

Prevention and management of hypertrophic scars after laparoscopic surgery using silicone gel sheets: a pilot study

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Abstract

Objective: To assess the effectiveness and safety of modified silicone gel sheets applied to hypertrophic scars and keloids following laparoscopic surgery.

Methods: Patients who had undergone laparoscopic surgery and who had either conventional or modified silicone gel sheets affixed to their surgical lesions for 6 months postoperatively (treatment groups), and control patients who had not received postsurgical treatment involving silicone gel sheets, were enrolled. The surgical wounds were assessed visually and using the Japan Scar Workshop (JSW) Scar Scale. Patients were interviewed before, 3 months after, and 6 months after sheet affixation.

Results: A total of 45 patients were included, comprising 15 patients per group. Both silicone gel-sheet groups had significantly lower JSW Scar Scale scores at 3 and 6 months after affixation compared with controls. The scores were not significantly different between the conventional and modified treatment groups and no adverse events were observed in the latter.

Conclusions: Modified silicone gel sheets were more effective than controls and comparable to conventional gel sheets, and there were no adverse events related to laparoscopic surgical wounds in the improved silicone gel sheet group, demonstrating the safety and effectiveness of the modified silicone gel sheets.

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Keywords

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Introduction

The prevention and management of keloids and hypertrophic scars is clinically important.¹ Such lesions develop in response to skin damage caused by trauma or surgical injury along with the unwarranted expression of cytokines and growth factors that trigger wound healing mechanisms.² Keloids and hypertrophic scars are characterized by an excess of extracellular matrix components, especially collagen, in the dermis and subcutaneous skin tissue that spreads beyond the original wound margins.^{1,2} Despite advanced treatment options for keloids and hypertrophic scars, including medical and surgical therapies, their incidence has continued to increase, and the lesions rarely resolve spontaneously.³ Following surgical excision, the recurrence rate of these lesions remains very high despite current treatment methods, and in some cases, excision aggravates the condition. Furthermore, keloids and hypertrophic scars can be a major burden in genetically susceptible individuals in terms of cosmetic harm, pruritus, pain, and limited physical and mental distress in severe cases.^{4,5}

Many clinical studies have attempted to identify the ultimate treatment modalities for hypertrophic scars and keloids, however, information regarding the ideal treatment duration remains limited, and a suitable preventive therapy is lacking. Furthermore, the exact pathogenesis of these lesions remains unknown. To date, no single definite factor has been acknowledged to cause the development of hypertrophic scars and keloids, although several

pathologic aetiologies have been identified.^{6,7} Some regulators of the fibrotic cascade, such as transforming growth factor β and fibronectin extra domain A, have been shown to play a role in collagen deposition during the development of keloids and hypertrophic scars, but their involvement in the initiation and subsequent persistence of collagen deposition remains uncertain.⁸ Therefore, gaining an understanding of the pathomechanisms that lead to keloids and formation of hypertrophic scars might help identify signalling pathways that may serve as precise targets for lesion therapy.⁹⁻¹²

Liquid silicone was the first silicone-based therapeutic modality used to treat hypertrophic scars and keloids, followed by topical silicone sheets. Clinical use of silicone appears to be safe and effective as a result of its occlusion and hydration mechanisms rather than due to the silicone itself. In addition, application of silicone gel sheets is progressively being used in the treatment of hypertrophic scars and keloids as a component of multidisciplinary therapy. The safety and effectiveness of silicone gel sheets (Lady Care 3; Gyne Mom Co. Ltd, Saitama, Japan) has been reported for post-laparoscopic surgery wounds.¹³ However, some adverse events, including itchiness, have been observed in affected patients after laparoscopic surgery.^{4,5} Therefore, the aim of the present study was to develop a new product that is thinner than conventional silicone gel sheeting, and to investigate and report on its usefulness and safety in treating post-laparoscopic surgery injuries.

Patients and methods

Study population and study design

This retrospective pilot study included patients who had undergone laparoscopic surgery between March 2019 and March 2020 at the Department of Obstetrics and Gynaecology, International University of Health and Welfare Hospital, Nasushiobara City, Japan. Patient data were extracted from medical records and analysed retrospectively. There were no specific exclusion criteria. At the time of surgery, the 4-port parallel method was used to insert 12-mm (umbilical region) and 5-mm (lower abdomen) closed trocars (Endopath Trocar System; Johnson & Johnson, Tokyo, Japan) (Figure 1). Following surgery, all trocars (12-mm trocar for the rectus abdominis subcutaneous muscle tissue and 5-mm trocar for the subcutaneous tissue) were detached, and the surgical lesions were closed using blunt needles and 2-0 absorbable sutures (Vicryl; Johnson & Johnson). Wounds were closed by applying dermatologic adhesive tapes (Dermabond Advanced; Johnson & Johnson) to the outer epidermal surface. Patients were allocated to three different groups depending on the type of post-laparoscopic wound treatment they had received: group A, patients whose laparoscopic wounds had been postoperatively treated with a conventional silicone gel sheet between March 2019 and August 2019; group B, patients whose laparoscopic wounds had been postoperatively treated with a modified silicone gel sheet between September 2019 and March 2020; and group C (control group), patients whose laparoscopic wounds were not postoperative treated with any silicone gel sheets. In group A, conventional 30-mm diameter, 4-mm thick silicone gel sheeting (Lady Care 3; Gyne Mom Co. Ltd) was attached to the surgical lesions in the umbilicus and lower abdomen. In group B,

thinner modified silicone gel sheeting, composed of the same material as conventional silicone gel sheeting but only 2-mm thick, and was affixed to surgical lesions in the umbilicus and lower abdomen. The silicone gel sheets were applied from 1 week following surgery. The surgical lesion sites were evaluated by a physician before and at 3 and 6 months after sheet attachment, scored using the Japan Scar Workshop (JSW) Scar Scale (Table 1),¹⁴ where the higher the sum score, the greater the symptoms. The patients continued to apply silicone gel sheeting except during bathing hours.

The study was approved by the Ethics Committee of the International University of Health and Welfare Hospital (referral number: 13-B-384, referral date: 19 February, 2020) and conducted according to the principles of the World Medical Association Declaration of Helsinki. All study participants provided verbal and written informed consent.

The study complied with the Strengthening the Reporting of

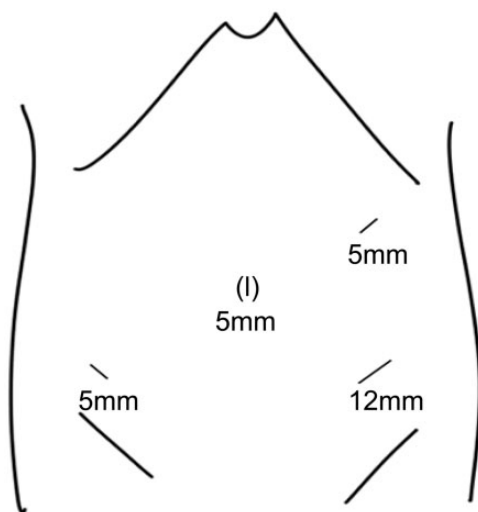


Figure 1. Diagram of trocar insertion sites for abdominal laparoscopy.

Observational studies in Epidemiology (STROBE) guidelines.

Statistical analyses

Data are presented as *n* prevalence or mean ± SD. All statistical analyses were performed using JMP® software, version 14.2 (SAS Institute Japan Co. Ltd, Tokyo, Japan) and between-group differences were analysed with one-way analysis of variance and Tukey-Kramer multiple comparison test. Statistical significance was set at *P* < 0.05.

Results

A total of 45 patients were included (15 patients in each group), and the clinical

and demographic characteristics are summarised in Table 2. No statistically significant differences in age, body mass index or surgery duration were shown between the three groups (all *P* > 0.05; Table 2).

The JSW Scar Scale scores for the umbilical wounds before, and at 3 and 6 months after gel sheet affixation, respectively, were 7.6 ± 2.4, 2.7 ± 1.6, and 1.2 ± 0.7 in the conventional group, 7.7 ± 1.5, 2.7 ± 1.3, and 1.1 ± 0.7 in the modified group, and 7.9 ± 0.7, 4.8 ± 0.8, and 2.4 ± 0.7 in the control group. The JSW Scar Scale scores at 3 and 6 months post-affixation were significantly lower in both treatment groups compared with the control group, indicating reduced symptoms related to wound scarring (Figure 2; *P* < 0.01 versus controls).

Table 1. Japan Scar Workshop Scar Scale used to assess therapeutic efficacy of silicone gel sheets applied to abdominal lesions following laparoscopic surgery.

Evaluation item	Score			
Induration	0: None	1: Weak	2: Mild	3: Strong
Elevation	0: None	1: Weak	2: Mild	3: Strong
Redness of scars	0: None	1: Weak	2: Mild	3: Strong
Erythema around pressing pain	0: None	1: Weak	2: Mild	3: Strong
Itchiness	0: None	0: Weak	2: Mild	3: Strong

Weak, symptoms exist in less than 1/3 of the area, or are intermittent; Mild, between weak and strong; Strong, symptoms exist in the entire region, or are continuous.

Table 2. Background demographic and clinical characteristics of 45 patients who underwent laparoscopic surgery and assessment of post-surgical scars for 6 months following surgery.

Background characteristic	Control group (<i>n</i> = 15)	Conventional silicone group (<i>n</i> = 15)	Modified silicone group (<i>n</i> = 15)	Statistical significance
Mean age, years	46.2 ± 8.0	49.9 ± 2.5	48.8 ± 12.8	NS
Nulliparous, times	2.0 ± 1.1	1.9 ± 0.8	1.9 ± 1.2	NS
Multiparous, times	1.8 ± 1.1	1.6 ± 0.9	1.5 ± 1.2	NS
Body mass index, kg/m ²	21.4 ± 3.1	22.4 ± 3.5	21.7 ± 4.6	NS
Duration of surgery, min	111.7 ± 46.3	99.6 ± 38.5	96.6 ± 32.9	NS
Surgery type				
Laparoscopic hysterectomy	10	6	6	
Laparoscopic myomectomy	2	1	1	
Laparoscopic adnexectomy	2	4	4	
Laparoscopic ovarian cyst resection	1	4	4	

Data presented as mean ± SD or *n* cases.
NS, no statistically significant between-group difference (*P* > 0.05; one-way analysis of variance).

The JSW Scar Scale scores were not significantly different between the two treatment groups at any time period.

The JSW Scar Scale scores for the lower abdominal wounds before, and at 3 and 6 months after affixation, respectively, were 4.7 ± 2.3 , 1.9 ± 1.0 , and 0.6 ± 0.5 in the conventional group, 5.3 ± 1.4 , 1.9 ± 1.1 , and 0.5 ± 0.5 in the modified group, and 4.4 ± 1.5 , 2.9 ± 0.7 , and 1.1 ± 0.6 in the control group. Similar to the umbilical wounds, both treatment groups also had significantly lower JSW Scar Scale scores for the lower abdominal wounds at 3 and 6 months post-affixation compared with controls, indicating reduced symptoms related to wound scarring (Figure 3; $P < 0.01$ versus controls). The JSW Scar Scale scores were not significantly different between the two treatment groups at any time period (Figure 3).

There were no major adverse effects in either treatment group, however, three patients (20%) experienced itchiness in the conventional group. There were no reported adhesion problems in patients who used the modified sheet.

Discussion

Keloids and hypertrophic scarring are unique human dermal fibroproliferative disorders of the lacerated skin that are frequently seen in daily medical practice.⁸ They occur commonly at surgical wound sites and are associated with pain and itchiness, and can cause functional constraints. Such lesions are a significant problem faced by all surgical specialists, and thus, healing without the development of scars is often an objective for affected patients.

Several systemic, local, and genetic factors have been identified to induce the formation of white mature scars, known as hypertrophic scars and keloids. Some of these instigating factors include single nucleotide polymorphisms, circulating sex hormones, cytokines, and growth factors, which cause wound healing to be postponed and maintained over a longer time than normal.^{15–19} However, the specific pathologic aetiology remains unknown and needs to be established.

Several treatment options are available for hypertrophic scarring and keloids,

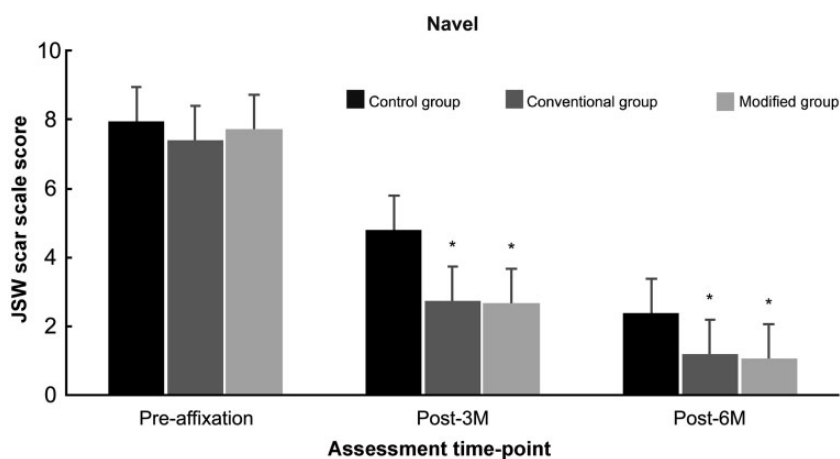


Figure 2. Variations in Japan Scar Workshop (JSW) Scar Scale scores for the umbilicus region at different time-points in 45 patients treated with conventional or modified silicone gel sheets or no gel sheet following laparoscopic surgery ($n = 15$ per group). Data presented as mean $\pm$ SD; * $P < 0.01$ versus controls (Tukey-Kramer multiple comparison test).

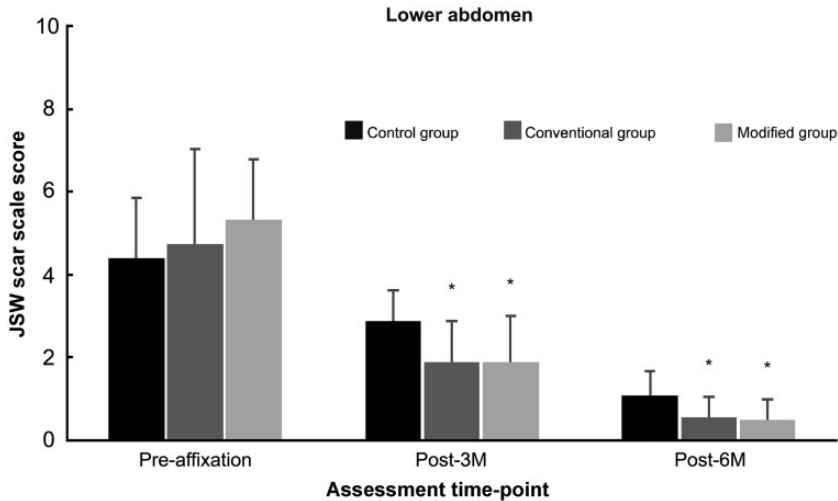


Figure 3. Variations in JSW Scar Scale scores for the lower abdomen at different time-points in 45 patients treated with conventional or modified silicone gel sheets or no gel sheet following laparoscopic surgery ($n = 15$ per group). Data presented as mean $\pm$ SD; * $P < 0.01$ versus controls (Tukey-Kramer multiple comparison test).

such as surgery, pharmacotherapy, compression therapy, cryotherapy, and laser therapy. Conservative or minimally invasive management options, such as splinting, steroid injections, and silicone sheeting, as well as autologous fat grafting, are also well reported in the literature.²⁰ Although these conditions are often hard to manage, efforts should continue to avoid their occurrence.

Silicone sheet therapy was first established as a novel cure of post-burn scarring in children by Perkins et al. in 1982,²¹ yet its specific mechanism of action remains undetermined and much debated. In a study by Quinn,²² the loss of water vapor was shown to be slower at sites where silicone sheeting had been attached than at sites of scraping, and silicone sheeting has been described to act as an alternate stratum corneum that decreases the loss of water vapor, collagen proliferation, and capillary action.^{23,24} The alternate stratum corneum is reported to provide a level of moisturization conducive to improving

symptoms and exerts a defensive effect that may occur from disproportionate traction applied by the silicone gel sheeting on the scar site and the surrounding tissues.^{24,25} Furthermore, it is plausible that silicone gel sheeting may allow the epidermis to rest without causing any type of contact dermatitis, which occurs with many types of plastic film that use organic solvents as adhesives.²⁶ These theories are all possible explanations, but none have demonstrated specificity concerning hypertrophic scars and keloids.

Several studies have evaluated the effectiveness of silicone gel on itching, pain, scar height, redness, and hardness as part of the multidisciplinary treatment of hypertrophic scarring and keloids, and have shown that use of silicone gel exerted a substantial protective effect on damaged tissue.^{10,27} The present investigation demonstrated significantly lower JSW Scar Scale scores at 3 and 6 months postoperatively in groups of patients treated with

conventional or modified silicone gel sheets compared with untreated controls, suggesting an early postoperative wound-healing improvement.

The Lady Care 3 is an elliptical (30-mm diameter, 4-mm thick), malleable, silicone gel sheet that is reusable for at least 2 months, and can directly adhere to the affected site. However, during the summer seasons, the adhesiveness of the silicone gel sheeting may be lowered or lost, and itching has been described by many patients.¹³ In the present study, only three patients (20%) experienced mild itching and continued to use the Lady Care 3 sheets. Therefore, it has been assumed by the current authors that a thinner silicone gel sheet may be necessary, that tolerates sweat being wiped off more regularly. As a result, a modified silicone gel sheet of the same size as the Lady Care 3, but only 2 mm in thickness, was developed by the authors to be used on abdominal laparoscopic surgical wounds. The results of the present study show that the modified silicone gel sheet had no problems associated with adhesion, and none of the patients using this product experienced itchiness as an adverse effect.

In the field of obstetrics and gynaecology, there is an increasing trend toward minimally invasive surgery, which in turn has led to an increasing trend in the number of abdominal laparoscopic procedures performed. The present results of the present pilot study showed that the modified silicone gel sheet is effective in the healing of postoperative abdominal laparoscopic wounds, and may be effective in reducing the formation of hypertrophic scars and keloids. Since this was a single-centre study that retrospectively examined a relatively small number of target cases, larger, randomized controlled studies should be conducted to validate the present results.

In conclusion, the use of modified and conventional silicone gel sheets following laparoscopic surgery was associated with

significantly lower JSW Scar Scale scores after affixation compared with the control group. In addition, the modified silicone gel sheet was not associated with itchiness, as experienced by patients using the conventional sheet. These results suggest that the modified silicone gel sheet is effective and safe when used to support wound healing following abdominal laparoscopic surgery.

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Author contributions

TK developed and drafted the manuscript. All authors designed the data collection instruments, collected data, and conducted the initial analyses. All authors approved the final manuscript for submission and agree to be accountable for all aspects of the work.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

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