Recording urinary flow and lower urinary tract symptoms using sonouroflowmetry

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Introduction: *To assess the accuracy of sonouroflow (SUF), an at-home, wireless-based acoustic system for recording lower urinary tract symptoms (LUTS) and urinary flow rate, and to compare test-to-test variability in flow parameters recorded using this new portable method with those obtained by conventional uroflowmetry.*

Materials and methods: *An initial pilot study evaluated the technical feasibility of the SUF system. Subsequently, test-to-test variability was compared between sonourograms (SUFm) and standard uroflowmetry recordings. Uroflowmetry tests were performed at the urology office at pre-set times. SUF tests were performed at home on a schedule in keeping with the subjects' normal habits.*

Results: *In the initial feasibility study, 94% of SUFm recordings obtained from male volunteers displayed regular bell-shaped flow curves comparable to those recorded by standard uroflowmetry; significant variability was noted among female volunteers. In the comparative study, the coefficient of variation for SUFm-derived values was significantly lower for voiding time ($p < 0.001$) and significantly higher for average flow rate ($p = 0.009$) than that obtained from standard uroflowmetry recordings; maximum flow rate and time to maximum flow were not significantly different between methods. Box-and-whisker plots showed reduced test-to-test variability in the SUFm dataset for voiding time, maximum flow rate and time to maximum flow rate in 62.5%, 43.75% and 56%, respectively, of study subjects.*

Conclusions*: The SUF system is easy to use and yields results comparable to those of standard uroflowmetry. Integration of recordings of LUTS with flow parameters and lower test-to-test variability suggest the potential of SUF for clinical applications.*

Key Words: uroflow, test-to-test reproducibility, volunteer study

Introduction

More than 33 million adults in the United States suffer from lower urinary tract dysfunction, with an estimated annual cost approaching $26 billion.[1,2] Successful treatment depends on establishing the etiology, and determining the severity of symptoms and the degree of bother associated with these symptoms. Quantification of symptoms is essential for making the initial diagnostic assessment, as well as later in determining the response to treatment. The accuracy of questionnaires and paper-based frequency–volume charts or voiding diaries in recording symptoms depends on the patients' compliance and capacity to correctly remember symptoms. Errors in retrograde data entry is a major cause of inaccurate recordings, and compliance with pen and paper approaches has been shown to vary significantly.[3] A National Cancer Institute study measuring pain showed that the overall compliance with paper diary upkeep was 90%, but when patients were asked to complete these

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diaries three times a day at predetermined times, the compliance dropped to a mere 11%.[4] In men suffering from benign prostatic hyperplasia (BPH), the compliance with maintaining frequency–volume charts reported in the urology literature varies from 57% to 97%.[3,5,6]

Evaluation of urinary flow rate is often used to support the diagnoses of bladder outflow obstruction and poorly functioning detrusor that might be suspected based on a patient's history.[7,8] The American Urological Association Guidelines on BPH list uroflowmetry as an optional diagnostic test.[9] Although this test is only recommended for selected patients, it has proven valuable both prior to initiation of active therapy and subsequently in assessing treatment outcomes.[10] In most cases, uroflowmetry is performed in a clinic where patients must urinate on demand instead of when they are physiologically ready. As a result, conventional uroflowmetry suffers from significant test-to-test variability in an individual's test results.[11] It has been recommended that at least two uroflow tests be performed, ideally each with a voided volume greater than 150 mL. This is often not possible, necessitating additional testing.[10] Due to the hardships and costs associated with repeated trips to the clinic, treatment follow up is often suboptimal.[12]

To address these limitations, we have developed sonouroflow (SUF), an automated portable testing tool that allows objective prospective recording of both uroflowmetry and LUTS, including the degree of urgency and urinary flow rate. Here, we performed an initial pilot study to test the feasibility of the SUF system, and then compared the reliability and test-to-test variability of sonourograms (SUFm) – processed SUF audio signals converted into a flow curve – with that of standard uroflowmetry in a subsequent study to evaluate the potential clinical applicability of SUF.

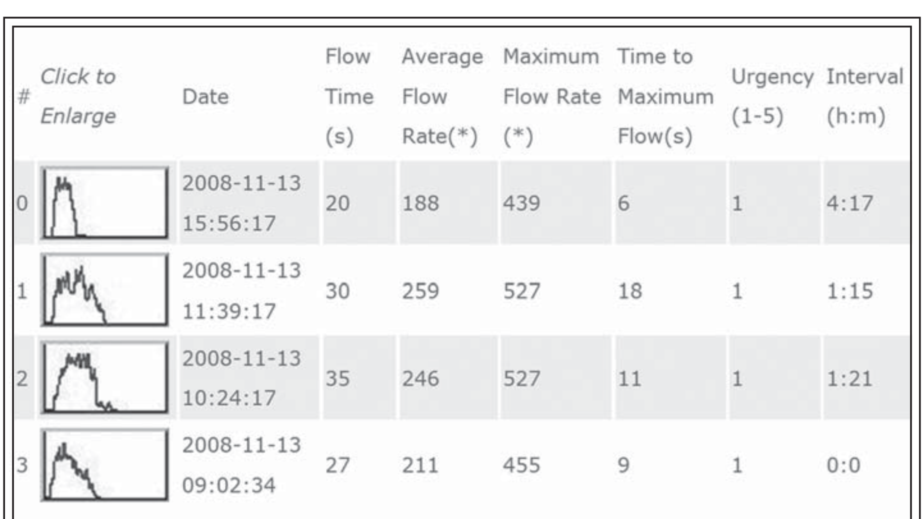
Materials and methods

Study subjects

A total of 52 healthy student volunteers age 20–25 (13 women and 39 men) were enrolled in the initial pilot feasibility study. The subsequent comparative study of the SUF system with conventional uroflowmetry included 32 healthy asymptomatic male volunteers. All volunteers provided informed written consent to participate in the study, and all procedures were approved by the Institutional Review Board at the University of Vermont.

SUF system

The SUF system uses wireless and web technologies to digitally capture, analyze and store LUTS and urinary flow data. The data are recorded in real time using a conventional cellular phone. Urinary flow curve patterns (regular, irregular or intermittent) and urinary flow rate parameters (flow time, average flow rate, maximum flow rate and time to maximum flow rate) are derived from the acoustic emissions associated with urination resulting from the impact of a urine stream onto an air-water interface within a toilet bowl. The recorded sound is transformed into a flow curve (sonourogram or SUFm) representing the amplitude of the audio signal versus time corresponding to the strength and duration of the urinary flow. Graphic and metric analyses of multiple tests are stored in a prospective manner, providing a voiding record of each patient, Figure 1.



#	Click to Enlarge	Date	Flow Time (s)	Average Flow Rate(*)	Maximum Flow Rate (*)	Time to Maximum Flow(s)	Urgency (1-5)	Interval (h:m)
0		2008-11-13 15:56:17	20	188	439	6	1	4:17
1		2008-11-13 11:39:17	30	259	527	18	1	1:15
2		2008-11-13 10:24:17	35	246	527	11	1	1:21
3		2008-11-13 09:02:34	27	211	455	9	1	0:0

Figure 1. Four consecutive micturitions recorded by a single study participant as displayed on the password-protected website.

Symptoms, including voiding frequency and nocturia, are recorded automatically and stored with an associated time stamp. The degree of urgency and the presence or absence of urge incontinence are recorded manually by the patient at the end of the recording by entering an urgency score. This is accomplished by pressing a number from 1 to 5 on the phone key pad corresponding to the following previously described five point Urgency Rating Scale:[13,14] 1, no urgency ("I felt no need to empty my bladder but did so for other reasons"); 2, mild urgency ("I could postpone voiding as long as necessary without fear of wetting myself"); 3, moderate urgency ("I could postpone voiding for a short time without fear of wetting myself"); 4, severe urgency ("I could not postpone voiding but had to rush to the toilet in order not to wet myself"); 5, urgency urinary incontinence ("I leaked before arriving at the toilet").

Pilot and comparative trials

In the initial pilot feasibility test of the SUF system on student volunteers, each participant was first trained in the use of the system and then asked to collect a minimum of two SUF recordings and respond to investigators with a list of problems encountered using the system and suggestions for possible improvements. The students were instructed to perform tests under standard in-home conditions when physiologically ready. In the subsequent comparative study, male volunteers were asked to record their urinary flow rate using both the SUF system and conventional uroflowmetry. Flow parameters were first recorded using the Dantec Urodyn 1000 flowmeter at pre-set times, thus mimicking outpatient clinic appointments. Participants subsequently recorded natural urination events at home using SUF. Test-to-test variability was compared between the two data sets. Flow time, maximum flow rate, time to maximum flow rate and average flow rate were compared, Figure 2. Unmodified personal cell phones were used for all audio recording and data acquisition.

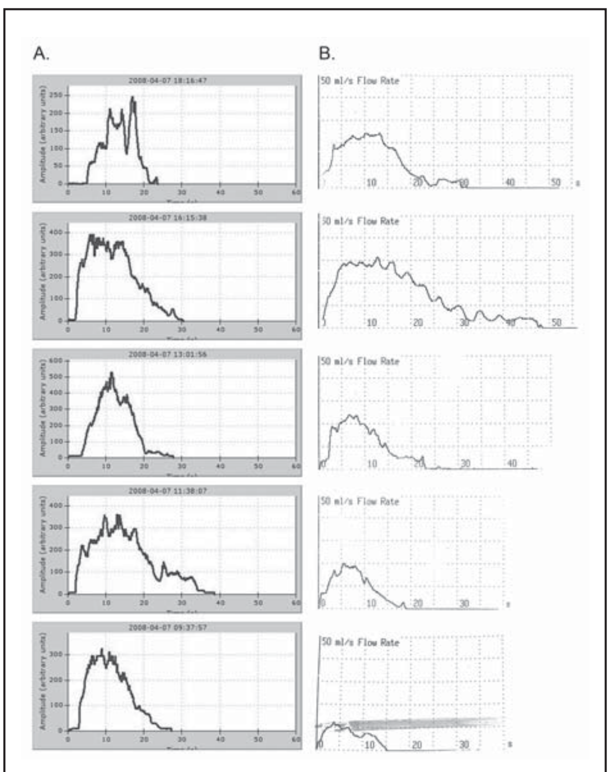


Figure 2. Example of a side-by-side comparison of five uroflow recordings performed by a single volunteer at preset times in the clinic (B) with five SUFm recordings subsequently performed at home when physiologically ready (A). SUFm showed significantly higher test-retest reproducibility.

Statistical analysis

We compared the reproducibility of each test by calculating the standard deviations and coefficients of variation for each category of recorded data. The coefficient of variation for values obtained from uroflowmetry recordings and SUFm were compared for each parameter using paired Student's t-tests. Individual test-to-test variability was evaluated using box-and-whisker plots in which the box displays the standard deviation for that particular individual in that particular data set, and the lines (whiskers) show the maximum and minimum values. A p value < 0.05 was considered significant.

Results

In the pilot feasibility study, the values recorded from the 52 participants differed between men ($n = 39$) and women ($n = 13$). In 23% of cases, one or two initial sonourograms contained artifacts that were not seen in subsequent tests, suggesting a modest learning curve for some individuals. Ninety-four percent of the recordings obtained from male volunteers displayed bell-shaped flow curves typical for a voiding pattern of a healthy individual, Figure 1. Significant variability was noted among female volunteers. The approach for data entry and acquisition of the test results were well accepted, and all participants judged the SUF system easy to use.

In the comparative study of standard uroflowmetry recordings and SUFm examining 32 healthy asymptomatic male volunteers (age 18-61), the coefficient of variation for values obtained from SUFm was significantly lower for voiding time ($p < 0.001$) and significantly higher for average flow rate ($p = 0.009$); maximum flow rate and time to maximum flow rate were not significantly different between the two testing methods, Table 1.

TABLE 1. **Mean coefficient of variation.**

	Voiding time	Maximum flow rate	Time to maximum	Average flow rate
Uroflowmetry	0.34	0.35	0.25	0.17
SUFm	0.17	0.32	0.20	0.29
CV difference (SUFm-UF)	-0.17	-0.03	-0.05	0.11
p value*	< 0.001	0.73	0.30	0.009

*paired t-test.
The coefficient of variation (CV) was significantly lower for voiding time, significantly higher for average flow rate, and not significantly different for maximum flow rate or time to maximum flow rate.

A box-and-whiskers analysis was applied to display the differences in variability between the data sets for two methods for each individual participant. In 62% of study subjects, test-to-test variability for voiding time was lower for SUFm than for standard uroflowmetry; in 43.8% of subjects, the variability in maximum flow rate values was lower for SUFm; and in 56% of subjects, the variability in time to maximum flow rate values was lower for SUFm, Figure 3 and 4. The ten subjects with the highest standard deviation with respect to

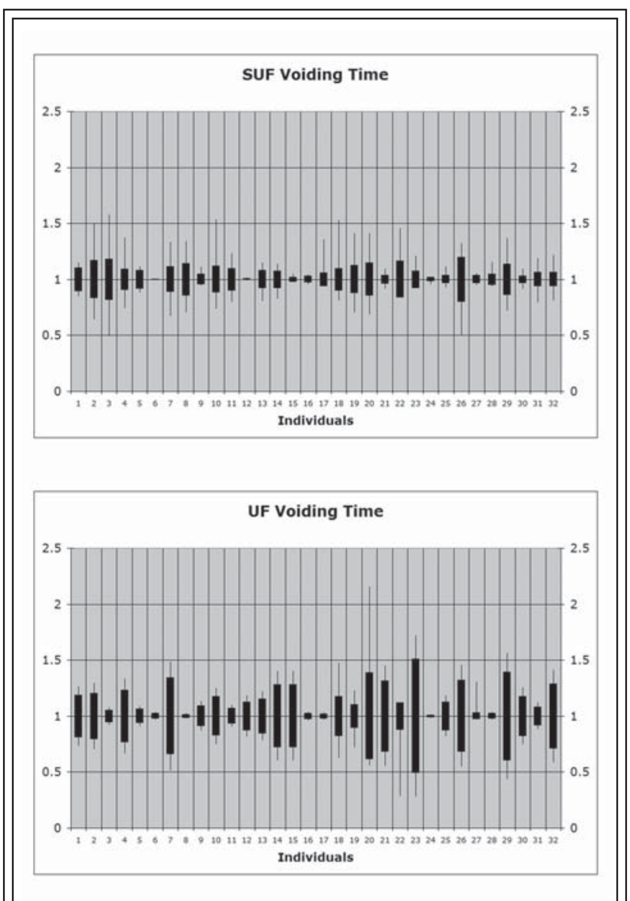


Figure 3. A box-and-whiskers-plot comparison of test-to-test variability of voiding time values. Note that test-retest variability was significantly lower in the SUF group ($p < 0.001$), and the ten individuals with the most extreme variability (highest standard deviation) in flow time were all in the uroflowmetry (UF) group.

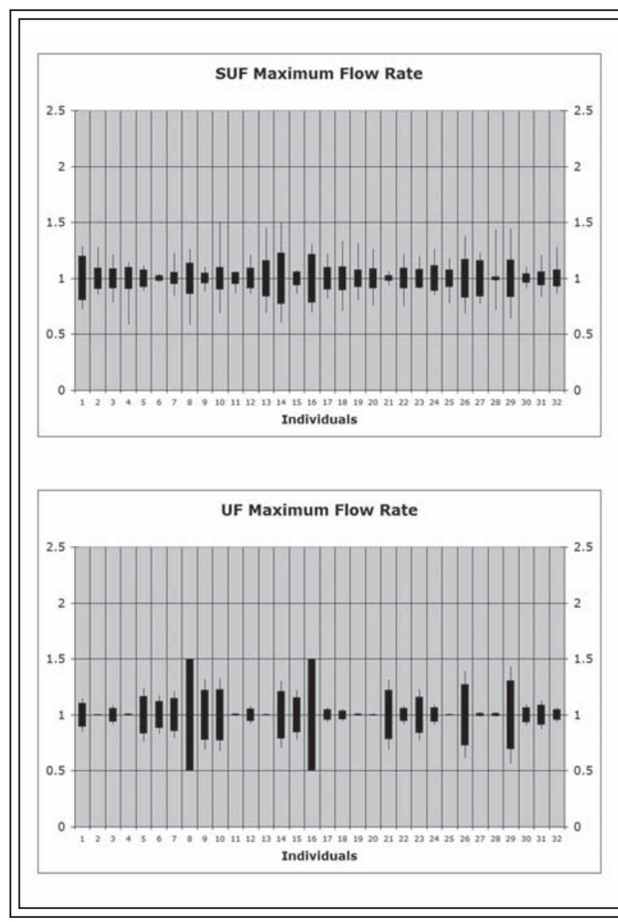


Figure 4. A box-and-whiskers-plot comparison of test-to-test variability in maximum flow rate. Although the number of subjects with greater variability was slightly higher in the SUF group, all four individuals with very high variability were in the uroflowmetry (UF) group.

voiding time values and the four subjects with highest standard deviation with respect to maximum flow values all occurred in the data set obtained by standard uroflowmetry.

Discussion

It has long been recognized that lower urinary tract dysfunction can be suspected simply by listening to the sound of a patient's voiding. In 1954 Nesbit suggested observation of a male child while voiding, and subsequently several studies have demonstrated a correlation between the sounds associated with micturition and urinary flow strength and pattern.[15] In 1966, Keitzer and Huffman first proposed a voiding audiograph as a test for voiding dysfunction.[16] This method was based on converting the kinetic energy from the force of the urinary stream into sound energy. Their measuring device consisted of steel graduate which served both as a urine collection device and a resonance chamber, microphone, tape recorder and a rectifying unit which transformed the sound into a voiding curve. A research team, consisting of an urologist and a physicist, analyzed recordings from almost three thousand voiding audiograms and described patterns consistent with normal, compensated, and decompensated voiding curves. A similar method was examined in 1991 by Koiso et al, who identified disturbances in the urinary stream based on analysis of the urethral sounds during micturition.[17] This study documented that in contrast to healthy volunteers, patients with BPH exhibited sounds in the posterior urethra caused by turbulent urine flow. While previous methods required substantial equipment, current technologies allow this principle to be applied as a user-friendly, portable testing system that does not require a specialized device. With more than 2 billion cell phones in use around the world and wireless networks growing faster and more capable each year, mobile cell technology offers a powerful new platform to support and extend healthcare delivery.

SUF, in its current form, is equivalent to conventional uroflowmetry in its capacity to identify hesitancy, intermittency, and weak or irregular urinary stream. Test-to-test variability in voiding time obtained from SUFm is significantly lower than that recorded using standard uroflowmetry, indicating that when the patient has the opportunity to record uroflow under natural conditions, the voided volume is likely to be more reproducible than when the test is administered on demand in the doctor's office. This confirms previous studies that have documented greater consistency in voided volumes with home uroflowmetry.[18,19] The variability in values for maximum flow rate and time to maximum flow rate obtained from SUFm and uroflowmetry was comparable, although even here there was a trend toward lower variability in SUFm-measured values. Overall, parameters obtained from SUFm were more consistent, with all extreme variations occurring in the uroflowmetry group. It is reasonable to expect the difference in test-to-test variability between the two methods to be even greater in patients suffering from lower urinary tract dysfunction, for whom urgency makes delaying urination difficult.

The currently used SUFm algorithm measures the intensity (amplitude) of the recorded sound as a function of the volume of urine passed per unit time. At this stage of development, it captures maximum and average urinary flow rates in relative, not absolute, values. The system in its current form could be used to monitor changes in flow parameters in a single patient. Because individual patients serve as their own controls, SUF could prove useful for monitoring disease progression or as a follow-up tool to evaluate treatment outcome. Ongoing studies seek to correlate sound parameters with flow-rate parameters expressed in milliliters per second. Identification of a suitable algorithm for extracting flow parameters with a sufficient degree of accuracy will allow for calculation of voided volume. Together with medical history, physical examinations, and post-void residual measurements, SUF could help establish the degree of lower urinary tract dysfunction and severity of LUTS. In addition, it could be used in epidemiological studies designed to evaluate voiding function in selected populations and in clinical studies testing new treatment options.

Unlike previously used electronic methods for recording of LUTS,[20,21] SUF does not require a specially designed device. It is easier to use and records a significant proportion of the information automatically. The system also allows for recording and quantification of every urgency episode, regardless of whether it is accompanied by a micturition, simply by dialing the pre-programmed SUF number and entering a number from 1 to 5 to grade the level of urgency. We believe that using a cell phone for this purpose is more reliable then entering the same information on a paper chart, and certainly more cost-effective than using a specialized electronic data-entry device.

Currently, symptoms in men with BPH are generally quantified based on the International Prostate Symptom Score (IPSS). IPSS does not include a question for quantification of urgency. Moreover, voiding diaries frequently used to quantify urinary urgency do not record characteristics of urinary flow (hesitancy, intermittency and weak urinary stream). Since BPH patients frequently suffer from both obstructive and irritative voiding symptoms, a test capable of reliably recording both types of symptoms could complement current diagnostic methods.

Conclusions

SUF in its current form reliably records urinary frequency, degree of urgency, urge incontinence and nocturia. Urgency can be recorded whether it is followed by micturition or not. Although not yet equivalent to uroflowmetry in recording flow-rate parameters, SUF allows for evaluation of hesitancy, intermittency, weak urinary stream, flow time and time to maximum flow. We believe that if developed to its full potential, SUF would be as accurate and reliable as uroflowmetry, and the flow parameters obtained could subsequently be used to record the even more clinically relevant parameter of voided volume. □

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