



Amniotic Fluid for the Treatment of Erectile Dysfunction

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Introduction

Erectile dysfunction (ED) is usually a microvascular disease characterized by difficulty obtaining and / or maintaining an erection firm enough for intercourse. Aging has been associated with resistance in penile blood flow, possibly due to decreases in nitric oxide synthase-containing nerve fibers. In the present study, we report on the use and safety profile of ProFlo, Amniotic Fluid (AF). Although Amniotic Fluid has been used for years in various medicinal fields, we are the first to explore the safety and quantity that can be used in Urology for ED.

ProFlo is amniotic fluid from an FDA cleared tissue bank, Vivex. It meets all the criteria to be regulated under the Public Health Service Act section 361. It is minimally manipulated, not combined with anything, not dependent on the metabolic activity of living cells, and being used homologously, since it is from the Genitourinary System and being used on the Genitourinary system.

ProFlo contains various cytokines and growth factors and is believed to facilitate angiogenesis and decrease inflammation.

The aim of this study was to determine the effectiveness of AF as a sustainable treatment for ED.

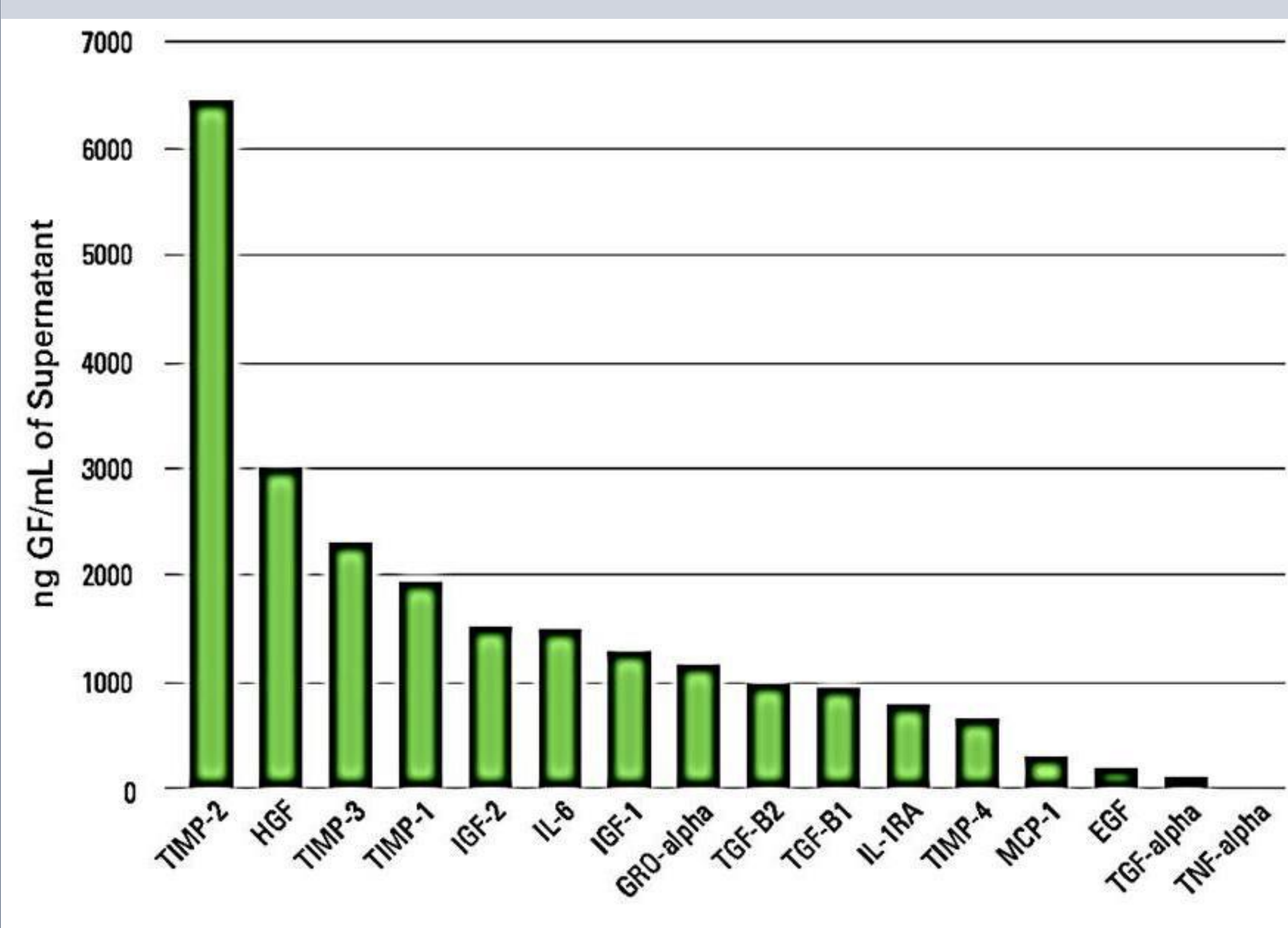


Figure 1 shows the relative growth factors and cytokines in ProFlo, amniotic fluid.

Materials and Methods

A retrospective chart review of 35 patients injected with ProFlo AF from February 2016 through July 2016 was performed. Prior to injections, patients filled out the International Index of Erectile Function (IIEF-5) questionnaire to obtain an initial assessment of the severity of their ED. All patients were initially injected intracavernosally at the base of the penis with 0.1 cc of trimix for standardization. Penile Doppler ultrasound was then used to measure Peak Systolic Velocity (PSV) in ED patients. Two weeks after initial trimix injection and PSV measurement, patients returned for AF injection. ProFlo was used for the frozen allograft for these studies and 1.0 cc to 2.0 cc of AF were injected intracavernosally at the base of the penis based on surgeon preference. Patients were instructed to follow-up at six months post-injection. To stimulate erections, patients were once again injected with 0.1 cc of trimix. Penile Doppler ultrasound to measure PSV at 6 months post-AF injection was conducted and patients were once again instructed to fill out the IIEF-5 questionnaire.

Results

Of the 35 patients undergoing injection, only two adverse effects were noted. One patient (2.85% of the cohort) noticed skin discoloration around the injection site 2 days post-injection. A second patient (2.85% of the cohort) self-reported painful erections 7 days after injection of ProFlo. No adverse effects such as corporal rupture, penile fracture, or hematoma were observed.

15 patients had follow-up at 6 months who underwent penile Doppler ultrasound; of which, 12 of those patients completed both pre and post IIEF questionnaires. Mean PSV after trimix injection and before AF injection was found to be 26.65 (+/- 10.2) cm/s with IIEF scores ranging from 5-21.5, with a mean of 12.54 (+/- 4.93). At 6-months follow-up after injection of AF, mean post-PSV increased to 37.83 (+/- 9.37) cm/s p<0.05 and IIEF scores ranged from 8-24, with a mean of 15.42(+/- 5.58) p<0.05.

Figure 1: Pre and Post PSV Data for Patients Injected with ProFlo

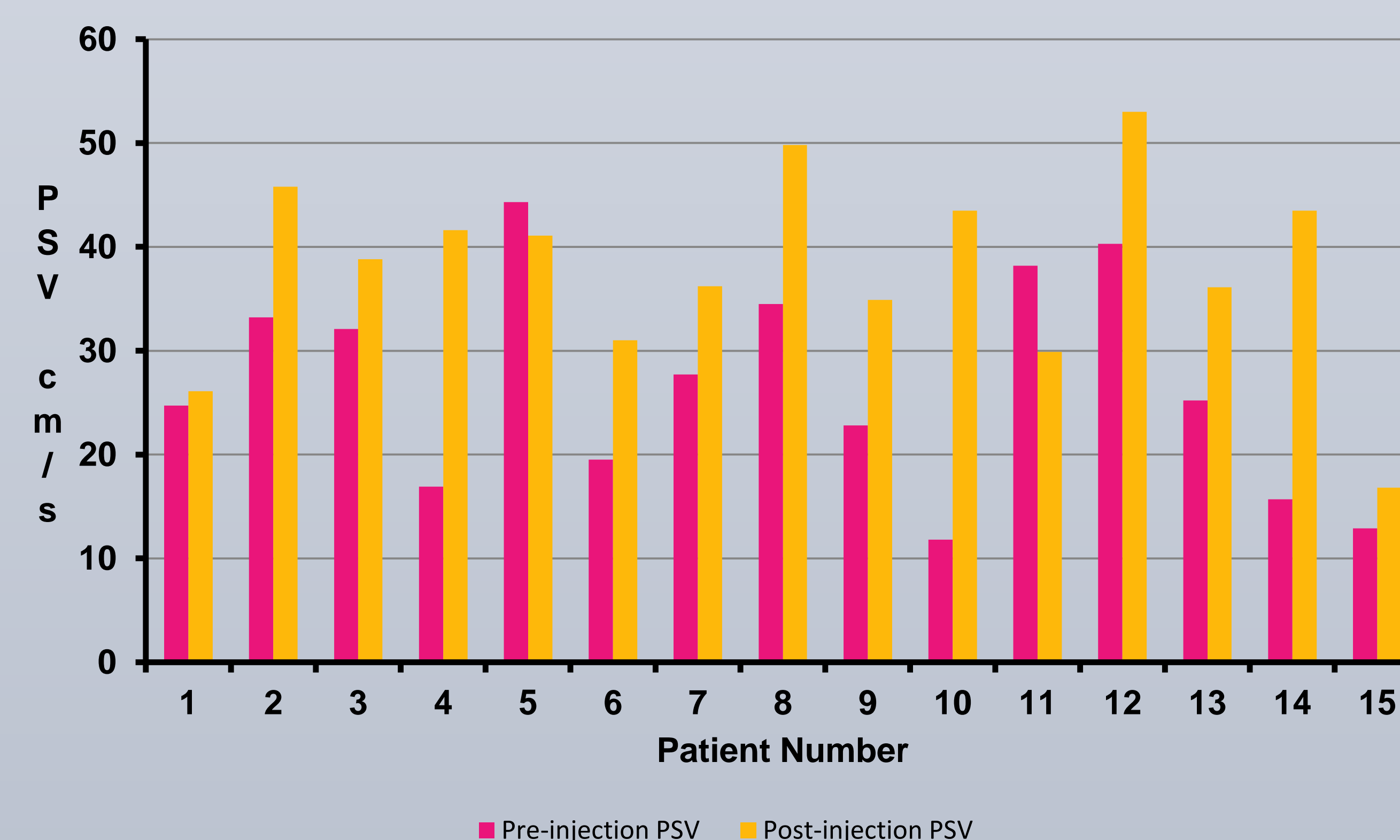


Figure 2 demonstrates peak systolic velocity measured for 15 of the patients pre- and post- injection of amniotic fluid.

Figure 2: Pre and Post IIEF Values

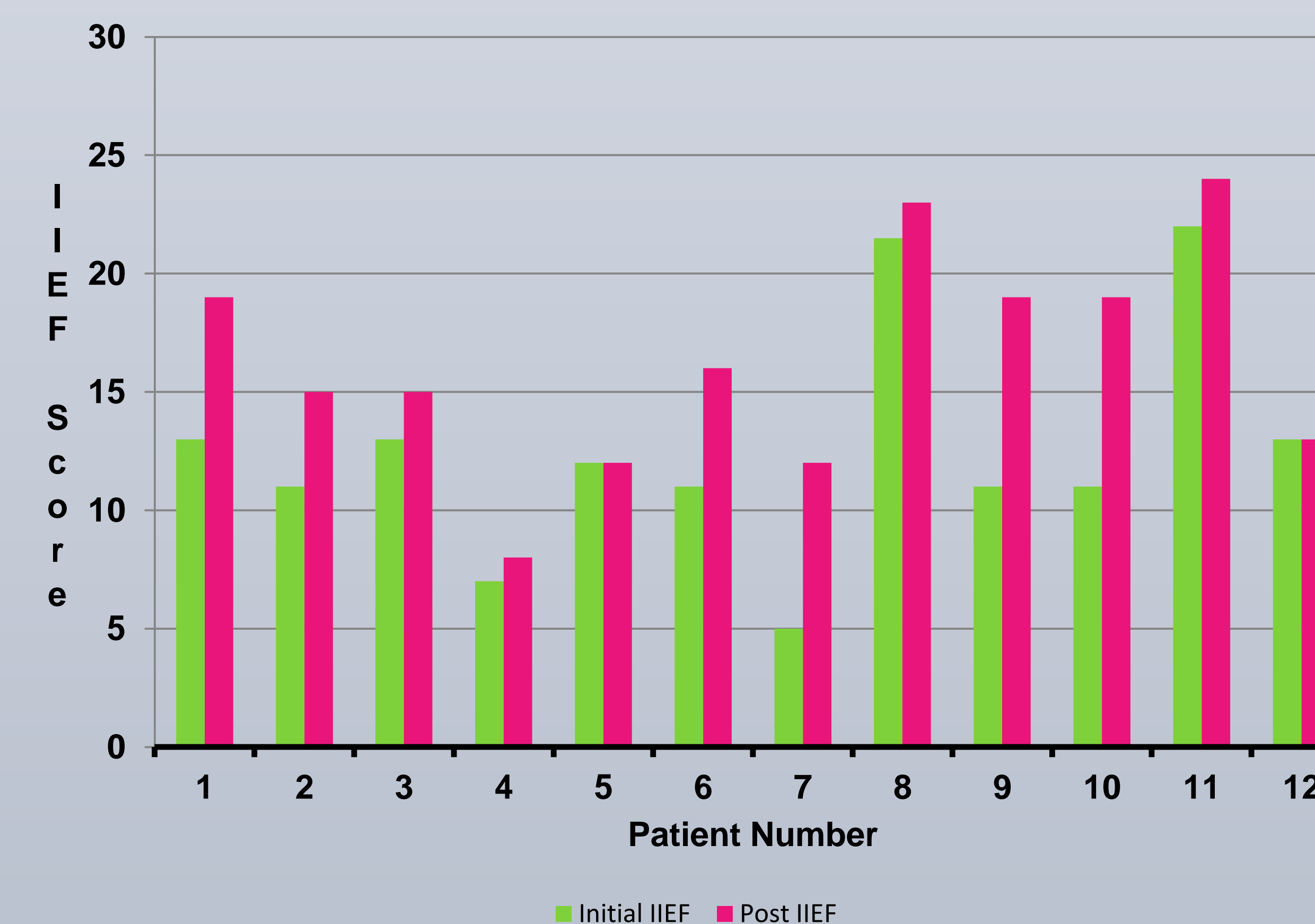


Figure 3 demonstrates 12 of the patients measured IIEF scores pre and post injection of amniotic fluid.

Conclusion

Based on the data accumulated, there have been no significant adverse effects found in the 35 patients. ProFlo appears to be a safe alternative treatment option for men with ED.

Of the 35 patients retrospectively reviewed, 15 patients were shown to have follow-up at 6 months. Pre-injection peak systolic velocity for the 15 patients were 26.65 cm/s after a standardization with trimix injection. At 6-months follow-up peak systolic velocity in this cohort increased to 37.83 cm/s after injection with ProFlo amniotic fluid with a two-tailed p-value <0.05.

Furthermore, 12 patients who were retrospectively reviewed completed pre and post-injection international index of erectile function questionnaires. Prior to amniotic fluid injection IIEF scores ranged from 5-21.5 after injection of a standardized trimix mixture. Post-amniotic fluid injection IIEF scores ranged from 8-24 with a p-value of <0.05.

This is the first documented study to demonstrate the safety of using amniotic fluid injections in humans in the treatment of erectile dysfunction.

Further investigational studies should be and are currently being carried out to further assess the safety and efficacy of amniotic fluid injections in patients suffering from erectile dysfunction.

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