



Original Article

# Efficacy and safety of mesoporosil treatment in enhancing skin firmness, hydration, and elasticity: An 84-day clinical trial

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## ABSTRACT

**Objectives:** Silicium (silicon), an essential trace element, plays a critical role in maintaining skin health, including collagen synthesis, hydration, and elasticity. Mesoporosil<sup>®</sup>, a novel bioavailable form of silicium, offers a promising solution for enhancing skin properties. This study evaluates the efficacy and safety of Mesoporosil<sup>®</sup> in improving skin firmness, hydration, and elasticity in women with aging skin.

**Materials and Methods:** This 84-day interventional study involved 22 female volunteers aged 40–66 years with moderate to severe facial aging and dry skin. Participants consumed one daily tablet of Mesoporosil<sup>®</sup> containing 14 mg of silicon. Assessments were conducted at baseline, day 28, day 56, and day 84. Primary outcomes included subjective improvements in skin firmness, hydration, elasticity, and radiance, assessed through a detailed 24-item questionnaire.

**Results:** All 22 participants completed the study without dropouts. Subjective assessments showed progressive improvements in skin parameters over the treatment period. Significant acceptance was observed on day 28 (55.8%), day 56 (62.7%), and day 84 (61.4%). Three sensory experience parameters – ease of oral intake, absence of aftertaste, and lack of gastric distress – met the 80% satisfaction threshold consistently. Skin firmness, hydration, wrinkle reduction, radiance, and elasticity showed cumulative enhancement over the 12 weeks. No adverse events or discomforts were reported, indicating excellent tolerance and safety of the supplement.

**Conclusion:** Mesoporosil<sup>®</sup> demonstrated significant efficacy in enhancing skin firmness, hydration, and elasticity, with high levels of participant satisfaction and excellent safety. These findings support the potential of Mesoporosil<sup>®</sup> as an effective supplement for promoting healthy aging in women with aging skin.

**Keywords:** Aging skin, Collagen synthesis, Mesoporosil, Silicium, Wrinkles

## INTRODUCTION

Silicon, also known as silicium, ranks as the third most abundant trace element in the human body, following iron and zinc.<sup>[1]</sup> Silicon should not be confused with silicone, a synthetic polymer used in sealants, adhesives, medical implants, and skincare products such as moisturizers, primers, and scar treatments. Therefore, to avoid any confusion, throughout this study, we will use the term “silicium” instead of “silicon.” Silicium activates hydroxylation enzymes, synthesizes collagen and glycosaminoglycans, prevents free-radical-induced collagen breakdown, and

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maintains skin's strength, elasticity, hydration, and antioxidative defense.<sup>[2]</sup> Orthosilicic acid (OSA), the most bioavailable form of silicon, has been studied in relation to its possible uses and benefits for the skin.<sup>[3]</sup> Research indicates that OSA stimulates fibroblasts, which are responsible for laying down new Type I collagen and wound healing. High silicon content in hair promotes growth and reduces brittleness, while its presence in nails contributes to their strength. Dietary supplements containing silicon aim to increase serum silicon levels, but their bioavailability is often limited due to variable gastric absorption.<sup>[4,5]</sup>

The majority of silicon-based dietary supplements are typically found in liquid form. However, liquid mineral dietary supplements have several disadvantages, such as temperature storage, precise dosing, taste, odor, and portability. These factors can make liquid supplements less practical for regular use. For these reasons, extensive research has been conducted to develop solutions that address the challenges associated with liquid forms. In 2021, the first highly bioavailable form of mesoporous silica particles (MPS), called Mesoporous Silica Particles (MPS), called Mesoporousil<sup>®</sup>, for dietary supplementation has entered the European market. This material demonstrates a significantly higher degradation rate and bioavailability than conventional MPS, making it a more efficient vehicle for delivering OSA to the body. MPS composed of amorphous silicon dioxide is particularly impressive due to its structural properties. It has a pore size distribution between 2 nm and 50 nm and contains a three-dimensional periodic arrangement of atoms with structural pores, resulting in a high specific surface area. This enormous surface area significantly enhances its bioavailability and effectiveness as a dietary supplement.<sup>[6-8]</sup>

One of our previous animal model studies confirmed the solubility, absorbability, and bioavailability of the solid silicon source (Mesoporousil<sup>®</sup>) through a series of *in vitro*, *ex vivo*, and *in vivo* trials. Mesoporousil<sup>®</sup>, developed by Sil'innov, demonstrates an impressive degradation profile, with over 80% of the product dissolving in water within 4 h. This high degradation rate translates to enhanced bioavailability, as confirmed by transintestinal absorption studies using rat jejunum. The absorption fraction of Mesoporousil<sup>®</sup> was found to be 96.7% after 2 h, significantly higher than standard MPS. These findings suggest that Mesoporousil<sup>®</sup> can effectively deliver silicon, making it a promising candidate for various food, cosmetics, and pharmaceutical applications.<sup>[6]</sup> A preclinical trial on silicon shows that age significantly affects endogenous silicon levels. Its pharmacokinetic profile indicates efficient systemic exposure, making Mesoporousil<sup>®</sup> a promising candidate for human applications. Building on these previous preclinical studies, it has been concluded that Mesoporousil<sup>®</sup>-supplemented as a bioavailable form of silicon – exerts a beneficial functional effect on skin properties

related to aging, repairing, rebuilding, and stimulating the synthesis of extracellular matrix proteins like collagen. Therefore, the goal of this study is to evaluate the efficacy and safety of Mesoporousil<sup>®</sup>, containing the active ingredient OSA, on improving facial skin aging, nails, hair, and mobility in females with dry skin. Participants' experiences and satisfaction with the treatment are also evaluated.

## MATERIALS AND METHODS

### Study design and participants

This interventional study recruited 22 female volunteers between the ages of 40 and 66 years, presenting with moderate to very severe signs of facial aging (grades 2–4 on the Eiben-Nielson photometric scale for wrinkles) and having dry skin (30–45 A.U.) or very dry skin (<30 A.U.). Only those subjects who had not participated in similar studies or used similar products in the past three months were included in this study. A 15-day wash-out period was observed before treatment, during which no topical or oral products were used. Participants maintained their usual routines and avoided other products with similar effects, were in good health, and provided written consent to participate. The demographic data of the participants are summarized in Table 2.

### Exclusion criteria

Exclusion criteria aimed to eliminate confounding variables and ensure participant safety. These criteria included a history of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes, or any disease that could increase the risk associated with study participation. Allergy or reactivity to any components of the test product or similar products, current medical treatments that could mask or interfere with the test results, and recent relevant esthetic treatments over the face were also grounds for exclusion. In addition, pregnant or lactating women, those who had given birth within six months before the study, individuals anticipating significant routine or lifestyle changes during the study period, and those who had recently taken hormonal treatments were excluded from participation.

### Intervention

Participants consumed one tablet daily, containing 14 mg silicon, with water before breakfast over 12 weeks, with assessments conducted at 4 weeks (D28), 8 weeks (D56), and 12 weeks (D84). The tablet consisted of a product marketed as "Preblend Mesoporousil<sup>®</sup>." It contains a mesoporous silica named Mesoporousil<sup>®</sup>, which releases ortho-silicic acid when dissolved in a gastrointestinal medium. They were required to adhere to daily treatment conditions, maintain personal eating habits, and avoid taking any other drugs or dietary

supplements during the study. Compliance was monitored using DailyLog, where volunteers recorded their daily adherence. Direct contact was maintained with volunteers to minimize dropout and ensure proper treatment application.

**Subject withdrawal criteria**

Subjects presenting any gastrointestinal or allergic reactions were to be withdrawn from the study, with the reaction documented and follow-up maintained to confirm resolution.

**Assessments**

The study measured the participants’ subjective experiences using detailed questionnaires administered at D28, D56, and

D84. The evaluation used a 24-item questionnaire graded on a Likert scale from 1 to 4, where 1 indicated “strongly disagree,” 2 “disagree,” 3 “agree,” and 4 “strongly agree.” Satisfaction was considered significant for scores of 3 and 4, with a threshold of 80% satisfaction set for noteworthy results. The questionnaire was divided into three sections: sensory experience, treatment effectiveness, and consumer behavior. Each item was designed to capture a comprehensive view of the participants’ experiences and perceived benefits of the treatment [Table 1].

In the sensory experience section (Q 1–3), participants rated the ease of oral intake, whether the product left an aftertaste, and whether it caused stomach discomfort. The treatment effectiveness section (Q 4–19) included perceived youthfulness, firmness, elasticity, hydration, radiance, and

**Table 1:** Questionnaire to measure subjective experiences on D28, D56, and D84.

Questionnaire	Strongly disagree	Disagree	Agree	Strongly Agree	% Satisfaction
Sensory Experience					
1. The oral intake of the product is easy					
2. The oral intake leaves no aftertaste					
3. The oral intake does not cause sour stomach					
Treatment Effectiveness					
4. My skin looks younger					
5. My skin feels firmer					
6. My skin feels more elastic (flexible)					
7. The treatment provides a smoothing/calming effect to my skin					
8. I feel more beautiful					
9. The treatment improves the complexion of my skin					
10. My skin is more hydrated after the treatment					
11. My skin seems more radiant after the treatment					
12. The treatment reduces wrinkles					
13. The treatment improves the growth of my nails					
14. My nails are stronger					
15. The treatment reduces hair loss					
16. My hair has more volume					
17. My hair is stronger					
18. I had some pain or mobility/movement challenge at D0, and now I have less pain.					
19. I had some pain or mobility/movement challenge at D0, and now I move more freely (less stiff, easier walking, stepping)					
Consumer Behavior					
20. I am satisfied with the tested treatment					
21. I would use the treatment again for my skin					
22. I would use the treatment again for my nails					
23. I would use the treatment again for my hair					
24. I would use the treatment again for my mobility/flexibility					
25. I would recommend the treatment					
Overall Acceptance					
D0: Study start date, D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.					

skin wrinkle reduction. It also covered the impact of the treatment on nails and hair, such as improved nail growth and strength, reduced hair loss, and increased hair volume. In addition, the ancillary effects of OSA on the participants' musculoskeletal system were evaluated, with participants reporting any improvement in pain or mobility challenges that they experienced at the beginning of the study (Q18–19).

The consumer behavior section (Q 20–24) addressed participants' overall satisfaction with the treatment and their likelihood of continuing its use for skin, nails, hair, and mobility improvements.

### Ethical approval

The study protocol was reviewed by an Ethics Committee and conducted according to the Declaration of Helsinki and International Council for Harmonization guidelines. All participants provided written informed consent, including consent for data protection and communication.

### Statistical analysis

Data were normalized to baseline values and analyzed using one-way analysis of variance with Dunnett's multiple comparison tests. Significance levels were set at  $P < 0.05$ .

## RESULTS

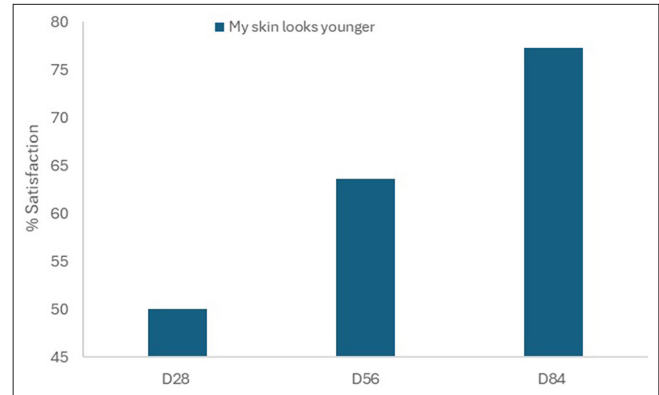
In this interventional study, all 22 initially recruited subjects successfully completed the study without any dropouts. The mean age was  $52.7 \pm 5.5$  years.

### Subjective improvement data

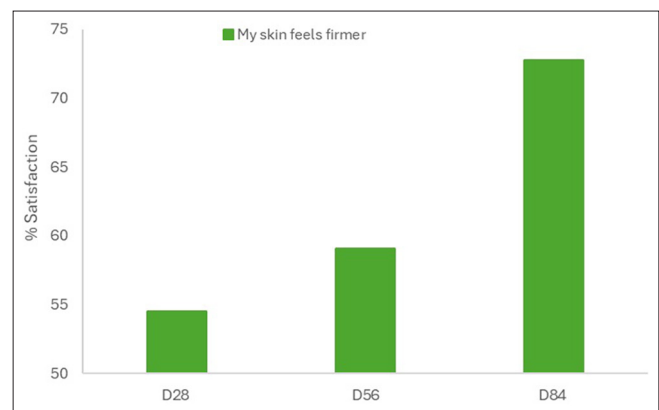
The subjective assessments revealed significant and progressive improvements in several skin parameters throughout the treatment period. Results showed an overall acceptance of 55.8% after 4 weeks of treatment (D28), 62.7% after 8 weeks of treatment (D56), and 61.4% after 12 weeks of oral intake (D84). Specifically, three out of 25 parameters yielded significant results ( $\geq 80\%$ ) at each of the time points but only referred to sensory experience – namely, ease of oral intake, absence of aftertaste, and gastric distress – not to treatment effectiveness or consumer behavior. No significant improvement in mobility or movement was observed. However, over 12 weeks, skin firmness, hydration, wrinkles, radiance, and skin elasticity progressively enhanced, signifying the cumulative effect of the Silxpert treatment on skin firmness over time [Figures 1-8].

### Cutaneous compatibility and acceptability

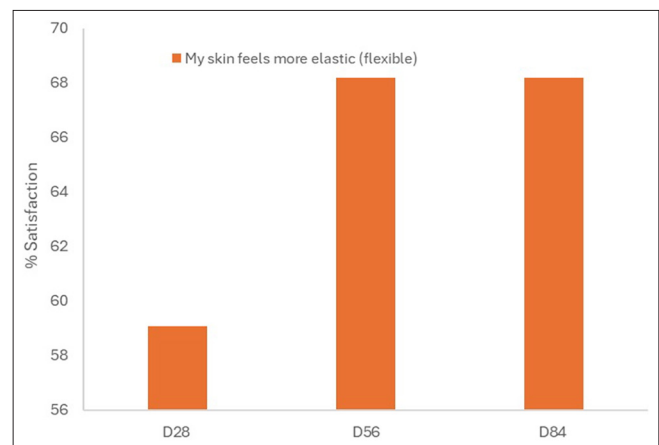
Throughout the treatment period and the subsequent 10 days, the participants reported no undesirable severe effects or



**Figure 1:** Serial improvement in skin youth. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.

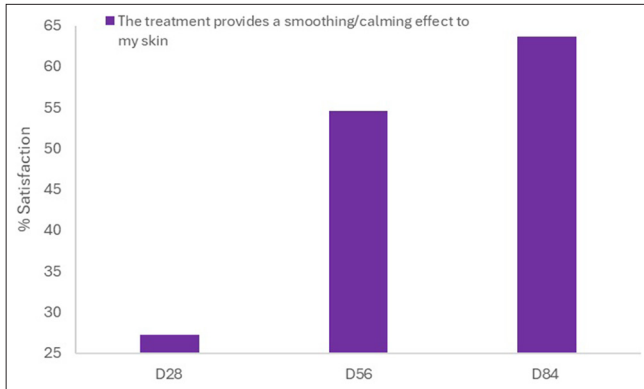


**Figure 2:** Serial improvement in skin firmer. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.

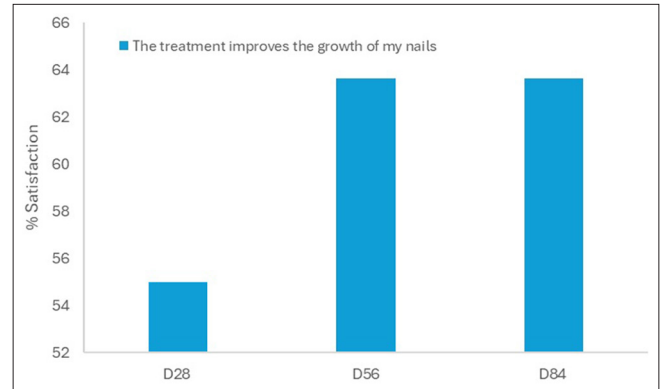


**Figure 3:** Serial improvement in skin elasticity. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.

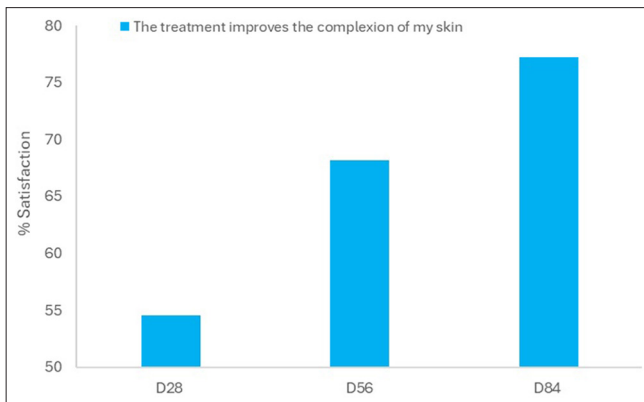
undesirable effects. There were no reports of gastric distress or other adverse events, indicating excellent tolerance of the oral supplements. Participants were instructed to report any reactions or discomforts to the study technician, but none were observed.



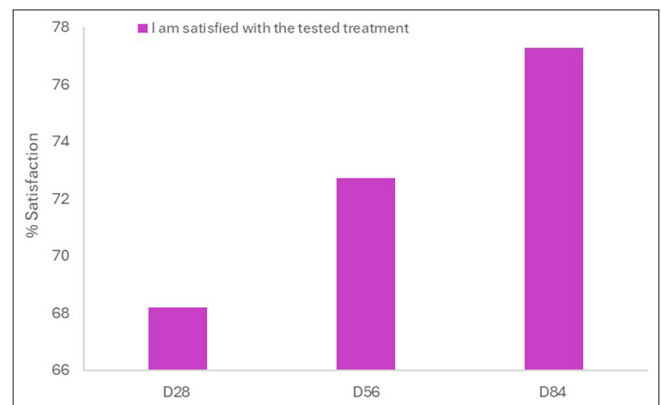
**Figure 4:** Serial improvement in the smoothing/calming effect on skin from the therapy. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.



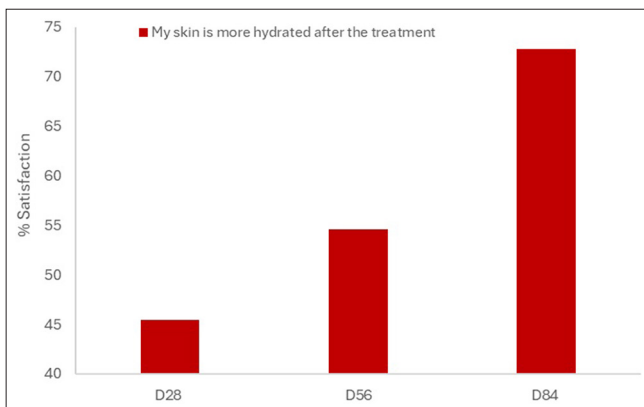
**Figure 7:** Serial improvement in nail growth. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.



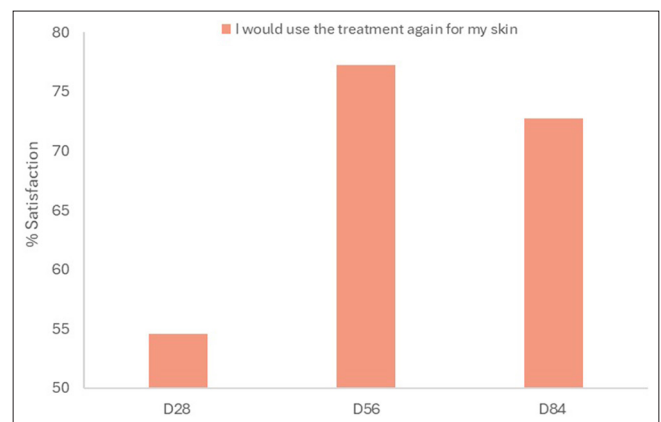
**Figure 5:** Serial improvement in the complexion of skin. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.



**Figure 8:** Serial improvement in treatment satisfaction. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.



**Figure 6:** Serial improvement in skin hydration. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.



**Figure 9:** Patients willing to use the treatment again. D28: 28 days of treatment, D56: 56 days of treatment, D84: 84 days of treatment.

## DISCUSSION

Few studies have investigated the impact of liquid oral mineral supplements like silicium on aging skin.<sup>[7,8]</sup> This study is one of the first to show that a solid oral silicium supplement

significantly improves skin firmness and hydration in women over 12 weeks, with trends toward wrinkle reduction. By the end of the study, 72.7% of participants reported firmer skin and improved skin hydration, and 68.2% noted better skin elasticity and skin radiance. Wrinkle reduction peaked



**Table 2:** Demographic data of participants.

Parameters	Details
Number of subjects initially recruited	22
Completing the study	22
Drop-outs ( <i>n</i> , % of total)	0 (0%)
Age range (Mean±SD)	42–66 (52.7±5.5)
Gender	Male: 0 Female: 22
Ethnicity (race)	Caucasian: 22
Skin type (according to hydration levels)	Very Dry: 7 Dry: 12 Normal: 3
Skin phototype (according to Fitzpatrick)	II (white): 12 III (light brown): 9 IV (moderate brown): 1

SD: Standard deviation

at 2 months, with 50% of participants noting a significant improvement in their wrinkles. Satisfaction remained strong, with 77.3% feeling good about their results, 72.7% were willing to use the product again for skin [Figure 9], and 50% for nails and hair. Furthermore, all participants found the oral intake of the therapy to be easy, with no aftertaste.

Aging is an inevitable facet of life. The global pursuit to reverse or at least delay aging has driven the development of numerous interventions, from topical formulations like retinoids to oral supplements such as rapamycin and collagen.<sup>[9–11]</sup> However, the focus should shift from anti-aging to promoting healthy aging. The reduction of collagen, proteoglycans, and glycosaminoglycans, along with elastic fiber degradation, leads to skin aging signs such as sagging and wrinkles.<sup>[12]</sup> Collagen is the backbone of our skin, bones, muscles, tendons, and connective tissues, holding everything together. However, starting at age 21, we lose about 1% of our collagen yearly.<sup>[13,14]</sup> By the age of 80 years, there is a 75% decrease in collagen production.<sup>[15]</sup> Most anti-aging treatments focus on preventing collagen breakdown and promoting its rebuilding. Unlike many products claiming to “reduce wrinkles,” silicium is foundational in promoting “healthy aging.” As we age, the amount of silicium in our bodies decreases significantly, potentially leading to degenerative diseases of the cardiovascular system, gastrointestinal tract, Alzheimer’s, and osteoporosis. This may be due to food sources not providing adequate minerals, such as silicium.<sup>[16]</sup>

Furthermore, as we age, our body’s ability to absorb and retain silica from dietary sources decreases. This can lead to lower overall silica levels in tissues over time. As discussed, silicium is vital for collagen production and the strength of connective tissues. With lower silicium levels, collagen synthesis may slow, impacting skin elasticity, joint flexibility, and bone strength. This contributes to common aging

signs such as wrinkles, weaker joints, and brittle bones. As noted, silicium aids in bone mineralization and plays a role in maintaining bone density. Lower silicium levels with age and hormonal conditions such as postmenopausal can contribute to a gradual loss of bone density, increasing the risk of osteoporosis and fractures. Silicium’s role in collagen formation and structural support also affects skin, hair, and nail health. Decreasing silicium levels can lead to thinning hair, weaker nails, and loss of skin elasticity, all of which are common as people age. That is why its supplementation becomes a necessity for promoting healthy aging. Silicium is crucial in collagen synthesis, activating enzymes for collagen hydroxylation, stabilizing collagen networks, increasing elastic fiber density, and improving skin strength and elasticity.<sup>[2,17]</sup> OSA at concentrations of 10 and 20  $\mu\text{M}$  significantly increases type I collagen synthesis. A critical step in collagen type I synthesis and its secretion into the extracellular space is the hydroxylation of the proline residues of the collagen chains, a reaction catalyzed by prolyl hydroxylase. Indeed, it has previously been reported that optimal activity of prolyl hydroxylase appears to depend on the presence of adequate concentrations of silicon.<sup>[4]</sup>

OSA, the most bioavailable form of silicium, is a water-soluble acid found in plants and animal fluids – with a bioavailability of about 50%.<sup>[18]</sup> At higher concentrations and neutral pH, OSA polymerizes into polysilicic acid, which has a low bioavailability (around 7%). Effective stabilization of OSA is essential to prevent polymerization for human absorption.<sup>[19]</sup> Traditional forms of silicium exhibit limited solubility and bioavailability, which restricts their effectiveness. However, bioabsorbable MPS, such as Mesoporesil<sup>®</sup>, undergoes rapid dissolution in the gastrointestinal tract, releasing silicic acid or OSA. This soluble form of silicium is readily absorbed into the bloodstream, where various tissues can utilize it. Studies have shown that ingesting bioabsorbable MPS increases serum silicium levels, which correlates with improved skin hydration, elasticity, and overall appearance, as observed in our study.

Apart from collagen growth, the improvement in skin, hair, and nails can also be attributed to the interaction of silicium with keratin. OSA is the primary chemical form of silicium found in bodily fluids. The silanol groups present in OSA form complexes with amino acids and peptides involved in forming keratin.<sup>[5,20,21]</sup> To date, most studies have only reported the role of ch-OSA for skin, making our study unique in its utilization of MPS. The subjective improvements reported by participants highlight the potential of Mesoporesil<sup>®</sup> supplementation in promoting healthy skin aging. It has also been highlighted that taking silicium in the form of Mesoporesil<sup>®</sup> was safe, as no adverse effects related to the study medication were reported. Furthermore, consumer behavior data showed high levels of willingness to continue

using the product, indicating strong consumer acceptance and satisfaction with the treatment's results. The tablet's sensory experience was also positive across all time points.

## CONCLUSION

The high bioavailability and absorption rates of Mesoporesil®, combined with its effectiveness in promoting skin health, make it a superior silicon supplement. The results demonstrate progressive and significant improvements in skin firmness, hydration, and elasticity, with high levels of overall satisfaction, excellent cutaneous compatibility, effectiveness, and safety of the Mesoporesil® treatment in women with aging skin. These findings pave the way for further studies to explore long-term skin improvements and the sustained benefits of Mesoporesil® over time.

**Ethical approval:** The Institutional Review Board has waived the ethical approval for this study, number 2023-777-1.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent.

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