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Six-Month Report Assessing the Feasibility and Effectiveness of Amniotic Membrane Injections in Patients with Short, Anterior, Urethral Strictures

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<u>Introduction:</u> Urethral stricture treatment has high recurrence rates and adjunct injectable agents have been explored. Amniotic membranes (AM) promote apoptosis of pro-inflammatory cells, prevent differentiation of pro-fibrotic cells, and decrease scar formation. These tissues generated interest in reconstructive urethral surgery. Thus, we performed urethral dilation combined with micronized AM injection in urethral scar tissue for treatment of urethral stricture.

Materials and Methods: Adult males with strictures ≤12Fr in diameter and ≤2 cm in length, International Prostate Symptom Score (IPSS) ≥11 and maximum flowrate <15 ml/s. Reconstituted 100mg micronized AM was injected at the time of urethral dilation. Primary study end point was anatomical success (≥14Fr by cystoscopy) at 6 months. Secondary end points were questionnaires, flow rate, and post void residual. Outcomes assessed at baseline, 5 days, 14 days, 3 months, and 6 months post-injection. Safety was analyzed.

Results: Ten men, mean age of 52 ± 15 years, were included. There were 7 patients with no prior endoscopic treatment and 3 patients with one prior dilation. At 6 months, 7 of 10 patients (70%) demonstrated recurrence on cystoscopy. Improvements in flow rate, PVR and IPSS and USS-PROM symptom scores noted in 10 of 10 patients at 3 months and 3 of 10 patients at 6 months. No adverse events observed.

<u>Conclusions:</u> This is the first study evaluating single layer amnion as an adjunct treatment at time of urethral dilation. The urethral stricture rate of recurrence did not improve with the injection of AM despite the hypothesized benefits of anti-fibrotic and anti-inflammatory properties.