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ABSTRACT

A self-retaining suture having particular application for treating obstructive sleep apnea and use thereof. The suture includes rising an elongated suture body having a periphery and first and second tissue-penetrating ends each with a bi-curve needle, and a plurality of first retainers on a first segment and oriented to the first end, and a plurality of second retainers a second segment and oriented to the second end, and a retainer-free transition segment disposed between the pluralities of first and second retainers.

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FIG. 1A

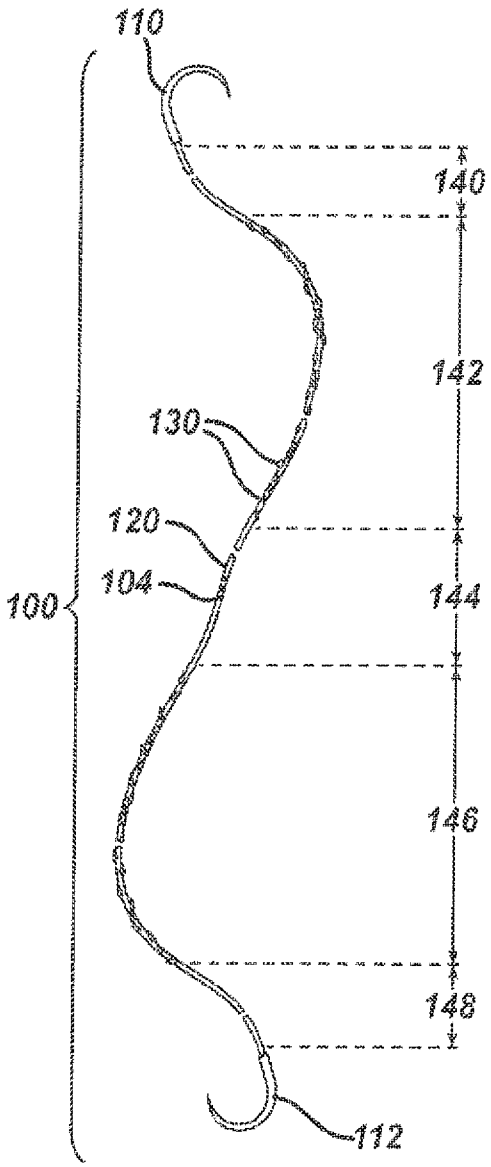
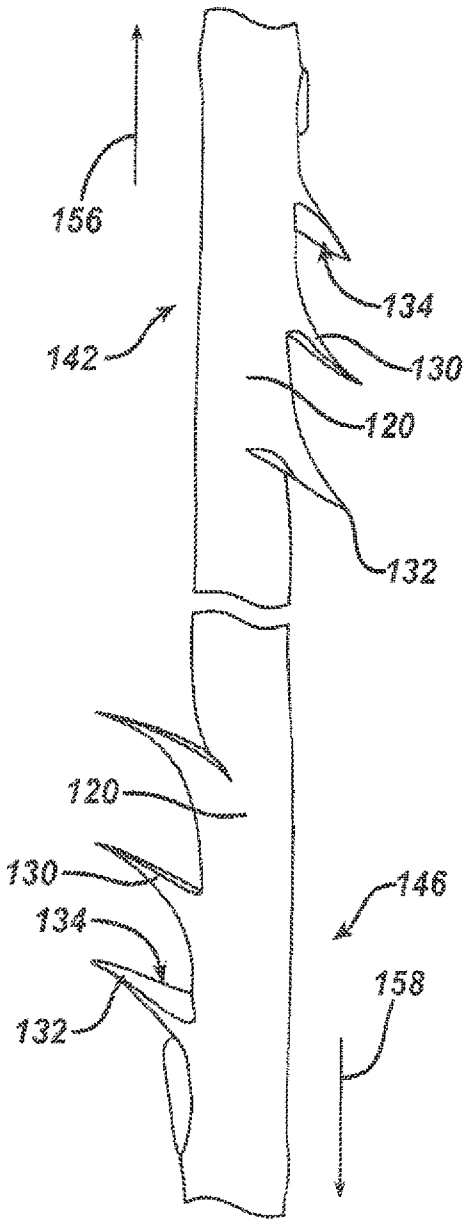


FIG. 1B



METHODS AND DEVICES FOR SOFT PALATE TISSUE ELEVATION PROCEDURES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Appln. Serial No. 61/493,941 filed on June 6, 2011 and US Non-Provisional Appln. Serial No. 13/488,527 filed on June 5, 2012.

FIELD OF THE INVENTION

[0002] The present invention relates generally to self-retaining sutures and methods for using self-retaining sutures in soft palate elevation procedures.

BACKGROUND OF THE INVENTION

[0003] Wound closure devices such as sutures, staples and tacks have been widely used in superficial and deep surgical procedures in humans and animals for closing wounds, repairing traumatic injuries or defects, joining tissues together (bringing severed tissues into approximation, closing an anatomical space, affixing single or multiple tissue layers together, creating an anastomosis between two hollow/luminal structures, adjoining tissues, attaching or reattaching tissues to their proper anatomical location), attaching foreign elements to tissues (affixing medical implants, devices, prostheses and other functional or supportive devices), and for repositioning tissues to new anatomical locations (repairs, tissue elevations, tissue grafting and related procedures) to name but a few examples.

[0004] Sutures are often used as wound closure devices. Sutures typically consist of a filamentous suture thread attached to a needle with a sharp point. Suture threads can be made from a wide variety of materials including bioabsorbable (i.e., that break down completely in the body over time), or non-absorbable (permanent; non-degradable) materials. Absorbable sutures have been found to be particularly useful in situations where suture removal might jeopardize the repair or where the natural healing process renders the support provided by the suture material unnecessary after wound healing has been completed; as in, for example, completing an uncomplicated skin closure. Non-degradable (non-absorbable) sutures are used in wounds where healing may be

expected to be protracted or where the suture material is needed to provide physical support to the wound for long periods of time; as in, for example, deep tissue repairs, high tension wounds, many orthopedic repairs and some types of surgical anastomosis. Also, a wide variety of surgical needles are available; the shape and size of the needle body and the configuration of the needle tip is typically selected based upon the needs of the particular application.

[0005] To use an ordinary suture, a suture needle is advanced through the desired tissue on one side of the wound and then through the adjacent side of the wound. The suture is then formed into a "loop" which is completed by tying a knot in the suture to hold the wound closed. Knot tying takes time and causes a range of complications, including, but not limited to (i) spitting, a condition where the suture, usually a knot, pushes through the skin after a subcutaneous closure), (ii) infection (bacteria are often able to attach and grow in the spaces created by a knot), (iii) bulk/mass (a significant amount of suture material left in a wound is the portion that comprises the knot), (iv) slippage (knots can slip or come untied), and (v) irritation (knots serve as a bulk "foreign body" in a wound). Suture loops associated with knot tying may lead to ischemia (knots can create tension points that can strangulate tissue and limit blood flow to the region) and increased risk of dehiscence or rupture at the surgical wound. Knot tying is also labor intensive and can comprise a significant percentage of the time spent closing a surgical wound. Additional operative procedure time is not only bad for the patient (complication rates rise with time spent under anesthesia), but it also adds to the overall cost of the operation (many surgical procedures are estimated to cost between $15 and $30 per minute of operating time).

[0006] Self-retaining sutures (including barbed sutures) differ from conventional sutures in that self-retaining sutures possess numerous tissue retainers (such as barbs) which anchor the self-retaining suture into the tissue following deployment and resist movement of the suture in a direction opposite to that in which the retainers face, thereby eliminating the need to tie knots to affix adjacent tissues together (a "knotless" closure). Knotless tissue-approximating devices having barbs have been previously described in, for example, U.S. Pat. No. 5,374,268, disclosing armed anchors having barb-like projections, while suture assemblies having barbed lateral members have been described in U.S. Pat. Nos. 5,584,859 and 6,264,675. Sutures having a plurality of barbs positioned along a greater portion of the suture are described in U.S. Pat No.

5,931,855, which discloses a unidirectional barbed suture, and U.S. Pat. No. 6,241,747, which discloses a bidirectional barbed suture. Methods and apparatus for forming barbs on sutures have been described in, for example, U.S. Pat. No. 6,848,152. Self-retaining systems for wound closure also result in better approximation of the wound edges, evenly distribute the tension along the length of the wound (reducing areas of tension that can break or lead to ischemia), decrease the bulk of suture material remaining in the wound (by eliminating knots) and reduce spitting (the extrusion of suture materia1-typically knots – through the surface of the skin). Various patterns and densities of retainer dispositions on sutures, and methods for making same, have been described, for example, in PCT/US2011/034660. All of these features are thought to reduce scarring, improve cosmesis, and increase wound strength relative to wound closures using plain sutures or staples. Thus, self-retaining sutures, because such sutures avoid knot tying, allow patients to experience an improved clinical outcome, and also save time and costs associated with extended surgeries and follow-up treatments. It is noted that all patents, patent applications and patent publications identified throughout are incorporated herein by reference in their entirety.

[0007] The ability of self-retaining sutures to anchor and hold tissues in place even in the absence of tension applied to the suture by a knot is a feature that also provides superiority over plain sutures. When closing a wound that is under tension, this advantage manifests itself in several ways: (i) self-retaining sutures have a multiplicity of retainers which can dissipate tension along the entire length of the suture (providing hundreds of "anchor" points that produce a superior cosmetic result and lessens the chance that the suture will "slip" or pull through) as opposed to knotted interrupted sutures which concentrate the tension at discrete points; (ii) complicated wound geometries can be closed (circles, arcs, jagged edges) in a uniform manner with more precision and accuracy than can be achieved with interrupted sutures; (iii) self-retaining sutures eliminate the need for a "third hand" which is often required for maintaining tension across the wound during traditional suturing and knot tying (to prevent "slippage" when tension is momentarily released during tying); (iv) self-retaining sutures are superior in procedures where knot tying is technically difficult, such as in deep wounds or laparoscopic/endoscopic procedures; and (v) self-retaining sutures can be used to approximate and hold the wound prior to definitive closure. As a result, self-retaining sutures provide easier handling in anatomically tight or deep places (such as

the pelvis, abdomen and thorax) and make it easier to approximate tissues in laparoscopic/endoscopic and minimally invasive procedures; all without having to secure the closure via a knot. Greater accuracy allows self-retaining sutures to be used for more complex closures (such as those with diameter mismatches, larger defects or purse string suturing) than can be accomplished with plain sutures.

[0008] A self-retaining suture may be unidirectional, having one or more retainers oriented in one direction along the length of the suture thread; or bidirectional, typically

having one or more retainers oriented in one direction along a portion of the thread, followed by one or more retainers oriented in another (often opposite) direction over a different portion of the thread (as described with barbed retainers in U.S. Pat. Nos. 5,931,855 and 6,241,747). Although any number of sequential or intermittent configurations of retainers are possible, a common form of bidirectional self-retaining suture involves a needle at one end of a suture thread which has barbs having tips projecting "away" from the needle until the transition point (often the midpoint) of the suture is reached; at the transition point the configuration of barbs reverses itself about 180° (such that the barbs are now facing in the opposite direction) along the remaining length of the suture thread before attaching to a second needle at the opposite end (with the result that the barbs on this portion of the suture also have tips projecting "away" from the nearest needle). Projecting "away" from the needle means that the tip of the barb is further away from the needle and the portion of suture comprising the barb may be pulled more easily through tissue in the direction of the needle than in the opposite direction. Put another way, the barbs on both "halves" of a typical bidirectional self-retaining suture have tips that point towards the middle, with a transition segment (lacking barbs) interspersed between them, and with a needle attached to either end.

[0009] Various devices and treatments have been developed for soft palate tissues to alleviate conditions such as sleep apnea and snoring, which can be caused by the relaxation and collapse of the soft palate into the airway. These include wearing of devices such as face masks providing continuous positive airway pressure and mandibular advancement devices; however, such treatments necessarily rely on ongoing

patient compliance to be effective. More permanent treatments include surgical

uvuloplasty and laser-assisted uvuloplasty, in which the volume of the uvula is irreversibly reduced by removal of uvular tissue. Reduction of uvula volume can result in adverse effects such as occlusion of the airway by the base of the tongue and restriction of the velopharynx and oropharynx due to postoperative scarring, both of which can contribute to an increase in sleep apnea. Other surgical treatments involve stiffening the soft palate to prevent the collapse of the soft palate into the airway by the introduction of implants or sclerosants into the soft palate. The former include the PILLAR™ Palatal Implant System (Restore Medical Inc., St. Paul, MN), and can have adverse effects such as extrusion of the implant and associated effects (including infection, further surgical procedures for removal of the implant, etc.). Introduction of sclerosants include procedures such as injection snoreplasty, in which the injection of a sclerosant is intended to result in scarring of the soft palate. These procedures can result

in ongoing patient discomfort (including sore throat, a perception of something being stuck in the throat), and in any event are not recommended for patients having obstructive sleep apnea.

[0010] To avoid these effects, procedures focussing on the height of the soft palate have also been developed. For example, in a procedure known as SNORELIFT™ developed by Dr. Bülent Ugurlu of the Hamburg Military Hospital, two unidirectional self-retaining sutures are deployed into the soft palate from opposing sides of the palate midline in a substantially mirror-image configuration. In this procedure, the first unidirectional suture is inserted into the soft palate on one side of the palate midline and

is pushed posteriorly through the palate and out at a first exit point. The first suture is then reinserted into the soft palate at a second insertion point posterior to the first exit point, potentially leaving a segment of the self-retaining suture in the oral cavity, and then pushed through the soft palate tissue diagonally across the midline to a second exit point. The process is repeated with a second unidirectional suture inserted into the soft palate at the other side of the midline, creating a criss-cross pattern. Drawing each suture out of its second exit point and tensioning the suture results in the elevation of the soft palate, particularly in the region where the suture is exposed in the oral cavity. As this procedure is performed with two unidirectional sutures, there is some risk of suture extrusion unless the trailing ends of each suture are somehow anchored (by, for

example, knot-tying), and such anchoring can itself provide a nidus for infection, etc, while any exposed suture remaining in the oral cavity can create issues with healing and infection. Moreover, the procedure can cause bunching of soft palate tissue.

SUMMARY OF THE INVENTION

[0011] It is desirable to provide bidirectional self-retaining sutures having configurations particularly suited to soft palate elevation procedures. Thus, it is desirable to provide improved self-retaining sutures having enhanced clinical performance in soft palate elevation.

[0012] It is also desirable to provide improved surgical methods of alleviating conditions of snoring and sleep apnea. Thus, it is desirable to provide surgical methods providing improved clinical outcomes in soft palate elevation procedures.

[0013] In one embodiment, the present invention provides a method of approximating soft palate tissue using a bidirectional self-retaining suture having first and second tissue-penetrating ends, first and second pluralities of tissue retainers oriented towards the first and second ends, respectively, and separated by a retainer-free transition segment. The method includes inserting the first end of a suture into the soft palate at an insertion point to one side of the palate midline and between the junction of the hard and soft palates and the posterior end of the soft palate, deploying the first end through the soft palate across the palate midline to a first exit point to the other side of the palate midline and between the junction of the hard and soft palates and the posterior end of the soft palate, urging the first end out of the soft palate at the first exit point and drawing the suture through the soft palate until the second plurality of tissue retainers engage the tissue, re-inserting the first end into the first exit point and deploying the first end through the soft palate posteriorly and away from the palate midline to a second exit point, urging the first end out of the soft palate at the second exit point and drawing the suture out through the second exit point, inserting the second end into the insertion point and deploying the second end through the soft palate posteriorly and away from the palate midline to a third exit point, and urging the second end out of the soft palate at the third exit point and drawing the suture out through the third exit point.

[0014] The method may further include trimming the suture flush with the second and third exit points.

[0015] In yet another embodiment, the method further includes drawing the suture anteriorly and cranially in the last urging step to increase elevation of the soft palate.

[0016] The drawing of the suture may result in a volumetric increase in the airway of a patient.

[0017] In yet another embodiment, the first and second tissue penetrating ends of the suture further include first and second bi-curve needles attached to first and second ends of the suture respectively. The bi-curve needles may have a length of approximately 28-32 mm.

[0018] Also provided is a surgical kit for soft palate elevation procedures having a suture assembly including an elongated suture body having a periphery and first and second tissue-penetrating ends, each of which are provided with a needle having a curvature, a plurality of first retainers disposed on a first segment of the elongated body and oriented to the first end, the first plurality of retainers yielding toward the suture body during movement of the suture through tissue in a direction of deployment of the first end, and resisting movement of the suture, when in tissue, in a direction substantially opposite to the direction of deployment of the first end, a plurality of second retainers disposed on a second segment of the elongated body and oriented to the second end, the plurality of second retainers yielding toward the suture body during movement of the suture through tissue in a direction of deployment of the second end, and resisting movement, when in tissue, in a direction substantially opposite the direction of deployment of the second end, and a retainer-free transition segment disposed between the pluralities of first and second retainers, the transition segment having a length of up to 10 mm. The kit further includes a needle driver, forceps, scissors, and a tongue depressor.

[0019] The suture assembly may be made of a bio-absorbable material, or a non-absorbable material.

[0020] According to one embodiment, the length of the transition segment is between 0.5 and 5 mm.

[0021] According to yet another embodiment, the first and second segments have a length less than 70 mm.

[0022] In yet another embodiment, the first and second retainers are arranged in a helical pattern, which may optionally be a double helix or a quadra-helix. The retainer density of the helical pattern may further be at least 250 per centimeter.

[0023] The present invention also provides a self-retaining suture including an elongated suture body having a periphery and first and second tissue-penetrating ends, each of the first and second ends being provided with a bi-curve needle, a plurality of first retainers disposed on a first segment of the elongated body and oriented to the first end, the first plurality of retainers yielding toward the suture body during movement of the suture through tissue in a direction of deployment of the first end, and resisting movement of the suture, when in tissue, in a direction substantially opposite to the direction of deployment of the first end, a plurality of second retainers disposed on a second segment of the elongated body and oriented to the second end, the plurality of second retainers yielding toward the suture body during movement of the suture through tissue in a direction of deployment of the second end, and resisting movement, when in tissue, in a direction substantially opposite the direction of deployment of the second end, and a retainer-free transition segment disposed between the pluralities of first and second retainers.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Features of the invention, and the nature and various advantages thereof will be apparent from the accompanying drawings and the following detailed description of various embodiments of the invention.

[0025] FIGS. 1A and 1B are views of a self-retaining suture in accordance with an embodiment of the present invention.

[0026] FIG. 2A is a perspective view of a self-retaining suture having retainers distributed in a single helix pattern according to an embodiment of the invention.

[0027] FIG. 2B is a perspective view of a self-retaining suture having retainers distributed in a double helix pattern according to an embodiment of the invention.

[0028] FIG. 2C is a perspective view of a self-retaining suture having retainers distributed in a quadra-helix pattern according to an embodiment of the invention.

[0029] FIGS. 3A and 3B are views of a method of soft palate elevation in accordance with an embodiment of the invention.

[0030] FIG. 4 is a view of a surgical kit for use in soft palate elevation procedures in accordance with an embodiment of the present invention.

[0031] FIGS. 5A and 5B illustrate an exemplary bi-curve needle according to an embodiment of the invention.

DETAILED DESCRIPTION

Definitions

[0032] Definitions of certain terms that may be used hereinafter include the following.

[0033] "Self-retaining suture" refers to a surgical suture that includes features on the suture thread for engaging tissue without the need for a knot or suture anchor. A "self-retaining suture" may also include devices for deploying the suture into tissue. Such deployment devices include, without limitation, suture needles and other deployment devices as well as sufficiently rigid and sharp ends on the suture itself to penetrate tissue.

[0034] "Tissue retainer" (or simply "retainer") refers to a physical feature of a suture thread which is adapted to mechanically engage tissue and resist movement of the suture in at least one axial direction. By way of example only, tissue retainer or retainers can include hooks, projections, barbs, darts, extensions, bulges, anchors, protuberances, spurs, bumps, points, cogs, tissue engagers, traction devices, surface roughness, surface irregularities, surface defects, edges, facets and the like. In certain configurations, tissue retainers are adapted to engage tissue to resist movement of the suture in a direction other than the direction in which the suture is deployed into the tissue by the surgeon, by being oriented to substantially face the deployment direction. In some embodiments the retainers lie flat when pulled in the deployment direction and open or "fan out" when pulled in a direction contrary to the deployment direction. As the tissue-penetrating end of each retainer faces away from the deployment direction when moving through tissue during deployment, the tissue retainers should not catch or grab tissue during this phase. Once the self-retaining suture has been deployed, a force exerted in another direction (often substantially opposite to the deployment direction) causes the retainers to be displaced from the deployment position (i.e. resting substantially along the suture body), forces the retainer ends to open (or "fan out") from the suture body in a manner that catches and penetrates into the surrounding tissue, and results in tissue being caught between the retainer and the suture body; thereby

"anchoring" or affixing the self-retaining suture in place. In certain other embodiments, the tissue retainers may be configured to permit motion of the suture in one direction and resist movement of the suture in another direction without fanning out or deploying. In each of the sutures and retainers of the present invention, in one optional embodiment, the retainers may be characterized as a plurality of barbs extending from the periphery of the body and tapering from a broad base to a narrow tip. In addition, or also optionally, the retainers may be characterized as a plurality of barbs that yield toward the suture body during movement of the suture through the tissue in the desired direction of movement of the suture through the tissue, and the barbs resist movement of the suture through the tissue in a direction opposite the desired direction of movement of the suture. Typically, a needle will be located at an end of the suture, and the barbs will yield toward the suture body as the suture is pulled through tissue in the direction that the needle is moving. In certain other configurations, the tissue retainer may be configured or combined with other tissue retainers to resist motion of the suture in either direction. Typically, a suture having such retainers is deployed through a device such as a cannula which prevents contact between the retainers and the tissue until the suture is in the desired location.

[0035] "Retainer configurations" refers to configurations of tissue retainers and can include features such as size, shape, flexibility, surface characteristics, and so forth. These are sometimes also referred to as "barb configurations".

[0036] "Retainer distribution" and "retainer pattern" refers to the arrangement of retainers along and around a suture thread and can include features such as density and orientation.

[0037] "Bidirectional suture" refers to a self-retaining suture having retainers oriented in one direction at one end and retainers oriented in the other direction at the other end. A bidirectional suture is typically armed with a needle at each end of the suture thread. A bidirectional suture may have a transition segment.

[0038] "Transition segment" refers to a retainer-free (barb-free) portion of a bidirectional suture located between a first set of retainers (barbs) oriented in one direction and a second set of retainers (barbs) oriented in another direction. The transition segment can be at about the midpoint of the self-retaining suture, or closer to one end of the self-retaining suture to form an asymmetrical self-retaining suture.

[0039] "Suture thread" refers to the filamentary body component of a suture or sutures.

The suture thread may be a monofilament, or contain multiple filaments as in a braided suture. The suture thread may be made of any suitable biocompatible material, and may be further treated with any suitable biocompatible material, whether to enhance the sutures' strength, resilience, longevity, or other qualities, or to equip the sutures to fulfill additional functions besides joining tissues together, repositioning tissues, or attaching foreign elements to tissues.

[0040] "Monofilament suture" refers to a suture comprising a monofilamentary suture thread.

[0041] "Braided suture" refers to a suture comprising a multifilamentary suture thread. The filaments in such suture threads are typically braided, twisted, or woven together.

[0042] "Degradable suture" (also referred to as "biodegradable suture" or "absorbable suture" or "bio-absorbable suture") refers to a suture which, after introduction into a tissue is broken down and absorbed by the body. Typically, the degradation process is at least partially mediated by, or performed in, a biological system. "Degradation" refers to a chain scission process by which a polymer chain is cleaved into oligomers and monomers. Chain scission may occur through various mechanisms, including, for example, by chemical reaction (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination of these) or by a thermal or photolytic process. Degradable suture material may include polymers such as polyglycolic acid, copolymers of glycolide and lactide, copolymers of trimethylene carbonate and glycolide with diethylene glycol (e.g., MAXON™, Tyco Healthcare Group), terpolymer composed of glycolide, trimethylene carbonate, and dioxanone (e.g., BIOSYN™ [glycolide (60%), trimethylene carbonate (26%), and dioxanone (14%)], Tyco Healthcare Group), copolymers of glycolide, caprolactone, trimethylene carbonate, and lactide (e.g., CAPROSYN™, Tyco Healthcare Group). A dissolvable suture can also include partially deacetylated polyvinyl alcohol. Polymers suitable for use in degradable sutures can be linear polymers, branched polymers or multi-axial polymers. Examples of multiaxial polymers used in sutures are described in U.S. Patent Application Publication Nos. 2002/0161168, 2004/0024169, and 2004/0116620. Sutures made from degradable suture material lose tensile strength as the material degrades. Degradable sutures can be in either a braided multifilament form or a monofilament form.

[0043] "Non-degradable suture" (also referred to as "non-absorbable suture") refers to a suture comprising material that is not degraded by chain scission such as chemical reaction processes (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination of these) or by a thermal or photolytic process. Non-degradable suture material includes polyamide (also known as nylon, such as nylon 6 and nylon 6.6), polyester (e.g., polyethylene terephthlate), polytetrafluoroethylene (e.g., expanded polytetrafluoroethylene), polyether-ester such as polybutester (block copolymer of butylene terephthalate and polytetra methylene ether glycol), polyurethane, metal alloys,
metal (e.g., stainless steel wire), polypropylene, polyethelene, silk, and cotton. Sutures made of non-degradable suture material are suitable for applications in which the suture is meant to remain permanently or is meant to be physically removed from the body.

[0044] "Suture diameter" refers to the diameter of the body of the suture. It is to be understood that a variety of suture lengths may be used with the sutures described herein and that while the term "diameter" is often associated with a circular periphery, it is to be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape. Suture sizing is based upon diameter. United States Pharmacopeia ("USP") designation of suture size runs from 0 to 7 in the larger range and 1-0 to 11-0 in the smaller range; in the smaller range, the higher the value preceding the hyphenated zero, the smaller the suture diameter. The actual diameter of a suture will depend on the suture material, so that, by way of example, a suture of size 5-0 and made of collagen will have a diameter of 0.15 mm, while sutures having the same USP size designation but made of a synthetic absorbable material or a non-absorbable material will each have a diameter of 0.1 mm. The selection of suture size for a particular purpose depends upon factors such as the nature of the tissue to be sutured and the importance of cosmetic concerns; while smaller sutures may be more easily manipulated through tight surgical sites and are associated with less scarring, the tensile strength of a suture manufactured from a given material tends to decrease with decreasing size. It is to be understood that the sutures and methods of manufacturing sutures disclosed herein are suited to a variety of diameters, including without limitation 7, 6, 5, 4, 3, 2, 1, 0, 1-0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0, 9-0,
10-0, 11-0 and 12-0.

[0045] "Suture deployment end" refers to an end of the suture to be deployed into

tissue; one or both ends of the suture may be suture deployment ends. The suture deployment end may be attached to a deployment device such as a suture needle, or may be sufficiently sharp and rigid to penetrate tissue on its own.

[0046] "Needle attachment" refers to the attachment of a needle to a suture requiring same for deployment into tissue, and can include methods such as crimping, swaging, using adhesives, and so forth. The suture thread is attached to the suture needle using methods such as crimping, swaging and adhesives. Attachment of sutures and surgical needles is described in U.S. Patent Nos. 3,981,307, 5,084,063, 5,102,418, 5,123,911, 5,500,991, 5,722,991, 6,012,216, and 6,163,948, and U.S. Patent Application Publication No. US 2004/0088003) all of which are incorporated herein by reference. The point of attachment of the suture to the needle is known as the swage. "Armed suture" refers to a suture having a suture needle on at least one suture deployment end.

[0047] "Suture needle" refers to needles used to deploy sutures into tissue, which come in many different shapes, forms and compositions. There are two main types of needles, traumatic needles and atraumatic needles. Traumatic needles have channels or drilled ends (that is, holes or eyes) and are supplied separate from the suture thread and are threaded on site. Atraumatic needles are eyeless and are attached to the suture at the factory by swaging or other methods whereby the suture material is inserted into a channel at the blunt end of the needle which is then deformed to a final shape to hold the suture and needle together. As such, atraumatic needles do not require extra time on site for threading and the suture end at the needle attachment site is generally smaller than the needle body. In the traumatic needle the thread comes out of the needle's hole on both sides and often the suture rips the tissues to a certain extent as it passes through. Most modern sutures are swaged atraumatic needles. Atraumatic needles may be permanently swaged to the suture or may be designed to come off the suture with a sharp straight tug. These "pop-offs" are commonly used for interrupted sutures, where each suture is only passed once and then tied. For barbed sutures that are uninterrupted, these atraumatic needles are preferred.

[0048] Suture needles may also be classified according to the geometry of the tip or point of the needle. For example, needles may be (i) "tapered" whereby the needle body is round and tapers smoothly to a point; (ii) "cutting" whereby the needle body is triangular and has sharpened cutting edge on the inside; (iii) "reverse cutting" whereby the cutting edge is on the outside; (iv) "trocar point" or "taper cut" whereby the needle

body is round and tapered, but ends in a small triangular cutting point; (v) "blunt" points for sewing friable tissues; (vi) "side cutting" or "spatula points" whereby the needle is flat on top and bottom with a cutting edge along the front to one side (these are typically used for eye surgery).

[0049] Suture needles may also be of several shapes including, (i) straight, (ii) half curved or ski, (iii) 1/4 circle, (iv) 3/8 circle, (v) 1/2 circle, (vi) 5/8 circle, (v) bi-curve, and (vi) compound curve. The sutures described herein may be deployed with a variety of needle types (including without limitation curved, straight, long, short, micro, and so forth), needle cutting surfaces (including without limitation, cutting, tapered, and so forth), and needle attachment techniques (including without limitation, drilled end, crimped, and so forth). Moreover, the sutures described herein may themselves include sufficiently rigid and sharp ends so as to dispense with the requirement for deployment needles altogether. Suturing needles are described, for example, in U.S. Patent Nos. 6,322,581; 6,214,030; 5,464,422; 5,941,899; 5,425,746; 5,306,288; 5,156,615; 5,312,422; 7,063,716; 6,129,741; 5,897,572; 5,676,675; and 5,693,072 all of which are incorporated herein by reference.

[0050] "Needle diameter" refers to the diameter of a suture deployment needle at the widest point of that needle. While the term "diameter" is often associated with a circular

periphery, it is to be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape. In preferred embodiments of self-retaining suture, the needle diameter is less than the maximum diameter/cross-sectional dimension of the retainers on the suture.

[0051] "Tissue elevation procedure" refers to a surgical procedure for repositioning tissue from a lower elevation to a higher elevation (i.e. moving the tissue in a direction opposite to the direction of gravity). The retaining ligaments of the face support facial soft tissue in the normal anatomic position. However, with age, gravitational effects and

loss of tissue volume effect downward migration of tissue, and fat descends into the plane between the superficial and deep facial fascia, thus allowing facial tissue to sag. Face-lift procedures are designed to lift these sagging tissues, and are one example of a more general class of medical procedure known as a tissue elevation procedure. More generally, a tissue elevation procedure reverses the appearance change that results from

effects of aging and gravity over time, and other temporal effects that cause tissue to sag, such as genetic effects. It should be noted that tissue can also be repositioned without elevation; in some procedures tissues are repositioned laterally (away from the midline), medially (towards the midline) or inferiorly (lowered) in order to restore symmetry (i.e., repositioned such that the left and right sides of the body "match").

[0052] "Medical device" or "implant" refers to any object placed in the body for the purpose of restoring physiological function, reducing/alleviating symptoms associated with disease, and/or repairing and/or replacing damaged or diseased organs and tissues. While normally composed of biologically compatible synthetic materials (e.g., medical-grade stainless steel, titanium and other metals or polymers such as polyurethane, silicon, PLA, PLGA and other materials) that are exogenous, some medical devices and implants include materials derived from animals (e.g., "xenografts" such as whole animal organs; animal tissues such as heart valves; naturally occurring or chemically-modified molecules such as collagen, hyaluronic acid, proteins, carbohydrates and others), human donors (e.g., "allografts" such as whole organs; tissues such as bone grafts, skin grafts and others), or from the patients themselves (e.g., "autografts" such as saphenous vein grafts, skin grafts, tendon/ligament/muscle transplants). Medical devices that can be used in procedures in conjunction with the present invention include, but are not restricted to, orthopedic implants (artificial joints, ligaments and tendons; screws, plates, and other implantable hardware), dental implants, intravascular implants (arterial and venous vascular bypass grafts, hemodialysis access grafts; both autologous and synthetic), skin grafts (autologous, synthetic), tubes, drains, implantable tissue bulking agents, pumps, shunts, sealants, surgical meshes (e.g., hernia repair meshes, tissue scaffolds), fistula treatments, spinal implants (e.g., artificial intervertebral discs, spinal fusion devices, etc.) and the like.

Self-Retaining Sutures

[0053] As discussed above, the present invention provides self-retaining sutures and methods of using self-retaining sutures in soft palate elevation surgical procedures.

[0054] FIG. 1A illustrates an embodiment of a bidirectional self-retaining suture 100. Self-retaining suture 100 includes needles 110, 112 attached to suture thread 120. Self-retaining suture 100 includes a plurality of retainers 130 distributed on the surface of a

suture thread 120. The retainers 130 are elevated as shown in FIG. 1A. In lead-in region 140 of suture thread 120 there are no retainers 130. In region 142 of suture thread 120 there are a plurality of retainers 130 arranged such that the suture can be moved through

tissue in the direction of needle 110 but resists movement in the direction of needle 112. In transition region 144, there are no retainers 130. In region 146, there is a plurality of retainers 130 arranged such that the suture can be moved through tissue in the direction of needle 112 but resists movement in the direction of needle 110. In lead-in region 148 of suture thread 120 there are no retainers 130. A break is shown in each of regions 140, 142, 144, 146 and 148 to indicate that the length of each region may be varied and selected depending upon different variables, such as the gauge of the suture being used or the surgeon's preference. For example, the transition segment 144 may have a length in the range of about 0.5 mm to about 5 mm, or in the range of about 0.5 mm to about 1.5 mm, or it may be about 1 mm. Similarly, by way of example, one or both of regions 142 and 146 may have a length of up to about 50 mm or up to about 70 mm; it is not necessary for these regions to have identical lengths.

[0055] Likewise the suture gauge and the configuration of each of needles 110 and 112 can be any of the range of different surgical needles suitable to the present purpose. For instance, sutures of the present invention may suitably be provided in sizes 2-0, 3-0,

4-0, and 5-0, depending on the material of the suture and retainer density, distribution, and configuration. Needles 110 and 112 may have the same configuration or different configurations, such as bi-curve or compound curve. The dimensions of the needles may also vary; they may be in the range of about 30 mm to 40 mm, or one or both may be about 32 mm.

[0056] FIG. IB illustrates a magnified view of self-retaining suture 100 in region 142. As shown in FIG. IB, a plurality of retainers 130 is distributed on the surface of suture thread 120. The affixation of self-retaining sutures after deployment in tissue entails the penetration of retainer tips 132 into the surrounding tissue resulting in tissue being caught between the retainer 130 and the body of suture thread 120. The inner retainer surface 134 of the retainer 130 that is in contact with the tissue that is caught between the retainer 130 and the body of suture thread 120, is referred to herein as the "tissue

engagement surface" or "inner retainer surface." As illustrated in FIG. IB, each retainer 130 has a tip 132 and inner retainer surface 134. When self-retaining suture 100 is moved in the direction of arrow 156, retainers 130 in region 142 lie flat against the body of suture thread 120. However, when self-retaining suture 100 is moved in the direction of arrow 158, tips 132 of retainers 130 in region 142 engage tissue surrounding suture thread 120 and causes retainers 130 to fan out from suture thread 120 and engage the tissue with inner retainer surface 134 thereby preventing movement of the suture in that direction. In region 146, there is a plurality of retainers 130 arranged such that the suture can be moved through tissue in the direction of arrow 158 but resists movement in the direction of arrow 156.

[0057] A self-retaining suture can, in some embodiments, include visible or visualizable markings indicating, for example, the presence, absence and/or orientation of retainers in a region of the suture. Thus, for example, the bidirectional self-retaining suture 100 of FIG. 1A includes visible markings 104 on the transition segment 144 which allow a surgeon to identify the location of transition segment 144. Many different kinds of markers may be suitable for marking the transition segment in the present invention, and can include, by way of example, different colors such as red, green, orange, yellow, green, blue etc. The markers can be formed by various conventional methods. For example, the markers can be coated, sprayed, glued, dyed, stained, or otherwise affixed to the self-retaining suture systems or components thereof. Traditional colourant application processes include, without limitation, dipping, spraying (by, for example, an ink jet), painting, printing, applying and/or coating colourants on the suture section of interest. Critical fluid extraction (such as carbon oxide) may also be used to add colourant locally to all or part of the section desired to be marked. Alternatively, colourant(s) for the suture section of interest may be included in a portion of the suture material that is used to form the suture body, wherein that portion is in the section of interest of the manufactured suture.

[0058] Additionally, the transition segment can be demarcated by using an energy-activated colourant. For example, when a laser-activated colourant (that is, a pigment or dye which permanently changes colour after being exposed to laser energy) is used to colour the suture, then the transition segment can be demarcated by using laser energy to permanently change the suture coating in the suture section of interest. This also

applies to using other energy activated colourants which are activated by other energy sources such as, but not limited to, heat, chemicals, microwaves, ultraviolet light, or x-rays. For example, bleaching chemicals such as sodium hypochlorite or hydrogen peroxide will permanently change the colourant's colour which allows for the demarcation of the eyelet or other region of the suture.

[0059] Additionally, the colourant(s) employed for demarcating the transition segment may be included on a plastic biocompatible material which is applied on the suture at the section of interest. Such a layer may be absorbable, such as a polyglycolide
coating which has a colourant to mark transition segment, or it may be a non-absorbable
material, such as silicone. The coloured material may be synthetic or may be derived from a natural source (whether the material be modified or unmodified), such as collagen. The plastic biocompatible material may be applied to the suture before or after the retainers are formed on the suture body.

[0060] Alternatively, the transition segment may be reverse-marked, such that where the suture body is already visibly coloured, the colourant may be absent from all or part of the suture section of interest such that at least a portion of the section of interest is optically distinguishable by the surgeon from the rest of the suture. Such a suture may be manufactured by including a colourant-free portion of suture material in the suture section of interest area during the manufacture of the suture body (for example, by extrusion) or by removal of colourant from the suture section of interest after the suture body has been manufactured, whether before or after retainers have been formed on the suture body. Colourant may be removed locally by, for example, critical fluid extraction
such as (e.g., carbon oxide). It is not necessary to remove all of the colourant from the section of interest of the suture as long as there is a difference detectible by a surgeon between the section of interest and the rest of the suture.

[0061] Another example of a reverse-marked suture is one that lacks a coloured layer that is present on the rest of the suture body. A plastic biocompatible material bearing a colourant may be applied on the other sections of the suture, and at least where the other sections border the section of interest. Examples of such materials are discussed

above. As in the foregoing examples, demarcating the suture section of interest may be effected in the suture manufacturing process either before or after forming retainers.

[0062] Another example of a reverse-marked suture is one having a coaxial structure wherein each coaxial layer having a different colour, and a portion of the outermost layer(s) is removed to visually expose a layer below. For example, a dual-layer monofilament polypropylene suture can be produced with a white inner core (intercoaxial layer) with a blue outer coaxial layer, and portions of the outer layer can be removed to visually expose the white inner monofilament to mark the suture section of interest.

[0063] Yet another example of a reverse-marked suture is one in which an external coating is removed (or partially removed) from the suture in the suture section of interest, and where either the coating or base suture has a contrasting colour difference. This technique of removing (or partially removing) material in the suture section of interest may also create a tactile demarcation of the suture section of interest.

[0064] The marking may include an echogenic compound, radio-detectable compound, or magnetic resonance imaging detectable compound. For example the suture section of interest provided with barium sulfate (BaS04), such as by impregnating the suture with barium sulfate or adding a coating containing barium sulfate, will be detectable by electromagnetic energy. In the case of x-ray detection, the barium sulfate marked section of interest would be radiopaque. Likewise, computed tomography (CT) scans or computed axial tomography (CAT) scans can be used to detect the radio detectable section of interest. The use of electromagnetic energy for radio detection of the transition section is not limited to using x-ray wavelengths as other radio frequencies may be used. Likewise, gadolinium (Gd) or gadolinium compounds can be used for the marking of the suture section of interest especially when the detection will be done by using magnetic resonance imaging (MRI). The use of radio detectable or magnetic resonance imaging detectable marking may be useful to later identify the transition segment for cutting in order to remove the suture. FIG. 1B illustrates a magnified view of self-retaining suture 100 in region 142. As shown in FIG. 1B, a plurality of retainers 130 is distributed on the surface of suture thread 120. The affixation of self-retaining sutures after deployment in tissue entails the penetration of retainer tips 132 into the surrounding tissue resulting in tissue being caught between the retainer 130 and the body of suture thread 120. The inner retainer surface 134 of the

retainer 130 that is in contact with the tissue that is caught between the retainer 130 and the body of suture thread 120, is referred to herein as the "tissue engagement surface" or "inner retainer surface." As illustrated in FIG. 1B, each retainer 130 has a tip 132 and inner retainer surface 134. When self-retaining suture 100 is moved in the direction of arrow 156, retainers 130 in region 142 lie flat against the body of suture thread 120. However, when self-retaining suture 100 is moved in the direction of arrow 158, tips 132 of retainers 130 in region 142 engage tissue surrounding suture thread 120 and causes retainers 130 to fan out from suture thread 120 and engage the tissue with inner retainer surface 134 thereby preventing movement of the suture in that direction. In region 146, there is a plurality of retainers 130 arranged such that the suture can be moved through tissue in the direction of arrow 158 but resists movement in the direction of arrow 156.

[0065] The distribution of retainers may also vary, in accordance with various embodiments of the invention. FIGS. 2A, 2B, and 2C show a range of retainer distributions and patterns that can be used in conjunction with a self-retaining suture. FIG. 2A shows a single helix distribution of retainers on a self-retaining suture according to an embodiment of the invention. FIG. 2B shows a double helix distribution of retainers on a self-retaining suture according to an embodiment of the invention. FIG. 2C shows a high quadra-helix density distribution of retainers on a self-retaining suture according to an embodiment of the invention.

[0066] As shown in FIG. 2A, the suture thread is a 4-0 suture having a diameter of 250μm. The self-retaining suture 200 includes a plurality of retainers 204 arranged in a helical pattern around and along the suture thread 202. As shown in FIG. 2A, the helix makes 5.7 twists per inch. In an embodiment the self-retaining suture has a barbed section 212 at least 60 mm in length and a 100 mm unbarbed lead 210, 214 on either side of the barbed section 212. The barbed section 212 may have retainers 204 in one orientation or in different orientations. Each retainer is 500μm from tip of depression to base of cut - measured axially - see arrow 216. The distance between the base of one retainer and the base of the adjacent retainer in the same helix (pitch) is 600μm - measured axially – see arrow 218.

[0067] In the embodiment shown in FIG. 2A, retainers 204 are distributed at a density of 42 retainers per inch or 0.50 retainers per suture diameter in axial length. The

retainer density of retainers in retainers per inch = n*25400/pitch (where n= no. of retainers in pattern e.g. n=1 for single helix, n=2 for double helix, n=4 for quadra-helix and wherein 25400 is the number of micrometers per inch). The retainer density of retainers in retainers per suture diameter in axial length = n*(suture diameter)/pitch (where n= no. of retainers in pattern e.g. n=l for single helix, n=2 for double helix, n=4 for quadra-helix and wherein 25400 is the number of micrometers per inch). Note that it

is not necessary that retainers be provided over one inch of suture thread.

[0068] Referring now to FIG. 2B which shows a double helix distribution of retainers 224 on a self-retaining suture 220. As shown in FIG. 2B, the suture thread is a 4-0 suture having a diameter of 250μm. The self-retaining suture 220 includes a plurality of retainers 224 arranged in a double helical pattern (n=2) around and along the suture thread 222. As shown in FIG. 2B, each helix makes 4.2 twists per inch. The helixes are also shifted axially by 0.49 mm relative to one another. In an embodiment, the self-retaining suture 220 has a barbed section 232 at least 100 mm in length and a 100 mm unbarbed lead 230, 234 on either side of the barbed section 232. The barbed section 232

may have retainers 224 in one orientation or in different orientations. Each retainer is 310μm from tip of depression to base of cut - measured axially - see arrow 236. The distance between the base of one retainer and the base of the adjacent retainer in the same helix (pitch) is 410μm - measured axially - see arrow 238. In the embodiment shown in FIG. 2B, the retainers 224 are distributed at a density of 123 retainers per inch or 1.21retainers per suture diameter in axial length. The ratio of combined retainer length to suture length can be calculated by the formula n*(retainer length)/pitch and in FIG. 2B the ratio is 2*310μm/410μm or 1.51.

[0069] Referring now to FIG. 2C which shows a high density distribution of retainers 244 on a self-retaining suture 240, the suture thread is a 4-0 suture 250μm nominal diameter. The self-retaining suture 240 includes a plurality of retainers 244 arranged in groups of four retainers in one plane (n=4), each arranged at 90 degrees spacing - a quadra-helix distribution. Each adjacent set of four retainers is offset to the adjacent sets by 45 degrees. In an embodiment, the self-retaining suture has a barbed section 252 at least 60 mm in length and a 100 mm unbarbed lead 250, 254 on either side of the barbed section 252. The barbed section 252 may have retainers 244 in one orientation

or in different orientations. Each retainer is 180μm from tip of depression to base of cut – measured axially - see arrow 256. The distance between the base of the retainer in one set and the base of the adjacent retainers (pitch) is 280μm - measured axially - see arrow 258. In the embodiment shown in FIG. 2C, the retainers 244 are distributed at a density of 362 retainers per inch or 3.57 retainers per suture diameter in axial length.

[0070] Kits may be provided in accordance with embodiments of the present invention. Referring to FIG. 4, kit 400 includes a packaged suture 410 (including a suture as disclosed herein), a needle driver 420, forceps 430, scissors 440, and a tongue depressor 450.

[0071] FIGS. 5A and 5B illustrates a bi-curve needle that is particularly suited for use with the devices and methods described herein. The bi-curve needle 500 includes a first portion 502 adjacent to the proximal end 503 and a second portion 504 adjacent to the distal, tapered end 505 of the needle, and the needle preferably has an overall length of 28-32 mm. The first portion has a smaller radius of curvature than the second portion, which is more clearly shown in the illustration of Fig. 5B. Bi-curve needles are known in the art for use in various procedures including ophthalmic procedures.

Soft Palate Elevation Procedures

[0072] The methods of the present invention include the deployment of a bidirectional self-retaining suture as disclosed above in a partially trapezoidal suture pathway into soft palate tissue to effect the elevation of the tissue. Referring now to FIG. 3A, the clinician first locates the junction of the soft and hard palate and inserts the first end of the suture into the soft palate at an insertion point indicated as "1" to one side of the palate midline and between the junction of the hard and soft palates and the posterior end of the soft palate. The clinician then passes the first end laterally across the medial portion of the soft palate to a first exit point, indicated as "2", to the other side of the palate midline and between the junction of the hard and soft palates and the posterior end of the soft palate. The points "1" and "2" may be about half the distance posterior to the junction of the soft and hard palate. Next, the clinician may pull the suture until some of the retainers in the plurality of retainers adjacent to and oriented to the second end of the suture engage around the midpoint of the suture, or, where the midpoint or transition segment is marked, until the clinician sees the marking approach the insertion point. The clinician then re-inserts the first end into the first exit

point "2" and deploys the first end through the soft palate posteriorly and away from the palate midline to a second exit point, indicated as "3", and urges the first end out of the soft palate at the second exit point "3", drawing the suture out through the second exit point "3". Finally, the clinician then takes the second end of the suture and inserts it into the insertion point "1" and deploys the second end through the soft palate posteriorly and away from the palate midline to a third exit point "4". The second end of the suture is then drawn out of the tissue at the exit point "4".

[0073] The clinician may adjust and trim each end of the suture either upon exiting the suture from points "3" and "4", respectively, or he or she may do so at the end of the procedure. In a further alternative, the clinician may leave some portion of the suture exposed at each of these points, for adjustment in 1-3 days in the clinic followed by cutting the suture flush with the mucosa allowing the distal ends to bury themselves below the mucosa. In addition, to further elevate the soft palate, the clinician may wish to draw the suture anteriorly and cranially when drawing the suture out of exit points "3" and "4".

[0074] Referring now to FIG. 3B, the volumetric increase in the airway passage can be seen as the difference "C" between the position of the soft palate before the procedure (indicated as "A") and the position of the soft palate after the procedure (indicated as "B").

Materials

[0075] Suture threads described herein may be produced by any suitable method, including without limitation, injection molding, stamping, cutting, extrusion, and so forth. In preferred embodiments, the suture threads are drawn polymeric monofilaments having a high strength to diameter ratio. Polymeric suture threads/filaments may be manufactured or purchased for the suture body, and the retainers can be subsequently cut onto the suture body. The suture threads/filaments can be biodegradable or nondegradable as desired for a particular application. The retainers can be mechanically-cut using blades, cutting wheels, grinding wheels, and so forth. During cutting, either the cutting device or the suture thread may be moved relative to the other, or both may be moved, to control the size, shape and depth.

[0076] Additionally, self-retaining sutures described herein may be provided with

compositions to promote healing and prevent undesirable effects such as scar formation, infection, pain, and so forth. This can be accomplished in a variety of manners, including for example: (a) by directly affixing to the suture a formulation (e.g., by either spraying the suture with a polymer/drug film, or by dipping the suture into a polymer/drug solution), (b) by coating the suture with a substance such as a hydrogel which will in turn absorb the composition, (c) by interweaving formulation-coated thread (or the polymer itself formed into a thread) into the suture structure in the case of multi-filamentary sutures, (d) by inserting the suture into a sleeve or mesh which is comprised of, or coated with, a formulation, or (e) constructing the suture itself with a composition. Such compositions may include without limitation anti-proliferative agents, anti-angiogenic agents, anti-infective agents, fibrosis-inducing agents, anti-scarring agents, lubricious agents, echogenic agents, anti-inflammatory agents, cell cycle inhibitors, analgesics, and anti-microtubule agents. For example, a composition can be applied to the suture before the retainers are formed, so that when the retainers engage, the engaging surface is substantially free of the coating. In this way, tissue being sutured contacts a coated surface of the suture as the suture is introduced, but when the retainer engages, a non-coated surface of the retainer contacts the tissue. Alternatively, the suture may be coated after or during formation of retainers on the suture if, for example, a fully-coated rather than selectively-coated suture is desired. In yet another alternative, a suture may be selectively coated either during or after formation of retainers by exposing only selected portions of the suture to the coating. The particular purpose to which the suture is to be put or the composition may determine whether a fully-coated or selectively-coated suture is appropriate; for example, with lubricious coatings, it may be desirable to selectively coat the suture, leaving, for instance, the tissue-engaging surfaces of the sutures uncoated in order to prevent the tissue engagement function of those surfaces from being impaired. On the other hand, coatings such as those comprising such compounds as anti-infective agents may suitably be applied to the entire suture, while coatings such as those comprising fibrosing agents may suitably be applied to all or part of the suture (such as the tissue-engaging surfaces). The purpose of the suture may also determine the sort of coating that is applied to the suture; for example, self-retaining sutures having anti-proliferative coatings may be used in closing tumour excision sites, while self-retaining sutures with fibrosing coatings may be used in tissue repositioning procedures and those having

anti-scarring coatings may be used for wound closure on the skin. As well, the structure of the suture may influence the choice and extent of coating; for example, sutures having an expanded segment may include a fibrosis-inducing composition on the expanded segment to further secure the segment in position in the tissue. Coatings may also include a plurality of compositions either together or on different portions of the suture, where the multiple compositions can be selected either for different purposes (such as combinations of analgesics, anti-infective and anti-scarring agents) or for their synergistic effects.

[0077] Although the present invention has been shown and described in detail with regard to only a few exemplary embodiments of the invention, it should be understood by those skilled in the art that it is not intended to limit the invention to the specific embodiments disclosed. Various modifications, omissions, and additions may be made to the disclosed embodiments without materially departing from the novel teachings and advantages of the invention, particularly in light of the foregoing teachings. Accordingly, it is intended to cover all such modifications, omissions, additions, and equivalents as may be included within the spirit and scope of the invention as defined by the following claims.

[0078] In this specification, the terms "comprise", "comprises", "comprising" or similar terms are intended to mean a non-exclusive inclusion, such that a system, method or apparatus that comprises a list of elements does not include those elements solely, but may well include other elements not listed.

[0079] The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that the prior art forms part of the common general knowledge.

CLAIMS:

1. A self-retaining suture for soft palate elevation procedures comprising:

a. an elongated suture body having a periphery and first and second tissue-penetrating ends, each of the first and second ends being provided with a bi-curve needle, wherein each of the bi-curve needles has a length of 28-32mm;

b. a plurality of first retainers disposed on a first segment of the elongated body and oriented to the first end, the first plurality of retainers yielding toward the suture body during movement of the suture through tissue in a direction of deployment of the first end, and resisting movement of the suture, when in tissue, in a direction substantially opposite to the direction of deployment of the first end;

c. a plurality of second retainers disposed on a second segment of the elongated body and oriented to the second end, the plurality of second retainers yielding toward the suture body during movement of the suture through tissue in a direction of deployment of the second end, and resisting movement, when in tissue, in a direction substantially opposite the direction of deployment of the second end; and

d. a retainer-free transition segment disposed between the pluralities of first and second retainers.

2. The self-retaining suture according to claim 1, wherein the plurality of first and second retainers are arranged in a helical pattern.

3. The self-retaining suture according to claim 2, wherein the first and second retainers have a retainer density of at least 250 per centimeter.

4. The self-retaining suture according to claim 2, wherein the helical pattern is a double helix.

5. The self retaining suture according to claim 2, wherein the helical pattern is a quadra-helix.

6. The self-retaining suture according to claim 2, wherein the length of the transition segment is between approximately 0.5 and 5 mm, and a length of the first and second segments is less than or equal to approximately 70 mm.

7. The self-retaining suture according to claim 6, wherein the length of the first and second segments is less than or equal to approximately 50 mm.

8. The self retaining suture according to claim 6, wherein the length of the transition segment is approximately 1 mm.

9. A surgical kit for soft palate elevation procedures, the kit comprising a suture package including:

a self-retaining suture according to claim 1, wherein the transition segment has a length of up to 10 mm;

a needle driver;

forceps;

scissors; and

a tongue depressor.

10. The surgical kit according to claim 9, wherein the length of the transition segment is between 0.5 and 5 mm.

11. The surgical kit according to claim 10, wherein the length of the transition segment is between 0.5 and 1.5 mm.

12. The surgical kit according to claim 11, wherein the length of the transition segment is approximately 1 mm.

13. The surgical kit according to claim 9, wherein the first and second segments have a length less than 70 mm.

14. The surgical kit according to claim 13, wherein the first and second segments have a length less than 50 mm.

15. The surgical kit according to claim 9, wherein the first and second retainers are arranged in a helical pattern.

16. The surgical kit according to claim 15, wherein the helical pattern is a double helix or a quadra helix.

17. The surgical kit according to claim 16, wherein the helical pattern further comprises a retainer density of at least 250 per centimeter.

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FIG. 1A

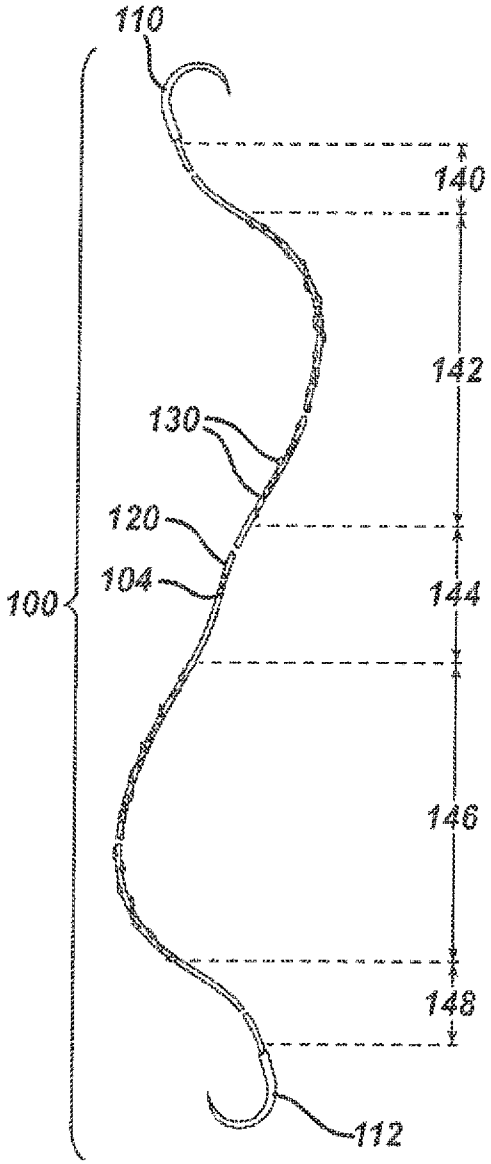

FIG. 1B

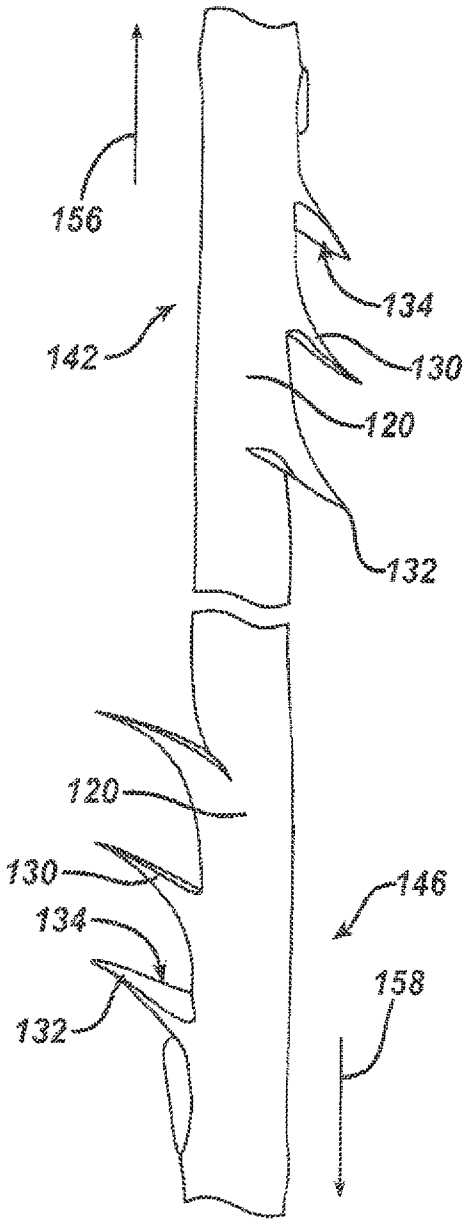

FIG. 2A

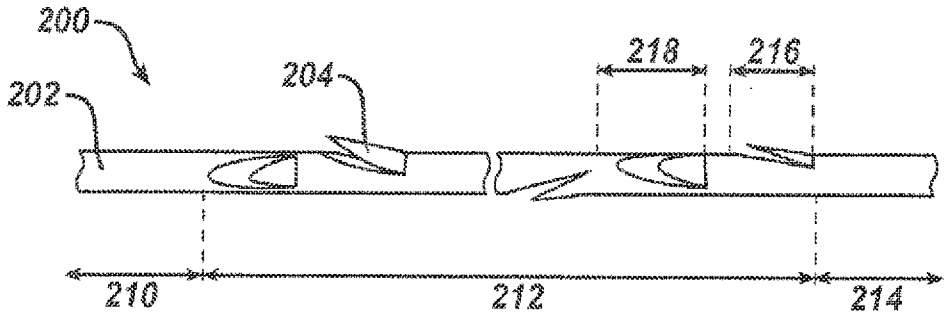

FIG. 2B

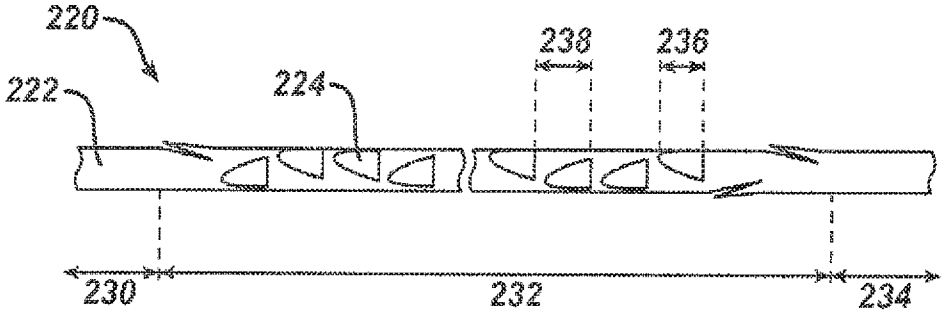

FIG. 2C

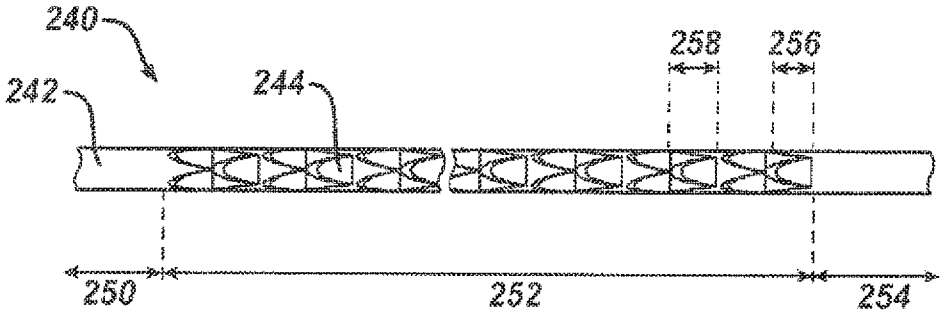

FIG. 3A

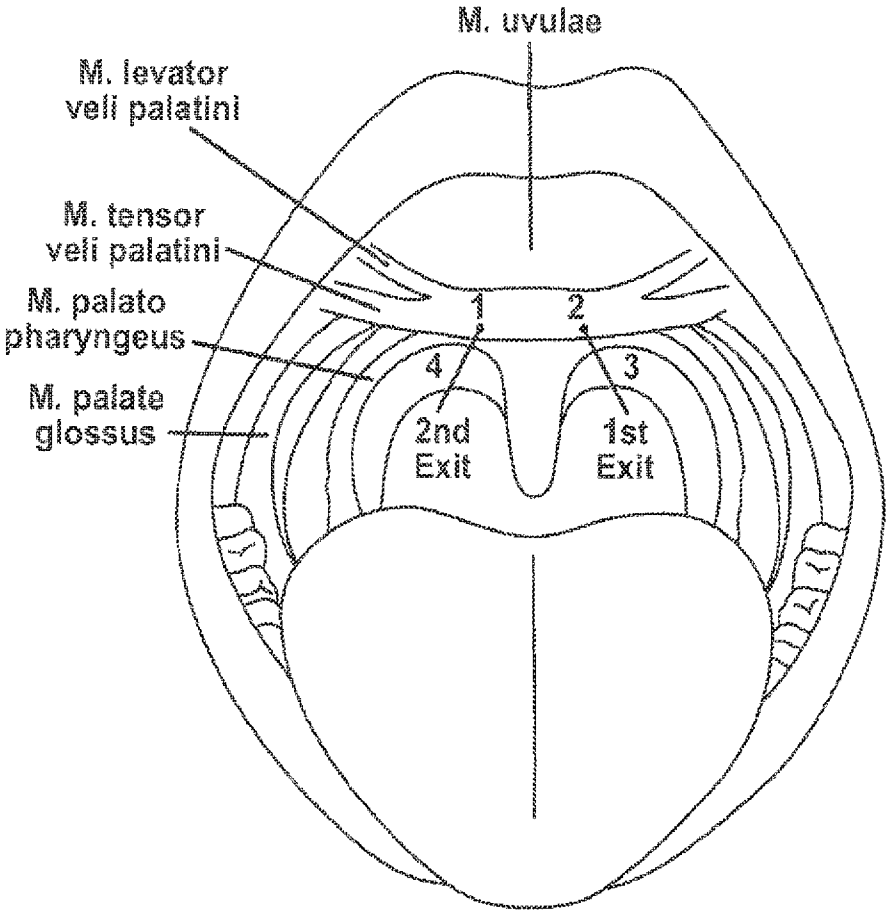

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FIG. 3B

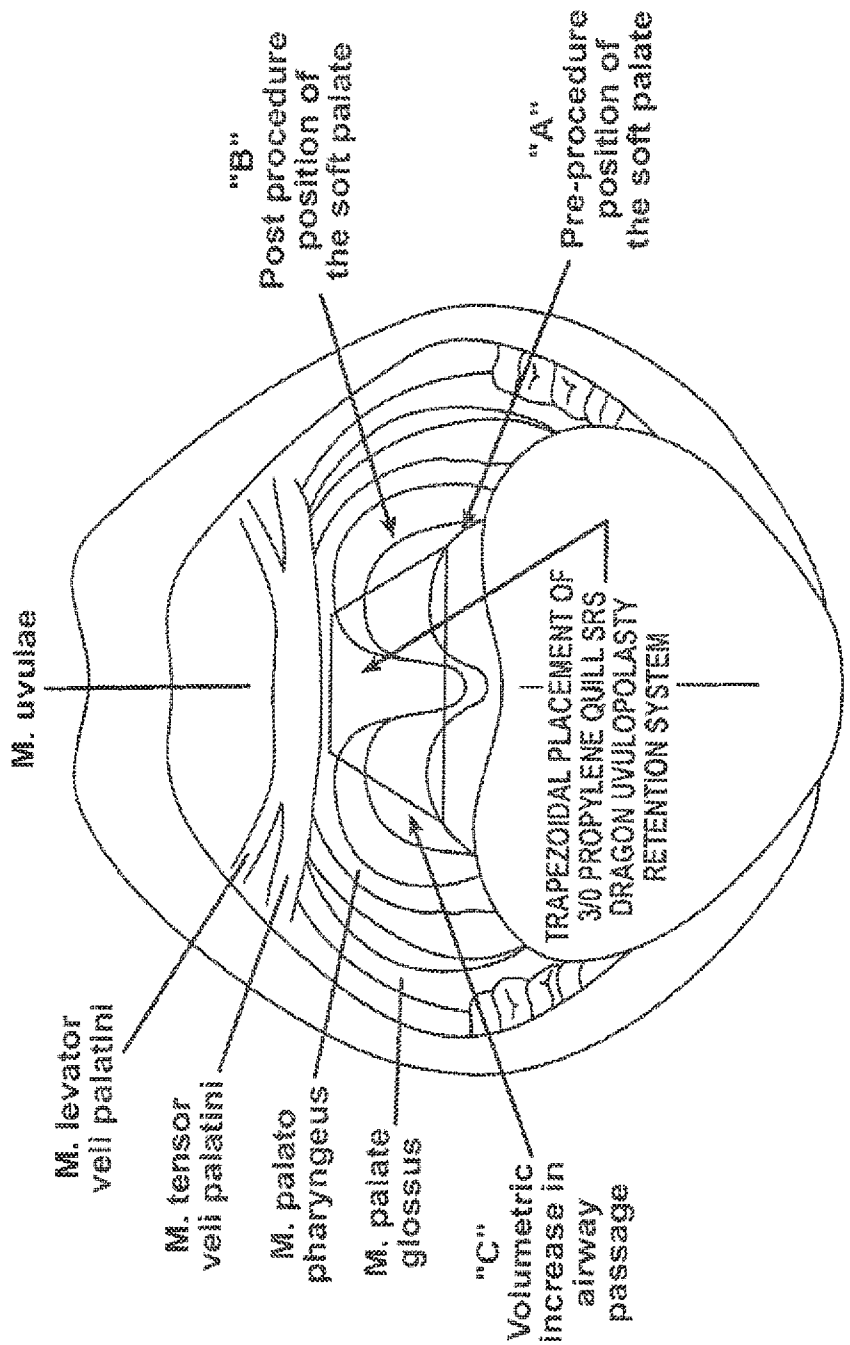

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FIG. 4

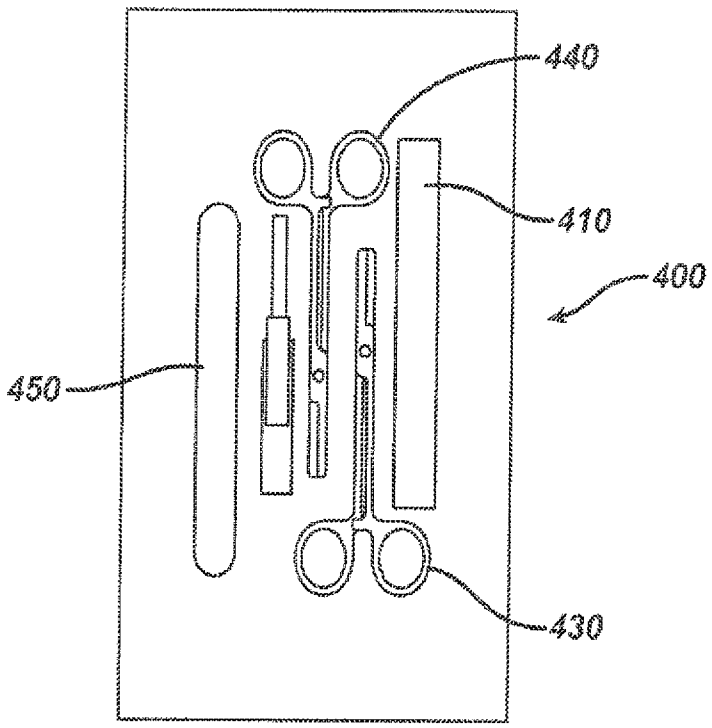

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FIG. 5A

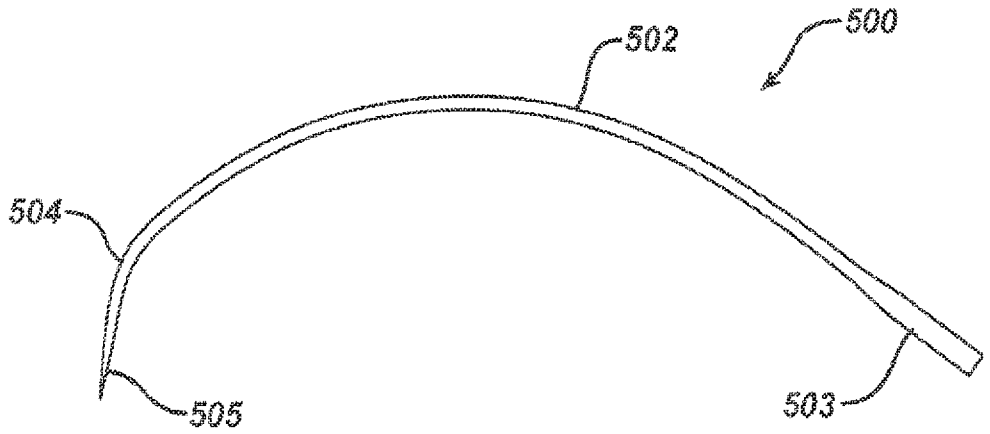

FIG. 5B