US00RE42438E

(19) **United States**

(12) **Reissued Patent**
Gildenberg

(10) **Patent Number: US RE42,438 E**

(45) **Date of Reissued Patent: Jun. 7, 2011**

(54) **HAIR TRANSPLANTATION METHOD AND APPARATUS**

(75) Inventor: **Philip L. Gildenberg**, Houston, TX (US)

(73) Assignee: **Restoration Robotics, Inc.**, Mountain View, CA (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/259,434**

(22) Filed: **Oct. 28, 2008**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **7,130,717**
Issued: **Oct. 31, 2006**
Appl. No.: **10/354,836**
Filed: **Jan. 30, 2003**

U.S. Applications:

(63) Continuation of application No. 09/774,154, filed on Jan. 30, 2001, now Pat. No. 6,585,746.

(51) **Int. Cl.**
G06F 19/00 (2006.01)

(52) **U.S. Cl.** **700/245**; 700/219; 700/220; 700/251; 700/252; 700/253; 606/133; 606/187; 901/1; 901/8; 901/14

(58) **Field of Classification Search** 700/245, 700/251, 252, 253, 213, 219, 220; 901/1, 901/8, 14; 602/540; 606/133, 187
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,867,942	A	2/1975	Bellantoni et al.
4,004,592	A	1/1977	Yamada
4,160,453	A	7/1979	Miller
4,451,254	A	5/1984	Dinius et al.
4,476,864	A	10/1984	Tezel
4,479,291	A	10/1984	Yamada
4,716,901	A	1/1988	Jackson et al.
4,751,927	A	6/1988	Yamada
4,768,517	A	9/1988	Joachim
4,807,163	A	2/1989	Gibbons
4,969,903	A	11/1990	Valle
5,036,860	A	8/1991	Leigh et al.
5,050,608	A	9/1991	Watanabe et al.
5,078,140	A	1/1992	Kwoh
5,183,053	A	2/1993	Yeh et al.

(Continued)

FOREIGN PATENT DOCUMENTS

JP	10-000210	1/1998

(Continued)

OTHER PUBLICATIONS

Brown University, Robotic Surgery, See URL http://images.google.com/imgres?imgurl=http://biomed.brown.edu/Courses/BI108/BI108_2008_Groups/group12/Robotic%2520surgery_clip_image002_0004.jpg&imgrefurl=http://biomed.brown.edu/Courses/BI108/BI108_2008_Groups/group12/Roboticsurgery.html&usg=__1pt_rMW711IdX4FxD8pVLigxg7s=&h=240&w=300&sz=13&hl=en&start=2&.*

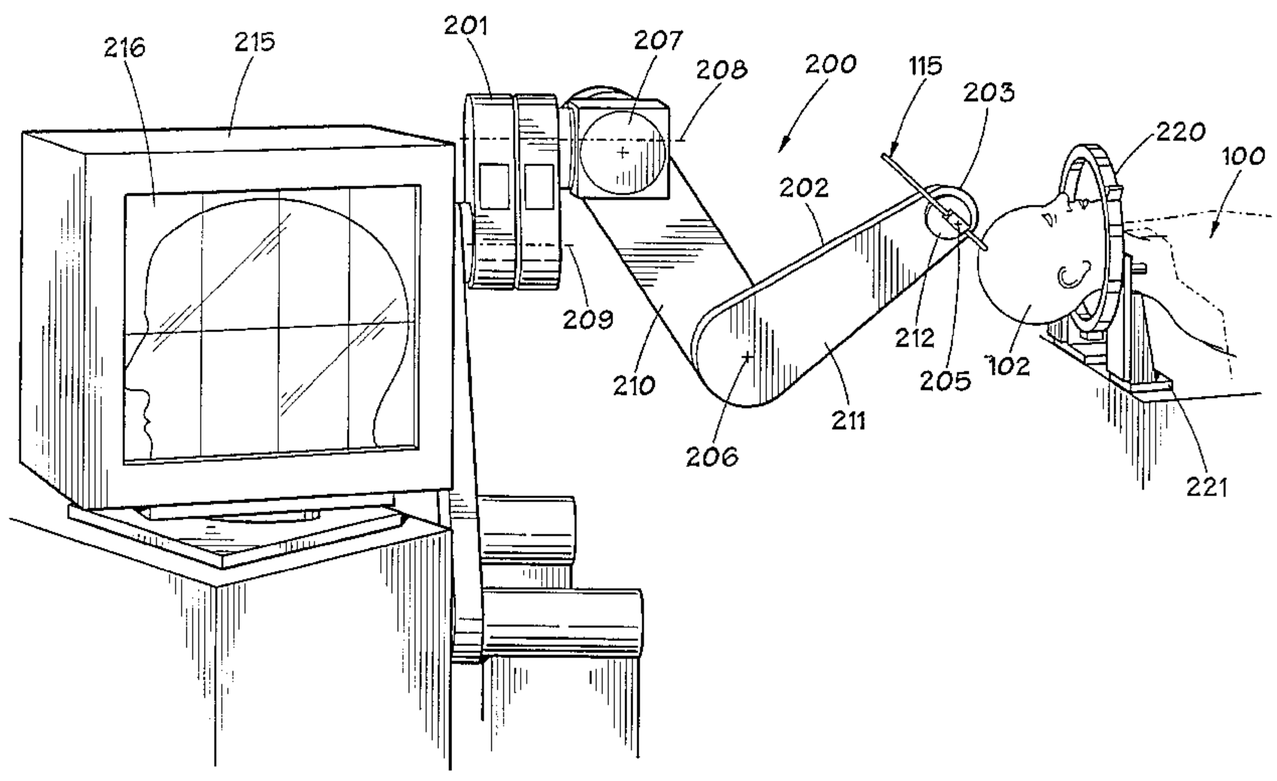
(Continued)

Primary Examiner — Khoi Tran
Assistant Examiner — Nikhil Sriraman
(74) *Attorney, Agent, or Firm* — Lena I. Vinitskaya; Sharon Upham

(57) **ABSTRACT**

A hair transplantation method and apparatus utilizes a robot, which includes a robotic arm, having a hair follicle effector associated with the robotic arm.

46 Claims, 4 Drawing Sheets



U.S. PATENT DOCUMENTS

5,251,127	A	10/1993	Raab	
5,331,472	A	7/1994	Rassman	
5,381,743	A	1/1995	Moll	
5,395,368	A	3/1995	Ellman et al.	
5,417,683	A	5/1995	Shiao	
5,439,475	A	8/1995	Bennett	
5,483,961	A	1/1996	Kelly et al.	
5,490,850	A	2/1996	Ellman et al.	
5,562,613	A	10/1996	Kaldany	
5,578,054	A	11/1996	Arnold	
5,584,841	A	12/1996	Rassman	
5,584,851	A	12/1996	Banuchi	
5,611,810	A	3/1997	Arnold et al.	
5,611,811	A	3/1997	Goldberg	
5,662,661	A	9/1997	Boudjema	
5,693,064	A	12/1997	Arnold	
5,733,278	A	3/1998	Slatkine et al.	
5,782,243	A	7/1998	Aasberg	
5,782,843	A	7/1998	Aasberg	
5,782,851	A	7/1998	Rassman	
5,782,853	A	7/1998	Zeevi et al.	
5,792,163	A	8/1998	Hitzig	
5,792,169	A	8/1998	Markham	
5,817,105	A	10/1998	Van Der Brug	
5,817,120	A	10/1998	Rassman	
5,827,217	A	10/1998	Silver et al.	
5,827,297	A	10/1998	Boudjema	
5,858,019	A	1/1999	Ashraf	
5,865,744	A	2/1999	Lemelson	
5,873,888	A	2/1999	Costanzo	
5,893,853	A	4/1999	Arnold	
5,895,403	A	4/1999	Collinsworth	
5,899,916	A	5/1999	Casparian	
5,951,572	A	9/1999	Markham	
5,961,529	A	10/1999	Arnold	
5,984,936	A	11/1999	Mangubat et al.	
5,989,273	A	11/1999	Arnold	
5,989,279	A	11/1999	Rassman	
5,997,550	A	12/1999	Russell	
6,013,087	A	1/2000	Adams et al.	
6,027,512	A	2/2000	Bridges	
6,056,736	A	5/2000	Markman	
6,059,807	A	5/2000	Boudjema	
6,110,189	A	8/2000	Markman	
6,120,521	A	9/2000	Casparian	
6,341,831	B1	1/2002	Weber et al.	
6,434,416	B1	8/2002	Mizoguchi et al.	
6,445,943	B1	9/2002	Ferre et al.	
6,461,369	B1	10/2002	Kim	
6,547,782	B1	4/2003	Taylor	
6,572,625	B1	6/2003	Rassman	
6,694,167	B1	2/2004	Ferre et al.	
6,973,931	B1	12/2005	King	
6,986,739	B2 *	1/2006	Warren et al.	600/159
7,806,121	B2	10/2010	Bodduluri	
2001/0034534	A1	10/2001	Transue	
2001/0055807	A1 *	12/2001	Vournakis et al.	435/366
2002/0050518	A1 *	5/2002	Roustaei	235/454

FOREIGN PATENT DOCUMENTS

WO	WO 98/25666	6/1998
WO	WO 00/64379	11/2000

OTHER PUBLICATIONS

The Application Accuracy of the Neuromate Robot—A Quantitative Comparison with Frameless and Frame-Based Surgical Localization Systems; Qing Hang Li, Wiley InterScience, pp. 90-98.*

MRI of human hair; Eveline Mettle, Institute of Biomendical Engineering, pp. 181-186.*

McInerney, James; Frameless Stereotaxy of the Brain; Sep. 2000; The Mount Sinai Journal of Medicine; vol. 67 No. 4; pp. 300-310.*

Kwoh Ysi; A Robot with Improved Absolute Positioning Accuracty for CT Guided Stereotactic Brain Surgery; 1988; IEE Trans Biomed Eng; pp. 153-160.*

WIPO Bibliographic Data of WO/2000/064379 Hair Transplantation Method and Apparatus; Feb. 11, 2000; WIPO.*

Robert M. Bernstein, MD; William R. Rassman, MD; Wojciech Szaniawski, MD and Alan J. Halperin, MD. "Follicular Tranplantation" Int. Journal of Aesthetic and Restoration Surgery, vol. 3, No. 2, 1995, pp. 119-132.

Robert M. Bernstein, MD and William R. Rassman, MD. "The Logic of Follicular Unit Transplantation". Dermatologic Clinics, vol. 17, No. 2, Apr. 1999.

Francsico Jimenez, MD and Jose M. Ruifernandez, Phd. Distribution of Human Hair in Follicular Units. Dermatologic Surgery 1999; 25: pp. 294-298.

William R. Rassman, MD and Sharon Carson, BA. "Micrografting in Extensive Quantities", http://www.newhair.com/resources/mp-1995-micrografting.asp (7 pages).

"Mini and Micrograft Megasession" advertising sheet, undated, Alfonso Barrera MD, Houston, TX.

Hair Transplantation, Third Edition, pp. 60-63.

"Neuro Mate —The Stereotactic Robot"; Advertising brochure, undated.

Annex to form PCT/ISA/206, Communication Relating to the Results of the Partial International Search, attached to PCT Invitation to Pay Additional Fees, PCT/ISA/206, for PCT/US2006/0038002, Applicant Restoration Robotics, Inc., dated Jan. 25, 2007 (5 pages).

Japanese office action mailed May 20, 2008 in the corresponding Japanese application No. 2000-613372 together with Attorney's English translation (5 pages).

Web site, http://www.medicamat.com/materiel/hair-transplant/punchhairmatic.html?L=1, Medicamat, Medical and Surgical Devices, Cosmetic Products, Hair Transplant/Punch Hair Matic®, accessed on Aug. 8, 2007 (1 page).

Web site, http://www.medicamat.com/materiel/hair-transplant/punchhairmatic/case-study.html?L=1, Medicamat, Medical and Surgical Devices, Cosmetic Products, Hair Transplant/Punch Hair Matic®/ Case Study, accessed on Aug. 8, 2007 (3 pages).

Brochure, "Punch-Hair-Matic® A New Robot to Fight Baldness", Medicamat, (3 pages).

EPO Communication pursuant to Article 96(2) EPC,dated Dec. 2, 2004, for Application No. 00 926 161.1-2310, Applicant Houston Stereotactic Concepts, Inc., (3 pages).

Web site, http://www.medicamat.com/materiel/hair-transplant/omnigraft/case-study.html?L=1, Omnigraft®, Medicamat, Medical and Surgical Devices, Cosmetic Products, Hair Transplant/Omnigraft®/Case Study, accessed on Aug. 8, 2007 (4 pages).

Brochure, Automated Hair Restoration System, OmniGraft™, Medicamat S.A. (4 pages).

M. Inaba and Y Inaba, "Androgenetic Alopecia, Modern Concepts of Pathogenesis and Treatment" pp. 238-244, 309, Springer-Verlag, published 1996 (9 pages).

PCT International Search Report for PCT/US00/10596, PCT/ISA forms 210 and 220, dated Aug. 16, 2000, Applicant: Philip L. Gildenberg, (7pages).

PCT International Preliminary Examination Report for PCT/US00/10596, form PCT/IPEA/409 and 406, Applicant: Philip L. Gildenberg, (7 pages).

EPO Communication pursuant to Article 96(2) EPC,dated Dec. 2, 2004, for Application No. 00 926 161.1-2310, Applicant Houston Stereotactic Concepts, Inc., (3 pages).

Examiner's Report for Canadian Application No. 2,368,254, Restoration Robotics, dated Aug. 14, 2006, (3 pages).

Hill et al., Telepresence Surgery Demonstration System, 1994, IEEE, p. 3202-3207.

Marshall, Semiconductor-Based Lasers in Medicine, 1998, IEEE, p. 1.

Response to Final Office Action submitted Mar. 12, 2010, in co-pending U.S. Reissue Patent Application No. 11/702,485, (21 pages).

P.L. Gleason, Ron Kikinis, David Altobelli, William Wells, Eben Alexander III, Peter MCL. Black, Ferenc Jolesz. "Video Registration Virtual Reality for Nonlinkage Stereotactic Surgery" . Stereotact Funct Neurosurg 1994; 63:pp. 139-143.

Supplemental Response to Office Action mailed Oct. 23, 2009 in relation to U.S. Appl. No. 11/702,485, (9 Pages).

Final Office Action mailed Dec. 15, 2009 in relation to U.S. Appl. No. 11/702,485, (14 pages).

STIC, Search Report, Dialog, Internet and EBSCO HOST, 2009, p. 1-71—provided with Final Office Action mailed Dec. 15, 200 in relation to U.S. Appl. No. 11/702,485, (71 pages).
Office Action mailed May 13, 2009 in relation to U.S. Appl. No. 12/259,456 (18 pages).
Interview Summary mailed Jul. 1, 2009 in relation to U.S. Appl. No. 12/259,456, (2 pages).
Response filed Jul. 2, 2009 in relation to U.S. Appl. No. 12/259,456, (9 pages).
Final Office Action mailed Sep. 16, 2009 in relation to U.S. Appl. No. 12/259,456, (15 pages).
Pre-Appeal Brief Request for Review filed Dec. 14, 2009 in relation to U.S. Appl. No. 12/259,456, (6 pages).
Office Action mailed Jun. 25, 2009 in relation to U.S. Appl. No. 12/259,482 (16 pages).
Interview Summary mailed Jun. 30, 2009 in relation to U.S. Appl. No. 12/259,482, (2 pages).
Response filed Jul. 2, 2009 in relation to U.S. Appl. No. 12/259,482, (6 pages).
Final Office Action mailed Sep. 17, 2009 in relation to U.S. Appl. No. 12/259,482, (12 pages).
Response and Amendment after Final, filed Nov. 4, 2009, in relation to U.S. Appl. No. 12/259,482, (6 pages).
Advisory Action Before the Filing of an Appeal Brief, mailed Nov. 9, 2009, in relation to U.S. Appl. No. 12/259,482, (3 pages).
RCE, Amendment and Response filed Nov. 13, 2009, in relation to U.S. Appl. No. 12/259,482, (9 pages).
FDA Correspondence and 510(k) Summary of Safey and Effectiveness for CyberKnife System for Stereotactic Radiosurgery/Radiotherapy, date stamped Jul. 14, 1999. (5 Pages).
FDA Correspondence and 510(k) Premarket Notification Summary for "CyberKnife System", date stamped Aug. 10, 2001. (4 Pages).
Supplemental Amendment after Final Office Action, submitted May 28, 2010, In relation to U.S. Appl. No. 11/702,485.
Examiner Intervier Summary Record, mailed Jun. 14, 2010, In relation to U.S. Appl. No. 11/702,485.
Non-Final Office Action mailed Jul. 2, 2010 In relation to U.S. Appl. No. 11/702,485.
Response to Non-Final Action, submitted Oct. 29, 2010, In relation to U.S. Appl. No. 11/702,485, including Bodduluri Declaration with Exhibit A and Supplemental Inventor Declaration.
Pre-Appeals Conference Decision mailed Jan. 26, 2010, In relation to U.S. Appl. No. 12/259,456.
Appeal Brief submitted Mar. 25, 2010, In relation to U.S. Appl. No. 12/259,456.
Examiner's Answer to Appeal Brief mailed Jun. 22, 2010, In relation to U.S. Appl. No. 12/259,456.
Reply Brief submitted Aug. 20, 2010, In relation to U.S. Appl. No. 12/259,456.
Supplemental Response submitted Jan. 21, 2010, In relation to U.S. Appl. No. 12/259,482.
Non-Final Office Action mailed Mar. 24, 2010, In relation U.S. Appl. No. 12/259,482.
Response after Non-Final Action, submitted Jun. 18, 2010, In relation to U.S. Appl. No. 12/259,482.
Final Office Action mailed Jul. 7, 2010, In relation to U.S. Appl. No. 12/259,482.
Request for Continued Examination mailed Oct. 6, 2010, In relation to U.S. Appl. No. 12/259,482.
Non-final Office Action Mailed Oct. 3, 2008 In relation to U.S. Appl. No. 11/702,485, 6 pages.
Response to Non-final Action submitted Nov. 3, 2008 In relation to U.S. Appl. No. 11/702,485, 26 pages.
Supplemental Response submitted Apr. 30, 2009 in relation to U.S. Appl. No. 11/702,485, (9 Pages).
Non-final Office Action Mailed Jul. 21, 2009 in relation to U.S. Appl. No. 11/702,485, (13 Pages).
Response to Non-final Office Action submitted Jul. 30, 2009 in relation to U.S. Appl. No. 11/702,485, (21 Pages).
BPAI Decision on Appeal mailed Jan. 28, 2011, in relation to commonly assigned U.S. Appl. No. 12/259,456 (15 pages).
"M.D. News" Feb. 1996; Article entitled "West Houston Plactic Surgery Clinic . . . Houston Physician Transplants . . . " *Hair Transplantation*, Third Edition, pp. 60-63.

* cited by examiner

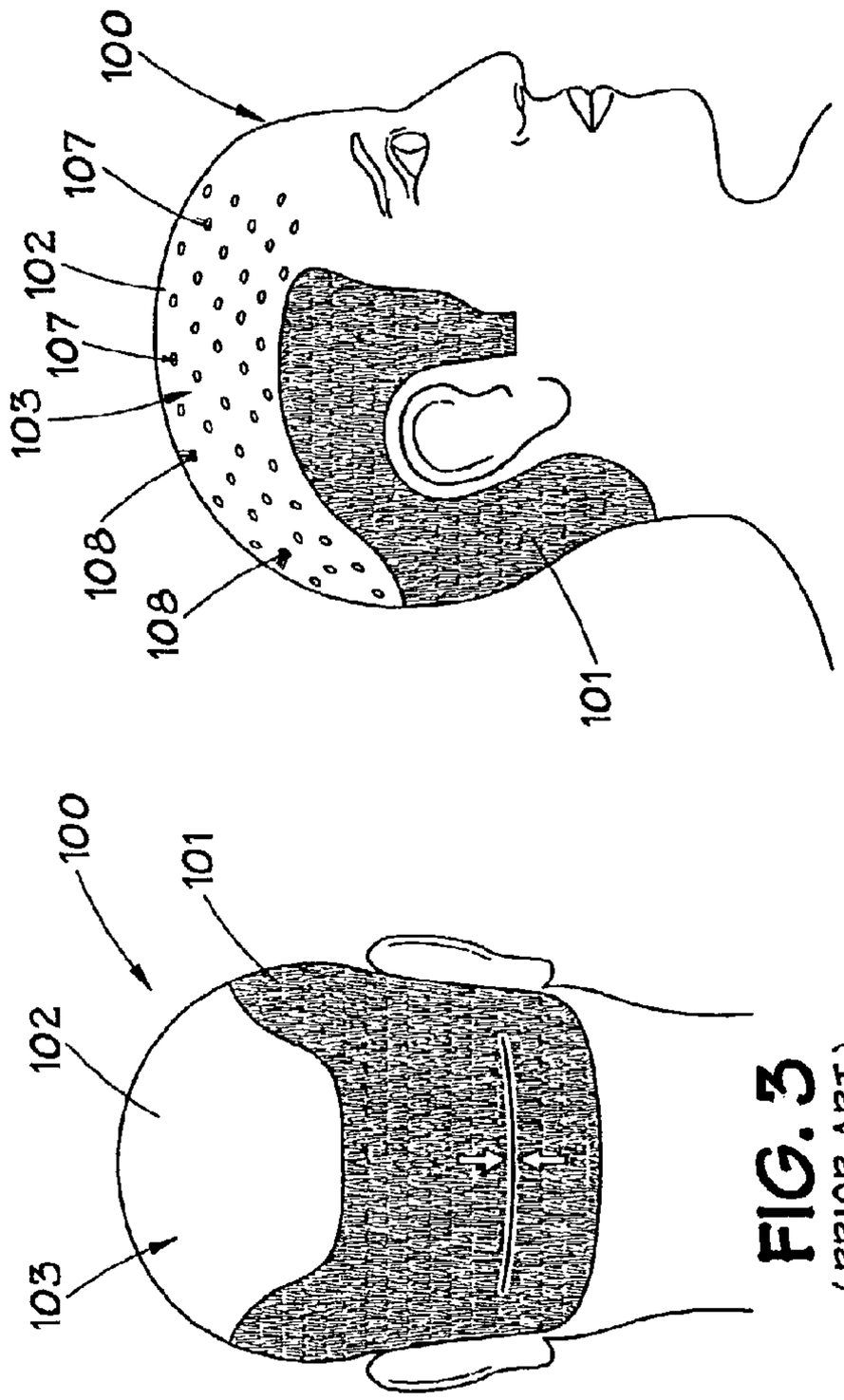


FIG. 4
(PRIOR ART)

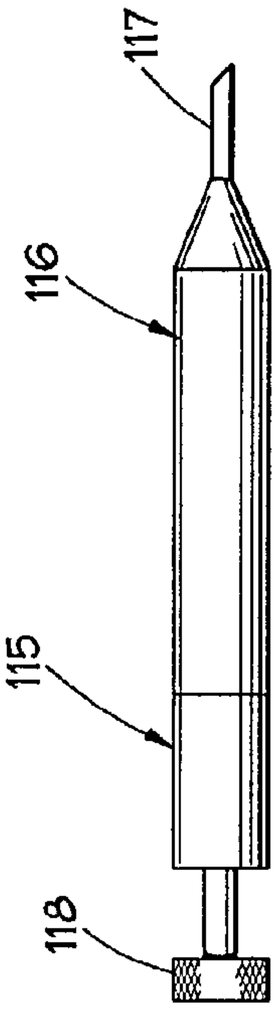


FIG. 5

FIG. 3
(PRIOR ART)

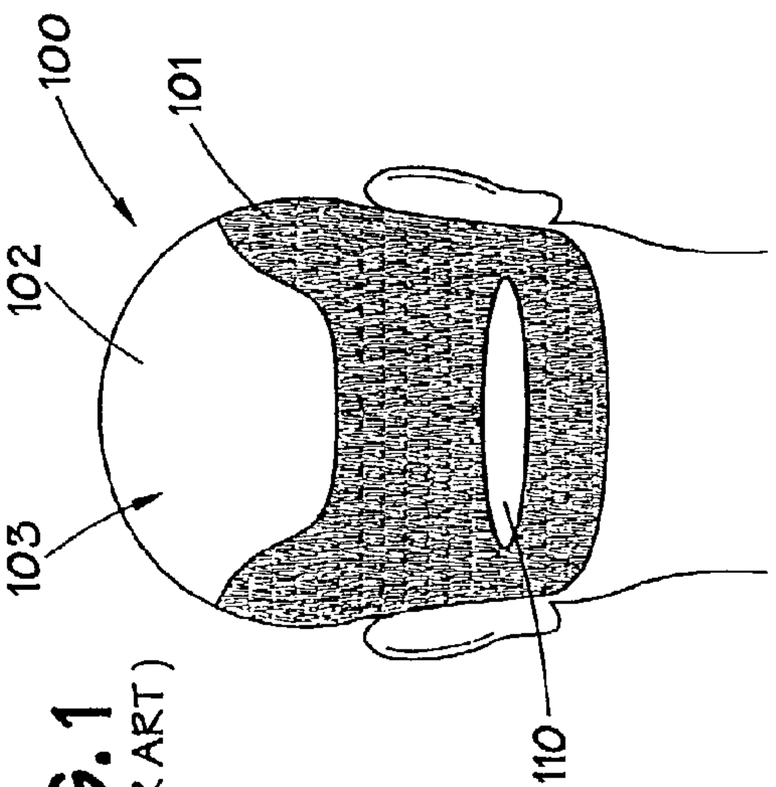


FIG. 1
(PRIOR ART)

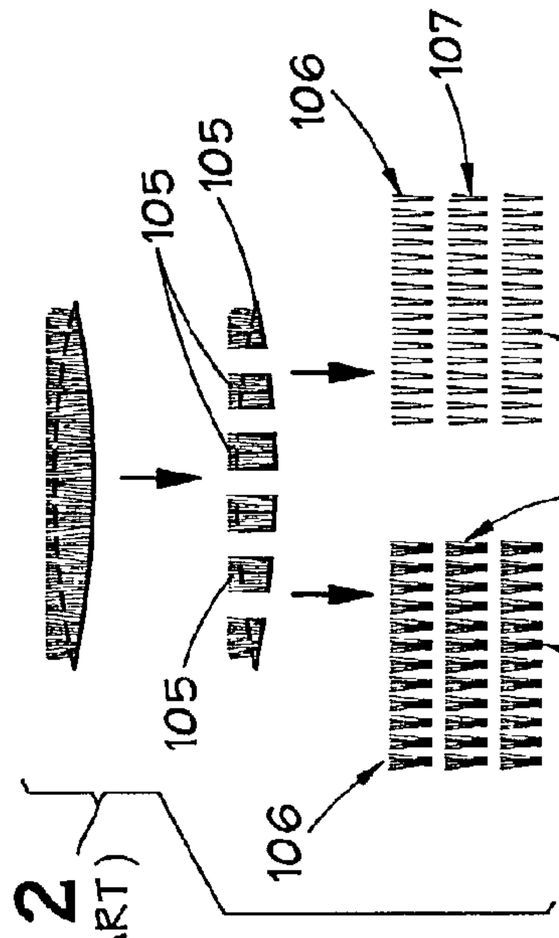


FIG. 2
(PRIOR ART)

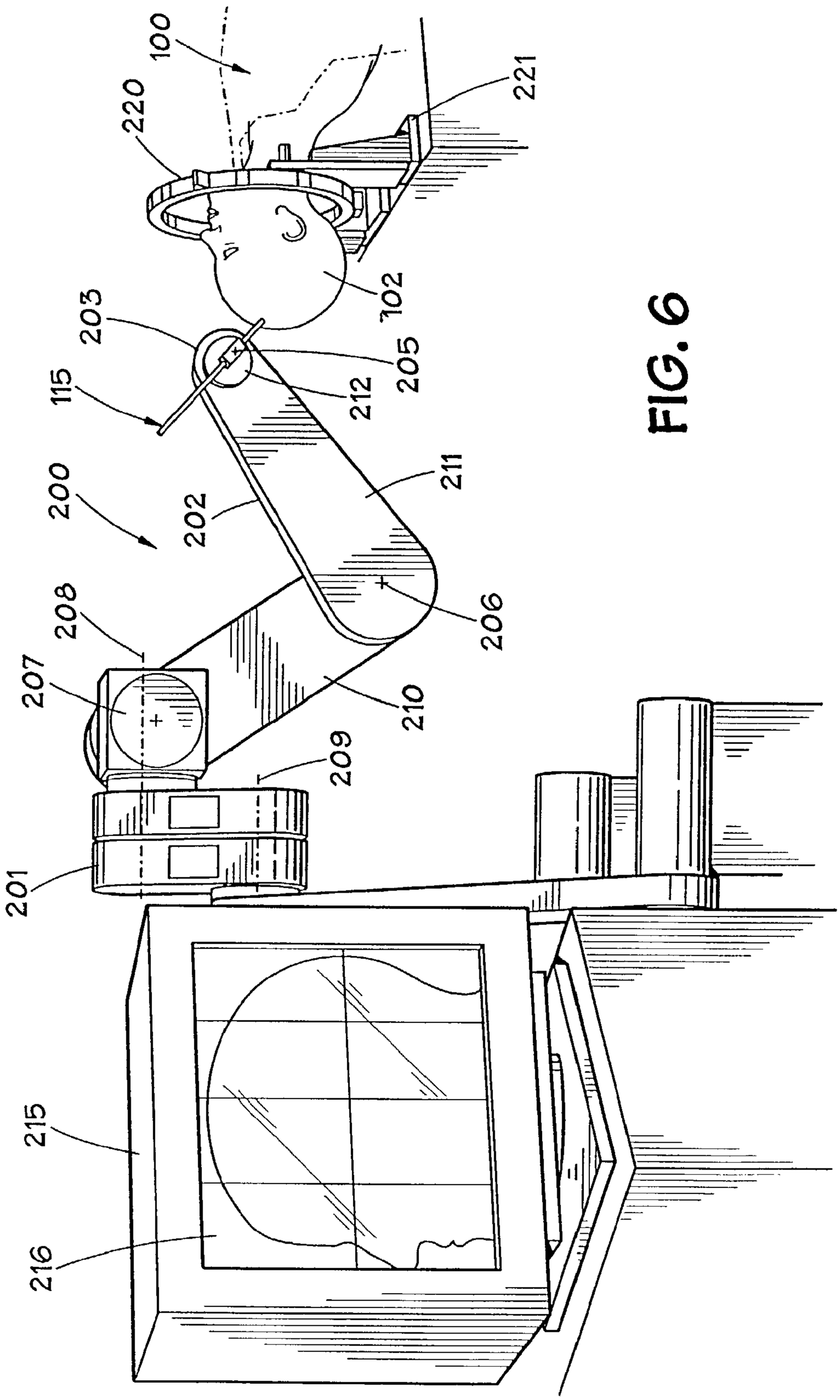

100
220
221
102
203
205
115
212
200
202
211
208
206
207
210
209
201
215
216

FIG. 6

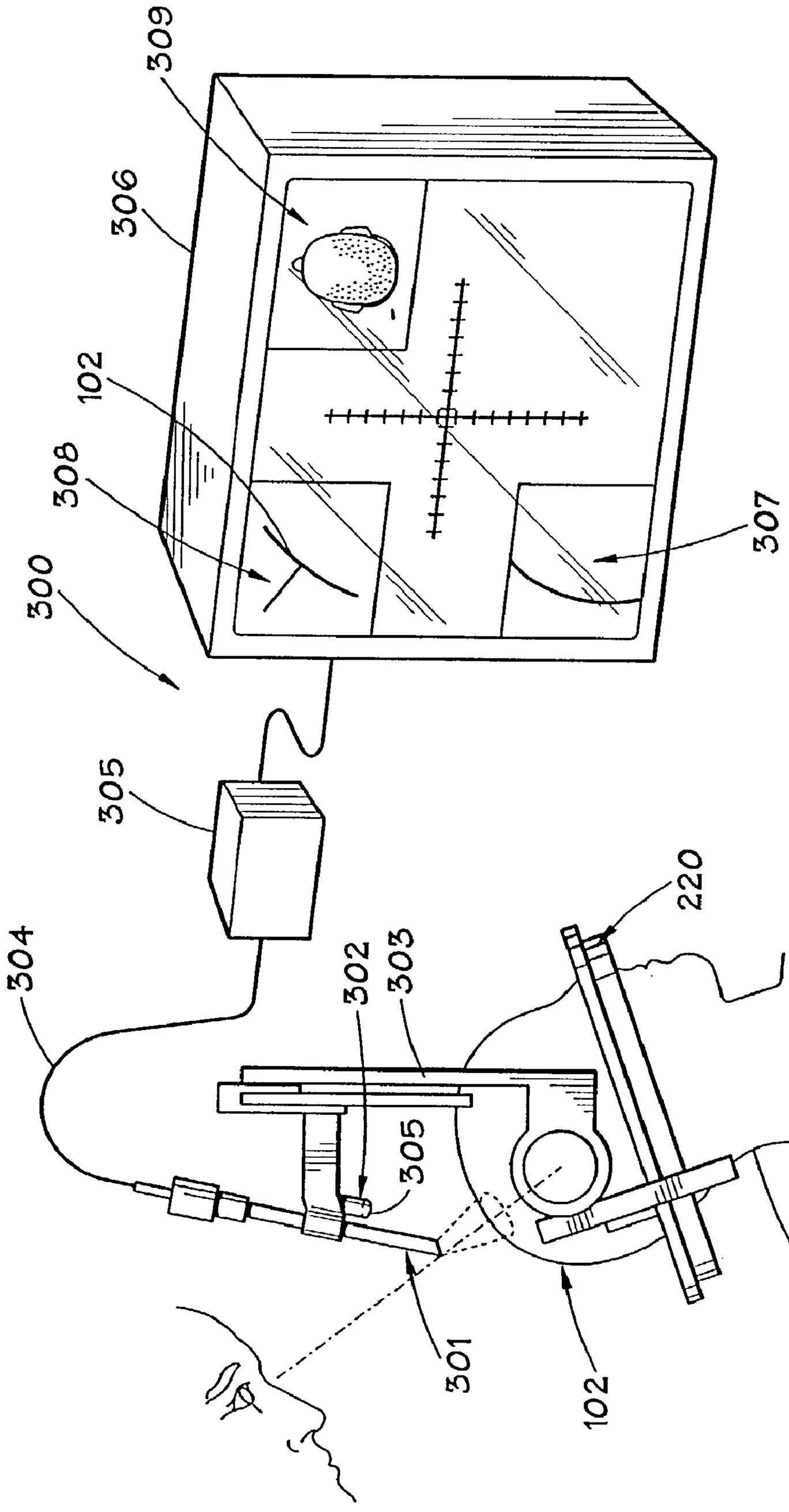


FIG. 7

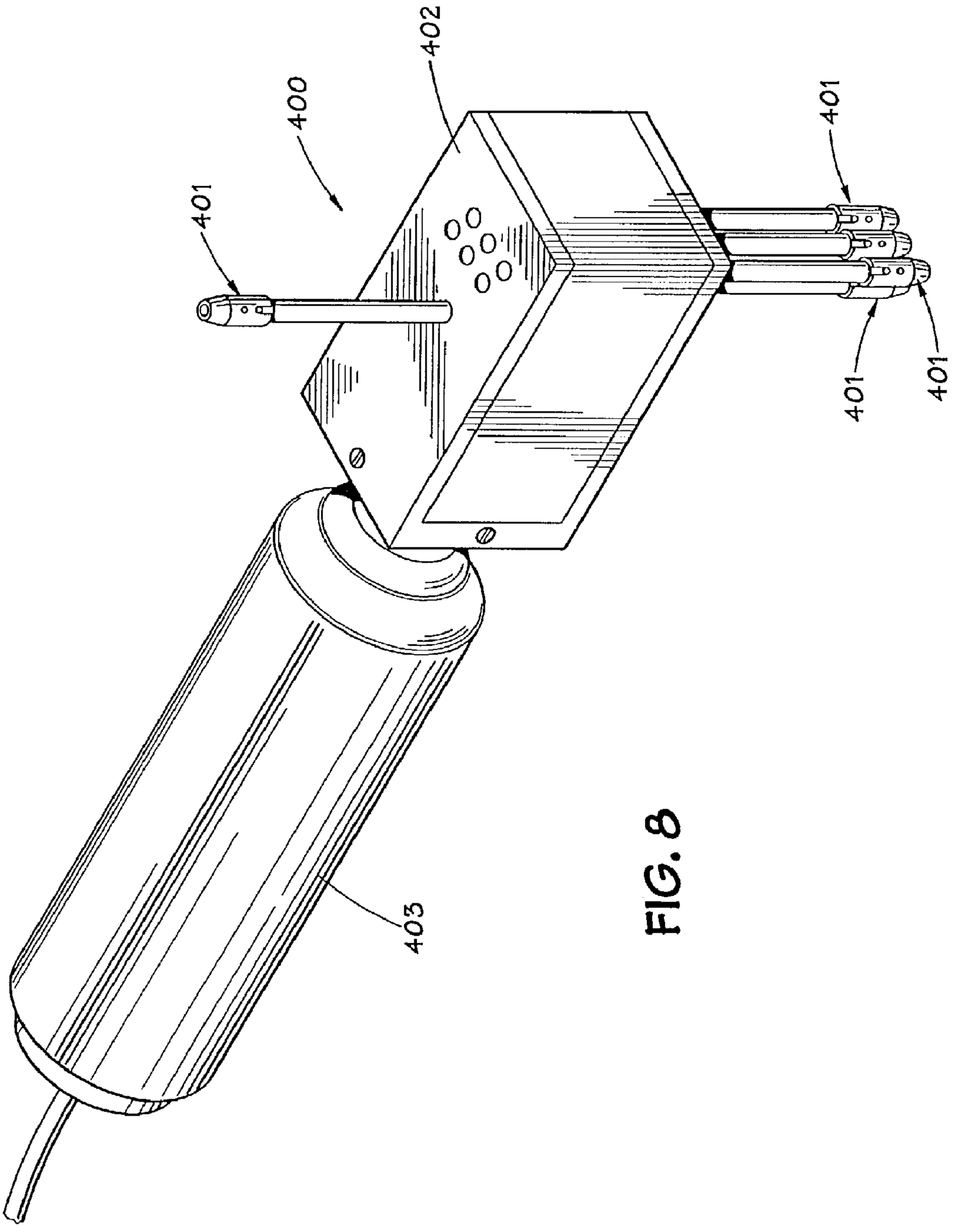


FIG. 8

HAIR TRANSPLANTATION METHOD AND APPARATUS

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

RELATED APPLICATION *DATA*

[This application] *More than one reissue application has been filed for the reissue of U.S. Pat. No. 7,130,717. The reissue applications are application Ser. No. 11/702,485 filed on Feb. 5, 2007, and divisional application Ser. Nos. 12/259,434 (the present application), 12/259,456, and 12/259,482, all filed on Oct. 28, 2008. U.S. Pat. No. 7,130,717* is a continuation of application Ser. No. 09/774,154, filed Jan. 30, 2001, now U.S. Pat. No. 6,585,746, which claims the benefit [of U.S. Provisional Application No. 60/130,877 filed Apr. 23, 1999. a] *under 35 U.S.C. § 119 to PCT Application PCT/00/10596, filed Apr. 20, 2000. A*pplication Ser. No. 09/774,154 is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to a method and apparatus for hair transplantation, and, more particularly, to a method and apparatus for hair transplantation which utilize a robot.

2. Description of the Related Art

Hair transplantation is presently a widely-performed procedure. Typically, it involves implanting many individual hair grafts. The individual grafts may be micrografts or minigrafts. In a "Megasession", or hair transplantation session, a large number of grafts, usually from 1000 to 2000 grafts, are implanted. Micrografts may contain one to two hair follicles and minigrafts may contain from three to five hair follicles Generally, the number of grafts done depends on the degree of baldness and density of hair desired for the transplantation.

The transplantation technique generally requires removal of an elliptical-shaped flap of scalp from the occiput, or back of the patient's head. The tiny micro and/or minigrafts may be removed from the flap of the patient's scalp which has been removed. The incision made to remove the flap is stitched together, and normally leaves a well-concealed scar. The new grafts, which might be micro or mini-grafts are then inserted in very small slits, or openings, formed in the patient's scalp where it is desired to have the grafts implanted. Usually, the grafts are implanted approximately 1.5 mm from each other into the bald area of the patient's scalp to be treated. Generally, the slits, or small openings, formed in the patient's scalp to receive the grafts, heal very well, normally without leaving any scars.

The Megasession procedure generally takes a complete workday of from five to eight hours to complete, depending upon the number of grafts to be transplanted. Normally, one team of physicians and/or physicians assistants and/or nurses work together form the micro and/or minigrafts from the flap of removed scalp. They carefully trim the flap of scalp into the desired number of micro and/or minigrafts, each micro and/or minigraft containing at least one hair follicle. This step is generally referred to as the harvesting step and requires the use of very sharp, fine knives, or scalpels, and the use of magnification devices, such as magnifying loops, by the first surgical team. Generally, a second surgical team forms the slits, or openings in the patient's scalp which are to receive the

hair grafts, and each hair graft, or plug, is individually placed within each incision, or opening, by the second surgical team. The angle of insertion and the distribution of the recipient sites generally reflects the experience and art of the individual surgeon performing the procedure.

The disadvantages associated with the foregoing described Megasession hair transplantation technique, are that it is a long, laborious, and tedious procedure, which may begin at 7:30 am and not be completed until 2:00 pm to 5:00 pm, dependent upon the number of grafts, or plugs, to be transplanted and the efficiency of the teams. Furthermore, because of the labor intensiveness of the procedure, and the fact that all the individuals involved in the procedure are highly skilled and well trained and experienced, the procedure can be a very expensive procedure, the cost varying from $2000 to $12,000 dollars or more, dependent upon the number of hair grafts, or plugs, to be implanted.

Accordingly, prior to the development of the present method and apparatus for hair transplantation, there has been no hair transplantation technique which is not a long, laborious, tedious, uneconomical procedure, and is not overly labor intensive. Therefore, the art has sought a hair transplantation technique which is less long, laborious, tedious, and more economical, and which technique is less labor intensive.

The present invention is directed to overcoming, or at least reducing the effects of, one or more of the problems set forth above.

SUMMARY OF THE INVENTION

In accordance with the invention, the foregoing advantages have been achieved through the present hair transplantation method and apparatus for implanting at least one hair follicle into a portion of a patient's scalp. The hair transplantation apparatus of the present invention includes: a robot, including at least one robotic arm having a first end adapted to be disposed adjacent the patient's scalp; a hair follicle effector associated with the first end of the robotic arm, the robotic arm being adjustably maneuverable so that the hair follicle effector is capable of being selectably placed proximate the patient's scalp and operated to implant the at least one hair follicle into a portion of the patient's scalp; and the hair follicle effector being moved and operated to implant the at least one hair follicle into a portion of the patient's scalp. A feature of the present invention is that the hair follicle effector may be either a single hair follicle insertion device which includes a needle, or a multiple hair follicle insertion device which includes multiple needles.

Another feature of the present invention is that the apparatus may include a video system adapted to be associated with the patient's scalp and adapted to identify at least one location on the scalp where the at least one hair follicle is to be implanted. The video system may include a camera and a distance measuring device to measure the distance from the patient's scalp to the camera. Another feature of the present invention is that a plug cutting device may be associated with the first end of the at least one robotic arm, the plug cutting device being adapted to remove a plug of the patient's scalp, the plug containing at least one hair follicle. The plug cutting device may be a single hair follicle insertion device which includes a needle. Another feature of the present invention is that a plug trimming device may be associated with the first end of the at least one robotic arm, the plug trimming device being adapted to trim a portion of a flap, removed from the patient's scalp, into a plurality of plugs of the patient's scalp, each plug containing at least one hair follicle. An additional feature of the present invention includes a stereotactic frame,

adapted to be releaseably secured to the patient's head, for restraining the patient's head with respect to a stereotactic robot.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for transplanting hair by implanting at least one hair follicle into a portion of a patient's scalp, the patient's scalp having a plurality of existing hair follicles. This aspect of the present invention includes the steps of: providing a robot, the robot including at least one robotic arm, the at least one robotic arm having a first end; associating a hair follicle effector with the first end of the robotic arm, the robotic arm being adjustably maneuverable so that the hair follicle effector is capable of being selectably placed proximate the patient's scalp; loading the hair follicle effector with at least one existing hair follicle; disposing the first end of the robotic arm adjacent to the patient's scalp; moving the hair follicle effector toward the patient's scalp; and operating the hair follicle effector to implant the at least one existing hair follicle into a portion of the patient's scalp.

Another feature of this aspect of the present invention may include the step of utilizing as the hair follicle effector either a single hair follicle insertion device which includes a needle, or a multiple hair follicle insertion device which includes multiple needles. A further feature of this aspect of the present invention may include, prior to implanting the at least one existing hair follicle, the steps of: providing a video system; associating the video system with the patient's scalp; scanning the patient's scalp with the video system to determine the locations of the existing hair follicles and the location of the patient's scalp in three dimensions. An additional feature of the present invention may include the steps of: utilizing a stereotactic video system which includes a camera and a distance measuring sensor; and measuring the distance from the patient's scalp to the camera while the patient's scalp is being scanned.

An additional feature of this aspect of the present invention may include the step of determining the angular disposition of the existing hair follicles with respect to the patient's scalp. Another feature of this aspect of the present invention may include the step of utilizing a single hair follicle insertion device, which includes a needle, as the plug cutting device.

Another feature of this aspect of the present invention, prior to the implantation of the at least one existing hair follicle, may include the steps of: providing a plug trimming device; associating the plug trimming device with the first end of the at least one robotic arm; disposing a flap containing a plurality of existing hair follicles, previously removed from the patient's scalp, upon a support surface; and trimming the flap into a plurality of plugs of the patient's scalp, each plug containing at least one existing hair follicle. An additional feature of this aspect of the present invention may include the steps of releaseably securing a stereotactic frame to the patient's head and restraining the patient's head with respect to a stereotactic robot.

The hair transplantation method and apparatus of the present invention, when compared to previously proposed operating the hair follicle effector to implant the at least one existing hair follicle into a portion of the patient's scalp hair transplantation methods and apparatus, are believed to have the advantages of providing a shorter, less laborious, less tedious, more economical, and less labor intensive hair transplantation procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be best understood by reference to the following description taken in conjunction with the accompanying drawings, in which like reference numerals identify like elements, and in which:

FIG. **1** is a rear view of a patient's head illustrating an elliptical-shaped piece of scalp having been removed from the occiput, or back of the patient's head;

FIG. **2** is a perspective view of the flap of scalp removed from the patient's head of FIG. **1**, and illustrating its division into a plurality of micrografts and minigrafts;

FIG. **3** is a rear view of a patient's head after the elliptical shaped incision has been sutured;

FIG. **4** is a side view of the patient's head of FIG. **1** with a plurality of hair follicles having been implanted in the patient's scalp;

FIG. **5** is a side view of a hair follicle introducer;

FIG. **6** is a perspective view of a stereotactic robot, in accordance with one embodiment of the present invention, implanting a hair follicle into the scalp of the patient of FIG. **1**;

FIG. **7** is a perspective view of the patient of FIG. **1** with a stereotactic video system associated with the patient's scalp; and

FIG. **8** is a perspective view of a plug cutting device for use in the present invention.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

With reference to FIGS. **1-4**, the prior art "Megasession" hair transplantation technique is illustrated. As seen in FIG. **1**, patient **100** has hair, or hair follicles, **101**, disposed upon the scalp **102** of patient **100**. In order to obtain the hair follicles **101** for transplantation into the bald portion **103** of the scalp **102** of patient **100**, a surgeon typically removes a elliptical-shaped flap **104** from the patient's scalp **102**, the flap **104** containing a plurality of existing hair follicles **101**. As to hair follicles **101**, throughout this written description and the claims appended hereto, the use of the term "hair follicle" encompasses both the follicle and the hair shaft disposed within the follicle.

With reference to FIG. **2**, a team of technicians, typically cleans the flap **104** and divides flap **104** into a plurality of smaller pieces **105**, each piece **105** containing a plurality of hair follicles **101**. The team of technicians would then trim and divide the smaller pieces **105** into a plurality of grafts, or small plugs, **106**. Generally, the grafts, or small plugs, **106**, are referred to as micrografts, **107** when they contain one to two hair follicles **101** and are referred to as "mini-grafts" **108** when they contain from three to five hair follicles **101**. As

illustrated in FIG. **3**, the elliptical-shaped incision **110** (FIG. **1**) is sutured by the surgeon in a conventional manner leaving a very fine scar, or no scar, in the back of the head of patient **100**.

With reference to FIG. **4**, the transplantation of a plurality of micrografts **107**, and minigrafts **108**, is illustrated as having been transplanted upon the bald portion **103** of the scalp **102** of patient **100**. The spacing depicted between the various grafts, or small plugs, is greatly exaggerated, for ease of illustration. Typically, the grafts **107**, **108** are spaced approximately 1.5 mm. from each other. As previously discussed, a surgical team performs the transplantation of the grafts **107**, **108** into the scalp **102** of patient **100**. Typically, the surgeon makes a small incision in the desired location in the bald portion **103** of the patient's scalp **102**, and each graft, or plug, **107**, **108** is inserted into the incision. The angle of insertion and the distribution and location of the incisions normally reflects the experience and art of the individual surgeon. Typically, the foregoing procedure is performed under a local anesthetic, and hemostasis, or the prevention and/or stopping of bleeding, is obtained by adding epinephrine to the local anesthetic, as well as by applying manual pressure following the transplantation, or insertion, of the grafts, or plugs, **107**, **108** into the scalp **102**. As previously described, from 1000 to 2000 grafts **107**, **108** may be transplanted in one surgical session or Megasession.

With reference to FIG. **5**, a hair follicle introducer **115** is illustrated. Hair follicle introducer **115** may be a single hair follicle insertion device **116**, such as that known as a Choi single hair insertion instrument, or similar instrument, as is known in the art. As will be hereinafter described in greater detail, the present invention may utilize the hair follicle hair introducer **115** of FIG. **5**. The single hair follicle insertion device **116** of FIG. **5** could also be used by the surgeon in the Megasession transplantation technique illustrated in FIGS. **1-4**. The single hair follicle insertion device **116** typically includes a needle **117**, as is known in the art, into which is loaded the hair follicle, as is known in the art.

With reference to FIG. **6**, the hair transplantation apparatus **200** of the present invention for implanting at least one hair follicle **101** into a portion of a patient's scalp **102** is illustrated. The hair transplantation apparatus **200** generally includes: a stereotactic robot **201**, having at least one robotic arm **202** and a hair follicle introducer **115**. Stereotactic robot **201** may be a commercially available stereotactic robot, such as the NeuroMate Stereotactic Robot manufactured by Immi Medical Robots of Grenoble, France and sold in the United States by its subsidiary Innovative Medical Machines International of Wellesley, Mass. Another commercially available stereotactic robot which may be utilized in the present invention is that designed by Tsubikawa. The NeuroMate Stereotactic Robot is illustrated in FIG. **6**. Stereotactic robot **201** is a computer-controlled, image-directed robotic assistant which includes robotic arm **202** which has a first end **203** adapted to be disposed adjacent the patient's scalp **102**. The robotic arm **202** may have a plurality of axes of rotation, associated therewith, robotic arm **202** having five axes of rotation, or rotatable joints **205-209**. As illustrated, robotic arm **202** includes two arms members **210**, **211**, rotatably journaled to each other about rotational axis **206**. The first end **203** of robotic arm **202** includes an instrument holder **212** which is rotatably mounted about axis of rotation **205**. The stereotactic robot **201** may include a PC compatible work station and image work station **215**, which may illustrate the location of the hair follicle introducer **115** with respect to the patient's scalp **102** on the screen **216** of the image work station **215**. The movements of robotic arm **202** and the operation of hair follicle introducer **115** may be controlled by any suitable computer software program.

As in the case of any stereotactic procedure, the head of the patient **100** must be fixed, or restrained. A conventional stereotactic frame, or a conventional head holder, such as one which makes three point contact with the patient's head, **220**, adapted to be releaseably secured to the patient's head, for restraining the patient's head with respect to the stereotactic robot **201** may be utilized. In this regard, the stereotactic frame, or head holder, **220** is typically fixedly secured to the operating room table **221**, and as known in the art, the location and disposition of the stereotactic robot **201** with respect to the operating room table **221** and frame **220**, in three-dimensional space, may be readily determined. Optionally, if desired for increasing the accuracy of apparatus **200**, a plurality of fiducial marks may be disposed on the stereotactic frame **220**, as well as on the patient's head. The location of the patient's head with respect to the stereotactic frame, or head holder, **220**, as well as the orientation of the stereotactic robot **201** with respect to the stereotactic frame, or head holder, **220** may then be readily determined, as is known in the art. It should be noted that, alternatively, the patient's head could be releaseably secured directly to the operating room table **221**, without the use of a stereotactic frame. So long as there is a fixed, known relationship in three-dimensional space between stereotactic robot **201** and the patient's head, apparatus **200** of the present invention may be used.

Still with reference to FIG. **6**, the hair follicle introducer **115** may be a single hair follicle insertion device **116** including a single needle **117**. The hair follicle introducer **115** may be modified to permit it to be operated by stereotactic robot **201**, such as by including a piston device, or other operating mechanism (not shown) to operate the plunger **118** (FIG. **5**) of hair follicle introducer **115**,device, a plurality of hair follicles **101** could be simultaneously implanted into the patient's scalp **102**. Alternatively, the individual hair follicle insertion devices, such as hair follicle introducer **115**, which are combined to form the multiple hair follicle insertion device, may be actuated sequentially by the stereotactic robot **201**, as desired. If single hair follicle insertion devices **116** are utilized, it would be necessary to reload the single hair follicle insertion device with a new hair follicle **101** after each use of the hair follicle introducer **115**, or alternatively, a loaded hair follicle introducer **115** could be associated, or loaded into the tool, or instrument, holder **212** at the first end **203** of the robotic arm **202**. By using a multiple hair follicle insertion device, including multiple needles, loaded with a plurality of hair follicles, set up, or down, time associated with the use of stereotactic robot **201** is decreased. As will be hereinafter described in greater detail, the apparatus **200** illustrated in FIG. **6** would be utilized in the present invention when it is desired to utilize stereotactic robot **201** to implant at least one hair follicle **101** into the patient's scalp **102**.

Turning now to FIG. **7**, a stereotactic video system **300** for use in the present invention is illustrated. A portion of the stereotactic video system **300** is adapted to be associated with the patient's scalp **102**, or head, and is adapted to identify at least one location on the scalp **102** where the at least one hair follicle, or graft, **107**, **108** containing the at least one hair follicle **101**, is to be implanted. Stereotactic video system **300** preferably includes a video camera **301** and a distance measuring device **302**, for measuring the distance from the patient's scalp **102** to the camera **301**. The stereotactic video system **300** is used in connection with the stereotactic frame **220** which has been releaseably secured to the patient's head. The camera **301** is mounted for rotation about the patient's head via a stereotactic arm **303** having a length which can be

varied and predetermined. The stereotactic video system may include suitable wiring **304** and circuitry contained within a housing **305**, which is in a signal transmitting relationship with a display device **306**. An example of a suitable stereotactic video system **300** for use in the present invention is that known as the Exoscope, as described in Chapter 23 of Advanced Neurosurgical Navigation published in 1999 by Thieme Medical Publishers, Inc. Whereas the Exoscope is used to view an intracerebral mass, or tumor, located within the patient's head, it can be modified as hereinafter described, to function with the present invention. The viewing equipment, or display device, **306** can include images of the patient's scalp as shown at **307**, and a graphic depiction of the distance to the patient's scalp **102**, as shown at **308**.

Stereotactic video system **300** is used in the following manner. Camera **301** is moved in controlled arcs across the patient's scalp **102** to map the location of existing hair follicles **101** (FIG. **1**) on the patients' scalp **102**. The distance measuring device **302** may be an infrared measuring device **305**, or any other suitable device which permits the distance from the patient's scalp **102** to the camera **301** to be measured. Since the radius of the stereotactic arc being scanned by the movement of the stereotactic arm **303** and the distance from the video camera **301** to the patient's scalp **102** are known, it is possible to calculate the position in three-dimensional space of each point on the surface of the patient's scalp **102** in three-dimensional space, including the location and three-dimensional coordinates of each existing hair follicle **101** on the patient's scalp **102** with respect to the stereotactic frame **220**. A three-dimensional virtual image of the patient's scalp and the location of each hair follicle may be reconstructed in the computer (not shown) associated with stereotactic video system **300** and the stereotactic robot **201** (FIG. **6**). For example, the image of the scalp and the hair follicles **101** may be viewed as shown at **309**. The contour of the patient's scalp **102** with respect to the stereotactic frame **220** in three-dimensional space is thus determined, as well as the location of existing hair follicles **101**. The three-dimensional virtual image of the patient's scalp **102** may then be utilized to plan at what locations upon scalp **102**, the various grafts, or plugs, **107**, **108**, will be implanted upon scalp **102** of the patient **100** by the stereotactic robot **201**.

If desired, the scanning of the patient's scalp **102** and existing hair follicles **101** may also be performed so as to determine the angular disposition of each hair follicle **101** with respect to the patient's scalp **102**, including the vector the existing hair follicle **101** is oriented in relation to the patient's scalp **102**. This information could be utilized, as will be hereinafter described in greater detail, when the present invention is utilized to also remove, or harvest, existing hair follicles from the patient's scalp **102**, or from flap **104**. In this regard, it is desirable to remove the entire hair follicle, including the hair shaft disposed above the patient's scalp **102**, as well as that portion of the hair shaft and follicle disposed beneath the surface of the patient's scalp **102**. To accomplish this, it is preferable to know at what angle the hair follicle, including its hair shaft, is disposed and oriented, both above and below the patient's scalp **102**.

With reference to FIG. **8**, a graft, or plug, cutting device **400** is illustrated. Plug cutting device **400** may be associated with the first end **203** of robotic arm **202** of stereotactic robot **201**, and is adapted to remove a plug, or graft, **107**, **108**, of the patient's scalp **102**, the plug, or graft, **107**, **108** containing at least one hair follicle **101**. Plug cutting device **400** may be received within the instrument holder **212** of stereotactic robot **201**. Plug cutting device **400** may include a plurality of cutting heads **401** associated with the housing **402** and the movement of which are powered by a motor **403**. As will be hereinafter described in greater detail, plug cutting device **400** may be used to remove a plug, or graft, **107**, **108** directly from patient's scalp **102**. An example of such a plug cutting device **400** may be found in U.S. Pat. No. 4,476,864, issued Oct. 16, 1984, which patent is incorporated herein by reference. Alternatively, a single hair follicle insertion device **116**, including a needle **117**, could be utilized as the plug cutting device.

As will be described in greater detail, the stereotactic robot **201** may be provided with a plug trimming device, or fine scalpel (not shown), which could be mounted, or associated, with the first end **203** of robotic arm **202** of stereotactic robot **201**. After the flap **104** (FIG. **2**) of the patient's scalp **102** has been surgically removed, the flap **104** could be positioned upon a suitable support surface, or table, or similar device. The stereotactic video system **300** of FIG. **7** could be utilized to scan the flap **104** and determine the three-dimensional location of the hair follicles **101** disposed upon and within flap **104** in three-dimensional space with respect to a set of predetermined markers, such as fiducial markers, associated with the support surface. The plug trimming device, or scalpel, associated with stereotactic robot **201** could then be utilized to trim the flap **104** into a plurality of plugs, or graft, **107**, **108**, each graft containing at least one existing hair follicle **101**. The grafts would then later be inserted into a hair follicle introducer, such as hair follicle introducer **115**, for implantation into the patient's scalp **102**.

With reference to FIG. **6**, the method of the present invention for transplanting hair will be described. In accordance with one aspect of the present invention, the stereotactic robot **201** may be used only to implant at least one hair follicle **101** contained within a graft **107**, **108** into a portion of the patient's scalp **102**. In this aspect of the present invention, the hair follicle introducer **115**, as previously described, is loaded with the graft **107**, **108** and the hair follicle introducer **115** disposed at the first end **203** of the robotic arm **202** of stereotactic robot **201** is moved toward the patient's scalp **102**. The hair follicle introducer **115** is then operated to implant the at least one existing hair follicle **101** contained in the graft **107**, **108** into the patient's scalp **102**. Preferably, the particular location where the hair follicle, or graft **107**, **108** is implanted within scalp **102**, and the control of stereotactic robot **201** is determined by the stereotactic video system **300** which has previously computed the three-dimensional virtual image of the patients's scalp and the location and three-dimensional spacing of the existing hair follicles **101** and the desired location of the hair follicles to be implanted in scalp **102**. The surgeon plans on the virtual three-dimensional image of the patient's scalp where each of the grafts **107**, **108** is to be implanted. Several methods of planning may used individually or in combination. For example, the graft insertion site on the patient's scalp, and the angle of each of the hair follicles **101** contained within grafts **107**, **108**, may be manually plotted individually. The planning can be computerized either all, or in part. In either case, the new hair line, formed by the transplantation of the hair follicles, is determined by the surgeon. The computer (not shown) associated with stereotactic robot **201** and stereotactic video system **300**, can distribute the grafts **107**, **108**, evenly throughout the bald portion **103** of the patient's scalp **102**, and can plot the individual implantation sites, or locations, according to selected degrees of randomness. The angle of insertion of each hair follicle **101** may be determined for each region of the bald portion **103** of the patient's scalp **102**, and/or the angle of insertion can be gradually adjusted from one region of the patient's scalp to another. Optionally, the computer (not shown) can display the

intended distribution of the existing and transplanted hair follicles as a three-dimensional rendering for final approval of the surgeon and the patient.

As to the robotic insertion of the grafts **107**, **108**, into the patient's scalp **102**, the hair follicle introducer **115** may be used to simultaneously make the necessary slit, or short incision, into the patient's scalp **102**, by use of the needle **117** associated with the hair follicle introducer. Alternatively, a separate device, such as a suitable scalpel, or laser, could be associated with the stereotactic robot **201** to make the necessary small opening, incision, or slit in the patient's scalp which is to receive the graft **107**, **108**.

Hemostasis, or cessation of bleeding, may be necessary, as in the prior Megasession procedure, and hemostasis may provided such as by injecting a vasoconstrictor along with the local anesthetic at the beginning of the procedure, and/or by applying local pressure for several seconds or minutes after the graft **107**, **108** is inserted in the patient's scalp. In order to minimize bleeding even more, a pneumatic band (not shown) can be placed around the patient's scalp at the beginning of the procedure. As previously discussed, single hair follicle insertion devices **115** or multiple hair follicle insertions devices could be utilized as previously described. As will be hereinafter discussed, the apparatus **200** of the present invention in addition to performing the hair transplantation method previously described may also be used, if desired, to perform additional functions; however, whether or not the following described additional functions are also performed by apparatus **200** does not detract from the usefulness of apparatus **200**.

If desired, the apparatus **200** of the present invention could also be utilized to trim the flap **104** of the patient's scalp which has been previously removed from the patient. As previously described, a plug trimming device, or suitable scalpel, can be associated with the first end **203** of the robotic arm **202** of the stereotactic robot **201**. The surgeon could mount the flap **104** containing the hair follicles **101** upon a suitable support surface. As previously described, after the location of the existing hair follicles **101** is determined and mapped by the stereotactic video system **300**, the plug trimming device, or scalpel, could be operated and controlled by the stereotactic robot **201** to cut the grafts **107**, **108** from the flap **104**. Preferably, each graft **107**, **108** would be cut along the longitudinal axis of the hair shaft of each hair follicle to minimize damage to the hair shaft and hair follicle. As previously described, if the angular disposition between the hair follicle and the patient's scalp has been determined the stereotactic video system **300**, the stereotactic robot **201** may be programmed to operate the plug trimming device along the longitudinal axis of each hair follicle **101**. Alternatively, a single hair follicle insertion device, such as device **116** of FIG. **5**, could be utilized as the plug cutting device, whereby the needle **117** would be inserted within flap **104** to retrieve a single hair follicle **101**, thus simultaneously loading the hair follicle to be implanted into the single hair follicle insertion device **116**.

Alternatively, if desired, the apparatus **200** of the present invention may be utilized to also directly obtain the grafts **107**, **108** directly from the patient's scalp **102** without surgically removing flap **104**. In this regard, as previously described, a plug cutting device **400** (FIG. **8**) could be associated with stereotactic robot **201** and the plug cutting device **400** could directly remove the grafts **107**, **108**, from the patient's scalp **102**. Alternatively, plug cutting device **400** could be a single hair follicle insertion device **116** (FIG. **5**) which includes a needle **117**, which could be used to remove the grafts **107**, **108**, directly from the patient's scalp **102**. As previously described, the patient's scalp is scanned robotically to identify the position of each hair follicle **101** and the plug cutting device **400** could be operated to select only every nth hair follicle **101**, rather than removing all the hair from a given location, which is comparable to the surgical removal of a flap **104**.

As to the transplantation of grafts **107**, **108**, into the patient's scalp **102**, it should be noted that the bald portion of the patient's scalp **102**, or recipient space, **103**, can be divided into any number of individual areas, each of which can be programmed individually. The recipient space, or bald area, **103** can overlap areas of existing hair in order to insert hair follicles **101** to increase the density of hair in those areas. The density of the transplanted hair follicles can be calculated, depending upon the number of hair follicles to be implanted. The spacing between hair follicles can be done either manually, or the computer can generate a random distribution. The angle of insertion may be determined for each area individually, or the computer can generate a plan to vary the angle of insertion progressively from one side of an area to the other. If some of the hair follicles to be transplanted are finer than the other hair follicles, they can be individually identified and reserved for insertion at the hair line. A three-dimensional rendered image simulating the post-operative appearance of the patient's scalp can be presented prior to hair follicle insertion for approval of the surgeon and possibly the patient.

Although the instrument holder **112** illustrated in FIG. **6** is shown to only hold a single tool, or instrument, such as hair follicle introducer **115**, it should be noted that a rotating head (not shown) may be utilized in connection with robotic arm **202** to hold all the desired tools, or instruments such as scalpel, plug cutting devices, plug trimming devices, and hair follicle insertion devices, the rotating head being sequentially moved, or rotated, to permit the desired tool, or instrument to be mounted at the first end **203** of robotic arm **202**.

The particular embodiments disclosed above are illustrative only, as the invention may be modified and practiced in different but equivalent manners apparent to those skilled in the art having the benefit of the teachings herein. Furthermore, no limitations are intended to the details of construction or design herein shown, other than as described in the claims below. It is therefore evident that the particular embodiments disclosed above may be altered or modified and all such variations are considered within the scope and spirit of the invention. Accordingly, the protection sought herein is as set forth in the claims below.

What is claimed:

[1. A hair transplantation apparatus for harvesting at least one hair follicle from a portion of a patient's scalp comprising:

a robot, including at least one robotic arm having a first end adapted to be disposed adjacent the patient's scalp;

a hair follicle plug cutting device associated with the first end of the robotic arm, the robotic arm being adjustably maneuverable so that the plug cutting device is capable of being selectably placed proximate the patient's scalp; and

the plug cutting device being operated using a substantially automated process to harvest the at least one hair follicle.**]**

[2. The hair transplantation apparatus of claim **1**, wherein the robot is at least a partially automated robot, and the robotic arm is moved to place the plug cutting device proximate the patient's scalp using a substantially automated process.**]**

[3. The hair transplantation apparatus of claim **1**, wherein the portion of the patient's scalp under consideration is a flap that has been removed from the patient's scalp.**]**

[4. The hair transplantation apparatus of claim 1, wherein the robot is a stereotactic robot.]

[5. The hair transplantation apparatus of claim 4, further comprising a plurality of fiducial marks strategically positioned in relation to the stereotactic robot so that the position of the robotic arm is known in relation to the patient's scalp.]

[6. The hair transplantation apparatus of claim 1, further comprising a video system that includes a camera and a monitor for displaying an image of the portion of patient's scalp under consideration.]

[7. The hair transplantation apparatus of claim 6, wherein the video system is used for mapping locations of existing hair follicles on the portion of the patient's scalp under consideration.]

[8. The hair transplantation apparatus of claim 7, wherein the video system is used to determine an angular disposition of the at least one hair follicle with respect to the patient's scalp.]

[9. The hair transplantation apparatus of claim 6, wherein the video system is used to create a virtual image of the portion of the patient's scalp under consideration.]

[10. The hair transplantation apparatus of claim 9, wherein the video system includes a stereo pair of video cameras, and the virtual image is created by scanning the patient's scalp using the stereo pair of video cameras.]

[11. The hair transplantation apparatus of claim 9, wherein the video system includes a video camera and a range finder, and the virtual image is created by scanning the patient's scalp using the video camera and the range finder.]

[12. The hair transplantation apparatus of claim 9, wherein the video system includes at least one camera, and the virtual image is acquired from a series of still images taken by the at least one camera at different perspectives.]

[13. The hair transplantation apparatus of claim 9, wherein the virtual image of the portion of the patient's scalp under consideration includes a location and three-dimensional spacing of the at least one hair follicle to be harvested.]

[14. The hair transplantation apparatus of claim 13, wherein the robot is at least a partially automated robot, and the virtual image of the portion of the patient's scalp under consideration is used to move the robotic arm and place the plug cutting device proximate the patient's scalp using a substantially automated process.]

[15. The hair transplantation apparatus of claim 13, wherein the video system is used to simultaneously display the virtual image and a real-time image of the portion of the patient's scalp under consideration.]

[16. The hair transplantation apparatus of claim 1, wherein the hair follicle plug cutting device is operated to harvest a follicular unit.]

[17. The hair transplantation apparatus of claim 16, wherein the follicular unit includes a single hair follicle.]

[18. The hair transplantation apparatus of claim 16, wherein the follicular unit includes a plurality of hair follicles.]

19. A hair transplantation apparatus for implanting [at least one] hair [follicle into a portion of a patient's scalp] *follicles*, comprising:

a robot, including [at least one] *a* robotic arm [having a first end adapted to be disposed adjacent the patient's scalp]; *and*

a hair follicle introducer [associated with the first end of] *carried by* the robotic arm, the robotic arm being adjustably maneuverable *and directed by an imaging system, the imaging system being configured to create an image that allows 1) recognizing a hair graft and 2) identifying a hair implantation location that does not have the hair graft, and*

[so that] *direct the robot to selectively place* the hair follicle introducer [is capable of being selectably placed] proximate [the patient's scalp; and] *the hair implantation location identified with use of the imaging system, and wherein* the hair follicle introducer is *configured to be* loaded with [the] at least one hair follicle and then operated using a substantially automated process to implant the at least one hair follicle.

20. The hair transplantation apparatus of claim 19, wherein the at least one hair follicle is loaded into the hair follicle introducer using a substantially automated process.

21. The hair transplantation apparatus of claim 19, wherein the [robot is at least a partially automated robot, and the robotic arm is moved to place the introducer proximate the patient's scalp using a substantially automated process] *imaging system comprises a computer.*

22. The hair transplantation apparatus of claim 19, wherein the [robot is a stereotactic robot] *imaging system comprises a camera.*

[23. The hair transplantation apparatus of claim 22, further comprising a plurality of fiducial marks strategically positioned in relation to the stereotactic robot so that the position of the robotic arm is known in relation to the patient's scalp.]

24. The hair transplantation apparatus of claim 19, [further comprising] *wherein the imaging system is* a video system that includes a camera [and a monitor], *and is configured* for displaying an image of [the portion of patient's scalp under consideration] *a location of one or more existing hair follicles and/or a recipient space.*

25. The hair transplantation apparatus of claim 24, wherein the video system is used for planning a desired location for [the] at least one hair follicle to be implanted [in the portion of the patient's scalp under consideration].

26. The hair transplantation apparatus of claim 25, wherein, in planning the desired location for the at least one hair follicle, the video system is used to calculate a distance between a plurality of hair follicles to be implanted [in the portion of the patient's scalp under consideration].

27. The hair transplantation apparatus of claim 25, wherein, in planning the desired location for the at least one hair follicle, the video system is used to [plan] *generate* a random distribution of a plurality of hair follicles *to be implanted.*

28. The hair transplantation apparatus of claim 24, wherein the video system is used to determine an angular disposition of [the] at least one hair follicle [with respect to the patient's scalp] *to be implanted.*

29. The hair transplantation apparatus of claim 24, wherein the video system is [used] *configured* to create a [virtual] *real time* image of the [portion of the patient's scalp under consideration] *location of one or more existing hair follicles and/or hair implantation location.*

30. The hair transplantation apparatus of claim [29]*24*, wherein the video system includes a stereo pair of video cameras, and [the] *a* virtual image is created by scanning [the] *a* patient's scalp using the stereo pair of video cameras.

31. The hair transplantation apparatus of claim [29]*24*, wherein the video system includes a video camera and a range finder, and [the] *a* virtual image is created by scanning [the] *a* patient's scalp using the video camera and the range finder.

32. The hair transplantation apparatus of claim [29]*24*, wherein [the video system includes at least one camera, and the] *a* virtual image is acquired from a series of still images taken by the [at least one] camera at different perspectives.

33. The hair transplantation apparatus of claim [29]*24*, wherein the [virtual] image [of the portion of the patient's scalp under consideration] includes a three-dimensional spacing of [a] *the hair implantation* location [the at least one hair follicle is to be implanted].

[34. The hair transplantation apparatus of claim 33, wherein the robot is at least a partially automated robot, and the virtual image of the portion of the patient's scalp under consideration is used to move the robotic arm and place the introducer proximate the patient's scalp using a substantially automated process.]

35. The hair transplantation apparatus of claim 29, wherein the video system is [used] *configured* to simultaneously display [the] *a* virtual image and [a] *the* real-time image [of the portion of the patient's scalp under consideration].

[36. The hair transplantation apparatus of claim 19, wherein the at least one hair follicle is implanted in the patient's scalp at a predetermined depth, and the robot determines when the predetermined depth is attained using the substantially automated process.]

37. [A] *The* hair transplantation apparatus *of claim 19, wherein* [for implanting at least one hair follicle into a portion of a patient's scalp comprising:

a robot, including at least one robotic arm having a first end adapted to be disposed adjacent the patient's scalp;

a hair follicle introducer associated with the first end of the robotic arm,]

the robot [being] *is* capable of registering a position of the introducer with at least a portion of [the] *a* patient's scalp [under consideration] so that the position of the introducer is known in three-dimensional space with respect to the portion of the patient's scalp [under consideration, and the robotic arm is moved to place the introducer proximate the patient's scalp using a substantially automated process; and

the hair follicle introducer is loaded with the at least one hair follicle and then operated using a substantially automated process to implant the at least one hair follicle].

[38. The hair transplantation apparatus of claim 37, wherein the at least one hair follicle is loaded into the hair follicle introducer using a substantially automated process.]

[39. The hair transplantation apparatus of claim 37, wherein the robot is a stereotactic robot.]

[40. The hair transplantation apparatus of claim 39, further comprising a plurality of fiducial marks strategically positioned in relation to the stereotactic robot so that the position of the robotic arm is known in relation to the patient's scalp.]

[41. The hair transplantation apparatus of claim 37, further comprising a video system that includes a camera and a monitor for displaying an image of the portion of patient's scalp under consideration.]

[42. The hair transplantation apparatus of claim 41, wherein the video system is used for planning a desired location for the at least one hair follicle to be implanted in the portion of the patient's scalp under consideration.]

[43. The hair transplantation apparatus of claim 42, wherein, in planning the desired location of the at least one hair follicle, the video system is used to calculate a distance between a plurality of hair follicles to be implanted in the portion of the patient's scalp under consideration.]

[44. The hair transplantation apparatus of claim 42, wherein, in planning the desired location of the at least one hair follicle, the video system is used to plan a random distribution of a plurality of hair follicles.]

[45. The hair transplantation apparatus of claim 41, wherein the video system is used to create a virtual image of the portion of the patient's scalp under consideration.]

[46. The hair transplantation apparatus of claim 45, wherein the video system includes a stereo pair of video cameras, and the virtual image is created by scanning the patient's scalp using the stereo pair of video cameras.]

[47. The hair transplantation apparatus of claim 45, wherein the video system includes a video camera and a range finder, and the virtual image is created by scanning the patient's scalp using the video camera and the range finder.]

[48. The hair transplantation apparatus of claim 45, wherein the video system includes at least one camera, and the virtual image is acquired from a series of still images taken by the at least one camera at different perspectives.]

[49. The hair transplantation apparatus of claim 45, wherein the virtual image of the portion of the patient's scalp under consideration includes a three-dimensional spacing of a location the at least one hair follicle is to be implanted.]

[50. The hair transplantation apparatus of claim 45, wherein the video system is used to simultaneously display the virtual image and a real-time image of the portion of the patient's scalp under consideration.]

[51. The hair transplantation apparatus of claim 37, wherein the at least one hair follicle is implanted in the patient's scalp at a predetermined depth, and the robot determines when the predetermined depth is attained using the substantially automated process.]

[52. A hair transplantation apparatus for harvesting at least one hair follicle from a portion of a patient's scalp comprising:

a robot, including at least one robotic arm having a first end adapted to be disposed adjacent the patient's scalp;

a hair follicle plug cutting device associated with the first end of the robotic arm, the robot being capable of registering a position of the plug cutting device with at least a portion of the patient's scalp under consideration so that the position of the plug cutting device is known in three-dimensional space with respect to the portion of the patient's scalp under consideration, and the robotic arm is moved to place the plug cutting device proximate the patient's scalp using a substantially automated process; and

the plug cutting device being operated using a substantially automated process to harvest the at least one hair follicle.]

[53. The hair transplantation apparatus of claim 52, wherein the portion of the patient's scalp under consideration is a flap that has been removed from the patient's scalp.]

[54. The hair transplantation apparatus of claim 52, wherein the robot is a stereotactic robot.]

[55. The hair transplantation apparatus of claim 54, further comprising a plurality of fiducial marks strategically positioned in relation to the stereotactic robot so that the position of the robotic arm is known in relation to the patient's scalp.]

[56. The hair transplantation apparatus of claim 52, further comprising a video system that includes a camera and a monitor for displaying an image of the portion of patient's scalp under consideration.]

[57. The hair transplantation apparatus of claim 56, wherein the video system is used for mapping locations of existing hair follicles on the portion of the patient's scalp under consideration.]

[58. The hair transplantation apparatus of claim 57, wherein the video system is used to determine the angular disposition of the at least one hair follicle with respect to the patient's scalp.]

[59. The hair transplantation apparatus of claim 56, wherein the video system is used to create a virtual image of the portion of the patient's scalp under consideration.]

[60. The hair transplantation apparatus of claim 59, wherein the video system includes a stereo pair of video cameras, and the virtual image is created by scanning the patient's scalp using the stereo pair of video cameras.]

[61. The hair transplantation apparatus of claim 59, wherein the video system includes a video camera and a range finder, and the virtual image is created by scanning the patient's scalp using the video camera and the range finder.]

[62. The hair transplantation apparatus of claim 59, wherein the video system includes at least one camera, and the virtual image is acquired from a series of still images taken by the at least one camera at different perspectives.]

[63. The hair transplantation apparatus of claim 59, wherein the virtual image of the portion of the patient's scalp under consideration includes a location and three-dimensional spacing of the at least one hair follicle to be harvested.]

[64. The hair transplantation apparatus of claim 59, wherein the video system is used to simultaneously display the virtual image and a real-time image of the portion of the patient's scalp under consideration.]

[65. The hair transplantation apparatus of claim 52, wherein the hair follicle plug cutting device is operated to harvest a follicular unit.]

[66. The hair transplantation apparatus of claim 65, wherein the follicular unit includes a single hair follicle.]

[67. The hair transplantation apparatus of claim 65, wherein the follicular unit includes a plurality of hair follicles.]

68. A hair transplantation apparatus for harvesting [at least one hair follicle] and implanting [the at least one] hair follicle*s* from/into [a portion of a patient's scalp] *respective harvesting and implantation locations,* comprising:

a robot, including [at least one] *a* robotic arm [having a first end adapted to be disposed adjacent the patient's scalp];

an instrument holder associated with [the first end of] the robotic arm;

a hair plug cutting device associated with the instrument holder, the [robot] *robotic arm* being adjustably maneuverable [so that] *and directed by an imaging system, the imaging system being configured to create an image including at least one hair follicle recognizable in the image, allow identifying a location of the at least one hair follicle and to direct the robotic arm based on the hair follicle location identified with use of the imaging system to selectively place* the *hair* plug cutting device [is capable of being selectably placed] proximate [the patient's scalp;] *the identified hair follicle location,* the *hair* plug cutting device being [operated] *operable* using a substantially automated process to harvest the at least one hair follicle from [a first] *the identified hair follicle* location [of the patient's scalp]; *and*

a hair follicle introducer associated with the instrument holder, the [robot] *robotic arm* being adjustably maneuverable so that the introducer is capable of being [selectably] *selectively* placed proximate the [patient's scalp;] *an implantation location,* and the hair follicle introducer being [operated] *operable* using a substantially automated process to implant the at least one *harvested* hair follicle into [a second] *the implantation* location [of the patient's scalp].

69. The hair transplantation apparatus of claim 68, wherein the plug cutting device and the hair follicle introducer are the same device.

70. The hair transplantation apparatus of claim 68, wherein [the robot is at least a partially automated robot, and] the robotic arm is moved to place [the plug cutting device and] the introducer proximate the [patient's scalp using a substantially automated process] *implantation location under control of a computer program.*

[71. The hair transplantation apparatus of claim 68, wherein the robot is a stereotactic robot.]

[72. The hair transplantation apparatus of claim 71, further comprising a plurality of fiducial marks strategically positioned in relation to the stereotactic robot so that the position of the robotic arm is known in relation to the patient's scalp.]

73. The hair transplantation apparatus of claim 68, [further comprising] *wherein the imaging system comprises* a video system that includes a camera [and a monitor for displaying an image of the portion of patient's scalp under consideration].

74. The hair transplantation apparatus of claim 73, wherein the video system is [used for mapping the first location of the patient's scalp] *configured to display an image of the identified hair follicle location and/or the implantation location.*

[75. The hair transplantation apparatus of claim 74, wherein the video system is used to determine the angular disposition of the at least one hair follicle with respect to the patient's scalp.]

76. The hair transplantation apparatus of claim 73, wherein the video system is used for planning the [second] *implantation* location [of the patient's scalp].

77. The hair transplantation apparatus of claim 76, wherein, in planning the [second] *implantation* location, the video system is used to calculate a distance between the [second] *implantation* location and a plurality of additional locations *in which* hair follicles are to be implanted [in the patient's scalp].

[78. The hair transplantation apparatus of claim 73, wherein the video system is used to create a virtual image of the portion of the patient's scalp under consideration.]

[79. The hair transplantation apparatus of claim 78, wherein the video system includes a stereo pair of video cameras, and the virtual image is created by scanning the patient's scalp using the stereo pair of video cameras.]

[80. The hair transplantation apparatus of claim 78, wherein the video system includes a video camera and a range finder, and the virtual image is created by scanning the patient's scalp using the video camera and the range finder.]

[81. The hair transplantation apparatus of claim 78, wherein the video system includes at least one camera, and the virtual image is acquired from a series of still images taken by the at least one camera at different perspectives.]

[82. The hair transplantation apparatus of claim 78, wherein the virtual image of the portion of the patient's scalp under consideration includes a three-dimensional image of the first location of the patient's scalp.]

[83. The hair transplantation apparatus of claim 82, wherein the robot is at least a partially automated robot, and the virtual image of the first location is used to move the robotic arm and place the plug cutting device proximate the patient's scalp using a substantially automated process.]

[84. The hair transplantation apparatus of claim 78, wherein the virtual image of the portion of the patient's scalp under consideration includes a three-dimensional image of the second location of the patient's scalp.]

[85. The hair transplantation apparatus of claim 84, wherein the robot is at least a partially automated robot, and the virtual image of the second location is used to move the robotic arm and place the introducer proximate the patient's scalp using a substantially automated process.]

86. The hair transplantation apparatus of claim [78] *68*, wherein the [video] *imaging* system is [used] *configured* to

[simultaneously] display [the virtual image and] a real-time image of [the portion of the] *a* patient's scalp under consideration.

[**87**. The hair transplantation apparatus of claim **68**, wherein the at least one hair follicle is implanted in the patient's scalp at a predetermined depth, and the robot determines when the predetermined depth is attained using the substantially automated process.]

[**88**. The hair transplantation apparatus of claim **68**, wherein the hair follicle plug cutting device is operated to harvest a follicular unit.]

[**89**. The hair transplantation apparatus of claim **88**, wherein the follicular unit includes a single hair follicle.]

[**90**. The hair transplantation apparatus of claim **88**, wherein the follicular unit includes a plurality of hair follicles.]

[**91**. A hair transplantation apparatus for harvesting at least one hair follicle and implanting the at least one hair follicle from/into a portion of a patient's scalp comprising:

a robot, including at least one robotic arm having a first end adapted to be disposed adjacent the patient's scalp;

an instrument holder associated with the first end of the robotic arm;

a hair follicle plug cutting device associated with the instrument holder, the robot being capable of registering a position of the plug cutting device with a first location of the patient's scalp so that the position of the plug cutting device is known in three-dimensional space with respect to the first location, and the robotic arm is moved to place the plug cutting device proximate the first location using a substantially automated process;

the plug cutting device being operated using a substantially automated process to harvest the at least one hair follicle;

a hair follicle introducer associated with the instrument holder, the robot being capable of registering a position of the introducer with a second location of the patient's scalp so that the position of the introducer is known in three-dimensional space with respect to the second location, and the robotic arm is moved to place the introducer proximate the second location using a substantially automated process; and

the hair follicle introducer is loaded with the at least one hair follicle and then operated using a substantially automated process to implant the at least one hair follicle.]

[**92**. The hair transplantation apparatus of claim **91**, wherein the plug cutting device and the hair follicle introducer are the same device.]

[**93**. The hair transplantation apparatus of claim **91**, wherein the robot is a stereotactic robot.]

[**94**. The hair transplantation apparatus of claim **93**, further comprising a plurality of fiducial marks strategically positioned in relation to the stereotactic robot so that the position of the robotic arm is known in relation to the patient's scalp.]

[**95**. The hair transplantation apparatus of claim **91**, further comprising a video system that includes a camera and a monitor for displaying an image of the portion of patient's scalp under consideration.]

[**96**. The hair transplantation apparatus of claim **95**, wherein the video system is used for mapping the first location of the patient's scalp.]

[**97**. The hair transplantation apparatus of claim **95**, wherein the video system is used for planning the second location of the patient's scalp.]

[**98**. The hair transplantation apparatus of claim **95**, wherein the video system is used to create a virtual image of the portion of the patient's scalp under consideration.]

[**99**. The hair transplantation apparatus of claim **98**, wherein the video system includes a stereo pair of video cameras, and the virtual image is created by scanning the patient's scalp using the stereo pair of video cameras.]

[**100**. The hair transplantation apparatus of claim **98**, wherein the video system includes a video camera and a range finder, and the virtual image is created by scanning the patient's scalp using the video camera and the range finder.]

[**101**. The hair transplantation apparatus of claim **98**, wherein the video system includes at least one camera, and the virtual image is acquired from a series of still images taken by the at least one camera at different perspectives.]

[**102**. The hair transplantation apparatus of claim **98**, wherein the virtual image of the portion of the patient's scalp under consideration includes a three-dimensional image of the first location of the patient's scalp.]

[**103**. The hair transplantation apparatus of claim **98**, wherein the virtual image of the portion of the patient's scalp under consideration includes a three-dimensional image of the second location of the patient's scalp.]

[**104**. The hair transplantation apparatus of claim **98**, wherein the video system simultaneously displays the virtual image and a real-time image of the portion of the patient's scalp under consideration.]

[**105**. The hair transplantation apparatus of claim **91**, wherein the at least one hair follicle is loaded into the hair follicle introducer using a substantially automated process.]

[**106**. The hair transplantation apparatus of claim **91**, wherein the at least one hair follicle is implanted in the patient's scalp at a predetermined depth, and the robot determines when the predetermined depth is attained using the substantially automated process.]

[**107**. The hair transplantation apparatus of claim **91**, wherein the hair follicle plug cutting device is operated to harvest a follicular unit.]

[**108**. The hair transplantation apparatus of claim **107**, wherein the follicular unit includes a single hair follicle.]

[**109**. The hair transplantation apparatus of claim **107**, wherein the follicular unit includes a plurality of hair follicles.]

110. A hair implantation apparatus, comprising:

a robot;

a hair follicle insertion device carried by the robot and configured to be operated using a substantially automated process to implant one or more hair grafts; and

an imaging system configured to create an image that allows recognizing a hair graft and identifying a hair implantation location that does not have the hair graft, and to direct the robot to selectively position the hair follicle insertion device proximate the hair implantation location identified with use of the imaging system.

111. The apparatus of claim 110, wherein the robot is computer-controlled.

112. The apparatus of claim 110, wherein operation of the hair follicle insertion device is computer-controlled.

113. The apparatus of claim 110, further comprising a plurality of fiducial marks.

114. The apparatus of claim 110, wherein the imaging system is configured to provide a 3D image of one or more existing hair follicles.

115. The apparatus of claim 110, wherein the imaging system is configured to allow identifying a location of one or more hair follicles and calculating three-dimensional coordinates of the one or more hair follicles.

116. The apparatus of claim 110, wherein the hair follicle insertion device comprises a scalpel.

117. The apparatus of claim 110, wherein the hair follicle insertion device comprises at least one needle.

118. The apparatus of claim 110, wherein the imaging system is configured to allow planning the hair implantation location.

119. The apparatus of claim 118, wherein the location planning is at least partially computerized.

120. The apparatus of claim 118, wherein the location planning comprises plotting individual implantation sites according to one or more of selected degrees of randomness or an angle of insertion.

121. The apparatus of claim 110, further comprising a hair harvesting tool maneuverable by a robot to harvest hair grafts.

122. The apparatus of claim 121, wherein the hair harvesting tool and the hair follicle insertion device are the same device.

123. The apparatus of claim 110, wherein the apparatus is further configured to perform one or more of mapping locations of existing hair follicles, determining an angular disposition of existing hair follicles, or determining an angular disposition of at least one hair graft to be implanted.

124. The apparatus of claim 110, wherein the imaging system comprises a computer.

125. The apparatus of claim 110, wherein the imaging system is a video imaging system comprising a camera.

126. The apparatus of claim 110, wherein the imaging system comprises a display, the imaging system being configured to display an image simulating a post-operative appearance of a recipient space.

127. The apparatus of claim 110, wherein the imaging system simultaneously displays a virtual image and a real-time image of the hair implantation location.

128. The apparatus of claim 110, wherein the imaging system is configured to create a real time image of a location of one or more existing hair follicles and/or the hair implantation location and to direct the robot to implant the one or more hair grafts based on the real time image.

129. A hair implantation apparatus, comprising:

a robot directed by an imaging system, the imaging system being configured to allow planning an implantation location for one or more hair grafts to be implanted, wherein the location planning comprises plotting individual hair implantation sites according to selected degrees of randomness; and

a hair follicle insertion device carried and maneuverable by the robot to be selectively positioned proximate the hair implantation location and configured to be operated using a substantially automated process to implant the one or more hair grafts into the hair implantation location.

130. The apparatus of claim 110, wherein the imaging system is configured to determine spacing between the one or more hair grafts.

131. The apparatus of claim 110, wherein the imaging system is configured to scan a bald area and/or one or more existing hair follicles.

* * * * *