From: Peter Petros
To: Community Affairs, Committee (SEN)
Cc:

Subject: Mesh evidence 19.9.17
Date: Wednesday, 20 September 2017 6:50:17 AM
Attachments:

To the Secretary
Mesh Implants Inquiry

Dear Secretary

I write as Education Officer on behalf of ISPP, a stakeholder in the RANZCOG
We would appreciate if you could pass these comments onto the Senate committee

Ranzcog evidence on the 19th September 2017
We endorse the College's position of government funded statutory reporting of all implanted devices.
The population is ageing and there will be far more such devices brought into the medical field in the future.
We congratulate Professor Robson for his insightful comments on this issue and also Professor Maher for his clear exposition of what is now and what should be in the future..

Dr Benness's evidence
We have a few problems with some of Professor Benness's evidence.

1. Professor Benness did not declare a major conflict of interest, his partnership in a large urodynamic business in Sydney.
This is important, as urodynamics goes to the core of the differences between the College urogynaecologists (who base their treatment of symptoms on urodynamics)
and ISPP (which bases their treatment on repair of ligaments).

2. Professor Benness stated that the Integral Theory was difficult to understand.
Actually it is a simple theory. It states that prolapse, pelvic pain, bladder and bowel symptoms are mainly caused by collagen weakening in 5 ligaments
"Repair the structure and you restore the function" (Integral Theory)
The TVT and TFS work by irritating the tissues to create new collagen to reinforce the ligaments. Mesh sheets work by creating a blocking layer.

3. Professor Benness stated that there were "severe" complications with the Integral Theory operations, but he omitted mention of the midurethral sling which he endorsed yesterday.
All operations implanting strips of tape are based on the Integral Theory including the midurethral sling. See references in the 1996 Ulmsten paper.
.
The TVT midurethral sling in particular has had severe complications, transected urethras, severe haemorrhages, bladder perforations, bowel perforations, severe infections (see FDA Maude website).
However, it has also revolutionised the treatment of urinary stress incontinence.

An operation cannot be condemned on the basis of a handful of reported complications as Drs Atherton and Tsokos did in Perth. All surgeries have complications: knees, hips even appendicectomies.

To condemn an operation unrelated to the wider picture, its benefits and total number of operations performed, is unscientific and unfair to the women whose problems are cured.. I provide two short examples below.

Yours sincerely

Peter Petros
Education officer, on behalf of ISPP.

Professor PEP Petros DSc DS (UWA) PhD (Uppsala) MB BS MD (Syd) FRCOG (Lond) FRANZCOG

Int Urogynecol J (1996) 7:81–86

International Urogynecology Journal

THIS IS THE ORIGINAL PAPER FOR THE
ETHICON TVT MIDURETHRAL SLING
THE 1ST COMMERCIAL MIDURETHRAL SLING

Original Article

An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence

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Abstract: The object was to study prospectively the results of a modified intravaginal slingplasty for the surgical treatment of female stress incontinence, carried out under local anesthesia as a day procedure. Seventy five patients with genuine stress incontinence were operated upon and followed for a 2-year period. All patients were diagnosed urodynamically to have genuine stress incontinence. Pad tests and quality of life assessments were carried out in all patients both pre- and postoperatively. There were no intra- or postoperative complications and 63 patients (84%) were completely cured throughout the 2-year follow-up period. Six patients (8%) were significantly improved, i.e. they did not loose urine apart from an occasional leakage during severe cold etc. In the remaining 6 patients (8%) no improvement was seen. These failures were obvious at the first postoperative check-up after 2 months. Thus, there were no relapses after 2 months. All but 5 patients were able to void properly directly after surgery. These 5 needed an indwelling catheter during the night directly after the operation. All 75 patients were released from the hospital the same day or the day after surgery without catheterization. Mean sick leave was 10 days and mean operation time 22 minutes. No defect healing or rejection of the sling occurred. It is concluded that the procedure described is a promising new technique for the surgical treatment of female stress incontinence. Prospective long-term studies including more patients are in progress to establish the definitive place of this technique in the clinical routine.

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Keywords: Ambulatory surgical procedure; Female stress incontinence; Local anesthetics; Slingplasty

Introduction

We have previously reported on the results of a new ambulatory surgical procedure, intravaginal slingplasty (IVS), for the treatment of female urinary incontinence [1]. Although the results of both this and a further study [2] have shown an almost 90% cure rate 2 years after surgery, some important problems have been identified. One is the rejection of both Gore-tex and mersilene tapes, which occurred in about 8–10% of all patients. Another problem involves the instrument, which was originally designed to insert free nylon tapes to create new pubourethral ligaments [3], but not to implant a permanent sling around the midurethra. As permanent slings have been found to have a significantly better cure rate, however, this procedure is to be preferred [1,4].

The present study reports on an improved surgical technique for IVS used in 75 patients with genuine stress incontinence. The basis of the operation was similar to that previously reported, suggesting that correction of inadequate urethral support from the pubourethral–vesical ligaments and the suburethral vaginal wall is essential to alleviate the patient's symptoms [3,4]. Moreover, the previous requisites on the surgical procedures remained, i.e. the operation was to be carried out under local anesthetic, as an ambulatory procedure, allowing the patient to return home on same day or the morning after surgery, without the need for postoperative catheterization.

Materials and Methods

Seventy-five consecutive patients with a typical history of stress incontinence but no previous surgery were entered into the study. Mean age was 52 years (range 36–81) and mean parity 1.5 (range 0–3). All women underwent a routine assessment in our continence clinic before they were considered for surgery. The assessment included full urodynamic investigation with urethral pressure profile measurements, urethrocystometry with stress provocation, urine flow measurement and a 24-hour pad test [5–7]. All patients were seen by experienced urogynecologists, who also undertook a gynecologic examination and made the final decision that the patient had stress urinary incontinence suitable for surgical correction. Before surgery the patients also completed a modified life quality assessment [8]. All postmenopausal women were on estrogen therapy, the majority using local estrogen rings (Estring®).

The postoperative evaluation, also undertaken in the continence clinic, was carried out after 2, 6, 12 and 24 months.

Informed consent was obtained from all patients and the study was approved by the local Ethics Committee of the University.

The instrument (Medscand AB, Johnson & Johnson, Sweden) (Fig. 1) comprises a non-disposable metal handle to which two metal or plastic disposable needles can be attached. The needles have an outer diameter of 5–6 mm. A prolene gauze sling 40 cm long and 10 mm wide, covered by a plastic sheath, is fixed to the needles. To insert the sling the proximal ends of the needles are attached to the handle with a specific coupling, allowing rapid and easy uncoupling once the needle tip has reached the abdominal skin, as described below.

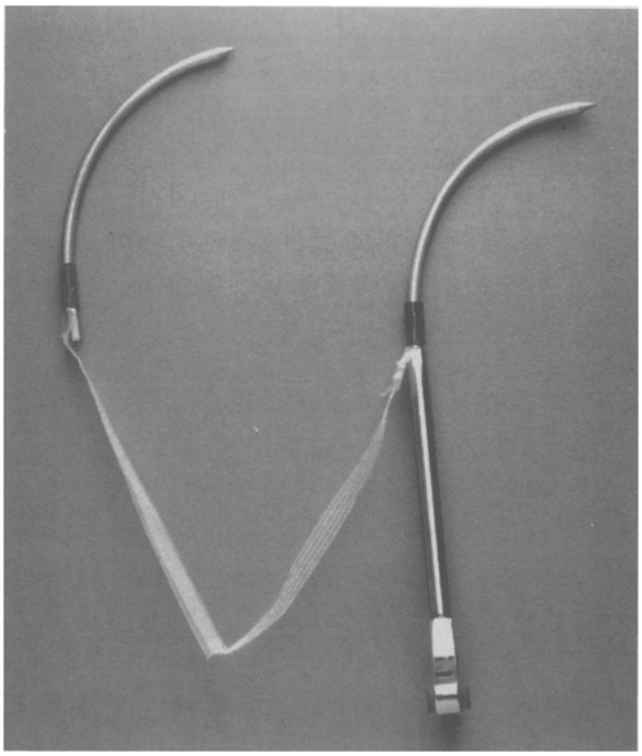

Fig. 1. Photo of the instrument used for implantation of the sling. The prolene sling covered by a plastic sheath connected to two needles which can be coupled to a metal handle (see also text).

Surgical Procedure (Fig. 2)

Immediately before the operation the patient was premedicated with 1 ml ketobemidone 5 mg/ml i.m. In the theatre she was initially sedated with 1 mg midazolam i.v., which was repeated as necessary to a maximum 5 mg during surgery. At the start of the operation fentanyl 0.05 mg was given i.v. and this dose was repeated at implantation of the sling.

The bladder was emptied via a transurethral Foley catheter. Local anesthetics (60–70 ml Citanest-Adrenalin® 0.25%) were injected in the abdominal skin just above the pubis symphysis and downwards along the back of the pubic bone to the space of Retzius. A 2 cm long transverse skin incision was made close to the superior rim of the pubic bone. In the last 25 operations, two 1 cm long transverse incisions 6 cm apart were made instead of the initially described skin incision. Vaginally 40 ml of 0.25% Citanest-Adrenalin was injected into the vaginal wall sub- and paraurethrally. An incision ≤1.5 cm long was made in the midline of the suburethral vaginal wall, starting approximately 0.5 cm from the outer urethral meatus. The incision was not allowed to encroach on the bladder neck, to avoid the tethered vagina syndrome and/or postoperative micturition disturbances [3]. Laterally from this incision a blunt dissection 0.5–1.0 cm long was made with scissors to each side of the urethra. This made it possible to introduce the tip of the needle in the correct starting position (Fig. 2). With a straight inserter introduced into the Foley catheter, the urethra and the bladder neck were identified. Using the instrument, i.e the handle with the needles attached, the sling was placed around the urethra as follows: the tip of the needle was inserted into the prepared paraurethral incision on the right side of the urethra. The urogenital diaphragm was perforated and the tip of the needle was brought up to the abdominal incision by 'shaving' the back of the pubic bone. As soon as the needle tip had reached the abdominal skin incision the proximal end of the needle was disconnected from the handle and the sling, covered by the plastic sheath, was brought into position on this side of the urethra by pulling the needle upwards with the sling attached. The procedure was then repeated on the left side. When the sling had been placed in a U shape around the midurethra, the plastic sheath was withdrawn. The plastic sheath has two aims: it prevents contamination of the sling before insertion, and it enables the ends of the sling to be pulled up to the abdominal incision without trauma.

At this step of the operation the patient underwent cystoscopy to confirm an intact bladder. With 300 ml of

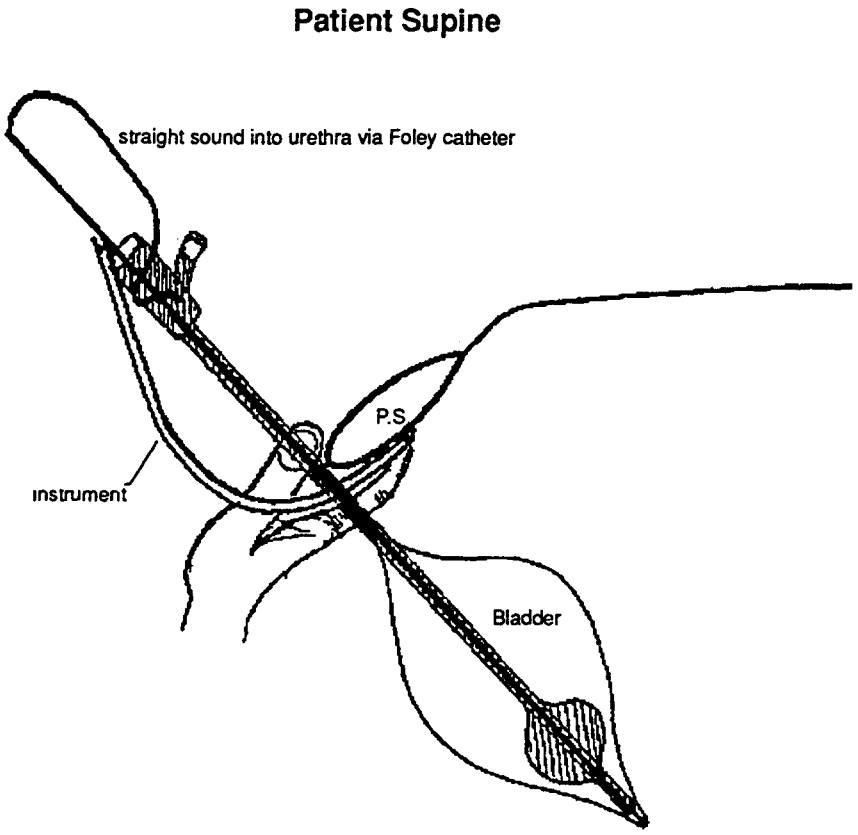

Fig. 2. Schematic outline of the initial part of the surgical procedure. The tip of the needle has perforated the urogenital diaphragm and entered into cavum Retzii. The straight inserter in the Foley catheter controls the urethra and bladder neck whereas the finger tip controls the needle tip at perforation. It is important that immediately after perforation into cavum Retzii a direct contact with the back of the pubic bone (PS) is established.

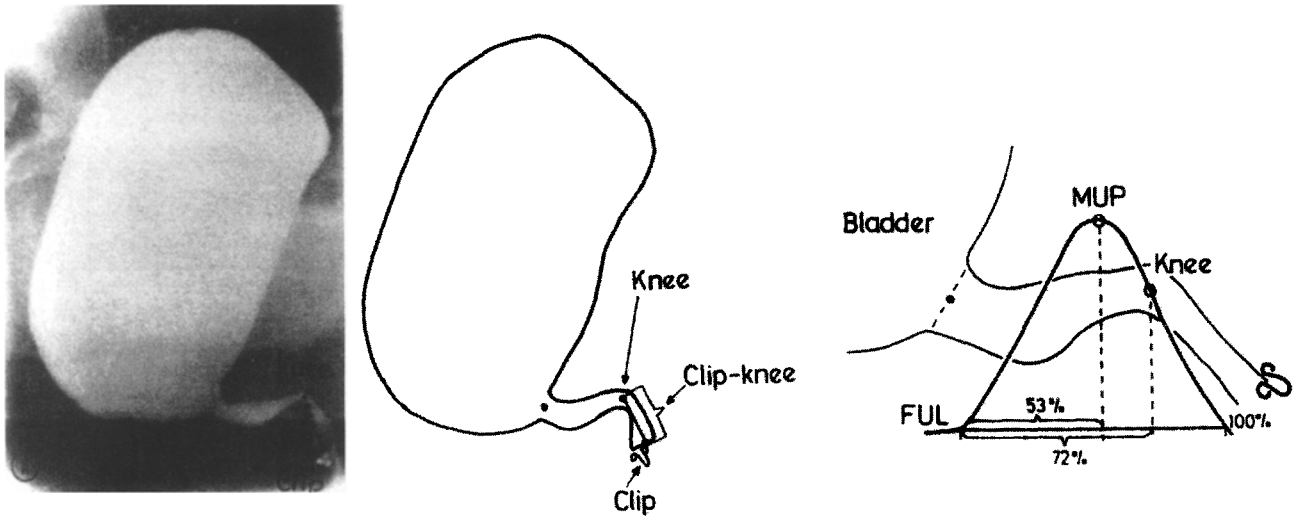

Fig. 3. Urethral profile measurement and lateral urethrocystography in a continent female. The 'urethral knee' indicates the main position and fixation of the pubourethral ligaments. As indicated the insertion is located close to the high pressure zone of the urethra. It is important that the sling is positioned at this site. FUL = functional urethral length; MUP = Maximum urethral pressure.

saline in the bladder she was then asked to cough vigorously to make sure that continence had been obtained.

Using the specially designed instrument the sling is placed around the midurethra, where the pubourethral ligaments are assumed to have their functional insertions, rather than at the bladder neck (Fig. 3) [4,9]. Importantly, the sling is only loosely placed – without elevation – around the urethra and the abdominal ends are not fixed but cut with scissors below the skin surface.

Pubourethral ligament :100% Integral Theor

Tightening suburethral
Vagina is100%
Integral Theory

Owing to the strong adhesive forces (friction) around the sling no fixation is necessary. Finally, the skin incision is sutured.

The vaginal incision is then closed. If there is excessive vaginal tissue this is cautiously excised, taking special care not to create too much tension in the suburethral vaginal wall. To check that the proximal urethra and bladder neck has an acceptable lumen and mobility a Hegar no. 7 sound is passed from the outer meatus into the bladder. Finally, the bladder is emptied and the patient leaves the theatre without an indwelling catheter.

Intraoperatively all patients received 4 g penicillin i.v. at the start of the operation. Postoperatively all were given Mecillinan 200 mg, 2 tablets/day for 1 week.

No immediate postoperative restrictions were given but the patient was encouraged to move about within the ward as soon as she wished. Depending on her wishes and general condition she was usually discharged from hospital the same evening or the following morning. If the patient lived a long distance away she was given the opportunity to stay overnight in the hospital.

Results

No significant intra- or postoperative complications occurred, i.e. no patient had bleeding >300 ml and no bladder perforation occurred. Mean operation time was 22 minutes (range 16–42 minutes). All patients were able to be released from hospital in the morning the day after the procedure. The mean time of absence from work was 10 days (range 7–21). In some patients with heavy work an extra week of sick leave was deliberately recommended.

During the subsequent check-ups, 63 (84%) of the 75 patients reported that they were completely dry, with no leakage whatsoever. This was confirmed by repeated stress tests in the continence clinic, i.e. vigorous coughing in the supine and standing positions with a comfortably filled bladder revealing no leakage. In 6 patients (8%) occasional leakage occurred postoperatively in severe stress situations, such as repeated vigorous coughing during severe cold. These patients considered themselves cured and did not wear pads. At check-ups in the continence clinic no urinary leakage was observed by stress tests in these patients. They were then considered significantly improved. The total leakage observed on pad tests was significantly reduced from a mean 72 g (range 8–258 g) before to a mean 5 g (range 0–32 g) after surgery, $P<0.001$ (t-test). In those patients in whom postoperative urodynamic assessments could be performed no significant changes in the urethral pressure profile or other parameters were observed. There were no signs of urge incontinence or micturition disturbances at the postoperative long-term follow-up.

In the remaining 6 patients no significant improvement of the incontinence problems was observed or registered, neither subjectively nor objectively. In these patients the failure was obvious within 2 months after surgery, and no relapses occurred after that time.

A preliminary interpretation of the life quality data revealed that in all patients, apart from the 6 who were not cured, there was a significant positive change after the operation. In 5 patients there were signs of postoperative urinary infection within 14 days after the operation. No specific bacterias were found and treatment with conventional antibiotics was successful. There were no signs of an increased incidence of urinary infections in the long-term follow-up.

Five patients had immediate postoperative voiding problems necessitating an indwelling catheter over the first postoperative night: otherwise no postoperative urinary retention was recognized and no long-term catheter treatment was necessary. There were no signs of defect healing or rejection of the sling in any of the patients.

Discussion

A comparison of the present results to those previously reported using a similar slingplasty technique shows a higher cure rate with the present technique, suggesting an improvement in the surgical technique. The number of cured patients was higher and the mean operation time less than that in the previous study, also indicating an improvement in surgical technique [1,2,4].

Most encouraging was the finding that there were no rejections of the sling and no defect healing. Most likely this was due to the properties of the sling material, prolene possibly being better accepted by the tissues in which it was implanted than mersilene or Gore-tex [10,11]. Another important positive effect was the strong adhesive forces created around the present sling which, compared to the previously used slings, prevented sliding. In fact it was found that due to a high degree of friction the prolene sling was difficult to move as soon as the surrounding plastic sheath had been removed. This in turn emphasized the need for the plastic sheath, facilitating placement of the sling into the correct position around the urethra. The plastic sheath also prevents the sling being contaminated at implantation. Hence the design of the instrument and the surgical technique enabled the sling not only to be located in a correct anatomical position, but also to be firmly secured immediately. An interesting observation in this context was that the majority of the patients reported that directly after the operation they had a far greater sense of 'security' than before surgery.

The small incisions and canals involved with this technique minimized the surgical trauma and enabled the operation to be performed under local anesthesia. By the same token it made fairly small demands on postoperative care.

It must be emphasized that the present procedure cannot be compared to conventional slingplasties, in which the surgical procedures are more extensive and the sling is located at the bladder neck, which is aimed to

Theoretical considerations
is 100%
Integral Theory refs 3&4

be elevated. If the sling is placed too close to the bladder neck there would be a risk of postoperative impairment of urine flow, which is avoided with the present technique in accordance with the theoretical and experimental background to the IVS operation presented earlier [1,3,4].

Compared to the previously described IVS procedure [1,4] the present technique does not require an 'extensive' vaginal plasty but only a minor incision of the suburethral vaginal wall. This in turn contributes to the shorter operation time.

It can be argued that the reported positive results were due to the fact that all surgeons involved in this study are quite experienced in vaginal surgery. However, preliminary findings from an ongoing extensive multicenter study involving also less experienced gynecologists, report almost the same results as those reported here.

Ambulatory surgical procedures have been introduced in gynecologic surgery for several reasons. There is at present great enthusiasm for endoscopic Burch colposuspensions, but we are still awaiting long-term follow-up studies. Compared to endoscopic colposuspension, a technique also familiar to us, the IVS plasty has an operation time which is less than half that of the Burch procedure. It is also carried out under local anesthetic, and the incidence of urinary retention is significantly lower than when the Burch procedure is performed. Also important is that the costs of the IVS plasty are about half those of endoscopic Burch and about four times less than those of conventional open surgery, according to the Scandinavian health economic system.

The pre- and postoperative urodynamic findings related to the outcome of the IVS plasty will be the subject of another article. It can, however, be mentioned that the present technique gave positive results also in patients with a low urethral pressure profile (maximum urethral pressure $\leqslant 20$ cmH_2O).

It is quite obvious that the operation failed in 6 patients. Considering the multifactorial etiology and pathophysiology of female stress urinary incontinence, as well as the complicated integration of the anatomical structures involved in maintaining continence [1,4,12–14], one must realize that no method can be expected to cure all patients. Based on the results presented here and experience over a 3-year period, the present technique has now been adopted as the primary method for surgical treatment of genuine stress incontinence in our department, and we now operate on about 200 patients annually with this technique. Even if the results so far are in accordance with those reported here, and by the same token the preliminary results from an ongoing Scandinavian multicenter study encompassing 500 patients seem to confirm these, we must bear in mind that long-term results are necessary before the ultimate place of a new surgical method can be established. Unfortunately, few surgical methods for the cure of stress incontinence have been exposed to prospective long-term follow-up studies. Until such an evaluation has been done the IVS plasty can only be characterized as a promising new technique that should be further evaluated in larger series of prospective studies over a longer period. As indicated above, such studies are in progress.

Acknowledgments This study was supported by grants from the Swedish Medical Research Council, no. 8310.

References

Refs 1-4 concern Int. Theory

1. Petros P, Ulmsten U. Intravaginal slingplasty. An ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol* 1995;29:75–82
2. Falconer C, Ekman G, Malmström A, Ulmsten U. Intravaginal slingplasty for treatment of female stress incontinence. 11th IUGA Meeting, Kuala Lumpur, 1995
3. Petros P, Ulmsten U. An integral theory on female urinary incontinence. Experimental and clinical considerations. *Acta Obstet Gynecol Scand* 1990;69(suppl):153
4. Petros P, Ulmsten U. An integral theory and its method for the diagnosis and management of female urinary incontinence. *Scand J Urol Nephrol* 1993;153:1–93
5. Asmussen M, Ulmsten U. Simultaneous urethrocystometry and urethral pressure profile measurements with a new technique. *Scand J Urol Nephrol* 1976;10:7–12
6. Ulmsten U, Asmussen M, Lindström K. A new technique for simultaneous urethrocystometry and measurement of the urethral pressure profile. *Urol Int* 1977;32:88–92
7. Victor A, Larsson G, Åsbrink AS. A patient administered test for objective quantitation of the symptom of urinary incontinence. *Scand J Urol Nephrol* 1988;21:277–279
8. Khullar V, Salvatore S, Cardozo LD, Yip A, Kelleher CJ. The importance of urinary symptoms and urodynamic parameters in quality of life assessment. *Neurourol Urodyn* 1995;14:540–542
9. Westby M, Asmussen M, Ulmsten U. Location of maximum intraurethral pressure related to urogenital diaphragm in the female studied by simultaneous urethrocystometry and voiding urethrocystography. *Am J Obstet Gynecol* 1982;144:408–412
10. Brenner J. Mesh materials in hernia repair. *Inguinal Hernia Repair* 1995 (in press)
11. Bent EA, Ostergard RD, Zwick-Zaffuto M. Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence. Clinical and histological study. *Am J Obstet Gynecol* 1993;169:1198–1204
12. Zacharin RF. The suspensory mechanisms of the female urethra. *J Anat* 1963;97:423–427
13. DeLancey JO. Correlative study of paraurethral anatomy. *Obstet Gynecol* 1986;68:91–97
14. DeLancey JO. A structural support of the urethral as it relates to stress urinary incontinence: the hammock hypothesis. *Am J Obstet Gynecol* 1994;170:1713–1723

EDITORIAL COMMENT: The authors present their initial results in treating female stress incontinence with a new surgical technique, the modified intravaginal slingplasty. The procedure is performed on an outpatient basis, under local anesthesia and heavy intravenous sedation. Mean operating time is less than 1 hour. There were no intraoperative or postoperative complications, including hemorrhage, requiring transfusion or lower urinary tract injury. No rejection or infection of the sling or operative site occurred. An 84% cure rate is reported at 2 years follow-up, based on subjective measures and confirmed by stress test in the office. Total leakage on pad testing was significantly improved. Unfortunately, objective measures (pre- versus postoperative urodynamic parameters) of operative success are not included in the report.

This procedure is of interest for several reasons. First, a new instrument is introduced which allows placement of the sling via a vaginal route, rather than the traditional abdominal passage of a needle or packing forceps to retrieve the sling arm. Secondly, the sling material (in this case prolene gauze) is covered by a plastic sheath to theoretically prevent contamination of the sling prior to placement. Thirdly, the surgical technique differs from the suburethral sling procedure in that the sling is placed at the level of the midurethra, is not elevated but loosely positioned, and the sling arms are not fixed to the rectus fascia or together in the midline. Finally, the entire procedure takes less than 1 hour, is performed under local anesthesia and as an outpatient – all attractive features in the new age of medicine.

The modified intravaginal slingplasty is a new and interesting procedure. Only time and further experience will determine its place among anti-incontinence surgical procedures for female stress incontinence.

AUTHORS' COMMENTS: In the editorial comment it is pointed out that the procedure is performed under heavy sedation. We do not agree completely with this view. To further clarify the matter of sedation we would like to advise that in this ongoing multicenter study, we have reduced the amount of sedation. Currently only 0.05 mg fentanyl just before the injection of the local anesthetics is given. This dose of fentanyl can be repeated once during the procedure. Our experience based on >100 patients has shown that this lighter sedation gives as good pain relief as that initially described.

Editor's Note: Obstetrics & Gynecology *welcomes letters as written or e-mail correspondence. Send e-mail addressed to jrscott@upa.edu*

Severe Mesh Complications Following Intravaginal Slingplasty

To the Editor:

I have performed more than 1,500 operations using the intravaginal slingplasty instrument since 1994,[1] without major problems. Although 110,000 intravaginal slingplasties have been successfully used to date, Baessler et al,[2] without personal experience, do not recommended its use. Their evidence is anecdotal, about one patient per center per annum. With no expertise in multifilament tape usage, they performed laparotomy in 7 patients. In the patients' interests, they should have consulted an expert in intravaginal slingplasty usage to advise them how best to remove the tape. I have never performed laparotomy to remove a multifilament tape. A partly rejected tape can generally be removed as an office procedure by pulling down the surfaced loop and cutting it off level with the vagina. Even in patients with abdominal sinuses, the tape is removed via a midurethral vaginal incision.

"Tension-free vaginal tape (TVT)" or "intravaginal slingplasty" are proprietary names. Proprietary names are not operations. The original publications of Petros and Ulmsten[3] and Ulmsten et al[4] nominated the midurethral tension-free sling as "intravaginal slingplasty."

The authors have diagnosed "infection" without clinical or bacteriological data. Their finding of giant cells confirms a foreign body etiology. A foreign body tape reaction is no different from a splinter. It is not surprising that all pain symptoms disappeared immediately after tape removal. Foreign body reactions do not respond to antibiotics, also reported by the authors. The median removal time (24 months) bears witness to the benign nature of these reactions.

Amid's "pore hypothesis" has been invalidated[5] by evidence of macrophages surrounding microfibrils in spaces less than 5 microns. A randomized trial[6] reported erosion rates of 13.1% and 3.3% for monofilament tape (Sparc, TVT) and 1.7% for a multifilament tape (intravaginal slingplasty) and concluded that tape erosions were technique-related.

Baessler et al reveal lack of insight. Their evidence has no reference point; they discuss "quality of life," yet recommend against a major scientific breakthrough—up to 80% cure of nocturia, abnormal emptying, pelvic pain, urgency, and frequency with posterior slings. The anatomical basis for this is described in *The Female Pelvic Floor.*[7]

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REFERENCES

1. Richardson PA. Ambulatory surgery for urinary incontinence and vaginal prolapse. Med J Aust 1994;161:511.
2. Baessler K, Hewson AD, Tunn R, Schuessler B, Maher CF. Severe mesh complications following intravaginal slingplasty. Obstet Gynecol 2005;106: 713–6.
3. Petros PE, Ulmsten UI. An integral theory of female urinary incontinence: experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl 1990;153:1–79.
4. Ulmsten U, Henrriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996;7:81–6.
5. Papadimitriou J, Petros P. Histological studies of monofilament and multifilament polypropylene mesh implants demonstrate equivalent penetration of macrophages between fibrils. Hernia 2005;9:75–8.
6. Lim YN, Muller R, Corstiaans A, Dietz HP, Barry C, Rane A. Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial. Aust N Z J Obstet Gynaecol 2005; 45:52–9.
7. Petros P. The female pelvic floor: function, dysfunction and management according to the integral theory. Heidelberg (Germany): Springer; 2004.

In Reply:

Thank you for the opportunity to respond to Dr. Richardson's letter. We congratulate him for his experience with the intravaginal slingplasty. Unfortunately, he and other surgeons have not published long-term data, and therefore we do not have a denominator. This is an unintentional limitation of our report; surgeons have to provide these data. Although we are not aware of Dr. Richardson's follow-up policy, we are not surprised that he denies problems with the intravaginal slingplasty. Most of our patients were NOT referred by their surgeons, who repeatedly oversewed, administered antibiotics, and failed to treat the complaints.

Dr. Richardson states that he had no "major problems," yet he admits that he performed vaginal mesh removal (never a laparotomy). He "generally" removes "partly rejected tape" as an office procedure, "even in patients with abdominal sinuses." Are not those major problems? Patients will have to answer this question, and a prospective follow-up, including quality of life assessment to determine severity and bothersomeness, is the method of choice.

Whether a laparotomy is necessary to remove the mesh depends on the fibrosis, and other authors have communicated this problem. Bafghi et al[1] reported 11 cases of intractable mesh infection out of 149 patients who underwent anterior intravaginal slingplasty, 6 of whom required laparotomy.

Dr. Richardson criticizes the use of the term "infection." In our paper we described clinical (purulent vaginal discharge and pain) and histological signs of infection (acute inflammation). Chronic inflammation including foreign-body giant cells is a typical reaction to mesh.[2] The definition of mesh rejection is not clear. Clinically, however, it might be characterized as recurrent symptomatic mesh erosion, infection, pain, and histological evidence of acute, rather than chronic, inflammation.

Dr. Richardson states that the long median removal time of 24 months "bears witness to the benign nature of these reactions." Quite the contrary. We think this means suffering and distress of patients, a long time to diagnosis and treatment, but also a slow or late infection because of the nature of the mesh. Although the theory of too-small interstices for macrophages to enter has been questioned by a study that is based on 1 patient and 8 rats (and was not available when we wrote the manuscript), other studies have shown that the adherence of bacteria is dependent on the surface area.[3] This fact explains cases of late tape infections. Multifilament mesh is associated with a higher incidence of complications in well-designed studies. In a randomized, controlled trial on intravaginal slingplasty versus TVT, 7% of 87 women in the intravaginal slingplasty group required mesh removal.[4]

Dr. Richardson speaks of "major scientific breakthrough." Unfortunately, there are no scientific data to confirm this statement. The National Institute for Health and Clinical Excellence of the National Health Service concludes in their guidelines that "Current evidence on the safety and efficacy of posterior infracoccygeal sacropexy for vaginal vault prolapse does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research."

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REFERENCES

1. Bafghi A, Benizri EI, Trastour C, Benizri EJ, Michiels J-F, Bongain A. Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling. BJOG. 2005 Mar 112:376–8.
2. Falconer C, Söderberg M, Blomgren B, Ulmsten U. Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 2001; 12 suppl 2:S19–23.
3. Klinge U, Junge K, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V. Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacteria adherence, and the in vivo consequences in a rat model. J Biomed Mater Res 2002;63:765–71.
4. Pifarotti P, Meschia M, Gattei U, Bernasconi F, Magatti F, Viganò R. Multicenter randomized trial of tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for the treatment of stress urinary incontinence in women. Neurourol Urodynam 2004;23:494–5.

Severe Mesh Complications Following Intravaginal Slingplasty

To the Editor:

I am writing to you as President of the Association for Ambulatory Vaginal and Incontinence Surgeons (AAVIS), which comprises of 100 Australian and New Zealand surgeons. Since 1995, they have mainly used the intravaginal slingplasty (IVS) multifilament tape. The complications arising from this tape are analyzed at our annual scientific meeting, of which the 7th is about to occur.

Baessler et al's[1] theme concerns underreporting. Reporting of complications always relates to their seriousness. The AAVIS group has experienced few major complications over several thousand cases. The tape rejection problems that concern Baessler et al are insignificant relative to complications such as major vessel and nerve injury and urethral and small bowel perforation experienced with other instruments.[2]

The association believes that its policy of built-in safety helps avoid such major complications. A hole is made in the urogenital diaphragm, and the instrument is set horizontally while, using 2 fingers, the surgeon slides the tip of the instrument along the posterior surface of the pubic symphysis. This technique virtually eliminates injury to the external iliac, obturator vessels, and nerves.

The tape is applied contiguously, with the urethra and vaginal fascia approximated as a "buttress" below the tape to decrease erosion rate. A 3-way randomized trial (n = 180) between suprapubic arc sling (SPARC, monofilament), tension-free vaginal tape (TVT, monofilament), and IVS (multifilament) recorded vaginal erosion rates of 13.1%, 3.3%, and 1.7%, respectively,[3] and concluded that tape rejections are technique-related.

Tape rejections are usually addressed as office procedures. Injury from the delivery instrument can be life-threatening. Ostergard, in his 2002 editorial[2] discussing the TVT, stated "Several deaths have resulted from bowel injury due to the inherent inability to avoid the peritoneal cavity during placement of the trocars. Other deaths have resulted from hemorrhage and obturator nerve injury has also occurred."

The Food and Drug Administration (FDA) Maude Web site (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm [USA only]) gives voluntary device reports. From 2002–2005: 709 TVT reports, many small bowel, urethral, major vessels and nerve damage, at least 6 deaths; 31 IVS reports, mainly minor problems.

Baessler et al recommend against IVS use because of 14 foreign body reactions (a minor problem that was resolved on tape removal). Having set themselves up as guardians of the public good, will they now recommend that TVT be withdrawn from the market for uniquely causing such devastating complications for a non–life-threatening condition?

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REFERENCES

1. Baessler K, Hewson AD, Tunn R, Schuessler B, Maher CF. Severe mesh complications following intravaginal slingplasty. Obstet Gynecol 2005;106: 713–6.
2. Ostergard DR. The epochs and ethics of incontinence surgery: is the direction forward or backwards? Int Urogynecol J Pelvic Floor Dysfunct 2002;13:1–3.
3. Lim YN, Muller R, Corstiaans A, Dietz HP, Barry C, Rane A. Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial. Aust N Z J Obstet Gynaecol 2005; 45:52–9.

In Reply:

We thank Dr. Molloy for his letter. He implies that there is no "underreporting" of complications following intravaginal slingplasty (IVS) procedures because there are no serious problems. He considers tape rejections insignificant.

Firstly, whether or not a problem is significant–that is, when it affects the patient's quality of life–should be assessed prospectively with self-administered quality-of-life questionnaires. It is not for a health profes-

sional to decide. Secondly, we saw patients with IVS complications who have had several unsuccessful "office procedures" performed; non-IVS surgeons finally removed the tape. Thirdly, the "theme" underreporting cannot be emphasized enough. How can we counsel patients and give informed consent if we cannot present cure and complication rates? Why has the Association for Ambulatory Vaginal and Incontinence Surgeons (AAVIS) failed to publish high-quality, MEDLINE-accessible studies?

The technique of the anterior IVS is comparable to the TVT. Dr. Molloy distracts from the IVS underreporting fact when he quotes a Web site that reports major complications including deaths after the TVT but only few minor problems with the IVS. Why should we believe that there have been no deaths with the IVS procedures if we cannot even find a simple, independent, long-term follow-up study? The compelling difference between the TVT and IVS is the amount of published data. Dr. Molloy cites a randomized controlled trial (RCT) with 6–12 weeks follow-up with no differences in mesh rejections.[1] In their reply to a letter to the editor, the authors caution that not all erosions seem to be technique-related and that the surface area of the multifilament meshes may be important (Richardson P. Re: Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial. Aust NZ J Obstet Gynaecol 2005;45:340–1). The longest-term follow-up is available from an RCT on IVS compared with TVT, with a median follow-up of 22 months. In this study, 7% of 87 women in the IVS group required mesh removal.[2]

We have the obligation to counsel our patients and inform them about benefits and risks of procedures. Neither the AAVIS information sheets nor the medical literature provides sufficient data on complications. The AAVIS patient information asserts "Rejection of the Tape–this problem has now been eliminated due to the use of polypropylene tapes." We reported our cases of IVS-complications to alert doctors and to indicate that this statement does not seem to be true and that there might be problems associated with multifilament mesh and new techniques.

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REFERENCES

1. Lim YN, Muller R, Corstiaans A, Dietz HP, Barry C, Rane A. Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial Aust NZ J Obstet Gynaecol 2005; 45:52–9.
2. Pifarotti P, Meschia M, Gattei U, Bernasconi F, Magatti F, Vigano R. Multicenter randomized trial of tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for the treatment of stress urinary incontinence in women. Neurourol Urodynam 2004;23:494–5.

First-Trimester Septated Cystic Hygroma: Prevalence, Natural History, and Pediatric Outcome

To the Editor:

There are several serious problems with the study by Malone et al.[1] First is the definition of their "unique marker" (cystic hygroma): "enlarged hypoechoic space extending along the length of the fetal back, and in which septations are clearly visible." What is the minimum measurement that fulfills the definition of "enlarged"? What is the minimum length and thickness of the space necessary to fulfill the criterion of "extending along the length of the fetal back"? How are the septations looked for, transvaginally or transabdominally, and with the fetus facing toward or away from the transducer? Was a transverse view obtained, and was this done in each fetus in the study, regardless of nuchal translucency measurement? Were these images reviewed in a central location, as were the nuchal translucency measurements, for quality assurance? If so, in what percentage of cases were these views deemed to be adequate?

The second problem relates to the overall design of the FASTER study. The declared purpose was to assess the utility of screening using the combination of nuchal translucency measurement and biochemical markers. Why were the patients with "cystic hygromas" managed differently from all others and offered a chorionic villus sampling without biochemical assessment? There was no a priori reason to assume that enlarged nuchal translucency with "septations" has more sinister implications than nuchal translucency of the same thickness without "septations." Indeed, their recommendation that in cases of cystic hygroma "it is reasonable to immediately counsel patients regarding their extremely high risks of adverse outcome" may well have led to the termination of some normal fetuses. In the study, there were 15 cases of cystic hygromas that ended in elective pregnancy termination before completing their work-up. Eleven of these turned out to have normal karyotypes.

The third problem relates to the statistical analysis. Several studies have shown that the prevalence of trisomy 21, other aneuploidies, cardiac, skeletal, and other defects, and adverse pregnancy outcome increases as the nuchal translucency measurement increases.[2] The authors[1] disregard this literature and do not present the relation between the thickness of their "cystic hygromas" and the likelihood ratios for adverse outcome. Instead, they compare the outcome of fetuses with "cystic hygromas" (with a mean nuchal translucency measurement of 6.9 multiples of the median [MoM]) with that of fetuses with "simple" increased nuchal translucency (nuchal translucency measurement of 3 MoM or greater) and conclude that the former have a worse outcome than the latter. Such a conclusion could be reached only if the nuchal translucency distributions in the 2 groups were identical and the outcome of those with the "cystic hygroma" was worse than those with "simple" increased nuchal translucency.

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REFERENCES

1. MaloneFD, Ball RH, Nyberg DA, Comstock CH, Saade GR, Berkowitz RL, et al, for the FASTER Trial Research Consortium. First-trimester septated cystic hygroma: prevalence, natural history, and pediatric outcome. Obstet Gynecol 2005;106:288–24.
2. Nicolaides KH. Nuchal translucency and other first-trimester sonographic markers of chromosomal abnormalities. Am J Obstet Gynecol 2004;191:45–67.

In Reply:

Sonek and colleagues appear unclear about our definition of septated cystic hygroma and feel that it was inappropriate for us to advise patients immediately when this diagnosis was made. Our definition of septated cystic hygroma is clear, with both written and illustrative description already provided in our paper. This sonographic diagnosis was easily learned by 102 sonographers at 15 centers throughout the United States and was successfully implemented in the screening of over 38,000 patients. Septated cystic hygroma is an easily and instantly recognizable major sonographic abnormality of the first-trimester fetus and does not rely on various planes, probes, or the mechanics of nuchal translucency measurement. Our results have completely validated our methodology in that over 50% of such pregnancies had aneuploidy and only 17% of cases had a normal outcome. It would be difficult to provide any more clear validation of our approach than that.

A key aspect of the study design of FASTER was that patients with septated cystic hygroma were informed of this finding immediately, without delaying counseling for several more weeks to complete serum screening. This followed extensive discussion and input from multiple institutional review boards and was approved by both the FASTER Steering Committee and National Institute of Child Health and Human Development (NICHD). As early as 1989, there was a well-recognized association between cystic hygroma and a range of adverse outcomes, and we have carefully summarized this literature in the references section of our paper. Sonek and colleagues appear to have missed the cited literature in their assertion that there was no a priori reason to assume poor prognosis with such cases. To hide this information from patients, as implied by Sonek and colleagues, while awaiting blood tests over the next several weeks would, we believe, be quite unethical.

The analysis in our study is statistically sound and appropriate. Documentation of the outcome of such fetuses does not depend on "nuchal translucency distributions." Our comparison of the outcomes of 2 different extreme groups of fetuses is appropriate and proves that those fetuses with septated cystic hygroma can and should be distinguished from simple increased nuchal translucency. Further research should focus on establishing a registry of such cases for long-term pediatric follow-up. We conclude, therefore, that during first-trimester ultrasonography, the recognition of septated cystic hygroma will allow for immediate patient counseling, without having to delay results until serum markers are obtained. From both an ethical and a practical perspective, this is clearly the right thing to do.

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Genital Herpes Complicating Pregnancy

To the Editor:

We have several concerns with the article "Genital Herpes Complicating Pregnancy" in your Clinical Expert Series.[1] First, Dr. Brown discloses his financial relationship with GlaxoSmith-Kline (manufacturer of acyclovir and valacyclovir). We have great respect for Dr. Brown's contributions to this field. However, there is an obvious conflict of interest present when the "clinical expert" makes a recommendation (ie, more widespread use of antivirals in pregnancy) that will financially benefit a company that pays him. Of note, in the Instructions for Authors document for *Obstetrics & Gynecology*, it states, "Authors of reviews and current commentary articles cannot have any financial involvement or commercial interests in the product discussed in the paper." Certainly a paper such as this would be considered a review article.

In addition, regarding the paper's recommendation of "universal [herpes simplex virus] HSV serologic screening in pregnancy," we wish to inquire regarding the financial support of 2 coauthors, Drs. Ashley Morrow and Corey, neither of whom made a financial disclosure. The Web site mentioned in Table 1, www.herpeselect.com, appears to be the home page for a commercial HSV test (HerpeSelect, Focus Diagnostics). This site lists Rhoda Ashley Morrow as the "laboratory professional host" for the site, and a picture of her appears there. This site also directs viewers to another Web site, www.herpesdiagnosis.com, stating "This website was designed by Drs. Lawrence Corey, Rhoda Ashley...." This latter Web site (ie, www.herpesdiagnosis.com), under the heading "Tests to Use," recommends HerpeSelect HSV-1 and HSV-2 enzyme-linked immunosorbent assay (ELISA). This seems to imply ties between these authors and companies that sell or perform HSV tests. Again, we respect the distinguished careers of these authors, but there is a significant conflict of interest present when the "clinical experts" make a recommendation ("universal HSV serologic screening in pregnancy") that will benefit companies with which they are associated.

Neonatal HSV is a devastating disease and further study of the problem may lead to new American College of Obstetricians and Gynecologists (ACOG) recommendations. Currently, however, it should be emphasized that universal screening and more widespread suppressive treatment are not recommended by ACOG. The fact that these strategies are recommended in your Clinical Experts

Series by author(s) associated with companies that financially benefit from such strategies represents, at best, a questionable editorial decision.

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REFERENCES

1. Brown ZA, Gardella C, Wald A, Morrow RA, Corey L. Genital herpes complicating pregnancy. Obstet Gynecol 2005;106:845–56.

In Reply:

Drs. Urato and Caughey criticize our review based upon our recommendation that HSV serologic testing be used to define women at risk for transmitting a herpes virus infection to their newborn, as well as our recommendations for antiviral chemotherapy during pregnancy. Their criticism is not based upon any factual analysis of the risks of genital herpes complicating pregnancy, nor do they take issue with any of our data upon which we base our recommendations. In addition, they do not offer any useful alternative ideas on the issues involved. Instead, they criticize the article because they feel that some of the authors might be making these recommendations for secondary gain.

In reply to these criticisms, we offer the following: The editor of *Obstetrics & Gynecology* requested that we write this review, which was modified according to the suggestions in the peer reviews. The research upon which all of the recommendations were based began in the early 1980s and was supported initially by the March of Dimes and then by the National Institutes of Health. We have never received any support from the pharmaceutical industry for this research. The need for HSV serologic screening in early pregnancy became apparent to us in the 1980s as this research developed.

Our data clearly show that the women at greatest risk of infecting their newborns are those who acquire genital herpes during the third trimester of pregnancy. Because of the subclinical nature of the infection in the mother, the susceptibility to acquiring or transmitting the infection to the newborn cannot be based on history, viral culture, or physical examination but can only be determined by serologic testing. To that end, the text provides a table of all commercially available type-specific, gG-2 based serologic assays that are currently approved by the Food and Drug Administration. The "gold standard" for these commercial assays is the Western blot, which is performed at the University of Washington virology laboratories. Although this laboratory is directed by Drs. Morrow and Corey, all of the authors of the review are salaried employees of the State of Washington, and the revenues from these assays go to the University of Washington.

We were surprised that someone could conclude from reading the review that we would be advocating increased use of antiviral drugs during pregnancy. Our article defines the susceptibility for acquiring genital herpes during pregnancy and provides tools for counseling patients about unprotected oral or genital sex during the latter part of pregnancy. In the brief discussions of antiviral chemotherapy, we recommend the use of acyclovir, which is a generic, inexpensive drug made by over 15 separate generic manufacturers, none of which pay us any consulting fees. Our discussion of antiviral chemotherapy in pregnancy follows published guidelines.

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Editor's Note:

We are grateful to Drs. Urato and Caughey for having brought this issue to our attention. The financial disclosure statements from the authors arrived late in the production process. Financial disclosures from Drs. Brown and Wald were published with the article, and statements from Drs. Gardella, Morrow, and Corey are included in an errata notice on page **428**. We have modified our policy and will now ask all authors of Editorials, Clinical Expert Series, and In the Trenches to disclose, in writing, any potential conflicts of interest when invited to contribute to the journal. These will be reviewed by the editors before proceeding. Authors of letters to the editor will also be required to declare conflicts of interest. We hope this will alleviate any future problems along these lines.

Forceps Compared With Vacuum: Rates of Neonatal and Maternal Morbidity

To the Editor:

The recent study by Caughey et al[1] that compared maternal and neonatal morbidity between vacuum- and forceps-associated deliveries revives the debate about the best choice for instrumental deliveries. Their conclusion is slightly different from most previous studies, which revealed that maternal soft tissue injuries are more common in women who delivered with the use of forceps and that immediate neonatal complications are more common with vacuum extractions. It is also different from our recent findings, which did not reveal any significant difference in newborn and maternal morbidity between both modes of instrumental delivery.[2] There may be several explanations for this discrepancy. First, Caughey et al report extremely high rates of third- and fourth-degree tears (36.9% and 28.6%). For comparison, we had only 0.4–1.9%.[2] This could be explained by the relatively high station at which instrumental deliveries were performed in their study. Also, occurrence of perineal tears is dependable on obstetric provider expertise; for example, it is not clear whether a senior obstetrician was always present. It is obvious that such presence might lower the rate of perineal injury. Second, shoulder dystocia is not caused by the instrument that is used for delivery, but rather by an inappropriately large fetus. Caughey et al report a very high rate of shoulder dystocia (1.5–3.5%), compared with 0.6–1.4% reported in the literature.[3] A higher mean birth weight or an unusually higher percentage of diabetic mothers could well bias the results. Third, despite a higher rate of shoulder dystocia in the vacuum group, the Erb's palsy and clavicle fracture rates in Caughey's study were low and similar (0.5% versus 0.75% and 0.6% versus 0.9%, respectively). Perhaps shoulder dystocia was overdiagnosed.

In general, we think that, because vacuum- and forceps-associated deliveries are implicated in different complications, for comparison matter the total complication rate is more important rather than the rate of each particular complication. We believe that, by performing instrumental delivery only as an outlet procedure and by using strict criteria for vacuum or forceps application, it is possible to lower the complication rate.[2] However, in spite of all the above criticism, we agree with the authors concluding sentence. We believe that it is the obstetrician's expertise that should determine which instrument should be used.

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REFERENCES

1. Caughey AB, Sandberg PL, Zlatnik MG, Thiet MP, Parer JT, Laros RK Jr. Forceps compared with vacuum: rates of neonatal and maternal morbidity. Obstet Gynecol 2005;106:908–12.
2. Lurie S, Glezerman M, Sadan O. Maternal and neonatal effects of forceps versus vacuum operative vaginal delivery. Int J Gynaecol Obstet 2005;89: 293–4.
3. Cunningham FG, Gant NF, Leveno KJ, Gilstrap III LC, Hauth JC, Wenstrom KD. Williams obstetrics. 21st ed. : ; 2001. p. 459.

In Reply:

We offer our responses to the comments of Lurie et al. First, they note in their recent brief communication[1] that they found no differences in neonatal morbidity. However, their study of 215 vacuum-assisted and 106 forceps deliveries was not powered to examine neonatal outcomes. Of interest, they had 3 shoulder dystocias and 10 fractured clavicles in the vacuum group and no shoulder dystocias and 2 fractured clavicles in the forceps group. To examine the rate of fractured clavicles and report a robust negative finding, we estimate that they would have needed 654 women in each group to have 80% power with a 2-sided alpha of 0.05.

Second, they state that our rate of third- or fourth-degree perineal lacerations[2] was notably higher than theirs. Although this is true, we note that in a prospective, randomized controlled trial (RCT) of operative vaginal delivery, Bofill et al[3] experienced a rate of third- or fourth-degree lacerations of 28.6% with forceps and 11.8% with vacuum. In fact, in a paper Lurie et al cited in their prior publication,[4] the rate of third- or fourth-degree lacerations were 44.4% for forceps and 27.9% for vacuum, higher than our rates. One reason for their particularly low rate of third- or fourth-degree lacerations may be that the majority of their perineal lacerations were listed as "unspecified."

In response to their query, we note that every operative delivery at our institution is attended by an experienced obstetrician. Regarding their comment that our rates of shoulder dystocia are high and may be overdiagnosed, we again refer to Bofill et al's study,[3] which revealed rates of shoulder dystocia of 1.9% with forceps and 4.7% with vacuum. We suggest that studies that find rates lower than these may be underreporting. Certainly, in retrospective studies, underreporting rather than overreporting is the bigger problem.

Finally, they state that shoulder dystocia is not caused by the instrument of choice. However, if the rate is higher with vacuum delivery in the setting of a prospective RCT, modern epidemiological theory would suggest that this relationship is causal in nature. Shoulder dystocia is not simply caused by a fetus that is "too big" but is also related to the geometry of the anatomical relationships between the fetus and the maternal pelvis. It is in this relationship that the vectors applied by the instruments used in operative vaginal delivery may interact.

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REFERENCES

1. Lurie S, Glezerman M, Sadan O. Maternal and neonatal effects of forceps versus vacuum operative vaginal delivery. Int J Gynaecol Obstet 2005;89:293–4.
2. Caughey AB, Sandberg PL, Zlatnik MG, Thiet MP, Parer JT, Laros RK Jr. Forceps compared with vacuum: rates of neonatal and maternal morbidity. Obstet Gynecol 2005;106:908–12.
3. Bofill JA, Rust OA, Schorr SJ, Brown RC, Martin RW, Martin JN Jr, Morrison JC. A randomized prospective trial of the obstetric forceps versus the M-cup vacuum extractor. Am J Obstet Gynecol 1996;175:1325–30.
4. Johnson JH, Figueroa R, Garry D, Elimian A, Maulik D. Immediate maternal and neonatal effects of forceps and vacuum-assisted deliveries. Obstet Gynecol 2004;103:513–8.

Management of Interstitial Pregnancy Using Selective Uterine Artery Embolization

To the Editor:

We recently published an article about a case of interstitial pregnancy that was treated by combination of systemic methotrexate and selective uterine artery embolization.[1] We would like to add further information. One year after this treatment, the patient started a new pregnancy. Early transvaginal ultrasonography demonstrated an intrauterine gestational sac. A round nonvascular structure of 10 by 8 mm with an echogenic ring and a tiny central hypoechoic area was observed in the right interstitial area. This structure progressively decreased in size, and at 22 weeks of gestation, the uterine wall thickness was similar between the 2 horns. The pregnancy was uneventful. A healthy, 3,100 g, normal male infant was delivered by cesarean at 38 weeks of gestation. Macroscopic examination of the right uterine horn during the procedure showed a small brown area on the external uterine wall without deformation.

This is the first report of subsequent pregnancy after uterine artery embolization for interstitial pregnancy. Our case demonstrated that intrauterine artery embolization is useful for interstitial pregnancy. Moreover, the successful outcome of this case suggests that this procedure may preserve fertility. This conservative management was also proposed to avoid surgery and uterine scar. However, actual risk of uterine rupture in subsequent pregnancies remains unknown. Uterine rupture has previously been described after surgery at the site of a previous intersti-

tial pregnancy as well as after conservative treatment.[2,3] In our case, we performed an elective cesarean delivery as suggested by Lau and Tulandi.[4]

In conclusion, subsequent pregnancy after uterine artery embolization for interstitial pregnancy can be allowed under close antenatal follow-up. In this situation, elective cesarean delivery seems to be more secure, as the risk of uterine rupture is unknown.

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REFERENCES

1. Deruelle P, Lucot JP, Lions C, Robert Y. Management of interstitial pregnancy using selective uterine artery embolization. Obstet Gynecol 2005; 106:1165–7.
2. Downey GP, Tuck SM. Spontaneous uterine rupture during subsequent pregnancy following non-excision of an interstitial ectopic gestation. Br J Obstet Gynaecol 1994;101:162–3.
3. Weissman A, Fishman A. Uterine rupture following conservative surgery for interstitial pregnancy. Eur J Obstet Gynecol Reprod Biol 1992;44:237–9.
4. Lau S, Tulandi T. Conservative medical and surgical management of interstitial ectopic pregnancy. Fertil Steril 1999;72: 207–15.

Errata

In "Genital Herpes Complicating Pregnancy" by Z. A. Brown, C. Gardella, A. Wald, R. A. Morrow, and L. Corey (Obstet Gynecol 2005;106:845–856), the following financial disclosure information was omitted: "Rhoda Morrow has received research support from GlaxoSmithKline, 3M, Trinity Biotech, and Biokit. She has also received honoraria or consulting fees from Focus, Bio Rad, Biovail, and Novartis. Drs. Gardella and Corey do not have anything to disclose."

ACOG Practice Bulletin Number 70 ("Intrapartum Fetal Heart Rate Monitoring") was reissued in December 2005 (Obstet Gynecol 2005; 106:1453–61). It replaces ACOG Practice Bulletin Number 62 of the same name (Obstet Gynecol 2005;105:1161–9), which had an error in it. In the corrected version, the word "decelerations" was changed to "accelerations" at the bottom of column 1, page 1457.

Letter to the Editor

Re: Atherton MJ, Daborn JP, Tsokos N, Jeffery JT & Yin MJ, Complications associated with tissue anchor migration after vaginal surgery using the tissue fixation system – a case series, ANZJOG 2012; 52 (1): 83–86

Dear Editor,

A common criticism of new operations is under reporting of complications. The confined geography of the initial TFS operations (Perth, WA) gives added importance to Atherton *et al.*'s[1] report: most complications are likely to be managed at the only tertiary urogynecology unit in that state, as acknowledged.[1]

The artificial neoligament concept behind 'tension-free surgery'[2,3] was tested in 1987 in 13 large animals with implanted retropubic Mersilene tapes, ends free in vagina.[2] Even animals with purulent sinuses were afebrile and well. Sinuses were sterile and settled immediately on tape removal. Histology, bacteriology and radioactive gallium studies demonstrated foreign body inflammatory reaction (FBIR), not infection, an important distinction. FBIRs (even purulent) are benign, not infections. Putting the case series[1] in this perspective:

1 It is not possible to avoid tape FBIRs. Permanent tapes are required for cure.[4]
2 Most patients do not have FBIRs to polypropylene implants.
3 The 'infections' reported[1] were most likely FBIRs, an important distinction: the 'infection' patient is febrile, looks & feels ill, with pathogenic bacteria >100 000/mL.
4 Though benign (like a splinter), FBIRs may nevertheless cause discomfort, purulent discharge (sterile), and dyspareunia, relieved immediately by removal/trimming of the tape, usually as an office procedure.
5 We performed 1012 TFS operations in Perth between 2003–2009 (audited manufacturer's figures).
6 Expected FBIR (erosion) rates are 4.8–10.5%.[5]

Reports of urethral transection (elastic tape), bowel and vessel injuries (instrument) by the TVT motivated us to develop the TFS.[6] According to,[7] reinforcing damaged ligaments with tapes would also cure pelvic organ prolapse (POP). The Tyco type 3 tape was the only non-stretch tape available in 2002 (replaced by a lightweight monofilament tape in 2008). 'Non-stretch' is critical to TFS function.

Animal studies (2002) proved that the anchors were encapsulated with collagen by 2 weeks, immobilising the anchors and infiltrating the tape,[6] Figure 1.

Translating this study to 'anchor migration',[1] 'migrations' are not possible without FBIR. With FBIR, collagenolysis occurs; scar dissolves, laying the anchor bare as in fig. 3;[1] and sterile pus surrounds anchor and tape that slide, surface and erode towards the medial (insertion) point as reported.[1] An infiltrated tape links hiatal muscles/perineal bodies to prevent displacement and POP, sometimes felt as a 'tight', but not painful, band.

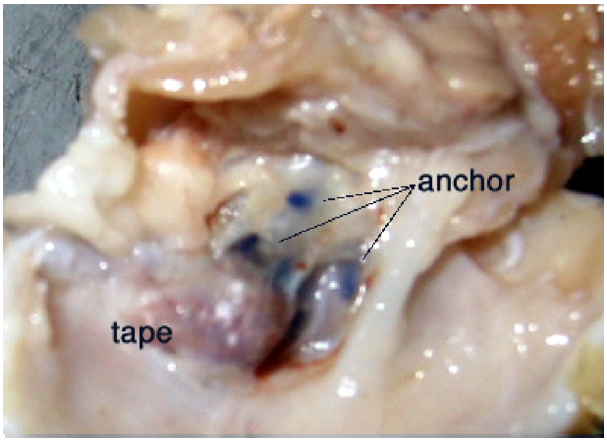

Figure 1 Fibrous tissue at 2 weeks. This shows how tissue encapsulates the polypropylene anchors of the TFS system and densely infiltrates the tape, rendering any movement of the anchor impossible.

We were concerned that laparotomy was performed to remove an anchor.[1] Tape and anchor in our experience are eminently accessible vaginally, a matter of simple dissection.

Conclusions

The TFS is a logical evolution of the 'tension-free' method that has revolutionised pelvic floor surgery. The TFS repairs pubourethral, cardinal, uterosacral, ATFP ligaments and perineal body, the ultimate causes of USI and POP.[7] The TFS uses only small segments of tape, a potential solution to the problems inherent in the recent FDA report on mesh. However, the TFS is not complication free. There is no surgery which is complication free. We agree that only an RCT can give a true picture of this method.[1]

Conflict of interest

Petros PE: Inventor of TFS instrument and technique-consultant for TFS surgical- no other conflict. Richardson PA: no conflicts.

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References

1 Atherton MJ, Daborn JP, Tsokos N *et al.* Complications associated with tissue anchor migration after vaginal surgery using the tissue fixation system – a case series. *Aust N Z J Obstet Gynaecol* 2012; **52** (1): 83–86.

2 Petros PE, Ulmsten U, Papadimitriou J. The autogenic neoligament procedure: a technique for planned formation of an artificial neo-ligament. *Acta Obstet Gynecol Scand*, 1990; **69** (Suppl. 153): 43–51.

3 Petros PE, Ulmsten U. The combined intravaginal sling and tuck operation. An ambulatory procedure for stress and urge incontinence. *Acta Obstet Gynecol Scand* 1990; **69** (Suppl. 153): 53–59.

4 Petros PE, Ulmsten U. The development of the intravaginal slingplasty procedure. *Scand J Urol Nephrol* 1993; **27** (Suppl. 153), Part IV: 61–84.

5 Lord HE, Taylor JD, Finn JC *et al.* A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence. *BJU Int* 2006; **98**: 367–376.

6 Petros PEP, Richardson PA. The midurethral TFS sling- a 'micro-method' for cure of stress incontinence- preliminary report. *Aust N Z J Obstet Gynaecol* 2005; **45**: 372–375.

7 Petros PE, Ulmsten U. An integral theory of female urinary incontinence. *Acta Obstet Gynecol Scand* 1990; **69** (Suppl. 153): 1–79.