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ORIGINAL ARTICLE NON-SURGICAL AESTHETIC

Stabilized Hyaluronic Acid Gel for Volume Restoration and Contouring of the Buttocks: 24-Month Efficacy and Safety

Bruno De Meyere · Sebastian Mir-Mir · Juan Peñas · Colette C. Camenisch · Per Hedén

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Abstract
Background Stabilized hyaluronic acid (HA) of nonanimal origin manufactured using the patented NASHA® technology has been developed for use in body shaping. This study was performed to assess the safety and efficacy of stabilized HA gel when used for volume restoration and contouring of the buttocks.
Methods Subjects 20 years of age or older seeking buttock augmentation were recruited to this noncomparative multicenter study (NCT01331408). Gel at a maximum volume of 400 mL per subject was injected during one or two treatment visits. Safety and efficacy assessments (24-month follow-up evaluation) included adverse event (AE) reporting, aesthetic improvement (Global Aesthetic Improvement Scale [GAIS]), and subject satisfaction.
Results In this study, 61 subjects received a mean total volume of 340 mL (range 200–420 mL) of stabilized HA gel. According to subject GAIS assessment, buttock appearance was rated as "improved," "much improved," or "very much improved" by 80, 68, 42, and 40 % of subjects after 6, 12, 18, and 24 months, respectively. Subject satisfaction with buttock size, shape, firmness, and general appearance was higher than before treatment at all the time points, with a peak of 70 % of the subjects satisfied 1 month after treatment. During the 24 months, no unexpected or serious treatment-related AEs occurred. One subject experienced gel dislocation to the sacral area.
Conclusions The data show that stabilized HA gel is a safe and effective treatment for temporary aesthetic augmentation of the buttocks. Although the substance degrades over time, a good proportion of the subjects still rated their buttocks as improved (40 %) and expressed satisfaction (33 %) 24 months after treatment.
Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Macrolane® · Stabilized HA gel · Buttocks · Contouring · Safety · Efficacy

During the last few decades, the demand for techniques to enhance or alter body surfaces or body contours has increased for both medical and aesthetic reasons. According to the American Society for Aesthetic Plastic Surgery, buttock enhancement was one of the fastest growing areas of aesthetic surgery in 2010 [9]. The main reasons why people request buttock augmentation are as follows: to regain shape lost by weight loss or aging [1], to increase attractiveness [24, 31] and to correct human immunodeficiency virus (HIV)-associated lipoatrophy [7].

In 1969, Bartels et al. [2] used breast silicone implants to achieve volume restoration in buttocks with atrophy of the gluteal muscles, which then were followed by gluteal implants [16]. With the advent of liposuction in the 1980s [20], autologous fat grafting was subsequently developed

B. De Meyere
Artemedis Center for Plastic Surgery, Sint-Denijs-Westrem, Ghent, Belgium

S. Mir-Mir
Centro Clínico Mir-Mir, Barcelona, Spain

J. Peñas
Hospital San Rafael, Madrid, Spain

C. C. Camenisch · P. Hedén (✉)
Akademikliniken, Storängsvägen 10, 115 42 Stockholm, Sweden
e-mail: per.heden@ak.se

for buttock augmentation. However, together with flap surgery, all these traditional methods of buttock enhancement are surgical procedures, some of which (e.g., flap surgery and implants) can produce scarring. Additionally, implant augmentation is associated with a high rate of complications (e.g., poor wound healing and dehiscence) [3, 26], whereas successful autologous fat grafting requires experience and excellent execution [8] and has unpredictable results [4, 13, 22]. Although findings generally have shown fat transfer to be safe and relatively effective [6, 11, 29], the technique is suitable only for subjects with a sufficient amount of body fat, and many people are now seeking other less invasive procedures.

Stabilized hyaluronic acid (HA) of nonanimal origin manufactured using the patented NASHA® technology was developed during the early 1990s as a dermal filler for use in facial aesthetics (Restylane®; Q-Med AB, Uppsala, Sweden) and has established an excellent efficacy and safety profile [12, 14, 15, 28, 33, 34] in more than 15 million treatments worldwide (unpublished data, Galderma, Uppsala Sweden). A specific formulation (Macrolane® VRF; Q-Med AB) has since been developed and was launched for use in body contouring in 2007. Although stabilized HA gel is no longer marketed for the breast indication due to an ongoing debate on issues with radiologic imaging for breast screening, findings have shown that volumes reaching 220 mL of stabilized HA gel injected into the breast are efficacious and well tolerated [17, 19, 21].

Stabilized HA gel is composed primarily of water (98 %) and HA (2 %). It is biocompatible and biodegradable and, like implants and fat grafts, adds volume simply by occupying space within the tissue. The gel's biodegradable nature means that any treatment effects are not permanent, allowing for reassessment and retreatment as the body changes with time. Like fat injections, stabilized HA gel injections also require expert knowledge concerning the anatomy of the treatment site and experience with injection techniques in the relevant area.

This 24-month follow-up study aimed to determine the safety and efficacy of stabilized HA gel up to 400 mL used for buttock augmentation.

Methods

This prospective, open-label, noncomparative, multicenter study (NCT01331408) performed in Belgium, Spain, and Sweden analyzed subjects 20 years of age or older seeking augmentation of the buttocks. The study was conducted in accordance with the Declaration of Helsinki and approved by the following independent ethics committees: Commissie voor medische ethiek, UZ, Gent; CEIC Fundació Unió Catalana d'Hospitals, Barcelona; CEIC Hospital, Universitario La Princesa, Madrid; Regionala etikprövningsnämnden i Stockholm.

The exclusion criteria for the study ruled out active skin disease, HIV-associated lipoatrophy, tumors or premalignant tissue disorder near or on the area to be treated, scar tissue on the area to be treated, liposuction or other surgical procedures in the area performed 6 months or less before study inclusion, body mass index (BMI) lower than 20 kg/m^2 or unstable weight, skin fold thickness less than 2 cm, and excessive skin laxity (>50 %).

Skin fold thickness and laxity were determined during a pretreatment evaluation of the area to be treated. Skin fold thickness was measured using calipers over the subcutaneous layer (where possible), and skin laxity was determined by measuring the distance between two points marked on the skin while the skin was relaxed, and once again when the skin was stretched. Skin laxity was defined as the percentage difference between these two measurements.

A maximum of 400 mL of stabilized HA gel (Macrolane® VRF30, 20 mg/mL HA stabilized in phosphate-buffered saline) per subject was injected into the deep subcutaneous fatty tissue supramuscularly through a 5-mm incision created using a no. 15 scalpel blade. The position of the incision was determined at the discretion of the investigators. The subjects received local anesthesia in the injection area (the majority of subjects received 0.5 or 1 % lidocaine with epinephrine), with some also receiving sedatives (the majority of the subjects received low doses of propofol, rapifen, or both).

The stabilized HA gel was injected in small aliquots spread across the area (not as a single bolus) using a multi-tunneling technique similar to that used for fat grafting, performed with a 15-cm, 12-gauge cannula with a blunt tip. The cannula was pulled backward slowly during the injection. Because a blunt cannula was used, deposit of the stabilized HA gel was allowed in both the ante- and retrograde directions.

The subjects were followed up for safety and efficacy 1 month (3–6 weeks) and then 6, 12, 18, and 24 months after treatment (Fig. 1). An optional touch-up treatment could be performed within 8 weeks after the initial treatment if the following criteria were fulfilled: the subject was willing; the investigator's or subject's Global Aesthetic Improvement Scale (GAIS) score at visit 3 was less than "very much improved" (see details on GAIS ratings presented later). No persisting adverse events (AEs) related to the stabilized HA gel occurred, and no medical reason prohibited touch-up treatment.

The subjects were advised to avoid strenuous activity, including constant pressure in the treated area, for a 2- to 3-week period after the initial treatment and after the touch-up treatment. To avoid constant pressure in the injected area, the subjects were instructed to be careful when sitting upright and to avoid putting pressure on the

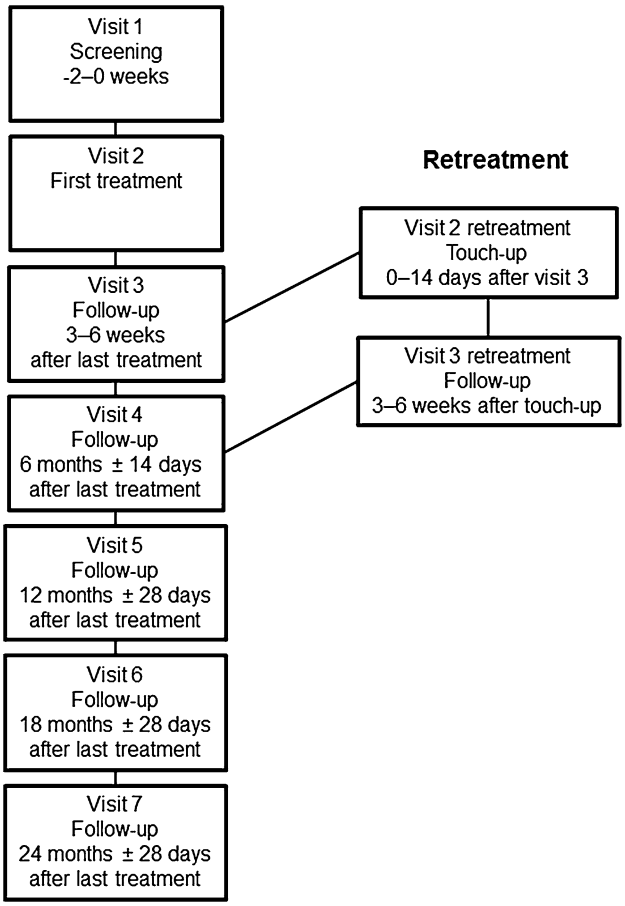

Fig. 1 Study flow

injected areas. However, the subjects were not specifically asked to avoid lying in the supine position, although sleeping in the prone position could avoid putting pressure on the injected areas.

Magnetic resonance imaging (MRI) was performed on a subset of eight subjects in Sweden to determine the location of stabilized HA gel within the tissue [5].

Efficacy was assessed independently by the subjects and the investigator at each follow-up visit by comparing pre- and postprocedure photographs. The treatment result for each buttock was rated according to GAIS using the following categorical scale: "very much improved," "much improved," "improved," "no change," or "worse." Subject satisfaction was assessed in terms of buttock size, shape, and firmness as well as general patient satisfaction using an evenly weighted 7-point scale ranging from "completely satisfied" to "completely dissatisfied."

All efficacy analyses were performed on the intention-to-treat population, which included all the subjects treated with the study product. No imputations for missing data were made. In addition to descriptive statistics, the primary efficacy analysis (proportion of improved subjects based on subjects' GAIS assessment at 6 months) was performed using a two-sided 95 % confidence interval (CI).

Safety was assessed by AE reporting and examination by the investigator. A modified four-grade capsular contracture scale was used to assess consistency across the area, tenderness, and appearance. The following grades were used: "normally soft and looks natural" (grade 1), "a little firm and looks normal" (grade 2), "firm and looks abnormal" (grade 3), and "hard, painful, and looks abnormal" (grade 4). The subjects' satisfaction with the injection procedure and assessment of expected events (e.g., redness, swelling, tenderness, pain, bruising, and itching at implant site) were recorded. Expected events were classed as AEs if they lasted for more than 2 weeks. The safety analysis included all the subjects treated with the study product.

Results

Treatment Groups

In this study, 61 subjects were treated with stabilized HA gel injections in the buttocks, and 17 subjects received touch-up treatment within 8 weeks after the initial treatment. Of the 61 subjects, 50 completed the 24-month follow-up period. Nine were lost to follow-up evaluation. One subject moved, and one subject withdrew from the study due to removal of the gel because of its complete dislocation (discussed later). The demographic characteristics of the subjects are summarized in Table 1.

Table 1 Summary of demographic characteristics

Baseline characteristics	$n = 61$
Mean age, years (range)	41.3 (20.1–64.5)
Sex, *n* (%)	
Female	57 (93)
Male	4 (7)
Ethnicity, *n* (%)	
Caucasian	54 (88.5)
Hispanic/Latino	4 (6.6)
Black/African American	1 (1.6)
Other	2 (3.3)
Mean weight, kg (range)	60.7 (47.0–77.0)
Mean height, cm (range)	166.6 (153.0–179.0)
Mean BMI, kg/m^2 (range)	21.8 (18.6–27.9)
Mean skin-fold thickness, cm (range)	3.5 (1.8–7.5)
Mean skin laxity, % (range)	31.2 (10.0–50.0)
Prophylactic antibiotics, *n* (%)	38 (62.3)
IV flucloxacillin 2 g	16 (26.2)
Oral antibiotics only	22 (36.1)

BMI body mass index, *IV* intravenous

Injection Procedure

The total volume (mean ± standard deviation) of the stabilized HA gel injected per subject was 340 ± 62 mL, including the touch-up volume. On average, the initial treatment involved approximately 300 mL per subject. A total of 17 subjects received touch-up involving approximately 120 mL per subject.

The number of incision sites was generally one per buttock (maximum of two per buttock), except in six subjects, who had one midline incision. In most of the subjects, the stabilized HA gel was implanted in the mid third (97 %) and upper third (92 %) of each buttock at the initial treatment. Stabilized HA gel also was placed in the lower third and lateral part of the buttocks in 36–46 % of the subjects. Touch-up was done in the mid third of each buttock for 82 % of the subjects, and 41–53 % of the subjects also had touch-up in the lower third and lateral part of the buttocks. The upper third of the buttocks was treated with touch-up less frequently (in 6–18 % of the subjects).

Across all the study sites, local anesthesia was used for initial treatments in 92 % of the subjects and sedatives in 38 % of the subjects. General anesthesia was used in six subjects at one study site, which was a protocol violation.

The injections required an average 21 min for the initial treatment and 15 min for the touch-up treatment. A total of 38 subjects (62 %) from three study sites in Sweden and Spain received prophylactic antibiotics before treatment, administered at the discretion of the investigator, which were not part of the study protocol.

The majority of the subjects (65 %) found the initial and touch-up treatments acceptable (from a score of "acceptable," "unpleasant," or "very unpleasant"). During the treatment, 31 subjects receiving initial treatment (51 %) and 7 subjects receiving touch-up treatment (41 %) experienced mild or no pain. Pain was less during the initial treatment when both local anesthesia and sedatives were used (16 subjects [84 %] reporting no or mild pain) than when local anesthesia alone was used (15 subjects [42 %] reporting no or mild pain). No subjects received sedatives for touch-up treatment.

Efficacy

As reported in the substudy of eight subjects who underwent MRI assessment, 100, 56, 36, and 24 % of stabilized HA gel remained in the buttocks per subject respectively 1–5 days, and then 6, 12, and 24 months after treatment [5]. Aesthetic improvement in two representative subjects is shown in Fig. 2. According to GAIS assessment, 6 months after treatment, buttock appearance was rated as improved or better (i.e., "improved," "much improved," or "very much improved") in 80 % of the subjects as assessed by the subjects themselves (95 % CI 68–90 %), and in 91 % of the subjects as assessed by the investigators (Table 2; Fig. 3). At 1 year after treatment, buttock appearance was assessed as improved or better in the majority of subjects by both the subjects themselves (68 % improved subjects) and the investigators (62 % improved subjects). The improvement rates reported by subjects still were 42 % at 18 months and 40 % at 24 months.

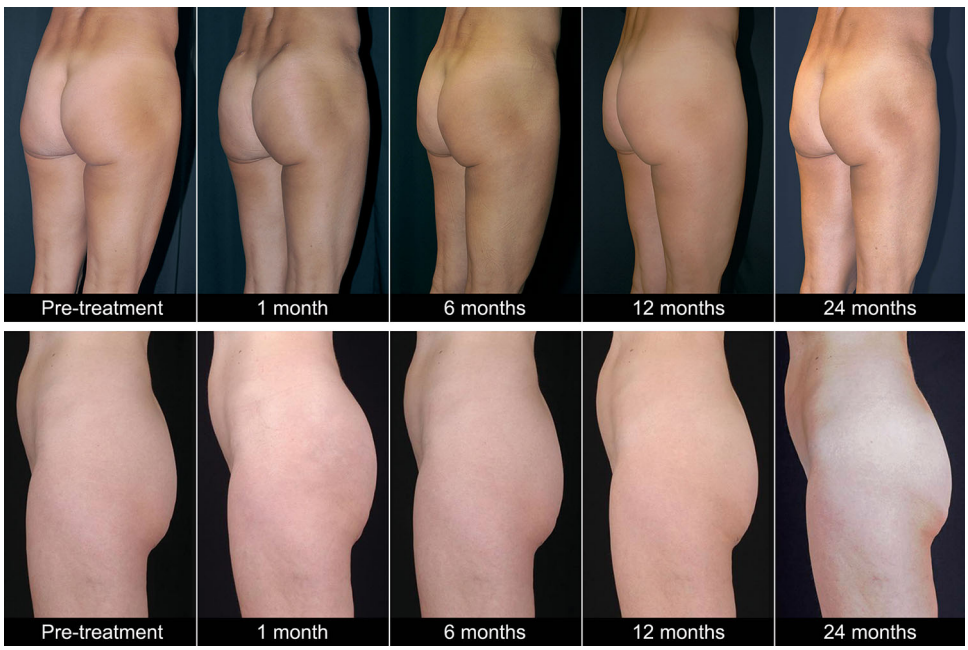

Fig. 2 Aesthetic results of treatment with stabilized hyaluronic acid (HA) gel for two representative subjects

Table 2 Subject-reported score on the Global Aesthetic Improvement Scale (GAIS)

GAIS	3–6 weeks after last treatment		6 months after last treatment		12 months after last treatment		18 months after last treatment		24 months after last treatment	
	n	%[a]	*n*	%[a]	*n*	%[a]	*n*	%[a]	*n*	%[a]
Worse	1[b]	1.8	1	1.8	2	4.0	–	–	–	–
No change	4	7.0	10	17.9	14	28.0	25	58.1	28	59.6
Improved	22	38.6	28	50.0	27	54.0	15	34.9	14	29.8
Much improved	21	36.8	13	23.2	3	6.0	1	2.3	3	6.4
Very much improved	9	15.8	4	7.1	4	8.0	2	4.7	2	4.3
Total	57	100.0	56	100.0	50	100.0	43	100.0	47	100.0

[a] %, percentage of subjects with data

[b] Subject was withdrawn after visit 3 (3–6 weeks after last treatment) due to an adverse event (see Safety and Tolerability section)

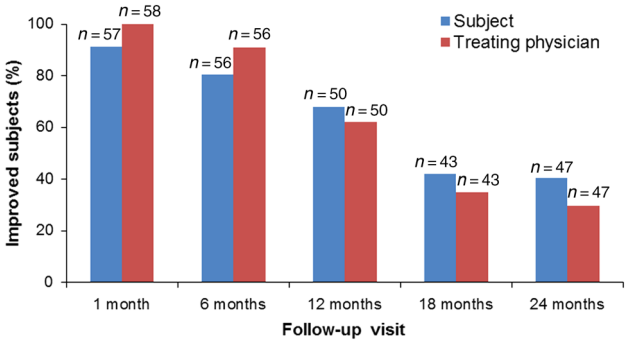

Fig. 3 Percentage of subjects graded as "improved," "much improved," or "very much improved" by the subjects and the treating physician using the Global Aesthetic Improvement Scale (GAIS). The percentages shown include all the patients graded as "improved," "much improved," or "very much improved."

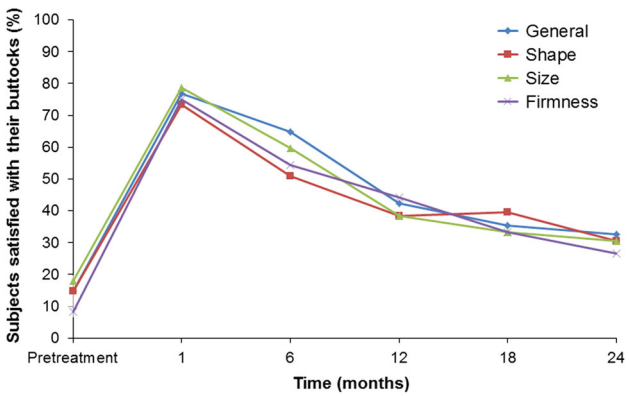

Fig. 4 Subject satisfaction with buttock appearance after stabilized hyaluronic acid (HA) gel treatment

Investigator assessments of improvement rates were 35 % at 18 months and 30 % at 24 months.

Before entering the study, approximately half of the subjects were dissatisfied with their buttocks in general: 75 % with the firmness, 61 % with the size, and 64 % with the shape. After treatment, the subjects' satisfaction with the general appearance, shape, size, and firmness of their buttocks increased and remained higher throughout the study period than before treatment (Fig. 4). For example, general satisfaction rose from below 20 % before treatment to above 70 % 1 month after treatment, then declined thereafter to about 40 % of subjects being satisfied 12 months after treatment. Even after 24 months, at least 33 % of subjects still reported general satisfaction with their buttocks.

Safety and Tolerability

The incidences of expected events (tenderness, pain, swelling, itching, redness, and bruising) are shown in Table 3. An increased number of the subjects showed a tendency to report swelling, pain, and redness when a higher volume of stabilized HA gel was injected. Most events (>80 %) were mild to moderate in intensity and resolved after a mean duration of 7 days.

During the entire 24-month follow-up period, 39 % of the subjects did not report any AEs, whereas 34 % of the subjects reported 37 treatment-related AEs during the 24 months after treatment. None of the AEs assessed by the investigator as related to treatment were serious.

The most common treatment-related AE was implant-site swelling, which occurred for five of the subjects (Table 4). Implant-site swelling was reported as an AE only if it lasted more than 2 weeks. The 37 treatment-related AEs included one infection of moderate severity, which resolved after treatment. The infected subject had received prophylactic antibiotics before treatment. None of the subjects who received no prophylactic antibiotics before treatment experienced posttreatment infections judged to be treatment related by the investigator.

Investigator assessment of capsular contracture to determine consistency, tenderness, and appearance showed that 1 month after initial treatment and touch-up treatment, 50–60 % of the subjects had slightly firmer buttocks, with

Table 3 Incidence of expected events reported in the subject diaries occurring within 2 weeks after initial treatment and touch-up treatment

Expected event	Initial treatment			Touch-up treatment		
	n (%)[a]	% Mild/moderate	Mean duration (days)	*n* (%)[a]	% Mild/moderate	Mean duration (days)
Subjects affected	57 (93.4)	–	–	12 (70.6)	–	–
Expected event						
Tenderness	49 (80.3)	82.9[b]	7.9	8 (47.1)	75.0	6.0
Pain	44 (72.1)	65.9	6.5	7 (41.2)	57.1	5.6
Swelling	41 (67.2)	92.7	6.7	8 (47.1)	87.5	6.2
Itching	26 (42.6)	96.2	6.0	7 (41.2)	100	9.0
Redness	22 (36.1)	90.9	7.0	6 (35.3)	83.3	6.0
Bruising	21 (34.4)	80.9	10.5	4 (23.5)	100	7.8

[a] No. of subjects for whom an expected event occurred at least once

[b] Severity data not available for two subjects

Table 4 Summary of treatment-related adverse events (AEs) experienced by three or more subjects classified according to the *Medical Dictionary for Regulatory Activities* (MedDRA) system organ class and preferred term

MedDRA system organ class preferred term	No. of subjects	Total no. of AEs	No. of mild AEs	No. of moderate AEs	Mean time to onset (days)	Mean duration (days)
General disorders and administration-site conditions						
Device dislocation	3	3	3	0	0	433.7
Injection-site pain	4	4	2	1	5.5	28.3
Implant-site pain[a]	3	3	1	2	14.0	12.0[b]
Implant-site pruritis[a]	4	4	3	0	3.5	28.7[b]
Implant-site hematoma	4	4	3	0	4.8	17.3
Implant-site swelling[a]	5	5	4	0	4.4	76.8

[a] Classified as an AE because it lasted for more than 2 weeks

[b] One event still ongoing at study end

18 % of the subjects still showing slightly firmer buttocks at 6 months. Capsular contracture rates were minimal up to 24 months after treatment, at which point, 98 % of subjects were graded as having normally soft buttocks.

During the entire study period, only one subject had abnormal-looking firm buttocks 12 months after treatment. The subject felt no pain or discomfort from this, and the buttocks had returned to normal softness by the 18-month visit.

Local displacement of the injected material into the injection tunnel was reported in two subjects but resolved spontaneously and required no action. A third subject with a low BMI (19 kg/m^2) experienced dislocation of the gel outside the buttock, with formation of a small nodule cranially toward the iliac crest and also a nodule laterally toward the tensor fascia lata. After removal of the scar at the injection point, this dislocation was easily resolved by pressing out the gel through the incision hole and by the injecting 3,000 IU of hyaluronidase dissolved in 100 mL saline using a 15-cm infiltration cannula.

Discussion

Buttock augmentation aims to create a round and projected buttock contour. The current study showed that stabilized HA gel is an effective, minimally invasive treatment for volume restoration and contouring of the buttocks, with high improvement rates and levels of subject satisfaction observed up to 12 months after treatment. Interestingly, improvement rates were still as high as 40 % 24 months after treatment although much of the gel had degraded [5].

These results are consistent with improvement rates observed after breast enhancement with stabilized HA gel [17, 18]. The reduction in volume with time reflects the biodegradable nature of stabilized HA gel and allows for retreatment that can adapt to changes in the body that occur through aging.

The same injection technique used for fat grafting with small deposits in multiple channels was used. Ultimately, the skin entry site will vary according to individual subject

anatomy, planned area of injection, and physician preference. However, a proximal injection site minimizes the risk of gravitational migration and nodule formation at the injection site.

This was the first study to use a volume of stabilized HA gel as high as 400 mL injected into the body. Up to 1,200 mL of fat has been injected during fat grafting [27]. Therefore, volume per se is not a limiting factor for augmentation of the buttock.

In the current study, more swelling, pain, and redness were reported when higher volumes were injected. This is similar to the increased reports of complications observed when higher volumes of fat are injected during fat grafting of the buttocks [3]. Further studies using higher volumes of stabilized HA gel in the buttocks are required to determine the efficacy and complication rates. However, it is the authors' experience that the anatomic borders during injection procedures should be respected to minimize the risk for these local complications. Additionally, "overfilling" can potentially increase other complications, such as dislocation of the stabilized HA gel.

The results of the current study suggest that subjects with a low BMI are not suitable candidates for buttock enhancement because they have a higher risk of visibility or palpability of the gel. The BMI of the subject who required treatment for dislocation of stabilized HA gel was 19 kg/m^2. Additionally, a low BMI could result in placement of the gel in the intramuscular region, which might be associated with a higher rate of degradation of stabilized HA gel [5]. The risk for dislocation of the gel is likely to be reduced if subjects avoid pressure on the treated area for the first 2–3 weeks after treatment (e.g., caused by sitting upright). Another potential reason for dislocation of the gel is the use of tight underwear after treatment, which caused noticeable lumps on either side of the buttocks for one subject in the current study.

Most AEs were mild and expected (e.g., bruising and itching) and resolved spontaneously. Common AEs resulting from breast enhancement (e.g., capsular contracture and stabilized HA gel nodules) appeared to be less of an issue in the buttocks because only one subject had abnormal-looking firm buttocks during the entire study period. Moreover, mild capsular contracture results in firmness, which could be viewed as an advantage in the buttocks, and only one subject reported implant site nodules of stabilized HA gel (1.6 %), compared with 33 % of the subjects who received stabilized HA gel injections in the breast [18].

In other studies of stabilized HA gel injections into the breast, infection rates have been very low (0–0.5 %) [17, 21]. The infection rate of 1.6 % reported in the current study generally is lower than infection rates reported with fat grafting and silicone implants in the breast and buttocks ($\leq$14 %) [3, 30, 32], although infection rates as low as 1.1–2.7 % have been reported after fat grafting in the buttocks when intraoperative intravenous antibiotics have been administered [3, 29]. In fact, infection is the most common major complication after autologous fat grafting [3].

In the current study, a single dose of prophylactic antibiotics (e.g., intravenous flucloxacillin or oral ciprofloxacillin) was given to 62 % of the subjects before the initial treatment and to 72 % before the touch-up treatment, although this was not a requirement of the study protocol. Although the only patient to experience an infection in this study had received prophylactic antibiotics, the literature suggests that, as with all implant surgeries, the use of intravenous antibiotics before surgery, a sterile environment, and appropriate skin preparation are important to help prevent infection during the postoperative period [23]. Additionally, any signs of postoperative infection should be treated with antibiotics as suggested by implant site cultures taken before the start of antibiotic treatment.

Buttock enhancement with stabilized HA gel offers several advantages over other forms of buttock augmentation. In this study, for example, the treatment time was shorter ($\sim$15–20 min) than for the surgical interventions of fat grafting and implant surgery. In addition, no other method can produce such a dramatic change in buttock shape so simply and quickly and with so little discomfort. Although buttock implants can cause subjects to be incapacitated for 15–30 days after surgery and can cause extreme pain when the patient lies down [11], most of the expected events reported by the subjects in this study were mild or moderate in nature and resolved within 7 days.

Additionally, treatment with stabilized HA gel resulted in fewer reports of intense pain when a combination of sedatives and local anesthetics was used. The proportion of subjects experiencing pain was as low as for those who receive breast augmentation using stabilized HA gel [17]. Also, stabilized HA gel treatment does not require any pretreatment preparation such as liposuction, which is associated with risks such as fat embolism and hemorrhage [10, 25]. Stabilized HA gel also is a suitable treatment for those subjects who may not have sufficient fat deposits for grafting as long as their BMI is higher than 20 kg/m^2.

The cost effectiveness of stabilized HA gel for buttock treatment has not been studied. However, the cost of the treatment should be weighed against the subject's wish not to undergo surgery, the volume that would be required, and the fact that injection treatment generally is a less complicated procedure than implant insertion surgery. Stabilized HA gel also is more versatile than permanent implants and can be used for both contouring and augmentation purposes. In addition, its biodegradable properties allow it to be used as an indicator of the effect that could be achieved with permanent implants.

As with any aesthetic procedure, only subjects with realistic expectations should receive stabilized HA gel treatment, and thus it is important that they be well informed about the highly variable degradation time. Physicians should have a thorough knowledge of buttock anatomy and injection technique before attempting buttock enhancement with stabilized HA gel.

Conclusion

In summary, the data show that stabilized HA gel is a safe and effective minimally invasive alternative to permanent implants and fat grafting for volume enhancement and contouring of the buttocks. Although the substance degrades over time, a good proportion of subjects still rated their buttocks as improved and expressed satisfaction with the results 24 months after treatment.

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