

ALLOWRAP® CLINICAL REPORT SERIES

VOLUME 3 - CASE STUDY

RESTORING THE NEUROVASCULAR BUNDLE FOLLOWING A ROBOTIC-ASSISTED RADICAL PROSTATECTOMY USING ALLOWRAP® DS SURGICAL BARRIER

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ABSTRACT

During prostatectomy procedures, minor trauma to the neurovascular bundles (NVB) along the capsule of the prostate can cause urinary incontinence and erectile dysfunction. Amniotic membrane often is applied to the bundle after the prostate is removed to promote rejuvenation of those nerves and provide a barrier preventing tissue adhesions, scarring and excessive fibrosis.

We present a case of a robotic-assisted radical prostatectomy (RARP) accompanied by the placement of AlloWrap® DS (AlloSource®, Centennial, CO) amniotic membrane on the patient's NVB.

After seven weeks, the patient reported urinary continence and spontaneous erectile function near pre-prostatectomy rates.

Introduction

Dehydrated human amnion/chorion membrane (dHACM) allograft is applied in many types of surgical sites to reduce scar tissue formation and promote healing. This tissue is commonly used for urologic applications, for example, as a matrix for bladder and urethral reconstruction^{1,2} and in conjunction with radical prostatectomies in cases of prostate cancer.^{3,4}

During an RARP, the NVB are surgically manipulated because of their course and communication in relation to the prostate. Damage and inflammatory change to the NVB during surgery and the healing phase can prolong a patient's return to urinary continence and spontaneous erectile function.

For that reason, following the excision of the prostate, the NVB are typically wrapped with an amniotic membrane. Amniotic membranes are naturally immune-privileged⁵ and contain bioactive proteins that promote healing, as well as cytokines that control excess fibrosis and formulation of scar tissue.⁶ Amniotic membrane has been shown to control inflammation and limit bacterial and viral activity where it is applied.⁶

AlloWrap DS (*Figure 1*) is a human amniotic membrane graft derived from consenting donors who undergo cesarean births. Following a proprietary aseptic cleaning process, it is sterilized and packaged in 0.9% sterile saline solution between two pieces of non-woven gauze backing material.

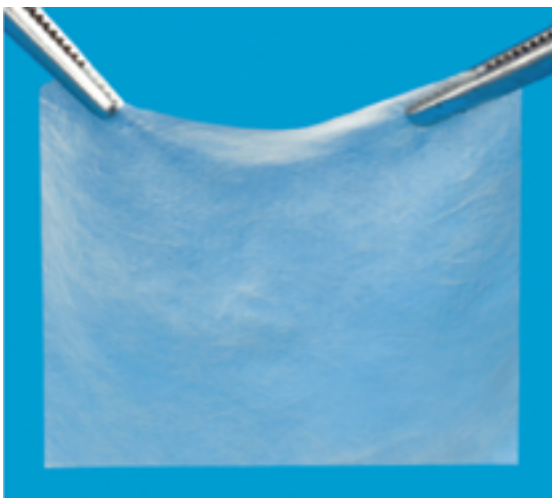


Figure 1. AlloWrap DS (Dual Sided) amniotic membrane separated from the gauze pad protective backing.

Case Presentation

The patient was a 58-year-old male with an elevated prostate-specific antigen (PSA) level of 6.9 nanograms per milliliter who was diagnosed with stage T1c Gleason 6 prostate cancer. He elected to undergo RARP after thorough discussion and counseling. He had no baseline voiding complaints (IPSS 5) and reported good potency (SHIM score 23).

The patient underwent successful removal of his prostate with bilateral nerve sparing (BNS). The bladder neck-urethral anastomosis was performed with 3-0 Monocryl (Ethicon, Inc) suture. A water-tight anastomosis was confirmed.

In the sterile field, the gauze protective pad was removed with forceps from one side of a 4 cm X 8 cm AlloWrap DS surgical barrier (*Figure 2*).

The amniotic membrane (with the second backing material attached) is then placed through a 10–12mm trochar port into the surgical space. The backing material is used as a carrier to robotically position the graft in desired location. Once in place over the exposed neuromuscular bundles, the second backing material is removed. Final positioning of the graft is then performed with gentle manipulation using the robotic needle drivers.



Figure 2. Gauze pad removed from one side of the AlloWrap DS prior to insertion.

The AlloWrap DS, with the second side backing material still attached, was then placed through a 10 mm laparoscopic assistant port into the surgical space. The backing material on the second side of the AlloWrap DS remained in place during this step so it could be used as a carrier to robotically position the graft. Once in place on the NVB, the backing on the second side of the AlloWrap DS was removed (*Figure 3*).

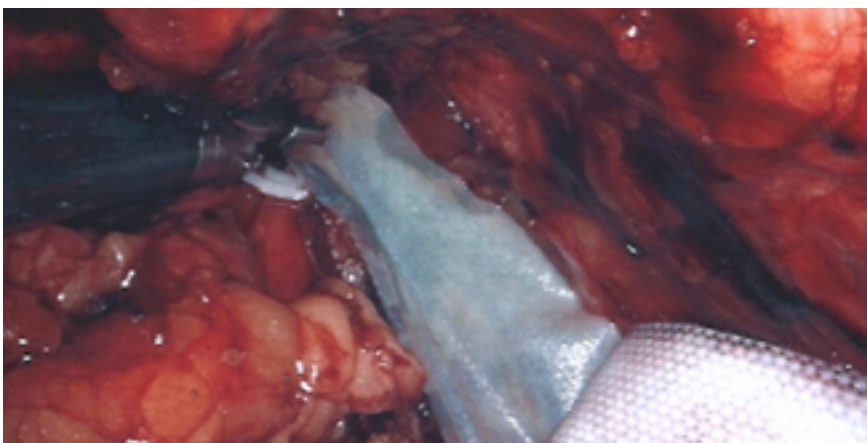


Figure 3. Removing the gauze pad backing from the second side of the AlloWrap DS once it is in place.

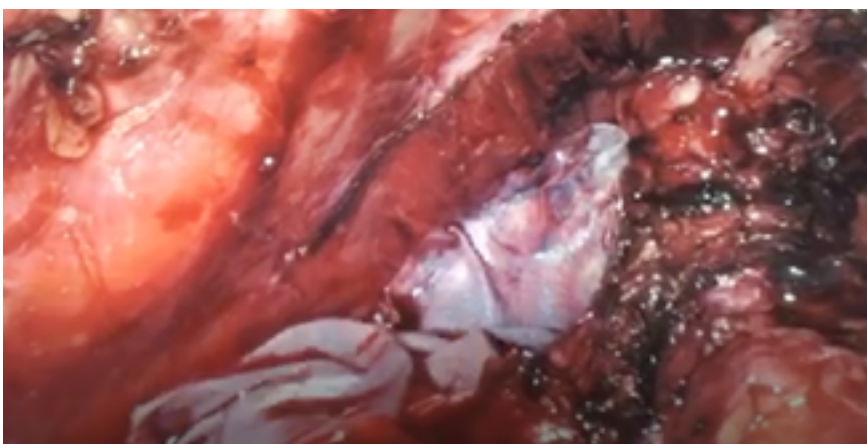


Figure 4. Final placement of the AlloWrap DS.

The pre-moistened AlloWrap DS was pliable and conformed well to surrounding tissue, allowing for easy manipulation and tucking without suturing (*Figure 4*). The membrane covered the NVB in their entirety.

The patient had an uneventful recovery and his Foley catheter was removed seven days after surgery. Seven weeks after surgery, the patient report significant improvement in urinary continence using only one pad daily for urinary leakage control. He also reported 40-50% return of erectile function. At ten weeks, the patient reported only rare stress-induced urinary incontinence and he was not using pads. His potency had returned to 75-85% of his pre-prostatectomy rate.

Discussion

Given the prostate gland's location deep in the pelvis, surgeons prefer to remove it using a minimally invasive laparoscopic process and robotic instrumentation. Following excision of the gland, surgeons place amniotic membrane around the NVB to promote healing and limit adhesions from contiguous tissue. NVB healing is essential for regaining urinary continence and spontaneous erectile function.

The most distinctive feature of AlloWrap DS is its dual-layered configuration. It is made up of two amniotic tissues with the epithelial layers facing out to promote easy orientation and repositioning. This helps ensure free movement of the healing tissue with no adhesions. Further, due to a proprietary processing protocol, AlloWrap DS remains intact and in place eight weeks or longer, well into the remodeling phase of the healing process.⁷

This amniotic membrane has been utilized in approximately fifty cases at my practice since its adoption.

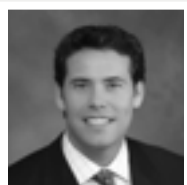
Conclusion

Application of the AlloWrap DS amniotic membrane effectively protects the NVB and can improve the patient's reported rates of urinary continence and spontaneous erectile function following an RARP procedure.

Two features of AlloWrap DS make it well-suited for this purpose. First, it remains intact in the surgical site longer than many other amniotic membrane products. Second, its two-layer design, with epithelial layers on both outward sides, improves its handling characteristics so it is easier to place with precision.

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Dr. Geoff Ledgerwood is a board-certified urologist who has been practicing in Denver, Colorado for the past ten years with areas of expertise in genitourinary cancers, minimally invasive surgery and reconstructive surgery. Dr. Ledgerwood completed his medical schooling at the University of Washington (Seattle) and finished his urologic training and residency at the University of Arizona (Tucson). While in Arizona, he helped establish one of the first robotics programs in that state. Dr. Ledgerwood is on the clinical faculty for Rocky Vista University/Sky Ridge Medical Center where he works with both medical students and surgical residents.

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