

# Patient-Reported Benefit and Satisfaction with Botulinum Toxin Type A Treatment of Moderate to Severe Glabellar Rhytides: Results from a Prospective Open-Label Study

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**Background:** Patient satisfaction is a key measure of success when using botulinum toxin type A to treat glabellar rhytides. However, lack of a standardized method of assessing satisfaction has limited its evaluation.

**Methods:** In this open-label study, 58 women with moderate or severe glabellar rhytides at maximum frown were treated with 20 units of botulinum toxin type A (divided injections in corrugator and procerus muscles). Patients' self-perceptions were assessed at baseline and the following were assessed at days 30 and 120: investigator- and patient-rated global assessment of change in glabellar line severity, patient self-perception of age, and patient satisfaction with the effects of treatment and the procedure itself (using the Facial Lines Treatment Satisfaction Questionnaire).

**Results:** Overall, patients had a positive self-image at baseline. At day 30, the investigator reported that all patients had 50 percent or greater improvement in glabellar line severity. At days 30 and 120, 95 percent and 86 percent of patients, respectively, reported satisfaction with treatment overall and 82 percent or more reported satisfaction with various aspects of the effects of treatment (time to onset of action, improvement in facial lines and appearance, and appearing better and relaxed) and the procedure itself (absence of downtime and side effects). More than one-third of patients considered that they looked younger than they did before treatment (by a median of 5 years at both time points).

**Conclusions:** Botulinum toxin type A treatment of glabellar rhytides resulted in high levels of patient satisfaction, and more than one-third of patients thought they appeared younger than they did before treatment. (*Plast. Reconstr. Surg.* 120: 1386, 2007.)

Facial rhytides are often unwelcome either because they are a sign of aging or because they can be misinterpreted and mistakenly perceived to signify stress, anxiety, annoyance, disapproval, or anger.<sup>1,2</sup> The presence of facial rhytides can have a negative impact on patients' perception of themselves and also on other

people's impressions of them and, as a result, they may seek treatment to achieve a more youthful appearance, to help them appear their best, to help prevent miscues of facial communication, or simply to feel better about their appearance.<sup>2,3</sup>

The use of botulinum toxin type A for the treatment of glabellar lines was approved by the U.S. Food and Drug Administration in 2002.<sup>4</sup> The durable efficacy and good safety profile of botulinum toxin type A therapy are well established in the literature.<sup>4-6</sup> Nevertheless, in the field of facial aesthetic therapy, a key measure of the success of treatment is actually patient satisfaction—as one goal of any cosmetic treatment is not to eliminate imperfections but to increase the patient's happiness.<sup>2</sup> Although the level of

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clinical improvement remains an important outcome measure, particularly in research studies, ultimately it is the patient's impression of the treatment that is of most importance to them and a key determinant of whether the effects of treatment translate into benefits in their well-being. Furthermore, patient satisfaction is particularly important for therapies such as botulinum toxin type A that require repeated treatments for the maintenance of efficacy.

Although patient satisfaction associated with botulinum toxin type A therapy has not been evaluated as extensively as efficacy and safety, reports do indicate that levels of satisfaction are high.<sup>7,8</sup> However, the assessment of patient satisfaction has not been standardized. In previous reports, satisfaction was assessed using either a simple nonstandardized questionnaire<sup>7</sup> or an instrument designed for a general cosmetic dermatology setting<sup>8</sup> and not specifically for facial rhytides.

Patient satisfaction is multidimensional and a difficult concept to define and assess accurately and reliably. It can be influenced by many factors, including efficacy, perceptions of efficacy (the patient's and other people's), durability of efficacy, tolerability, safety, convenience, and cost, with the relative importance of each of these differing between patients. Given the importance of patient satisfaction in the field of facial aesthetic enhancement, the challenge of standardizing its assessment needs to be addressed. Because of the many subjective factors that may be involved, it should ideally be an assessment made by the patient.

The Facial Lines Treatment Satisfaction Questionnaire was developed to evaluate patient satisfaction specifically in patients receiving minimally invasive treatment for hyperfunctional facial rhytides.<sup>9,10</sup> In the case of botulinum toxin type A therapy, patient satisfaction can be influenced both by the effects of treatment and by the patient's impression of the procedure itself, and this questionnaire takes account of both of these. The questionnaire evaluates 14 parameters that have been found to be important in influencing patient satisfaction—11 that can influence satisfaction with the effects of treatment and three that can influence satisfaction with the procedure. The relative importance of the parameters varies between individual patients.

We report here the results from the first prospective study to use this instrument to evaluate patient satisfaction with botulinum toxin type A treatment for glabellar rhytides. In addition to

assessing patient satisfaction prospectively, this study also assessed patients' perceptions of their age after treatment, which has not to our knowledge been reported in the literature previously.

## PATIENTS AND METHODS

Patients were eligible for enrollment into the study if they were female and between 35 and 60 years of age, with glabellar rhytides of at least moderate severity at maximum frown (glabellar line severity was graded as none, mild, moderate, or severe using a photonumeric guide). Patients were recruited through advertisements in local newspapers.

### Exclusion Criteria

Patients were excluded from the study if they had previously been treated with botulinum toxin type A; had received facial rejuvenation treatment or undergone facial aesthetic surgery in the preceding year or were planning such treatment during the study period; had a significant facial movement disorder; had preexisting brow or eyelid ptosis; had a history of cerebrovascular accident, head injury, or other cerebral damage affecting the recognition or expression of emotion; had any psychiatric illness that might interfere with the ability to produce facial expressions or experience emotion normally; had any disorder or were using any agent that might interfere with neuromuscular function; or were pregnant, breastfeeding, or of childbearing potential and not using reliable contraception.

### Treatment Regimen

A total dose of 20 units of botulinum toxin type A (Botox Cosmetic; Allergan, Inc., Irvine, Calif.) was injected (five injections of 4 units, two in each corrugator muscle and one in the procerus muscle) using a 30-gauge needle.<sup>4</sup> Reconstitution of botulinum toxin type A (4 units/0.1 ml) was performed immediately before injection using non-preserved injectable saline. All injections were administered by a single investigator. The study was approved by the institutional review board for the Dartmouth-Hitchcock Medical Center, and all patients were required to sign informed consent.

### Baseline Assessments

#### Glabellar Line Severity

The investigator used a photonumeric guide to grade the severity of the patient's glabellar lines at baseline (as none, mild, moderate, or severe), both at rest and at maximum frown.

### Patients' Self-Perceptions

Patients were asked to rate their level of agreement with nine possible self-perceptions related to either self-confidence (confidence in their own attractiveness, feeling good, appearing their best, and appearing young) or other self-perceptions (self-consciousness, attractiveness, appearing tired, appearing stressed, and worrying about facial lines) on a seven-point scale (where 1 = strongly disagree, 2 = disagree, 3 = slightly disagree, 4 = neutral, 5 = slightly agree, 6 = agree, and 7 = strongly agree).

### Efficacy Outcome Measures

#### Global Assessment of Change in Glabellar Line Severity

At days 30 and 120, the investigator and patients reported their global assessment of change in glabellar line severity on a nine-point scale [where +4 = 100 percent better (complete improvement), +3 = 75 percent better, +2 = 50 percent better, +1 = 25 percent better, 0 = unchanged, -1 = 25 percent worse, -2 = 50 percent worse, -3 = 75 percent worse, and -4 = 100 percent worse]. The investigator considered the change in glabellar line severity at both rest and maximum frown when determining the global level of improvement and used preinjection baseline photography (at both rest and maximum frown) to assist in the evaluation.

#### Patients' Self-Perception of Age

At days 30 and 120, patients were asked to report whether they thought they appeared younger, the same age, or older compared with before treatment. If they thought they appeared younger or older, they were asked to report how many years younger or older they thought they appeared compared with before treatment.

#### Patient Satisfaction

At days 30 and 120, patients were asked to rate their satisfaction using the validated and reliable Facial Lines Treatment Satisfaction Questionnaire, a 14-item measure in which patients rate their satisfaction on a seven-point scale (where 1 = very dissatisfied, 2 = dissatisfied, 3 = somewhat dissatisfied, 4 = neutral, 5 = somewhat satisfied, 6 = satisfied, and 7 = very satisfied).<sup>9,10</sup> The Facial Lines Treatment Satisfaction Questionnaire consists of a Satisfaction with Effects of Treatment domain (11 items) and a Satisfaction with the Experience of the Procedure domain (three items). The domain scores are calculated by taking the mean of all item scores in that domain. Patients with a mean score of at least 5 were considered to have achieved satisfaction in

that domain. For each patient, the total score and the score for each of the domains were recorded.

### Statistical Analyses

Patients' demographic characteristics, glabellar line severity assessments, and self-perceptions were summarized as mean values or the percentage of patients in each category. The degree of correlation between the investigator and patient ratings of the global assessment of change in glabellar line severity was evaluated by calculating the Spearman correlation coefficient together with the 95 percent upper and lower confidence limits. For the Facial Lines Treatment Satisfaction Questionnaire data, the means of all patients' total scores and domain scores were calculated to give the overall total and domain scores, respectively, and their associated standard deviations for the study population.

## RESULTS

### Patients

A total of 58 women received treatment and 56 (97 percent) completed the study. Two discontinued because of adverse events considered possibly related to treatment (headache, pulling sensation in eye, and aching pressure across forehead). Overall, the patients had a positive perception of themselves (95 percent agreed with the statement "I feel good about myself") and had confidence in their appearance (64 percent agreed with the statement "I feel confident others find me attractive") (Table 1). However, the majority also reported that their facial lines made them appear stressed (69 percent) or tired (69 percent) or made them feel less attractive than when younger (67 percent) (Table 1). In addition, 50 percent were self-conscious about their facial lines and 45 percent worried that others noticed their facial lines. Two-thirds of the patients (66 percent) did not agree with the statement "I look as young on the outside as I feel on the inside," suggesting a difference in how young they feel relative to how old they perceive themselves to appear when looking in the mirror.

### Efficacy

#### Global Assessment of Change in Glabellar Line Severity: Investigator Assessment

At day 30, the investigator considered 100 percent of patients to have achieved greater than or equal to 50 percent improvement from baseline,

**Table 1. Patient Details and Self-Perceptions at Baseline**

	Value (%)
<b>Demographics</b>	
No. of patients (all female)	58
<b>Age, years</b>	
Mean	49
Range	38–59
<b>Ethnicity, no. of patients (%)</b>	
Caucasian	57/58 (98)
Hispanic	1/58 (2)
<b>Investigator rating of glabellar line severity</b>	
<b>At rest</b>	
Mild	6/58 (10)
Moderate	37/58 (64)
Severe	15/58 (26)
<b>At maximum frown</b>	
Moderate	25/58 (43)
Severe	33/58 (57)
<b>Patient self-perceptions (based on your appearance over the past week, how much do you agree or disagree with each statement below?)*</b>	
“I feel good about myself.”	55/58 (95)
“I look tired because of my facial lines.”	40/58 (69)
“I look stressed because of my facial lines.”	40/58 (69)
“I feel less attractive than I did when I was younger because of my facial lines.”	39/58 (67)
“I feel confident others find me to be attractive.”	37/58 (64)
“I look the best I can.”	37/58 (64)
“I am self-conscious about my facial lines.”	29/58 (50)
“I worry other people notice my facial lines.”	26/58 (45)
“I look as young on the outside as I feel on the inside.”	20/58 (34)

\*Data are expressed as number of patients (with percentage in parentheses) who slightly agree, agree, or strongly agree.

with 66 percent of patients still showing greater than or equal to 50 percent improvement at day 120 (Fig. 1).

**Global Assessment of Change in Glabellar Line Severity: Patient Assessment**

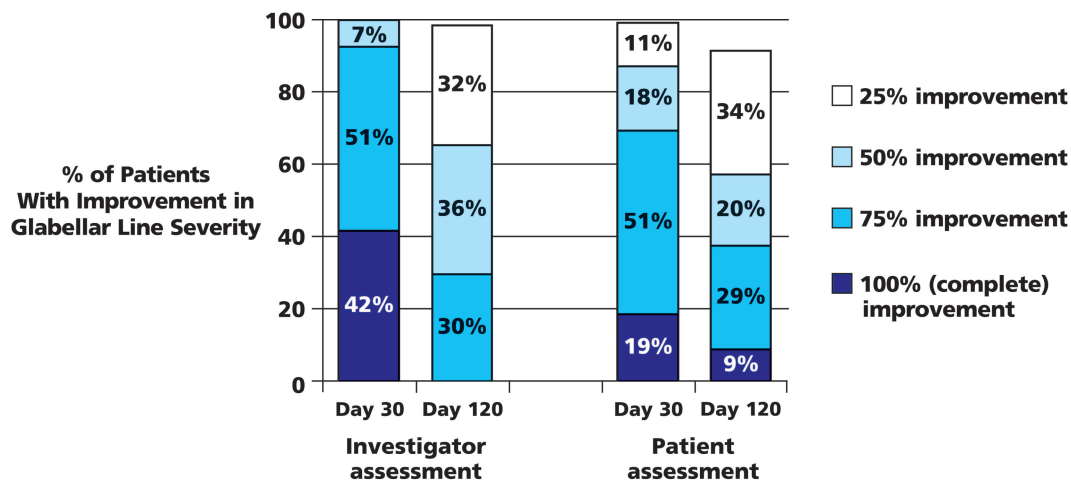
At day 30, 88 percent of patients considered they had greater than or equal to 50 percent improvement from baseline, with 57 percent considering they still had greater than or equal to 50 percent improvement at day 120 (Fig. 1). The investigator and patient ratings of change in glabellar line severity were moderately correlated with each other—the Spearman correlation coefficient was 0.34 at day 30 (95 percent confidence interval, 0.11 to 0.57; *p* = 0.009) and 0.53 at day 120 (95 percent confidence interval, 0.33 to 0.73; *p* = 0.00004).

**Patients’ Self-Perception of Age**

The percentage of patients reporting that they appeared younger after treatment was 37 percent at day 30 and 34 percent at day 120. At both time points, these patients perceived that they appeared younger by a median of 5 years (Table 2). No patient thought they appeared older after treatment.

**Patient Satisfaction**

A high proportion of patients reported satisfaction (i.e., a mean total score on the Facial Lines Treatment Satisfaction Questionnaire of ≥5) with the treatment overall (95 percent at day 30 and 86 percent at day 120), the effects of their treatment (88 percent at day 30 and 82 percent at day 120), and the experience of the botulinum toxin type A injection procedure itself (93 percent at day 30 and 95 percent at day 120) (Fig. 2).

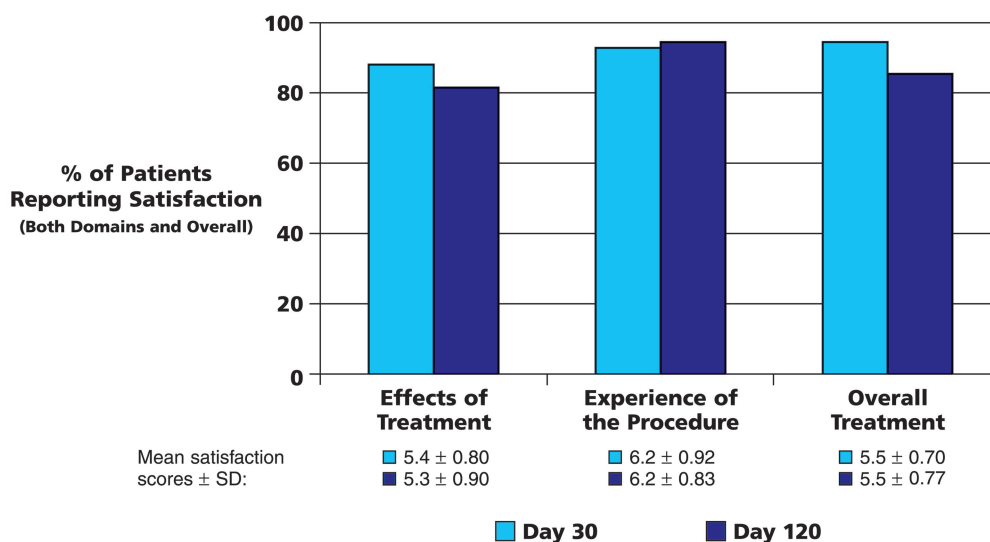


**Fig. 1.** Percentage of patients with improvement in the severity of glabellar lines 30 days and 120 days after treatment with botulinum toxin type A.



**Table 2. Patients' Self-Perception of Age**

Patient's Self-Perception	Day 30				Day 120			
	No. of Patients (%)	Perceived Change in Age (yr)		No. of Patients (%)	Perceived Change in Age (yr)			
		Mean $\pm$ SD	Median		Mean $\pm$ SD	Median		
Appear younger	21/57 (37)	4.9 $\pm$ 2.59	5.0	19/56 (34)	4.8 $\pm$ 2.12	5.0		
Appear the same age	36/57 (63)	—	—	37/56 (66)	—	—		
Appear older	0/57 (0)	—	—	0/56 (0)	—	—		



**Fig. 2.** Percentage of patients reporting satisfaction with the effects of their treatment, the experience of the procedure, and the treatment overall (satisfaction is defined as a mean total score of at least 5 on the seven-point scale of the Facial Lines Treatment Satisfaction Questionnaire).

At both day 30 and day 120, the majority of patients reported satisfaction with various aspects of their study treatment as indicated by individual items on the Facial Lines Treatment Satisfaction Questionnaire (Figs. 3 and 4).

### Tolerability

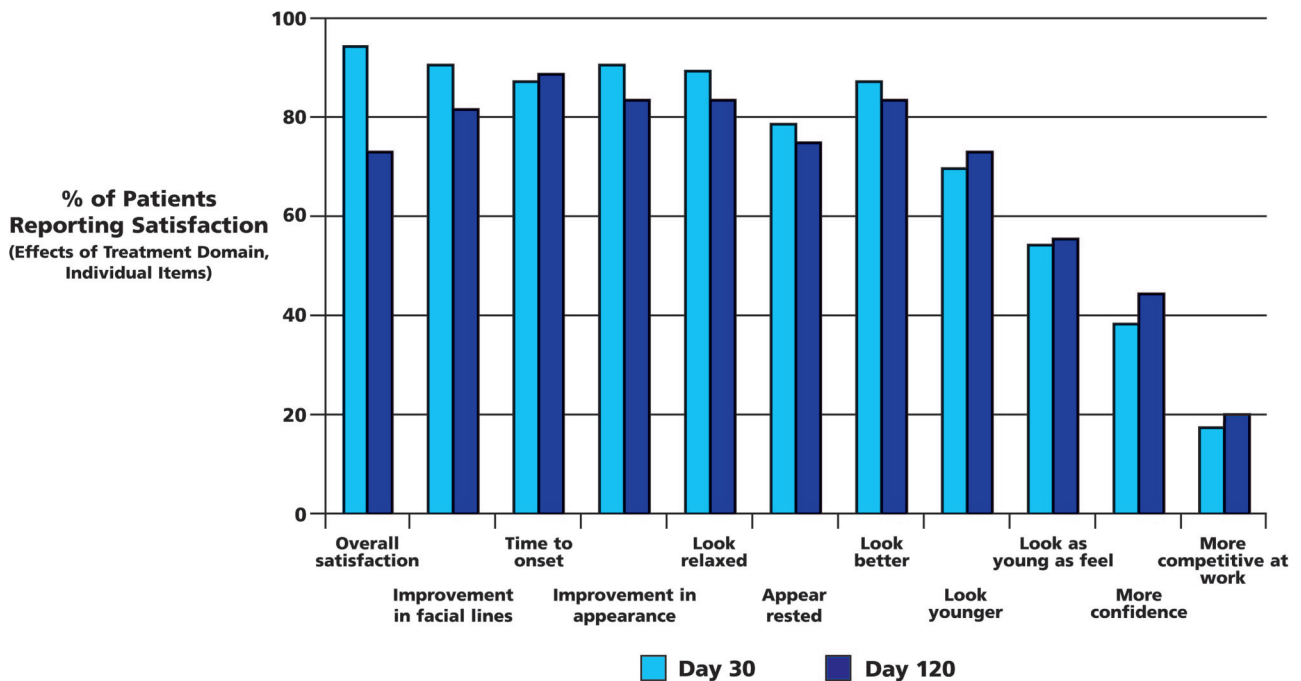
Adverse events that were considered probably or definitely related to treatment were limited to headache (reported in 12 percent of patients), soreness/itching at the injection site (5 percent), and feeling pressure (2 percent). None was serious and all were mild except for a moderate headache in one patient.

## DISCUSSION

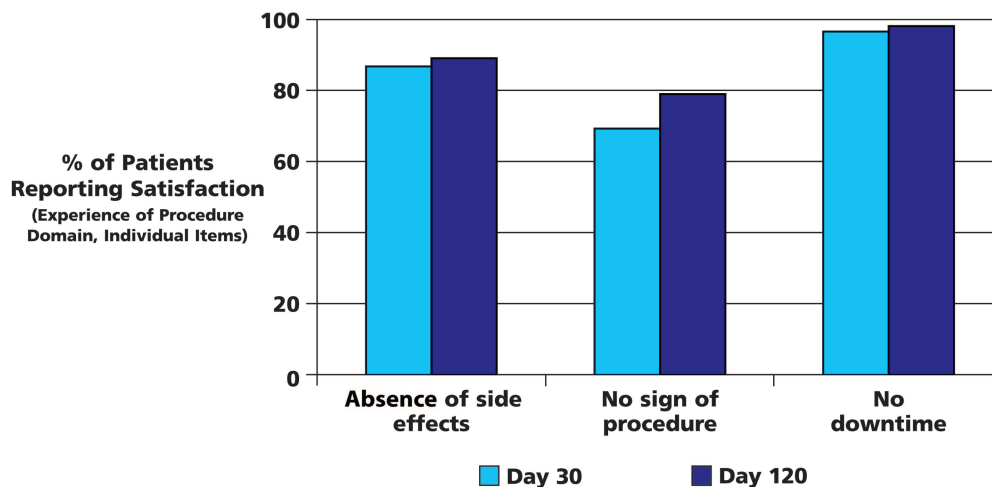
Data from this study confirm that botulinum toxin type A treatment offers durable efficacy in the treatment of glabellar lines. Importantly, the results also revealed that more than one-third of patients perceived themselves to appear younger after treatment than before (by a median of 5 years

at both day 30 and day 120). Given that glabellar lines are considered to be primarily lines of facial expression and communication, the extent of the effect of botulinum toxin type A therapy on patients' perception of their age is remarkable. We believe this is the first report in the literature of patients perceiving themselves to be younger after treatment with botulinum toxin type A, and it is especially noteworthy that this effect was achieved with a single treatment modality even though combination therapies are commonly used in the pursuit of facial rejuvenation.

Although not all patients considered that they appeared younger (some did not perceive any difference, but none thought they appeared older), this may be related to the fact that the goals of treatment are different in different patients—whereas some wish to appear younger, others simply want to appear or feel their best, and others wish to eradicate the lines of expression that cause facial wrinkles.<sup>2</sup> One limitation of this study was that the level of importance to



**Fig. 3.** Percentage of patients reporting satisfaction with items in the Effects of Treatment domain of the Facial Lines Treatment Satisfaction Questionnaire (satisfaction is defined as a mean score of at least 5 on the seven-point scale).



**Fig. 4.** Percentage of patients reporting satisfaction with items in the Experience of Procedure domain of the Facial Lines Treatment Satisfaction Questionnaire (satisfaction is defined as a mean score of at least 5 on the seven-point scale).

each patient of each item on the Facial Lines Treatment Satisfaction Questionnaire was not assessed before treatment.

The percentage of patients who felt more confident after botulinum toxin type A treatment of facial rhytides has been assessed previously using the Freiburg questionnaire on aesthetic dermatology and cosmetic surgery (an instrument that is specific to cosmetic dermatology but not to the treatment of facial lines).<sup>8</sup> The incidence of these

improvements was comparable in the earlier assessment and the present study. In the earlier study, 45 percent of patients (at approximately days 56 to 84) had more confidence in their appearance and, in the present study, 39 percent (at day 30) and 45 percent (at day 120) were at least somewhat satisfied with the ability of the treatment to make them feel more confident. It should be noted that, in the present study, confidence was already high at baseline, with 64 percent of pa-

tients reporting they were confident they were attractive to others. Important differences between the two studies were the different methods of assessment, different timings of assessment, and the fact that nearly 50 percent of the patients in the earlier study were being treated for nonglabellar facial rhytides. Furthermore, patients who were being treated for glabellar rhytides received a higher dose (24 to 30 units) than the 20 units used in the present study and approved by the U.S. Food and Drug Administration.

The study presented here is the first to evaluate patient satisfaction with botulinum toxin type A using a validated and reliable instrument designed for use in patients undergoing minimally invasive treatment for facial rhytides. Patient satisfaction was high, with 91 and 84 percent of patients at least somewhat satisfied with the improvement in their facial appearance at days 30 and 120, respectively (Fig. 3). In addition, 88 and 82 percent of patients reported satisfaction with the effects of their treatment at days 30 and 120, respectively, and 93 and 95 percent reported satisfaction with the procedure. High levels of satisfaction were reported for the procedure itself (specifically, the absence of downtime, the absence of side effects, and the feeling that no one knew they had received treatment for their facial lines) and also for aspects related to the effects of treatment (e.g., overall satisfaction, improvement in facial lines, improvement in facial appearance, time to onset of action, the ability to appear better, and the ability to appear relaxed). The high patient satisfaction ratings are consistent with previously reported findings. In other studies, 91 percent of patients considered their treatment successful<sup>7</sup> and 100 percent reported they would recommend the treatment to others.<sup>8</sup>

The observed moderate correlations between the investigator and patient ratings of improvement in glabellar line severity are not unexpected. However, the lack of strong correlations emphasizes the importance in clinical practice of obtaining patient assessments, as investigator ratings cannot be relied on as a surrogate or sole indicator of patient satisfaction or perception of treatment success. Thus, patient ratings are important even though, in this study, they appeared to be less sensitive than investigator ratings to changes occurring between days 30 and 120.

Botulinum toxin type A treatment of glabellar rhytides enhanced the self-image of the patients in this study even though they already had a positive perception of themselves at baseline. This confirms that it is an appropriate and valuable treat-

ment in patients who are already self-confident and feel good about themselves. It would be interesting to evaluate whether the effects may be even more marked in individuals with a lower self-image before treatment. Future research could also address other limitations of the present study by including controls, men, non-Caucasians, and patients who had previously received botulinum toxin type A treatment.

In the early days of botulinum toxin type A treatment for facial lines, it was questioned whether such therapy might result in a loss of facial affect. However, Heckmann et al. have shown that botulinum toxin type A enhances the facial expression of positive emotions and reduces the facial expression of negative emotions, resulting in a *shift* toward a more positive facial affect (rather than a *loss* of facial affect).<sup>11</sup> This likely plays a role in improving patients' perceptions of themselves. It would be interesting to understand whether the change in appearance resulting from botulinum toxin type A treatment is the only factor involved in improving patients' self-perceptions or whether the effect of inhibiting the contraction of certain muscles, and thereby minimizing or preventing certain expressions such as frowning, has a direct physiologic role in influencing emotions. Anger, fear, and sadness are the emotions most closely associated with increased corrugator muscle activity<sup>11</sup> and so could be the most likely to be affected. Research is currently underway to further expand our knowledge in this area.

## CONCLUSIONS

Botulinum toxin type A treatment of glabellar rhytides was highly effective—at day 30, the investigator considered that 100 percent of patients had achieved greater than or equal to 50 percent global improvement from baseline, and the patient evaluations showed that 88 percent considered they had achieved this level of improvement. Patient satisfaction was assessed comprehensively in terms of satisfaction with the treatment overall, satisfaction with the effects of treatment, satisfaction with the procedure, and patients' self-perception of age. A high proportion of patients reported satisfaction with the treatment overall (95 percent at day 30 and 86 percent at day 120), the effects of their treatment (88 percent at day 30 and 82 percent at day 120), and the botulinum toxin type A injection procedure itself (93 percent at day 30 and 95 percent at day 120). Furthermore, more than one-third of patients considered that they appeared younger than before treatment (by a median of 5 years at both day 30 and day 120).

Importantly, botulinum toxin type A treatment of glabellar rhytides enhanced the self-image of the patients in this study even though they already had a positive perception of themselves at baseline.

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#### DISCLOSURES

*Mitchell A. Stotland, M.D., and Belinda B. Ray are not employed by Allergan, Inc., and have no financial interest in the company. Jonathan W. Kowalski, Pharm.D., M.S., is an employee of, and owns stock in, Allergan, Inc. Dosing and results reported in this study are specific to the Botox Cosmetic formulation of botulinum toxin type A manufactured by Allergan, Inc. (Irvine, Calif.). Botox Cosmetic is not interchangeable with other botulinum toxin products and cannot be converted by using a dose ratio. The Facial Lines Treatment Satisfaction Questionnaire is a copyright of Allergan, Inc., 2002.*

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