Original article

Development of a third generation surgical technique for mesh repair for pelvic organ prolapse using a lightweight monofilament polypropylene mesh. A preliminary report of efficacy and safety

BRUCE FARNSWORTH

Director, Centre for Pelvic Reconstructive Surgery, Sydney Adventist Hospital, Sydney, Australia

Abstract: A comprehensive 3 level repair technique for prolapse is presented with preliminary results of efficacy and safety after short term follow up of 42 patients.

Key words: POP; Genital prolapse; Lightweight macroporous polypropylene mesh; Comprehensive 3 level repair.

INTRODUCTION

As a result of audit and evaluation of existing techniques of pelvic reconstruction over 10 years (1997-2007), a third generation technique of prolapse repair with mesh has evolved into a standardized technique. Other mesh techniques have been associated with a high success rate and good functional results but erosion rates associated with defective healing have been reported at 5-10% and higher in the first three months after surgery using a number of commercially available mesh kits[2,3,4] and slings.[5,6] Reports of the significant advantages of light weight wide pore monofilament meshes in hernia and other surgery led to the adoption of this material.

MATERIALS AND METHODS

A total of 42 patients were followed prospectively as part of an ongoing quality assurance program. Ethics committee approval was obtained to report the outcomes of all patients undergoing reconstructive surgery on the condition that patient anonymity was preserved.

All patients underwent surgery using a specialized prosthesis (CR Mesh) developed at the Centre for Pelvic Reconstructive Surgery and manufactured by Agency for Medical Innovation (AMI GmbH, Feldkirch, Austria). The author performed all surgery using a standardized technique documented in the Appendix 1.

TECHNIQUE

The CR Mesh technique involves comprehensive reconstruction of all three levels of pelvic support.

Level 1 support is provided by an independent suspension of the cervix or vaginal vault, using a monofilament non absorbable Prolene suture which is attached to the proximal end of the sacrospinous ligament using a specialized instrument, either the AMI Suture Instrument or the AMI I-Stitch device.

Level 2 support involves reattachment of the fascia to the adjacent levator and obturator complex by the passage of transobturator and translevator slings. Separate distal slings are also able to recreate the Level 3 support of the perineum or bladder neck.

Demographic data of the 42 patients are shown below (Table 1).

All patients operated with this procedure underwent full clinical assessment including pelvic organ quantification (POPQ) examination and a 3 dimensional pelvic ultrasound. Each patient prior to surgery and again 3 months after surgery completed a series of quality of life questionnaires. Ongoing follow-up is planned with annual review and quality of life assessment.

Table 1: Demographic data.

Age: 39 – 86 (Mean age 67)
Previous repair surgery 28 patients
Previous hysterectomy 13 patients

All 42 patients in this study presented with a significant pelvic organ prolapse (POPQ stage 3 or 4). Three patients also required a hysterectomy for other pathology and two patients had a co-existing rectal prolapse.

Table 2: Procedures performed

Anterior CR Mesh 12 patients
Posterior CR Mesh 9 patients
Anterior and Posterior CR Mesh 21 patients

RESULTS

Surgery was successfully completed in all 42 patients. The range of follow-up was 4 – 15 weeks. There were no significant intraoperative complications. No patients needed blood transfusion and there was no evidence of any surgical morbidity. No patient suffered from any bladder or urethral injury. There was no incidence of bowel injury.

Initial postoperative assessment showed restoration of apical support in all 42 patients. Two patients also had resolution of their rectal prolapse. One patient reported a slight deterioration of anterior wall support at 3 months postop in association with mild stress incontinence. There was no incidence of early mesh erosion or defective healing. All patients reported significant resolution of the symptoms of prolapse. Three patients, two of which required a concurrent hysterectomy complained of severe postoperative pain and in one patient this was still present after 6 weeks. No assessment was made of sexual function at this stage due to the short length of follow-up. This aspect will be reported in future reviews. Two patients reported de-novo stress incontinence.

DISCUSSION

The early outcomes of 42 patients who underwent CR Mesh implantation show a reduction in the incidence of mesh erosion and no early evidence of defective vaginal wound healing.

Ongoing data collection and quality of life assessments after longer follow up will clarify long-term outcomes and facilitate the planning of comparative trials. Early results indicate that the combination of this technique together with

the new lightweight low density macroporous CR mesh will result in at least equal outcomes for patients and a significant reduction in mesh related complications.

REFERENCES

1. Farnsworth B. Suspended mesh reconstruction for the treatment of total vaginal prolapse. Presentation AAVIS Annual Scientific meeting Noosa Queensland 1st August 2009
2. Prospective study of the Perigee system for the management of cystocoeles--medium-term follow up. Aust N Z J Obstet Gynaecol. 2008;48:427-32.
3. Farnsworth B, Parodi M. Total Vaginal Reconstruction with Polypropylene Mesh. Objective and Functional Outcome Assessment. Int Urogynecol J 2005; 16: Supplement 2 Number 55
4. Fatton B, Amblard J, Debodinance P, Cosson M, Jacquetin B. Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)--a case series multicentric study. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:743-52.
5. Farnsworth B. Posterior IVS (Infracoccygeal Sacropexy) for Vaginal Vault Prolapse. A Preliminary Report of Efficacy and Safety. Int Urogynecol J 2002; 13:4-8
6. Farnsworth B. Posterior IVS for vault suspension: a re-evaluation. Pelviperineology 2007; 26:70-72.
7. Informal meeting of CR Mesh surgeons, Modena, Italy September 27th 2008
8. Reported data. Sydney Adventist Hospital Pelvic Surgery Complications meetings (2004-2007)

This paper was first presented at the AMI Pelvic Surgery Symposium at the 10th Annual AAVIS Scientific Meeting, International Pelviperineology Congress, Westin Excelsior Resort, Venice Lido on Friday 3rd October 2008

APPENDIX 1

A.M.I. ADVANCED PELVIC FLOOR REPAIR SYSTEM using CR-Mesh and AMI suture instrument

DETAILED PROCEDURE INSTRUCTIONS (version 2.1)

These detailed step by step instructions describe a total vaginal reconstruction procedure using a CR-Mesh prosthesis in both anterior and posterior vaginal compartments including restoration of Level 1 apical support using the AMI Suture instrument.

Prior to commencing surgery an intra-operative assessment is made and the surgeon decides whether anterior, middle and posterior compartments are to be repaired. The procedure is performed through an anterior, posterior or both incisions. If a hysterectomy has been performed then the vault epithelium should be left intact for at least an anterior-posterior length of 4cm.

STEP 1: ANTERIOR INFILTRATION

Dilute normal saline 100-200mls in Local Anaesthetic (e.g., xylocaine 1%) +/- adrenalin.

Pull down the cervix to visualize the anterior vaginal wall and infiltrate with the saline mixture. Choose a point half way between the vault and the cervix and inject 20 mls at a depth of 2-4 mm. The subcutaneous tissues should expand evenly in every direction. If the infiltration seems to expand locally only at the site of infiltration then the needle needs to be a little deeper. Inject another 20-40ml at about the same point. Inject the fluid centrally so that it spreads laterally and hydrodissects under the fascia in all directions.

STEP 2: ANTERIOR INCISION

This is a full thickness vertical incision initially 2-3 cm long in the central portion of the anterior vaginal wall. The incision is deep enough to reach the dark clear layer under the fascia created by the hydro-dissection The incision is extended distally to the transverse vaginal sulcus at the level of the bladder neck and proximally to a point 2cm from the cervix or vault.

The anterior vaginal incision is further developed by reflecting the central tissue overlying the bladder away from the skin edge. This done by starting the lateral dissection at the midpoint of the incision. Do one side at a time. The surgeon's assistant or nurse holds the epithelial edge laterally on each side with two Alliss or Littlewood forceps. The surgeon holds the central tissues medially with his forceps and extends the lateral dissection to the sulcus on each side and proximally to the cervix or vault . Distally, the bladder neck also needs to be dissected free from the overlying epithelium but at this stage the dissection is limited to the superficial space under the skin to avoid penetrating the venous plexus in each vaginal sulcus until the last possible moment in order to reduce potential bleeding.

STEP 3: POSTERIOR INFILTRATION

Pull the cervix up to visualize the posterior vaginal wall and infiltrate at a point 3-5cm distal to the posterior cervix in a similar manner to the anterior vaginal wall.

STEP 4: POSTERIOR INCISION

Start the incision 3-4cm distal to the cervix at the site of infiltration and extend the incision towards the perineum once the correct layer under the fascia is identified and entered. Be wary of an enterocoele close to the cervix. As the incision reaches the perineum be careful of causing any rectal damage as the rectum may be caught up in the scar tissue associated with previous perineal repairs or episiotomies. Do not use blunt dissection to reflect the rectum off the perineal body.

The proximal end of the posterior vaginal incision should be 1-2cm from the cervix or 2-3cm from the vaginal vault. At each end of the incision dissection is performed to provide good access to the back of the cervix, the perineal body and distal levator muscles. Complete this dissection at this time as it will be difficult to complete once the mesh is in place.

STEP 5: PREPARE THE CERVICAL RING

The cervical ring is the central support structure of the upper vagina. If the uterus is absent then a cervical structure has to be recreated as described below.

A. UTERUS PRESENT

Place a single 2/0 monofilament polypropylene suture in the anterior and posterior cervix under the skin edge at the cervical end of each vaginal incision. Ensure that a good strong bite of cervical connective tissue is included in these sutures. Each suture is then held by a clamp which can be placed to rest temporarily on the suprapubic area. These sutures should be long enough to not fall down into the operative site.

B. UTERUS ABSENT

The epithelium and fascia of the vault is preserved for an antero-posterior length of at least 3cm. This enables a central structure to be created which is made up of a body of fascial tissue behind the intact vault held together by three double 2/0 monofilament polypropylene sutures which are passed from the anterior to posterior vaginal incision using a large Mayo needle.

The six sutures are passed carefully from the anterior vaginal incision to the posterior vaginal incision without button holing the vault or damaging any viscera. The three pairs of sutures are tied above and below the vault to firmly hold the fascia behind the vault. The first pair of sutures are tied in the midline and then the two lateral pairs are tied 1-2cm on each side of the midline.

It is impossible to recreate the cervical ring in this way if the fascia behind the vault is broken down to link the anterior and posterior incisions. Ensure adequate tissue is left to facilitate this step. Care is also taken not to tie these sutures too tight and compromise the tissue held in the sutures or bunch up the overlying epithelium excessively.

Once the three pairs of sutures are tied above and below the vault all six clamps holding these sutures are placed out of the way on the suprapubic area.

STEP 6: OPEN THE PARARECTAL SPACE

First ensure that the central rectal tissues under the posterior incision have been dissected away from the lateral vagina and adequate access to the back of the cervix and the perineal body has

been achieved. The lateral dissection should extend to the sulcus on each side.

This dissection is completed by getting an assistant to hold part of the edge of the posterior vaginal incision using two Allis clamps held apart and retracting the central tissues with a pair of forceps held by the surgeon. The Allis clamps are moved around the skin edge in segments until the lateral dissection is completed. By lifting up the central tissues with a forcep while the assistant provides counter traction using two Allis forceps the correct plane can be seen and usually the yellow fat associated with an enterocoele is identified in the pararectal tissues.

Use a single index finger to probe the upper lateral aspect of the dissection on each side aiming in the general direction of the ischial spine which should be palpable through the fascial tissues overlying the pelvic sidewall. In some cases the fascia falls away easily with this digital examination and the ischial spine can then be felt clearly together with the arcus ligament above and the sacrospinous ligament below. Remember that with the patient lying on her back in the lithotomy position the arcus and sacrospinous ligaments will be vertical in their orientation above and below the ischial spine respectively.

If this dissection is not straightforward and relatively easy then use the index finger to sweep up and down over the lateral sacrospinous ligament and the arcus ligament until a defect is created in the fascia.

If this also proves to be unsuccessful then introduce a pair of scissors into the upper lateral aspect of this dissection on each side and open the fascia with the scissors by using a push-open-withdraw technique. Do not cut tissue with the scissors. Use the index finger to open up the fascial defect created by the scissors.

Sometimes opening this fascia can be quite difficult. Resist the temptation to use excessive force or sharp dissection. Rather, repetitive push-open-withdraw technique with scissors should be effective. Sometimes counter-traction using 2-3 clamps on the skin edge will facilitate this dissection.

STEP 7: CREATE THE POSTERIOR APICAL ATTACHMENTS

The apical attachments are created using 2/0 monofilament polypropylene sutures placed in position using the AMI Suture instrument.

Apical attachments are placed on each side in the medial posterior aspect of the sacrospinous ligament immediately adjacent to the sacrum/coccyx. This placement is only possible with a narrow instrument such as the AMI Suture Instrument which can access this medial position on the sacrospinous ligament.

TECHNIQUE OF SUTURE ATTACHMENT USING AMI SUTURE INSTRUMENT

The AMI Suture instrument is loaded with a 2/0 monofilament polypropylene suture. Once the surgeon is confident that he has adequate access to the attachment point an index finger is placed in position on the ligament through the incision and the loaded suture device is slid along this pre-positioned finger. Once the surgeon can feel the suture instrument is in the correct position the index finger is used to push the instrument tip into the body of the ligament. The assistant steadies the handle of the suture instrument and the surgeon uses his free hand to release the suture from the holding point on the handle. During this time the surgeon keeps pressure on the tip of the instrument with his index finger so that it does not become dislodged from the ligament prior to completing the fixation.

The handle of the suture instrument is then slowly closed until a click is felt which indicates the suture has been harpooned. The ring pull handle is then slowly withdrawn until it is locked in the second position.

Only then can the index finger holding the tip of the instrument on to the ligament be released. The suture instrument then has to be lifted forward to disengage the tip from the ligament without dislodging the suture from the instrument.

Once it is withdrawn the suture can be released from the second position on the instrument and the suture is pulled through and held with a large clip. Pull firmly on the suture to ensure that the attachment is strong. It is better for the suture to break or the tissue to give way at this stage when the attachment can be easily repeated.

The posterior sutures are then clipped to the drapes with a distinctive large clamp. These are the only sutures in the procedure that need to be specially identified.

Notes:

1. There is a potential for damage to the suture when using the AMI Suture instrument and this is more of a problem for some surgeons due to their technique.

a. Always ensure that the suture has been released from the handle before closing the device as any tension in the suture could lead to the suture being cut.

b. Use the instrument smoothly and slowly. Do not close the instrument rapidly or it might also cut the suture at this point.

c. When placing the suture in the instrument do not centre the suture. Attach the suture to the tip of the AMI Suture instrument away from the midpoint of the suture so as to ensure that any point of potential weakness or damage to the suture is not at the midpoint.

d. After placing the suture in position around the ligament tie it gently without tension to ensure that if one of the threads was to break the other will still be able to be used (The Bath Knot).

e. Some surgeons would prefer to use a 2/0 braided polyester to place the suture and then use the braided polyester to pull the 2/0 monofilament polypropylene into position.

Standard practice for apical attachments:

A. UTERUS PRESENT

In the presence of the uterus two apical attachments are performed on each side through the posterior incision and there is NO apical attachment through the anterior incision.

These sutures will eventually pass through the cervix to be tied anterior to the cervix so that the cervix is pulled back to the sacrum and uterine retroversion is corrected.

These sutures are clipped to the drapes with large clamps. Make sure that this is always done using DISTINCTIVE LARGE CLAMPS to signify that these attachments are through the posterior vaginal incision. The two attachments on each side are made to the same area on the ligament, i.e., the medial posterior surface of the ligament.

B. UTERUS ABSENT

When the uterus is absent two separate apical attachments are performed on each side of the pelvis with one passing through the posterior vaginal incision and one through the anterior vaginal incision. These sutures will later be attached separately to the anterior and posterior CR Mesh on each side.

Again, it is critical that these sutures are distinguished from each other by always placing a distinctive large clamp on the posterior apical attachments and a small clamp on the anterior apical attachment as once the mesh has been pulled into position it will be difficult to identify which suture is which.

Once these sutures are in place they are clipped to the drapes on either side to keep them away from the operative field.

NOTE: Vault or cervical attachments are lying freely on the suprapubic area whilst the apical attachments are clipped laterally to the drapes.

STEP 8: OPEN THE PARAVESICAL SPACE

This dissection is not performed until the steps above have been completed due to the possibility of bleeding from the venous plexus when entering the paravesical space lateral to the paravaginal sulcus.

By delaying this step until this point in the procedure the potential for bleeding is reduced. This bleeding could potentially slow down the previous steps and lengthen the operation. Bleeding due to damage to the paravaginal venous plexus is usually easily controlled once the anterior mesh is pulled into place.

Each side of the dissection is done separately. The assistant grasps the edge of the vaginal incision with two Allis forceps and a Briesky or similar retractor is used to inspect the vaginal sulcus and ensure that it is not buttonholed.

The dissection is behind the fascia initially (in the vagina) but passes through the fascia at the pelvic side wall as the sulcus is reached. It is at this point that bleeding is more likely to occur.

The lateral dissection should always be commenced midway between the urethra and the vaginal apex. It is initially sharp

dissection behind the fascia and this is facilitated by hydrodissection. The fascia is breached to enter the paravesical space with scissors using a push-open-withdraw technique.

Once the the paravesical space is opened the dissection needs to be extended along the incision to allow a Sims speculum to be placed between the vaginal incision and the bladder (into the paravesical space) to enable inspection of the pelvic side wall. The lateral support tissue of the urethra is reflcted medially by extending the dissection anteriorly with blunt dissection pushing the urethra medially and sharp dissection cutting laterally.

The ischial spine, arcus ligament and sacrospinous ligament(SSL) are identified and the SSL is explored through the anterior incision to facilitate attachment of the anterior apical suspension sutures. (As mentioned above these anterior apical sutures are only inserted when there is no uterus).

STEP 9: PREPARATION OF BLADDER NECK AND ANTERIOR CERVIX

The anterior vaginal dissection is completed by preparing the bladder neck and anterior cervix for subsequent placement of the CR Mesh.

The bladder neck is prepared by dissecting free the lateral supports of the upper urethra using blunt and sharp dissection as described above. This should be done until the surgeon's index finger can pass lateral to the urethra and easily feel the inner surface of the obturator fossa at the level of the clitoris without being restricted by a band of connective tissue lateral to the urethra.

The anterior cervix has already been prepared to accept the anterior mesh and this task is completed by ensuring that there is good access to the strong fibrous tissue of the anterior cervix with a flap of epithelium of at least 1cm to cover the attachment point.

STEP 10: PRELIMINARY STEPS TO ATTACH CR-MESH

Prior to attaching the CR Mesh to the anterior and posterior vaginal apex preparation is completed so as to enable the attachment to be done smoothly without confusion or suture entanglement.

Before commencing check that the following have been done:

1. Anterior and posterior vaginal incisions have been completed with preparation of the bladder neck and perineum.
2. Cervical ring has been prepared for attachment of the CR Mesh with pre-placement of sutures. This is either a single 2/0 Prolene suture in the front and back of the cervix or three pairs of 2/0 Prolene sutures tied around the central fascia behind the vault.
3. Four apical attachment sutures are in position with correct clamps used for identification. Distinctive large clamps are placed on the apical attachments through the posterior vaginal incision while smaller clamps identify any apical attachments through the anterior vaginal incision.
4. The operative field is made tidy with removal of extraneous instruments, suture material and needle holders and their return to the scrub sister.
5. At this point drapes can be refreshed and gloves changed if necessary.

STEP 11: PLACEMENT OF POSTERIOR CR MESH

First unpack and unfold the CR Mesh. Identify the proximal and distal ends as well as the FRONT and BACK of the mesh. The proximal sling passes through the mesh and attaches laterally to the back of the mesh with a nylon holding suture.

The mesh is positioned by the surgeon 4-5 cm in front of the vagina and held in the anatomical position by the assistant(s) who hold the proximal corner of the mesh on each side. The proximal 1-2 cm of the mesh is folded over to create a double layer.

The back of the mesh is orientated to face the rectum while the front of the mesh faces the vaginal lumen.

The Mesh is held by the assistant(s) until attached to the cervix or vault. It is important that they not release the Mesh until this attachment is complete.

The CR Mesh is attached differently depending on the presence or absence of a cervix. The following sections are potentially the most confusing and difficult parts of this procedure.

A. UTERUS PRESENT

First a single Allis forcep is attached to the skin edge of the posterior incision on each side 2cm lateral to the midline and these two clips are allowed to fall down behind the mesh. They will be important in a subsequent step but for now they sit in the background.

The surgeon first passes the solitary 2/0 monofilament polypropylene suture which has been pre-positioned in the posterior aspect of the cervix through the proximal end of the mesh in the midline 2-3mm from the edge of the mesh. The posterior cervical suture passes through this point from the FRONT of the mesh to the BACK. A clamp is used to hold the suture behind the mesh and this clamp is also allowed to fall down behind the mesh which is held in position by the assistant(s). The assistant(s) must not release the Mesh at this point.

Both of the pre-positioned apical (medial sacrospinous) attachment sutures are then passed through the two layers of the posterior CR Mesh from the BACK of the mesh to the FRONT 2-3 mm from the folded proximal edge of the mesh and about 1cm lateral to the central cervical attachment suture that is already being held by the clamp hanging behind the mesh in the midline. Try to ensure that each suture of the apical attachments passes through a different hole in the mesh.

NOTE: The cervical attachment sutures and the apical sacrospinous attachment sutures pass through the proximal part of the CR Mesh in opposite directions.

A large Mayo needle is then used to pass the two pairs of apical attachment sutures through the cervix from back to front on each side. These sutures emerge through the anterior cervix and a LARGE DISTINCTIVE clip is placed on the end of each pair of sutures. All four apical sutures should be positioned from the back of the mesh through the mesh then through the cervix to emerge through the anterior incision. Throughout this procedure the assistant(s) have continued to hold the posterior mesh in position.

The proximal end of the mesh is lifted up to lie flush with the posterior cervix and the midline suture is tied firmly from behind to lock the central upper (proximal) folded edge of the mesh to the cervix in the midline.

The assistant(s) can now release the corners of the mesh and carefully lift up and hold laterally the two pre-positioned Allis clamps holding the skin edge of the posterior incision 2cm lateral to the midline on either side.

The surgeon can then add a 2/0 Vicryl or similar suture to secure the mesh to the fascia under the skin over the posterior cervix lateral to the apical attachments that pass through the cervix to emerge anteriorly.

The posterior aspect of the cervix will be secured to the posterior mesh by the following:

1. the midline suture which has been tied firmly to hold the proximal edge of the posterior CR Mesh to the posterior cervix.
2. the two pairs of apical attachment sutures which pass from behind the posterior CR Mesh on each side to emerge 2-3 mm from the proximal edge of the mesh and 1cm lateral to the midline and then pass through the body of the cervix to emerge from the anterior aspect of the lower cervix.
3. a fascial attachment suture lateral to the above sutures which also holds the proximal edge of the mesh onto the posterior cervix or fascia

The apical sutures which emerge through the anterior cervix are clipped but not tied.

Once this attachment is complete the surgeon should ensure that the main body of the mesh is lying flat and the two lateral slings are also lying flat in the anatomical position.

B. UTERUS ABSENT

First a single Allis forcep is attached to the skin edge of the posterior incision on each side 2cm lateral to the midline and these two clips are allowed to fall down behind the mesh. Once again, they will be important in a subsequent step but for now they sit in the background.

The surgeon first passes the central 2/0 monofilament polypropylene suture which has been prepositioned in the fascia behind the vault through the proximal end of the mesh in the midline 2-3mm from the edge of the mesh. The posterior central vault suture passes through this point from the FRONT of the mesh to the BACK. A clamp is used to hold the suture and this clamp is

allowed to fall down behind the mesh which is held in position by the assistant(s).

The assistant(s) must now hold the Mesh in position without releasing it until it is firmly secured to the vault.

The lateral vault sutures are now also passed through the mesh from FRONT to BACK approximately 1cm on each side of the central suture. All three clamps holding these sutures are allowed to fall down behind the mesh.

The prepostioned POSTERIOR apical attachment sutures (one on each side) are then passed through the posterior CR Mesh from BACK to FRONT about 2-3 mm from the folded proximal edge of the mesh and just lateral to the most lateral vault attachment suture. Note that the clamps holding the vault attachments will hang down behind the Posterior CR Mesh while the two apical attachments will lie on the front of the mesh so they can later be tied in the vaginal lumen. Try to ensure that each of the posterior apical attachment sutures passes through a different hole in the mesh.

Ensure that the large clamp used to identify each of the posterior apical attachment sutures is repositioned on the end of the sutures once they have been passed through the mesh.

The proximal end of the mesh is then lifted up by the assistant(s)to lie flush with the posterior vault and the vault sutures are tied firmly from behind to lock the upper (proximal) folded edge of the mesh onto the posterior aspect of the vault in the midline.

The assistant(s) can now release the corners of the mesh and carefully lift up and hold laterally the two pre-positioned Allis clamps holding the skin edge of the posterior incision 2cm lateral to the midline on each side.

The surgeon can then add a 2/0 Vicryl or similar suture to secure the mesh to the fascia behind the skin lateral to the apical attachments.

At the end of this part of the procedure there should be the following attachments on the posterior vault:

- the three sutures which have been tied firmly to hold the mesh to the posterior vault.
- the single pair of posterior apical attachment sutures which pass from behind the mesh on each side to emerge 2-3 mm from the proximal edge of the mesh 1cm lateral to the midline and then lie on top of the posterior CR Mesh and can be identified as posterior by the attachment of a large clip.
- a fascial attachment suture lateral to the apical sutures

The apical sutures which emerge through the posterior mesh are clipped but not tied at this point.

Once this attachment is complete the surgeon should ensure that the main body of the mesh is lying flat and the two lateral slings are also lying flat in the anatomical position.

STEP 12: PLACEMENT OF ANTERIOR CR-MESH

The CR Mesh is removed from sterile packaging and unfolded so that the FRONT and BACK of the mesh can be identified. The mesh is held by the assistant(s) in the anatomical position with the BACK of the mesh facing the bladder and the FRONT of the mesh facing the vaginal lumen.

A. UTERUS PRESENT

First the central anterior cervical attachment suture is passed through the edge of the mesh in the midline passing from the FRONT to the BACK of the mesh.

Both pairs of apical attachment sutures that emerge through the anterior cervix are now passed from the BACK to the FRONT of the anterior CR Mesh and the LARGE DISTINCTIVE clips are allowed to fall down in front of the mesh.

The central suture is tied firmly to hold the mesh onto the cervix in the midline. The apical sutures are left hanging down in the vaginal lumen.

Once the central suture has been secured the assistant(s) can let go of the corners of the mesh and then lift up the two pre-positioned Allis forceps to facilitate placement of any lateral fascial sutures using 2/0 Vicryl or similar suture.

B. UTERUS ABSENT

The mesh is orientated with the FRONT of the mesh facing the vaginal lumen and held by the assistant(s) in the manner described above.

The three pairs of sutures attached to the anterior vault are passed through the mesh from FRONT to BACK. The anterior apical attachment sutures which are identified by the presence of SMALL CLAMPS are passed from the BACK of the mesh adjacent to the vault attachment sutures. They are then able to hang down below the mesh in the vaginal lumen.

The mesh is moved close to the cervix and the three anterior vault sutures are tied pulling the proximal end of the anterior CR Mesh into position attached to the vault. Once in position the assistant(s) can release the mesh and carefully hold and lift up the two Allis forceps attached to the skin edge on either side. Further sutures to fix the mesh to the fascial tissue can then be placed in position if necessary.

At all times through this part of the procedure the surgeon should ensure that the mesh is not twisted and maintains its anatomical position. The assistant(s) must concentrate on holding the mesh still because if they release the mesh at this stage it may be difficult to orientate and could slow the procedure down considerably.

At the end of this step both anterior and posterior mesh should be lying flat over the perineum with the four apical sutures lying between the two meshes and able to be identified by their different clamps.

STEP 13: PLACEMENT OF PROXIMAL TRANSOBTURATOR SLINGS

The proximal transobturator slings are placed in position without moving the mesh from its resting position at the end of the previous step.

First make a small vertical skin incision 1cm above the ischial tuberosity on each side.

Next, check that the Sims speculum and small Briesky retractor are sitting on the perineal table ready to be placed in position. Attach the pulling suture of the first sling to be positioned onto a needle holder and also rest it on the perineal table.

Hold the A.M.I. TVA tunneller with both hands and pass it through the proximal medial aspect of the obturator fossa. This is done by holding it in a horizontal position and sliding the tip into the subcutaneous tissue and then for 1-2cm onto the pelvic bone before lifting the handle 90 degrees to penetrate the obturator fossa. At this point transfer the alternative index finger into the paravesical incision and guide the TVA tunneller medially through the arcus ligament 1cm anterior to the ischial spine.

The assistant surgeon then holds the TVA tunneller so that the surgeon can carefully place the Sims speculum into the paravesical dissection and then under the tip of the tunneller. The Briesky retractor is then placed in position to retract the bladder medially and ensure good vision of the tunneller tip. Using the pre-positioned needle holder the pulling suture of the appropriate sling is carefully attached to the end of the tunneller and the suture pulled through the obturator fossa as far as possible without disrupting the mesh. Once the sling is in position cut the pulling suture off the end of the sling but do not cut the sling or the protective plastic cover at this stage.

The same procedure is then repeated on the other side.

STEP 14: PLACEMENT OF THE PROXIMAL TRANSLEVATOR SLINGS

Before placing the translevator slings the anterior and posterior CR Mesh and associated clamps and sutures have to be carefully lifted up out of the way and onto the suprapubic area. First remove any retractors or speculums from the vagina. Lift the anterior CR Mesh up and lie it down on the suprapubic area starting with the distal sutures (level 3 attachments) then the four apical sutures, then the posterior mesh and its associated distal sutures, then finally the posterior proximal levator slings that are about to be placed in position.

Make a small skin incision approximately 3cm lateral and 3cm posterior to the anus on each side. Use the A.M.I. TVA tunneller to pass through the ischiorectal fossa from below and with the alternative index finger resting on the inner surface of the levator muscle guide the tip of the tunneller through the levator 2cm medial and below the ischial spine. Attach the pulling suture and pull the translevator slings through as far as possible without moving the mesh.

Cut the pulling suture off the end of each sling but do not cut the sling or protective plastic cover at this stage.

STEP 15: SECURE THE UPPER VAGINAL ATTACHMENTS

If necessary due to a deep narrow vagina it is sometimes appropriate to commence the posterior vaginal skin closure suture at this time as access to the posterior fornix may be difficult when everything is pulled up into position. Use a 2/0 Vicryl or equivalent suture for this purpose.

Use a speculum to visualize the vaginal apex and then grasp the cervix or vault with an Allis forceps. Carefully push the vault back into the pelvis with this instrument. The assistant should make sure that the main body of the mesh does not get caught on anything during this process.

Whilst holding the cervix or vault in the correct position carefully pull on the four upper vaginal slings to take up any laxity. DO NOT USE THE TRANSOBTURATOR OR TRANSLEVATOR SLINGS TO PULL THE CERVIX OR VAULT INTO POSITION.

STEP 16: FIX APICAL SUTURES

When these sutures are being tied ensure that the vaginal apex is held down into the pelvis by using either a speculum or retractor at all times. This ensures that the vaginal length is maximized.

A. UTERUS INTACT

Place the speculum in the posterior fornix to ensure good vision. There are four apical sutures that need to be tied anterior to the cervix.

First pull each suture into position in turn until the cervix is sitting nicely in its new position. Once all four sutures have been tensioned complete the job of securing them with at least 7 knots on each suture as monofilament polypropylene has a tendency to unravel and these attachments are critical to the success of the procedure.

B. UTERUS ABSENT

There are two posterior apical attachment sutures and two anterior. These sutures should be carefully pulled into position before tying with the two anterior sutures left relatively loose compared to the two posterior ones. Once again, tie all four sutures with at least 7 knots to avoid them unraveling.

Note: The four apical suspension sutures are not meant to pull the vaginal vault or cervix up and attach it to the sacrospinous ligament. rather, they are designed to replace the uterosacral ligament and suspend the apex from its' normal anatomical origin.

Excessive tension on these attachments will increase the amount of postoperative pain and limit the mobility of the upper vagina.

Once the four apical sutures are secure gently pull on the transobturator and translevator slings then cut off the distal ends of each sling half way along. Carefully remove the protective plastic sheaths but do not remove the nylon holding sutures at this time.

The upper vagina is now secure.

STEP 17: POSTERIOR MESH ADJUSTMENT

During this part of the operation a large Briesky retractor should be used to hold the vagina open and hold the anterior mesh out of the way. This instrument will also ensure that the vaginal length is maximized when adjusting the mesh.

First check that the perineal dissection performed early is adequate. Grasp the posterior skin edge 2cm lateral to the midline on each side and pull the vagina open to visualize the posterior mesh. Check the mesh has not been twisted or caught in any of the earlier sutures.

If only one assistant is available secure the two Allis forceps holding the vaginal epithelium with towel clips. Prepare a 2/0 PDS suture to secure the mesh to the midline and hold one side of the distal end of the mesh. The assistant surgeon holds a retractor deeply into the posterior fornix to maximize the vaginal length with one hand and the other side of the distal mesh with the other. The surgeon can then cut the distal mesh in the midline until he reaches the perineal body where the mesh is secured with a single 2/0 PDS suture in the midline. Once this suture has been placed in position the assistant can remove the anterior retractor unless it is still needed to keep the anterior mesh away from the operative field.

STEP 18: PERINEAL SLINGS

The divided posterior CR Mesh distal to the attachment to the perineum in the midline forms two slings which pass posteriorly through the perineum, around the anus and emerge from the same skin incision as the proximal translevator sling

The pulling suture of the distal mesh on each side is attached to the TVA Tuneller and this instrument is then passed laterally at the distal end of the levator muscle adjacent to the perineal body for a maximum distance of 1cm. It is then turned posteriorly to pass lateral to the anus and exit the skin through the same incision as the proximal translevator sling. This is done on each side.

When passing the TVA tunneller posteriorly on each side be sure to remain very superficial, just under the skin, as the rectal artery and vein cross the path of this instrument adjacent to the anus but at a deeper level.

The perineal slings are pulled through and if necessary lateral holding sutures are added at the edge of the mesh in the vagina to ensure that the mesh lies smoothly and does not curl up or move to a different position. Cut off the excess mesh and the pulling suture from each distal sling to leave 2-3cm of mesh on each side.

STEP 19: BLADDER NECK

Place an Allis forcep on the skin edge on either side of the bladder neck to lift up the anterior vaginal skin incision so as to visualize the bladder neck and paraurethral tissues. Make sure a speculum or Briesky retractor is placed in position posteriorly to hold the vaginal apex deep back into the pit of the sacrum while any anterior vaginal measurement and adjustment of the mesh is performed.

Ask your assistant(s) to hold the distal corners of the anterior CR Mesh while you cut the mesh in the midline to reach the bladder neck. The midpoint and length can be marked by placing a small clamp on the mesh to identify this point. Use a 2/0 PDS or equivalent suture to secure the mesh to the paraurethral tissues close to the bladder neck on either side.

STEP 20: DISTAL TRANSOBTURATOR SLINGS

First ensure that there is adequate dissection lateral to the bladder neck and that a finger placed through the incision between the mesh and the vaginal side wall adjacent to the bladder neck can reach the inner surface of the obturator foramen.

The TOA Universal tunneller is used with an outside in approach to enter the vagina from a skin incision at a point 1cm medial to the skin fold at the level of the clitoris.

Hold the TOA Universal tuneller in a vertical position with the tip inside the skin incision. Use the free hand to place an index finger on the undersurface of the obturator membrane by passing it through the vaginal incision lateral to the mesh. Place the thumb of the same hand on top of the TOA tuneller and use it to feel the tunneller passing adjacent to the bone to enter the upper medial aspect of the obturator.

Use the other hand holding the handle of the tunneller to move the handle 45 degrees lateral and then rotate the tunneller onto the tip of the index finger inside the vaginal incision then guide the needle out into the vagina. Be careful not to perforate the vaginal epithelium in the sulcus by keeping close contact with the tip of the needle at all times.

Attach the correct pulling suture and hold the mesh in the correct alignment to facilitate it pulling through the obturator successfully. Complete the procedure on the contralateral side.

STEP 21: ADJUSTMENT OF DISTAL TRANSOBTURATOR SLINGS

The distal transobturator slings are attached to the bladder neck and are similar to a traditional bladder neck sling but they are suspended from the medial anterior aspect of the obturator foramen rather than retropubically.

These slings can be adjusted using a coaptation test, once they have been pulled into position. Excessive tension may result in voiding difficulty, although this is usually temporary.

STEP 22: VAGINAL SKIN CLOSURE

The anterior vaginal incision is closed with interrupted 2/0 Vicryl sutures. The posterior vaginal incision is closed with a 2/0 Vicryl continuous suture.

STEP 23: REMOVE HOLDING SUTURES

Nylon holding sutures are removed from the four proximal slings.

STEP 24: TRIM EXCESS SLING AND MESH

All slings and mesh are cut off at the skin. Push the skin down before cutting. Lift the skin edge up after cutting each sling or mesh extension to ensure there is no residual prosthesis close to the surface within each incision.

STEP 25: EXTERNAL SKIN CLOSURE

External skin closure is performed using 2/0 Vicryl sutures or Steristrips or Skin adhesive.

STEP 26: CYSTOSCOPY

Cystoscopy should be performed if there is any suspicion of bladder trauma or unexplained haematuria. Some surgeons prefer to perform cystoscopy as a routine.

At cystoscopy check the following

- Integrity of the bladder.
- Presence or absence of any signs of obstructed voiding.
- Ureteric orifices with normal flow
- Urethra

STEP 27: CATHETER AND PACK

Place a Size14 Silastic catheter in the bladder and connected to a drainage bag at the end of the procedure. This catheter is left on free drainage for 2 days after the surgery.

A vaginal pack or bandage soaked in a suitable cream or fluid such as Betadine, Hibitane or oestrogen is placed in the vagina at the end of the procedure.

STEP 28: RECTAL EXAMINATION

Check the rectal mucosa and sacrospinous attachments at the end of the procedure.

Correspondence to:
Dr Bruce Farnsworth
Director, Centre for Pelvic Reconstructive Surgery
Sydney Adventist Hospital
185 Fox Valley Road
WAHROONGA 2076
Tel: +61 2 94738555
Fax: +61 2 94738559