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ORIGINAL ARTICLE

Randomised comparison of silicone gel and onion extract gel for post-surgical scars

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ABSTRACT

To compare the efficacy of silicone gel and onion extract gel on new surgical wounds, we performed a randomised controlled trial evaluating the appearance of the laparoscopic surgical scars of 60 subjects after 12 weeks of two times daily application of either silicone gel or onion extract gel. Objective scar assessment by the Vancouver Scar Scale (VSS) and the Image Panel Scale (IPS) and subjective scar assessment by the Body Image Scale (BIS) and Cosmetic Scale (CS) were performed after 12 weeks of treatment. Safety was also evaluated by gathering adverse events related to application of the gel. After 12 weeks of applying the assigned gel, there were no differences between the two groups in VSS ($p = .779$), IPS ($p = .621$), BIS ($p = .924$), or CS ($p = .843$). Subject compliance and safety with the assigned gel was similar between the two study groups. Our conclusion was that silicone gel and onion extract gel had similar compliance, side effects and efficacy in making surgical scars less distinct.

IMPACT STATEMENT

- **What is already known on this subject:** There are commercially available, topical scar emollients for prevention of surgical scarring. Despite their popularity, data demonstrating the efficacy of these scar emollients are lacking.
- **What do the results of this study add:** After 12 weeks of applying the assigned topical scar emollients, there were no differences between the two groups in terms of cosmesis and satisfaction.
- **What are the implications of these findings for clinical practice and/or further research:** Silicone gel and onion extract gel had similar compliance, side effects and efficacy in making surgical scars less distinct.

KEYWORDS
Silicone gel; onion extract gel; surgical wound; scar

Introduction

Surgical wound healing without noticeable scarring is an important aspect of cosmesis. Surgical scars can also cause pain, itching, discomfort, contracture, and other functional impairment (Niessen et al. 1999; Shaffer et al. 2002). The subjective opinion of patients regarding the surgical scar often constitutes the standard for judging the success or failure of the procedure (Rosio 1994). Various treatment options exist for treating hypertrophic scars and keloids, including intralesional steroid injection, dermabrasion, pressure therapy, surgical excision, radiotherapy, cryotherapy, pulsed dye laser, and carbon dioxide laser ablation (English and Shenefelt 1999; Mustoe et al. 2002; Shaffer et al. 2002; Widgerow et al. 2009). However, these treatments often require multiple visits and have limited success. Therefore, prevention and early recognition of hypertrophic scar and keloid formation in surgical wounds are very important in determining cosmetic outcomes.

There are commercially available, topical scar emollients for the prevention of surgical scarring. The current market in scar emollient has divided into silicone gel (Chan et al. 2005; Chernoff et al. 2007) and onion extract gel (Chung et al. 2006; Chanprapaph et al. 2012). Despite their popularity, data demonstrating the efficacy of these scar emollients are lacking. Furthermore, there is no comparative study of silicone gel and onion extract gel for making new surgical scars less distinct. We therefore conducted this randomised controlled trial to compare the efficacy of silicone gel and onion extract gel on surgical wounds. We also compared patient compliance and adverse effect between the two topical gels.

Materials and methods

Participants

This study was conducted prospectively between April 2013 and December 2015 at the Department of Obstetrics and Gynecology at the CHA Gangnam Medical Center. Women with new surgical wounds that resulted from a recent gynaecologic laparoscopy were invited to participate. Eligible participants were those that (1) were over 18 years of age; (2) were Asian; (3) had total surgical wound length of at least 2.5 cm; and (4) were able to read and write to understand

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and complete the informed consent and questionnaire. Participants were excluded if they (1) received nearly scar-free surgery such as laparoendoscopic single-site (LESS) surgery or natural orifice transluminal surgery (NOTES); (2) developed surgical complications such as wound infection; (3) were taking chemotherapeutic agents or other medications, such as steroids, that would affect wound healing; (4) had comorbidities such as diabetes, contractive skin disorders (e.g. scleroderma), or active dermatologic conditions; or (5) had allergy to silicone or onion.

Study design

This study was approved by the Institutional Review Board and registered with ClinicalTrials.gov (NCT01861119). Before randomisation, all eligible subjects received standardised information about the trial from the clinician orally and in writing. Upon agreeing to participate in the study, the subjects were asked to complete the informed consent and baseline questionnaires for socio-demographic information, medical history, and surgical history. A study nurse, who was not involved in the randomisation procedure, prepared all sequentially numbered, opaque, sealed envelopes containing the assigned intervention to ensure that the sequence was concealed. At the time of suture removal, 60 subjects were randomly assigned in a 1:1 ratio through a random permuted block generated by an interactive web-based response system (http://www.randomisation.com). Surgical wounds were treated with either silicone gel (Kelo-cort; Advanced Bio-Technologies, Silverdale, WA, USA) or onion extract gel (Contractubex; Merz Pharma, Frankfurt, Germany) for 12 weeks. After the randomisation process of 60 subjects was completed, we enrolled additional 30 subjects assigning in the no treatment group to compare the efficacy of topical scar emollients between the two gel groups and no treatment group.

Treatment

Four skin wounds resulted from laparoscopic surgery using four trocars: a single 12 mm trocar was inserted in the umbilicus and three ancillary 5 mm trocars were inserted in the lower abdomen (one in the suprapubic area and two bilaterally in the lower quadrant). Two-level wound closure was completed with a running subcutaneous suture with 3-0 Vicryl (Ethicon, Somerville, NJ, USA) and restraint of wound edges with skin tape (Steri-Strip; 3 M, Neuss, Germany). In the umbilical wound, the fascia and subcutaneous tissue were approximated and closed layer-by-layer with 1-0 Vicryl. After removal of the skin tape on the seventh postoperative day, 60 subjects in the silicone gel group and the onion extract gel group were instructed to apply gel two times daily for 12 weeks after cleansing and drying the skin, and 30 subjects in the no treatment group did not receive any topical scar emollients. During the study period, no additional treatment options for preventing or treating hypertrophic scars and keloids were used in either group. All subjects were scheduled for follow-up 12 weeks after initiation of treatment. At this visit, physicians and subjects independently evaluated the scars. Photographs were also taken to evaluate surgical scars by independent assessors, irrelevant to this study.

Outcome measure

The primary outcome was objective scar assessment. Secondary outcomes were subjective scar assessment and subject-reported compliance and adverse effects related to the gel. Objective scar assessment was performed by the physician blind to the treatment using the Vancouver Scar Scale (VSS) (Nedelec et al. 2000), a 0–14 scale with higher scores indicating worse scar. The score is based on scar pigmentation, vascularity, pliability, and height (Figure 1). The VSS was selected for the study because it is widely used for objective scar assessment (Nedelec et al. 2000). The Image Panel Assessment, developed by Beausang et al. (1998), was also performed by a panel consisting of one dermatologist and two gynaecologists. All subjects had photos of their scars taken after 12 weeks of treatment. All photographs for scar were taken in the same outpatient clinic room under controlled lighting conditions and standardised for white balance and colour via standards within the image field. The photos were sent to the panel without identifying information and were scored using the Image Panel Scale (IPS), in which higher scores indicate worse scars (Figure 1).

Subjective scar assessment was performed through the Body Image Questionnaire, as previously described by Dunker et al. (Dunker et al. 1998; Song et al. 2012). Subjects were asked to complete the questionnaire after 12 weeks of treatment before seeing the clinician. The Body Image Questionnaire is consisted of two domains: Body Image Scale (BIS) and cosmetic scale (CS). The maximum BIS and CS scores are 20 and 24, respectively, and higher scores indicate greater body image and cosmetic satisfaction (Figure 1). Additionally, subjects were asked about their compliance with self-application and any irritation, erythema, itching, burning, or other gel-associated adverse effects through a self-reported questionnaire with the Body Image Questionnaire, which was collected by independent assessors. If the subject was lost to follow-up at the 12-week follow-up appointment, independent assessors conducted a phone interview for subjective scar assessment.

Statistical analysis

The sample size was calculated based on the difference in primary outcome (VSS score after 12 weeks of treatment), collected retrospectively from subjects who applied silicone gel or onion extract gel at our institution before this study. Significance level and power were set at 5% and 80%, respectively. Assuming a standard deviation of 2.0 points for VSS score measured three months after treatment and allowing for a 5% dropout rate, we estimated that 30 subjects would be needed per group to detect the 1.5 point difference that was considered clinically relevant between the two groups.

SPSS 13.0 (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis. All analyses were performed according to the

Vancouver Scar Scale (VSS)

Vascularity	Pigmentation	Pliability	Height
0 = Normal	0 = Normal	0 = Normal	0 = Flat
1 = Pink	1 = Hypopigmentation	1 = Supple	1 = <2 mm
2 = Red	2 = Hyperpigmentation	2 = Yielding	2 = 2-5 mm
3 = Purple		3 = Firm	3 = >5 mm
		4 = Ropes	
		5 = Contracture	

Image Panel Scale (IPS)

Color	Brightness	Contour	Distortion
1 = Perfect with surrounding skin	1 = Matte	1 = Flush with surrounding skin	1 = None
2 = Slightly mismatch	2 = Shiny	2 = Slightly proud/indented	2 = Mild
3 = Obvious mismatch		3 = Hypertrophic	3 = Moderate
4 = Gross mismatch		4 = Keloid	4 = Severe

Body Image Scale (BIS)

1. Have you been feeling self-conscious about your appearance?
   1. No, not at all 2. A little 3. Quite a bit 4. Yes, extremely
2. Have you felt less physically attractive as a result of operation scar?
   1. No, not at all 2. A little 3. Quite a bit 4. Yes, extremely
3. Have you been dissatisfied with your appearance when dressed?
   1. No, not at all 2. A little 3. Quite a bit 4. Yes, extremely
4. Did you find it difficult to look at yourself naked?
   1. No, not at all 2. A little 3. Quite a bit 4. Yes, extremely
5. Have you been feeling less sexually attractive as a result of operation?
   1. No, not at all 2. A little 3. Quite a bit 4. Yes, extremely

Cosmetic Scale (CS)

1. On a scale from 1 to 7, how satisfied are you with your scar?

1	2	3	4	5	6	7
Very unsatisfied			Not unsatisfied/not satisfied			Very satisfied

2. On a scale from 1 to 7, how would you describe your scar?

1	2	3	4	5	6	7
Very unsatisfied			Not unsatisfied/not satisfied			Very satisfied

3. Could you score your own scar on a scale from 1 to 10?

1	2	3	4	5	6	7	8	9	10
The worst									The best

Figure 1. Scar scales used in this study.

intention-to-treat principle. Data are presented as mean ± standard deviation (SD) or median (range) for quantitative variables and frequency (percentage) for qualitative variables. The baseline clinical characteristics and primary and secondary outcomes between the three study groups were compared with the Kruskal-Wallis test or analysis of variance (ANOVA) for quantitative variables, and the χ^2 test or Fisher's exact test for qualitative variables, as appropriate. A p-value $<.05$ was considered statistically significant.

Results

Enrollment for the randomisation process took place between April 2013 and February 2014, and follow-up visits were concluded in May 2014. Of the 65 subjects who were invited to participate for the initial randomisation process, 3 declined participate in this study, and 2 were ineligible for the study because of inclusion and exclusion criteria. Therefore, 60 subjects underwent randomisation (Figure 2) to apply either silicone gel or onion extract gel on their own surgical wounds. Then, 30 subjects in the no treatment group were enrolled without a randomisation process and followed between January 2015 and December 2015. None of the study subjects switched assigned study groups or stopped participating in the study.

Baseline demographic characteristics of the study subjects are listed in Table 1. The three groups were comparable in age, body mass index, marital status, education achievement level, employment status, comorbidities, parity, menopause, abdominal surgical history, and scars on body. Baseline body image satisfaction, cosmetic satisfaction with surgical wounds, interest in personal appearance, and satisfaction with personal appearance did not significantly differ between the three groups.

The scar assessments performed after 12 weeks of treatment are shown in Table 2. The mean VSS scores were 3.9 ± 1.1, 3.8 ± 1.4, and 5.4 ± 1.1 for the silicone gel and the onion extract gels, respectively, with no statistical difference ($p = .492$). There was also no significant difference in IPS scores between two gel groups ($p = .331$). When post-surgical scars were evaluated using the subjective scar assessment tools including BIS and CS, there was also no significant difference between two gel groups ($p = .175$ and $p = .847$, respectively). However, VVS ($p = .003$), IPS ($p = .017$), BIS ($p = .004$), and CS ($p = .035$) scores of the no treatment group were statistically different from those of the two gel groups, indicating the efficacy of silicone gel and onion extract gel on new surgical wound.

Subject compliance with application of the assigned gel was similar between the two gel groups ($p = .836$). Overall, 41

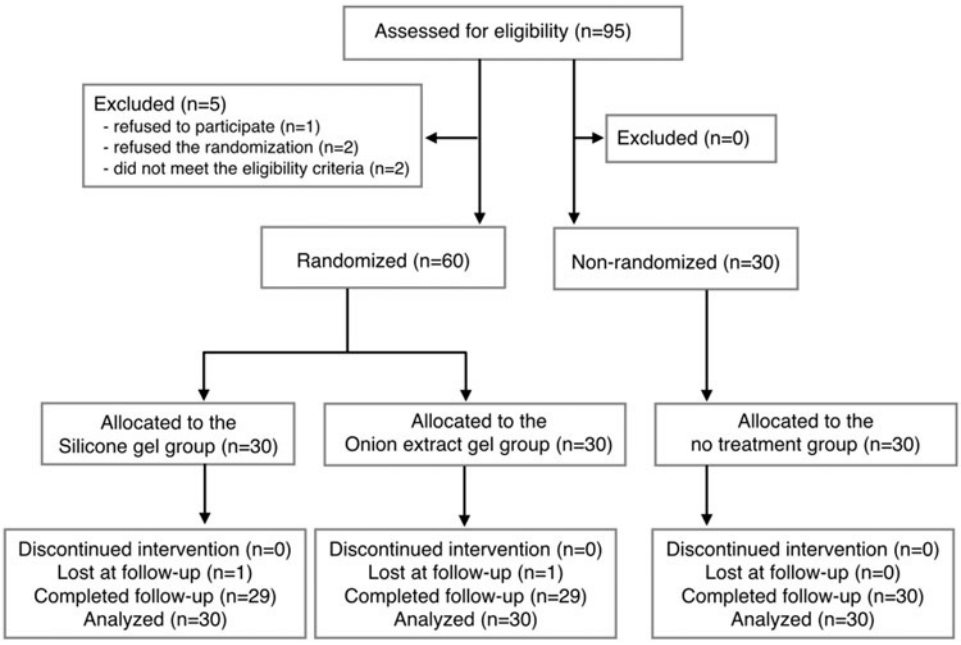

Figure 2. Enrollment, randomisation, and follow-up of the study subjects.

Table 1. Baseline characteristics.

	Silicone gel group ($n = 30$)	Onion extract gel group ($n = 30$)	No treatment group ($n = 30$)	p-value
Age (year)	38.0 ± 6.5	39.1 ± 6.0	38.5 ± 6.7	.596
Body mass index (kg/m^2)	22.3 ± 3.2	21.7 ± 2.6	22.5 ± 2.9	.386
Marital status				.600
Married/cohabitating	23 (77%)	20 (67%)	23 (77%)	
Single/separated/widowed/divorced	7 (23%)	10 (33%)	7 (23%)	
Education achievement level				.664
High school or less	8 (27%)	9 (30%)	6 (20%)	
College or more	22 (73%)	21 (70%)	24 (80%)	
Employment status				.853
Employed	21 (70%)	20 (67%)	22 (73%)	
Unemployed	9 (30%)	10 (33%)	8 (27%)	
Comorbidities[a]	3 (10%)	2 (7%)	2 (7%)	.856
Parity				.733
Nulliparous	16 (53%)	13 (43%)	15 (50%)	
Parous	14 (47%)	17 (57%)	15 (50%)	
Menopause	0	1 (3%)	1 (3%)	.596
Abdominal surgery history	8 (27%)	6 (20%)	5 (17%)	.627
Scars on body	12 (40%)	9 (30%)	12 (40%)	.622
Body Image Scale[b]	17.1 ± 3.7	16.3 ± 4.0	16.8 ± 3.8	.449
Cosmetic Scale[b]	15.6 ± 4.5	16.3 ± 4.5	15.8 ± 4.2	.702
Interest in personal appearance[c]	2.6 ± 1.0	2.5 ± 0.7	2.5 ± 0.8	.643
Satisfaction with personal appearance[c]	2.3 ± 0.6	2.2 ± 0.6	2.2 ± 0.5	.766

[a]Comorbidities include hypertension, heart disease, stroke, and severe psychiatric illness.
[b]Higher scores mean better body image and higher cosmetic satisfaction.
[c]For calculation of mean, categories were assigned the following values: 1 = no, not at all; 2 = a little; 3 = quite a bit; and 4 = yes, extremely. Higher mean indicates higher interest or satisfaction with personal appearance.

subjects (68%) had excellent compliance and never forgot to apply the gel. Sixteen subjects (27%) had good compliance and sometimes forgot to apply the gel. Three subjects (5%) had poor compliance and forgot to apply the gel most of the time.

Although there were no serious adverse events related to the applied gel in either study group, transient non-serious adverse events were observed in 2 subjects (7%) of the silicone gel group and 2 subjects (7%) of the onion extract group. These subjects experienced irritation or itching when they began applying the gel on their surgical wounds. These symptoms disappeared soon thereafter, and the subjects were able to continue gel application.

Discussion

In this randomised trial, we found that silicone gel and onion extract gel had similar effects in making surgical scars less distinct. We also found that these two scar emollients had excellent or good compliances, with no obvious side effects during application to surgical wounds. To the best of our knowledge, this is the first study to compare the effects of silicone gel and onion extract gel on surgical scars.

The action mechanism of silicone gel is considered as the promotion of hydration of the skin surface (Chan et al. 2005). Davey et al. (Perkins et al. 1983; Quinn et al. 1985) reported that the relatively impermeable silicone material acts in the

Table 2. Scar assessment after 12 weeks of treatment.

	Silicone gel group ($n = 30$)	Onion extract gel group ($n = 30$)	No treatment group ($n = 30$)	p-value[a]	p-value[b]
Objective scar assessment					
Vancouver Scar Scale[c]	3.9 ± 1.1	3.8 ± 1.4	5.4 ± 1.1	.492	.003
Image Panel Scale[c]	5.4 ± 1.1	5.2 ± 1.7	6.2 ± 1.3	.331	.017
Subjective scar assessment					
Body Image Scale[d]	16.8 ± 3.8	16.3 ± 2.3	14.9 ± 1.9	.175	.004
Cosmetic Scale[d]	15.7 ± 4.2	15.9 ± 3.6	13.7 ± 3.0	.847	.035
Patient compliance with the gel			–	.836	
Excellent[e]	21(70%)	20 (67%)			
Good[f]	8 (27%)	8 (27%)			
Poor[g]	1 (3%)	2 (7%)			
Adverse events with the gel	2 (7%)	2 (7%)	–	>.999	
Irritation	1 (3%)	2 (7%)			
Erythema	0	0			
Itching	1 (3%)	0			
Burning sense	0	0			

[a]The comparison between the silicone gel group and onion extract gel group.
[b]The comparison between three groups.
[c]Higher scores indicate worse scar.
[d]Higher scores indicate greater satisfaction.
[e]Never forgot to apply the gel.
[f]Sometimes forgot to apply the gel.
[g]Forgot most of the time to apply to gel.

same way as the stratum corneum. Another mechanism was described by, McCauley et al. (McCauley et al. 1990), who reported the inhibitory effect on fibroblast growth in cultured human skin fibroblasts and cultured bottles coated with silicone gel. Currently, these two hypotheses are thought to be the main mechanisms of silicone gel's effect on scar formation. Silicone gel has demonstrated positive effects on hypertrophic scars and keloids in many previous studies (Sproat et al. 1992; Cruz-Korchin, 1996). The authors hypothesised that the positive effects of the silicone gel at the cellular level would translate to newly created surgical scars. Moreover, the positive effect of the silicone gel has been most frequently reported for the induction of good scar maturation among many adjunctive methods (Sproat et al. 1992; Cruz-Korchin, 1996; Chan et al. 2005).

Contractubex gel, which was selected as the onion extract gel in this trial, includes 10% aqueous onion extract, 50 U heparin per gram of gel, and 1% allantoin. Onion extract possesses fibroblast-inhibiting properties, which reduce both fiibroproliferative activity and the production of extracellular matrix (Atiyeh 2007). In addition, heparin interacts strongly with collagen molecules by inducing the formation of thicker fibrils typical of mature tissue and promoting inter-molecular bonding in collagen (Ho et al. 2006). Therefore, heparin and onion extract affect scar development by their inhibitory effects on inflammatory processes, fibroblast proliferation, and the synthesising capacity of fibroblasts (Ho et al. 2006).

In this trial, we utilised several tools for assessing surgical scars including VSS, IPS, BIS, and CS. The selection of tools to evaluate surgical scars was the most difficult and important part of this study design. Although the VSS was developed to provide a more objective measurement of burn scars, this scale also was widely used and validated also in surgical scars (Bayat et al. 2003; Chan et al. 2005; Ho et al. 2006; Widgerow et al. 2009). We chose to use IPS because this scale assesses objectively scars without subject information by a panel, irrelevant to the physician who sutured the wound. BIS and CS were used to subjectively assess patients' impressions of their surgical scars. BIS assessed the subject's perception of general body image after surgery, and CS asked more detailed questions about the aesthetic postoperative appearance of their scar and abdominal wall contour. We chose to use BIS and CS because these scales were well-validated tools and have been widely used to assess cosmetic satisfaction with surgical scars in previous studies involving laparoscopic gynaecologic surgery (Song et al. 2014), ileo-colectomy (Dunker et al. 1998), nephrectomy (Lind et al. 2004), and appendectomy (Gill et al. 2012). We believe that the use of these validated tools is essential to the assessment of the effects of scar emollient on surgical scars.

The dynamics of wound healing and scar formation are affected by endogenous factors (Bayat et al. 2003; Diegelmann and Evans 2004), including age, ethnic origin, sex, pregnancy status, and location of the wound. Participants in our study had higher risk of developing scars (e.g. younger age, Asian and scar located at lower abdomen). These endogenous factors were well controlled in this trial. There was no difference in age between the two study groups. All study subjects were Asian women the same number of surgical scars at the same sites.

In this study, all subjects tolerated the products well without any reports of serious adverse effects. Only transient non-serious adverse events were observed in 7% of the silicone gel group and 7% of the onion extract group. This rate was consistent with the results of previous studies. Ho et al. (Ho et al. 2006) reported that 6.8% of patients developed transient adverse effect such as light itchiness after the application of Contractubex gel. Moreover, the itchiness was also diminished soon after. These findings were similar in most studies as well (Janicki et al. 1988; Janicki and Sznitowska 1991; Willital and Heine 1994), although Jackson and Shelton reported that irritation occurred in 33.3% of patients using Contractubex gel (Jackson and Shelton 1999).

There are several limitations of this trial. First, our 90 subjects in the three groups were not randomly assigned in a 1:1:1 ratio, and 30 subjects in the no treatment group was

added later in this trial. Second, the lack of long-term follow-up may result in under-reporting keloids since they may not develop until years after the event (Niessen et al. 1999; Shaffer et al. 2002). Further studies, incorporating a larger number of subjects and a longer follow-up period (up to several years) are essential to provide additional information. Third, this study was not designated as a split-scar study, in which each scar was divided into two equal portions, and each half was assigned treatment with either silicone gel or onion extract gel.

In conclusion, the results of this study provide evidence that silicone gel and onion extract gel have similar compliance, side effects, and efficacy in making surgical scars less distinct. However, a randomised controlled trial comparing different treatments to each surgical site in one individual is required to confirm the results of this study.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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