

Safety and Efficacy Evaluation of CandyLipz Xtreme Lip-Shaper System

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Study Design

Study Participants

- Twenty-one (21) women and men aged 18-45
- Thin to Medium lip size by clinical grading
- No previous use of injectable filler or implants in their lips
- Free of lip or skin conditions around lip area

Test Material

- CandyLipz Xtreme Lip Shaper System:
 - CandyLipz Model D
 - Jelly-soft mouth cushion (if needed)

Study Design

- Sixty (60) day clinical and home-usage study
- Clinical Evaluations at Baseline, Day 4, Day 10, Day 28, and Day 60
- Baseline Day 1 pump lips 4 times
- Seven (7) day Conditioning Phase starting Day 4 after Baseline
- Used product 2 or 3 times daily for 2 or 4 minutes to condition lips to pumping
- After Day 10, used the product at home twice a day for 2 minutes each time

Evaluations

- Clinical grading for Efficacy
 - Lip Volume using Photonumeric Scale
- Clinical grading for Safety
 - Dermatology evaluation – erythema, edema, dryness
- Lip hydration – Corneometry and NOVA DPM 9003
- Lip plumping – Digital Caliper Measurements
- Canfield Visia-CR2.2
- Digital Photography
- Participant self-evaluation questionnaire
- Statistical Analysis by Paired-T Test

Results

Clinical Evaluation of Lip Volume

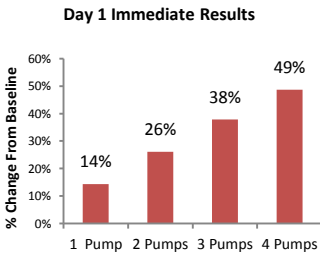


Figure 1: Increase in lip volume Clinical Evaluator's assessment, scale 1-5 (p<0.001)

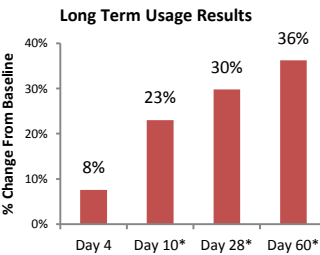


Figure 2*: Increase in lip volume Clinical Evaluator's assessment, scale 1-5 *(p<0.001)

Clinical Evaluation of Lip Condition

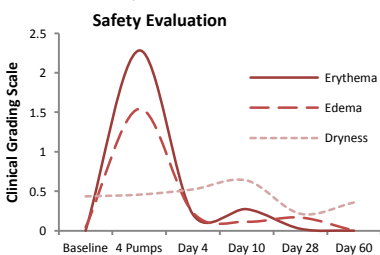


Figure 3: Dermatologist grading of lip condition, scale 0-4

Digital Images Lips at Baseline and Day 60 Clinical Efficacy



Figure 4: Unaltered images of participant lips taken before and after 4 pump applications.

Figure 5: Unaltered images of participant lips taken before and after 60 days of pump applications



Individual Results May Vary

Patient Self-Assessment of Product Performance (% Agree), n=21

Question	Baseline	Day 60	Δ
My lip is thin to medium size	80%	55%	-26%
My lip is voluminous	11%	50%	39%
My lip is pouty	2%	38%	36%
My lip is moist	9%	40%	32%

Question	After First Use	Day 60	Δ
Increased lip volume	37%	76%	39%
Improved lip appearance	35%	62%	27%
My lip has a natural rosy color	43%	67%	23%
Improved over all lip condition	22%	50%	28%
Younger-looking lip	22%	48%	26%

Question	% Excellent or Good
Easy to use	76%
Feel of the pump on the lip	62%
Amount of suction	71%
Accommodate your lips comfortably	67%
Over all basis	62%

Conclusions

Clinically Proven To:

- Increase Lip Volume immediately after application
- Increase Lip Volume for up to 2 hours after first use
- Increase Lip Volume after 10, 28 and 60 days of use
- Reduce side effects of product application (erythema, edema, and dryness) after continued use