Evaluation of proudP: A sound-based approach to uroflowmetry

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ABSTRACT

Introduction: We sought to assess the performance of the proudP AI algorithm, integrated into a mobile application, in estimating uroflow curves and parameters using recorded urination sounds.

Methods: A direct comparison was made between the peak flow rate (Qmax), voided volume, and uroflow curves predicted by the proudP algorithm and those obtained through established validation methods. A hardware uroflow simulator replicated uroflow profiles by precisely controlling water flow rates and extracting corresponding sound data. Ten uroflow profiles, representing typical patterns observed in male subjects, were

KEY MESSAGES

- The proudP AI algorithm reliably estimates uroflow parameters based on urination sounds, closely matching traditional uroflowmetry devices.
- A specially designed uroflow simulator validated the algorithm, replicating varied uroflow patterns for accurate comparison.
- The proudP application shows consistent accuracy across different smartphone models, offering robust performance metrics.
- The application facilitates at-home uroflowmetry, addressing common issues like insufficient voided volumes and diurnal variations seen in office settings.
- ProudP provides a viable option for remote monitoring of urinary health, improving patient convenience and clinical outcomes.

selected. Simulation experiments with proudP were conducted using a standard toilet setup. The uroflow simulator was calibrated to reproduce uroflow profiles, and validation was performed against a Flowmaster uroflowmetry device. Statistical analysis included descriptive summaries, Bland-Altman analysis, and Concordance Correlation Coefficient (CCC) analysis.
Results: The proudP accurately captured various uroflow patterns generated by the simulator, with low standard deviations in Qmax predictions and biases near zero. The SDs of voided volume were slightly larger, primarily due to uroflow patterns with extended voiding times. The study validated the accuracy of proudP against in-office uroflowmetry, demonstrating robustness across different smartphone models.
Conclusions: proudP proved to be as accurate as in-office uroflowmetry in estimating uroflow rate across various patterns. Its convenience in home monitoring offers patients a means to observe their urination patterns accurately, while enabling healthcare professionals to gain detailed insights remotely. proudP emerges as an essential solution for clinical practice and urological research.

INTRODUCTION
Uroflowmetry stands as a vital noninvasive method for quantifying urine flow, encompassing measurements of flow rate, voided volume, and voiding time. However, its efficacy can be hindered by challenges such as a high rate of nondiagnostic outcomes or delays in achieving adequate voided volume [1,2]. The American Urological Association (AUA) guidelines recommend a minimum voided volume of 150 ml for precise clinical interpretation. Yet, attaining uroflow data exceeding this threshold proves challenging [3]. Notably, over 50% of in-office uroflowmetry results fall short of this volume, rendering them inefficient and wasteful [3]. Additionally, uroflow patterns exhibit significant diurnal variations [4], and a single in-office measurement may not accurately reflect a patient's typical voiding habits [5]. Recognizing these limitations, there is growing interest in sound-based home uroflowmetry as a potential solution to enhance the efficacy of uroflow assessment.

This study aimed to evaluate the performance of our AI algorithm, named proudP, integrated into a personal urinary health monitoring mobile application developed by Soundable Health, Inc (San Jose, CA, USA). The primary objective is to assess the proudP's ability to estimate uroflow curves and parameters based on recorded urination sounds.

METHODS
The study design facilitated a direct 1:1 comparison of the Qmax, voided volume, and uroflow curves predicted by the proudP algorithm with those obtained through established validation methods. A hardware uroflow simulator was employed to replicate uroflow profiles by precisely controlling water flow rates and extracting corresponding sound data. These simulated profiles were then compared with the predictions generated by the AI algorithm.

Ten uroflow profiles, covering a spectrum of typical patterns observed in male subjects, were selected for the study. Simulation experiments with the proudP were conducted using a standard toilet setup, with controlled water streams directed at the toilet bowl's center while sound analysis was performed.

Uroflow simulator

The main component of the uroflow simulator is a MCP-Z pump standard gear drive (Ismatec, Germany). The pump gear drive consists of a pump-head with an input and an output channel for the water to flow in one direction and a PC-controllable-RS232 interface to adjust the RPM (Revolutions Per Minute) of the DC motor inside the pump gear drive for controlling the water flow rate. The pump gear drive was instructed to adjust the water flow rates at an interval of 0.1 sec, which allows for a uroflow profile to be reproduced at a high resolution. The pump gear drive was calibrated once at each setup. Python3.6.9 was used to create a software program to convert the flow rate of the uroflow profiles into RS232 codes runnable on the gear drive [6].

Experimental setup

To mitigate interference from ambient noise, the study was conducted in two separate rooms. In one room (the storage room), the pump gear drive was placed on a chair with 6mm (inner diameter) silicone tubes connected to each channel of the pump head. Other ends of the input- and output-channel tubes were placed at the bottom of a water tank and carried to another room, respectively.

In the second room (the bathroom), the output-channel tube was bent to point its end to the center of the toilet bowl at an angle of 30 degrees by fixing the tube to a metal stand with a rotatable arm. Next, a hose screw clamp was placed at the end of the output-channel tube and tightened to distort the circular shape of the tube end into a vertical slit to imitate human physiology. [7] Additionally, two smartphones (iPhoneXR and Galaxy S21 5G) with the proudP applications were placed on a toilet stand to record sound for analysis. The comparison test was repeated 5 times for each uroflow profile. The setup figures are shown in Figure 1 and Supplementary Figure 1.

Simulated profiles

The shape or pattern of the uroflow curve is typically classified into various patterns such as normal, plateau, intermittent, saw-tooth, and supervoider as shown in Supplementary Figure 2. [19]

We considered targeting various uroflow curve patterns that have typical clinical ranges of Qmax, VV, and VT values. The profiles consist of 4 normal flows, 3 saw-tooth flows, 1 intermittent flow, and 2 plateau flows (Supplementary Figure 3). The supervoider flow was excluded because the uroflowmeter Flowmaster used to validate the uroflow simulator was unable to measure flow rates above 30 ml/s.

Validation of uroflow simulator

The uroflow simulator was validated with a Flowmaster(MMS, Netherlands) to see if the uroflow simulator can accurately reproduce the selected 10 uroflow profiles. The Flowmaster is a hardware based uroflowmetry used as in-office uroflowmetry widely around world., and it calculates the uroflow parameters by analyzing the change of urine weight.

Each uroflow profile was simulated with the uroflow simulator on the Flowmaster 3 times to check repeatability. The Qmax, Q(t), and VV values from the Flowmaster were compared with the uroflow measures from the originally selected uroflow profiles for validation.

Statistical analysis

A descriptive summary of the 10 uroflow profile results from the Flowmaster was given in means and standard deviation (SD) for Qmax and VV. Comparison analysis of the Flowmaster measures and the estimated uroflow profile measures from the proudP algorithm for each type of smartphone was performed using Bland-Altman analysis, where the Bland-Altman analysis provided biases(mean of differences), SD of differences, and limits of agreement of the two uroflow measures (Qmax and VV) for all 10 uroflow profiles. The regression analysis of Qmax, Q(t), and VV measures was demonstrated with Concordance correlation coefficient (CCC). The CCC captures the agreement of two parameters by measuring variation from the line y = x. [9] Statistical analysis of these measures was done with Python3.6.9 (https://www.python.org) and the scientific computing package Numpy, version 1.5.3 (https://numpy.org).

RESULTS

A detailed report of the 10 uroflow profiles from the Flowmaster is summarized in Table 1, which shows the results of 3 repeated measurements of each uroflow pattern. The ranges of Qmax and VV measures were 4.2 to 25.1 ml/s and 134.0 to 521.3 ml, respectively, and the standard deviations of all uroflow patterns for Qmax were within 0.8 ml/s and 0.9 ml for VV. Since the variation between the measurements is low, only the first measure of the Flowmaster is used to compare with the subsequent proudp data in each profile.

The comparison analysis of the Qmax, VV, Q(t) measures between the Flowmaster and the proudP application were provided in the Bland-Altman plots shown in Supplementary Figures 4 to 9 and summarized in Table 2 for the iPhone XR and Table 3 for the Galaxy S20 G5. Bland-Altman analysis of the bias of the mean Qmax was within 0.9 ml/s, and the bias of the mean VV did not exceed 36 ml for both smartphones. In terms of standard deviation, the mean Qmax had SD less than 1.4 ml/s, and the SD of the mean VV was within 31 ml for both smartphones. The Galaxy smartphone showed larger limits of agreement for the mean VV than the iPhone (97 ml vs 44ml) and a smaller limit of agreement for Qmax (3.7 ml/s vs 2.8 ml/s, respectively). The Flowmaster graphs for normal, saw-tooth, and intermittent flow are showing in Supplementary Figure 10.

The associations of the three uroflow measures between the Flowmaster results and the proudP application were provided in CCC analysis. The CCC measures of the Qmax, VV, and

Q(t) for the iPhone were 0.968, 0.989, and 0.931 respectively and the measures for the Galaxy phone were 0.981, 0.949, and 0.910 respectively.

DISCUSSION

Our results show that the proudP can accurately capture the various uroflow patterns generated by the uroflow simulator, which was well validated against an in-office uroflowmetry. The SD of Qmax predicted by the proudP were within 2 ml/s, which is very low considering the error range of Qmax of the simulator is 1 ml/s [10] and the biases of Qmax were near zero. This result was the same for both phone types, which indicate that the proudP is robust to different microphone types. The SDs of VV predicted by the proudP were slightly large, but they were mainly raised by the few uroflow patterns with long voiding time, which accumulates small bias over time, but does not distort the overall uroflow pattern shape which is supported by the high CCC measure of Q(t).

Several limitations should be noted in this study. Confounding factors, such as variations in ambient noise levels, smartphone microphone sensitivity, and the fixed incident angle of the water stream, could affect reliability and reproducibility. The small sample size of ten simulated uroflow profiles may not capture the full spectrum of voiding patterns observed in clinical settings. Theoretical cases may not encompass every voiding pattern variable, with differences in urine stream characteristics and patient behavior presenting potential limitations. Further validation with more diverse samples is needed to ensure robustness and generalizability. Additionally, variations between urine weight and voided volume could impact measurement accuracy. However, load cell and spinning disk uroflowmeters, which are already widely used in clinical practice, calculate voided volume by assuming the density of urine is approximately 1 g/ml. Therefore, we assumed that the change in weight of water from the simulator was equivalent to the voided volume in this study.

Some limitations specific to the the study design of the uroflow simulator also exist and must be noted. First, the 6 mm-tubing of the uroflow simulator was chosen to simulate the male urethra whose meatal size is on average 6 mm according to [11]. However, the meatus varies by age, shape, and ethnicity [12][13], and a single tubing size may not represent the entire population.

Another point to address is the fixed incident angle of the uroflow simulator. The incident angle was fixed to 30 degrees to ensure the same outcome during multiple measurements and restrict water stream to fall only onto the water surface in the toilet bowl. However, in the real world, male subjects may constantly vary the incident angle of urination.

Other variables, such as the height and the direction of the stream, may also affect the sounds the uroflow simulator produces. However, to our knowledge, this is the first study to use a human-like uroflow simulator to directly compare the flow rates of the various uroflow patterns on a standard toilet with a sound-based uroflowmeter, in this case, proudP application. The design of the uroflow simulator can be further enhanced by including the aforementioned cases, but even with the current design, this study well validates the accuracy of the proudP performance in the various uroflow patterns if used by average male subjects.

CONCLUSIONS

This study shows that proudP is as accurate as in-office uroflowmetry for estimating uroflow rate of the various uroflow patterns while also providing the convenience of monitoring at home. It can help patients observe their own natural urination patterns accurately, easily, conveniently by capturing urination sounds in their daily lives, and enable doctors to gain more detailed and deeper insight by monitoring it remotely. The proudP is an essential solution for clinical practice and research in urology.

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Competing interests: B. Chughtai is a consultant for Soundable Health.

FIGURES AND TABLES

Figure 1. Uroflow simulator experiment diagram.

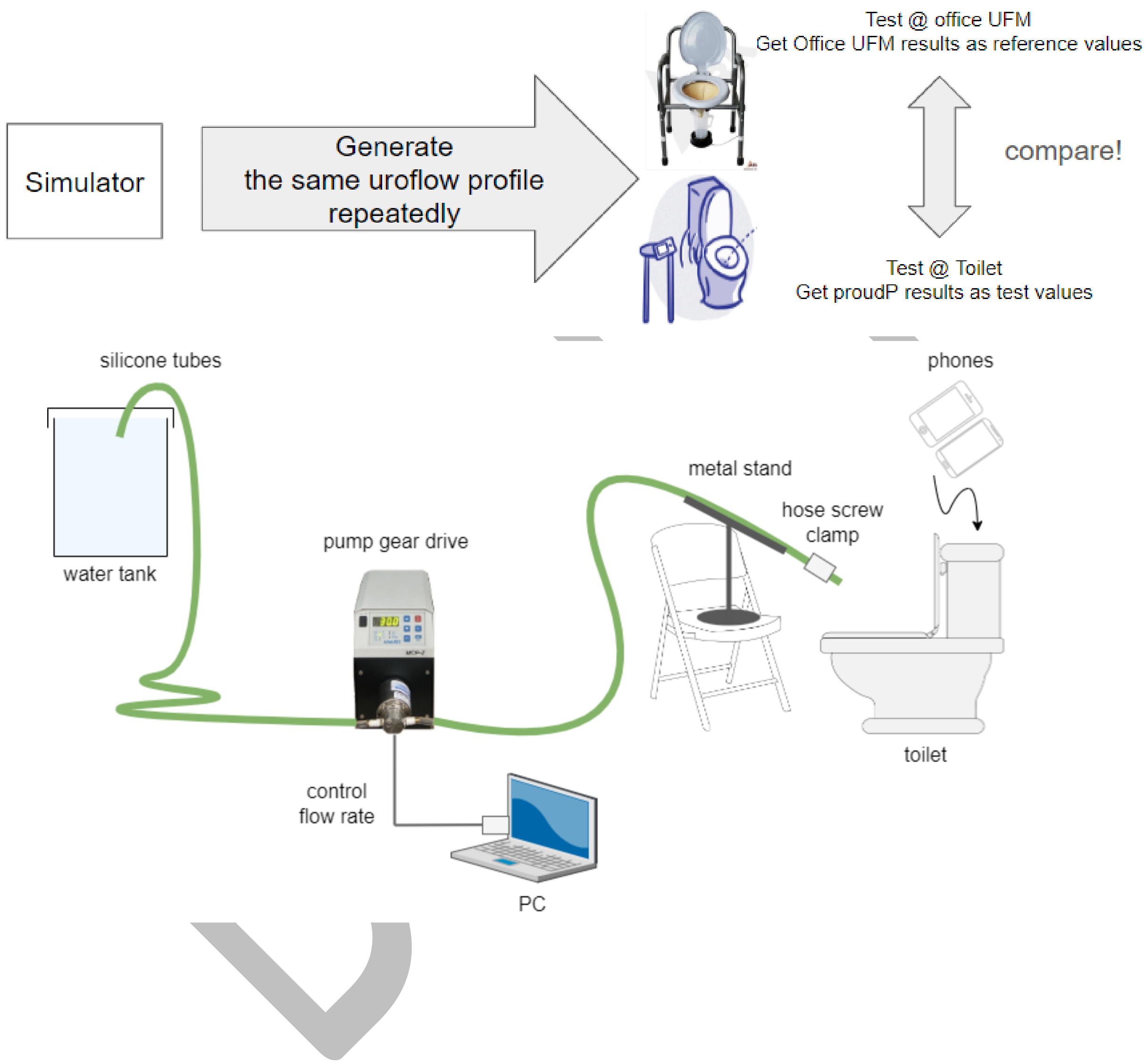

Table 1. Uroflow parameters of the uroflow patterns from Flowmaster		
Uroflow patterns	**Qmax (ml/s)**	**VV (ml)**
Normal flow 1	22.0±0.8	142.0±0.9
Normal flow 2	15.0±0.2	180.7±0.2
Normal flow 3	14.0±0.1	380.0±0.5
Normal flow 4	25.1±0.1	289.3±0.5
Saw-tooth flow 1	12.2±0.1	317.9±0.9
Saw-tooth flow 2	6.2±0.2	134.1±2.2
Saw-tooth flow 3	15.7±0.2	447.6±1.4
Intermittent flow 1	21.6±0.5	521.3±0.2
Plateau flow 1	4.2±0.1	214.9±1.0
Plateau flow 2	6.4±0.2	428.9±2.3

*Values are shown in mean ± SD. See Appendix B for each uroflow pattern measured from Flowmaster.

Table 2. Bland-Altman analysis of uroflow parameters between Flowmaster and proudP for the iPhone XR.		
	Qmax (ml/s)	**VV (ml)**
Bias	-0.930	6.520
SD	1.415	19.204
Limit of agreement	[-3.704, 1.844]	[-31.119, 44.159]

Table 3. Bland-Altman analysis of void parameters between the Flowmaster and proudP for the Galaxy phone		
	Qmax (ml/s)	**VV (ml)**
Bias	0.310	35.520
SD	1.285	31.310
Limit of agreement	[-2.208, 2,.828]	[-25.848, 96.888.]