

## Original Research Article

# Assessment of anti-ageing effects of oral choline-stabilized orthosilicic acid on hair, skin and nails: an open label, non-randomized interventional study

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## ABSTRACT

**Background:** Ageing is a continuous process and efforts are being made to reverse or rather slow the process. It is evident through changes in the skin, hair and nails. Due to changes in these, aesthetic appearance is compromised. Choline-stabilized orthosilicic acid (ch-OSA<sup>®</sup>) has shown results in improving skin, hair and nail health. The aim of the present study was to assess these effects in the Indian population taking oral ch-OSA<sup>®</sup>.

**Methods:** Randomly selected 39 participants were assigned to 4 groups to study alopecia, hair quality, skin health and nail health. Ch-OSA<sup>®</sup> was administered for 5 months. Assessment was made at baseline, 2, 3 and 5 months. After this ch-OSA<sup>®</sup> was stopped and further assessment was made at 8 months.

**Results:** There was a significant improvement in terms of all the 11 parameters related to alopecia and hair quality from baseline to 8 months ( $p < 0.001$ ). Most of the participants reported grade-1 skin wrinkling at 5 or 8 months. Skin hydration also improved significantly after the ch-OSA<sup>®</sup> administration. Greater percentage of participants reported of reduced roughness and dyschromia at the end of the study. Nail parameters were also significantly improved. No side-effect was reported by the participants throughout study.

**Conclusions:** Oral intake of ch-OSA<sup>®</sup> showed significant beneficial effects on the health of hair, skin and nails with good tolerability.

**Keywords:** BioSil<sup>®</sup>, Choline-stabilized orthosilicic acid, Hair, Nail, Skin

## INTRODUCTION

The present day calls for an everlasting youthful appearance. Even though ageing is a solid truth, the efforts to revert the process or rather slow it is progressing tremendous all over the world. It is a continuous process that is characterized by an increased susceptibility and vulnerability to diseases and death.<sup>1</sup> Ageing is evident through the many changes in the skin, hair as well as nails.<sup>2</sup> They can be either chronobiological or actinic in nature. With increased cutaneous changes,

there is a compromise of the aesthetic appearance of the individual.<sup>3</sup> With the advanced ageing, aesthetic appearances are affected and it is a challenge to revert the process.<sup>4</sup> Almost 30% of the protein content of our body is made up of collagen. Of the 28 different collagen fibres, the type 1 is the most abundant observed. A quarter of human bones and 75% of the skin is made of collagen. With advancing age, one tends to lose this collagen causing wrinkles, loss of hair and a non-elastic skin.<sup>5,6</sup> Quality and quantity of hair are crucial factors contributing to physical as well as psychological self-

esteem across all the cultures.<sup>7</sup> Apart from aesthetic element, hair plays a variety of physiological roles including skin defender, thermoregulation, sensory information collection, social communication.<sup>8,9</sup> Various morphologic components and chemical species like keratin proteins as major component and building block of hair making around 65-95% of hair weight, pigment, lipids, trace elements and water act jointly to form human hair fibres. Keratin present in the cells gets converted into more crystalline form as the cell starts differentiating during hair formation to form hair fibres. Keratinized cells due to its extremely organized material provide significant protection against the hair against friction, flexion, UV radiation as well as chemical assaults.<sup>10</sup> Nail is a keratinized epithelial structure consisting of nail plate, nail matrix, nail folds and nail bed. Enhanced fragility of nail plate is a trait of brittle nails.<sup>11</sup> Brittle nails are soft, dry, weak, easily breakable, and unable to grow. Abnormal keratin and keratin associated proteins are associated with brittle nail.<sup>12</sup> Hence, stimulation of nail keratin production should be one of the approaches for the treatment of brittle nails.<sup>12</sup> Nourishing the body with components crucial for the synthesis of the factors like collagen by using Silicon can surely assist in delaying the ageing process. Silicon is actually a trace element in the body and plants being the richest source, replenish the same till lifetime.<sup>13</sup> It triggers the enzymes that play a pivotal role in the regenerative as well as synthesis process of the body system.<sup>14</sup> Choline-stabilized orthosilicic acid (ch-OSA<sup>®</sup>) is a clinically proven supplement that consists of silicon with choline. This choline component binds to the cellular membrane and helps in easy penetration of the material inside the cells.<sup>15</sup> A high silicon is inversely proportional to rate of loss of hair and ensures a less wrinkled face and smoother nails.<sup>16</sup> No Indian data is available in literature reporting of the effects of ch-OSA<sup>®</sup> in the Indian population. This study was therefore the first of its kind to evaluate the effect of orally administered ch-OSA<sup>®</sup> on the skin, hair and nail health of Indian population.

## METHODS

The study was an open label single-arm observational trial which was carried out at Cutis Academy of Cutaneous Sciences, Bengaluru, India from February 2017 to January 2018. All the participants were included as per the inclusion and exclusion criteria and a written informed consent was taken from all the study participants. The study comprised of 4 groups and the inclusion and exclusion criteria were as follows.

### Group 1

Poor hair quality - 10 females between 40 to 65 years age group with poor hair quality as per the foto finder tricho scale instrument were included in the study (Figure 1). All those women who had any allergy to the ingredients of the medication or were on biotin or other therapy for hair health, coloured or permed hair or those using any

form of chemical treatment for hair or having any form of known allergy to the contents of the ch-OSA<sup>®</sup> capsules were excluded from the study.



**Figure 1: Foto finder tricho scale instrument.**

### Group 2

Alopecia - 5 males and 4 females between 17-54 years age group with hair loss as per the diagnosis of investigator were included in the study. All those who were using any form of topical or systemic hair growth products or drugs in the past 6 months, suffering from hair loss due to underlying disease like malnourishment or diabetes mellitus, those who have already undergone some form of successful hair health treatment and having any form of known allergy to the contents of ch-OSA<sup>®</sup> capsules were excluded from the study.

### Group 3

Photodamaged skin - 10 females between 40-65 years age group with clear clinical signs of photodamage on the forehead skin were included in the study. Those using silicon supplements 3 months previous to the start of this particular study, on any form of therapy for anti- ageing, regular usage of lotions and creams and having known allergy to the contents of the ch-OSA<sup>®</sup> capsules were excluded from the study.

### Group 4

Brittle nails - 10 females between 40-65 years age group having brittle nails on hands as well as feet were included in this group. Those who were either allergic to the contents of the ch-OSA<sup>®</sup> capsules or those who were on some form of therapy for the same were excluded from the study.

Each participant across all the 4 groups was given orally administered ch-OSA<sup>®</sup> in form of BioSil<sup>®</sup> capsule consisting of elemental silicon (Si) 5 mg (as ch-OSA<sup>®</sup>) and choline 100 mg (as ch-OSA<sup>®</sup>) twice daily for a period of 5 months. They were followed up for further 3 months. BioSil<sup>®</sup> capsules were provided by Sundyota

Numandis Pharmaceuticals Pvt Ltd India. The effect of BioSil® capsules was observed on hair quality, alopecia, skin and nails. Poor hair quality and alopecia were determined by 11 parameters - hair count, hair density, anagen and telogen hair length, anagen, telogen, terminal and vellus hair density, cumulative hair thickness and total follicular unit and follicular unit density. We recorded skin wrinkles, hydration, dyschromia, tactile and visual skin roughness. For skin wrinkles Fitzpatrick classification scale of facial wrinkles was used.<sup>18</sup> Grade 1 indicates fine wrinkles, grade 2 indicates fine to moderate depth and moderate number of lines and grade 3 indicates fine to deep wrinkles, numerous lines, with or without redundant skin. Skin hydration was measured using a digital moisture monitor instrument (Figure 2).



**Figure 2: Digital moisture monitor for skin.**

Dyschromia, visual and tactile skin roughness were assessed through visual examination at each visit. Nail parameters like broken nails, rough nails, yellow nails and white nails for upper and lower limbs were assessed by visual examination at each visit. The data at each visit was collected. Statistical analysis was performed using

SPSS statistics 22.0 (IBM analytics, U.S.A). The normality distribution was checked using the Shapiro-Wilk test. One-way ANOVA for repeated measurements was carried out to evaluate the statistical significance with respect to the variables in terms of hair quality improvement. Chi square test was used to test significance for improvement in health of nails and skin health.

**RESULTS**

The present study had overall 39 participants followed up for a period of 8 months. ch-OSA® treatment showed statistically significant improvement from baseline to month 8 in various parameters in all groups of participants. All the parameters of hair quality and alopecia group showed rise in the mean observations from baseline to 8 months and this was found to be statistically significant (p<0.001) (Table 1, Table 2 and Figure 3).



**Figure 3: Improvement in hair growth in alopecia participants.**

**Table 1: Analysis of hair quality parameters (mean±SEM) from baseline to 8 months (using ANOVA).**

Parameters	Month-0	Month-2	Month-3	Month-5	Month-8	P value (vs month-0)
<b>Hair count</b>	184.40±0.93	209.50±0.79*	226.10±0.87*	240±0.82*	256.80±0.84*	<0.001*
<b>Hair density</b>	204.14±0.98	231.92±0.83*	250.28±0.92*	265.69±0.87*	284.29±0.89*	<0.001*
<b>Anagen hair length</b>	92.60±0.65	112.6±0.59*	117.3±0.61*	119.4±0.54*	122.3±0.57*	<0.001*
<b>Telogen hair length</b>	54.40±0.69	62.10±0.54*	61.90±0.64*	77.9±0.70*	85±0.69*	<0.001*
<b>Anagen hair density</b>	102.52±0.69	124.64±0.62*	129.86±0.64*	132.18±0.56*	135.4±0.60*	<0.001*
<b>Telogen hair density</b>	60.21±0.72	68.75±0.57*	68.54±0.67*	86.25±0.73*	94.08±0.73*	<0.001*
<b>Terminal hair density</b>	82.7±0.64	125.32±0.63*	127.63±0.58*	141.15±0.78*	149.78±0.78*	<0.001*
<b>Vellus hair density</b>	80.04±0.84	68.08±0.70*	70.74±0.79*	77.28±0.61*	79.72±0.66*	<0.001*
<b>Cumulative hair thickness</b>	7.06±0.18	9.5±0.17*	9.37±0.17*	10.3±0.18*	10.77±0.2*	<0.001*
<b>Total follicular units</b>	103.1±0.61	117.1±0.55*	124.8±0.55*	127.5±0.52*	133.6±0.54*	<0.001*
<b>Follicular unit density</b>	114.14±0.64	129.63±0.57*	138.16±0.58*	141.15±0.55*	147.89±0.57*	<0.001*

\*statistical significance.

**Table 2: Analysis of alopecia parameters (mean±SEM) from baseline to 8 months (using ANOVA).**

Parameters	Month-0	Month-2	Month-3	Month-5	Month-8	P value (vs month-0)
Hair count	201.44±0.96	246.5±1.08*	233.22±0.67*	229.56±0.85*	258.56±0.70*	<0.001*
Hair density	223.02±1.01	272.89±1.14*	258.19±0.71*	254.13±0.89*	286.24±0.73*	<0.001*
Anagen hair length	102.11±0.71	128.13±0.78*	121.56±0.57*	118.56±0.54*	141.44±0.45*	<0.001*
Telogen hair length	53±0.61	73.88±0.78*	61.11±0.53*	70.33±0.69*	69.89±0.56*	<0.001*
Anagen hair density	113.04±0.74	141.86±0.82*	134.58±0.60*	131.24±0.57*	156.58±0.48*	<0.001*
Telogen hair density	56.68±0.64	81.79±0.82*	67.64±0.55*	77.87±0.72*	77.38±0.59*	<0.001*
Terminal hair density	73.56±0.79	85.11±0.85*	116.23±0.91*	92.38±0.77*	114.41±0.82*	<0.001*
Vellus hair density	98.16±0.81	138.51±1.02*	85.97±0.75*	116.73±0.77*	119.57±0.67*	<0.001*
Cumulative hair thickness	6.77±0.20	8.59±0.21*	9.17±0.20*	8.36±0.19*	9.58±0.18*	<0.001*
Total follicular units	110.67±0.66	130.63±0.71*	128.67±0.40*	125.22±0.58*	137±0.47*	<0.001*
Follicular unit density	122.50±0.70	144.63±0.74*	142.51±0.42*	138.61±0.61*	152.04±0.50*	<0.001*

\*statistical significance.

**Table 3: Percentage distribution of the study participants with respects to the grades of skin wrinkling in photodamaged skin group (compared using chi-square test).**

Months	Grade-1 (%)	Grade-2 (%)	Grade-3 (%)	P value (vs month-0)
Month-0	60	30	10	0.01
Month-2	50	40	10	
Month-3	50	40	10	
Month-5	70	20	10	
Month-8	70	20	10	

**Table 4: Skin hydration (compared using chi-square test).**

Parameters	Month-0	Month-2	Month-3	Month-5	Month-8	P value (vs month-0)
Skin hydration (%)	29±0.14	35.1±0.21*	38.4±0.21*	38.4±0.21*	45.3±0.19*	<0.005*

\*statistical significance.

**Table 5: Percentage distribution of the study participants with respects to the visual skin roughness, tactile skin roughness and dyschromia in photodamaged skin group.**

Parameters	Month-0 (%)	Month-2 (%)	Month-3 (%)	Month-5 (%)	Month-8 (%)
Dyschromia	100	70 (p=0.06)	80% (p=0.06)	40 (p=0.0034)	40 (p=0.0034)
Tactile skin roughness	70	80 (p=0.61)	50 (p=0.36)	10 (p=0.006)	10 (p=0.006)
Visual skin roughness	30	30	30	20	20

Compared using chi-square test, p value vs month-0.

**Table 6: Percentage distribution of the study participants based on nail health.**

Parameters	Month-0 (%)	Month-2 (%)	Month-3 (%)	Month-5 (%)	Month-8 (%)
Nail roughness	60	20 (p=0.0251)	13.33 (p=0.008)	20 (p=0.0251)	13.33 (p=0.008)
Nail smoothness	40	80 (p=0.0251)	86.67 (p=0.008)	80 (p=0.0251)	86.67 (p=0.008)
Broken nails	53.33	14.28 (p=0.027)	0 (p=0.027)	0 (p=0.027)	0 (p=0.027)
Unbroken nails	46.66	85.71 (p=0.027)	100 (p=0.027)	100 (p=0.027)	100 (p=0.027)
Yellow nails	50	21.42 (p=0.11)	0 (p=0.002)	14.28 (p=0.043)	0 (p=0.002)
White nails	50	78.58 (p=0.11)	100 (p=0.002)	85.72 (p=0.043)	100 (p=0.002)

Compared using chi-square test; p value vs month-0.



We recorded the effects of the ch-OSA<sup>®</sup> on skin wrinkles as per the Fitzpatrick's classification (Table 3). We observed that with time, there was a decrease in the reporting of fine to deep wrinkles and numerous lines by the participants. At the end of the study, significantly more participants reported of grade 1 (60%) than grade 2 (40%) skin wrinkles ( $p=0.027$ ). The skin hydration was  $29\pm 2\%$  at baseline which significantly increased to  $45.3\pm 3.62\%$  after 8 months ( $p=0.005$ ) (Table 4). At the start of the study all participants reported of dyschromia which eventually came down to 70% ( $p=0.06$ ) after 2 months and 3 months, 40% ( $p=0.0034$ ) from 5 to 8 months. There was no significant change observed between 5th and 8th month observations. Tactile skin roughness was reported by 70% participants at baseline. It did not change after 2 months ( $p=0.61$ ). 50% of participants have reported tactile skin roughness at month 3 ( $p=0.36$ ). There was a significant reduction in tactile skin roughness reported at month 5 ( $p=0.006$ ) Only 10% of the participants reported tactile skin roughness at month 5 and at month 8. At baseline, the visual skin roughness was reported by 30% of the participants. This was reduced by 10% at the end of the study overall (Table 5).

There was a significant reduction in the percentage of broken nails (53.3%) at baseline as compared to 14.28% ( $p=0.027$ ) after 2 months. There were no cases of broken nails reported till the end of the study period. The percentage of unbroken nails rose significantly from 46.67% at the start of the study to 85.71% at the end of 8 months ( $p=0.027$ ). There was significant improvement reported with respect to nails in terms of roughness, smoothness, yellowish discoloration and white nails. In all these cases a significant improvement was seen at the end of 8 months as compared to the baseline (Table 6).

## DISCUSSION

Research reports of silicon deficiency associated with impaired connective tissue compound synthesis; especially collagen.<sup>16</sup> A clinical trial among female participants aged between 40-65 with 10mg oral silicon as ch-OSA<sup>®</sup> per day for 20 weeks, showed a remarkable decrease in the skin roughness, increased skin hydration and decreased nail brittleness.<sup>17</sup> Even though we cannot directly compare our results with this study, nevertheless the results are similar to that of ours. This can be definitely associated with a higher collagen production induced by silicon that may have strengthened the nails, skin tissue as well as the hair follicles. Another trial on 48 women's over a span of 9 months concluded that taking 10mg oral silicon as ch-OSA<sup>®</sup> per day improved the hair tensile strength and produced thicker hair as compared to before treatment.<sup>18</sup> In the present study too, we observed a significant rise in the hair quality after 8 months. Kim et al reported that orthosilicic acid increased anagen expression among rat models. Orthosilicic acid regulates the activity of the dermal papillary cells. Thus, it adds to the strength of the hair and improves hair quality in turn.<sup>19</sup> In the present study, hair thickness (in terms of

hair count, unit of hair and average hair) increased after 2 months of administration of ch-OSA<sup>®</sup>. A 2007 study reported that oral ch-OSA<sup>®</sup> improved tensile strength and produced thicker hair. It also decreased nail fragility.<sup>20</sup> We observed a decrease in nail roughness and yellowing of the nails. Also, there were more cases of white and smooth nails with time in the study.

Higher percentage of participants showed reduced skin wrinkles in our study. This was similar to another trial where betterment of facial wrinkles was reported following monomethylsilanetriol and maltodextrin-stabilized orthosilicic acid.<sup>21</sup> There was a significant rise in the skin hydration in the present study after 8 months. This was in contrast to the study by Calomme et al where no significant difference was seen after 20 weeks of ch-OSA<sup>®</sup> administration.<sup>18</sup> Kalil et al reported that 90 days of oral ortho silicic acid improved the skin texture, firmness, and hydration. This was similar to our study findings.<sup>22</sup> Changes in the climatic conditions may affect the skin hydration process. We did not record parameters like environment or the level of fluid intake which may have had an impetus on the skin texture. Collagen type 1 and hydroxyproline are main components of the skin. In the present study, with ch-OSA<sup>®</sup> supplementation, there could be an underlying regeneration of collagen fibres. Silicon has a definitive role to play in glycosaminoglycans synthesis. This also acts as a cross linking agent resulting in strengthening of the keratin structure and the nails. Choline on the other hand is a part of the cell membrane and participates in cell growth and division.<sup>18,23</sup> The main concern in using silicon is its low bioavailability and body fixation. Hence modes of making increased bioavailability are essential.<sup>24</sup> Mostly Si is excreted via urine. Our study has certain limitations. The sample size was less. We also did not include equal number of men and women in the study. Overall, the present study adds to the existing literature about the success of ch-OSA<sup>®</sup> as an anti-aging solution.

## CONCLUSION

ch-OSA<sup>®</sup> as an oral ingredient improved hair quality. Hence as an anti-ageing it can be successfully used in cases of poor hair and also alopecia. It helped to improve nail health and reduce brittleness. The skin health also significantly improved in terms of wrinkle reduction and smoothness. There was greater hydration observed. Not only does ch-OSA<sup>®</sup> has an effect during the administration but it is also able to perhaps bring about irreversible changes to the underlying tissues for long lasting effects. Further studies are needed to demonstrate the same.

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