Improvements in Facial Hydration Following a Single TrufacialTM Treatment: A Pilot <u>Study</u>

David B. Vasily, MD, board-certified dermatologist and a fellow of the American Academy of Dermatology, American Society for Laser Medicine & Surgery, and the American Society for Dermatologic Surgery.

Introduction

Skin is the largest organ in the human body and consists of 15% of total body weight.^{1,2} It plays several important roles, including protection against the external environment, sensory perception, body temperature regulation and providing metabolic and immune system functions.¹ Water is essential for maintaining the health and function of the skin, especially in the stratum corneum (SC), also known as the outer layer of the skin, giving it flexibility and elasticity.^{3,4} Without adequate hydration, the skin desquamation process becomes impaired, leaving skin cells unable to replace themselves normally.³ This leads to the visible appearance of dry, scaly and flaky skin, superficial lines, wrinkles and premature aging.^{3,5}

Loss of skin hydration can be caused by exposure to harsh environmental factors such as wind, sun/UV rays, low humidity and air conditioning.^{3,6} Lifestyle habits can also affect skin hydration levels, including insufficient water intake, excessive alcohol use, caffeine and smoking.⁷⁻⁹ Skin hydration also decreases with age, which can worsen the appearance of wrinkles and furrows on the face.^{10,11}

Adequate skin hydration is necessary to maintain youthful, healthier looking skin.¹² Currently, this can be achieved through several methods, including lifestyle choices like increasing water intake, diet and sufficient sleep.¹³ Moisturizers are also widely used as a barrier to stop water loss from skin, usually formulated with humectants, which are substances that attract water, such as hyaluronic acid and glycerin.¹⁴ In-office procedures ranging from injectables to medical devices, have also become increasingly popular to increase skin hydration.¹⁵

TrufacialTM is a new at-home, noninvasive, patented skincare device designed for painless skin rejuvenation and hydration. The device works in three steps to exfoliate, purify and nourish skin. In the first step, a microdermabrasion diamond tip works in tandem with an exfoliating serum to remove the dead skin cells from the outer layer of skin. The second step employs the massage tip and offers two serum options: anti-aging serum to reduce the appearance of fine lines, wrinkles and age spots; or a dual-action skin brightening and acne serum. The third step involves a microneedling dermal roller paired with hyaluronic serum for skin hydration.

This study is the first to assess the efficacy of Trufacial on skin hydration after one treatment.

Methods

This was an uncontrolled, single-site monadic study to evaluate the efficacy of Trufacial on the improvement of facial hydration after one treatment. All subjects provided written consent prior to treatment. Treatments and assessments were performed at Aesthetica Cosmetic and Laser Surgery Center, Bethlehem, PA between March 1-11, 2024. Eligible subjects were healthy adults between the ages of 18-60 with regular to dry skin. Subjects did not have any cosmetic procedure one week prior to the Trufacial study.

Prior to treatment, all subjects were asked to wash their face, and pre-treatment photos were taken. Baseline skin moisture levels were measured with the bt-analyze[®] Skin Moisture Analyzer (Bio-Therapeutic, Seattle, WA). One subject also underwent a facial ultrasound to capture the stratum corneum and epidermis using the Longport EPISCAN with a 50 mHZ probe (Longport Inc, Chadds Fort, PA). Each subject received one Trufacial treatment by a trained professional provider. This consisted of an exfoliation step with a microdermabrasion diamond tip and exfoliating serum; a purification step with a massage tip and dual-action skin brightening & acne serum; and a protection step with a microneedling dermal roller and hyaluronic serum. A single treatment was administered, and the subjects waited 30 minutes before the assessments. After 30 minutes, subjects underwent skin moisture analysis with bt-analyze[®] Skin Moisture Analyzer, and one subject underwent ultrasound with the Longport EPISCAN.

Results

A total of 11 subjects enrolled in the study. All subjects received one Trufacial treatment and completed the post-treatment assessments. Subjects were all female between the ages of 18-60 with normal to dry skin who had not undergone any cosmetic treatment for at least one week. All subjects showed an increase in skin hydration after one Trufacial treatment on the forehead and left and right cheeks (Table 1; Table 2; Table 3). There was a numerical hydration increase of between 1-116% in the forehead (Table 1), a 15-125% increase in the right cheek (Table 2), and a 16-152% increase in the left cheek (Table 3) after one treatment. The right cheek experienced a higher average numerical increase in hydration compared to the forehead and left cheek (Figure 1). The difference between the hydration levels from the forehead to the cheeks may be attributed to the facial anatomy of the two areas.

All 11 subjects showed increased hydration in facial skin following one Trufacial treatment. Facial skin ultrasound on one patient revealed a visible difference post-treatment in the stratum corneum and epidermis, the outermost layers that comprise the skin (Figure 2). Both layers appear to be smoother, less wrinkled and more hydrated after one treatment (Figure 2B) compared to baseline (Figure 2A). All subjects

Discussion

This is the first study to demonstrate that Trufacial increases hydration in facial skin after one treatment. All subjects showed increases in hydration, although some changes were smaller than

others. At baseline, apart from one subject's forehead, all other subjects had below optimal skin hydration values as defined by the manufacturers of bt-analyze[®] Skin Moisture Analyzer (optimum hydration: 35-45).¹⁶

After treatment, most patients' hydration values increased to above optimum and high levels of hydration (55+).¹⁶ In the forehead area, subject 5 had a baseline that fell into the dry category (dry: 25 or below), however, after treatment, the value doubled and was classified as optimum skin hydration.¹⁶ Similarly, subject 9's left cheek hydration baseline fell in the dry category, and increased by 152% after treatment, pushing the hydration value to high levels of hydration.¹⁶ The ability of Trufacial to increase skin hydration was also demonstrated via ultrasound, and the stratum corneum and epidermis visually appeared smoother and more hydrated.

This effect could be explained by the unique combination of Trufacial's patented device and serums. Microdermabrasion has been shown to increase hydration 30 minutes after treatment.¹⁷ In addition, it is used in conjunction with an exfoliation serum rich in alpha hydroxy acids such as lactic acid that has proven hydrating effects on skin.¹⁸ Microneedling dermal roller is also another very popular method for facial rejuvenation.¹⁹ Studies have shown that hyaluronic acid with a microneedling dermal roller can increase skin hydration and skin smoothness; therefore, it may also contribute to the hydrating effect of the treatment.^{19,20}

This study was not without limitations. It had a small sample size and no statistical analysis; however, the ultrasound images appear to confirm the hydration results. This study provides good observational insight into the benefits of Trufacial, and a foundation for future studies.

Conclusion

This study demonstrated that facial skin hydration was increased after just one Trufacial treatment.

Notes from the Investigator

Dr. David B. Vasily has nearly 40 years of experience as a practicing, board certified dermatologist. He is a recognized thought leader in the field of cosmetic dermatology who has been involved in the development of many innovative breakthroughs in laser technology.

Why is skin hydration so important?

It's fascinating, when you look at patients' level of skin hydration on a day-to-day basis, you realize that many people have dehydrated skin. In my experience, skin hydration is a very important and underrecognized factor in all cosmetic and laser surgery procedures. If you start out with dry skin, you're not going to get optimal results from these energy devices and procedures.

What are your key takeaways from this study?

The results of Trufacial are comparable to professional-level skincare at home. It hydrates skin, plumping it up, leaving it smooth, soft, silky looking and glowing. It may not give you the exact same level of results as in-office procedures, but it allows you to have a very high-level home treatment to keep your skin looking amazing.

What are your thoughts on Trufacial?

The first time I saw Trufacial, I was intrigued right away, and I knew it was going to be special. Firstly, it is very well designed; secondly, the results are very impressive. After Trufacial treatment, skin is visibly smoother and softer and hydrated. Some patients even have reduced appearance of periorbital lines, which are the lines around the eyes. Results last a couple of days, so it is recommended that you perform two Trufacial treatments a week for optimal results. Currently, there are no other at-home treatments that will give you the same professional-level results – it's a home run.

As a professional laser dermatologist, I must be convinced before recommending any treatments, and I'm hard to please. I personally love Trufacial and so do my wife and my staff members. It's a great at-home complement to in-office procedures to enhance those results. In-office procedures are a big investment, and Trufacial can keep skin hydrated and looking good in between those in-office treatments.

Who would benefit from using Trufacial?

Anyone who wants their skin to look their best will benefit from using Trufacial, especially those who are preparing for a big event and make up users, as make up goes on beautifully after treatment. People should invest in their skin. You have to like what you see in the mirror as your skin is a mirror of yourself internally. If you see healthy glowing skin, you will feel better and perform better. Trufacial is a device that helps you maintain not just your skin, but also your wellbeing.

References

- 1. Champion RH, Burton JL, Ebling FJG, eds. Rook's Textbook of Dermatology. 8th ed. Oxford: Blackwell; 2010.
- 2. Richardson M. Understanding the structure and function of the skin. *Nurs Times*. 2003;99(31):46-48.
- 3. Verdier-Sévrain S, Bonté F. Skin hydration: a review on its molecular mechanisms. *J Cosmet Dermatol.* 2007;6(2):75-82.
- 4. Lodén M. Role of topical emollients and moisturizers in the treatment of dry skin barrier disorders. *Am J Clin Dermatol*. 2003;4(11):771-788.
- Werschler WP, Trookman NS, Rizer RL, et al. Enhanced efficacy of a facial hydrating serum in subjects with normal or self-perceived dry skin. *J Clin Aesthet Dermatol*. 2011;4(2):51-55.
- 6. Ohno H, Nishimura N, Yamada K, et al. Effects of water nanodroplets on skin moisture and viscoelasticity during air-conditioning. *Skin Res Technol*. 2013;19(4):375-383.
- Akdeniz M, Tomova-Simitchieva T, Dobos G, et al. Does dietary fluid intake affect skin hydration in healthy humans? A systematic literature review. *Skin Res Technol*. 2018;24(3):459-465.
- 8. Yazdanparast T, Hassanzadeh H, Nasrollahi SA, et al. Cigarettes Smoking and Skin: A Comparison Study of the Biophysical Properties of Skin in Smokers and Non-Smokers. *Tanaffos*. 2019;18(2):163-168.

- 9. Healthline. Is my skin dehydrated? <u>https://www.healthline.com/health/dehydrated-skin</u>. Accessed Mar. 27, 2024.
- 10. Farage MA, Miller KW, Elsner P, et al. Characteristics of the Aging Skin. *Adv Wound Care (New Rochelle)*. 2013;2(1):5-10.
- 11. Choi JW, Kwon SH, Huh CH, et al. The influences of skin visco-elasticity, hydration level and aging on the formation of wrinkles: a comprehensive and objective approach. *Skin Res Technol*. 2013;19(1):e349-e355.
- 12. Palma L, Marques LT, Bujan J, et al. Dietary water affects human skin hydration and biomechanics. *Clin Cosmet Investig Dermatol*. 2015;8:413-421.
- Healthline. How to Hydrate Skin from the Inside: Daily Guide and Quick Tips. <u>https://www.healthline.com/health/beauty-skin-care/better-skin-in-3-days</u>. Accessed Mar. 27, 2024.
- 14. Draelos ZD. The science behind skin care: Moisturizers. *J Cosmet Dermatol*. 2018;17(2):138-144.
- 15. Ghatge AS, Ghatge SB. The Effectiveness of Injectable Hyaluronic Acid in the Improvement of the Facial Skin Quality: A Systematic Review. *Clin Cosmet Investig Dermatol.* 2023;16:891-899.
- 16. Data on File. bt-analyze[®] quick start guide. Bio-Therapeutic. SA-58/REV071918.
- 17. Fąk M, Rotsztejn H, Erkiert-Polguj A. The early effect of microdermabrasion on hydration and sebum level. *Skin Res Technol*. 2018;24(4):650-655.
- 18. Smith WP. Comparative effectiveness of alpha-hydroxy acids on skin properties. *Int J Cosmet Sci.* 1996;18(2):75-83.
- 19. Merati M, Woods C, Reznik N, et al. An Assessment of Microneedling with Topical Growth Factors for Facial Skin Rejuvenation: A Randomized Controlled Trial. *J Clin Aesthet Dermatol.* 2020;13(11):22-27.
- 20. Papakonstantinou E, Roth M, Karakiulakis G. Hyaluronic acid: A key molecule in skin aging. *Dermatoendocrinol*. 2012;4(3):253-258.

Subject	Baseline	Post-	Percentage
		treatment	increase
1	44.2	50.9	15%
2	29.3	51.9	77%
3	30.9	31.3	1%
4	32.9	56.1	71%
5	22.1	44.1	100%
6	27.8	32.7	18%
7	39.1	50.7	30%
8	30.1	65.1	116%
9	26.6	52.9	99%
10	30.7	52.6	71%
11	32.7	44.7	37%

Table 1. Baseline and post-treatment hydration levels in the forehead after one Trufacial treatment

 Table 2. Baseline and post-treatment hydration levels in the right cheek after one Trufacial treatment

Right Cheek					
Subject	Baseline	Post-	Percentage		
		treatment	increase		
1	31.6	52.8	67%		
2	26.2	59.0	125%		
3	27.3	56.3	106%		
4	31.4	56.8	81%		
5	31.3	53.2	70%		
6	31.3	55.7	78%		
7	26.0	54.6	110%		
8	30.0	35.0	17%		
9	29.0	57.9	100%		
10	28.1	58.7	109%		
11	31.2	36.0	15%		

Left Cheek					
Subject	Baseline	Post-	Percentage		
Subject		treatment	increase		
1	31.6	52.8	67%		
2	28.5	55.6	95%		
3	29.1	51.9	78%		
4	33.4	57.8	73%		
5	30.5	51.2	68%		
6	29.4	51.9	77%		
7	26.0	54.6	110%		
8	30.2	35.0	16%		
9	23.0	57.9	152%		
10	28.1	58.7	109%		
11	28.1	36.0	28%		

 Table 3. Baseline and post-treatment hydration levels in the left cheek after one Trufacial treatment



Figure 1. Average increase in skin hydration 30 minutes after one Trufacial treatment Average percentage increase in hydration as measured by the bt-analyze[®] Skin Moisture Analyzer



Figure 2. Facial skin ultrasound at (A) baseline and (B) 30 minutes after one Trufacial treatment using the Longport EPISCAN with a 50 mHZ probe