

Satisfying Patient Expectations With Poly-L-Lactic Acid Soft Tissue Augmentation

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ABSTRACT

Patient interest and physician use of soft tissue augmentation have increased significantly in recent years, especially among younger patients. A recent consumer survey conducted on behalf of the American Society of Plastic Surgeons found that the majority of respondents would rather have a facial injectable treatment than a surgical treatment. In another recent survey, consumers gave the highest overall satisfaction ratings to injectable filler treatments (92%), including poly-L-lactic acid (PLLA), and injectable wrinkle relaxers (92%), with injectable fillers receiving the highest "extremely satisfied" rating (45%). Long-lasting benefit is a desirable attribute in soft tissue augmentation, making PLLA a favorable alternative for many patients. When considering the use of PLLA, clinicians should ensure that their patients understand its benefit profile, and that these benefits are consistent with the patients' cosmetic goals. The implementation of the latest recommendations on methodological approaches in the use of PLLA will minimize the occurrence of adverse events, further enhancing patient satisfaction.

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INTRODUCTION

There has been significant growth in both patient interest and physician use of soft tissue augmentation in recent years, especially among younger patients. Patients' motivation behind this increased interest is complex. Studies using digitally enhanced photographs¹ and those conducted using botulinum toxin type A injections² have shown that improvement in facial appearance increases overall attractiveness, reduces perceived age by up to 5 years,^{2,3} and promotes a positive effect on mood⁴ and self-esteem.⁵

A 2006 Harris Interactive Survey involving nearly 800 women aged 35 to 69 years, conducted on behalf of the American Society of Plastic Surgeons, found that the reasons women consider cosmetic interventions include: looking younger, improving intimate relationships, and increasing their confidence.⁶ Sixty-three percent of the respondents reported that they would much rather have a facial injectable treatment than a surgical treatment. The facial signs of aging that women are most likely to be very concerned or extremely concerned about are wrinkles (44%) and sagging skin (41%).⁶

Recently, the first ever American Society for Dermatologic Surgery (ASDS) Consumer Survey on Cosmetic Dermatologic Procedures solicited feedback from over 6,300 consumers.⁷ While 6.4% of those surveyed had previously had a cosmetic treatment, 53% said they were considering injectable fillers in the future.^{7a} Consumers gave the highest overall satisfaction ratings to injectable filler treatments (92%), including poly-L-lactic acid

(PLLA), and injectable wrinkle relaxers (92%),⁹ with injectable fillers receiving the highest "extremely satisfied" rating (45%).⁷

Another study conducted by the ASDS found that among women considering using medical anti-aging treatments, 89% and 75% would prefer gradual results lasting 2 years, compared with immediate results lasting 6 months or 1 year, respectively (Figure 1).¹⁰ It is interesting to note that long-lasting effects were more important than cost as a factor in treatment decisions, particularly among women who had already used an injectable product.¹⁰

To optimize outcomes, cosmetic treatment must be tailored for each patient; communication is thus paramount. Clinicians need to understand their patients' treatment goals, including areas for correction and the desired timeframe for cosmetic benefit.¹¹ The cosmetic deficits of patients considered for PLLA should match its benefit profile of increased soft tissue volume. If PLLA is agreed upon, patients should be educated on the nature of their underlying deficits (eg, volume depletion), the gradual onset of cosmetic improvement, the need for multiple sessions, and the long-lasting benefits of the approach.¹¹ Clinicians should also take measures to minimize the occurrence of adverse events, such as nodule formation, through the implementation of the latest recommendations on methodological approaches.^{11,12}

There is a growing trend in the use of injectable dermal fillers for soft tissue augmentation in patients 35 to 50 years of age (Figure 2)¹¹; in fact, in 2012, about 75% of respondents receiving

FIGURE 1. Paired comparison analysis of factors impacting women’s medical anti-aging treatment decisions.¹⁰ Adapted with permission from Susan Weinkle, Mary Lupo. Attitudes, awareness, and usage of medical antiaging treatments: results of a patient survey. *The Journal of Clinical and Aesthetic Dermatology*. 2010;3(9):30-33. Copyright © 2010 Matrix Medical Communications. All rights reserved.

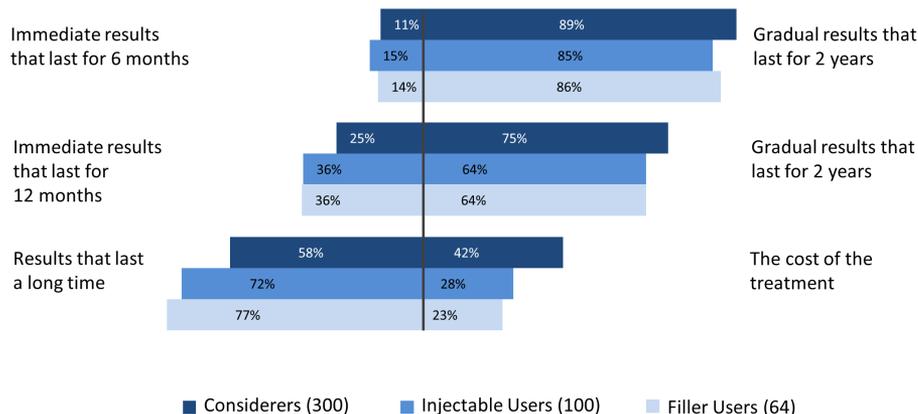
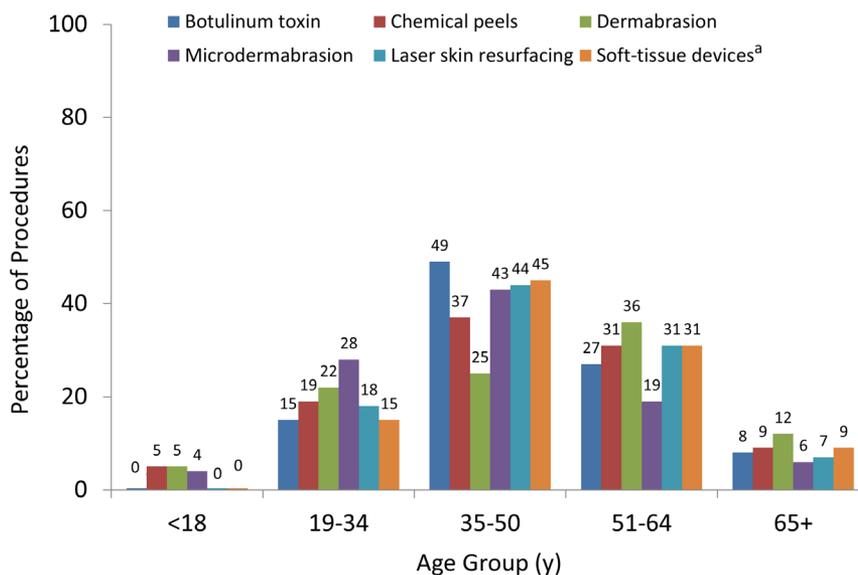


FIGURE 2. Use of cosmetic procedures across different age groups.¹¹ Reprinted with permission from Stephen H. Mandy. Satisfying patient expectations with soft-tissue augmentation. *Dermatology Online Journal*, Volume 15, Pages 1-16. Copyright © 2009.



^aSoft-tissue devices include autologous fat, calcium hydroxylapatite, bovine-derived and human-derived collagen, hyaluronic acid, and poly-L-lactic acid.

PLLA were 54 years of age or younger.¹³ In light of this trend, it may behoove the clinician who has limited experience with the use of PLLA to begin with a younger patient. The selection of a younger patient, with less complex cosmetic deficits, may result in greater patient satisfaction, with the added benefit of increasing the familiarity and comfort level of the practitioner.

Studies Reporting on Patient Satisfaction With Poly-L-Lactic Acid for Soft Tissue Augmentation

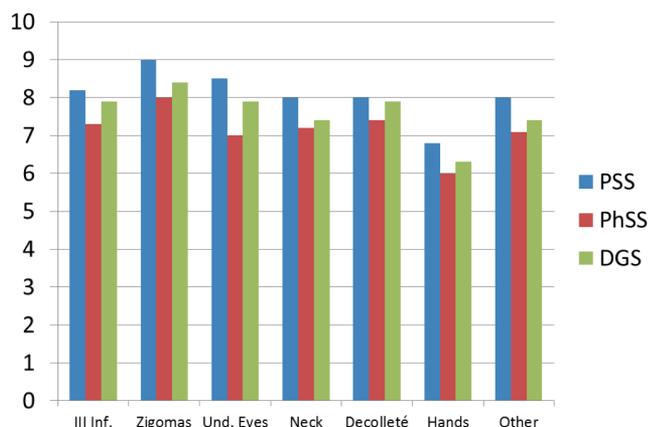
There are several published studies and surveys on the use of PLLA in soft tissue augmentation in non-HIV patients that included patient satisfaction as an endpoint.¹⁴⁻²²

The largest such study included 2,131 patients, 95.9% of whom were seeking cosmetic augmentation.¹⁴ Treatment satisfaction was based on patient-physician discussions and aided by a retrospective review of photographs taken during and at the conclusion of the treatment. Approximately 95% of patients were satisfied with the achieved cosmetic result.¹⁴

In a large retrospective case history review of 568 patients receiving PLLA for cosmetic problems, patient and physician satisfaction were scored on a scale of 1 to 10.¹⁵ A Definitive Graduated Score (DGS) was also calculated using both photographic results and the average patient/physician scores. Overall, the

DGS averaged 7.6 (range, 6.3-8.4 depending on area treated), with average patient satisfaction scores higher than those of physicians (Figure 3).¹⁵ The most favorable results were achieved from treatments to the cheekbones and malar areas.¹⁵

FIGURE 3. Average patient and physician satisfaction scores with poly-L-lactic acid, with definitive graduated scores, stratified by facial region.¹⁵ Reprinted with permission from Alessio Redaelli, Riccardo Forte. Cosmetic use of polylactic acid: report of 568 patients. *Journal of Cosmetic Dermatology*, Volume 8, Pages 239-248. Copyright © 2009 Wiley Periodicals, Inc.



DGS, Definitive graduated score; III Inf, lower third of the face; PhSS, physician satisfaction score; PSS, patient satisfaction score; Und, under.

In a retrospective survey, 130 respondents who received PLLA for cosmetic enhancement across a 5-year period rated the results of their treatment.¹⁶ Although not stratified by duration since treatment, 55% of patients overall indicated that they had "good" or "excellent" correction of their cosmetic issues. Patient assessment correlated roughly to the number of treatment sessions, with 75% of patients having 5 or more sessions reporting at least "good" correction.¹⁶ In another retrospective survey with 40 respondents who had been treated with PLLA for facial atrophy, 80% of patients were satisfied with their cosmetic outcome ($P=.0001$) in relation to their expectations prior to treatment.¹⁷

In a study that included both non-HIV ($n=38$) and HIV ($n=27$) patients, satisfaction with PLLA was assessed on a 5-point scale.¹⁸ Ninety-one percent of patients overall, and 89.5% of the non-HIV patients seeking cosmetic enhancement, were "very satisfied" with their treatment at study end. In a 3-year follow-up investigation, satisfaction with PLLA proved durable; 86% of non-HIV patients ($n=35$) remained "very satisfied" or "somewhat satisfied" with the results of their treatment.¹⁹

A small study investigated the satisfaction of women treated with PLLA for sunken nasolabial folds.²⁰ Each patient received 1 injection per month for 3 consecutive months. Patient satisfaction was assessed on a 4-point scale at each application, at 6 months, and 36 months after treatment. After 6 months, 60%

of patients initially indicated that they were "satisfied" or "very satisfied" with the results, but this increased to 80% when the patients were shown the clinical photographs of their improvement. Even 3 years after their injections, 60% of patients remained at least "satisfied."²⁰

In a study in which 36 patients with varying degrees of cutaneous aging in the neck and chest (presternal area) were treated with PLLA, 92% indicated that they were pleased with the results and would choose to do it again.²¹ Those patients treated in the presternal region reported optimal improvement and high satisfaction.²¹

"To optimize outcomes, cosmetic treatment must be tailored for each patient; communication is thus paramount."

SUMMARY

Patients seek cosmetic enhancement for a number of reasons and soft tissue augmentation is increasingly viewed as an attractive option, especially among younger patients. Long-lasting benefit is a desirable attribute, making PLLA a favorable alternative for many patients. A high level of patient satisfaction with PLLA has been established in a rigorous series of clinical studies and surveys.

To improve the likelihood of satisfaction with PLLA treatment for individual patients, it is important for clinicians to select patients appropriately, have a firm grasp on their cosmetic goals, and calibrate their expectations regarding its benefit profile.¹² Clinicians should take every measure to minimize adverse events, and for those with little prior PLLA experience, selection of a younger patient with a less complex array of cosmetic deficits may enhance patient satisfaction, as well as afford clinicians the opportunity to increase their experience and comfort level.

DISCLOSURES

Danny Vlegaar MD has been a medical consultant for Sinclair IS Pharma, France; PharmaSwiss SA, Switzerland; Valeant Eastern Europe; and Cutanea Life Sciences, Inc. He also has been a trainer for Valeant Pharmaceuticals International, Inc./Medicis Corporation.

Rebecca Fitzgerald MD has been a consultant and speaker for Valeant Pharmaceuticals North America LLC/Medicis Corporation; Merz Aesthetic, Inc; and Allergan USA, Inc.

Z. Paul Lorenc MD has been a consultant for Johnson & Johnson; La Lumiere, LLC; Medicis Corporation; Merz Corporation; and Mentor Corporation. In addition, he holds the following

patents: US Patent 5/611,814–Resorbable Surgical Appliance for Use in Supporting Soft Tissue in a Superior Position; US Patent 60/950,423–Composition and Method of Use for Soft Tissue Augmentation/Drug Delivery; US Patent 12/797,710–Method for Measuring Change in Lip Size After Augmentation; and US Patent 13/604,012–Light Therapy Platform System.

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