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(54) **METHOD AND APPARATUS FOR
EXTRACTION OF FOLLICULAR UNITS**

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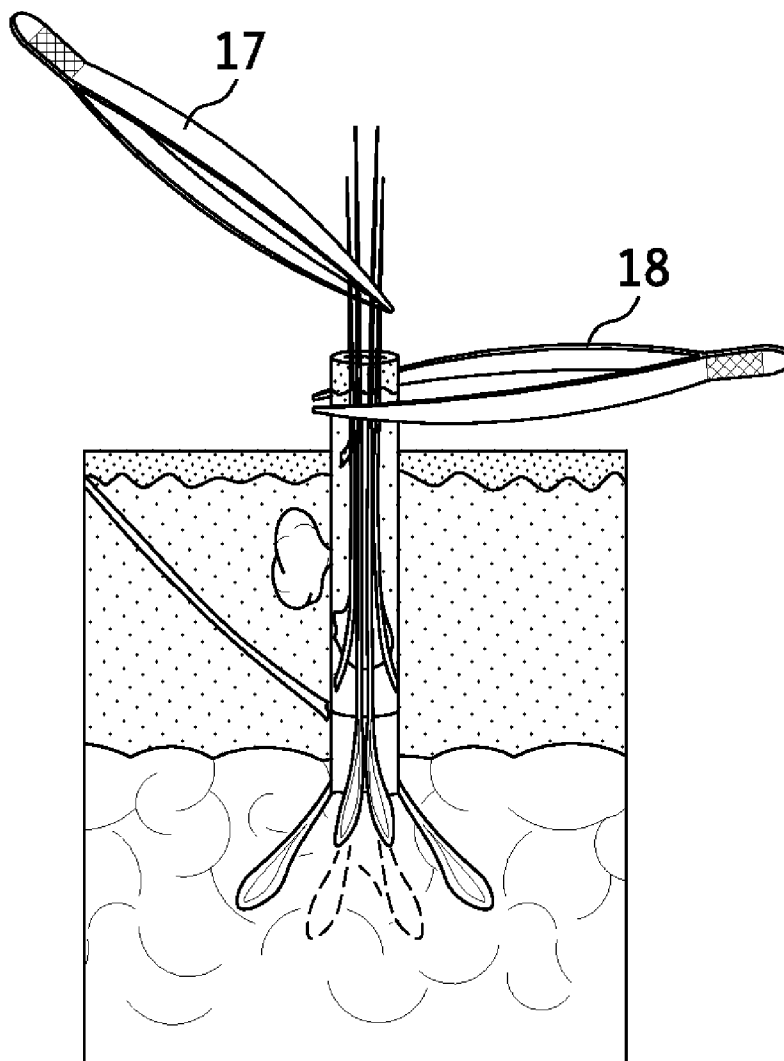
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A45D 26/00 (2006.01)

(57) **ABSTRACT**

A punch for drilling around a follicular unit may be provided. The punch may include an elongated cylindrical tubing having a proximal end, a distal end and a central lumen therebetween. The punch may further include a bulging body with an elongated cylindrical portion at a distal end and an about 45 degree sloping conical portion at a proximal end. The punch may further include an elongated handle having a proximal end and a distal end.



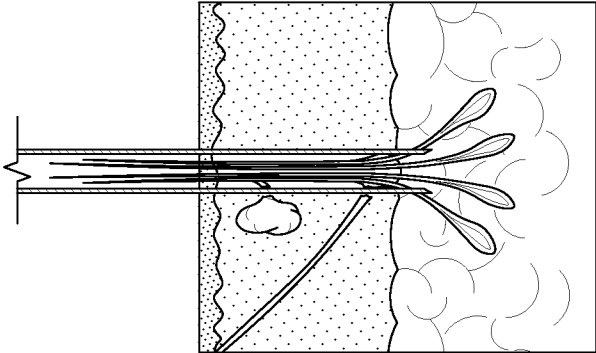


FIG. 1C

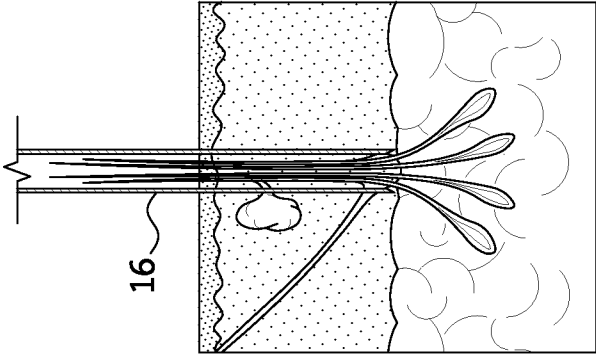


FIG. 1B

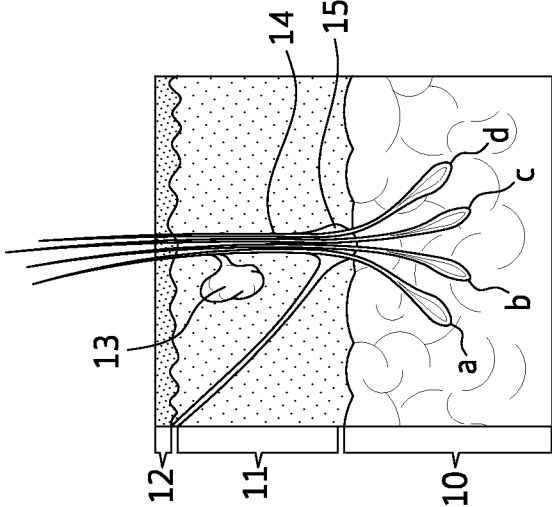


FIG. 1A

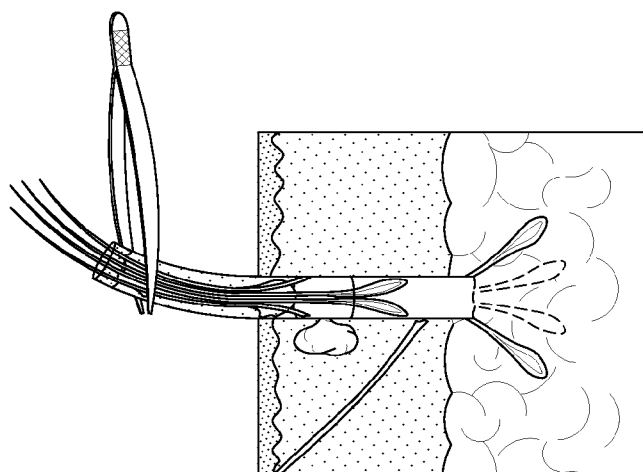


FIG. 1D

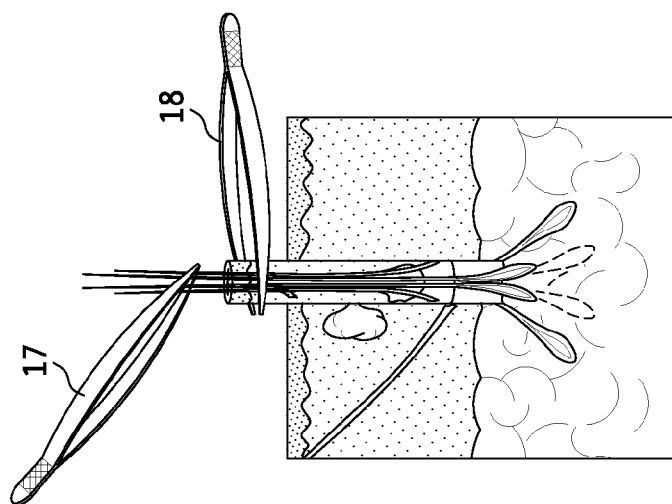


FIG. 1E

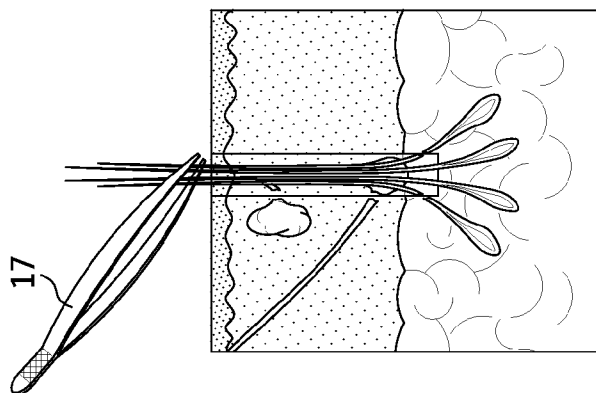


FIG. 1F

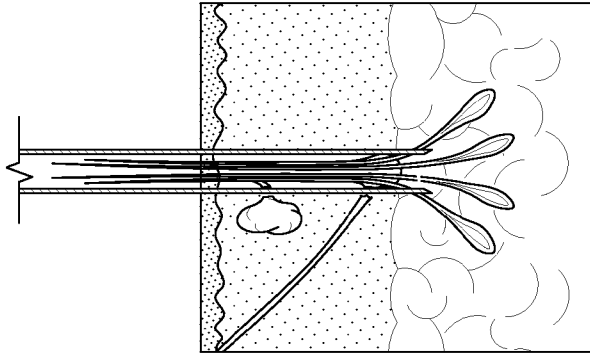


FIG. 2C

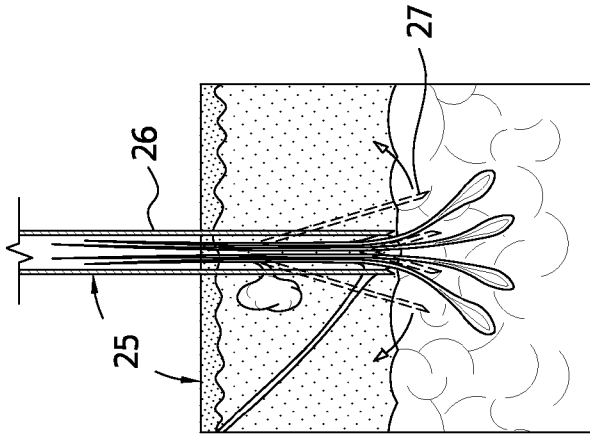


FIG. 2B

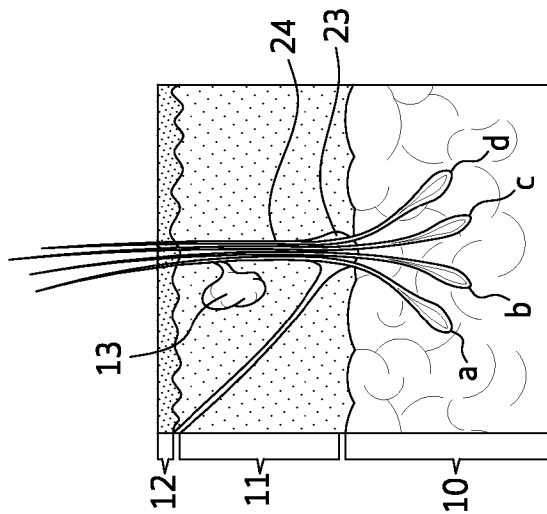


FIG. 2A

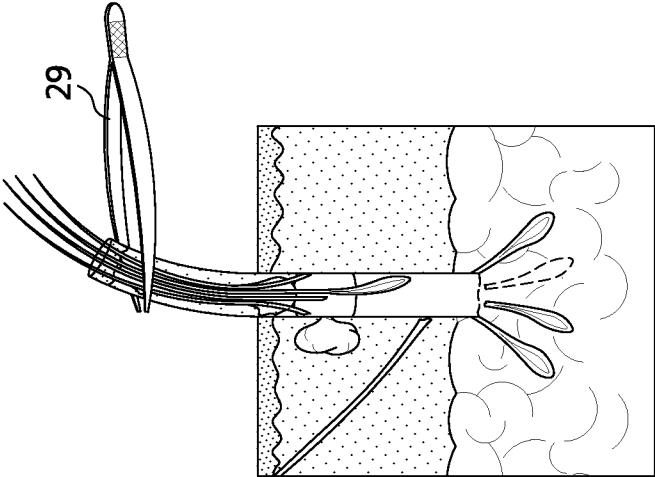


FIG. 2F

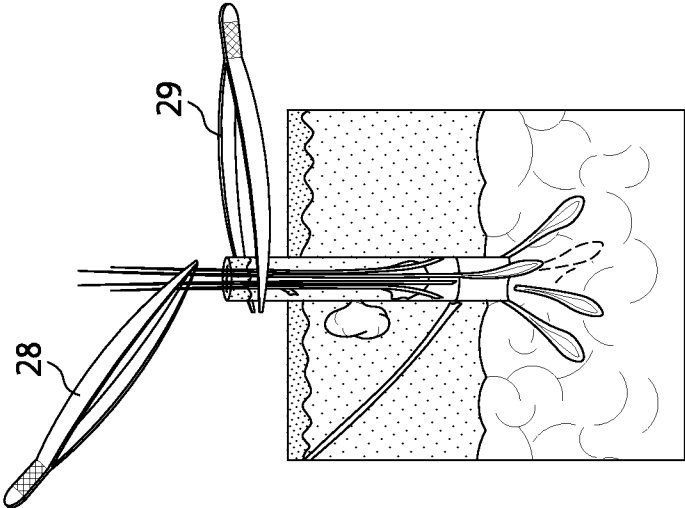


FIG. 2E

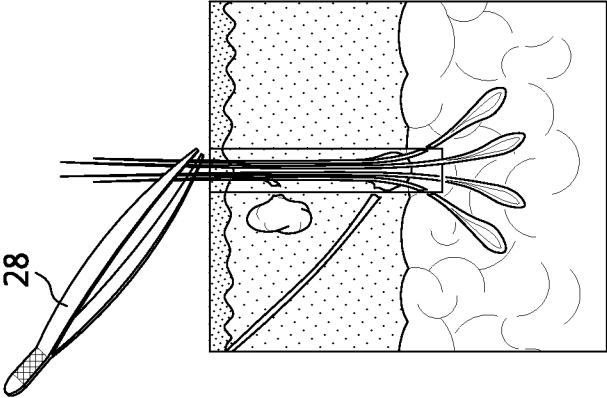


FIG. 2D

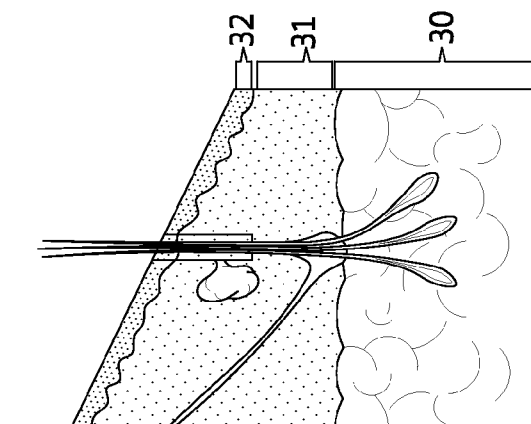


FIG. 3C

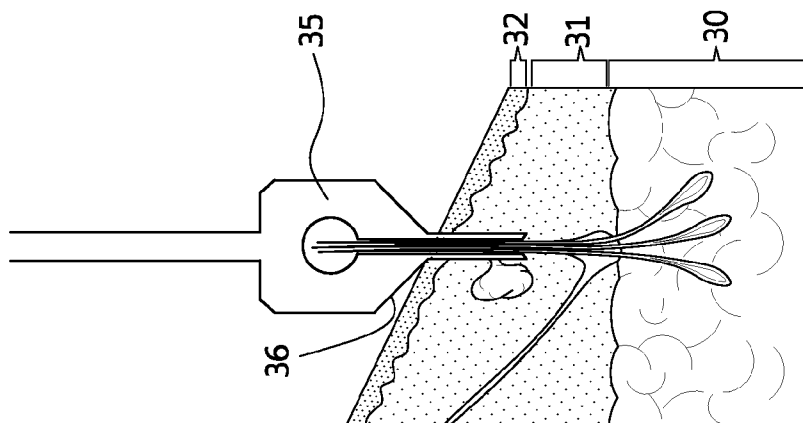


FIG. 3B

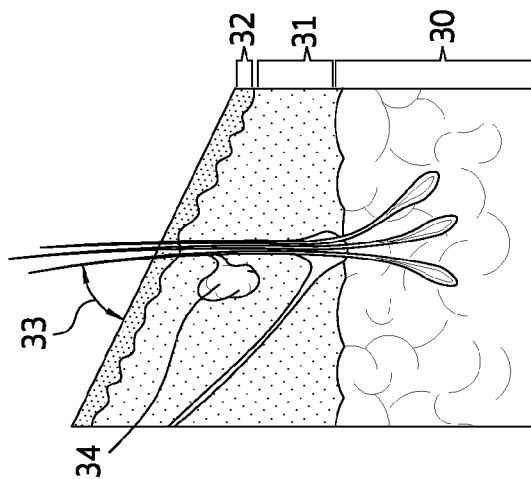


FIG. 3A

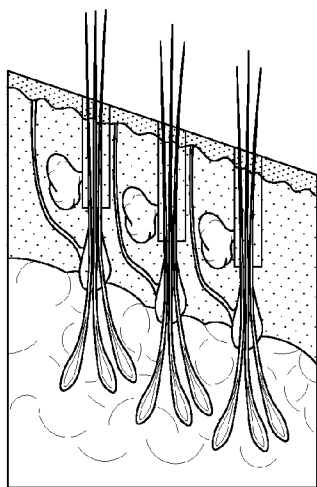


FIG. 4A

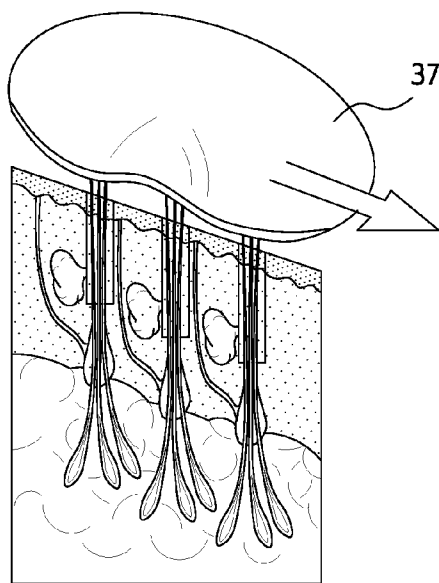


FIG. 4B

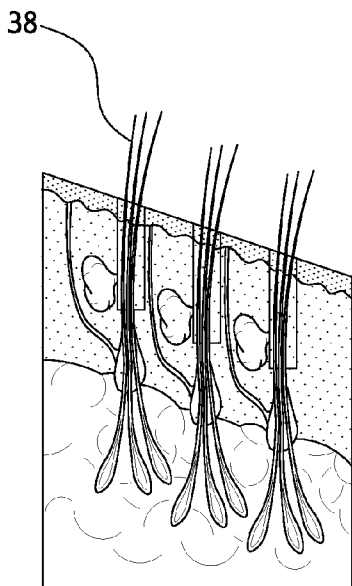


FIG. 4C

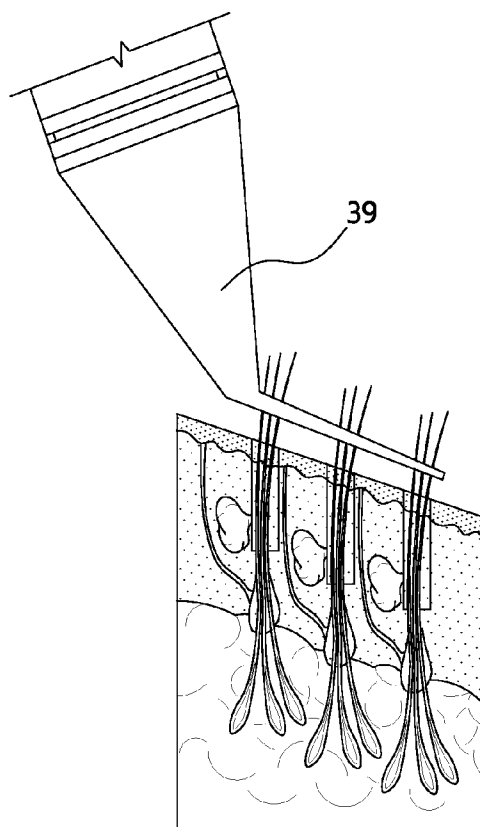


FIG. 4D

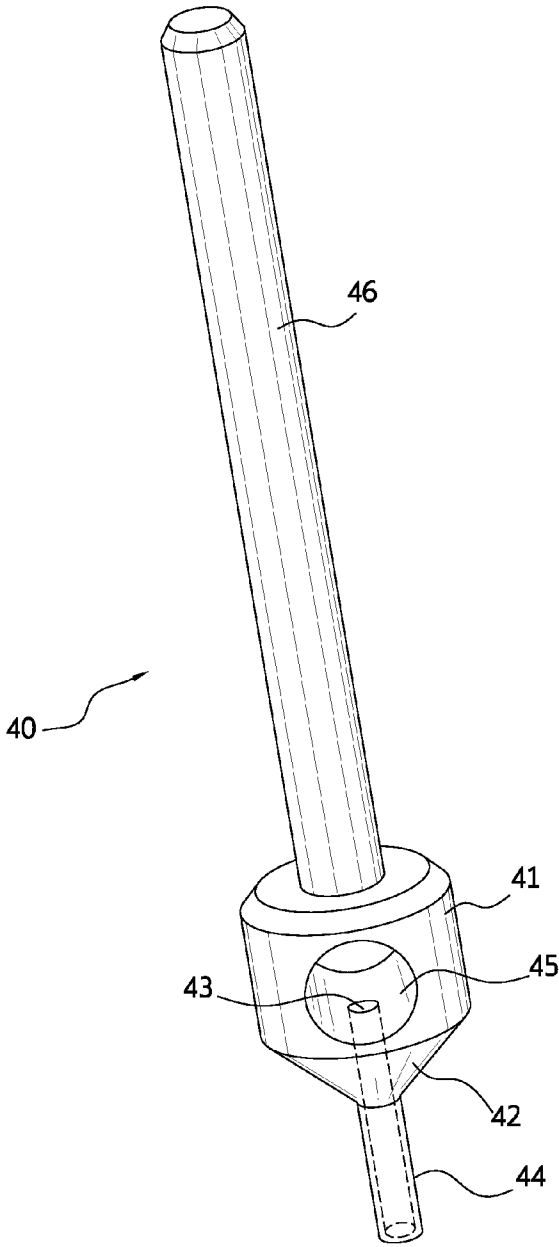


FIG. 5

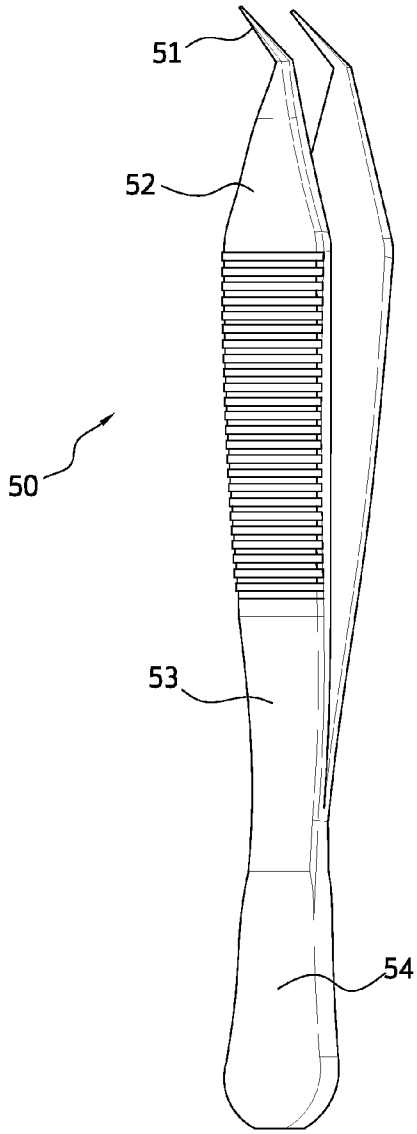


FIG. 6

METHOD AND APPARATUS FOR EXTRACTION OF FOLICULAR UNITS

BACKGROUND

[0001] There are various medical and cosmetic procedures that are performed now using handheld and automated tools for hair transplantation as disclosed below for reference.

[0002] Hair transplantation by strip method is widely performed. Typically, it involves removing a strip of graft of scalp from a donor region of the patient, which extends from ear to ear located in the occipital region at the back of the head. The strip of graft taken from the donor area is dissected under microscope, where a person can separate about 300 grafts per hour. However, some hair follicles may be damaged during microscopic dissection and harvesting. It is laborious and time consuming.

[0003] The long incision made at the back of the patient for removing strip of graft from the donor area located from ear to ear. The graft area of the patient is stitched together, and normally leaves a visible scar. The hair that grows around the scar cannot be shortened or combed and causes significant cosmetic deformity. Sometimes, the process of skin grafting may result in complications resulting in injuries to the arteries which supply the blood to the scar and thus create pain, numbness, paresthesia and ischemia to the scar tissue. It may require more surgery to correct the problem and would result in creating more scars.

[0004] Another technique, called follicular unit extraction (FUE), uses a 1 mm punch for coring through the dermis and epidermis and then extracting a follicular unit by forceps from the donor area. This method results in high transaction rate due to lack of control of angle of entry and depth of the punch and sometime makes visible scars.

[0005] A machine, called a PCID (programmable Cole isolation device), and a sharp, programmable punch, called a PID (Cole isolation device), that limits the depth to just below the attachment of the arrector pili muscle for hair transplants. This punch is programmed to drill a graft at a specific angle by oscillation and rotation and reverse action.

[0006] Still another known process utilizes a sharp punch to score the skin and separate follicular unit from the scalp. In order to avoid transaction, the sharp punch of about 1 mm diameter is inserted to a limited depth of about 0.3 mm to 1.5mm, then a 1 mm diameter blunt punch is used about 4 mm to 6 mm deep enough to loosen the graft and removes the follicular unit with forceps.

[0007] Another known system, called the ARTAS SYSTEM, discloses a "RESTORATION RONOtics" which includes a punch of 1.65 mm diameter and capable of extraction of 600 grafts per hour. This system also uses a dull punch, and this system is limited to a square area.

[0008] As noted above, the instruments, devices and machines are complex, expensive, and time consuming. Thus, there is a need for a new method and apparatus which is simpler, cheaper and more efficient.

SUMMARY

[0009] A punch for drilling around a follicular unit may be provided. The punch may include an elongated cylindrical tubing having a proximal end, a distal end and a central lumen therebetween. The punch may further include a bulging body with an elongated cylindrical portion at a distal end and an about 45 degree sloping conical portion at a proximal end.

The punch may further include an elongated handle having a proximal end and a distal end.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The present embodiments are illustrated by way of example and not limitation in the figures of the accompanying drawings, in which like references indicate similar elements and in which:

[0011] FIG. 1A illustrates a typical cross-section through hair follicles, a technique of extraction of hair follicles according to a prior art.

[0012] FIG. 1B illustrates a positioning of a punch, a technique of extraction of hair follicles according to a prior art.

[0013] FIG. 1C illustrates a depth of penetration of a punch, a technique of extraction of hair follicles according to a prior art.

[0014] FIG. 1D illustrates schematically a first forceps holding several hair follicles according to a prior art.

[0015] FIG. 1E illustrates schematically two forceps one for holding and other for pulling several hair follicles according to a prior art.

[0016] FIG. 1F illustrates schematically a remaining forceps for pulling several hair follicles according to a prior art.

[0017] FIG. 2A a typical cross-section through hair follicles, a technique of extraction of hair follicles according to other prior art.

[0018] FIG. 2B illustrates a positioning of a punch, a technique of extraction of hair follicles according to other prior art.

[0019] FIG. 2C illustrates a depth of penetration of a punch, a technique of extraction of hair follicles according to other prior art.

[0020] FIG. 2D illustrates schematically a first forceps holding several hair follicles according to other prior art.

[0021] FIG. 2E illustrates schematically two forceps one for holding and other for pulling several hair follicles according to other prior art.

[0022] FIG. 2F illustrates schematically a remaining forceps for pulling several hair follicles according to other prior art.

[0023] FIG. 3A illustrates an exemplary positioning and insertion of new innovated punch.

[0024] FIG. 3B illustrates an exemplary view of the bulging portion of new innovated punch.

[0025] FIG. 3C illustrates an exemplary schematic view through a drilled hair follicles of new invention.

[0026] FIG. 4A illustrates an exemplary view of angle of emergence of hair of several drilled follicular units of a new invention.

[0027] FIG. 4B illustrates an exemplary view of swiping a sterile gauze against the angle of emergence of hair of several drilled follicular units of a new innovated technique.

[0028] FIG. 4C illustrates an exemplary view of the angle of emergence of hair follicles after swiping with a sterile gauge of drilled follicular units of a new invention.

[0029] FIG. 4D illustrates an exemplary view of a new innovated forceps grabbing and pulling out the drilled follicular units.

[0030] FIG. 5 illustrates an exemplary a front view of the punch.

[0031] FIG. 6 illustrates an exemplary front view of the extraction forceps.

DETAILED DESCRIPTION OF THE PREFERRED
EMBODIMENTS

[0032] Aspects of the invention are disclosed in the following description and related drawings directed to specific embodiments of the invention. Alternate embodiments may be devised without departing from the spirit or the scope of the invention. Additionally, well-known elements of exemplary embodiments of the invention will not be described in detail or will be omitted so as not to obscure the relevant details of the invention. Further, to facilitate an understanding of the description, a discussion of several terms used herein follows.

[0033] As used herein, the word “exemplary” means “serving as an example, instance or illustration.” The embodiments described herein are not limiting, but rather are exemplary only. It should be understood that the described embodiments are not necessarily to be construed as preferred or advantageous over other embodiments. Moreover, the terms “embodiments of the invention”, “embodiments” or “invention” do not require that all embodiments of the invention include the discussed feature, advantage or mode of operation.

[0034] Generally referring to a prior art in FIGS. 1A-1C, wherein FIG. 1A shows a cross-section of a patient’s skin in a donor area through a follicular unit 14 that has hair follicles a, b, c, d extending through a fatty layer 10, a dermis layer 11, and an epidermis layer 12, having bulbs anchored into the fatty layer 10, a sebaceous gland 13, and an arrector pili muscle 15. A follicular unit may include more or less than two hair follicles. FIG. 1B show a punch 16 inserted downward through epidermis layer 12, dermis layer 11 and cutting sebaceous gland 13 to the level just deeper to insertion of arrector pili muscle attachment 15 and may transect hair follicular unit 14 as shown in FIG. 1C.

[0035] With reference to the prior art in FIGS. 1D-1F, wherein FIG. 1D shows a drilled follicular unit 14 before extraction and a forceps 17 is used for grasping a superior end of a follicular unit. The follicular unit is then pulled out a few millimeters so as to be able to grasp the follicular unit hair below forceps 17 by a second forceps 18, as shown in FIG. 1E, which assists the extraction of the drilled follicular unit. The first forceps 17 is then released and the second forceps 18 is used to pull out the remaining hair follicles of the follicular unit hair 14, as shown in FIG. 1D.

[0036] With reference to other prior art in FIGS. 2A-2C, wherein FIG. 2A shows a cross-section of a patient’s skin of a donor area through a follicular unit 24 that has hair follicles a, b, c, d extending through a fatty layer 10, a dermis layer 11 and an epidermis layer 12, having bulbs anchored into the fatty layer 10 a sebaceous gland 13 and an arrector pili muscle 23. A follicular unit may include more or less than two hair follicles. In FIG. 2B a punch 26 is inserted downward through epidermis layer 12, dermis layer 11 and into fatty layer 10. It is noted that while pushing punch 26 into the skin, there would be side to side movement of the punch as indicated by arrows 25 on entry, and 27 at the bottom around the drilled follicular unit 24. Instability of the punch 26 for lack of support to the operator’s hand may result in transecting hair follicle a, b, c or d as shown in FIG. 2C.

[0037] With reference to the other prior art in FIGS. 2D-2F, wherein FIG. 2D shows extraction of a follicular unit 24 using a forceps 28 for grasping a superior end of a follicular unit and pulling the follicular unit out by few millimeters. This allows for the grasping of the follicular unit hair below forceps 28 by

a second forceps 29, which further assists assist the extraction, as shown in FIG. 2E. Next, the first forceps 28 can be released, and only using forceps 29, the whole follicular unit hair 24 is pulled out, as illustrated in FIG. 2D. Using the second forceps 29, the operator would be able to extract one hair each time as shown in FIG. 2F.

[0038] Exemplary FIG. 3A is a schematic view showing the orientation and the depth of penetration of a punch, through a patient’s skin of a donor area for extraction of a follicular unit. The depth of drilling is limited to the depth of a sebaceous gland and does not traverse to an arrector pile muscle located below. The orientation of drilling follows the inclination of the angle of emergence of hair in order to avoid any hair follicle being transected. Exemplary FIG. 3B shows a punch 35 having a bulging body with a 45 degrees sloping shoulder 36 which when resting on the skin surface limits the drilling depth. Exemplary FIGS. 3C shows as how the sloping shoulder of the punch when supported on the skin surface automatically assumes an angle 33 which is close to the angle of hair protrusion from the skin surface. Exemplary FIGS. 3A-3C exhibit as to how a depth and orientation of drilling is attained automatically without guessing and manipulation which expedites the process and saves time.

[0039] Before starting a drilling procedure, a patient can be positioned in a prone position, which is considered a simple and safe method to improve oxygenation and comfortable position, and then a tumescent solution can be injected into the papillary dermis. The injected tumescent solution may flow further into the reticular dermis, but may not penetrate the hair follicle. For example, penetration of the hair follicle may be avoided because of a sheath around the follicle. However the tumescent solution can compress the hair follicle circumferentially. This procedure can stretch and harden the patient’s skin, including a fatty layer 30, a dermis layer 31, and an epidermis layer 32 at a top portion, and can compress around a hair follicular unit which includes about two hair follicles.

[0040] Exemplary FIGS. 4A-4D shows a cross-section through a several drilled follicular units of a patient’s skin in a donor area. Exemplary FIG. 4A shows the cross-section through several drilled follicular units ready for extraction. Exemplary FIG. 4B shows a piece of sterile gauze 37 is being used to swipe across a localized area of skin surface opposite to the direction of hair protrusion in order to loosen the drilled follicular units and also to straighten the hair follicles for facilitating the gripping of hair before extraction. Exemplary FIG. 4C shows the straightened hair follicles 38 ready for extraction. Exemplary FIG. 4D shows a special forceps 39 which can have a longer tip and a more rigid structure, as compared to other hair extraction forceps now being used. The forceps 39 in the present exemplary embodiment may have a longer gripping handle and firmer tip which can be pressed on the skin surface. Thus, forceps 39 can allow for grasping firmly several hair follicles 38 more deeply at the skin surface and pulling out the hair in one step, instead of using two. Thus a shorter and shorten the procedure time.

[0041] Exemplary FIG. 5 illustrates an embodiment of the punch 40 having a cylindrical portion 41 with a 45 degrees sloping conical portion 42. The conical portion 42 further can include a hollow punch barrel 44 that may have a sharp cutting edge at a proximal end and an elongated handle portion 46 at a distal end. The distal end of the elongated handle may be connected to a micromotor for manipulation of drilling. The cylindrical portion 41 can be provided with a hole 45

of about 3.16 mm which opens into the hollow barrel 43 of the punch, although it may be appreciated that any other dimensions of the hole 45 may be utilized, as desired. The punch barrel may further have an inner diameter less than an outer diameter.

[0042] The length of the elongated cylindrical tubing 44 of the punch can be variable and may be selected based on the size of a sebaceous gland, which often ranges from 3 mm to 4 mm or more in thickness. The diameter of the punch barrel can be sized based on thickness of a hair measured in micrometers which is about 0.75 μmm, about 0.80 μmm, about 0.85 μmm or about 0.90 μmm. In some exemplary embodiments, however, the cylindrical portion 41 with a conical portion 42 can limit the entry of the punch tubing 44 into the skin. In some exemplary embodiments, selecting a 45 degree sloping conical portion 42 may be based on the angle of hair exiting from the skin. Such an angle may be detrimental in controlling the angle of the entry of the punch and also stabilizing the movement of operation when drilling through the skin. The length of the handle 46 is about 23.25 mm and the diameter is about 2.4 mm, which is the longest component of the punch 40, although variations in size and shape may be made, as desired.

[0043] Exemplary FIG. 6, illustrates a forceps 50 used in some embodiments described herein. The forceps 50 can be held between a thumb and two fingers of a user in operation. The forceps 50 can have a pair of elongated, separable and flexible arms that may include of a serrated handle 53 and joined at top 54. Additionally, the arms 53 may be spring biased which may allow for quick and easily grasping the hair follicle, for example, by a bow shaped curved portion of the shaft 52, 53 which is joined at top 54 having a tip 51 at an end portion. The tip 51 can have a tapered shape having an inner dimension of about 6.1 mm and outer dimension about 9.2 mm, although other dimension may be utilized, as desired. The serrated portion 53 of the forceps 50 can be about 36 mm long, which may allow for comfortable holding by a thumb and two fingers. The forceps 50 may allow for exerting pressure on the skin and controlling depth and angle of the extraction of follicular unit, as shown in exemplary FIG. 4D.

[0044] Advantages of disclosed methods and apparatuses may be numerous. For example, they may provide fast healing, non-invasive procedure, no visible scarring, no post-operative pain, decrease in follicular units transaction, scalp is ready for another session, operation is not dependent on skin laxity, less staff is required, does not need microscope, less time spent on grafting, easy and friendly procedure, cheaper, no complications such as, necrosis, numbness on the back of the head, requires no prior estimation as a follicular unit extracted from the donor and planted in the balding region, white hair can benefit from this procedure, less staff is needed

and provides more dense packing. These and other benefits of the present invention may become readily apparent to those of skill in the art.

[0045] The foregoing description and accompanying figures illustrate the principles, preferred embodiments and modes of operation of the invention. However, the invention should not be construed as being limited to the particular embodiments discussed above. Additional variations of the embodiments discussed above will be appreciated by those skilled in the art.

[0046] Therefore, the above-described embodiments should be regarded as illustrative rather than restrictive. Accordingly, it should be appreciated that variations to those embodiments can be made by those skilled in the art without departing from the scope of the invention as defined by the following claims.

What is claimed is:

1. A punch for drilling around a follicular unit comprising: an elongated cylindrical tubing having a proximal end, a distal end and a central lumen therebetween; a bulging body comprising an elongated cylindrical portion at a distal end and a 45 degree sloping conical portion at a proximal end; and an elongated handle having a proximal end and a distal end.
2. A punch for drilling according to claim 1, wherein a sharp cutting edge is located at the proximal end of the cylindrical tubing, having an internal diameter less than the outer diameter, defined as a tip, wherein the tip is capable of punching a hole around a follicular unit for extraction.
3. A punch for drilling according to claim 1, wherein the elongated cylindrical portion comprises a transverse bore of 3.16 mm diameter therethrough for removing any occluded skin tissue.
4. A punch for drilling according to claim 3, wherein the central lumen is extended into the transverse bore in the elongated cylindrical portion.
5. A punch for drilling according to claim 1, wherein the proximal end of sloping conical portion is connected to the distal end of the elongated cylindrical tubing, and wherein the sloping conical portion limits the drilling depth.
6. A punch for drilling according to claim 5, wherein the sloping conical portion generally conforms to an angle of emergence of a hair protruding out of an epidermis layer and further the sloping portion of the punch resting on the skin stabilizes the movement of hand while drilling.
7. A punch for drilling according to claim 1, wherein the proximal end of the elongated handle is connected to the distal end of the elongated cylindrical portion, and wherein the distal end of the elongated handle is connected to a micro-motor for manipulation of drilling.
8. A punch for drilling according to claim 5, wherein the drilling depth is limited to a sebaceous gland thickness.

* * * * *