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Intralesional Cryosurgery to Treat Keloid Scars: Results from a Retrospective Study

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Key Words
Keloid scars · Cryosurgery · Intralesional cryosurgery

Abstract
Background: A variety of treatment modalities have been proposed to treat keloid scars, but outcomes are often disappointing. Intralesional cryosurgery may significantly reduce these scars. ***Objective:*** To evaluate the clinical safety and efficacy of intralesional cryosurgery to treat keloid scars. Feedback from patients on pain, pruritus and aesthetic discomfort was recorded before and after treatment. ***Methods:*** A total of 10 patients with 14 keloid scars resistant to conventional treatments were enrolled in a retrospective study between October 2007 and October 2013. The efficacy of this treatment was evaluated by measuring the reduction in scar surface. ***Results:*** Scar surface was reduced by an average of 58.5% after intralesional cryosurgery treatment for all scars (average pre-operative keloid scar surface: 874.6 ± 954.1 mm^2; average post-operative keloid scar surface: 505.8 ± 1,024.7 mm^2; $p = 0.002$). Pain and aesthetic discomfort were significantly decreased after treatment in all patients ($p = 0.008$ and $p = 0.012$, respectively). ***Conclusion:*** Our data suggest that intralesional cryosurgery is an effective treatment for keloids.

Introduction

Keloid scars are benign dermal fibro-proliferative tumours that are a result of abnormal healing after injury [1]. They occur in predisposed individuals and represent the response of connective tissue to trauma, inflammation, surgery or burns [2]. Keloids are often symptomatic, with frequent pruritus and pain, and may have a major social and psychological impact on affected patients [3]. They occur more frequently on the shoulders, chest, earlobes, upper arms and cheeks, although the reason for this distribution is unknown [4]. Keloids are a real health care challenge as numerous treatments, including surgical excision, intralesional corticosteroid injections, radiotherapy, laser therapy, cryotherapy and cryosurgery, are often disappointing [5]. An intralesional cryosurgery method has recently been developed to treat keloids [6–9]. Our study was designed to determine the clinical safety and efficacy of the intralesional cryoneedle method to treat keloid scars in 10 patients.

Patients and Methods

Patients and Protocol

This retrospective study was performed between October 2007 and October 2013 in the Dermatology Department of Caen University Hospital (France).

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Table 1. Patient characteristics and responses to intralesional cryosurgery

Patient No.	Age/ gender	Ethnic group	Duration of scar, years	Scar location	Previous scar therapy	Time of follow-up, months	Intralesional cryosurgery sessions, n	Reduction of surface category	Predisposing factor
1	31/M	Caucasian	2	retroauricular	EXC, ST, SIL	72	1	1	otoplasty
2	21/F	Caucasian	5	trunk	EXC, ST	36	3	2	surgery
3	42/M	African	3	retroauricular	EXC, ST	24	3	1	piercing
4	62/F	Caucasian	5	retroauricular	EXC, ST	18	1	1	piercing
5	39/F	Caucasian	4	retroauricular	ST	48	3	1	piercing
6	38/F	Caucasian	3	post-helix	EXC, ST	24	1	1	piercing
7	70/M	African	10	trunk	EXC, ST	24	3	3	surgery
8	14/M	Asian	2	trunk	EXC, ST	24	2	2	spontaneous
9	33/M	African	6	face	EXC, ST	18	1	1	shearing
10	22/F	African	3	trunk	ST	10	1	2	acne
Average number	37.2±17.7	–	4.3±2.4	–	–	29.8±18.1	1.9±0.9	–	–

Reduction of surface category: 1 = ≥61%, 2 = 21–60%, 3 = ≤20%. M = Male; F = female; ST = intralesional steroids; EXC = surgical excision; SIL = silicone gel.

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Fig. 1. The CryoShape cryoprobe, an elongated double-lumen uninsulated needle connected to a cryogen source.

Patients with keloid scars of more than 2 years' duration and with failed conventional treatments were eligible for inclusion. They were generally seeking a new treatment and all patients accepted a minimum follow-up period of 18 months.

A total of 10 patients with 14 keloid scars were included in this study; 6 patients had 1 keloid and 4 patients had 2. All patients had thick keloids except for a 70-year-old patient who had 2 extensive flat keloids on the trunk.

The characteristics of the patients are presented in tables 1 and 2, and measurements of the scar surface areas before and after treatment are shown in table 3. Patients were followed up every 6 months after treatment. At each evaluation, the scars were measured and photographed. The lesions were evaluated clinically by two investigators (A.D. and M.C.). The surface area of the keloid was calculated by measuring the two largest diameters of the raised part of the scar. The main objective of this study was to evaluate the efficacy of intralesional cryosurgery by measuring the reduction in scar surface area. The reduction in scar surface area was divided into the following three categories (table 1): (1) ≥61% reduction in surface area (good), (2) 21–60% reduction in surface area (moderate) and (3) ≤20% reduction in surface area (failure). The secondary objective of this study was to evaluate the patients' feedback related to their keloids. Factors assessed by a questionnaire before and after treatment were pain, pruritus and aesthetic discomfort (table 4). Aesthetic discomfort included the thickness and softness of the lesion. Pain was measured using a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worst pain) and divided into three categories, as follows: severe = VAS between 7 and 10, moderate = VAS between 3 and 6 and mild = VAS between 0 and 2. Pruritus and aesthetic discomfort were also divided into three categories: severe, moderate and none. This assessment was performed before treatment, 1 month after treatment and during the follow-up at 6, 12 and 18 months.

Methods

A novel intralesional (FDA and CE approved) cryoneedle (CryoShape; Etgar Group International Ltd., Kfar Saba, Israel) was used in this study (fig. 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 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 the formation of an ice ball around the cryoneedle, leaving the surrounding scar tissue completely frozen.

The surface skin of the scar was disinfected. The area of penetration into the scar and the underlying subcutaneous tissue were anaesthetized locally with 1% lidocaine. The sterile cryoprobe was

Table 2. Statistics of the subgroup of auricular keloids

	Auricular keloids (n = 5)	Other locations (n = 5)	p
Continuous variables			
Age, years	39 (38–42)	22 (21–33)	0.39
Number of scars	1 (1–2)	1 (1–2)	1.00
Duration of scar, years	3 (3–4)	5 (3–6)	0.26
Time of follow-up, months	24 (24–48)	24 (18–24)	0.21
Number of intralesional cryosurgery sessions	1 (1–3)	2 (1–3)	0.77
Surface of first scar, mm^2	600 (450–600)	900 (875–1,350)	0.14
Categorical variables			
Gender			
Male	2 (40)	3 (60)	1.00
Female	3 (60)	2 (40)	
Previous scar therapy			
EXC, ST	3 (60)	4 (80)	1.00
ST	1 (20)	1 (20)	
EXC, ST, SIL	1 (20)	0 (0)	
Predisposing factor			
Otoplasty	1 (20)	0 (0)	0.03
Surgery	0 (0)	2 (40)	
Piercing	4 (80)	0 (0)	
Spontaneous	0 (0)	1 (20)	
Shearing	0 (0)	1 (20)	
Acne	0 (0)	1 (20)	
Reduction of scar surface, %	73.8 ± 15.738	40.4 ± 25.156	0.036

Values are presented as medians (with IQR), numbers (with percentages) or means + standard deviations. ST = Intralesional steroids; EXC = surgical excision; SIL = silicone gel.

Table 3. Scar surfaces before and after treatment with intralesional cryosurgery

Patient No.	Number of scars	S_1 before treatment, mm^2	S_2 before treatment, mm^2	S_1 after treatment, mm^2	S_2 after treatment, mm^2
1	2	450	500	0	70
2	1	1,350	–	600	–
3	1	600	–	225	–
4	1	600	–	210	–
5	2	250	70	96	25
6	1	875	–	200	–
7	2	4,000	600	4,000	600
8	1	900	–	360	–
9	2	875	375	300	0
10	1	800	–	320[a]	–

S_1: surface of the scar (n = 10 patients). S_2: surface of a second scar (n = 4 patients). S_1 and S_2 after treatment: at 1, 6, 12 and 18 months and at the end of follow-up.

[a] Follow-up of this patient: 10 months.

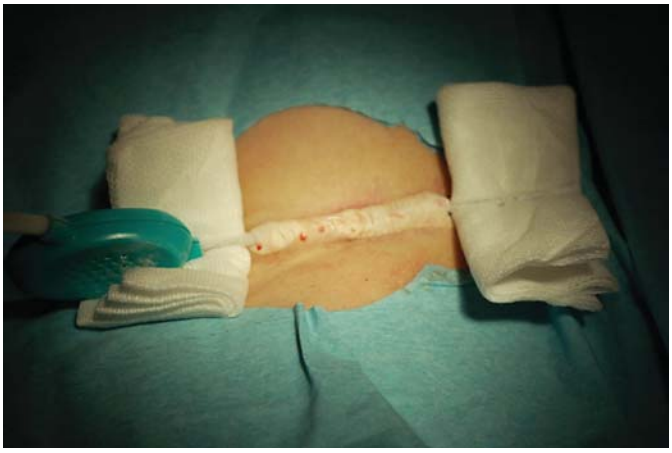

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Fig. 2. Peri-operative view of the intralesional cryosurgery technique using the CryoShape cryoprobe to treat a keloid. Frozen scar at the end of the procedure.

then inserted into the long axis of the scar in a rotary movement parallel to the skin surface. The 14-gauge cryoneedle was inserted into the core of the scar and was aimed at the mid-height point of the scar. The scar itself was held between the index and thumb of the other hand until the sharp tip of the needle penetrated to the opposite distal edge of the scar, thus maximizing the volume of scar tissue to be frozen. Precaution focused on preventing any penetration of the cryoneedle into uninvolved healthy surrounding skin. Sterile gauzes were placed under the proximal and distal parts of the cryoprobe, and the nostril vent 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 connected to the cryogun (Brymill Cryogenic Systems, Ellington, Conn., USA), which was filled with liquid nitrogen to 75% of cryogen volume. This was done about 30 min beforehand to allow sufficient pressure to build up inside (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 cryogun trigger, the pressure valve was opened and the cryogen entered the cryoneedle, thereby freezing the scar. A forced stream of liquid nitrogen gas flowed out from the nostril vent during the entire freezing process. The strength of the stream flow was an approximation of the working pressure; this stream could be observed by the naked eye during the entire freezing procedure. Two ice balls appeared shortly at the two cryoprobe penetration sites and, with time, they gradually spread towards each other until the scar was clinically completely frozen (fig. 2). Following 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 1–2 min, after which it was withdrawn in a reverse rotary movement. After complete thawing of the scar was observed, the small amount of bleeding that occurred from the penetration points of the needle was covered with a sterile dressing. The patients were instructed to wash the treated scar daily and to apply an antibiotic ointment until full healing occurred.

Table 4. Patient feedback before and after intralesional cryosurgery

Patient No.	Age/ Gender	Before treatment			After treatment		
		pain	pruritus	aesthetic discomfort	pain	pruritus	aesthetic discomfort
1	31/M	severe	severe	severe	mild	none	none
2	21/F	moderate	moderate	severe	mild	none	moderate
3	42/M	moderate	moderate	severe	mild	none	none
4	62/F	severe	severe	severe	mild	none	none
5	39/F	mild	none	severe	mild	none	none
6	38/F	moderate	moderate	severe	mild	none	none
7	70/M	severe	severe	severe	mild	none	severe
8	14/M	moderate	moderate	severe	mild	none	moderate
9	33/M	moderate	moderate	severe	mild	none	none
10	22/F	moderate	none	severe	mild	none	moderate

M = Male; F = female. Pain (VAS): severe = VAS between 7 and 10, moderate = VAS between 3 and 6, mild = VAS between 0 and 2.

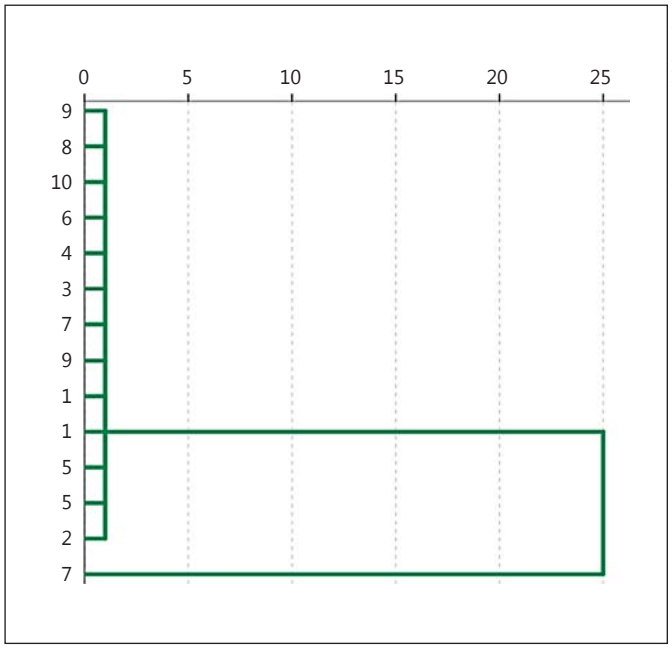

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Fig. 3. Dendrogram of scar surfaces before and after treatment (patients numbered from 1 to 10).

An analgesic treatment was given at the end of the intralesional cryosurgery. Depending on the response, the intralesional cryosurgery was repeated at intervals of 3–4 weeks to a maximum of 3 sessions.

Statistical Analyses

Statistical analyses were conducted using SPSS IBM version 20.0 software. The scar surfaces before and after treatment were compared using the Wilcoxon signed-rank test for pairs. Pruritus, pain and aesthetic discomfort before and after treatment were compared using the McNemar test with Yates' correction. A two-tailed value of $p < 0.05$ was considered statistically significant. To check whether there were differences between patients who had 1 scar and patients who had 2 scars, we performed a hierarchical cluster analysis by taking into account the measurements before and after treatment. This method showed that all measures could be considered homogeneous except for 1 patient who had 2 scars (fig. 3). This patient had the largest scar surface. We analysed the data from patients with 1 scar, patients with 2 scars and also the overall combined data.

Results

Patients

A total of 14 keloid scars on 10 patients (5 women and 5 men) were treated by intralesional cryosurgery. The mean age of the patients was 37.2 ± 17.7 years (range: 14–70) and the duration of keloids ranged from 2 to 10 years (average: 4.3 ± 2.4 years).

The follow-up period was between 10 and 72 months (average: 29.8 ± 18.1 months). Of the entire group, 6 patients had 1 keloid and 4 patients had 2. Overall, 5 of the patients were Caucasian, 4 were African and 1 was Asian.

Of the 10 patients, 8 had been previously treated by surgery associated with intralesional injection of corticosteroids; 2 patients have been treated by intralesional injection of corticosteroids alone because they refused surgery.

In detail, 4 patients had retro-auricular keloids, 1 patient had a post-helix scar, 4 patients had keloids on the trunk, and 1 patient presented with 2 keloids on the face (table 1).

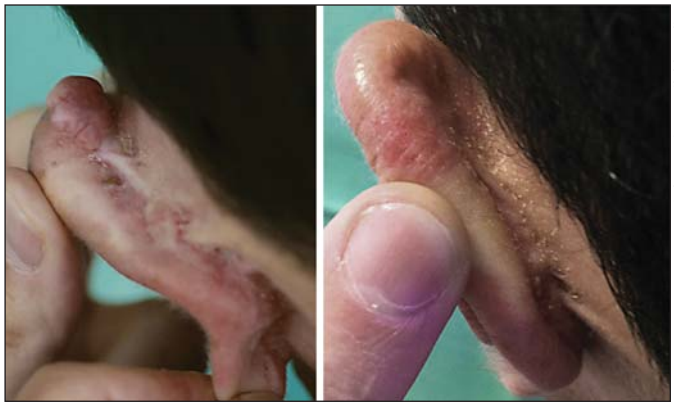

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Fig. 4. Patient No. 1. Keloid on the posterior helical sulcus after otoplasty, before and after a single session of intralesional cryosurgery.

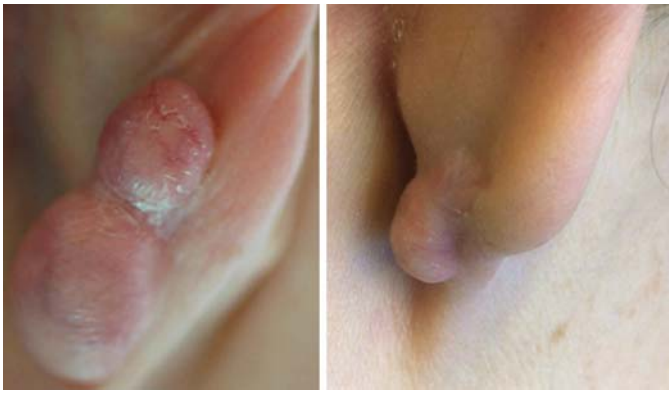

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Fig. 5. Patient No. 5. Keloid on the right ear lobe before and after 3 sessions of intralesional cryosurgery.

Reduction of Scar Surface Area

The mean initial scar surface area of the keloids was 874.6 ± 954.1 mm^2 (range: 70–4,000). The time needed to achieve complete freezing of the keloids was between 10 and 30 min, depending on the volume of the scars.

Classified as category 1, 6 of the 10 patients achieved >60% reduction of scar surface area after 1–3 sessions of therapy and showed no signs of recurrence during the 18–72 months of follow-up (table 1, fig. 4, 5). In this category, 5 patients had keloids on their ears and 1 patient had facial keloids (tables 1, 2). Classified as category 2, 3 patients with keloids on the trunk showed 40–56% reduction of scar surface area after 2–3 sessions of therapy, with no recurrence during the 10–36 months of follow-up. Classified as category 3, 1 patient with 2 keloids on the trunk had treatment failure with no reduction in keloid surface area after 3 sessions (table 1, fig. 6).

An average of 58.5% of scar surface area reduction was obtained after intralesional cryosurgery treatment for all scars (average pre-operative keloid scar surface area: 874.6 ± 954.1 mm^2; average post-operative keloid scar surface area: 505.8 ± 1,024.7 mm^2; p = 0.002). Treatment of the 6 patients with 1 scar had an average of 56.7% scar surface reduction (average pre-operative keloid scar surface area: 854.2 ± 275.9 mm^2; average post-operative keloid scar surface area: 331.7 ± 145.6 mm^2; p = 0.027). The 4 patients with 2 keloids had 59.9% scar surface reduction (average pre-operative keloid scar surface area: 890.0 ± 1,278.9 mm^2; average post-operative keloid scar surface area: 636.4 ± 1,374.5 mm^2; p = 0.028; tables 5, 6). In the subgroup of ear keloids, we obtained an average of 73.8% of scar surface reduction after intralesional cryosurgery (p = 0.036; table 2).

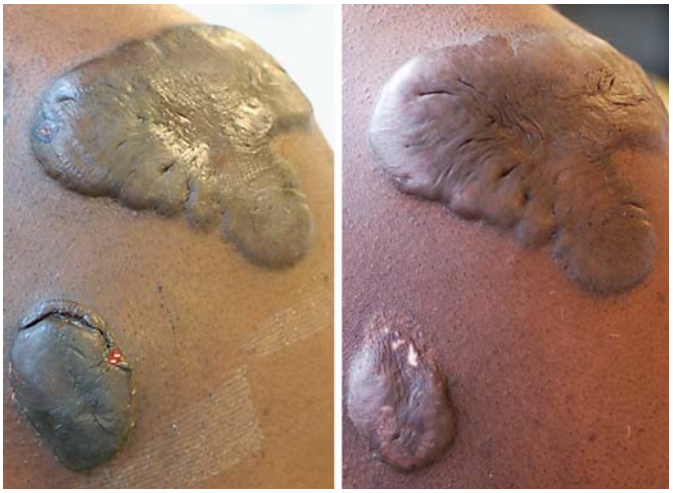

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Fig. 6. Patient No. 7. A patient with treatment failure with 2 flat scars on his back and no definitive hypopigmentation.

Patient Feedback

Pain and aesthetic discomfort had significantly decreased at 1 month after the first session of treatment (p = 0.008 and p = 0.012, respectively). All our patients had no pruritus after treatment; 8 of the 10 patients were relieved of this symptom and 2 of them had no pruritus before and after treatment (nonsignificant; p = 0.480; table 7).

Side Effects

A total of 5 patients with black skin developed moderate temporary post-inflammatory hypopigmentation

Table 5. Average keloid scar surface area before and after treatment with intralesional cryosurgery

Scar surface, mm^2	Patients with 1 scar (n = 6)	Patients with 2 scars (n = 4)	All patients (n = 10)
Before treatment	854.2±275.9	890.0±1,278.9	874.6±954.1
After treatment	331.7±145.7	636.4±1,374.5	505.8±1,024.7
p	0.028	0.028	0.002

Values are presented as means ± standard deviations.

Table 6. Average reduction in scar surface area after intralesional cryosurgery

	6 patients with 1 scar (n = 6)	4 patients with 2 scars (n = 8)	All scars (n = 14)
Reduction, %	56.7±14.6	59.9±39.9	58.5±30.7
p	0.027	0.027	0.002

Values are presented as means ± standard deviations.

Table 7. Patient feedback on the distribution of pruritus, pain, and aesthetic discomfort before and after intralesional cryosurgery treatment

	Before treatment		After treatment		p
			yes	no	
Pruritus	yes	8 (80)	0 (0.0)	8 (80.0)	0.480
	no	2 (20)	0 (0.0)	2 (20.0)	
Pain	yes	9 (90)	0 (0.0)	9 (90.0)	0.008
	no	1 (10)	0 (0.0)	1 (10.0)	
Aesthetic discomfort	yes	10 (100)	4 (40.0)	6 (60.0)	0.012
	no	0 (0)	0 (0.0)	0 (0.0)	

Values are presented as numbers (with percentages). The McNemar test with Yates' correction was used.

along the tracks of the needle, which disappeared after a few months (fig. 6, 7). During the 10–72 months of follow-up, no recurrence, bleeding, infection or permanent hypopigmentation occurred.

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Fig. 7. The temporary post-inflammatory hypopigmentation after treatment.

Discussion

In 1982, Shepherd and Dawber [8] were the first to report that contact cryosurgery, as a monotherapy, was an effective treatment for hypertrophic scars and keloids. After a single cryosurgical session, they obtained 80% improvement but a high recurrence rate of 33%. Since then, other studies have reported that keloids can be treated effectively with contact cryosurgery, with transient side effects such as the formation of blisters and local oedema but also a significant risk of long-term hypopigmentation [9, 10]. Recently, Litrowski et al. [11] reported that the combination of surgical excision and contact cryosurgery can effectively treat large keloids of the ears.

Intralesional cryosurgery was first developed by Weshahy [12], using one or more curved hypodermic needles introduced into the skin and inserted through the deeper part of a cutaneous lesion. The cryogen is passed through the lumen and exits to the atmosphere from the other end of the needle. Zouboulis [13] and Gupta and Kumar [14] modified this technique to treat keloids and hypertrophic scars by using a 20- to 18-gauge hypodermic/lumbar-puncture needle. Then, Har-Shai et al. [6] used a newly developed intralesional cryoneedle, which consists of an elongated double-lumen uninsulated needle (CryoShape; Etgar Group International Ltd.). This 14-gauge, stainless steel needle has a sharp-cutting, sealed, distal tip that enhances penetration into the hard, rubbery hypertrophic scar without the need for a stylet and causes less tissue trauma than might occur with an open cutting tip [6, 7]. The inbuilt cryogen safety vent situated at the proximal end of the needle enables the creation of a uniform ice cylinder along the entire length of the needle and prevents direct spillage of liquid nitrogen onto the surrounding normal skin, which might occur with open-tip needles [15, 16].

The main advantage of intralesional cryotherapy compared to contact and spray techniques is its minimal sur-

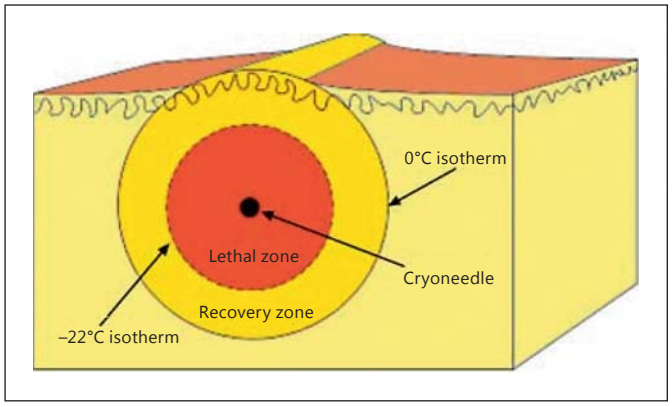

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Fig. 8. Ice ball induced by the intralesional cryoneedle. The interface between the ice ball and the unfrozen tissue represents the 0°C isotherm. The volume of tissue located between the –22°C isotherm and contact probe is the lethal zone in which cells undergo cryonecrosis. Cells situated in the warmer region, between –22°C isotherm and the 0°C isotherm (recovery zone), generally survive the freeze.

face destruction and the large volume of frozen scar tissue that can be treated. Its benefit lies in freezing excess fibrous tissue. The area frozen by cryosurgery can be divided into a lethal zone, in which the temperature is lower than –22°C, and a recovery zone, with temperatures of between 22 and 0°C (fig. 8). Cells within the lethal zone undergo cryonecrosis, whereas cells situated in the recovery zone generally survive the freeze. In surface cryosurgery, the lethal zone includes the surface epithelium but not the dermis, which is the domain of the main pathological disorder. In this manner, the dermis is within the recovery zone and thus survives freezing. The intralesional cryoneedle is inserted directly into the dermis of the pathological scar, where the ice cylinder surrounding the length of the needle produces a 360°C area lethal zone. The recovery zone is situated toward the epithelium and the subcutaneous tissue. Thus, the surface reactions are minimal and the maximal destruction occurs deep in the lesion, increasing the chances of therapeutic success with less depigmentation because melanocytes can survive in the recovery zone [6].

Our data demonstrate that intralesional cryosurgery is a well-tolerated, reproducible, safe and efficient method to treat keloid scars. We obtained a significant reduction in scar surface areas and in pain and aesthetic discomfort.

The first patients were treated in October 2007 (using the same protocol) but all patients were evaluated in October 2013, thus explaining the relatively long follow-up for some patients (table 1). The results were similar at 1, 6, 12 and 18 months, which shows that maximum efficiency was obtained at 1 month after treatment. The sessions were repeated for 5 patients because clinical improvement was interesting and very encouraging (at least 30% of surface reduction). The patients were satisfied but they had experienced a relapse with previous treatments so they wanted to confirm and improve these first results as the treatment was well tolerated; 3 sessions seemed adequate to obtain optimal results. Only 1 patient (patient No. 7) had 3 sessions, although there was no clinical improvement; this patient was one of our first patients, who had great hope in the results of cryosurgery and really wanted to be sure that it was not efficient. With our experience now, we would not repeat the sessions.

We obtained better results for keloids of the ears (average of 73.8% of surface reduction) compared with other locations (average of 40.4% of surface reduction; table 2). These keloids were nodular, thick and away from the healthy skin. However, it is necessary to have more patients for this to be statistically significant.

Our results are consistent with those of Har-Shai et al. [6], who found an average of 51.4% scar volume reduction when they used intralesional cryosurgery to treat 10 patients with 12 keloid scars ($p < 0.0022$).

During their 18-month follow-up, there was no evidence of bleeding, infection, adverse effects, recurrence or permanent depigmentation.

Weshahy and Abdel Hay [17] showed a significant reduction of volume of 93.5% ($p < 0.01$) in 28 patients with 35 keloid scars 4 months after a single session of intralesional cryosurgery followed by intralesional steroid injections. Gupta and Kumar [14] showed a flattening of more than 75% in 7 of 12 patients with large, bulky and recalcitrant keloids after 6–10 sessions of therapy.

Other studies have confirmed these good results, showing that intralesional cryosurgery reduced scar volume, hardness, colour and subjective symptoms of pain, tenderness, itching and discomfort [15, 16]. Studies have also highlighted the fact that keloids on black skin exhibit less depigmentation following intralesional cryosurgery compared to the contact method [18]. Therefore, this new technique should be considered for dark-skinned patients because it does not cause definitive hypopigmentation. It can be repeated (with minor side effects), unlike intralesional injections of corticosteroids, and can also performed by surgeons and dermatologists in outpatient settings.

We noted 1 treatment failure in a 70-year-old African patient with 2 keloids on the trunk. This may be because the scars were very large and flat and had less relief com-

pared to the scars of other patients (fig. 6). Thus, the lethal zone (–22°C) may have been more difficult to access and the risk of damaging non-fibrotic dermis was greater. In our experience, contact cryosurgery is more successful for flat scars but was not performed on this patient because of the risk of permanent hypopigmentation.

Although these results are interesting, this study has limitations. First, we have included a limited number of patients. Second, the assessment of the results is difficult and subjective.

In conclusion, this preliminary study may encourage the use of intralesional cryosurgery for thick keloids scars, particularly for dark-skinned individuals suffering from large keloids. The outcomes can be rapidly evaluated after 1 month and treatment sessions can be repeated. However, this interesting and innovative treatment needs further large prospective studies in several centres with long follow-up periods to confirm the interesting results of this preliminary study.

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Disclosure Statement

The authors have no conflicts of interest.

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