Huang Y-C, Wei S-H, et al. Ultrasonographic guided botulinum toxin type A treatment for plantar fasciitis: an outcome-based investigation for treating pain and gait changes. J Rehabil Med 2010;42:136-140.

Design: randomized clinical trial

Purpose of study: to evaluate the effectiveness of an ultrasound-guided botulinum toxin (BTX) injection in patients with plantar fasciitis who have persistent symptoms

Population/sample size/setting:

- 50 patients (12 men, 38 women, mean age 54) treated for plantar fasciitis at a physical medicine and rehabilitation clinic in Taiwan
- Inclusion criteria were age at least 18 with at least three months of unilateral heel pain diagnosed with plantar fasciitis with clinical examination and ultrasonography showing plantar fascia rupture or fascia thicker than 4 mm
- Exclusion criteria were foot deformity, pes cavus, any systemic disease whose symptoms include foot pain or a sensory disorder, any previous surgery on the affected foot, any neuromuscular junction disorder, pregnancy, or allergy to BTX

Interventions:

- Randomization was to either injection with 50 units of BTX type A (n=25) or 1 ml normal saline placebo (n=25)
- Both injections were done ultrasound guidance into the fascia via a posterior approach below the calcaneus

Outcomes:

- Pain VAS, plantar fascia thickness, and fat pad thickness were measured at prior to injection and again at three weeks and three months
- Pain VAS scores decreased in the BTX group but not the control group
    - VAS scores for the BTX group at baseline, 3 weeks, and 3 months were 5.9, 3.4, and 2.0
    - VAS scores for the control group at baseline, 3 weeks, and 3 months were 5.4, 5.1, and 5.2
- Plantar fascia thickness decreased in the BTX group but not in the control group
    - Fascia thicknesses for the BTX group at baseline, 3 weeks, and 3 months were 5.5, 4.2, and 3.6
    - Fascia thickness for the control group at baseline, 3 weeks, and 3 months were 5.5, 5.5, and 5.6
- Plantar fascia thickness did not change after injection in either the BTX or the control group

Authors' conclusions:

- BTX injection under ultrasound guidance led to significant pain relief at 3 weeks and at 3 months, with concomitant reduction in plantar fascia thickness, but without compromising the thickness of the plantar fat pad
- The thickness of the plantar fascia is closely correlated with pain scores on the VAS, and can be a tool for evaluating the severity of plantar fasciitis

Comments:

- Details of randomization do not include the method of sequence generation and allocation concealment but the outcome assessment and the patients were blinded; there is some risk of bias but probably not sufficient to invalidate the findings
- The patients may or may not have attempted other treatment interventions before being injected with BTX; this should not be a first line treatment, and whether the patients had tried stretching and orthotics is not discussed
- There was another outcome, center of pressure velocity movement, which was undertaken with special equipment to analyze gait, and which is not of clear clinical relevance
- The discussion section has some poorly explained comments about plantar fascia thickness as an indicator of the extent of inflammation, accompanied by a reference to a study of tendon thickness in patients with Behçet's disease, which is a non sequitur, since Behçet's is a systemic vasculitis involving other body systems, and the cited article looked at the thickness of the Achilles tendon and not the plantar fascia
- Because plantar fasciitis is not considered to be an inflammatory condition, and is often referred to as plantar fasciopathy to clarify this fact, the overall quality of the study suffers
- Because the study does not present the biomedical principles on which the intervention is based, it does not meet criteria for evidence of the effectiveness of BTX injection into the plantar fascia

Assessment: Inadequate for evidence that an ultrasound guided injection of 50 units of botulinum toxin type A relieves symptoms of plantar fasciopathy