Placental Tissue Matrix Skye Biologics PX50®
& Alpha-2 Macroglobulin Platelet-Rich Plasma

Case Report
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Problem

Low Back Pain, Degeneration and spondylolisthesis of L4 on L5, L5 lateral canal stenosis

Intro

On May 4, 2016, a 59-year-old female presented to the clinic with over 8 years of progressively worsening low back pain. She takes multiple narcotic pain-relieving medications in order to sleep and perform activities of daily living. Her average pain levels were 5/10, and her worst pain was 10/10.

Diagnosis

Lumbosacral x-ray revealed:
1. Degenerative disc and joint disease with anterior lysthesis of L4 on L5
2. Severe degenerative disc disease at L5 S1

MRI revealed:

1. Spondylolisthesis at L45, impingement of the L5 nerve roots bilaterally
2. L5-S1 moderate neuroforaminal encroachment with disc extrusion
3. S1 nerve root effected by disc extrusion

4. L3-L4 mild central canal stenosis lateral recess stenosis and bilateral neuroforaminal encroachment
5. L4-L5 mild central canal stenosis lateral recess stenosis and bilateral neuroforaminal encroachment
6. L5-S1 mild central canal stenosis lateral recess stenosis and bilateral neuroforaminal encroachment
7. L1-L2 minimal central canal stenosis lateral recess stenosis and bilateral neuroforaminal encroachment

Patient was examined by Shawn Tierney, DC, RMSK Musculoskeletal Sonologist, using a GE R6 B-mode ultrasound using 8 to 13MHz high frequency GE 12L linear transducer and a 2 to 5.3MHz 4C curvilinear transducer. His ultrasound exam revealed

1. Tenderness to ultrasound guided palpation of the bilateral 34 lumbar facet joints with hypertrophy of the left L45 lumbar facet joints irritation the superior cluneal nerves and median branch with hypertrophy noted
2. L4 on L5 spondylolisthesis
3. L5 lateral canal stenosis bilaterally
4. Left acromioclavicular joint instability irritating the left supraclavicular nerve
5. Thinning of left knee hyaline cartilage
6. Medial left knee joint line spurring
7. Right gluteus medius and gluteus minimus insertional tears on the right trochanter
8. Bilateral distal patellar tendon tendinosis / partial tearing
9. Right sciatic nerve impingement in the gluteal musculature

Patient was recommended to have PX50® on the low back, and A2M PRP on the gluteus muscle tears and the bilateral knees and right shoulder.

PX50® Treatment

On May 26, 2016, 0.5 cc .5% Ropivacaine with 0.5 cc Skye Biologics Placental Tissue Matrix Allograft, PX50®, was injected under ultrasound guidance into the right L4-L5 lumbar facet joints in the patient's low back. The goal was to provide sustaining regeneration to the patient's low back and to prevent further lumbar facet joint degeneration.

Follow-up Visit and A2M PRP Treatment

On June 29, 2016, six weeks after the injection, she reported little change in her back pain. Her average pain levels dropped to 4/10, but her pain reached 10/10 at its worst.

Under ultrasound guidance, the following procedures were performed:

1. A percutaneous tenotomy was performed on the left gluteus minimus insertion by injection of a solution of 3 cc 1% Lidocaine and 3cc .5% Ropivacaine, followed by an injection of alpha 2 macroglobulin platelet rich plasma.
2. The left anterior femoral circumflex with a solution of 3 cc 1% Lidocaine and 3cc .5% Ropivacaine, then the anterior knee joint was injected with alpha 2 macroglobulin platelet rich plasma.
3. The right supra patellar pouch was injected with a solution of 3 cc 1% Lidocaine and 3cc .5% Ropivacaine, followed by an injection of alpha 2 macroglobulin platelet rich plasma.
4. The left medial collateral ligament medial meniscus was injected with a solution of 3 cc 1% Lidocaine and 3cc .5% Ropivacaine, followed by an injection of alpha 2 macroglobulin platelet rich plasma.

5. The left supra patellar pouch was injected with a solution of 3 cc 1% Lidocaine and 3cc .5% Ropivacaine, followed by an injection of alpha 2 macroglobulin platelet rich plasma.
6. The supraclavicular nerve over the left acromioclavicular joint was hydrodissected with a solution of 6cc .5% Ropivacaine.
7. The caudal epidural space was injected with 2cc 1% Lidocaine, 16cc Normal Saline, 2cc 50% Dextrose Solution.

On July 25, 2016, patient reports persistent pain in low back and sacrum, as well as her gluteus. She reports worse pain in bilateral knees since the PRP procedure. She felt disappointed that the low back injections had not worked as she hoped.

On August 4, 2016, patient reported that she had not noticed any low back pain relief. She reported that at times her knees felt a little better, but occasional medial knee pain still persists with a burning sensation. She continues to take 10mg-325mg hydrocodone-acetaminophen every 4 hours for her back pain. Her husband reported that he did not notice a change in her activities of daily living since her injections.

On August 4, 2016, her pain was appearing to be nerve-related, so she received hydrodissections of the bilateral obturator nerves and saphenous nerves through the medial collateral ligament bilaterally, followed by hydrodissections of the bilaterally superior lateral geniculate nerves under the Iliotibial band.

While patient reported no noticeable improvement, her pain did seem to empirically decrease after the placental tissue matrix. Further time may be required to evaluate the effectiveness of the A2M PRP. Her self-reported pain scores did demonstrate a reduction, with an average of 7/10 after the procedure, compared to an average of 8/10 before the procedure. Additionally, her pain used to reach a severity of 10/10, but her scores were only 8/10 on the last two reports, 6/29/16 and 8/4/16,

respectively. Patient was still amenable to receive additional treatments in 2017 if it could provide her with additional relief.

Figure 1. Reduction in Self-Reported Pain on a 1-10 Scale, before and after PTM Placental Tissue Matrix

Level of Pain	Pre- PX50®	Post- PX50®
Average Pain	8	7
% Reduction in Pain	13%	