

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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Most patient-involved clinical research trials compare the ratings of the expert observer with the ratings of the subjects using the same validated visual clinical rating scale. In other words, the subject is being made to function as an expert observer too, but perhaps without the same educational background and clinical experience of the expert physician observer.

The counterintuitive notion of actually asking the subjects to respond using a completely different paradigm—"How does this treatment make you feel?"—allows the subjects to respond also as expert observers.

The authors chose to use a very conservative dosing regimen, 20 units only for moderate to severe glabellar rhytides in female subjects only. The questions were weighted toward the outcome of the cosmetic treatment at different time points, but also added in three questions referring to the actual injection experience itself. We all know that, with respect to treatments that will need repetition, subjects will go elsewhere if the treatment was not viewed as comfortable and safe. Two subjects did not complete the study because of their subjective discomfort with the injection experience.

The Facial Lines Outcome Questionnaire was carefully validated before its use in this study. The correlations between the expert observer analysis based on the standard glabellar furrow rating scale and the subject's perception of satisfaction with the treatment trended together but were not exactly correlated. For example, at day 30, the investigators considered 100 percent of subjects to have achieved 50 percent improvement; at the same point, only 88 percent of subjects felt they had achieved 50 percent improvement. The Spearman correlation coefficient was 0.34 at day 30.

When the subjects were asked how they *felt* about the treatments, 95 percent were happy at day 30, 93 percent were comfortable with the injection

experience at day 30, and 37 percent felt they appeared younger by a median of 5 years. The drop-off in positive feeling about the experience at day 120 may relate to the relatively conservative Botox (Allergan, Inc., Irvine, Calif.) dosing.

This is an important article because it nicely demonstrates that it is important to ask the subjects the right subjective questions. One might have felt they were relatively unhappy with the actual objective results until one asked them how they felt, rather than what they saw.

The methodology in this article has been applied in two subsequent studies—one about the glabella¹ and one about multiple upper facial lines.² In both of these studies, the subjective questionnaire was able also to titrate a dose-response curve that correlated with the objective evaluations. This methodology will be extremely valuable too in studying the effects over time of many other facial enhancement procedures.

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DISCLOSURE

Dr. Carruthers is a consultant and investigator for and receives honoraria from Allergan, Inc.; a stockholder and member of the advisory board for Artes Medical Inc; a consultant and investigator for Bioform Medical, Inc.; an investigator for BioPelle (formally Ferndale Laboratories, Inc.); a consultant and investigator for and receives honoraria from Medicis, Inc.; a consultant and investigator for Merz Pharmaceuticals; an investigator for Organogenesis Inc.; an investigator for Q-Med; and on the advisory board for Solstice Neurosciences. In addition, Dr. Carruthers is on the advisory board for Lumenis, Inc.

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