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# Safety and Efficacy Report

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## Nonsurgical Breast Enhancement—Fact or Fiction?

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The “perfect result” in plastic surgery would be to achieve the exact improvement desired by the patient with no evidence that the improvement had been performed. This would be further enhanced by the opportunity to avoid the risks of surgery. When evaluating the “perfect result” in the context of breast enhancement, one must consider whether the nonsurgical external soft tissue expansion system (BRAVA) fills the role.

At the 1999 Annual Meeting of the American Society for Aesthetic Plastic Surgery (ASAPS), Drs. Baker and Khouri presented their early follow-up on 10 patients who had developed and maintained nonsurgical enhancement of their breasts using their mechanical bra system. They explained that the device exerts negative pressure on the breast, which reportedly stimulated breast tissue growth.<sup>1</sup> In June of 2000, they published their results with 17 patients in *Plastic and Reconstructive Surgery*. In this group of patients 12 women completed the study; their breasts were enlarged an average of 103 ( $\pm$  35) ml after wearing the device. The patients wore the device an average of 10.2 hours per day for a 10-week period. It took the women an average of 14.7 (range, 10 to 18) weeks to complete the required 10-week treatment period. All women expressed satisfaction with their outcome.<sup>2</sup>

Drs. Baker and Khouri presented additional data at the 2000 Annual Meeting of the ASAPS that showed that these 12 patients maintained their growth 15 months later. In addition, MRI and breast biopsy studies demonstrated that the increase in volume was attributable to an increase in normal breast tissue.<sup>3</sup> Subsequently a clinical study of 100 patients has been completed; the results are discussed later.

An early review of this technique, “Mechanical Bra for Breast Enlargement,” was written by Dr.

Thomas Mustoe.<sup>4</sup> Dr. Mustoe pointed out many questions that must be answered before plastic surgeons will embrace this new technology. We will further evaluate some of these questions in this article.

### *Description of the Device*

The device is made up of two semirigid plastic domes that are sized for the specific patient. Each dome has a silicone gel border, which makes them more comfortable and allows the device to seal with the skin of the chest wall. Each dome has an outlet that is connected to a small, computerized vacuum device (smart box) via Silastic tubing. The device is battery operated, records the time used, and maintains a negative pressure of 15 to 25 mm Hg through the use of pressure sensors and relief valves. The entire apparatus is contained in a fabric bra designed for ease and comfort.

### *Protocol for Use*

The system is designed to be worn at least 10 hours a day for 10 weeks. If a patient misses a day, they must add one additional week to their total number of weeks worn. After 5 weeks the patient is re-evaluated; at this time many patients require a larger dome to accommodate the new growth and larger size of the breast.

### *Mechanism of Action*

Retrospectively, tissue expansion has been identified for centuries in ancient tribes.<sup>5,6</sup> Neumann described the use of operatively implanted tissue expansion devices<sup>7</sup> for the creation of soft tissue, and many others have subsequently made tissue expansion part of the routine practice of plastic surgery. Ilizarov has made similar demonstrations in the growth of hard tissues with his

technique of bone distraction<sup>8</sup>, and others have utilized these principles on facial bones and in other regions of plastic surgery.<sup>9,10</sup> Cell biologists have described the process of "mechanotransduction" or the process by which mechanical tension induces growth promoting signals and new tissue.<sup>11-13</sup> Baker and Khouri theorize that the sustained negative pressure creates an outward distractive force or tension that stimulates growth of breast tissue.<sup>2</sup>

#### *Pilot Study*

The only data available regarding the effectiveness of the mechanical bra had been published or presented by the inventors. Therefore, to evaluate and verify the practical effectiveness of this product we elected to conduct a small independent pilot study.

The initial response to the technique was extremely enthusiastic, however many women became uninterested after learning that they had to wear the device for 10 hours a day for 10 weeks without interruption and that the end result was only going to be 100 cc of growth, roughly one cup size. Of the interested patients, many had to be rejected for the following reasons: too large already, chest too narrow for the smallest domes resulting in a poorly sustained "seal," and history of previous breast surgery. A few patients dropped out because we could not make a definite statement as to whether or not this tissue growth stimulation would increase their likelihood of breast cancer in the future.

Eight patients were enrolled into the pilot program. One patient had an outstanding result with more than one cup of growth. She suffered some skin irritation and difficulties with her smart box, but she was extremely happy overall. Two patients had approximately one cup of growth (100 cc). Three patients completed their 10-week commitment with a fair number of problems with skin irritation and approximately 50-65 ml of growth. They were underwhelmed but still enthusiastic about going through an additional cycle because neither was interested in undergoing operative enlargement and both desired further enhancement. Two patients dropped out after 3 weeks because of the inconvenience the device created in their lives.

We, and our patients, have shared in the growing pains of the manufacturer with regard to the problems created by large-scale growth: new problems have been identified (significant skin irritation), we have experienced technical difficulties (smart box malfunctioning), and we have

noted the strains on the manufacturer's customer service department. All of these problems made it more difficult for our patients to complete the program easily. Although the manufacturer has made improvements and modifications, each patient required at least 15 to 30 minutes on a biweekly basis to help them through the process.

#### DISCUSSION

A large population of women are interested in breast enlargement. Many of these women are not interested in surgical enhancement. Drs. Baker and Khouri have demonstrated that true growth has been maintained more than 15 months later and have demonstrated by magnetic resonance imaging and breast biopsy that the growth is true breast tissue, not merely edema. The device does work.

The breast volume enhancement in their study of 100 women was over 100 ml on average<sup>14</sup>; however, 3 of our 6 patients who completed the study failed in this respect. Evaluation of their Wear Pattern Charts demonstrated periods of less than 10 hours of sustained tension despite the patients wearing the device during these intervals. They have used this device in a second cycle on numerous patients and report approximately 50 ml of growth in the subsequent session.<sup>14</sup>

The greatest drawback with this device is patient compliance. It is difficult for me to imagine wearing the same anything for 10 hours a day 10 weeks in a row. The device is relatively cumbersome, is heavy, and induces a fair amount of skin irritation along the silicone border/skin interface. Yet the motivation to have larger breasts seems to overcome this in the correctly chosen individual. We had a 25 percent dropout rate; the inventors had 5 of their initial 17 patients drop out as well. The question is how happy is the customer who pays over \$2,000.00 for a device they stop using after 3 weeks because its use was more overwhelming in their life than they anticipated? To whom do they look to obtain a refund?

Additionally, even for a patient who is the perfect candidate psychologically, the device might not fit. The device is limited to a B cup-sized breast or smaller because of the size of the domes necessary to prevent skin irritation at the site of the skin/dome interface. Further, some patients' chest walls are too narrow to accommodate even the smallest domes.

## CONCLUSIONS

Nonsurgical breast enlargement with the use of an external soft-tissue expansion system does work. It is a great advance for women who desire breast enhancement and do not wish to undergo the risks or discomfort of surgery. For the select group of women that can comply with the rigorous schedule of wearing the device and who only desire a one-cup enlargement, this technique may achieve the ideal plastic surgery result.

This device should remain in the domain of plastic surgeons, and it should be discussed as an option when discussing breast augmentation with potential patients. No other group can offer all the alternatives to patients. However, potential patients must be closely screened, and to improve the dropout rate, they must be made painfully aware of the required commitment in time and effort. A fair number of potential BRAVA patients were converted to surgical patients after considering the options more closely. The device allowed patients to feel more comfortable coming in to find out what their options were.

BRAVA patients require a lot of time and attention. Patients who drop out always ask about getting credit towards surgery or a refund for the device. It is not dramatically profitable for your office, but it is a technique that we should have access to for the appropriate patient. As the manufacturer continues to make improvements in both the device and their customer service department the technique should become more user friendly.

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## REFERENCES

1. Baker, T. J., and Khouri, R. K. A nonsurgical device for breast enlargement. Presented at the Annual Meeting of American Society for Aesthetic Plastic Surgery. Dallas, Texas, May 14-19, 1999.
2. Khouri, R. K., Schlenz, I., Murphy, B., and Baker, T. J. Nonsurgical breast enlargement using an external soft-tissue expansion system. *Plast. Reconstr. Surg.* 105: 2500, 2000.
3. Baker, T. J., and Khouri, R. K. A nonsurgical device for breast enlargement. Presented at the Annual Meeting of American Society for Aesthetic Plastic Surgery. New York, May 3-6, 2000.
4. Mustoe, T. A. The mechanical bra for breast enlargement. *Aesthetic Surgery Journal* 20: 176, 2000.
5. Burnett, W. Yank meets native. *Natl. Geogr.* 88: 105, 1945.
6. Weeks, G. S. Into the heart of Africa. *Natl. Geog.* 110: 257, 1956.
7. Neuman, C. G. The expansion of skin by a progressive distension of a subcutaneous balloon. *Plast. Reconstr. Surg.* 19, 124, 1957.
8. Illzarov, G. A. Clinical application of a tension-stress effect for limb lengthening. *Clin. Orthop.* 238: 249, 1990.
9. McCarthy, J. G., Schreiber, J., Karp, N., Thorne, C. H., and Grayson, B. H. Lengthening the human mandible by gradual distraction. *Plast. Reconstr. Surg.* 89: 1, 1992.
10. Polley, J. W., and Figueroa, R. A. Management of severe maxillary deficiency in childhood and adolescence through distraction osteogenesis with an external, adjustable, rigid distraction device. *J. Craniofac. Surg.* 8: 181, 1997.
11. Chen, C. S., Mrksich, M., Huang, S., Whitesides, G. M., and Ingber, D. E. Geometric control of cell life and death. *Science* 276: 1425, 1997.
12. Ingber, D. E. Tensegrity: The architectural basis of cellular mechanotransduction. *Annu. Rev. Physiol.* 59: 575, 1997.
13. Sachs, F. Biophysics of mechanoreception. *Memb. Biochem.* 6: 173, 1986.
14. Khouri, R. K. Personal correspondence, October, 2001.