

Article

Protocol for the RoboSling Trial: A Randomised Study Assessing Urinary Continence Following Robotic Radical Prostatectomy with or without an Intraoperative Retropubic Vascularised Fascial Sling (RoboSling)

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Abstract: Objectives: To determine if early (three months) and late (one year) post-operative continence is improved by performing a novel retropubic vascularised fascial sling (RoboSling) procedure concurrently with robot-assisted radical prostatectomy in men undergoing treatment for localised prostate cancer. To additionally assess surgical outcomes, quality of life and health economic outcomes in patients undergoing the novel RoboSling technique. **Methods:** This study aims to recruit 120 consecutive patients with clinically localised prostate cancer who have chosen to undergo robot-assisted radical prostatectomy in the Sydney Local Health District, Australia. A prospective assessment of early and late post-operative continence following robot-assisted radical prostatectomy with and without a RoboSling procedure will be performed in a two-group, 1:1, parallel, randomized controlled trial. Four surgeons will take part in the study, all of whom are beyond their learning curve. Patients will be blinded as to whether the RoboSling procedure is performed for them, as will be the research officers collecting the post-operative data on urinary function. Trial Registration: ACTRN12618002058257. **Results:** The trial is currently underway. **Conclusions:** The RoboSling technique is unique in that the sling is vascularised and has a broad surface area compared to previously described slings in the literature. If a clinically significant improvement in post-operative continence is established with the RoboSling, then, we can in turn expect improvements in quality of life for men undergoing this technique with radical prostatectomy.

Keywords: incontinence; intraoperative sling; prostate cancer; prostatectomy; robotic surgery



Citation: Virk, A.; Treacy, P.-J.; Zhong, W.; Jackson, S.R.; Ahmadi, N.; Jeffery, N.N.; Chan, L.; Sved, P.; Vasilaras, A.; Thanigasalam, R.; et al. Protocol for the RoboSling Trial: A Randomised Study Assessing Urinary Continence Following Robotic Radical Prostatectomy with or without an Intraoperative Retropubic Vascularised Fascial Sling (RoboSling). *Soc. Int. Urol. J.* **2024**, *5*, 148–159. <https://doi.org/10.3390/siuj5020024>

Received: 19 July 2023

Revised: 15 September 2023

Accepted: 18 November 2023

Published: 17 April 2024



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1. Introduction

Prostate cancer is the most common cancer diagnosed in Australian men, accounting for 27% of all new cancer diagnoses [1]. The incidence of prostate cancer is rising because of a high uptake of prostate-specific antigen screening combined with the increasing life expectancy [1]. Radical prostatectomy remains a common treatment option for men with localized prostate cancer. The loss of urinary function and potency are the two functional deterrents in choosing surgery for treatment [2].

The recovery of continence 12 months following surgery for open radical prostatectomy ranges from 60% to 93%, depending on the specific criteria used to define continence [3]. However, early continence post-prostatectomy is much lower and varies more

widely between 32% and 84% [4,5]. The return of urinary function following radical prostatectomy is determined by patient factors, surgeon factors, and specific intra-operative surgical techniques.

Specific intraoperative manoeuvres at the time of radical prostatectomy have been described, with a potential to reduce the risk of post-operative urinary incontinence. Among these techniques include sparing the pubo-prostatic ligaments, bladder neck preservation, sparing the neuro-vascular bundles, posterior rhabdosphincter reconstruction, and periurethral suspension stitch [6–8]. However, many of these techniques have not been externally validated, and systematic reviews suggest only minor improvements in early post-operative continence [9].

Two recent randomised studies assessed novel slings positioned behind the urethra/bladder neck in patients undergoing robot-assisted radical prostatectomy (RARP). Nguyen et al. utilised an autologous sling fashioned from vas deferens, placed around the urethra, and then secured to the pubic bone [10]. Bahler et al. used porcine small intestinal submucosa as a bladder neck sling, also positioned underneath the urethra and secured to the pubic bone [11]. The slings failed to demonstrate any statistically significant improvement in urinary continence in either study.

The RoboSling technique has been developed as a novel method to improve recovery of continence in men undergoing RARP. The RoboSling is a vascularised flap of peritoneum positioned as a sling underneath the urethrovesical junction and then hitched to the pubic bone with dissolvable sutures [12]. The placement of this sling is intended to improve post-operative continence by restoring pelvic/urethral support, maintaining a greater length of urethra exposed to increases in intra-abdominal pressure, and providing outlet resistance.

RoboSling Technique

A rectangular flap of peritoneum is dissected off the detrusor muscle from the posterior aspect of the bladder. The flap is mobilised from the superior aspect inferiorly with a broad base to maintain vascularity (Figure 1). A posterior approach is used to expose the seminal vesicles and vas deferens bilaterally and dissect the posterior plan between the prostate and the Denonvilliers' fascia.

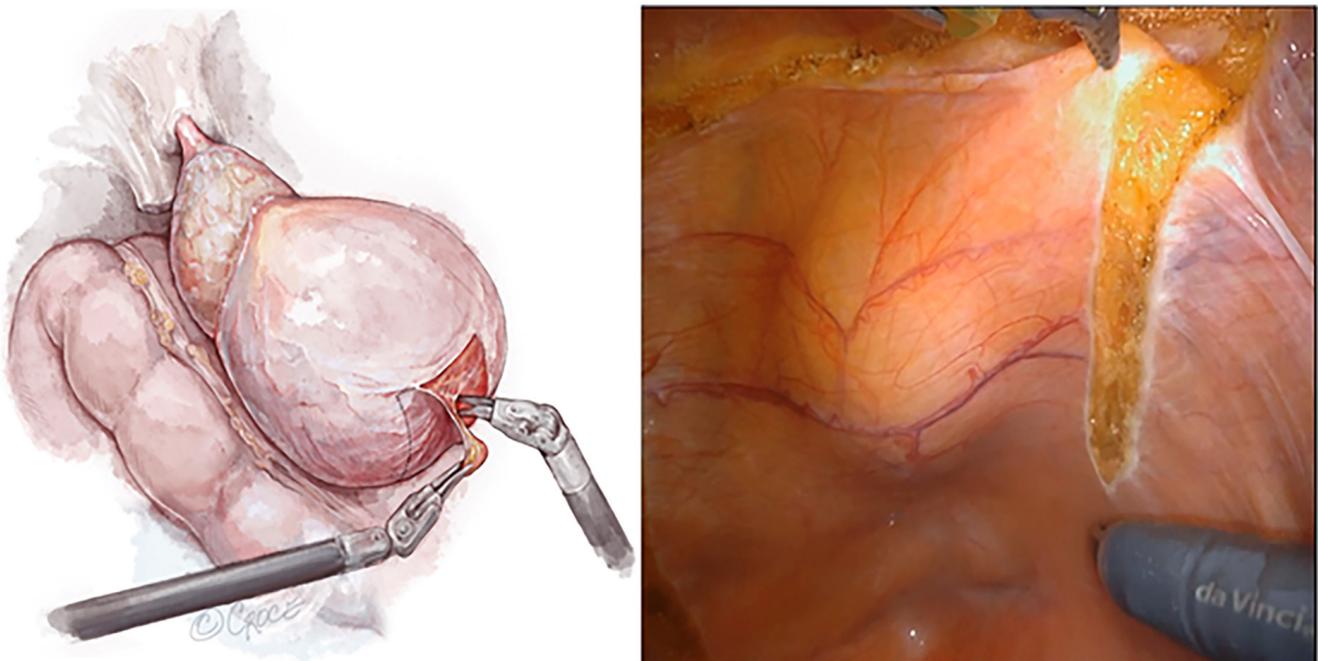


Figure 1. Dissecting the vascularised sling out from the posterior bladder peritoneum.

After the prostate is removed and any required lymph node dissection is completed, the peritoneal flap is tunneled underneath the bladder (Figure 2). The free end of the flap is incorporated into the breadth of a modified Rocco Stitch using 3-0 V-Loc suture (Figure 3). The vesicourethral anastomosis is completed with a standard approach.



Figure 2. Tunneling the sling underneath the bladder following the completion of the radical prostatectomy.

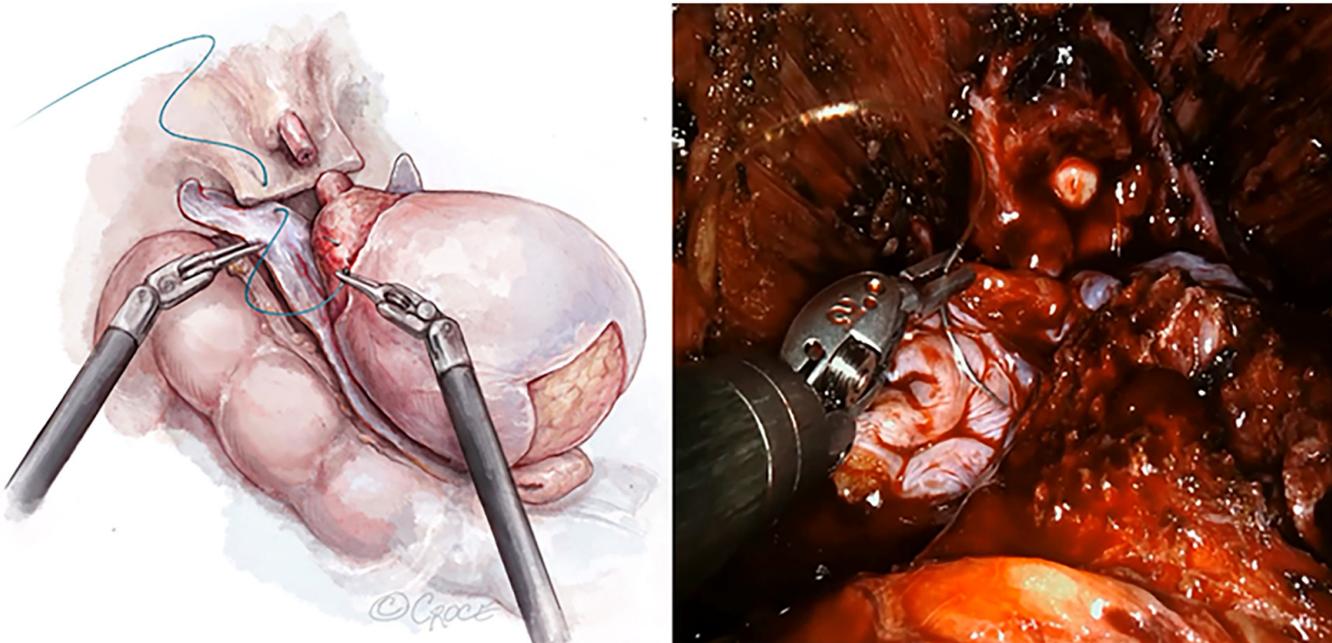


Figure 3. Incorporation of the sling into the Rocco stitch.

Each corner of the flap is then hitched up to the pectineal ligament on either side using 3-0 V-Loc suture (Figure 4). These are tensioned by sliding the barbed sutures and securing the tensioned position in place using two Hem-o-lok clips on either side (Figure 4). Tensioning is performed symmetrically with an 18Fr Foley indwelling catheter in place to prevent the overtensioning of the sling. The sling lifts and supports the bladder neck, rectourethralis, and vesicourethral anastomosis [12].

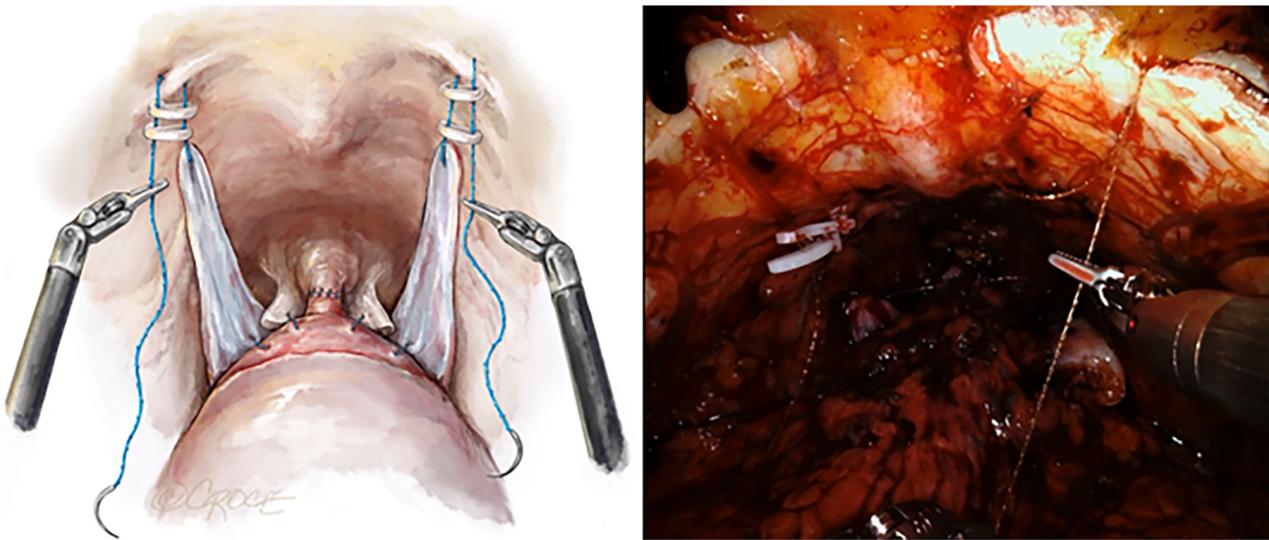


Figure 4. Tensioning flap laterally to the pectineal ligament.

2. Materials and Methods

2.1. Study Design

This is a prospective, two-group, 1:1 randomised controlled trial assessing urinary function following RARP in patients with and without a concurrent RoboSling procedure. Four surgeons beyond their learning curve and performing RARP at Royal Prince Alfred Hospital (RPAH) in Sydney, Australia, will take part in the study. Patients will be blinded as to whether the RoboSling procedure is performed for them, as will be the research officers collecting the post-operative data on urinary function. The primary and secondary endpoints are listed in Table 1. This randomised controlled trial has been approved (Protocol Number: X17-0339, HREC/17/RPAH/518) by the Sydney Local Health District Human Research Ethics Committee (HREC) and has been registered (ACTRN12618002058257) on the Australian New Zealand Clinical Trials Registry. The trial schematic is outlined in Figure 5.

Table 1. Primary and secondary objectives.

Primary Endpoint
To determine if incorporating the RoboSling procedure with RARP improves early (three months) and late (one year) post-operative urinary continence compared to RARP alone.
Secondary Endpoints
To identify urinary functional parameters (using uroflow, urodynamics, and dynamic 3D pelvic floor ultrasound), which may differ between the RoboSling group and the control group.
To identify differences in perioperative complications.
To identify anatomic features on pre-op imaging (MRI scan/3D pelvic floor ultrasound scan), which may result in poorer post-operative functional outcome post RARP (prostate volume; pelvic volume; urethral length; BMI).
To prospectively assess the following:
(a) Clinical outcomes;
(b) Quality of life;
(c) Health economic outcomes;
(d) Decision regret.

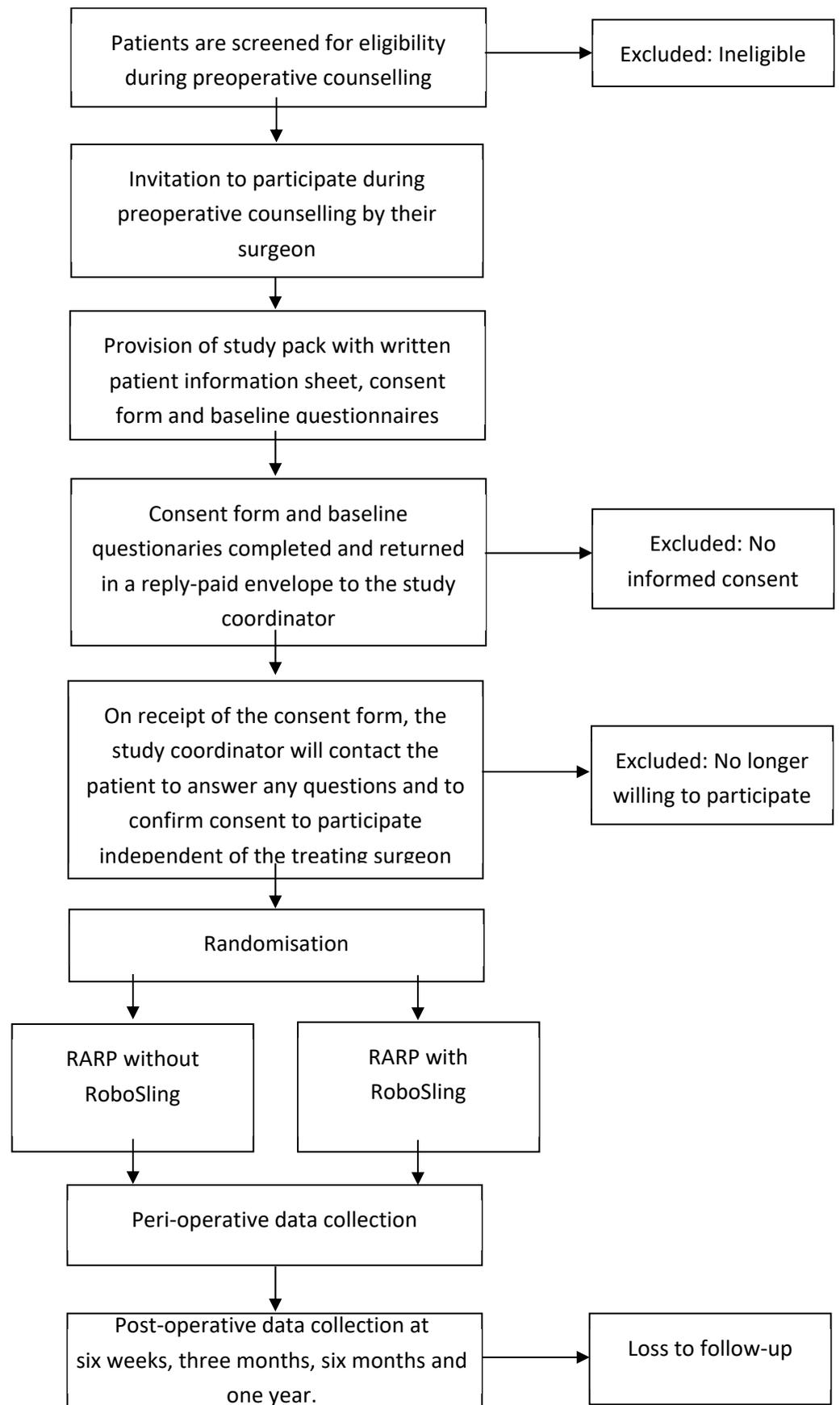


Figure 5. Study schematic.

2.2. Patient Recruitment

This study aims to recruit 120 consecutive patients with clinically localised prostate cancer undergoing RARP under the care of Sydney Local Health District urologists at the RPAH. Eligible patients will be informed about the study by their surgeon during pre-operative counselling and will be given a study pack containing a written patient information sheet, consent form, and baseline study questionnaire to complete and return to the study coordinator in a reply-paid envelope. Patient inclusion and exclusion criteria are listed in Table 2. On receipt of the consent form, the study coordinator will contact the patient to provide additional information about the study, answer any questions, and to confirm the consent to participate independent of the treating surgeon.

Table 2. Inclusion and exclusion criteria.

Inclusion Criteria
Adult men aged 18 years and over
Undergoing prostatectomy for prostate cancer at RPA hospital
Clinically suitable for robotic prostatectomy
Cognitively able to provide written informed consent for participation
Elective procedure
Exclusion Criteria
The patient lacks the ability to consent for themselves
Patient or tumour factors precluding robotic surgery
The lack of available tissue behind the bladder to create the vascularised flap

Consenting patients will be allocated a unique study identification number. The list that matches individual patients with study identification numbers will be kept securely by the study coordinator in a separate excel file on a password-protected computer within the Department of Urology at the RPAH. Study data will be entered into a REDCap database with individuals identified by their study identification number (a re-identifiable format). Only the study coordinator and study investigators will have access to these data.

2.3. Intervention Randomisation

Assignment to the RoboSling procedure or to the standard RARP technique will be randomly determined by a computer-generated code. Random assignment will be generated just prior to the operation. Patients, data collectors, and study personnel will be blinded to randomisation assignments.

2.4. Sample Size Determination

Urinary continence at three months was the primary outcome used for power and sample size calculation. In this prospective RCT, based on previous studies and on the authors' own experience and data, the rate of no urinary pad use (continence) at three months post-surgery between robotic prostatectomy with and without the RoboSling procedure is approximately 50% and 20%, respectively. If the true urinary continence rate in the intervention group (RARP + RoboSling) is 50% at three months, we will need to study 51 intervention subjects and 51 control subjects (RARP only) to be able to reject the null hypothesis that the urinary continence rates for both groups are equal with a probability of 90% power and type I error probability of 0.05. We will use an uncorrected Chi-square statistical method to evaluate this null hypothesis. The sample size was calculated using the Power and Sample Size Calculations software (Vanderbilt University, Nashville, TN, USA, version 3.0).

We anticipate that around two procedures (one RoboSling and one without RoboSling) will be performed each week, approximately 100 per year. Assuming a maximum drop-

out rate of 15%, a total of at least 120 patients (60 in each group) will be accrued over approximately 1.5 years and followed-up for disease progression and continence.

2.5. Methods of Data Collection

The study coordinator in each hospital will collect the participant data from different sources. Demographic, clinical, and tumour characteristics will be collected from the electronic medical records. Procedure details will be collected from the theatre records. See the complete study schedule of assessments in Table 3.

Table 3. Study measurements and timepoints.

Measurement	Timepoint					
	Pre-Op	Peri-Op	Post-Operative			
			Six W	Three M	Six M	One Y
Demographic and Clinical Factors						
Age (years)	x					
Body Mass Index (BMI)	x					
American Society of Anaesthesiologists (ASA) Grade	x					
Prostate-specific antigen1 (PSA) level	x		x	x	x	x
Multiparametric MRI (mpMRI)/CT	x					
Pelvic Cavity Index (PCI)	x					
Prostate Volume: Pelvic Cavity Index (PCI) ratio	x					
Tumour Characteristics						
Clinical stage	x					
Biopsy Gleason Score	x					
Prostate Volume	x					
Procedure Details						
Surgical access (robotic or open)		x				
Operative time/console time, minutes		x				
Conversions to non-robotic procedure, number		x				
Patient Reported Outcomes						
International Index of erectile Function (IIEF)	x		x	x	x	x
International Prostate Symptom Score (I-PSS)	x					x
SF-36v2 Quality of Life	x		x		x	x
Decision Regret Scale			x	x		x
Expanded Prostate Cancer Index Composite (EPIC)	x		x	x	x	x
International Consultation on Incontinence Questionnaire Urinary Incontinence (ICIQ-UI)	x		x	x	x	x
Clinical (Functional) Outcomes						
Pad weight and number/24 h	x		x	x	x	x
Urodynamics assessment *	x					x
Uro-flow/pelvic floor ultrasound assessment *	x		x	x	x	x
Clinical (Operative) Outcomes						
Complications, number		x				
Complications (Clavien–Dindo), classification I-V		x				
Blood loss, mL		x				

Table 3. Cont.

Measurement	Timepoint					
	Pre-Op	Peri-Op	Post-Operative			
			Six W	Three M	Six M	One Y
Transfusions, mL		x				
Numerical Pain Rating Scores (NPRS), score 0–10	x		x	x		x
Length of hospital stay, days						
Death: date, cause		x	x	x	x	x
Pathology Outcomes						
Weight of resected tissue		x				
Extracapsular extension		x				
Seminal vesical Invasion		x				
Lymph node involvement/yield		x				
Margin involvement		x				
Adjuvant treatment		x				
Economic Evaluation						
Hospital discharge data						
Work and care responsibilities	x		x		x	x
Assistance at home			x		x	x
Financial issues			x		x	x

* After the initial 40 patients, urodynamic testing will cease, and uroflow and pelvic ultrasound will occur at preop and three and 12 months.

The first 40 patients enrolled will be invited to attend the hospital clinic for functional diagnostic assessment with the following:

1. Urodynamics (to study bladder storage function, voiding function, and continence).
2. Pelvic floor ultrasound (to assess pelvic floor contraction and urethral mobility and measure urethral sphincter length).
3. Uroflow assessment (to assess bladder and sphincter function and to determine urine obstructions).

These 40 patients will undergo urodynamic testing pre-operatively and at 12 months post-operatively. They will undergo uroflow and pelvic floor ultrasound assessments pre-operatively and at six weeks, three months, six months, and 12 months post-operatively. The following 80 patients will undergo uroflow and pelvic floor ultrasound assessments pre-operatively and only at three and 12 months post-operatively.

All patients participating will be contacted by an authorised member of the study team at six weeks, three months, six months, and one year post-operatively and asked to complete a follow-up questionnaire that will be emailed or posted to them (with a reply-paid envelope), according to the patient's preference. Patients will have the option of completing the questionnaire by telephone if this is more convenient.

3. Results

3.1. Outcome Measures

The primary outcome measures will be continence defined as zero pad per day at three months and 12 months post-operatively. Secondary outcomes will be 24 h pad weight, EPIC and ICIQ scores, time of return of continence, SF-36 scores, and decision regret scale. Uroflow, urodynamic parameters (Qmax, Detrusor Leak point pressure, bladder compliance), and pelvic floor contraction and mobility on pelvic floor ultrasound (PFUS) will be recorded pre-operatively and post-operatively. The anatomic factors of sphincter

length, prostate size and configuration (intraprostatic protrusion), and pelvic dimensions will be assessed with MRI/CT/PFUS, and operative factors will be recorded to assess functional outcomes.

3.2. Analysis Plan

Clinically relevant baseline variables will be tabulated and compared between groups. Categorical variables will be compared between groups using the Chi-squared test (frequencies and proportions). Continuous variables will be compared using *t*-test (means) or Wilcoxon 2-sample test (median). Unadjusted rates of continence will be compared between groups with the Fisher exact test. All data will be stored in a REDCap database and statistical analysis will be performed using SPSS version 22 (SPSS Inc., Chicago, IL, USA).

4. Discussion

The RoboSling technique is unique from the previously described continence slings due to it being vascularised and having a wide surface area. The primary benefit of the study is to scientifically evaluate whether a novel sling procedure will improve post-operative continence following RARP. If early and late continence rates are improved with the RoboSling, then, improved quality of life could also be expected in men following surgery for their prostate cancer.

The risks of the study are the surgical risks of the RARP operation and the novel RoboSling procedure. Specific to the RoboSling, the possible risks include intraoperative complications such as bladder and ureteric injury. Post-operative complications may include urinary retention, urinary tract infection, and diminished urinary flow. There will be regular interaction between the medical staff and the investigators to ensure that any issues are raised and addressed. Summarised and de-identified data will be reported monthly to the institutional data and safety monitoring board, which includes independent senior clinicians and external data monitors. Annual reports will also be submitted to the ethics board. Should any unforeseen circumstances or concerns arise, the principal investigators will report these to the ethics board (HREC).

To assess the safety and efficacy of this technique prior to the completion of randomised controlled trial testing, a prospective non-randomised cohort study was performed. The outcomes of 30 patients undergoing RARP with the RoboSling was compared to 163 patients undergoing RARP without the RoboSling [12]. Baseline characteristics between the two groups were comparable. Early continence was significantly improved in the RoboSling intervention arm with better zero pad use rates (44% compared to 16.5%, $p = 0.005$) and higher mean Epic scores (62 compared to 43, $p = 0.008$) at 3 months post-operatively [12]. Both groups showed improvement in mean EPIC scores at 12 months post-operatively, and there was no longer a significant difference in mean scores between the two groups at this timepoint (73 compared to 65, $p = 0.237$) [12]. Notably, however, zero pad use at 12 months remained higher in the RoboSling intervention group (72.2% compared to 44.7%, $p = 0.029$) [12].

There were no significant differences in estimated blood loss, complication rate, pathological outcome, or length of stay between the two groups [12]. There was an increased operative time of 16 min, which can be attributed to the additional steps required to perform the RoboSling [12]. We anticipate this additional operative time to decrease as surgeons gain experience and overcome the learning curve associated with any new technique.

One of the reasons for the wide variance in the rates of post-prostatectomy continence in the literature has been the definition itself. Earlier studies typically described continence as zero or one pad per day. However, most centres now define urinary continence as no pads at all [13]. Furthermore, when assessing the degree of incontinence, the number of pads used per day is not a reliable measure owing to the wide variety of pads available. A more accurate measure of incontinence is 24 h pad weight; however, this has not been routinely used in most studies assessing post-prostatectomy incontinence [14,15]. We have

incorporated both measures in this protocol to compare this technique to the literature more accurately.

As mentioned earlier, the return of urinary function following radical prostatectomy is also determined by patient factors, surgeon factors, and other operative factors. The most important patient factor is age, with younger patients (<70 years) having rates of continence at 12 months between 93% and 95%, compared to only 86% for men 70 years or older at the time of radical prostatectomy [16]. Urethral length on pre-operative imaging may be associated with the return of urinary function with one study demonstrating continence at 12 months of 89% for patients with a membranous urethra greater than 1.2 cm on MRI compared with 77% for those with urethral lengths of 1.2 cm or less [17]. Prostate volume has been suggested to affect the return of continence following surgery with one study demonstrating higher rates of urinary incontinence in patients with larger prostates [18]. Larger prostates tend to be found in older men, require a larger dissection at the bladder neck, and are associated with more voiding dysfunction at baseline, all of which may have a negative impact on post-operative urinary continence [19]. Patients that undergo dedicated pre-operative pelvic floor physiotherapy have a quicker return to continence following radical prostatectomy. A systematic review of the literature demonstrated that pre-operative pelvic floor exercises improved early continence rates; however, they did not change the long-term rates of continence [20].

The impact of surgeon experience and learning curve on functional outcomes remains controversial. Systematic reviews indicate superior oncological and functional outcomes in higher volume centres [21]. Several prospective studies demonstrate that rates of continence continue to improve with increasing surgeon volume beyond 500 cases [22].

Ongoing improvements in robotic surgery technology with advanced 3D vision and endo-wristed instruments for more minimally invasive surgery and more precise movements potentially allow for the better preservation of the anatomic structures involved in the urinary continence mechanism. A systematic review of the literature showed 12-month urinary continence following RARP to range between 66% and 95% [10]. This review also suggested that RARP demonstrated superior continence outcomes at 12 months compared to both open and laparoscopic radical prostatectomies. However, this systematic review has several limitations including selection bias, the variable definition of continence between the studies, inability to control for surgical experience, and a poor quality of reviewed individual studies. The only randomised study comparing RARP with open radical prostatectomy was reported in the *Lancet* in 2018 and found urinary function did not differ between the two groups at early or late timepoints up to 24 months [23,24]. A more recent randomised control trial comparing RARP to laparoscopic radical prostatectomy found more favourable early continence in the RARP group. They found better continence at three months, six months, and 12 months post-operatively in the RARP group, but the difference was only statistically significant at three months [25,26].

This protocol addresses these known factors affecting continence post radical prostatectomy to allow for the accurate assessment of the RoboSling technique. Relevant patient factors are assessed, the investigation is performed in the RARP cohort only, and all participating surgeons are beyond their learning curves. This randomised control study is currently underway with an estimated date of completion in early 2024.

Author Contributions: Conceptualization, S.L.; methodology, S.L.; resources, S.L., R.T., A.V. (Arthur Vasilaras), P.S., L.C., N.N.J. and N.A.; data curation, S.L., A.V. (Amandeep Virk), P.-J.T., W.Z. and S.R.J.; writing—original draft preparation, S.L., A.V. (Amandeep Virk), P.-J.T., W.Z. and S.R.J.; writing—review and editing, S.L. and A.V. (Amandeep Virk); visualization, S.L., A.V. (Amandeep Virk), P.-J.T., W.Z. and S.R.J.; supervision, S.L., R.T., A.V. (Arthur Vasilaras), P.S., L.C., N.N.J. and N.A.; project administration, S.L. and A.V. (Amandeep Virk). All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: This investigation was performed following the principles of the Declaration of Helsinki. This randomised controlled trial has been approved (Protocol Number: X17-0339, HREC/17/RPAH/518) by the Sydney Local Health District Human Research Ethics Committee (HREC) and has been registered (ACTRN12618002058257) on the Australian New Zealand Clinical Trials Registry.

Informed Consent Statement: Not applicable.

Data Availability Statement: The patient information sheet, patient consent form, and patient investigation booklets used in this clinical trial are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflicts of interest.

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