influx of blood, and this should be the first option for covering the fracture site. However, no muscle flaps have been described as reliable in providing good coverage for the distal third of the leg, ankle, and heel. This would leave only microsurgical flaps, which have been subject to much criticism, and the fasciocutaneous flaps.

In 1999, Arnez, this time with the participation of Dr. Khan—who referenced this article incorrectly in his letter—suggested a new classification of soft-tissue injury, based on the modification of the Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation (AO/ASIF) classification. This represents an interesting approach, albeit extremely complex. Most orthopedic services still prefer the Gustillo classification.

Despite the fact that a fast and complete bony union is the goal sought with the reverse-flow island sural flap when it is used for covering exposed fractures, it is not possible to cover in detail all of the topics related to a flap in a single article. I do indicate that all of our patients were followed up by orthopedic service with respect to fracture healing using clinical/radiologic criteria, and that their recovery was considered satisfactory. For our intent, this was considered sufficient.

"An exercise in elegant dissection" occurred only in a university environment on cadavers that preceded the first *in vivo* case performed. The ideal flap—one that would be safe, easy to execute, and widely applicable and would provide an abundant irrigation of the focus of the fracture with a minimum of aesthetic and functional aftereffects—is what we all seek. There is no bony union without the covering of the fracture's site by viable tissue. We, as surgeons who work with trauma on a daily basis and know how difficult it is to repair the loss of substance in the distal third of the leg, ankle, and heel, have incorporated with great satisfaction the reverse-flow island sural flap into our routine as the first option for the treatment of these regions.

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INITIAL EXPERIENCE WITH THE BRAVA NONSURGICAL SYSTEM OF BREAST ENHANCEMENT

Sir:

For the past 6 months I have been using the new Brava system (Brava, LLC, Coconut Grove, Fla.) of nonsurgical breast enhancement. My initial results with the system have been inconsistent with the results reported by Khouri et al.,[1] and I believe it to be important to share this information with plastic surgeons who might be considering promoting the product. I was attracted to the system by the *Journal*'s publication of the excellent study of Khouri et al.,[1] the endorsement of the product by a number of prestigious members of our organization, and my frustration over the years with the challenge of treating the very small-breasted woman who wants only a very minimal enlargement with an implant because of the implant's narrow diameter. The Brava company provides the physician dispensing their product with a fitting kit that contains a silicone mold equivalent to the shape of a 100-cc increase in breast tissue that the patient places on her breast to judge the anticipated average result. That potential improvement has met the objectives of almost all of the women investigating the Brava system seeking the elusive minimal enlargement. Here, I thought, was the answer to my dilemma.

The women in Khouri et al.'s study obtained an average increase of 55 percent of their breast volume (range, 115 percent down to 15 percent), representing approximately one cup size for the small cup-sized woman. Khouri et al.'s summary of their results following the treatment of 12 women (five of the original 17 excluded because of noncompliance) included the following observations:

1. "All participants were very pleased with the outcome. . .."
2. ". . .the device was comfortable to wear."
3. "No adverse events were recorded. . .."

I have provided the system to over 25 women since July of 2001, with 13 far enough along in their treatment to be able to judge their response. My initial findings included the following:

1. Six were pleased with the outcome and seven were displeased.
2. None described the device as comfortable.
3. Two patients had significant adverse events requiring discontinuation of therapy. One developed a systemic allergic skin reaction to the silicone domes and the other developed a tender, hard, nonsuppurative subcutaneous mass from dome pressure—fortunately, there was no skin breakdown and the mass is spontaneously resolving.

Why the striking difference in the percentage of "very pleased" individuals between my group and Khouri et al.'s? That is easy to explain. They did not consider the opinions of the five women excluded from their original 17 participants, their focus was appropriately on the objective scientific measurement of the efficacy of the device, and they provided the device free of charge. Conversely, when the physician in clinical practice assesses the success rate of a treatment method he or she does not have the luxury of simply ignoring the noncompliant individuals; the focus, by necessity, is on the subjective perception of the fulfillment of a perceived goal by the individual under treatment; and a fee is charged. Khouri et al.'s determination of being pleased was based on a short multi-question test measuring self-image. My deter-

Date	Start	End	TOTAL WEAR TIME	WEAR TIME BEFORE MIDNIGHT	WEAR TIME AFTER MIDNIGHT	APPARENT WEAR TIME
12/27/01	8:38PM	6:40AM	10:02	3:22		3:22
12/28/01	11:12PM	9:20AM	10:08	0:48	6:40	7:28
12/29/01	1:20AM	11:30AM	10:10		9:20	9:20
12/30/01	8:40PM	6:50AM	10:10	3:20	10:10	13:30
12/31/01	2:27AM	12:30PM	10:03		6:50	6:50
01/01/02	8:25PM	6:30AM	10:05	3:35	10:03	13:38
01/02/02	8:30PM	6:30AM	10:00	3:30	6:30	10:00
01/03/02	8:46PM	6:50AM	10:04	3:14	6:30	9:44
01/04/02	10:30PM	9:00AM	10:30	1:30	6:50	8:20
01/05/02	8:51PM	9:00AM	12:09	3:09	9:00	12:09
01/06/02	8:00PM	6:30AM	10:30	4:00	9:00	13:00
01/07/02	7:20PM	6:45AM	11:25	4:40	6:30	11:10
01/08/02	9:10PM	7:15AM	10:05	2:50	6:45	9:35
01/09/02	7:10PM	6:10AM	11:00	4:50	7:15	12:05
01/10/02	9:15PM	7:15AM	10:00	2:45	6:10	8:55
01/11/02	9:05PM	11:30AM	14:25	2:55	7:15	10:10
01/12/02	10:16PM	9:17AM	11:01	1:44	11:30	13:14
01/13/02	8:21PM	6:23AM	10:02	3:39	9:17	12:56
01/14/02	7:53PM	6:23AM	10:30	4:07	6:23	10:30
01/15/02	9:24PM	7:30AM	10:06	2:36	6:23	8:59
01/16/02	9:07PM	7:17AM	10:10	2:53	7:30	10:23
01/17/02	7:35PM	6:05AM	10:30	4:25	7:17	11:42
01/18/02	10:30PM	8:50AM	10:20	1:30	6:05	7:35

FIG. 1. Chart demonstrating problem with wear-time recording (total wear-time versus apparent wear-time) of Brava system.

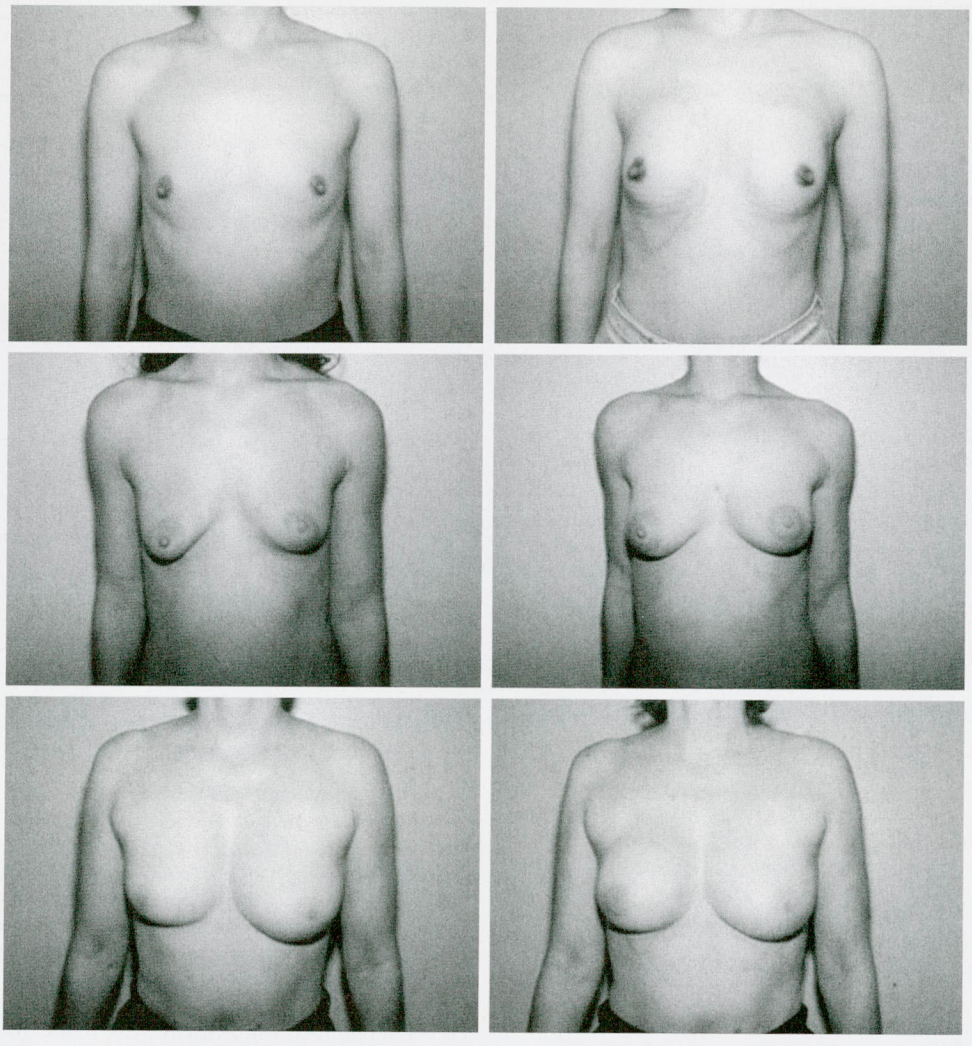

FIG. 2. Pretreatment (*above, left*) and posttreatment (*above, right*) photographs of Asian patient with little pretreatment breast tissue. (*Center, left* and *right*) Patient with significant pretreatment ptosis who thought she gained a full cup size and improved contour. (*Below, left* and *right*) Patient with asymmetry who underwent treatment to only the smaller right breast. All of these patients were very pleased with their results.

mination was based on the simple, age-old single question test, "Would you recommend the Brava system to a friend?" The individuals in their group were "participants," whereas mine were patients. It is safe to predict that in the future I shall still not find patients who have paid approximately $2000 for the Brava system telling me that they are "very pleased" after achieving only a 15 percent increase in breast volume.

It has also become readily apparent from my experience, and the experience shared with me by others, that the recommended minimal wear-time of 10 hours a day for 10 weeks is insufficient for most women, with the actual wear-time requirement closer to 12 to 14 hours a day and, possibly, 12 to 14 weeks.

The concept of enlarging the breasts using a vacuum device is not new,[2] but the technologic innovation called the SmartBox, which maintains the constant vacuum and by means of a computer chip records the patient wear-time and average pressure, is an ingenious concept. The patient downloads the data weekly by modem into the Brava central computer where it can then be accessed using an individual code by the patient, physician, and company. The objective is to confirm patient compliance (or noncompliance) with less than 9 hours of continuous wear-time constituting a missed day, which requires an additional week of wear-time. Unfortunately, the monitoring system does not work as intended because the device divides continuous wear-time into 2 separate days at midnight. One might think that it would all even out, and it would were the device to be worn at the same time each day, but that is impractical. One patient's husband cleverly charted the actual daily wear-time and the total hours divided into each 24-hour period, which clearly demonstrated why that when his wife wore it the required minimum of 10 hours every day, the Brava computer would frequently and erroneously identify her as noncompliant (Fig. 1). This would seem to be a correctable glitch.

There were also issues of product reliability and performance and customer service. Although there have been frequent breakdowns of the device components, I have been very impressed with the company's ready willingness to promptly provide replacement parts for our patients and by

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