

Botulinum Toxin A (Botox) for Relieving Penile Retraction

Osama Shaeer, MD,* Kamal Shaeer, MD,* and Ahmad Shaeer, MBBCh†

*Department of Andrology, Kasr El Aini Faculty of Medicine, Cairo University, Cairo, Egypt; †Kamal Shaeer Hospital, Cairo, Egypt

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ABSTRACT

Introduction. The flaccid penis undergoes retraction upon contraction of the dartos muscle. These contractions are most pronounced in the situations of cold, stress, and upon exercising, and can be the source of embarrassment to those who have a hyperactive retraction reflex, especially when exposed to their partners or to others in showers and dressing rooms, despite a normal and satisfactory length in the erect state.

Aim. In this work, we propose an alternative to surgery and penile extenders for alleviating penile retraction, by injection of botulinum toxin into the dartos to induce muscle relaxation. This is the first report of the technique.

Methods. Ten male patients complaining of a short penis exclusively in the flaccid state, despite normal and satisfactory erect and outstretched lengths, were selected for the study. One hundred units of BOTOX were injected into the dartos muscle.

Main Outcome Measures. Frequency and amplitude of penile retraction, flaccid unstretched length, and patient satisfaction.

Results. Seven out of 10 cases (70%) subjectively reported a decrease in the frequency and amplitude of penile retraction, as well as improvement in flaccid length. Clinical measurements were less pronounced but still showed an improvement that was mainly in terms of less retraction rather than more length. No side effects were reported. Improvement faded completely by the 6th month.

Conclusion. This preliminary report of botulinum toxin A (Botox) injection into the dartos muscle shows that Botox may have a potential effect in temporarily decreasing penile retractions in terms of frequency and amplitude. **Shaeer O, Shaeer K, and Shaeer A. Botulinum toxin A (Botox) for relieving penile retraction. J Sex Med 2009;6:2788–2794.**

Key Words. Botulinum; Botox; Retraction; Length; Elongation; Short Penis

Introduction

The size of the penis is a concern that haunts many. True or not, there exists a widespread notion that phallic size is linked to satisfaction of the female partner. It is clearly proportionate to self-esteem. Concerns about genital size may develop into dysmorphophobia, which can either be functional (i.e., patients are concerned about an unsatisfactory sexual performance because of small penile size) or aesthetic (i.e., the so-called locker-room syndrome, which causes loss of self-esteem, social problems, and limitation of the range of

normal activities one can participate in to avoid comparing penile sizes) [1].

The erect and flaccid outstretched penile lengths seem to be the main criteria for clinical evaluation of phallic size, and basis for selection for surgical enhancement. Both measurements have functional and cosmetic importance, and are usually proportionate and in accord. On the contrary, the unstretched flaccid length may be in discrepancy with the former two, yet has very little clinical significance, despite being a very important indicator of cosmetic outlook and satisfaction with body image.

The flaccid penis undergoes retraction upon contraction of the dartos muscle, a subcutaneous muscle sheet that ensheathes the phallus. These contractions are most pronounced in situations of cold and stress and upon exercising, and can be the source of embarrassment to those who have a hyperactive retraction reflex, especially when exposed to their partners or to others in showers and dressing rooms, despite a normal and satisfactory length in the erect state. As long as it is not caused by a massive suprapubic fat pad or by over-circumcision, this phenomenon has been considered normal and managed by reassurance or on psychiatric basis. These measures may not always be successful.

Several methods exist for elongation of the penis. Division of the suspensory ligament allows separation of the corpora from the pubis. The crura can also be detached from the pubic rami [2]. This released portion of the penis should be covered by skin whether by VY plasty or T closure [3]. More invasive surgical procedures include disassembly of the three corpora with interposition of rib cartilage between the glans and the corporal tips [4]. Furthermore, excision of the suprapubic fat pad and covering the revealed penis by a skin flap have been described for management of the truly buried penis [5]. Surgical elongation remains controversial as to the extent of length gain which is mostly in the range of 1–2 cm with few exceptions [3,5], and is not without complications [6]. The motivation for seeking surgical enhancement may be less pressing in subjects whose complaints are restricted to the flaccid length but sport an adequate erect length. On the other hand, there are the penile stretching devices. There is paucity of data supporting the use of penile extenders for elongation of the penis. Among the rare reports on this issue is one stating that daily use of the extender for more than 6 hours per day over a 4-month period may enhance the stretched length by 1.8 cm [7]. In addition to the unconfirmed efficacy and safety, penile stretching poses a burden on daily life, with its effect being proportionate to the duration of application.

In this work, we propose an alternative to surgery and penile extenders for alleviating the complaint of penile retraction, by injection of botulinum toxin into the dartos muscle aiming at muscle relaxation. This is the first report of the technique.

Botulinum toxin is a product of the gram-positive anaerobe *Clostridium botulinum*, and has been known for causing the food-borne illness

botulism, characterized by symptoms of muscular weakness ranging from mild ptosis and diplopia to life-threatening respiratory failure. Although the capability of botulinum toxin to inhibit acetylcholine release by motor neurons was discovered in the early 1950s, it was not until the late 1970s that the clinical potential of this substance was initially appreciated. Dr. Alan Scott, an ophthalmologist and researcher, successfully pioneered the use of botulinum toxin in humans by injecting it into extraocular muscles to correct strabismus [8]. Ever since, the clinical applications of botulinum toxin have been expanding. The off-label uses far outnumber approved uses and include applications in the fields of ophthalmology, neurology, gastroenterology, urology, and gynecology [9], and most of all, for aesthetic procedures.

Patients and Methods

Ten male patients were recruited for this study. Age range was 22–28 years. They were selected from among patients presenting with the complaint of a short penis, on the basis of suffering penile retraction that shortens the penis exclusively in the flaccid state, despite normal and satisfactory erect and outstretched lengths, and confirmed episodes of satisfactory flaccid unstretched length. Other prerequisites for selection included persistent annoyance from retraction despite adequate counseling and reassurance, sexual function as confirmed by International Index of Erectile Function (IIEF)-5, normal body mass index, absence of an abnormally large suprapubic fat pad/inadequate shaft skin (to avoid bias generated by true penile concealment), and absence of any other physical abnormality. Patients with a neuromuscular disorder were excluded.

All patients were aware of the experimental nature of the procedure and provided a written informed consent entailing approval of all possible results and complications including failure to respond, the possibility of rarely reported heart problems and allergic reactions, infection, hematoma formation, and even erectile dysfunction that would possibly develop as a psychosomatic disorder. Injection was performed free of charge.

Patients were asked to subjectively evaluate and report on penile retraction over a period of 3 weeks, by noting how many episodes of retraction occurred daily and reporting on the prevailing state: retracted or unretracted. They reported on the length of the flaccid penis at its most retracted

and least retracted states from the pubic skin surface outward, measured by ruler or—when unavailable—by finger knuckles (to be interpreted into centimeters). Patients were asked to exclude days with unusual mental or physical stress, or extremes of temperature. Finally, patients were asked a general question about their satisfaction with flaccid length (subjective measurements, Table 1).

In addition, aiming at more objective evaluation of penile retractability, was measured the flaccid unstretched shaft length in the clinic, in three states: at base level and following application of ice packs and hot foment, for 10 minutes each. Length was measured from the pubic skin surface outward. Length was measured in the three states on three separate sessions and the mean was recorded (objective measurements, Table 2). In addition, the retraction reflex was elicited by scratching the medial thigh, scrotum, and/or perineum with a sterile needle, and penile length was recorded before and after eliciting the reflex (objective measurements, Table 2).

Injection was performed as an office procedure. BOTOX powder (botulinum toxin Type A, by Allergan Pharmaceuticals; Irvine, CA, USA) was reconstituted in 0.9% sterile, nonpreserved saline (100 units [U] in 2.5 mL saline). Penile shaft was scrubbed by antiseptic solution. A local anesthetic cream was applied. BOTOX was injected into the dartos muscle: Penile skin was pinched off of the shaft, the needle was introduced at the base of the pyramid formed, and Botox was injected. Aspiration preceded injection to make sure Botox was not injected into a blood vessel. The 100 U of Botox were injected as follows: approximately 30 U at 5 and 7 o'clock positions, respectively, 1 cm above the penoscrotal junction, and 20 U at the 2 and 10 o'clock positions, respectively, 1 cm above the penopubic junction. The penis was not dressed.

Following injection, all subjects were allowed to leave the hospital after 2 hours of monitoring for any possible early side effects. They were followed up every week for the first month, then at 2, 4, 6, and 8 months, where penile retraction and sexual function were evaluated in the same way as prior to surgery. On follow-up visits, the subjects were also asked if they would like to have injection repeated once the effect fades.

Results

Seven out of 10 subjects (70%) reported abolishment of penile retraction to a noticeable extent.

Table 1 Subjective evaluation

	Flaccid unstretched length				Prevaling state				Satisfaction with flaccid length				Agreement to reinjection		
	Most retracted		Least retracted		Pre-injection		Post-injection		Pre-injection		Post-injection			Pre-injection	Post-injection
	Pre-injection	Post-injection	Pre-injection	Post-injection	Pre-injection	Post-injection	Pre-injection	Post-injection	Pre-injection	Post-injection					
1	4.2	5.9	8.1	11	Retracted	Unretracted	25	25	Dissatisfied	Satisfied	Agree	Agree			
2	1.7	4.1	5	7.1	Retracted	Unretracted	24	25	Dissatisfied	Satisfied	Agree	Agree			
3	2.5	3.7	4.1	8.3	Retracted	Unretracted	25	25	Dissatisfied	Satisfied	Agree	Agree			
4	2.3	5.1	5.1	9.5	Retracted	Unretracted	25	25	Dissatisfied	Satisfied	Agree	Agree			
5	3.2	7.1	6.3	9.8	Retracted	Unretracted	24	25	Dissatisfied	Satisfied	Agree	Agree			
6	2.3	7.1	5.5	8.7	Retracted	Unretracted	25	25	Dissatisfied	Satisfied	Agree	Agree			
7	2.2	3.5	4.3	8.1	Retracted	Unretracted	25	25	Dissatisfied	Satisfied	Agree	Agree			
8	2	3.2	4.7	4.7	Retracted	Retracted	23	24	Dissatisfied	Dissatisfied	Disagree	Disagree			
9	1.9	3	4.3	4.3	Retracted	Retracted	25	25	Dissatisfied	Dissatisfied	Disagree	Disagree			
10	1.1	1.8	4.7	4.7	Retracted	Retracted	25	25	Dissatisfied	Dissatisfied	Disagree	Disagree			
Mean (cm)	2.34	4.45	5.21	7.62											
Improvement %	90.2		46.3												
P value	0.000813		0.002080187												

IEF = International Index of Erectile Function.

Table 2 Objective evaluation

	Flaccid unstretched length						Retraction reflex							
	Basal state		Hot foment		Ice packs		Pre-injection		Post-injection		Pre-injection		Post-injection	
	Pre-injection	Post-injection	Pre-injection	Post-injection	Pre-injection	Post-injection	Before eliciting	After eliciting	Before eliciting	After eliciting	Before eliciting	After eliciting	Before eliciting	After eliciting
1	6.5	6.7	9.2	10.4	4	6.2	6.4	3.9	6.7	6.6	6.7	6.6	6.7	6.6
2	2.1	2.5	4.1	4.7	1.6	2.3	2	1.4	2.4	2.4	2.4	2.4	2.4	2.4
3	2.5	2.8	4	5.3	2.1	2.5	2.6	2	2.9	2.7	2.9	2.7	2.9	2.7
4	3.5	3.7	4.1	4.6	2.1	3.5	3.4	2.2	3.5	3.5	3.5	3.5	3.5	3.5
5	4.3	4.7	5.3	5.9	3	4.7	4.2	3	4.7	4.5	4.7	4.5	4.7	4.5
6	3.7	4.1	4.6	5	2.3	4	3.6	2.4	4	4	4	4	4	4
7	2.7	3	4.3	4.9	2.2	2.9	2.8	2.1	3.1	2.9	3.1	2.9	3.1	2.9
8	3.1	3.2	3.9	4.4	1.9	3	3	1.6	3.3	3.1	3.3	3.1	3.3	3.1
9	2.9	3	3.2	4.1	1.7	3	2.9	1.7	3	3	3	3	3	3
10	1.9	2	2.4	2.7	1.3	2	2	1.2	2	2	2	2	2	2
Mean (cm)	3.32	3.57	4.51	5.2	2.22	3.41	3.29	2.15	3.56	3.47	3.56	3.47	3.56	3.47
Improvement %	7.5		15.3		53.6		40.0							
P value	0.000154		0.000109		0.000102		0.00005425							

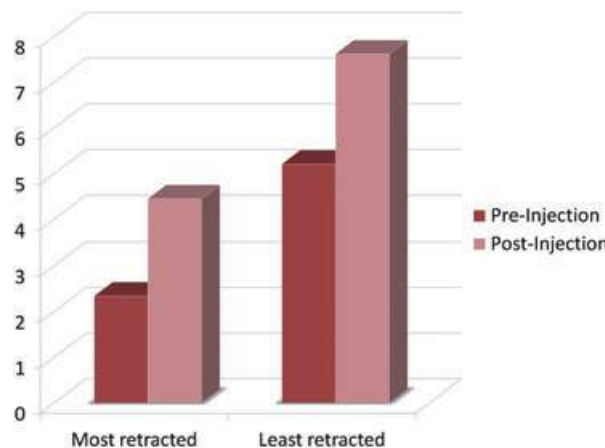


Figure 1 Subjective measurement of the flaccid unstretched length in the most retracted and least retracted states.

Retractions still occurred, but were much less in both frequency and severity. The unretracted state prevailed. Self-measured flaccid unstretched length was longer than prior to surgery. The seven subjects who reported improvement were satisfied with the resultant flaccid length. When asked whether they would choose to repeat injection, they confirmed that they would like injection to be repeated once the effect fades, biannually or triannually, if cost was not an issue. On the contrary, three patients (30%) denied any improvement and were still dissatisfied with the flaccid length. Overall, there was a statistically significant improvement in both “most retracted length” (21.1 mm, 90.2%, $P = 0.0008$) and “least retracted length” (24.1 mm, 46.3%, $P = 0.002$) (Student’s *t*-test) (Figure 1, Table 1).

As for the objective measurements, improvement was less pronounced. Average improvement was 2.5 mm (7.5%, $P = 0.0002$) in the basal state, 6.9 mm (15.3%, $P = 0.0001$) with hot foment. There was less retraction upon application of ice packs (11.9 mm, 53.6%, $P = 0.0001$) and upon eliciting the retraction reflex (11 mm, 40%, $P = 0.00005$) (Figures 2 and 3, Table 2).

The reported improvement started at 3–4 weeks following injection, peaked at 5 weeks, then started to fade by the 4th to 5th month and faded completely at the 6th month.

In all 10 cases, no side effects occurred. Four out of 10 patients reported a sensation of heaviness that started 3–5 days following injection and faded by the 2nd week. IIEF was comparable to the preoperative score (Table 1). The flaccid out-

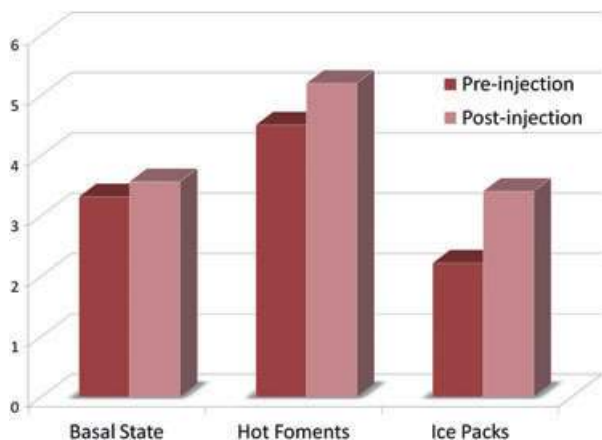


Figure 2 Objective/clinical measurement of flaccid unstretched length in the three states: basal, hot, and cold.

stretched length did not change in any of the patients, nor did the erect length.

Discussion

There are seven structurally distinct subtypes of botulinum neurotoxins (BTX) designated as A, B, C, D, E, F, and G. Commercial preparations of toxins A and B are currently approved by the Food and Drug Administration for use in humans [9]. Botox purified neurotoxin complex is a sterile, vacuum-dried, purified extract of BTX type A, produced from fermentation of the Hall strain of *C. botulinum* type A. This strain is grown in culture medium containing casein hydrolyzate, glucose, and yeast extract. It is purified from the culture solution by dialysis and a series of acid precipitations to a complex consisting of the neurotoxin

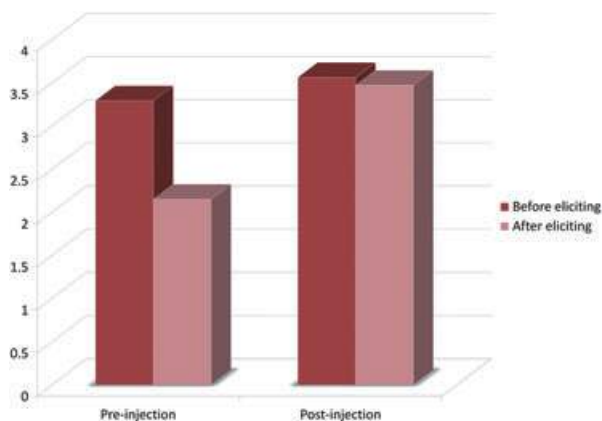


Figure 3 Flaccid unstretched length upon eliciting the retraction reflex.

and several accessory proteins. The complex is dissolved in sterile sodium chloride solution containing human albumin and subjected to microfiltration prior to lyophilization. Each vial of Botox contains 100 U of *C. botulinum* type A neurotoxin complex, 0.5 mg of human albumin, and 0.9 mg of sodium chloride in a sterile, vacuum-dried solid without preservatives. The toxin must be kept frozen at -5°C or colder until reconstituted [10].

Intramuscular administration of BTX causes paralysis of muscle tissue by inhibiting the release of Acetylcholine (Ach) from presynaptic motor neurons. The mechanism of action involves three steps: (i) binding of the heavy chain of the toxin to the neuronal membrane; (ii) internalization of the toxin by receptor-level endocytosis; and (iii) inhibition of Ach release by modification of an intracellular complex of proteins (referred to as the SNARE complex) involved in the docking and fusion of Ach-containing vesicles to the cell membrane in anticipation to exocytosis [11]. Injection of botulinum toxin results in varying degrees of muscle weakness, depending on the concentration and dose of toxin administered. Effects are noticeable within 1 to 14 days, peak after 2 to 6 weeks and begin to subside approximately 10 to 12 weeks after administration. Patients typically require 3 to 6 months to regain full strength [12,13].

Although administration of BTX is generally safe and well tolerated, there are a number of side effects that one should be aware of when using this medication [9]. Rare reports of generalized muscle weakness have been associated with large doses (600–900 U) for cervical dystonia and hemidystonia. However, there are no reports of generalized weakness after aesthetic doses of BTX (usually around 100 U). Immunologic type I anaphylactic reactions and rashes have also been reported after BTX A injection [14]. A history of neuromuscular disease (i.e., myasthenia gravis, Eaton–Lambert syndrome), however, is an absolute contraindication for BTX injection, given the increased risk for systemic side effects [15].

In this preliminary experience with the utility of BTX for prevention of penile retraction, injection achieved the anticipated relaxing effect in the majority of patients. Improvement and patient satisfaction was subjectively confirmed in seven out of 10 patients. They decided that the simplicity, safety, and efficacy involved would encourage them to repeat it whenever the effect fades, several sessions a year. It is yet to be explored whether the cost of injection would defer the candidates from

seeking BTX treatment. However, there appears to be a conflict between the subjective self-measurements and the clinical measurements as to the extent of improvement in the basal and least retracted/hot foment states, where subjective improvement was more pronounced, while the clinically measured improvement was very subtle, contrary to the results obtained in the cold state and upon eliciting the retraction reflex. We propose several theories to explain this conflict. Self-measurement bias and/or error may exaggerate the results (satisfied group: 7/10) or underestimate them (dissatisfied group: 3/10). Its accuracy down to the millimeter scale may not be dependable especially when finger knuckles are used as a measuring tool. The stress accompanying clinical examination may lead to more retraction compared with self-measurement, thereby undermining the objective results. Considering the more pronounced improvement with ice packs and upon eliciting the retraction reflex, which goes along with the subjective report of less retraction and prevailing unretracted state, we propose that the common factor between subjective and objective measurements is less retraction rather than more elongation. As for the dose used (100 U), this is a relatively high—although safe—dose. The reason why we opted for a higher dose was to avoid false negative results on account of a smaller dose than possibly needed. We intend to titrate the dose in another ongoing study.

We believe that adequate counseling and realistic expectations were fundamental factors for patient satisfaction. Patients were aware beforehand that BTX injection will not give them a truly longer phallus but will only decrease retractions to an extent, with no effect of the erect length. They were informed that retraction will still occur, but hopefully in lesser frequency and amplitude. They knew that this effect is temporary and that reinjection will be required to maintain it. Finally, they were aware of the possible sense of heaviness that may follow injection.

Among the shortcomings of this study is failure to exclude a possible placebo effect of injection that may decrease stress and concern about penile length, hence decreasing muscle tone and improving the flaccid length. The objective results were not completely objective considering the stress accompanying clinical evaluation and undermining the results. It appears that the subjective results may better reflect the real-life value of Botox injection if placebo effect can be excluded. The humble number of patients involved classifies this clinical

trial as a pilot study that may justify further exploration of BTX injection rather than recommend it for clinical use. A double-blind, placebo controlled cross-over study with a larger series of subjects is ongoing and will possibly yield more reliable results and solid recommendations.

Conclusion

This preliminary report of Botox injection into the dartos muscle shows that Botox may have a potential effect in temporarily decreasing penile retractions in terms of frequency and amplitude, with a favorable effect on aesthetics and on patient satisfaction. Injection has been found to be well tolerated and with no apparent side effects.

Corresponding Author: Osama Kamal Zaki Shaeer, MD, Kasr El Aini Faculty of Medicine, Cairo University, Egypt, 21 Gaber Ibn Hayan Street, Dokki, Cairo 12311 ARE, Egypt. Tel: (202)33359047; Fax: (202)37605181; E-mail: dr.osama@alrijal.com; www.maleGENITALsurgery.com

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Statement of Authorship

Category 1

(a) Conception and Design

Osama Shaeer

(b) Acquisition of Data

Osama Shaeer; Kamal Shaeer; Ahmad Shaeer

(c) Analysis and Interpretation of Data

Osama Shaeer; Kamal Shaeer; Ahmad Shaeer

Category 2

(a) Drafting the Article

Osama Shaeer; Kamal Shaeer; Ahmad Shaeer

(b) Revising It for Intellectual Content

Osama Shaeer; Kamal Shaeer; Ahmad Shaeer

Category 3

(a) Final Approval of the Completed Article

Osama Shaeer; Kamal Shaeer; Ahmad Shaeer

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