

A randomized, placebo-controlled, single-blinded, split-faced clinical trial evaluating the efficacy and safety of KLOX-001 gel formulation with KLOX light-emitting diode light on facial rejuvenation

NIKOLIS *ET AL.* 2016

INTRODUCTION

The purpose was to evaluate the efficacy and safety of the treatment. 32 patients enrolled for a 12-week study, randomized into one of four groups:

- **GROUP A:** KLOX-001 gel + LED (placebo) light
- **GROUP B:** placebo/base gel (no active chromophore) + KLOX LED light
- **GROUP C:** KLOX-001 gel + KLOX LED light
- **GROUP D:** standard skin rejuvenating treatment (0.1% retinol-based cream)

RESULTS

EFFICACY

Skin biopsies were performed at week 0 and 12 on the subjects and was stained using Gomori Trichrome. The average score and % of change from baseline was calculated for each group.

Group C shows a particularly notable 400% increase in the amount of collagen from baseline to week 12.

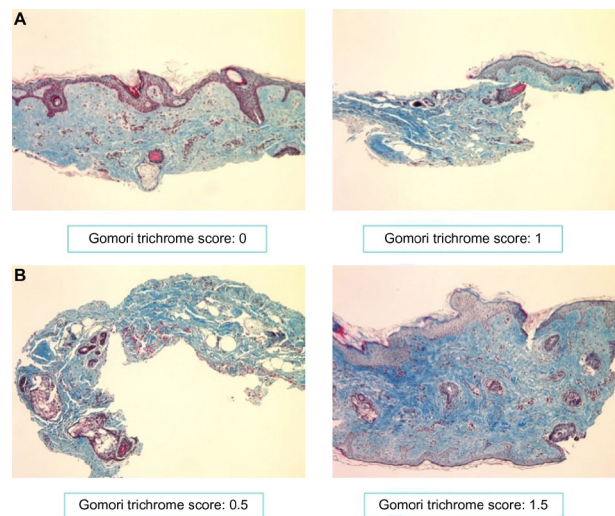


Fig. 1. Somori staining of retroauricular biopsy samples: (A) week 0; (B) week 12. Visual increase of collagen amount (blue) was still visible 12 weeks after the first treatment).

Group A KLOX-001 gel formulation + sham light			Group B Sham gel + KLOX LED light			Group C KLOX-001 gel formulation + KLOX LED light			Group D Standard treatment		
ID #	Week 0	Week 12	ID #	Week 0	Week 12	ID #	Week 0	Week 12	ID #	Week 0	Week 12
100	0.5	2	106	0	0	102	0	3	103	1	0
101	1	2	107	0.5	2	104	0	1	108	0.5	3
105	0.5	3	110	1	2.5	114	0.5	1.5	118	0.5	3
109	0	2	112	1	2.5	116	0.5	1.5	120	2	2.5
111	0.5	1	122	0.5	3	121	1	0	125	0.5	3
115	1	3	123	0.5	1.5	124	0	3	131	0	1.5
117	0.5	1.5	126	0.5	3	127	1	3			
128	3	3	129	0.5	3	130	0	2			
Av.	0.875	2.188	Av.	0.563	2.188	Av.	0.375	1.875	Av.	0.750	2.167
Change from week 0		+150%	Change from week 0		+287%	Change from week 0		+400%	Change from week 0		+189%

Note: Mean score at week 0 (baseline) and at week 12 for each treatment group was calculated, allowing the determination of the percentage of change from week 0.
Abbreviation: LED, light-emitting diode; ID, identification; Av., average.

Fig. 2. Skin biopsy results (collagen in Gomori Trichrome staining)

SAFETY

All the adverse events (AEs) reported were transient and mild in intensity, without any subject being discontinued from the study due to AE. The number of subjects reporting AEs was small and no clear differences were noted between the groups.

CONCLUSIONS

"The study results show that KLOX LED light with KLOX-001 gel formulation and KLOX LED light with KLOX placebo/base gel are effective, safe, well-tolerated, and painless treatment modalities for skin rejuvenation."