Two- and four-year clinical follow-up on the DeneverX® System for Facet Joint Syndrome at two clinical locations demonstrates significant reduction in pain with no adverse events or complications

Medovex Corporation is the developer of the novel device, DenerveX®, for treatment of Facet Joint Syndrome (FJS). The DenerveX® System is a novel, non-addictive, non-opioid drug alternative, designed for enduring relief of FJS related chronic back pain.

FJS is a significant cause of chronic lower back pain in both young and elderly populations, and presents a worldwide burden with significant health, social and economic impacts [1]. Facet joints can face joint degeneration or hypermobility and thereby significantly contribute to chronic spinal pain [1-3]. Facet joint wear and tear due to either spinal osteoarthritis, degenerative processes, spondylolisthesis, septic arthritis, or systemic inflammatory phenomena, typically characterise FJS [1]. FJS is a painful, chronic condition whose treatment options are usually only temporary and have seen little advancement in the last 40 years.

The minimally invasive DenerveX® System has been developed to provide potential long-term relief via a combination of controlled thermal energy and rotational capsular tissue shaving of the facet joint capsule, to disrupt nociceptive signals and receptors. The rotational, monopolar, radiofrequency denervation device, DenerveX®, works with the DenerveX Pro-40 RF Generator, to ablate the nerve and capsular tissue on the posterior surface of the facet joint. This enables denervation through the delivery of controlled radiofrequency (RF) energy with tissue debris removed from the site via the rotating action of the probe. Each DenerveX® device is provided in a procedure tray with the following accessories: 1mm K-Wire, Procedure Dilator, Portal Tube, Portal Driver and Tissue Stabilizer.

Here we present the following clinical patient outcomes after two- and four-years post-treatment using the DenerveX® System, from two different clinical locations. Outcomes are reported through visual analogue scores (VAS). The results of this study will be presented at Spine Week in Australia, 2023.

METHOD

Participants

One prospective study of FJS patients receiving DenerveX® treatment, took place between 2017 to 2020, at three hospitals across Greater Manchester in the United Kingdom. This study recruited 80 patients. Unfortunately, 11 patients were lost during the follow-up period. In total, 69 patients were included in the following analysis. Outcomes of leg and back pain were assessed using the visual analogue score (VAS). All outcomes were measured at baseline and at follow-ups conducted at 1-, 3-, 6-, 12- and 24-months post-treatment; data reported corresponds to these time points.

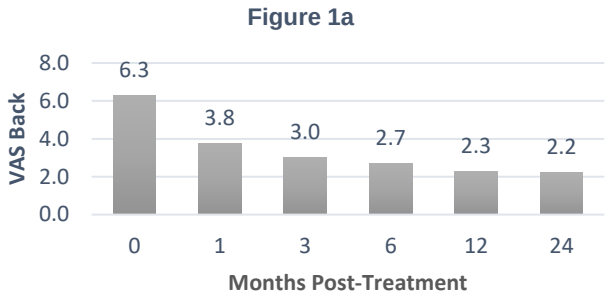
A second prospective study was undertaken in 2018 in Medellín, Antioquia, Columbia at Clínica CES and Clínica Las Vegas. It consisted of eight patients who received DenerveX® treatment for FJS. Clinical outcome was measured using VAS for back pain, at baseline and at follow-up conducted 48-months post-treatment; data reported corresponds to these time points.

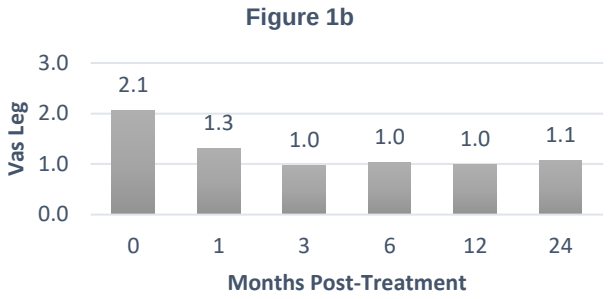
Surgical Procedure

The DenerveX® System (MedoveX Corporation, Georgia, USA) procedure was performed as a day case procedure in the prone position either under local, regional or general anaesthesia. After patient positioning, the return electrode was placed under either the thigh or abdomen, after which the return electrode cord was connected to the DenerveX™ Pro-40 Generator (MedoveX Corporation, Georgia, USA). The treated facet joint was located using fluoroscopy and marked for K-Wire placement. Once located, a 10-15cm incision at the determined location was made considering the angle of approach for reaching the treated facet joint. Using fluoroscopic guidance, the K-Wire (MedoveX Corporation, Georgia, USA) was advanced into the incision until reaching target facet joint, after which it was tapped into the bone, and confirmed via fluoroscopy. Procedure Dilator (MedoveX Corporation, Georgia, USA) was then inserted over the K-Wire and correct positioning was confirmed by fluoroscopy. Portal Tube (MedoveX Corporation, Georgia, USA) was then inserted over the Procedure Dilator and K-Wire. Portal Driver (MedoveX Corporation, Georgia, USA) was then attached, and procedure tube was advanced as far as possible. The correct position of the K-Wire, Procedure Dilator, and Portal Tube were confirmed by fluoroscopy. The Portal Driver was then removed and K-Wire positioning was checked. The suction tubing was then connected to the side port of the Tissue Stabilizer (MedoveX Corporation, Georgia, USA), and then advanced over the Portal Tube, where positioning was maintained with firm hand pressure. A flow rate of at least 40LPM was established for the DenerveX™ Pro-40 Generator and then connected to the DenerveX® Device (MedoveX Corporation, Georgia, USA). The Procedure Dilator and K-Wire were then removed, with Portal Tube held in place. The DenerveX® device was then inserted into the Portal Tube, delivering RF energy to the treatment site.

RESULTS

Results from 69 patients undergoing DenerveX® treatment for FJS across three Hospitals in the Greater Manchester area of the United Kingdom, were evaluated for their clinical outcomes using the VAS for back and leg pain.





Figures 1a-b. Demonstates mean visual analog scale (VAS) scores (in cm) for back and leg pain, for patinets who underwent DenerveX® treatment at the UK clincal location **(a)** Mean VAS scores for back pain presented as bar graphs at 0- (baseline), 1-, 3-, 6-, 12-, and 24-months post-treatment **(b)** Mean VAS scores for leg pain presented as bar graphs at 0- (baseline), 1-, 3-, 6-, 12-, and 24-months post-treatment

Baseline mean scores for the 69 patients prior to treatment for VAS_{Back} was recorded as 6.3cm and VAS_{Leg} as 2.1cm on 10cm scales, as depicted in Figures 1a-b. Post-treatment VAS_{Back} mean scores reduced to 3.8cm, 3.0cm, 2.7cm, 2.3cm, 2.2cm, at follow-ups 1-, 3-, 6-, 12-, and 24-months respectively, as depicted in Figure 1a. Post-treatment VAS_{Leg} mean scores reduced to 1.3cm, 1cm, 1cm, 1cm, 1.1cm, at follow-ups 1-, 3-, 6-, 12-, and 24-months respectively, as depicted in Figure 1b.

Results from eight patients who underwent DenerveX® treatment for FJS in Medellín, Antioquia, Columbia, were evaluated for their outcomes using VAS for back pain at 48-months post-treatment. The baseline mean scores for VAS_{Back} for the eight patients prior to treatment was recorded as 9.25cm on a 10cm scale, and reduced to a mean of 0.5cm at 48-months post-treatment, as illustrated in Figure 2.

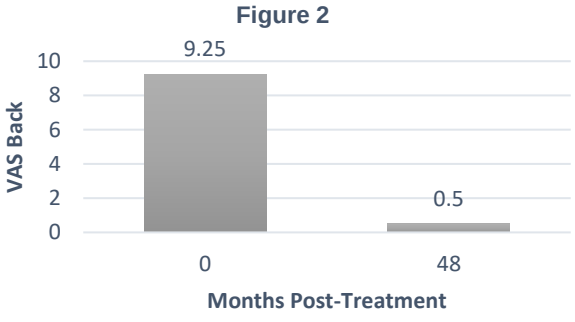


Figure 2. Mean visual analog scale (VAS) scores (in cm) for back pain from Columbian clincal location, presented as bar graphs at 0- (baseline) and 48-months post DenerveX® treatment

DISCUSSION

Prospective clinical data of patients who underwent DenerveX® treatment for FJS at two independent clinical locations revealed a reduction in mean back pain scores demonstrated by outcomes for VAS_{Back} over periods of two- and four-years post-treatment. For the treatment group in the United Kingdom, VAS_{Back} scores for 69 patients who received DenerveX® treatment demonstrated a 65% reduction in mean VAS_{Back} scores over a two-year period. For the treatment group in Columbia, VAS_{Back} scores for eight patients who received DenerveX® treatment demonstrated a 95% reduction in mean VAS_{Back} scores over a four-year period. Additionally, participants of the UK study saw a 48% decrease in VAS_{Leg} mean scores. Reference values define a 30-50% reduction in VAS_{Back} and VAS_{Leg} scores at post-treatment, as significant [4]. The reduction in VAS_{Back} in both the United Kingdom and Columbian clinical studies, and reduction in VAS_{Leg} in the UK study, demonstrates significant reduction in mean VAS scores from DenerveX® treatment for FJS. This result therefore demonstrates the enduring clinical benefits of the DenerveX® System for reducing pain in patients suffering from FJS at two- and four-years post-treatment. In conjunction with the demonstrated clinical benefits of DenerveX® for treatment of FJS back pain, both studies in Columbia and the United Kingdom did not report any adverse events or complications.

CONCLUSION

We have presented here two clinical studies looking at outcomes at two- and four-years post-treatment with the DenerveX® System for FJS. Both studies showed significant post-treatment reduction in back pain, with mean VAS_{Back} reducing 65% in two-years post-treatment (n=69) and 95% in four-years post-treatment (n=8) using the DenerveX® System. No adverse events or complications were reported in either study.

Through outcome measures VAS_{Back} and VAS_{Leg}, collected at two separate clinical locations, the DenerveX® System has demonstrated to offer a minimally invasive, non-opioid drug alternative that provides significant sustained long-term relief from pain in patients with FJS, and presents no

identifiable risks of adverse events or complications associated with the device.

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CLINICAL LOCATIONS

United Kingdom Study

Dates: 2017-2020

Study Location: 3 Hospitals across the Greater Manchester region, United Kingdom – Stepping Hill Hospital Stockport, Regency Hospital Macclesfield, Alexandra Hospital Cheadle
Surgeon Team:

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MBBS FRCS FRCS (Tr and Orth)
Consultant Spinal Surgeon
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Columbia Study

Dates: 2018

Study Location: Clínica CES Columbia
Surgeon and Clinical Lead: Gabriel Jaime Davila Jaramillo M.D.
Hospital: Clínica CES, Universidad CES, Columbia
Address: Calle 58-51 N° 50C – 2. Prado Centro, Medellín, Antioquia, Colombia

Study Location: Clinica Las Vegas
Surgeon and Clinical Lead: Gabriel Jaime Davila Jaramillo M.D.
Hospital: Clinica Las Vegas
Address: Cl. 2 Sur #46-55, El Poblado, Medellín, El Poblado, Medellín, Antioquia, Colombia

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