

A SYSTEM FOR COSMETIC ENHANCEMENT

Field

The present invention relates to an anchor for use in a system for cosmetic enhancement, a suture assembly comprising the anchor, a procedure kit and/or a method of cosmetic enhancement.

Background

Many devices and methods have been developed over the years for face lift procedures, with the aim to minimise the wounding, scarring and tissue dissection caused by these procedures. One such device is barbed suture.

Typically each suture is stitched through the tissue with a needle, with the barbs oriented away from the needle, in a direction opposite the thread tension. After a number of sutures are inserted in appropriate locations the facial tissue may then be lifted manually and the barbs hold the tissue in place in the new configuration. The tension on the thread is then readjusted and then secured at a final position with about three to four knots. The thread is then cut flush to the knot and urged under the skin.

Prior art examples are given in WO2005096955 and WO2008020937.

Generally some or all of these prior art methods may result in two entry/exit wounds per suture, may be subject to single sutures breaking, multiple entry and exit points, significant bleeding, significant anaesthetic may be required, and/or the recovery time may be significant.

Summary

In general terms in a first aspect the present invention proposes a minimally invasive technique for cosmetic suturing.

In a second aspect the invention proposes a suture for a cosmetic procedure comprising a clear section and barbs on either side of the clear section, wherein the clear section is devoid of barbs, and the barbs on both sides of the clear section are inclined away from the clear section, and towards the edges of the suture.

In a third aspect the invention proposes an anchor assembled with a suture configured to assist with anchoring the end of the suture within the patient's tissue and/or to assist with implanting the suture into the patient's tissue. The anchor may be a knot and/or a stopper in the shape of a sphere, cylinder or cone.

In a forth aspect the invention proposes an anchor secured to a plurality of barbed sutures configured to assist with anchoring the end of the suture within the patient's tissue. The anchor may be moulded or affixed to the sutures.

In a fifth aspect the invention proposes a suture for a cosmetic procedure comprising barbs staggered on either side of the suture.

In a sixth aspect the invention proposes a procedure for cosmetic enhancement where a single puncture site is used to implant multiple sutures in multiple orientations. This may allow only a single entry wound for either side of the face.

In a seventh aspect the invention proposes a procedure for cosmetic enhancement where an entry site is used to implant a suture without an exit site.

In an eighth aspect the invention proposes a procedure kit for upwardly implanting the sutures under or in the facial tissue.

In an ninth aspect the invention proposes a procedure kit which significantly reduces skill required to carry out the non-surgical, non-therapeutic entirely cosmetic procedure. The suture may be kept within the cannula during insertion, so that no guiding of the suture outside of the cannula may be required.

In a tenth aspect the invention proposes implanting a suture for a cosmetic procedure instead of stitching. This may reduce tissue damage compared to the use of a needle.

One or more of these aspects may have one or more of the additional advantages that

- less skill required for procedure,
- less training time for the practitioner,
- less qualified practitioner may be required for procedure,
- barbs are smaller and more effective,
- less invasive,
- shorter procedure,
- less puncture and insertion wounds,
- less bleeding,
- less chance of infection or complications,
- more distributed and increased lifting force,
- high tensile strength of the suture,

- shorter recovery time,
- less anaesthetic,
- more tension able to be applied,
- less chance of failures during implanting as less tension than needle drawing,
- less chance of early failures during normal lifetime,
- lower chance of error in positioning and insertion of the suture,
- faster scar healing,
- less residual scar tissue,
- less noticeable scar location,
- no external knot, loop or anchor, and/or
- previously unreachable tissue can be lifted.

In a first particular expression of the invention there is provided an anchor as claimed in claim 1.

In a second particular expression of the invention there is provided a suture assembly as claimed in claim 6 or 15.

In a third particular expression of the invention there is provided a method as claimed in claim 16, 19 or 31.

In a fourth particular expression of the invention there is provided a trocar assembly as claimed in claim 20.

In a fifth particular expression of the invention there is provided a system as claimed in claim 39.

Embodiment may be implemented according to any of claims 2 to 5, 7 to 14, 17 to 18, 21 to 30, and 32 to 38.

Brief Description of Drawings

One or more example embodiments of the invention will now be described, with reference to the following figures, in which:

Figure 1 is a front view showing a series of suture implanted within a patient's facial tissue according to a first embodiment;

Figure 2 is a schematic view of the suture assembly;

Figure 3 is a cross section view of the barbs;

Figure 4 are orthographic views of the stopper;

Figure 5 are orthographic views of the insertion hub;

Figure 6 is a flow diagram of a method for cosmetic procedure;

Figure 7 is a schematic view of a punch;
Figure 8 is a schematic view of a trocar;
Figures 9 and 10 are schematic views of the trocar and sharpened shaft;
Figure 11 is a schematic view of the suture assembly and trocar;
Figures 12a to 12c are schematic views of the suture assembly, trocar and pushing rod;
Figure 13 is schematic view of an alternative trocar;
Figure 14 is schematic view of an alternative stopper;
Figure 15 is schematic view of an alternative stopper;
Figure 16 is schematic view of an alternative stopper;
Figure 17 is schematic view of an alternative stopper;
Figure 18 are orthographic views of the stopper of Figure 17;
Figure 19 is a cross section view of the alternative stopper of Figure 17;
Figure 20 are orthographic views of an alternative stopper; and
Figure 21 is a cross section view of the alternative stopper of Figure 20.

Detailed Description

A system 100 according to an example embodiment will now be described with reference to Figure 1. The system 100 is designed to affect a distributed lifting force to desired portions of facial tissue. The patient's face may be subject to rhytides/wrinkles or ptosis/sagging. The system may be used to lift tissue in the cheeks 102, temples 104, neck or forehead 106 zones. In each zone a plurality of barbed sutures are upwardly implanted within or under the tissue, so that the entry site is at the bottom, and without an exit site.

Known suture face lifts already involve a low risk to the patient. However the system according to the example embodiment thus allows an even lower risk entirely cosmetic procedure which is non-surgical and non-therapeutic. The skill involved in the procedure is reduced due to the assistance of the procedure equipment. Due to the reduced skill required this may mean that a less experienced practitioner may be used for the procedure compared to prior art methods, and the learning process will be shortened significantly. Depending on the regulations in the country concerned, there is a small possibility that non-doctor clinicians, cosmetic technicians or practitioners, nurses or other medical staff may be able to more significant assist, or actually carry out major parts of the non-therapeutic entirely cosmetic procedure, rather than a doctor or surgeon. Alternatively a non-doctor clinician may be able to do the entire procedure supervised by a doctor.

The system may reduce the number of wounds significantly compared to known methods, and the practitioner is able to provide lift in any location, as there is no need to provide an exit site at an unobtrusive location.

Each entry site 108 may for example include 3 implanted suture assemblies 110 at different angles. Each suture assembly 108 may include a single or multiple sutures, which are anchored 112 at the top.

Suture

As shown in Figure 2 the suture assembly 110 may include a looped suture 202 which is knotted at the end 204. The knot 204, together with an adjacent toggle, stopper or fastener 206 forms the anchor 114 at the top. The suture 202 includes barbs 208 alternating on either side. At the bottom the suture 202 loops into a barb free zone 210. The barbs 208 are inclined away from the barb free zone 210, towards the anchor 114.

The suture may be 345mm long. Alternatively multiple lengths may be provided for different zones of the face, or different sized faces for example 375mm long. The suture may be 0.3mm thick. Alternatively multiple thicknesses may be provided for obtaining different tensile strengths. The assembly 100 may be formed from a single looped suture 202, multiple looped sutures, multiple linear sutures, or a single linear suture. The sutures may be secured using the knot 204 or may be moulded or otherwise secured to stopper 206 with or without a knot.

The suture 202 may be extruded from polypropylene or from polydioxanone. The latter material is biocompatible and biodegradable. As such the face lift effect is temporary and the suture does not stay implanted permanently. This also reduces the risk of complications.

As shown in Figure 3 the barbs 208 are at an angle 302 of 13° . They are spaced 304 on each side by 4mm. The barbs are staggered or alternate on either side of the suture every 2mm as shown in the inset. . They are cut into the suture to a depth of 0.05mm. The staggering of the barbs minimises the reduction in the effective diameter of the suture from cutting and maximises the tensile strength. These parameters are carefully chosen to optimise tensile strength and distributed lifting force.

At the opposite end of the looped suture to the knot 204 is the no barb zone 210. This no barb zone 210 may be between 25mm and 65mm in length.

Upon insertion of the suture into the tissue, this no barb zone 210 is left outside the tissue, and may be cut away. Practically the looped suture results in the insertion of a double suture, increasing lifting force.

Stopper

The stopper 206 shown in Figure 4 may be moulded from a biodegradable material. This will degrade and the stopper does not stay implanted permanently. This also reduces the risk of complications. However the stopper will stay inside the tissue and dissolve equally or slower than the suture, ensuring the reliability of the lift over the lifetime of the system.

The stopper may be provided to anchor the suture in place to provide the reaction force to the lifting force provided by the barbs to the facial tissue. The stopper may also, or alternatively, be provided to allow the suture assembly 110 to be pushed into the cannula (described later).

The stopper 206 may be in shape of a cuboid, sphere, cylinder or cone. It has one or more internal channels 402 of an oval diameter larger than the sutures threaded through it, for example 0.4-0.8mm. In Figure 4 it is shown as a frusto-elliptical-cone outer shell, with a wing 404 on either longer side, and a recess 406 on either short side. The wing 404 may be at an angle to the longitudinal axis of 10° .

The stopper 206 may alternatively be provided without the recesses 406. In a further alternative the stopper 206 may be provided without internal channel 402, where the suture is knotted, moulded or otherwise secured to stopper 206 at a lower fixture or loop.

Alternative stoppers are shown in Figures 14 to 16. In Figure 14 the stopper 206 and/or knot 204 are replaced by a loop 1402, that forms multiple barbs 1404 (facing back towards the suture 1406). The barbs 1404 may be a portion of the suture 1406, and may be 3mm long at an angle of between $30-60^{\circ}$. In Figure 15 the stopper 206 is replaced by a barbed stopper 1502. The barbs 1504 are provided on either side in an outwardly projecting arrow tip configuration, at an angle of $30-60^{\circ}$ from the longitudinal axis. The barbed stopper 1502 may be moulded from a biodegradable material. In Figure 16 the stopper 206 and/or knot 204 are replaced by a cage structure 1602, which is open at the end facing back towards the suture 1604. The cage 1602 includes a circumferential rib 1606 a multiple curved beams 1608. The cage 1602 may be moulded from a biodegradable material.

A further alternative stopper to replace stopper 206 may be a stopper which has a portion which exhibits resilience, such that a diameter of the stopper may be altered, depending on whether the stopper is in an expanded state or in a compressed state. In particular, the further alternative stopper in its expanded state may have a diameter which is larger than the diameter of the entry site from which the stopper entered (explained below). In this way, better anchoring may be achieved as the further alternative stopper will be unable to exit from the entry site. For example, the stopper may comprise a rigid portion and a resilient portion projecting from the

rigid portion. In particular, the stopper may comprise a rigid portion intermediate to at least two resilient portions. The two resilient portions may comprise at least two wings projecting from opposing sides of the rigid portion, the at least two wings being resiliently compressible towards one another. The stopper may have a first diameter and the at least two wings may be transversely spaced by a second diameter which is larger than the first diameter. The wings may be resiliently compressible towards one another sufficiently to permit reduction of the transverse spacing between the at least two wings.

An example of such a further alternative stopper is as shown in Figures 17 to 19. In Figure 17, the stopper 206 is replaced by a winged stopper 1702. The winged stopper 1702 has a generally cylindrical shape. However, it would be obvious to a skilled person that the winged stopper may have other shapes, such as but not limited to cuboid, conical or spherical. The winged stopper 1702 comprises a first surface 1704 and a second surface 1706. A pair of wings 1708 is provided towards the bottom surface 1704 of the winged stopper 1702. The wings 1708 exhibit resilience by being capable of being compressed towards one another or expanding out away from each other.

According to a particular embodiment, the two wings 1708, when unconstrained, have their ends 1709 spaced at a distance that is greater than the diameter of a cannula into which the winged stopper 1702 is to be pushed into. However, when the winged stopper 1702 is pushed into a cannula (described later), the two wings 1708 are capable of getting compressed towards each other such that the ends 1709 of the wings 1708 are spaced at a distance smaller than the diameter of the cannula to enable the winged stopper 1702 to be pushed through the cannula. Upon exiting the cannula, the two wings 1708 of the winged stopper 1702 expand back into the uncompressed position.

Figure 18 shows different cross-sectional views of the winged stopper 1702. Figure 19 shows the winged stopper 1702 of Figure 17 with a suture assembly 110 threaded through an internal channel 1710 of the winged stopper 1702. Although the diameter of the internal channel 1710 as shown in Figure 19 changes across the length of the internal channel 1710, it would be understood that the internal channel 1710 may also have a constant diameter across the length of the internal channel. A stopper with a constant diameter internal channel is shown in Figures 20 and 21. Figures 20 and 21 show a winged stopper 1802 comprising a constant diameter internal channel 1810. The other parts of the winged stopper 1802 are the same as that as shown in Figures 17 to 19, except for first surface 1804 which has dimensions slightly different from corresponding first surface 1704 in view of the difference in the diameters of the internal channels 1710 and 1810.

Insertion hub

Prior to insertion the assembly 110 includes an insertion hub 214 to assist with implantation. It connects the front end of the assembly 110 with the procedure equipment in a stable way such that the suture thread can be inserted easily into and through the cannula. It is moulded from polycarbonate or polypropylene

As shown in Figure 5 it is frustoconical shaped with an angle of 24° , a length 502 of 19.75mm and an outer diameter 504 of 5.9mm. Its internal cavity is shaped as a circle with an inner diameter 506 of 1.44mm. The outer surface includes a mating ledge 508 for the procedure equipment and four spaced ribs 510 for rigidity.

Lifetime

The suture 202 and the stopper 206 will degrade by hydrolysis in approximately 18-24 months after implantation. After this point the procedure will need to be redone.

Suture assembly process

The suture 202 is extruded then the barbs 208 are cut into it. The two ends are threaded through the insertion hub 214. The two ends are then threaded through the stopper 206, or any of the alternative stoppers described above. The knot is then formed between X and Y from the end, preferably Z. In this way the knot 204 holds the stopper 206 and the stopper holds the insertion hub 214. The assembly 110 can thus be self-contained and packaged in a sterile enclosure prior to the procedure.

Alternatively multiple loops are inserted through a single hub and stopper and knotted together. The loop ends may be integrally moulded or glued to the stopper, with or without a knot. Instead of loops, the suture may be a linear suture or multiple linear sutures knotted at the anchor end.

Cosmetic procedure and procedure kit

A method 600 for cosmetic procedure is shown in Figure 6. Anaesthetic may be applied to the area 601. An entry site is formed 602 just above the jaw bone, near the middle of each cheek. A trocar, comprising a plastic cannula and a sharp tip metal shaft, is inserted through the entry site 604 towards an anchor site. The metal shaft is withdrawn and the Insertion hub is engaged 606 with the trocar. A pusher rod seats the stopper and transports 608 the anchor 112 up to the anchor site. The cannula is withdrawn 610. The pusher rod is withdrawn 612. The facial tissue is reconfigured 614 according to the desired outcome. The suture 202 is tensioned. Any excess suture is trimmed 616.

According to a particular embodiment, when the winged stopper 1702 is used in the method 600 at step 608, the two wings 1708 compress towards each other such that the two wings are almost a continuation of the cylindrical portion of the winged stopper 1702. In particular, the overall diameter of the winged stopper 1702 compresses to be smaller than the diameter of the cannula, thereby allowing the winged stopper 1702 to be pushed through the cannula to the anchor site. Upon exiting the cannula when reaching the anchor site, the two wings 1708 of the winged stopper 1702 expand back into the uncompressed position such that the two wings 1708 are spaced at a distance that is greater than the diameter of the cannula. In this way, the winged stopper 1702 is unable to be pulled back into the cannula. Further, since the two wings 1708 of the winged stopper 1702 in their uncompressed position are spaced at a distance that is greater than the diameter of the cannula, the overall diameter of the winged stopper 1702 would be larger than the diameter of the entry site, thereby effectively acting as an anchor and staying fixed within the facial tissue.

The entry site is formed using an entry punch 700 as shown in Figure 7. The entry punch may be shipped in a sterile state, with a sealed cover in a sterile inert gas. The entry punch 700 has a hollow metal shaft with a bevelled sharpened tip for puncturing the skin to make the initial opening for the entry site.

The trocar 800 is shown in Figure 8. The trocar 800 is integrally moulded from plastic with the cannula 802. Figures 9 and 10 shows the metal shaft 804 inserted in the cannula 802. The shaft 804 may have a sharpened tip 806 which extends from the cannula 802. The trocar 800 and the shaft 804 may shipped together in a sterile state, with a sealed cover in a sterile inert gas. Alternatively they may be supplied separately. The cannula 802 and the shaft 804, may be 45mm or 100mm long. The cannula 802 has a slightly tapered tip, to assist entry into the tissue. The sharpened tip 806 is at an angle of $45-30^{\circ}$ from the longitudinal axis to assist entry into the tissue.

The cannula 802 may alternatively be extruded from metal, and/or may have the same or higher stiffness as the metal shaft 804.

An alternative trocar 800 is shown in Figure 13. It has a thumb and forefinger grip 1302 to aid with dexterity and control during the insertion process. The grip 1302 is made from a non-slip surface and is arced to minimise the chance of the practitioner's finger slipping during insertion.

The Insertion Hub 214 engages the trocar 800, as shown in Figure 11. Figures 12a to 12c show the pushing rod 900 forcing the stopper 206 into the cannula 802, but no further than the end of

the cannula. The pushing rod 900 includes a silicon cover 1202 in Figure 12c, that the practitioner uses as a handle for moving the rod in and out.

The pushing rod 900 may include a seat designed to engage with the stopper 206 to reliably push it into the cannula. The seat should distribute the force around the stopper 206, to avoid twisting or jamming, and to easily disengage when retracted.

Alternatively the Insertion Hub 214 may be dispensed with, in which case the trocar 800 includes a guided entrance so that pushing rod 900 can insert the seated stopper 206 directly into the cannula 802.

Whilst example embodiments of the invention have been described in detail, many variations are possible within the scope of the invention as will be clear to a skilled reader.

Claims:

1. A suture assembly comprising:
 - an anchor comprising a stopper, the stopper comprising a rigid portion and a resilient portion projecting from the rigid portion,
 - a looped suture having two ends engaged to the anchor, having two barbed zones, and
 - a barb free zone distant from the anchor, wherein the barbs are inclined toward the anchor and/or away from the barb free zone.
2. The suture assembly according to claim 1, wherein the stopper comprises a rigid portion intermediate to at least two resilient portions, the at least two resilient portions projecting from the rigid portion.
3. The suture assembly according to claim 2, wherein the at least two resilient portions comprise at least two wings projecting from opposing sides of the rigid portion, the at least two wings being resiliently compressible towards one another.
4. The suture assembly according to claim 3, wherein the stopper has a first diameter and the at least two wings are transversely spaced by a second diameter which is larger than the first diameter, the wings being resiliently compressible towards one another sufficiently to permit reduction of the transverse spacing between the at least two wings.
5. The suture assembly according to any preceding claim, wherein the stopper is a cylinder, cuboid, cone, or sphere.
6. The suture assembly according to any preceding claim, wherein the suture assembly comprises:
 - a plurality of looped sutures each having a plurality of barbs inclined toward the anchor.
7. The suture assembly according to any preceding claim, wherein the anchor further comprises:
 - a knot at one ends of the looped sutures, wherein the plurality of looped sutures each have a plurality of barbs inclined towards the stopper and the stopper abuts the knot.
8. The suture assembly according to any preceding claim, wherein the barbs are staggered.

9. The suture assembly according to any of claims 1 to 6, wherein the sutures are moulded or secured to the anchor.
10. The suture assembly according to any of claims 1 to 6, wherein the anchor comprises a knot at the ends of the suture, and the stopper abutting the knot.
11. The suture assembly according to claim 10, wherein the stopper includes an internal channel for the suture to pass through.
12. The suture assembly according to any of claims 1 to 6, wherein the anchor comprises a plurality of larger barbs at the end of the suture.
13. The suture assembly according to any preceding claim, further comprising an insertion hub.
14. A method of assembling a suture kit comprising:
providing one or more barbed sutures,
inserting the ends of the suture through an insertion hub;
inserting the ends of the suture through a stopper, the stopper comprising a rigid portion and a resilient portion projecting from the rigid portion; and
knotting the ends of the sutures.
15. The method of claim 14, wherein the stopper comprises a rigid portion intermediate to at least two resilient portions, the at least two resilient portions projecting from the rigid portion.
16. The method of claim 15, wherein the at least two resilient portions comprise at least two wings projecting from opposing sides of the rigid portion, the at least two wings being resiliently compressible towards one another.
17. The method of claim 16, wherein the stopper has a first diameter and the at least two wings are transversely spaced by a second diameter which is larger than the first diameter, the wings being resiliently compressible towards one another sufficiently to permit reduction of the transverse spacing between the at least two wings.
18. The method of any of claims 14 to 17, wherein the stopper is a cylinder, cuboid, cone, or sphere.

19. The method of claim 14 wherein the barbed sutures are looped sutures.
20. The method of claim 14 wherein the barbed sutures are linear sutures.
21. A method of assembling a suture kit comprising:
providing one or more barbed sutures,
moulding or securing the ends of the sutures to a stopper, the stopper comprising a rigid portion and a resilient portion projecting from the rigid portion; and
inserting the suture through an insertion hub.
22. The method of claim 21, wherein the stopper comprises a rigid portion intermediate to at least two resilient portions, the at least two resilient portions projecting from the rigid portion.
23. The method of claim 22, wherein the at least two resilient portions comprise at least two wings projecting from opposing sides of the rigid portion, the at least two wings being resiliently compressible towards one another.
24. The method of claim 23, wherein the stopper has a first diameter and the at least two wings are transversely spaced by a second diameter which is larger than the first diameter, the wings being resiliently compressible towards one another sufficiently to permit reduction of the transverse spacing between the at least two wings.
25. The method of any of claims 21 to 24, wherein the stopper is a cylinder, cuboid, cone, or sphere.