

# Maximizing Patient Satisfaction With Facial Soft Tissue Fillers: A Question of Balance

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Clinical trials in aesthetic medicine increasingly have incorporated a variety of patient-reported outcomes (PROs), including satisfaction, as key end points. Once effectiveness and safety are documented in trials, patient satisfaction with a product, procedure, and ultimately the perceived outcome is key to a successful treatment in practice. The extent of patient satisfaction can affect the quality of the clinician-patient relationship, subsequent interactions, and retention in practice. The author explores factors in practice that contribute to the satisfaction of patients receiving facial soft tissue fillers both alone and in combination with other modalities. These factors include the unique properties of the filling agents, the technical skills of the clinician, patient expectations, immediate and extended aesthetic outcomes, length of downtime, pain management during the procedure, office environment, and overall perceived value of the treatment. Clinicians must be thoroughly familiar with the strengths and limitations of available fillers, as well as understand individual patient needs and goals, counsel patients so that the most appropriate therapeutic option is selected, must master the requisite technical skills, and be familiar with the potential adverse events associated with each agent and technique to be able to intervene when necessary. The author presents several case reports to illustrate the ways in which many of these factors can be brought together to help patients achieve highly satisfactory outcomes.

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## WEIGHING SUCCESS WITH MINIMALLY INVASIVE AESTHETIC PROCEDURES

As the number of minimally invasive aesthetic procedures performed annually continues to grow at an exponential

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rate, clinical thinking regarding the measurement of success has evolved. Taking botulinum toxins as an example, the key measures of success in early clinical trials comprised predominantly objective measures of efficacy (reduction in wrinkle severity) and safety, typically compared with a placebo treatment. Subsequently, some key trials also included patient evaluations of the degree of improvement in their wrinkles.<sup>1-3</sup> Less frequently, variously defined estimates of patient satisfaction with procedures and outcomes were included.<sup>4,5</sup> With time, patient-reported outcomes (PROs) with aesthetic procedures have become increasingly refined.<sup>3,6-8</sup> Correspondingly, and as experience with the full spectrum

of procedures has expanded, clinicians have come to recognize that PROs in clinical practice are the acid test for determining success in aesthetic medicine. Patient reported outcomes are crucial because they have the most direct association with the reasons patients seek aesthetic treatments,<sup>6,9</sup> eg, how they feel about themselves, how others perceive them, and the consequent impact on psychosocial functioning.<sup>9-12</sup> Finally, given the ubiquity of media attention to aesthetic procedures, including the dissemination of both useful and misleading information, it becomes even more imperative for clinicians to understand PROs as the most accurate reflection of what patients want to know and what they expect from their treatments.

Initial clinical trials on dermal fillers also place the greatest emphasis on safety and effectiveness. Usually, new agents are compared with an older, established filler that has met basic criteria for effectiveness and safety but which may not be an optimal comparator. However, once effectiveness and safety have been documented, the goal in clinical practice is to make decisions that allow a concerted effort between clinicians and patients to determine which product is most likely to satisfy their needs and goals, and to ensure that patients are satisfied with the process as well as the outcome. Notably, *satisfaction* is an ambiguous term and can be influenced by a large number of variables. Satisfaction with a particular product in clinical trials may not provide an accurate representation of satisfaction in clinical practice. In trials, for instance, patients commonly are treated with a larger than usual amount of product to achieve a preordained end point, and there is no cost to them for these procedures. These factors may influence perception of satisfaction. In clinical practice, on the other hand, the barometer of satisfaction takes into account a host of issues, including patient expectations and aesthetic outcomes (immediate and extended), the amount of downtime, pain and comfort management during the procedure, the office environment, and the overall perceived value (cost-benefit ratio) of the treatment, in itself a complicated issue. Taken together, the patient's perceptions of and satisfaction with the experience can influence the quality of the clinician-patient relationship and determine the likelihood of the patient continuing treatment, remaining with the same clinician, switching products, undergoing new or additional treatments, and referring others to the office practice. Therefore, clinical trials that include PROs can give a glimpse of what to expect in actual clinical practice, yet these other factors may ultimately determine the success of any procedure in the hands of the individual clinician.

## ENSURING SATISFACTION IN CLINICAL PRACTICE

In the quest to improve clinical and aesthetic outcomes, both the number and types of available fillers have grown dramatically in recent years. This provides both opportunities and challenges. Regarding facial soft tissue augmentation agents, for example, clinicians can now draw on various filler properties to select products that best meet individual patient needs and goals. Further to this, they can combine these agents with other modalities, including neuromodulation, energy-based skin resurfacing options, and skin care products (eg, cosmeceuticals), as well as with surgical approaches. Thus, individualized treatment plans can be devised to maximize patient satisfaction.

The challenges for clinicians are to understand the presenting issues, to know how to achieve a specified goal, and succeed in meeting their patients' expectations. Understanding the strengths and limitations of each available option is critical. Clinicians must have a thorough knowledge of the physicochemical properties of products, their mechanisms of action, their optimal and suboptimal uses, and strategies to avoid and manage potential complications. Clinicians must recognize that all fillers differ in many respects, including their technical requirements for use. Thus, increasing experience with various products usually leads to a better understanding of the best applications for the products, in addition to improvements and refinements in technical skills. Such mastery ultimately helps clinicians to optimize the match between products and patients, thereby leading to predictable and satisfactory results.

Clinicians can also help increase the probability that their patients will be satisfied by establishing realistic expectations for products and procedures. Patients should be encouraged to articulate their aesthetic goals and to understand the various options for achieving these goals. At the same time, they must be made cognizant of the barriers to attaining unrealistic goals. This becomes particularly relevant for patients who choose to partake in an abbreviated version of the recommended treatments (for many reasons including cost), which may address only some of their presenting issues. Explaining advantages and disadvantages of the various treatment approaches in the context of the patient's clinical presentation and expressed desires can help patients make informed decisions.

## THE NATURE OF DERMAL AND OTHER SOFT TISSUE FILLERS

A few facts deserve particular attention. Although many of these agents have been classified as dermal fillers, experience dictates that the target tissue plane

for most of these agents (with the exception of the collagen-based fillers) is either in the deep dermis, dermal/subcutaneous junction, or the subcutaneous (including the preperiosteal) space. The effects of most dermal fillers, like other minimally invasive approaches to facial rejuvenation, are largely temporary. Although this means repeated treatments with attendant costs, patients make this tradeoff to reap the benefits of an aesthetically pleasing outcome with minimal downtime and complications. One of the trends in the development of new fillers has been toward increasing duration of effect. The challenge, however, has been to optimize the balance between duration and other properties, such as the predictability and quality of the aesthetic outcome, versatility, safety, adverse events, reversibility, and the potential consequences of subsequent treatments with either the same or different agents. Existing soft tissue augmentation agents differ in these respects as well as in the extent to which they meet criteria for an “ideal” filler (Table).<sup>13-15</sup> Ultimately, they also may vary in the degree to which they optimize patient satisfaction.

Fillers have been classified in various ways to reflect their clinical properties. These general categories, however, may not be entirely useful, mutually exclusive, nor fully descriptive of the advantages or limitations of any particular agent; however, they can be segregated for a basic understanding: temporary (short duration), mostly irreversible (eg, most collagens); reversible, durable (eg, hyaluronic acids [HAs]); irreversible, semi-permanent (eg, calcium hydroxylapatite [CaHA], poly-L-lactic acid); and permanent, mostly irreversible (eg, polymethylmethacrylate, liquid silicone). Note that some categories overlap. For example, the newer and/or longer-duration HAs, specifically the smooth, cohesive, 24-mg/mL HA gel filler (Juvéderm) and the 20-mg/mL HA fillers with granular consistency (Restylane) can have durations (9–18 mo) approaching that of CaHA, depending on the target facial area, injected volume, plane of injection, number of previous treatments (with filling agents), concomitant therapy, skin type, and other characteristics of the specific treatment.<sup>16</sup> In contrast, the duration of effect of the shorter-acting HAs, such as the 5.5-mg/mL avian-derived HA gel without lidocaine (Hylaform), the 5.5-mg/mL bacteria-derived HA gel without lidocaine (Captique), or the 5.5-mg/mL bacteria-derived HA gel with lidocaine (Prevelle Silk), is similar to that of collagens such as the 35-mg/mL human-derived collagen (CosmoDerm) and the 35-mg/mL, cross-linked, human-derived collagen (CosmoPlast), though they may be used for different applications.

## Properties of an Ideal Filler

### Properties of the Material

- Nonallergenic (decreased risk for hypersensitivity; noninfectious)
- Noncarcinogenic/nonteratogenic
- Biocompatible
- Stable (inert)
- Nonmigratory
- Documented effectiveness and safety; FDA approved
- Resistant to phagocytosis
- Low potential to induce foreign body reaction

### Administration Considerations

- Uncomplicated preparation and administration
- Minimal patient discomfort
- Outpatient procedure (minimal recuperation)
- User friendly
- Readily available
- Easy storage
- Low technique sensitivity

### Clinical Features

- Does not cause overt cutaneous change
- Predictable aesthetic effects
- Durable but not permanent
- Minimal adverse sequelae
- Affordable
- Versatile
- Reversible

Abbreviation: FDA, US Food and Drug Administration.

## THE CONCEPT OF TRADEOFFS

In clinical practice, it has become apparent that the perceived advantages of a “permanent” soft tissue filler may come at the cost of other valuable attributes, including versatility for a range of aesthetic applications, reversibility, and overall safety profile. For example, it appears that the permanent fillers may be associated with an increased probability of more serious and/or delayed adverse events, such as granulomas and infection. In selecting a

specific treatment, clinicians must assess the totality of product attributes to make a selection that will achieve optimal outcomes and patient satisfaction, and consider the likelihood of complications and any care required for their resolution.

In making their assessments and selections, clinicians and patients increasingly are looking toward combination treatments for facial rejuvenation. Fillers need to be compatible with each other, with botulinum neurotoxins, and with other modalities, such as light and laser treatments. Although the potential risks of treating a patient with multiple fillers have not been addressed in systematic clinical studies, clinical experience has shown that a multitude of filler combinations can be performed with reasonable safety and optimal results. It has been noted anecdotally that caution may be required when performing procedures with additional fillers subsequent to placement of permanent fillers. It has been speculated that placing a nonpermanent filler on top of or around a permanent filler may foster complications, such as granulomas or even the activation of biofilms, but the causal relations are unclear and additional controlled clinical research is needed.<sup>17</sup> The lack of data warrants caution in determining the treatment history of your patients and in the use of permanent fillers in general.

Published studies have shown that HAs can be used in combination with botulinum neurotoxin type A (BoNTA) and with laser, radiofrequency, and intense pulsed light treatments.<sup>18,19</sup> A study conducted on nonfacial skin showed that radiofrequency treatment could be used safely in combination with either HAs or CaHA.<sup>20</sup> In addition, another study in an animal model demonstrated that radiofrequency treatment resulted in no increase in adverse effects when used in conjunction with a range of soft tissue fillers (collagen, HA, CaHA, poly-L-lactic acid, injectable liquid silicone).<sup>21</sup> More research and controlled clinical studies are required in this area, as combination use of fillers is becoming the rule rather than the exception.

Longer-lasting fillers have been associated with the risk for delayed foreign body reactions, such as true granulomas, as well as nodule formation.<sup>22,23</sup> Although the causes are not clearly understood, it appears that the risk remains as long as the implant is in place and is therefore greatest with some of the known semipermanent and permanent fillers.<sup>24,25</sup> Unfortunately, risk factors have not been clearly identified, so it is not possible to predict the likelihood of a delayed reaction for specific patients.<sup>25</sup> Based on clinical experience, however, it has been speculated that performing additional procedures, including with other fillers, on areas previously treated with a permanent implant may introduce an infection or activate

a quiescent biofilm or other reaction, in turn leading to granulomatous reactions.<sup>17,26</sup> Such complications have been observed several years after apparently satisfactory results and uneventful posttreatment courses with agents such as silicone-based products. Although the reported incidence of granulomatous reactions is relatively low (approximately 0.01%–0.1% or higher), underreporting is highly likely, so the true risks for these types of reactions are unknown, and they are likely to be substantially higher. When they do occur, they may require surgical intervention to correct; in some cases, antibiotics and intralesional steroids can be effective.<sup>25,27</sup> These events are rare with nonpermanent filling agents. In contrast, most untoward reactions with HAs are self-limiting and either resolve without treatment, respond to conservative treatment, or are reversible with hyaluronidase or direct excision.<sup>28</sup>

## ENSURING SATISFACTION IN CLINICAL PRACTICE: CASE REPORTS AND PRODUCT SELECTIONS

### Deep Horizontal Forehead Furrows in a Male Patient

*Patient 1*—A 45-year-old man presented for treatment of his deep horizontal forehead furrows (Figure 1A).<sup>29</sup> He had previously received treatments with high doses of BoNTA (>20 U) in a diffuse grid pattern to his forehead that improved the appearance of his lines; however, he experienced substantial eyebrow ptosis and reported a feeling of heaviness in his upper eyelids with this treatment. He was less concerned with total line effacement than with the unwanted effects of brow ptosis and heaviness. It was decided to re-treat him with a low dose of BoNTA (4 U total) in the midforehead and eyebrow depressors (standard dose to the corrugators, 20 U; standard dose to lateral brow depressors/orbicularis muscles, 12 U per side), in combination with human-derived collagen (CosmoDerm) injections (1 mL total) in the horizontal forehead lines. Human-derived collagen was chosen as the filling agent because of the requirement for superficial dermal line filling rather than volume augmentation in this area. Two weeks later, the patient reported being highly satisfied with this combination treatment (Figure 1B).<sup>29</sup>

In making treatment selections for this patient, it was important to assess his overall appearance and anatomical presentation. He had deep horizontal forehead furrows with a typical male-configured low eyebrow position. It was explained to him that monotherapy with BoNTA was unlikely to diminish his furrows to his satisfaction; like many males with low brows, he was at risk for brow ptosis, which he had already experienced with prior



**Figure 1.** A 45-year-old man with deep horizontal forehead furrows (A). The patient was treated with a low dose of botulinum toxin type A (4 U total) in the midforehead and eyebrow depressors, in combination with human-derived collagen injections (1 mL total) in the horizontal forehead lines (B). Photographs published in *Putterman's Cosmetic Oculoplastic Surgery*, Copyright Elsevier (2008).<sup>29</sup>

treatments. Consequently, the combination of BoNTA plus a superficial filling agent was selected to provide the optimal outcome.

### Lip Augmentation in a Female Patient

*Patient 2*—A 35-year-old woman presented for lip augmentation having had no previous treatments (Figure 2A).<sup>29</sup> She believed that her lips were not as full as they were in her teens and early 20s, and they had some lines and a dry appearance. Treatment options were discussed including a variety of HA and collagen products. One of her greatest concerns was looking unnatural. She also expressed concern about potential posttreatment swelling. After reviewing and discussing her options, she decided on treatment

with a smooth, cohesive, 24-mg/mL HA gel filler with 6% cross-linking (Juvéderm Ultra) and received a total of 2 mL in her upper and lower lips for volume augmentation. This included treatment of the central body of the lip and the vermilion borders, all of which was performed under a dental block to minimize pain. Ten months posttreatment, she retained an excellent aesthetic outcome without touch-ups, which is consistent with documented effectiveness of up to 1 year (Figure 2B).<sup>16,29,30</sup> Her outcome was characterized by a natural, smooth look that lacked the stigma of an obvious injection procedure.

This patient was satisfied with the outcome of her treatment, including the regained/enhanced lip volume and the correction of the dry, cracked appearance of her lips.



**Figure 2.** A 35-year-old woman presented to the clinic for lip augmentation to restore volume and enhance the appearance of dry cracked lips (A). The patient decided to undergo treatment with a smooth, cohesive, 24-mg/mL hyaluronic acid gel filler with 6% cross-linking and received a total of 2 mL in her upper and lower lips for volume augmentation (B). Photographs published in *Putterman's Cosmetic Oculoplastic Surgery*, Copyright Elsevier (2008).<sup>29</sup>

In practice, clinicians have found the smooth, cohesive, 24-mg/mL HA gel fillers offer patients a smooth, natural look because of their softness and malleability. In addition, smooth, cohesive, 24-mg/mL HA gel fillers tend to result in less initial swelling than with the 20-mg/mL HA fillers with granular consistency, which can be unwanted by patients new to treatment and those most concerned with a natural appearance. For some treatment-naïve patients who express concern about a “too obvious”

effect, the use of collagens provides a shorter-duration trial with minimal edema and bruising and may serve well as an entry-level treatment. Many patients may then prefer to continue treatment with an HA agent.

#### Rejuvenation of the Lower Face in an Older Female Patient

*Patient 3*—A 65-year-old woman with no previous facial treatments presented with typical signs of lower facial



**Figure 3.** A 65-year-old woman with typical signs of lower facial aging, including prominent nasolabial folds and volume loss, marionette lines, and a sagging jaw line and jowls (A). The patient was treated with 3 mL of a 20-mg/mL hyaluronic acid gel filler with a granular consistency in conjunction with anesthesia to reduce discomfort (B). Photographs published in *Putterman's Cosmetic Oculoplastic Surgery*, Copyright Elsevier (2008).<sup>29</sup>

aging, including prominent nasolabial folds (NLFs) and volume loss, marionette lines, and a sagging jaw line and jowls (Figure 3A).<sup>29</sup> Importantly, she was told that she was not a good candidate for surgery because of health reasons. She was not concerned or bothered by the appearance of her lips. In consideration of her significant volume depletion in various facial regions and after reviewing and discussing her options, she received a total of 3 mL of a 20-mg/mL HA gel filler with granular consistency to

treat her NLFs, prejowl sulcus, and oral commissures in conjunction with anesthesia to reduce discomfort. The 20-mg/mL HA gel filler with granular consistency, a relatively more rigid product, was chosen to maximize her volumetric projection and radial expansion with a reasonably affordable and conservative amount of product. It would be anticipated that a smooth, cohesive, 24-mg/mL HA gel filler with 8% cross-linking (Juvéderm Ultra Plus) would provide a similar outcome because of its

physicochemical properties.<sup>29</sup> The results were still satisfactory at 6 months, at which time the patient felt the need for retreatment (Figure 3B).<sup>29</sup> She required a lesser volume of 2 mL of a 20-mg/mL HA gel filler with granular consistency at the second treatment and subsequently has returned yearly for retreatments.

This case illustrates that older patients remain suitable candidates for treatments with fillers and are able to achieve satisfactory outcomes. This is important because many older patients are not candidates for surgical treatments because of health issues. In addition, as illustrated in this case, retreatment with any filler often requires lesser volumes than the initial treatment. The causes for this phenomenon are likely multifold. First, typically, the patient's appearance has not returned to baseline, but the patient perceives the need for retreatment before all product has been depleted. This may be because the patient has become accustomed to his or her more rejuvenated appearance and is sensitive to any diminution of effect. Second, there appears to be a consistent effect of a lesser required volume for full correction on subsequent visits that extends beyond the time expected for dissipation of most of the product, for which explanation at this time is speculative and beyond the scope of this article. This older patient discussed above was satisfied with retreatment at approximately yearly intervals.

## COMMENT

The 3 case reports discussed in this article illustrate how satisfactory outcomes can be achieved in patients presenting with different aesthetic challenges: a middle-aged man previously overtreated with BoNTA, a younger woman with aesthetic issues limited to lip appearance and volume, and an older woman with typical signs of lower facial aging. The man wanted to have his deep horizontal forehead lines diminished but did not want total effacement or monotherapy by neuromodulation alone, as with prior experiences. He believed he would appear and feel unnatural unless the lines could be improved without altering his eyebrow position and some level of forehead mobility could be maintained. Many women on the other hand, desire improvement of forehead lines in combination with brow shaping; thus, treatment selection for these patients may differ. For this 45-year-old man, a collagen product used superficially in combination with a low dose of BoNTA delivered a highly satisfactory outcome. The previously untreated younger woman was interested in a natural augmentation of her lips, which was achieved with a smooth, cohesive, 24-mg/mL HA gel filler with 6% cross-linking, distinguished by its softer, natural look and feel coupled with an extended duration. The older woman, who was not a candidate for

surgery, was able to achieve satisfactory outcomes with the 20-mg/mL HA filler with granular consistency, which allowed for satisfactory reflation of the volume-depleted regions, with the understanding that these treatments would need to be repeated at some interval to maintain this effect.

Several important considerations helped each patient achieve the most satisfactory outcome for his or her individual needs. Foremost in my view was the consultation with in-depth evaluation and counseling. Consultations such as this encompass a comprehensive aesthetic assessment, a thorough understanding of each patient's unique needs and goals, and a full discussion of the strengths and limitations of available options, including what cannot be achieved realistically. It also is important to use the consultation time to uncover any trepidation the patient may have, such as concern about pain or discomfort. Minimizing pain and discomfort with appropriate anesthetic techniques suited to the specific treatment or facial area can make the difference between a satisfactory or highly unsatisfactory experience, where a patient may never return. It is incumbent on the clinician to develop mastery of various anesthetic techniques, including how to give a consistently effective regional or infiltrative local anesthesia.

The variety of products available today enables clinicians to present their patients with a broad choice of treatment options and combinations and the opportunity to explore what will work best for each patient. In many instances, the optimal approach is a combination of modalities; for example, BoNTA plus fillers. In many practices, the newer HA fillers are the foundation of rejuvenation treatments because of their versatility, reversibility, predictability of effect, and ability to provide a natural look and feel. Regardless of the ultimate product selection, in-depth and ongoing consultation and counseling will help clinicians and patients together determine the overall treatment plan that best fits each patient's budget and aesthetic expectations.

In summary, although clinical trials are necessary to document the safety and effectiveness of facial soft tissue fillers and to evaluate other outcome measures in a controlled setting, the true test of patient satisfaction comes through use in actual clinical practice. Patient reported outcomes will remain the ultimate barometer by which patients can measure their degree of satisfaction with a particular treatment. They likely will be more universally incorporated in registration trials for new products and should be used in some way in our personal practices. In the real world, both expert training and ongoing clinical experience provide the opportunity to determine the techniques and applications most suitable for use

with specific products and patients. As shown by these 3 case reports, highly satisfactory results can be obtained with different products across a spectrum of patient presentations given appropriate evaluation, technique, and patient counseling as to expectations and outcomes.

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