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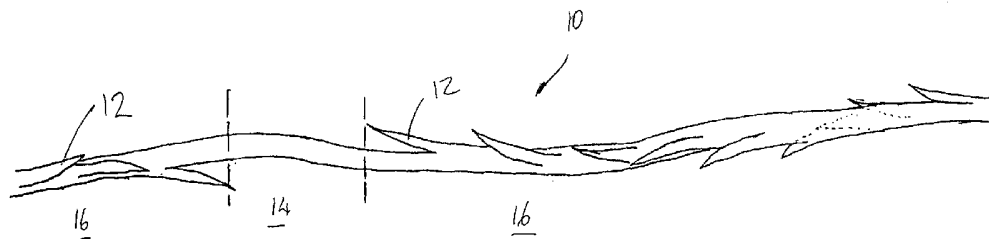
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(54) Title: SURGICAL THREAD



(57) Abstract: Surgical thread includes clear section devoid of projections (12) and multiple sharp projections (12) on either side of clear section, inclined toward clear section (14). Method of use threading subcutaneously through tissue or muscle such that thread is folded back on itself. Thread tension adjusted from both ends at separate exit points (34, 36) to achieve lift. Projections resist thread pull in direction of entry point and clear section is located at fold.



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SURGICAL THREAD

The present invention relates generally to a surgical thread for use in plastic surgery operations and a method of performing plastic surgery operations using the surgical thread.

Background of the Invention

Traditional face lifting techniques involve extensive dissection of the different layers of facial tissue and skin. These tissues are then redraped and rearranged in an upward and posterior direction.

This face lift technique inevitably results in long scars and the risk of complications including skin necrosis, nerve damage, vascular damage, hair loss, displacement of the ears and an unnatural attitude of the face. The largest drawback of these surgical techniques is the significant swelling and bruising caused with downtime from recovery lasting between 2 to 6 weeks, in which time patients are unable to work and prefer to avoid social situations.

Various techniques have been developed over the years to minimise the scarring and tissue dissection caused by face lift procedures. One known technique uses a barbed suture where the barbs are oriented in a direction opposite the thread tension. This suture is inserted as a gentle curve under soft tissue conferring a modest lift as well as a bunching up of the soft tissue, which is desirable in the malar or cheek area.

While this technique has eliminated the need for dissecting and lifting facial tissue and eliminated the scarring and consequential complications, it fails to be as effective in lifting heavy facial soft tissues such as

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that in the forehead and brow, mid face, jowls, lateral face and neck. Heavier tissue in these areas impart a significant pull against the barbs on the surgical thread leading to early slackening and dropping of the facial tissue. Additionally, the "bunching up" effect is not as desirable in the areas of the forehead, jowls, neck and lateral face where tissue is expected to be smooth and taut for a youthful look.

There is thus a need for an improved surgical thread and procedure that is minimally invasive and will effectively suspend tissue.

Summary of the Invention

In one aspect, a surgical thread for plastic surgery operations comprising a clear section and multiple sharp projections on either side of the clear section, wherein the clear section is devoid of projections, and the projections on both sides of the clear section are inclined toward the clear section.

In another aspect, a method of performing plastic surgery operations using a surgical thread having a clear section and multiple sharp projections on either side of the clear section, wherein the clear section is devoid of projections, and the projections on both sides of the clear section are inclined toward the clear section, the method including:

making an incision into tissue at an entry point defining the point of tissue lift;

inserting a cannula in a first pass subcutaneously between the entry point and a first exit point from where tissue is to be suspended;

threading one end of the surgical thread from the entry point through the cannula and out of the first exit

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point until the clear section nears or enters the
incision;

removing the cannula and reinserting the cannula in a
second pass between the entry point and a second exit
5 point spaced from the first exit point;

threading the other end of the surgical thread
through the cannula and out of the second exit point
thereby folding the thread back on itself;

removing the cannula and adjusting the thread tension
10 from both ends of the thread to achieve a desired lift,
the projections resisting thread pull in the direction of
the entry point and the clear section being located at the
fold;

cutting the thread ends; and
15 closing the incision at the entry point.

In yet another aspect, a method of performing plastic
surgery operations using a surgical thread having a clear
section and multiple sharp projections on either side of
20 the clear section, wherein the clear section is devoid of
projections, and the projections on both sides of the
clear section are inclined toward the clear section, the
method including:

making an incision into tissue at an entry point
25 defining the point of tissue lift;

threading one end of the surgical thread from the
entry point subcutaneously through tissue and/or muscle
and out of a first exit point from where tissue is to be
suspended, whereby the thread is threaded until the clear
30 section nears or enters the incision;

threading the other end of the surgical thread
through the entry point and subcutaneously through tissue
and/or muscle and out of a second exit point spaced from a
first exit point thereby folding the thread back on
35 itself;

adjusting the thread tension from both ends of the
thread to achieve a desired lift, the projections

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resisting thread pull in the direction of the entry point and the clear section being located at the fold; and cutting the thread ends and closing the incision at the entry point.

5

Brief Description of the Drawings

The present invention is described further by way of example with reference to the accompanying drawings of which:

10

Figure 1 is a side view of a surgical thread according to an embodiment of the present invention;

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Figure 2 is an enlarged view of a section of the surgical thread;

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Figure 3A illustrates a first step in a face lift procedure according to an embodiment of the present invention;

25

Figure 3B illustrates a second step in the surgical procedure;

Figure 3C illustrates a third step in the surgical procedure; and

30

Figure 4 illustrates various locations of performing a surgical procedure on a person's face according to an embodiment of the invention.

Detailed Description of Preferred Embodiments

The drawings illustrate a surgical thread and method of performing an operation with the surgical thread which produces an improved soft tissue lift capable of

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sustaining a longer lift than that achievable with known surgical threads and face lift procedures.

In the following description specific examples are made to surgical lifting operations on a person's face. However, it is to be understood that the procedure finds equal applicability, and is likely to be used in, other procedures including breast lifting, buttock lifting and the lifting of any other part of the human body that may be desired to be lifted.

While the description herein refers specifically to surgical procedures performed on humans, it is conceivable that the procedure could be performed on non-humans, and specifically in veterinary medicine on animals.

Figure 1 illustrates a length of surgical thread for use in surgical procedures, and in particular plastic and cosmetic surgery. The thread can be made of any soft, resilient and bio-compatible material. In a preferred embodiment the thread material is made of polypropylene but it is also envisaged that other suitable materials could include gold, stainless steel and dissolvable suture materials such as polydioxanone. Additionally, the thread may be made of varying grades and thicknesses of these materials, depending on the area being lifted and on the desired effect. In this embodiment the thread thickness is between a 3.0 gauge (0.3mm diameter) and a 2.0 gauge (0.35mm diameter) suture.

The surface of the thread contains a number of spaced bi-directional sharp projections known as barbs. The surgical thread is divided into sections or zones and barbs occupy two of these zones. Specifically, a clear zone or section is located substantially at the mid center of the length of thread and is devoid of any

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barbs 12. The surface of the surgical thread 10 in the clear zone 14 is relatively smooth.

On either side of the clear zone 14 are barb sections 5 16 where the surface of the thread is provided with barbs 12. The barbs 12 are inclined relative to the thread such that when inserted into soft tissues the barbs allow the thread to be pulled with ease through the tissue in one direction but resist pulling, or unthreading, of the 10 thread in the opposite direction by digging their sharp ends into the surrounding soft tissue in resistance.

The inclination of the barbs in the two barb sections 16 on either side of the clear zone 14 are oriented in 15 opposite directions. Figure 2 shows in an enlarged view the clear zone 14 and barb zones 16 on either side of the clear zone. It can be seen from this figure that the barbs 12 to the left of the clear zone 14 are inclined towards the right hand side of the figure, whereas the 20 barbs 12 to the right of the clear zone 14 are inclined in the opposite direction to the left hand side of the figure. The barbs in both barb zones are all pointing towards the clear zone 14.

25 The barbs are created by cutting or etching into the surface of the surgical thread 10 in a manner to produce a sharp tip 18 of the barb 12.

The barbs are furthermore spaced around the surgical 30 thread in a spiral formation. This can be seen in Figure 2. The spiral nature of the barbs means that when the surgical thread is threaded subcutaneously through soft tissue the thread is able to achieve a better hold on the surrounding tissue in all directions.

35

End zones 20 are located at the ends of the surgical thread and next to barb zones 16. End zones 20 are also devoid of barbs 12.

5 In a preferred embodiment the surgical thread is 60 to 65cm long. This includes the clear zone 14 being about 4cm in length, two barbed zones 16 each about 20cm in length and two end zones 20 each 10 to 15cm in length.

10 The barbs are spaced at intervals of about 1 to 2mm. One 360° spiral revolution spans about approximately 35 to 45mm. Approximately 18 to 22 barbs are contained in one spiral revolution. Therefore, a barbed zoned 20cm in length contains about 5 spirals.

15 Each barb is 1 to 2mm long and occupies 1/6 to 1/4 the thickness of the thread.

20 The above dimensions are illustrative of a working embodiment of the surgical thread but are not to be considered in a restrictive manner.

25 Variations to the above preferred dimensions while retaining the concept of the surgical thread are possible. For example, the barb revolutions may be quite tight with only 4 to 6 barbs per revolution. Alternatively, the spacing between barbs may vary, or the barb lengths themselves may be shorter or longer, depending on the precise end use of the thread and limitations of the manufacturing equipment.

30 The present surgical thread 10 is used in a manner to create a "sling" effect on the tissue portion to be lifted by the surgery. In other words, the thread is intended to be doubled back on itself with the clear zone 14 defining the fold and engaging the portion of tissue to be lifted. Accordingly, rather than the tissue being lifted at a

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single point defined by the end of the threads, as currently known, the present thread lifts, or takes hold of, more tissue by using the sling created by the looped fold to lift the tissue, resulting in a more secure and reliable lift.

Meanwhile, the lift is anchored at end zones 20 (or in barb zones 16 if the thread is cut short) which are held at a higher gravitational point in tissue or muscle. End zones 20 are not, however, burdened with bearing the entire load of the lift. Owing to the distribution of inclined barbs along the embedded length of the surgical thread 10 the load is evenly borne against gravity along the thread length in a self retaining manner.

To illustrate more clearly the manner in which the thread is used, the steps in performing the surgical lift procedure are illustrated in Figure 3A to 3C. These figures illustrate the surgical technique in conducting a mid face suspension, or brow lift, on a person's face.

To begin, a surgeon first assesses the degree of slack in the pre-operational face and decides on the desired shape of the cheek or mid face area. The surgeon then marks the patient's skin identifying the point that will be lifted and the position of the two anchor points higher up the face from where the lift will be supported.

After administering to the patient local anesthetic blocks and local infiltration, the surgeon makes a small stab incision in the soft tissue at the lift point defining the entry point 30 as illustrated in Figure 3A. Bluntly dissecting the stab incision the surgeon creates a space at the entry point 30 subcutaneously of about 0.5cm radially around the stab incision. By creating this space dimpling in the post operative period is avoided.

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A cannula 32, or insertion needle, is next introduced into the entry point 30 and threaded in a first pass 25 through the soft tissue and/or muscle under the skin following the markings on the skin and passing upwards 5 along a glide plane to exit at a first exit point 34 at the scalp 35 behind the hairline, and namely on the hair bearing scalp.

As illustrated in Figure 3A, one end of the surgical 10 thread 10 is passed from the entry point 30 through the cannula 32 and up through the first exit point 34. The surgical thread is threaded through the cannula until the clear zone 14 nears or begins to enter the cannula at the incision entry point 30. The threading of the thread 15 stops at this point, so that typically half the length of surgical thread is threaded and half remains hanging from the cannula at the entry point. Accordingly, at this stage the mid point of the thread is usually located around the entry point 30.

20

The cannula is then removed and compression is applied to the bleeding points.

Figure 3B illustrates the next step and shows the 25 second pass 26 of the cannula which begins at a second exit point 36 in the scalp behind the hair line a short distance from the first exit point 34. The second exit point is about 0.5 to 1cm away from the first exit point. The cannula is then inserted down from the second exit 30 point 36 through subcutaneous muscle and soft tissue to emerge through the initial stab incision at entry point 30. The path of this second path of the cannula is substantially parallel to the first path.

35

With the cannula forming a clear path through the facial tissue the other unthreaded end of the surgical thread 10 is threaded from entry point 30 up through the

- 10 -

cannula to exit out of the second exit point 36. This step is illustrated by Figure 3C.

5 The cannula is then removed and compression is applied to the bleeding points.

10 The surgical thread thus extends from the scalp 35 down through to the initial entry point 30 where the tissue is to be lifted, looped (or folded) back on itself to extend back up through the soft tissue and muscle below the skin to exit back at the scalp 35.

15 Loop 38 of the surgical thread 10 in Figure 3C is at this point still located above the surface of the face. If threaded correctly, the loop 38 is formed by the clear zone 14 of the surgical thread 10. Additionally, the embedded sections of thread should include the barbed zones 16 in which the barbs are pointed downward toward the clear zone and hence towards the point of lift.

20

Tension is then applied to the thread by pulling up ends 22 at the exit points 34,36 in the directions illustrated by the arrows in Figure 3C. Because the barbs point away from thread ends 22, the threads are able to be easily pulled and loop 38 is drawn through the entry point 25 30 incision grabbing hold of the tissue thereunder. Thread ends 22 are carefully adjusted to ensure that clear zone 14 is positioned substantially central of loop 38. The barbs on the embedded thread prevent the surgical threads slipping down or being pulled down under the 30 natural gravitational tension in the tissue.

35 Once loop 38 has been drawn into the space created subcutaneously under entry point 30, further tension is applied on thread ends 22 until the desired level of mid face lift is achieved.

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A needle (not shown) is then passed subcutaneously through the first and second exit points 34,36 on scalp 35 and one end of the surgical thread 10 is passed through the needle such that both ends now exit from the same exit point.

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. The tissue openings at the entry point 30 is then closed over by regular means such as stitching or compression.

In an alternative embodiment the thread ends can be simply left protruding from their respective exit points and cut flush with the exit opening. In this embodiment the thread relies on the angled barbs to retain it under the skin without slipping and to ensure stable elevation of the tissue.

If during the operation it is anticipated that a post operative adjustment will be required, the surgical thread 10 should only be knotted once and fair length of thread ends retained to enable subsequent tensioning and knotting of the thread.

The mid face lift procedure would then be repeated on the opposite side of the face at a suspension point symmetrical to the first point lifted.

The surgical procedure described above incorporates subcutaneous insertion of a cannula through which the surgical thread can be threaded. However, it is envisaged that other instruments may be used to pass the thread between the entry and the two exit points. A cannula is a suitable instrument to achieve this but other suitable

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instruments, such as a solid needle-type instrument, or the like, may also be used.

5 Other face lift procedures are performed in a similar manner with minor variations. For example, another kind of mid face malar mound suspension may require lift of two points on each malar mound. These points are illustrated in Figure 4 as point 40 which is just below mid point of the malar mound and a second point 42 at the bottom of the
10 malar mound, where a natural dimple occurs. In this procedure all four threads exiting two pairs of first and second exit points 34, 36 would need to be adjusted simultaneously to acquire the desired mid face lift.

15 An example of an intra hair line lift is illustrated in Figure 4 with the lift occurring at point 44 on the hair line 46. A shorter length of surgical thread 10 would be required for this procedure. In practice, the normal thread length would be used and cut back to the
20 appropriate length.

While all these operations may be performed with a standard length of surgical thread, the thread may be manufactured at different lengths to serve different
25 lifting purposes for different areas of the anatomy. Similarly, the clear zone 14 may not necessarily be central to the length of thread but may be more to one side depending on the purpose for which the thread is used.

30

Figure 4 also illustrates an eye lift 48, a brow lift 50 and a neck lift where the incisions for suspension are made at the platysmal bands 52 and 53. In this case the incision would be specifically made in the midline
35 just medial to each band at the level of the mentocervical angle.

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A technique for performing a jowl suspension is not illustrated but such a procedure would commence with making two stab incisions at the level of the angle of mandible through the bulk of the jowl mound and a third
5 stab may be required at the level of the marionette line.

In all of the above examples, the surgical thread would be threaded in a similar fashion to that explained in relation to Figures 3A to 3C. In a similar manner, any
10 tissue suspensions not involving the face, such as breast and buttocks, would involve the careful assessment of optimal thread entry and exit points followed by insertion of the cannula and threading the surgical thread in a sling as described above.

15

With the present "sling"-technique a stronger lift of tissue and muscle may be achieved and in fact the lift is doubled in strength because two lengths of thread are used to lift the tissue. The bi-directional spiral barbs
20 prevent the tissue sagging and the thread slipping into early slackening. The clear zone of the thread allows room for adjusting and manipulating the thread once inserted subcutaneously and to provide strength and reliability to the 'sling' portion of the thread holding
25 the lift.

The present surgical thread and method can be used for lifting more than just full, soft tissue but will also pull skin taut along the length of the thread to give the
30 appearance of evenly smooth and taut skin. The overall result is a non-invasive procedure and a non-obvious, smooth face lift that will reliably last for years.

It will be understood to persons skilled in the art
35 of the invention that many modifications may be made without departing from the spirit and scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A surgical thread for plastic surgery operations comprising a clear section and multiple sharp projections on either side of the clear section, wherein the clear section is devoid of projections, and the projections on both sides of the clear section are inclined toward the clear section.
2. The surgical thread claimed in claim 1, wherein the clear section is located substantially midway along the thread.
3. The surgical thread claimed in claim 1, wherein the sharp projections are arranged in a spiral around the thread.
4. The surgical thread claimed in claim 1, wherein the thread has end zones at the end of the thread that are clear of sharp projections.
5. The surgical thread claimed in claim 1, wherein the sharp projections are barbs cut into or etched into the thread.
6. The surgical thread claimed in claim 3, wherein one spiral revolution of sharp projections contains approximately 18 to 22 sharp projections.
7. The surgical thread claimed in claim 6, wherein one spiral revolution of sharp projections spans approximately 35 to 45mm.
8. The surgical thread claimed in claim 1, wherein the sharp projections are spaced at intervals of about 1 to 2mm.

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9. The surgical thread claimed in claim 1, wherein each sharp projection is 1 to 2mm in length.

5 10. The surgical thread claimed in claim 1, wherein each sharp projection occupies 1/6 to 1/4 the thickness of the thread.

10 11. The surgical thread claimed in claim 1, wherein the thread is approximately 60 to 65cm long and has a diameter of approximately 0.30 to 0.35mm.

15 12. The surgical thread claimed in claim 4, wherein the clear section is approximately 4cm in length, the sharp projections occupy a length of about 20cm on either side of the clear section, and the end zones are approximately 10 to 15cm in length.

20 13. The surgical thread claimed in claim 12, wherein the surgical thread is approximately 60 to 65cm in length.

14. The surgical thread claimed in claim 1, wherein the thread is made of polypropylene.

25 15. A method of performing plastic surgery operations using a surgical thread having a clear section and multiple sharp projections on either side of the clear section, wherein the clear section is devoid of projections, and the projections on both sides of the clear section are inclined toward the clear section, the
30 method including:

making an incision into tissue at an entry point defining the point of tissue lift;

35 inserting a cannula in a first pass subcutaneously between the entry point and a first exit point from where tissue is to be suspended;

threading one end of the surgical thread from the entry point through the cannula and out of the first exit

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point until the clear section nears or enters the
incision;

removing the cannula and reinserting the cannula in a
second pass between the entry point and a second exit
5 point spaced from the first exit point;

threading the other end of the surgical thread
through the cannula and out of the second exit point
thereby folding the thread back on itself;

removing the cannula and adjusting the thread tension
10 from both ends of the thread to achieve a desired lift,
the projections resisting thread pull in the direction of
the entry point and the clear section being located at the
fold;

cutting the thread ends; and
15 closing the incision at the entry point.

16. The method claimed in claim 15, further including
inserting a cannula in the first pass from the entry point
to the first exit point and inserting a cannula in the
20 second pass from the second exit point to the entry point.

17. The method claimed in claim 15, further including
tying at least one knot in the thread ends.

25 18. The method claimed in claim 15, further including
inserting a needle between the two threaded exit points
and threading one end of the thread through the needle
such that both threads emerge from the same exit point,
tying the thread ends together in a knot and cutting the
30 ends flush to the knot.

19. The method claimed in claim 15, including selecting
exit points on the scalp behind the hairline.

35 20. The method claimed in claim 15, including locating
the entry point above the brow for a brow lift.

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21. The method claimed in claim 15, including locating the entry point on the mid point of the malar mound for a mid face suspension.

5 22. The method claimed in claim 21, including making a second entry point for a second lift on the bottom of the malar mound for a fuller mid face suspension.

10 23. The method claimed in claim 15, including locating an entry point anterior to the hair line and the exit points high in the temporal scalp for an intra hairline suspension.

15 24. The method claimed in claim 15, including locating the entry point just below the lateral canthus for a lateral canthal suspension.

20 25. The method claimed in claim 15, including locating the entry point at the level of the angle of mandible through the bulk of the jowl mound for a jowl suspension.

25 26. The method claimed in claim 15, including locating two separate entry points for two separate lifts in two of the platysmal bands for a neck lift.

30 27. A method of performing plastic surgery operations using a surgical thread having a clear section and multiple sharp projections on either side of the clear section, wherein the clear section is devoid of projections, and the projections on both sides of the clear section are inclined toward the clear section, the method including:

making an incision into tissue at an entry point defining the point of tissue lift;

35 threading one end of the surgical thread from the entry point subcutaneously through tissue and/or muscle and out of a first exit point from where tissue is to be

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suspended, whereby the thread is threaded until the clear section nears or enters the incision;

threading the other end of the surgical thread through the entry point and subcutaneously through tissue
5 and/or muscle and out of a second exit point spaced from a first exit point thereby folding the thread back on itself;

adjusting the thread tension from both ends of the thread to achieve a desired lift, the projections
10 resisting thread pull in the direction of the entry point and the clear section being located at the fold; and

cutting the thread ends and closing the incision at the entry point.

15 28. The method claimed in claim 26, further including inserting a cannula between the entry point and each exit point, whereby the surgical thread is threaded through the cannula the cannula being removed after threading.

FIGURE 1

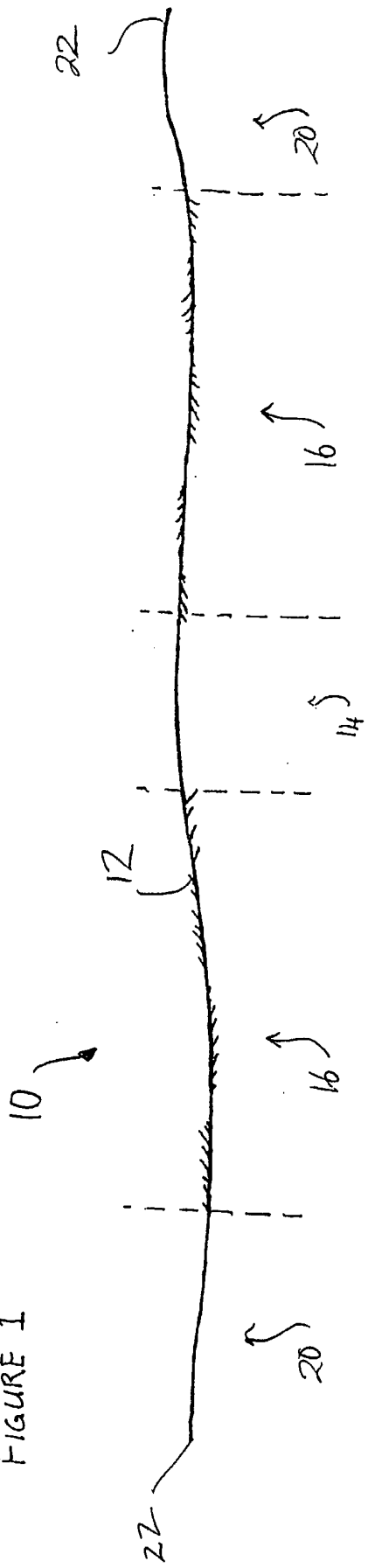


FIGURE 2



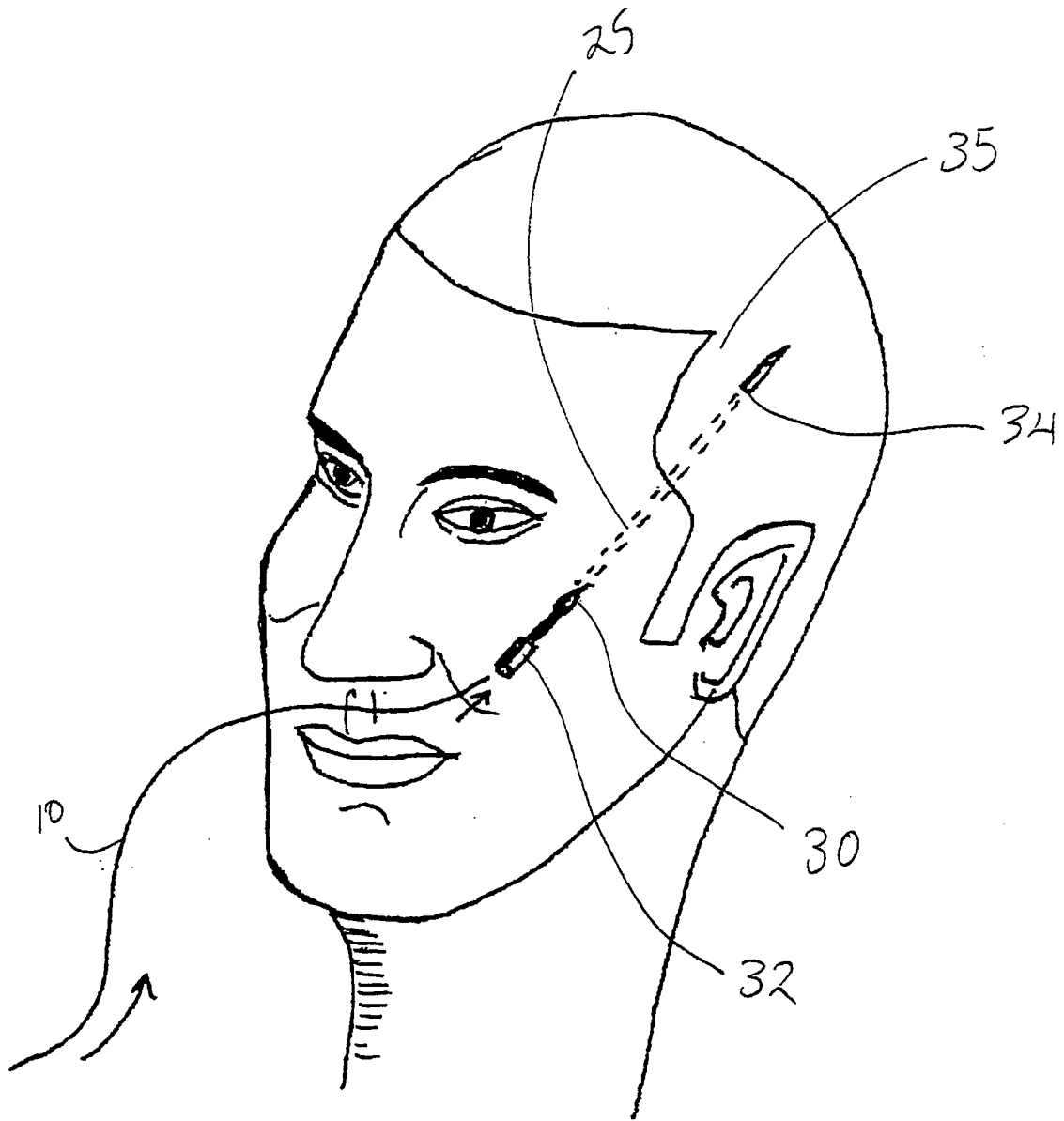


FIGURE 3A

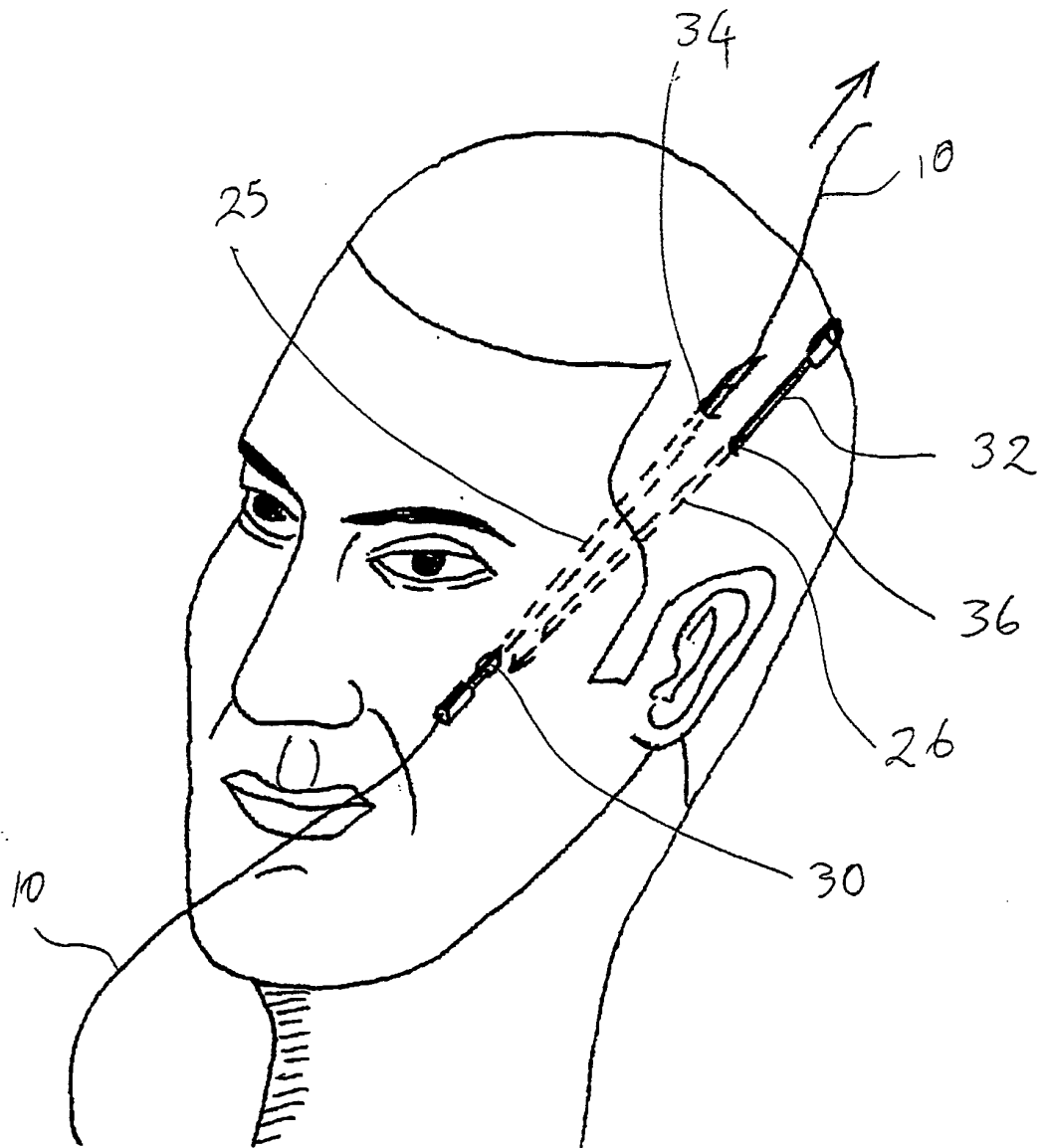


FIGURE 3B

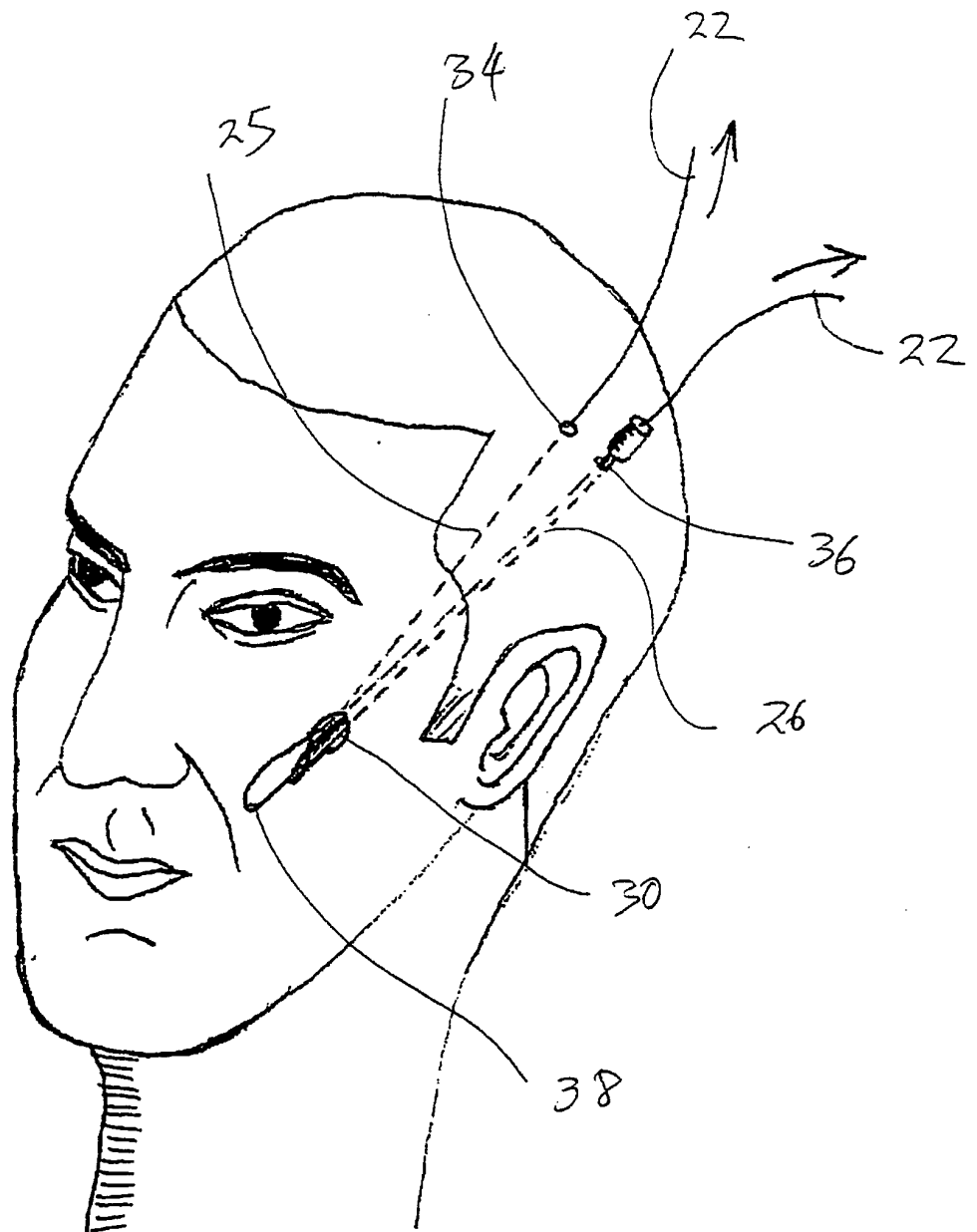


FIGURE 3C

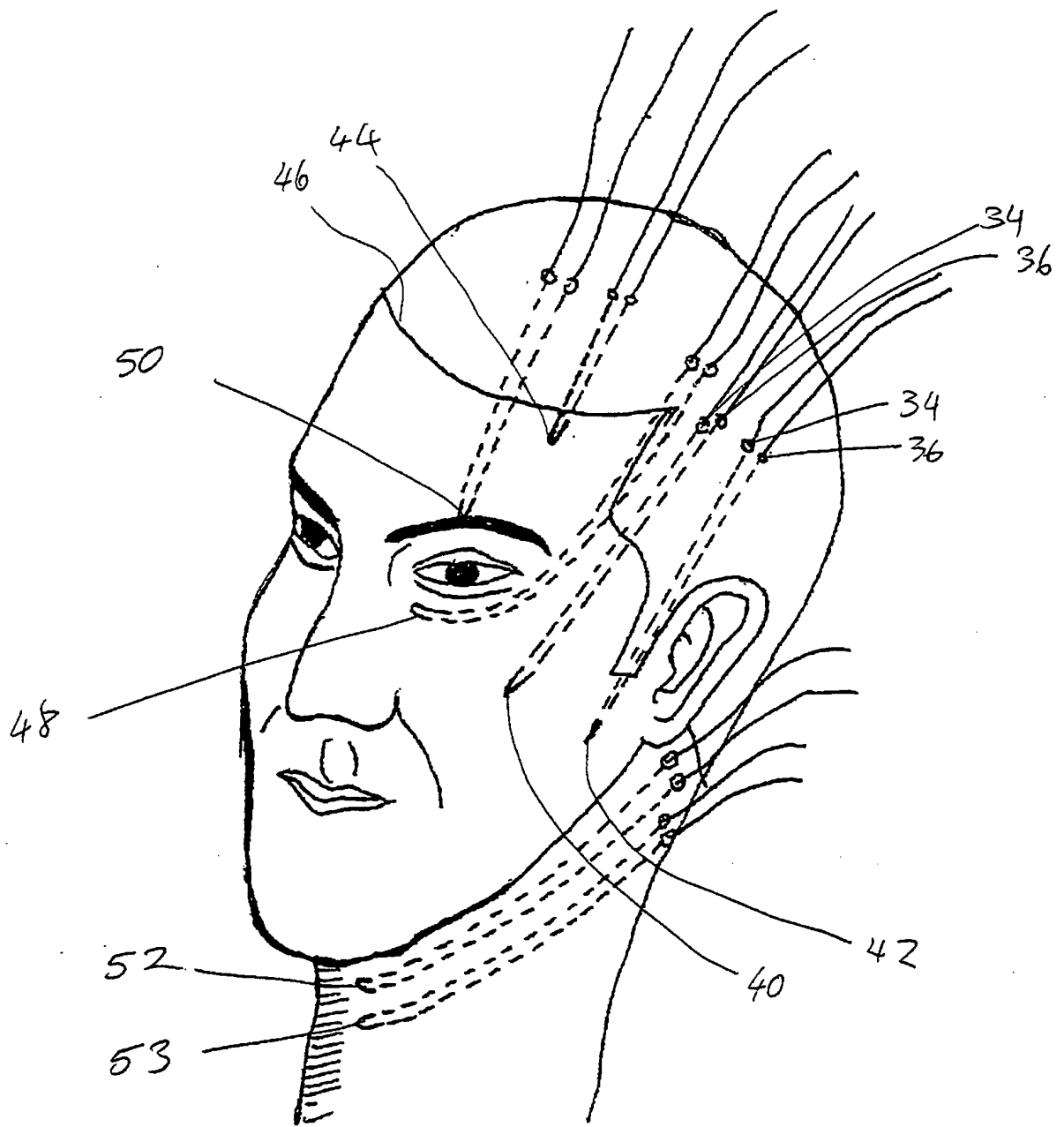


FIGURE 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2004/000090

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁷ : A61B 17/04 According to International Patent Classification (IPC) or to both national classification and IPC																	
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI + keywords: surg thread suture barb spine hook spur and similar terms																	
C. DOCUMENTS CONSIDERED TO BE RELEVANT																	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.															
X	US 6270517 B1 (BROTZ) 7 August 2001 Columns 4-6 and figures.	1, 2, 4, 5															
X	US 5584859 B1 (BROTZ) 17 December 1996 Columns 3-5 and figures	1, 2, 4, 5															
X	BE 1014364 A6 (COLLETTE) 2 September 2003 Pages 3-13	1, 2, 4, 15-17, 27, 28															
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																	
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Date of the actual completion of the international search 19 May 2004	Date of mailing of the international search report 25 MAY 2004																
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer Sue Thomas Telephone No : (02) 6283 2454																

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2004/000090

Information on patent family members

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member
BE 1014364	NIL
US 5584859	US 5425747
US 6270517	NIL

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX