

A clinical study to evaluate the safety and performance of DKL Crosslinked Sodium Hyaluronate 26 mg/mL dermal filler for cheek augmentation

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INTRODUCTION

- Hyaluronic acid (HA)-based dermal fillers have become the top injected soft filler agent around the world, with over 1.8 million procedures reported in 2021 in the United States.¹
- Once injected into the skin, crosslinked HA-based fillers integrate into dermal tissue and bind water molecules which volumize, soften, and hydrate the skin. The gel's physical properties influence how it spreads in tissue after the injection.² These properties also affect the product's durability.
- RadiaNt Ultra (DKL 26 mg/mL) is a sterile, injectable, pyrogen-free crosslinked sodium hyaluronate 26 mg/mL dermal filler from non-animal origin in a phosphate-buffered saline solution. The gel is latex-free, viscoelastic, clear, colorless and biodegradable. The crosslinking agent is 1,4 butanediol diglyceryl ether (BDDE). The device is provided in a disposable graduated and pre-filled syringe.
- DKL 26 mg/mL is intended for facial volume restoration. Intended use is specific to a country of approval. Refer to product IFU.
- The purpose of the study (NCT 05021926) was to collect performance and safety data associated with the implantation of DKL 26 mg/mL in healthy subjects desiring aesthetic improvement in cheek augmentation and/or age-related facial volume deficit.

METHODS

- The study was a single-center pivotal, prospective, active-controlled, randomized, evaluator- and subject-blinded, intra-individual split-face comparison study conducted by CTC Clinical Trial Consultants AB in Uppsala, Sweden.
- Study population: Males and females aged 18-65 years with age-related bilateral moderate to substantial loss of fullness in the midface area, classified as grade 3 or 4 according to the Medicis Midface Volume Scale (MMVS). ³ Both sides of the midface were to be of the same grade (i.e., approximate bilateral symmetry).
- The subjects were randomized to be treated with DKL 26 mg/mL in the right midface and Juvéderm Voluma + lidocaine 0.3 % in the left midface or vice versa.
- At baseline (Day 0) Subjects were injected with up to 2 mL of filler per side (per investigator discretion). Prior to treatment with the filler, the treatment areas of both sides were anesthetized with lidocaine solution for injection 10 mg/mL.
- Optional touch-up was performed after 30 days (the same dermal filler was injected into each side).
- Follow-up was performed at 30, 90, 180 and 270 days.
- Performance was evaluated by a blinded investigator.
- Performance outcomes: MMVS, investigator-rated Global Aesthetics Improvement Scale (GAIS)⁴ Subject-rated GAIS.
- Safety was evaluated by adverse events (AEs). Local tolerability including symptoms of redness, tenderness, swelling, bruising, and pain was assessed using subject diaries for 14 days after the first treatment session and after touch-up.
- Subject Satisfaction Questionnaire
- The per protocol (PP) population included subjects who received the initial treatment and had the 6-months assessment.

Table 1. Subject demographics

Characteristic	Study population N = 48
Age, years, median (range)	56.0 (34-65)
Sex, n (%)	
Female	42 (88%)
Male	6 (13%)
Fitzpatrick skin type	
Type II	15 (31%)
Type III	25 (52%)
Type IV	8 (17%)
Race	
White	42 (88%)
Asian	2 (4.2%)
Black or African American	1 (2.1%)
American Indian or Alaska Native	1 (2.1%)
Unknown	2 (4.2%)

Values may not add to 100% due to rounding.

Table 2. Injection volume, mL, median (range)

Time	DKL 26 mg/mL	Juvéderm Voluma
Initial treatment	1 (0.8-2) n=48	1 (0.8-2) n=48
Touch-up	1 (0.2-1) n=31	1 (0.3-1) n=32

Medicis Midface Volume Scale (MMVS) ³

Grade	Description
1	Fairly full
2	Mild loss of fullness
3	Moderate loss, slight hollowing
4	Substantial loss, clearly apparent hollowing

Global Aesthetics Improvement Scale (GAIS)⁴

Score	Grade	Description
3	Very Much Improved	Optimal cosmetic result for the implant in this patient.
2	Much Improved	Marked improvement in appearance but not completely optimal for this patient. A touch-up would slightly improve the result.*
1	Improved	Obvious improvement in appearance from the initial condition, but a touch-up is indicated.*
0	No Change	The appearance is essentially the same as the original condition
-1	Worse	The appearance is worse than the original condition

*Touch-up in could only be done once - at the 30 day visit.

RESULTS

Figure 1. Percent of responders (PP population)

Response was defined as ≥ 1-point improvement on the MMVS for each side of the midface compared to baseline. Each side of the midface was assessed separately.

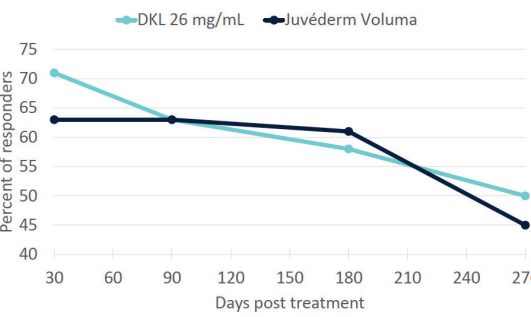
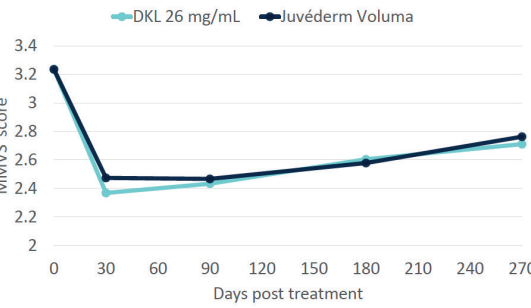


Figure 2. Midface improvement according to MMVS (PP population)



- Statistically significant improvements in MMVS were observed between each time point assessed and baseline (p< 0.0001)
- No statistically significant differences were observed at each time point between DKL 26 mg/mL and Juvéderm Voluma

Figure 3. Mean investigator-rated GAIS score at follow-up (PP population)

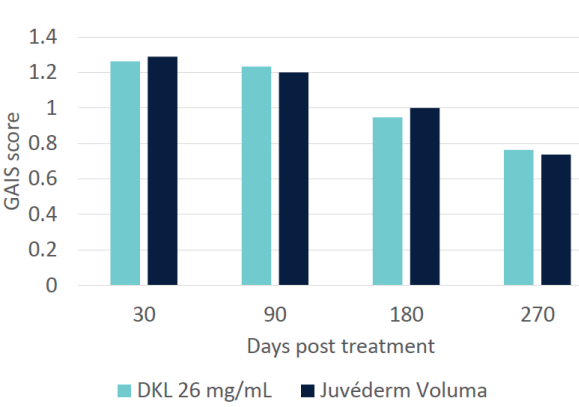


Figure 4. Mean subject-rated GAIS score at follow-up (PP population)

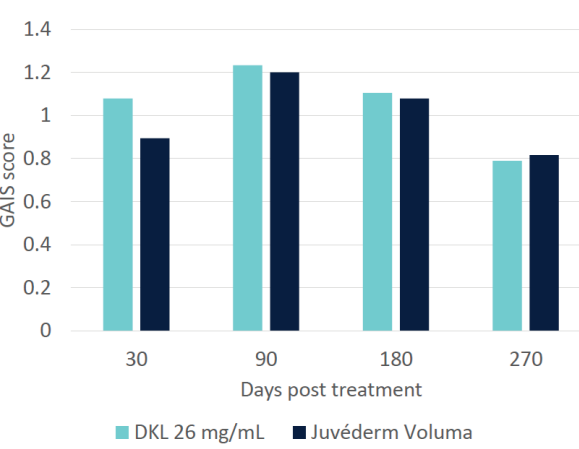


Figure 5. Percent of subjects satisfied + very satisfied with the dermal filler

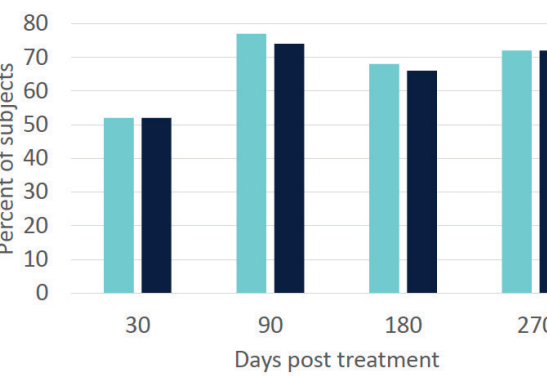


Figure 6. Percent of subjects who would recommend the product to family and friends

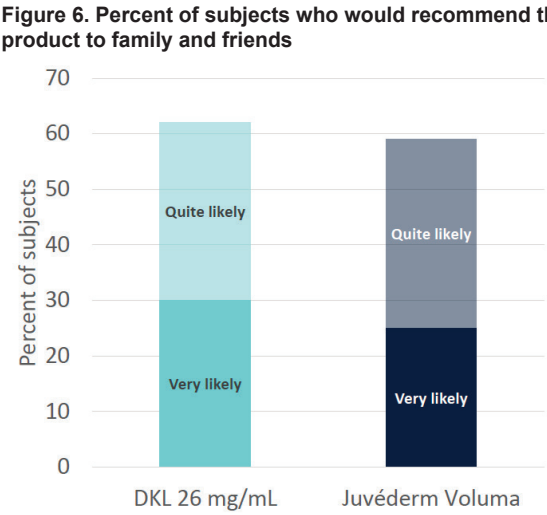


Figure 7. Representative image of a subject at baseline and at 6 months after the initial treatment



Safety

- Most subjects experienced local tolerability symptoms.
- The most common reactions reported in subject diaries were transient injection site pain, swelling/edema, bruising, erythema and pruritis, which are generally expected post-treatment injection site reactions in hyaluronic acid dermal fillers.
- The median duration for each reaction ranged between 1 and 6 days, with swelling/edema having the longest duration for DKL 26 mg/mL (median 6 days, maximum 14 days) and bruising having the longest duration for Juvéderm Voluma (median 4.5 days, maximum 14 days).
- The majority of symptoms were mild or moderate in intensity.
- No unexpected related AEs were reported during the study.
- Four serious adverse events in 2 subjects that occurred during the study were not related to the study products, procedures or local anesthetics

CONCLUSIONS

- DKL 26 mg/mL showed statistically significant improvement from baseline in MMVS at all follow-up timepoints evaluated.
- DKL 26 mg/mL demonstrated outcomes comparable to Juvéderm Voluma across all performance parameters tested during the study: MMVS and investigator-and subject-rated GAIS.
- The higher proportion of responders in the DKL 26 mg/mL group vs the Juvéderm Voluma group at one month after treatment, suggests better lifting capacity of the tissue.
- The improvement lasted for the duration of the study, which was 9 months.
- Satisfaction with DKL 26 mg/mL was highly comparable to satisfaction with Juvéderm Voluma throughout the study.
- The treatment was well tolerated with only transient AEs and with no serious or unexpected treatment-related AEs. The rate and type of AEs were comparable between both products.

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