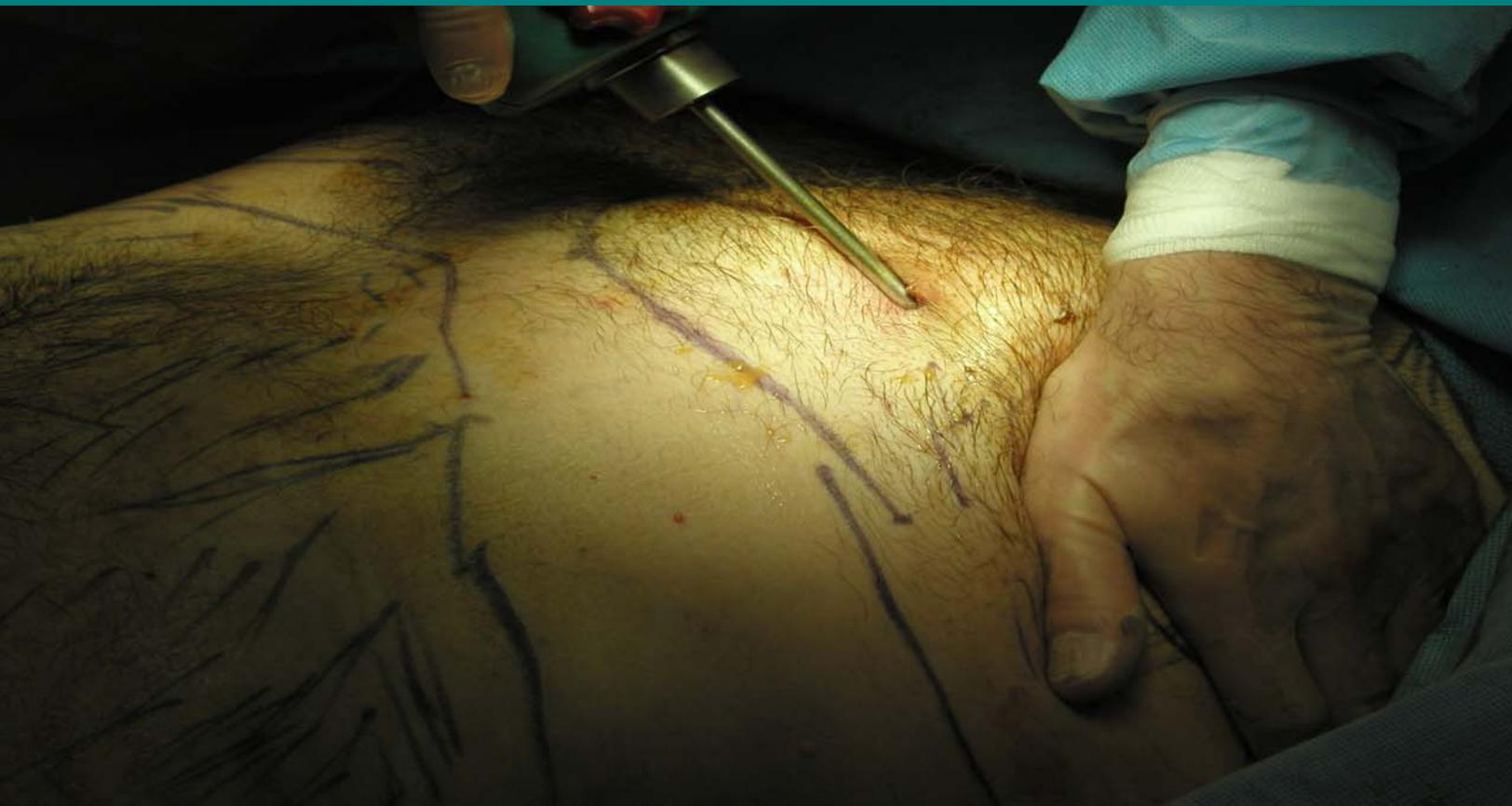


A Safer and Faster Alternative to Bariatric Surgery

BioSculpture Technology, Inc.

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Serial Twin Cannula Assisted Liposuction in a combined modality treatment can accomplish an end run to a better body and healthier metabolic profile in overweight and frankly obese patients.



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Executive Summary

→ Overview

Two thirds of Americans are overweight and one third are frankly obese and the trend towards obesity is increasing. The medical conditions associated with obesity aggravate the health care cost issues facing us today.

Current solutions to the problem are unsatisfactory in that bariatric surgery, extensive lipectomies with their concomitant hospitalizations, medical management, convalescences, and complications take a protracted toll on the medical insurance system, the patient's finances, and their lives. Even an uneventful course is accompanied by extensive scarring and metabolic changes that compromise any health benefit obtained.

There is every indication that we can help these obese and overweight patients both cosmetically and functionally and do so more cheaply, with less risk, and in a shorter period of time with serial twin cannula assisted liposuction (TCAL) and limited, no-undermining skin excisions.

The Obesity Problem

→ Increasing Obesity Prevalence and Associated Medical Costs

The U.S. obesity prevalence increased from 13% to 32% between the 1960's and 2004. According to recent statistics, two-thirds of America is overweight and one-third is frankly obese. Abdominal obesity as measured by waist to hip circumference ratio (WHR) is an independent predictor of mortality. Increased WHR is a risk factor for the metabolic syndrome which is associated with insulin resistant diabetes, hypertension and coronary artery disease.

→ Current Treatment – Bariatric Surgery Followed by Panniculectomies

Traditional surgical treatment of obesity first focused on either decreasing the transit time of food in the digestive tract to reduce the absorption of calories or decreasing the volume of the stomach to trigger satiety with smaller portions. In either case, required vitamins and nutrients are lost to the patient's detriment in addition to the unwanted calories. Patients dramatically lose large amounts of weight over the next year, require careful medical monitoring, and not infrequently have accompanying hepatic or renal complications of their surgery as well as diarrhea. Chronic malnutrition states of hypoalbuminemia and anemia are not infrequent.

Although patients with BMI (body mass indices > 40) usually have their bariatric surgeries reimbursed by insurance if the physician is sufficiently persistent in his appeals, many and those with lower BMI's are out of pocket for the typical \$25,000 for the currently favored gastric banding as well as the required regular postoperative

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medical monitoring with expensive blood tests. The co-pays alone can be staggering. And that's just the beginning if there are complications to the initial surgery.

When these patients inevitably desire cosmetic improvement of their sagging skin which comes to resemble a deflated balloon or that of a Chinese Shar-Pei dog, they require hospitalizations for major panniculectomies. The skin has been stretched beyond the point of no return and rapid weight loss simply leaves it hanging on a slimmed-down frame in a most unattractive and almost grotesque fashion in some cases. This redundant skin has to be cut away and incisions must extend the length of the bulges to be removed to obtain smooth contours - frequently fully circumferential or near-circumferential about the waist and thighs and linearly down the inside upper arms. Breast lifts in women and gynecomastia excisions in men are almost always required to return the patient to satisfactory appearance.

→ Current Treatment Is Unsatisfactory as Bariatric Surgery Creates New Problems

Unfortunately at the time of these plastic surgical interventions, many post-bariatric surgery patients are no longer ideal surgical candidates due to chronic anemia and hypoalbuminemia related to their gastric surgery and therefore experience concomitant complications such as poor wound healing and increased infection rates. These surgeries, hospitalizations, medical management, convalescences, and complications take a protracted toll on the medical insurance system, the patient's finances, and the quality of their lives. Even an uneventful course is accompanied by extensive scarring and metabolic changes that compromise any health benefit obtained.

The Airbrush® Advantage

→ Patented Twin Cannula Technology

Recent advances in power assisted liposuction technology allow it to be employed earlier as a more direct approach to the obesity problem. Post liposuction flaccidity previously has been a major complaint of patient and physician alike. This new technology allows more fat to be removed with better control and speed in each surgical sitting and the surgeon to safely direct efforts at obtaining improved skin contraction.

This new twin cannula assisted liposuction (TCAL) consists of a reciprocating inner cannula ensheathed within a stationary outer cannula. A hole in the inner cannula is in continuity to the traditional vacuum source as with other means of liposuction to aspirate the fat. This inner cannula aperture is aligned with a slot in the outer cannula sheath and is mechanically reciprocated to and fro within it. The surgeon may adjust this excursion from zero to 2" as desired to replicate a manual stroke, but without effort and with greater precision and control. The patient and the surgeon's upper extremity are both spared the battering ram effect of the cannula against the patient's tissues – about 10,000 times per hour. This translates into lessened bruising and swelling, reduced blood loss, shortened operating times, briefer convalescences, improved surgical ease and control, and fewer revisions. Unlike LASER or ultrasound assisted liposuction (LAL or UAL), the tip of the cannula does not get warm, so burns are not possible and there is no increased incidence of seromas. Furthermore, the stationary outer cannula acts as a spacer which allows the surgeon to safely aspirate subdermally to encourage greater skin contraction.



Fig. 1 *TCAL design in which the aperture of the reciprocating inner cannula is aligned with the slot of the stationary outer cannula to reduce labor and tissue trauma from the tip of the moving inner cannula while simulating an adjustable normal stroke excursion ≤ 2 ".*

Traditional power assisted liposuction (PAL) offers minimal mechanical assistance because it consists simply of a single cannula vibrating a small fraction of an inch and many surgeons find this vibration annoying. In LAL, traditional PAL and UAL the surgeon must still stroke the cannula back and forth manually to remove the fat in contrast to TCAL.

→ More Gentle Liposuction

Since TCAL fat removal is faster and more controlled by design, operations are shorter, and more fat can be safely removed in sessions that may be scheduled closer together. Patients tolerate conscious sedation more easily for these shorter surgeries which allows them to stand during the procedure so the surgeon can appreciate conditions that are concealed with the patient recumbent on the operating table. Patients have shorter convalescences, revisions and complications are less frequent, results are more dramatic, and blood loss is less – allowing more fat to be safely removed in a session. TCAL removes the fat and leaves the fascial vascular lattice and dermis uninjured.

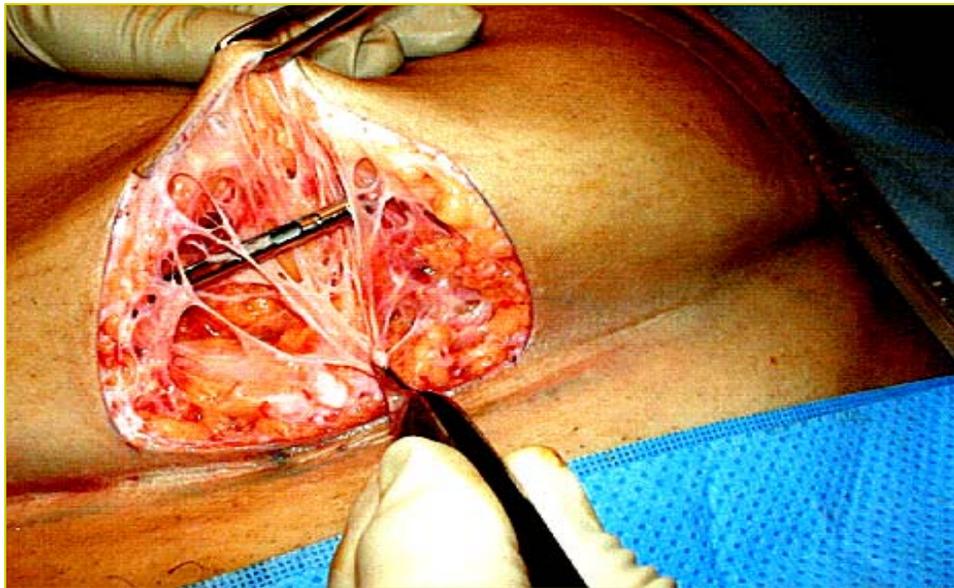


Fig. 2 *Vasculature left intact as TCAL removes fat both above and below the fascia without heat.*

The Airbrush® Combined Modality Alternative

→ Short Interval Serial Liposuction Under Conscious Sedation

It was inevitable that this new technology would be applied to the treatment of obesity. **Serial TCAL** may be performed at short intervals of days or weeks between sessions, each carried out below the limits for safe out patient treatment with aspiration subdermally to stimulate skin contraction. Rather than sending away a significantly overweight or frankly obese patients with the statement, “Liposuction is not a treatment of obesity,” as before, the surgeon can now safely accomplish *megaloliposuction* ($\geq 8-9$ L) with smaller, closely spaced, *serial* sessions. Each session is carried out below the safe limits of outpatient fat removal, (generally 5.5-6.5 L or 12-14 lbs) per session, on an ambulatory basis, and under local anesthesia at intervals of days to weeks. Inches and pounds come off quickly as adjoining areas are treated as if each were only a “localized

deposit” of a thinner patient. The patients are fat, but they are otherwise healthy, and heal from liposuction rapidly as expected without complications.

→ **Skin Excision With Limited Incision Without Undermining**

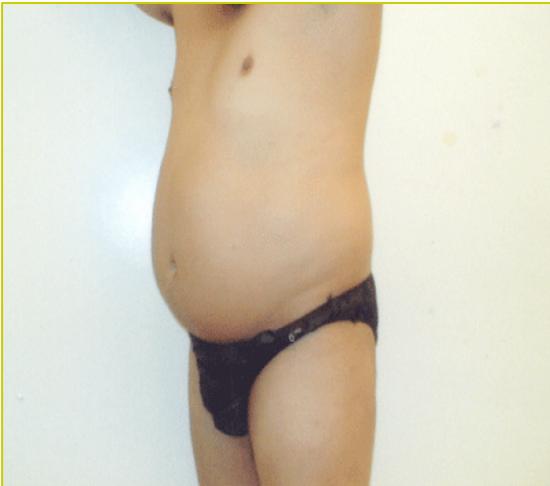
At the final liposuction session, also under conscious sedation on an ambulatory basis without hospitalization, redundant skin excision can be performed simultaneously *without undermining* to enhance the result. In the majority of patients with truncal obesity, a lower abdominal skin incision below the umbilicus in the bikini line suffices; the resultant scar is more limited than that of traditional abdominoplasty and without the necessity of drains since no undermining or deep dissection is required.

The cosmetic result that can be achieved with this **combined modality approach** using **TCAL** in the span of several weeks in these obese patients is nothing short of dramatic. The results are not only impressive, but doubly so because of the rapidity with which they are achieved and the fact that they are obtained by *operating on obese but otherwise healthy patients* – patients uncompromised by the digestive and metabolic consequences of prior bariatric surgery. They equal or surpass the results obtained years after bariatric surgery and can be achieved in weeks with less risk, fewer complications, and less expense.



Fig. 3 *The Airbrush Liposculpture® System has computerized control and adjustment of stroke using a closed feed back loop for safety.*

Case Studies



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Airbrush Liposculpture® for Overweight Patients

Target Market

Surgeons desiring to perform more liposuction, do so with greater ease and control, and expand their practice can include a large and eager patient population with generally realistic expectations who can be dramatically improved in a short period of time.

The otherwise healthy members of the overweight two-thirds of American citizenry all comprise potential candidates for surgery.

Metabolic Implications

Were these cosmetic results not impressive enough alone, we are reminded of the fact that an elevated waist to hips circumference ratio (WHR) of patients is one of the risk factors for the metabolic syndrome associated with insulin resistant diabetes and coronary artery disease. Earlier studies have suggested that reducing elevated WHR of affected patients renders the metabolism of these patients more normal and tends to reduce blood pressure. Thus there is every indication that we can help these obese and overweight patients both cosmetically and functionally and do so more cheaply, with less risk, and in a shorter period of time.

BioSculpture Technology, Inc. which manufactures the Airbrush Liposculpture® Systems based on their patented TCAL design instituted the CINCH IT!™ program to allow physicians to acquire their systems at a discount in an effort to promote this promising new obesity treatment, encourage physicians to obtain the required clinical documentation to justify insurance reimbursement, and to reduce the health care costs associated with America's growing obesity problem.

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