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Efficacy of custom-made pressure clips for ear keloid treatment after surgical excision

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Summary *Background:* Mechanical pressure is increasingly applied as a means to prevent or treat keloid scars.
Aim: The aim of this study is to analyze the long-term efficacy of our custom-molded pressure-adjustable earclips to prevent keloid recurrence after surgical excision.
Methods: Using our custom-molded earclip, 88 patients who had undergone ear surgery for keloid scars were treated for 12 h a day for 6—18 months. The mean follow-up was 6.5 years. The primary outcome was the recurrence of keloids with patient satisfaction being the secondary outcome as assessed by Patient and Observer Scale (POSAS).
Results: Keloid scars did not recur in 70.5% of treated patients. The Fitzpatrick scale, which classifies human skin by type, was significantly different between the recurrence and nonrecurrence group. Differences in other patient characteristics were not found between both groups. All parameters mentioned in the POSAS patient scale drastically improved after therapy. There were no severe side effects observed after the therapy.
Conclusion: Our pressure-adjustable earclip model is an effective tool in the prevention of ear keloid recurrence and is associated with high patient satisfaction. Its benefits should prompt further studies on its value as an adjuvant therapy to surgery in keloid treatment.
Level of evidence: Level III on the Evidence Rating Scale for Therapeutic Studies.

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Introduction

Both the clinician and the patient face challenges in the management of keloid scars of the ear because of the ear's intricate anatomical structure.

Common treatments include occlusive dressings, intralesional corticosteroid injection,[1] fluorouracil injections,[2] pressure therapy,[3] radiotherapy,[4] laser therapy,[5] surgical excision,[6] or a combination of these therapies.[7] However, the variety of treatments suggests that so far none of these single treatments lead to satisfactory esthetic results.[8,9] When mechanical pressure is used, one of the major challenges is the exertion of constant pressure to the keloid, because of the convoluted shape of the ear. Inefficient compression may consequently lead to therapy failure and, therefore, keloid recurrence.

In recent years, ear pressure clips have been developed with different outcomes in terms of effectiveness, comfort, and cosmetic appearance.[8–11] These include clips made from methyl methacrylate, which has the advantage of being molded to the ear's shape and can therefore evenly distribute pressure to the keloid.[8] We have designed a device made from uvex, which shares the same principles, but has the additional benefit of ensuring pressure adjustment. In this study, we analyzed the long-term efficacy of this new pressure-adjustable device to prevent recurrence after surgical excision of keloid scars. In this study, we focus on the impact of the device in addition to surgery.

Methods

In this retrospective study, we collected the data on patient records and planned outpatient clinic appointments to investigate 88 consecutive patients who were treated for keloid scars of the ear between 2000 and 2011 in the Academic Medical Center Maastricht in the Netherlands. A combination therapy consisting of surgical excision and pressure therapy with the custom-molded earclip was used, which started 4–5 weeks after surgery (Figure 1). After 3–4 weeks of surgery, a plaster mold of the ear was taken that served to fabricate the pressure clip with a silicon liner matching the shape and surface of the ear. The silicone liner was then covered with an artificial pre- and retroauricular thermoplastic auricle. The fitting of the clip was optimized by the properties of the silicone elastomer called uvex, as well as by an optimal combination of liner and thermoplastic orthosis. In addition, a U-shaped screw-and-pin system made pressure adjustment possible exactly on these points where keloid recurrence was suspected. The effectiveness of the earclips relies on their adjustability of pressure. The pressure is adjusted based on the patient's discomfort and the blanching of the scar area with the option to readjust by turning the screw-and-pin system appropriately. To get accustomed to the device and minimize discomfort, a gradual buildup of therapy was recommended.

On the first day of wearing the clip, the pressure was maximized to a degree upon which the patient could wear it comfortably for 1 h. On the second day, the pressure was adjusted to the extent that the patient could wear it for 2 consecutive hours. A further increase in time of wearing the clip was then achieved by gradually adjusting the pressure in the following days until it could be worn for twelve consecutive hours with a minimum amount of discomfort. Patients were instructed to use the pressure clip for at least 12 h a day for a total period of 6–18 months. Follow-up was every 3 months in our outpatient clinic or by telephone interview as appropriate. An assessment was conducted on the area of excision of the former keloid and keloid recurrence was monitored closely by a multidisciplinary team specialized in scar treatment. If recurrence of scarring was suspected, the pressure was readjusted or relocated on the pressure points in case the scar area was not targeted properly.

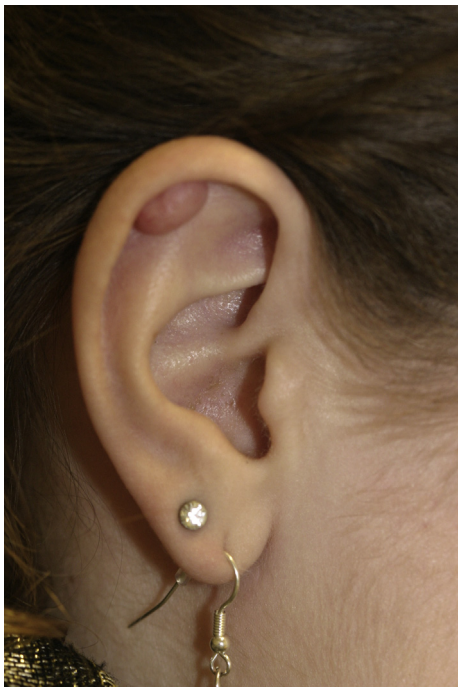

Figure 1 Before earclip treatment.

Despite the treatment, the primary outcome was the recurrence of keloid scars. Differences between the recurrence and nonrecurrence group were identified by assessing the demographic and clinical variables of the patient population as a means to define risk factors for failure of treatment in the recurrence group. Secondary outcomes were perceived comfort and appearance of the earclip, side effects, quality of life, and satisfaction with the treatment outcome. Comfort and appearance of the earclip were scored on a 1 (worst) to 10 (best) scale. Patients were also screened for side effects of the therapy. Quality of life was assessed using the Short-Form (SF)-8 questionnaire. The Patient and Observer Scar Assessment Scale (POSAS) was used to evaluate satisfaction with the treatment outcome (i.e., subjective experience of changes in keloid morphology measured by the patient and an independent doctor).[12,13]

All patients gave written informed consent before inclusion in the study. The study was approved by the Medical Ethical committee of the University of Maastricht and has been performed in accordance with the ethical standards following the Declaration of Helsinki.