The Role of Topical Vitamin K Oxide Gel in the Resolution of Postprocedural Purpura

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INTRODUCTION

Facial purpura, a transient adverse effect of pulsed dye laser (PDL) treatment and other cosmetic procedures, is a barrier to patient acceptance and satisfaction with results. A post-procedural treatment that reduces the time to resolve purpura would benefit both patients and aesthetic practitioners.

It is widely believed that topical vitamin K accelerates the clearing of purpura by an unknown peripheral mechanism. Vitamin K is sensitive to ultraviolet light and soluble in fats. The active metabolite of vitamin K is vitamin K oxide.[1,2] Preliminary studies suggest that cosmetic creams with vitamin K oxide are more active for dermal indications than creams with vitamin K.[2,3] Compared to vitamin K, vitamin K oxide is more heat stable, less sensitive to UV light, and less allergenic. This study evaluates the effects of a topical gel containing vitamin K oxide, versus placebo (gel without vitamin K oxide) in the resolution of purpura resulting from cosmetic procedures such as surgery, dermal filler injections, and botulinum toxin injections. In this study, purpura was induced by a PDL device on the faces of patients with facial telangiectasias. Laser settings were carefully selected to produce a similar bruise on both sides of the face.

MATERIALS AND METHODS

In this randomized, single-blinded, placebo-controlled study, 20 subjects with bilateral facial telangiectasia were treated once on both sides of the face with a pulsed dye laser (PDL). Treatment parameters were carefully selected to produce approximately the same amount of purpura on each side of the face. Subjects received an equal number of pulses to each side of the face. The test articles (active product and placebo) were randomized to a side of the subject's face. Both gel preparations were encapsulated in proprietary nanosomes that contained phospholipids to enhance penetration into skin, vitamin C, vitamin E, and other ingredients. Fifteen to 30 minutes after irradiation active product was applied to one side of the face and placebo to the other side. Subjects were instructed to apply test articles daily for the next 9 (± 1) days unless purpura resolved earlier.

Purpura and adverse effects were evaluated 2, 4, 6, and 9 days after treatment. Initial severity of purpura (focal and field) on each side of the face was classified as none, mild, moderate, severe, or very severe. Photographs of each treated area were obtained at each visit and used as a basis for assessing resolution of purpura at each posttreatment visit. Improvement in both focal and field purpura on each side of the face was estimated using a scale of -100% to 100% when compared to the photograph obtained 15 to 30 minutes after laser irradiation.

Data were analyzed by descriptive statistics. Non-parametric statistics were used when data were not normally distributed.

RESULTS

All subjects completed the study. Only subjects with discernable purpura and complete data for all evaluation visits (n=16) were included in the analysis. Analysis was limited to field data because they indicated a wider area of purpura than focal data. Data are tabulated in Table 1 and presented graphically in Figures 1 and 2.

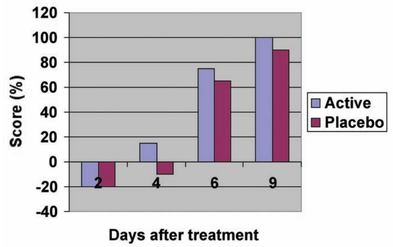

Figure 1. Median improvement in field purpura (n = 16) after a single treatment with a pulsed dye laser. Four patients with either incomplete data or insignificant bruising were not included.

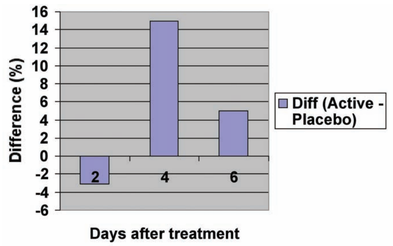

Figure 2. Mean difference (active – placebo) in field purpura score (n=16) after a single treatment with a pulsed dye laser. Four patients with either incomplete data or insignificant bruising were not included.

Resolution was consistently greater with the active product after the second day (Figure 1). The difference in paired data did not reach statistical significance (p = 0.3716) by the Wilcoxon signed rank test. The greatest difference between active and placebo scores occurred on the fourth day after treatment (Figure 2). The reduced improvement on day 6 is due to natural resolution processes and does not indicate that the active product is less effective over time. Treatment-related adverse effects were not observed in any subject.

Table 1. Resolution of field purpura after treatment with a pulsed dye laser

	Day After Treatment			
	2	4	6	9
Median (IQR) Score (%)				
Active	-20.0 (21.7)	15.0 (55.8)	75.0 (40.0)	100.0 (10.0)
Placebo	-20.0 (30.0)	-10.0 (51.7)	65.0 (35.8)	90.0 (10.0)
Mean (SD) Diff*	-3.1 (14.5)	15.0 (38.1)	5.0 (36.3)	—

*Active – Placebo Score
IQR = interquartile range, the difference between the third and first quartiles; a measure of statistical dispersion.
SD = standard deviation.

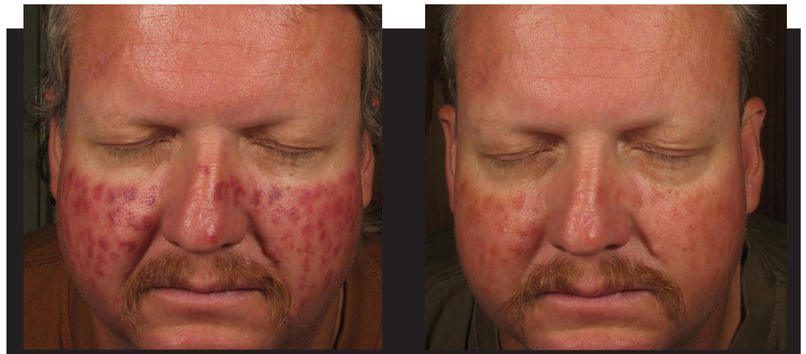

Figure 3. The left photograph shows a male subject 2 days after a single treatment with the pulsed dye laser. Field purpura was rated severe on both sides of the face. The right photograph shows the same patient six days after treatment. Purpura on the patient's left side (active product) is more improved than the right side (placebo).

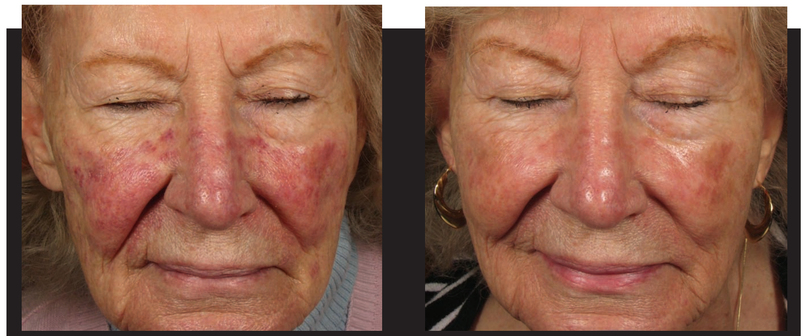

Figure 4. The left photograph shows a female subject 30 minutes after a single treatment with the pulsed dye laser. Field purpura was rated moderate on both sides of the face. The right photograph shows the same patient 6 days after treatment. Purpura on the patient's right side (active product) is more improved than the left side (placebo).

Clinical examples are shown in Figures 3 and 4.

DISCUSSION

The results of this study suggest that the vitamin K oxide gel resolves PDL-induced purpura earlier than the gel-only preparation. Although differences in active vs. placebo scores did not reach statistical significance during the 9-day study period (Figure 1), a trend toward faster resolution of purpura with the active product is clear, with the most rapid increase occurring approximately 4 days after treatment (Figure 2). The absence of statistical significance is attributed to the inherent side-to-side variation in laser-induced purpura.

These data are similar to those obtained by Shah and colleagues[4] in their study of the ability of topical vitamin K to resolve PDL-induced bruises on the faces of 22 patients with bilateral facial telangiectasias. Although improvement in bruising was significantly greater on the vitamin K-side of the face than on the placebo-treated side, the differences were small during the 10 days after laser irradiation. The authors stated, however, that even small differences in reduced severity of bruising are clinically relevant to patients.

Since the completion of this study the author has used the active product gel for months in patients treated with the PDL. The efficacy of the product appears to be superior to the 15% maximum (Figure 2) observed in this study.

CONCLUSION

Vitamin K oxide gel appears to hasten resolution of laser-induced purpura in subjects with bilateral facial telangiectasia. The product appears to be useful in accelerating resolution of facial bruising from cosmetic procedures; the absence of statistical significance may be attributed to the inherent side-to-side variation in laser-induced purpura and the small sample size. The encouraging results justify additional studies with more patients, a method to produce more consistent bruising, and use of a placebo that lacks nanosomes and active ingredients (vitamin C, vitamin E, and others).

REFERENCES

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