



# SMOOTH, NATURAL AND KISSABLE Lips

POST-MARKETING STUDY TO EVALUATE LIP ENHANCEMENT, NATURALNESS AND BOTH PARTNER AND SUBJECT SATISFACTION AFTER TREATMENT WITH RESTYLANE® KY SSE™

## 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 Restylane Kysse when compared to pre-treatment baseline
- Secondary objectives included partner and subject satisfaction with lips and kissability, aesthetic improvement (assessed by treating investigators), and adverse events

## METHODS

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.

OUTLINE OF STUDY DETAILS	
<b>Study design</b> 	<ul style="list-style-type: none"> <li>Open-label multi-center study (NCT03967444)</li> <li>3 centers (59 subjects) in Canada</li> </ul>
<b>Assessments</b> 	<ul style="list-style-type: none"> <li>Aesthetic improvement of lip fullness: GAIS</li> <li>Subject satisfaction with lips: FACE-Q scales<sup>4</sup></li> <li>Subject and partner satisfaction: Kissability questionnaire</li> <li>Adverse events</li> </ul>
<b>Treatment</b> 	<ul style="list-style-type: none"> <li><b>Day 1</b> <ul style="list-style-type: none"> <li>RK* treatment of lips alone, or</li> <li>RK in lips in combination with RR and/or RD in facial wrinkles and folds surrounding the lips</li> </ul> </li> <li><b>Week 4</b> <ul style="list-style-type: none"> <li>Optional touch-up</li> </ul> </li> </ul>
<b>Assessment schedule</b> 	<ul style="list-style-type: none"> <li>Assessments were done at screening/baseline, and at Weeks 4 and 8 following the subjects' last injection</li> </ul>

**NOTE**  
\*The products used were Restylane Kysse (RK), Restylane Defyne (RD) and Refyne (RR)

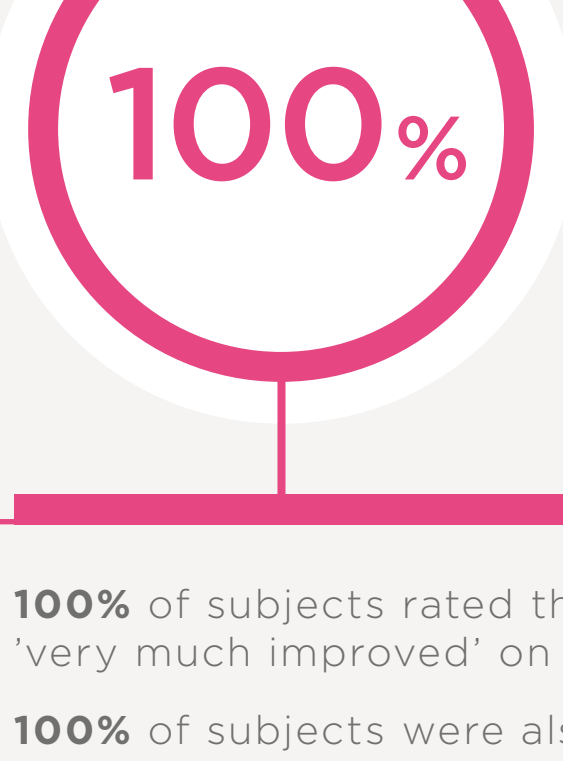
## IMPROVED LIP FULLNESS

### DEMOGRAPHICS AND TREATMENTS

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

## TREATMENT RESULTS

### AESTHETIC IMPROVEMENT



LIP FULLNESS IMPROVED

100% of subjects rated their lip fullness as 'improved', 'much improved' or 'very much improved' on the GAIS 8 weeks following their last treatment.

100% of subjects were also rated by the treating investigator to have 'improved', 'much improved' or 'very much improved' lip fullness.

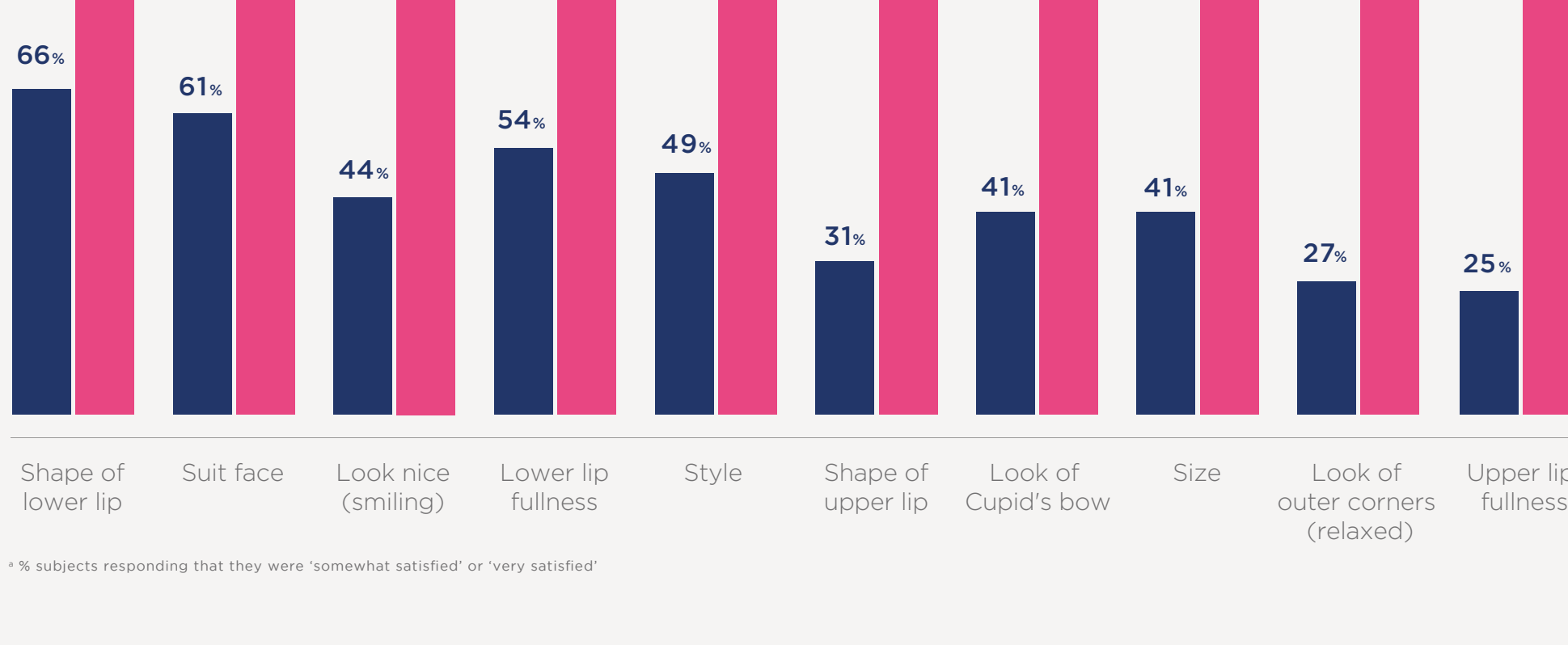
### SUBJECT SATISFACTION (FACE-Q)



LIPS AND KISSABILITY SATISFACTION

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

### SUBJECT SATISFACTION\* WITH LIPS - FACE-Q



\* % subjects responding that they were 'somewhat satisfied' or 'very satisfied'

### SUBJECT SATISFACTION (KISSABILITY)



SUBJECT SATISFACTION\* AFTER TREATMENT

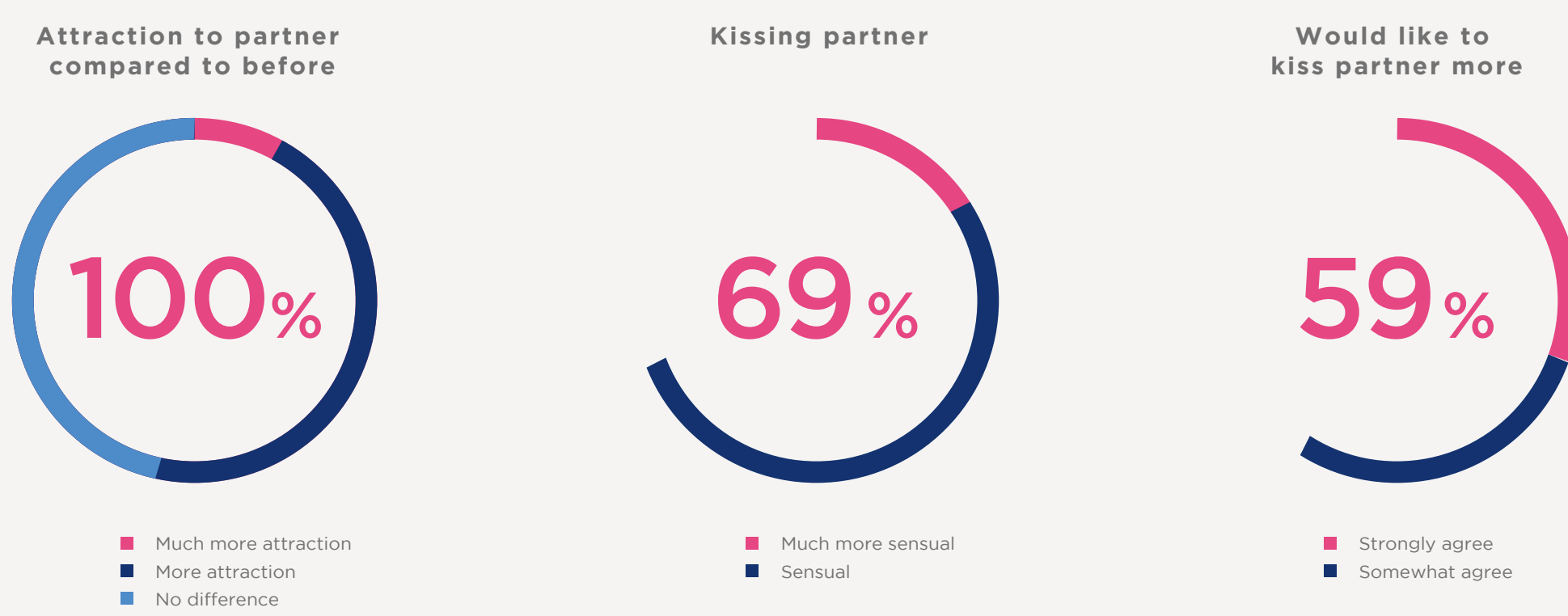


\*Percentage of subjects who were satisfied with questionnaire items

### PARTNER SATISFACTION (KISSABILITY)



PARTNER SATISFACTION\* AFTER TREATMENT



\*Percentage of partners who were satisfied with questionnaire items

### SAFETY



RESTYLANE KY SSE WAS WELL TOLERATED AND IMPROVED LIP FULLNESS WHILE MAINTAINING A NATURAL LOOK

## STUDY CONCLUSIONS

SUBJECTS AND TREATING INVESTIGATORS AGREED THAT RESTYLANE KY SSE LIP TREATMENT SUCCESSFULLY ACHIEVED AESTHETIC IMPROVEMENT

PARTNERS WERE HIGHLY SATISFIED WITH SUBJECTS' LIPS

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