United States Patent

Allen

[15] **3,699,969**

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[54] **METHOD FOR IMPLANTING NATURAL OR SYNTHETIC FIBERS INTO LIVING TISSUE**

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[51] **Int. Cl.**.....**A61b 17/00,** A61b 17/34, A61f 1/00

[58] **Field of Search** 3/1; 128/329, 330

[56] **References Cited**

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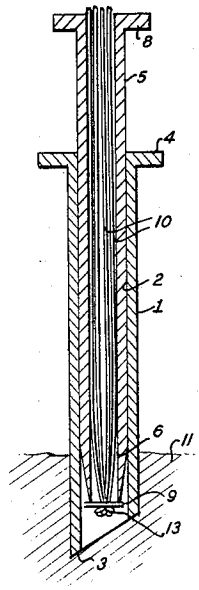
[57] **ABSTRACT**

A method for implanting natural or synthetic fibers directly into the skin, particularly the scalp. The method is effected by the use of a concentric dual needle arrangement that comprises a first, outer needle and a second, inner needle slideably mounted within the outer needle. The fibrous material to be implanted is threaded within the inner needle, the latter then being "loaded" or mounted within the bore of the outer needle. The two needles are then inserted simultaneously into the scalp. The outer needle is withdrawn first to expose the fibrous strands to the tissue. The inner needle is next withdrawn leaving the fibrous strands implanted in the tissue. The method is highly effective, safe and requires a minimum of manipulative steps.

4 Claims, 6 Drawing Figures



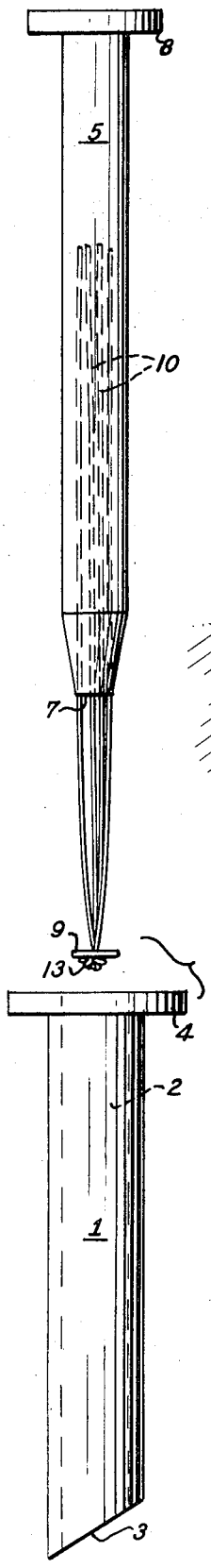


FIG. 1

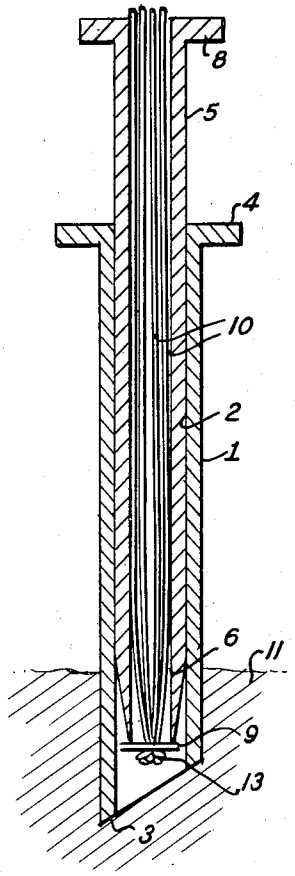


FIG. 2

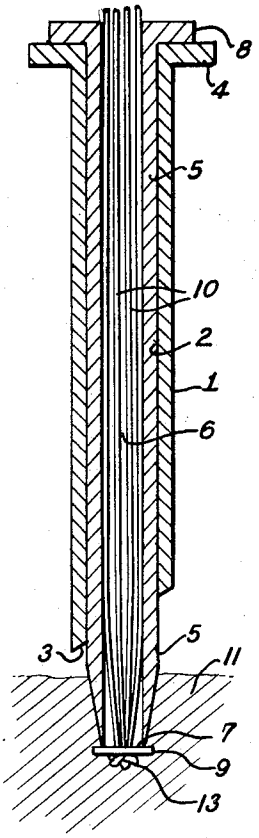


FIG. 3

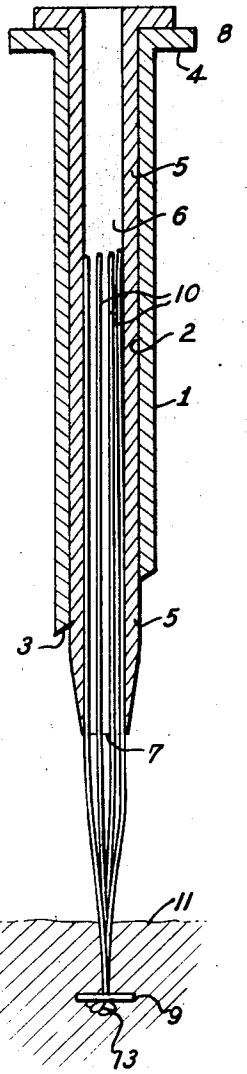


FIG. 4

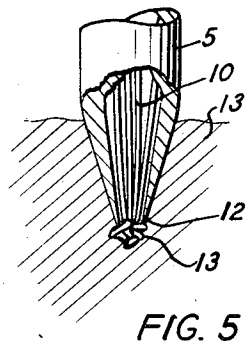


FIG. 5

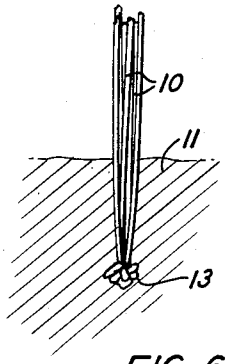


FIG. 6

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METHOD FOR IMPLANTING NATURAL OR SYNTHETIC FIBERS INTO LIVING TISSUE

The present invention relates to the treatment of living tissue. More particularly the present invention relates to an improved method for implanting natural or synthetic fibers into human skin, i.e., the scalp, in a manner such that the artificial hair thus produced appears completely natural and can be cared for as if it were natural hair.

As is well known in the art, prior art workers have for many years focused much time and attention with the problem of "baldness." Thus the use of hairpieces, i.e., wigs or toupees, is now common place. In general, conventional hairpieces suffer from a number of disadvantages including the requirement of special care e.g., combing, and added bulk and discomfort to the wearer. In more recent years special techniques, such as so-called "hair transplants" have been developed and employed in the treatment of baldness. While satisfactory, such procedures are relatively expensive, time consuming and often result in scars due to the requirement of "donor sites."

In summary, the present invention relates to the method for implanting natural or synthetic fibers directly into the skin, particularly the scalp, with such a degree of perfection so as to render the hair covering thus produced substantially unnoticeable and natural looking in all respects. Stated broadly, the method of the invention is highly efficient, requires a minimum of manipulative steps and involves the use of a concentric-dual needle arrangement that, as will be described in detail hereinbelow, comprises a first, outer needle and a second, inner needle slideably mounted within the outer needle. By reciprocating (in accordance with the method steps of the invention) the pointed end of the outer hollow needle, into, through and out of the tissue area being treated, there is produce an artificial hair covering that gives the appearance of completely natural hair and which may be cared for as one would his own natural hair. In accordance with one method embodiment of the invention, the natural or synthetic fibers are firmly attached to the skin by the use of novel retaining elements. The method of the present invention is not subject to the disadvantages of the above discussed, prior known techniques and has been found to be safe, practical and highly efficient, there being little or no tendency for the body to reject the artificially implanted fibers.

It is accordingly a general object of the invention to provide an improved method for implanting natural or synthetic fibers directly into living tissue.

Another, and more particular object of the invention, is to provide a method for implanting natural or synthetic fibers into the skin, especially the scalp, which method is highly efficient, safe and involves a minimum of manipulative steps.

Yet another object is to provide a method for producing an artificial hair covering that may be cared for in the same manner as natural hair and requires no special treatment other than normal hygenic care.

A further object is to provide an improved method for implanting natural or synthetic fibers directly into the skin or scalp in a manner to form a hair covering that in all respects give the impression of natural hair, said method not being subject to the disadvantages of prior known techniques.

Still a further object is to provide a unique method for implanting artificial hair into the skin or scalp which does not result in the body rejection of said artificially implanted hair.

The manner in which the foregoing and other objects are achieved in accordance with the present invention will be better understood in view of the following detailed description and accompanying drawings which form a part of the specification, and wherein:

FIG. 1 is an exploded view in side elevation illustrating a preferred apparatus embodiment employed in the method of the present invention with, as shown, fibers partly threaded into an inner needle and an outer needle below said inner needle;

FIG. 2 is a sectional view in side elevational illustrating the manner of inserting the needles in the tissue;

FIG. 3 is a view corresponding to FIG. 2 showing the outer needle withdrawn from the tissue;

FIG. 4 is a view corresponding to FIGS. 2 and 3 showing the outer and inner needles withdrawn from the tissue and further illustrating the fibrous strands anchored or held in place by means of retaining elements employed in a first embodiment of the method of the invention; and

FIGS. 5 and 6 are sectional views in side elevation illustrating a second embodiment for anchoring the fibrous strands to the tissue and the method of implanting same into the tissue.

Turning now to the drawings in detail and first to FIGS. 1–4, there is shown a preferred and particularly advantageous apparatus embodiment for carrying out the method of the invention. As shown, the apparatus, referred to herein as a concentric, dual needle arrangement, comprises a first, outer needle indicated generally at 1. The needle 1 is generally tubular and includes an elongated bore 2 extending therethrough. At its forward end, the needle 1 is formed with a sharp pointed bevel tip 3. A concentric flange or shoulder 4 is provided at the opposite of the needle 1 as clearly shown in the drawings. The flange 4 may be formed integral with the tubular body of the needle 1 or may be secured thereto in any suitable manner as is well known in the art.

With reference again to FIGS. 1–4, a second, inner needle, indicated at 5, is provided and adapted to be reciprocably or slideably mounted within the bore 2 of the needle 1. The outer diameter of the needle 5 is, of course, of a size slightly smaller than the diameter of the bore 2 so that the needle 5 can slide freely within the bore of the outer needle. The inner needle 5 is also generally tubular and includes a longitudinally extending bore or opening 6. The diameter of the bore 6 should be such so as to allow threading of a plurality of natural or synthetic fibers, indicated generally at 10. In general from one to eight fibrous strands may be implanted by a single needle insertion.

As shown the inner needle 5 is provided, at its forward end, with a flat tip 7 which is generally perpendicular to bore or body portion of the needle 5. A flange or shoulder portion 8 is also provided at the opposite end of the needle 5.

Turning now to more specific details of the invention and again with reference to the embodiment shown in FIGS. 1–4, the forward ends of the natural or synthetic fibers are attached or secured to a retaining or anchoring member, indicated at 9. The retaining member 9 is

preferably disc-shaped and is formed from any suitable inert plastic, such as Teflon or Nylon. The disc-shaped retaining means **9** may include a number of perforations so that the fibrous strands **10** may be secured thereto simply by tying the ends of strands into a suitable knot or loop **13** as illustrated in FIGS. **1–4**. The outer diameter of the disc-shaped member **9** should be such that it cannot slip or pass through the bore **6** of the inner needle **5** but must be smaller than the diameter of the bore **2** of the outer needle **1**.

In practicing the method of the invention, the forward ends of the fibrous strands **10** are secured to the retaining element **9**, as discussed above, and the fibrous material is then threaded through the bore **6** of the needle **5** as shown in FIG. **1**. With the fibers being held or drawn tight, the inner needle **5** is inserted into the outer needle **1** to a point such that the retaining element **9** is recessed from, or above, the uppermost point of the beveled tip **3**.

With the needles in this "loaded" position, and again with the fibers being held tight, the needles are inserted or introduced into the scalp or skin tissue, indicated generally at **11**, as shown in FIG. **2**. As indicated above, the forward tip of the inner needle is recessed from the uppermost point of the beveled tip **3**. As illustrated in FIG. **2**, this positional relationship is maintained during the initial insertion of the needle into the scalp.

The outer needle **1** is then gently withdrawn as, for example, by grasping the upper flange **4** until this flange is flush or butts against the lower surface of the flange **8** as illustrated in FIG. **3**. After the outer needle is withdrawn, the small retaining element **9** is exposed to the tissue of the scalp which falls around it, holding it in place. Thereafter, and with reference to FIG. **4**, the inner needle is gently withdrawn, leaving the fibrous strands firmly implanted in the scalp.

At this point it may be noted that the fibrous strands employed in the method of the invention may be either natural or synthetic fibers as is well known in the art. Thus the expression "synthetic fibers" is intended to include, but is not limited to, polymeric materials such as polyamides, e.g., nylon; polyolefins, as e.g., polyethylene, polypropylene; polyesters and the like. A preferred class of synthetic fibers include poly (alpha) olefins, e.g., polyethylene and polypropylene. Preparation of the latter polymeric products are disclosed e.g., in U.S. Pat. Nos. 2,825,721; 2,911,304; 3,008,829; 3,062,801 and 3,078,280. As indicated, the above materials are well known in the art. "Natural fibers" include e.g., animal or human hairs, which preferably have been treated or coated to preserve the life thereof and to render same relatively inert. Also in recent years it has become known to coat the above discussed synthetic fibers with various materials, e.g., silicons, and the use of such coated strands has been found to be particularly advantageous in the practice of the instant invention.

Turning now to FIGS. **5** and **6**, and in accordance with a second embodiment of the present invention, the forward end of the inner needle **5** may be formed such that the tip thereof converges to form a small opening, indicated generally at **12**. In this manner the use of the retaining element is not required,i.e., the ends of the fibers **10** are restrained by merely forming a knot or loop of an appropriate size. In this regard, and as will be readily appreciated by those skilled in the art, the needles employed in the present invention are so-called "-hypodermic" needles and, while the drawings have shown same in exploded or enlarged views, such needles are in fact small in size.

Notwithstanding which embodiment is employed, the above discussed procedure i.e., inserting and withdrawing the dual needles, is repeated until the area of "baldness" is sufficiently covered with the artificial fibers. In general an average bald head has approximately 25 square inches. In accordance with the present invention it has been found that 64 insertions (four strands per insertion) are required to cover about 1 ½ square inches.

In accordance with the instant invention it has been discovered that there is little or no tendency for the body to reject the implanted natural or synthetic fibers even when the small disc or retaining element **9** is employed. This is believed to be due, in part, to the fact that the tendency for body rejection is related to the mass or caliber of the foreign objects. Thus in a series of tests, and employing the dual hypodermic needle arrangement illustrated in FIGS. **1–4**, 320 implantations were made on four male subjects of the ages of from 30 to 45. High density polypropylene fibers were employed. After a period of 6 weeks no evidence of body rejection was noted for the implanted fibers. In a series of further tests, nylon fibers were substituted for the polypropylene fibers. The results of these tests evidenced no body rejection or allergies.

While preferred embodiments have been disclosed for illustrative purposes, it will be understood by those skilled in the art that numerous modifications may be made without departing from the scope of the invention as defined in the following claims. For example, the method of the present invention may be practiced by mounting a plurality of the dual-needles, as illustrated in FIGS. **1–4**, onto a suitable machine or on a support member, the configuration of which, conforms to the area, e.g., the scalp, being treated.

What is claimed is:

1. A method for implanting natural or synthetic fibers into living tissue comprises the steps of providing an outer needle; said outer needle having a longitudinal bore extending therethrough and a sharp tip at a forward end thereof; providing an inner needle, said inner needle being adapted to be reciprocably mounted in said bore of said outer needle and having a longitudinal bore extending therethrough and a forward end; providing an enlargement on the end of at least one fibrous strand selected from the group consisting of natural and synthetic fibers, said enlargement having a diameter greater than the diameter of said bore of said inner needle; inserting said fibrous strand into the bore of said inner needle with said enlargement adjacent the forward end of said inner needle; inserting said inner needle and fibrous strand into the bore of said outer needle to a position in which said forward end of said inner needle is adjacent the tip of said outer needle and said enlargement is within said tip; simultaneously inserting the outer and inner needles into living tissue and to a depth in which the enlargement is below the surface of said tissue; withdrawing said outer needle from said tissue while holding said inner needle and fibrous strand against movement relative to said tissue; and

withdrawing said inner needle from said tissue whereby said enlargement retains said fibrous strand in said tissue.

2. The method in accordance with claim 1 wherein the steps of providing said enlargement comprising connecting the common ends of two or more of said fibrous strands to a disc-shaped retaining element, said disc having a diameter greater than the bore of said inner needle and less than the bore of said outer needle.

3. The method in accordance with claim 2 wherein said fibrous strand is a synthetic fiber.

4. The method in accordance with claim 1 wherein the steps of providing said enlargement comprises tying at least two fibrous strands together adjacent a common end thereof such that said enlargement is larger than the opening formed at the forward end of said inner needle.

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