Nonsurgical Breast Enlargement Using an External Soft-Tissue Expansion System

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Less than 1 percent of the women interested in having larger breasts elect to have surgical augmentation mammaplasty with insertion of breast implants. The purpose of this report is to describe and test the efficacy of a nonsurgical method for breast enlargement that is based on the ability of tissues to grow when subjected to controlled distractive mechanical forces. Seventeen healthy women (aged 18 to 40 years) who were motivated to achieve breast enlargement were enrolled in a single-group study. The participants were asked to wear a brassiere-like system that applies a 20-mmHg vacuum distraction force to each breast for 10 to 12 hours/day over a 10-week period. Breast size was measured by three separate methods at regular intervals during and after treatment. Breast tissue water density and architecture were visualized before and after treatment by magnetic resonance imaging scans obtained in the same phase of the menstrual cycle. Twelve subjects completed the study; five withdrawals occurred due to protocol noncompliance. Breast size increased in all women over the 10-week treatment course and peaked at week 10 (final treatment); the average increase per woman was 98 ± 67 percent over starting size. Partial recoil was seen in the first week after terminating treatment, with no significant further size reduction after up to 30 weeks of follow-up. The stable long-term increase in breast size was 55 percent (range, 15 to 115 percent). Magnetic resonance images showed no edema and confirmed the proportionate enlargement of both adipose and fibroglandular tissue components. A statistically significant decrease in body weight occurred during the course of the study, and scores on the self-esteem questionnaire improved significantly. All participants were very pleased with the outcome and reported that the device was comfortable to wear. No adverse events were recorded during the use of the device or after treatment. We conclude that true breast enlargement can be achieved with the daily use of an appropriately designed external expansion system. This nonsurgical and noninvasive alternative for breast enlargement is effective and well tolerated. (*Plast. Reconstr. Surg.* 105: 2500, 2000.)

Approximately 16 to 19 million women in the United States between the ages of 18 and 49 have an expressed interest in breast enlargement[1,2]; however, despite a resurgence in popularity, only about 130,000 (0.7 percent) of these women underwent surgical breast augmentation in 1998.[3] Reluctance to undergo surgery for cosmetic reasons, perceived adverse sequelae from the implants, and cost are the most cited deterrents to this surgical recourse.[2]

We developed a system and a method of external soft-tissue expansion and tested its efficacy as a nonsurgical alternative for breast enlargement. The principle behind this approach is the capacity of tissues to grow when subjected to sustained, low-level, mechanical distraction. For centuries, tribes from several cultures have applied this principle to enlarge various body parts.[4,5] Surgically implanted tissue expanders are now routinely used in plastic surgery to incrementally increase the amount of skin and soft tissue available to perform multiple staged reconstructive procedures.[6–8] Orthopedic experience with the Ilizarov procedure has demonstrated the feasibility of lengthening extremities by a process of gradual distraction that grows the bones and associated soft tissues.[9–11] New devices have extended the use of this principle to advance facial bones and correct retruded faces.[12,13] Cell biologists have devoted considerable research toward elucidating the mechanism of mechanotransduction, the process by which mechanical ten-

sion is converted into growth-promoting signals.[14–17]

Current therapeutic applications of tension-induced tissue growth require surgical intervention to insert either an inflatable silicone shell as the force-transducing device or bone pins and screws as links to the distraction frame; however, the approach presented here is entirely nonsurgical. Sustained, low-level negative pressure (vacuum) provides the outward distractive force that stimulates breast tissue enlargement. The nonsurgical breast-enlargement system was designed by one of the authors (R.K.K.); in a pilot study on two subjects (four breasts), he found evidence that the device was effective (unpublished data). The present study represents an independent test of its safety and efficacy in a larger population.

MATERIALS AND METHODS

Soft-Tissue Expansion

The nonsurgical breast-enlargement system incorporates two semirigid plastic domes, each slightly larger in volume than the corresponding breast to be enlarged. A brassiere garment supports the two domes, and the device is worn like a brassiere (Fig. 1). Each dome has an outlet port for vacuum application and a gel-filled bladder at the rim that circumscribes the outer margins of the breast. An adhesive, hypoallergenic silicone gel applied to the skin-contact surface of each bladder maintains a vacuum seal with the skin. A battery-powered, microcomputer-controlled vacuum pump is connected to outlet ports on each dome by plastic tubing. Pressure sensors and relief valves are used to maintain a vacuum pressure of 15 to 25 mmHg. To document protocol compliance, the microcomputer records temperature and pressure every 10 minutes and stores the data in its memory.

A number of suction-based devices have touted the ability to induce breast enlargement.[18] These are considered to be mostly ineffective novelty items and are ridiculed by the establishment in plastic surgery.[19] Although the basic idea behind stretching to induce enlargement is sound, these novelty devices lack the necessary design elements to appropriately deliver, over a prolonged period of time, a sustained, controlled mechanical distraction to cause breast growth.

We built the system by deliberately taking into account known physiologic constraints and bioengineering principles. Pilot testing of a succession of prototypes led us to identify and refine four novel critical design features that ensure safe and effective function (U.S. patent #5536,233; U.S. patent #5662,583; U.S. patent #5676,634; U.S. patent #5695,445; U.S. patent #5701,917; and other patents pending).

Balancing of Forces and Optimization of Pressures

The total outward force (F_{out}) exerted by the vacuum on the breast is equal to the product of the aperture area of the dome (A) and the vacuum pressure (P_v). This force is balanced by an equal counter-force against the chest skin under the bladder rim (F_{in}) that is equal to the product of the area of the bladder rim (R) and the pressure transferred to the skin (P_s). Capillary perfusion starts to drop precipitously when the pressure (whether positive or negative) exerted on the skin and underlying tissues exceeds 20 to 30 mmHg.[20–23] Sustained pres-

FIG. 1. (*Left*) Diagram showing the translucent plastic domes and gel-filled bladder rims placed over the breasts. The microcomputer-controlled vacuum pump fits inside a pocket of the brassiere garment. (*Right*) Photograph of the nonsurgical breast-enlargement system as worn by a participant in the study.

sures above this limit lead to tissue damage. To maximize distraction without compromising the circulation of the distracted breast or that of the compressed skin under the rim, the absolute values of P_s and P_v must equal this upper limit of tissue tolerance. This optimization of the absolute pressures requires the area of the bladder rim (R) to be equal to the aperture area of the dome (A), as shown in the following equations.

$$F_{in} = F_{out}$$

$$A \times P_v = R \times P_s$$

If $P_v = P_s$, then R = A

The skin contact area of the rim bladder is therefore designed to be approximately equal to the area of the aperture of the dome (Fig. 2). This constraint can only be avoided if the pressure is allowed to alternate, decreasing the vacuum level every few minutes to allow the skin under the rim to reperfuse, and then reestablishing the vacuum for the next cycle. We elected not to use alternating pressure because of the power drain it imposes on the battery pack.

Cross Section   **Frontal Projection**

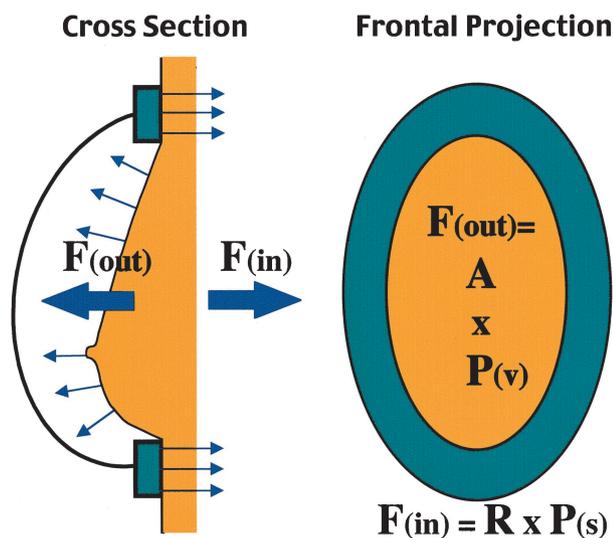F(out)   F(in)

F(out)= A x P(v)

F(in) = R x P(s)

FIG. 2. The contact area of the rim with the skin surrounding each breast must be relatively large to distribute the pressure caused by the distraction counter-force. F(out) indicates the resultant force of distraction applied to the breast enclosed under the dome aperture area (A) by the vacuum pressure [P(v)]; F(in), the resultant counter-force inflicting a pressure [P(s)] to the chest wall under the rim area (R). To balance the forces and to optimize the pressure to the highest continuously tolerable level, the rim contact area (R) is approximately equal to the dome aperture area (A).

Control of Shear Forces on the Skin

The inward pull of expansion stretches the breast skin close to the limit of its elastic deformation.

At the periphery of the breast, if the skin is held firmly by the inner lip of the bladder rim, this stretch imparts a strong shearing force (F_s) to the skin, which can combine locally with the counter-force (F_{in}) to cause peripheral skin blistering and breakdown.[24] To reduce this potentially damaging shear force, the peripheral breast skin under the inner lip of the rim should not be fixed but allowed to move inward. To accomplish that, the rim must deflect radially inward for the distance needed to recruit additional skin and reduce the shear stress to a tolerable level. In addition, this feature reduces skin stretching and the resultant undesirable skin expansion, while focusing the distraction on the deeper breast tissue. Through a succession of prototypes, we found that a rim bladder approximately 2.5 cm high provides the necessary arc of inward deflection (Fig. 3).

Pressure Distribution and Avoidance of Pressure Points

To evenly distribute the pressure on the skin, the rim must be a fluid-filled bladder. A semifluid silicone gel, however, has mechanical characteristics closer to those of live tissues and interfaces better with the torso. We found that the conforming cushion effect of a gel-filled rim complies best with the motion of the torso during routine activities, while evenly distributing the pressure and accommodating individual variations in surface contour. This feature of the system allows it to prevent both the development of localized pressure points and breaks in skin contact that can lead to loss of vacuum.

Maintenance of Low-Level Vacuum Seal

To prevent air leaks and to maintain the low vacuum seal with a low contact pressure, the contact surface of the rim against the skin must be sticky. Loss of the stickiness led to repeated loss of vacuum, excessive activity of the pump, and a rapid power drain of the battery pack. A layer of tacky, hypoallergenic silicone gel was added to achieve the proper seal effect.

Methods

After Institutional Review Board (IRB) approval for the study and after obtaining written

Distraction Stretches Skin
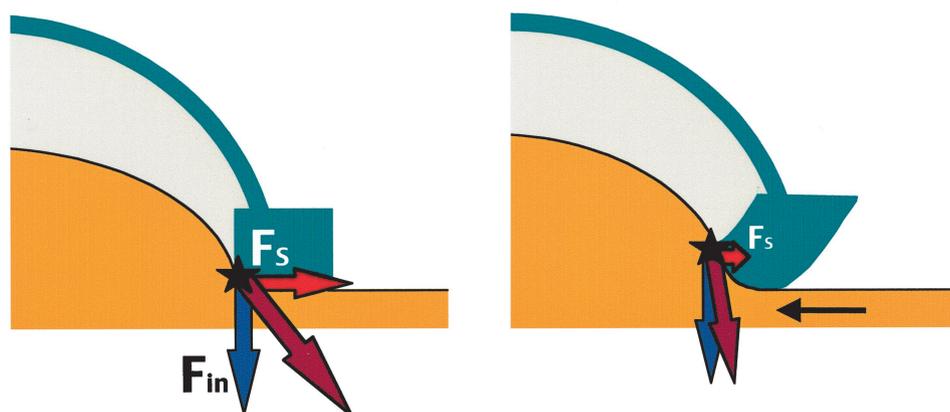
Firmly Held Skin at Inner Lip of Rim (*) Subjected to High Shear Force

Inward Deflection of Rim Recruits Skin To Reduce Shear Force

FIG. 3. Distraction of the breast inside the dome stretches the skin. If the peripheral breast skin is held firmly at the inner edge of the rim, a strong shear force [F(s)] combines with the counter-force [F(in)] to cause skin damage (*left*). A rim that can deflect inward allows peripheral chest wall skin to move inside the dome. This recruitment of skin reduces the amount of breast skin stretch and the potentially damaging shear force [F(s)] (*right*).

consent, we enrolled 17 female volunteers at one study center. Inclusion criteria were an age between 18 and 40 years; general good health; high motivation for breast enlargement; current cup size of AA, A, or small B; agreement to use medically accepted birth control for the duration of the study; and willingness to comply with stringent protocol requirements. Volunteers were excluded from the study on the basis of a positive urine pregnancy test; ongoing lactation; history of breast surgery, disease, cyclic engorgement, trauma, or pain; presence of a breast mass; severe ptosis of the breast; history of chronic dermatitis; and any hormonal therapy besides birth control pills.

Participants were required to wear the breast-enlargement system for 10 to 12 hours per day every day for 10 weeks. Failure to use the system for 2 consecutive days or for more than 3 separate days in any given 2-week period was compensated for by an extra 2 weeks of applied use. Progress was monitored by visits at 1, 3, 5, 7, and 10 weeks into treatment, and at 1, 4, 8, 20, and 30 weeks after the termination of treatment. Breast dome size of the system was increased as needed to accommodate the growing breasts. Breast size was monitored during visits by standardized photographs, volume measurement using both a bead displacement

technique (modified from Campaigne et al.[25]) and the Grossman-Roudner device,[26] and the difference in chest circumference measured at the level of the nipple versus the level of the inframammary fold. Body weight was closely monitored, and a larger than 5 percent variation was grounds for study withdrawal. Plaster moulages of the torso were made at baseline, at the end of the treatment period, and at the 4-week follow-up visit.

Baseline magnetic resonance imaging (MRI) examinations with breast surface coils were conducted before treatment began between days 6 and 14 of the menstrual cycle. Axial and coronal views were obtained using T1 and STIR imaging sequences.[27–29] At least 1 week after completion of the treatment phase (and in the same phase of the menstrual cycle as the first MRI), a follow-up breast MRI was obtained using the same imaging planes and pulse sequences. The paired scans were read and graded by a radiologist experienced in MRI who was blinded as to the sequence of the examinations.

Three of the women who experienced the greatest amount of growth were recalled 26 weeks after treatment for random needle biopsies of the breast. The tissue was processed for histologic examination with hematoxylin and

eosin staining; the samples were read by a breast pathologist.

All participants also completed self-esteem and opinion-of-use surveys both before and after treatment. To obtain direct feedback on the change produced by the use of the system, a simple linear numeric scale was designed. In a 10-item satisfaction questionnaire, the participants gave responses using a five-point scale, ranging from "strongly disagree" to "strongly agree" with each statement.

Changes in breast volume, chest measurement, and body weight were statistically compared with a paired *t* test. Changes in responses to the questionnaire were analyzed with a nonparametric (Wilcoxon sign rank) test.

RESULTS

Seventeen women were enrolled, and 12 completed the study; the five withdrawals were due to protocol noncompliance. All participants found the breast-enlargement system comfortable to wear although somewhat obtrusive under tight-fitting clothes. Most preferred to wear it at home and slept with it at night. They used the system an average of 10.4 hours per day. It took an average of 14.7 weeks (range, 10 to 18 weeks) to complete the effective 10-week treatment period because of setbacks from the occasional inability to use the device. At some point during the course of expansion, some women experienced transient and completely reversible dysesthesia of the nipple that was probably caused by stretch of the sensory nerves. There were no serious adverse events, pressure sores, or significant dermatological reactions attributable to the use of the device.

The average breast volume (mean ± standard error of the mean) of the participants before initiating treatment was 192 ± 64 ml or 203 ± 73 ml, as measured by bead displacement or the Grossman-Roudner device, respectively. The volume immediately after the 10-week treatment was 347 ± 67 ml or 344 ± 62 ml (bead displacement or Grossman-Roudner device methods, respectively; $p < 0.0001$ compared with baseline volumes for both measures). An immediate recoil effect (loss of enlargement) occurred over the first follow-up week; this was followed by a plateau and a net stable volume increase of 103 ± 35 ml or 111 ± 46 ml (bead displacement or Grossman-Roudner device methods, respectively; $p < 0.0001$ compared with baseline volumes for

both measures). This is a net increase of 55 percent over the initial breast volume (Fig. 4). Every participant experienced a net volume increase (range, 15 to 115 percent of initial volume). The volume changes were paralleled by a 5.3 ± 0.7 cm increase in the difference between circumferential chest measurements at the nipple level versus the inframammary fold ($p < 0.01$ compared with the baseline difference; Fig. 5). Volume measurement of the plaster moulages showed the same increase in breast size as measured by the bead displacement and the Grossman-Roudner device. At last follow-up, the participants were still wearing new bras at least one cup size larger than their pretreatment size.

The breast volume enlargement was not associated with an increase in body weight during the course of study. Quite the contrary, a statistically significant trend toward body weight reduction occurred in the months after
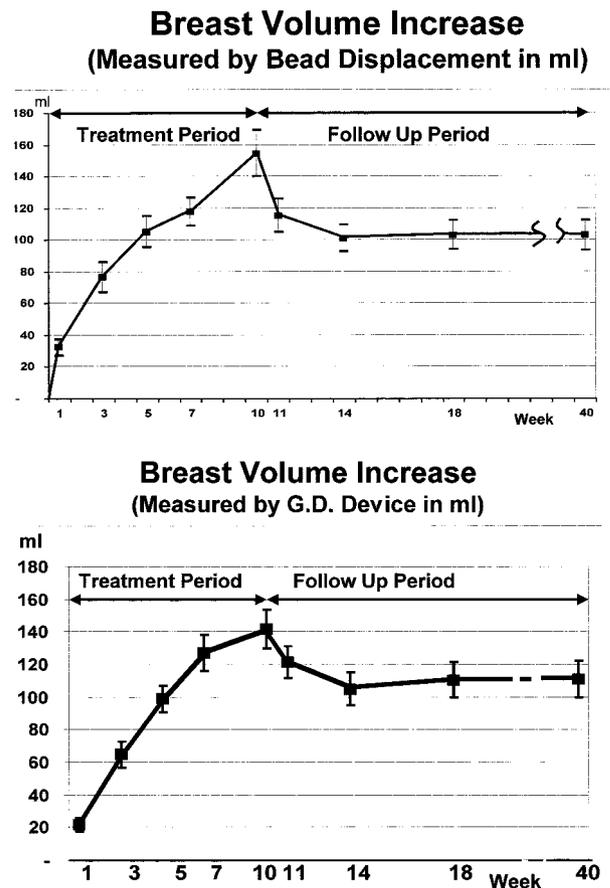

FIG. 4. Breast volume increase over the course of the 10 weeks of treatment and the additional 30 weeks of follow-up. (*Above*) Measurements obtained by the bead displacement method. (*Below*) Measurements obtained by the Grossman-Roudner device. Data are means ± standard deviations.

Increase in the Difference in Chest Circumference Between Nipple and Inframammary Fold
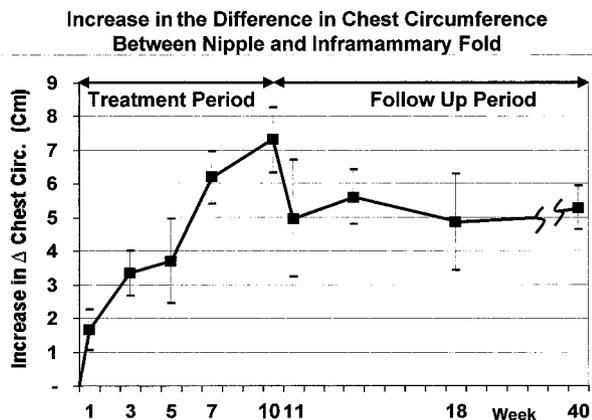
FIG. 5. Breast enlargement as determined by the increase in the difference between the chest circumference at the nipple level and that measured at the inframammary fold (mean ± standard deviation).

treatment ($p < 0.02$; Fig. 6), possibly as a response to improved self-image.

All women expressed satisfaction with the outcome. This was reflected by changes in the baseline scores on the questionnaire after completing the treatment (Table I). The women felt their breasts were lifted after treatment and that the enlargement had a natural and aesthetically pleasing shape (Figs. 7 through 9).

In each case, the posttreatment MRI confirmed an overall increase in breast size. No space-occupying lesions, breast cysts, or other masses were present on pretreatment or posttreatment MRI scans. The T1 images showed a proportionate amount of fat and fibroglandular tissue, with preservation of the native architecture of the breast. STIR images of posttreatment breast tissue did not demonstrate substantial increased signal intensity, i.e., there was no evidence of significant breast edema (Fig. 10). However, when the peak-enlarged
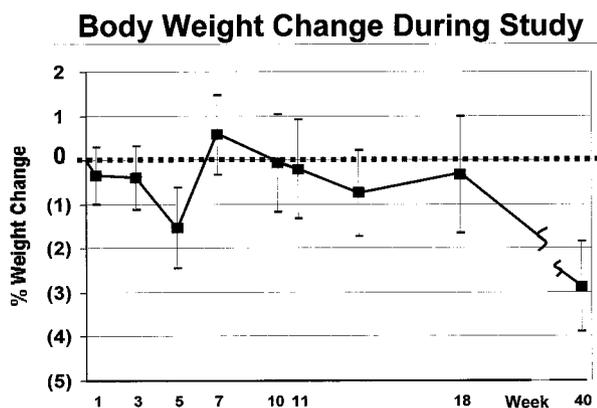
Body Weight Change During Study

FIG. 6. Relative change in body weight during the study compared with the enrollment weight (mean ± standard deviation).

breasts were imaged within hours of device application, a higher water tissue content was apparent (unpublished data).

Histologic examination of the biopsies taken from six of the most enlarged breasts revealed unremarkable, normal breast tissue parenchyma and architecture.

DISCUSSION

Breast size in the healthy premenopausal adult woman is stable and varies only with pregnancy, hormonal intake, body weight fluctuation and, to a smaller extent, during the menstrual cycle. Our study carefully controlled for all these factors. The participants were initially screened with a pregnancy test, and they used contraceptive measures throughout. If the women were on birth control pills before enrollment, they kept taking the pills and no additional hormonal treatment was given. Body weight was carefully monitored during the study and, in fact, significantly decreased while breast size increased. The most consistent decrease in body weight was seen after the participants had completed their initial wearing period. Except for the interim recordings, all breast volume measurements were made during the first phase of the menstrual cycle. Therefore, although the study could not be blinded and it included no controls, the substantial breast growth measured should be attributed to the use of the device.

To our knowledge, this noninvasive external distraction device is the only documented method of nonsurgical, nonpharmacologic breast enlargement. The nonsurgical system was well tolerated, with no complications. All patients who completed the effective 10-week treatment course achieved a significant increase in breast size, even after posttreatment recoil. This increase in breast size was still observed at 30 weeks posttreatment. The growth appears to be evenly distributed among all tissue elements of the breast, with preservation of the normal composite tissue architecture.

Stretch is good for a cell; it is the mechanism involved in normal tissue growth, regeneration, and homeostasis.[15] The phenomenon of stretch-induced tissue growth is widely prevalent, and it has been studied in vitro and in vivo for many years. Cells in culture will respond to longitudinal stretching by an increased mitotic rate and by realigning their shape and cytoskeleton parallel to the direction of force.[30–32] Experimental studies of tissue expansion have

TABLE I

Change in Response to Self-Esteem Questionnaire

Questionnaire Statement	Change in Score	p
1. I like my breasts just as they are now.	1.8	<0.01
2. I like the size of my breasts just as they are now.	1.9	<0.01
3. I am satisfied with feedback from others concerning the change in my breasts.	0.9	NS
4. I am now concerned that my body image is not attractive unless I have larger breasts.	−0.7	NS
5. I now have difficulty wearing light clothes or bikini beach wear due to my small breast size.	−1.0	NS
6. I now feel comfortable wearing beach wear.	1.4	<0.05
7. I have difficulty showing my breasts during intimate interaction with my partner.	−0.6	NS
8. I enjoy looking at myself in the mirror in the nude.	1.1	<0.05
9. I feel embarrassed when I or someone else looks at my breasts.	−1.2	NS
10. I feel embarrassed when someone else touches my breasts.	−1.3	<0.05

Subject responses to the 10 questions ranged from 1 to 5: 1 indicated "least likely to be true" and 5, "most likely to be true." The numbers in the table indicate the difference in responses for each question (after − before treatment). Numbers greater than zero identify questions for which the participant response was more strongly in agreement after treatment. Statistical comparisons for each question were made with the Wilcoxon sign rank test. $p > 0.05$ was considered not significant (NS).

shown fibroblast changes consistent with the production of new extracellular matrix.[33,34] All types of tissues studied grow and regenerate normal tissue when subjected to mechanical stretch, including the skin,[6,35,36] bones,[9–12] bowels,[37] lungs,[38] urogenital viscera,[39] blood vessels,[30,40] nerves,[40,41] skeletal muscle,[10,42] cardiac tissue,[43] and smooth muscles.[30] A number of widely used medical devices rely on this principle to generate skin for wound closure,[7,44,45] to reconstruct the breast after a mastectomy,[46,47] to elongate entire extremities[9] and,

more recently, to restore deficient mandibles[12] and entire faces[13] to normal. Ilizarov[9,10] demonstrated in the laboratory and in the clinic that distraction is the only known means of inducing true tissue regeneration in the adult.

How the tissue responds to external distractive forces is not fully known. Cells experience a variety of forces throughout their lifetime. They sense the balance of mechanical forces that surround them and translate changes into biochemical signals by a mechanism called mechanotransduction.[15] Cells are mechanically
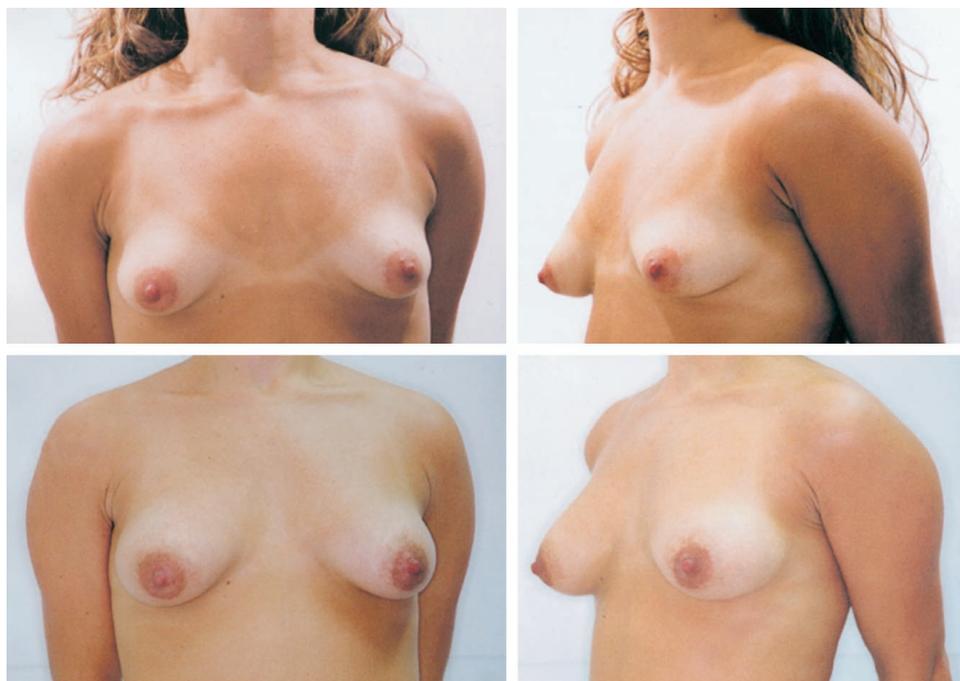

FIG. 7. Representative photographs of a woman in the study. *Left*, frontal views; *right*, oblique views; *above*, views before treatment; *below*, views after treatment with the nonsurgical breast-enlargement system at 30 weeks of follow-up.

FIG. 8. Representative photographs of a woman in the study. *Left,* frontal views; *right,* oblique views; *above,* views before treatment; *below,* views after treatment with the nonsurgical breast-enlargement system at 30 weeks of follow-up.
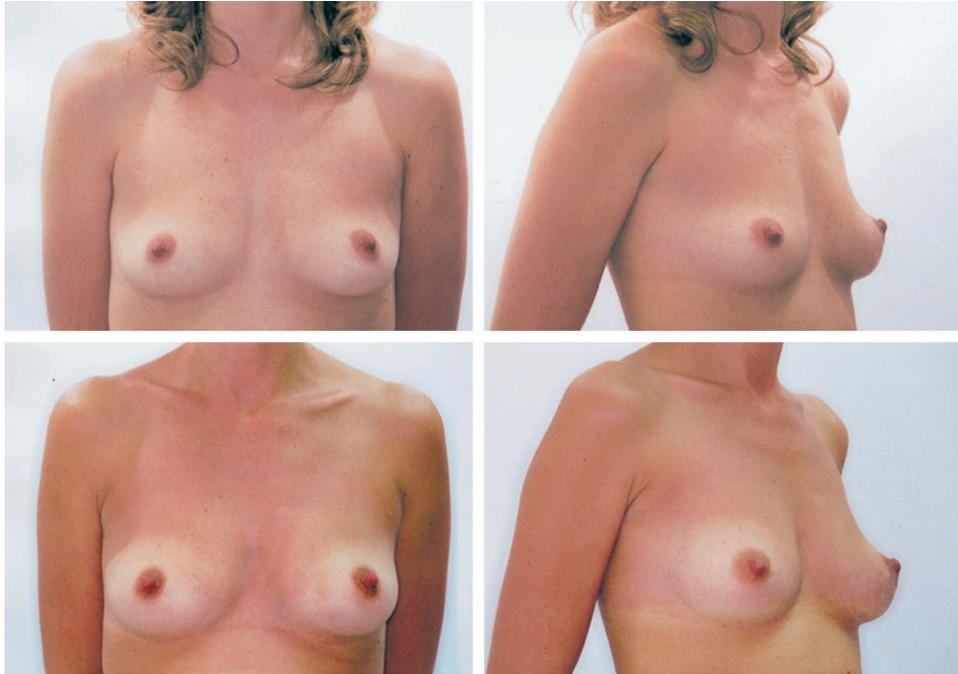
linked to other cells and to the extracellular matrix through their cytoskeleton and its surface receptor system.[15] Integrins are thought to be the transmembrane receptor link between the mechanical deformation of the extracellular matrix caused by external forces and the resultant internal cytoskeletal conformational response. Mechanical stretching of the extracellular matrix induces integrin clustering and ligand binding to form macromolecular scaffolds called focal adhesion complexes, which mechanically link the extracellular matrix with the cytoskeleton and bring the tensional forces into balance.[48] This balancing of the mechanical forces involves tensegrity, an architectural system in which structures stabilize themselves by counteracting the forces of compression and tension.[49] The formation of focal adhesion complexes also mediates the stimulus-coupling response with the activation of kinases, ion channels, and growth factor receptors.[48,50–53] Mechanically induced rearrangements of the cellular cytoskeleton are also directly linked to the nucleus to initiate cell division. This process is the subject of intense research and many authoritative reviews.[14–17,48–54] From a teleological viewpoint, whenever stretched and deformed, cells in the tissue sense the need to spread; they then respond by proliferating un-

til the gap is filled and the normal balance is restored again.[15]

In view of the substantial societal demand for breast enlargement (16 to 19 million women in the United States), the application of this phenomenon of stretch-induced tissue growth to the breast was bound to be forthcoming. By taking into account biomechanical and physiologic constraints and after extensive prototyping, we discovered four critical design features and determined the most effective and safe distraction pressure. The nonsurgical system used in this study applies an external, low-level, sustained traction that is effective and well tolerated. To stimulate tissue growth, however, the distraction must be continuous and sustained over a prolonged period of time. This is the reason why failure to continuously use the device leads to setbacks and necessitates additional compensatory wear time. Although the numbers are too small to evaluate statistically, it seems that the greatest effect was observed in the participants who used the system the most intensively (hours/day) and the most continuously (missed no days).

The tissue growth achieved in this study is generated by the same basic mechanism of physical distraction as occurs with surgically implanted bone lengthening and tissue expan-
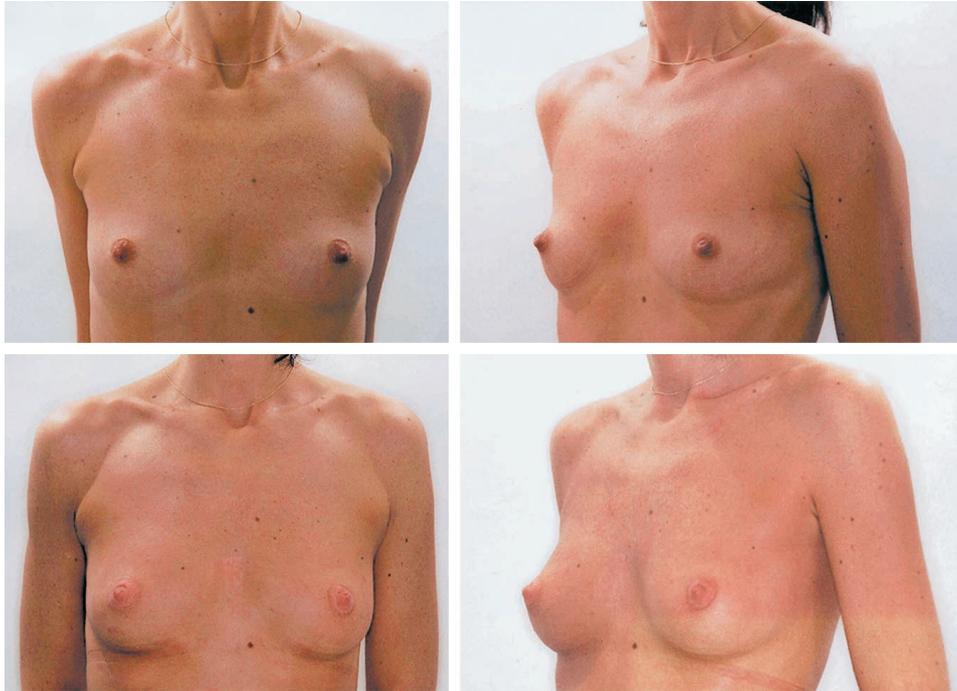
FIG. 9. Representative photographs of a woman in the study. *Left*, frontal views; *right*, oblique views; *above*, views before treatment; *below*, views after treatment with the nonsurgical breast-reduction system at 30 weeks of follow-up.

sion devices.[6–13] Subcutaneously implanted tissue expanders, silicone bladders that are filled with saline, act on the overlying skin and associated tissues. There is an initial elastic (stretch) response, followed by the induction of mitosis[35] and a remodeling of the connective tissue extracellular matrix[36] in the stretched tissue. As the tissue expands (with a resultant reduction in tension), more saline is added to the bladder to continually exert tension and cause growth. The Ilizarov bone-lengthening system and related devices work similarly: a transverse osteotomy sets up bone callus formation, which is then gradually distracted, allowing the newly forming bone to be extracted (grown) at the callus site.[9–11] Associated soft tissues (muscle, nerve, vessels, etc.) are also distracted, with an initial stretch and deformation response followed by true tissue growth, which occurs evenly along the distracted area, not just at the level of the callus.[40]

Under the effect of the external three-dimensional pull applied by the nonsurgical breast-enlargement system, the breast tissue goes through several stages in its expansion. During the early phase, fibroelastic fibers, initially loosely spaced around fat and fibroglandular cells, are stretched. Elastic deformations, along with some increased water edema ac-

count for some noticeable growth after a short period of use. This early volume increase includes no true tissue growth and is totally reversible. It is only after continued use and sustained stretch that true tissue growth is stimulated. The stretched cells respond to the sustained deformation by undergoing mitosis and the deposition of additional extracellular matrix. With sustained use over a number of weeks, the incremental component of true tissue growth adds up on top of the reversible elastic deformation and extracellular fluid accumulation. This accounts for the marked peak enlargement seen at the end of the treatment phase and the recoil observed 1 week later as both old and new tissues return to their resting state. At the end of a 10-week cycle of use, breast volume is expected to approximately double, with half of this gain remaining as long-term growth. The final tissue seems to be stable over a 30-week follow-up, and it has a normal histologic appearance.

The MRI evaluation was used to gauge whether breast augmentation changed the ratio and distribution of fatty and fibroglandular tissue (as depicted on T1 images) and to determine whether there was increased water content or inflammation after treatment (seen on STIR images). In all cases, the increase in
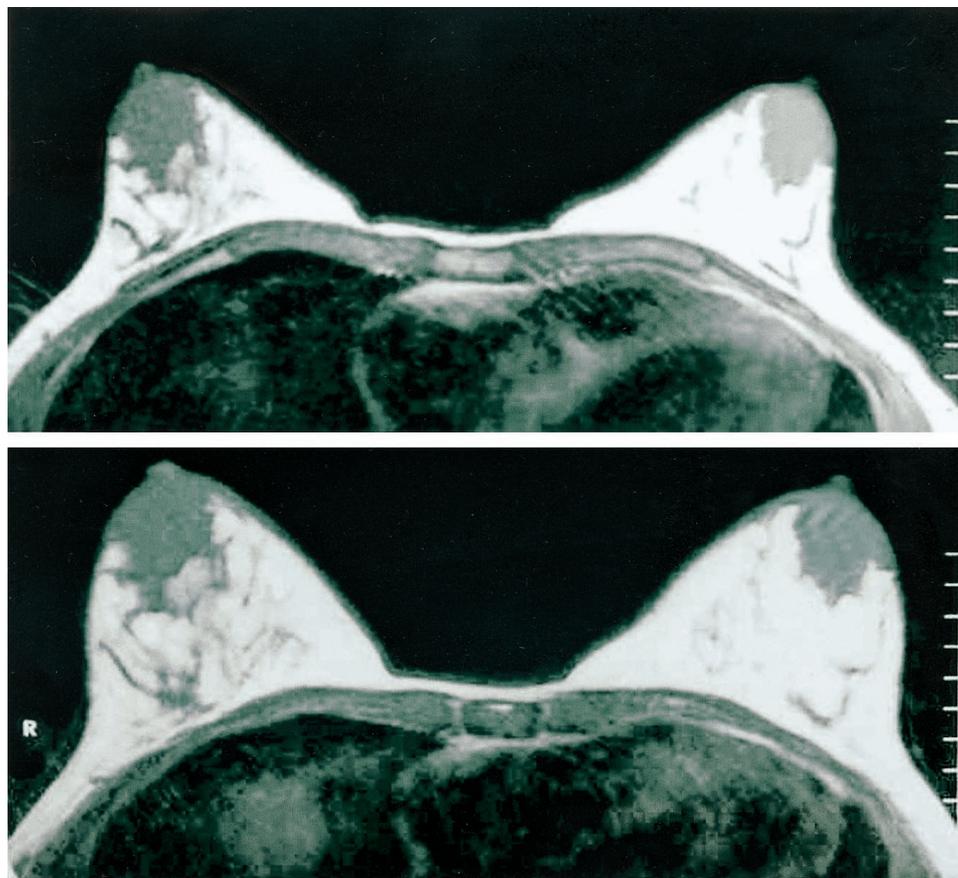
FIG. 10. T1-weighted coronal MRIs of a participant at baseline (*above*) and after treatment (*below*) show an increase in size with a proportionate increase in fatty tissue (*white*) and fibroglandular tissue (*gray*). Note that there is no change in the distribution or appearance of the fatty and fibroglandular components.

the size of breasts after treatment correlated with nearly equal increases in fatty and fibroglandular tissue, without discernible changes in the tissue architecture. Increased signal intensity on STIR images was not apparent; this suggests that increased water content (due to edema and/or inflammation) was not present. Although contrast-enhanced MRI is more sensitive in the detection of breast cancer and benign processes, such as dysplasia and inflammatory breast disease,[28,29] the noncontrast images did not demonstrate any overt changes that would suggest the development of disease when comparing posttreatment and pretreatment images.

Concern that stretching the breast would accentuate any degree of ptosis was not borne out by the study results. The most noticeable initial impression by all the participants was that of a breast fill and lift. In the ptotic breast, there is a discrepancy between the loose skin envelope and the relatively smaller contents. The forces of distraction, therefore, are di-

rectly transmitted through the loose skin to cause an enlargement of the tighter contents before skin enlargement occurs. It is expected, however, that gravity acting on the now-larger breast will naturally tend to cause some ptosis with time.

Another major concern about this breast-enlargement system is whether its application stimulates or accelerates latent breast cancer. Although the number of participants and the time course for follow-up are too small to determine this, several related findings do not support a cancer-inducing/stimulating effect by tension-induced tissue growth. Mechanical forces are not known to be carcinogens. The force used by the device is trivial compared with the ones that constantly act upon the body. This vacuum pressure of 20 mmHg represents a 2.5 percent drop in atmospheric pressure. It is equivalent to the pressure change experienced before a storm or when climbing to the top of a high tower, and it is 4 to 7 times less than the pressure change experienced in-

side the cabin of a commercial aircraft. The total mechanical pull exerted by the device on the breast is approximately equivalent to the force exerted by gravity on a large, 2-kg breast. This amount of force leads to downward (unidimensional) growth of the unsupported larger breast, an effect well-known to plastic surgeons performing reduction mammaplasties. Numerous epidemiologic studies have failed to reveal any increased cancer incidence in the larger, heavier breasts that are subjected, over a lifetime, to a mechanical stretch similar to that of the nonsurgical breast-enlargement system.[55–58] This experiment of nature proves that mechanical forces acting on the breast are not carcinogenic.

Ilizarov devices do not have an associated cancer induction with their use in distraction of the extremities.[9] Skin is the most cancer-prone organ in the body, yet skin expanders have been used for decades without any report of cancer arising in the expanded skin.[7,8,59,60] Furthermore, these tissue expanders have been applied in breast reconstruction after mastectomy, stretching the residual breast tissue that has a high likelihood of tumor recurrence (it is well accepted that even the most radical of the mastectomies leaves some breast tissue behind). Yet more than 20 years of experience in thousands of women has confirmed that breast reconstruction with tissue expansion does not increase the incidence of cancer recurrence.[42,43,60–63] Furthermore, in an experimental model of rat mammary carcinoma, tissue expansion induced engrafted tumor regression and even a reduction in the spread of visceral metastasis.[64]

We can only speculate as to why the breasts seem to retain their newly gained growth after the rapid elastic recoil and the loss of tissue edema. Aside from mechanical stretch, growth factors and hormones can also stimulate tissue growth. The administration of these factors stimulates new tissue growth; the survival of this growth is critically dependent on the continued presence of the hormonal stimulus.[65–68] The new tissues regress by apoptosis on withdrawal of the growth factor. Tissue growth induced by mechanical stretching, however, may remain, even after the withdrawal of the mechanical stimulus. Experiments of nature familiar to plastic surgeons demonstrate how these two types of induced tissue growth may differ. With weight gain or pregnancies, growth of the adipose tissue or of the uterus is hor-

monally mediated, whereas the growth of the overlying skin is induced by secondary mechanical stretch. After weight loss or deliveries, the mechanical stretch and the supporting scaffold regress, while skin growth often remains as a cosmetic problem.

Plastic surgeons are also familiar with the ptosis that follows the removal of a breast implant. Here, sustained stretch by the implant induces the growth of the tissue in the breast envelope. The resultant ptosis will not recoil with time, and the enlarged tissues will not shrink back. Similarly, when a tissue expander is rapidly inflated and removed, no significant tissue growth occurs, only reversible stretch and recruitment. However, when an inflated expander is kept for a few months, its removal is followed by permanent wrinkling of the skin. That soft tissues recoil after losing their structural support is not universally true. It is the presence of inflammation that may cause underlying scarring and some degree of contraction. The nonsurgical breast-enlargement system was designed to specifically avoid any significant tissue inflammation.

In summary, this system offers women a means of enlarging their breasts without the pain and risk of surgery or the perceived long-term health risks associated with surgical implants. The process is slow and gradual; the arbitrarily chosen 10-week course does not match the immediate size gain that follows the insertion of an average sized breast implant. Additional use beyond 10 weeks is required to achieve further growth. This gradual process gives women more control over the change in their appearance. Because the tissue growth is local and autogenous, the result is more natural looking, as opposed to the artificial appearance that can often accompany breast implants.

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