Clinical Outcome and Quality of Life After a Multimodal Therapy Approach to Ear Keloids

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IMPORTANCE Keloids are fibroproliferative scars that can cause a huge psychological burden and severe problems for patients, such as depression. Many treatment options exist; however, recurrence rates, especially with monotherapy, remain high.

OBJECTIVE To investigate the recurrence rate and changes in quality of life after multimodal therapy.

DESIGN, SETTING, AND PARTICIPANTS A total of 33 patients with 42 auricle keloids (24 female and 9 male patients; mean [SD] age, 27 [17] years) were enrolled in a prospective cohort study and underwent intramarginal keloid excision and multimodal therapy. Patients were observed postoperatively in the outpatient Department of Otorhinolaryngology–Head and Neck Surgery, University Hospital of Mannheim, from August 1, 2007, through September 30, 2014, with a mean (SD) follow-up of 30 (19) months (through August 31, 2014). A retrospective analysis of clinical outcomes was performed from September 1 through November 15, 2014.

INTERVENTIONS Excision followed by 6 intralesional corticosteroid injections at 4- to 6-week intervals and individually customized pressure splints applied at least 5 nights a week for 6 months.

MAIN OUTCOMES AND MEASURES Keloid recurrence rate and subjective handling of the pressure splint were evaluated during clinical visits. Quality of life was measured after the end of therapy with a 3-part questionnaire, including the Glasgow Benefit Inventory (GBI).

RESULTS After excluding 4 patients (with 5 keloids) for nonadherence to treatment, 3 of 37 keloids recurred, for a recurrence rate of 8% among 29 patients. Insecure handling of the pressure splint significantly correlated with a higher relapse rate (mean subjective handling score in patients with a relapse, 3.60; \( P = .02 \)). Four of 8 patients with recurrent keloids had poor adherence to adjuvant pressure therapy, which suggests an association between keloid recurrence and adherence to adjuvant pressure therapy. Patients received the 3-part questionnaire by mail to collect data on quality of life. Of 43 patients approached, 33 treated with multimodal therapy completed the questionnaire for a return rate of 77%. Improvement in quality of life after keloid treatment was significant in recurrence-free patients, with a mean GBI score of 22.53 (\( P < .001 \)).

CONCLUSIONS AND RELEVANCE The present study showed an improvement in quality-of-life scores after multimodal therapy for keloids. Because poor adherence to the use of ear splints correlated with a higher recurrence rate of keloids, efforts are needed to improve adherence and minimize recurrence.

LEVEL OF EVIDENCE 3.

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As the largest organ of the body, the skin protects the individual from damaging influences of the environment. After a skin injury, the organism attempts to restore integrity. The restoration of the original state before the injury (restitutio ad integrum) exists in mammals only in the embryonal stage. After birth, the physiological result of wound healing is the formation of replacement tissue or a scar. As an expression of excessive wound healing, a keloid may result. Keloids are benign proliferations of connective tissue that do not degenerate by themselves and result from the irregular interaction of cytokines, the matrix of the connective tissue, and the extracellular matrix after a trauma, such as an operation (Figure 1). Keloids spread beyond the initial borders of the primary lesion and surmount the surface of the skin, without the tendency of spontaneous regression. Locations tend toward the chest, back, and shoulder area, which have a high density of sebaceous glands. A frequent location in the head and neck region is the ear.

Macroscopically, keloids appear as delicate pink to bright red tissue proliferations, with a texture ranging from rigid to rigid elastic. Keloids are only known in human beings; no animal model exists. The detailed mechanisms of their pathogenesis are not fully understood. The frequency of keloid development is correlated with skin pigmentation; they occur 15 times more often in patients with darker skin pigmentation. No case of keloids has ever been reported in an albino individual, which underlines this theory. The worldwide prevalence varies from 0.09% in Great Britain to 16% in Congo. The highest incidence is in the third and fourth decades of life.

Keloids may cause subjective aesthetic discomfort that can lead to severe psychological stress, depression, and social withdrawal. Patients often have pruritus, especially during a change of weather pattern. In addition, pain and paresthesia, similar to a burning sensation, can occur, which overall can lead to reduced quality of life (QOL). The World Health Organization defines QOL as “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.” In colloquial speech, the term quality of life is understood as the grade of well-being, which is a subjective sensation that is influenced by outer and inner factors.

The measurement of QOL is complex and often surveyed by questionnaires, such as the Glasgow Benefit Inventory (GBI) developed in 1996. The GBI was designed to analyze the changes in QOL retrospectively, depending on an intervention, especially after interventions of the ear, nose, and throat. In this study, the GBI has been used to measure changes in QOL after keloid treatment. The GBI uses 18 questions to measure QOL, including social support and physical health.

According to the guideline of the German Society of Dermatology, numerous therapy approaches exist for keloids, such as corticosteroid injection, surgical excision, radiotherapy, pressure therapy, and interferon therapy. The plurality of clinically established therapies combined with a high rate of relapse illustrates the challenge in keloid treatment. In particular, monotherapy shows disappointing results. Hence, a combination of therapies is recommended to reduce the risk for relapse of a keloid in predisposed individuals.

Surgical excision often remains the basis of treatment. Excision should be performed gently andatraumatically so that the borders of the wound can be adapted without tension. The surgical “fillet” technique used in the present study fulfills these requirements. The technique is based on a strict intramarginal keloid excision in which the keloid scar is sharply dissected from the covering skin and the keloid mass is completely removed (Figure 2). The keloid mass functions as an endogenous expander of the skin, and removal results in an excess of skin so as to adapt the wound edges without tension. In contrast, extramarginal keloid excision, which is defined as an incision of physiological skin and removal of the entire lesion, produces a linear scar. The disadvantage occurs in maintaining tension in the suture. Particularly after resection of larger keloids, skin grafts or local flaps often are required to perform the primary wound closure. Match of skin color in such cases is challenging.

Possible adverse effects of surgery are disturbances in wound healing or wound dehiscence. To reduce recurrence rates, surgery is often combined with adjuvant treatment, such as corticosteroid injections. In addition to their anti-inflammatory effect, corticosteroids reduce collagen and glycosaminoglycan synthesis and the proliferation of fibroblasts. Triamcinolone acetonide, 10 to 40 mg, is often used as an active ingredient in intralesional injections. Injection at the correct depth in the middermis is important to prevent undesired adverse effects, such as atrophy of the skin, telangiectasia, or pigmentary abnormalities.

Another possible component in adjuvant keloid treatment is pressure therapy. Topical controlled pressure is considered to reduce the capillary perfusion that causes local hypoxia and leads to a decrease of myofibroblasts and collagen synthesis, acceleration of collagen maturation, and consequent flattening of the keloid. The applied pressure should...
Figure 2. Intramarginal Keloid Excision

A Preoperative keloid appearance
B Intraoperative dissected keloid using fillet technique
C Situs without the removed keloid mass
D Immediate postoperative view

Methods

Study Population
We enrolled 33 patients who underwent an elective excision of an auricle keloid in the context of multimodal sequential keloid treatment in the Department of Otorhinolaryngology-Head and Neck Surgery at the University Hospital of Mannheim from August 1, 2007, through September 30, 2014. We excluded patients with nonauricle keloids, surgical excision using a nonfillet technique, and absence of adjuvant therapy with triamcinolone and pressure therapy. The study was approved by the ethics commission of the University of Heidelberg and was authorized under agreement 256N in 2011. We obtained written informed consent from all participants of the study.

Therapy Regimen
Within the therapy regimen, auricle keloids were surgically excised en bloc using the fillet technique. A nonabsorbable monofilament suture was used for intradermal wound closure to avoid any new trauma when removing the sutures after approximately 7 days (Figure 2). Subcutaneous sutures were not used to avoid the possibility of foreign material stimulating a new keloid growth. Surgical intervention was followed by 6 intrafocal injections of triamcinolone. To avoid injection pain, 1 mL of triamcinolone acetonide (40 mg/mL) was diluted in 1 mL of local anesthesia (lidocaine hydrochloride [Xylocaine], 1%, with adrenaline, 1:200 000). Depending on the size and volume of the former keloid, 1 to 2 mL of the drug mixture was injected intradermally. The first dose was injected perioptatively. Subsequent injections were administered at 4- to 6-week intervals. The drug was injected intradermally, with the aim of having a blanching effect (ie, paling) of the injected area. After termination of the corticosteroid therapy, a customized pressure splint was adapted to the ear to apply topical pressure on the former scar tissue (Figure 3). Because the contours of the ear were changing during the corticosteroid therapy, the impression for the splint was obtained after termination of the corticosteroid therapy. The splint could be adapted to all subregions of the ear. First, an individual negative impression of the auricle was made using soft purple sili-
cone (A&B Co-Form soft Thixo; Principality House), and then an outer shell for stabilization was made of hard green silicone (A&B Co-Form hard). We then created a plaster model (positive) that was used to take measurements for the production of the splints. The first half of the splint was produced with transparent acrylate. After hardening, elaboration, and pre-polishing, the splint was positioned on the model, and magnets were included. Next, the second half of the splint was produced from acrylate and casted on the first half. The splint was elaborated and polished. Before adaptation on the patient, both halves of the splint were adjusted and checked on the plaster model. Transparent acrylate was used so that pressure could be optically controlled and titrated to avoid necrosis. Patients were advised to wear the splint 5 nights a week for 6 months. Contrary to the S2k guidelines (based on a consensus), the pressure splint was worn just during the night, not 24 h/d, to increase patient adherence to treatment. The volume of the en bloc resected keloids was calculated postoperatively from the histopathologic measurement.

**Measurement of QOL**

Patients received a 3-part questionnaire by mail to collect data. Of the total 43 patients treated with multimodal therapy, 33 returned the questionnaire for a return rate of 77%. The questionnaire consisted of 3 parts. The first part focused on the keloid recurrence and positive family history for excessive scarring; the second, pain, pruritus, satisfaction with the result of the therapy, and security with handling of the splint. Thus, after terminating keloid therapy, patients retrospectively evaluated their preinterventional pruritus and pain caused by the

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**Figure 3. Adaption of Customized Transparent Acrylate Pressure Splint to the Ear Conch**

A. Right earlobe 6 months after excision of the keloid mass and glucocorticoid injection. B. Plaster model of the patient’s ear (left) and negative individual silicone impression of the auricle for the pressure splint (right). C. Frontal view of the pressure splint on the ear. D. Rear view of the pressure splint on the ear.
keloid and scored their handling of the pressure splint and satisfaction with the result of the therapy using a 4-point system. For pain and pruritus, 1 point indicated no pain or pruritus; 4 points, maximum. For satisfaction, 1 point indicated that patients were not at all satisfied with the therapy result; 4 points, very satisfied. For security with handling of the splint, 1 point indicated that patients were very insecure with handling the pressure splint; 4 points, very secure.

The third part of the questionnaire consisted of the GBI, which included 18 questions. Each question had 5 answer options that represented a specific number of points that indicated clear decline (−5 points), slight decline (−3 points), no change (0 points), slight improvement (3 points), and clear improvement (5 points). To analyze the answers, we generated a total score and 3 subcategory scores, which included General Health, Social Support, and Physical Health. The score of each category had a range of −100 to 100 points. A score of −100 points indicated a clear decline; 0 points, no change; and 100 points, a clear improvement. The data were registered and analyzed descriptively from September 1 through November 15, 2014.

### Statistical Analysis

We calculated mean (SD) values for all data. A P value of no more than .05 was considered statistically significant. The statistical tests included the Mann-Whitney test, the Wilcoxon rank sum test (using SAS software; SAS Institute Inc), and the paired and unpaired t test.

### Results

We evaluated data from 33 patients with 42 auricular keloids; 24 patients were female and 9 were male. Mean (SD) age of the patients was 27 (17 [range, 9-71]) years at the time of surgery. Seventeen of 42 keloids (40%) were located on the earlobe; 17 (40%), in the middle part of the helix region; and 8 (19%), in the apex of the helix region. Two of the 33 patients (6%) developed postoperative wound dehiscence. Both patients initially presented with large recurrent keloids. Owing to the complication, a wound revision was performed.

Eight of 42 keloids (19%) in 7 patients had a relapsed keloid scar after the multimodal keloid therapy. Four of these 7 patients with 5 keloids showed poor adherence to the pressure splint (adherence rate, 29 of 33 patients [88%]). When we excluded the 4 patients with nonadherence, we detected recurrence in 3 of 37 keloid scars (8%) among 29 patients. Patients justified their poor adherence with an unpleasant fit of the splint during the night leading to sleep disturbance and insecure handling of the splint. The mean (SD) time to recurrence was 9 (9) months. The mean (SD) follow-up was 30 (19) months (through August 31, 2014). A total of 22 patients (67%) presented to our department with recurrent keloids that had been treated elsewhere previously. The remaining 11 patients (33%) presented with a keloid that had not been treated before.

Patients’ mean (SD) score of preoperative pain was 2.06 (1.12) points. The mean score of preoperative pruritus was 2.73 (1.10) points. Thirty of 33 patients (91%) reported that they were satisfied or very satisfied with the therapy (specified with a score of 3 to 4 points). Security with handling of the compression splint was scored with a mean (SD) of 3.60 (0.66) points (Table 1). The evaluation of QOL changes after the multimodal keloid treatment was performed retrospectively after the intervention with the GBI. The mean total score for all 33 patients was 21.53 (15.86 [range, 0-58]) points (Table 2). Patients without a relapse specified an amelioration of their QOL with a total GBI score of 22.53 points (P < .001). Patients who had a relapse of the keloid rated their QOL with a mean total GBI score of 17.07 points (P = .02).

We detected a statistically significant correlation between the handling of the pressure splint and recurrence (P = .02). Patients with a recurrence rated their handling with the splint with a mean score of 3.60; patients without a recurrence, 4.00. Better handling lowered the recurrence rate. No statistically significant correlation was seen between reappearance of the keloid and pruritus or pain. Patients with a recurrence rated their preoperative pruritus with a mean score of 2.73 compared with patients without a relapse, who had a mean score of 3.00 (P = .14). Patients with a recurrence rated their preoperative pain with a mean score of 2.06 compared with patients without a relapse with a mean score of 2.00 (P = .08). A statistically significant correlation between the volume of the initial keloid and relapse could not be found (P = .07). The postoperative histopathologic measurements of the keloids had a median of 2.88 (SD, 8.28; range, 0.3-28.9) cm³. The volume of the keloids with a relapse had a median of 7.20 (SD, 9.56; range, 1.20-28.9) cm³, and the volume of the keloids without a recurrence had a median of 2.90 (SD, 8.01; range, 0.30-27.0) cm³. No statistical significance between a positive family history and the relapse rate was found (P = .56). Furthermore, no statistical significance was found between keloids that underwent repeated treatment and the relapse rate (P = .63). Five of the 7 patients (5 keloids) with a relapse underwent treatment elsewhere.

### Discussion

Keloids are fibroproliferative scars for which therapy challenges plastic surgeons, dermatologists, and ear, nose, and throat specialists. The various therapy approaches all have a potential risk for keloid recurrence. This multimodal therapy reflects that the pathophysiological features of keloids are not

<table>
<thead>
<tr>
<th>Measure</th>
<th>Score</th>
<th>Mean (SD)</th>
<th>Median (Range)</th>
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<tr>
<td>Preintervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>2.73</td>
<td>(1.10)</td>
<td>3 (1-4)</td>
</tr>
<tr>
<td>Pain</td>
<td>2.06</td>
<td>(1.12)</td>
<td>2 (1-4)</td>
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<tr>
<td>Postintervention</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Subjective satisfaction</td>
<td>3.60</td>
<td>(0.82)</td>
<td>4 (1-4)</td>
</tr>
<tr>
<td>Security handling the</td>
<td>3.60</td>
<td>(0.66)</td>
<td>4 (2-4)</td>
</tr>
<tr>
<td>pressure splint</td>
<td></td>
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* Scores range from 1 (indicating no pain or pruritus, not satisfied at all, or very insecure) to 4 (indicating maximum pain or pruritus, very satisfied, or very secure).
Table 2. Postinterventional QOL Assessment Measured With the GBI After Multimodal Keloid Therapy

<table>
<thead>
<tr>
<th>GBI Category</th>
<th>GBI Score</th>
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<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median (Range)</td>
<td></td>
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<tr>
<td>All patients (N = 33)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>21.53 (15.86)</td>
<td>16.6 (0 to 58)</td>
<td></td>
</tr>
<tr>
<td>General Health</td>
<td>31.93 (23.72)</td>
<td>25.0 (0 to 88)</td>
<td></td>
</tr>
<tr>
<td>Social Support</td>
<td>1.51 (6.38)</td>
<td>0 (−17 to 17)</td>
<td></td>
</tr>
<tr>
<td>Physical Health</td>
<td>−1.50 (12.73)</td>
<td>0 (−67 to 17)</td>
<td></td>
</tr>
<tr>
<td>Patients with relapse (n = 7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>17.07 (11.8)</td>
<td>17.3 (3 to 33)</td>
<td></td>
</tr>
<tr>
<td>General Health</td>
<td>32.12 (23.72)</td>
<td>27.0 (0 to 50)</td>
<td></td>
</tr>
<tr>
<td>Social Support</td>
<td>1.51 (6.77)</td>
<td>0 (0 to 17)</td>
<td></td>
</tr>
<tr>
<td>Physical Health</td>
<td>−1.50 (29.31)</td>
<td>0 (−67 to 17)</td>
<td></td>
</tr>
<tr>
<td>Patients without relapse (n = 26)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>22.53 (16.6)</td>
<td>22.6 (0 to 58)</td>
<td></td>
</tr>
<tr>
<td>General Health</td>
<td>33.03 (24.6)</td>
<td>33.3 (0 to 88)</td>
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<tr>
<td>Social Support</td>
<td>1.51 (6.39)</td>
<td>0 (−17 to 17)</td>
<td></td>
</tr>
<tr>
<td>Physical Health</td>
<td>−1.50 (4.60)</td>
<td>0 (−17 to 17)</td>
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</table>

Abbreviations: GBI, Glasgow Benefit Inventory; QOL, quality of life.

yet fully understood. To this day, no single first-line therapy is recommended.13,20 Most of the existing therapeutic options have high relapse rates. Monotherapy consisting of a corticosteroid injection, for example, has a recurrence rate of 9% to 50% with a response rate of 50% to 100%. For ablative carbon dioxide laser excision, a recurrence rate of 92% has been reported,19 and intralesional interferon therapy has a response rate of 20% to 66%.13,14 Fluorouracil monotherapy has a response rate of 50%.22 Radiotherapy has a relapse rate of approximately 14% to 27%.13,21,22 However, it carries a potential risk for development of a radiation-induced malignant neoplasm.23 Pure surgical excision of the keloid has a recurrence rate of 45% to 100%.13,24

Surgery followed by different adjuvant treatments often remains the basis for multimodal treatments. Surgical approaches frequently are combined with corticosteroid injections, which show recurrence rates of approximately 25%,19,25-27 Music and Engel26 analyzed treatment of 12 patients with keloids of the earlobe who underwent surgical excision using the wedge section technique and monthly adjuvant intralesional glucocorticoid injections for at least 3 months during 3 to 16 months of follow-up without experiencing a relapse. A comparable therapy protocol by Rosen et al27 included excision of the keloid followed by intraoperative and 2 postoperative glucocorticoid injections. They reported a relapse rate of 23% among 64 patients with 92 ear keloids during 60 months of follow-up. Other therapy regimens combine surgical excision with pressure therapy, which is considered to be very efficient in reducing recurrence with minimal adverse effects. Park et al28 evaluated a cohort of 883 patients with 1436 keloids that were surgically excised and followed by pressure therapy using magnets for 12 h/d for 6 months with a follow-up of 18 months. A recurrence rate of about 10% was reported, which was associated with poor adherence to the pressure therapy. Hassel et al29 analyzed treatment of 10 patients with ear keloids who underwent excision followed by pressure therapy with a splint made of an acrylic resin applied on a silicone gel sheet. Patients were asked to use the splint for at least 8 months for 23 h/d. If the scar showed the tendency to form a recurrent keloid, corticosteroids were injected intralesionally. A recurrence rate of 20% was seen. The success of the treatment correlated with regular use of the compression splint. The splint used in the present study could be attached by the patient without external help, which increased individual comfort. In contrast, splints with a screw cap require external help to apply. Patients used the splint for at least 6 months for no less than 5 nights per week, which was considered to be more comfortable. This regimen would indicate that nightly use at least 5 times a week is sufficient to reduce keloid recurrence. Another therapeutic concept combines surgical excision, glucocorticoid injections, and pressure therapy, as in the present study. Bran et al30 evaluated treatment in 7 patients with ear keloids who received multimodal therapy consisting of excision using the fillet technique followed by monthly intralesional triamcinolone injections for at least 6 months and pressure therapy with an individually customized pressure splint. No recurrence was seen during the follow-up of 36 months. The important limiting factor of their study30 was the small number of enrolled patients.

In the present study, we included 33 patients with 42 auricle keloids. Eight keloids (19%) in 7 patients demonstrated a relapse after the multimodal therapy. Four of the 7 patients (with 5 recurrent keloids) showed poor adherence to the pressure splint. Excluding these 4 patients produced an adherence-adjusted recurrence rate of 8% (3 of 37 keloid scars). Twenty-two patients (67%) presented with a recurrent keloid after receiving treatment elsewhere, including any combination of surgical therapy, corticosteroid therapy, cryotherapy, pressure therapy, and/or radiotherapy, which shows the difficulty in successfully treating keloids.

We hypothesize that those keloids are even more difficult to treat. However, successful therapy requires that patients feel secure in their ability to handle the splint, that the therapy is secure without severe adverse reactions, and that the treatment is effective. In addition, treatment must be easy to manage and well tolerated. Adverse effects occurred in only 2 patients; thus, the therapy may be considered successful as a treatment with which patients felt secure. An adherence-adjusted relapse rate of 8% suggested that the therapy also may be considered effective. The mean score for security with handling of the compression splint was 3.60 points, so the therapy also could be considered easy to manage and well tolerated.

We assume that the success of the treatment depended on the patients’ regular use of the splint. Patients who felt insecure about handling the compression splint had a higher relapse rate (P = .02). We presume that improvement in the handling of the splint and consequently the use of the splint may increase patient adherence to treatment and lead to a reduced relapse rate after this multimodal keloid therapy. One goal of keloid therapy is the lowest possible recurrence rate, whereas another aim is an aesthetically satisfactory result to minimize patients’ psychological stress, which can impair QOL.
Outcomes of Multimodal Therapy for Ear Keloids

**ARTICLE INFORMATION**

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**Study concept and design:** Walliczek, Engel, Aderhold, Lippert, Hörmann, Schultz.

**Acquisition, analysis, or interpretation of data:** Walliczek, Engel, Weiss, Aderhold, Wenzel, Schultz.

**Drafting of the manuscript:** Walliczek, Engel, Aderhold, Wenzel, Hörmann.

**Critical revision of the manuscript for important intellectual content:** Walliczek, Weiss, Aderhold, Lippert, Schultz.

**Statistical analysis:** Weiss, Schultz.

**Obtained funding:** Schultz.

**Administrative, technical, or material support:** Walliczek, Schultz.

**Study supervision:** Walliczek, Aderhold, Schultz.

**Conflict of Interest Disclosures:** None reported.

**Additional Contributions:** Jörn Brom, Institute for Anaplastology, Heidelberg, Germany, provided outstanding technical support for the pressure splint he developed. He received no compensation for this role.

**REFERENCES**


Conclusions

This study used the GBI to investigate the changes in QOL for patients after multimodal therapy for keloids and found a significant improvement of QOL after the therapy (P < .001). The QOL enhancement and high patient satisfaction with the treatment results indicate a strong relationship between QOL and successful keloid therapy. These findings also underscore the necessity of constant improvements in therapy for keloids to reduce recurrence rates after treatment.