

A Proof Of Concept Case Series Of Botulinum Toxin A Treatment For Ischemic Feet Due To Raynaud’s Phenomenon

J.E. Eeuwen, L.F. Stadelmeier, T. Engmann, M. Göben, R. Faulhaber, L. Hilbig-Vlatten, B.J. Carroll, J. Nashel, A.S. Dowlatshahi

¹Department of Orthopaedic surgery, Orthoplastic division, Beth Israel Deaconess Medical Center, Boston, MA

²Department of Cardiology, Harvard Medical School, Boston, MA

BACKGROUND

- Raynaud's Phenomenon (RP) is a vasospastic disorder primarily impacting the hands and feet
- Secondary RP can lead to severe ischemic complications like ischemia (ulceration / gangrene)
- Treatment options for RP range from lifestyle adjustments to pharmacological approaches.
- For resistant symptoms resulting in severe ischemia, there are two avenues:
 - surgical sympathectomy (invasive / high complication rate)
 - chemical sympathectomy with Botulinum Toxin A (BTX-A), which shows potential efficacy in alleviating advanced symptoms in the hands
- This case series unveils a new application of BTX-A treatment for ischemic symptoms in the foot, an approach well-documented for hands but not previously described for feet

METHODS

- Data was collected retrospectively from the OMR of 7 patients who were treated with BTX-A injections for RP of the feet between 2019 and 2023, encompassing a total of 11 treatment episodes
- Collected parameters from 7 patients
 - patient demographics, prior treatments, diagnosis based on the ICD-9/10 code
- Collected parameters from 11 treatment episodes
 - BTX-A treatment specifics, treatment intervals, duration since last treatment, and pain using the visual analog scale (VAS)
- Follow-up after 6 weeks
 - Symptom resolution (yes/no)
 - VAS-scores obtained via questionnaire and categorized into ordinal groups. Analyzed via chi-square test
 - Reported side-effects

After administration of 22 BTX-A injections, a significant decrease in VAS-scores and a symptom resolution of 81.9% after 6 weeks was achieved in patients with severe ischemic symptoms

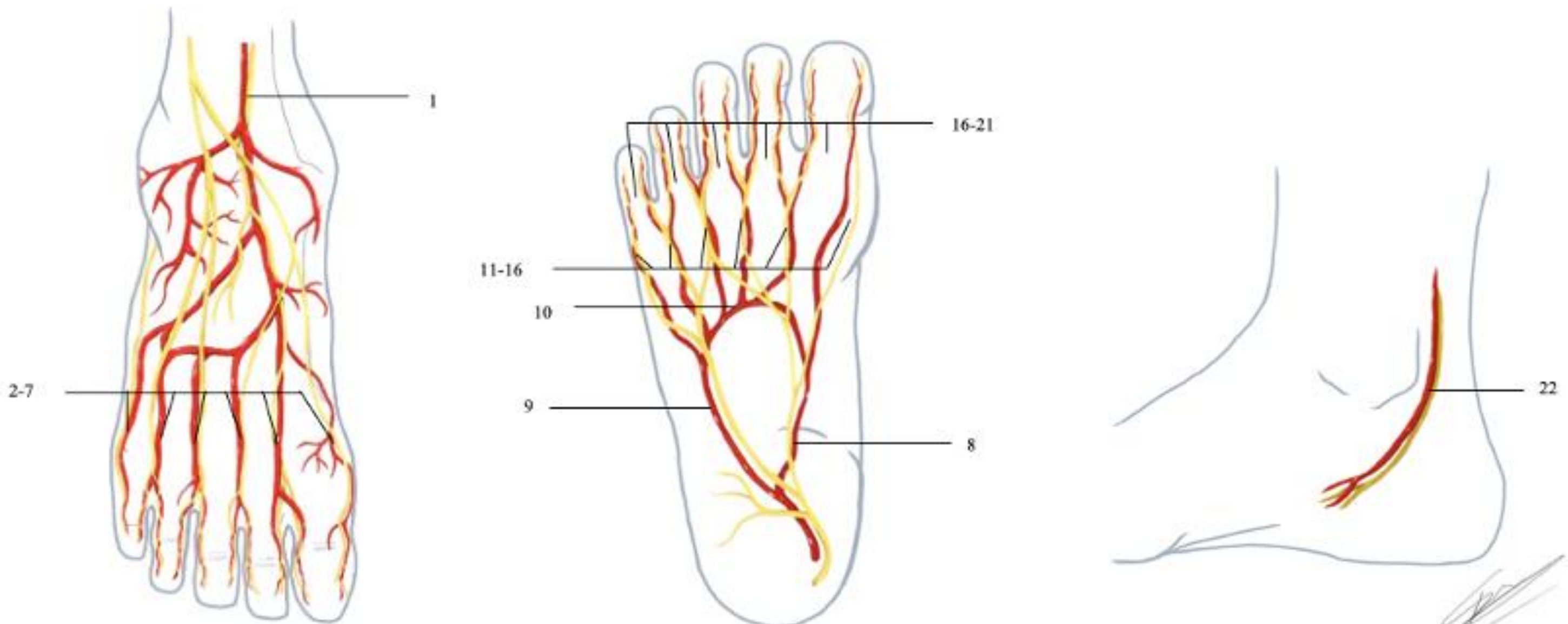


Figure 1. BTX-A injection sites: 1 a. dorsalis pedis, 2-7 dorsal metatarsal a., 8 medial plantar a., 9 lateral plantar a., 10 deep plantar arch, 11-16 plantar metatarsal a., 16-21 base of toe, 22 a. tibialis posterior

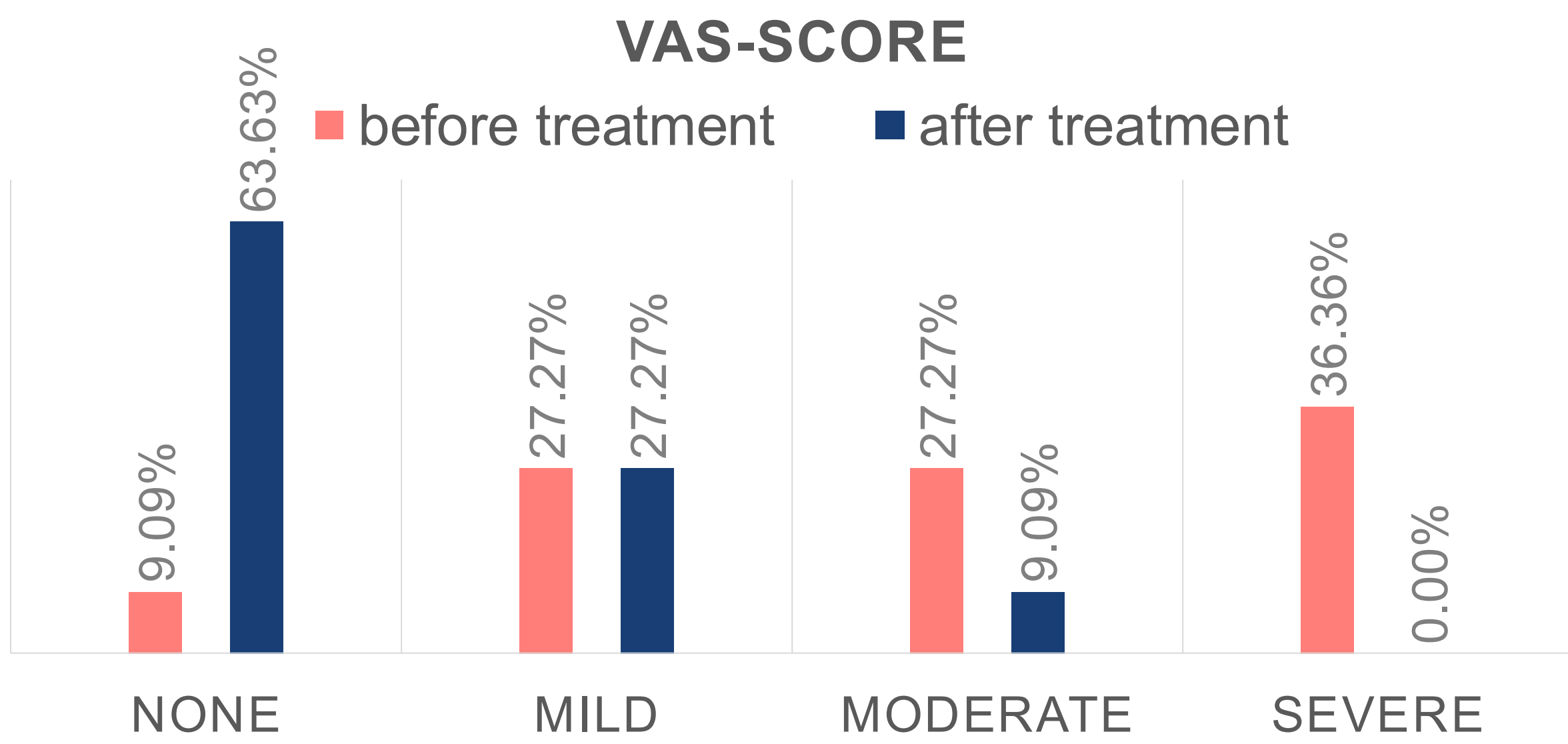


Figure 2. VAS-scores before and after treatment



Figure 3. Progression of symptomatic ischemic feet before treatment(A) and six weeks after treatment (B)

Surgical technique

- OR in supine position
- 100 units BTX-A diluted with 10cc of lidocaine without epinephrine, distributed in 3cc syringes
- Administration using a 30-gauge 1-inch needle, under US guidance, around the neurovascular bundles of the foot
- A total of 22 injections per foot were given (fig 1.)
- Thermal images were obtained before and after treatment

RESULTS

- Ulcers and/or gangrene resolved in 81.9% within six weeks after treatment
- Significant improvement in VAS-scores after treatment ($X^2 = p < 0.023$)
- In one instance, temporary intrinsic muscle weakness was reported post-treatment, which did not require extra care
- no other adverse effects observed

CONCLUSION

- Provides a detailed description of the surgical technique
- Highlights the potential safety and the promising efficacy and benefits of BTX-A injections in the feet for patients with persistent advanced symptoms due to RP
- Foundation for subsequent prospective studies aimed at assessing the precise impact

Reference

- Flavahan NA. A vascular mechanistic approach to understanding Raynaud phenomenon. Vol. 11, Nature Reviews Rheumatology. Nature Publishing Group; 2015. p. 146–58.
- Riera G, Vilardell M, Vaqué J, Fonollosa V, Bermejo B. Prevalence of Raynaud's phenomenon in a healthy Spanish population. J Rheumatol. 1993 Jan;20(1):66–9.
- Maundrell A, Proudman SM. Epidemiology of Raynaud's Phenomenon. In: Raynaud's Phenomenon. Springer New York; 2015. p. 21–35.
- Stringer T, Femia AN. Raynaud's phenomenon: Current concepts. Clin Dermatol. 2018 Jul 1;36(4):498–507.
- Grassi W, De Angelis R, Lapadula G, Leardini G, Scarpa R. Clinical diagnosis found in patients with Raynaud's phenomenon: a multicentre study. Rheumatol Int. 1998 Jun 20;18(1):17–20.
- Nagarajan M, McArthur P. Targeted high concentration botulinum toxin A injections in patients with Raynaud's phenomenon: a retrospective single-centre experience. Rheumatol Int. 2021 May 1;41(5):943–9.
- Maverakis E, Patel F, Kronenberg DG, Chung L, Fiorentino D, Allamore Y, et al. International consensus criteria for the diagnosis of Raynaud's phenomenon. J Autoimmun. 2014 Feb;48–49:60–5.