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Review Article

Innovative, affordable and easily obtainable ear pressure devices for keloid management

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ABSTRACT

Keloids, characterized by excessive collagen production leading to raised, fibrous scars, present a persistent challenge in dermatological care, particularly when they affect sensitive areas such as the ear. This analysis introduces a thorough review of easily accessible specialized ear pressure devices designed to manage and prevent keloid formation through localized, controlled pressure application. These clips feature an advanced pressure-regulating mechanism that delivers consistent, low-level compression to the keloid-affected ear tissue, harnessing principles of mechanotransduction to reduce excessive collagen deposition and promote effective scar remodeling. Constructed from biocompatible, lightweight materials, the easy-to-obtain device features an adjustable fit to accommodate varying ear sizes and shapes, ensuring optimal pressure distribution and patient comfort. This design aims to minimize the need for invasive treatments by providing a non-surgical, patient-controlled method of keloid management. Preliminary research demonstrates improvements in keloid flattening and reduction in associated symptoms, such as itching and discomfort. Future research should focus on refining the device's pressure modulation capabilities, exploring long-term efficacy across diverse patient populations, and evaluating its potential integration into comprehensive keloid treatment protocols. Easily accessible and affordable keloid pressure clips represent a significant advancement in keloid care, offering a targeted, minimally invasive solution with the potential to transform therapeutic approaches and improve patient outcomes in dermatology.

Keywords: Keloid pressure devices, Keloid management, Skin, Dermatology, Innovation

INTRODUCTION

Keloids are benign dermal tumors that arise due to excessive collagen deposition after cutaneous trauma or injury.[1] They are distinguished by their raised, firm, bosselated appearance and extend past the margins of the original wound without spontaneous regression.[1,2] Keloid lesions commonly occur on the anterior chest, shoulders, earlobes, upper arms, and cheeks and may develop years following injury.[3] The highest incidence of keloids is seen in the second to third decade and in dark-skinned individuals, with 15-20% of cases seen in Black, Asian, and Hispanic populations.[1] There have been no reported cases of keloid scars in albino individuals and there is a lower risk of keloid scar formation in Caucasians.[1] Interestingly, however, a study done by Brown et al, has

shown genetic susceptibility to keloid scar formation in Caucasians that possess the HLA-DRB1×15 phenotype. It was found that the frequency of the HLA-DRB1×15 phenotype was significantly higher in keloid patients (38.8%) compared to controls (20.9%) (p=0.0013) (p=0.017 after corrections) and was associated with a 2.4 times increased risk of developing keloids (OR 2.41, CI 95%).[4]

These findings underscore the role of genetic factors in keloid formation, thereby warranting a closer examination of the underlying scar formation process, which occurs through three primary stages: inflammation, cell proliferation, and matrix remodeling. Following cutaneous injury, platelet degranulation leads to the release and activation of cytokines, including transforming growth factor-beta (TGF-β), epidermal growth factor (EGF), platelet-derived growth factor (PDGF), and insulin-like growth factor I (IGF-I).

These cytokines act as chemotactic agents for the recruitment of immune cells, which activate the complement system and the clotting cascade, leading to the formation of a fibrin clot that promotes hemostasis. After this initial inflammation phase, cell proliferation begins, during which fibroblasts synthesize the extracellular matrix (ECM), consisting of proteoglycans, procollagen, and elastin.

This establishes a structural framework to facilitate wound closure and promotes vascularization. Finally, during matrix remodeling, the ECM undergoes degradation and immature type III cells transform into mature type I collagen. Keloid scars develop when there is dysfunction in one of the regulatory mechanisms of tissue remodeling discussed above, leading to excessive scar formation.[2,3] For example, this can occur due to a prolonged inflammatory period, during which fibroblast activity and collagen deposition increase.[3]

During this inflammatory phase, the differential expression of TGF-B isoforms contributes to keloid scar pathogenesis. Of the 3 isoforms of TGF-B, TGF-B1 and B2 are overexpressed and stimulate collagen and proteoglycan synthesis, thereby preventing ECM breakdown. In contrast, TGF-B3 exhibits reduced mRNA expression as it functions to decrease connective tissue deposition.[3]

Furthermore, the persistence nature and high recurrence rate of keloids makes definitive treatment a challenge. Direder et al, highlight the feedback loop that exists between repair Schwann cells and macrophages, which contributes to fibrosis following cutaneous injury. During the wound repair process, an abundance of Schwann cells found in scar tissue signal macrophages via chemokines and cytokines and induce M2 polarization of macrophages, which subsequently stimulates the re-differentiation of Schwann cells by macrophages. This complex interplay between Schwann cells and macrophages results in fibrosis and keloid persistence.[5] Additionally, keloid scars recur in 70-100% cases after surgical excision, which further makes finding a definitive treatment for keloids challenging.[1,3] Identifying an effective therapeutic modality for keloid eradication in sensitive areas is essential, both to address aesthetic concerns and to prevent a decline in quality of life. Patients that have keloid lesions usually report symptoms of pain, pruritus, numbness, and redness.[6] More specifically, scars on exposed areas of the body, especially the auricular, facial, and thoracic region, can lead to psychological distress and the development of body dysmorphia.[7] Motoki et al, report that up to 40% of patients with keloid scars in exposed areas experience negative body image, highlighting the need for prompt and effective management of keloid lesions.[7]

Moreover, considering that surgical treatment is often ineffective in preventing keloid recurrence and may entail significant costs, the application of ear pressure devices represents a viable conservative treatment option. Pressure devices operate by inducing localized tissue hypoxia, which subsequently downregulates fibroblast activity and inhibits collagen deposition.[1] The device is required to have a pressure between 24-30 mmHg in order to exceed capillary pressure, thereby inducing tissue hypoxia and exerting its therapeutic effect.[8] There are various pressure devices that exist, including: pressure clips, buttons, earrings, and form-pressure garments that can be applied to the pinna.

Rathee et al, detail a low-cost methyl methacrylate pressure device designed to apply sustained pressure to the patient's pinna, constructed from materials that discreetly conceal the device. The patient was instructed to wear the device 24 hours a day, 7 days a week for 4-6 months and was educated about proper hygiene and maintenance of the device. During each two month follow up with the patient, it was noted that the keloid lesion had reduced in size by 2 mm.[8] This illustrated the efficacy of sustained pressure in promoting local hypoxia and collagenase activity, consequently reducing keloid scar size. Pressure devices serve as an effective conservative alternative to surgical interventions, offering a cost-efficient solution. Additionally, they are widely accessible to patients and help reduce surgical burden.[8]

KELOID PATHOPHYSIOLOGY AND TREATMENT CHALLENGES

Keloid formation is suggested to result from an imbalance between the overproduction and insufficient breakdown of collagen and extracellular matrix (ECM).[9,10] Berman et al, believed this pathophysiologic mechanism to be driven by the upregulation of growth factors and pro-inflammatory proteins, such as transforming growth factor-beta (TGF-β), interleukins (IL-6, IL-8, IL-10), platelet-derived growth factor (PDGF), and vascular endothelial growth factor (VEGF).[9] Specifically, the imbalance between TGF-β isoforms

results in an upregulation of fibroblast activity, which drives the excessive collagen buildup in keloids.[9,10] This imbalance in collagen regulation highlights the critical role of growth factors and inflammatory mediators in driving the pathological scarring process characteristic of keloid formation.

Additionally, mechanotransduction, or the process by which cells sense and respond to mechanical forces, is hypothesized to contribute to keloid development. The mechanical tension present within a wound triggers cellular and molecular changes that contribute to pathological scarring.[12] During wound healing, mechanosensitive cells, such as fibroblasts and myofibroblasts, respond to external mechanical forces by modulating key signaling pathways, including the integrin-mediated transforming growth factor β (TGF-β) and focal adhesion kinase (FAK) pathways.[12]

These pathways regulate the alignment and behavior of fibroblasts, driving increased collagen production, excessive extracellular matrix (ECM) deposition, and fibroblast-to-myofibroblast differentiation. This results in increased ECM stiffness and creates a feedback loop that perpetuates fibrosis. Moreover, increased matrix stiffness activates integrins that bind to ECM components, triggering a cascade of intracellular signals that promote fibroblast activity and collagen synthesis. This cycle of increased mechanical force, matrix stiffening, and cellular response contributes to abnormal scar formation seen in keloids. The dynamic interplay between ECM rigidity and cell stiffness underlines the critical role of mechanotransduction in keloid development.[12]

As various treatment modalities for keloids exist, there is not one definitive treatment due to varying recurrence rates. While surgical excision is a common treatment modality for keloids, monotherapy can result in high recurrence rates ranging from 65-99%.[11] Adjunctive non-surgical therapies following excision such as triamcinolone acetonide, 5-Fluorouracil, radiotherapy, pressure therapy, or topical silicone are recommended.[9] It is suggested that a combination of both surgical and non-surgical treatment modalities be implemented to produce significantly lower recurrence rates and better outcomes.

Several reviews have demonstrated high recurrence rates to be a significant limitation to the efficacious treatment of keloids. In a review of recurrence rates amongst combinations of therapeutic modalities, Ellis et al, determined the overall keloid recurrence rate to be 19% in the dual therapy group and 11.2% in the triple therapy group, which was not a significant difference.[13] Of importance, there was a significantly lower recurrence rate for keloids treated with triple therapy that included surgical excision plus radiation plus an additional treatment modality when compared with keloids treated with dual therapy using surgical excision and radiation alone.[13] Specifically, auricular keloids often recur and are challenging to treat. In patients with auricular keloid treated with excision followed by 5-aminolevulinic acid photodynamic therapy (ALA-PDT), there were no recurrences at the follow-up visit 2-3 years later, concluding that the combination of surgical excision and ALA-PDT is an effective and safe treatment for auricular keloids.[14] Auricular keloids can significantly impact patients' quality of life due to cosmetic and functional impairment. Implementation of combination treatment modalities may result in lower recurrence rates and promising results in the management of keloids; however, additional larger randomized controlled trials are needed to compare the effectiveness of these combination treatments.

PRESSURE THERAPY IN KELOID MANAGEMENT

Normal wound repair is characterized by a delicate balance of proliferation and degradation. A framework for wound healing is initiated through platelet degranulation and fibrin clot formation. Cytokines including epidermal growth factor (EGF), insulin-like growth factor-I (IGF-I), platelet-derived growth factor (PDGF) and transforming growth factor-β (TGF-β) are strong chemotactic agents participating in wound healing.[15] The involvement of these cytokines suggests a complex inflammatory response which leads to granulation tissue. Additionally, abnormal signaling response from fibroblasts in keloids has shown greater proliferation and levels of type I collagen, elastin, fibronectin, and proteoglycan.[16]

The altered responses seen in the inflammatory stages are implicated in an increased risk for keloid and hypertrophic scar formation. Van Daele et al, described fibroblasts affected by tension-induced mechanosignaling, including integrin-mediated TGF-β signaling and integrin-FAK signaling, as key effectors for extracellular matrix (ECM) remodeling. ECM molecular remodeling occurs from transfer of tension through integrin receptors.[12] However, failure of such mechanosignaling pathways present as extracellular matrix stiffening and accumulation are thought to lead to excessive scar formation. Therefore, the effects of tensile forces can be utilized as potential targets for the management of scarring.

Exact mechanisms of keloid and hypertrophic scars are not completely understood, yet the use of compression forces has been reported in literature to improve scar symptoms. Tanzi et al, discussed continuous compression exerting its effect on scars through induction of tissue ischemia, metabolism decrease and amplified collagenase activity.[16] Thus, pressure therapy has shown to decrease size and thickness of keloids and hypertrophic scars. Additionally, Atiyeh et al, noted scar improvement from pressure therapy through rapid reduction of collagen production and regulation of wound remodeling via extracellular membrane organization.[17] These effects suggest a reduction in scar height and potential decreased

need for surgical intervention. Kim et al, reported alleviation of pain and itchiness with use of pressure garment therapy for keloids or burn scars.[18] Despite improvement in scar symptoms patients experienced discomfort and financial burdens from use of continuous compression devices. Moreover, treatment compliance could pose challenges in overall scar improvement.

The use of pressure therapy has been widely recognized since the late 1900s. Anthonissen et al, described early use of vascular support garments in burn injuries and individually fitted silicone devices worn under pressure garments, masks or splints for scar minimization.[19] Thus, early compression devices as adjunct treatment in burn patients allowed for the exploration of pressure as a treatment modality for hypertrophic and keloid scars. Gauglitz et al, noted stockings, bandages, suits, and pants as forms of pressure garments utilized for prolonged treatment of months to a year.[20] Moreover, the extensive daily use required patients to acquire multiple garment pairs to provide adequate treatment.[20] Despite noticeable scar improvement, the use of pressure garments posed individualized challenges from scar location to improperly fitted devices. Hence, pressure devices were seen as advantageous for the modulation of scar while needing further development to enhance treatment outcomes.

Advancement in pressure mechanisms have been described in literature to better suit patient needs and support positive outcomes on scar treatment. There are now custom-fitted pressure garments, face masks, and splints available to be monitored by trained providers.[19] The use of more tailored devices implies the potential for better individualized clinical results in scarring. Furthermore, a pneumatic pressure sensor has been studied for regular monitoring of pressure and found to be a reliable tool for pressure garment therapy.[19]

This pressure sensor opens the opportunity for tight control of pressure settings, which plays a crucial role in mechanotransduction of scar formation. Additionally, a 71% reduction in keloid recurrence was described with well-tolerated custom molded adjustable pressure clips or magnets surrounding silicone sheets in patients who underwent surgical excision of helical keloids.[21] The tailored developments in compression devices allows for better patient compliance and diminish keloid or hypertrophic scar reappearance. Promising advances in pressure therapies continue to broaden the effective non-invasive therapy options available to patients.

SPECIALIZED EAR PRESSURE DEVICES: DESIGN AND FUNCTION

Ear pressure devices for keloid treatment are designed using biocompatible, lightweight materials such as silicone, which ensures comfort for long-term use. Silicone's flexibility allows it to conform to the complex shapes of the ear, particularly in areas like the lobule and cartilaginous regions, which are often difficult to treat effectively with standard compression methods. Custom silicone molds provide uniform pressure across these areas, improving treatment outcomes by maintaining consistent contact.[22] The durability and adaptability of these materials help prevent irritation, ensuring that patients can wear the devices for extended periods, which is crucial since pressure therapy typically needs to be sustained for several months to prevent keloid recurrence. Additionally, the use of medical-grade silicone reduces the risk of adverse reactions, such as skin irritation or inflammation, which can worsen scarring. By molding these devices to each patient's anatomy, personalized treatment enhances efficacy, especially for patients with unique ear shapes or keloids in hard-to-treat areas. This patient-specific approach positions silicone-based devices as an essential tool in the non-invasive management of keloids.

An adjustable fit is another critical design feature of ear pressure devices, enhancing their effectiveness. Devices such as spring-pressure earrings allow patients to modify the pressure to ensure it is both comfortable and therapeutic.[10] This adjustability is essential because improperly fitted devices can cause discomfort or fail to apply adequate pressure, which could result in suboptimal outcomes. The ability to adjust pressure also ensures that the device can accommodate changes in the keloid over time. For example, as the keloid flattens, the patient may need to reduce the applied pressure to avoid discomfort or pressure sores. This adaptability not only enhances patient adherence to the treatment regimen but also minimizes the risk of complications, making adjustable pressure devices a preferred option for personalized keloid management.

The primary mechanism through which ear pressure devices aid in keloid management is by applying consistent, low-level pressure to the affected area. This sustained pressure triggers mechanotransduction, a process where mechanical forces influence cellular behavior, particularly in fibroblasts. Fibroblast activity is reduced when pressure is applied, which in turn decreases collagen production-a key factor in keloid formation.[23]

By consistently applying pressure, these devices prevent excessive fibroblast proliferation, thereby limiting the development and recurrence of keloids. Pressure therapy is most effective when used immediately after wound healing, as it prevents the buildup of excess scar tissue during the early stages of recovery. In post-surgical settings, this technique has been shown to significantly reduce the risk of keloid recurrence. By maintaining a steady compressive force, pressure devices inhibit the biological processes leading to keloid formation, making them an effective alternative to surgical or pharmaceutical interventions.

Ear pressure devices also play a crucial role in targeting collagen overproduction, one of the hallmark

characteristics of keloid formation. Sustained pressure inhibits this process by interfering with the TGF-β signaling pathway, which regulates fibroblast activity. When pressure is applied soon after keloid excision, it significantly reduces the likelihood of recurrence, addressing one of the biggest challenges in keloid management—high recurrence rates after surgery.[24] Also, patients who consistently used pressure earrings for six months experienced significant flattening of their keloids, indicating that long-term pressure is necessary to achieve optimal results.[25] By regulating the fibroblast response and reducing collagen buildup, pressure therapy not only minimizes the size of existing keloids but also prevents new ones from forming, making it a cornerstone in comprehensive keloid management strategies. The non-invasive nature of pressure devices, combined with their targeted biological effects, makes them a versatile option for both mild and severe keloid scars.

One of the most notable benefits of ear pressure devices is their affordability. Most commercially available devices, such as pressure earrings, are priced around $20, making them accessible to a wide range of patients. This affordability makes pressure devices a practical option for keloid treatment, particularly for those seeking non-invasive and cost-effective solutions. Furthermore, a study by Zhuang et al, introduces the use of magnetic discs combined with thin silicone gel sheets as an innovative yet affordable option for keloid pressure therapy.[26]

This method provides sustained, evenly distributed pressure, making it particularly useful after keloid excision. Integrating magnetic discs enhances pressure control and patient comfort, offering another affordable option to improve outcomes in keloid treatment. However, certain populations, particularly those without internet access or credit cards, may still face challenges in purchasing these devices online. This highlights the need for healthcare systems to provide affordable pressure devices in clinics or pharmacies, especially in underserved areas, to ensure equitable access to effective keloid management.

For those unable to access or afford specialized devices, alternative low-cost options have been explored. Ellis et al, discussed the use of binder clips as a highly affordable and easily obtainable alternative for treating auricular keloids.[27] Binder clips, typically used in office settings, have been repurposed as a simple and low-cost option for applying consistent pressure to the ear, proving effective in reducing keloid size. This method exemplifies how everyday items can be adapted for medical use, particularly in resource-constrained environments. Additionally, some patients have turned to other low-cost alternatives, such as using household items like coins or clothespins to create makeshift pressure devices.[28] These DIY solutions, though less precise than medically designed devices, offer practical options for those who cannot afford or access commercial products.

In addition to being affordable, pressure devices offer a non-invasive, patient-controlled treatment option. Kim et al, emphasize that the ability to self-manage treatment at home allows patients to control both the pressure and duration of therapy, improving comfort and adherence.[29] This patient-centered approach not only enhances the likelihood of successful outcomes but also reduces the need for frequent follow-up visits, making it a convenient option for long-term care.

Furthermore, pressure therapy has been shown to alleviate symptoms such as pain, itching, and discomfort, in addition to reducing the size of keloids. Patients who used pressure devices consistently over an 18-month period not only experienced keloid flattening but also significant relief from associated symptoms.[30] This dual benefit-addressing both the cosmetic and symptomatic aspects of keloid formation-makes pressure devices a comprehensive solution for patients seeking non-invasive management options. By providing effective at-home treatment, pressure devices empower patients to take control of their own care, improving both quality of life and treatment outcomes.

CLINICAL EFFICACY AND PRELIMINARY RESEARCH

Improvements in keloid flattening via pressure devices, such as pressure earrings, have been described in literature for nearly half a century. Brent (1978) discussed one of the first formal studies performed, which showed promising results in flattening keloids, particularly as adjunctive therapy to surgical excision.[24] These devices apply sustained pressure to the keloid area, reducing blood flow and inflammation which subsequently inhibits fibroblast activity and collagen production, essential components in keloid growth.[23] This pathophysiologic understanding of keloid and hypertrophic scar formation gave way to a minimally invasive therapy whose efficacy could easily be studied.

Patients who used pressure earrings for at least 12 hours a day over a six-month period saw significant size reductions in keloids on their ears, with noticeable flattening in over 70% of cases.[25] The timing of applying the device was found to be crucial, with better results observed when pressure therapy began immediately after keloid excision surgery. Early interventions minimize scar tissue formation, leading to improved outcomes.[29]

Despite these encouraging results, not all patients responded equally to the treatment, as effectiveness could be influenced by individual factors such as skin type, keloid size, and patient adherence. Larger keloids or older scars were often more resistant to flattening, suggesting that pressure therapy may be most effective when initiated during the first occurrence of a keloid and when combined with other treatments. In addition to reducing keloid size, ear pressure devices have been shown to significantly alleviate symptoms commonly associated

with keloids, such as itching and pain. These symptoms are often the result of nerve irritation and inflammation within the keloid, creating persistent physical discomfort for patients. Park et al, reported an 18-month recurrence-free rate of 95% alongside a significant reduction in associated symptoms, such as pain, itch, and stiffness.[30] Tanaydin et al, corroborated these findings, showing that all parameters mentioned in the Patient and Observer Scale (POSAS) drastically improved after therapy.[31] This suggests that the mechanical pressure may help reduce the symptoms of local inflammation in addition to keloid size, making the treatment appealing to patients seeking both aesthetic and functional relief.

While the goal is to reduce symptoms with therapy, some patients have experienced mild discomfort from heat and perspiration due to the device itself, particularly if it was not custom-fitted, or if they wore the device for extended periods without proper adjustment.[32] This discomfort combined with poor appearance of ear pressure devices present notable obstacles to patient adherence and may limit efficacy of the device as a therapeutic option. These studies suggest that, when fitted properly, pressure devices can be an effective means of reducing keloid symptoms, making them a valuable non-invasive option for patients.

Several case studies have reported successful outcomes using various models of ear pressure devices, meaning there are options that can appeal to different patient needs. Oliviera et al, describes two patients who created low-cost pressure devices using household items, such as a coin and clothespin.[28] While the exact pressures exerted by these objects may be difficult to measure, their simplicity and effectiveness suggests a new area for research into low-cost alternatives in pressure therapy. Similar positive outcomes were reported when utilizing a pressure device with a V-loop component, which allows for adjustment in the direction and pressure of the device, unlike conventional models.[33]

This case offers an effective option that limits the risk of discomfort and ulceration from excessive pressure. For more challenging keloids, the “ESCAPE” model has had the most success; it combines the therapeutic components of excision, skin grafting, corticosteroids, adjuvant radiotherapy, pressure therapy, and emancipation.[34] Such a model illustrates the effectiveness of pressure therapy as part of a comprehensive treatment plan for those with recurrent, aggressive keloids that have thwarted monotherapy in the past. These cases broaden our idea of effective pressure devices and propose alternatives for specific patient needs, whether it be low-cost, improved comfort, or management of persistent keloids.

Patient satisfaction with ear pressure devices has generally been positive, with many reporting significant improvements in both cosmetic appearance and quality of life. A prospective study by Tanaydin et al, found significant improvement in quality of life in recurrence-free patients, noting a marked reduction in keloid size and improved aesthetics of their ears.[35] This cosmetic improvement often translated into enhanced self-esteem, as many patients felt less self-conscious about the appearance of their keloids. Walliczek et al, also reported that symptom relief, such as reductions in pruritus and pain, contributed to improved patient comfort and overall quality of life.[36] Generally speaking, patients who adhered to prescribed treatment regimens are more likely to report satisfaction with the therapy. However, some patients have expressed dissatisfaction with the relatively unattractive aesthetic appearance of the device as well as physical discomfort due to the pressure of the device, particularly if worn for long periods without proper adjustment.[31] While 89% of patients would agree to retreatment in lieu of these concerns, it is important that we continue to develop more comfortable devices to improve patient quality of life throughout the management process, not simply at the end of treatment.

Despite promising initial results, the research on ear pressure devices is limited by small sample sizes and short follow-up periods. Studies like those by Bran et al, have emphasized the need for larger, randomized controlled trials (RCTs) to fully assess the long-term efficacy of pressure therapy, especially in preventing keloid recurrence.[25] Most existing studies have included fewer than 50 patients and followed them for less than a year. This makes it difficult to draw definitive conclusions about the therapy’s long-term sustainability, particularly since keloids are known to recur even after treatment.

Larger studies with longer follow-up periods would help establish clearer guidelines for clinicians, including how long pressure therapy should be maintained to achieve the best outcomes Walsh et al.[21] These larger studies would allow for more detailed analysis of factors such as device design, patient adherence, and the impact of combining pressure therapy with other treatments. Multiple systematic reviews and meta-analyses have echoed these needs with hopes to determine the most efficacious treatment(s) for preventing post-excisional keloid recurrence.[37] Without such studies, it remains difficult to standardize pressure therapy as a reliable and sustainable keloid treatment modality.

One of the key limitations in the existing research on ear pressure devices is the variation in treatment outcomes across different patient populations. Keloids are more common in individuals with darker skin types, such as those of African, Asian, or Hispanic descent, and studies have shown that these patients may experience higher recurrence rates even with pressure therapy.[31] Incidence of keloids has been linked to other medical conditions, such as leiomyomas, which implicates the need for further research exposing such clinical associations.[38] Poor representation of certain demographics in the literature risks delayed treatment and poor clinical outcomes. Further, as more inclusive research is

performed and published, keloid recurrence rates among different populations could guide treatment decisions and reduce the duration of time patients suffer with keloids. Addressing these differences in future research is essential for improving the generalizability, reliability, and accessibility of pressure therapy as a keloid treatment.

FUTURE DIRECTIONS FOR RESEARCH AND DEVICE DEVELOPMENT

The application of keloid pressure devices has demonstrated promising outcomes as a minimally invasive therapeutic approach. While preliminary data has shown pressure devices to be effective, further research is warranted to ensure safety, integration into treatment protocols, and effectiveness across diverse populations.

While these devices have demonstrated efficacy, a standardized protocol for optimal treatment has yet to be established. It is crucial the devices provide effective pressure without inducing ischemia. According to Tahir et al. research indicated that optimal pressure should be at least 24 mm Hg while other studies suggest a pressure range of pressure to be from 24-30 mmHg. Conversely, other studies reported effective pressures between 10-25 mmHg for treatment.[37] This variability across studies complicates the determination of the ideal hypoxic state and length of treatment duration. Currently, there is a lack of standardization regarding pressure applied, duration of treatment, and the types of devices used. Future studies should prioritize identifying the optimal pressure parameters, which may require individualized approaches.

Additionally, it is essential to consider the developmental stage of keloids when determining treatment strategies. The efficacy of devices that can deliver variable yet consistent pressure to the keloid is paramount. Previous studies have shown that spring clip devices were most effective for treatment along with magnet clips that could be effective with proper sizing and strength.[39] Establishing pressure standardization and enhancing our understanding of treatment protocols for different keloid stages will significantly advance the effectiveness of keloid pressure treatment.

Variability in skin types and keloid size presents significant challenges to the efficacy of treatment devices. The inherent differences in skin type complicate the standardization of therapeutic approaches. Hypopigmentation persisted in patients with Fitzpatrick skin types IV to VI following cryotherapy, highlighting the need for tailored interventions.[10] To optimize the effectiveness of pressure devices, it is important to consider factors such as skin elasticity, wound healing responses, and individual genetic predispositions. Addressing these variables is vital for developing effective treatment management strategies and preventing recurrence. Additionally, keloid size is a critical consideration. Future research should explore the maximum dimensions a pressure device can accommodate while delivering sufficient pressure, as there may be a threshold beyond which surgical intervention becomes necessary. Ensuring that pressure devices maintain consistent performance throughout the treatment duration is crucial for their success. Continuous pressure therapy over a period of seven months resulted in no recurrence at a 2.5-year follow-up.[40] In the same article, authors mention devices that were worn for 10 hours a day for 6 months.[40] Therefore, establishing a pressure device capable of sustaining its effectiveness throughout the entire treatment period is essential for optimal outcomes.

While pressure devices have demonstrated promising results in the management of keloids, it is essential to clarify their role within a comprehensive treatment protocol. Currently, the absence of a standardized treatment approach for keloids highlights the potential of pressure devices as a viable therapeutic option. Future research should aim to evaluate the efficacy of various treatments and establish a standardized protocol for keloid management. Keloids exhibit complex pathophysiology and the body of research addressing their treatment remains limited. Although multiple treatment modalities exist, no definitive studies have identified a superior approach. The existing literature primarily consists of low-quality randomized controlled trials (RCTs) with a lack of high-quality RTCs assessing the comparative effectiveness of keloid treatments.[10]

Such investigations are crucial for understanding how pressure therapy might synergize with other modalities, including corticosteroids, laser therapy, and cryotherapy. Furthermore, it would be important to explore the role of how pressure therapy would take a role in preventative care for high-risk patients. Many risk factors have been associated with severe keloid formation, including low to middle socioeconomic status, infections, the presence of multiple keloids at various sites, and a history of persistence lasting over 15 years, to name a few.[41] Addressing these risk factors is critical for slowing disease progression, and understanding how pressure devices could contribute to prevention in individuals with these vulnerabilities will be an important area for future investigation.

The application of pressure devices for keloid treatment shows significant promise although several critical areas require further investigation to establish their viability and efficacy. Establishing optimal pressure levels tailored to the various stages of keloid development is essential for achieving favorable therapeutic outcomes. Additionally, assessing device efficacy across different skin types and accounting for keloid size will enhance the overall effectiveness of these interventions. Furthermore, elucidating the role of pressure therapy in conjunction with other treatment modalities will contribute to the

development of a comprehensive treatment protocol. Another important avenue of research involves exploring the potential of pressure therapy for the prevention of keloids in high-risk patients, who may be predisposed to severe keloid formation. By focusing on these key areas, pressure therapy could emerge as a minimally invasive and cost-effective treatment option offering long-term benefits for individuals affected by keloids.

CONCLUSION

Surgical excision is a widely used treatment for keloids, though it often carries a significant risk of recurrence. The most effective strategy to improve outcomes and minimize recurrence involves combining surgery with additional therapies. In contrast, pressure therapy provides a non-invasive, patient-controlled alternative that has been associated with a lower risk of recurrence. Specialized ear pressure devices have demonstrated effectiveness in reducing keloid size and alleviating symptoms such as pruritus and pain, particularly when used immediately after excision surgery.

However, the larger and older scars did not decrease in size as significantly as the smaller and newer keloids. A major challenge to the effectiveness of these devices is patient adherence, which can be hindered by discomfort or the unattractive appearance of the device. Customizing these devices to fit each patient may improve adherence and outcomes. The patient can adjust the settings and the fit as the keloid changes. Further research is needed to establish standardized treatment protocols for keloid management. Large-scale, randomized controlled trials are crucial to compare various therapies and determine optimal pressure settings, as well as recurrence rates when using pressure devices.

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