

# Bocox

# BOTOX® (onabotulinumtoxin A) / 'bəʊtɒks', noun

# Let's begin:

Botox® (botulinum neurotoxin, produced by the bacterium, 'Clostridium A') is a trademark preparation of botulinum toxin used to treat muscle spasm and to remove wrinkles.

Well... Botox® isn't just used to treat fine lines and wrinkles anymore. No, no. That may be its only 'on label use', but this FDA approved toxin for relaxing facial muscles is currently being used to treat a whole host of other, 'off label', conditions:

- Hyperhidrosis (excessive sweating)
- Migraine headaches
- TMJ (temporalmandibular joint disorder)
- Overactive bladder
- Strabismus (crossed eyes)
- Acne
- Testicular pain
- Scrotal wrinkles ('Ball ironing' or 'Scrotox')

And most recently, Erectile Dysfunction.

Yes - BOTOX® for the penis. A new take on an old procedure, brilliantly named **Bocox™.** 

It's exciting stuff, folks. BOTOX® may prove to be the stiffest competitor in the erection dysfunction market yet.

## Breakthroughs In Treating ED

There are many therapies either FDA approved, or simply used, for improving erectile function: medications, shockwaves, peptides, injections, and more recently – the 'P-Shot®'. Dr. Charles Runnels was the first brilliant (brave? crazy? – you decide.) physician to imagine he might improve erectile function by **injecting** platelets into a penis. His own penis, to be exact. One

dark and stormy evening, he drew blood from his arm, spun out the platelets, and injected them back into his penis – and that is how the P-Shot® was born.

Knowing this, I can't say I'm entirely surprised that on another dark and stormy evening, many years later, Dr. Runnels would try injecting BOTOX® into his penis instead. Whatever he had lying around, right? I should clarify by saying it wasn't a direct leap. Over the years physicians have been injecting a long list of substances into the penis with the aim of erecting something great. I thought BOTOX® a bit of a counterintuitive idea, however - injecting a well-known 'softening' agent like BOTOX®, into an organ ultimately desiring firmness? Well, that just sounded crazy. But I was wrong. Hard, hard wrong. (Pretty sure the puns end here - you're safe to read on.)

The data on Bocox<sup>™</sup>, or BOTOX<sup>®</sup> for treating erectile dysfunction (ED), was first published last year – and contrary to what I expected, it was seriously compelling.

For those of you not familiar with BOTOX®, here's a brief primer:

## What is BOTOX®

BOTOX® is Botulinum toxin - one of the most poisonous biological substances known to humankind. A lethal dose is estimated to be 2 nanograms per kilogram of body weight (so approximately one drop could off an elephant). Botulinum toxin is a neurotoxin produced by the bacterium, Clostridium botulinum, which works by causing muscle paralysis.

The sentinel trial testing the theory of BOTOX® for erectile dysfunction (ED) was quite impressive. The authors studied 176 men with severe ED. This was an ambitious group to study because they had failed treatment with everything else - medications, injections, shockwave, you name it. The participants selected were guys who could not obtain an erection naturally or mechanically with any known modality. Usually when principal study investigators are designing a clinical trial to demonstrate efficacy, they select a patient population that's likely to have a positive outcome. A group of guys with mild to moderate ED would have been much more likely to yield a positive outcome, so props to these folks for selecting a stiff challenge. (Ugh, I lied about the puns)

OK - So what did they do? The study participants all received a P-Shot®. For those of you not familiar, the P-Shot® is a procedure that's been used for more than 10 years to treat ED. Dr. Runnel's original P-Shot® utilized PRP or 'platelet rich plasma' injected into the penis to improve erectile function. Platelet rich plasma is obtained by taking a sample of the patient's blood, spinning it down in a centrifuge, and getting rid of all the red and white blood cells. The platelets are then isolated and reinjected to be used as growth factors. This tricks the body into

thinking there's been an injury with the erectile tissue causing the platelets to release chemical signals to fix it, thus restoring youthful erectile function.

As time went on, physicians started injecting penises with other things using the same technique: stem cells, exosomes, hyaluronic acid fillers - you name it, anything, and everything to restore spontaneous erections has been injected into some man's penis. Some with the promise of even enhancing size - although using BOTOX® for Bocox™ seems to take the triple crown on this...

Back to our study: The participants were divided into 3 groups. Each man in the study was given a P-Shot® – one group received a P-Shot® with saline and the other two groups got BOTOX®. The placebo group received a saline solution – so no BOTOX®. The first treatment group got 50 units of BOTOX® and the other treatment group got 100 units of Botox. These are solid doses of BOTOX®. For reference, a face full of BOTOX® usually gets about 60 units, so 100 is a big boy dose.

What happened? The short answer – It worked. Recall, this study was investigating only men with severe ED – men who didn't respond to medications, shockwave, or injections. But BOTOX®? BOTOX® worked. Both doses worked – the 50-unit dose worked for about 3 months and the 100-unit dose for about 6.

#### WOW.

# How Does This Work?

How is it that the same substance that relaxes muscles in the face causes firmness in the penis? In most situations, the penis is in a flaccid state. When a man becomes aroused, the smooth muscle controlling the vascular tone of the penis relaxes, allowing blood to flow into the penis which causes an erection. BOTOX® enhances the relaxation of that smooth muscle which results in more blood flow to the erectile tissue and more reliable, sustainable erections.

## Is This Safe?

Is BOTOX® safe? BOTOX® was FDA approved for medical indications in 1989 but has been studied and used in humans for far longer. As mentioned above, it is only FDA approved for treating a limited number of conditions such as strabismus, blepharospasm, and fine lines and wrinkles in the face. But like many medications, its off-label use is extensive and includes a long list of other indications including but not limited to those listed above. BOTOX® should not be used in people who have had reactions to BOTOX® injections in the past, those who are pregnant, expecting to become pregnant, are breastfeeding, or who have a history of neuromuscular disorders.

## What Does This Cost?

What does Bocox™ cost? Not going to lie – this price tag on this procedure is not for the faint of heart. Botox typically retails at \$10-12 per unit – just for the BOTOX® so don't be yelling at me

for the dollars here - you take that straight to the makers of BOTOX®. Nationwide, Bocox™ procedures typically range from \$2000-\$4000. This includes the BOTOX®, any other regenerative products that might be added, anesthesia costs, and physician fees.

Although nothing works 100% of the time in 100% of the patients, the studies are mounting that support the successful repurposing of two safe and effective therapies. Used together, BOTOX® and the P-Shot® are showing promise in treating even the most severe cases of ED. As always, more studies are needed - because size matters.

### References:

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