Clinical efficacy of intermittent magnetic pressure therapy for ear keloid treatment after excision

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Background: Keloids are benign fibro-proliferative lesion, related to excessive inflammatory reactions in certain anatomical areas, including the auricles. Their specific etiology remains unclear; nonetheless they exhibit tumor-like characteristics of significant recurrence and cause emotional distress, even with various treatment strategies. We applied intermittent magnetic pressure therapy on ear keloids in combination with surgical excision, and present its effectiveness herein.

Methods: Ear keloid patients were treated with surgical excision followed by magnetic pressure therapy. The keloid tissues underwent excision and keloid marginal flaps were utilized for wound closure. Intermittent magnetic pressure therapy was applied 2 weeks after the surgical procedure. The pressure therapy consisted of a 3-hour application and 2-hour resting protocol (9 hr/day), and lasted for 6 months. The results were analyzed 6 months after the therapeutic procedures, using the scar assessment scale.

Results: Twenty-two ear keloids from 20 patients were finally reviewed. Among the keloids that completed the therapeutic course, 20 ear keloids out of 22 in total (90.9%) were successfully eradicated. Two patients (2 keloids) exhibited slight under-correction. Postoperative complications such as wound dehiscence or surgical site infection were not noted. The scar assessment scale demonstrated a significant improvement in each index. The intermittent pressure therapy led to patient compliance, and avoided pressure-related pain and discomfort.

Conclusion: Excision followed by intermittent pressure application using a magnet successfully reduced the burden of fibro-proliferative keloids, and had good patient compliance. The role of intermittent pressure application and resting should be studied with regard to keloid tissue remodeling.

Keywords: Keloid / Magnet / Pressure / Therapy

INTRODUCTION

Keloids are fibro-proliferative accumulation of extracellular matrices, especially collagen fibers, which are induced in the circumstances of exaggerated expression of cytokine and growth factors. They are one of the most common complications in patients who have had mechanical trauma, undergone surgery, or have an inflammation history in the auricular area. Although the specific etiology of keloids remains unclear, they seem to develop following traumatic dermal injuries in patients with genetic predispositions or past keloid histories [1]. Because keloid scars show benign skin tumor-like properties, such as a continuous growth tendency, they are excised with primary closure and treated with multimodal adjuvant therapies, which include intralesional steroid injections, radiation treatment, pressure therapy, and cryotherapy [2]. These affect
the healing process to be finalized adequately until the epithelialization of the wound [3]. However, even with the multimodal management procedures, a complete resolution of the recurrence issue seems unaccomplished [4].

For the keloid tissue suppressing effect, continuous applying of the pressure devices has been introduced and recommended in most studies. Park et al. [5] reported the efficacy of magnetic disks for earlobe keloids which is applied to the patients for 12 hours per day for 6 months following surgical excisions, whereas Tanaydin et al. [6] suggested the use of pressure clips for at least 12 hours per day for 6 to 18 months as an adjuvant treatment of the ear keloids following surgical excisions. However, in various clinical trials, there have been no definite application protocols or discussions on how to apply the pressure generating devices specifically.

An intermittent application concept of mechanical forces has been introduced from other wound treatment methods. The effectiveness of the intermittent application of the mechanical pressure or elastic traction was reported in former studies [7-9]. We tried to adopt this concept into keloid adjuvant therapy, so that we could accomplish to set up a patient-convenient combinational modality after surgical excision treatments.

METHODS

Patients with ear keloids were reviewed in this retrospective study. The patients were treated with surgical excision followed by magnetic pressure therapy over a period of 3 years, from May 2015 to April 2018, at Konkuk University Medical Center. The study protocol conformed to the ethical guidelines of the Declaration of Helsinki, as reflected in the approval by the Konkuk University School of Medicine human research review committee.

Patient data were collected and reviewed in accordance with the following inclusion criteria: (1) primary and secondary keloids that had developed on the auricular area caused by ear trauma or piercings; (2) keloids that protruded and extended beyond the margin of the initial injury lesion; (3) patients who underwent surgical excision with primary closure; and (4) patients who did not undergo additional ear piercing or surgical procedures during the follow-up period.

Patients were excluded when their follow-up data were not available. All studied patients complied with our treatment protocol, and consented to the final follow-up after 6 months since the completion of management.

Surgical techniques

Surgical procedures were performed under local anesthesia. We performed near-complete excision, 1–2 mm within the keloid edge. The keloid marginal flap, which consisted of the epidermis and the thin dermis overlying the keloid, was raised from the fibrous keloid core. The flap was utilized for wound closure without sion. Bleeding was controlled using bipolar coagulation. We closed wounds with appropriate approximation using Prolene 5-0 and 6-0 interrupted sutures (Fig. 1). Compressive dressing was applied to prevent hematoma. The stitches were removed on postoperative days 7 to 14. Pain was controlled with the administration of nonsteroidal anti-inflammatory medication.

Intermittent magnetic pressure therapy protocol

Intermittent magnetic pressure therapy was initiated 2 weeks after the surgical procedure. In case of delayed wound healing, due to an unstable wound margin and serous discharge, the intermittent pressure therapy was considered 3 weeks postopera-

Fig. 1. (A) A 20-year-old male patient presented a pedunculated-pattern keloid on the left ear lobule. (B) Excised keloid was composed of whitish connective tissue, measured 1.5×1.5 cm.
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Outcome measurement
With regard to the comparative analysis between pre- and postoperative states, the scar assessment scale was adopted from previous studies on keloid scar treatments [10]. The scar assessment scale was assigned by three different plastic surgeons and the median value was utilized for analysis. Patients’ satisfaction was evaluated on the basis of symptom relief during the postoperative follow-up visits. The postoperative assessment was performed at the final follow-up after 6 months, since the completion of intermittent pressure therapy.

Statistical analysis
For each scale index, values at pre- and post-treatments were compared using a two-tailed paired t-test. All data were expressed as mean ± standard deviation. Data analyses were performed with standard software SPSS for Windows version 22.0 (IBM Corp., Armonk, NY, USA). Statistical significance was assumed if p-value was less than 0.05.

RESULTS

Twenty patients with ear keloids were finally included in the study, and a total of 22 ear keloid cases were reviewed. The average patient age was 22 years (range, 15–40 years). The average diameter of keloids was 1.7 ± 0.8 cm, ranging from 0.9 to 2.8 cm. Among the 20 patients in total, 18 were females and two males. Two patients exhibited keloids on bilateral ears, meanwhile eight on the right ear and 10 on the left ear. Twenty-two keloids underwent excision including the two bilateral cases. With regard to the anatomical site, eight were at the ear helix, two at the ear concha, and 12 at the ear lobule. Two patients have undergone keloid excision previously, and they were categorized as secondary cases. The rest 18 patients were primary cases. In the majority of the cases (n = 19), the keloids were caused by ear piercing, while in one case, the lesion was caused by a traumatic injury (Table 1).

All patients completed the treatment protocol with a follow-up interval of 6 months. Of the 22 keloid tissues, 20 keloids have been successfully eradicated (90.9%), while two keloids presented remnant fibrous tissue, showing slight under-correction. The postoperative course related to wound healing was uneventful in all patients. The representative pre- and post-operative images are demonstrated in clinical photographs (Figs. 3, 4).

Table 1. Patient demographics

| Index                    | Measurement                  |
|--------------------------|------------------------------|
| Age (yr)                 | 22 ± 5 (15–40)              |
| Sex (female/male)        | 18/2                         |
| Location                 |                              |
| Right/left/bilateral (n = 20) | 8/10/2                     |
| Helix/concha/lobule (n = 22) | 8/2/12                     |
| Diameter (cm)            | 1.7 ± 0.8 (0.9–2.8)         |
| Follow-up (mo)           | 12 ± 5 (6–19)               |
| Surgical history         |                              |
| Primary/secondary        | 20/2                        |
| Cause                    |                              |
| Piercing/trauma          | 21/1                        |

Values are presented as mean ± standard deviation (range) or number.

Fig. 2. Intermittent pressure therapy protocol included 3 cycles of magnet application per day. Each cycle consisted of 3 hours of magnet application followed by 2 hours of relief (9 hr/day). The protocol was introduced to avoid patient discomfort, allowing compressive effects. Three alternative magnets were used and a lighter magnet with less pull strength was applied when patients notified discomfort or pain. With regard to the pressure measurement, three magnets presented values in regular sequence (magnet diameter 8 mm, 24 kPa; diameter 10 mm, 42 kPa; diameter 12 mm, 60 kPa).
The scar assessment scale demonstrated a significant improvement in each index, namely vascularity, pigmentation, thickness, relief, pliability, and surface area (Table 2). With regard to patients’ satisfaction in symptoms, 18 patients (20 keloids) were satisfied with the outcome as well as treatment course. Nonetheless, two patients (2 keloids) with remnant keloids showed dissatisfaction on the final outcome. Recurrence of keloid was not presented in overall patients.

Treatment with intermittent magnetic pressure therapy resulted in notable improvement, without any therapy-related discomfort or skin ulceration. During the therapy period, the patients were observed once a month, because pressure-related pain and discomfort could reduce patient compliance. On each visit, pressure maintenance and resting periods were checked, and the patients were encouraged to figure out adequate magnetic strength.

Table 2. Preoperative and postoperative analysis based on scar assessment scale (n=22)

| Index       | Preoperative measurement | Postoperative measurement | p-value |
|-------------|--------------------------|---------------------------|---------|
| Vascularity | 4.5 ± 1.9                | 3.2 ± 1.4                 | 0.02*   |
| Pigmentation| 3.8 ± 1.1                | 2.4 ± 0.8                 | 0.01*   |
| Thickness   | 6.4 ± 2.3                | 3.5 ± 2.1                 | <0.001* |
| Relief      | 3.6 ± 1.2                | 2.8 ± 0.7                 | 0.04*   |
| Pliability  | 5.7 ± 1.6                | 3.0 ± 1.4                 | <0.001* |
| Surface area| 6.3 ± 2.5                | 3.8 ± 1.7                 | 0.03*   |

Values are presented as mean ± standard deviation.

* p < 0.05.

**DISCUSSION**

Pressure therapy combined with surgical excision has been clinically applied worldwide, and the efficacy of this combina-
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flow velocity, skin blood flow, and skin temperature. Mean

[19]. Intermittent negative pressure resulted in higher blood

plication induced better blood flow than the constant protocol

ro- and microcirculation of lower extremities, intermittent ap

vascular destruction or disappearance were increased.

unloading intervals, the chances of unpredictable bleeding and

physiologic conditions of capillary structures. Without proper

quate loading and unloading intervals helped maintain the

normal skin dermis, while fibroblasts derived from hypertro

proliferation with DNA degradation [14,15]. In a comparative

study using hypertrophic scar and normal skin, apoptotic cells

are genetically programmed for maintaining tissue integrity

regulate the physiological pathways of cellular apoptosis, which

were observed in hypertrophic scars. This means that mechanical compression forces may af

fect the level of release and expression of MMP-28; therefore,

the compressive environment modulates the wound remodel-

ing phase in hypertrophic scars.

These compression-related molecular-biological modulators

regulate the physiological pathways of cellular apoptosis, which

are genetically programmed for maintaining tissue integrity

and homeostasis, and microscopically marked as nuclear con-

densation with DNA degradation [14,15]. In a comparative

study using hypertrophic scar and normal skin, apoptotic cells

with degraded DNA were observed more frequently on the

normal skin dermis, while fibroblasts derived from hypertro-

phic scars were less prone to apoptotic triggering [16,17].

With regard to the magnetic pressure application protocol, we

hypothesized that intermittent application could be more effi-

cient than continuous usage in tissue remodeling. This concept

was based on the result of an animal study by Shoman et al.

[18], in which the applications of intermittent forces with ade-

quate loading and unloading intervals helped maintain the

physiologic conditions of capillary structures. Without proper

loading intervals, the chances of unpredictable bleeding and

vascular destruction or disappearance were increased.

In a study on intermittent negative pressure effect on the mac-

ro- and microcirculation of lower extremities, intermittent ap-

lication induced better blood flow than the constant protocol

[19]. Intermittent negative pressure resulted in higher blood

flow velocity, skin blood flow, and skin temperature. Mean-

while, the constant negative pressure group showed decreased

blood flow velocity, skin blood flow, and skin temperature. Ac-

cordingly, increased foot perfusion was observed after the ap-

plication of intermittent negative pressure.

We broke one application cycle into three separated sub-cy-

cles, rather than applying the device for 9 hours continuously.

Each sub-cycle included 3 hours of pressure-on period followed

by 2 hours of pressure-off period, in which the devices were re-

moved and accordingly, the pressures were relieved. When the

third pressure-on period finished, the cycle of the day which

composed of total 15 hours of intermittent on- and off-magneti-

c pressure was finalized. Our protocol has been designated to

avoid keloid recurrence as well as pressure-related complica-

tion. The unwanted sequels are generated, when application

method causes discomfort and aversion. In this context, we

designated the 3-hour loading and 2-hour unloading protocol,

which included a long relieving period relatively, to achieve ef-

cient application and patients’ comfort during regular daily

activities.

Two of the patients in the current study exhibited remnant

keloid tissue (n = 2, 9.1%), indicating slight under-correction.

Various surgical excision protocols have been used to reduce

keloid tissues, with complete excision without any remaining

overlying skin, namely a keloid marginal flap, being one of

them [20]. Eradication is advantageous in reducing the keloid

burden; however, surgeons should be cautious to avoid soft tis-

sue tension in the post-excision state. Excision is another surgi-

cal method to treat keloids [21]. This technique utilizes the

overlying epidermis and the thin dermis at the keloid marginal

areas; therefore, the soft skin layer can be used for wound clo-

sure, avoiding related complications. We employed the excision

method to facilitate the wound healing process. Nonetheless,

sufficient resection of the keloid burden is a surgical goal, and

additional reduction should be considered when remnant fib-

rous tissue is noted during the intraoperative wound examina-

tion. In this context, surgeons should evaluate the keloid mar-

gin cautiously in both preoperative and intraoperative proce-

dures.

This study has a few limitations. The sample size was relatively

small and there was no control group. Additionally, considering

its retrospective nature and relatively short period of postopera-

tive follow-up period, studies with longer follow-up and larger-

ized patient samples are needed to confirm the long-term effi-

cacy of our management protocol.

In conclusion, the intermittent pressure therapy as per our

post-excision protocol can lead to efficient postoperative man-

agement, avoiding the recurrence of ear keloids. We laid more

emphasis on the maintenance of the natural anatomical posi-
tion of innate soft tissues rather than on the pressure effect. A thorough understanding of the pathomechanisms causing keloid formation can help identify pathways that serve as adequate targets to achieve an effective therapy for this intractable disorder.

NOTES

Conflict of interest
No potential conflict of interest relevant to this article was reported.

Ethical approval
The study was approved by the Institutional Review Board of Konkuk University School of Medicine (IRB No. KUMC 2019-06-009) and performed in accordance with the principles of the Declaration of Helsinki. Written informed consents were obtained.

Patient consent
The patients provided written informed consent for the publication and the use of their images.

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