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(54) **TISSUE FASTENER**

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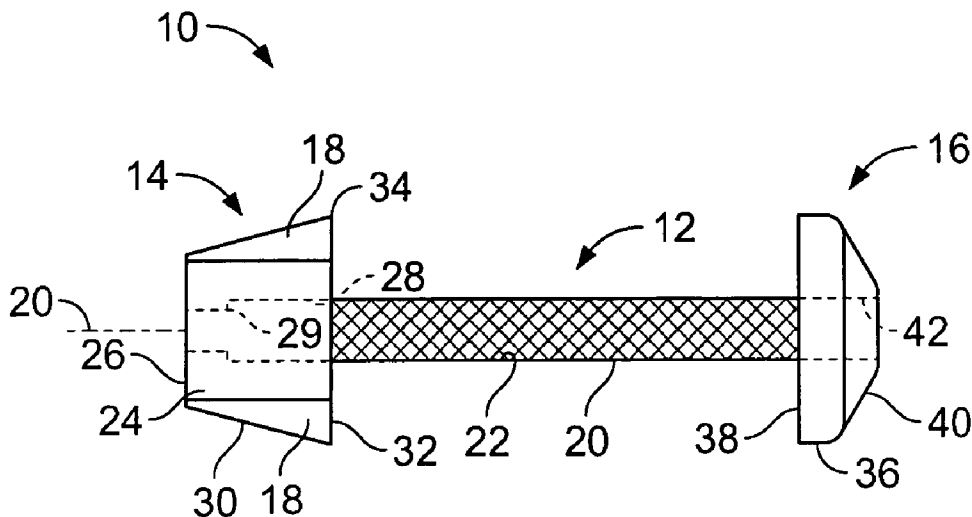
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(57) **ABSTRACT**

A tissue fastener comprises a shaft having a member disposed thereon for lodging the shaft within the tissue, the shaft having a region that is relatively flexible to render a tissue engaging head disposed at a proximal end of the shaft movable with respect to the shaft. In one embodiment, the region comprises substantially an entire length of the shaft and is made from flexible material, such as a mesh, onto which the member and the head are molded. In another embodiment, the shaft comprises generally rigid material, and the region comprises a flexible joint between the shaft and the head. The flexible joint comprises a breakable (e.g., frangible) section of the shaft, and a flexible member (e.g., a plurality of filaments or a flexible tube) extends between the shaft and the head past the breakable section.



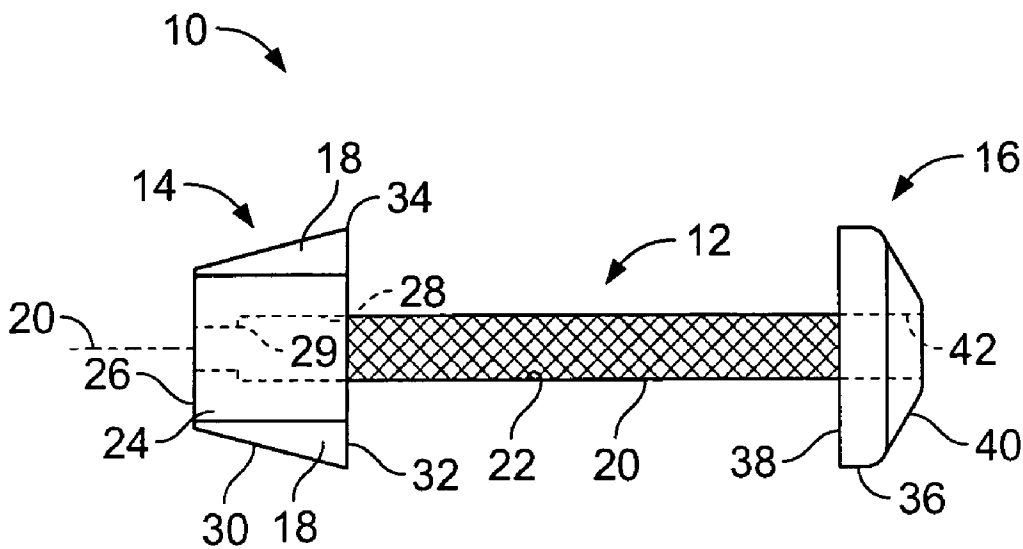


FIG. 1

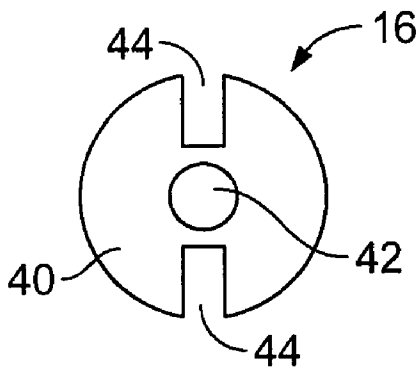


FIG. 2

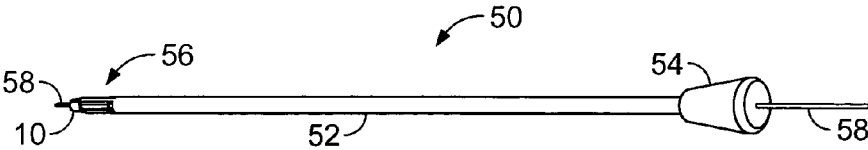


FIG. 3

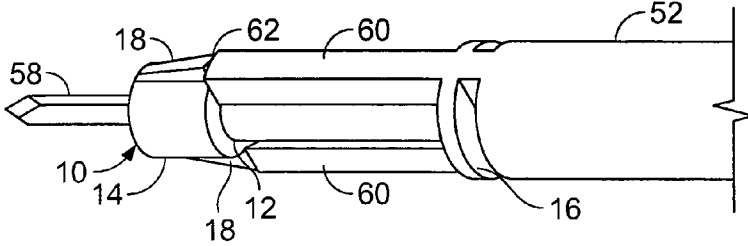


FIG. 4

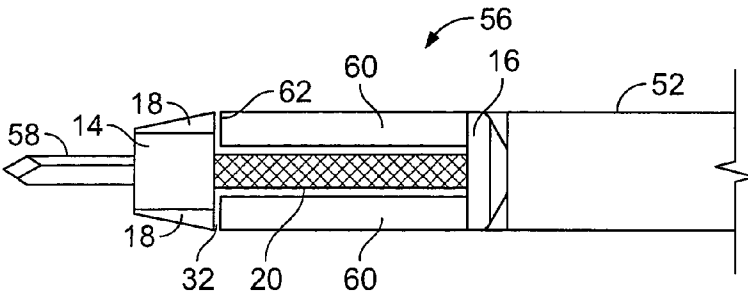


FIG. 5

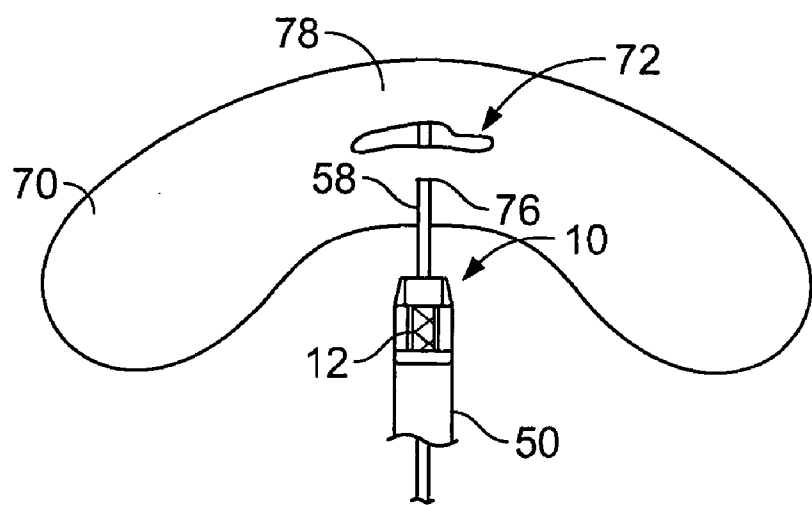


FIG. 6A

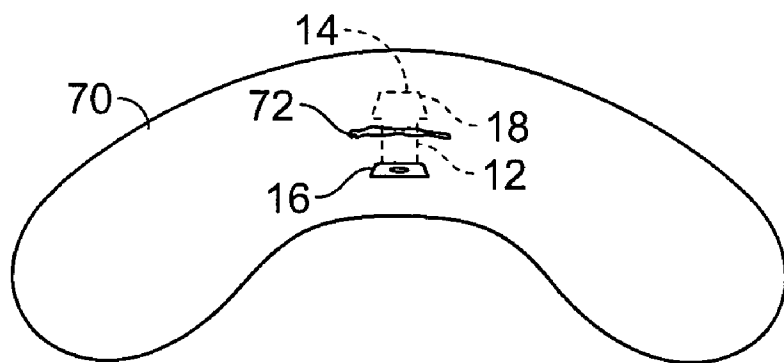


FIG. 6B

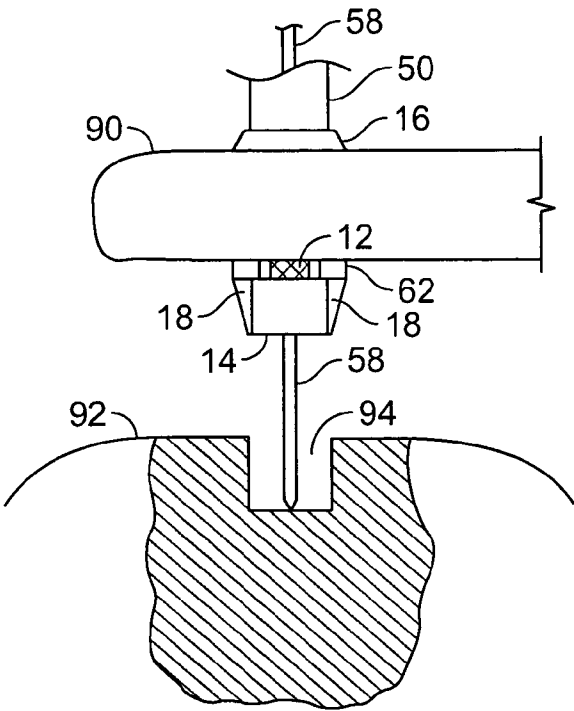


FIG. 7A

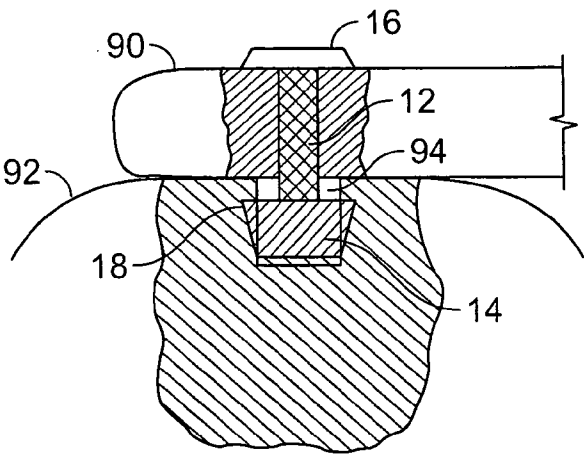


FIG. 7B

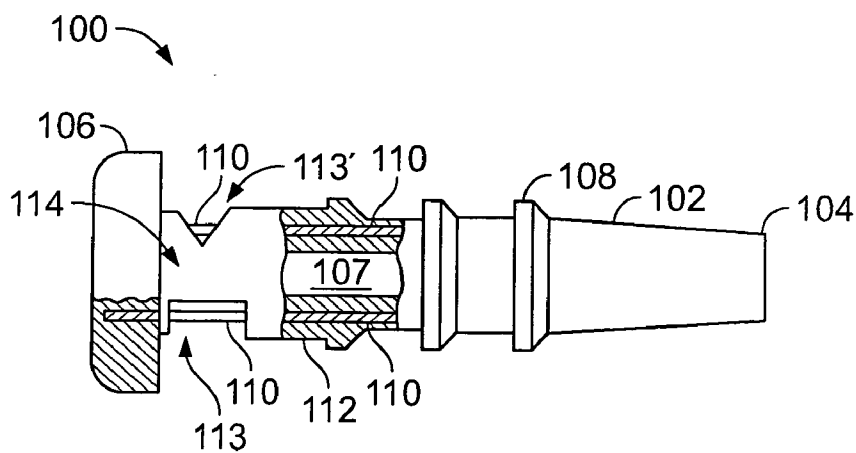


FIG. 8

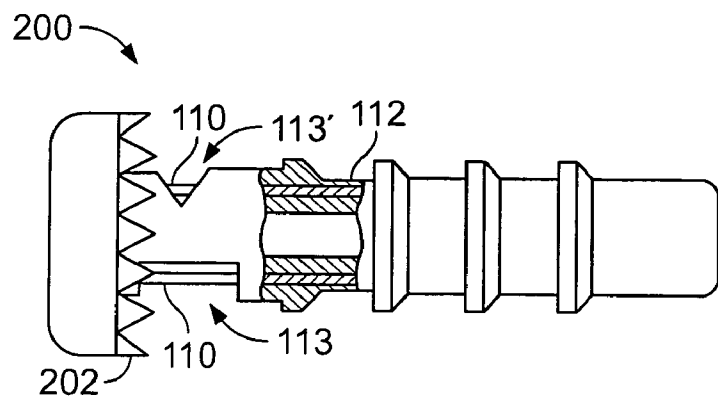


FIG. 9

## TISSUE FASTENER

### BACKGROUND

[0001] This invention relates to tissue fasteners, in particular to devices for attaching soft tissue (e.g., tendons, ligaments, or cartilage) to bone or to other soft tissue.

[0002] One conventional tissue fastener used to re-attach cartilage to bone comprises an elongated shaft with a series of barbs that enable the shaft to be inserted through tissue but resist withdrawal thereafter. The distal tip of the shaft is sharp, and the proximal end of the shaft terminates at an enlarged head. To re-attach soft tissue to bone, the fastener is pushed through the soft tissue into a pre-formed hole in the bone until the soft tissue is secured between the head and the bone surface. The barbs resist withdrawal from the hole, thereby holding the fastener (and thus the soft tissue) in place.

### SUMMARY

[0003] One aspect of the invention features a tissue fastener comprising a shaft having a member disposed thereon for lodging the shaft within the tissue, the shaft having a region that is relatively flexible to render a tissue engaging head disposed at a proximal end of the shaft movable with respect to the shaft.

[0004] Preferred embodiments may include one or more of the following features.

[0005] In one embodiment, the region comprises substantially an entire length of the shaft. The region comprises flexible material, such as a mesh. The member and the head are molded onto the mesh. The member comprises at least one barb.

[0006] In another embodiment, the shaft comprises generally rigid material, and the region comprises a flexible joint between the shaft and the head. The flexible joint comprises a breakable section of the shaft. For example, the section is constructed to be frangible (i.e., readily broken). A flexible member extends between the shaft and the head past the breakable section. The flexible member comprises, e.g., a plurality of filaments or a flexible tube. The flexible member extends along substantially an entire length of the shaft. The breakable section is defined by at least one opening disposed through a wall of the shaft. The shaft and the head comprise an integral molded unit, and the flexible member is molded therewithin.

[0007] The tissue fastener is made from polymeric material, such as a bioabsorbable material. The shaft is hollow and defines an interior passage. The head includes an opening in communication with the passage. The passage may be open or closed at a distal end of the shaft.

[0008] In one embodiment, the head has a flat distal surface. In another approach, the head has a toothed distal surface.

[0009] Another aspect of the invention features the tissue fastener and an insertion tool engageable with the tissue fastener for inserting the tissue fastener into tissue.

[0010] Preferred embodiments may include one or more of the following features. The tissue fastener member is disposed at a distal region of the shaft for lodging the shaft

within the tissue, and the tissue engaging head is disposed at a proximal end of the shaft, and the shaft is relatively flexible between the member and the head. The insertion tool has an engagement portion for engaging the member. The head includes an aperture, and the engagement portion of the tool is configured to extend through the aperture when engaged with the member.

[0011] Other aspects of the invention feature methods for tissue attachment using the tissue fastener. One such method comprises inserting the tissue fastener through a first tissue and into a second tissue so that the member lodges within the second tissue and the head urges the first tissue against the second tissue.

[0012] Preferred embodiments may include one or more of the following features.

[0013] The first tissue and the second tissue are regions of a common tissue structure. For example, the tissue is cartilage and, prior to the inserting, the first region is separated from the second region by a tear in the cartilage.

[0014] Alternatively, the first tissue is soft tissue and the second tissue is bone.

[0015] Another aspect of the invention features a method for making a tissue fastener comprising providing a shaft having a member disposed thereon for lodging the shaft within the tissue, and a tissue engaging head disposed at a proximal end of the shaft, and making a region of the shaft relatively flexible to render the head movable with respect to the shaft.

[0016] Preferred embodiments include making the tissue fastener so as to have the structural features discussed above.

[0017] The flexibility of the tissue fastener allows the head to move (either from side to side or up and down) in response to loads imposed by the tissue, without compromising the security of the tissue attachment. As a result, healing is promoted even in high stress applications, with little risk of the head digging into, and potentially damaging, the tissue. The tissue fastener is particularly (but by no means exclusively) useful in the treatment of shoulder and knee instability, and in small joint repairs. These applications include meniscal repair, rotator cuff repair, Bankhart procedures, and treatment of "slap" lesions.

[0018] Other features and advantages of the invention will become apparent from the following description, and from the claims.

### DRAWINGS

[0019] FIGS. 1 and 2 show a tissue fastener.

[0020] FIGS. 3-5 show the tissue fastener of FIG. 1 with an insertion tool.

[0021] FIGS. 6A and 6B show the use of the tissue fastener of FIG. 1 to repair a tear in soft tissue.

[0022] FIGS. 7A and 7B show the use of the tissue fastener of FIG. 1 to attach soft tissue to bone tissue.

[0023] FIGS. 8 and 9 illustrate alternative embodiments of a tissue fastener.

### DESCRIPTION OF EMBODIMENTS

[0024] FIGS. 1 and 2 show one embodiment of a flexible tissue fastener 10 that includes a flexible shaft 12 and a

generally rigid tip **14** and head **16** mounted at opposite ends of shaft **12**. A pair of generally rigid barbs **18** extend from tip **14** for anchoring fastener in place within tissue. Shaft **12**, tip **14**, and head **16** are hollow and have open-ended passages which are in communication along a longitudinal axis **20** of fastener **10** for purposes to be described.

[0025] Shaft **12** comprises a woven polymeric mesh **20** made from a bioabsorbable polymer, preferably polylactic acid (PLA), that defines an interior passage **22** open at both its proximal and distal ends. The woven nature of mesh **20** renders shaft **12** flexible both transversely to and along longitudinal axis **20**. Thus, when fastener **10** is in vivo, shaft **12** can flex from side to side with respect to axis **20** as the tissue applies shear forces to shaft **12** or head **16**, thereby avoiding tearing of the tissue that might otherwise occur if shaft **12** was immobile. Additionally, shaft **12** can flex to allow head **18** to lie flush with the tissue after insertion in applications in which fastener **10** is not inserted perpendicularly to the tissue surface. Thus, fastener **10** is less obtrusive in vivo than rigid fasteners, and is less prone to damage either the tissue being fastened or surrounding tissue.

[0026] The woven nature of mesh **20** also makes shaft **12** radially compressible, allowing fastener **10** to be even less obtrusive when subject to compressive forces that may be encountered when fastener is used to attached soft tissue to other soft tissue. An example of such an application is the use of fastener **10** to repair meniscal tissue (i.e., cartilage) tears.

[0027] Mesh **20** further also provides structure and surface area for insert molding tip **14** and head **16**—which are preferably made from polymeric material—onto shaft **12**. Insert molding these features **14**, **16** allows the polymeric material to melt around the fibers of the mesh and mechanically lock features **14**, **16** to shaft **12** upon cooling. A bioabsorbable material such as PLA is preferred for tip **14** (as well as barbs **18**) and head **16**, because PLA has a uniform rate of absorbability. Features **14**, **16** are further integrated with woven mesh **20** by melting them into as well as around mesh **20**.

[0028] Tip **14** is generally cylindrical and has an outer surface **24** from which barbs **18** radially extend. Tip **14** terminates at a flat, annular distal surface **26** that defines an open end of a passage **28** which extends through tip **14** and communicates with the hollow interior **22** of shaft **12**. Passage **28** is sized to receive a K-wire to assist in guiding fastener **10** to the correct location in the tissue during emplacement (described below).

[0029] Barbs **18** are circumferentially spaced by 180 degrees around tip exterior surface **24** (although two barbs **18** are shown, it will be appreciated that more or fewer barbs **18** may be used, and that barbs **18** may be unevenly spaced around tip **14**). Each barb **18** has a flat, inclined exterior surface **30** that slopes outwardly as barb **18** extends proximally. Barb **18** terminates at a proximal surface **32** oriented generally perpendicularly to axis **20**. The junction of surfaces **30**, **32** defines a sharp edge **34** which lodges barb **18** within tissue during use, as will be explained.

[0030] Head **16** includes an annular body **36** having a flat, tissue-engaging underside **38** and a rounded upper surface **40**. A passage **42** extends through body **36**, is aligned with the hollow interior **13** of shaft **12** and tip passage **28**, and is

open at both ends for receiving the K-wire during insertion. A pair of diametrically opposed slots **44** extend through body **36** between underside **38** and upper surface **40** for purposes to be described.

[0031] Body **36** is relatively thin to provide fastener **10** with a low profile when the device in place in vivo. The outer diameter of body **36** is approximately the same as (or slightly larger than) the maximum radial dimension defined by barbs **18**. Body **36** has a substantially larger outer diameter than shaft **12**, thereby enabling head **16** to capture tissue beneath it in a tac-like fashion when fastener **10** is emplaced, as will be described. The corners of body **36** are rounded at underside **38** and upper surface **40** to avoid tissue damage when shaft **12** flexes from side to side in response to movement of the tissue being tacked down by head **16**.

[0032] Fastener **10** is manufactured by insert molding. More specifically, a length of woven mesh **20** is cut to a specific length for fastener **10** and is inserted over a core pin. The injection mold then closes on the core pin and polymeric material is then molded onto and around woven mesh **20**. Fastener **10** has an overall length of 0.100-0.500 inch (of which approximately 0.060-0.300 inch corresponds to the length of shaft **12** between tip **14** and head **16**) and a maximum width (defined by barbs **18** and the diameter of head **16**) of 0.040-0.300 inch.

[0033] Referring also to FIGS. 3-5, an insertion tool **50** for emplacing fastener **10** in tissue includes a hollow, elongated rod **52** with a handle **54** at its proximal end and a fastener mount **56** at its distal end. Rod **52**, handle **54**, and mount **56** are hollow to accommodate a K-wire **58** used to guide fastener **10** into place in the body. Rod **52** is sufficiently narrow to pass through a conventional cannula to the surgical site, and handle **54** is large enough to fit comfortably in the user's hand.

[0034] Mount **56** includes a pair of diametrically opposed arms **60** which extend from the distal end of rod **52**. The circumferential spacing between arms **60** corresponds to that between barbs **18** and slots **44** in head **16**. Arms **60** terminate at flat barb engaging surfaces **62**. Fastener **10** is loaded onto insertion tool **50** by aligning slots **44** in head **16** with arms **60**, and sliding fastener **10** proximally over arms **60** until surfaces **62** abut barb proximal surfaces **32**.

[0035] Referring to FIGS. 6A and 6B, in use, fastener **10** is used to repair torn meniscal tissue **70** (e.g., in the knee) as follows. As a first step in repairing tear **72**, the surgeon determines the proper insertion site (or sites) **74** at which fastener **10** (or a plurality of fasteners **10**) are to be emplaced. A relatively small tear **72** like that shown in FIGS. 6A and 6B may be repaired using only one fastener **10**; multiple fasteners **10** may be needed to close larger tears. Insertion site **74** is located on the proximal side **76** of tear **72** (but the distal side of the tear may be used instead as the insertion site).

[0036] The surgeon then introduces K-wire **58** to the surgical site through a cannula (not shown), and stabs the tip of K-wire **58** into meniscal tissue at insertion site **74**. The surgeon urges K-wire **58** distally until its tip spans tear **72** and becomes embedded in meniscal tissue **78** located distally of tear **72**. Next, the surgeon attaches fastener **10** to mount **56** of insertion tool **50**, as described above, slides the assembly over the proximal end of K-wire **58**, and feeds the assembly over K-wire **58** to the surgical site.



[0037] Then, the surgeon holds K-wire 58 securely in place with one hand, and pushes insertion tool 50 distally with the other. The engagement between arms 60 and barbs 18, as well as the engagement of the distal end of rod 52 against head upper surface 40, pushes fastener 10 over K-wire 58. Fastener 10 thus enters insertion site 76 and passes through proximal meniscal tissue 76 and across tear 72. The sloped nature of barb surfaces 30 allow barbs 18 to smoothly pass through the meniscal tissue in the distal direction of movement.

[0038] The surgeon continues distally advancing fastener 10 to slide tip 15 further over K-wire 58 and into meniscal tissue 78 distally of tear 72. As fastener 10 moves distally, underside 38 of head 16 engages meniscal tissue 76 on the proximal side of the tear. The enlarged diameter of head 16 relative to shaft keeps head 16 from passing through the puncture behind shaft 12. As a result, head 16 urges proximal tissue 76 toward distal meniscal tissue 78 and gradually closes tear 72 as fastener 10 is advanced distally.

[0039] When barbs 18 have fully entered distal meniscal tissue 78, the tissue attempts to close against shaft 12. Thus, perpendicular barb surfaces 32 (FIG. 1) and edges 34 securely engage the meniscal tissue, and firmly lodge tip 14 in place therein. Tear 72 is now closed (FIG. 6B), and the surgeon withdraws insertion tool 50 and K-wire 58. With the meniscal tissue 76, 78 on the two sides of the tear held together by fastener 10, healing can begin. Over time, meniscal tissue 76, 78 will grow together, thereby permanently closing tear 72. In embodiments in which the materials of fastener 10 are biodegradable, fastener 10 gradually dissolves.

[0040] FIGS. 7A and 7B show the use of fastener 10 to re-attach soft tissue 90 to bone 92 (e.g., during the repair of a torn rotator cuff). First, a hole 94 is formed in bone 92 at the desired attachment site, e.g., by drilling. K-wire 58 is introduced to the surgical site, punched through soft tissue 90 at the selected attachment location, and positioned in hole 94 to serve as a guide for fastener 10 and insertion tool 50. After fastener 10 is placed on insertion tool mount 56 as discussed above, the assembly is inserted over K-wire 58 and advanced to the surgical site. The surgeon holds K-wire 58 with one hand, and urges insertion tool 50 distally with the other, thereby punching fastener 10 through soft tissue 90 (FIG. 7A).

[0041] The surgeon continues to advance insertion tool 50 distally to insert fastener 10 into hole 94 (FIG. 7B). Barbs 18 lodge tip 14 securely within hole 94 by digging into the bone tissue (e.g., the cancellous bone) around hole 94. As fastener 10 moves into hole 94, underside 38 of fastener head 16 engages the upper surface of soft tissue 90, thereby urging the soft tissue toward and against the upper surface of bone 92. The enlarged nature of head 16 prevents fastener 10 from passing completely through soft tissue 90 and enabling fastener 10 to securely re-attach the tissue to the bone in a tack-like manner. When fastener 10 has been fully inserted into hole 94, the surgeon removes insertion tool 50 and K-wire 58.

[0042] Other embodiments are within the scope of the following claims.

[0043] For example, other materials may be used for mesh 20 and the generally rigid features (tip 14, head 16, and

barbs 18). One alternative material is polyglycolic acid (PGA), which is a bioabsorbable material that degrades more rapidly in the body than PLA. The tissue fastener may alternatively be made from non-bioabsorbable material.

[0044] Barbs 18 may be located elsewhere on fastener 10, for example on shaft 12. Barbs 18 may be blunt, rather than sharp. Tip 14 may be tapered or beveled distally; tip 14 may have a sharpened distal edge to further facilitate insertion.

[0045] Other insertion tools may be employed. For example, the insertion tool may be configured to engage the interior of tip 14 (e.g., a shoulder 29, FIG. 1, formed in the walls that define the passage through tip 14). Alternatively, tip 14 may be solid.

[0046] Other kinds of flexible shafts are contemplated. Shaft 12 may comprise a braided or knitted mesh or comprise a non-mesh or non-polymeric material. Shaft 12 may be solid rather than defining a passage 22.

[0047] Shaft 12 may be rendered flexible in other ways. For example, a generally rigid tissue fastener may be modified to render it flexible at one or more places.

[0048] FIG. 8 shows a fastener 100 that has been so modified. Fastener 100 is, e.g., a modified version of the Suretac™ fastener, manufactured by Smith & Nephew, Inc. and described in U.S. Pat. Nos. 5,100,417, 5,258,016, and 5,690,676, all of which are incorporated herein by reference. Fastener 100 includes a hollow shaft 102 that extends proximally from a distal end 104 to a radially enlarged head 106. An interior passage 107 extends through shaft 102 and is open at distal end 104 and head 106. Fastener 100 is formed by molding so that shaft 102 and head 106 define an integral, unitary body.

[0049] A plurality of (e.g., three) axially spaced, circumferential ribs 108 are disposed on shaft between end 104 and head 106. Ribs 108 have beveled leading (i.e., distal) surfaces to facilitate advancement of fastener through tissue, and flat side and proximal surfaces that lodge within the tissue.

[0050] Fastener 10 is made from polymeric material, such as the aforementioned PLA. During fabrication, flexible material 110 is embedded within the walls 112 of fastener 10, and shaft 102 is relieved to provide a breakable connection 114 between shaft 102 and head 106. Connection 114 is preferably frangible (i.e., easily breakable). This enables the rigid material of head 106 to break free from that of shaft 102 in response to side-loading imposed by the re-attached tissue, to reduce the risk of head 106 digging into or otherwise damaging the tissue. Flexible material 110 tethers head 106 to shaft 102, however, so that the tissue captured beneath head 106 remains securely attached to the tissue (e.g., bone tissue) into which shaft 102 has been inserted. In addition, flexible material 110 reinforces the walls of shaft 102.

[0051] Flexible material 110 may have a wide variety of configurations. For example, flexible material 110 may include individual strands of material (such as man-made or natural fibers or suture) or a flexible member such as a braided tube or braided mesh. Suitable materials include PLA, PGA, polyester, cat gut, polydioxanone, polypropylene, polyvinyl acetate, and natural materials such as wool, silk, and cotton.

[0052] Flexible material **110** is insert molded into shaft **102** and head **106** during the fabrication of fastener **10**. Flexible material **110** preferably extends along the entire length of shaft **102**, but alternatively may terminate proximally of end **104**. Flexible material **110** is disposed uniformly around the circumference of shaft **102** and head **106**, although flexible material **110** may alternatively be concentrated in, e.g., the segments of shaft **102** that are relieved. (Only one strand of flexible material **110** is shown on each side of shaft **102** for simplicity.)

[0053] Shaft **102** may be relieved in a variety of ways, only two of which—one or more rectangular holes **113** or one or more notches **113'**—are shown. Shaft **102** may be relieved in as few or as many places as are suitable to provide the frangible connection. Preferably, shaft **102** is relieved in two diametrically opposed locations, and the same type of relief (e.g., openings such as holes **113** or notches **113'**) is used in each location. If insufficient relief is provided, frangible connection **114** may not break during use to achieve the desired flexibility. In contrast, care should be taken not to excessively relieve shaft **102**, or frangible connection **114** may break during insertion of fastener **100** into tissue. As an alternative (or in addition) to openings **113**, **113'**, shaft **102** may be relieved by making walls **112** relatively thin in the region of connection **114**.

[0054] In use to, e.g., re-attach soft tissue to bone (the procedure shown in FIGS. 7A and 7B), fastener **110** is introduced to the surgical site over a K-wire, and an insertion tool (not shown) is advanced over the K-wire behind fastener **100**. The insertion tool has a sufficient outer diameter to engage the upper surface of head **106** around the opening of passage **107**. Thus, as the surgeon advances the insertion tool, he pushes shaft **102** through the soft tissue and into the bone hole. Ribs **108** engage against the sides of the bone hole to lodge fastener **100** in place, and head **106** captures the soft tissue against the upper surface of the bone.

[0055] Thereafter, when side loads are placed on the soft tissue (e.g., during movement by the patient), the side loads impose sufficient force to break frangible connections **114**, thereby separating the rigid material of head **106** from that of shaft **102**. Head **106** continues to press the soft tissue against the bone, however, due to the tethering provided by flexible material **100**. The flexible connection of head **106** to shaft **102** acts as a hinge that allows head **106** to move from side to side (i.e., horizontally with respect to shaft **102**) in response to further side loads. This avoids head **106** digging into, and perhaps damaging, the soft tissue.

[0056] Other embodiments of a tethered fastener are possible. For example, shaft **102** may be relieved after molding (such as by cutting holes **113** or notches **113'**).

[0057] Referring to FIG. 9, fastener **200** is similar to fastener **100**, except that teeth **202** protrude from the underside of the head for more secure tissue attachment. Flexible material **110** is insert molded within the walls of the shaft and head of fastener, and shaft is relieved with holes (**113**) or notches (**113'**) to provide the frangible connection.

[0058] Still other embodiments are within the scope of the claims.

What is claimed is:

1. A tissue fastener comprising
  - a shaft having a member disposed thereon for lodging the shaft within the tissue, and
  - a tissue engaging head disposed at a proximal end of the shaft,
    - a region of the shaft being relatively flexible to render the head movable with respect to the shaft.
2. The tissue fastener of claim 1 wherein the region comprises substantially an entire length of the shaft.
3. The tissue fastener of claim 2 wherein the region comprises flexible material.
4. The tissue fastener of claim 3 wherein the flexible material comprises a mesh.
5. The tissue fastener of claim 1 wherein the shaft comprises a mesh material, the member and the head being molded onto the mesh.
6. The tissue fastener of claim 1 wherein the member comprises at least one barb.
7. The tissue fastener of claim 1 wherein the shaft comprises generally rigid material and the region comprises a flexible joint between the shaft and the head.
8. The tissue fastener of claim 7 wherein the flexible joint comprises a frangible section of the shaft, and further comprising a flexible member extending between the shaft and the head past the frangible section.
9. The tissue fastener of claim 8 wherein the breakable section is defined by at least one opening disposed through a wall of the shaft.
10. The tissue fastener of claim 8 wherein the flexible member comprises a plurality of filaments.
11. The tissue fastener of claim 8 wherein the flexible member comprises a flexible tube.
12. The tissue fastener of claim 8 wherein the flexible member extends along substantially an entire length of the shaft.
13. The tissue fastener of claim 8 wherein the shaft and the head comprise an integral molded unit, the flexible member being molded therewithin.
14. The tissue fastener of claim 1 made from polymeric material.
15. The tissue fastener of claim 1 made from bioabsorbable material.
16. The tissue fastener of claim 1 wherein the shaft is hollow and defines an interior passage, the head including an opening in communication with the passage.
17. The tissue fastener of claim 16 wherein the passage is open at a distal end of the shaft.
18. The tissue fastener of claim 16 wherein the passage is closed at a distal end of the shaft.
19. The tissue fastener of claim 1 wherein the head has a flat distal surface.
20. The tissue fastener of claim 1 wherein the head has a toothed distal surface.
21. A tissue fastener comprising
  - a shaft,
  - a member disposed at a distal region of the shaft for lodging the shaft within the tissue, and
  - a tissue engaging head disposed at a proximal end of the shaft,

the shaft being relatively flexible between the member and the head to render the head movable with respect to the shaft.

**22.** The tissue fastener of claim 21 wherein the shaft comprises a mesh extending between the member and the head.

**23.** A tissue fastener comprising

a generally rigid shaft having a member disposed thereon for lodging the shaft within the tissue,

a tissue engaging head disposed at a proximal end of the shaft, and

a flexible joint between the shaft and the head to render the head movable with respect to the shaft.

**24.** The tissue fastener of claim 23 wherein the flexible joint comprises a breakable section of the shaft, and further comprising a flexible member extending between the shaft and the head past the breakable section.

**25.** The tissue fastener of claim 24 wherein the breakable section is frangible.

**26.** The tissue fastener of claim 23 wherein the flexible member comprises a plurality of filaments.

**27.** The tissue fastener of claim 23 wherein the flexible member comprises a flexible tube.

**28.** Apparatus comprising

a tissue fastener comprising a shaft having a member disposed thereon for lodging the shaft within the tissue, and a tissue engaging head disposed at a proximal end of the shaft, a region of the shaft being relatively flexible to render the head movable with respect to the shaft, and

an insertion tool engageable with the tissue fastener for inserting the tissue fastener into tissue.

**29.** The apparatus of claim 28 wherein

the member is disposed at a distal region of the shaft for lodging the shaft within the tissue, the tissue engaging head is disposed at a proximal end of the shaft, and the shaft is relatively flexible between the member and the head,

the insertion tool comprising an engagement portion for engaging the member.

**30.** The apparatus of claim 29 wherein the head includes an aperture, the engagement portion of the tool being configured to extend through the aperture when engaged with the member.

**31.** A method for tissue attachment comprising

providing a tissue fastener comprising a shaft having a member disposed thereon for lodging the shaft within the tissue, and a tissue engaging head disposed at a proximal end of the shaft, a region of the shaft being relatively flexible to render the head movable with respect to the shaft, and

inserting the tissue fastener through a first tissue and into a second tissue so that the member lodges within the second tissue and the head urges the first tissue against the second tissue.

**32.** The method of claim 31 wherein the first tissue and the second tissue are regions of a common tissue structure.

**33.** The method of claim 32 wherein the tissue structure is cartilage and, prior to the inserting, the first region is separated from the second region by a tear in the cartilage.

**34.** The method of claim 31 wherein the first tissue is soft tissue and the second tissue is bone.

**35.** A method for making a tissue fastener comprising

providing a shaft having a member disposed thereon for lodging the shaft within the tissue, and a tissue engaging head disposed at a proximal end of the shaft, and

making a region of the shaft relatively flexible to render the head movable with respect to the shaft.

**36.** The method of claim 35 further comprising making the region comprise substantially an entire length of the shaft.

**37.** The method of claim 36 further comprising making the region from flexible material.

**38.** The method of claim 37 wherein the flexible material comprises a mesh.

**39.** The method of claim 35 wherein the shaft comprises a mesh material, and further comprising molding the member and the head onto the mesh.

**40.** The method of claim 35 wherein the shaft comprises generally rigid material, the making comprising forming a flexible joint between the shaft and the head in the region.

**41.** The method of claim 40 wherein the forming comprises providing a breakable section of the shaft, and further comprising extending a flexible member between the shaft and the head past the breakable section.

**42.** The method of claim 41 further comprising forming the breakable section to be frangible.

**43.** The method of claim 42 further comprising defining the breakable section by at least one opening disposed through a wall of the shaft.

**44.** The method of claim 41 wherein the flexible member comprises a plurality of filaments.

**45.** The method of claim 41 wherein the flexible member comprises a flexible tube.

**46.** The method of claim 41 further comprising extending the flexible member along substantially an entire length of the shaft.

**47.** The method of claim 41 further comprising molding the shaft and the head as an integral unit, and molding the flexible member therewithin.

**48.** The method of claim 35 further comprising making the tissue fastener from polymeric material.

**49.** The method of claim 35 further comprising making the tissue fastener from bioabsorbable material.

**50.** The method of claim 35 further comprising providing the shaft with an interior passage, and forming an opening in the head in communication with the passage.

**51.** The method of claim 50 further comprising opening the passage at a distal end of the shaft.

**52.** The method of claim 50 further comprising closing the passage at a distal end of the shaft.

**53.** The method of claim 35 further comprising providing the head with a flat distal surface.

**54.** The method of claim 35 further comprising providing the head with a toothed distal surface.

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