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Intralesional Cryosurgery for the Treatment of Hypertrophic Scars and Keloids Following Aesthetic Surgery: The Results of a Prospective Observational Study

Yaron Har-Shai, MD, Wifred Brown, MD, FACS, Daniel Labbé, MD, Anne Dompmartin, MD, Irina Goldine, RN, BA, Tamir Gil, MD, Issa Mettanes, MD, and Norbert Pallua, MD

Hypertrophic scars and keloids following aesthetic surgery, which ignite patient dissatisfaction, are difficult to handle. Intralesional cryosurgery for the treatment of such scars has been introduced. This study was designed to evaluate the efficacy of this technology in the treatment of such scars and to assess the reduction of dissatisfaction. Eleven scars (on 11 patients) were treated by intralesional cryosurgery, following breast surgery, otoplasty, face-lifting, and brachioplasty. Each patient scored the concern from the scar and the scar deformity (scale from 1 to 5) prior and following treatment (higher score represents least satisfaction and a severe deformity). The follow-up period was between 3 months and 8 years. The results demonstrated a significant reduction in concern and deformity scores compared with before the cryotreatment (P = .001). The intralesional cryosurgery technique provides the plastic surgeon with an effective instrument to treat hypertrophic scars and keloids following aesthetic surgery, thus reducing the dissatisfaction of patients.

Keywords: intralesional cryosurgery; hypertrophic scars; keloids; aesthetic surgery

Keloids and hypertrophic scars are an abnormal healing response of injured skin, causing impaired quality of life, severe psychological and physical disturbances, and aesthetic disfigurement. Several studies have shown the incidence of emotional disturbances in connection with aesthetic surgical procedures of up to 47.7% in Japan and 50% in France.[1] Patients undergoing elective aesthetic surgery have higher anxiety scores in comparison with patients undergoing plastic reconstructive surgery. Bock et al[2] reported on 2 scales, that is, "psychological impairment" and "physical impairment," in which both keloids and hypertrophic scars were found to have caused significant impairment of quality-of-life factors. In the plastic surgery literature only scant data exist concerning the prevalence of hypertrophic scars and keloids following aesthetic surgery. Baker and Converse[3] reported the development of keloid scars following protruding ear surgery with an incidence of 11% in the African American population compared with 2.1% in Caucasians. Leist[4] demonstrated that following face-lift surgery, 11.8% of the 119 patients had complaints regarding scars.

It seems reasonable to state that the development of hypertrophic scars and keloids following

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aesthetic surgery often leads to patient dissatisfaction and subsequent unfavorable psychological reactions.[5] An intralesional cryosurgery method for the treatment of hypertrophic scars and keloids was recently introduced.[6-9] The results of a prospective nonrandomized observational study of procedures using an intralesional cryosurgery needle and technique are presented in this report. We assessed the reduction of dissatisfaction among patients included in this study population.

Materials and Methods

A novel intralesional cryoneedle (CryoShape, FDA and CE approved, Etgar Group International Ltd, Kfar Saba) was used in this study[6-9] (Figure 1). This probe consists of an elongated double-lumen uninsulated needle with a safety vent and a sharp-cutting, sealed, distal tip, which is designed to enhance the penetration of the often hard, rubbery, and dense hypertrophic scars and keloids. The proximal end of the cryoprobe is connected via an elongation tube to a cryogen source. Liquid nitrogen is pressurized to circulate through the needle, which leads to an ice ball forming around the cryoneedle leaving the abutting scar tissue completely frozen.

Patients

Intralesional cryosurgery treatment was done on 11 patients, with a total of 11 scars, following aesthetic surgery: reduction mammoplasty (1), mastopexy (1), otoplasty (4), face-lifting (3), gynecomastia repair (1), and brachioplasty (1). Patients' personal details and details regarding gender, age, type of aesthetic surgery and location of the hypertrophic scars/keloids, duration of the scars, previous scar therapy, and the follow-up period following the cryotreatment are presented in Table 1. In Israel, this study was done with the approval of the hospital ethical committee. Because the intralesional cryosurgery technology has been approved by the FDA and CE, the patients included in this study gave signed informed consent. Four plastic surgeons, all coauthors of this report, carried out the treatment described in the following sections.

Method

The skin surface of the scar was cleansed with disinfecting solution and draped, with the patient lying in a supine position. The area of penetration into the scar and the underlying subcutaneous tissue were anesthetized locally, using a translesional approach (Figure 2), with bupivacaine hydrochloride 0.5% (marcaine). Thereafter, the sterile cryoprobe was forced into the long axis of the scar in a forward rotary movement, which is parallel to the skin surface. The cryoneedle was inserted at the core of the scar aiming to be at the midheight point of the scar. The scar itself was grasped between the index and thumb of the other hand until the sharp tip of the needle penetrated the opposite distal edge of the scar, thus maximizing the volume of scar tissue to be frozen. Attention was taken to prevent any penetration of the cryoneedle into uninvolved healthy surrounding skin. Sterile gauzes were placed under the proximal and distal parts of the cryoprobe, and care was taken to ensure that the vent nostril was positioned away from the patient to prevent accidental freezing of adjacent skin or tissue.

The proximal part of the probe was connected via an elongation tube to the cryogun (Brymill Cryogenic Systems, Ellington, CT), which was filled with liquid nitrogen to three fourths of the cryogen volume; this was done about 30 minutes beforehand to allow sufficient pressure to build up inside it (about 0.7 atm or 10 psi). The cryogun was placed on a steady surface taking care to avoid any direct contact with the patient's body. By activating the

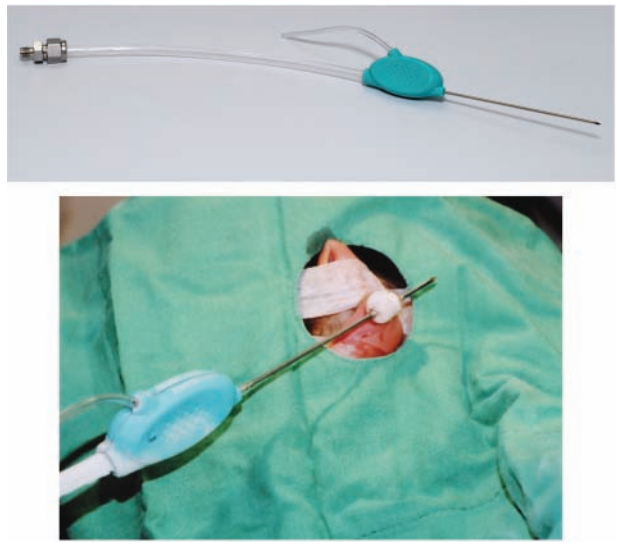

Figure 1. Upper: the CryoShape cryoprobe. Lower: intraoperative view of the intralesional cryosurgery technique using the CryoShape for the treatment of a left helical keloid.

Table 1. Patients' Data: Patient Personal Details, Gender, Age, Type of Aesthetic Surgery, and Location of the Hypertrophic Scars/Keloid, Duration of the Scars, Previous Scar Therapy, and the Follow-Up Period Following the Intralesional Cryosurgery Treatment

Patient (n)	Gender (M/F)	Initials	Age (years)	Duration of Scars (Years)	Aesthetic Procedure	Scar Location	Previous Scar Therapy	Time of Follow-Up (months)	Intralesional Cryosurgery Sessions (n)	Concern[a]		Deformity[b]	
										Pretreatment	Posttreatment	Pretreatment	Posttreatment
1[c]	F	HN	49	4	Face-lift	Retroauricular	EXC, ST, SIL	4	1	5	3	5	4
2[c]	F	EZ	62	1	Face-lift	Retroauricular	ST, SIL	4	1	4	2	4	2
3	M	LY	16	3	Otoplasty	Posthelix	ST	10	1	5	1	5	1
4	M	AN	23	5	Otoplasty	Posthelix	EXC × 2, ST, SIL	60	4	5	1	5	1
5	F	LT	53	2	Face-lift	Retroauricular	ST	22	1	5	1	5	1
6	M	FO	22	1.5	Gynecomastia	Lower nipple	ST	60	1	5	1	5	1
7	F	BN	46	3	Reduction mammoplasty	Lateral inframammary	ST, SIL	72	1	5	1	5	1
8	M	CA	18	1	Otoplasty	Retroauricular	ST, CC	96	1	5	1	5	1
9[d]	M	BV	30	2	Otoplasty	Retroauricular	EXC	6	1	4	1	5	2
10[e]	F	SS	42	0.5	Mastopexy	Periareolar	SIL	6	1	5	2	5	3
11[e]	F	BR	36	0.3	Brachioplasty	Right medial arm	—	6	1	5	3	5	3
Median months								10					
P value											.001		.001

NOTES: ST = intralesional steroids; EXC = surgical excision; SIL = silicone gel/sheeting; CC = contact cryosurgery.

[a]Patient concern from the scar (on a scale from 1 to 5) prior to and following intralesional cryosurgery (higher score represents least satisfaction).

[b]Patient evaluation of scar deformity (on a scale from 1 to 5) prior to and following intralesional cryosurgery (higher score represents severe deformity).

[c]Intralesional cryosurgery executed at Aachen, Germany.

[d]Intralesional cryosurgery executed at Caen, France.

[e]Intralesional cryosurgery executed at Middlebury, Connecticut.

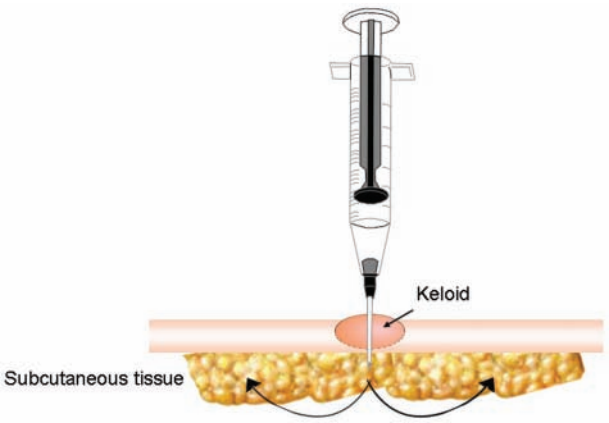

Figure 2. A schematic diagram demonstrating the translesional technique to achieve local anesthesia prior to inserting the cryoneedle probe into the scar.

cryogun trigger, the pressure valve is opened and the cryogen enters the cryoneedle, thereby freezing the scar. A forced steam of the liquid nitrogen gas flows out from the vent nostril during the entire freezing process. The strength of the steam flow is an approximation of the working pressure; this steam was observed by the naked eye during the entire freezing procedure. Two ice balls appeared shortly at the 2 cryoprobe penetration sites, and with time, they gradually spread toward each other until the scar was complete frozen clinically. Following the complete freezing of the scar, regardless of the duration of the cryosurgery process, the cryogun trigger was released to stop the freezing process, and the cryoneedle was left to thaw for 1 to 2 minutes after which it was withdrawn in a reverse rotary movement. After a complete thawing of the scar was observed, the bleeding from the penetration points of the needle was treated with a sterile dressing. The patients were instructed to wash the treated scar daily and apply an antibiotic ointment until full healing occurred. In cases where the scar was longer than the cryoneedle or very wide, 2 or 3 successive insertions of the same needle were necessary to freeze the entire keloid in the same session.

To evaluate patient dissatisfaction prior to and after the intralesional cryosurgery treatment, a modified Gorney Gram Scale was used. This modified scale was designed and used by the authors to assess the patient's degree of concern and the deformity from his/her keloid or hypertrophic scars. In the original Gorney Gram,[10] the deformity is judged by the surgeon, whereas the degree of concern is scored by the patient. In this modified scale, patients were asked to score both parameters: Every patient was asked to describe in words and thereafter to score his/her concerns about the scar on a scale from 1 to 5 prior to and following the treatment. A higher score is associated with a lower level of satisfaction.

For the second parameter, every patient was asked to describe in words and thereafter to score the magnitude of his/her scar deformity (on a scale from 1 to 5) prior to and following the treatment (higher score represents severe deformity).

Statistical Evaluation

Preoperative and postoperative clinical scores of concern and deformity regarding the scars were compared using the Wilcoxon signed ranks test. The Mann-Whitney test was used to compare the clinical scores of concern and deformity between patients with short postoperative periods (up to 10 months) and patients with long follow-up (more than 10 months). *P* values less than .05 were considered statistically significant.

Results

Results are presented in tabular form in Table 1 and 2 and in Figures 3 to 8. The median follow-up was 10 months (range 4-96).

The concern score at the end of the follow-up was significantly lower prior to cryosurgery ($P = .001$), and the median (range) of change in the concern score was −4 (−4 to −2); thus 6 (55%) had a 4-point decrease, 2 (18%) had a 3-point decrease, and 3 (27%) had a 2-point decrease.

The deformity score at the end of the follow-up was significantly lower than that before cryosurgery ($P = .001$), and the median (range) of change in the deformity score was −4 (−4 to −1); thus, 6 patients had a decrease in score of 4 points, 2 had a decrease of 3 points, 2 had a decrease of 2 points, and 1 had a decrease of 1 point.

Patients with a long postoperative period (greater than 10 months) had a larger decrease in concern and deformity than patients with a short postoperative period (up to 10 months; $P = .004$ in both scales); that is, the 6 patients who were followed for at least 10 months had a 4-point decrease

Figure 3. Patient number 10. Left: periareolar hypertrophic scars following mastopexy (concern, 5; deformity, 5). Right: a follow-up of 5 months following a single session of intralesional cryosurgery demonstrates flatter and softer scars (concern, 2; deformity, 3).

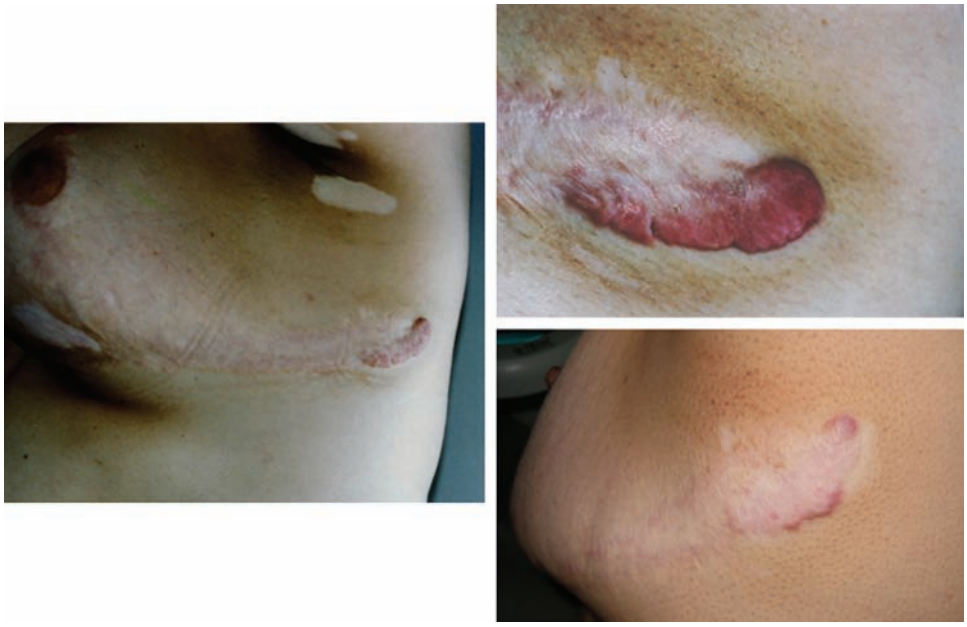

Figure 4. Patient number 7. Left and upper right: keloid at the left lateral horizontal scar following reduction mammoplasty (concern, 5; deformity, 5). Right lower, 4 years after applying a single session of intralesional cryosurgery, the scar is flat and asymptomatic (concern, 1; deformity, 1).

in both concern and deformity scores, whereas the 5 patients followed for 4 or 6 months had a median decrease of 2 (range −3 to −1) in their concern and deformity scales (Table 2).

Discussion

The aim of this study was to evaluate the intralesional cryosurgery technique in terms of the patient's own appreciation of concerns and deformities after scar treatment. The method used was prospective and nonrandomized. For evaluation, patients were asked to score concerns and deformity using a modified Gorney Gram. The advantage of this approach is that the patient's appreciation is realized. The results showed that both patients' concerns and patients' assessment of their deformities (scar) decreased statistically significantly at the end of the surgical process, as presented in the preceding section. It was also observed that there was a significant decrease in both these parameters in patients who had a long follow-up. These data suggest that

Figure 5. Patient number 4. Left: severe keloid on the posterior helical sulcus following right otoplasty. Previous 2 surgical excisions were executed followed by a complete recurrence (concern, 5; deformity, 5). Right: 5 years following 4 sessions of intralesional cryosurgery. The scar is flat and asymptomatic (concern, 1; deformity, 1).

Figure 6. Patient number 3. Left: hypertrophic scar on the posterior auricular aspect following right otoplasty. Previous treatments with intralesional steroid injections had failed (concern, 5; deformity, 5). Right: 10 months following a single session of intralesional cryosurgery, the scar is flat and asymptomatic (concern, 1; deformity, 1).

Figure 7. Patient number 8. Left: hypertrophic scar on the posterior auricular aspect following left otoplasty (concern, 5; deformity, 5). Right: 8 years following a single session of intralesional cryosurgery, the scar is flat and asymptomatic (concern, 1; deformity, 1).

Figure 8. Patient number 5: Left: keloid on the right posterior-auricular and occipital aspect following cervicofacial lift. Previous treatments with intralesional steroid injections had failed (concern, 5; deformity, 5). Right: 22 months following a single session of intralesional cryosurgery, the scar is flat and asymptomatic (concern, 1; deformity, 1).

there is an inherent value for this technique.[11] We have previously reported that the intralesional cryosurgery technique reduced scar volume, hardness, color, and subjective symptoms of pain and tenderness, itching, and discomfort.[6-8]

We took care to minimize pain and discomfort during and following the intralesional cryosurgery technique. There was no evidence of infection in any of the patients in this study. This also speaks in favor of the technique, though we cannot offer any scientific explanation. We speculate that the cryosurgery insult creates an immunological response, which plays a significant role in the prevention of possible wound infection.[12,13]

The thermal history of the skin surface during the intralesional cryosurgery technique provides a

Table 2. Pre-cryosurgery and Post-cryosurgery Concern and Deformity Scores and the Median (Range) Change From Pre-cryosurgery to Post-cryosurgery

	Pre-cryosurgery	Post-cryosurgery[a]	Change
Concern score	5 (4 to 5)	1 (1 to 3)	−4 (−4 to −2)
Deformity score	5 (4 to 5)	1 (1 to 4)	−4 (−4 to −1)

[a]Evaluated at end of follow-up.

better survival environment for the melanocytes, thus producing less permanent hypopigmentation and disfigurement.[8,9] Experience suggests that hypertrophic scars and keloids of black/darker-colored skin exhibit less depigmentation following intralesional cryosurgery when compared with the contact method.[8] These findings may encourage the use of intralesional cryosurgery for dark-skinned individuals[14] suffering from such scars following aesthetic surgery, thus minimizing the depigmentation problem, though more controlled studies are necessary to conclude with confidence.

We are excited about the potential of this technique. We are also aware of the limitations of this study, which was small, prospective, nonrandomized, and lacking in control. However, the problem of treating hypertrophic scars and keloids is complex. The final goal of the treatment of hypertrophic scars and keloids is a complete and entire flattening of the scar, which is acceptable to both patients and clinicians. Further studies are required to determine the full potential of this technique to treat scars and keloids of different sizes and on different locations on the body.

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