Rapid Fire Hair Implanter Carousel

A New Surgical Instrument for the Automation of Hair Transplantation

WILLIAM R. RASSMAN, MD
ROBERT M. BERNSTEIN, MD

BACKGROUND. *As hair transplantation evolved into a procedure in which large numbers of very small grafts are moved in a single session, new problems have emerged. These include greater staffing requirements, longer operating time, additional technical difficulties, and increasing problems with quality control.*

OBJECTIVE. *To introduce a new surgical instrument, the Rapid Fire Hair Implanter Carousel (Carousel), which can automate the most labor-intensive parts of the hair transplantation process, site creation and implant placement, by combining them into a single step and delivering them in rapid sequence. This instrumentation should help to minimize some of the human factors contributing to graft injury and to simplify and increase the speed of the hair transplant procedure.*

METHODS. *In a patient with a Norwood IIIA balding pattern, 400 follicular implants were placed into a specific section of the bald scalp. The remainder of the bald scalp was transplanted with 800 follicular implants placed in the traditional way. The two areas were monitored and compared for intraoperative bleeding, ease of placing, total placing time, postoperative healing, and hair growth. Photographic documentation was obtained after surgery and at each postoperative visit.*

RESULTS. *The Carousel visually produced less bleeding when compared with the manual approach. The Carousel was easier to use than the manual technique, since it eliminated graft insertion as a separate step. This was evidenced by the significantly shorter time required to insert the implants (40 grafts/minute with the Carousel vs 6.6 grafts/minute manually) and the decreased need for secondary manipulation once the grafts were inserted. Postoperative healing of the two groups were the same with regard to the duration of crusting and erythema. The rate of hair growth and the total amount of hair observed at 4 months were the same when identical size areas in test and control sides were compared.*

CONCLUSION. *In this single patient pilot study, the Carousel greatly facilitated the placement of grafts by decreasing bleeding and obviating the extra step needed for the insertion of the implants. As a result, the total operative time decreased, shortening the time the grafts were outside the body, and decreasing the risk of desiccation and warming. By minimizing the human factor in this labor-intensive part of the procedure, the quality of the hair transplant should increase. It is anticipated that these benefits will result in increased hair yield. Further studies are needed, in a larger patient group, so that these benefits can be demonstrated. © 1998 by the American Society for Dermatologic Surgery, Inc. Dermatol Surg 1998;24:623–627.*

Hair transplantation in the 1990s has rapidly evolved from a simple 1–2-hour procedure, easily accomplished by a physician and one or two assistants, into a labor intensive, 3–10 hour "mega-session" procedure, involving the movement of hundreds to thousands of grafts in a single sitting, requiring a large coordinated team of highly trained staff.[1] These techniques have produced extremely natural looking hair transplants that can be achieved in just a few treatment sessions. However, the technical difficulties and issues of quality control have proved to be a significant problem, even for the most experienced transplant teams.

From the New Hair Institute (WRR), Los Angeles, California; and the New Hair Institute (RMB), Fort Lee, New Jersey, and New York, New York.

Address correspondence and reprint requests to: William R. Rassman, MD, 9911 West Pico Boulevard, Suite 301, Los Angeles, CA 90035.

Dr. Rassman has been awarded a U.S. Patent for the device, #5,584,841, and has two additional U.S. Patents pending. He has pending patents in a number of foreign countries as well. He has developed the instrument for commercial release and is presently the majority owner of the company that owns the technology.

As the number of technicians and medical assistants involved with the procedure increases, so do the problems of organization, management, and quality control. With a large staff, ensuring that the technical aspects of the procedure are carried out with uniformity and precision becomes a major concern of the physician. As the number of implants moved per session increases, so do the problems associated with graft desiccation, warming, and survival, since the implants must now be kept outside the body for longer periods of time. Also increased are the problems associated with the tedium of filling hundreds to thousands of recipient sites. Staff fatigue and decreased attention spans can result in missed sites, piggybacking, and trauma to the grafts.

Large sessions of closely spaced sites also pose additional problems of hemostasis and graft popping, all of which contribute to an increased risk of mechanical injury as grafts are re-inserted. A well-trained technician will carefully grasp the graft by the fat below the bulb, or by the connective tissue beside the follicular structure. However, once a second pass is needed to reinsert or reposition a partially placed graft, especially

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with decreased visibility from even minor amounts of bleeding, problems arise. The grafts are no longer held carefully by the edge, but often hastily grabbed across their surface, traumatizing the growth elements and possibly causing permanent injury to the implants.[2–4]

A new disposable instrument, the Rapid Fire Hair Implanter Carousel (Carousel), has been developed which automates the most difficult and labor intensive components of the hair transplant process: the creation of the recipient sites and the insertion of the implants. These two steps can now be performed in rapid sequence and in one simple motion. The implants are stored in a cartridge while they await placement. Large numbers of implants can then be placed in a relatively short time span, decreasing both the length of the surgery and the requirement for a large staff. The Carousel reduces the risk of damage to the implants from desiccation and manual manipulation. The instrument can be used equally well for micrografting[5] or for follicular transplantation,[1,6,7] although these authors feel that a superior cosmetic results will be obtained if the Carousel is loaded exclusively with follicular units, rather than with micrografts cut to size. This paper describes the new instrumentation and examines its use in a single case study.

Materials and Methods

A 34-year-old Caucasian male with a Norwood Class IIIA, male pattern alopecia volunteered for this study. The patient had dark brown hair of average diameter, medium colored skin, and had a donor density measuring 2.8–3.0 hairs/mm^2. He showed normal levels of donor site miniaturization and his scalp laxity was average. The surgical plan was to restore his frontal hairline and to add coverage to the front part of his scalp.

After consent forms were signed and preoperative photographs taken, the patient was premedicated with Celestone 9 mg IM, dicloxacillin 500 mg PO, and diazepam 10 mg PO. The hair in the mid-portion of the permanent zone was clipped to a length of 1.5 mm. Local anesthesia, containing a mixture of 40% bupivicane, 60% lidocaine, and 1/200,000 epinephrine was administered in a ring block fashion to the donor area. A single donor strip was harvested with two parallel blades set 1.5 cm apart on a Rassman Handle. The donor area was closed with a single running suture. The donor strip was dissected into 1,200 implants consisting of one-, two-, and three-hair follicular units. Four hundred units were temporarily placed in chilled saline and then loaded into the Carousel cartridges (see Figure 3), which was then sealed awaiting use. Eight hundred implants were stored in chilled saline to be used with the manual placing technique. The dissection was carried out using 2–4× magnification with the aid of transillumination.[8] Both groups were prepared in an identical manner except that during dissection the superficial portion of the epidermis was removed from the implants that were to be used in the Carousel. Subsequent experience has shown that routine removal of the epidermis is not necessary.

Four hundred follicular units were transplanted with the Carousel into the test site, which consisted of an area on the right side of the patient's scalp approximately 1 cm behind the right frontal hairline. The remainder of the frontal area on the right side and the entire contralateral side, serving as a control, was transplanted with 800 follicular units using manual techniques. This consisted of using an 18-g NoKor needle to create the recipient sites and jewelers forceps to manually insert the implants.[1,7]

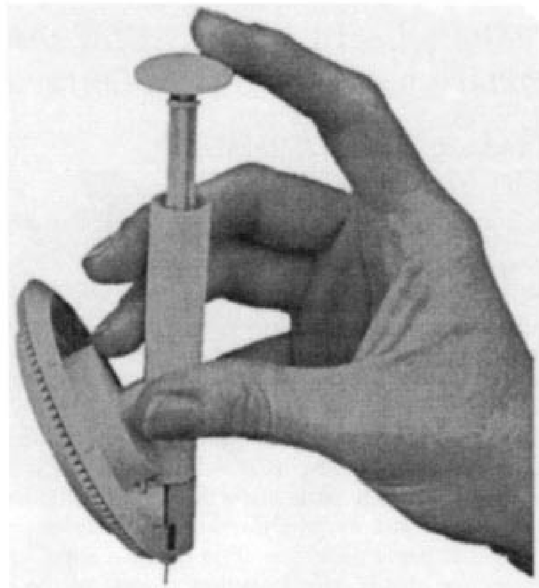
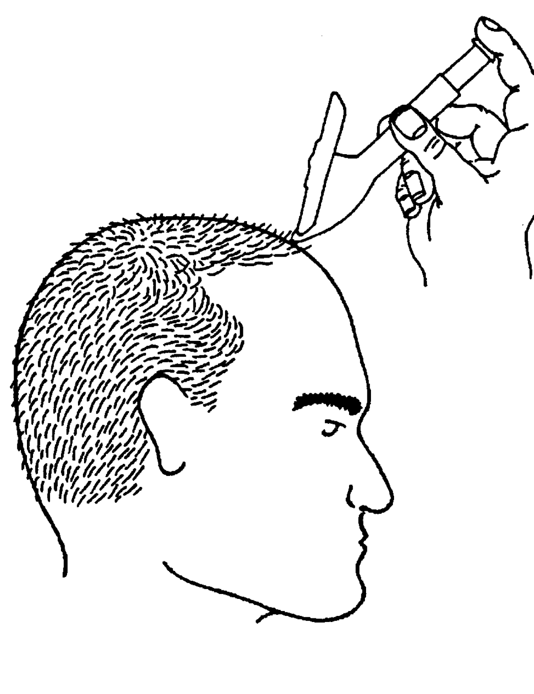


Figure 1. The Rapid Fire Hair Implanter Carousel.

The Carousel was used for the test area. This instrument is a disposable, hand-held mechanical device (Figures 1 and 2). The Carousel has a sharp end designed to pierce the scalp, an insertion element to move the implants into the recipient site, and a button end that is the activator of the mechanical components. The button end is similar to the activation button of a ball point pen. A circular cartridge is located in the central portion of the Carousel that houses the individual follicular grafts. When placed in the cartridge, the grafts are oriented with the skin

Figure 2. The Carousel in position.



A

B

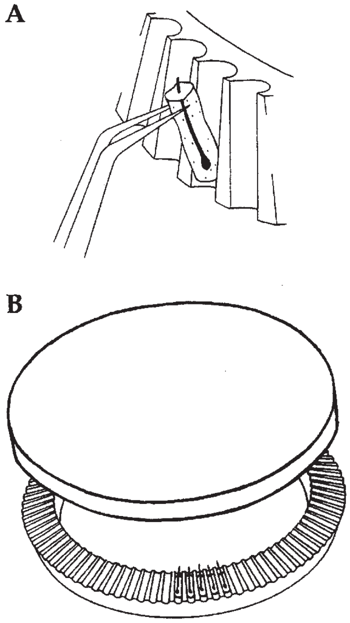


Figure 3. *A) Once the grafts are harvested, they are placed into slots of a cartridge. Small droplets of saline are placed with the grafts. B) Once the slots are filled, a cover is placed over the cartridge and the entire apparatus is refrigerated until the grafts are implanted.*

surface facing toward the center of the cylinder, and the hair bulb facing outward. Each cartridge is designed with 100 cylindrical slots to house 100 micrografts or follicular implants. The cartridge is secured onto the Carousel with a locking ring.

The loaded instrument is held between the thumb and the middle and ring fingers. In a short, quick downward motion, the cutting edge at the tip of the Carousel is made to penetrate the patient's scalp, creating a tiny slit for the implant. The angle of penetration is at the discretion of the surgeon. The index finger activates the instrument by placing pressure on the button on top of the Carousel. This allows the mechanical components of the instrument to pick up a graft from the chamber. As the graft continues down its path, it is carried through a needle bore into proper position in the patient's scalp. The instrument is withdrawn, leaving the graft in place. It is then moved to a new position on the scalp. The Carousel functions so that the placing of one implant automatically advances the next implant into position. Four Carousels, loaded with 100 implants each, were used for the test area.

Note

For recipient site creation, the Carousel functions in a manner similar to other tools used in the hair transplant process such as trochars, punches, and knives, which create openings in the scalp. Any instrument used to penetrate the scalp can also penetrate the skull if significant forces are applied. The depth of penetration can be determined by observation or by contact with the bony skull. The physician must use his judgment in determining both the depth and the force that must be applied to make the opening in the recipient area of the scalp. Prior to use on the scalp, the physician must assess the integrity of the bony skull. If any defects in the bony skull are present, or suspected, the physician must not proceed without further evaluation.

Results

The Carousel incorporates a one-step approach that was used for the site creation and placement of the 400 grafts transplanted to the right side of the study patient's scalp. It produced visibly less bleeding overall when compared with the manual two-step approach (using a Nokor needle and forceps). Since the Carousel inserted the grafts as the sites were made, the implants appeared to tamponade the bleeding from those recipient sites. In contrast, the conventional Nokor needle was used for the remaining 800 grafts. These sites were made and left open until hemostasis was complete and all of the sites were created.

In the manual technique, many of the implants were manipulated several times as they were regrasped. This was especially evident if bleeding caused poor visibility. In addition, implants that were elevated from bleeding (or popping) had to be reinserted or adjusted.

The Carousel, which created the recipient sites and implanted the grafts in one step, took approximately 10 minutes (40 grafts/minute). With the manual technique, placement of the equivalent 400 implants took 1 hour (6.6 grafts/minute). The remaining 400 grafts took an additional hour. We used our most experienced technician to place all of the manual grafts, in order to minimize the human variables in the control group.

Postoperative wound examination showed no difference between those sites made with the Carousel and those made with the conventional needle. An independent observer felt that they were similar with respect to the rate of healing as indicated by the time it took for the crusting to disappear (approximately 6 days), and the time for the erythema to fade (approximately 3 days).

Healing and hair growth were followed by serial photography. Photographs were taken before surgery (Figure 4A), and then at the following intervals: 1 day post-op, 2 days post-op, 3 days post-op, 9 days post-op, 1 month post-op, 2 months post-op, 3 months post-op, 4 months post-op (Figure 4B), and 8 months post-op (Figure 4C).

In viewing the photographs, or directly viewing the patients, there was no difference observed between the site healing or graft growth when the Carousel and manual techniques with compared. Growth commenced at about 90 days following surgery in both sides. When identical size areas in the test and control sides were compared, there was no difference noted in the total amount of hair observed at 4 months and 8 months.

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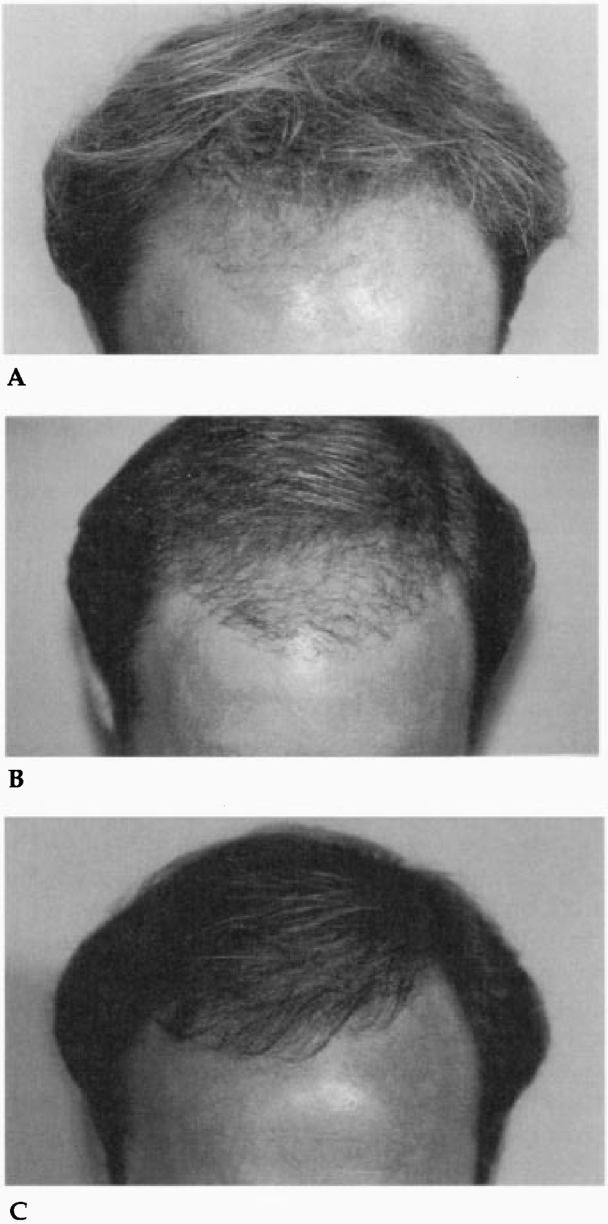

Figure 4. A) Before and B) 4 months post-op; C) 8 months post-op.

Discussion

The purpose of this paper is to introduce the Rapid Fire Hair Implanter Carousel. The major advantages of the Carousel are:

1. The Carousel is able to simultaneously create sites and insert the implants. Since the placing of implants into premade sites has been the most time consuming part of the manual transplant procedure, the automation of this step greatly reduces the total operative time.
2. The skilled staff needed to insert the implants (the most labor-intensive and difficult part of the transplant procedure) can be reduced significantly.
3. In performing larger transplant procedures with the manual process, grafts must often remain outside the body for hours awaiting placement. With the Carousel, this time is reduced significantly, since the grafts are implanted at the same time the sites are made. This reduces the risk of damage from desiccation and warming. It also theoretically minimizes the chance of poor graft growth, by decreasing the time the grafts are separated from their blood supply.
4. Human manipulation of the grafts during the insertion process in the manual technique has been a significant source of injury to the implants, since the grafts are often inadvertently squeezed and/or crushed by the placer's forceps. This is often compounded by the decreased visibility caused by bleeding from the sites prior to and during graft insertion. The Carousel can greatly reduce or eliminate this source of injury.

The conclusions that can be drawn from a single case study that lacks true bilateral controls are obviously limited. Ongoing clinical trials will be conducted by these authors on additional patients and under a more formal protocol as more instruments become available. Although this pilot study involved the placement of only 400 test implants, it seems clear that the instrument significantly simplifies the hair transplantation procedure and will be equally versatile when larger numbers of grafts are used in a single session since several individuals can use different Carousels simultaneously.

The actual quantitative advantage that automation holds in the implantation process by bypassing the need for "human placers" is still speculative. What this case study shows is that in one patient, under ideal conditions, the instrument compares favorably with the manual technique. In addition to speeding up operative time and reducing staffing requirements, the elimination of some of the human factors contributing to graft injury certainly presents a compelling argument to use this new instrument. Studies comparing the Carousel with that of the manual technique using objective measurements of hair growth, under strict bilateral controls and in multiple patients, must still be performed. These studies would, of course, be best performed by researchers not involved in the development of the instrument.

Conclusion

Preliminary results from a single pilot study demonstrated that the partial automation of the hair transplant process is technically feasible. It showed that the Rapid Fire Hair Implanter Carousel has the potential to significantly reduce the operative time of a hair transplant, decrease staffing requirements, and minimize the risk of iatrogenic trauma to grafts during the implantation part of the procedure. The benefits that this new technology may offer in surgical hair restoration still need to be explored in well-controlled studies.

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Commentary

Rumors of a new hair transplantation device from the creative energy of Dr. William Rassman and colleagues have circulated for the past year. Intriguing hints of "a major break through" and "great savings in time" fueled the rumors. The basis of the rumors was the Rapid Fire Hair Implanter described above. The device was first unveiled at the International Society of Hair Restoration Surgery (ISHRS) meeting in October 1997. A published report of the ISHRS meeting, by the society's President Russell Knudsen, MD, stated the device was "the highlight of the day (the year?)" reflecting the great interest expressed by the surgeons in attendance.[1] *To balance the enthusiastic reception of the Rapid Fire Implanter concept, an awareness of several historical and scientific facts may be of value.*

Devices for creating a recipient site and immediately inserting a graft are not new. Anthony Pignataro, MD described a "Micrograft Implanter" in 1996 at the ASHRS meeting in Orlando. Eric Eisenberg, MD published a technique/device in this journal in 1995 and spoke of both his method and instruments a year earlier.[2] *Paul Goldberg, MD applied for a patent on a device to make incisions and insert grafts from a multi-graft magazine in 1994. I personally viewed a videotape in 1996 of Dr. Goldberg's device used on a patient. Dr. Jung Chul Kim of Korea invented the Choi Implanter plus the second-generation device, "The Hair Bundle Inplanter," which have been used in the Orient for thousands of hair transplants over the last 5 years. Like the Rapid Fire, most previous implanters employ a sharpened tube to penetrate the scalp and a graft passed through the lumen is left in place as the tube is withdrawn.*

Technical problems for the surgeon may arise when the two steps of recipient site creation and graft insertion are combined. In my limited experience with implanters, four problems seem to commonly occur.

1. *Insertion of the implanter may displace nearby grafts. This tendency to dislodge other grafts can quickly offset the advantage of speed as each affected graft must be manually reinserted.*
2. *Freshly created recipient sites tend to be slippery, allowing grafts to migrate out of position. Graft sites become "sticky" after 20–30 minutes, helping grafts maintain position after placement.*
3. *The process of preloading implanters can take more time than expected. The time spent inserting the grafts into the implanter could be spent inserting grafts into the patient.*
4. *Graft positioning within the recipient site is inconsistent. Both the dermal thickness of the scalp and the length of individual grafts vary greatly. Proper insertion depth for some grafts may be too deep or too shallow for other grafts.*

In addition, elemental questions addressing the use of an implanter remain unanswered. The questions are quite simple: Will a device designed for both creating a recipient site and inserting a graft create the perfect recipient site? And, conversely, is such a device truly the best instrument for inserting a graft? Does the design for one task compromise the other?

I find it curious that surgeons are so fascinated with combining the multiple steps of transplantation when in fact important improvement in hair transplantation has occurred with movement in the opposite direction. For example, hair transplantation originally used 4-mm grafts taken directly from the donor site, ie, donor harvesting and graft creation in one step. Currently, a two-step approach is used. The first step harvests donor tissue as strips or an ellipse, and the second step focuses on generating high quality grafts.

On a positive note it must be said that none of the problems with implanters are insurmountable. The people working on the Rapid Fire and other implanters must be commended for tackling the awkward, time-consuming problem of graft insertion. Graft insertion is tedious work and in addition damage to the grafts may occur. The Rapid Fire Implanter appears to minimize graft trauma. This device, working as planned, has the potential of both saving time and simplifying the surgeons work.

Pioneers with creative dreams have carried the science of hair transplantation further than anyone could have dreamed just a decade ago. Like Olympic runners approaching the finish line, we can all express our hopes for an effective, automated implanter by cheering them on.

JAMES ARNOLD, MD
San Jose, California

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