

An assessment of the functional outcome and quality of life before and after trans-obturator tape surgery for stress urinary incontinence

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Abstract: Introduction and hypothesis. The study aims to evaluate the functional outcome of Trans-Obturator Tape (TOT) in the management of female Stress Urinary Incontinence (SUI) and its impact on patients' quality of life (QOL) and symptom change by using the King's Health Questionnaire (KHQ) pre- and post-operatively. **Methods.** Seventy-six female patients with SUI underwent a TOT operation, which used the outside-in technique. A prospective cohort analysis was conducted on 63 of the women with pure SUI who completed the KHQ before and after the TOT, at a 6-24 month interval post-operatively. The study was performed at the Charlotte Maxeke Academic Johannesburg Hospital in South Africa, from 1 January 2010 to 1 June 2013. **Results.** The mean follow up was 18 months. Thirteen out of 63 patients with pure SUI, after answering positively to the presence of urgency and/or urge symptoms, were placed into a separate group, SUI with the sensation of urgency. There was a general improvement in all areas of KHQ quality of life in both groups of patients postoperatively. Improvement in QOL for SUI (n=50) for both the SUI and the sensation of urgency (n=13) groups were 80% and 92%, respectively. Improvement in stress symptoms score for the SUI group was 91%, while a 100% improvement was noted in the urgency group. There were no cases of bladder perforation, urethral injury, or post-operative urinary retention. Post-operative complications during follow-up included one sling failure, two *de novo* Detrusor Instability (DI), two incidences of groin/thigh pain, and one urinary infection necessitating intravenous treatment. **Conclusion.** The TOT outside-in procedure is a safe and effective procedure in treating SUI, and conclusively improves the quality of life for women with this condition. The King's Health Questionnaire is an easy and reliable instrument to assess symptoms of incontinence and the quality of life.

Keywords: Urinary stress Incontinence; Quality of life; Trans Obturator Tape; KHQ.

INTRODUCTION

Stress urinary incontinence (SUI) may be defined as the involuntary leakage of urine on effort, exertion or coughing without a rise in detrusor pressure¹. It is a physiologically, emotionally, and physically devastating condition and can adversely affect a woman's quality of life. SUI is a social and hygienic problem that negatively affects multiple aspects of a woman's life, such as interpersonal relationships, social interaction, careers, health, and psychological well-being². It is estimated that SUI affects up to one-third of women older than 18 years of age with a median age of 45 years³. Over the last twenty years, the procedure of urethral suspension using mid-urethral slings has become the most common form of surgery for the treatment of female stress urinary incontinence.

In 2001 Delorme described the Trans-Obturator Tape (TOT) as a mid-urethral sling for the surgical treatment of SUI⁴. This is a minimally invasive procedure, termed "outside-in," in which the tape is inserted underneath the middle of the urethra between the two obturator foramina. TOT has almost replaced the Tension-free Vaginal Tape (TVT), which was introduced by Ulmsten in 1995⁵, as it is safer due to the minimal risk of entry into the retro-pubic space⁴. The TOT has a low risk of bladder injuries, vascular injuries and post-operative voiding difficulties^{6, 7, 8, 9} as compared with TVT. Although cystoscopy is mandatory with a TVT, it is not always recommended for the TOT technique^{10, 11}.

The TOT approach has been found to have high success rates, with an objective and subjective cure rate of 90% and 97%, respectively, as well as a low morbidity rate^{11, 12}.

Quality of life (QOL), on the other hand, is more difficult to quantify, as it lacks a defined progression or biochemical measure. However, the success of a treatment cannot be determined based on the objective findings alone; the QOL of the patient in question must also be taken into account. Moreover, despite the fact that QOL is subjective, clinical parameters have shown to be in keeping with these subjective

findings². Since the King's Health Questionnaire (KHQ) is a well-validated, disease specific questionnaire, it was the tool utilised to measure the outcome and the post-operative QOL in the 63 patients treated with TOT surgery from January 2010 to December 2012 in the Uro-gynaecology clinic at the University of the Witwatersrand.

MATERIALS AND METHODS

The study was conducted in a tertiary uro-gynaecology unit in Johannesburg, South Africa, with the approval of the Human Research Ethics Committee of the University of the Witwatersrand. All women who underwent a TOT procedure in the unit from January 2010 to December 2012 were included in the study. These study participants were women with SUI, where the diagnosis of SUI was based on subjective complaints of involuntary leakage of urine on effort, sneezing or coughing without symptoms, suggesting overactive bladder (as recommended by ICS³).

Objective bedside investigations included a cough test (performed in the lithotomy or standing position with a comfortably filled bladder), residual volume, and urine dipstick to exclude infection. Uro-dynamic studies (UDS) were not systematically performed in patients with pure SUI following a history, clinical, and bedside investigations, but without exception was mandatory for those patients who were presented with overactive bladder (OAB) symptoms. The surgical technique was as described by Delorme in 2004⁴.

Postoperative evaluations as per unit protocol were scheduled at 6 weeks, 6 months, 1 year, and annually thereafter. Evaluations included a cough stress test, a vaginal examination, and residual volume. If a patient presented with OAB symptoms during follow-up, UDS were performed. A 24-hour pad test was not performed. Patients unable to present at the clinic were contacted telephonically to assess subjective cure. Patients were contacted by a qualified nurse working in the uro-gynaecology clinic and asked if

symptoms were present; however, the patients were not subjected to a formal questionnaire. All patients who reported dissatisfaction with the procedure or on-going symptoms were asked to return to the uro-gynaecology clinic for further assessment.

Patients were considered to be objectively cured if they did not demonstrate SUI during the stress provocation test (cough test) and were deemed not to have urinary retention if a residual volume of less than 100 ml was recorded. Tape erosion, *de novo* Detrusor Instability (DI), groin or thigh pain were considered as a failure. Subjective success rates were assessed through the use of the KHQ before and after the TOT procedure.

A prospective cohort analysis was conducted on 63 women with pure SUI who completed the KHQ before and after the TOT procedure at 6-24 months. The study was approved by the ethics committee at the Witwatersrand University.

Inclusion criteria were pure SUI, and women with both SUI and sensation of urgency. The last group of patients were initially categorized as SUI by the unit doctors based on the initial workup (pelvic examination, demonstrating a positive cough test, and excluding urinary tract infection). However, after completion of the preoperative questionnaire on admission, these patients had significant SUI but also answered positively to both the presence of sensation of urgency and urge urinary incontinence questions. These patients were included in the study and analyzed separately because these symptoms were only elicited after answering the questionnaire. The questionnaire was done on admission so it was not feasible to perform uro dynamic studies as the patients' procedures were scheduled for the following day.

Exclusion criteria included uncomplicated mixed urinary incontinence (MUI) with a predominant stress component, urge or overactive bladder, infection (perineal skin, urethral and urinary tract), pelvic organ prolapse (stage $\geq +1$ according to POP-Q classification system), pregnancy, and neurogenic bladder.

All the TOT procedures were performed by the same surgeon: the author (AC). The KHQ was repeated between 6 months and 2 years later, either at the follow-up outpatient clinic or telephonically. The patients' information was kept confidential, through the assigning of a study number to each participant. Data was analyzed after completion of the post-operative questionnaire into two groups for statistical ease and interpretation. The data sheet and the KHQ were filled out on admission of the patient before the TOT procedure. The clinical variables used in the data sheet included surgery date, age, parity, gravidity, menopausal status, height, weight, body mass index (BMI), smoking status, previous surgical history, type of incontinence, and problems after the TOT procedure.

Written or telephonic consent was obtained for each participant in the study. The primary objective was to determine the effect of urinary incontinence before and after the TOT procedure on the different aspects of a woman's QOL, as well as the subjective symptoms using the KHQ.

Information collected from the KHQ consisted of nine different domains from section 1-3. Each domain consists of questions, which are used to assess a certain aspect of QOL. Sections 1-3 have a four-point likert rating scale. The score was calculated according to the KHQ formula, with the total score being between 0 and 100; the higher the score, the worse the outcome of QOL. Section 4 assesses the impact of 10 different urinary symptoms.

The data was captured and analyzed using Excel (2010). No patient-identifying clinical variables were included. Comparisons of continuous variables were done through

the use of a Student T-test. The frequencies, means, medians, and ranges were calculated for the data variables.

Analytical statistics were done using a Chi-Squared and a Fischer's exact test. Statistical significance was determined by achieving a p-value of <0.05 , whereas a p-value <0.01 was considered to be highly significant.

Logistic regression models were used to determine any changes in QOL between 6 and 24 months. The data for each objective were analyzed in two different groups: SUI and SUI with urgency

RESULTS

76 patients were operated upon, in total. There were thirteen (17.1%) patients excluded from this study. Of the patients who were excluded, seven patients did not return for the follow-up visit, whilst one patient died 6 months post-operatively from pulmonary hypertension. An additional patient failed to consent to be involved in the study and four patients presented with MUI. Patients with MUI were excluded as the study was focusing on patients who presented with pure SUI.

Thus, the study included 63 patients that fulfilled the inclusion criteria. Baseline characteristics are shown on table 1

TABLE 1. Patient characteristics and type of SUI analyse in the study.

Patient characteristics	N=63
Age, mean years (sd)	57.3 (11.4)
Race, N (% of total)	
Black	18 (28.6)
White	38 (60.3)
Coloured	3 (4.7)
Indian	4 (6.3)
Parity, mean (sd)	2.9 (1.5)
Normal vaginal deliveries, mean (sd)	2.8 (1.5)
Number of Caesarean sections, mean (sd)	0.1 (0.5)
Menopause, n (%)	51 (80.9)
BMI: kg/m ² , mean (range)	30.2 (18.7-50.8)
Smoking history, n (%)	17 (27.0)
Stress UI, n (%)	50 (79.4)
Stress UI with sensation of urgency, n (%)	13 (20.7)

There were 50 (79,3 %) patients in the SUI group, and 13 (20,7%) patients in the SUI with urgency group. Concomitant surgery during TOT procedure is presented in table 2.

TABLE 2. Concurrent operations performed during TOT procedure.

Concomitant Surgery	(N=63)
Vaginal hysterectomy, n (%)	5 (7.9)
Anterior Repair, n (%)	14 (22.2)
Posterior Repair, n (%)	3 (4.8)
Posterior Intra-Vaginal Sling, n (%)	1 (1.6)

The intra and postoperative complications during follow up period are presented in table 3.

TABLE 3. Intra and post-operative complications encountered during the procedure and the follow-up.

Intra and Post-operative complications	(n=63)
Groin and Thigh pain, n (%)	2 (3.2)
Erosion, n (%)	0
de novo urgency UI, n (%)	2 (3.2)
Sling Failure, n (%)	1 (1.6)
Perforation of bladder, vagina, and urethra, n (%)	0

There were a total of five failures throughout the 24 months of follow-up period, leading to an objective success rate of 92%. Follow up data was censored at the end of June 2013, when the last patient who underwent TOT completed the six months follow up. The follow up time varied between 6 and 30 months, with a mean follow up of 18 months.

The KHQ results classified by type of incontinence showing the mean score for the different KHQ variables before and after the TOT procedure are shown in table 5. The mean values ($p < 0.0001$) for all the patients in each group under each domain.

When comparing the KHQ results, the most relatively improved variable is incontinence impact of 89%. The least improved is general health perception of 52%. The most absolute improved in post-operative success is social limitation. The X-axis corresponds to the key (KHQ variables) on the right side of the graph, while the Y-axis shows the mean score (0-100) (Fig 1)

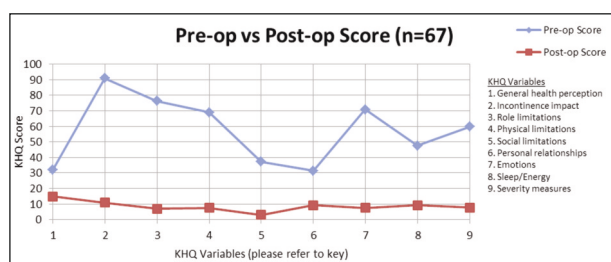


Figure 1. – Comparing the KHQ results.

There were 50 patients in the SUI group. Fig 2 measures the mean score for the patients in each KHQ variable. The relative best improvement is social limitations of 100%. The relative least improved is general health perceptions of 52%. The absolute best improvement is incontinence impact of 89%. The least improvement in absolute terms is general health perception of 15%.

There were 13 patients in the SUI and urgency group. Fig 3 measures the mean score for the patients in each KHQ variable. The relative best improvement is social limitations of 96%. The relative least improved is general health perceptions of 43%. The absolute best improvement was incontinence impact of 89%. The least improvement for absolute terms was personal relationships of 11%.

Comparative changes in each variable before and after the surgery are shown in table 5. The values given are the mean patient score for that variable. The higher the mean

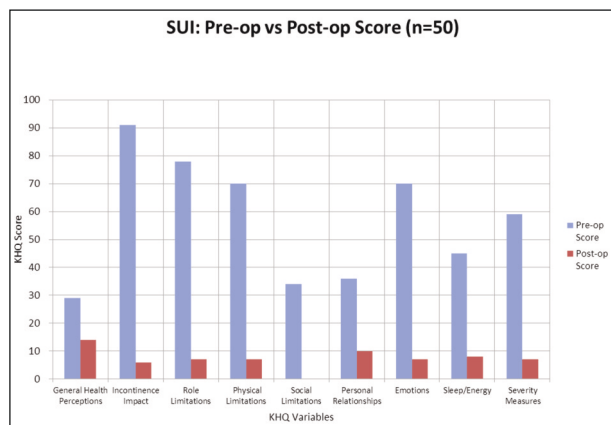


Figure 2. – Pre and post-operative change for SUI.

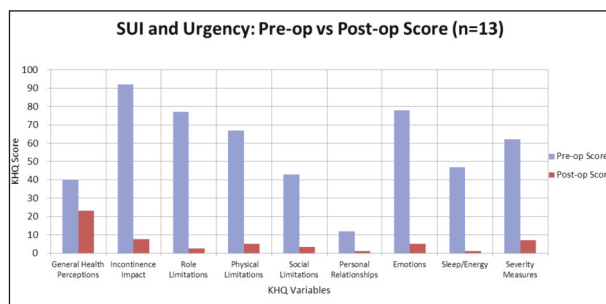


Figure 3. – Pre and post- operative change for SUI and urgency.

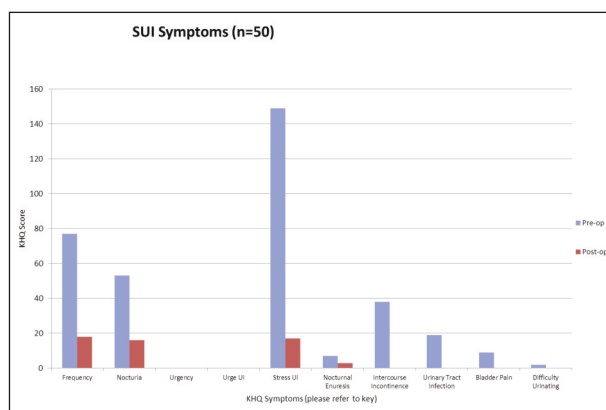


Figure 4. – Pre-operative and post-operative changes in symptoms for SUI.

TABLE 4. KHQ scores before and one year after the TOT surgery.

KHQ Variables (mean)	Pre-Operative			Post-Operative		
	SUI	SUI + Urgency	P value	SUI	SUI + Urgency	P value
General Health Perceptions	29	40	<0.0001	14	23	<0.0001
Incontinence Impact	91	92	<0.0001	6	8	<0.0001
Role Limitations	78	77	<0.0001	7	3	<0.0001
Physical Limitations	70	67	<0.0001	7	5	<0.0001
Social Limitations	34	43	<0.0001	0	3	<0.0001
Personal Relationships	36	12	<0.0001	10	1	<0.0001
Emotions	70	78	<0.0001	7	5	<0.0001
Sleep/Energy	45	47	<0.0001	8	1	<0.0001
Severity Measures	59	62	<0.0001	7	7	<0.01

score for each variable, the worse the average patient level is for that variable.

Mean values ($p < 0.0001$) for all the patients in each group under each KHQ symptoms.

The greatest improvement in the SUI group was in the stress symptom of 96% (Fig 4).

In the SUI and urgency group, the relative and absolute greatest improvement was for stress symptom, which was

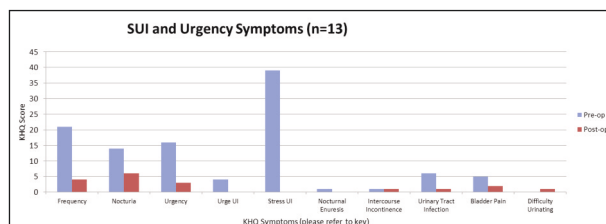


Figure 5. – Pre-operative and post-operative changes in symptoms for SUI and urgency.

TABLE 5. Pre-operative and post-operative KHQ results classified by type of incontinence showing the mean score for the different KHQ symptoms. Comparing pre-operative and post-operative changes in the symptoms.

KHQ Variables (mean)	Pre-Operative			Post-Operative		
	SUI	SUI+ Urgency	P value	SUI	SUI+ Urgency	P value
Frequency	77	21	<0.0001	18	4	<0.0001
Nocturia	53	14	<0.0001	16	6	<0.0001
Urgency	0	16	<0.0001	0	3	<0.0001
Urge UI	0	4	<0.0001	0	0	<0.0001
Stress UI	149	39	<0.0001	17	0	<0.0001
Nocturnal Enuresis	7	1	<0.0001	3	0	<0.0001
Intercourse Incontinence	36	1	<0.0001	8	1	<0.0001
Urinary Tract Infection	19	6	<0.0001	14	1	<0.0001
Bladder Pain	9	5	<0.0001	2	2	<0.0001
Difficulty Urinating	2	0	<0.0001	3	1	<0.0001

reduced to nil (Fig 5). There was an overall improvement in all the other symptoms, except intercourse incontinence, which indicated no change. Only two patients had urinary leakage during intercourse.

Logistic regression models were used to determine pre-operative and postoperative changes in KHQ between baseline and 12 months, as minimal change in QOL was noted between 6 and 24 months. It was found that the 6 month results correlated with the 2 year results.

DISCUSSION

Most studies that addressed the outcome of the TOT procedure focus on the objective cure rates without a real focus on the functional outcome. Therefore, the aim of this prospective study was to evaluate mainly the functional outcome of the TOT procedure in the management of female SUI and its impact on quality of life using the KHQ before and after the TOT operation.

Sixty-three patients were initially classified as having pure SUI, objectively. Thirteen of these patients (20.7%), after answering positively to the presence of urgency and/or urge symptoms, were placed into a separate group, SUI with the sensation of urgency; these patients were initially categorized as a pure SUI by the unit doctors based on the initial workup (pelvic examination, demonstrating a positive cough test and excluding urinary tract infection). However, after the completion of the preoperative questionnaire on admission, these patients also answered positively to both the presence of sensation of urgency and urge.

A study by Dooley Y et al.¹³ performed a comparison between women with MUI versus pure SUI, using two validated questionnaires. This was done in an attempt to compare the patients' history with their physical findings. The study indicated that the majority of the women who presented for surgical treatment of SUI were classified as MUI once subjective measures were used⁶. The prevalence ranged from 50% to 93%, depending on the questions used and severity selected. However, when the data was analysed, the women who presented with MUI responded similarly to the SUI group with QOL and symptom change. When using objective measures, only 8% of women were diagnosed with having MUI⁶.

In our study, only 5.2% (4 out of 76 patients) were diagnosed with MUI, using objective measures. There was an increase in prevalence after completion of the KHQ to 22.3% (17 out of 76 patients). This illustrates how the def-

inition and severity of symptoms can affect the classification and outcome of studies.

A study by Chou E et al.¹⁴, suggests that urge incontinence may be over-diagnosed in patients with SUI who misinterpret their fear of leaking (because of SUI) for urge incontinence. This adds to the discrepancy between the subjective and objective diagnosis. Not surprisingly, the subjective classification yields a higher prevalence rate of MUI as compared to using objective measures. For this reason, thirteen patients in our study who were diagnosed as having MUI after completion of the KHQ before the TOT procedure were grouped separately and analysed as SUI with a sensation of urgency. When the data was analyzed this group (SUI with sensation of urgency) responded similarly to the SUI group with QOL and symptom change. (Fig2 and Fig3)

There was a general improvement in all areas of the KHQ quality of life in all groups of patients post-operatively (table 4). In the SUI group, the social limitations improved by 100%, and the incontinence impact improved by 89% (Fig 1). Patients in the SUI group scored better for incontinence impact. Most women in all the groups considered their general health perception to be good, but scored the worst in incontinence impact on their life pre-operatively. This shows that urinary incontinence is major impediment to good QOL. The mean operative change in the score showed an 87% improvement in the SUI group, and 89% in the SUI with a sensation of urgency group. The SUI with a sensation of urgency group had a similar response to the SUI group. The literature supports this study, showing that women with mixed symptoms reported a higher degree of effect on daily activities, social life, and mental symptoms. More women with mixed symptoms reported an insult on the overall quality of life compared to stress symptoms alone¹⁵.

In our study, although following history and clinical examination, there were a number of patients considered as pure SUI who were found to have a sensation of urgency after completing the KHQ. These patients, following the TOT procedure for SUI, did very well. The SUI group and SUI with urgency had a reduction in the stress symptoms of 89% and 100%, respectively (Fig4 and Fig5).

In the SUI with sensation of urgency group, urge urinary incontinence disappeared while the urgency symptoms were reduced. This could suggest that urgency may be caused by an inflow of urine into the urethra, activating parasympathetic sensory nerves and causing the urgency sensation; however urine leakage is prevented by the TOT procedure.

The possible explanations of why the TOT procedure might improve the urge component is based on the fact that it may prevent urine from entering the upper posterior urethra, with an increase in intra-abdominal pressure, which prevents the reflex urgency^{16,17}. Leakage of urine into the proximal urethra may stimulate urethral afferents and facilitate voiding reflexes¹⁸.

Taking intra- and post-operative complications into consideration, no major intra-operative complications (such as bowel, vascular, bladder, or urethral injuries) were reported in this study, confirming the results of other studies that indicate the safety of the procedure^{19,20}. One sling failure with positive cough test diagnosed at the six months follow-up, was managed by reinserting a new sling.

In addition, post-operative voiding problems were found to be low in our study, which also agrees with other studies^{6,21}. *De novo* detrusor instability was noted in two patients (1.2%) during the follow-up period, and were successfully resolved with antimuscarinics. This is definitely

much lower than the rate reported with TVT^{6,8}. It is suggested that the TOT is more horizontal as compared to the U-shape of the retro-pubic slings, thereby making less contact with the urethra and so diminishing the likelihood of this complication. Urinary retention following TOT has been reported in literature as between 1.5 and 15%, respectively^{9,12}. No cases of urinary retention occurred in this series. This may be attributed to the fact that, in all cases, the catheter was clamped on the first post-operative day, and removed on the second day before discharge. This not only allowed bladder retraining, but may also have decreased the tension on the sling in the immediate post-operative period.

Six (9%) of the women had a post-operative urinary tract infection (UTI). These women presented with symptomatic dysuria but not voiding difficulties. One of them was admitted for intravenous administration of Kanamycin based on sensitivity of the culture of midstream urine. The other five patients were treated successfully with antibiotics at home. The incidence of UTI is in keeping with current literature²¹ of 3.1-22%. There were two (1.2%) women who presented with groin and thigh complications; with one of the woman's groin pain resolving spontaneously at the six weeks follow-up. The other woman had unilateral groin pain affecting left groin, inner thigh, and left labia majora persisting after the six weeks follow-up, in spite of analgesia and anti-inflammatory treatment. This burning sensation was not relieved even after administration of amitriptyline. The pain and burning sensation was resolved after partial removal of the tape, and continence was preserved.

Injury to the ilioinguinal nerve and rarely the obturator nerve has been described in the literature. The ilioinguinal nerve supplies the sensory innervation to the skin over the groin, inner thigh and labia majora. The incidence of groin pain has been reported in three (1.5%) out of 204 women following TOT procedure²¹. Groin or thigh pain has been found to be more common with TVT-O inside-out procedure with reported incidence of 16-17%^{22,23}. A sub-analysis performed by Cheng Yu Long²⁴ found that TVT-O inside-out appears to be more painful, and the possible cause was that the exit point of the TVT-O needle is closer to the adductor muscle and the obturator neurovascular bundle compared with outside-in TOT. Cadaveric studies confirmed that tapes inserted via the Transobturator route using an outside-in technique have a lower risk of pudendal neurovascular bundle injury, as the tape is inserted further from the obturator canal and closer to inferior ischiopubic rami²⁵.

In twenty three (34%) of the women involved in the study, the TOT procedure was combined with an additional pelvic surgery. The results of this study are in agreement with Costa et al.²⁶ and demonstrate that pelvic procedures during TOT surgery do not compromise the cure rate of female SUI.

There was a general improvement in all areas of the KHQ quality of life in all groups of patients post-operatively. In the SUI group, the social limitations improved by 100%, and incontinence impact by 93%. The SUI with a sensation of urgency group had a similar response to the SUI group.

The literature states that patients may experience a deterioration of their sexual function following the mid-urethral sling procedure. This can occur as a result of the development of dyspareunia after the surgery²⁷ or due to decreased blood supply to the clitoris. De novo dyspareunia might be caused by the position of the tape, as the use of the tape may result in vaginal narrowing, para urethral banding or erosion²⁷. The effect on clitoral blood supply after the TVT

and TOT procedures was investigated by Caruso et al., with the aid of colour Doppler ultrasonography²⁸. It was concluded that blood flow to the clitoris was negatively affected by TVT, but not by the TOT. Thus, the TOT was proved to be an anatomically safer approach, which does not impair the sexual function of the patient.

However, none of the sexually active patients in our study suffered from a decline in their sexual function. Additionally, there was no case of de novo dyspareunia in this study – as opposed to Elsevier et al.²⁹, who reported that 10% of his patients who underwent the TOT procedure reported vaginal narrowing, which caused dyspareunia.

The impact of the QOL cure rate was analysed separately from the symptoms. This study demonstrates that the QOL cure rate, as well as the subjective symptom cure rate, was defined as statistically significant, post-operatively (Table 5). The KHQ shows the negative impact of urinary incontinence in patients' QOL. There was a significant improvement in the QOL of patients that underwent the TOT outside-in surgery for female SUI, and the data obtained from the KHQ correlate with the objective cure rates

CONCLUSION

In summary, the TOT outside-in procedure is a simple, effective, safe, and minimally invasive technique for the treatment of SUI. The KHQ shows the negative impact of stress urinary incontinence in the quality of life of patients. There was a significant improvement in the quality of life of patients that underwent the TOT outside-in surgery for the treatment of their SUI; thus, there is a correlation between the subjective cure rate and the objective cure rates.

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Editorial commentary

Hostile environment. In June 2014, politicians in Scotland called for mesh operations to be suspended. Across the UK, women are considering surgical treatment of stress urinary incontinence with mesh slings an operation with potential life-changing risks and are demanding it to be suspended until additional information. The Scottish parliament has petitioned a full investigation and audit to be carried out into how many women have been adversely affected by vaginal mesh implants and tapes 1. This 'anti mesh sling' atmosphere following its older sister 'anti vaginal mesh surgery' atmosphere is spreading worldwide like a fire in a field of thorns.

In this kind of environment the study by Chrysostomou et al. gains the utmost importance demonstrating once again that suburethral sling procedures (specifically, the TOT outside-in procedure) are safe and effective in treating SUI. Moreover they have conclusively demonstrated that it improves the quality of life for women with this condition. Although surgeons many times tend to focus on anatomical outcomes or objective cure rates to define surgical success, patients are more concerned with functional outcomes. While there is no doubt that urinary incontinence has a negative impact on patients' QoL, this study has demonstrated that the QoL cure rate, as well as the subjective symptom cure rate, was statistically significant, post-operatively.

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