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Patient-Controlled Expansion: Applying a New Technique to Breast Reconstruction

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Abstract. Tissue expansion has been used as a technique to increase the amount of skin (and/or soft tissues) available for closing a defect or reconstructing an anatomic unit. Although the technique has undergone many modifications, the basic principles have remained more or less constant. The shortcomings of tissue expansion have remained unsolved for many years, namely, long periods of expansion with concomitant abnormal appearance with increased risk of complications over this extended period. Decreasing the expansion period would significantly contribute to patient convenience, decreased costs, and improved acceptance of the technique. This would need to be done within a background of safety without compromise to the reconstructive effort. With minor modification to the existing tissue expanders and their attachments together with modified patient-controlled infusion devices, a new method has been devised for tissue expansion in which the patient can control and expedite the entire process. As ''proof of concept,'' 10 patients were selected for this trial. All had undergone mastectomies without concomitant radiotherapy. Successful full expansion, beginning the day after surgery, was achieved in all cases in approximately 3 weeks with minimal complications. Patent pending design modifications have been made that expedite the process, making it easier, more efficient, and cheaper to achieve full expansion.Although the numbers in this series were small, proof of concept was achieved, and trials are ongoing with increasing numbers expected. The concept is applicable to all forms of tissue expansion, including aesthetic indications such as hair restoration, tubular breast correction, and the like.

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Tissue expansion is still a very important technique in plastic and reconstructive surgery used for a variety of reconstructive purposes [1,2,4,5,9,15]. The technique allows the surgeon to replace deficient, lost, or surgically excised tissue with neighboring tissue of similar color, texture, sensation, and thickness. In addition, hair-bearing capability is retained, and a remote donor site is avoided [1,2,4,5,9,15].

Neumann [17] is credited with the original work on the concept, but it was Radovan [19] who refined and popularized this technique in the 1970s. Since that time, many new innovations in expansion have been reported such as continuous tissue expansion [12,24], intraoperative expansion [14,18,22,23], and pharmacologic enhancement of expansion [11,16,20,26]. The purpose of these new innovations was to decrease the time of expansion.

Breast reconstruction with tissue expansion offers satisfactory aesthetic results with minimal patient morbidity [6,7,25]. The traditional period of expansion, however, continues to be a significant problem for the patient. Currently, a complete expansion process involves multiple office visits over a prolonged period, each associated with considerable patient discomfort and often a protracted disfigured appearance related to the expander.

This study aimed to develop and evaluate a technique for rapid home-based tissue expansion controlled by the patient.

Materials and Methods

A pilot study of 10 patients was undertaken to establish proof of concept and assess possible problems and complications. Contraindications to rapid expansion were considered to be previous radiation, mastectomy skin flaps of questionable viability, confirmed diabetes, and anticipated patient noncompliance. Most cases involved delayed reconstructions. However, two cases involved an immediate reconstruction at the time of mastectomy. All expanders were placed submuscularly, and patient-controlled expansion was started the day after surgery in most cases. Patient-controlled expansion (PCE) was limited by measured dosage (infusion device) and patient tolerance.

The infusion device selected was the Vygon PCA 7301.10 (Vygon Group, Ecouen, France)., which consists of the Freedom 5 kit containing a reservoir carrier, a 60-ml reservoir, a capping device with a lever, an attachment cord, a female/female Luer-lock adaptor for syringe filling, a female Luer lock obturator for temporary capping of a filled reservoir, and a single-lumen extension tube with an antibacterial agent and an antisiphon valve (Fig. 1).

Fig. 1. Vygon PCA 7301.10.

Surgical Technique

The tissue expander was placed retropectorally on the mastectomy side in the normal fashion. In most cases (delayed reconstruction), an inframmamary incision was used. This allowed easier placement and reinforcement of the inframmamary fold. In the immediate reconstructive cases, the mastectomy incision was used for placement of the expander. Subcutaneous closure was performed in layers with nonabsorbable periosteal-to-dermis stitches (3-0 Ethibond; Ethicon, Somerville, NJ) for fold accentuation combined with subcutaneous absorbable and subcuticular sutures (3-0 Monocryl; Ethicon). The nonabsorbable stitches were removed later at the time of definitive implant placement.

The conventional expander with a distant valve has a permanently attached silicone tube, the end of which usually is attached to the valve. Modification for PCE involves attaching a trocar to the tube for skin penetration and exteriorizing the silicone tube after subcutaneous tunneling (Fig. 2). Once the expander is placed in the appropriate position, the trocar is introduced through the skin to the external environment on the lower lateral chest. A purse-string suture (4-0 silk) secures the tube and skin. A dressing is applied to the tube as it exits the skin. Initial fluid is instilled at surgery (100–200 ml) as a start to the process.

The external tube is attached to the interconnector piece. A one-way stopcock is attached and closed, remaining attached to the skin in preparation for the start of expansion the day after surgery. At that time,

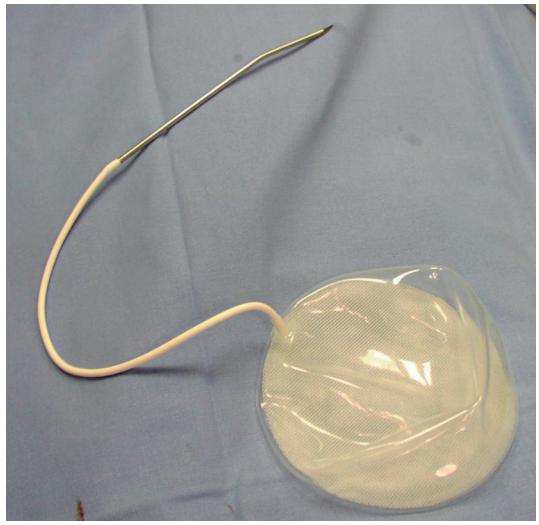

Fig. 2. Expander with trocar attached to tube.

the patient-controlled reservoir device is attached. The reservoir is filled with 60 ml of fluid, and a trade representative (Vygon) trains the patient in ambulatory control of the device and the technique of refilling the reservoir (Fig. 3). It is stressed to the patient that the process should be discontinued temporarily if pain is experienced. Visits to the surgeon once or twice a week were scheduled for the current trial, and the process was monitored constantly. The breast was slightly overexpanded and left as such for approximately 1 month before the normal routine of breast reconstruction was continued.

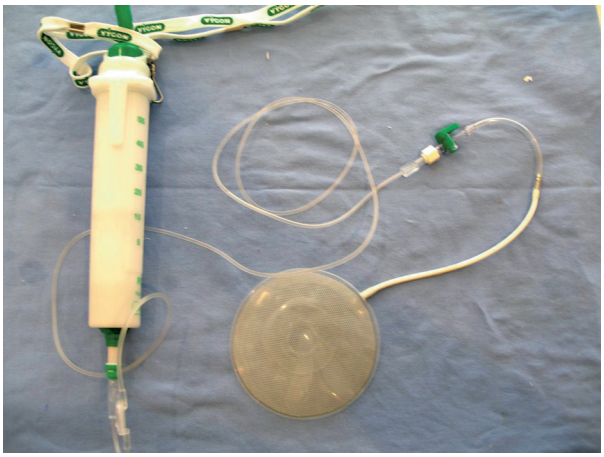

Fig. 3. Combined assembly.

Results

In this study, 10 patients with a mean age of 49 years (range, 39–69 years) were assessed. One patient had a bilateral reconstruction. Two patients had immediate reconstructions. The remaining reconstructions were delayed. The mean tissue expander size was 413.88 ± 52.7 cm^3, and the mean intraoperative expansion was 136.33 ± 49.72 cm^3. The expansion was started 1 day after the operation and completed in 17.62 ± 5.85 days. The mean final expander volume was 467.68 ± 74.54 cm^3, and the expanders were overexpanded by 14.3% ± 7.07% (Fig. 4). The overall complication rate was 4%. Cellulitis developed in one patient, requiring antibiotics. No patients experienced hematomas requiring drainage. One patient was removed from the trial after a diagnosis of diabetes and opted for a traditional expansion technique. This patient is not included with the 10 reported patients.

At the completion of the study period, all 10 patients had undergone an exchange for a permanent implant. The mean volume of the permanent implant was 395.44 ± 54.49 cm^3. Eurosilicone round smooth silicone breast implants and Mentor Silicone and saline anatomic implants were used. Two of these were saline implants, and eight were silicone implants.

Discussion

A major drawback to tissue expansion as currently performed is the time required for completion of the process. Most surgeons expand patients slowly at intervals varying from 1 to 3 weeks [2,4,5,9,15]. A minimum of 3 to 4 months is thus necessary for completion of the expansion process.

Patients invariably complain about the number of postoperative visits, the discomfort of individual expansions, and the prolonged period until completion of the expansion [14,18,22–24]. A variety of techniques have been described in an effort to attain more rapid tissue expansion [12,14,18,22–24].

Sasaki [22,23] described a technique of rapid intraoperative tissue expansion (RITE). This approach is used for situations in which primary closure of a skin defect may be problematic due to limited availability of donor skin or difficulty mobilizing donor skin because of tethering or tightness over underlying skeletal or cartilaginous frameworks. The RITE procedure does not yield any true tissue gain and has not been found to provide any great advantage over undermining because the tissue obtained is mostly by recruitment [14,18].

Another technique of rapid expansion was reported for a large series of patients by Pusic et al. [18]. The concept was based on the premise that patients could easily and safely receive 40% to 50% of expansion volume at the time of mastectomy. Rapid expansion over 4 to 6 weeks in four or five visits was completed with minimal complications. As these authors point out, the principal concern with this approach is that it could increase the tissue expander extrusion rate because the procedure could potentially compromise skin integrity. However, this was not the case. The extrusion rate of less than 1% was comparable with that of other series. [6,7,25]. As with PCE, the patients were selectively chosen for this approach. The inclusion criteria required good quality skin flaps and no previous irradiation.

However, in contrast to the aforementioned series, patients undergoing PCE need not have undergone a maximal skin-sparing technique because PCE can proceed irrespective of the amount of skin resected and the tightness of the closure. With PCE, the tiny amounts instilled at a time allow a very early start to the process and continued expansion even in the case of tight envelopes. In the case of immediate skin-sparing mastectomies, the initial amount instilled is obviously more than that for delayed reconstructions, and the advantage of the immediate start to the expansion process allows early completion of the process. The PCE approach does not have the same limitations as 'rapid expansion' in terms of the type of surgery performed. It is suited to all types of tissue expansion procedures regardless of the tightness or laxity of the skin envelope.

An experimental form of tissue expansion has been published that involves continual tissue expansion using a pressure-dependent continuous infusion device [24]. Studies with dogs show that continuous tissue expansion achieves significant amounts of additional tissue as compared with intraoperative expansion. The authors of these studies found that continuous tissue expansion using a device that infuses saline at a constant infusing pressure less than capillary-filling pressure will expand in 3 days to amounts similar to those achieved by a model of conventional expansion [12,24]. However, this technique excludes much patient participation and is cumbersome, complex and costly compared with PCE. It also has not been tested for humans.

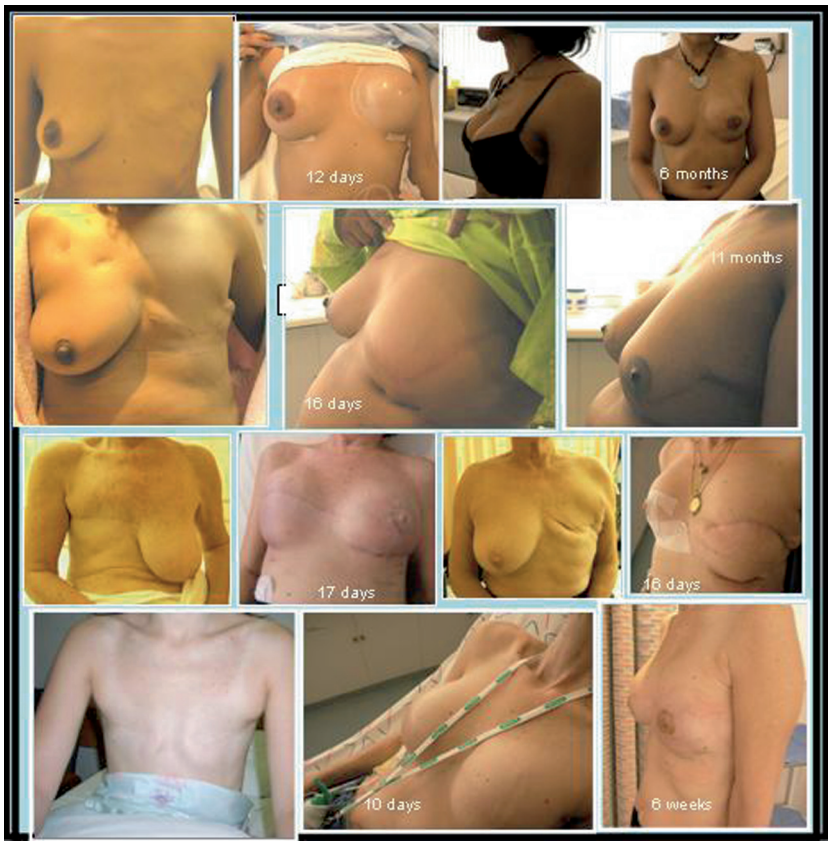

Fig. 4. Examples of breast reconstructions at varying stages—some at full expansion, some at completion of the reconstruction.

It is believed that much of the skin achieved in true tissue expansion represents stretch and reorganization of dermal collagen fibers rather than new skin created by mitosis [24]. A capsule forms around the expander as in most foreign body reactions. These capsules are thickest after 2 to 2.5 months of expansion. Within 7 days, there is a two-layer capsule comprising an inner layer of macrophages and an outer layer of fibroblasts and some lymphocytes. Over time, the outer layer becomes richer in collagen fibers. It appears that PCE results in a much thinner, more pliable capsule. At the time of definitive implant placement, the capsule is easily manipulated and separated where needed, and noted to be far less rigid. Supposedly, this relates to less vascularity and collagen organization of the capsule in the reduced expansion time. Cyclic loading (i.e., stretching followed by relaxation vs continual stretching) appears to be the most effective method of recruiting extra tissue [3]. This appears to be the case with PCE.

In all cases of PCE in which the full reconstructive process has been completed, no shrinkage or rebound tightening of the skin envelope was observed. In fact, the tissue seemed softer and more pliable, possibly in relation to the thinner capsule observed at definitive implant placement.

The overall complication rate of tissue expansion is 5% to 7% [6,7,25]. The rate can be reduced by appropriate patient selection and surgical experience. The most serious complications are overlying skin necrosis, implant exposure, and extrusion. These may occur secondary to infection, trauma, erosion of the flap due to folds in the expander, overly aggressive expansion, or placement of the valve over a bony prominence.

On the basis of previous publications and experience gained with the current small series, complications are not anticipated to increase with PCE. The first possible complication that needed to be carefully assessed was that related to external port/filler valves. The series reported by Lozano and Drucker [13], and more recently in the publication by Keskin et al. [10], which follows up an earlier report by Jackson et al. [8], clearly shows the major benefits and the low rate of complications related to external ports. The use of external ports has become standard in expansion as practiced by Jackson [10]. As noted by these authors, although this technique has distinct clinical advantages for both the surgeon and the patient, there has been reluctance to use it because of an anticipated high infection rate.

In the study by Keskin et al. [10], all the patients who underwent tissue expansion with external filling ports in the past 10 years were surveyed. According to the report, the "patients had no difficulty participating in the expansion process; they easily learned and performed the technique with no problems. Home inflation allows for small amounts of saline

infiltration at frequent intervals. This is safer, better tolerated by the patients, and more effective than inflation of large amounts of saline at infrequent intervals. We do not limit the expansion frequency by days, but encourage the patients to expand when the skin relaxes and when they are available. The patient or the family members expand according to the patient's tolerance and by considering skin color for blanching and capillary refill.'' [10]

This is very much the same routine followed by the PCE protocol. The aforementioned authors also reported seroma fluid leak from the skin–tube interface, stating that ''during the early stages of expansion, it is not rare to see drainage from where the filling tube penetrates the skin. This should not be mistaken for infection. As daily expansion proceeds, any remaining seroma or hematoma will drain from the entrance site of the filling tube. This has occurred even in the presence of a suction drain. Crusting around the filling tube's entrance to skin also is seen occasionally. This should not be considered a sign of infection'' [10].

We found the same exudates, but a purse string-suture and good absorbent dressings at this interface seem to have helped with this inconvenience. Finally, the aforementioned authors reported another significant benefit of using external filling ports: overall stress reduction for the patient. They eliminate the need for repeated skin punctures, which is of considerable value for children. Both adult patients and parents of pediatric patients had no difficulty with self-inflation or anxiety about it. The authors conclude that soft tissue expansion with external filling ports is safe (no increased infection rate) and effective and can be applied anywhere on the surface of the body [10].

Other ancillary techniques and agents to facilitate rapid expansion have been described including the use of creams such as papaverine, dimethyl sulphoxide, and verapamil [11,20,26].

The osmotic tissue expander is a device made of a hydrogel expanding skin that does not require external fillings. Once implanted, it absorbs body fluids, which leads to a gradual swelling of the device [21]. Unfortunately, the osmatic expanders tend to be heavy, lacking predictability and negating any patient or surgeon control in the process.

The PCE approach was used primarily for delayed breast reconstruction, but it became apparent that PCE can be used with equal success for immediate skin-sparing mastectomy. In fact, the process of expansion appears to be easier in the immediate cases because the process of fibrosis in the mastectomy scar is less. In both cases, but especially in immediate reconstruction, nonabsorbable suture placement is mandatory to provide security for early expansion. Although inframammary incisions were used in these cases, the experience, albeit limited, with the immediate reconstructions appeared to show that the mastectomy scar tolerated PCE as well, if not better than, the inframammary scar. We suspect that this may be attributable to the equal mobility of both skin flaps as compared with the relatively fixed lower skin flap with the inframammary incision.

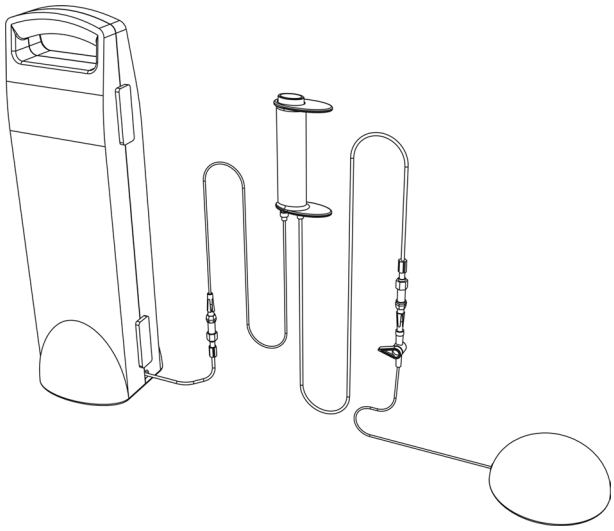

Fig. 5. New device design with carrier.

Of course PCE would be ideally suited for all other forms of tissue expansion reconstruction, not only for breast reconstruction. Trials will be conducted to investigate these reconstructive cases.

The problems with PCE evident from this trial mainly involved device design rather than complications of the procedure. Thus the following potential problems were identified with solutions offered:

1. To counteract any potential for dehiscence of the wound, nonabsorbable sutures were used to close the wound.
2. Refill of the device was relatively complex and costly. The solution is a newly patented design of the PCE device. This simplified device attaches to a vacoliter of fluid (usually 200 ml), making refill cheap, efficient, and user friendly (Fig. 5).
3. Occasional leakage has occurred from the junction of the stopcock and tube. The solution is a newly designed adaptor extension (Fig. 6) simple in concept. It uses a single composite appendage consisting of a one-way antibacterial valve permanently connected to tubing that then connects to the expander tube. This obviated all the problems associated with the multiple junctions adapted for this trial.
4. Leakage of fluid around skin–tube interface does occur. The solution is a purse-string stitch around the tube, but a daily change of dressing with a highly absorbent pad is of great help with this self-limiting seromatous phase (about 2 weeks).

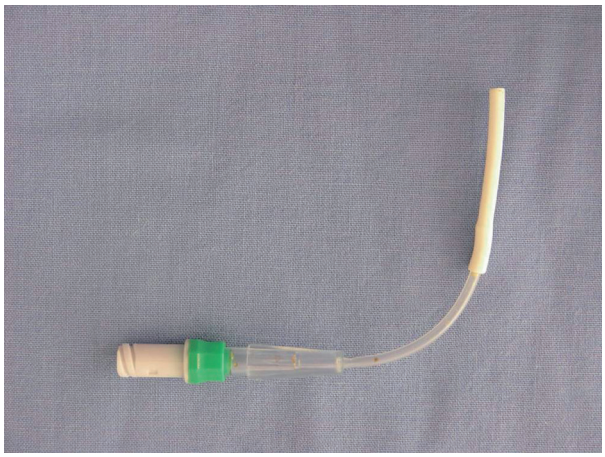

Fig. 6. Tube attachment with one way valve.

Conclusion

Patient-controlled tissue expansion appears to be a safe and reliable technique that offers definite advantages over conventional techniques. Using this technique, expansion may be completed in less than 3 weeks in most cases, but the speed of the process may be determined by the patient's needs. The technique is empowering to patients who seem to enjoy participating in the process. It appears to offer no increase in morbidity while providing an equivalent aesthetic result in a far more efficient process.

This is a new approach to tissue expansion, but one based on the proven efficacy of external ports [8,10,13] and the concept of patient-controlled infusion devices. The reported series was a small introductory one, undertaken to demonstrate "proof of concept." There will be changes in technique, cautionary situations, new indications, and contraindications that will identify themselves once larger trial series are analyzed. However, this pilot study does demonstrate the potential advantages in the practice of tissue expansion to both the patient and the surgeon.

With the new device designs described, PCE promises to be cost effective, user friendly, and extremely efficient in its outcome. It can be adapted to immediate or delayed reconstruction, simple mastectomy, or skin-sparing mastectomy, and should prove useful in all cases for which tissue expansion is indicated. We believe PCE constitutes a significant advance in the field of tissue expansion.

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