**NON-INVASVE LIPOLYSIS TREATMENT – A COMPARISON BETWEEN LASER SYSTEM (1060NM) AND LED SYSTEM (940NM)**

**Test Report**

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## INTRODUCTION

Hyperthermic treatment increase adipose tissue temperature to 42-47$^{o}$C for sustained time, induce adipocytes injury and eliciting an inflammatory response. The amount of temperature increase needed to achieve this target temperature is less than 10$^{o}$C. The amount of tissue damage can be quantified from the relationship between exposure time and tissue temperature. At moderate increase in temperature to 6$^{o}$C above normal (i.e., 43$^{o}$C), the structural integrity of the lipid bilayer is lost and at 45$^{o}$C for more than 5 minutes, cell membranes show damage. The injured adipocytes are removed through body inflammatory process.

A variety of energy sources can potentially be used to produce such heating for example ultrasound[1], radiofrequency or 1060 nm diode laser. Preliminary laboratory and clinical studies demonstrated the ability to damage adipocytes using a 1060 nm diode laser device to target this endpoint [2., 3].

Radiation at 1060nm wavelength heats the fat layer with controlled temperature elevation, distributing the heating more evenly over a broad zone conspired to higher wavelengths[4, 7]. 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 [4-6].

Other treatment that depends on heat destruction of adipose tissue is a diode Light Emitting Diode (LED) system. The LightFective's ReBorn system is a diode Light Emitting Diode (LED) system, intended for non-invasive lipolysis of the flank and abdomen to achieve destruction of adipocytes cells. The main components of the Reborn system are a console and four (4) applicators that deliver LED energy to the patient. The LightFective's ReBorn operation principle is based on LED energy that generates Infra-Red Light (940 nm) which is absorbed Inside the adipocytes tissue and generate heat to subcutaneous tissue layers. ReBorn cooling and electrical system (cooled sapphire window placed on the skin surface in treatment area) assist in maintaining safe and comfortable skin surface temperatures. The LightFective's ReBorn system is capable of delivering 940nm of radiation to peak power output of 210 Watts in continuous wave (CW) mode.

## OBJECTIVE

As these technologies provides hypothermic treatments, this test was design in order to evaluate and compare temperature buildup inside a fat tissue at different depth points following single session of hyperthermic treatment using 1060nm laser system versus 940nm LED system.

## MATERIALS AND METHOD

### *Study devices*

The hyperthermic treatment was performed by the following devices:

- Laser system at 1060nm (Cynosure's SculpSure Laser system, spot size 4x6 cm^2)
- IR LED system at 940nm (LightFective's ReBorn system spot size 7x5cm^2).

### *Study Participants*

The study included healthy male or female between 20 to 65 years of age with BMI of 32 or under, and with unwanted fat in abdominal region.

### *Study Procedure*

The comparison test was performed at renowned dermatology Clinic in NYC (NY, USA) on June 2017.

Hyperthermic treatment procedure was performed by both devices. A single treatment session was performed. Treatment procedure included:

- The laser head/LED applicator was applied on treated areas (using elastic belt) for single exposure.
- Hypothermic treatment started at light flounce of 1.1 watt/cm2, continues for 4 min, the applicator maintained at 15$^{o}$C through the entire treatment.
- After 4min of continues operation the device starts cycles of 20 second “ON” power and 10 second of “OFF” power for 16 min.
- Total hyperthermic treatment duration - 20 min.

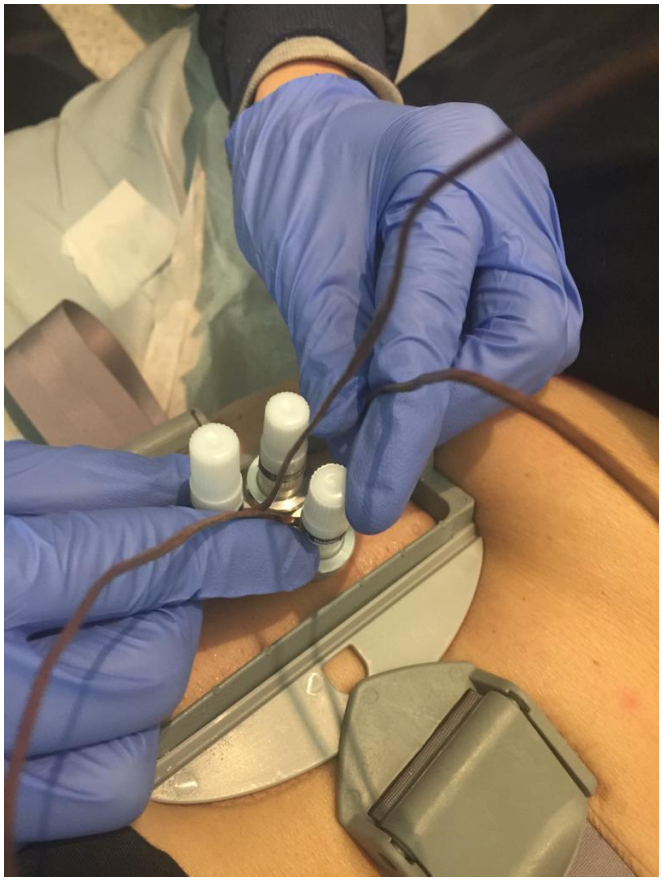
Light exposure was performed through a 4X6 cm optical window. In order to prevent skin overheating light exposure was simultaneously cooled with circulating fluid to 15$^{o}$C (while using the Cynosure’s SculpSure Laser system) or by cooled sapphire window placed on the skin surface in treatment area (while using LightFective's ReBorn system). Energy densities ranging at 0.9-1.4 W/cm$^2$.

Each subject was treated by both devices. Single pulse was provided by one device (e.g. SculpSure) at one side of the waist and 5 minutes following treatment end additional pulse was provided by the other device (e.g. ReBorn) at the other side of the waist. Treatment order (SculpSure/Reborn) was changed for each subject.

Tissue heat level was measured 2 to 3 second following treatment end. Three needles with thermocouple sensors at the tip were inserted to 5mm, 9.5mm and 14mm depths. Tissue temperature was recorded. Figure 1 represents heat measurement by needles with thermocouple sensors.

Patient discomfort was assessed periodically during the treatment and energy density was adjusted to subjects responses.

**FIGURE 1**: heat measurement following hyperthermic treatment.



**RESULTS**

Altogether 10 participants were recruited to the comparative study. No adverse events were noted or recorded.

Table 1, Figure 2, and Figure 3 represents heat buildup inside a fat tissue at different depth points following single session of hyperthermic treatment using 1060nm laser system versus 940nm LED system.

**Table 1**: heat buildup inside a fat tissue at different depth points

| **Heat buildup - Measurement Results** | | | | | | |
|---|---|---|---|---|---|---|
| **Subject #** | **Measurement depth** | | | | | |
| | **14mm** | | **9.5mm** | | **5mm** | |
| | **Technology** | | **Technology** | | **Technology** | |
| | **LED** | **1060 Laser** | **LED** | **1060 Laser** | **LED** | **1060 Laser** |
| **1** | 40.22 | 42.3 | 43.2 | 39.7 | 33.6 | 27.5 |
| **2** | 44.59 | 39.81 | 41.39 | 40.44 | 28.3 | 29.5 |
| **3** | 45.11 | 37.18 | 44.51 | NA | 30.13 | 30.3 |
| **4** | 45.55 | 41.53 | 44.5 | 41.97 | --- | --- |
| **5** | 47.3 | 43.4 | 37.5 | 33.49 | --- | --- |
| **6** | 44 | 44 | 45.11 | 42 | --- | --- |
| **7** | 48.17 | 46.5 | 47.16 | 47.9 | --- | --- |
| **8** | 42.6 | 41.92 | 44.94 | 43.45 | --- | --- |
| **9** | 44.83 | 44.07 | 46.91 | 41.3 | --- | --- |
| **10** | 46.6 | 44.25 | 44.4 | 43.52 | --- | --- |
| **Mean** | **44.9** | **42.5** | **44.0** | **41.5** | **30.7** | **29.1** |
| **StDev** | **2.3** | **2.6** | **2.8** | **3.8** | **2.7** | **1.4** |
| **Median** | **45.0** | **42.9** | **44.5** | **42.0** | **30.1** | **29.5** |
| **Min** | **40.22** | **37.18** | **37.5** | **33.49** | **28.3** | **27.5** |
| **Max** | **48.17** | **46.5** | **47.16** | **47.9** | **33.6** | **30.3** |

Table 1 shows that only three measurements were recorded at 5mm depth. Measurements results show that no heat was build up at this depth following the hyperthermic treatment (average tissue temperature LED and 1060 laser technology was 30.7 (±2.7) and 29.1 (±1.4) respectively). Therefore, no additional heat measurements were conducted at this depth.

Figure 2 and 3 show temperature measurement results at 9.5 and 14 mm depth respectively.

Table 1 and both figures show the similarity in heat buildup in the tissue at 9.5 and 14 mm depth. Hence, both technologies – the 1060 laser and LED systems - can induce similar heat buildup in the tissue as a result of hyperthermic treatment - Indicating the effectiveness of the treatment to induce adipocytes injury and removal. Furthermore, as a result of efficient cooling system (cooled sapphire window placed on the skin surface in treatment area) subjects could contained slightly higher heat levels comfortably during treatment.

**Figure 1**: Temperature Measured at 9.5 mm depth

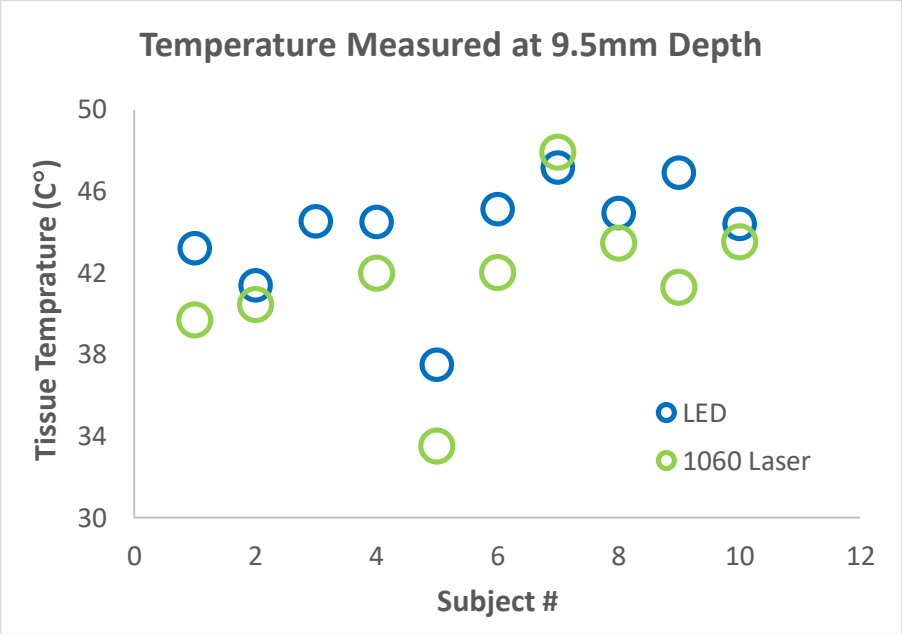
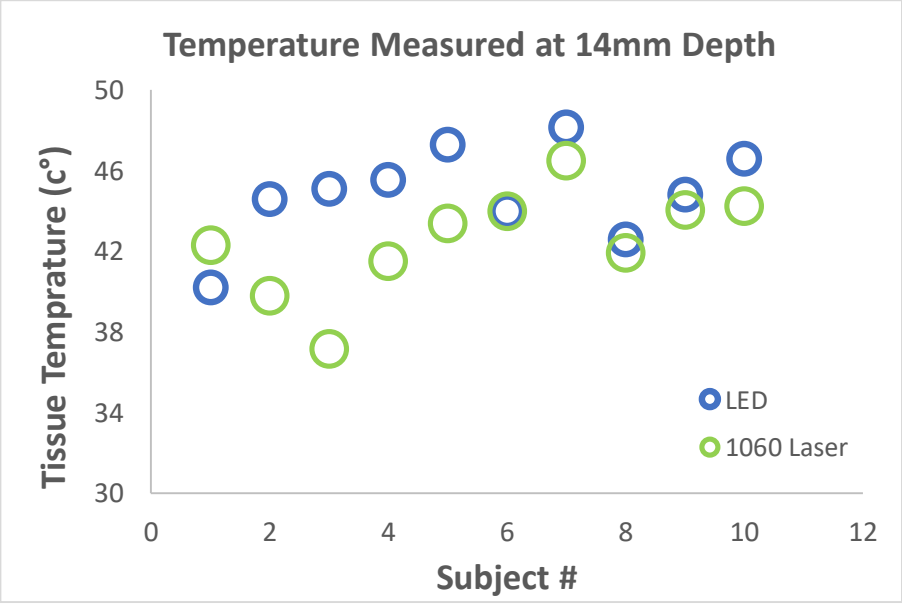



**Figure 2**: Temperature Measured at 14 mm depth



## CONCLUSION

The results suggest that there is a similarity in heat buildup in the tissues as a result of the hyperthermic treatment provided by 1060 laser system and LED system,

The depth of max temperature is close to 14mm (from skin surface) and the average temperature at 14mm with the LED 940nm is 2.4d$^{o}$C higher than the LASER 1060nm with the same degree of comfort.

The results suggest that the LED at 940nm can use less power to achieve the same temperature gradient with more comfort to the patient.

Temperature Error of measurement is up to $\pm$2 $^{o}$C.

## REFERENCES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