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Efficacy of Hyperthermic LED 940 nm System to Reach Required Adipose Tissue Temperatures for Apoptosis: A Case Series Study

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Abstract

Background: Alternative or adjunctive methods to liposuction, including lasers, high-intensity focused ultrasound, radiofrequency devices, and selective cryolipolysis, are increasingly being utilized for localized fat destruction. The objective of this case series was to evaluate the efficacy of a novel hyperthermic 940 nm LED non-invasive system (ReBorn by Lightfective Ltd.) to reach the required therapeutic temperature of 42°C-47°C in subcutaneous fat to cause adipose apoptosis.

Methods: Thirteen subjects aged 18 years and older, who were undergoing ReBorn or similar hyperthermic fat reduction treatment, had a BMI of 30 or less and pinchable fat in the treatment area were recruited. Hyperthermic treatment with the Lightfective ReBorn system was performed in a single, 35-minute treatment session. The tissue temperature was recorded after the 35-minute treatment period, immediately after removal of the applicator (ReBorn system handpiece), by inserting a hypodermic needle microprobe into the treatment area.

Results: Of the 35 applicator sites with temperatures recorded, 82.86% (n=29) reached the desired temperature range (mean: 44.91°C, median: 43.9°C). The remaining 6 (17.14%) applicator sites did not reach the desired temperature ranges. It is expected that a delay in reading the temperatures at these sites is responsible for the reduced temperatures. No adverse events were noted.

Conclusion: The ReBorn system reaches the desired temperature range of 42-47°C, necessary to illicit adipose apoptosis during a 35-minute treatment session, with no recorded adverse events and within the patient's comfort level. Further research using a larger patient population is required to replicate the results and confirm the efficacy of the hyperthermic

LED-based Lightfective ReBorn system technology to induce apoptosis and non-invasive lipolysis.

Keywords: Hyperthermic Treatment; Adipose Apoptosis; Body Contouring; Non-Invasive Lipolysis, LED, 940nm, Thermocouple Needle, Hypodermic Needle Microprobe

Background

Body contouring may be achieved by invasive surgical operations or else by adopting non-invasive tools. The results with surgical methods are dramatic and immediate [1]. Liposuction has been the most common modality for fat reduction and body contouring; however it has been associated with risks such as post-operative morbidity, recovery, and downtime [2]. Alternative or adjunctive methods for localized fat destruction are increasingly being utilized as they are not associated with the risks and adverse effects that are otherwise always possible with the surgical options [1,2]. There are currently five prominent non-invasive techniques for reduction of subcutaneous adipose tissue namely cryolipolysis, high-intensity focused ultrasound (HIFU), radio frequency (RF), 1060 nm laser diode and low-level laser therapy (LLLT) [3].

Non-invasive reduction of fat tissue relies on energy, achieved through either diminishing fat stores or permanently removing adipocytes. Stimulating adipocytes with energies at lower intensities, triggers lipolysis and breaks down triglycerides into glycerol and free fatty acids (FFA). Besides lipolysis, adipose tissue can be permanently eliminated through regulated cell death processes like pyroptosis, necroptosis, and apoptosis. Apoptosis, a complex intracellular pathway for controlling cell number and tissue size, requires a specific amount of energy transformed into heat, elevating fat temperatures to 42-45°C [4].

The temperature increase needed to achieve this target temperature is less than 10°C. The amount of tissue damage can be quantified by the relationship between exposure time and tissue temperature. At a moderate increase in temperature to 6°C above normal (i.e., 43°C), the structural integrity of the lipid bilayer is lost and, at 45°C for more than 5 minutes, cell membranes show damage.

The Lightfective ReBorn system is a Light Emitting Diode (LED) system, intended for non-invasive lipolysis of the flank and abdomen to achieve destruction of adipocyte cells. The main components of the ReBorn system are a console and four [4] applicators (handpieces) that deliver LED energy to the patient (Figure 1). The Lightfective's ReBorn operation principle is based on LED energy that generates Infra-Red Light (940 nm) which is absorbed in the adipocyte tissue. The ReBorn cooling and electrical system (cooled sapphire window placed on the skin surface in treatment area) assists in maintaining safe and comfortable skin surface temperatures. The Lightfective ReBorn system delivers power of up-to 49 Watts,per applicator, and up to 196W in total, in continuous wave (CW) mode.

To evaluate the efficacy of the Lightfective ReBorn system to reach the required temperature of 42°C-47°C to cause adipose apoptosis, a case series consisting of single sessions of hyperthermic treatment using the 940nm LED system was conducted at a single center in Milan, Italy in May 2023.

Figure 1: Lightfective ReBorn Non-Invasive Fat Reduction System

Materials and Methods

Study participants

Thirteen subjects were recruited for this case series, which was conducted between 8th and 9th of May 2023. Subjects were between the ages of 27 and 60 years old (median age of 45 years). 76% (n=10) of the participants were female (Table 1). Subjects were eligible to participate in the trial if they were older than 18 years, were undergoing ReBorn or similar hyperthermic fat reduction treatment, had a BMI of 30 or less and had pinchable fat in the treatment area. Exclusion criteria included subjects with large, firm protruding abdomens (visceral fat), moderate to severe skin laxity in the treatment area and severely dimpled skin (cellulite) in the treatment area. For full contraindications for the use of the Lightfective ReBorn system, please refer to Appendix 1. All subjects provided written informed consent for the study.

Table 1: Subject demographics

	N=13	
	Female	**Male**
Gender, n (%)	10 (76.9%)	3 (23.07%)
Age, years (study mean)	45.08	
Age	42.6	53.3
BMI (study mean)	21.45	
BMI mean	20.96	23.11
Skin type (Fitzpatrick scale), n (%)		
Type 2	3 (30%)	0 (0%)
Type 3	7 (70%)	(100%)
Smoker	2 (20%)	1 (33%)
Previous treatments		
ReBorn	5 (50%)	2 (66%)
Other	6 (60%)	2(66%)

Study procedure

The case series was performed at an aesthetic Clinic, Medical Beauty Spot Clinic, in Milan, Italy in May 2023.

Hyperthermic treatment was performed in a single treatment session. Each subject was either at the beginning or at the end of a series of ReBorn treatments (each series consisting of 3 treatments) at the clinic.

The Treatment Procedure Included

- The LED applicator was applied on treated areas (using an elastic belt) for single treatment exposure. The applicators were placed on the abdomen, flanks, inner thighs, or outer thighs, respectively, and either anteriorly or posteriorly (Figure 2 and Table 2).

- The LED energy emitted was gradually increased in a linear fashion over a period of 10 minutes ("Comfort Mode"), and then raised manually according to the subjects' level of comfort for the remainder of the treatment period.

- The system duty cycle (on/off ratio) was 20/10sec on/off. i.e. the LEDs heated tissue for 20 sec followed by 10 sec without heating. System contact cooling was set to 20°C

- The total hyperthermic treatment duration was 35 minutes.

Tissue temperature was recorded using an Omega Datalogger Thermometer HH520 by inserting a MT-26/2HT hypodermic needle with thermocouple sensors at the tip into the treatment area at a depth of 15 mm - 20 mm immediately after the treatment applicator was removed.

On review of results, it was determined that the thermocouple sensors on the hypodermic needle microprobe used to assess the temperatures in patient 5 were faulty, and the results for this patient have therefore not been included in the final analysis.

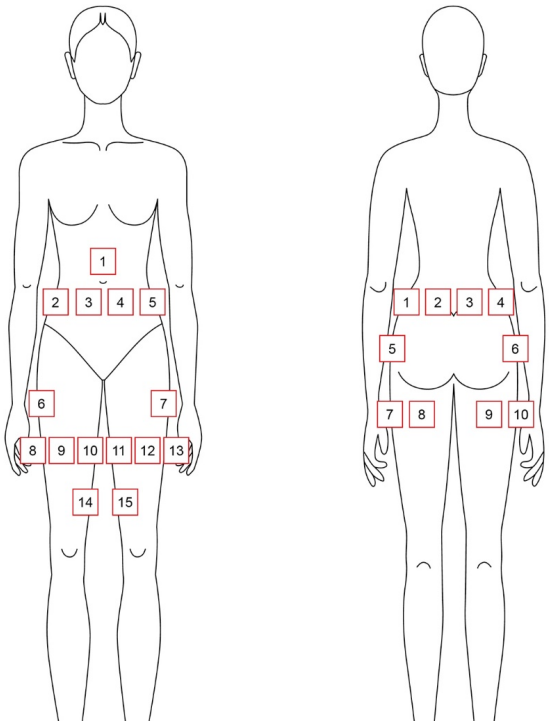

Figure 2: Applicator positioning: a) anterior; b) posterior

During the time that treatment was completed, the applicator was removed, and the hypodermic needle microprobe was successfully inserted, the temperature in the adipose tissue decreased. By monitoring the

temperatures for the duration of the treatment, it was noted that there was a linear decrease in temperature, with an average decrease of 1°C / 22.5 seconds (Figure 3). To account for this decrease in temperature, the final measured temperatures were adjusted using the following formula:

Adjusted temperature = (time delay (seconds) / 22.5) + recorded temperature

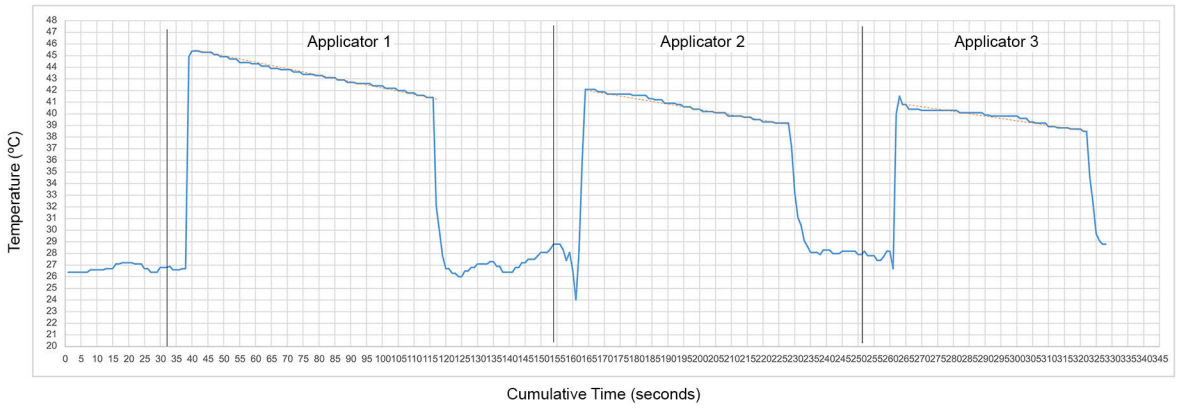

Figure 3: Example of temperature decrease from time of applicator removal to time of final temperature measurement in the treatment areas on a single patient (Patient 12)

Results

The results of 12 participants were reviewed. 91.67 % (n=11) had applicators positioned anteriorly. 41.67% (n=5) of all subjects had 4 applicators positioned during the treatment period (4 in the anterior group, 1 in the posterior group), with the remaining 58.33% (n=7) of participants having 2 or 3 applicators positioned respectively. (Table 2)

Table 2: Placement of applicators per participant

		Position of applicator			
		AP 1	AP 2	AP 3	AP 4
Patient 1	Anterior	8	9	12	13
Patient 2	Anterior	6	7	X	X
Patient 3	Posterior	1	2	3	4
Patient 4	Anterior	3	4	X	X
Patient 6	Anterior	2	3	4	5
Patient 7	Anterior	3	4	X	X
Patient 8	Anterior	3	4	X	X
Patient 9	Anterior	10	11	X	X
Patient 10	Anterior	1	3	4	X
Patient 11	Anterior	10	14	11	15
Patient 12	Anterior	8	12	13	X
Patient 13	Anterior	2	3	4	5

X indicates no placement of an applicator

Patient discomfort was assessed periodically during the treatment and energy density was adjusted to subjects' responses (Table 3). The "Comfort Mode" option of the ReBorn allows operator to raise the energy automatically, gradually, and linearly in order to maximize patient comfort. The Comfort Mode can be operated only at the beginning of the treatment. To operate Comfort Mode, the operator sets the desired time-duration for automatic energy raise, as well as initial and final energy levels per each applicator. In this case series, the intention was to end the gradual increase in energy using Comfort Mode over 10 minutes. The energy levels were then increased manually, according to each patient's threshold.

Table 3: Comfort Mode setting per participant. Comfort mode allows for the desired time-duration for automatic energy raise, as well as initial and final energy levels per each applicator

	Initial and final energy levels per each applicator over 10 minutes in Comfort Mode			
	Applicator 1	Applicator 2	Applicator 3	Applicator 4
Patient 1	65%-90%	65%-90%	65%-90%	65%-90%
Patient 2	70%-90%	70%-90%	X	X
Patient 3	70%-80%	70%-80%	70%-90%	70%-90%
Patient 4	70%-95%	70%-95%	X	X
Patient 6	70%-90%	70%-90%	70%-100%	70%-100%
Patient 7	65%-90%	65%-90%	X	X
Patient 8	70%-90%	70%-90%	X	X
Patient 9	65%-90%	65%-90%	X	X
Patient 10	65%-80%	65%-80%	65%-80%	X
Patient 11	65%-80%	65%-80%	65%-80%	65%-80%
Patient 12	65%-85%	65%-85%	65%-85%	X
Patient 13	65%-80%	65%-80%	65%-80%	65%-80%

X indicates no placement of an applicator

After the 35-minute treatment period with Lightfective's ReBorn system, the applicator was removed and a hypodermic needle microprobe with thermocouple sensor at the tip was inserted into the adipose tissue to measure the temperature in the tissues under the applicator site. (Appendix B; Video supplemental material)

In patient 10, the area where applicator 1 was positioned was unsafe for probe insertion, and temperature was therefore not recorded.

Of the 35 applicator sites with temperatures recorded, 82.86% (n=29) reaching the desired temperature range (mean: 44.91°C, median: 43.9°C). (Table 4). The highest treatment recorded was 52°C, with no adverse effects noted. This patient had received radiofrequency in the applicator area the day before, which may explain the higher temperature measured in this case series.

The remaining 6 (17.14%) applicator sites did not reach the desired temperature ranges. There was an extended delay in the temperature reading for patient 13 due to difficult hypodermic needle microprobe insertion. It is expected that this delay was significant enough that the tissue had begun cooling down, which is why a lower temperature was recorded. It is expected that a similar delay is responsible for the reduced temperatures at the other 5 sites.

The mean LED power output percentage required

to reach the desired temperature range at the 29 respective applicator sites was 91% (median: 90%) (Table 4).

No adverse events were noted or recorded in any of the participants in the study.

Table 4: Adjusted adipose tissue temperature (°C) vs percentage LED power output energy after 35-minute treatment period per participant

	AP1 + delay		AP2 + delay		AP3 + delay		AP4 + delay	
Patient 1	42°C	100%	40.9°C	100%	42.2°C	90%	43.9°C	90%
Patient 2	48.9°C	90%	52°C	100%				
Patient 3	43.8°C	80%	46°C	80%	45.9°C	90%	44°C	90%
Patient 4	42.9°C	95%	43.5°C	100%				
Patient 6	47.5°C	90%	43.1°C	90%	46.3°C	100%	46.3°C	100%
Patient 7	42°C	90%	41.9°C	100%				
Patient 8	44°C	90%	48.5°C	100%				
Patient 9	42.5°C	90%	43.9°C	100%				
Patient 10	*	*	43.3°C	90%	47.6°C	90%		
Patient 11	45.8°C	80%	42.2°C	80%	47.7°C	90%	43.7°C	90%
Patient 12	45.7°C	95%	40.8°C	85%	40.9°C	85%		
Patient 13	39°C	80%	44°C	80%	43.3°C	85%	40.9°C	85%

* unsafe area for hypodermic needle microprobe insertion

Discussion

This short case series demonstrates that LightFective's ReBorn system employing Infra-Red Light (940 nm) is able to reach the desired temperature range of 42-47°C (mean: 44.91°C, median: 43.9°C) necessary to illicit damage to adipocytes, required for apoptosis. These temperatures are reached within the patient's comfort range, with no adverse events being noted.

Studies of hyperthermia-induced tissue damage and ex-vivo temperature measurements have shown that hyperthermic temperature can be achieved and maintained in subcutaneous adipose tissue by a 1060 nm lased in conjunction with surface cooling [5,6]. Radiation using 1060 nm diode laser device heats the fat layer with controlled temperature elevation, distributing the heat more evenly over a broad zone compared to higher wavelengths [5,7].

The results of this case series are supported by a study conducted by Decorato JW, et al who demonstrated the potential to induce damage in adipocytes through a treatment protocol characterized by subjecting the target tissue to a 1,060nm laser treatment for 25 minutes, while maintaining temperatures within the range of 42–47℃. Furthermore, the investigation encompassed analysis of both short- and long-term of tissue responses, extending up to six months post-treatment. These histological changes included an inflammatory response, followed by macrophage infiltration, which typically initiated around the two-week mark. The process of clearing cellular debris was observed to conclude at approximately six-months. The clinical findings revealed that, over the course of 2, 3, and 6 months, there was an average reduction in fat thickness of 14%, 18%, and 18%, respectively. Additionally, when assessing average fat volume reduction using MRI at 3 and 6 months, it was found to be 24% and 21%, respectively [2].

In a study conducted by Katz et al., the safety and efficacy of a 1,060-nm Diode Laser for reducing fat in the flank area were assessed in a cohort of 49 participants following a single treatment session. Evaluation utilizing ultrasound and high-resolution imaging at both baseline and three months after the treatment revealed a substantial reduction in adipose tissue. Notably, 96% of the subjects

expressed satisfaction with the outcomes [8].

Our case series was limited by a small number of patients and the delay in hypodermic needle microprobe insertion which causes a drop in temperature as the tissues were cooling, resulting in an adjusted temperature calculation. In addition, VAS pain scores for each patient were not uniformly recorded and have therefore not been included in the results. However, as a result of the efficient cooling system (cooled sapphire window placed on the skin surface in treatment area) subjects could maintain the higher heat levels comfortably during treatment.

Conclusions

The LightFective ReBorn system reaches the desired temperature range of 42-47°C during a 35-minute treatment session, necessary to illicit adipose apoptosis, with individualized settings for each patient's comfort level and with no adverse events. Further research using a larger patient population is required to replicate the results to demonstrate the efficacy of adipose tissue apoptosis of this LED-based technology as an alternative to currently available non-invasive lipolysis technologies.

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