



A SINGLE-SITE, CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF THE MAGMA SYSTEM FOR PROGRESSIVE HAIR REDUCTION

Sharona Levi – Friedman CRA,
Eran Krieger M.D

November 14, 2016

STUDY SUMMARY

The study evaluates the efficacy and safety of the Magma system in the hair reduction application. 33 volunteers (16 females and 17 males) in the age of 18 - 56 were enrolled in the baseline and underwent a cycle of 6 treatments each, once every 8 - 12 weeks. Some of the participants were treated in more than one area, totally 46 cycles of treatments were performed in 7 different anatomical regions. Hair follicles' counting was performed prior to each treatment and a final follow up control 12 weeks after the last treatment. The analysis takes into consideration the following variables: gender, working mode (Fast - Slow) and the anatomical region. The overall average reduction percentage, detected at the final follow up control, through proper "counting windows" was 77.1%. The hair follicles density showed a consistent and progressive reduction over time compared to baseline. The participants considered moderate and acceptable the level of pain perceived during the treatments and totally tolerable. They all filled up a questionnaire, indicating the level of pain on a visual analogue scale from 1 to 10 (VAS) where a total average reported was 4.5 No adverse events were reported at all during the whole study period.

INTRODUCTION

The purpose of this clinical evaluation was to assess treatment efficacy and safety with the Magma System, using the ALD, LLD (808 nm diode laser) and ND (1064 nm diode laser) applicators for progressive hair reduction in different anatomical regions and skin types. The Magma System is cleared by American FDA (K153566) for this indication. Therefore, the purpose of this study is to extend the clinical data and provide further effectiveness and safety evidences using the Magma system. A total of 33 subjects were enrolled to this study and underwent 6 treatments with the Magma System diode laser.



DEVICE INDICATIONS AND DESCRIPTION

The Magma System is a platform for hair removal treatments that combines a diode laser 808nm (ALD applicator – 1.2cm² and LLD applicator- 4.5cm²) and ND1064nm applicator for the treatment of hair reduction in dark skin types. The optical energy delivered into the skin interacts with the hair follicles through the principle of selective photothermolysis causing permanent thermal damage to the hair structure. The process that requires more sessions, leads to a progressive reduction in the density of the superficial unwanted hair as a result of atrophying process that undergoes the hair structure. It is intended therefore for progressive and permanent non-invasive hair reduction. The Magma System has a 510(k) FDA clearance (K153566) for the same indications. The Magma system is comprised of two main parts: the main console, which includes the touch screen interface, cooling system, power supplier, etc.; and the applicators: ALD (Advance Laser Diode) 808nm diode laser with a tip size of 10X12mm (1.2cm²), up to 120J, max. rate 10 Hz. ; LLD (Large Laser Diode) 808nm diode laser with a tip size of 30X15mm (4.5cm²), up to 180J, max rate. 4 Hz; ND - long pulse 1064nm diode laser with 3 tip sizes: 3, 5 and 8 mm. up to 220J/cm², max. rate 2 Hz. All the applicators have a cooling system that cools the tips and frames to 4° C. The Magma system allows working in several modes: Slow – a single pulse, Medium – a double pulse splitting to two equal parts , the amount of energy, Fast – up to 10Hz delivering the energy through accumulation effect of repeated pulses, 100ms – long single pulse for skin type V and 400ms – very long single pulse for skin type VI.

STUDY OBJECTIVES AND ENDPOINTS

The study objectives and endpoints are listed below, and are generally consistent with those submitted for the American FDA approval as part of the clinical studies for the Magma System predicates (K153566). In addition, the current study also includes evaluations of several other variables: slow vs fast modes, Male vs Female and a comparison evaluation of the results obtained in 7 different anatomical regions. This study provides further efficacy data for the Magma system.

Primary objectives

- Demonstrate the efficacy in progressive hair reduction at 12 weeks after 6th treatment using the Magma System in the presence of various conditions and settings.
- Demonstrate the safety of the Magma System in hair reduction treatments.

Secondary Objectives

- Evaluate the variation of efficacy in different anatomical areas, genders and operational modes.
- Assess the pain perception level during treatment, as reported by the subjects.

Primary Effectiveness Endpoints

Statistically significant superfluous hair reduction post Magma treatments at 12 weeks follow-up (12wk FU) versus baseline, as measured by hair follicles direct counting. Considered an average cycle of treatments in the range between 6 and 10 sessions and considered the minimum number of sessions – six (6), we have established an average reduction of 70% percent as a target for the definition of the effectiveness of the treatment of hair reduction $\geq 70\%$.

Secondary Effectiveness Endpoints

1. Significant hair reduction post Magma treatment at each visit
Formatk Systems Ltd Page 2 of 6 November 14, 2016
(starting at the second treatment) compared to baseline, using hair follicles direct counting.
2. Comparison analysis between “Slow” and “Fast” operational modes, demonstrating the efficacy of both ways of working.
3. Comparison analysis between females and males subjects. The subdivision according to gender demonstrates the effectiveness reached for both groups. Means, it has been achieved and exceeded the hair reduction over 70% for each group.
4. Comparison analysis between 7 different anatomical regions. The study has verified obtaining reduction of at least 70% for each of the anatomical areas.
5. Subject's pain level perceived during each treatment (Tx.1-Tx.6), reported by the participants using a 1 -10 VAS scale.

Primary Safety Endpoint

The report of any type of adverse event recorded throughout the study and post treatment.

CLINICAL STUDY RESULTS

A total of 33 volunteers were enrolled to the study and underwent 6 treatments once every 8 – 12 weeks using the Magma system. The chosen group of participants was widely heterogeneous regarding all demographics parameters and skin conditions as shown in the tables below.

Participants		n	%
All		33	100
Gender	Male	17	51.5
	Female	16	48.5
Skin type	I	2	6.1
	II	3	9.1
	III	17	51.5
	IV	8	24.2
	V	2	6.1
	VI	1	3
Age	18 - 25	4	12.1
	26 - 33	10	30.3
	34 - 41	9	27.3
	42 - 49	8	24.2
	50 - 56	2	6.1

A. Demographic distribution

As shown in table 1 the distribution of parameters such as gender, skin type and age follows a heterogenic segmentation which statistically corresponds to natural tendencies.

Table 1: Baseline Demographic Distribution

GENDER
 ● MALE
 ● FEMALE

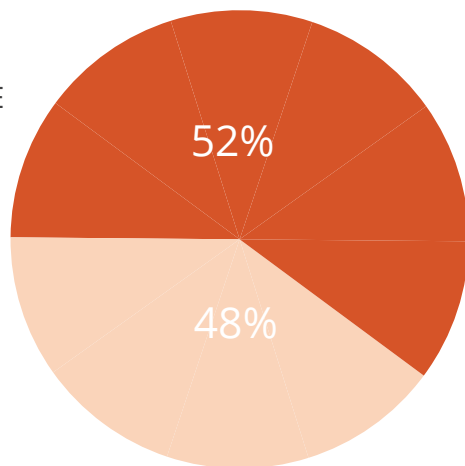


Diagram 1: Distribution by Gender

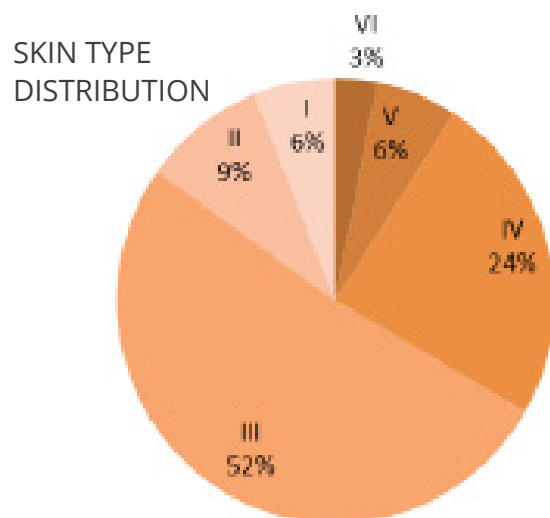


Diagram 2: Distribution by skin type

Anatomical Region	n	%
Abdominal	4	8.7
Legs	12	26.1
Chest	9	19.6
Back	6	13
Axilla	9	19.6
Bikini line	2	4.3
Neck	4	8.7
Total treated areas	46	100

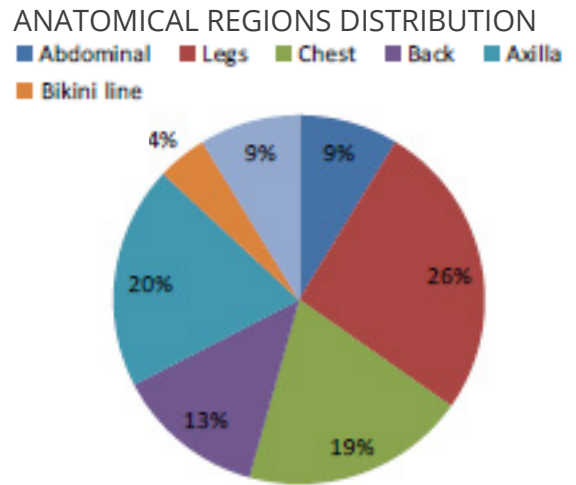


Table 2: Baseline Treatments according Anatomical Regions

Diagram 4: Distribution by anatomical region

B. Anatomical regions

Table 2 shows the distribution of the treatments according the most popular 7 anatomical body zones required for hair removal procedures.

C. The procedures

All participants have signed a proper informed consent during the enrolment phase. In each area to be treated prior each treatment, a labe in the form of a window, large 1.5 x 1.5 cm (2.25cm²) has been applied in a specific point, then, a count of the hairs present within this area was performed (Fig.1). Photographs were taken at the baseline, before every treatment and at the end of the study (Fig. 1). The setting of the electrophysical parameters was applied according to the skin's physiological conditions of each participant at a given time and therefore we have adjusted the optimal settings for each participant ad hoc, based on the conditions that could have varied between one person and another and even between one session and another for the same subject. (I.e. amount of melanin, hair type, etc.)

D. Hair reduction

As can be seen in diagram 5, the general rate of hair reduction follows a linear trend with continuous and accumulative improvements of approximately -13% per treatment. The spatial distribution of the totality of the results obtained with Magma demonstrates a uniform consistency having a minimum and sporadic deviation as expected. As shown in diagram 6 and 7.

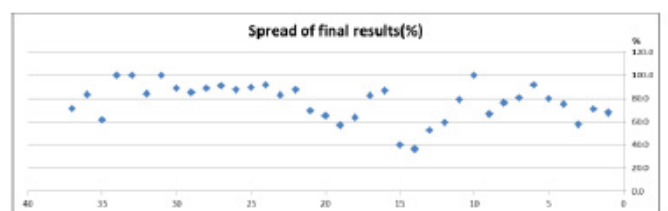
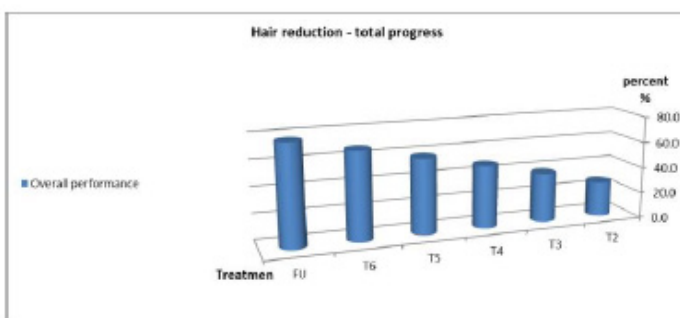


Diagram 5: Hair reduction total performance

Diagram 6: Spatial distribution of the results of the treated areas with LLD applicator

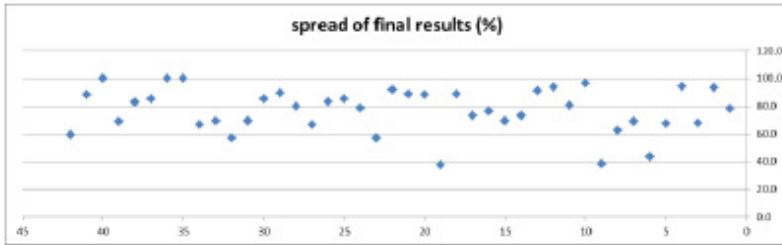


Diagram 7: Spatial distribution of the results of the treated areas with ALD applicator

E. Effectiveness Endpoints

1. Hair Follicles Reduction

The number of hair follicles was detected for each visit (for each treatment visit the measurement was taken prior to the treatments) counting the amount of follicles through a window large 1.5 x 1.5 cm, positioned in a reference point for each participant. (Fig. 1)

a) Primary Effectiveness Endpoint:

Hair Reduction at 12 weeks, follicles counting $\geq 70\%$ reduction vs baseline The primary effectiveness endpoint of this study was at least 70% of hair reduction at 12 weeks after the 6th and final session. The overall average percentage of hair reduction measured by counting the hair follicles was 77.1 % at 12 week follow-up as shown in table 3 below. Therefore, the study met the primary effectiveness endpoint

T2	T3	T4	T5	T6	(FU)	STD DEV	Avg	Median
27	38	48.3	58	67.6	77	7	15	14

Table 3: Hair reduction averages of final results in percentage (%)

b) Secondary Effectiveness Endpoint

1. Significant hair reduction post Magma treatment at each visit (starting at the second treatment) compared to baseline, using hair follicles direct counting. As shown in diagram 8 the improvement after each session follows linear and consistent values. The total average of hair reduction for each visit is 12.8%

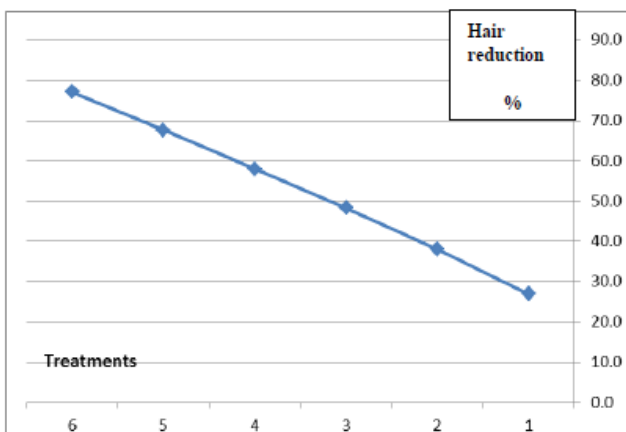


Diagram 8: Improvement in percentage (%) for each Treatment

2. Comparison analysis of efficacy using two different operation modes. Slow Vs Fast The Magma system allows the operator to use a single T2 T3 T4 T5 T6 FU STD DEV Avg Median 27 38 48.3 58 67.6 77 7 15 14 Hair reduction % Formatk Systems Ltd Page 4 of 6 November 14, 2016 pulse emittance which requires a static pass by pass way of working – “Slow” mode or a dynamic and continuous emittance of the pulses of lower energy with accumulative effect of the energy obtained by passes repetition - “Fast” mode. The study includes a comparison “split” trial, testing both ways, one on each side. The results summarized in table 4 below demonstrate the effectiveness of both modes that met the expectation of 70% of hair reduction as endpoint definition; however we can observe a slight dominance of the “Slow” mode that has reached 80% reduction over the “Fast” mode that obtained 74% of hair reduction.

Slow vs Fast						
	T2	T3	T4	T5	T6	FU
Fast	23.7	35.4	45.3	56.4	65.4	74.1
Slow	30.2	40.6	51.3	59.7	69.7	80.0

Table 4: Percentage (%) of hair reduction in modes comparison

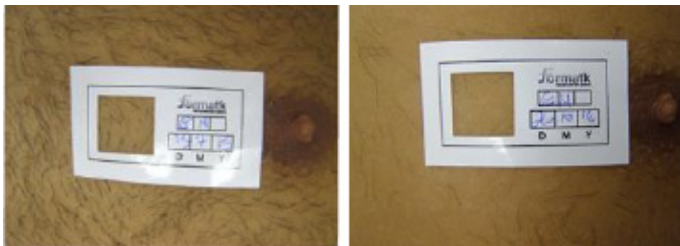


Figure 1: Counting area for male chest hair reduction after 5 treatments

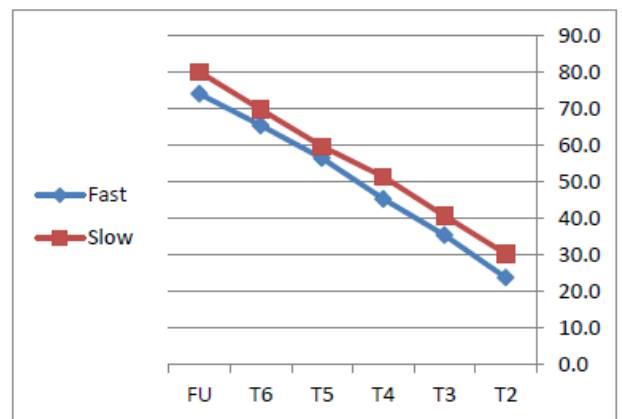


Diagram 9: The parallel linear trend of both working modes with the slight dominance of the slow method

3. Comparison analysis between females and male subjects. Table 5 below highlights the achievement of the target of 70% reduction in both the masculine and feminine gender. As expected, by virtue of the androgenic nature of the male gender, there is a greater resistance although passed the end point

	T2	T3	T4	T5	T6	FU
Males	28.9	37.8	48.7	55.4	65.8	74.9
Females	24.4	40.3	54.2	63.5	71.3	82.0

Table 5: Percentage (%) of hair reduction trends in male vs female groups

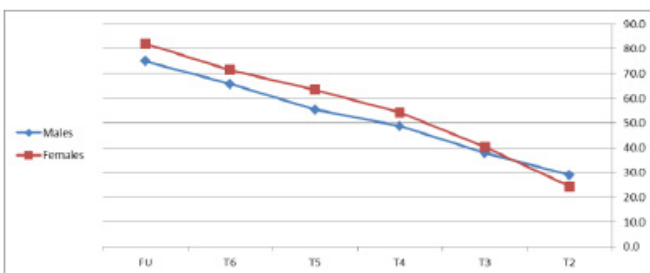


Diagram 10: Parallel linear trend of hair reduction in comparison between males and females. Major resistance of androgenic male hair

4. Comparison analysis between 7 different anatomical regions The results relating to each treated anatomical region are grouped in table 6 below. As we can notice, all regions have obtained the clearance of 70% or more. We can further notice the correlation between the more resistant areas such as the abdomen, chest and back that are commonly subjected to treatments of hair removal by males’ subjects. This corresponds to the comparison made in point 3 between male and females.

	T2	T3	T4	T5	T6	FU
Abdomen	35.4	36.1	49.9	53.8	60.2	70.1
Legs	32.1	44.1	56.1	65.1	72.0	83.6
Chest	31.5	37.6	49.3	57.8	64.4	71.9
Back	24.3	33.8	37.7	47.7	61.7	72.2
Neck	40.2	59.6	66.9	69.1	76.5	86.5
Axilla	18.1	33.9	48.0	59.8	71.6	80.4
Bikini Line	27.3	25.4	36.5	55.8	63.2	75.4

Table 6: Percentage (%) of hair reduction trends according the anatomical regions treated during the trial

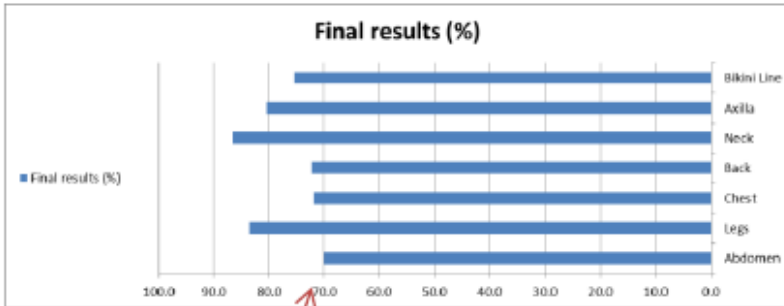


Diagram 11: Distribution of final results – 7 different anatomical

All anatomical regions met the effectiveness endpoint defined as 70% for 6 treatments

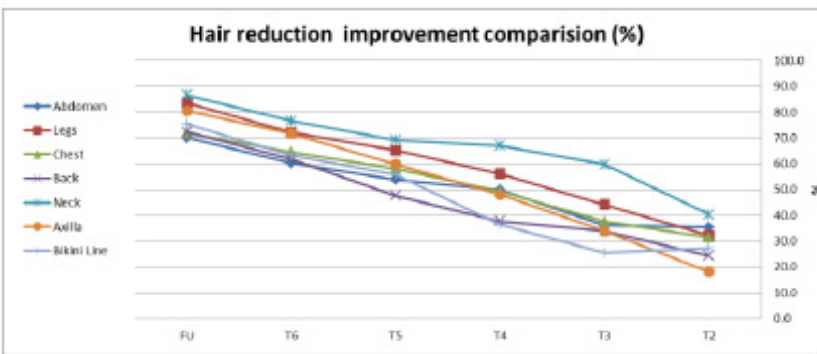


Diagram 12: Hair reduction trend, expressed in percentage for each anatomical area.

5. Pain perception averages as reported by all the participants after each treatment through VAS 0 - 10. Since the subjects have experienced two different working modes; Slow and Fast, they could have compared them one to each other. The results show a double scoring for each participant; one refers to the pain perception when using the slow way, the other while using the fast one. Although moderate pain is perceived in both modes, there is a discrete relevance in the perception of painful stimulus between these two working modes. The accumulation of many low-energetic pulses, occur in the fast mode, turns out to be less painful then the single pulse that delivers a greater quantum of energy as happens by using the slow mode. Diagram 13 below shows the VAS scale used by the participants to indicate the level of pain perceived during the treatments.

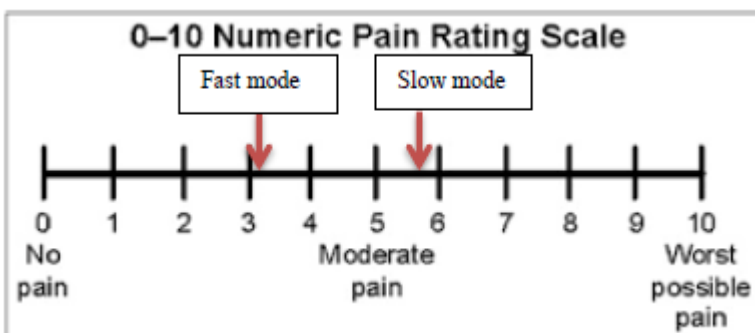


Diagram 13: VAS 0 -10 numeric pain rating scale; average of pain levels reported for fast and slow modes

Table 7: Summary of averages of VAS scores expressed by all participants and after each treatment in Fast and Slow modes

Patient #	S pain VAS	F pain VAS
1	3.9	1.5
2	8.6	4.3
3	5.2	3
4	5	3
5	7.2	4
6	5.5	2.6
7	5.7	1.6
8	5.2	2.6
9	4.8	2.6
10	7.2	6.3
11	8	5.25
12	6	5
13	4.6	1.1
14	8.1	4.1
15	4.1	1
16	4.6	1
17	6	1
18	5.2	1.2
19	7.1	6.8
20	5.5	3.5
21	2	1
22	7	6.6
23	7.2	4.4
24	4.8	3
25	5.8	2.8
26	4.4	4.7
27	6.1	4.8
28	5.3	2.4
29	5.4	3.3
30	4.5	2.8
31	8	2.7
32	6.8	2.8
33	7	5.6
Avg	5.8	3.3
Std Dev	1.4	1.7

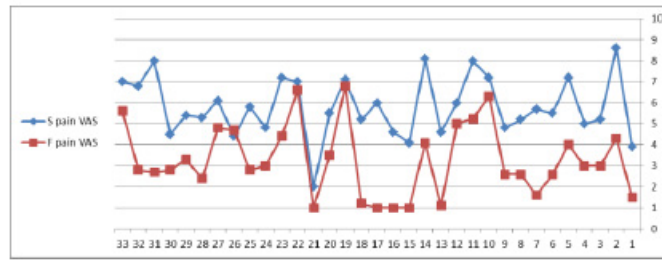


Diagram 14: Averages values of pain perception evaluated on VAS 0 - 10 numeric pain rating scale. "Fast" mode Vs "Slow" mode

The results in diagram 14 above show a certain gap in the painful perception between the fast and the slow modes although the average values of both remain in the moderate pain tract.

E. Safety Endpoints

1. Adverse Events

The safety of the Magma system was evaluated based on the rate of occurrence of adverse events (AE) reported during the study. Adverse events are defined in the study as any undesired clinical occurrence, in a study subject undergoing Magma hair reduction treatment, which does not apply a causal relationship with the study device. An AE can, therefore, be any unfavorable and unintended sign, symptom, or disease temporarily associated with the use of the Magma system, whether or not considered related directly to the device. All adverse events were evaluated by the investigator for severity of the effect and relationship to the device. No adverse events were observed or reported during the study course. Thus, the study met the primary safety endpoint, and confirmed that the optical energy of the device does not raise new types of safety concerns compared to the Magma predicates.

V. CONCLUSION

The results of this prospective clinical study demonstrated the safety and effectiveness profile of the Magma system. The study met the predefined primary efficacy endpoints. Specifically, subjects achieved and overpassed the desired percentage $\geq 70\%$ of hair reduction of the superfluous hair after only 6 treatments. An overall average of $77\% \pm 1\%$ was observed at final follow up. The study also met the secondary efficacy endpoints by demonstrating a constant and linear hair reduction at each session of about 13%. In addition, sub-groups analyses demonstrated that the effectiveness end point of 70% reduction is obtained for all examined variables: gender, operation mode and different anatomical regions. Therefore, across several assessments, the study demonstrated that the Magma system with all its applicators performs as intended to achieve an efficient hair reduction in various physiological conditions. Overall, the subjects indicated that the treatments were associated with minimal to moderate pain. No adverse events were reported at all during the whole period of the study.

Thus, the clinical study described above strongly demonstrated that the Magma system presents a safe and effective profile for the intended use of hair reduction.