The Beginning of a New Era in Tissue Expansion: Self-Filling Osmotic Tissue Expander—Four-Year Clinical Experience

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The osmotic tissue expander is a new 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. The swelling phase is completed in 6 to 8 weeks and results in skin gain. Different shapes and sizes are available, and the devices can be used in almost every area of the body. Over a 4-year period, the osmotic tissue expander was used in 58 patients in different areas of the body. A round osmotic tissue expander was mainly used in breast reconstruction, and a rectangular expander was used for defect coverage after excision (i.e., of scars and tumors). The mean age of the patients was 49.34 years (range, 4 to 76 years). During the expansion phase, the patients noted only a little discomfort and pain for the first few days. Without a silicone membrane in the first-generation expander, the rate of successful explantation and good final result was 81.5 percent. In a few cases, rapid swelling of the device led to the introduction of a silicone membrane that encloses the expander and leads to a slower, more gradual, and consistent swelling. After introduction of the silicone envelope, the success rate improved to 91 percent. The expander is now used with a silicone membrane in every case. The osmotic tissue expander has many advantages compared with the conventional expander: there is no need for painful external fillings and the risk of external infections is avoided. The expander is 10 percent of its final volume and only requires a short incision and a small pocket. An operation can easily be performed under local anesthesia, with minimal tissue mobilization in older children and compliant patients. (Plast. Reconstr. Surg. 114: 1025, 2004.)

The self-filling device consists of an osmotic active hydrogel, a vinyl pyrrolidone, and methylmethacrylate, a material that is also used in contact lenses and that has been proven to be nontoxic and without any systemic effects. It is solid—not liquid—before and after expansion. It is designed and engineered by Osmed (Ilmenau, Germany).

Different sizes and shapes are available, and the device can be used in almost every area of the body. The round shape is used mainly in breast reconstruction, and the rectangular shape can be used in defect coverage (i.e., after excision of large skin tumors, scars, and burns).

The first generation of osmotic tissue expander was originally designed without an envelope. These expanders swelled relatively quickly, especially in the first few days, which resulted in complications in some cases. Therefore, a silicone membrane with small pores of a specific number and size was introduced. The silicone membrane loosely encloses the osmotic tissue expander (Figs. 1 and 2). The membrane is 0.2 to 0.5 mm thick before expansion and thins to 0.1 to 0.25 mm after expansion. After swelling is completed, the volume and size that are precisely consistent for each expander. After expansion is complete, the swelling volume remains stable. The size of the expander is only approximately 10 percent of its final volume. The swelling results in skin gain.

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membrane is double its original size. The membrane significantly decreases expansion speed and thus enables better tissue allowance, especially in areas with thin tissue coverage (Fig. 3).

PATIENTS AND METHODS

Since 1999, 55 patients have presented to our clinic. During the first 2 years, the osmotic tissue expander was used only in breast reconstruction (31 breast cancer patients seeking a secondary breast reconstruction after mastectomy; in two patients, we implanted the osmotic expander simultaneously after performing a mastectomy, and nine patients received an osmotic expander for correction of tubular breast deformities). The round osmotic tissue expander is available in 30/330-cc, 40/450-cc, and 50/500-cc preswelling/postswelling volumes.

After introduction of the second-generation silicone membrane osmotic expanders in 2001, we also implanted 26 expanders (in 14 patients) in different areas of the body for reconstructive purposes; four expanders were used in tumors of the face, 17 expanders were used for scar revision on extremities, and five expanders were used in nevi treatment. The rectangular osmotic tissue expander is available in 5/50-cc and 13/130-cc volumes. The success rate in cases of the rectangular osmotic tissue expander was 88.5 percent. In every case, the osmotic tissue expander is now only available and used with a silicone membrane (second generation).

Indications and Contraindications

Breast. The main indication for using the round osmotic tissue expander is secondary reconstruction of the breast after mastectomy. It is important to stress that it is not meant to be a permanent implant. It has to be exchanged for a prosthesis after the desired skin expansion has been achieved. It is mandatory that the osmotic tissue expander be covered by healthy muscle and soft skin and placed in the area of the lower breast pole. A radiated breast is a contraindication for secondary implantation of an expander.

The expander can also be used in breast deformities (i.e., tubular breasts) to expand especially the lower pole of the breast to create enough skin for later reconstruction with an implant. In all cases, the expander is exchanged for a permanent implant after 4 to 6 months.

Other parts of the body. The osmotic expander is excellent in covering defects of the skull, thoracic wall, and upper extremities. It can be also used in preparation for direct closure of the donor defect of the radial forearm flap or the...
forehead flap. The cosmetic result is significantly better than that possible with split-thick-ness skin grafts. It is not useful in cases of subcutaneous tissue loss. The expander has to be implanted on a firm, solid surface; otherwise, the three-dimensional expansion also leads to soft-tissue displacement and not to a sufficient skin gain because of its rather small dimensions in the beginning. In cases of malignant skin tumors, the tumor must be completely excised before implantation in this region. Infections are a contraindication for using osmotic tissue expanders.

**Implantation and Surgical Procedure**

**Breast.** Implantation of the osmotic tissue expander in breast reconstruction is performed under general or local anesthesia with sedation. In secondary cases, a 5- to 6-cm-long incision is made in the lateral part of the old mastectomy scar. After creating a pocket under the lower part of the pectoralis muscle, the device is brought in place in the midclavicular line in the area of the new inframammary fold. The created pocket should be at least double the size of the expander, and the envelope must be spread out. With expansion, the expander itself opens and enlarges its pocket on the thoracic fascia. A tape dressing is used to keep the expander in place for the first few days. In breast deformi-ties, a 5- to 6-cm-long incision is made in the inframammary fold and the expander is placed subglandularly.

**Other parts of the body.** The small osmotic tis-sue expander is implanted subcutaneously and epifascially on top of the muscle next to the defect. The pocket should be at least double the size of the device. A drain is not always necessary but does not interfere with osmotic expansion. Implantation can be performed under local anesthesia and in the outpatient clinic.

**Self-Filling Phase**

During the self-filling phase of expansion, swelling was observed by ultrasound and di-mensions were measured. We observed that the swelling in vivo was even slightly slower and more gradual than in vitro. The filling phase was completed in approximately 40 to 60 days and stopped automatically. Any pain or dis-comfort was noted on a visual analogue scale. The osmotic tissue expander stays in place for approximately 4 to 6 months in cases of breast reconstruction. Duration of use in other parts of the body depends on location and size of the defect and varies between 10 days and 2 months.

**Explantation**

**Breast.** The expander can be cut into pieces and removed easily. After explantation, the pocket should be rinsed with saline water. A permanent silicone implant can be put in place in the preformed pocket. In some cases, the pocket has to be modified slightly. If necessary, the contralateral side is adjusted. Nipple-areola complex reconstruction is performed 3 months later. In tubular breast deformities, augmentation is combined with a periareolar operation to correct the herniated nipple-areola complex.

**Other parts of the body.** After explantation of the osmotic tissue expander, the defect (e.g., after excision of scars or skin tumors) can be easily covered with lax skin.

**RESULTS**

Since 1999, we have implanted 75 osmotic tissue expanders in 55 patients. The mean age of the patients was 49.34 years (range, 4 to 76 years).

The patients noted only a little discomfort and pain shortly after the operation. Only a few patients noted pain after the first week. The representative visual analogue scale curve is shown in Figure 4.

Swelling and a feeling of tension were mostly recognized after the third or fourth day post-operatively and were well tolerated. Sometimes, skin redness occurred that was treated with a cold pack.

**FIG. 4.** Visual analogue scale (VAS) of pain (0 = no pain, 100 = extremely painful). Twelve patients were questioned during morning rounds.
We implanted a total of 49 round expanders of different sizes in 41 patients, according to the physical findings of each patient. The rate of successful explantation and a good final result was 81.5 percent in the first-generation round expander, which did not use a silicone membrane. The rate increased to 91 percent in the new expander with the silicone envelope (Table I). In seven cases, the round osmotic tissue expander had to be removed because of local complications; in five cases, a dehiscence developed (one after prior irradiation and two of which could be salvaged); in three cases, a seroma and infection occurred; and in one case, a painful fibrosis resulted in early explantation (Table II).

**Round Osmotic Tissue Expander**

We implanted a total of 49 round expanders of different sizes in 41 patients, according to the physical findings of each patient. The rate of successful explantation and a good final result was 81.5 percent in the first-generation round expander, which did not use a silicone membrane. The rate increased to 91 percent in the new expander with the silicone envelope (Table I). In seven cases, the round osmotic tissue expander had to be removed because of local complications; in five cases, a dehiscence developed (one after prior irradiation and two of which could be salvaged); in three cases, a seroma and infection occurred; and in one case, a painful fibrosis resulted in early explantation (Table II).

**Anatomic-Shaped Osmotic Implant for Breast Reconstruction**

Six anatomic-shaped osmotic tissue expanders were implanted at the beginning of the study. The goal of a large skin gain with potential ptosis was not reached with this shape. Because of rotation that could not be prevented because of a lack of a possible fixation \((n = 4)\), it was necessary to exclude this type of expander (Figs. 5 and 6).

**Rectangular Osmotic Implant for Defect Coverage**

Twenty-three of 26 cases could be completed with a good result, although two infections occurred and one expander had to be removed because of serious health problems not related to the expander (Table III).

**DISCUSSION**

The enormous adaptability of the skin is a feature that can be exploited in tissue expansion for skin gain to cover defects. In 1957, Neumann was the first in plastic surgery to use a rubber balloon to expand skin in the temporo-occipital area for ear reconstruction.4 Twenty years later, tissue expansion was introduced in breast reconstruction using a silicone expander.5 Since then, silicone expanders including ports for serial saline filling have been widely used for reconstruction.4 The idea of a self-filling expander was theoretically conceived but never widely practically attempted. Austad and Rose6 described a self-inflating device that contained hypertonic, saturated saline water that drew body fluids into the expander by osmotic force. When there were leaks, tissue necrosis occurred; this led to the abandonment of this idea. In 1998, Wiese7 invented an osmotic active expander. It was successfully tested in animals and is now designed and engineered by the Osmed, in Ilmenau, Germany.

We have been using this type of self-filling osmotic expander now for approximately 4 years in our department in an increasing number of cases. In the first years, it was used for

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**TABLE I**

<table>
<thead>
<tr>
<th>Round Osmotic Tissue Expanders ((n = 49))</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Expanders</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td><strong>First generation</strong></td>
</tr>
<tr>
<td>Primary reconstruction</td>
</tr>
<tr>
<td>Secondary reconstruction</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td><strong>Second generation</strong></td>
</tr>
<tr>
<td>Secondary reconstruction</td>
</tr>
<tr>
<td>Tubular breast</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

* Irradiated. † Two of these expanders were irradiated.

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**TABLE II**

Complications in Round Osmotic Tissue Expanders \((n = 49)\)*

<table>
<thead>
<tr>
<th>Dehiscence</th>
<th>Seroma/Infection</th>
<th>Inflammation</th>
<th>Fibrosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First generation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without radiotherapy ((n = 22))</td>
<td>2 (11%)</td>
<td>5 (41%)</td>
<td>0</td>
</tr>
<tr>
<td>Radiotherapy ((n = 7))</td>
<td>2 (11%)</td>
<td>1</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Total ((n = 27))</td>
<td>4 (14.8%)</td>
<td>6 (22%)</td>
<td>2 (4.1%)</td>
</tr>
<tr>
<td><strong>Second generation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without radiotherapy ((n = 7))</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tubular breast ((n = 15))</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total ((n = 22))</td>
<td>1 (4.5%)</td>
<td>1 (4.5%)</td>
<td>0</td>
</tr>
</tbody>
</table>

* A complication did not necessarily result in early expander loss. † No. of expanders where a salvage was possible.
reconstruction of the breast after mastectomy. A prospective study showed that round expanders are best for tissue expansion in the area of the breast (85.7 percent of first- and second-generation cases combined were successful). The great negative impact of radiation on skin elasticity resulted in two failed reconstructions of five irradiated cases because of wound dehiscence. Although we do not recommend use of an expander before radiation and never did with osmotic tissue expanders, if necessary, radiation therapy should only start after completion of the expansion phase (i.e., 5 to 6 weeks after implantation). In our experience with conventional expanders, in 50 percent of the cases, after radiation, local complications (i.e., pain) can occur. In these cases, the expanded skin has to be filled with autologous muscular tissue such as a latissimus dorsi flap. We now try to exclude patients for whom pre-
operative or postoperative irradiation is planned.

Our success rate in delayed reconstruction after mastectomy without radiation was 90 percent \((n = 29)\), a rate comparable to that for conventional expanders. The wound dehiscence in four cases (14.8 percent) led to the introduction of a silicone membrane to reduce the initial expansion speed, which was also documented by Berge et al., who used the expander without a silicone membrane. In the first-generation device, the expansion speed was high, especially in the first few days, when the wound was still vulnerable. The silicone membrane, with its small pores, reduces the absorption of body fluids. Although it achieves the same final volume, the swelling is now gradual and gives the wound time to heal. The osmotic expander is now only available with a silicone membrane (second generation).

Anatomically shaped osmotic expanders failed to meet our expectations of natural skin expansion because of rotation. The expander is too small to keep from rotating in its pocket. Therefore, exclusion from the beginning of the study was necessary.

The rectangular osmotic tissue expanders were developed mainly for defect coverage. All of them were developed with a silicone membrane (second generation). Also, Berge et al.

<table>
<thead>
<tr>
<th>Reason for Use</th>
<th>No. of Expanders</th>
<th>No. of Patients</th>
<th>Completed (n)</th>
<th>Failed (n)</th>
<th>Success of Expanders Implanted (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant tumors</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Scars</td>
<td>17</td>
<td>7</td>
<td>15</td>
<td>2</td>
<td>80</td>
</tr>
<tr>
<td>Nevi</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>80</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>14</td>
<td>19</td>
<td>3</td>
<td>88.5</td>
</tr>
</tbody>
</table>
used rectangular osmotic expanders (without a silicone membrane) for closure of the donor defect of the radial forearm flap. Twenty-three cases were completed with a good result. Interestingly, even though a few mild complications occurred, the final result was not impaired (88.5 percent success rate). In one case of a 76-year-old man, a cardiac problem and pneumonia forced us to explant the device. Also, two infections had to be treated with systemic antibiotics. One patient, a 4-year-old boy with a large retroauricular nevus, was treated in our outpatient clinic. The total operating room time was 12 minutes, during which a 4.6-ml, small expander was implanted. Skin gain is best in areas with a resistant base (i.e., thoracic wall, skull, or upper extremities; thus, expansion is then only toward the skin).

We see many advantages, not just in children, to using the small, self-expanding tissue expanders without the need for external fillings. First, there are no painful external punctures and no risk of iatrogenic infections. Second, the expander is extremely small and requires only a short incision. In addition, the operating room time is significantly shorter than that for conventional expanders. An operation under local anesthesia with minimal tissue mobilization can be performed easily in older children and compliant adults.

In our opinion, the former disadvantage and fear of an initial swelling phase that was too fast is now eliminated by the introduction of the new silicone membrane. Even though the expansion is autonomous, it is precisely predictable and accurate for each expander. Once the final size is reached, the expander does not change its volume or shape.

We continue using the osmotic tissue expander as a supplement to replace the conventional expander in a broad spectrum of cases. Our current spectrum now includes breast reconstruction after mastectomy, correction of breast anomalies (i.e., tubular breasts, asymmetry, or anisomastia and micromastia), and defect coverage after excision of tumors, scars, burns, and alopecia. Further investigation is still necessary to evaluate the usefulness of the expander in a primary breast reconstruction simultaneously after mastectomy. It is also a future goal of ours to evaluate the long-term capsular contracture rate after using an osmotic tissue expander. Improvements will be made in the design of the silicone membrane that now loosely encloses the expander. The goal is to find a flexible envelope with no dead space so that expansion is even more gradual.

**CONCLUSIONS**

1. There is no need for external fillings, so the risk of external infections is avoided. No injections means no pain, which is an excellent alternative in children.
2. The osmotic tissue expander is fast and simple to implant and reliable, with excellent results in breast reconstruction and coverage of skin defects.
3. The final volume after the swelling phase is completed is accurately defined for each expander, which facilitates surgical planning.
4. The silicone membrane now used in each expander reduces the initial expansion speed and thus allows better tissue allowance, even in thin-skin areas.
5. Surgical correction of skin defects can be performed in the outpatient clinic under local anesthesia without drains.

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**REFERENCES**