CHAPTER 20

Committee 16

Surgery for Urinary Incontinence in Women

Chairman

A. R.B. SMITH (UK)

Members

F. DANESHGARI (USA), R. DMOCHOWSKI (USA), R. MILANI (ITALY), K. MILLER (USA), M. F. PARAISO (USA), E. ROVNER (USA) CONTENTS

A. REVIEW OF PROCEDURES

B. COMPLICATIONS OF SURGERY FOR STRESS INCONTINENCE

C. INCONTINENCE WITH PROLAPSE

D. CONFOUNDING VARIABLES

E. URETHRAL DIVERTICULAE

F. SURGERY FOR REFRACTORY DETRUSOR OVERACTIVITY

G. NEUROMODULATION

H. NON-OBSTETRIC URINARY FISTULAE

REFERENCES

Surgery for Urinary Incontinence in Women

A.R.B. SMITH,

F. DANESHGARI, R. DMOCHOWSKI, R. MILANI, K. MILLER, M. F. PARAISO, E. ROVNER

INTRODUCTION

This chapter critically reviews the literature on surgery for incontinence in women. Randomised controlled trials (RCT) still represent less than 10% of the surgical literature compared to over 50% of trials in other therapeutic areas such as drug therapy (Buchwald H 1996). Furthermore, in over half of the RCTs performed in laparoscopic general surgery, for example, the studies are underpowered or poorly analysed (Slim et al 1997) and this was well illustrated in our literature review on laparoscopic colposuspension.

The chapter in the second edition highlighted the difficulty in comparing different operations when confounding variables were not detailed or acknowledged. This chapter has further researched the evidence on confounding variables which may influence the outcome of surgery for stress incontinence whilst recognising that in many areas the data are poor. Since most of the research data analysed are from case series it is important to recognize the limitations of our knowledge of the influence of any of the confounding variables.

A further variable which has been recognized in determining the value of a procedure is the outcome measure used. The introduction of pre-operative urodynamics coincided with concern that objective rather than subjective evidence of cure of stress incontinence was important in demonstrating whether an operation was effective. The RCT comparing colposuspension with the Tension free vaginal Tape (TVT) illustrated that whilst both techniques achieved a similar outcome, the outcome measure used had a marked effect on the cure rate; objective testing employing Cystometry and a one hour pad test gave a 60% cure rate whilst only just over 30% patients reported complete absence of urinary symptoms. Furthermore, the combined objective and subjective cure rate for both procedures was only 26% (Ward et al 2002). Further research is clearly required to clarify which outcome measures should be employed in the treatment of incontinence with the acceptance that one measure may not be suitable for all forms of treatment. The further development of Quality of Life questionnaires may help address some of the outcome questions and this is covered in the relevant Chapter.

A. REVIEW OF PROCEDURES

I. ANTERIOR COLPORRHAPHY

The anterior colporrhaphy procedure is perhaps better termed the anterior repair with bladder buttress when relating to the surgery for urodynamic stress incontinence. Anterior colporrhaphy and the Kelly type repair are also a part of pelvic reconstructive surgery for prolapse (vide infra). Case report literature indicates a wide range of continence rates following this procedure, ranging between 31% and 100% continence (Jarvis 1994a). Meta-analyses of heterogenous studies suggest a continence rate of between 67.8 and 72.0% (Jarvis 1994a,b). Randomised trials which include anterior colporrhaphy in one arm and suprapubic surgery in the other show a continence rate of 66% (Jarvis 1998). Only 257 women received anterior repair and were compared, in seven trials, with 454 comparable women randomised to another intervention. The anterior colporrhaphy procedure is still used largely because of the relatively low morbidity of the procedure. The "serious complication rate" is in the region of 1%, the incidence of de novo detrusor overactivity is not greater than 6%, and compared with colposuspension there may be a shorter hospital stay and a 50% decrease in blood loss. The incidence of long-term voiding disorders following this procedure approaches zero (Jarvis 1994b, Beck 1991, Jarvis 1981, Loughlin 1982).

Figure A-I : The anterior repair is conventionally performed through a midline anterior vaginal wall incision. The diagram illustrates the creation of a layer of endopelvic fascia to provide additional support to the urethra.

Long-term results decrease with time such that a 63% cure rate at 1 year of follow up fell to 37% at 5 years of follow up (Bergman 1995). Long term follow up beyond the first year was only available in 3 randomised control trials (RCT). (Bergman 1989), (Liapis 1996), (Colombo 2000).

The view of the American Urological Association is that "Anterior repairs are the least likely of the four major operative categories (anterior repair, suburethral sling, colposuspension, long needle suspension) to be efficacious in the long-term" (Leach 1997). The literature regarding the anterior vaginal repair has also been reviewed fully by the Cochrane Library (Glazener 2000). Little new data has emerged for anterior colporraphy as an intervention for SUI over the last three years. However, two recent Level 4 studies have analyzed long term results for anterior colporraphy compared to other SUI interventions. Demirci et al (2002), found at ten year follow up, success rates with anterior colporraphy were 38% (21 of 67 women) as compared to 68% (14 of 28) with the Marshall Marchetti Krantz procedure and concluded that this intervention was inferior to the retropubic suspension. De Tayrac et al (2002) compared the anterior colporraphy with the Bologna operation. Similarly, they noted that the anterior colporraphy resulted in a 57% subjective and 53% objective cure rate in 28 women, whereas the Bologna procedure resulted in 87% subjective and 85% objective rates in 26 women at a mean follow up of 3 years.

CONCLUSION AND RECOMMENDATION

The view of the First International Consultation on Incontinence was "Perhaps the major indication for bladder buttress in contemporary practice must be the patient who prefers to sacrifice some degree of chance of becoming continent for a reduced chance of complication" (Jarvis 1998)(Level 1). There is no new literature which indicates that this recommendation should be revised. (Recommendation Grade A)

II. COLPOSUSPENSION

Based on a Pub-Med search 19 papers were reviewed, 6 of which were RCTs and 13 were observational cohort studies. These papers included an overall population of 1788 women submitted to Burch colposuspension; 311 were the ones considered in the RCTs and 1477 in the rest of the published studies. In 1651 women colposuspension was the primary procedure whereas in 137 it was a secondary one. The mean age of the women included was 54.4 years (26-88). The evaluation criteria of the surgical outcome were very heterogeneous, such as: subjective measures (symptoms) in 9 studies, objective measures (urodynamics) in 10 studies, complications (infections, visceral injuries, voiding dysfunction, post-op detrusor overactivity) in 8 studies; anatomical criteria in 3 studies, pre and post-operative QoL analysis in 4 studies. The mean follow-up was 29.7 months ranging from 3 months to 15 years. The subjective and objective cure rate was 78.4% (37-96%) and 85.5% (76-94%) respectively, with an overall average improvement of 90.5%.

Ward et al performed a RCT between the Tension Free Vaginal Tape (TVT) and colposuspension. When analysed on an intention-to-treat basis after 2 years they reported an objective success rate for Burch colposuspension of 51% versus 63% for the TVT group. (Ward et al 2004 Level 1/2) This trial analysed different outcome measures, both objective and subjective, and found similar cure rates for colposuspension with all outcome measures although the cure rates varied according to the outcome measure used. Subjective measures demonstrated a lower cure rate (**Table A-II.1**).

Burch colposuspension can achieve a high cure rate as a secondary procedure: Thakar (Thakar et al 2002) [level 2] reported an objective success rate of 80% and a subjective success rate of 71% with a mean follow-up of 4 years and Bidmead (Bidmead et al 2001) [level 3] reported an objective success of 81%. Using a pre and postoperative MRI evaluation DiGesù (DiGesu et al 2004) [level 3] found a significant association between surgical success and a shorter distance between bladder neck and levator ani muscle; the author reported an objective cure rate of 86% in 28 women 1 year after surgery.

The long term results of the Burch colposuspension have shown that its efficacy is maintained on a longterm basis: Langer et al (Langer et al 2001) [level 3] studied 127 women with a mean follow-up of 12.4 years (10-15 years) and reported an objective cure rate of 93.7%. All failure to repair urinary stress incontinence occurred within one year of the operation.

Demirci (Demerci et al 2001) [level 3] reported that cure rate dropped from 87.7% at a mean follow-up of 1.5 years to 77.4% at a mean follow-up of 4.5 years.

Persistent voiding difficulties were reported by Viereck (Viereck et al 2004) [level 2] in 3.5% of 310 women who underwent a Burch colposuspension with a mean follow-up of 36 months. Non-persistent voiding dysfunction defined and evaluated in different ways, have been reported in 12.5% (6-37.2%) women after colposuspension following primary surgery; Bidmead (Bidmead et al 2001)[level 3] reported 6% of voiding difficulties requiring intermittent self catheterisation (CISC) following use of colposuspension as a secondary procedure.

Postoperative detrusor overactivity has been described in 6.6% of women (range 1.0-16.6%) following colposuspension. However, Bidmead (Bidmead et al 2001) [level 3] did not report any case of detrusor overactivity after secondary colposuspension.

Genitourinary prolapse has been reported as a sequel to Burch colposuspension in 22.1% of women (range 9.5-38.2%). Most women are symptomatic and less than 5% request further reconstructive surgery. Ward (2004) [level 1 / 2] report 4.8% women needing a posterior repair whereas Kwon et al 2003 [level 3] report 4.7% required subsequent pelvic reconstructive surgery).

Other complications are described in the section on complications below.

CONCLUSIONS AND RECOMMENDATIONS

Open colposuspension is as effective in curing stress urinary incontinence as any other procedure in primary or secondary surgery. [Level 1]

Voiding dysfunction, detrusor overactivity and utero-vaginal prolapse are consistently reported sequelae to colposuspension. [Level 1]

There is some evidence that the benefit of colposuspension is maintained over time although, in common with all other continence procedures, recurrence does develop in some cases. The precise cause for the development of recurrence has not been studied.

Open colposuspension can be recommended as a procedure which is as effective as any other procedure for primary or secondary surgery and with long term proven success. [Grade A]

The widespread adoption of other procedures such as the TVT has been primarily driven by the reduced surgical morbidity of such procedures. It is not yet clear whether the TVT has the same longevity of action, associated detrusor overactivity, voiding dysfunction and vaginal prolapse (see section on TVT below) or whether other complications develop with time.

III. MARSHALL-MARCHETTI-KRANTZ PROCEDURE

The Marshall-Marchetti-Krantz (MMK) retropubic procedure was a common anti-incontinence procedure between 1950-90's. Krantz (Krantz 1980) described a personal series of 3861 cases with a follow up of up to 31 years and a 96% subjective cure rate. The success of MMK in treating SUI in women is reviewed in 58 articles that are predominantly retrospective studies between 1951-1998. The preoperative assessment was mainly with history and physical examination, with few studies reporting on other objective data such as urodynamic or pad test. These articles reported the treatment outcomes in a total of 3238 cases. The reported cure rate (mostly subjectively defined) was 88% (2850 patients). The improvement rate is reported as 91% (2946 patients). As a primary procedure in 1211 cases, the MMK had a success rate of 92%. In 1046 repeat cases, the success rate was 84%. The remaining 981 procedures could not be classified as primary or repeat. The mortality was 0.2%, with 22% overall complication rate. The one complication which would appear to limit the value of this procedure is osteitis pubis, a complication in 2.5% of these patients who undergo a MMK procedure (Mainprize 1988).

The longer term follow up data is limited. In the largest long term follow up series published, McDuffie reported a subjective continence rate of 89.7% at one year 85.7% at 5 years and 75% at 15 years (McDuffie 1981) Only one paper on the Marshall-Marchetti-Krantz was found (Demirci F et al, 2002). It was a 10 year follow-up comparing MMK to anterior repair.

		Type of study					
Authors	Journal reference		N. OF PTS	F. UP	CURE		Level of
					OBJ	SUBJ	evidence
Ward KL, Hilton P; UK and	Am J Obstet Gynecol 2004	Prospective	169 Burch	2 years	51%		-
Ireland TVT Trial Group	Feb; 190(2): 324-3	Randomised Trial	colposuspension				
Cheon WC, Mak JH, Liu JY	Hong Kong Med J. 2003	Prospective	43 Burch	1 year	86.0%	86.0%	1
	Feb;9(1):10-4	Randomised Trial	colposuspension				
Liapis A, Bakas P, Creatsas G	Eur Urol 2002; 41(4): 469-	Prospective	35	2 years	86.0%		2
	73	Randomised Trial					
Culligan PJ, Goldberg RP,	Int Urogynecol J Pelvic	Prospective	19	6.5 years	84.6%	93%	2
Sand PK	Floor Dysfunct. 2003	Randomised Trial					
	Nov;14:229-233						
Langer R, Lipshitz Y, Halperin	Int Urogynecol J Pelvic	Case series study	127	12.4 years	93.7%		3
R, Pansky M, Bukovsky I,	Floor Dysfunct.						
Sherman D	2001;12(5):323-6						
Demirci F, Yucel O, Eren S,	Gynecol Obstet Invest	Case series study	220	4.5 years	77.4%		ŝ
Alkan A, Demirci E,	2001;51(4):243-7						
Yldirium U							
Thakar R, Stanton S,	BJOG. 2002	Prospective cohort	56	4 years	80%	71%	2
Prodigalidad L, den Boon J	Oct;109(10):1115-20	study					
Bidmead J, Cardozo L,	BJOG. 2001	Prospective Case	83	6-12	92% (81%	71% cured	ю
McLellan A, Khullar V,	Apr;108(4):408-13	series study		months	secondary	21%	
Kelleher C					procedure)	occasional	
						leakage	
DiGesu GA, Bombieri L,	Am J Obstet Gynecol. 2004	Case series study	28	l year	86.0%		n
Hutchings A, Khullar V,	Mar; 190(3): 614-9						
Freeman R							
Viereck V, Pauer HU, Bader	Ultrasound Obstet Gynecol.	Prospective cohort	310	4 years	76.8%		2
W, Oppermann M, Hilgers R,	2004 Mar;23(3):277-83	study					
Gauruder-Burmester A, Lange							
R, Emons G, Hackenberg R,							
Krauss T							
Kwon CH, Culligan PJ, Koduri	Int Urogynecol J Pelvic	Case series study	09	4.5 years	4.7% of subsequent pelvic	quent pelvic	С
S, Goldberg RP, Sand PK	Floor Dysfunct. 2003				surgery	×	
	C-126:(C)+1;VON						

Table A-II.1 tabulates further LEVEL 2 and 3 evidence studies to illustrate the efficacy of colposuspension

However it was not considered for review because only 50% of the patients were contacted for followup (14 of the initial 28) and just with subjective measures.

CONCLUSION AND RECOMMENDATION

The MMK procedure appears to produce a similar cure rate to colposuspension according to Level 3 evidence. The complication of osteitis pubis in 2.5% women detracts from the value of the procedure. There seems little evidence to support its use instead of colposuspension. (Grade C)

IV. PARAVAGINAL REPAIR

The concept of a paravaginal defect repair is, at least in theory, a logical one. It was first described by White in 1909 (White 1909) but the type of repair described by Kelly four years later (Kelly 1913) became more popluar. The Kelly type of anterior repair for urodynamic stress incontinence provides some central support but if there is deficiency in lateral support, then a central repair is likely to be of limited benefit.

Several groups have reported results with paravaginal repair for SUI. Miklos et al (2000) reported laparoscopic paravaginal repair and Burch urethopexy as combined procedures in 130 patients. 4 women (2.3%) suffered lower urinary tract injuries (cystotomies) and 70% were cured. However, these authors present a combined procedure and not results for isolated paravaginal repair. Ostrzenski reported a SUI cure rate of 93% in 28 women after laparoscopic paravaginal repair (Level 4). Bruce et al (1999) evaluated paravaginal repair alone and in combination with rectus fascia sling in two groups of women with SUI. At a mean follow up of 17 months the cure and improved rate for paravaginal repair alone was 84%, and 93% for the combined procedures. These authors felt that a sling should be performed for any woman with minimal bladder neck mobility at time of paravaginal repair (Level 4). Similarly, Clemons et al (2003), noted that in 17 of 19 (89%) women with SUI who underwent paravaginal repair with human dermal graft (33 women underwent the procedure -19 were incontinent), incontinence resolved and urgency improved in 20 of 23 (87%) (Level 4). Scotti et al (1998) noted that in 34 of 36 women with SUI, cure was achieved at a mean of 39 months after surgery with vaginal paravaginal repair (Level 4).

Mallipeddi et al (2001) followed 45 patients after vaginal paravaginal repair for a mean of 1.6 years. Of those women with SUI (21), twelve (57%) had persistent SUI after surgery. They concluded that this technique has "limited" applicability for SUI (Level 2).

However, there is as yet only a single published randomised comparison of colposuspension with paravaginal defect repair. In this study 36 patients were identified at the time of surgery when they were randomly allocated to treatment by either colposuspension or defect repair using non-absorbable suture material. At follow-up six months after surgery, there was an objective cure rate of 100% for those patients undergoing colposuspension but only 72% for those undergoing paravaginal repair (Colombo 1996) (Level 1 / 2).

CONCLUSIONS AND RECOMMENDATION

Whilst there is some evidence that repair of paravaginal defects may result in cure of stress incontinence (Level 3) there is also Level 1/2 evidence that paravaginal repair, performed abdominally, is less effective than colposuspension. Paravaginal repair may be approached via open abdominal, laparoscopic, or vaginal routes. Level 3 and 4 evidence suggests a reasonable level of efficacy in most studies, although the approach is often combined with other types of incontinence procedures and therefore overall continence rates derived from this technique must be viewed in light of these combined procedures. (Grade A)

V. LAPAROSCOPIC COLPOSUSPENSION

Five randomized controlled trials (Table A-V.1, Burton 1999, Carey 2000, Fatthy 2001, Su 1997, Summitt 2000) comparing laparoscopic with open colposuspension show similar or lower cure rates associated with laparoscopic Burch. Moehrer (Moehrer et al 2003) recently published a systematic review on laparoscopic colposuspension using the Cochrane Incontinence Review Group's specialized registrar of controlled trials. The authors' meta-analysis of four RCTs (Carey 2000, Fatthy 2001, Su 1997, Summitt 2000) demonstrated that subjective perception of cure showed no difference between groups ranging from 85% to 96% in the laparoscopic group and 85% to 100% in the open group after 6-18 months of follow up. When analyzing urodynamic studies, a significantly lower success rate was shown for laparoscopic compared with open colposuspension (relative risk [RR] 0.89 confidence interval [CI] 0.82 to 0.98) (Burton 1999, Carey 2000, Fatthy 2001, Su 1997, Summitt 2000) with an additional 9% risk of failure for laparoscopic versus open colposuspension (risk difference [RD] -0.09, 95% CI -0.16 to 0.02). When one poor quality trial (Su 2000, problems with randomization) was excluded from the analysis for objective cure, the cure rate for stress urinary incontinence was lower but not significantly so for the laparoscopic compared to the open colposuspension (RR 0.91; 95% CI 0.82-1.01) with 8% more failures for laparoscopy compared to open procedures (RD -0.08, 95% CI -0.15 to 0.00).

Based on a single trial, two stitches placed on each side of the bladder neck are better than one (Table A-V.1, Persson 2000). When further analyzing the methods of the RCTs, Carey (2000), Fatthy (2000), and Summitt (2000) performed identical procedures by both routes and showed similar cure rates; however, Fatthy et al used only one polypropylene suture on each side.

The main criticisms of Burton's trial (1999) are that he had not gained sufficient experience with laparoscopic colposuspension prior to initiating the study and that the suture used was absorbable with a smaller needle, which may have included insufficient thickness of tissue. Similarly, Su et al (1997) used three absorbable sutures in the open Burch compared to a single nonabsorbable suture in the laparoscopic procedure. Unfortunately, three of the five RCTs, those of Burton (1999), Carey et al (2000), and Summitt et al (2000) have only been published as abstracts. In 2001 Morris et al (Morris 2001) reported on the 5 year follow-up of a RCT of 72 patients, which is not listed in the Cochrane Incontinence Review. Laparoscopic colposuspension produced an objective cure rate of 77% at 5 years compared to a cure rate of only 48% for open colposuspension. It is uncertain how much the experience of the surgeons influenced the results since the majority of the laparoscopic procedures were performed by a single surgeon whereas the open procedures were performed by a variety of surgeons.

A number of cohort studies (Ross 1995, Miannay 1998, Saidi 1998) have shown similar cure rates between laparoscopic and open colposuspension (**Table A-V.1**). An objective cure rate of 89% to98% with follow-up to 36 months has been reported in several case series (Liu 1994, Lam 1995, Ross 1998).

Moehrer et al (Moehrer 2003) showed that trends (no statistical difference) were shown towards a higher complication rate (bladder injury (Burton 1999, Carey 2000, Fatthy 2001, Summitt), obturator vein laceration (Carey 2000, Summitt], retropubic haematoma, wound infection, voiding difficulties, UTI), less postoperative pain, less analgesia requirement, shorter hospital stay and time to return to normal function for laparoscopic compared with open colposuspension. Operating time was longer for laparoscopic than for open colposuspension in four RCTs (Burton 1999, Carey 2000, Fatthy 2001, Su 1997, Summitt 2000).

Estimated blood loss was higher (Burton 1999, Carey 2000, Fatthy 2001, Su 1997, Summitt 2000) and duration of catheterization was longer (Burton 1999, Carey 2000, Fatthy 2001, Su 1997) in the open colposuspension group when compared to the laparoscopic group. In a previous review article of laparoscopic colposuspension (Paraiso 1999), major intraoperative and short-term complications (urinary tract injury, bowel injury, inferior epigastric and other major vessel injury, blood loss requiring transfusion, and abscess formation in the space of Retzius) were noted in up to 25% of cases. Bladder injury was the most common intraoperative complication but declined with increased experience.

Long-term complications included failure requiring reoperation, new onset intrinsic sphincter deficiency, de novo detrusor overactivity, urinary retention requiring permanent catheterization, voiding pain with or without suture material noted in the bladder during follow up cystoscopy, ureteral obstuction requiring reoperation, vesicovaginal fistula, vesicocutaneous fistula (resulting from a patent urachus), posterior and apical segment compensatory defects requiring surgery, and incisional hernias. No deaths have been reported.

Two cases of multiple foreign body erosion (tacks) into the bladder have been reported after modification of laparoscopic colposuspension using mesh and tacks (Kenton 2002). Modifications of laparoscopic colposuspension using mesh and tacks or staples and diminishing the number of sutures in order to decrease operating time are not recommended because of compromise to the procedure. Generalisability of the data regarding laparoscopic Burch colposuspension is a concern because the majority of investigations were carried out by expert laparoscopists. Despite the steep learning curve associated with laparoscopic colposuspension, implementation of modifications should be avoided.

CONCLUSIONS AND RECOMMENDATIONS

Although there are 56 articles published on laparoscopic colposuspension, the data is influenced by many confounding variables. A meta-analysis by Moehrer et al (2003) of the RCTs comparing laparoscopic and open colposuspensions published by Burton (1999), Carey (2000), Fatthy (2001), and Summitt (2000) show similar subjective cure rates (RR 1.00, 95% CI 0.95 to 1.06) and a lower objective cure rate but not significantly so (RR 0.91, 95% CI 0.82 to 1.01) with an additional 8% risk of failure for laparoscopic compared with open colposuspension (risk difference [RD] -0.08, 95% CI -0.15 to 0.00) (Level 2). Although it is possible that no difference exists between laparoscopic and open colposuspension, there appears to be a trend towards higher cure rates with the open Burch procedure (Level 1/2). The evidence on laparoscopic Burch colposuspension is limited by short-term follow-up, small numbers and poor methodology in some studies; therefore, the value of this procedure cannot be determined. Further well-designed and adequately powered randomized trials are required.

No recommendation is possible at this time for the use of laparoscopic Burch colposuspension.

VI. NEEDLE SUSPENSION

Multiple suspension procedures have been described in the past. The first procedure being described by Pereyra (Pereyra 1959) [level 3]. This was a standard needle type suspension. Numerous procedures have subsequently evolved from this including the Gittes procedure (an incision-less needle suspension procedure) and the Stamey procedure (Stamey 1973) (level 3), utilizing suspending sutures and patch materials.

Needle suspensions are indicated for either primary or recurrent urinary stress incontinence and used to be considered a second-choice option when a formal retropubic procedures were considered unsuitable. An example might be the old or frail woman or where colposusopension may be technically difficult because of poor vaginal mobility, narrowing; or where recurrent surgery has led to scarring.

Glazener and Cooper (Cochrane Database Systematic Review 2002) performed a meta-analysis of randomised or quasi-randomised trials that included needle suspension for the treatment of urinary incontinence. Eight trials were identified evaluating six different types of needle suspension in 327 women compared with 407 who had other anti-incontinence procedures. Although the reliability of the evidence was limited by poor quality and small trials, some conclusions can be drawn for primary incontinence: the calculated subjective success rate of the needle suspension procedures was 74% at one year followup. Needle suspension resulted in a 48% perioperative complication rate. In secondary operations too few women with recurrent incontinence were studied to draw conclusions.

The remaining literature provides a lower level of evidence. Wennberg et al (2003) [level 3] report on 24 women prospectively observed and treated with the Stamey procedure, attaining an 83% improvement rate in clinical symptoms for a mean follow-up of 37 months. Concern on the complication rate has recently been reported by Takahashi et al (2002) (level 3). In 86 women undergoing the Stamey procedure he observed a 37.2% overall complication rate.

Recently, procedures have been described utilizing bone anchors and a suspending system. Results with this procedure are extremely poor. Tebyani et al (2000) [level 3] reported on 49 patients of whom 42 were available for interview, with a mean follow-up of 29 months (range 16- 52). Only 5% of patients were cured, 12% significantly improved and 83% considered themselves a failure. However more concern has been raised on the safety aspects of this procedure. Tsivian et al (2003) [level 3] reported on 31 women who underwent to an incision-less transvaginal bone anchor cystourethropexy. Twenty-eight women were available for a 60 months follow-up with a 21.4% cure rate. In 5 patients 11 sutures passed through the bladder and only 5 were detected intraoperatively. In 8 patients 12 anchors had become detached from the bone. In one case a vesicovaginal fistula developed, and in another one a pubic osteomyelitis occurred. On this basis the authors conclude that this procedure is unsuitable for urinary stress incontinece.

The needle suspension approach has been criticised because of a reduced efficacy in the long term. Kursch et al (1972) [level 3] reported a 64% efficacy rate at initial follow-up in 25 patients, but this fell to 50% after one year. Employing the Stamey procedure Hilton and Mayne (1991) reported an objective cure rate of 83% at 3 months, falling to 68% at 4 years. Athanasopoulos et al (2003) [level 3] reported

Reference	Type of Operation	No. of Pts Total/Grp	Duration Follow up	Cure criteria	Cure*/ Success Rate	Level of Evidence
Burton G 1997		60	5 yrs	Pad tests, urinary diaries,	57% Lsc	_
Abstract	Lsc Burch	30		video cystourethrographs, UPP	90% Open	
	Open Burch	30				
Carey M 2001	Lsc Burch	200	6 months	Urodynamic studies		_
Abstract	Open Burch	104				
		96				
Fatthy H 2001	Lsc Burch	74	1.5 yrs	Urodynamic studies	Success	_
	Open Burch	34			88% Lsc	
		40			85% Open	
Summitt RL 2000	Lsc Burch	62	1 yr	Urodynamic studies	93% Lsc	_
Abstract	Open Burch	28			88% Open	
		34				
Su TH 1997	Lsc Burch	92	1 yr	Urodynamic studies	80% Lsc	2
	One-stitch	46			96% Open	
	Open Burch	46				
	Three-stitch					
Persson J 2000	Lsc Burch	108	1 yr median	"Ultrashort" pad test	Cured: Objective	_
	Two-stitch (2)			cured—no leaking, improved <33% preop	83% (2) vs 58% (1)	
	One-stitch (1)			pad test	Subjective	
				Subjectively "cured",	89% (2) vs 65% (1)	
				"improved"on questionnaire	Improved: Objective	
					12% (2) vs 27% (1)	
					Subjective	
					7% (2) vs 32% (1)	
Ross JW 1995	Lsc Burch	62	1 yr	Urodynamic studies	94% Lsc	2
	Open Burch	30			93% Open	
		32				
Miannay E 1998	Lsc Burch	72	2 yrs		68% Lsc	3
	Open Burch	36			64% Open	
		36				
Saidi NH	Lsc Burch	157	13 mos Lsc		91% Lsc	3
1998	Open Burch	70	16 mos		92% Open	
		87	Open			

Table A-V.1. Summary of reported data on laparoscopic Burch colposuspension for treatment of Urodynamic Stress Incontinence in Women

*Cured and improved are listed if defined

on 32 women treated with a modified transvaginal needle suspension. The 84% cure rate at one year follow-up fell to 72% five years postoperatively. However more recently small case series [level 3] have been reported with more sustained results in the long term as can be seen from the **table A-VI.1**.

Glazener and Cooper compared open colposuspension with the needle suspension and reported that the latter produced an inferior subjective success rate at one year follow-up (86% vs. 74%). In the same review needle suspension resulted in a higher perioperative complication rate: 48% vs 30%. When compared with anterior repair the needle suspension procedure cure rate was similar (64% vs. 61%), but the data were insufficient to be reliable and there was little information about morbidity (Cochrane Database Systematic Review 2002).

CONCLUSION AND RECOMMENDATION

The limited evidence available indicates that needle suspension is less effective in the short and the long term than open colposuspension. Needle suspension does not appear to produce a lower complication rate than open colposuspension.

Bone anchor procedures are associated with a lower cure rate and a higher complication rate.

There is little evidence available to support the continued use of needle suspension procedures. (Grade A)

VII. SLINGS

Pubovaginal slings have been described since the beginning of the twentieth century. Significant advancements have occurred since those early slings yet many variables remain which may influence the results. It is unclear from the literature whether the numerous modifications described materially influence the outcome. The type of incision has evolved. Initially, a combined abdominovaginal approach was used. An abdominal incision(s) was used to expose the rectus fascia which acts as the fulcrum for suspension. Through the vaginal incision, the periurethral fascia is exposed at the level of the bladder neck and the endopelvic fascia perforated laterally. After suburethral positioning, sling ends (for a fulllength sling) or sutures are transferred into the abdominal incision. After vaginal closure, sutures are tied above the rectus fascia without tension. Slings using the pubic symphysis and Cooper's ligament as points of fixation have been described. Free suspension in order to shorten the length of the sling have been descibed. More recently bone anchoring has been used as an alternative form of suspension.

Sling material varies and even the length of material used has been changed from study to study. Materials have included; autologous materials (fascia, dermis, tendon), allografts (fascia, dermis, dura) and xenograft (porcine dermis, bovine pericardium, dura). Sling length varies from "full-length" (>20cm) to "patch slings" (3-5cm).

1. AUTOLOGOUS SLINGS (LEVEL 3, 4 EVIDEN-CE)

The first autologous tissues used to augment bladder outlet resistance included transplanted gracilis muscle (Hohenfellner and Petrie 1986), pyramidalis flaps, (Goebel R 1910) and levator ani. (Squier JB 1911). Aldridge popularized the use of rectus fascia in the 1940's; (Aldridge 1942). However, this material only achieved widespread use nearly 40 years later, after groups headed by McGuire (McGuire EJ et al 1978) and Blaivas (Blaivas JG and Jacobs BZ 1991) confirmed its efficacy. Fascia lata is the other common autologous material, having been first used by Price in 1933 (Price PB 1933). Both rectus fascia and fascia lata appear to have common properties. They are available in nearly all patients although the quality may vary and are not rejected. There has been no scientific study of the biological processes which occur when these materials are used; some women replace the fascia with dense fibrosis whilst others produce minimal fibrosis. Harvest of either material requires additional tissue dissection or a second incision. The results of autologous slings with rectus fascia and fascia lata are summarized in Table A-VII.1.

There is a considerable volume of autologous sling literature. While the subjective and objective cure rates range from 50% (Beck RP et al 1988) to 100%, (Hassouna ME & Ghoniem GM 1999, Gormley EA et al 2002, Richter HE et al 2001) the mean cure rate is nearly 87%. Follow-up has exceeded 10 years in some studies. (Kane L et al 1999, Groutz A et al 2001, Karram MM & Bhatia NN 1990, Handa VL & Stone A 1999). Both materials result in a similar incidence of de novo voiding symptoms post-operatively (0-27%). After initial studies reported long-term voiding dysfunction (refractory urge incontinence, clean intermittent catheterization, and sling revision)

	evidence.
4	5
1	siana
	mun
	articles
7	g
1.1.1	businand
	3
- 11 - 1 V	N eeate
	-
TTT A TTTT	Iable. A-VI.

		Type of study			CURE		I arra af
Authons	Journal reference	type of study	N. OF PTS	F. UP			Tevel of
Aumors					UBJ	SUBJ	evidence
Glazener CM, Cooper K	Cochrane Database Syst Rev 2002;(2): CD003636	Meta-analysis of randomized or quasi- randomised studies	327 n. s. procedures versus 407 other procedures	~		74%	1
Hilton P & Mayne CJ	Br J O&G 1991;98:1141-9	Uncontrolled observational study	100	27 months		53% (< 65 yrs old) 76% (> 65 yrs old)	ŝ
Wennberg AL, Edlund C, Fall M, Peeker R	Scand J Urol Nephrol 2003; 37(5):419-23	Prospective observational study	24	28 to 100 months	42%	83%	3
Athanasopoulos A, Barlas P, Perimenis P, et al.	Urol Int. 2003; 71(1):41- 4	Prospective observational study	32	1 to 5 years	84.4% (1 year) 72.4% (5 years)		с,
Takahashi S, Miyao N, Hisataki T, et al.	Urol Int 2002; 68(3): 148-51	Prospective observational study	86	37.6 months	Complications 37.2%		3
Tebyani N, Patel H, et al	J Urol 2000 May; 163(5): 1510-2	Retrospective cohort study (Bone anchors suspension)	49	29 months		5% cure 12% improvement	3
Tsivian A, Shtricker A, et al	J Urol. 2003 Jun;169(6):2244-5.	Prospective observational study (Bone anchors suspension)	31	60 months	21.4%		3
Costantini E,Pajoncini C, Zucchi A, et al.	Int Urogynecol J Pelvic Floor Dysfunct 2003 Jun; 14 (2): 113-8	Prospective observational study	37	62 months	85%		3
Nguyen JK, Bhatia NN	Urology 2001 Dec; 58(6):947-52	Retrospective cohort study	34	23 +/- 14.4 months	88%	91%	3
Klutke JJ, Bergman J, et al	J Reprod Med 2000 Jul; 45(7): 541-5	Prospective observational study	19	60 months	86%		3

Author	Matari	Z	(m) 1	F/I mos (moan)	0% Curo	0/, noreiet	0/ do novo	Voiding Dusfunction
	al					storage sx	storage sx	
Kaufman('82)	Rectus	15	15	<48	93.3	1	I	Obstruction (33%): dilation/VIU (27%), excision (7%)
Schultz-Lampel('95)	Rectus	Ξ		3-63 (24)	63.6	0	0	
Loughlin('96)	Rectus	22	5	4-22 (15)	72.7	40	6	ST retention/dilation (23%)
Mason('96)	Rectus	63	4	3-27 (12)	93.7	16 ^a	1	CIC: 3m (19%); CIC: 6m (6%); LT CIC (3%); revision (2%)
Zaragoza('96)	Rectus	60	6-8	11-34 (25)	100	31	12	
Siegel('97)	Rectus	20^{b}		144-216 (185)	80	55 ^a	1	Incision (30%)
Carr('97)	Rectus	96	11-13	3-43 (22)	97.9	22^{a}		Refractory UI (6%); CIC<3m (7%); pCIC (3%); early revision (1%)
Barbalias('97)	Rectus	32	12	30-38	65.6	19 ^a	0	
Chaikin('98)	Rectus	251	15	12-180 (37)	72.9	23	8	CIC>1m (2%)
Maheshkumar('98)	Rectus	43°		3-29(17.4)	95.3			iCIC (42%); incision (5%)
Hassouna('99)	Rectus	82	7	6-96 (41)	89.1 ^d			
Kane('99)	Rectus	13	5°	19-38 (26)	100	0	8	Dilation/VIU (8%)
Morgan('00)	Rectus	247	6-8	22-68 (51)	82.2	26	7	Retention>3m, urethrolysis (2%)
Kochakarn('01)	Rectus	100		4-36 (12.1)	94	0	5	mCIC: 8.9w (39%)
Groutz('01)	Rectus	67	15	12-60 (34)	67.2	ı	10	Posture/weak stream: 3w (22%)
Kuo('01)	Rectus	24	20	19-35(24)	95.8	I	8	Retention: 3m, urethrolysis (4%)
Borup('02)	Rectus	31	12	60	96.8	29	13	CIC: 6m (39%), CIC: 1y (16%), CIC: 5y (3%); revision: 1y (3%)
Gormley('02)	Rectus	41		74-91	95.1		I	
de Rossi('02)	Rectus	27	8	20	100	21^{a}	7	Weak stream (7%)
Kreder('96)	Rectus/ FL	27	ı	9-32 (22)	96.3	63	12	LT CIC (7%)
Golomb('97)	Rectus/ FL	18	15	12-53 (30.7)	88.9	0	5	Refractory urge (6%)
Haab('97)	Rectus/ FL	37	12-15	24-60 (48.2)	73	40	27	Refractory urge (24%); CIC (3%)
Wright('98)	Rectus/ FL	33	13-15	15-28 (16)	93.9	40	10	Urethrolysis (3%)
Petrou('01)	Rectus/ FL	14	10	5-41 (17)	50	25	0	LT CIC (7%)
Richter('01)	Rectus/ FL	57 ^f	24	0.5-134 (42)	84	18 ^a	1	High PVR (16%), posture (4%), CIC (7%)
Flynn('02)	Rectus/	71	12	30-56 (44)	90.1	28	5	Retention>45d (3%); urethrolysis: 1w (1%)

slings
lata
fascia
and
rectus
5
Results
Table A-VII.1.

slings
lata
ascia
and f
rectus
ts of
Resul
-
continued)
to be
(to
A-VII.I.
Table

		LT retention (6%)	Mean void dysf: 2m; incision (3%)	Mean spont void: 20d, max: 39d	CIC: 3m (13%), incision (13%)	Mean CIC: 3.3w, CIC: 4m (3%), incision	(0)		
I	•	LT	Me	Me	CIC	Me	(0%C)	'	5
ı		1		ı	0	14			
51 ^h	86		6 ^a	20^{a}	33	18		,	
94.1 ^g	94.4 ⁱ	86.6	98.2	06	93.3^{j}	69.7		71.4	
(30.5)	24-84	12	1.5-264 (>24)	12-24	6-42	3-33 (14)		10-22(14.9)	
10	24+		>17	5x7	15-20	24-28		>17	
23	36	97	170	10	60	30		14	~
 Rectus/ FL	FL	FL	FL	FL	FL	FL		FL	ļ
Chien('02)	Low('69)	Addison('85)	Beck('88)	Karram('90)	Breen('97)	Govier('97)		Berman('97)	1000

a: % total postoperative symptoms; b: includes one non-rectus sling; c: 18 patients had sling attached to Cooper's ligament; d: includes cured and improved patients; e: suprapubic bone anchors; f: includes Aldridge-style rectus slings; g: includes cured and improved patients; h: % difference between total postoperative and preoperative symptoms; i: includes 3 urethrovaginal fistulas that were diagnosed and repaired shortly after initial sling surgery; j: includes patients with <3 leakage episodes weekly.

N = number of patients; F/U mos = months of follow-up; %Cure = patients cured (%); % persist storage sx = persistent storage symptoms; %de novo storage sx = de novo storage symptoms; LT = long-term; CIC = clean intermittent catheterization; iCIC = intermittent unexpected CIC; pCIC = permanent unexpected CIC; void dysf = voiding dysfunction; posture = assuming a posture to void; m = months; d = days; w = weeks. in as many as 33%, (Carr LK et al 1997, Kane L et al 1999) more recent reports have reported these findings in less than 10% of patients. Other rare complications have resulted almost exclusively from excessive sling tension. Two cases of urethral erosion have been reported with rectus fascia and one case with fascia lata (Wright EJ et al 1998, Wall LL et al 1996, Neal DE & Foster L 2001). Three cases of urethro-vaginal fistula were reported in early experience with fascia lata (Berman CJ & Kreder KJ 1997). Both rectus sheath fascia and fascia lata vary in quality on harvesting; it is not known how much this influences outcome. While harvesting fascia lata avoids a larger suprapubic incision, a change in patient position and an additional incision is necessary. Additionally, incisional leg pain and seroma formation are complications unique to fascia lata harvest. There is little documentation about the incidence of problems associated with harvesting autologous fascia. In summary, rectus fascia and fascia lata slings are safe, associated with few complications and result in long term cure. On the available evidence they should be considered the "gold standard" of materials available for sling surgery. It should be noted, however, that this statement is made from Level 3 evidence alone.

Other autologous materials have also been used for sling construction. These have included dermis (Muller SC 1993), extensor brevis (Choe JM et al 2000), palmaris longus tendon (Buck BR & Malinin TI 1994), skin (Amundsen CL et al 2000), rectus abdominis muscle flap (Von Kolmorgen K 1980), semitendinosus (Iosif CS 1983), aponeurosis of external oblique Rottenberg RD 1985), and vaginal wall free graft (Enzelsberger H et al 1996). While some authors report encouraging short-term results, little long-term information is available to support use of these tissues.

2. Allograft Slings (Level 3, 4)

The motivation for the development of alternative sling materials has been the desire to reduce surgical time and morbidity and to improve convalescence. Cadaveric allografts have been used in ophthalmic and orthopedic procedures for over 20 years. The main advantage of allografts is the elimination of the need and time for harvesting autologous fascia, thus minimizing morbidities such as wound complications and post-operative pain. A theoretical advantage of allografts over synthetic materials is biocompatibility and lower risk of erosion. A theoretical disadvantage is the potential for disease transmission. Although all cadaveric tissues undergo serologic screening for human immunodeficiency virus (HIV) and hepatitis B, false negative results are possible. The risk of HIV transmission from a frozen allograft has been estimated to be 1 in 8 million (Liscic RM et al 1999), while the risk of developing Creutzfeldt-Jakob's disease (CJD) is approximately 1 in 3.5 million (Handa VL et al 1996). The allografts used in sling surgery have been lyophilized dura mater, several preparations of fascia lata, and acellular dermis.

Lyophilized human dura mater has been used in urologic surgery for many years in Europe. With followup ranging from 6 to 150 months, cure rates of lyophilized dura slings have ranged from 86% to 94% (Sutaria PM & Staskin DR 1999, Lerner ML et al 1999, Elliott DS & Boone TB 2000), Brown SL & Govier FE 2000). No specific complications were reported with this material. While no urological surgery has, to date, been complicated by transmission of infection, a case of CJD has been reported in a Croatian male who had received a cadaveric dura graft 12 years earlier (O'Reilly KJ & Govier FE 2002).

Cadaveric fascia lata (CFL) has also been used extensively for repair of various tissue defects, but has been used for sling surgery only since 1996.(Vereecken RL & Lechat A 2001). There are 2 main techniques of processing CFL: solvent dehydration and gamma irradiation (Tutoplast®, Mentor) and freeze drying (tissue banks and FasLata®, Bard). Studies regarding the strength of the 2 preparations reveal conflicting results. Sutaria and Staskin found no statistical difference in tissue thickness or maximum load to failure between freeze-dried CFL, solvent-dehydrated CFL, and acellular cadaveric dermis (Walsh IK et al 2002). However, Lemer et al found that solvent-dehydrated CFL and acellular dermis had a similar load to failure as autologous rectus fascia, while freeze-dried CFL was significantly less stiff and had a significantly lower maximum load to failure (Bodell DM & Leach GE 2002). Both preparations require 15-30 minutes to rehydrate in saline before implantation. Results of studies using CFL are reported in Table A-VII.2.

Since a report of early allograft failure (Wright EJ et al 1998), much attention has been focused on this topic. The literature suggests that early failure of allograft slings (within 3 months of surgery) may approach 20%, especially after using CFL that has been freeze-dried in processing (Jarvis GJ & Fowlie A 1985, Iosif CS 1987). In addition, recent reports

Author	Preparation	Ν	L (cm)	F/U mos	%Cure (mean)	% persist	%de novo storage sx	Voiding Dysfunction storage sx
Elliott('00)	Solvent- dehydrated	26	12	12-20 (15)	76.9	82	13	-
Amundsen('00)	Freeze-dried	91	15	3-37 (19.4)	62.6	59	44	Urethrolysis (1%)
Govier('00)	Freeze-dried	104	24	(12)	66.3a	-	-	LT retention (2%)
Vereecken('01)	Freeze-dried	8	>20	24	100	0	13	Incision (13%)
Walsh('02)	Freeze-dried	31	10	12-14 (13.5)) 93.5	52	-	Posture (77%), CIC: 4m (35%), CIC: 1y (3%)
Flynn('02)	Freeze-dried	63	12	24-36 (29)	87.3	21	28	Retention: 56d (2%)
Chien('02)	-	83	10	(27.4)	90.1b	51c	-	-
Bodell('02)	Solvent-dehydr	ated	186	7d	12-38 (16.4)	75.8e	28f	-Osteitis (1%)

Table A-VII.2. Results of cadaveric fascia lata slings

a: updated cure rate with 8 additional failures between 4-13 months postoperatively71; b: includes cured and improved patients; c: % difference between total postoperative and preoperative sx; d: transvaginal approach, infrapubic bone anchors; e: patients reporting >50% improvement and no complaints of SUI; f: % total postoperative symptoms.

N = number of patients; F/U mos = months of follow-up; %Cure = patients cured (%); % persist storage sx = persistent storage symptoms; %de novo storage sx = de novo storage symptoms; LT = long-term; CIC = clean intermittent catheterization; posture = assuming a posture to void; y = year; m = months; d = days; w = weeks.

suggest that intermediate-term failure (4-13 months after surgery may approach 7% (Fitzgerald MP et al 1999). Several mechanisms of allograft loss have been proposed (host versus graft reaction, potential accelerated immunity, autolysis); however, as preparation techniques vary between companies and tissue banks, the processing of allografts has yet to become standardized. To date, there have been no clinical trials comparing outcomes of different processing techniques in vivo.

As with any non-autologous material, tissue acceptance is a theoretical concern. While tissue rejection has not been reported, one study has reported a 23%vaginal erosion rate in their series of 22 slings (Nicholson SC & Brown ADG 2001), and another reported the excision of 2 infected slings (Govier FE et al 1997). Since inflammation is virtually indistinguishable from rejection without specific tissue staining, it is not yet clear whether frank rejection of cadaveric tissue takes place. Other complications have been rare. While there has been no reported disease transmission from an allograft sling, DNA has been detected in freeze-dried CFL, solvent-dehydrated CFL, and acellular dermis (Arunkalaivanan AS & Barrington JW 2003 Rutner AB et al 2002). These findings are a concern, as it is currently unknown whether the genetic material found in these slings is transmissible or poses a long-term health risk.

Currently, several companies produce acellular dermal allografts (AllodermTM, Life Cell Corp., Repliform[®], Microvasive/Boston Scientific Corp., and Bard[®] Dermal Allograft) for sling construction. Dermal allografts are strong, exhibiting similar properties to autologous tissue in mechanical load-to-failure tests. This material may be more pliable than CFL and rehydrates more quickly (5-10 minutes). Acellular dermis has been found to integrate into tissue consistently; however, there is the potential risk of hair follicle and sebaceous gland ingrowth. To date, no results of sling surgery using these materials are available. As with cadaveric fascia lata, cadaveric dermis carries the potential for disease transmission.

In summary, the use of cadaveric allografts has decreased operating time, reduced hospitalization time, and minimized the incidence of harvest siterelated complications (Kubricht WS III et al 2001). Short-term cure rates approach those of autologous tissues, but allografts lack long-term follow-up. In addition, since preparation of allografts is not standardized, the durability of these tissues in vivo may be unpredictable. Specifically, freeze-dried allografts may have a significant short-term failure rate as compared with solvent-dehydrated specimens. In the immediate post-operative period, cadaveric allograft implantation is typically associated with few complications (Level 3 evidence). However, rigorous longterm surveillance for rejection and disease transmission is required before conclusions can be drawn. Furthermore, the potential for these delayed complications underscores the need for obtaining informed consent prior to implantation.

3. XENOGRAFT SLINGS (LEVEL OF EVIDENCE 3, 4)

Like cadaveric allografts, animal tissues have been used for cutaneous and soft tissue reconstruction for many years. The first urologic implant, Zenoderm® (Ethicon), was derived from porcine corium that was initially treated with proteolytic enzymes to remove non-collagenous material. The strips were subsequently immersed in glutaraldehyde to cross-link the collagen molecules and reduce antigenicity. Finally, the matrix was freeze-dried (lyophilized) and sterilized with gamma irradiation. Recently, porcine corium has become available under the trade names DermMatrix[™] (Advanced Uroscience Inc.) and Pelvicol[™] (Bard). As opposed to Zenoderm[®], these new materials have been cross-linked by diisocyanate. This substance is non-toxic and causes no graft mineralization, as may be seen after cross-linking with glutaraldehyde. Follow-up, as with cadaveric allografts, has been brief in most studies (Table A-VII.3).

Porcine small intestinal submucosa (SIS) has recently been marketed for pubovaginal sling surgery as STRATASIS® (Cook Urological). SIS is harvested from small intestine and the extracellular collagen matrix remains intact. The collagen, growth factors, glycosaminoglycans, proteoglycans, and glycoproteins promote host cell proliferation through SIS layers. In effect, the SIS scaffold is entirely remodelled and replaced by the host's connective tissue structures. Recently, Rutner et al reported results of a SIS sling suspended with infrapubic bone screws in 115 adults (Rutner AB et al 2002). At 36 months follow-up, 94% were continent, while only 1 patient required urethrolysis from excessive sling tension. As with other allografts and xenografts, the tensile strength of SIS is questionable. Kubricht et al found the mean suture pull through load of freeze-dried SIS to be less than freeze-dried CFL (Kubricht WS III et al 2001).

Bovine pericardium is currently available in several preparations. The UroPatchTM (YAMA, Inc.) is composed of purified and detoxified bovine pericardium that has been cross-linked with glutaraldehyde. Pelosi et al reported a 95% cure rate at a mean follow-up of 20 months in 22 patients who underwent a Uro-PatchTM sling suspended with infrapubic bone anchors (Pelosi MA et al 2002). Another preparation is a non-crosslinked, propylene oxide-treated, acellular collagen matrix derived from bovine pericardium. Marketed as VeritasTM Collagen Matrix (Bio-Vascular Inc.), this tissue is reportedly thinner than freeze-

Author	Material	Ν	L(cm)	F/U mos (mean)	%Cure	% persist storage sx	%de novo storage sx	Voiding Dysfunction
Jarvis ['85]	Porcine dermis	50	-	6-48 (21)	82	6 ^a	-	-
Iosif ['87]	Porcine dermis	53	30	18-48	88.7	-	-	Retention>2m (8%)
Nicholson ['01]	Porcine dermis	24	-	12-132 (49)	79.2	-	-	Delayed retention after 1y (13%)
Arunkalaivanan ['03]	Porcine dermis	74	10-12	6-24 (12)	89	-	6	CIC (1%), release (7%), dilation (3%)
Rutner ['02]	SISb	115	-	36	94	-	-	Urethrolysis (1%)
Pelosi ['02]	Bovine pericardium ^b	22 9	9-26 (20)	95	-	-	-	-

Table A-VII.3.. Results of xenograft slings

a: % total postoperative sx; b: transvaginal approach, infrapubic bone anchors.

N = number of patients; F/U mos = months of follow-up; %Cure = patients cured (%); % persist storage sx = persistent storage symptoms; %de novo storage sx = de novo storage symptoms; CIC = clean intermittent catheterization; y = year; m = months

dried or solvent-dehydrated CFL, but has similar, or greater, tensile strength Oray et al 2002). No results of this product's efficacy in vivo are available. DNA has also been extracted from bovine pericardium, but this amount may be much less than either freezedried or solvent-dehydrated CFL, or cadaveric dermis (Mooradian DL et al 2002). It is not clear if this DNA is transmissible.

In summary, manufacturers claim that each of these tissues is biocompatible, has excellent tensile strength, is non-immunogenic, and is devoid of viruses or prions. There is only Level 3 evidence to support these claims. These issues remain unresolved without prospective, long-term evaluation At present, porcine dermis is the only tissue with long-term follow-up. Approximately 85% of patients are cured and complications have been rare. Both porcine SIS and bovine pericardium are promising; however, it is too early to comment on long-term efficacy. All of these materials appear to be similar to cadaveric allografts in tensile strength and biocompatibility. Like allografts, these products may also contain DNA which may pose an unknown long-term health risk to the patient. Therefore, as when using allografts, informed consent is vital.

CONCLUSIONS AND RECOMMENDATIONS

A large volume of data (Level 3 and 4) evidence exists to support the efficacy of biologic materials as sling materials. Surgical results reporting for autologous fascia (Level 3,4) represents the longest term data for biological materials (4 years or longer). Long term results with other biological materials (allo- and xenografts) have not been yet been reported and therefore the efficacy of these materials is based on relatively short term experience (1 - 2 years). Therefore, although readily available, alternative biological materials have yet to show long term cure/ improved rates equivalent to those reported for autologous fascia.

There is no high level evidence comparing different types of biological materials. Such evidence is required to determine whether autologous materials should be replaced by alternative biological materials.

Autologous slings can be used to provide effective long term cure for stress incontinence (Grade B)

Allograft and Xenograft slings should only be used in the context of well constructed research trials.

VIII. TENSION FREE VAGINAL TAPE (TVT)

Since the TVT procedure was first described in 1996 (Ulmsten 1996), widespread adoption of this suburethral sling procedure has ensued. The TVT procedure is based on a theory of pathophysiology of stress urinary incontinence (SUI) presented by Petros and Ulmsten (Petros, 1990). In their "integral theory", impairment of the pubourethral ligaments is one of the primary causes of SUI. The authors contend that in order to compensate for the inefficiency of the pubourethral ligaments, a narrow strip of polypropylene mesh is placed at the point of maximal urethral closure pressure at the mid-urethra. However, there is no clinical evidence to support the value of midurethral placement of the sling. Although the originators of the TVT claim the procedure to be "ambulatory" surgery, performed with small incisions under local anaesthesia, the optimum anaesthetic / analgesia protocol has not been determined.

The RCTs comparing TVT with other procedures (Ward 2002, Ward 2004, Liapis 2002, Wang 2003) are listed in **Table A-VIII.1**.

In a United Kingdom and Ireland multicentre randomized trial of open Burch colposuspension and TVT for primary treatment of urodynamic SUI, Ward and Hilton found no difference between groups for objective cure rates (negative pad test and negative cystometry) at six months: 66% in the TVT group and 57% in the colposuspension group (Ward 2002). Complete dryness was reported by 38% in the TVT group and 40% in the colposuspension group. Dryness with stress was reported in 66% and 68% of women, respectively. Strict definitions of cure and the fact that data were analyzed on an intention-totreat basis, assuming patients with missing data to be treatment failures explain lower cure rates from both procedures compared to other studies. In fact, this study highlights the difficulty of defining "cure" and the need to standardize the definition for clinical trials. Bladder injury was more common during the TVT procedure compared to colposuspension, 9% versus 3%, respectively (p=0.013). There were no long term sequelae from the bladder injury reported. Delayed voiding, operation time, hospital stay, and return to normal activity were all significantly longer after colposuspension. The same authors recently reported 2-year follow-up (Ward 2004). Objective cure rates did not differ; 63% for the TVT group and 51% for colposuspension (odds ratio [OR] 1.67,95% CI 1.09-2.58). When the data were analysed assuming that all withdrawals from the investigation were cured, cure rates were 85% and 87% for TVT and colposuspension, respectively. The rates of reoperation for urodynamic stress incontinence did not differ between groups; however, significantly more women in the colposuspension group underwent reoperation for pelvic organ prolapse (p=.0042) and required intermittent self-catheterisation for voiding dysfunction (p=.0045). Although the trial is one of the largest for stress incontinence surgery, power was limited by failure to recruit up to the calculated sample size (262 per arm). Liapis (Liapis 2002) reported comparable cure rates between groups and significantly shorter operation time, hospital stay, and time to normal activity in the TVT group when comparing TVT with open colposuspension in a smaller trial. Wang and Chen (Wang 2003) conducted a trial using a standardised protocol, including strict criteria for exclusion of preexisting bladder outlet obstruction (BOO). Patients with previous anti-incontinece surgery were excluded. The Blaivas and Groutz nomogram (Blaivas 2000) was used as one criteria to assess preoperative and postoperative BOO. Cure rates and complications did not differ between procedures. The authors concluded that a properly performed TVT does not cause urethral obstruction.

There are three comparative studies in the literature thus far comparing TVT with laparoscopic retropubic procedures (Table A-VIII.1). In a prospective randomized trial comparing TVT and laparoscopic Burch urethropexy, Üstun et al (Üstun 2003) showed 83% cure in both groups. Longer operative times, hospital stay, and duration of catheterization were reported in the laparoscopic Burch group. In a twocentre randomized trial comparing TVT and laparoscopic Burch colposuspension, Paraiso et al (Paraiso 2004—in press) found a higher cure rate of 97% versus 81%, respectively, based on urodynamics studies at one year (p=.056). Postoperative subjective symptoms of incontinence (stress, urge and any) were reported significantly more often in the laparoscopic Burch group than the TVT group (p<.04 for each category). Operative times were significantly longer for the laparoscopic Burch group. Hospital stay and duration of catheterization did not differ between groups. In a prospective nonrandomized study comparing TVT with single-stitch laparoscopic bladder neck suspension, Liang and Soong (Liang 2002) showed no difference in subjective and objective cure. Operative time and time to resumption of spontaneous urination was significantly lower in the TVT group.

Cure rates ranging from 84% to 95% have been reported in several prospective cohorts (Ulmsten 1999, Nilsson 2001, Meschia 2001) and a large retospective review (Debodinance 2002) of the TVT procedure. Long-term objective results of TVT procedure for primary SUI in 90 women were shown in a Nordic multicentre trial by Nilsson et al (Nilsson 2001); at a median follow-up of 56 months, 85% of patients were objectively and subjectively cured, 10.6% were improved and 4.7% were regarded as failures. There were no cases of mesh erosion or permanent retention. A presentation at the International Urogynaecology Association in Buenos Aires by the same authors (Nilsson 2003) reported on 80 participants from the original cohort of 90 women (mean follow-up of 7.6 years). Objective testing with a stress test and pad test was negative in 61 of 64 women who returned for clinical evaluation thus 81% of participants were objectively cured. Subjective cure rates based on a visual analogue scale and questionnaire indicated that 81% were cured and 16% were improved.

1. COMPLICATIONS OF TVT

Although TVT results in high cure rates, there are concerns regarding the complications associated with this procedure. The most common complication is bladder perforation ranging from 0.8% to 21% in previous reports (Ulmsten 1999, Nilsson 2001, Meschia 2001, Debodinance 2002, Soulie 2001, Tamussino 1999, Ulmsten 1998, Klutke 2001, Karram 2003). Urethral perforation, mesh erosion into the vagina or urinary tract, pelvic hemorrhage or hematoma due to vascular injury, bowel perforation, and death (resulting from bowel perforation, coagulation disorders, or introperative myocardial infarction) can occur but are very rare (Soulie 2001, Tamussino 1999, Ulmsten 1998, Klutke 2001, Karram 2003, Gynecare "Surgeon's Resource Monograph" 2003). Short-term voiding disorder is described in 4% to 11% of women, and retention requiring transection of the tape occurs in 1% to 2.8% (Ward 2002, Arunkalaivanan 2003, Tamussino 1999, Klutke 2001). Release of TVT does not seem to jeopardize overall improvement in stress urinary incontinence symptoms (Klutke 2001, Rardin 2002).

• TVT vs other sling procedures

The success of TVT has led to the introduction of

en
m
Wo
n
e i.
nc
ne
uti
10
Įnc
S
res
Sh
ic.
un
nc
(p)
ro
Ū.
б
nt
ne
atı
rei
rt
fo
S
in
sl
er
th
<i>q</i> (
un
L
N.
L
01
ta
da
p
rte
00
re
£
à
an
un
un
S
Γ.
VIII.
Ν
A-
le
p
T_{c}

Reference	Type of Op	No. of Pts	Duration Follow up	Cure criteria	Cure/ Improvement	Level of Evidence
Ward K 2000	TVT Burch	344 175 169	6 mos	Negative cystometrogram and negative pad test	Rate 66% TVT 57% Burch	1/2
Ward K 2004	TVT Burch	344 175 169	2 yrs	Negative 1-hour pad test	63% TVT 51% Burch	1/2
Liapis A 2002	TVT Burch	71 36 35	2 yrs	Cure: 1-hour pad test with pad weight difference < 1 g Improved: 1-hour pad test showing a reduction of urine loss < 50% of preoperative value	84% TVT 86% Burch/ 7% TV T 6% Burch	1/2
Wang AC 2003	TVT Burch	98 49 49	22 mos median (12-36)	Objective Cure: 1-hour pad test with pad weight ≤ 2 g Improved: Pad weight < 50% preoperative value Subjective Cure: No loss of urine during physical exercise	Objective 82% TVT 76% Burch/ 8% TVT 12%Burch Subjective 92% TVT 93% Burch	1/2
Üstun Y 2003	TVT LBC	46 23 23	11 mos TVT 14 mos LB (3-24)	Urodynamic studies, negative stress test, and subjectively "no need for pads"	83% TVT 83% LBC	1/2
Paraiso MFR 2004	TVT LBC	72 36 36	21 mos (12-43)	Urodynamic studies at 1 yr—no leakage	97% TVT 81% LBC	1/2
Liang CC 2002	TVT LBC (1 stitch)	45 23 22	18 mos TVT 23 mos LBC	Urinary diary, pad test, urodynamics at 6 mos Subjectively "dry" telephone follow-up	Objective 83% TVT 77% LBC Subjective 87% TVT 86% LBC	2
De Tayrac R 2004	TVT TOT	61 31 30	1 yr	Cured: Negative cough stress test and symptomatically dry Improved: Positive cough stress test and symptomatically dry	Cured 84% TVT 90% TOT Improved 10% TVT 3% TOT	1/2

1/2	1/2	2	ę
Cured 74% TVT 76% PVS Improved 10% TVT 14% PVS Patient-determined continence Dry 85% TVT 89% PVS Improved 9% TVT 33% PVS	Cured 88% TVT 80% IVS Improved 10% TVT 18% IVS	91% TVT 93% PVS Urge symptoms: 85% TVT 85% PVS	Objective 94% TVT 78% SPARC Subjective 85% TVT 92% SPARC
Cured: Negative cough stress test , QoL improvement>90%, symptomatically dry Improved: Negative cough stress test, QoL improvement>75% but <90%, symptomatically improved continence	Cured: Negative supine and standing cough stress test and symptomatically free of SUI Improved: Negative cough stress test, symptoms of SUI but less frequent than preop. occasionally wet pads	Cured: Negative cough stress test and no reports of urine leakage during stress Improved: Negative cough stress test with SUI symptoms	Cured Objective Negative cough stress test Subjective of SUI occurring occasionally or less
12 mos median (6-24)	13.5 mos median (4-18)	23 mos TVT 20 mos PVS	0.6 yrs (0.1-1.5)
142 68 74	100 50 50	89 23 57	106 69 37
TVT PVS porcine dermis (mid- urethra)	TVT IVS	TVT PVS Polypro- pylene	TVT SPARC
Arunkalaivanan AS 2002	Rechberger T 2003	Hung MJ 2001	Dietz HP 2004

Table A-VIII.1. Summary of reported data on TVT and other slings for treatment of Urodynamic Stress Incontinence in Women

LBC=Laparoscopic Burch colposuspension TOT=Transobturator suburethral tape PVS=Pubovaginal sling IVS=Intravaginal slingplasty similar products with modified methods of sling placement (retropubic "top-down" and transobturator "outside-in, inside-out"). As with all slings, the true comparison between the outcome of these materials and modified methods compared to TVT can only be done in properly designed clinical trials.

The transobturator suburethral tape (TOT) was introduced by Delorme in 2001 (Delorme 2001). He reported no perioperative complications or voiding difficulties and a 90% cure rate. Dargent (Dargent et al 2002) reported no bladder injuries after performing cystoscopy in their first 71 cases. Based on a recent case of bladder injury during TOT in a patient who had associated cystocele (Hervieu 2003), de Tayrac (de Tayrac et al 2004) did not recommend concurrent cystoscopy during the TOT procedure when it is performed under normal anatomic conditions (defined as no associated cystocele).

The trials comparing TVT to other similar sling procedures (DeTayrac 2004, Arunkalaivanan 2003, Rechberger 2003, Hung 2004, Dietz 2004) are listed in Table x. DeTayrac et al (DeTayrac 2004) recently published a prospective randomized trial comparing TVT and transobturator suburethral tape (TOT-see corresponding section), which showed similar 1-year cure rates between groups. Mean operative time was significantly shorter in the TOT group when compared to the TVT group (p<.001) because concurrent cystoscopy was performed solely in the TVT group. Intraoperative cough stress test was not performed after adjustment of the tape in either group. Pressure flow studies were performed at one year in order to compare bladder outlet obstruction between groups according to the Blaivas and Groutz nomogram (Blaivas 2000). The 1-yr postoperative rates of bladder outlet obstruction between groups were no different, 11% and 17% for TOT and TVT, respectively. However, one patient in the TOT group underwent lateral mesh transection on postoperative day 25 and one patient in the TVT group underwent subsequent surgery for urethral mesh erosion.

Arunkalaivanan and Barrington (Arunkalaivanan 2003) reported similar cure rates in a questionnairebased randomized trial comparing TVT and porcine dermal pubovaginal sling (PVS) placed at the midurethra. It is unclear from the methods what type of randomization schedule and allocation concealment were implemented in the trial. A 10-12 x 2 cm strip of porcine dermis (PelvicolTM implant, Bard) was use with No. 1 polyglactin (Vicryl, Ethicon) sutured to each end. Release of the sling was required to treat voiding dysfunction in 3% of the TVT group and 7% of the Pelvicol PVS group. Permanent catheterization was required in 3% of the TVT group and 1% of the PVS group. Complication rates were similar. Use of such biological materials is discussed further in the section above.

Rechberger (Rechberger et al 2003) compared the monofilament tape using the TVT procedure with the multifilament tape using the IVS tunneler (Tyco) in a prospective randomized trial and found similar cure rates. Urinary retention defined as the inability to void spontaneously after postoperative catheter removal was significantly greater in the TVT group when compared to the IVS group, 20% vs 4%, respectively (p=.023). The authors reported no long-term urinary obstruction in this study.

Hung et al (Hung 2001) found similar cure rates between TVT and a 1.5 x 30 cm self-fashioned polypropylene mesh (Prolene, Ethicon) midurethral sling in a nonrandomized prospective trial of 80 consecutive patients. After a multivariable logistic regression analysis, the treatment outcome was significantly related to procedures and their interaction with patient BMI. The authors found that TVT performs better than their sling when BMI is <27.27 kg/m2, and that the advantage of TVT decreased as BMI increased. In a case-controlled series comparing TVT with SPARC, Dietz et al (Dietz 2004) found similar subjective cure rates between groups but significantly higher objective cure in the TVT group (p=.019). Translabial ultrasound showed that the SPARC was situated more cranially at rest and further away from the pubic symphysis, and was more mobile when compared to TVT placement (p=.001). The authors hypothesized that a difference in tape elasticity due to a central absorbable suture in SPARC, different tape paths, and variations in dissection may influence in vivo biomechanics of the two procedures.

All comparative studies involving other midurethral slings, excluding the case-control series by Dietz et al (Dietz 2004), showed similar short-term objective and subjective cure rates when compared to TVT.

CONCLUSIONS AND RECOMMENDATIONS

There are more than 220 published reports on the Tension-free Vaginal Tape procedure. Two-year follow up data from 3 RCTs demonstrate similar cure to open colposuspension (Level 1/2). One to two year follow-up data from two RCTs and one nonrandomized prospective trial show similar cure rates of TVT to laparoscopic colposuspension (Level 1/2 and Level 2). Comparison of TVT to

the transobturator suburethral sling, porcine dermis pubovaginal sling, and polypropylene multifilament sling in prospespective randomized controlled trials showed similar cure rates at one year (Level 1/2). A single case-control study showed significantly higher objective cure (but similar subjective cure) with TVT compared to Sparc (Level 2/3). Large cohort analysis and long-term (7 years) prospective evaluation show cure rates of 81% and an improvement rate of 94% (Level 2).

IX. INJECTABLE AGENTS

Periurethral injectable agents have been used for the treatment of stress urinary incontinence in women for the past century. A variety of substances have been reported to be safe and effective in the peer reviewed literature including bovine glutaraldehyde cross linked (GAX) collagen, polytetrafluoroethylene (Teflon), polydimethyl-siloxane elastomer (silicone), carbon coated zirconium beads, hyaluronic acid/dextranomer, and autologous tissues such as fat and cartilage(Barranger et al. 2000;Bent et al. 2001a;Bent et al. 2001b;Chrouser et al. 2004;Corcos & Fournier 1999; Cross et al. 1998; Dmochowski & Appell 2000; Eckford & Abrams 1991; Faerber 1996; Gorton et al. 1999;Groutz et al. 2000;Haab, Zimmern, & Leach 1997; Harriss, Iacovou, & Lemberger 1996;Henalla et al. 2000;Herschorn & Glazer 2000; Herschorn, Radomski, & Steele 1992;Herschorn, Steele, & Radomski 1996;Kershen, Dmochowski, & Appell 2002;Khullar et al. 1997;Koelbl et al. 1998;Kreder & Austin 1996;Lee, Kung, & Drutz 2001; Lightner et al. 2001;Lim, Ball, & Feneley 1983; Lopez et al. 1993; McGuire & Appell 1994; McGuire & English 1997; Monga, Robinson, & Stanton 1995;Moore et al. 1995;O'Connell et al. 1995; Peeker et al. 2002;Pickard et al. 2003;Politano 1982; Radley et al. 2001; Richardson, Kennelly, & Faerber 1995; Smith et al. 1997;Steele, Kohli, & Karram 2000; Tamanini et al. 2003;van Kerrebroeck et al. 2004; Winters et al. 2000; Winters & Appell 1995). Each of these different agents has variable biophysical properties that influence factors such as tissue compatibility, tendency for migration, radiographic density, durability and safety. The ideal periurethral injectable agent has not yet been identified.

Most periurethral agents are injected in a retrograde fashion under direct cystoscopic guidance although not all materials require endoscopic guidance (van Kerrebroeck, ter Meulen, Larsson, Farrelly, Edwall, & Fianu-Jonasson 2004). Retrograde approaches have also been described through a suprapubic puncture site especially in males with post-prostatectomy urinary incontinence. In women, most of these agents can be applied without general or regional anaesthesia. There is no universally accepted or standardized injection method, technique, or equipment. The ideal location for injection has not been optimally defined and reported injection locations have included from the level of the midurethra all the way to the bladder neck. The optimal volume of material for injection during a single session, ideal site orientation for injection, or the optimal number of reinjection sessions for any given agent (until clinical "failure" has been determined) has not been defined. Long term success may not correlate with the endoscopic appearance at the conclusion of the injection session or certain preoperative urodynamic parameters (Kim et al 1997).

The exact mechanism by which periurethral injectable agents exert their effects on continence has not been defined although an obstructive effect or an improved "seal" effect has been suggested (Dmochowski & Appell 2000). Furthermore, the eventual mechanism of failure for most of these agents is not well understood although it is felt that biological reabsorption (e.g. GAX collagen), particle migration, and ongoing degeneration of the sphincteric apparatus may be contributing factors. Although initially it was thought that injectable agents would be most effective in patients with intrinsic sphincter deficiency (ISD) alone, subsequent reports have suggested clinical efficacy in patients with urethral hypermobility as well (Bent et al 2001a;Herschorn et al 1996;Monga et al 1995;Steele, Kohli et al 2000).

1. LIMITATIONS OF THE LITERATURE

A total of 30 published studies were reviewed (see **Table A-IX.1**). These studies were chosen based on several factors including numbers of patients, quality of the methods and timing with respect to appearance in the scientific peer reviewed literature.

Despite careful selection, the majority of these trials were of short duration with brief follow-up periods. Only 13/30 studies reported follow-up periods of greater than 1 year. Most of the reviewed trials represent isolated case series with small numbers of patients from a single center without a placebo or active comparator (Level 4 evidence). As noted above, technical details of the procedure (e.g. location of injection, volume of material injected, end-

Reference	Year	No. pts*	Mean age	Bulking agent	Mean ^a median ^{b,} or minimal ^c f/u	Mean no. injections
Eckford, et al	1991	25	52,3	GAX collagen	3 months ^b	1,67
Herschorn, et al	1992	31	n/a	GAX collagen	8.4 months from last injection (cured group), 4.5 months from last injection (improved group) ^a	2
Herschoff, et al					months normast injection (improved group)	
O'Connell et al	1995	44	72 (median)	GAX collagen	n/a	1,5
Monga, et al	1995	29	n/a	GAX collagen	24 months °	1,6
Richardson et al	1995	42	64	GAX collagen	46 months from initial injection ^a	2 (median)
Richardson et al	1335	42	04	OAX conagen	22 months from last injection (cure and improved	2.5 (in
Herschorn, et al	1996	187	63	GAX collagen	groups) ^a	cure/improved groups)
Faerber	1996	12	76	GAX collagen	10.3 months from last injection ^a	1,25
	1000	00		GAX collagen (vs.		
Kreder et al	1996	22	n/a	sling)	n/a	n/a 2.1 (in
						cure/improved
Smith et al	1997	94	67,4	GAX collagen	14 months ^b	group)
				GAX collagen (vs.		
Haab, et al	1997	22	63,7	autologous fat)	7 months ^a	1,9
Khullar et al	1997	21	76	GAX collagen	24 months ^c	n/a
Cross et al	1998	139	72 (median)	GAX collagen	18 months from last injection ^a	n/a
Corcos et al	1999	40	62.3	GAX collagen	48 months	n/a
	2000		67.7		6 1 months from last inication	2.1
Groutz et al	2000	63	67,7	GAX collagen	6.4 months from last injection ^a	2,1
Winters, et al	2000	58	73,2	GAX collagen	2 months ³	1,9
Lightner, et al	2001	68	n/a	GAX collagen (vs. Durasphere)	12 months from last injection ³	1,55
Bent et al	2001	58	n/a	GAX collagen	12 months ^c	n/a
Lightner, et al	2001	61	n/a	Durasphere (vs. GAX collagen)	12 months from last injection °	1,69
				Autologous fat		
Haab, et al	1997	45	63,3	(vs. GAX collagen)	7 months ^a	1.67
Lee et al	2001	27	57	Autologous fat	3 months ^c	3
				Autologous ear		
Bent et al	2001	32	59,6	chondrocytes	12 months	1
Politano et al	1982	51	n/a	Polytetrafluoroeth ylene (Teflon)	6 months	1,8
				Polytetrafluoroeth		
Lim et al	1983	28	n/a	ylene (Teflon)	12 months	1
Lopez et al	1993	128	n/a	Polytetrafluoroeth ylene (Teflon)	31 months ^a	1,5
				Polytetrafluoroeth	17.9 months(cured group), 15.9 months (improved	
Herschorn et al	2000	46	73,8	ylene (Teflon)	group) from last injection ^a	2
Koelbl et al	1998	32	n/a	Silicone	12 months	1
-						n/a
Barranger et al	2000	21	68	Silicone	31 months ^b	11/a

Table. A-IX.1 Injectable agents. Results from published series with levels of evidence.

*patient group with longest reported follow-up in each series

Table. A-IX.1

	1	1		
Success criteria	Cure rate	Success rate (cure + improved)	Level of evidence	Comments
Subjective report: Cured = "complete cessation" of SUI symptoms and negative pad test, Improved = reduction in SUI	64%	80%	Level IV	
Subjective report: Cure = "no incontinence at all", Improved = <2 pads/day	48%	90,3	Level IV	
Subjective report: Cure = no pads, Improved = < 2 pads	45%	63%	Level IV	
Cured (objective)= negative pad test or stress test, Improved = subjective improvement from daily to intermittent incontinence	48%	68%	Level IV	
Subjective report: Cure = incontinence grade 0, Improved = incontinence grade improved over baseline	40%	83%	Level IV	
Subjective report: Cure = no incontinence symptoms or pad use on questioning, Improved = any decrease in grade of incontinence	23%	75%	Level IV	
Subjective report Subjective report: Cure = dry or "rarely" requiring a pad, Improved = 50% decrease in pad use	83% 40%	100%	Level IV Level IV	
Subjective report: Cure = patient reports "dry", Socially continent = patient reports < 1 pad/day	38.30%	67%	Level IV	
Subjective report: visual analog scale Cured (objective)= pad test<1g, Improved = >50% improvement on	24%	86%	Level IV	
pad test Subjective report: Substantially improved = >70% reduction in pad usage or Grade 0 incontinence, Improved = 50-70% reduction in pad	48%	57%	Level IV	
usage or improvement of > 1 in incontinence grade Cure = negative pad test+no leak on VLPP testing+symptomatic	n/a	74%	Level IV	
"dryness", improved = patient satisfaction+>50% improvement in pad test and VLPP	30%	70%	Level IV	reinjections performed during follow-up period
Objective "outcome" score: Cure = No SUI on diary and pad test < 8 g and patient considers herself cured	13%	40% (cure+good+fair)	Level IV	
Subjective report: Cure = "no leakage at all", social continence = ≤ 1 pad/day	48,30%	79,30%	Level IV	
Improvement in Stamey continence grade	n/a	69,10%	Level I	RCT: vs. Durasphere
Subjective report: Cure = Stamey continence grade 0, improved = improvement of Stamey continence grade > 1 compared to baseline	33%	66%	Level IV	
Improvement in Stamey continence grade	n/a	80,30%	Level I	RCT: vs. GAX collagen
Subjective report: visual analog scale Cure = negative pad test+negative stress test + continence questionaire score of 0, improved = decrease in continence	14%	43%	Level IV	
questionaire score of > 5 points	n/a	22,20%	Level 1	RCT: fat vs. saline placebo
Subjective report: Cure: Incontinence Grade 0, improved = improvement in continence grade > 1 compared to baseline	50%	81,30%	Level IV	
Subjective report	n/a	71%	Level IV	
Subjective report	21,40%	75%	Level IV	
Subjective report: Cure: "completely continent", improved: "need for minimal protection only"	54,30%	73%	Level IV	Mixed indications including NGB, trauma, congenital
Subjective questionaire/pad report: Cure: "no incontinence", Improved: "decrease in no. of pads and subjective improvement"	30,40%	71,70%	Level IV	
Subjective report questionaire: Cure: "dry", Improved: "only rare or	60%	n/a	Level IV	
minimal leakage" Subjective report questionaire/standardized quantification test: Cure: "dry", Improved: "not completely dry"	19% 68,80%	48%	Level IV Level IV	
Subjective report	57,10%	76,10%	Level IV	

point for injection, number of injection sessions until failure, etc.) varied considerably between studies making direct comparisons difficult. Furthermore, definitions of cure/improved/failure were variable with the majority of studies relying on subjective patient report in one form or another (see **Table A-IX.1**). Few studies utilized objective pad test data or validated questionnaires especially with respect to quality of life as an outcome measure.

Patient populations in the reviewed studies were often heterogeneous. There was no uniform urodynamic definition of ISD nor was the degree of urethral hypermobility usually quantified or defined uniformly in those studies in which it was utilized as a variable. Most studies excluded neurogenic patients and patients with extensive prior urethral reconstruction. Several studies looked at the efficacy of periurethral injectables in selected populations. In those studies where patients were selected based on specific parameters (e.g. Type I SUI, elderly, etc.), there was often no cohort population for comparison (i.e. Level 4 evidence). Because of the heterogeneity of the patient populations, type of study design, and variable outcome measures it is difficult to come to definite conclusions regarding the comparative efficacy of these therapies in selected populations or the optimal patient parameters for the application of these agents (VLPP, age, weight, parity, prior surgery, etc.). Finally, the long-term durability of these agents is unknown. The follow-up period in most studies is brief. Few studies have directly compared a periurethral injectable to other types of anti-incontinence surgery such as retropubic suspensions, or slings or to another periurethral injectable.

2. Level 1 evidence

There is a dearth of well-done published, peer reviewed, randomized, placebo controlled trials or comparator trials involving periurethral injectables(Pickard et al 2003). We found no studies comparing periurethral injectable agents to conservative therapy (behavioral modification, pelvic floor exercises, etc.) or no therapy. There is only a single published randomized, double blind, placebo-controlled trial in the literature utilizing a periurethral injectable. Lee (Lee et al 2001) randomized 68 women to either autologous fat or saline (placebo) injection. At 3 month follow-up using objective outcome parameters including a pad test, questionnaire, stress test and urodynamics, these authors found no difference between the active agent (fat) and placebo. Only a single study has compared 2 periurethral injectable agents to each other in a randomized double blind fashion. Lightner el al compared GAX collagen to carbon coated zirconium beads (Durasphere®) (Lightner et al 2001). In this multi-center trial, the authors noted no statistical difference between the 2 agents with respect to pad test results and continence grade in the 129 patients who had at least one year follow-up.

3. Remaining evidence

Haab and colleagues prospectively compared the results of collagen to autologous fat injection in 67 women with ISD (Haab et al 1997). This study was not randomized or blinded but the two cohorts were comparable for age, parity, number of previously failed procedures, VLPP and number of pads used daily (Level 2 evidence). At a follow-up of 7 months the cure rate and cure/improved rates both significantly favored collagen over the autologous fat (24% vs 13% and 70.95 vs. 31.2%, collagen vs. autologous fat, respectively). In a cohort study comparing Durasphere to age matched historical controls receiving GAX collagen, Chrouser et al noted that at last follow-up (median 51 vs. 62 months for Durasphere vs GAX collagen respectively) there was no statistically significant difference in time to failure between the two agents(Chrouser et al 2004). However, at last follow-up treatment was noted to be effective in only 21% of Durasphere treated patients as compared to 5% of the GAX collagen treated patients. One uncontrolled, retrospective study compared GAX collagen to autologous pubovaginal slings in 50 consecutive patients with SUI due to both ISD and urethral hypermobility(Kreder & Austin 1996) (Level 4 evidence). At a mean follow-up of 22 months, the respective cure rates were 81% vs. 25%, sling vs. GAX collagen respectively.

The majority of the studies on periurethral injectable are uncontrolled, case series (Level 4 evidence) with the significant limitations noted above. Short term cure rates and cure/improved rates are variable (see Table A-IX.1). When strict objective and subjective definitions of cure and cure/improved are utilized, the success of periurethral injectable therapy appears to be inferior compared to that reported historically for other types of anti-incontinence surgery(Groutz et al 2000;Lee et al 2001). Groutz et al looked at the success rate of GAX collagen using very strict objective and subjective outcome parameters(Groutz et al 2000). At a mean follow-up of 6.4 months, only 40% of 63 consecutive patients with SUI treated with GAX collagen could be classified as a cure/good/fair result. The remaining 60% were classified as a failed or poor result.

4. COMPLICATIONS

In general, the morbidity associated with periurethral injectable agents is low. UTI, short term voiding dys-function(Bernier et al. 1997) including urinary retention and hematuria are common with all of the periurethral injectable agents. Minor complications have been reported in up to 20% of patients receiving GAX collagen however the vast majority of these are self limited. (Stothers et al 1998).

GAX collagen has been associated with a systemic allergic reaction and therefore intradermal skin testing is recommended prior to injection into the urinary tract. GAX collagen has also been rarely associated with a delayed hypersensitivity reaction(Stothers & Goldenberg 1998).

Particle migration locally and systemically has been reported for several agents including Teflon, silicone and carbon coated zirconium beads (Henly et al. 1995;Malizia, Jr. et al. 1984;Mittleman & Marraccini 1983;Pannek et al 2001). Teflon may incite a granulomatous reaction locally or at distant migration sites. The short and long term ramifications of this are not well understood.

CONCLUSIONS AND RECOMMENDATIONS

Short term efficacy (<3 months) of some periurethral injectables in selected patients with SUI is satisfactory (Level 4)

There are few studies that have meaningful long term efficacy data for periurethral injectable therapy for SUI. However, available evidence suggests that long term durability (>4 years) of available periurethral injectables appears to be inferior to retropubic suspensions and slings (Level 4)

There is no evidence to suggest that any of the available periurethral injectable agents is superior to the others with respect to efficacy, durability, or safety. (Level 4)

The most widely studied periurethral injectable agent is GAX collagen. The short and long term morbidity associated with the use of this agent is low (Level 4).

Para-urethral injections can be offered to women with urodynamic stress incontinence on the basis of low operative morbidity and low long term success rate (Grade C)

B. COMPLICATIONS OF SURGERY FOR STRESS INCONTINENCE

I. IMMEDIATE COMPLICATIONS

1. HAEMORRHAGE

The perivescical/periurethral venous plexus can be a source of substantial haemorrhage during surgery for stress incontinence. The mean blood loss following anterior repair has been reported as 200ml compared to 260ml following a Burch colposuspension. (Van Geeland 1998).

Alcalay et al (1995) in a retrospective review of 109 Burch colposuspensions did not note any difference in blood loss between primary and secondary procedures but a blood loss of more than 1 litre was associated with a higher risk of failure to cure stress incontinence. Haematoma formation following bladder neck surgery may lead to the development of an abscess and possible wound breakdown. However, the relationship between haematoma formation and outcome from surgery has not been studied.

Needle suspension is associated with a low blood loss (mean 53 ml) (Spencer 1987) and laparoscopic colposuspension is described by authors in cohort series as being associated with minimal blood loss (Liu 1993, Dorsey 1994).

Sling procedures which may involve more extensive dissection may be associated with haemorrhage requiring surgical drainage, Morgan et al. (Morgan 2000) required drainage in 2.1% of cases. In a randomised prospective study comparing TVT and colposuspension blood loss was 50 ml and 135 ml respectively. (Ward 2000)

2. URINARY TRACT AND VISCERAL INJURIES

Bladder, ureteric and urethral injuries have been reported during surgery for stress incontinence. Mainprize and Drutz (1998) reported 0.7% bladder injury in nearly 3,000 women undergoing an MMK procedure. Up to 6% of women may sustain injury to the bladder or ureter at open colposuspension. However more recently Kenton (2002) reported the rate 0.7% (1 case out of 151) of stitches passing

through the bladder during colposuspension. Reports on laparoscopic colposuspension note a risk of bladder injury in up to 10% cases (Smith 1998). In a randomised trial comparing open colposuspension with the TVT procedure an average of 9% bladder perforation was reported in the TVT group compared to 2% in the open colposuspension group (Ward 2000). Urethral injury during anterior repair appears to be uncommon but may follow the opening of an undetected urethral diverticulum.

Laparoscopic surgery, when performed through a transperitoneal approach will also carry a risk of injury to intra-peritoneal viscera, particularly when previous surgery has been performed through the anterior abdominal wall. Suprapubic catheterisation, when performed blind, also carries a risk of bowel injury (Noller 1976, Louhglin 1990, Cundiff 1995).

Urinary tract infection is not uncommon following surgery for stress incontinence. In a randomized controlled trial comparing open to laparoscopic colposuspension, Cheon (2003)²[level 2] reported a urinary tract infection rate of 6.9 in the first group and 2.1 in the latter. Its frequency will increase with the duration of catheterisation at the rate of 6 to 7.5% per day (Foucher 1983). Anderson. (Anderson et al 1985) compared suprapubic and transurethral catheterisation in a randomised trial and reported a lower incidence of bactiuria on the 5th post-operative day following suprapubic catheterisation (21% versus 46%). A similar difference was reported by Bergman et al (1987) following a needle suspension procedure (**Table B-I.1**).

II. SHORT TERM COMPLICATIONS

1. INFECTION

Wound infection appears to be uncommon, unrecognised or unreported following vaginal surgery. Ghezzi (2002) [level 3] recently reported an overall incidence of infections after colposuspension of 22.6%; in the same study the authors described an association between wound and pelvic infection regardless the use of suction drains in the perivesical space. Vaginal hysterectomy however is associated with a vault haematoma in one in four women (Tincello 1998).

There is no direct evidence that wound infection influences the cure rate for stress incontinence surgery, although infection in the presence of synthetic support materials may lead to removal. Mundy (1983) removed 16% of Dacron Stamey buffers. Erosion rates of up to 21% have been reported with synthetic pubo-vaginal slings (Beck 1988, Bent 1993, Byrans 1979, Muznai 1992). Granuloma and abscess formation have been reported following peri-urethral injection (Politano 1974, Politano 1982, Lotenfoe 1993). Infection of artificial sphincters has been reported in up to 9.5% of cases (Appell 1988, light 1988, Scott 1989).

Osteitis pubis is discussed within the section on MMK procedure but it has also been reported after needle suspension (Green 1986) (**Table B-II.2**).

Authors	Journal reference	Type of study	N. OF	PTS F. UP	Type of complication	Complication rate	Level of evidence
Kenton P, Oldham L, Brubaker L	Am J Obstet Gynecol 2002 Jul; 187 (1): 107-10	Case series study	151		Burch suture in the bladder	0.7%	3
Cheon WC, Mak JH, Liu JY	Hong Kong Med J. 2003 Feb;9(1):10-4	Rando- mized control trial	90	1 year	Urinary tract infection	6.9%	2

Table B-I.1 Complications of open and needle colposuspension.

Table B-II.2 Complications of MMK procedure.

Authors	Journal reference	Type of study	N. OF	PTS F. UP	Type of complication	Complication rate	Level of evidence
Ghezzi F, Franchi M, Buttarelli M, Serati M, Raio L, Maddalena F	Arch Gynecol Obstet. 2003 Apr;268(1): 41-4. Epub 2002 Jun 06	Case series study	62		Overall infections	22.6%	3

2. VOIDING DYSFUNCTION

Voiding dysfunction is discussed under each of the operative procedures and Section 6 on Post surgical Outlet Obstruction Surgery.

3. URO-GENITAL FISTULAE

As described later in the Chapter, fistulae most commonly follow gynaecological surgery in the developed world. Fistulae may also develop following surgery for stress incontinence.

Beck et al (1991) reviewed a series of over 500 women who underwent anterior repair and found two cases of urethro-vaginal fistula. Fistulae have also been reported following needle suspension procedures (Guam 1984), MMK (Mainprize 1988) and sling (Kersey 1983).

4. NERVE INJURIES

No direct injuries have been reported to nerves following the anterior colporrhaphy but the abduction and flexion of the thigh in the lithotomy position may lead to femoral nerve injury. (Wang 1993).

Denervation of the urethral sphincter may occur (see section on prolapse). Nerve injuries after needle suspension have been reported to the common perineal, sciatic, obturator, femoral, saphenous, and ilio-inguinal nerves (Karram 1992).

Seven cases of ilio-inguinal nerve entrapment were described following 402 needle suspension procedures. In three cases the suture was removed which led to resolution of the pain in two cases (Miyazaki 1992).

The "post-colposuspension syndrome" has ben described to include women who have pain in one or both ilio-inguinal regions following colposuspension (Galloway 1987). Demirci (2001) reported the occurrence of groin or suprapubic pain in 15 of 220 women (6.8%) after Burch colposuspension with an average follow-up of 4.5 years (**Table B-II.3**)

III. LONG TERM COMPLICATIONS

Detrusor overactivity and uro-genital prolapse are discussed under the relevant procedures and also in the section for surgery for stress incontinence and prolapse. Ano-rectal dysfunction, in association with or independant of posterior vaginal wall prolapse has not been reported in the literature.

Dyspareunia is seldom mentioned in reports on surgery for stress incontinence. It may be produced by the vaginal wound itself through scarring or vaginal narrowing. Erosion of synthetic material may also lead to dyspareunia in either partner. Alteration of the vaginal axis and the development of prolapse may lead to difficulty with intercourse. Dyspareunia has been reported in up to 40% of women after colposuspension (Galloway 1987, Eriksen 1990), but less frequently after needle suspension 1.5% (Raz 1991).

1. QUALITY OF LIFE ISSUES

Surgeons have tended to assume that the most significant outcome measure for surgery for stress incontinence is whether complete continence is achieved. This is despite evidence that patients may be satisfied with the outcome without complete continence. Given that surgery for stress incontinence does not always produce continence and that this procedure can produce significant complications, it may be more relevant to consider the overall impact on the quality of life of the surgery rather than the single issue of continence. In a prospective cohort study of 442 women undergoing surgery for stress incontinence by various techniques, 68% of women declared themselves satisfied with the outcome of the surgery at one year follow up. However, 7% of women reported a deterioration in their general health by this time and 25% reported a deterioration in their mental health. Only 28% of these women achieved total continence. (Black 1997). Berglund et al (1996) reported, in a prospective cohort study that, in addi-

Table B-II.3 Pain after colposuspension.

Authors	Journal reference	Type of study	N. OF	PTS F. UP	Type of complication	Complication rate	Level of evidence
Demirci F, Yucel O, Eren S, Alkan A, Demirci E Yldirium U	, , ,	Case series study	220	1.5 year for65 women4.5 year for155 women	Groin or suprapubic pain	6.8%	3

tion to age and duration of symptoms, increased patient neuroticism had a significant association with poorer outcome from surgery for stress incontinence.

It appears that clarification about most significant factors which influence satisfaction and improved quality of life after surgery for stress incontinence is required. More recently Bidmead et al (2001) [level 3] investigated the impact on quality of life of 83 women submitted to Burch colposuspension with a follow-up at 6-12 months since the operation. Using the King's Health Questionnaire, analysis of the total scores for all domains showed an improvement in 95% of women, with an improvement by over 25% in the total scores of 70% of women and by over 50% in 28% of women compared to the pre-operative evaluation. A deterioration in quality of life after surgery was observed in 2.4% of women (**Table. B-III.1**)

Further research on relevant outcome measures for surgery for incontinence is clearly required and is discussed in the chapters on Quality of Life and Research Outcomes.

C. INCONTINENCE WITH PROLAPSE

I. URODYNAMIC STRESS INCONTI-NENCE AND POTENTIAL INCONTINENCE WITH PROLAPSE

Stress incontinence frequently coexists with pelvic organ prolapse especially of the anterior vaginal wall. Detrusor overactivity with and without urge incontinence often coexists with pelvic organ prolapse, however the incidence has not been determined. Prolapse of the uterus/vaginal apex and posterior vaginal wall may also be found in women with stress incontinence. Pelvic floor weakness is a common denominator to both conditions. Symptoms of stress incontinence can be overt or the patient can be asymptomatic but may develop stress incontinence if the vaginal prolapse is reduced or repaired (potential or occult stress urinary incontinence). It has been suggested that if there is loss of support at the level of the bladder neck, stress incontinence will occur (Richardson 1983, Bump 1988—Level 2) If the bladder neck is supported but the bladder base is not supported stress incontinence may not occur due to urethral kinking. Surgery, which elevates the bladder base, can unmask stress incontinence as the urethral kinking is resolved.

Women who have severe pelvic organ prolapse but potential stress incontinence present a unique challenge to the surgeon. Evidence supporting a specific recommendation in these patients is limited and there are several opposing opinions. The correct method for making the diagnosis of potential SUI is controversial. Urethra-vesical pressure dynamics have been studied by Richardson (Richardson et al 1983) and Bump (Bump et al 1988). Richardson demonstrated that women who did not demonstrate stress incontinence had a much higher urethral closure pressure with straining suggesting that mechanical dysfunction of the urethra was preventing stress incontinence. Bump demonstrated a significant drop in pressure transmission and resting urethral closure pressure when the bladder base was supported (barrier testing with Sim's speculum) in women with stress incontinence. These findings suggest that replacing or supporting the prolapse prior to surgery will reveal "latent incontinence" in women who are more likely to develop stress incontinence after prolapse surgery. Other investigators have shown that reduction of prolapse during preoperative urodynamic testing may reveal potential incontinence in 36% to 80% of women with severe pelvic organ prolapse (Richardson 1983, Bump 1988, Bergman 1988, Rosenzweig 1992, Drutz 1998). No reports have validated any of the theories proposed in a prospective study. A recent systematic review presented at the 2003 American Urogynecologic Society meeting by Barber (Barber

Table B-III.1 Quality of Life after colposuspension.

Authors	Journal reference	Type of study	N. OF	PTS F. UP	Improvement in QOL	Deterioration in QOL	Level of evidence
Bidmead J, Cardozo L, McLellan A, Khullar V,	BJOG. 2001 Apr; 108(4):408-13	Prospective Case series study	83	6-12 months	95%	2.4%	3
Kelleher C							

et al 2003) analyzed 15 articles evaluating the utility of pre-operative urodynamic testing for predicting post-operative stress incontinence in continent women undergoing surgery for pelvic organ prolapse. Urodynamics with reduction of the prolapsed vagina (using a pessary, speculum or vaginal packing) resulted in either a positive stress test or decreased pressure transmission ratios(<100%) in 17%-69% of continent women with prolapse beyond the introitus (7 studies). The test characteristics (sensitivity, specificity, predictive value) of urodynamics with prolapse reduction for predicting postoperative SUI could not be calculated for any study due to either inadequate data or subjects receiving different anti-incontinence procedures based on the result of the urodynamics (treatment paradox).

Many authors have recommended concurrent antiincontinence surgery during pelvic reconstruction to prevent postoperative stress incontinence (Gordon 2001, Chaikin 2000, Klutke 2000, Colombo 1997). Some surgeons (Karram 1999) prefer to provide preferential support to the bladder neck at the time of a prolapse repair. Over-elevation of the bladder neck may result in voiding dysfunction and urgency. However, there is no consensus on the optimal prophylactic procedure for treatment of potential incontinence.

The data on continence procedures for occult incontinence performed concomitantly with vaginal reconstruction are shown in Table III. Investigations involving occult incontinence are listed at the top of the table. A recent RCT of 50 women with stage II or greater genital prolapse and occult stress urinary incontinence (Meschia 2004) has shown that placing a TVT results in higher 2-year objective continence rates than endopelvic fascia plication at the urethrovesical junction (92% vs 56%, respectively; p<.01). The subjective cure rates were 96% vs 64% for TVT compared to suburethral plication. Time for resumption of spontaneous voiding, rates of urinary retention, de novo urge incontinence, and complications did not differ between groups. Despite negative cystometrograms, de novo urge incontinence symptoms were reported in 12% of the TVT group compared to 4% of the suburethral plication group (p=.66). Although not statistically significant, the authors recommend that data from a larger series are required to define the risk:benefit ratio associated with TVT versus endopelvic fascia plication. In a larger RCT including patients with occult and clinical stress incontinence, Colombo et al (Colombo 1997) showed that the Pereyra needle suspension resulted in higher long-term objective and subjective cure rates when compared to the pubourethral ligament plication. Another RCT showed that a needle suspension procedure did not result in less incontinence postoperatively than a suburethral plication, but resulted in more short-term complications (Bump et al, 1996). Gordon (Gordon et al 2001) prospectively followed 30 patients short-term who underwent TVT concurrent with surgery for severe genitourinary prolapse. No patients developed postoperative symptoms of stress incontinence despite 3 patients (10%) having positive postoperative stress tests. De novo detrusor overactivity occurred in 13% of subjects. In a small prospective Chaikin (Chaikin et al 2000) showed an 86% success rate for occult incontinence when combining pubovaginal slings with anterior colporrhaphy. Klutke and Ramos (Klutke 2000) reviewed 125 women with grade III or IV uterovaginal prolapse of whom 55 patients (Group 1) underwent concomitant Burch urethropexy for occult incontinence. The remaining 70 subjects (Group 2) underwent hysterectomy and vaginal reconstruction alone. Only 23 patients in Group 1 and 20 patient in Group 2 had postoperative urodynamic testing. The authors found that 30% of patients in Group 1 versus 5% of patients in Group 2 had de novo urge incontinence thus casting doubt on the prophylactic use of the Burch procedure for occult incontinence.

Patients with stage II to IV vaginal prolapse with coexistent symptomatic stress incontinence have a number of treatment options. The route of antiincontinence surgery may follow the route of prolapse repair; otherwise, a combination of surgical routes may be utilized. There is no evidence to indicate which form of urethral support is most effective.

Milani et al (Milani 1985) noted that the presence of vaginal prolapse preoperatively led to a lower cure rate of stress incontinence with either the Burch colposuspension or the MMK procedure; the greater the severity of the prolapse, the greater the reduction in cure rate. (Level 3) More recent data on continence procedures with concurrent vaginal reconstruction for severe pelvic organ prolapse is listed at the bottom of Table C-I.1. In one RCT Colombo et al (Colombo 1996) compared cystopexy to cystopexy combined with pubourethral ligament plication for prevention of postoperative stress incontinence in women undergoing surgery for genitourinary prolapse. All women had a negative stress test with prolapse repositioned with a Sim's speculum. At one year 8% of patients in each group had developed postoperative stress incontinence; however; cystopexy alone produced lower morbidity in terms of resumption of spontaneous voiding and long-term voiding difficulties. In an additional RCT Colombo et al (Colombo 2000) compared Burch colposuspension with anterior colporrhaphy in women with stress urinary incontinence and Grade 2-3 anterior vaginal wall prolapse and found that the Burch colposuspension was better in controlling stress incontinence but that cystocele recurred in 34% of patients. The cure rate for cystocele with anterior colporrhaphy was high (97%) but stress incontinence cure rate was very low. The authors concluded that neither operation was recommended for combined stress incontinence and advanced cystocele. The TVT procedure combined with vaginal reconstruction resulted in 85% to 95% cure rates for urodynamic stress incontinence in a prospective cohort (Huang 2003) and case series (Partoll 2002). Huang et al (Huang 2003) reported urinary urgency and voiding dysfunction rates of 10% and 11%, respectively. Voiding difficulties and postvoid residuals of > 100 ml were treated with urethral dilatation. The authors did not report any cases of long-standing urinary retention.

II. PROLAPSE AFTER SURGERY FOR INCONTINENCE

A recent review by Robinson and Cardozo (Robinson 2004) summarized the effect of various anticontinence procedures on urogenital prolapse. They found that pelvic support defects, particularly posterior compartment defects, increased after colposuspension (open and laparoscopic). Vaginal route procedures with the exception of needle suspension procedures did not increase pelvic support defects. The sling procedure was found to have a protective effect against recurrent cystocele (Goldberg 2001). Burch (Burch 1968) recognized at an early stage that colposuspension led to the development of posterior vaginal wall prolapse in a significant number of women and recommended that a Moschcowitz operation be incorporated into the colposuspension procedure. Despite introduction of this modification Burch found an 8% incidence of posterior vaginal wall prolapse after colposuspension. Wiskind et al (Wiskind 1992) demonstrated that 27% of women develop symptomatic prolapse within four years of a colposuspension and did not find that correction of prolapse at primary surgery prevented recurrence. Langer (Langer et al 1988) reported that 13.6% of patients who had undergone Burch procedures, but no hysterectomy or cul-de-sac obliteration, developed an enterocele 1 to 2 years postoperatively. In a recent study of 127 women who underwent Burch colposuspension with mean follow-up of 12.4 years, Langer et al (Langer 2001) noted that 19% overall complained of anatomical defects but that most were noted > 5 years after surgery. Alcalay (Alcalay et al 1995) noted that 26% of patients during a 10 to 20 year follow-up period after Burch colposuspension underwent a rectocele repair and 5% underwent an enterocele repair.

III. DENERVATION AFTER PROLAPSE SURGERY

Tanagho (Tanagho 1985) first suggested that prolapse surgery such as anterior repair damaged urethral innervation. Zivkovic (Zivkovic et al 1996) found evidence of greater prolongation of nerve latencies in women whose bladder neck surgery had failed to cure stress incontinence one year after follow up suggesting that surgery may increase denervation. Benson (Benson and McClellan 1993) in a randomized single blinded trial, found clinically significant increases in pudendal or perineal nerve terminal motor latency in women who underwent vaginal dissection during pelvic organ prolapse repair + antiincontinence surgery compared to patients who underwent abdominal route repair without vaginal dissection (OR 5.78 [95% CI 1.6-20]). In a follow up study (Welgoss 1999), surgically induced perineal neuropathy during prolapse surgery was associated with suboptimal outcome (RR 1.82 [95% CI 1.13-2.93]). The data on denervation is not conclusive. The literature on continence procedures combined with prolapse surgery is summarised in Table C-I.1.

Reference/ Type of incontinence	Type of Op	No. of Pts	Duration Follow up	Cure criteria	Cure/ Improvement Rate	Level of Evidence
Meschia M 2004 Occult incontinence	TVT EFP	50 25 25	26 mos TVT 24 mos plication median	Objective Negative cough stress test Subjective No de novo	Objective 92% TVT 56% EFP Subiective	1/2
				SUI	96% TVT 64% EFP	
Colombo M 1997	PULP	109 55 (40)*	3-9 years	Objective Negative cough stress test	Objective 50% PULP	1/2
Occult and clinical SUI	Peyrera	54 (33)*		Subjective No SUI	76% Percyra Subjective 85% PULP 100% Perevra	
Bump RC 1996 Occult incontinence	Muzsnai NC EFP	29 14 15	6 mos	Objective Urodynamics at 6 months Pad tests UDI, IIQ	Objective 86% Muzsnai 93% EFP No difference pad test,UDI, and IIQ	1/2
Gordon D 2001 Occult incontinence	TVT	30	14.3 mos (12-24)	Objective Negative stress test Subjective No SUI	Objective 90% Subjective 100%	2
Klutke JJ 2000 Occult incontinence	Burch for occult SUI No Burch	125 55* 70	3.5 years (1-7)	Urodynamic studies	No de novo USI: 96% Burch 100% No Burch Positive for de novo OAB: 30% Burch 5% No Burch	4
Chaikin DC 2000 Occult incontinence	AR + sling (Group 1) AR (Group 2)	24 14* 10	47mos (12-108) 44 mos (12-96)	Success <u>> 50%</u> decrease incontinence	86% Group 1 100% Group 2	2

Table C-I.I. Summary of Reported Data on Continence Procedures with Concurrent Vaginal Reconstruction for Severe Pelvic Organ Prolapse

Table C-I.1. Summary of Reported Data on Continence Procedures with Concurrent Vaginal Reconstruction for Severe Pelvic Organ Prolapse

ue Use of the constraint of the constr	Colombo M		102	1 year	Objective	Objective	1/2
Onte, Ior And Cystopexy Journess (Cystopexy) Journess (Cystopexy) Journess (Cystopexy) M Burch 35 8-17 years Objective stress test Subjective No 22% AR Burch 35 8-17 years Objective stress test Subjective No 22% AR AR 33 SUI Negative stress test Subjective No 22% AR AR 33 SUI Subjective Subje	1996 Declaration	Cystopexy-	52		Negative stress test	92% AK	
orUsedoexyNo SUIMwith PULP35 $8-17$ yearsObjectiveObjective 74% BurchMBurch35 $8-17$ yearsObjective stress test Subjective No 42% ARAR33SUINegative stress test Subjective No 42% AR 52% ARAR33SUINegative stress test Subjective No 2% ARAR33Cured: No 2% Subjective 2% ARAR53Objective 2% ARLAVH +53Cured: Negative cough stress test, 85% Group 1,TVT53Negative cough stress test, 3% Group 2TVH+APC+TNegative cough stress test, 3% Group 2TVH+APC+TNegative cough stress test, 3% Group 2TVH+APC+T376 mosCured: Negative cough stress test, 1-hrTVH+APC+T376 mosSUI symptomsTVT376 mosSUI symptoms	Frotapse atone,	AK O	00		Subjective	92% AK \pm PULF	
M with PULP Objective Objective Objective Planch 35 Burch 35 Burch 35 Burch 35 Burch 35 Burch 35 Burch 33 Burch 30 Burch 42% AR Burch 42% AR Burch 42% AR Burch 42% AR Burch 30 Burch 30 Burch 30 Burch 30 Burch 30 Burch	no clinical or	Cystopexy			No SUI		
M Burch 35 8-17 years Objective Objective 74% Burch AR 33 SUI Negative stress test Subjective No 25% AR AR 33 SUI SUI SUI AR 33 SUI SUI SUI AR 33 SUI SUI Subjective No AR 33 SUI Subjective No Subjective Subjective No ILVH+ 53 Uncet. Negative stress test. S2% AR TVT 53 Objective cough stress test. S5% Group 2 TVH+APC+T 53 Cured. Negative cough stress test. Negative cough stress test. VT VT Negative cough stress test. S5% Group 2 VT 37 6 mos Cured. Negative stress test. ITVT 37 6 mos SUI symptoms	occult SUI	with PULP					
Burch35Negative stress test Subjective NoAR3333AR3333AR330bjectiveLAVH +530bjectiveLAVH +530bjectiveTVT530bjectiveTVT530bjectiveTVH+APC+T530bjectiveTVH+APC+T530bjectiveTVH+APC+T530bjectiveTVT530bjective cough stress test, 1-hrGroup 2)530bjective cough stress test, 1-hrTVT376 mos0 cured: Negative cough stress test, 1-hrarryTVT376 mostest 50% preop,leakage0 uning CCarry50 nos0 nostest 50% preop,leakage0 noste	Colombo M			8-17 years	Objective	Objective 74% Burch	1/2
AR 33 SUI LAVH + 53 106 18 mos (12-36) Objective LAVH + 53 Objective Cured: Negative cough stress test, < 5g on 1-hr pad test,	2000	Burch	35		Negative stress test Subjective No	42% AR	
LAVH + 106 18 mos (12-36) Objective LAVH + 53 18 mos (12-36) Objective TVT 53 Cured: Negative cough stress test, TVT 53 < 55 on 1-hr pad test,	USI and	AR	33		SUI	Subjective	
$ \begin{array}{ c c c c c c } LAVH + & 53 & 106 & 18 mos (12-36) & Objective \\ LAVH + & 53 & 0bjective \\ TVT & 53 & 0bjective \\ TVH + APC + T & 53 & cured: Negative cough stress test, \\ Cured: Negative urodynamics \\ ITVH + APC + T & negative urodynamics \\ TVH + APC + T & negative urodynamics \\ TVH + APC + T & negative urodynamics \\ TVT & VT & negative urodynamics \\ Coup 2) & negative urodynamics \\ Improved: & neff \\ Improved: & negative urodynamics \\ Improved: & neff \\ Improve$	advanced					86% Burch	
$ \begin{array}{ c c c c c c } LAVH + & 53 & 106 & 18 mos (12-36) & Objective \\ LAVH + & 53 & 0.05 & 0.0$	cystocele					52% AR	
LAVH +53Cured: Negative cough stress test, < 5g on 1-hr pad test, negative urodynamics Improved:TVT53< 5g on 1-hr pad test, negative urodynamics Improved:TVH+APC+TVTNegative cough stress test, 1-hr pad test 50% preop,leakage during CCTVT376 mosTVT376 mostecSUI symptoms	Huang K		106	18 mos (12-36)	Objective	Cured: 87% Group 1,	2
TVT 53 < 5g on 1-hr pad test,	2003	LAVH +	53		Cured: Negative cough stress test,	85% Group 2	
(Group 1) 53 negative urodynamics TVH+APC+T 53 improved: VT VT Negative cough stress test, 1-hr (Group 2) ad test < 50% preop,leakage	ISU	TVT			< 5g on 1-hr pad test,		
TVH+APC+T Improved: VT VT VT Negative cough stress test, 1-hr VT 37 6 mos TVT 37 6 mos nary SUI symptoms		(Group 1)	53		negative urodynamics	Improved: 4% Group 1	
VT Negative cough stress test, 1-hr (Group 2) Negative cough stress test, 1-hr TVT 37 6 mos advring CC Cured: Negative stress test and no nary SUI symptoms		TVH+APC+T			Improved:	3% Group 2	
(Group 2) pad test ≤ 50% preop,leakage TVT 37 6 mos Cured: Negative stress test and no nary		VT			Negative cough stress test, 1-hr		
TVT 37 6 mos dump CC nary SUI symptoms		(Group 2)			pad test $\leq 50\%$ preop, leakage		
nary SUI symptoms	Dottoll I	TVT	77	6 mag	Curred: Monsting strang foot and no	0407	~
	ration L	1 / 1	10	0 11105	CUICU. INEGAUVE SUESS LESE AND IN	24/0	t
Stress or mixed urinary incontinence	2002				SUI symptoms		
mixed urinary incontinence	Stress or						
incontinence	mixed urinary						
	incontinence						

EFP=endopelvic fascia plication SUI=stress urinary incontinence PULP=pubourethral ligament plication NC=needle colposuspension AR=anterior repair GSI=urodynamic stress incontinence LAVH=laparoscopic assisted vaginal hysterectomy TVH=total vaginal hysterectomy APC=anterior posterior colporrhaphy VAS=visual analogue scale CC=cystometric capacity

CONCLUSIONS AND RECOMMENDATIONS

There is no reliable method to predict which women will develop stress incontinence after anterior vaginal wall surgery. Recommendations on the need of preoperative urodynamics, the appropriate test for diagnosis of occult incontinence, or the most effective treatment for postoperative stress urinary incontinence cannot be based on scientific evidence.

The TVT procedure results in a significantly higher cure rate for "occult" incontinence than endopelvic fascia plication (Level 2). The Burch colposuspen sion is not recommended for prophylaxis of occult incontinence (Level 3). There is some evidence to suggest that surgery for stress incontinence may increase denervation of the striated muscle of the urethral sphincter (Level 3). Adequately powered well-designed RCTs of current surgical treatment for prevention of postoperative stress urinary incontinence are needed. The National Institute of Health Pelvic Floor Disorders Network is currently in the midst of the CARE protocol, a multicentered RCT comparing open sacral colpopexy with and without concomitant Burch colposuspension in women who suffer from POP without incontinence. The surgeons are blinded to the results of barrier testing. Preliminary data should be available during the next consultation.

Surgery for stress incontinence may lead to the development of symptomatic prolapse in up to 27% women (Level 3). There is no evidence to support the view that surgery to prevent prolapse performed at the time of incontinence surgery prevents the development of future prolapse.

There is some evidence to suggest that prolapse, when present at the time of incontinence surgery, is associated with a poorer outcome for cure of stress incontinence with retropubic colposuspension procedures (Level 3). However, the TVT procedure concomitant with pelvic organ prolapse results in high short-term cure rates for stress incontinence (Level 2/3).

Grade C—There are no recommendations on the appropriate test for diagnosis of de novo postoperative stress urinary incontinence.

Grade C—There are no recommendations on the appropriate procedure for prevention of de novo postoperative stress urinary incontinence or correction of urodynamic stress incontinence when concomitant prolapse surgery is required.

Grade C—Surgery for urodynamic stress incontinence should be performed with concomitant pelvic reconstruction in symptomatic patients.

D. CONFOUNDING VARIABLES

I. AGE

Both the number and percentage of operations for stress urinary incontinence in women over age 65 are increasing (Korn AP & Leearman LA 1996). Mortality is increased over age 80, but is still very low, and usually becomes a statistically insignificant risk factor when comorbidities are considered (Sultana CJ et al 1997). Medical, functional, psychosocial, and quality of life considerations enter into decisions about surgery in the older and more frail geriatric population. Chapter 13 addresses perioperative risks and caveats in older persons.

Several studies have looked at the relationship of age to surgical success with inconsistent results. None are prospective, hypothesis-driven investigations. Most are small, and none evaluate a balance of risk and benefits important to older women. Furthermore, an association of age with outcome does not establish causation. Any study in older women may include a technical bias of less aggressive urethral elevation or support to avert voiding dysfunction.

Tamussino et al found 69% objective cure at 5 years in 42 women over age 50 compared to 50% cure in 24 younger women who had undergone <u>anterior col-</u> **porrhaphy** (p<.05) (Tamussino KE et al 1999). Three of six frail elderly women who underwent suburethral plication at the time of colpocleisis had persistent stress incontinence postoperatively (Fitzgerald MP & Brubaker L 2003).

Studies of **needle suspension** procedures limited to older women with short term followup have shown good or adequate (Griffth-Jones MD & Abrams PH 1990), (Nitti VW et al 1993) and poor results (Peattie AB & Stanton SL 1989). Most needle procedure studies (Hilton P & Mayne CJ 1991), Golumb J et al 1994), (Groutz A et al 2000), (Kondo K et al 1998), (Clemens JQ et al 1998), (Tammuussino KE et al 1999), (Kelly MJ et al 1991), but not all (Elkabir JJ & Mee AD 1998), have found equal or better outcomes, whether good or poor, in older women compared to younger ones.

Results reported from **pubovaginal and vaginal wall sling** procedures show favorable outcomes in older women, with series limited to older women reporting short-term cured/satisfied rates of 86% to 100% (Chaikin DC et al 2000), (Chaikin DC et al 2000), (Fitzgerald MP & Brubaker L 2003), Couillaard DR et al 1994), Elersgany R et al 1998), or comparisons with younger women showing no difference in outcome (Carr LK et al 1997), (Hawkins E et al 2002), (Sand PK et al 2000), (schostak M et al 2002). One study of 42 women found age only associated with outcome over age 80 (Litwiller SE et al 1997). The incidence of 5 erosions out of 22 cadaveric fascial slings was not related to patients' ages (Kammerer-Doak DN 2002).

A 3 to 5-year follow-up of retropubic colposuspension in 35 women age 65 to 82 found subjective 91% and objective 89% cure rates (Gillon G & Stanton SL 1984). At 5 years Tamussino et al found 78%-80% success of colposuspension in 106 women both under and over age 50 (Tamussiono KE et al 1999). Five to 11 year follow-up of 131 women ages 27 to 79 at the time of operation found 83% satisfaction, 54% subjective continence and 93% objective continence (Tegerstedt G et al 2001). In multivariable analysis age was not associated with success. One study with shorter follow-up in older women reported good results (Stanton SL & Cardozo LD 1980), and some recent studies including younger and older women have found no statistical difference between their success rates (Sand PK et al 2000), Thaker R et al 2002), Amaye-Obu FA & Drutz HP 1999). Others have shown significantly less success with increasing age (Chilaka VN et al 2002), Berglund A et al 1997), Nitahara KS et al 1999), (Langer R et al 2001). In the study by Berglund et al, age became insignificant in the multivariable logistic regression model that included neuroticism and duration of incontinence (Beglund A 1997). Dolan et al found both lower postoperative opening pressures and increasing age in women not objectively cured following laparoscopic or open Burch colposuspension; subjective outcomes were not associated with age (Dolan LM et al 2004). Investigators have found less success in postmenopausal (but few elderly) women compared to premenopausal women (Liapis A et al 1998), Langer R et al 1990).

Three **TVT** series with short follow-up that have evaluated age and outcomes found no association (Walsh K et al 2004), (Rardin CR et al 2002), (Frital X et al 2002). One found that failure had univariate associations with age, older age, lower urethral closure pressure, and immobility (Nilsson CG et al 2001). Fifty-one of 76 women (67%) age 70 and older evaluated at a minimum of 16 months were subjectively cured and 82% were satisfied (Sevestre S et al 2003). The 18% with urge incontinence were

not included in those "cured". Kinn et al found lower success in women over age 75 with lower MUCP (Kinn AC 2001). Nilsson et al reported 3 of 5 frail women over age 80 cured or improved (Nilsson CG et al 2001). Moore and Miklos reported 93% subjective or objective cure at a minimum of 2 months in 30 frail women age 65 to 93 with TVT and colpocleisis under local anaesthesia (Moore RD & Miklos JR 2003). A study of 187 TVT recipients with a mean age of 55, s.d. 11 years, found a lower subjective cure rate in women over age 70 (65%) compared to under 70 (71%), but age was not associated with the degree of satisfaction (Deval B et al 2002).

Case series of periurethral bulking agents including only elderly women report results ranging from favorable to poor (Herschorn S et al 1996), Khullar V et al 1997), (Stanton SL & Monga AK 1997), (Faerber GJ 1996).. In 58 women, mean age 73 (range 65-86), Winters et al found that 80% achieved social continence subjectively, but 41% experienced recurrent incontinence, which was more difficult to treat Winters JC et al 2000). Age is not associated with outcomes of periurethral bulking agents in most studies that have compared older to younger women, (Kuczyk MA et al 1998), Herschorne S & Radomski SB 1997), (Gorton E et al 1999), (Chrouser KL et al 2004), (Herschorn S & Glazer AA 2000). In 54 women age 20 to 90, failures were older, but the data were not statistically analyzed (Monga AK & Stanton SL 1997).

A survey of 54 women age 60 and over who had undergone **any continence surgery** found 71% continence within 2 years of the procedure, but 39% continence beyond 2 years, median 12 years (Diokno AC et al 2003). Other surveys combining continence procedures found greater symptom improvement in women under age 50 but fewer complications in women over age 50 (Hutchings A et al 1998), and more dissatisfaction with having had past incontinence surgery in women over age 70 (Diokno AC et al 2003). Age is not a risk factor for reoperation for the combined outcome of pelvic organ prolapse and urinary incontinence (Clark AL et al 2003).

The best information available, summarizing the the larger studies with the most information about women age 65 and above, shows that short and long term retropubic colposuspension results in older women are not statistically different from those in younger women, although numerically the success rate is often lower (Baker KR & Drutz HP 1992), (Kjølhede P & Rydén G 1994), (Tamussino KE et al 1999), (Tegerstedt G et al 2001). The study showing

a statistically significant poorer outcome had only 22 women over age 70 (Chilaka VN et al 2002). Success at 5 years and beyond is 77%-79% (Chilaka VN et al 2002), (Tamussino KE et al 1999), to 93% (Tegerstedt G et al 2001) objectively and 54% subjectively (Tegerstedt G et al 2001) dry. Needle procedures (Kondo A et al 1998), (Clemens JQ et al 1998), (Kuczyk MA et al 1998) and periurethral bulking agents (Herschorn S et al 1996), (Herschorn S & Radomski SB 1997), (Gorton E et al 1999), (Chrouser KL et al 2004) have equivalent long-term results in older and younger women. Too little information is available about other procedures.

Age can be associated, often nonsignficantly, with postoperative voiding dysfunction (Smith RNJ & Cardozo L 1997), (Stanton SL & Cardozo L 1980), (Mutone N et al 2003), (Murphy M et al 2003), (Kapoor R et al 1993), (McLennan MT et al 1998).. One study of 375 women in whom transvaginal tape was placed, mean age 57 (40-91), found that age was associated with urinary retention in univariate analysis, but became insignificant in the multivariable model (Hong B et al 2003). Only peak flow remained significant.

There is Level 3 evidence that older women respond to continence surgery as well as younger women, although a small decrement in satisfactory outcome cannot be ruled out. There is Level 3 evidence that the association of age with poorer outcomes has to do with other factors, such as urethral pressure.

II. ACTIVITY

No data inform appropriate postoperative activity instructions. Cross et al found that one fourth women with a mean age of 72 who received periurethral collagen attributed an increase in physical activity to less incontinence (Cross CA et al 1998). However, in a observational intervention study of 82 women evaluated at a minimum of 6 months, Stach-Lempinen et al obtained prospective preoperative and postoperative self-report of activity as well as objective data from an electronic motion sensor worn for one week. They found no change in any parameters of physical activity, including among those who were completely dry (Stach-Lempinen B et al 2004).

III. MEDICAL ILLNESS

Medical illness such as respiratory problems and diabetes might be expected to reduce the likelihood of successful incontinence surgery, but data are largely lacking. Significant chest disease and a chronic cough were associated with failure of the Stamey procedure in an early series, but details are not given (Ashken MH et al 1984). Eighty-eight women who underwent polypropylene pubovaginal sling were followed for 1 month or more, mean 4 years (Morgan JE et al 1995). Compared to nine percent of the cohort with pulmonary conditions, but 50% (2/4) of the "persistent failures" had bronchitis or asthma (p=.04). This was not controlled for the obesity in 3 of the 4 failures. Tegerstedt et al reported 5 to 11 year outcomes in 169 women who underwent abdominal urethropexy-colposuspension (Tegerstedt G et al 2001). In multivariable analysis, the presence of chronic disease (bronchial asthma, diabetes [14%]) was not associated with subjective continence, nor were age and low urethral closure pressure. Moore and Miklos performed colpocleisis and pubovaginal sling in 30 women age 65 to 93, with medical conditions including previous MI or cardiovascular disease (18), pulmonary disease (7), and stroke (2) (Moore RD & Miklos JR 2003). Stress incontinence was subjectively cured in 93% at a minimum of 2, average 19 months, but no analysis of medical conditions and success were offered. A 91 year old sustained a myocardial infarction and congestive heart failure, but there were no perioperative deaths.

Predictors of success one year following incontinence surgery in 232 women depended upon which outcomes were being evaluated: impairment (complications), disability (symptom severity) or handicap (symptom impact and Activities of Daily Living [ADL]) (Hutchings A et al 1998). In multivariable analysis, limitations in ADL predicted less improvement in symptom severity, along with younger age and absent urgency/urge incontinence. Postoperative complications (pain, wound problems, vaginal bleeding, infection) in the year following surgery were more likely in women with preoperative comorbidities (not defined), as well as in younger women who underwent additional prolapse procedures. Preoperative limitation was predicted by an improvement in ADL, but not by age, presence of comorbidity, urge incontinence, obesity, or type of procedure.

In a series of 121 patients who underwent a pubovaginal sling using fresh frozen cadaveric fascial lata, stress incontinence recurred at 4 to 13 months in 8 patients (O'Reilly KJ & Govier FE 2002). Comorbidities included demyelinating polyneuropathy (2), diabetes mellitus (2), previous pelvic irradiation (1), and previous abdominoperineal resection (1). Seven had had prior incontinence surgery. Comorbidities in the women whose incontinence did not recur are not stated. The incidence of 5 erosions out of 22 cadaveric fascial sling procedures was not related to a history of diabetes mellitus or smoking (Ka,,erer-Doak DN et al 2002).

CONCLUSION

There is level 4 evidence that medical comorbidities impact surgical outcomes. The impact of various comorbidities will depend in part on the outcomes chosen. There is level 4 evidence that medical comorbidities influence failure and complications in cadaveric fascial sling procedures.

IV. PSYCHIATRIC ILLNESS

Despite the obvious association between psychological or personality factors and satisfaction with treatment, minimal research has been done on the influence of such factors on subjective or objective surgical success. Black et al found women undergoing stress incontinence surgery in the United Kingdom to be demographically similar to the general population, although mental health status was not specifically compared (Black NA et al 1996). Baseline symptom impact correlated positively with mental health, symptom severity, poorer socioeconomic status, and youth.

In a study of 45 women who underwent retropubic cystourethropexy or puboccygeal repair, baseline lower neuroticism correlated with subjective and pad test cure at one year ((Berglund A et al 1997). Higher extraversion correlated with subjective but not objective cure. Depression decreased in women objectively cured, but not those improved/failed; the decrease in depression in those subjectively cured did not reach statistical significance. Baseline somatic anxiety, psychic anxiety, and psychasthenia (obsessive-compulsive) characteristics were higher in women subjectively failed/improved than those cured or than a reference group. The multiple comparisons and small sample size in this study make some chance associations likely. The same subjects analyzed in a different study showed the cured group to have a higher baseline degree of social integration and than the improved group ((Betglund A et al 1996). No differences were found in baseline or follow-up intimate relationship measures.

Öbrink et al detected above-average levels of neuroticism and depression in women who reported failure of their continence surgery without objective urine loss at 10 to 20 year follow-up (?brink A et al 1979). Below-average levels were found in women with objective but not subjective failure. In 63 women who underwent a Burch procedure, symptomatic improvement was associated with fewer sleep disturbances and less tension (Rosenzweig BA et al 1991). Subjectively persistent incontinence was associated with more depression and sleep disturbance.

There is Level 3 evidence that psychological factors impact subjective and objective surgical outcomes in different ways. No data inform psychological interventions to improve the outcome of persistent incontinence or its impact.

RECOMMENDATIONS FROM I-IV

Prospective studies should be performed that evaluate in multivariable analysis the associations of age, measurable lower urinary tract factors (e.g., urethral pressure), and comorbidities with surgical outcomes.

Clinical investigations are needed to understand the mechanisms of urge and mixed incontinence, to determine which persons will obtain relief of urge incontinence postoperatively and in which persons this problem will arise or worsen.

Randomized clinical trials are needed to establish effective prediction and management of postoperative voiding dysfunction.

Measures need to be developed to improve assessment of elderly women's quality of life and values with regard to continence issues, so that surgeons can adequately counsel older women regarding the risks and benefits to them of continence procedures.

"Geriatric" complications of urologic surgery, such as delirium and falls, need to be determined in large prospective studies, then randomized interventional trials to reduce complications are needed.

Prospective evaluation of newer procedures, such as tension-free vaginal tape, must be adequately studied in elderly women, as well as in those with medical comorbidities, before such procedures are used in these populations.

Clinical trials are needed to determine appropriate postoperative activity instructions, particularly following less invasive procedures.

Prospective clinical studies are needed to determine associations of personality factors as well as psychological comorbidities with surgical outcomes, after which randomized interventional trials are needed to improve outcomes.

V. OBESITY

There are no prospective randomized studies that have examined obesity as an independent variable across different anti-incontinence surgical procedures or within the same procedure. Obesity has been studied only retrospectively in case series as a risk factor for success or morbidity in stress incontinence surgery (Level 4 evidence).

There are no prospective, randomized trials that suggest superiority of one surgical technique over another in the obese population. Several studies have suggested increased failure rates among obese patients undergoing needle bladder neck suspensions (O'Sullivan DC et al 1995), (Lo TS et al 2003), (Varner RE et al 1990) or retropubic suspensions (Alcalay M et al 1995), (Brieger G & Korda A 1991). In contrast a retrospective study of anti-incontinence surgery in 198 women demonstrated that overall continence did not correlate with obesity in patients undergoing anterior colporrhaphy, anterior colporrhaphy with needle bladder neck suspension or Burch colposuspension although cure rates were markedly better in those in the Burch colposuspension cohort overall (Zivkopvic F et al 1999). One small case series suggested that fascial slings are effective in the morbidly obese patient (Cummings JM et all 1998). In this study, 2/4 patients failed bladder neck suspension surgery whereas there were no failures in the 12 patients undergoing fascial slings. Two retrospective studies have demonstrated satisfactory efficacy for TVT in the obese population comparable to that in non-obese patients (Mukherjee K & Constantine G 2001), (Rafii A et al 2003). One study suggested an increased incidence of post-operative urge incontinence in patients with a high body mass index (BMI>30) undergoing TVT but no difference in subjective or objective cure rates (Rafii A et al 2003).

It is generally accepted that although obesity may be associated with other factors (i.e. coronary artery disease, ventilatory/airway problems, thromboembolic phenomenon, etc.) that may place the patient at a somewhat higher surgical risk overall, it is unclear whether obesity alone is an independent predictor for surgical risk or morbidity specifically in stress incontinence surgery.

There are no studies, prospective or retrospective, that have suggested obesity has a positive or favorable influence on outcome in stress incontinence surgery.

CONCLUSION

There is conflicting evidence on the impact of obesity on outcome of stress incontinence surgery.

VI. PREVIOUS CONTINENCE SURGERY

Women who have successful correction of urodynamic stress incontinence (GSI), 10-40% may have recurrence. (Bent, 1990). Recurrence of urodynamic stress urinary incontinence, after anti-incontinence surgery remains a challenging situation for patient and surgeon alike.

1. METHODOLOGY

A literature search was performed using, Ovid Medline 1996-April Week5 2004, EBM Reviews -Cochrane Database of Systematic Reviews 1st Quarter 2004, and EBM Reviews - Cochrane Central Register of Controlled Trials 1st Quarter 2004. Search for "Recurrent Stress Urinary Incontinence" in EBM Reviews - Cochrane Database of Systematic Reviews 1st Quarter 2004, resulted in 0 results returned. Search for "Recurrent Stress Urinary Incontinence" in EBM Reviews - Cochrane Central Register of Controlled Trials, resulted in 2 results returned. Neither of these where related to topic of interest.

Search for "Recurrent Stress Urinary Incontinence" in Ovid Medline 1996-April Week5 2004 resulted in 54 results. 4 articles where to our topic of interest. (Nguyen & Bhatia, 2001), (Amaye-Obu & Drutz, 1999), (Rardin et al., 2002), (Riachi, Kohli, & Miklos, 2002).

Review of these articles and there bibliography, resulted in finding 6 more articles, related to our topic of interest.(Rezapour & Ulmsten, 2001), (Petrou & Frank, 2001), (Holschneider, Solh, Lebherz, & Montz, 1994), (Bent & Ostergard, 1988), and(Bent, 1990), (Nilsson, Kuuva, Falconer, Rezapour, & Ulmsten, 2001)

The data analysis has been divided into, Tension-Free Vaginal Tape, and other surgeries.

2. DATA ANALYSIS

a) TVT

(Rardin et al., 2002) A retrospective multicenter study of 245 consecutive women who were treated

with tension-free vaginal tape for urodynamic stress urinary incontinence and recurrent stress urinary incontinence. 157 had primary stress incontinence and 88 had recurrent stress incontinence. Cure rates were 87% in the primary stress incontinence population, and 85% in the recurrent stress incontinence population. Cure was defined as an absence of urine leakage by patient report. Mean patient follow was 38 weeks. This study concluded that TVT tape is a highly effective treatment among patients with recurrent stress incontinence, with outcomes comparable with those among patients with primary incontinence. (Rezapour & Ulmsten, 2001)

A prospective study evaluating results of TVT surgery on 34 women with recurrent stress urinary incontinence. Mean follow-up was 4 years. Success rate was (82%). This success rate similar to the success rates, published by his hospital, for stress urinary incontinence, in the following article. (Nilsson et al., 2001)

A prospective multicenter study, evaluating TVT surgery in 90 patients with stress urinary incontinence. Mean follow was 5 years. Success rate was 84.7%.

b) Non-TVT surgery

(Holschneider et al., 1994) A retrospective study, evaluating Modified Pereyra Procedure in 54 patients with Recurrent Stress Urinary Incontinence. Mean follow up of 36.3 months. Patients where divided in 2 groups. Group 1 low risk, Group 2 high risks. Risk was determined by the presence of the following factors, Detrusor overactivity on preoperative cystometry, low-pressure urethra (less than 20cm H20 at rest), fibrotic urethra, rigid urethra with significant periurethral scarring, negative Q-tip test and neurogenic incontinence.

Group 1 success rate was 81.6%. Group 2 success rate was 43.8%. (Amaye-Obu & Drutz, 1999)

A retrospective study evaluating 198 patients who were surgically treated for recurrent stress urinary incontinence. This study compared the effectiveness of sling procedures, verse Burch procedure, for recurrent stress urinary incontinence. Also analyzed data related to number of previous surgeries done.

Cure rates

2-TERM SLING PROCEDURE

1 previous surgery	2 previous surgery	3 previous surgery
77%	73%	38%
Burch procedure		
1 previous surgery	2 previous surgery	3 previous surgery
81%	25%	0%

This study indicated Burch procedure should be avoided after >1 previous surgery. (Petrou & Frank, 2001)

A retrospective review of 14 patients who where surgically treated with pubovaginal sling for recurrent stress urinary incontinence. Mean follow was for was 17 months. Cure rate was 50%.

c) Conclusion:

The role of previous anti-incontinence surgery as a confounding factor is poorly understood. Further high level studies are needed to assess the true role of previous anti-incontinence surgery as a confounding factor in the outcome of surgical treatment of SUI.

Before the advent of TVT, it was generally accepted that the first approach to the treatment of urodynamic stress urinary incontinence is the most likely to produce a cure (Bent & Ostergard, 1988), because the cure rate declines more or less proportionately with the number of subsequent operations performed (Amaye-Obu & Drutz, 1999). This was consistent with the literature we reviewed and analyzed, using non TVT procedures.

To reduce failure rates of surgery of recurrent urodynamic stress incontinence, Amaye et al, showed selection of surgery used can influence the outcome. They concluded Burch procedure should not be used after > 1 previous operation due to low success rates compared to sling procedures. (Holschneider et al., 1994) showed patient with certain characteristics have increased risk of failure after surgery for recurrent stress urinary incontinence. (Detrusor overactivity on preoperative cystometry, low-pressure urethra (less than 20cm H20 at rest), fibrotic urethra, rigid urethra with significant periurethral scarring, negative Q-tip test and neurogenic incontinence).

In contrast to the above studies (Rardin et al., 2002) and (Rezapour & Ulmsten, 2001), showed that success rates of TVT surgery on recurrent urodynamic stress incontinence had been comparable to success rates in TVT surgery on primary stress incontinence. Mean follow up in (Rardin et al., 2002) was 38 weeks. In (Holschneider et al., 1994) mean of occurrence of failure was 11.9 months, and (Amaye-Obu & Drutz, 1999), had 100% of it failure after 6 years. Longer-term follow-up is needed to truly analyze TVT success rates on recurrent stress urinary incontinence, but the pattern so far on TVT data does not support the generally accepted hypothesis that risk of failure increases with number of previous procedures. It should be noted that the recurrent stress urinary incontinence patient population, had failed non-TVT surgery. Use of TVT as treatment on patients with failed TVT surgery has not been thoroughly studied. (Riachi et al., 2002), published 2 case studies showing repeat TVT Sling for the treatment of recurrent stress urinary incontinence was successful in the 2 patients they attempted it in.

Preliminary data on TVT procedure on recurrent stress urinary incontinence has shown some promising results, as be a highly effective procedure for recurrent stress urinary incontinence, but longer follow-up studies are needed.

d) Recommendations

Women should be advised that surgical procedures for recurrent stress incontinence have been shown to have a lower success rate (Grade B)

Preliminary data suggests that the TVT procedure produces a similar cure rate in women who have had previous surgery for stress incontinence to women who have not had any previous surgery. The TVT can therefore be offered for recurrent stress incontinence with a similar cure rate to first time surgery. (Grade B)

VII. HYSTERECTOMY DURING CONTINENCE PROCEDURE

In a retrospective review of 147 patients who underwent a MMK procedure with hysterectomy, Green (Green 1975) noted an improved success rate of 95% compared to 81% in 47 women who underwent MMK alone (Level 3). This series largely involved vaginal hysterectomy, which may have produced a bias to women with uterine prolapse. Further retrospective reviews by Stanton and Cardozo (Stanton 1979, Level 3) and Milani et al (Milani 1985, Level 3) did not show any advantage to performing an abdominal hysterectomy at the same time as Burch colposuspension or MMK procedure. Langer et al (Langer 1988) demonstrated no advantage with respect to outcome of urinary symptoms at a mean follow-up of 25 months when an abdominal hysterectomy was performed at the time of colposuspension in a RCT of 45 women, 22 of whom underwent Burch colposuspension alone (Level 1/2). The 23 women who underwent hysterectomy also had a Moschcowitz procedure performed, which appeared to offer some protection against enterocele formation although not statistically significant (three in the no hysterectomy group compared to none in the Burch group). More recently, Meltomaa et al (Meltomaa 2001) compared 65 women who underwent Burch colposuspension alone with 78 women who had concomitant hysterectomy in a questionnaire-based prospective cohort with a mean follow up of 4.9 years (Level 2). Complications related to the operation occurred in 29% of the Burch group and 46% of the hysterectomy group (p=0.038). No statistically significant difference in the frequency of any subgroup of complications was found. Long-term subjective cure or improvement was similar (77% in the Burch group and 81% in the hysterectomy group). Since the majority of the patients in the Burch group had previously undergone hysterectomy, the authors performed a subgroup analysis comparing hysterectomized patients with non-hysterectomized patient. There was no difference in time to normal voiding or long-term subjective cure rate. Daraï et al (Daraï 2002) retrospectively compared 41 women who underwent TVT alone with 40 women who had concomitant vaginal hysterectomy (Level 3). Objective cure was evaluated by clinical and urodynamic examination and by the contilife questionnaire (Richard 1999). All patients received regional anaesthesia. Post-operative urinary flow was significantly slower in the hysterectomy group, 14 versus 24 ml/sec (P=0.02). At a mean follow-up of 23 months, objective and subjective cure rates were similar between TVT and TVT-hysterectomy groups: 97% versus 93% and 68% versus 75%, respectively.

1. CONCLUSION

Abdominal hysterectomy performed at the time of retropubic colposuspension has no adverse effect on the cure rate of SUI (Level 1 for modified Burch colposuspension, Level 3 for MMK). There is some evidence that operation-related complications are significantly increased when concomitant abdominal hysterectomy is performed with Burch colposuspension (Level 2). Vaginal hysterectomy performed at the time of TVT has no adverse effect on surgical outcome (Level 3).

2. RECOMMENDATION

Grade B-concomitant hysterectomy is not indicated for the treatment of stress incontinence in women.

VIII. SEVERITY AND DURATION OF SYMPTOMS

The natural history of untreated stress urinary incontinence is not well defined, although it is assumed by most experts to be slowly progressive. The significance of the severity of incontinence at initial presentation may play a role in the rapidity with a woman progresses as well.

Severity and duration of urinary incontinence (SUI) might be assumed to have some role in the overall success of interventions for SUI. Severity of symptomatic SUI, however, has been stratified in numerous ways including; subjective symptom severity (quality of life or physical activity scales), pad use (quantitative), or objective criteria (stress test, leak point pressure / urethral closure pressure). Since the definitions of severity differ, the ability to stratify results based upon this parameter is problematic.

Berglund et al found that duration of symptoms was a significant predictor of response to surgical intervention. In a study of 45 women who were interviewed 3 months before surgery and one year after, 76% reported that they were cured of urinary incontinence and the remainder improved. The duration of presurgical symptoms was significantly shorter in the cured group. As this study mainly dealt with social and spousal relationships and the influence of SUI thereupon the study author made no conclusions concerning this finding. (Berglund 1996) The results were independent of type of surgical intervention or approach (vaginal vs. suprapubic). (Berglund, 1997) Using a previously validated questionnaire, Hawkins et al found no relationship between degree of symptomatic severity and overall procedural success in a group of 246 women undergoing pubovaginal sling for either primary or recurrent incontinence. (Hawkins, 2002) In a randomized comparison of TVT and colposuspension, Ward and Hilton found no significant impact of symptomatic severity as assessed by various quality of life instruments (SF-36, BFLUTS, and EQ 5D) on outcomes of either the TVT or suspension procedure. (Ward, 2002) In another retrospective study of 245 women undergoing TVT, results were similar in women having the procedure as a primary operation and in those having it as a secondary intervention (who were more severe than the primary intervention group and with a higher incidence of ISD - 70.5 vs. 47.1% on the basis of urodynamics investigation). (Rardin, 2003) Black (1997, 1998) found that preoperative severity of symptoms impacted post operative symptoms as measured by questionnaire in that women with sever symptoms obtained greater reductions after surgery than did those with mild or moderate symptoms; however, women with severe preoperative symptoms tended to have more severe scores after surgery. In contradistinction, Tamussino et al found that women with moderate to severe incontinence fared more poorly after surgical repair(anterior repair, or needle suspension) than did those women with mild SUI as defined by symptoms (assessed by physician) and urodynamics. Three hundred twenty seven women were re-evaluated at a minimum of five years post- operatively and independent of the surgical procedure used, mild patients had higher success rates as defined by clinical continence than did the moderate to severe group (anterior repair 82%/ 49%, needle suspension 61% / 49%). Only Burch colposuspension was unaffected by severity (79% in both groups). (Tamussino, 1999)

In considering severity as measured by pad weight changes, O'Sullivan et al (2003) reported that women with mild incontinence (as defined by less than 10 gram urinary loss on one hour pad testing) experienced an 81% cure rate and 41% satisfaction rate after conservative treatment as compared to moderate patients (10 - 50 gram urinary loss) who noted a 36.8% cure rate and a 30% satisfaction rate.

Other authors have found that urodynamic parameters of severity were not predictive of outcome. Culligan et al (2003) found no relationship between urethral pressure and outcomes in two groups of women undergoing either sling or Burch colposuspension. (Culligan, 2003) Rodriguez et al (2004) found that leak point pressure magnitude was also unable to predict outcome of vaginal sling procedures. (Rodriguez, 2004) Therefore it would seem that urethral functional parameters (as a determinant of severity) are not predictive of surgical outcomes.

SUMMARY

Level 1 - 4 studies are disparate on the effects on duration and severity of SUI symptoms on outcome of intervention. Whereas some studies have identified these factors as influencing surgical results, others have found no substantial impact whatsoever. These findings in part are due to differences in definitions of severity between studies and limited ability to assess duration of symptoms in an objective manner. Further standardization of reporting will be necessary to define the role of these parameters in overall outcomes obtained with surgical intervention for SUI.

IX. OVERACTIVE BLADDER

Clarke (Clarke 1997) showed that 23% of women undergoing urodynamics have mixed urodynamic stress incontinence and detrusor overactivity. The management of these women is still difficult due to the lack of good quality studies.

There are no prospective randomised trials which compare the outcome of colposuspension in women with and without detrusor overactivity. Colombo et al (Colombo 1996, level 3 evidence) performed a retrospective cohort study and compared 44 stress incontinent women with detrusor overactivity with a matched group of women with stress incontinence and a stable bladder. A cure rate of 95% in the stable group compared to 75% in the unstable group two years after surgery was reported. These results, although showing a less favourable outcome in women with stress incontinence with detrusor overactivity, show a more favourable outcome than cure rates of 24-43% shown in other series (Stanton 1978, Lose 1988, Milani 1985, level 3 evidence).

Laurikainen et al (Laurikainen 2003, retrospective review, level 3 evidence) performed TVT in 191 patients without a preoperative urodynamic evaluation. They demonstrated a cure rate of 69% in patients with mixed incontinence compared to a 97% in patients with stress incontinence alone.

Only Chou et al. (Chou EC 2003, retrospective study, level 3 evidence) demonstrated a comparable outcome after sling procedures performed in stress incontinent patients with or without overactive bladder but the number of women with detrusor overactivity was low (26%) in the group of the mixed incontinent patients.

Pow-Sang et al (Pow-Sang 1986, level 3 evidence) demonstrated in a retrospective study that high pressure detrusor overactivity is associated with a poorer outcome from bladder neck surgery.

In a series of 46 women with urodinamically proved mixed incontinence Scotti et al (Scotti 1998, retrospective study, level 3 evidence) noted a significantly higher cure rate in women whose primary symptom had been stress incontinence. Jung et al (Jung 1999) found a relationship between stress urinary incontinence and detrusor overactivity. His study on the anesthetized rat showed that the activation of urethral afferents by urethral perfusion can modulate the micturition reflex. Thus in patients with stress incontinence leakage of urine into the proximal urethra may stimulate urethral afferents facilitate voiding reflex inducing and/or increasing detrusor overactivity. This implies that correction of stress incontinence by surgery in patients with mixed incontinence may resolve the detrusor overactivity. This finding has not been confirmed by a study on patients with urinary symptoms (Sutherst 1978). A retrospective review of 36 women who underwent a sling procedure for stress incontinence and Valsalva induced detrusor overactivity revealed a cure rate of stress incontinence of 92% and urge incontinence of 75% (Serels 2000, level 3 evidence). Koonings et al. (Koonings 1988, retrospective study, level 3 evidence) demonstrated that in women with mixed incontinence where bladder contraction is preceded by urethral relaxation, there is a more than 90% chance that bladder overactivity will disappear after successful operation for stress urinary incontinence (Table D-IX.1).

Operation	Authors	Reference	Type of study	N° pts	Cure rate	Evidence level
Burch colposuspension	Colombo M Zanetta G Vitobello D Milani R	1996 Br J Obstet Gynecol 103(3):255-60	Retrospective cohort study	44 mixed incont.44 stress incont.	75% 95%	3
Tension-free vaginal tape	Laurikainen E Kiilholma P	2003 J AM Coll Surg 196(4):579-83	Retrospective study	64 mixed incont. 127stress incont.	69% 97%	3
Sling	Chou EC Flisser AJ PanagopoulosG Blaivas JG	2003 J Urol 170:494-7	Retrospective study	52 mixed incont.46 stress incont.	93% 97%	3

Table D-IX.1 Bladder function after stress incontinence surgery.

CONCLUSION

There is a level 3 evidence that women who have detrusor overactivity pre-operatively are more likely to have a less favourable outcome from surgery but level 1 evidence studies are required to confirm this observation.

Further studies are required to clarify what type of detrusor overactivity is most likely to influence the surgical outcome.

X. URETHRAL OCCLUSIVE FORCES

McGuire et al. (McGuire 1976) classified type III incontinence as intrinsic sphincteric deficiency characterized by an incompetent sphincteric unit with a urethrovescical angle not compromised. At present this classification system has become less popular because the overlap between the type III incontinence and Green's type I or II incontinence characterized on the contrary by a lost of the posterior urethrovescical angle (type I) or a rotational descent of the bladder base (type II).

Urethral pressure profilometry is commonly used to detect intrinsic sphincteric deficiency, despite a great deal of overlap in results between continent and incontinent women (Hilton 1983). Intrinsic sphincteric deficiency defined as a MUCP of less than 20 cmH2O is present in 15-23% of women that undergo surgery for stress urinary incontinence (McGuire 1981, Koonings 1990).

Several authors have reported a lower success rate for surgical treatment of stress incontinence in women with an ISD (Koonings 1990, Bergman 1989, Sand 1987, Stanton 1979 level 3 evidence). Sand et al (Sand 1987, retrospective study, level 3 evidence) compared two similar groups of women who underwent colposuspension for stress incontinence. The group of women with a resting maximum urethral closure pressure of 20 cm water were less likely to be cured of stress incontinence if they were under 50 years of age but in women over 50 years the MUCP was not a discriminator. Koonings et al. (Koonings 1990, retrospective study, level 3 evidence) demonstrated that the failure rate in women with stress urinary incontinence and low urethral pressure was significantly higher compared with women with good urethral pressure after both Pereyra and Burch procedures.

In contrast Meschia et al. (Meschia 1991), retrospec-

tive study, level 3 evidence) could not find a statistically significant difference in failure rate when comparing two groups of patients undergoing colposuspension with normal and low MUCP. Similarly, Monga et al (Monga 1997,???,level ??? evidence) couldn't find that MUCP represent a risk factor for poor outcome after bladder neck surgery.

Bergman et al. (Bergman 1991), retrospective study, level 3 evidence) performed modified Burch procedures ,with plication of the paraurethral tissues over the proximal urethra aiming to increase urethral resistance, showing a 1-year cure rate of 90%.

McGuire et al. (McGuire 1987), retrospective study, level 3 evidence) suggested that patients with ISD should be managed by pubovaginal sling procedure demonstrating a cure rate of 95%. Similarly Horbach et al. (Horbach 1988, retrospective study, level 3 evidence) reported a success rate of 85% with slings in patients with low-pressure urethras.

McGuire and Appell (McGuire 1994) reported that the injection of a bulking agent improve the ability of the urethra to resist raised intra-abdominal pressure and therefore recommended such treatment for women who have intrinsic sphincter weakness with no urethral hypermobility. Kreden and Austin (Kreden 1996, retrospective study, level 3 evidence) demonstrated better cure rates with injectable agents in women without urethral hypermobility and concluded that injectable agents were only suitable for women with ISD in whom urethral support was satisfactory. Other authors have also used injectables on women with and without urethral hypermobility founding similar cure rates between the two groups of patients (Steele 2000, Monga 1995, O'Connell 1995, level 3 evidence).

A single definitive test for the diagnosis of intrinsic urethral sphincteric deficiency does not exist. Instead, multiple tests should be employed to reach consensus for the diagnosis (Betson 2003).

Bump et al. (Bump 1997) studied urethral competence in 159 women with stress incontinence by measurement of MUCP, Valsalva leak point pressure and straining urethral axis (urethral hypermobility). They found that a composite of a MUCP <20 cm water, a Valsalva leak point pressure (VLPP) of <50 cm water and a stress urethral axis <20 degrees was required to diagnose intrinsic sphincteric deficiency. Only low MUCP and VLPP had a significant association with the severity of incontinence. Similarly Pajoncini et al. (Pajoncini 2003) showed that lower VLPP, lower MUCP and previous surgery correlate more significantly with ISD (**Table D-X.1**).

Operation	Authors	Reference	Type of study	N° pts	Cure rate	Evidence level
Burch colposuspension	Sand et al.	1987 Obstet and Gyaecol 69:399-402	Retrospective study	86	46% (Mucp≤20) 82% (Mucp>20)	3
Burch colposuspension and Pereyra	Koonings et al.	1990 Urology 36(3):245-8	Retrospective study	19 ISD 106 no ISD	Burch: 67% ISD 88% no ISD Pereyra: 50% ISD 77% no ISD	3
Burch colposuspension	Meschia et al.	1991 Int Urogyn J 2:19-21	Retrospective study	???	???	3
Burch colposuspension	Monga et al.	1997 Neurourol Urodyn 16(5):354-355	???	???	???	3
Pubovaginal sling	McGuire et al	1987 J Urol 138:525	Retrospective study	82	95%	3
Sling	Horbach et al	1988 Obstet Gynecol 71:648-652	Retrospective study	17 (MUCP ≤20)	85%	3
Ball-Burch procedure	Bergman et al.	1991 J Reprod Med 36(2):137-40	Retrospective study	48 (MUCP ≤20)	90%	3
Injectable	Kreden et al	1996 J Urol 156:1995-8	Retrospective study	4 VLPP <60+ Urethral	25%	
				Hypermobility 18 VLPP<60	44%	3
Injectable	Steele et al	2000 Obstet Gynecol 95:327	Retrospective study	9 with urethral hypermobility	71% no differences in pts without hypermobility	3

Table D-X.1 Urethral function tests and outcome from stress incontinence surgery.

CONCLUSION

There are no data in the literature supporting that ISD could either influence the outcomes or the type of the surgical treatment.

The main problem is that there is no uniform consensus about the meaning of ISD. Moreover there are a lot of poor quality studies and so the conclusion are not based on evidence but are only conjecture.

XI. SURGICAL FACTORS

Several surgical factors may impact on the success of stress incontinence surgery including experience of the operating surgeon overall, experience of the surgeon with a given procedure, and teaching status of the hospital (i.e. academic vs. non-academic institution, etc.). None of these factors have been studied prospectively or in a randomized, blinded fashion. One case series looked at surgical factors in 232 stress incontinence surgical procedures that were predictive for a successful outcome (Gormley EA et al 2002). In this series, experience ("grade") of the surgeon, surgical workload or teaching status of the hospital did not affect surgical success. Several case series have suggested that a "learning curve" may exist for those undertaking TVT procedures especially as regards the incidence of related complications (Richter HE et al 2001), (Kane L et al 1999), (Groutz A et al 2001) . Lebret and colleagues noted a 22% complication rate among the first 50 patients undergoing TVT as compared to an 8% complication rate for the next 50 patients undergoing the same surgery (Groutz A et al 2001). All patients were operated on by senior surgeons. Kuuva and colleagues reviewed a nationwide database of 1455 TVT cases and found that the complication rate was greater in those hospitals performing less than 15 TVT procedures per year as compared to those performing 15 or more (Kane L et al 1999). These retrospective data suggest but do not prove that surgical familiarity with TVT procedure may influence the rate of intraoperative and postoperative complications.

With respect to the use of specific suture materials such as synthetic absorbable suture vs. non-absorbable suture, and braided vs. monofilament suture for each type of anti-incontinence procedure (Burch, MMK, fascial sling, etc.), there are no prospective randomized, blinded data to suggest superiority of one choice of suture material over another. The use of bone anchors for stress incontinence surgery is also controversial. There are known risks associated with use of bone anchor stabilization (Karram MM & Bhatia Nn 1990), (Handa VL & Stone A 1999), (Wright EJ et al 1998) However, objective scientific evidence supporting their benefits is lacking (Wall LL et al 1996).

It is unclear whether the type of anaesthesia (Goebel R 1910), (Nell DE & Foster L 2001), positioning of the patient, and other factors such as post-operative catheter drainage (i.e. size, type, duration, and location: suprapubic vs. urethral catheterization) influences the outcome of stress incontinence surgery.

CONCLUSION

There are many possible surgical factors which may influence the outcome of stress incontinence surgery. These factors should be examined in a prospective, randomized fashion.

E. URETHRAL DIVERTICULAE

Search of Medline for urethral diverticulum (UD) and female resulted in 425 published articles from 1952 to 2004. Reports of diagnosis and treatment of UD in women have appeared in the literature since 1786 (Hey: essay of Collections of Pus in the Vagina). The majority of the subsequent case series were sporadic and consisted of small numbers until Davis and Cian introduced Double Balloon Positive Pressure Urethrography in 1956. This report not only supplemented the diagnostic armamentarium but also increased the awareness of urethral diverticulae as a more common problem than previously thought. Over the past decade or so, the increasing use of more advanced imaging techniques such as magnetic resonance imaging (MRI) has led to increased clinical awareness and diagnosis of this condition. (Daneshgari 1999)

The important clinical topics concerning UD are:

a) Classification

b) Imaging modality

c) Use of concomitant procedures such as anti-incontinence procedures,

d) Use of interpositioning tissues.

e) Outcome measures and complications of UD repair

I. CLASSIFICATIONS

Leach (Leach et al. 1993) originated a classification system designed to accurately describe the characteristics of urethral diverticulae. The system utilizes the acronym LNSC3, which represents descriptive parameters for L = Location, N = Number, S = Size, C1 = Configuration, C2 = Communication, and C3 = Continence. In a series of 61 patients, urethral diverticulae were most commonly single in number (90 percent) and shape (62 percent). The location of the diverticulum swelling (62 percent), and ostium (60 percent) was mid-urethra. Fifty-six percent of the patients were incontinent (Leach et al 1993). Leng and McGuire divided diverticulae based on the integrity of the periurethral fascia, although diverticulae were described generally as primary diverticulae consisting of a mucosal layer only with narrow neck ostia bound by intact periurethral fascia. In contrast, pseudodiverticulae are often multi-layered with wide mouthed ostia on cystoscopic examination in association with a periurethral fascia defect. Rupture or erosion of the periurethral fascia often correlates with a history of prior suspension or a recurrent urethral diverticulae (Leng and McGuire 1998).

II. IMAGING MODALITIES

The choice of optimal imaging modality for diagnosis of UD continues to be discussed in the literature. The existing modalities include:

1) Voiding Cysto Urethrogram (VCUG) /Double Balloon Retrograde Urethrography

2) Ultrasound

3) MRI

1. VOIDING CYSTO URETHROGRAM (VCUG) /DOUBLE BALLOON RETROGRADE URE-THROGRAPHY

In 1928, Norris and Kimbrough were the first to utilize cysto urethrography to define female bladder and urethral anatomy. A variation of this technique was repeated by Davis using a specialized double balloon catheter. Reported sensitivity for these techniques has ranged widely from 44 to 100 percent (Ganabathi 1994; Jacoby 1999; Golomb 2003 Level 3).

2. Ultrasound

In 1977, Lee and Keller reported the use of abdominal ultrasound to identify urethral diverticulae (Lee 1977) (Level 3). This modality may be used when a high clinical suspicion exists and when urethrographic results are negative. Diverticulae appears as anechoic or hypoechoic (to periurethral tissue) cavities with enhanced through transmission.

3. MRI

MRI has the advantage of multiplanar capabilities and excellent soft tissue definition. These qualities allow for differentiation between urethral diverticulae and other periurethral masses. Both T1 rated and T2 weighted images have been used or could be used for diagnosis of MRI. The T2 weighted images allow a high signal intensity of the urine, and collections within the urethral diverticulae making it a preferred method of imaging for urethral diverticulae (Level 3). The multiplanar capability of the MRI allows for a) identification of multiple urethral diverticulae; and, b) surgical planning for repair of the urethral diverticulae. Neitlich et al. applied a high-resolution fast stain echo MRI technique using a torso multicoil resulting in an examination time of 15 minutes. This study prospectively compared double balloon urethrography with MRI imaging of the urethra for detection of urethral diverticulae with a resultant sensitivity of 25 and 100 percent respectively. (Neitlich 1998 Level 2)

There is no Level 1 evidence on the optimal imaging modality. There are differences in the calculated sensitivity of each imaging modality between the various recorded studies. Moreover, the results of the studies are limited by differences in the patient population, study techniques, and interpretive skills of the radiologists.

III. USE OF CONCOMITANT PROCEDURES

Surgery for stress incontinence may be successfully performed along with urethral diverticulectomy. Leach (Leach and Bavendam 1987) described simultaneous needle bladder neck suspension in 22 women with stress incontinence (Level 3). At the main follow-up of 20.5 months, 77 percent were totally continent and no significant complications were noted. Four of the five failures were secondary to ISD. Swierzewski (Swierzewski and McGuire 1993) performed simultaneous autologous rectus fascia vaginal sling and urethral diverticulectomy in 14 women (Level 3). All were cured of the stress continence and one developed severe detrusor overactivity. The diverticulae recurred in one patient (**Table E-III.1**).

IV. USE OF INTERPOSITIONING TISSUE

Use of labial (Martius) fat pad, vaginal wall bipedicled flap and autologus fascia in forms of pubovaginal sling has been used as interpositioning techniques for repair of UD. All reported cases are case series (Level 3). In several series, use of perivesical fascia as the interpositioning layer has been reported.

Reference	No. Women	Follow up (mos)	No. Urethro- vaginal Fistula	No. Recurrent Diverticulum	No. Stress Incontinence	No. Urethral Stricture (%)	No. Recurrent Urinary Tract
			(%)	(%)	(%)		Infections (%)
Wharton and	58	Not	4(7)		1 (1.7)	3(5.2)	5 (8.6)
Telinde		available					
Davis and	84	Not		10 (11.9)			11 (13.1)
Telinde		available					
MacKinnon et al	130	Not	7 (5.4)	2 (1.5)	Several		13 (10)
		available					
Boatwright and	48	Not	4(8.3)		2 (4.2)	1 (2.1)	
Moore		available					
Hoffman and	60	Not	1 (1.7)		4 (6.7)	1 (1.7)	
Adams		available					
Ward	24	Not	2 (8.3)	7 (29.2)	3 (12.5)		
		available					
Davis and	98	Not	4 (4.1)	1(1)			
Robinson		available					
Pathak and	42	Not					
House		available					
Benjamin et al	30	Not	1 (3.3)	1 (3.3)	1 (3.3)		
·		available					
Peters and	32	24	3 (6.3)	8 (25)			10 (31.3)
Vaughan							
Ginsburg and	52	12-240	1 (1.9)	13 (25)		1 (1.9)	
Genadry							
Rozsahegyi et al	50	Not	1 (2)			1 (2)	
20		available					
Lee RA	108	24-204	1 (0.9)	10 (9.3)	16 (15)	2 (1.9)	
Ganabathi et al	56	6 -136	1 (1.8)	2 (3.6)	9 (16.1)	0	0

TALE E-III.1 Complications of diverticulectomy from published series since 1956 in 872 women

(Revised and reprinted from Leach GE, Trockman BA. Surgery for Vesicovaginal, and urethrovaginal fistula and urethral diverticulum. In Walsh PC, Retik AB, Vaughn ED, Wein A, eds:Campbell's Urology, 7th ed. Philadelphia, W.B. Saunders Company, 1997, pp1135 – 1153.)

V. OUTCOME MEASURES AND COMPLICATIONS OF UD REPAIR

The optimal outcome of repair of UD is a) absence of UD recurrence; b) relief of symptoms; and c) absence of complications. A wide range of measured outcomes is reported in the literature mostly in form of case series (Level 3). The potential complications of the UD repair are reported as either short term (bleeding, urinary tract infection) or long term (urethrovaginal fistula, urethral pain syndrome, urinary incontinence, recurrent diverticulum). Recurrence of UD has been reported as long as 5 years after surgery. Presence or absence of additional pathologies such as neoplasm (squamous cell carcinoma, clear cell carcinoma, nephrogenic adenoma, vaginal leiomyoma), malakoplakia, and calculi formation within the UD has also been reported as an outcome measure. The incidence of concomitant pathology is reported in less than 5% of large series (Kochakarn 2000)

VI. REVIEW OF SURGICAL PROCEDURES

In 1875, Tait was the first to report complete excision of a urethral diverticulae (Tait 1875). The following approaches have been reported in the literature for urethral diverticulum.

- Endoscopic Approach This technique uses a transurethral marsupialization. (Davis 1970; Lapides 1979).
- 2. Packing/Obliterative Procedures The diverticulae cavity is packed with oxidized cellulose followed by closure of the diverticular and vaginal wall. (Ellik 1957)
- 3. Open Marsupialization The Spence technique, which is essentially a meatotomy, is often performed for distal diverticulum connecting the posterior aspect of the urethral wall. (Spence 1970)

- 4. Open Diverticulectomy This technique uses mostly vaginal exposure to a) identify the diverticulum, b) dissect the diverticulum, c) repair the defect in the periurethral fascia. This technique has been the most widely used technique and the most widely reported in the literature. For the majority of the cases, a single closure of the periurethral fascia suffices for repair; however, use of additional inter-positioning tissues such as Martius fat pad has been reported.
- 5. Retropubic approach for ventrally based proximal diverticulae This is used for very proximal and ventrally positioned proximal diverticulae, which are not the most common type of presentation for diverticulum.
- 6. Supra-Urethral meatus Approach to Ventrally Based Diverticulum – In this approach for urethrolysis, a semi-circle incision is made above the urethral meatus thereby gaining an approach to the ventral urethral space.

All the reported surgical techniques are case series (Level 3), and there is no published report of comparing the techniques or the outcomes in a prospective, randomized manner.

F. SURGERY FOR REFRACTORY DETRUSOR OVERACTIVITY

The presumed aetiology of overactive bladder is detrusor overactivity (Abrams P et al 2002). Symptomatically, only 1/3 of patients with overactive bladder have associated urinary incontinence Stewart WF et al 2003). Many of these patients can be successfully treated with a combination of non-surgical measures including behavioural modification, pelvic floor physiotherapy and pharmacological therapy (see chapter on Conservative Management of Urinary Incontinence). Surgical therapy of nonneuropathic overactive bladder incontinence is generally reserved for those patients who have failed an adequate trial of these measures (Appell RA 1998), (Chapple CR & Bryan NP 1998). Overall, there are few studies on the surgical therapy of non-neurogenic detrusor overactivity urinary incontinence. Surgical interventions for urinary incontinence related to neurogenic detrusor overactivity incontinence are covered elsewhere (see chapter on Neuropathic Bladder).

I. ENDOSCOPIC APPROACHES

1. ENDOSCOPIC BLADDER TRANSECTION

Modelled after an open procedure, designed, in part to denervate the bladder, circumferential endoscopic incision proximal to the bladder neck, termed endoscopic bladder transection, was reported by Parsons et al as an effective technique of treating symptomatic bladder overactivity (Level 4 evidence) (Parsons KF et al 1984). Subsequent reports (Level 4 evidence) (Hasan ST et al 1995), (Lucas MG & Thomas DG 1987) have been less favourable especially with long-term follow-up and this procedure is now rarely, if ever, performed. There is no Level 1 evidence regarding this modality in the therapy of non-neurogenic detrusor overactivity incontinence.

2. HYDRODISTENTION OR BLADDER OVERDIS-TENTION

Bladder overdistention was originally described by Helmstein et al for the treatment of bladder cancer (Helmstein K 1972) but has also been cited as therapy for the treatment of some types of voiding dysfunction, including interstitial cystitis. Several reports have described its use for the treatment of detrusor overactivity. In practice, this procedure is performed under general or regional anaesthesia and utilizes a hydrostatic column of fluid under high pressure infused into the urinary bladder and left indwelling for a variable period of time. The mechanism by which this therapy purportedly treats detrusor overactivity is not well understood.

a) Level I evidence:

There have been no randomized controlled trials, double blind trials or cohort studies which have examined the effects of bladder overdistention or hydrodistention for the treatment of non-neurogenic detrusor overactivity incontinence.

b) Other Evidence

There are only a few reports on hydrodistention for the therapy of detrusor overactivity or non-neurogenic detrusor overactivity incontinence. The existing literature consists of primarily small retrospective case series with brief follow-up and subjective outcome parameters (Level 4 evidence). Of the few favourable reports on hydrodistention for urinary incontinence, Ramsden reported that 41/51 patients (80.4%) had substantial improvement or were free of urinary symptoms at a follow-up of 13 months (Ramsden PD et al 1976). Dunn et al noted that

19/20 patients with urge incontinence or severe urgency and frequency were either improved or cured following bladder distention (Dunn M et al 1974). Corroborative objective outcomes data such as pad tests or voiding diaries were lacking in both of these studies. In contrast, Delaere and colleagues reported on 63 patients with involuntary bladder contractions on cystometry and urge incontinence undergoing prolonged bladder distention (Delaere KP et al 1980). Results were tabulated according to symptomatic outcome. Continence was not a primary outcome measure. At 1 year follow-up 11% of patients were cured and 21% improved. Whitfield noted that none of 11 patients with detrusor overactivity treated with a classical Helmstein balloon bladder overdistention "reverted" to a normal cystogram although 6/11 noted some symptomatic improvement (Whitfield HN & Mayo ME 1975). Poor results were also seen by Pengelly and colleagues in whom only 4/46 patients noted symptomatic improvement following hydrodistention (Pengelly AW et al 1978). Of the 43 patients undergoing postoperative urodynamics in this study, none had "conversion" to a stable detrusor on cystometry.

There are no long-term follow-up studies demonstrating an objective or durable response to hydrodistension for detrusor overactivity incontinence. Outcome measures have included mostly retrospective subjective patient assessments. Validated general or disease specific quality of life instruments have not been utilized to assess outcomes in these patients.

Bladder rupture, hematuria, infection, voiding dysfunction, and urinary retention are potential risks of bladder overdistention.

3. TRANSVESICAL PHENOL INJECTION

Several uncontrolled studies have examined the effects of subtrigonal phenol injection for the treatment of both non-neurogenic and neurogenic detrusor overactivity (Level 4 evidence). A 5%-6% aqueous solution is injected endoscopically in the region of the trigone of the bladder. The mechanism by which phenol exerts its effects is purported to be via chemical denervation (neurolysis agent) (Parkhouse HF et al 1987). Initial studies suggested that this therapy was safe and effective in the short term with response rates between 58-83% (Blackford HN et al 1984), (Cameron-Strange A & Millard RJ 1988), (Ewing R et al 1982), (Ewing R et al 1983). Better response rates were seen in neurogenic as compared to non-neurogenic voiding dysfunction, especially in patients with multiple sclerosis (Cameron-Strange A & Millard RJ 1988), (Ewing R et al 1983). In one study, neurogenic bladder patients had a markedly greater response rate (82%) as compared to younger (<55 years old) non-neurogenic patients (14%) (Blackford HN et al 1984). Subsequent studies with longer-term follow-up have not reproduced these results. Chapple and colleagues reported that only 4 out of 24 patients derived any ongoing benefit from phenol injection at 6 months follow-up (Chapple CR et al 1991), whereas Ramsay and colleagues reported a subjective response rate of only 14% in 36 patients at a mean follow-up of 13.7 months. Wall et al reported a 29% initial response rate with all patients eventually failing at up to 4 years follow-up Wall LL & Stanton SL 1989). A similar long term failure rate was seen by Rosenbaum et al where only 1 out of 60 patients maintained a satisfactory result at 2 years (Rosenbaum TP et al 1990).

There are no randomized, double blind, placebo controlled studies that have examined the efficacy of subtrigonal phenol or compared it to another therapy for detrusor overactivity incontinence. Outcome measures have included mostly subjective patient assessments done in a retrospective fashion. Validated general or disease specific quality of life instruments have not been utilized to assess outcomes in these patients.

Overall an 11.3% complication rate has been attributed to subtrigonal phenol injection including urinary retention, fistula and significant hematuria¹⁹.

RECOMMENDATION

There is no evidence that women gain long term benefit from a transvesical phenol injection and its use can not be recommended (Grade B).

4. PERCUTANEOUS APPROACHES

Neuromodulation - see later section

5. OPEN SURGICAL INTERVENTIONS

a) Ingelman-Sundberg Denervation

In 1959 Ingelman-Sundberg described an operation for the treatment of urge incontinence that selectively divided the preganglionic pelvic nerves near the inferior surface of the bladder through a transvaginal approach. This involved considerable dissection near the cervix and bilateral transection of the pelvic nerves in this region. Hodgkinson et al reported good results with this procedure in a case series of 23 patients, with 12 patients subjectively cured and an additional 9 improved (Level 4 evidence) (Hodgkinson CP & Drukker BH 1977). The results of a modified Ingelman-Sundberg procedure by Cespedes and colleagues suggested a 64% cure of urge incontinence in carefully selected patients at a mean follow-up of 14.8 months (Cespedes RD et al 1996). In this case series (Level 4 evidence) the authors preselected the 25 patients based on a satisfactory clinical response to a transvaginal injection of local anaesthetic in the region of the trigone. Westney and colleagues reported long term results with the same modified Ingelman-Sundberg procedure in a case series of 28 women (Level 4 evidence) (Westney OL et al 2002). Using the same preselection criteria as Cespedes et al, these authors noted a 54% cure of urge incontinence and a 68% cure/improved rate at a mean follow-up 44.1 months. To date however, there are no randomized, blinded or placebo controlled studies, comparative studies or cohort studies examining the efficacy of the Ingelman-Sundberg procedure or the modified Ingelman-Sundberg procedure for the treatment of detrusor overactivity incontinence. Outcome measures have included mostly subjective patient assessments done in a retrospective fashion. Validated general or disease specific quality of life instruments have not been utilized to assess outcomes in these patients.

Complications associated with the Ingleman-Sundberg procedure have included voiding dysfunction, bleeding, and transient urinary retention.

b) Sacral rhizotomy

This procedure is primarily performed in the neuropathic bladder population and is discussed further elsewhere (*See chapter on Neuropathic bladder*).

c) Enlargement (augmentation) cystoplasty

1. Enterocystoplasty

Augmentation cystoplasty has been used for many years with varying degrees of success for refractory detrusor overactivity and related incontinence. Indications for enterocystoplasty (other than non-neurogenic detrusor overactivity) include small capacity bladders due to fibrosis, tuberculosis, radiation, or chronic infection, neurogenic detrusor overactivity, poor bladder compliance, as well as others (Goldwasser B & Webster GD 1986), (Gough DC 2001), (Greenwell TJ et al 2001), (Niknejad KG & Atala A 2000). Virtually any portion of the GI tract can be utilized for enterocystoplasty with each segment having it's own unique favourable properties as well as inherent complications (Niknejad KG & Atala A 2000), (Duel BP et al 1998). The goal of enterocystoplasty is to create a high capacity, low-pressure reservoir during the filling/storage phase of the micturition cycle. When successful, and properly combined with other concomitant reconstructive procedures (i.e. ureteroneocystostomy, slings, artificial urinary sphincters, etc.), enterocystoplasty protects the upper urinary tract from pressure-related injury, infection and reflux while ideally providing complete urinary continence.

• Level 1 evidence

There have been no randomized controlled trials, double blind or placebo controlled trials or cohort studies which have examined the effects of enterocystoplasty for the treatment of non-neurogenic detrusor overactivity incontinence or directly compared it to another therapy for the same indication.

• Other evidence

There are only a small number of reports in the literature that have examined the results of enterocystoplasty in adult patients with non-neurogenic detrusor overactivity incontinence. These include only case series (Level 4 evidence). One series comprised solely females (Awad SA et al 1998) with the other series including both males and females as well as varying numbers of neuropathic bladder patients (Bramble FJ 1982), (George VK et al 1991), (Hasan ST et al 1995), (Kelly JD & Keane PF 1998), (Kockelbergh RC 1991), (Mundy AR & Stephenson TP 1985). (See Table x). Outcome measures have included mostly unvalidated questionnaires and subjective patient assessments. Validated general or disease specific quality of life instruments have not been widely utilized to assess outcomes in these patients.

Awad et al reported on a series of 51 female patients undergoing augmentation cystoplasty for refractory non-neurogenic bladder related incontinence (Awad SA et al 1998). 18% of patients continued to have disabling symptoms of urinary incontinence, and only 53% of patients classified themselves as "happy" with the outcome of the surgery. One series noted a deterioration in outcomes over time (Hasan ST et al 1995). In this mixed series, symptomatic improvement was reported in 83% of non-neurogenic patients at 3 months postoperatively, but decreased to just 58% at last follow-up (mean follow-up 38 months). In contrast, 92% of neuropathic bladder patients in this series reported a "good" or "moderate" result at last follow-up. Similarly, Herschorn and colleagues reported a very high degree of patient satisfaction in a series composed of only neuropathic bladder patients with all 59 patients reporting that they were delighted, pleased or mostly satisfied with the surgery (Herschorn S & Hewitt RJ 1985). The reasons for apparent superior patient satisfaction in neuropathic patients as compared to non-neuropathic patients are unclear.

• Complications of enterocystoplasty

Complications associated with enterocystoplasty are significant and include those related to factors derived from the bowel segment being in direct contact with the urine as well as other operative and perioperative morbidity. Short and long term complications of enterocystoplasty have been recently reviewed by Greenwell et al and are summarized in Table 2 ((Greenwell TJ et al 2001). Especially clinically relevant is the potential need for long-term clean intermittent catheterization in these patients. This possibility must be discussed with the patient preoperatively as patients should be willing and able to accept permanent clean intermittent catheterization (CIC) as a method of bladder emptying. Inability or unwillingness to perform CIC in those in whom it is necessary can lead to life threatening complications such as pouch perforation, urosepsis and death. Mucous build-up in the augmented bladder may also be troublesome but can be controlled by a number of measures (Gillon G & Mundy AR 1990). Malignant transformation is a long-term risk of bladder augmentation and requires ongoing lifetime surveillance (Filmer RB & Spencer JR 1990), (Barrington JW et al 1997), (Golomb J et al 1989).

2. AUTOAUGMENTATION

As an alternative to enterocystoplasty especially in children with neuropathic bladder, autoaugmentation of the bladder was initially described by Cartwright and Snow (Cartwright OC & Snow BW 1989), (Cartwright PC & Snow BW (1989). Autoaugmentation may be performed by incision (detrusor myotomy) or excision (detrusor myectomy) of a portion of the detrusor muscle. One small series demonstrated no difference between the techniques however followup was short (Strothers L et al 1994). Either technique purportedly creates an iatrogenic bladder mucosal "bulge" or pseudodiverticulum and an increase in the storage capacity of the bladder with a concomitant decrease in storage pressures. The reported advantages of detrusor autoaugmentation over enterocystoplasty is the avoidance of complications related to the use of bowel in the urinary tract including malignancy, mucous formation, stones, surgical morbidity related to opening and reanastomosis of the GI tract, and metabolic acidosis (Appell RA 1998), (Niknejad KG & ATala A 2000). (Dewan PA 1998).

Long term follow-up of autoaugmentation in children with neurogenic bladder has demonstrated disappointing results (MacNeily AE et al 2003), (Marte A et al 2002). This has been attributed to eventual fibrosis of the pseudodiverticulum (Dewan PA 1998). In an attempt to improve long-term outcomes with this procedure and create a biological "backing" and blood supply (Snow BW & Cartwright PC 1996) for the pseudodiverticulum, a number of variations of this procedure have been described. These variations have included the use of demucosalized bowel segments, stomach, peritoneum and rectus abdominis muscle (Dewan PA 1998), (Close CE 2001), (Dewan PA & Stefanek W 1994), (Oge O et al 2000), (Perovic SV et al 2002), (Shekarriz B et al 2000). Long-term follow-up with significant numbers of patients is awaited.

There are few studies on autoaugmentation in the adult non-neurogenic population (See Table 1). These are all small case series (Level 4 evidence). One small study of 5 patients with urge incontinence showed promising results in all patients at the initial postoperative visit, but clinical deterioration and failure occurred in 4 of the 5 patients at 3 months follow-up (ter Meulen PH et al !997). Mean bladder capacity increased but mean volume to first unstable bladder contraction decreased. 4 of the 5 patients continued to have involuntary bladder contractions on cystometry.

• Complications of autoaugmentation

Complications associated with autoaugmentation have included UTI's, prolonged urinary extravasation and inadequate pressure reduction and volume expansion (Snow BW & Cartwright PC 1996). Whether the complications associated with detrusor myectomy are less than that associated with detrusor myectomy are less than that associated with enterocystoplasty is unclear. One study compared detrusor myectomy to enterocystoplasty in 61 patients (Leng WW et al 1999). These authors reported similar clinical success for the two procedures however there was a 22% incidence of serious complications in the 27 patients undergoing enterocystoplasty, compared to only 3% of the 33 patients undergoing detrusor myectomy.

3. TISSUE ENGINEERING

Various tissue engineering techniques have been uti-

lized in an attempt to create a suitable alternative to enterocystoplasty or autoaugmentation. Many of these techniques rely on the use of native urologic tissues either partially or fully. Techniques have included the use of fetal tissues as well as collagen matrices overgrown with transplanted cells especially autologous cells ((Atala A 2001). Future clinical studies are anticipated as these techniques evolve into clinical trials from laboratory and animal studies. Currently there are no published studies utilizing these procedures in humans.

d) Urinary diversion

Urinary diversion away from the bladder is rarely needed for the treatment of non-neurogenic detrusor overactivity. This is usually reserved for patients who fail other surgical measures or who have intractable detrusor overactivity and desire a simplified method of management such as an abdominal urostomy. An ileovesicostomy ("chimney") procedure (Leng WW et al 1999) or Bricker bilateral ureteroileostomy may be considered depending on the clinical circumstances including the presence or absence of native vesicoureteral reflux. There are no studies that have examined these techniques in the treatment of non-neurogenic detrusor overactivity incontinence (Level 5 evidence).

6. CONCLUSIONS

Prospective, randomized, placebo controlled trials of surgical therapy for detrusor overactivity incontinence are lacking. There is an urgent need to assess these procedures critically.

7. RECOMMENDATIONS

Augmentation enterocystoplasty should be reserved for patients who fail all forms of conservative therapy and are willing to accept the potential perioperative, and postoperative morbidity associated with the procedure as well as the potential need for permanent intermittent urethral catheterization. Women should be advised that, in the long term, only 50% women are satisfied with the outcome from the procedure. (Grade B).

G. NEUROMODULATION

Neuromodulation is becoming a part of clinical armamentarium for treatment of a variety of lower urinary tract conditions. It increased usage stems from the need of patients who have exhausted all other therapeutic options. Currently neuromodulation may consist of the use of nerve stimulation and injectable therapy (Botulinum A toxin). In this section we will concentrate on nerve stimulation.

Currently there are two nerve stimulation modalities. Sacral nerve stimulation (SNS) and peripheral nerve stimulation (SANS). The exact mechanism of action is not understood.

I. SACRAL NERVE STIMULATION (SNS)

Sacral nerve stimulation (SNS) involves the stimulation of the sacral nerves to modulate the neural reflexes that influence the bladder, sphincter and pelvic floor. The initial experience with sacral nerve stimulation for use in bladder dysfunction was reported by Tanagho and Schmidt (1981). Since then, SNS using the Interstim (Medtronic, Minneapolis, Minnesota, U.S.A.) has been an invasive therapy that was approved by the FDA in 1997 for treatment of refractory urge incontinence. Use has been extended to include significant urgency, frequency and idiopathic urinary retention. World-wide, the number of implants passed 10,000 in 2003 with more than 70% of the implants in the U.S.

1. SURGICAL METHODS

Implantation of SNS consists of two steps: a) Stage I, or the trial stage – This involves the placement of a stimulation lead next to the dorsal root of S3 for a time period between 1-4 weeks. If the patient's symptoms under the existing list of indications for SNS improves more than 50 % then the patient is a candidate to undergo the second step; b) Stage II or Permanent Step – In this step the permanent neurostimulator is implanted in the soft tissue of the buttock of the patient.

2. REPORTS OF RCT ON THREE INDICATIONS OF UI, U/F AND UR

The initial report on the efficacy of SNS on treatment

of refractory urinary urge incontinence was reported in 1999 (Schmidt 1999) (Level 2- as no placebo or sham control was used). This study reported the treatment of 76 patients with refractory urgent urinary incontinence from 16 contributing worldwide centres. The patients were randomized to immediate implantation and a control group with delayed implantation for a six-month period. At six months, the number of daily incontinence episodes, severity of episodes, and absorbent pads or diapers replaced daily due to incontinence were significantly reduced in the stimulation group compared to the delayed group. Of the 34 stimulation group patients, 16 (47 percent) were completely dry, and an additional 10 (29 percent) demonstrated a greater than 50 percent reduction in incontinence episodes. The interesting finding was that during the therapy evaluation, the group returned to the baseline level of incontinence when the stimulation was inactivated. Complications were site pain of the stimulator implantation in 16 percent, implants infection in 19 percent, and leak migration in 7 percent.

The use of SNS in urgency frequency was reported in 2000 (Hassouna 2000). Similar to the previous design, 51 patients from 12 centers were randomized into an immediate stimulation group and a control group (25 and 26 patients respectively) ((Level 2- as no placebo or sham control was used)). Patients were followed for one, three and six months, and afterwards at six-month intervals up to two years. At the six-month evaluation, the stimulation group showed improvement in the number of voiding episodes $(16.9 \pm 9.7 \text{ to } 9.3 \pm 5.1)$ volume per void $(118 \pm 74$ to 226 ± 124 ml) and degree of urgency (the rank 2.2 \pm .6 to $1.6 \pm .9$). In addition, significant improvement in quality of life was demonstrated, as measured by SF-36.

Use of SNS for urinary retention was published in 2001 (Jonas 2001), and in this study 177 patients with urinary retention refractory to conservative therapy were enrolled from 13 worldwide centers between 1993 and 1998 (Level 2- as no placebo or sham control was used). Thirty-seven patients were assigned to treatment and 31 to the control group. The follow-up was done at one, three, six, twelve and eighteen months. The treatment group showed 69 percent elimination of catheterization at six months and an additional 14 percent with a greater than 50 percent reduction in catheter volume per catheterization. Temporary inactivation of SNS therapy resulted in significant increase in residual volume, but the effectiveness of central nervous stimulation was sustained for 18 months after implantation.

In 2000, a follow-up report of *some* of these patients was published (Siegl 2000) (Level 3). This report showed follow-up results after three years in all the indications. Fifty-nine percent of 41 had urinary urge incontinence. 46 percent of these patients were completely dry. After two years, 56 percent of the urgency frequency patients showed greater than 50 percent reduction in voids per day, and after 1-1/2 years, 70 percent of 42 retention patients showed greater than 50 percent reduction of catheter volume per catheterization.

The results of the use of SNS in the U.S. population were published in 2002 (Pettit 2000) (Level 3). This publication showed the data collected from the U.S. patient registry. The report included the use of SNS in 81 patients with all three indications: 27 for urgent continence, 10 with urgency frequency and 10 with urinary retention. In this report, 27 from 43 patients with urgent continence, 10 out of 19 with urgency frequency and 10 out of 19 with urinary retention showed improvement of more than 50 percent.

The results of an Italian registry was published in 2001 (Spinelli 2001) (Level 3). This report included the reports of 196 patients – 46 males and 150 females – for idiopathic urinary retention. 50 percent of patients stopped catheterization and another 13 percent catheterized once a day at one year after implantation. At the 12-month follow-up, 50 percent of patients with hyperreflexia had less than one incontinence episode daily and the problem was completely solved in 66 patients. Of the patients with urgent continence, 39 percent were completely dry and 23 percent had less than one incontinence episode daily.

In Norway, the results of users of this modality were published in 2002 (Hedlund 2002) (Level 3). The author reported the first three years of experience with 53 patients: 45 women and 8 men. This study showed similar results to previous studies.

3. URINARY RETENTION

Aboseif et al 2002 reported on the use of SNS in functional urinary retention (Level 3). 32 patients were evaluated and underwent temporary PNE. Those who had a least a 50% improvement in symptoms during the test period underwent permanent generator placement. All patients who went to permanent generator placement were able to void spontaneously. There was both and increase in voided volume (48 to 198ml) and decrease in post void residual (315ml to 60 ml). 18/20 patients reported a greater than 50% improvement in quality of life.

4. OTHER INDICATIONS

Use of SNS for other off-labelled applications has been reported in the form of abstracts. The off-labelled usage has included use of SNS in neurogenic bladder; interstitial cystitis, and chronic pelvic pain. All these results are limited case series reports. (Level 5)

5. COMPLICATIONS

The reported complications of SNS includes infection, revision of stage I or II, lead migration, and undesirable stimulus. Changes in other visceral functions (sexual function; bowel function) has also been reported.

II. PERIPHERAL NERVE STIMULATION (SANS)

Stoller in 1987 reported that stimulation of the peripheral tibial nerve in pig-tailed monkeys was able to inhibit bladder overactivity (Stoller 1987) (Level 3). This initial work led to its use in patients with refractory overactive bladder.

1. RESULTS

In 2000 Klinger et al performed a prospective trial on 15 patients with urgency-frequency syndrome. They underwent 12 weeks of stimulation with the SANS device (Level 3). Ten patients responded with a reduction in voiding frequency per day (16 to 4) and daily leakage episodes (4 to 2.4). The only complication was one haematoma at the puncture site.

Govier et al.(2001) (Level 3) in a multicenter study reported the efficacy of SANS in 53 patients. All patients had refractory OAB and were seen at 5 different sites in the U.S. The patients completed a 12week stimulation. 71% of the patients had at least a 25% decrease in daytime or night time frequency. No adverse effects were noted.

III. CONCLUSIONS

Level 2-3 evidence suggests that sacral neuromodulation may provide benefit in the treatment of patients with refractory urinary incontinence, urgency/frequency and idiopathic, non-obstructive urinary retention.

The mechanism of action of neuromodulation remains unknown.

The predictors of outcome and patient response to neuromodulation remain unknown.

Longer term and independent observational studies are needed to examine the longitivity of the neuromodulation and identification of the most appropriate patient who should undergo this treatment.

RECOMMENDATIONS

Sacral neuromodulation may be offered for women with urinary incontinence due to refractory detrusor overactivity and refractory irritative symptoms. (Grade B)

Sacral neuromodulation may be offered to women with non-obstructive urinary retention. (Grade C)

H. NON-OBSTETRIC URINARY FISTULAE

I. VESICOVAGINAL FISTULAE

1. INTRODUCTION

In developing countries birth trauma still accounts for the majority of fistulae. (Arrowsmith 1996). In developed countries, modern obstetric care has substantially limited the risk of vesicovaginal fistulae and fistulae are usually the result of complications of gynecologic or other pelvic surgery. Evidence for timing of intervention, methods of correction, and associated management strategies is based on clinical series and / or case studies and lacks definitive randomized control analysis.

2. Specific Etiologies

In developed countries the most common cause of vesicovaginal fistula is routine abdominal or vaginal hysterectomy. Approximately 75% of genitourinary fistulae are subsequent to this cause (Jonas 1984, Symmonds 1984, Lee 1988, Tancer 1992). Fistulae occurring after hysterectomy are thought to be due to unrecognized direct bladder trauma, tissue necrosis caused by inadvertent suture placement though the bladder wall, or thermal injury from electrocautery either as an isolated factor or in association with direct surgical injury. Tissue necrosis may also occur following previous surgery and with pelvic abscess or infection. Tissue necrosis results in fibrosis and

induration, finally resulting in an epithelial or mucosal lining of the fistula tract (Kursh, 1988).

In 1980 Goodwin reported 32 patients with fistulae as a direct result of gynecologic intervention (Goodwin 1980). Tancer (1992) noted a similar group of 151 patients and found that 91% (137) were postsurgical with 125 caused by gynecologic surgery. The most common procedure accounting for fistula was hysterectomy in 73% (110) of cases (99 of which were performed transabdominally). Factors thought to contribute to the risk of fistula formation due to hysterectomy include: prior caesarean section, intrinsic uterine disease (endometriosis) and prior ablative treatment for carcinomas (pelvic radiation therapy). Similar risk factors were identified by Blandy et al. (1991). The incidence of fistula after hysterectomy is generally accepted to be 0.1 - 0.2%. (Harris, 1995) Recent meta- analysis of the gynecologic literature suggests that the rate of iatrogenic ureteral injury during hysterectomy approaches a crude occurrence rate of 6.2 per 1000 cases, while bladder injury occurs at 10.4 per 1000 cases. (Gilmour, 1999)

Other causes of fistulae to include malignancy (Kottmeier, 1964), radiation (Cushing, 1968, Stockbine 1970, and Villasanta, 1972), gastrointestinal surgery (low anterior resection) (Cross, 1993), inflammatory bowel disease and urinary tuberculosis (Ba-Thike et al, 1992). Symmonds' experience at the Mayo clinic revealed only 5% of 800 vesicovaginal fistulae to be due to obstetric causes (Symmonds, 1984). Rarely, foreign bodies such as pessaries, diaphragms, and intrauterine devices also may lead to fistula formation (Goldstein et al, 1990). Iatrogenic CO2 laser therapy for cervical disease has also resulted in bladder fistulae. (Colombel, 1995) Autoimmune diseases such as Behcet's have also been implicated as causative for vesicovaginal fistulae, due to extensive vasculitis related bladder wall necrosis. (Monteiro, 1995)

SUMMARY

The most common aetiology for vesicovaginal fistulae in developed countries is pelvic surgery, usually hysterectomy. Other causes are much less prevalent.

Evidence for Aetiology Level 3-5

3. EVALUATION

Physical examination is the most important diagnostic component in the evaluation of a woman with a suspected genitourinary fistula. Vaginal examination should try to identify the fistula tract and the degree of vaginal access. Cystoscopy is a crucial adjunct to demonstrate the location and size of the fistula as well as proximity to one or both ureteral orifices. Cystoscopy also assesses the bladder mucosa for oedema and persistent necrosis which may complicate planned surgical repair.

Patients may present while in the hospital with prolonged ileus, excessive pain, hematuria or flank pain (if a simultaneous ureteral injury also is present) (Kursh, 1998). If the fistula tract is large enough a significant amount, if not all, urine drains through the vagina, producing continuous or total incontinence. In other cases, fistula drainage may be minimal and intermittent and may be initially mistaken for stress incontinence occurring postoperatively. Patients with urethrovaginal fistulae arising from urethral catheter trauma may not develop symptoms until catheter removal has occurred. Incontinence arising from a urethrovaginal fistula may be intermittent unless the fistula extends across the bladder neck, in these cases severe and total incontinence is usually encountered. Fistulae may develop up to twenty years post radiation (Graham 1965; Raz 1992). Additionally, persistent clear vaginal discharge after hysterectomy may arise from leakage of peritoneal fluid from a vaginal cuff through a peritoneal sinus tract (posthysterectomy pseudo incontinence) (Ball, 1995). Ginsberg et al, 1998, reported five patients with this finding, all of whom were cured by vaginal cuff revision.

Intravenous pyelography should be performed in women with any urinary fistula primarily to detect ureteric injury but also for congenital ureteric anomalies. Symmonds (1984) reported a 10% risk of a simultaneous ureteral component with vesicovaginal fistulae. The cystogram phase of the IVP may also suggest the presence of a fistula if early pooling of urine in the vagina occurs or wisps of urinary extravasation are noted. Retrograde pyelography may be employed for diagnosing the site of a ureterovaginal fistula or the possibility of a combined uretero- and vesicovaginal fistula, although no direct studies have evaluated this diagnostic technique against other imaging modalities.

Voiding cystourethrography (VCUG) may also help determine fistula presence and location. Also, the VCUG may demonstrate other lower urinary tract abnormalities that may impact upon surgical reconstruction (vesicoureteral reflux, cystocele, urethral diverticulum). Occasionally contrast examination of the vagina (vaginography) may help demonstrate an irregular fistulous tract. Zimmern et al (1994) described the procedure for injecting contrast material through the vagina with a large balloon occluding the vaginal introitus. Level 3 evidence supports the use of this study.

Hilton (1998) argues that urodynamics are necessary in the woman with a lower urinary tract fistula. He noted the following urodynamic abnormalities while evaluating 30 women with fistulae: 47% urodynamic stress incontinence, 44% detrusor overactivity, and 17% with poor bladder compliance. Urodynamics, however, are often difficult to perform due to continuous loss of instilled fluid through the fistula tract and therefore in many cases may not be additive to the overall evaluation of the patient. No evidence exists as to the role of urodynamics in predicting post-operative stress incontinence after fistula repair.

SUMMARY

The evaluation of urinary fistulae is based on evidence of loss of urine on physical evaluation, cystoscopic inspection of the bladder, and assessment of lower ureteral integrity (either IVP of retrograde pyelography).

Mandatory evaluation includes clinical examination with or without the use of dyes (Level 3) Intravenous urogram (Level 3,4),

Cystoscopy (Level 3)

Optional testing: Voiding cystourethrography (Level 3,4), Urodynamics (Level 4)

4. TREATMENT

a) Conservative and minimally Invasive treatment

Regardless of the timing of presentation, a trial of conservative therapy may be implemented which uses continuous urethral catheter drainage. Level 4,5 evidence suggests that a variety of conservative techniques may be curative and possibly should be attempted first in patients with single fistula tracts which are less than 1 cm in size, and which are not associated with complicating factors such as prior radiation. Tancer et al (1992) reported 3 of 151 patients with spontaneous closure of fistula using this strategy. Spontaneous closure occurred with 3 fistula tracts identified early in the postoperative period in 45 women managed in this fashion. Often, however, the patient has already undergone a trial of catheter drainage at the time of initial evaluation and therefore further catheter drainage may be helpful. No definitive evidence suggests the optimal time for catheter drainage. (Level 4)

Another possible conservative therapy utilizes electrocoagulation or fulguration of the lining of the fistulous tract (O'Connor 1980, Alonso 1985, Molina 1989, Stovsky, 1994). In Stovsky's experience 11 of 17 (73%) of patients with small (less than 3mm) fistulae treated with electrofulguration and 2 weeks of catheter drainage resolved. McKay (1997) recently described successful cystoscopically placed suture closure of a vesicovaginal fistula, with no secondary incision.

Recently, the use of tissue adhesives has been described as a sealant for fistula tracts. Evans et al (2003) reported the use of fibrin sealant for five patients who had complex vesicovaginal fistulae. All five were successfully managed without complication. (Level 4)

SUMMARY

Level 4/5 evidence suggests that conservative management techniques may be utilized in selected patients with small fistulae. More research is needed to better identify the patients who would best be managed in this manner.

b) Surgical Therapy

1. TIMING OF INTERVENTION

Previously, many authors have advocated a waiting period of at least 3 to 6 months before intervening with surgical therapy (O' Connor 1951, Wein 1980, Blandy 1991). No specific evidence exists as to the need for this delay in intervention. More recently surgeons have advocated an individualized approach without an observational period. Several authors have reported excellent results with early interventions (Persky, 1979, Goodwin 1980, Wang 1990, Raz 1992, Blaivas 1995, Raz 2000). There is Level 3 evidence that fistulae identified within the first 24 to 48 hours postoperatively can be safely repaired immediately. Those identified days to weeks after surgery require careful planning and selection. Wang and Hadley successfully managed 15 of 16 (94%) high lying (vaginal apical) fistulae through a transvaginal approach, with all 7 patients who were less than three months from initial surgery cured of fistula. (Wang 1990).

SUMMARY

The timing for surgical intervention may depend on presenting factors such as tissue integrity. Intervention immediately following early diagnosis is successful in some series. More research is necessary to identify optimal timing of fistula repair.

Evidence for timing of Surgery Level 4,5

2. PREOPERATIVE PREPARATION

No specific evidence supports any preoperative preparation as being crucial for surgical success. Local preparation such as vaginal douches with antiseptic agents the evening before and the morning of surgery have been used in the past but no evidence supports this technique. A recent RCT evaluating the use of antibiotic prophylaxis for fistula surgery showed no benefit to use of perioperative antibiotics (Tomlinson AJ & Thornton JG 1998). Oestrogen replacement therapy has also used in those patients with poor quality of vaginal tissues (Raz 1992). (Level 4/5)

SUMMARY

No specific preoperative preparation has been shown to alter outcome. Antibiotic prophylaxis does not influence post-operative infective morbidity or outcome. (Level 1/2)

3. SURGICAL APPROACHES

Surgical approaches used for vesicovaginal fistulae include: combined abdominal vaginal, vaginal, or abdominal approaches. The approach chosen is dependant upon several factors, including location of fistula, quality of the tissues, and surgical experience and training. Vaginal surgery is more rapid and results in less morbidity and more rapid recovery; however, the vaginal route is difficult in patients with a significant degree of fibrosis, pelvic immobility, or with large fistula tracts with possible injury in close proximity to the ureteral orifices. The abdominal approach may be more appropriate for the poorly visualized tract, the narrow or immobile vagina, and those with close proximity to a ureteral orifice. Laparoscopic repair also provides an alternative approach.

Other considerations for surgical repair include; type of suture, method of urinary drainage, and the use of tissue interposition graft. There is only level 4 and 5 evidence to support any of the surgical techniques.

5. VAGINAL APPROACH

The vaginal approach utilizes an anterior vaginal wall flap for coverage. Subsequently a tension free closure is performed utilizing a long acting (polyglycolic acid or polydioxanone) suture and non-overlapping multiple closure lines. Interposition tissue may be mobilized from labia, peritoneum, or vagina. There is only level 4,5 evidence to support these techniques.

A suprapubic catheter should be placed (Zeidman 1988). Urinary drainage may also be supplemented with a urethral catheter. If the fistula communication occurs in proximity to the ureteral orifices, ureteric catheterization with cystoscopic assistance is generally performed prior to fistula closure. Optimal visualization is dependent on tissue mobility. The use of lateral relaxing incisions may help operative visualization and approach to the fistulous tract (Zimmern 1994). If the fistula repair is tenuous or there is concern regarding apposition of suture lines a Martius interpositional graft may be utilized. If this is not obtainable, alternative graft sources include a peritoneal flap (Raz 2000) or an interposition graft utilizing gracilis muscle tissue. The peritoneum can be freed from the posterior aspect of the bladder and easily advanced to cover the layers of the closure as well (Raz 1993). (Level 4)

Level 4,5 evidence suggests that the Martius labial interposition graft provides a satisfactory graft material (Martius 1928, Raz 1992, Blaivas 1995, Blaivas 2000, Hoskins, 1984). Several authors have used this graft as an adjunct to repair associated with complicated incontinence with excellent results. (Ghoniem 1995, Carr 1996)

The vast majority of vesicovaginal fistulae can be closed in one operation using the previously described approach. Raz reported a success rate of 92% (64/69) for vesicovaginal fistulae, 2/3 of which had failed 1 to 3 prior repairs using this technique (Raz 1992). Recently, Nesrallah et al reported a 100% success rate using the O'Conor transabdominal supratrigonal.technique in 29 patients. (Nesrallah 1999) Other authors have reported similar results. (**Table H-I.1**)

Eilber et al recently reported a 10 year experience with interposition graft use in 120 patients undergoing vaginal repair of fistula. In 83 a peritoneal graft was used, in another 34 a Martius graft was interposed, and in 3 a labial interposition was applied. The success rates were 96, 97, and 33% respectively. (Level 3) No intraoperative complications were reported.

6. ABDOMINAL APPROACH

All bladder fistulae (except those extending into the urethra) may be approached utilizing the abdominal approach, and this is the preferred approach in those

Author (Date)	Number of	Success (%)	Fistula	Surgical
	patients		duration	technique
			before surgery	
Collins (1960)	24	16(67)	20 (<2 mth)	24 vag
			8 (> 4 mth)	
Eisen (1974)	29	26(90)	29 (> 3 mths)	29 abd
Persky(1979)	7	6(86)	7 (< 10 wks)	6 abd/1 vag
Tancer (1980)	45	42(93)	8 – 16 wks	43 vag / 1abd/
				1sp
Wein (1980)	34	30(88)	> 3 mths	34 abd
Keetel (1982)	168	(94)	> 3 mths	156 vag/ 6 abd/
				6 com
	7		NS	7 abd
Bisada(1983		7(100)		
Cruikshank	11	11(100)	< 1 mth	9 vag/ 1 abd / 1
(1988)				comb
Lee(1988)	182	178(98)	15 < 2 mths	15 vag/
			167 > 2 mths	130 vag/ 37 abd
Elkins (1990)	23	21(91)	> 2 mths	23 vag
Wang (1990)	16	15(94)	7 < 3 mths	16 vag
			9 > 3 mths	
Blandy(1991)	25	25(100)	12 < 1.5 mths	25 abd
			13 > 1.5 mths	
O'Conor(1991)	77	70(91)	> 2 mths	77 abd
Raz (1993)	19	16(84)	>2 mths	19 vag
Demnirel (1993)	26	(88)	> 3 mths	8 vag /18 abd
Kristensen	18	17(94)	>2 mths	18 Abd
(1994)				
Brandt (1998)	80	(96)	>1 mths	80 abd
Nesrallah (1999)	29	29(100)	> 6 wks	29 abd

Vag = vaginal

Abd = Abdominal

Spon = spontaneous closure

Comb = combined abdominal and vaginal approach

patients requiring bladder augmentation or ureteral re-implantation. The earliest experience was reported by O'Conor (1951, 1973) for abdominal transvesical repair of vesicovaginal fistulae. This technique may require placement of ureteral catheters to localize the ureteral orifices. An abdominal incision is then performed (midline or pfannenstiel), followed by bisection of the bladder to the level of fistula. The bladder and vagina are mobilized and separated from each other by dissecting along the vesicovaginal septum. A complete excision of the fistula tract is completed. If the tract is extensively indurated, a posterior bladder flap may be mobilized to repair the defect. (Gil-Vernet, 1989)

Separate closure of the vagina and bladder are performed utilizing absorbable sutures (polydioxanone or polyglycolic) and may be performed intra - or extraperitoneally. The intraperitoneal technique allows for easy harvest of the omentum.

Level 4 evidence supports the use of omentum as an interpositional graft. Wein (1980b) utilizing an omentum graft based on the right gastroepiploic artery noted adequate length and tension free apposition of this tissue between the vaginal and vesical components of the fistula repair. Other authors have found the omentum to be reproducibly present for interpositional uses.(Turner-Warwick, 1976) (Kiricuta, 1972) The omentum is secured between the bladder and vagina with 3-0 polyglycolic acid sutures.

Bladder augmentation can also be performed with the intraperitoneal approach into the already bivalved bladder. Large or small bowel may be utilized. This closure is often reinforced with an omentum pedicle graft. Reported success rates with this approach are approximately 85% - 90% and have been reported by numerous authors. (Marshall 1979, Wein 1980a, Gil-Vernet 1989, Udeh 1985, Demirel 1993, Kristensen 1994, Blaivas 1995, Raz 2000).

7. LAPAROSCOPIC APPROACH

Laparoscopy provides an alternative approach for fistula repair. Level 3,4 evidence suggests that this approach may be successful for some patients. Nehzat et al (1994) reported a successful repair of a laparoscopically caused fistula is a single patient. In a larger series Ou et al (2004) evaluated retrospectively the value of laparoscopic repair as compared to vaginal or abdominal repair in 16 patients. Only two patients actually underwent laparoscopic repair, and both repairs were successful, however one patient had a prolonged hospitalization. (Level 5 Evidence)

8. COMPLICATED VESICOVAGINAL FISTULAE

Complicated vesicovaginal fistulae can be defined as those fistulae of large size (3 to 5 centimeters or greater in diameter), fistulae occurring after prior attempt at closure, fistulae associated with prior radiation therapy, fistulae associated with malignancy, fistulae occurring in compromised operative fields due to poor healing or host characteristics, and fistulae that involve the trigone, bladder neck and/or urethra

Several Level 4/5 studies report results for complicated fistulae. Reconstructive techniques have been described utilizing a variety of interpositional tissues including fibrofatty labial interposition tissues, anterior/posterior bladder flaps (autografts), myocutaneous flaps including rectus, sartorius, gluteus, and gracilis muscle flaps as well as combined myocutaneous flaps (Garlock 1928, Byron 1969, Stirnemann 1969, Menchaca 1990, Blaivas 1991, Raz 1992, Candiani 1993, Tancer 1993, Brandt 1998, Raz 2000) as adjuncts to repair of the complex vesicovaginal fistula (Patil 1980,Bissada, 1992) (Level 4 / 5 Evidence)

Prior radiation therapy may increase the risk of vesicovaginal fistula despite the use of the tissue interposition (Obrink 1978, Raz 1992). Overall results range around 50% successful closure, but Bissada achieved 80% successful closure in his group of 10 post-radiation patients.(Bissada, 1992 Level 5 Evidence)

SUMMARY

No specific intra-operative intervention has been shown to influence outcome.

II. URETHROVAGINAL FISTULAE

Urethrovaginal fistulae may be very small pinpoint fistulae demonstrated by vaginal voiding or may present as complete urethral and bladder neck loss with total urinary incontinence. This circumstance most commonly results from prior gynecological surgery, with anterior repair and urethral diverticulectomy comprising the most common inciting procedures (Blaivas 1989, Raz 2000). (Level 4 Evidence)

Previously, birth trauma was a cause of majority of urethral defects; however, in developed nations this is now a rare cause of urethrovaginal fistulae. Prolonged obstructive labour, however, remains a major cause of urethral injury in developing nations (Elkins 1994). Level 4 Evidence suggests that techniques used for urethrovaginal fistula closure are very similar to those utilized for transvaginal vesicovaginal fistula repair (Webster 1984). A significant difference however is that the urethrovaginal fistula should not be completely excised but rather circumscribed and oversewn. Complete urethral loss is a more daunting surgical challenge and a multiplicity of techniques has been described for this (Blaivas 1989, Blaivas 1996, Hendren 1980 and 1998, Patil 1980). These techniques usually employ some type of flap utilizing either vaginal, bladder, or alternative tissue in an onlay versus tubularized reconstruction (Blaivas 1989). Simultaneous stress incontinence procedures should be performed to obviate the risk of postoperative incontinence (Blaivas 1990). (Level 3,4 Evidence)

1. PREOPERATIVE EVALUATION

The physical examination is important to identify the extent and amount of urethral loss and associated vaginal pathologies such as prolapse and functional problems such as stress incontinence.

2. OPERATIVE TECHNIQUE

Small to intermediate size fistulae may be managed with a tension-free layered closure. Distal fistulae may be managed with extended meatotomy (Spence 1970). (Level 5) Complete reconstruction is necessary for large fistulae with extensive loss including those that involve the bladder neck. The optimal continence procedure required in such cases has not been critically studied.

Interpositional tissue should be considered whenever the closure lines or vaginal tissues are of poorer quality (Webster 1984, Leach 1991). (Level 4,5 Evidence)

SUMMARY

Although the risk of non-obstetric fistulae after gynecological surgery approaches 0.1% in developed countries, evidence supporting optimal surgical preparation, approach and technique, and post surgical management is predominantly based on case series (Level 4).

Conservative or minimally invasive management (including catheter drainage, cystoscopic fulguration of fistula tract, and use of occlusive agents) has been reported the overall results for vesicovaginal fistulae with these methods are highly variable. Expert opinion suggests that an attempt at conservative management should be considered during the early management of a newly diagnosed vesicovaginal fistula. (Level 4 / 5)

Although vaginal, abdominal, and laparoscopic techniques have been described no clear advantage exists between these techniques. Very little evidence supports laparoscopic management. Surgeon preference, fistula location, and complicating factors (such as prior pelvic radiation, altered wound healing – ie chronic steroid use, proximity to ureteral orifices, and time of diagnosis) may all impact on method of repair. Timing of repair (Level 4) appears not to influence long term success and surgical repair may be performed at time of identification if factors such as wound healing are considered optimal by the operative surgeon.

Evidence supporting surgical adjuncts such as use and type of interpositional tissues and effect on outcome of repair is limited (Level 4).

REFERENCES

Aboseif, S., et al., *Sacral neuromodulation in functional urinary retention: an effective way to restore voiding*. BJU Int, 2002. **90**(7): p. 662-5.

Abrams, P., et al., *The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society.* Am J Obstet Gynecol, 2002. **187**(1): p. 116-26.

Adamiak, A., et al., *The efficacy and safety of the tension-free vag nal tape procedure do not depend on the method of analgesia*. Eur Urol, 2002. **42**(1): p. 29-33.

Addison, W.A., V. Haygood, and R.T. Parker, *Recurrent stress urina*ry incontinence. Obstet Gynecol Annu, 1985. **14**: p. 253-65.

Alcalay, M., A. Monga, and S.L. Stanton, *Burch colposuspension: a* 10-20 year follow up. Br J Obstet Gynaecol, 1995. **102**(9): p. 740-5.

Aldridge, A., Transplantation of fascia for relief of urinary stress incontinence. Am J Obstet Gynecol, 1942. 44: p. 398-411.

Aldridge, C.W., Jr., J.H. Beaton, and R.P. Nanzig, *A review of office urethroscopy and cystometry*. Am J Obstet Gynecol, 1978. **131**(4): p. 432-7.

Alonso, G., Z. Fernandez, and M. SJF, *Spontaneous healing of utero*vesicucovaginal fistulas. Eur Urology, 1985. **11**: p. 341-344.

Maye-Obu, F.A. and H.P. Drutz, *Surgical management of recurrent stress urinary incontinence: A 12-year experience*. Am J Obstet Gynecol, 1999. **181**(6): p. 1296-307; discussion 1307-9.

Amundsen, C.L., et al., *Outcome in 104 pubovaginal slings using freeze-dried allograft fascia lata from a single tissue bank*. Urology, 2000. **56**(6 Suppl 1): p. 2-8.

Andersen, J.T., et al., *Suprapubic versus transurethral bladder drainage after colposuspension/vaginal repair*. Acta Obstet Gynecol Scand, 1985. **64**(2): p. 139-43.

Appell, *Techniques and results in the implantation of the artificial urinary sphincter in women with type III stress urinary incontinence by the vaginal approach*Neuro-urology and Urodynamics, 1988. 7: p. 613-619.

Appell, R.A., *Surgery for the treatment of overactive bladder*. Urology, 1998. **51**(2A Suppl): p. 27-9.

Arrowsmith, S., E.C. Hamlin, and L.L. Wall, *Obstructed labor injury complex: obstetric fistula formation and the multifaceted morbidity of maternal birth trauma in the developing world*. Obstet Gynecol Surv, 1996. **51**(9): p. 568-74.

Arrowsmith, S.D., *Genitourinary reconstruction in obstetric fistulas*. J Urol, 1994. **152**(2 Pt 1): p. 403-6.

Arunkalaivanan, A.S. and J.W. Barrington, *Randomized trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape* (*TVT*) *in the surgical treatment of stress incontinence: a questionnaire-based study*.Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(1): p. 17-23; discussion 21-2.

Ashken, M.H., P.H. Abrams, and W.T. Lawrence, *Stamey endoscopic bladder neck suspension for stress incontinence*. BJU, 1984. **56**: p. 629-634.

Atala, A., *Bladder regeneration by tissue engineering*. BJU Int, 2001. **88**(7): p. 765-70.

Athanasopoulos, A., et al., *Long-term results of transvaginal colposuspension for the treatment of genuine stress incontinence combined with vaginal hysterectomy.* Urol Int, 2003. **71**(1): p. 41-4.

Awad, S.A., et al., Long-term results and complications of augmentation ileocystoplasty for idiopathic urge incontinence in women. Br J Urol, 1998. **81**(4): p. 569-73.

Baker, K.R. and H.P. Drutz, *Age as a risk factor in genitourinary surgery*. Can J Surg, 1992. **35**(2): p. 188-191.

Ball, T., *Editorial comment on Ginsberg et al: Posthysterectomy vaginal vault fistula: diagnosis and management.* Urology, 1998. **51**: p. 61-65.

Barbalias, G., E. Liatsikos, and D. Barbalias, *Use of slings made of indigenous and allogenic material (Goretex) in type III urinary incontinence and comparison between them*. Eur Urol, 1997. **31**(4): p. 394-400.

Barber, M., et al., *Prediction and prevention of post-operative stress urinary incontinence in women undergoingsurgery for prolapse: a systemic review.* 2003.

Barranger, E., et al., *Results of transurethral injection of silicone micro-implants for females with intrinsic sphincterdeficiency*. J Urol, 2000. **164**(5): p. 1619-22.

Barranger, E., et al., *Results of transurethral injection of silicone micro-implants for females with intrinsic sphincter deficiency*. J Urol, 2000. **164**(5): p. 1619-22.

Ba-Thike, K., A. Than, and O. Nan, *Tuberculous vesico-vaginal fistula*. Int J Gynaecol Obstet, 1992. **37**(2): p. 127-30.

Beck, R.P., S. McCormick, and L. Nordstrom, *The fascia lata sling procedure for treating recurrent genuine stress incontinence of urine*. Obstet Gynecol, 1988. **72**(5): p. 699-703.

Beck, R.P., S. McCormick, and L. Nordstrom, *A 25-year experience with 519 anterior colporrhaphy procedures*. Obstet Gynecol, 1991. **78**(6): p. 1011-8.

Benson, J.T. and E. McClellan, *The effect of vaginal dissection on the pudendal nerve*. Obstet Gynecol, 1993. **82**(3): p. 387-9.

Bent, A.E., Management of recurrent genuine stress incontinence. Clin Obstet Gynecol, 1990. 33(2): p. 358-66.

Bent, A.E., et al., *Collagen implant for treating stress urinary incontinence in women with urethral hypermobility.* J Urol, 2001. **166**(4): p. 1354-7.

Bent, A.E., et al., *Collagen implant for treating stress urinary incontinence in women with urethral hypermobility.* J Urol, 2001. **166**(4): p. 1354-7.

Bent, A.E., D.R. Ostergard, and M. Zwick-Zaffuto, *Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence:clinical and histologic study.* Am J Obstet Gynecol, 1993. **169**(5): p. 1198-204.

Bent, A.E., et al., Treatment of intrinsic sphincter deficiency using autologous ear chondrocytes as a bulking agent.Neurourol Urodyn, 2001. **20**(2): p. 157-65.

Berglund, A.L., et al., Social adjustment and spouse relationships among women with stress incontinence before and after surgical treatment. Soc Sci Med, 1996. **42**(11): p. 1537-44.

Berglund, A.L., et al., Social adjustment and spouse relationships among women with stress incontinence before and after surgical treatment. Soc Sci Med, 1996. **42**(11): p. 1537-44.

Bergman, A., P.P. Koonings, and C.A. Ballard, *Predicting postoperative urinary incontinence development in women undergoing operation for r genitourinary prolapse.* Am J Obstet Gynecol, 1988. **158**(5): p. 1171-5.

Bergman, A., P.P. Koonings, and C.A. Ballard, *Proposed management of low urethral pressure type of genuine stress urinary incontinence*. Gynecol Obstet Invest, 1989. **27**(3): p. 155-9.

Bergman, A., et al., *Suprapubic versus transurethral bladder drainage after surgery for stress urinary incontinence*Obstet Gynecol, 1987. **69**(4): p. 546-9.

Berman, C.J. and K.J. Kreder, *Comparative cost analysis of collagen injection and fascia lata sling cystourethropexy for the treatment of type III incontinence in women [see comments]*. J Urol, 1997. **157**(1): p. 122-4.

Bernier, P.A., et al., *Female outlet obstruction after repeated collagen injections*. Urology, 1997. **50**(4): p. 618-21.

Betson, L.H., G. Siddiqui, and N.N. Bhatia, *Intrinsic urethral sphincteric deficiency: critical analysis of various diagnostic modalities*. Curr Opin Obstet Gynecol, 2003. **15**(5): p. 411-7.

Bidmead, J., et al., A comparison of the objective and subjective outcomes of colposuspension for stress incontinence in women. BJOG, 2001. **108**(4): p. 408-13.

Bissada, N.K., Vesicovaginal fistulas, in Urinary Incontinence, P. O'Donnell, Editor. 1997, Mosby.

Bissada, N.K. and D. McDonald, *Management of giant vesicovaginal* and vesicourethrovaginal fistulas. J Urol, 1983. **130**(6): p. 1073-5.

Bissada, S. and R. Morcos, *Voiding patterns and urinary control after repair of giant vesicovaginal and vesicourethrovaginal fistulas and neourethral construction*. Neuro-urology and Urodynamics, 1986. **5**: p. 321-326.

Bissada, S.A. and N.K. Bissada, Repair of active radiation-induced vesicovaginal fistula using combined gastric and omentalsegments based on the gastroepiploic vessels. J Urol, 1992. 147(5): p. 1368-70.

Black, N., et al., *Impact of surgery for stress incontinence on morbidity: cohort study.* BMJ, 1997. **315**(7121): p. 1493-8.

Black, N.A., et al., *Impact of surgery for stress incontinence on the social lives of women.* Br J Obstet Gynaecol, 1998. **105**(6): p. 605-12.

Black.N.A., et al., Sociodemographic and symptomatic characteristics of women undergoing stress incontinence surgery in the UK. BJU, 1996. **78**: p. 847-855.

Blackford, H.N., et al., *Results of transvesical infiltration of the pelvic plexuses with phenol in 116 patients*. Br J Urol, 1984. **56**(6): p. 647-9.

Blaivas, J.G., Vaginal flap urethral reconstruction: an alternative to the bladder flap neourethra. J Urol, 1989. **141**(3): p. 542-5.

Blaivas, J.G., *Treatment of female incontinence secondary to urethral damage or loss*. Urol Clin North Am, 1991. **18**(2): p. 355-63.

Blaivas, J.G. and A. Groutz, *Bladder outlet obstruction nomogram* for women with lower urinary tract symptomatology. Neurourol Urodyn, 2000. **19**(5): p. 553-64.

Blaivas, J.G. and A. Groutz, *Bladder outlet obstruction nomogram* for women with lower urinary tract symptomatology. Neurourol Urodyn, 2000. **19**(5): p. 553-64. Blaivas, J.G., D.M. Heritz, and L.J. Romanzi, *Early versus late repair of vesicovaginal fistulas: vaginal and abdominal approaches.* J Urol, 1995. **153**(4): p. 1110-2; discussion 1112-3.

Blaivas, J.G. and B.Z. Jacobs, *Pubovaginal fascial sling for the treatment of complicated stress urinary incontinence*. J Urol, 1991. **145**(6): p. 1214-8.

Blandy, J.P., et al., *Early repair of iatrogenic injury to the ureter or bladder after gynecological surgery*. J Urol, 1991. **146**(3): p. 761-5.

Bodell, D. and G. Leach, *Update on the results of the cadaveric trans*vaginal sling. J Urol, 2002. **167**(Supplement 78): p. 308.

Borup, K. and J.B. Nielsen, *Results in 32 women operated for genui*ne stress incontinence with the pubovaginal sling procedure ad modum Ed McGuire. Scand J Urol Nephrol, 2002. **36**(2): p. 128-33.

Bosch, J.L., Sacral neuromodulation: treatment success is not just a matter of optimal electrode position. BJU Int, 2000. **85 Suppl 3**: p. 20-1; discussion 22-3.

Bramble, F.J., *The treatment of adult enuresis and urge incontinence by enterocystoplasty.* Br J Urol, 1982. **54**(6): p. 693-6.

Brandt, F.T., F.R. Lorenzato, and C.D. Albuquerque, *Treatment of vesicovaginal fistula by bladder mucosa autograft technique*. J Am Coll Surg, 1998. **186**(6): p. 645-8.

Breen, J.M., B.E. Geer, and G.E. May, *The fascia lata suburethral sling for treating recurrent urinary stress incontinence*. Am J Obstet Gynecol, 1997. **177**(6): p. 1363-5; discussion 1365-6.

Brieger, G. and A. Korda, *The effect of obesity on the outcome of successful surgery for genuine stress incontinence*. Aust N Z J Obstet Gynaecol, 1992. **32**(1): p. 71-2.

TM brink, A., et al., *Mental factors influencing recurrence of stress incontinence*. Acta Obstet Gynecol Scand, 1979. **58**: p. 91-94.

Brown, S.L. and F.E. Govier, *Cadaveric versus autologous fascia lata* for the pubovaginal sling: surgical outcome and patientsatisfaction.

J Urol, 2000. 164(5): p. 1633-7.

Bruce, R., et al., Use of rectus abdominis muscle flap for the treatment of complex and refractory urethrovaginal fistulas. J Urol, 2000. **163**: p. 1212-1215.

Bruce, R.G., R.E. El-Galley, and N.T. Galloway, *Paravaginal defect repair in the treatment of female stress urinary incontinence and cystocele*. Urology, 1999. **54**(4): p. 647-51.

Bryans, F.E., Marlex gauze hammock sling operation with Cooper's ligament attachment in the management of recurrent urinary stress incontinence. Am J Obstet Gynecol, 1979. **133**(3): p.292-4.

Buchwald, H., *Surgical procedures and devices should be evaluated in the same way as medical therapy*. Control Clin Trials, 1997. **18**(6): p. 478-87.

Buck, B.E. and T.I. Malinin, Human bone and tissue allografts. Preparation and safety. Clin Orthop, 1994(303): p. 8-17.

Bump, R.C., et al., *Diagnosing intrinsic sphincteric deficiency: com*paring urethral closure pressure, urethral axis, and Valsalva leak point pressures. Am J Obstet Gynecol, 1997. **177**(2): p. 303-10.

Bump, R.C., J.A. Fantl, and W.G. Hurt, *The mechanism of urinary* continence in women with severe uterovaginal prolapse: results of barrier studies. Obstet Gynecol, 1988. **72**(3 Pt 1): p. 291-5.

Bump, R.C., et al., Randomized prospective comparison of needle colposuspension versus endopelvic fascia placation for potential stress incontinence prophylaxis in women undergoing vaginal reconstruction for stage III or IV pelvic organ prolapse. The Continence Program for Women Research Group. Am J Obstet Gynecol, 1996. **175**(2): p. 326-33; discussion 333-5.

Burch, J.C., *Cooper's ligament urethrovesical suspension for stress incontinence. Nine years' experience–results, complications, technique.* Am J Obstet Gynecol, 1968. **100**(6): p. 764-74.

Burton, G., A five year prospective randomized urodynamics study comparing open and laparoscopic colpsuspension. Neuro-urology and Urodynamics, 1999. **18**.

Byron, R.L., Jr. and D.R. Ostergard, *Sartorius muscle interposition for the treatment of the radiation-induced vaginal fistula*. Am J Obstet Gynecol, 1969. **104**(1): p. 104-7.

Cameron-Strange, A. and R.J. Millard, *Management of refractory detrusor instability by transvesical phenol injection*. Br J Urol, 1988. **62**(4): p. 323-5.

Candiani, P., et al., *Repair of a recurrent urethrovaginal fistula with an island bulbocavernous musculocutaneous flap.* Plast Reconstr Surg, 1993. **92**(7): p. 1393-6.

Carr, L.K., et al., Favorable outcome of pubovaginal slings for geriatric women with stress incontinence. J Urol, 1997. **157**(1): p. 125-8.

Carr, L.K. and G.D. Webster, *Full-thickness cutaneous martius flaps: a useful technique in female reconstructive urology*. Urology, 1996. **48**(3): p. 461-3.

Cartwright, P.C. and B.W. Snow, *Bladder autoaugmentation: early clinical experience*. J Urol, 1989. **142**(2 Pt 2): p. 505-8; discussion 520-1.

Cartwright, P.C. and B.W. Snow, *Bladder autoaugmentation: partial detrusor excision to augment the bladder without use of bowel.* J Urol, 1989. **142**(4): p. 1050-3.

Cespedes, R.D., C.A. Cross, and E.J. McGuire, *Modified Ingelman-Sundberg bladder denervation procedure for intractable urge incontinence*. J Urol, 1996. **156**(5): p. 1744-7.

Chaikin, D.C. and J.G. Blaivas, *Weakened cadaveric fascial sling: an unexpected cause of failure*. J Urol, 1998. **160**(6 Pt 1): p. 2151.

Chaikin, D.C., A. Groutz, and J.G. Blaivas, *Predicting the need for anti-incontinence surgery in continent women undergoing repair of*

severe urogenital prolapse. J Urol, 2000. 163(2): p. 531-4

Chaikin, D.C., J. Rosenthal, and J.G. Blaivas, *Pubovaginal fascial sling for all types of stress urinary incontinence: long-term analysis.* J Urol, 1998. **160**(4): p. 1312-6.

Chapple, C.R. and N.P. Bryan, *Surgery for detrusor overactivity*. World J Urol, 1998. **16**(4): p. 268-73.

Chapple, C.R., et al., Subtrigonal phenol injection. How safe and effective is it? Br J Urol, 1991. 68(5): p. 483-6.

Chartier-Kastler, E.J., et al., Long-term results of sacral nerve stimulation (S3) for the treatment of neurogenic refractory urge incontinence related to detrusor hyperreflexia. J Urol, 2000. **164**(5): p. 1476-80.

Cheon WC, M.J., Liu JY, *Prospective randomised controlled trial comparing laparoscopic and open colposuspension*. Hong Kong Med. J, 2003. **1**(9): p. 10-14.

Chien, G.W., et al., Surgical treatment for stress urinary incontinence with urethral hypermobility: what is the best approach? World J Urol, 2002. **20**(4): p. 234-9.

Chilaka, V.N., O. Amu, and C.J. Mayne, Factors affecting outcome of colposuspension. J Obstet Gynaecol, 2002. 22(1): p. 72-4.

Choe, J.M. and T. Bell, *Genetic material is present in cadaveric dermis and cadaveric fascia lata.* J Urol, 2001. **166**: p. 122-124.

Choe, J.M., K. Ogan, and B.S. Battino, *Antimicrobial mesh versus vaginal wall sling: a comparative outcomes analysis.* J Urol, 2000. **163**(6): p. 1829-34.

Chou, E.C., et al., *Effective treatment for mixed urinary incontinence with a pubovaginal sling*. J Urol, 2003. **170**(2 Pt 1): p. 494-7.

Chrouser, K.L., et al., Carbon coated zirconium beads in beta-glucan gel and bovine glutaraldehyde cross-linked collagen injections for intrinsic sphincter deficiency: continence and satisfaction after extended followup. J Urol, 2004. **171**(3): p. 1152-5.

Clark, A.L., et al., *Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence*. Am J Obstet Gynecol, 2003. **189**: p. 1261-1267.

Clarke, B., *The role of urodynamic assessment in the diagnosis of lower urinary tract disorders*. Int Urogynecol J Pelvic Floor Dysfunct, 1997. **8**(4): p. 196-9.

Clemens, J.Q., et al., Long-term results of the Stamey bladder neck suspension: direct comparison with the Marshall-Marchetti-Krantz procedure. J Urol, 1998. **160**(2): p. 372-6.

Clemons, J.L., et al., *Vaginal paravaginal repair with an AlloDerm graft*.Am J Obstet Gynecol, 2003. **189**(6): p. 1612-8; discussion 1618-9.

Close, C.E., Autoaugmentation gastrocystoplasty. BJU Int, 2001. 88(7): p. 757-61.

Collins, C.G., et al., *Early repair of vesicovaginal fistula*. Am J Obstet Gynecol, 1971. **111**(4): p. 524-8.

Colombel, M., et al., Vesicovaginal fistula after laser vaporization of vaginal condyloma. J Urol, 1995. **154**(5): p. 1860.

Colombo, M., et al., Surgery for genitourinary prolapse and stress incontinence: a randomized trial of posterior pubourethral ligament plication and Pereyra suspension. Am J Obstet Gynecol, 1997. **176**(2): p. 337-43.

Colombo, M., et al., Prevention of postoperative urinary stress incontinence after surgery for genitourinary prolapse. Obstet Gynecol, 1996. **87**(2): p. 266-71.

Colombo, M., et al., Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women ;with stress urinary incontinence and anterior vaginal wall prolapse. BJO 2000. **107**(4): p. 544-51.

Colombo, M., et al., *The Burch colposuspension for women with and without detrusor overactivity*. Br J Obstet Gynaecol, 1996. **103**(3): p. 255-60.

Corcos, J. and C. Fournier, *Periurethral collagen injection for the treatment of female stress urinary incontinence: 4-year follow-up results.* Urology, 1999. **54**(5): p. 815-8.

Costa, P., et al., *The use of an artificial urinary sphincter in women with type III incontinence and a negative Marshall test.* J Urol, 2001. **165**(4): p. 1172-6

Costantini, E., et al., *Four-corner colposuspension: clinical and functional results.* Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(2): p. 113-8.

Couillard, D.R., K.A. Deckard-Janatpour, and A.R. Stone, *The vagi*nal wall sling: a compressive suspension procedure for recurrent incontinence in elderly patients. Urology, 1994. **43**(2): p. 203-8.

Cross, C.A., et al., A followup on transurethral collagen injection therapy for urinary incontinence. J Urol, 1998. **159**(1): p. 106-8.

Cross, S.B. and P.R. Copas, *Colovaginal fistula secondary to diverticular disease. A report of two cases.* J Reprod Med, 1993. **38**(11): p. 905-6.

Culligan, P.J., R.P. Goldberg, and P.K. Sand, *A randomized controlled trial comparing a modified Burch procedure and a suburethral sling: long-term follow-up.* Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(4): p. 229-33; discussion 233.

Cummings, J.M., J.A. Boullier, and R.O. Parra, *Surgical correction of stress incontinence in morbidly obese women*. J Urol, 1998. **160**(3 Pt 1): p. 754-5.

Cundiff, G.W. and A.E. Bent, *The contribution of urethrocystoscopy* to evaluation of lower urinary tract dysfunction in women. Int Urogynecol J Pelvic Floor Dysfunct, 1996. 7(6): p. 307-11.

Daneshgari, F., P.E. Zimmern, and L. Jacomides, *Magnetic resonance imaging detection of symptomatic noncommunicating intraure-thral wal diverticula in women*. J Urol, 1999. **161**(4): p. 1259-61; discussion 1261-2.

Darai, E., et al., *Results of tension-free vaginal tape in patients with or without vaginal hysterectomy*. Eur J Obstet Gynecol Reprod Biol, 2002. **103**(2): p. 163-7.

Dargent, D., et al., [Insertion of a sub-urethral sling through the obturating membrane for treatment of female urinary incontinence]. Gynecol Obstet Fertil, 2002. **30**(7-8): p. 576-82.

Davis, B.L. and D.G. Robinson, *Diverticula of the female urethra: assay of 120 cases.* J Urol, 1970. **104**(6): p. 850-3.

De Rossi, P., *Clinical outcome of fascial slings for female stress incontinence*. Medscape Womens Health, 2002(7): p. 1-8.

De Tayrac, R., D. Salet-Lizee, and R. Villet, *Comparison of anterior colporrhaphy versus Bologna procedure in women with genuinestress incontinence*. Int Urogynecol J Pelvic Floor Dysfunct, 2002. **13**(1): p. 36-9.

Debodinance, P., et al., *Tension-free vaginal tape (TVT) in the treatment of urinary stress incontinence: 3 years experience involving 256 operations*. Eur J Obstet Gynecol Reprod Biol, 2002. **105**(1): p. 49-58.

DeLaere, K.P., et al., *Prolonged bladder distension in the management of the unstable bladder*. J Urol, 1980. **124**(3): p. 334-7.

Delorme, E., [Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women]. Prog Urol, 2001. **11**(6): p. 1306-13.

Demirci, F., et al., *Ten-year results of Marshall Marchetti Krantz and anterior colporraphy procedures*. Aust N Z J Obstet Gynaecol, 2002. **42**(5): p. 513-4.

Demirci, F., et al., *Long-term results of Burch colposuspension*. Gynecol Obstet Invest, 2001. **51**(4): p. 243-7.

Demirel, A., et al., *Transvesical and transvaginal reparation in urinary vaginal fistulas*. Int Urol Nephrol, 1993. **25**(5): p. 439-44.

Derry, D., *Notes on five pelves of women of the eleventh dynasty in Egypt*. Brit J Obstet Gynecol, 1935. **42**: p. 490-494.

DeTayrac, R., et al., A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence. Am J Obstet Gynecol, 2004. **190**(3): p. 602-8.

Deval, B., et al. Determinants of patient dissatisfaction after a tension-free vaginal tape procedure forurinary incontinence. J Urol, 2002. **167**(5): p. 2093-7.

Dewan, P.A. and W. Stefanek, *Autoaugmentation gastrocystoplasty: early clinical results.* Br J Urol, 1994. **74**(4): p. 460-4.

Dietz, H.P., et al., *TVT and Sparc suburethral slings: a case-control series*. Int Urogynecol J Pelvic Floor Dysfunct, 2004. **15**(2): p. 129-31; discussion 131.

Digesu, G.A., et al., *Effects of Burch colposuspension on the relative positions of the bladder neck to the levator ani muscle: An observational study that used magnetic resonance imaging.* Am J Obstet Gynecol, 2004. **190**(3): p. 614-9.

Diokno, A.C., et al., *Prevalence and outcome of surgery for female incontinence*. Urology, 1989. **33**(4): p. 285.

Diokno, A.C., et al., *Prevalence and outcomes of continence surgery in community dwelling women.* J Urol, 2003. **170**: p. 507-511.

Dmochowski, R.R. and R.A. Appell, *Injectable agents in the treatment of stress urinary incontinence in women: where are we now?* Urology, 2000. **56**(6 Suppl 1): p. 32-40.

Dolan, L.M., et al., *Stress incontinence and pelvic floor neurophysiology 15 years after the first delivery*. BJOG, 2003. **110**(12): p. 1107-14.

Dolan, L.M., A.R.B. Smith, and G.L. Hosker, *Opening detrusor pressure and the influence of age on success following colposuspension*. Neurourol Urodynam, 2004. **23**: p. 10-15.

Dorsey, J.H. and G. Cundiff, Laparoscopic procedures for inconti-

nence and prolapse. Curr Opin Obstet Gynecol, 1994. 6(3): p. 223-30.

Drutz, H.P. and B. Alnaif, *Surgical management of pelvic organ prolapse and stress urinary incontinence*. Clin Obstet Gynecol, 1998. **41**(3): p. 786-93.

Duel, B.P., R. Gonzalez, and J.S. Barthold, *Alternative techniques for augmentation cystoplasty*. J Urol, 1998. **159**(3): p. 998-1005.

Dunn, M., J.C. Smith, and G.M. Ardran, *Prolonged bladder disten*sion as a treatment of urgency and urge incontinence of urine. Br J Urol, 1974. **46**(6): p. 645-52.

Eilber, K.S., et al., *Ten-year experience with transvaginal vesicovaginal fistula repair using tissue interposition*. J Urol, 2003. **169**(3): p. 1033-6.

Elersgany, R., A.-N. Elgamasy, and G.M. Ghoniem, *Transurethral* collagen injection for female stress incontinence. Int Urogynecol J, 1998. 9: p. 13-18.

Elkabir, J.J. and A.D. Mee, Long-term evaluation of the Gittes procedure for urinary stress incontinence. J Urol, 1998. **159**(4): p. 1203-5.

Elkins, T.E., *Surgery for the obstetric vesicovaginal fistula: a review of 100 operations in 82 patients*. Am J Obstet Gynecol, 1994. **170**(4): p. 1108-18; discussion 1118-20.

Elkins, T.E., et al., *Transvaginal mobilization and utilization of the anterior bladder wall to repair vesicovaginal fistulas involving the urethra*. Obstet Gynecol, 1992. **79**(3): p. 455-60.

Ellik, M., Diverticulum of the female urethra: a new method of ablation. J Urol, 1957. 77(2): p. 243-6.

Elliott, D.S. and T.B. Boone, *Is fascia lata allograft material trust-worthy for pubovaginal sling repair?* Urology, 2000. **56**(5): p. 772-6.

Elsergany, R., A.N. Elgamasy, and G.M. Ghoniem, *Transurethral collagen injection for female stress incontinence*. Int Urogynecol J Pelvic Floor Dysfunct, 1998. **9**(1): p. 13-8.

Enzelsberger, H., H. Helmer, and C. Schatten, *Comparison of Burch* and lyodura sling procedures for repair of unsuccessful incontinence

surgery. Obstet Gynecol, 1996. 88(2): p. 251-6.

Enzler, M., et al., Osteomyelitis of the pubis following suspension of the neck of the bladder with use of bone anchors. A report of four cases. J Bone Joint Surg Am, 1999. **81**(12): p. 1736-40.

Eriksen, B.C., et al., *Long-term effectiveness of the Burch colposuspension in female urinary stress incontinence*. Acta Obstet Gynecol Scand, 1990. **69**(1): p. 45-50.

Evans, L.A., et al., Fibrin sealant for the management of genitourinary injuries, fistulas and surgical complications. J Urol, 2003. **169**(4): p. 1360-2.

Ewing, R., M.I. Bultitude, and K.E. Shuttleworth, *Subtrigonal phe*nol injection for urge incontinence secondary to detrusor instability in females. Br J Urol, 1982. **54**(6): p. 689-92.

Ewing, R., M.I. Bultitude, and K.E. Shuttleworth, *Subtrigonal phenol* injection therapy for incontinence in female patients with multiple

sclerosis.Lancet, 1983. 1(8337): p. 1304-6.

Faerber, G.J., *Endoscopic collagen injection therapy in elderly women with type I stress urinary incontinence*.J Urol, 1996. **155**(2): p. 512-4.

Falk, H. and M. Tancer, *Vesicovaginal fistula: An historical survey*. Obstet Gynecol, 1954. **3**: p. 337-341.

Fatthy, H., et al., *Modified Burch colposuspension: laparoscopy versus laparotomy*. J Am Assoc Gynecol Laparosc, 2001. **8**(1): p. 99-106.

Filmer, R.B. and J.R. Spencer, *Malignancies in bladder augmentations and intestinal conduits.*J Urol, 1990. **143**(4): p. 671-8.

FitzGerald, M.P. and L. Brubaker, *Colpocleisis and urinary incontinence*. Am J Obstet Gynecol, 2003. **189**(5): p. 1241-4.

FitzGerald, M.P., S. Gitelis, and L. Brubaker, *Pubic osteomyelitis and granuloma after bone anchor placement*. Int Urogynecol J Pelvic Floor Dysfunct, 1999. **10**(5): p. 346-8.

FitzGerald, M.P., et al., Functional failure of fascia lata allografts.

Am J Obstet Gynecol, 1999. 181(6): p. 1339-44; discussion 1344-6.

Fitzgerald, M.P., J. Mollenhauer, and L. Brubaker, Failure of allograft suburethral slings. BJU Int, 1999. 84(7): p. 785-8.

Flynn, B.J. and W.T. Yap, *Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum followup.* J Urol, 2002. **167**(2 Pt 1): p. 608-12.

Foucher JE, M.V., Nosocomial catheter associated urinary tract infections. Infect Surg, 1983. 2: p. 43.

Franks, M.E., et al., *Metastatic osteomyelitis after pubovaginal sling using bone anchors*. Urology, 2000. **56**(2): p. 330-1.

Fritel, X., et al., *Predictive value of urethral mobility before suburethral tape procedure for urinary stress incontinence in women.*

J Urol, 2002. 168: p. 2472-2475.

Galloway, N.T., N. Davies, and T.P. Stephenson, *The complications of colposuspension*. Br J Urol, 1987. **60**(2): p. 122-4.

Ganabathi, K., et al., *Experience with the management of urethral diverticulum in 63 women.* J Urol, 1994. **152**(5 Pt 1): p. 1445-52.

Garlock, J., *The cure of an intractable vesicovaginal fistula by the use of a pedicled muscle flap*. Surg Gynecol Obstet, 1928. **47**: p. 255.

Gaum, L., N.A. Ricciotti, and W.R. Fair, *Endoscopic bladder neck* suspension for stress urinary incontinence. J Urol, 1984. **132**(6): p. 1119-21.

Gaum, L., N.A. Ricciotti, and W.R. Fair, *Endoscopic bladder neck* suspension for stress urinary incontinence. J Urol, 1984. **132**(6): p. 1119-21.

Gaum, L., N.A. Ricciotti, and W.R. Fair, *Endoscopic bladder neck suspension for stress urinary incontinence*. J Urol, 1984. **132**(6): p. 1119-21.

Ghezzi, F., et al., *The use of suction drains at burch colposuspension and postoperative infectious morbidity*. Arch Gynecol Obstet, 2003. **268**(1): p. 41-4.

Ghoniem, G.M. and M. Monga, *Modified pubovaginal sling and Martius graft for repair of the recurrent vesicovaginal fistula involving the internal urinary sphincter*. Eur Urol, 1995. **27**(3): p. 241-5.

Gierup, H.J. and L. Hakelius, *Free autogenous muscle transplantation in the treatment of urinary incontinence in children: background, surgical technique and preliminary results.* J Urol, 1978. **120**(2): p. 223-6.

Gillon, G. and A.R. Mundy, *The dissolution of urinary mucus after cystoplasty*. Br J Urol, 1989. **63**(4): p. 372-4.

Gillon, G. and S.L. Stanton, *Long term.follow-up of surgery for urinary incontinence in elderly women*. Br J Urol, 1984. **56**(5): p. 478-81.

Gil-Vernet, J.M., A. Gil-Vernet, and J.A. Campos, *New surgical approach for treatment of complex vesicovaginal fistula*. J Urol, 1989. **141**(3): p. 513-6.

Ginsberg, D.A., E.S. Rovner, and S. Raz, *Posthysterectomy vaginal* cuff fistula: diagnosis and management of an unusual cause of "incontinence". Urology, 1998. **52**(1): p. 61-4; discussion 64-5.

Glazener, C.M. and K. Cooper, *Bladder neck needle suspension for urinary incontinence in women*. Cochrane Database Syst Rev, 2002(2): p. CD003636.

Goebel, R., Zur operativen Beseitigung der Angelborenen incontinenz vesicae. Zeitschr Gynakol Urol, 1910. 2: p. 187-190.

Goldberg, R.P., et al., *Protective effect of suburethral slings on post*operative cystocele recurrence after reconstructive pelvic operation. Am J Obstet Gynecol, 2001. **185**(6): p. 1307-12; discussion 1312-3. Goldstein, I., G.J. Wise, and M.L. Tancer, *A vesicovaginal fistula and intravesical foreign body. A rare case of the neglected pessary.* Am J Obstet Gynecol, 1990. **163**(2): p. 589-91.

Goldwasser, B. and G.D. Webster, Augmentation and substitution enterocystoplasty. J Urol, 1986. **135**(2): p. 215-24.

Golomb, J., B. Goldwasser, and S. Mashiach, *Raz bladder neck suspension in women younger than sixty-five years compared with elder-ly women: three years' experience*. Urology, 1994. **43**(1): p. 40-3.

Golomb, J., et al., *Management of urethral erosion caused by a pubo*vaginal fascial sling. Urology, 2001. **57**(1): p. 159-60.

Golomb, J., et al., *Bladder neoplasms associated with augmentation cystoplasty: report of 2 cases and literature review.* J Urol, 1989. **142**(2 Pt 1): p. 377-80.

Golomb, J., et al., *Comparison of voiding cystourethrography and double-balloon urethrography in the diagnosis of complex female urethral diverticula*. Eur Radiol, 2003. **13**(3): p. 536-42.

Golomb, J., et al., Suspended pubovaginal fascial sling for the correction of complicated stress urinary incontinence. Eur Urol, 1997. **32**(2): p. 170-4.

Goodwin, W.E. and P.T. Scardino, *Vesicovaginal and ureterovaginal fistulas: a summary of 25 years of experience*. J Urol, 1980. **123**(3): p. 370-4.

Gordon, D., et al., Combined genitourinary prolapse repair and prophylactic tension-free vaginal tape in women with severe prolapse and occult stress urinary incontinence: preliminary results. Urology, 2001. **58**(4): p. 547-50.

Gormley, E.A., J. Latini, and L. Hanlon, *Long-term effect of pubovaginal sling on quality of life*. J Urol, 2002. **167 Supplement**(105): p. 418.

Gorton, E., et al., *Periurethral collagen injection: a long-term follow-up study.* BJU Int, 1999. **84**(9): p. 966-71.

Gough, D.C., Enterocystoplasty. BJU Int, 2001. 88(7): p. 739-43.

Govier, F.E., et al., *Pubovaginal slings using fascia lata for the treatment of intrinsic sphincter deficiency*. J Urol, 1997. **157**(1): p. 117-21.

Govier, F.E., et al., *Percutaneous afferent neuromodulation for the refractory overactive bladder: results of a multicenter study.* J Urol, 2001. **165**(4): p. 1193-8.

Graham, J.B., Vaginal Fistulas Following Radiotherapy. Surg Gynecol Obstet, 1965. **120**: p. 1019-30.

Green, D.F., E.J. McGuire, and B. Lytton, A comparison of endoscopic suspension of the vesical neck versus anterior urethropexy for the treatment of stress urinary incontinence. J Urol, 1986. **136**(6): p. 1205-7.

Green, T.H., Jr., Urinary stress incontinence: differential diagnosis, pathophysiology, and management. Am J Obstet Gynecol, 1975. **122**(3): p. 368-400.

Greenwell, T.J., S.N. Venn, and A.R. Mundy, Augmentation cystoplasty. BJU Int, 2001. 88(6): p. 511-25.

Griffith-Jones, M.D. and P.H. Abrams, *The Stamey endoscopic bladder neck suspension in the elderly*. Br J Urol, 1990. **65**(2): p. 170-2.

Groutz, A., et al., *Pubovaginal sling surgery for simple stress urinary incontinence: analysis by an outcome score.* J Urol, 2001. **165**(5): p. 1597-600.

Groutz, A., et al., *Outcome results of transurethral collagen injection for female stress incontinence: assessment by urinary incontinence score.* J Urol, 2000. **164**(6): p. 2006-9.

Groutz, A., et al., *Tension-free vaginal tape for stress urinary incontinence: Is there a learning curve?* Neurourol Urodyn, 2002. **21**(5): p. 470-2.

Groutz, A., et al., *The use of prophylactic Stamey bladder neck suspension to prevent post-operative stress urinary incontinence in clinically continent women undergoing genitourinary prolapse repair.* Neurourol Urodyn, 2000. **19**(6): p. 671-6. Groutz, A., et al., *The use of prophylactic Stamey bladder neck suspension to prevent postoperative urinary incontinence in clinically continent women undergoing genitourinary prolapse repair*.Neurourol Urodynam, 2000. **19**: p. 671-676.

Grunewald, V., et al., Sacral electrical neuromodulation as an alternative treatment option for lower urinary tract dysfunction. Restor Neurol Neurosci, 1999. **14**(2-3): p. 189-193.

Haab, F., et al., *Results of pubovaginal sling for the treatment of intrinsic sphincteric deficiency determined by questionnaire analysis.* J Urol, 1997. **158**(5): p. 1738-41.

Haab, F., P.E. Zimmern, and G.E. Leach, Urinary stress incontinence due to intrinsic sphincteric deficiency: experience with fat and collagen periurethral injections. J Urol, 1997. **157**(4): p. 1283-6.

Handa, V.L., et al., *Banked human fascia lata for the suburethral sling procedure: a preliminary report*. Obstet Gynecol, 1996. **88**(6): p. 1045-9.

Handa, V.L. and A. Stone, *Erosion of a fascial sling into the urethra*. Urology, 1999. **54**(5): p. 923.

Harris, W.J., *Early complications of abdominal and vaginal hysterectomy*. Obstet Gynecol Surv, 1995. **50**(11): p. 795-805.

Harriss, D.R., J.W. Iacovou, and R.J. Lemberger, *Peri-urethral silicone microimplants (Macroplastique) for the treatment of genuine stress incontinence*. Br J Urol, 1996. **78**(5): p. 722-5;

Hasan, S.T., et al., *Clinical outcome and quality of life following enterocystoplasty for idiopathic detrusor instability and neurogenic bladder dysfunction*. Br J Urol, 1995. **76**(5): p. 551-7.

Hasan, S.T., et al., *Outcome of endoscopic bladder transection*. Br J Urol, 1995. **75**(5): p. 592-6.

Hassouna, M.E. and G.M. Ghoniem, *Long-term outcome and quality* of life after modified pubovaginal sling for intrinsic sphincteric deficiency. Urology, 1999. **53**(2): p. 287-91.

Hathaway, J.K. and J.M. Choe, *Intact genetic material is present in commercially processed cadaver allografts used for pubovaginal slings*. J Urol, 2002. **168**(3): p. 1040-3.

Hawkins, E., D. Taylor, and J. Hughes-Nurse, *Long term follow up of the cruciate fascial sling for women with genuine stress incontinence.*

BJOG, 2002. 109(3): p. 327-38.

Hawkins, E., D. Taylor, and J. Hughes-Nurse, *Long term follow up of the cruciate fascial sling for women with genuine stress incontinence*. BJOG, 2002. **109**(3): p. 327-38.

Hedlund, H., et al., *Sacral neuromodulation in Norway: clinical experience of the first three years.* Scand J Urol Nephrol Suppl, 2002(210): p. 87-95.

Heit, M., What is the scientific evidence for bone anchor use during bladder neck suspension? International Urogynecology Journal, 2002. **13**: p. 143-144.

Helmstein, K., *Treatment of bladder carcinoma by a hydrostatic pressure technique. Report on 43 cases.* Br J Urol, 1972. **44**(4): p. 434-50.

Henalla, S.M., et al., A multicentre evaluation of a new surgical technique for urethral bulking in the treatment of genuine stress incontinence. Bjog, 2000. **107**(8): p. 1035-9.

Hendren, W.H., *Construction of female urethra from vaginal wall and a perineal flap.* J Urol, 1980. **123**(5): p. 657-64.

Hendren, W.H., *Construction of a female urethra using the vaginal wall and a buttock flap: experience with 40 cases.* J Pediatr Surg, 1998. **33**(2): p. 180-7.

Henly, D.R., et al., *Particulate silicone for use in periurethral injections: local tissue effects and search for migration.* J Urol, 1995. **153**(6): p. 2039-43.

Hermieu, J.F., et al., *[Bladder injury after TVT transobturator]*.Prog Urol, 2003. **13**(1): p. 115-7.

Herschorn, S. and A.A. Glazer, *Early experience with small volume periurethral polytetrafluoroethylene for female stress urinary incontinence*. J Urol, 2000. **163**(6): p. 1838-42.

Herschorn, S. and R.J. Hewitt, *Patient perspective of long-term outcome of augmentation cystoplasty for neurogenic bladder*. Urology, 1998. **52**(4): p. 672-8.

Herschorn, S. and S.B. Radomski, *Collagen injections for genuine stress urinary incontinence: patient selection and durability.* Int Urogynecol J Pelvic Floor Dysfunct, 1997. **8**(1): p. 18-24.

Herschorn, S., S.B. Radomski, and D.J. Steele, *Early experience with intraurethral collagen injections for urinary incontinence*. J Urol, 1992. **148**(6): p. 1797-800.

Herschorn, S., D.J. Steele, and S.B. Radomski, *Followup of intraure-thral collagen for female stress urinary incontinence*. J Urol, 1996. **156**(4): p. 1305-9.

Hey, W., Practical Observations in Surgery, in Practical Observations in Surgery, James Hympheys: Philadelphia. p. 303.

Hilton, P. and C.J. Mayne, *The Stamey endoscopic bladder neck suspension: a clinical and urodynamic investigation, including actuarial follow-up over four years.* Br J Obstet Gynaecol, 1991. **98**(11): p. 1141-9.

Hilton, P. and S.L. Stanton, Urethral pressure measurement by microtransducer: the results in symptom-free women and in those with genuine stress incontinence. Br J Obstet Gynaecol, 1983. **90**(10): p. 919-33.

Hodgkinson, C.P. and B.H. Drukker, *Infravesical nerve resection for detrusor dyssynergia*. *The Ingelman-Sundberg operation*. Acta Obstet Gynecol Scand, 1977. **56**(4): p. 401-8.

Hohenfellner, R. and E. Petrie, *Sling procedure in surgery*, in *Surgery of Female Incontinence*, *2nd edition*, S.S.a.E. Tanagho, Editor. 1986, Berlin:

Holschneider, C.H., et al., *The modified Pereyra procedure in recurrent stress urinary incontinence: a 15-year review.* Obstet Gynecol, 1994. **83**(4): p.

Hong, B., et al., Factors predictive of urinary retention after a tension-free vaginal tape procedure for female stress urinary incontinence. J Urol, 2003. **170**: p. 852-856.

Horbach, N.S., et al., A suburethral sling procedure with polytetrafluoroethylene for the treatment of genuine stress incontinence in patients with low urethral closure pressure.Obstet Gynecol, 1988. **71**(4): p. 648-52.

Hoskins, W.J., et al., *Repair of urinary tract fistulas with bulbocavernosus myocutaneous flaps*. Obstet Gynecol, 1984. **63**(4): p. 588-93.

Huang, H., et al., *Concomitant surgery with tension free vaginal tape*. Acta Obstet Gynecol Scand, 2003. **82**: p. 948-53.

Huffman, A., *The detailed anatomy of the pareurethral ducts in the adult human female*. Am J Obstet Gynecol, 1948. **55**: p. 86.

Hung, M., et al., *Analysis of two sling procedures using polyprophylene mesh for treatment of stress urinary incontinence*. Int J Gynaecol Obstet, 2004. **84**: p. 133-41.

Hutchings, A., J. Griffiths, and N.A. Black, *Surgery for stress incontinence: factors associated with a successful outcome*. Br J Urol, 1998. **82**(5): p. 634-41.

Iosif, C.S., *Results of various operations for urinary stress incontinence*. Arch Gynecol, 1983. **233**(2): p. 93-100.

Iosif, C.S., Porcine corium sling in the treatment of urinary stress incontinence. Arch Gynecol, 1987. 240(3): p. 131-6.

Jacoby, K. and R.K. Rowbotham, *Double balloon positive pressure urethrography is a more sensitive test than voiding cystourethrography for diagnosing urethral diverticulum in women.* J Urol, 1999. **162**(6): p. 2066-9.

Janknegt, R.A., et al., *Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence*. Eur Urol, 2001. **39**(1): p. 101-6.

Jarvis, G.J., *Surgery for genuine stress incontinence*. Br J Obstet Gynaecol, 1994. **101**(5): p. 371-4.

Jarvis, G.J. and A. Fowlie, *Clinical and urodynamic assessment of the porcine dermis bladder sling in the treatment of genuine stress incontinence.* Br J Obstet Gynaecol, 1985. **92**(11): p. 1189-91.

Jonas, U., et al., *Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation.* J Urol, 2001. **165**(1): p. 15-9.

Jonas, U. and E. Petrie, *Genitourinary fistulae*, in *Clinical Gynecologic Urology*, S. SL, Editor. 1984, Mosby Co: St Louis. p. 238-255.

Jung, S.Y., et al., Urethral afferent nerve activity affects the micturition reflex; implication for the relationship between stress incontinence and detrusor instability. J Urol, 1999. **162**(1): p. 204-12.

Kammerer-Doak, D.N., G.R. Rogers, and B. Bellar, *Vaginal erosion of cadaveric fascia lata following abdominal sacrocolpopexy and suburethral sling urethropexy*. Int Urogynecol J Pelvic Floor Dysfunct, 2002. **13**(2): p. 106-109.

Kane, L., et al., *The pubofascial anchor sling procedure for recurrent genuine urinary stress incontinence*. BJU Int, 1999. **83**(9): p. 1010-4.

Kapoor, R., et al., *Recovery of bladder function following surgery for stress incontinence: Is it delayed in elderly patients?* Int Urogynecol J, 1993. **4**: p. 266-270.

Karram, M.M., What is the optimal anti-incontinence procedure in women with advanced prolapse and 'potential' stress incontinence?

Int Urogynecol J Pelvic Floor Dysfunct, 1999. 10(1): p. 1-2.

Karram, M.M., et al., *The modified Pereyra procedure: a clinical and urodynamic review*. Br J Obstet Gynaecol, 1992. **99**(8): p. 655-8.

Karram, M.M. and N.N. Bhatia, *Patch procedure: modified transvaginal fascia lata sling for recurrent or severe stress urinary incontinence*. Obstet Gynecol, 1990. **75**(3 Pt 1): p. 461-3.

Karram, M.M., et al., *Complications and untoward effects of the tension-free vaginal tape procedure*. Obstet Gynecol, 2003. **101**(5 Pt 1): p. 929-32.

Keefe, B., et al., *Diverticula of the female urethra: diagnosis by endovaginal and transperineal sonography*. AJR Am J Roentgenol, 1991. **156**(6): p. 1195-7.

Kelly, J.D. and P.F. Keane, *Long-term results and complications of augmentation ileocystoplasty for idiopathic urge incontinence in women.* Br J Urol, 1998. **82**(4): p. 609-10.

Kelly, M.J., et al., Symptom analysis of patients undergoing modified Pereyra bladder neck suspension for stress urinary incontinence. Pre- and postoperative findings. Urology, 1991. **37**(3): p.

Kenton, K., M.P. FitzGerald, and L. Brubaker, *Multiple foreign body* erosions after laparoscopic colposuspension with mesh.Am J Obstet Gynecol, 2002. **187**(1): p. 252-3.

Kenton, K., L. Oldham, and L. Brubaker, *Open Burch urethropexy* has a low rate of perioperative complications. Am J Obstet Gynecol, 2002. **187**(1): p. 107-10.

Kersey, J., *The gauze hammock sling operation in the treatment of stress incontinence*. Br J Obstet Gynaecol, 1983. **90**(10): p. 945-9.

Kershen, R.T., R.R. Dmochowski, and R.A. Appell, *Beyond collagen: injectable therapies for the treatment of female stress urinary incontinence in the new millennium.* Urol Clin North Am, 2002. **29**(3): p. 559-74.

Khanna, S., Posterior bladder flap plasty for repair of vesicourethrovaginal fistula. J Urol, 1992. 147(3): p. 656-7.

Khullar, V., et al., *GAX collagen in the treatment of urinary incontinence in elderly women: a two year follow-up*.Br J Obstet Gynaecol, 1997. **104**(1): p. 96-9. Kim, Y.H., M.W. Kattan, and T.B. Boone, *Correlation of urodynamic results and urethral coaptation with success after transurethral collagen injection*. Urology, 1997. **50**(6): p. 941-8.

Kinn, A.C., Tension-free vaginal tape evaluated using patient selfreports and urodynamic testing—a two-year follow-up. Scand J Urol Nephrol, 2001. **35**(6): p. 484-90.

Kinn, A.C., Tension-free vaginal tape evaluated using patient selfreports and urodynamic testing. A two-year follow-up. Scand J Urol Nephrol, 2001. **35**: p. 484-490.

Kiricuta, I. and A.M. Goldstein, *The repair of extensive vesicovaginal fistulas with pedicled omentum: a review of 27 cases.* J Urol, 1972. **108**(5): p. 724-7.

Kjolhede, P. and G. Ryd, n, *Prognostic factors and long-term results of the Burch colposuspension*. Acta Obstet Gynecol Scand, 1994. **73**: p. 642-647.

Klingler, H.C., et al., Use of peripheral neuromodulation of the S3 region for treatment of detrusor overactivity: aurodynamic-based study.Urology, 2000. **56**(5): p. 766-71.

Klutke, C., et al., Urinary retention after tension-free vaginal tape procedure: incidence and treatment. Urology, 2001. **58**(5): p. 697-701.

Klutke, J.J., J. Bergman, and C.G. Klutke, *Transvaginal bladder neck suspension with Cooper's ligament fixation. Long-term urodynamic results.* J Reprod Med, 2000. **45**(7): p. 541-5.

Klutke, J.J. and S. Ramos, *Urodynamic outcome after surgery for* severe prolapse and potential stress incontinence. Am J Obstet Gynecol, 2000. **182**(6): p. 1378-81.

Kochakarn, W., et al., *Pubovaginal sling for the treatment of female stress urinary incontinence: experience of 100 cases at Ramathibodi Hospital.* J Med Assoc Thai, 2001. **84**(10): p. 1412-5.

Kochakarn, W., et al., Urethral diverticulum in females: 25 years experience at Ramathibodi Hospital. J Med Assoc Thai, 2000. 83(12): p. 1437-41.

Kockelbergh, R.C., et al., *Clam enterocystoplasty in general urological practice*.Br J Urol, 1991. **68**(1): p. 38-41.

Koelbl, H., et al., *Transurethral injection of silicone microimplants for intrinsic urethral sphincter deficiency*.Obstet Gynecol, 1998. **92**(3): p. 332-6.

Kondo, A., et al., *The Stamey and Gittes procedures: long-term followup in relation to incontinence types and patient age*. J Urol, 1998. **160**(3 Pt 1): p. 756-8.

Koonings, P., A. Bergman, and C.A. Ballard, *Combined detrusor instability and stress urinary incontinence: where is the primary pathology?* Gynecol Obstet Invest, 1988. **26**(3): p. 250-6.

Koonings, P.P., A. Bergman, and C.A. Ballard, *Low urethral pressu*re and stress urinary incontinence in women: risk factor for failed

retropubic surgical procedure. Urology, 1990. 36(3): p. 245-8.

Korn, A.P. and L.A. Learman, *Operations for stress urinary incontinence in the United States*, *1988-1992*. Urology, 1996. **48**(4): p. 609-12.

Kottmeier, H.L., *Complications Following Radiation Therapy in Carcinoma of the Cervix and Their Treatment*. Am J Obstet Gynecol, 1964. **88**: p. 854-66.

Kreder, K.J. and J.C. Austin, *Treatment of stress urinary incontinence in women with urethral hypermobility and intrinsic sphincter deficiency*. J Urol, 1996. **156**(6): p. 1995-8.

Kreiger, J., Vaginitis syndromes: a practical approach to diagnosis and treatment. AUA Update Series, 1990. 9: p. 161-169.

Kristensen, J.K. and G. Lose, *Vesicovaginal fistulas: the transperitoneal repair revisited*. Scand J Urol Nephrol Suppl, 1994. **157**: p. 101-5. Kubricht, W.S., 3rd, et al., *Tensile strength of cadaveric fascia lata compared to small intestinal submucosa using suture pull through analysis.* J Urol, 2001. **165**(2): p. 486-90.

Kuczyk, M.A., et al., A questionnaire-based outcome analysis of the Stamey bladder neck suspension procedure for the treatment of urinary stress incontinence: the Hannover experience.BJU, 1998. 82: p. 174-180.

Kuo, H.C., Comparison of video urodynamic results after the pubovaginal sling procedure using rectus fascia and polypropylene mesh for stress urinary incontinence. J Urol, 2001. **165**(1): p. 163-8.

Kursh, E.D., et al., *Prevention of the development of a vesicovaginal fistula*. Surg Gynecol Obstet, 1988. **166**(5): p. 409-12.

Kuuva, N. and C.G. Nilsson, A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand, 2002. **81**(1): p. 72-7.

Kwon, C.H., et al., *The development of pelvic organ prolapse following isolated Burch retropubic urethropexy*. Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(5): p. 321-5; discussion 325.

Lam, A.M., G.J. Jenkins, and R.S. Hyslop, *Laparoscopic Burch colposuspension for stress incontinence: preliminary results*. Med J Aust, 1995. **162**(1): p. 18-21.

Langer, R., et al., *Colposuspension for urinary stress incontinence in premenopausal and postmenopausal women*. Surg Gynecol Obstet, 1990. **171**(1): p. 13-6.

Langer, R., et al., *Long-Term (10-15 years) follow-up after Burch colposuspension for urinary stress incontinence*. Int Urogynecol J Pelvic Floor Dysfunct, 2001. **12**(5): p. 323-6; discussion 326-7.

Langer, R., et al., *The value of simultaneous hysterectomy during Burch colposuspension for urinary stress incontinence*. Obstet Gynecol, 1988. **72**(6): p. 866-9.

Lapides, J., *Transurethral treatment of urethral diverticula in women*. J Urol, 1979. **121**(6): p. 736-8.

Latzko, W., Postoperative vesicovaginal fistulas: genesis and therapy. Am J Surg, 1942. 58: p. 211-228.

Lau, T.K. and W.S. Wong, *Lymphatic vaginal fistula after Wertheim-Taussig hysterectomy: a case report*. Gynecol Oncol, 1994. **52**(3): p. 411-2.

Laurikainen, E. and P. Kiilholma, *The tension-free vaginal tape procedure for female urinary incontinence without preoperative urodynamic evaluation.* J Am Coll Surg, 2003. **196**(4): p. 579-83.

Leach, G.E., Urethrovaginal fistula repair with Martius labial fat pad graft. Urol Clin North Am, 1991. **18**(2): p. 409-13.

Leach, G.E., et al., *LNS C3: a proposed classification system for female urethral diverticula*. Neurourol Urodyn, 1993. **12**(6): p. 523-31.

Leach, G.E., et al., *Tubovaginal leakage: an unusual cause of incontinence*. J Urol, 1987. **137**(2): p. 287-8

Lebret, T., et al., Evaluation of tension-free vaginal tape procedure. Its safety and efficacy in the treatment of female stress urinary incontinence during the learning phase. Eur Urol, 2001. **40**(5): p. 543-7.

Lee, P.E., R.C. Kung, and H.P. Drutz, *Periurethral autologous fat injection as treatment for female stress urinary incontinence: aran-domized double-blind controlled trial.* J Urol, 2001. **165**(1): p. 153-8.

Lee, R.A., Diverticulum of the female urethra: postoperative complications and results. Obstet Gynecol, 1983. **61**(1): p. 52-8.

Lee, R.A., R.E. Symmonds, and T.J. Williams, *Current status of genitourinary fistula*. Obstet Gynecol, 1988. **72**(3 Pt 1): p. 313-9.

Lee, T.G. and F.S. Keller, *Urethral diverticulum: diagnosis by ultrasound*. AJR Am J Roentgenol, 1977. **128**(4): p. 690-1.

Leng, W.W., et al., *Enterocystoplasty or detrusor myectomy? Comparison of indications and outcomes for bladder augmentation*. J Urol, 1999. **161**(3): p. 758-63. Leng, W.W., et al., *Long-term outcome of incontinent ileovesicostomy* management of severe lower urinary tract dysfunction. J Urol, 1999. **161**(6): p. 1803-6.

Leng, W.W. and E.J. McGuire, *Management of female urethral diverticula: a new classification.* J Urol, 1998. **160**(4): p. 1297-300.

Lerner, M., D.C. Chaikin, and B. JG., *Tissue strength analysis of autologous and cadaveric allografts for the pubovaginal sling*. Neuro-urology and Urodynamics, 1999. **18**: p. 1633-1637.

Liang, C. and Y. Soong, *Tension-free vaginal tape versus laparoscopic bladder neck suspension for stress urinary incontinence.* Chang Gung Med J, 2002. **25**: p. 360-366.

Liapis, A., P. Bakas, and G. Creatsas, *Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women*. Eur Urol, 2002. **41**(4): p. 469-73.

Liapis, A., et al., Results of the colposuspension operation in pre and postmenopausal incontinent women. Maturitas, 1998. **31**(1): p. 69-75.

Light, Abdominal approach for the implantation of the AS800 artifical sphincter in females. Neuro-urology and Urodynamics, 1988. 7: p. 603-611.

Lightner, D., et al., A new injectable bulking agent for treatment of stress urinary incontinence: results of a multicenter, randomized, controlled, double-blind study of Durasphere. Urology, 2001. **58**(1): p. 12-5.

Lim, K.B., A.J. Ball, and R.C. Feneley, *Periurethral Teflon injection: a simple treatment for urinary incontinence*. Br J Urol, 1983. **55**(2): p. 208-10.

Liscic, R.M., et al., *Creutzfeldt-Jakob disease in a patient with a lyo-philized dura mater graft*. Acta Med Croatica, 1999. **53**(2): p. 93-6.

Litwiller, S.E., et al., *Vaginal wall sling: long-term outcome analysis of factors contributing to patient satisfaction and surgical success.* J Urol, 1997. **157**(4): p. 1279-82.

Liu, C.Y., Laparoscopic treatment for genuine urinary stress incontinence. Baillieres Clin Obstet Gynaecol, 1994. 8(4): p. 789-98.

Liu, C.Y. and W. Paek, *Laparoscopic retropubic colposuspension* (*Burch procedure*). J Am Assoc Gynecol Laparosc, 1993. **1**(1): p. 31-5

Lo, T., et al., *The use of general anaesthesia for the tension-free vaginal tape procedure and concomitant surgery*. Acta Obstetrica et Gynecologica Scan, 2003. **82**: p. 367-373.

Lopez, A.E., et al., Transurethral polytetrafluoroethylene injection in female patients with urinary continence. J Urol, 1993. **150**(3): p. 856-8.

Loran, O. and D. Pushkar, *Conventional and minimized pubovaginal sling (PVS): long term outcome*. J Urol, 1997. **157**(Supplement 461A): p. 1804.

Lose, G., J. L, and J. A, *Predictive value of detrusor instability index in surgery for femal urinary incontinence*. Neuro-urology and Urodynamics, 1988. 7: p. 141-148.

Lotenfoe, R., et al., Periurethral polytetrafluoroethylene paste injection in incontinent female subjects: surgical indications and improved surgical technique. J Urol, 1993. **149**(2): p. 279-82.

Loughlin, K.R., et al., *Review of an 8-year experience with modifications of endoscopic suspension of the bladderneck for female stress urinary incontinence.* J Urol, 1990. **143**(1): p. 44-5.

Low, J.A., Management of severe anatomic deficiencies of urethral sphincter function by a combined procedure with a fascia lata sling.

Am J Obstet Gynecol, 1969. 105(2): p. 149-55.

Lucas, M.G. and D.G. Thomas, *Endoscopic bladder transection for detrusor instability*. Br J Urol, 1987. **59**(6): p. 526-8.

MacNeily, A.E., et al., Autoaugmentation by detrusor myotomy: its lack of effectiveness in the management of congenital neuropathic bladder. J Urol, 2003. **170**(4 Pt 2): p. 1643-6; discussion 1646

Maheshkumar, P., I. Ramsay, and I. Conn, A randomized study of "dynamic" versus "static" rectus fascial suburethral sling: early results.Brit J Urol, 1998. **81**(Supplement 4, 65): p. 169.

Mainprize, T.C. and H.P. Drutz, *The Marshall-Marchetti-Krantz procedure: a critical review*. Obstet Gynecol Surv, 1988. **43**(12): p. 724-9.

Malizia, A.A., Jr., et al., *Migration and granulomatous reaction after periurethral injection of polytef (Teflon)*. Jama, 1984. **251**(24): p. 3277-81.

Mallipeddi, P.K., et al., Anatomic and functional outcome of vaginal paravaginal repair in the correction of anterior vaginal wall prolapse. Int Urogynecol J Pelvic Floor Dysfunct, 2001. **12**(2): p. 83-8.

Marshall, V.F., Vesicovaginal fistulas on one urological service.

J Urol, 1979. **121**(1): p. 25-9

Marte, A., et al., A long-term follow-up of autoaugmentation in myelodysplastic children. BJU Int, 2002. **89**(9): p. 928-31.

Martius, H., Dis operative Wiedeherstellung der volkommen fehicnden Harn-rehre und des Schiessmuskels derselben. Zentfubl Gynak, 1928. **52**: p. 480.

McGuire, E.J., Urodynamic findings in patients after failure of stress incontinence operations. Prog Clin Biol Res, 1981. **78**: p. 351-60.

McGuire, E.J. and R.A. Appell, *Transurethral collagen injection for urinary incontinence*. Urology, 1994. **43**(4): p. 413-5.

McGuire, E.J., et al., *Experience with pubovaginal slings for urinary incontinence at the University of Michigan.*J Urol, 1987. **138**(3): p. 525-6.

McGuire, E.J. and S.F. English, *Periurethral collagen injection for* male and female sphincteric incontinence: indications, techniques, and result. World J Urol, 1997. **15**(5): p. 306-9.

McGuire, E.J. and B. Lytton, *Pubovaginal sling procedure for stress incontinence*. J Urol, 1978. **119**(1): p. 82-4.

McGuire, E.J., et al., *Stress Urinary Incontinence*. Obstet Gynecol, 1976. **47**(3): p. 255-64.

McKay, H.A., Vesicovaginal and vesicocutaneous fistulas: transurethral suture cystorrhaphy as a new closure technique. J Urol, 1997. **158**(4): p. 1513-6.

McLennan, M.T., C.F. Melick, and A.E. Bent, *Clinical and urodynamic predictors of delayed voiding after fascia lata suburethral sling*. Obstet Gynecol, 1998. **92**(4 Pt 1): p. 608-12.

Meltomaa, S.S., et al., *Outcome of Burch retropubic urethropexy and the effect of concomitant abdominal hysterectomy: a prospective long-term follow-up study*.Int Urogynecol J Pelvic Floor Dysfunct, 2001. **12**(1): p. 3-8.

Menchaca, A., et al., *The rectus abdominis muscle flap in a combined abdominovaginal repair of difficult vesicovaginal fistulae. A report of three cases.* J Reprod Med, 1990. **35**(5): p. 565-8.

Meschia, M., et al., Unsuccessful Burch colposuspension: analysis of risk factors. Int Urogynecol J, 1991. 2: p. 19-21.

Meschia, M., et al., *Tension-Free vaginal tape: analysis of outcomes and complications in 404 stress Incontinent women*.Int Urogynecol J Pelvic Floor Dysfunct, 2001. **12 Suppl 2**: p. S24-27.

Meschia, M., et al., A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence. Am J Obstet Gynecol, 2004. **190**(3): p. 609-13.

Miannay, E., et al., *Comparison of open retropubic and laparoscopic colposuspension for treatment of stress urinary incontinence*. Eur J Obstet Gynecol Reprod Biol, 1998. **79**(2): p. 159-66.

Migliari, R., et al., *Tension-free vaginal mesh repair for anterior vaginal wall prolapse*. Eur Urol, 2000. **38**(2): p. 151-155.

Miklos, J.R. and N. Kohli, Laparoscopic paravaginal repair plus

burch colposuspension: review and descriptive technique. Urology, 2000. **56**(6 Suppl 1): p. 64-9.

Milani, R., et al., Marshall-Marchetti-Krantz procedure and Burch colposuspension in the surgical treatment of female urinary incontinence. Br J Obstet Gynaecol, 1985. **92**(10): p. 1050-3.

Miller, N., *Treatment of vesicovaginal fistulas*. Am J Obstet Gynecol, 1935. **30**: p. 675-679.

Mittleman, R.E. and J.V. Marraccini, *Pulmonary Teflon granulomas following periurethral Teflon injection for urinary incontinence*. Arch Pathol Lab Med, 1983. **107**(11): p. 611-2.

Miyazaki, F. and G. Shook, *Ilioinguinal nerve entrapment during needle suspension for stress incontinence*. Obstet Gynecol, 1992. **80**(2): p. 246-8.

Moehrer, B., M. Carey, and D. Wilson, *Laparoscopic colposuspension: a systematic review*. Bjog, 2003. **110**(3): p. 230-5.

Monga, A. and S. Stanton, *Predicting outcome of colposuspension. A prospective evaluation*.Neuro-urology and Urodynamics, 1997. **16**(5): p. 354-355.

Monga, A.K., D. Robinson, and S.L. Stanton, *Periurethral collagen injections for genuine stress incontinence: a 2-year follow-up.* Br J Urol, 1995. **76**(2): p. 156-60.

Monga, A.K. and S.L. Stanton, *Urodynamics: prediction, outcome* and analysis of mechanism for cure of stress incontinence by periure-thral collagen. Br J Obstet Gynaecol, 1997. **104**(2): p. 158-62.

Monseur, J., [Repair of the female urethra and its natural support. Another surgical concept. 224 cases over 9 years]. J Urol (Paris), 1989. **95**(6): p. 357-62.

Monteiro, H., R. Nogueira, and H. de Carvalho, *Behcet's syndrome* and vesicovaginal fistula: an unusual complication. J Urol, 1995. **153**(2): p. 407-8.

Moore, K.N., et al., *Periurethral implantation of glutaraldehyde* cross-linked collagen (Contigen) in women withtype I or III stress incontinence: quantitative outcome measures. Br J Urol, 1995. **75**(3): p. 359-63.

Moore, R.D. and J.R. Miklos, *Colpocleisis and tension-free vaginal tape sling for severe uterine and vaginal prolapse and stress urinary incontinence under local anesthesia.* J Am Assoc Gynecol Laparosc, 2003. **10**(2): p. 276-80.

Morgan, J.E., et al., *The polypropylene pubovaginal sling for the treatment of recurrent stress urinary incontinence*. J Urol, 1995. **154**(3): p. 1013-1014.

Morgan, T.O., Jr., O.L. Westney, and E.J. McGuire, *Pubovaginal sling: 4-YEAR outcome analysis and quality of life assessment.* J Urol, 2000. **163**(6): p. 1845-8.

Morris, A., et al., 7 year follow up of a randomized trial comparing laparoscopic colposuspension and open colposuspension in the treatment of genuine stress incontinence. International Urogynecology Journal, 2001. **12**(3 S6).

Mukherjee, K. and G. Constantine, *Urinary stress incontinence in obese women: tension-free vaginal tape is the answer.* BJU Int, 2001. **88**(9): p. 881-3.

Muller, S., et al., *Long-term results of fascial sling procedure*. Int Urogynecol J, 1993. **4**: p. 199-2003.

Mundy, A.R., A trial comparing the Stamey bladder neck suspension procedure with colposuspension for the treatment of stress incontinence. Br J Urol, 1983. **55**(6): p. 687-90.

Mundy, A.R. and T.P. Stephenson, "*Clam*" ileocystoplasty for the treatment of refractory urge incontinence. Br J Urol, 1985. **57**(6): p. 641-6.

Murphy, M., et al., *Effect of anesthesia on voiding function after tension-free vaginal tape procedure*. Obstet Gynecol, 2003. **101**: p. 666-670. Mutone, N., E. Brizendine, and D. Hale, *Factors that influence voiding function after the tension-free vaginal tape procedure for stress urinary incontinence.* J Urol, 2003. **188**: p. 1477-1483.

Muznai D, C.E., Dubin C, Sliverman I, Retropubic vaginopexy for the correction of urinary stress incontinence. Obstet Gynecol, 1992. **59**: p. 113-117.

Neal, D.E., Jr. and L. Foster, *Southern Illinois University (SIU) slingbone anchored semitendinosus*. Tech Urol, 2001. **7**(1): p. 62-3.

Neitlich, J.D., et al., *Detection of urethral diverticula in women: comparison of a high resolution fast spin echo technique with double balloon urethrography.* J Urol, 1998. **159**(2): p. 408-10.

Nesrallah, L.J., M. Srougi, and R.F. Gittes, *The O'Conor technique: the gold standard for supratrigonal vesicovaginal fistula repair.* J Urol, 1999. **161**(2): p. 566-8.

Nezhat, C.H., et al., *Laparoscopic repair of a vesicovaginal fistula: a case report*. Obstet Gynecol, 1994. **83**(5 Pt 2): p. 899-901.

Nguyen, J.K. and N.N. Bhatia, *Risk of recurrent stress incontinence in women undergoing the combined modified pereyra procedure and transvaginal sacrospinous ligament vault suspension*. Urology, 2001. **58**(6): p. 947-52.

Nicholson, S. and A. Brown, *The long term success of abdominova*ginal sling operations for genuine stress incontinenceand a cystocele- a questionnaire based study. J Obstet Gynaecol, 2001. **21**: p. 162-165.

Niknejad, K.G. and A. Atala, *Bladder augmentation techniques in women*. Int Urogynecol J Pelvic Floor Dysfunct, 2000. **11**(3): p. 156-69.

Nilsson, C.G. and N. Kuuva, *The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence*. Bjog, 2001. **108**(4): p. 414-9.

Nilsson, C.G., et al., *Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence*.Int Urogynecol J Pelvic Floor Dysfunct, 2001. **12 Suppl 2**: p. S5-8.

Nilsson, C.G., M. Rezapour, and C. Falconer, 7 year follow-up of the tension free vaginal tape procedure. International Urogynecology Journal, 2003. **14**(Supplement 1): p. 1:S35.

Nitahara, K.S., S. Aboseif, and E.A. Tanagho, *Long-term results of colpocystourethropexy for persistent or recurrent stress urinary incontinence*. J Urol, 1999. **162**(1): p. 138-41.

Nitti, V.W., et al., The Raz bladder neck suspension in patients 65 years old and older.J Urol, 1993. 149(4): p. 802-7.

Nolan, J., et al., *Gracilis interposition in fistulas following radiotherapy for cervical cancer.* Urol Int, 1991. **33**: p. 370-376.

Noller, K.L., J.H. Pratt, and R.E. Symmonds, *Bowel perforation with suprapubic cystostomy Report of two cases*. Obstet Gynecol, 1976. **48**(1 Suppl): p. 67S-69S.

Obrink, A. and G. Bunne, *Gracilis interposition in fistulas following radiotherapy for cervical cancer. A retrospective study.* Urol Int, 1978. **33**(5): p. 370-6.

Obrink, A., et al., *Mental factors influencing recurrence of stress incontinence*. Acta Obstet Gynecol Scand, 1979. **58**(1): p. 91-4.

O'Connell, H.E., et al., *Transurethral collagen therapy in women*. J Urol, 1995. **154**(4): p. 1463-5.

O'Conor, V.J., *Review of experience with vesicovaginal fistula repair.* J Urol, 1980. **123**: p. 367-369.

O'Conor, V.J. and K. Kropp, eds. *Surgery of the female urethra*. Urologic Surgery, ed. J. Glenn and W. Boyce. 1969, Harper and Row: New York.

O'Conor, V.J. and J.K. Sokol, Vesicovaginal fistula from the standpoint of urologists.J Urol, 1951. 66: p. 367-369. O'Conor, V.J., Jr., et al., *Suprapubic closure of vesicovaginal fistula*. J Urol, 1973. **109**(1): p. 51-4.

Oge, O., et al., Urothelium-preserving augmentation cystoplasty covered with a peritoneal flap. BJU Int, 2000. **85**(7): p. 802-5.

O'Reilly, K.J. and F.E. Govier, *Intermediate term failure of pubovaginal slings using cadaveric fascia lata: a case series.* J Urol, 2002. **167**(3): p. 1356-8.

O'Reilly, K.J. and F.E. Govier, *Intermediate term failure of pubovaginal slings using cadaveridc fascia lata: a case series.*J Urol, 2002. **167**: p. 1356-1358.

Ostrzenski, A., Genuine stress urinary incontinence in women. New laparoscopic paravaginal reconstruction. J Reprod Med, 1998. **43**(6): p. 477-82.

O'Sullivan, D.C., C.P. Chilton, and K.W. Munson, *Should Stamey colposuspension be our primary surgery for stress incontinence*?Br J Urol, 1995. **75**(4): p. 457-60.

O'Sullivan, R., et al., *Is objective cure of mild undifferentiated incontinence more readily achieved than that of moderate incontinence? Costs and 2-year outcome.* Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(3): p. 193-8; discussion 198.

Ou, C.S., et al., *Laparoscopic repair of vesicovaginal fistula*. J Laparoendosc Adv Surg Tech A, 2004. **14**(1): p. 17-21.

Pajoncini, C., et al., *Clinical and urodynamic features of intrinsic sphincter deficiency*. Neurourol Urodyn, 2003. **22**(4): p. 264-8.

Pannek, J., F.H. Brands, and T. Senge, *Particle migration after transurethral injection of carbon coated beads for stress urinary incontinence*. J Urol, 2001. **166**(4): p. 1350-3.

Paraiso, M.F., T. Falcone, and M.D. Walters, *Laparoscopic surgery for genuine stress incontinence*. Int Urogynecol J Pelvic Floor Dysfunct, 1999. **10**(4): p. 237-47.

Paraiso, M.F., et al., *Laparoscopic Burch colposuspension versus the tension-free vaginal tape procedure: a randomized clinical trial*. Obstet Gynecol (in press), 2004 (in press).

Parkhouse, H.F., et al., *Quantitative study of phenol as a neurolytic agent in the urinary bladder*. Br J Urol, 1987. **60**(5): p. 410-2.

Parks, J., Section of the urethral wall for correction of urethrovaginal fistulae and urethral diverticula.Am J Obstet Gynecol, 1965. **93**(5): p. 683-92.

Parsons, K.F., et al., *Endoscopic bladder transection*. Br J Urol, 1984. **56**(6): p. 625-8.

Partoll, L.M., *Efficacy of tension-free vaginal tape with other pelvic reconstructive surgery*. Am J Obstet Gynecol, 2002. **186**(6): p. 1292-5; discussion 1295-8.

Patil, U., K. Waterhouse, and G. Laungani, *Management of 18 diffi*cult vesicovaginal and urethrovaginal fistulas with modified Ingelman-Sundberg and Martius operations. J Urol, 1980. **123**(5): p. 653-6.

Peattie, A.B. and S.L. Stanton, *The Stamey operation for correction of genuine stress incontinence in the elderly woman.* Br J Obstet Gynaecol, 1989. **96**(8): p. 983-6.

Peeker, R., et al., *The treatment of sphincter incontinence with periurethral silicone implants (macroplastique)*. Scand J Urol Nephrol, 2002. **36**(3): p. 194-8.

Pelosi, M.A., et al., *Treatment of urinary stress incontinence. Use of dermal graft in the sling procedure.* Obstet Gynecol, 1976. **47**(3): p. 377-9.

Pelosi, M.A., 2nd, M.A. Pelosi, 3rd, and M. Pelekanos, *The YAMA* UroPatch sling for treatment of female stress urinary incontinence: a pilot study. J Laparoendosc Adv Surg Tech A, 2002. **12**(1): p. 27-33.

Pengelly, A., et al., *Results of prolonged bladder distension as treatment for detrusor instability*. Br J of Urology, 1978. **50**: p. 243-245. Pereyra, A.J., A simplified surgical procedure for the correction of stress incontinence in women. West J Surg Obstet Gynecol, 1959. **67**(4): p. 223-6.

Perovic, S.V., et al., *Bladder autoaugmentation with rectus muscle backing*. J Urol, 2002. **168**(4 Pt 2): p. 1877-80.

Persky, L., G. Herman, and K. Guerrier, *Nondelay in vesicovaginal fistula repair*. Urology, 1979. **13**(3): p. 273-5.

Persson, J. and P. Wolner-Hanssen, *Laparoscopic Burch colposus*pension for stress urinary incontinence: a randomized comparison of one or two sutures on each side of the urethra. Obstet Gynecol, 2000. **95**(1): p. 151-5.

Petros, P.E. and U.I. Ulmsten, *An integral theory of female urinary incontinence. Experimental and clinical considerations*. Acta Obstet Gynecol Scand Suppl, 1990. **153**: p. 7-31.

Petros, P.P., *Medium-term follow-up of the intravaginal slingplasty* operation indicates minimal deterioration of urinary continence with time. Aust N Z J Obstet Gynaecol, 1999. **39**(3): p. 354-6.

Petrou, S.P. and I. Frank, *Complications and initial continence rates after a repeat pubovaginal sling procedure for recurrent stress urinary incontinence* J Urol, 2001. **165**(6 Pt 1): p. 1979-81.

Pettit, P.D., J.R. Thompson, and A.H. Chen, *Sacral neuromodulation: new applications in the treatment of female pelvic floor dysfunction.* Curr Opin Obstet Gynecol, 2002. **14**(5): p. 521-5.

Pickard, R., et al., *Periurethral injection therapy for urinary incontinence in women*. Cochrane Database Syst Rev, 2003(2): p. CD003881.

Poliak, A., A. Daniller, and R. Liebling, *Sling operation for recurrent stress incontinence using the tendon of the palmaris longus*. Obstet Gynecol, 1983. **63**: p. 850-854.

Politano, V.A., *Periurethral polytetrafluoroethylene injection for uri*nary incontinence. J Urol, 1982. **127**(3): p. 439-42.

Politano, V.A., et al., *Periurethral teflon injection for urinary incontinence*. J Urol, 1974. **111**(2): p. 180-3.

Pow-Sang, J.M., et al., *Female urinary incontinence: preoperative selection, surgical complications and results.* J Urol, 1986. **136**(4): p. 831-3.

Price, P., Plastic operation for incontinence of urine and faeces.

Arch Surg, 1933. 26: p. 1043-1053.

Radley, S.C., et al., *Transurethral implantation of macroplastique for the treatment of female stress urinary incontinence secondary to urethral sphincter deficiency*.Eur Urol, 2001. **39**(4): p. 383-9.

Rafii, A., et al., *Body mass index and outcome of tension-free vaginal tape*. Eur Urol, 2003. **43**(3): p. 288-92.

Ramsden, P.D., et al., *Distension therapy for the unstable bladder: later results including an assessment of repeatdistensions.* Br J Urol, 1976. **48**(7): p. 623-9.

Rardin, C.R., et al., *Tension-free vaginal tape: outcomes among women with primary versus recurrent stress urinary incontinence.*

Obstet Gynecol, 2002. 100(5 Pt 1): p. 893-7.

Rardin, C.R., et al., *Release of tension-free vaginal tape for the treatment of refractory postoperative voiding dysfunction*. Obstet Gynecol, 2002. **100**(5 Pt 1): p. 898-902.

Raz, S., et al., *Transvaginal repair of vesicovaginal fistula using a peritoneal flap.* J Urol, 1993. **150**(1): p. 56-9.

Raz, S., et al., *The Raz bladder neck suspension: results in 206 patients*. J Urol, 1992. **148**(3): p. 845-50.

Rechberger, T., et al., A randomized comparison between monofilament and multifilament tapes for stressincontinence surgery. Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(6): p. 432-6.

Redman, J.F., *Female urologic diagnostic techniques*. Urol Clin North Am, 1990. **17**(1): p. 5-8.

Rezapour, M. and U. Ulmsten, *Tension-Free vaginal tape (TVT) in women with recurrent stress urinary incontinence—a long-term follow up.* Int Urogynecol J Pelvic Floor Dysfunct, 2001. **12 Suppl 2**: p. S9-11.

Riachi, L., N. Kohli, and J. Miklos, *Repeat tension-free transvaginal tape (TVT) sling for the treatment of recurrent stress urinary incontinence*. Int Urogynecol J Pelvic Floor Dysfunct, 2002. **13**(2): p. 133-5; discussion 135.

Richard, F. Development et validation d'un questionnaire specifique evaluant la qualite de vies de femme souffrant d'une incontinence urinaire. In XXII SIFUD. 1999. Nimes, France.

Richardson, D.A., A.E. Bent, and D.R. Ostergard, *The effect of utero*vaginal prolapse on urethrovesical pressure dynamics. Am J Obstet Gynecol, 1983. **146**(8): p. 901-5.

Richardson, T.D., M.J. Kennelly, and G.J. Faerber, *Endoscopic injection of glutaraldehyde cross-linked collagen for the treatment of intrinsic sphincter deficiency in women*. Urology, 1995. **46**(3): p. 378-81.

Richter, H.E., et al., *Effects of pubovaginal sling procedure on patients with urethral hypermobility and intrinsic sphincteric deficiency: would they do it again?* Am J Obstet Gynecol, 2001. **184**(2): p. 14-9.

Robinson, D. and L. Cardozo, *The effect of continence surgery on urogenital prolapse*. BJU Int, 2004. **93**(1): p. 25-30.

Rodriguez, L.V., et al.*Does valsalva leak point pressure predict outcome after the distal urethral polypropylene sling? Role of urodynamics in the sling era.* J Urol, 2004. **172**(1): p. 210-4.

Rosenbaum, T.P., P.J. Shaw, and P.H. Worth, *Trans-trigonal phenol failed the test of time*. Br J Urol, 1990. **66**(2): p. 164-9.

Rosenzweig, B.A., et al., *Stress incontinence in women. Psychological status before and after treatment.* Journal of Reproductive Medicine, 1991. **36**(12): p. 835.

Rosenzweig, B.A., et al., *Prevalence of abnormal urodynamic test results in continent women with severe genitourinary prolapse*. Obstet Gynecol, 1992. **79**(4): p. 539-42.

Ross, J.W., Laparoscopic Burch repair compared to laparotomy Burch for cure of urinary stress incontinence. International Urogynecology Journal, 1995. 6(3): p. 323-328.

Ross, J.W., Multichannel urodynamic evaluation of laparoscopic Burch colposuspension for genuine stress incontinence. Obstet Gynecol, 1998. **91**(1): p. 55-9.

Rottenberg, R.D., et al., *Urodynamic and clinical assessment of the Lyodura sling operation for urinary stressincontinence*. Br J Obstet Gynaecol, 1985. **92**(8): p. 829-34.

Roupret, M., et al., Sacral neuromodulation for refractory detrusor overactivity in women with an artificial urinary sphincter. J Urol, 2004. **172**(1): p. 236-9.

Rutner, A., S. Levine, and J. Schmaelzle. *Procine small intestinal submucosa implanted as a pubovaginal sling in 115 female patients*

with stress urinary incontinence: a 3 year series evaluated for durability of the results. in Society for Urology & Engineering, 17th Annual Meeting, 2002.

Saidi, M.H., et al., *Extraperitoneal laparoscopic colposuspension: short-term cure rate, complications, and duration of hospital stay in comparison with Burch colposuspension.* Obstet Gynecol, 1998. **92**(4 Pt 1): p. 619-21.

Sand, P.K., et al., *The low pressure urethra as a factor in failed retropubic urethropexy*. Obstet Gynecol, 1987. **69**(3 Pt 1): p. 399-402.

Sand, P.K., et al., A prospective randomized study comparing modified Burch retropubic urethropexy and suburethral sling for treatment of genuine stress incontinence with low-pressure urethra. Am J Obstet Gynecol, 2000. **182**(1 Pt 1): p. 30-4. Schmidt, R.A., et al., *Sacral nerve stimulation for treatment of refractory urinary urge incontinence. Sacral NerveStimulation Study Group.* J Urol, 1999. **162**(2): p. 352-7.

Schostak, M., et al., *Transvaginal bone anchors in female stress urinary incontinence: poor results*. Gynecol Obstet Invest, 2002. **54**(3): p. 154-8.

Scott, *The artificial urinary sphincter*. Urol Clin North Am, 1989. **16**: p. 105-117.

Scotti, R.J., et al., *Antecedent history as a predictor of surgical cure of urgency symptoms in mixed incontinence*. Obstet Gynecol, 1998. **91**(1): p. 51-4.

Scotti, R.J., et al., *Paravaginal repair of lateral vaginal wall defects by fixation to the ischial periosteum and obturator membrane*. Am J Obstet Gynecol, 1998. **179**(6 Pt 1): p. 1436-45.

Serels, S.R., R.R. Rackley, and R.A. Appell, *Surgical treatment for stress urinary incontinence associated with valsalva induced detrusor instability*. J Urol, 2000. **163**(3): p. 884-7.

Sevestre, S., et al., *Results of the tension-free vaginal tape technique in the elderly*. Eur Urol, 2003. **44**(1): p. 128-31.

Shaker, H. and M.M. Hassouna, *Sacral root neuromodulation in the treatment of various voiding and storage problems*. Int Urogynecol J Pelvic Floor Dysfunct, 1999. **10**(5): p. 336-43.

Shaker, H.S. and M. Hassouna, *Sacral nerve root neuromodulation: an effective treatment for refractory urge incontinence*. J Urol, 1998. **159**(5): p. 1516-9.

Shekarriz, B., et al., Surgical complications of bladder augmentation: comparison between various enterocystoplasties in 133 patients. Urology, 2000. **55**(1): p. 123-8.

Siegel, S.W., et al., *Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinaryurge incontinence, urgency-frequency, and retention.* Urology, 2000. **56**(6 Suppl 1): p. 87-91.

Sims, J., On the treatment of vesicovaginal fistulas. Am J Med Sci, 1852. 23: p. 59.

Slim, K., et al., Analysis of randomized controlled trials in laparoscopic surgery. Br J Surg, 1997. **84**(5): p. 610-4.

Smith, A.R. and S.L. Stanton, *Laparoscopic colposuspension*. Br J Obstet Gynaecol, 1998. **105**(4): p. 383-4.

Smith, D.N., et al., *Collagen injection therapy for female intrinsic sphincteric deficiency*. J Urol, 1997. **157**(4): p. 1275-8.

Smith, R.N.J. and L. Cardozo, *Early voiding difficulty after colposuspension*. BJU, 1997. **80**(6): p. 911-914.

Snow, B.W. and P.C. Cartwright, *Bladder autoaugmentation*. Urologic Clinics of North America, 1996. **23**: p. 323-331.

Soulie, M., et al., *The tension-free transvaginal tape procedure in the treatment of female urinary stress incontinence: a French prospective multicentre study.* Eur Urol, 2001. **39**(6): p. 709-14; discussion 715.

Spence, H.M. and J.W. Duckett, Jr., *Diverticulum of the female urethra: clinical aspects and presentation of a simple operativetechnique for cure.* J Urol, 1970. **104**(3): p. 432-7.

Spencer, J.R., V.J. O'Conor, Jr., and A.J. Schaeffer, A comparison of endoscopic suspension of the vesical neck with suprapubic vesicourethropexy for treatment of stress urinary incontinence. J Urol, 1987. **137**(3): p. 411-5.

Spinelli, M., et al., *Chronic sacral neuromodulation in patients with lower urinary tract symptoms: results from a national register.*

J Urol, 2001. 166(2): p. 541-5.

Squier, J., *Postoperative urinary incontinence*. Med Rec, 1911. **79**: p. 868.

Stach-Lempinen, B., et al., *Is physical activity influenced by urinary incontinence?* BJOG, 2004. **111**: p. 475-480.

Stamey, T.A., Endoscopic suspension of the vesical neck for urinary incontinence. Surg Gynecol Obstet, 1973. 136(4): p. 547-54.

Stanton, S.L., et al., *Clinical and urodynamic features of failed incontinence surgery in the female*. Obstet Gynecol, 1978. **51**(5): p. 515-20.

Stanton, S.L. and L.D. Cardozo, *Results of the colposuspension operation for incontinence and prolapse*.Br J Obstet Gynaecol, 1979. **86**(9): p. 693-7.

Stanton, S.L. and L.D. Cardozo, *Surgical treatment of incontinence in elderly women*. Surg Gynecol Obstet, 1980. **150**(4): p. 555-7.

Stanton, S.L. and A.K. Monga, *Incontinence in elderly women: is periurethral collagen an advance?* Br J Obstet Gynaecol, 1997. **104**(2): p. 154-7.

Steele, A.C., N. Kohli, and M.M. Karram, *Periurethral collagen injection for stress incontinence with and without urethral hypermobility*. Obstet Gynecol, 2000. **95**(3): p. 327-31.

Stember, D.S., H.M. Scarpero, and V.W. Nitti, *Vaginal granulation tissue secondary to bone anchors: experience in two patients*. J Urol, 2003. **169**(6): p. 2300-1.

Stewart, W.F., et al., *Prevalence and burden of overactive bladder in the United States*. World J Urol, 2003. **20**(6): p. 327-36.

Stirnemann, H., *Treatment of recurrent recto-vaginal fistula by interposition of a glutaeus maximus muscle flap.* Am J Proctol, 1969. **20**(1): p. 52-4.

Stockbine, M., J. Hancock, and G. Fletcher, *Complications in 831 patients with squamous cell carcinoma of the intact uterine cervix-treated with 3,00 rads or more whole pelvis radiation*. AJR Am J Roentgenol, 1970. **108**: p. 239-304.

Stoller, M., et al., *The efficacy of acupuncture in reversing the unstable bladder in pig-tailed monkeys.* Journal of Urology, 1987. **Supplement 137**(104A): p. Abstract 2.

Stothers, L. and S.L. Goldenberg, *Delayed hypersensitivity and systemic arthralgia following transurethral collagen injection for stress urinary incontinence*. J Urol, 1998. **159**(5): p. 1507-9.

Stothers, L., S.L. Goldenberg, and E.F. Leone, *Complications of periurethral collagen injection for stress urinary incontinence*. J Urol, 1998. **159**(3): p. 806-7.

Stovsky, M.D., et al., Use of electrocoagulation in the treatment of vesicovaginal fistulas. J Urol, 1994. **152**(5 Pt 1): p. 1443-4.

Su, T.H., et al., *Prospective comparison of laparoscopic and traditio*nal colposuspensions in the treatment of genuine stress incontinence.

Acta Obstet Gynecol Scand, 1997. 76(6): p. 576-82.

Sultana, C.J., et al., *Morbidity and mortality of incontinence surgery in elderly women: an analysis of Medicare data*. Am J Obstet Gynecol, 1997. **176**(2): p. 344-348.

Summitt, R., et al., *Randomised comparison of laparoscopic and transabdominal Burch urethropexy for the treatment of genuine stress incontinence*. Obstet Gynecol, 2000. **95**(4/suppl.1).

Sutaria, P. and D. Staskin, A comparison of fascial "pull-through" strength using four different suture fixation techniques. J Urology, 1999. **161**: p. 79-80.

Sutherst, J.R. and M. Brown, *The effect on the bladder pressure of sudden entry of fluid into the posterior urethra*. Br J Urol, 1978. **50**(6): p. 406-9.

Symmonds, R.E., *Incontinence: vesical and urethral fistulas*. Clin Obstet Gynecol, 1984. **27**(2): p. 499-514.

Tait, L., Saccular Violation of the Urethra. Lancet. 1875(2): p. 625.

Takahashi, S., et al., *Complications of Stamey needle suspension for female stress urinary incontinence*.Urol Int, 2002. **68**(3): p. 148-51.

Tamanini, J.T., et al., Macroplastique implantation system for the

treatment of female stress urinary incontinence. J Urol, 2003. 169(6): p. 2229-33

Tamussino, K., et al., *Tension free vaginal tape operation: results of the Austrian registry*. Obstet Gynecol, 1999. **106**: p. 345-50.

Tamussino, K.E., et al., *Five-year results after anti-incontinence operations*. Am J Obstet Gynecol, 1999. **181**: p. 1347-1352.

Tanagho, E.A., *Effect of hysterectomy and peri-urethral surgery on urethrovesical function*. Int Gynaecologic Urology and Urodynamics, 1985: p.

Tancer, M.L., *The post-total hysterectomy (vault) vesicovaginal fistu- la*. J Urol, 1980. **123**(6): p. 839-40.

Tancer, M.L., *Observations on prevention and management of vesicovaginal fistula after total hysterectomy*.Surg Gynecol Obstet, 1992. **175**(6): p. 501-6.

Tancer, M.L., A report of thirty-four instances of urethrovaginal and bladder neck fistulas. Surg Gynecol Obstet, 1993. **177**(1): p. 77-80.

Tebyani, N., et al., *Percutaneous needle bladder neck suspension for* the treatment of stress urinary incontinence in women: long-term results. J Urol, 2000. **163**(5): p. 1510-2.

Tegerstedt, G., B. Sj"berg, and M. Hammarstrom, *Clinical outcome* or abdominal urethropexy-colposuspension: a long-term follow-up.

Int Urogynecol J, 2001. 12: p. 161-165.

Ter Meulen, P., J. Heesakkers, and R. Janknegt, A study on the fesibility of vesicomyotomy in patients with motor urge incontinence.

European Urology, 1997. 32: p. 166-169.

Thakar, R., et al., *Secondary colposuspension: results of a prospective study from a tertiary referral centre*. Bjog, 2002. **109**(10): p. 1115-20.

Thomas, K., S.N. Venn, and A.R. Mundy, *Outcome of the artificial urinary sphincter in female patients*. J Urol, 2002. **167**(4): p. 1720-2.

Thomas, R.B. and B. Maguire, *Adenocarcinoma in a female urethral diverticulum*. Aust N Z J Surg, 1991. **61**(11): p. 869-71.

Tincello, D.G., *Ultrasound detection of vault haematoma following vaginal hysterectomy*. Br J Obstet Gynaecol, 1998. **105**(12): p. 1336-7.

Toh, K. and A.C. Diokno, *Management of intrinsic sphincter deficiency in adolescent females with normal bladder emptying function.* J Urol, 2002. **168**(3): p. 1150-3.

Tomlinson, A.J. and J.G. Thornton, A randomised controlled trial of antibiotic prophylaxis for vesico-vaginal fistula repair. Br J Obstet Gynaecol, 1998. **105**(4): p. 397-9.

Tsivian, A., et al., *Bone anchor 4-corner cystourethropexy: long-term results.* J Urol, 2003. **169**(6): p. 2244-5.

Turner-Warwick, R., *The use of the omental pedicle graft in urinary tract reconstruction.* J Urol, 1976. **116**(3): p. 341-7.

Udeh, F.N., Simple management of difficult vesicovaginal fistulas by anterior transvesical approach. J Urol, 1985. **133**(4): p. 591-3.

Ulmsten, U., et al., A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence.Int Urogynecol J Pelvic Floor Dysfunct, 1998. **9**(4): p. 210-3.

Ulmsten, U., et al., An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct, 1996. **7**(2): p. 81-5; discussion 85-6.

Ulmsten, U., P. Johnson, and M. Rezapour, A three-year follow up of tension free vaginal tape for surgical treatment of female stress

urinary incontinence. Br J Obstet Gynaecol, 1999. 106(4): p. 345-50.

Ustun, Y., et al., *Tension-free vaginal tape compared with laparoscopic Burch urethropexy*. J Am Assoc Gynecol Laparosc, 2003. **10**(3): p. 386-9. Van Geeland JM, T.A., Eskes TKAB, Martin Jr CB, *The clinical and urodynamic effect of anterior vaginal repair and Burch colposuspension*. Am J Obstet Gynecol and Gynae, 1988. **159**(1): p. 137-144.

van Kerrebroeck, P., et al., *Efficacy and safety of a novel system* (*NASH/Dx copolymer via the Implacer device*) for the treatment of *SUI*. Journal of Urology, 2004 in press.

Varner, R.E., *Retropubic long-needle suspension procedures for stress urinary incontinence*. Am J Obstet Gynecol, 1990. **163**(2): p. 551-7.

Vereecken, R.L. and A. Lechat, *Cadaver fascia lata sling in the treat*ment of intrinsic sphincter weakness. Urol Int, 2001. **67**(3): p. 232-4.

Viereck, V., et al., *Introital ultrasound of the lower genital tract before and after colposuspension: a 4-year objective follow-up*. Ultrasound Obstet Gynecol, 2004. **23**(3): p. 277-83.

Villasanta, U., *Complications of radiotherapy for carcinoma of the uterine cervix*. Am J Obstet Gynecol, 1972. **114**(6): p. 717-26.

Von Kolmorgen, K., *Duraschlingenoperationen und deren ergebnisse bei der opeativen harninkontinenzbehandlung der frau*. Zentralbl Gynakol, 1980. **102**: p. 850-856.

Wall, L.L., P. Copas, and N.T. Galloway, *Use of a pedicled rectus abdominis muscle flap sling in the treatment of complicated stress urinary incontinence*. Am J Obstet Gynecol, 1996. **175**(6): p. 1460-4; discussion 1464-6.

Wall, L.L. and S.L. Stanton, *Transvesical phenol injection of pelvic nerve plexuses in females with refractory urgeincontinence*. Br J Urol, 1989. **63**(5): p. 465-8.

Walsh, I.K., et al., *Cadaveric fascia lata pubovaginal slings: early results on safety, efficacy and patient satisfaction.* BJU Int, 2002. **90**(4): p. 415-9.

Walsh, K., et al., *The influence of age on quality of life outcome in women following a tension-free vaginal tape procedure.* J Urol, 2004. **171**(3): p. 1185-8.

Walsh, P., A. Retik, and T. Stamey, eds. *Female Urology*. 6th Edition ed. 1992, WB Saunders Co: Philadelphia.

Wang, M. D, and H. R, *The anatomical basis for femoral neuropathy due to procedures performed in the modified lithotomy position.* ;Int Orogynecol, 1993. 4: p. 390.

Wang, A.C. and M.C. Chen, *Comparison of tension-free vaginal* taping versus modified Burch colposuspension on urethral obstruction: a randomized controlled trial. Neurourol Urodyn, 2003. **22**(3): p. 185-90.

Wang, Y. and H.R. Hadley, *Nondelayed transvaginal repair of high lying vesicovaginal fistula*. J Urol, 1990. **144**(1): p. 34-6.

Ward, J.N., *Technique to visualize urethral diverticula in female patients*. Surg Gynecol Obstet, 1989. **168**(3): p. 278-9.

Ward, K. and P. Hilton, *Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension ;as primary treatment for stress incontinence*. Bmj, 2002. **325**(7355): p. 67.

Ward, K.L. and P. Hilton, A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. Am J Obstet Gynecol, 2004. **190**(2): p. 324-31.

Ward KL, H.P.a.B.J., A randomised trial of colposuspension and tension free vaginal tape for primary genuine stress incontince. Neurourology and Urodynamics, 2000. **19**: p. 386-388.

Webster, G.D., et al., *Management of type III stress urinary incontinence using artificial urinary sphincter*. Urology, 1992. **39**(6): p. 499-503.

Webster, G.D., S.A. Sihelnik, and A.R. Stone, *Urethrovaginal fistula:* a review of the surgical management. J Urol, 1984. **132**(3): p. 460-2.

Wein, A.J. and T.R. Malloy, *Simple omental mobilization for genitou*rinary surgery. Urology, 1980. **16**(5): p. 515-8.

Wein, A.J., et al., *Repair of vesicovaginal fistula by a suprapubic transvesical approach*. Surg Gynecol Obstet, 1980. **150**(1): p. 57-60.

Welgoss, J.A., et al., *Relationship between surgically induced neuropathy and outcome of pelvic organ prolapse surgery*. Int Urogynecol J Pelvic Floor Dysfunct, 1999. **10**(1): p. 11-4.

Wennberg, A.L., et al., Stamey's abdominovaginal needle colposuspension for the correction of female genuine stress urinary incontinence-long-term results. Scand J Urol Nephrol, 2003. **37**(5): p. 419-23.

Westney, O.L., et al., *Long-term results of Ingelman-Sundberg denervation procedure for urge incontinence refractory to medical therapy.* J Urol, 2002. **168**(3): p. 1044-7.

Whitfield, H.N. and M.E. Mayo, *Prolonged bladder distension in the treatment of the unstable bladder.* Br J Urol, 1975. **47**(6): p. 635-9.

Winters, J.C. and R. Appell, *Periurethral injection of collagen in the treatment of intrinsic sphincteric deficiency in thefemale patient*.Urol Clin North Am, 1995. **22**(3): p. 673-8.

Winters, J.C., et al., *Collagen injection therapy in elderly women: long-term results and patient satisfaction*. Urology, 2000. **55**(6): p. 856-61.

Wiskind, A.K., S.M. Creighton, and S.L. Stanton, *The incidence of genital prolapse after the Burch colposuspension*. Am J Obstet Gynecol, 1992. **167**(2): p. 399-404; discussion 404-5.

Woodhouse, C.R., et al., *Urethral diverticulum in females*. Br J Urol, 1980. **52**(4): p. 305-10.

Wright, E.J., et al., *Pubovaginal sling using cadaveric allograft fascia for the treatment of intrinsic sphincter deficiency*. J Urol, 1998. **160**(3 Pt 1): p. 759-62.

Zacharin, R., Obstetric Fistula. 1988, Springer-verlag: New York.

Zeidman, E.J., et al., *Suprapubic cystostomy using Lowsley retractor*. Urology, 1988. **32**(1): p. 54-5.

Zimmern, P., K. Ganabathi, and G. Leach, *Vesicovaginal fistula repair*. Atlas Urol Clin North Am, 1994. **2**: p. 67-99.

Zivkovic, F., et al., *Body mass index and outcome of incontinence surgery*. Obstet Gynecol, 1999. **93**(5 Pt 1): p. 753-6.

Zivkovic, F., et al., Long-term effects of vaginal dissection on the innervation of the striated urethral sphincter. Obstet Gynecol, 1996. **87**(2): p. 257-60.