Restylane Skinboosters for improved facial skin quality using two treatment sessions

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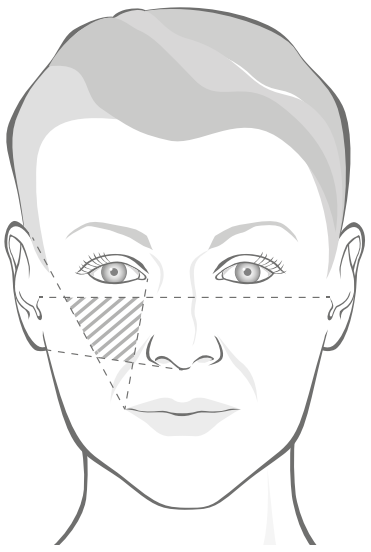
Introduction/objective

- Stabilised hyaluronic acid (HA) gel injections have been used successfully for facial skin rejuvenation and improved skin quality. Restylane® Skinboosters™ Vital Lidocaine (HA-RSB) (Galderma) contains 20 mg/mL HA stabilised using the NASHA™ technology and has shown to be effective and safe for improving skin hydration, texture, and elasticity.[1-6]
- Treatments with HA-RSB are usually administered over three treatment sessions four weeks apart to give a total of 3 mL. However, some injectors advocate the use of two treatment sessions to deliver the same total volume of product.
- The purpose of this study was to evaluate the efficacy and safety of facial skin treatment with HA-RSB using two treatment sessions and long-term follow-up.

Materials and methods

- The study (NCT02403986) was performed at two centres in Germany and enrolled females 35 to 45 years old with moderate facial ageing intending to improve their facial skin quality in terms of hydration, texture, and elasticity.
- Subjects received HA-RSB in both sides of the middle third of the face (Figure 1) using two treatment sessions scheduled four weeks apart. HA-RSB was injected in dermis using the SmartClick™ system and the multi puncture injection technique in 10 µL deposits; 2 mL of product was administered at the first treatment session and 1 mL at the second session.

Fig. 1 Treatment area, subjects were treated bilaterally



- Follow-up visits were scheduled at 1, 3, 6, and 9 months after the second treatment session and a single maintenance treatment (1 mL of product) was performed at six months. Subjects will be followed for up to 18 months (data not yet available).
- The treating investigators and subjects assessed aesthetic change using the Global Aesthetic Improvement Scale (GAIS) (Table 1) and photographs, responding to the question:"How would you describe the aesthetic change of the treatment area compared to the photos taken before the first treatment session?" Subject satisfaction was evaluated using subject satisfaction questionnaires (SSQs) collected before treatment and at follow-up visits.

Table 1 Global Aesthetic Improvement Scale (GAIS)

Rating	Definition
Very much improved	Optimal cosmetic result for this subject.
Much improved	Marked improvement in appearance from the original condition, but not completely optimal for this subject.
Improved	Obvious improvement in appearance from the original condition.
No change	The appearance is essentially the same as the original condition.
Worse	The appearance is worse than the original condition.

Subject rated according to left column only

- Non-invasive biophysical skin hydration measurements were carried out at baseline and at all follow-up visits using a Corneometer 825® (Courage + Khazaka electronic GmbH).
- Safety was assessed by adverse event (AE) reporting. Local tolerability including symptoms of redness, tenderness, swelling, bruising, and pain was assessed using subject diaries 14 days after the first treatment session and after the maintenance treatment at six months.

Results

- A total of 27 females with a mean age of 41 years (SD 3.3 years) were enrolled and received the study treatment.

GAIS

- For investigator-reported GAIS, 96% of subjects showed aesthetic improvement at one month after treatment and 92% after three months. At six months, GAIS improvement was observed in 88% of subjects and 71% were still improved after nine months (Figure 2).
- For subject-reported GAIS, 80% of subjects reported improvement at one month and 72% after three months. A total of 58% of subjects assessed themselves as improved after six months and 50% after nine months.

SSQ

- For almost all subjects (96%), the primary aim for undergoing treatment was to improve the quality of the skin.
- One month after treatment, 80% of subjects were satisfied with their skin in the treatment area in contrast to 19% at baseline (Figure 3).
- One month after treatment, 76% of subjects agreed that the treatment improved the overall quality of their skin.
- Skin quality parameters including hydration, elasticity, softness, radiance, smoothness, and freshness were rated as improved by a majority of subjects (Figure 4).

Fig. 2 Aesthetic improvement of subjects on the Global Aesthetic Improvement Scale (GAIS) assessed by investigators

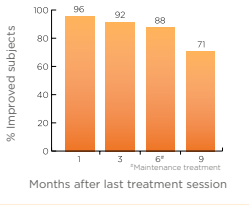


Fig. 3 Subject satisfaction with the skin in the treatment area

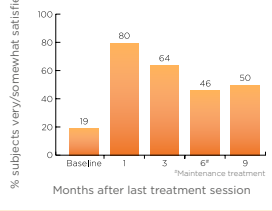
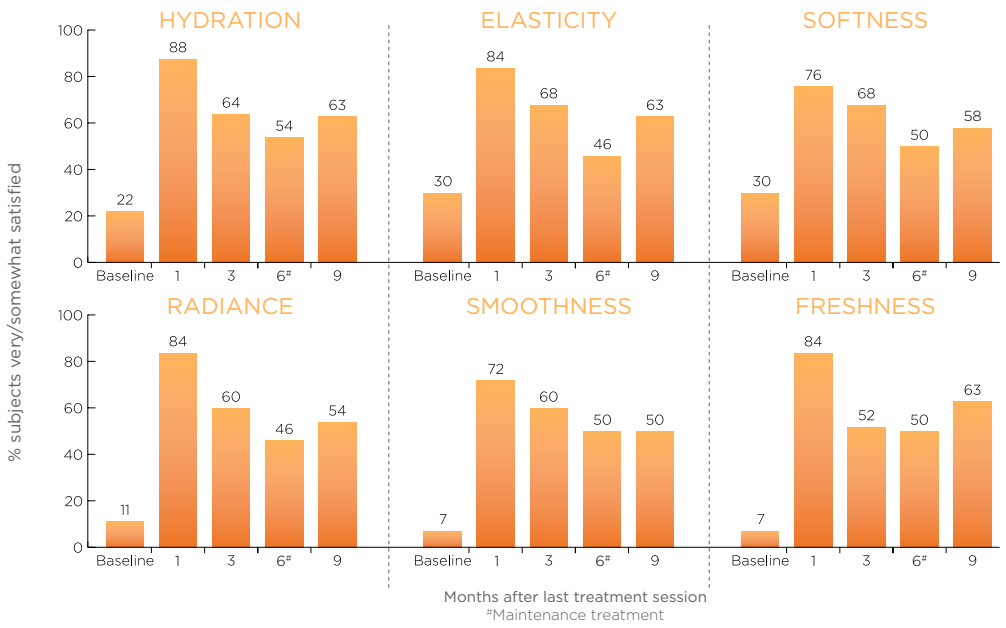


Fig. 4 Subject satisfaction with skin quality



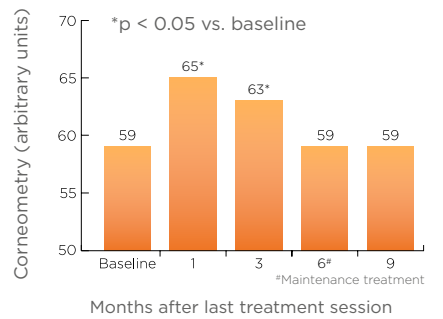
SKIN HYDRATION

- In line with the results on subject satisfaction with skin hydration, corneometry measurements showed a statistically significant increase in subjects' skin hydration compared to baseline at one and three months after second treatment session (Figure 5).

SAFETY

- Most subjects experienced local tolerability symptoms. Common symptoms reported from subject diaries were redness, swelling, and pain. The majority of symptoms were mild in intensity and resolved by day 14 without any intervention.
- Twelve related AEs in four subjects were reported in total, all cases were mild in intensity except two that were moderate. The most commonly reported were pain and swelling with four events each. No serious or unexpected related AEs were reported during the study.

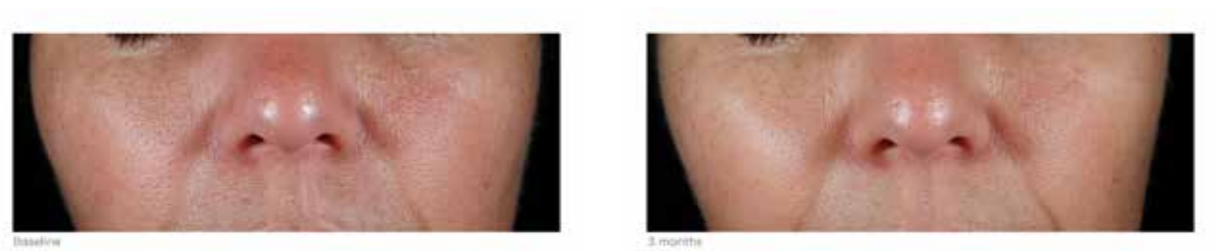
Fig. 5 Skin hydration assessments using a corneometer from baseline up to nine months after treatment (Mean values)



Conclusions

- The results of this study showed that treatment with 3 mL of Restylane® Skinboosters™ Vital Lidocaine administered over two treatment sessions was sufficient in providing the majority of subjects with aesthetic improvement (GAIS) and improvement in skin quality of the face. See Figure 6 for photographs of a representative subject.
- Subjects' treatment expectations were met as high subject satisfaction rates were reported for all skin quality parameters.
- Subjects' satisfaction with skin hydration was corroborated by the biophysical measurements of skin hydration that showed significant increases compared to baseline.
- The treatment was well-tolerated with no serious or unexpected treatment-related AEs reported by any subject.

Fig. 6 Representative subject at baseline and at three months after treatment



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