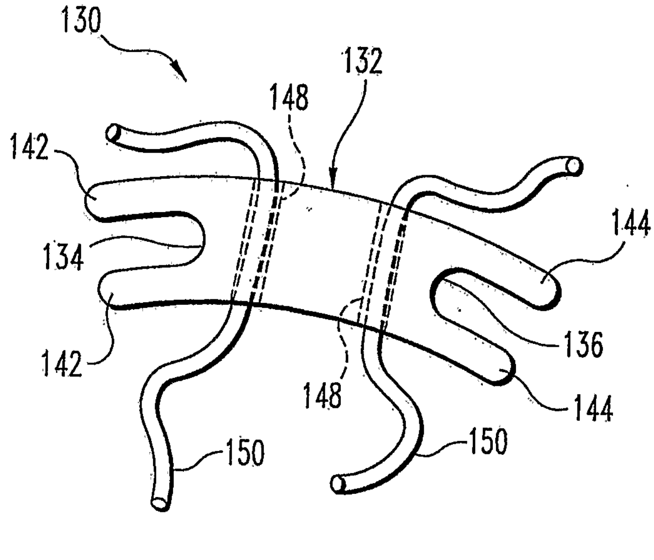

Fig. 5