# The Brava External Tissue Expander: Is Breast Enlargement without Surgery a Reality?

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Background: Controlled trials have shown that an external breast tissue expander (Brava; Brava LLC Miami, Fla.) can effectively enlarge the breast without surgery. However, satisfaction with the results has varied among doctors and patients. The first author critically evaluated her clinical experience with Brava and attempted to identify factors associated with a successful outcome.

Methods: Between May of 2003 and September of 2005, the first author supervised the treatment of 50 women. Volume measurements and standardized photographs of the breasts were obtained at the beginning of treatment and up to 12 months after treatment ended. At the final visit, women completed a satisfaction questionnaire.

Results: Forty women were evaluated at an average of 10 months after discontinuation of treatment (range, 7 to 20 months). Reasons for drop-out were noncompliance with the treatment (n = 6), unwillingness to attend follow-up visits (n = 3), and more than 5 percent body weight change (n = 1). The women used Brava 11 hours a day for a median period of 18.5 weeks (range, 14 to 52 weeks). The median volume increase was 155 cc (range, 95 to 300 cc). Thirty women (75 percent) were satisfied or very satisfied with the results, five (12.5 percent) acknowledged enlargement of their breasts but considered the treatment too bothersome, and five (12.5 percent) were disappointed because of little growth. Factors associated with poor growth included lesser intensity of wear (p < 0.002) and low body mass index (p = 0.055).

Conclusions: Long-term breast enlargement without surgery is possible with an external tissue expander. The more it is used, the more the breasts grow. To avoid disappointments and drop-outs, women have to be well informed about the time and lifestyle commitment. (*Plast. Reconstr. Surg.* 120: 1680, 2007.)

n 1999, an external breast tissue expander was introduced as a nonsurgical alternative to breast augmentation when used consistently for 10 hours a day for a minimum of 10 weeks.<sup>1</sup> The Brava device (Brava LLC, Miami, Fla.) consists of two semirigid polyurethane domes that are placed around the breasts and that interface with the skin through silicone gel-filled donut bladders. These bladder rims serve to maintain an airtight seal and to dissipate pressure and shear

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forces. A small, battery-operated, microchipcontrolled minipump maintains 20 mm/Hg of negative pressure inside the domes. This vacuum effectively exerts an isotropic distractive force to the breast. The entire system is contained within fabric and worn like a brassiere (Fig. 1).

Since 1999, several reports have confirmed that the distractive force exerted on the breasts by the device can stimulate tissue growth and thereby effectively enlarge the breasts.<sup>2-5</sup> However, in the clinical experience, not all patients achieved the promised one-cup enlargement, and satisfaction with the results varied among doctors and patients.<sup>2,4</sup> This study was undertaken to critically evaluate the clinical experience of a single plastic surgeon and to identify factors associated with a successful outcome.

# PATIENTS AND METHODS

From May of 2003 to September of 2005, the first author treated 50 women seeking breast enlargement without surgery using the Brava device.





Fig. 1. Woman wearing the Brava system. Reprinted with permission from Brava LLC (Miami, Fla.).

Informed consent was obtained, and the need for consistent wear and a minimum wear time of 10 hours a day for a minimum of 10 weeks was explained to the women. The women were also informed that average breast growth in other studies had been 100 cc. All of the women stated that they would rather have little growth than undergo surgery for breast implants. Standardized photographs, a breast examination, measurements of chest circumference at the height of the nipple and the inframammary fold, and volume measurements of the breasts with the Grossman-Roudner device were obtained at the beginning of treatment, after 6 weeks of use, and periodically up to 14 months after the end of the treatment. Body weight was measured at the beginning of treatment and throughout the follow-up period. All women under the age of 35 years had a pretreatment sonogram of their breasts. All women older than 35 years had a breast mammogram taken before starting. All women had a negative family history of breast cancer.

At the final visit, women completed a questionnaire to judge their results, any side effects, and their satisfaction with treatment (Table 1). The questions were rated using a five-point scale, ranging from "not at all" to "very much." Wear time was based on the patient's recollection and was not always corroborated by an objective measurement.

Women were excluded from the study if they wore the Brava device for less than 8 hours a day, if their total wear time was less than 10 weeks, if they did not come for the minimum follow-up visits required (6 to 10 weeks after the beginning of the treatment, 4 weeks after the end of the treatment, and 6 to 20 months after the end of the

treatment), or if their body weight changed more than 5 percent.

Univariate and multiple linear regression techniques were used to analyze the potential influences on breast volume increase of several factors, such as body mass index, children (yes versus no), initial breast volume, and intensity of wear (total usage of the breast tissue expander, measured in hours). In all statistical analyses, both breast volume and breast volume increase were considered using the mean of the right and left breasts. Due to their skewed distribution, log-transformed values were used for the variables intensity of wear and breast volume increase.

## RESULTS

Of the 50 women enrolled, 40 (ages 17 to 53 years) could be evaluated. Ten dropped out for the following reasons: loss of interest and non-compliance with the treatment protocol (n = 6), unwillingness to come for the minimum follow-up visits required (n = 3), and more than 5 percent

## **Table 1. Patient Questionnaire\***

Are you satisfied with the result?
Was the effort worth the result?
How much do you estimate that your breasts grew?
How much did you increase in terms of bra size?
Grade any improvements (volume, lift, asymmetry).
Grade any side effects (sweating, itching, skin rashes, pain).
How much did Brava restrict your social life?
How uncomfortable was Brava to wear?
Do you feel any change in your self-esteem?
Would you recommend Brava to a friend?

<sup>\*</sup>Rating according to a five-point scale, with 1 = not at all, 2 = a little, 3 = moderate, 4 = good, and 5 = excellent/significant.

bodyweight weight change (n = 1). As patient selection improved, only one of the last 10 patients dropped out, compared with nine of the first 40 patients (25 percent).

Seventy-two percent of the women who used Brava had completed high school or acquired a university degree. Fifty percent had children and stated that they had suffered moderate to large breast volume loss after pregnancy and breast feeding. Patients' characteristics are summarized in Table 2.

The women used the Brava device on average for 11 hours a day for a median period of 18.5 weeks (range, 14 to 52 weeks). Posttreatment follow-up averaged 10 months (range, 7 to 20 months). The median volume increase measured with the Grossman-Roudner device was 155 cc (range, 95 to 300 cc). Chest circumference at the

height of the nipple increased by a median of 4.4 cm (range, 1 to 11 cm). Measurements taken 4 weeks after the end of the treatment remained constant until the latest follow-up (Fig. 2 and Table 3). Breast growth from Brava use appears different from that with implant enlargement. It is more subtle and involves the entire breast. The visible enlargement and the increase in nipple circumference depended on the shape and diameter of the breast and, therefore, sometimes did not completely correlate with the volume increase measured with the Grossman-Roudner device (Table 3 and Figs. 3 through 7).

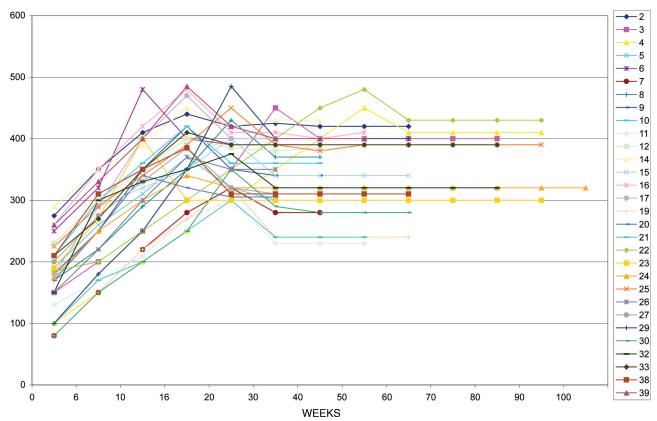
All women admitted that the treatment was painless. The side effects included sweating, itching, and skin irritation (Table 4). With the exception of two women, sweating and itching were limited to the

**Table 2. Patient Characteristics** 

Patient	Age	BMI	Marital Status	Education	Children/BF	Volume Change after BF*	Sport (hr/wk)
1	34	21.5	Life partner	Middle school	0		3
2	37	20	Married	High school	2	3	3
3	43	20.8	Married	Middle school	2	3	0
4	28	18	Single	University	0		4
5	42	19.5	Married	Middle school	2	3	2
6	40	18.5	Divorced	Middle school	2 2		2 3 3 4
7	32	18.7	Married	Middle school	2	3	3
8	27	18.5	Single	High school	0		
9	39	19	Married	High school	2	3	4
10	21	19.2	Single	University	0		
11	26	17.7	Single	High school	0		5
12	42	18	Single	University	0		4 5 5 2 7
13	42	22	Married	Middle school	2	2	2
14	20	21.2	Single	High school	0		7
15	37	21.5	Married	Middle school	2	2	12
16	37	18	Life partner	University	0		3
17	24	23.5	Life partner	University	0		0
18	53	22.5	Married	High school	2	1	2
19	42	22.2	Single	University	1	1	4
20	42	20.8	Married	University	2	3	2
21	34	17.7	Single	High school	0		3
22	33	19	Single	High school	0		3
23	41	19.5	Married	University	1	2	2
24	31	20	Single	Middle school	1	2 3	3
25	41	21	Married	High school	1	2	3
26	36	19.1	Divorced	Middle school	0		2 4 2 3 3 2 3 7 5
27	30	19.5	Single	University	0		5
28	21	17.5	Single	University	0		4
29	42	18.5	Married	High school	3	3	0
30	17	19.8	Single	University	0		10
31	25	17.5	Single	High school	0		7
32	44	21.8	Married	High school	3	2	2
33	50	21	Single	University	0		2 3 5
34	43	21.2	Divorced	High school	3	3	5
35	29	17.2	Married	Middle school	4	3	3
36	36	18.1	Married	High school	1	3	4
37	24	18	Single	University	0	-	4 5
38	31	21.5	Married	Middle school	3	3	4
39	39	21.5	Married	High school	2	ĭ	3
40	20	15.5	Single	University	$\bar{0}$	_	3 5
Mean	$\frac{20}{34.4}$	19.7	8C	- 1111 01010)	v		3.8

BMI, body mass index; BF, breast feeding.

<sup>\*</sup>Volume change after breast feeding: 1 = little, 2 = moderate, 3 = substantial.



**Fig. 2.** Breast volume change of the women with regular follow-up visits during Brava treatment; measurements were taken with the Grossman-Roudner device. Women who came only for the minimum follow-up visits are not included.

summer months when the women used the Brava device in nonacclimatized rooms. Skin rashes were the most common problem; they occurred either within the first week, when women with sensitive skin used the expander for more than 10 hours, or after 6 to 8 weeks, when the silicone rim was worn out or colonized with bacteria due to improper cleaning. Ten women developed rashes when they used the roll-on (part of the first-generation skin care by Brava LLC). With the second-generation skin care and the development of a special dome cleanser, the skin rash problem was essentially resolved.

Thirty women (75 percent) were satisfied or very satisfied with the results (Figs. 3 through 6). They felt that their breasts were fuller and firmer and that they filled up or even outgrew their brassieres. Five women (12.5 percent) acknowledged enlargement of their breasts but considered the treatment too bothersome for the result. Two of these women acknowledged the sizeable enlargement only after being confronted with their before-and-after photographs (Fig. 7). Five women (12.5 percent) were disappointed because of little growth. So far, two of the latter group have proceeded to surgical augmentation.

Factors associated with poor growth included lesser intensity of wear and low body mass index. (Although this was not tested by statistical methods due to the small sample numbers, it was striking that women with a body mass index <18 had the least increase in volume.) The effect of total wear time on breast growth was statistically significant in adjusted (p = 0.02) and unadjusted models (p = 0.005), while the influence of body mass index was borderline significant in the adjusted model (p = 0.055) (Table 5).

Twenty women (50 percent) reported an improvement in their self-esteem. Although most women stated that the Brava device was not comfortable to wear and that their social life was quite restricted during the treatment period, 85.5 percent would recommend it to a friend.

# **DISCUSSION**

Tissue expansion has well-established applications in plastic and orthopedic surgery and is the only clinically applicable method of tissue generation in adults.<sup>6-9</sup> The mechanisms by which sustained gentle mechanical tension induces tissue growth have recently been reviewed.<sup>10-12</sup> Nonsur-

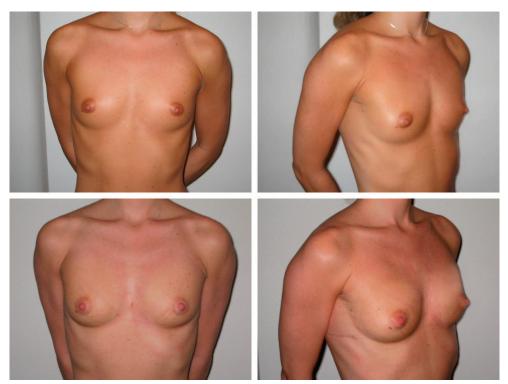
Table 3. Breast Growth and Brava Wear Time

		GRD Difference				
Patient	Nipple Difference (cm)	Right Breast	Left Breast	Weeks Brava Worn	Hours Worn per Day	Follow-Up (days)
1	4.5	150	150	16	11	300
9	6	150	150	14	11.5	420
2 3	8.5	250	240	30	12	420
4	7	300	300	52	12	390
5	3	110	110	18	12	270
6	3	140	140	10	10	$\frac{240}{240}$
7	3	200	200	19	10	$\frac{270}{270}$
8	3.5	200	200	20	12	210
9	3.5	160	160	16	11	210
10	3.3	150	150	16	10	300
11	1	100	100	20	11	240
12	5	180	0	22	10	300
13	2.5	140	140	14	10	270
14	3	0	165	14	12	240
15	3.5	160	160	22	11.5	270
16	3.3	150	150	16	13	330
17	8	215	220	17	11	270
18	o 4	160	160	20	10	270 270
19	2.5	160	160	20 24	10	270 270
20	2.5					
	6.5	135	135	14	9	360
21	4	120	120	22	10	240
22	8	145	145	52	8	270
23	$\frac{4}{7}$	95	125	10	10	360
24	7	160	155	15	11	600
25	4.5	165	160	24	12.5	270
26	6	235	235	14	10	300
27	4.5	110	110	19.5	13	300
28	2	140	140	20	12	240
29	$\overline{5}.5$	300	300	25	20	360
30	8 3	300	300	20	12	300
31	3	120	120	24	11.33	210
32	5.5	170	170	24	11	360
33	4	180	190	14	10	540
34	5	150	150	12	14	300
35	4	150	150	18	12	270
36	3	150	150	12	12	330
37	3.5	155	145	20	10	240
38	4	150	150	22	11	240
39	2.5	150	150	16	12.84	270
40	2.5	120	120	16	11	300
Mean	4.4	162	162	20	11	304
SD	1.9	56.8	55.9	8.7	1.9	81.6

gical breast enlargement with the Brava external soft-tissue expander device is the latest development based on this principle. Several controlled studies have proven that it is effective. <sup>1–5</sup> It is a good alternative for women looking for one-cup enlargement of their breasts and who do not wish to undergo the risks of surgery and implants. There are several factors, however, that make it difficult for the patient and the doctor to achieve the desired results. <sup>13</sup>

First, as an external tissue expander, the Brava device is compliance-dependent and only works well for women who are willing to put up with the rigorous wear schedule. Ten hours per day is the minimum amount of time required, and patients

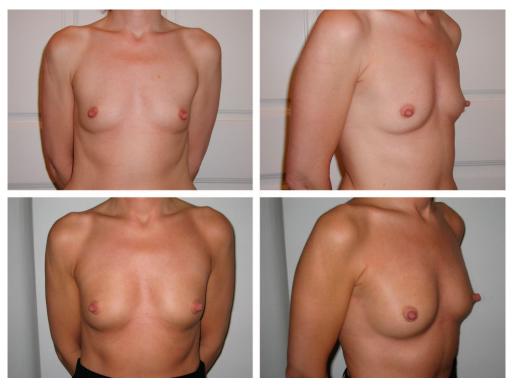
who are able to wear it longer show statistically significantly better growth. For some women, this does not seem to be a problem; they almost get addicted and work or study while wearing the device. The majority of women, however, have to restrict their social life, spending their evenings at home to manage 10 hours of wear per day. Since they have to do that for several months, it is understandable that some women lose interest or do not manage to wear the device for enough hours. Unfortunately, it is very difficult to foresee which patient will be compliant. Dependence on compliance to achieve results is unfamiliar to plastic surgeons, who are used to immediate postoperative gratification. The first author realized that the more



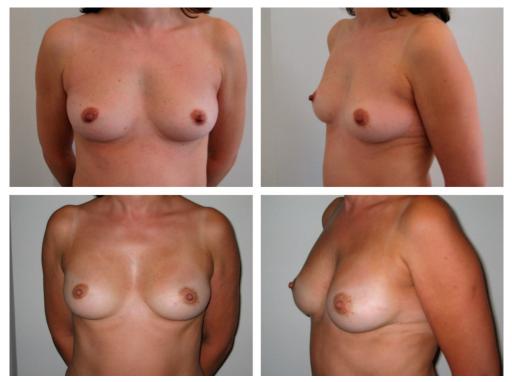
**Fig. 3.** An 18-year-old patient with no children at baseline (*above*) and at 13-month follow-up after 1 year of treatment and 200 cc of growth (*below*). Her breasts became fuller in the lower and upper quadrants. The relationship of the nipple level to the inframammary fold did not change.



**Fig. 4.** A 37-year-old patient with two children at baseline (*above*) and at 14-month follow-up after 14 weeks of treatment and 150 cc of growth (*below*). Her breasts are pseudoptotic before and after Brava treatment. The relationship of the nipple level to the inframammary fold did not change because of the treatment.



**Fig. 5.** A 44-year-old patient with three children at baseline (*above*) and at 12-month follow-up after 24 weeks of treatment and 170 cc of growth (*below*). Breasts became fuller in the lower and upper quadrants. The relationship of the nipple level to the inframammary fold did not change.



**Fig. 6.** A 39-year-old patient with two children at baseline (*above*) and at 9-month follow-up after 16 weeks of treatment and 150 cc of growth (*below*). Her breasts outgrew the biggest Grossman-Roudner device (425 cc) due to Brava treatment; therefore, her growth was more than what we could measure.



**Fig. 7.** A 39-year-old patient with two children at baseline (*above*) and at 7-month follow-up after 16 weeks of treatment and 160 cc of growth (*below*). The patient acknowledged enlargement only after being confronted with her before and after photographs.

Table 4. Side Effects\*

	None	Little	Moderate	Often	Significant	Total
Sweating	14	10	12	2	2	40
Itching	16	6	8	4	6	40
Skin rashes	6	10	10	7	7	40
Pain	40	0	0	0	0	40

<sup>\*</sup>According to patient questionnaires, n = 40.

Table 5. Results of Univariate and Multiple Linear Regression Models Analyzing Breast Volume Increase (Log Transformed)

	Parameter	95% Confidence	
Variable	Estimate $(\beta)$	Interval	þ
Univariate regression models			_
BMI	0.024	-0.024 to $0.073$	0.320
Children (yes vs. no)	-0.025	-0.198 to $0.148$	0.769
Initial breast volume	-0.0009	-0.0023 to $0.0004$	0.172
Intensity of wear, total	0.306	0.097 to 0.516	0.005**
usage in hours (log-			
transformed)			
Multiple regression model			
BMI	0.052	-0.001 to $0.105$	0.055*
Children (yes vs. no)	-0.037	-0.204 to $0.130$	0.657
Initial breast volume	-0.001	-0.003 to $0.0005$	0.180
Intensity of wear, total	0.267	0.044 to 0.490	0.020**
usage in hours (log-			
transformed)			

BMI, body mass index.

<sup>\*</sup>Borderline statistically significant.

<sup>\*\*</sup>Highly statistically significant.

patients she supervised, the more rigorous she became in telling them what they had to endure during the treatment, which changed the drop-out rate from 25 percent for the first 40 patients to 10 percent for the last 10 patients. A 10 percent rate of noncompliance is actually very low compared with studies evaluating adherence to medication (range, 22 to 67 percent noncompliance), 14,15 especially if one considers how much women have to do when they use Brava; other patients just have to swallow pills. To avoid disappointment, all women have to be very well informed about the wear protocol, and they have to consider whether they can manage to comply with it. For most women, this means a restricted social life during the treatment period.

Second, it was difficult to keep the women motivated while they perceived that their breasts were not growing. Within 6 weeks, every woman had forgotten how small her breasts were originally. They kept comparing their deflated breasts in the evening to their swollen, edematous breasts in the morning after removing the domes. Tissue growth takes place very slowly, at about 1 to 1.5 ml per day of sustained use, 1,15 and is not comparable with the amount of swelling observed during the first weeks. Even after 10 weeks, 50 percent of the volume increase is due to swelling.<sup>1,3</sup> Therefore, it is important to have the women view their pretreatment photographs, to show them their progress and to keep them motivated. Some Brava women need a lot of attention.

Third, it is a problem to satisfy a woman with only 160 cc of growth after she has seen what her breasts look like with a 300-cc increase due to the swelling and she likes that better. Although all women were informed, before starting, that breast enlargement with Brava is not comparable to that with an implant, and they all stated that they would be happy with just a little more volume, they always wanted more once they had seen what their breasts could look like. For the women with very small breasts and a body mass index less than 18. 100 to 150 ml of growth from Brava was still not enough to fill a B-cup and did not satisfy them. Although they were adverse to surgery at the beginning, two of these women ended up opting for surgical augmentation. The first author believes that they still had a benefit from the Brava treatment, since there was more breast tissue to cover the implants, making the augmented breasts look more natural. From my experience, if the body mass index is less than 18, it is unlikely that women with AA breasts will grow to fit a B-cup, despite prolonged Brava wear. It is difficult to generate substantial amounts of tissue when the initial mass is so limited





**Fig. 8.** A 39-year-old woman with two children at baseline (*above*) and at 9-month follow-up after 16 weeks of treatment and 150 cc of growth (*below*).

and when the overall metabolic balance is not permissive.

Another problem that made women complain was the fact that they were led to believe by advertisements that they could grow one cup within 10 weeks. In the first author's experience, it takes 16 to 20 weeks and then depends on the shape and size of the brassiere the woman wears. Almost all women with small breasts in the first author's office wear brassieres that are too big for them to make their breasts look bigger under clothes. After the treatment, they complained that they still wear the same brassieres, not considering that they now fit them. If before-and-after photographs are taken with the subject wearing the same brassiere, this can easily be demonstrated (Fig. 8).

Side effects such as sweating, itching, and skin irritation were bothersome, but they were not enough to make any of the women discontinue wearing the Brava system. Good skin care and

effective cleaning of the domes can prevent many problems. Women with sensitive skin should only gradually increase their wear time to allow their skin to adapt to the pressure.

Sleeping with the system was only uncomfortable during the first week. After that time, most women became used to it. Six women could not sleep with it; four of them stopped wearing it and two stated that they would not have bought it if they had known how bothersome it was.

These difficulties and complaints must not make one overlook the fact that in the end 75 percent of the women were satisfied or very satisfied with the result and 85 percent would recommend it to a friend. In comparison to patients looking for breast implants, 16 the women interested in Brava tended to have reached higher levels of education and were much more aware and concerned about their bodies. They played sports on a regular basis and stated that they are healthy foods (Table 2). Most of them had been unhappy with the size of their breasts for many years but would never consider implants because of their knowledge and fear of possible side effects. All the women who had children and had lost volume after breast-feeding stated that they just wanted to regain what they had before pregnancy; the others also initially stated that they would rather have less growth than an implant in their healthy breasts. The women were followed for up to 20 months after the end of the treatment and they had kept the volume growth observed at 1 month. Figure 2 shows that after the initial volume loss within the first 3 weeks after the end of the treatment, the volume remained constant. This confirms what Baker et al. found, that the remaining volume is real tissue growth and long-lasting.<sup>5</sup>

# **SUMMARY**

The Brava system is a good solution for a woman looking for a one-cup enlargement without changing the shape of her breasts and who does not wish to undergo the risks of surgery and implants. To avoid disappointments and dropouts, patients have to be closely screened with respect to their motivations and expectations, as well as informed about the rigorous wear schedule and the time realistically necessary to achieve a one-cup enlargement. They should also be made aware that their social life will be restricted during the treatment period. Women with a body mass index less than 18 and very small breasts should not be considered Brava candidates. Brava will not

replace implants, but it will bring women to the physician's office who otherwise would have not considered visiting a plastic surgeon.

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### **DISCLOSURE**

The authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence their work.

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