Injection Adipocytolysis with ATX-101 (Deoxycholic Acid) for Body Contouring

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**INTRODUCTION:** Deoxycholic acid currently approved only for minimally invasive treatment of submental fat. The effects of deoxycholic acid on fat need not be limited to submental fat and represents an opportunity to treat undesired fat in many other body parts. Injection lipolysis has the potential risks of skin loss/necrosis, hyperpigmentation, neovascular response, and contour irregularities. There are no reports to date of results of body contouring using deoxycholic acid. This study shows the first real-world use of deoxycholic acid for non-submental locations for body contouring, and characterizes safety and efficacy of treatment.

**METHODS:** A retrospective review was conducted of 14 patients treated at a single-center between June 2015-December 2016. Each patient was assessed for excess undesired fat in specific regions, thereby identifying the target treatment area. Deoxycholic acid was injected into the subcutaneous fat of each respective region (0.2 mL per injection of 10mg/mL to achieve a dose of 2mg/cm²) for a maximum of 3 treatments. Response was defined as decreased palpable and/or visible fullness due to decreased overall adipose deposits. Injection-site adverse events (AEs) and other AEs were recorded at each visit. Follow-up was at 10 weeks.

**RESULTS:** Desired regions treated were peri-axillary fat (n=6), inner thighs (n=3), outer thighs (n=5), upper arm (n=6), knees (n=6), abdomen (n=2), and jowls (n=4). Improvement in fat reduction in the desired regions was achieved in 100% of patients with follow-up (n=12). No AEs were reported at 10 week follow-up of all patients (n=14) including skin loss/necrosis, hyperpigmentation, neovascular response, contour irregularities, numbness, or motor dysfunction.

**CONCLUSION:** Body contouring using deoxycholic acid is effective with no significant adverse events at early follow-up in this pilot small sample of patients. Continued follow-up with safety data monitoring of a larger set of patients will be needed to inform future on-label non-submental indications for deoxycholic acid. This represents an attractively minimally invasive alternative to liposuction and other forms of injection lipolysis for body contouring.

**Reference Citations:**
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Paradoxical Adipose Hyperplasia: A Report on Increased Incidence, Clinical Management, and Outcomes

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**INTRODUCTION:** Paradoxical adipose hyperplasia (PAH) is a rare complication of cryolipolysis, the most commonly used non-surgical fat reduction technique in the world. PAH is diagnosed when the treated area enlarges over a few months after treatment rather than showing reduction in subcutaneous fat. In this study, we report our experience with 11 patients seen in our office with a diagnosis of PAH over the past 3 years. Their clinical presentation, management, and corrective treatment options are reviewed.

**METHODS:** This is a retrospective review of 11 patients with PAH following cryolipolysis. The treatment parameters, demographics, onset of findings, and subsequent treatment were chronicled.

**RESULTS:** All eleven cases of PAH (8 males, 3 females) were of Hispanic background. The average age was 42.5 years and the mean body mass index was 26.7 kg/m². These patients presented with a painless, enlarged area of subcutaneous tissue at the treatment site, which occurred on average at 2.85 months following cryolipolysis. Nine
cases occurred in the abdomen, seven of which were originally treated using the large cryolipolysis applicator. Four patients were first-degree relatives with similar clinical presentations. Of the 11 patients with PAH, five patients were subsequently treated with liposuction and one was treated with a combination of liposuction and an abdominoplasty, achieving both good cosmetic results and patient satisfaction. Our incidence of 0.38% (8 PAH events in 2073 treatment cycles) was significantly higher than the incidence reported by the manufacturer (0.025%).

CONCLUSION: Despite following appropriate treatment guidelines, our PAH incidence shows a 15-fold increase when compared to that reported by the manufacturer. We believe PAH is an underreported clinical entity of significant burden to the patients. Hispanic, middle-aged men undergoing cryolipolysis of the abdomen with a large applicator seem to be at increased risk for developing PAH. Further studies are needed to define the role of genetics, androgens, and other potential risk factors for PAH. Liposuction and/or abdominoplasty at the appropriate time after diagnosis, are helpful in treating this problem.

A Novel Breast Implant Surface Chemistry Significantly Reduces Acute and Chronic Peri-Prosthetic Capsule Formation in a Murine Model

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INTRODUCTION: Capsular contracture (CC) is the most common complication of implant-based breast surgery and the source of significant patient morbidity. Yet, there are no clinically approved therapies for prevention or treatment of CC. Rather, the complication is mitigated with re-operation and capsule excision, which often necessitates implant removal and replacement. The mechanism underlying CC remains unknown, however is understood to involve an excessive and pathologic foreign body response (FBR). As such, herein we coated the surface of silicone implants with proprietary, anti-inflammatory, anti-fibrotic molecules developed by Sigilon, Inc. We hypothesized that covalently bonding these novel anti-inflammatory molecules to silicone implants would reduce the FBR for the lifetime of the implant, thus reducing later downstream effects of capsule formation and CC.

METHODS: Silicone implants were created from polydimethylsiloxane and coated with RZA15 or E9, two biocompatible and non-degradable, anti-fibrotic, proprietary molecules. Uncoated, RZA15- and E9-coated implants were implanted subcutaneously into the dorsa of wildtype C57BI/6 mice. After 21, 90 and 180 days (equal to approximately 3, 10 and 20 years post-operatively in human years) peri-prosthetic tissue was removed for histologic analysis, and stained with Hematoxylin & Eosin and Masson’s Trichrome. The capsule was identified at five equidistant regions throughout the implant and outlined in ImageJ software. Capsule area was calculated, and divided by capsule length to determine the average capsule thickness per implant.

RESULTS: We compared mean capsule thickness at three time points across the three groups: E9-coated, RZA15-coated, and uncoated implants. At 21, 90 and 180 days, there was a statistically significant reduction in capsule thickness of RZA15- and E9-coated implants compared to uncoated implants ($p < 0.05$).

CONCLUSION: Coating the surface of silicone implants with RZA15 and E9 significantly reduced acute and chronic capsule formation in a mouse model for implant-based breast augmentation and reconstruction. As capsule formation obligatorily precedes capsular contracture, these results suggest contracture itself may be significantly attenuated. Furthermore, as peri-prosthetic capsule formation is a complication without anatomical boundaries, the chemistry of this novel compound may have additional applications beyond breast implants, to a myriad of other implantable medical devices.