XO Biologics: Assessment of MaviX™ in Reducing Pain and Improving Function in Patients with Chronic Spinal Conditions: A Retrospective Analysis

Final Report

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Title: Assessment of MaviX™ in Reducing Pain and Improving Function in Patients with Chronic Spinal Conditions: A Retrospective Analysis"

Abstract:

Background: Orthopedic practices have increasingly shifted towards including regenerative medicine orthobiologic treatments for spinal conditions. This study evaluates the outcomes of patients undergoing spine procedures who were treated by MaviX™. MaviX™ is a connective tissue biologic matrix that is manufactured as a lyophilized, sterile product for clinical consideration.

Methods: A single site, investigator-initiated, retrospective review of patients receiving MaviX™ as part of their medical treatment was conducted. Eligible patients, aged 21-80, who had experienced chronic back pain for over three months and were treated with MaviX™ as part of their standard care, were assessed. Pain and functional outcomes were assessed using the Pain, Enjoyment and General Activity (PEG) scale, Oswestry Disability Index (ODI), and Functional Status Index (FSI) at baseline and at multiple postoperative intervals.

Results: Fifty-eight patients met the study's eligibility criteria. Significant improvements in pain and functional outcomes were observed. Pain scores decreased from a mean of 6.8 at baseline to 1.8 at 12 months ($p < 0.01$). ODI scores decreased from 33.5 to 9.2 ($p < 0.01$), and FSI scores increased from 7.2 to 9.2 ($p < 0.01$). No procedure-related adverse events or deaths were reported.

Conclusion: Data from the study demonstrate significant improvements in pain and functional outcomes among patients treated with MaviX™. While MaviX™ shows promise for improving pain and function in chronic back pain patients, further research would benefit from larger, multi-center, prospective studies.

Keywords: MaviX™, Orthobiologics, Spine procedures, Chronic back pain, Functional outcomes

Background

The evolution of orthopedic practices has witnessed a significant shift from conventional fracture fixation and joint reconstruction towards regenerative medicine; prominently employing orthobiologic treatments to address musculoskeletal injuries and degeneration [1]. The course of this transition has been underscored by the increasing utilization of orthobiologics in both surgical and nonsurgical orthopedic settings. Notably, 66.1% of physicians affiliated with the American Orthopaedic Society for Sports Medicine reporting their use [2]. The term “orthobiologics” encompasses a diverse range of synthetic or biological materials that have been appropriated to use in orthopedic surgeries with the thought that they will enhance the body's biochemical processes, and facilitate regeneration of damaged bone, ligaments, muscles, and tendons [3,4]. With ongoing research efforts and increasing clinical trial data, orthobiologics holds the potential to evolutionize if not revolutionize regenerative therapies for various orthopedic pathologies[5].

MaviX™ is a lyophilized, sterile product specifically formulated for spinal conditions, comprised of enriched lipoprotein vesicles, matrisomes, proteins, and extracellular matrix (ECM) components [6]. Achieving this complex mixture of tissue, and cytokines that provide building blocks required for spinal tissue repair and regeneration. When compared to widely accepted treatments like Platelet-Rich Plasma (PRP) and Mesenchymal Stem Cell (MSC) therapies, MaviX™ provides a broad spectrum of bioactive molecules, thus potentially enhancing therapeutic outcomes in degenerated and injured spine tissues. Unlike MSC therapies that involve live cell transplantation, MaviX™ offers a cell-free alternative that facilitates standardization, consistency, and, thereby, ease of use. Additionally, unlike

traditional bone grafts and allografts, MaviX™ delivers a concentrated matrix of subcellular exponents sourced from healthy donors, eliminating the need for bone tissue transplantation.

The objective of this study was to assess clinical outcomes for patients who underwent spine procedures where MaviX™ was used as a standard of care.

Methods

Following IRB review, medical records from a single site were retrospectively collected through secure, remote Electronic Medical Record (EMR) Abstraction. Eligible patients,aged 21-80 at the time of the procedure, had experienced back pain for over three months, and were treated with MaviX™ as part of their standard clinical care. Exclusion criteria included severe back pain from other causes, certain pathologies, recent major pelvic trauma, untreated osteoporosis, osteomalacia, chronic rheumatologic conditions, anatomical infeasibility for MaviX™ treatment, medication known to be detrimental to bone quality, prominent neurologic conditions hindering therapy, infections raising surgery risks, involvement in compensation or litigation, pregnancy, imprisonment, suspected substance abuse, or diagnosed psychiatric diseases interfering with study participation.

The MaviX™ treatment protocol, uniquely developed by Dr. Aldon Williams, and referred to as the "Williams Methodology," involved patients receiving a combination of MaviX™ (10 ml/5 -10ml normal saline), ozone (33 mcg/ml – 5-10ml), Decadron (2 ml, 4 mg/ml), magnesium sulfate (500 mg/ml - 1 ml), and no local anesthetic in the injectable solution. The injection techniques varied based on the anatomical region being treated. For cervical treatments, an intralaminar approach was used. In the thoracic region, high levels required

epidural catheter placement, while lower levels were treated using a transforaminal approach. For lumbar treatments, a transforaminal approach was used, depending on the number of levels injected.

Data collection comprised demographic details, medical history, medication use, insurance information, pain and function assessments, procedural data, and post-procedure follow-up data. Pain levels were assessed utilizing the three-component Pain, Enjoyment and General Activity (PEG) scale, a tool gauging chronic pain intensity on a scale ranging from 0 to 10. Functional capacity was evaluated through the Oswestry Disability Index (ODI) and Functional Status Index (FSI). The ODI assesses the degree of disability and functional impairment in patients, with scores ranging from 0% to 100%, where higher scores indicate greater disability, and FSI delineates function based on three interconnected dimensions: dependency level, difficulty level, and pain severity during specific daily activities, with higher scores indicative of enhanced functioning. These evaluations occurred at baseline and at various postoperative intervals: 2 weeks, 2 months, 5-7 months, and 12 months.

Statistical analysis was conducted using Stata 17 (Statacorp, College Station, TX, USA). Descriptive statistics, comprising counts, frequencies, means, and standard deviations, were computed for patient demographics, procedural attributes, concurrent medication use, and patient-reported outcomes. T-tests were employed to compare mean scores between two time points, while one-way ANOVA tests were utilized to evaluate the impact of time on mean scores.

Results

A total of 58 patients met the study's eligibility criteria. Of these, 60.3% were male and 39.7% female (Table 1). Most were White (81.1%), and non-Hispanic (75.9%), with an average age of 55.3 years (SD=12.0) and an average BMI of 27.9 kg/m² (SD=4.9). Most patients were employed (57.9%); 74.2% and 17.2% had Private and Medicare respectively as their primary insurance . A majority of patients were non-smokers (89.6%) and 69.0% had had previous surgeries. Hypertension and stroke/transient ischemic attack (TIA) were reported by 43.1% and 1.7% of patients, respectively. A total of 5 patients (8.6%) had Type II, Diabetes mellitus, of which 4 (80%) reported no current treatment and 1 (20%) reported taking oral diabetic agent for treatment. Other relevant medical conditions were noted in 27.6% of patients, with hypothyroidism being the most common (50.0%).

The procedural characteristics of the 58 patients who underwent spine procedures using MaviX™ are summarized in Table 2. Patients were classified under the American Society of Anesthesiologists (ASA) physical status classification system to offer perioperative clinicians a simple categorization of a patient's physiological status that might predict operative risk. (74.1%) were assessed as ASA II, 24.1% were classified as ASA III, and no patients were considered as ASA I, IV, or V. Thus the bulk of the population would have been considered to have mild, or severe systemic disease. The specific spine areas treated included caudal (13.8%), cervical (29.3%), lumbar (53.5%), and thoracic (2.5%). All patients received a mean volume of 4 mg/mL of dexamethasone and 500 mg/mL of magnesium sulfate. The mean volume of MaviX™ used was 10.3 mL (SD = 4.8; median:10 mL; range: 5 to 20). In addition, the mean volume of

ozone used was 9.1 mcg/mL (SD = 4.1; Median = 10 mcg/mL; range: 5 to 20). No procedure-related adverse events or deaths were reported among the patients.

Table 3 summarizes the usage patterns of concomitant medications and their indications among patients who underwent spine procedures with MaviX™. Pain management was the most common indication for medication use following the surgical procedure. The most frequently used medications for pain included Ibuprofen (200 mg) taken PRN by 11 patients, Hydrocodone-Acetaminophen (325 mg) used PRN by 10 patients, and Tramadol HCL (50 mg) taken PRN by 7 patients. Additionally, various dosages of Gabapentin (300 mg) were used by 5 patients, for pain relief. For muscle relaxation, Tizanidine (4 mg) was the taken three times daily (TID) by 3 patients. Cyclobenzaprine (10 mg) was another muscle relaxant used daily (QD) by 2 patients and TID by 1 patient. Anti-convulsant medication was also used, with Topiramate (100 mg) taken twice daily (BID) by 2 patients. Furthermore, a variety of other medications were prescribed for specific conditions such as hypertension, diabetes, insomnia, and ulcers, highlighting the diverse therapeutic needs of the patient population. These findings reflect the comprehensive medication management strategies employed alongside MaviX™ treatment in spine procedures.

Table 4 presents the pain and functional characteristics of patients at baseline and at subsequent follow-up intervals. Pain scores, assessed at baseline, 2 weeks, 2 months, 5-7 months, and 12 months, showed significant improvement over time ($P < 0.01$). The mean pain score decreased from 6.8 (SD = 2.4) at baseline to 1.8 (SD = 2.4) at 12 months, with median scores dropping from 7 to 1. ODI also indicated substantial functional improvement, with mean scores reducing from 33.5 (SD = 13.3) at baseline to 9.2 SD = 12.6) at 12 months ($P < 0.01$).

Similarly, FSI showed an increase in mean scores from 7.2 (SD = 0.5) at baseline to 9.2 (SD = 1.0) at 12 months ($P < 0.01$), suggesting enhanced functional capacity over the follow-up period.

Figure 1 shows MRI images taken before and after the administration of intradiscal and transforaminal ozone combined with MaviX™ therapy. Image (a) illustrates the condition of the spinal disc prior to treatment, highlighting areas of degeneration and damage. Image (b) depicts the post-treatment state, revealing notable improvements in disc integrity and overall spinal health, suggesting the efficacy of MaviX™ in promoting spinal repair and regeneration

Discussion

This study assessed the outcomes of patients undergoing spine procedures involving MaviX™, a novel orthobiologic product specifically formulated for spinal conditions. The data demonstrate significant improvements in pain and functional outcomes among patients treated with MaviX™.

Pain scores, as measured by the PEG scale, show a substantial reduction from a mean of 6.8 at baseline to 1.8 at 12 months postoperatively. This improvement is comparable to, if not better than, the results reported in studies investigating PRP and MSC therapies for spinal conditions [7]. Several studies have reported a significant pain reduction in patients treated with PRP for chronic lower back pain [8-10]. Similarly, MSC therapy led to a significant decrease in pain scores in patients with chronic back pain, although the extent of improvement varied among studies [11-14]. The notable pain reduction observed with MaviX™ could be attributed to its enriched composition of lipoprotein vesicles, matrisomes, proteins, and extracellular matrix (ECM) components, collectively providing a more comprehensive therapeutic effect.

Functional outcomes measured by ODI and FSI scores decreased significantly, indicating a notable functional improvement. These findings are consistent with studies on PRP and MSC therapies that have reported variable improvements in functional scores. Results from a meta-analysis found that MSC therapy resulted in a modest improvement in functional outcomes, with mean ODI scores decreasing by approximately 10 points on average [13]. PRP treatments have shown similar trends, with improvements often limited by the variability in PRP formulations and patient response [8,9].

Despite these encouraging results, the study has its limitations. The retrospective design and the single-site setting may limit the generalizability of our findings. Furthermore, the relatively small sample size and the reduction in follow-up numbers over time could introduce bias. Future research should focus on larger, multi-center, prospective studies to confirm the effectiveness of MaviX™ and to explore its long-term benefits.

Conclusion

The positive outcomes associated with MaviX™ suggest its potential to become a valuable asset when physicians consider spine care, particularly for patients with chronic back pain who have not responded well to other treatments. The significant improvements observed in our study underscore the potential of MaviX™ to impact the treatment of spinal conditions as a promising therapeutic option. Additionally, the lack of procedure-related adverse events or deaths further supports its safety profile, particularly in a population where nearly 100% of the patients treated (98.6%) were assessed with systemic disease.

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Table 1: Patient Characteristics, MaviX™ Retrospective Study for Spine Procedures (N=58)

Characteristics	Number (Percent)
Sex, n (%)	
Female	23 (39.7)
Male	35 (60.3)
Age (years)	
Mean (SD)	55.3 (12.0)
Min-Max	33-80
Race, n (%)	
White	47 (81.1)
Multiracial	1 (1.7)
Missing	10 (17.2)
Ethnicity, n (%)	
Hispanic	4 (6.9)
Non-Hispanic	44 (75.9)
Missing	10 (17.2)
BMI (kg/m^2)	
Mean (SD)	27.9 (4.9)
Min-Max	18.0 – 42.0
Employed	
Yes	33 (57.9)
No	24 (42.1)
Primary Insurance Type, n (%)	
Private:	43 (74.2)
Blue Cross	*14 (32.6)*
Humana	*1 (2.3)*
United	*2 (4.7)*
Other Private Insurance	*26 (60.5)*
Medicare	10 (17.2)
Other	5 (8.6)
Hypertension, n (%)	
No	33 (56.9)
Yes	25 (43.1)
Diabetes Mellitus, n (%)	
No	53 (91.4)
Yes:	5 (8.6)
Type (N =5), n (%):	
Type I	0 (0)
Type II	5 (100.0)
Current Treatment (N =5), n (%):	

No Treatment	4 (80.0)
Diet-Controlled treatment	0 (0)
Insulin	0 (0)
Oral Diabetic Agent treatment	1 (20.0)
Other Non-Insulin Injectable Medications	0 (0)
Stroke/ Transient Ischemic Attack (TIA), n (%)	
No	57 (98.3)
Yes	1 (1.7)
Other Pertinent Medical Condition, n (%)	
No	42 (72.4)
Yes:	16 (27.6)
If yes, type of medical conditions (N=16):	
Asthma	*4 (25.0)*
Glomerulonephritis	*2 (12.5)*
Hepatitis A	*1 (6.3)*
Hypothyroidism	*8 (50.0)*
Hysterectomy	*1 (6.3)*
Had Previous Surgeries, n (%)	
No	18 (31.0)
Yes	40 (69.0)
Smoking History, n (%)	
Current Smoker:	3 (5.2)
Number of Packs (N=3):	
1	*2 (66.7)*
2	*1 (33.3)*
3	*0 (0)*
Former Smoker	3 (5.2)
Never Smoker	52 (89.6)

Table 2: Procedure Characteristics, MaviX™ Retrospective Study of Spine Procedures (N=58)

Characteristic	Number (Percent)
ASA Classification	
ASA I	0 (0)
ASA II	43 (74.1)
ASA III	14 (24.1)
ASA IV	0 (0)
ASA V	0 (0)
Not in Patient Record	1 (1.7)
Spine Area	
Caudal	8 (13.8)
Cervical	17 (29.3)
Lumbar	31 (53.5)
Thoracic	2 (2.5)
Mean Volume of Dexamethasone Used (mg/mL)	
4	58 (100.0)
Missing	0 (0)
Mean Volume of Magnesium Sulfate used(mg/mL)	
500	58 (100.0)
Missing	0 (0)
Mean Volume of MaviX used (mL)	
Mean (SD)	10.3 (4.8)
Median	10
Min-Max	5-20
Mean Volume of Ozone used (mcg/mL)	
Mean (SD)	9.1 (4.1)
Median	10
Min-Max	5-20
Procedure-related Adverse Events	
No	58 (100.0)
Yes	0 (0)
Procedure-related Deaths	
No	58 (100.0)
Yes	0 (0)

Table 3: Concomitant Medications, MaviX™ Retrospective Study for Spine Procedures (N=58)

Name and Dose	Total Number	Frequency					Indication
		PRN	QD	BID	TID	QID	
Acetaminophen 325mg	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Celebrex 200mg	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Cyclobenzaprine 10mg	3	0 (0)	2 (66.7)	0 (0)	1 (33.3)	0 (0)	Muscle Relaxant
Gabapentin 75mg	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Gabapentin 100mg	2	0 (0)	1 (50.0)	0 (0)	1 (50.0)	0 (0)	Pain
Gabapentin 300mg	5	1 (20.0)	1 (20.0)	0 (0)	3 (60.0)	0 (0)	Pain
Gabapentin 600mg	2	1 (50.0)	1 (50.0)	0 (0)	0 (0)	0 (0)	Pain
Hydrocodone-Acetaminophen 325mg	10	10 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Ibuprofen 200mg	11	11 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Ibuprofen 400mg	2	1 (50.0)	1 (50.0)	0 (0)	0 (0)	0 (0)	Pain
Ibuprofen 600mg	1	0 (0)	0 (0)	0 (0)	1 (100.0)	0 (0)	Pain
Ibuprofen 800mg	8	5 (62.5)	0 (0)	1 (12.5)	2 (25.0)	0 (0)	Pain
Meloxicam 15mg	2	0 (0)	2 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Tizanidine 4mg	5	2 (40.0)	0 (0)	0 (0)	3 (60.0)	0 (0)	Muscle Relaxant; Muscle Spasm
Topiramate 100mg	2	0 (0)	0 (0)	2 (100.0)	0 (0)	0 (0)	Anti-Convulsant
Tramadol HCL 50mg	7	7 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Tylenol 325g	1	1 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Tylenol 600mg	1	1 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Tylenol 650mg	2	2 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Tylenol 1000mg	2	2 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Other 0.4mg	1	0	1 (100.0)	0 (0)	0 (0)	0 (0)	Prostate Hyperplasia
Other 1mg	1	0	1 (100.0)	0 (0)	0 (0)	0 (0)	Anti Estrogenic
Other 4mg	1	1 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Corticosteroid
Other 5mg	1	1 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Meniere's
Other 10mg	8	1 (12.5)	7 (87.5)	0 (0)	0 (0)	0 (0)	Diabetes Before Scan/MRI, Insomnia, Lower Cholesterol; Hypertension
Other 15mg	1	0 (0)	0 (0)	1 (100.0)	0 (0)	0 (0)	Hypertension

Other 20mg	4	0 (0)	4 (100.0)	0 (0)	0 (0)	0 (0)	Diuretics; Edema
Other 25mg	6	1 (16.7)	4 (66.7)	1 (16.7)	0 (0)	0 (0)	Hypertension
Other 40mg	2	0 (0)	2 (100.0)	0 (0)	0 (0)	0 (0)	Hypertension, Ulcer
Other 50mg	2	1 (50.0)	1 (50.0)	0 (0)	0 (0)	0 (0)	Pain, Diuretics
Other 100mg	3	0 (0)	2 (66.7)	1 (33.3)	0 (0)	0 (0)	Anti-Depressant; Hypertension
Other 150mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	0 (0)	Anti-Depressant
Other 220mg	5	5 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	Pain
Other 300mg	2	0 (0)	1 (50.0)	1 (50.0)	0 (0)	0 (0)	Hypertension, Pain
Other 500mg	2	1 (50.0)	0 (0)	1 (50.0)	0 (0)	0 (0)	Pain
Other 1000mg	1	0 (0)	0 (0)	0 (0)	0 (0)	1 (100.0)	Muscle Relaxant

Table 4: Average Pain and Functional Characteristics at baseline and each time point, MaviX™ Retrospective Study for Spine Procedures (N=58)

	Baseline	2 weeks	2 months	5-7months	12 months	*P* value†
Pain Score						
Number	58	47	44	40	26	
Mean (SD)	6.8 (2.4)	5.4 (3.2)	3.7 (3.2)	2.4 (2.9)	1.8 (2.4)	<0.01
Median	7	5	3	1	1	
Range	2-10	0-10	0-10	0-10	0-8	
P value‡	NA	0.02	<0.01	<0.01	<0.01	
ODI Percent Score						
Number	45	34	27	24	13	
Mean (SD)	33.47 (13.3)	27.4 (11.9)	19.4 (13.9)	14.8 (14.5)	9.2 (12.6)	<0.01
Median	34	26	20	13	4	
Range	6-84	0-44	0-40	0-44	0-32	
P value‡	NA	0.04	<0.01	<0.01	<0.01	
Functional Status Index						
Number	58	47	44	41	25	
Mean (SD)	7.2 (0.5)	7.7 (1.0)	8.3 (1.2)	8.7 (1.7)	9.2 (1.0)	<0.01
Median	7	7.5	8	9.5	9.5	
Range	6.5-9.5	6.5-10	7-10	0.5 -10	7-10	
P value†	NA	<0.01	<0.01	<0.01	<0.01	

†ANOVA *P* Value: effect of time

‡ t-test P value for mean comparison to baseline

— No Data Available

NA: Not Applicable

Figure 1. MRI images of **(a)** Before and **(b)** after intradiscal and transforaminal ozone and MAVIX Therapy