

Use of a Human Amniotic Membrane and Umbilical Cord Regenerative Matrix for the Management of Recalcitrant Bladder Neck Contractures

Introduction

- The management of bladder neck contractures (BNC) with injectable therapeutic agents after prior incision or resection has been primarily limited to mitomycin and steroid injection.
- Both mitomycin and steroids have not consistently demonstrated prevention of BNC recurrence, with steroids only having been shown to have an effect in delaying BNC recurrence.

Objectives

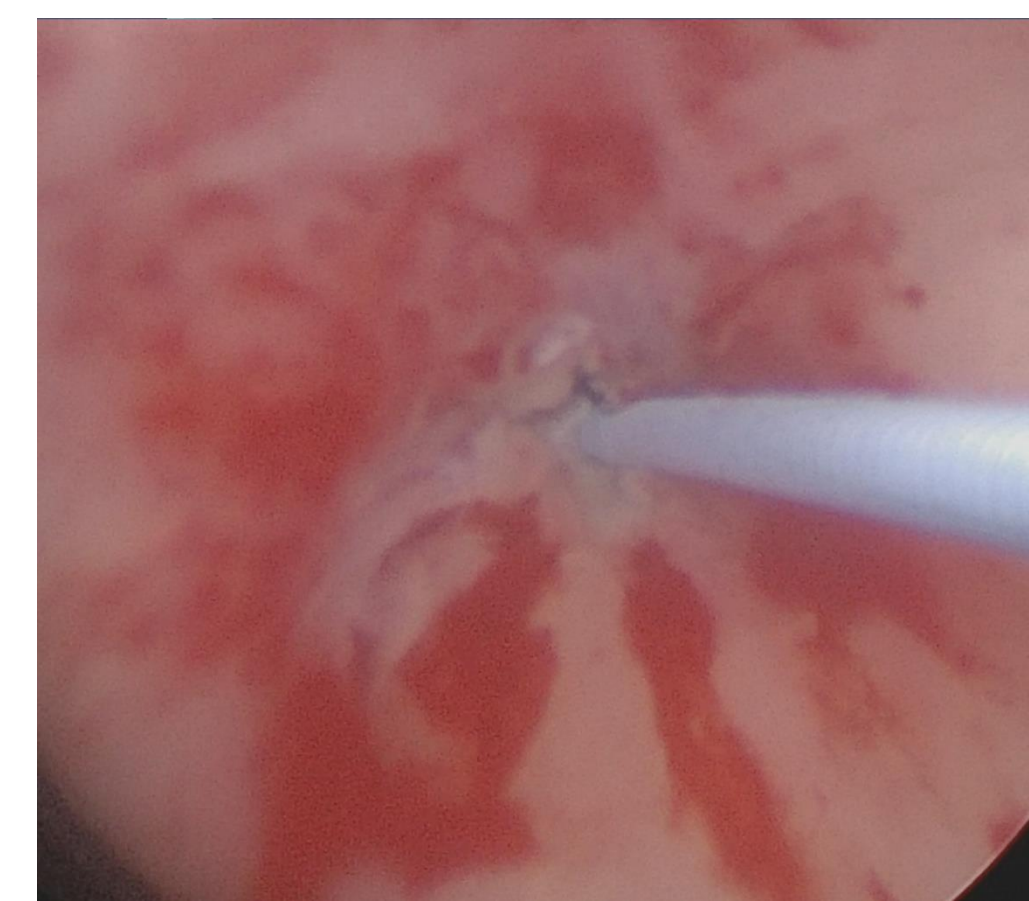
- We aimed to assess a series of recalcitrant BNCs that previously failed prior therapies and were subsequently managed with a novel amniotic membrane and umbilical cord injectable regenerative matrix agent, Clarix Flo (Amniox Medical, Inc.), which reduces inflammation and promotes healing.

Methods

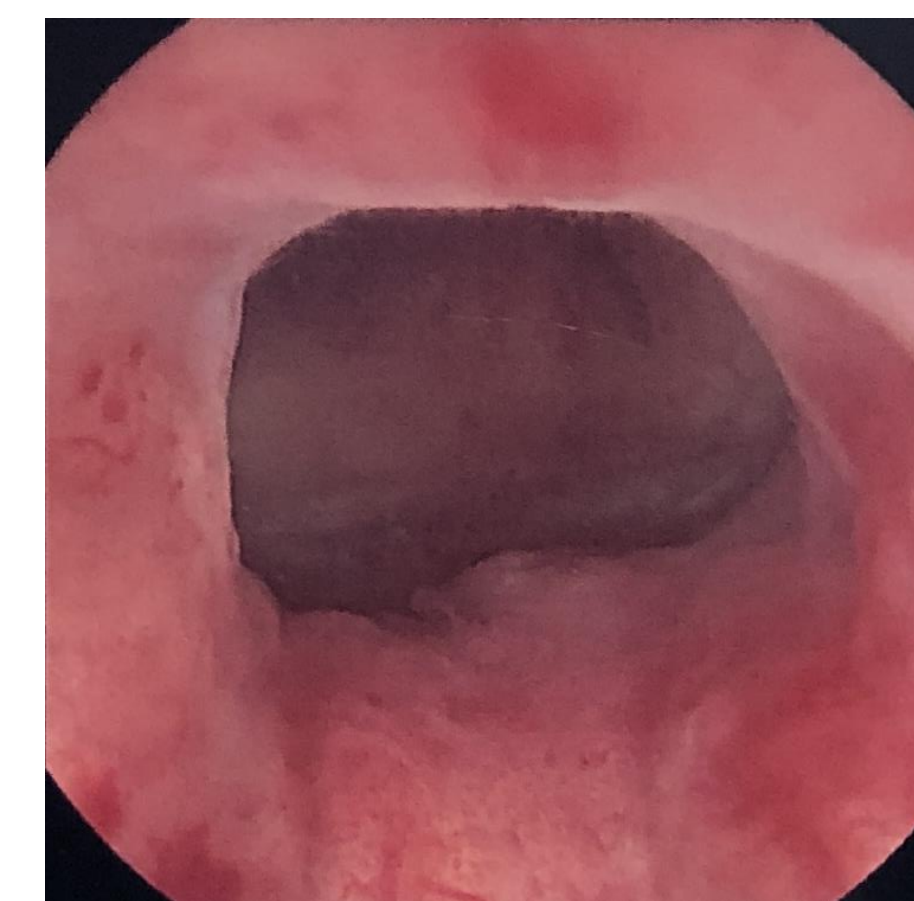
- Five men with prostate cancer developed BNC from:
 1. Salvage external beam radiation therapy (XRT) following robot-assisted radical prostatectomy (RARP) (n=3)
 2. Anastomotic urine leak after RARP (n=1)
 3. After primary XRT for prostate cancer (n=1)
- Mean age was 67 years (range: 57-81)

Methods (Continued)

- Patient cancer staging included: 3C, Gleason 4+5 (n=1), 3B, Gleason 4+3 (n=1), 3B, Gleason 4+4 (n=2), & prostate cancer of unknown stage (n=1).
- All patients were managed initially with direct vision internal urethrotomy (DVIU) or transurethral resection of bladder neck (TURBN) with steroid injection therapy, and then developed BNC recurrence.
- One patient had 2 previous TURBNs, 3 patients had 1 previous DVIU or TURBN, and 1 patient had 3 prior endoscopic surgeries for BNC.
- All patients subsequently underwent TURBN or DVIU at time of circumferential injection of 100 mg of Clarix Flo. Postoperative urethral catheters were removed in 1 week.



(A) Before



(B) 6 Months After

Image 1: Representative of the injection of Clarix Flo into the stricture in a patient with persistent bladder neck contracture, (A) intraoperatively prior to injection, (B) 6 months after injection.

Results

- At a median follow-up of 12 months, no patients developed BNC recurrence nor required repeat catheterization or urethral calibration.
- All patients continue to void with a steady stream without retention of urine.
- On longest follow-up, at 17 months, the patient remains without bladder neck contracture recurrence and continues to void without complaints.
- All patients are continent of urine with 4 patients using no pads and 1 patient using 1 liner daily.
- Follow-up cystoscopy on all patients at 1 month and 6 months postoperatively demonstrated an open bladder neck that easily accommodated a 16F flexible cystoscope.

Conclusions

- The use of an amniotic membrane and umbilical cord regenerative matrix agent adds to the armamentarium of injectable therapeutic agents for the management of bladder neck contractures.
- The long-term benefits of Clarix Flo in the management of BNC appears favorable as compared to other injectable agents.