

Enhanced Hair Removal based on the “Avalanche Effect” of the AvalancheLase® Hair Removal Laser System

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ABSTRACT

The "avalanche effect," in which the absorption of laser light in hair is increasingly enhanced following each successively delivered laser pulse, was measured for two laser hair removal wavelengths, alexandrite (755 nm) and Nd:YAG (1064 nm).

Based on the results of the study, an "avalanche" laser hair removal protocol was developed for the alexandrite and Nd:YAG laser wavelengths of the AvalancheLase® hair removal system, which is equipped with novel DMCT™ (Dry Molecular spray Cooling) skin-cooling technology. In conclusion, the measured avalanche effect enables the performance of very effective “avalanche” hair removal by delivering a series of relatively low fluence pulses to hair follicles.

Key words: hair removal, avalanche effect, alexandrite laser, Nd:YAG laser.

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I. INTRODUCTION

Excess or unwanted hair is a common problem affecting both genders. First introduced in the mid-1990's, laser hair removal has become an accepted treatment modality for patients seeking to reduce unwanted hair, and it has also been found to improve quality of life for many patients [1, 2]. The types of lasers currently in use for hair removal include alexandrite, neodymium: yttrium-aluminum-garnet (Nd:YAG) and diode [3-12].

While all skin types can be treated (given the appropriate laser), in general, the greater the difference in pigmentation between the skin and hair, the better the result. The darker an individual's skin becomes, the more

melanin they have, so the skin begins to heat more with the application of the laser, potentially leading to pain and epidermal damage. Therefore, darker skinned individuals must be treated at lower fluence levels and often require more treatments to attain good hair reduction [14-17].

Another challenge involves patients whose hair contains low melanin content, resulting in low absorption of laser light in treated hair. For this reason, early hair removal techniques were based on infiltrating black carbon into hair ducts in order to increase the absorption of hair at the treatment laser's wavelength [18].

However, more recently, it has been proposed that the absorption of laser light in hair could be enhanced by the treatment laser light itself [19, 20]. An “avalanche” effect was observed where the absorption of the treated hair became increasingly enhanced following each subsequently delivered laser pulse.

This phenomenon has led to an improved, “avalanche” hair removal protocol that consists of delivering a series of laser pulses to the same skin area, with the laser pulse parameters being optimized for the maximal avalanche effect. This technique is different from a standard “stamping” technique where the laser handpiece is positioned over the treated skin from spot to spot without any overlapping, and single high fluence pulses are delivered to each of the spots [7, 12].

In this paper, we study the avalanche effect by measuring hair temperature changes during the avalanche hair removal pulse series modality of an AvalancheLase® laser system that is capable of delivering extremely powerful and controlled outputs at alexandrite (755 nm) and Nd:YAG (1064 nm) wavelengths, and utilizes a novel DMCT™ (Dry Molecular spray Cooling) skin-cooling technology.

II. MATERIALS AND METHODS

a) Laser system

The laser system used in the study was an

AvalancheLase® (manufactured by Fotona d.o.o., Slovenia; see Fig. 1) consisting of two ultra-performance solid crystal laser sources delivering two highly effective and well-known hair removal laser wavelengths, the Alexandrite (755 nm) and Nd:YAG (1064 nm) wavelengths. The system can be fitted either with an R35 manual handpiece (with 2-30 mm spot sizes) or an LX-Runner scanning handpiece (with individual spot size diameters of 9 and 11 mm, and an adjustable scan area of up to approximately 8 x 8 cm²).



Fig. 1: AvalancheLase® alexandrite and Nd:YAG laser system.

In addition, AvalancheLase® is equipped with a novel proprietary DMCT™ (Dry Molecular spray Cooling) technology integrated into the handpieces to allow for very fast, effective and non-contact cooling of the irradiated skin using a controlled very fine (“dry”) water spray mist. This technology improves comfort and safety since it uses room temperature air and water, avoiding the risk of cryo-injury by over-cooling the skin [25].

b) Hair temperature measurements

The experimental set-up is shown in Fig. 2.

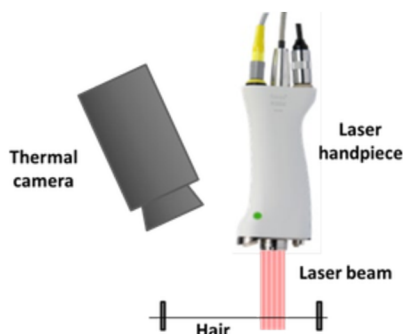


Fig. 2: Experimental set-up. A human hair was pulled out of a human scalp, and fixed in the air in a straight horizontal position. The Nd:YAG or alexandrite laser beam was directed onto the hair, and the resulting hair temperature increase was measured with a thermal video camera.

The Nd:YAG or alexandrite individual laser pulses ($t_p = 2$ ms) were directed onto the hair, and the resulting hair temperature increase following each laser pulse was

measured with a thermal video camera (Flir ThermaCAM P45), set to record the maximal pump temperature increase (ΔT) of the hair sample. A room temperature air blower was used to shorten the hair cooling time following pulsed irradiation. The pulses were delivered at sufficiently long separation times ($t_s \geq 2$ s) to allow the hair to cool down to the ambient temperature in-between pulses.

A typical thermal image of the irradiated hair following a laser pulse is shown in Fig. 3.

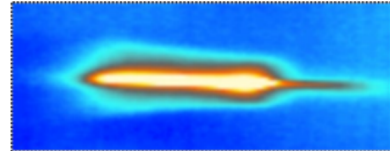


Fig. 3: A typical thermal image of the irradiated hair following a laser pulse.

c) Skin temperature measurements

In order to study how the skin temperature increase may limit the maximal laser pulse repetition rates during avalanche hair removal, the temporal evolution of the superficial skin temperature following a single Nd:YAG or an alexandrite laser pulse was also measured. Measurements were made for conditions without external skin cooling, and as well with DMCT™ and cold air cooling.

III. RESULTS

a) Hair temperature results

Fig 4 shows the evolution of temperatures as observed by applying a series of individual Nd:YAG laser pulses to the same hair section with consecutively increased fluence (F_p) from $F_p = 5$ J/cm² up to $F_p = 25$ J/cm².

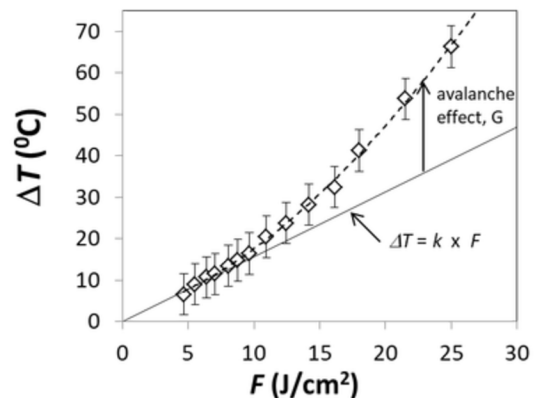


Fig. 4: Temperature increase ΔT of the same hair section following a series of individual Nd:YAG laser pulses with consecutively increased fluence. The pulses were delivered at sufficiently long separation times to allow the hair to cool down in-between pulses.

The line in Fig. 4 represents the linear dependence

of the temperature increase on the delivered fluence according to:

$$\Delta T_{lin} = K \times F, \quad (1)$$

as would be expected if there was no influence of laser irradiation on the hair’s thermal characteristics. The temperature coefficient K (with $KNd = 1.56 \text{ } ^\circ\text{C}\cdot\text{cm}^2/\text{J}$) defines the linear growth of ΔT with F as observed at low laser fluences.

We attribute the observed deviation of ΔT from the linear dependence of Eq. 1 to the “avalanche” effect, i.e. to the increased thermal response of the human hair after being irradiated by a laser pulse with $F > F_a$, where F_a is the threshold fluence for the avalanche effect. For the used Nd:YAG laser parameters and the measured hair, the avalanche threshold was found to be at about $F_a \approx 10 \text{ J/cm}^2$. Similarly, for the alexandrite laser we determined the avalanche threshold to be at about $F_a \approx 3 \text{ J/cm}^2$.

Taking the avalanche effect into account, the dependence of the temperature increase on the delivered fluence can be expressed as:

$$\Delta T = Ga \times \Delta T_{lin} = Ga \times K \times F,$$

where Ga is the “avalanche gain”, characterizing the influence of the avalanche effect on the measured hair’s thermal response. The total temperature increase is therefore represented by the sum $\Delta T = \Delta T_{lin} + \Delta T_a$, where $\Delta T_a = (Ga - 1) \times \Delta T_{lin}$ is the additional temperature increase caused by the avalanche effect.

Figure 5 shows the evolution of temperatures during the delivery of a series of $N = 50$ Nd:YAG or alexandrite laser pulses with the fluences (F) of 14.4 J/cm^2 (for Nd:YAG) and 5 J/cm^2 (for alexandrite) set to be just above the corresponding avalanche threshold values.

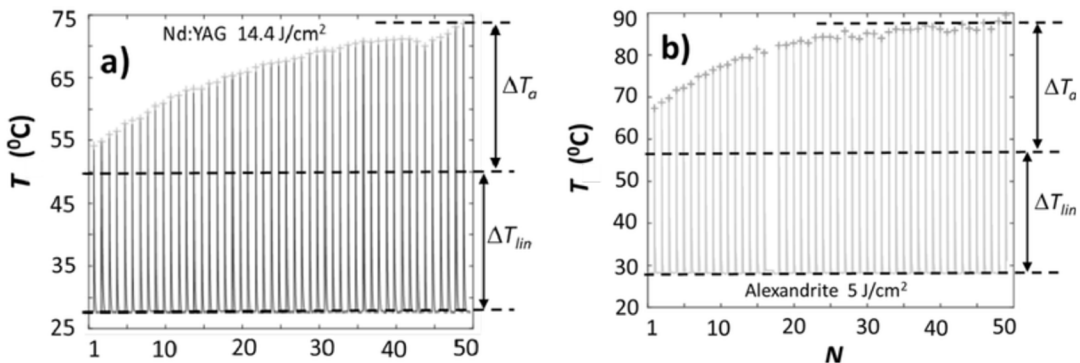


Fig. 5: Temperature evolution during the delivery of $N = 50$ Nd:YAG (a) or alexandrite (b) laser pulses with $F_p = 14.4 \text{ J/cm}^2$ and $F_p = 5.0 \text{ J/cm}^2$, correspondingly. The pulse repetition rate was 0.5 Hz . Room temperature forced air was used to cool down the hair in-between measurements.

As can be seen from Fig. 6, the initial avalanche gain as observed for the first pulse in the sequence becomes significantly further enhanced during the first 20-30 pulses in the series.

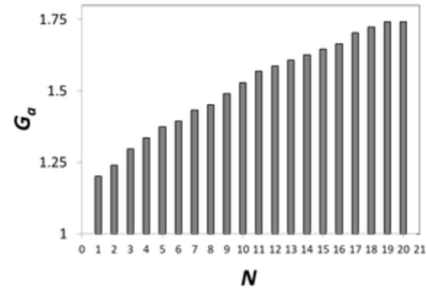


Fig. 6: Gradual increase of the avalanche gain G_a during the delivery of Nd:YAG pulses from Fig. 5a.

b) Skin temperature results

Figure 7 shows the measured skin temperature evolution following a single Nd:YAG or an alexandrite laser pulse when no external cooling was used. The observed initial fast decay is caused by the large temperature gradient between the melanin-rich epidermis and the deeper-lying dermis. As expected, the decay is faster for Nd:YAG due to the larger initial temperature difference between the epidermis and dermis. Therefore, the avalanche repetition rates can be faster when using an Nd:YAG laser.

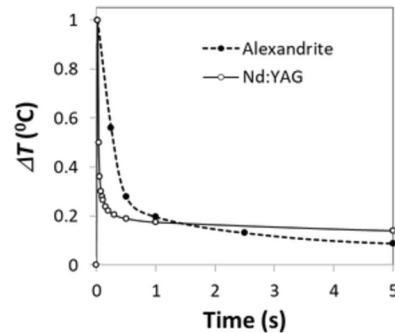


Fig. 7: Temperature evolution following a single Nd:YAG or alexandrite laser pulse when no external skin cooling is used.

Figure 8 shows the measured skin cooling rate of non-irradiated skin during cold-air and DMCTM cooling. Therefore, the hair temperatures under a clinical setting are expected to be above the avalanche threshold when using relatively low fluence values for the Nd:YAG and alexandrite laser epilation.

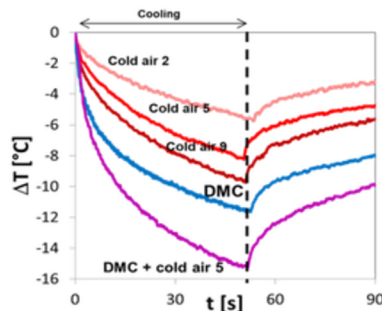


Fig. 8: Comparison of the DMCTM cooling characteristic with that of the standard cold-air cooling.

As can be seen from Fig. 8, the DMCTM cooling technology delivers fast cooling rates, enabling fast and comfortable non-contact avalanche hair removal on all body areas.

IV. DISCUSSION

Our measurements demonstrate an avalanche effect which occurs when hair is subjected to an individual laser pulse of a sufficiently high fluence, or to a series of lower fluence laser pulses. This effect leads to an enhancement of the temperature response of the irradiated hair.

Based on the results of our study, laser hair removal treatment can be performed at laser fluences much lower than what is required when performing hair removal using the stamping technique [7, 12, 14]. By repeating the treatment irradiation within the same treatment session, the effect of each treatment irradiation is enhanced, until the hair removal temperatures within the hair follicle are reached.

A major limitation of the study is that temperature measurements were carried out on hair suspended in air, while in a clinical situation the hair is embedded within the skin matrix. Nevertheless, simulations of the hair temperature under Nd:YAG and alexandrite irradiation indicate that the observed avalanche phenomenon may apply also to hair located within the skin matrix. In a study by Žaneček and Milanič [24], a numerical model of laser epilation was developed, which also used experimentally obtained hair and skin parameters to calculate the temperature increase along the hair shaft down to the hair follicle. The temperatures of the hair located within the skin matrix were found to be similar or higher than those obtained for the hair suspended in air. This is due to the scattering of the laser light within the skin matrix, effectively enhancing the number of photons that become trapped within the highly absorbing hair, in spite of the beam being progressively absorbed by the skin chromophores.

When performing hair removal based on the observed avalanche effect using a manual handpiece, the treatment is performed using a brushing technique. This technique involves higher pulse rates (3-5 Hz), with the R35 handpiece in a constant movement backwards and forwards at a speed of 2-3 cm/s until a sufficiently high cumulative energy is delivered to the whole treated area. So rather than lasing each hair follicle individually with a high powered beam, the avalanche technique accumulates the delivered energy into the entire treated area over a larger number (N) of lower-fluence pulses, to a point in which the hair follicles get damaged.

An example of the clinical efficacy of the avalanche hair removal technique is presented in Fig. 9, which shows the persistent avalanche hair removal effect four (4) months following only a single treatment with the alexandrite wavelength of the AvalancheLase® hair removal laser system.

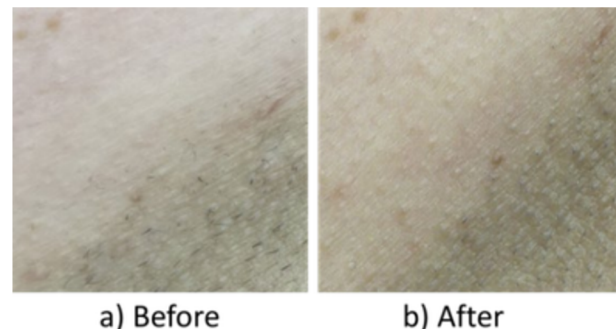


Fig. 9: Underarm hair removal a) before; and b) 4 months after a single avalanche treatment with alexandrite laser using the following parameters R35X handpiece, 10 Jcm², 3 Hz, 2 ms, 12 mm.

V. CONCLUSIONS

In conclusion, the measured avalanche effect enables the performance of very effective “avalanche” hair removal by delivering a series of relatively low fluence pulses to hair follicles. This characteristic, combined with the proprietary skin cooling DMCTM technology, enables fast, painless and very effective hair removal using the AvalancheLase® laser system.

Based on the carried out temperature measurements and clinical experience, the following treatment parameters are recommended for performing avalanche hair removal with the Alexandrite (Figure 10) and Nd:YAG laser (Figure 11), in conjunction with the AvalancheLase’s DMCTM skin cooling technology. The

parameters are given for different body areas, skin types (I-VI) and hair thicknesses (thin, medium and thick). The estimated number (N) of delivered avalanche pulses to the same follicle, and the estimated time (in minutes) required to treat the whole selected body area, are also provided.

Alexandrite (755 nm)						
Avalanche Hair Removal Parameters						
Body area	Fluence F_p (J/cm ²)	Spot size (mm)	Pulse duration (ms)	Freq (Hz)	N	Estimated total treatment time (min)
	I-II-III-IV-V-VI	I-VI	Thin-Medium-Thick	I-VI	I-VI	I-VI
Thigh	11-9-7-5-4-3	20	2-3-4	3	4-10	7-26
Lower leg	11-9-7-5-4-3	20	2-3-4	3	4-10	6-24
Chest & Abdomen	11-9-7-5-4-3	20	2-3-4	3	4-10	10-38
Underarm	11-9-7-5-4-3	12	2-3-4	5	4-10	1-2
Bikini	11-9-7-5-4-3	12	2-3-4	5	4-10	1-4
Face	11-9-7-5-4-3	12	2-3-4	5	4-10	0.5-1.5
Back	11-9-7-5-4-3	20	2-3-4	3	4-10	9-32

Fig. 10: Recommended avalanche hair removal parameters for the alexandrite (755 nm) laser wavelength of AvalancheLase® system, equipped with an R35X laser handpiece and DMCT™ skin cooling technology (water 1-2, air 5).

Nd:YAG (1064 nm)						
Avalanche Hair Removal Parameters						
Body area	Fluence F_p (J/cm ²)	Spot size (mm)	Pulse duration (ms)	Freq (Hz)	N	Estimated total treatment time (min)
	I-II-III-IV-V-VI	I-III, IV-VI	Thin-Medium-Thick	I-VI	I-VI	I-VI
Thigh	22-18-14-10-8-6	12,20	2-3-4	3	4-15	13-29
Lower leg	22-18-14-10-8-6	12,20	2-3-4	3	4-15	12-26
Chest & Abdomen	22-18-14-10-8-6	12,20	2-3-4	3	4-15	19-42
Underarm	22-18-14-10-8-6	12	2-3-4	5	4-15	1-2.5
Bikini	22-18-14-10-8-6	12	2-3-4	5	4-15	1.5-4.5
Face	22-18-14-10-8-6	12	2-3-4	5	4-15	0.5-1.5
Back	22-18-14-10-8-6	12,20	2-3-4	3	4-15	16-36

Fig. 11: Recommended avalanche hair removal parameters for the Nd:YAG (1064 nm) laser wavelength of the AvalancheLase® system equipped with an R35X laser handpiece and DMCT™ skin cooling technology (water 1-2, air 5)

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Dry Molecular Cooling (DMC™) in Laser Aesthetics and Dermatology

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ABSTRACT

Skin cooling is often used during laser treatments in aesthetics and dermatology to avoid or minimize patient discomfort and skin damage. All currently used cooling methods have certain disadvantages, such as having to be in contact with the skin, not being fast or continuous enough, or posing a risk of cryo-injury. The commonly used non-contact methods include cryogen spray cooling (CSC) and forced cold air cooling (CAC).

In this paper, a novel non-contact skin cooling method is presented that is based on dry molecular cooling (DMC™). DMC™ improves upon the currently used methods, with some of the following advantages:

- The maximal cooling rate of DMC is significantly faster in comparison with CAC.
- DMC is characterized by a self-regulating feature of the evaporating water molecules, which limits the lowest skin temperature to about 16°C. The DMC cooling, therefore, avoids the risks of over-cooling posed by the CAC and especially by the CSC method.
- As opposed to CSC spray droplets, the DMC's water droplets deposited over the skin persist on the skin for longer time periods. The prolonged passive post-cooling by DMC acts in a similar manner as other cryo-protective measures in medicine, including therapeutic hypothermia in cardiac arrest or cerebral ischemia. For example, the sooner and longer a burn is cooled with cold running water, the smaller the impact of the injury will be. Clinically, this soothing effect has been observed to result in milder or no edema within first 10-20 minutes following the treatment, and in milder or no erythema within several hours following the treatment.

Key words: dry molecular cooling, DMC™, cryogen spray cooling, cold air cooling, alexandrite laser, Nd:YAG laser, thermal imaging.

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I. INTRODUCTION

General

With laser treatments in dermatology and aesthetics, a non-specific heating of the surface tissue (such as the epidermis) is a common side effect [1]. Often, the threshold fluence which is needed for destroying the target chromophore or structure is very close to the threshold fluence for epidermal injury. For example, in hair removal the optimal laser wavelengths are the ones which get absorbed in the hair's melanin. Since melanin is abundantly present in the epidermis, heating of the epidermis is an inevitable consequence of the laser light's penetration to the hair bulb to achieve its destruction [2]. Consequently, if the temperature of the epidermis is not controlled this can in addition to pain induce acute epidermal damage or blistering and can also lead to scarring and hyperpigmentation [3].

To avoid or minimize the above complications, the epidermal surface layer needs to be cooled. Examples of applications where high-fluence laser pulses are used and cooling is necessary for avoiding epidermal damage include laser hair removal and coagulation of veins and vascular lesions [4,5]. In other applications, such as transdermal lipolysis, relatively low single-pulse fluences are delivered during a prolonged exposure to repetitively delivered laser pulses. In these applications, epidermal cooling is applied to prevent a temperature rise of the epidermis while the deeper lying subdermal fat is heated to temperatures above 42°C, which causes apoptosis of adipose cells and subsequent reduction of the fat layer [6].

There are various methods of skin cooling that are being used during laser treatments, ranging from ice packs to sophisticated equipment. The most frequently used advanced methods include contact cooling with a chilled solid surface [7], cryogen spray cooling (CSC) [8, 9], and forced cold air cooling (CAC) [2, 6].

Contact cooling with chilled glass achieves localized and rapid cooling but has several disadvantages, including absorption and reflection of

the laser light in the chilled glass, skin compression, mandatory use of heat conductive gels, and relatively slow positioning of the small laser spot over the larger treated skin area.

Cooling with cryogen spray is another commonly used method. In this cooling method, a cryogen spray is sprayed for a very short period only prior to laser pulse delivery, minimizing the exposure of skin to cryogen spray cooled to very low temperatures (down to -58°C) [9]. This method is efficient in epidermal protection when high fluences are used, however, side effects from excessive skin cooling, such as hyperpigmentation and skin irritations have been reported [3]. The method is also very sensitive to the exact timing of the CSC's spurt prior to the laser pulse. Additionally, the pressurized cryogen gas is demanding to transport, and burdensome for the environment, as it has a high global warming potential. It is also expensive since gas cylinders require regular replacements.

Forced cold air cooling (CAC) is also often used in laser treatments wherein cold air is directed to the treatment area before and during the laser treatment [4]. A disadvantage of air cooling is the relative inefficiency of the medium air for cooling tissues, thus requiring long exposure times to cold air. To speed up the cooling rate the air is typically cooled to very low temperatures which can lead to patient discomfort and over-cooling.

Consequently, all currently used cooling methods have certain disadvantages such as having to be delivered in a contact with the skin, not being fast enough or presenting the risk of tissue over-cooling.

In this paper, we report on a novel skin-cooling technology, CoolMist™ [10, 11], 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.

Water-based spray has been commonly used in dental laser applications, mainly for moistening of the hard tissues, debris removal and as an aid for a more efficient ablation. However, water-based spray has been rarely used for cooling soft-tissue surfaces, and especially not for cooling skin surfaces. The reason for this is that the commonly available liquid sprays, e.g., such as the ones used with dental lasers, operate continuously, and would generate a liquid film on the skin surface which acts as a thermal barrier for the heat transfer. Namely, when a thick liquid layer is

present a quick evaporation of droplets cannot take place anymore, thus preventing efficient cooling. To avoid the formation of a liquid layer, the liquid must be in a constant flow and must be constantly removed from the treatment area. Such a removal of the liquid can be relatively easily achieved by means of a suction device in an enclosed treatment area that is already wet, such as the mouth, but becomes very impractical when trying to cool large body surfaces. In addition, in many dermatological applications such as hair removal, skin tightening and fat reduction, an effective and homogeneous cooling of large skin areas of up to about 5000 cm² is required; this has represented a considerable technical challenge for liquid spray cooling.

The CoolMist™ cooling technology 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 the formation of a water layer on the skin surface is avoided. Further, the CoolMist™ nozzle is operated in such a way as 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 quick evaporation of the molecular droplets [11].

II. MATERIALS AND METHODS

a) Laser system

The laser devices used in the study were AvalancheLase® LXP (with Alexandrite and Nd:YAG laser sources) and Nx Dynamis SP (with Er:YAG and Nd:YAG laser sources), both manufactured by Fotona, d.o.o., Ljubljana (See Fig. 1). Both systems incorporate the CoolMist™ skin cooling technology for cooling the skin during Alexandrite or Nd:YAG laser treatments. The long-pulsed Alexandrite (755 nm) and Nd:YAG (1064 nm) solid crystal lasers have become preferred wavelengths for various dermatological and aesthetic treatments due to their effective absorption in the skin pigments, with sufficient penetration to the deeply located pigmented targets within the skin. In addition, as compared to other devices, it is only these two types of light sources that can deliver sufficiently high pulse powers at sufficiently short pulse durations (in a range of milliseconds) as required for effective selective thermolysis of the hair within the surrounding skin matrix [2, 4, 12-15].



Fig. 1: Fotona AvalancheLase® LXP laser system, incorporating the CoolMist™ technology and two solid-crystal hair-removal laser sources: Alexandrite (755 nm) and Nd:YAG (1064 nm).

In addition to DMC, the CoolMist™ handpieces are designed to also enable cold air cooling, either separately or in parallel with the DMC™ cooling.

In order to compare the cooling characteristics of DMC, cryogenic spray cooling (CSC) and cold air cooling (CAC), the following additional devices were used in the study: i) the Cryo 6 cold air chilling device (manufactured by Zimmer, G.m.b.H, Germany) that was for certain tests connected to the AvalancheLase's handpieces; and ii) the GentleMAX alexandrite laser system and handpiece incorporating a CSC assembly (manufactured by Candela corp, USA). The cold air flow of the Zimmer's device is adjustable through FC = 1- 9 different levels. The Candela's CSC device offers adjustments of the pre-spray, post-spray, and spray delay durations in milliseconds.

b) CoolMist™ technology

CoolMist™ is a skin cooling technology integrated within the latest Fotona laser systems, such as AvalancheLase® and SP Dynamis Nx.

The CoolMist assembly contains a microprocessor-controlled system for precise DMC spray adjustment for the R35X/Nx manual handpiece (Fig. 2) and the LX/Nx-Runner scanning handpiece (Fig. 3). 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.

Both handpieces are equipped with a non-contact temperature sensor MatrixView™ having an array of thermopile detectors as sensors and infra-red optics for imaging the skin surface. The infra-red image of skin on the thermopile detector array is analyzed, processed, and sent to the host laser system's graphical user interface (GUI) to display the temperature of the treated skin. The handpieces also incorporate multicolor LED diodes for displaying a quick visual indication of the skin's temperature.



Fig. 2: R35X/Nx manual handpiece (spot sizes 2-30 mm) with DMCTM spray emanating from the CoolMist™ nozzle.

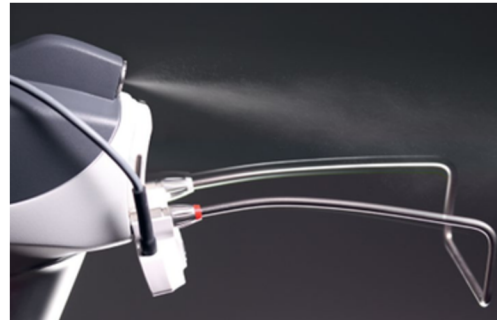


Fig. 3: LX/Nx-Runner scanning handpiece (spot sizes 9 and 11 mm; scan area up to 8 x 8 cm²) with DMCTM spray emanating from the CoolMist™ nozzle.

A detachable cooling water reservoir enables the user to easily re-fill the reservoir with the cooling liquid (Fig. 4).



Fig. 4: CoolMist's re-fillable cooling liquid reservoir.

c) Thermal imaging

The temporal evolution of the skin temperature T_S , before, during and following skin cooling and laser irradiation was measured with a commercial thermal camera (ThermaCAM P45, manufactured by FLIR Systems, USA). The camera was fixed in position above the patient's skin surface and focused on the treated skin site (Fig. 5).

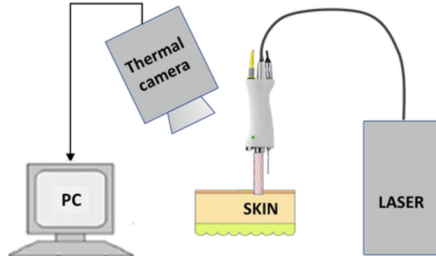


Fig. 5: Experimental set-up.

d) Measurements of skin temperature during laser hair removal procedure

The following set of thermal camera measurements was made during an alexandrite laser hair removal treatment on a patient's legs. Three methods of skin cooling were used: dry molecular cooling (DMC), cold air cooling (CAC) and cryogen spray cooling (CSC). DMC and CAC were delivered using the manual R35 handpiece. The DMC setting was Water 7/Air 5. The cold air cooling was generated by the Zimmer Cryo 6 device, set to level FC5. The cryogenic spray cooling was generated by the Candela GentleMax's handpiece, with the CSC setting of 30/20 (20 ms long spurt delivered with 30 ms delay).

Hair removal was performed in a stamping manner. The same laser parameters were used with both alexandrite laser devices (AvalancheLase with DMC and CAC cooling, and GentleMax with CSC cooling): laser spotsize $d = 15$ mm, pulse duration $t_p = 3$ ms and laser pulse fluence $F = 14$ J/cm².

III. RESULTS

a) Cooling rate measurements in absence of laser radiation

i) DMC and CAC cooling with R35 manual handpiece

Figure 6 shows the temporal evolution of the reduction of the skin temperature $\Delta T_S = T_S - T_0$ in the absence of laser radiation during and following a period of skin cooling with DMC using the manual R35 handpiece.

Similarly, Fig. 7 shows the temperatures achieved with the R35's CAC cooling during the first 5 seconds of skin cooling. A comparison with DMC cooling shows that the initial rate of skin cooling by CAC is about 3-times slower than DMC.

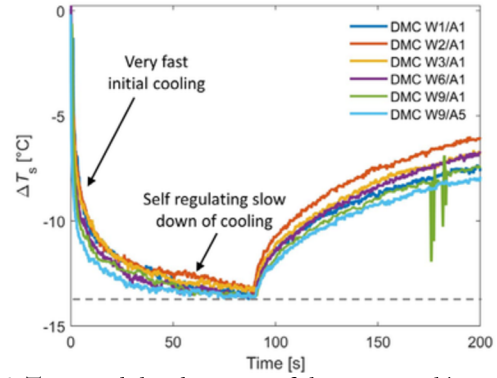


Fig. 6: Temporal development of the average skin temperature decrease ΔT_S during and following the skin cooling period of $t = 0-90$ s, for different DMC's water/air settings of the manual R35 handpiece.

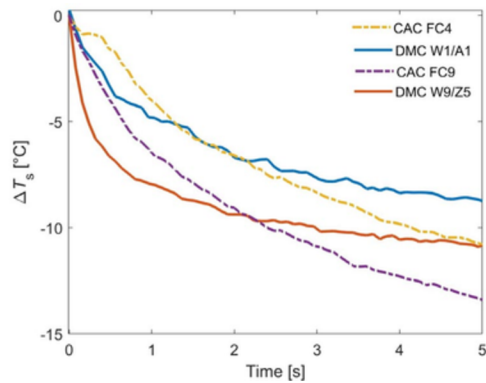


Fig. 7: Temporal development of the average skin temperature decrease ΔT_S following the start of skin cooling for two CAC settings (FC4 and FC9) with the R35 manual handpiece. For comparison, the temperature evolution during DMC cooling (W1/A1 and W9/A5) is also shown.

There are two important differences between DMC and CAC (See Fig. 8).

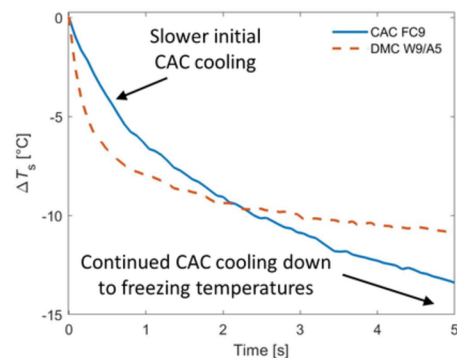


Fig. 8: Comparison of the cooling rates during CAC and DMC cooling.

First, the initial rate of skin cooling by DMC is significantly faster (~3-times) than with CAC. Second, the DMC's cooling rate is self-regulating, with the cooling rates saturating at $\Delta T_S \sim 14^\circ\text{C}$ (see Fig. 7), meaning that the skin temperature will not be reduced below the safe and comfortable temperature of about

16°C. On the other hand, during long exposures the CAC cooling continues down to $\Delta T_s \sim 30^\circ\text{C}$ (see Fig. 9), i.e., down to freezing temperatures.

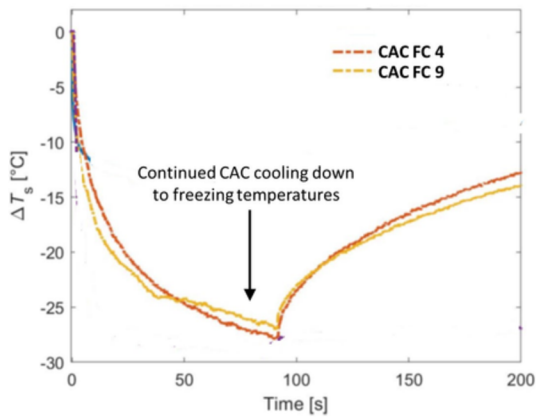


Fig. 9: Temporal development of the average skin temperature decrease ΔT_s during and following the skin cooling period of $t = 0\text{-}90\text{s}$, for CAC's settings FC4 and FC9, with the manual R35 handpiece. During long exposures the CAC cooling continues down to freezing temperatures.

ii) CSC cooling with GentleMax manual handpiece

Figure 10 shows the measured temporal development of ΔT_s in the absence of laser radiation during and following the GentleMax's cryogen spray's spurt.

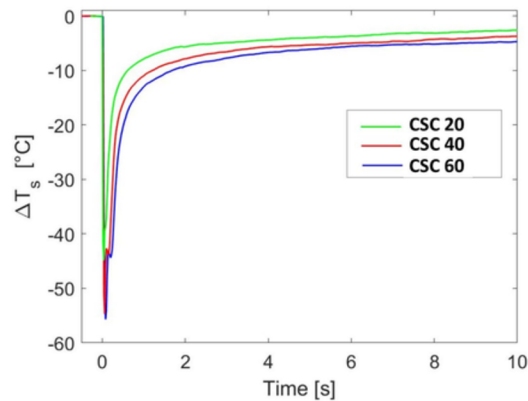


Fig. 10: Temporal development of the average skin temperature decrease ΔT_s following the start of skin cooling at $t = 0$ by CSC using the Candela GentleMax device. The temporal duration of the cryogen spray's spurt was set to 30, 40 or 60 ms. Notice that following the cryogen spray's spurt, the skin temperature returns rapidly back to the initial temperature.

iii) DMC and CAC cooling with LX/Nx-Runner scanning handpiece

Figures 11 and 12 shows the temporal evolution of the reduction of the skin temperature $\Delta T_s = T_s - T_0$ in the absence of laser radiation during and following a period of skin cooling with DMC or CAC using the LX/Nx Runner scanning handpiece.

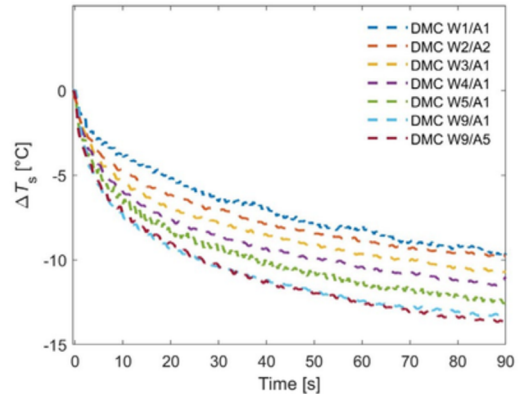


Fig. 11: Temporal development of the average skin temperature decrease ΔT_s following the start of skin cooling for different DMC settings with the LX/Nx-Runner scanning handpiece.

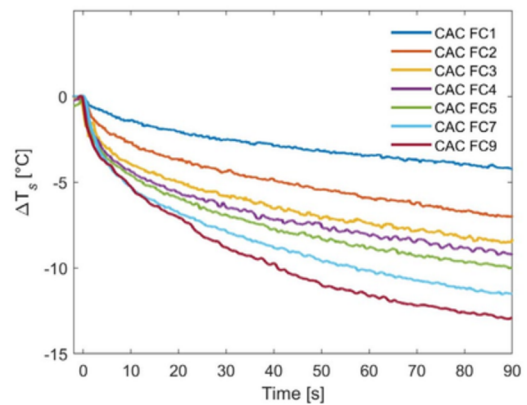


Fig. 12: Temporal development of the average skin temperature decrease ΔT_s following the start of skin cooling for different CAC settings with the LX/Nx-Runner scanning handpiece.

A comparison of the temperature developments during DMC and CAC cooling using the LX/Nx-Runner scanning handpiece is shown in Fig. 13. As is the case with the R35 manual handpiece, the cooling rate of DMC is higher than that of CAC.

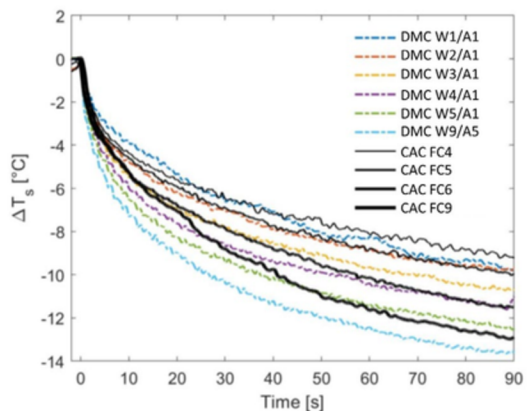


Fig. 13: Comparison of the development of the average skin temperature decrease ΔT_s during skin cooling with DMC and CAC for different settings

The homogeneity of the reduced temperature over the scanned area as achieved with DMC can be seen in the thermal image shown in Fig. 14 below.

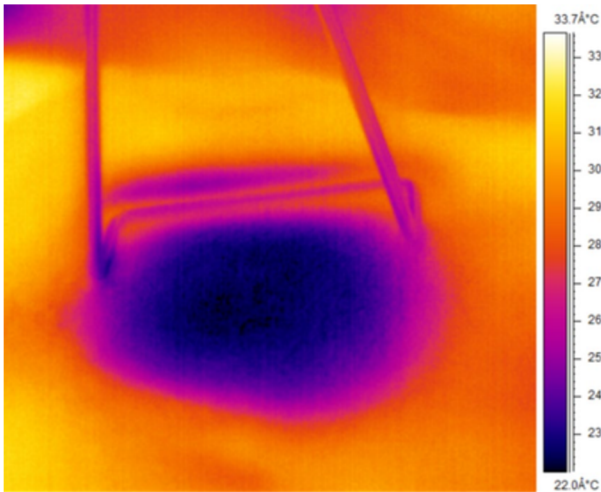


Fig. 14: Thermal image of the DMC-cooled skin area of the LX/Nx-Runner scanning handpiece.

iv) Combined DMC and CAC cooling

The design of the DMC's manual and scanning handpieces offers an interesting possibility where both methods of skin cooling, DMC and CAC are applied simultaneously. As can be seen in Fig. 15, a combined use of both methods results in extremely fast cooling rates.

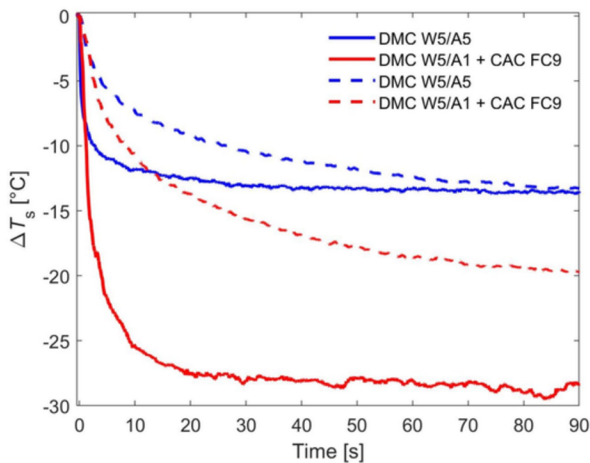


Fig. 15: Comparison of the development of the average skin temperature decrease ΔT_s during skin cooling either under DMC W9/A5 alone, or under the combination of DMC W9/A5 and CAC FC9 cooling. The dashed lines represent temperatures obtained with the LX/Nx-Runner scanning handpiece, and full lines represent temperatures obtained with the R35 manual handpiece.

Further research is needed to evaluate where and how this unique capability can be utilized clinically.

b) Measurements of skin temperature during laser hair removal procedure

Thermal images of the patient's legs during the hair

removal treatment are shown in Fig. 16. The image of the calf being pre-and post-cooled by DMC is shown in Fig. 16a, and the image of the calf being pre-cooled by CSC is shown in Fig. 16b.

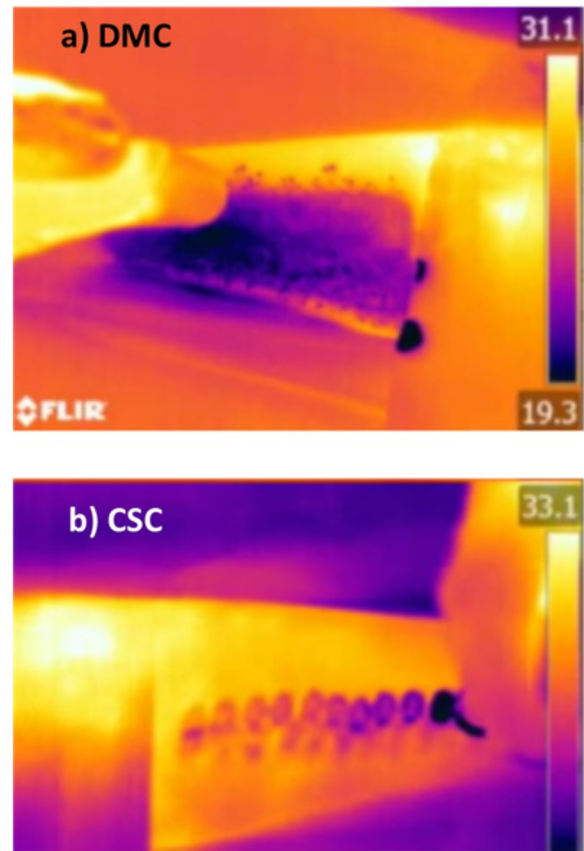


Fig. 16: Thermal images during a hair removal treatment on the patient's calves. One calf was pre-and post-cooled by DMC during the stamping treatment (Fig. 16a), and the other calf was being pre-cooled by CSC.

As can be seen from Fig. 16, the cooling with CSC remains predominantly limited to a currently treated laser spot, while with DMC the skin cooling persists over the whole treated area of the calf. This observation is attributed to the thin water film that remains on the skin for longer times following the laser pulse delivery.

The above effect can be observed also in Fig. 17, which shows the temperature dynamics of a single spot before, during and following a laser pulse. While the temperature of the CSC-cooled laser spot returns to the initial temperature within less than a second, the reduced temperature of the DMC-cooled spot persists for several minutes.

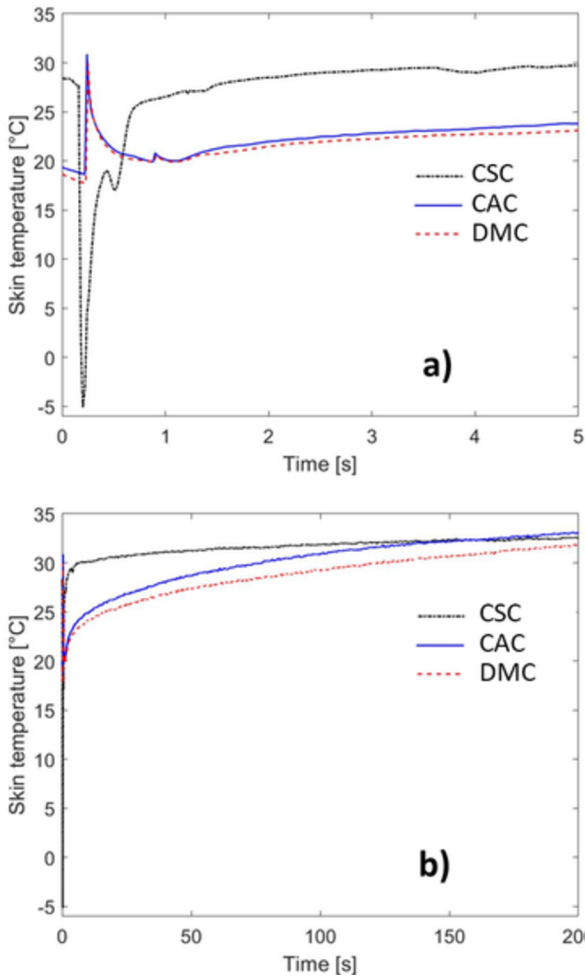


Fig. 17: Temporal evolution of the skin temperature within a laser spot area ($d = 15$ mm) for times starting at 0.25s before the initiation of an alexandrite laser pulse, and during and following the laser pulse, for three methods of skin cooling: DMC, CAC and CSC. The temperature development is presented over two timescales: $t = 0 - 5$ s (a) and $t = 0 - 200$ s (b).

A more detailed depiction of the temporal evolution of the skin temperature within one of the first initially irradiated laser spots is shown in Fig. 18 for times starting 0.5 s before the initiation of an alexandrite laser pulse, and during and following the laser pulse, for three methods of skin cooling: DMC, CAC and CSC. The observed skin temperature's rise during the laser pulse of about 10°C is approximately the same for all three skin cooling methods.

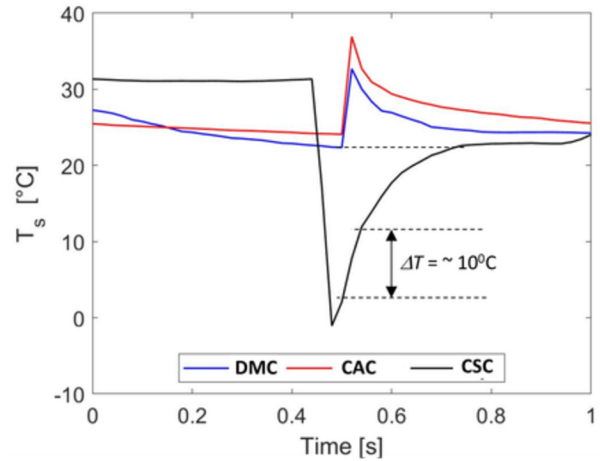


Fig. 18: Temporal evolution of the skin temperature within one of the first initially irradiated laser spots for times starting 0.5 s before the initiation of an alexandrite laser pulse, and during and following the laser pulse, for three methods of skin cooling: DMC, CAC and CSC.

There is also a difference in the thermal images during the time following the treatment. Figures 19 and 20 show thermal images of the two differently treated calves at 5 s and 10 minutes following the treatment.

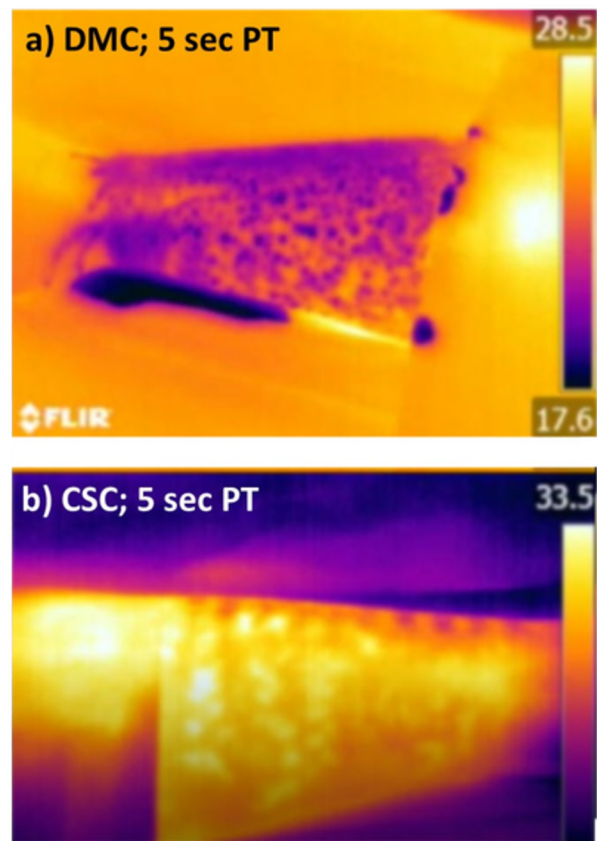


Fig. 19: Thermal images at 5 seconds following the hair removal treatment on the patient's calves. The upper image shows the calf that was pre-and post-cooled by DMC during the treatment, and the lower image shows the calf that was being pre-cooled by CSC during the treatment.

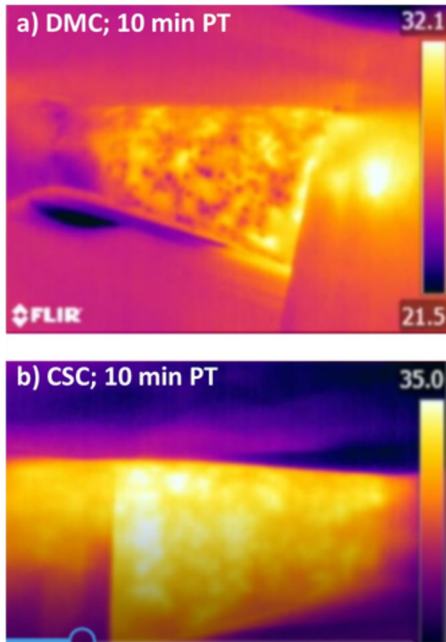


Fig. 20: Thermal images taken at 10 minutes following the hair removal treatment on the patient’s calves. The upper image shows the calf that was pre-and post-cooled by DMC during the stamping treatment, and the lower image shows the calf that was pre-cooled by CSC during the treatment.

Figures 19 and 20 demonstrate that in the absence of post-cooling by DMC, the heat diffusion from the heated deeper skin layers to the un-cooled skin surface results in thermal hot spots. This effect can be even more clearly seen in Fig. 21, which shows the temporal evolution of the maximal temperature (T_{S-max}) within the whole treated area, for both treatment methods.

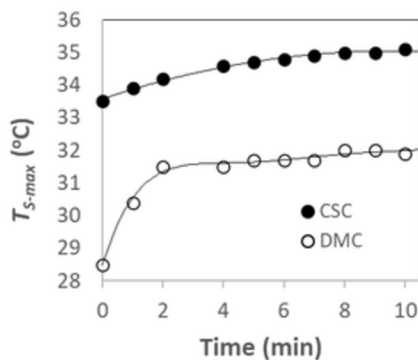


Fig. 21: Temporal evolution of the maximal temperature over the treated area during the time following a hair removal treatment using either the DMC or CSC skin cooling method.

IV. DISCUSSION

All three tested methods of skin cooling, CSC, CAC or DMC, perform in a similar manner, by removing heat from the skin to a cooling agent (either gas or liquid) in “contact” with the skin. However, the heat transfer dynamics of the three methods are

significantly different, which can have a significant influence on the clinical outcome of a laser procedure.

The cryogen and cold air cooling are both characterized by below-freezing temperatures of the cooling agent. This can be uncomfortable to the patient and can result in cryo-injury [3,8].

For cryogen spray cooling (CSC), the cooling agent is a pressurized cryogen liquid at room temperature whose boiling temperature is significantly lower than the skin surface temperature (-26.1°C for commonly used tetrafluoroethane) [8]. Heat is removed by conduction from the skin into the cryogen liquid sprayed over the skin, and the cryogen is cooled down by rapid evaporation.

On the other hand, there is no evaporation process during cold air cooling. Additionally, air is a bad conductor of heat. For this reason, the air that is blown over the skin surface needs to be cooled to very low temperatures (down to $\sim -30^{\circ}\text{C}$) by an external chiller prior to being blown over the skin area.

The most effective form of cooling is where the skin undergoes post-cooling in addition to the cooling prior and during an irradiation by the laser pulse. This is because, apart from protecting the epidermis by reducing the skin temperature before and during a laser pulse, a post-cooling of the laser-induced “burn” reduces pain, swelling and the risk of scarring. In this regard, CSC is at a disadvantage since the cooling rate by the evaporating cryogen is extremely fast, with the heat transfer coefficient hT of about $10,000 \text{ W/m}^2\text{K}$ [8, 9]. For this reason, to reduce the risk of cryo-injury the duration of the cryogen spurt is limited to below 100 milliseconds. The cryogen cooling is therefore not very suitable for prolonged post-cooling.

On the other hand, the cold air cooling (CAC) can be used for post-cooling since the skin-to-air heat conduction is slow, with hT in the range of $50\text{-}100 \text{ W/m}^2\text{K}$ [6]. However, the small heat transfer coefficient of CAC also means that the pre-cooling phase needs to be long in order for the skin to get sufficiently cooled down prior to the delivery of a laser pulse. Additionally, due to the low temperature of the delivered cold air, the skin can get over-cooled during prolonged post-cooling.

Based on the above, the newly developed dry molecular cooling (DMC) represents “the best of both worlds” solution. On one hand, the DMC is faster than CAC, enabling appropriately short pre-cooling times. And on the other hand, the DMC is not as intense as CSC, thus allowing longer duration post-cooling periods.

Additionally, since with DMC the post cooling is accomplished in a passive manner, i.e., by the molecular water droplets remaining on the skin following a laser pulse, there is no need for continued active cooling as is the case with CAC. Further, as opposed to CSC and CAC, the DMC method is self-regulating. Namely, since the evaporation of water droplets takes place at temperatures significantly below the water's boiling temperature of 100°C, the evaporation process is (for standard relative humidity levels within medical facilities) effective only at skin temperatures above about 16°C. Therefore, the skin temperature cannot be reduced to significantly below this temperature. With DMC, the risk of over-cooling or cryo-injury has been eliminated.

The clinical advantage of post-cooling with DMC as opposed to no post-cooling with CSC can be observed in Figs. 22 and 23, which show the skin reaction post hair removal treatment according to the protocols presented in section III b.



Fig. 22: Skin reactions following a stamping alexandrite laser hair removal treatment on a patient's right and left calf. The right calf was pre-cooled by the cryogen spray cooling (CSC) (Figs a and b); and the left calf was pre-and post-cooled by DMC (Fig. c). An edema can be observed at 5- and 10-minutes post treatment (PT) on the CSC's cooled leg while no edema was observed during the same time on the DMC-cooled leg. For the DMC-cooled leg, the edema started to develop only after the water droplets had been wiped away at 13 minutes post-treatment (Fig. c).

The earlier development of edema on the CSC-cooled leg is attributed to the difference of the skin temperature dynamics of the CSC and DMC cooling (see Figs. 16 and 17). The prolonged passive post-cooling by DMC acts in a similar manner as other cryo-protective measures in medicine, including therapeutic hypothermia in cardiac arrest or cerebral ischemia [16]. For example, the sooner and longer a burn is cooled with cold running water, the smaller the impact of the injury will be.

Similarly, the observed erythema on the CSC-cooled leg at 5 hours following the treatment (see Fig. 23) is attributed to the observed development of hot spots immediately following the CSC-assisted treatment (see Figs. 19 and 20), whose increased temperature continues to grow and persist for significantly longer than ten minutes (see Fig. 21).

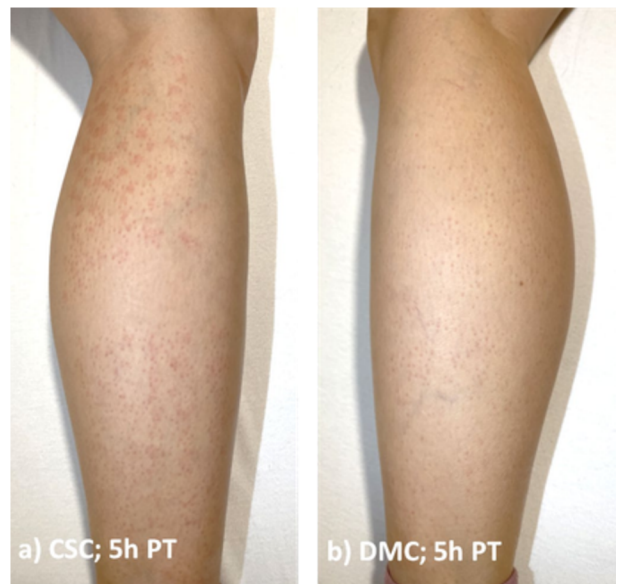


Fig. 23: Skin reactions following a treatment as in Fig. 16, at 5 hours post treatment. A strong erythema can be observed on the CSC-cooled leg.

V. CONCLUSIONS

In conclusion, a novel non-contact skin cooling method (DMC™) has been studied and compared with two standard non-contact cooling methods, cryogen spray cooling (CSC) and cold air cooling (CAC). A comparison of thermal camera measurements and clinical outcomes has shown the following:

The maximal cooling rate of DMC is significantly faster in comparison with CAC, especially for the manual handpiece. This is important since it is typically with the manual handpiece that the operator moves the position of the handpiece relatively quickly from spot to spot, not allowing much time for the cooling to take effect.

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 (DMCTM) 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].

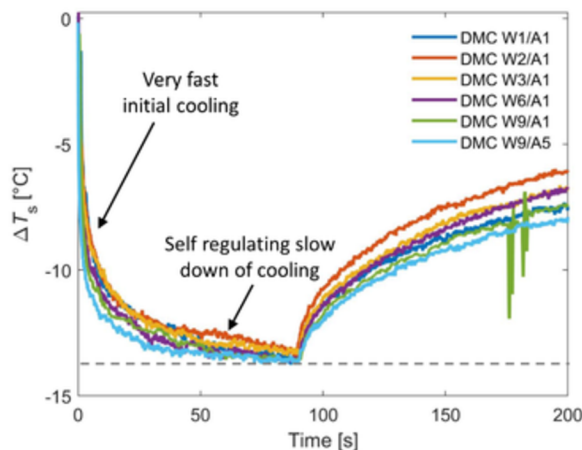


Figure 1. Temporal development of the average skin temperature decrease ΔT_s during and following the skin cooling period of $t = 0-90s$, for different DMC water/air settings of the manual R35X handpiece (adapted from [17] with permission of the authors and publisher). DMC cooling is characterized by a fast initial cooling rate, and self-regulating saturation of the cooling rate once the skin temperature reaches about 16 °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/cm ²)	Hz	Pulse duration (ms)	Protocol	Spot size (mm)	Fluence (J/cm ²)	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.

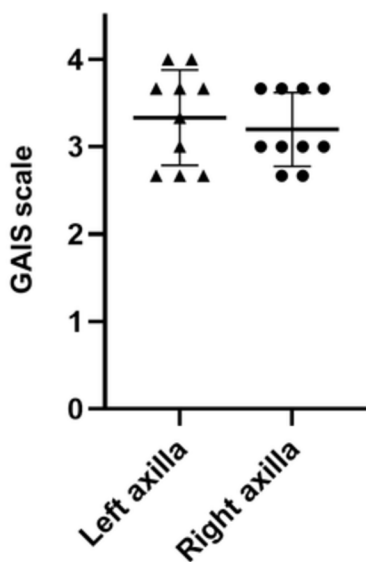


Figure 2. Results of blind evaluation of photographs using the GAIS scale. The graph represents mean values from 3 independent evaluators for 10 patients, where images at baseline and at the 6-month follow up were available. There was no significant difference between treatments as evaluated by the Wilcoxon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

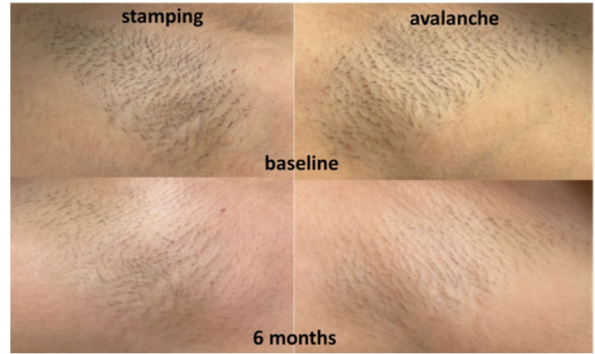


Figure 3A. Representative results (patient No. 6) before and at the 6-month follow up after laser treatments with stamping mode used during the last three sessions (left photos), and with avalanche mode during all sessions (right photos).



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).

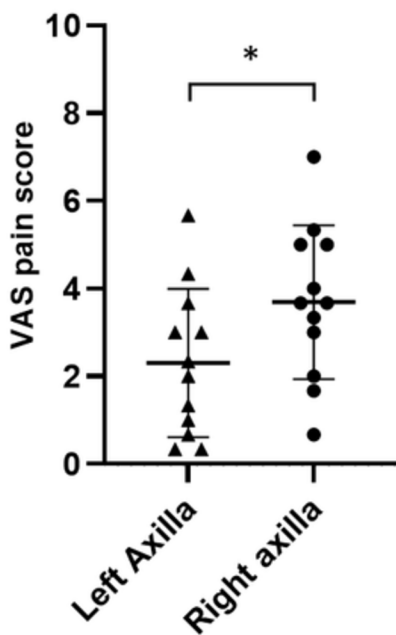


Figure 4. Mean patient-reported VAS pain scores in the last three treatment sessions, which were performed using the avalanche technique in the left axilla and with the stamping mode in the right axilla. Mean±SD is annotated in the graph. The asterisk denotes a statistically significant difference as 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 DMCTM cooling using the patented CoolMistTM 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 DMCTM 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.

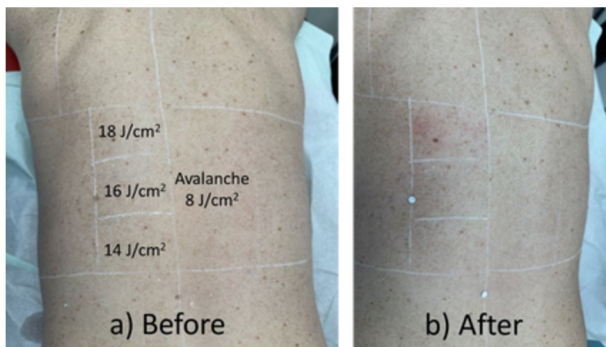


Figure 5. a) Four areas of a male back before being treated with four different protocols during the first alexandrite laser hair removal session. The three areas on the left side of the back were treated with a stamping mode using three different laser pulse fluences: 14.0, 16.0 and 18.0 J/cm². And 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/cm ²)	Pain assessment (0-10 VAS scale)	Fluence (J/cm ²)	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™ 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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