

ORIGINAL RESEARCH—MEN'S SEXUAL HEALTH

The Effects of Penile Girth Enhancement using Injectable Hyaluronic Acid Gel, a Filler

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ABSTRACT

Introduction. Despite the debates on penile girth enhancement (PGE), demands for enhancement are increasing. Recently, various fillers have been widely used for soft tissue augmentation with proven efficacy and safety.

Aims. To identify the feasibility and efficacy of PGE by injection of filler.

Methods. Fifty patients with subjective small penis who visited Korea University Guro outpatient clinic were enrolled and prospectively followed. Restylane Sub-Q (Q-med, Upssala, Sweden) was injected into the fascial layer of penile body via 21G cannula with “Back & Forth Technique” and homogenized with a roller.

Main Outcome Measures. From April 2006 to February 2008, 50 patients were enrolled and 41 patients were followed until 18 months after PGE. Changes in penile girth at midshaft were measured by tapeline at 1 and 18 months. Patient's visual estimation of residual volume (Gr 0–4), patient's satisfaction (Gr 0–4), and any adverse reactions were also evaluated.

Results. Mean injected volume was 20.56 cc (18–22). Compared with basal girth of 7.48 ± 0.35 cm, maximal circumference was significantly increased to 11.41 ± 0.34 cm at 1 month ($P < 0.0001$) and maintained as 11.26 ± 0.33 cm until 18 months. In patient's visual estimation, two patients complained the decrease as Gr 3 with focal depression at 1 month. At 18 months, all patients answered as Gr 4 without asymmetry. Patient's and partner's satisfaction score was 3.71 ± 0.46 and 3.65 ± 0.48 at 1 month and 3.34 ± 0.53 and 3.38 ± 0.49 at 18 months. There were no inflammatory signs or serious adverse reactions in all cases.

Conclusions. Considering the property of material, methods, and follow-up results of 18 months, PGE using filler is a very effective and safe technique for penile augmentation. **Kwak TI, Oh MM, Kim JJ, and Moon DG. The effects of penile girth enhancement using injectable hyaluronic acid gel, a filler. J Sex Med 2011;8:3407–3413.**

Key Words. Penis; Augmentation; Filler; Hyaluronic Acid; Penile Size

Introduction

Current criticisms to penile augmentation are that there is no established procedure, poorly defined indications, unacceptably high reported complications, and no reliable long-term satisfactory results [1–3]. To save debilitated patients from the adverse effects of previous penile augmentation technique and fulfill the request of the patients, it is necessary to develop a new, safer, and more effective technique rather

than criticize penile augmentation or regard it as evil magic.

In the last decade, hyaluronic acid (HA) has been shown to possess many properties that suggest its value in several medical applications, particularly in ophthalmology, orthopedics, and esthetic soft-tissue augmentation with proven efficacy and safety [4–6].

The authors already reported the feasibility and 5 year's results of penile glans augmentation (PGA) using injectable HA gel [7–9].

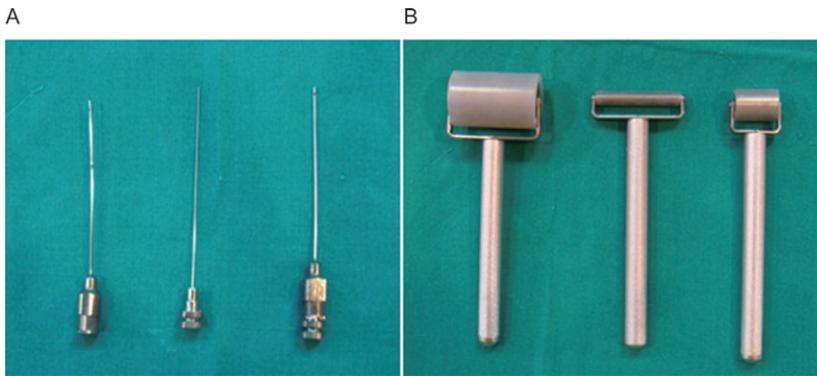


Figure 1 (A) Various-sized (19, 21, 23G) cannula for easy injection. (B) Roller for homogenization.

Based on the proven safety of HA gel and our experience of PGA, the authors created penile girth enhancement (PGE) using filler. We performed this study to identify the feasibility and efficacy of PGE using injectable filler.

Methods

This study was conducted under the approval of the Institutional Review Boards of Korea University Medical Center, and the study populations agreed to informed consent. A total of 41 patients (mean age: 42.5 years, range: 27–61 years), who were dissatisfied with their small penis, were enrolled in this study. All patients were counseled by a psychiatrist for their sense of inferiority and body image with small penis.

Penile Girth Enhancement by Filler

Under local anesthesia with Emla® (lidocaine 25 mg, prilocaine 25 mg, Astra Xeneca Limited, Auckland, New Zealand), Restylane Sub-Q® (Q-med, Uppsala, Sweden) was injected into the fascial layer of penile body in flaccid state using 21 G cannula (Figure 1) with the “Back & Forth Technique.” Figure 2 shows the anatomic diagrams showing planes of injection. For the ease of injection into the whole length of the penis, cannula was inserted just above penopubic junction or just below the coronal sulcus at 10–11 o’clock and 1–2 o’clock to avoid dorsal pedicle injury (Figure 3). In long penis or insufficient enhancement of proximal part of penis, additional injection was done at just below penopubic junction toward distal penis bilaterally. To avoid urethral injury, ventral side was not enhanced directly. After injection of enough amounts, the penis was stretched and homogenized with roller for even distribution and to flatten focal lump (Figures 1 and 3). Postoperative compressive dressing with

elastic bandage was applied and oral antibiotics were prescribed for 1 week. Additional nighttime compressive dressing with elastic bandage was recommended to prevent the focal depression from dependent position of the penis and sexual intercourse was prohibited for 1 month.

Penile girth measurement was performed with the penis on full stretch. Changes of penile girth at midshaft were measured by tapeline at 1 month for early results and were followed at 18 months for long-term results. Every measurement of the circumference was performed by one doctor to exclude interpersonal variation. Patient’s subjective visual estimation of penile girth was requested to assess the residual volume of HA gel at 1 month and at 18 month. The patients estimated using the visual analogue scale from Grade (Gr) 0 to Gr 4 where: Gr 0, no residual volume; Gr 1, less than 25% of initial volume; Gr 2, less than 50%; Gr 3, less than 75%; and Gr 4, more than 75% or nearly same as initial volume. Both patient’s and partner’s satisfaction were assessed

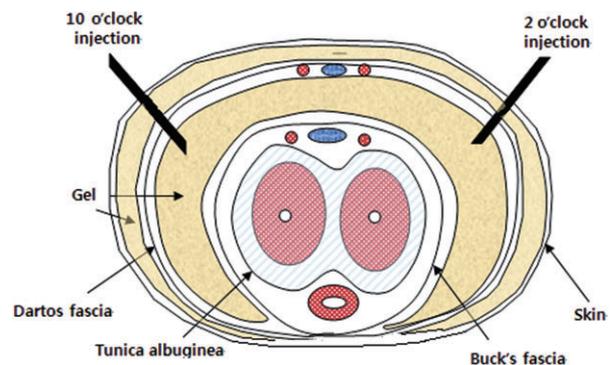


Figure 2 Cross-sectional view of anatomic diagram showing planes of HA gel injection. The hyaluronic acid (HA) gel was injected in the subcutaneous layer, just “deep to” the dartos fascia just below the coronary sulcus and just above the penopubic junction.

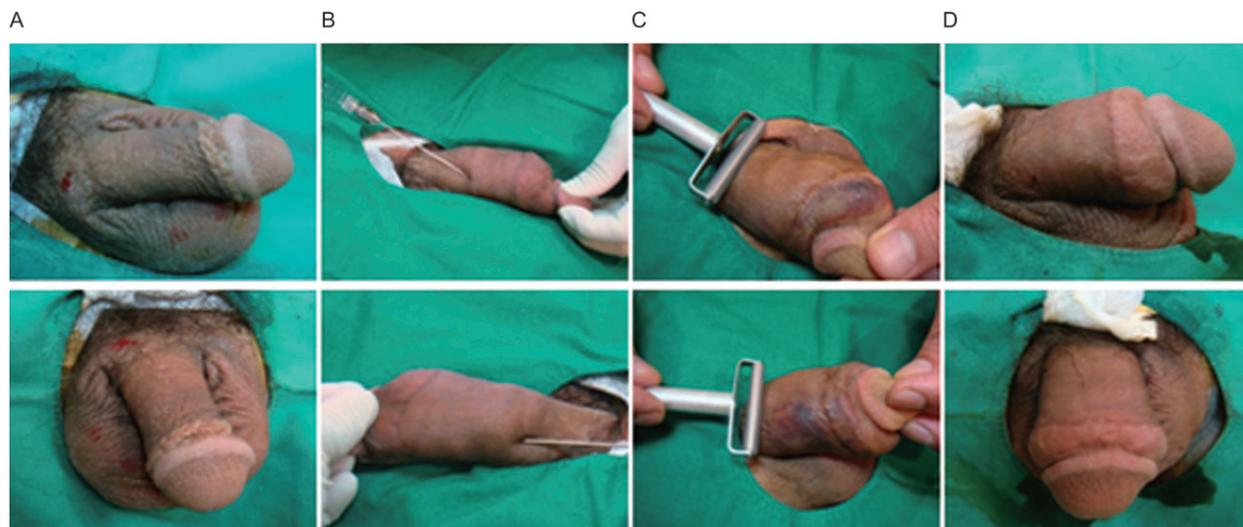


Figure 3 Representative figure of penile girth enhancement using injectable hyaluronic acid gel. (A) Preoperative figure of penile girth. (B) Filler was injected into the fascial layer of penile body using 21G cannula with the “Back & Forth Technique” For the ease of injection into the whole length of the penis, cannula was inserted just above penopubic junction or just below the coronal sulcus at 10–11 o’clock and 1–2 o’clock to avoid dorsal pedicle injury. (C) Initial uneven distribution can be manipulated with roller. (D) Immediate postoperative figure of penis.

using five Grades (Gr 0, very dissatisfied; Gr 1, moderately dissatisfied; Gr 2, about equally satisfied and dissatisfied; Gr 3, moderately satisfied; Gr 4, very satisfied) at 18 month. Adverse reactions were evaluated.

Statistics

Data in the table and figures are expressed as mean and standard deviation or range. Statistical comparisons were conducted using Student’s *t*-test. Results were considered significant at *P* < 0.05.

Results

Mean injected volume of Restylane Sub-Q® was 20.56 cc (18–22). Compared with basal girth of

7.48 ± 0.35 cm, the maximal circumference of midshaft was significantly increased to 11.41 ± 0.34 cm at 1 month (*P* < 0.0001) and maintained as 11.26 ± 0.33 cm until 18 months (Table 1). There was no significant difference between the maximal circumference at 1 month and at 18 months. The net increase in girth was 3.92 ± 0.25 cm (3.4–4.4) at 1 month and significantly decreased to 3.78 ± 0.26 cm (3.2–4.2) at 18 months (Table 1).

In patient’s visual estimation of residual volume, two patients complained the decrease of the girth as Gr 3 with focal depression and the rest was Gr 4 at 1 month. In those 2 patients, refill was done at 1 month (Figure 4) and was followed together. At 18 months, all patients answered as Gr 4 without asymmetry (Table 1, Figure 5).

Table 1 Changes of penile girth and patient and partner’s satisfaction after penile girth enhancement

	Preoperative	1 month	18 months
Maximum circumference (cm)	7.48 ± 0.35	11.41 ± 0.34*	11.26 ± 0.33*
Patient’s satisfaction		3.71 ± 0.46	3.34 ± 0.53
Partner’s satisfaction		3.65 ± 0.48	3.38 ± 0.49
Patient’s visual estimation (Gr)	0	0	0
0		0	0
1		0	0
2		0	0
3		2	0
4		39	41

**P* < 0.001.

Data are expressed as mean ± standard deviation.

Maximal circumference: measured at midshaft by tapeline.

Residual volume estimated the visual analogue scale from Gr 0 to Gr 4: Gr 0, no residual volume; Gr 1, less than 25% of initial volume; Gr 2, less than 50%; Gr 3, less than 75%; Gr 4, more than 75% or nearly same as initial volume.

Satisfaction (5 Gr): Gr 0, very dissatisfied; Gr 1, moderately dissatisfied; Gr 2, about equally satisfied and dissatisfied; Gr 3, moderately satisfied; Gr 4, very satisfied.

Gr = grade.

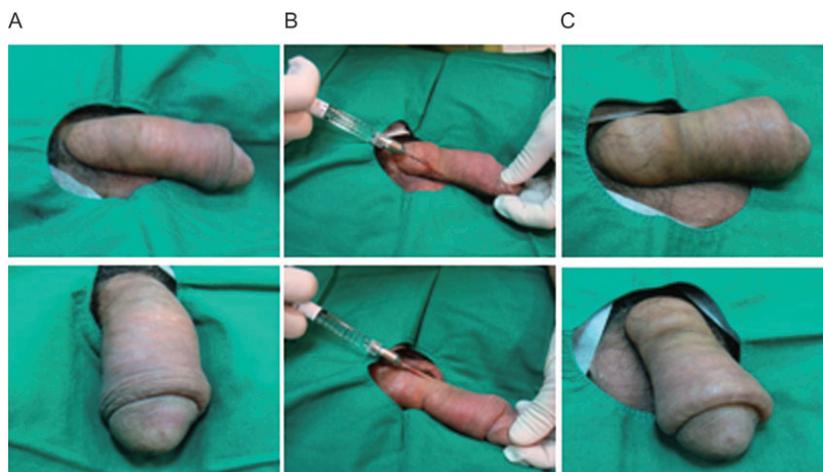


Figure 4 Reinjection for correction of focal depression at 1 month. Focal depression developed from early sexual intercourse can be easily corrected by more superficial refill using 19G cannula. (A) Pre-corrective view. (B) Intra-corrective view. (C) Post-corrective view.

Patient's satisfaction score was 3.71 ± 0.46 at 1 month and 3.34 ± 0.53 at 18 months (Table 1). In terms of percentage, 29.3% scored 3 and 70.7% scored 4 at 1 month and 61% scored 3 and 36.6% scored 4 at 18 months. Partner's satisfaction score was 3.65 ± 0.48 at 1 month and 3.38 ± 0.49 at 18 months (Table 1). Most patients answered that slight decrease of tactile sense of penile body. There was no deformity with erection compared with the flaccid state. There were no signs of inflammation and no serious adverse reactions in all cases.

Discussion

The authors applied the principle of soft tissue enhancement for PGE by injection of filler into the subcutaneous fascial layers of penile body and followed the efficacy and satisfaction until 18 months.

The main principle of current PGE techniques is the implantation of various bulking agents into the space between Buck's and Dartos fascias. But these fascial structures and overlying skin are vulnerable according to the nature of the bulking

agents, the technique's invasiveness, and the experience of the practitioner.

The main limitations of current PGE procedures such as dermofat graft, autologous fat injection, and scaffold insertion, are invasiveness, long operation time, poor implant survival from mobility and reabsorption, and uncommon devastating necrosis from poor blood supply with inflammatory reactions [2,10–12].

Possible complications of previous techniques are seroma, palpable nodules, asymmetry, curvatures from fibrosis, penile shortening or deformity, and large donor site scar in case of dermofat graft [11,13].

Recently, allograft dermal scaffold (AlloDerm; LifeCell Corp, Branchburg, NJ, USA) has been used for the advantages of no donor-site scarring [2], no complex harvesting with resultant short operation time, good graft survival, low complication rate [14], cosmetic benefit of symmetry, and durability. Although AlloDerm easily provides an increase in penile girth, it can induce penile skin necrosis by prohibiting blood supply to the overlying penile skin [12]. Other complications associated

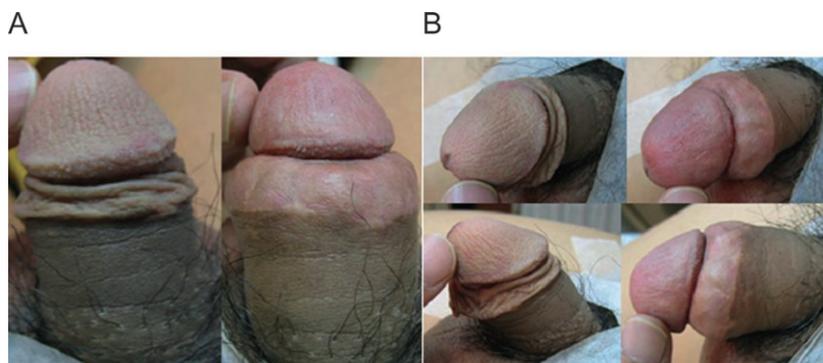


Figure 5 (A) Shows dorsal view of the representative figure for penile girth enhancement. (B) Shows lateral view with glans penis augmentation using injectable hyaluronic acid (HA) gel at 18 months. The injected HA gel effectively enhanced penile girth and the implants are well maintained without asymmetry until 18 months. In the augmented penis, the girth and glans are looking good esthetically.

with the use of AlloDerm include erosion, fibrosis, infection, reabsorption, and skin loss [2]. To avoid irreversible devastating complications of PGE, the most important consideration should be safety. In terms of material properties, HA seems to be an ideal filling material for soft-tissue augmentation because it is biocompatible, non-antigenic, nonpyrogenic, noninflammatory, nontoxic, easy to use, stable after injection, non-migratory, long-lasting, but reabsorbable and natural looking [15,16]. The material used in this study is based on HA, which has already been used in its native form as an implant for more than 20 years and in millions of individuals without causing adverse reactions [17–20].

In this study, there was no serious adverse reaction, like delayed and recurrent chronic inflammatory and granulomatous reactions, after 1.5 years follow up.

The major factors influencing long-term efficacy is volume persistence, but there is no established method to measure the residual volume of the filler. The authors estimated the changes of maximal circumference of penile body and patient's subjective visual estimation for volume of residual implants. In two patients, residual volume was decreased to Gr 3 with focal depression at 1 month. On careful interview, they confessed that they had sexual intercourse after 1 week despite our warning. Although the filler was injected into the restricted spaces of multiple fascial layers, the implants might be displaced because the HA gel needs 2–4 weeks for stabilization after injection. Although focal depression or volume loss by displacement can be easily corrected by reinjection, sexual intercourse should be prohibited until 1 month. Additional nighttime compressive dressing with elastic bandage would be better to prevent focal depression by dependent position of the penis until 1 month. All men have preferential dependency e.g., right or left side and the resultant skin fold might be develop at one side of penile root in case of enhanced bulky penis. At 18 months, all patients answered as Gr 4. Grossly, all patients might not recognize the volume loss by naked eye.

A major advantage of HA gel over nonpermanent fillers, such as fat and collagen, is the increased tissue longevity and low complication rate. The slow degradation of HA gel through cross-linkage enables the several hundred folds longevity of implants compared with the natural polymer, without decreased biocompatibility.

The main limitations of penile augmentation using injectable HA gel is not the efficacy but the

difficulties associated with the injection technique and the poor learning curve for the beginners. To increase the efficacy of PGE, even distribution of implants at the subcutaneous layer just “deep to” the dartos fascia and patient selection are necessary. The implant has a property of degradation but has a characteristic of isovolemic degradation. Isovolemic degradation always keeps the gel in balance with the water in the tissue, and this increased capacity to bind with water of a less concentrated hyaluronan network allows the maintenance of the correction even in the low presence of materials. So, the gross appearance of penis did not show major deformity but small undulation in surface can occur in some patients because of initial uneven distribution and slow biodegradation.

There were no signs of inflammation and no serious adverse reactions in all cases. But, most patients answered slight decrease of tactile sense of penile body. Theoretically, hyaluronidase infiltration is effective to resolve granulomatous reaction or overcorrection but we have no patients who used hyaluronidase [21].

For the patient selection, uncircumcised men with redundant prepuce, severe phimosis, and concealed penis with obesity, enhanced penile girth, and thick skin using filler might be problematic. Despite the effort for even distribution into different fascial layers, the fillers might be migrated to the distal prepuce. For severe phimosis or redundant prepuce, circumcision can be recommended. For small penis with obesity or concealed penis, penile elongation should be done before injection of filler. In the contrary, the enhanced girth makes the glans relatively small. Although glans penis augmentation using filler is not widely accepted by the professional society, the glans can be augmented simultaneously or later for esthetic appearance as shown in our previous reports (Figure 5) [8].

Among the limitations and debates of PGE, the long-term satisfaction is very important. All couples were satisfied until 18 months in this study. Patient's satisfaction score was 3.71 ± 0.46 at 1 month and 3.34 ± 0.53 at 18 months. In terms of percentage, 29.3% scored 3 and 70.7% scored 4 at 1 month and 61% scored 3 and 36.6% scored 4 at 18 months. Partner's satisfaction score was 3.65 ± 0.48 at 1 month and 3.38 ± 0.49 at 18 months. The relatively low satisfaction rate of both patient and partners was not from the size because the visual grade was not changed significantly. The low satisfaction rate was partly from

lack of total rigidity because the outer enhanced girth is softer than the hard corpus cavernosum in an erected status.

Recently, Perovic et al. reported the preliminary esthetic and functional results of autologous ex-vivo tissue engineering for PGE [22].

They implanted primary cultured fibroblast seeded poly(lactic-co-glycolic acid) (PLGA) scaffold in 84 patients and postoperative complications such as infections, skin necrosis seroma occurred in 8% of patients. They suggested that their advantages over the previously established procedures are simplicity, low complication and morbidity, reduced operative time, and preliminary good results. They also hypothesized that expanded cells harvested from the scrotum could migrate into the scaffold, would form viable tissue and would start its degradation to support the growth of a completely normal tissue without inflammation. Unlike their suggestions, their technique is not simple but is a complex procedure because primary tissue culture, seeding technique, and facilities are essential. The role and fate of implanted PLGA scaffold and primary cultured fibroblast are still unknown and are the subjects of on-going debates in the field of tissue engineering for human transplantation.

Studies of the common problems of penile augmentation rarely contain good published data on short-term results, so it raises speculation regarding the true efficacy and morbidity of these procedures. Vardi et al. reviewed the articles published between 1965 and 2008 regarding penile enhancement [3].

Because of disappointing results, they suggested the development of improved criteria for better patient selection, as well as new and better surgical methods of penile enhancement. As presented in our followup data, PGE by injection of filler is not the best procedure, but its advantages over other techniques are safety and tolerable efficacy. PGE with filler can be done easily with a little experience and might be the better option until future development of an ideal technique. We will continue follow up with these patients and report longer-term results especially regarding longevity of the implants.

Conclusions

Although penile augmentation of normal-sized penis is contentious, the recent preferable method for PGE has been changed from invasive, scarful dermofat graft to less invasive and safer alternatives. Considering the property of the materials,

methods, and follow up results of 18 months, this technique is very safe and with rare complications from the proven properties of HA gels. Proper patient selection and lack of total rigidity with corpus cavernosum are the limitations of this technique.

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