



WORLDPLAST

Minimally Invasive Macro Implants

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ABSTRACT

The problems associated with previous tissue augmentation substances combined with the advantages of minimally invasive techniques which are revolutionizing most areas of surgery has created the need for a new augmentation substance that can be implanted easily, safely, and with a more permanent result.

Research beginning in 1968 has led to the development of an inert copolymer substance that can be implanted subcutaneously through a remote 1 mm incision. The implant consists of solid dimethyl siloxane particles of average diameter 150 urn (100-600 urn) fabricated with a textured surface designed for stability within the tissue.

Key Words: Tissue augmentation, macro implants, bioplastique.

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The particles were suspended within a carrier gel, a polymer of n-vinyl-2-pyrrolidone having an average molecular weight of 13,600, before being manually dispersed within preformed tunnels through a 20 gauge cannula attached to a leveraged injection gun. Our clinical experience beginning in 1988 has included 195 injection sites in 96 patients. Various case histories illustrate the effectiveness in the treatment of ectopic excavatum and defects of the chin, nose bridge, orbital rim, lips and cheeks. The results indicate that this minimally invasive implantation method will be useful in many other disciplines. It appears that the procedure can be performed safely and with minimal trauma and the implant provides an improvement of various defects that is permanent over the three years followed thus far.

INTRODUCTION

Minimally invasive surgical techniques are revolutionizing the way common surgical procedures are performed. The early descriptions of aspiration or minimally invasive removal of large amounts of tissue came from Schrudde¹ and Kesselring.² The development of the blunt technique of lipo-aspiration by Illouz³ led these methods for subtraction of subcutaneous tissue to become the most frequently performed plastic surgery procedures worldwide within a decade.

Unfortunately, attempts to adapt such minimally invasive procedures to those providing soft-tissue augmentation, rather than subtraction, have been fraught with difficulty. In years past attempts have been made to inject paraffin,⁴ petroleum jelly,⁵ silicone oil⁶ and autologous fat⁷ with varying results. All of these substances are subject to migration and varying degrees of inflammatory responses. Teflon dust was suspended in glycerin - and injected for a variety of soft tissue augmentation problems but was found to cause a chronic granulomatous response and the initial improvement was found to deteriorate in a

matter of weeks or months.^{8,9} However the temporary benefit was found to be useful for the treatment of the paralyzed vocal chord and urinary incontinence. More recently, various forms of bovine and porcine collagen have been reconstituted, suspended in water and used for temporary contour improvement in fine wrinkles of the skin and urinary incontinence.¹⁰ The results however have been temporary, reportedly lasting for weeks or months. Therefore, a need exists for a biocompatible substance that can be injected for a more permanent subcutaneous soft-tissue augmentation.

In 1968 we began working on the alteration of the host/prosthesis interface to prevent micro-motion and to improve the biocompatibility of inert polymer surfaces." That work led to the development of textured breast implants¹² that had three dimensional caves formed in the outer surface of the methyl-methyl siloxane shell. These textured indentations allowed fibroblastic tissue ingrowth that resulted in a mechanical bond of the host/prosthesis interface. Studies of particle migration within the human body have shown that particles below 60 microns in diameter can be engulfed by macrophages, harbored in lymph nodes and can be seen migrating along tissue surface planes. Since multi-nucleated giant cells may be as large as 100 microns in diameter, any particle that size or larger could not be engulfed by such a cell. Therefore we fabricated surface textured particles that were greater than 100 microns in diameter - hence "macro"implants. However, the maximum diameter of these macroparticles was maintained under 600 microns, well below the size at which they could be palpated individually when implanted into the subdermal plane. We have furthermore developed new techniques whereby it is possible to add these macroimplants through a small, 1 mm remote incision and by blunt atraumatic techniques to develop pre-tunnel channels and then through the same channels to deposit the miniature implants.

MATERIALS AND METHODS

Macroimplant Particles

Miniature implant particles of average diameter 150 μm (100-600 μm) were fabricated by dissolving methyl-methyl siloxane, silicone rubber, and then evaporating the solvent in the gravity free environment where the textured particles were formed. The formed particles were then vulcanized and suspended in a biocompatible gel vehicle. This gel was comprised of the water soluble homopolymer of n-vinyl-2-pyrrolidone having a molecular weight of between 2,500 and 24,000 daltons with an average of 13,600. The gel has the trade name of Plasdone AU24K. Particles of methyl-methyl siloxane were mixed with the plasdone in a ratio of approximately 3:2 and, under sterile conditions, placed within a cartridge.

Cannula

Two special cannulas are required for these minimally invasive techniques. One is a pencil tipped pocar for use in pre-tunneling. This is fabricated of the same diameter (usually 20 gauge) as the cannula. The cannula has a blunt tip with the orifice carefully placed on the taper of the tip and is fitted with a Luer-lock fitting to adapt to the cartridge.

Injection Gun

A hand operated, highly leveraged injection gun is necessary to allow precise macro implantations. The material can easily be injected through a standard syringe and 20 gauge needle or cannula but the highly leveraged injection system allows small amounts, i.e. a twenty gauge width of the gel particle mixture, to be precisely and accurately implanted at the defect site.

Procedure

In practice, the area to be treated is first outlined with a surgical marker and the volume of the defect is estimated at this initial evaluation. The entire area is then infiltrated

with Xylocaine 1% and Epinephrine, 1:100,000. The volume of infiltration depends of course on the size of the area to be treated because it is necessary to infiltrate the entire area and not just perform a regional block for anesthesia purposes. The skin is then punctured through a remote site more than a centimeter away from the defect and through this puncture the pencil tip pocar is passed to create a multitude of pre-tunneled channels in the area of the defect. These channels are created by passing the pocar to and fro in many different planes. The cannula is then passed through the same puncture site and passed to and fro through the pre-tunneled channels while pressure is gently and carefully applied to the injection gun, care being taken to apply only that amount of pressure required to deliver a twenty gauge wide amount of material as the gun passes to and fro. This ability can only be developed through practice. After the predetermined amount has been delivered through a multitude of channels, pressure is applied to the area between the remote puncture site and the defect (no man's land) by an overlying finger and the pressure is released within the injection gun. Then, with no material oozing from the cannula it is quickly withdrawn through no man's land and from the puncture site. With pressure still applied to this area, the puncture site is rinsed with local anesthesia. Elastic tapes are then applied around the defect over no man's land and the remote puncture site. We have developed a training system for the entire implantation procedure using rabbit ears as a model.

CLINICAL CASES

Since 1988 we have treated more than 95 patients for a variety of soft tissue defects. Implant volume ranges from 1 or 2 tenths of a cc. for the tip of the cleft lip deformity nose to 45.5 ccs. in the case of pectus excavatum. We have used these techniques to augment the softest of tissues such as the lips of a 19 year old model, to the firmest of tissues such as the chin and sternum. The overall distribution of

the applications can be seen below in Table I.

Four specific cases demonstrating a variety of defects are also shown below.

TABLE 1

Macroparticle Implantations

Diagnosis	No. Patients	Amount Inj. (ea)	Operations	Complications/Comments
Microcheilia congenital/acquired	33	.2 - 2.0cc	1-3	4 pts. required partial removal
Microgenia	14	.3 - 2.0cc	1 - 2	1 case partial microsuction; good cosmetic results
Nasal Contour Defect	14	.2 - 2.0cc	1 - 2	Effective for saddlenose deformity and post-rhinoplasty defects
Hollowness of Cheeks	8	.5-3.0CC	1 - 2	
Orbital Rim Defect	6	.1 - 1.0cc	1 - 3	1 pt. required microsuction along interior lateral canthus; globe-canthus competence achieved
Rhytids of Forehead	5	.1 - 0.3cc	1 - 2	2 pts. required removal due to too superficial placement
Cleft Lip	2	.4 - 1.5cc	1 - 2	Effective when injected into deficient obicularis oris
Other Facial Defects	29	.2 - 2.0cc	1 - 3	Nasolabial folds, infraophthalmal rhytids, etc.
Atrophic Hand Dorsum	3	2.0 - 4.0cc	1 - 2	Good contour results after 2.5 years
Pectus Excavatum	2	4.0-45.5cc	1 - 3	Near normal contour achieved in both cases
Post-liposuction Indentations	2	1.3-10.2cc	2 - 5	1 pt. required 5 augmentations - 3 suction removals for contour restoration
Wrist Rhytid	1	0.1cc	1	Early demonstration case

Over 119 defects (many above were bilateral/multiple defects), falling into the 12 types listed above, have been corrected, usually by multiple procedures spaced at least 6 weeks

apart. No infections have been detected, however 7 patients have required partial removal.

Patient #1

This 27 year old male sought treatment for congenital pectus excavatum. After discussing various procedures including a custom solid implant and surgical reversal of the sternum, we elected to use Bioplastique macroparticles due to their minimally invasive implantation. Near normal contour was achieved after two procedures of 16.0 and 29.5 ccs. spaced thirteen weeks apart.

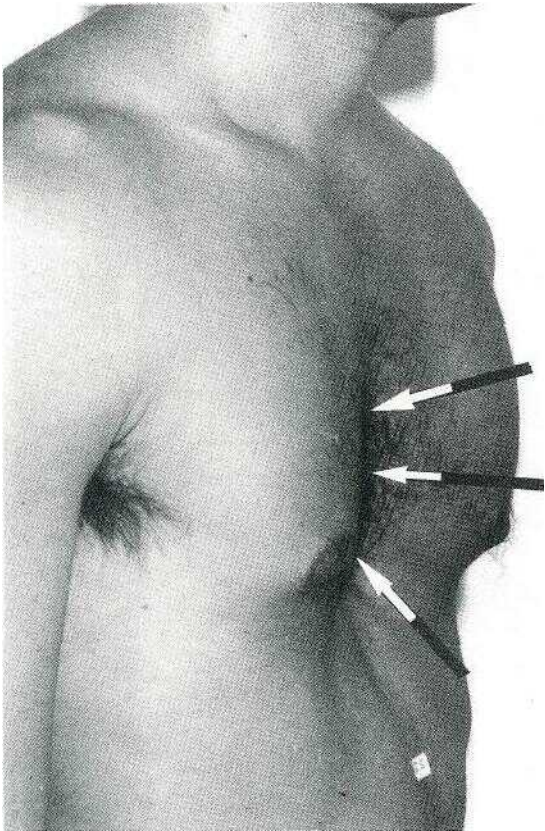


FIGURE 1A
Six weeks after the second augmentation.

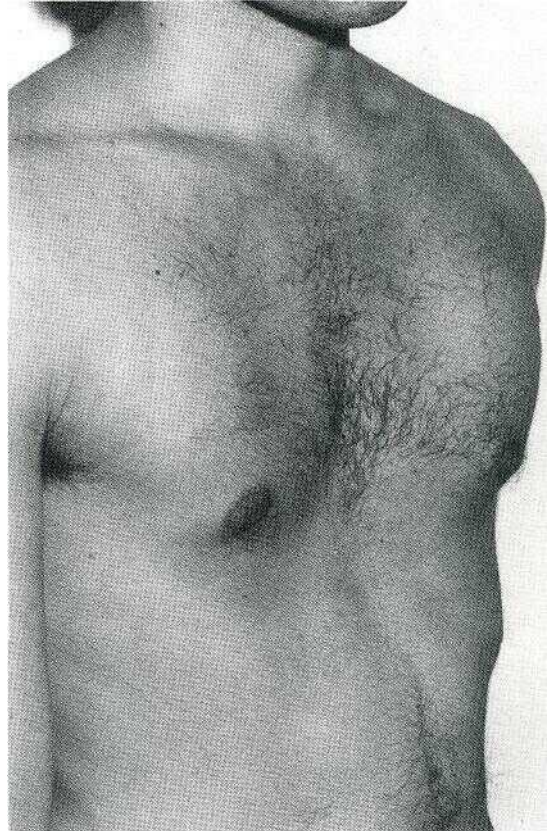


FIGURE 1B
The patient is seen before treatment.

Patient #2

This 20 year old female underwent rhinoplasty to correct a grossly deviated septum and hypertrophic turbinates after which the bridge collapsed. She then received 1.0 cc. of implants to the bridge and 1.0 cc. to her chin to balance the profile.

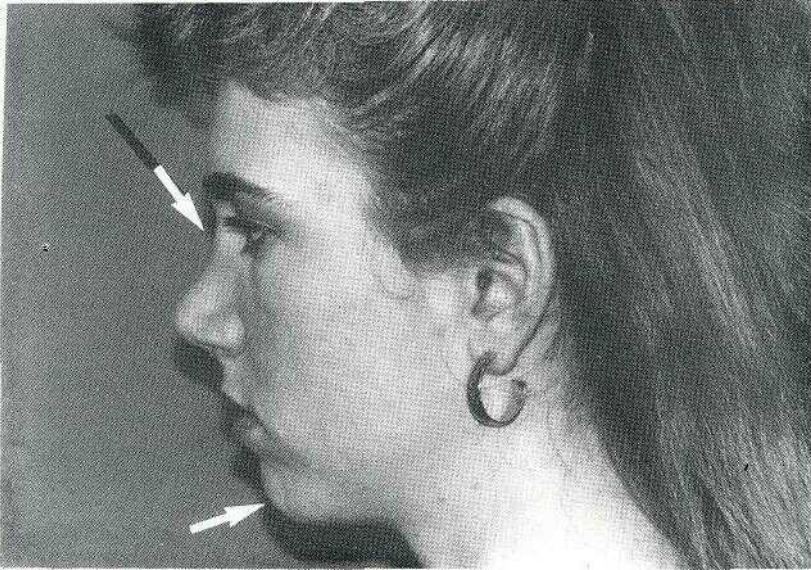


FIGURE 2A

She is seen seven months after the initial rhinoplasty.



FIGURE 2B

She is seen five and one half months after the subsequent implantation.

Patient #3

This 21 year old female had a prominent indentation of the left superior orbital rim and of her cheek below the malar eminence subsequent to a facial fracture sustained in an automobile accident several years ago. She was treated by macroparticle implantation in four procedures spaced over nine months. A total of .9 cc. was placed around the orbital rim and 2.4 ccs. below the malar eminence.



FIGURE 3A
She is seen before treatment



FIGURE 3B
She is seen three months after the last augmentation.

Patient #4-

This 42 year old female sought relief for the hollowness of her cheeks and various facial rhytids. In two procedures spaced six weeks apart she received 1.0 cc. to each cheek, .2 cc. to both upper and lower lips and .2 cc to her glabellar lines for a total of 2.6 cc.

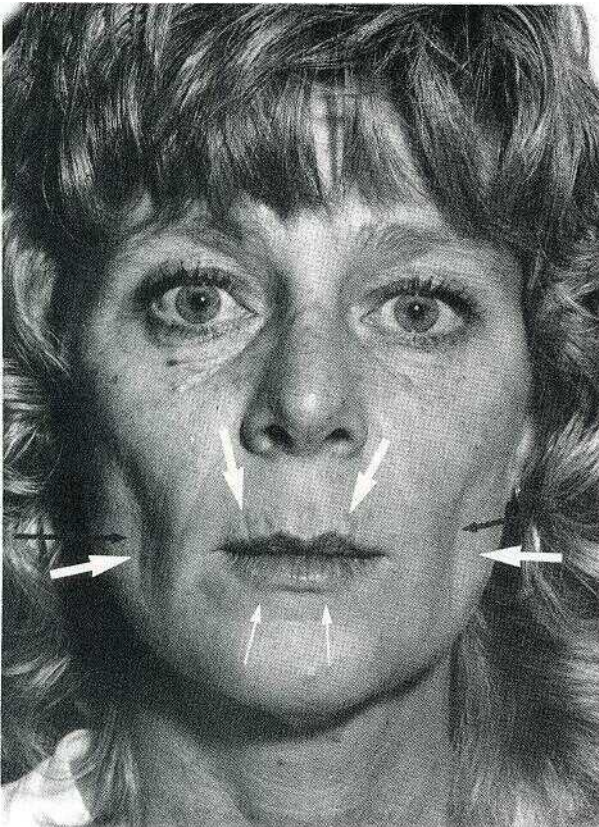


FIGURE 4A

She is seen before the second procedure.



FIGURE 4B

She is seen seven weeks after the second procedure. She has had no other procedures.

RESULTS

In general the soft tissue augmentation with the methods described herein are safe and desired results can be achieved. Our complications have been limited to those where we have placed too much material in one position or placed it too superficial, i.e. in or near the skin. In these cases the Bioplastique scar could be palpated or seen and its removal was necessary. Removal can be accomplished either by direct excision or minimally invasively by core drilling with an 18 gauge needle attached to an evacuated syringe. In this way the Bioplastique particles and their surrounding scar encapsulation are removed as a unit. Of the 195 injection sites listed, reinjection was necessary in 71 cases while removal of the material was necessary in 9 cases.

DISCUSSION

The techniques described herein have enabled us to treat a wide variety of soft tissue defects with these macroimplants. Although liquid silicone may be considered a permanent implantation, it has been seen to migrate and may impair lymphatic and phagocytic function even years after injection.^{13,14} Collagen, fibrin, and autologous fat have been used for prompt, relatively simple soft tissue augmentation but results are inconsistent and temporary. Studies we have previously published in rabbits have shown that the textured macroparticles having a diameter greater than 100 microns are biocompatible and after injection the plasdone hydrogel is quickly dispersed by the body and replaced by the host fibrin. This fibrin acts as a spacer and a matrix upon which host fibroblasts can form autogenous collagen to engulf each individual particle. Ingrowth of the host collagen through the textured, tunneled surface of the particles allows an intimate and intricate bond to form between host tissue and implant. Because of this slight induced tissue growth, we recommend underfilling of the defect and a six week healing period before reinjection.

Our studies conducted in rabbits have shown that the thickness of the deposits in the subcutaneous plane will remain constant as confirmed by micrometer measurements and transillumination for the one year span of the studies.

Urology

An independent animal study using this material was undertaken by Barret and his colleagues¹⁵ to determine tissue reaction and propensity for migration of two groups of radiolabelled particulate silicone implants injected periurethrally in female mongrel dogs. Those receiving "micro" implants consisting of particulate silicone of mean diameter 73 microns, below the migratory threshold diameter established at 80 microns, grossly showed injection site dissipation and histologically showed local and distant migration to cells of the lung, kidney, brain and lymph nodes. "Macro" implant animals which received textured particles of mean diameter 110 microns, well above threshold, locally exhibited a well encapsulated fibrous sheath which maintained the integrity of the injection site and minimal propensity for distant migration.

Incontinence: Studies have been completed that demonstrate the efficacy of these techniques in the treatment of urinary stress incontinence in females. The macroimplants are injected transurethrally via a modified nephroscope in the submucosal layer just distal to the bladder to provide closure in a stretched but functioning sphincter. John Buckley's experience with approximately 100 such patients indicates over an 80% dry rate after average follow-up of one year.¹⁶ Similar techniques used by Dr. John Iacovou have produced good to excellent results in 80% of his patients thus far.¹⁷ Treatment of male incontinence shows less dramatic improvements but since this can be done endoscopically under local anesthesia without precluding future surgery, it is a reasonable first line of treatment for these difficult problems.

Ureteral Reflux: This can be corrected by an endoscopic submucosal injection of macroimplants at the ureterovesicle junction. The success rate is approximately 90% thus far.¹⁸

Otolaryngology

Professor Thumfart has begun a study in Cologne, Germany using a special set of instruments to implant these materials in the paralyzed vocal chord to enable it to meet the normal chord for approximation and phonation. When one chord is completely missing through scar or resection, it is possible to augment the normal chord to make up the gap and achieve approximation and phonation. When a small lesion is removed from the chord by laser alveolation, it is possible to immediately reconstruct the defect by the injection of these macroimplants in the mucosa surrounding the ablated defect.¹⁹

Velo-pharyngeal Incompetence

Studies are presently being carried out in which these materials are implanted through a pharyngoscope at Passavant's Ridge and the posterior pharyngeal wall and/or the free border of the soft palate to provide for velo-pharyngeal competence and prevent hypo-nasal speech in the cleft palate.²⁰

Micro Tissue Expansion

Work is being done to increase available tissue for local flaps by repeated and frequent injections of these materials near the edge of a defect to create expansion of the local tissue.

Esophageal Reflux

Esophageal Reflux occurs because of incompetence of the gastro-esophageal valve.

Preliminary studies by Russell Broadbent in Australia have shown that transgastroscopic injection of macro-particles into the submucosal plane will provide competence to this valve.²¹

Studies are also being performed to prevent hiatus hernia by subserosal injection through a laparoscope. It is hoped this will create a retention ring similar to the Angelchick procedure but will be performed minimally invasively through a laparoscope.

Hand Augmentation

Subcutaneous infiltration of these micro implants throughout the dorsum of the hand has been successful with two years follow up in providing a smooth contour to the atrophic withered dorsum.

CONCLUSION

Minimally invasive atraumatic techniques allow for soft tissue augmentation of a few tenths of a cc. to over 45 ccs. under local anesthesia. Although three years is not a sufficient clinical experience from which to draw permanent conclusions, these results do appear to be persistent and without measurable change for the period studied. Further experiments are indicated.

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