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(54) Title: IMPLANT FOR ADHESION OF TISSUE LAYERS

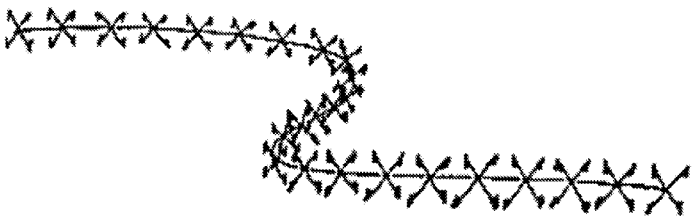

FIG. 1A

(57) Abstract: Surgical implants and methods are disclosed for promoting adhesion of tissue layers, where the implants comprise a longitudinal body, one or more clusters of projections extending from the body of the implant, and a hook on the end of the projection that is distal to the body of the implant, and where application of external pressure on the tissue at the site of the surgical implant causes the hooks on the ends of the projections to pierce the tissue layers and hold them together.

IMPLANT FOR ADHESION OF TISSUE LAYERS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/130,642, filed on March 10, 2015, the content of which is incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] Plastic surgery involves reconstruction and improvement of structure and function. The human body has a complex topography, and a plastic surgeon needs to have the technical ability to recreate it. The topography is commonly described by terms such as crests, folds, grooves, prominences, creases, indentations, etc. All of these are basically elevations or depressions of various shapes. A plastic surgeon has a lot of tools in his arsenal to create elevations. He can use fillers, implants, fat injections, etc. However, making depressions, especially precise linear grooves, is tedious and problematic. There is no good way to make grooves. For example, in making an infra-mammary crease after breast reconstruction, a surgeon faces difficulties trying to put in stitches to pull tissues together while at the same time trying to obtain exposure.

[0003] The present invention addresses the need for improved surgical implants and methods. In particular, the present invention provides a device that expands the surgeon's technical ability to create grooves and fill voids between tissues. As such, the surgical procedures become simpler, cheaper, more accurate, and more efficient.

SUMMARY OF THE INVENTION

[0004] The present invention provides surgical implants for promoting adhesion of tissue layers, where the implants comprise a longitudinal body, one or more clusters of projections extending from the body of the implant, and a hook on the end of the projection that is distal to the body of the implant.

[0005] The invention also provides methods of promoting adhesion of two tissue layers comprising placing the surgical implants between the two layers and applying external pressure on the tissue at the site of the surgical implant to cause the hooks on the ends of the projections to pierce the two tissue layers and hold them together.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Fig. 1A. Example of the surgical implant, showing the longitudinal body, plurality of clusters of projections extending in different directions from the body of the implant, and hooks at the ends of the projections distal from the body of the implant.

[0007] Fig. 1B. Detail of the surgical implant shown in Fig. 1 showing examples of longitudinal body (a), a projection (b), a hook (c), and a cluster of projections (brackets).

[0008] Fig. 2. Prophetic example of binding two tissue layers together using an example of the implant of the present invention. Top: A single cluster of projections is shown between two tissue layers (layer 1 and layer 2). Bottom: After application of external pressure (illustrated by downward pointing arrow), e.g., using a finger or surgical instrument, the hooks on the ends of the projections pierce the tissue and hold the two layers together.

[0009] Fig. 3. Prophetic example of using a finger to apply external pressure to cause the hooks on the ends of the projections to pierce two tissue layers and hold the layers together.

[0010] Fig. 4. Prophetic example of a linear adhesion created between two tissue layers using an implant of the present invention.

[0011] Fig. 5. Prophetic example of using an implant of the present invention to eliminate dead space between tissues. The top portion of the figure illustrates implants positioned in the dead space between tissue layers. The bottom portion of the figure illustrates the use of the implant to bind the tissue layers and eliminate dead space.

[0012] Fig. 6. Prophetic example of using an implant of the present invention to create topographical linear grooves during reconstructive surgery. The arrow points toward the groove.

[0013] Fig. 7. Prophetic example of using an implant of the present invention for inframmamary fold creation (indicated by arrow) during breast reconstruction.

[0014] Fig. 8. Prophetic example of using an implant of the present invention to create a supratarsal crease (indicated by arrow) during blepharoplasty.

[0015] Fig. 9. Prophetic example of using an implant of the present invention to create abdominal cube etchings during abdominal operations. The arrow points to one of the etchings.

[0016] Fig 10. Prophetic example of using an implant of the present invention for approximation of soft tissue repair, such as muscle repair, following an injury.

[0017] Fig. 11. Prophetic example of using an implant of the present invention for obliteration of dead space in soft tissue operations. The upper part of the figure illustrates a tumor mass in the tissue. The lower portion of the figure illustrates the use of the implant to eliminate dead space after tumor excision.

[0018] Fig. 12. Prophetic example of using an implant of the present invention to create naturally looking indentations during a facelift.

[0019] Fig. 13. Comparison of an example of the present invention with a barbed suture device. Right: The present surgical implant holds tissues together by forces perpendicular to the tissue layers. Left: The barbed suture holds tissue in place by forces parallel to the tissue layers. Forces indicated by arrows.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The present invention provides a surgical implant for promoting adhesion of tissue layers, the implant comprising

a longitudinal body,

one or more clusters of projections extending from the body of the implant, and

a hook on the end of the projection that is distal to the body of the implant.

[0021] The surgical implant can be made from or include one or more polymers, such as, for example, polymethylmethacrylate, polyethylene and/or polypropylene. The polymer or polymers can be biodegradable polymers such as, for example, polyglycolic acid and/or poly L lactic acid. The surgical implant can be made from or include one or more metals, such as, for example, vitallium and/or nitinol.

[0022] The body of the implant can be provided in different lengths, The body can be, for example, 1 cm to 100 cm in length. Preferred lengths include 10-50 cm and 40 cm. The lengths can be further cut to a desired size in a surgical setting depending upon the surgical requirments. The body can also be provided in different diameters. The body can be, for example, 0.1 mm to 5 mm in diameter. Preferred diameters include 0.5 to 1.5 mm and 1.0 mm. The ends of the body can be, e.g., sharp or dull. The body can be straight or forked with two or more branches.

[0023] The projections, which extend from the body of the implant, are grouped in clusters. The implant can be provided with different spacings between clusters. The distance between clusters can be, for example, 0.1 mm to 2 cm. Preferred distances between clusters include 3-5 mm and 4 mm. The projections can extend at different angles from the body of the implant. The angle between the projections and the body can be, for

example, from 30 degrees to 150 degrees. Preferred angles include 75 degrees to 105 degrees and 90 degrees (i.e., at a right angle to the body of the implant). The clusters can consist of a different number of projections. The number of projections in a cluster can vary, for example, from 2 to 12. Preferred clusters include 4-6 projections. The projections can be provided in different lengths. The projections along the body can be the same length or different lengths. The projections in a cluster can be the same length or different lengths. The length of individual projections can vary between, for example, 1 mm to 6 cm. Preferred lengths of the projections include 2-5 mm. The projections can be provided in different diameters. The diameter of the projections, can be, for example, 0.1 to 5 mm. Preferred diameters of the projections include 0.5 to 1.5 mm and 1 mm. The projections can be tapered along their length or constant in diameter. The projections can be straight or forked with two or more branches. The projections extend from the body of the implant in different directions. The projections can extend at different angles with respect to other projections. Projections can extend from the body, for example, at an angle of 10 degrees to 350 degrees with respect to other projections. Each projection begins at the body and ends as a hook, a barb, an arrowhead shape, or another shape suitable for attaching to tissue. The projections can include one or more additional hooks (or barbs, arrowhead shapes, or another shape suitable for attaching to tissue) along the length of the projection between the body and the hook at the end of the projection. Apart from the one or more hooks, the projections themselves are smooth.

[0024] Each hook (or barb, arrowhead shape, or another shape suitable for attaching to tissue) has a sharp end. It is made to pierce through tissue and catch on the tissue so as not pull out. Its anatomy is variable but the function is the same: to pierce and catch tissue. It can have a single projection that does this, or circular or multiple projections.

[0025] The invention also provides a method of promoting adhesion of two tissue layers comprising placing any of the surgical implants disclosed herein between the two layers and applying external pressure on the tissue at the site of the surgical implant to cause the hooks on the ends of the projections to pierce the two tissue layers and hold them together. The external pressure can be applied, for example, by using a finger or by a surgical instrument. Preferably, the force is applied perpendicular to the tissue layers.

[0026] The method has a number of advantageous uses including, but not limited to, eliminating dead space between tissues, creating a topographical linear groove in the tissue, inframmamary fold creation during breast reconstruction, creating a supratarsal crease

during blepharoplasty, creating abdominal cube etchings during abdominal operations, creating naturally looking indentations during a facelift, approximation of soft tissue repair following an injury, obliteration of dead space in a soft tissue operation, where the soft tissue can be, for example, muscle, and elimation of dead space following removal of a tumor mass.

[0027] This invention will be better understood from the Experimental Details, which follow. However, one skilled in the art will readily appreciate that the specifics discussed are merely illustrative of the invention as described more fully in the claims that follow thereafter.

EXPERIMENTAL DETAILS AND PROPHETIC EXAMPLES

[0028] The invention is a type of suture, absorbable or permanent, which is placed between layers of tissue during surgery, and is then fixed into place with external pressure. It has projections with multiple small hooks pointing in different directions (Fig. 1A and 1B). These hooks bind tissues. When fixed, it joins the two layers in a linear fashion. As such it can be used to eliminate dead space or to make topographical creases, such as the inframammary fold during breast reconstruction or a crisp and precise supratarsal crease during a blepharoplasty.

[0029] The surgical implant device is an alloplastic implant. It is comprises a longitudinal body with multiple hook projections that are capable of securing two layers from all sides (Fig. 2). Upon placement between soft tissue layers, external pressure can be applied, e.g., either with a finger or a surgical instrument to cause the hooks to pierce the tissues (partial thickness) and secure them in place (Fig. 3). The result is a linear adhesion created between the two layers (Fig. 4).

[0030] The surgical implant can be used to eliminate dead space (Fig. 5). It can also be used to create topographical linear grooves (Fig. 6). The arrow points to the creation of a natural appearing crease or groove. Additional advantageous features of the invention are elaborated below.

[0031] *Fix tissues at non-end points.* The body naturally fixes layers of tissues to each other with fibrous attachments. These attachments are physically disrupted during surgery leading to non-approximation of layers and thus dead space. Also, these fibrous attachments get attenuated and stretch during aging, causing diminishing and shifting topographical features. Sometimes, it is necessary to recreate these attachments. The present surgical implant is made specifically to re-form these attachments. It can be placed

and secured in place between tissue layers to fix the tissue layers tightly together at that point. If resorbable, with time it resorbs, leaving behind an attachment point/line.

[0032] *Provide accurate and consistent approximation of tissues.* Current techniques to recreate adhesion areas between layers are very tedious. Such is the case with infra-mammary fold creation during breast reconstruction. A surgeon works against oneself trying to approximate the layers by throwing stitches to close the layers and at the same time pulling the layers apart to provide exposure. The bites are uneven and often they create skin puckering or are not deep enough. There is great inconsistency. Instead, the present invention would allow a surgeon to mark out the area of infra-mammary crease, place the present surgical implant at the mark, and press on the top layer to recreate the fold. This method is faster, easier, and gives more consistent results.

[0033] *The surgical implant can be manufactured in different sizes to allow for various applications.* Just like sutures are manufactured in different sizes, the present surgical implant will have different sizes also. A surgeon would choose the size and length based on indication. The length could be further trimmed as needed.

[0034] *Additional prophetic applications.* Additional possible applications include, e.g., inframmamary fold creation during breast reconstruction (Fig. 7), supratarsal crease during blepharoplasty (Fig. 8), abdominal cube etching during abdominal operations (Fig. 9), approximation of soft tissue repair such as muscle during injuries (Fig. 10), obliteration of dead space in various soft tissue operations (Fig. 11), and creation of naturally looking indentations during a facelift (Fig. 12).

[0035] *Comparisons with other surgical devices.* Barbed sutures are made to be driven through tissues using needles at edges of the cut tissue. In contrast, the present surgical implant is placed between layers and is secured in place with pressure. The barbed suture devices cannot be placed in the middle of the tissue layers and as such are not useful in making grooves. The present surgical implant is made to be placed in the middle of layers and to make crisp depressions. The present surgical implant is not attached to needles and is not driven through tissue with needles but pierces the tissue with pressure. Furthermore, whereas barbed sutures hold tissue in place by parallel forces (on the suture), the present surgical implant holds tissue together by perpendicular forces (on the hooks) (Fig 13).

[0036] Other surgical devices have little hooks that fix tissues after the tissue is moved with vertical vector forces. It can be used to screw into bone. The present surgical implant has hooks on multiple sides; however, no screws are used or required. The present surgical

implant is made to provide perpendicular forces, not vertical (as illustrated in Fig. 13). The goal of present surgical implant is to fix tissue layers to tissue layers, not to fix layers at sliding tensions.

What is claimed is:

1. A surgical implant for promoting adhesion of tissue layers, the implant comprising
a longitudinal body,
one or more clusters of projections extending from the body of the implant, and
a hook on the end of the projection that is distal to the body of the implant.

2. The surgical implant of claim 1, wherein the implant comprises one or more polymers selected from the group consisting of polymethylmethacrylate, polyethylene and polypropylene.

3. The surgical implant of claim 1, wherein the implant is made of a biodegradable polymer.

4. The surgical implant of claim 1, wherein the implant is made of polyglycolic acid and/or poly L lactic acid.

5. The surgical implant of claim 1, wherein the implant is made from or includes vitallium and/or nitinol.

6. The surgical implant of any of claims 1-5, wherein the body of the implant is from 1 cm to 100 cm in length.

7. The surgical implant of any of claims 1-5, wherein the body of the implant is from 10 cm to 50 cm in length.

8. The surgical implant of any of claims 1-7, wherein the body of the implant is from 0.1 mm to 5 mm in diameter.

9. The surgical implant of any of claims 1-7, wherein the body of the implant is from 0.5 mm to 1.5 mm in diameter.

10. The surgical implant of any of claims 1-9, wherein the body of the implant is straight or forked with two or more branches.

11. The surgical implant of any of claims 1-10, wherein the clusters of projections are separated by a distance of 0.1 mm to 2 cm.

12. The surgical implant of any of claims 1-10, wherein the clusters of projections are separated by a distance of 3-5 mm.

13. The surgical implant of any of claims 1-12, wherein the projections extend from the body of the implant at an angle between 30 degrees and 150 degrees.

14. The surgical implant of any of claims 1-12, wherein the projections extend from the body of the implant at an angle between 75 degrees and 105 degrees.

15. The surgical implant of any of claims 1-14, wherein the clusters comprise 2 to 12 projections.

16. The surgical implant of any of claims 1-14, wherein the clusters comprise 4 to 6 projections.

17. The surgical implant of any of claims 1-14, wherein the projections are the same length or different lengths.

18. The surgical implant of any of claims 1-17, wherein the projections are 1 mm to 6 cm in length.

19. The surgical implant of any of claims 1-17, wherein the projections are 2-5 mm in length.

20. The surgical implant of any of claims 1-19, wherein the projections are 0.1 to 5 mm in diameter.

21. The surgical implant of any of claims 1-19, wherein the projections are 0.5 to 1.5 mm in diameter.

22. The surgical implant of any of claims 1-21, wherein the projections are tapered along their length or constant in diameter.

23. The surgical implant of any of claims 1-22, wherein the projections are straight or forked with two or more branches.

24. The surgical implant of any of claims 1-23, wherein the projections include one or more hooks along the length of the projection between the body of the implant and the hook at the end of the projection.

25. A method of promoting adhesion of two tissue layers comprising placing the surgical implant of any of claims 1-24 between the two layers and applying external pressure on the tissue at the site of the surgical implant to cause the hooks on the ends of the projections to pierce the two tissue layers and hold them together.

26. The method of claim 25, wherein the external pressure is applied by a finger or by a surgical instrument.

27. The method of claim 25 or 26, wherein the method is used to eliminate dead space between tissues.

28. The method of claim 25 or 26, wherein the method is used to create a topographical linear groove in the tissue.

29. The method of claim 25 or 26, wherein the method is used for inframmamary fold creation during breast reconstruction.

30. The method of claim 25, wherein the method is used to create a supratarsal crease during blepharoplasty.

31. The method of claim 25 or 26, wherein the method is used to create abdominal cube etchings during abdominal operations.

32. The method of claim 25 or 26, wherein the method is used for approximation of soft tissue repair following an injury.

33. The method of claim 25 or 26, wherein the method is used for obliteration of dead space in a soft tissue operation.

34. The method of claim 32 or 33, wherein the soft tissue is muscle.

35. The method of claim 25 or 26, wherein the method is used to eliminate dead space following removal of a tumor mass.

36. The method of claim 25 or 26, wherein the method is used to create naturally looking indentations during a facelift.

37 The method of any of claims 25-36, wherein external pressure is applied perpendicular to the tissue layers.

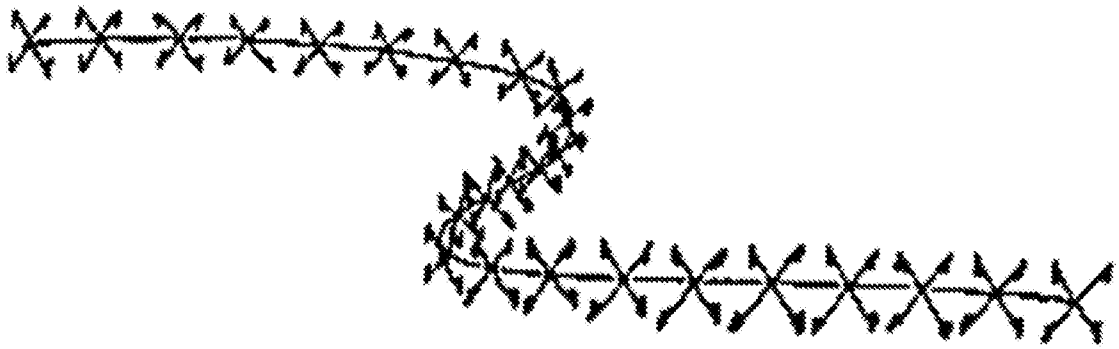

FIG. 1A

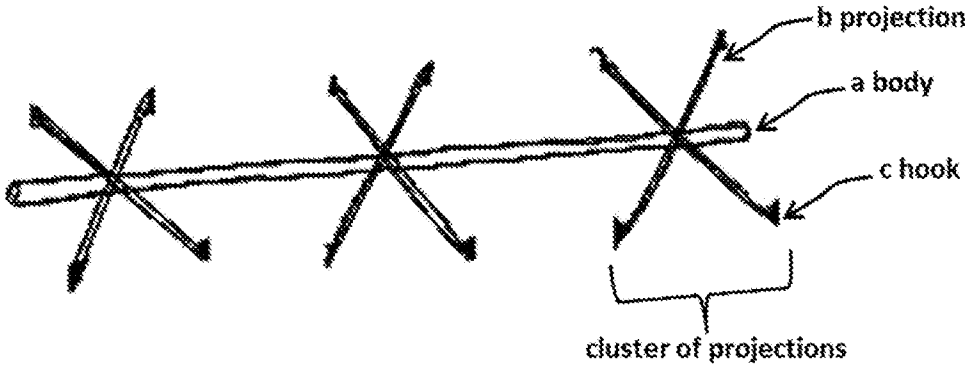

FIG. 1B

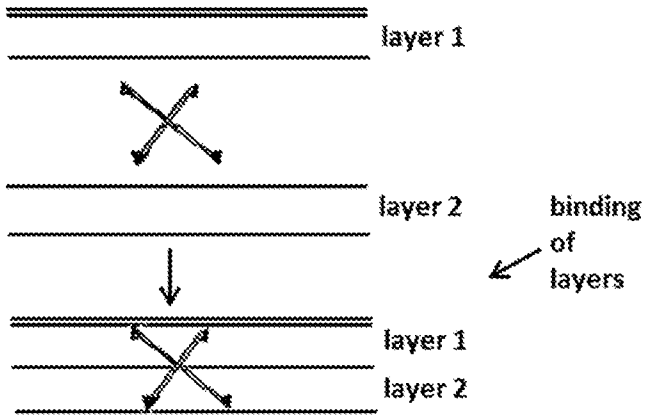
layer 1
layer 2
binding
of
layers
layer 1
layer 2

FIG. 2

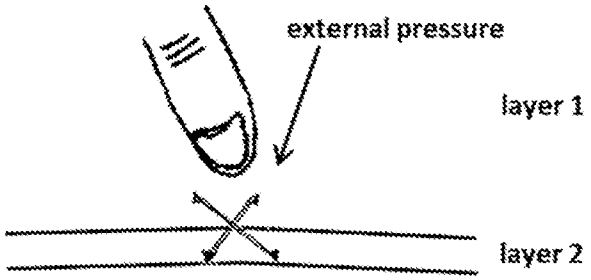
external pressure
layer 1
layer 2

FIG. 3

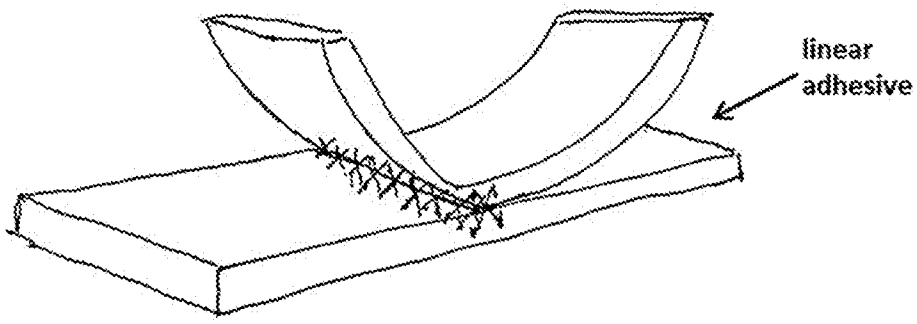

FIG. 4

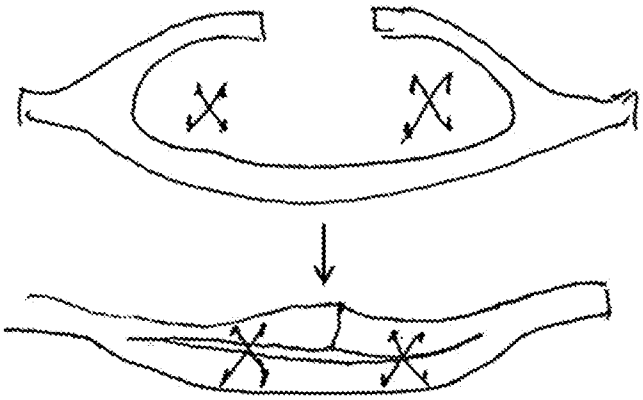

FIG. 5

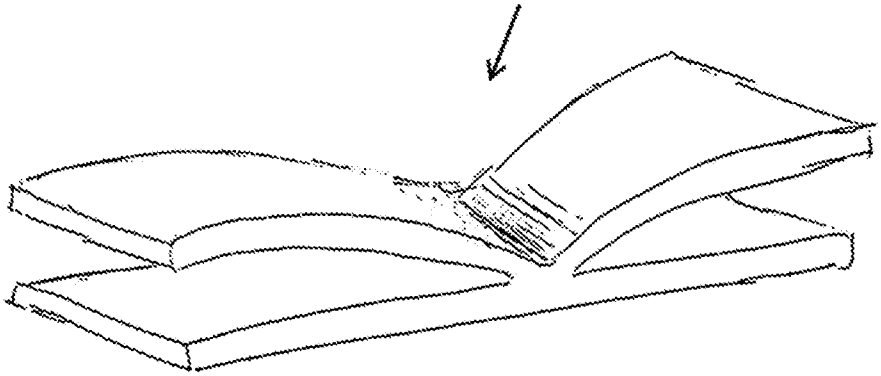

FIG. 6

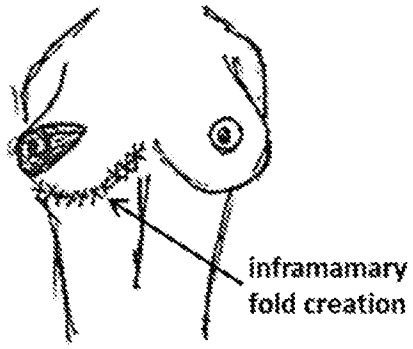

FIG. 7

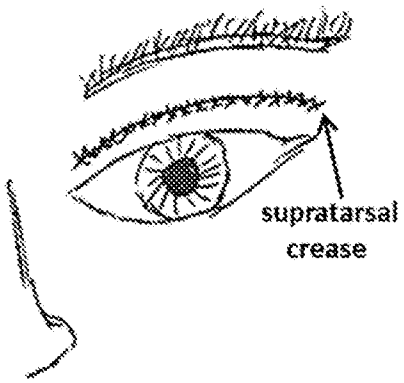

FIG. 8

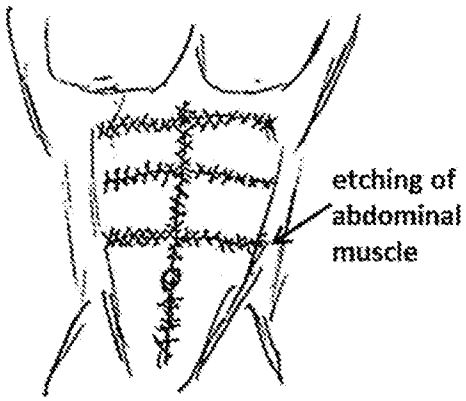

FIG. 9

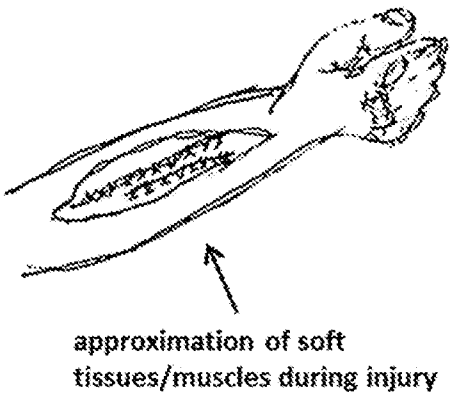

FIG. 10

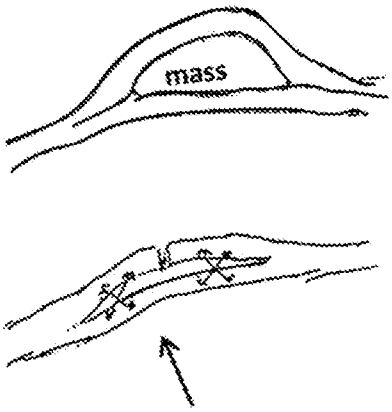

FIG. 11

FIG. 12

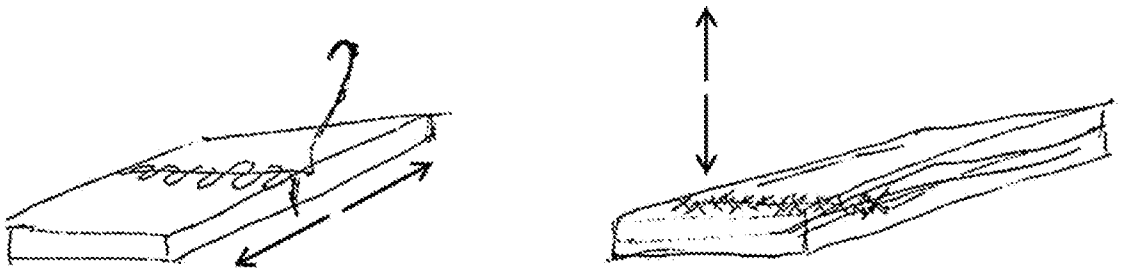

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/20152

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/04 (2016.01)
CPC - A61B 2017/06176
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
CPC - A61B 2017/06176; IPC(8) - A61B 17/04 (2016.01); USPC - 606/230

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 17/04, A61B 17/06166, A61B 2017/086, A61L 17/06, A61L 17/04, A61L 17/10, A61B 2017/0412; USPC - 606/228, 606/232, 606/231 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google (Web, Patents, Scholar) Search Terms Used: surgical implant adhesion tissue layers stiches suture projections arms cluster hooks barbs claws grip bind pierce polymers polymethylmethacrylate polyethylene polypropylene polyglycolic acid poly L lactic acid vitallium nitinol biodegradable bioabsorbable bioresorbable length cm centim

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2006/0135995 A1 (Ruff et al.), 22 June 2006 (22.06.2006), entire document, especially Fig. 1-9; para [0014], [0054]-[0060], [0105], [0119] and [0183]	1-4 and 6-7/(1-4) ---------- 5 and 6-7/(5)
Y	US 8,679,157 B2 (Stopek et al.), 25 March 2014 (25.03.2014), entire document, especially Fig. 1-2 and 5A-5B; col 4, ln 45-58; col 8, ln 40-42	5 and 6-7/(5)
A	US 4,259,959 A (Walker), 07 April 1981 (07.04.1981), entire document	1-7
A	US 2003/0153947 A1 (Kosek), 14 August 2003 (14.08.2003), entire document	1-7
A	US 2007/0224237 A1 (Hwang et al.), 27 September 2007 (27.09.2007), entire document	1-7
A	US 2011/0022086 A1 (D'Agostino et al.), 27 January 2011 (27.01.2011), entire document	1-7
A	US 2003/0149447 A1 (Morency et al.), 07 August 2003 (07.08.2003), entire document	1-7

☐ Further documents are listed in the continuation of Box C. ☐

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"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 April 2016	20 MAY 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/20152

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 8-37
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.