

Clinical study

Magma Platform ALD (Advanced Laser Diode) Applicator 808 nm For long-term hair reduction Formatk Systems Ltd.

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Background: Hair removal procedures have become some of the most common treatment offered by medical aesthetics clinics today. Forma-tk has developed a range of innovative technologies to offer the safest and most effective hair removal treatments. Forma-tk features hair removal treatments using IPL (Intense Pulsed Light), 808nm Diode Laser and Diode Laser 1064nm Nd:Yag technologies. The MAGMA Platform is a precise device that can be adjusted to damage the hair follicle only, while minimally affecting the surrounding skin. Lasertrolysis is a method of removing unwanted hair, utilizing laser energy that's targeted at the hair follicle to cause permanent thermal damage. The near-infrared laser light is emitted by the ALD 10X12mm spot applicator and preferentially absorbed by the pigment located in the hair follicle. The laser is pulsed, or turned on, for only a fraction of a second. The duration of each pulse is just long enough to damage the follicle, while the system's unique contact-cooling system helps protect the skin by conductive cooling during the laser energy delivery. The MAGMA Platform provides practitioners with multiple treatments modes. Treatment flow and mode selections are made easy by the seamless integration with the melanin-meter (a diagnostic device - see picture no. 1).

The Melanin-meter collects live readings of melanin



Photo no. 1 - Melanin meter

concentration levels in the patient's skin and recommends a treatment program accordingly, thereby allowing better control, increased efficiency and reduced risk across all skin types.

The MAGMA Platform advanced treatment's software will allow the doctor to choose among five different operation modes. In this clinical evaluation we decided to focus on and compare the two most popular modes, the FAST mode and SLOW mode.

Slow mode: the classic technique that delivers a high fluence to the tissue in a single pulse. In this study the average pulse duration was 40 msec and the average fluence was 25.6 J/cm².

Fast mode: a latest but popular technique due to fast coverage of large body zones and maximal patient's comfort. In this method a low fluence is being delivered to the skin. In this study the average fluence was 8.4 J/cm² and the pulse duration was short, 10-15 msec. Treatment area was divided into 10X10cm grids, to each grid 250 pulses were applied at 10Hz.

Objective:

1. To test the effectiveness of the two aforementioned modes of operation on different body zones.
2. To test pain level perception when treating with the Slow Vs. Fast mode.
3. To examine and report side effects of the Magma™ (Formatk Ltd. Israel) system.

Method: 28 volunteers participated in this clinical trail, 12 males & 16 females. Skin types I-IV, ages 21-56.

The following body zones were treated: Chest, Abdomen, Back, Axilla, Bikini line, Neck & Legs.

The inclusion criteria were healthy males & females above 18 years old who never removed the hair in the desired body zone by any method, or people who used to remove the hair by shaving or trimming only.

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Inclusion criteria for hair type: black or brown only, coarse or fine.

Patients were invited every 6-8 weeks for treatment/evaluation, and in each visit a counting sticker (see picture no. 2) was placed on the patients' skin, in the same place each time, according to permanent mark on the skin such as nevi. The no. of hairs in the 1.5X1.5 cm sticker window was counted and photographed in each visit. Patients were asked not to remove hairs in between visits.

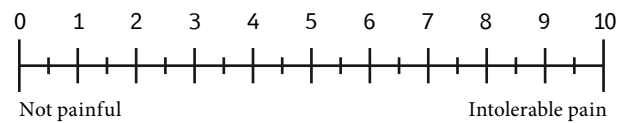


Photo no. 2 - Counting sticker

The Mode of operation selected interchangeably between the right and left sides of the treated body area. After the hair count, the hair was shaved to a zero level and a melanin reading (1-100) was sampled by the melanin meter device.

Melanin reading data was entered to the Magma system, using the on screen treatment interface, hair type was than defined (Fine/Coarse) in order to let the Magma select the optimal treatment parameters.

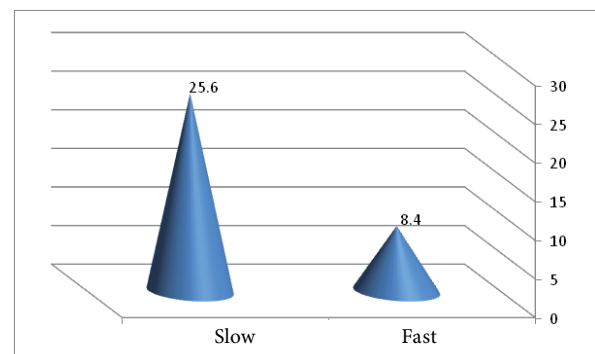
At the end of each session, patients were asked to evaluate the pain associated with the treatment on a scale of 0 - 10.



Results:

| Description\Mode | Slow 1Hz | Fast 10Hz | Units | Remarks |
|--|-------------|--------------|-------------------|------------|
| Average fluence level | 25.6 | 8.4 | J/cm ² | |
| Average pain level | 5.7 | 3.1 | | Scale 0-10 |
| Average hair reduction 3 months following 4th treatment (all treated body zones) | 69.7 | 53.2 | % | |
| Average hair reduction 3 months following 4th treatment at the Axilla area (females) | 72.3 | 66.7 | % | |
| Average hair reduction 3 months following 4th treatment at the Back area (males) | 60.4 | 51.6 | % | |

Table no. 1 - Slow vs Fast results



Graph no. 1 - Average fluence

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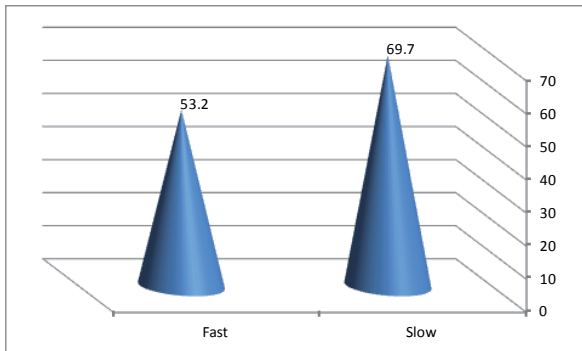
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Conclusion:

Hair reduction rating

The clinical study results showed better results in hair reduction when treating with the "SLOW" mode parameters.

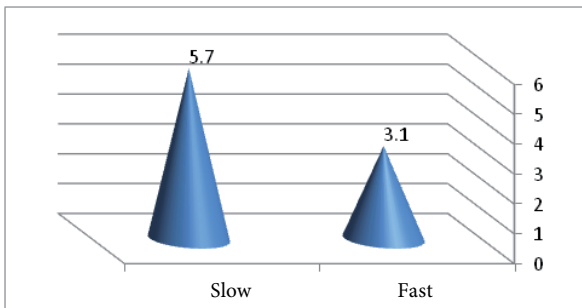
More than 30% improvement of hair reduction, using the slow mode vs fast mode was sampled.



Graph no. 2 - Average hair reduction

Pain level rating

When checking the pain level grades, the clinical study showed that participants treated with FAST mode reported a significant 54% reduction in treatment discomfort compared with SLOW mode.



Graph no. 3 - Average pain level

Side effects: 70% of the patients developed skin erythema and perifollicular edema on the body area that was treated with the "SLOW" mode technique. Those symptoms disappeared after few hours and are considered a normal reaction for high power diode laser treatments. No prolonged side effects were observed.

Even though the clinical results of the slow (SLOW) mode showed better results in hair reduction, this does not mean it is the optimal treatment option in each case. There are cases where the patient will benefit more from the FAST mode technique, such as:

- Patients with high sensitivity to pain
- Summer season and tanned patients
- Short treatment time
- Low risk for side effects

Magma™ system (Formatk systems Ltd.) resulted highly effective, fast, painless and safe technology to reduce unwanted hair in various body areas of skin types I-VI.



Photo no. 3 - ALD Applicator



Photo no. 4 - Magma System