

## Case Series of Weekly Low Intensity Shock Wave Therapy for Erectile Dysfunction

All Cleveland Clinic, Department of Urology, Glickman Urological and Kidney Institute  
Daniel A Shoskes MD, Nic Tadros MD, Brandon Mooney PA

**Background & Aim:** Low Intensity Shock Wave (LiSW) has emerged as a therapy for vasculogenic erectile dysfunction (ED). Mechanism may be related to angiogenesis, release of growth factors and/or recruitment of stem cells. Several sham controlled studies have shown improvement in peak arterial velocity and efficacy in the 60-65% range depending on the definition. The initial protocol of twice weekly treatments for 3 weeks with a rest period and repeat has remained the standard, although this can be very inconvenient for patients. We wished to study the efficacy and safety of LiSW using a modified protocol of 4 weekly treatments.

**Methods:** Men were enrolled in this IRB approved study provided they had a diagnosis of ED for at least 6 months and were able to return for weekly treatments. Low Intensity Shockwave was delivered with the Urogold 100 machine (Tissue Regeneration Technologies, Woodstock, GA) using the soft wide focused applicator probe (figure 1). There were 6 treatment sites: one at each crus of the penis and 2 on the shaft bilaterally with about 500 shocks each for a total of 3000 shocks. Energy flux was  $0.13 \text{ mJ/mm}^2$  and frequency was 4 Hz yielding a biologic energy density of 1560. ED severity was measured with the Sexual Health Inventory for Men (SHIM) score at baseline and 1 month following the 4 weekly treatments. Pre and post SHIM values were compared with the paired t test with significance set at  $p < 0.05$ .

**Results:** Eight men enrolled with a mean age of 56.8 years (range 26-70) and median duration of 36 months (range 12-120). Five had previously tried PDE5 inhibitor (PDE5i) oral medications without adequate success. One patient stopped after 3 treatments but was included for an intent to treat analysis. The treatments were painless and there were no side effects. Overall, SHIM score improved from  $11.0 \pm 3.6$  to  $17.2 \pm 5.2$  ( $p = 0.01$ ). SHIM was unchanged in 2 patients (25%), mildly improved in 1 patient but not sufficiently for intercourse and significantly improved with erection sufficient for intercourse in 5 patients (62.5%) (figure 2). Two of these 5 men required a PDE5i for optimal erections however both had failed PDE5i in the past.

**Discussion:** Low Intensity Shockwave Lithotripsy with the Urogold 100 using a once a week protocol produced a similar success rate to previously published twice weekly protocols. One of the treatment failures had psychogenic ED suggesting that inclusion criteria should focus on men with an arteriogenic etiology. Whether this once weekly therapy remains durable will await longer term follow up. Since in the United States this device is not approved by the FDA and patients will need to pay cash for therapy, a protocol that minimizes time away from work and out of pocket expense is highly desirable.

**Conclusion:** Once weekly low intensity shock wave lithotripsy improved erections sufficient for intercourse in 62.5% of our patients without side effects.