

THE SCAR WARS PROJECT: A PILOT STUDY EVALUATING THE EFFECTIVENESS AND SAFETY OF A COMPRESSIVE DEVICE INTENDED TO PREVENT RECURRENCE OF KELOID SCARS AFTER SURGICAL RESECTION

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Running Title

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BACKGROUND

Management of keloid scars is difficult and random. Different treatments are proposed, ranging from the injection of corticosteroids, to cryotherapy and the administration of anticancer molecules (Ud-Din et al., 2013). At present no treatment, or combination of treatments, have been described as effective. The classical management remaining intra keloid resection, it too often leads to a more serious recurrence of keloid in 45 to 100% of cases (Andrews et al., 2016). For many years, home-made compression techniques have been described in the literature to prevent recurrence of keloids after surgery (Brent et al., 1978, Vachiramon et al., 2004, Chang et al., 2005, Yigit et al. Coll., 2009; Park and Chang, 2013; Tanaydin et al., 2016), especially at the ear lobe, area of frequent occurrence of this type of pathological scar, often after piercing. The effectiveness of these means of compression reduces the post-surgical relapse of the earlobe keloid to a range of 10 to 30% (Vachiramon et al., 2004, Park and Chang, 2013, Tanaydin et al. 2016). Correlation between keloid recurrence of the ear and discomfort in wearing a device has been also correlated (Tanaydin et al, 2016), which may be related to poor application of pressure at the ear. One of the causes being also the lack of solid clinical trials on the subject (Louis and Gracia, 2010).

METHODS

We proposed a work gathering different experts that led to the development of a quite simple device, which materialize in fact the center of complex considerations.

Our device under study is an innovative ear clip offering the possibility of adjustment of the pressure by the patient himself, that aimed to favor the observance of the device and its comfort.

The main objective of the study was defined as the evaluation of the effectiveness and safety of the compressive device; the main endpoint being then the recurrence (yes/no) of the pathology in the year after intervention. The study concerned patients (more than 18 years old) presenting keloid earlobe scars that needed to be treated by surgery, and excluded patients with known allergy to nickel.

After usual management of the keloid scar of the ear (resection surgery and injection of corticosteroids - triamcinolone acetonide), the patients had to wear 12 hours a day the compressive device and to adjust the compression with the magnets provided. The compression had to be sufficient, without being painful.

The patients were planned to be seen at 3, 6 and 12 months after surgery in the traditional course of visits during the usual care.

The secondary objectives of the Scar Wars trial focused on a multimodal and interdisciplinary assessment of scar tissues by (Chambert et al., 2019) evaluation of patient acceptance and satisfaction, evaluation by the surgeon (POSAS Patient and Observer Scar Assessment Scale, Draaijers et al., 2004, Deslauriers et al., 2009), non-invasive imaging, and creation of a keloid cell bank for perspective works.

RESULTS

31 subjects have been included in the study (22 women, 9 men, aged $33.3y \pm 11.7$), with 4 lost to follow-up, 25 successes and 2 recurrences; on these two, one subject cannot have applied the device for a long period due to professional constraints. No serious adverse event has been reported with a link to the use of the device. 52 non-serious adverse events were recorded, with 13 assessed by the investigator as related to the investigational device: they presented all a favorable outcome, and did not result in discontinuation of treatment (pain in several patients, itching at the device application site, bleeding, swelling, ear tingling), except for 2 patients who

experienced a change in the use of the investigational device: 1 ear bleeding that led to a temporary suspension and had a favorable outcome, and 1 mild lobe pain that led to a reduction in pressure applied to the device and also had a favorable outcome. Auto evaluation by patients shew a satisfaction by patients (29.7 ± 8.5 to 14.1 ± 9.1 , $p < 0.001$), and clinical scoring by surgeon decreased (37.0 ± 11.2 to 12.0 ± 10.6 , $p < 0.0001$). The talk will also present illustrative imaging of the evolution of the groups, the results suggest that all lesions types may be associated with a measurable psychological burden.

CONCLUSION

This pilot study presented encouraging results on the efficacy and safety of our prototype. The next steps will consist in finding a manufacturer for this potential medical device, and confirm these results on a larger

scale. The original and multimodal approach of the SCAR WARS project will participate in the understanding of the pathology, and provide perspectives for new areas of improvement in keloid management.

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