LIP ENHANCEMENT, NATURALNESS, AND SUBJECT AND PARTNER SATISFACTION AFTER HA_{RK} TREATMENT

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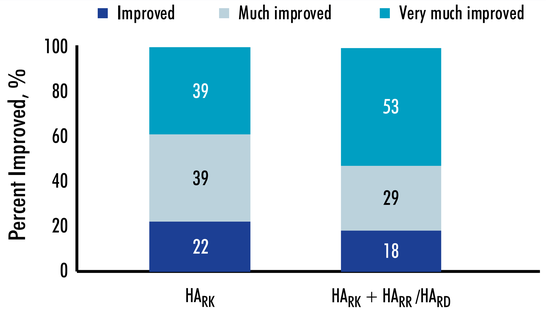
INTRODUCTION

- The hyaluronic acid filler HA_{RK} is available in Canada and the EU and in many other countries outside of the US
  - Approved for augmentation and/or restoration of lip volume.
- This open-label post-marketing study was done to evaluate lip enhancement treatment with HA_{RK}.
- Apart from the conventional assessments by subjects and treating investigators, we also collected questionnaire data from the subjects' partners to evaluate their own satisfaction with the subjects' lips after treatment.

Table 1. Outline of study details

• Study design	• Open-label multi-center study (NCT03967444) • 3 centers (59 subjects) in Canada
• Assessments	• Aesthetic improvement of lip fullness: GAIS • Naturalness of facial expressions: Independent Photographic Reviewer assessment • Subject satisfaction with lips: FACE-Q scales[2] • Subject and partner satisfaction: Kissability questionnaire • Adverse events
• Treatment	• Day 1 - HA_{RK} treatment of lips alone, or - HA_{RK} in lips in combination with HA_{RR} and/or HA_{RD} in perioral facial wrinkles and folds • Week 4: - Optional touch-up
• Assessment schedule	• Assessments were done at screening/baseline, and at Weeks 4 and 8 following the subjects' last injection

Figure 1. GAIS Responder Rate at Week 8 – By Subjects



Percent of subjects rated as 'improved', 'much improved' or 'very much improved
95% CIs: 0.81-1.00 (HA_{RK}); 0.91-1.00 (HA_{RK} + HA_{RR}/HA_{RK})

OBJECTIVES

- The primary objective was to evaluate
  - The degree of aesthetic improvement in managing lip fullness, using the Global Aesthetic Improvement Scale (GAIS), 8 weeks following the subjects' last treatment with HA_{RK} when compared to pre-treatment baseline.
    - Primary endpoint: percentage of subjects rating themselves as 'improved', 'much improved', or 'very much improved', calculated with a 95% confidence interval (CI).
- Secondary objectives included
  - lip fullness and naturalness (assessed by an independent photographic reviewer),
  - partner and subject satisfaction with lips and kissability,
  - aesthetic improvement (assessed by treating investigators), and
  - adverse events.

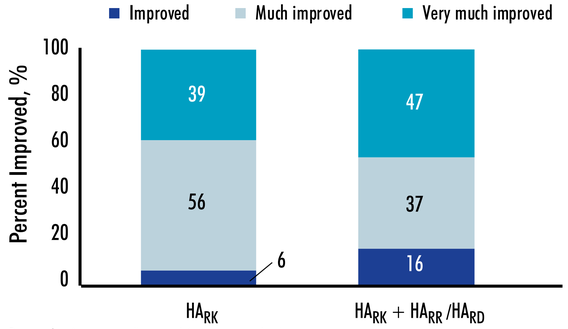
METHODS (Table 1)

- Adults who intended to undergo lip augmentation and who had a steady relationship with a partner were eligible for this 8-week Phase IV study.
- Treating investigators determined which treatment group to assign each subject to, based on expected optimal outcome for the subject.
  - If needed, HA_{RR} was to be used for correction of moderate facial wrinkles and folds, and HA_{RD} for severe facial wrinkles and folds.
- In this study, HA_{RK} was injected using a new needle with lower extrusion force[1]:
- Sterile 30G x ½" Ultra-Thin Wall (Terumo). Sterile 30G x ½" Ultra-Thin Wall (Terumo).

Table 2. Total (initial and touch-up) mean volumes

	n	Mean volume	Range
Both lips	59	1.67 mL	0.80 - 3.00 mL
Perioral facial wrinkles and folds	40	2.65 mL	0.40 – 4.20 mL

Figure 2. GAIS Responder Rate at Week 8 – By Investigators



Percent of subjects rated as 'improved', 'much improved' or 'very much improved
95% CIs: 0.81-1.00 (HA_{RK}); 0.91-1.00 (HA_{RK} + HA_{RR}/HA_{RD})

REFERENCES

1. Data on file. MA-40954 Study Report. Galderma Laboratories, LP., 2019.
2. Klassen AF, Cano SJ, Schwitzer JA, Baker SB, Carruthers A, Carruthers J, Chopas A, Pusic AL. Development and Psychometric Validation of the FACE-Q Skin, Lips, and Facial Rhytids Appearance Scales and Adverse Effects Checklists for Cosmetic Procedures. *JAMA Dermatol.* 2016 Apr;152(4):443-51.

RESULTS

Demographics and treatments (Table 2)

- 59 subjects were enrolled in the study
  - 19 received HA_{RK} only
  - 40 received HA_{RK} in combination with HA_{RR} (n=21) and/or HA_{RD} (n=37)
- Overall mean age: 46 years
  - Mean age HA_{RK} only: 36 years (range: 22-67)
  - Mean age HA_{RK} + HA_{RR}/HA_{RD}: 51 years (range: 23-66)
- Overall, 95% were women, 90% were white, and 93% were Non-Hispanic
  - Proportions were similar between treatment groups.

Aesthetic improvement (Figures 1 and 2)

- The primary objective was met:
  - 100% of subjects rated themselves as 'improved', 'much improved' or 'very much improved' on the GAIS 8 weeks following their last treatment.
  - 95% CIs were above the pre-determined lower confidence limit of 0.50.
- Treating investigators' ratings were similar to the subjects'.

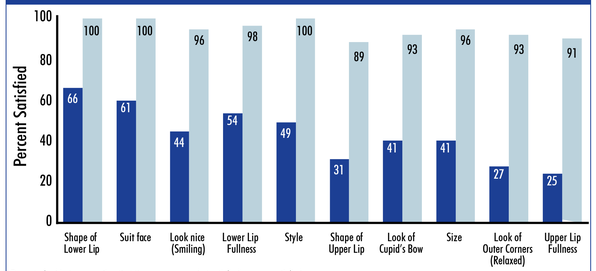
Naturalness of facial expressions - assessed by an Independent Photographic Reviewer

- Naturalness of facial expressions was maintained for ≥80% of subjects 8 weeks following their last treatment
  - At rest (neutral): 89%
  - Closed big smile: 91%
  - Big smile: 88%
  - Pursed kiss: 86%
  - Blow a kiss: 80%
- Lip texture was improved in 77% of subjects.

Subject satisfaction (FACE-Q; Figure 3)

- ≥89% of subjects were satisfied with all FACE-Q lip questions 8 weeks following their last treatment
  - ≥50% were 'very satisfied'.

Figure 3. Subject Satisfaction with Lips – FACE-Q



Percent of subjects responding that they were 'somewhat satisfied' or 'very satisfied'.

Subject satisfaction (kissability; Figure 4)

- ≥87% of subjects were satisfied with all kissability questions 8 weeks following their last treatment
  - ≥51% of subjects rated their satisfaction in the highest satisfaction category of each question.
- 100% of subjects were satisfied with the result of their lip treatment
- 98% of subjects were satisfied with the kissability of their lips after treatment
- 96% of subjects agreed that their lips had a natural look after treatment

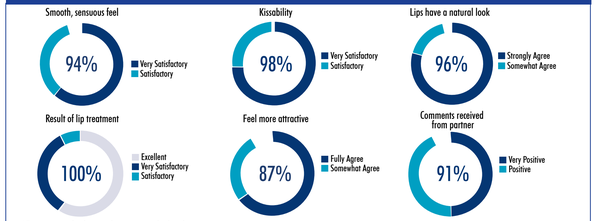
Partner satisfaction (kissability; Figure 5)

- ≥59% of partners were satisfied with all kissability questions pertaining to subjects' lips 8 weeks following the subjects' last treatment.
- 90% of partners were satisfied with the appearance of subjects' lips after treatment
- 73% of partners agreed that subjects' lips had a more kissable and natural feel after treatment

Safety

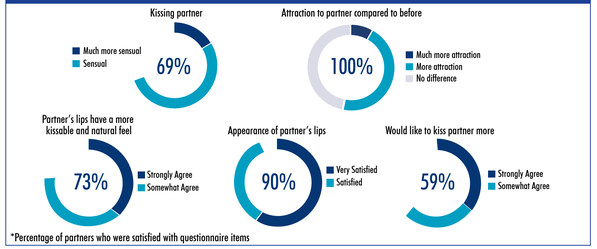
- Treatment-emergent treatment-related adverse events were:
- Non-serious
- Mild (96%)
  - One subject in the HA_{RK} + HA_{RR}/HA_{RD} group had one event of severe implant-site bruising in the lower lip. This event resolved after 6 days.
- Transient
  - Median duration: 2.5 days
- Most commonly implant-site reactions
  - Bruising HA_{RK}: 32% of subjects; HA_{RK} + HA_{RR}/HA_{RD}: 43% of subjects
  - Pain HA_{RK}: 32% of subjects; HA_{RK} + HA_{RR}/HA_{RD}: 35% of subjects
  - Oedema HA_{RK}: 37% of subjects; HA_{RK} + HA_{RR}/HA_{RD}: 23% of subjects
  - Erythema HA_{RK}: 16% of subjects; HA_{RK} + HA_{RR}/HA_{RD}: 25% of subjects

Figure 4. Subject Satisfaction* After Treatment



*Percentage of subjects who were satisfied with questionnaire items

Figure 5. Partner Satisfaction* After Treatment



*Percentage of partners who were satisfied with questionnaire items

SUMMARY

- Lip treatment with HA_{RK} alone or combined with HA_{RR} and/or HA_{RD} was well tolerated and effectively achieved aesthetic improvement of the lips compared to baseline.
- Facial expressions at rest and with animation maintained a natural appearance following treatment, and lip texture improved.
- Both subjects and partners were satisfied with the post-treatment look and feel of the subjects' lips.

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