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Update on Injectable Facial Rejuvenation

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Introduction

The Cosmetic Bootcamp was established to present information that is cutting edge and relevant to assist the board-certified core physician in establishing and growing a cosmetic practice with improved patient outcomes and experience as the ultimate goal. Faculty participation in the meetings is unique: there is no compensation so the lectures can be unbiased. Corporate sponsors cannot dictate the terms of the discussion. The intimate format, panel discussions and faculty availability after presentations ensure access and interaction with attendees. Strengths and weaknesses of products and procedures are reviewed in the hope of achieving better outcomes and helping physicians make wise choices for their patients. The meeting has grown from its original version, with 60 people gathered in Jackson Hole, to become the leader in aesthetic training available only to board-certified core aesthetic physicians. We now have an advisory board that includes several luminaries in the field. Our meetings now include a marketing and management symposium, a financial roundtable, a clinical trials meeting and a textbook that will encapsulate the comprehensive, cross-disciplinary approach to aesthetic medicine and surgery. In this, our first supplement, we endeavor to create something useful that will help to bring information about new fillers and new ways to use existing fillers.

In addition to the hyaluronic acids and collagens, poly-L-lactic acid (PLLA) and calcium hydroxylapatite have also become popular soft-tissue augmentation products. No longer limited by durations measured in months, and now armed with the ability to correct on initial patient consultation, the number of injections has increased significantly.

Shortfalls with bovine collagen were barriers to patient acceptance. The company that manufactured this tried to address these by first creating a cross-linked product (Zyplast®) that had a more robust consistency and slightly better duration than its non-crosslinked predecessor (Zyderm®). The concentration of collagen in Zyplast and Zyderm I was the same (35 mg/ml) but by using glutaraldehyde to bond the collagen fibers, the Zyplast was able to treat deeper creases (including the nasolabial crease). Zyderm II contained 65 mg/ml of collagen but was not crosslinked and did not add appreciably to the repertoire of soft-tissue augmentation. To help physicians treat patients at the initial patient consultation, the molecules were produced from human foreskin cells cultured in medium. One benefit is that when massaged after injection, the fibers would expand. The human derived collagen molecules were both cross-linked and non-crosslinked (CosmoPlast™ and CosmoDerm™ I and II, respectively). Although they eliminated the need for skin testing, they did little to improve the duration of correction and nothing to enhance the value proposition for patients or physicians. Physicians and patients alike responded as expected, and these products failed to expand the number of patients treated in any significant manner.

Improvements in collagen technology waited approximately 20 years after the initial introduction of the product. Seeking to address some of the shortcomings from the earlier collagens, a product has been developed that has six-month persistence and does not require skin testing. Attempts to grow autologous collagen from human punch biopsies have, to date, not produced a commercially viable product. It is possible, however, that the technology will yield a product that is highly biocompatible and expandable; this outcome would be welcome.

The first newly approved collagen in recent history is Evolence®. It is a porcine derived collagen crosslinked with a novel mechanism. To improve duration and decrease immunogenicity, the telomers of the collagen molecules are degraded using telomerase. This greatly enhances the persistence of the collagen. Stabilization of the molecules is obtained using ribose molecules to bond the fibers together. The collagen used for this product is derived from porcine sources. Porcine collagen is remarkably similar to human collagen and it does not engender significant immune responses. Ribose, a sugar moiety used for stability, is biocompatible and does not elicit an immune response. This combination of improvements has enabled Evolence to increase the duration of its correction to six months and, in some cases, for up to a year.

The ribose-crosslinked porcine collagen has two versions in Europe: Evolence and Evolence Breeze. Evolence is a long chain molecule that is suitable for correction of nasolabial creases, marionette lines and other folds. It is not suitable for lips, periorbital rhytids or perioral rhytids. Evolence Breeze was created to address these areas, and its short-chain molecule may be used to augment lips and fill perioral and periorbital wrinkles. It is covered, in depth, in Dr. Monheit's chapter.

Calcium hydroxylapatite (CaHa) is another soft-tissue augmentation product that has been approved for use in the U.S., Canada and Europe. It is a biocompatible bioceramic molecule that may be injected to correct moderate-to-severe rhytids and volume loss. The mechanisms of action for CaHa include direct soft-tissue augmentation as well as fibroblast ingrowth and deposition of collagen. It does not require allergy testing and is available in large (1.3 mL) syringes that are cost-effective. Duration for this product is between 8-12 months in most cases. While suitable for nasolabial creases, marionette lines, zygomatic sculpting and treatment of dorsal hand aging, it is not suitable for injections into the lips (despite early reports to the contrary). Potential complications from this product may include migration, nodule formation and discoloration when placed superficially. There are many methods for treating these various complications and most will abate with either time or cortisone. Dr. Vic Narurkar provides an outstanding review of this product.

In her chapter on poly-L-lactic acid (Sculptra™), Dr. Rebecca Fitzgerald discusses how this collagen stimulator is used for volume loss. Unlike others, this product relies upon the body's ability to produce collagen in response to low grade inflammation. PLLA comes as a lyophilized powder that can be reconstituted in various dilutions. The variability in dilution creates a great deal of variability between different injectors in terms of the complication rate as well as efficacy. Most physicians advocate using a dilution of between 6 and 9 mL per bottle and spacing the interval between injections to approximately 4 weeks. European data demonstrated a higher risk of subcutaneous papule formation when higher concentrations and more frequent intervals were used.

Kenneth Beer MD

A Grading System for the Malar Crease Region and its Implications for Treatment of This Region With Soft-Tissue Augmentation Products

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ABSTRACT

Facial aging is one of the most common problems patients present to dermatologic surgeons. Aging of the mid-face is typically a significant factor in the overall appearance of the face. Mid-facial descent and volume loss manifest as malar crease formation, which contributes to the appearance of facial aging. Presently, there is no uniformly accepted scale for the grading the appearance of the malar crease region. In this article, the authors present a malar grading scale and discuss its treatment alternatives it. It is hoped that this scale will help physicians and patients assess mid-face aging and objectively evaluate treatments to this area.

INTRODUCTION

Until recently, the face was thought of as a homogenous structure. Consequently, treating facial aging was achieved using one-dimensional surgical approaches such as rhytidectomies. Recent advances demonstrate that facial aging is a three-dimensional process that manifests as volume loss, most evident in mid-facial descent. Volume loss is the result of changes of underlying fat, bone structure and dermal support structures. These factors impact the aging face, in general, and the malar area, in particular.[1] Treatment of the latter region is vital to rejuvenating the aging face.

When treating the malar region, the techniques utilized for injection, depth of injection, choice of material utilized and volume injected each impact the malar region differently. Presently, because there are no consistent protocols for correcting this cosmetically vital region, it is difficult to have a meaningful discussion as to what products or techniques result in optimal outcomes.

In order to best treat the malar area, it is important to have an objective assessment tool to measure patient outcomes and improve patient treatments. The malar rating scale is one possible tool to achieve these goals.

DISCUSSION

Etiology of the Malar Crease

Perhaps the most critical component of the malar crease is the malar fat pad. According to Rohrich and Pessa, the malar fat pad has three distinct components: the medial, middle and lateral temporal-cheek fat.[1] These components atrophy at different rates and contribute in differing amounts to the visible signs of the malar crease, each producing medial, middle or lateral malar aging dominance. Concomitant with the loss of the malar fat pad, less suspension of the skin in this area changes the contour of the mid-face. As the malar fat pads lose volume, the entire malar compartment descends. However, the upper anterior cheek remains firmly tethered by the orbitomalar septum. This prevents downward migration of this area and accounts for the superior border of the malar crease.[2]

A second factor in the malar crease is bone structure, which serves as the scaffolding for facial muscles and soft tissue.

The third factor is the loss of dermal support structures. Without these supports, the overlying skin begins to sag. The degeneration of connective tissues, such as collagen and elastic fibers, is directly correlated with the skin's degree of ultraviolet damage. Without the resilience and support afforded by these two elements of the dermis, the malar fat pad lacks structural support and it will tend to sag.

Each of the aforementioned factors affects mid-face appearance differently: fat pad atrophy and bony resorption result in mid-face descent, whereas loss of collagen and elastic fibers result in facial skin sagging. All of these factors contribute to the development of the malar crease.

Options for Treatment of the Malar Crease

The signs of mid-face aging can be very difficult to correct. The treatments for correction of malar crease range from medical devices to surgical correction utilizing a mid-face lift.[3–6]

At one end of this spectrum is the mid-face lift, which theoretically reverses mid-face ptosis by directly repositioning the mid-face into a more youthful position. Unfortunately, the procedure is difficult to perform correctly and many surgeons opt for more traditional face-lifts. Since traditional face-lifts create vectors that draw the superficial musculoaponeurotic system (SMAS) and overlying skin laterally instead of superiorly, patients tend to look as if they are in a wind tunnel rather than youthful.

There are less invasive, albeit less effective approaches, being used currently. Approaches utilizing threads have been sub-optimal to date. Radiofrequency and infrared energy sources may tighten the mid-face area, but do not produce substantive results. These deficient modalities have created an opportunity for physicians to utilize soft-tissue augmentation and dramatically alter the landscape of the malar crease corrective treatments; this is provided the physicians performing these treatments possess sufficient anatomic expertise with which to correctly treat the area and an evaluation tool to measure improvements. Objective evaluation scales for malar crease evaluation will enable physicians (and patients) to determine the degree to which a given treatment has, or has not, improved the malar crease.

As noted, treatments range from surgical mid-face lifts and implants, to injections with synthetic and autologous soft-tissue augmentation products.[3–6]

Product Selection for Malar Crease Treatments by Malar Crease Severity Classification

Products currently available for treatment of malar rhytids include silicone, poly-L-lactic acid (PLLA), calcium hydroxylapatite, hyaluronic acids, collagen and autologous fat. Optimal product selection depends on a host of factors including the texture and thickness of the patient's skin, patient risk tolerance, the patient's budget as well as the injector's experience.

Silicone is a permanent filler whose efficacy has been well documented.[7] Medical-grade silicone injected using the micro-droplet technique has been used for correction of lipoatrophy in patients with human immunodeficiency virus (HIV) with substantial, and durable improvement in patient appearance.[8] Its use for malar crease injections lacks significant experience, but it is possible that this product could improve grade 2-4 malar rhytids.

PLLA has similar efficacy and safety in treating HIV lipoatrophy as silicone, and it has been utilized for esthetic indications.[9] It has a unique mechanism of action, stimulating fibroblasts to produce collagen and elastic tissue, which results in an increase in volume. It has been used to fill voids in adjacent areas including the tear trough and malar areas. One potential drawback associated with its use is the formation of granulomas and nodules. With proper techniques, thickening of the skin and volume restoration have been reliably obtained. PLLA is appropriate for grade 3-5 malar rhytids.

Calcium hydroxylapatite (CaHa) has been utilized for the treatment of moderate rhytids. It has also been effectively used in the zygomatic arch and other parts of the face.[10] Its use in certain portions of the face has been associated with the formation of nodules, and it is not indicated for injection into the lips. There are limited data regarding its injection into the malar crease, but it is likely that CaHa could be used effectively to treat this area. Given its potential to form nodules, it should be reserved for patients with thick skin and grade 4-5 malar creases.

FIGURE 1. Grade 1: Malar crease is not visible

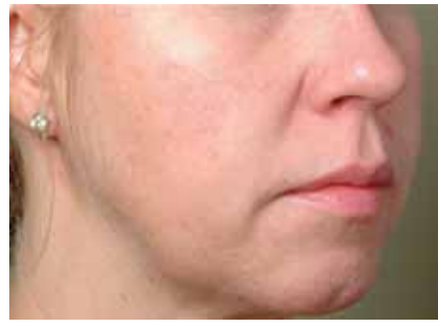

FIGURE 2. Grade 2: Small shallow and narrow malar crease

FIGURE 3. Grade 3: Easily visible malar crease, corrected with manual stretching of the skin

FIGURE 4. Grade 4: Prominent malar crease greater than 2 mm associated with facial desent and volume loss. Some correction with stretching of the skin

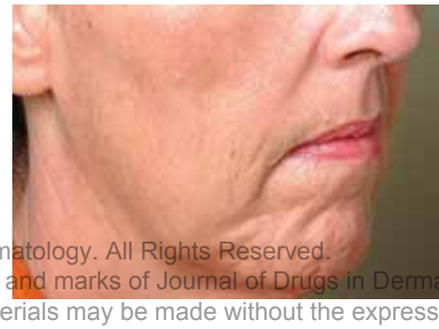

FIGURE 5. Grade 5: Very deep and wide malar crease associated with significant volume loss

Hyaluronic acids (HAs) offer a high degree of safety as well as the potential to reverse any undesirable outcomes with the use of hyaluronidase. Hyaluronic acids can be placed in all layers of the skin and subcutis, and they have the ability to layer different products of different sizes on top of each other. These products are appropriate for grade 2-5 malar creases and have the advantage of being amenable to correction with hyaluronidase.

Collagen products can also be injected with similar techniques to HAs. Disadvantages include the inability to remove collagen if misplaced or overcorrected. Newer, longer lasting cross-linked products like Evolence® may improve longevity over current, commercially available collagens.[11] There is little data to indicate whether or not Evolence is appropriate for treatment in the malar area, but it is likely that Evolence® Breeze will be more suited for this indication.

Autologous fat has been used both alone and in conjunction with surgical procedures to improve the mid-face.[4] Disadvantages of these techniques are the requirements of a procedure to obtain the fat, the unpredictable longevity of fat and the potential for uneven results. With these treatments, there is generally a longer "downtime" consisting of edema and risk of ecchymosis when compared to other fillers. Autologous fat is appropriate for the treatment of grade 3-5 malar creases.

Techniques for Injection of the Malar Creases

The technique for injections, and consequent degree of improvement, varies by individual cases. Superficial creases are usually relatively easy to fill. More distensible creases usually give a higher degree of improvement. Deep injections at the supraperisoteal level help bridge the gap between the orbitomalar septum and the malar fat pad, which will usually yield the majority of the correction.

The authors prefer to inject vertically (approximately 90° to the skin), starting in the most lateral part of the crease and injecting at the supraperiosteal plane until maximal correction is achieved, then moving more medially, repeating the process. After completion, if further correction is required, more superficial injections in the mid-dermis can be used by injecting in different planes and in different directions. This may yield further improvement to the malar crease. Of course, full correction is not always possible. Volumes of product range from 0.5 cc per side to 2 cc or more per side, depending on the depth and width of the crease and the quality and elasticity of the skin above.

The Solish Beer Remington or SOBER Scale

We propose a 5-point rating scale. This scale is similar to validated scales used to grade rhytids in other portions of the face. In addition to the definitions provided, archetypal photographs are also presented.

Grade 1: None. Malar crease is not visible. Patient usually less than 30 years of age
Grade 2: Mild. There is a shallow but visible line with a slight indentation. Patient is usually between 30-40 years.
Grade 3: Moderate. There is a clear line that is easily discernible; this is easily corrected with stretching. Patient is usually between 40-50 years.
Grade 4: Severe. A prominent line, greater than 2 mm in depth. Patient is usually 50-55 years.
Grade 5: Extreme. Very deep crease, not fully corrected with stretching. Patient is usually older than 55 years.

Representative Examples of Malar Creases With Treatment Options

Case 1

A 40-year-old male with grade 1 malar crease was injected with 0.5 cc of Perlane® per side. Alternatives for this individual would include Prevelle® Silk and Juvéderm.® Results obtained are attainable with any of these products. Evolence® Breeze (when approved) will also be suitable (Figure 6).

FIGURE 6. Grade 1 **a)** pre-injection **b)** 2 weeks post-injection

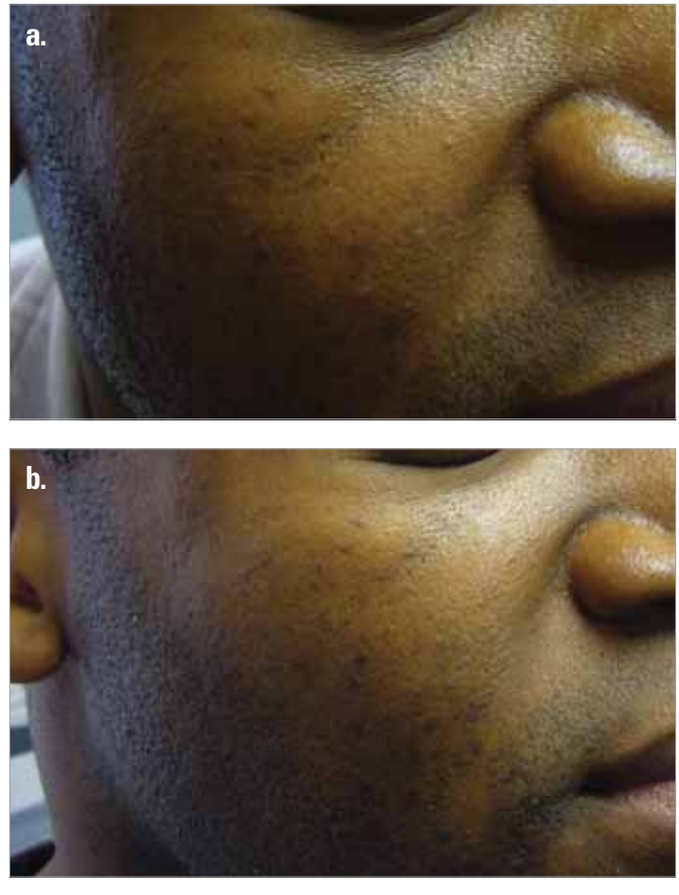

FIGURE 7. Grade 4 **a)** Pre-injection **b)** 2 weeks post-injection

FIGURE 8. a) Pre-injection **b)** 2 weeks post-injection

Case 2.

A 65-year-old woman presented with a SOBER grade 4 crease. She was injected for facial aging with Perlane®. Periosteal plane injections were utilized for this treatment. She was also treated in her nasolabial folds and oral commisures. A total of 4 cc were injected (Figure 7).

Case 3.

Case 3 is another example of a Grade 4 malar crease. Injections were accomplished with with 2 cc of Perlane™ to right cheek and 4 cc of Perlane™ to left side. Follow up is 4 months post-injection (Figure 8)

CONCLUSION

The malar crease is a major contributor to facial aging. Without addressing mid-face descent, in general, and the malar crease, in particular, facial rejuvenation treatment is incomplete. While popular methods for correcting the malar crease, such as hyaluronic acids, have proved safe and effective, the discussion of standardizing corrective treatments has been inhibited by a lack of a method to measure progress. Adopting a routine grading system for this region should help to standardize assessments of patient needs as well as their degree of improvement with different treatments. The SOBER scoring system is the first means by which uniform measurement of the malar crease can be made. Validation of this system should be performed during a clinical trial to develop optimal techniques for correction of the malar crease using hyaluronic acids and other fillers.

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The Beer Hand Scale: A Validated Scale to Grade Dorsal Hand Aging and Response to Treatments

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ABSTRACT

A validated scale is presented to provide an objective measurement tool to evaluate dorsal hand aging. Representative cases are utilized to demonstrate the various stages of the rating scale. Various modalities for hand rejuvenation are considered as they relate to the scale. Limitations of the proposed scale include the facts that only one geographic location was used to obtain the validation and that it uses one ethnic skin type as archetypes. Despite these limitations, the scale is a valid method of evaluating dorsal hand aging and treatments to improve the appearance of the hands.

INTRODUCTION

One of the cardinal signs of aging is the appearance of the skin of the dorsal hands. Although lines, creases and photodamage of the face may be treated with fillers, toxins and lasers, the appearance of the dorsal hands frequently contrasts with the newly rejuvenated face. It is widely accepted among dermatologists and plastic surgeons that rejuvenation of the dorsal hands is a desirable goal and an important facet of a global aesthetic program.

Measuring the changes associated with aging hands has been accomplished by a variety of methods, including a survey which concluded that aging hands are marked by visible veins, spots of discoloration and by wrinkles of the skin.[1] Attempts to provide a framework to measure relative degrees of hand aging include a recent study that evaluated hand changes in 143 volunteers. These study participants were graded by a single observer for the appearance of wrinkles, trophic changes and visibility of subcutaneous structures. Despite the advance represented by this study, it is limited by the fact that it is not a global scale validated by different individuals and, because of these limitations, has not been widely adopted.[2] To date, there is no widely utilized, validated scale to measure dorsal hand aging or improvements following treatments to that location.

A reliable scale for comparing aging hands should be easily adopted with widespread agreement among those who utilize it. It should be analogous to other readily used global aesthetic scales so that practitioners can adopt it. The proposed scale is a 4-point system that has been validated by 50 people and represents an effort to provide a standardized framework with which to evaluate hands at baseline, as well as after treatments, to enhance their appearance.

It has only been within the past few years that hand rejuvenation has become a reasonable goal for dermatologic and plastic surgeons. Prior to this era, the only fillers utilized were limited to collagen and autologous fat. Despite studies advocating the use of structural fat for dorsal hand rejuvenation, its widespread use is limited by the need for harvesting and somewhat unpredictable outcomes. Collagen was limited by its short duration and cost. Recently, however, interest in hand rejuvenation has been rekindled by advances in fillers, which can provide durable volume restoration, and by lasers, intense pulsed light (IPL) and cosmeceuticals, which can resurface and rejuvenate the dorsal hands.

Fillers presently used to replenish volume in the hands include poly-L-lactic acid (PLLA), calcium hydroxylapatite (CaHa), hyaluronic acid (HA), collagen and autologous fat. Poly-L-lactic acid stimulates collagen formation and has been utilized widely for aesthetic rejuvenation of the face as well for the treatment of facial lipoatrophy. Its use in the hands has been advocated with dilutions from between 6 to 9 mL.[3] Repeated injections typically improve the appearance of the dorsal hands by stimulating collagen and elastic fibers. The author of one study utilizing PLLA for dorsal hand rejuvenation used a Definitive Graduated Scale (DGS) to quantitate the improvement following treatment.[4] Patients in this trial reported a high degree of satisfaction with the rejuvenation attained with PLLA injections as 21 of the 27 patients treated reporting outcomes rated as at least satisfactory. The incidence of papule formation in this study was confined to a single patient.

Calcium hydroxylapatite has been espoused for hand rejuvenation by those who point to its relative ease of use and relative low cost. Various techniques for dorsal hand rejuvenation with this product have been described. On average, volumes of approximately 1.3 mL per hand are typically utilized. Another advantage of this product is that it may easily be mixed with anesthetic to provide a comfortable procedure.

Hyaluronic acids were one of the first modern fillers utilized for hand rejuvenation. Their advantages include their transparent nature and their gel texture, which is easily dispersed in the subcutaneous space. Typical volumes required for most procedures are approximately 1 to 2 mL per hand.

While each of these approaches has its own advantages, and disadvantages, there is no agreed upon scale by which baseline measurements and treatment results may be measured. When compared with cross-linked, human collagen, hyaluronic acid was shown to provide a more cosmetically acceptable result.[5] In this study, a 5-point scale was utilized to score satisfaction.

Treatment for the "palette," or surface of the dorsal hands, attempts to restore a more homogenous appearance and to impart a more uniform texture. Among the options that may be considered are fractional resurfacing, chemical peels, lasers, and IPL. These latter devices have been reported to improve the appearance of lentigines and other pigment issues; they also improve the texture of the skin and thickness of the dermal support layer.[6]

DISCUSSION

The Scale

The Beer Hand Scale (BHS) is a 4-point scale that rates the appearance of aging on hands as none, mild, moderate or severe. It has been validated in a survey of 50 people and has a high degree of concordance (Figure 5). The scale is a useful tool with which to assess dorsal hand appearance, and it is reasonable to use as a basis for hand evaluations and to quantify progress (or lack thereof) in a hand-rejuvenation regimen.

On one end of the spectrum is a "none" or grade 0 rating (Figure 1). This hand would be typical of someone who is under 30 years of age. The extensor tendons are not prominent as they are masked by a layer of connective tissue. Veins that are visible are straight rather than tortuous. No substantial degree of photodamage is apparent.

The next gradation on the scale is a "mild" or grade 1 rating (Figure 2). This is typical of a 40-year-old hand where some of the buffering connective tissue has been lost. Extensor tendons begin to be visible and, for the first time, hands begin to look old. The epidermal correlate of these dermal changes is an occasional lentigo and/ or actinic keratosis which impart a less homogenous surface appearance. Both the "none" and the "mild" hands would be treatment goals rather than indications for treatment.

Once the transition to "moderate" (grade 2) has occurred, patients look at their hands as visible stigmata of aging and they begin to seek treatments with fillers, cosmeceuticals and lasers. Many of them will already have had treatments for their face with botulinum toxins, fillers and other modalities. They see the hands as a "disconnect" — a sign of aging that needs to be addressed. Typically, grade 2 patients are in their 50s and the veins are beginning to become tortuous. The extensor tendons are visible and there seems to be little separating them from the overlying skin (in fact, this is frequently the case). Epidermal changes correspond to the dermal changes and, depending

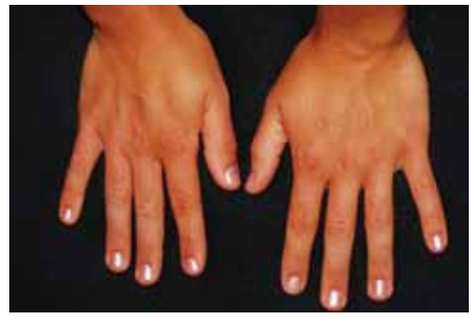


FIGURE 1. A grade 0 hand; no significant tendon or vessel prominence, no visible photodamage.

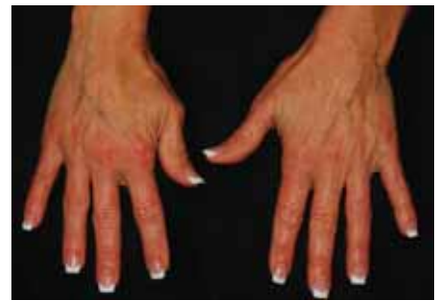


FIGURE 2. A grade 1 hand shows the beginning of the aging process with some prominence of the tendons, some increased visibility of the veins and mild photodamage.

on the photodamage, there are typically many lentigines and/ or actinic keratoses noted (Figure 3). Patients with moderate dorsal hand aging are good candidates for treatment as they have enough changes that improvements will be noticeable and not so much that it is difficult to effect a change.

Patients with "severe" (grade 3) dorsal hand aging are typically over the age of 65. Their extensor tendons are plainly visible with no significant connective tissue barrier separating them from the atrophic epidermis. Vessels are stringy and tortuous. The epidermis is marked by diffuse photodamage changes with hyper- and hypo-pigmentation, actinic purpura, actinic keratoses and lentigines (Figure 4).

The use of a 4-point, validated scale to grade dorsal hand aging has several useful features for clinicians as well as for researcher comparing different treatments for dorsal hand aging. It enables physicians and patients to assess a starting point for their treatment and agree upon what goals may be attainable with different treatments. During a treatment program, photographs may be utilized to compare progress with reference photographs in addition to the patient's "before" photographs to better measure progress.

Clinical trials involving treatments for dorsal hand rejuvenation have, to date, not been able to make use of any means by which objective measurements could be obtained. Although similar scales have been utilized for other cosmetic areas treated, to the author's knowledge, the Beer Hand Scale is the first objective measurement.

The hand validation scale was obtained by showing reference photographs to 50 people and tabulating the data (Figure 5). Grade 0 (none) dorsal hand aging had a concordance rate of

FIGURE 3. Grade 2 hands demonstrate clear evidence of photodamage as well as easily identified tendons and vessels signifying loss of the dermal and subcutaneous layers.

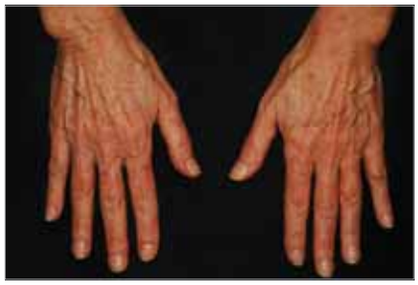


FIGURE 4. Grade 3 hands show advanced aging with tortuous vessels, stringy visible tendons, and severe photodamage.

92% with the other 8% rating the reference photograph for grade 0 as a grade 1. The photograph for grade 1 (mild) had a concordance rating of 86% with 6% rating the photograph as grade 0 and another 6% rating them as moderate. The grade 3 (moderate) example had 88% agreement with 8% rating it as a mild and 4% rating it as a severe. Finally, grade 4 had a 94% concordance rate with 6% rating the example as a moderate.

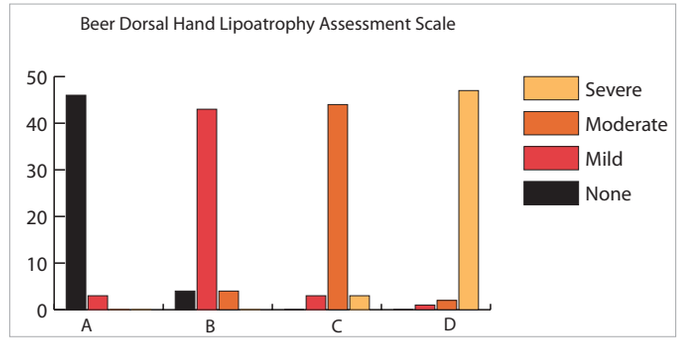
It is interesting to note that the highest rates of concordance are at the extreme ends of the scale (none and severe). When observers were given opportunities to select gradations that were more or less severe, a few observers rated these as a little worse or a little better than the author's characterization. However, it was valid for the majority of observers.

Limitations and Future Directions

As with every rating scale, there are limitations to the BHS. For instance, a larger survey population and a population that is geographically diverse (this population was from one South Florida dermatology practice) may give a more representative and useful refinement of the scale. Ethnic diversity is another consideration that should be addressed in future revisions. An additional significant limiting factor stems from the use of only one archetype of each hand grade that was utilized for grading. Future refinements should include multiple archetypes for each grade. Finally, a physician-derived grading scale should be developed to extend the validation to expert evaluators.

Future directions for the scale will most likely include larger, more geographic and ethnically diverse populations. It seems likely that refinements to the scale will include half point gradations and sub-typing for epidermal and dermal components of the scale.

FIGURE 5. The percentage of concordance for each grade is demonstrated by this graph. Each stage has a high rate of inter-observer agreement.



CONCLUSION

The Beer Hand Scale (BHS) represents one possible method of grading the aesthetic appearance of the dorsal hand. It should enable physicians to agree upon common reference points when evaluating their patients and those engaged in clinical trials to measure the degree of progress on a standardized 4-point rating system. At present, most clinicians who treat the face for aesthetic improvement are treating or considering treatment options for the hands. To date, there has not been any method of enabling patients or physicians to systematically rate the grade of hand aging or improvements gained with various treatments. This scale should help to definitively categorize dorsal hand aging and establish what is, and is not, a good hand rejuvenation.

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Advances in Collagen Fillers

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INTRODUCTION

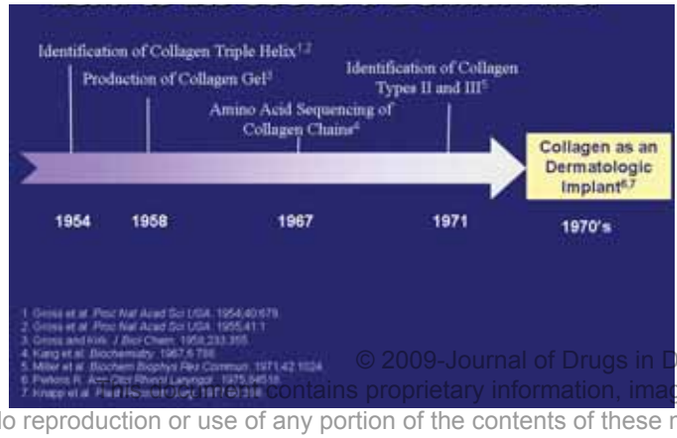
Collagen has been recognized as the major building block of dermal structures and has, since the advent of collagen-filler technology, always been considered an important source for soft-tissue injectable implants. Collagen gives support and structural integrity to the skin and associated soft tissue, and its loss conversely leads to the thinning and atrophic appearance of both intrinsic and photoaging skin. Collagen's triple-helix protein structure has a fiber architecture in which intermolecular cross-linking determines its biodurability in its natural state within the body. The natural balance of collagen degradation and regeneration is upset by ultraviolet (UV) radiation, creating photodamage that destroys collagen's structure and leads to such further damage as dermal loss, facial volume loss and consequent facial aging.[1]

BACKGROUND

The science and development of collagen began in 1964 with the identification of its triple helix. In 1968, collagen was first purified and it was soon discovered by Gross and Kirk that collagen gel could be produced by warming a solution of natural collagen. As collagen subtypes in mammals were identified, it was discovered that autogenic antibodies could be reduced by removing the non-helical amino acid carboxyl terminal telopeptides[2] (Figure 1).

In 1974, the first animal-model injections of collagen were performed successfully as dermal implants and, in 1978, the first injections of human and bovine collagen were performed into eight patients. These were to correct acne scars, subcutaneous atrophy and wrinkling. The results demonstrated a 50-80% correction of the conditions and were maintained up to 3 months. This was followed by the Tromovitch-Stegman multicenter trial from 1979–1980 of 5,109 subjects using a cross-linked collagen suspension with lidocaine that proved both the safety and efficacy of the product. The U.S. Food and Drug Administration (FDA) approved it for general usage as a dermal filler for the nasolabial fold in 1981. Thus, Zyderm® I (McGhan Medical, Santa Barbara, CA), later manufactured by Inamed Medical and then Allergan (Irvine, CA), became the first xenogenic agent for soft-tissue filling to be followed by two additional formulations of bovine collagen; Zyderm II (1983) and Zyplast® (1985)[3]. These collagen fillers are xenografts in that they are derived from different animal species (bovine). These products do meet many of the criteria of an ideal soft-tissue filling agent as they are ambulatory, reproducible, minimally invasive with little side effects or down time, and predictable efficacy.

FIGURE 1. Discoveries in collagen biology lead to its use as a dermal filler



In the late 1980s, research began on human cadaveric collagens such as AlloDderm® and Cymetra® (LifeCell Corporation, Branchburg, NJ). They are an acellular layer of collagen and elastin derived from cadaveric tissue banks. The products Cymetra (from LifeCell) and Dermalogen® (originally from Collagenesis) are pulverized and micronized for deep dermal injection to correct depressed acne scars and wrinkles. Because these substances required a large bore needle for injection and created a moderate amount of inflammation, they rapidly lost popularity and presently are not available.

Subsequently, bovine collagen products rapidly gained popularity and, since then, over 2.5 million individuals have received collagen implants. The products are divided into three types based on viscosity, concentration and cross-linking (Table 1), and all contain lidocaine. All three products may be injected through 30-gauge needles, although the technique and product placement of each differs.[4]

Because of the need for prior skin testing, a more recent form of human-derived collagen was developed without the need for skin tests, and was approved by the FDA in 2003. The three formulations of this human tissue engineered product are CosmoDerm™ 1, CosmoDerm 2 and CosmoPlast™; they correspond to the bovine products in viscosity but do not require skin tests.[5]

FIGURE 2. Surface Deformity: Correction vs. Overcorrection

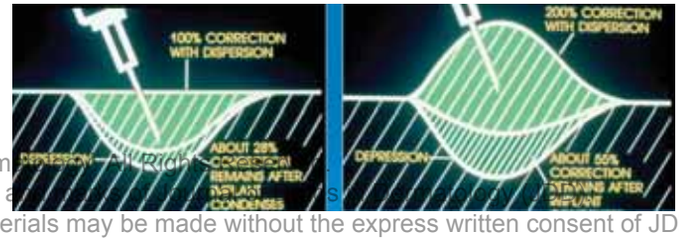


TABLE 1.

Collagen Types FDA Approved					
Type of Collagen	**Concentration of Collagen**	**Indications**	**Size of Syringe Available**	**Placement**	**Degree of Overcorrection**
Zyderm 1®	35 mg/ml Bovine	Fine lines: perioral, periocular, glabellar	0.5; 1.0; 1.5 cc	Superficial papillary dermis	150-200x
Zyderm 2®	65 mg/ml Bovine	Mild-moderate rhytids: scars, perioral	0.5; 1.0 cc	Mid dermis	100-150x
Zyplast®	35 mg/ml Cross-linked with glutaraldehyde Bovine	Deeper rhytids and folds: nasolabial, vermilion border, marionette lines	1.0; 1.5; 2.0; 2.5 cc	Deep dermis	No overcorrection
CosmoDerm 1™	35 mg/ml Human derived	Fine lines: perioral, periocular, glabellar	1.0 cc	Superficial papillary dermis	150-200x
CosmoDerm 2™	65 mg/ml Bovine	Mild-moderate rhytids: Scars, perioral	0.5; 1.0 cc	Mid dermis	100-150x
CosmoPlast™	35 mg/ml Cross-linked with gluteraldehyde Human derived	Deeper rhytids and folds: nasolabial, vermilion border, marionette lines	1.0 cc	Deep dermis	No overcorrection
Evolence®	35 mg/ml Cross-linked gel	Deep dermis	0.8 cc	Mid-to-deep dermis	No overcorrection

Zyderm and CosmoDerm at 35 mg/ml can be injected in the superficial dermis or mid-dermis. It is generally used as a superficial filling agent or placed in a layered fashion above the deeper more concentrated products. It requires an overcorrection of up to 150% as a significant amount of saline is absorbed. One can appreciate superficial placement by the color blanching of skin or *peau d'orange* (or "orange skin") with proper injection (Figure 2). Because Zyderm 2 and CosmoDerm 2 are 65 mg/ml collagen dispersed in saline, they do not require overcorrection and are placed in the mid-to-deep dermis. These collagen products will maintain correction for approximately three months after injection. Zyplast and CosmoPlast injectable collagens are different in that the collagen fibers are cross-linked with gluteraldehyde, enhancing the product's stability and longevity. It should be injected into the mid-to-deep dermis, with no *peau d'orange* effect, and it may last longer than the non-cross-linked forms.

FIGURE 3. a) Before and **b)** after CosmoPlast™ to nasolabial fold

The collagen implants were the first used to correct skin scars, wrinkles and folds and thus most of our basic injection techniques were developed using these products. Wrinkles and scars amenable for treatment are distensible, static as opposed to dynamic wrinkles and not caused by gravitation pull alone. They represent dermal volume depletion and, thus, the lost collagen is most appropriate for replacement. Glabellar lines, forehead wrinkles and crow's feet have a primary dynamic component which is effectively treated with Botox® but a static component can be treated with collagens. A primary indication for collagen replacement dermal filling is nasolabial wrinkles and folds, lip wrinkles and lip-volume filling, and perioral marionette lines.[5] The success of treatment is to choose the appropriate patient matched with the appropriate filler. To a large degree, the hyaluronic acid fillers (Restylane™, Juvéderm®) have replaced collagen as volume fillers for lips, deeper folds and volumizing. The need for collagen still exists for wrinkles and folds, and finer surface lines on the lips and other areas.

It has been 25 years since the first collagen fillers were released, and they still are used effectively. Their popularity though has greatly diminished by the release of the more versatile and longer lasting hyaluronic acid fillers. It is the author's belief,

TABLE 2

Glymatrix Technology

	Glymatrix™	Other
Biomaterial	Collagen	Vary (e.g., collagen, hyaluronic acid)
Cross-Linking Material	Natural sugar	Chemicals: Fixatives (formalin, glutaraldehyde, etc,)
Cross-Linking Degree	Controlled – producing programmed biomaterials	Limited – Either due to toxicity or adverse reaction
Durability	Enhanced At least 12 months	Limited 3-9 months
Matrix Properties	Mimics skin's three dimensional matrix, both structurally and functionally	Altered biologic properties

TABLE 3.

Pivotal Study (DP101 US-01): Study Design

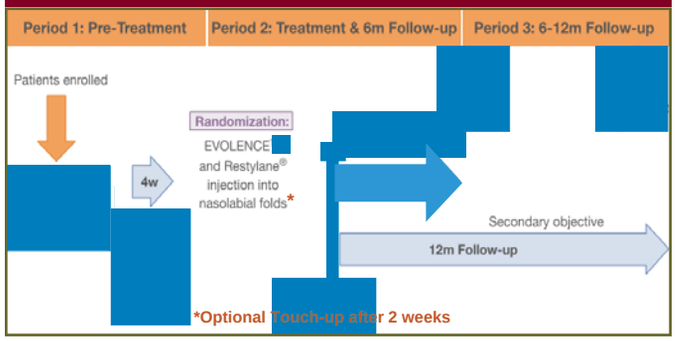
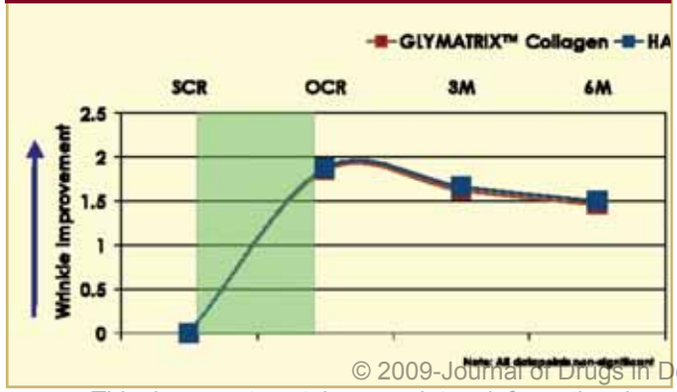


TABLE 4.

Improvement in Wrinkle



however, that there is still a place for injectable collagen filling material and his expectation that the supplier will keep these products on the commercial market (Figure 3).

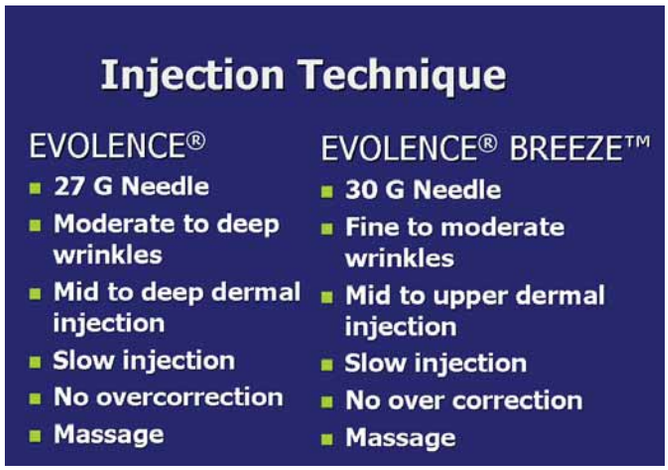
The need for a longer-lasting, less immunogenic—yet robust—dermal filer has led to the development of a new porcine-based dermal filler, Evolence®. It was developed in Haifa, Israel, by Col-Bar LifeScience, now a division of Johnson and Johnson. Rather than using mixed dermal collagen (types I, II and III), this product uses only type I collagen harvested from porcine Achilles tendon. Type I collagen forms the largest and strongest of fibers, making it ideal for implants and other medical devices, including heart valve replacements, corneal shields, wound dressings and surgical meshes for tissue repair. The fibers are then digested with pepsin for separation to monomeric collagen fibers and the immunogenic telopeptides are removed, eliminating the risk of xenogenic allergy. The fillers are then polymerized as reconstituted polymeric collagen. The polymeric collagen is then cross-linked with ribose-creating Evolence collagen.

This "glymatrix" process of cross-linking is unique to fillers in that the sugar has no known toxicity and thus larger amounts are used than found with glutaraldehyde, BDDE *(1,4 butanediol diglycidulether)* or other cross-linkers that are potentially toxic and permitted sparingly by FDA safety parameters. The glymatrix technology creates a longer lasting, more robust product which can provide correction for up to one year (Table 2). It has been used in Europe for over five years, with success, as a facial wrinkle and groove filler with little reported side effects or complications.[6]

Evolence is used for moderate-to-deep wrinkles and injected in the deep dermis with a 27-gauge needle. It is effective for correction of nasolabial folds and marionette lines. Evolence does have a thinner, more refined companion product—Evolence Breeze—which is intended for more superficial placement and lip filling. Evolence Breeze is injected through a 30-gauge needle in the mid dermis. Both products are different from their bovine collagen predecessors and the technique of injection is, thus, different (Figure 4). Evolence should be injected with a linear threading technique with a slow, steady injection and no overcorrection. It was FDA-approved in June 2008 and released on the open market in September 2008 that same year. Evolence Breeze is not yet FDA approved but is available in Europe and Canada.

Evolence has been thoroughly studied for hypersensitivity with skin-test and antibody studies that confirmed its safety so that no skin test is required.[7] Multiple biopsy studies in animal models and humans confirm the good tissue integration, and host response, with demonstrable evidence of fibroblastic activity and neocollagenesis. Evolence is also non-hydrophilic, which minimizes swelling, and is hemostatic, which minimizes bruising and bleeding. It thus offers predictable correction with little down time.[8]

FIGURE 4. Injection Technique



Contraindications and precautions include: hypersensitivity reactions to collagen, patients with bleeding disorders, and patients with compromised immune function. The product is tested and indicated for injection into dermis of the face and care should be taken to avoid blood vessels because of vascular occlusion and subsequent necrosis, especially in the glabella.

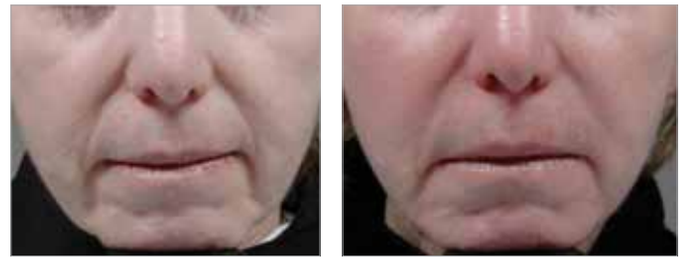
The pivotal FDA study for Evolence was a double-blind, within-subject, bilateral facial comparison of Evolence vs. Restylane for the correction of nasolabial folds. Its evaluation was for efficacy, safety and longevity. Testing was conducted at six investigator sites with Rhoda Narins, MD and the author[9] as principal investigators (Table 3).

Subjects were selected with moderate-to-deep nasolabial folds on the modified Fitzpatrick wrinkle scale (2 or greater) and up to two injections were used to correct both folds: one with Evolence, the other with Restylane. The subjects were followed for 6 months, initially, and then for 1 year for efficacy and safety. Although the product has been used with no clinical allergic reactions, skin tests as well as sequential antibody levels were performed and followed throughout the study. The results from immunoglobulin titers and skin tests indicated no potential for allergic reactions and the FDA did, in fact, release the product without the need for prior skin testing.

The data from the initial 6 months of the study indicated no meaningful difference between the Evolence treatment sides and the Restylane treated nasolabial folds at any point (Figure 5). Patient evaluation also indicated a 90% improvement over baseline at 6 months on both sides. In addition, the safety profiles were similar for both with no significant reaction. The reaction of induration, swelling, bruising and pain was higher on the non-animal stabilized hyaluronic acid (NASHA) treatment side (Table 4).

The study thus demonstrated non-inferiority to HA in the correction of nasolabial folds at six months with a 90% report of patient satisfaction as compared to baseline.

FIGURE 5. Six months post-treatment with Evolence and Restylane



Out of the 148 subjects followed for six months, 145 patients were followed for efficacy and safety for an additional 12 months. Filler persistence or a wrinkle severity score of 1 over baseline was maintained at 12 months in 75% of the subjects. In addition, long-term safety was good with no delayed granulomas or infections.[10]

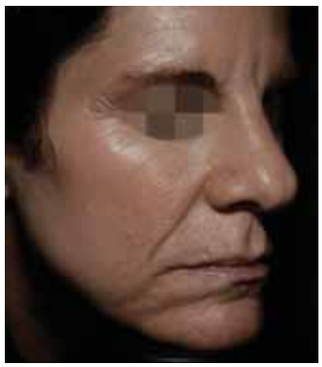
The Practical Application of Evolence

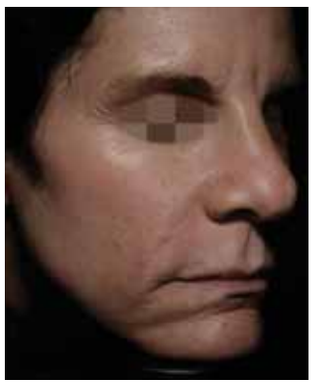
Evolence is supplied in a 1 ml syringe with a 27-gauge needle. The recommended treatment protocol is a mid-to-deep dermal injection using antero- or retro-grade tunneling technique. The slow continuous flow of the product during injection will give an even distribution of implant through the area to be corrected. Following and during injection, the implant should be massaged to ensure even correction with no papules or nodules. This collagen "sets up" quickly and if the product is injected too quickly or with stops and starts, it will be lumpy and will produce nodules. Overcorrection in any area is not recommended as it will remain if not vigorously massaged early on (Fig 6).

As one evaluates a patient for injection, volume for correction should be estimated which will relate to the number of syringes needed. There is no lidocaine in the product, therefore adequate local or topical anesthesia is needed. Some of the topical "caine" mixtures may suffice for nasolabial fold injections or patients can have an infraorbital and/or mental nerve block for full local anesthesia. Make-up should be removed and the area should be cleaned thoroughly with alcohol wipes. The product is stored at room temperature and in fact should be warmed between hands prior to injection. A cold product may clog the needle or clump up within the skin. This is further reason to abstain from the use of ice with Evolence for pre-or post-injection. The needle is tightly affixed to the luer lock and the product should be used immediately after assembling and priming the syringe and needle. One should inject at a slow and steady pace, without interruption. This product flows easier and smoother than many HAs, so less pressure should be used on the plunger to give that slow even flow.

Immediately after injection, gentle massage is needed to remodel and sculpt the injected area and also to palpate for any papules or bumps. This should be done immediately as the product will set up quickly. Once done, the product will not migrate.

Undesired problems that can occur are generally those that appear with most fillers. These include pain on injection, erythema, edema, ecchymosis and urticaria. Of special concern





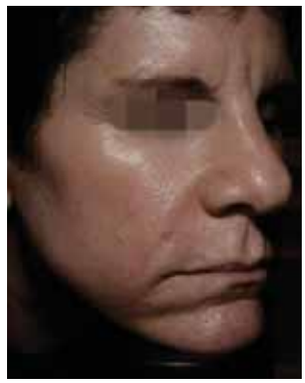
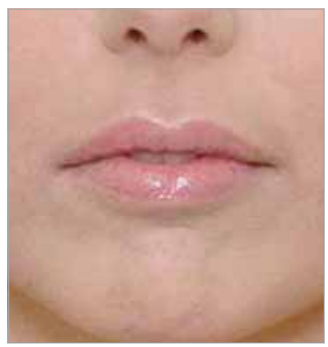


FIGURE 6. a) Pre-injection of Evolence® to nasolabial fold, **b)** 30-60 minutes post-injection and **c)** 12-16 hours post-injection

FIGURE 7. Nasolabial lines **a)** before treated and **b)** after treatment with Evolence



are the embolism, ulceration and necrosis that can occur with injection in an artery. It is, thus, not indicated in the glabellar region as other cross-linked collagen fillers have also been so restricted. Nodularity and post injection bumps are an unwanted problem and have been seen with Evolence injected into the lips. The product thus should not be used as a lip filler. Evolence Breeze, which is not yet available in the U.S., will be the collagen product for lip use. Nodules and papules can be avoided with good injection technique and appropriate placement of the product in the mid to deep dermis.

If a nodule is present after 24 hours, it may be difficult to eradicate. One can try saline injection to break up the collagen fibers or conservative use of diluted triamcinolone acetamide (2.5 mg/ml dispersed in saline). Overuse of steroid injection, however, will produce atrophy in surrounding skin, making the situation worse.

Evolence thus has a real value in our armamentarium of dermal fillers as a longer lasting collagen delivering good correction with immediate results and minimal down time (Figure 7). It is expected that the soon-to-be-released Evolence® Breeze product will be a valuable addition for use in lips and more superficial filling.

CONCLUSION

Collagen products were the first injectable implant for use in the U.S. and today remain a mainstay for dermal filling. It replaces aging and atrophic collagen in photoaging skin and gives a very natural, predictable correction. Whether bovine, synthetically human based or porcine, the collagen family will remain an important tool for treatment of the aging face

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Advanced Techniques for Sculptra

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ABSTRACT

Poly-L-lactic acid (PLLA) is one of several products known as bioactivators that have a unique mechanism of action, stimulating fibroblasts to produce collagen causing an increase in volume. This mechanism of action has important implications in the way these products are used in order to optimize outcomes and avoid adverse events. The purpose of this article is to review the currently recommended techniques, as well as to illustrate some of the lesser known "off label" cosmetic uses for which it is appropriate.

INTRODUCTION

Poly-L-lactic acid (PLLA) is one of a number of products known as bioactivators that have a unique mechanism of action, stimulating fibroblasts to produce collagen causing an increase in volume. This mechanism of action has important implications in the way these products are used in order to optimize outcomes and avoid adverse events. Initial studies evaluating the use of PLLA in the treatment of human immunodeficiency virus (HIV) lipoatrophy revealed it to be a safe and effective product capable of replacing significant amounts of volume, but with a relatively high number of palpable, non-visible subcutaneous papules.[1] Subsequent isolated case reports of purported "granulomas" caused some physicians to avoid the product altogether.[2] As experience has been gained with this product over the last decade of use, and parameters adjusted accordingly, we have seen a dramatic decrease in the number of device-related adverse events.[1,3,4] The purpose of this article is to review the currently recommended techniques, as well as to illustrate some of the lesser known "off label" cosmetic uses for which PLLA is well suited.

DISCUSSION

Product Composition and Mechanism of Action

PLLA is a synthetic polymer derived from the alpha-hydroxy-acid family that is both biocompatible and biodegradable. Injectable PLLA (Sculptra®, Dermik Labs, Bridgewater, NJ) is a resorbable soft-tissue augmentation material of non-animal origin containing microparticles of PLLA measuring an average of 40-63 microns in diameter. This particle size ensures that the particles are large enough to avoid phagocytosis by dermal macrophages or passage through capillary walls, but small enough to be easily injected by needles as fine as 26-gauge[5]. The mechanism of action of injectable PLLA involves the degradation of the microsphere particles, in which an inflammatory tissue response is initiated and a fibrous capsule surrounds the polylactides. Over time, the product degrades, the inflammatory response wanes, and the ensuing collagen deposition increases. This fibroplasia produces the desired cosmetic result.[5] As noted above, this has important clinical implications dictating both how and where the product can be used in order to optimize results and avoid adverse events.

Technical Considerations with PLLA

There are some simple but critical technical differences in the manner in which bioactivators/collagen stimulators are used as opposed to replacement fillers. Given that subclinical granulomatous inflammation is a normal tissue response to injected collagen stimulators, the clinical significance of granulomatous inflammation should be based on the extent, severity and long-term progression of the response.[6] Mention should be made of the issue of granulomas, and these should be recognized as a separate entity than "lumps and bumps" resulting from an overabundance of microparticles.

Granulomatous reactions, sometimes occurring months to years after administration, have been reported with all currently available commercial devices including collagen, hyaluronic acid, PLLA, silicone, calcium hydroxylapatite (CaHa), polymethylmethacrylate (PMMA), hydroxyl-ethyl-methacrylate and polyacrylamide gel[6]; in fact, this list seems to grow with every newly introduced product. True inflammatory granulomas are rare and unpredictable, and the events leading to their appearance are not yet clearly understood. Fortunately, the rate of clinically detectable granuloma formation is very low (reported to vary between 0.01 and 0.1%) and most resolve with or without treatment.[6]

Lumps and bumps, as opposed to true granulomas, are not rare. However, unlike true granulomas, they are both predictable and preventable with proper technique—the silicone "microdroplet" technique, for example, has proven safe and effective after a long history otherwise shrouded in controversy.[6]

While replacement fillers such as hyaluronic acid can be used in any amount desired to achieve full correction at a single session, "too much, too soon" with collagen stimulators may lead to overcorrection, where an overabundance of stimulating microparticles may lead to a vigorous host response and the subsequent the appearance of lumps and bumps. Very early lumps and bumps are likely accumulations of product microparticles alone, while later lumps and bumps likely signify product plus host reaction. It is for this reason that it is recommended that the patients are brought to a gradual progressive correction with multiple treatment sessions with these agents. Important techni-

cal considerations of which the practitioner should be aware *all relate to avoiding overcorrection* and include the following:

Product Reconstitution

PLLA is supplied as a lyophilized powder that is diluted with sterile water for injection and then left to hydrate to disperse the particles. Although it is obvious why too concentrated a solution would overcorrect, it is less obvious, but just as important, to give the particles enough time to hydrate and disperse to avoid injecting dry microclumps of product into the patient. A constantly clogging needle may reflect this (although it is usually secondary to too much foam in the syringe). A dilution of at least 5 cubic centimeters (cc) left to hydrate a minimum of over 2 hours, and preferably overnight, is currently recommended. Be aware that dilutions of over 10 cc may diffuse widely. This is useful when covering a wide surface area, such as the preauricular area in a post-facelift patient with atrophy, but may result in a "chipmunk" appearance when used to shape a cheek.

Product Amount

The amount of product used at any single treatment session should be determined solely, and completely, by the amount of surface area to be treated at that session using approximately 0.1-0.2cc/cm^2. The final volumetric correction is addressed by the number of treatment sessions. The novice injector should be aware that it is initially difficult to resist the temptation to treat to full correction at any one session (although this may be possible with patients needing minimal treatment), and recall that blanketing the surface area to be treated at that session is the endpoint.

Product Placement

This can be done with a 1 cc or 3 cc syringe and a 25-gauge (long or short) or 26-gauge (short) needle. Depth of placement varies with location. The product is placed in the dermal subcutaneous junction or subcutaneous layer in the cheeks, nasolabial folds, and lower face using the cross-hatch or fanning technique and may be placed as depot injections supraperiosteally along the zygoma, maxilla and mandible. Be aware that deep supraperiosteal treatments with bulking agents in the area of the canine fossa/pyriform aperature has led to ischemia and necrosis.[7] Temple injections are placed deeply, under the temporalis fascia. Manufacturer instructions are to place 0.05 cc depots in the temple, however, it is common practice among experienced users to place 0.3–0.5 cc depot in this area, followed by vigorous massage. Inject slowly in a cross-hatch pattern when becoming familiar with the product. Recall that it is mixed in water, making for a very low viscosity solution when compared with a hyaluronic acid gel. The novice injector must be vigilant to ration the product carefully to avoid inadvertent overcorrection. Fanning has the advantage of less needle sticks, but again the novice injector should be vigilant to avoid multiple deposits at the apex of the fan.

Product Placement Precaution

Avoid placement in or through areas of dynamic muscle movement. Frequent reports of "lip lumps" led to recommendations against the use of PMMA, PLLA and calcium hydroxylapatite in this area. It is assumed that the perioral muscle movement in this area leads to a clumping of particles, which in turn leads to localized overcorrection and lumps. Injections in the modiolus or depressor anguli oris muscle may behave in a similar fashion. Additionally, periorbital supraperiosteal injections approached through the orbicularis oculi muscle have resulted in papules shown on histopathology to be clumps of product embedded in muscle.[8] *Treat. Wait. Assess.* Wait a minimum of 4 weeks between treatments to avoid lumps and bumps. Also be aware that although the majority of the response will be clinically apparent approximately 4 weeks after treatment, it may continue to improve for up to one year. This means that a patient who has had three monthly treatments may still see another 30% improvement at one year with no additional treatments. A fourth treatment in this case may result in a fat face.

After-care

Massage after every 2 to 3 injections and again at the end of the treatment. The patient should be instructed to massage over the next few days using the "rule of 5s" (5 minutes/5 times daily/5 days).

FIGURE 1. Case 1: Before and after. 38-year-old HIV+ female; 2 vials per treatment; 3 treatments

FIGURE 2. Case 2: 36-year-old female; 1 vial per treatment; 2 treatments

Clinical Implications of Mechanism of Action/ Volume Loss and Structural Changes in Multiple Tissue Layers

It is now recognized that contributions to changes seen in facial aging stem from volume changes in all structures of the face including the skin, subcutaneous fat, muscle and underlying bony support. These structural changes are occurring not independently, but interdependently, leading to morphological changes in both the three-dimensional topography of the face as well as in the proportions and balance of the face.[9] PLLA may be used to address many of these changes as its mechanism of action allows the product to be used to strengthen dermal support and structure, as well as to add volume to the subcutaneous soft-tissue layer or the craniofacial skeleton. Our experience with PLLA in the human immunodeficiency virus (HIV) population has made us all aware that this product is capable of producing significant amounts of volume when used in multiple treatment sessions (almost like an "off the shelf" fat), but that this may require significant amounts of product. It has also been used for this purpose in older cosmetic patients to restore youthful contours to the face and jawline, which serves to lift "sagging" skin from the neck. A recent study published by Hanke *et al.* notes that non-HIV patients require less product to achieve and sustain correction than do HIV patients with similar volume loss.[10,11]

In this author's practice, PLLA is a cost-effective choice for younger patients with early volume changes. Subtle, natural changes ("I just want to look less tired, but I don't want to look 'done'") are achievable in this 30–40-year-old age group with very conservative amounts of product. Small changes in shape, topography, proportions, balance and symmetry can have a large impact on the face. Figures 1 through 5 illustrate the use of PLLA in a younger population. Note the improved skin texture and tone in all patients. Also note the improvement in lower eyelid bags seen with treatment along the medial zygoma and maxilla as well as around the deep medial cheek fat pad[12,13]—no periorbital treatments were done on these patients. This supports the speculation that just as volume loss may lead to undesirable changes in adjacent areas, the replacement of volume in one area may possibly lead to desirable changes in another area.

This has been eloquently discussed by Rohrich and Pessa in their recent examination of the fat compartments of the face.[12,13] Additionally, note the changes in facial balance and shape achieved by combining temple injections with those of the midface. As the temple is restored to its youthful convexity the face is returned to a more oval shape and the brows are lifted. No botulinum toxin was used in patients 1 through 4. Finally, supraperiosteal treatments along the canine fossa, pyriform aperature and mandible can help restore the "golden ratio" (of 1/3:2/3s) of the perioral area in the lower third of the face

CONCLUSION

PLLA is a safe and effective treatment for facial aging in both younger and older patients. The unique mechanism of action of this product requires attention to the technical details outlined above. This mechanism of action, coupled with its low viscosity, has several important implications. Where to use it to best advantage is enhanced by looking at the face as a whole, rather than focusing on nasolabial folds or marionette lines as isolated entities. It can be used to address aging changes in several struc-

FIGURE 3. Case 3: 39-year-old female; 1 vial per treatment; 2 treatments

FIGURE 4. Case 4. 37-year-old female; 1 vial per treatment; 3 treatments

FIGURE 5. Case 5: 35-year-old female; 2 vials per treatment; 1 treatment

tural layers of the face serving to improve dermal strength and support, add subcutaneous volume, as well as act as an "injectable craniofacial implant" in a supraperiosteal location to more closely approximate the facial proportions of youth.[9] As the final result is thought to be contingent upon new collagen formation, this procedure is not carried out in one step but through multiple treatments. Follow the patient's progress using the manufacturer's mantra of *Treat. Wait. Assess*. Younger patients may need less product and fewer sessions as well as fewer retreatment sessions. Treatments are usually administered at one-month intervals. This is not the optimal choice for someone looking for a quick fix for an upcoming event. However, an injectable-savvy patient is often happy to accept the gradual result in exchange for the long duration of the result-usually about 2 years.

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Combination Therapy of the Aging Hand Using Non-Ablative Fractional Resurfacing, Radiofrequency & Calcium Hydroxylapatite

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ABSTRACT

The aging hand poses a number of therapeutic challenges for rejuvenation and multiple factors are involved, including: dyschromia, lentigines, textural anomalies, volume loss, laxity and the visibility of superficial veins. As with facial aging, multimodal approaches using technologies such as injectables are necessary for complete non-surgical hand rejuvenation. A newly defined scale, the Merz scale, allows for a systematic approach to the aging hands, using a five-point scale stratified for consistent rating. Using elements from the Merz scale, an algorithm has been developed for combined rejuvenation of the aging hand using: fractional resurfacing to address dyschromia, pigmentary anomalies and textural change; unipolar radiofrequency for laxity; and calcium hydroxylapatite injections for volume loss. While each of the three modalities address unique aspects of the aging hands, all three together play synergistic roles in neocollagenesis for sustained improvement and, further, all three procedures can be performed on the same day or in a staged fashion.

INTRODUCTION

The aging hand poses several therapeutic challenges for rejuvenation. Multiple factors are involved including dyschromia, lentigines, textural anomalies, volume loss, laxity and the visibility of superficial veins. As with facial aging, multimodal approaches using devices and injectables are necessary for complete non-surgical hand rejuvenation. This paper reports the combined use of non-ablative fractional resurfacing, unipolar radiofrequency and calcium hydroxylapatite injections as a systematic approach to hand-rejuvenation.

BACKGROUND

The approach to hand rejuvenation has generally been a piecemeal one, usually capitalizing on monotherapy. Surface dyschromia and anomalies of pigmentation, such as lentigines, have been addressed with the use of lasers, pulsed light and superficial chemical peels.[1,2,3] Volume restoration has been addressed with the use of autologous fat and dermal fillers such as poly-L-lactic acid and calcium hydroxylapatite.[4,5,6] Laxity has been addressed with the use of chemical peels.

While each of these montherapies has its merits, individually each is generally incomplete as a standardized, systematic approach to hand rejuvenation has not yet been established. Recently, a Merz scale for hand grading was introduced to objectively quantify the severity of the aging hand[7] and to establish a photonumeric scale for clinical research and practice. The author has incorporated the Merz scale for hand rejuvenation into an algorithm for combined rejuvenation of the aging hand.

The Merz Scale for Hand Rejuvenation

The Merz hand grading scale[7] is a 5-point photonumetic rating scale which quantifies the severity of the aging hand and was developed by expert-rated photographs of aging hands in correlation with morphed images. The scale ratings are primarily based on volume loss and appearance of superficial veins, with scale ratings of 0 for no loss of fatty tissue, 1 for mild loss of fatty tissue and slight visibility of veins, 2 for moderate loss of fatty tissue and mild visibility of veins, 3 for severe loss of fatty tissue and moderate visibility of veins and tendons, and 4 for very severe loss of fatty tissue and marked visibility of veins and tendons.

Development of an Algorithm for Hand Rejuvenation Using the Merz Scale

The Merz scale is an excellent guide with which to address the use of dermal fillers for the aging hand. **[AU Pls. supply Table]** Table 1 describes the Merz scale, in combination with ratings of laxity and superifical dyschromia, to create a systematic approach to hand rejuvenation. For example, patients in their 30s present with Merz scale 1 and mild laxity and dyschromia; patients in their 40s present with Merz scale 2 and moderate laxity and dyschromia; patients in their 50s and 60s present with more advanced Merz scales 3 and 4, along with severe laxity and dyschromia. An algorithm has been designed to incorporate these scales for combined hand rejuvenation using fractional resurfacing, radiofrequency and calcium hydroxylapatite

Technique

Combined hand rejuvenation can be performed on the same day or as a staged process. We will describe both approaches. Same-day multimodal hand rejuvenation is often the preferred treatment as it is safe and patients see a more immediate result due to the rapidly volumizing effects of dermal fillers.

The first technology to be utilized is unipolar radiofrequency, as patient feedback is necessary to assess adequate delivery of the

FIGURE 1. Before-and-after same-day hand rejuvenation with unipolar radiofrequency, single-treatment 1550 nm non-ablative fractional resurfacing and calcium hydroxylapatite injections

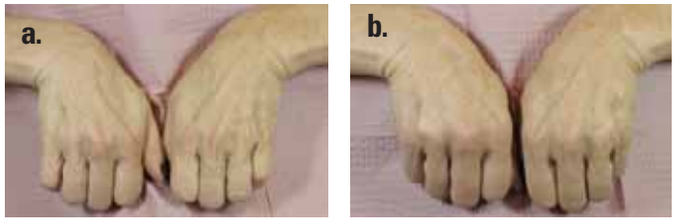
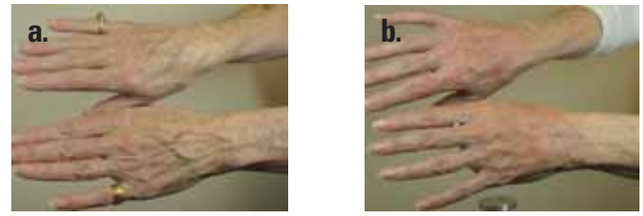


FIGURE 2. Before-and-after staged treatments for hand rejuvenation of single-treatment unipolar radiofrequency, three 1550 nm non-ablative fractional laser treatments and calcium hydoxylapatite injections



radiofrequency energy. A shallow tip using a unipolar radiofrequency device (Thermage NXT, Thermage-Solta Medical, Hayward, CA) is utilized on one hand to deliver approximately 200 pulses. After completion, topical anesthetic using a mixture of 7% lidocaine and 7% tetracaine is utilized to provide anesthesia in preparation for fractional resurfacing. The contralateral hand is then treated with radiofrequency and, upon completion, topical anesthetic is applied to that hand. Upon completion of the radiofrequency treatment, the initially treated hand is now ready for fractional resurfacing.

Patients who display Merz scale 1 to 3 typically are best treated with non-ablative fractional resurfacing using a 1550 nm erbium doped laser (Fraxel Restore, Fraxel Labs-Solta Medical, Hayward, CA) at settings of 20 to 30 mJ and treatment densities of 20 to 30% (Figure 1). Upon completion of one hand, the contralateral hand is then treated. Upon completion of non-ablative fractional resurfacing, volumetric restoration is addressed using calcium hydroxylapatite with a modified technique originally described by Busso *et al*.[8] A suspension mixture of 1.3 cc of calcium hydroxylapatite (Radiesse™, BioForm Medical, San Mateo, CA) with 0.15 cc of 2% lidocaine using a female-to-female connector is utilized immediately before injection. For Merz scale 1 to 2, typically one syringe is required per hand. For more advanced Merz scales, 3 and 4, two syringes per hand may be necessary for adequate volume correction. The suspension of calcium hydroxylapatite produces significant ease of flow of injection, reduced resistance, reduced post-injection edema and eccymoses, as well as reduced anesthesia requirements. Ablative fractional resurfacing may also be appropriate for certain patients, such as those with Merz scale 4. If this is performed, we usually delay dermal filler injection and perform it after two-to-three weeks in order to ensure optimal wound healing.

Staged multimodal hand rejuvenation is also appropriate and can fit nicely with timing and sequence. On the first treatment schedule, radiofrequency and the first non-ablative fractional resurfacing procedure is performed and, after a series of non-ablative fractional resurfacing treatments, which are usually spaced four weeks apart, calcium hydroxylapatite injections are performed on the last fractional laser resurfacing treatment date (Figure 2). It is also safe, and effective, to perform radiofrequency and non-ablative fractional resurfacing over calcium hydroxylapatite[9] if volumetric treatments are done first.

DISCUSSION

The aging hand has posed numerous challenges for rejuvenation. Most approaches have tackled aging hands with monotherapy, which does not address all aspects of hand rejuvenation. Moreover, a systematic approach to hand rejuvenation, one using standardized scales and algorithms, have never been established. This paper describes the first systematic approach to multimodal hand rejuvenation using fractional laser resurfacing, unipolar radiofrequency and calcium hydroxylapatite.

Non-ablative fractional resurfacing is a safe and effective modality with which to address dyschromia, pigmentary anomalies and texture of the aging hand and is safe and effective off the face.[10] Typically, skin resurfacing on the hand has been limited due to the risks of hypertrophic scarring and pigmentary loss. Ablative fractional resurfacing may offer a solution for more advanced photoaging of the hands. Moreover, non-ablative fractional resurfacing is safe in all skin types and, in darker skin, the main superficial aspect of hand aging is textural change. Unipolar radiofrequency of the hands addresses laxity. The development of shallow tips using lower fluencies has dramatically increased the safety and efficacy of radiofrequency on and off face.[11] As with non-ablative fractional resurfacing, unipolar radiofrequency is truly color-blind and can be used on all skin types.

Device-based hand rejuvenation does not offer "immediate" gratification, as the results of fractional resurfacing take multiple treatments in the non-ablative mode, with results best appreciated several months after treatment. Unipolar radiofrequency is often a single-treatment approach but also requires several months to realize final outcomes.

The ideal filler for the aging hand is one that produces both immediate and delayed results. Calcium hydoxylapatite is an example of such a dermal filler, as it is immediately volumizing, with long duration, and shows incremental improvements. Calcium hydoxrylapatite produces an immediate correction when injected into soft tissue. The aqueous carrier is gradually absorbed over time but the calcium hydroxylapatite microspheres remain intact, serving as a matrix for the development of new tissue. The production of new collagen around the implanted microspheres is the result of a local fibrohistiocytic response.[12] One month after injection, fibrin surrounds the microspheres without evidence of inflammation. At three months, an outer capsule—comprised of fibrin, fibroblasts

TABLE 1.

ORIGINAL MERZ SCALE FOR HANDS	MODIFIED SCALE	TREATMENT APPROACH
0- No loss of fatty tissue	Merz scale 0 and no photodamage	Sunscreen and topical agents (retinoids)
1- Mild loss of fatty tissue and slight visibility of veins	Merz scale 0 and early photodamage	Intense pulsed light, Q-switched laser or light nonablative fractional resurfacing +/- unipolar radiofrequency
2- Moderate loss of fatty tissue and mild visibility of veins and tendons	Merz scale 2 and mild photodamage and early laxity	Nonablative fractional resurfacing, dermal filler +/- unipolar radiofrequency
3- Severe loss of fatty tissue and moderate visibility of veins and tendons	Merz scale 3 and moderate photodamage and moderate laxity	Nonablative fractional resurfacing, dermal filler, unipolar radiofrequency
4- Very severe loss of fatty tissue and marked visibility of veins and tendons	Merz scale 4 and severe photodamage and severe laxity	Ablative fractional resurfacing and staged dermal fillers, unipolar radiofrequency

and macrophages—surrounds the calcium hydroxylapatite microspheres. At nine months, the microspheres become deformed, irregular and begin to be absorbed.[13] Studies have demonstrated integration of collagen fibers in and around the calcium hydroxylapatite microspheres.[14] Longevity of calcium hydroxylapatite has been demonstrated to be from 10 to 14 months.[14]

Therefore, the combination of delayed effects of fractional resurfacing and radiofrequency are synergistic with the immediate and delayed effects of calcium hydorxylapatite injections. Each of the three modalities address distinct entitites of the hands, with all modalities, combined, offering the benefit of sustained neocollagenesis.

CONCLUSION

The aging hand is manifested by a myriad of anomalies including dyschromia, lentigines, textural change, laxity and volume loss. A newly defined scale, the Merz scale, allows for a systematic approach to the aging hands, using a five-point scale stratified for consistent rating. Using elements from the Merz scale, an algorithm has been developed for combined rejuvenation of the aging hand using: fractional resurfacing to address dyschromia, pigmentary anomalies and textural change; unipolar radiofrequency for laxity; and calcium hydroxylapatite injections for volume loss. While each of these three modalities address unique aspects of the aging hands, all three combined play synergistic roles in neocollagenesis for sustained improvement. All three procedures can be performed on the same day or in a staged fashion. Future studies will examine the synergistic roles, such as increased longevity, of dermal fillers after radiofrequency and fractional laser treatments.

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Introduction of a Validated Rating Scale for the Management of Lip Fullness and Aging Options

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ABSTRACT

Lip fullness declines with aging. Injectable dermal fillers, most commonly hyaluronic acid and collagen-derived, are used to treat the border of the upper and lower lip to enhance lip contour and definition, although in the U.S. dermal filler use in the lips is off label. Dermal fillers can also effectively treat lip lines and perioral wrinkles that accompany facial aging and photodamage. Lip volume can also be improved with treatment in the lip body to create or restore fullness. In order to establish a method for objective quantification of lip volume, a 5-point photonumeric rating scale was developed in conjunction with Merz Pharmaceuticals for use in clinical research and practice. The scales are a series of visual guides that have been developed to address regional areas of the face, including the perioral region. Lip fullness is rated from 0 or "Very Thin" to 4 or "Full." The lip fullness scale is helpful in the clinical as well as research setting.

INTRODUCTION

Anatomy of the Lips and Perioral Region

The anatomy of the lips includes skin and mucous membranes, which surround soft tissue and a muscular interior. The lips begin the entrance to the oral cavity. Lip functions are multi-factorial, which requires a complex system of muscles and supporting structures. The upper lip extends from the base of the nose superiorly, to the nasolabial folds laterally, and to the free edge of the vermilion border inferiorly. The lower lip extends from the superior free vermilion edge superiorly, to the commissures laterally, and to the mandible inferiorly. Around the lip border where the vermilion meets the skin, a fine line of pale skin, known as the white line of the lip, accentuates the color difference between the vermilion and normal skin. Along the upper vermilion border, two paramedian elevations of the vermilion form what is known as the Cupid's bow. Two raised vertical columns of tissue form a midline structure called the philtrum. The labiomental crease passes horizontally in an inverted u-shape across the lower lip. From superficial to deep, the layers of the upper and lower lips include the epidermis, subcutaneous tissue, orbicularis oris muscle fibers and mucosa. Perioral musculature consists of three groups of muscles categorized by their insertion. Group 1 muscles insert into the modiolus, group 2 muscles insert into the upper lip and group 3 muscles insert into the lower lip.[1]

The Effects of Lip Aging

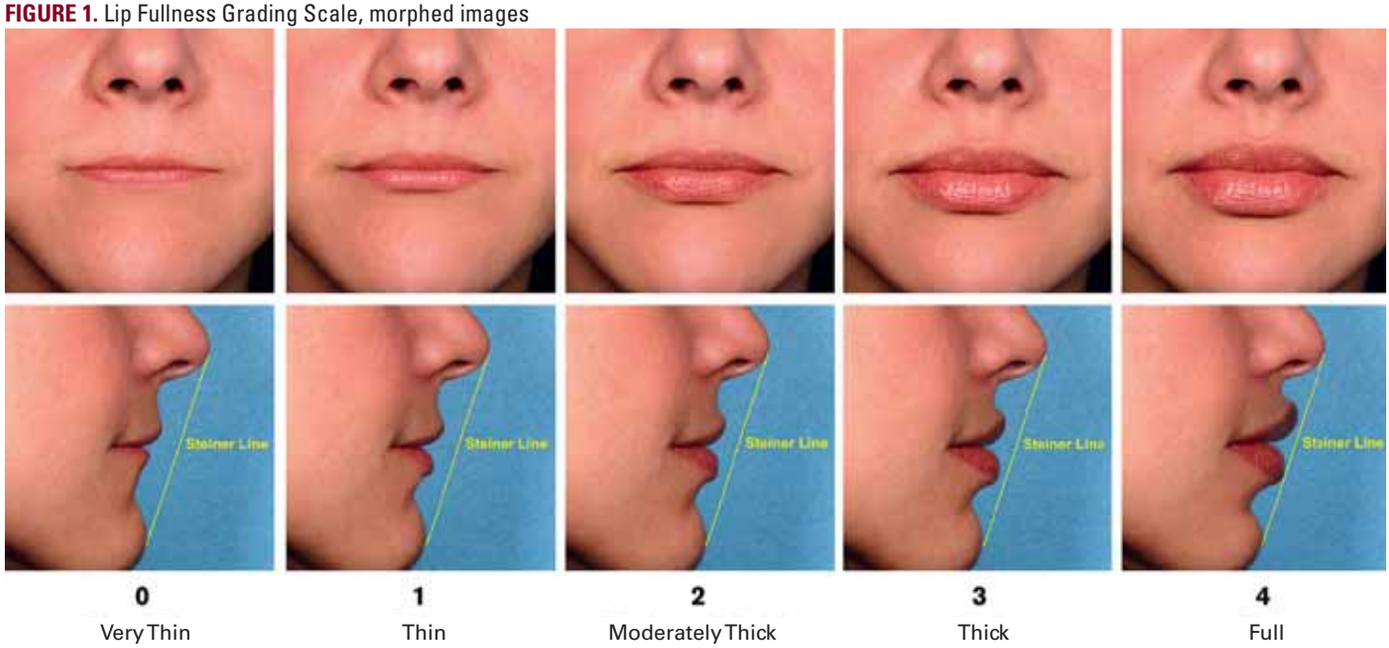
The lips, next to the eyes, may be the most visible and noticed features of the face. The lips are the base of the "beauty triangle." As skin ages, the epidermis thins. The skin of the lips is thinner than the skin of other facial regions. Collagen, elastin and hyaluronic acid provide the skin of the lips with structure and volume decrease with age. The lips, in particular, have an extremely thin outer skin layer which becomes progressively thinner with age. They lose volume and lip wrinkles form over time due to the effects of decreased levels of collagen, elastin and hyaluronic acid, muscle activity, and photo damage. Hard tissues, such as the skull and soft tissues in the lips, resorb with age. Over time the corners of the mouth can begin to droop, the Cupid's bow begins to flatten out, and there is a loss of fullness and contour. Lip lines and perioral wrinkles will also appear due to lip muscle movement and hard- and soft-tissue volume loss.

The Evolution of the Assessment Scale

Historically, there has been an absence of a universal classification system for the perioral region. This void has resulted in a wide variety of terminology being applied to the management of aging options and lip fullness. Sstandardization of characteristics presented to grade lip fullness, the relationship of the position, dimensions and symmetry between the upper and lower lip, the state of vermilion borders and the degree of "red show" are all beneficial to the practitioner.

To determine an effective method for classification, a five-point photonumeric rating scale was developed to objectively quantify fullness of upper and lower lip separately. A total of nine experts in the field of aesthetic medicine rated 35 sets of photographs. Images were created using imaging tools that showed lips at a range of stages of fullness. Through looking at a series of multiple photographs of individual subjects, the clinicians evaluated the degree of lip volume and degree of red show by rating the upper and lower lips using the morphed scale that shows both parts of the lips (Figure 1).

FIGURE 1. Lip Fullness Grading Scale, morphed images



Inter- and intrarater variability was assessed by computing intraclass correlation coefficients. Agreement between the experts was very high. Bubble plots (bivariate scatter plots) demonstrated linearity in judgment by the experts. The data were were further retested and validated.

Another important distinguishing factor of the Lip Fullness Scale is that it was developed by physicians across specialty lines who are experts in their field. All of the experts reviewed the series of photographs that was produced analyzed, and arrived at an agreement between them. Therefore, the Merz scale has been proven to be reliable and reproducible in clinical practice to accurately assess where each patients fits on the spectrum. This represents a significant improvement in the field of aesthetic medicine towards standardization of terminology and aesthetic endpoints, as well as treatment algorithms.

Using Rating Scales in Clinical Practice

The Lip Fullness Scale has proven to be a valuable clinical tool. It is used directly in consultation with patients to get them to assess current degree of lip fullness, and discuss where and how much they want to change the aesthetics of the perioral region. By asking a patient to look in the mirror and grade herself or himself as the practitioner grades them may reveal underlying differences of interpretation (Figure 2). The photographic scale thus enables the practitioner to ask the patient to show where he or she thinks the appearance is now and where he or she wants to be. This allows for an improved patient dialogue and clarification of each individual patient's goals to avoid miscommunication.

Different patients desire different degrees of lip fullness outcomes from dermal-filler treatments. For example, if a patient starts out at a 1 on the Merz scale and states a desire to achieve a 6 on the scale, the practitioner may need to re-educate the patient as to what results are realistic to expect from a treatment. Frequently patients come in to a practice and ask, "Can you make my lips look fuller but not too full?" It is often impossible to ascertain exactly how full each patient wants her or his lips to be, which represents a failure of communication. The practitioner can use a visual guide so that the patient can point to the degree of fullness desired. The practitioner can proceed to take out the Merz scale and work closely with the patient to manage goals and expectations. "You are a level 2 here. If we treat you with two syringes of hyaluronic acid, we can try to move you from a 2 over to a 4." This exchange will allow the patient to gain a clear understanding of what can be achieved.

Alternatively, if a patient presented with very thin lips of 0, and he ore she was under the impression that one syringe of hyaluronic acid would bring the lips up to a 3, or thick, rating, the practitioner would then have the opportunity to help adjust the patient's goals to a more realistic level to avoid disappointment. The practitioner might respond by saying, "I think we can improve you slightly, but if you want to get more fullness on your top and bottom lip, we are going to have to use a thicker product and it will also require using more material or a combination treatment." This exercise encourages the practitioner and the patient to work together as a team to achieve the best possible outcome.

Most patients desire a change of one or two grades in the lip fullness scale, which is a reasonable degree of improvement in most cases, and usually attainable by using one or several syringes of material. The rating scale allows the practitioner to

estimate how many syringes will be needed based on their desired change in advance of treatment. Therefore, patients may be informed that they will need a specific number of syringes of hyaluronic acid to achieve the fullness they are seeking, so they will know exactly what the cost of the treatment will be. The practitioner can guide the patient through each scale, and discuss a number of aspects of facial aging that the patient is either experiencing or will experience in the future and fully explain the aging process with the aid of clear visuals for each stage.

In addition, the Merz scale is useful for patients to view in a practitioner's office (Figure 2) on their own, so they can determine where they are and where they want to be even before they are seen by the injector. This presents a myriad of opportunities to manage the patient's aging options before, during and after treatment, as well as to determine the natural course of follow-up and touch-ups that may be needed. Use of this sophisticated system, as well as other aesthetic scales, gives the patient confidence that the physician has good tools to help them achieve their goals.

Cosmetic patients have their own self-image and understanding of how they look and how they want to look. They are not always able to articulate these goals to the practitioner. Before patients consult with a physician, they often have in their mind how severe their wrinkles are. Now by using these validated 5-point scales, we can show them the actual spectrum of the degree of facial wrinkles and loss of lip volume they may have. They may learn that they are aging better or worse than they thought originally. By taking them through the process, it will allow the patient to be educated in the language of aging, and to have a better idea of how their treatment will progress (Figure 2).

Furthermore, the patient can be educated about preventative measures based on where he or she is on the scale at the current time (Figure 2). For example, if the patient is at the early stages of the aging process in the 30s, or just starting to be concerned about the changes seen in the mirror, the patient may wonder where he or she fits on the Merz scale. The next step is to determine a plan for what the patient needs to be doing now to slow down the aging process. It also allows the practitioner to illustrate the inevitable results of failing to be proactive about smoking, sun exposure, drinking, lack of exercise and good skincare practices. It presents an ideal opportunity to discuss maintenance therapies and offer patients a range of options to consider for the future as they progress to the more severe end of the spectrum of aging.

Lastly, by viewing the Merz scale backwards, from a 4 down to a 0, practitioners can illustrate to patients where they may be headed as they will continue to lose volume. The morphed photographs (Figure 2) demonstrate that with age, lips grow further together, which decreases the degree of red show, and the loss of muscle tone in the upper lip creates a wider distance from the tip of the nose to the Cupid's bow. Patients will come to be diligent about watching for these telltale signs of lip aging to stay ahead of the curve.

FIGURE 2. Physician using the Merz scale as a consultation tool with a patient

Patients today are critical aesthetic assessors of themselves, and of other patients. After having a dermal filler treatment, in a few days or a week, they may grow concerned that they didn't have enough injected or that they are still swollen or bruised or wonder if the results will last. The Merz scale will become an indispensable tool to follow up after the patient has been treated to help practitioners judge their response and delineate patient expectations. It will enhance the cosmetic consultation and advance patient education on the art and science of dermal filling agents.

Comprehensive Applications for the 5-Point Scales in Research

Although we have had other scales in the past, such as the Fitzpatrick Skin Type Classification Scale and the Glogau Wrinkle Severity Scale, up until now we have not had scales designed to address specific aesthetic regions of the face, such as brow position, lip fullness, and the hands, that have more recently become common areas for treatment. The Merz scale represents a complete aesthetic package that practitioners can adapt for clinical investigation. For the first time, researchers will have a well-defined scale that will be universally available. This will enable patient outcomes in a variety of research settings to be analyzed using the same assessment system.

In addition, the Merz scale may also afford new and improved options for research. For example, it may facilitate our ability to compare raw photographic data from one study with photographs from another study, and re-analyze data by comparing

those parameters of aging options and lip fullness to the new 5-point standardized scales. We may be able to determine the volumizing ability of different fillers by estimating how much of each specific dermal filler will be needed to take a patient up the lip fullness scale by one point. It will also allow practitioners to discuss patients among their colleagues so that everyone is speaking the same language. Being able to identify a patient as a "2" on the Lip Fullness Scale allows for a new degree of accuracy that has previously not been available to practitioners. These are very powerful tools that are destined to become the standard of practice in the very near future.

CONCLUSION

With the increasing number of well-informed patients in an aesthetic practice, and their evolving demands, the need for diagnostic tools and patient education is paramount. There are multiple factors that may impact a patient's dissatisfaction with the appearance of his or her perioral region ranging from inadequate lip fullness, loss of definition, asymmetry, contour, to droopy corners of the mouth. These may be due to genetics or to aging or a combination of both. This new lip-fullness classification scale provides a method of assessing patients in order to more accurately propose a treatment plan that will successfully meet their goals.

The 5-point photonumeric rating scale spans the fullness of the upper and lower lip for which patients commonly seek correction. The Merz scale will be an effective adjunct to clinical practice and will serve to enable practitioners to better understand patient goals and desires. It will also be key in collecting data in the research setting.

DISCLOSURES

Dr. Timothy Flynn is a consultant to Merz, Solstice, Coapt and Revance; is involved with (or has been involved with) research for Allergan, Medicis, Merz, Solstice, Revance and SkinMedica; and is a stockholder in Allergan Inc.

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