Reservoir Alternate Surgical Implantation Technique: Preliminary Outcomes of Initial PROPPER Study of Low Profile or Spherical Reservoir Implantation in Submuscular Location or Traditional Prevesical Space

Edward Karpman,* William O. Brant,† Bryan Kansas, Anthony J. Bella, LeRoy A. Jones, Elizabeth Eisenhart and Gerard Henry

From the El Camino Urology Medical Group (EK), Mountain View, California, University of Utah Department of Surgery (Urology), Center for Reconstructive Urology and Men's Health (WOB), Salt Lake City, Utah, The Urology Team, P.A. (BK), Austin and Urology San Antonio (LAJ), San Antonio, Texas, Department of Surgery, Neuroscience, Ottawa Health Research Institute, University of Ottawa (AJB), Ottawa, Ontario, Canada, and Regional Urology (EE, GH), Shreveport, Louisiana

Purpose: Alternative reservoir site placement has become an accepted technique for patients who require an inflatable penile prosthesis. To our knowledge there has been no prospective evaluation of this technique, which is currently off label. We performed a prospective, multicenter, multinational, internal review board approved study to evaluate the effectiveness and safety of alternative reservoir site placement.

Materials and Methods: PROPPER initiated in June 2011, is a database containing patient outcomes of inflatable penile prosthesis implantation. Patients with AMS® penile prostheses continue to be enrolled at 13 North American sites. We examined PROPPER study data to determine surgical implantation use patterns for the AMS 700™ series. We evaluated reservoir implantation site and complications by implantation site.

Results: A total of 759 patients had been implanted with an AMS 700 series implant by the time of evaluation. Mean patient followup was 17.8 months (range 0 to 36). There was no reported case of revision surgery for a palpable reservoir and no report of vascular or hollow viscous injury associated with alternative reservoir site placement. Two cases of reservoir herniation in the alternative reservoir site placement group and 2 in the space of Retzius group were treated with reservoir reimplantation. Patients with 1-year assessment available were satisfied or very satisfied with the device and reported a frequency of use of more than once per month.

Conclusions: Alternative reservoir placement in the submuscular location is an option in patients who undergo inflatable penile prosthesis surgery. Implant surgeons should consider alternative reservoir site placement a safe, effective alternative to reservoir placement in the space of Retzius.

Key Words: penis, erectile dysfunction, prostheses and implants, complications, quality of life

Abbreviations and Acronyms

ARP = alternative reservoir placement

ED = erectile dysfunction

IPP = inflatable penile prosthesis

PROPPER = Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration

RALP = robot-assisted laparoscopic prostatectomy

SOR = space of Retzius

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* Correspondence: El Camino Urology Medical Group, 2490 Hospital Dr., Suite 210, Mountain View, California 94040 (telephone: 650-962-4662; FAX: 650-962-4652; e-mail: edwardkarpman@yahoo.com).

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Reservoir placement for the 3-piece IPP is associated with some devastating complications during the implantation procedure.[1] Although the incidence of these problems is estimated to be less than 1% of all cases, blind reservoir placement causes surgical anxiety during implantation.

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This has led to greater use of malleable and 2-piece prostheses to minimize the risks of blind reservoir placement despite the higher patient satisfaction rate associated with the 3-piece prosthesis.[2] Thus, concern about bladder, bowel and vascular complications have led to increased alternative reservoir placement (ectopic reservoir placement).[1,3–5] A recent study of important anatomical landmarks of the prevesical space (SOR) highlighted the potential perils of placing a reservoir in the SOR.[6]

There is also increasing concern among surgeons when placing an IPP in patients after RALP.[7] In the RALP approach during transperitoneal surgery the SOR is violated when the peritoneal veil is taken down and the bladder is mobilized aggressively with respect to the traditional open retropubic prostatectomy approach. Significantly the latest estimates revealed that approximately 70% of all prostatectomies in this country are now performed using RALP and 27% of implants are placed in patients after radical prostatectomy.[8,9] To date published techniques of ARP have been variations of submuscular placement and reports have included only a small series of single surgeon retrospective experience with their techniques and not a prospective or large multicenter evaluation.[10]

The AMS Conceal™ Low Profile Reservoir was first released in 2010. This reservoir has a maximum profile of only 2.5 cm, making it ideal for placement in the submuscular location. The release of this reservoir was coincident with the sharp increase in patients treated with RALP. In a recent study 57% of high volume implant surgeons said that they would be more likely to use a 3-piece prosthesis over a malleable or 2-piece prosthesis because of the availability of this low profile reservoir.[7] Additionally, 90% of high volume implanters would use an alternative reservoir location due to the availability of these low profile reservoirs despite the lack of FDA (Food and Drug Administration) approval for using any reservoir in an ectopic location.

We now report what is to our knowledge the first prospective, multicenter evaluation of the Conceal Low Profile Reservoir and spherical reservoirs implanted in the ectopic location. Patients with submuscular low profile and spherical reservoirs were evaluated to determine baseline characteristics and initial outcomes related to this ectopic reservoir placement technique. The multicenter, clinical PROPPER study (AMS No. ER1005) collects real world outcomes in patients with a penile implant.

MATERIALS AND METHODS

We examined PROPPER study data to determine surgical implantation use patterns of the recently introduced AMS 700 device component, the Conceal Low Profile Reservoir, and of spherical reservoirs. Specific surgical implantation locations were documented for the AMS 700 reservoirs, including the traditional prevesical space/SOR, a submuscular site, defined as anterior to (above) the transversalis fascia and posterior to (below) the transversus or rectus abdominis muscle, or other, a category that was left blank for the physician to complete. Specific nuances of the different submuscular placement techniques, such as using a nasal speculum or ring clamp to place the reservoir in a higher location, were not recorded in this study. Any complications reported through postimplantation followup were summarized for patients implanted with AMS 700 Conceal or spherical reservoirs.

Objective and Design

PROPPER collects data on patients implanted with AMS 700, Ambicor® and Spectra™ penile implants. PROPPER was designed to quantify penile prosthesis durability, complications and effectiveness, including patient reported functionality, satisfaction and quality of life outcomes. Patients who underwent penile implantation were invited to participate in the study if they were willing and provided consent for study enrollment. Internal review board approval was obtained at all sites and the study consent process varied based on site requirements. Physician investigators record baseline patient characteristics and surgical implantation details. These data are used to prospectively measure patient responses to treatment with penile prostheses at regular intervals during a 1 to 5-year postimplantation period using validated patient survey questionnaires and electronic data collection. Followup questionnaires were obtained in person, by mail and by telephone by the surgeon or authorized study personnel. Data were collected in an online secured database.

PROPPER was initiated in June 2011 and patients with AMS penile prostheses continue to be enrolled at a total of 13 North American sites. Initial questionnaire assessment is done 1 year after implantation and any complications are documented immediately. During this initial annual evaluation patient reported data include responses on the International Index of Erectile Function-5/Sexual Health Inventory for Men, SF-12® health related quality of life and Erectile Hardness Score questionnaires, American Urological Association Symptom Index and UCLA Prostate Cancer Index. Patients are asked 2 standardized questions to assess device use and satisfaction, including 1) whether they use the device and 2) if used, with what frequency. The satisfaction question is gauged on a 5-point Likert scale of very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied and very dissatisfied. The question on use is answered yes or no.

Alternate Reservoir Placement Analysis

Patients included in analysis completed registry database records, including study informed consent date, ED primary etiology, device specific implant details such as reservoir placement information, and surgical implantation date. Specific surgical implantation locations