LUSCENT

CLINICAL EVIDENCE REPORT

STUDY LUM-DL-2024-01

DualLight Face Mask: Twelve-Week Clinical Efficacy Study

Single-centre, prospective, controlled, instrument-led efficacy study.

Sponsor	Luscent
Testing facility	Meridian Dermatology Research, Melbourne
Study duration	84 days (12 weeks)
Participants	42 enrolled, 40 completed
Report status	Final
Classification	Confidential

Synopsis

Study code	LUM-DL-2024-01
Title	DualLight Face Mask: Twelve-Week Clinical Efficacy Study
Testing facility	Meridian Dermatology Research, Melbourne
Sponsor	Luscent
Design	Single-centre, prospective, controlled, instrument-led efficacy study
Duration	84 days (12 weeks)
Treatment	10 minutes daily for days 1 to 28, then five sessions per week for days 29 to 84
Setting	Single-centre laboratory, 21 +/- 2 C, 50 +/- 10% relative humidity, 30-minute acclimatisation before each visit
Assessment visits	Baseline, Day 14, Day 28, Day 56, Day 84
Participants	42 enrolled, 40 completed
Statistics	SPSS, paired t test and Wilcoxon signed-rank, significance $p < 0.05$

All efficacy endpoints reported in this document reached statistical significance versus baseline at the final visit. No device-related adverse events were recorded.

Executive summary

This report presents the methods and results of the duallight face mask: twelve-week clinical efficacy study. The study evaluated the DualLight Face Mask under controlled, instrument-led conditions over 84 days (12 weeks), with each participant assessed against their own baseline.

- 40 of 42 enrolled participants completed every scheduled visit.
- Forehead wrinkle volume changed by -27.4% at the final visit (p <0.001, 88% of participants improved).
- Gross elasticity (R2) changed by +31.8% at the final visit (p <0.001, 93% of participants improved).
- Dermal collagen density changed by +18.9% at the final visit (p <0.001, 86% of participants improved).
- Skin hydration (Corneometer) changed by +29.7% at the final visit (p <0.001, 100% of participants improved).
- Brightness (ITA) changed by +14.2% at the final visit (p <0.001, 97% of participants improved).
- 92 percent of participants said they would recommend the device.
- No device-related adverse events were recorded at any visit.

Table ES1. Primary endpoints at final visit

Endpoint	Change	p	Responders
Forehead wrinkle volume	-27.4%	<0.001	88%
Gross elasticity (R2)	+31.8%	<0.001	93%
Dermal collagen density	+18.9%	<0.001	86%
Skin hydration (Corneometer)	+29.7%	<0.001	100%
Brightness (ITA)	+14.2%	<0.001	97%
Surface roughness (Antera Ra)	-21.0%	<0.001	85%

Contents

1. Introduction and background

Photobiomodulation describes the absorption of red and near-infrared light by cytochrome c oxidase in the mitochondria, which raises adenosine triphosphate production, releases nitric oxide, and modulates reactive oxygen species. In skin, these events upregulate fibroblast activity and collagen synthesis and support an organised extracellular matrix.

A substantial peer-reviewed literature has reported improvements in intradermal collagen density, fine lines, elasticity and skin tone after repeated red and near-infrared exposure. The DualLight mask combines blue at 460 nm, red at 665 nm, near-infrared at 850 nm and a 1064 nm laser, selected to address the epidermis through to the deeper dermis within a single ten-minute session.

This study was designed to quantify the effect of the DualLight mask on objective, instrument-measured skin parameters across twelve weeks of home-pattern use under controlled assessment conditions, supported by expert clinical grading and participant self-assessment.

2. Study objectives and endpoints

Primary objective

To determine the change from baseline in objective skin parameters, principally wrinkle volume, elasticity and dermal collagen density, after twelve weeks of DualLight use.

Secondary objectives

- To assess changes in hydration, barrier function, skin tone and surface texture.
- To assess change in expert clinical grading of photoageing.
- To capture participant-reported outcomes and tolerability.

Endpoints

- Primary: instrument-measured wrinkle volume, Cutometer elasticity, ultrasound collagen density at Day 84.
- Secondary: Corneometer hydration, Tewameter barrier, tone and melanin, Antera texture, clinical grading, self-assessment.
- Safety: incidence of adverse events at every visit.

3. Study design

This was a single-centre, prospective, controlled, instrument-led efficacy study. Each participant served as their own control, with all parameters compared against their own baseline values.

Assessments were performed in a temperature and humidity controlled laboratory held at 21 plus or minus 2 C and 50 plus or minus 10 percent relative humidity. Participants acclimatised for 30 minutes before each session, and no new skincare was introduced during the study window. Assessors performing instrument measurements and grading were blinded to the visit sequence where the imaging workflow allowed.

4. Materials and methods

4.1 Participants

Volunteers were screened against the criteria below and provided written informed consent before enrolment.

Inclusion criteria

- Healthy adults aged 35 to 65 with visible signs of facial photoageing.
- Fitzpatrick skin types I to VI.
- Willing to keep their existing routine stable and add only the study device.
- Able to attend all scheduled visits and provide informed consent.

Exclusion criteria

- Active facial dermatosis, recent facial procedure or laser treatment within 6 months.
- Use of retinoids or energy-based devices on the face during the study.
- Photosensitivity, photosensitising medication, or pregnancy.
- Any condition the investigator judged likely to confound assessment.

Table 1. Participant characteristics

Characteristic	Value
Enrolled / completed	**42 / 40**
Sex	**Female, 100%**
Age range (mean)	**35 to 65 years (49.6)**
Fitzpatrick skin types	**I to VI**
Primary concern	**Photoageing, loss of firmness, uneven tone**
Withdrawals	**2 (relocation and schedule, neither device-related)**

4.2 Device under test

The DualLight mask is a flexible silicone facial device carrying 236 emitters: 72 light-emitting diodes and 164 vertical-cavity surface-emitting laser diodes, across four wavelengths of 460, 665, 850 and 1064 nm. Irradiance is at least 50 mW/cm2 at the laser diodes and at least 30 mW/cm2 at the LEDs. The device is certified as a Class 1 laser product.

4.3 Treatment protocol

- Days 1 to 28: one 10-minute session daily.
- Days 29 to 84: five 10-minute sessions per week.
- Device worn in full contact with clean, dry skin, eyes closed during each session.

4.4 Assessment schedule

Participants attended 5 visits: Baseline, Day 14, Day 28, Day 56, Day 84. Identical measurements were taken at each visit under the controlled conditions described above, in the same order, to limit measurement drift.

4.5 Instrumentation

- VISIA-CR standardised facial imaging for tone, brightness and redness.
- PRIMOS 3D for wrinkle volume and depth.
- Cutometer for elasticity and firmness (R0, R2, R5, R7).
- Corneometer for hydration and Tewameter for transepidermal water loss.
- Mexameter and Colorimeter for melanin and erythema.
- Antera 3D for surface texture and roughness.
- DermaLab high-frequency ultrasound for dermal collagen density and thickness.
- Expert clinical grading on a standard 0 to 9 scale, plus a self-assessment questionnaire.

4.6 Statistical analysis

Data were analysed in SPSS. Normality was assessed with the Shapiro-Wilk test. Within-participant change from baseline was tested with the paired t test, or the Wilcoxon signed-rank test where data were not normally distributed. Significance was set at $p < 0.05$. Results are reported as group means, with per-parameter standard deviations provided in Appendix A.

4.7 Quality control and data integrity

All instruments were calibrated to manufacturer specification before each measurement session. Where possible the same trained operator performed each instrument, images were captured under fixed lighting and head positioning, and probe pressure was standardised. Data were double-entered and range-checked before analysis, and source records are retained by the testing facility for audit.

5. Results

5.1 Participant disposition

Of 42 enrolled participants, 40 completed all visits. Two withdrew for reasons unrelated to the device (relocation and a scheduling conflict). The completer population was used for the efficacy analysis.

5.2 Efficacy outcomes by domain

Table 2. Wrinkles

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change	p
Forehead wrinkle volume (mm3)	12.4	11.4	10.7	9.6	9.0	-27.4%	<0.001
Crow's feet wrinkle volume (mm3)	9.8	9.2	8.7	7.9	7.5	-23.1%	<0.001
Periorbital wrinkle depth (um)	142	134	128	119	114	-19.7%	<0.001
Overall wrinkle roughness (Ra) (um)	38.6	36.2	34.2	31.4	29.9	-22.6%	<0.001

Values are group means. Change is from baseline to the final visit. p from paired t test or Wilcoxon signed-rank; significance was reached from Day 28 onward for all parameters shown.

Wrinkle volume and depth fell progressively from Day 14, with the largest reductions at the forehead and crow's feet by Day 84, consistent with cumulative dermal remodelling.

Table 3. Elasticity and firmness

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change	p
Gross elasticity (R2) (ratio)	0.72	0.78	0.83	0.91	0.95	+31.8%	<0.001
Net elasticity (R5) (ratio)	0.58	0.62	0.65	0.69	0.72	+24.0%	<0.001
Biological elasticity (R7) (ratio)	0.41	0.44	0.47	0.51	0.53	+28.3%	<0.001
Skin firmness (R0, lower is firmer) (mm)	0.32	0.30	0.29	0.27	0.26	-18.5%	<0.001

Values are group means. Change is from baseline to the final visit. p from paired t test or Wilcoxon signed-rank; significance was reached from Day 28 onward for all parameters shown.

All Cutometer elasticity parameters improved, led by gross elasticity (R2). The reduction in R0 indicates firmer, more resistant skin.

Table 4. Dermal structure

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change	p
Dermal collagen density (AU)	28.9	30.4	31.6	33.4	34.4	+18.9%	<0.001
Dermal thickness (mm)	1.42	1.46	1.49	1.53	1.55	+9.4%	<0.01

Values are group means. Change is from baseline to the final visit. p from paired t test or Wilcoxon signed-rank; significance was reached from Day 28 onward for all parameters shown.

Ultrasound showed a clear rise in dermal collagen density, supporting the elasticity and wrinkle findings at a structural level.

Table 5. Hydration and barrier

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change	p
Skin hydration (Corneometer) (AU)	41.5	45.0	47.7	51.6	53.8	+29.7%	<0.001
Transepidermal water loss (g/m2/h)	13.8	13.2	12.7	11.9	11.5	-16.4%	<0.001

Values are group means. Change is from baseline to the final visit. p from paired t test or Wilcoxon signed-rank; significance was reached from Day 28 onward for all parameters shown.

Hydration rose in every participant while transepidermal water loss fell, indicating an improved, better-functioning barrier.

Table 6. Tone and radiance

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change	p
Brightness (ITA) (deg)	38.2	39.7	40.9	42.6	43.6	+14.2%	<0.001
Melanin index (AU)	198	192	187	179	175	-11.5%	<0.001
Redness (a*)	9.6	9.2	8.9	8.4	8.1	-15.3%	<0.001

Values are group means. Change is from baseline to the final visit. p from paired t test or Wilcoxon signed-rank; significance was reached from Day 28 onward for all parameters shown.

Brightness increased and both melanin and redness decreased, giving a more even, luminous tone.

Table 7. Texture

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change	p
Surface roughness (Antera Ra) (um)	24.1	22.7	21.6	19.9	19.0	-21.0%	<0.001

Values are group means. Change is from baseline to the final visit. p from paired t test or Wilcoxon signed-rank; significance was reached from Day 28 onward for all parameters shown.

Surface roughness decreased, consistent with the grading and self-assessment of smoother skin.

5.3 Subgroup analysis

Primary endpoints were examined by age band and, where applicable, by skin type. The direction and significance of effect were consistent across subgroups, with differences in magnitude that were not statistically significant between groups.

Table 8. Primary endpoint change by age band

Endpoint	Under 50	50 and over
Forehead wrinkle volume	-25.5%	-29.0%
Gross elasticity (R2)	+29.6%	+33.7%
Dermal collagen density	+17.6%	+20.0%
Skin hydration (Corneometer)	+27.6%	+31.5%
Brightness (ITA)	+13.2%	+15.1%
Surface roughness (Antera Ra)	-19.5%	-22.3%

5.4 Expert clinical grading (0 to 9 scale)

Table 9. Clinical grading, baseline to final visit

Attribute	Change	Baseline to final	p
Fine lines (lower is better)	-1.8 pts	5.3 to 3.5	<0.001
Radiance and luminosity	+2.1 pts	4.1 to 6.2	<0.001
Visual firmness	+1.9 pts	4.4 to 6.3	<0.001
Tone evenness	+1.7 pts	4.6 to 6.3	<0.001
Overall photoageing (lower is better)	-1.6 pts	5.1 to 3.5	<0.001

5.5 Participant self-assessment

At the final visit participants rated their agreement with the statements below. Figures show the proportion who agreed or strongly agreed.

Table 10. Participant self-assessment, final visit

Statement	Agreed
My fine lines look softened	96%
My skin looks more radiant	94%
My skin feels firmer and more supple	91%
My skin tone looks more even	91%
My skin looks clearer	89%
I would recommend this device	92%

5.6 Responder analysis

A responder was defined as any participant showing measurable improvement from baseline in a given parameter. Responder rates ranged from 79 to 100 percent across endpoints, with the highest rates in hydration, elasticity and pain outcomes. No parameter showed a worsening group mean at any visit.

6. Safety and tolerability

The DualLight mask was well tolerated. No device-related adverse events were reported at any visit. In a separate 48-hour occlusive patch assessment of 52 subjects, no irritation or sensitisation was observed, and the device was rated suitable for sensitive skin. The 1064 nm wavelength passes through melanin readily, supporting use across Fitzpatrick skin types I to VI, and the device is certified as a Class 1 laser product requiring no eye protection in normal use.

7. Discussion

The improvements in collagen density, elasticity and wrinkle parameters are consistent with the established mechanism of red and near-infrared photobiomodulation and with prior controlled research. Wunsch and Matuschka reported significant increases in ultrasound-measured collagen density and reductions in wrinkles and roughness after repeated red and near-infrared treatment [1], and a Harvard review by Avci and colleagues summarised the stimulating and restorative effects of these wavelengths on skin [4].

The blue and red components address surface clarity, in line with combined blue and red phototherapy studies of facial skin [2], while the mechanistic basis for the changes seen here, raised mitochondrial activity and modulated inflammatory signalling, is described by Hamblin [5]. The magnitude and direction of effects observed in this study fall within the range previously reported for this class of light.

Across the program, instrument measurement, expert grading and participant self-assessment moved in the same direction, which strengthens confidence in the findings. Effects emerged within the first two to four weeks and continued to build to the final visit, a pattern consistent with the cumulative, dose-dependent nature of photobiomodulation rather than a transient cosmetic effect.

8. Limitations

- Single-centre design with each participant as their own control rather than a separate placebo arm.
- Twelve-week duration; longer-term durability was not assessed.
- Predominantly female cohort, reflecting the intended user.

9. Conclusion

Twelve weeks of DualLight use produced statistically significant, instrument-measured improvements across wrinkles, elasticity, dermal collagen density, hydration, barrier function, tone and texture, confirmed by expert grading and participant self-assessment. The device was well tolerated across all skin types, with no device-related adverse events.

10. References

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Appendix A. Complete efficacy dataset

Table A1. All efficacy parameters

Parameter	Baseline (SD)	Final	Change	p	Resp.
Forehead wrinkle volume	12.4 (3.1)	9.0	-27.4%	<0.001	88%
Crow's feet wrinkle volume	9.8 (2.6)	7.5	-23.1%	<0.001	86%
Periorbital wrinkle depth	142 (28)	114	-19.7%	<0.001	84%
Overall wrinkle roughness (Ra)	38.6 (7.4)	29.9	-22.6%	<0.001	88%
Gross elasticity (R2)	0.72 (0.08)	0.95	+31.8%	<0.001	93%
Net elasticity (R5)	0.58 (0.09)	0.72	+24.0%	<0.001	90%
Biological elasticity (R7)	0.41 (0.07)	0.53	+28.3%	<0.001	91%
Skin firmness (R0, lower is firmer)	0.32 (0.05)	0.26	-18.5%	<0.001	88%
Dermal collagen density	28.9 (5.2)	34.4	+18.9%	<0.001	86%
Dermal thickness	1.42 (0.21)	1.55	+9.4%	<0.01	79%
Skin hydration (Corneometer)	41.5 (6.8)	53.8	+29.7%	<0.001	100%
Transepidermal water loss	13.8 (2.9)	11.5	-16.4%	<0.001	95%
Brightness (ITA)	38.2 (5.1)	43.6	+14.2%	<0.001	97%
Melanin index	198 (34)	175	-11.5%	<0.001	88%
Redness (a*)	9.6 (1.8)	8.1	-15.3%	<0.001	90%
Surface roughness (Antera Ra)	24.1 (4.0)	19.0	-21.0%	<0.001	85%

Appendix B. Self-assessment instrument

At the final visit, participants recorded their agreement with each statement on a five-point scale (strongly disagree, disagree, neutral, agree, strongly agree). Figures in Section 5 report the combined agree and strongly agree proportion.

- My fine lines look softened
- My skin looks more radiant
- My skin feels firmer and more supple
- My skin tone looks more even
- My skin looks clearer
- I would recommend this device
- I noticed a difference within the first two weeks.
- The device was comfortable to use.
- The device was easy to fit into my routine.

Appendix C. Per-visit means

Group mean values at each visit for every efficacy parameter.

Table C1. Per-visit group means

Parameter	Base	Day 14	Day 28	Day 56	Day 84	Change
Forehead wrinkle volume	12.4	11.4	10.7	9.6	9.0	-27.4%
Crow's feet wrinkle volume	9.8	9.2	8.7	7.9	7.5	-23.1%
Periorbital wrinkle depth	142	134	128	119	114	-19.7%
Overall wrinkle roughness (Ra)	38.6	36.2	34.2	31.4	29.9	-22.6%
Gross elasticity (R2)	0.72	0.78	0.83	0.91	0.95	+31.8%
Net elasticity (R5)	0.58	0.62	0.65	0.69	0.72	+24.0%
Biological elasticity (R7)	0.41	0.44	0.47	0.51	0.53	+28.3%
Skin firmness (R0, lower is firmer)	0.32	0.30	0.29	0.27	0.26	-18.5%
Dermal collagen density	28.9	30.4	31.6	33.4	34.4	+18.9%
Dermal thickness	1.42	1.46	1.49	1.53	1.55	+9.4%
Skin hydration (Corneometer)	41.5	45.0	47.7	51.6	53.8	+29.7%
Transepidermal water loss	13.8	13.2	12.7	11.9	11.5	-16.4%
Brightness (ITA)	38.2	39.7	40.9	42.6	43.6	+14.2%
Melanin index	198	192	187	179	175	-11.5%
Redness (a*)	9.6	9.2	8.9	8.4	8.1	-15.3%
Surface roughness (Antera Ra)	24.1	22.7	21.6	19.9	19.0	-21.0%