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Original article

Low G', small particle, hyaluronic acid filler for body reshaping: a retrospective observational study

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Abstract. *Introduction:* At the beginning of 21st century, large particle hyaluronic acid body fillers were developed for non-surgical body reshaping, however they soon presented complications such as hardening and foreign body reactions. To address this issue small particles, low G' hyaluronic acid fillers, were introduced into the market. This study aims to retrospectively evaluate the safety and efficacy of these hyaluronic acid fillers for body reshaping procedures. *Material and Methods:* This retrospective observational was conducted on 21 consecutive patients treated with low G' hyaluronic acid body fillers for different body contouring procedures, between March and June 2022. The efficacy of this treatment was assessed using the BODY-Q scale, comparing results obtained preoperatively, and no earlier than 6 months post-treatment. *Results:* The most performed procedures were buttock and calf reshaping. The mean number of vials used for these treatments were 30.25 and 11.5, respectively. Six months after treatment a significant increase in the mean BODY-Q score was observed (52 preop versus 70.8 postop), indicating the treatment efficacy in achieving the desired aesthetic result. No major complications were reported in the treated cohort. No delayed granulomas were observed. *Conclusion:* The results of this study suggest that low G' small particle hyaluronic acid fillers for body reshaping represent a safe and effective procedure, leading to favorable outcomes. The absence of major complications in the study cohort further supports the safety profile of this recently introduced treatment device. This preliminary experience can contribute to understand the benefits and safety of low G' small particle hyaluronic acid fillers.

Key words: body filler, rheology, body contouring, minimally invasive

Introduction

During the past few years, there has been a significant increase in the demand for minimally invasive procedures aimed at enhancing body appearance[1]. Surgical body remodeling remains the gold standard for body contouring; however, various factors, including fear of surgery, postoperative downtime, and scarring, have prompted both physicians and patients to seek alternative approaches. At the beginning of the 21st century, large particle (macromolecular) hyaluronic acid body fillers (HABF) were developed to achieve breast enlargement without surgery. Unfortunately, this procedure led to numerous and poorly understood complications, ultimately resulting in the removal of the implanted filler[2-4].

Despite various applications of HABF were explored, the occurrence of hardening and foreign body reactions resulted in a gradual decline of their use, and they were progressively withdrawn from the market[5]. Nevertheless, the growing demand for non-surgical body contouring alternatives promoted the introduction of several "new" HABF in the market over the last decade. To address the complications associated

with large particle HABF, modifications were made to the rheologic properties of these fillers[6]. Drawing from experience in facial sculpting with small particle hyaluronic acid (HA) fillers, physicians recognized that higher G' (storage modulus) fillers yielded greater projection. However, implanting high G' fillers in the subcutaneous tissue could lead to palpable irregularities. As a result, high G' fillers are typically placed behind facial muscles in the deep fat pads or just over the periosteum[7,8]. In non-surgical body contouring, fillers can only be injected in the subcutaneous tissue, making it imperative to use low G' filler with small particle HA to prevent palpable irregularities. Despite the increasing use of these small particle low G' HABF, there is still limited scientific literature available on their efficacy and safety. This paper describes the authors' preliminary experience with this new class of HABF, and aims to contribute in understanding its efficacy and safety profile.

Material and methods

This retrospective observational investigation involved 21 consecutive patients, who underwent various body contouring procedures (as detailed in Table 1) between March and June 2022. This study was conducted in accordance with the ethical standards expressed in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Patient data and information were collected at baseline (first visit) and at the 6-months follow up visits.

Table 1. Patient's features, treatment performed and numbers of vials used.

Patient	Gender	Age (year's old)	Type of treatment	Number of vials used (10 mL per each vial)
1	M	32	Calves reshaping	8
2	M	41	Calves reshaping	12
3	F	38	Buttock reshaping	30
4	F	48	Deltoid reshaping	6
5	F	37	Buttock reshaping	32
6	F	42	Buttock reshaping	32
7	M	37	Calves reshaping	10
8	M	27	Depressed scar treatment	4
9	M	32	Calves reshaping	12
10	F	28	Buttock reshaping	24
11	M	29	Depressed scar treatment	5
12	F	54	Buttock reshaping	34
13	F	27	Inner tight reshaping	8
14	M	34	Calves reshaping	14
15	M	31	Calves reshaping	12
16	F	28	Inner tight reshaping	8
17	F	33	Buttock reshaping	28
18	F	31	Buttock reshaping	30
19	F	30	Buttock reshaping	32
20	M	30	Calves reshaping	12
21	M	44	Calves reshaping	12

Patients selection

The selection of an appropriate study group played a pivotal role in achieving successful results with HABF reshaping. The exclusion criteria were the following: patients under 18 years of age, pregnant or breast-feeding women, patients with a medical history of anaphylactic reactions and/or severe allergies, patients with any acute or chronic skin disease in the affected area, patients with severe organic diseases, patients previously injected with absorbable or non-absorbable fillers in the same area, the presence of permanent implants in the treated area (e.g., calf implants, gluteal implants), underweight (BMI<18) or obese (BMI>30) patients, patients with ptotic tissue in the targeted area.

Assessment

Treatment efficacy was assessed using the BODY-Q scale[9], a meticulously designed patient-reported outcome measure. The BODY-Q scale was specifically designed to assess outcomes for obesity, weight loss treatments (e.g., diet, exercise, and bariatric surgery/medicine), and body contouring, allowing to remove excess skin after massive weight loss and for cosmetic reasons. Clinicians and researchers could administer the subset of scales relevant to their field of interest. The scale's "satisfaction with body" section comprises a 10-item scale that measures satisfaction with body appearance. The items inquire about the body size, shape, clothing fit, as well as how body appearance from different angles, such as at the side, rear, in swimwear and when unclothed. Each item is rated on a scale of 1 to 10, and the maximum satisfaction score is 100 (10 points per item). The BODY-Q scale was used with permission from the Memorial Sloan-Kettering Cancer Center, New York, USA. Patients completed the BODY-Q scale "satisfaction with body" questionnaire at baseline (before treatment), and at their 6-months follow up visits.

Characteristics of the filler

The filler used in the present study (Hyamira body, Nyuma Pharma, Arona -NO-, Italy) was a monophasic, cross linked HA product with a concentration of 20mg/ml, commercialized in 10ml sterile vials. The HA molecular weight was 1500 kDa with BDDE cross-linking. This HA filler has low cohesivity, with G' at 20 Pa and G" at 10 Pa.

Technique

Each treatment was tailored to the patients' needs. The targeted areas were marked with patients in a standing position; they were asked to contract the underlying muscles in order to assess the presence of any volume deficit during movement. The areas which needed to be injected were marked with the aid of a mirror and photographs. Preceding the injection, the treatment area was disinfected using 80% isopropyl alcohol. An 18G cannula was used for the injection procedure. Local anesthesia was administered at the entry points of the cannula (0.2 mL of 1% lidocaine 1% (10 mg/mL) with adrenaline (1:500,000) solutions per point. Typically, two entry holes were identified, one on each side of the targeted area. The filler was introduced into the subcutaneous fat tissue exclusively in a retrograde fashion, through a continuous, streaming technique. The target area was filled as necessary, avoiding over-filling. Following the injection, a massage was performed over the injected area. Sterile stripes were used to close the entry hole. Patients were advised to avoid compression over the injected area and to refrain from any physical activity for 48 hours. Antibiotics were not prescribed, and in case of any post-treatment pain, 1g of paracetamol was recommended.

Results

Between March and June 2022, 21 consecutive patients underwent HABF injections for various indications in different anatomical areas, including buttock reshaping (n=8), calves reshaping (n=8), depressed scars (n=3), deltoids (n=1) and inner thighs (n=1). Among the participants, 11 patients were female, and 10 were male. The patients' age ranged from 27 to 54 years old, with a mean age of 33,1 years.

Table 2. BODY-Q score at baseline and at 6 months follow up.

Patient	BODY-Q score at base line	BODY-Q score at 6 months follow up
1	60	80
2	50	70
3	30	50
4	30	60
5	40	60
6	40	60
7	40	70
8	40	60
9	40	60
10	50	70
11	50	60
12	50	70
13	60	80
14	70	90
15	70	80
16	60	70
17	50	70
18	70	90
19	60	80
20	60	70
21	60	80

At baseline, the BODY-Q score ranged from a minimum of 30 to a maximum of 70 points, with a mean of 51.4 points. The most commonly performed procedures were buttock and calf reshaping, with a mean vial usage of 30.3 and 11.5, respectively. Notably, 6 months after treatment the mean BODY-Q score was observed to increase noticeably, rising from 51.4 to 70.9 (Table 2).

Throughout the study, no major complications or delayed granuloma were observed. Following the injections, patients experienced self-resolving firmness in the treated area and mild swelling within the first 2 weeks. Figures 1 to 6 show different patients' pictures taken before and 6 months after treatment.

Discussion

A significant increase in mean BODY-Q scores was observed 6 months after the procedures, indicating the patients' satisfaction with the results of HABF injections.

The first HABF introduced into the market was Macrolane, a NASHA-based (stabilized hyaluronic acid of non-animal origin) medical implant, which was developed and approved in Europe in 2006 but later withdrawn in 2011 due to reported issues[10]. Despite, its approval in Europe, Macrolane was never approved by the U.S. Federal Drug Administration (FDA) and, consequently, not commercialized in the U.S.

The use of HABF remains a topic of debate and received limited investigation in the current literature. Over the past decade, a few papers were published, particularly focusing on buttock reshaping[6,11-13].

In a recent review, Atiyeh et al. examined the "safety and efficiency of minimally invasive buttock augmentation". The analysis included 12 highly biased clinical reports which presented minimal evidence. These reports involved different fillers, including Polymethylmethacrylate (PMMA), Poly-L-lactic acid, Calcium hydroxyapatite and HA[14]. The authors concluded that gluteal augmentation with soft tissue fillers is not as straightforward and harmless as advertised, as serious complications may occur, particularly with the use of non-permanent fillers like PMMA[14].

Several case series suggest that HABF injections lead to long-lasting results with a high safety profile. Cerqua et al. demonstrated that a 60-70% correction persisted in 90% of participants 8 months post-injection. They asserted that HABF injections are a predictable, safe, and long-lasting non-surgical procedure for filling contour defects that arise following liposuction[15]. De Meyere et al. observed that 24 months after buttock reshaping with HABF, a good proportion of patients rated their buttocks as improved (40%), and expressed satisfaction (33%)[11]. Also, Santorelli et al., in a recent case series, reported a statistically significative improvement in buttock appearance following HABF injections at the 6-months follow-up[6].

While major complications following HABF are rare, minor issues, such as delayed granuloma, excessive firmness and superficial irregularities were frequently described, especially when large volumes of HABF were used[6]. In the present study, no complications were observed. However, the rheology properties of the involved filler are largely different compared to

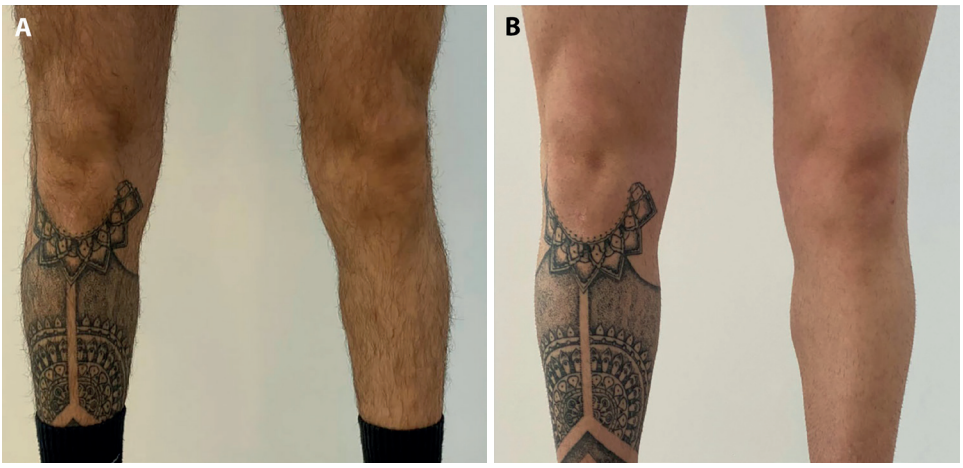

Figure 1. Frontal view of calves reshaping in a 32 years old male patient. Pre (a) and post 6 months (b) from the treatment.

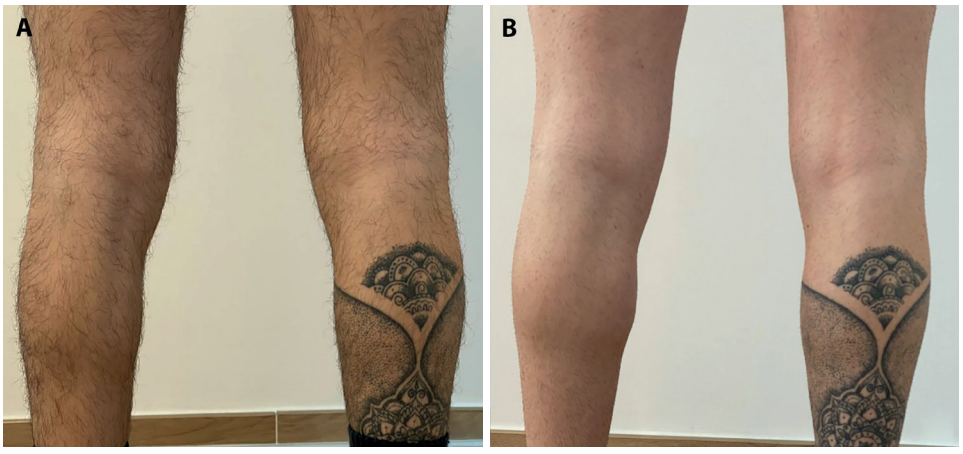

Figure 2. Back view of calves reshaping in a 32 years old male patient. Pre (a) and post 6 months (b) from the treatment.

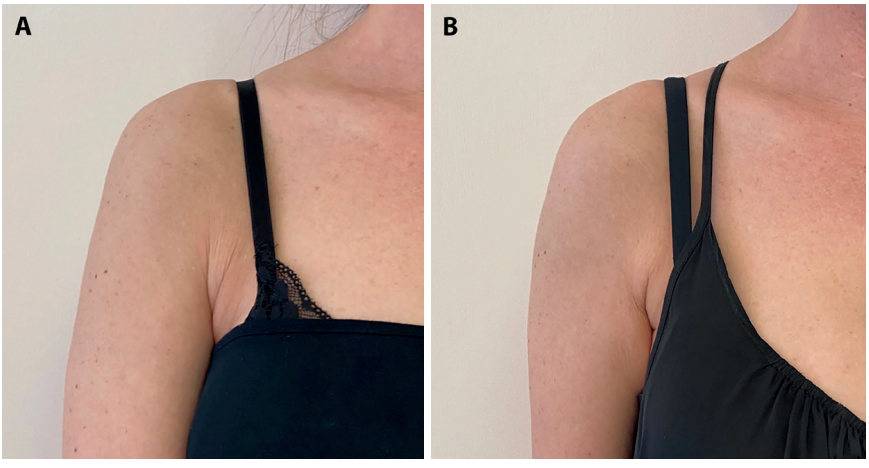

Figure 3. Frontal view of right deltoid reshaping in a 48 years old female patient. Pre (a) and post 6 months (b) from the treatment.

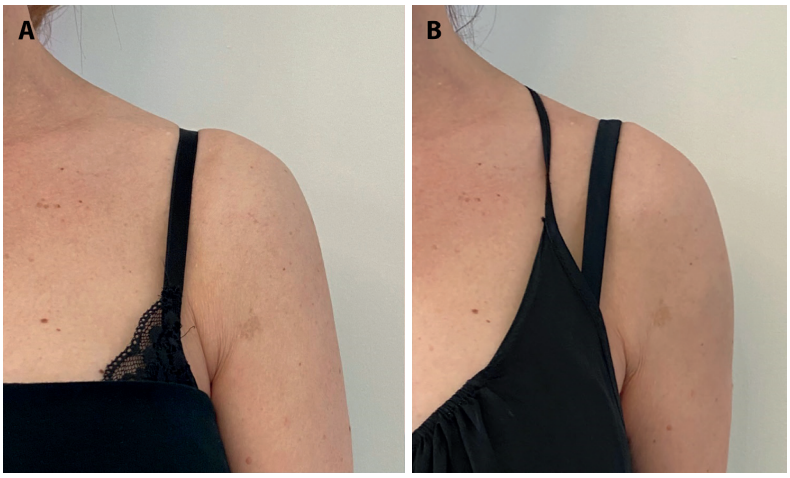

Figure 4. Frontal view of left deltoid reshaping in a 48 years old female patient. Pre (a) and post 6 months (b) from the treatment.

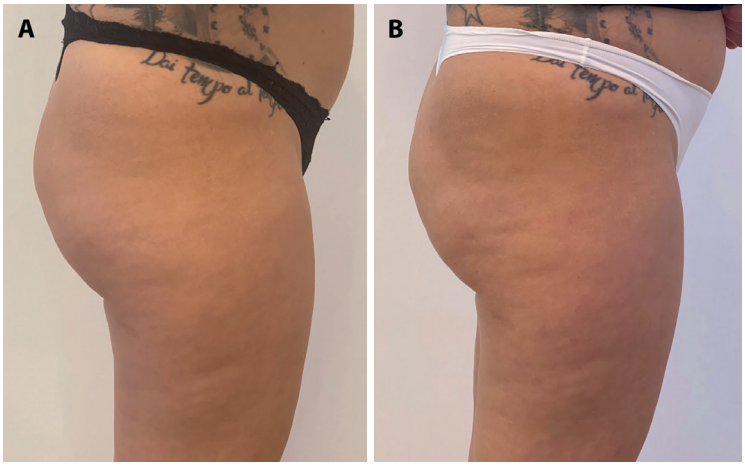

Figure 5. Right lateral view of buttock reshaping in a 38 years old female patient. Pre (a) and post 6 months (b) from the treatment.

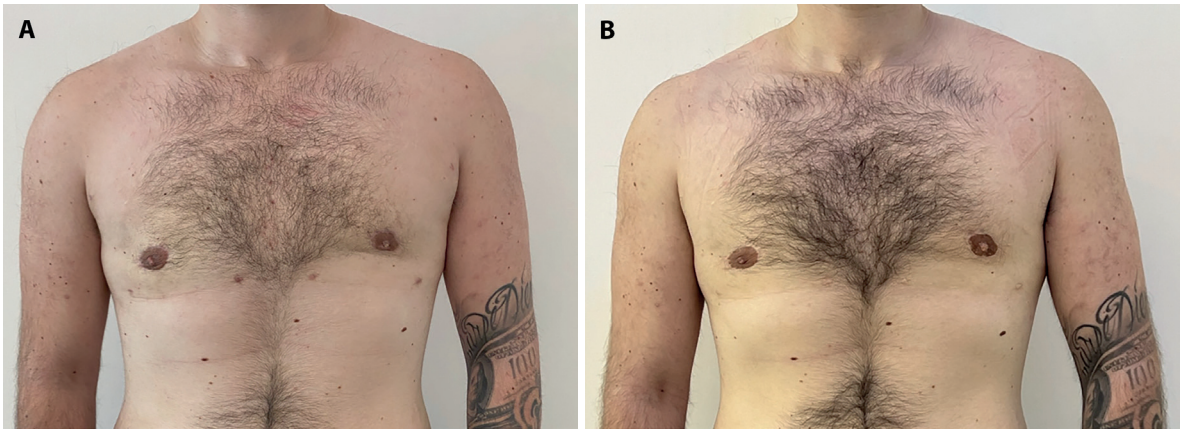

Figure 6. Frontal view of a 29 years old male patient. Pre (a) and 6 months after the filling procedures to release the skin retraction of the left lower edge of pec major muscle secondary to gynecomastia treatment.

those investigated by other authors. Most frequently, large particle HA fillers are used to restore or reshape the body areas. Despite the filler being injected subcutaneously more than in the superficial skin layers, the large HA particle can be easily seen and palpated. Moreover, the use of a large volume of large particle HA fillers may induce hardening or firmness of the injected area[6,15].

A small-particle, low G' (20 Pa) HA filler was used in the present study. G' represents the "storage/elastic" modulus, measuring the gel elastic behavior and its ability to recover its shape after shear deformation. Higher G' values indicate stronger projection achieved after filler injection but are associated with stiffness[8]. For this reason, high G' filler is usually injected at direct contact with the facial skeleton to avoid visibility, whereas lower G' fillers are more suitable for subcutaneous injections, as performed in body reshaping[7]. Understanding the behavior of fillers with different rheologic properties is of paramount importance to prevent post-treatment issues, especially if large volumes are involved to treat extended contour deficits.

Santorelli et al. affirmed that gluteal augmentation with HA should be managed as a prosthetic implant procedure, particularly within the first two years. According to the authors any treatment that uses more than 30 mL of HA should be performed in a sterile field as for surgical procedures[6].

In the present paper an average of 302.5 mL of HABF was employed for buttock reshaping. All the procedures were performed at the office with the same setting of a facial filler, without post-operative antibiotic therapy. Despite the variability of the treated defects and the considerable filler volume used in specific instances (i.e. the buttock reshaping meanly received three times the volume compared to the other procedures), no major or minor complication occurred.

Our case series suggests that using low G' HA filler in body contouring reduces the risk of visible irregularities and tissue hardening, without necessitating larger volume injections compared to fillers used in previously published studies.

Limitations of the present study may be the retrospective design and the relatively small study group, though it highlighted interesting insights in using small particle low G', HA fillers in body reshaping. Additionally, the short six-month follow-up period might be considered another limitation, but it aligns with the mean lifetime of the filler used, which is nine months. While imaging techniques were not employed to evaluate the results, the use of the BODY-Q scale provided a subjective assessment of the obtained outcomes.

Conclusion

In this study we observed that the use of small particle low G', HA fillers for body reshaping represent a safe and minimally invasive procedure with satisfactory aesthetic results and adequate safety profile.

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