

## ORIGINAL CONTRIBUTION

# Evaluation of the efficacy and tolerance of a cosmetic mask containing 89% of vichy volcanic mineralizing water and hyaluronic acid after facial laser procedures

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## Funding information

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## Abstract

**Background:** M89 M (Mineral 89 mask, Laboratoires Vichy, France), containing 89% Vichy volcanic mineralizing water and hyaluronic acid, aims to strengthen and repair skin barrier.

**Aims:** To assess the efficacy, tolerance, patient satisfaction, and quality of life (QOL) using M89 M after laser procedures (LP).

**Methods:** M89 M was applied immediately post-LP for 10 minutes, then daily for 5 days and 2-3 times a week, up to 28 days on the faces of 51 women. Evaluations were performed immediately post-LP, immediately after M89 M application at D0, D1, D5, and D28, and included criteria such as erythema and skin dryness. Subjects scored burning and warm sensations, itching, skin tightness, and stinging. Skin hydration using a Corneometer, skin barrier integrity using a Tewameter, and erythema using a Chromameter were assessed. Local tolerance and adverse events were recorded. After 28 days, subjects answered a questionnaire regarding the M89 M subjective cosmetic properties and QOL.

**Results:** All subjects were in their mid-forties with a phototype of II, III, or IV. M89 M significantly ( $P < .001$ ) reduced the immediate cutaneous discomfort sensation and laser procedure-related symptoms (burning, warmth sensation, itching/stinging, skin tightness). Skin hydration, and erythema, assessed using instrumental measures, were also significantly improved immediately after mask application ( $P \leq .01$ ). Subjects highly appreciated M89 M and their QOL improved after 28 days of use. Local tolerance was good to excellent in both studies.

**Conclusion:** M89 M is effective and safe immediately after esthetic procedures such as ablative and nonablative lasers and also improves the subject's QOL.

Paulo Torreao was an employee of Centre International de Développement Pharmaceutique (Research Institute), Rio de Janeiro, Brazil, the time the study was conducted.

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## KEY WORDS

erythema, facial laser, M89 mask, quality of life, skin, skin hydration

## 1 | INTRODUCTION

The number of dermatological or cosmetic procedures has continuously increased over the last decades. The main population requesting dermatological procedures are women over the age of 40 (92%).<sup>1</sup>

Dermatological procedures, including ablative and nonablative fractional lasers, microneedling, radiofrequency, microfocused ultrasound, and intense pulsed light, are mainly performed on the face and may result in transient local side effects, such as erythema, blistering, crusts, scaling, hypo- or hyperpigmentation, or hemorrhagic lesions. They may even alter the natural skin barrier.<sup>2-7</sup>

Skin hydration is essential to repair the natural skin barrier.<sup>8</sup> M89 M (Mineral 89 Instant Recovery Sheet Mask, Laboratoires Vichy, France) contains 89% Vichy volcanic mineralizing water (VVMW) as a hydrating agent and 0.4% sodium hyaluronate, the water-soluble salt form of hyaluronic acid (HA), an extracellular matrix component with viscoelastic and hygroscopic properties which help to fight against external aggressions.<sup>9</sup> M89 M is formulated on a micro-alginate fiber tissue as a single-use mask.

Vichy volcanic mineralizing water is highly enriched in 15 minerals and has shown to strengthen the skin's natural defenses, such as restoring the physical skin barrier, and stimulating both antioxidant activity and innate immunity.<sup>9-13</sup> HA is a polysaccharide that belongs to the glycosaminoglycan family and consists of a basic unit of two sugars, glucuronic acid, and N-acetyl-glucosamine. HA usually exists as a high molecular mass in the synovial fluid that surrounds joints, cartilage, and eye tissue and has been shown to play an important role in skin repair.<sup>14,15</sup>

It has been demonstrated that M89 improves the clinical signs and symptoms associated with various facial dermatoses, including rosacea, and even those appearing postprocedure.<sup>16,17</sup> Additionally, unpublished data confirm that M89 protects against the adhesion of pollution microparticles.

The aim of these studies was to assess the cutaneous acceptability and clinical efficacy of M89 M when applied for 28 days immediately after a nonablative laser procedure. The main criteria assessed were postprocedure signs and symptoms (erythema, burning, warmth sensation, itching/stinging, skin tightness), cutaneous discomfort, and skin barrier function (skin hydration and transepidermal water loss). Finally, the studies assessed the evolution of the subjects' quality of life (QOL) over the 28 day period.

## 2 | METHODS

### 2.1 | Study design

These 2 single-center, open label, nonrandomized studies were conducted between January and March 2020.

Both studies adhered to the principles of Good Clinical Practices and the Declaration of Helsinki. The Brazilian study was conducted in accordance with the principles of Resolution 466/2012 of the Conselho Nacional de Saúde do Brazil and received ethics committee approval from the Pró-Cardíaco Hospital, Rio de Janeiro, Brazil, prior to study start. The Singapore study received ethics committee approval from the Parkway Independent Ethics Committee (PIEC) in Singapore. All subjects provided written informed consent prior to participation in this study.

### 2.2 | Study participants

Twenty-five (25) and twenty-eight (28) adult female subjects undergoing facial laser treatment were recruited in Singapore (study 1) and Brazil (study 2), respectively. Subjects had to be aged between 18 and 65 and have a phototype II, III, or IV on the Fitzpatrick scale. All subjects in Brazil underwent a dermatological superficial facial procedure using an Er:YAG (erbium-doped yttrium aluminum garnet) and, in Singapore, an Nd:YAG (neodymium-doped yttrium aluminum garnet) laser.

### 2.3 | M89 mask use

Study duration was 28 days, with 4 visits at day 0 (DOT1 after laser procedure and DOT2, after M89 M had been applied for 10 minutes), day 1 (D1), day 5 (D5), and day 28 (D28). At D0, subjects underwent the laser procedure followed immediately by an application of M89 M for 10 minutes, under the supervision of the dermatologist. Thereafter, they were asked to apply M89 M at home for 10 minutes, once daily, for the following 4 days, and 2-3 times/wk for the remaining 3 weeks. Subjects were asked not to apply M89 M < 4 hours before study visits and were instructed to wash their faces with their current skin cleansing products prior to M89 M application. They were also instructed to apply their usual sunscreen as necessary throughout the study and to avoid excessive sun exposure for the entire study duration.

### 2.4 | Efficacy assessments

During each study visit, subjects underwent both clinical and instrumental assessments.

#### 2.4.1 | Clinical assessments

Clinical signs, including the severity of erythema, desquamation, and skin dryness, were assessed at each postlaser procedure visit.

Subject-reported symptoms, such as burning sensations, itching, the sensation of warmth, skin tightness, and skin discomfort, were assessed at the same time points.

All signs and symptoms were rated on a 5-point scale, from 0 = none to 4 = severe.

## 2.4.2 | Instrumental assessments

Skin hydration in the stratum corneum was assessed using a Corneometer (CM825<sup>®</sup>, Courage & Khazaka). Three measurements were obtained on three different zones on the subjects' cheek bones.

To determine transepidermal water loss (TEWL), a Tewameter (TM330T<sup>®</sup>, Courage & Khazaka), measuring the density gradient of water evaporation from the skin, was employed. Measurements were carried out on the cheek of the subjects, as far from the mouth or nose as possible.

Skin color was measured using a Chromameter (CR400<sup>®</sup>, Konika-Minolta) and the L\*a\*b\* color system. As the laser procedure was expected to induce erythema, the main parameter of interest was the a\* value. Triplicates of a single flash on 3 different zones on the cheekbones were measured.

## 2.5 | Skin discomfort, quality of life, and subject evaluation

Subjects graded the intensity of discomfort with the M89 mask on their face on a scale from 0 (no discomfort) to 10 (very severe discomfort).

The Dermatology Life Quality Index Questionnaire (DLQI questionnaire) was completed by each subject at each postlaser visit, except at DOT1.<sup>18</sup> The DLQI consists of 10 questions concerning the subjects' perception of the impact of skin diseases on various aspects of their health-related QOL.

In addition, at D28, subjects completed a satisfaction questionnaire ("The mask is soothing" and "I would like to use this product for my next laser procedure") on a 5-point scale (from disagree to agree).

## 2.6 | Local tolerance

Local tolerance and safety were assessed through the study based on adverse events, signs, and symptoms.

## 2.7 | Statistical methods

SPSS 19.0 or Microsoft Excel 2010 or above were used for statistical analysis purposes.

Quantitative variables were summarized using mean, median, minimum and maximum and measures of dispersion, such as the

standard deviation. Qualitative variables were summarized using frequencies and percentages.

A confidential interval of 95% for means was provided for the evolution over time for each parameter. The percentage efficacy at time point "t" was calculated on the mean value observed for each parameter. Evolution over time was investigated by using either the Student's paired *t* test or the Wilcoxon signed rank test, depending on the normality of the difference data. The latter was tested using a Shapiro-Wilk test at 1% of significance. The count and percentage of subjects responding to questionnaires were provided for each time point.

The *P* value was set at .05 (5% significance level).

## 3 | RESULTS

### 3.1 | Subject demographic and baseline data

Demographic and subject data at DOT1 are provided in Table 1.

A total of 25 healthy women were recruited in study 1 and 28 in study 2. Data from 24 and 27 subjects were available for efficacy analysis, respectively. One subject from each study dropped out, due to administrative reasons.

In study 1, subjects were aged between 22 and 52 years (mean age:  $40 \pm 2$  years) and were all of Chinese origin. Subjects in study 2 were aged between 32 and 46 years (mean age:  $46 \pm 2$  years), and 52.0% were Caucasian. All subjects had a phototype II, III, or IV. Detailed demographic data are given in Table 1.

### 3.2 | Skin discomfort sensation

Figure 1 provides visual results for skin discomfort sensation scores for both studies.

In study 1, the score for cutaneous discomfort sensation was  $5.4 \pm 1.6$  at DOT1. This decreased by 88.0% after the first application of M89 M and remained at 0 thereafter ( $P < .001$  for each time point, when compared to DOT1).

In study 2, skin discomfort sensation at baseline was scored at  $5.6 \pm 2.2$ , significantly decreased by 67.0% at DOT2, remained at very low levels at D1 and D5, and dropped to 0 at the end of the study ( $P < .001$  for all time points compared to DOT1).

### 3.3 | Efficacy

#### 3.3.1 | Clinical signs

Figure 2 provides details about evolution over time for erythema scores for both studies.

In study 1, a statistically significant ( $P \leq .001$ ) improvement of erythema was observed as early as after the first application (baseline mean score  $2.5 \pm 0.5$  decreased by 74%; see Figure 2A). Similarly,

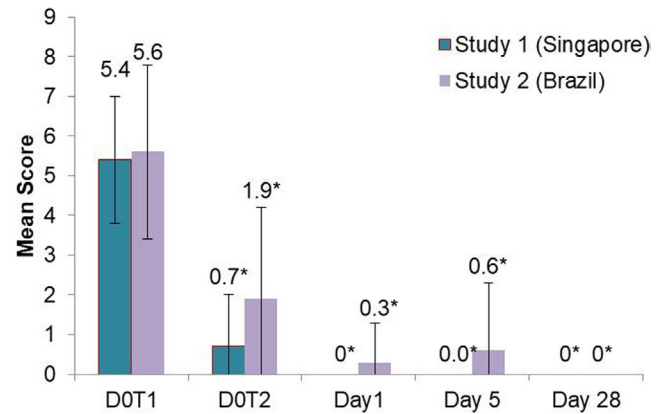
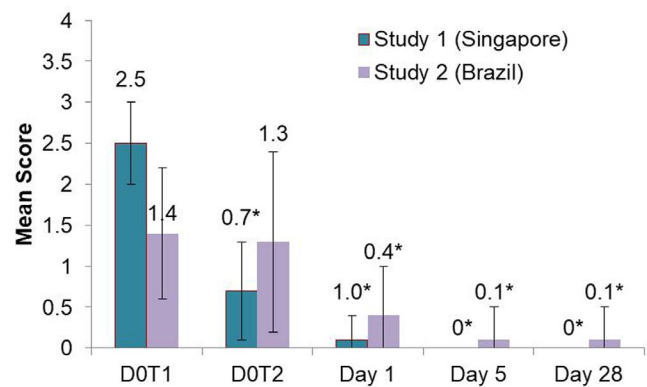
**TABLE 1** Demographic and baseline characteristics of the subjects (efficacy population, immediately after laser procedure and before M89 mask application)

Parameters	Study 1	Study 2
Number	24	27
Age range (y, Mean $\pm$ SD)	22-52 (40 $\pm$ 2)	32-64 (46 $\pm$ 2)
Phototype (n, %)		
I	0	0
II	11 (46%)	0
III	13 (54%)	22 (81%)
IV	0	5 (19%)
V	0	0
Ethnic origins		
Caucasian	0	14 (52%)
Mixed	0	13 (48%)
Black	0	0
Asian	24 (100%)	0
Other	0	0
Skin hydration (Corneometer reading; a.u., mean $\pm$ SD)	78.33 $\pm$ 18.70	64.21 $\pm$ 12.34
TEWL (Tewameter reading; a.u., mean $\pm$ SD)	10.80 $\pm$ 3.97	17.75 $\pm$ 7.97
Skin redness (Chromameter reading, a* value; a.u., mean $\pm$ SD)	10.48 $\pm$ 2.48	12.06 $\pm$ 1.66
Signs (assessed by investigator; score 0-4, mean $\pm$ SD)		
Erythema	2.5 $\pm$ 0.5	1.4 $\pm$ 0.8
Skin dryness	1.4 $\pm$ 0.7	2.0 $\pm$ 0.8
Edema	0 $\pm$ 0	0.3 $\pm$ 0.7
Symptoms (reported by the subjects; score 0-4, mean $\pm$ SD)		
Burning sensation	1.5 $\pm$ 1.1	2.0 $\pm$ 0.8
Sensation of warmth	1.5 $\pm$ 1.1	0.6 $\pm$ 1.1
Itching	0 $\pm$ 0	0.5 $\pm$ 0.8
Skin tightness	1.0 $\pm$ 1.3	1.0 $\pm$ 1.3
Stinging	1.4 $\pm$ 1.0	0.3 $\pm$ 1.0

Abbreviations: a.u., arbitrary units; N.; not assessed; TEWL, transepidermal water loss.

skin dryness dropped from 1.4  $\pm$  0.7 to 0 at DOT2 ( $P < .001$ ). The mean scores remained around 0 from D1 onwards for both parameters. No other clinical signs were reported.

In study 2, the baseline value for erythema mean score was 1.4  $\pm$  0.8, as is shown in Figure 2B. An 8.0% decrease was recorded at DOT1, followed by a 74.0% decrease on day 1 ( $P \leq .001$ ). Very low values were reported thereafter, until day 28 ( $P < .001$ ). Scores of more than 0 were observed anecdotally for the other clinical signs,

**FIGURE 1** Evolution of skin discomfort sensation scores over time. \* $P < .001$ **FIGURE 2** Evolution of erythema scores over time. \* $P \leq .001$ 

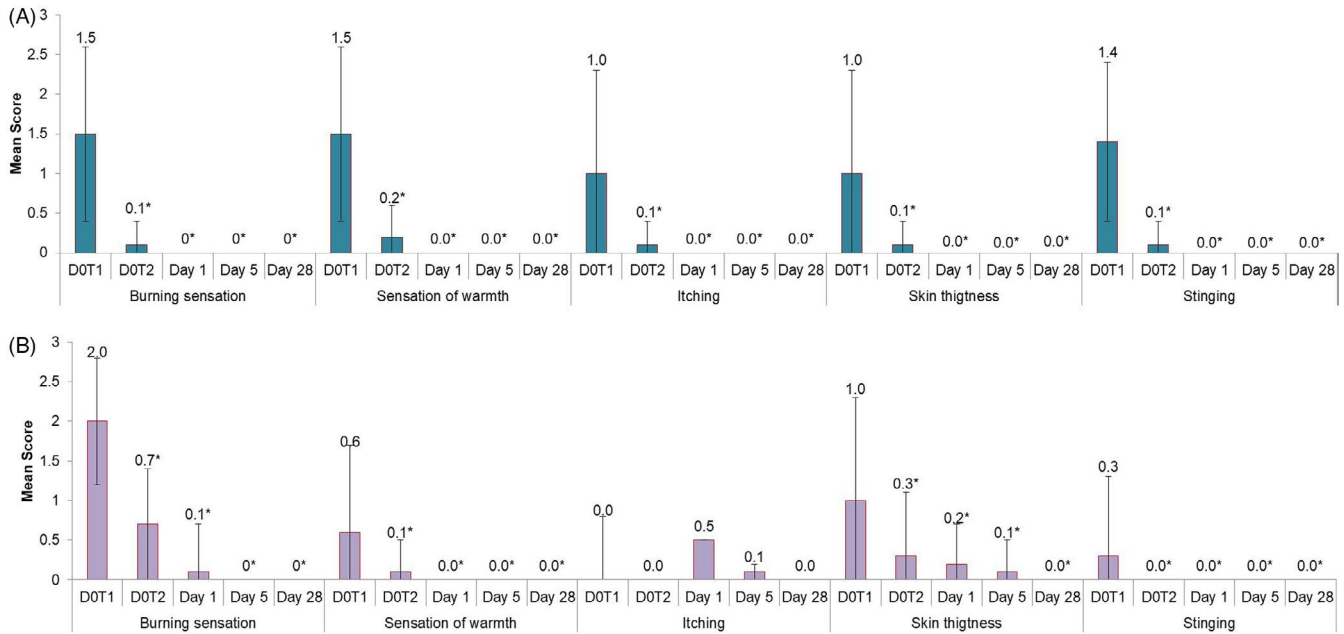
which disappeared during the follow-up. Very mild to diffuse edema was found for 4 subjects shortly after the laser procedure, disappearing between D0 and D5. Very mild or mild diffuse skin dryness was recorded for 4 subjects, starting immediately after the laser procedure to D5, disappearing before the end of the study. Four subjects reported very mild desquamation or discrete crusts (5 women) at D5, which had disappeared by the time of the final visit.

### 3.3.2 | Symptoms

Mean scores of the symptoms reported by the subjects at baseline dropped to very low levels soon after M89 M application and remained around 0 thereafter, both in study 1 and study 2.

In study 1, the decrease at DOT2 was 92.0% for burning sensation, 88.0% for skin tightness, 89.0% for the sensation of warmth, and 94.0% for stinging ( $P < .001$  for all time points, when compared to baseline; see Figure 3A). In addition, 2 subjects reported very mild itching at baseline, which had disappeared by DOT2.

In study 2, burning sensation dropped by 67.0% after the first application of M89 M (with  $P < .001$  for all time points, as compared to DOT1), skin tightness by 71.0% ( $P < .01$ ), sensation of warmth by



**FIGURE 3** Subject-reported symptoms. A, Study 1 (Singapore). B, Study (Brazil). \* $P < .001$

80.0% ( $P < .05$ ), and itching by 100% ( $P < .05$ ), see Figure 3B. All other symptoms that were reported anecdotally had totally disappeared by the time of the final visit at the latest (stinging for 3, pricking for 2, and mild for one subject).

### 3.3.3 | Instrumental evaluations

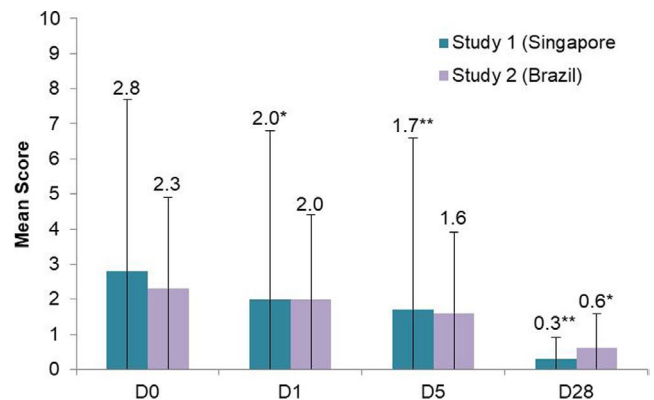
In both studies, a statistically significant increase of the skin hydration compared to the baseline level was recorded rapidly after the first application of M89 M (15% in study 1 and 19% in study 2,  $P < .001$ ), followed by oscillations at subsequent time points, comprised between  $-10.0\%$  and  $+9.0\%$ .

In study 1, TEWL was not impacted by M89 M application. In study 2, the mean value was significantly lower at D5 and D28, when compared to DOT1 ( $-26\%$  with  $P$ value = .003 and  $-24\%$  with  $P$ value  $< .001$ , respectively).

In both studies, the mean value for the intensity of erythema using the  $a^*$  parameter was significantly lower at all time points, when compared to DOT1. In study 1, it decreased by 12.0% at DOT2, 13.0% at D1, and 15.0% at D5 and D28 ( $P < .001$ ). In study 2, the reduction was 5.0% at DOT2 ( $P = .01$ ), 10.0% at D1, 12.0% at D5, and 14.0% at D28 ( $P < .001$ ).

### 3.3.4 | Subject feedback and quality of life

The subject's perception of the effect of M89 M on their health-related QOL, measured with the DLQI, had improved in both studies at D28, compared to D0.



**FIGURE 4** Evolution of DLQI over time. \* $P \leq .01$ , \*\* $P \leq .001$ . DLQI at D0 was assessed before laser procedure

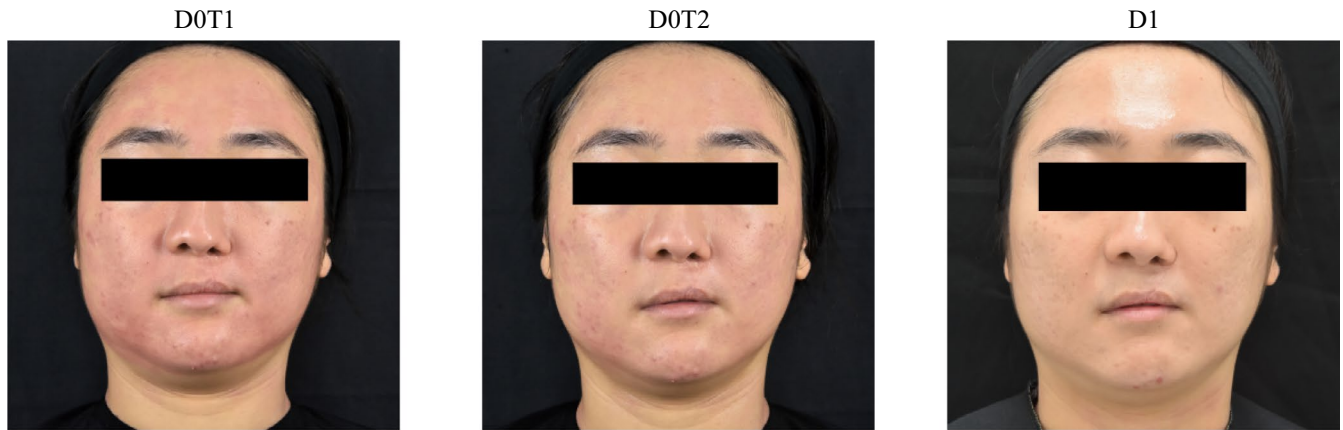
In study 1, the mean score was  $2.8 \pm$  at D0, decreasing by 28.0% at D1 ( $P < .01$ ), 40.0% at D5, and 88.0% at D28 ( $P < .001$ ). In study 2, starting from  $2.3 \pm 2.6$  at baseline, the score had decreased by 13% at D1 and 33.0% at D5 (nonstatistically significant), while it had significantly ( $P = .002$ ) improved ( $-76\%$ ) by the final visit. Evolution of the DLQI over time is given in Figure 4.

According to their answers to the 2 questions asked at the final visit, the subjects considered that M89 M is soothing and they were willing to use M89 M after future laser procedures (LP; 100.0% of subjects in study 1 and 96.0% in study 2, where one woman (4.0%) responded that she neither agreed nor disagreed).

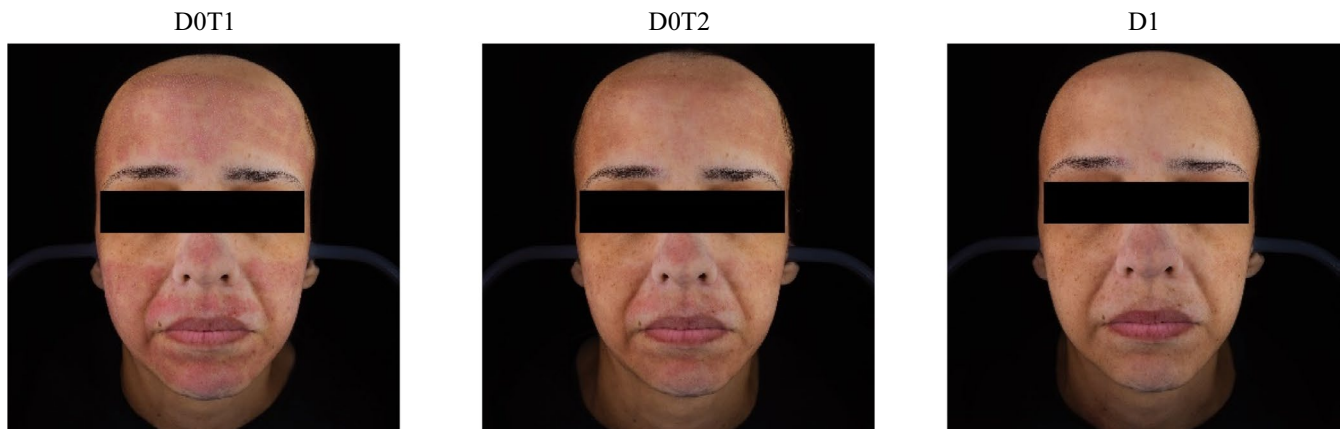
Figure 5 provides visual results of the clinical benefit of M89 mask right after LP.



## (A) Study 1 (Singapore)



## (B) Study 2 (Brazil)



**FIGURE 5** Outcome of use of M89 mask. A, Study 1 (Singapore). B, Study 2 (Brazil)

### 3.3.5 | Local tolerance

No M89 M related tolerance issues were reported in study 1.

In study 2, 6 out of 28 subjects reported undesirable signs and/or symptoms after M89 use. Out of these, 3 were considered related to M89 M. They were burning sensation, tightness, and erythema; none of them led to M89 M discontinuation.

## 4 | DISCUSSION AND CONCLUSION

Results from both studies show that M89 formulated as a mask reduces rapidly and significantly erythema and patient reported symptoms, thus significantly improving 2940 nm Er:YAG and 1064-nm Nd:YAG laser procedure-related sensations of discomfort, with a sustaining benefit up to 28 days postprocedure.

Instrumental assessments confirmed that M89 M improves skin hydration and reduces TEWL, thus restoring the skin barrier, as well as reducing skin redness, a symptom of erythema and inflammation,

which confirms results from a split-face study conducted by Berardesca et al published in 2020, assessing the benefits of M89 in subjects with rosacea.<sup>17</sup> In another recent study conducted on M89 proposed in a topical gel formulation, M89 significantly improved clinical signs and symptoms of dermatological procedures and met the investigators' and subjects' expectations.<sup>16</sup> While M89 gel applied once or twice daily allows for a significant reduction of clinical signs and symptoms following esthetic procedures over a prolonged and continued period, the use of M89 mask from right after the procedure and then twice or three-times per week allows for an immediate improvement of clinical signs and discomfort symptoms. Thus, both products may be considered complementary and an ideal combination after esthetic procedures for a long-term improvement of skin hydration as well as for the restoration and maintenance of the natural skin. In both studies, the subjects' QOL had significantly ( $P \leq .01$ ) improved after 28 days and subjects were highly satisfied with M89 M.

Despite a similar study design and similar results, several discrepancies between the 2 studies have been observed. Subjects participating in the Brazilian study had more frequent edema, skin dryness,

and erythema reported than those participating in the Singapore study, probably due to differences in the laser wavelength, but also possibly due to climate and racial differences, as many aspects play a role in the interpretations of the events.

Some transient and mild events were observed immediately after the first application of M89 M in study 2. These observed effects may be due to the fact that the laser procedure might have caused superficial lesions, making the skin even more sensitive and reactive. However, this did not lead in any case to the discontinuation of M89 M use. M89 helps the skin to restore its natural barrier as shown in the reduction of erythema, subjective patient reported symptoms, as well as in skin hydration and TEWL findings. Therefore, M89 M is suitable for users with sensitive and irritated skin, being hypoallergenic, fragrance-free, and including only 11 ingredients.

One major limitation of these studies is the absence of a control group. However, assessing clinical signs and symptoms immediately after the procedure at DOT2 allowed for an objective comparison with baseline values.

Despite this limitation, the present studies on M89 formulation proposed as a mask confirm efficacy results observed with M89 in a topical formulation, while showing a significantly improved QOL for subjects after LP.<sup>16</sup> Though results regarding QOL should be considered with caution, as the laser treatment outcome itself may play a substantial role in the improvement of the subjects' QOL.

In conclusion, M89 M is effective and safe immediately after esthetic procedures such as nonablative lasers, while improving the subject's QOL.

## ACKNOWLEDGMENTS

The authors acknowledge the participation of the subjects, SMWS France for the writing support.

## CONFLICT OF INTEREST

Marion Nielsen, Audrey Valois, and Delphine Kerob are employees of Laboratoire Vichy International, Levallois-Perret. Raphael Clark and Bandana Seesurn received honoraria from Laboratoire Vichy International. The other authors are employees of Centre International de Développement Pharmaceutique and PRA Health Sciences and have no conflict of interest to report.

## AUTHOR CONTRIBUTIONS

PT, EP, RC, EF, TP, APF, NS, and BS were experts and participated in the conduct of the study. DK MN and AV provided medical and scientific input. All authors participated in writing the manuscript, and all approved its content.

## DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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**How to cite this article:** Torreao P, Phua E, Clark R, et al.

Evaluation of the efficacy and tolerance of a cosmetic mask containing 89% of vichy volcanic mineralizing water and hyaluronic acid after facial laser procedures. *J Cosmet Dermatol.* 2021;20:2860-2866. <https://doi.org/10.1111/jocd.13972>