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Case Report

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Initial Experience with an Absorbable Urologic Scaffold to Mitigate Early Urinary Incontinence following Radical Prostatectomy: A Report of 2 Cases

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Radical prostatectomy · Prostate cancer · Urinary incontinence · Urologic scaffold

Abstract
Introduction: Stress urinary incontinence (SUI) is a frequent, known complication following robot-assisted radical prostatectomy (RARP) for prostate cancer. Urethral shortening and reduced urethral support following RARP are contributing factors. ***Case Presentations:*** Herein, we describe a surgical approach using a novel absorbable urologic scaffold to mitigate SUI in 2 patients enrolled in an ongoing single-arm prospective study. The scaffold is designed to relieve the burden on the urinary sphincter by lengthening the effective urethra following RARP. The scaffold is placed at the anastomotic site, overlying the bladder neck and urethral stump following prostate removal and prior to the creation of the anastomosis. Both patients successfully underwent the prostatectomy and urologic scaffold placement with no reported perioperative complications. Neither patient suffered from early SUI following RARP as measured by pad weight and usage at 1 and 3 months following the procedure. ***Conclusion:*** Early experience with the absorbable urologic scaffold suggests it could safely and effectively prevent SUI following RARP. Early and long-term results derived from the ongoing prospective study with this device will better define its potential role in the prevention of SUI.

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Introduction

Stress urinary incontinence (SUI) is a frequent side effect following radical prostatectomy (RP) for prostate cancer [1]. Reports indicate between 66 and 80% of men experience continued incontinence at 3 months post-RP [2, 3] and 5–20% will go on to develop chronic incontinence [1, 3, 4]. Patients suffering from incontinence also experience a decline in quality of life (QoL) and increased regret of having undergone the procedure as a result of the emotional, social, occupational, and hygienic issues associated with the SUI [5, 6].

The removal of the prostatic urethra yields a wider bladder neck that is anastomosed in closer proximity to the urinary sphincter. This anatomical change following RP is a key contributor to the development of post-prostatectomy SUI. An absorbable scaffold (Voro Urologic Scaffold, Levee

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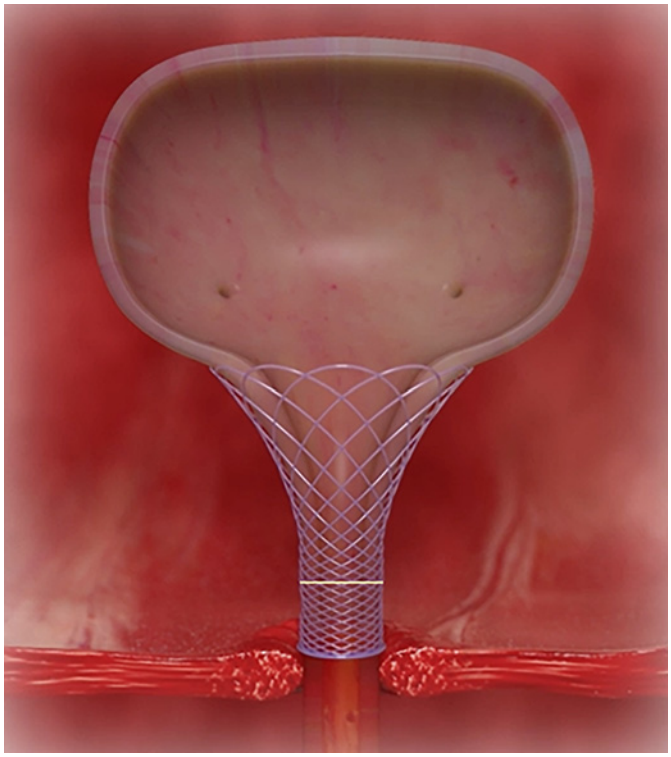

Fig. 1. Absorbable urologic scaffold positioned over the anastomotic site between the bladder neck and urethral stump. The yellow line indicates the location of the anastomosis between the urethra and the bladder neck.

Medical, Durham, NC, USA) has been developed to increase urethral length to support the urinary sphincter following the procedure. The device is constructed of poly-p-dioxanone, a commonly used material for medical devices, and is completely absorbed within 180–210 days following implantation [7]. The device is placed over the anastomotic site between the bladder neck and urethral stump as shown in Figure 1. Durable connective tissue forms as the anastomosis heals in the scaffold geometry prior to its complete resorption. This enables early and long-term restoration of bladder neck geometry that is conducive to normal urinary function. In this case report, we present 2 patients enrolled in the ARID study (NCT06275945) who underwent urologic scaffold placement at the time of RP to prevent SUI.

Case Presentation

From September 2023 to December 2023, two men with prostate cancer underwent robot-assisted radical prostatectomy (RARP) with the concomitant placement of an absorbable urologic scaffold at the National Hospital in Panama City, Panama. The study was approved by the Research Bioethics Committee at Pacífica Salud Hospital Punta Pacífica (approval date March 5, 2023). Both patients signed written informed consents to participate in the study and undergo surgery with the placement of the absorbable scaffold. Patient demographics, disease information, procedural data, and early post-operative outcomes were collected prospectively.

Surgical Technique

Both subjects underwent a standard RARP under general anesthesia using the da Vinci Xi system (Intuitive Surgical, Sunnyvale, CA, USA). The urologic scaffold was compressed and introduced into the pelvic cavity through a trocar using Maryland graspers. The atraumatic hem (smaller diameter end) was oriented facing the urethral stump as shown in Figure 2. While compressed, the scaffold was placed over the urethral stump at the pelvic floor with pressure applied to the perineum to improve access to the urethral stump. After correct positioning, the anastomosis between the urethra and the bladder neck was completed through the center of the scaffold using barbed sutures.

Following confirmation that there were no anastomotic leaks, the scaffold was expanded and the base was secured to the urethra using two absorbable sutures positioned opposite of each other. The scaffold was then expanded toward the bladder neck using gentle lateral compression along each side of the device. Once completely expanded and sized to ensure urethral support, two sutures were placed near the midpoint of the device as shown in Figure 3 to prevent it from sliding distally upon filling of the bladder. The widest portion of the scaffold was then secured to the bladder neck using two sutures, ensuring the suture passed through muscular tissues for proper anchoring. A final pressure test was performed by filling the bladder with sterile saline to ensure the desired bladder neck geometry.

Case 1

A 67-year-old male diagnosed with Grade Group 1 prostate cancer underwent RARP with the placement of the absorbable urologic scaffold. The patient had a Gleason Grade Group 1, a BMI of 23.1 and a prostate volume of 20.1 mL. The total procedure time was 147 min with urologic scaffold placement requiring 27 min. The device was successfully deployed with an estimated elongated urethral length within the scaffold of 9 mm. At 6 months post-RRP, no procedure or device-related complications were identified. The 1 h and 24 h pad weights 1 month following the procedure were 0.7 g and 2.8 g above baseline (prior to RARP) and 0.0 and 1.5 g at 3 months. The patient reported that they did not require any pads at 1-month and 3-month follow-up visits.

Case 2

A 60-year-old male diagnosed with Gleason Grade Group 2 prostate cancer and a history of hypertension and type II diabetes underwent RARP with the placement of the absorbable urologic scaffold. The patient had a BMI of 26.6 and a prostate volume of 14.2 mL. The total procedure time was 202 min with urologic scaffold insertion and placement requiring 21 min. The device was successfully deployed with an estimated elongated urethral length within the scaffold of 12 mm following placement. At 3 months

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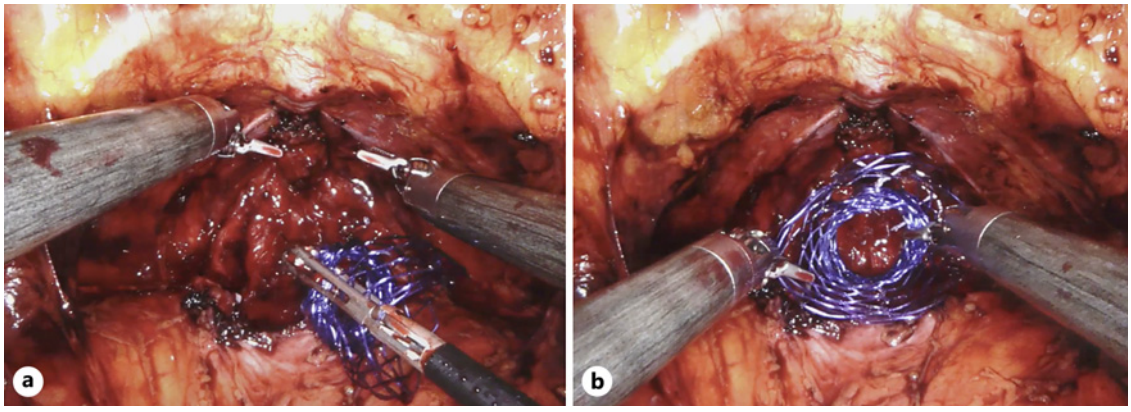

Fig. 2. a Prior to performing the anastomosis, the urologic scaffold (purple) is inserted in a compressed state. **b** Following placement over the ureteral stump, the urethra is shown projecting through the central lumen of the scaffold prior to anastomosis. The anastomosis is subsequently performed through the device.

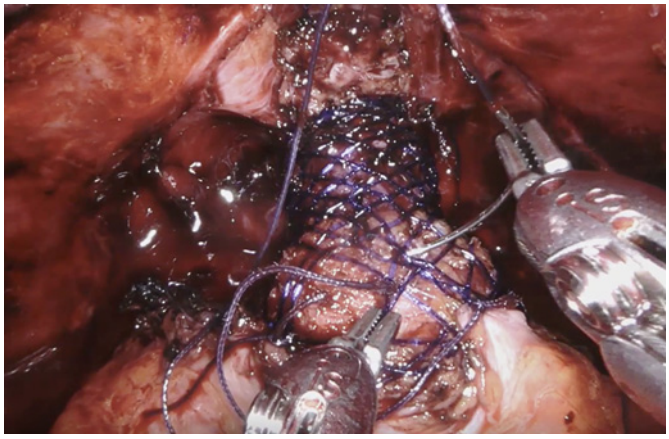

Fig. 3. Suture placement to secure urologic scaffold in place following creation of the anastomosis.

post-RARP, no procedure or device-related complications were identified. The 1 h and 24 h pad weights 1 month following the procedure were 0.2 g and 0 g (prior to RARP). The patient reported that he did not require any pads at 1 month. These results were sustained at 3 months follow-up.

Discussion

Post-operative SUI remains a frequent and often debilitating problem for patients undergoing RARP. Many patients who develop UI experience a negative QOL, along with other psychological issues [6]. As a result, the potential of SUI is often the main driver in patients choosing to not undergo RARP for the treatment of prostate cancer [8]. In addition, there are economic costs to SUI such as the need for supplies (pads/diapers) and subsequent surgical intervention (male sling, AUS). Lastly, there can be a decline in the productivity of men experiencing significant SUI [9].

This study represents the first report using a novel, absorbable urologic scaffold for the prevention of SUI following RARP. Of the patients treated, neither experienced SUI during the early post-procedure follow-up. This favorable outcome provides encouraging results for the use of a novel urologic scaffold in the prevention of SUI after RARP. Further, the device was easily inserted and deployed at the time of surgery with no perioperative complications identified. These patients will continue to be followed along with other subjects enrolled in the ARID study and plan to report the full results of both early and longer-term outcomes associated with the device's use.

Conclusion

Newer approaches to further prevent the development of UI following RARP are needed. While early experience with the absorbable urologic scaffold is promising, further results reporting device use in a larger patient population with longer follow-up is needed.

Statement of Ethics

The ARID study protocol was reviewed and approved by the Research Bioethics Committee at Pacífica Salud Hospital Punta Pacífica, Panama City, Panama on March 5, 2023. Written

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informed consent was obtained from the participants for participation in the study and publication of their medical details and the accompanying images.

Conflict of Interest Statement

M.N.F. and J.C.G. report being paid consultants to Levee Medical and also having equity with the company in the form of stock options. The remaining authors report having no conflicts of interest to declare.

Funding Sources

Funding for the ARID study (NCT06275945) is being provided by Levee Medical, Inc., who was involved with the design of the study and is also responsible for study monitoring, data collection, statistical analysis, and interpretation of the data.

Author Contributions

M.N.F. and J.C.G. were involved with the study design and the procedural technique used to place the absorbable urologic scaffold. G.E. and M.Y. were responsible for the coordination of the study. M.N.F. and E.B. performed the procedures described by the case reports. M.N.F. drafted the manuscript and coordinated the review of the manuscript and manuscript revisions. All authors read and approved the final version of the manuscript.

Data Availability Statement

The data that support the findings reported in this paper are not available publicly due to it containing information that could compromise the privacy of study subjects. The data are available from the corresponding author (M.N.F.) upon reasonable request.

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