

ORIGINAL ARTICLE

Evaluating efficacy and safety of the topical silicone gel containing onion extract in the treatment of post-cesarean surgical scars

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Abstract

Background: Cesarean section scars are post-surgical problems in women. Many active ingredients have been found to diminish scar formation. Clinical investigations on the onion extract have gained more attention due to its properties, such as improvement of scar appearance and texture. However, published studies evaluating the usefulness of the onion extract in the treatment of scars are controversial.

Methods: The three-month study period followed a prospective, randomized, and double-blinded design. Each enrolled subject's post-cesarean completely sealed wounds were divided into two halves along the closure axis. Each half was randomly assigned to the treatment with either silicone gel containing 5% onion extract or the silicone gel containing vitamin C. All subjects were respectively evaluated at the one, two, and three months of the treatment.

Results: After the three-month follow-up, there was a statistically significant difference in scar improvement between before and after treatment. None of statistically significant difference in the Patient and Observer Scar Assessment Scale (POSAS) and Vancouver Scar Scale (VSS) scores and melanin value was found between silicone gel containing 5% onion extract and the control silicone gel. However, the improvement of scar erythema by treatment with the silicone gel containing 5% onion extract was significantly greater than in the control group. No adverse effects were reported in either group.

KEYWORDS

C-section, onion, scar, topical treatment

1 | INTRODUCTION

Cesarean section (C-section) is the most frequently performed major obstetrical surgical procedure aimed to save the lives of

mothers and fetuses in most developed countries.¹ Several million women worldwide annually acquire abdominal scars. The presence of a post-surgical scar frequently affects patients' physical and mental health.² The appearance of the scar is an

important criterion to judge the success or failure of the operation.³ Moreover, the interruption of normal wound healing process in patients can cause an abnormal hypertrophic scar or keloid. Although there is no universally accepted modality for the treatment of post-surgical scars, different techniques are accessible to reduce the presence of scars.

Therapeutic modalities for the post-operative scars management have been developed to reduce scar formation. There are many invasive and non-invasive options available for the treatment of unesthetic scar appearance. Topically applied agents, including silicone sheet and gel, are recommended as the first-line options for hypertrophic scars and keloids.² This non-invasive therapy has been demonstrated to be more effective for scar management in many clinical studies. Silicone-based products may help to prevent excessive scar formation by restoring the water barrier through occlusion and hydration of the stratum corneum.⁴ Product development researches have focused on strengthening the wound-healing efficacy of silicone-based products by adding the natural extract as the active ingredient in the formulation.

Allium cepa (*A. cepa*), commonly known as the onion, is an either biannual or perennial plant belonging to the family Liliaceae. It has received attention for its biological properties and potential applications, such as antioxidant, antimicrobial activity,⁵ treatment of obesity,⁶ and anti-cancer properties.⁷ Moreover, the wound-healing potential of onion's bioactive components and their possible mechanisms of action are reported. Onion extract-based topical gel has been marketed as a product that improves the appearance and texture of surgical scars.⁸ However, data on scar minimization approaches have been contradictory, with regard to their efficacy and side effects. Due to the advantages of both silicone and onion extract for scar treatment, a topical gel containing both materials has been formulated. The present study was designed to investigate the topical silicone gel containing 5% onion extract which may reduce scar formation in women who underwent cesarean delivery.

2 | MATERIALS

Topical silicone gel containing 5% onion extract (Biopharm Chemicals, Co., Ltd.) was used as the test while the commercialized silicone gel containing vitamin C ester was applied as the control.

3 | METHODS

3.1 | Enrolled subjects

All subjects gave their written and informed consents, following the protocol by the Ethics Committee of King Chulalongkorn Memorial Hospital and Faculty of Medicine, Chulalongkorn University. A total of 22 healthy women included in our study had given birth up to

TABLE 1 Baseline demographic characteristics

Data	Amount	Percentage
Subjects	22	100
Age (years) (Mean \pm SD (Max, min))	32.63 \pm 6.42 (44.00,22.58)	
BMI (kg/m ²) (Mean \pm SD (Max, min))	24.46 \pm 4.43 (33.95,17.37)	
History of food and chemical allergy		
Seafood allergy	1	4.55
No history	21	95.45
History of drug allergy		
Ibuprofen	2	9.09
No history	20	90.91
Chronic disease		
Diabetes and heart disease	1	4.55
Thyroid disease	2	9.09
No chronic disease	19	86.36
Scar products used in the past 2 weeks		
No scar product application	22	100
Drugs or supplements used in the past 2 weeks		
Insulin and aspirin	1	4.55
Calcium	1	4.55
Iron	2	9.09
Multivitamin	1	4.55
Vitamin C	1	4.55
No medications or supplements	16	72.72

one month before entering the study with a post-cesarean wound that did not heal despite standard treatment or any severe or chronic systemic disease. The characteristics of the patients are shown in Table 1.

3.2 | Study design and treatment

This prospective double-blind split-scar study and the randomized controlled clinical trial included 22 patients requiring scar improvement of cesarean surgical scars. The tested samples were divided into 2 tubes including gel A and gel B. Two similar tubes, labeled A and B, were given to each patient. One tube (A or B) was the silicone gel containing 5% onion extract (the test), and the other was the commercialized silicone gel containing vitamin C ester (the control).

The post-cesarean scars were divided into two halves along the closure axis. Each half was randomly applied with either gel A or B. The content of the tubes was blinded for all participants and medical staff. In each patient, gel A or B was applied twice daily on two separate areas of the scar for three months. At the beginning and end of each month, the test tube is weighed with a digital scale to monitor the same amount of gel from each tube. Photographs were taken of the test sites at baseline and then every month throughout the study. All patients included in the study continued with the

treatment protocol without additional interventions to improve the scar appearance.

3.3 | Scar assessment

The scar improvement was evaluated by using the Patient and Observer Scar Assessment Scale (POSAS) and the Vancouver Scar Scale (VSS).⁹ POSAS and VASS are instruments available in clinical practice that was developed to evaluate scar quality. The scar color was evaluated by using the cutometer (Courage+Khazaka electronic GmbH). The investigators scored the parameters including vascularization, pigmentation, thickness, relief, pliability, and surface area on a scale ranging from 1 (normal skin) to 10 (worst scar imaginable). The total score on the POSAS was the sum of the scores of each item. The VSS is generally used as a scar assessment tool and allows clinical evaluation of four parameters of scar tissue including vascularity, pigmentation, pliability, and height.¹⁰ The total score on the VSS was the sum of the scores of each item. Moreover, scar pigmentation and erythema were assessed by the cutometer (Courage+Khazaka electronic GmbH).¹¹ The mexameter probe (Courage+Khazaka electronic GmbH) was used to determine pigmentation by collecting three readings from within the right and the left halves of each scar for comparison with normal skin. The order of the scar evaluation devices and observer order was randomized for each patient. All subjects were asked to rate their overall satisfaction for each scar half by grading scale from 0 (not satisfied) to 10 (very satisfied) after the last treatment.

3.4 | Statistics

The data at a baseline and three months after the end of the treatment were compared using the repeated measure ANOVA.

Significance was defined as p -value ≤ 0.05 . All statistical analyses were performed using SPSS for Windows (version 17.0; SPSS Inc.).

4 | RESULTS

4.1 | Evaluation of post-cesarean scars by POSAS

All subjects applied the silicone gel containing 5% onion extract and the control silicone gel two times daily to the scar for three months. The silicone gel containing 5% onion extract showed a significant beneficial effect for scar improvement (Figure 1). At three months, statistically significant reductions in vascularization, pigmentation, thickness, relief, pliability, and surface area were found between pre-treatment and post-treatment evaluations in both groups of treatments (Figures 2–7). Apparently, after one month of the treatment, vascularization, pigmentation, thickness, relief, pliability, and surface area were statistically significantly lower in the silicone gel containing 5% onion extract group. Differently, after one month of the treatment, the vascularization, thickness, and surface area were not significantly improved in the control group when compared with a pre-treatment. However, when comparing between groups after three months of treatment, there was no statistically significant difference in scores. The mean overall scores assessed by observers and subjects are shown in Figures 8–9.

4.2 | Evaluation of post-cesarean scars by VSS

The VSS scores were significantly lower in the silicone gel containing 5% onion extract group after two months of treatment when compared with the pre-treatment. There was no statistically significant difference between groups after three months of treatment.

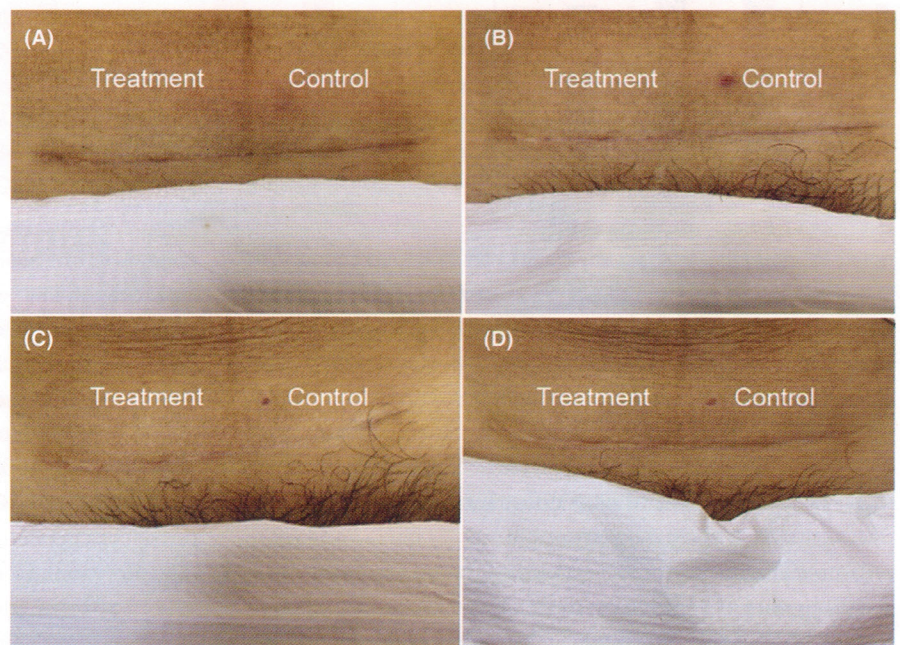


FIGURE 1 Clinical features of post-cesarean section scarring. (A) Appearance of a scar before treatment with the silicone gel containing 5% onion extract and control group. (B) Appearance of the same scar 1 month after initiation of treatment. (C) Appearance of the same scar 2 months after treatment. (D) Appearance of the same scar 3 months after treatment

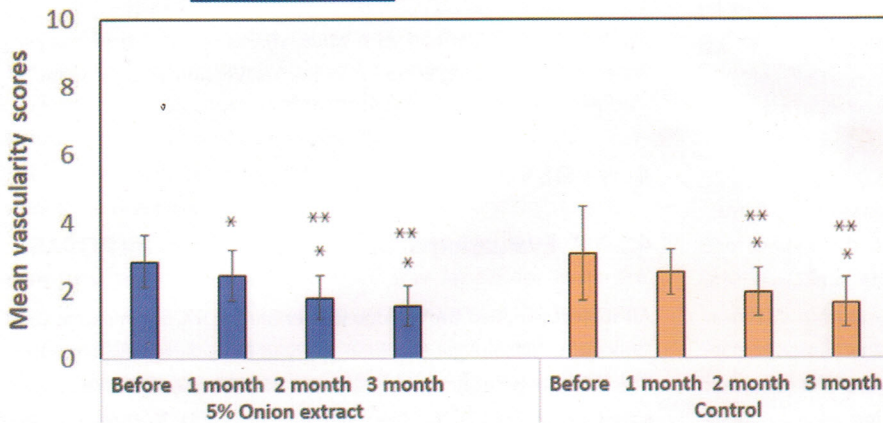


FIGURE 2 Mean vascularity scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

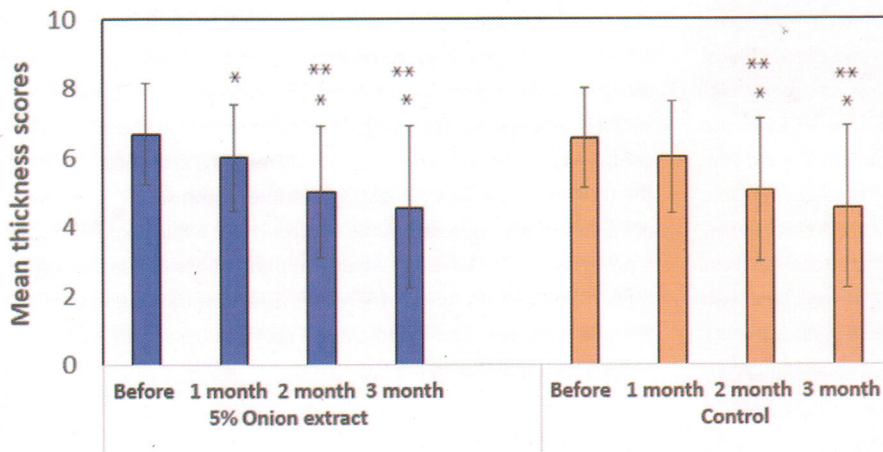


FIGURE 3 Mean thickness scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

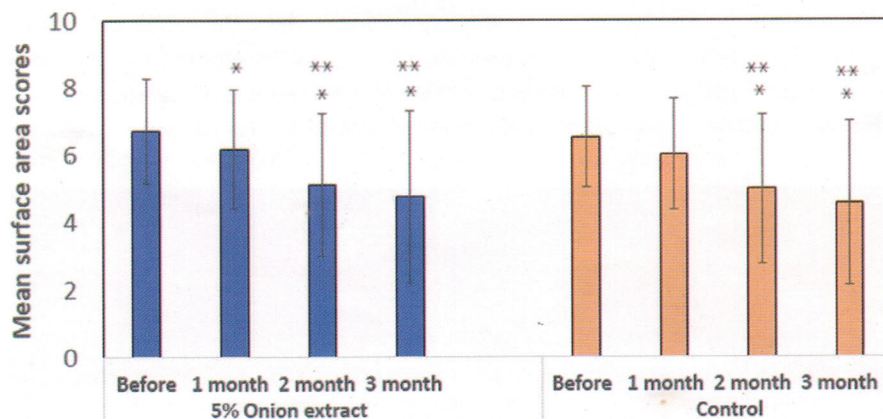


FIGURE 4 Mean surface area scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

Together, both POSAS and VSS mean scores after three months of treatment of the silicone gel containing 5% onion extract group were significantly lower when compared with the status before treatment. The VSS scores are shown in Figure 10.

4.3 | Assessment of scar color by cutometer

Measurements of erythema and melanin index using the mexameter probe are shown in Figure 11. At the one, two, and three months of the treatment, the minimal redness and the melanin

index were found, with a time-related improvement in scar color in both groups. The silicone gel containing 5% onion extract exhibited a significant improvement in erythema and melanin index at the one month of the treatment. At three months of the treatment, the silicone gel containing 5% onion extract showed no significant difference in erythema and melanin index when compared with normal skin color. On the contrary, scars treated with the control silicone gel were significantly more erythematous than normal skin. However, no statistically significant difference in melanin index was found at the three-month follow-up. The results suggested that the silicone gel containing 5% onion extract rapidly

FIGURE 5 Mean pigmentation scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

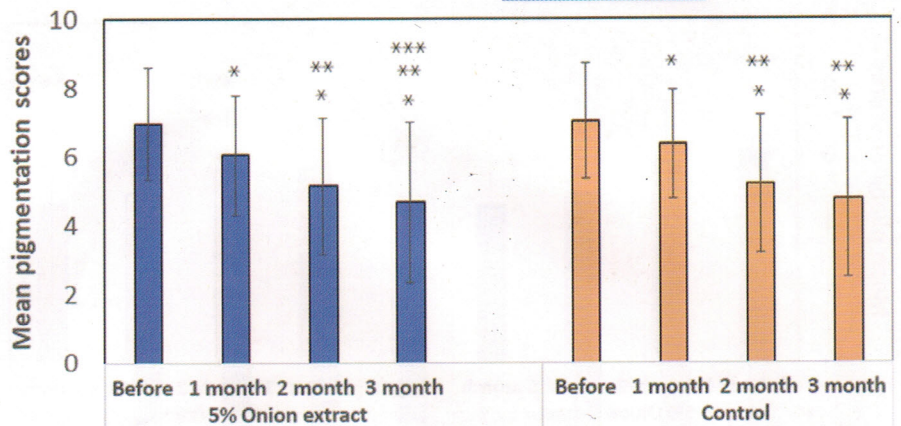
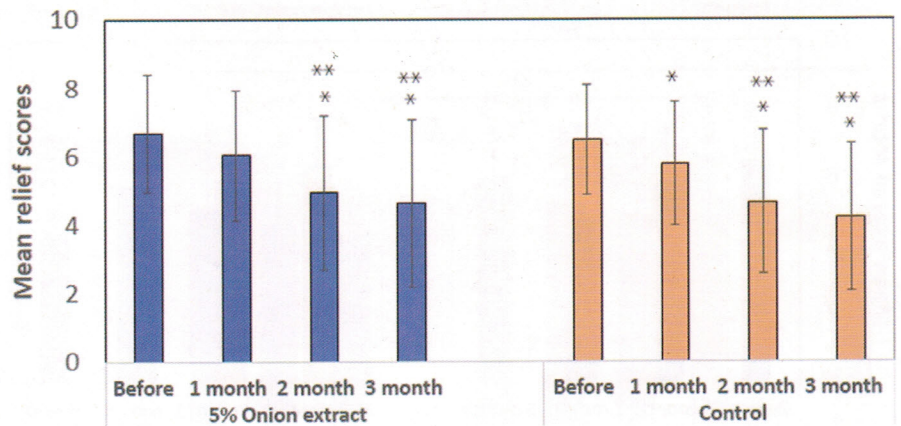


FIGURE 6 Mean relief scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)



improved overall appearance of post-cesarean scars after at least one month of the treatment.

5 | DISCUSSION

The formation of a scar resulted from a surgical procedure is frequently cosmetically and emotionally unacceptable to the patient.¹² Several women around the world have abdominal scars after cesarean section.¹³ There are several methods available for scar improvement. Many topical products are designed to reduce the appearance of scars. Among these products, the onion extract has shown its proof for scar management. A topical gel containing onion extract has been demonstrated to provide optimal scar prevention and improve a convenience for users.¹⁴⁻¹⁷ The results of this clinical study showed that the silicone gel containing 5% onion extract has the therapeutic efficacy and safety which are comparable with the control silicone gel in preventing post-cesarean scars. The natural extracts contained in the silicone gel justify the obtained results. In particular, the onion extract is rich in organosulfur compounds and flavonoids, which account for its numerous activities in scar treatment and skin quality improvement.¹⁸

The onion extract has several bioactive ingredients, such as quercetin, kaempferol, and thiosulfates, showing the potential in scar prevention. In an *in vitro* study, the onion extract possibly affects

the up-regulation of matrix metalloproteinase-1 in fibroblasts, which plays a role in the reduction of scars.¹⁹ Furthermore, onion extract has fibroblast inhibitory properties, which can reduce fibroproliferative activity and extracellular matrix production, resulting in scar reduction.²⁰ A randomized, controlled, blinded-investigator study of onion extract gel formulation compared with no treatment found that onion extract gel improved the appearance of new scars after eight weeks of once-daily application.²¹ A recent prospective, double-blinded study showed that the use of 5% onion extract silicone gel on the hypertrophic scar of median sternotomy wounds resulted in decreasing severity of hypertrophic scars for six months.²² Although a previous clinical study suggested that 12% onion extract presents the improvement on cesarean section scars,²³ results of this clinical study support the medical claim that 5% onion extract is beneficial in reducing the appearance of post-cesarean scars after at least one month of treatment without adverse events (Supplementary Information). The quality of the onion extract, such as the concentration of active ingredients, may strengthen the efficacy of the silicone-based products.

This clinical study aims not only to minimize bias and confounding factors but also to ensure the reliability, relative validity, and safety of the onion extract. There are several assessment scales that evaluate the appearance and potential symptomatology of the scars. The observer-blinded POSAS is a validated score for assessing scars.^{9,24} A previous study reported that a patch containing onion extract and

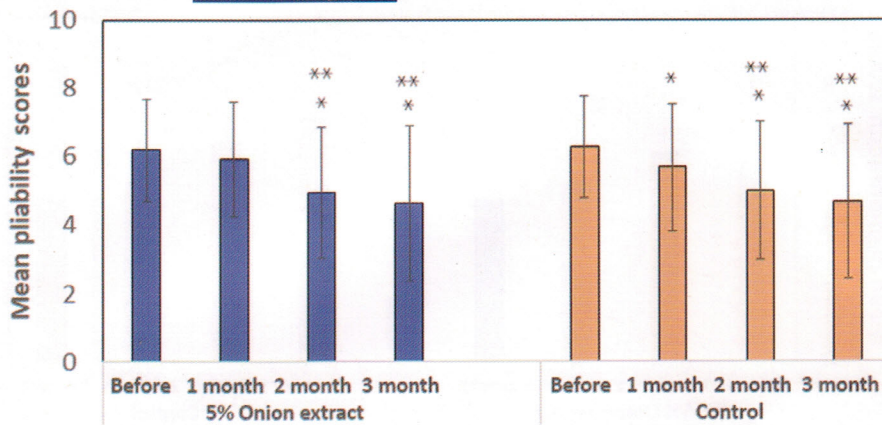


FIGURE 7 Mean pliability scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

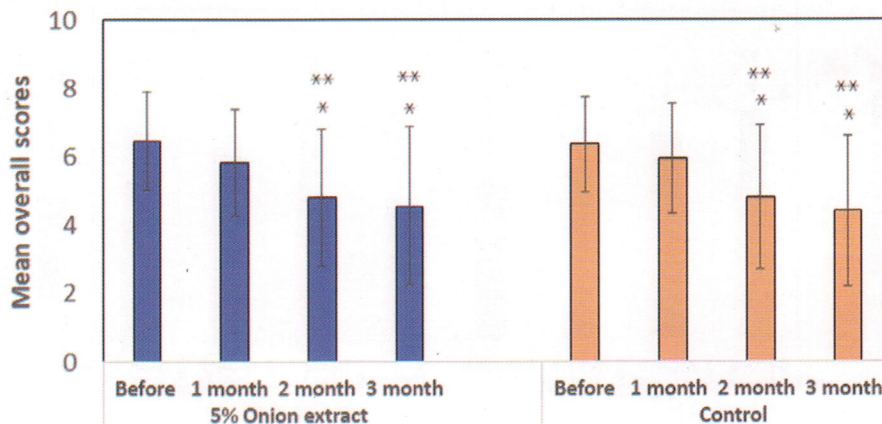


FIGURE 8 Mean overall scores of observers-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

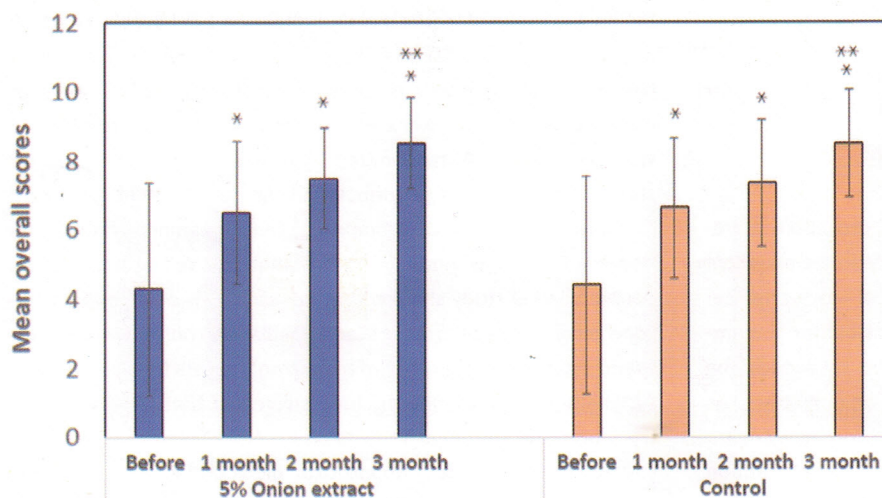


FIGURE 9 Mean overall scores of patients-evaluated POSAS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment)

allantoin on post-cesarean scars showed an improvement in POSAS scores when compared to controls.²⁵ Reduced scarring after a cesarean section by the application of a gel containing onion extract revealed a significant change in POSAS and VSS scores.^{14,26} These results were consistent with those of previous studies, in which the onion extract was successfully used for scar improvement. The improvement of scars was statistically significant at the three-month follow-up timeframe in both groups. This was further supported by the comparisons of enrolled subjects' evaluations by POSAS, as well

as investigator's evaluation by VSS scores. The results showed that the silicone gel containing 5% onion extract was rapidly effective in improving vascularization, pigmentation, thickness, relief, pliability, and surface area. In addition, a cutometer was used to determine the scar color between treated and normal skin. Results of this clinical study demonstrated that the silicone gel containing 5% onion extract presented a significant improvement in the erythema index which is different from the former clinical study showing none of scar color improvement by the use of 12% onion extract gel.²³ Interestingly,

FIGURE 10 Mean overall scores of observers-evaluated VSS for the silicone gel containing 5% onion extract (blue columns) compared with the control group (orange columns) at baseline and the 1-, 2-, and 3 months follow-up. Results are expressed as mean scores \pm SD. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 2 months treatment)

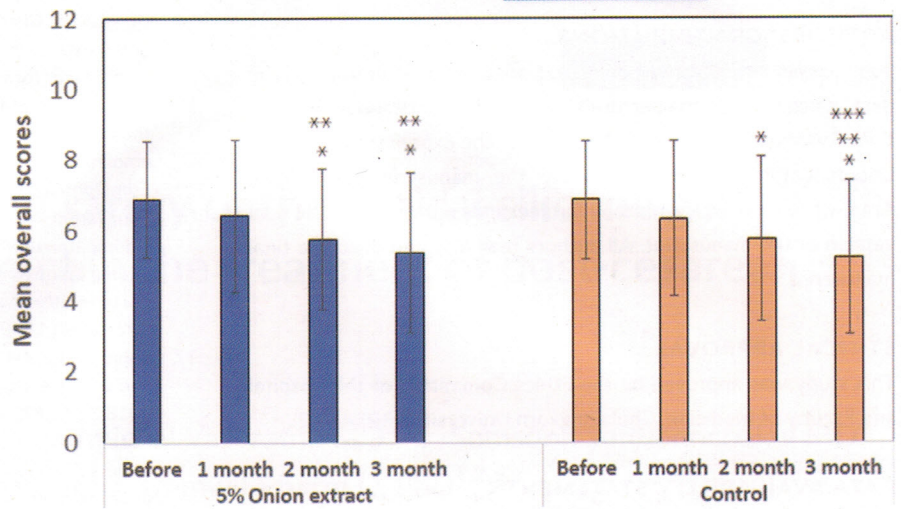
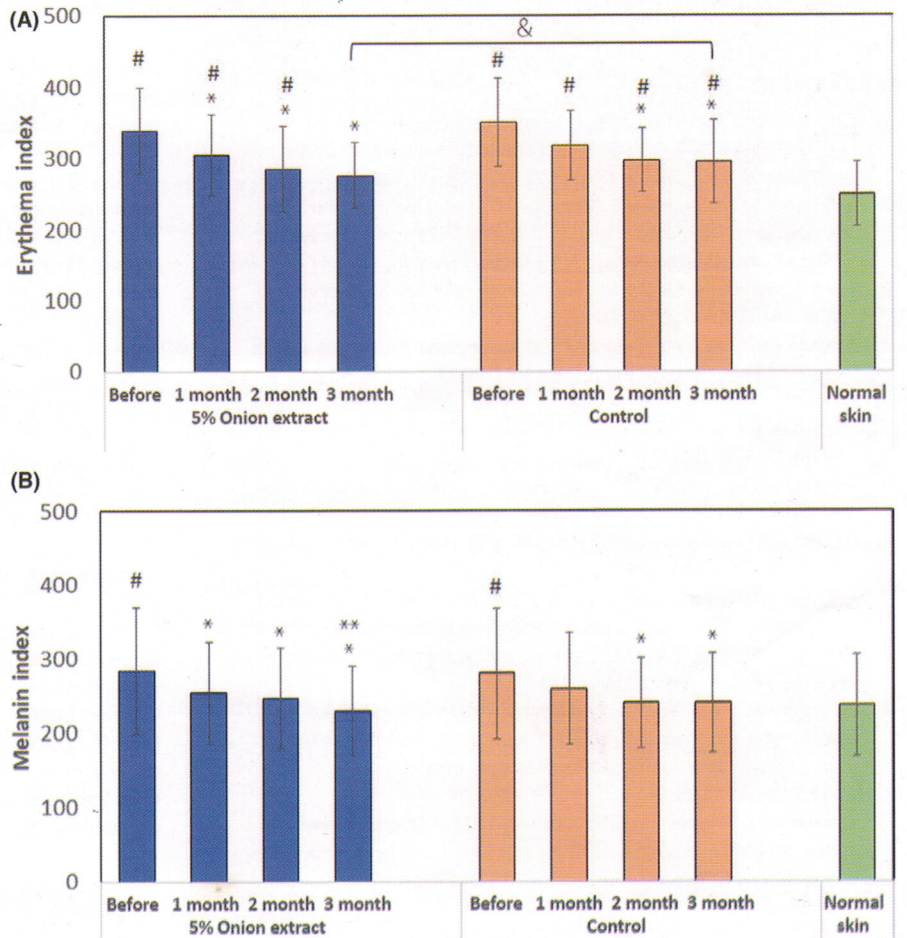


FIGURE 11 Quantitative assessment of scar color using cutometer. (A) Erythema index and (B) melanin index for the silicone gel containing 5% onion extract (blue columns) compared with the Control group (orange columns) and normal skin (green columns) at baseline and the 1-, 2-, and 3 months follow-up. (* $p < 0.05$ compared with before treatment, ** $p < 0.05$ compared with after 1 month treatment, # $p < 0.05$ compared with normal skin)



this clinical study showed that the erythema index was reduced significantly compared with the control silicone gel regardless of none of differences in the melanin index. Hence, the longer follow-up is recommended in further studies.

6 | CONCLUSIONS

This is the first study to evaluate a comparison of the effectiveness of onion extract and vitamin C for scar improvement. The results

of this clinical study confirmed that the silicone gel containing 5% onion extract can be safely used for not only minimizing but also improving the appearance of the post-cesarean scars. Earlier than the commercialized silicone gel containing vitamin C ester, the silicone gel containing 5% onion extract starts improving scar appearances to be significantly better at the first month of treatment, without adverse effects.

CONFLICTS OF INTEREST

No potential conflict of interest was reported by the authors.

AUTHORS' CONTRIBUTIONS

Supamas Napavichayanun conducted, analyzed, and interpreted the data. Apichai Vasuratna performed the experiments and interpretation. Somsook Santibenchakul performed the experiments. Sarocha Cherdchom interpreted and wrote the manuscript. Pornanong Aramwit supervised the research project and contributed to the final version of the manuscript. All authors read and approved the final manuscript.

ETHICAL APPROVAL

This study was approved by the Ethics Committee of the hospital and Faculty of Medicine, Chulalongkorn University (IRB547/62).

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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