

The Mechanical Bra for Breast Enlargement

Although breast implants are widely used today and are associated with a high satisfaction rate, they have well-known disadvantages, including the need for surgery and the potential for capsular contracture, implant palpability, and eventual replacement. Certainly many women would consider or prefer a non-surgical alternative to breast implants. At the May 1999 American Society for Aesthetic Plastic Surgery (ASAPS) meeting in Dallas,¹ an alternative was presented: a mechanical bra that exerts negative pressure on the breast, with induction of increased breast size. Short-term follow-up of a group of 10 patients showed that results were maintained. Given the potential impact of this alternative on the field of breast augmentation, an analysis of this emerging technology is timely.

Device Description

The device consists of a fabric bra containing 2 semirigid shells, which enclose the breasts. A silicone gel-filled bladder at the rim provides a seal with the skin and allows a relative vacuum of negative pressure to be created. Each dome contains an outlet port connected to a battery-operated, computer chip-controlled vacuum pump that maintains a negative pressure of 15 to 25 mm Hg. Pressure sensors and valves are used to help control the pressure of the device. The bra is designed to maintain continuous negative pressure and is meant to be worn 10 to 12 hours a day for at least 10 weeks. The device has patent protection.² The mechanical bra is illustrated in the Figure.

Mechanism for the Effect

Biologic responses to mechanical forces are well known in a number of systems. At the cellular level, every cell has an internal actin cytoskeleton that is linked to the cellular membrane by focal adhesions, which are linked to the extracellular matrix by integrin receptors. In response to external forces on the extracellular matrix, the cell shape changes with intracellular signaling via the integrin receptors that control both cell survival and growth.³ At the hard-tissue level, response to a mechanical signal causes hard-tissue responses (new bone forma-

tion) with the Ilizarov device⁴ and other multiple modifications of bony distraction. At the soft-tissue level, the principle of tissue expansion first described by Neumann⁵ has had many well-known applications that have recently been related back to the cellular level.⁶

Conceptually, the continuous application of negative pressure to soft tissue would be expected to stimulate mechanoreceptors, and the observation of apparent cell growth and breast enlargement is not surprising.

Clinical Studies

In studies reported at the 1999 ASAPS meeting by Thomas Baker, MD, the principal clinical investigator, and Roger Khouri, MD, the inventor, a total of 10 subjects completed a 10-week treatment period, wearing the bra for an average of 10 hours a day, with a 4-week follow-up. An additional 5 patients failed to complete the study because of lack of compliance. The patients were carefully studied with 2 different volume displacement measurements, moulages, MRI scans, photographic documentation, and lengthy questionnaires. Each of the study patients had an A or B cup bra size when the study began and showed an average increase in size of 100 cc, or approximately 50%, after a 4-week follow-up. There was an initial loss of volume of 16% over the first week after discontinuation of use of the bra; this recoil was attributed to edema. At 20 weeks after discontinuation of use, the remaining increase in breast size had been maintained (R. Khouri, MD, personal communication). Photographic documentation presented at the ASAPS meeting confirms a modest but definite increase in breast size.

No adverse effects were seen, and magnetic resonance imaging scans confirmed a normal breast architecture that consisted of new tissue rather than edema.



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Regulatory Issues

The device has already been approved by the US Food and Drug Administration for human use under a 510(k) classification, the "Niplette" ⁷ being the most closely related device. In this device, negative pressure is used to nonsurgically correct inverted nipples. Information on the mechanical bra is already available to the public at the following Web site address: biomecanicainc.com. Product availability is projected for early in 2000.

Unanswered Questions

Although the number of patients studied was small, the results were consistent and the clinical studies described were carefully executed, with issues of safety, patient satisfaction, and objective increase in breast volume being addressed. Yet these early studies have left a number of questions unanswered:

1. Will the increased breast volume be maintained over the long term? In most aesthetic procedures, 1 year represents the benchmark for success; peer-reviewed results of the mechanical bra have not yet cleared this important hurdle.
2. Is the product reliable and economical? Several patients failed to complete the study and were apparently not completely satisfied, although they incurred no cost. Apparently, some of the problems were due to prototype malfunction (R. Khouri, personal communication). This is a sophisticated device, which has not yet been mass-produced.
3. Is the increase in breast size limited to 100 cc? The average breast augmentation in this country is much larger.
4. Where in the breast does the major volume increase take place? Breast augmentation with implants can correct the loss of superior-pole fullness that is seen postpartum and with gravitational descent in a partially selective way.
5. Is the device limited to smaller breasts? By the nature of its design, the mechanical bra is somewhat bulky; this may limit its acceptance by patients with larger breasts.
6. Will there be any long-term changes in the architecture of the breast over time or with a changing hormonal milieu? Such changes are unlikely, judging from extensive previous experience with soft-tissue and hard tissue devices designed to induce new tissue. However, this remains an important question.

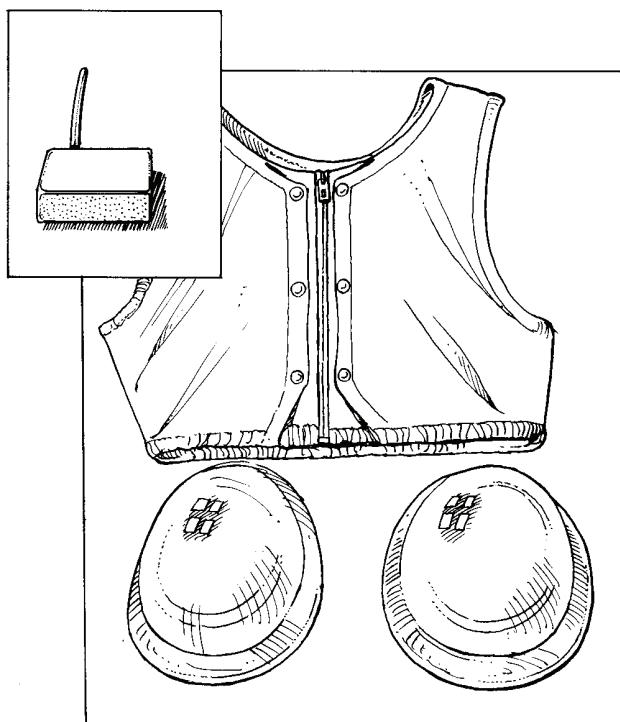


Figure. Breast augmentation system consists of 2 transparent polyurethane domes bonded to a silicone rim, a microchip-controlled pump, and a support garment.

7. Will this device be prescribed by plastic surgeons, or will it stimulate interest among practitioners in other medical specialties? Current plans are to restrict it to physician use only.

Conclusion

The mechanical bra is a highly promising nonsurgical alternative to breast augmentation with implants. Although there are a number of unanswered questions, it is quite possible that the device will have a significant impact on the field of aesthetic plastic surgery. There is a sound scientific basis for the device, and the clinical studies to date have been carefully performed, yielding modest yet significant results. Every plastic surgeon performing breast augmentation will need to clearly understand this device to intelligently discuss it with patients as a possible alternative to surgery. ■

Editor's Note: *Aesthetic Surgery Journal* requested from Bio-mecanica, Inc. (Key Biscayne, FL), developer of the mechanical bra, one or more patient photographs illustrating the results of the device, but no examples were forthcoming by our publication date.

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