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The Outcomes Assessment of the Plasma Blade Technology in Upper Blepharoplasties: A Prospective Study on a Series of 25 Patients

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Abstract

Background The Dermo Ablation Surgery (DAS) Medical® (Technolux, Italy) device is a plasma blade which induces a plasma voltaic arc causing a retraction in the epidermis and superficial dermis.

Objective The aim of our study is to prove the efficacy and safety of the DAS Medical® device in dermatochalasis size reduction.

Methods Our prospective study included 25 adult patients presenting with upper eyelid dermatochalasis undergoing a two-session treatment protocol with the DAS Medical® device (with a month treatment-free interval). The primary end point was the reduction in the size of the dermatochalasis. The secondary end points were patient satisfaction, and a blinded assessment of the outcomes was carried out by 15 plastic surgery specialists on post-procedural pictures.

Results The mean reduction in the size of the dermatochalasis was estimated at 2.47 mm on a 6-month follow-up (13.5 mm at T0 vs. 11.03 mm at 6 months, $p = 0.0002$) and 1.97 mm on a 12-month follow-up ((13.5 mm at T0 vs. 11.53 mm at 12 months, $p = 0.0055$). Eighty per cent of the patients and 78% of the assessing clinicians were globally satisfied with the results on a 12-month follow-up. The mean visual analogue pain score reported during the treatment was 4.5/10; MEOPA® was used in 23% of cases. No irreversible post-procedural sequelae (complications) were observed.

Conclusion Voltaic plasma arc treatment with DAS Medical® is an effective technique for non-invasive blepharoplasty on moderate dermatochalasis patients not suffering from palpebral lipoptosis and is very well tolerated. It can be usefully and successfully associated with surgery.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Arc plasma · Medical blepharoplasty · Skin retraction · DAS Medical®

Introduction

Dermatochalasis is a condition leading to the alteration of the skin texture of the upper eyelid, frequently associated with tissue ageing.

It is characterized by a cutaneous excess affecting either the eyelid fold or the eyelid margin. It is frequently associated with the lipoptosis caused by the laxity of the septum and the orbicular muscle. This condition leads to multiple functional and cosmetic issues [1].

Functional problems include upper visual field defects and impaired vision caused by the skin excess of the upper eyelid, the lateral erosion of the skin and the eyelashes ptosis subsequent to the gravity-related ptosis of the exceeding skin.

The eyelashes ptosis, also known as lashes ptosis (LP), refers to a global declination of the eyelash follicles, which occurs in blepharochalasis.

Dermatochalasis can be corrected with an upper blepharoplasty procedure which allows an immediate

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rejuvenation of the entire cosmetic unit (eyelid). Nevertheless, this procedure can lead to complications such as haematomas and dehiscences [2].

Sometimes, patients are reluctant to undergo surgery or the post-operative results are unsatisfactory and no further revision procedure can be offered.

Multiple surface (resurfacing) treatments, such as laser therapy, can be offered to alleviate blepharochalasis.

Different types of laser devices have been used in ophthalmology for resurfacing and have been combined with upper blepharoplasty procedures to improve the texture of the upper eyelid skin [3, 4].

The CO_2 laser vaporizes the epidermis and the reticular dermis through a thermal effect.

This option requires an average healing time of 15 days and can lead to multiple complications such as infections or pathological scarring [3].

The erbium laser vaporizes the epidermis and the superficial dermis, the healing and recovery time are shorter compared to the CO_2 laser, and the risk of complications is lower. On the other hand, its efficacy is lower compared to the CO_2 laser [4].

The DAS (Dermo Ablation Surgery) Medical® is a plasma blade, an electrocautery device which induces a plasma voltaic arc causing the tightening of epidermis and superficial dermis.

The energy generated by the DAS Medical® device is direct voltage current which elevates the temperature of the skin. The mechanism of direct voltage current fulguration is different from the controlled delivery of voltage current achieved discharge with AC: it affects a much smaller area of skin and does not damage the surrounding tissues.

When the tip of the device is applied to the skin with a 2 mm distance, the electrons present in the atmosphere tend to sequestrate part of the energy delivered. Air stops being an insulator and becomes a conductor. Electric current is conducted; the ionized air is led: the ionization is called "plasma".

The indications for the plasma blade in cosmetic medicine and the efficacy of this device have been recently accurately described in multiple studies [5–8].

Nevertheless, its tightening effect on specific layers of the skin has not been proven yet.

Plasma blade devices are commonly used to treat facial wrinkles. As a matter of fact, four clinical studies have assessed the effectiveness of the plasma arc alone ($n = 2$) and combined with cosmetic surgery procedures ($n = 1$) (facelift, blepharoplasties, lipofilling). [5–8].

The aim of our study is to prove the effectiveness and safety of the DAS Medical device in dermatochalasis size reduction in non-invasive upper blepharoplasties and to assess the tolerance and global patient satisfaction relevant to this procedure.

Materials and Methods

Study Design and Patients

A prospective study was designed. The series included 25 adults presenting with dermatochalasis and requesting a youthful and refreshed look.

All the patients with a past medical history of upper eyelid surgery, upper lid lipoptosis and pathological scarring (keloids, hypertrophic scars), infections or skin cancer, current pregnancy or breastfeeding were excluded from the study.

This study was conducted according to the standards of good medical practice (ICH-E6) and according to the principles of the Declaration of Helsinki. The BRC (biological research and collections) identification number is 2018-A03111-54. All the patients taking part to the study were properly consented (signed a detailed consent form).

The DAS Medical Procedure

All blepharoplasties were performed with a DAS (Dermo Ablation Surgery) Medical® electrocautery device (Capactuel, Paris, France). The same surgeon performed all the treatment sessions for all the patients.

On their first clinic appointment, the patients included in the study were clinically examined and their dermatochalasis was accurately assessed and measured with an Adson non-toothed forceps and a compass.

The size of the dermatochalasis was accurately recorded by the same clinician (first author) by the end of every treatment session. To obtain an accurate and reproducible assessment, the protocol was the following: the dermatochalasis was assessed and measured on the patient lying on his back with an Adson forceps, and the pre-operative markings of the upper blepharoplasty were drawn (Fig. 1).

The clinician measured then the height of the markings across the hemipupillary line while performing the Sheen's manoeuvre (patient looking 45° downwards, the clinician pulls the eyebrow upwards to correct the upper eyelid cutaneous laxity). The tension applied was unvaried in all the assessments.

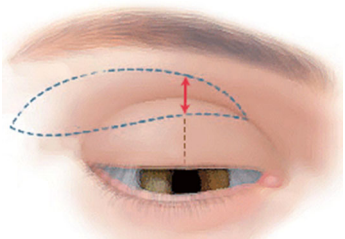

Fig. 1 Procedure for the measurement of the skin excess

A two-session treatment protocol (with a month treatment-free interval) was performed and designed taking into account the outcomes obtained and the patient's tolerance.

All patients presenting with a past medical history of facial herpes virus infection were started on a prophylaxis protocol with valacyclovir (Zelitrex®, GSK, England) (500 mg the night before and 500 mg on the day of the procedure).

Each treatment session was performed with the patient in a dorsal decubitus position. The target areas were marked with a dermographic pen. A 5-mm safety margin from the upper eyelashes border, a 5-mm safety margin from the eyebrows line and a 3-mm safety margin from the medial canthus were measured, marked and respected during the procedure.

The lateral boundary of this area was calculated specifically on each patient and could include part of the lateral periorbital lines.

An anaesthetic cream containing 2.5% lidocaine and 2.5% prilocaine (EMLA®, Astrazeneca, England) was applied 45 min before the beginning of the treatment.

In case of pain during the session, an equimolar gas mixture of 50% nitrogen monoxide and 50% oxygen (MEOPA®) was administered to the patient.

The marked upper eyelid was treated with the following settings: 3/5 (0.35 W) power and 2.18 Hz frequency. The device targeted several points. (The distance between each point was calculated as 1 mm.) Intra-operative photographs are shown in Fig. 2. After the treatment session, vitamin A ointment was applied and rubbed on both upper lids to remove any residual crusts. Post-procedural care was based on saline solution washouts to be carried out twice a day.

Fig. 2 Peri-procedural photographs

Oral analgesia with paracetamol was prescribed and given as required.

Pain during the treatment was quantified through the visual analogue pain scale ranging from 1 to 10 (VAS 0–10) [9], and the administration of a nitrogen monoxide–oxygen solution was accurately documented.

Outcomes Assessment

The main criterion taken into account in this study was the reduction in the size of the dermatochalasis accurately assessed and measured with a compass on 6- and 12-month clinic follow-up appointments following treatment with the plasma device: moreover, a general satisfaction questionnaire (based on 5 criteria) was filled out by the patients on their 12-month follow-up appointment and the blinded post-procedural photographs assessment by 15 plastic surgery specialists. The assessment was based on 3 criteria: the size of the dermatochalasis, the skin texture and the global rejuvenation of the upper eyelid. For each criterion, the assessors had to rate the outcomes according to the surgeons' Likert satisfaction scale [10] ranging from "Not satisfied at all" to "Extremely satisfied". "Satisfied", "Very satisfied" and "Extremely satisfied" were considered as an improvement. Patient tolerance to the treatment and complication rates (oedema, erythema, eschars and pain) using VAS were accurately documented after each session.

Statistical Analysis

The statistical analysis was performed using the software Prism (version 5, GraphPad, USA).

The variables were reported and represented as mean ± standard deviation. A nonparametric Kruskal–Wallis test was used to compare the average sizes of the dermatochalasis over time. The significance threshold was set on a $p < 0.05$.

Results

Our study included a series of 25 patients (21 female and 4 male patients) followed up after the last session of plasma-assisted non-invasive blepharoplasty for 12 months. The age of the patients ranged from 48 to 68 years old (mean 56 ± 7).

Fifty sessions of bilateral plasma blepharoplasties were performed.

The average size of the dermatochalasis was estimated as 13.5 ± 2.9 mm on T 0, 11.03 ± 2.32 mm on a 6-month follow-up ($p = 0.0002$) and 11.53 ± 2.4 mm on a 12-month follow-up ($p = 0.0055$). The average reduction

in the size of the dermatochalasis was calculated as 2.47 mm (18.3%) on a 6-month follow-up and 1.97 mm (14.6%) on a 12-month follow-up (Fig. 3).

Regarding the tolerance to the treatment and its secondary effects, the intra-operative pain was described as tolerable by 19 patients (76%) and the average pain score was calculated as 4.5 ± 1.4. A nitrogen monoxide–oxygen solution was administered to 8 patients (32%). Post-procedural pain was reported by 4 patients (16%), and the average pain score was 2 ± 0.9/10 for 1 ± 0.4 days.

Twenty-one patients developed oedema (84%). In 12 cases, the oedema was extending to the lower eyelids. The average resolution time was 3.6 ± 1.9 days.

Twenty-four patients (96%) presented with a post-procedural erythema of the treated areas on the same day of the treatment. The average subsiding time of the erythema was reported as 12.3 ± 10.3 days (Fig. 4).

Post-operative eschars appeared in 23 patients (92%). The average resolution time was reported as 4.1 ± 1.4 days. No permanent dyschromia, hyperpigmentation or pathological scar formation was reported on 6- and 12-month follow-ups.

One case of upper lid herpes simplex virus infection recurrence was reported during the study in a patient who had not taken the oral prophylaxis prescribe. This episode required an ophthalmology referral and was treated with a full course of oral and topical valacyclovir (Zelitrex®, GSK, England).

No permanent cosmetic or ophthalmologic sequelae were reported on the follow-up clinic appointments.

Two cases of unilateral conjunctivitis were diagnosed and treated successfully by the general practitioner with antibiotic eye drops (macrolides) and topical vitamin A ointment.

Fig. 3 Clinical outcomes; left: photographs on day 0; right: photographs at 12-month follow-up appointment

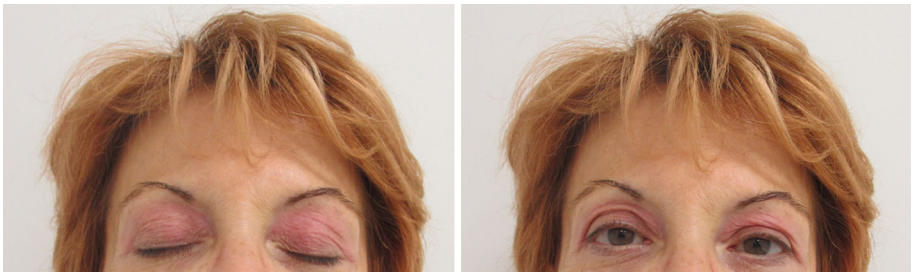

Fig. 4 Post-procedural erythema on day 10

The analysis of the questionnaires filled out by the patients on the 12-month follow-up clinic appointment (Table 1) shows a global satisfaction rate of 80% and a global cosmetic improvement in the eyelid skin texture of 85%.

Seventy-five per cent of the patients would recommend the plasma blepharoplasty to a relative or a friend.

A blinded assessment conducted by 15 plastic surgery specialists was conducted on the 12-month follow-up appointment comparing pre- and post-procedural (M12) photographs (Table 2).

The global rejuvenation of the cosmetic unit was assessed as satisfied in 54% of the cases, 19% are very satisfied, 5% are extremely satisfied, and only 2% are unsatisfied. A reduction in the size of the dermatochalasis was reported in 43% of cases who were satisfied with this reduction, and 12% and 8% of cases were very satisfied or extremely satisfied, respectively. For global improvement in the upper eyelid skin texture, 42% of patients were satisfied, and 23% and 7% of cases were very satisfied or extremely satisfied, respectively (Table 2).

Discussion

Our study was aimed at assessing the effectiveness of the plasma DAS device on a series of 25 patients who underwent upper non-invasive blepharoplasties. This procedure allows a significant reduction in the size of the dermatochalasis and a global rejuvenation of the entire cosmetic unit.

The dermo ablative function of DAS is based on the amplification of energy that allows to cut and coagulate the skin. The principle of induction used by the device during a treatment is obtained by a succession of electrical discharges generated by a high-voltage current. By maintaining a distance of 0.5 mm between the tip of the device and the skin, the air charged with free electrons absorbs a large amount of energy, ceases to be an insulator and begins to conduct the electric current, generating the discharges. The air is ionized and it becomes plasma. Discharges provide heat that increases the temperature of the skin and can treat many indications without risk of injury to the patient.

Two clinical studies reported a high level of patient satisfaction relevant to the use of the DAS medical device alone on a 90-day and 6-month follow-up in two clinical studies [5, 7].

Potter et al. noted a 24% decrease in the number of wrinkles on a 6-month follow-up ($p = 0.005$).

Regarding the intra-operative use of the plasma blade device in combination with facial cosmetic surgery procedures [5], Holcomb et al. reported a good clinical tolerance to the procedure. No higher rates or increased severity of post-operative complications was reported when the DAS medical device was used in combination with facial cosmetic surgical procedures (non-significant) [7].

In a recent study, Rossi et al. reported in a pilot study ($n = 10$) that plasma exeresis shows promising remodelling effects on the collagen of the upper eyelid assessed with reflectance confocal microscopy and seems to improve appearance [11].

Table 1 Satisfaction questionnaire results filled out by patients on M12 (results reported in percentage of positive answers)

Questions	%
Are you satisfied with the plasma blepharoplasty?	80
Did the eyelid skin texture improve in the last 12 months?	85
Would you recommend this procedure to your relatives and friends?	75
Did you suffer from heavy eyelids before being included in the study?	45
If so, improvement rate of this symptom on a 12-month follow-up	77
Was your visual field limited before the study?	35
If so, improvement rate of the symptom on a 12-month follow-up	71

Table 2 Results of the assessment of 15 plastic surgery specialists comparing pre-procedural and post-procedural (12 months) photographs

Questions	Extremely satisfied (%)	Very satisfied (%)	Satisfied (%)	Neutral (%)	Unsatisfied (%)	Very unsatisfied	Extremely unsatisfied
Is the cosmetic unit (eyelid) globally rejuvenated?	5	19	54	20	2	0	0
Is the size of the dermatochalasis reduced?	8	12	43	31	6	0	0
Is the eyelid skin texture improved? (wrinkles)?	7	23	42	24	4	0	0

Two clinical studies [5, 9] have assessed the benefits of the plasma device on facial acne scars. Potter et al. noted a significant cosmetic improvement in facial acne scars (23%) ($p = 0.001$) [5].

Gonzalez et al. reported a cosmetic improvement in the acne scars of 33% (patient self-assessment) and 34% (blinded outcome assessment on post-procedural pictures carried out by other clinicians) in 10 patients, but no statistical analysis was performed on the data [12].

Higashimori et al. published a case series of 4 patients presenting with unaesthetic scars after tissue loss resurfacing with meshed split thickness grafts [13]. The global cosmetic improvement was reported as higher than 50% in 100% of the patients (no statistical analysis was performed on the data) on a 3-month post-procedural follow-up.

Kono et al. studied the effectiveness of the plasma device in the treatment of scars subsequent to different depths wounds (classification based on the average healing time) [14]. In this case series, the plasma device was found to be inefficacious on deep wound scars (wounds with an initial healing time longer than 4 weeks). Moreover, in only 9 patients (on a series of 20 patients) an improved cosmetic result of more than 50% was noted.

Alster et al. studied the effectiveness of the plasma device in the treatment of sun-related skin lesions of the neck, thorax and dorsal aspect of the hands [15]. An overall clinical improvement of, respectively, 57%, 48% and 41% was observed on the thorax, the dorsal aspect of the hands and the neck. Moreover, a reduction in the number of wrinkles ($p < 0.001$), hyperpigmented lesions ($p < 0.001$) and the skin laxity ($p < 0.05$) was noted.

DAS plasma has multiple indications: medical blepharoplasty, condyloma acuminata resection, minimally invasive facelift, mini facelift, wrinkle resurfacing, scar resurfacing, hyperpigmentation treatment, acne scar resurfacing, cutaneous papillae resection, xanthélasma resection, fibrous papulae resection, ruby, fibrous papule, angioma resection, seborrhoeic keratosis resection, lentigo simplex resection, viral wart resection, spider naevus resection, hemangioma resection and fibroma pendulum resection.

Its main contraindications are severe infections, severe phlebitis, hypotension, severe hypertension, vertebral tuberculosis, infectious dermatitis, neurological disorders and epilepsy.

In our study, the majority of the patients (80%) were highly satisfied with the outcomes. Unsatisfactory results were found to be associated with a more severe degree of pre-operative dermatochalasis or a coexisting lipoptosis misdiagnosed on inclusion. These two elements are to be taken into account and accurately assessed pre-operatively to improve the level of patient satisfaction in our future practice.

The secondary effects and complications were frequent but expected as previously described in the current literature. Nevertheless, a very good tolerance for complications was shown by our patients and a prompt recovery was observed.

In fact, erythema was reported in 98% of cases and subsided in 12.3 ± 10.3 days (Fig. 4). The observed data were similar to those found in the current literature.

Post-procedural erythema and oedema were frequently reported (observed) [1, 2, 5, 6, 12]; they appeared on the same or the next day and subsided spontaneously in the following 6 to 30 days.

No residual dyschromia has been reported on a 6- to 12-month follow-up.

However, in our study, 3 cases of erythema of the treated areas have persisted up to one month after the treatment. Erythema was easily camouflaged (concealed) with makeup and had no impact on our patients' daily activities.

Three studies presented 2 cases (out of a total of 4 patients) of post-procedural temporary and localized hypopigmentations [13]. Unspecified and unquantified cases of hypopigmentation were reported in the Holcomb et al. study [7]. Two cases (out of 10 patients) of hyperpigmentation subside in 3 to 6 months from the start of a

combined treatment protocol of high SPF (sun protection factor) and Triluma® (Galderma, Switzerland) [12].

The only post-procedural complication that could affect and impair the patient in his daily lifestyle and activities would be the post-operative oedema that could prevent the patient from working or driving on day 1 after the plasma-assisted blepharoplasty. It is extremely important to provide patients with clear and detailed instructions regarding the post-operative care so that they can make the due arrangements for the 24 h following the procedure (driving, sick leave).

The only case of herpetic recurrence reported in our study regarded a patient that did not follow the oral prophylaxis protocol with valacyclovir (Zelitrex®, GSK, England) as advised.

Oral prophylaxis is due before every session of plasma-assisted blepharoplasty in patients with a past medical history of herpes simplex virus (HSV) infection.

HSV recurrence cases have been reported in the current literature after plasma treatment sessions: Holcomb (multiple unspecified cases) [7], 1 labial HSV infection recurrence treated successfully with aciclovir [12].

Two cases of erythema with acneiform eruption following the treatment were reported in the literature (in a case series of 95 patients) and subsided spontaneously.

As described, the observed secondary effects of the plasma treatment were milder than the complications observed with other medical treatments and lasers [16–19]. In particular, we noted the absence of dyschromic sequelae following the plasma blade treatment and its remarkable eye safety.

Previous studies assessing the plasma blade technology provided data relevant to a short follow-up (maximum 6 months). Our study is the first offering data collected during a 12-month follow-up.

The plasma blade treatment has shown consistent and stable effects on a 1-year follow-up (M6 vs M12 $p > 0.05$). More prospective studies will be needed to assess the consistency of the results and the need for revision procedures.

Our study relies on a relatively limited sample size (25 patients) which justifies the paucity of the data. However, no studies have been found in the literature providing data from a larger sample size.

Conclusion

The use of the plasma arc device is becoming extremely common in cosmetic medicine.

The modulation of the power and frequency settings when using a DAS medical device allows the practitioner to deliver a tailored approach to the treated condition.

This technical improvement extends the indications of the DAS Medical® device.

Based on the findings of our study, we recommend a non-invasive plasma-assisted upper blepharoplasty approach only in mild and moderate dermatochalasis without lipoptosis. This device becomes a useful tool in our daily plastic surgery practice allowing post-operative and non-invasive minimal definitions or corrections in patients undergoing surgical blepharoplasty.

Regarding the size reduction in the dermatochalasis, our study is the first case series measuring and documenting accurately and objectively the cutaneous retraction induced by the plasma arc. The dermatochalasis size retraction is estimated at 2 mm on a 12-month follow-up.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval This study was conducted according to the standards of good medical practice (ICH-E6) and according to the principles of the Declaration of Helsinki. The BRC (biological research and collections) Identification Number is 2018-A03111-54.

Informed Consent All the patients taking part to the study were properly consented (signed a detailed consent form).

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