Objective: To develop a new, custom-made pressure device that can be used with established designs as an adjuvant therapy for optimized treatment of auricular keloids.

Methods: Seven patients (4 males, 3 females; mean [SD] age, 22.6 [8.3] years) were treated with surgical excision and corticosteroid injection followed by application of our new auricular pressure device.

Results: All patients tolerated the adjuvant therapy and wore the device overnight for 5 nights per week. Usage was not interrupted or cancelled. No recurrence was observed during the follow-up period (mean [SD] duration of follow-up, 24 [6] months). All patients were satisfied with the results; none described pruritus, pain, or dysesthesia.

Conclusion: Overnight usage of the new pressure device seems to be a safe and effective extension of established auricular keloid therapy with the potential for prophylaxis of recurrence.

loids includes surgical excision combined with subsequent corticosteroid injection.\textsuperscript{1,5,8} Incorporating adjuvant treatment modalities, such as silicone-based occlusive dressings, radiotherapy, or application of pressure, is widely observed. Since cutaneous scar management relies heavily on the experience of the physicians rather than on the results of large-scale randomized controlled trials and evidence-based techniques, the combinations of therapeutic modalities are as numerous as the units and departments focusing on the treatment of this pathologic condition. The polypragmasia of therapeutic approaches, combined with the variable efficacy and the relatively high recurrence rates after application of a single therapy, underscores the therapeutic challenge keloids present to the plastic surgeon.

Sites susceptible to keloid formation are the anterior chest, shoulders, flexor surfaces of the extremities, cheeks, and ears.\textsuperscript{11} Treatment of auricular keloids is a unique challenge owing to the complex anatomy of the auricle, from a cartilaginous skeleton underneath a delicate layer of skin to a fat pad enveloped in thicker skin that forms the earlobe. Surgery must be executed carefully to avoid damage to the healthy skin and lesions in the cartilage. Keloid scar mass often invades the auricular cartilage, especially if cartilaginous structures were damaged during the initial trauma, impeding clean excision of scar tissue. To improve success rates after steroid injection and to minimize the probability of recurrence, we decided to apply pressure as an adjuvant treatment strategy using a newly designed pressure device.

Pressure devices are widely used as an adjunct to surgery and other therapeutic treatments of auricular keloids.\textsuperscript{12-15} However, many customized devices do not fulfill all technical requirements. The design of an auricular pressure device should adhere to the following guidelines\textsuperscript{12}:

- High-tensile strength
- Lightweight
- Aesthetically acceptable
- Easy and inexpensive to fabricate
- Made from nonflammable materials
- High precision without compromising hearing
- Comfortable to wear
- Easy for the patient to apply and remove
- Allows for proper hygiene
- Provides uniform pressure over the tissue with high precision during pressure-correction procedures
- Allows continuous control of perfusion in order to avoid pressure lesions

We introduced a new, custom-fitted device for optimized pressure therapy of auricular keloids that meets all of these criteria. On account of this, we believe that this device is of greater usefulness in clinical assignment than other designs described in literature. Herein, we present several clinical examples of this device to illustrate its applicability in any area of the auricle.

**METHODS**

All patients were consecutively treated from December 2007 to March 2009 for primary or recurrent auricular keloids at the University Hospital of Mannheim, University of Heidelberg, Germany. Seven patients (4 male and 3 female; mean [SD] age, 22.6 [8.3] years) were treated with the therapeutic regimen described herein, composed of surgical excision, subsequent corticosteroid injection, followed by pressure therapy using our new custom-designed pressure device. The duration of follow-up ranged from 13 to 32 months. All patients received a follow-up examination at our institution for functional and aesthetic evaluation and assessment of subjective treatment success. The following 3 clinical examples were selected to demonstrate the therapeutic concept.

**CASE 1**

A 12-year-old male patient, with Fitzgerald skin type V, had primary, bilateral posterior auricular keloid formation 6 months after otoplasty. The patient experienced cosmetic nuisance and denied having pain, pruritus, or any other adverse symptoms (Figure 1).

**CASE 2**

A 16-year-old female patient, with Fitzgerald skin type III, had keloids in both earlobes. She had not undergone any recent piercing procedures of the earlobes. Each earlobe had been pierced once during early childhood, and she had continuously used these perforations ever since. Keloid formation started spontaneously at age 15 years, accompanied by pruritus but no pain (Figure 2).

**CASE 3**

An 18-year-old female patient, with Fitzgerald skin type II, had keloid formation on the anterior and posterior surface of the upper third of the auricle. The initial skin trauma was a piercing 2 years before keloid formation. The patient experienced aesthetic impairment and occasional pruritus and dysesthesia in the area of keloid scarring (Figure 3).

**SURGICAL, MEDICAL, AND INSTRUMENTAL TREATMENT**

**Surgery**

Intramarginal excision of the keloid with discrete lateral undermining and primary wound closure was performed without subcutaneous sutures. For intradermal wound adaptation, a nonabsorbable, monofilamentous suture was preferred. The main goal of wound closure was tension-free adaptation of the margins using the minimum amount of suture material required. We aimed to remove the sutures as soon as possible (6-14 days later), depending on the skin type and wound size.

**Steroids**

The first intralateral steroid (triamcinolone acetonide) injection was administered after the surgical excision. Our routine for steroid therapy is based on a total of 6 injections that were administered at intervals of 4 to 8 weeks, depending on the skin type and clinical symptoms of the scar tissue. Dark-skinned patients were associated with shorter intervals than light-skinned patients. For avoidance of injection pain, 1 mL of triamcinolone acetonide (40 mg/mL) was diluted in 1 mL of local anesthesia (1% xylocaine with adrenaline 1:200 000).
To fit wound areas of any size, an epithetic device fabricated with acrylate (Palapress; Haraeus Kulzer, Hanau, Germany) was custom-made for every patient at the end of steroid treatment. For this purpose, a cast of the ear was manufactured using silicone for plastic impression (Technovent Ltd, Newport, England), which was then filled with super-hard dental plaster (Kettenbach GmbH & Co KG, Eschenburg, Germany). The design and development of the device was put into execution by one of us (J.B.; Brom Epithetik, Heidelberg, Germany).

The device consisted of 2 different subunits that were produced consecutively. After polymerization of each subunit, cavities were milled for insertion of the magnets (Technovent Ltd), which were fixated with acrylate. Production time was on average 4 hours, with material costs of approximately $350.

The 2 transparent subunits fitted the anterior and corresponding posterior surface of the auricle to cover the area requiring treatment. The subunits were held together by magnets at the exterior rim of the auricle (Figures 1-3). After reduction of scar elevation from pressure therapy, additional pressure was added by superimposing a transparent liquid plastic on the area of interest, which was then stabilized with UV light (Figure 4). The time intervals between each adjustment of pressure therapy varied from 4 to 8 weeks, depending on the reduction of scar elevation. Pressure therapy ended once the scar level matched the level of the surrounding healthy skin or after 2 consecutive pressure adjustments without further improvement of the scar level. Patients were instructed to wear the device overnight for at least 5 nights per week.

All 7 patients treated according to our regimen were eligible for the study and could be enrolled (Table). The

Pressure Device

Figure 1. A patient with keloid formation. A, Primary, bilateral, posterior auricular keloid formation 6 months after otoplasty. B, Four weeks after surgery; note the unnatural, edgy appearance of the helical rim in the upper thirds on both sides. C, Patient with the customized pressure device. Owing to the complex concavities of the auricle, application of the device could be performed by the patient himself. D, End result 4 weeks after completion of the combined treatment regimen. The edgy shape of the helical rim was dismantled, providing a smooth, natural appearance of both auricles.
oldest patient at the time of keloid treatment was 39 years old, and the youngest patient was 12 years old. The longest follow-up interval was 32 months, and the shortest was 15 months (mean [SD], 24 [6] months) after completion of pressure therapy. One patient had a keloid of both earlobes, 3 patients had a retroauricular keloid, 2 had a keloid extending the posterior and anterior surface of the auricle, and 1 patient had a keloid in the posterior sulcus. The etiology of most keloids was surgery (eg, otoplasty and tympanoplasty; retroauricular keloids) or piercing (earlobe and preauricular and retroauricular keloids). One patient developed a preauricular and retroauricular keloid 5 months after being struck with a tennis racket.

All patients were treated by intramarginal keloid excision, intralesional injection of triamcinolone, and a custom-designed device for optimized pressure therapy. Primary keloids were treated in 6 patients, and a recurrent keloid was treated in 1 patient.

No recurrence of a keloid was observed in any of the patients during follow-up. All patients were satisfied with the results, and none described pruritus, pain, or dysesthesia within the resulting scar area.

All patients tolerated the device well and reported that wearing it overnight for at least 5 nights per week was very practicable. No patient interrupted or cancelled usage of the pressure device during the treatment period. Application and removal of the device was well performed by all patients. No inflammatory skin reaction or pressure lesions were observed.

In a 21-year-old patient (with Fitzgerald skin type II), a wound dehiscence was observed after removal of sutures 8 days after the surgical procedure. Scar revision with primary closure was conducted, and the sutures were left in situ for 12 days. After this incident, the time interval between surgery and removal of sutures in light-skinned patients was extended to 10 to 14 days with no recurrence of this complication.

In 1 patient with Fitzgerald skin type V, dyspigmentation from steroid injection was observed (Figure 5). Dyspigmentation remained observable during the entire follow-up period of 20 months and up to November 2010.

**COMMENT**

The aim of our study was to evaluate the presented treatment regimen for therapy of auricular keloids using a newly designed, custom-fitted pressure device. One major problem of clinical evaluation is the small number of patients owing to the infrequent incidence of this specific diagnosis at a single health care center. Fortunately, patient follow-up was not a problem for our group.

Surgical excision alone (evidence level III) has been repeatedly proven ineffective, with recurrence rates of 40%
Subtotal excision with lateral undermining has been credited with improved outcomes and fewer recurrences. The rim of keloidal scar tissue serves to splint the wound and relieve tension, a pivotal stimulus for collagen synthesis. Combining surgery with an intralesional steroid (triamcinolone) injections reduces the recurrence rate of keloids to less than 50%. Injections may be used alone or combined with other therapies. The combination of injections and surgery is the most common modality in clinical practice. Although intralesional corticosteroid administration (evidence level III) presents highly variable response rates from 50% to 100%, it is also accompanied by recurrence rates of 9% to 50%. Triamcinolone inhibits proliferation of normal and keloid fibroblast, inhibits collagen synthesis, increases collagenase production, and reduces levels of collagenase inhibitors. Furthermore, ultrastructural changes in collagen synthesis are induced, which enhance the organization of collagen bundles and degenerate the characteristic keloidal collagen nodules. No clear advantage has been shown for 1 specific type of corticosteroid.

Pressure therapy was popularized in the 1970s after clinicians noticed that pressure stockings used over lower extremity burns caused scars to mature faster with decreased erythema and thickness. Pressure causes localized hypoxia, resulting in fibroblast degeneration and disintegration owing to decreased intercollagenous cohesion and increased collagenase activity. Furthermore, pressure has been shown to shorten scar formation time, reorient collagen fibers within the scar to become parallel to skin surface, increase hyaluronic acid levels, and decrease chondroitin sulfate levels, all of which help to flatten the initially elevated scar tissue and reduce recurrence rates.

According to various reviews and guidelines, pressure
therapy is a long-standing therapeutic option for keloids, producing thinning and pliability. Although the precise biomolecular mechanism of compression is not understood, success rates of at least a partial reduction of deranged scars, from 60% to 85%, have been reported from a monotherapeutic regimen of pressure therapy. The combination of surgery with postoperative pressure treatment showed good response rates of about 90% to 100%, especially after excision of auricular keloids.11

Neither the use of pressure therapy nor the application of custom-made devices in postoperative management of auricular keloids is a new finding.12-15 However, we believe that the pressure device described herein is the first design introduced in literature that meets all requirements to which an auricular pressure device should adhere. The results are not part of a comparative study. However, after application of the newly designed pressure device our outcome is highlighted by the absence of recurrence to date. This observation contrasts with the recurrence rates previously noticed among clinics after combined therapy of surgical removal and postoperative steroid injections (approximately 20% within the first 24 months).

The pressure devices need to be designed on an individual patient basis with the goal of providing adequate, direct, and continuous pressure during usage. Owing to the complex and highly sensitive anatomy of the auricle, compression therapy is ultimately limited by optimal alignment of the device and indemnification of sufficient long-term pressure. The pressure exerted should be at least 24 mm Hg to exceed the inherent capillary pressure but must remain below 30 mm Hg; otherwise, peripheral blood circulation is diminished resulting in tissue necrosis.11,14

Objective measurement of adequate pressure is hindered by the variable shape and consistency of the tissue beneath the pressure device, which ranges from fatty tissue in the earlobe to collagen beneath a very thin layer of skin that is cranial to the lobule. With the new device we were able to ensure adequate pressure by aiming to blanch the scar site, an effect that commences once the command variable of the pressure is reached. Adjustment of pressure was easily accomplished using a liquid plastic that was superimposed on the area of interest and subsequently hardened using UV light (Figure 4). If too much material was added initially, correction was performed after hardening by using a No. 15 scalpel blade to scrape off some of the excess material. By designing the device to attach magnetically, we were able to provide a safe and lightweight device that was easy for even the youngest patients to attach to their auricle by themselves.

Other devices presented in the literature do not allow an adequate control of intralesional blood circulation owing to an absence of transparency. Furthermore, high-precision pressure adjustment is limited by potential instability on the ear lobe, or introduced systems are suitable only for the ear lobe region.12-15

All patients strictly followed the instructions they were given. None of the patients described any discomfort dur-

<table>
<thead>
<tr>
<th>Patient No./Sex/Age, y</th>
<th>Fitzgerald Skin Type</th>
<th>Localization</th>
<th>Scar Type</th>
<th>Initial Trauma</th>
<th>Time Interval Before Appearance</th>
<th>Follow-up Time, mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/M/12</td>
<td>V</td>
<td>Posterior auricle, bilateral</td>
<td>Primary keloid</td>
<td>Otoplasty</td>
<td>6 mo</td>
<td>32</td>
</tr>
<tr>
<td>2/F/16</td>
<td>III</td>
<td>Lobule, posterior and anterior, bilateral</td>
<td>Primary keloid</td>
<td>Piercing</td>
<td>15 y</td>
<td>29</td>
</tr>
<tr>
<td>3/M/24</td>
<td>V</td>
<td>Mastoid region, right</td>
<td>Primary keloid</td>
<td>Tymanoplasty</td>
<td>12 mo</td>
<td>20</td>
</tr>
<tr>
<td>4/M/21</td>
<td>II</td>
<td>Posterior auricle, right</td>
<td>Primary keloid</td>
<td>Otoplasty</td>
<td>4 mo</td>
<td>17</td>
</tr>
<tr>
<td>5/F/18</td>
<td>II</td>
<td>Posterior and anterior upper third, right</td>
<td>Primary keloid</td>
<td>Piercing</td>
<td>24 m</td>
<td>26</td>
</tr>
<tr>
<td>6/F/39</td>
<td>II</td>
<td>Posterior surface of helical rim, right</td>
<td>Recurrence</td>
<td>Otoplasty</td>
<td>1 mo</td>
<td>28</td>
</tr>
<tr>
<td>7/M/28</td>
<td>I</td>
<td>Posterior and anterior upper third, right</td>
<td>Primary keloid</td>
<td>Hit with tennis racket</td>
<td>5 mo</td>
<td>15</td>
</tr>
</tbody>
</table>

Figure 4. Objective measurement of adequate pressure is hindered by the variable shape and consistency of the tissue beneath the pressure device, which ranges from fatty tissue in the earlobe to collagen beneath a very thin layer of skin that is cranial to the lobule. With the new device we were able to ensure adequate pressure by aiming to blanch the scar site, an effect that commences once the command variable of the pressure is reached. Adjustment of pressure was easily accomplished using a liquid plastic that was superimposed on the area of interest and subsequently hardened using UV light (Figure 4). If too much material was added initially, correction was performed after hardening by using a No. 15 scalp blade to scrape off some of the excess material. By designing the device to attach magnetically, we were able to provide a safe and lightweight device that was easy for even the youngest patients to attach to their auricle by themselves. Other devices presented in the literature do not allow an adequate control of intralesional blood circulation owing to an absence of transparency. Furthermore, high-precision pressure adjustment is limited by potential instability on the ear lobe, or introduced systems are suitable only for the ear lobe region.12-15

All patients strictly followed the instructions they were given. None of the patients described any discomfort dur-
ing compression therapy and did not report interruption of nocturnal usage. During the entire treatment, all patients had 1 contact person (G.M.B.) and were able to communicate with him at any time. Patients were given a thorough explanation of the regimen, with emphasis on the time frame, before the start of treatment. We believe that observed compliance rates, especially concerning pressure therapy, are the result of intensive and personalized patient care.

All patients were well informed about the potential risk of recurrence. Regular application of the pressure device resulted in familiarization, and after completion of the therapy, patients felt confident in examining the scar region by themselves and affixing the device in case of recurrence. To date, no recurrences have been observed; however, we are quite aware of the unpredictable nature of this pathologic scar type. Therefore, the most important therapeutic concept for patients with susceptibility to keloids is timely identification and prevention.

Avoidance of any cutaneous trauma in keloid-prone patients needs to be kept in mind before any invasive treatment. When wounding occurs, the challenge remains to limit excessive scarring by reducing known stimuli for scar overgrowth, such as a prolonged inflammatory response or any factor resulting in unbalanced wound healing reactions. Sound reviews concerning clinical scar management are recommended for further study.9,11,16

Within this study we demonstrated the safety and efficacy of a combination of surgical excision and steroid injection with a newly designed, custom-fitted device for optimized pressure therapy of auricular keloids. The device consolidates clinical advantages by adhering to approved guidelines. To improve scar management, larger, center-based trials with long-term follow-up should be conducted. Evaluation of efficacy may be ameliorated by large-scale, randomized controlled trials using evidence-based techniques; however, judgment of efficacy is significantly limited by clinical difficulties such as correct diagnosis of scar type and change in scar appearance. Thus, keloid management, like management of any cutaneous scar type, heavily relies on the experience of practitioners, which conversely reveals a significant limitation for large-scale, multicentered clinical trials.

Overtight use of the new pressure device seems to be an effective extension of established auricular keloid therapy, with additional potential for prophylaxis of recurrence. Preliminary work was presented and intended to produce a demonstration of an optimized treatment modality. Analysis of this therapeutic regimen based on a larger sample size, and long-term follow-up will be the substance of a future report.

Scarce knowledge about the pathogenesis of keloids is reflected by the multitude of therapeutic approaches. There is still no molecular mechanism defined for keloid development. Ongoing investigation to increase biomolecular understanding will result in the development of new, more effective therapies. Until then we have to continue our quest for the establishment of the most conclusive regimen, which combines minimal risks for the patient with high therapeutic success rates and a perspective of prophylaxis once treatment is finished.

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Author Contributions: Dr Bran had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Bran, Brom, Hormann, and Stuck. Acquisition of data: Bran and Brom. Analysis and interpretation of data: Bran and Stuck. Drafting of the manuscript: Bran, Hormann, and Stuck. Critical revision of the manuscript for important intellectual content: Bran, Brom, Hormann, and Stuck. Administrative, technical, and material support: Bran, Brom, and Stuck. Study supervision: Bran, Hormann, and Stuck.

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Additional Information: Mr Bran is an anaplastologist and is certified by the International Association for Surgical Prosthetics and Epithetics.

REFERENCES