Efficacy of breast augmentation using an external breast tissue expander for a shorter period while applying higher pressure: a preliminary study

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INTRODUCTION
Cosmetic breast augmentation using external breast tissue expand-

Background Various types of external breast tissue expanders have been found to be effective for aesthetic breast augmentation. However, their use has been limited when compared with implant-based breast augmentation due to the burdensome nature of their application. This article reports the possibility that external breast tissue expanders may be applied safely and effectively with higher pressure and shorter application time.

Methods The participants comprised patients who desired breast augmentation using the EVERA-RAPHA device between January 2020 and March 2020. A double-blinded prospective study was conducted on two groups of eight patients each, with either 60 mmHg or 100 mmHg of pressure applied. Standardized photographs were taken and blinded measurements of volume and circumference were made. The Mann-Whitney and paired t-tests were conducted.

Results Sixteen patients were evaluated after 1 month of treatment. The women in groups 1 and 2 (60 mmHg and 100 mmHg, respectively) used EVERA-RAPHA for 15.400±0.704 and 15.300±0.477 minutes per day, respectively. The mean volume increases in groups 1 and 2 were 39.000±42.526 cc and 27.700±20.260 cc, respectively. No patients dropped out of the study. All patients reported that the device was tolerable. Mild bruising was found in 62.5% of the patients in group 2.

Conclusions Breast augmentation using external tissue expanders can be a safe, effective, and practical option. Pressures of 60 mmHg or 100 mmHg can be safely applied for a shorter duration. Larger studies are needed to further confirm our findings.

Keywords Tissue expansion / Mammoplasty / Tissue expansion devices
along with economic growth [7]. However, the ongoing crisis of breast implant-associated anaplastic large cell lymphoma has led to growing concerns for patient safety, which in turn have prompted increasing interest in non-surgical breast augmentation [8].

Despite the extensive literature on external breast tissue expanders, several non-negligible limitations of these expanders remain unresolved [1]. With a minimum application duration of 10 hours per day, adequate compliance cannot be guaranteed, which is further aggravated by the lack of immediate results. Patients tend to lose motivation due to the slow growth of their breasts, which is often difficult to recognize as they cannot compare it to their initial breast size. Moreover, prolonged application of the device often causes skin irritation, which could lead to contact dermatitis and sometimes leaves permanent pigmentation.

Some reports have described performing tissue expansion at pressures as high as 100 mmHg in clinical settings [9]. The application of a higher pressure for a shorter duration could resolve the limitations mentioned previously.

The aim of this prospective clinical study was to investigate the safety and efficacy of decreasing duration and increasing pressure while using external breast tissue expander devices.

**METHODS**

This prospective, double-blinded, randomized controlled study was approved by our institutional review board. Sixteen patients aged 21 to 40 years were enrolled in the study. All women preferred the possibility of less extensive breast augmentation using external devices over the more guaranteed results of breast augmentation surgery using breast implants. Individuals with a history of breast surgery, those who were currently pregnant or active smokers, and those who had active infections, diabetes, cancer, or connective tissue diseases were excluded from the study. The patients were randomly assigned into two groups.

The device consisted of two semi-rigid dome-shaped ports connected to a vacuum device. The ports were designed to sustain up to 100 mmHg of pressure while minimizing patient discomfort. The gel-like silicone surface sealed the skin surface to maintain a vacuum (Fig. 1). The settings for this study were 60 mmHg (±20%) and 100 mmHg (±20%) for groups 1 and 2, respectively. While wearing the device, patients were blinded to the pressure applied using their device to remove bias.

Informed consent was obtained from the participants, and instructions for using the device were provided. All procedures were carried out in accordance with the ethical standards of the Ethics Committee and the Certified Review Board of the hospital (No. E1910/571-003), and within the framework of the Helsinki Declaration of 1975, as revised in 1983. After cleansing both breasts, an...
external expansion device was used. A brassiere-shaped jacket was placed over the device to maintain it in the correct position (Fig. 2.). The patients were instructed to apply the device continuously for at least 15 minutes at the same time each day, and no maximum time was set. The device recorded the duration of application and participants were also asked to record the duration of application to double-check the data. The study was an exploratory clinical trial, and therefore was conducted for a short period of 4 weeks. Participants were instructed to visit the outpatient clinic after 4 weeks of application for follow-up.

The upper, lower, and nipple-areolar complex (NAC)-level circumferences of the breast were measured and medical photographs of the breasts were taken when patients visited the outpatient clinic at the start of the study (Fig. 3), and device application was initiated on the same day for 4 weeks. The participants were asked to visit our clinic for final measurements on the day that was precisely 4 weeks after the final application (Fig. 4). Breast volumetric analysis was conducted using a 3D scanner (Geomagic Studio; 3D Systems, Rock Hill, SC, USA) and an Artec 3D scanner (Luxembourg). Breast volume was measured when patients visited the outpatient clinic after 4 weeks of application (Fig. 5). The NAC, inframammary fold, medial breast border, lateral breast border, and supramammary border, which can be seen when the breast is pushed upward, were marked by a single board-certified plastic surgeon for consistent measurements. Participants were asked to raise their arms to ensure complete exposure of the breasts when scanned. Previous stud-

Fig. 3. Medical photograph of breasts before application of the external breast expander. (A) Frontal view and (B, C) side views.

Fig. 4. Medical photograph of breasts after 4 weeks’ application of external breast expander. The photograph is of the same participant as in Fig. 3. The right breast and left breast showed 27.8 cm$^3$ (34.09%) and 36.53 cm$^3$ (27.74%) increases in volume, respectively. (A) Frontal view and (B, C) side views.
ies have demonstrated the accuracy of the 3D scanning technique with the specific device used in this study, with a reported mean percentage of error of 1.4% of the criterion volume [10,11].

RESULTS

Sixteen patients completed the study, and there were no dropouts. All of them felt that the EVERA device (a generic term for the specific breast expander) did not cause any discomfort that could potentially lead to discontinuation of use. No patient complained of any disruption in their daily activities. No serious events, abrasions, pressure sores, or allergic reactions occurred. The patients’ demographic data are shown in Table 1.

As shown in Table 2, there was a statistically significant increase in breast volume in both groups, regardless of breast laterality. In group 1, the volume of the left breast showed an average increase
of 45.1 cc (27.84% increase in volume; standard deviation [SD]: ±51.584 cc; P = 0.043), while the right breast showed an average increase of 32.9 cc (21.63% increase in volume; SD: ±40.543 cc; P = 0.050). Conversely, in group 2, the volume of the left breast showed an average increase of 26.6 cc (20.02% increase in volume; SD: ±27.075 cc; P = 0.028) while the right breast showed an average increase of 28.8 cc (27.53% increase in volume; SD: ±27.308 cc; P = 0.012).

As presented in Table 3, a statistically significant increase was found when evaluating the average volume of the bilateral breasts. Group 1 showed an average increase of 39.0 cc (24.84% increase in volume; SD: ±42.526 cc; P = 0.036), while group 2 showed an average increase of 27.7 cc (23.34% increase in volume; SD: ±20.260 cc; P = 0.006). No statistically significant between-group differences were found, regardless of the breast laterality.

As shown in Table 4, when the patients were not divided into groups, the left breast showed an average volume increase of 35.8 cc (24.27% increase in volume; SD: ±40.934 cc; P = 0.003), the right breast showed an average volume increase of 30.8 cc (24.01% increase in volume; SD: ±33.458 cc; P = 0.002), and the mean volume of the bilateral breasts showed an average volume increase of

Table 1. Demographic data and clinical characteristics of the participants in each group

| Characteristics       | Group 1                  | Group 2                  | P-value |
|-----------------------|--------------------------|--------------------------|---------|
| Age (yr)              | 22.500 ± 1.690           | 27.800 ± 2.621           | 0.051   |
| Height (cm)           | 164.000 ± 5.195          | 161.600 ± 6.540          | 0.347   |
| Weight (kg)           | 54.700 ± 4.216           | 52.800 ± 6.435           | 0.485   |
| BMI (kg/m²)           | 20.078 ± 1.585           | 20.192 ± 2.120           | 0.446   |
| Comorbidities         | 0                        | 0                        | NA      |
| Breast volume (cc)    |                          |                          |         |
| Right                 | 152.100 ± 60.348         | 104.600 ± 56.896         | 0.127   |
| Left                  | 162.000 ± 80.363         | 132.900 ± 79.661         | 0.479   |
| Circumference (cm)    |                          |                          |         |
| Upper breast          | 83.100 ± 2.999           | 81.200 ± 3.991           | 0.291   |
| Lower breast          | 73.600 ± 3.736           | 71.700 ± 5.042           | 0.412   |
| NAC level             | 80.700 ± 4.350           | 77.700 ± 5.566           | 0.244   |

Values are presented as mean ± SD or number (%).

Group 1, 60 mmHg pressure applied group using an EVRA-RAPHA device for breast augmentation; Group 2, 100 mmHg pressure applied group using an EVRA-RAPHA device for breast augmentation; BMI, body mass index; NAC, nipple-areolar complex; NA, not available.

Table 2. Volume changes of each breast of participants in each group after 4 weeks of application

| Breast volume         | Group 1 (n = 8) | Group 2 (n = 8) | P-value (group 1 vs. group 2) |
|-----------------------|----------------|----------------|------------------------------|
|                       | Mean ± SD     | Range (min–max)| Mean ± SD                    | Range (min–max)| P-value |
| Left breast volume (cc)|               |               |                             |               |         |
| Visit 1               | 162.000 ± 80.363 | 57.09 to 315.37 | 132.900 ± 79.661               | 49.17 to 304.59 | 0.028   |
| Visit 4               | 207.100 ± 100.261 | 93.68 to 343.06  | 159.500 ± 82.666               | 58.58 to 311.23 | 0.317   |
| Change from baseline  | 45.100 ± 51.584 | 2.11 to 149.92 | 26.600 ± 27.075              | 6.64 to 86.62 | 0.674   |
| Right breast volume (cc)|               |               |                             |               |         |
| Visit 1               | 152.100 ± 60.348 | 53.20 to 242.47 | 104.600 ± 56.896               | 57.32 to 233.76 | 0.127   |
| Visit 4               | 184.900 ± 71.482 | 83.49 to 259.13 | 133.400 ± 81.162               | 61.41 to 319.19 | 0.199   |
| Change from baseline  | 32.900 ± 40.543 | –27.08 to 87.68 | 28.800 ± 27.308               | 3.34 to 85.43 | 0.818   |

Group 1, 60 mmHg pressure applied group using an EVRA-RAPHA device for breast augmentation; Group 2, 100 mmHg pressure applied group using an EVRA-RAPHA device for breast augmentation. Statistically significant, P < 0.05. *P-value (visit 1 vs. visit 4).

Table 3. Average breast volume changes in both breasts after 4 weeks of application

| Breast volume         | Group 1 (n = 8) | Group 2 (n = 8) | P-value (group 1 vs. group 2) |
|-----------------------|----------------|----------------|------------------------------|
|                       | Mean ± SD     | Range (min–max)| Mean ± SD                    | Range (min–max)| P-value |
| Average breast volume (cc)|               |               |                             |               |         |
| Visit 1               | 157.000 ± 69.692 | 55.15 to 278.92 | 118.700 ± 67.876               | 54.72 to 269.18 | 0.006   |
| Visit 4               | 196.000 ± 84.145 | 89.90 to 301.10 | 146.400 ± 80.455               | 61.10 to 315.21 | 0.028   |
| Change from baseline  | 39.000 ± 42.526 | –10.34 to 107.01| 27.700 ± 20.260               | 5.49 to 60.50 | 0.513   |

Group 1, 60 mmHg pressure applied group using an EVRA-RAPHA device for breast augmentation; Group 2, 100 mmHg pressure applied group using an EVRA-RAPHA device for breast augmentation. Statistically significant, P < 0.05. *P-value (visit 1 vs. visit 4).
As presented in Table 5, the circumferences measured at the level of the NAC in both groups 1 and 2 increased. However, only group 1 showed statistically significant results, revealing an increase of 1.46 cm (SD: ± 1.297 cm; P = 0.015). In contrast, group 2 showed a slight increase of 0.60 cm (SD: ± 1.228 cm; P = 0.210), but this difference was not statistically significant.

The circumferences of the upper and lower breasts were also measured. However, the upper breast circumference did not show statistically significant results. Groups 1 and 2 showed a slight decrease in the circumference of the upper breasts (~0.19 and ~0.88 cm, respectively), although this difference was not statistically significant. Similarly, the circumference of the lower breast did not show any statistically significant results. Groups 1 and 2 showed a slight decrease in circumference (~0.5 and ~0.63 cm, respectively). A decrease in circumference can be considered a compensatory response since most of the pressure was applied to the center mound of the breast, which could increase the volume and circumference of the middle portion of the breast. However, further studies are needed to corroborate our findings.

As shown in Table 6, all patients complied with the instructions and applied the device for a minimum of 15 minutes every day.

**DISCUSSION**

Cosmetic breast augmentation is a widely performed procedure. The first report of breast expansion techniques dates to 1895 [12], and the first patient underwent breast enlargement in 1889 [13]. Currently, the mainstay of breast augmentation procedures is implant-based surgery, since it offers promising results with acceptable complications. However, non-surgical methods are still an option for patients who are reluctant to undergo surgical procedures. This is especially true in East Asian cultures, since there is a stigma against surgical scars. Furthermore, even a small volume of breast augmentation from an external device may give satisfactory results, as Asian women tend to have smaller breasts and body frame. The numerous crises involving silicone implants may lead patients to seek breast augmentation without implants, and several reports on breast tissue expansion have shown satisfactory outcomes [14].

Our study was an exploratory clinical trial aiming to establish...
the potential of an external breast expander for various applications and as a pilot study before a larger-scale study. Therefore, the study only had a short period of device application and follow-up. However, even after applying the expander for a short period of 4 weeks, participants showed statistically significant increases in volume. The authors asked participants to visit 4 weeks after cessation of device usage given the finding of previous studies that volume recoil stops after 4 weeks. Stimulation and edema are known to play roles in adipogenesis [15]. Since cyclic stimulation is inherently more effective than constant stimulation, our team focused on intense cyclic stimulation for breast augmentation rather than long continuous stimulation [16]. According to a previous study, participants who used settings of 20 mmHg for 10–12 hours a day during an average of 14.7 weeks showed about a 55% increase in volume after 4 weeks of application [8]. Our study results showed about a 20%–25% increase in volume in 4 weeks of application. The time period of the study was short; since the study was planned as exploratory clinical trial; therefore, even though the increased volume was not as substantial as previously reported, our team found potential for further studies, which could involve extending the application period or supplementing the procedure with an additional fat graft. Furthermore, the purpose of the study was to find alternative options other than implant insertion for breast augmentation in general Asian female populations. Asian women tend to have smaller breasts than women of other races; therefore, even small volume increases are not negligible, and the authors see the possibility for further research.

Sustaining the volume increase is another important issue that needs to be addressed. Studies have shown that volume recoil occurs approximately 1 week after the protocol and that only half of the volume gain remains in the long term after applying 20 mmHg of pressure for 10–12 hours a day, for an average of 14.7 weeks of application of an external breast expander [8]. Participants in our study were asked to visit the clinic for breast volume measurements 4 weeks after cessation of device usage, which is when recoil stops and volume is sustained according to a previous study. Further studies are required to evaluate the long-term effects of our findings. Moreover, some patients desired short-term breast enlargement and were satisfied with the short-term results. An example could be women expecting to participate in a photoshoot on special occasions such as a wedding. Although the device may seem like a demanding procedure for just a photoshoot, it should be kept in mind that many women go on a diet and receive expensive beauty care precisely for those purposes. In this context, the EVERA device may not be an excessively demanding procedure. This advantage can be further highlighted in our social networking era and for generation Z [17,18].

The amount of volume increase was larger in the lower-pressure group with 60 mmHg than in the higher-pressure group. The factors inducing adipogenesis in external breast augmentation are mechanical stimulation and edema [15]. Logically, a higher pressure would be expected to result in larger augmentation, which was not in accordance with the outcome of our study. Further study is needed to corroborate various possibilities. The ultimate goal of this and further studies is to find potential and optimal values of different settings for external breast expanders.

The changes in the circumference of the breast at the NAC level were not significant, even though there was an increase in volume. However, the volume increase was not substantial, and the simple circumference of the breast has limitations as a reflection of breast shape. The volume might not have increased evenly throughout the breasts; because most of the volume of the breast is located in the lower pole, most of the increase would have occurred in the lower pole. Thus, an increase in breast volume may not necessarily result in a significant increase in breast circumference in the upper and middle areas.

Applying negative pressure to shift the biomechanical properties of soft tissues involves a similar mechanism to that of negative pressure wound therapy (NPWT), which has revolutionized wound care, ranging from chronic wounds to acute surgical wounds. Facilitation of tissue perfusion and aiding microcirculation are among the many benefits of NPWT [19]. The application of various pressures ranging up to 200 mmHg and numerous modes of continuous and intermittent pressure application has widened its clinical use. We expect the same outcomes for external breast tissue expanders, since the basic principles of both devices are similar. The worldwide use of NPWT without any serious complications favors potential advancements in various settings for external breast tissue expanders.

The study had several limitations because it was planned and conducted as an exploratory pilot study prior to a large-scale study. For this reason, the study was designed with a minimal number of participants, a short duration, few patient visits, and few variations. Neither formal questionnaires nor surveys were administered, although regular surveys or questionnaires would have been necessary to obtain more generalizable findings. Additionally, the specific settings of the device were limited due to the small number of participants. To further evaluate the effectiveness of the device, applying various pressures or application times would have been necessary. Due to the small number of participants, only two specific settings of the device were used. The follow-up intervals of the participants should be shortened and the number of visits should be increased. A previous study found that the recoil of increased volume from external breast expansion started to decrease 1 week after the cessation of application of the device. Beyond 4 weeks after cessation, the volume of the breasts stopped decreasing and remained static [8]. Since the volume recoil plateaued after 4 weeks, the patients in the present study were asked to visit 4 weeks after discontinuing device usage. However, more frequent follow-up visits would have been better for observing changes in volume. In future stud-
ies, the abovementioned limitations should be handled.

In conclusion, high-pressure expansion with a shorter period of device use can be safely applied to women seeking breast enlargement without surgical complications. This can be an option worth considering for short-term breast enlargement, and it has potential for improvement by extending its application period or supplementing the augmentation with an additional fat graft. Further studies should be conducted to investigate the long-term safety and efficacy of these modifications. We hope that this preliminary study will be a new beginning for the revolutionary use of external breast tissue expanders. Just as NPWT has paved the way to become the "new normal" of wound care, the same basic science could be applied to external breast tissue expanders.

NOTES

Conflict of interest
The authors declare that the medical device utilized in this study was provided by the EVERA company. Jeongseok Oh and Chan Yeong Heo are medical consultants of the EVERA company. No other potential conflict of interest relevant to this article was reported.

Ethical approval
The study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (IRB No. E1910/571-003) and performed in accordance with the principles of the Declaration of Helsinki.

Patient consent
The patients provided written informed consent for the publication and the use of their images.

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