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A pilot study on the efficacy of silicium gel on the thickness of hair in healthy women with thin hair

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Key Words
hair diameter, hair thickness, Silicium Gel, thin hair

Summary
People suffering from thin hair and hair loss often experience considerable psychological strain and seek for dermatological help, in spite of the limited range of therapies currently available. Silicic acid preparations are among those products attributed with an effect on the structure of hair. The objective of the following Clinical Phase II pilot study was to determine the increase in volume of hair over a 6-month period of silicium gel use in n = 55 healthy adult women with thin hair (< 100 mm in diameter), who took one measuring spoon (15 ml) of silicium gel orally once a day. Aspected assessed were hair thickness, measured microscopically; hair status; quality of life (with the FLQA-ha); subjective assessments of efficacy and tolerability; satisfaction and willingness-to-pay. Hair volume increased over the 6-month trial period from 58.96 ± 8.23 to 66.42 ± 9.67 mm ($p < 0.001$). The study physicians and the subjects reported positively on the effect of the treatment on thickness, shine and healthof the hair. The participants' satisfaction with the preparation was good (2.2 on a scale ranging from 1 = very good to 5 = bad) while its tolerability was assessed as very good. The results indicate that hair volume increases after a 6-month treatment with silicium gel and reduces the subjective strain associated with thin hair. Tolerability and efficacy of Silicium Gel were rated very good. The results of this pilot study should be evaluated in confirmatory controlled studies.

Introduction

From a medical point of view, hair is a cutaneous appendage. On average, an individual's scalp is covered with approximately 100,000 hairs in a density of 175-300/cm². The hair's growth rate of approx. 0.35 mm/day is subject to a physiological hair cycle that is asynchronous and cyclic, characterised by fluctuations depending on time of day and season, and by growth and rest phases. The hair cycle consists of three stages: the anagen or active growth phase, which can last from 2 to 6 years and accounts for approx. 80-90% of total scalp hair, the catagen or transition phase, which lasts 1-2 weeks and accounts for 1-3% of scalp hair, and the telogen or resting phase, lasting from 2-4 months. 10-20% of scalp hair is in the resting phase at any given time. Normal hair loss ranges from 25 to 100 hairs per day. Hair growth is significantly affected by sexual hormones (androgens and estrogens). Regardless of the hair cycle, hair structure varies strongly from one individual to the next, with an average thickness between 0.1 and 0.25 mm. Though largely determined by heredity, hair thickness is also influenced by various factors such as nutrition. Persons with thin hair frequently suffer a considerable psychological strain, and a great many patients seek help from dermatologists and health care centres for treatment. Various studies (1-4) have established that hair diseases have strong adverse effects on an individual's quality of life.

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Table 1: Evaluation of hair by the test subjects and the Study Doctor

	Evaluation by Test Subjects			Evaluation by Study Doctor		
	Day 0	After 3 months	After 6 months	Day 0	After 3 months	After 6 months
How healthy does your hair look? *	5.4 ± 1.8	6.2 ± 1.83	6.4 ± 1.9	6.3 ± 2.0	6.5 ± 1.5	7.1 ± 1.2
How thin is your hair?*	2.9 ± 1.5	4.1 ± 2.0	4.5 ± 1.9	4.2 ± 2.0	5.6 ± 2.0	6.3 ± 2.2
How dull does your hair look?*	4.8 ± 2.0	5.6 ± 2.1	5.6 ± 2.1	4.9 ± 2.0	5.3 ± 1.6	6.2 ± 1.6
How badly are you currently suffering from thin hair?**	4.6 ± 2.7	3.6 ± 2.3	2.6 ± 2.1	n.a.	n.a.	n.a.
How strongly does your hair affect your current well-being?**	3.7 ± 2.8	3.0 ± 2.1	2.4 ± 1.8	n.a.	n.a.	n.a.

* VAS scale 0-10, high values stand for positive hair condition
** VAS scale 0-10, high values stand for heavy strain

Table 2: Effects of treatment as assessed by Study Doctor and test subjects*

	Assessment by Study Doctor		Assessment by Test Subjects	
	After 3 months	After 6 months	After 3 months	After 6 months
Appearance of hair	2.5 ± 0.8	2.9 ± 1.0	2.5 ± 0.9	2.9 ± 1.1
Thickness of hair	2.3 ± 0.9	2.5 ± 1.0	2.3 ± 0.9	2.6 ± 1.1
Dullness of hair	2.4 ± 1.0	2.8 ± 1.2	2.4 ± 1.1	2.7 ± 1.1
Health condition of hair (split ends)	2.3 ± 1.0	2.7 ± 1.1	2.3 ± 1.2	2.8 ± 1.1
Accelerated hair growth	2.4 ± 1.1	3.5 ± 1.3	2.5 ± 1.3	3.5 ± 1.3

* Scale: 1=no effect at all, 2=minor effect, 3=slight/moderate effect, 4=effective, 5=very effective

Silicium gel is traditionally administered orally to strengthen connective tissue and prevent brittle fingernails and hair. There are many indications that silicium gel has an influence on the hair structure (hair thickness); however, these indications have to date not been corroborated by clinical studies. The objective of this study is to review the assumption that the intake of silicium gel has a provable effect on the hair thickness of healthy hair.

The silicium gel used contains as its active ingredient 2.8 g of precipitated colloidal silica dispersed in 100 ml of gel without further additives, is a purely mineral product, and is available from health food shops (Original silicea-Balsam by Anton Hübner) and pharmacies (Sikapur Silicium Gel F by Medopharm).

Material, Procedures, and Patients

The study was conducted as a prospective, uncontrolled pilot study. The test subjects enrolled in the study were n = 55 healthy adult women whose hair thickness was established by microscopic examination to be less than 100 µm and who did not suffer from any hair diseases. The test subjects were examined over a period of six months during treatment with silicium gel at five check-up times: Day 0, after 6 weeks (Day 42 ± 7), 13 weeks (Day 91 ± 7), 19 weeks (Day 134 ± 10), and 6 months (Day 182 ± 10). For the screening visit and after 13 weeks and 6 months the test subjects were asked to present themselves at the study centre. At the second and fourth check-up dates (after 6 and 19 weeks), the subjects were interviewed by telephone. The study and the statistical evaluation of data were conducted in accordance with the ICH Guideline "Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) based on the principles of the Declaration of Helsinki. The study was duly conducted in accordance with the German Medicines Act, 14th Amendment (§§40-42). A positive vote on the part of the respective ethics committee was obtained prior to the start of the study.

Primary Test Variable Hair Diameter

The primary test criterion was the increase of mean hair diameter of a random sample of hairs within the treatment period. At the start of the study, after 3 months, and after 6 months, hairs in a defined area of 1 cm² were cut off the subjects' scalps at the roots. The diameter of 60 hairs was ascertained under a microscope with an integrated µm scale by an external, certified laboratory. The measurements were validated by a comparison of three readers. The mean value of each set of 60 hairs measured was defined as the target value. A control group was not set up, as a comparable change in hair thickness within the study period without administering a preparation was not to be expected [5,6].

Secondary Test Variables and Adverse Effects

The following secondary target criteria were evaluated:

a) Study Doctor's assessment/test subjects' assessment of the efficacy of the test preparation
b) Study Doctor's assessment/test subjects' assessment of the hair status (healthy appearance, hair thickness, dullness, hair health/split ends, faster growth)
c) Disease-specific quality of life
d) Tolerability of the test preparation

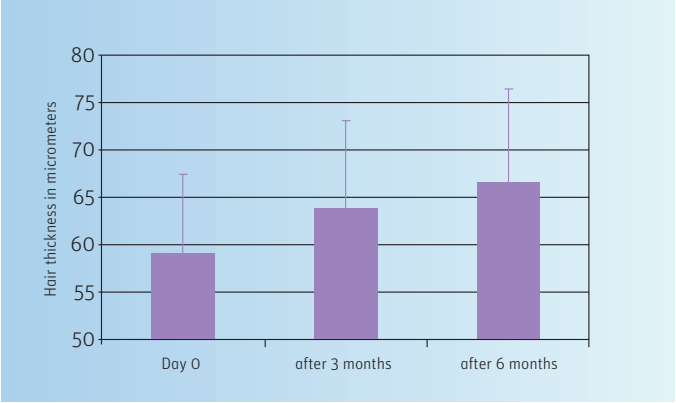

Fig. 1: Average hair thickness, measured under the microscope, in the course of treatment (mean value ± SD)

The hair status was evaluated by the test subjects and the Study Doctor by means of Visual Analogue Scales (VAS). The VAS consisted of a horizontal line of 10 cm length with defined end points of "0", e.g. "extremely poor", "extremely low" and "10", e.g. "excellent", "very strong". All points in between could be marked according to the subjective assessment of the subjects.

The Study Doctor's assessment/subject's assessment of the efficacy of the test preparation, the subjects' satisfaction with the treatment, and the product's tolerability were evaluated by a five-step Likert scale. From the second sample time (Day 42 ± 7) through the final examination, both the subjects and the Study Doctor evaluated overall tolerability according to a 5-step scale (1 = excellent, 2 = good, 3 = moderate, 4 = poor, 5 = very poor. The quality of life was evaluated by means of the FLQA-ha questionnaire, which records both the disease-specific and the generic life quality of patients suffering from diseases of the hair [7]. It is a multidimensional construction based on the items "Physical status", "Everyday life and work situation", "Social relations", "Emotional status". In addition, the criteria "Adverse effects of the treatment" and "Satisfaction" were included as independent areas of evaluation. Adverse Effects were described separately.

Etiological Conception; WTP

The test subjects were interviewed as to their etiological conception of thin hair. Apart from evaluating five given influential factors, the subjects were given the opportunity to freely describe additional factors. At the final visit, the test subjects were asked how much they would be willing to pay for a treatment which, applied once, would result in a permanent visible improvement (Willingness to Pay, WTP).

Statistical Analysis

The mean value of the hair thickness at the beginning of treatment and at the end of treatment was compared using the t-test for dependent random samples. The level of significance was defined as α=5%. All other data was evaluated descriptively (mean and standard deviation for continuous data; number and percentage of frequencies for categorical values).

Results

Test Subjects

The statistical evaluation was performed on the basis of the Full Analysis Set. At the time of final evaluation, n=53 full data sets were available; n = 2 test subjects had terminated the study prematurely without indicating why after the screening visit and after the second visit to the Study Doctor, respectively. This corresponds to a rate of return of 96.4%. The test subjects were on average 27.0 ± 7.5 years of age, 169.3 cm tall, and had a mean BMI of 21.2. 78.2% of the women claimed to have "thin hair" all the time, 5.5% in bouts, and 10.9% at varying periods. 5.5% were unable to provide a clear response to this question. Every fifth subject (20%) stated that she suffered from hair loss, but not one of these subjects was known to have a hair disease. Nor were any of the subjects suffering from any other acute diseases at the start of the study. About one fourth of the test subjects (25.5%) had already undergone hair treatment (iron supplements, silica, biotin, hair tonic, Pantovigar, hair conditioning treatments, vitamins, henna). Three test subjects (5.6%) were being treated at the time the study started (Keratase, shampoo, Glisskur hair repair). Asked what therapies had proven successful in the past, the following were named once each: hair tonic, zinc, biotin, henna and aloe vera. At the start of the study, 69.1% (n = 38) of the test subjects had permed, colour-rinsed, or dyed hair.

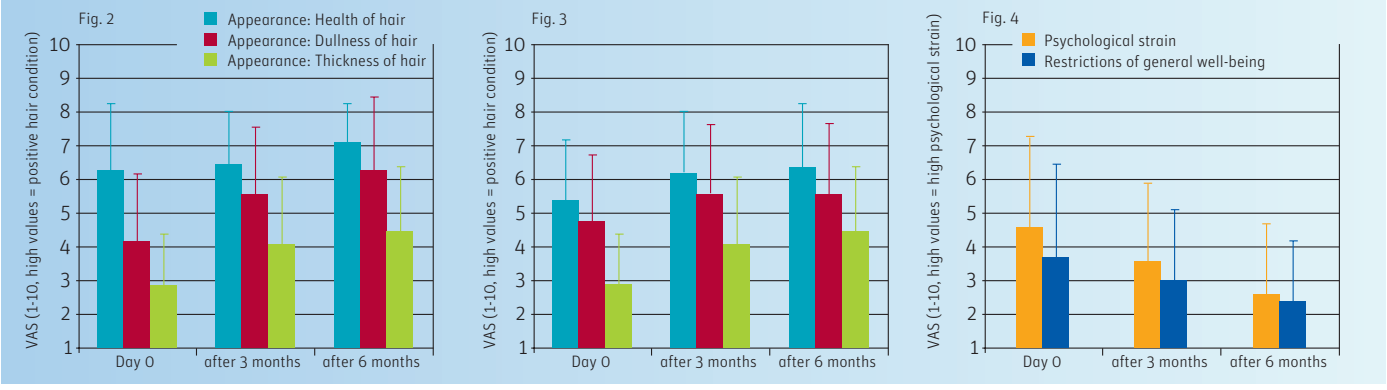

Fig. 2: Evaluation of hair condition by the Study Doctor – Fig. 3: Evaluation of hair condition by the test subjects
Fig. 4: Psychological strain of the test subjects caused by thin hair (mean value ± SD)

Primary Test Variable Hair Diameter

The average hair thickness at the start of the study was 58.96 ± 8.23 µm and increased over the 6-month treatment period (after 3 months: 63.65 ± 9.14 µm, at the end of the study: 66.42 ± 9.67 µm; see Fig. 1). The increase of hair thickness in the first three months of treatment was highly significant ($p < 0.001$), a result that was confirmed for the full treatment period. The increase of hair thickness within months 4 to 6 of treatment was also significantly positive, though less pronounced in its tendency.

Secondary Test Variables and Adverse Effects

In all recorded variables, from the doctor's view, the hair condition displayed a tendency towards improvement over the 6 months (Table 1, Fig. 2). Clearer still was the assessment by the subjects themselves (Table 1, Fig. 3); in particular, the hair was perceived as increasingly strong and glossy during the 6-month period. The psychological strain caused by thin hair decreased over this period of time, as did the negative impact on the subjects' general well-being (Table 1, Fig. 4). In accordance with the positive subjective evaluations of the changes perceived in the hair, the influence of the silicium preparation on the hair was evaluated as increasingly positive both by the Study Doctor and by the test subjects (Table 2). Both the Study Doctor and the test subjects observed in particular that hair growth accelerated in response to treatment. The tolerability of the preparation was rated as excellent by the test subjects (Table 3). There is a slight downward tendency over the 6-month period; however, even after six months' treatment with silicium gel, tolerability was still rated at 1.5 ± 0.8 on the five-step scale (with 1 = excellent tolerability). After 3 months, 7 test subjects stated that their fingernails were more brittle than prior to treatment with silicium gel, one subject said she was shedding hair, and three subjects had come down with an influenzal infection since the first time. One test subject had temporarily suffered from diarrhoea during this time. These adverse effects (AEs) had disappeared without exception by the end of the study. With a view to the adverse effect of "brittle fingernails" the results of the test subjects' evaluations on the efficacy of silicium gel regarding a strengthening of the fingernails are of interest: the subjective evaluation of the efficacy of silicium gel with a view to fingernails was initially rated as moderate (after 6 weeks: 2.6 ± 1.5, after 13 weeks: 2.7 ± 1.4, after 19 weeks: 2.3 ± 1.5) and increased by the end of treatment to an average of 3.5 (± 1.3), which corresponds to a medium to good efficacy. The subjects' satisfaction with treatment with silicium gel was in the upper mid-range, with a slight upward tendency (Table 4). Especially at the beginning of treatment a large proportion of the subjects were only moderately satisfied with the product, while at the end of the treatment the majority of the subjects (n = 32, 60.3%) expressed an excellent to good satisfaction. The FLQA results show the test subjects to have a high standard of quality of life (Table 5) which improved in three of six scales. Merely the subjects' satisfaction increased slightly over the 6-month treatment period.

Table 3: Test subjects' evaluation of tolerability

	After 6 weeks	After 3 months	After 19 weeks	After 6 months
Tolerability (mean ± std)	1.2 ± 0.5	1.4 ± 0.6	1.4 ± 0.6	1.5 ± 0.8
Frequencies (n/%)				
Excellent	43 / 79.6	34 / 63.3	37 / 69.8	32 / 60.4
Good	10 / 18.5	18 / 33.3	12 / 22.6	16 / 30.2
Moderate	1 / 1.9	1 / 1.9	4 / 7.5	4 / 7.5
Poor	0	1 / 1.9	0	0
Very poor	0	0	0	1 / 1.9

*5-step scale: 1=excellent, 5=very poor tolerability

Table 4: Subjects' assessment of satisfaction with treatment

	After 6 weeks	After 3 months	After 19 weeks	After 6 months
Satisfaction with treatment (mean ± std)	2.6 ± 0.6	2.5 ± 0.8	2.3 ± 0.9	2.2 ± 0.9
Frequencies (n/%)				
Excellent	2 / 3.7	3 / 5.7	8 / 15.1	13 / 24.5
Good	19 / 35.2	27 / 50.9	25 / 47.2	19 / 35.8
Moderate	30 / 55.6	17 / 32.1	14 / 26.4	18 / 34.0
Poor	3 / 5.6	5 / 9.4	6 / 11.3	2 / 3.8
Very poor	0	1.9	0	1 / 1.9

*5-step scale: 1=excellent, 5=very poor tolerability

Table 5: Quality of life, FLQA-ha scales (mean ± std)			
FLQA-ha Scales	**Day 0**	**After 3 months**	**After 6 months**
Physical status*	1.64 ± 0.47	1.60 ± 0.44	1.61 ± 0.43
Everyday life/work situation*	1.47 ± 0.54	1.53 ± 0.62	1.46 ± 0.59
Social life*	1.31 ± 0.52	1.35 ± 0.38	1.41 ± 0.48
Emotional status*	2.22 ± 0.53	2.20 ± 0.56	2.23 ± 0.53
Therapy*	1.37 ± 0.52	1.42 ± 0.31	1.46 ± 0.44
Satisfaction**	3.36 ± 0.84	3.61 ± 0.65	3.62 ± 0.76

* High values stand for high level of pressure
** high values stand for low level of pressure

Etiological Conception; WTP

A majority of the test subjects (70.4%) saw a connection between their dietary habits and the thickness of their hair, 63.6% between stress and hair thickness, followed by general pressures, which 54.5% of the subjects believed to have an influence on their hair. Half of the test subjects specified additional influencing factors: genetic disposition (23.6%), hair treatment/cosmetics (12.7%), medication (7.2%).

On average, the test subjects were prepared to spend a one-time amount of 748.64 € (± 1329.74).

Discussion

The object of this pilot study was to establish the increase of the microscopically ascertained hair thickness under a six-month treatment with silicium gel as well as changes in other hair qualities such as lack of shine, split ends, and appearance of the hair. The results prove that the hair volume increases significantly over the six-month course of treatment with silicium gel. Even after 3 months of oral administration of silicium gel, the efficacy of the product on hair thickness was in evidence; this thickness increased continuously over an additional period of three months. The objective increase of hair thickness, measured under the microscope, is corroborated by the subjective assessment by both the Study Doctor and the test subjects. However, the increase of hair volume is in the micrometre range, so that the subjective evaluation of the study doctor can only confirm the microscopic hair results in terms of a trend. In addition, the glossiness of the hair after treatment and the health of the hair were rated to be higher. According to the assessment by the Study Doctor and the test subjects, hair growth in particular is promoted. The psychological strain caused by thin hair and the adverse effects on the subjects' general well-being decreased, and in the scales referring to Social Life, Therapy, and Satisfaction, a continuous improvement of the quality of life was established. The subjects' satisfaction with treatment was in the upper mid-range. Possibly the means of administration, i.e. oral intake of the gel together with a liquid, was perceived as unpleasant. The tolerability of silicium gel is very good, no major side effects were observed. The symptom of brittle nails encountered repeatedly during the treatment period should be examined further in controlled clinical studies. This may possibly be a temporary reaction experienced by a sub-group of the subjects, while the total group describes a strengthening of the fingernails over the entire period of treatment.

Conclusion

In view of the excellent tolerability of silicium gel, the preparation can be used without restrictions for the treatment of thin hair. The results of this pilot study should be confirmed by a randomised, double blind study in which the effects of silicium gel are compared with those of a placebo.

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