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Evaluation of Safety, Comfort and Efficacy of "Avalanche" Method of DMC-Assisted Alexandrite Laser Hair Removal

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ABSTRACT

Objective

The aim of the study was to evaluate the effectiveness and safety profile of alexandrite laser hair removal performed with the avalanche technique in conjunction with dry molecular cooling (DMC™), and compare it with a hair removal treatment sequence combining both the avalanche and stamping techniques.

Methods

A cohort of 12 female subjects received 6 hair removal treatments in the axillary area using 755 nm alexandrite laser at 4-week intervals. The left axilla was treated only with avalanche mode in all sessions, while the right axilla was treated with avalanche mode in the first three sessions, and with the stamping technique in the last three sessions. Patients were followed up to 6 months after finishing the treatments. Effectiveness was evaluated by blind evaluation of before and after photographs, using the Global Aesthetic Improvement Scale (GAIS). Patient-reported measures – patient global assessment of improvement (PGI-I), pain during treatment and adverse effects were also assessed.

Results

Both treatment modalities have shown similarly high effectiveness, with the avalanche modality being more comfortable to the patient. There were no adverse events reported.

Conclusion

Hair removal using alexandrite laser in avalanche mode in conjunction with DMC™ cooling is a highly effective, safe and durable method for laser hair removal.

Key words: fractional skin rejuvenation, FRAC3, Nd:YAG laser, port wine stain, hemangioma.

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I. INTRODUCTION

Laser hair removal is a safe and effective method for removal of unwanted hair, delivering long-term results and improving quality of life [1,2]. As light is absorbed by melanin, it is converted into heat that damages the hair follicle and prevents hair regrowth. Selective photothermolysis is a laser-tissue interaction mechanism that explains the selective absorption of the laser light in the melanin contained within the hair shaft and hair follicle [3]. Commercial laser systems used for hair removal differ by wavelength, pulse duration, fluence, spot size and skin cooling method, all of which may affect the outcome of the treatment, as these parameters are crucial for optimal selective photothermolysis [4]. Laser-tissue interactions should be thoroughly analyzed and taken into consideration when deciding on the most appropriate device for laser hair removal treatments.

Long-pulsed alexandrite (755 nm) and Nd:YAG (1064 nm) solid crystal lasers have become the preferred laser sources for hair removal due to their effective absorption in melanin and sufficient penetration to reach deeply located hair follicles [5]. These two types of light sources can deliver sufficiently high pulse powers at sufficiently short pulse durations (in the millisecond range) that are required for effective selective photothermolysis of the hair within the surrounding skin matrix, with minimum collateral damage, in contrast to other types of devices that cannot achieve optimal parameters for ensuring safety and effectiveness for all skin types.

In terms of efficacy, the shorter 755 nm wavelength alexandrite laser is generally regarded as more effective because of melanin's higher absorption value, which decreases with increasing laser wavelength. However, the longer wavelength 1064 nm Nd:YAG laser has been shown to be effective for hair removal as well [6–11] and is considered to be safer and is especially well suited for treating patients with darker skin types. This is due to its reduced scattering and deeper penetration in skin, resulting in less absorption in the epidermis and therefore safer and more comfortable procedures [12].

Since melanin is present not only in hair, but also in the epidermis, epidermal heating is an inevitable consequence of the laser light's penetration to the hair follicle [4]. Consequently, epidermal cooling is necessary in most cases to protect the epidermis from excessive heat. Cooling increases treatment safety, patient comfort and treatment efficacy since it allows for higher fluence delivery to the hair follicle, while avoiding thermal injury to the epidermis [4]. There are various methods of skin cooling that are commonly used during laser hair removal. The most frequently used advanced methods include contact cooling with a chilled solid surface, cryogen spray cooling (CSC) , and forced cold-air cooling (CAC) [13,14].

While the above three skin cooling methods have been used successfully for hair removal, each of them has certain disadvantages. For example, contact cooling needs to be delivered in direct contact with the skin, which can be a challenge in small, rounded areas of the body. Air cooling does not require contact but can be relatively slow in achieving the target temperature. On the other hand, cryogenic cooling can present the risk of tissue over-cooling and cryo-injury, and due to its very localized cooling effect, skin burns may occur if the cryogen spray is misaligned relative to the laser beam [15,16].

Recently, a novel non-contact skin-cooling technology has been developed, known as Cool Mist™ [17,18], which improves upon the currently used skin cooling methods. The CoolMist™ technology is based on dry molecular cooling (DMC™) of the skin surface, overcoming some of the disadvantages of the standard cooling methods by delivering a digitally controlled, very fine water mist to the laser-treated skin surface. The AvalancheLase® platform is the first laser device on the market incorporating the patented CoolMist™ cooling solution.

Another recent advance in laser hair removal involves a new, so-called "avalanche" treatment method using alexandrite and Nd:YAG lasers. This new method has been developed with a goal to further improve the comfort and safety of hair removal treatments. It differs from the standard "stamping" method where the laser handpiece is positioned over the treated skin from spot to spot without any overlapping and with single high-fluence pulses delivered to each of the spots [19].

The new avalanche method is based on a recent discovery of an enhancement of the temperature response of irradiated hair, resulting from exposure of the hair to a series of lower fluence alexandrite or Nd:YAG laser pulses [20,21]. The response in this case is enhanced and deviates from the linear behavior that occurs when hair is subjected to an individual laser pulse of a sufficiently high fluence. This means that by delivering an appropriate sequence of lower fluence laser pulses, the hair follicle will experience progressively increasing temperature in an "avalanche-like" manner, which will finally result in the hair follicle's destruction. The avalanche method thus represents an ideal example of selective photothermolysis, whereby the laser absorption of the treated hair gets selectively enhanced by each subsequent pulse of the laser light itself, while the absorption of the laser energy in the less-melanin rich epidermis remains unchanged and at a comfortably low level.

Although the avalanche protocol enables optimal safety and comfort in treatments, while remaining effective, the stamping protocol might still be preferable in situations where higher peak power is needed to destroy hair, e.g, in thin and lighter hairs that might require higher pulse energies to be destroyed. Therefore, in some cases it might be beneficial to combine the avalanche and stamping protocols, starting with avalanche mode sessions, which are more comfortable with high hair thickness and density; and continuing with stamping mode in later sessions, where higher powers might be needed to tackle remaining thin and lighter hair.

In this paper, we report the results of a study where the safety and efficacy of DMC-assisted hair removal with alexandrite laser was compared using two methods of hair removal, the avalanche protocol and a combined avalanche plus stamping protocol.

II. MATERIALS AND METHODS

a) Laser system

The laser device used in the study was the AvalancheLase® LXP (manufactured by Fotona, d.o.o., Ljubljana), incorporating both alexandrite and Nd:YAG laser sources. Only the alexandrite laser wavelength (755 nm) was used in this study. The system includes the integrated patented CoolMist™ cooling technology that generates an atomized liquid spray for the treatment area, wherein the atomized pulsed liquid spray is based on a digitally controlled mixture of liquid and gas. The pulsed application of the spray on the tissue has the advantage that, in between two subsequent pulses, the evaporation of the droplets leads to a drying of the tissue so that a formation of a thick water layer on the skin surface is avoided. Further, the CoolMist™ nozzle is operated in such a way to achieve a fine "micro-pulsed" liquid spray with optimal liquid content, droplet size and velocity, which together enable "dry" molecular cooling (DMC™) based on the quick evaporation of the molecular droplets [11,12].

The CoolMist™ assembly contains a microprocessor-controlled system for precise DMC spray adjustment for the R35X manual laser handpiece used in the study. The R35X handpiece enables spot sizes in the range from 2 to 30 mm. The 12 mm spot size was chosen for the study, due to the small treatment area (axillae). The DMC spray control allows the user to adjust the spray to different water spray (W = 1-9) and air spray (A = 1-5) level combinations. The dependence of the measured DMC cooling rates on the chosen setting is shown in Fig. 1 [17].

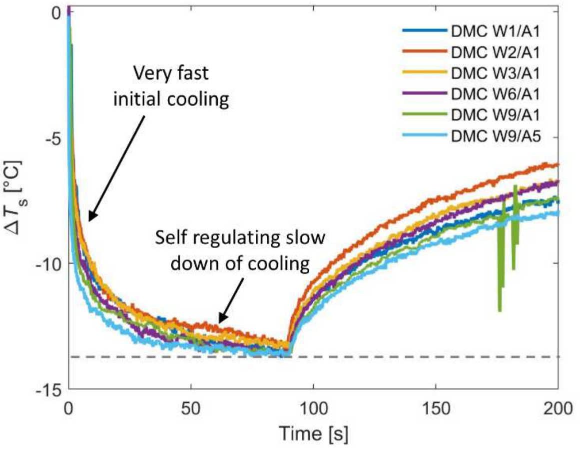

Figure 1. Temporal development of the average skin temperature decrease ΔT_s during and following the skin cooling period of t = 0-90s, for different DMC water/air settings of the manual R35X handpiece (adapted from [17] with permission of the authors and publisher). DMC cooling is characterized by a fast initial cooling rate, and self-regulating saturation of the cooling rate once the skin temperature reaches about 16 ^{0}C. With DMC, the risk of over-cooling or cryo-injury has thus been eliminated.

b) Clinical protocols

Twelve (12) patients were included in the study. All patients gave informed written consent before enrolment to participate and to allow the use of their photographs for scientific purposes. The inclusion criteria were: age >18 years old with dark hair in the axillary area, willingness to complete the treatment session and follow-ups, non-waxed or non-shaved axillae six weeks prior to the first treatment. Exclusion criteria were as follows: pregnancy, previous laser hair removal in the axillary area and light hair. Patients with ages ranging between 28 and 60 years old and skin type I-III were included in the study.

The study participants were instructed to shave their axillary hair one day before each laser treatment. The treatment was conducted on both axillary areas. Each patient received a total of six treatments of their underarms at 1-month intervals. In all patients, the left axilla was treated with the avalanche protocol in all 6 sessions while the right axilla was treated with the avalanche protocol in sessions 1-3 and with the stamping protocol in sessions 4-6. A detailed description of the treatments' parameters is shown in Table 1. With the avalanche protocol, the cumulatively delivered energy per treatment session per axilla was 4 kJ, while for the stamping protocol it ranged from 1.6 to 2.2 kJ per axilla.

The DMC cooling method with spray settings of water 4-5 and air 5 was used during all sessions.

Digital photographs were taken at baseline and after the 4th, 5th and 6th sessions and at the 1, 3 and 6-month follow ups. All photographs were taken exactly on the 7th day after shaving in order to ensure the same conditions for comparison.

Photographs from 10 patients that completed the 6-month follow-up were blindly evaluated by 3 independent medical professionals. Two patients that completed the treatment missed the 6-month follow up due to circumstances unrelated to the study. The Global Aesthetic Improvement Scale (GAIS) was used to evaluate the outcome – see Table 2.

The patients' satisfaction with effectiveness was assessed before the second, fourth and sixth treatments, and at each follow-up visit, using a 7-degree Patients Global Impression of Improvement (PGI-I) scale. (How

Table 1. Alexandrite laser treatment parameters

Session	LEFT AXILLA					RIGHT AXILLA				
	Protocol	Spot size (mm)	Fluence (J/cm²)	Hz	Pulse duration (ms)	Protocol	Spot size (mm)	Fluence (J/cm²)	Hz	Pulse duration (ms)
	avalanche	12	8–11	4	2–3	**avalanche**	12	8–11	4	2–3
	avalanche	12	9–11	4	2–3	**avalanche**	12	9–11	4	2–3
	avalanche	12	11–12	3–4	2–3	**avalanche**	12	11–12	3–4	2–3
	avalanche	12	14	3–4	2–3	**stamping**	12	15–18	2	2–3
	avalanche	12	14	4	2	**stamping**	12	16–18	2	2
	avalanche	12	14	4	2	**stamping**	12	16–18	2	2

Table 2. The Global Aesthetic Improvement Scale, as used in blind evaluation of photographs

Score	Rating	Description
4	Very much improved	An excellent corrective result
3	Much improved	Marked improvement of the appearance
2	Improved	Improvement in the appearance, as compared with the original condition
1	No change	The appearance substantially remains the same compared with the original condition
0	Worse	The appearance has worsened compared with the baseline condition

would you rate your condition now, compared with how it was before you had the treatment? 1- very much improved, 2 - much improved, 3 - slightly improved, 4 - no change, 5 - slightly worse, 6 - much worse, 7 - very much worse).

Immediately after each treatment session, the patients were also asked to rate their pain level using an 11-grade VAS scale from 0 (no pain) to 10 (worst pain possible).

Statistical analysis was performed using Prism software (GraphPad, California). The non-parametric Wilcoxon signed rank test was used for comparing the results between the two treatment groups.

III. RESULTS

The average GAIS score (0-4 scale) at the 6-month follow up was 3.2 on the right (avalanche plus stamping) axilla and 3.3 on the left (avalanche) axilla, with no statistical difference between the sides, as evaluated by the Wilcoxon signed rank test (Figure 2). See Figures 3A, 3B and 3C for representative examples of results from the right and left axillae.

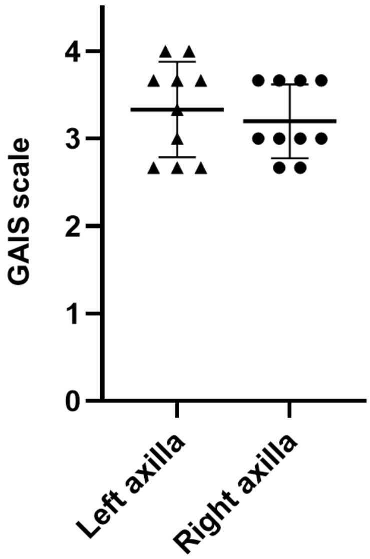

Figure 2. Results of blind evaluation of photographs using the GAIS scale. The graph represents mean values from 3 independent evaluators for 10 patients, where images at baseline and at the 6-month follow up were available. There was no significant difference between treatments as evaluated by the Wilcoxon signed rank test.

Figure 3A. Representative results (patient No. 6) before and at the 6-month follow up after laser treatments with stamping mode used during the last three sessions (left photos), and with avalanche mode during all sessions (right photos).

Figure 3 B. Representative results (patient No. 4) before and at the 6-month follow up after laser treatments with stamping mode used during the last three sessions (left photos), and with avalanche mode during all sessions (right photos).

Figure 3 C. Representative results (patient No. 11) before and at the 6-month follow up after laser treatments with stamping mode used during the last three sessions (left photos), and with avalanche mode during all sessions (right photos).

Pain was assessed during each treatment by a 0-10 VAS scale, 0 indicating no pain and 10 indicating the worst imaginable pain. The patients' evaluation of treatment-related pain during the treatments is shown in Table 3.

Average pain scores were significantly higher in the right axilla for the last three treatment sessions, when the stamping protocol was used (p=0.002, Wilcoxon signed rank test), even though the avalanche mode settings in the last three sessions were elevated compared to first three sessions (see Table 1 and Figure 4). There were no differences in pain between axillae in first three sessions, where avalanche protocol was used on both sides (see Table 3).

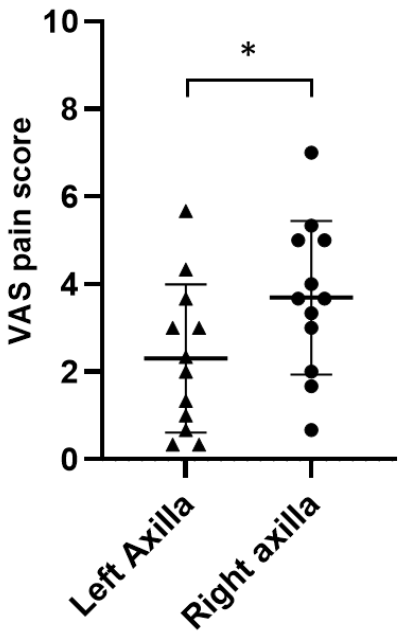

Figure 4. Mean patient-reported VAS pain scores in the last three treatment sessions, which were performed using the avalanche technique in the left axilla and with the stamping mode in the right axilla. Mean±SD is annotated in the graph. The asterisk denotes a statistically significant difference as assessed by the Wilcoxon signed rank test (p=0.002).

The patients' evaluation of effectiveness was monitored after each session and at all follow-ups using the Patients Global Impression of Improvement (PGI-I) scale. The effectiveness was high in both groups already after the 1st session (1.6 on average) and stayed stable at the 6-month follow up in both groups (average 2±0.78 in the left axilla and 2.1±0.83 in the right axilla). There were no differences between groups as evaluated by the Wilcoxon signed rank test (complete data not shown). The results indicate excellent patient satisfaction with the results.

No side events were reported during the study period.

IV. DISCUSSION

According to our results, hair removal using the avalanche method is a highly safe and effective method for hair removal. Additionally, the DMC™ cooling using the patented CoolMist™ technology has proven to be a comfortable and highly effective method for epidermal skin cooling during hair removal.

Although laser hair removal has been performed for many years already, the recent introductions of the novel DMC™ cooling and avalanche hair removal method have contributed to further improvement in the safety and comfort of alexandrite and Nd:YAG laser hair removal treatments. Due to higher cumulative energies that can be delivered as a result of these innovations, the efficacy of alexandrite and Nd:YAG laser hair removal procedures is also expected to benefit from using the avalanche approach.

Effective hair removal was observed at the 6-month follow up for both treatment groups. Similar effectiveness in axillary hair removal was achieved after 6 sessions of either avalanche mode hair removal, or a combination of 3 sessions of avalanche mode followed by 3 sessions of stamping mode hair removal.

No side effects apart from slight discomfort during treatment was reported. In this regard, the avalanche protocol is advantageous since, due to the lower fluences used, the avalanche treatment is more comfortable for the patients.

Table 3. Patient assessment of pain during each laser treatment session (VAS pain scale 0–10).

Session	LEFT AXILLA		RIGHT AXILLA	
	Mode	Mean pain assessment (0-10 VAS scale) ± SD	Mode	Mean pain assessment (0-10 VAS scale) ±SD
1	avalanche	1.8 ± 1.4	avalanche	1.6 ±1.1
2	avalanche	1.5 ± 1.3	avalanche	1.5 ± 1.3
3	avalanche	1.4 ± 1.6	avalanche	1.4 ± 1.4
4	avalanche	2.6 ± 1.7	stamping	3.8 ±1.8
5	avalanche	2.3 ± 1.9	stamping	3.7 ±1.7
6	avalanche	1.9 ± 1.9	stamping	3.6 ±2.0

In this study, there was no advantage observed in using the stamping mode in the latter sessions in terms of safety or effectiveness. The avalanche mode proved to be less painful than stamping, especially considering that the stamping mode was applied only after the completed 3 initial avalanche mode sessions, when the hair density had been already significantly reduced.

The avalanche protocol thus represents a welcome alternative to the standard stamping hair removal protocol. Since discomfort is typically higher during initial treatment sessions during which the density of hair follicles is still relatively high, this suggests a combined treatment protocol, as was performed also in this study. With this combined treatment protocol, the initial sessions are performed using the more comfortable avalanche protocol, followed by the stamping sessions when the density of hair follicles has been already reduced.

An example of a case where the avalanche protocol would represent a particularly preferred method, at least during the initial hair removal sessions when the density of hair follicles is still high, is presented in Fig. 5, which shows four areas of a male back, treated with four different protocols during the first alexandrite laser hair removal session. The three areas on the left side of the back were treated with a stamping mode using three different laser pulse fluences, 14.0, 16.0 and 18.0 J/cm². And the area on the right side of the back, marked with an A, was treated with the avalanche mode using 8 J/cm². The pain scores as reported by the patient (see Table 4) clearly show why that patient decided for the avalanche protocol.

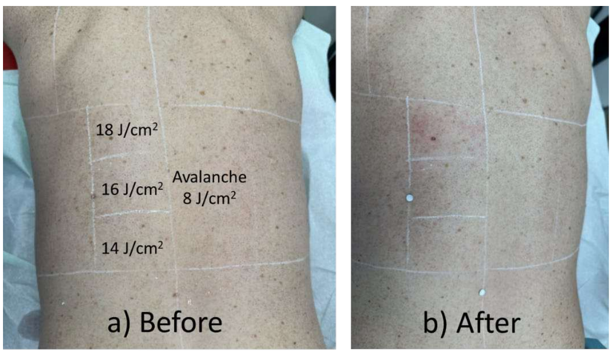

Figure 5. a) Four areas of a male back before being treated with four different protocols during the first alexandrite laser hair removal session. The three areas on the left side of the back were treated with a stamping mode using three different laser pulse fluences: 14.0, 16.0 and 18.0 J/cm². And the area on the right side of the back, marked with an A, was treated with the avalanche mode using 8 J/cm²; b) patient photo taken 10 minutes post-treatment. The skin exhibits mild to strong erythema in the areas treated in the stamping mode with 14-18 J/cm², correspondingly. There is no erythema on the avalanche side.

Table 4: Patient assessment of pain during the first hair removal session on the skin areas shown in Fig. 5.

STAMPING HAIR REMOVAL		AVALANCHE HAIR REMOVAL	
2 Hz		4 Hz	
Fluence (J/cm2)	Pain assessment (0-10 VAS scale)	Fluence (J/cm2)	Pain assessment (0-10 VAS scale)
14.0	3 - 4	8.0	2
16.0	6 (could not endure for longer than 1 minute)		
18.0	8 (unbearable)		

While our study did not show any advantage in terms of effectiveness in using the stamping mode during the last three sessions, further research is needed to determine whether the use of the stamping mode during later sessions may be advantageous for treating areas with remaining lighter and thinner hair, e.g. legs, arms, facial hair. The stamping mode performed with larger spot sizes also tends to be quicker, and to require less cumulative energy, so combining modalities in the course of multiple hair removal sessions can be advantageous also from the operator's perspective.

Finally, our study has demonstrated that DMC™ is an effective skin cooling method enabling comfortable, safe and effective hair removal treatments. In another study, a comparison of the discomfort during the stamping alexandrite hair removal has shown the DMC cooling to be more comfortable in comparison to the cryogen spray cooling (CSC) [17]. An important advantage of DMC in comparison with CSC is that the water droplets deposited over the skin persist on the skin for longer time periods, resulting in the whole treated area remaining at a comfortably reduced temperature. On the other hand, with CSC the skin temperature not only returns to the initial skin temperature very quickly, but following the treatment continues to increase in the form of hot spots. The prolonged passive post-cooling by DMC acts in a similar manner as when a burn is cooled under cold running water. Clinically, this soothing effect has been observed to result in a milder or no edema within the initial minutes following the treatment, and in milder or no erythema within several hours following the treatment.

V. CONCLUSIONS

The present study shows that hair removal using AvalancheLase® alexandrite laser in avalanche mode in conjunction with DMC™ cooling enabled by the novel CoolMist™ technology is a highly effective, safe and durable method for laser hair removal.

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