

## Evaluation of the Therapeutic Effect of Botulinum toxin A on Hallux Valgus Deformity and Pain

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### Abstract

**Background:** Hallux Valgus is a kind of Toes aberration where the Metatarsophalangeal joint that connects the big toe to the foot, leading to the inner side and a protrusion on the inner surface of toe arise. This study aimed to determine the effect of botulinum toxin A Dysport injection to reduce pain and deviation angle of the thumb in Hallux Valgus and to increase outcomes of treatment as an adjuvant therapy.

**Material and methods:** Randomized clinical study was performed on 18 patients at the Clinic of Physical Medicine and Rehabilitation, Isfahan University of Medical Sciences. In this study the Hallux valgus angle (HVA) between the metatarsals (IMA) and cartilage distal metatarsal angle (DMAA) and pain was assessed before and after injection.

**Results:** Average of Hallux Valgus angle before and after Botox injections were  $28/89 \pm 10/21$  and  $21/56 \pm 8/22$  degrees and the angle deviation in the 6 months after treatment was significantly improved ( $p < 0.001$ ).

**Conclusion:** Injection of botulinum toxin A (Dysport) is a suitable and acceptable method to reform the skeleton deformities and also to reduce the pain in patients with Hallux valgus.

**Keywords:** Hallux valgus; Bunion; Botox; Botulinum toxin A Dysport; Metatarsal bone; Pain

### Introduction

Hallux Valgus deformity or Bunion is one of the most painful and motion limiting cases of lower limb [1-3]. Hallux Valgus angle (HVA) (long axis of 1<sup>st</sup> MT and prox Phal) is the angle between the metatarsals (IMA) (between long axis of 1<sup>st</sup> and 2<sup>nd</sup> MT) and cartilage distal metatarsal angle (DMAA) (between 1<sup>st</sup> MT long axis and line through base of distal articular cap). Bunion usually causes a deviation of the big toe toward the second toes and also the angle deviation between the first and second metatarsal foot bone [4-6]. Hallux valgus or Bunion is a common deformity of the big toe tilt and it is happened when the first joint of MTP is deflected out [3-5]. Deviation of 15 to 20 degrees of motion is abnormal and causes discomfort [7,8]. This situation causes displacement of first joint of MTP so that the thumb is placed on the adjacent finger. Thumbs sideways movement causes the protrusion at the head of the metatarsal bone. This situation is happened commonly however the exact cause is still unknown. Mostly the genetic backgrounds, flat feet and inappropriate shoes are influence [9]. Women are affected more than men. The incidence and prevalence in children is less and increased with age. Since the factors influence on both sides, the condition is usually bilateral, nevertheless it can be seen as unilateral as well. Deformations associated with this condition include deformation of the second toe, flexible or rigid metatarsus. Instability in the second toe can cause bunion progression since it

could not work well as a relying side. A common problem in patients with hallux valgus is one or more abnormalities in their gait pattern due to deformation of the first metatarsophalangeal joint [1,4]. Deformations associated with this condition are deformation of the second toe and/or metatarsus flexibility or rigidity. Instability in the second toe can cause bunion progressed because it could rely as well on the side. Dysfunctions which might be present: gait deviations in the midstance (middle stage) and the propulsion phase (late stance). As the patient body weight moves ahead on a foot, the patient will tend to put his weight on the lateral border of the foot. This results in a lateral and posterior weight movement.

### Materials and Methods

This randomized clinical trial is performed on 18 patients at the Clinic of Physical Medicine and Rehabilitation, Isfahan University of Medical Sciences in the years 2013-2016. Bisection was performed first using metatarsal shaft including two points according to Miller [10,11]; the middle of the base and the middle of the head of the metatarsal; which were connected *via* a line to each other, representing the bisection of the metatarsal. This method has been reported as a more reliable post-operative method compared to traditional method [10,11]. Target population studied were patients with Hallux Valgus deformity or Bunion. Inclusion criteria were the deviation of the hallux valgus angle (HVA) above 10° and Bilateral and/or unilateral Bunion [12,13]. Exclusion criteria were patients with rheumatoid arthritis, neurological pain, infection, gout, fractures, and patients with

rigidious hallux. In this study the Hallux Valgus angle (HVA) between the metatarsals (IMA) and cartilage distal metatarsal angle (DMAA) and pain was assessed before and after injection [14,15]. After obtaining informed consent from patients for the study and justification of medical patients about possible side effects, patients for further examination were underwent physical examination and radiographs of foot. X-ray was performed standing view, profile view and sesameoid view to evaluate the distortion and deformity. Conformity or incompatibility of the first joint of metatarsophalangeal is determined by the DMMA angle that this angle was normal in most cases. In physical and clinical assessment, patients were evaluated from the different viewpoints including; lateral deviation of the MTP joint, swelling of first MTP joint, shortening of flexor hallucis brevis muscle, tenderness of hallux, weakness of hallux abductor muscles and pain (primary symptoms). Physical examination was carried out with the patient both standing and seated. During weight bearing, the deformity is usually emphasized. During evaluation, the presence of pes planus and contracture of the Achilles tendon should be figured out. The height of the longitudinal arch and hallux, with its relation to the lesser toes, are also evaluated. Patients were divided into three groups: the first group has a temperature of 10° to 20° Hallux Valgus (low), the second group of 20 to 40 Hallux Valgus (mild), and the third group 40 degrees Hallux Valgus or more (severe) (Table 1). Botox is injected with a sterile needle while the patient is lying on the bed.

During a session injection is guided sonographically and by use of EMG.

Severity	HVA	IMA
Normal	≤ 16°	≤ 9°
Mild	>16° ≤ 25	>9° ≤ 11°
Moderate	>25° ≤ 40°	>11° ≤ 16°
Severe	>40°	>16°

Table 1: Showing severity in HVA and IMA.

Equal to 75 IU of botulinum toxin A Dysport is injected intramuscular into the diagonal head of the adductor hallucis muscle fibular sesamoid and equal to 25 IU of botulinum toxin A is injected into transverse head and the lateral aspect of the proximal phalanx base. Patients a week, two months and 6 months after injection were examined again with new graphics and physical examination. The pain intensity is measured *via* VAS scale. In this way, the patient is asked to rate their pain intensity in a range from 0 to 10; where zero represents no pain and 10 is maximum pain. Based on the pain scale, 1 to 3 represents mild, 4-7 is average and 8-10 represents severe pain [13].

Variable	Time	Patients	Sex			Age		
			P	Female	Male	≥ 30	<30	
Deviation of hallux valgus angle	Before treatment	28/89 ± 10/21	0/37	30/9 ± 11/8	26/4 ± 7/9	28/89 ± 10/21	30 ± 11/6	28 ± 9/5
	After treatment	21/56 ± 8/22	0/89	14/3 ± 2/2	21/3 ± 8/4	21/56 ± 8/22	24 ± 9/5	19/6 ± 6/9
	Percent of angle correction	-0/25 ± 0/1	0/52	-0/29 ± 0/11	-0/21 ± 0/08	-0/25 ± 0/1	-0/2 ± 0/08	-0/3 ± 0/1
Reform of metatarsus angle	Before treatment	13/94 ± 2/58	0/56	14/3 ± 2/2	13/5 ± 3/1	13/94 ± 2/58	14/9 ± 2/4	13/2 ± 2/6
	After treatment	10/61 ± 2/43	0/11	10/3 ± 2/5	11 ± 2/5	10/61 ± 2/43	11/1 ± 2/5	10/2 ± 2/4
	Percent of angle correction	-24 ± 0/11	0/048	-0/28 ± 0/11	-0/28 ± 0/11	-0/24 ± 0/11	-0/25 ± 0/13	-0/23 ± 0/1

Table 2: Mean and standard deviation of hallux valgus angle and metatarsus angle and its reform in general and by age and sex.

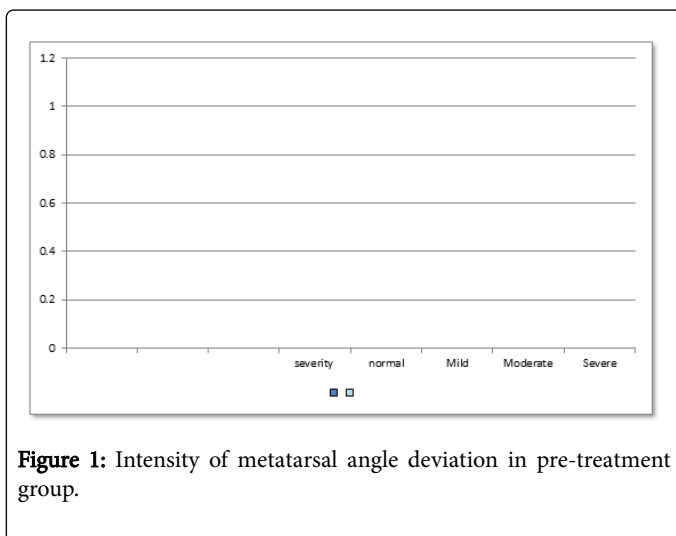
## Result

In this study, 18 patients were studied for deviation of the big toe. The mean age of these patients were 29/9 ± 8/25 with the range of 21-48 years. 10 patients (55/6%) were under 30 and 8 (44/4%) were aged 30 years and older. 8 patients (44/4%) were male and 10 patients (55/6%) were female. Average of Hallux Valgus angle before and after Botox injections were 28/89 ± 10/21 and 21/56 ± 8/22 degrees and the angle deviation in the 6 months after treatment was significantly improved (p<0.001). Average of metatarsal angle before and after treatment were 13/94 ± 2/58 and 10/61 ± 2/43 and the difference before and after treatment was significant (P<0.001). The mean percent correction of hallux valgus angle and metatarsal angle were -0/25 ± 0/1 and -0/24 ± 0/11 respectively. In Table 2, the mean and standard deviation of hallux valgus angle and metatarsal and the reform extent

in general, and by age and sex is shown. Based on the above table, the average of hallux valgus angle before and after treatment in the two age groups was not different significantly however the correction angle percent in people under 30 years was significantly higher (p=0.036). The data analysis based on the age also showed that percent correct metatarsal angle in women is more desirable than men (p=0.048).

Evaluation of the extent of disease in the study population showed that in pre-treatment group, 7 patients (38/9%) had minor complications, 6 patients (33/3%) had medium complications and 5 (27/8%) had severe complications while in the post-treatment group, 4 patients (22/2%) had natural hallux valgus angle, 8 (44/4%) had minor complications and 6 (33/3%) had medium complications and cases of severe illness was not observed in this group and according to Friedman test, change of severity after treatment was significant (P <0.001). From the viewpoint of the intensity of metatarsal angle

deviation in pre-treatment group, 4 patients (22/2%) were mild deviation, 8 (44/4%) were medium deviation and 6 (33/3%) were severe deviation, while after treatment 5 people (27/8%) were normal, 7 patients (38/9%) were minor and 6 (33/3%) were medium and according to the Friedman test, differences before and after treatment were significant ( $p < 0.001$ ) (Figure 1).



**Figure 1:** Intensity of metatarsal angle deviation in pre-treatment group.

Averages of pain intensity in patients before and after treatment were as follows:  $5/65 \pm 1/76$  and  $1/17 \pm 0/86$  and the pain were reduced significantly ( $p < 0.001$ ). Based on the VAS scale before treatment, 3 patients (16/7%) had mild pain, 12 patients (66/7%) had moderate pain and 3 patients (16/7%) had severe pain while in the post-treatment group, 17 patients (94/4%) had mild pain and 1 (5/6%) had moderate pain.

## Discussion

Hallux valgus is one of the most common diseases worldwide [15]. The prevalence of it is not clear. In a report, the prevalence of the disease in young adults was 1/6 of the total population and the disease in female is 4 to 9 times more frequent than male. Difference has led to considering no treatment for this disease. In this study, a new method for treatment is represented. Treatment with surgery, in addition to the high cost is also accompanied with some problems such as the duration of treatment and the risks involved as well. Of the advantages the method presented here is its low cost and the fact that it is an outpatient surgery. Hence surgery can be considered as a conservative treatment [16] botox type A (Dysport) has good prospects in the future in physical therapy to reduce chronic muscle pain and help restore normal muscle length and biomechanical balance. This study aimed to determine the effect of botulinum toxin A injection to reduce pain and deviation angle of the thumb and to increase outcomes of treatment as an adjuvant therapy [17].

Botulinum toxin A is used to cure certain muscular conditions as well as cosmetically removing appearance of facial wrinkles in older adults by temporarily paralyzing muscles. It has proven to be a successful and valuable therapeutic antigen when considering dosage, diversity of treated clinical conditions and frequency of treatment [18,19]. Over 20 other different medical conditions such as eye squints, Severe primary axillary hyperhidrosis (excess sweating), chronic migraines, Overactive bladder (leaky bladders), Idiopathic rotational cervical dystonia (severe neck and shoulder muscle spasms),

Blepharospasm (spasm of the eyelids), Strabismus (crossed eyes), Post-stroke upper limb spasticity Glabellar lines (frown lines between the eyebrows), Cerebral Palsy, Achalasia (an esophageal issue causing symptoms such as difficulty swallowing), anal fissure and Anismus (dysfunction of the anal sphincter), Sialorrhea (hypersalivation), Allergic Rhinitis1, Sphincter of oddi (hepatopancreatic) dysfunction, Oromandibular dystonia (forceful contraction of the jaw, face and/or tongue) and Laryngeal Dystonia (forceful contraction of the vocal cords) reported to be treated by this method [18,19]. Botulinum toxin is administered by diluting the powder in saline (sodium chloride) and injecting it directly into neuromuscular tissue. It takes 24-72 h for botulinum toxin to take effect, which reflects the time needed for the toxin to disrupt the synaptosomal process. In very rare circumstances, it may take as long as 5 days for the full effect of botulinum toxin to be observed. Botulinum toxin should not be used in pregnant or lactating women, or by people who have had a previous allergic reaction to the drug or any of its ingredients.

The present study revealed that the Hallux Valgus angle before and after Botox injections were  $28/89 \pm 10/21$  and  $21/56 \pm 8/22$  degrees and the angle deviation in the 6 months after treatment was significantly improved ( $p < 0.001$ ). Of these results it can be concluded that injection of botulinum type A Dysport is a suitable and acceptable method to reduce and reform the skeleton deformities and also to reduce the pain in patients with Hallux valgus. We believe that botulinum type A therapy will play a critical role when used as a prophylactic treatment option during the initial stages of Bunion deformity and may possibly slowdown its progression. The pain also can be managed by this therapy and may have also long-term benefits with serial applications.

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