The Pelleve Procedure: an Effective Method for Facial Wrinkle Reduction and Skin Tightening

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The use of thermal injury to rejuvenate and repair aging facial skin has been part of the nonsurgical skin treatment for decades. Ablative light-based energies, the gold standard being full carbon dioxide laser resurfacing, offered the potential for remarkable smoothing and moderate tightening at a superficial level but came with significant pain, downtime, healing complications, and unwanted pigment-related changes. To reduce the downtime and complications, lesser-ablative and nonablative wavelengths were devised, but consistent results were still dependent on having the proper skin type, dosing, and healing response. The advent of the use of radiofrequency (RF) energy represented a change away from light-based energy, dependant on generating heat by absorption of energy by a target chromophore.

High-frequency electron flow, RF, generates heat because of the differences in impedance between tissue types (Fig. 1).

Streaming electrons flow through the low resistance of the epidermis and dermis and meet the highly resistant fat at the dermal-subdermal junction. The sudden change in impedance turns kinetic energy into thermal energy, and the surrounding tissues are heated. This method not only eliminates the problem of heating unwanted target chromophores in the skin, such as melanin, as seen with light-based lasers, but also allows the heat to be generated in the deep dermis where existing residual collagen bundles are most plentiful. Also present at the dermal-subdermal junction are the connections of subdermal connective tissue bands that run through the subdermal fat to the underlying fascia. A controlled thermal injury reaching the threshold temperature for denaturing collagen of 60°C to 65°C can cause contraction of the thinned collagen in the deep dermis immediately and trigger an inflammatory response that generates new collagen bundle reorganization and thickening evident at 12 weeks as seen on electron microscopy. Controlled thermal contraction down the deep connective tissue bands causes a vertical and 3-dimensional tissue contraction, compacting the fatty globules without injuring the fat itself (Fig. 2).

This mechanism is in contrast to that of uncontrolled thermal injury in which temperatures obtained in deep tissue can reach or exceed 70°C, causing a necrotic injury, irregular wound contraction, fat loss, and atrophy, which has been reported with pulsed devices. Despite the potential benefits of deep RF dermal heating, the pain associated with the treatments and the inability to generate consistently predictable results continue to plague this technology.

The shortcomings of pulsed RF-based devices include the need to deliver a safe dose without crossing the heat threshold that results in tissue...
necrosis.\textsuperscript{7} To assure this safety, the treatment protocols are typically the same for all patients, not allowing customization of the dosing to improve treatment outcomes. However, it is obvious that not all skins respond equally to the same amount of energy, thus, the reputation for unpredictable results. Pulsed devices also raise the temperatures rapidly, which can cause pain and necessitates surface cooling to prevent superficial burns. However, without the control of the actual depth of cooling, favorable thermal effects on the dermis, such as wrinkle reduction, horizontal contraction, and shrinkage of pores, can be limited in thinned-skin individuals because of the excessive cooling of the middle to upper dermis. The need to optimize these treatment parameters of the myriad of devices available has been emphasized by many investigators who have evaluated the devices that have come into the market.\textsuperscript{8,9}

MECHANISM OF CONTROLLED THERMAL INJURY

The Pelleve procedure, performed using the 4.0 S5 Surgitron (Ellman International, Oceanside, NY, USA), differs from other methods of delivering RF energy because it delivers a progressive but controlled thermal injury to the dermis and subdermis and overcomes many of the shortcomings associated with pulsed and fixed dosed methods.
A 4.0-MHz high-frequency energy is used, so the difference in resistance between the dermal skin and underlying fat is maximal and results in heat generation and diffusion only from the dermal-subdermal junction. The energy delivery is continuous, but because of the constant movement of the electrode over the treatment area, heating is gradual, rather than sudden, allowing the procedure to be painless but thorough when performed properly. A dispersion gel is used on the skin to allow smooth movement of the electrode and immediate dispersion of the energy of the otherwise-focused flow of electrons. Because all the heat generated emanates from deep at the dermal-subdermal junction as seen on infrared images (Fig. 3), no direct surface cooling is required and potentially beneficial effects to the middle and upper dermis are not compromised. In addition, because the heat conducted down connective tissue bands is also gradual and progressive, it has been demonstrated that the fat compartments are contracted, giving 3-dimensional deep tissue contraction without the fat cells reaching temperatures that could cause atrophy or necrosis.

This process has been demonstrated in vivo (Fig. 4). With progressive heating, the “cloud” of thermal energy rises up into the dermis and down the connective bands. Temperature levels at the surface have been documented to be approximately 20°C cooler than those at the dermal-subdermal junction as seen in Fig. 3.

The optimal threshold temperatures at, and adjacent to, the dermal-subdermal junction can be reached repeatedly in a controlled manner by monitoring the surface temperature and staying aware of the patient’s pain response, which correlates nicely with temperature levels and seems to be consistent from patient to patient.

It has been shown with the Thermage device (Solta Medical, Hayward, CA, USA) that multiple passes at lower energy levels produce more collagen contraction and new collagen production than single passes at higher energy levels.\(^{10,11}\)

With the gradual heating characteristic of the Pelleve procedure, the patient’s response to a threshold temperature of 40°C to 45°C at the surface correlates with a heat sensation of “just getting hot” or a heat perception level of 7 to 8 out of 10. An infrared surface temperature monitor can be used in addition to the patient’s feedback so that repeated passes can be preformed to the therapeutic threshold until clinically significant smoothing or tightening is seen in every patient without pain or unforeseeable jumps in temperature to dangerous levels. This subjective goal of repeating passes to threshold temperature until no additional contraction or smoothing is seen in each treatment session can be objectively stated to be 1 pass per decade of age plus or minus one pass depending on the anatomic area and the skin’s age and condition. In the case of the Pelleve procedure, a pass is defined as reaching threshold temperature confluently over the entire section being treated, not just covering the area with the probe passing over it, followed by forced cooling for 10 to 20 seconds. This procedure may take 30 seconds to a minute or more of persistently going over an area to bring it to the threshold temperature depending on energy output settings, the speed of the operator’s hand movement, and how much area is being treated at once. With experience, higher settings can be used comfortably and passes can be completed more efficiently, which reduces the overall treatment time. So again, a pass is defined as bringing the selected treatment area, that is, half the forehead, cheek, and periorbicular area, confluently to a threshold temperature of 40°C to 45°C and then cooling for 10 to 20 seconds, maximal 3-dimensional contraction is desired. One pass per decade of age plus or minus one pass in each area seems to be the amount of treatment in a given session to achieve clinically reliable and lasting results. One to 3 sessions may be required to achieve the desired degree of improvement that depends on multiple factors. These factors include age, degree of collagen loss, degree of volume loss, stage of volume loss, and genetic factors. Therefore, a session, single complete procedure, is the completion of the appropriate number of passes to all planned treatment areas. Clinically, it seems that each additional pass generates progressively greater contraction to a point to which no further benefit is seen or palpated, and this technique is what yields predictable results painlessly.

**COOLING CONTROVERSY**

After several months’ experience, using multiple passes from 40°C to 45°C, going on to an adjacent
area to allow spontaneous cooling of the treated area, and then returning to the treatment area, the possibility that the progressive swelling occurring with each pass might overcome the ability for acute tissue contraction became apparent. At that time, I began cooling the treated area directly with frozen reusable cold packs to force contraction of the solid proteins that were being heated and, at the same time, minimized the acute swelling associated with repeated heating. The immediate contraction and firming of the treated area was apparent, and it allowed repeated passes of continuing RF energy on the same areas until maximal contraction was seen without having to go to adjacent areas to allow passive cooling to occur. After only 20 to 30 seconds of cooling, the subsequent passes seemed to trigger an even more significant contraction without the swelling seen when letting the tissue cool passively. The distance between a point on the nasolabial fold and the tragus, for instance, increases after a pass of heat solely but decreases after a pass followed by cooling. The principle of physics governing cooling solids is that all solids, except water, contract with cooling. If application of cold causes even a fraction of a millimeter of additional contraction of the denatured collagen, then each subsequent pass would reach that much deeper and cause greater contraction and increase the density of the layers of deep dermal collagen. This occurrence is apparent on pinching the skin after each pass of hot and cold application.

Some investigators have suggested that heat shock proteins triggered by the injury could be adversely affected. It was shown that only cooling at or less than 5°C adversely affected the tissue’s response to injury, and cooling to that level is not advocated here.

To document what I have observed over the past several years, 10 consecutive patients were treated with one side heated to threshold temperature and then cooled for 30 seconds using an iced stainless steel roller and the other side of the face heated to threshold but left to cool passively while an adjacent area was treated. The midface was treated at a setting of 80 for 5 passes; the forced cooling for 30 seconds reduced the temperature to 20°C to 24°C. The opposite midface was treated at the same level for 5 passes but allowed to come to baseline temperature of approximately 33°C passively while an adjacent area was treated. The acute evaluation at the end of the treatment session and an evaluation 1 month later revealed significantly more contraction and lift on the side with cold applied for forced contraction at both end points. All 10 patients felt that the side with cold applied for forced contraction felt tighter at rest and felt denser when pinched relative to the passively cooled side. All patients were then treated the opposite way, and, at the end of the second month, all felt equally tight. The acute response at the end session was the same, the cooled side felt tighter and denser. All 10 patients also felt that the 2 treatments gave significant firmness and tightening to their skin, greater with the second treatment, and each could see an obvious contraction through the midface relative to their pretreatment photos.

**INDICATIONS**

The ideal candidates for the Pelleve procedure are from their late 30s to mid-40s showing some visible lines at rest, some midface laxity and upper face volume loss, and early neck softening. At this stage, with firm dermal support, all these signs of aging can be significantly reduced or erased with a single treatment or with a second treatment if complete improvement is not seen 4 to 6 months later. The typical Pelleve patients in Southwest
Florida are in their early 50s to mid-60s and have significant wrinkles at rest, nasolabial and melolabial folds, neck laxity, and midface ptosis. The degree of severity of these findings relative to the patient’s chronologic age helps predict the success of the procedure outcome and how many sessions will be required to achieve a clinically obvious and satisfactory result. Most patients respond to 2 sessions delivering a pass per decade to each treated area, but fuller faces, extremely thick dermis, and male faces require 3 sessions. Regardless of the chronologic age, the skin responds more promptly with generous dermal density; those with a greater overall volume loss and loss of dermal collagen integrity respond less favorably. However, all skins become more smooth and firm when enough passes to threshold temperature are delivered in a single session. Long-term observations allow patients to be told in the middle of their aging process that the procedure typically needs to be repeated every 12 to 18 months. The youngest and oldest patients are told that it may last for 2 years or more, always relative to how fast they are losing volume. Treatment sessions 4 to 6 weeks apart allow the acute response to the thermal injury to subside. Several experienced physicians from Japan and Russia treat every 2 weeks for a total of 3 sessions and feel no detriment to this schedule. Some patients have been treated as soon as 3 weeks and have seen significant additional smoothing and tightening at that time. In fuller faces, less dramatic changes should be expected with the first procedure because much of the initial contraction is in the anteroposterior dimension, which is more difficult for the patient to appreciate. Once this slack is taken up, further contraction results in more obvious horizontal contraction. One patient considered a failure after 4 sessions returned after 2 years and showed a remarkable and persistent improvement in skin laxity and the depth of several facial folds (Figs. 5 and 6).

In the United States, the Pelleve procedure has received the Food and Drug Administration (FDA) clearance for the treatment of mild to moderate facial wrinkles for skin types I to IV with a duration claim of 6 months. In their submission to the FDA, 87% of the patients receiving a single treatment showed persistent results at 6 months (Fig. 7).

In my experience since April 2007, I have seen results last 18 months or more and as long as 4 years in a case of sculpting the midface. Most patients older than 50 years, having no other cosmetic treatment other than 1 to 2 treatment sessions with the Pelleve procedure, return 18 to 24 months later with complaints of progressive aging. Examination of the treated areas usually reveals volume loss resulting in recurring skin laxity. No patient failed to respond to a single additional Pelleve procedure at the time of retreatment, with improved skin tightness, density, and smoothing.

Given that the process of denaturing and contracting the collagen proteins is irreversible, persistence of the result depends on the degree of improvement achieved, the degree of volume loss, and the rate of aging, which includes further loss of collagen, native or newly developed with the procedure. Obviously, the younger the patient and thicker the dermal collagen at the time of the procedure, the longer the result remains visibly apparent. From the perspective of an acute response, no patient has failed to respond to 1 to

Fig. 5. Two years after failure after 4 treatments.
3 sessions of Pelleve procedure performed as described.

In the process of developing a reliable method to truly “iron” the skin, providing significant and lasting wrinkle reduction and skin tightening, the procedure has been used in almost all patients presenting with aging concerns alone or as an adjunct to neurotoxin therapy, fillers, volume replacement, or surgery for more than 3 years. All patients seeking reversal of visibly aging aspects of their appearance have a loss of collagen integrity, thickness, and facial volume to some extent. Therefore, all patients need a modality that can contract and firm existing collagen and trigger new collagen formation to slow or reverse, to some degree, the process of facial aging.

WRINKLE REDUCTION WITH OR WITHOUT FILLER OR NEUROTOXIN

Surgeons encounter the dense adhesion of the base of wrinkles every time they undermine a neck and struggle with elevating the adherent base from the underlying soft tissue. The “valley” of any wrinkle is made of dense collagen, and the “shoulders” are made of less-dense collagen, creating the depth discrepancy to be lessened with neurotoxin or effaced with dermal fillers. Most experienced injectors know that some degree of subcision improves filler results by facilitating the migration of the filler material under the deepest aspect of the valley of the wrinkle. Previously, only ablative surface treatments could reduce the shoulder height of wrinkle reduction, but this is not practical for immediate wrinkle manipulation before injecting filler.

Using the Pelleve procedure as a modality to reduce the height discrepancy, reliably, painlessly, and with no added downtime before injection, has created a new treatment paradigm for true wrinkle reduction. This method addresses the cause and then restores the local soft tissue volume loss with the filler material. Vertical contraction of the high sides of a wrinkle or fold is achieved by repeatedly heating and cooling the shoulders of the wrinkle or fold, as well as the adjacent tissue, to flatten and redistribute the associated excess skin. Heating the base of the wrinkle to therapeutic temperatures denatures and softens the collagenous scar, making it pliable, capable of being flattened manually, or more easily manipulated during filler insertion. This deep thermal injury in the therapeutic temperature range, meaning that which triggers neocollagenesis, is synergistic with the filler therapy and should leave the patient with an improved appearance relative to baseline, even after the filler itself is reabsorbed (see Fig. 8).

Similarly, using a neurotoxin to immobilize a wrinkled area, so that new collagen formation
after the Pelleve procedure can be generated without the repetitive crush-inducing movement that caused the wrinkle, should lead to more effective flattening of the wrinkle. The denatured collagen is softened and flattened, and new collagen can be laid down to restore some of the loss that led to the wrinkle being visible at rest. These expected results have now been observed routinely. Patients who underwent filler therapy returning 1 year after filler placement pretreated with Pelleve procedure persist to have an improvement over baseline, despite the need to augment the soft volume deficit. Although the Pelleve procedure can reduce the resting depth of wrinkles when used alone, patients who have undergone the procedure in the forehead and periocular area while the area is immobilized with neurotoxin return for repeat neurotoxin treatment and show reduced or, occasionally, imperceptible wrinkles at rest relative to their appearance before the procedure.

**SKIN TIGHTENING AND VOLUME CONTRACTION WITH OR WITHOUT VOLUME REPLACEMENT**

The Pelleve procedure is also a valuable adjunct therapy to facial volume restoration. The midfacial skin envelope becomes lax as panfacial volume loss occurs. Contraction of the connective tissue bands that tether the skin to the deep fascia contracts and firms the soft tissue compartment. With decreased compliance, the volume delivered has a greater volumizing effect. I have used the Pelleve procedure as an adjunct to facial volume restoration for more than 3 years and seen a synergistic effect of triggering new collagen formation. With poly-L-lactic acid (PLLA), “seeds of new collagen growth” via a controlled foreign body reaction are laid down in the same anatomic plane that the Pelleve is triggering new collagen growth via a response to thermal injury. The PLLA injection procedure can be administered immediately after the Pelleve procedure to bolster the lift and contraction achieved with a properly performed midface tightening (Fig. 9). This routine example shows how the skin envelope can be contracted to the residual volume even with an acute weight loss in a woman in her late 50s.

**METHOD**

It should be noted that this method is consistently referred to as a procedure, not a treatment, a semantic distinction important to obtaining consistent results. Most light-based technology and other RF energy devices have set dosing protocols that define a treatment session, usually developed to be within established safe dosing parameters. The use of the continuous RF energy delivery, with the end point being an obvious clinically evident smoothing and tightening of the skin, has to be approached as a procedure, not unlike a surgery in which certain steps are taken and customized to the patient’s needs to reach an optimal end point. As with surgery, that end point should satisfy the provider and the patient.

In evaluating each patient before starting the procedure, standard 5 position photos, vertically oriented hairline to clavicle in height and pinna-to-pinna in width, should be taken. The subject’s face should then be assessed for asymmetry side to side in cheek height and fullness and in the flair of the jaw line. See Video 1 online [www.facialplastic.theclinics.com]. With few exceptions, all patients have 3 to 10 mm of asymmetry in the vertical height and length of one side of the face compared with the other when measuring from the lateral canthus to a point on the jawline directly below it. The higher side is also most often fuller with greater overall midface volume, whereas the lower side is shorter with greater volume loss. It is important that this difference be demonstrated to the patient for 2 reasons. First, the patient
should not notice this difference for the first time in the postprocedure period and think that the procedure created the asymmetry. Second, it is vital to treat the high side first and exaggerate the asymmetry so that at the half-treated point, the patient will be impressed with the degree of change achieved. If the low side is treated first, the patients who may have never seen themselves as anything but symmetric in the past will be unimpressed if the low side is brought up even with the untreated high side. The flair of the body of the jaw is less often an issue, but, in many patients, one side tapers posteriorly at 45°, whereas the other side tapers back at 60°. If the providers fail to notice this asymmetry, they may grow frustrated trying to get the midface to taper symmetrically when the bony skeletal support is the cause, and not soft tissue fullness. Discussing these findings builds patient confidence in the providers' understanding of the anatomy and also opens the door to discuss volume replacement filler therapy to achieve more youthful height on the low side or balance the face overall after the skin sleeve has been tightened (Fig. 10).

All makeup should be removed from treatment areas; jewelry and hearing aids should be removed. Men should be clean shaven. Bearded skin cannot be treated because of the spark gap created by the hair density and thickness, but no effect on underlying hair follicle growth has been observed clinically. The Pelleve procedure is performed on the facial skin surface where wrinkles and underlying laxity predisposing to wrinkles are present. A 7.5, 10.0, 15.0, or 20.0 mm monopolar electrode handpiece transfers the energy to the patient from the ellman S5 Surgitron RF generator and adhesive disposable return pad that is placed on the upper back skin between the shoulder blades. Pelleve gel is used on all treated skin and adjacent skin areas to avoid burn injury from applying the RF energy to unprotected skin. Only a thin layer is needed to provide smooth gliding of the electrode on the skin. The treatment electrode must always be in contact with the patient’s skin and gel before activation to avoid generating a spark gap that can cause pain and a superficial burn similar in size to a razor nick. The treatment electrode should be deactivated before breaking contact with the skin. Any treatment of the periocular skin within the orbital rim requires plastic eye shields inserted after a topical anesthetic drop is applied to the cornea.

Using settings comfortable for the patient which can range from 15-80 depending on the area undergoing treatment, and no anesthetic of any kind that might impair heat perception, the area of skin is gradually heated to a surface temperature of 40°C to 45°C monitored by a handheld

Fig. 9. The 6-month result after 2 treatments (despite 10-kg weight loss).
infrared heat gun or the patient’s response to the level of heat as “that’s getting hot.” After hundreds of treatments, the patient’s level of pain perception has been observed to reliably predict skin surface temperature. The patient is advised that the sensation goes from warm to warmer but does not have to hurt to work and hotter does not mean a better result. The patients are encouraged to signal if they feel that the heat is about to get too hot to avoid allowing the heat to get to the point of the patient reflexively pulling away. Although the handheld infrared temperature gun is helpful in monitoring treatment temperatures, experience allows the treating personnel to move to adjacent areas or stop treating at the appropriate temperature. Close observation of skin color and texture as well as subtle body language projected by the patient prevents getting to uncomfortable treatment levels.

The ability to rely on patient feedback to guide the treatment comes from the fact that the tolerable target therapeutic temperature of 40°C to 44°C at the surface reflects a 20°C differential at the dermal-subdermal junction, and the response to the gradual heating is consistent within a few degrees from patient to patient. Within that temperature range, based on thousands of observations by the author, patients report “that’s getting hot” or a 7 to 8 out of 10 on a 10-point pain scale. There should be no pain if the provider remains aware of the tissue and patient response. At 45°C to 46°C, most patients spontaneously pull away. Surface temperatures of 48°C to 50°C, which can cause a necrotic thermal injury, cannot be reached in an awake subject with no anesthesia. Temperatures less than 40°C does not denature type I collagen and does not give effective lasting results and can be tolerated indefinitely. The infrared temperature gun is useful in preventing undertreatment in patient’s whose skin turns red easily at subthreshold temperatures, such as those with rosacea.

Passes of the energy are repeated after cooling the area with cold application to force solid tissue and collagen contractions. The cooling is transient, 10 to 15 seconds per area, and typically takes the tissue down to temperatures in the mid-20s. This heating and cooling is repeated until no additional visible or palpable tightening and smoothing is evident. Objectively this procedure translates to approximately 1 pass per decade of age plus or minus 1 pass (ie, 4 passes for a 42-year-old individual and 6 passes for a 65-year-old individual). Foreheads take fewer passes than the lower face and heavier skin takes more passes than thin skin. The cooling can be achieved with any reusable frozen cold pack or a stainless steel roller soaked in ice water. Typically, the face is treated half at a time, forehead to below the jawline, to allow comparison with the untreated side. Again, as a rule of thumb, 1 pass per decade of age is needed for optimum contraction, and 1 to 3 treatment sessions are needed 4 to 6 weeks apart for maximal long-term results. Single treatment sessions can last for 1 year or more in patients younger than 45 years, 2 treatments are needed for most patients, and 3 or more treatments may be required in extremely heavy or

Fig. 10. Common congenital facial asymmetry.
wrinkled skin. No special skin care before or after the treatment is needed, and patients can return to normal activities immediately.

RESULTS

In 4 years of observing hundreds of treated areas, all patients treated had good to excellent results. Although the number of treatment sessions needed may vary with age and skin condition, all skins smoothen and tighten when heated repeatedly in each session to a visible clinical end point. Additional sessions have always yielded greater smoothing and contraction, and no adverse effect has been seen with as many as 5 sessions in 6 months. Performed properly, the procedure should be painless and should present little risk of inadvertent superficial burn injury. Results can last for more than 1.5 years in many patients depending on age and indications, with some wrinkle results showing persistent improvement beyond 1.5 years (Fig. 11).

SUMMARY

The Pelleve procedure, done properly and to a truly significant clinical end point with each treatment, can reliably smooth and contract facial and neck skin without pain or downtime. The Pelleve represents a vital adjunct to filler procedures and any antiaging treatment plan, be it surgical or nonsurgical. The key to success in tightening and smoothing skin seems to be the ability to customize the dose, number of passes without concern for safety, discomfort, or cost. Additional safety in performing the Pelleve procedure comes in the form of GlideSafe treatment tips that will be pressure activated, greatly reducing the possibility of a spark gap if patient contact is lost.

TREATMENT PEARLS

- Always start the procedure on the side of the face where the midface appears higher and more full, so at the half-treated point, the result is obvious.
- Always assure you are in contact with the gel and skin before activating the electrode, and deactivate the electrode before breaking contact.
- Use a gloved hand and 4 × 4 sponges to stretch the skin in the lateral brow and lower lateral face while heating, and maintain the tension until cooling is complete.
- In areas, such as the midforehead, upper lip, lateral orbit, and neck, where wrinkle reduction is the first priority, do not apply cold for forced contraction after the last 1 to 2 passes so that the denatured collagen

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Fig. 11. Full face treated twice 6 weeks apart in January 2008 (January 23, 2008, to September 9, 2009).
can remain hot and amorphous. Physically smoothing over these areas firmly with 4 × 4 sponges may give even better long-term results.

- Encourage these patients to be pretreated with neurotoxin 2 weeks before their Pelleve procedure to avoid “wrinkling your work,” and essentially allow the wrinkles to heal immobilized as if they were in a cast.

VIDEO ON PATIENT EVALUATION FOR PELLEVE PROCEDURE

A video showing patient evaluation prior to the performing the Pelleve Procedure is available online at www.facialplastic.theclinics.com. This video focuses on the assessment for asymmetry and other considerations to demonstrate for and discuss with the patient.

REFERENCES