clarix CORD 1K

UROLOGY

Robot Assisted Radical Prostatectomy

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CLINICAL HISTORY

52-year-old healthy male with no other medical history was found to have elevated PSA of 4.5. A multiple core biopsy of the prostate showed evidence of high grade cancer with Gleason 7 (4+3) score, while the metastatic work-up came back negative. Patient had no voiding issues, and has excellent erectile function with SHIM score of 24/25.

There are many different treatment options for prostate cancer, however in this individual, Robot Assisted Laparoscopic Prostatectomy (RALP) with nerve sparing was the best option due to his disease status and long life expectancy.

TECHNOLOGY OVERVIEW

CLARIX® CORD 1K is an allograft comprised of human Umbilical Cord and Amniotic Membrane. Amniox Medical's proprietary CRYOTEK® preservation process is the only method proven to produce a matrix that is comparable to the native tissue, delivering the benefits of the innate benefits of the natural tissue to the surgical site. In this application, CLARIX CORD 1K was used as a surgical wrap for the neurovascular bundle.

FIGURE 1. INTRODUCTION OF CLARIX CORD 1K

PROCEDURE

After anesthesia was obtained and preoperative antibiotics were given, the patient was positioned in a modified lithotomy position with all of the anatomical pressure points padded. Patient was then prepped and draped and the incision made above the umbilicus. Insufflation of the abdomen was completed and additional ports were placed. At this point, the patient was placed in the trendelenburg position and the Robot was docked.

An intraperitoneal approach was used to access the prostate (some may use extraperitoneal approach). The endopelvic fascia was excised and then the dorsal vein was controlled with suture. The bladder neck is identified, dissected and divided from the prostate. Seminal vesicle and vas deferens were identified and dissected free. A posterior plane was created between the rectum and prostate, and in retrograde fashion, the nerve is carefully dissected athermally followed by the pedicle being divided bilaterally.

FIG. 2. PLACING CLARIX OVER THE NVB

Apically, the prostate was divided from the urethra (paying special attention to the sphincter muscle and posterior lateral nerve bundle on each side) allowing the prostate to be removed. Following removal, the anastomosis of the bladder to the urethra was completed in order to reinstate continuity of the urinary system. Foley catheter was then replaced and irrigation was appliced to check for leaks at the anastomosis site.

At this point, surgical site bleeding was confirmed to be adequately managed and the CLARIX Cord 1K was introduced through the portal (Figure 1). The tissue is then placed over to effectively wrap the neurovascular bundle (NVB) on each side (Figures 2 &3). Care must be taken to ensure the tissue is placed flat, utilizing a suture to keep it in place if necessary.

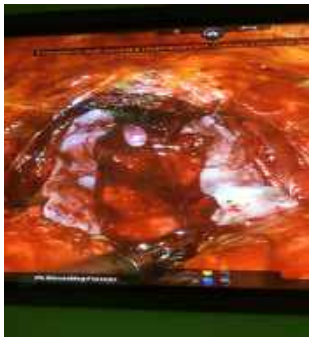

FIG. 3. FINAL PLACEMENT OF CLARIX CORD 1K OVER THE NVB'S.

Finally, the lymph nodes dissection is performed. This usually includes the obturator packet, however, some may choose to perform extended node dissections or none at all. Following dissection, the ports are removed and the incision is closed.

POST-OPERATIVE HEALING

Survival rates following diagnosis and treatment of prostate cancer are 98% at 10 years[1]. When the prostate is removed, sexual and urinary function are interrupted. It has been reported that up to 32% of patients cannot return to potency at 6 months following RALP[2], and up to 24% of patients cannot return to continence at 3 months[3]. The introduction of CLARIX Cord 1K to the NVB's provides a well documented anti-inflammatory healing environment supporting the optimal healing required for an efficient return to sexual and urinary function.

[1]American Cancer Society. http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics
[2]Joseph et al. Hosp Med (2003) Jan; 61(1):179-83
[3]Ahlering et al. " Urology (2004) May; 63(5):819-22.

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