



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™, A LIP FILLER BASED ON HYALURONIC ACID

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	
Study design 	<ul style="list-style-type: none"> Open-label multi-center study (NCT03967444) 3 centers (59 subjects) in Canada
Assessments 	<ul style="list-style-type: none"> Aesthetic improvement of lip fullness: GAIS Subject satisfaction with lips: FACE-Q scales⁴ Subject and partner satisfaction: Kissability questionnaire Adverse events
Treatment 	<ul style="list-style-type: none"> Day 1 <ul style="list-style-type: none"> RK* treatment of lips alone, or RK in lips in combination with RR and/or RD in facial wrinkles and folds surrounding the lips Week 4 <ul style="list-style-type: none"> Optional touch-up
Assessment schedule 	<ul style="list-style-type: none"> Assessments were done at screening/baseline, and at Weeks 4 and 8 following the subjects' last injection

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

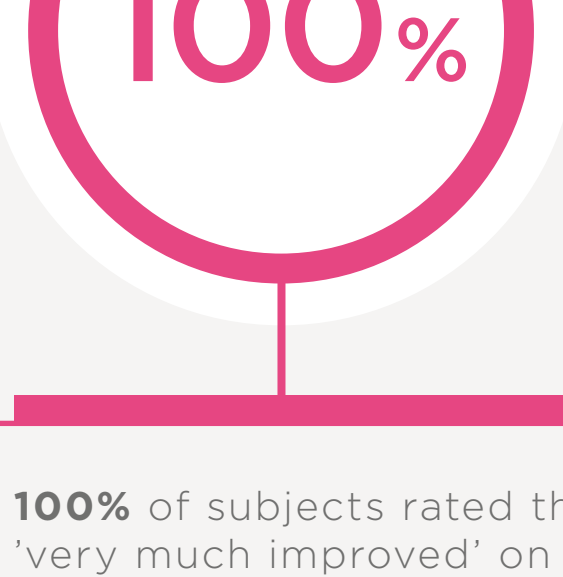
IMPROVED LIP FULLNESS

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

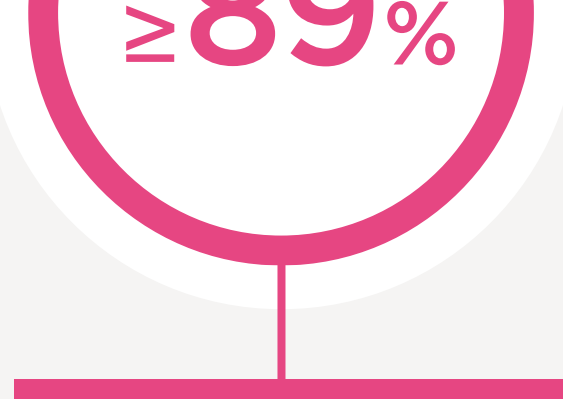


LIP FULLNESS IMPROVED

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.

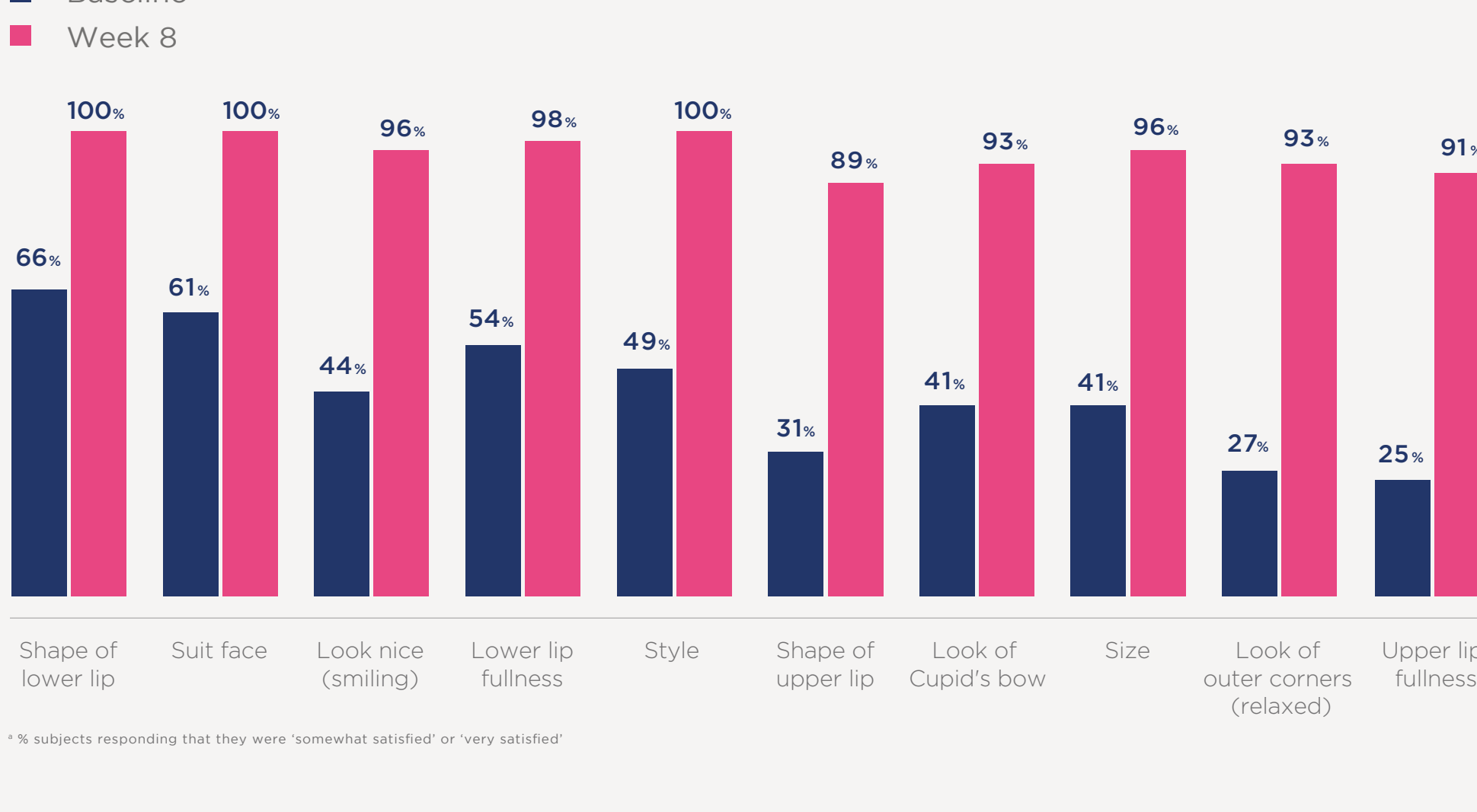
SUBJECT SATISFACTION (FACE-Q)



LIPS AND KISSABILITY SATISFACTION

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

SUBJECT SATISFACTION^a WITH LIPS - FACE-Q



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

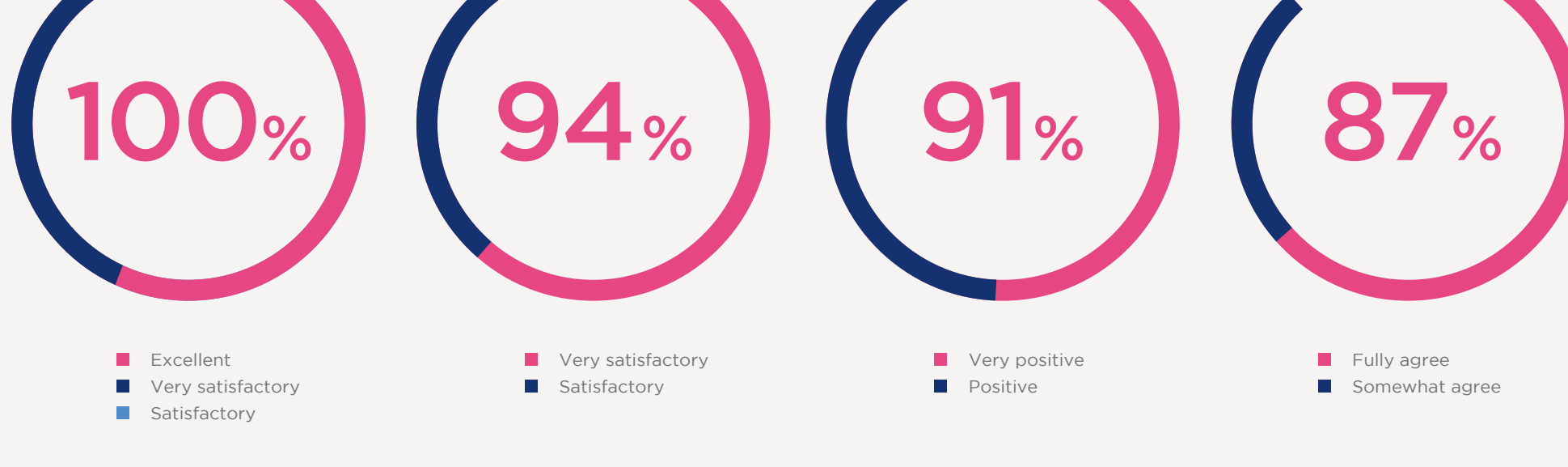
SUBJECT SATISFACTION (KISSABILITY)



96% OF SUBJECTS AGREED THAT THEIR LIPS HAD A NATURAL LOOK AFTER TREATMENT

98% OF SUBJECTS WERE SATISFIED WITH THE KISSABILITY OF THEIR LIPS AFTER TREATMENT

SUBJECT SATISFACTION^a AFTER TREATMENT



*Percentage of subjects who were satisfied with questionnaire items

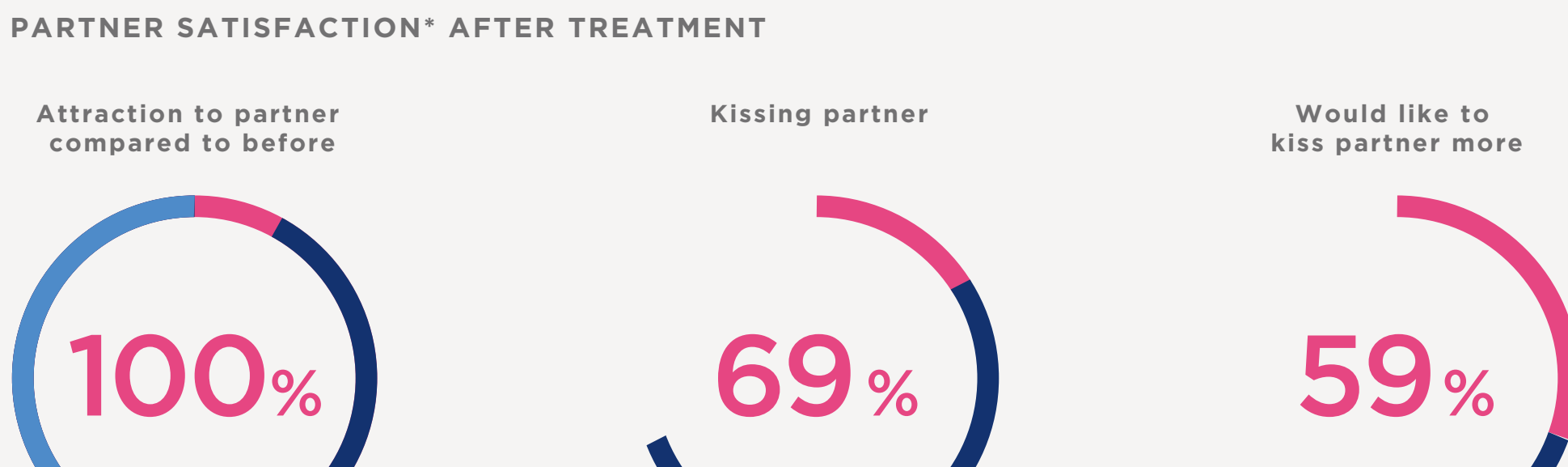
PARTNER SATISFACTION (KISSABILITY)



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

PARTNER SATISFACTION^a AFTER TREATMENT



*Percentage of partners who were satisfied with questionnaire items

STUDY CONCLUSIONS

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

PARTNERS WERE HIGHLY SATISFIED WITH SUBJECTS' LIPS

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

REFERENCES
1 Nikolis A., Bertucci V., Solish N.: Post-marketing study to evaluate lip enhancement, naturalness and both partner and subject satisfaction after treatment with RK. Poster presented at IMCAS, France, Feb 2020.