Comparison of Minimally Invasive Ossatron Procedure Versus Amniotic Membrane Injections in the treatment of Recalcitrant Plantar Fasciitis

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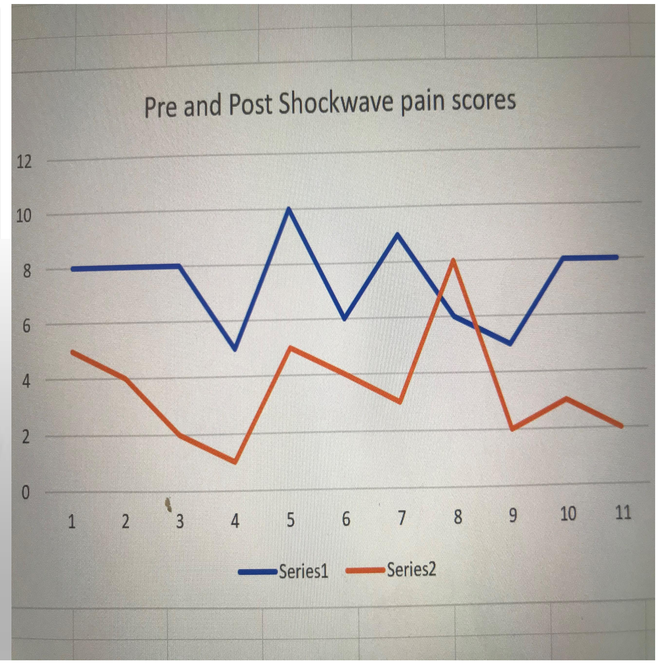
Statement of Purpose

Plantar fasciitis is the most common cause of heel pain in the adults. The primary symptom is pain in the plantar aspect of the arch and heel. Initial treatment consist of conservative measures including stretching, icing, custom orthotics, physical therapy, non steroidal anti-inflammatories, night splint, cortisone injections and amniotic membrane injection. Failure of conservative measures often lead to surgical intervention. The Ossatron shockwave therapy is a minimally invasive surgical approach to plantar fasciitis with a 80% success rate after 12 weeks (Wang CJ et 2006). The amniotic membrane injections has been used for tissue and regeneration with evidence supporting an 87% success rate compared to cortisone injections after 12 weeks (Zelen et al 2013). This case study compares Minimally invasive Ossatron Shockwave therapy to Amniotic Membrane injections for recalcitrant chronic plantar fasciitis as an alternative to invasive surgical approaches.

Case Study

50 subjects consisting of 25 Ossatron Shockwave and 25 Amniotic membrane injection recipients were included in this study. All patients has been clinically diagnosed with chronic (>6 months) recalcitrant plantar fasciitis that failed at least 6 months of conservative measures. A comparison of pain scores ranging from a score of 0, which indicates no pain to a score of 10, indicating severe pain was used pre and post procedure for record continuity for 24 months.



Literature Review

The OssaTron® is a high-energy shockwave device that provides a non-invasive surgical alternative for patients diagnosed with chronic plantar fasciitis (severe heel pain).
Ossatron was developed in 1991 and FDA-approved for orthopaedic use with clinical studies and tests supporting safety and efficacy. In some cases it may cause skin reddening, bruising, temporary numbness or tingling. In rare instances it may cause the plantar fascia to tear.
The therapy allows 24-48 hour recovery period compared to 4-6 weeks of recovery from more invasive surgical procedures and patients can bear weight immediately to tolerance (Wang 2002).

Fetal tissues, consisting of the amniotic membrane, chorionic membrane, and umbilical cord, are well known for their healing characteristics properties are a potential therapeutic modality for plantar fasciitis. Utilization of amniotic membranes are activated in the regenerative stages, and reduces inflammation and scarring (Hanelman 2015).

The literature that was reviewed in this case study reported a 80% success rate after 12 weeks (Wang CJ et 2006) and a 87% success rate after 12 weeks with amniotic membrane injections (Zelen et al 2013). This case study reviewed patients data over the course of 24 months to determine their level of pain after these initial therapies were performed to have a perspective of a longer course of success rate up to 24 months. Long term it appears that the benefits of these therapies may reduce but overall still showed 44% to 74% reduction of pain .

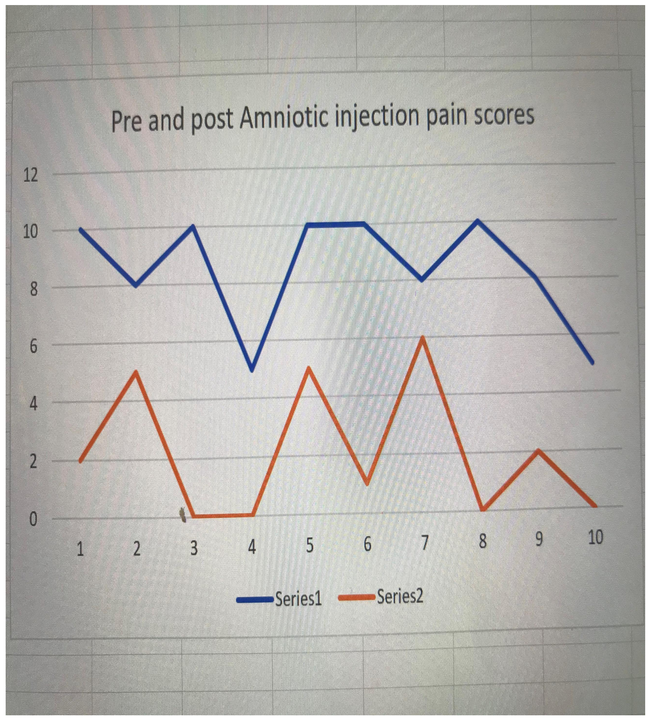
Procedure

Minimally invasive Ossatron Shockwave therapy at 1800 shocks at 2.0Hz under local and Intravenous sedation was administered compared to 1mL of Amniotic membrane Injections diluted with 1mL of 1% Lidocain plain or normal saline 0.9%

Analysis and Discussion

Plantar fasciitis is the most common cause of heel pain in adults. Initial treatment consists of a host of conservative measures, a change in treatment plan may be discussed to include surgical options such as Open plantar fasciotomy or Endoscopic Plantar fasciotomy. In this Study, Shockwave Ossatron therapy was found to have 44% improvement in pain compared with Amniotic injections, which was found to have a 74% reduction of pain in 24 months. The amniotic injection therapy outperformed the Shockwave therapy but both therapies had overall positive results in pain. All patients continued to require conservative treatment with stretching, custom orthotics, physical therapy, non sterioidal anti-inflammatories and night splints after the procedures were performed. The benefit of the Ossatron procedure is that the procedure is typicaly performed in the operating room under Intravenous sedation with local anesthesia versus the amniotic membrane injection where the patient has to endure a needle stick injection typically done in a clinic setting.

If a patient is not an ideal candidate for an open surgical procedure to address recalcitrant plantar fasciitis, due medical contraindications, time off from work, recovery time, or financial constraints, this study shows that there are alternative advanced options such as Shockwave Ossatron and Amniotic membrane injections with a range of 44%-74% reduction of pain in 24 months with the Amniotic injection therapy performing the best with continued conservative treatment stated.



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No Disclosures to report