

FEEL THE DIFFERENCE















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Abstract

Background: The aesthetic appearance of the skin, with the emergence of wrinkles, blemishes, and infraorbital hollowing, can be a cause of social distress and is a process exacerbated by aging. The presence of skin imperfections and aging is partly due to a loss of hyaluronic acid (HA), which normally contributes to a maintain a healthy and voluminous skin. Attempts to restore volume and revert the signs of aging have there-

fore focused on the use of dermatologic fillers based on HA.

Aim: Here, we tested the safety and efficacy of MelHA®-Monophasic Elastic $Hy aluronic\ Acid\ (Concilium\ FEEL \circledast\ filler\ products)\ containing\ HA\ at\ different\ concentrations\ and\ injected\ at\ different\ sites\ according\ to\ recommendations.$

Methods: Five different physicians assessed 42 patients across five different medical facilities in Italy, where they performed the treatment and assessed the patients after a follow-up visit. Safety and efficacy of the treatment and change in quality of life after treatment were evaluated with two surveys, one directed to medical personnel, and one directed to patients.

Results: Our results show that, across all products and personalized treatments, patients', physicians' and "independent photography reviewer" satisfaction was very high and that the treatment show a favorable safety profile.

Conclusion: These results are promising and suggest the use of Concilium Feel® filler products can contribute to an increased self-esteem and quality of life in aging patients.

KEYWORDS efficacy, filler, hyaluronic acid, patient satisfaction, safety

1 | INTRODUCTION
times deteriorates with the aging process, which is characterized by an increasing loss of function in various organ systems, and is individuals who desire to have a relaxed appearance, and who seek to change the aesthetic appearance of their skin, are often seeking for a minimally invasive, effective treatment with no consequences and a natural look, which does not extensively trans-form their appearance. This aesthetic perceived appearance, often their appearance. This aesthetic perceived appearance of the period of productivity in life, and to an increase of worries due

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FIGURE 3 Appresentative pictures of before and after Concilium FEEL treatment. (A) Before and after treatment with Concilium FEEL Deep, the injections were performed with a 1 mL pre-filled syringe, using 50 -mL for each side of the face. Right side and left side: each two supraperiosteal 0.25 mL micro-bolus injections at the level of the zygomatic arch. For Concilium FEEL Solarse, the injections were performed with flow syringes of 1 mL each, two per side. For each side, one injection was performed in the malar area (0.5 mL), one at the level of the zygomatic arch. For Concilium FEEL Solarse, the injections were performed with flow plots and 1 mL was used for the mandibular subcutaneous injection with retrograde linear technique with cannula 25.6. (B) Before and after treatment with Concilium FEEL Booster, the injection was performed with five boluses of 0.1 mL in the middle dermis with bap technique, in five specific points; on the projection of the cheekbone, at least 2 cm from the outer corner of the eye; at the intersection of the line that pions the wing of the nose to the tragus and the line that passes through the uppli.1 cm anterior to the tragus; 1 cm below the mandibular angle; 1.5 cm taleral to the line passing through the center of the chin. For Concilium FEEL Booster, in large was used, and 5. mL were injected each side of the face. For each side the injection was performed in the zygomatic-malar area (1.5 mL). (C) Before and after treatment with Concilium FEEL Booster in combination with Concilium FEEL Booster in combination with Concilium FEEL Booster in chine and the combination with Concilium FEEL Booster in chine and the stream of the chine the combination with Concilium FEEL Booster in chine and the combination with Concilium FEEL Booster retainment following peeling, two syringes of a that of the strategic point in the trage and the line that present forms of the new that the strategic point is listed below: on the projection of the cheekbone, at least 2 cm from the outer corner of the eye;

T&BBLE 2 esteem survey across patients following

Did the treatment affect your self-esteem? (%) (n pat/tot n pat)				
Yes	90% (38/42)			
No	10% (4/42)			
If yes, how?				
It increased a lot	50% (19/38)			
It increased	50% (19/38)			
It decreased	0% (0/38)			
It decreased a lot	0% (0/38)			
Ldo not know	09((0/38)			

Note: Patients overwhelmingly declared that the treatment, irrespectively of the product used for the treatment, increased their self-esteem (90%), and among the patients with increased self-esteer 50% had a great increase in self-esteem.

used for rejuvenating an aging face, but they are also employed in the treatment of structural alterations such as facial asymmetry and consequent aesthetic and psychologic disturbances.

Here we showed that Concilium Feel® products containing

cross-linked HA constitute safe and effective treatments to reduce skin aging and improving the aesthetic appearance—as reported by patients and physicians and as confirmed by the independent by patients and physicians and as confirmed by the independent reviewer-after tearment. Five products have shown safety and effectiveness, and this included Concilium Feel® Body, Booster (alone or in combination with Concilium B-Twin System peeling), Global, Deep, and Volume.

Most patients did not experience any AEs following treatment, with

just a small fraction of patients experiencing mild to moderate pain, edema and erythema, hematoma, or bruises, ranging from 1 to 2 days after treatment, to more than 10 days after treatment. Such AEs were ant only after treatment with Concilium Feel® Body, and irrelevant for all other specific treatments. That said, bruises were generally

ies using HA-fillers, and therefore we do not consider necessary a fille treatment associated with lidocaine. 16 The presence of bruises did not require any medical therapy and was self-limiting, and furthermore the require any medical therapy and was self-limiting, and furthermore the busies did not impact the perceived effectiveness of the treatment, with patients' satisfaction, as measured with the Global Assisthetic improvement Scale (GAIS), at very high level, both immediately after the treatment, and after a follow-up violat 15 days after treatment. The aesthetic perception was classified as ranging from improved to exceptionally improved through the follow-up violat vagesting a progressive action of remodeling and an optimal integration with the Issua. This assert allows the followers to set ornorosis immilrone.

the tissue. This aspect allows the injectors to set protocols implying some sessions of treatment leading to consistent progressive results

some sessions of treatment leading to consistent progressive results and minimization of AE.

Perceived aesthetic improvement was recorded across all reatment types, including Concilium Feel® Body. Furthermore, the treatment influenced the patients' self-esteem, improving it or greatly improving it. Concilium Feel® was well-tolerated and safe, as demonstrated by successful treatment effect, with positive assessments by investigators and patients for all endpoints considered.

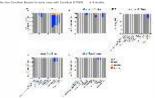
A potential limitation of this preliminary study could be the relative sestificated seamled or halfest restard. Despite his is, the bind

atively restricted sample of patients treated. Despite this, the high expertise of injectors in this field and the evaluation of the inde-

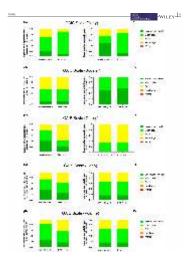
expertise of injectors in this field and the evaluation of the inde-pendent photography reviewer, allow for suggesting that Concilium Feel® HA-based fillers have excellent tolerance and efficacy profile. In conclusion, the performance of Concilium Feel® HA-based fillers and their safety profiles supports the use of such products for cosmetic purposes with rejuvenating effects on the skin regardless of the area of application.

AUTHOR CONTRIBUTIONS

E.T., S.V., S.V., M.Z., and R.R. designed and performed the research. E.T., S.V., S.V., M.Z., and R.R. analyzed the data and wrote the paper. All authors have read and approved the final manuscript.



E/% of patients	No All	0-1 days	3-4days	5-7 days	8-10days	>90 days
welling	71% (30/42)	19% (5.42)	5% (2/42)	5% (2.42)	0% (0.42)	0% (0.42)
feakness	74% (81/42)	179(17/42)	7% (3/42)	295 (1,142)	0% (0.42)	0.00/421
nuises	45% (18/42)	12% (5.42)	12% (5/42)	5% (2/42)	2% (1,42)	24%
famoution	00% (37/42)	10% (4.42)	2% (1/42)	0% (0/42)	0% (0,442)	0% (0,42)
ense area	86% (36/42)	10% (4/42)	2% (1/42)	2% (1.42)	0% (0.42)	0% (0.42)
ain	90% (38.42)	79(13/42)	2% (1/42)	095 (0/42)	0% (0.42)	0% 00/425
lumbness	90% (38,42)	7% (3,42)	2% (1/42)	0% (0/42)	0% (0,442)	0% (0,42)
inging	90% (38.42)	5% (2/42)	5% (2/42)	0% (0/42)	0% (0.42)	0% (0.42)
ulsing sensation	93% (39/42)	5% (2.42)	2% (1/42)	095 (0/42)	0% (0.42)	0% (0.42)
urring	93% (39/42)	7% (3,42)	0% (0.42)	0% (0/42)	0% (0,442)	0% (0,42)
tage:	95% (40/42)	5% (2/42)	0% (0/42)	0% (0/42)	0% (0.42)	0% (0.42)
leadache	98% (41/42)	29(11/42)	0% (0.42)	0% (0/42)	0% (0.42)	0% (0.42)
ever feeling	95% (40/42)	5% (2.42)	0% (0/42)	0% (0/42)	0% (0.42)	0% 03/425





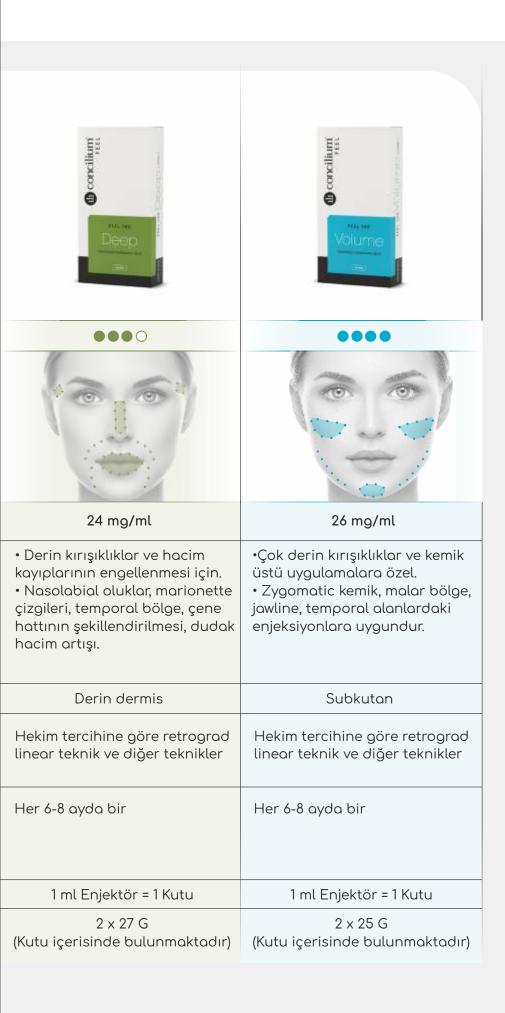
4 | CONCLUSION AND DISCUSSION

HA filler are considered the gold standard for facial rejuveration, facial contouring and volume augmentation. HA fillers are typically

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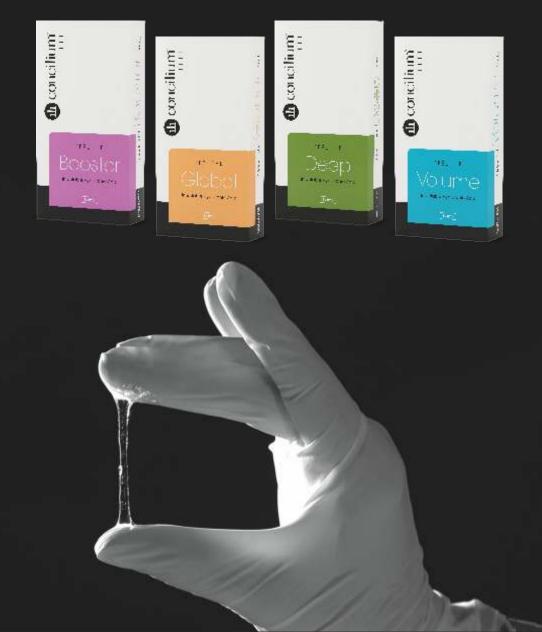




MelHA®-Monofazik Elastik Hiyalüronik Asit

BDDE Kalıntısı --> 0,065/1 ppm (FDA limiti < 2 ppm) FDA tarafından belirlenen sınırın çok altındadır.

Düşük ve homojen enjeksiyon basıncı rahat ve hassas çalışmayı mümkün kılar. Reolojik özellikleri optimal bir şekilde dengelendiği için Concilium Feel® cilt dokusunda muntazam sonuçlar ve mükemmel bir cilt entegrasyonu sağlar.





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