Skin Accommodation using MicroAire's PAL LipoSculptor™

A synopsis of "Power-Assisted Lipoplasty (PAL) vs. Traditional Lipoplasty: Quantification and Comparison of Skin Tightening and Retraction"

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Introduction

Since the introduction of power-assisted Lipoplasty (PAL) by MicroAire Surgical Instruments in 1998, the device has undergone developmental changes to improve mechanical disruption of normal and fibrotic fatty areas, in gynecomastia and within firmer tissues after secondary surgery for superior fat extraction. The purpose of this limited clinical study was to obtain additional quantitative data on skin shrinkage (accommodation) comparing PAL liposuction vs. traditional liposuction alone.

Device

The current upgraded MicroAire PAL™ device was an electrically powered and ergonomically re-designed model that was lighter and transmitted less vibration, allowing easier penetration, removal of fatty tissue and reduced surgeon fatigue. The use of a multi-fenestrated 4.0mm helixed triport 3 cannula in this study reciprocated at 4000 cpm at a 2-3mm stroke. Although the speed of cannula movement could be adjusted by surgeon-preference, the instrument was operated either at full power (4000 cpm) or without power (manual) for this study.

Study Design

A randomized, controlled study was designed to measure skin shrinkage in 3 female volunteers who were selected based on their demographic and presence of localized lower abdominal adiposity, minimal-moderate skin laxity, and absence of rectus abdominis diastasis. Two 10cmx10cm square templates were marked on the lower half of each abdomen and were separated by a 5cmx10cm rectangular zone at the midline of the abdomen. The corners of each treated site were tattooed with India ink deposited through a 21-gauge multipronged needle. The Vectra 3D System software (Canfield Scientific, Fairfield, New Jersey) would capture the permanent markers around each targeted site and calculate quantitative changes in skin shrinkage by measuring the horizontal, vertical, and perimeter distances at baseline compared at 3 and 6 month follow up visits (Figure 1). One subject consented to tissue punch biopsies with the target zones 6 months after completion of the study.

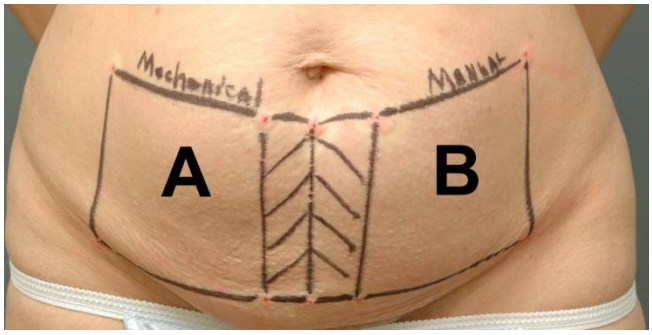


Figure 1.
Two 10cmx10cm target zones are identified by 8 tattoos whose surface areas are assessed by Vectra 3D Analyses between manual and powered-driven procedures.

Clinical Protocol

In a random fashion amongst the three subjects, each area received one of the following assignments, as shown in Table 1.

Table 1. Assignment and Treatment per Target Zone

Time	Panel Zone	Treatment
Baseline Vectra 3D & Intraop Temp. Monitoring	A	200ml tumescent solution (500mg plain Lidocaine, 1 mg epinephrine, 20ml of 8.4% sodium bicarbonate in 1000ml normal saline); 500 **manual** passes of a 4.0mm helixed triport 3 cannula in the **non-suction mode*** throughout the superficial and deep layers of subcutaneous fat.
Baseline Vectra 3D & Intraop Temp. Monitoring	B	200ml tumescent solution; 500 **power-driven** passes of a 4.0mm helixed triport 3 cannula in the **non-suction mode*** throughout the superficial and deep layers of subcutaneous fat.
3 Months Vectra 3D & Intraop Temp. Monitoring	A	200ml tumescent solution (500mg plain Lidocaine, 1 mg epinephrine, 20ml of 8.4% sodium bicarbonate in 1000ml normal saline); 500 **manual** passes of a 4.0mm helixed triport 3 cannula in the **suction mode*** throughout the superficial and deep layers of subcutaneous fat (250 ml aspirate).
3 Months Vectra 3D & Intraop Temp. Monitoring	B	200ml tumescent solution; 500 **power-driven** passes of a 4.0mm helixed triport 3 cannula in the **suction mode*** throughout the superficial and deep layers of subcutaneous fat. (250ml aspirate)
6 months	A & B	Vectra 3D & Elasticity Measurements, Biopsies

*MicroAire Surgical Instruments, Inc. Charlottesville, VA,USA

RESULTS

Patient Demographic Data

The mean age of the three female patients was 46.7± 2.2 years. The average pretreatment weight (57.7 kg), percent body (fat 33%), BMI (25 kg/m^2), waist diameter (85.3 cm), and hip diameter (95cm) varied during the post-treatment measurements at 3 and 6 months (Table 2). Preoperative caliper measurements of skin-fat folds varied between 1.7-2.3 cm in the sitting position. Subjects experience no complications from surgery that required revisions and returned to their normal activity levels within 1 to 3 days.

Table 2. Patient Demographic Data

Subject	Weight (kg)			Body Fat %*			BMI (kg/m$^{2)}$*			Waist (cm)			Hips (cm)		
	0 Months	3	6	0	3	6	0	3	6	0	3	6	0	3	6
Pt. #1 (48y)	58	56	59	33.5	34.4	36	23.6	22.6	23.9	81	81	85	95.5	91	93
Pt. #2 (45y)	61	64	67	34.6	37.6	38.7	24.7	25.8	27.1	86	88.5	92.5	95	94	96
Pt. #3 (47y)	54	54	54	31.2	32.9	32.9	21.7	21.9	22.1	89	88.5	85	95	93	92

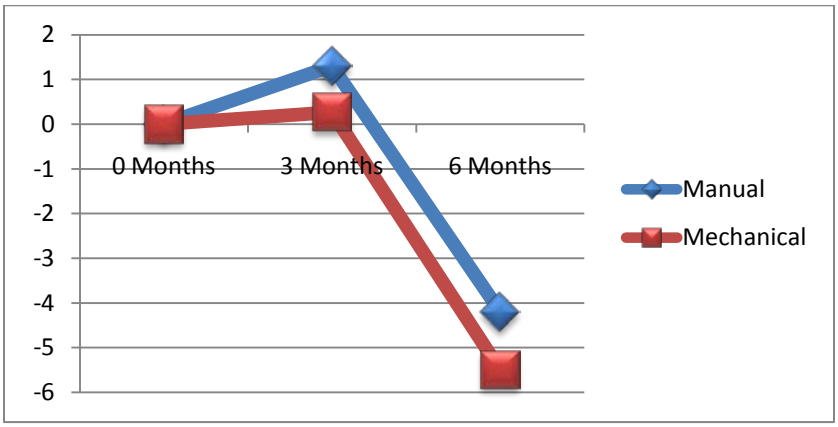
*Body Fat Analysis Futrex-5500

Vectra 3D Skin Surface Area Changes

Results of surface area changes from baseline measurement, as determined by Vectra 3D Analyses at 3 months after **non-suction** manual or power-driven cannulations and at 6 months after manual or power-driven **liposuctions**, are shown in Table 3. A positive change in percentage surface area within the tattooed square reflected an increase of target site compared to baseline value. In contrast, a negative percentage value in surface area indicated a smaller area after treatment compared to baseline measurement. Outcomes were tested for significance with a paired *t* test, using $p<0.05$ as the cutoff value.

	Zone A Manual/ Non-Suction 3 Mos	Zone B Power-Driven/ Non-Suction 3 Mos	Zone A Manual/Suction 6 Mos	Zone B Power-Driven/ Suction 6 Mos
Subject 1	0.0%	-2.40%	-1.70%	-5.20%
Subject 2	3.30%	6.10%	-10.10%	-3.80%
Subject 3	0.70%	-2.90%	-0.90%	-7.50%
Average	1.3%	0.27%	-4.2%	-5.50%

Table 3.
Zonal Surface Area Changes after Manual or Motor-Driven Procedures over Time



At the 3 month evaluation period, manual cannulations without suctioning demonstrated an small increase in the area measurement from its baseline value (average + 1.3%), while power-driven cannulations without suctioning resulted in no appreciable surface area change from its baseline value (average + 0.27%). At 6 months the surface area after power-driven suctioning exhibited a greater reduced surface area (average -5.5%) than after manual suctioning (average -4.2%) from their baseline values.

Histology

Microscopic examination of punch tissue biopsies after the 6th month procedures did no demonstrate any significant epidermal, dermal or subdermal changes by hematoxyline-eosine and trichome staining (Figure 2). The use of manual suctioning or motor-driven suctioning did not produce any visible damage within the epithelial cell layers, dermal collagen or elastin fibers, and subdermal septae.

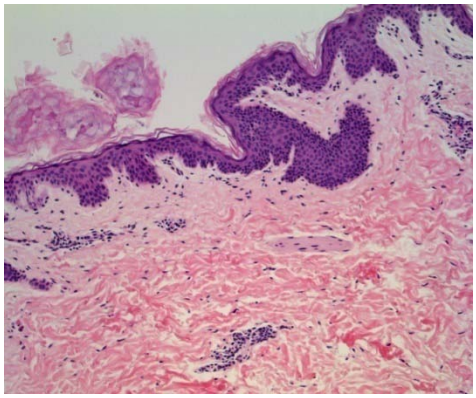


Figure 2.
Histologic changes at six months after power-dri ven suctioning in subject 3 demonstrating no observable damage to the epidermis, dermal or subdermal structures.

Conclusions

This limited clinical study obtained quantitative measurements of non-significant differences in shrinkage of skin surfaces in zones treated by either manual cannulations without suctioning or by power-driven liposuction without suctioning under identical assignments (blunt cannula, tumescent volumes, number of stroke passages). Greater differences in surface area reductions were observed, however, in the same zones that were treated by power-driven liposuction than by manual liposuction only, under the same identical treatment conditions (blunt cannula, tumescent volumes, number of stroke passages, and volumes of aspiration). Since skin surface and deep subcutaneous temperatures, measured but not reported, did not approach threshold levels for collagen denaturation of 40-42^{o}C with these non-thermal treatments, the observed shrinkage of surface areas may be due to skin accommodation and retraction from volume reductions rather than to active skin contraction from denatured collagen fibers and their subsequent reorganization. These conclusions are substantiated by the normal microscopic findings after manual or power-driven liposuction at the 6th month evaluation period within the skin and subdermal layers. Further objective studies will be required to validate these observations.

References

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Conflict of Interest Statement

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