BACKGROUND

Juvederm® HYDRATE is a new un-crosslinked hyaluronic acid (HA) injectable treatment with mannitol comprising 13.5 mg/g un-crosslinked hyaluronic acid plus 0.9% mannitol. It is indicated for improving skin hydration and elasticity by multi-injection into the dermal/epidermal junction and into the superficial dermis to improve skin tone and reduce fine lines and wrinkles. The addition of mannitol leads to reduced free radical degradation of the hyaluronic acid to extend longevity.

METHOD

Objectives:

Primary Objective:
- To evaluate the efficacy of Juvederm® HYDRATE on skin hydration at day 60

Secondary Objective:
- Evaluation of subject and physician satisfaction

Study Design:
- Prospective
- Multicentre
- Non-interventional
- Post-marketing surveillance

Study Centres:
- 3 study centres in France, each recruiting a maximum of 10 subjects per centre
- All 3 investigators used the ‘depot’ injection technique comprising small injections into the middle to deep dermis (Figure 1)
- Physicians used Juvederm® HYDRATE as per their normal clinical practice and in line with the Directions For Use

Figure 1: Depot Technique

Subjects:
- A total of 27 healthy female subjects (mean age: 42.6 years) were enrolled by 3 investigators

Exclusion Criteria:
- Breast-feeding or pregnant
- Allergy to hyaluronic acid
- Tendency to keloids
- Treatment with permanent filters
- Mesotherapy treatment in the last 6 months

Study Schedule:
- Total study duration was 60 days
- On Baseline visit (Day 0), all baseline data were collected and eligible subjects were injected with Juvederm® HYDRATE according to the injector’s usual practice
- Follow-up visits were planned in accordance with the subject’s normal clinic schedule (typically on Days 15, 30 and 60)

Outcome Measures:
- Skin measurements were performed at each of the 4 visits on different areas (i.e. eye, cheek, peri-oral and neck-line areas) using a probe-based system to assess physical and visual skin.
- The biophysical and mechanical properties of the skin were measured using the Visio Probe, a high-resolution sensor to capture precise skin images (i.e. wrinkles, sebum, hair distribution, dark spots and clogged pores/bacterial infection) (Figure 2).

Figure 2: The Visio Probe

CONFLICT OF INTEREST STATEMENT

This study was sponsored by Allergan and the presenting author received payment for participation in the study, as well as payments for consultancy services.

RESULTS

Hydration:

There was a statistically significant improvement in skin hydration for the cheek at Day 30 (mean 56.4%) and Day 60 (mean 59.3%) compared to baseline (p<0.0022 and 0.0021, respectively) (Figure 3).

There was a statistically significant improvement in skin hydration for the perioral area at Day 30 (mean 61.2%) and Day 60 (mean 59.3%) compared to baseline (p<0.0041 and 0.0467, respectively) (Figure 4).

There was a statistically significant improvement in skin hydration for the neck-line area at Day 30 (mean 66.5%) and Day 60 (mean 65.3%) compared to baseline (p<0.0022 and 0.0448, respectively) (Figure 4).

Figure 3: The Visio Probe

Subject Discomfort:

At Day 0, mean subject discomfort was 4.1 (range: 0-9).

Injection Technique:

All subjects underwent manual injection using a 30 G 1/6" needle. Mean total volume injected into the face was approximately 1.0 mL at each visit, and mean total volume injected in the neck-line area was 0.8 mL. The majority of investigators found ease of injection to be ‘easy’ or ‘very easy’.

Physician Satisfaction:

Physician satisfaction showed that skin texture, brightness, hydration and appearance were ‘improved’ or ‘very improved’ for >90% of subjects at Day 60.

There is a strong anisotropy

Table 1: Percentage Skin Improvement (Combined ‘Very Improved’ and ‘Improved’)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Day 15</th>
<th>Day 30</th>
<th>Day 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Texture</td>
<td>88.9%</td>
<td>100%</td>
<td>95.8%</td>
</tr>
<tr>
<td>Brightness</td>
<td>74.1%</td>
<td>87.5%</td>
<td>91.3%</td>
</tr>
<tr>
<td>Hydration</td>
<td>88.9%</td>
<td>100%</td>
<td>96.5%</td>
</tr>
<tr>
<td>Appearance</td>
<td>48.1%</td>
<td>91.7%</td>
<td>93.1%</td>
</tr>
</tbody>
</table>

Further assessment of subject satisfaction at Day 60 revealed that global aesthetic result and skin revitalisation were ‘very improved’ or ‘improved’ in 100% of subjects, and face fullness was ‘much better’ or ‘better’ in 78.9% of subjects. 95% of subjects were delighted with treatment, with 85% being both happy to undergo repeat treatment and would recommend treatment to a friend.

SKIN APPEARANCE

Patients are very satisfied with the brightness and texture of the skin after treatment. Although skin brightness is not easy to assess with physical parameter both the patient and the physician observed a clear improvement in the brightness of the skin.

However an improvement of the skin texture is not only observed by both patient an injector but also objectively assessed by the Intuiskin machine that measures anisotrophy of the skin.

This improvement is shown in figures 5 and 6.

Figure 4: Mean improvement in Hydration over time per area

Figure 5: Right cheek of a patient before Juvederm® HYDRATE treatment. There is a strong anisotropy.

Figure 6: After 3 injections of Juvederm® HYDRATE, the skin has a better isotropy.

ADVERSE EFFECTS

Treatment was well-tolerated with all adverse events related to injection technique rather than to the product. All adverse events were transient with no sequelae.

CONCLUSIONS

Juvederm® HYDRATE delivered significant improvements in skin hydration at Day 60 in the cheek, neck-line and peri-oral areas compared to baseline. Physician and subject satisfaction of aesthetic results showed that skin texture, brightness, hydration and appearance were ‘improved’ or ‘very improved’ for >80% and >80% of subjects at Day 60, respectively.

Further assessment of subject satisfaction at Day 60 revealed that global aesthetic result and skin revitalisation were ‘very improved’ or ‘improved’ in 100% of subjects, and face fullness was ‘much better’ or ‘better’ in 78.9% of subjects. 95% of subjects were delighted with treatment, with 85% being both happy to undergo repeat treatment and would recommend treatment to a friend.

REFERENCES