

# Determining the Feasibility of Using Stem Cells to Treat Erectile Dysfunction in Humans

**Michael P. Zahalsky, MD**

Melissa Marchand

Leanne Iorio

Walquiria Cassini

Lauren Pomerantz

954-714-8200

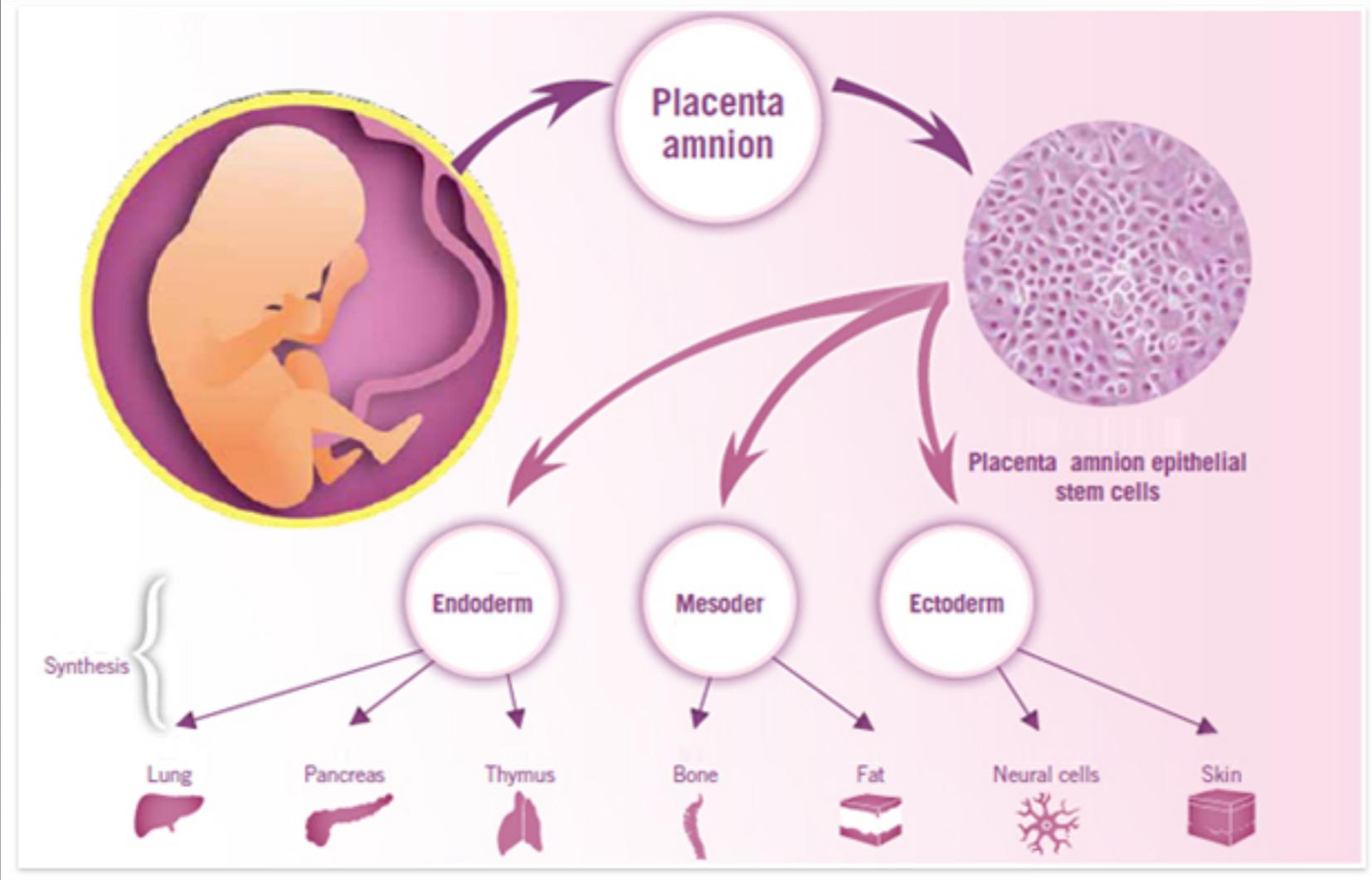
**Clinical Professor at Florida Atlantic University**

# Stem Cells

- Stem cells are undifferentiated cells that can differentiate into specialized cells
- Promote vasculogenesis and wound healing
  - Vasculogenesis: de novo development of blood vessels from endothelial progenitor cells (EPCs)
  - Angiogenesis: reorganization of endothelial cells from preexisting blood vessels

# Stem Cells

- **Placental Derived Stem Cells**
  - **Amniotic**
  - **Chorionic**
- **Adipose-derived stem and regenerative cells (ADRC's)**
- **Bone Marrow - Mesenchymal Stem Cells (MSC's)**
- **Embryonic**
- **Skin - 4/17/2014**



# Erectile Dysfunction

- Erectile Dysfunction (ED) is largely from microvascular disease
  - Diabetes
  - Hypertension

# Objective

- To evaluate the feasibility and effects of intracavernosal injections of **Placental Matrix derived Mesenchymal Stem Cells (PM-MSCs)** for the treatment of ED

# Methods

- We obtained IRB approval
- Patients were given the International Index of Erectile Function (IIEF)
- We excluded post prostatectomy patients and focused on microvascular pathology such as DM and HTN
- Once patients were selected they underwent informed consent and Doppler Ultrasound of their penis' 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

# Methods

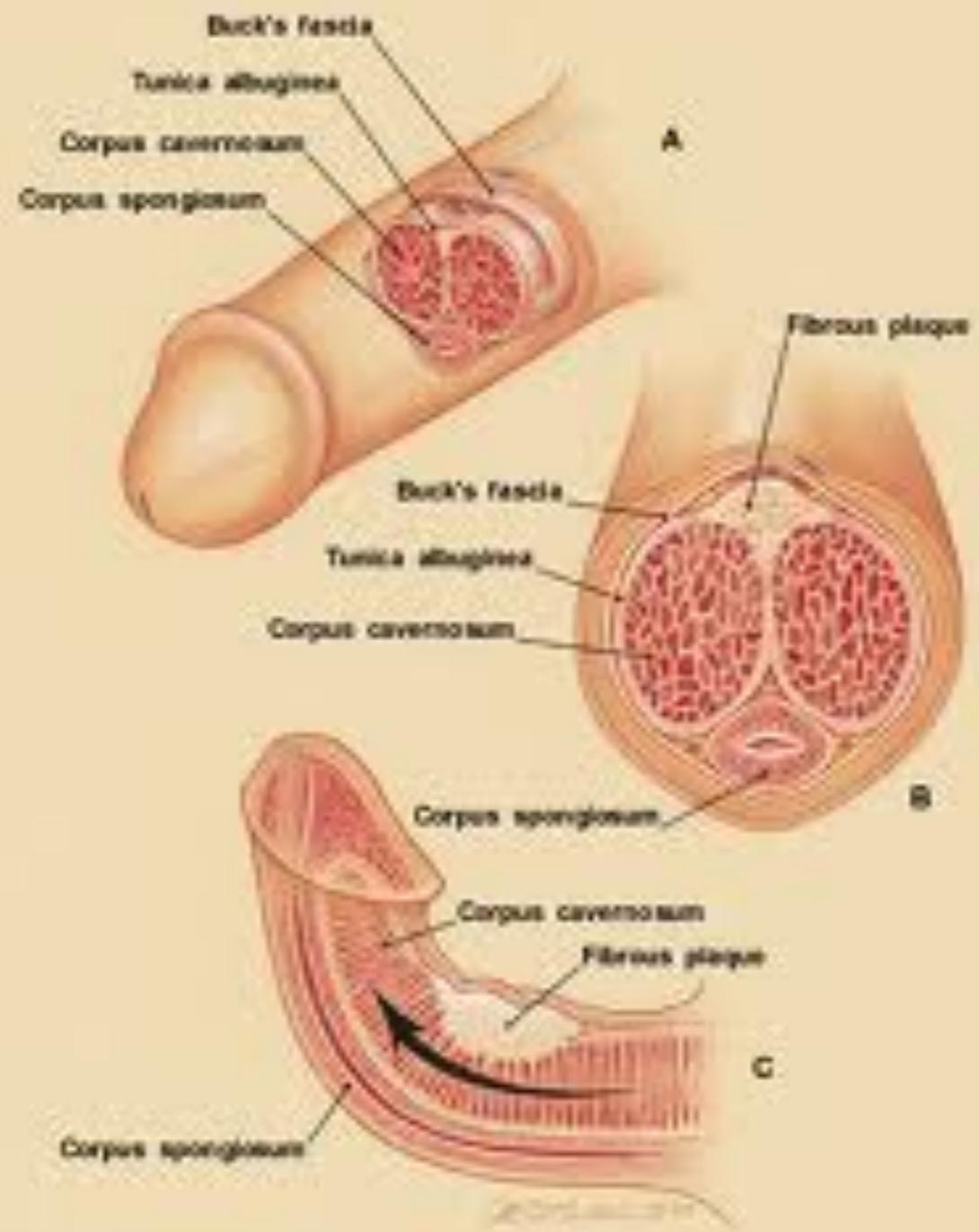
- On a separate visit, 1 cc of PM-MSCs was diluted with 2 cc of isotonic saline to a total of 3 cc
- 1.5 cc was injected into each corpora at the base of the penis
- Patients were reevaluated pre and post injection of trimix at 6 weeks, 3 months, and 6 months

# Erectile Dysfunction Results

	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8
Initial PSV w/ Trimix	26.5	49.3	32.1	29.8	31.6	23.1	31.8	35
6 wk PSV	45.1	56.5	40.1	31.4	45	25.5	36	48.8
3 mo PSV * P<0.05	40.3 52%	66.7 35%	41.2 28%		47.3 50%	32.5 41%	53 67%	
6 mo PSV * P<0.01	53.2	73.9	50.7					

# Erectile Dysfunction Results

- PSV in normal men is typically  $> 35$  cm/s
- IIEF scores varied
- 3 patients now get erections on own, 2 with PDE-5 Inhibitors
- All happy
- All had small increases in stretched penile length and width
- No complications



# My Hypothesis

- By injecting MSC's into Peyronies Plaques, we will induce vasculogenesis and wound healing allowing us to treat Peyronies diseases
  - Disorganized Collagen will be replaced with organized collagen
  - Current treatments include injecting collagenase, corticosteroids, and calcium channel blockers into the plaques

# Study Measures

- Penile Doppler Studies with ultrasound
  - Pre and Post Injection to measure the change in:
    - Peak Systolic Velocity
    - Size of plaque
    - Angle of curvature

# Peyronie's Disease Results

	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5
Initial PSV with Trimix	25.5	14.1	23.5	22.1	24.8
6 week PSV	35.4 <b>38.8%</b>	23 <b>63.1%</b>	42.6 <b>81.3%</b>	37.6 <b>70.1%</b>	33.3 <b>34.3%</b>
3 mo PSV * P<0.01			49 <b>108.5%</b>	43.5 <b>101.8%</b>	38.9 <b>56.9%</b>

# Peyronie's Disease Results

	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5
Initial Penile Plaques	2	3	2	2	1
% Decrease in Size at 3 months	95% 100%	100% 96% 100%	92% 94%	100% 100%	46%
% Decrease in Size at 6 months	99% 100%	100% 100% 100%	98% 100%	100% 100%	

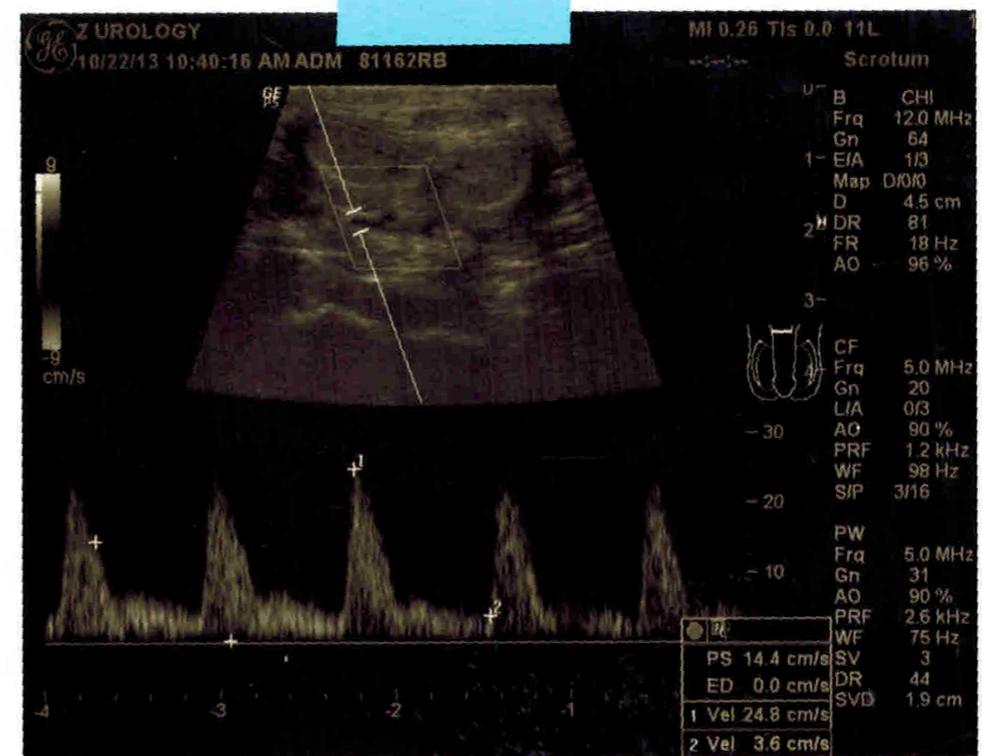
# Peyronie's Disease Results

	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5
Initial Curvature	70°	60°	None	120°	70°
6 week Follow Up	40° 43% Decrease	0° 100% decrease	None	70° 42% decrease	60° 14.3% decrease
3 Month Follow Up	Refused	Refused	None	35° 70.1% decrease	40° 43% decrease
6 Month Follow Up	Refused	Refused	None	0° 100% decrease	

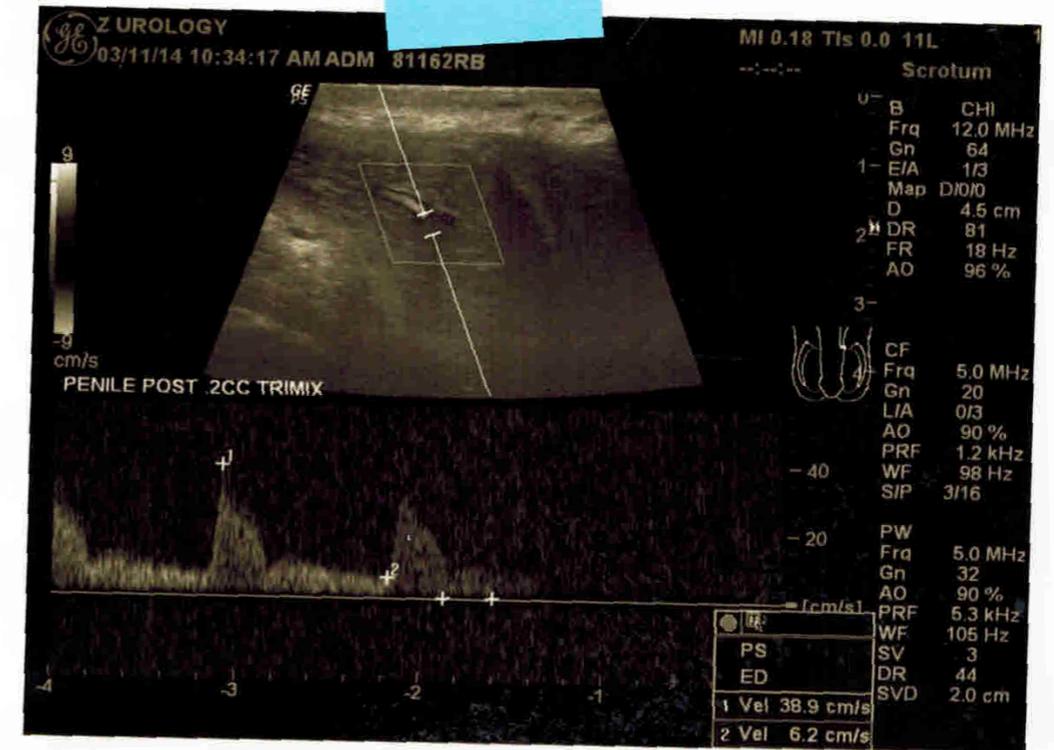
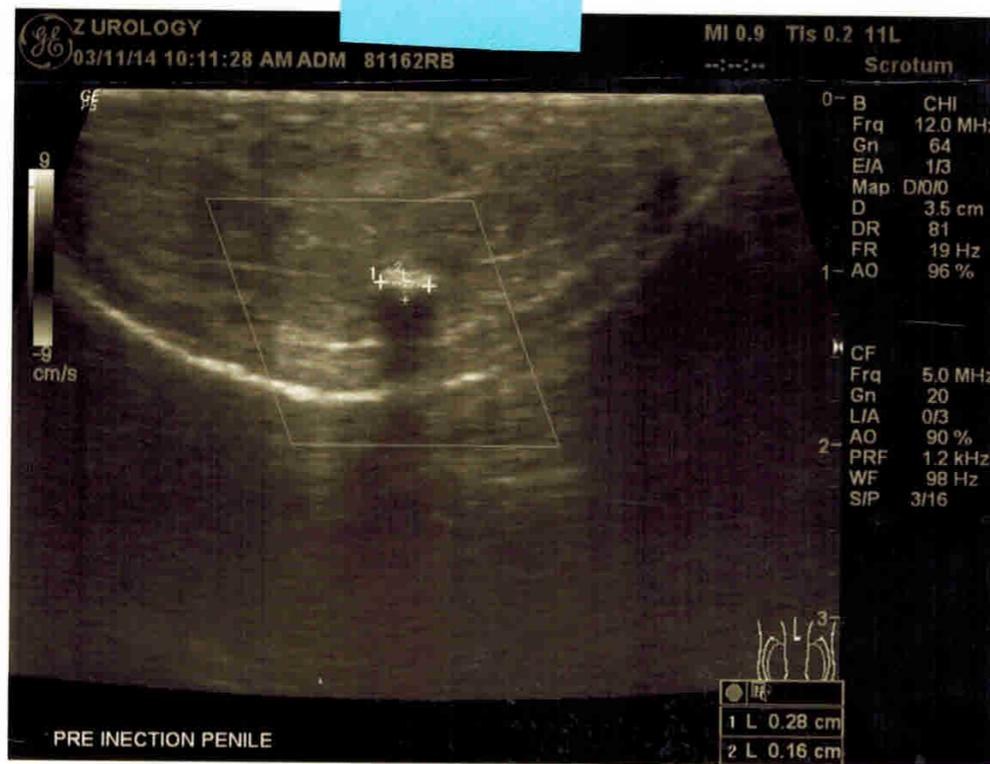
# Peyronie's Disease results

- All 5 patients now get erections on their own
- All happy they did treatment
  - Complications:
    - Patient #2 developed a priapism after Trimix injection at 6 weeks
    - Patient then developed a new plaque 0.06 x 0.03 x 0.06 cm

# BEFORE



# After



# Questions?

- Techniques?
- How long does it work for?
- Optimal Protocol?
- The Zahalsky Protocol:
  - 1 injection every month for 3 months
  - Followed by 1 injection Annually

# Conclusions

- This is one of the first studies to evaluate the ability and effects of using Stem Cells to treat erectile dysfunction in humans
- The sample size is small, but the results are very promising
- There is a sustained improvement in blood flow to the penis after PM-MSC injection
- This needs to be evaluated further
- **The Zahalsky Protocol** is what I would recommend studying first
- **This is the most promising development in the field of Male Sexual Dysfunction since the Invention of Viagra**