

WHITE PAPER

PART I

Body-jet® (WAL) Experience in 50 Consecutive Patients: Body Contouring and Lipo-Harvesting

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Introduction: Liposuction remains the standard for removal of undesired localized fat. Continued advancements in the use of tumescent subcutaneous infiltrations, techniques/devices, and indications for ideal patient selection have improved patient safety and effectiveness. Water-assisted-lipoplasty (WAL) by body-jet® prepares fatty tissue for removal and harvesting by saline washings for body contouring and fat grafting¹⁻⁵. This preliminary report attempts to define the beneficial effects of saline rinsing on the removal of fatty tissue with safe fluid and lidocaine management, minimal blood loss, consistent lipo-shaping, efficient fat harvesting, and low incidence of side-effects with acceptable outcomes.

Material and Methods: body-jet® uses a dual-chambered cannula that simultaneously emits fan-shaped jets of tumescent solution and removes fatty tissue with the infiltrated subcutaneous fluid. By selecting one of five settings on the device panel (1=90ml/min, 2=110ml/min, 3=130ml/min, 4=160ml/min, 5=190ml/min), a variable force infusion pump pulsates the infiltration solution into a tubing connected to the cannula. The fluid

streams out from the cannula's nozzle tip at a 30-45° angle, impacting the lobules of fat. The fatty tissue is evacuated from the treated sites through a separate channel within the cannula attached by tubing to an integrated suction unit. The application cannulas come in a variety of diameters, lengths and arrangements/sharpness of openings, depending on their purposes. A sterile in-line container may be connected between the cannula and suction pump to collect the aspirate under reduced negative pressures. The fatty portion is separated from the infranate by a variable pore-size meshed filter, ready for immediate loading into injection syringes without centrifugation. Body-jet® treatments were indicated for patients with moderate collections of adiposity and mild-to-moderate degrees of skin laxity and for those who wanted augmentation with their own fat. Patient exclusion criteria included, but not limited to, pregnancy, uncontrolled diabetes mellitus, collagen disorders, cardiovascular diseases, bleeding disorders and body mass indices greater than 30%. Patients were marked in the standing and sitting positions to designate treatment areas. Patients were offered oral medications for

pain and sedation during surgery. An intravenous access catheter was inserted prior to surgery and removed at discharge. All surgeries were performed in an office setting under local subcutaneous infiltration technique.

Pre-Infiltration of Anesthetic Solution: Low volumes of buffered 0.5% lidocaine, containing 1:200,000 of epinephrine (8 parts lidocaine: 2 parts 8.4% sodium bicarbonate) were injected above the fascio-muscular planes by grasping tissues in a skin-fat fold. Smaller volumes of 0.5% ropivacaine, up to a maximum of 50mls, were injected into sensitive areas overlying bony structures, around the umbilicus and along the anticipated suctioned borders for more prolonged anesthesia.

Phase 1. Infiltration of Subcutaneous Solution: The infiltration solution, utilized in Phases 1-3, contained identical ingredients with the exception of the milligrams of lidocaine/liter of normal saline (Table 1). A selected cannula was positioned in the deep subcutaneous fat by grasping the skin-fat fold away from the underlying fascio-muscular structures. The cannula is moved slowly back and forth in the same tract, creating paths of hydrodissection at settings

Phase 1		Phase 2 and Phase 3	
Normal Saline	1,000 ml	Normal Saline	1,000 ml
1% Lidocaine	50 ml (500 mg)	1% Lidocaine	25 ml (250 mg)
1 mg/ml Epinephrine	1 ml	1 mg/ml Epinephrine	1 ml
8.4% Sodium Bicarbonate	20 ml	8.4% Sodium Bicarbonate	20 ml

Table 1. Standard Infiltration Solution

1-2 by first spraying downward (toward the fascia) and next aiming the spray upward (towards the fat) with twisting motions. Corridors of infiltration are generated in a fan-shape pattern over the entire treatment zone, providing sufficient level of anesthesia, rinsing of fatty tissue and limiting tissue bogginess in preparation for suction.

Phase 2. Simultaneous Infiltration and Aspiration: During Phase 2, a low infiltration setting of 1 and a high 750mm Hg of negative suctioning are preferred in order to have efficient aspiration of minimally turgid fatty tissues. The purposeful to-and-fro motion of the cannula through predetermined fan-shaped pathways within distracted skin-fat fold was the most economical maneuver fat removal and contouring. When denser tissue was encountered, a larger diameter cannula with sharper openings may be used with higher infiltration setting of 2-3. The clinical endpoints of fat elimination are determined by the scantiness of fatty tissue withdrawn in the tubing, reduction in the thickness of the fat fold, and minimal tissue resistance of the cannula during repetitive passages.

Phase 3. Infiltration and Drying: During Phase 3, a cannula with openings on its undersurface was used to remove remnants of fat beneath the dermis with simultaneous low rate of infiltration and high level of suctioning. Further refinement may be obtained by passing the cannula back and forth without the infiltration and suctioning functions and “feathering and breaking down” stubborn irregular areas of subdermal tissues.

Post-operative Management: A ¼ inch penrose drain was inserted into one of the most dependent openings to facilitate drainage over 24 hours. Other openings were loosely closed with a single suture. Patients were dressed with foam sponge inserts under a compression garments which were worn for two to three weeks.

Results: Since 2009, fifty consecutive patients (46 females; 4 males) received

body-jet® one hundred and seventy-four treatments in twelve anatomic sites. Twenty-eight patients (56%) elected to liposuction more than a single site at the same session (average 3.6 sites; range 2-6 sites), of which the most common combinations were hip rolls and abdomen (Table 2). Participants averaged a mean age of 48.3 years of age (range 25-70 years), mean height of 164.8 cm (range 149-188 cm), mean weight of 69.2 kg (range 50.4-112.0 kg), mean body fat of 30.4% (range 17.5-39.4%), and mean body mass index of 24.6 (range 21.7-30.0 BMI).

Anatomic Site (Number)	
Brachia (18)	Breast (2)
Gynecomastia (2)	Axilla (10)
Abdomen (35)	Neck (1)
Brassiere Roll (20)	Saddle Bag (16)
Hip Roll (32)	Banana Roll (6)
Lumbar Roll (18)	Thigh (14)

Table 2. Distribution & Number of Treated Sites in Fifty Patients

Group 1: Twenty-one patients were estimated to have small volumes of fat for liposuction at a single site. In these patients, the average infiltration volume was measured at 2465ml (range 450-4375), while the average aspiration volume was determined to be about 2247ml (range 340-4150ml). The average infiltration-to-aspiration ratio was calculated to be 1.1:1. The average volume of fat removed was 813ml; the average infiltration-to-fat ratio was calculated to be 2.8:1, i.e., for every 1000ml of fat removed, 2800ml of infiltrate was delivered. The average aspirate contained 44.3% fat (range 14.8-73.5%), 54.7% infranate, and less than 1% blood. The average lidocaine dosage was 10.5mg/kg (range 1.4-19.5mg/kg). None of the patients received additional fluid replacement; each patient was hemodynamically stable throughout the procedure and in the 24 hour recovery period. Lipocrits, estimated from millimeters of red blood cell

presence and millimeters of non-red blood cell containing fluid from aspirates centrifuged in capillary tubes, were obtained from final aspirates in 15 randomly selected patients.

Group 2: Twenty-nine patients were estimated for larger volumes of liposuction at multiple sites. In these patients the average infiltration volume was measured at 3853ml (range 650-6000ml), while the average aspiration volume was 3642ml (range 705-6310ml). The average infiltration-to-aspiration ratio was 1.0:1. The average volume of fat removed was 1670ml; the average infiltration-to-fat ratio was calculated to be 2.3:1, i.e., for every 1000ml of fat removed, 2300ml of infiltrate was delivered. The average aspirate contained 44.7% fat (range 26.8-79.5%), 54.0% infranate, and less than 1% blood. The average lidocaine dosage was 20.0mg/kg (range 3.6-28.8 mg/kg). None of the patients received fluid replacement and each remained hemodynamically stable throughout the procedure and in the 24 hour recovery period.

Fat Augmentation: Thirty-one patients harvested their fat for augmentation in eight anatomical sites (Table 3). The abdominal fatty tissues were removed under reduced negative pressure at 450-500mm Hg, collected and separated from the infranate at room temperature in the sterile container without washing or centrifugation, and loaded into 1-10ml syringes. Fat grafting technique was performed within one to two hours after harvesting. Depending on the structural requirements, the blunt-tip microcannula deposited the fat microdroplets in a fan-shaped pattern at varying levels in the supraperiosteal, submuscular and/or subcutaneous planes. Volume restoration was completed when a slight overcorrection was achieved. Fat aliquots from five patients were incubated with trypan blue dye within an hour and 8 hours after extraction. Dye exclusion demonstrated that about 90% of adipocytes

expelled the dye after an hour from aspiration, while less than 10% of cells were free of dye after 8 hours from aspiration.

Lower lid-Face (11 Pts) (5-10ml/site)	Calf (1Pt) (75-100ml/site)
Buttock (4 Pts) (200-500ml/site)	Knee (1 Pt) (25ml/site)
Hand (4 Pts) (5-10ml/site)	Ankle (1Pt) (25ml/site)
Breast (2 Pts) (100-125ml/site)	Depressions (7 Pts) (2.5-30ml/site)

Table 3. Anatomical Sites, Number of Patients, Average Volumes of Lipografting

Post-operative Result, Morbidity and Recovery: Patients were satisfied with their improved body contouring and tissue accommodation after body-jet® liposuction and fat grafting. Patients estimated significant clinical improvements to both procedures. Patient response to the degree of intraoperative and post-operative pain (visual analog scale from 1-10) averaged levels of 1-3. Almost all patients were able to resume their normal pre-surgical routines by one to two weeks, depending on the extent and number of treatment sites.

About 3% of patients developed nodularities that resolved themselves after 3 months without treatments. There were no incidences of infec-

tions, seromas, hematomas, skin changes, or permanent nerve injuries. No patient required fluid resuscitation or experience any recognized lidocaine side-effects within 24 hours after surgery. To date, there has been no request for revision surgeries. The results of fat augmentation have been gratifying at the three to eight month evaluation periods but will require longer and more sophisticated quantitative assessments.

Conclusions: On the basis of our limited clinical experience, body-jet® represents a safe and effective addition to our armamentarium of liposuction devices and has the potential to improve our efforts for fat harvesting and grafting.

Figure 1. This 56 year old patient presented with moderate accumulation of fat to the waist and abdomen following an abdominoplasty. The total infiltration (I)/ aspirate (A) volumes were 2500mls (I)/ 2000 ml (A). The average aspirate contained 35% fat, 65% infranate and less than 1% blood. The post operative results at 6 months demonstrated improved contouring to waist and abdomen and skin accommodation.





Figure 2. This 42 year old patient desired body contouring to her brassiere, lumbar and hip rolls. The total infiltration (I)/aspiration (A) volumes were 1250ml (I)/1475ml(A) for her left back rolls and 1028 (I)/1225 (A) for her right back rolls. The average aspirate contained about 36% fat, 63% infranate and less than 1% blood. The postoperative results at 8 months demonstrated improved contouring of the back rolls.

Figure 3. This 40 year old patient presented with moderate accumulation of fat and skin laxity to the brachii. The total infiltration (I)/aspiration (A) volumes were 257ml (I)/275ml (A) on the right arm and 300ml (I)/325ml (A) on the left arm. The average aspirate contained 45% fat, 64% infranate and less than 1% blood. The postoperative results at 7 months demonstrated reduction of fat volume and improved skin accommodation.



Figure 4. This 45 year old patient requested volumization to the anterior midface with her own fat. After collection of aspirated fat from her abdomen by body-jet®, the loaded syringes injected between 5-8ml of fat to each side in the deep supraperiosteal layers with microdeposit technique. The postoperative results at one year demonstrated retention of the fat grafts to the lid-cheek junction, tear trough- nasojugal groove, malar fat pad, and nasolabial line.



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WHITE PAPER

PART II

Plasma Lidocaine Levels and Quantitative Comparison of Abdominal Tissue Accommodation after Water-Assisted Lipoplasty (body-jet®): Preliminary Report on Safety and Efficacy

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Introduction: Traditional liposuction with blunt-tip fenestrated cannulas remains the gold standard for removal of localized fat deposits. Since the introduction of water-assisted lipoplasty¹⁻⁵ in the United States less than two years ago for both small-moderate volume liposuction and fat harvesting, the use of relative large volumes of subcutaneous infiltration solutions has raised potential concerns for lidocaine side-effects or toxicities. In addition, there have been claims that skin, overlying the suctioned area, has an enhanced capability to tighten because of the preservation of septal structures that can undergo eventual shortening. To date, there have been no studies addressing these issues with body-jet® WAL.

The purposes of this preliminary report were, firstly, to obtain safety profiles on plasma and tissue lidocaine concentrations over twenty-four hours and, secondly, to determine quantitatively the predominant element (s) that contribute to tissue accommodation during **individual** treatment-phases, which comprised, en toto, a complete body-jet® procedure.

Materials and Methods: body-jet® employs a dual-chambered cannula that can simultaneously or independently release fan-shaped pulsations of infiltration solutions and suction away the rinsed, loosened fatty tissues. Depending on their purposes, the operator modifies the procedure from a selection of 1) application

cannulas with different diameters, lengths and arrangements/sharpness of openings, 2) infusion rates (90-190 ml/min) of five settings from a variable force infusion pump, 3) ranges of aspiration negative pressures (mm Hg) from an integrated suction unit, and 4) two standardized infiltrations solutions differing only in milligrams of lidocaine. The complete procedure is performed in three stages:

Phase 1. Infiltration solution (50ml 1% lidocaine, 1mg/ml epinephrine, 20ml 8.4% sodium bicarbonate, 1000ml normal saline) produces generalized anesthetization, vasoconstriction and tissue rinsing.

Phase 2. Simultaneous suctioning and infiltration, using solutions containing a reduced dose (250mg) of lidocaine/liter of saline, with 1mg/ml epinephrine and 20ml 8.4% sodium bicarbonate, removes efficiently the non-turgid fatty tissue and a significant portion of the infusate.

Phase 3. A cannula with openings on its undersurface removes remnants of fat beneath the dermis with simultaneous suctioning and lower rate of infiltration with the Phase 2 solution.

Plasma and Tissue Lidocaine Study Design: Two female patients under IRB and HIPPA- approved protocols volunteered for plasma and tissue lidocaine concentration measurements obtained over 24 hours following body-jet® abdominal liposuction to determine the time and magnitude of peak values. The time and magnitude of an individual patient's peak lidocaine concentration were

plotted by connecting the sequential plasma levels for a continuous curve. The peak time is defined as the length of time between the start of lidocaine infiltration in Phase 1 until the occurrence of the peak plasma lidocaine concentration. Lidocaine concentrations from abdominal tissue fluid were obtained also during mid-Phase 2 and after completion of Phase 3. Emit 2000 Lidocaine Assay (Dade Behring, Inc., Cupertino, CA) is a homogeneous enzyme immunoassay technique based on competition between drug in the sample and drug labeled with recombinant glucose-6-phosphate dehydrogenase for antibody binding sites. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically.

Results: Demographic and study data on the two subjects who volunteered for tissue and plasma lidocaine levels are shown in Table 1 and Figure 1.

The pharmacokinetics of dilute amounts of lidocaine and epinephrine into abdominal subcutaneous fat with relatively large volumes of fluid reduces the absorption profile of lidocaine to safe plasma levels over 24 hours following body-jet® liposuction. Both patients exhibited peak plasma levels of 0.8-0.95µg/ml and peak time at about 9 hours after start of lidocaine infiltration. Although sequential plasma measurements

Pt	Weight (kg)	Total Dosage (mg)	Dosage (mg/kg)	Peak Magnitude (µg/ml)	Peak Time (hr)	Infiltration (ml)	Fat (ml)	Infranate* (ml)
1	58	1700	30	.95	9	5900	750	4750
2	98	975	10	.80	9	3050	575	1875

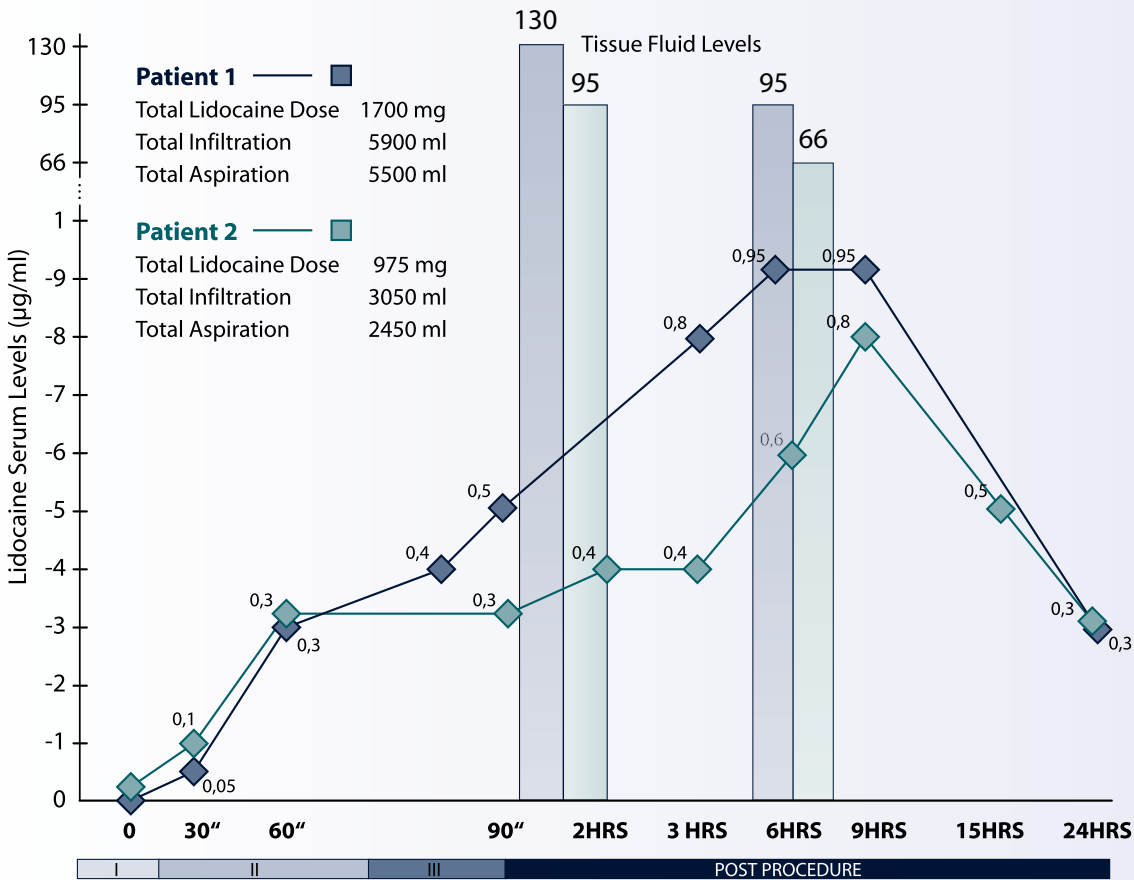
Table 1. Demographics, Total lidocaine Dosages/Peak Magnitudes/ Peak Times and Infiltration/ Aspiration Volumes * Blood loss than 1% of infranate

demonstrated a gradual rise from 0.05-0.1µg/ml at 30 minutes to 0.4-0.8µg/ml between 3-6 hours after the procedure, all recorded plasma levels were lower than peak levels even though fluid within the abdominal tissues recorded higher amounts between 1-1½ hours (95-130µg/ml) and after 2 hours (66-95µg/ml) from

the start of lidocaine infiltration. Although the lidocaine dosages in these two study patients, calculated at 10.0mg/kg and 30mg/kg, exceeded the recommended the safe limit of lidocaine dosage of 7mg/kg with epinephrine in normal healthy adults, they were still lower than the estimated maximal safe dosage of 35mg/kg,

as recommended in the Klein tumescent technique⁶. Furthermore, lidocaine dosages less than 35mg/kg appear to be safe, especially when used in small and moderate volume cases (<2500ml of fat removal), as they resulted in safe plasma concentrations below toxicity threshold (5µg/ml) for the majority of patients. One of the

Figure 1. Lidocaine Levels in Plasma and Abdominal Tissues



Pt. 1			Pt. 2		
<u>Phase I Infiltration</u>	<u>Phase II Irrigation and Aspiration</u>	<u>Phase III Drying</u>	<u>Phase I Infiltration</u>	<u>Phase II Irrigation and Aspiration</u>	<u>Phase III Drying</u>
900 ml Wetting Solution	4200 ml Wetting Solution	800 ml Wetting Solution	850 ml Wetting Solution	2000 ml Wetting Solution	200 ml Wetting Solution
500 mg Lidocaine/ 1000 ml saline	250 mg Lidocaine/ 1000 ml saline	250 mg Lidocaine/ 1000 ml saline	500 mg Lidocaine/ 1000ml saline	250 mg Lidocaine/ 1000 ml saline	250 mg Lidocaine/ 1000 ml saline
0.5 mg/ml X 900 ml =	0.25 mg/ml X 4200 ml =	0.25 mg/ml X 800 ml =	0.5mg/ml X 900 ml =	0.25 mg/ml X 2000 ml =	0.25 mg/ml X 800 ml =
450mg Lidocaine	1050 mg Lidocaine	200 mg Lidocaine	425mg Lidocaine	500 mg Lidocaine	50 mg Lidocaine
	4600 ml Aspiration (500 ml fat)	400 ml Aspiration (50 ml fat)		2090 ml Aspiration (450 ml fat)	210 ml Aspiration (50 ml fat)

Zone	Treatment Assignment
1	Control
2	Phase 1: Infiltration Solution (25ml) (25 cannula passes)
3	Phase 1: Infiltration Solution (25ml) (25 cannula passes) Phase 2: Simultaneous Suctioning (100ml) and Infiltration (225ml) (25 cannula passes)
4	Phase 1: 25ml Infiltration Solution (25 cannula passes) Phase 2: Simultaneous Suctioning (100ml) and Infiltration (225ml) (25 cannula passes) Phase 3: Simultaneous Suctioning (25ml) and Infiltration (50ml) (10 cannula passes)

Table 2. Target Zones and Treatments

Pt #	Weight (kg)		% Body Fat		Body Mass Index		Waist Circum. (cm)		Hip Circum. (cm)	
	0mos	3mos	0mos	3mos	0mos	3mos	0mos	3mos	0mos	3mos
1	67.3	68.6	40.8	42.6	26.2	26.8	94.5	92.0	106.0	106.0
2	79.5	79.1	38.1	37.5	25.9	25.8	109.5	105.0	108.0	107.5
3	83.6	83.2	39.6	40.5	30.7	30.5	105.0	101.0	107.0	106.0

Table 3. Patient Demographics in Abdominal Tissue Tightening Study

limitations of the enzyme immunoassay technique, used in this study, however, was its inability to measure the variability in protein binding and active metabolites of lidocaine (monoethylglycinexylide and glycinexylide).

Tissue Tightening Study Design:

A randomized, controlled study measured tissue tightening in three female volunteers with localized abdominal adiposity and minimal-moderate skin laxity. Standardized photography, weight, body fat analysis (Futrex 5500, Futrex Inc., Hagerstown, MD), waist and hip circumferences were obtained at baseline and three months after treatments. Tissue tightening was assessed by using the Vectra3D System (Canfield Scientific, Fairfield, NJ). The lower abdomen was marked into four target zones of 4x10cm rectangles each separated by 4x10 cm partitions. The corners of each treated zone were tattooed with India ink. Software analysis identified the permanent markers around each targeted site and calculated the changes in horizontal, vertical, diagonal and perimeter baseline measurements compared to findings at three months. At the completion of the

study, total abdominal liposuction was performed to achieve an aesthetic result in each patient. Informed consents were obtained with IRB and HIPPA-approved protocols.

Surgical Procedure: Patients were offered preoperative pain medications. Each of the four 4x10cm target zones was treated randomly by one of the following assignments (Table 2).

Results: Demographics on three subjects, who participated in the tissue tightening study after individual phases of the complete body-jet® procedure, are shown in Table 3.

The mean age of the three patients was 46. The average pretreatment weights (76.8kg), percent body fat (39.5%), BMI (27.6), and hip circumferences (107.0cm) did not vary significantly from their 3 months measurements. A reduction in waist circumferences at baseline (average 103.0cm) from 3 month (average 99.3cm) values was observed.

Results of surface area changes from baseline to 3 months within the four isolated rectangles, as determined by Vectra 3D analysis, are shown in Figure 2 Each target zone received a

component of the standard treatment protocol for a body-jet® procedure. At the three month evaluation period, the mean percent area difference in tissue tightening between zone 1 (control) and zone 2 (subcutaneous infiltration) was negligible. However, the mean percent area differences in tissue tightening, observed in zone 3 (6.8%) and in zone 4 (6.7%) over control and zone 1, indicate that the removal of fat facilitates either increased accommodation, retraction or contraction by the overlying skin. Although the data is underpowered for statistical significance, the observed results suggest a positive trend in tissue tightening after body-jet® treatments. There exists no evidence from this study that this beneficial finding is due to the preservation and activity of the septal architecture.

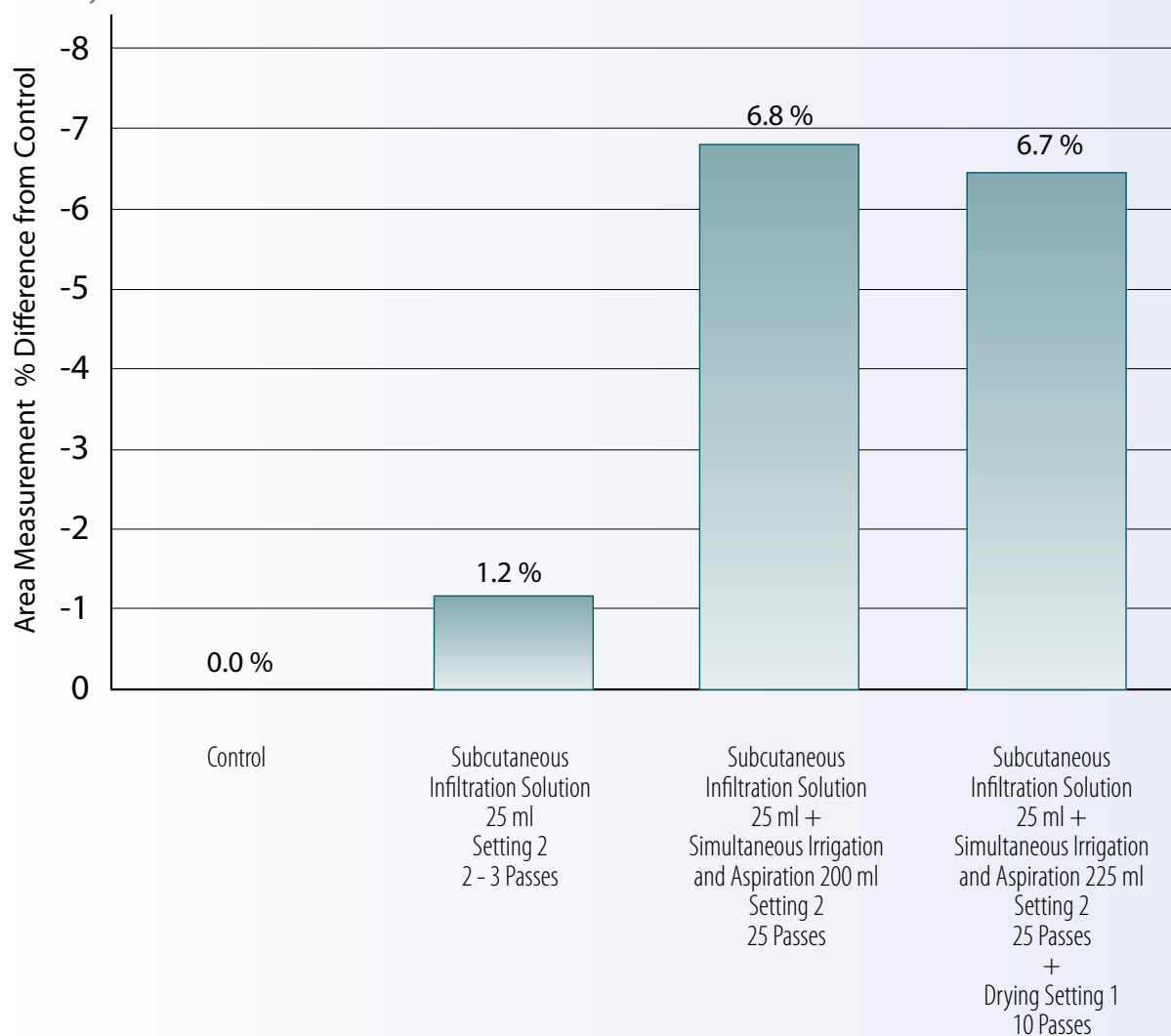
Conclusions: On the basis of our limited and preliminary study, the current protocol for body-jet® procedures is safe from lidocaine side-effects and toxicities in the majority of patients who undergo small to moderate volume liposuction with lidocaine dosages less than 30mg/kg. Although the correlation between total plasma lidocaine concentrati-

on (<5µg/ml) and the predictability of specific toxicity is tenuous at best and can lead to false sense of security, the surgeon must always be mindful of careful monitoring during and

at least 24 hours after completion of the procedure. The preliminary results suggesting tissue tightening by Vectra 3D analysis is underpowered for significance and will require larger

number of patients for statistical validation.

Figure 2. Average 3-Dimensional Abdominal Surface Area Shrinkage in 3 Patients by WAL Canfield Vector 3D Analyses at 3 Months



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