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ORIGINAL ARTICLE

Combined laser treatment for ear keloids: Case series

Comparison between two mini-invasive protocols

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Abstract

Background: Keloids are benign fibrous tumors derived by excessive proliferation of fibroblasts and collagen synthesis after an injury, and they do not regress spontaneously. Earlobes keloids may develop either on the helix or on the anterior or posterior lobe, up to several years after piercing.

Aims: To evaluate the effectiveness of a combined protocol of CO2 laser + dye laser versus CO2 laser + dye laser + Enerjet.

Methods: Eighty patients with a total of 83 ear keloids were divided in two groups: One group has been treated in the same session with a single CO2 laser procedure + a pulsed Dye laser procedure; the second group has been treated as the group one with an adjunctive Enerjet procedure.

Results: Of the 40 patients for a total of 41 treated keloids in the first group, 85.4% of keloids did not recur during a follow-up period (3 months–7 years), 14.6% of the lesions recurred (6/41) with mild thickening of the scar and underwent to further treatments. The second group (40 patients, 42 keloids) results showed a 90.5% of keloids which did not recur during a follow-up period (3 months–2 years), while 9.5% of the lesions recurred (4/42) with mild thickening of the scar and underwent to further treatments.

Conclusions: Lasers demonstrated a synergistic effect when combined together and an excellent outcome has been obtained in the 88% of treated lesions, with a slighter higher prevalence of excellent outcome of the group treated with a further procedure with Enerjet.

KEYWORDS
carbon dioxide laser, Enerjet, keloids, pulsed dye laser

1 | INTRODUCTION

Keloids are benign fibrous tumors derived by excessive proliferation of fibroblasts and collagen synthesis after an injury. The term originates from the Greek word χηλή (chele, crab's claw), and it is used to describe the lateral growth of tissue, extending beyond the margins of the original skin wound, into unaffected skin.[1,2]

They can arise potentially on every wound after major or minor injuries (such as trauma, burns, piercing, surgical procedures), without difference between age or gender, in predisposed individuals, even though darker skin and range age between 10 and 30 years seem to be the most affected categories. Keloids can affect each body site, with a predilection for shoulder, chest, and above all, ears; as a matter of fact, keloids are particularly

observed after ear piercing, with an incidence, approximately, of the 2.5%. Ear keloids may develop up to several years after piercing, arising from a mature scar and do not regress spontaneously. They can be observed either on the helix or on the anterior or posterior lobe.[3,4]

Clinically, keloids appear as pink to purple, sometimes hyperpigmented, irregular, fixed, sometimes pedunculated, mildly tender, single or multi-nodular, with well-circumscribed margins, a shiny surface, and sometimes visible telangiectasia.[3,4] Keloids may even be symptomatic, causing pruritus, pain (from mild to moderate-severe) and hyperesthesia. By expanding far beyond the site of initiation and encompassing entire anatomic areas, these lesions can be disfiguring, and if occurring near a flexor or extensor joint, the patient may experience reduced limb mobility. In addition, keloids have a higher tendency to recur following surgical excision (45 up to 100%), whereas new hypertrophic scar formation is rare after its excision (10%).[1-4]

The diagnosis of keloids is based on the clinical appearance along with a history of a preceding trauma or surgery and differential diagnosis mainly include hypertrophic scars, which have the similar look, but the latter are commonly linear following the shape of wound, more frequently occur on shoulders, neck, pre-sternum, knees, and ankles, and the major symptom is represented by pruritus. Especially for the ear site, other differential diagnoses should include embedded foreign bodies, sarcoid granuloma, and epidermal cyst. In general, histological examination is recommended only in case of lesions mimicking atypical infections or malignancies.[1-5]

2 | MATERIAL AND METHODS

We herein report our clinical experience with CO2 laser, pulsed dye laser, and Enerjet applied on 80 patients aged from 6- to 82-year-old (mean 32 years), presented with earlobe and helix keloids and with a follow-up time of between 3 months and 7 years after the last treatment.

Each patient signed an informed consent before starting treatment and the keloid lesion presented has been classified based on modified Chang–Park classification.[6]

All patients who came to our private clinic asking for an evaluation for their keloids were proposed to participate in our comparative study with two experimental protocols. Through our social channels (Facebook and Instagram), many patients called us from all over Italy after seeing the results of the protocol we had proposed. All patients who presented with keloids presente after ear-piercings or otoplastic surgery, previously treated in other renters with surgery: all of them had relapsed multiple times, and thus all patients decided to be enrolled in our study and appeared extremely motivated to try something different in order to reduce any risk of recurrence.

We thus enrolled 80 patients, which we divided into two groups for the comparative study of the two protocols. We thus enrolled 80 patients, which we divided into two groups for the comparative study of the two protocols.

Our population counted 41 males (8–82 years, mean 36 years) and 39 women (6–77 years, mean 25 years) with a total of 83 keloids

FIGURE 1 Type I: a 1.5 cm in-diameter pedunculated Keloid of the helix, in a 35-year-old woman

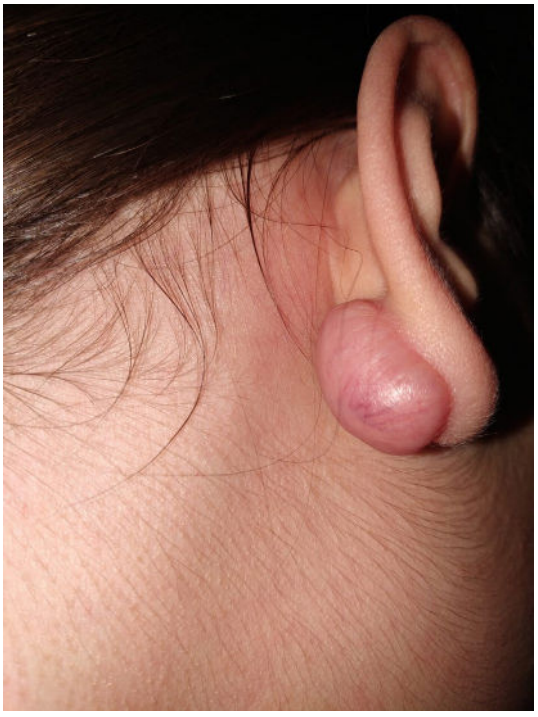

FIGURE 2 Type II: a sessile Keloid with single nodular pattern in a 23-year-old man (2 cm indiameter), sited on the posterior surface of the earlobe, arose after an ear piercing

FIGURE 3 Type III: a sessile with multi nodular pattern Keloid in a 33-year-old man, arose after otoplastic surgery

FIGURE 4 Type IV: a buried Keloid of the helix in a 19-year-old woman

lesions, classified according the modified Chang-Park classification as follows: 24 lesions of type I—pedunculated (29%) (Figure 1), 29 lesions of type II—sessile with single nodular pattern (35%) (Figure 2), fives lesions of type III—sessile with multinodular pattern (6%) (Figure 3), five lesions of type VI—buried (6%) (Figure 4), and 20 lesions of type V—mixed (24%) (Figure 5).

Three dimensional (3D) and 2D pictures were collected from each patient at the first visit and in all following control by using two different 3D digital cameras (Vectra H2, Canfield, USA and Lifeviz mini, Quantificare, France) and a smartphone for 2D images (Samsung S9).

Dermoscopic digital images of all lesions were taken at the initial visit and at follow-up control by using a HEINE Cube hardware (connected to I-Phone 7 equipped with HEINE Cube software, Monaco, Germany). Each picture has been stored in a digital database. The use of dermoscopy has proved to be very useful in the treatment of keloids (as well as hypertrophic scars and other lesions), due to its capability of highlights the presence of possible pigmentation and neo-vascularization, thus helping physician in the therapeutic choice: by identifying the targets to hit, lasers can be properly chosen.[7]

We decided to divide patients in two groups and performed two different protocols: one group has been treated in the same session with a single session with a CO2 laser procedure immediately followed by a pulsed dye laser procedure; the second group has been treated in the same session with a single CO2 laser

FIGURE 5 Type V: a 4.7 cm in diameter mixed Keloid of 3 cm in diameter was diagnosed in a 27-year-old man, arose after an ear piercing

procedure, immediately followed by a pulsed Dye laser procedure and a Enerjet procedure.

Specifically, the first 40 patients we have enrolled have been treated in the same session with a single CO2 laser (Smartxide Touch, DEKA M.E.L.A., Calenzano, Italy) procedure, by shaving keloid (Power 4 W and frequency 80 Hz in ultra pulsed mode) followed by a single pulsed dye laser (VasQ, DEKA M.E.L.A., Calenzano, Italy) procedure (fluency: 11 J/cm^2; single pulse, pulse duration 1.5 ms, PDL spot 5–7 mm) on each lesion. If the lesion was greater than 2.5 cm in diameter, an adjunctive pulsed dye laser session has been performed 40 days earlier (fluence: 14 J/cm^2; single pulse, pulse duration 3 ms, PDL spot 5–7 mm), in the aim to reduce the blood vessels number and, secondarly, the release of pro-inflammatory cytokines such as VEGF, thus leading the lesion to become smaller, softer and less vascularized. A topic antibiotic and silver sulfadiazine cream were prescribed to each patient as home care.

All patients of the second group underwent to a single CO2 laser procedure followed by a single pulsed dye laser procedure (fluence: 11 J/cm^2; single pulse, pulse duration 1.5 ms, PDL spot 5–7 mm) on each keloid in the same session, followed by a further session with a pneumatic injection without needle (Enerjet 2.0, PerFaction, Rehovot, Israel) of drugs (a solution of 1 ml of Triamcinolone, 3 ml of polyribonucleotides, and 2 ml of sodium chloride; protocol: pressure started at 35%, increased in 5% increments until an adequate bump achieved; filling level: 80–90 μl). Also in this group, if the lesion was greater than 2.5 cm in diameter, an adjunctive pulsed dye laser procedure has been performed 40 days earlier (fluence: 14 J/cm^2; single pulse, pulse duration 3 ms, PDL spot 5–7 mm). A topic antibiotic and silver sulfadiazine cream were prescribed to each patient as home care.

All patients were followed up for at least 3 months (but some for 7 years) as follows: a first visit was arranged one week after the combined treatment performed. A second follow-up visit after 30–40 days have been performed, and then a follow-up visit has been planned at 3 months, 6 months, 1 year and then annually.

All patients were examined both clinically and with dermoscopy at each follow-up visit and clinical images were saved in our database for comparison.

The use of dermoscopy at follow-up visit was extraordinary importance in the aim to recognise any sign of neo-angiogenesis, so that we could immediately treat the patient with a pulsed dye laser session to extinguish the inflammatory fibro-vascular reaction in progress (typically within 3 months from the first treatment).

3 | RESULTS

Of the 83 total lesions, 73 (88.5%) lesions did not recur at all, while a total of 10 keloids recurred between the third and the twelfth month of follow-up.

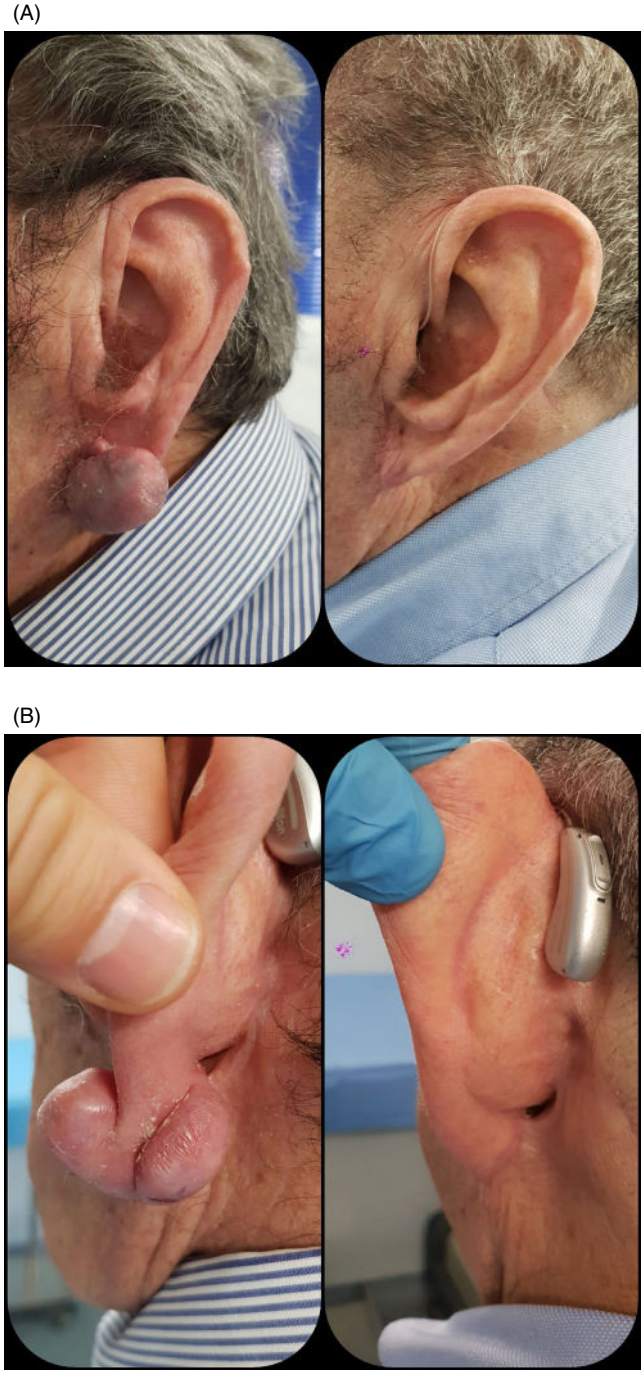

FIGURE 6 (A) Before (left) and after (right) a single protocol session with CO2 laser and PDL. Follow-up: 6 months (right). (B) Same patient, keloid of the posterior earlobe: before (left) and after (right) a single protocol session with CO2 laser and PDL. Follow-up: 6 months (right)

Specifically, of 40 patients for a total of 41 treated keloids in the first group, 85.4% of keloids did not recurred during a follow-up period of 3.5 years (average 3 months–7 years), while 14.6% of the lesions recurred (6/41) with mild thickening of the scar and thus we decide to perform further treatments (Figures 6-11).

Enerjet group enchanted 40 treated patients and 42 keloids: 90.5% of keloids did not recur during a follow-up period of 2 years (average 3 months–2 years), while 9.5% of the lesions recurred (4/42) with mild thickening of the scar and thus we decide to perform further treatments (Figures 12-17).

We would like to highlight that recurrences are mainly represented by a mild thickening and new vascularization (neoangiogenesis evidenced by dermoscopy) of the scar and have been immediately retreated with a dye laser session. Only the biggest recurrence occurred in a 37-year-old man sited on the right helix (2.5 cm in diameter) after a surgical excision in another center and have been treated with another session of CO2 laser plus dye laser plus Enerjet and did not recur during 10-month follow-up (Figure 18).

For both groups, patients applied and ear clip immediately after healing. All recurrences did not relapse anymore. In all cases, patients applied a pressure earring for 2 weeks after combined treatment.

4 | DISCUSSION

According to the literature and recent reviews, there is still no concordance on a single therapeutic modality proposed as golden standard in the treatment of keloids.[8,9] This is mainly due to the limited amount of data derived from well-designed, prospective, randomized controlled clinical trials and to the complex pathophysiologic mechanism which causes keloids and which it is not fully understood.[10]

Thus, treatment options for a keloid are selected by considering the costs/benefits of a topical or an invasive therapy, the type of lesion (location, depth, and size), patient's age, past response to treatment, aesthetic presentation, and expected outcome and, last but not least, patient's economic conditions. Moreover, the clinician should consider that some treatments showed consistent adverse effects and high rates of recurrence, as largely reported in the literature.[11]

Proposed topical treatments include silicone gels and sheeting, pressure dressings and pressure earrings, aggressive deep-tissue massage, and imiquimod 5% cream.[12,13]

Invasive treatments vary from intralesional injections of active principles (such as triamcinolone, bleomycin, verapamil and 5-fluorouracil), up to cryosurgery, radiation, and surgical excision.[12-14] The latter alone shows the highest recurrence rate (50%–100% at 5-year follow-up in all reported studies. Furthermore, surgery shows important potential complications such as infections, wound dehiscence, hematomas, and aesthetic disfigurement. Thus, treatment needs to be carefully planned and the benefit of keloid excision, with or without adjuvant treatment must outweigh its potential risks.[12-17]

Recently, advances in the field of laser therapy have led to the development of devices that have also been tested in the removal of keloids: ablative lasers, non-ablative lasers, and non-coherent light sources have been proposed and different outcomes have been reported.[18]

FIGURE 7 Before (left, first picture) and after (second picture) a single protocol session with CO2 laser and PDL. Follow-up: after 3 months (third picture) and 6 months (last picture)

Ablative lasers include the 2940-nm erbium-doped: yttrium, aluminum, and garnet (Er:YAG) laser and 10 600-nm carbon dioxide (CO2). They have water as a target chromophore in skin and therefore can provoke local tissue destruction.

Non-ablative lasers include pulsed-dye laser (PDL), the 1064-nm neodymium-doped: yttrium, aluminum and garnet (Nd:YAG) laser, and the 532-nm neodymium-doped/vanadate (Nd:Van) laser. Through selective photothermolysis, PDL targets hemoglobin chromophore and coagulates the microvasculature in the capillary and reticular dermis, resulting in the destruction of pathologic neovascularization.[19] This leads to hypoxemia that in turn may alter the local collagen production or may deprive a scar of nutrients to prevent scar hypertrophy.[20] In addition to its vascular specificity, PDL may produce a direct effect on collagen and cause keloid fibroblast functional modification.

Non-coherent light sources include intense pulsed light therapy (IPL), light-emitting diode (LED) phototherapy, and photodynamic therapy (PDT). IPL basis mechanism is still not fully understood. Given that targets both melanin and vascular structure, IPL most probably acts on vascular proliferation, essential for collagen overgrowth, as well as on pigmentation resulting from scar formation, improving thus the appearance and/or symptoms of hypertrophic scars and keloids. The best results following several IPL treatments are more noticeable after a few months, probably due to the inhibition of the vascular action provoked by the IPL on the scar tissue and by the subsequent proliferation of neocollagen.[18,19]

Among the above-mentioned lasers, nowadays, pulsed dye lasers (PDL, wavelength: 585–595 nm) has become an emerging tool in the treatment of keloid and hypertrophic scars. Several studies have shown that PDL can induce significant overall clinical improvement in terms of vascularity, height, texture, color, and pliability of scars and may resolve scar-associated symptoms such as pruritus.[20] However, the greater limit in the efficacy of PDL is represented by the thickness of the lesion: keloids thicker than 1 cm may be reach mild results since PDL has an approximate 1.2 mm depth of penetration. In these cases, combination PDL therapy plus intralesional corticosteroids or 5-fluorouracil injections or other lasers like the fractional CO2 laser has shown to enhance clinical outcomes. Adverse effects include blistering, crusting, post inflammatory pigmentary changes, and purpura, which are more common in individuals with darker skin tones. Epidermal cooling has been shown to be a useful adjunct treatment to reduce adverse complications.[21-23]

There is evidence that multiple ablative CO2 treatments are necessary for longer-lasting scar improvement. Multiple ablative fractional CO2 laser treatments have been tested and treatments with varying laser frequencies have improved keloid pigmentation, pliability, and scar bulk at six months after the last treatment. Scrimali et al.[22] reported a protocol consistent in monthly fractional CO2 treatments resulting in no recurrence of keloid and hypertrophic

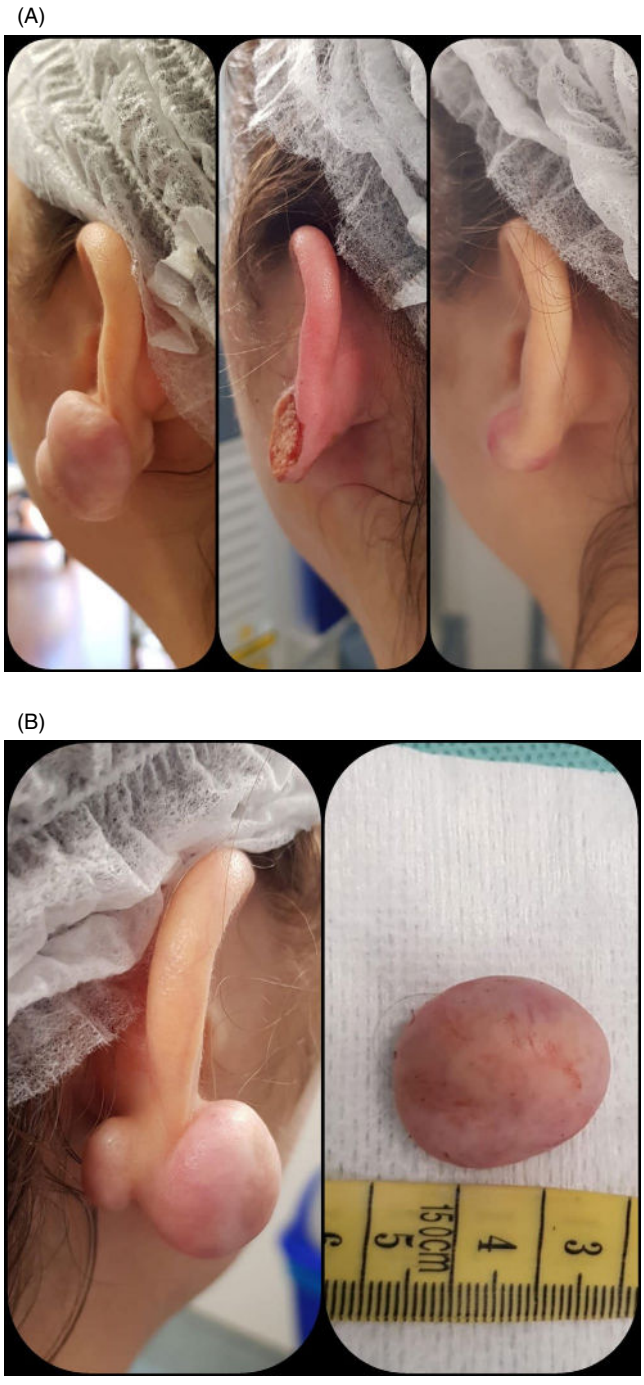

FIGURE 8 (A) Before (left) and after (second picture) a single protocol session with CO2 laser and PDL. Follow-up: 5 years (last picture on the right). (B) Another picture of the 2.5 cm in-diameter keloid before (left) and after (right) CO2 laser excision

FIGURE 9 Before (left, first picture) a single protocol session with CO2 laser and PDL. Follow-up: after 3 months (right)

FIGURE 10 Before (left) and after a single protocol session with CO2 laser and PDL. Follow-up: after 6 months (right)

scars at one year after 6–12 treatments.[25] In contrast, complete earlobe keloid recurrence after a single ablative CO2 treatment has been reported as well.

Compared to simple scalpel surgical excision of keloids, CO2 laser excision without adjunctive therapy has similarly high rates of recurrence, ranging from 74 to 100 percent at one year, but decreased blood loss and postoperative pain. Adjunctive intralesional steroid therapy and cyanoacrylate glue have been shown to improve scar revision results of CO2 laser keloid excision.

Strengthened by our decades of experience in the field of biomedical lasers,[24,25] by mixing two or three types of laser therapy, we obtained interesting results, mainly due to the different target hit

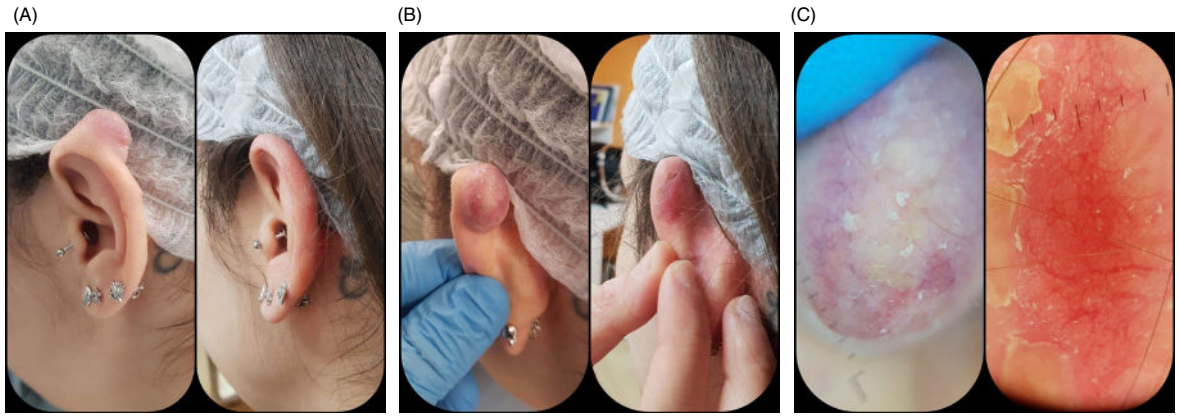

FIGURE 11 (A and B) Before (left) a single protocol session with CO2 laser and PDL and after 6 months (right). (C) Dermoscopic examination before the first session (left) and at the follow-up visit (right): please note the increased number of new vessels. On the basis of this examination, we decided to perform a single session of PDL immediately

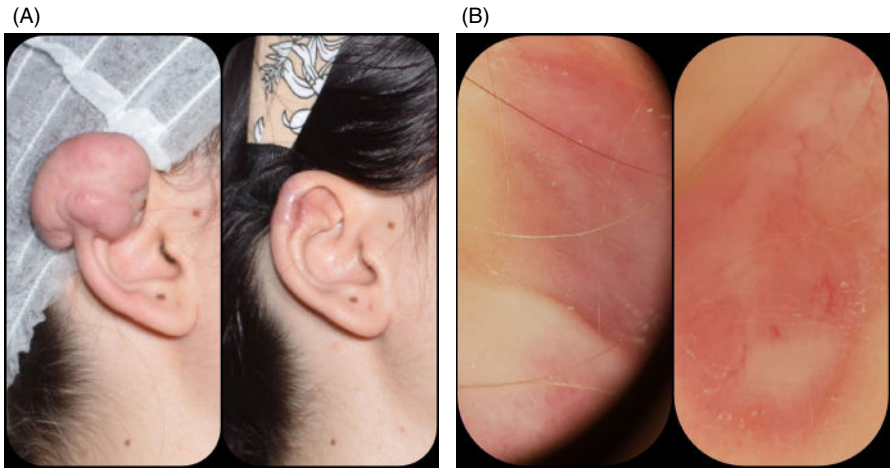

FIGURE 12 (A) Before (left) and after a single protocol session with PDL + CO2 laser + Enerjet. Follow up: 6 months (right). Please note, a slight thickening of the scar is visible. (B) Dermoscopic examination before the first session (left) and at the follow-up visit (right): please note the increased number of new vessels. On the basis of this examination, we decided to perform a single session of PDL immediately

FIGURE 13 Before (up) and after a single protocol session with PDL + CO2 laser + Enerjet in a 24-year-old woman with a 2.8 cm in diameter sessile, multinodulated keloid of the helix. The keloid's weight folded the helix, thus causing a severe psychological distress in the young lady. Follow-up: 8 months (down)

FIGURE 14 Before (left) a single protocol session with PDL + CO2 laser + Enerjet and after 12 months (right)

FIGURE 15 Before (left) a single protocol session with PDL + CO2 laser + Enerjet and after 5 months (right)

FIGURE 17 Before (left) and after (right) a single protocol session with PDL + CO2 laser + Enerjet, and after 14 months (right)

FIGURE 16 Before (left) a single protocol session with PDL + CO2 laser + Enerjet and after 12 months (right)

by CO2 laser and PDL, which seem to be more effective than single monotherapy (or single laser therapy in this case).

EnerJet (2.0, PerFaction, Rehovot, Israel)) uses a Jet Volumetric Remodeling (JVR) technology, an advanced, Israeli patented tissue remodeling tool. Kinetic energy and active substances are simultaneously released by JVR technology with minimal epidermal damage, generating a deep microtrauma with a controlled effect for skin remodeling (the so-called blast effect). It has been tested as an innovative tool in the treatment of acne scars, stretch marks, non-surgical lifting, wrinkle reduction, and keloids.

A powerful jet injection without needles "shoots" the active ingredients into the deeper layers of the skin, creating a microtrauma with a deep volumetric effect and optimal diffusion. The blast effect diffuses the active ingredients (a solution of 1 ml of triamcinolone, 3 ml of polyribonucleotides and 2 ml of sodium chloride seems to be very effective on keloids) into the skin laterally, covering 100 times the area of the entry point of a 32-G (200-μ) needle.

The synergy between energy release and delivery induces a natural healing and hydration process that generates the production of new collagen and subsequent plumping and firming of the skin. This synergy, by activating natural healing, hydration and creation of collagen and elastin, ultimately promotes smoother, hydrated and youthful skin with long-term structural benefits.

By considering its mechanism, we decided to apply Enerjet technology as a third step in our keloid-treatment protocol, in the aim to improve local dermal remodeling after the lasers injury and to try to inhibit recurrences.

5 | CONCLUSION

The effectiveness reported by our double or triple protocol is based on the concept of differentiating each lesion based on its size and on this basis, choosing to directly apply the CO2 laser therapeutic protocol followed by pulsed dye laser or possibly add an Enerjet session. A PDL session 40 days before is required in any lesion greater

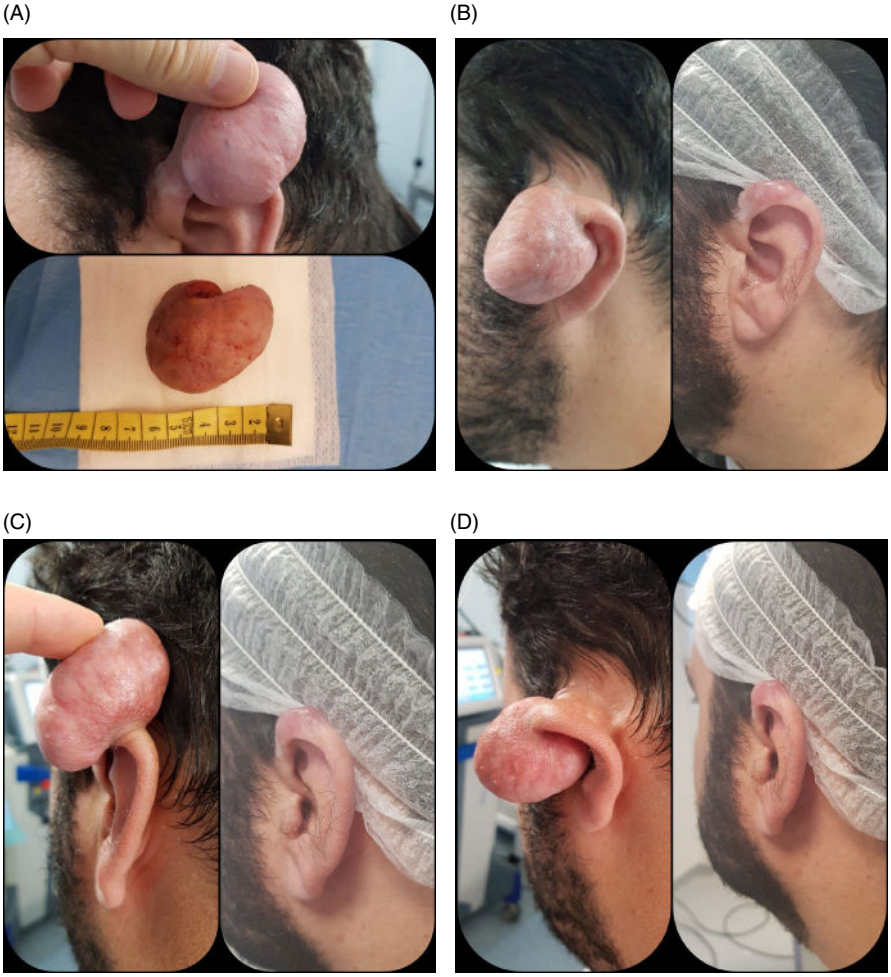

FIGURE 18 (A) Exceptional lesion occurred as recurrence in a 37-year old man sited on the right helix (5 cm in diameter) after a surgical excision in another center. (B–D) The keloid's weight fold the helix causing a severe psychological distress (three perspective on left pictures) and have been treated with another session of Dye laser followed by CO2 laser followed Enerjet and did not recur again during 10-month follow-up (all right images)

than 2.5 cm in diameter. Our results confirmed the disappearance of the lesion in the absence of recurrences in the 88% of cases, even over the long term, and even if these lesions have been treated with traditional surgery in the meantime. Our results are thus promising, although further data of new lesions treated are mandatory.

CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

Domenico Piccolo: has made substantial contributions to conception and design, to acquisition of data, to analysis and interpretation of data. He has been involved in drafting the manuscript and revising it critically for important intellectual content, has given final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Giuliana Crisman, Claudio Conforti:** have made substantial contributions to conception and design, to analysis and interpretation of data, and have been involved in drafting the manuscript and in revising it critically for important intellectual content. **Bruno Bovani, Alessandro Gennai, Fabrizio Melfa:** have made substantial contributions to conception and design, to acquisition and analysis of data, have been involved in drafting the manuscript, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Matteo Tretti Clementoni:** has made substantial contributions to conception and design, to acquisition of data, to analysis and interpretation of data, has been involved in drafting the manuscript and revising it critically for important intellectual content, and has given final approval of the version to be published.

ETHICAL APPROVAL

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available on simple request to the authors.

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