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A new argon gas-based device for the treatment of keloid scars with the use of intralesional cryotherapy

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Summary *Background:* Intralesional (IL) cryotherapy is a new promising technique for the treatment of keloid scars, in which the scar is frozen from inside. Multiple devices are available, mostly based on a simple liquid nitrogen Dewar system, which have a limited freezing capacity. Argon gas-based systems ensure accurate and highly controlled freezing and have shown to be effective within the field of oncologic surgery. However, this technique has never been used for the treatment of keloid scars.
Objective: This prospective study evaluates an argon gas-based system for the treatment of keloids in a patient population including all Fitzpatrick skin types with a 1-year follow-up.
Methods: Twenty-five patients with 30 keloid scars were included and treated with a device called Seednet (Galil Medical, Yokneam, Israel). Scar quality and possible scar recurrence were assessed before treatment and post treatment (6 and 12 months) with objective devices determining scar color, scar elasticity, scar volume, and patient's skin type. In addition, scars were evaluated using the Patient and Observer Scar Assessment Scale.
Results: After 12 months, a significant volume reduction of 62% was obtained, $p = 0.05$. Moreover, complaints of pain and itching were alleviated and scar quality had improved according to the Patient and Observer Scar Assessment Scale. Scar pigmentation recovered in 62% of all keloid scars within 12 months.

Five out of 30 (17%) scars recurred within 12 months, three of which had previously been treated with liquid nitrogen-based IL cryotherapy. Both recurrent and persistent hypopigmentation were mainly seen in Afro-American patients.
Conclusions: IL cryotherapy with the use of an argon gas-based system proves to be effective in the treatment of keloid scars, yielding volume reduction and low recurrence rates. Although

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hypopigmentation recovered in most cases, it is strongly related to non-Caucasian patients. Finally, additional treatment of keloid scars previously unresponsive to IL cryotherapy is predisposed to a high recurrence rate.

Trial number: NCT02063243.

Introduction

Keloids are tumor-like fibrous nodules, which result from an abnormal healing response of the injured skin. They can greatly reduce the quality of life by causing a cosmetic burden as well as physical complaints of pain and pruritis.[1–4] The treatment of keloid scars is a great challenge, with high recurrence rates and even growth stimulus following treatment as the main problems.[1] Intralesional (IL) cryotherapy is a promising treatment technique in which the scar tissue is frozen from *within* the lesion. It was introduced by Weshahy in 1993 to overcome problems commonly associated with surface or external cryotherapy.[5] Since then, promising results have been released.[6–10]

Multiple devices are available for the use of IL cryotherapy, most based on a simple Dewar cylinder, in which liquid nitrogen is stored. The scar is frozen from inside by a hollow cryoneedle, which is attached to the Dewar cylinder through an elongation tube allowing liquid nitrogen to be passed through the needle.

Our experience in clinical practice has shown the freezing capacity of these devices to be limited, occasionally resulting in elongated freezing times and even in dysfunctional treatments. This not only is undesirable from a therapeutic point of view but also resulted in traumatic experiences for the patients, since in those cases, (local) anesthesia had already been administered.

Argon gas-based systems relying on the Joule–Thomson effect require no precooling (as opposed to the available liquid nitrogen devices) and offer controlled and accurate freezing.[11] Freezing is induced through the rapid expansion of argon gas through a small valve situated at the tip of the needle. Clinically, these systems are well integrated and showed excellent outcomes in prostate and renal oncology cryoablation surgery.[12–14] Therefore, we designed a prospective study to evaluate this promising technique for the treatment of keloid scars. Scar assessment was performed using the Patient and Observer Scar Assessment Scale (POSAS) and four objective devices to determine the patient's *skin type*, scar *color*, scar *elasticity*, and scar *volume*.[15,16]

Patients and methods

Patients

All patients visiting the plastic surgery department of the VU University Medical Centre (Amsterdam, the Netherlands) between 2010 and 2012, meeting inclusion criteria, were included in a prospective study. Inclusion criteria were: (1) Patients with keloid scars.[1] Keloids were distinguished from hypertrophic scars based on the clinical judgment of their growth pattern and were defined as a fibroproliferative disorder of the skin that grew beyond the boundaries of the original wound or had an unrecognized origin, as described by Ogawa.[17] (2) The period between previous treatment and IL cryotherapy covered a minimum of 6 months. (3) Patients with all Fitzpatrick skin types.[18] (4) Patients older than 10 years of age. Exclusion criteria were: pregnancy, diabetes mellitus, and patients with collagen diseases.

Patient characteristics are listed in Table 1. Twenty-seven patients were included, of which two were lost to follow-up. Twenty-five patients with a total of 30 keloid scars completed the 1-year follow-up. Five patients with two scars were included, whose scars were of different etiology, scar duration, and anatomical location. These scars were therefore considered as separate entities. The study group consisted of 11 males and 14 females with a mean age 41.5 (range 17–84) and mean scar duration of 8 years (range 1–34). Mean scar size was 2.86 $\pm$ 0.5 cm^3 (range 0.2–8.8). Patients with all Fitzpatrick scores (F1-6) were included: 30% of the patients had an F1-3 skin type (Caucasian/Mediterranean) and 70% an F4-6 skin type (Asian/Afro-American). Most patients were previously treated with other scar treatments, of which all covered a minimum of 6 months until current treatment. Eight patients, who had previously been treated with liquid nitrogen-based IL cryotherapy, received an additional argon gas-based IL-cryotherapy 6 months later due to unsatisfactory results. Patients were subdivided according to Fitzpatrick score into two groups: Fitzpatrick (F) 1–3; Caucasian/Mediterranean patients, F3-6; Asian patients/Afro-American patients.

Surgical procedure

Skin surface was disinfected and the scar was anesthetized locally using an extralesional approach with bupivacaine 0.5% with adrenaline. Next, the 17-gauge cryoneedle (IseSeed®, Galil Medical, Yokneam, Israel) was introduced longitudinally at mid-height and mid-width of the scar in a forward rotary movement until the center was reached. The needle was connected to the Seednet® device (Galil Medical, Yokneam, Israel), which uses high-pressured argon (freezing) and helium (warming) gases, supplied from an external gas source, via the same needle. Freezing and subsequent thawing intensity can be controlled in a