



## Case Report

# First Case of Debilitating Lower Back Pain Induced by Severe Inflammation of Lumbar Joints, Healed by Intravenous Infusions of Purified Amniotic Fluid

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### Abstract

We report the first case of debilitating lower back pain induced by spondylitis with end plate inflammation of the lumbar spine, treated successfully by bi-weekly intravenous injections of a sterile fraction (1ml) from human purified amniotic fluid (ViX001) obtained from thoroughly screened volunteers at the time of planned c-section at the term of normal pregnancies. Our product ViX001 was generated through a proprietary process and kept in frozen one milliliter (1 ml) cryovials (protein content was ~1mg/ml) and thawed just prior to injections. Pain improvement was recorded weekly, and inflammation suppression was confirmed by monthly MRIs of the lumbar spine. While our findings need to be reproduced with a larger cohort of patients, it is instructive that ViX001 resolved pain and inflammation for a patient with severe lower back pain, the most common form of pain reported by U.S. adults.

**Keywords:** Purified Amniotic Fluid; Perinatal Products; Back Pain; Spine; Vertebral Disc; Inflammation, Extracellular Vesicles; Exosomes; Healing; Tissue Repair; Regenerative Medicine; Immunity

### Introduction

According to the most recent data from the National Health Interview Survey, back pain is the most frequent source of pain in the U.S. [1]. Most cases of back pain result from osteoarthritis of the spine, back injuries, and herniated discs [2], three causes of back pain that involve substantial inflammation. Back pain has short- and long-term health effects, from minor discomfort to musculoskeletal impairment, diminished quality of life, and escalating health care costs [3,4]. Back pain is currently the major

reported reason for sickness absence from the workplace in the UK and many other nations [5]. Back pain often leads to a sedentary lifestyle which itself can lead to metabolic syndrome with a myriad of complications including cardiovascular events, like myocardial infarction and stroke [6]. There are no definite cures for lower back pain, and current treatments are usually protracted and of unpredictable effectiveness. Reports have suggested that extracellular vesicles (EVs) produced by mesenchymal signaling cells (MSCs) may help with the treatment of intervertebral disc degeneration and ensuing back pain [7]. Since amniotic fluid has evolved over more than 7,000,000 years for the human species [8], it is likely that it has evolved to maximally protect the fetus tissues from severe inflammation. Hence, we sought to study the impact of repeated intravenous injections of ViX001, a proprietary fraction

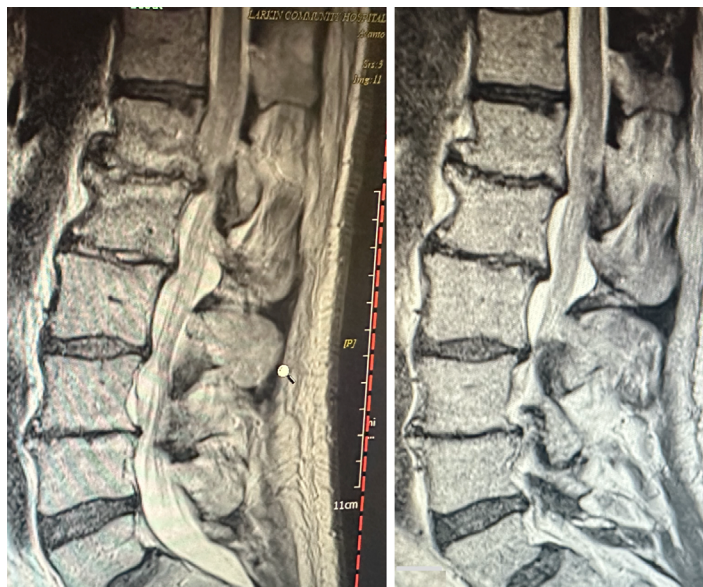
derived from purified human amniotic fluid, on the healing of a severe case of lower back pain induced by debilitating spondylitis with end plate inflammation of the lower spine.

Spondylitis with end plate inflammation is a condition that presents significant challenges in the medical field. Existing treatments, although diverse, often fail to offer a definitive cure, pushing patients towards more invasive interventions. Drawing parallels from the improved neurological outcomes in prenatal surgeries such as those for spina bifida [9], which are operated in the presence of amniotic fluid, we explored the therapeutic potential of ViX001 on pain and inflammation refractory to conventional, standard-of-care, treatments.

### Case Presentation

The patient, a 65-year-old man came to the Miami Neuroscience Center with debilitating back pain stemming from spondylitis with end plate inflammation. Initial assessments placed his pain level at a distressing 10/10. Traditional treatment regimens had yielded minimal relief. In search of an innovative solution, our team provided ViX001 to be used for a novel treatment lead by a neurosurgeon who was managing the patient, after signing an informed consent, the patient received bi-weekly intravenous (i.v.) injections of ViX001, to directly address the persistent inflammation and debilitating pain. The therapeutic ViX001 has received Food and Drug Administration (FDA) approval for an Investigator New Drug (IND) phase I/II human clinical trial to treat the inflammatory component of post-COVID syndrome.

Over the course of treatment, the patient received a total of 24 ViX001 i.v. injections (1 ml each). The patient did not experience any allergic reaction or adverse event during the entire duration of treatment. Remarkably, after the first month, the pain had already decreased by 50%, and by twelve weeks, the pain level had markedly decreased to a manageable 2/10. The efficacy of the treatment was meticulously evaluated using the Siemens Avanto 1.5 T MRI, which provided detailed images essential for assessing the effectiveness of this therapeutic approach [Figure 1]. Notably, after a period of improvement that lasted 18 months the patient experienced a resurgence of pain, indicating the need for ongoing evaluation and potentially additional administration of ViX001.



**Figure 1:** Magnetic Resonance Imaging (MRI) with Siemens Avanto 1.5 T instrument was used to study the lower spine of our patient before (left) and after (right) treatment with 24 biweekly intravenous infusions of ViX001, 1 ml dose for each infusion. Before treatment, the joints between vertebra T12-L1, and to a lesser degree L3-L4, show marked spondylitis with end plate inflammation (whiter area), which nearly resolved after treatment completion, and resolution of inflammation was associated with stabilization of the end plates on each side of the joints.

### Discussion

The significant improvement observed in our patient's condition suggests a promising opportunity for the application of ViX001 in treating conditions like spondylitis with end plate inflammation. Although encouraging, these findings originate from a single case and thus necessitate further investigation, which we are already planning. Indeed, a broader clinical phase I/II study is imperative to fully understand the capabilities and limitations of intravenous administration of ViX001 for severe and recalcitrant cases of lower back pain associated with marked inflammation.

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We have previously reported on the ability of ViX001 to reduce pain drastically in two prior reports. First, a 24-year-old woman who had suffered from full-thickness burns to her legs resulting from a rogue firework [10]. Her pain dropped from 10/10 to 2/10 within thirty minutes of application of ViX001, and with such receding of the pain, we also observed accelerated skin regeneration induced by ViX001. Second, in a 79-year-old man with diabetic wound that had been recalcitrant to all prior treatments, we confirmed that ViX001 has an immediate beneficial impact on wound pain and inflammation surrounding the wound. And again, healing of the diabetic ulcer was markedly accelerated by ViX001 application. [11]

### Conclusion

Our data suggest a biological precedent for the protective and regenerative properties of perinatal products involved in fetal development, specifically a proprietary fraction derived from amniotic fluid, ViX001, for the treatment of lower back pain and inflammation produced by various forms of spinal osteoarthritis, spondylitis with end plate inflammation of the lower spine in this case, that are not resolving with standard-of-care therapy.

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