

## THE ALIGN URETHRAL SUPPORT SYSTEM FOR THE SURGICAL MANAGEMENT OF STRESS URINARY INCONTINENCE IN WOMEN.

### Hypothesis / aims of study

The tension-free vaginal tape (TVT) has revolutionised the management of women with stress urinary incontinence. Since its inception in 1995 [1] most major medical equipment manufacturers have introduced their own TVT version, which vary in their insertion technique and mesh composition. Align (Bard Urology) is a new macroporous lightweight polypropylene mesh which differs from the original TVT with smaller diameter fibres leading to a reduced mesh density. This study was carried out to compare its effectiveness with existing TVT slings [2] [3].

### Study design, materials and methods

Women with urodynamic stress incontinence and who were thought suitable for TVT were recruited into the study. Pre-operatively, a Kings College Hospital Quality of Life (KCHQoL) questionnaire was completed together with a Visual Analogue Scale (VAS) of incontinence severity. The daily pad usage was calculated and the International Consultation on Incontinence Questionnaire (ICI-Q) was completed. This calculates the amount of urine leakage scored from none [n=1], a small amount [n=2], a moderate amount [n=3] to a large amount [n=4], and also the frequency of urinary leakage which was scored from never [n=1], <once a week [n=2], 2-3 times a week [n=3], once a day [n=4], several times a day [n=5] to all the time [n=6]. A routine retropubic Align sling was then inserted and the women followed up at 3-6 months and again at 12 months using the same subjective methods.

### Results

102 women have been recruited into the study to date. There were no intra-operative problems and no case of vaginal erosion has occurred. 54 women have completed 3-6 month follow up of which a further 19 have completed 12 month follow up. The results are shown in Table 1.

9.62% women at initial review and 11.11% at 12 months described some voiding problems but no patients require to self catheterize. Only 75% of women were still performing pelvic floor exercises at 3-6 months and surprisingly this fell to 35.29% at 12 months. 100% of women would recommend the operation to a friend or relative at 3-6 months and 89% at 12 months. The average improvement at 3-6 months was 87.7% (median 100%) and 88.9% (median 100%) at 12 months.

### Interpretation of results

The results show that all parameters of the KCHQoL with the exception of General Health are improved by the Align procedure at 3-6 months and this is sustained at 12 months. There is also a highly statistical reduction in the severity of incontinence measured by the VAS and pad usage. The frequency of incontinence and the amount of urinary losses were also statistically reduced.

### Concluding message

The Align urethral support system is highly effective in the management of women with stress urinary incontinence, which is comparable to other commercially available slings or tapes. The study is continuing in recruitment and length of follow up.

Table 1.	Pre		3-6 Month			12 Month		
	Mean	Median	Mean	Median	P value from baseline	Mean	Median	P value from baseline
General Health	24.1	25	23.6	25	0.9851	8.8	0	0.0001
Incontinence Impact	89.5	100	30.7	33	0.0001	10.3	0	0.0001
Role Limitations	67.3	67	16.3	0	0.0001	12.0	0	0.0001
Physical Limitations	71.1	67	18.7	0	0.0001	13.7	0	0.0001
Social Limitations	44.5	44	8.4	0	0.0001	6.3	0	0.0001
Personal Limitations	53.3	41.67	10.2	0	0.0001	12.2	0	0.0001
Emotions	62.3	67	14.0	0	0.0001	10.5	0	0.0001
Sleep/Energy	27.2	16.67	16.3	16.67	0.0066	22.5	16.67	0.2102
Severity Measures	67.1	66.67	18.5	8.33	0.0001	22.5	8.33	0.0001
VAS	8.21	8	1.94	1	0.0001	1.88	1	0.0001
Frequency Of Incontinence	3.849	4	1.08	1	0.0001	0.647	1	0.0001
Amount of	3.58	4	1.06	0	0.0001	0.88	0	0.0001

Urinary Leakage								
Daily Pad Usage	3.68	3	0.426	0	0.0000	0.267	0	0.0000

### References

1. Ulmsten U, Petros P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scandinavian J of Urology & Nephrology 1995: 29(1); 75-82
2. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, Olsson I. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. International Urogynecology Journal 1998: 9(4); 210-3
3. Ward KL, Hilton P. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008: 115(2); 226-33

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<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Torbay Research Ethics Committee</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>