The University of Hull

Faculty of Health

Department of Obstetrics and Gynaecology

MD Thesis

"Non-invasive and minimally invasive techniques for urodynamic stress incontinence of urine in women"

Dr. Sharif Ibrahim Muhammad Farag Ismail

June, 2006

To

My Mother

Dr. Rasheedah Abd-El-Fattah
Muhammad El-Sheikh

who gave up her own

MD

In obstetrics and gynaecology

to look after me

and my two sisters

when we were young children,

I hope

this makes it up to her

Acknowledgement:

My foremost thanks to Allaah, without whom I would have never been able to complete this thesis.

I am pleased to record my gratitude to my supervisor, Professor Stephen Killick, who welcomed me as a student and guided this thesis from planning to completion. His exceptional patience, unlimited help, kind co-operation, timely feedback and sincere advice have been most invaluable. I am also grateful to the examiners, Mr. Stephen Lindow and Mr. Paul Ballard, whose comments helped shaping the final draft of the thesis. Thanks are also due to Professor Peter Thomas, at Dorset Research and Development Department, for his invaluable statistical advice. The kind help of Prof. Killick's secretary, Linda Browne, has been appreciated.

I am also grateful to the patients who took part in the studies included in the thesis and the staff who helped with it at Singleton and Morriston hospitals, in Swansea, and Barnsley District General hospital, in South Yorkshire. Special thanks are due to Mr. Simon Emery, Mr. Malcolm Lucas, Mr. Samir Henalla, Mr. Khaled Farag, Kathie Wareham, Gill Forward and Lisa Bastin for their co-operation. The sincere and continued help of Mr. Emery's secretary, Lorna Keyes, has been most appreciated.

Finally, I wish to thank the library staff at Singleton and Royal Glamorgan hospitals, in South Wales as well as the Royal Bournemouth hospital, in Southern England, for coping enthusiastically with the demands for reference material.

Dr. Sharif I. M. F. Ismail

June 4th., 2006.

Yeovil District Hospital, Somerset, England, UK.

Abstracts:

1. Extra-corporeal magnetic energy stimulation of pelvic floor muscles for urodynamic stress incontinence:

Objective: To assess the efficacy and practicalities of extra-corporeal magnetic energy stimulation of pelvic floor muscles as a non-invasive technique for urodynamic stress incontinence of urine in women.

Design: Prospective non-controlled study.

Setting: 2 district general hospitals.

Population: Female patients with urodynamic stress incontinence of urine.

Main outcome measures: Pad test, continence diary, quality of life assessment using the King's health and EuroQol questionnaires as well as side effects and drop out.

Method: 18, twice weekly sessions. Assessment was made on recruitment, at the end of treatment and at 3 months follow up.

Results: 48 patients were recruited, 31 completed treatment sessions and 27 attended for follow up at 3 months. There was no significant change in outcome measures at the end of treatment as well as at 3 months follow up. Side effects were encountered by 52.1% of patients and the drop out rate was 35.4%. Relevant side effects were significantly more common in those who dropped out.

Conclusions: Extra-corporeal magnetic energy stimulation of pelvic floor muscles seems unlikely to improve urodynamic stress incontinence of urine. This appears to be due to the passive nature of the contractions evoked. Side effects are prominent and appear to contribute to the drop out rate.

2. Transvaginal radiofrequency remodelling of the endopelvic fascia for urodynamic stress incontinence due to urethral hypermobility:

Objective: To assess the efficacy and safety of transvaginal radiofrequency remodelling of the endopelvic fascia as a minimally invasive technique for urodynamic stress incontinence of urine due to urethral hypermobility in women.

Design: Prospective non-controlled study.

Setting: 3 district general hospitals and 1 university hospital.

Population: Female patients with urodynamic stress incontinence of urine due to urethral hypermobility.

Main outcome measures: Pad test, urodynamic assessment, continence diary, pain scores and operative as well as post-operative complications.

Method: Transvaginal radiofrequency of the endopelvic fascia. Assessment was made on recruitment, during hospital admission and at 3, 6 and 12 months follow up.

Results: 24 patients were available for analysis. A rising failure rate was noted as early as 3 months, leading to a cumulative cure rate of 36% at 12 months follow up. No major complications were encountered and pain scores were mild.

Conclusions: The effectiveness of transvaginal radiofrequency remodelling of the endopelvic fascia for urodynamic stress incontinence of urine due to urethral hypermobility appears to be low. Inherent weakness of the endopelvic fascia appears to be the main reason. The technique has a low complication and pain profile.

3. Comparison between the tension-free vaginal tape (TVT), pelvicol as well as short autologous slings for urodynamic stress incontinence:

Objective: To compare the efficacy and morbidity of the tension-free vaginal tape (TVT), pelvicol as well as short autologous slings, as minimally invasive technique for urodynamic stress incontinence of urine in women.

Design: Muticentre randomised controlled single blind study.

Setting: 4 district general hospitals and 2 teaching university hospitals.

Population: Female patients with urodynamic stress incontinence of urine.

Main outcome measures: Quality of life and symptom assessment using Bristol Female Lower Urinary Tract Symptoms as well as EuroQol questionnaires, pad test, continence diary, operating time, stay in hospital, operative as well as post-operative complications.

Method: Tension-free vaginal tape (TVT), pelvicol or short autologous sling insertion. Assessment was made on recruitment, during hospital stay and at 6 weeks as well as 6 and 12 months follow up.

Results: A total of 181 patients were recruited. An interim analysis of re-operation rate showed a significantly higher rate with pelvicol, necessitating closure of this arm. All pelvicol failures appeared after 6 months, raising the possibility of a delayed reaction. No significant difference was observed between the tension-free vaginal tape (TVT) and short autologous slings in terms of operative as well as post-operative complications, pad test and continence diary. Operating time and post-operative stay in hospital were significantly shorter following the tension-free vaginal tape (TVT) sling than after the short autologous one. This reduces the higher capital cost of the tension free vaginal tape (TVT) sling. There was also a short term advantage in quality of life assessment.

Conclusions: Pelvicol slings are associated with a delayed failure, and should not therefore be used for continence surgery. Although both the tension-free vaginal tape (TVT) and short autologous slings are equally effective and have a comparable complications profile, the tension-free vaginal tape (TVT) sling is quicker to insert and is followed by a shorter stay in hospital; 2 features that reduce its higher cost. It is also associated with a better quality of life change in the short term.

Table of contents:

	Page
1. Introduction	**1**
Urodynamic stress incontinence of urine in women	1
New non-invasive and minimally invasive techniques	3
Aim and objectives	4
Sequence	4
Involvement in the work	5
2. Management options	**7**
A. Non-invasive measures	7
1. Pelvic floor exercises	7
2. Electrical stimulation	10
3. Mechanical devices	15
4. Medical treatment	15
B. Surgical measures	16
1. Anterior repair with bladder neck buttressing	16
2. Colposuspension	17
3. Sling operations	20
4. Needle suspension	23
5. Bladder neck injections (urethral bulking agents)	24
3. Extra-corporeal magnetic energy stimulation	**29**
Background	29
Method	45
Results	49
Primary outcome measure	50
Secondary outcome measures	51
The relation between side effects and drop out	69
The end of treatment outcome in those who had 20% reduction in pad test	72

Discussion 77
Conclusions 85
Recommendations 86
4. Radiofrequency remodelling of the endopelvic fascia 87
Background 87
Method 104
Results 110
Primary outcome measure 112
Secondary outcome measures 113
Comparison between those who had failure and those who did not 117
Discussion 120
Conclusions 129
Recommendation 130
5. The tension-free vaginal tape (TVT) sling 131
Background 131
Comparison with other minimally invasive slings 137
Method 140
Results 146
Comparison between the tension-free vaginal tape (TVT) and short autologous slings 149
Interim analysis of re-operation rate 161
Comparison between those who had failed pelvicol sling and those who did not 162
Outcome in those patients who had a successful pelvicol sling 169
Outcome in those patients who had a failed pelvicol sling 179
Discussion 190
Conclusions 201
Recommendations 202
6. References 203
7. Appendix 1 226

List of tables:

Number	Title	Page
Extra-corporeal magnetic stimulation of pelvic floor muscles:		
3.1	The distribution of the cohort according to their background features, in the magnetic stimulation study	49
3.2	The distribution of the cohort according to their medical, surgical and medication history, in the magnetic stimulation study	49
3.3	Comparison between pad test at recruitment and end of treatment visits, in the magnetic stimulation study	50
3.4	Comparison between pad test at recruitment and 3 months follow up visits, in the magnetic stimulation study	51
3.5	Comparison between continence parameters at recruitment and end of treatment visits, in the magnetic stimulation study	51
3.6	Comparison between continence parameters at recruitment and 3 months follow up visits, in the magnetic stimulation study	51
3.7	Comparison between quality of life scores, as measured by the domains of King's health questionnaire, at recruitment and end of treatment visits, in the magnetic stimulation study	52
3.8	Comparison of symptom scores, as measured by of the King's health questionnaire, at recruitment and end of treatment visits, in the magnetic stimulation study	53
3.9	Comparison of quality of life domains, as measured by the King's health questionnaire, at recruitment and 3 months follow up visits, in the magnetic stimulation study	54
3.10	Comparison of symptom scores, as measured by of the King's health questionnaire, at recruitment and 3 months follow up visits, in the magnetic stimulation study	55
3.11	Comparison between the EuroQol values at recruitment and end of	

	treatment visits, in the magnetic stimulation study	56
3.12	Comparison of EuroQol values at recruitment and 3 months follow up visits, in the magnetic stimulation study	56
3.13	The incidence of side effects during the magnetic stimulation study.	57
3.14	The incidence of side effects during various visits, in the magnetic stimulation study	58
3.15	The frequency of side effects encountered in the magnetic stimulation study	60
3.16	The rate of drop out in the magnetic stimulation study	61
3.17	The rate of drop out following various visits, in the magnetic stimulation study	62
3.18	The reasons for drop out, in the magnetic stimulation study	63
3.19	Comparison of demographic data between those who completed all treatment session and who dropped out, in the magnetic stimulation study	64
3.20	Comparison of the duration of incontinence between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study	64
3.21	Comparison of the medical, surgical as well as medication history between those who completed all treatment session and who dropped out, in the magnetic stimulation study	65
3.22	Comparison of the continence parameters on recruitment between those who completed all treatment session and who dropped out, in the magnetic stimulation study	65
3.23	Comparison of the quality of life domains, as measured by the King's health questionnaire, on recruitment between those who completed all treatment session and who dropped out, in the magnetic stimulation study	66
3.24	Comparison of symptom scores in the King's health questionnaire,	

according to completion of treatment sessions, in the magnetic stimulation study 67

3.25 Comparison of the EuroQol values on recruitment between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study 68

3.26 Comparison of the incidence of side effects and relevant side effects between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study 69

3.27 Comparison of the weight of those who had relevant side effects and those who did not, in the magnetic stimulation study 71

3.28 The distribution of patients according to the reduction in pad test leakage at the end of treatment visit, in the magnetic stimulation study 72

3.29 Comparison of daily pad use and leakage episodes values at recruitment and end of treatment visits, in those patients who had a ≥ 20% in pad test, in the magnetic stimulation study 72

3.30 Comparison of scores of quality of life domains, as measured by the King's health questionnaire, at recruitment and end of treatment visits, in those patients who had a ≥ 20% in pad test, in the magnetic stimulation study 73

3.31 Comparison of scores of symptom scores, as measured by the King's health questionnaire, at recruitment and end of treatment visits, in those patients who had a ≥ 20% in pad test, in the magnetic stimulation study 74

3.32 Comparison of EurQol values at recruitment and end of treatment visits in those patients who had a ≥ 20% reduction in pad test, in the magnetic stimulation study 75

Radiofrequency remodelling of the endopelvic fascia:

4.1 The demographic data and duration of incontinence for cases included in the radiofrequency study 110

4.2	The distribution of the cohort according to their medical and surgical history as well as the degree of cystocele, in the radiofrequency study	111
4.3	The operative data for cases included in the radiofrequency remodelling study	111
4.4	Comparison of pad test between pre-operative and 3 months follow up visits, in the radiofrequency remodelling study	112
4.5	Comparison of pad test between pre-operative and 6 months follow up visits, in the radiofrequency study	112
4.6	Comparison of pad test between pre-operative and 12 months follow up visits, in the radiofrequency study	112
4.7	Comparison of continence parameters between pre-operative and 3 months follow up visits, in the radiofrequency study	113
4.8	Comparison of continence parameters between pre-operative and 6 months follow up visits, in the radiofrequency study	113
4.9	Comparison of continence parameters between pre-operative and 12 months follow up visits, in the radiofrequency study	113
4.10	The operating time for cases included in the radiofrequency study	114
4.11	The distribution of post-operative pain in the radiofrequency study	114
4.12	Operative and post-operative complications in the radiofrequency study	114
4.13	Post-operative stay in hospital for cases included in the radiofrequency remodelling study	115
4.14	Comparison of anterior vaginal wall prolapse between pre-operative and 6 months follow up visits, in the radiofrequency study	115
4.15	Comparison of anterior vaginal wall prolapse between pre-operative and 12 months follow up visits, in the radiofrequency study	115
4.16	The outcome of urodynamic assessment at 6 months follow up in the radiofrequency study	116
4.17	Cumulative failure rate across follow up visits in the radiofrequency	

	remodelling study	116
4.18	Cumulative re-operation rate across follow up visits in the radiofrequency remodelling study	116
4.19	Comparison of demographic data between those who had a failed radiofrequency remodelling and those who did not	117
4.20	Comparison of continence parameters between those who had a failed radiofrequency remodelling and those who did not	118
4.21	Comparison of history data between those who had a failed radiofrequency remodelling and those who did not	118
4.22	Comparison of degree of cystocele between those who had a failed radiofrequency remodelling and those who did not	118
4.23	Comparison of operative data between those who had a failed radiofrequency remodelling and those who did not	119
Comparison between TVT and other minimally invasive slings:		
5.1	Comparison of demographic data between different sling groups, in the comparative sling study	147
5.2	Comparison of continence features between different sling groups, in the comparative sling study	147
5.3	Comparison of different sling groups according to their surgical history, in the comparative sling study	147
5.4	Comparison of different sling groups according to their medical history, in the comparative sling study	148
5.5	Comparison of the type of anaesthesia and the percentage of those having additional surgery in different sling groups, in the comparative sling study	148
5.6	The type of additional surgery in different sling groups, in the comparative sling study	148
5.7	A comparison of urinary symptoms at 6 months follow up, as measured by the Bristol Female Lower Urinary Tract Symptoms	

Questionnaire, between those who had a TVT sling and those who had a short autologous one 150

5.8 A comparison of sexual matters at 6 months follow up, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between those who had a TVT sling and those who had a short autologous one 151

5.9 A comparison of life style at 6 months follow up, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between those who had a TVT sling and those who had a short autologous one 152

5.10 A comparison of the urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one 153

5.11 A comparison of the sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one 154

5.12 A comparison of the life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one 155

5.13 A comparison of EurQol score at 6 months follow up, between those who had a TVT sling and those who had a short autologous one 156

5.14 A comparison of the EuroQol scores, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one 156

5.15 A comparison of operative data between those who had a TVT sling and those who had a short autologous one 157

5.16 A comparison of the incidence of +ve pad test at 6 months follow up between those who had a TVT sling and those who had a short

	autologous one	158
5.17	A comparison of the incidence of +ve pad test at 12 months follow up between those who had a TVT sling and those who had a short autologous one	158
5.18	A comparison of the incidence of intra-operative complications between those who had a TVT sling and those who had a short autologous one	159
5.19	A comparison of the incidence of post-operative complications between those who had a TVT sling and those who had a short autologous one	159
5.20	A comparison of incidence of problems at 6 weeks follow up between those who had a TVT sling and those who had a short autologous one	159
5.21	A comparison of the incidence of problems at 6 months follow up between those who had a TVT sling and those who had a short autologous one	160
5.22	A comparison of the incidence of problems at 12 months follow up, between those who had a TVT sling and those who had a short autologous one	160
5.23	A comparison of the rate of re-operation in different sling groups, in the comparative sling study	161
5.24	A comparison of the demographic features between those who had a failed pelvicol sling and those who did not	162
5.25	A comparison of the continence features between those who had a failed pelvicol sling by 12 months follow up and those who did not	162
5.26	A comparison of the medical history between those who had a failed pelvicol sling and those who did not	162
5.27	A comparison of the surgical history between those who had a failed pelvicol sling and those who did not	163
5.28	A comparison of urinary symptoms, as measured by the Bristol	

Female Lower Urinary Tract Symptoms Questionnaire, at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not 164

5.29 A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not 165

5.30 A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not 166

5.31 A comparison of the EuroQol scores at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not 166

5.32 A comparison of the operative data between those who had a failed pelvicol sling by 12 months follow up and those who did not 167

5.33 The additional surgery performed in those who had a failed pelvicol sling by 12 months follow up and those who did not 167

5.34 A comparison of the operating time and post-operative stay between those who had a failed pelvicol sling by 12 months follow up and those who did not 167

5.35 A comparison of the incidence of operative complications between those who had a failed pelvicol sling by 12 months follow up and those who did not 168

5.36 A comparison of the incidence of post-operative complications between those who had a failed pelvicol sling by 12 months follow up and those who did not 168

5.37 A comparison of the incidence of problems at 6 weeks follow up between those who had a failed pelvicol sling by 12 months follow up

	and those who did not	168
5.38	A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	170
5.39	A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	171
5.40	A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	172
5.41	A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	173
5.42	A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	174
5.43	A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	175
5.44	A comparison of EuroQol scores at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up	175
5.45	A comparison of the EuroQol scores, at recruitment and 12 months	

follow up in those patients whose pelvicol sling did not fail up till 12 months follow up 176

5.46 The incidence of +ve pad test at 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up 177

5.47 The incidence of +ve pad test at 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up 177

5.48 The incidence of problems at 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up 177

5.49 The incidence of problems at 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up 178

5.50 A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 6 months follow up in those who had a failed pelvicol sling by 12 months follow up 180

5.51 A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 6 months follow up in those who had a failed pelvicol sling by 12 months follow up 181

5.52 A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 6 months follow up in those who had a failed pelvicol sling by 12 months follow up 182

5.53 A comparison of the urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 12 months follow up in those who had a failed pelvicol sling by 12 months follow up 183

5.54 A comparison of the sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 12 months follow up in those who had a failed pelvicol

	sling by 12 months follow up	184
5.55	A comparison of the life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 12 months follow up in those who had a failed pelvicol sling by 12 months follow up	185
5.56	A comparison between the EuroQol scores at recruitment and at 6 months follow up in those who had a failed pelvicol sling by 12 months follow up	185
5.57	A comparison between the EuroQol scores at recruitment and at 12 months follow up in those who had a failed pelvicol sling by 12 months follow up	186
5.58	The incidence of +ve pad test at 6 months follow up in the patients who had a failed pelvicol sling by 12 months follow up	187
5.59	The incidence of +ve pad test at 12 months follow up in the patients who had a failed pelvicol sling by 12 months follow up	187
5.60	The incidence of problems at 6 months follow up in those who had a failed pelvicol sling by 12 months follow up	187
5.61	The incidence of problems at 12 months follow up in those who had a failed pelvicol sling by 12 months follow up	188

List of figures:

Number	Title	Page
2.1	The position of the bladder neck in relation to the pelvic floor	7
2.2	Vaginal cones	8
2.3	Modern portable electrical stimulation device and electrode	12
2.4	The bladder neck support prosthesis	15
2.5	Anterior repair with bladder neck buttressing	17
2.6	The Burch colposuspension	17
2.7	Laparoscopic colposuspension	19
2.8	Sling operation	21
2.9	Needle suspension	23
2.10	Paraurethral injection of urethral bulking agents	24
3.1	The control unit, the treatment chair and a diagram of the electromagnetic fields traversing across pelvic floor muscles	35
3.2	The electric circuit used for magnetic stimulation	36
3.3	Three dimensional view of the stimulation coil	37
4.1	The steps of transvaginal radiofrequency of the endopelvic fascia	93
4.2	The laparoscopic and transvaginal applicators	95
5.1	The tension-free vaginal tape (TVT) sling	129

List of charts:

Number	Title	Page
3.1	The incidence rate of side effects during treatment visits	59
3.2	The incidence of relevant side effects in those who completed treatment sessions and those who dropped out	70
4.1	Box plot of the weight of those who had a successful radiofrequency remodelling and those who had a failed one	117
5.1	Dotplot of the operating time	157
5.2	Dotplot of postoperative stay in hospital	158
5.3	Interim analysis failure rate	161

Swansea NHS Trust - Physiotherapy Department

PAD TESTING SCHEDULE

1. Test started without patient voiding.

2. A pre-weighted pad is put on by the patient and the test begins.
   *Patient is told not to void at all during the test.

3. The patient drinks ½ litre (500mls) of sodium free liquid.

4. The patient to sit down for ½ hour.

5. Then the patient must go for a 10 minute walk around the hospital.

6. Patient performs the following exercises:
   a) coughing x 10
   b) standing to pick up object from floor x 10
   c) standing to sitting x 10
   d) running on the spot or stepping up and down off stool x 10
   e) washing hands under water for 1 minute
   f) jumping on spot x 10

   (Obviously with certain patient e.g. asthmatics, elderly, considerations have to be taken with certain exercises).

* Some patient may require extra pads.

7. After the pad(s) have been in place for one hour the patient is given a measuring jug and asked to remove pad(s). Place it in a polythene bag (which the pad is initially weighed in), and void into the jug.

   The amount of urine passed and weight of pad post test are recorded. A loss of 1 gram can be considered due to sweating or vaginal discharge.

KING'S HEALTH QUESTIONNAIRE

1993

Name _____

Age _____ years

Todays date ___/___ 199

Office use

How would you describe your health at present ?

Please tick one answer

- Very good ○
- Good ○
- Fair ○
- Poor ○
- Very poor ○

/5

How much do you think your bladder problem affects your life ?

Please tick one answer

- Not at all ○
- A little ○
- Moderately ○
- Alot ○

/4

Please turn the page

We would like to know what your bladder problems are and how much they affect you. From the list below choose ONLY THOSE PROBLEMS that you have at present.

How much do they affect you ?

	A Little	Moderately	Alot	
FREQUENCY; going to the toilet very often.	○	○	○	☐
NOCTURIA; getting up at night to pass urine.	○	○	○	☐
URGENCY; a strong and difficult to control desire to pass urine.	○	○	○	☐
URGE INCONTINENCE; urinary leakage associated with a strong desire to pass urine.	○	○	○	☐
STRESS INCONTINENCE; urinary leakage with physical activity eg coughing, sneezing, running.	○	○	○	☐
NOCTURNAL ENURESIS; wetting the bed at night.	○	○	○	☐
INTERCOURSE INCONTINENCE; urinary leakage with sexual intercourse.	○	○	○	☐
FREQUENT WATERWORKS INFECTIONS;	○	○	○	☐
BLADDER PAIN;	○	○	○	☐
OTHER SPECIFY; _____	○	○	○	☐

Please turn the page

Office use ☐ + ☐ + ☐

King's Health Questionnaire, Version 7

Below are some daily activities that can be affected by bladder problems. How much does your bladder problem affect you ?
We would like you to answer every question. Simply tick the circle that applies to you.

ROLE LIMITATIONS	Not at all	Slightly	Moderately	Alot
To what extent does your bladder problem affect your household tasks (eg cleaning, shopping etc)	○	○	○	○
Does your bladder problem affect your job, or your normal daily activities outside the home?	○	○	○	○

PHYSICAL/SOCIAL LIMITATIONS	Not at all	Slightly	Moderately	Alot
Does your bladder problem affect your physical activities (eg going for a walk, run, sport, gymn etc)?	○	○	○	○
Does your bladder problem affect your ability to travel?	○	○	○	○
Does your bladder problem limit your social life ?	○	○	○	○
Does your bladder problem limit your ability to see/visit friends ?	○	○	○	○

PERSONAL RELATIONSHIPS	Not applicable	Not at all	Slightly	Moderately	Alot
Does your bladder problem affect your relationship with your partner?	○	○	○	○	○
Does your bladder problem affect your sex life?	○	○	○	○	○
Does your bladder problem affect your family life?	○	○	○	○	○

Please turn the page

Office use ☐☐ ☐☐ ☐☐ ☐☐☐

EMOTIONS

	Not at all	Slightly	Moderately	Very much
Does your bladder problem make you feel depressed?	○	○	○	○
Does your bladder problem make you feel anxious or nervous?	○	○	○	○
Does your bladder problem make you feel bad about yourself?	○	○	○	○

SLEEP / ENERGY

	Never	Sometimes	Often	All the time
Does your bladder problem affect your sleep ?	○	○	○	○
Do you feel worn out / tired?	○	○	○	○

Do you do any of the following?;

If so how much ?	Never	Sometimes	Often	All the time
Wear pads to keep dry?	○	○	○	○
Be careful how much fluid you drink?	○	○	○	○
Change your underclothes when they get wet?	○	○	○	○
Worry in case you smell?	○	○	○	○

Office use ☐☐☐ ☐☐ ☐☐☐☐

THANKYOU, NOW CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS

By placing a tick (thus ☑) in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

: I have no problems in walking about
: I have some problems in walking about
: I am confined to bed

Self-Care

: I have no problems with self-care
: I have some problems washing or dressing myself
: I am unable to wash or dress myself

Usual Activities

: I have no problems with performing my usual activities (eg work, study, housework, family or leisure activities)
: I have some problems with performing my usual activities
: I am unable to perform my usual activities

Pain/Discomfort

: I have no pain or discomfort
: I have moderate pain or discomfort
: I have extreme pain or discomfort

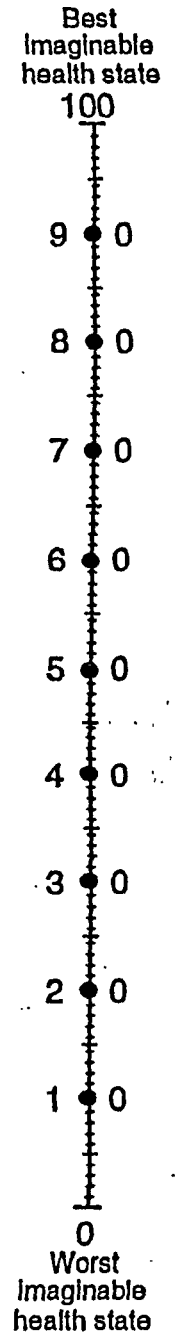
Anxiety/Depression

: I am not anxious or depressed
: I am moderately anxious or depressed
: I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale how good or bad is your own health today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your current health state is.

Your own health state today



Name..... Patient No

Date Date of Birth

URINARY SYMPTOMS QUESTIONNAIRE

We are trying to find out how much of a problem your urinary symptoms are to you. We would be grateful if you could help us by filling out this questionnaire

When answering the questions think about the **symptoms you have experienced in the past month.**

You will see that some questions ask if you have a problem occasionally, sometimes or most of the time.

Occasionally = **less than one third of the time**
Sometimes = **between one third and two thirds of the time**
Most of the time = **more than two thirds of the time**

Please tick one box for each question

1. During the day, how many times do you urinate on average?

1 to 6 times ☐	1
7 to 8 times ☐	2
9 to 10 times ☐	3
11 to 12 times ☐	4
13 or more times ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

2. During the night, how many times do you have to get up to urinate, on average?

none ☐	1
1 ☐	2
2 ☐	3
3 ☐	4
4 or more ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

3.	**Do you have to rush to the toilet to urinate?**	
	never ☐	1
	occasionally (less than one third of the time) ☐	2
	sometimes (between one and two thirds of the time) ☐	3
	most of the time (more than two thirds of the time) ☐	4
	all of the time ☐	5
	How much of a problem is this for you?	
	not a problem ☐	1
	a bit of a problem ☐	2
	quite a problem ☐	3
	a serious problem ☐	4

4.	**Does urine leak before you can get to the toilet?**	
	never ☐	1
	occasionally ☐	2
	sometimes ☐	3
	most of the time ☐	4
	all of the time ☐	5
	How much of a problem is this for you?	
	not a problem ☐	1
	a bit of a problem ☐	2
	quite a problem ☐	3
	a serious problem ☐	4

5.	**Do you have pain in your bladder?**	
	never ☐	1
	occasionally ☐	2
	sometimes ☐	3
	most of the time ☐	4
	all of the time ☐	5
	How much of a problem is this for you?	
	not a problem ☐	1
	a bit of a problem ☐	2
	quite a problem ☐	3
	a serious problem ☐	4

6. How often do you leak urine?

never ☐	1
once or less per week ☐	2
2-3 times per week ☐	3
once per day ☐	4
several times per day ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

7. Does urine leak when you are physically active, exert yourself, cough or sneeze?

never ☐	1
occasionally (less than one third of the time) ☐	2
sometimes (between one and two thirds of the time) ☐	3
most of the time (more than two thirds of the time) ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

8. Do you ever leak urine for no obvious reason and without feeling that you want to go?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

9. How much urinary leakage occurs?

No leakage ☐	1
Drops/pants damp ☐	2
Dribble/pants wet ☐	3
Floods, soaking through to outer clothing ☐	4
Floods, running down legs or onto floor ☐	5

10A. Do you have to change your underclothes or wear protection because of your leakage?

YES/NO

If NO please go to question 12

If YES please answer below

Change underclothes ☐	1
Panty liners/mini pads ☐	2
Maxi/super sanitary towels ☐	3
Nappies/Incontinence products ☐	4

Other; please specify.....

10B How many times a day do you change the above items because of leakage

No change required ☐	1
1 ☐	2
2-3 ☐	3
4-5 ☐	4
More than 5 times ☐	5

11. Do you need to change your <u>outer clothing</u> during the day because of urine leakage?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

12. Is there a delay before you can start to urinate?

never ☐	1
occasionally (less than one third of the time) ☐	2
sometimes (between one and two thirds of the time) ☐	3
most of the time (more than two thirds of the time) ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

13. Do you have to strain to urinate?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

14. Do you stop and start more than once while you urinate without meaning to?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

15. Do you leak urine when you are asleep?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

16. **Would you say that the strength of your urinary stream is...**

not reduced ☐	1
reduced a little ☐	2
quite reduced ☐	3
reduced a great deal ☐	4
no stream ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

17. **Have you ever blocked up completely so that you could not urinate at all and had to have a catheter to drain the bladder?**

no ☐	1
yes, once ☐	2
yes, twice ☐	3
yes, more than twice ☐	4

18. **Do you have a burning feeling when you urinate?**

never ☐	1
occasionally (less than one third of the time) ☐	2
sometimes (between one and two thirds of the time) ☐	3
most of the time (more than two thirds of the time) ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

19. **How often do you feel that your bladder has not emptied properly after you have urinated?**

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

20.	Can you stop the flow of urine if you try while you are urinating?	
	Yes, easily ☐	1
	Yes, with difficulty ☐	2
	No, cannot stop it flowing ☐	3

Sexual Matters

Please think about the past month

21. Do you have pain or discomfort because of a dry vagina?

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

Do you have a sex life at present?

YES/NO

If YES please go to question 22

If NO please go to question 25

22. To what extent do you feel that your sex life has been spoilt by your urinary symptoms

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

23. Do you have pain when you have sexual intercourse?

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

24.	**Do you leak urine when you have sexual intercourse?**	
	not at all ☐	1
	a little ☐	2
	somewhat ☐	3
	a lot ☐	4
	How much of a problem is this for you?	
	not a problem ☐	1
	a bit of a problem ☐	2
	quite a problem ☐	3
	a serious problem ☐	4

Lifestyle

Please think about the past month

25. How often do you pass urine during the day?

Hourly ☐	1
Every 2 hours ☐	2
Every 3 hours ☐	3
Every 4 hours or more ☐	4

How much of a problem is this for you?

Not a problem ☐	1
A bit of a problem ☐	2
Quite a problem ☐	3
A serious problem ☐	4

26. Do you cut down on the amount of fluid you drink so that your urinary symptoms improve, and you can do the things that you want to do?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

27. To what extent have your urinary symptoms affected your ability to perform daily tasks (e.g. cleaning, DIY, lifting objects)?

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

How much of a problem is this for you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

28. Do you avoid places and situations where you know a toilet is not nearby (e.g. shopping, travelling, theatre, church)?

never ☐	1
occasionally ☐	2
sometimes ☐	3
most of the time ☐	4
all of the time ☐	5

How much of a problem is this to you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

29. Do your urinary symptoms interfere with physical activity (e.g. walking, dancing, swimming)?

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

How much of a problem is this to you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

30. How much do your urinary symptoms interfere with your social life (going out, meeting friends and so on)?

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

How much of a problem is this to you?

not a problem ☐	1
a bit of a problem ☐	2
quite a problem ☐	3
a serious problem ☐	4

31. Overall, how much do your urinary symptoms interfere with your life?

not at all ☐	1
a little ☐	2
somewhat ☐	3
a lot ☐	4

32.	**How long have you had urinary symptoms <u>that bother you?</u>**	
	less than 1 year ☐	1
	1-2 years ☐	2
	2-3 years ☐	3
	more than 3 years ☐	4

33.	**If you had to spend the rest of your life with your urinary symptoms as they are now, how would you feel?**	
	Perfectly happy ☐	1
	Pleased ☐	2
	Mostly satisfied ☐	3
	Mixed feelings ☐	4
	Mostly dissatisfied ☐	5
	Very unhappy ☐	6
	Desperate ☐	7

34. **Which of your urinary symptoms bother you most at the moment?**
(please list the symptoms that bother you most below. Please describe the symptoms in your own words, or write the number of the question that comes closest to describing them):

1.

2.

3.

THANK YOU FOR YOUR HELP

If you have any comments you would like to make about the questionnaire or your urinary symptoms please use the space below

1. Introduction:

This thesis considers three non-invasive and minimally invasive techniques for urodynamic stress incontinence of urine in women. The three techniques are extra-corporeal magnetic energy stimulation of pelvic floor muscles, radiofrequency remodelling of the endopelvic fascia and the tension-free vaginal tape (TVT) sling. This introduction explains why this condition as well as these techniques have been selected, indicates the aim and objectives of evaluating these procedures and outlines how the evaluation is handled in various chapters.

Urodynamic stress incontinence of urine in women:

Definition:

The International Continence Society defines urodynamic stress incontinence of urine (formerly known as genuine stress incontinence) as the involuntary loss of urine during increased intra-abdominal pressure, in the absence of a detrusor contraction (Abrams et al, 2002). This distinguishes it from other forms of stress urinary incontinence such as detrusor overactivity (Abrams et al, 2002) as well as cases where there is a mixture of the two (Colombo et al, 1996).

Size of the problem:

The incidence of stress incontinence varies from 8.5% of the adult population, 2.5 million in the United Kingdom (Fenely et al, 1979; Elving et al, 1989) to 25% (Hannestad et al, 2000) and 30% (Thomas et al, 1980). Almost half of all women would admit to some degree of urinary incontinence (Yarnell et al, 1981), with urodynamic stress incontinence being the cause in half of these; 25% of the population (Jensen et al, 1994). With demographic changes and increase in elderly population, these figures are likely to rise even further (Yokoyama et al, 2004).

Impact of the condition:

Loss of bladder control can be distressing and most humiliating (Gardner & Fonda, 1994). Patients feel dirty, and this affects their self-esteem and wellbeing (Lagro-Janssen et al, 1992). They limit their activity, for fear of leakage, leading to their isolation (Nygaard et al, 1990). They feel embarrassed by their symptoms (Benness, 1997) such that only 10-20% of affected patients actually complain to their doctors (Yokoyama et al, 2004). For Muslems, who must be clean to pray and read the Koran, it affects their ability to fulfil their religious and worship obligations (Wood, 1998). The low self-esteem and limited activity reduce the quality of life (Norton et al, 1988; Hunskaar & Vinsens, 1991) and there are negative effects on sexual function (Temml et al, 2000; Barber et al, 2002) and marital relationship (Yip et al, 2003).

Outline of management options:

Management options include non-invasive approaches as well as surgery. Pelvic floor exercises and electrical stimulation of pelvic floor muscles have been the main stay of non-invasive techniques (Royal College of Obstetricians and Gynaecologists, 2003). Commonly performed operations include the Burch colposuspension and pubo-vaginal slings (Bidmead & Cardozo, 2000).

Whilst surgery has a better success rate, it entails risks. Common operative complications include bleeding and bladder injury and post-operative problems include voiding dysfunction and de novo detrusor overactivity (Chaliha & Stanton, 1999). Although minimally invasive slings, like the tension-free vaginal tape (TVT) sling, are associated with less complications, especially when such techniques are performed as day case, problems like tape erosion, bleeding and voiding dysfunction can still happen (Ward & Hilton, 2002).

It is therefore advisable for all patients to try conservative measures before considering surgical interventions. These measures have a reasonable chance of cure, reaching 50% (one in two patients) in some reports (Bo et al, 1999) and do not have major side effects (National Institute of Clinical Excellence, 2003). Yet, these measures have their limitations. Both pelvic floor exercises and electrical stimulation take time and depend on patient compliance (Yalcin et al, 1998). Electrical stimulation entails the insertion of electrodes in the vagina or anal canal (Eriksen et al, 1987) and this can be inconvenient for patients, who may also experience side effects like irritation and discomfort (Eriksen & Eik-Nes, 1989).

New non-invasive and minimally invasive techniques:

The thesis focuses on 3 new non-invasive and minimally invasive techniques for urodynamic stress incontinence of urine in women;

1. Extra-corporeal magnetic stimulation of pelvic floor muscles is a new non-invasive technique. It involves the generation of electromagnetic fields that can stimulate pelvic floor muscle contraction, as with electrical stimulation. Patients however do not have to undress and insert electrodes, as with electrical stimulation, because the electromagnetic fields spread easily through tissues (Galloway et al, 1999). There is however limited information about the effect of this technique to support its routine use in clinical practice.
2. Transvaginal radiofrequency remodelling of the endopelvic fascia restores normal support to the urethra. As the technique requires limited dissection, operative complications are minimal and patient recovery is quick. There is no need for catheterisation and there are no voiding problems (Dmochowski et al, 2003). Yet, there is limited information about the value of this technique to support its use alongside other minimally invasive procedures.
3. The tension-free vaginal tape (TVT) sling is a new minimally invasive sling that restores continence by creating a neo-pubo-urethral ligament to support the urethra. It has been

shown to have a comparable success rate to the Burch colposuspension, with lower incidence of complications (Ward & Hilton, 2002). However, little work has been carried out to compare it to other minimally invasive slings, such as the pelvicol and short autologous slings.

Aim and objectives:

The aim of this thesis was to explore the uncertain areas about these three non-invasive and minimally invasive techniques.

Its objectives were to;

1. assess the value of extra-corporeal magnetic stimulation of pelvic floor muscles.
2. assess the effect of transvaginal radiofrequency remodelling of the endopelvic fascia.
3. compare the tension-free vaginal tape (TVT) sling against the pelvicol and short autologous slings.

Sequence:

The thesis lies in four sections;

1. an overview of the management options for urodynamic stress incontinence of urine in women. This includes both non-invasive as well as surgical measures.
2. an outline of extra-corporeal magnetic stimulation of pelvic floor muscles. This is followed by the study assessing this technique.
3. an outline of radiofrequency remodelling of the endopelvic fascia. This is followed by the study looking at its value.
4. an outline of the tension-free vaginal tape (TVT) sling, followed by the study comparing it to other minimally invasive slings.

Some of the investigation tools, like urodynamic assessment and quality of life questionnaires, as well as the statistical tests used for data analysis were used in a number of studies. In order to avoid repetition, these tools are outlined in an appendix at the end.

Involvement in the work:

The candidate was involved in these studies as follows;

- extra-corporeal magnetic stimulation of pelvic floor muscles; as a specialist registrar in obstetrics and gynaecology, with special interest in urogynaecology, at Singleton hospital, the candidate recruited cases, carried out tests and followed patients up, as part of the study team. This study was supervised by Mr. Simon Emery, at Singleton hospital, and Mr. Malcolm Lucas, at Morriston hospital, in Swansea.
- Radiofrequency re-modelling of the endopelvic fascia; as a clinical research fellow in obstetrics and gynaecology at Bradford Royal Infirmary, the candidate was involved in the design of the study protocol. As a specialist registrar in obstetrics and gynaecology, with special interest in urogynaecology at Singleton hospital, the candidate was part of the team that recruited cases, carried out tests and treatment and followed patients up. The candidate trained previously at Barnsley District General hospital, and was therefore involved in the work done at this hospital as well. The study was supervised by Mr. Simon Emery, at Singleton hospital, in Swansea, Professor Peter O'Donovan and Dr. Susan Calvert at Bradford Royal Infirmary and Mr. Samir Henalla and Mr. Khaled Farag at Barnsley District General hospital.
- Three way sling trial; as a specialist registrar in obstetrics and gynaecology, with special interest in urogynaecology, at Singleton hospital, the candidate was part of the team that recruited cases, carried out tests and surgery and followed up patients. This work was

supervised by Mr. Simon Emery, at Singleton hospital, and Mr. Malcolm Lucas, at Morriston hospital, in Swansea.

All statistical analysis was the candidate's work, apart from the Fisher's exact test for three groups, included in the 3 way sling trial. Help for this analysis was obtained from Professor Peter Thomas PhD, who is the Professor of Health Care Statistics and Epidemiology at the University of Bournemouth and adviser to Dorset Research and Development Department. This help was sought locally while covering as locum consultant at the Royal Bournemouth Hospital, in Dorset. Professor Peter Thomas also provided guidance regarding the plan of analysis for the 3 way sling trial, after closing the pelvicol arm. All the literature search and appraisal, writing and production of graphs was the candidate's work.

2. Management options:

Management options include non-invasive approaches as well as surgery.

A. Non-invasive measures:

1. Pelvic floor exercises:

Pelvic floor exercises were first described by Arnold Kegel (1948) and entail repeated voluntary rhythmic contraction and relaxation of the levator ani muscles. These muscles support the bladder neck and contribute to the skeletal muscle component of the urethral sphincter (Bo, 1995). The aim is to strengthen muscle support to the bladder neck and the urethral sphincter, so as to prevent leakage on coughing and straining (Bump et al, 1991).

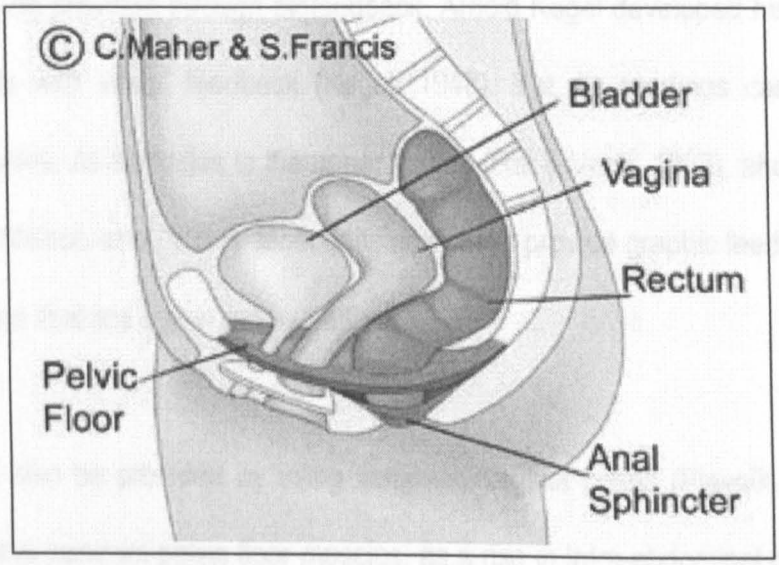


Figure No. 2.1. The position of the bladder neck in relation to the pelvic floor*.

An increase in the power of voluntary contraction alone does not prevent leakage (Dougherty et al, 1993). It is the speed and strength of contraction during stress that matter (Bo et al, 1990).

* http://www.urogynaecology.com.au/CM.htm, at 22:15GMT on 26.10.2004.

Training therefore needs to cover both types of muscle fibres, type I (slow twitch) and type II (fast twitch) (Berghmans et al 1998), in the form of sustained contractions as well as the stop test. The process however takes time and a minimum of 8 weeks is needed for any improvement (Wilson, 1990; DiNubile, 1991; Cammu & Hnylen, 1995).

Technique:

The first step is for the patient to identify and contract her pelvic floor muscles. Verbal instruction alone is insufficient to get patients to contract the right muscles (Bo et al, 1988). Up to a third of patients might not be able to locate and contract their pelvic floor muscles properly (Bo et al, 1990; Laycock & Holmes, 2003). The pubococcygeus is identified by palpation with one finger, 1cm above the interoitus and immediately inside the pubic rami.

Assistance can be provided through biofeedback. Arnold Kegel developed his perineometer to provide patients with visual feedback (Kegel, 1948). Yet, its readings can be affected by abdominal muscles, as its tip lies in the upper vagina (Rai & Versi, 1993), and reproducibility is therefore poor (Wilson et al, 1991). Most units nowadays provide graphic feedback on the basis of vaginal probes that are squeezed by patients.

Feedback can also be provided by using weighted vaginal cones (Plevnik, 1985). Their use guides patients to contract pelvic floor muscles, as a rise in intra-abdominal pressure will make it difficult to retain the cones in the vagina (Rai & Versi, 1993). Yet, they are messy such that continuation rates are low, reaching 42% at 12 months, and most patients (58%) prefer pelvic floor exercises alone (Wilson & Borland, 1988). Their use is also time-consuming and requires professional input on a number of occasions (Mantle & Versi, 1991).

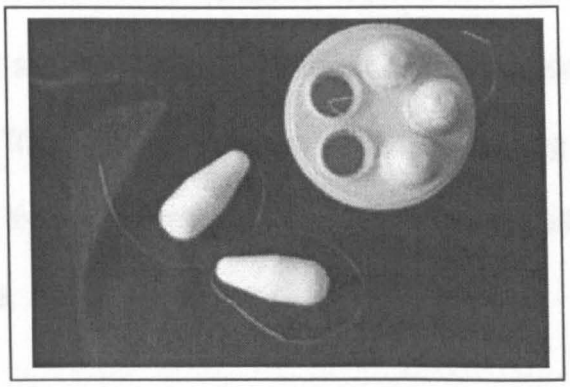


Figure No. 2.2. Vaginal cones*.

Patients are also taught about the Knack (Miller et al, 1996), which is contracting their pelvic floor muscles before and after stress, such as cough or sneezing. Likewise, they are instructed about the stop test (Gosling, 1979), which entails attempting to stop the flow of urine several times during micturition.

Value:

Pelvic floor exercises are more effective than no treatment, as shown in randomised controlled trials (Lagro-Janseen et al, 1991; Burns et al, 1993) and endorsed in a recent Cochrane review (Hay-Smith et al, 2004). However, there is significant variation in success rates. Kegel reported 80% cure rate and 100% improvement rate (Kegel, 1951; Kegel, 1956). Yet, such high rates have never been reproduced even by those who followed his scheme (Sand et al, 1995). Others reported cure rates of 36% (Amuzu, 1998) and 50% (Morkved et al, 2002), which are modest in comparison to surgery (Yalcin et al, 1998). Biofeedback does not improve these rates (Berghmans et al, 1998; Morkved et al, 2002) and vaginal cones do not provide any advantage either (Peattie & Plevnik, 1988; Haken et al, 1991; Pieber et al, 1995).

* http://www.obgyn.net/women/articles/sm_slide5.jpg, at 22: 40GMT, on 26.10.04.

This limited effectiveness undermines the appeal of pelvic floor exercises. Although they have no side effects, patient satisfaction lies in the range of 40%, compared to 70% with surgery (Klarskov et al, 1991). Those leading active life would prefer having an operation, with all the possible complications, than having to perform exercises daily and attend clinics repeatedly, for such a low success rate.

Pelvic floor exercises require input from physiotherapists and this has its economic implications. In addition to providing initial instruction, as outlined already, hospital based programmes have better compliance and cure rates than home exercises (Wilson et al, 1987; Henalla et al 1988, Bo et al, 1990; Yalcin et al, 1998). Whilst exercises do not require expensive equipment or patient stay in hospital, it takes about 40 minutes to orientate patients about pelvic anatomy and teach them how to contract their muscles (Mantle & Versi et al, 1991). Similarly, community based programmes avoid the need for hospital attendance (Holtedahl et al, 1998), yet they rely on the presence of physiotherapists, with relevant equipment and material, and this reduces cost savings.

Pelvic floor exercises are patient dependent (Wilson, 1990). Exercises need to be carried out several times each day and patients need to hold contractions for few seconds each time. This requires high degree of motivation to succeed (Mantle & Versi, 1991). Over a third of patients may not comply (Yalcin et al, 1998), leading to low success rate (Rai & Versi, 1993).

2. Electrical stimulation:

Mechanism of action:

Electrical stimulation effects passive contraction of the pelvic floor muscles (Alexander et al, 1970), through action on the muscles and the pudendal nerve that supplies them (Yamanishi &

Yasuda, 1998). As with pelvic floor exercises, the process takes time and some suggested a minimum of 14 weeks before judging the effect (Miller et al, 1998).

Current characteristics are important. The stimulation threshold varies inversely with the distance between the nerve and the stimulating electrode (Fall, 1998). That is why electrodes need to be inserted in the vagina or anus. There is also an inverse relationship between the duration of stimulation and current intensity, such that sessions can be shortened by increasing intensity (Fall & Lindstrom, 1991). Yet, as the pelvic area is sensitive, stimulation can lead to pain at an intensity that is not too far from that effecting contraction (Ohlsson, 1988). This leaves limited room for increasing the intensity to shorten treatment sessions (Geirsson & Fall, 1997).

The frequency is also important. The contractile properties of the fast and slow motor units necessitate a relatively high stimulation frequency. This is fortunate, as low frequency is unpleasant to patients, who will be aware of each pulsation (Fall, 1998). Commonly used frequency ranges between 20 and 50 Hz (Erlandson et al, 1978; Jonasson et al, 1990; Yasuda & Yamanishi, 1999).

Two types of stimulation have been tried (Yasuda & Yamanishi, 1999). First came chronic (long term) stimulation, relying on low intensity current delivered for several hours a day over several months (Eriksen et al, 1987; Fall, 1984). Then came maximal (short term) stimulation, utilising current of maximal intensity delivered intermittently over a short period of time (Shepherd et al, 1984; Plevnik & Janez, 1979). As there is little difference in outcome between the two types, maximal (short term) stimulation is preferred because it is more practical (Geirsson & Fall, 1997; Sand et al, 1995).

Technique:

Modern electrical stimulation of pelvic floor muscles uses vaginal and anal electrodes (Eriksen et al, 1987). There is no difference in effectiveness between the two (Erikson et al, 1987) and as anal electrodes can cause discomfort (Eriksen & Eik-Nes, 1989), vaginal electrodes are more popular.

Figure No. 2.3. Modern portable electrical stimulation device and electrode*.

Modern devices are small (portable) and can therefore be used at home or in general practice. A device is composed of an electrode and a control unit, which contains the battery. Vaginal electrodes are more commonly used, as with the Innova device (Miller et al, 1998), though anal electrodes are also available, as with Incontan device (Leach & Bavendam, 1989).

* http://www.biomation.com/inco/products.html#Microgyn%20II at 22:20GMT on 26.10.04.

Reports on the format of treatment varied. Sessions ranged from 15 minutes (Miller et al, 1998) to 20 (Caldwell et al, 1968) and 60 minutes (Smith, 1996). Whilst some recommended a minimum of 4-6 weeks (Plevnik et al, 1986), others indicated that 14 weeks of stimulation is necessary before improvements are noticed (Miller et al, 1998). The frequency of sessions varied from twice daily (Sand et al, 1995) and alternate days (Miller et al, 1998) to twice weekly (Geirsson & Fall, 1997).

In practice, electrical stimulation is often used with other non-invasive approaches (Bo, 1998). Before electrical stimulation is used, patient assessment is carried out, as outlined already. Then the physiotherapist describes the device to the patients, tests it, to ensure that it works and is safe, and then demonstrates its use to the patient. Home treatment and follow up are arranged according to patients' needs as well as clinic protocols.

Value:

Whilst some reported improvement rates ranging from 60% to 90% (Plevnik & Janez, 1979; Fall et al, 1986; Eriksen & Eik-Nes, 1989), others showed no benefit at all (Hahn et al, 1991; Smith, 1996). Although some controlled studies found significant improvement with active device (Laycock & Jerwood, 1993), others did not (Sand et al, 1995; Brubaker et al, 1997).

Some studies showed pelvic floor exercises to be better than electrical stimulation (Henalla et al, 1989; Bo et al, 1999), yet others showed no difference (Berghmans et al, 1998; Bo, 1998). Likewise, one study showed better outcome with electrical stimulation in combination with pelvic floor exercises (Blowman et al, 1991), though another showed no difference (Wilson et al, 1987). The view that electrical stimulation is no better than pelvic floor exercises is

supported by evidence from muscle training in general, where voluntary contractions are considered to be more effective than passive ones (Dudley & Harris, 1992).

Unlike pelvic floor exercises, the technique can have side effects and this can affect patient compliance (Eriksen & Eik-Nes, 1989). Common side effects include irritation, pain, discomfort and mucosal injury (Okada et al, 1998, Indrekvam & Hunskaar, 2002). Such side effects have been reported with active and sham devices (Sand et al, 1995), suggesting that the mere introduction of internal electrodes can be unpleasant to patients.

The technique is still patient dependent. Although patients do not have to contract their muscles, they still have to undress, insert electrodes and operate machines, which can be inconvenient for elderly patients. When sessions are provided in hospitals or general practice, patients will have to attend, which can be difficult for some (Miller et al, 1998). This affects continuation and compliance, just as with pelvic floor exercises. Although compliance rates of 80% have been reported (Sand et al, 1995; Smith, 1996), it is questionable whether this represents patients seen in day to day practice.

The technique also relies on professional input (Yasuda & Yamanishi, 1999) and this has its implications. Patients need not only to be orientated about the pelvic floor, as with pelvic floor exercises, but to know how to operate devices and to attend for follow up as well. This reliance on staff reduces the economic benefit of the relatively inexpensive equipment (Fall, 1998) as well as any cost savings from providing treatment in general practice (Plevnik et al, 1986; Holtedahl et al, 1998).

3. Mechanical devices:

Mechanical devices include intra-urethral ones, such as urethral plugs (Nielsen et al, 1990; Staskin et al, 1996) and bladder neck support prosthesis (Moore et al, 1999). They occlude the urethra so as to prevent leakage on stress. They are quite cumbersome, especially for elderly patients, and their use has been associated with pain, haematuria and urinary tract infection; and as a result they are seldom used nowadays (Junemann, 2001).

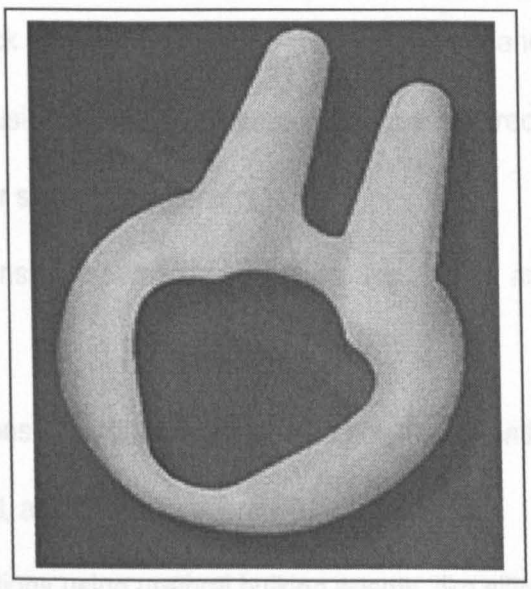


Figure No. 2.4. The bladder neck support prosthesis*.

4. Medical treatment:

Estrogens, imipramine and duloxetine have been tried. Estrogen improves postmenopausal atrophy, yet the effect in improving incontinence is limited (Jackson et al, 1999). Imipramine is a tricylcic antidepressant with α-agonist and anticholinergic effects, but never gained much popularity (Lin et al, 1999). Duloxetine inhibits the re-uptake of serotinin and noradrenaline and is currently under investigation (Norton et al, 2002). A randomised double blind controlled study showed a 50% decrease in incontinence episodes in 50% of patients. Cure (no leakage) was not reported and over a fifth (22%) stopped the medication because of side effects (Van

* http://www.aafp.org/afp/20000501/2719_f5.jpg at 22:35GMT on 26.10.04.

Kerrebroeck et al, 2004). Whilst this might be better than other medications, it is still less effective than surgery and patients need to take tablets regularly, which depends on their compliance.

B. Surgical measures:

Many continence operations have been described, but they can be broadly grouped into the following categories (Jarvis, 1994);

- vaginal bladder neck buttressing, as done in anterior repair and Kelly's sutures.
- sling operations, using either autologous, such as the rectus sheath and fascia lata, cadavers, animal or synthetic material.
- retropubic suspension operations, such as the Burch and Marshall-Marchetti-Krantz colposuspensions.
- long needle suspension, without cystoscopic control, as with Pereyra procedure, or with cystoscopic control, as in Stamey operation.
- bladder neck injections using urethral bulking agents, like silicone or collagen.

1. Anterior repair with bladder neck buttressing:

This is a commonly performed operation for cases associated with anterior vaginal wall prolapse (cystocele), making it a familiar procedure for the ordinary gynaecologist (Royal College of Obstetricians and Gynaecologists, 2003). Although short term results are good, with cure rates in the range of 67.8 - 72% (Jarvis, 1994), there is a definite decline with time, reaching 30% at 5 years (Bergman & Elia, 1995). A recent Cochrane review concluded that the procedure is inferior to open retropubic operations (Galzer & Cooper, 2004).

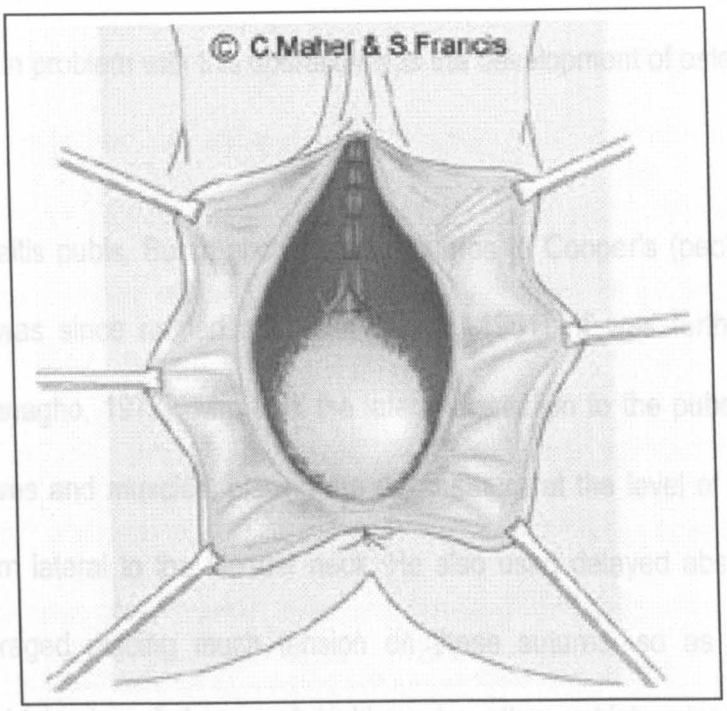


Figure No. 2.5. Anterior repair with bladder neck butressing*.

2. Colposuspension:

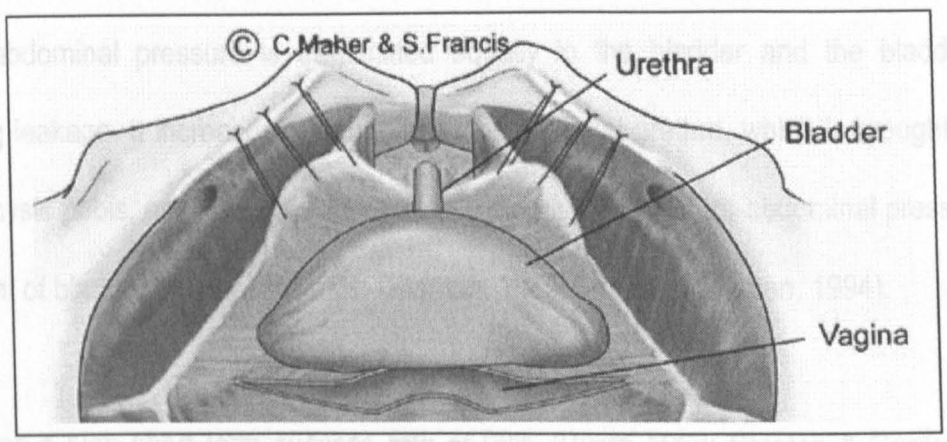


Figure No. 2.6. The Burch colposuspension*.

Marshall-Marchetti-Krantz operation was the first colposuspension to be described. It entails suturing the area on either side of the bladder neck to the periosteum of symphysis pubis

* http://www.urogynaecology.com.au/images/Vag_ant_rep2.jpg at 14:06GMT, on 3.11.04.
* http://www.urogynaecology.com.au/images/Sml_Colposuspension1.jpg at 21:12 GMT on 26.10.2004.

(Marshall et al, 1949). The success rate was 82%, with a further 7% showing some improvement. The main problem with this operation was the development of osteitis pubis.

In order to avoid osteitis pubis, Burch anchored the sutures to Cooper's (pectineal) ligament and the procedure was since named after him (Burch, 1961). It was further modified by Tanagho in 1976 (Tanagho, 1976), who took the lateral dissection to the pubocervical fascia, avoiding midline nerves and muscles, placing the distal suture at the level of the mid-urethra and the proximal 2cm lateral to the bladder neck. He also used delayed absorbable sutures (dexon) and discouraged placing much tension on these sutures, so as to avoid tissue necrosis, which could lead to failure, and kinking of urethra, which might cause voiding dysfunction.

The procedure works by elevating the bladder neck above the pelvic floor such that any rise in the intra-abdominal pressure is transmitted equally to the bladder and the bladder neck, preventing leakage. It increases the support to the proximal urethra, which is brought close to the symphysis pubis, enabling its compression during increased intra-abdominal pressure, with an element of bladder outlet obstruction (Stanton, 1985; Monga & Stanton, 1994).

It combines a high short term success rate of 90% (Burch 1968; Stanton & Cardozo, 1979; Jarvis 1994) and slow decline over time (Bergman et al, 1989), reaching a plateau of 69% at 10 years (Alcalay et al, 1995), which is better than most surgical procedures (Herbertsson & Iosif, 1993). It has therefore been regarded as the gold standard for assessing new procedures (Cardozo et al, 1999), a view endorsed by a recent Chocrane review (Lapitan et al, 2004).

It is usually done under general anaesthesia through a long abdominal incision and entails extensive dissection of the retropubic space, which can lead to bleeding. A suprapubic catheter is left for clamping few days later, while the patient remains in hospital. There is also the risk of bladder perforation that can pass undetected (Stevenson et al, 1999). Elderly patients are particularly at risk of early voiding difficulty after colposuspension (Smith & Cardozo, 1997).

Long term problems include voiding dysfunction, which has been reported in up to 20% of cases (Lose et al, 1987) and de novo detrusor overactivity, in up to 18% of patients (Cardozo et al, 1979). Vaginal prolapse may develop in 25% of cases and dyspareunia in 10% within 5 years (Wiskind et al, 1992). Burch encountered enterocele in 7.6% of cases, prompting him to advocate obliterating the cul-de-sac, as a preventive measure (Burch, 1968).

Laparoscopic colposuspension:

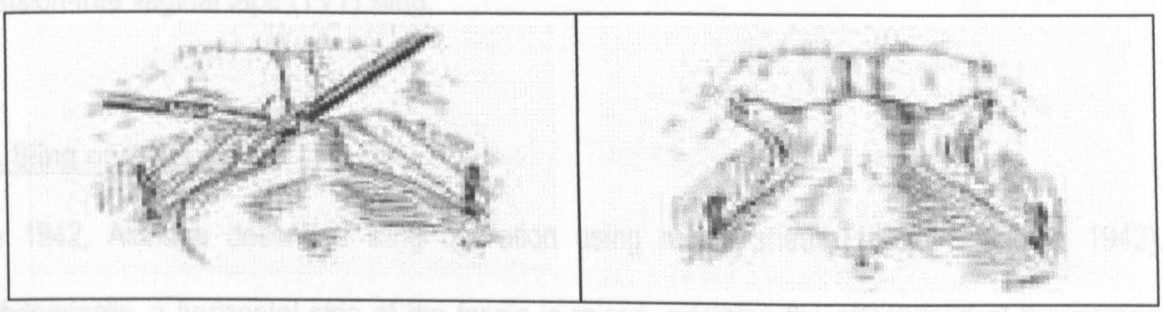


Figure No. 2.7. Laparoscopic colposuspension*.

With advances in instrument and imaging design, it became possible to perform colposuspension laparoscopically (Smith & Stanton, 1998). The effectiveness of the technique

*http://uk.search.yahoo.com/search/images?p=laparoscopic+colposuspension&ei=UTF-8&fl=0&fr=fp-tab-web-t&b=21, at 14:25GMT, on 3.11.2004.

however varied in different reports. Subjective cure rate ranged from 70% (Flax, 1996) to 100% (Carter, 1995) and objective cure rate from 89% (Ross, 1998) to 100% (Pelosi & Pelosi, 1998).

As a minimally invasive technique, it has several advantages. Incisions are small (Liu, 1994), which, in addition to being cosmetic, reduces post-operative pain and analgesic requirements (Su, 1997). Patients are often discharged home early (Vancaillie & Schuessler, 1991) and their recovery is shorter (Liu, 1993; Su et al, 1997; Fatthy et al, 2001).

Nonetheless, the technique has a steep learning curve (Buller & Cundiff, 2000) and thus a long operating time (Kohli et al, 1997; Summitt et al, 2000). A recent Cochrane review (Moehrer, 2004) concluded that laparoscopic colposuspension has a poorer long term success rate than open colposuspension. Although it does speed patient recovery, it takes longer to perform and might be associated with increased surgical complications. This meant that the role of laparoscopic colposuspension is certain to be limited, especially with the introduction of tension-free vaginal tape (TVT) sling.

3. Sling operations:

In 1942, Aldridge described sling operation using rectus sheath fascia (Aldridge, 1942). Abdominally, a horizontal strip of the fascia is raised, retaining the attachment at the midline. Vaginally, a tunnel is made on either side of the urethra at the level of the bladder neck. After plicating the endopelvic fascia underneath the bladder neck, the fascial strips are brought down through the tunnel, to be sutured underneath the bladder neck. A long abdominal incision is needed to raise the sling (Barrington et al, 2002) and the fascia might be inherently weak in patients with stress incontinence (Ulmsten et al, 1987).

Since then, several natural and synthetic sling materials have been used. Autologous fascia lata slings require an additional incision. Allografts, like fascia lata (Handa et al, 1996), and xenografts, like porcine dermis (Iosif, 1987), have been tried as well. Both need to be treated to eliminate their antigenicity (Buck & Malinin, 1994) and reduce the risk of viral transmission (Bidmead & Cardozo, 2000a). Whilst synthetic slings are easily available, there is the risk of local tissue reaction, which might lead to infection or erosion (Chin & Stanton, 1995).

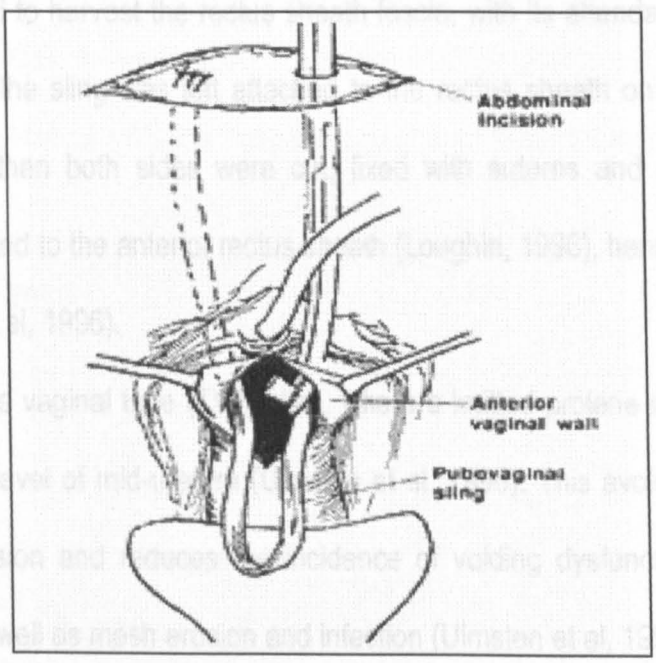


Figure No. 2.8. Sling operation*.

Cure rates ranged between 82% (Leach et al, 1997) and 85% (Jarvis, 1994). Yet, complication rates were higher than with colposuspension (Black & Downs, 1996). Up to 16% developed voiding dysfunction (Ghonheim & Shaaban, 1994) and the rate of de novo detrusor overactivity was 33% (Weinberger & Ostergard, 1995). Besides, there were the usual problems of bleeding and wound infection. These features and those related to the wounds for autologous slings as well as the risk of mesh erosion made slings rather unpopular (Bidmead & Cardozo, 2000).

* http://www.urogynaecology.com.au/images/sling.gif, at 14:15GMT, on 3.11.04

Minimally invasive slings:

Three minimally invasive sling techniques have been explored to reduce the problems associated with sling surgery;

1. Short autologous (modified pubovaginal) sling, which reduced the length of the abdominal incision required to harvest the rectus sheath fascia, with its attendant problems (Loughin, 1996). Initially, the sling was left attached to the rectus sheath on one side (McGuire & Lytton, 1978), then both sides were cut, fixed with sutures and passed alongside the urethra to be fixed to the anterior rectus sheath (Loughin, 1996), hence the name sling on a string (Lucas et al, 1996).
2. The tension-free vaginal tape (TVT) sling, where a knitted prolene mesh is placed without tension at the level of mid-urethra (Ulmsten et al, 1996). This avoids the need for a long abdominal incision and reduces the incidence of voiding dysfunction, de novo detrusor overactivity as well as mesh erosion and infection (Ulmsten et al, 1999).
3. Pelvicol, a diisocyanate cross linked porcine dermal implant, was tried to shorten the abdominal incision (Barrington et al, 2002). The ends of the pelvicol mesh are fixed with sutures and passed alongside the urethra to be fixed to the anterior rectus sheath, as with the short autologous sling (sling on a string).

The tension-free vaginal tape (TVT) sling, has revived interest in sling procedures (Bidmead & Cardozo et al, 2000). It has been shown to have similar effectiveness to the Burch colposuspension in a randomised controlled trial (Ward & Hilton, 2002). However, it is rather expensive, costing over £600 (Arunkalaivanan & Barrington, 2003) and still carries the risk of erosion (Hilton et al, 2003). The pelvicol sling had a subjective cure rate of 85% at 6 months

(Barrington et al, 2002), yet there are those who may not be happy with the use animal and pig material. The short autologous sling had a subjective cure rate of 73% at a mean follow up duration of 15 months (Loughin, 1996). Little work however has been carried out to compare all three techniques.

Alternative versions of the tension-free vaginal tape have been described including intravaginal slingoplasty (IVS) (Petros, 1999) and suprapubic (Deval et al, 2003) as well as transobturator tapes (De Leval, 2003). A randomised controlled trial comparing tension-free vaginal tape (TVT) and transobturator slings is currently underway in the United Kingdom.

4. Needle suspension:

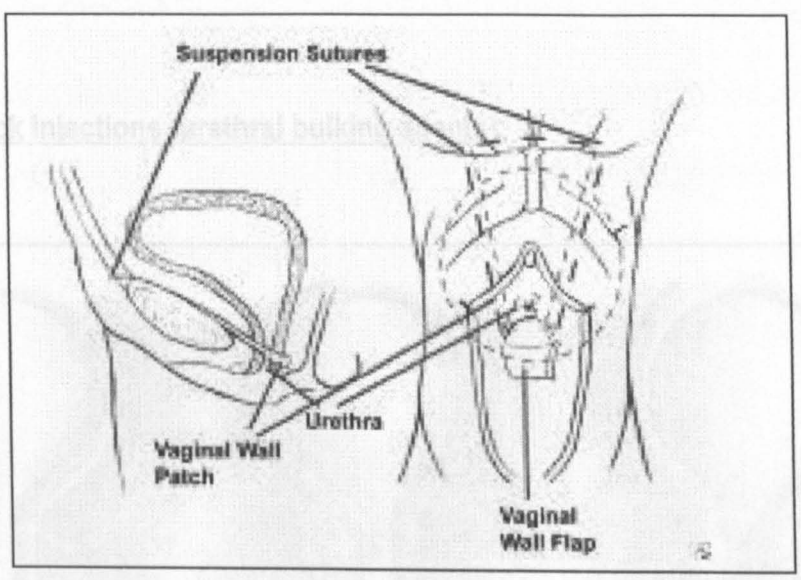


Figure No. 2.9. Needle suspension*.

In 1959, Pereyra described needle suspension as a simplified alternative to suprapubic bladder neck surgery (Pereyra, 1959). A steel wire suture was passed through the vagina on each side

* http://www.emedicine.com/med/images/1471med3057-19.jpg.jpg, at 14:14GMT, on 3.11.2004

of the bladder neck to be tied over the anterior rectus sheath, approached through two small suprapubic skin incisions. He used a long needle with an eye near its end to pass the suture. He later used an absorbable suture and incorporated an anterior vaginal wall repair (Pereyra & Lebhertz, 1967).

Further modification were introduced by Stamey, (1973), incorporating a dacron buffer into the periurethral suture, to prevent cutting through tissues, and adding cystoscopic examination of the bladder, to ensure its integrity. Although early success rate was good, 91% (Stamey, 1980), long term studies showed a drop reaching 50-70% at one year (Hilton & Mayne, 1991; Bosman et al, 1993) and 40% at 5 years (Bergman & Elia, 1995). A recent Cochrane review concluded that needle suspension is inferior to open retropubic bladder surgery (Glazer & Cooper, 2004a).

5. Bladder neck injections (urethral bulking agents):

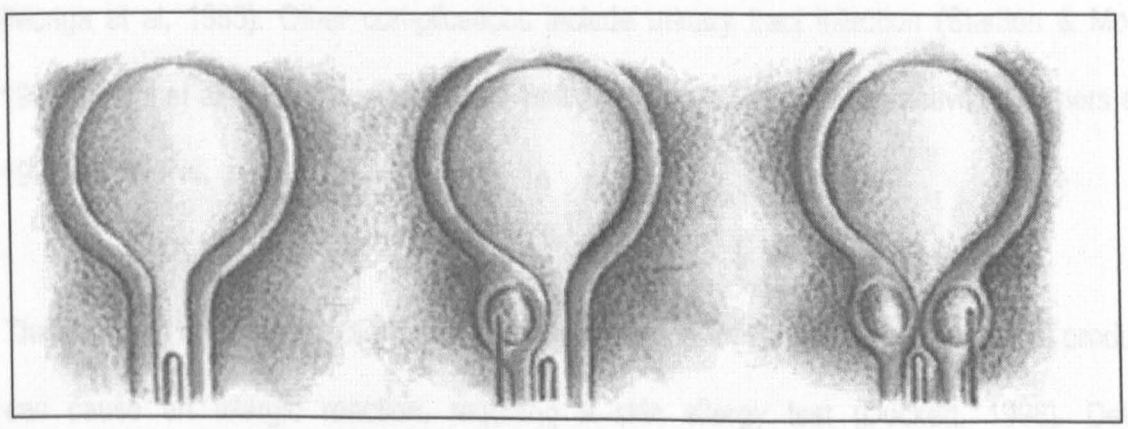


Figure No. 2.10. Paraurethral injection of urethral bulking agents*.

* http://www.barditalia.it/urologia/incontinenza/images/contigen_r3_c4.gif, at 14:40GMT, on 3.11.2004.

The term "injectables" has been used to describe compounds implanted into the periurethral tissues to bulk the area (Stricker & Haylen, 1993). Agents exert pressure on the lumen by coapting the urethral mucosa (Eckford & Abrams, 1991) such that the intrinsic sphincter becomes more able to stand increases in intra-abdominal pressure (Duckett, 1998). Collagen and silicone are the most commonly used agents.

Injections are made either transurethrally through the cystoscope, (Cross et al, 1998) or paraurethrally under cystoscopic guidance (Khullar et al, 1997). Injections are carried out till good coaptation of the mucosa is observed. They can be carried out under local anaesthesia in outpatient clinic, which suits high risk patients (Stanton & Monga, 1997; Cross et al, 1998).

Cure rates of over 50% at 1 year have been reported (Monga et al, 1995; Koelbl et al, 1998). However, there is a decline over time, necessitating repeat injection (Khullar et al, 1997; Sheriff et al, 1997). Complications are minor. Retention of urine usually resolves within 24 hours (Monga et al, 1995). Other complications include urinary tract infection (Stanton & Monga, 1997; Koelbl et al, 1998), haematuria as well as de novo detrusor overactivity (Stothers et al, 1998).

The nature of collagen injections has some implications for its use. Being an animal product, it can cause an allergic reaction, requiring a skin allergy test (Duckett, 1998). Delayed hypersensitivity reactions have been reported after a negative skin test, which might necessitate double skin testing (Stothers & Goldenberg, 1998, Stothers et al, 1998). As it is obtained from cows, it can, at least in theory, transmit Creutzfeldt-Jakob disease (CJD), the human form of bovine spongiform encephalopathy (mad cow disease). This is insignificant at

the moment as all injections are prepared from a special herd grown on grain products in the United States of America, where no such cases have been encountered up till now.

A recent Cochrane review (Pickard et al, 2004) concluded that bladder neck injections provide short term subjective and objective improvement in symptoms. Two or three injections might be required to ease symptoms for 12 months, which is inferior to other surgical procedures like the Burch colposuspension and the tension-free vaginal tape (TVT) sling. Whilst they suit high risk patients, the introduction of the tension-free vaginal tape (TVT) sling reduced their role, as even frail patients can have a TVT sling inserted under local anaesthesia as a day case (National Institute of Clinical Excellence, 2003).

Summary:

Pelvic floor exercises are the most commonly used non-invasive measure for urodynamic stress incontinence of urine. They entail regular active contraction of pelvic floor muscles to improve their tone and reflex contractility, so as to prevent leakage of urine during stress-provoked increase in intra-abdominal pressure. The technique is simple and has no side effects. However, it requires explanation and training of patients, which in turn relies on input from physiotherapists. It also takes time, which makes the method dependent on patient compliance. Cure rates are in the range of 30-50%, which is inferior to surgery, and do not get better with the use of biofeedback or vaginal cones.

Electrical stimulation effects passive contraction of pelvic floor muscles, so as to improve their tone and reflex contraction and thus avoid urinary leakage on stress, as with pelvic floor exercises. Although modern equipment is simple, consisting of single electrodes and portable

devices, the technique requires the same level of explanation and professional input as with pelvic floor exercises, so that patients can apply the technique properly.

The technique was meant to reduce dependence on patients, as they need not actively contract their muscles. Nonetheless, active patient involvement seems to be central to the success of treatment, with results of electrical stimulation being less than pelvic floor exercises. Furthermore, patient compliance remains important, as patients need to insert electrodes and operate devices on schedule. Moreover, they can experience side effects, which can lead to discontinuation of treatment.

Other non-invasive methods rely on devices and medication. Devices control, rather than treat, leakage as long as they are kept in place. They have never been popular, as they are quite difficult to handle, especially for elderly patients, and can lead to pain, haematuria as well as urinary tract infection. Medical treatment never reached wide use, due to limited impact and side effects.

The Burch colposuspension has long been regarded as the gold standard operation for its durable long term success rate. It works by restoring the intra-abdominal position of the bladder neck, to ensure equal transmission of any rise in the intra-abdominal pressure to the bladder and the bladder neck, so as to prevent leakage. It requires general anaesthesia and entails a long abdominal incision. There is extensive dissection of the retropubic space, which can lead to bleeding as well as bladder injury. A suprapubic catheter is inserted at the end and patients need to stay in hospital for few days till they are able to void satisfactorily. In the long term, there is the risk of voiding dysfunction and de novo detrusor overactivity.

Slings have evolved from long strips of rectus sheath fascia left attached to the rectus sheath in the midline to small strips that are fixed with sutures to the rectus sheath. A variety of other materials have been tried, including autologous and allogenic fascia lata as well as synthetic and animal material. Although success rates have been good, the incidence of complications was higher than with colposuspension. These complications included voiding dysfunction, de novo detrusor overactivity as well as sling erosion, especially with synthetic material.

Interest in slings however was revived with the introduction of the tension-free vaginal tape (TVT) sling. The minimal dissection involved enabled performing the procedure as a day case and the tension-free insertion reduced the incidence of voiding dysfunction, de novo detrusor overactivity as well as tape erosion. Its effectiveness is comparable to that of the Burch colposuspension. The procedure however is expensive and still carries the risk of tape erosion. Newer forms of such minimally invasive slings are being explored.

Other forms of surgery, such as anterior repair and bladder neck buttressing, needle suspension as well as bladder neck injection, have fallen out of fashion due to poor long term results.

3. Extra-corporeal magnetic energy stimulation:

Background:

In recent years, magnetic energy has become an important tool in investigation and treatment. Electromagnetic stimulation has been used in nerve conduction studies (Evans, 1991) as well as stimulation of brain tissue (Barker et al, 1985), as an alternative to electroconvulsive therapy (Goldberg & Sand, 2001). Magnetic resonance imaging (MRI) has become a standard investigation of masses, known for accuracy and precision (Salvatore, 1996). Electromagnetic stimulation has been applied in chronic pelvic pain (Rowe et al, 2005) and erectile dysfunction (Pelka et al, 2002). In urogynaecology, it has been used for detrusor overactivity (McFarlane et al, 1997), stress incontinence of urine (Galloway et al, 1999) as well as mixed incontinence (Almeida et al, 2004). It has also been investigated for atonic urinary retention, such as following spinal cord injury (Brodak et al, 1993).

Physics of electromagnetic stimulation:

The technique relies on the close link between electricity and magnetism. The passage of electric current generates a circular magnetic field (Goldberg & Sand, 2000) and exposure to such magnetic field generates an electric current, according to Faraday's law (Roth et al, 1991). Tissue exposure to electromagnetic fields generates eddy currents, which leads to stimulation of nerves and muscles (Ishikawa et al, 1998) in a similar way to electrical stimulation (Brodak et al, 1993).

Factors affecting electromagnetic fields:

Electromagnetic fields are influenced by a number of factors, which will influence their effects;

1. Frequency:

Higher frequency waves have shorter wave lengths and carry more energy than lower frequency waves, which have longer wave lengths. Extremely low frequency fields are generated around electric appliances. These have frequencies up to 300 Hz. Intermediate frequency fields have frequencies from 300 Hz to 10 MHz. Radiofrequency waves, like those generated by mobile phones, television and radio transmission, range from 10 MHz to 300 GHz. At very high levels, electromagnetic fields can break bonds between molecules, leading to ionisation of tissues, such as gamma rays generated by radioactive materials. Less powerful fields are called non-ionising*. Extra-corporeal magnetic stimulation of the pelvic floor muscles utilises low frequency, 10-50Hz (Yamanishi et al, 2000).

2. Type of current used to generate them:

A direct current (DC), where electricity flows only in one direction, creates a static field. On the other hand, an alternating current (AC) changes its direction at regular intervals, creating a time varying field that changes its orientation at the regular intervals*. In addition to providing repeat stimulation with each change in direction, it enables stimulation at low energy levels (Lyskov et al, 1993). Extra-corporeal magnetic stimulation of the pelvic floor muscles relies on alternating current to generate time varying fields (Yamanishi et al, 2000).

3. The stimulation coil:

The distribution and focal length of penetration of the electromagnetic field generated depend on the diameter and shape of the coil used (Goldberg & Sand, 2001; Charlet de Sauvage et al,

* http://www.who.int/peh-emf/about/WhatisEMF/en/, at 14:00GMT, on 22.7.2005.

2003). For pelvic floor muscles, a concave coil, bent at the front and the back, like a saddle matching the perineum, helps better focus on the pelvic floor than a circular one (Yamanishi et al, 2000). Computer modelling showed that a coil 12cm long, 9cm wide and 5cm thick is the most suitable design for stimulation of the pudendal nerves and pelvic floor muscles (Ishikawa et al, 1998).

The orientation of the coil in relation to the target organ is vital for proper exposure of the target organ to the electromagnetic fields (Maccabee et al, 1988). For pelvic floor muscles, the coil is placed horizontally under the treatment chair, such that the fields are generated towards the perineum when patients are in the seating position. The flux is perpendicular to the coil plane (Hallett & Cohen, 1989), hence it is important for patients to sit straight on the chair, to ensure that the field generated is focused on the pudendal nerves and the pelvic floor muscles.

4. Distance between the source and target organ:

The density of electromagnetic fields, referred to as flux density and measured in microtesla units (μT), diminishes predictably with the inverse square of the distance from the source (Goldberg & Sand, 2001). In the case of extra-corporeal magnetic stimulation of pelvic floor muscles, the distance is between the stimulation coil, located underneath the treatment chair, and the pelvic floor muscles. Experimental work showed this to be about 5cm distance, and guided adjustment of the current used to generate fields at density (strength) appropriate for the stimulation required.

The limits of stimulation area however are rather difficult to define (Barker, 1991). Patients therefore should not use electronic equipment during treatment and the treatment is contra-

---

* http://www.who.int/peh-emf/about/WhatisEMF/en/, at 14:00GMT, on 22.7.2005.

indicated in those with metal prosthesis, such as cardiac pacemakers. Electromagnetic fields can generate electric current, and possibly heat, around these objects, causing tissue damage.

4. Resistance to transmission:

Tissue permeability to electromagnetic fields is equal to that of air (Roth et al, 1991). There is no need therefore to insert stimulation electrodes (Barker et al, 1987). The lack of tissue impedance also means that no current is generated at the skin surface; avoiding pain, discomfort and heat generation at the surface, which can be encountered with electrical stimulation (Hallett & Cohen, 1989; Goldberg & Sand, 2001). Furthermore, the fields pass easily through clothes (Yokoyama et al, 2004) and patients therefore do not have to undress. All these features apply to extra-corpreal magnetic stimulation of pelvic floor muscles (Galloway et al, 1999).

Safety of electromagnetic fields:

As electromagnetic fields are generated by the passage of electric current, they have existed for many years around electric equipment at home and near power lines outside. Everyone is exposed to them as part of day to day life nowadays, for example upon watching television and using mobile phones. It is fair to say that any link to disease or untoward effects would have been detected by now*.

In theory, exposure of human tissue to electromagnetic fields leads to generation of electric current, which in addition to its stimulatory effect on nerves and muscles, can generate heat. Both the current and the heat generated depend on field strength, proximity to its source as

* http://www.who.int/peh-emf/about/WhatisEMF/en/, at 14:00GMT, on 22.7.2005.

well as duration of exposure. Notwithstanding its limitations, research has so far shown no risk from day to day exposure either to health in general, pregnancy or causation of cancer*.

The risk of more focused and sustained exposure during investigation and treatment is different from that of background exposure. Laboratory research has so far shown no specific hazard to general health, genetic division, which is related to procreation (Grandolfo et al 1991; McCann et al, 1998; Charlet de Sauvage et al, 2003), or causation of cancer (de Seze et al, 2000). Electromagnetic fields have been investigated and refined (Wassermann et al, 1996) with clear definition of safety limits (Pascual-Leone et al, 1993). No harmful effects have been reported up till now for proper use of the licensed techniques (Cohen & Hallett, 1988; Jalinous, 1991; Chen et al, 1997). The device used for Extra-corporeal Magnetic Innervation (ExMI) has undergone several tests and was approved by the Food and Drug Administration (FDA) in the United States of America (Goldberg & Sand, 2000).

The safety of exposure to electromagnetic fields during pregnancy is yet to be established (De Wilde et al, 2005). Most of the work done in this area relates to assessing the use of magnetic resonance imaging (MRI) and covers a number of areas;

1. Tissue heating: This has raised concern (Kanal, 1994), as it can affect brain development (Edwards et al, 2003).
2. Gadodiamide, which is used in enhanced films: It has been linked to skeletal malformation in animal studies, hence it should not be used in the first trimester (Birchard et al, 2004).
3. Time varying electromagnetic fields, which are applied in extra-corporeal magnetic innervation: No significant teratogenic effect has been reported (Rodegerdts et al, 2000), but an increased incidence of miscarriage has been noted (Li et al, 2002). In addition, rapid

* http://www.who.int/peh-emf/about/WhatisEMF/en/, at 14:00GMT, on 22.7.2005.

changes in current can cause coil vibrations, generating noise. Whilst mothers are protected by earplugs or headphones, the fetus is not. Transmission is reduced as the noise passes through the abdomen, though the effect on fetal hearing development remains unclear (De Wilde et al, 2005).

However, no actual adverse fetal side effects have been reported and the advice is to weigh the likely benefit against potential risk in individual cases (Birchard et al, 2004). For extra-corporeal magnetic stimulation of pelvic floor muscles, the effect remains unknown.

Mechanism of action:

The technique involves stimulation of pelvic floor muscles by time-varying electromagnetic fields, generated by alternating current (AC) passed around a metal bar. According to Faraday's law of magnetic induction, an electric current is generated in response to changing magnetic fields (Liboff & Jenrow, 2002). Such current will lead to depolarisation of the resting electric potential of the nerves and muscles in the pelvic area into an action potential, causing muscle contraction (Barker, 1991). The level of these fields, and thus the contractions they induce, is adjusted by altering the level of current, according to the level of pain perceived by patients (Galloway et al, 1999).

The nature of electromagnetic fields enhances their stimulatory effect. Whereas nerve conduction is uni-directional, magnetic fields spread both distally, leading to depolarisation of the muscle cell, directly effecting a contraction, as well as proximally, stimulating the nerve cell body in the spinal cord, leading to another contraction. Collateral transmission leads to more contraction of the pelvic floor muscles, both smooth and striated (Galloway et al, 2000).

The aim is to build muscle strength and endurance as with electrical stimulation. Repeated contractions lead to hypertrophy of these muscles, especially those supporting the bladder and urethra, so as to improve stress incontinence. Likewise, patients will have an increased awareness of their pelvic floor.

Equipment:

During early stages of technique development, stimulation was carried out with patients in the prone position and coils were fixed over the sacral area (Fujishiro et al, 2000). The aim was to stimulate the sacral nerve roots supplying pelvic floor muscles. This was rather inconvenient for patients, who had to lie face down for half an hour.

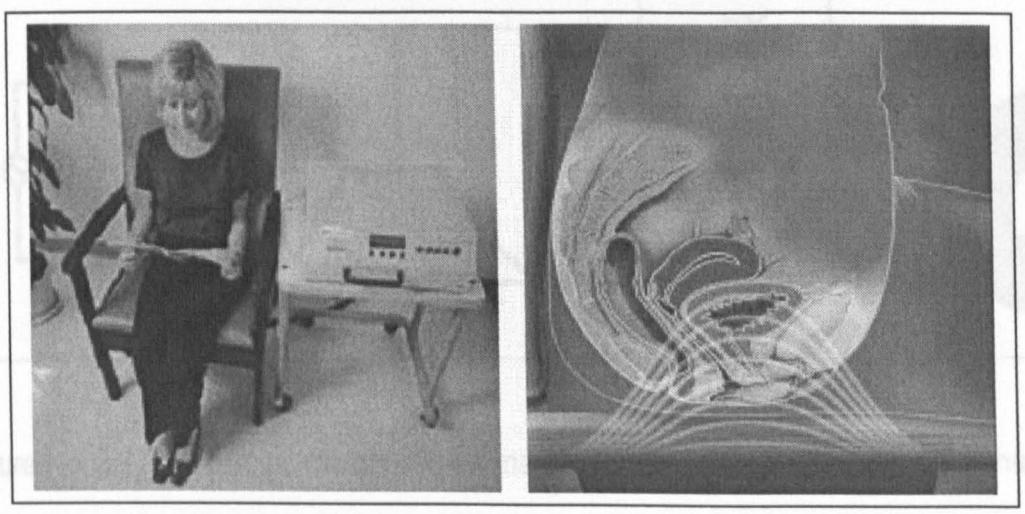


Figure No. 3.1. The control unit and the treatment chair (left) and a diagrammatic representation of electromagnetic fields traversing across pelvic floor muscles (right)*.

Further improvements were made by Neotonus Incorporation in collaboration with the Georgia Institute of Technology and Emory School of Medicine, in the United States of America (www.neocontrol.com). The stimulation coil was placed underneath a chair so as to target both

* http://www11.medica.de/cache/pica/1/7/5/9/85801077892819/Kombibild.jpg, at 22:35GMT, on 26.10.2004.

pelvic floor muscles and the pudendal nerves. As a result, patients can sit comfortably during treatment session. The new machine consists of a control unit and a treatment chair.

1. The control unit:

The control unit is computerised to set the pulses at which the waves of magnetic fields are generated. It contains control buttons and switches, a monitoring screen as well as a modem for external communication, needed for paying for treatment sessions. It also contains the generator that produces the current, which then passes through the coil. The unit is compact and has the size of a personal computer "C" drive.

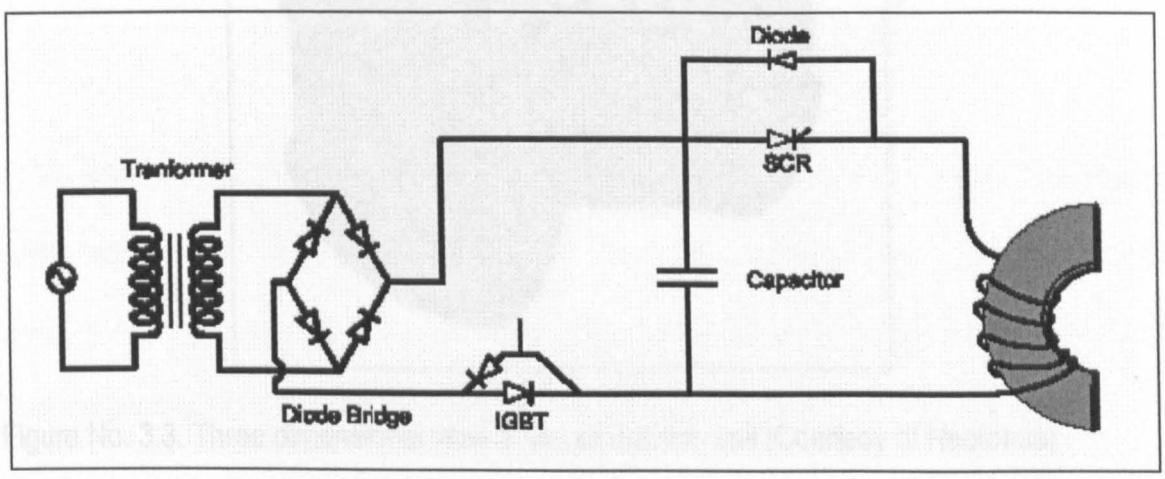


Figure No. 3.2. The electric circuit used for magnetic stimulation (Courtesy of Neotonus).

The control unit is operated using programmed patient cards, which contain planned treatment for individual patients, stored in a small memory chip. Cards are inserted into the control unit before each treatment session begins, and all completed sessions are tracked by the system to ensure matching the treatment plan.

2. The treatment chair:

The treatment chair fits easily into a clinic and has arms to provide comfortable seating for patients. It has the therapy head (stimulation coil) from which magnetic fields are generated. This is situated underneath the chair, so as to ensure a direct focus on pelvic floor muscles. The coil is wrapped around a hollow copper conductor pipe which is cooled from inside to keep the temperature below 25°C (Ishikawa et al, 1998; Yamanishi et al, 2000).

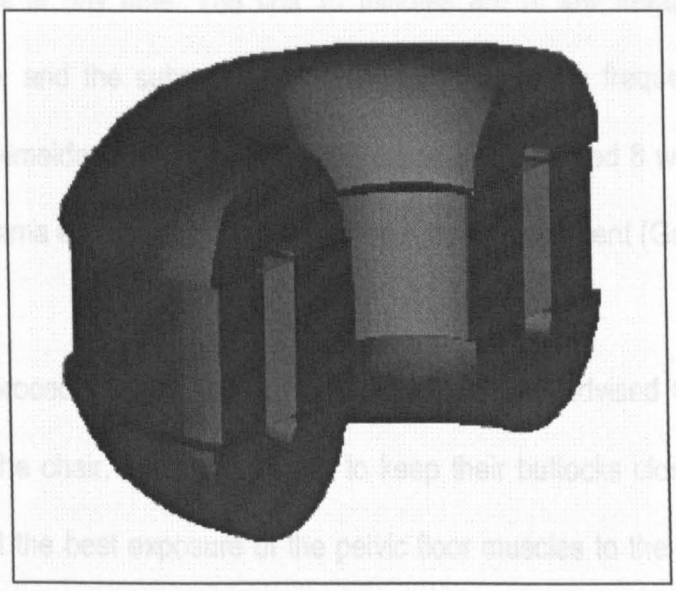


Figure No. 3.3. Three dimensional view of the stimulation coil (Courtesy of Neotonus)

Treatment:

Contraindications:

Contraindications to the use of the technique include;

- Pregnancy, as the impact of this treatment on pregnancy is still to be determined.
- Diminished sensory perception, as this will make it difficult to adjust power level.
- Patients with cardiac pacemaker or defibrillator, metallic prosthesis and metal-containing intrauterine contraceptive device, as the metal part of the device could become hot upon exposure to electromagnetic fields, and this heat might cause tissue damage.

- Patients recovering from pelvic surgery, to avoid possible effects on tissue healing, such as stretch by pelvic muscle contraction.

Sessions:

Treatment sessions are held twice a week, each lasting 20 minutes. To prevent muscle fatigue, intermittent stimulation is used, 5 seconds on and 5 seconds off, and sessions should not exceed 30 minutes at any time. The first 10 minutes are of low frequency (5 HZ), to build muscle endurance, and the subsequent 10 minutes are of high frequency (50 Hz), to build muscle strength (Almeida et al, 2004). Whilst most studies reported 8 weeks treatment (Unsal et al, 2003; Yokoyama et al, 2004), some reported 6 weeks treatment (Galloway et al, 1999) .

At the start, the procedure is explained to patients, who are advised to empty their bladder before sitting on the chair. They should aim to keep their buttocks close to the centre of the chair, so as to get the best exposure of the pelvic floor muscles to the electromagnetic fields. They do not have to remain still, but they should not slide forwards or shift to one side.

Value:

Urodynamic studies:

One study described cystometric assessment of 24 female patients with urodynamic stress incontinence of urine before and after treatment (Almeida et al, 2004). It showed an increase in valsalva leak point pressure (VLPP) that correlated with clinical improvement. Another study provided urethral pressure profilometry before and after treatment (Yamanishi et al, 2000). However, it included male and female patients with a mixture of urodynamic stress incontinence of urine and detrusor overactivity. Maximum urethral closure pressure and

maximum intraurethral pressure were significantly increased, but there was no significant change in functional urethral length.

Clinical effectiveness:

There have been a number of published papers to date;

The first one (Galloway et al, 1999) was unusual in many respects;

1. The study was intended for patients with stress incontinence of urine. However, its methodology does not indicate that patients had urodynamic assessment to confirm the diagnosis of urodynamic stress incontinence and rule out detrusor overactivity and mixed incontinence. Yet, the results imply that 5 patients had detrusor overactivity before treatment, falling to 1 after treatment.
2. The study included patients with significant degrees of vaginal wall prolapse (reaching grade III cystocele). These patients are usually excluded from studies assessing treatment for stress incontinence of urine, as such degrees of prolapse can confound the outcome.
3. The study included a validated quality of life survey. Nonetheless, no questionnaire was specified and information was not provided about values before and after treatment.
4. The study included a pad test for objective assessment of outcome. Yet, the test used was referred to as "dynamic pad test", without any reference to look it up. Whereas other pad tests, such as the International Continence Society's 1 hour pad test (Abrams et al, 1989), are specified with known cut levels of leakage, no information was provided about this test.
5. No information was provided about the outcome at the end of treatment. Instead, outcome was described at three months follow up.
6. Pad test results do not show how many patients were considered dry and how many patients were still incontinent. Instead, mean values were provided, with no standard deviation given. This makes it difficult to reach a conclusion as to the effect of treatment.

7. It showed a subjective cure rate of 34%, on the basis of not requiring a pad, rather than having no leakage, with further 32% using one pad per day. Although there was significant reduction in the number of leakage episodes, no information was provided as to the number of those patients having no leakage or a small number of leakage episodes per day. This makes it difficult to judge the outcome in terms of cure.
8. The authors indicated that the technique is painless, yet no information was provided about patients perception of pain or the reason why only 64 patients, out of an initial of 83, completed the study (22.9% drop out rate).

Six months follow up results of the same study were reported later, using the same methodology (Galloway et al, 2000). Again, no information was provided about patients having detrusor overactivity, mixed incontinence or prolapse and pad test values were not given. The cure rate was 28%, defined as patient not using pads, and the improvement rate was 53%, defined as using no more than 1 pad per day. Leakage episodes were significantly less, but the range was wide. The validated quality of life survey was specified as the Incontinence Quality of Life Instrument (I-Qol), but total scores, rather than individual subscales, were given.

A drop in cure rate can be seen between the two reports, from 34% at 3 months to 28% at 6 months. The improvement rate increased from 32% to 53%, which might suggest that those who deteriorated over the three months period were still better off, though this was not specifically confirmed by the authors (Galloway et al, 2000). The median frequency of leakage episodes remained the same, 1.7, but no further information was provided. No information was given about the pad test or the quality of life.

The second study included 7 female patients with urodynamic stress incontinence (Yamanishi et al, 2000). Two patients were cured (28.6%), and 4 patients were improved (57.1%). There was a significant reduction in daily leakage episodes and a significant improvement in quality of life scores. Yet, there was no change in nocturnal leakage or the number of pads used per day. No adverse effects were encountered but a patient dropped out of the study.

The third study (Unsal et al, 2003) included 37 patients with urodynamic stress incontinence. Cure was defined as a negative pad test. One year follow up data was available for only 29 patients (78.4%), showing 37.9% cure rate, 41.4% improvement rate and 20.7% failure rate. Urodynamic evaluation showed significant increases in bladder volume at first desire to void, maximum cystometric capacity and valsalva leak point pressure. The frequency of leakage episodes decreased significantly as well, from 3.8 $\pm$ 1.7 to 1.5 $\pm$ 1.4. No patient experienced pain and there were no adverse effects either during or after treatment.

The fourth study (Yokoyama et al, 2004) included 17 patients with urodynamic stress incontinence. It reported a cure rate of 52.9%, defined as no incontinence and <2g leakage on 1 hour pad test, and an improvement rate of 41%, defined as 50% reduction in incontinence frequency or pad test. At 24 weeks follow up, the cure rate dropped to 31.3% and three patients out of the 9 that were considered cured at the end of treatment (33.3%) required surgery.

The fifth study (Almeida et al, 2004) included 91 patients. Yet, only 41 of them had urodynamics before treatment and of these only 24 had urodynamic stress incontinence of urine. Although 37% of patients were dry at the end of treatment, patients were pooled together, making it difficult to assess the outcome in the urodynamic stress incontinence group

alone. Moreover, there was a rapid and progressive recurrence rate reaching 47% at 3 months, 61.7% at 6 months and 94% at 12 months.

It is difficult therefore to reach a meaningful conclusion as to the effectiveness of this technique, given the limitations of available research.

Side effects:

No serious side effects have been reported, however data are limited as outlined already (Yamanishi et al, 2000). Patients may feel some discomfort, tingling and/or heat in the perineal area or involuntary movements the lower limb(s).

Limitations:

- The method is a form of passive muscle exercise, which is not as effective as active muscle exercises, as referred to when discussing electrical stimulation of the pelvic floor muscles.
- The technique depends on communication with the manufacturer in the United States of America to register patient data and initiate cards. This requires communication support and treatment can be interrupted as a result of problems.
- The treatment relies on payment, as communication is made for individual patients, which represents a form of recurrent cost. On the other hand, payment for electrical stimulation devices is made only on purchase, capital cost.
- The technique requires the presence of a health professional, in the form of a nurse or a physiotherapist. Although such professional does not have to be with the patient for the 20 minutes duration of the session, the machine will need to be operated by her/him.

- The technique requires hospital attendance, as there are no home devices as yet. The technique therefore still depends on some form of patient compliance.

Summary:

Extra-corporeal magnetic energy stimulation of pelvic floor muscles relies on intermittent pulses of magnetic fields for stimulating pelvic floor muscles. These fields traverse the pelvic area easily such that patients do not have to undress or insert electrodes, as with electrical stimulation. Yet, they have to be seated during treatment sessions, to ensure good exposure of pelvic floor muscles to the stimulating fields. As these fields can generate heat around metal objects, the method is contraindicated in those with metal prosthesis. Likewise, patients should remove all metal objects from their pockets and refrain from using electronic equipment during treatment session.

Treatment is provided using a small office machine and relies on communication with the manufacturer in the United States of America, to pay for individual sessions. Sessions are scheduled twice weekly over 8 weeks, lasting 20 minutes each and the stimulation power is adjusted according to patients' perception of pain. Information about the value of the technique is limited, in the number of studies as well as their scientific rigor, but suggest 40% cure rate and 40% improvement rate. Side effects are said to be minimal, although a 20% drop out rate has been reported.

For patients considering non-invasive management of their urodynamic stress incontinence, the technique represents an alternative to electrical stimulation. It avoids the need to undress and insert electrodes, but requires repeated hospital attendance as well as remaining seated during treatment sessions. It promises a painless treatment but has not been proven to be an

effective method as yet. It is therefore difficult to recommend introducing it into clinical practice without further research.

Method:

Aim:

The aim of the study was to assess the efficacy and side effects of extra-corporeal magnetic energy stimulation pelvic floor muscles, as a non-invasive approach for urodynamic stress incontinence of urine in women.

Study design:

The study was a prospective one, without a control arm.

Outcome measures:

A 20% reduction in leakage according to the standard International Continence Society 1 hour pad test (Abrams et al, 1989) was considered the primary outcome measure.

Successful completion of treatment and changes in leakage episodes, pad usage as well as quality of life scores were considered secondary outcome measures. Patients kept a continence diary (frequency/volume chart) for the estimation of average daily leakage episodes and pad usage. Quality of life was assessed using 2 validated questionnaires; the King's Health Questionnaire and EuroQol. The King's health questionnaire measures the quality of life and covers both general health and incontinence specific elements (Kelleher, 2000) and the EuroQol, is a general health questionnaire (Kind, 1996). All questionnaires and diaries were completed before attending the clinic.

Sample size:

The primary outcome measure was specified as 20% reduction in pad test. The sample size calculation was based on noting 70% improvement rate, defined as 20% reduction in pad test, with pelvic floor exercises (Van Kerrebroeck, 1998). To detect a 20% increase this level of improvement, to 90%, with 80% power and 95% confidence (0.05 significance) would require 60 cases.

Study candidates:

Female patients with pure urodynamic stress incontinence were invited to take part in the study as they are seen in outpatient departments. They were provided with a patient information leaflet and counselled by the nurse co-ordinating the trial. All participants signed a consent form.

Inclusion criteria:

- female patients with urodynamic stress incontinence of urine.
- negative pregnancy test in fertile women who were not sterilised.

Exclusion criteria:

- patients with arrhythmia or metal prosthesis.
- patients with marked uterine and/or vaginal prolapse (grade 2 or more on clinical examination).
- patients with proven neurological disease.
- patients with diabetes mellitus.
- patients under 18 years of age.

- patients taking anticholinergic medication, neuromuscular stimulants or relaxants.

The intervention:

The scheme described by Galloway et al (1999) was followed. Stimulation started at a frequency of 5Hz in 5 second pulses alternating with 5 second breaks. Intensity was increased gradually till reaching 50Hz. This level was maintained for 10 minutes, followed by 2 minutes rest period and then repeated for another 10 minutes. The longer treatment duration of 8 weeks (Unsal et al, 2003; Yokoyama et al, 2004) was followed.

Follow up:

Patients were seen at three months after completion of treatment.

Study centres:

The study was carried out at Singleton and Morriston hospitals, in Swansea, South Wales.

Ethical approval:

The study was approved by the local research ethics committee.

Data collection:

Data was collected using case report forms and downloaded onto Microsoft Works 5.0 for windows database (www.microsoft.com).

Statistics:

All tests were carried out according to standard statistical methods (Altman, 1991) on Stata 6.0 for windows (www.stata.com).

Summary of outcome measures per visits:

Recruitment visit:

- 3 day continence diary.
- 1hr International Continence Society pad test.
- King's health questionnaire.
- EuroQol questionnaire.

End of treatment visit:

- 3 day continence diary.
- 1hr International Continence Society pad test.
- King's health questionnaire.
- EuroQol questionnaire.

Three months follow up visit:

- 3 day continence diary.
- 1 hr International Continence Society pad test.
- King's health questionnaire.
- EuroQol questionnaire.

Results:

A total of 48 patients were recruited at Singleton and Morriston hospital. Of these 48 patients, 31 completed all 16 treatment sessions and 27 attended for follow up at 3 months.

Background features:

Variable	Mean (Median)	SD (Interquantile range)
Age (years)	51	13
Weight (Kg)	70.0	12.9
Duration of symptoms (months)	(60)	(33-150)

Table No. 3.1. The distribution of the cohort according to their background features, in the magnetic stimulation study.

History:

Feature	Number (%)	Main groups	Number (%)
Medical problems	34 (70.8%)	Cardio-pulmonary Bone and joint	18 (37.5%) 14 (29.2%)
Previous surgery	38 (79.9%)	Hysterectomy Continence/repair	21 (43.8%) 14 (29.2%)
On medication	32 (66.7%)	HRT/COP* Antidepressants	10 (20.8%) 7 (14.6%)

* HRT: hormone replacement therapy, COP: combined oral contraceptive pill

Table No. 3.2. The distribution of the cohort according to their medical, surgical and medication history, in the magnetic stimulation study.

Primary outcome measure:

Outcome at the end of treatment:

Parameter	Recruitment	End of treatment	Wilcoxon signed rank test
	Median (Interquantile range)		
Pad test (gm)	6.4 (1.1-28.7)	3 (0.1-36)	P 0.83

Table No. 3.3. Comparison between pad test at recruitment and end of treatment visits, in the magnetic stimulation study.

Outcome at the 3 months follow up:

Parameter	Recruitment	3 months follow up	Wilcoxon signed rank test
	Median (Interquantile range)		
Pad test (gm)	6.4 (1.1-28.7)	6.3 (0.7-48.5)	P 0.40

Table No. 3.4. Comparison of pad test at recruitment and 3 months follow up visits, in the magnetic stimulation study.

Secondary outcome measures:

Continence parameters:

Outcome at the end of treatment:

Parameter	Recruitment	End of treatment	Wilcoxon signed rank test
	Median (Interquantile range)		
Daily pad use	1.7 (0-3)	1 (0-4)	P 0.14
Daily leakage episodes	2.3 (1-3.3)	2 (0.3-2.7)	P 0.35

Table No. 3.5. Comparison between continence parameters at recruitment and end of treatment visits, in the magnetic stimulation study.

Outcome at the 3 months follow up:

Parameter	Recruitment	3 months follow up	Wilcoxon signed rank test
	Median (Interquantile range)		
Daily pad use	1.7 (0-3)	1.2 (0-3)	P 0.83
Daily leakage episodes	2.3 (1-3.3)	2 (1-4)	P 0.59

Table No. 3.6. Comparison of continence parameters at recruitment and 3 months follow up visits, in the magnetic stimulation study.

Quality of life:

Kings health questionnaire:

Outcome at the end of treatment:

Domains:

Domain	Recruitment	End of treatment	Wilcoxon signed rank test
	Median (Interquantile range)		
General health	0.25 (0.00-0.50)	0.25 (0.00-0.50)	**P 0.02**
Incontinence impact	0.67 (0.66-1.00)	0.66 (0.33-1.00)	P 0.10
Role limitations	0.66 (0.33-0.83)	0.50 (0.33-0.67)	P 0.57
Physical limitations	0.66 (0.33-0.66)	0.50 (0.32-0.83)	P 0.97
Social limitations	0.22 (0.11-0.83)	0.22 (0.00-0.55)	P 0.56
Personal relationships	0.16 (0.00-0.50)	0.16 (0.00-0.50)	P 0.31
Emotions	0.66 (0.22-0.88)	0.33 (0.11-0.66)	P 0.20
Sleep/energy	0.33 (0.32-0.50)	0.50 (0.17-0.66)	P 0.53
Severity measures	0.66 (0.50-0.75)	0.58 (0.50-0.83)	P 0.93

Table No. 3.7. Comparison between quality of life scores, as measured by the domains of King's health questionnaire, at recruitment and end of treatment visits, in the magnetic stimulation study.

Symptom scores:

Symptom		None	A little	Moderately	A lot	P *
Frequency	Recruitment	13 (27.7%)	7 (14.9%)	12 (25.5%)	15 (31.9%)	0.43
	End of treatment	11 (35.5%)	5 (16.1%)	11 (35.5%)	4 (12.9%)	
Nocturia	Recruitment	13 (27.7%)	17 (36.2%)	9 (19.2%)	8 (17.0%)	0.34
	End of treatment	10 (32.3%)	14 (45.2%)	4 (12.9%)	3 (9.6%)	
Urgency	Recruitment	15 (32.6%)	7 (15.2%)	7 (15.2%)	17 (37.0%)	0.37
	End of treatment	10 (32.3%)	8 (25.8%)	5 (16.1%)	8 (25.8%)	
Urge incontinence	Recruitment	12 (25.5%)	12 (25.5%)	14 (29.8%)	9 (19.2%)	0.43
	End of treatment	11 (35.5%)	10 (32.3%)	3 (9.6%)	7 (22.6%)	
Stress incontinence	Recruitment	3 (6.4%)	4 (8.5%)	9 (19.2%)	31 (66.0%)	0.06
	End of treatment	5 (16.1%)	1 (3.2%)	11 (35.5%)	14 (45.2%)	
Nocturnal enuresis	Recruitment	36 (76.6%)	7 (14.9%)	2 (4.3%)	2 (4.3%)	1.00
	End of treatment	25 (80.7%)	4 (12.9%)	1 (3.2%)	1 (3.2%)	
Intercourse incontinence	Recruitment	28 (59.6%)	7 (14.9%)	5 (10.6%)	7 (14.9%)	0.27
	End of treatment	23 (74.2%)	5 (16.1%)	1 (3.2%)	3 (6.5%)	
Frequent water works infection	Recruitment	31 (66.0%)	8 (17.0%)	4 (8.5%)	4 (8.5%)	0.60
	End of treatment	23 (74.2%)	5 (16.1%)	1 (3.2%)	2 (6.5%)	
Bladder pain	Recruitment	29 (61.7%)	9 (19.2%)	7 (14.9%)	2 (4.3%)	0.24
	End of treatment	24 (77.4%)	6 (19.4%)	1 (3.2%)	0 (0%)	
Other symptom(s)	Recruitment	45 (97.8%)	0 (0%)	0 (0%)	1** (2.2%)	0.32
	End of treatment	30 (96.8%)	0 (0%)	0 (0%)	1*** (3.2%)	

* Mann-Whitney test ** back pain, *** bladder spasm

Table No. 3.8. Comparison of symptom scores, as measured by of the King's health questionnaire, at recruitment and end of treatment visits, in the magnetic stimulation study.

Outcome at the 3 months follow up:

Domains:

Domain	Recruitment	3 months follow up	Wilcoxon signed rank test
	Median (Interquantile range)		
General health	0.25 (0.00-0.50)	0.25 (0.00-0.50)	P 0.00
Incontinence impact	0.67 (0.66-1.00)	0.67 (0.33-1.00)	P 0.53
Role limitations	0.66 (0.33-0.83)	0.48 (0.33-0.67)	P 0.50
Physical limitations	0.66 (0.33-0.66)	0.65 (0.17-0.83)	P 0.71
Social limitations	0.22 (0.11-0.83)	0.28 (0.11-0.44)	P 0.09
Personal relationships	0.16 (0.00-0.50)	0.33 (0.16-0.33)	P 0.01
Emotions	0.66 (0.22-0.88)	0.39 (0.22-0.61)	P 0.85
Sleep/energy	0.33 (0.32-0.50)	0.33 (0.25-0.66)	P 0.06
Severity measures	0.66 (0.50-0.75)	0.66 (0.50-0.75)	P 0.47

Table No. 3.9. Comparison of quality of life domains, as measured by the King's health questionnaire, at recruitment and 3 months follow up visits, in the magnetic stimulation study.

Symptom scores:

Symptom	Visit*	None	A little	Moderately	A lot	P**
Frequency	Recruitment	13 (27.7%)	7 (14.9%)	12 (25.5%)	15 (31.9%)	0.86
	3 months F/U	8 (32.0%)	3 (12.0%)	10 (40.0%)	4 (16.0%)	
Nocturia	Recruitment	13 (27.7%)	17 (36.2%)	9 (19.2%)	8 (17.0%)	0.87
	3 months F/U	10 (40.0%)	5 (20.0%)	7 (28.0%)	3 (12.0%)	
Urgency	Recruitment	15 (32.6%)	7 (15.2%)	7 (15.2%)	17 (37.0%)	0.15
	3 months F/U	12 (48.0%)	4 (16.0%)	4 (16.0%)	5 (20.0%)	
Urge incontinence	Recruitment	12 (25.5%)	12 (25.5%)	14 (29.8%)	9 (19.2%)	0.94
	3 months F/U	9 (36.0%)	2 (8.0%)	8 (32.0%)	6 (24.0%)	
Stress incontinence	Recruitment	3 (6.4%)	4 (8.5%)	9 (19.2%)	31 (66.0%)	0.06
	3 months F/U	5 (20.0%)	2 (8.0%)	6 (24.0%)	12 (48.0%)	
Nocturnal enuresis	Recruitment	36 (76.6%)	7 (14.9%)	2 (4.3%)	2 (4.3%)	0.57
	3 months F/U	18 (72.0%)	5 (20.0%)	2 (8.0%)	0 (0%)	
Intercourse incontinence	Recruitment	28 (59.6%)	7 (14.9%)	5 (10.6%)	7 (14.9%)	0.58
	3 months F/U	15 (60.0%)	8 (32.0%)	1 (4.0%)	1 (4.0%)	
Frequent water works infection	Recruitment	31 (66.0%)	8 (17.0%)	4 (8.5%)	4 (8.5%)	0.57
	3 months F/U	16 (64.0%)	8 (32.0%)	1 (4.0%)	0 (0%)	
Bladder pain	Recruitment	29 (61.7%)	9 (19.2%)	7 (14.9%)	2 (4.3%)	0.57
	3 months F/U	19 (76.0%)	4 (16.0%)	2 (8.0%)	0 (0%)	
Other symptom(s)	Recruitment	45 (97.8%)	0 (0%)	0 (0%)	1*** (2.2%)	0.15
	3 months F/U	23 (92.0%)	1**** (4.0)	0 (0)	1***** (4.0%)	

* F/U: follow up, ** Mann-Whitney test, ***back pain, ***Not specified, **** Post micturition dribbling.

Table No. 3.10. Comparison of symptom scores, as measured by of the King's health questionnaire, at recruitment and 3 months follow up visits, in the magnetic stimulation study.

EuroQol:

Outcome at the end of treatment:

Item	Recruitment	End of treatment	Wilcoxon signed rank test
	Median (Interquantile range)		
EuroQol Score	0.812 (0.656-0.919)	0.848 (0.691-0.919)	P 0.54
Total health scale	0.78 (0.60-0.90)	0.80 (0.60-0.90)	P 0.96

Table No. 3.11. Comparison between the EuroQol values at recruitment and end of treatment visits, in the magnetic stimulation study.

Outcome at three months follow up:

Item	Recruitment	3 months follow up	Wilcoxon signed rank test
	Median (Interquantile range)		
EuroQol Score	0.812 (0.656-0.919)	0.848 (0.689-0.919)	P 0.62
Total health scale	0.78 (0.60-0.90)	0.80 (0.60-0.92)	P 0.77

Table No. 3.12. Comparison of EuroQol values at recruitment and 3 months follow up visits, in the magnetic stimulation study.

Side effects:

The incidence of side effects:

Side effects	No. of patients	%
Side effects	25	52.1 %
No side effects	23	47.9 %
Total	48	100 %

Table No. 3.13. The incidence of side effects during the magnetic stimulation study.

Frequency of side effects:

Session No.	No. of patients	Side effects	%
1	48	6	12.5 %
2	44	11	25.0 %
3	43	10	23.3 %
4	43	6	14.0 %
5	42	6	14.3 %
6	42	2	4.8 %
7	42	3	7.1 %
8	40	4	10.0 %
9	39	2	5.1 %
10	39	2	5.1 %
11	39	2	5.1 %
12	36	0	0 %
13	34	0	0 %
14	34	1	0 %
15	33	0	0 %
16	31	0	0 %
Mann-Whitney test		**P 0.00**	

Table No. 3.14. The incidence of side effects during various visits, in the magnetic stimulation study.

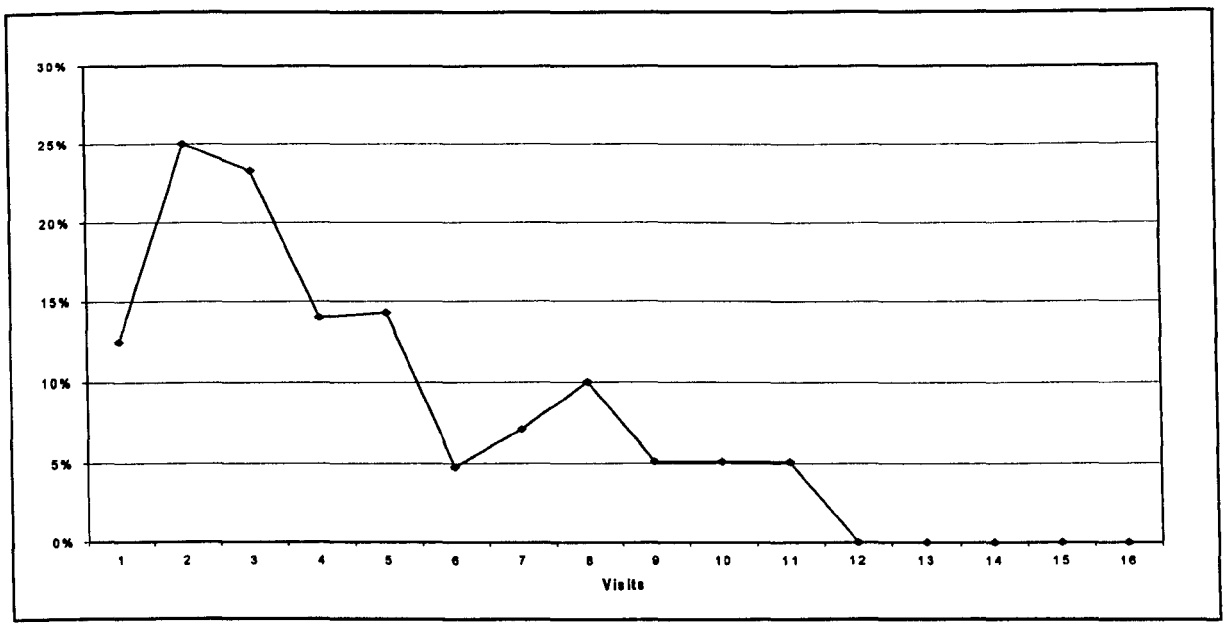


Chart No.3.1. The incidence rate of side effects during treatment visits

Nature of side effects:

Side effect	Patients	%
Lower limb pain	9	18.8 %
Abdominal pain	7	14.6 %
Cystitis	6	12.5 %
Bowel symptoms	6	12.5 %
Backache	5	10.4 %
Chair powerful	3	6.3 %
Difficult positioning	2	4.2 %
Tingling, pins and needles	2	4.2 %
Perineal pain	2	4.2 %
Neck pain	2	4.2 %
Shoulder pain	1	2.1 %
Headache	1	2.1 %
Palpitation	1	2.1 %
Asthma worse	1	2.1 %
Dyspareunia	1	2.1 %

Table No. 3.15. The frequency of side effects encountered, in the magnetic stimulation study.

Drop out:

Rate of drop out:

Session No.	No. of patients	%
Dropped out	17	35.4 %
Completed all treatment sessions	31	64.6 %
Total	48	100 %

Table No. 3.16. The rate of drop out in the magnetic stimulation study.

Rate of drop out per visit:

Session No.	No. of patients	Drop out	%
1	48	4	8.3 %
2	44	1	2.3 %
3	43	0	0 %
4	43	1	2.3 %
5	42	0	0 %
6	42	0	0 %
7	42	2	4.8 %
8	40	1	2.5 %
9	39	0	0 %
10	39	0	0 %
11	39	3	7.7 %
12	36	2	5.6 %
13	34	0	0 %
14	34	1	2.9 %
15	33	2	6/1 %
16	31	N/A	N/A
Mann-Whitney test		P 0.86	

Table No. 3.17. The rate of drop out following various visits, in the magnetic stimulation study.

Reasons for drop out:

Given reason for drop out	Number (%)
Neck pain	2 (4.2 %)
Backache	1 (2.1 %)
Pain	1 (2.1 %)
Urinary tract infection	1 (2.1 %)
Anticholinergic medication for detrusor overactivity	1 (2.1 %)
Bereavement and no improvement	1 (2.1 %)
Could not keep appointment	1 (2.1 %)
Irritable bowel syndrome and no improvement	1 (2.1 %)
Patient did not like to continue the treatment	1 (2.1 %)
No given reason	7 (14.6 %)

Table No. 3.18. The reasons for drop out, in the magnetic stimulation study.

Baseline criteria and drop out:

Demographic data:

Feature	Completed (31)	Dropped out (17)	2 sample t test
Age (Years)	50.48 + 13.42	50.71 + 11.06	P 0.97
Weight (Kg)	73.11 ± 13.29	64.57 ± 10.60	P 0.03

Table No. 3.19. Comparison of demographic data between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

Symptoms duration:

Symptoms duration (Months)	Completed (31)	Dropped out (17)	P value*
Median (Interquantile range)	44 (30-120)	84 (52-204)	0.18

*Mann Whitney test

Table No. 3.20. Comparison of the duration of incontinence between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

Background:

Feature	Completed (31)	Dropped out (17)	X^2 test
Medical problems	22 (71%)	12 (70.6%)	P 0.98
Cardio-pulmonary diseases	14 (45.2%)	4 (23.5%)	P 0.14
Bone / joint diseases	25 (80.6%)	7 (41.2%)	P 0.18
Previous surgery	25 (80.6%)	13 (76.5%)	0.73*
Continence/repair operation	8 (25.8%)	6 (35.3%)	P 0.49
On medication	22 (71.0%)	10 (85.8%)	P 0.39
On bladder affecting medication	10 (32.3%)	6 (35.3%)	P 0.83

*Fisher's exact test

Table No. 3.21. Comparison of the medical, surgical as well as medication history between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

Continence parameters:

Parameter	Completed (31)	Dropped out (17)	Mann Whitney test
	Median (Interquantile range)		
Pad test (gm)*	4.9 (1-27.8)	7 (3.9-23)	P 0.72
Daily pad use	1.35 (0-3)	2 (1-3.3)	P 0.52
Daily leakage episodes	2 (1-2.7)	3.4 (1.7-4.2)	P 0.16

* Primary outcome measure

Table No. 3.22. Comparison of the continence parameters on recruitment between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

Kings Health Questionnaire:

Domains:

Domain	Completed (31)	Dropped out (17)	Mann Whitney test
	Median (Interquantile range)		
General health	0.25 (0.00-0.25)	0.25 (0.13-0.50)	P 0.14
Incontinence impact	0.66 (0.33-0.66)	1.00 (0.67-1.00)	P 0.44
Role limitations	0.66 (0.33-0.66)	0.50 (0.33-0.66)	P 0.79
Physical limitations	0.50 (0.16-0.66)	0.50 (0.33-0.66)	P 0.48
Social limitations	0.19 (0.11-0.33)	0.22 (0.11-0.33)	P 0.35
Personal relationships	0.16 (0.00-0.33)	0.50 (0.16-0.83)	P 0.05
Emotions	0.44 (0.22-0.78)	0.67 (0.33-0.88)	P 0.24
Sleep/energy	0.33 (0.17-0.50)	0.33 (0.33-0.50)	P 0.33
Severity measures	0.66 (0.56-0.75)	0.66 (0.42-0.75)	P 0.54

Table No. 3.23. Comparison of the quality of life domains, as measured by the King's health questionnaire, on recruitment between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

Symptom scores:

Symptom	Drop out	None	A little	Moderately	A lot	P*
Frequency	Completed	10 (32.3%)	4 (12.9%)	9 (29.0%)	8 (25.8%)	0.27
	Dropped out	3 (18.7%)	3 (18.7%)	3 (18.7%)	7 (43.9%)	
Nocturia	Completed	8 (25.8%)	12 (38.7%)	7 (22.6%)	4 (12.9%)	0.91
	Dropped out	5 (31.3%)	5 (31.3%)	2 (12.4%)	4 (25.0%)	
Urgency	Completed	9 (29.0%)	4 (12.9%)	7 (22.5%)	11 (35.5%)	0.63
	Dropped out	6 (40.0%)	3 (20.0%)	0 (0%)	6 (40.0%)	
Urge incontinence	Completed	9 (29.0%)	7 (22.6%)	8 (25.8%)	7 (22.6%)	0.94
	Dropped out	3 (18.7%)	5 (31.3%)	6 (37.5%)	2 (12.5%)	
Stress incontinence	Completed	1 (3.2%)	2 (6.5%)	7 (22.6%)	21 (67.7%)	0.50
	Dropped out	2 (12.5%)	2 (12.5%)	2 (12.5%)	10 (62.5%)	
Nocturnal enuresis	Completed	25 (80.7%)	4 (12.9%)	1 (3.2%)	1 (3.2%)	0.35
	Dropped out	11(68.8%)	3 (18.8%)	1 (6.2%)	1 (6.2%)	
Intercourse incontinence	Completed	19 (61.3%)	6 (19.4%)	4 (12.9%)	2 (6.4%)	0.35
	Dropped out	9 (56.3%)	1 (6.2%)	1 (6.2%	5 (31.3%)	
Frequent waterworks infections	Completed	21 (67.7%)	7 (22.6%)	2 (6.5%)	1 (3.2%)	0.41
	Dropped out	10 (62.5%)	1 (6.2%)	2 (12.5)	3 (18.8%)	
Bladder pain	Completed	20 (64.5%)	8 (25.8%)	3 (9.7%)	0 (0%)	0.23
	Dropped out	9 (56.3%)	1 (6.2%)	4 (25.0%)	2 (12.5%)	
Other symptoms	Completed	31 (100%)	0 (0%)	0 (0%)	0 (0%)	0.15
	Dropped out	14 (93.3%)	0 (0%)	0 (0%)	1(6.7%)**	

* Mann-Whitney test, ** Bladder pain.

Table No. 3.24. Comparison of symptom scores in the King's health questionnaire, according to completion of treatment sessions, in the magnetic stimulation study.

EuroQol:

Item	Completed (31)	Dropped out (17)	Mann Whitney test
	Median (Interquantile range)		
EuroQol Score	0.830 (0.689 - 0.919)	0.725 (0.587 - 0.919)	P 0.24
Total health scale	0.80 (0.65 - 0.90)	0.60 (0.60 - 0.90)	P 0.55

Table No. 3.25. Comparison of the EuroQol values on recruitment between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

The relationship between side effects and drop out:

Some of the side effects might be perceived as relevant to magnetic stimulation. For example, tingling sensation and pelvic pain could be perceived to be due to nerve and muscle stimulation by extra-corporeal magnetic treatment. On the other hand, headache is less likely to be linked to the treatment such that patients might continue attending.

Incidence of any side effects and relevant side effects:

Side effects	Completed (31)	Dropped out (17)	X^2 test
Any	13 (41.9%)	12 (70.6%)	P 0.06
Relevant	11 (35.5%)	12 (70.6%)	P 0.02

Table No. 3.26. Comparison of the incidence of side effects and relevant side effects between those who completed all treatment sessions and those who dropped out, in the magnetic stimulation study.

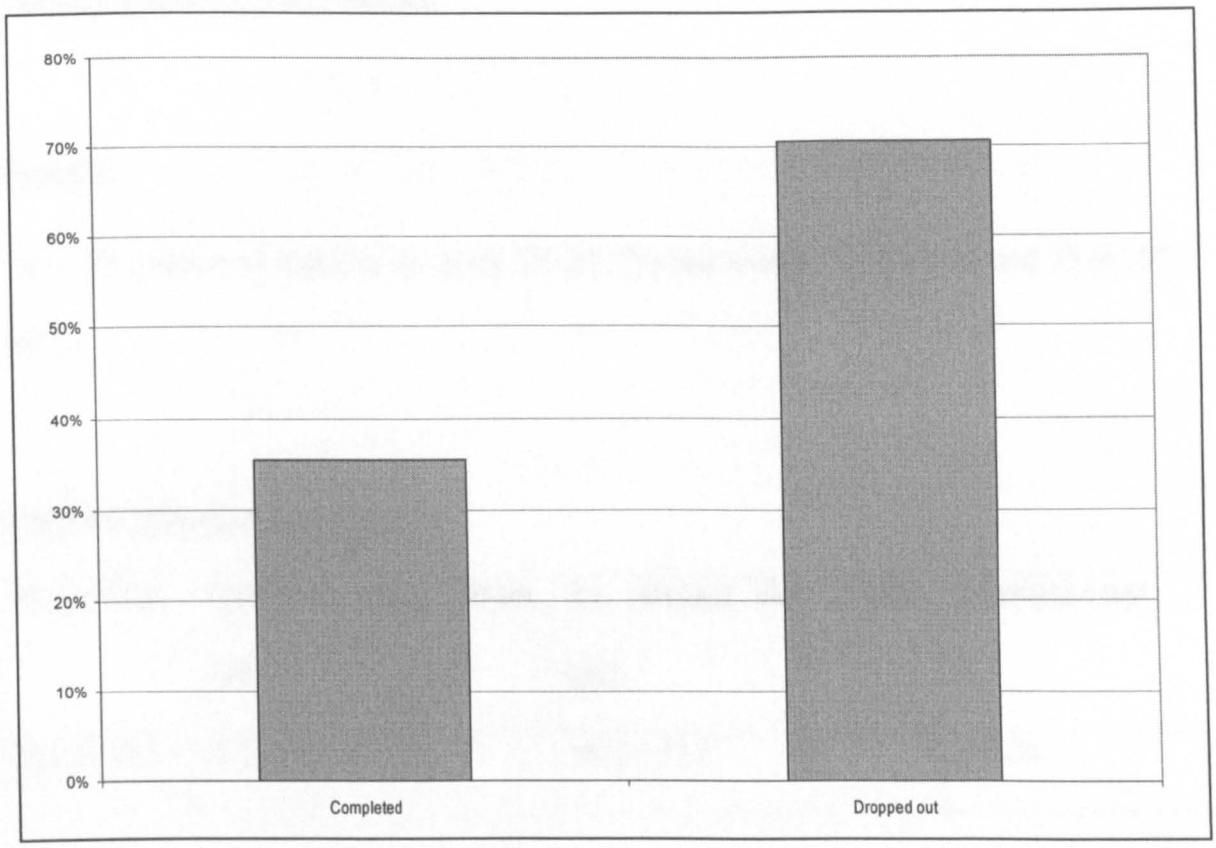


Chart No. 3.2. The incidence of relevant side effects in those who completed treatment sessions and those who dropped out

Relevant side effects and weight:

Patients:

Out of 48 patients recruited to the study, 25 (52.1%) had relevant side effects and 23 (47.9%) did not.

Relevant side effects and weight:

Weight (Kg)	Relevant side effects (25)	No relevant side effects (23)	2 sample t test
Mean ± SD	72.0 ± 14.22	68.3 ± 11.7	P 0.34

Table No. 3.27. Comparison of the weight of those who had relevant side effects and those who did not, in the magnetic stimulation study.

The end of treatment outcome in those who had 20% reduction in pad test:

Pad test at the end of treatment visit:

Pad test at end of treatment visit	No. (%)	95% confidence interval
≥ 20% reduction in leakage	16 (51.7%)	33.1 –69.8 %
No ≥ 20% reduction in leakage	13 (42%)	24.5 – 60.9 %
Either or both pad tests not done	2 (6.3%)	
Total	31 (100%)	

Table No. 3.28. The distribution of patients according to the reduction in pad test leakage at the end of treatment visit, in the magnetic stimulation study.

Continence parameters:

Parameter (Mean ± SD)	Recruitment	End of treatment	t test
Daily pad use	1.7 ± 2.1	1.2 ± 1.6	P 0.96
Daily leakage episodes	2.1 ± 1.4	1.0 ± 1.1	P 0.07

Table No. 3.29. Comparison of daily pad use and leakage episodes values at recruitment and end of treatment visits, in those patients who had a ≥ 20% in pad test, in the magnetic stimulation study.

Quality of life:

Kings Health Questionnaire:

Domains:

Domain	Recruitment	End of treatment	Wilcoxon signed rank test
	Median (Interquantile range)		
General health	0.13 (0.00-0.36)	0.13 (0.00-0.05)	P 0.32
Incontinence impact	0.66 (0.33-1.00)	0.50 (0.33-0.67)	P 0.17
Role limitations	0.50 (0.33-0.66)	0.33 (0.33-0.66)	P 0.39
Physical limitations	0.50 (0.16-0.58)	0.33 (0.17-0.66)	P 0.68
Social limitations	0.11 (0.00-0.33)	0.11 (0.00-0.33)	P 0.63
Personal relationships	0.08 (0.00-0.16)	0.00 (0.00-0.17)	P 0.86
Emotions	0.50 (0.11-0.67)	0.28 (0.11-0.39)	P 0.24
Sleep/energy	0.33 (0.17-0.65)	0.33 (0.16-0.58)	P 0.38
Severity measures	0.58 (0.41-0.66)	0.58 (0.37-0.75)	P 0.91

Table No. 3.30. Comparison of scores of quality of life domains, as measured by the King's health questionnaire, at recruitment and end of treatment visits, in those patients who had a ≥ 20% in pad test, in the magnetic stimulation study.

Symptom scores:

Symptom	Visit	None	A little	Moderately	A lot	P *
Frequency	Recruitment	6 (37.5%)	2 (12.5%)	5 (31.3%)	3 (18.7%)	0.86
	End of treatment	5 (31.2%)	2 (12.5%)	9 (56.3%)	0 (0%)	
Nocturia	Recruitment	4 (25.0%)	6 (37.4%)	3 (18.8%)	3 (18.8%)	0.63
	End of treatment	4 (25.0%)	8 (50.0%)	2 (12.5%)	2 (12.5%)	
Urgency	Recruitment	8 (50.0%)	2 (12.4%)	3 (18.8%)	3 (18.8%)	0.69
	End of treatment	6 (37.4%)	4 (25.0%)	3 (18.8%)	3 (18.8%)	
Urge incontinence	Recruitment	5 (31.3%)	5 (31.3%)	3 (18.7%)	3 (18.7%)	0.58
	End of treatment	7 (43.8%)	4 (25.0%)	2 (12.5%)	3 (8.7%)	
Stress incontinence	Recruitment	0 (0%)	2 (12.5%)	6 (37.5%)	8 (50.0%)	0.19
	End of treatment	3 (18.7%)	1 (6.2%)	7 (43.8%)	5 (31.3%)	
Nocturnal enuresis	Recruitment	15 (93.8%)	1 (6.2%)	0 (0%)	0 (0%)	0.28
	End of treatment	13 (81.3%)	2 (12.5%)	1 (6.2%)	0 (0%)	
Intercourse incontinence	Recruitment	12 (75.0%)	4 (25.0%)	0 (0%)	0 (0%)	0.37
	End of treatment	14 (87.5%)	2 (12.5%)	0 (0%)	0 (0%)	
Frequent water works infection	Recruitment	11 (68.8%)	2 (12.5%)	2 (12.5%)	1 (6.2%)	0.70
	End of treatment	12 (75.0%)	1 (6.2%)	3 (18.8%)	0 (0%)	
Bladder pain	Recruitment	10 (62.5%)	5 (31.3%)	1 (6.2%)	0 (0%)	0.49
	End of treatment	12 (75.0%)	3 (18.8%)	1 (6.2%)	0 (0%)	
Other symptom(s)	Recruitment	16 (100%)	0 (0%)	0 (0%)	0 (0%)	N/A
	End of treatment	16 (100%)	0 (0%)	0 (0%)	0 (0%)	

* Mann-Whitney test

Table No. 3.31. Comparison of scores of symptom scores, as measured by the King's health questionnaire, at recruitment and end of treatment visits, in those patients who had a $\geq$ 20% in pad test, in the magnetic stimulation study.

EuroQol:

Item	Recruitment	End of treatment	Wilcoxon signed rank test
	Median (Interquantile range)		
EuroQol Score	0.848 (0.689-0.919)	0.848 (0.656-0.919)	P 0.55
Total health scale	0.75 (0.60-0.90)	0.80 (0.66-0.90)	P 0.37

Table No. 3.32. Comparison of EuroQol values at recruitment and end of treatment visits, in those patients who had a ≥ 20% in pad test, in the magnetic stimulation study.

Summary:

With the exception of general health, as measured by the King's Health Questionnaire, there was no significant change in incontinence parameters or other quality of life elements at the end of treatment. With the exception of general health and personal relationships, as measured by the King's Health Questionnaire, there was no significant change in incontinence parameters or other quality of life elements at 3 months follow up. There was no significant change in incontinence parameters or the quality of life of those patients who had ≥ 20% drop in their pad test at the end of treatment sessions.

Over half the patients had side effects, which became significantly less frequent as treatment sessions progressed. Pain in different forms was the most commonly encountered side effect. Over a third of patients did not complete all treatment sessions. Although almost half of them gave no reason for dropping out, pain, which could have been perceived as a side effect, as well as non improvement seemed rather prominent.

With the exception of weight, there was no significant difference in baseline features between those who completed all treatment sessions and those who dropped out. There was no

significant difference in the mere occurrence of side effects between those who completed all treatment sessions and those who dropped out. However, the incidence of relevant side effects was significantly more common in those who dropped out. The weight of those who had relevant side effects was not significantly different from those who did not have relevant side effects.

Discussion:

Primary outcome measure:

There was no significant difference in the primary outcome measure (pad test) between recruitment and end of treatment visits. Likewise, there was no significant difference between recruitment and 3 months follow visits.

Secondary outcome measures:

With the exception of general health, in the King's Health Questionnaire, there was no significant difference in incontinence parameters or quality of life measures between recruitment and end of treatment visits. Likewise, there was no significant difference in incontinence parameters or quality of life measures between recruitment and 3 months follow up visits, except for general health and personal relationships, as measured by the King's Health Questionnaire. Furthermore, there was no significant difference in incontinence parameters or quality of life measures between recruitment and end of treatment visits in those who had $\geq$ 20% reduction in pad test at the end of treatment visit.

Effectiveness:

There was no significant change in the primary or secondary outcome measures at the end of treatment sessions or at 3 months follow up. Although 16 out of 31 patients (51.7%) had $\geq$ 20 drop in pad test at the end of treatment, this was not associated with significant change in any of the outcome measures. Extra-corporeal magnetic energy stimulation of pelvic floor muscles did not improve urodynamic stress incontinence for the patients who tried this method in this study.

Although only 31 patients completed all treatment sessions and were available for assessment, which is almost half the number planned (60). The fact that no improvement was noticed, even in those who had $\geq$ 20% reduction in pad test at the end of treatment sessions, meant that it was unlikely that the treatment actually improve urodynamic stress incontinence. The lack of any significant difference in outcome measures at 3 months follow up further supported the conclusion that that the treatment does not improve urodynamic stress incontinence of urine in women.

This result is in direct contrast to the studies published already, reporting beneficial effect from using the technique for urodynamic stress incontinence of urine in women. Nonetheless, some of these studies did not report the outcome at the end of treatment. One reported the outcome at 3 months follow up (Galloway et al, 1999) and then at 6 months follow up (Galloway et al, 2000). Another (Unsal et al, 2003) provided one year follow up data only. It is therefore not possible to compare the immediate outcome of this study with the long term outcome of these two studies.

One study (Yamanishi et al, 2000) showed a mixed outcome. Whilst there was a significant improvement in daily leakage episodes and quality of life scores, there was no change in nocturnal leakage or the number of pads used per day. It also showed a drop in cure rate from 34% at 3 months to 28% at 6 months (Galloway et al, 2000). A similar drop was reported by Yokoyama et al, (2004) from 52.9% at the end of treatment to 31.3% at 6 months follow up. The same pattern was noted in another study (Almeida et al, 2004). Although 37% of patients were dry at the end of treatment, there was a rapid and progressive recurrence reaching 47% at 3 months, 61.7% at 6 months and 94%, which is near 100%, at 12 months. Other methodological limitations of these studies have been outlined already.

Some studies had different inclusion and exclusion criteria. One study (Galloway et al, 1999) specifically excluded patients with intrinsic sphincter deficiency, type III urodynamic stress incontinence. These patients were not excluded from this study. It also included patients with significant degrees of prolapse, who were excluded from this study. Some studies were not limited to patients with urodynamic stress incontinence (Galloway et al, 1999; Almeida et al, 2004)

Some studies used a different primary outcome measure. Galloway et al, (1999) had a subjective one; a reduction in the number of pads used each day. On the other hand, this study had an objective one; 20% reduction of leakage on a standard International Continence Society 1 hour pad test (Abrams et al, 1989). Another study (Unsal et al, 2003) defined cure as a negative pad test, while this study was looking for a 20% reduction in leakage on pad testing.

Only one study looked at the long term results of electrical stimulation (Caputo et al, 1993). Outcome was assessed subjectively at an average of 6 months. They attempted to telephone 17 patients, who had $\geq$ 50% reduction in leakage episodes, at the end of six weeks programme, out of an initial cohort of 19 patients with urodynamic stress incontinence. Yet, only 8 patients were contacted, of whom 7 (87.5%) felt their incontinence was still improved and 1 (12.5%) reported a relapse. These numbers are too small to judge any result against.

The outcome of this study is lower than that reported for other non-invasive techniques, as outlined in the review earlier. Extra-corporeal magnetic energy stimulation effects passive contractions of pelvic floor muscles, in very much the same way electrical stimulation does.

Patients do not get involved in the process, to contract their muscles actively, as happens in pelvic floor exercises, with or without feedback.

There are doubts about the value of such passive forms of muscle stimulation (Bo, 1998). Although some reported improvements, ranging from 60 to 90% (Erlandson et al, 1978a; Plevnik & Janez, 1979; Scott & Hsueh, 1979; Fall et al, 1986; Eriksen & Eik-Nes, 1989), others showed no benefit (Hahn et al, 1991). Controlled studies showed no advantage over pelvic floor exercises (Wilson et al, 1987; Henalla et al, 1989). Whilst some randomised trails showed significant improvement with active devices (Laycock & Jerwood, 1993; Sand et al, 1995), others showed no difference from sham devices (Brubaker et al, 1997) and some even reported better outcome with sham devices (Luber & Wolde-Tsadik, 1997). The outlook for passive stimulation is not good to start with.

Patient involvement does appear to be more important than mere occurrence of contractions. The knack (Miller et al, 1996) and the stop tests (Gosling 1979), outlined earlier, are examples of how patients develop neuromuscular co-ordination in a variety of ways under different circumstances. Pelvic floor exercises entail patient education about their pelvic floor, which further enhances their involvement in the pelvic floor exercise. Such involvement and training build not only muscle strength, but also improves the tone and reflex contraction upon sudden increase in intra-abdominal pressure. Passive contractions do not entail these elements.

Some have suggested using electrical stimulation as an adjunct to pelvic floor exercises (Blowman et al, 1991), especially in those who are unable to contract their muscles on their own, to get them used to what a contraction feels like. Extra-corporeal magnetic energy stimulation offers an advantage in not requiring patients to undress or have electrodes inserted

in the vagina. It would be interesting to look at the value of the technique in conjunction with pelvic floor exercises. The machine's manual specifically indicates that patients should not try to contract their muscles during treatment sessions. Nonetheless, patients can contract their muscles between sessions.

Side effects:

A total of 25 patients (52.1%) experienced side effects and 23 (47.9%) had side effects that could be perceived as related to the treatment. This is high, especially when other studies reported no side effects (Galloway et al, 2000; Yamanishi et al, 2000; Unsal et al, 2003). The machine's manual indicates that patients might experience some muscle fatigue from effected contractions and abdominal cramps if they are menstruating. Yet, it does stress that the treatment is painless, which was not the case in this study.

Several patients experienced pain in the pelvis and lower limbs. In fact, a third of patients (16 out of 48) experienced some form of pain. Tingling sensation was also encountered and might be due to nerve stimulation from the electromagnetic field. Of special interest is the fact that some patients had pain outside the pelvis. Examples include backache, knee pain as well as neck pain. One of the patients had to have an X-ray of her neck because of the pain she had following one of the sessions. It is known that the electromagnetic fields are ill defined with this form of treatment (Barker, 1991), and the effect of muscle stimulation might extend further away from the pelvic floor. Although the neck would seem rather distant, it might not be that far in elderly women suffering from osteoporosis. This side effect should be taken into consideration when counselling patients before offering them this treatment.

When compared to other non-invasive methods, the rate was still high. It is difficult to see side effects from pelvic floor exercises (Yalcin et al, 1998) and the same applies to biofeedback (Morkved et al, 2002). Side effects of electrical stimulation include persistent vaginal irritation in 14% of patients and pelvic pain in 9% of patients (Sand et al, 1995) as well as anal discomfort in 20% of patients using anal electrical stimulation (Eriksen & Eik-Nes, 1989). Such side effects have been known to cause patients to discontinue electrical stimulation (Indrekvam & Hunskaar, 2002). Extra-corporeal magnetic energy stimulation was hailed as an improvement, as patients do not have to undress and insert electrodes, and it was hoped that compliance would improve. Not only it was associated with a higher rate of side effects, but these side effects were implicated in causing a much higher drop out rate as well.

Drop out:

Establishing the rate of completion of treatment sessions was one of the objectives of this study. Only 31 patients, out of the 48, completed all 16 sessions, 64.6%, which is almost two thirds. The drop out rate of 35.4% is higher than that reported in other studies. The two reports on the study by Galloway et al (1999; 2000), reported 22.9 % and 12.6% drop out rates, respectively. Another study (Yamanishi et al, 2000) reported a drop out rate of 14.3% (1 patient out of 7). These are lower than encountered in this study.

A significantly high proportion of those patients who completed treatment sessions attended for follow up at three months. Only 4, out of 31 (12.9%), defaulted. This is good in comparison to the number of patients who dropped during treatment sessions. In fact the difference in drop out rate was significant, when assessed using Fisher's exact test (P 0.04). There were no treatment sessions, and consequently no side effects, during the follow up period, further

supporting the suggestion that side effects were central to patients' drop out during the study period.

With home based pelvic floor exercises, continuation is often expressed as compliance. This can be as low as was 61% (Yalcin et al, 1998), which means a non continuation rate of over a third. For pelvic floor exercises and biofeedback, rates around 8% were reported (Bo et al, 1990; Morkved et al, 2002). In another study, (Dougherty et al, 1993), 19 out of 80 patients (23.8%) withdrew. Likewise, 22% withdrew from a study assessing biofeedback, in addition to 12% who completed all sessions but refused the final examination (Hirsch et al, 1999). The same applies to electrical stimulation, where the rates varied from 9.7% (Miller et al, 1998) and 15.4% (Sand et al, 1995) to 18% (Brubaker et al, 1997) and 27% (Laycock & Jerwood, 1993). All these figures are lower than encountered in this study.

Although 41.2% of those who did not complete all treatment sessions gave no reason for dropping out, pain, inability to attend and lack of improvement were rather prominent. Patients looking for a quick improvement on non-invasive measures may not persevere and drop out relatively early. Those keen on avoiding surgery and its possible complications tend to comply with non-invasive measures and complete sessions (Rai & Versi, 1993).

When those who completed all treatment sessions were compared to those who dropped out, only two factors were found to be significantly different; patients' weight on recruitment and the occurrence of relevant side effects. The weight of those who dropped out was lighter and they had a higher incidence of those side effects that can be perceived to result from magnetic stimulation. There was no difference in weight between those who had relevant side effects

and those who did not. This leaves relevant side effects as the likely contributing factor behind drop out.

Although there was no significant increase in the drop out rate as treatment sessions progressed, there was a significant reduction in side effects. This could be due to patients having side effects from the treatment dropping out early in the study and/or patients getting used to these side effects. Side effects were therefore an important factor behind the high drop out rate in this study.

This finding is not supported by published work using the same technique. The study by Galloway et al (2000) showed the drop out was due to conflicting commitments and travel problems. A variety of reasons have been quoted with other non-invasive techniques. For pelvic floor exercises, inability to attend and having operations were mentioned (Bo et al, 1990). With biofeedback, changes in circumstances, including job, family, death and relocation, and not liking the technique (Morkved et al, 2002) as well as pregnancy, muscle disease, abdominal surgery and insufficient motivation (Hirsch et al, 1999) were implicated. For electrical stimulation, persistent vaginal irritation, development of urgency (Sand et al, 1995) as well as postmenopausal bleeding (Miller et al, 1998) were encountered. The prominence of side effects as a possible contributing factor behind drop out limits the value of extra-corporeal magnetic stimulation as a non-invasive method.

Conclusions:

As the study did not reach its recruitment target of 60 patients, it is not possible to conclude that extra-corporeal magnetic stimulation of pelvic floor muscles does or does not lead to 20% reduction in leakage on pad test with 80% power and 95% confidence (0.05 significance). Nonetheless, it is unlikely that the technique improves urodynamic stress incontinence of urine in women, given the results encountered in this study. The technique did not change pad usage, leakage episodes or patients' quality of life at the end of treatment or at 3 months follow up either and had a drop out rate of 35.4%. Even those who had $\geq$ 20% reduction in pad leakage did not have any other features of improvement at the end of treatment. In addition, over half the patients had side effects and these appear to contribute to drop out.

Recommendations:

1. Extra-corporeal magnetic stimulation of pelvic floor muscles should not be offered as a standard treatment for female patients presenting with urodynamic stress incontinence of urine. If provided, patients should be aware of the evidence in relation to its effectiveness and side effects. Since this study, the machine has been used selectively on individual patient basis at Singleton and Morriston hospitals.
2. Special care should be taken when discussing this method of treatment with patients known to have arthritis, even if this is distant from the pelvis. They should be made aware of possible side effects, in the form of pain, and ideally they should try other forms of non-invasive treatment first.
3. Patients embarking on this treatment might better have a trial session first, to see if they can tolerate it or not, to avoid drop out later on.
4. This technique is worth assessing in conjunction with pelvic floor exercises and also as an aid for physiotherapists when instructing patients, especially those who can not contract their pelvic floor muscles properly.

4. Radiofrequency remodelling of the endopelvic fascia:

Background:

Various forms of energy have bee used in surgery, including diathermy (Farquhar, 2006), laser (Goldrath et al, 1981), harmonic scalpel (Wacha et al, 2002), microwave (Wallage et al, 2003) and radiofrequency (Lewis, 1995). Radiofrequency has been used for endometrial ablation (Phipps et al, 1990; Lewis, 1995), nasal turbinate diathermy (Elwany et al, 1999), anal incontinence (Takahashi et al, 2002) as well as recurrent shoulder joint dislocation (Selecky et al, 2003).

Physics of radiofrequency remodelling:

Radiofrequency is a form of electrosurgery that utilises high frequency alternating current. Low frequency current (>100,00 Hz) effects neuromuscular stimulation. Higher frequency currents are used in surgical diathermy and cutting (Smith & Smith, 2001). The term radiofrequency is used when current frequency lies within the radiofrequency range of the electromagnetic spectrum, as explained earlier in dealing with extra-corporeal magnetic energy stimulation of pelvic floor muscles (Wright, 1994). A generator is required to convert domestic, low frequency, electricity to high frequency (radiofrequency) current (Applegate, 1989).

- The effect of radiofrequency applied depends on a number of factors;

1. Voltage: voltage is the term used to describe the force that pushes electrons along the stream. The greater the voltage, the stronger is the impact of electricity on tissues. High voltage current (200-500) can bridge the gap to the tissues, leading to the sparking often

seen on diathermy. Very high voltage (600) can lead to tissue carbonisation, hence it is unsafe to come close to high-voltage power-transmission cables.

2. Power: electric power describes the amount of energy produced or consumed over time and is measured in watts. It is reflected in the heat generated at tissue surface. At low power, heat leads to tissue shrinkage, whereas high power causes ablation and cutting (Haupt et al, 1997). Power is the only factor that can be changed on most generators nowadays. Radiofrequency remodelling of the endopelvic fascia applies low power (15 watts) that leads to shrinkage of the fascia. The generator can not be used for other purposes.

3. Resistance: resistance is an indication of tissue conductivity of electric current and is measured in Ohms. Heated tissues become more resistant to current transmission. Prolonged application leads to accumulation of energy and burns. In radiofrequency remodelling of the endopelvic fascia, tissue temperature is constantly monitored to avoid over heating.

4. Current:: this refers to the flow of electrons during a given period of time. For a given voltage, current is inversely related to tissue resistance, according to Ohm's law;

   Voltage = current X resistance

   In radiofrequency remodelling of the endopelvic fascia, current flow gets less with increased resistance of the endopelvic fascia as a result of heating. Instrument design

guides proper application of the probe to ensure continued flow of current, by monitoring of local tissue temperature (Massarweh et al, 2006).

5. Circuit: electrons flow in a circuit. With unipolar applications, the current passes from the site of application through the tissues to the return electrode. If there is a contact with metal in between the site of application, the current will follow the path of least resistance to the metal object, such as pace maker or bone pins. This might cause tissue damage around the contact with the metal. Similarly, if the return electrode is not properly applied to the body, energy will accumulate leading to burns. Bipolar applications avoid such problems as the current passes between two electrodes through the target tissue area (Wicker, 1992, Nduka et al, 1994).

   Radiofrequency remodelling of the endopelvic fascia applies bipolar circuit. This approach limits heat delivery to the part of the endopelvic fascia being treated. Consequently, there is no need for a return electrode and there is no risk of distant site damage from unlimited field. There is no restriction as to the anaesthetic equipment that can be used and patients with metal prosthesis are not excluded from this form of treatment.

6. Area of tissue exposed: this determines the amount of heat generated, according to Joules law;

   $$\text{Energy} = (\text{current/cross sectional area})^2 \times \text{resistance} \times \text{time}.$$

   Higher energy is delivered when using small electrodes and larger electrodes will require longer time to generate a similar amount of heat (Massarweh et al, 2006). Radiofrequency

of the endopelvic fascia utilises a probe with a fixed size leaving the duration of application as the only factor that affects the level of energy. This is guided through measuring tissue temperature, as explained already.

The effect of electrosurgery can be divided into 3 types (Massarweh et al, 2006);

1. Cutting: a continuous current delivers continuous energy to a very limited tissue area over a short period of time. The classical example is the pin used to make skin incisions. This causes tissue temperature to rise rapidly beyond 100°C, leading to vaporisation of intracellular contents. Tissue division happens as cells explode from increased intracellular volume. The high level of electrons accumulated at the tip of the cutting electrode makes it possible to create a spark cutting into the tissues when the electrode is slightly away from tissue surface.
2. Fulguration: an interrupted generation of current delivers energy for about 6% of electrode activation time. The level of heat generated is less than with continuous current, as in cutting mode. This leads to the tissue coagulation, rather than vaporisation. Energy here is delivered to a larger tissue area over a longer duration of time, hence the need for higher voltage. Energy can still be delivered with the electrode slightly away from tissues.
3. Desiccation: tissue contact with electrodes reduces current concentration, which in turn reduces energy (heat) generation. This leads to tissue drying out and coagulum formation.

The effect of application will depend of the level of heat generated. Below, 42°C, the effect is reversible (Coakley, 1987). As the temperature rises above this level, enzymatic denaturation and nuclear destruction take place (Phipps & Lewis, 1993). When the temperature exceeds 90°C, tissue fluids evaporates, leading to vaporisation when energy is delivered rapidly, as in cutting mode, or desiccation if heat delivery is slow. In radiofrequency re-modelling of the

endopelvic fascia, the bipolar probe is directly applied to tissues (desiccation). The temperature rises to an average of 82°C (Dmochowski & Appell, 2003), leading to tissue necrosis and gross shrinkage (Lopez et al, 1998). Healing entails remodelling leading to altered tissue compliance (stretch) without gross change in morphology (Sotomayer & Bernal, 2003).

Continence theory:

The technique is based on the Hammock hypothesis (DeLancey, 1994), which postulates that the urethra lies on a supportive layer, in the form of the endopelvic fascia and the anterior vaginal wall. The endopelvic fascia is a tense layer that stretches, like a hammock, from the arcus tendinous fascia, on the lateral pelvic wall, to the vaginal wall medially. The urethra lies above and anterior to this supportive layer, getting compressed backwards and downwards against it during increased intra-abdominal pressure, preventing any leakage of urine.

The supportive function of the endopelvic fascia is further enhanced by its link to the levator ani. The arcus tendinous fascia, where the endopelvic fascia gets it lateral attachment, stretches from the pubic bone to the ischeal spine. Its posterior part is aponeurotic, forming the white line, which lies close to the inner surface of the levator ani muscle. Around the vagina, the endopelvic fascia merges with the medial margin of the levator ani muscle as well. This explains why a voluntary contraction the pelvic floor can elevate the bladder neck, through pulling and tightening the endopelvic fascia. Magnetic resonance imaging studies support this hypothesis (Aronson et al, 1995).

This hammock theory is distinct from the equal transmission theory, which is based on intra-abdominal placement of the bladder neck and proximal urethra (Quinn, 1996). It suggests that continence is not based on the location of the proximal urethra, but rather the tense layer of

endopelvic fascia and anterior vaginal wall lying underneath the urethra. This layer acts like a hammock, to prevent opening of the proximal urethra, and thus leakage of urine, during stress related increased abdominal pressure. This hammock can work even when the proximal urethra lies outside the abdomen, as in some cases of anterior vaginal wall prolapse, and there is no link between urethral axis and stress incontinence (Fantl et al, 1986).

The implication of this hypothesis is that correction of stress incontinence need not necessarily entail elevation of the bladder neck and proximal urethra back to an intra-abdominal position, as in colposuspension, but rather restoring the support underneath the proximal urethra (DeLancey, 1994). Whilst bladder neck elevation will enhance its closure during stress, it may create other problems, such as voiding dysfunction (Galloway et al, 1987) as well as detrusor overactivity (Cardozo et al, 1979).

A lax endopelvic fascia therefore leads to urodynamic stress incontinence, according to the hammock hypothesis. This laxity can result from a number of factors; including childbirth (Allen et al, 1990), nerve damage (Snooks et al, 1985; Smith et al, 1989) and possibly postmenopausal status. As a result, the proximal urethra will not be compressed during increased intra-abdominal pressure, leading to leakage of urine. It can be detected in the form of bladder neck hypermobility and/or paravaginal defects in incontinent patients (Aronson et al, 1995). Correction of this deficiency relies on tightening the endopelvic fascia, rather than elevation of the bladder neck. This is of course distinct from cases where there is intrinsic sphincter deficiency, type III urodynamic stress incontinence.

The hammock theory shares a common feature with the integral one, which is the basis for the tension-free vaginal tape (TVT) sling. The integral theory suggests that continence relies on an

intact urethra that is capable, regardless of the position of its proximal part, of standing increased intra-abdominal pressure during episodes of stress (Petros & Ulmsten, 1990). The main form of support is the pubo-urethral ligament, which is a condensation of tissue between the posterior aspect of the symphysis pubis to the endopelvic fascia (DeLancey, 1994; Aronson et al, 1995). Whilst the main supportive element, and thus aim of corrective surgery, are different in the 2 theories, both focus on urethral support, rather than position, which is the basis for equal transmission theory and colposuspension.

This hammock theory however raises some questions about the name of the radiofrequency technique. One article (Fulmer et al, 2002) described the technique as bladder neck suspension whereas others called it radiofrequency of the endopelvic fascia (Dmochowski et al, 2003) and radiofrequency bipolar energy for treatment (Ross et al, 2002). Although the technique is new, such that it may take some time for a name to be agreed, it is unlikely that bladder neck suspension is an accurate one. Radiofrequency remodelling represents a more precise description of the technique, hence its use here.

Technique:

This technique was introduced by Surx incorporation (California, United States of America), before being acquired by CooperSurgical Inc., Connecticut, United States of America in 2003*.

- Laparoscopic approach:

A laparoscopic approach to the endopelvic fascia was used first (Dmochowski, 2002). Exposure of this fascia was made by laparoscopic dissection and radiofrequency, provided

* CooperSurgical, Inc., News Flash, Cooper companies' unit acquires SURx product lines. Available: http://www.leisegang.com/csweb/news_flash.asp?id=47, on 03/10/2004, at 18:15GMT.

from a special generator, was delivered through a laparoscopic probe. The probe had to match other laparoscopic tools, especially in its size and length, so as to reach the endopelvic fascia through a secondary 5 mm port. The technique was approved by the Food and Drug Administration (FDA).

A transperitoneal or extraperitoneal approach is used and the cave of Retzius is reached, as in laparoscopic colposuspension. Two 5mm lateral ports are introduced and retroperitoneal fat is mobilised, exposing the endopelvic fascia on either side of the proximal urethra and bladder neck, keeping a margin of at least 2cm. The area of treatment is measured before introducing the probe and applying radiofrequency energy. Dissection and treatment are helped by vaginal manipulation, to locate and stabilise the area (Ross et al, 2002).

- Transvaginal approach:

Subsequently, the transvaginal approach was developed (Dmochowski, 2002). It was felt that the endopelvic fascia is easier to access vaginally, without the need for laparoscopic dissection, avoiding abdominal incisions and scarring as well as all the possible complications of laparoscopy. A shorter transvaginal probe was subsequently designed. It was approved by the Food and Drug Administration (FDA), in the United States of America, and granted the Europe-wide CE mark as well.

Patients are placed in the lithotomy position and prepared as for vaginal procedures. Infiltration is then made with local anaesthetic with or without vasoconstrictor agent or saline to help dissection and reduce bleeding. Two parallel vaginal incisions are made lateral to the urethra at the level of the proximal urethra and the bladder neck, as guided by a Foley catheter. The vagina is dissected laterally exposing the endopelvic fascia, keeping a minimum of 1cm from

the urethra, to avoid subsequent retention, and paying attention to haemostasis, to ensure good contact with treatment probe. An area of 1.5 X 2cm is measured and energy is delivered using small sweeps till complete blanching or charring of tissue is noted, when a special tone is emitted from the generator. This indicates tissue impedance consistent with adequate treatment (Dmochowski et al, 2003).

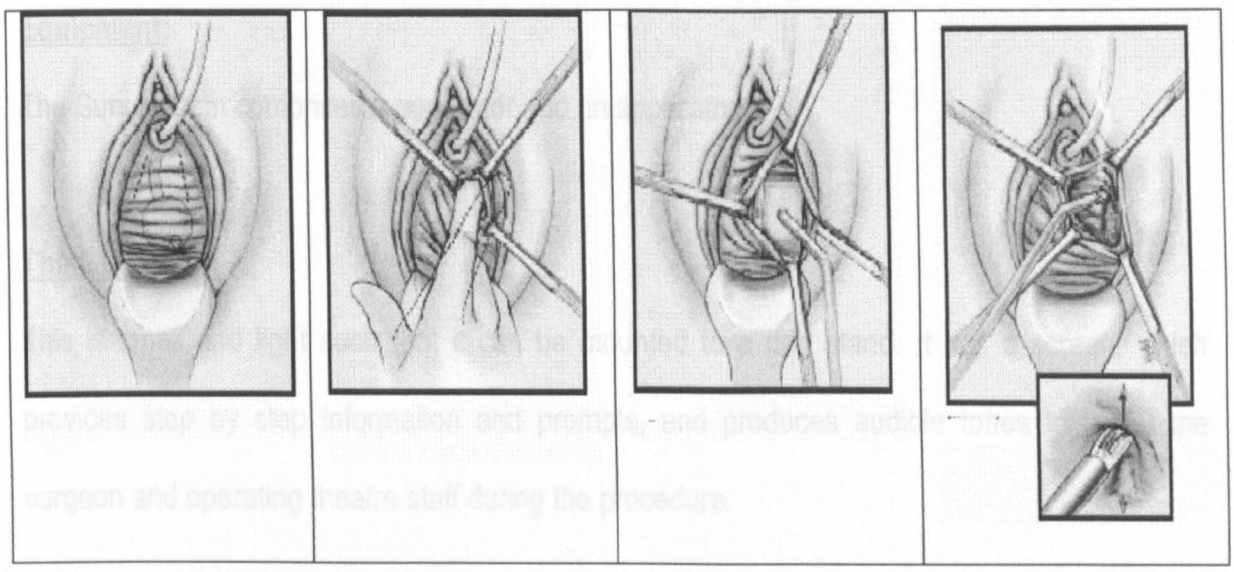


Figure No. 4.1. The steps of transvaginal radiofrequency of the endopelvic fascia*.

Safety features:

In addition to the bipolar approach, described already, the technique has the following features;

- The device shows light on, indicating to the surgeon and operating theatre staff that energy is being delivered. When delivery is interrupted, then there is a need to move to a new area or look for a reason that is preventing good contact with the treatment site.
- The device can detect temperature at the treatment site to avoid overheating.
- Treatment is always provided under direct vision, either laparoscopically or transvaginally, ensuring that only intended areas get treated. The treatment is not therefore a blind procedure, like other techniques used for endometrial ablation (Lewis, 1995).

* Downloaded from the company web site, www.surx.com, before it was closed.

- The technique entails irrigation with saline to keep tissues moist, which facilitates conduction of energy to the endopelvic fascia.
- The effect is limited to the endopelvic fascia. As tissue fluids boils away, its conductivity drops, impeding transmission of energy to adjacent tissues. The depth of effect on tissues is 1.5 mm, which limits any damage to adjacent structures (Ross et al, 2002).

Equipment:

The Surx system comprises a generator and an applicator.

The Generator:

This is small and light such that it can be mounted to a drip stand. It has a screen, which provides step by step information and prompts, and produces audible tones to assist the surgeon and operating theatre staff during the procedure.

The Applicator:

As outlined already, there are 2 applicators, laparoscopic and transvaginal. Both are disposable and consist of a handle and a shaft;

- The handle has an on/off trigger, green and amber lights, indicating ready and on signals, as well as an irrigation port, for the attachment of saline, and is connected to the generator through a cable.

- The shaft is attached to the handle and ends with the tip, where the bipolar electrodes are located. In addition to delivering radiofrequency energy, the tip also delivers saline for irrigation and detects tissue temperature. A thermistor is located between the bipolar

electrodes, to monitor the temperature of the area being treated, so as to avoid excess heat and possible tissue damage. If the temperature rises above a set limit, energy delivery is automatically cut off. Temperature control is further helped by continuous irrigation with saline, delivered through a drip at the distal end of the probe.

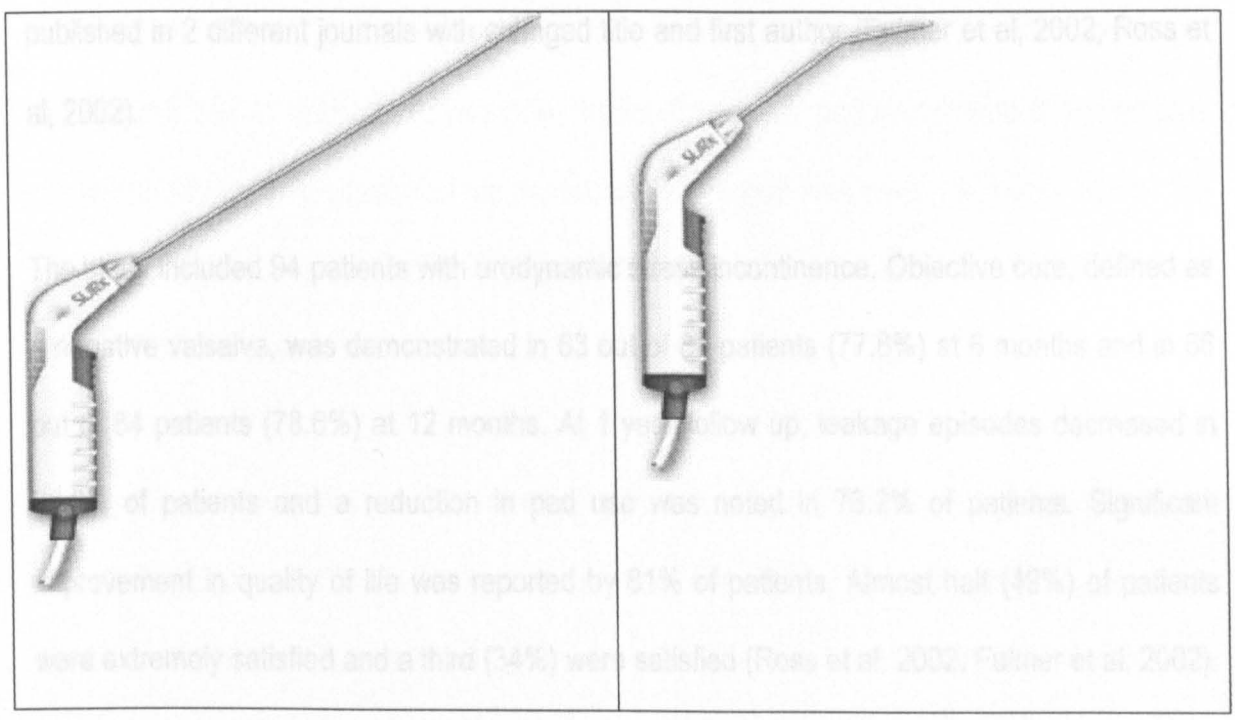


Figure No. 4.2. The laparoscopic (left) and transvaginal (right) applicators*.

Laparoscopic applicator:

The shaft is 5 mm wide, and thus can be passed easily through a 5mm port, and 34cm long, so as to reach the pelvic floor from a secondary port. The tip can be rotated 270 degrees in order to facilitate its application to the endopelvic fascia on both sides with minimal adjustment.

Transvaginal applicator:

This applicator is short, 16.5cm long, to suite a vaginal approach. Otherwise, it has the same features as the laparoscopic one (Dmochowski et al, 2003).

* downloaded from the company web site, www.surx.com, before it was closed.

Effectiveness:

Laparoscopic approach:

There is only one published study that seems to have been reported 3 times. The first appears to have been an abstract at an early stage (Galen et al, 2000) and the other two are full reports published in 2 different journals with changed title and first author (Fulmer et al, 2002; Ross et al, 2002).

The study included 94 patients with urodynamic stress incontinence. Objective cure, defined as a negative valsalva, was demonstrated in 63 out of 81 patients (77.8%) at 6 months and in 66 out of 84 patients (78.6%) at 12 months. At 1 year follow up, leakage episodes decreased in 72.8% of patients and a reduction in pad use was noted in 78.2% of patients. Significant improvement in quality of life was reported by 81% of patients. Almost half (49%) of patients were extremely satisfied and a third (34%) were satisfied (Ross et al, 2002; Fulmer et al, 2002).

There are some discrepancies between the two papers reporting the study;

- In the paper by Ross et al, (2002), the authors confirmed that there was 1 case of de novo detrusor overactivity, whereas in the paper by Fulmer et al, (2002), the case was described as having urgency without detrusor overactivity actually being identified on urodynamic testing.
- In the paper by Ross et al, (2002), a valsalva leak point pressure of 60cm H2O at 250ml filling bladder volume was used to exclude intrinsic sphincter deficiency. This was raised to 90cm H2O in the paper by Fulmer et al, (2002).

Transvaginal approach:

Two studies have been published to date;

1. an abstract of an ongoing study that has not been published as a completed piece of work as yet (Galen et al, 2000), including 17 patients and showing a success rate, without defining success, of 90% at 3 and 6 months (Galen et al, 2000).

2. a completed study (Dmochowski et al, 2003), involving 120 patients with urodynamic stress incontinence due to urethral hypermobility. Intrinsic sphincter deficiency (type III urodynamic stress incontinence) was excluded, on the basis of a valsalva leak point pressure $\geq$ 90cm H2O at 250ml filling bladder volume. Only 96 patients (80%) were seen at 12 months, of whom 86 (82.6%) had urodynamic assessment.

Objective cure, defined as negative valsalva, is rather unclear. The authors first indicate that 66 out of 106 patients (60.6%), including known failures who did not have urodynamic assessment at 12 months, had negative valsalva, and were thus considered cured. They later mention that 76% out of 86 patients had negative valsalva on urodynamic assessment (Dmochowski et al, 2003).

The same problem surrounds subjective outcome. The study indicated that 21 out of 95 patients (22.1%), who completed their voiding diaries at 12 months follow up, had increased incontinence episodes. However, it calculated the percentage on the basis of the total cohort that was recruited (120), giving the lower rate of 19%. The authors acknowledged that 27% of patients had no improvement (Dmochowski et al, 2003).

The effect of treatment on other parameters is even less clear. The authors report that 64% of patients either improved or remained with mild incontinence episodes, without dividing the two

groups. The percentage of those using a pad or more than one pad per day dropped from 57% before treatment to 28% at 12 months after treatment, with 52% not using pads at all, compared to 13% before treatment. A significant improvement in quality of life was noted, but no detail was provided. Although 68% of patients were satisfied with the procedure at 12 months, 12.6% were very dissatisfied (Dmochowski et al, 2003).

The authors acknowledged that these results were inferior to the laparoscopic approach and highlighted two possible causes;

1. the presence of fluid in the operating field dissipates energy leading to superficial treatment of the endopelvic fascia. This seems rather strange, given the fact that the machine does irrigate saline as a safety measure for temperature control, both in laparoscopic and vaginal approaches.
2. the quality of radiofrequency application to the underlying tissues. They suggested that continuous application, with mild pressure, is better than interrupted application, which they later referred to as minimum on/off cycles.

It is very difficult to reach a firm conclusion on the value of this technique from a single study, especially in the absence of long-term results.

Side effects:

Laparoscopic approach:

In a study involving 94 patients (Ross et al, 2002), 4 patients had intra-operative complications (4.3%). Two had bladder perforation during entry to the space of Retzius and both were

repaired laparoscopically. One had an abdominal wall haematoma and the fourth had hypotension due to anaesthesia.

In the same study (Ross et al, 2002), 4 patients had postoperative complications (4.3%). Two had urinary tract infection, one had abdominal wound infection and one had nausea and vomiting. Two patients were sent home with Foley catheters that were removed within 3 days.

Transvaginal approach:

There were no intra-operative or postoperative complications amongst 17 cases followed up for 6 months in the abstract (Galen et al, 2000).

There were no intra-operative complications in the study that included 120 patients. However, there were 3 minor postoperative problems (2.5%); a patient had vaginal bleeding due to vaginal wound dehiscence at 3 weeks, another had urinary tract infection and a third had urgency (Dmochowski et al, 2003).

Advantages:

- Both techniques have a short operating time. For the laparoscopic approach, the average operating time was 54.3±10.3 minutes and the average time of radiofrequency energy application time was 2.2 minutes (Ross et al, 2002). For the transvaginal approach, the average operating time was 30 minutes and average time of applying radiofrequency energy was 2-3 minutes (Dmochowski et al, 2003).
- Both techniques avoid the need for post-operative catheterisation, with its attendant risks. With the laparoscopic approach, only 2 patients, out of 94 (2.1%), required catheterisation

for 2-3 days (Ross et al, 2002). Catheterisation was not needed with the transvaginal approach (Dmochowski et al, 2003).

- Both techniques can be carried out as a day case. In the laparoscopic study of 94 laparoscopic cases, one report indicated that all patients went home on the same day (Ross et al, 2002), whereas only 2 patients in another report (Fulmer et al, 2002) had to stay over night for monitoring of a superficial haematoma in one and hypotension in the other. All patients went home on the same day in the transvaginal study (Dmochowski et al, 2003).
- The transvaginal approach avoids abdominal scarring, though it leaves 2 small vaginal ones. The laparoscopic approach leaves 3 small abdominal scars, with no vaginal scarring.

Limitations:

- There are no long-term results, as acknowledged by those reporting the technique (Fulmer et al, 2002; Dmochowski et al, 2003).
- All transvaginal cases were done under general anaesthesia (Dmochowski et al, 2003). The technique however can be carried out under spinal anaesthesia.

Summary:

The technique relies on heat-induced shrinkage of lax endopelvic fascia without alteration of its shape. Heat is generated as a result of exposing the endopelvic fascia to radiofrequency energy, which is produced from a generator and applied using a bipolar probe. The resultant effect is a reduction of urethral hypermobility and improvement in urinary incontinence.

Transvaginal application entails making two small incisions in the anterior vaginal wall 2cm lateral to the bladder neck, where the probe is applied to the lax endopelvic fascia. Continuous

tissue contact with mild pressure is important for energy delivery. A bipolar approach is used, limiting the effect to the tissue in contact with the electrodes and enabling the use of the technique in those patients with metal prosthesis. Local tissue temperature is monitored and kept low by constant saline irrigation. Earlier, a laparoscopic approach was used, whereby the retropubic space was accessed as in laparoscopic colposuspension, exposing the endopelvic fascia on either side of the bladder neck, which is the treated with radiofrequency.

Reported objective cure rate is 60% for the transvaginal approach, which is less than the 78% reported at 1 year following the laparoscopic approach. Complications are minor and rare but long term results are not available. The technique takes a short duration and avoids abdominal scarring. Although intended to be done under local or regional anaesthesia, reported cases have so far been carried out under general anaesthesia. Published material however is limited.

Method:

Aim:

The aim of the study was to assess the efficacy and safety of transvaginal application of low power radiofrequency energy to the endopelvic fascia using a bipolar probe as a primary surgical procedure for urodynamic stress incontinence of urine, due to urethral hypermobility, in female patients.

Study design:

The study was a prospective one, without a control arm.

Outcome measures:

Cure/improvement rates were decided according to the International Continence Society (ICS) 1hr pad test (Abrams et al, 1989), was considered the primary outcome measure.

Other measures of effectiveness, operative as well as post-operative complications, duration of stay in hospital and pain were considered secondary outcome measures. Patients kept a continence diary for the estimation of average daily leakage episodes and pad usage. They also had cystometry at 6 months follow up. Pain was assessed on 1-10 visual analogue scale.

Sample size:

This was a pilot study that aimed to recruit up to 150 patients.

Study candidates:

Female patients with urodynamic stress incontinence of urine, due to urethral hypermobility, were invited to take part in the study as they are seen in outpatient departments. A valsalva leak point pressure of 60cm H2O at 200ml filling volume, with the patient in the sitting position, was used as a cut level, below which patients were excluded. They were provided with a patient information leaflet and counselled by the nurse co-ordinating the trial. All participants signed a consent form.

Inclusion criteria:

- female patients with urodynamic stress incontinence of urine, due to urethral hypermobility.
- no significant improvement in urinary incontinence for at least three months of conservative non-invasive therapies, such as pelvic floor exercises as well as electric stimulation.
- negative pregnancy test in fertile women who were not sterilised.

Exclusion criteria:

- pre-existing urinary tract pathology, such as tumours, urinary tract infection and enuresis.
- previous surgery for incontinence.
- antidepressants, antihistamines, antiallergic medication 60 days prior to surgery.
- radical pelvic surgery.
- significant fibroids and/or endometriosis in the year prior to surgery.
- severe uterine and/or vaginal prolapse (grade 3 on clinical examination).
- detrusor overactivity or neurogenic bladder.
- Bladder capacity <300ml or RU >50ml.
- Vesicovaginal fistula.
- Other research study.

The intervention:

The procedure was carried out as a day case procedure, with patients admitted few hours before the operation, having been nil by mouth for 6 hours earlier. General or spinal anaesthesia was used and patients were given a dose of prophylactic antibiotics intravenously.

Patients were placed in the lithotomy position, cleaned and draped as for any vaginal procedure. Exposure of the periurethral area was enhanced by inserting a weighted speculum into the vagina and tilting the head of the operating table down. A Foley's catheter was inserted, to empty the bladder and help identification of the urethra as well as the bladder neck. Local anaesthetic with adrenaline or saline was injected to enable dissection of the vaginal mucosa from the endopelvic fascia.

A 3cm incision was made in the vaginal mucosa 1cm lateral to the urethra. The incision was made such that its centre lies at the level of the mid-urethra, relying on the inflated balloon of the Foley's catheter as a mark for the urethrovesical junction. The vaginal mucosa was dissected laterally for 2cm to expose the endopelvic fascia, paying special attention to avoid disturbing the underlying fascial layer or creating a pocket for fluid to collect. A special instrument, the Surx Transvaginal Sizer, was used to confirm that an adequate surface area of the endopelvic fascia has been exposed. Special attention was given to haemostasis.

When a midline incision was made, dissection was carried out laterally, as with anterior repair. This dissection was continued till the target area of the endopelvic fascia, 2cm away from the urethra, was reached. Size check was carried out as with bilateral incisions.

Radio-Frequency treatment was then initiated by applying the tip of the applicator. The vaginal wound was closed using vicryl sutures and patients were returned to the ward without a catheter. They were allowed home when they were comfortable and able to pass urine without problems.

Follow up:

Patients were seen at 3, 6 and 12 months after surgery.

Study centres:

The study was carried out at Barnsley District General and the Royal Hallamshire hospitals in South Yorkshire, Singleton hospital in Swansea, South Wales and Bradford Royal Infirmary, in West Yorkshire. Training was provided at Barnsley District General Hospital and each centre had several cases done locally before starting the trial.

Ethical approval:

The study was approved by the local research ethics committee.

Data collection:

Data was collected using case report forms and downloaded onto Microsoft Works 5.0 for windows database (www.microsoft.com).

Statistics:

All tests were carried out according to standard statistical methods (Altman, 1991) on Stata 6.0 for windows (www.stata.com).

Summary of outcome measures per visits:

Recruitment visit:

- 5 day continence diary.
- 1hr International Continence Society pad test.

Operation:

- complications.
- operating time.
- post-operative pain.
- stay in hospital.

Three months visit:

- 5 day continence diary.
- 1hr International Continence Society pad test.

Six months visit:

- 5 day continence diary.
- 1hr International Continence Society pad test.
- urodynamic assessment.
- vaginal examination, to assess for anterior vaginal wall prolapse.

Twelve months visit:

- 5 day continence diary.
- 1hr International Continence Society pad test.

- vaginal examination, to assess for anterior vaginal wall prolapse.

Results:

The study had to be stopped after recruiting 35 patients in the four UK centres, in view of a high failure rate. Data about 24 cases from Barnsley and Singleton hospital were available for analysis. Failures were noted as early as 3 months and some patients went on to have other continence procedures and were therefore withdrawn from the study. As a result of withdrawals and failure to attend, only 16 patients were available for follow up at 6 months and 13 at12 months.

Back ground features:

Variable	Mean (Median)	SD (Interquantile range)
Age (years)	47.0	9.4
Weight (Kg)	(70)	(64-74)
Parity	2.5	1.1
Duration of symptoms (months)	(48)	(36-60)

Table No. 4.1. The demographic data and duration of incontinence for cases included in the radiofrequency study.

History and examination:

Feature	Number (%)	Main groups	Number (%)
Medical problems	11 (45.8%)	Cardio-pulmonary	5 (20.1%)
		Bone and joint	4 (16.7%)
Previous surgery	5 (20.1%)	Hysterectomy	4 (16.7%)
Cystocele	22 (91.7%)	1st degree	19 (79.2%)
		2nd degree	3 (12.5%)

Table No. 4.2. The distribution of the cohort according to their medical and surgical history as well as the degree of cystocele, in the radiofrequency study.

Operative data:

Feature		Number (Mean)	% (SD)
Anaesthesia	General	22	91.7
	Spinal	2	8.3
Incision	Bilateral	21	87.5
	Midline	3	12.5

Table No. 4.3. The operative data for cases included in the radiofrequency study.

Primary outcome measure:

Outcome at 3 months follow up:

Parameter	Pre-operative	3 months	Wilcoxon singed rank test
	Median (Interquantile range)		
Pad test (gram)	19.2 (4-40.5)	2.25 (0.5-20.1)	P 0.06

Table No. 4.4. Comparison of pad test between pre-operative and 3 months follow up visits, in the radiofrequency study.

Outcome at 6 months follow up:

Parameter	Pre-operative	6 months	Wilcoxon singed rank test
	Median (Interquantile range)		
Pad test (gram)	19.2 (3.9-33)	0.7 (0.2-18.2)	P 0.13

Table No. 4.5. Comparison of pad test between pre-operative and 6 months follow up visits, in the radiofrequency study.

Outcome at12 months follow up:

Parameter	Pre-operative	12 months	Wilcoxon singed rank test
	Median (Interquantile range)		
Pad test (gm)	24.5 (6.2-38.6)	1 (0.4-41.9)	P 0.22

Table No. 4.6. Comparison of pad test between pre-operative and 12 months follow up visits, in the radiofrequency study.

Secondary outcome measures:

Continence parameters:

Outcome at 3 months follow up:

Parameter	Pre-operative	3 months	Wilcoxon singed rank test
	Median (Interquantile range)		
Daily leakage episodes	3 (1.5-5)	0 (0-2)	**P 0.01**
Daily pad use	2 (1-3.5)	1 (0-2)	**P 0.02**

Table No. 4.7. Comparison of continence parameters between pre-operative and 3 months follow up visits, in the radiofrequency study.

Outcome at 6 months follow up:

Parameter	Pre-operative	6 months	Wilcoxon singed rank test
	Median (Interquantile range)		P value
Daily leakage episodes	3 (1-5)	1 (0-2)	**<0.01**
Daily pad use	2 (1-3)	1 (0-10)	0.87

Table No. 4.8. Comparison of continence parameters between pre-operative and 6 months follow up visits, in the radiofrequency study.

Outcome at 12 months follow up:

Parameter	Pre-operative	12 months	Wilcoxon singed rank test
	Median (Interquantile range)		
Daily leakage episodes	3 (1-5)	1 (0-3)	**P 0.04**
Daily pad use	2 (1-3)	1 (0-5)	P 0.47

Table No. 4.9. Comparison of continence parameters between pre-operative and 12 months follow up visits, in the radiofrequency study.

Operating time:

Feature	Mean)	SD
Operating time (minutes)	38	15.5

Table No. 4.10. The operating time for cases included in the radiofrequency study.

Post-operative pain:

Pain	Median	Interquantile range
Post-operative pain score	1	0.5-1

Table No. 4.11. The distribution of post-operative pain in the radiofrequency study.

Operative and post-operative complications:

Complication	Number	%
Vaginal bleeding	2	8.3
Lower abdominal pain	2	8.3
Haematuria	1	4.2
Catheterisation	1	4.2
Vaginal discharge	1	4.2
Total	5	20.1

Table No. 4.12. Operative and post-operative complications in the radiofrequency study.

One patient had haematuria at the end of the operation and was catheterised for 24 hours following a normal cystoscopy. Two patients, including the one who had haematuria, had lower abdominal pain that resolved on simple analgesia. Two cases had mild vaginal bleeding that did not necessitate any investigation or treatment. One patient had vaginal discharge that was treated with antibiotics. No other operative or post-operative complications were encountered.

Post-operative stay in hospital:

Feature	Number	%
Stay > 24 hrs	0	0%

Table No. 4.13. Post-operative stay in hospital for cases included in the radiofrequency remodelling study.

Anterior vaginal wall prolapse:

Outcome at 6 months follow up:

Degree of cystocele	Pre-operative	6 months follow up	Mann-Whitney test
0	1	4	P 0.32
1	10	7	
2	2	2	

Table No. 4.14. Comparison of anterior vaginal wall prolapse between pre-operative and 6 months follow up visits, in the radiofrequency study.

Outcome at 12 months follow up:

Degree of cystocele	Pre-operative	12 months follow up	Mann-Whitney test P
0	2	4	0.69
1	9	6	
2	1	2	

Table No. 4.15. Comparison of anterior vaginal wall prolapse between pre-operative and 12 months follow up visits, in the radiofrequency study.

Urodynamic outcome at 6 months:

Urodynamic outcome	Number of patients	%
No urodynamic stress incontinence	13/18	72.2%
Urodynamic stress incontinent	5/18	27.8%
Type I/II	3/18	16.7%
Type III	2/18	11.1%
Detrusor overactivity	0	0%

Table No. 4.16. The outcome of urodynamic assessment at 6 months follow up in the radiofrequency study.

Cumulative failure rate across the visits:

Visit	3 months	6 months	12 months	X^2 test
Success	12 (57.1%)	13 (65%)	5 (27.8%)	P 0.06
Failure	9 (42.9%)	7 (35%)	13 (72.2%)	
Total	21	20	18	

Table No. 4.17. Cumulative failure rate across follow up visits in the radiofrequency remodelling study.

Cumulative re-operation rate across the visits:

Visit	3 months	6 months	12 months	X^2 test
No re-operation	16 (76.2%)	14 (70%)	9 (50%)	P 0.21
Re-operation	5 (23.8%)	6 (30%)	9 (50%)	
Total	21	20	18	

Table No. 4.18. Cumulative re-operation rate across follow up visits in the radiofrequency remodelling study.

Comparison between those who had failed radiofrequency remodelling of the endopelvic fascia and those who did not:

Background features:

Feature	Successful (8)	Failed (13)	2 sample t test
Age (years)	45.1 ± 11.1	47.2 ± 9.0	P 0.69
Weight (Kg)	83.0 ± 20.8	66.8 ± 4.8	**P 0.02**
Parity	2 (2-2)*	2 (2-3)*	P 0.70**

* Median (interquantile range) ** Wilcoxon signed rank test

Table No. 4.19. Comparison of demographic data between those who had a failed radiofrequency remodelling and those who did not.

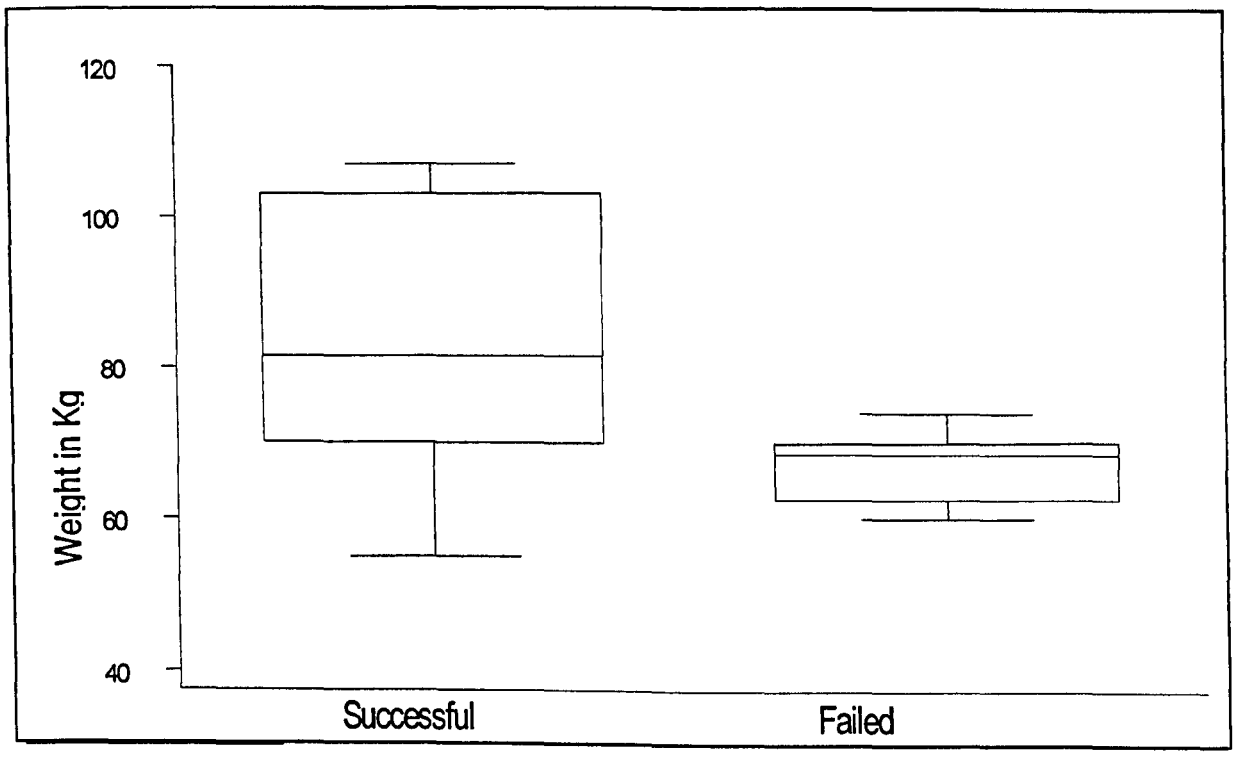


Chart 4.1. Box plot of the weight of those who had a successful radiofrequencey remodelling and those who had a failed one.

Feature	Successful (8)	Failed (13)	Wilcoxon signed rank test
	Median (Interquantile range)		
Pad test (gm)	10.7 (3.3–31.5)	21.4 (4.3–38.6)	P 0.58
Daily leakage episodes	3 (1.5–5)	3 (2-4)	P 0.52
Daily pad use	2 (1–3.5)	2 (1-3)	P 0.38

Table No. 4.20. Comparison of continence parameters between those who had a failed radiofrequency remodelling and those who did not.

History:

Element	Successful (8)	Failed (13)	Fisher's exact test
Medical problems	3 (37.5%)	6 (46.2%)	P 1.00
Cardio-pulmonary problems	2 (25%)	1 (7.7%)	P 0.53
Bone-joint problems	2 (25%)	2 (15.4%)	P 0.62
Previous surgery	1 (12.5%)	3 (23.1%)	P 1.00
Previous hysterectomy	1 (12.5%)	2 (15.4%)	P 1.00

Table No. 4.21. Comparison of history data between those who had a failed radiofrequency remodelling and those who did not.

Cystocele:

Degree of Cystocele	Successful (8)	Failed (13)	Mann-Whitney test
0	0 (0%)	2 (15.4%)	P 1.00
1	8 (100%)	9 (69.2%)	
2	0 (0%)	2 (15.4%)	

Table No. 4.22. Comparison of degree of cystocele between those who had a failed radiofrequency remodelling and those who did not.

Operative data:

Feature	Successful (8)	Failed (13)	Fisher's exact test
Spinal anaesthesia	1 (12.5%)	0 (0%)	P 0.38
Midline incision	2 (25%)	0 (0%)	P 0.13
Operating time (minutes)	33.4 ± 14.6*	38.1 ± 13.5*	P 0.48**
Complications	1 (12.5%)	4 (30.8%)	P 0.61

* Mean ± SD ** 2 sample 2 test

Table No. 4.23. Comparison of operative data between those who had a failed radiofrequency remodelling and those who did not.

Summary:

There was no significant change in pad test at any follow up visit. Although there was a significant reduction in the number of daily leakage episodes at all follow up visit, there was significant reduction in daily pad use at 3 months follow up only. At 1 year follow up, the success rate was 36%. Although failure and re-operations rates increased with follow up duration, the rise with not significant as a trend.

The mean operating time was 38 minutes and all patients were discharged home within 24 hours. Three quarters of them had minimal post-operative pain. A fifth of the patients had minor post-operative complication, like vaginal bleeding and lower abdominal pain. There was no significant change in the incidence of anterior vaginal wall prolpase and no one developed de novo detrusor overactivity.

With the exception of weight, there was no significant difference in baseline features or operative data between those who had a failed radiofrequency remodelling of the endopelvic fascia and those who had a successful one. The weight was significantly less in those who had a failure than those who had a success.

Discussion:

Primary outcome measure:

There was no significant difference in pad test between recruitment visit and any follow up visit, bearing in mind that those seen at 6 and 12 months follow up did not include those who had re-operation for urodynamically proven failure.

Secondary outcome measures:

The number of daily leakage episodes as well as pad usage was significantly less at 3 months follow up visits than at recruitment. Nonetheless, only the number of daily leakage episodes remained significantly less than at recruitment when patients were seen at 6 and 12 months follow up visits. It is worth noting however that those seen at 6 and 12 months follow up did not include patients who had other surgical procedures for failure.

Operating time was less than 70 minutes in 97.5% of cases. The overall complication rate was 20.1%, mainly in the form of mild vaginal bleeding and lower abdominal pain. Three quarters of patients had minimal post-operative pain. All patients were discharged home within 24 hours. There was no significant change in the incidence of anterior vaginal wall prolapse at any of the follow up visits.

Effectiveness:

The primary outcome measure of this study was a negative 1hr pad test (Abrams et al, 1989). There was no significant drop in the pad test results between recruitment and any follow up visit. Although the pad test is only one of the outcome measures used to assess the effectiveness of radiofrequency remodelling of the endopelvic fascia as a primary surgical procedure for urodynamic stress incontinence of urine in women, and in spite of the fact that

some of the other outcome measures showed improvement, this lack of improvement in the primary outcome measure in itself symbolises the failure of the procedure.

The number of daily leakage episodes and pad usage was significantly improved when patients were seen at 3 months follow up. However, only the number of daily leakage episodes was significantly less in subsequent follow up visits, which did not include those who had another surgical procedure following a proven urodynamic failure. The fact that the improved daily pad usage was short lived supports the impression from the pad test, as well as the urodynamic assessment, that the technique is not that effective.

The significant reduction in the number of daily leakage episodes at all follow up visits and the number of daily pad use at 3 months may appear to contradict the lack of improvement in pad test as well as the rising failure detected on urodynamic assessment. Yet, measures like pad test quantify, rather diagnose, urodynamic stress incontinence (Sutherst et al, 1981). They can therefore be significantly reduced in those patients who are still suffering from stress incontinence. In fact, only 10 patients (47.6%) had a negative pad test (>2gm), 9 (42.8 %) had no leakage and 7 (33.3%) were not using pads at 3 months, which is consistent with the 42.9% failure rate detected on urodynamics.

Urodynamic failure was diagnosed from the first follow up visit at 3 months, when 5 patients (23.8%) went to have a different surgical procedure. This pattern continued even in those who preferred to wait before having another operation. Although the number of urodynamic successes improved from 12 (57.1%) to 13 (65%) at 6 months follow up, this was a transient and a small rise that was followed by more failures reaching 13 (72.2%) at 12 months follow up. The re-operation rate rose steadily across the follow up visits to reach 50% at 12 months.

Whilst the rise in failure and re-operation rates was not significant across the visits, it was rising and this alone signifies the short-lived effectiveness of the technique.

One important aspect of failure relates to the type of urodynamic stress incontinence. All the cases included in this study had urodynamic stress incontinence due to urethral hypermobility (type I and II), as indicated by a valsalva leak point pressure $\geq$ 60cm H_2O. Nonetheless, 2 of the patients who had failures had a valsalva leak point pressure < 60cm H_2O, which is consistent with intrinsic sphincter deficiency (type III urodynamic stress incontinence). This is a more severe and difficult to treat type of urodynamic stress incontinence, in comparison to urethral hypermobility (Hsieh et al, 2001). Although the numbers are small, the fact that 2 patients ended up worse than they started might suggest that the technique not only fails to improve the condition, but might worsen it as well; a factor that needs to be borne in mind when assessing various surgical options.

The cure rate shown in this study is low in comparison to established procedures like the Burch colposuspension (Jarvis, 1994) and the tension-free vaginal tape sling (TVT) (Ward & Hilton, 2002). It is close to the anterior repair and bladder neck buttressing, which is no longer recommended, in view of the decline in success rate over time, reaching 30% at 5 years (Bergman & Elia, 1995). The low success rate even puts the technique at the same level as non-invasive techniques, like pelvic floor exercises (Amuzu, 1998) and electrical stimulation (Plevnik & Janez, 1979). In fact some reported higher success rates with non-invasive techniques, reaching 50% with pelvic floor exercises (Morkved et al, 2002). Moreover, these techniques might have an advantage over radiofrequency remodelling of the endopelvic fascia, as they do not entail hospital admission or exposure to anaesthetic and they also cost less.

Complications and side effects:

The overall rate of operative and early postoperative complications was 20.1%. All of these complications were minor, such that no patient stayed more than 24 hours. There was no urinary tract infection and only 1 patient left theatre with a catheter, as a result of unexplained haematuria that cleared on its own. Serious bleeding, wound infection and voiding dysfunction were not encountered and laparotomy was never required. Post-operative pain was minimal in most cases, with 75% of cases grading it as 1 out of 10, on visual analogue scale.

This low incidence and profile of operative and early post-operative complications, alongside the short operating time and post-operative stay in hospital, confirm the minimally invasive nature of radiofrequency re-modelling of the endopelvic fascia. There were no intra-operative complications amongst 120 patients having the procedure and only 3 (2.5%) had minor post-operative complications; vaginal bleeding at 3 weeks due to vaginal wound dehiscence, urinary tract infection and urgency. The average operating time was 30 minutes and the average duration of active application of radiofrequency was 2-3 minutes. All 120 patients went home on the same day (Dmochowski et al, 2003).

This rate is lower than with open operations, like the Burch colposuspension, as well as minimally invasive ones, like the tension-free vaginal tape (TVT) sling. The randomised trial that compared the 2 operations (Ward & Hilton, 2002) showed a 44.5% complication rate with the Burch colposuspension and 39% with the tension-free vaginal tape (TVT) sling. Although urinary tract infection was the commonest problem with both operations, serious complications were encountered including bladder and vascular injury, wound infection and deep vein thrombosis.

There were no long term complications. No one suffered from de novo detrusor overactivity and voiding dysfunction was not encountered either. There were no such cases in the published study that included 120 cases (Dmochowski et al, 2003). Likewise, there was no significant change in the incidence of anterior vaginal wall prolapse. The Burch colposuspension has delayed complications like voiding dysfunction (Lose et al, 1987) and de novo detrusor overactivity (Cardozo et al, 1979). Both complications are possible, though less common, with tension-free vaginal tape (TVT) sling (Merlin et al, 2001; Ward et al, 200a). Tape erosion is another complication that can follow tension-free vaginal tape (TVT) sling insertion (Ward & Hilton, 2002). In addition, both procedures can be followed by increased vaginal wall prolapse (Ward & Hilton, 2004).

The low complication rate reflects the technique's mechanism of action. Radiofrequency aims at correcting lax endopelvic fascia to restore it as a tense supporting layer underneath the urethra. Unlike the Burch colposuspension and sling operation, prior to the introduction of tension-free insertion, there is neither elevation of the bladder neck nor obstruction to the urethra. Similarly, there is no disruption to fascial support to the anterior vaginal wall, as happens upon passing the tension-free vaginal tape (TVT) sling, or alteration of the vaginal axis, as a result of pulling the top of the vagina forwards in colposuspension, there is no increase in anterior or posterior vaginal wall prolapse. Yet, the low complication profile is not that much of an advantage, if the technique is of limited effectiveness.

In theory, the technique's mechanism of restoring a normal, pre-incontinence, status resembles the tension-free vaginal tape (TVT) sling, as both aim at increasing support for the mid urethra. The difference however is in the way in which this support is secured. Whilst the tension-free vaginal tape (TVT) is a synthetic mesh that works as a neo-ligament between the pubic bone

and the urethra, radiofrequency relies on the endopelvic fascia being restored to its original length. The limited effect raises doubt about the value of support the endopelvic fascia can provide as a result of this shrinkage.

Cause of failure:

Patient weight was the only factor that was significantly different between those who had failure within a 1 year from surgery and those who did not. This suggests that the failure was not related to factors like age, severity of stress incontinence, medical history, degree of cystocele, operative technique or occurrence of complications. On the other hand, the difference in weight was significant, P 0.02, with the weight of those who had failure by the end of the first year following the operation being less than those who had a success.

Obesity however has long been recognised as a risk factor for stress incontinence of urine (Dwyer et al, 1988). This applies to incontinence developing after pregnancy and delivery (Rasmuseen et al, 1997). It has also been associated with higher failure rate after some procedures, like the Burch colposuspension (Kjolhede, 2005), but not others, such as the tension-free vaginal tape (TVT) sling (Mukherjee & Constantine, 2001). The reasons for this are poorly understood (Cummings & Rodning, 2000), but increased intra-abdominal pressure was found in morbidly obese patients (Lambert et al, 2005).

It is difficult thus to explain the significantly lower weight in those who had failure in this study. The study however included a small number of patients. It is unlikely that factors like age and parity have played a part in this group, as there was no significant difference in the age and parity between the those who had a failure and those who did not. Nonetheless, it is possible that other factors, that have not been adequately researched as yet, might be responsible.

The technique was selectively used in those patients with urodynamic stress incontinence of urine due to urethral hypermobility. It is based on the hammock hypothesis, which identifies a tense endopelvic fascia as the main support underlying the urethra (DeLancy, 1994). Laxity of this layer weakens urethral support, leading to the development of stress incontinence. Whilst factors like childbirth and chronic strain predispose to and expose such weakness (Norton, 1993; Fitzpatrick & O'Herlihy, 2001), interest has recently shifted to the fascial and connective tissue structure as an important factor behind such weakness (Ulmsten et al, 1987).

Several studies have shown significant differences in collagen content between those suffering from stress incontinence and those who are continent. Two types of collagen have been described in this respect, type III, which is considered a weak type of collagen, and type I, which is a stronger type. Collagen fibres are held together by cross links (Norton, 1993). Both types of collagen fibres are reduced in stress incontinent patients (Liapis et al, 2000a; Liapis et al, 2001). A significant reduction in collagen content, the ratio between type I: type III ratio as well as the cross linking between collagen fibres have been found in stress incontinent premenopausal nulliparous women comparison to those who are stress continent (Keane et al, 1997). There is also a reduced concentration of hydroxyproline (Rechberger et al, 1993), which is one of the amino acids included in the structure of collagen fibres (Norton, 1993).

Whilst the technique shrinks the endopelvic fascia, it does not change its structure or metabolism (Galen, 2000). A weak endopelvic fascia, that stretched over time, causing urodynamic stress incontinence due to urethral hypermobility, might stretch and become lax again after shortening, regardless of the method of shortening. Whilst a small study showed lack of re-stretching at 6 weeks (Galen, 2000), no long term evaluation is available. Anterior

repair and bladder neck buttressing has been known to have rapid drop in success rate (Bergman & Elia, 1994). Radiofrequency re-modelling appears to be a minimally invasive technique that effects the same outcome, though without the use of sutures.

Procedures that do not rely on the endopelvic fascia have a better effect. Autologous slings rely on strips from the rectus sheath, which has a different structure and metabolism to the endopelvic fascia (Norton, 1993), even though it might be weaker in those who develop stress incontinence of urine than in those who do not (Ulmsten et al, 1987). The tension-free vaginal tape (TVT) sling uses a synthetic non-antigenic mesh that does not get metabolised or absorbed, and its effectiveness is therefore independent of the strength of endogenous connective tissue (Bakas et al, 2004). The Burch colposuspension lifts the bladder neck above the pelvic floor, which is made of several muscles and ligaments (Stanton, 1985; Monga & Stanton, 1994). The failure of the radiofrequency remodelling appears therefore to be due to recurrent relaxation of inherently weak endopelvic fascia.

Although the drop in the success rate over the 1 year follow up period was not significant in this small group, it was considerable as is reached 36% at the end of that period. This is low, bearing in mind that anterior repair and bladder neck buttressing had 30% success rate at 5 years (Bergman & Elia, 1995). The anterior repair and bladder neck buttressing entail more dissection and suturing than radiofrequency re-modelling of the endopelvic fascia. Such excess dissection and suturing might provoke fibrosis, which could lead to more durable support to the bladder neck. Under such a speculation, the minimally invasive nature of radiofrequency remodelling of the endoplevic fascia is not an advantage.

It is rather difficult to see a role for this technique as a method of treating urodynamic stress incontinence due to urethral hypermobility. With the availability of minimally invasive techniques, such as the tension-free vaginal tape (TVT) sling, patients can have better outcome. Although side effects and complications are more with the tension-free vaginal tape (TVT) sling, they are rare and usually minimal. Voiding dysfunction tend to improve spontaneously over time leaving limited long term impact (Mishra et al, 2005). Even frail patients can have it inserted under local anaesthesia as a day case (National Institute of Clinical Excellence, 2003).

Conclusions:

This study did not reach its target of 150 cases, yet it was clear from the small number of cases recruited that the technique has a poor effectiveness. Failures were encountered as early as 3 months and increased with longer follow up duration. At 1 year follow up, a cure rate of 36% was observed, with a re-operation rate of 50%. In terms of safety, the technique is associated with a low incidence of minimal short and long term complications and very short stay in hospital. However, this is of limited clinical value in view of the low success rate.

Recommendation:

Radiofrequency re-modelling of the endopelvic fascia should not be used as a treatment for urodynamic stress incontinence due to urethral hypermobility. Since stopping this study, no patient was offered this technique at Singleton or Barnsley hospitals.

5. The tension-free vaginal tape (TVT) sling:

Background:

Mechanism of action:

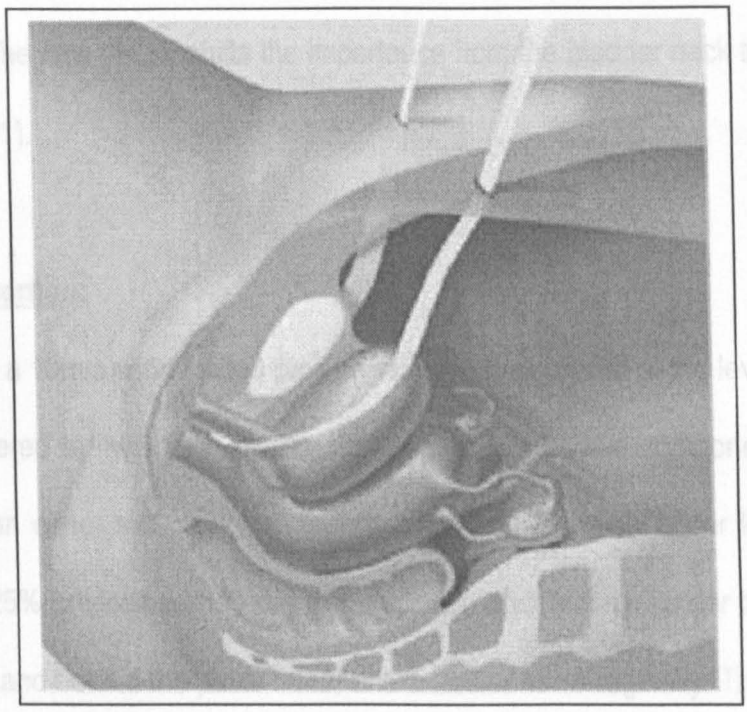


Figure No. 5.1. The tension-free vaginal tape (TVT) sling*.

The tension free vaginal tape (TVT) acts as a new pubourethral ligament (Ward & Hilton, 2002). This secures the fixation of mid-urethra to the pubic bone, supporting the suburethral vaginal hammock and its connection to pelvic floor muscles (Ulmsten et al, 1996). As a result, a dynamic kinking of the urethra occurs during stress, as with increased intra-abdominal pressure, preventing urine leakage. The midurethra is the insertion of pubourethral ligament and the pubococcygeus muscles, and point of highest pressure on urethral pressure profilometry (Westby et al, 1982).

* http://www.singer.ch/images/tvt2.jpg, at 21:30GMT, on 26.10.2004.

This focus on the mid-urethra has been the basis of the integral theory of continence (Petros & Ulmsten, 1990). The theory suggests that continence relies on a properly functioning and well supported urethra, especially at its mid area. This is distinct from the equal transmission theory, where the emphasis was on elevating the bladder neck above the pelvic floor, so that any rise in intra-abdominal pressure is transmitted equally to the bladder and the proximal urethra (Stanton, 1985). The new theory shifts the importance from the bladder neck to the mid-urethra (Nilsson et al, 2001).

Technique of insertion:

In this procedure, a 10mm wide knitted prolene tape mesh is placed at the level of mid-urethra. The mesh is covered by two-piece plastic sheath and held by two component metal needles (6mm trochars) on either side. Original reports described insertion under local anaesthesia, using 60ml of 0.25% prilocaine and adrenaline solution abdominally, under the skin above the symphysis pubis and behind the pubic bone, and a further 40ml vaginally. The patient is asked to cough and the tape tension is adjusted accordingly. In addition to providing anaesthesia, the injections help dissection and haemostasis (Ulmsten et al, 1999).

More and more cases however are done under spinal anaesthesia, to provide better pain relief for patients (Adamiak et al, 2002). Although some found higher incidence of voiding dysfunction and thus hospital stay with regional anaesthesia (Wang & Lo, 1998), which might suggest that insertion under regional block does not help adjusting the tension, others did not (Jeffry et al, 2001). Tension-free insertions under general anaesthesia, without the cough test, were not associated with reduction in effectiveness or increase in complications (Ghezzi et al, 2005).

Placement begins by making two small (1cm) transverse incisions, 5cm apart, just above the upper border of the pubic bone and a small (1.5cm) longitudinal incision in the anterior vaginal wall, at the level of the mid-urethra. After dissection of the vagina on both sides, a catheter mounted urethral guide is passed into the urethra and the needle holding one end of tape is passed on one side of the urethra, which is kept on the opposite side, using the guide. The needle is directed such that its tip perforates the urogenital diaphragm and passed behind the pubic bone towards the ipsilateral suprapubic incision. The procedure is the repeated on the other side, leaving the tape as a U-shaped sling around the mid-urethra.

After tape placement, perforation of the bladder is excluded by cystoscopy. The tape is adjusted to lie straight without tension under the mid-urethra by moving the needles holding the tape ends through the abdominal wounds. The patient is then asked to cough, to ensure that she is continent. The sheath covered tape is cut from the needles and the plastic sheath are gradually pulled up, so as not to cause any tension under the urethra. The abdominal ends of the tape are cut under the skin and the abdominal as well as the vaginal incisions are closed. As the tape is knitted, it stays in place and does not need fixation (Ulmsten et al, 1999).

Value:

The procedure is effective with 86% cure rate, 12% improvement rate and 2% failure rate (Ulmsten et al, 1999) and these figures were maintained up to 5 years (Nilsson et al, 2001). Randomised controlled studies have shown comparable effectiveness to that of the Burch colposuspension, which is considered to be the gold standard, objectively and subjectively, at 6 months (Ward & Hilton, 2002) as well as 2 years (Ward & Hilton, 2004).

The procedure can be carried out under local or spinal anaesthesia, thereby avoiding the risks associated with general anaesthesia (Ulmsten et al, 1999). However most cases are done under spinal anaesthesia, to avoid patient discomfort and any pressure on the surgeon, and patients often stay over night, as was the case in one study (Ulmsten et al, 1999).

The minimally invasive nature of the procedure affords a number of advantages. Blood loss is limited, with an average of 50 ml (Ward & Hilton, 2002) and the need for blood transfusion, with its attendant risks, is therefore reduced. Post-operative pain is mild (Ulmsten et al, 1999), both in intensity (Ward et al, 2000) and duration (Liapis et al, 2000), due to limited dissection. It does not require thromboprophylaxis nor insertion of drains, as with colposuspension (Cardozo et al, 1999). Scarring is minimal as the abdominal incisions are small (Ulmsten et al, 1999). The incidence of wound infection and post-operative fever is low and there are no incisional hernias (Ward & Hilton, 2002).

There no need for routine catheterisation. In a randomised trial that compared it to the Burch colposuspension (Ward & Hilton, 2002), only 38% of patients had to be catheterised at the end, whilst catheters were inserted in all patients after colposuspension. This reduces patient discomfort and saves expenses. However, there was no significant difference in the incidence of urinary tract infection.

The procedure has a low post-operative complication rate. No recurrent urinary tract infection or tape rejection has been reported (Ulmsten et al, 1999). Defective healing is rare (Galvind & Sander, 2004). Urinary retention and voiding dysfunction are less than after open operations (Merlin et al, 2001) and the pattern is maintained in the long term (Nilsson et al, 2001).

Likewise, de novo detrusor overactivity is less common (Ward et al, 2000a). This is attributed to insertion without tension (Ward et al, 2000a, Liapis et al, 2000; Rezapour et al, 2001).

The minimally invasive nature of the procedure, the shorter stay in hospital and quicker recovery and return to normal activity improve patient experience and well being. This is reflected in better emotional, social as well as physical functions and vitality quality of life domains, as assessed by Short Form 36, which is a validated general quality of life questionnaire (Jenkinson et al, 1993). These better improvements were observed at 6 weeks, 6 months (Ward & Hilton, 2002) as well as at 2 years (Ward & Hilton, 2004).

The procedure is cost effective, with a mean saving of £243 (Mancca et al, 2003). Although it costs more in terms of consumables, it has a short hospital stay, leading to reduced overall cost, even when re-admission and follow up are taken into account. As it can be done under local anaesthesia and sedation, patient stay in the anaesthetic and the recovery rooms is reduced (Ward & Hilton, 2002). This allows more insertions during theatre sessions, further enhancing efficiency. It is also associated with higher quality-adjusted life years (QALY's), as measured at six months follow up (Kind, 1996)

The procedure however has its unique complications;

- bladder perforation happens in 6% (Meschia et al, 2001) to 9.6% (Haab et al, 2001) of cases and is higher than with Burch colposuspension (Ward & Hilton, 2002). Yet, it only requires bladder drainage for 48 hours, whereas formal repair and longer drainage are needed if it occurs during colposuspension. In addition, perforation may pass undetected at the time of insertion, presenting later with other complications (Hilton et al, 2003). Whilst this is rare, it

shows that the technique can have long term complications and that perforation can be missed on cysto-urethroscopy at insertion.

- vascular injuries can take place. Most of these injuries happen as the needles are passed blindly behind the pubic bone. Although rare (2.4%), these injuries can be serious enough to cause haematoma and require laparotomy (Ward & Hilton, 2002). Bleeding from the vaginal wound can also be significant sometimes, requiring catheterisation and vaginal packing (Wang & Lo, 1998). This shows that careful dissection and passing of trochars is important.

- the procedure is followed by a higher rate of anterior vaginal wall prolapse (cystocele and/or urethrocele) than the Burch colposuspension, both at 6 months and 2 years follow up, though the rate of symptomatic prolapse was more or less the same (Ward & Hilton, 2004). This could be due to an iatrogenic paravaginal defect or denervation of the anterior vaginal wall, as the sling is being inserted (Kohli et al, 1996). The colposuspension on the other hand is followed by more vault prolapse and rectocele, also at 6 months and 2 years follow up (Ward & Hilton, 2004).

Despite its simplicity, the procedure has the potential for complications and therefore requires training (National Institute for Clinical Excellence, 2003). Experience in cystoscopy, knowledge of the anatomy of the retropubic space and surgical training are important. Some suggested observing 5 and doing 5 under supervision (Stanton, 2001) whilst others recommended a minimum of 10 supervised insertions (Ulmsten, 2001). It is equally important to insert slings under the vaginal wall, rather than the pubocervical fascia (Appell, 1998), so as to avoid possible neuro-vascular injury at the level of the bladder outlet (Ball et al, 1997).

Comparison with other minimally invasive slings:

There are 2 published studies comparing the tension-free vaginal tape (TVT) and pelvicol slings, both coming from the same institution (Arunkalaivanan & Barrington, 2003, Abdel-Fattah et al, 2004).

The first study (Arunkalaivanan & Barrington, 2003) was a randomised controlled study that included 142 patients with urodynamic stress incontinence There was no significant difference between the 2 groups in terms of the type of anaesthetic used, operating time or duration of stay.

The incidence of operative and post-operative complications appeared to be similar with both types of slings, but no formal statistical comparison was provided. Follow up was on the basis of a questionnaire constructed by the authors and extended from a minimum of 6 months to a maximum of 2 years, with a median duration of 1 year. No comparison of the duration of follow up was provided. This showed a dry rate of 85.3% with the tension-free vaginal tape (TVT) sling and 89.2% with pelvicol sling. Although these rates are not far from each other, no statistical comparison was given.

The second report (Abdel-Fattah et al, 2004) was a longer follow up of the first one The median follow up duration was 36 months for the tension-free vaginal tape (TVT) sling and 34 months for the pelvicol sling. Again, a self-constructed questionnaire was used, showing no significant difference in self reported dry rates between the 2 groups.

There was one study (Wadie et al, 2005) that compared the short autologous sling to the tension-free vaginal tape (TVT) sling. This was a randomised controlled trial that included 53

patients with urodynamic stress incontinence. All procedures were done under spinal anaesthesia and the short autologous sling was fixed to the periurethral fascia. There was no significant difference between the 2 groups in baseline features. All patients were followed up at 6 months, when urodynamic evaluation was repeated.

Apart from a significantly shorter operating time with the tension-free vaginal tape (TVT) sling, there was no significant difference in operative or postoperative complications. In terms of outcome at 6 months, there were 2 failures with each group and 1 patient developed de novo detrusor overactivity in the short autologous sling group. Although these figures are comparable, no statistical test was done.

Summary:

The tension free vaginal tape (TVT) sling acts by anchoring the mid-urethra to the pubic bone, like a new pubourethral ligament, preventing leakage during stress. Insertion is carried out under local or spinal anaesthesia and entails checking continence by asking patients to cough, as the tension of the ape is adjusted. Tension is avoided, so as not to have voiding problems, tape erosion or de novo detrusor overactivity. The technique has a comparable effectiveness to that of the Burch colposuspension, which has been widely regarded as the gold standard.

Compared to open surgery, it is associated with less blood loss, postoperative pain, wound infection and catheterisation as well as quicker recovery. Scarring is minimal and thromboprophylaxis and drains are not required. No cases of defective healing, tape rejection, incisional hernia have been reported. Long term voiding dysfunction and de novo detrusor overactivity are also less common. These features are associated with better patient

experience and well being, which are maintained in the long term. The procedure is cost effective in terms of patients' quality of life as well as cost.

The technique however has is complications, though these are limited. Bladder perforations are more common than with open surgery, yet they are easier to manage, as long as they are detected during cystoscopy. Undetected ones can cause long term problems. Serious bleeding can result from injuring blood vessels during needle passing, though this is rare. Anterior vaginal wall prolapse is more common than after the Burch colposuspension, though not all patients develop symptoms. Careful dissection and good training are important to avoid complications.

There is insufficient material to recommend any of the three minimally invasive slings over the others. Available evidence suggest that all 3 are more or less of equal short term safety and effectiveness.

Method:

Aim of study:

To compare the clinical efficacy and operative morbidity of the tension free vaginal tape (TVT) sling against other minimally invasive slings for urodynamic stress incontinence of urine in women. The other minimally invasive slings are the pelvicol and the short autologous rectus sheath pubovaginal fascial sling (sling on a string).

Study design:

The study was a randomised controlled, single blind study. Randomisation was administered centrally from Swansea in sequence regardless of hospitals, according to computer generated schedule and the type of sling was faxed on the morning of the operation. Patients were not told which sling they had. All abdominal wounds were covered by a single dressing of a similar size. The staff looking after the patient and those seeing them during follow up visits had access to the notes and case report forms, and therefore knew which patients had which sling.

Outcome measures:

Primary outcome measure:

Quality of life was considered the primary outcome measure in this study. It was assessed using 2 validated questionnaires; the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire, which is a specific symptoms as well as quality of life questionnaire for urinary incontinence, (Jackson et al, 1996) and the EuroQol, which is a general quality of life questionnaire (Kind, 1996). All questionnaires were completed by patients prior to clinic attendance.

Secondary outcome measures:

The pad test as well as operative and post-operative complications were considered secondary outcome measures.

Sample size:

The sample size was 240 patients. This was calculated to detect a 0.65 standardised difference in patients' quality of life as measured by Bristol Female Lower Urinary Tract Symptoms and EuroQol quality of life questionnaires with 80% power and 0.05 significance (95% confidence).

Study candidates:

Female patients with pure urodynamic stress incontinence of urine were invited to take part as they were seen in outpatient departments. They were provided with a patient information leaflet as well as adequate counselling by the nurse co-ordinating the trial at each site and all participants signed a consent form.

Inclusion criteria:

- female patients with pure urodynamic stress incontinence of urine requiring surgical management.

Exclusion criteria:

- patients with neurological disease.
- patients under 18 years of age.
- patients who would decline a xenograft or pig material.

Surgical technique:

The tension free vaginal tape (TVT) sling was inserted according to the technique descried by Ulmsten et al, (1996), and outlined earlier in the review.

The pelvicol sling was inserted according to the technique described by Barrington et al, (2002). The pelvicol sling was taken out of its pack and each end was mounted on a double length of PDS thread, which was held using Robert's forceps. Two small (1cm) transverse incisions were made 5cm apart, just above the upper border of the pubic bone and a small (1.5cm) longitudinal incision was made in the anterior vaginal wall, at the level of the mid-urethra. After dissection of the vagina on both sides, a catheter mounted urethral guide was passed into the urethra and the forceps holding one end of tape was passed on one side of the urethra, which was kept on the opposite side, using the guide. The forceps was directed such that the tip perforated the urogenital diaphragm and passed through the retropubic space towards the ipsilateral suprapubic incision. The procedure was the repeated on the other side, leaving the pelvicol sling as a U-shaped sling underneath the mid-urethra. Perforation of the bladder was excluded by cystoscopy.

For the short autologous rectus sheath fascial sling (sling on a string), a small Pfannenstiel's incision was made to mobilise, a 8cm long and 1.5cm wide piece of rectus sheath. Each end of this piece of sheath was mounted on a double length of PDS thread, which was held using Robert's forceps. A 1.5cm long midline incision was made in the anterior vaginal wall at the level of the mid-urethra. A tunnel was created laterally on either side to reach the inferior pubic ramus and a catheter mounted urethral guide was passed into the urethra. The forceps, holding the thread mounted fascial sling, were then used to perforate through the endopelvic fascia into the retropubic space on one side of the urethra, which was kept on the opposite side, using the

guide. The procedure was repeated on the other side, leaving the rectus sheath strip as a U-shaped sling below the mid-urethra. Perforation of the bladder is excluded by cystoscopy.

Tension adjustment and wound closure were more or less the same for both slings. The PDS threads were then pulled and the sling adjusted in position without tension, underneath the mid-urethra. After that, the PDS threads were passed separately through the anterior rectus sheath, to enable tying over a bridge of the rectus sheath. The gap in the rectus sheath, in the case of the short autologous sling, was closed using continuous sutures and the abdominal and vaginal wounds were closed as usual.

Some of the insertions were made under general anaesthesia and others were made under spinal anaesthesia. In all three types, the sling was inserted without tension. When done under spinal anaesthesia, patients were asked to cough and the sling position was adjusted to just control leakage.

Follow up:

Patients were seen at 6 weeks as well as 6 and 12 months after sling insertion.

Study centres:

The study was carried out at Singleton and Morriston hospitals in Swansea, the University of Wales hospital, in Cardiff, as well as the Princess of Wales hospital, in Bridgend, in South Wales, the Royal Hallamshire hospital, in Sheffield, in South Yorkshire and Kingston hospital, in Kingston upon Thames, in Surrey.

Ethical approval:

The study was approved by the local research ethics committee of each hospital.

Data collection:

Data were collected using case report forms and down loaded onto Microsoft Works 5.0 for windows database (www.microsoft.com).

Statistics:

All tests were carried out according to standard statistical methods (Altman, 1991). Fisher's exact test for 3 groups was carried out on SPSS 12 for windows (www.spss.com). All other tests were carried out on Stata 6.0 for windows (www.stata.com).

Summary of outcome measures per visit:

Recruitment visit:

- Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire.
- EuroQol questionnaire.
- 1 hour International Continence Society pad test.

Operation:

- duration of surgery.
- operative complications; like bleeding and bladder perforation.

Admission:

- length of hospital stay.

- complications, including voiding dysfunction.

Six weeks:

- complications, including voiding dysfunction.

Six months follow up visit:

- Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire.
- EuroQol questionnaire.
- 1 hour International Continence Society pad test.
- Complications, including voiding dysfunction.

Twelve months follow up visit:

- Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire.
- EuroQol questionnaire.
- 1 hour International Continence Society pad test.
- Complications, including voiding dysfunction.

Results:

A total of 181 patients were recruited in the study. Five patients did not have their operation performed. In addition, operative and follow up data of 19 patients (17 from Kingston and 2 from Bridgend) were never returned, despite repeat requests. This reduced the number of patients available for analysis of operative data to 157.

The pelvicol arm was closed during the trial, in view of a higher re-operation rate detected upon reviewing the outcome of 74 cases at 12 months follow up. All patient information leaflets were amended accordingly. A total of 48 patients had the pelvicol sling by the time this arm was closed and they were kept under follow up to ensure detecting any complications. Of these patients, 12 had confirmed failures (25%) and 8 had repeat surgery at the time of writing this thesis (16.6%). All recruited patients however were included in the comparison of baseline features, to ensure an intention to treat analysis.

Comparison of baseline features between the 3 study groups:

Demographic features:

Variable (Mean ± SD)	TVT (61)	Pelvicol (52)	Autologous (68)	ANOVA
Age (years)	55.4 ± 9.7	52.2 ± 11.1	51.5 ± 9.9	P 0.095
Weight (Kg)	75.6 ± 13.3	63 ± 0	72.8 ± 14.1	P 0.41

Table No. 5.1. Comparison of demographic data between different sling groups, in the comparative sling study.

Stress incontinence features:

Variable	TVT (61)	Pelvicol (52)	Autologous (68)	K-W test**
Duration of symptoms* (years)	10 (4-20)	9 (5-12)	7 (3-10)	P 0.11
Pad test* (gm)	23 (11-75)	45 (15-80)	21.5 (10-38)	P 0.17

* Median (Interquantile range) ** Kruskal-Wallis test (non parametric ANOVA)

Table No. 5.2. Comparison of continence features between different sling groups, in the comparative sling study.

Previous surgery:

Previous surgery	TVT (61)	Pelvicol (52)	Autologous (68)	X^2 test
Hysterectomy	31 (50.8%)	20 (38.5%)	23 (33.8%)	P 0.13
Continence surgery	14 (23.0%)	11 (21.2%)	16 (23.5%)	P 0.95
Prolapse surgery	14 (23.0%)	12 (23.1%)	10 (14.7%)	P 0.40

Table No. 5.3. Comparison of different sling groups according to their surgical history, in the comparative sling study.

Medical history:

Medical	TVT (61)	Pelvicol (52)	Autologous (68)	X^2 test
Hormone replacement therapy	11 (18.0%)	9 (17.3%)	9 (13.2%)	P 0.73
Cardio-pulmonary disease	17 (27.9%)	14 (26.9%)	10 (14.7%)	P 0.14
Bone-joint disease	18 (29.5%)	12 (23.1%)	21 (30.9%)	P 0.62

Table No. 5.4. Comparison of different sling groups according to their medical history, in the comparative sling study.

Operative data:

Item	TVT (52)	Pelvicol (48)	Autologous (57)	X^2 test
Anaesthesia				
General	33 (63.5%)	33 (68.8%)	41 (71.9%)	P 0.64
Spinal	19 (36.5%)	15 (31.2%)	16 (28.1%)	
Additional surgery	8 (15.4%)	5 (10.4%)	4 (7%)	P 0.37

Table No. 5.5. Comparison of the type of anaesthesia and the percentage of those having additional surgery in different sling groups, in the comparative sling study.

Type of additional surgery:

Operation	TVT (52)	Pelvicol (48)	Autologous (57)
Hysteroscopy	1	1	0
Laparoscopic sterilisation	0	1	1
Hysterectomy	1	0	0
Sacrocolpopexy	2	0	0
Vaginal repair	2	2	2
Other	3	1	2

Table No. 5.6. The type of additional surgery in different sling groups, in the comparative sling study.

Comparison between the tension-free vaginal tape (TVT) and short autologous slings:

Primary outcome measure (quality of life):

Bristol Female Lower Urinary Tract Symptoms (B-FLUTS):

Outcome at 6 months follow up:

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)				
	TVT		Autologous		P value*
	Baseline (61)	6 months (41)	Baseline (68)	6 months (42)	Mann-Whitney test
Daytime frequency (>7)	57 (56)	34 (24)	41 (46)	33 (31)	**0.01** (0.28)
Night time frequency (>0)	62 (51)	54 (24)	47 (41)	57 (21)	0.27 (0.60)
Urgency	64 (62)	54 (29)	54 (49)	64 (38)	0.29 (0.35)
Urge incontinence	62 (64)	39 24)	56 (54)	48 (33)	**0.03** (0.17)
Bladder pain	48 (34)	17 (10)	22 (19)	21 (14)	**0.03** (0.14)
Frequency of incontinent episodes (>never)	63 (63)	31 (12)	59 (56)	40 (29)	0.97 (0.19)
Stress incontinence	63 (63)	29 (12)	59 (57)	21 (17)	0.59 (0.71)
Unexplained incontinence	54 (54)	12 (7)	53 (47)	19 (12)	0.71 (0.46)
Quantity of urine loss (>none)	63 (N/A)	27 (N/A)	59 (N/A)	38 (N/A)	0.51 (N/A)
Wearing protection	64 (N/A)	24 (N/A)	59 (N/A)	36 (N/A)	0.24 (N/A)
Changing outer clothing	51 (N/A)	17 (N/A)	47 (N/A)	24 (N/A)	**0.03** (N/A)
Hesitancy	18 (21)	32 (17)	18 (18)	40 (12)	0.34 (0.63)
Straining	18 (11)	20 (12)	7 (7)	24 (7)	0.21 (0.71)
Intermittent stream	30 (21)	37 (17)	21 (10)	36 (12)	0.23 (0.83)
Nocturnal enuresis	41 (39)	15 (10)	37 (29)	5 (5)	0.51 (0.43)
Abnormal urinary stream	26 (18)	39 (17)	16 (9)	48 (14)	**0.02** (0.21)
History of retention	0 (N/A)	5 (N/A)	0 (N/A)	14 (N/A)	0.05 (N/A)
Dysuria	25 (21)	20 (10)	21 (10)	31 (19)	0.23 (0.06)
Incomplete emptying	52 (41)	49 (24)	47 (37)	43 (31)	0.53 (0.98)
Inability to stop midstream	52 (N/A)	34 (N/A)	49 (N/A)	33 (N/A)	0.38 (N/A)

* Comparing the change from baseline between the 2 groups, using the full ordinal scale.

Table No. 5.7. A comparison of urinary symptoms at 6 months follow up, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between those who had a TVT sling and those who had a short autologous one.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)				
	TVT		**Autologous**		P value*
	Baseline (61)	6 months (41)	Baseline (68)	6 months (42)	Mann-Whitney test
Pain due to dry vagina	39 (21)	22 (10)	15 (15)	19 (17)	0.24 (0.39)
Sex life spoilt by urinary symptoms	33 (33)	10 (7)	34 (31)	24 (21)	0.29 (0.65)
Pain with intercourse	20 (20)	10 (7)	13 (13)	17 (14)	0.18 (0.16)
Incontinence with intercourse	31 (30)	7 (2)	22 (21)	7 (7)	0.10 (0.36)

* Comparing the change from baseline between the 2 groups, using the full ordinal scale.

Table No. 5.8. A comparison of sexual matters at 6 months follow up, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between those who had a TVT sling and those who had a short autologous one.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)				
	TVT		**Autologous**		P value*
	Baseline (61)	6 months (41)	Baseline (68)	6 months (42)	Mann-Whitney test
Fluid restriction	46 (39)	29 (17)	38 (29)	36 (14)	0.38 (0.99)
Ability to perform daily tasks	57 (54)	22 (17)	50 (46)	14 (14)	0.90 (0.57)
Avoiding places or situations	57 (54)	37 (24)	46 (44)	38 (26)	0.33 (0.92)
Interfering with physical activity	57 (56)	20 (17)	54 (51)	19 (19)	0.67 (0.65)
Interfering with social activity	54 (52)	20 (17)	49 (47)	24 (21)	0.57 (0.32)
Interfering with life overall	61 (N/A)	32 (N/A)	59 (N/A)	36 (N/A)	0.68 (N/A)

* Comparing the change from baseline between the 2 groups, using the full ordinal scale.

Table No. 5.9. A comparison of life style at 6 months follow up, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between those who had a TVT sling and those who had a short autologous one.

Outcome at 12 months follow up:

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)				
	TVT		Autologous		P value* Mann-Whitney test
	Baseline (61)	12 months (35)	Baseline (68)	12 months (28)	
Daytime frequency (>7)	57 (56)	34 (14)	41 (46)	36 (29)	0.19 (0.26)
Night time frequency (>0)	62 (51)	49 (14)	47 (41)	64 (39)	0.52 (0.57)
Urgency	64 (62)	46 (23)	54 (49)	64 (46)	0.69 (0.82)
Urge incontinence	62 (64)	40 (23)	56 (54)	57 (43)	0.28 (0.37)
Bladder pain	48 (34)	29 (11)	22 (19)	21 (14)	0.40 (0.72)
Frequency of incontinent episodes (>never)	63 (63)	29 (17)	59 (56)	50 (39)	0.90 (0.65)
Stress incontinence	63 (63)	26 (9)	59 (57)	21 (18)	0.56 (0.59)
Unexplained incontinence	54 (54)	14 (11)	53 (47)	21 (18)	0.80 (0.87)
Quantity of urine loss (>none)	63 (N/A)	26 (N/A)	59 (N/A)	34 (N/A)	0.73 (N/A)
Wearing protection	64 (N/A)	23 (N/A)	59 (N/A)	39 (N/A)	0.63 (N/A)
Changing outer clothing	51 (N/A)	17 (N/A)	47 (N/A)	21 (N/A)	0.81 (N/A)
Hesitancy	18 (21)	26 (14)	18 (18)	43 (18)	0.55 (0.39)
Straining	18 (11)	20 (11)	7 (7)	14 (7)	0.80 (0.86)
Intermittent stream	30 (21)	23 (11)	21 (10)	36 (14)	0.68 (0.63)
Nocturnal enuresis	41 (39)	11 (9)	37 (29)	14 (14)	0.32 (0.14)
Abnormal urinary stream	26 (18)	34 (9)	16 (9)	46 (11)	0.24 (0.35)
History of retention	0 (N/A)	3 (N/A)	0 (N/A)	11 (N/A)	0.48 (N/A)
Dysuria	25 (21)	26 (14)	21 (10)	21 (18)	0.17 (0.43)
Incomplete emptying	52 (41)	46 (26)	47 (37)	57 (29)	0.86 (0.55)
Inability to stop midstream	52 (N/A)	34 (N/A)	49 (N/A)	43 (N/A)	0.44 (N/A)

* Comparing the change from baseline between the 2 groups, using the full ordinal scale.

Table No. 5.10. A comparison of the urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)				
	TVT		Autologous		Mann-Whitney test P value
	Baseline (61)	12 months (35)	Baseline (68)	12 months (28)	
Pain due to dry vagina	39 (21)	20 (9)	15 (15)	18 (11)	0.48 (0.75)
Sex life spoilt by urinary symptoms	33 (33)	17 (11)	34 (31)	21 (14)	0.45 (0.64)
Pain with intercourse	20 (20)	20 (11)	13 (13)	21 (11)	0.46 (0.31)
Incontinence with intercourse	31 (30)	6 (6)	22 (21)	14 (14)	0.13 (0.12)

* Comparing the change from baseline between the 2 groups, using the full ordinal scale.

Table No. 5.11. A comparison of the sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)				
	TVT		**Autologous**		Mann-Whitney test P value
	Baseline (61)	12 months (35)	Baseline (68)	12 months (28)	
Fluid restriction	46 (39)	29 (14)	38 (29)	43 (21)	0.63 (0.46)
Ability to perform daily tasks	57 (54)	17 (11)	50 (46)	25 (18)	0.13 (0.07)
Avoiding places or situations	57 (54)	31 (14)	46 (44)	36 (21)	0.33 (0.59)
Interfering with physical activity	57 (56)	17 (14)	54 (51)	21 (18)	0.25 (0.49)
Interfering with social activity	54 (52)	14 (14)	49 (47)	14 (14)	0.17 (0.75)
Interfering with life overall	61 (N/A)	29 (N/A)	59 (N/A)	36 (N/A)	0.46 (N/A)

* Comparing the change from baseline between the 2 groups, using the full ordinal scale.

Table No. 5.12. A comparison of the life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one.

EuroQol:

Outcome at 12 months:

Item	Median (Interquantile range)				Mann Whitney test*
	TVT		**Autologous**		
	Baseline (61)	6 months (41)	Baseline (68)	6 months (42)	
EuroQol score	0.725 (0 .516-0.908)	0.848 (0.620-0.919)	0.788 (0.604-0.919)	0.848 (0.725-0.919)	P 0.80
Total health scale	0.73 (0.55-0.80)	0.80 (0.60-0.90)	0.78 (0.64-0.90)	0.80 (0.65-0.90)	P 0.84

* Comparing the change from baseline between the 2 groups.

Table No. 5.13. A comparison of EurQol score at 6 months follow up, between those who had a TVT sling and those who had a short autologous one.

Outcome at 12 months:

Item	Median (Interquantile range)				Mann Whitney test*
	TVT		**Autologous**		
	Baseline (61)	12 months (35)	Baseline (68)	12 months (28)	
EuroQol score	0.725 (0 .516-0.908)	0.771 (0.181-0.919)	0.788 (0.604-0.919)	0.884 (0.781-0.919)	P 0.06
Total health scale	0.73 (0.55-0.80)	0.50 (0.70-0.90)	0.78 (0.64-0.90)	0.78 (0.60-0.90)	P 0.88

* Comparing the change from baseline between the 2 groups.

Table No. 5.14. A comparison of the EuroQol scores, at 12 months follow up, between those who had a TVT sling and those who had a short autologous one.

Secondary outcome measures:

Operative outcome measures:

Item	TVT (52)	Autologous (57)	Mann-Whitney test
Operating time* (minutes)	30 (25-38)	45 (40-60)	P <0.001
Stay in hospital* (days)	3 (1-5)	5 (3-6)	P 0.00

*Median (Interquantile range)

Table No. 5.15. A comparison of operative data between those who had a TVT sling and those who had a short autologous one.

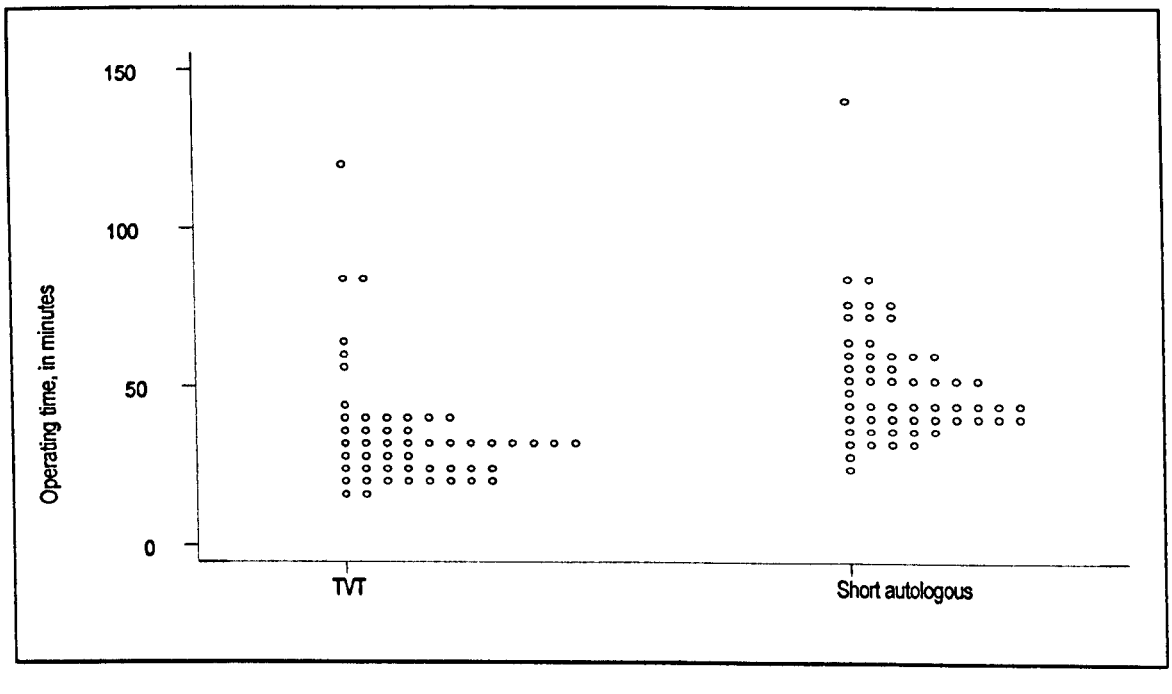


Chart No. 5. 1. Dotplot of the operating time

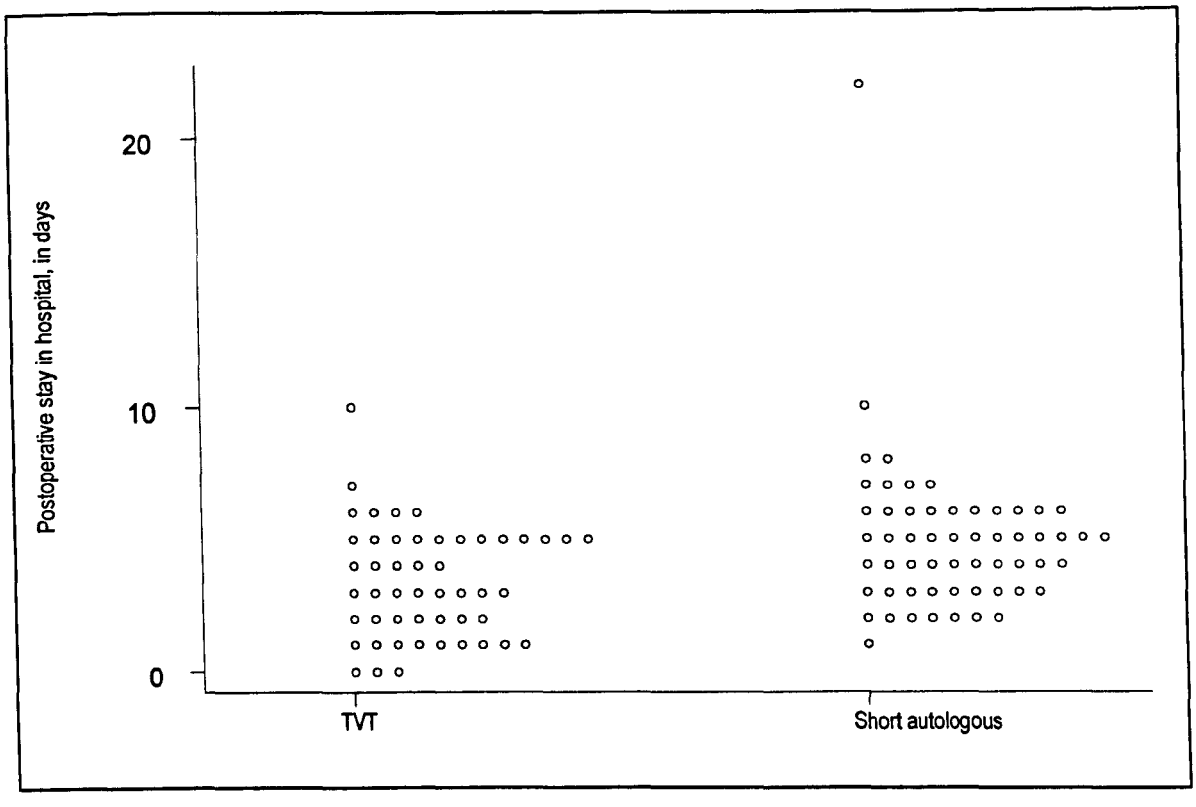


Chart No. 5.2. Postoperative stay

Pad test:

Outcome at 6 months:

Problem	TVT (41)	Autologous (42)	Fisher's Exact
+ve Pad test	13 (31.7%)	20 (47.6%)	(X^2 P 0.21)

Table No. 5.16. A comparison of the incidence of +ve pad test at 6 months follow up between those who had a TVT sling and those who had a short autologous one.

Outcome at 12 months:

Problem	TVT (35)	Autologous (28)	Fisher's Exact
+ve Pad test	2 (5.7%)	4 (14.3%)	P 0.39

Table No. 5.17. A comparison of the incidence of +ve pad test at 12 months follow up between those who had a TVT sling and those who had a short autologous one.

Intra-operative complications:

Complication	TVT (52)	Autologous (57)	Fisher's Exact test
Bladder perforation	0 (0%)	1 (1.8%)	P 1.00
Excessive bleeding	0 (0%)	2 (3.5%)	P 0.50

Table No. 5.18. A comparison of the incidence of intra-operative complications between those who had a TVT sling and those who had a short autologous one.

Post-operative problems:

Problem	TVT (52)	Autologous (57)	Statistical test
Home on ISC*	10 (19.2%)	14 (24.6%)	X^2 test P 0.79
Sling stretch	1 (1.9%)	2 (3.5%)	Fisher's exact P 1.00
Urinary tract infection	4 (7.7%)	5 (8.8%)	Fisher's exact P 1.00
Wound problems	2 (3.8%)	8 (14%)	Fisher's exact P 1.00
Overall	12 (23.1%)	16 (28.1%)	X^2 test P 0.71

*ISC intermittent self catheterisation

Table No. 5.19. A comparison of the incidence of post-operative complications between those who had a TVT sling and those who had a short autologous one.

Problems at 6 weeks follow up:

Problem	TVT (52)	Autologous (57)	Fisher's exact test
Intermittent self catheterisation	2 (3.8%)	6 (10.5%)	P 0.27
Wound problems	2 (3.3%)	8 (4.3%)	P 0.10
Urinary tract infection	0 (0%)	2 (4.3%)	P 0.50
Overall	4 (7.7%)	16 (28.1%)	*P 0.01

*X^2 test

Table No. 5.20. A comparison of incidence of problems at 6 weeks follow up between those who had a TVT sling and those who had a short autologous one.

PAGE

NUMBERING

AS ORIGINAL

Outcome at 6 months follow up:

Problem	TVT (41)	Autologous (42)	Fisher's exact test
Intermittent self catheterisation	4 (9.8%)	4 (9.5%)	P 1.00
Sling release	0 (0%)	1 (2.4%)	P 1.00
Recurrent urinary tract infection	2 (4.9%)	2 (4.8%)	P 1.00
Wound problems	1* (2.4%)	1** (2.4%)	P 1.00
Further surgery	0 (0%)	1*** (2.4%)	P 1.00
Tape erosion	1 (2.4%)	0 (0%)	P 0.49
Overall	8 (19.5%)	7 (16.7%)	P 0.96****

* Pain ** Numbness 1*** Had stretch for voiding problems ****X^2

Table No. 5.21. A comparison of the incidence of problems at 6 months follow up between those who had a TVT sling and those who had a short autologous one.

Outcome at 12 months follow up:

Problem	TVT (35)	Autologous (28)	Fisher's exact test
Recurrent urinary tract infection	2 (5.7%)	0 (0%)	P 0.50
Sling stretch	0 (0%)	1* (3.6%)	P 0.44
Wound problems	0 (0%)	2** (7.1%)	P 0.19
Further surgery	0 (0%)	1*** (3.6%)	P 0.44
Overall	2 (5.7%)	4 (14.3%)	P 0.39

* Stretch and release ** Pain ***Had stretch earlier

Table No. 5.22. A comparison of the incidence of problems at 12 months follow up, between those who had a TVT sling and those who had a short autologous one.

Interim analysis of re-operation rate:

Sling type	At 6 months	At 12 months
Tension-free vaginal tape (TVT)	0/31 (0%)	0/26 (0%)
Pelvicol	0/40 (0%)	6/28 (21.4%)
Short autologous	0/47 (0%)	0/20 (0%)
Fisher's exact (3 way)		P 0.01
Pelvicol versus TVT (Fisher's exact test)		P 0.03
Pelvicol versus autologous (Fisher's exact test)		P 0.03

Table No. 5.23. A comparison of the rate of re-operation in different sling groups at the time of the interim analysis, in the comparative sling study.

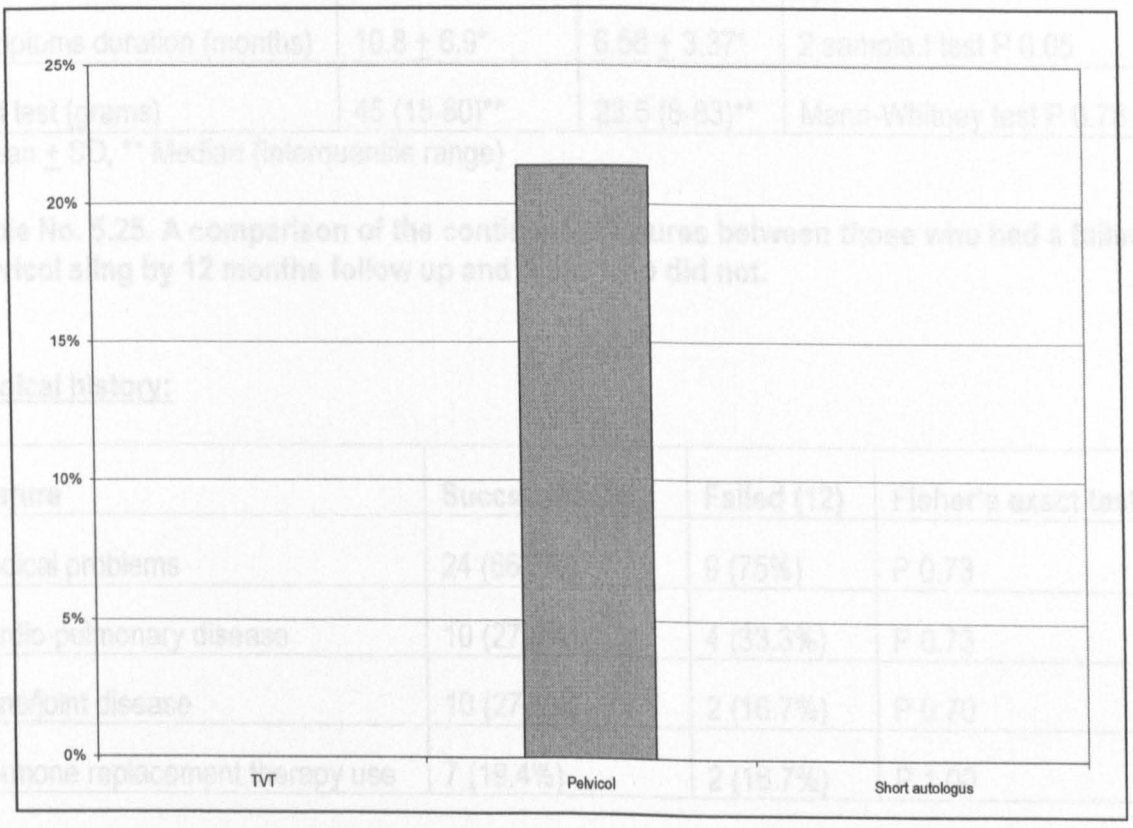


Chart No. 5.3. Interim analysis failure rate.

Comparison between those who had failed pelvicol sling and those who did not:

Demographic data:

	Successful (36)	Failed (12)	Test
Age* (years)	51.72 ± 11.24	53.5 ± 11.43	2 Sample t test P 0.64
Weight** (Kg)	75 (68-83)	80 (63.5-92.5)	Mann-Whitney test P 0.56

*Mean ± SD, ** Median (Interquantile range)

Table No. 5.24. A comparison of the demographic features between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Continence features:

Feature	Successful (36)	Failed (12)	Test
Symptoms duration (months)	10.8 ± 6.9*	6.58 ± 3.37*	2 sample t test P 0.05
Pad test (grams)	45 (15-80)**	23.5 (8-83)**	Mann-Whitney test P 0.78

*Mean ± SD, ** Median (Interquantile range)

Table No. 5.25. A comparison of the continence features between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Medical history:

Feature	Successful (36)	Failed (12)	Fisher's exact test
Medical problems	24 (66.7%)	9 (75%)	P 0.73
Cardio-pulmonary disease	10 (27.8%)	4 (33.3%)	P 0.73
Bone/joint disease	10 (27.8%)	2 (16.7%)	P 0.70
Hormone replacement therapy use	7 (19.4%)	2 (16.7%)	P 1.00

Table No. 5.26. A comparison of the medical history between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Surgical history:

Previous surgery	Successful (36)	Failed (12)	Fisher's exact test
Hysterectomy	17 (47.2%)	3 (25%)	P 0.31
Continence	8 (22.2%)	3 (25%)	P 1.00
Prolapse	8 (22.2%)	4 (33.3%)	P 0.46

Table No. 5.27. A comparison of the surgical history between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Quality of life:

Bristol Female Lower Urinary Tract Symptoms (B-FLUTS):

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Successful (35)	**Failed (12)**	**Mann Whitney Test P value**
Daytime frequency (>7)	74 (77)	83 (92)	0.57 (0.77)
Night time frequency (>0)	94 (71)	83 (75)	0.37 (0.74)
Urgency	100 (89)	100 (92)	0.47 (0.68)
Urge incontinence	100 (91)	100 (100)	0.11 (0.50)
Bladder pain	74 (46)	42 (33)	0.66 (0.35)
Frequency of incontinent episodes (>never)	97 (97)	100 (100)	0.92 (0.90)
Stress incontinence	100 (100)	100 (100)	0.19 (0.86)
Unexplained incontinence	89 (89)	100 (100)	0.38 (0.18)
Quantity of urine loss (>none)	94 (N/A)	100 (N/A)	0.44 (N/A)
Wearing protection	63 (N/A)	67 (N/A)	0.91 (N/A)
Changing outer clothing	80 (N/A)	83 (N/A)	0.81 (N/A)
Hesitancy	34 (26)	17 (33)	0.34 (0.67)
Straining	14 (6)	25 (17)	0.40 (0.38)
Intermittent stream	37 (26)	33 (10)	0.93 (0.18)
Nocturnal enuresis	71 (69)	83 (82)	0.34 (0.21)
Abnormal urinary stream	31 (29)	58 (33)	0.25 (0.96)
History of retention	11 (N/A)	0 (N/A)	0.22 (N/A)
Dysuria	40 (34)	17 (20)	0.21 (0.22)
Incomplete emptying	89 (74)	42 (42)	**0.04 (0.03)**
Inability to stop midstream	77 (N/A)	92 (N/A)	0.07 (N/A)

Table No. 5.28. A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Successful (35)	**Failed (12)**	**Mann Whitney Test P value**
Pain due to dry vagina	40 (37)	25 (25)	0.25 (0.23)
Sex life spoilt by urinary symptoms	54 (54)	58 (58)	0.24 (0.15)
Pain with intercourse	26 (26)	25 (25)	0.45 (0.38)
Incontinence with intercourse	51 (49)	50 (50)	0.28 (0.17)

Table No. 5.29. A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Successful (35)	**Failed (12)**	**Mann Whitney Test P value**
Fluid restriction	91 (77)	92 (75)	0.47 (0.57)
Ability to perform daily tasks	86 (86)	100 (100)	0.08 (0.08)
Avoiding places or situations	86 (86)	100 (100)	0.09 (0.08)
Interfering with physical activity	91 (91)	100 (100)	0.65 (0.32)
Interfering with social activity	86 (86)	92 (92)	0.05 (0.29)
Interfering with life overall	100 (N/A)	100 (N/A)	0.72 (N/A)

Table No. 5.30. A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not.

EuroQol:

Item	Median (Interquantile range)		
	Successful (35)	**Failed (12)**	**Mann Whitney Test**
EuroQol score	0.725 (0.62-0.883)	0.814 (0.378-0.883)	P 0.67
Total health scale	0.725 (0.62 -0.883)	0.814 (0.378-0.883)	P 0.32

Table No. 5.31. A comparison of the EuroQol scores at recruitment between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Operative data:

Feature	Successful (36)	Failed (12)	Fisher's exact test
Anaesthesia			
General	27 (75%)	6 (50%)	
Spinal	9 (25%)	6 (50%)	P 0.15
Additional surgery	3 (83%)	2 (16.7%)	P 1.00
Middle grade surgeon	9 (25%)	2 (16.7%)	P 0.71

Table No. 5.32. A comparison of the operative data between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Type of additional surgery:

Operation	Successful (36)	Failed (12)
Hysteroscopy	1 (2.8%)	0 (0%)
Laparoscopy	0 (0%)	1 (8.3%)
Vaginal repair	1 (2.8%)	1 (8.3%)
Other	1 (2.8%)	0 (0%)

Table No. 5.33. The additional surgery performed in those who had a failed pelvicol sling by 12 months follow up and those who did not.

Operating time and post-operative stay:

Feature	Successful (36)	Failed (12)	Mann Whitney test
Operating time* (minutes)	35 (25-40)	25 (25-40)	P 0.46
Post-operative stay* (days)	4 (3-5)	3.5 (3-5.5)	P 0.89

* Median (interquantile range)

Table No. 5.34. A comparison of the operating time and post-operative stay between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Operative complications:

Complication	Successful (36)	Failed (12)	Fisher's exact test
Excessive bleeding	0 (0%)	1 (8.3%)	P 0.25

Table No. 5.35. A comparison of the incidence of operative complications between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Post-operative complications:

Complication	Successful (36)	Failed (12)	Fisher's exact test
Home on intermittent self catheterisation	7 (19.4%)	4* (33.3%)	P 0.43
Sling stretch	1 (2.8%)	0 (0%)	P 1.00
Urinary tract infection	2 (5.6%)	0 (0%)	P 1.00
Deep vein thrombosis/ pulmonary embolism	1 (2.8%)	0 (0%)	P 1.00
Wound problems	2 (5.6%)	1 (8.3%)	P 0.59
Overall	14 (38.9%)	4 (33.3%)	P 1.00

* 1 with suprapubic catheter

Table No. 5.36. A comparison of the incidence of operative as well as post-operative complications between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Problems at 6 weeks follow up:

Problem	Successful (33)	Failed (12)	Fisher's exact test
Intermittent self catheterisation	4 (12.1%)	2 (16.7%)	P 0.65
Wound	1 (3%)	0 (0%)	P 1.00
Urinary tract infection	1 (3%)	0 (0%)	P 1.00
Overall	6 (18.2%)	2 (16.7%)	P 1.00

Table No. 5.37. A comparison of incidence of problems at 6 weeks follow up between those who had a failed pelvicol sling by 12 months follow up and those who did not.

Outcome in those patients who had a successful pelvicol sling:

Primary outcome measure (Quality of life):

Bristol Female Lower Urinary Tract Symptoms Questionnaire:

Outcome at 6 months:

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (35)	**6 months (23)**	**Mann-Whitney test P value**
Daytime frequency (>7)	74 (77)	39 (35)	**0.002 (<0.001)**
Night time frequency (>0)	94 (71)	74 (22)	**0.003 (0.003)**
Urgency	100 (89)	78 (61)	**0.005 (0.01)**
Urge incontinence	100 (91)	74 (61)	**<0.001 (<0.001)**
Bladder pain	74 (46)	17 (17)	**0.03 (0.04)**
Frequency of incontinent episodes (>never)	97 (97)	61 (35)	**<0.001 (<0.001)**
Stress incontinence	100 (100)	35 (26)	**<0.001 (<0.001)**
Unexplained incontinence	89 (89)	26 (26)	**<0.001 (<0.001)**
Quantity of urine loss (>none)	94 (N/A)	61 (N/A)	**<0.001** (N/A)
Wearing protection	63 (N/A)	26 (N/A)	**0.04** (N/A)
Changing outer clothing	80 (N/A)	22 (N/A)	**0.002** (N/A)
Hesitancy	34 (26)	48 (22)	0.32 (0.80)
Straining	14 (6)	17 (13)	0.72 (0.33)
Intermittent stream	37 (26)	43 (26)	0.43 (0.65)
Nocturnal enuresis	71 (69)	22 (22)	**0.002 (0.02)**
Abnormal urinary stream	31 (29)	61 (30)	**0.03** (0.92)
History of retention	11 (N/A)	26 (N/A)	0.11 (N/A)
Dysuria	40 (34)	22 (17)	0.28 (0.16)
Incomplete emptying	89 (74)	70 (39)	0.14 (0.06)
Inability to stop midstream	77 (N/A)	52 (N/A)	0.29 (N/A)

Table No. 5.38. A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (35)	**6 months (23)**	**Mann-Whitney test P value**
Pain due to dry vagina	40 (37)	17 (9)	0.15 (0.08)
Sex life spoilt by urinary symptoms	54 (54)	26 (22)	**0.02 (0.01)**
Pain with intercourse	26 (26)	22 (17)	0.92 (0.65)
Incontinence with intercourse	51 (49)	13 (13)	**0.03 (0.03)**

Table No. 5.39. A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (35)	**6 months (23)**	**Mann-Whitney test P value**
Fluid restriction	91 (77)	43 (17)	**<0.001 (0.001)**
Ability to perform daily tasks	86 (86)	26 (26)	**<0.001 (<0.001)**
Avoiding places or situations	86 (86)	43 (22)	**<0.001 (<0.001)**
Interfering with physical activity	91 (91)	26 (26)	**<0.001 (<0.001)**
Interfering with social activity	86 (86)	26 (26)	**<0.001 (<0.001)**
Interfering with life overall	100 (N/A)	26 (N/A)	**<0.001** (N/A)

Table No. 5.40. A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Twelve months:

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (35)	**12 months (19)**	**Mann-Whitney test P value**
Daytime frequency (>7)	74 (77)	42 (68)	0.06 **(0.007)**
Night time frequency (>0)	94 (71)	79 (42)	**0.03 (0.04)**
Urgency	100 (89)	100 (74)	0.10 **(0.01)**
Urge incontinence	100 (91)	89 (79)	**0.001 (0.001)**
Bladder pain	74 (46)	32 (26)	0.41 (0.19)
Frequency of incontinent episodes (>never)	97 (97)	79 (68)	**<0.001 (0.002)**
Stress incontinence	100 (100)	79 (74)	**<0.001 (<0.001)**
Unexplained incontinence	89 (89)	53 (53)	**0.002 (0.001)**
Quantity of urine loss (>none)	94 (N/A)	84 (N/A)	**<0.001** (N/A)
Wearing protection	63 (N/A)	63 (N/A)	0.37 (N/A)
Changing outer clothing	80 (N/A)	32 (N/A)	**0.01** (N/A)
Hesitancy	34 (26)	42 (32)	0.53 (0.92)
Straining	14 (6)	0 (5)	0.10 (0.83)
Intermittent stream	37 (26)	37 (32)	0.70 (0.82)
Nocturnal enuresis	71 (69)	26 (26)	**0.01 (0.03)**
Abnormal urinary stream	31 (29)	63 (32)	0.05 (0.94)
History of retention	11 (N/A)	11 (N/A)	1.00 (N/A)
Dysuria	40 (34)	42 (26)	0.65 (0.48)
Incomplete emptying	89 (74)	63 (42)	0.43 (0.24)
Inability to stop midstream	77 (N/A)	68 (N/A)	0.34 (N/A)

Table No. 5.41. A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (35)	**12 months (19)**	**Mann-Whitney test P value**
Pain due to dry vagina	40 (37)	21 (11)	0.14 **(0.02)**
Sex life spoilt by urinary symptoms	54 (54)	37 (32)	0.35 (0.19)
Pain with intercourse	26 (26)	26 (16)	0.97 (0.49)
Incontinence with intercourse	51 (49)	32 (32)	0.80 (0.16)

Table No. 5.42. A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (35)	**12 months (19)**	**Mann-Whitney test P value**
Fluid restriction	91 (77)	58 (47)	**0.002** (0.06)
Ability to perform daily tasks	86 (86)	58 (42)	**0.01 (0.002)**
Avoiding places or situations	86 (86)	58 (63)	**0.01 (0.04)**
Interfering with physical activity	91 (91)	63 (63)	**<0.001 (<0.001)**
Interfering with social activity	86 (86)	41 (42)	**<0.001 (<0.001)**
Interfering with life overall	100 (N/A)	68 (N/A)	**<0.001** (N/A)

Table No. 5.43. A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

EuroQol:

Outcome at 6 months:

EuroQol:

Item	Median (Interquantile range)		**Mann-Whitney test P value**
	Baseline (35)	**6 months (23)**	
EuroQol score	0.725 (0.62-0.883)	0.848 (0.689-0.919)	P 0.33
Total health scale	0.70 (0.60 -0.90)	0.78 (0.60-0.90)	P 0.57

Table No. 5.44. A comparison of EuroQol scores at recruitment and 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Outcome at 12 months:

Item	Median (Interquantile range)		Mann-Whitney test P value
	Baseline (35)	**12 months (19)**	
EuroQol score	0.725 (0.62-0.883)	0.796 (0.689-0.919)	P 0.44
Total health scale	0.70 (0.60 -0.90)	0.70 (0.60-0.80)	P 0.47

Table No. 5.45. A comparison of the EuroQol scores, at recruitment and 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Secondary outcome measures:

Pad test:

At 6 months:

Problem	No (%)
+ve Pad test	4/23 (17.4%)

Table No. 5.46. The incidence of +ve pad test at 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Pad test:

At 12 months:

Problem	No (%)
+ve Pad test	3/19 (15.8%)

Table No. 5.47. The incidence of +ve pad test at 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Problems

At 6 months:

Problem	No (%)
Intermittent self catheterisation	1/23 (4.3%)
Sling release	0/23 (0%)
Wound problems	0/23 (0%)
Recurrent urinary tract infection	0/23 (%)
Overall	1/23 (4.3%)

Table No. 5.48. The incidence of problems at 6 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

At 12 months:

Problem	No (%)
Intermittent self catheterisation	0/19 (0%)
Sling release	1/19 (5.3%)
Vaginal irritation and redness	1/19* (5.3%)
Wound problems	1/19 (5.3%)
Recurrent urinary tract infection	1/19 (4.2%)
Overall	4/19 (21.1%)

*Was booked for sling removal, but this was not done as the irritation and redness subsided. The patient however became incontinent later on.

Table No. 5.49. The incidence of problems at 12 months follow up in those patients whose pelvicol sling did not fail up till 12 months follow up.

Outcome in those who had a failed pelvicol sling:

Primary outcome measure (Quality of life):

Bristol Female Lower Urinary Tract Symptoms (B-FLUTS):

Outcome at 6 months:

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (12)	**6 months (11)**	**Mann-Whitney test P value**
Daytime frequency (>7)	83 (92)	55 (36)	0.07 **(0.02)**
Night time frequency (>0)	83 (75)	73 (45)	0.27 (0.17)
Urgency	100 (92)	100 (73)	0.74 (0.27)
Urge incontinence	100 (100)	91 (64)	**0.02 (0.10)**
Bladder pain	42 (33)	36 (27)	0.75 (0.76)
Frequency of incontinent episodes (>never)	100 (100)	91 (64)	**0.03** (0.24)
Stress incontinence	100 (100)	73 (73)	**0.003 (0.01)**
Unexplained incontinence	100 (100)	73 (73)	0.05 **(0.02)**
Quantity of urine loss (>none)	100 (N/A)	73 (N/A)	0.11 (N/A)
Wearing protection	67 (N/A)	45 (N/A)	0.81 (N/A)
Changing outer clothing	83 (N/A)	45 (N/A)	0.56 (N/A)
Hesitancy	17 (33)	27 (18)	0.67 (0.42)
Straining	25 (17)	27 (0)	0.90 (0.15)
Intermittent stream	33 (10)	27 (9)	0.71 (0.94)
Nocturnal enuresis	83 (82)	18 (18)	**0.002 (0.002)**
Abnormal urinary stream	58 (33)	45 (18)	0.82 (0.60)
History of retention	0 (N/A)	0 (N/A)	N/P* (N/A)
Dysuria	17 (20)	36 (18)	0.36 (0.91)
Incomplete emptying	42 (42)	36 (27)	0.60 (0.51)
Inability to stop midstream	92 (N/A)	81 (N/A)	0.50 (N/A)

* N/P not possible.

Table No. 5.50. A comparison of urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 6 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (12)	**6 months (11)**	**Mann-Whitney test P value**
Pain due to dry vagina	25 (25)	18 (18)	0.70 (0.65)
Sex life spoilt by urinary symptoms	58 (58)	36 (36)	0.81 (1.00)
Pain with intercourse	25 (25)	27 (27)	0.75 (0.73)
Incontinence with intercourse	50 (50)	18 (18)	0.14 (0.15)

Table No. 5.51. A comparison of sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 6 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (12)	**6 months (11)**	**Mann-Whitney test P value**
Fluid restriction	92 (75)	64 (45)	**0.04** (0.18)
Ability to perform daily tasks	100 (100)	81 (81)	**0.03 (0.02)**
Avoiding places or situations	100 (100)	73 (64)	0.07 **(0.03)**
Interfering with physical activity	100 (100)	81 (81)	0.10 **(0.04)**
Interfering with social activity	92 (92)	64 (64)	**0.004 (0.07)**
Interfering with life overall	100 (N/A)	64 (N/A)	0.09 (N/A)

Table No. 5.52. A comparison of life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 6 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Outcome at 12 months:

Urinary symptoms:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (12)	**12 months (5)**	**Mann-Whitney test P value**
Daytime frequency (>7)	83 (92)	80 (80)	0.79 (0.47)
Night time frequency (>0)	83 (75)	80 (60)	0.95 (0.87)
Urgency	100 (92)	100 (80)	0.44 (0.95)
Urge incontinence	100 (100)	100 (80)	0.38 (0.40)
Bladder pain	42 (33)	40 (40)	0.68 (0.89)
Frequency of incontinent episodes (>never)	100 (100)	100 (80)	0.11 (0.13)
Stress incontinence	100 (100)	100 (80)	**0.01 (0.04)**
Unexplained incontinence	100 (100)	80 (80)	0.24 (0.06)
Quantity of urine loss (>none)	100 (N/A)	100 (N/A)	0.38 (N/A)
Wearing protection	67 (N/A)	80 (N/A)	0.58 (N/A)
Changing outer clothing	83 (N/A)	60 (N/A)	0.70 (N/A)
Hesitancy	17 (33)	40 (60)	0.32 (0.41)
Straining	25 (17)	20 (20)	0.72 (1.00)
Intermittent stream	33 (10)	20 (20)	0.74 (0.42)
Nocturnal enuresis	83 (82)	60 (60)	0.85 (0.47)
Abnormal urinary stream	58 (33)	60 (20)	0.82 (0.73)
History of retention	0 (N/A)	0 (N/A)	N/P* (N/A)
Dysuria	17 (20)	20 (20)	0.87 (0.93)
Incomplete emptying	42 (42)	80 (60)	0.26 (0.41)
Inability to stop midstream	92 (N/A)	80 (N/A)	0.71 (N/A)

*N/P Not possible.

Table No. 5.53. A comparison of the urinary symptoms, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 12 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Sexual Matters:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (12)	**12 months (5)**	**Mann-Whitney test P value**
Pain due to dry vagina	25 (25)	60 (60)	0.09 (0.09)
Sex life spoilt by urinary symptoms	58 (58)	80 (80)	0.16 (0.34)
Pain with intercourse	25 (25)	60 (60)	0.29 (0.18)
Incontinence with intercourse	50 (50)	80 (80)	0.44 (0.23)

Table No. 5.54. A comparison of the sexual matters, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 12 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Lifestyle:

Symptom	% reporting symptom (% reporting symptom as a problem)		
	Baseline (12)	**12 months (5)**	**Mann-Whitney test P value**
Fluid restriction	92 (75)	80 (40)	0.58 (0.59)
Ability to perform daily tasks	100 (100)	80 (80)	0.13 (0.24)
Avoiding places or situations	100 (100)	60 (60)	0.62 (0.54)
Interfering with physical activity	100 (100)	80 (60)	**0.03** (0.05)
Interfering with social activity	92 (92)	60 (60)	0.06 (0.20)
Interfering with life overall	100 (N/A)	80 (N/A)	0.08 (N/A)

Table No. 5.55. A comparison of the life style, as measured by the Bristol Female Lower Urinary Tract Symptoms Questionnaire, between recruitment and 12 months follow up in those who had a failed pelvicol sling by 12 months follow up.

EuroQol:

Outcome at 6 months:

Item	Median (Interquantile range)		**Mann-Whitney test P value**
	Baseline (12)	**6 months (11)**	
EuroQol score	0.814 (0.378-0.883)	0.814 (0.806-0.901)	P 0.69
Total health scale	0.60 (0.50-0.90)	0.75 (0.58-0.90)	P 0.25

Table No. 5.56. A comparison between the EuroQol scores at recruitment and at 6 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Outcome at 12 months:

Item	Median (Interquantile range)		Mann-Whitney test P value
	Baseline (12)	**12 months (5)**	
EuroQol score	0.814 (0.378-0.883)	0.866 (0.806-0.901)	P 0.34
Total health scale	0.60 (0.50-0.90)	0.8 (0.7-0.9)	P 0.27

Table No. 5.57. A comparison between the EuroQol scores at recruitment and at 12 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Secondary outcome measures:

Pad test:

At 6 months:

Problem	No. (%)
+ve Pad test	6/11 (54.5%)

Table No. 5.58. The incidence of +ve pad test at 6 months follow up in the patients who had a failed pelvicol sling by 12 months follow up.

At 12 months:

Problem	No. (%)
+ve Pad test	4/5 (80%)

Table No. 5.59. The incidence of +ve pad test at 12 months follow up in the patients who had a failed pelvicol sling by 12 months follow up.

Problems:

At 6 months:

Problem	No. (%)
Intermittent self catheterisation	0/11 (0%)
Sling release	0/11 (0%)
Wound problems	0/11 (0%)
Recurrent urinary tract infection	0/11 (0%)
Overall	0/11 (0%)

Table No. 5.60. The incidence of problems at 6 months follow up in those who had a failed pelvicol sling by 12 months follow up.

At 12 months:

Problem	No. (%)
Intermittent self catheterisation	0/5 (0%)
Sling release	0/5 (0%)
Sling removal	0/5 (0%)
Wound problems	0/5 (0%)
Recurrent Urinary tract infection	1/5 (20%)
Overall	1/5 (20%)

Table No. 5.61. The incidence of problems at 12 months follow up in those who had a failed pelvicol sling by 12 months follow up.

Summary:

The drop in reporting of daytime frequency, urge incontinence, bladder pain, changing outer clothes and abnormal urinary stream, as assessed by the Bristol Female Lower Urinary Tract Symptoms questionnaire, was significantly more in those who had a tension-free vaginal tape (TVT) sling than in those who had a short autologous sling, at 6 months follow up. Otherwise, there was no significant difference in the change in quality of life assessment between the 2 groups.

The tension-free vaginal tape (TVT) sling required significantly less time to insert than the autologous slings and was followed by a significantly shorter post-operative stay than the autologous sling. There was no significant difference between the two slings in the incidence of post-operative complications or voiding problems. At 6 weeks follow up, those who had tension-free vaginal tape (TVT) sling had a significantly lower overall rate of problems than those who had the short autologous one.

There was a significant difference in the re-operation rate at 12 months following the pelvicol sling than the tension-free vaginal tape (TVT) and short autologous slings. There was no significant difference in background features, operative and post operative data or problems at 6 weeks follow up between those who had a failed pelvicol sling by 12 months follow up and those who did not, apart from incidence of incomplete emptying, as assessed by the Bristol Female Lower Urinary Tract Symptoms questionnaire, in those who had a failed pelvicol sling by 12 months follow up.

Although there was a significant improvement in some quality of life aspects at 6 months in those who had a failed pelvicol sling by 12 months follow up and those who did not, these improvements became less at 12 months follow up for both subgroups. The incidence of complications was low in both subgroups.

Discussion:

The tension-free vaginal tape (TVT) versus the short autologous slings:

Primary outcome measure:

The reduction in daytime frequency, urge incontinence, bladder pain as well as changing outer clothes was significantly less at 6 months follow up after tension-free vaginal tape (TVT) sling insertion than after short autologous sling insertion, as assessed by the Bristol Female Lower Urinary Tract Symptoms quality of life questionnaire. Likewise, significantly more patients felt a change in urinary stream at 6 months follow up after the tension-free vaginal tape (TVT) sling than after the short autologous sling. However, these significant differences were limited to those reporting the symptoms, rather than those reporting them as problems. There was no significant difference in the change of any other aspect of quality of life, as assessed by the Bristol Female Lower Urinary Tract Symptoms and EuroQol questionnaires. Similarly, there was no significant difference in quality of life, as assessed by the 2 questionnaires, between the two groups of patients at 12 months. The published study did not include quality of life assessment (Wadie et al, 2005).

Such limited and short term differences in quality of life contrast with more sustained differences observed in the randomised trial that compared the tension-free vaginal tape (TVT) sling and the Burch colposuspension (Ward & Hilton, 2002). This trial showed significant differences in physical function, emotional role as well as social functioning at 6 weeks, as measured by Short Form 36 (SF-3). These differences mirror the limited tissue dissection involved in the tension free vaginal tape (TVT) sling, in comparison to the extensive dissection involved in the Burch colposuspension. These differences persisted at 6 months (Ward & Hilton, 2002) as well as at 2 years (Ward & Hilton, 2004).

This trial did not include quality of life assessment at 6 weeks, to show any difference at that stage. Yet, the overall impression is of a more or less equal impact on quality of life improvement in the long term. Although the short autologous sling entails more dissection that the tension-free vaginal tape (TVT) sling, both are minimally invasive slings, and this might explain the limited and short term difference in quality of life impact. On the other hand, the Burch colposuspension entails more extensive dissection in comparison to the tension-free vaginal tape (TVT) sling, which might account for longer differences in quality of life, observed in the randomised trial (Ward & Hilton, 2002; Ward & Hilton, 2004).

Secondary outcome measures:

The tension-free vaginal tape (TVT) sling was associated with significantly shorter operating time and post-operative stay in hospital. The median operating time was 15 minutes shorter with the tension-free vaginal tape (TVT) sling than with the short autologous sling. Likewise, the median post-operative hospital stay was 2 days shorter following the tension-free vaginal tape than after the short autologous sling. The published series (Wadie et al, 2005), showed a mean difference of 20 minutes in favour of the tension-free vaginal tape (TVT) sling. No information was about patient stay in hospital was provided.

Although the short autologous sling is less invasive than the long one, it is entails more dissection than the tension-free vaginal tape (TVT) sling (Wadie et al, 2005). It requires a longer skin incision and entails re-suturing of the rectus sheath. Consequently, it took longer to perform and patients stayed longer than with the tension-free vaginal tape (TVT) sling. The study did not include assessment of post-operative pain and analgesic requirements. Such assessment could have allowed comparing the degree of minimal invasiveness of both techniques.

There were more intra-operative and post-operative complications with the short autologous sling than the tension-free vaginal tape. Bladder perforation and wound problems were more common with the short autologous sling than with the tension-free vaginal tape (TVT) sling, though the difference was not significant. This may reflect the fact that the short autologous sling entails more tissue dissection and takes longer than the tension-free vaginal tape (TVT) sling. However, the difference was insignificant, both in terms of individual complications as well as the over all incidence of problems. This matches the findings in the published series (Wadie et al, 2005).

At 6 weeks, the incidence of individual complications was not significantly different between the two groups. There was no significant difference in voiding dysfunction, urinary tract infection or wound problems. Nonetheless, the overall incidence of problems was significantly higher with the short autologous sling. This may reflect the fact that the short autologous sling entails more dissection, and thus tissue trauma, than the tension-free vaginal tape (TVT) sling. This study did not include an assessment of recovery and return to normal activity in its outcome measures. Such an assessment would have provided information about possible differences between the 2 techniques during the recovery period.

The trend towards more post-operative problems with the short autologous sling does not seem to persist in the long term. There was no significant difference in the incidence of individual problems or overall incidence of complications at 6 or 12 months between the 2 groups. This shows that both techniques match up eventually, as forms of minimally invasive slings, and have more or less the same long term safety. This pattern matches a similar trend in quality of life assessment, as outlined above.

Voiding dysfunction is a complication that can manifest in the early post-operative period as well as in long term follow up. Although more patients went home on intermittent self catheterisation after the short autologous sling, the difference was not significant. Likewise, more patients required sling stretch following the short autologous sling, but the difference was not significant. This matches the findings in the published series (Wadie et al, 2005), where more patients required catheterisation following the autologous sling than after the tension-free vaginal tape (TVT) sling. The significance of the difference between the two techniques however was not assessed in the published series.

The development of the tension-free vaginal tape (TVT) marked a new era in sling surgery. It introduced the concept of tension-free insertion, which reduces post-operative voiding dysfunction. The comparable incidence of post-operative voiding dysfunction shows that tension-free insertion of the short autologous sling can be associated with low incidence of voiding dysfunction, as with the tension-free vaginal tape (TVT) sling. This matches the finding and conclusion of the published series (Wadie et al, 2005).

The rates of early voiding dysfunction seem rather high. In an earlier study at the main study centre (Lucas et al, 1996), 14% of patients required intermittent self catheterisation on discharge from hospital following the short autologous sling. This is lower than the 24.6% found in this study. It is difficult to judge the rate of early voiding dysfunction after tension-free vaginal tape (TVT) sling insertion. No uniform method has been used in describing voiding dysfunction after the insertion of this sling. The randomised controlled trial that compared the tension-free vaginal tape (TVT) sling against the Burch colposuspension provided information about the duration of catheterisation, including all those who had a catheter for up to a week together

(Ward & Hilton, 2002). Another study (Mishra et al, 2005) described initial retention requiring re-catheterisation for up to a week in 12 out of 52 patients (23.1%). A third study reported post-operative retention in 38 out of 274 patients (13.9%), with 14 requiring urethral dilatation within the first month, starting from the second post-operative day (Paick et al, 2005).

Delayed voiding dysfunction was more common after the short autologous sling, though the difference was not significant. More patients used intermittent self catheterisation at 6 weeks and 6 months, though the difference was not significant. Similarly, more patients required sling stretch and release at 6 and 12 months, but the difference was not significant. Tension-free insertion of the short autologous sling can therefore be as good as the tension-free vaginal tape (TVT) sling in reducing long term voiding dysfunction. This concords with the results of the published series (Wadie et al, 2005).

There was no significant difference in the incidence of positive pad test between the 2 groups at any of the follow up visits. Pad tests are better in quantifying, rather than diagnosing, urodynamic stress incontinence (Sutherst et al, 1981). Nonetheless, they provided an objective evaluation of the effectiveness of both sling techniques. This, in conjunction with a more or less similar change in quality of life scores, especially in relation to stress incontinence on the Bristol Female Lower Urinary Tract Symptoms (B-FLUTS) questionnaire, does support the impression that both slings are equally effective for urodynamic stress incontinence. The published series (Wadie et al, 2005) showed no significant difference in effectiveness at 6 months, on the basis of urodynamic assessment.

Tape erosion was encountered in one case following the tension-free vaginal tape (TVT) sling (2%). This is a rather low rate and does support the hypothesis that tension-free insertion helps

reducing tape erosion. The rate was equally low (1%) in the randomised trial that compared the tension-free vaginal tape to the Burch colposuspension (Ward & Hilton, 2002). Although tape erosion is very rare with autologous slings (Clemens et al, 2000), it can happen (Amundsen et al, 2003). No erosions were noted in the published series that compared the 2 sling techniques (Wadie et al, 2005). The rare occurrence of such a complication with tension-free insertion of the tension-free vaginal tape (TVT) sling reduces the advantage of using autologous slings.

Another merit of using autologous sling is the reduced cost. Whilst the tension-free vaginal tape (TVT) sling costs about £600 (Arunkalaivanan & Barrington, 2003), the rectus sheath is free. Yet, one must take note of the longer operating time as well as patient stay in hospital after the autologous sling. In a typical 4 hour theatre session, a 15minute difference per case can mean 1 or 2 more cases having sling insertion when inserting the tension-free vaginal tape (TVT) sling than with the short autologous sling. Likewise, a 2day shorter stay in hospital can save £300 (Department of Health, 2005). This reduces any economic advantage for the short autologous sling, even without making any adjustment for the higher, though insignificant, increase in intermittent self-catheterisation and other post-operative complications with the short autologous sling.

The pelvicol sling:

An interim analysis became necessary in view of the re-operation rate observed. At the time of the analysis, 6 out of 28 patients (21.4%) who completed 12 months follow up since the pelvicol sling insertion required re-operation, compared to none (0%) following the tension-free vaginal tape (TVT) or short autologous slings (P 0.01). It was unethical to continue the trial as planned beyond that point, knowing that the re-operation rate is higher with pelvicol. By the time all patients were seen at 12 months follow up, the total failure rate rose to 25%.

The pattern of failure requiring re-operation was consistent. It happened after an initial improvement lasting 6 months and manifested in the form of total failure, rather than mere deterioration. The incidence of problems, such as voiding dysfunction or wound problems, was not particularly higher amongst these patients than those who had a successful pelvicol sling at any follow up visit. This pattern matches experience with the material in other hospitals, where pelvicol was used for sling insertion and sacrocolpopexy.

Quality of life assessment using the Bristol Female Lower Urinary Tract Symptoms questionnaire demonstrates this pattern. There was a significant improvement in the incidence and bother of several symptoms at 6 months in those who subsequently had a failed one. At 12 months, improvements were less obvious, bearing in mind that those seen in the failed group at this follow up stage were those who did not have a repeat operation by that time. They could thus be seen as a subgroup with a less unfavourable outcome than those who had re-operation prior to this follow up visit. Such drop in this subgroup shows the non sustainable effect of the pelvicol sling. The same pattern can be seen with the pad test.

A similar pattern can be observed in those who had a successful pelvicol sling. Significant improvements were noted at 6 months, when assessed by the Bristol Female Lower Urinary Tract Symptoms questionnaire. These improvements however were less pronounced at 12 months. Nonetheless, there was no matching increase in the number of patients with a positive pad test nor there were patients requiring urodynamic assessment for recurrent symptoms. A longer follow up of these patients may well detect future failure. This is particularly important in view of the fact that a patient who had recurrence stress incontinence following transient vaginal irritation and redness 12 months follow up.

This finding however is in direct contract to published reports on pelvicol sling. Nonetheless, all published reports come from the same centre and included a prospective series (Barrington et al, 2002) and a randomised controlled trial that compared the sling against the tension-free vaginal tape (TVT) sling (Arunkalaivanan & Barrington, 2003; Abdel-Fattah et al, 2004). As outlined already, these reports have their limitations.

The prospective series included 40 patients with no power calculation and relied on a non validated questionnaire in assessing outcome. Although the stated follow up duration ranged from 6 to 18 months, the results describe the outcome at 6 months. As all the failures observed in this study happened after 6 months follow up, the follow up period was not the same. Although a failure (2.5%) was reported in the series, it is possible, at least in theory, that more failures were encountered since this report, especially when no longer follow up of that particular study has been published.

The randomised controlled trial was based on a non-validated questionnaire (Arunkalaivanan & Barrington, 2003; Abdel-Fattah et al, 2004). At a median follow up duration of 12 months, there were 6 failures in the pelvicol arm (8.1%). At a median follow up duration of 34 months, with 68 out of the original 74 patients replying, the number of failures dropped to 5 failures (8%). No comment was given as to when the diagnosis of failure was made, whether it was preceded by good outcome or not and whether the sling was still present at repeat surgery, in case of re-operation, or not.

A recent report described the surgical and histopathological findings in patients who required repeat surgery following pelvicol slings (Gandhi et al, 2005). There were 66 patients in total, 10 (15.2%) of them required surgery for retention and 2 (3%) for failure. The 2 failures had repeat

surgery at 58 and 67 weeks after insertion and both were cured on urodynamic assessment before that. This matches the pattern of the failures encountered in this study. Fibrous bands were found below the urethra and the sling appeared to be intact.

One of the features found on histopathological examination in this study was a foreign body reaction in those patients who had retention of urine. Although repeat surgery for these cases was done at an earlier stage, ranging from 15 to 42 weeks, the authors raised the possibility of a varied human body response to pelvicol (Gandhi et al, 2005). This may undermine the value of the material in inducing tissue remodelling that provides adequate support for the urethra to prevent stress incontinence.

A similar report described the histopathological features of the autologous sling at the time of repeat surgery (FitzGerald et al, 2000). It involved 5 patients, 3 of whom had voiding dysfunction and 2 had failure. It showed fibroblast proliferation and neovascularisation consistent with tissue remodelling to match new lines of tension alongside the new ligament. There was however no evidence of inflammatory response up to 4 years following sling insertion. This shows a different tissue response, which was free from a foreign body reaction, even in failed cases.

Although these 2 studies are limited in numbers, they demonstrate a difference in the fate of pelvicol and autologous rectus sheath slings. Whilst the pelvicol can be perceived as a foreign antigen, the rectus sheath fascia can not. The foreign body reaction may not happen with each patient, yet it can happen and this shows the material to be capable of provoking such a response, at least in some patients. One of the patients who had a successful pelvicol sling, in the 3 way sling trial, presented with vaginal irritation and redness at 12 months follow up.

Reaction to pelvicol was suspected and she was booked for sling removal. Although this was cancelled, as the patient symptoms improved, she subsequently had a failure. This was not included in the failure group in the analysis, as her failure was diagnosed after the 12 months follow up, which is the latest follow up included in this thesis. This was a single case, nonetheless it illustrates the very likely cause of failure.

A third study looked at the effect of Polypropylene (Prolene) mesh, which is used in the tension-free vaginal tape (TVT) sling (Falconer et al, 2001). It included 10 patients who had punch biopsies before inserting the tape and 2 years later. This was part of a comparison with mersilene tape and normal control, rather than on re-operation for retention of urine or failure, as in the above 2 studies. Characteristically, minimal reaction was observed with the tapes and there was no change in collagen status.

Although delayed reaction was not proven in this study, as tissue specimens were not obtained at the time of repeat surgery, there are no other possible reasons to explain the failures. There was no significant difference in baseline features between those who had failures with pelvicol and those who did not, apart from incomplete emptying, as assessed by the Bristol Female Lower Urinary Tract Symptoms quality of life questionnaire. The fact that those who subsequently had failure were better in this symptom further support the idea that failure was not related to patients. There was no significant difference in operative data, including the grade of the surgeon, or in post-operative complications.

Although some methodological issues may have limited the scientific value of this trial, it is unlikely that they have influenced the result in relation to pelvicol failure. Training in pelvicol sling insertion was not specifically provided prior to including centres. Yet, it was not provided

in the short autologous sling either. It is also true that randomisation was continuous for all centres, rather than in blocks. In theory, this might lead unbalanced distribution of cases with a particular centre having more cases allocated to one arm of the study than the other 2 arms. If this centre were to have a bad technique, then this would have affected the results. Nonetheless, failures were seen across the centres where pelvicol slings were inserted. It is equally true that those assessing outcome were not blinded to the sling used. However, it is unlikely that this would have influenced failures to appear only with pelvicol and only after 6 months, without any increase in complications.

One other limitation of the trial relates to its primary outcome measure and sample size. Quality of life has never been used as a primary outcome measure before. Randomised controlled trials tended to use objective measures, such as the pad test and urodynamic assessment, as in the trial that comparing the tension-free vaginal tape (TVT) sling and the Burch colposuspension (Ward & Hilton, 2002). Moreover, sample size calculation should be based on a reported figure with specific indication to the magnitude of difference to be detected, either above or below the figure quoted from literature. This was not the case in this study. It is unlikely however that a properly calculated sample size would have found a different outcome, given the nature and extent of the findings detected in this trial. This applies to the failure of the pelvicol sling as well as the limited difference between the tension-free vaginal tape (TVT) and short autologous slings.

Conclusions:

This trial has not reached its target number of 240. It can not therefore rule out a 0.65 standardised difference in patient's quality of life, as measured by the Bristol Lower Urinary Tract Symptoms questionnaire, with 80% power and 95% confidence (0.05 significance). Nonetheless, it does suggest that the tension-free vaginal tape (TVT) and short autologous slings have a comparable incidence of post-operative complications, both early and delayed. This study did not entail direct evaluation of effectiveness, through urodynamic assessment. Yet, it entailed an objective measure, the pad test, as well as a subjective one, quality of life assessment, and these measures showed both techniques have a comparable effectiveness. The tension-free vaginal tape (TVT) sling however requires less operating time and shorter post-operative stay in hospital than the short autologous sling. The reduced cost of operating time and hospital stay lessens the higher cost of the tension-free vaginal tape (TVT) sling. It also affords a short term advantage in quality of life status as well as a reduced incidence of overall complications at 6 weeks follow up.

Pelvicol sling however has a significantly higher delayed failure rate compared to the tension-free vaginal tape (TVT) and the short autologous (sling on a string) slings. The delayed failure appears to be related to the antigenicity of the pelvicol material, which provokes a slow immune response.

Recommendations:

1- Patients should be advised that the tension-free vaginal tape (TVT) sling has equal safety and effectiveness to the short autologous sling. It is also associated with shorter operating time as well as post-operative stay in hospital. Besides, there is some advantage in quality of life in the short term.

2- Trusts should be advised that the additional cost of the tension-free vaginal tape (TVT) sling entails is reduced by shorter operating time and early discharge from hospital.

3- Patients are to be advised that the use of pelvicol sling carries a higher risk of failure requiring re-operation than either the tension-free vaginal tape (TVT) or short autologous slings.

6. References:

Abdel-Fattah M, Barrington J W and Arunkalaivanan A S (2004): Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence; A prospective randomised three-year follow-up study, European Urology 46: 629-35.

Abrams P, Blaivas J G, Stanton S L and Anderson J T (1989): The standardisation of terminology of lower urinary tract function, World Journal of Urology, 6: 233-45.

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Kerrebroeck P, Victor A and Wein A (2002): The standardisation of terminology of lower urinary tract function; Report from the standardisation sub-committee of the International Continence Society, Neurology and Urodynamics 21:167-78.

Adamiak A, Milart P, Skorupski P, Kuchnicka K, Nestorowicz A, Jakowicki J and Rechberger T (2002): The efficacy and safety of the tension-free vaginal tape procedure do not depend on the method of analgesia, European Urology 42: 29-33.

Alcalay M, Monga A and Stanton S L (1995): Burch colposuspension; A 10-20 year follow up, British Journal of Obstetrics and Gynaecology 102: 740-5.

Aldridge A H (1942): Transplantation of fascia for the relief of urinary incontinence, American Journal of Obstetrics and Gynecology 44: 398-411.

Alexander S, Rowan D, Miller W and Scott R (1970): Treatment of urinary incontinence by electric pessary; A report of 18 patients, British Journal of Urology 42: 184-90.

Allen R, Hokser G L, Smith A R and Warrell D W (1990): Pelvic floor damage and childbirth; A neurophysiological study, British Journal of Obstetrics and Gynaecology 97: 770-9.

Almeida F G, Bruschini H and Srougi M (2004): Urodynamic and clinical evaluation of 91 female patients with urinary incontinence treated with perineal magnetic stimulation; 1 year follow up, The Journal of Urology 171: 1571-5.

Altman D G (1991): Practical statistics for medical research, Chapman & Hall, London, UK.

Amundsen C L, Flynn B J and Webster G D (2003): Urethral erosion after synthetic and nonsynthetic pubovaginal slings; Differences in management and continence outcome, The Journal of Urology 170: 134-7.

Amuzu B J (1998): Nonsurgical therapies for urinary incontinence, Clinical Obstetrics and Gynecology, 41(3): 702-11.

Applegate S (1989): An introduction to electrosurgery units, Biomedical Instrumentation and Technology 23: 407-8.

Aronson M P, Bates S M, Jacoby A F, Chelmow D and Sant G R (1995): Periurethral and paravaginal anatomy; An endovaginal magnetic resonance imaging study, American Journal of Obstetrics and Gynecology 173: 1702-10.

Arunkalaivanan A S and Barrington J W (2003): Randomised trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence; A questionnaire based study, International Urogynecology Journal 14: 17-23.

Bakas P, Liapis A, Salamalekis E, Pafiti A and Creatsas G (2004): Tension-free vaginal tape efficacy in relation to collagen quantity of pubocervical fascia, Gynecologic and Obstetric Investigation 57: 149-52.

Ball T P Jr, Teichman M H, Sharkey F E, Rogenes V J and Adrian E K Jr (1997): Terminal nerve distribution to the urethra and bladder neck; Considerations in the management of stress incontinence, The Journal of Urology 158: 822-6.

Barber M D, Visco A G, Wyman J F, Fantl J A and Bump R C (2002): Sexual function in women with urinary incontinence and pelvic organ prolapse, Obstetrics and Gynecology 99: 281-9.

Barker A T (1991): An introduction to the basic principles of magnetic nerve stimulation, Journal of Clinical Neurolphysiology 8: 26-37.

Barker A T, Jalinous R and Freeston I L (1985): Noninvasive magnetic stimulation of human motor cortex, Lancet 2: 1106-7.

Barker A T, Freeston I L, Jalinous R and Jarratt J A (1987): Magnetic stimulation of the human brain and peripheral nervous system; An introduction and the results of an initial clinical evaluation, Neurosurgery 20: 100-9.

Barrington J W, Edwards G, Arunkalaivanan A S and Swart M (2002): The use of porcine dermal implant in a minimally invasive pubovaginal sling procedure for genuine stress incontinence, BJU International 90: 224-7.

Benness C (1997): The elderly, In: Cardozo L (ed.): Urogynaecology, Churchill Livingstone, New York, United States of America, pp. 461-80

Berghmans L C M, Hendriks H J M, Bo K, Hay-Smith E J, de Bie R A, van Waalwijk, van Doorn E S C (1998): Conservative treatment of stress urinary incontinence in women; A systematic review of randomised clinical trials, British Journal of Urology 82: 181-91.

Bergman A and Eli G (1995): Three surgical procedures for genuine stress incontinence; Five-year follow up of a prospective randomised study, American Journal of Obstetrics and Gynecology 173: 66-71.

Bergman A, Ballard C and Koonings P (1989): Comparison of three different surgical procedures for genuine stress incontinence; Prospective randomised study, American Journal of Obstetrics and Gynecology 160: 1102-6.

Bidmead J and Cardozo L (2000): Surgery for genuine stress incontinence, In: Studd J (ed.): Progress in obstetrics and gynaecology, vol.14, Churchill Livingstone, Edinburgh, United Kingdom: 329-58.

Bidmead J and Cardozo L (2000a): Sling techniques in the treatment of genuine stress incontinence, BJOG; An International Journal of Obstetrics and Gynaecology 107: 147-56.

Birchard K R, Brown M A, Hyslop W B, Firat Z and Semelka R C (2004): MRI of acute abdominal and pelvic pain in pregnant patients, American Journal of Roentgenology 184: 452-8.

Black N and Downs S H (1996): The effectiveness of surgery for stress incontinence in women; A systematic review, British Journal of Urology 78: 497-510.

Blowman C, Pickles C, Emery S, Creates V, Towell L and Blackburn N, Doyle N and Walkden B (1991): Prospective double blind controlled trial of intensive physiotherapy with and without stimulation of the pelvic floor in the treatment of genuine stress incontinence, Physiotherapy 77: 661-4.

Bo K (1995): Pelvic floor muscle exercise for the treatment of stress urinary incontinence; An exercise physiology perspective, International Urogynecology Journal 6: 282-91.

Bo K (1998): Effect of electrical stimulation on stress and urge incontinence; Clinical outcome and practical recommendations based on randomised controlled trials, Acta Obstetricia et Gynecologica Scandinavica 77 (Supplement 168): 3-11.

Bo K, Larsen S, Oseid S and Kuarstein B (1988): Knowledge about and ability to correct pelvic floor muscle exercise in women with urinary stress incontinence, Neurology and Urodynamics 7: 261-6.

Bo K, Hagen R H, Kvarstein B, Jorgensen J and Larsen S (1990): Pelvic floor muscle exercise for the treatment of female stress urinary incontinence; III effects of two different degrees of pelvic muscle exercises, Neurology and Urodynamics 9: 489-502.

Bo K, Talseth T and Holme I (1999): Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones and no treatment in the management of genuine stress incontinence in women, BMJ 318: 487-93.

Bosman G, Vierhout M E and Huikeshoven F J (1993): A modified Raz bladder neck suspension operation; Results of a one to three year follow-up investigation, Acta Obstetricia et Gynecologica Scandinavica 72: 47-9.

Brodak P P, Bidair M, Joseph A, Szollar S and Juma S (1993): Magnetic stimulation of the sacral roots, Neurology and Urodynamics 12: 533-40.

Brubaker L, Benson J T, Bent A, Clark A and Shott S (1997): Transvaginal electrical stimulation for female urinary incontinence, American Journal of Obstetrics and Gynecology 177: 536-40.

Buck B E and Malinin T I (1994): Human bone and tissue allografts; Preparation and safety, Clinical Orthopaedics and Related Research 303: 2 8-17.

Buller J L and Cundiff G W (2000): Laparoscopic surgeries for urinary incontinence, Clinical Obstetrics and Gynecology 43(3): 604-18.

Bump R C, Hurt W G, Fant J A and Wyman J F (1991): Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction, American Journal of Obstetrics and Gynecology 165: 322-9.

Burch J C (1961): Urethrovesical fixation to Cooper's ligament for correction of stress incontinence, cystocele and prolapse, American Journal of Obstetrics and Gynecology 81: 281-9.

Burch J C (1968): Cooper's ligament urethrovesical suspension for stress incontinence, American Journal of Obstetrics and Gynecology 100: 764-74.

Burns P A, Pranikoff K, Nochajski T H, Hadley E C, Levy K L and Ory M G (1993): A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community dwelling women, Journal of Geronotology 48: 167-74.

Caldwell K P S, Cook P J, Flack F C and James E D (1968): Stress incontinence in females; Report on 31 cases treated by electrical implant, Journal of Obstetrics and Gynaecology of Britain and the Commonwealth 75: 777-80.

Cammu H and Nylen M V (1995): Pelvic floor muscle exercise; 5 years later, Urology 45: 113-7.

Caputo R M, Besnon J T and McClellan E (1993): Intravaginal maximal electrical stimulation in the treatment of urinary incontinence, The Journal of Reproductive Medicine 38: 667-71.

Cardozo L D, Stanton S L and Williams J E (1979): Detrusor instability following surgery for genuine stress incontinence, British Journal of Urology 51: 204-7.

Cardozo L, Hextall A, Bailey J and Boos K (1999): Colposuspension after previous failed incontinence surgery; A prospective observational study, British Journal of Obstetrics and Gynaecology 106: 340-4.

Carter J (1995): Laparoscopic bladder neck suspension, Endoscopic Surgery 3: 81-7.

Chaliha C and Stanton S L (1999): Complications of surgery for genuine stress incontinence, British Journal of Obstetrics and Gynaecology 106: 1238-45.

Charlet de Sauvage R, Grattepanche F, Gassand P, Caubet R and Moreau J M (2003): Safety of the magnetic field generated by a neuronal stimulator; Evaluation of possible magnetic effects, Clinical Neurophysiology 114: 581-8.

Chen R, Gerloff C, Classen J, Wassermann E M, Hallet M, Cohen L G (1997): Safety of different inter-train intervals for repetitive transcranial magnetic stimulation and recommendations for safe ranges of stimulation parameters, Electroencephalography and Clinical Neurophysiology 105: 415-21.

Chin Y K and Stanton S L (1995): A follow up of silastic slings for genuine stress incontinence, British Journal of Obstetrics and Gynaecology 102: 143-7.

Clemens J Q, DeLancey J O, Faerber G J, Westney O L and McGuire E J (2000): Urinary tract erosions after synthetic pubovaginal slings, Diagnosis and management strategy, Urology 56: 589-95.

Coakley W T (1987): Hyperthermia effect on the cytoskeleton and on cell morphology, Symposia of the Society for Experimental Biology 41: 187-211.

Cohen L G and Hallett M (1988): Non-invasive electrical stimulation of the brain does not cause short-term changes in the electroencephalogram, In: Rossini P M and Marsden C D (Eds.): Non-invasive stimulation of brain and spinal cord; Fundamentals and clinical applications, Alan R Liss Inc., New York, United States of America: 159-61.

Colombo M, Zanetta G, Vitobello D and Milani R (1996): The Burch Colposuspension for women with and without detrusor overactivity, British Journal of Obstetrics and Gynaecology, 103(3): 255-260.

Cross C A, English S F, Crespedes R D and McGuire E J (1998): A follow up on transurethral collagen injection therapy for urinary incontinence, The Journal of Urology, 159: 106-8.

Cummings J M and Rodning C B (2000): Urinary stress incontinence among obese women; Review of pathophysiology therapy, International Urogynecology Journal 11: 41-4.

Department of Health (2005): NHS costing manual, version 4.1, Department of Health, London, United Kingdom.

DeLancy J O L (1994): Structural support of the urethra as it relates to stress urinary incontinence; The hammock hypothesis, American Journal of Obstetrics and Gynecology 170: 1713-23.

De Leval (2003): Novel surgical technique for the treatment of female stress urinary incontinence; Transobturator vaginal tape inside-out, European Urology 44: 724-30.

de Seze R, Tuffet S, Moreau J M and Veyret B (2000): Effects of 100 mT time varying magnetic fields on the growth of tumours in mice, Bioelectromagnetics 21: 107-11.

Deval B, Levardon M, Samain E, Rafii A, Cortesse A, Amarenco G, Ciofu C and Haab F (2003): A French multicentre clinical trial of SPARC for stress urinary incontinence, European Urology 44: 254-8.

De Wilde J P, Rivers A W and Price D L (2005): A review of the current use of magnetic resonance imaging in pregnancy and safety implications for the fetus, Progress in Biophysics and Molecular Biology 87: 335-53.

DiNubile N A (1991): Strength training, Clinics in Sports Medicine (10): 33-62.

Dmochowski R R (2002): Radiofrequency bladder neck suspension for the treatment of genuine stress urinary incontinence, Current Urology Reports 3: 378-81.

Dmochowski R and Appell R A (2003): Advancements in minimally invasive treatments for female stress urinary incontinence; Radiofrequency and bulking agents, Current Urology Reports 4: 350-5.

Dmochowski R R, Avon M, Ross J, Cooper J M, Kaplan R, Love B, Kohli N, Alabal D and Shingleton B (2003): Transvaginal radiofrequency treatment of the endopelvic fascia; A prospective evaluation for the treatment of genuine stress urinary incontinence, The Journal of Urology 169: 1028-32.

Dougherty M, Bishop K, Mooney R, Gimotty P and Williams B (1993): Graded pelvic muscle exercise; Effect on stress urinary incontinence, The Journal of Reproductive Medicine 38: 684-91.

Duckett J R A (1998): The use of periurethral injectables in the treatment of genuine stress incontinence, British Journal of Obstetrics and Gynaecology 105: 390-6.

Dudley G A and Harris R T (1992): Use of electrical stimulation in strength and power training, In: Komi P V (ed.): Strength and power in sport, Blackwell Scientific Publications, Oxford, United Kingdom: 329-37.

Dwyer P L, Lee E T C, Hay D M (1988): Obesity and urinary incontinence in women, British Journal of Obstetrics and Gynecology 95: 91-6.

Eckford S D and Abrams P (1991): Paraurethral Collagen implantation for female stress incontinence, British Journal of Urology, 68: 586-9.

Edwards M J, Saunders R D and Shiota K (2003): Effect of heat on embryos and foetuses, International Journal of Hyperthermia 19: 295-324.

Elving L B, Foldspang A, Lam G W and Mommsen S (1989): Descriptive epidemiology of urinary incontinence in 3100 women age 30-59, Scandinavian Journal of Urology and Nephrology 125 (Supplement): 37-43.

Elwany S, Gaimaee R, Fattah H A (1999): Radiofrequency bipolar submucosal diathermy of the inferior turbinates, American Journal of Rhinology 13: 145-9.

Eriksen B C and Eik-Nes S H (1989): Long-term electrostimulation of the pelvic floor; Primary therapy in female stress incontinence?, Urologia Internationalis 44: 90-5.

Eriksen B C, Bergmann S, Mjolnerod O K (1987): Effect of anal electrostimulation with the "Inocontan" device in women with urinary incontinence, British Journal of Obstetrics and Gynaecology 94: 147-56.

Erlandson B E, Fall M and Carlsson C A (1978): The effect of intravaginal electrical stimulation on the feline urethra and urinary bladder; Electrical parameters, Scandinavian Journal of Urology and Nephrology 44 (Supplement): 5-18.

Erlandson B E, Fall M and Sundin T (1978a): Intravaginal electrical stimulation; Clinical experiments on urethral closure, Scandinavian Journal of Urology and Nephrology 44 (Supplement): 31-9.

Evans B A (1991): Magnetic stimulation of the peripheral nervous system, Journal of Clinical Neurophysiology 8: 77-84.

Falconer C, Soderberg M, Blomgren B and Ulmsten U (2001): Influences of different sling materials on connective tissue metabolism in stress urinary incontinent women, International Urogynecology Journal Suppl 2: S19-23.

Fall M (1984): Does electrostimulation cure urinary incontinence?, The Journal of Urology 131: 664-7.

Fall M (1998): Advantages and pitfalls of functional electrical stimulation, Acta Obstetricia et Gynecologica Scandinavica 77 (Supplement 168): 16-21.

Fall M and Lindstrom S (1991): Electrical stimulation; a physiologic approach to the treatment of urinary incontinence, Urologic Clinics of North America 18: 393-407.

Fall M, Ahlstrom K, Carlsson C A, Ek A, Erlandson B E, Frankenberg S and Mattiasson A (1986): Contelle; Pelvic floor stimulator for female stress-urge incontinence, Urology 27: 282-7.

Fantl J A, Hurt W G, Bump R C, Dunn L J and Choi S C (1986): Urethral axis and sphincteric function, American Journal of Obstetrics and Gynecology 155: 554-8.

Farquhar C M (2005): An economic evaluation of laparoscopic ovarian diathermy versus gonadotrophin therapy for women with clomiphene-resistant polycystic ovarian syndrome, Current Opinion in Obstetrics and Gynecology 17: 347-53.

Fatthy H, El Hao M, Samaha I and Abdallah K (2001): Modified Burch colposuspension; Laparoscopy versus laparotomy, The Journal of the American Association of Gynecologic Laparoscopists 8: 99-106.

Fenely R C L, Shepherd A M, Powell P H and Blannin J (1979): Urinary incontinence; Prevalence and needs, British Journal of Urology 51: 493-6.

FitzGerald M P, Mollenhauer J and Brubaker L (2000): The fate of rectus sheath fascia suburethral slings, American Journal of Obstetrics and Gynecology 183: 964-6.

Fitzpatrick M and O'Herlihy C (2001): The effects of labour and delivery on the pelvic floor, Best Practice and Research Clinical Obstetrics and Gynaecology 15: 63-79.

Flax S (1996): The gasless laparoscopic Burch bladder neck suspension; Early experience, The Journal of Urology 156: 1105-7.

Fujishiro T, Enomoto H, Ugawa Y, Takahashi S, Ueno S and Kitamura T (2000): Magnetic stimulation of the sacral roots for the treatment of stress incontinence; An investigational and placebo controlled trial, The Journal of Urology 164: 1277-9.

Fulmer B R, Sakamoto K, Turk T M, Galen D, Presthus J B, Abbott K, Ross J, Ou C S and Albala D M (2002): Acute and long term outcomes of radiofrequency bladder neck suspension, The Journal of Urology 167(1): 141-5.

Galen D (2000): Histologic results of a new treatment for stress urinary incontinence without implantable materials, Obstetrics and Gynecology 95: 30S.

Galen D L, Abbott K, Albala A D, Kaplan R and Presthus J (2000): Thermal urethroplasty; Short and intermediate results of a new treatment for stress urinary incontinence, Obstetrics and Gynecology 95: 54S.

Galloway N T M, Davies N and Stephenson T P (1987): The complications of colposuspension, British Journal of Urology 60: 122-4.

Galloway N T, El-Galley R E, Sand P K, Appell R A, Russell H W and Carlan S J (1999): Extra-corporeal magnetic innervation therapy for stress urinary incontinence, Urology 54(4): 647-51.

Galloway N T, El-Galley R E, Sand P K, Appell R A, Russell H W and Carlan S J (2000): Update on extra-corporeal magnetic innervation (EXMI) therapy for stress urinary incontinence, Urology 56 (Supplement 1): 82-6.

Galvind K and Sander P (2004): Erosion, defective healing and extrusion after tension-free urethropexy for the treatment of stress urinary incontinence, International Urogynecology Journal 15: 179-82.

Gandhi S, Kubba L M, Abramov Y, Botros S M, Goldberg R P, Victor T A and Sand P K (2005): Histopathologic changes of porcine dermis xenografts for transvaginal suburethral slings, American Journal of Obstetrics and Gynecology 192: 1643-8.

Gardner J and Fonda D (1994): Urinary incontinence in the elderly, Disability and Rehabilitation 16: 140-8.

Geirsson G and Fall M (1997): Maximal functional electrical stimulation in routine practice, Neurology and Urodynamics 16: 559-65.

Ghezzi F, Cromi A, Raio L, Bergamini V, Triacca P, Serati M and Kuhn A (2005): Influence of the type of anaesthesia and hydrodissection on the complication rate after tension-free vaginal tape procedure, European Journal of Obstetrics, Gynecology and Reproductive Biology 118: 96-100.

Ghonheim G and Shaaban A (1994): Sub-urethral slings for the treatment of stress urinary incontinence, International Urogynecology Journal 5: 228-39.

Glazer C M A and Copper K (2004): Anterior vaginal repair for urinary incontinence in women, Cochrane Database of Systematic Reviews: 2.

Glazer C M A and Copper K (2004a): Bladder neck needle suspension for urinary incontinence in women, Cochrane Database of Systematic Reviews: 2.

Goldberg R P and Sand P K (2000): Electromagnetic pelvic floor stimulation; Applications for the gynecologist, Obstetrical and Gynecological Survey 55: 715-20.

Goldberg R P and Sand P K (2001): Electromagnetic pelvic floor stimulation for urinary incontinence and bladder disease, International Urogynecology Journal 12: 401-4.

Goldrath M H, Fuller T A, Segal S (1981): Laser photovaporisation of the endometrium for the treatment of menorrhagia, American Journal of Obstetrics and Gynecology 140: 14-9.

Gosling J (1979): The structure of the bladder and urethra in relation to function, Clinical Obstetrics and Gynecology 6: 270-81.

Grandolfo M, Santini M T, Vecchia P, Bonincontro A, Cametti C and Indovina P L (1991): Non-linear dependence of the dielectric properties of chick embryo myoblast membranes exposed to a sinusoidal 50 Hz magnetic field, International Journal of Radiation Biology 60: 877-90.

Haab F, Sananes S, Amarenco G, Ciofu C, Uzan S, Gattengno B and Thibault P (2001): Results of the tension-free vaginal tape procedure for the treatment of type II stress urinary incontinence at a minimum follow up of 1 year, The Journal of Urology 165: 159-62.

Hahn I, Sommar S and Fall M (1991): A comparative study of pelvic floor training and electrical stimulation for the treatment of genuine female stress urinary incontinence, Neurology and Urodynamics 10: 545-55.

Haken J, Benness C, Cardozo C A and Cutnar A A (1991): A randomised trial of vaginal cones and pelvic floor exercises in the management of genuine stress incontinence, Neurology and Urodynamics 10: 393-4.

Hallett M and Cohen L G (1989): Magnetism; A new method for stimulation of the nerve and brain, Journal of the American Medical Association 262: 538-41.

Handa V, Jensen J, Germain M, Ostergard D (1996): Banked human fascia lata for suburethral sling procedure; A preliminary report, Obstetrics and Gynecology 88: 1045-9.

Hannestad Y, Rortveit G, Sandvik H and Hunskaar S (2000): A community epidemiological survey of female urinary incontinence; the Norwegian EPINCONT study, Journal of Clinical Epidemiology 53: 1150-7.

Haupt G, Panic J, Berrkert S, Heinrich C, Schulz H and Senge T (1997): Transurethral resection of prostate with microprocessor controlled electrosurgical unit, The Journal of Urology 158: 497-501.

Hay-Smith E J C, Bo K, Berghmans L C M, Hendriks H J M, de Bie R A and van Waalwijk van Droon E S C (2004): Pelvic floor muscle training for urinary incontinence in women, Cochrane Database of Systematic Reviews: 2.

Henalla S M, Kirvan P and Castleden D M (1988): The effect of pelvic floor exercise in the treatment of genuine stress incontinence in women at two hospitals, British Journal of Obstetrics and Gynaecology 95: 602-9.

Henalla S M, Hutchins C J, Robinson P and Macvicar J (1989): Non-operative methods in the treatment of female genuine stress incontinence of urine, Journal of Obstetrics and Gynaecology 9: 222-5.

Herbertsson G and Iosif C S (1993): Surgical results and urodynamics studies after retropubic colpourethrocystopexy, Acta Obstetricia et Gynecologica Scandinavica 72: 298-301.

Hilton P and Mayne C J (1991): The Stamey endoscopic bladder neck suspension; A clinical and urodynamic investigation including actuorial follow-up over four years, British Journal of Obstetrics and Gynaecology 98: 1141-9.

Hilton P, Mohammed K A and Wood K (2003): Postural perineal pain associated with perforation of the lower urinary tract due to insertion of tension-free vaginal tape, BJOG: An International Journal of Obstetrics and Gynaecology 110: 79-82.

Hirsch A, Weirauch G, Steimer B, Bihler K, Peschers U, Bergauer F, Leib B and Dimpfl (1999): Treatment of female urinary incontinence with EMG-controlled biofeedback home training, International Urogynecology Journal 10: 7-10.

Holtedahl K, Verelst M and Schiefloe A (1998): A population based, randomised, controlled trial of conservative treatment for urinary incontinence in women, Acta Obstetricia et Gynecologica Scandinavica 77: 671-7.

Hsieh G C, Klutke J J and Kobak W H (2001): Low valsalva leak-point pressure and success of retropubic urethropexy, International Urogynecology Journal 12: 46-50.

Hunskaar S and Vinsnes A (1991): The quality of life in women with urinary incontinence as measured by the sickness impact profile, Journal of the American Geriatric Society 39: 378-82.

Indrekvam S and Hunskaar S (2002): Side effects, feasibility and adherence to treatment during home-managed electrical stimulation for urinary incontinence; A Norwegian national cohort of 3,198 women, Neurology and Urodynamics 21: 546-52.

Iosif C S (1987): Porcine corium sling in the treatment of urinary stress incontinence, Archives of Gynecology 240: 131-6.

Ishikawa N, Suda S, Sasaki T, Yamanishi T, Hosaka H, Yasuda K and Ito H (1998): Development of a non-invasive treatment system for urinary incontinence using functional continuous magnetic stimulator (FCMS): Medical and Biological Engineering and Computing 36: 704-10.

Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L and Abrams P (1996): The Bristol Female Lower Urinary Tract Symptoms questionnaire; Development and psychometric testing, British Journal of Urology 77: 805-12.

Jackson S, Shepherd A, Brookes S and Abrams P (1999): The effect of oestrogen supplementation on post-menopausal urinary incontinence; A double-blind placebo-controlled trial, British Journal of Obstetrics and Gynaecology 106: 711-8.

Jalinous R (1991): Technical and practical aspects of magnetic nerve stimulation, Journal of Clinical Neurophysiology 8: 10-25.

Jarvis G J (1994): Surgery for genuine stress incontinence, British Journal of Obstetrics and Gynaecology 101:371-4.

Jeffry L, Deval B, Birsan A, Soriano D, Darai E (2001): Objective and subjective cure rates after tension-free vaginal tape for the treatment of urinary incontinence, Urology 58: 702-6.

Jenkinson C, Coulter A and Wright L (1993): Short form 36 (SF36) health survey questionnaire; Normative data for adults of working age, BMJ 306: 1437-40.

Jensen J K, Neilsen F R Jr and Ostergard D R (1994): The role of history in the diagnosis of urinary incontinence, Obstetrics and Gynecology, 83: 904-10.

Jonasson A, Larsson B, Pschera H and Nylund L (1990): Short-term maximal electrical stimulation; A conservative treatment of urinary incontinence, Gynecologic and Obstetric Investigation 30: 120-3.

Junemann K P (2001): The management of female urinary stress incontinence; The use of devices, BJU International 87: 449-55.

Kanal E (1994): Pregnancy and the safety of magnetic resonance imaging, Magnetic Resonance Imaging Clinics of North America 2: 309-317.

Keane D P, Sims T J, Abrams P and Bailey A J (1997): Analysis of collagen status in premenopausal nulliparous women with genuine stress incontinence, British Journal of Obstetrics and Gynaecology 104: 994-8.

Kegel A H (1948): Progressive resistance exercise in the functional restoration of the perineal muscles, American Journal of Obstetrics and Gynecology 56: 238-49.

Kegel A H (1951): Physiologic therapy for urinary stress incontinence, Journal of the American Medical Association 146: 915-7.

Kegel A H (1956): Stress incontinence of urine in women; Physiologic treatment, Journal of the International College of Surgeons 25: 487-99.

Kelleher C (2000): Quality of life and urinary incontinence, Baillere's Clinical Obstetrics and Gynaecology, 14(2): 363-79.

Kelleher C J, Cardozo L D, Khullar V and Salvatore S (1997): A new questionnaire to assess the quality of life of urinary incontinent women, British Journal of Obstetrics and Gynaecology, 104: 1374-9.

Khullar V, Cardozo L, Abbott D and Anders K (1997): GAX collagen in the treatment of urinary incontinence in elderly women; A two year follow up, British Journal of Obstetrics and Gynaecology 104: 96-9.

Kind P (1996): The EuroQol instrument; An index of health-related quality of life, In: Spilker B (ed.): Quality of life and pharmacoeconomics in clinical trials, Lippincott-Rivera, Philadelphia, Pennsylvania, United States of America: 191-201.

Kjolhede P (2005): Long-term efficacy of Burch colposuspension; A 14-year follow-up study, Acta Obstetricia et Gynecologica Scandinavica 84: 767-72.

Klarskov P, Nielson K K, Kromann-Andersen B and Maegaard E (1991): Long term results of pelvic floor training and surgery to female genuine stress incontinence, International Urogynecology Journal 2: 132-5.

Koelbl H, Saz V, Doerfler D, Heusler G, Sam C and Hanzal E (1998): Transurethral injection of silicone microimplants for intrinsic sphincter deficiency, Obstetrics and Gynecology 92: 322-6.

Kohli N, Sze E H M, Roat T W and Karram M (1996): Incidence of recurrent cystocele after anterior colporrahphy with and without concomitant transvaginal needle suspension, American Journal of Obstetrics and Gynecology 175: 1476-82.

Kohli N, Jacobs P A, Sze E H, Roat T W and Karram M M (1997): Open compared with laparoscopic approach to Burch colposuspension; A cost analysis, Obstetrics and Gynecology 90: 411-5.

Lagro-Janseen T L M, Debuyne F M J, Smits A J A and Van Weel C (1991): Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice, British Journal of General Practice 41: 445-9.

Lagro-Janssen A, Smits A and Van Weel C (1992): Urinary incontinence in women and the effects on their lives, Scandinavian Journal of Primary Health Care 10: 211-6.

Lambert D M, Maceau S and Forse R A (2005): Intra-abdominal pressure in the morbidly obese, Obesity Surgery 15: 1225-32.

Lapitan M C, Cody D J and Grant A M (2004): Open retropubic colposuspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2.

Laycock J and Holmes D M (2003): The place of physiotherapy in the management of pelvic floor dysfunction, The Obstetrician and Gynaecologist 5: 194-9.

Laycock J and Jerwood D (1993): Does pre-modulated interferential therapy cure genuine stress incontinence?, Physical Therapy 79: 553-60.

Leach G E and Bavendam T G (1989): Prospective evaluation of the "Incontan" transrectal stimulator in women with urinary incontinence, Neurology and Urodynamics 14: 635-46.

Leach G E, Dmochowski R R, Appell R A, Blaivas J G, Hadley H R, Luber K M, Mostwin J L, O'Donnell P D and Roehrborn (1997): Female stress urinary incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence, The Journal of Urology 158: 875-80.

Lewis B V (1995): Radiofrequency induced endometrial ablation; Baillere's Clinical Obstetrics and Gynaecology 9: 347-55.

Li D K, Odouli R W S, Janevic T, Golditch I, Bracken D T, Senior R, Rankin R and Iriye R (2002): A population-based prospective cohort study of personal exposure to magnetic field during pregnancy and the risk of miscarriage, Epidemiology 13: 9-20.

Liapis A, Bakas P and Creatsas G (2000): Comparison of open retropubic colposuspension and tension-free vaginal tape for the treatment of genuine stress incontinence in women, Neurology and Urodynamics 19: 385-6.

Liapis A, Bakas P, Hassiakos D, Frangos-Plemenos M and Creatsas G (2000a): Changes in the quantity of collagen type I in women with genuine stress incontinence, Urological Research 28: 323-6.

Liapis A, Bakas P, Frangos-Plemenos M, Arnoyannaki N and Creatsas G (2001): Changes in the quantity of collagen type III in female patients with genuine stress incontinence and pelvic floor prolapse, European Journal of Obstetrics, Gynecology and Reproductive Biology 97: 76-9.

Liboff A R and Jenrow K A (2002): Physical mechanisms in neuroelectromagnetic therapies, Neurorehabilitation 17: 9-22.

Lin H, Sheu B, Lo M and Huang S (1999): Comparison of treatment outcomes of imipramine for female genuine stress incontinence, British Journal of Obstetrics and Gynaecology 106: 1089-92.

Liu C Y (1993): Laparoscopic retropubic colposuspension (Burch procedure); A review of 58 cases, The Journal of Reproductive Medicine 38: 526-30.

Liu C Y (1994): Laparoscopic treatment for genuine urinary stress incontinence, Bailliere's Clinical Obstetrics and Gynaecology 8: 789-98.

Lo T S, Huang H J, Chang C L, Wong S Y, Horng S G and Liang CC (2002): Use of intravenous anaesthesia for tension-free vaginal tape therapy in elderly women with genuine stress incontinence, Urology 59: 349-52.

Lopez M J, Hayashi K, Fanton G S, Thabit G 3rd and Markel M D (1998): The effect of radiofrequency energy on the ultrastructure of joint capsular collagen, Arthrosopy 14: 495-501.

Lose G, Jorgensen L, Mortensen S O, Molsted-Pedersen L and Kristensen J K (1987): Voiding difficulties after colposuspension, Obstetrics and Gynecology 69: 33-8.

Loughlin K R (1996): The endoscopic fascial sling for treatment of female urinary stress incontinence, The Journal of Urology 155: 1265-7.

Luber K M and Wolde-Tsadik G (1997): Efficacy of functional electrical stimulation in treating genuine stress incontinence; A randomised clinical trial, Neurology and Urodynamics 16: 543-51.

Lucas M G, Emery S J, Thomas J A, Holt B A, Wareham K and C Roberts (1996): Sling on a string for the surgical treatment of stress incontinence, British Journal of Urology 77 Sup 1: 3.

Lyskov E B, Juutilainen J, Jousmaki V, Partanen J, Medvedev S and Hanninen O (1993): Effects of 45-Hz magnetic fields on the functional state of the human brain, Bioelectromagnetics 14: 87-95.

Maccabee P J, Amassian V E, Cracco R Q and Cadwell J A (1988): An analysis of peripheral motor nerve stimulation in humans using the magnetic coil, Eectroencephalography and Clinical Neurophysiology 70: 524-33.

Manca A, Sculpher M J, Ward K and Hilton P (2003): A cost-utility analysis of tension free vaginal tape versus colposuspension for primary urodynamic stress incontinence, BJOG: An International Journal of Obstetrics and Gynaecology 110: 255-62.

Mantle J and Versi E (1991): Physiotherapy for stress urinary incontinence; A national survey, BMJ 302: 753-5.

Marshall V F, Marchetti A A and Krantz K C (1949): The correction of stress incontinence by simple vesico-urethral suspension, Surgery, Gynecology and Obstetrics 88: 509-18.

Massarweh N N, Cosgriff N and Slakey D P (2006): Electrosurgery; History, principles and current and future uses, Journal of the American College of Surgeons 202: 520-30.

McCann J, Dietrich F and Rafferty C (1998): The genotoxic potential of electric and magnetic fields; An update, Mutation Research 411: 45-86.

McFarlane J P, Foley S J, Winter P De, Shah P J R and Craggs M D (1997): Acute suppression of idiopathic detrusor instability with magnetic stimulation of the sacral nerve roots, British Journal of Urology 80: 734-41.

McGuire E J and Lytton B (1978): Pubovaginal sling procedure for stress incontinence, The Journal of Urology 119: 82-4.

Merlin T, Arnold E, Petros P, MacTaggar P, Tulloch A, Faulkner K and Maddern G (2001): A systematic review of tension-free urethropexy for stress urinary incontinence; Intravaginal slingoplasty and the tension-free vaginal tape procedures, BJU International 88: 871-80.

Meschia M, Pifarotti P, Bernasconi F, Guercio E, Maffiolini M, Magatti F and Spreafico (2001): Tension-free vaginal tape; Analysis of outcomes and complications in 404 stress incontinent women, International Urogynecology Journal (Supplement 2): S24-7.

Miller J, Asthon-Miller J and DeLancey JOL (1996): The Knack; Use of precisely-timed pelvic muscle contraction can reduce leakage in stress urinary incontinence, Neurology and Urodynamics 15: 392-3.

Miller K, Richardson D A, Siegel S W, Karram M M, Blackwood N B and Sand P K (1998): Pelvic floor electrical stimulation for genuine stress incontinence; Who will benefit and when?, International Urogynecology Journal 9: 265-70.

Mishra V C, Mishra N, Karim O M A and Motiwala H G (2005): Voiding dysfunction after tension-free vaginal tape; A conservative approach is often successful, International Urogynecology Journal 16: 210-4.

Moehrer B, Ellis G, Carey M and Wilson P D (2004): Laparoscopic colposuspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2.

Monga A and Stanton S L (1994): The Burch colposuspension, Current Obstetrics and Gynaecology 4: 210-4.

Monga A, Robinson D and Stanton S L (1995): Periurethral collagen injections for genuine stress incontinence; A 2-year follow-up, British Journal of Urology 76: 156-60.

Moore K H, Foote A, Burton G and King J (1999): An open study of the bladder neck support prosthesis in genuine stress incontinence, British Journal of Obstetrics and Gynaecology, 106: 42-9.

Morkved S, Bo K and Fjortoft T (2002): Effect of adding biofeedback to pelvic floor muscle training to treat urodynamic stress incontinence, Obstetrics and Gynecology 100: 730-9.

Mukherjee K and Constantine G (2001): Urinary stress incontinence in obese women; Tension-free vaginal tape is the answer, BJU International 88: 881-3.

National Institute for Clinical Excellence (2003): Guidance of the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence, Technology Appraisal Guidance No. 56, National Institute for Clinical Excellence, London, United Kingdom.

Nielsen K K, Kromann-Anderson B, Jacobsen H, Nielsen E M, Nordling J, Holm H H and Larsen J F (1990): The urethral plug; A new treatment modality for genuine urinary stress incontinence in women, The Journal of Urology 144: 1199-202.

Nduka CC, Super PA, Monson JRT, Darzi A W (1994): Cause and prevention of electrosurgical injuries in laparoscopy, Journal of the American College of Surgeons 179: 161-70.

Nilsson CG, Kuuva N, Falconer C, Rezapour M and Ulmsten U (2001): Long-term results of the tension-free vaginal tape (TVT) procedure or surgical treatment of female stress urinary incontinence, International Urogynecology Journal (Supplement 2): S5-8.

Norton P A (1993): Pelvic floor disorders; The role of fascia and ligaments, Clinical Obstetrics and Gynecology 36: 926-38.

Norton P, MacDonald L D, Sedwick P M and Stanton S L (1988): Distress and delay associated with urinary incontinence, frequency and urgency in women, BMJ 297: 1187-9.

Norton P A, Zinner N R, Yalcin I, Bump R C (2002): Duloxetine versus placebo in the treatment of stress urinary incontinence, American Journal of Obstetrics and Gynecology 187: 40-8.

Nygaard I, DeLancey J O L, Arnsdorf I and Murphy E (1990): Exercise and incontinence, Obstetrics and Gynecology 75: 848-51.

Ohlsson B L (1988): Effects of some different pulse parameters on the perception of intravaginal and intraanal electrical stimulation, Medical and Biological Engineering and Computing 26: 503-5.

Okada N, Igawa Y, Ogawa A and Nishizawa O (1998): Transcutaneous electrical stimulation of thigh muscles in the treatment of detrusor overactivity, British Journal of Urology 81: 560-4.

Olsson I and Kroon U (1999): A three-year postoperative evaluation of tension-free vaginal tape, Gynecologic and Obstetric Investigation 48: 267-9.

Paick J S, Ku J H, Shin J W, Oh S J and Kim S W (2005): Complications associated with the tension-free vaginal tape procedure; The Korean experience, International Urogynecology Journal 16: 251-9.

Pascual-Leone A, Houser C M, Reese K, Shotland L I, Grafman J, Sato S, Valls-Sole J, Brasil-Neto J P, Wassermann E M, Cohen L G and Hallett M (1993): Safety of rapid-rate transcranial magnetic stimulation in normal volunteers, Electroencephalography and Clinical Neurophysiology 89: 120-30.

Peattie A B and Plevnik S (1988): Cones versus physiotherapy as conservative management of genuine stress incontinence, Neurology and Urodynamics 7: 265-6.

Pelka R B, Jaenicke C and Gruenwald J (2002): Impulse magnetic-field therapy for erectile dysfunction; A double-blind, placebo-controlled study, Advances in Therapy 19: 53-60.

Pelosi III M A and Pelosi M A (1998): Laparoscopic-assisted transpectineal needle suspension of the bladder neck, The Journal of the American Association of Gynecologic Laparoscopists, 5(1): 563-6.

Pereyra A J (1959): A simplified surgical procedure for the correction of stress incontinence in women, Western Journal of Surgery, Obstetrics and Gynecology 67: 223-30.

Pereyra A J and Lebhertz T B (1967): The combined urethrovesical suspension and vaginourethroplasty for correction of urinary stress incontinence, Obstetrics and Gynecology 30: 537-46.

Petros P (1999): Medium-term follow-up of the intravaginal slingoplasty operation indicates minimal deterioration of urinary continence with time, Australian and New Zealand Journal of Obstetrics and Gynaecology 39: 354-6.

Petros P and Ulmsten U (1990): An integral theory of female urinary incontinence; Experimental and clinical considerations, Acta Obstetricia et Gynecologica Scandinavica (Supplement 153): 7-31.

Phipps J H and Lewis B V (1993): Radiofrequency endometrial ablation (RaFEA), In: Sutton C and Diamond M (ed.): Endoscopic surgery for gynaecologists, W B Saunders Company Ltd, London, United Kingdom, pp.: 365-71.

Phipps J H, Lewis B V, Roberts T, Prior M V, Hand J W, Elder M and Field S B (1990): Treatment of functional menorrhagia with radiofrequency endometrial ablation, Lancet 335: 374-6.

Pickard R, Reaper J, Wyness L, Cody D J, McClinton S and N'Dow J (2004): Periurethral injection therapy for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2.

Pieber D, Zivkovic F, Tamussino G, Ralph G, Lippitt G and Fauland B (1995): Pelvic floor exercises alone or with vaginal cones for the treatment of mild to moderate stress urinary incontinence in premenopausal women, International Urogynecology Journal 6: 14-17.

Plevnik S (1985): New methods for testing and strengthening the pelvic floor muscles, Neurology and Urodynamics 4: 295-66.

Plevnik S and Janez J (1979): Maximal electrical stimulation for urinary incontinence; Report of 98 cases, Urology 14: 638-45.

Plevnik S, Janez J, Vrtacnik P, Trsinar B and Vodusek D B (1986): Short-term electrical stimulation; Home treatment for urinary incontinence, World Journal of Urology 4: 24-6.

Quinn M J (1996): Anatomy of female continence, In: Studd J (ed.): Progress in obstetrics and gynaecology, Vol. 13, Churchill Livingstone, Edinburgh, United Kingdom, pp. 235-57.

Rai R S and Versi E (1993): Alternatives to surgery for stress incontinence, In: Studd J (ed.): Progress in obstetrics and gynaecology, Vol. 10, Churchill Livingstone, Edinburgh, United Kingdom, pp. 297-316.

Rajasri A G and Byrne D L (2005): Outcome of "no cough" tension-free vaginal tape in treatment of urodynamic stress incontinence, Journal of Obstetrics and Gynaecology 25: 506-7.

Rasmussen K L, Krue S, Johansson L E, Knudsen H J and Agger A O (1997): Obesity as a predictor of postpartum urinary symptoms, Acta Obstetricia et Gynecologica Scandinavica 76: 359-62.

Rechberger T, Donica H, Baranowski W and Jakowicki J (1993): Female urinary stress incontinence in terms of connective tissue biochemistry, European Journal of Obstetrics, Gynecology and Reproductive Biology 49: 187-91.

Rezapour M, Falconer C and Ulmsten U (2001): Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD); A long-term follow-up, International Urogynecology Journal (Supplement 2): S12-14.

Rodegerdts E A, Gronewaller E F, Kehlbach R, Roth P, Wiskerchen J, Gebert R, Claussen C D and Duda S H (2000): In vitro evaluation of teratogenic effects by time-varying MR gradient fields in fetal human fibroblasts, Journal of Magnetic Resonance Imaging 12: 1506.

Ross J W (1998): Multichannel urodynamic evaluation of laparoscopic Burch colposuspension for genuine stress incontinence, Obstetrics and Gynecology 91: 55-9.

Ross J W, Galen D, Abbott K, Albala D, Presthus J, Su-Ou C and Turk T (2002): A prospective multisite study of radiofrequency bipolar energy for treatment of genuine stress incontinence, The Journal of the American Association of Gynecologic Laparoscopists 9: 493-9.

Roth B J, Cohen L G and Hallett M (1991): The electric field induced during magnetic stimulation, In: Levy W J, Cracco R Q, Barker A T and Rothwell J (Eds.): Magnetic Motor Stimulation; Basic Principles and Clinical Experience, Elsevier Science Publishers, Amsterdam, Holland: 268-78.

Rowe E, Smith C, Laverick L, Elkabir J, O'n Witherow R and Patel A (2005): A prospective randomised placebo controlled double blind study of pelvic electromagnetic therapy for the treatment of chronic pelvic pain syndrome with 1 year of follow up, The Journal of Urology 173: 2044-7.

Royal College of Obstetricians and Gynaecologists (2003): Surgical treatment of urodynamic stress incontinence, Guideline No.35, Royal College of Obstetricians and Gynaecologists, London, United Kingdom.

Salvatore J R, Weitberg A B and Mehta S (1996): Nonionizing electromagnetic fields and cancer; A review, Oncology 10: 563-70.

Sand P K, Richardson D A, Staskin D R, Swift S E, Appell R A, Whitmore K E and Ostergard D R (1995): Pelvic floor electrical stimulation in the treatment of genuine stress incontinence; A multicentre, placebo-controlled trial, American Journal of Obstetrics and Gynecology 173: 72-9.

Scott R S and Hsueh G S (1979): A clinical study of the effects of galvanic vaginal stimulation in urinary stress incontinence and sexual dysfunction, American Journal of Obstetrics and Gynecology 135: 663-5.

Selecky M T, Tibone J E, Yang B Y, McMahon P J and Lee T Q (2003): Glenohumeral joint translation after arthroscopic thermal capsuloplasty of the posterior capsule, Journal of Shoulder and Elbow Surgery 12: 242-6.

Shepherd A, Tribe E and Bainton D (1984): Maximum perineal stimulation; A controlled study, British Journal of Urology 56: 644-6.

Sheriff M K M, Foley S, Mcfarlane J, Nauth-Misir R and Shah P J R (1997): Endoscopic correction of intractable stress incontinence with silicone micro-implants, European Urology 32: 284-8.

Smith J (1996): Intravaginal stimulation randomised trial, The Journal of Urology 155: 127-30.

Smith R N J and Cardozo L (1997): Early voiding difficulty after colposuspension, British Journal of Urology 80: 911-4.

Smith T L and Smith J M (2001): Electrosurgery in otolaryngology, head and neck surgery; Principles, advances and complications, The Laryngoscope 111: 769-80.

Smith A R B and Stanton S L (1998): Laparoscopic colposuspension, British Journal of Obstetrics and Gynaecology 105: 383-4.

Smith A R B, Hosker G L and Warrell D W (1989): The role of partial denervation of the pelvic floor in the aetiology of genitourinary prolapse and stress incontinence of urine; A neurophysiologic study, British Journal of Obstetrics and Gynecology 96: 24-8.

Snooks S T, Badenoch D F, Tipaft R C and Swash M (1985): Perineal nerve damage in genuine stress urinary incontinence; An electrophysiologic study, British Journal of Urology 57: 422-6.

Sotomayor M and Bernal G F (2005): Twelve-month results of nonsurgical radiofrequency energy micro-remodelling for stress incontinence, International Urogynecology Journal 16: 192-6.

Stamey T A (1973): Endoscopic suspension of the vesical neck for urinary incontinence, Surgery, Gynecology and Obstetrics 136: 547-54.

Stamey T A (1980): Endoscopic suspension of the vesical neck for urinary incontinence females; Report on 203 consecutive patients, Annals of Surgery 192: 465-71.

Stanton S L (1985): Stress incontinence; Why and how operations work, Urologic Clinics of North America 12: 279-84.

Stanton S L (2001): Some reflections on tension-free vaginal tape; A new surgical procedure for treatment of female urinary incontinence (Editorial), International Urogynecology Journal (Supplement 2): S1-2.

Stanton S L and Cardozo L (1979): Results of colposuspension operation for incontinence and prolapse, British Journal of Obstetrics and Gynaecology 86: 693-7.

Stanton S L and Monga A K (1997): Incontinence in elderly women; Is periurethral collagen an advance?, British Journal of Obstetrics and Gynaecology 104: 154-7.

Staskin D, Bevendam T, Miller J, Davila G W, Diokno A, Knapp P, Rappaport S, Sand P, Sant G and Tutrone R (1996): Effectiveness of a urinary control insert in the management of stress urinary incontinence; Early results of a multicentre study, Urology 47: 629-36.

Stevenson K R, Cholan H J, Hartmann D M, Bucsbaum G M and Guzick D S (1999): Lower urinary tract injury during the Burch procedure; Is there a role for routine cystoscopy?, American Journal of Obstetrics and Gynecology 181: 35-8.

Stothers L and Goldenberg S L (1998): Delayed hypersensitivity and systemic arthralgia following transurethral collagen injection for stress urinary incontinence, The Journal of Urology 159: 1507-9.

Stothers L, Goldenberg S L and Leone E F (1998): Complications of periurethral collagen injection for stress urinary incontinence, The Journal of Urology 159: 806-7.

Stricker P and Haylen B (1993): Injectable collagen for type 3 female stress incontinence; The first 50 Australian patients, The Medical Journal of Australia 158: 89-91.

Su T, Wang K G, Hsu C Y, Wei H J and Hong B K (1997): Prospective comparison of laparoscopic and traditional colposuspension in the treatment of genuine stress incontinence, Acta Obstetricia et Gynecologica Scandinavica 76: 576-82.

Summitt R L, Lucente V L, Karram M M, Shull B L and Bent A E (2000): Randomised comparison of laparoscopic and transabdominal Burch urethropexy for the treatment of genuine stress incontinence, Obstetrics and Gynecology 95 (Supplement 1): S2.

Sutherst J L, Brown M and Shawer M (1981): Assessing the severity of urine incontinence in women by weighing perineal pads, Lancet 1: 1128-30.

Takahashi T, Gracia Osogobio S, Vladvinos M A, Mass W, Jimenez R, Jauregui L A, Bohadilla J, Belmonte C, Edelstein P S, Utley D S (2002): Radiofrequency energy delivery to the anal canal for the treatment of fecal incontinence, Diseases of the Colon and Rectum 45: 915-22.

Tanagho E (1976): Colpocystourethropexy; The way we do it?, The Journal of Urology 116: 751-3.

Temml C, Haidinger G, Schmidbauer J, Schatzi G and Madersbacher S (2000): Urinary incontinence in both sexes; Prevalence rates and impact on quality of life and sexual function, Neurology and Urodynamics 19: 259-71.

Thomas T M, Plymat K R, Blannin J and Meade T W (1980): Prevalence of urinary incontinence, BMJ 281: 1243-5.

Ulmsten U (2001): An introduction to tension-free vaginal tape (TVT); A new surgical procedure for treatment of female urinary incontinence (Introduction), International Urogynecology Journal (Supplement 2): S3-4.

Ulmsten U, Ekman G, Giertz G, Malstrom A (1987): Different biochemical composition of connective tissue in continent and stress incontinent women, Acta Obstetricia et Gynecologica Scandinavica 66: 455-7.

Ulmsten U, Henriksson L, Johnson P and Varhos G (1996): An ambulatory surgical procedure under local anaesthesia for treatment of female urinary incontinence, International Urogynecology Journal 7: 81-6.

Ulmsten U, Johnson P and Rezapour (1999): A three year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence, British Journal of Obstetrics and Gynaecology, 106(4): 345-50.

Unsal A, Saglam R and Cimentepe E (2003): Extraoproreal magnetic stimulation for the treatment of stress and urge incontinence in women, Scandinavian Journal of Urology and Nephrology 37: 424-8.

Van Kerrboeck P E V (1998): The role of electrical stimulation in voiding dysfunction, European Urology 34 (supplement 1): 27-30.

Van Kerrboeck P, Abrams P, Lange R, Slack M, Wyndaele J, Yalcin I and Bump R (2004): Duloxetine versus placebo in the treatment of European and Canadian women with stress urinary incontinence, BJOG: An International Journal of Obstetrics and Gynaecology 111: 249-57.

Vancaillie T G and Schuessler W (1991): Laparoscopic bladder neck suspension, Journal of Laparoendoscopic Surgery 3: 169-73.

Wacha M, Danis J and Wayand W (2002): Laparoscopic resection of an accessory spleen in a patient with chronic lower abdominal pain, Surgical Endoscopy 16: 1242-3.

Wadie B S, Edwan A and Nabeeh A M (2005): Autologous fascial sling vs polypropylene tape at short term follow up; A prospective randomised study, The Journal of Urology 174: 990-3.

Wallage S, Cooper K G, Graham W J and Parkin D E (2003): A randomised trial comparing local versus general anaesthesia for microwave endometrial ablation, BJOG: An International Journal of Obstetrics and Gynaecology 110: 799-807.

Wang A C and Lo T S (1998): A minimally invasive solution to stress urinary incontinence in women, The Journal of Reproductive Medicine 43: 429-34.

Ward K, Hilton P and Browning J (2000): A randomised trial of colposuspension and tension free vaginal tape (TVT) for primary genuine stress incontinence, Neurology and Urodynamics 19: 386-8.

Ward K, Hilton P and Browning J (2000a): Urodynamic variables in a randomised comparison of colposuspension and tension-free vaginal tape (TVT) for primary GSI, Neurology and Urodynamics 19: 388-9.

Ward K and Hilton P (2002): Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence, BMJ 325: 67-73.

Ward K and Hilton P (2004): A prospective multicentre randomised trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence; Two-year follow-up, American Journal of Obstetrics and Gynecology 190: 324-31.

Wassermann E M, Grafman J, Berry C, Hollnagel C, Wild K, Clark K and Hallett M (1996): Use and safety of a new repetitive transcranial magnetic stimulator, Electroencephalography and Clinical Neurophysiology 101: 412-7.

Weinberger M and Ostergard D (1995): Long-term clinical and urodynamic evaluation of the polyteraflouroethylene suburethral sling for treatment of genuine stress incontinence, Obstetrics and Gynecology 86: 92-6.

Westby M, Asmussen M and Ulmsten U (1982): Location of maximum intraurethral pressure related to urogenital diaphragm in the female studied by simultaneous urethrocystometry and voiding urethrocystography, American Journal of Obstetrics and Gynecology 144: 408-12.

Wicker P (1992): Making sense of eletrosurgery, Canadian Journal of Surgery 88: 31-3.

Wilson P D (1990): Conservative management of urethral sphincter incompetence, Clinical Obstetrics and Gynecology 33: 330-45.

Wilson P D and Borland M (1988): A preliminary study of vaginal cones for the treatment of genuine stress incontinence, Proceedings of the University of Otago Medical School 66:37.

Wilson P D, Al Sammari T, Deakin M, Kolbe E and Brown A D G (1987): An objective assessment of physiotherapy for female genuine stress incontinence, British Journal of Obstetrics and Gynaecology 94: 575-82.

Wilson P D, Herbison G P and Heer K (1991): Reproducibility of perineometry measurements, Neurology and Urodynamics 10: 399-400.

Wiskind A K, Creighton S M and Stanton S L (1992): The incidence of genital prolapse after the Burch colposuspension, American Journal of Obstetrics and Gynecology 167: 399-405.

Wood A (1998): Islam for today; Religion for today series, Oxford University Press, Oxford, United Kingdom: 20-1.

Wright A C (1994): Contemporary electrosurgery; Physics for physicians, The Journal of Family Practice 39: 119-22.

Yalcin O T, Hassa H, Ozlap S, Yildirim A and Sener T (1998): Results of the anti-incontinence operations and Kegel exercises in patients with type II anatomic stress incontinence, Acta Obstetricia et Gynecologica Scandinavica 77: 341-6.

Yamanishi T and Yasuda K (1998): Electrical stimulation for stress incontinence, International Urogynecology Journal 9: 281-90.

Yamanishi T, Yasuda K, Suda S, Ishikawa N, Sakakibara R and Hattori T (2000): Effect of functional continuous magnetic stimulation for urinary incontinence, The Journal of Urology 163: 456-9.

Yarnell J W, Voyle G J, Richards C J, Stephenson T P (1981): The prevalence and severity of urinary incontinence in women, Journal of Epidemiology and Community Health, 35:71-4.

Yasuda K and Yamanishi T (1999): Critical evaluation of elctro-stimulation for the management of female urinary incontinence, Current Opinion in Obstetrics and Gynecology 11: 503-7.

Yip S, Chan A, Pang S, Leung P, Tang C, Shek D and Chung T (2003): The impact of urodynamic stress incontinence and detrusor overactivity on marital relationship and sexual function, American Journal of Obstetrics and Gynecology 188: 1244-8.

Yokoyama T, Fujita O, Nishiguchi J, Nozaki K, Nose H, Inoue M, Ozawa H and Kumon H (2004): Extra-corporeal magnetic innervation treatment for urinary incontinence, International Journal of Urology 11: 602-6.

7. Appendix 1:

1. Urodynamic assessment.
2. Statistical tests used for analysis.
3. International Continence Society (ICS)1hr pad test.
4. King's health questionnaire.
5. EuroQol questionnaire.
6. Bristol Female Lower Urinary Tract Symptoms Questionnaire.

Urodynamic assessment:

Subtraction dual channel cystometry was performed according to International Continence Society standards (Abrams et al, 1989; Abrams et al, 2002). Patients were in the sitting position and an 8Fr double lumen catheter was used for filling and measurement of intravesical pressure. Rectal, or vaginal, pressure was measured using fluid filled catheter. Moderate filling rate of 50ml/min was followed. Detrusor overactivity was diagnosed upon detecting uninhibited detrusor contractions during filling or on provocation or if there was a rise in baseline detrusor pressure of 20cm of water. Urodynamic stress incontinence is diagnosed upon leakage of urine in the absence of detrusor contraction. Valsalva leak point pressure was measured at 200ml filling volume, in the sitting position. A cut level of 60cm of water was used for the diagnosis of intrinsic sphincter deficiency.

Statistical tests:

Statistical analysis was carried out according to standard tests (Altman, 1991) on Stata version 6 for Windows (www.stata.com), with the exception of the Fisher's exact test for more than 2 variables. This was carried out on SPSS version 12 for Windows (www.spss.com).

The distribution of continuous data was checked for normality using Shapiro-Wilk test. Parametric tests were used for normally distributed data. The mean and standard deviation were used for description, 2 sample t test was used for comparing 2 groups and ANOVA (analysis of the variance) was used for comparing more than 2 groups. Non parametric tests were used when data did not fit a normal distribution. The median and interquantile range were calculated for description. The Wilcoxon signed rank test was used for comparing 2 groups and Kruskal-Wallis test (non parametric ANOVA) was used for comparing more than 2 groups.

Categorical data were described in numbers and percentage. The X^2 test was used for comparing groups, resorting to the Mann-Whitney test when expected frequencies were < 5 in 20% of cells. Alternatively, Fisher's exact test was used when data fitted 2X2 table. Fisher's exact test for more than 2 groups was used for comparing more than 2 groups when only 2 observations were encountered, fitting 2X3 table, as in the case of re-operation rate in the sling trial.