

A Randomized, Controlled Trial to Determine the Efficacy of Paper Tape in Preventing Hypertrophic Scar Formation in Surgical Incisions that Traverse Langer's Skin Tension Lines

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Background: How a scar is managed post-operatively influences its cosmetic outcome. After suture removal, scars are susceptible to skin tension, which may be the trigger for hypertrophic scarring. Paper tape to support the scar may reduce multidirectional forces and prevent hypertrophic scarring.

Methods: Seventy patients who had undergone cesarean section at the Royal Brisbane and Women's Hospital were randomized to treatment and control groups. Patients in the control group received no postoperative intervention. Patients in the treatment group applied paper tape to their scars for 12 weeks. Scars were assessed at 6 weeks, 12 weeks, and 6 months after surgery using ultrasound to measure intradermal scar volume. Scars were also assessed using the International Clinical Recommendations.

Results: Paper tape significantly decreased scar volume by a mean of 0.16 cm³, (95 percent confidence interval, 0.00 to 0.29 cm³). At 12 weeks after surgery, 41 percent of the control group developed hypertrophic scars compared with none in the treatment group

(exact test, $p = 0.003$). In the treatment group, one patient developed a hypertrophic scar and four developed stretched scars only after the tape was removed. The odds of developing a hypertrophic scar were 13.6 times greater in the control than in the treatment group (95 percent confidence interval, 3.6 to 66.9). Of the 70 patients randomized, 39 completed the study. Four patients in the treatment group developed a localized red rash beneath the tape. These reactions were minor and transient and resolved without medical intervention.

Conclusions: The development of hypertrophic and stretched scars in the treatment group only after the tape was removed suggests that tension acting on a scar is the trigger for hypertrophic scarring. Paper tape is likely to be an effective modality for the prevention of hypertrophic scarring through its ability to eliminate scar tension. (*Plast. Reconstr. Surg.* 116: 1648, 2005.)

In some individuals, the normal wound-healing process becomes derailed and results

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in an overabundance of scar tissue. This is known as hypertrophic scarring. A hypertrophic scar has been defined as follows: "a red, raised, sometimes itchy scar confined to the border of the original surgical incision. These scars may increase in size rapidly for 3 to 6 months . . . and then regress. They generally mature to have an elevated, slightly rope-like appearance with increased width."¹

Hypertrophic scarring can cause itching, pain, and discomfort, and can affect joint range of movement and reduce functional performance. In Western society, hypertrophic scarring is often viewed as aesthetically displeasing.

Hypertrophic scarring is a frequent and undesirable complication of surgical incision, reportedly occurring in up to 64 percent of surgical incisions.² Given that an estimated 55 million elective operations and 25 million operations following trauma occur each year in the developed world alone, this is a significant and perplexing problem.³

METHODS OF SCAR PREVENTION

Methods of scar prevention have been attempted, with variable success, including compressive dressings, splints, silicone gel pads, steroid injections, laser treatment, medications, irradiation, ultrasound, cryotherapy, chemotherapy, and application of zinc.^{1,4} Some have been associated with side effects such as pain, skin atrophy, altered pigmentation, contact dermatitis, thermal injury, and further scar formation.¹ Where techniques have been successful, the mode of action by which they are effective is unknown.²

Three main modalities are thought to beneficially influence the aesthetic outcome of a scar. These are wound support, hydration, and hastened maturity of the scar.⁵

Tension Theory and Wound Support

Research into wound healing and scar formation has failed to identify a single causative factor for hypertrophic scarring. However, it has been suggested that the common initiating factor is tension acting on the scar, with a higher incidence of hypertrophic scarring reported in areas of increased skin tension.⁶⁻⁹ With sutures in place, there is little tension across a scar, and collagen is laid down along it longitudinally.⁹ However, these initial collagen bonds are thought to be mechanically weak.^{9,10}

A gradual gain in a scar's tensile strength occurs with increased production and remodeling of type I collagen and an alteration in the type of crosslinks formed.¹⁰⁻¹² During the proliferative phase of normal wound healing, the initial type III collagen fibers are replaced by more closely woven type I fibers. These type I fibers are more stable, as they are crosslinked through the formation of covalent bonds.¹² It has been shown that in normal scarring, there is a time-dependent change in the crosslinking pattern, which becomes more comparable to normal skin.¹¹ This corresponds with the prolonged presence of type III collagen in hypertrophic scars.¹³ Therefore, the cause for overabundant collagen deposition in hypertrophic scars may be a defect in the crosslinking of collagen fibers caused by tension, which would reduce the tensile strength of a scar. This would in turn result in further collagen production as the scar attempts to regain its tensile strength and return homeostasis to the skin.

This gain in wound tensile strength is slow, with only 20 percent of a scar's final strength evident by the third week.¹⁰ The maximum strength of a scar is not achieved until approximately 12 weeks after wounding.¹⁴ Therefore, once the sutures are removed, the scar is susceptible to skin tension forces.⁹ Should the forces across a scar be sufficient to overcome the initial collagen bonds, prolongation of the inflammatory phase occurs, as indicated by the increased presence and persistence of inflammatory cells in hypertrophic scars.^{5,15-18} This results in a further increase in fibroblast activity, forming the basis of increased collagen production, which is then laid down haphazardly across the scar.^{9,19}

Normally in the skin, collagen fibers are orientated along lines of maximal tension, or Langer's relaxed skin tension lines.²⁰ Scars lying perpendicular to Langer's skin tension lines show a higher incidence of hypertrophic scar formation.^{6,8,21} Intermittent force on a scar's longitudinal axis is suggested to stimulate hypertrophic scar formation.⁸ Where lines of skin tension exist, such as along Langer's lines, skin extensibility or elongation is minimal. Conversely, skin extensibility and movement is maximal perpendicular to Langer's lines.²² Therefore, a scar lying perpendicular to Langer's skin tension lines is exposed to not only forces along these lines but also longitudinal tension/compression forces along the scar's axis from local joint movement. This

exerts an intermittent and multidirectional force, resulting in a widened, exaggerated, "hypertrophic" scar.^{8,9} In contrast, incisions that are placed parallel to Langer's skin tension lines have a static, unidirectional force exerted along their axis, which also significantly reduces closing tension of the wound margins and is thus unlikely to form a hypertrophic scar.^{8,23}

Hydration and Hastened Scar Maturity

The second modality thought to improve scar outcome is hydration, which is the basis of the use of silicone gel sheeting for scar management.²⁴ The stratum corneum controls water vapor transmission in normal skin.²⁵ When this skin layer is disrupted, as in a laceration or burn, dehydration may occur, contributing to a scar's inelastic property.²⁶ Quinn used an evaporimeter to measure the rate of water vapor transmission from the surface of a scar. She found that the water vapor transmission rate beneath the silicone gel was half that of normal skin.²⁷ She also showed that when silicone is removed, the water loss from a scar increases dramatically. A moist environment has been shown to be required to down-regulate fibroblast, collagen, and glycosaminoglycan production.²⁴ The use of an adhesive microporous product that mimics the function of the stratum corneum in reducing evaporative water loss is therefore thought to return homeostasis to the scar, thus shortening the period to scar maturation.²⁶⁻²⁸

PAPER TAPE FOR SCAR PREVENTION

The use of a nonstretch microporous contact media fulfils the criteria for effective scar management. Although the use of paper tape to support surgical scars after suture removal is standard practice, it is usually only continued for a few weeks.¹ This would appear to be insufficient, considering that the maximum strength of a scar is not achieved until approximately 12 weeks after wounding.¹⁴ Long-term use of paper tape is proposed to prevent the formation of a hypertrophic scar for the following reasons. It is inflexible and provides good scar support. It is microporous and is thought to mimic the stratum corneum and accelerate healing without creating the bacterial growth seen with more occlusive media.²⁹ It can be worn for 4 to 7 days continuously, even when bathing or swimming. It places fewer demands on the patient than modalities such as silicone

and compression, which have daily hygiene requirements. It is cost effective, with most scars requiring only a single roll of 2.5-cm tape for treatment, costing less than \$1.

There is a lack of rigorous clinical research that has evaluated the efficacy of paper tape. The purpose of this study is to evaluate the effectiveness of paper tape in preventing hypertrophic scarring in surgical incisions and, by doing so, demonstrate whether tension is indeed the initiating factor for hypertrophic scarring.

PATIENTS AND METHODS

Participants

Participants were recruited from the antenatal clinics or postoperatively from the maternity wards of the Royal Brisbane & Women's Hospital, Queensland, Australia. Those invited to participate were all female participants of Caucasian descent, over 18 years of age, residing in the Brisbane area, and undergoing their first cesarean section. Participants were also required to be able to read and write English sufficiently well to give informed consent and to be able to comply with the paper tape application regimen. Participants were excluded if they (1) developed surgical complications such as wound infection; (2) had a history of keloid scarring (because of the morphological and immunohistochemical differences between keloid and hypertrophic scarring); (3) were taking chemotherapeutic agents or other medications that would affect wound healing, such as steroids; (4) had comorbidities such as diabetes, contractive skin disorders (e.g., scleroderma), or active dermatologic conditions; or (5) had a negative paper tape skin allergy test. Eligible patients who consented were randomly assigned by concealed allocation to the control or treatment groups using a computer-generated random-number table and sealed-envelope system. Recruitment of participants was carried out over a 6-month period from February to July of 2003.

PROCEDURE

Patients in the control group received no intervention (according to current practice). Patients in the treatment group were instructed in the application of Micropore tape (3M, St. Paul, Minn.) directly over the scar once the wound had closed or sutures/staples were removed (days 4 through 6 after surgery).

They kept a record of their use of the tape by recording when the tape was changed and the time spent without the tape in place. Patients in both groups attended the hospital's medical imaging department for scar assessment on three occasions postoperatively (6 weeks, 3 months, and 6 months).

DATA COLLECTION

Scar outcome data were collected at each of the follow-up times by the first and fourth authors (J.M.A. and D.J.M., respectively). Ultrasound was used to objectively assess the size of linear surgical incisions.² Ultrasound is superior to other methods of scar assessment because it is accurate and reliable, objective, quantitative, noninvasive, and sufficiently sensitive to be useful in assessing a scar's response to treatment.^{30–33} The sonographer who used ultrasound to obtain the cross-sectional dimensions of the scar (Fig. 1) was blind to treatment allocation. The intradermal height and width of each scar were measured and scar volume was calculated. In addition, a subjective evaluation of whether the scar appeared hypertrophic (i.e., red, raised above the level of surrounding skin) was made by an unblinded assessor using the scar classification guidelines consistent with the international clinical recommendations on scar management.¹

Information on postoperative complications, suture materials, and method of wound closure was extracted from medical charts. At each visit, information was collected on the patient's weight and height (to calculate body mass in-

dex), abdominal circumference, skinfold thickness, and midarm circumference (to determine nutritional status). Information was also gathered on their age, skin color (pale or olive), medical history, current medications, allergies, smoking status (number of cigarettes per day), alcohol intake (units per week), general exercise and activity levels (using a quantitative physical activity survey),³⁴ and compliance with the treatment (using a treatment diary), to determine any potential effect these factors may have had on scar outcome. Adverse reactions (i.e., itch, pain, blistering) were also recorded. The participant rated itch and pain using a 10-point scale. Information about each patient's marital status and distance from home to the hospital was collected as factors likely to determine study participation and compliance.

STATISTICAL ANALYSIS

To investigate whether there were differences between women who did and did not complete the study, we used a multiple logistic regression model. We examined the covariates of treatment, age, marital status, distance to the hospital, and the local area–based covariates of average income and education level. The local area income and education information was taken from the Australian 2001 census and matched to patients using postal codes.

The volume of the scar was analyzed using a mixed effects model with a random intercept and slope (time effect) for each patient.³⁵ This method controls for the nonindependence in results from the same participant at different follow-up time points and allows for heterogeneity between patients. The covariates defined earlier as having a possible impact on scar outcome were analyzed as fixed effects. The fixed effect of treatment was forced into all candidate models, as were the random effects of intercept and slope. A final model was chosen using the Akaike information criterion. The residuals from the final model were tested for normality. All analyses were carried out using SAS version 8.³⁶ We ran both an intention-to-treat (all randomized women) and per-protocol analyses. The per-protocol group was defined as those women who were compliant with the paper tape regimen for the entire 12-week period and attended the 6- and 12-week follow-up visits.

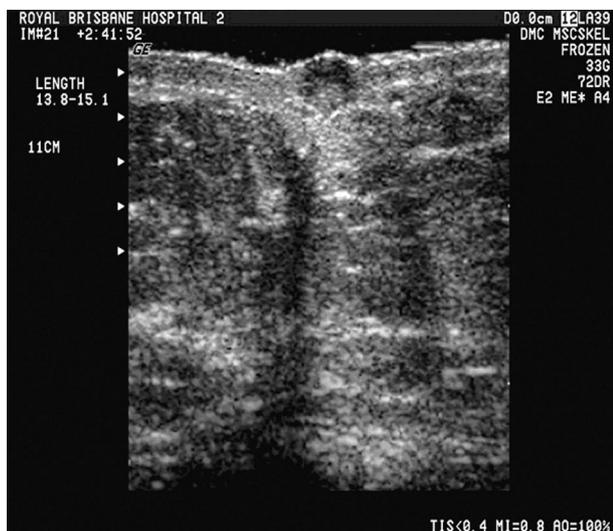


FIG. 1. Ultrasound appearance of surgical scar fibrosis within the dermal and epidermal layers.

ETHICAL APPROVAL

Approval for this research was obtained from the hospital and university human ethics committees in conformance with the *Declaration of Helsinki 2000*.

RESULTS

Table I summarizes the characteristics of patients in the control and treatment groups. The equal distribution of characteristics between these two groups verifies that the randomization procedure was successful, with no selection bias being introduced.

Figure 2 shows the flow diagram of the patients from approach to final analysis, as recommended by the CONSORT group.³⁷ There were more dropouts in the treatment compared with the control arm.

Using multiple logistic regression, we found that the likelihood of patients completing the trial depended on traveling distance from the hospital and treatment. For every (log-transformed) kilometer increase in distance from the hospital, the chance of dropping out increased by 1.9 (95 percent confidence interval, 1.0 to 3.5). Those in the treatment group were 3.8 times more likely not to complete the trial

TABLE I
Clinical Characteristics of the Sample

	Treatment Group (n = 34)	Control Group (n = 36)
Age, years (range)	30 (19–41)	27 (20–43)
Weeks' gestation (range)	38.9 (26–42)	39.5 (31–42)
Body mass index (range)	27.7 (21–42)	29.9 (22–43)
Abdominal skinfold, mm (range)	19.3 (6–30)	19.1 (8.5–36.0)
Prepregnancy weight, kg (range)	66.6 (43.0–110.0)	71.5 (49.0–126.0)
Method of wound closure, no.		
External sutures	4	3
Internal sutures	13	21
Staples	17	12
Suture material used, no.		
Staples	17	12
Monocryl	12	8
Dexon	1	8
Prolene	2	4
Vicryl	2	4
Distance from hospital, km (range)*	14.3 (0.5–70.7)	14.3 (4.0–73.2)

*Local area–based information.

than those in the control group (95 percent confidence interval, 1.3 to 10.5).

Table II shows the regression estimates of scar volume using the mixed model for both the intention-to-treat and per-protocol groups. Scar volume decreased significantly over time, although this decrease was not consistent among patients (Fig. 3) (thus, we used a random slope effect). The random intercept and slope terms were negatively correlated ($r = -0.46$); thus, higher mean scar volumes were associated with greater improvements over time. Other than treatment and time, the only other factor that affected scar volume was prepregnancy weight (larger women had larger scar volumes). The changes in scar size in Table II are scaled to a 5-kg increase in weight and a 10-day increase in time. The paper tape significantly decreased scar volume by an average of 0.16 cm³ (95 percent confidence interval, 0.00 to 0.29 cm³) after accounting for prepregnancy weight and the change over time. The treatment effect was greater when only considering those women who were compliant with the tape use for 12 weeks and returned for the 6- and 12-week follow-up visits. This per-protocol analysis showed that the paper tape reduced scar volume by an average of 0.22 cm³ (95 percent confidence interval, 0.05 to 0.36).

There was a high correlation between subjective scar rating and intradermal scar volume ($p < 0.001$). On completion of the therapy at 12 weeks after surgery, none (0 percent) of the patients in the treatment group developed hypertrophic scarring, compared with 12 patients (41 percent) in the control group (exact test, $p = 0.003$). In the treatment group, one patient developed a hypertrophic scar and four developed stretched scars only after the tape was removed. Over the entire study, the odds of developing a hypertrophic scar were 13.6 times greater in the control compared with the treatment group (95 percent CI, 3.6 to 66.9).

Exclusions

Four patients (12 percent) from the treatment group developed an adverse reaction to the tape within the first 6 weeks of use and were subsequently excluded from the study. A further three patients in the treatment group

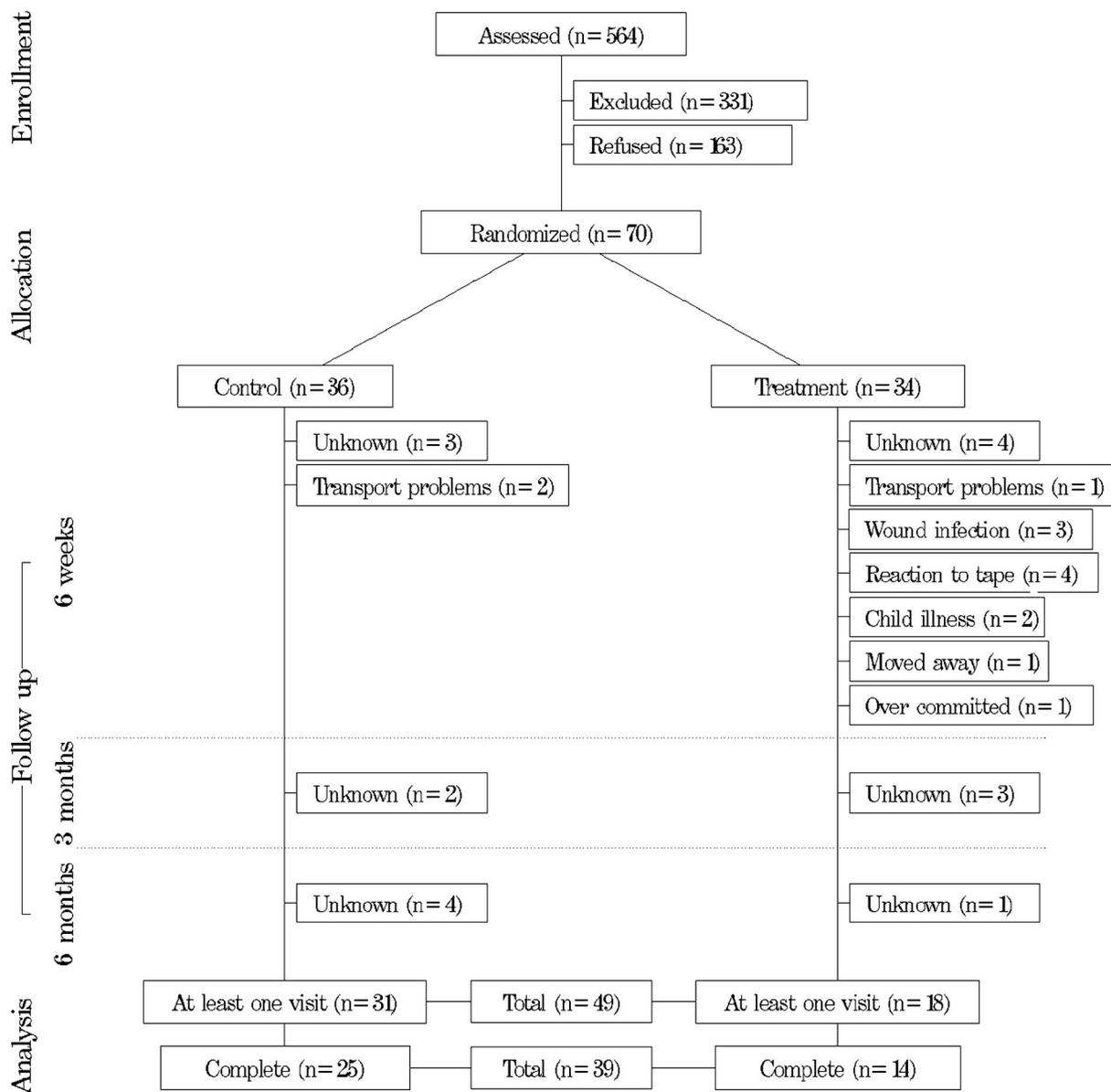


FIG. 2. Flow of subject numbers from assessment to final analysis.

(9 percent) were excluded from the study because of the development of a wound infection.

DISCUSSION

The results of this research support the suggestion that tension acting on a scar is the elusive trigger for hypertrophic scarring. It provides evidence for scar support (using paper tape) as the critical element needed to counteract scar tension and prevent hypertrophic scar formation, as proposed by Reiffel.⁸

Mode of Action

The development of hypertrophic and stretched scars in the treatment group occurred only after the tape was removed. This implies that the cellular derailing of the wound-healing process results from a mechanical stimulus (scar tension) that only occurs once scar support has been removed. The increased treatment effect demonstrated by the per-protocol analysis confirms that compliance with the wearing regimen for at least 12 weeks is essential for maximizing treatment outcome. Therefore, paper tape may act by preventing

TABLE II
Estimates of the Change in Scar Volume by Treatment and Time*

	Estimate	95% CI		<i>p</i>
		Lower	Upper	
Intention-to-treat				
Mean†	0.67	0.56	0.79	—
Tape (versus control)	-0.16	-0.29	-0.00	0.045
Time (10 days)	-0.03	-0.04	-0.01	<0.0001
Pregnancy weight (5 kg)	0.04	0.01	0.06	0.007
Per protocol				
Mean	0.70	0.59	0.83	—
Tape (versus control)	-0.22	-0.36	-0.05	0.015
Time (10 days)	-0.03	-0.04	-0.02	<0.0001
Pregnancy weight (5 kg)	0.04	0.02	0.07	0.001

CI, confidence interval.

*Estimates from a mixed model with a random subject-specific intercept and slope.

†Mean scar volume for women of average weight in the control group at time zero.

an exacerbation of the inflammatory response during wound healing and allowing the more stable, closely woven type I fibers to form their covalent bonds and create a crosslinking pattern that is more comparable to normal skin.

The microporous nature of the paper tape may also exert a degree of scar occlusion.^{26,28} The tape may act in the same way as the stratum corneum in reducing evaporative water loss and restoring homeostasis to the scar by down-regulating fibroblast, collagen, and glycosaminoglycan production, thus shortening the period to scar maturation.^{24,26}

It is often assumed that the erythema of hypertrophic scars is a result of an excess of regenerated microvasculature compared with normal scars. However, Berry et al. found no significant difference between the surface temperature of normal and erythematous scars, indicating that hypertrophic scars do not have an increased blood flow.^{38,39} In addition, they found the transcutaneous oxygen tension of immature scars to be lower than normal skin and suggested hypoxia as the mechanism responsible for the formation of hypertrophic scars.³⁹ A number of studies support this theory and indicate that an excess of endothelial cells created in the granulation phase is responsible for significant microvascular occlusion. The resultant hypoxia is thought to stimulate excessive production of collagen from fibroblasts, with the compartmentalization of fibroblasts between microvascular branches said to be responsible for the charac-

teristic nodular appearance of the hypertrophic scar.^{38,40,41} This process is thought to continue until an eventual excessive loss of oxygen and reduced nutritional supply causes fibroblast death and a release of enzymes important for scar maturation.⁴² It therefore possible that adhesive paper tape also acts to provides light topical pressure that compresses the patent microvessels and accelerates the normal process of fibroblast degradation through hypoxia.⁴²

Complications

The adverse reaction experienced by four patients involved a localized red rash beneath the tape. These reactions were minor and transient and resolved without medical intervention.

Regarding the increased rate of wound infection in the treatment group, we feel it is unlikely that this was caused by the more frequent touching of the scar (with the application of paper tape twice weekly). Paper tape application did not commence until day 5 after surgery, allowing epithelialization of the wound to have occurred. Also, of the three patients in the treatment group who developed infections, one had not commenced use of the paper tape before developing the infection, and another experienced recurrent pelvic pain and infections over a 6-month period, found to be caused by retained products in her uterus.

Limitations of the Study

There are some limitations of this research. Although 70 participants were initially randomized, only 39 completed the study, and the noncompletion rate was higher in the treatment arm. This may be attributable to several reasons. The treatment demands may have been greater than its perceived benefits, given the location of these scars below the level of standard underwear. Stress and the new role of caring for a baby may have acted as a deterrent to participation. The treatment may have been so effective that their scar was no longer of concern, and they therefore were no longer interested in being involved in the study. Strategies that would increase sample size and reduce dropout may include a more substantial recruitment period, a mobile home assessment service for follow-up visits (including a mobile ultrasound), and remuneration for participants attending hospital outpatient visits.

The person completing the subjective rating of scars (as hypertrophic or not hypertrophic) using the international clinical recommendations on scar management¹ was unblinded to treatment. Scars were also independently assessed by

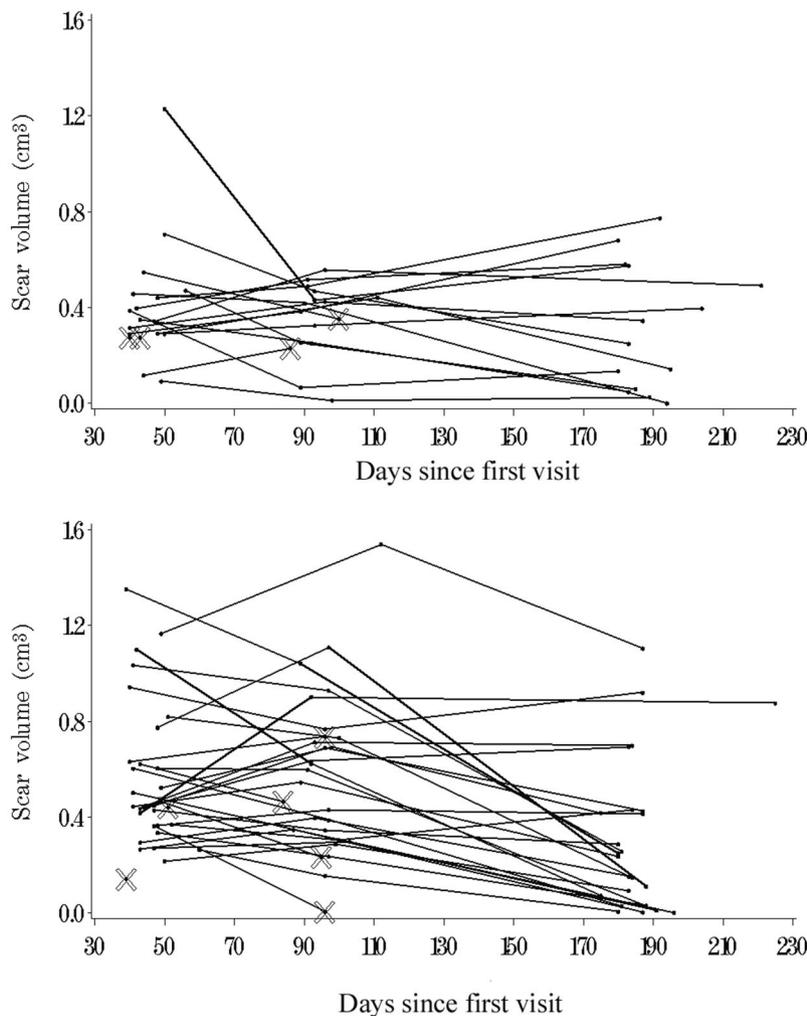


FIG. 3. Scar volume over time in the control and treatment groups. Subjects who dropped out of the trial have their last known scar volume marked with an X.

a radiographer blinded to treatment using ultrasound to determine intradermal scar volume. There was a high correlation between subjective scar rating and intradermal volume ($p < 0.001$), suggesting that the unblinded scar ratings were not affected by bias. Finally, as patients with a history of keloid scarring were excluded from this study, these results cannot predict the efficacy of this treatment in preventing these scars.

CONCLUSIONS

The results of this study provide evidence for the effectiveness of paper tape in reducing scar volume and preventing hypertrophic scar formation following cesarean section surgery. This treatment has applicability to any other surgical incisions, for example, following cardiac, general, orthopedic, and plastic surgery. To ensure success using this treatment, it is recommended that individuals at greater risk

of developing hypertrophic scars should support their scars using paper tape for a longer period of time—until the scar matures. Paper tape is a noninvasive, inexpensive means of preventing hypertrophic scarring and places minimal demands on patients.

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