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Quantitative Dermal Measurements Following Treatment With AirGent

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Abstract

Background: As an alternative to other minimally-invasive approaches to facial rejuvenation, enhancement and treatment of the dermis with a compressed air molecule of hyaluronic acid (HA) is a promising method in that it lacks some of the drawbacks of other procedures. The novelty of these systems, one of which is tested in this study, is based on the supposition that jet lateral dispersion of HA produces both instant dermal augmentation and specific wound-healing processes, leading to its long-term dermal thickening.

Objectives: The authors report on the efficacy and safety of the AirGent system (PerfAction, Rehovot, Israel), which is a renewal system designed to initiate a wound-healing process in the dermal layer. It is a computer-guided system that delivers treatment through compressed air molecules of HA to the dermal layer of the skin.

Methods: The authors treated 20 patients (a total of 105 treatment sessions) with the AirGent system between May 2008 and November 2008. Each patient received three treatments at three- to four-week intervals. Each patient's skin thickness was measured with ultrasonography pretreatment, immediately after each session, and at six months posttreatment.

Results: Seven days after the last procedure, an increase in skin thickness was observed in all patients. The most significant differences were noted in the upper lip area, where the thickness had increased by an average of 1.3 mm. Six months after the last session, an increase in skin thickness was still noted in most patients, at which time the biggest difference was noted around the eyes, where the skin remained thicker by an average of 0.77 mm over baseline. According to the results of the Global Improvement Assessment questionnaire, at the six-month follow-up to evaluate their satisfaction with the long-term results, at least 59.9% of patients still noted at least a slight improvement in their appearance.

Conclusions: Although a small group of patients and a relatively short period of observation limit the scope of our conclusions, the data show that the AirGent system is efficacious in producing increases in skin thickness that correlate with at least a substantial or slight improvement of appearance, as reported by the patients themselves.

Keywords

facial rejuvenation, hyaluronic acid, cosmetic medicine

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Skin aging is an unavoidable process that occurs through two biologically-distinct processes, intrinsic and extrinsic. The first results from slow tissue degeneration characterized by three features: atrophy of the dermis due to loss of collagen, degeneration in the elastic fiber network, and loss of hydration.[1,2] Estrogen deficiency particularly affects the fibroblasts of the dermis and thinning of the skin is mostly related to a reduction in collagen. The sebaceous glands are responsible for oil production, which facilitates skin lubrication,[1,3,4] but with the passage of time, the body produces less oil in these glands, which results in dryness of the skin.

Extrinsic aging, on the other hand, is due to environmental factors and there are causes for the accumulated cellular damage. Among these are the oxidative processes and related free-radical damage that results from UV sunlight, smog, toxins, cigarette smoking, X-rays, drugs, and other stressors. The skin's protein collagen is particularly susceptible to free radicals, and when the damage occurs, it causes the collagen protein molecules to break down and crosslink. Collagen crosslinking results in increased stiffness and reduced mobility for the collagen. Sunlight

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also causes the messenger molecules present in skin cells to become active, which in turn causes inflammation. Fisher et al[5] showed that multiple small exposures to ultraviolet irradiation can lead to a sustained elevation of enzymes that degrades skin collagen and contributes to photoaging.

The term *facial skin rejuvenation* applies to both surgical and minimally-invasive (or nonsurgical) methods. Procedures such as facelifts and blepharoplasty exclusively focus on the surgical remodeling and/or removal of surplus tissue. However, with these procedures, the structure of these anatomical areas remains unchanged and a patient's postoperative skin condition can become worse as a result of skin tightening. It has even been posited that this postoperative skin may be more prone to unfavorable acceleration of the aging process.[6]

Thus, the efficiency of so-called causative treatment can be rather limited in the cosmetic sense. Although these changes can result in some slowdown of unavoidable aging or slight improvement of skin condition, the lasting efficacy in terms of skin condition takes time to show itself and is poorly documented. Furthermore, replacement of deficient elements in the skin (and their rearrangement with possible stimulation of collagen production) is admittedly limited in terms of the areas to which it can be applied, such as the nasolabial folds and lips. Rejuvenation of large surfaces with chemical agents or lasers is known for some shortcomings, too.[7-11]

As an alternative, enhancement and treatment of the dermis with a compressed air molecule of hyaluronic acid (HA) is a promising method. The novelty of these systems, one of which is tested in this study, is based on the supposition that jet lateral dispersion of HA produces both instant dermal augmentation and specific wound-healing processes, leading to its long-term dermal thickening. AirGent (PerfAction, Rehovot, Israel) is a novel skin renewal system based on patent-pending Subdermal Minimal Surgery (SMS), which initiates a wound-healing process in the dermal layer. It is a computer-guided system that delivers treatment through compressed air molecules of HA to the dermal layer of the skin.

The AirGent device accelerates and laterally disperses high molecular mass, skin-enhancing particles of HA via pneumatic needleless tiny entry points. The particles reach a controlled depth within the dermis, leaving the surrounding tissue intact while inducing dermal microtrauma that mechanically stretches the fibroblasts, stimulating growth factors and inhibiting collagen breakdown. The skin-enhancing agent (HA) attracts water molecules in the dermis, immediately thickening and hydrating the dermis, thereby resulting in visible aesthetic improvement. The microtrauma to the dermal cells triggers natural wound healing and augmented collagen generation for long-term effectiveness and long-lasting changes in the dermis.

The HA employed by the AirGent system is a nonanimal formulation that is 90% crosslinked, 10% non-crosslinked. The proprietary product, named SMS solution, is CE marked and is approved for treatment in the European Union countries. It was developed specifically according to the device's specifications and action mechanism, aimed to induce collagen remodeling due to its large molecules. The amount of HA deposition in a given area is chosen according to the treatment site, with options of 100 mL, 150 mL, or 200 mL per application. Each application covers 1 cm^2 due to the AirGent system's unique lateral dispersion mechanism, which allows easy coverage of large skin areas. Approximately 2 mg of HA is deposited in a given 5-cm^2 treatment area. After reaching the dermis, the jet immediately spreads laterally in all directions to create a lateral dispersion. Thus, a 10-by-10-mm square is treated from a single entry point. HA molecules disrupt the dermal cells upon passage, and this disruption initiates the wound-healing process, which provides the desired long-term collagen remodeling. In this way, treatment with the AirGent device commences the process of skin rebuilding, which is supposed to improve skin structure for one to two years.

The authors describe their experiences with AirGent in a series of patients who presented for facial rejuvenation treatment.

METHODS

Between May and November 2008, 20 patients were treated with the AirGent system, for a total of 105 treatment sessions. All patients were women; the average patient age was 47 years (range, 36-60). Three sessions per patient were spread out over three- to four-week intervals. Due to inflammatory reactions, the whole procedure was repeated with application of hyaluronic acid solution delivered by another producer. The treatment areas for the 20 patients included in this study were distributed as follows: around the eyes area in eight patients, in the forehead area in eight patients, around the neck in three patients, in the nasolabial folds in eight patients, in the upper lip region in two patients, and along the neckline in six patients.

Local anesthetic (lidocaine 2.5% and prilocaine 2.5%; EMLA, APP Pharmaceuticals, Inc, Schaumberg, Illinois) was applied to each patient for pain reduction. The area to be treated was also disinfected with alcohol prior to treatment initiation. Once treatment commenced, each application covered a 10-by-10-mm square until the entire treatment area was covered. After the procedure, a gentle massage was performed with anti-inflammatory cream (hydrocortisomum 0.5%; not available in the United States). The duration of the procedure generally ranged from 20 to 30 minutes.

Each patient's skin thickness was measured by 10 Mhz Antares Acuson 11343 (Siemens Medical Solutions USA, Inc, Malvern, Pennsylvania). The same measurements were taken over each of the three sessions and six months after the last session. Also at six-month follow-up, each patient completed a Global Aesthetic Improvement questionnaire with a five-degree scale of satisfaction: very much improved, much improved, improved, no change, and worse. Statistical evaluation was performed with a Student *t*-test.

Table 1. Skin Thickness (mm)—I: Pretreatment, II: After Three Sessions, and III: Six Months Posttreatment

Perorbital			Neck			Neckline			Lip			Nasolabial Folds			Forehead		
I	II	III	I	II	III	I	II	III	I	II	III	I	II	III	I	II	III
1.2	1.7	3.1	1.2	1.6	1.8	1.1	2.3	2.5	1.1	2.4	2.4	1.1	2.2	2.6	2	2.4	2.8
0.7	1.4	3.1	0.8	1.5	2.6	1.9	2.8	2.4	1.5	2.8	2.9	1.5	2.1	2	1	1.8	3.3
0.5	2.5	3	1.3	1.6	1.6	1.2	1.4	2.2				1.3	2.1	2.3	1.2	2.3	3.3
1.2	1.5	3.3	1.5	2.2	2.1	0.9	1.6	1.8				1	1.5	2	1.5	2.1	2.7
1.4	2	2.2				2.6	3.1	3.12				0.8	1.7	2	1.1	1.3	2.1
0.5	1.6	1.8				1.5	1.8	1.8				1.7	2.2	2.5	1.7	2.2	3
1.5	1.7	1.7										0.8	1.8	1.4	0.8	2.3	2.2
0.9	1.6	1.8										1.6	2.2	3.4	2.8	3.7	4.3

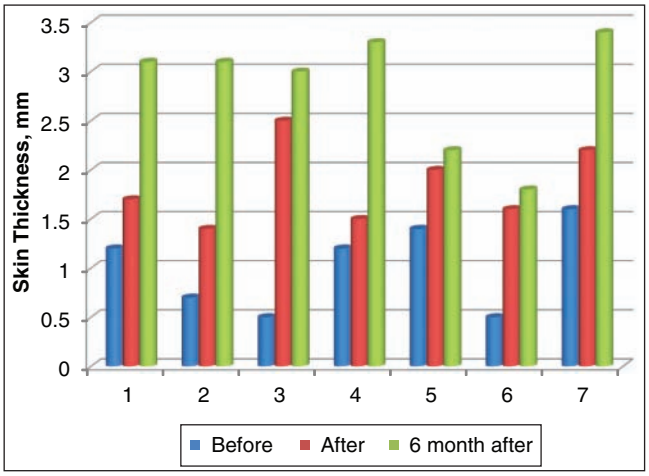

Figure 1. Increases in periorbital skin thickness are shown pretreatment, immediately after the final session, and six months posttreatment.

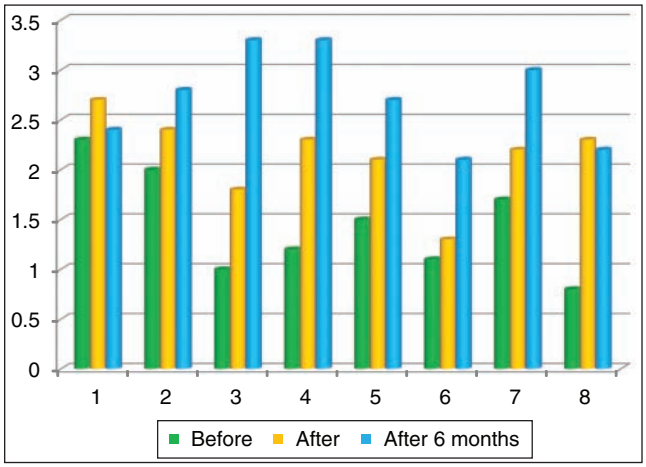

Figure 2. Increases in forehead skin thickness are shown pretreatment, immediately after the final session, and six months posttreatment.

RESULTS

Seven days after the last procedure, an increase in skin thickness was observed in all patients. The most significant differences were noted in the upper lip area, where the thickness had increased by an average of 1.3 mm; the smallest amount of change was observed in neckline area, where the thickness increased by only 0.64 mm on average. Six months after the last session, an increase in skin thickness was still noted in most patients (Table 1). At that time, the biggest difference was noted around the eyes, where the skin remained thicker by an average of 0.77 mm over baseline; the smallest difference was observed in neckline region, where thickness remained at an average of only 0.05 mm over baseline (Figures 1 and 2).

The *t*-test comparison of the pre- and intratreatment values, as well as the six-month posttreatment values, showed statistical significance ($P < .05$) in neckline area, nasolabial folds, forehead region, and periorbital area. There was no statistical significance in the neck group when pre- and six-month posttreatment values were compared.

Global Aesthetic Improvement scores by the patients at their six-month follow-up visit were reported as follows: very much improved, 2.8%; improved, 51.4%; much improved, 5.7%; no change, 43.3%; and worse, 5.7%.

DISCUSSION

The signs and symptoms of aging are preceded by structural changes in the reduction of dermis density and skin thickness.[5,12] The ultrasound imagery employed in this study is a noninvasive, quantitative, and reproductive method for measuring skin thickness and displaying skin structure. Ultrasonography measurements can also help to evaluate the improvement of internal skin layers.[13] The data in our study supported the well-documented theory[13-15] that skin on the face is the thinnest in the periorbital region and the thickest on the forehead. Moreover, skin is generally thicker in young women than in older ones.[14-16]

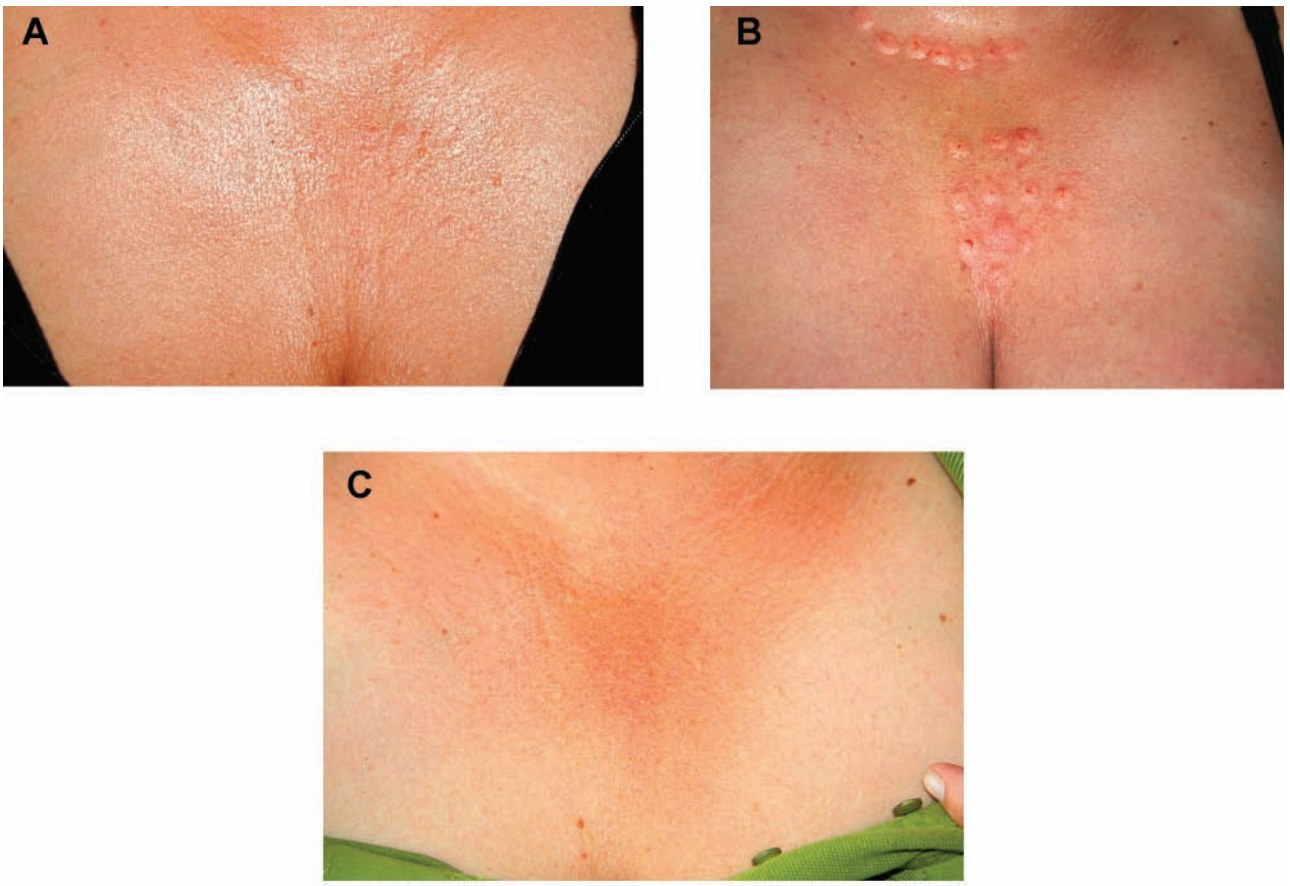

Figure 3. (A) An 45-year-old woman is shown before treatment of her neckline (décolletage) with AirGent. (B) Immediately after treatment. (C) Six months posttreatment.

When a patient seeks minimally-invasive treatment of wrinkles or facial aging, a number of methods exist that are designed to achieve the desired improvements. Reestablishment of a youthful facial appearance can be obtained through tissue augmentation (fillers) or skin resurfacing (dermabrasion, laser, etc). In fact, soft tissue augmentation dates back more than 100 years, yet the search for the ideal filler continues. Currently accepted methods of facial filling include autologous fat, collagen, HA, hydroxylapatite, polymethylmethacrylate (PMMA), poly-L-lactic acid, and polymer implants, among others.[17,18] Among the options, permanent fillers are actually uncommon because of the associated risks, including ongoing lumps, infection, and ulceration. Bovine-derived collagen is immunogenic, requiring skin tests. HA, on the other hand, is produced by fermentation in cultures of equine streptococci and does not cause immunologic sensitization; moreover, there is virtually no risk of allergic reactions.[18,19]

In 2005, a Professional Education Panel meeting in Berlin established that the ideal filler material should be biodegradable but ought to demonstrate a longevity of at least 12 months and no more than two years.[19] To that end, in our study, fluid with high-mass molecules of HA being administered as "nano-bullets" with accelerated pneumatic force passed through the dermis. This produced a doubled effect, both retaining the water molecules that improve skin hydration and initiating dermis-healing action and collagen remodeling (Figure 3). In essence, it showed precisely the effect the panel described.

The wound healing initiated by AirGent treatments is a natural restorative response to tissue injury. Healing is the interaction of a complex cascade of cellular events that generates resurfacing, reconstitution, and restoration of the tensile strength of injured skin.[20,21] This wound-healing process has three phases: the inflammatory phase, the proliferative phase, and the remodeling phase. In the remodeling phase, there is an increase of collagen production and breakdown that continues from six months to one year after injury.[21] In our study, we observed increased skin thickness immediately posttreatment, which seemed to be produced by the immediate function of the HA, and also at the six-month follow-up visit, which can be explained by the remodeling occurring during the final phase of the healing process as the collagen reorganizes.

This treatment protocol would benefit from further study with a larger cohort of patients and an even longer follow-up period.

CONCLUSIONS

Although the small number of patients and relatively short period of posttreatment observation render this report somewhat preliminary, from the data generated by this study of the AirGent facial rejuvenation technology, we found that the technique was successful in producing lasting increases in skin thickness. It resulted in at least a slight (51.4% of patients) and in some cases substantial (5.7%) improvement of appearance at the six-month follow-up, as reported by the patients themselves. These data are promising and support further research on the delivery of HA through systems such as these in facial rejuvenation.

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Disclosures

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