

COMPARATIVE STUDY OF THE UNIPOLAR AND THE NEW UNIPOLAR LARGE HAND PIECE IN MOTION RADIOFREQUENCY TO TREAT BODY LAXITY AND CONTOUR.

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SUMMARY

Newer technologies have emerged, making possible the use of radiofrequency (RF) in non-invasive aesthetic applications, such as skin laxity. The purpose of this study is compare regular unipolar and newer unipolar large (UniLarge) hand piece of Accent XL (Alma Laser). Time of treatment, energy, responses and side effects profiles were documented. Standard and three-dimensional photography (VECTRA 3D, Canfield) were performed before and after 15 days of the last treatment. Patients and physicians assessment by questionnaires. In our study both Unipolar and UniLarge hand piece proved to be safe and effective in the treatment of body laxity. Moreover, the larger diameter of the UniLarge hand piece ensures a more homogenous, 30% faster induction phase, with a decrease of 20% energy.

BACKGROUND AND OBJECTIVES

Newer technologies have emerged, making possible the use of RF in non-invasive aesthetic applications, such as skin laxity. This new use of RF is due to its ability to produce heat in to the deep dermis and subcutaneous fat tissue, with consequent shortening and remodeling of collagen.

The Accent XL (Alma Lasers) is an 40.68 MH frequency dynamic RF equipment. The Accent's waves generator delivers the RF by an unipolar or unipolar large (UniLarge) hand piece that protects the epidermis with an electronic cooling surface and emits an electromagnetic field causing the movement of activated particles generating heat in the dermis to the subcutaneous. The thermal injury controlled by the high impedance of the fat tissue, not requiring plate coupling. The final results is a shortening of the collagen, followed by an inflammatory response, and late neo collagen, which allows the treatment of skin laxity.

The objectives of this study is to compare unipolar and UniLarge hand piece of Accent XL (Alma Laser) evaluating efficacy, safety, time and energy of the treatments.

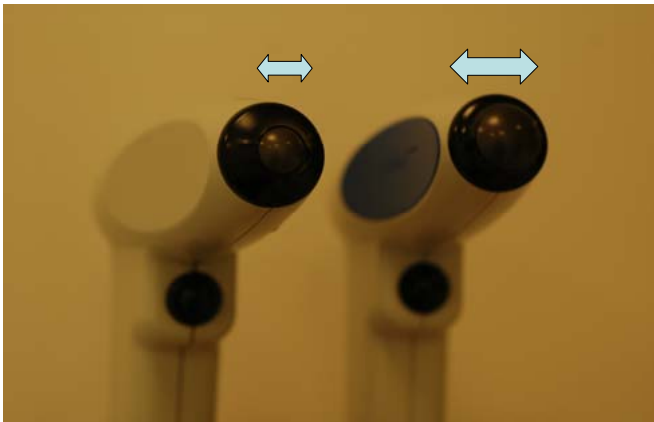


Figure 1: Comparison of the diameter of unipolar and unilarge hand piece.

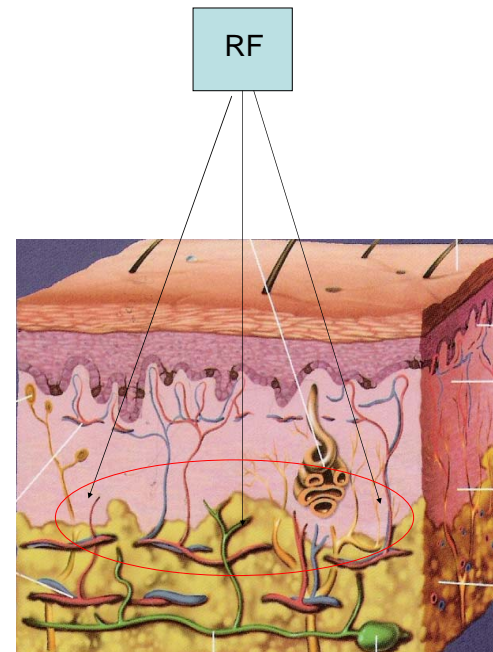


Figure 2: Project of RF heat in to the deep dermis and subcutaneous fat tissue, with consequent shortening and remodeling of collagen.

STUDY DESIGN AND METHODS

We have performed 3570 treatments in 595 patients with the unipolar hand piece over a period time of 41 months. and 1392 treatments in 232 patients with UniLarge hand piece in the period of 13 months. The median age was 35 years (ranging from 18 to 82 years), with 95% female patient. Exclusion criteria included pregnancy, the use of pace maker, other previous treatment for body laxity in the last 6 months and only the patients that had finished the 6 consecutive weekly sessions were included in the study.

The Accent^{XL} treatment protocol was the same for both hand piece., began applying mineral oil over dry skin to ease the friction of the dynamic hand piece. The induction phase is made by an operator that rubs the epidermis until a homogeneous clinical skin contraction is seen, which is obtained reaching epidermal temperatures from 38 to 42 degrees C (monitored by infrared thermometer),. erythema and edema were considered normal effects. Then comes a maintenance phase with subsequent ascendant passes, for a period time of 4 minutes. The sessions for treatment of body laxity were weekly during a 6 weeks period of time, There is no guidance, no specific restrictions after application.

The mean time to obtain the skin shrinkage at induction phase and the energy used measured in Watts , responses and side effects profiles) were noted by the investigator at each and at the final treatment. Results were evaluated by standard and three-dimensional photography (VECTRA 3D, Canfield) before and after 15 days the last treatment. Both patient and physician investigator evaluation assessment of improvement were recorded using a grading scale of improvement ranging from I (no) , II (less than 25%), III (26-50%), IV(51-75%), V (76-100%). Only grades IV e V were considered satisfactory.



Figures 3 to 8: Standard and **three-dimensional photography (VECTRA 3D, Canfield)** were performed before and after 15 days of the last treatment with unipolar hand piece.

Figure 9 to14: Standard and **three-dimensional photography (VECTRA 3D, Canfield)** were performed before and after 15 days of the last treatment with UniLarge hand piece

RESULTS

With twice the surface area the new UniLarge hand piece (figure1) performed up to 30 percent faster and obtain the same kind of clinical results with decrease of 20 % energy measured in W. The induction phase to obtain clinical contraction with the unipolar hand piece takes a mean time of 5 minutes with 150 W; while the UniLarge hand piece took 3.5 minutes and with 120 W. We noticed that the largest diameter of the UniLarge hand piece making the treated area more homogeneous shrinkage of the skin . No major collateral effects were noted, 4 cases of superficial burns with no subsequent scar or mark was seen over a 3570 treatments with unipolar hand piece. The patient related that the UniLarge hand piece was more comfortable in achieving the same kind of results. The mean patient rate of satisfaction with a grade 4 or 5 on the scale of satisfaction was 69 % to unipolar 73% to UniLarge.

Grade	Improvement from the baseline	Unipolar Hand piece n (%)	UniLarge Hand piece n (%)
I	None	0	0
II	<25%	65 (11)	23(10)
III	26-50%	119(20)	39(17)
IV	51-75%	332(56)	135(58)
V	76-100%	77(13)	35(15)

Table 1: Compare the improvement of unipolar and UniLarge hand piece of Accent XL (Alma Laser) after 6 weeks of treatment of body laxity .

	Unipolar Hand Piece	UniLarge Hand piece
High Rate of satisfaction (IV and V)	69%	73%
mean induction time in minutes	5	3,5
mean energy used in Watts	150W	120W

Table 2: Compare high rate of satisfaction, mean induction times in minutes and energy used in W of unipolar and UniLarge hand piece of Accent XL (Alma Laser) after 6 weeks of treatment of body laxity .

CONCLUSION

Unipolar and UniLarge hand piece are safe and effective in the treatment of body laxity. Moreover, the larger diameter of the UniLarge hand piece ensures a more homogenous, fast and comfortable for the patient.