

Ultra-deformable Drug-free Sequeosome™ Vesicles (TDT 064) for the Treatment of Joint Pain Following Exercise: A Case Report and Clinical Data

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Abstract : Background: Oral non-steroidal anti-inflammatory drugs (NSAIDs) are widely used for the relief of joint pain during and post-exercise. However, oral NSAIDs increase the risk of systemic side effects, even in healthy individuals, and retard recovery from muscle soreness. TDT 064 (Flexiseq®), a topical formulation containing ultra-deformable drug-free Sequeosome™ vesicles, has demonstrated equivalent efficacy to oral celecoxib in reducing osteoarthritis-associated joint pain and stiffness. TDT 064 does not cause NSAID-related adverse effects. We describe clinical study data and a case report on the effectiveness of TDT 064 in reducing joint pain after exercise. Methods: Participants with a pain score ≥ 3 (10-point scale) 12-16 hours post-exercise were randomized to receive TDT 064 plus oral placebo, TDT 064 plus oral ketoprofen, or ketoprofen in ultra-deformable phospholipid vesicles plus oral placebo. Results: In the 168 study participants, pain scores were significantly higher with oral ketoprofen plus TDT 064 than with TDT 064 plus placebo in the 7 days post-exercise ($P = 0.0240$) and recovery from muscle soreness was significantly longer ($P = 0.0262$). There was a low incidence of adverse events. These data are supported by clinical experience. A 24-year-old male professional rugby player suffered a traumatic lisfranc fracture in March 2014 and underwent operative reconstruction. He had no relevant medical history and was not receiving concomitant medications. He had undergone anterior cruciate ligament reconstruction in 2008. The patient reported restricted training due to pain (score 7/10), stiffness (score 9/10) and poor function, as well as pain when changing direction and running on consecutive days. In July 2014 he started using TDT 064 twice daily at the recommended dose. In November 2014 he noted reduced pain on running (score 2-3/10), decreased morning stiffness (score 4/10) and improved joint mobility and was able to return to competitive rugby without restrictions. No side effects of TDT 064 were reported. Conclusions: TDT 064 shows efficacy against exercise- and injury-induced joint pain, as well as that associated with osteoarthritis. It does not retard muscle soreness recovery after exercise compared with an oral NSAID, making it an alternative approach for the treatment of joint pain during and post-exercise.

Keywords : exercise, joint pain, TDT 064, phospholipid vesicles

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