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Preoperative urethral parameters at rest and objective cure following laparoscopic colposuspension.

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Abstract

Introduction

To investigate associations between preoperative resting urethral parameters and objective outcome of laparoscopic colposuspension.

Methods

Data from 219 stress incontinent women which underwent laparoscopic colposuspension ,with leakage at standardized pad-test repeated after surgery, were collected. Associations between objective cure and preoperative maximum urethral closure pressure, functional urethral length and continence area were analysed using Receiving Operator Characteristics (ROC) curves. The level for 75% cure for each parameter was identified.

Results

All parameters were positively associated with cure. Continence area showed the strongest association. No cut-off values for prediction of failure were found. Women having levels equal or higher than the "75% cure level" for all urethral parameters had a cure rate of 88 % compared with 55% for women with all parameters lower than this level.

Conclusion

A combination of the urethral parameters may be useful for identifying patients with excellent chance for cure after colposuspension. Further studies are needed on continence area.

Summary

All studied resting urethral parameters showed a positive association with objective cure after laparoscopic colposuspension in stress incontinent women. Continence area showed the strongest association.

Introduction

Preoperative resting urethral parameters have been demonstrated to be associated with outcome following stress incontinence surgery in women. The "low pressure urethra" has been generally accepted as predictive of surgical failure [1-5], even if the diagnostic role of traditional urodynamic investigation prior to surgery remains controversial [6, 7].

In later years there has been a search for alternative ways of assessing urethral function in correlation with surgical outcome. Two studies on urethral electromyography have demonstrated a relationship between urethral sphincter neuropathy and outcome of continence surgery [8, 9]. However, electrodiagnostic testing is not recommended by the International Urogynecological Association to evaluate female stress urinary incontinence in a neurologically normal woman [10].

Recently Digesu et al. showed that three-dimensional ultrasound of the urethral sphincter could predict outcome following Burch colposuspension [11]. Studies on urethral retro-resistance pressure (the pressure required to achieve and maintain an open urethral sphincter) have demonstrated contradictory results regarding surgical outcome [12-15]. So urodynamics still have a substantial place when evaluating incontinent women prior to surgery [10, 16].

The aim of our study was to further investigate the correlations between resting urethral parameters and objective surgical outcome after laparoscopic colposuspension and, if possible, to identify cutoff values useful in clinical practice.

Materials and Methods

The present study is based on data from an existing incontinence registry containing prospective data retrieved between 1994 and 2004 at the Department of Obstetrics and Gynecology, Lund University Hospital, Sweden. The registry was constructed for four different original studies :1: a prospective non-randomized study describing surgical technique and outcome of laparoscopic colposuspension.; 2: a prospective randomized study comparing one with two bilateral sutures on each side of the urethra for the colposuspension.; 3: a prospective randomized study comparing costs between laparoscopic colposuspension and the TVT procedure[17-19], the latter being a part of a larger currently ongoing study (study nr 4) comparing clinical outcome for these two procedures.

Relevant demographic, urodynamic and clinical data, as well as follow-up data, were prospectively retrieved using written protocols. Those data were consecutively entered and stored in a separate computer based registry (StatView database, SAS Institute Inc., Cary, NC) which fullfilled the hospital's regulations for research registries.

For the present study, we used this registry to retrieve follow up data and the results from the preoperative urodynamic evaluation. We then compared objective cure data with the maximum urethral closure pressure, urethral functional length and urethral continence area (area under the urethral pressure profile at rest) on all women having underwent laparoscopic colposuspension with two bilateral paraurethral sutures (n=219) in order to investigate possible correlations. Objective cure was defined as no leakage at the postoperative pad test used throughout all the original studies. Deviant values for the respective resting urethral parameter were controlled against the original urodynamic worksheets.

The inclusion criteria for the original studies were women with pure stress incontinence women and stress incontinent women with subdominant symptoms of overactive bladder with a urethral closing pressure of 20 cm of H2O or more, a minimum of five ml of leaking at the

preoperative pad-test and a urethra with a straining angle of at least 45 degrees at Valsalva manoeuvre. In addition, for the last two studies [18, 19] a urethral functional length of 25 mm or more was required. The exclusion criteria were symptomatic urge incontinence, urodynamicaly demonstrable detrusor instability, previous incontinence or prolapse surgery or a vaginal descent more than grade one cystocele according to Beecham's classification [20]

The preoperative investigation was performed by a restricted number of physicians (n=4) and included demographic and contraceptive history, urodynamics, gynaecological investigation, measurement of residual urine, cystoscopy and a standardized short term pad-test [21]. The urodymamic investigation was performed in a dorsal lithotomy position using the Dantec Menuet® system (Dantec Inc., Skovlunde, Denmark) and a dual micro-tip 7 Gauge transducer (Gaeltec CTU- 2, Isle of Man, Scotland). The pressure transducers were directed against the lateral urethral wall, clockwise three and nine. The withdrawal rate was 2 mm/sec. At least two resting urethral profiles were obtained and the maximum urethral closure pressure, the functional urethral length and the continence area were recorded. The urethral profile with the highest urethral closure pressure wasused also for obtaining the values of urethral functional length and continence area. All parameters were automatically calculated by the equipment's software. Endpoints were controlled by the investigator.

The pad-test consisted of standardized physical activity during one minute with a bladder volume of 300 mL [21]. The pad was weighed before and after the test to estimate urine loss. The same padtest was performed median 13 months after surgery. The postoperative evaluation was performed by either one of the surgeons or one urotherapist, blinded to the results from the preoperative urodynamic evaluation.In all patients, the laparoscopic colposuspension was performed according to the technique described by Persson et al. [17, 18]. To prevent urethral hypermobility, we elevated the vaginal fascia halfway towards the dorsal rim of the pubic bone by the use of two bilateral single bite polytetrafluoroethylene

sutures (Gore-tex® CV2, WL Gore., Flagstaff, AZ) anchored in the Cooper's ligament. The sutures were placed in the periurethral vaginal wall approximately two centimetres lateral to each side of the urethra and two centimetres distal to the bladder neck.

For the statistical analysis, we used the $\chi 2$ test, the Wilcoxon's, the Mann-Whitney's or the Kruskall-Wallis' test as appropriate. A p-value $\leq .05$ was considered statistically significant. Receiving operator characteristics (ROC) curves were performed to identify any cut-off values. All studies were approved by the local ethics committee and all participants gave their informed consent.

Results

For the present study, we could identify 219 women with adequate pre- and postoperative data in the registry. In three women, a deviant urodynamic observation was considered a measurement or calculation error (urethral functional length of 62 mm, *n*=1, urethral closing pressure of 125 cm H2O, *n*=1, and urethral continence area of 1796 cmH2Ox mm, *n*=1). Those women were excluded, leaving 216 women for the final analysis. At follow up 179 women (83 %) were objectively cured and 37 (17 %) uncured using the chosen criteria.The median age of the women was 49 years (range 28-71) and median parity was 2 (range 0-6).They had a median body mass index of 24.6 kg/m2 (range19-38) and had been incontinent a median of 7.5 years (range 1-37) prior to surgery. At the time of surgery, 120 women (56%) werepremenopausal and 94 women (43%) postmenopausal of which 79 (88%) were using systemic hormonal replacement therapy. Information on hormonal status was missing on two women. No significant association was found between hormonal status and objective surgical outcome.

Urethral parameters at rest were as follows: median maximum urethral closure pressure of 46 cm H2O (range 20–112), median functional urethral length of 28 mm (range 16–39) and a median continence area of 464 mm x cm H2O (range 45–1162). 111 patients were operated on by surgeon A, 84 by surgeon B and the remaining 21 by either of four surgeons. No significant relationship was identified between surgeons and objective cure or between surgeons and preoperative urethral parameters (table 1). Therefore we used only univariate analyses in the further analyses between objective cure and preoperative resting urethral parameters. We identified significant associations between all studied urethral parameters and objective cure, but we were unable to identify cut off values for any of the chosen resting urethral parameters using ROC curves (figures 1-3). However, we identified the level of 75% cure for each urethral parameter (≥ 37 cm H2O for maximum urethral closure pressure, ≥ 24

mm for functional urethral length and ≥ 380 mm x cm H2O for continence area). Women having levels equal or higher than the "75% cure rate level" (*n*=109) for all the parameters had an objective cure rate of 88 %. In contrast, women having levels lower than the "75% cure rate level" (*n*=11) for all the parameters had a cure rate of only 55% (*p*=.0002).

Discussion

The ideal preoperative evaluation of the urethral function should help the clinician to assess the severity of the incontinence and provide tools for counseling prior to incontinence surgery.

In 1976 McGuire et al. showed that a maximum urethral closure pressure of less 20 cm H2O was associated with surgical failure [22]. In a later study comparing women who underwent surgery for recurrent incontinence, the same author reported a failure rate of 75% compared with 25% if the preoperative maximum urethral closure pressure was lower respectively higher/equal to 20 cm H2O (23). Using the same cut-off value, Sand et al. reported a threefold increase in surgical failure among 86 women following colposuspension [4]. Similar results were reported by Bowen et al. in a case control study of 42 women [5]. However, we have not been able to identify the statistical rationale for choosing 20 cm H2O as cut-off value in those studies [4, 5, 22, 23]. Moreover, the authors either used different types of catheters or did not describe which type was used [22-26]. It is known that different types of catheters (open end, micro tip, balloon) produce different values [25,26].

Possible correlations with other urethral parameters have also been studied. Bunne et al. showed in 1978 that incontinent women had shorter urethral functional length and lower continence area compared to continent women [27]. Later, Peters and Roemer found urethral closure pressure and urethral functional length to be individually associated with outcome of incontinence surgery [28].

Our study shows significant associations between all studied resting urethral parameters and objective cure median 13 months after surgery. These associations are, in general, in accordance with previous reports, but our study fails to identify any clinically useful cut-off value to predict surgical failure. Instead, associations appear almost linear. However, this could be secondary to the few number of failures among included women.

The strongest statistical association was found for urethral continence area. This is logical as this parameter combines the properties of both maximum urethral closure pressure and urethral functional length and implies that a combination of the parameters may provide better predictive information.

As we were unable to mathematically combine the ROC curves and could not find any cut-off values, we decided to choose an arbitrary 75% cure rate level for each of the parameters and combine them. In that way, we could identify a large group of women with an 88% cure rate and a smaller group of women with a cure rate of only 55%.

The strength of our study resides in the relatively large number of studied women, the uniform preoperative investigation and inclusion criteria, the standardized surgical technique and the objective follow up in a prospective blinded setting. Moreover, a restricted number of surgeons was involved. Finally, although we do not consider a cystocele a contraindication for incontinence surgery, women with a combination of a cystocele and stress urinary incontinence were excluded from the original studies in order to achieve a well defined patient material.

We certainly agree that a multimodality evaluation, e.g. including subjective cure and symptom specific Quality of Life measurements, is necessary to highlight all aspects of surgical treatment for stress urinary incontinence. However, as the sole aim of this study was to evaluate the association between cure and preoperative resting urethral parameters, we wanted to use an outcome measure as standardized and free of bias as possible. We believe that an objective evaluation with areproducible test designed to evaluate stress urinary incontinence only, such as the pad-test used in our studies, is superior to long term pad-tests (which are unable to distinguish urinary leakage caused by the different types of incontinence) [21].

We also believe that the pad-test used in our study set-up is superior to subjective outcome. There are several reasons for this. First, some women may decrease their physical activity after a surgical procedure of fear of harming the surgical result or the opposite, resume physical exercise previously abandoned due to bothersome incontinence. Second, women with some degree of overactive bladder symptoms may still consider themselves only improved despite cure of the stress induced leaking. Third, patient's reports of outcome may be biased by psychological interactions between the patient and the therapist or by misunderstandings of questions during an interview or in a questionnaire. Fourth, we wanted to assure that our approach could be reproduced by others for comparison with both ours and later results. Nevertheless, for clarification, we have compared the objective and subjective cure results in the registry for included women (Table 2). Analyzing the subjective cure results, we found similar associations between subjective cure (subdivided in two groups: cured and improved/unimproved) and continence area (p=.02) whereas the associations with urethral closing pressure and urethral functional length no longer remained statistically significant (p=.09 and p=.35 respectively). As seen in Table 2, 15/179 (8%) women considered themselves only improved from stress incontinence symptoms despite no leaking at the fairly provocative pad-test. On the contrary, 11/37 (30%) women considered themselves cured despite leaking at the postoperative pad-test. We believe this reflects the weakness of patients report of cure for the purpose of studies like the present.

There are some weaknesses in our study. First, we did not include women with maximum urethral closure pressure lower than 20 cm H2O. Thus, we cannot exclude the possibility of a cut-off value below our variables. We believe the almost linear appearance of the ROC curves in this study makes the existence of such a cut-off value unlikely.

Second, as all women were operated on with laparoscopic colposuspension, we do not know whether our results are also applicable to other surgical procedures.

Conclusion

Our data shows linear associations between objective cure after colposuspension and preoperative maximum urethral closure pressure, functional urethral length and continence area. A cut off value for prediction of failure could not be identified for any of these parameters. However, using a combination of the urethral parameters we were able to identify a group of women with excellent cure following colposuspension. The strong association found between continence area and objective cure is interesting and motivates further investigations to possibly confirm our result We therefore believe that this new approach could be clinically useful. Studies similar to the present, preferably on sub/midurethral polypropylene slings, would provide further knowledge.

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Legends

Figure 1: Receiving operator characteristics curve for maximum urethral closure pressure on the risk for unsuccessful colposuspension

Figure 2: Receiving operator characteristics curve for urethral functional length on the risk for unsuccessful colposuspension

Figure 3: Receiving operator characteristics curve for urethral continence area on the risk for unsuccessful colposuspension

Table 1: Objective cure rate 1 year after colposuspension

	Cured	Uncured	Total
Total count	83 % (*n*=179)	17 % (*n*=37)	*n*=216
Surgeon A	87 % (*n*=97)	13 % (*n*=14)	*n*=111
Surgeon B	79 % (*n*=67)	21 % (*n*=17)	*n*=84
Miscellaneous	71 % (*n*=15)	29 % (*n*=6)	*n*=21

Surgeon A compared with B (*p*=.15), compared with Miscellaneous (*p*=.61), compared with all others (*p*=.07)

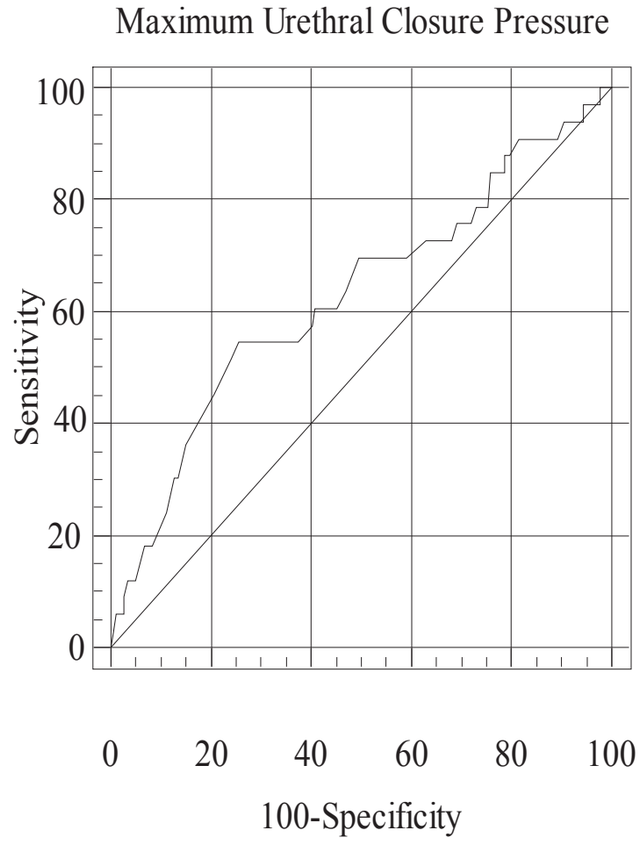
Surgeon B Compared with Miscellaneous (*P*=0,40), compared with all others (*p*=.33)

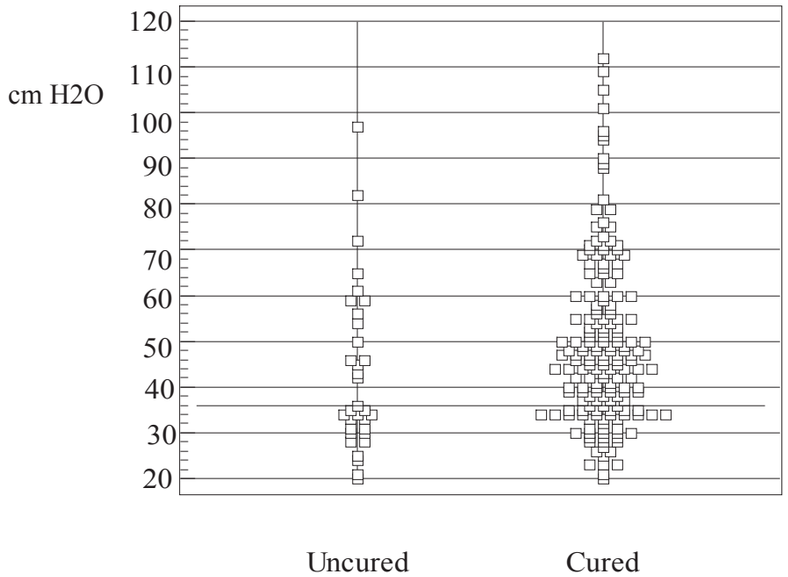
Miscellaneous compared with all others (*p*=.18)

Table 2: Comparison between objective cure (no leaking at a postoperative standardized one minute pad-test) and subjective cure (women's report of outcome) on women with s urinary incontinence at follow-up a median 13 months after laparoscopic colposuspens

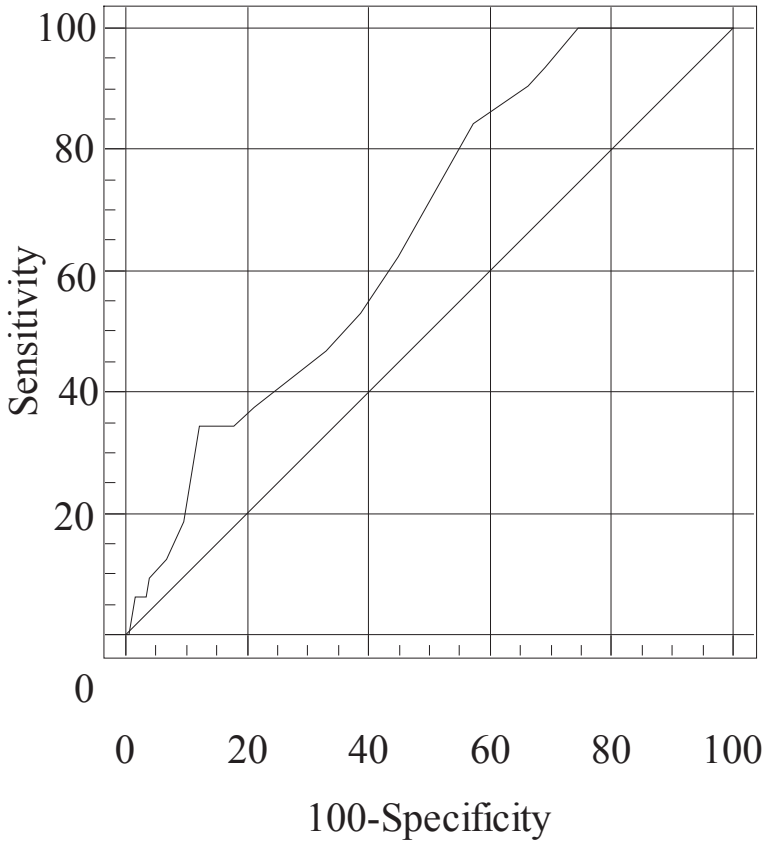
Result of postoperative pad-test	Subjective report of stress incontinence symptoms			
	Cured	Improved	Unimproved	Total
No leaking *	164	15	0	179
Leaking*	11	20	6	37
Subdivision of *"leaking"*				
	Cured	Improved	Unimproved	Total
< 1/3 of the preoperative leaking**	11	16	1	29
≥ 1/3 of the preoperative leaking **	0	4	5	9

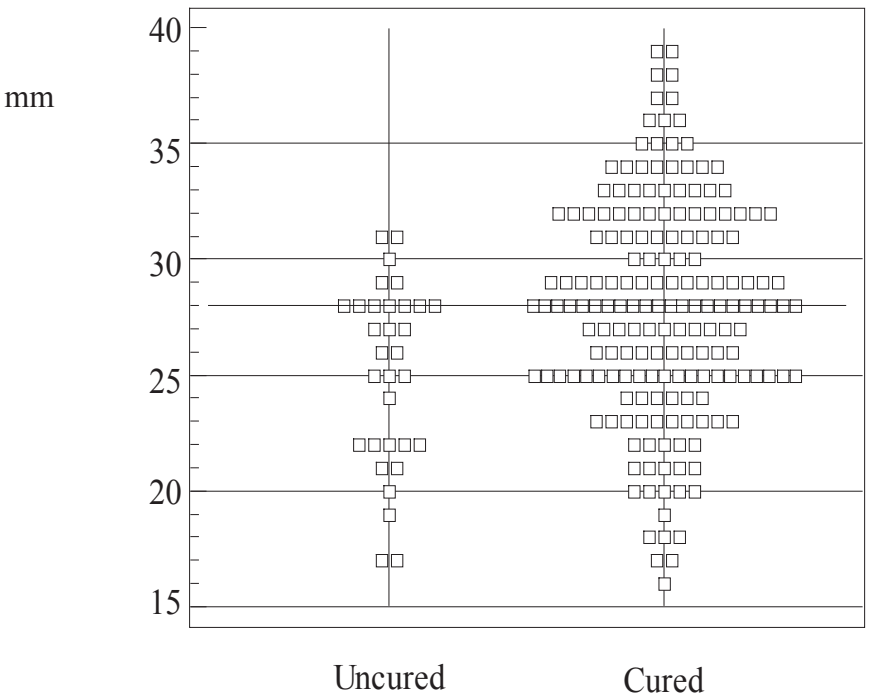
* Criterion used for "cured / uncured" in the present study.
** All women leaked during an identical pad-test before surgery

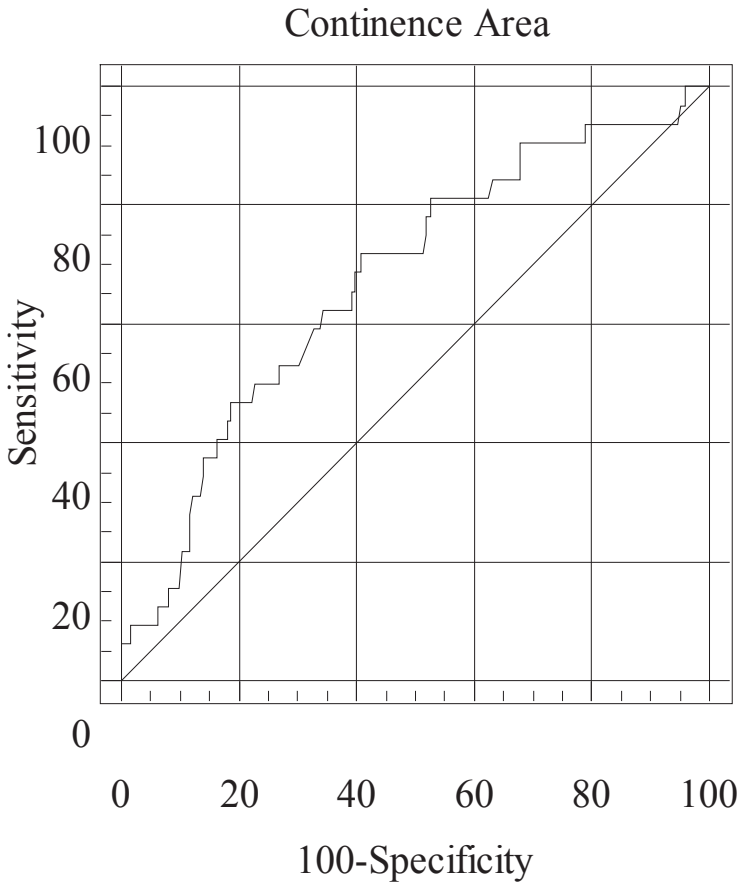

Maximum Urethral Closure Pressure
Sensitivity
100
80
60
40
20
0
0
20
40
60
80
100
100-Specificity

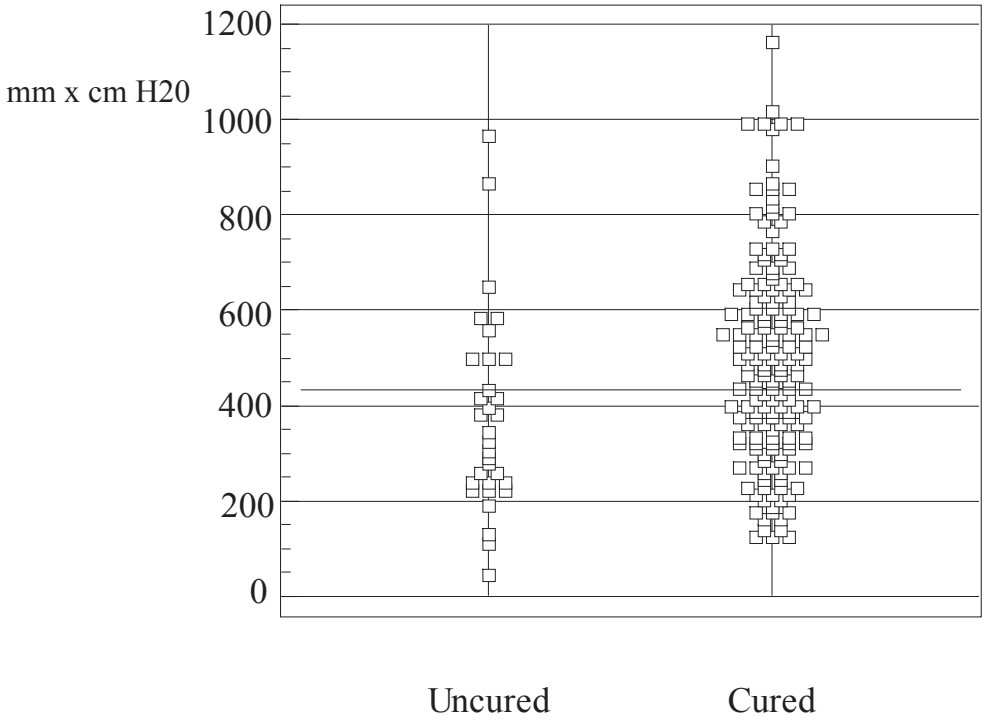

cm H2O
120
110
100
90
80
70
60
50
40
30
20
Uncured
Cured

Functional Urethral Length






Continence Area
Sensitivity
100
80
60
40
20
0
0
20
40
60
80
100
100-Specificity


mm x cm H20
1200
1000
800
600
400
200
0
Uncured
Cured