DETERMING THE EFFECTS OF STEM CELL TREATMENT ON PEYRONIE'S DISEASE IN HUMANS

Michael Zahalsky MD, Melissa Marchand PA, Leanne Iorio, Walquiria Cassini, and Jason Levy
Z Urology

INTRODUCTION AND OBJECTIVES:

Peyronies' disease (PD) forms fibrous plaques in the tunica albuginea causing erectile dysfunction (ED), abnormal curvature and plaque formation in the penis. Stem Cells are thought to be able to assist in wound healing and improve vasulogenesis. We believe our study is the first human study to provide the results of using Stem Cells to treat PD.

METHODS:

This study evaluated the feasibility and effects of using Plancetal Matrix derived Mesenchymal Stem Cells (PM−MSCs) in the treatment of PD. PM−MSC's are a plancental stem cell product that mixes mesenchymal stem cells with growth factors, cytokines, and an extracellular matrix to promote wound healing, angiogenesis, and tissue repair. After obtaining Western IRB approval, patients with PD underwent informed consent and were evaluated using penile ultrasound to measure the number and size of the Peyronie's Plaques. Next, patients were injected with 0.2 cc of Trimix for standardization of data and were evaluated for peak systolic velocity (PSV) and angle of curvature.

On a separate visit, PM−MSCs were injected intracavernosally. First, 1 cc of PM−MSCs was diluted with 2 cc of isotonic saline to a total of 3 cc. Up to 2.0 cc of our diluted PM−MSCs was then injected in and around the Peyronie's plaques. The remainder of the PM−MSCs was then injected evenly into each corpora at the base at the base of the penis.

Patients were re−evaluated at 6 weeks then 3 months.

RESULTS:

There are 5 patients enrolled in the study. At 6 weeks, PSV increased in all patients (39%−81%). Using unpaired t−tests this was statistically significant ($p<0.01$).

All 5 patients demonstrated a reduction on ultrasound in the size of the plaques. The 4 patients with 3 month follow up had a 99%−100% reduction in plaque size. In total there were 10 plaques between 5 people in the study, and 7 of those plaques completely disappeared on ultrasound.

In the 4 patients that had curvature caused by plaques, the angle showed a 10°−85° improvement, corresponding to a 14%−100% reduction in curvature. The reduction is 43%−100% in patients in the study for 3 months or more.

All patients are happy with the treatment.

CONCLUSIONS:

This is possibly the first human study to report on the ability to use Stem Cells in the treatment of PD. Although the sample size is small, the results are statistically significant and very promising. The results show that PM−MSC treatment is likely the most effective non−surgical treatment for PD. PM−MSCs also increased the blood flow to the penis a statistically significant amount.

This was a feasibility study using PM−MSCs on PD in humans. PM−MSCs need to be further studied in a multicenter clinical trial to validate these significant results.

Sexual Function/Dysfunction/Andrology: Peyronie's Disease

Funding: Product Donated

PD22-01: **Determining the Feasibility of Using Stem Cells to Treat Erectile Dysfunction in Humans**

Michael Zahalsky*, Melissa Marchand, Leanne Iorio, Walquiria Cassini, Lauren Pomerantz, Coral Springs, FL

Abstract: PD22-01

Introduction and Objectives

Stem cell therapy is thought to improve wound healing and promote vasculogenesis. Erectile Dysfunction (ED) is largely from microvascular disease such as diabetes and hypertension. This study seeks to evaluate the feasibility and effects of intracavernosal injection of Placental Matrix derived Mesenchymal Stem Cells (PM-MSCs) for the treatment of ED.

Methods

After obtaining Western IRB approval, patients with ED were screened with the International Index of Erectile Function (IIEF). We excluded post prostatectomy patients. Once patients were selected they underwent informed consent and Doppler Ultrasound of their penises pre and post injection with 0.2cc of Trimix for standardization of results. Measurements were obtained for Peak systolic Velocity (PSV) and End Diastolic Velocity (EDV), stretched penile length (SPL) pre-injection, and width post-injection of trimix. On a separate visit, 1 cc of PM-MSCs was diluted with 2 cc of isotonic saline to a total of 3 cc. Next, 1.5 cc was injected into each corpora at the base of the penis. The product injected is a placental stem cell product that mixes mesenchymal stem cells with growth factors and cytokines and an extracellular matrix to promote wound healing, angiogenesis, and tissue repair. At 6 weeks and 3 months patients were reevaluated pre and post injection of trimix.

Results

There are 7 patients that have been injected with PM-MSCs with 6 week follow up. Follow up data at 3 months exists for 3 patients. At 6 weeks, all 7 patients' PSV post trimix injection increased (5.4% - 70.2%). All patients' SPL increased (1.3% to 7.1 %) and all patients' penile width increased (1.6%-23.8%). All 7 patients were happy they had the treatment, and 2 patients that had previously failed all oral therapies were now getting erections on their own. At 3 months, PSV post trimix injection had increased in all 3 patients (28.4% - 52.1%) Using unpaired t-tests, this was statistically significant with a $p < 0.05$. EDV post trimix increased in 2 patients achieving statistical significance ($p < 0.05$). At 3 months, 1 additional patient was now able to achieve erections on his own. IIEF increased in all of these patients (21.4% -36.8%). There were no reported complications.

Conclusions
This is one of the first studies to evaluate the ability and effects of using Stem Cells to treat erectile dysfunction. Although the sample size is small , the results are very promising. PM-MSCs needs to be evaluated further to determine their ability to repair the Corpora Cavernosum and assist patients in achieving erections.

Date & Time: May 19, 2014 1:00 PM-3:00 PM
Session Title: Sexual Function/Dysfunction/Andrology: Peyronie's Disease
Sources of Funding: Product Donated