the continued improvement in their customer support. This new company seems intent on resolving the predictable growing problems as they arise.

As a final observation and admonition, the physician should not tell the patient that the device "can. . .be worn during the day while at work," as claimed by the company on their Web site.[3] The smallest set of domes might be worn discreetly under loose clothing, but the large and extra-large units certainly cannot. In addition, the SmartBox motor is designed to periodically turn on if the pressure drops below a certain level, and even with the alarm system turned off the motor can be easily heard. Not only would the patient be wearing conspicuously large devices under her blouse but her breasts might also periodically "hum."

Certainly, I have had satisfied patients who did obtain a minimal but noticeable increase in size that pleased us both (Fig. 2). It seems to me that the Brava system has merit and does work for selected patients. Nevertheless, an even more accurate predictor of those patients who are suitable candidates,[4] both psychologically and physically, is needed. Patients also must be more accurately informed of the reasonable probability that they will indeed be "very pleased."

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REPLY

Sir:

We thank Dr. Smith for thoughtfully sharing with us his initial experience with Brava. He is to be congratulated for his results and for pointing out that Brava is a good way to correct breast asymmetry. We are also thankful for this opportunity to comment on Brava.

External tissue expansion to enlarge the breast without an operation is a paradigm shift. A number of years ago, one of us (R.K.K.) pursued this with an original design for an external breast expander. Pilot testing of the early prototype demonstrated that it worked. In 1996, we shared these results with a few trusted colleagues but decided against publishing preliminary data. With the help of talented collaborators, we improved the prototype and manufactured an effective external breast expander. In 1999 we teamed up to conduct the tightly controlled study we published in the *Journal*.[1] We later confirmed that the breast enlargement persisted at 15 months follow-up.[2] This time we proved it! To remove any shadow of a doubt that external breast expansion leads to long-lasting breast enlargement, a multicenter study involving more than 100 women was concluded in 2001. We found a dose-response relationship between expansion and enlargement. That is, the more intensively (hours per day) and the longer (number of continuous treatment days) it is used, the more the breast grows (manuscript submitted). After a series of technical design improvements, Brava was born.

Brava became available to the public last year, and thousands of women have successfully used it since to enlarge their breasts. Some journalists have even reported their personal experience with Brava.[3] Brava is dispensed by a number of esteemed colleagues (the Brava Authorized Physicians) who are gaining considerable real-world experience with its potential and its limitations. The consensus among physicians providing Brava is exactly Dr. Smith's quote: "Brava has merit and does work for selected patients." It works! But it is not for everybody.

Key to patient satisfaction is good patient selection. Good selection, however, comes from experience, and experience from poor selections. Dr. Smith and many other Brava providers are gathering the experience we need to recognize the profile of the woman who will not be satisfied so we could focus on the ideal Brava woman. But before we elaborate on this crucial issue, let us review what we face with this novel technology.

True tissue generation, in contrast to visco-elastic deformation, is a very slow result of sustained tissue expansion. For tissues to grow substantially, the distracting force must be continuous over many weeks, sometimes even months. Herein lies the challenge for an external device. It is not possible to keep it on all the time, and even the compromise of trying to keep it on more often than it is off rests on the whims of the user. The minimal therapeutic dose of at least 10 hours/day (42 percent of the time), every day, is truly difficult to comply with. With experience, we found that we needed additional time to compensate for the loss of sustained tension caused by occasional missed days or days with less than 10 hours. The algorithm detailed in the published clinical study[1] considered 2-week segments at a time; for every 2 consecutive or every 3 separate days missed (or used for less than 10 hours) within these 2 weeks, 2 additional weeks of compensatory wear-time were required. Therefore, to receive the effective therapeutic dose of 10 weeks, we reported that the average compliant woman wore the device for 14.7 calendar weeks. Furthermore, that the 10-week treatment dose would suffice to demonstrate growth was in itself an educated guess. The recent multicenter study and the real-world experience confirm that the more one uses it the more one grows; with some women growing over 250 ml after 6 months (Fig. 1). The caveat, however, is that prolonged treatment did not quite make up for sub-therapeutic daily doses. And, to get a consistent response, some women may require doses as high as 12 to 14 hours per day. We found this to be particularly true for the very small-breasted athletic women with low body fat who are pursuing intensive physical exercise programs. For obvious metabolic reasons, these women have difficulty accumulating tissue in their breasts.

Just as with everything else in medicine, we cannot expect everybody to respond at the same rate with the same treatment dose. People require different doses and will respond at different rates. The problem with the expectation of a 100-ml *average* growth after the 10-week dose (14.7 calendar weeks for the average compliant women responding at an average rate) is that half the women will end up with less than 100 ml. Unless these slow responders are willing to prolong

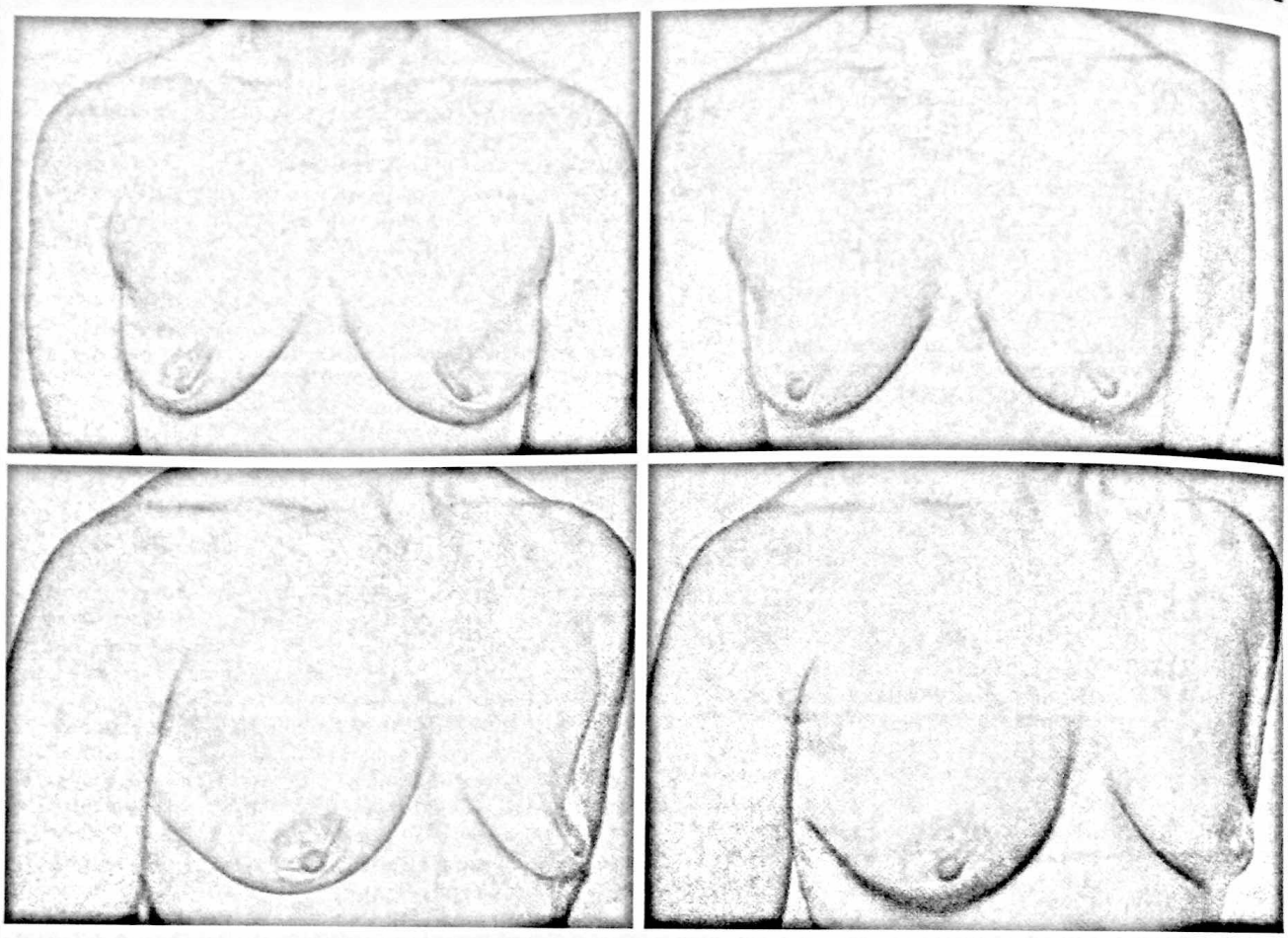

FIG. 1. Before (*left*) and after (*right*) two 12-week cycles of Brava use interrupted by an 8-week reprieve. Posttreatment photographs were obtained 1 month after cessation of use and after recoil had stabilized, as evidenced by two equal measurements 2 weeks apart. Post-lactation and weight loss involution treated with Brava resulted in 250-ml larger and fuller breasts.

and/or intensify their treatment to achieve the 100-ml response, they may be "dissatisfied." To further complicate the matter, some women keep longing for "just a little more," and their satisfaction end point becomes a moving target.

Dr. Smith correctly identified the reason for the discrepancy in satisfaction rate between his real-world experience and our clinical study.[1] Had they actually presented as regular cosmetic patients, the five dropouts (who could not keep up with the protocol requirement) and the one who grew only 15 percent would have been displeased. Fortunately, most Brava providers are becoming more sophisticated in their patient selection. Of the thousands of Brava users, the incidence of dissatisfied women as tracked by Brava customer support is very low considering the extremely novel nature of this technology.

Despite Dr. Smith's reservations, the SmartBox did accomplish its assigned role of being a reasonably accurate global compliance monitor. His patient painstakingly chartered her wear-time versus the downloaded record. Because the microchip in the SmartBox only records the time during which the pressure is therapeutic, the relatively minor discrepancy in the global average can be explained by the occasional vacuum leaks during wear. This is why, to end up with 10 hours of effective expansion, we recommend more than 10 hours of daily wear.

Standard tissue expansion is well accepted despite a 10 to 30 percent complication rate requiring re-operation or discontinuation of treatment. Dr. Smith's initial experience with breast expansion had an 8 percent incidence (two patients) of cutaneous reaction that resolved with simple cessation of wear. Despite the inherent safety of an external device, we believe that the potential for cutaneous reaction is the primary reason Brava should remain under medical supervision. Brava might be cumbersome and uncomfortable at times, but it should never be painful. Pain heralds tissue damage and is an important safety feature. Whenever she has pain, or at the earliest sign of a fixed rash, the Brava user should contact her physician and at least temporarily stop using it. Fortunately, Brava has recently introduced a protective skin-care kit that has largely decreased the incidence of cutaneous reactions.

In response to Dr. Smith's plea for guidance with patient selection, these are the criteria we learned from experience to be important:

1. Brava women are well informed.
   Most successful Brava practices have an assigned woman in the office who educates the patients on what it will take to effectively use Brava. Ideally, this office person has gone through the treatment herself and can describe it from firsthand experience. Prospective candidates are told that Brava will lead to real breast enlargement without an operation or implants but that it is not a quick fix. It will require commitment and perseverance. They need to know how they will look while wearing it to decide

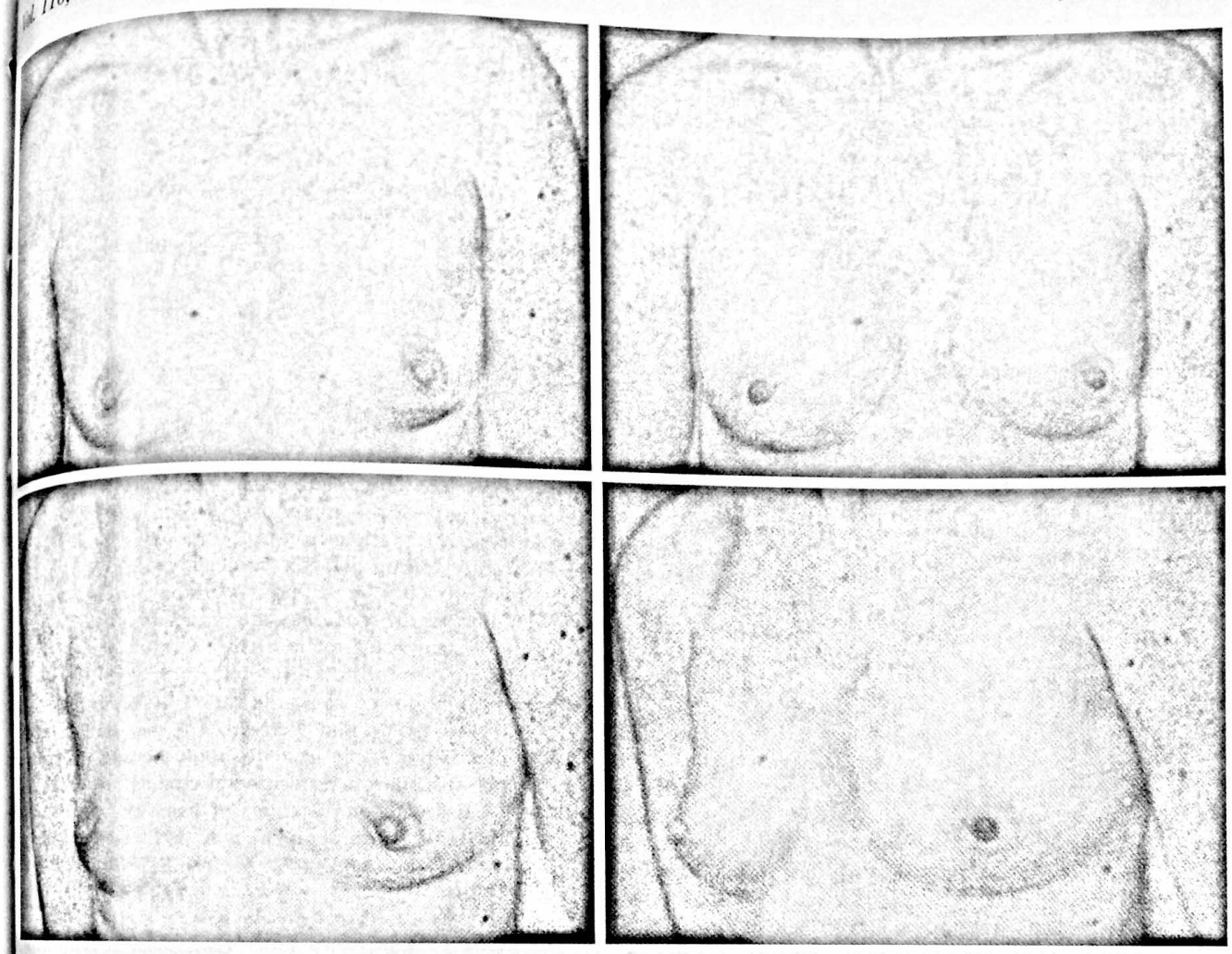

FIG. 2. Before (*left*) and after (*right*) 12 weeks of Brava use. Posttreatment photographs were obtained 1 month after cessation of use and after recoil had stabilized, as evidenced by two equal measurements 2 weeks apart. Notice that the 120-ml volume growth is subtle and diffuse and mostly fills up the supra-areolar tissue deficiency.

whether they are comfortable using it in public or will restrict it to home use. This is crucial in terms of lifestyle and social impact.

2. Brava women have reasonable expectations.
It is unrealistic to compare Brava's slow and moderate growth with the immediate enlargement that can be achieved with an implant. The volume gain with Brava is no match to that of an implant and the enlargement is more diffuse, natural-looking, and subtle than the ball-like effect often associated with implants. A diffuse volume increase of 120 ml creates fullness more than round projection and may not be strikingly noticeable (Fig. 2). It will, however, provide the needed bulk to augment cleavage with push-up bras. As in good plastic surgery, Brava's effect is subtle. The patient must have realistic expectations of what she can reasonably attain and the effort she will need to invest to get there. To that effect, a pictorial guide of before-and-after photographs showing several breast types has been very useful.

3. Brava women are compliant with treatment.
Brava is not as simple as swallowing a pill, yet many patients do not even comply with life-saving medication. Unlike other measures we usually provide as plastic surgeons, successful Brava treatment requires compliance. Dissatisfied patients reporting no growth are usually, for one reason or another, noncompliant. Brava is not for the fickle; it requires steadfast determination and discipline. No wonder the overwhelming majority of Brava women are professionals with a college degree or higher.

4. Brava women are patient.
Breast or any tissue cannot substantially grow within just a few weeks. One cannot expect Brava to generate in 10 weeks what nature has failed to accomplish in all the teenage years. With experience, we found there are two kinds of Brava users, those who count the days and the hours until the end of their 10-week protocol and those who patiently come to accept that the more they use it the more they grow. It is important to recognize the former group before initiation of therapy, because many of them could end up dissatisfied. Brava women recognize that they will grow their own breasts at the rate of 1 to 1.5 ml/day and that good results will take time. Brava is for patients with patience.

Brava empowers women with the ability to actually grow their own breasts without drugs or operation. This is in-vivo tissue engineering applied for cosmetic enhancement and a medical scientific feat. With stringent compliance requirement and slow growth rate, Brava's practicality limits its popularity. Because it is still easier to get the 300-ml average breast implant volume through an operation than to patiently grow the real thing, Brava does not compete with implants and will

not replace them. It is, however, an attractive alternative to a significant number of women for whom an operation is not an option and who otherwise would have not visited a plastic surgeon's office. If it expands our reach, it is good for the specialty.

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LITIGATION

Sir:

I enjoyed the editorials by Dr. Mark Gorney and Dr. Robert Goldwyn in the March issue, both dealing with litigation issues.

The core change that must occur is for legislatures to adopt a sliding scale, loser pays approach in civil cases. A sliding scale protects the indigent; loser pays protects the innocent. Even responsible plaintiffs' attorneys agree with this concept because the present silliness is going to lead to the golden goose syndrome. This requires political change, and the emphasis should begin now.

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WOUND COMPLICATIONS OF INFUSION PAIN PUMP THERAPY

Sir:

We recently have provided consultations and wound management for ischemic wound complications following knee arthroplasties, each treated with a postoperative infusion pain pump. Three cases were referred by the same orthopedic surgeon, who has had many years of experience in knee joint replacement. That surgeon was very distressed to have these older patients develop ischemic skin and soft-tissue complications along the anterior knee incision within the same 6 weeks after arthroplasty. Two of these patients required débridement and gastrocnemius flaps, and the other required repeated débridements and skin grafting. All of the joints were salvaged. These cases have been reviewed to determine the underlying cause for the wound margin necrosis.

On review of the similarities and changes in the orthopedist's routine, it was discovered that the likely source of the wound ischemia and necrosis was the use of a postoperative infusion pain pump with a catheter placed directly beneath the operative site. Infusion of Marcaine with epinephrine as recommended by the infusion pump vendor company proceeded at 2 cc an hour. There was adequate drainage of the operative sites, and no apparent compartment compression was created. The same surgeon had used anesthetic infusion solutions without epinephrine previously and had no wound complications. The company's recent recommendation to add epinephrine to the Marcaine infusion solution became suspect.

The orthopedic surgeon contacted the products manager for that company, and they reviewed these cases. They concluded that continuous infusion of epinephrine in the vicinity of a soft-tissue incision might result in prolonged vasoconstriction, which could progress to wound necrosis as seen with these three patients. At this time, the company is considering rescinding their recommendation to include epinephrine in the local anesthetic infusion.

After reviewing all factors associated with these three cases, it seems that the continuous infusion of epinephrine was probably the direct cause of the wound complications. Plastic surgeons may want to be aware of this potential problem should they see consults of a similar nature. The infusion pain pump is being used in a wide variety of surgical wounds for postoperative pain management. The inclusion of epinephrine in this pain relief system should be weighed carefully. Patients with marginal peripheral circulation may be at increased risk for complications of tissue necrosis along the wound site when epinephrine is infused continuously.

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ECTOPIC TOOTH IN A CLEFT LIP AND PALATE PATIENT

Sir:

Ectopic eruption of teeth can occur in a wide variety of sites. Although it is rare, a few ectopic tooth cases have been presented in the literature. A 6-year-old boy was reported to have an extraoral eruption of a mandibular permanent canine and a loosely attached lateral incisor in the labial vestibule 3 months after trauma to the chin. The author concluded that the trauma not only caused displacement of the permanent tooth buds, but it also resulted in transposition of the lateral incisor and canine with subsequent ectopic eruption.[1] In another case report, an extremely rare location for the third molar in the maxillary antrum was reported. The patient presented in that report was a 35-year-old Caucasian man.[3] A case of a large dentigerous cyst containing a canine tooth in the maxillary antrum was also presented.[4]

Ectopic eruption of the teeth in the sinonasal tract and the migration of a displaced dental fragment from the maxillary sinus to the nose have also been presented as two rare phenomena in three cases. One article mentioned an asymptomatic ectopic tooth within the nasal septum.[2]

I recently saw a 10-month-old male patient with abnormal tooth eruption in the nasal vestibule following cleft lip operation. He had an unoperated alveolar and a palatal cleft located on the right side. In the nasal vestibule, there was an