Peyronie’s disease and the role of therapeutic ultrasound: a randomized controlled trial


**Introduction:**
- Peyronie's Disease (PD) affects 1 out of every 10 men whereas therapeutic ultrasound may stimulate tissue repair to increase blood flow, reduce inflammation, and reduce pain.
- The cause of PD is the formation of inelastic scar tissue that creates plaques in the tunica albuginea of the penis; this condition is often permanent over time.
- Incidence of PD is age 55-60 and it is associated with other health factors listed on page one of the article. This is often underdiagnosed in men under 40 or even teenagers that first complain of difficulty maintaining erections.
- Of note, the article mentions that 16% of men undergoing prostatectomy experience PD.
- Treatment options for PD are usually a “watch and wait approach” with no known cure. Some treatments that are not always effective may include: injections, vacuums, traction devices, and surgery - all of which have side effects that sometimes worsen ED or sexual function.
- During history a client might complain of “buckling” of the penis during sexual activity, pain, deformity, curvature, and shortening (seen in the erect state).
- The gold standard to diagnose PD is doppler ultrasound (PDDU).
- 81% of men with PD report emotional difficulties and over half report relationship difficulties.

**Primary aim:**
- There is no known cure or non-invasive treatment option for PD, this study aimed to determine if ultrasound could be beneficial for these clients.
- There have been no RCTs for this technique in this patient population but there have been experimental studies ranging back to the 1950s.

**Study Design/ Study Format:**
- Randomized Control Trial of 46 participants referred by their Urologist, GP or radiological clinic following confirmation of PD with doppler ultrasound - 43 participated.
- Excluded from the study were men with DM, smokers, and those undergoing radiation.
- The control group had no treatment with a delayed entry study design.

**Methods**
- The participants participated in giving a medical history where the timing and cause of PD was recorded.
- Intervention group - 4-6 weeks receiving therapeutic ultrasound (TUS) for 10 mins for a total of 12 sessions. 2-3x a week, 2cm diameter head. They used gel on ultrasound head, a condom on the head, and then gel on the condom.
  - Parameters - 1.5-2.5 W/cm², 3 MHz x 10mins/session
- The control group received the intervention for the same amount of time 4 weeks later than the first group.
- The effectiveness was measured using the PDD, the Erectile Function outcome measure and the PDQ outcome measure, goniometer to measure curvature.

Results
- The PDDU Score (reduction in the size of the plaque was statistically significant in the intervention group)
- Reduction of angle of deformity was 38% over time in the intervention group
- The IIEF-5 Scores - Only the intervention group improved over time
- PDQ Scores - Too small of a sample size to make statistical meaning of data

Discussion
- This is a 2cm sound head, 2-3x a week at 1.5-2.5 W/cm², 3 MHz, is this applicable for our clients?
- From the Author Jo Milios
  - “This is only relevant to CALCIFIED plaques less than 0.5mm, commonly known as ‘foci calcification’. If the plaques are soft or fibrous and not hard, the TUS will be effective.
  - The results indicated poor response in CALCIFIED plaques larger than 0.5mm but complete resolution of the smaller foci calcifications was observed.
  - The tunica measurements are completely different to individual plaques, 1mm being normal. If there is trauma, there is usually thickening of the ligamentous tunica. All of these measurements were taken by the sonographer.”
- The angle of deformity was the most important outcome for patients and this was greatly improved in this study by an average of 17 degrees.
- Early diagnosis and interventions could reduce the severity of PD symptoms.

Clinical Applications
- TUS may be an effective treatment option for clients with Peyronie's disease.
- This option could provide psychological as well as physical benefits to our clients.

Questions
1. Have any of you used this protocol? Do you have any insight?
2. Have you come across Peronies disease in your clients? Have you considered this as a cause of complaints of pain with insertion.