Original article

Preliminary retrospective case series study of the outcome of ProliftTM technique in thirty women with pelvic organ prolapse including its effect on stress urinary incontinence

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Abstract: In this retrospective case series analysis of thirty Prolift procedures the authors describe aspects of the surgical technique as well as outcomes. The latter specifically addresses intraoperative, immediate and medium term post procedure periods with particular analysis of its effect on urodynamic stress incontinence (UDSI). The results of this study showed that the Prolift procedure is safe and very successful in treating women with a severe degree of pelvic organ prolapse. Primary haemorrhage of more than 500 mls in one patient during difficult vaginal hysterectomy was the only significant complication in this study and was not associated with the Prolift procedure in itself. The patient did not require blood transfusion. One of the important findings in this study is the fact that in six (43%) out of 14 women with UDSI the urinary symptoms were cured after the Prolift procedure alone. Indeed out of twenty-two women with symptoms of stress urinary incontinence (SUI), thirteen women (59%) had these symptoms cured by the Prolift procedure alone. This supports the practice of the main author in management of women with combined POP and SUI by offering these women a two stage procedure: first treat the POP by Prolift procedure then few months later perform Tension-free Vaginal Tape- Obturator (TVT-O) or Tension-free Vaginal Tape (TVT) procedure to treat UDSI.

Key words: Pelvic organ prolapse; Pelvic reconstructive surgery; Prolift; TVT-O; Stress urinary incontinence.

HISTORY & EXAMINATION

Pelvic organ prolapse (POP) and associated stress urinary incontinence (SUI) is a major health care problem. It is estimated that 50% of parous women lose pelvic support ¹ and an American woman has a 11.1% lifetime risk of undergoing an operation for pelvic floor support. ² An ageing population is likely to increase the prevelance of POP and DeLancey describes this anticipated increasing health burden as a "hidden epidemic". ³

Current methods of pelvic reconstructive surgery for treating POP are suboptimal. The Olson study found that 29% of the patients requiring one operation for pelvic floor support will have an organ prolapse recurrence (OPR) sufficiently severe as to require at least one re-operation.2 Even when the conventional procedure of anterior and posterior repair is supplemented with other procedures such as sacrospinous ligament fixation, transvaginal needle suspension and enterocele repair, the recurrence rate is still high at 20-30%.4 Shull et al. reported an incidence of 30% cystocele following vaginal vault suspension with half of these noted within the six weeks postoperative period. The same group reported a 24% cystocele recurrence rate after vaginal and paravaginal repair.⁵ Paraiso et al. reported their long term follow-up data after sacrospinous ligament fixation of the vaginal vault prolapse: the recurrence rate was 37% for cystocele and 14% for rectocele.6 The utilisation of the weak native tissues may be the contributing factor in the high recurrence rate. These classical pelvic reconstructive techniques can only restore 50% of the pre-operative tissue strength.⁷

Synthetic material has been used to reconstruct pelvic floor anatomy and restore function and has been shown to reduce the OPR rate.⁴ Its effectiveness has however been marred by the occurence of adverse effects such as granuloma formation (GF), vaginal erosion and mesh shrinkage. The increased use of Tension-free Vaginal Tape (TVT) has created evidence that polypropylene mesh is better tolerated and the new Prolift mesh (Ethicon, USA) is now being used in an attempt to treat POP. Preliminary studies give cause for cautious optimism. The TVM Group from France first described the procedure in 687 patients.⁸ A subsequent study has looked at the optimal anatomical positioning of the mesh,⁹ but there have also been reported cases of serious adverse effects.¹⁰⁻¹¹

In this retrospective case series analysis of Prolift procedures we describe specific aspects of the surgical technique

that developed during operating on these thirty patients. Intraoperative complications, immediate and medium term post procedure outcomes with particular analysis on its effect on urodynamic stress incontinence (UDSI) are also described. The results shall be compared with those of the retrospective study of the TVM Group reported in 2005 International Meeting of the ICS ⁸ and the Fatton et al. case series multicentre study. ¹²

MATERIALS AND METHODS

This series of thirty cases was carried out by a single operator (main author) at two hospitals in Australia (thirteen public patients at Royal Darwin Hospital and seventeen private patients at Darwin Private Hospital) over a period of nineteen months (December 2005 to June 2007). The patients' notes were analysed retrospectively on a purpose made master sheet.

All women were assessed preoperatively with regard to their symptoms, parity and previous urogynaecological surgical history. The degree of the prolapse was classified using the Baden-Walker halfway staging system.¹³ Women were encouraged to use pelvic floor exercises preoperatively and to continue postoperatively. Postmenopausal women were instructed to use vaginal oestrogen preoperatively and to recommence a maintenance dose of one to two nights a week, starting six weeks postoperatively.

Urodynamic assessments (UDA) were performed preoperatively in most patients with urinary symptoms. UDA included uroflowmetry and filling cystometry. When SUI was confirmed on UDA preoperatively women were counselled regarding a two-stage procedure to address both complaints, namely a Prolift procedure to correct the POP, followed by a Tension-free Vaginal Tape Obturator (TVT-O) about three months later. TVT procedure was offered to women with intrinsic sphincter deficiency (ISD). Both the TVT-O and TVT procedures were performed under local anaesthesia and sedation with cough test performed in theatre. Intraoperative complications were classified in terms of bladder, rectum or bowel perforation, blood loss greater than 500 mls, blood transfusion or any other significant adverse event. Immediate postoperative complications were classified according to infection, thromboembolic event, urinary retention, return to theatre, blood transfusion or any other specific complication.

The medium term post operative assessment was performed in most women six weeks after surgery. This included history, with special reference to the effect of the procedure on the preoperative symptoms and physical examination looking at any evidence of complications such as mesh erosion or shrinkage, urinary or rectal fistula formation or recurrence of prolapse. In this study prolapse was considered to recur if there is POP stage 2, 3 or 4 even in absence of symptoms. In addition, any symptomatic patient with POP stage 1 is considered as having a recurrence of her prolapse.

The authors analysed the preoperative urinary symptoms of these women and paid particular attention to the effect of the Prolift procedure on women with preoperative diagnosis of UDSI and on subsequent post operative management of those who were remained symptomatic.

Surgical Technique

All patients are administered intravenous prophylactic antibiotics in the form of 1g Cephazolin and 500 mg metronidazole (these to continue for the first 48 hours, followed by an oral course for three to five days). Full thickness dissection of the vagina from the underlying structures (rectum or bladder) is achieved by generous infiltration of a 40 ml solution of prilocaine 0.25% and adrenaline 1:200,000 in the relevant compartment (anteriorly or posteriorly as per specific procedure). The infiltration needs to be injected into the correct plane of dissection between the full thickness vaginal wall and the underlying structures.

A sharp knife is used to cut the full thickness of the vagina and electro-surgical incisions are avoided in all cases.

The length of vaginal incisions is minimised in all cases. In the anterior Prolift the length of the skin incision usually comprises the middle third of the distance between the level of the urethro-vesical junction (UVJ) and the vaginal vault, or the reflection of the anterior vaginal wall of the cervix in women with an intact uterus. The dissection continues under the full thickness of the vaginal skin distally and proximally to the incision to the limit of the UVJ and the vaginal vault / reflection of the anterior vaginal wall of the cervix respectively. In the posterior Prolift, the length of the incision comprises the middle third of the distance between the level of the hymen and the vaginal vault or the reflection of the posterior vaginal wall of the cervix in women with an intact uterus. The dissection under the intact vaginal skin is continued from the level of the hymen to the vaginal vault or to the reflection of the posterior vaginal wall off the cervix in women with an intact uterus.

Tearing of the vaginal skin or damaging the underlying structures during dissection may be avoided by the local infiltration described above and by sharp dissection in the proper anatomical plane. When blunt dissection is needed a peanut dissector is used gently. In most women the initial opening of the paravesical and pararectal space including exposure of the ischial spines is achieved by sharp dissection using large scissors with push and open technique. During the anterior Prolift procedure it is important to ensure that the distance between the exit points of the superficial and deep Cannula-equipped Guides (CEG) should be at least 6 cm. This can be achieved by the superficial CEG entering the paravesical space within 1cm from the proximal end of the ATFP, and that of the deep CEG entering the space within one centimetre from the ischial spine.

Crumpling of the mesh must also be avoided. At the same time the tension on the mesh must be neither too tight nor loose. This is ensured through the following steps:

Firstly the surgeon avoids crumpling of the mesh. This can be achieved by ensuring that it is spread out by pulling

on the free ends of its arms while the inner ends of the canulae are just projecting outside the inner aspect of the side pelvic wall (in the anterior Prolift) or the sacrospinous ligament (in the posterior Prolift procedure). Subsequently any excess tension in the anterior compartment is eased off by exerting pressure with the index finger on the far lateral aspect of each side of the anterior fornix until no tension by the arms of the mesh are felt. Any excess tension in the posterior compartment is eased off by exerting pressure with the index finger on the far lateral aspect of each side of the posterior fornix until no tension by the arms of the mesh are felt. This can be further aided by inserting an index finger per rectum and pressing on the lateral anterior aspect of the rectal mucosa until no tension is felt around the rectum.

In the anterior compartment, anteriorly the mesh is sutured at the midpoint of its proximal edge to the endopelvic fascia that is attached to the undersurface of the vaginal skin using 2/0 PDS after trimming any excess length of mesh. The distal edge of the mesh is sutured in its middle to the vaginal vault or the anterior aspect of the cervix (in women with intact uterus) using 2/0 prolene. In this series none of the patients requiring an anterior Prolift had previously undergone a hysterectomy. This latter subgroup of patients would have required the mesh to be attached to the vaginal vault. In the posterior compartment, after trimming any excess length of the mesh, the lower edge of the mesh is sutured at both its corners to the sides of the perineal body using 2/0 PDS. Two sutures of 2/0 Prolene are used to attach the upper edge of the mesh, one suture to the corresponding remnant of the uterosacral ligament. In women with intact uterus only one suture of 2/0 Prolene is inserted in the centre of the upper edge of the mesh to the posterior wall of the cervix. When a total Prolift is performed in women who have had a hysterectomy in the past there is no need for any suturing of the mesh to the vaginal vault. In these women the mesh is fed from anterior to posterior compartment through a tunnel, approximately 3 cm wide, created by the sharp dissection using a large pair of scissors with the push and open technique. It is essential to ensure that the mesh does not rotate during its retrieval posteriorly. No excision of vaginal skin is necessary. The vaginal skin is sutured using No. 1 vicryl suture in two continuous layers. The deep layer is a continuous running mattress suture, with particular caution not to involve the mesh material in the suturing. The superficial layer is a continuous running simple suture. Locking sutures are avoided. Hysterectomy should be avoided during Prolift procedures if possible.

If a woman does require or request a hysterectomy during the Prolift repair, the following precautions may be helpful: T-shaped incisions should be avoided. A collar incision is made around the cervix and it extends anteriorly, cutting the full thickness of the vaginal skin, to encompass not more than the lower third of the distance between the cervix and the level of the urethro-vesical junction. This incision should be enough for completing the hysterectomy and the exposure of the paravesical space and ischial spines and is then sutured as a single incision longitudinally. The pedicles of the cardinal-utero-sacral ligaments complex on both sides are tied together, through the anterior compartment, medially in front of the mesh.

RESULTS

Thirteen (43%) of the thirty women were referred by other specialists (either private or public). The age of the women in this study at the time of their surgery ranged from 36 to 79 years. Eighteen women (60%) were in the age group between 51 and 65 years old and only 6 women (20%) were 50 years or younger. The remaining 20% were 66 years or older. The distibution by age is illustrated in Figure 1.

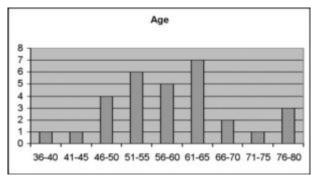


Fig. 1. – Number of patients in each age group.

The range of parity in these women ranged from 1 to 10 deliveries with an average of 3.7 deliveries. All the women had at least one vaginal delivery with the highest parity is 10 vaginal deliveries. Only one woman had 2 caesarean sections in addition to 2 normal vaginal deliveries.

The main author performed six types of Prolift operation according to the individual patient's needs as illustrated in Figure 2.

Seventeen patients (56.7%) previously had a hysterectomy prior to the Prolift procedure. Four women (30.8%) out of the thirteen women with an intact uterus had a hysterectomy performed during the Prolift procedure. This represents 13.3% of the women in the study. It was also noted that 11 women (37%) had undergone previous pelvic floor repair prior to their Prolift procedure with seven of them (23%) having had more than one repair.

Urinary symptoms were the most common presenting symptom (93%) followed by feeling a bulge (77%). Figure 3 illustrates the presenting symptoms of the women in the study.

In this study no one woman had prolapse in only one compartment. Rectocoele was present in 90% and cystocoele in 70% of patients. No one patient was operated upon for whom her worst degree of prolapse out of all compartments was only stage 2 or less as all 30 patients had at least third stage prolapse in one or more compartments. Those who had a 4th stage prolapse in one or more compartment was 19 (63.3%). Enterocoele was present in eight patients (26.7%) and excessive vaginal scarring was present in four patients (13.3%).

Apart from blood loss greater than 500 ml in one patient, there was no significant complication noted in any woman during their surgery, hospital stay or in the follow-up visit. The range of hospital stay was 3 to 5 days with an average stay of 3.9 days. The medium term post operative assessment was performed in most women at six weeks after surgery. Only three patients (10%) were assessed earlier than

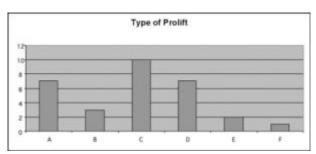


Fig. 2. – Numbers and types of Prolift procedures performed. A= Total Prolift and Uterine Conservation, B = Total Prolift and Hysterectomy, C = Total Prolift for vaginal vault support and anterior and posterior compartment repair, D = Posterior Prolift for vault prolapse and posterior compartment repair, E = Posterior Prolift for posterior compartment repair and uterine conservation, F = Posterior Prolift for posterior compartment repair and hysterectomy.

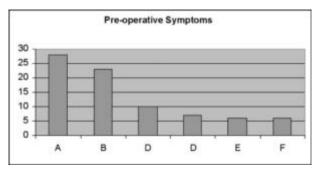


Fig. 3. – The presenting symptoms. A = Urinary symptoms, B = Feeling bulge, C = Bowel symptoms, D = Vaginal bleeding, including discharge, E = Sexual problems, F = Other - pain, embarrassing noise.

six weeks. The mean time of follow-up was 11.3 weeks (range 4-51 weeks). The mean duration between the Prolift procedure and time to audit was 44 weeks (range: 13-92 weeks). Table 1 compares the intraoperative, immediate post-operative and intermediate term postoperative complications in this study with that of Cosson et al. and Fatton et al.

Of the series, twenty-seven (90%) women had some type of urinary symptom prior to their Prolift. Twenty-two (73.3%) women had symptoms of stress incontinence (SI). Sixteen women (53.3%) also had additional urinary symptom(s) such as urgency, retention or feeling of incomplete emptying. Nineteen women (70.4%) of those with pre-operative urinary symptoms and 86.3% of those with stress incontinence had UDA. Of those women who had UDA, fourteen (73.7%) had UDSI and four (21.0%) had no UDSI. Six (43%) out of the 14 women with preoperative diagnosis of UDSI reported no further SI after the Prolift procedure. In fact out of twenty-two women with symptoms of SI, thirteen (59%) women reported no further SI after the Prolift procedure alone. The only patient who had an inconclusive UDSI was noted to have marked improvement of her SI following the Prolift procedure (Tab. 2).

Out of the 14 patients with preoperative diagnosis of UDSI, four (28.5%) had ISD. Two of these women opted to have TVT-O and not TVT to avoid any risk of bowel injury. The other two women had TVT. All seven women who had either TVT or TVT-O following their Prolift procedure reported subjective cure of their urinary symptoms including SUI.

One of the patients who had TVT-O seven months after a total Prolift procedure presented herself about 3 months following the TVT-O complaining of pain inside the vagina. There was no recurrence of her SUI. Clinical examination revealed a tender spot on the right side of the lower anterior vaginal wall where the TVT-O mesh penetrates the obturator foramen; there was no evidence of mesh erosion, granuloma formation or recurrence of the prolapse. The patient was admitted as a day procedure where she was examined under anaesthesia; there was no evidence of mesh erosion. The vaginal skin was incised over the tender spot described above and about 1 cm of the TVT-O mesh was excised up to where it penetrates the obturator foramen. The vaginal skin was then well mobilised before it was sutured. When she was reviewed in the out patient clinic, the patient was asymptomatic with no further pain or recurrence of SUI.

Of the sixteen women who had non SUI urinary symptoms either in isolation (5) or in addition to SUI (11), all had these symptoms cured after the Prolift.

DISCUSSION

The surgical technique was developed by the main author based on the established technique described by the Prolift

Table 1. – Comparison of the complications of this study with that of Cosson et al.8 and Fatton et al.12

Complications	Gad	Cosson	Fatton
Intraoperative			
Bladder or rectal injury	0	Vesical 4 (0.58%) Rectal 2 (0.30%)	
Blood loss greater 500 ml	1 (3.33%) (note 1)	3 (0.44%)	
Blood transfusion	0		
Immediate postoperative			
• Infection	0	Cellulitis 1 (0.15%)	T > 38.5C 2 (1.8)
		Perineal Abscess 2 (0.29%)	UTI 13 (11.8%)
			Pelvic abscess 0
		Pelvic haematoma 12 (1.75%)	Deep haematoma 2 (1.8%)
• Thromboembolism	0		
Urinary retention	0 (note 2)		13 (11.8%)
Return to theatre	0		
Blood transfusion	0		
Medium term postoperative			
Granuloma formation	0	46 (6.70%)	3 (2.8%)
Mesh exposure	0		5 (4.7%)
Urinary or rectal fistula	0	2 (0.30%)	
Mesh contraction	0	19 (2.77%)	18 (17%)
Recurrence	0	36 (5.24%)	5 (4.54%)
• De novo SUI	0	37 (5.39%)	

Note 1: In one patient there was an EBL > 500ml. This woman had a large fibroid uterus with 1st degree uterine prolapse. She requested a hysterectomy at the time of her Prolift due to pressure symptoms caused by the large fibroid uterus. Most of the blood loss occurred during the difficult vaginal hysterectomy part of the procedure and was not associated with the Prolift procedure itself. She did not require blood transfusion. The histology confirmed a large fibroid uterus weighing 481g (150mm x140mm x70mm).

Note 2: There were no cases of urinary retention by conventional definitions. There was one woman who passed 350ml on first void, the nursing staff measured residual urine of 96mls. For no clear indication she re-inserted an indwelling catheter again. On the same day the woman had to leave the hospital to attend to family business with the catheter still in situ. By the time she returned the next morning she had a successful trial after removal of the catheter.

Gynecare manufacturer ¹³ modified according to his personal experience with the intention of achieving an outcome with minimum complications and reduction of the risk of recurrence. The technique of the Prolift was fully described by Reisenauer et al. and Fatton et al.^{9, 12} Reisenauer et al. leave the endopelvic fascia attached to the bladder and the rectovaginal fascia attached to the rectum, a view that is not shared by Fatton et al. who perform full thickness dissection. The latter view is shared by the first author.

The incidence of POP doubles roughly with each decade between the ages of 20-59. The Major pelvic reconstructive surgery by Prolift procedure on women in the extremes of age may be controversial. In this study there was only one woman younger than 45 years (36 years). The youngest in the Fatton study is twenty-nine. Increasing longevity has resulted in a higher number of women presenting with symptoms of POP in later years. Increased activity, including sexual activity into older age means that older women should be considered as candidates for Prolift procedure. There were four women aged over 70 (13.3%). The oldest woman in the series (79) had a severely scarred vagina due to four previous pelvic floor repairs. The next oldest

woman, aged 78 years, had a longstanding severe procidentia with decubitus ulcers and oedema. Her treatment by the main author has been described elsewhere in this journal. ¹⁶ The oldest woman in the Fatton study is 90.

The association between parity and POP is well established. Vaginal delivery is the single most important risk factor for development of pelvic floor dysfunction. ^{16, 17} There is an eleven-fold increased risk of POP for women who have had more than four normal vaginal deliveries compared with nulliparous women. ¹⁵ All thirty women in this study had at least one vaginal delivery in the past.

When a hysterectomy is performed during a Prolift repair, it is associated with a higher risk of mesh exposure and recurrence.^{9,12} In this study there was a much higher proportion of women that had had a previous hysterectomy (56.7% vs 23.3% in Cosson and 28.2% in Fatton). This is consistent with the evidence that women with a previous hysterectomy are at a higher risk of POP compared with those with an intact uterus. The author was able to avoid a simultaneous hysterectomy in a larger proportion of patients (only 13.3% of women had a simultaneous hysterectomy compared with 52.8% in Cosson and 19% in Fatton). Whilst being conscious of the potential complications of having a hysterectomy at time of Prolift, it is inevitable that some women will still need to undergo this additional procedure for clinical reasons or patient request. The main author would therefore like to draw attention to the technique he described above to attempt to reduce complications associated with a hysterectomy performed at the time of Prolift.

As mentioned above, all patients had at least third stage prolapse in one or more compartments. Nineteen women (63.3%) had a 4th stage prolapse in one or more compartment. In Fatton study the degree of prolapse were classified using the classification of Jacquetin which is a modification of Baden-Walker Halfway staging system used in this study.

All patients had a hospital stay between three to five days with average stay of 4 days. In all patients the hospital stay was uneventful.

The number of complications in this study compares very favourably with that of the other two larger studies. There was only one significant intraoperative complication in this study was blood loss > 500ml occured to a patient during a hysterectomy part of her surgery which was unusually difficult due

Table 2. – Effect of Prolift procedure on associated SUI.

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SUI		Yes	No		
before Prolift	22 patients (73%)				8
UDA performed		Yes 19	No 3	No 8	
Result of UDA if performed	UDSI 14	no UDSI 4	Inconclusive UDSI 1		
No SI following prolift	6 (43%)	4 (100%)	0	3 (100%)	8 (100%)
Presence of SUI following Prolift	8 (57%) 5 had TVT-O & 2 had TVT 1 awaiting surgery	0	1 (100%) Marked improvement of SUI	0	0

to the large size of the uterus. The significance of hysterectomy during Prolift has been discussed elsewhere in the dis-

In three women (10%) the follow up visit was only four weeks postoperatively. Deviations from the routine six week follow-up are usually because of logistical constraints and patient convenience in the geographical area in which the surgeon practices. The absence of re-referral in these cases following their initial post operative review supports the assumption of a longer term successful post operative outcome right up to the time of audit. In this study the majority of women had urinary symptoms as it was the most presenting symptom with 3/4 of patients had symptoms of stress incontinence. One of the important findings in this study is the fact that six (43%) out of fourteen women with preoperative diagnosis of UDSI this was cured after the Prolift alone. Indeed out of twenty-two women with symptoms of SUI, thirteen (59%) women had these cured by the Prolift alone. The authors acknowledge that this is a subjective cure as none of these women had postoperative UDA. The only patient who had an inconclusive UDSI was noted to have marked improvement of SUI following the Prolift procedure and declined any further intervention or investigation. In eight women (57%) with preopertive diagnosis of UDSI, this was not cured by the Prolift alone. Five had a subsequent TVT-O procedure and two out of the four women with diagnosis of ISD had TVT. Both procedures were successful in all cases. The remaining woman is still waiting her procedure. It is of interest that the four women in this study with preoperative diagnosis of ISD remained to have SUI following their Prolift procedure. This represents 50% of the women who remained to have SUI following the Prolift procedure but only 28.5% of the women with preoperative diagnosis of UDSI.

The authors acknowledge that not all the women with urinary symptoms had a pre-operative UDA. Nevertheless, the main author's practice of performing a two-stage procedure starting with the Prolift procedure could result in some of the women opting to delay the UDA until after the Prolift procedure.

The main author separates the treatment of POP and UDSI for the following two reasons. Firstly, the degree of urinary incontinence may improve following POP repair. Secondly, he performs a TVT-O or TVT under sedation and local anaesthesia with a cough test performed in theatre which may contribute to very high success rate and no urinary retention problems in his own patients (unpublished audit data).

All the women who had non SUI urinary symptoms had these cured following Prolift.

CONCLUSIONS

This study shows that the Prolift procedure is a safe and effective option for women with a severe degree of POP. Forty three percent of women with preoperative diagnosis of UDSI were subjectively cured following Prolift. This supports the practice of the main author of performing a two stage procedure: Prolift for prolapse repair followed by a TVT-O or TVT procedure only in the group of women who their UDSI remains after the Prolift procedure. Women with ISD need to be warned that it is unlikely that they would have relief of their SUI following the Prolift procedure.

Both authors acknowledge the limitations of the study, such as the relatively short period of follow-up. Additionally, the small sample size may diminish the significance of the absence of rarer post operative complications. Nevertheless, even in a sample of thirty, the authors believe that the low incidence of all types of complications is significant.

Both authors would welcome a long term randomised controlled study comparing Prolift with a traditional repair with or without sacrospinous ligament fixation, abdominal sacrocolpopexy, or a laparoscopic paravaginal repair, or sacrocolpopexy. They would also be very interested in a randomised controlled trial in women with the diagnosis of POP and UDSI comparing the Prolift and TVT-O or TVT performed at the same time with that of a two-stage proce-

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