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

Final Report

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Title: Assessment of MaviX™ in Reducing Pain and Improving Function in Patients with Chronic Joint Conditions

Abstract:

Background: Orthobiologic treatments, including novel formulations like MaviX™, have been increasingly utilized in orthopedic practice for their regenerative potential in musculoskeletal conditions. This retrospective study evaluated patient outcomes following intra-articular treatments where MaviX™ was used.

Methods: Following IRB Review, a retrospective analysis of medical records from 67 patients, aged 21-80 years,who had been treated with MaviX™ for chronic joint pain, were analyzed. Pain was assessed using the Pain, Enjoyment and General Activity (PEG) scale, and functional outcomes were measured using the Functional Status Index (FSI) at baseline, 2 weeks, 2 months, 5-7 months, and 12 months post-procedure.

Results: Significant reductions in mean PEG pain scores were observed from 6.2 at baseline to 2.0 at 12 months, with corresponding improvements in FSI scores from 7.4 to 8.9 over the same period ($P < 0.01$ for both). No procedure-related adverse events were reported.

Conclusions: These findings suggest that MaviX™ holds promise as an effective treatment option for chronic joint pain, offering a non-invasive alternative to traditional surgical interventions. Further prospective studies are warranted to confirm these results and explore the long-term benefits of MaviX™ in diverse patient populations.

Keywords: MaviX™, Orthobiologics, Joint procedures, Regenerative medicine, Pain management, Functional outcomes

Background

Orthobiologic treatments have attracted growing interest for their potential in addressing musculoskeletal injuries and preventing degeneration. Orthobiologics therapies are developed from biologic (natural) substances that can be used by orthopedic specialists to relieve pain and other symptoms of certain orthopedic conditions such as early osteoarthritis with a goal of delaying a need for surgery. Further applications have also found a place to enhance the body's ability to heal from a repetitive use injury, such as a ligament or tendon strain, cartilage injuries, or broken bone (fracture), or to improve healing following orthopedic surgery [1,2]. This trend is reflected in the growing its adoption by orthopedic practitioners, underscoring their relevance in modern orthopedic practice [3,4].

MaviX™ has been engineered under GMP control as a lyophilized and sterile product designed for joint repair, a blend of enriched lipoprotein vesicles, matrisomes, proteins, and extracellular matrix (ECM) components specifically tailored for joint repair and rejuvenation [5]. This formulation is designed for buffering inflammation and facilitating tissue regeneration in joints affected by conditions such as joint inflammation, osteoarthritis, and cartilage degeneration. Hence, by leveraging the therapeutic potential of these bioactive molecules, MaviX™ aims to enhance joint mobility and alleviate discomfort without some of the drawbacks associated with conventional interventions.

Methods

Medical records were gathered from a single medical center using secure remote Electronic Medical Record (EMR) Abstraction. Patients eligible for inclusion were between the

ages of 21 and 80 at the time of their procedure, had experienced joint pain for over three months, and had received MaviX™ treatment as part of their standard clinical care. Exclusion criteria encompassed various conditions such as severe joint pain from other causes, specific pathologies, recent major pelvic trauma, untreated osteoporosis or osteomalacia, certain chronic rheumatologic conditions, anatomical constraints for MaviX™ treatment, medication usage detrimental to bone quality, significant neurological issues affecting therapy, infection risks associated with surgery, involvement in legal matters or compensation, pregnancy, incarceration, suspected substance abuse, or diagnosed psychiatric disorders impeding 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/5ml normal saline), ozone (33 mcg/ml – 10-20ml), Decadron (2-3 ml, (4 mg/ml)/5ml of normal saline, magnesium sulfate (500 mg/ml - 1 ml), and no local anesthetic in the injectable solution administered with ultrasound or fluoroscopic guidance to the targeted areas.

Demographic data, including age, sex, height, weight, employment status, and insurance details, were collected for eligible patients. Medical history, medication usage, and procedural details were also abstracted. Pain was evaluated using the Pain, Enjoyment and General Activity scale (PEG) scale, a three-item tool assessing chronic pain on a scale of 0 to 10. Function was assessed using the Functional Status Index (FSI), a tool used to assess functional capacity in patients that defines function based on three related dimensions: the degree of dependence, the degree of difficulty, and the amount of pain experienced during specific activities of daily

living where higher scores indicate better functioning. Assessments were conducted at baseline and postoperatively at 2 weeks, 2 months, 5-7 months, and 12 months.

Statistical analyses were performed using Stata 17 (Statacorp, College Station, TX, USA). Descriptive statistics (number, frequency, mean, and standard deviation) were calculated for patient and procedural characteristics, concomitant medications, and patient-reported outcomes. Mean scores at two different time points were compared using t-tests, while the effect of time on mean scores was assessed using one-way ANOVA test.

Results

A total of 67 patients received MaviX™ treatment for Joint Procedures and met the study's eligibility criteria. Table 1 below shows the patient characteristics. Most patients were male (59.7%), White (71.6%) and non-Hispanic (68.7%) with an average age of 58.7 years (SD= 12.3) and BMI of 27.2 kg/m^2 (SD=4.0). Just over half the patients were not employed (53.7%) and primary insurance types varied, with 74.6% reporting having private insurance, followed by 23.0% having Medicare. The majority of patients were non-smokers (91.0%) and had had previous surgery (71.6%). Only 31.3% reported having hypertension and 13.4% had diabetes mellitus, predominantly Type II (100.0%) with no current treatment. No patients reported having stroke/transient ischemic attack (TIA), and other pertinent medical conditions were reported in 22.4% of patients, of which colon cancer was the most common (33.3%).

Table 2 shows the procedural characteristics of the 67 patients who underwent joint procedures using MaviX™. 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. 52% of the patients were classified as ASA II, with a smaller proportion classified as ASA I (1.5%) and ASA III (3.0%), suggesting that systemic disease was mild in this population of patients treated for joint problems of the remaining patients did not have their ASA classification recorded.

Regarding the joint areas treated, 25.4% of procedures involved vertebral facets, 59.7% involved joints, and 14.9% targeted tendons. The specific locations categorized as “joints” treated included the knee (25.4%), shoulder (25.4%), hip (20.9%), sacroiliac (SI) joint (9.0%), ankle (6.0%), elbow (6.0%), acromioclavicular joint (1.5%), thumb (1.5%), toe (1.5%), and wrist (1.5%). Tendon treatments included the Achilles tendon (1.5%), epicondyle (3.0%), foot tendon (1.5%), heel (1.5%), rotator cuff (1.5%), subscapularis (3.0%), and supraspinatus (3.0%).

A standard volume of 4 mg/mL of dexamethasone was used in 73.1% of the procedures, and a standard volume of 500 mg/mL of Magnesium sulfate was used in 58.2% of the procedures. The mean volume of MaviX™ used was 5.0 mL (SD = 3.3; median: 4.0 mL; range: 0 to 10). The mean volume of ozone used was 8.3 mcg/mL (SD = 6.4; median: 5 mcg/mL; range from 1 to 50). No procedure-related adverse events or deaths were reported.

Table 3 summarizes the concomitant medications usage patterns and their indications among patients that underwent joint procedures with MaviX™. According to the primary

indication of use, medications were mainly taken for pain management, muscle relaxation, anti-convulsant use, and other specific treatments.

Ibuprofen (200 mg) was the most common pain medication, used by 12 patients PRN, followed by Hydrocodone-Acetaminophen (325 mg), taken PRN by 7 patients. Other common pain medications included Gabapentin (300 mg and 600 mg), Acetaminophen (500 mg), and Tramadol HCL (50 mg). The most common medication used for muscle relaxation was Tizanidine (4 mg) which was taken three times daily (TID) by 4 patients. Topiramate (100 mg) was used by 2 patients as an anti-convulsant on a twice-daily regimen. In addition, a variety of other medications with various dosages and frequencies were reported for conditions ranging from hypertension and cholesterol management to anti-parasitic and anti-estrogenic treatments.

Average pain and functional characteristics at baseline and at each subsequent follow-up interval for patients treated with MaviX™ for joint procedures are shown in Table 4. The PEG Pain Scores demonstrated significant improvement over time. The mean pain score decreased from 6.2 (SD = 2.6) at baseline to 2.0 (SD = 3.3) at 12 months ($P < 0.01$). Median pain scores also showed a marked reduction from 6 at baseline to 0 at 12 months. The range of pain scores decreased consistently across follow-up intervals, indicating an overall improvement in patient-reported pain levels ($P < 0.01$) for all time points compared to baseline.

The Functional Status Index (FSI) scores showed significant enhancements in functional capacity. The mean FSI score increased from 7.4 (SD = 0.5) at baseline to 8.9 (SD = 1.1) at 12 months ($P < 0.01$). The median FSI scores improved from 7.5 at baseline to 9.5 at 12 months.

The range of FSI scores indicated a positive trend towards better functional status over the follow-up period ($P < 0.01$ for all time points compared to baseline).

An MRI image of the biceps and subscapularis joint taken before and after MaviX™ therapy. highlightsthe condition of the joint prior to treatment, and depicts improvements in the joint at 12 months (Figure 1).

Discussion

This study demonstrates significant improvements in pain and functional outcomes among patients undergoing joint procedures where MaviX™ was used as part of the combined treatmentThe observed reductions in pain and enhancements in functional status suggest MaviX™ might present a promising therapeutic alternative for joint repair and regeneration.

The marked decrease in PEG pain scores at 12 months compared to baseline highlight significant pain relief, which coupled with the functional improvement (FSI) demonstrates patient satisfaction and improvement. These results are consistent with previous studies on orthobiologics, which have demonstrated substantial pain reduction in patients with chronic musculoskeletal conditions. Findings from studies on Platelet-Rich Plasma (PRP) have shown significant pain reduction in patients with osteoarthritis and other joint disorders [6,7]. Similarly, Mesenchymal Stem Cell (MSC) therapies have been reported to significantly decrease pain scores in patients with chronic joint pain [8,9].

Functional outcomes, as assessed by the Functional Status Index (FSI), also improved significantly. This enhancement in functional capacity is comparable to results from studies

evaluating other orthobiologic treatments. For example, a meta-analysis of MSC therapies reported modest improvements in functional outcomes [10]. PRP treatments have shown similar trends, although the extent of functional improvement often varies due to differences in PRP formulations and patient responses [11].

Despite these encouraging findings, this study has several limitations. The retrospective design and the single-site setting may limit the generalizability of our results. 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.

In conclusion, MaviX™ shows significant promise in improving pain and functional outcomes in patients with chronic joint pain. The positive results from this study suggest that MaviX™ could become a valuable component of joint care, particularly for patients who have not responded well to other treatments. Further research is warranted to validate these findings and to fully understand the potential of MaviX™ in orthopedic regenerative medicine.

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Table 1: Patient Characteristics, MaviX™ Retrospective Study for Joint Procedures (N=67)

Characteristics	Number (Percent)
Sex, n (%)	
Female	27 (40.3)
Male	40 (59.7)
Age (years)	
Mean (SD)	58.7 (12.3)
Min-Max	32-80
Race, n (%)	
White	48 (71.6)
Multiracial	0 (0)
Missing	19 (28.4)
Ethnicity, n (%)	
Hispanic	3 (4.5)
Non-Hispanic	46 (68.7)
Missing	18 (26.8)
BMI (kg/m^2), (N=63)	
Mean (SD)	27.2 (4.0)
Min-Max	18.0 – 38.1
Employed	
Yes	31 (46.3)
No	36 (53.7)
Primary Insurance Type, n (%)	
Private:	50 (74.6)
Blue Cross	*20 (40.0)*
Humana	*1 (2.0)*
United	*2 (4.0)*
Other Private Insurance	*27 (54.0)*
Medicare	16 (23.9)
Other	1 (1.5)
Hypertension, n (%)	
No	46 (68.7)
Yes	21 (31.3)
Diabetes Mellitus, n (%)	
No	58 (86.6)
Yes:	9 (13.4)
Type (N=9), n (%):	
Type I	*0 (0)*
Type II	*9 (100.0)*
Current Treatment (N=9), n (%):	
No Treatment	*9 (100.0)*
Diet-Controlled treatment	*0 (0)*

Insulin	*0 (0)*
Oral Diabetic Agent treatment	*0 (0)*
Other Non-Insulin Injectable Medications	*0 (0)*
Stroke/ Transient Ischemic Attack (TIA), n (%)	
No	67 (100.0)
Yes	0 (0)
Other Pertinent Medical Condition, n (%)	
No	52 (77.6)
Yes:	15 (22.4)
If yes, type of medical conditions (N=15):	
Asthma	*4 (26.7)*
Colon Cancer	*5 (33.3)*
Glomerulonephritis	*1 (6.7)*
Hepatitis C	*1 (6.7)*
Hypothyroidism	*3 (20.0)*
Sleep Apnea	*1 (6.7)*
Had Previous Surgeries, n (%)	
No	19 (28.4)
Yes	48 (71.6)
Smoking History, n (%)	
Current Smoker:	2 (3.0)
Number of Packs (N=):	
1	*1 (50.0)*
2	*0 (0)*
3	*1 (50.0)*
Former Smoker	4 (6.0)
Never Smoker	61 (91.0)

Table 2: Procedure Characteristics, MaviX™ Retrospective Study of Joint Procedures (N=67)

Characteristic	Number (Percent)
ASA Classification	
ASA I	1 (1.5)
ASA II	35 (52.2)
ASA III	2 (3.0)
ASA IV	0 (0)
ASA V	0 (0)
Not in Patient Record	29 (43.3)
Joint Area	
Facets	17 (25.4)
Joints	40 (59.7)
Tendons	10 (14.9)
Joint Location	
Acromioclavicular Joint	1 (1.5)
Ankle	4 (6.0)
Elbow	4 (6.0)
Hip	14 (20.9)
Knee	17 (25.4)
SI Joint	6 (9.0)
Shoulder	17 (25.4)
Thumb	1 (1.5)
Toe	1 (1.5)
Wrist	1 (1.5)
Missing	1 (1.5)
Tendon Location (N=10)	
Achilles	1 (1.5)
Epicondyle	2 (3.0)
Foor Tendon	1 (1.5)
Heel	1 (1.5)
Rotator Cuff	1 (1.5)
Subscapularis	2 (3.0)
Supraspinatus	2 (3.0)
Volume of Dexamethasone Used (mg/mL)	
4	49 (73.1)
Missing	18 (26.9)
Volume of Magnesium Sulfate used (mg/mL)	
500	39 (58.2)
Missing	28 (41.8)
Volume of MaviX used (mL)	

Mean (SD)	5.0 (3.3)
Median	4.0
Min-Max	0-10
Volume of Ozone used (mcg/mL)	
Mean (SD)	8.3 (6.4)
Median	5
Min-Max	1-50
Procedure-related Adverse Events	
No	67 (100.0)
Yes	0 (0)
Procedure-related Deaths	
No	67 (100.0)
Yes	0 (0)

Table 3: Concomitant Medications, MaviX™ Retrospective Study for Joint Procedures (N=67)

Name and Dose	Total Number	Frequency				Indication
		PRN	QD	BID	TID	
Acetaminophen 500mg	3	3 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Acetaminophen-Codeine 300mg	1	1 (000.0)	0 (0)	0 (0)	0 (0)	Pain
Celebrex 200mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Pain
Cyclobenzaprine 10mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Muscle Relaxant
Gabapentin 300mg	3	0 (0)	0 (0)	2 (66.7)	1 (33.3)	Pain
Gabapentin 600mg	1	1 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Hydrocodone-Acetaminophen 325mg	7	7 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Ibuprofen 200mg	12	12	0 (0)	0 (0)	0 (0)	Pain
Meloxicam 7.5mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Pain
Meloxicam 15mg	2	0 (0)	2 (100.0)	0 (0)	0 (0)	Pain
Tizanidine 4mg	4	0 (0)	0 (0)	0 (0)	4 (100.0)	Muscle Relaxant; Pain
Topiramate 100mg	2	0 (0)	0 (0)	2 (100.0)	0 (0)	Anti-Convulsant
Tramadol HCL 50mg	4	4 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Tylenol 325mg	4	4 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Other 1mg	1	1 (100.0)	0 (0)	0 (0)	0 (0)	Anti Estrogenic
Other 3mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Anti parasitic
Other 5mg	3	2 (66.7)	1 (33.3)	0 (0)	0 (0)	Meneries; Hypertension
Other 10mg	4	2 (50.0)	2 (50.0)	0 (0)	0 (0)	Anti Histamine; Before Scan; Hypertension; Lower Cholesterol
Other 20mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Anti-Cholesterol
Other 25mg	2	0 (0)	2 (100.0)	0 (0)	0 (0)	Hypertension
Other 40mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Ulcer
Other 81mg	1	0 (0)	1 (100.0)	0 (0)	0 (0)	Pain
Other 100mg	1	0 (0)	0 (0)	1 (100.0)	0 (0)	Anti-Depressant
Other 200mg	1	0 (0)	0 (0)	1 (100.0)	0 (0)	Malaria
Other 220mg	7	7 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Other 500mg	2	2 (100.0)	0 (0)	0 (0)	0 (0)	Pain
Other 800mg	3	3 (100.0)	0 (0)	0 (0)	0 (0)	Muscle Spasm, Muscle Relaxant

Table 4: Average Pain and Functional Characteristics at baseline and each time point, MaviX™ Retrospective Study for Joint Procedures (N=67)

	Baseline	2 weeks	2 months	5-7months	12 months	*P* value†
PEG Pain Score						
Number	67	62	61	58	57	
Mean (SD)	6.2 (2.6)	4.4 (3.0)	4.1 (3.3)	3.2 (3.6)	2.0 (3.3)	<0.01
Median	6	4.5	4	1	0	
Range	1-10	1-10	0-10	0-10	0-10	
P value‡	NA	<0.01	<0.01	<0.01	<0.01	
Functional Status Index						
Number	57	55	48	49	55	
Mean (SD)	7.4 (0.5)	8.0 (1.0)	8.2 (1.0)	8.5 (1.3)	8.9 (1.1)	<0.01
Median	7.5	8	8	8.5	9.5	
Range	6.5-8.5	6.5-10	6.5 -10	5.5 -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

NA: Not Applicable

Figure 1. MRI image of biceps and subscapularis **(a)** before and **(b)** after MAVIX Therapy

a) b)