Steven Harris, Ben Mathers, Don Othoro, and Saskia Sabelus discuss the results of their randomized, controlled comparative study between a silicone eye mask versus a regular eye mask in the reduction of glabellar lines and the promotion of emotional relaxation



STEVEN HARRIS, MD. The Harris Clinic, London, UK; BEN MATHERS, MD, Marie le Bon. London, UK: DON OTHORO, MD, Malmin Skin, London, UK: SASKIA SABELUS, Associate Lecturer, Goldsmiths University of London, London, UK;

email: steveharris001@yahoo.

ABSTRACT Background

The silicone eye mask is an eye mask that employs small raised silicone dots to effectively reduce glabellar lines while promoting emotional relaxation.

double-blind randomised controlled trial was conducted

on 30 subjects with mild to severe glabellar lines. Subjects in the experimental group (n=15) were instructed to wear the silicone eye mask for 15 minutes while those in the control group (n=15) were instructed to wear a regular eve mask for 15 minutes. Changes in glabellar lines were assessed by expert grading and image analysis of

digital images of subjects' Emotional relaxation faces. was assessed by subject selfassessment.

Results

The silicone eve mask significantly improved the appearance of glabellar lines after 15 minutes in comparison to the regular eye mask, with

comparable benefits at around 5 hours. The former also showed a greater tendency toward emotional relaxation.

Conclusions

The silicone eve mask can significantly improve the appearance of frown lines while promoting emotional relaxation.

VER 17,000 SENSORY RECEPTORS have been reported in the human face1. The response of the face to touch, or indentation of the skin is mediated via facial mechanoreceptors located in the superficial layers of skin. These may be divided into slowly adapting (SA) receptors firing with constant indentation of the skin and rapidly adapting (RA) receptors responding only to the onset and offset of indentation2.

SA receptors include Merkel cell disks (SA1), Ruffini corpuscles (SA2) and free nerve endings (10% thinly myelinated, SA3 and 90% unmyelinated, SA4). Free nerve endings are the most common mechanoreceptors in the face and may be further divided equally into lowthreshold pressure (LTP) units responding to light touch and high-threshold pressure (HTP) units responding to deep touch. RA receptors include Meissner corpuscles (RA1) and hair receptors (RA2)2.3.

It appears that stimulation of SA receptors involves not only the somatosensory pathways, but also the autonomic nervous system (ANS)13. The trigeminal nerve, which carries sensory information to the central nervous system (CNS), in particular the hypothalamus, is

accompanied by both sympathetic and parasympathetic fibres along its course¹. Indeed, stimulation of SA receptors has been associated with pleasurable touch sensation as well as the lowering of sympathetic activity³. According to the model of hypothalamic tuning, vagal activity also leads towards more trophotropic tuning of the hypothalamus (via an autonomic loop) to produce a decrease in both global muscle tone and emotional arousal4.

The silicone eye mask (SEM) is an anti-wrinkle eye mask that employs small raised silicone dots situated on a raised inner portion; it is hypothesized that the silicone dots stimulate SA receptors to inhibit sympathetic activity via trophotropic tuning of the hypothalamus. The result is a reduction in both facial muscle tone (improving overlying facial lines) and emotional arousal. A study was conducted to compare the efficacy of the SEM versus a REM in the reduction of glabellar lines and the promotion of emotional relaxation.

Materials and methods Study design and subjects

An independent double-blind randomised controlled study involving 30 subjects (28 women and 2 men) ▷

KEYWORDS

Silicone eye mask, mechanoreceptors, glabellar lines, trophotropic tuning, emotional relaxation.

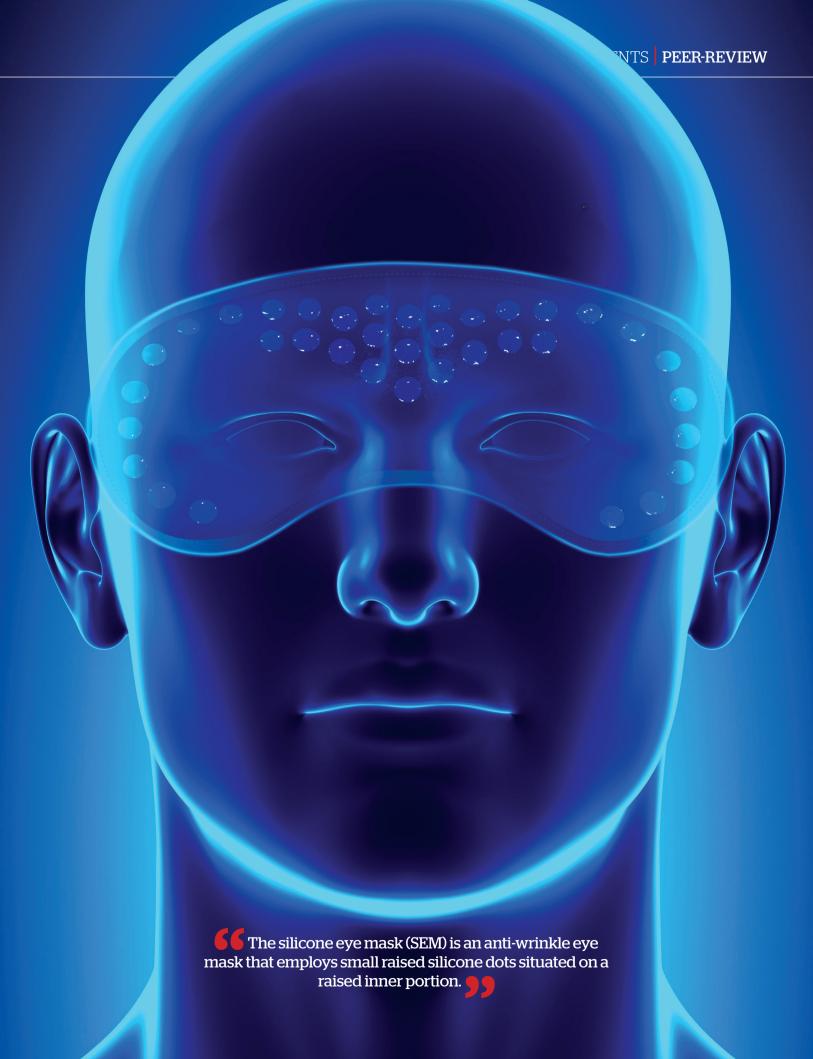




Figure 1 The inside lining of the silicone eye mask (SEM)

 \triangleright aged 28–69 (M=47.3, SD=13.4) was conducted in north London over a 2 week period in June, 2016. Eligible subjects all had Fitzpatrick gradable skin types and mild to severe frown lines. Wrinkle severity was assessed by using a four point scale for frown lines. Those excluded had received aesthetic treatment involving the frown area over the previous 6 months. Written informed consent for participation in this study was obtained from all subjects in accordance with WHO guidelines for clinical studies.

Study products

Subjects were randomly assigned to wear the silicone eye mask (SEM) (N=15), or a regular eye mask (REM) (N=15) for 15 minutes while lying down. The REM consisted of an outer and inner (face-side) layer of cotton drill with a middle layer of poly-cotton interlining. Two adjustable straps attached to the sides helped secure the mask to the face. The SEM was similar to the REM, but had small raised silicone dots positioned on the inner layer, itself raised by an interlining outline (Figure 1).

Table 1 Mean ratings of frown lines by experimental condition (type of mask worn) at pre-test and post-test

TYPE OF MASK WORN	PRE-TEST	POST-TEST	PAIRED T-TEST
SEM (N=15)	.87 (.44)	.53 (.44)	5.29*
REM (N=15)	.87 (.52)	.83 (.45)	.56¹

Note: Standard deviations are given in parentheses. Paired t-tests were conducted per condition from pre-test to post-test. *p<001, 1p = .58

Table 2 Number of patients who reported feeling emotionally relaxed (Yes/not feeling emotionally relaxed (No) by experimental condition

		SEM	REM	Total		
Emotionally relaxed	Yes	10	6	16		
	No	5	9	14		
	Total	15	15	30		

Assessments

The changes in appearance of glabellar lines were measured by expert visual grading of high-resolution digital images using a four point scale for frown lines with 0.5 grade increments (between 0-3), at baseline and 15 minutes after wearing the mask (REM or SEM); then hourly for up to 5 hours. Two trained external expert graders who were blinded to the treatments, independently assessed the changes by comparing baseline and post-treatment images side-by-side (using the four point scale for frown lines).

Emotional relaxation was assessed immediately before and after 15 minutes of wearing the mask (REM or SEM) by self-assessment using a patient questionnaire (O=not relaxed, 1=relaxed) before and after wearing the mask for 15 minutes.

Results

In order to compare the means between the different groups after the treatment, i.e., the difference in ratings of glabellar lines between patients who wore the SEM and those who wore the REM, an Analysis of Covariance (ANCOVA), the recommended analysis for pre-test post-test designs, was conducted. As the primary interest in our study relates to the post-test scores, i.e., whether the treatment had an effect, the pre-test scores were statistically controlled for and entered as covariates56. The ANCOVA was thus used as an extension of an analysis of variance (ANOVA) which compares two or more means. Criteria for use of ANCOVA were met-there were no significant differences between the conditions at pre-test, and the requirement regarding homogeneity of regression was met. Table 1 shows the mean ratings of glabellar lines for the two conditions (SEM vs. REM) at pre-test and post-test.

There was a significant difference in the ratings of glabellar lines at post-test between patients who wore the SEM compared to patients who wore the REM (F (1, 27)=13.69, p=.001, η p2=.34), with lower scores, thus an improved appearance of glabellar lines, shown in the experimental condition (*Figures 2-4*). The duration of improvement was also assessed in this condition; resulting in M = 4.90 hours (SD=2.73).

It was of further interest to examine whether patients in the two conditions (SEM vs. REM) differed on their ratings of emotional relaxation after 15 minutes of wearing the respective masks. *Table 2* shows the number of patients who reported feeling emotionally relaxed or those who reported not feeling emotionally relaxed by the experimental condition.

Table 2 also shows that the proportion of patients in the SEM condition who reported feeling emotionally relaxed (10 out of 15, 67%) was greater than patients who reported feeling emotionally relaxed in the REM condition (6 out of 15, 40%). A chi-square test revealed, however, no significant differences between the conditions: $\chi 2$ (1, N = 30)= 2.14, p >.05.

Discussion

To the authors' knowledge, the SEM is the first product of its kind which specifically targets cutaneous





Figure 2 (A) Before and (B) after treatment with the silicone eve mask

mechanoreceptors, especially the SA types, in order to exert its effects. Various facial stick-on patches and pads exist for overnight wear to correct facial lines, however, the authors have been unable to find any scientific studies that substantiate their claims and they certainly do not target mechanoreceptors as the SEM.

This study has found that when compared to a REM, the SEM significantly reduces glabellar lines. The proposed mechanism of action is that the small raised silicone dots cause temporary small indentations in the skin that stimulate all types of facial mechanoreceptors, especially SA free nerve endings with LTP units.

Stimulation of these mechanoreceptors sends somatosensory and autonomic signals to decrease sympathetic activity. The result is a decrease in muscle tone and emotional arousal, thereby reducing facial (glabellar) lines while promoting emotional relaxation. Both effects were found in this study.

The authors recognise that there are limitations to this study. A larger group size would have provided more statistical power for more robust conclusions. While the SEM showed a significant improvement in glabellar lines compared to the REM, the reducing arousal effect did not reach statistical significance, even though there was a clear tendency toward this effect.

While every attempt was made to blind the examiners and the subjects to the treatments, both may have





Figure 3 (A) Before and (B) after treatment with the silicone eye mask



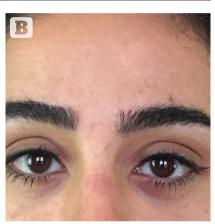


Figure 4 (A) Before and (B) after treatment with the silicone eye mask

NKey points

- The silicone eye mask (SEM) is an eye mask that employs small raised silicone dots to stimulate cutaneous mechanoreceptors, which in turn signal the brain to reduce sympathetic activity
- A more trophotropic hypothalamus leads to a reduction in both muscle tone and emotional arousal
- When compared to a regular eye mask (REM), the SEM was found to significantly reduce glabellar lines while promoting emotional relaxation

recognised the differences between the masks when fitting them on for the experiment. This may have introduced an element of bias toward the SEM.

These limitations notwithstanding, the study data, from both objective and subjective assessments, provided consistent results to show the SEM significantly improved glabellar lines when compared to the REM and the former also showed a greater tendency toward emotional relaxation.

- **▶ Declaration of interest** None
- ▶ Figures 1-4, tables 1-2 © Steven Harris

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