



Preliminary Report

# Injection of an Adipocytolytic Agent for Reduction of Excess Periaxillary Fat

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Aesthetic Surgery Journal  
2019, Vol 39(12) NP495–NP503  
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DOI: 10.1093/asj/sjz067  
[www.aestheticsurgeryjournal.com](http://www.aestheticsurgeryjournal.com)

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**Abstract**

**Background:** The principal current treatment options for reduction of excess anterior periaxillary fat (APAF) are invasive procedures such as excision and liposuction.

**Objectives:** The aim of this study was to evaluate the efficacy and safety of ATX-101 (deoxycholic acid injection) as a treatment to reduce APAF.

**Methods:** In this retrospective study, 12 women with periaxillary fullness underwent ATX-101 treatment. Patients were examined to confirm that fullness was due to excess APAF and sufficient subcutaneous fat was present to warrant treatment. Before treatment, the lateral and medial borders of the treatment area were identified and marked. A 1-cm grid was placed to guide the placement of the ATX-101 injections. Reduction in APAF was based on visual assessment and palpation by the clinician, and assessment of before/after patient photographs by the patient and 2 blinded plastic surgeons; all had to agree that APAF reduction had occurred. Patient satisfaction was also assessed. Safety was evaluated in terms of adverse events (AEs).

**Results:** Patients underwent a mean of 1.8 ATX-101 treatments; 5 patients received 1 treatment, whereas 7 received multiple treatments. Ten patients achieved a reduction in APAF and were satisfied with treatment. One patient was satisfied after 1 treatment but did not return for posttreatment photographs. One patient did not show any noticeable reduction in APAF after 1 treatment; however, this patient was satisfied and additional treatments are planned. Common AEs included injection-site numbness, edema, and tenderness that lasted for a mean of 18.6, 6.0, and 4.5 days, respectively.

**Conclusions:** ATX-101 effectively reduced APAF and was generally well tolerated in this small cohort. Larger prospective studies are needed to confirm these findings.

**Level of Evidence: 4**



Editorial Decision date: February 28, 2019; online publish-ahead-of-print March 14, 2019.

Prominent or excess anterior periaxillary fat (APAF) is a focal collection of fat that is an area of concern for some people. The presence of excess APAF may be unrelated to an individual's body mass index (BMI) and can become more pronounced with age.<sup>1,2</sup> In addition, APAF may be accentuated by the compressive effects of certain types of clothing such as bras.<sup>1</sup> Although rarely described in the literature, treatment options to reduce APAF are generally invasive and include surgical approaches such as excision<sup>3</sup> and liposuction,<sup>1,2,4</sup> which may be undertaken as part of a more extensive procedure such as brachioplasty (eg, in

patients being treated for upper-arm deformity after massive weight loss).<sup>5,6</sup>

Patients are increasingly interested in nonsurgical alternatives to treat areas of cosmetic and aesthetic concern

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that affect their body image. According to the American Society for Aesthetic Plastic Surgery, ~11.7 million non-surgical cosmetic treatments, comprising 86% of all cosmetic procedures, were performed in 2016—an increase of 7% from 2015.<sup>7</sup> Moreover, during the same time period, the number of treatments with injectables such as botulinum toxin A and dermal fillers rose by 10%, whereas surgical cosmetic procedures increased by less than half that rate (4%).<sup>7</sup>

ATX-101 (deoxycholic acid injection—marketed as Kybella in the United States, and as Belkyra in Canada, Australia, Europe, and South Korea; Allergan/Kythera Biopharmaceuticals, Inc., Parsippany, NJ [an affiliate of Allergan]) is a minimally invasive injectable treatment approved for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat.<sup>8,9</sup> Deoxycholic acid is a bile acid that emulsifies and solubilizes ingested fat, facilitating its digestion and absorption within the gastrointestinal tract.<sup>10</sup> ATX-101 is biologically equivalent to endogenous deoxycholic acid and is synthesized via a multistep chemical process.<sup>11</sup> When injected subcutaneously into fat, ATX-101 causes permanent adipocytolysis, resulting in a localized tissue response involving macrophage infiltration, which clears cellular debris and liberated lipids from the treatment area, and fibroblast recruitment, which may be responsible for neocollagenesis.<sup>12</sup>

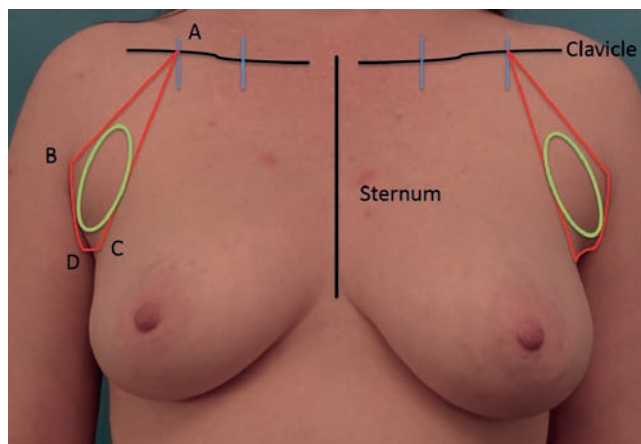
Since its initial approval in 2015 for reduction of submental fat, interest has grown regarding the use of ATX-101 for the treatment of focal fat deposits in other areas of the body that may be resistant to diet and exercise, including APAF.<sup>13-15</sup> The results from a retrospective study that evaluated the efficacy and safety of ATX-101 treatment for reduction of excess APAF are reported here.

## METHODS

### Study Design and Patient Selection

A retrospective chart review was performed for patients who underwent ATX-101 treatment to reduce excess APAF between November 2015 and June 2017 at a plastic surgery practice (LUXURGERY, New York, NY). Patients were treated in accordance with the principles of the Declaration of Helsinki and provided written informed consent.

Patients were considered for treatment of excess APAF at their request and/or based on the recommendation of the clinician (S.M.S.) when assessing them for other procedures such as breast surgery. Both clinician and patient had to agree that a sufficiently large fullness or convexity was present in the anterior periaxillary area to warrant treatment. A medical history was obtained, and patients reporting past or current pain or swelling in the anterior periaxillary area during their menstrual cycle, suggestive

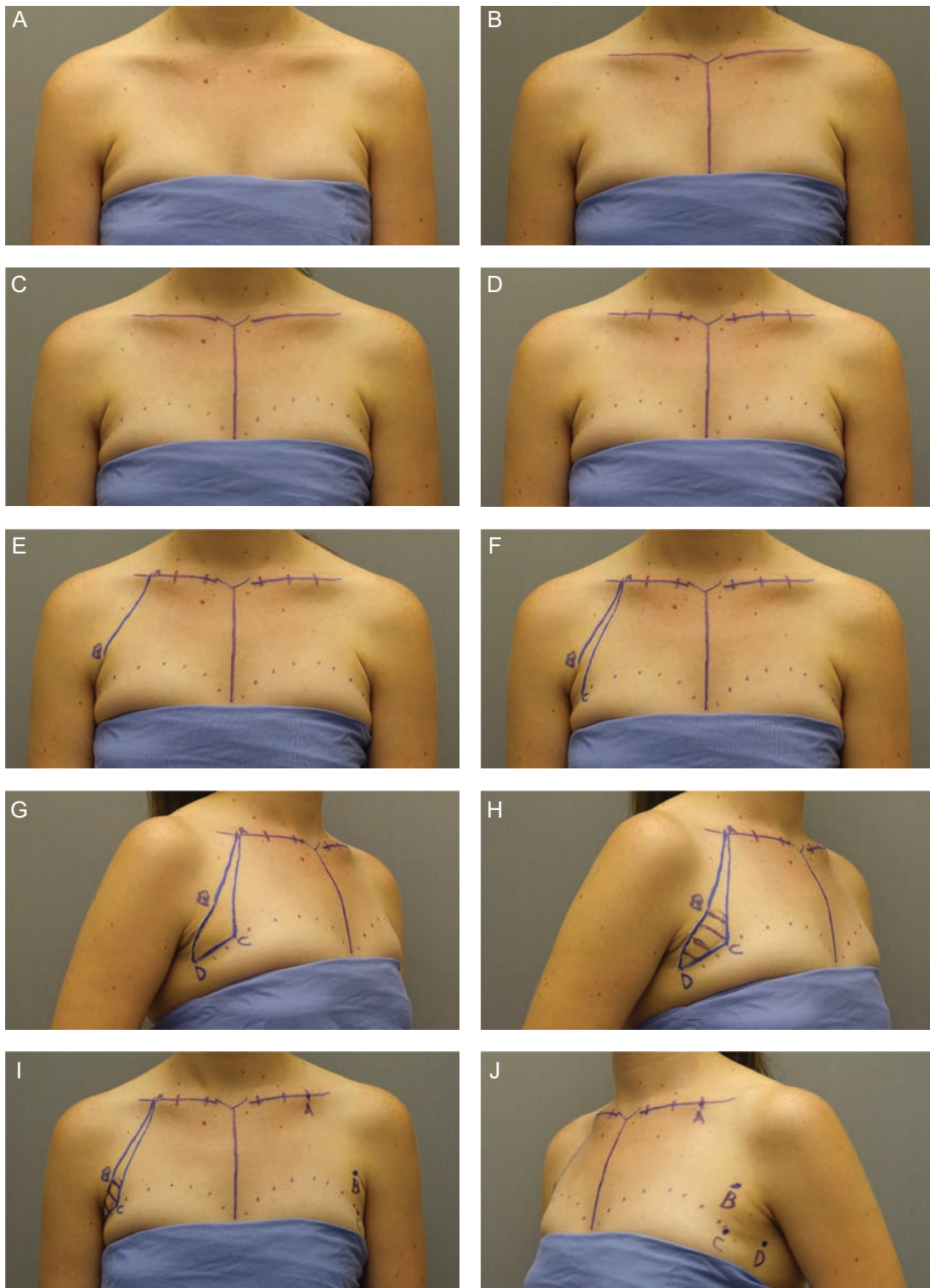


**Figure 1.** Identification of the treatment areas (ellipses), which lie within the lateral and medial borders of the right and left anterior periaxillary regions (demonstrated on a 46-year-old woman): (A) inner end of the lateral third of the clavicle; (B) start of the anterior axillary fold; (C) palpable junction of the breast upper outer quadrant and axillary skin; (D) midaxillary line.

of the presence of accessory breast tissue, were excluded. A physical examination was performed while the patient was in a standing position with arms at their sides. Patients were asked to abduct their arms, thereby activating the pectoralis major muscle, to ensure any periaxillary fullness was related to excess fat and not secondary to hypertrophy of the pectoralis major muscle or tendons. A pinch test further confirmed the presence of subcutaneous fat.

### Treatment Procedure

The APAF treatment area lies within an ellipse in the right and left anterior periaxillary region (Figure 1). To identify the anatomic landscape, avoid breast tissue, and ultimately achieve an optimal aesthetic outcome, a stepwise approach involving a system of novel markings was used to demarcate the lateral and medial borders of each treatment area (Figure 2). In contrast to ATX-101 treatment of submental fat, in which the marginal mandibular nerve represents a “no treatment zone,”<sup>16</sup> no anatomic structures such as nerves or major blood vessels are present in the anterior periaxillary region. Once the treatment area had been marked, the patient was placed in a relaxed, semireclined or reclined position, and a 1-cm injection grid was placed over the treatment area and trimmed as needed (Figure 3). ATX-101 (10 mg/mL; area-adjusted dose, 2 mg/cm<sup>2</sup>) was drawn into a 1-mL syringe with a 32G 0.5-inch needle. For each injection (volume, 0.2 mL), the needle was inserted perpendicular to the skin to a depth of 8 to 10 mm. Each injection was administered adjacent to a grid marking to avoid tattooing skin. Caution was taken to penetrate the epidermis and dermis (to



**Figure 2.** Stepwise marking of the treatment area with a surgical pen on a representative 25-year-old female model. (A) The model before marking. (B) The jugular notch, clavicle, and midline of the chest are first marked. (C) The superior section of each breast is then demarcated with a dotted line, part of which will form the lower boundary of the treatment area. (D) The line along the clavicle is marked into thirds. (E) A line is drawn from point A, located at the inner end of the lateral third of the clavicle, to point B, the start of the anterior axillary fold. (F) This is then followed by drawing of another line from point A to point C, the palpable junction of the breast upper outer quadrant and axillary skin. (G) Both lines are then extended to meet at point D, the midaxillary line. (H) The treatment area is then filled in with diagonal lines. (I) Frontal view of the marked-up treatment area. (J) Points A, B, and C marked on the left periaxillary treatment area.



**Figure 3.** A 1-cm grid used to guide ATX-101 injections in the marked treatment area shown on a 31-year-old woman.



**Video 1.** Watch now at <https://academic.oup.com/asj/article-lookup/doi/10.1093/asj/sjz067>

prevent necrosis) and to avoid any visible striae distensae. Injections began at the top outer part of the treatment area and proceeded vertically downward in columns across the area as illustrated in Video 1.

The number of injections per treatment as well as the need for multiple treatments were dependent on the amount and distribution of each patient's APAF. Anticipated minor discomfort associated with ATX-101 treatment was managed with the following protocol: oral analgesics (ie, acetaminophen) and local anesthetic injection administered within 1 hour and 10 minutes, respectively, before treatment. In addition, ice packs were applied prior to treatment. After each treatment was completed, ice packs were applied for 15 minutes before discharge, and patients were advised to utilize ice packs (10 minutes on/10 minutes off) where possible for 48 hours. Oral analgesics were also taken as needed for after-treatment. Patients who underwent other concomitant surgical procedures received general anesthesia as appropriate.

## Outcome Measures

Improvement in APAF was based on the following: (1) visual assessment and palpation of the anterior periaxillary area before and after treatment by the clinician; and (2) visual assessment of patient photographs by the patient and 2 independent board-certified plastic surgeons. Photographs were taken immediately before treatment and 12 weeks after the final treatment. The 2 plastic

surgeons were blinded to the patient's treatment and had to correctly identify which photograph of each patient was taken before vs after treatment. Twelve weeks was selected as the timepoint for posttreatment assessment (where possible, depending on patients' schedules) to allow for sufficient remodeling of tissue within the treatment area (and for consistency with the primary timepoint for efficacy evaluation in the phase 3 ATX-101 trials for submental fat). The clinician, patient, and blinded plastic surgeons had to agree that reduction in APAF occurred for a positive outcome to be recorded. At 12 weeks after the last treatment, patient satisfaction was assessed by a nurse via verbal response to the following questions: Are you satisfied with the treatment? Would you have the treatment again (specific to APAF)? Would you recommend the treatment to a friend? Safety was evaluated via the incidence and duration of adverse events (AEs), particularly injection-site reactions, at each visit. Patients also reported AEs by telephone as necessary.

## RESULTS

### Patient Characteristics

A total of 12 women with excess APAF underwent ATX-101 treatment (Table 1). Their mean age was 44.6 years (range, 26–61 years) and their mean BMI was 25.2 kg/m<sup>2</sup> (range, 19.8–31.0 kg/m<sup>2</sup>). Most patients (67%) had received previous cosmetic treatments. Details regarding previous and concurrent treatments/procedures are shown in Table

**Table 1.** Patient Characteristics

	Patients (n = 12)
Age, mean ± SD [range], years	44.6 ± 11.6 [26–61]
BMI, mean ± SD [range], kg/m <sup>2</sup>	25.2 ± 3.3 [19.8–31.0]
<25 kg/m <sup>2</sup> , n (%)	5 (42)
≥25 kg/m <sup>2</sup> , n (%)	7 (58)
Cosmetic treatment/procedure experienced, n (%)	8 (67)
Previous treatments/procedures, <sup>a</sup> n (%)	
Injectables	7 (58)
Liposuction	4 (33)
Submental contouring with ATX-101	4 (33)
Breast augmentation	2 (17)
Abdominoplasty	1 (8)
Breast reduction	1 (8)
Blepharoplasty	1 (8)
Concurrent treatments/procedures, n (%) <sup>a</sup>	
Injectables	7 (58)
Breast augmentation/mastopexy	2 (17)
Liposuction	2 (17) <sup>b</sup>
Submental contouring with ATX-101	1 (8)
Posterior bra roll contouring with ATX-101	1 (8)

BMI, body mass index; SD, standard deviation. <sup>a</sup>Patients may have had >1 treatment/procedure. <sup>b</sup>One patient also underwent concurrent buttock fat transfer.

1. The most common previous treatments were injectables (58%), liposuction (33%), and submental contouring with ATX-101 (33%); injectables (58%) were also the most common concurrent treatment. Of 4 patients who had no previous cosmetic treatments, 2 underwent breast augmentation/mastopexy concurrently with treatment of APAF. One of the 4 patients who had undergone earlier submental contouring with ATX-101 coordinated subsequent submental fat treatments with APAF treatments.

Patients were followed for a mean of 244.5 days (range, 185–341 days). One patient was lost to follow-up.

## Treatment Parameters

The mean ± standard deviation (SD) number of ATX-101 treatments per patient was 1.8 ± 0.9 (Table 2). Five patients underwent 1 ATX-101 treatment, whereas 7 underwent multiple treatments (2 treatments, n = 5; 3 treatments, n = 1; 4 treatments, n = 1). Among the 7 patients who underwent multiple treatments, the mean interval between treatments was 108.0 days (Table 2).

**Table 2.** ATX-101 Treatment Parameters

	Patients (n = 12)
Number of ATX-101 treatments, mean ± SD	1.8 ± 0.9
Received 1 treatment, n (%)	5 (42)
Received ≥2 treatments, n (%)	7 (58)
Interval between treatments, mean ± SD [range], days <sup>a</sup>	108.0 ± 76.4 [34–271]
Total ATX-101 volume, mean ± SD [range], mL	13.9 ± 8.4 [6–36]
ATX-101 volume per treatment, mean ± SD [range], mL	7.6 ± 2.4 [4–12]
Among patients who received 1 treatment	8.4 ± 1.5 [6–10]
Among patients who received ≥2 treatments	7.4 ± 2.5 [4–12]
Anesthesia, n (%) <sup>b</sup>	
General	5 (42)
Local	8 (67)
Volume per treatment, mean ± SD [range], mL	3.9 ± 1.0 [2–5]
Oral analgesia	8 (67)
Postinjection ice packs, n (%)	12 (100)

SD, standard deviation. <sup>a</sup>Among patients who received ≥2 treatments. <sup>b</sup>Patients could receive both general and local anesthesia depending on concurrent treatments/procedures.

The total mean ± SD volume of ATX-101 injected per patient was 13.9 ± 8.4 mL (right, 6.8 ± 4.2 mL; left, 7.1 ± 4.2 mL), and the mean ± SD volume of ATX-101 injected per treatment was 7.6 ± 2.4 mL (right, 3.7 ± 1.2 mL; left, 3.9 ± 1.2 mL; Table 2). In general, a greater volume of ATX-101 was injected per treatment in patients who underwent a single treatment (total, 8.4 ± 1.5 mL; right, 4.2 ± 0.7 mL; left 4.2 ± 0.7 mL) than in patients who underwent multiple treatments (total, 7.4 ± 2.5 mL; right, 3.6 ± 1.3 mL; left, 3.8 ± 1.3 mL).

Five patients were administered general anesthesia, including 4 who were undergoing other procedures concurrently (breast augmentation/mastopexy, n = 2; liposuction, n = 2). Eight patients received local anesthesia. The mean volume of local anesthesia per treatment was 3.9 mL. Eight patients used oral analgesia before treatment. All patients applied ice packs following treatment, although adherence was generally suboptimal beyond 24 hours posttreatment.

## Efficacy

In total, 10 of 12 patients achieved a reduction in APAF following ATX-101 treatment. In addition, all 10 of these patients were assessed as satisfied following treatment. Of the 2 remaining patients, 1 reported satisfaction after a single treatment (via telephone) but did not return for posttreatment photographs. The other patient underwent a single ATX-101



**Figure 4.** Representative photographs showing response for a 46-year-old woman with no previous treatment for anterior periaxillary fat who underwent 3 ATX-101 treatments (treatment 1, 3 mL/side; treatment 2, 5 mL/side; treatment 3, 5 mL/side). (A) Before treatment. (B) Eight weeks after second treatment. (C) Eight weeks after third (final) treatment. Efficacy was evaluated at 12 weeks after the final treatment by the clinician. These photographs, although taken earlier than 12 weeks after the final treatment, illustrate the improvement in anterior periaxillary fat.

treatment and, according to the patient, clinician, and 1 of the 2 blinded plastic surgeons, had not achieved a noticeable reduction in APAF (assessed at 5 weeks after treatment). Two of the 10 patients who had reduced APAF and were satisfied following ATX-101 treatment have requested additional APAF treatments. A representative patient who responded to ATX-101 treatment is shown in [Figure 4](#).

### Safety

All AEs were localized to the injection site. Numbness, edema, and tenderness were reported in 12, 12, and 11 patients, respectively, and lasted for a mean duration of 18.6, 6.0, and 4.5 days, respectively ([Table 3](#)). In patients who underwent multiple ATX-101 treatments, the duration of these AEs was generally shorter following subsequent treatments. Most patients (7/12) did not report bruising; in patients who did experience bruising, the mean duration was 4.8 days. Induration, reported by one patient, lasted for 7 days after the first treatment and 9 days after the

second treatment. No nodules were observed in any patient. All AEs resolved without sequelae.

### DISCUSSION

Multiple randomized, controlled clinical trials have demonstrated that ATX-101 treatment results in clinically meaningful reductions in submental fat.<sup>17-20</sup> Based on these findings, clinicians have considered whether ATX-101 treatment may find applications for reduction of other areas of focal fat, such as APAF.<sup>13-15</sup> In this retrospective study, ATX-101 treatment resulted in reductions in APAF in 10 of 12 patients. Of the 2 remaining patients, 1 was satisfied after a single ATX-101 treatment and did not return for posttreatment evaluation or photographs, and the other did not achieve a perceptible improvement after a single ATX-101 treatment. However, the duration of follow-up for this patient was short (5 weeks), and it is possible that an improvement in APAF would have been observed at a

**Table 3.** Incidence and Duration of Adverse Events

	Patients (n = 12)
<b>Numbness, n (%)</b>	12 (100)
Duration, all treatments, mean $\pm$ SD, days	18.6 $\pm$ 5.7 <sup>a</sup>
Duration among patients who received 1 treatment, mean $\pm$ SD, days	25.5 $\pm$ 2.9
Duration in first treatment, mean $\pm$ SD, days	20.8 $\pm$ 5.7
Duration among patients who received $\geq 2$ treatments, mean $\pm$ SD, days	16.8 $\pm$ 4.8
Duration in subsequent treatments, mean $\pm$ SD, days	15.8 $\pm$ 4.3
<b>Edema, n (%)</b>	12 (100)
Duration, all treatments, mean $\pm$ SD, days	6.0 $\pm$ 3.3 <sup>b</sup>
Duration among patients who received 1 treatment, mean $\pm$ SD, days	9.3 $\pm$ 4.6
Duration in first treatment, mean $\pm$ SD, days	8.1 $\pm$ 3.2
Duration among patients who received $\geq 2$ treatments, mean $\pm$ SD, days	5.2 $\pm$ 2.4
Duration in subsequent treatments, mean $\pm$ SD, days	3.6 $\pm$ 1.3
<b>Tenderness, n (%)</b>	11 (92)
Duration, all treatments, mean $\pm$ SD, days	4.5 $\pm$ 2.4
Duration among patients who received 1 treatment, mean $\pm$ SD, days	6.7 $\pm$ 2.9
Duration in first treatment, mean $\pm$ SD, days	4.7 $\pm$ 2.9
Duration among patients who received $\geq 2$ treatments, mean $\pm$ SD, days	4.1 $\pm$ 2.1
Duration in subsequent treatments, mean $\pm$ SD, days	3.7 $\pm$ 2.0
<b>Bruising, n (%)</b>	5 (42) <sup>c</sup>
Duration, all treatments, mean, days	4.8
Duration among patients who received 1 treatment, mean, days	4.0
Duration in first treatment, mean, days	5.2
Duration among patients who received $\geq 2$ treatments, mean, days	5.3
Duration in subsequent treatments, mean, days	3.0
<b>Induration, n (%)</b>	1 (8) <sup>d</sup>

SD, standard deviation. <sup>a</sup>Duration was unknown in 1 patient who received 1 treatment; duration was 18 days after the first treatment and of unknown duration after the second treatment in 1 patient. <sup>b</sup>Duration was unknown in 1 patient who received 1 treatment. <sup>c</sup>In 1 patient, bruising occurred on the left side only during the first treatment; in 1 patient, bruising occurred only after the third of 4 treatments. <sup>d</sup>Occurred in 1 patient and lasted for 7 and 9 days after the first and second treatments, respectively.

later timepoint (at least 12 weeks). It is worth noting that this patient was satisfied with the initial improvement, and additional ATX-101 treatments are planned. All 12 patients reported satisfaction. It should be noted that 4 patients had received earlier submental contouring with ATX-101, and

the outcome likely influenced their decision to seek ATX-101 treatment for APAF.

Five patients underwent 1 ATX-101 treatment and 7 underwent multiple treatments. The number of treatments that individual patients required and the volume of ATX-101 administered per treatment were dependent upon the amount of subcutaneous fat present because ATX-101 is a surface area-based treatment. Due to the off-label nature of using ATX-101 to reduce APAF, care should be taken not to exceed approved dosing by using the 1-cm injection grid provided with ATX-101 and ensuring that the volume administered per side does not exceed 10 mL per treatment or 0.2 mL per injection, which is the approved dose for reduction of submental fat.<sup>8,9</sup> Moreover, because ATX-101 causes a gradual reduction in subcutaneous fat, before each treatment the periaxillary area should be assessed to ensure sufficient subcutaneous fat is present to require additional treatment. Additionally, an accurate demarcation of the lateral and medial borders of the treatment area, as shown in [Figure 2](#), is strongly recommended to identify the anatomic landscape, avoid breast tissue, and produce an aesthetically pleasing outcome. Before treatment is initiated, patients should undergo a full breast exam that includes the axillary tail of Spence to confirm that no palpable nodules are present. One in 8 women (12%) will develop breast cancer over her lifetime,<sup>21,22</sup> and although occurrence in the axillary tail is rare (0.1%),<sup>23</sup> induration and nodules that may occur following ATX-101 treatment can potentially mask pre-existing masses. No imaging was performed in this study; however, women should undergo a screening mammography before treatment if age appropriate, as recommended by the American Cancer Society or other local guidelines.<sup>24,25</sup>

Although all patients in this study were women, ATX-101 is a potential treatment option for men with APAF. In this author's experience, a number of male patients have expressed concern about APAF, reflecting the increasing numbers of men undergoing cosmetic procedures,<sup>7</sup> and treatments for these individuals are planned or underway.

As there are no major nervous or vascular structures in the anterior periaxillary region, expected complications were those associated with the mechanism of action for ATX-101 and anticipated local tissue response to the drug and injection procedure. The types of injection site-related AEs observed in this study were generally consistent with the drug's safety profile reported in the phase 3 clinical trials in adults with moderate or severe submental fat.<sup>17-20</sup> The duration of AEs in the current study was similar to or shorter than in the phase 3 clinical trials,<sup>17-20</sup> and tended to decrease over subsequent treatments. This may have been due to the presence of less subcutaneous fat available at later treatments for adipocytolysis by ATX-101, leading to a less extensive inflammatory response.

Two published reports in which ATX-101 was used to treat fat deposits on the lateral sides of the breast in the axillary tail of Spence (similar to the current study) or adjacent to the bra strap in the posterior upper torso highlight the ongoing interest in using ATX-101 for body contouring.<sup>14,15</sup> The current study builds on these reports in multiple ways. Only 1 patient received ATX-101 treatment of APAF in each of the published reports, whereas the current study included 12 patients consistently evaluated and treated. This report also provides in-depth guidance for isolating and marking the appropriate treatment area, and includes a video demonstrating the injection technique. Additionally, the current study presents detailed information on AEs experienced after ATX-101 treatment of APAF.

In the first of these published reports, improvement was based on reduction in tissue thickness as measured with calipers,<sup>14</sup> while in the second, improvement was determined by visual assessment of patient photographs and patient feedback.<sup>15</sup> In the current study, the evaluation of the reduction in APAF was also based on interpretation of changes between before and after treatment photographs by the patient and 2 blinded plastic surgeons, and on visual assessment and palpation of the anterior periaxillary area by the clinician, as no validated instrument for measuring APAF currently exists. Hence, development of tools or scales (with photonumeric guides) is needed to help clinicians accurately assess fat deposits in regions such as the anterior periaxillary region and determine if treatment was successful.

Although the findings of the current study are promising, they should be interpreted with caution. The population was small (n = 12) and limited to females, and the analysis was retrospective without a control group for comparison.

## CONCLUSIONS

The results from this retrospective study in a limited cohort show that ATX-101 is an effective and well-tolerated treatment for women with excess APAF. Prospective, randomized, controlled clinical trials with diverse patient populations are needed to confirm these findings.

## Supplementary Material

This article contains supplementary material located online at [www.aestheticsurgeryjournal.com](http://www.aestheticsurgeryjournal.com).

## Disclosures

The author receives writing assistance, medicines, equipment, or administrative support from Allergan, and is an advisory board member for Galderma, Merz, and Miramar Labs.

## Funding

Medical writing and editorial assistance was provided by Meryl Mandle of Evidence Scientific Solutions (Philadelphia,

PA), which was funded via an independent grant by Allergan plc (Dublin, Ireland). No payments were made for authorship and Allergan was not involved in data generation and analysis or the development of this manuscript.

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