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ORIGINAL ARTICLE

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Efficacy of a multimodal approach of laser therapy for earlobe keloids management in dark population

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Abstract

Background: Patients with keloids are often younger than 30 years old and have darker skin.

Aim: To evaluate the efficacy and safety of CO_2 laser therapy in the management of earlobe and helix keloids in dark subjects.

Methods: A total of 21 dark patients (five men and 16 women) presented with the earlobe and ear helix keloids, with a mean age of 30.5 (±6.7) years and with phototype between III–VI, were enrolled. In order to improve their earlobe and helix keloids, all patients underwent a single session of CO_2 laser therapy immediately followed by a pulsed Dye laser procedure. A single well-experienced doctor performed all treatment sessions and the response to treatment. Patients were followed-up for 6 months after termination of therapy. Clinical images were examined and collected: all patients were examined clinically and with Dermoscopy.

Results: The majority of the patients treated show complete remission of keloid lesions. Clinical photographs show a visible aesthetic improvement of several types of keloids in dark subjects.

Conclusions: Our data demonstrate that this combined laser therapeutic protocol appears to be effective and well tolerated for the management of earlobe and helix keloids in dark subjects, with no high recurrence rate and avoiding the adverse effects and lengthy recovery time.

KEYWORDS
595 nm dye-laser, CO_2 laser therapy, dark subjects, earlobe keloids

1 | INTRODUCTION

Keloids are a relatively common type of raised scar caused by trauma after a wound heals. Keloids form when scar tissue continues to replicate after the skin's healing process is complete. Risk factors for the development of keloid, include prior keloids, a keloid family history, trauma-related stress, and dark skin.[1] Indeed, keloids are more common in darker-skinned races, Asian, African, and Hispanic descent.[2] Although the exact causes are unknown, the British Association of Dermatologists believes that keloids form when the body produces excessive collagen during the formation of a scar in response to an injury.[3] Even if there are several management options for keloids, they can be expensive, and recurrence rates are still high. The use of intralesional corticosteroid injection, pressure therapy, silicone,

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cryosurgery, radiation, surgical excision, and laser are just a few of the therapeutic techniques that have been documented.[4,5] Keloids continue to be a source of concern for clinicians because there are no viable therapies. It has been established that the first-line treatment for keloids is injections of triamcinolone acetonide.[6] However, the injection process was painful, and half of all patients experienced after treatment side effects, such as subcutaneous atrophy, telangiectasia, and hyperpigmentation. The recurrence rate of intralesional corticosteroid injections ranges from 9% to 50%. Surgical excision is also not recommended as monotherapy as it creates a new wound which can result in a similar or larger keloid,[7] and it causes high recurrence rates in the range of 45%–100%.[8,9] The use of superficial radiation therapy (SRT) is FDA approved technique for keloid management with minimal side effects.[10,11] Postsurgical treatment of keloid excision suture lines with SRT significantly reduces keloid recurrence rates with no evidence that exposing surrounding healthy skin causes skin cancer.[11] Cryotherapy has a success rate between 32 and 74 %. However, it is frequently accompanied by several side effects, particularly hypopigmentation.[12] Imiquimod 5% cream and Silicone-based products offer safe treatment methods with minimal side effects. Nevertheless, larger, controlled clinical studies are needed to further evaluate their safety and efficacy.[13] Keloid and hypertrophic scars have been treated with a variety of laser technologies.[9,14] The use of CO_2 laser therapy in treating keloid and hypertrophic scars is well-documented and compelling.[15–17] For many years, the carbon-dioxide laser has been used to treat keloids with its ability to eliminate all fibrotic tissue.[18] A clinical study of 50 patients with moderate to severe keloids treated with high-energy pulsed CO_2 laser found that the treatment was effective and well-tolerated, with few side effects.[16] Therefore, literature has already determined that carbon dioxide laser successfully treats keloids with long-term histologic and clinical effects. Carbon dioxide laser treatment resulted in significant, immediate, and sustained clinical improvement in skin tone, texture, and appearance, and the laser seems to be safe and well-tolerated for the treatment of keloids, with evidence of collagen remodelling without adverse effects and a prolonged recovery time.[16,19] Combining fractional technology, conventional ablative CO_2 lasers, once the gold standard for skin remodelling and scarring, can be utilised more safely.[20–22] Furthermore, published results support the use of laser as an adjunct therapy such as the case report where, the use of combination treatment including CO_2 laser, PDL and triamcinolone on keloid that was previously unresponsive to triamcinolone alone, showed alleviation of symptoms after two treatments and regression by seven.[23] Excision, which is a cornerstone of therapy and has been combined with other modalities to reduce recurrence rates, is one example. Compression, silicone sheets, and cyanoacrylate glue were additionally used in a study evaluating excision with CO_2 laser to enhance outcomes.[24] As compared to previous literature of the monotherapies, combination therapy using two types of laser (nonablative fractional erbium-glass and ablative fractional CO_2), superficial cryotherapy, and triamcinolone injection was found to produce a significant improvement in a relatively short period of time.[25] In addition, Behera et al. comparing results of keloid destruction with the use of cryotherapy verus CO_2 laser, both followed by steroid injections, they observed that the pain reduction was significantly higher in the CO_2 laser group. Carbon dioxide laser therapy causes enough inflammation by removing the fragmented collagenous matrix, promoting new collagen production.[26–28] Blisters, crusting, post-inflammatory pigmentary changes, and purpura are some adverse effects, which are more prevalent in those with darker skin tones. Numerous ablative fractional CO_2 laser treatments have been tried, and six months after the last treatment, keloid colouration, pliability, and scar bulk have improved.[29] Scrimali et al.[30] reported a protocol for monthly fractional CO_2 treatments resulting in no recurrence of keloid and hypertrophic scars at one year after 6–12 treatments. There is minimal pain in the immediate period after laser surgery.[31] On these bases, the current study was designed to evaluate the efficacy and post-treatment outcomes of CO_2 laser therapy using the freehand handpiece combined with Dye laser treatment in the management of earlobe and helix keloids in dark subjects.

2 | MATERIALS AND METHODS

2.1 | Patients

A total of 21 dark patients (five men and 16 women) with earlobe and ear helix keloids, with a mean age of 30.5 (±6.7) years and with phototype between III–VI (four patients (19%) were considered. Seven patients (33%) with phototype IV, five patients (24%) with phototype V and five patients (24%) with phototype VI were enrolled. The study was carried out at the outpatient clinics of the ''Skin Center'' in Avezzano, L'Aquila and Pescara (Italy). The earlobe keloid lesions have been classified based on modified Chang-Park classification[32] as follow: five lesions of type I—pedunculated (Figure 1), four lesions of type II—sessile with a single nodular pattern (Figure 2), seven lesions of type III—sessile with a multinodular pattern (Figure 3), five lesions of type V—mixed (Figure 4). A written and signed informed consent was signed by the whole patients. This clinical study was conducted in accordance with the Helsinki Declaration. The exclusion criteria concern the administration of: Anticoagulants; Retinoids (as isotretinoin, etc); Photo-sensitizers (as tetracycline, naproxen, auranofin, oestrogens and progestins, chloroquine etc.); Sun and UV lamp exposure.

2.2 | Study device and protocol

All treatments in this study were carried out with the Glide CO_2 laser (DEKA M.E.L.A., Calenzano, Italy) using freehand handpieces. The device at hand can provide various laser emission modes, including three ultrapulsed shapes: high peak pulse (HP), smart pulse (SP), and continuous pulse (CW).[33] With the variety of available pulse modes, this technology allows for the induction of various tissue biological effects. In particular, the SP pulse mode causes more homogeneous coagulation of the surrounding tissues so, it is used for the haemostatic process. On the contrary, with the HP pulse, which has a higher

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FIGURE 1 A 1.5 cm in diameter pedunculated Keloid was diagnosed.



FIGURE 2 A 0.5 cm in diameter sessile Keloid with a single nodular pattern was diagnosed.

peak power than the SP mode, it is possible to obtain a colder effect on the tissues and, if necessary, greater ablation. In order to improve their earlobe and helix keloids, a total of 21 patients underwent Glide CO_2 laser (DEKA, Florence, Italy) surgery immediately followed by a single pulsed Dye laser (VasQ, DEKA M.E.L.A., Calenzano, Italy) procedure (fluency: 6.5 J/cm^2; single pulse, pulse duration 0.5 ms, PDL spot 12 mm) on each lesion. The setting is developed by using the 7″ Handipiece and fits with the dimension a depth of the lesion. The

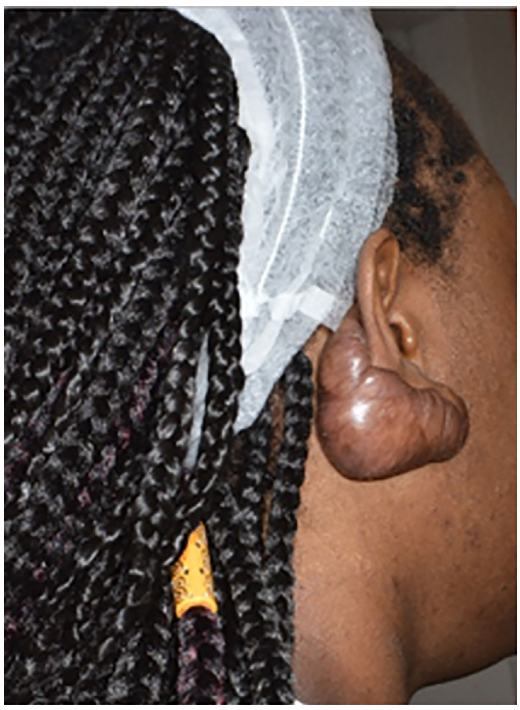


FIGURE 3 A 2.5 cm in diameter sessile Keloid with a multinodular pattern was diagnosed.



FIGURE 4 A 1 and 2 cm in diameter mixed Keloids were diagnosed.

operator has determined the best level of power and frequency to be used that vary during the ablative treatment. The higher level represents the higher ablation rate. The operator starts with the lower level to be used as a starting point to increase the work power to achieve the requested ablation and greater benefits, while monitoring the side effects, tolerability and depth of the lesion. Usually, after the detection of the best starting value, the procedure starts with the high-level value (corresponding to a deeper skin ablation effect) for the "rough-shape" phase. At the end of the procedure, the value level is reduced to perform more precise "final touches". In particular, the operator starts with a SP or CW mode, which represents the typical CO_2

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FIGURE 5 Upper panel: digital clinical images before (left) CO_2 laser session and after 6 months (right); bottom panel: 3D digital clinical images before (left) CO_2 laser session and after 6 months (right) acquired with Quantificare system.

ablation, and finally uses the HP mode to obtain a more precise finishing of the lesion with a "cold" effect like with Er:YAG. All treatment sessions and the response to treatment were performed by a single well-experienced doctor. Patients were followed-up for 6 months after termination of therapy. Clinical images were examined and collected: all patients were examined clinically and with dermoscopy using the HEINE Cube hardware (connected to I-Phone seven equipped with HEINE Cube hardware, Monaco, Germany) at the initial visit and every follow-up control. Due to its capacity to emphasise the potential existence of pigmentation and neo-vascularization by assisting doctors in the therapeutic treatment decision, dermoscopy has proven to be highly helpful in the treatment of keloids: laser may be properly chosen by identifying the targets to hit.[34]

2.3 | Assessment of keloids

2.3.1 | Photographic evaluation

Three-dimensional (3D) and 2D photographs were obtained from each patient before, immediately after the treatment session and at 6 months follow-up, by using two different 3D digital cameras (Vectra H2, Canfield, USA, and LifeViz Mini, Quantificare, France), to evaluate patient's aesthetic keloids' improvement and the recurrence rate.

2.3.2 | keloids improvement scoring

The following scoring scale was used to monitor the improvement of the patient's keloids: poor (˂25%); fair (25%–50%); good (51%–75%); excellent (75%–100%).

2.4 | Pre-treatment procedure

Especially with darker phototypes (III–VI) and Asian phototypes, it is recommended to apply a topical cream every day for four weeks before the treatment to inhibit melanin production. It is possible to use a cream containing hydroquinone or, as alternative lighteners, arbutin, azelaic acid, kojic acid or stabilised vitamin C. This procedure is highly recommended for darker and Asian skin types, while for phototype I and II, it is just a suggestion.

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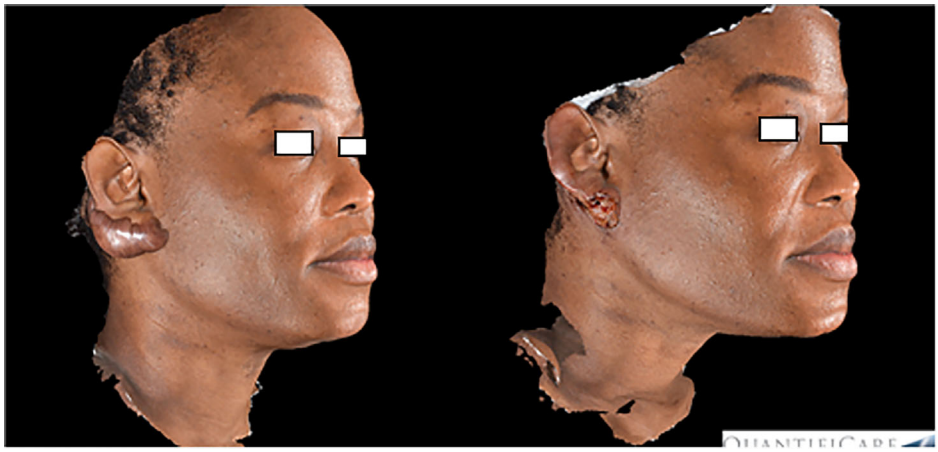


FIGURE 6 3D digital clinical images before (left) session and immediately after CO_2 laser (right) acquired with Quantificare system.

2.5 | Post-treatment procedures

In some cases, all patients were instructed to use a topic antibiotic and silver sulfadiazine cream formulation for a period of 7–8 days as home care after treatment.

2.6 | Side effects

Possible side effects such as dyschromia, burning sensation, bleeding and mild to moderate posttreatment erythema, itching, crusting, and oedema were monitored.

3 | RESULTS

All patients completed the 6 months of follow-up after the treatment conclusion. The majority of the patients showed a complete remission of keloid lesions. According to the scoring scale used to monitor the patient's keloid improvement, 38% of patients showed good results, while 62% of patient excellent results. Clinical photographs of some results are shown in Figures 5–10. It is clearly visible that an aesthetic improvement for several types of keloids was achieved in dark subjects. We would like to emphasise that recurrences are mostly manifested by a moderate scar thickening and new vascularisation (neoangiogenesis, demonstrated by dermoscopy), and have been rapidly treated again with laser sessions. The majority of relapses stopped occurring. No signs of hypopigmentation were seen in patients following treatment, and no significant side effects were detected during treatment sessions or at follow-up visits. Every patient used a pressure earring for two weeks following laser therapy.

4 | DISCUSSION

According to the literature and current evaluations, there is still no agreement on a single therapy approach offered as the gold standard for keloids' treatment.[35,36] This is mostly owing to the scarcity of evidence from well-designed, prospective, randomised controlled clinical studies, as well as the complicated pathophysiologic process that creates keloids, which is still not fully understood.[37] Furthermore, according to the majority of the research studies, certain therapies show recurring negative effects and significant recurrence rates.[38] Ablative lasers, non-ablative lasers, and non-coherent light sources have recently been proposed as an alternative strategy, and various results have been reported. These developments in the laser treatment field have also led to the creation of devices that were tested in the excision of keloids.[39] There is evidence that ablative CO_2 treatments lead to longer-lasting keloids improvement. Multiple ablative fractional CO_2 laser treatments have been tested, and treatments with varying laser frequencies have improved keloid pigmentation, pliability, and scar bulk six months after the last treatment.[29] High rates of recurrence, ranging from 74 to 100% at one year, are observed with CO_2 laser excision of keloids without adjuvant treatment, but

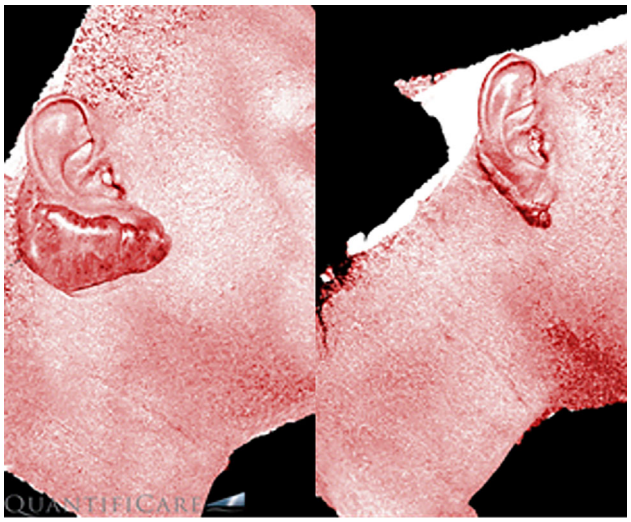


FIGURE 7 3D digital clinical images before (left) CO_2 laser session and after 6 months (right) acquired with Vectra H2 digital vascular filter system.

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FIGURE 8 Digital clinical images before (left) and immediately after CO_2 laser session (right).



FIGURE 9 3D digital clinical images before (left) CO_2 laser session and after 6 months (right) acquired with Quantificare system.

there is less blood loss and postoperative discomfort. Keloid causes significant physical and psychological distress in the patient. When compared to traditional resurfacing, fractional ablative resurfacing is the gold standard method for keloid treatment in patients who require short recovery times, with a partial restructuring of the epidermis, tissue shrinkage and formation of new collagen. As a matter of fact, scanning systems that generate thermal effects in micro-areas (20%) surrounded by healthy tissues, allow for faster healing with persistent erythema lasting only 3–7 days. On the second day, rapid re-epithelialization restores the epidermal barrier, allowing patients to resume normal social activities. That is why the patient well tolerates fractional resurfacing and it's the immediate clinical result (shrinkage) and the short recovery time after each session.[40] Basic fibroblast growth factor (bFGF) is stimulated by fractional CO_2 laser treatment, while TGF-1 is inhibited in keloids. These findings may provide an explanation for the advantageous cellular effects of laser resurfacing and support the use of CO_2 laser radiation in the treatment of keloid scar tissue.[41] Blisters, crusting, post-inflammatory pigmentary changes, and purpura are some of the side effects, which are more prevalent in those with darker skin tones. Epidermal cooling has been proven to be a helpful adjuvant therapy to lessen negative adverse effects.[30,42,43] Indeed, in our investigation, the study protocol can include the use of a skin cooling system (SmartCryo) during laser treatment. In this study, CO_2 laser treatment was administered to 21 dark patients with several types of earlobe and helix keloids with 6 months follow-up. Furthermore, immediately after keloid's removal with CO_2

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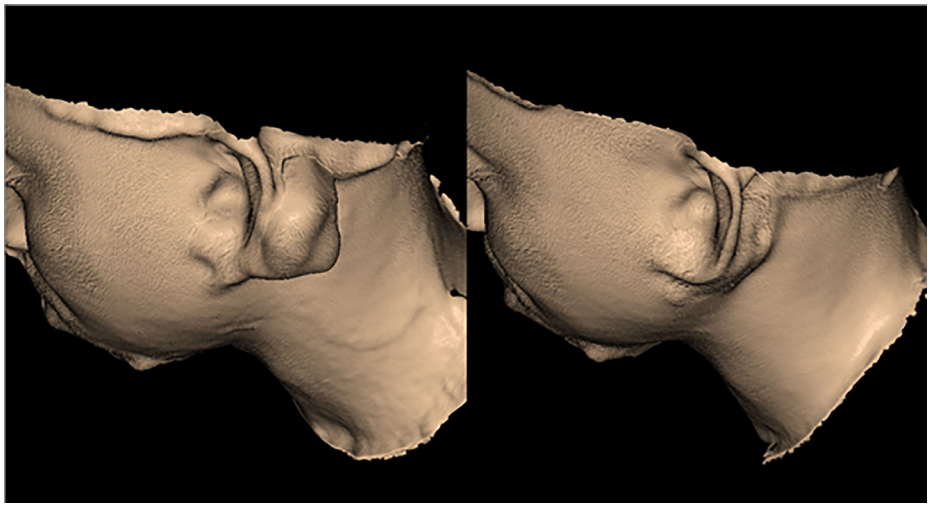


FIGURE 10 3D digital clinical images before (left) CO_2 laser session and after 6 months (right) acquired with Quantificare system.

laser each patient underwent to a single pulsed Dye laser procedure to extinguish the inflammatory fibro-vascular reaction in progress and to avoid keloids recurrence. This outcome illustrates how well CO_2 laser therapy works to treat keloids. This finding was attributed to its ability to modulate the impulses and generate more controlled thermal ablative effects on tissue. Norris[44] reported that 95% of 23 patients treated by CO_2 laser monotherapy had recurrences, while other researchers achieved positive results in the treatment of keloid with CO_2 laser. We believe that the high recurrence rate of keloids in 'Norris' literature is due to the high laser energy used during treatment and that laser thermal damage had stimulated scar tissue growth. This significant finding suggests that the high power of the laser does not help with keloids treatment. According to the author's experience, inappropriate high energy may stimulate keloids proliferation, whereas relatively conservative low energy is more appropriate for keloids management. To avoid this problem, we used the 7″ Handpiece which allowed us to obtain an effective and safe removal of the keloids through tissue incision and vaporisation without bleeding, also thanks to the coagulative action of the CW emission mode. Precisely, at the first step, the SP pulse waveform's high peak power vaporization of the epidermis and upper layers of the dermis, is followed by a long pulse width pulse waveform that radiates heat throughout the vaporised and coagulated area, producing thermal effects in the deep dermal tissues.[45] According to the scoring scale used to assess keloids improvement, the CO_2 laser demonstrated an excellent outcome which was obtained in the 62% of treated patients. Finally, our encouraging results confirmed the disappearance of the lesion in the absence of recurrences in all cases, even over the long term, and even if these lesions have been treated with traditional surgery in the meantime.

5 | CONCLUSIONS

Our data demonstrate that CO_2 laser therapeutic protocol followed by pulsed dye laser appears to be effective for the management of earlobe and helix keloids in dark subjects, giving optimal results with no need of suture and with good wound healing. The CO_2 laser treatment was well tolerated, with no high recurrence rate and avoided the adverse effects and lengthy recovery time.

ACKNOWLEDGMENT

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CONFLICT OF INTEREST STATEMENT

I.F. is employed at El.En. Group. The other authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

DATA AVAILABILITY STATEMENT

Data that support the study findings are available on request from the corresponding author.

ETHICS STATEMENT

The study was conducted in accordance with the Declaration of Helsinki. As the device has been an already CE-marked device since 14/04/2021, ethical review and approval were waived for this study.

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