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# Efficacy and safety of silicone adhesives in improving signs of periorbital aging: a pilot study

*Eficácia e segurança dos adesivos de silicone na melhora de sinais de envelhecimento periorbital: estudo piloto*

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**ABSTRACT**

**Introduction:** Multiple treatments that promise to prevent or treat skin aging act on cellular functions, reducing skin aggression mechanisms, or even on the loss of skin barrier properties. Silicone adhesives appear to have a positive effect on barrier function and modulation of inflammation, but their clinical effects have not yet been documented.

**Objective:** To evaluate the effectiveness of silicone adhesives in reducing the signs of periorbital aging.

**Methods:** 33 patients between 35 and 55 years old with a clinical diagnosis of aging in the periorbital region were selected; Of these, 23 underwent hydration measurements (corneometry) and skin relief (prophylometry). All participants used the patches daily for a period of 30 days.

**Results:** After four weeks of use, the application of silicone adhesives provided a significant improvement in hydration levels and the skins microrelief, making it smoother. The clinical and subjective evaluation corroborated these findings, and also showed a relevant improvement in clinical and subjective parameters such as hydration, softness, texture, and expression lines.

**Conclusion:** The continued use of silicone adhesives demonstrated a beneficial effect on some signs of aging, possibly related to improved hydration and modulation of inflammation.

**Keywords:** Skin Aging; Epidermis; Silicone Elastomers.

***RESUMO***

***Introdução:*** *Múltiplos tratamentos que prometem prevenir ou tratar o envelhecimento da pele atuam nas funções celulares, reduzindo os mecanismos de agressão à pele e minimizando a perda das propriedades da barreira cutânea. Os adesivos de silicone parecem ter uma ação positiva na função barreira e na modulação da inflamação, mas seus efeitos clínicos ainda não haviam sido documentados.*

***Objetivo:*** *Avaliar a eficácia dos adesivos de silicone na redução dos sinais do envelhecimento periorbital.*

***Métodos:*** *Foram selecionadas 33 pacientes, com idades entre 35 e 55 anos, com diagnóstico clínico de envelhecimento na região periorbital. Destas, 23 foram submetidas a medidas de hidratação (corneometria) e de relevo da pele (profilometria). Todas as participantes utilizaram diariamente os adesivos por um período de 30 dias.*

***Resultados:*** *Após 4 semanas de uso, a aplicação do adesivo de silicone proporcionou uma melhora significativa dos níveis de hidratação e do microrrelevo da pele, tornando-a mais lisa. As avaliações clínica e subjetiva corroboraram esses achados, além de haver melhora relevante em parâmetros clínicos e subjetivos como hidratação, maciez, textura e linhas de expressão.*

***Conclusão:*** *O uso continuado dos adesivos de silicone demonstrou efeitos benéficos sobre alguns sinais do envelhecimento, possivelmente relacionados à melhora da hidratação e à modulação da inflamação.*

***Palavras-chave:*** *Envelhecimento da Pele; Epiderme; Elastômeros de Silicone.*

## Original Article

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## INTRODUCTION

Skin aging consists of a decline in cellular function, with functional and clinical repercussions. In the epidermis, a reduction in the skin barrier leads to dryness and loss of immune function, while in the dermis, a reduction in the synthesis and organization of the extracellular matrix leads to progressive thinning and loss of biophysical properties such as density, firmness, and elasticity.[1] There are multiple treatments that promise to prevent or treat these phenomena, either by stimulating keratinocytes and fibroblasts, or by reducing mechanisms of aggression to the skin, such as oxidation, inflammation, or even the loss of skin barrier properties.[2-4] Silicone adhesives are widely used to prevent hypertrophic scars and keloids, and to complement the treatment of these conditions. The mechanism of action in modulating the healing response is still unclear, but studies show that, in addition to the mechanical effect of restricting mobilization of the skin under repair, silicone seems to modulate the inflammation present in the area.[5,6] It has been shown that reducing transepidermal water loss plays a role in this modulation, as it contributes to restoring the skin barrier.[7] Recently, the use of silicone gel patches has been propagated in the prevention and improvement of facial wrinkles (periorbital, frontal, glabellar), cervical and pre-sternal areas ("cleavage wrinkles") due to their mechanical effect, as they reduce skin mobilization in these areas; and a moisturizing effect has also been mentioned. However, no published evidence seems to exist on the effect of plaques on skin wrinkles. Given this scenario, this study aimed to learn about the possible contribution of this device to improving signs of skin aging, specifically periorbital wrinkles, and its possible role in other functional parameters linked to aging, such as hydration levels.

## MATERIAL AND METHODS

This is a pilot study including 33 women from a private research center, aged between 35 and 55, with a clinical diagnosis of aging in the periorbital region (presence of dark circles, infraorbital lines and bags). All patients agreed to participate in this study and signed an informed consent form (ICF) before dermatological assessment. After inclusion, all participants received a sample of a silicone patch (MEDGEL ANTIAGE®, Silimed Indústria de Implantes Ltda.) for nighttime application in the infraorbital area, and were instructed not to use any other product on the site, but a sanitizer. Medgel Antiage® is a medical-grade, biocompatible silicone adhesive patch. It is formed by a thin layer of silicone elastomer for support and flexibility, and a layer of silicone gel capable of adapting to the contour of the skin and adhering to the entire intended area. The surface in contact with the skin comes with a plastic film for wrapping, so as not to lose its adhesiveness. Medgel Antiage® comes in different shapes to suit the target anatomical regions: eye contour, nasolabial fold, forehead and glabella, and perilabial and neck. Table 1 shows the dimensions of each patch.

Patients were instructed to wash their patches daily as it is suitable to use for 30 days. Patients were evaluated by the research dermatologist at the beginning and at the end of the study, who was available for any cases of adverse reactions. Of these patients, 23 were randomly selected for hydration measurements using corneometry (Corneometer® MPA 580, Courage & Khazaka) and skin relief (fine lines) using profilometric image analysis (Primos lite®, GFMesstechnik GmgH), at the beginning and at the end of the study. On the first day of evaluation, these patients underwent an 8-hour hydration kinetics study to assess the effects of a single application of the adhesive on water levels in the stratum corneum. A total of six standardized patches were applied to the inner surface of the forearms in order to evaluate the hydration curve from a single application compared to a control area (no patches used). The patches were removed at 1, 2, 4, 6, and 8 hours and measurements were taken and compared to the control area. The study was conducted in accordance with Good Clinical Practice guidelines, Resolution No. 466/12, and was approved by the Research Ethics Committee of the Universidade São Francisco under opinion number: 5.887.621 and CAEE: 66692823.7.0000.5514 on February 10, 2023. The study was conducted between May and July.

## RESULTS

Of the 33 participants, two were excluded for no follow-up. In terms of safety of use, the adverse reactions reported were mild and transient, and did not require discontinuation of the product. Mild pruritus (4 participants) mild local heat (1 participant) and mild erythema with burning (1 participant) were reported, but spontaneous regression allowed use. The mean age was 46.1 years.

**Table 1: Characteristics of the Medgel Antiage® silicone adhesive models**

| área | heigh (mm) | lenght (mm) | thickness (mm) |
|---|---|---|---|
| Eye contour/nasolabial fold | 38.38 ±5 | 74.95 ±5 | 1.5 ±0,3 |
| Forehead and glabella | 69.53 ±5 | 149.47 ±5 | |
| Perilabial | 28.45 ±5 | 59.00 ±5 | |
| Esternal área | 175.00 ±5 | 234.00 ±5 | |

**Assessment of clinical efficacy**

As for the improvement rate, table 2 shows the results of the clinical evaluation.

Instrumental assessment: hydration of the corneal layer

The kinetic evaluation, to assess the effect of a single application, revealed a statistically significant improvement in hydration levels from hour one (37.1%) and progressively over time, reaching 50.78% in eight hours, as shown in table 3.

Chart 1 shows the effects of hydration levels over time after 28 days, which were statistically significant ($p<0.05$) with daily use at night.

**Instrumental assessment – Skin relief**

This assessment shows that lower medians mean an improvement in the parameter, as there is less relief (smoother skin). The results show a statistically significant 14.3% reduction in the depth of periorbital wrinkles after 28 days of use, as shown in chart 2.

**Subjective assessment – Questionnaire**

The participants completed a questionnaire on the effects of the product evaluated at the end of the study; responses of total or partial agreement for each question were considered positive. Two broader questions were included: improvement in the appearance of aging and appearance of younger skin. Most of the participants rated all the parameters positively, as shown in table 4.

## DISCUSSION

The use of silicone adhesives has been studied since the 1990s for the prevention and treatment of keloids and hypertrophic scars,[8] becoming the first-line treatment in the most recent guidelines.[9,10] As it is more effective in recent scars, it has been suspected that, in addition to a mechanical benefit, it may also have an effect on inflammation. There is evidence that, in addition to greater tissue hydration, silicone has an effect on mast cell activity and interleukin 1 expression, with possible effects on shaping the extracellular matrix.[11,12] Based on the assump-

**Table 2: Patient improvement rate according to clinical assessment – infraorbital area (n=31). *Hypothesis rejected: 5% significance level**

| Clinical parameters | % Improvement | *Valor p* | Conslusion |
|---|---|---|---|
| Luminosity | 74.19% | 0.0001 | Rejects the hypothesis* |
| Vitality | 74.19% | 0.0001 | Rejects the hypothesis* |
| Skin texture | 70.97% | 0.0001 | Rejects the hypothesis* |
| Hydration | 67.74% | 0.0001 | Rejects the hypothesis* |
| Freshness | 64.52% | 0.0001 | Rejects the hypothesis* |
| Softness | 61.29% | 0.0001 | Rejects the hypothesis* |
| Radiance | 61.29% | 0.0001 | Rejects the hypothesis* |
| Eye bags | 3.23% | 0.2008 | Does not reject the hypothesis* |
| Expression lines | 3.23% | 0.9999 | Does not reject the hypothesis* |

**Table 3: Changes in corneometric indices (hydration) up to eight hours after a single application (T0). N=23. *Hypothesis rejected: 5% signific ance level**

| Time | % patients with improvement | Variation | *Valor p* | Conclusion |
|---|---|---|---|---|
| **T1h –T0** | 100.00% | 37.10% | 0.0001 | Rejects the hypothesis* |
| **T2h –T0** | 100.00% | 45.21% | 0.0001 | Rejects the hypothesis* |
| **T4h –T0** | 95.65% | 46.71% | 0.0001 | Rejects the hypothesis* |
| **T6h –T0** | 100.00% | 47.92% | 0.0001 | Rejects the hypothesis* |
| **T8h –T0** | 100.00% | 50.78% | 0.0001 | Rejects the hypothesis* |

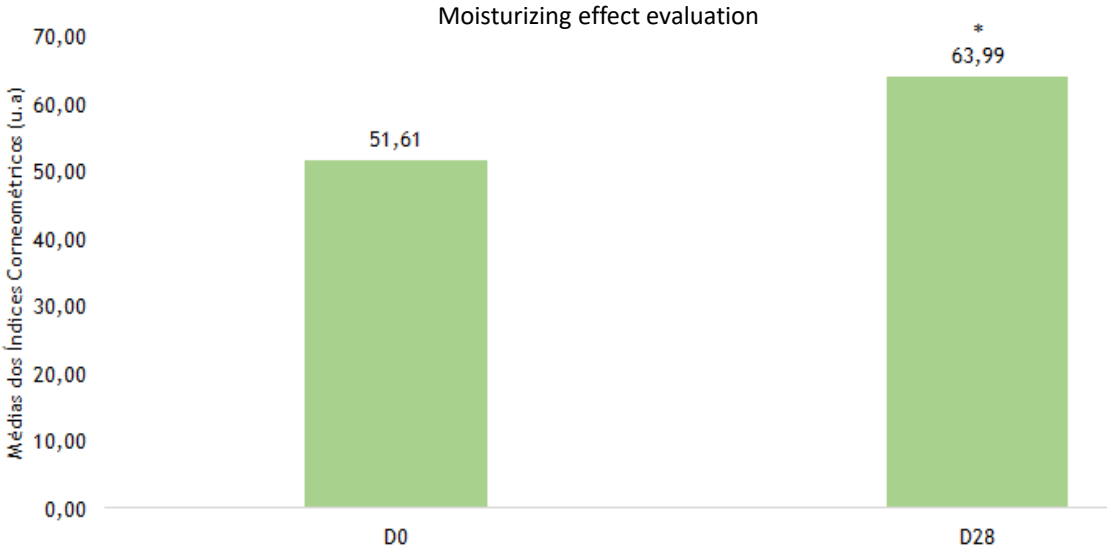


**Chart 1:** Means of corneometric indices before (D0) and after 28 days (D28) of use of the test product. N=22. P<0.05 in relation to D0

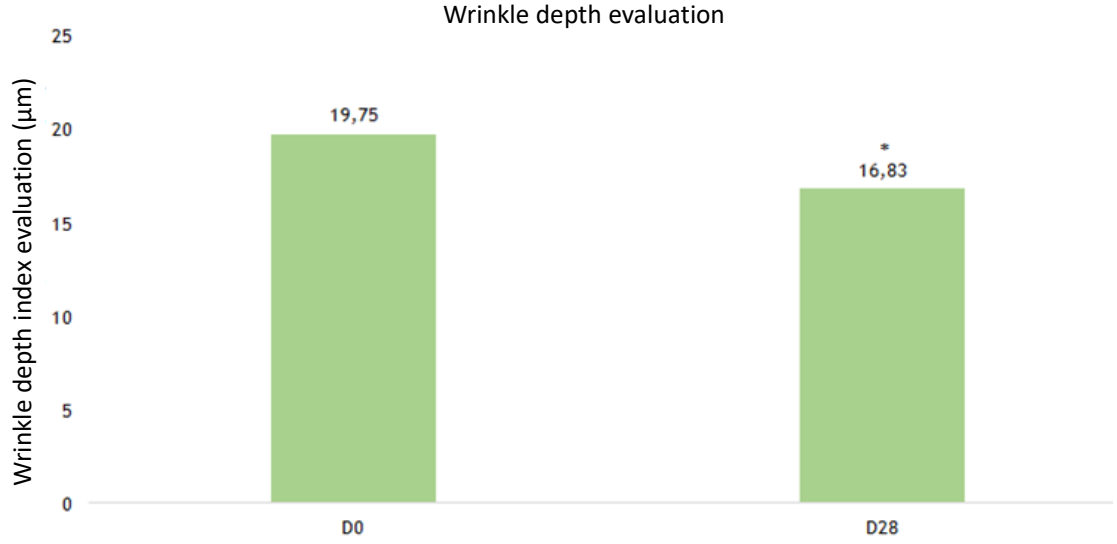


**Chart 2:** Median depth of wrinkles in the periorbital region before (D0) and after 28 days (D28) of use of the test product (N=22).
*p<0.01 in relation to D0

tion that aged skin finds it more difficult to maintain its barrier function and is more prone to irritation, and that external factors (solar radiation, pollution, etc.) can act as pro-inflammatory agents, silicone adhesives could exert a protective effect, creating a microenvironment conducive to modulating inflammation and restoring the barrier, but no study has yet demonstrated this phenomenon. Silicone adhesives have shown a positive and relevant effect on hydration levels from the first use, the first step in maintaining or even restoring the epidermis; their effects over time, demonstrated in both clinical and instrumental assessments, showed a significant reduction in periorbital lines, although a possible dermal mechanism of action remains undetermined. Increased hydration is obtained from a recovery of barrier integrity. A study on topical application of silicone showed a significant improvement in transepidermal water loss in patients after ablative procedures.[13] Silicone adhesives have been shown to be safe for daily use on the face and eye area, corroborating the safety already observed in several clinical studies. These encouraging results suggest that the use of silicone adhesives can be a safe and effective measure not only for the treatment of

skin aging signs, but possibly during the aftermath of procedures that involve barrier alteration (laser, microneedling, peels, etc.) as long as there are no raw areas, as is recommended for healing lesions.[14] Patients with a history of skin allergies and irritations can also benefit from these measures, with improved skin integrity. In short, the evidence found in this study points to promising results in this new alternative of aged skin care.

## CONCLUSION

The use of silicone adhesives demonstrated a significant patient-perceived improvement in parameters associated with periorbital skin aging: softness, hydration, texture, vitality, radiance, and participants' perception of improvement in luminosity, bags around the eyes, and expression lines. These results were corroborated by instrumental assessment, with a significant improvement in the time of hydration measurements (with statistically relevant results from the first use, at all assessment times) and skin relief. These findings indicate that the use of silicone adhesives is a promising resource for treating the signs of skin aging with their continued use, representing the first noncosmetic skin care for home use with proven safety and efficacy; their use should also help to improve the results of local aesthetic procedures, with no the risk of irritation or sensitization. ●

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