JOURNAL OF ENDOUROLOGY
Volume 00, Number 00, Month 2026
Mary Ann Liebert, A Part of Sage
Pp. 000–000
DOI: 10.1177/08927790261430997

# Comparative Pressure Measurement Performance of the Glean Urodynamics System—a Novel Wireless and Catheter-Free Urodynamics Device

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## Abstract

***Objective:*** The Glean® Urodynamics System was developed to enable catheter-free, wireless assessment of lower urinary tract function for use in ambulatory urodynamic testing. This study assesses the performance of the Glean Urodynamics System relative to the Laborie Goby™ conventional urodynamics (UDS) system using a human bladder model.

***Methods:*** Thirty Glean intravesical pressure sensors and 30 air-charged catheters were compared relative to a reference sensor. Three pressure simulations were conducted in the bench-top human bladder model (stepped, sinusoidal, and ramping) on each test device to evaluate rise and fall times, bandwidth, maximum error (accuracy), and linearity. Data are presented as means and standard deviations and compared using independent sample *t*-tests.

***Results:*** The Glean intravesical pressure sensors showed significantly faster rise time (0.104 seconds) and fall time (0.111 seconds) than the comparator (0.172 and 0.264 seconds, respectively; both, $p < 0.001$ between groups). The bandwidth of the Glean sensors more closely matched the tested maximum frequency of 5 Hertz (Hz) compared with the comparator (4.978 Hz *vs* 2.250 Hz; $p < 0.001$). The maximum error was significantly lower with the Glean sensors than the comparator (6.882 *vs* 21.549; $p < 0.001$). Linearity showed that both behaved linearly; however, the Glean sensors performed significantly better ($p < 0.001$ between groups).

***Conclusion:*** Comparative testing demonstrated equivalent or better performance of the Glean Urodynamics System's intravesical pressure sensors relative to a conventional UDS system's air-charged catheters, including greater bandwidth, increased dynamic response, and reduced maximum error. These results support the superior performance of the Glean Urodynamics System for urodynamic monitoring over a conventional catheter-based UDS system.

**Keywords:** urodynamics, lower urinary tract symptoms, urologic diseases, urinary bladder, medical device

## Introduction

Urodynamics (UDS) is widely used to assess the function of the lower urinary tract and aids in the diagnosis and treatment of lower urinary tract dysfunction, such as overactive bladder, urinary incontinence, and bladder outlet obstruction.[1,2] Conventional UDS systems rely on transurethral and rectal or vaginal catheters (e.g., air- or water-filled) connected to external consoles to measure intravesical and abdominal pressures. These conventional UDS systems, however, have several mechanical and practical limitations, including signal distortion, artifacts, and drift, causing inaccurate pressures that lead to incorrect diagnoses.[3–5] They also cause patient discomfort, limit the patient's mobility during testing, and often do not reproduce the patient's lower urinary tract symptoms,[1] which further contributes to misdiagnoses and overtreatment.[6–9] A high-quality UDS study relies on accurate measurements that capture the full range of physiological pressures over time.

The Glean® Urodynamics System (Bright Uro, Inc.; Irvine, CA) was developed to address these limitations through the use of a wireless, catheter-free, intravesical

Bright Uro, Inc., Irvine, California, USA.

sensor, which allows ambulatory measurement of vesical pressure.[10–13] Given its novel design, the performance and accuracy of the Glean Urodynamics System are not yet established. Previous studies characterizing and comparing the performance of existing conventional UDS catheters have demonstrated that accuracy, linearity, and frequency range (bandwidth) are critical analytic metrics in the evaluation of urodynamic pressure sensors.[14,15] The aim of this study was to evaluate the performance of the Glean Urodynamics System intravesical pressure sensor in comparison with a conventional UDS system's air-charged catheters using a human bladder model (HBM).

## Methods

### *Glean Urodynamics System*

The Glean Urodynamics System is composed of three integrated hardware components—an intravesical pressure sensor, an insertion tool, and a uroflowmeter—and interconnected software applications for event logging and analysis. This system allows clinicians to perform UDS, including uroflowmetry, cystometrogram, urethral pressure profile, and micturition studies. The Glean Urodynamics System is a Food and Drug Administration (FDA)-cleared diagnostic medical device.

The single-use Glean intravesical pressure sensor (Fig. 1) is a flexible device designed to collect pressure data while positioned inside the bladder. The sensor is a long, narrow silicone oil-filled tube (15 French [F]) with a coudé tip (18 F) that houses an internal flexible circuit board containing a microprocessor, a battery, a memory module, firmware, and a pressure sensor mated to a stainless steel "spine" to help define the curvature of the sensor. Changes in pressure surrounding the sensor are transmitted through the silicone oil to the pressure sensor and converted into a digital signal. The flexible nature of the sensor allows it to be straightened for insertion using the insertion tool (20 F); then, once placed in the bladder, the sensor relaxes back into its circular configuration, helping maintain appropriate positioning during ambulatory UDS monitoring. A removal string remains external to the body and is used to remove the sensor at the end of the UDS study to allow for transfer of the collected vesical pressure data to the web-based application.

### *Conventional urodynamics system*

The Laborie Goby™ system (Laborie Medical Technologies Corporation; Portsmouth, NH) is an FDA-cleared, commercially available, and widely used UDS system. It consists of a pressure recorder, central hub, computer with applicable software, disposable air-charged pressure catheters (urethral and abdominal; TDOC® Air-Charged™; Laborie Medical Technologies Corporation, Portsmouth, NH), uroflowmeter, and electromyography electrodes. The air-charged pressure catheter is composed of a small, sealed air-filled chamber at the catheter tip that is connected to an external pressure transducer, where changes in pressure compress the air, and those changes are transmitted through the air column to the transducer. In this study, only the components relevant to the evaluation of pressure were used.

### *Human bladder model*

The HBM is a custom-built bench-top closed feedback loop platform (Fig. 2) consisting of a rigid, water-filled test chamber, a calibrated reference pressure sensor (Omega Compound Gauge Pressure Transducer; Omega Engineering, Inc; Norwalk, CT), and a stepper motor lead screw linear actuation system that drives a hydraulic piston for precise control of chamber pressure. The distance traveled for the linear actuation system is dependent on pressure data collected from the reference pressure sensor. In this study, the chamber was filled with approximately 900 mL of tap water that was temperature controlled at 37°C. Pressure logs from the calibrated reference sensor provide reference measurements for all tests performed. Three identical HBMs were used in the study for efficiency.

### *Pressure simulations*

Thirty wireless Glean sensors and 30 air-charged catheters were tested under controlled simulation conditions. Three pressure stimuli were applied as follows: (1) step profiles with abrupt transitions between two pressure levels to evaluate rise and fall times; (2) sinusoidal profiles of oscillations (frequency sweep) as much as 5 Hertz (Hz) to evaluate bandwidth; and (3) ramp profiles consisting of successive step changes of 10 centimeters of water (cm $H_2O$) from 0 to

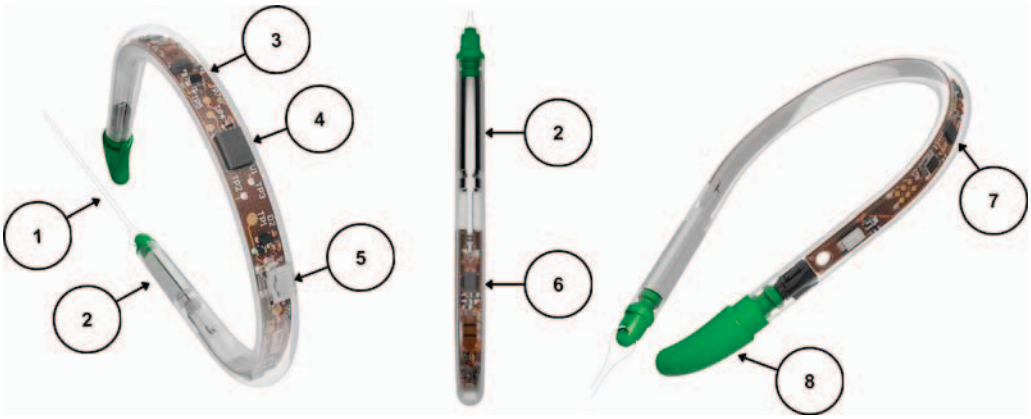


**FIG. 1.** Representative Glean Urodynamics System intravesical pressure sensor. The Glean Urodynamics System intravesical pressure sensor components include (1) removal string, (2) battery, (3) light-emitting diode (LED), (4) flash memory, (5) control button, (6) pressure sensor, (7) Bluetooth module, and (8) coudé tip.

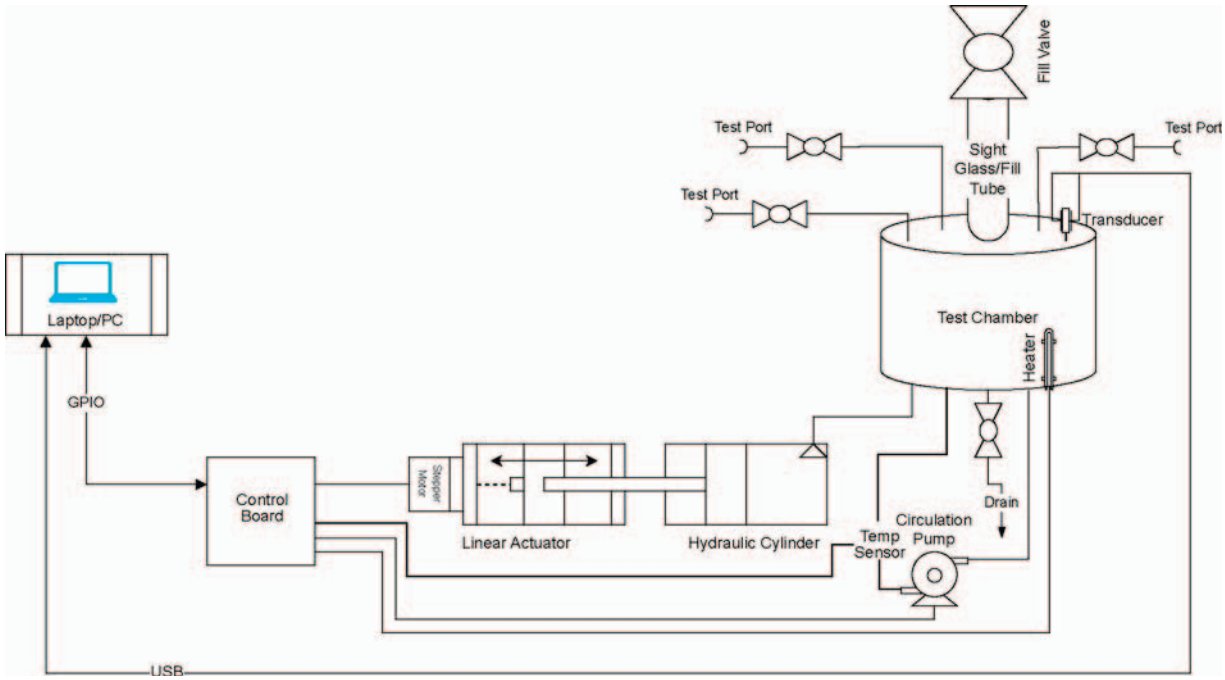


**FIG. 2.** Block diagram of the human bladder model. GPIO = general-purpose input/output; PC = personal computer; USB = universal serial bus.

320 cm $H_2O$ and back to evaluate maximum error (accuracy) and linearity. These simulations were selected to mimic rapid pressure changes in the bladder, like coughing and straining, and to evaluate the full range of bladder pressures that might be encountered in patients.

Three Glean sensors were placed in the HBM chamber during each test, whereas only one conventional catheter pair (i.e., urethral and abdominal) could be evaluated at one time, as they were required to be connected to an external transducer. Given the catheters are not wireless, they protruded from the chamber when tested with the tips inserted in sealed plugs to prevent any pressure leakage. The sensors and catheters were not tested in the chamber together. All Glean sensors and catheters were zeroed at the beginning of each test.

### *Performance metrics*

The following performance metrics for urodynamic pressure sensing were measured to evaluate the device's accuracy, responsiveness, and suitability for capturing both static and dynamic urodynamic signals. A brief review of relevant literature, including the International Continence Society guidelines, suggests these metrics for evaluating the performance of urodynamics equipment.[14,15]

Rise and fall times. Test devices were subjected to transient step changes and pulses in pressure from 0 to 320 cm $H_2O$ then held at 320 cm $H_2O$ for 60 seconds, followed by transient step changes and pulses in pressure from 320 to 0 cm $H_2O$. Rise time was defined as the time the device takes to change from 0% to 90% of the applied loading (upwards)

TABLE 1. MEAN (STANDARD DEVIATION) AND MEAN DIFFERENCES (95% CONFIDENCE INTERVAL) OF ANALYTIC METRICS BETWEEN THE GLEAN URODYNAMICS SYSTEM AND THE CONVENTIONAL URODYNAMICS SYSTEM

| *Metric (unit)* | *Glean Urodynamics System, mean (SD)* | *Conventional UDS system, mean (SD)* | *Mean difference between groups (95% CI)* | p-*value** |
|---|---|---|---|---|
| Rise time (s) | 0.104 (0.019)<br>*n* = 30 | 0.172 (0.053)<br>*n* = 29 | –0.068<br>(–0.089 to –0.048) | <0.001 |
| Fall time (s) | 0.111 (0.017)<br>*n* = 30 | 0.264 (0.054)<br>*n* = 28 | –0.154<br>(–0.174 to –0.133) | <0.001 |
| Frequency bandwidth (Hz) | 4.978 (0.013)<br>*n* = 30 | 2.250 (0.249)<br>*n* = 30 | 2.278<br>(2.637 to 2.819) | <0.001 |
| Maximum error (hPa) | 6.882 (1.477)<br>*n* = 30 | 21.549 (9.655)<br>*n* = 30 | –14.668<br>(–18.237 to –11.098) | <0.001 |
| Linearity (slope) | 0.988 (0.005)<br>*n* = 30 | 0.941 (0.048)<br>*n* = 28 | 0.0466<br>(0.029 to 0.064) | <0.001 |
| Linearity (*R*-squared) | 1.000 (0.000)<br>*n* = 30 | 0.999 (0.004)<br>*n* = 28 | 0.001<br>(–0.001 to 0.002) | 0.305 |

*Based on independent sample *t*-tests.
CI = confidence interval; hPa = hectopascals; Hz = Hertz; n = sample size; s = seconds; SD = standard deviation; UDS = urodynamics.

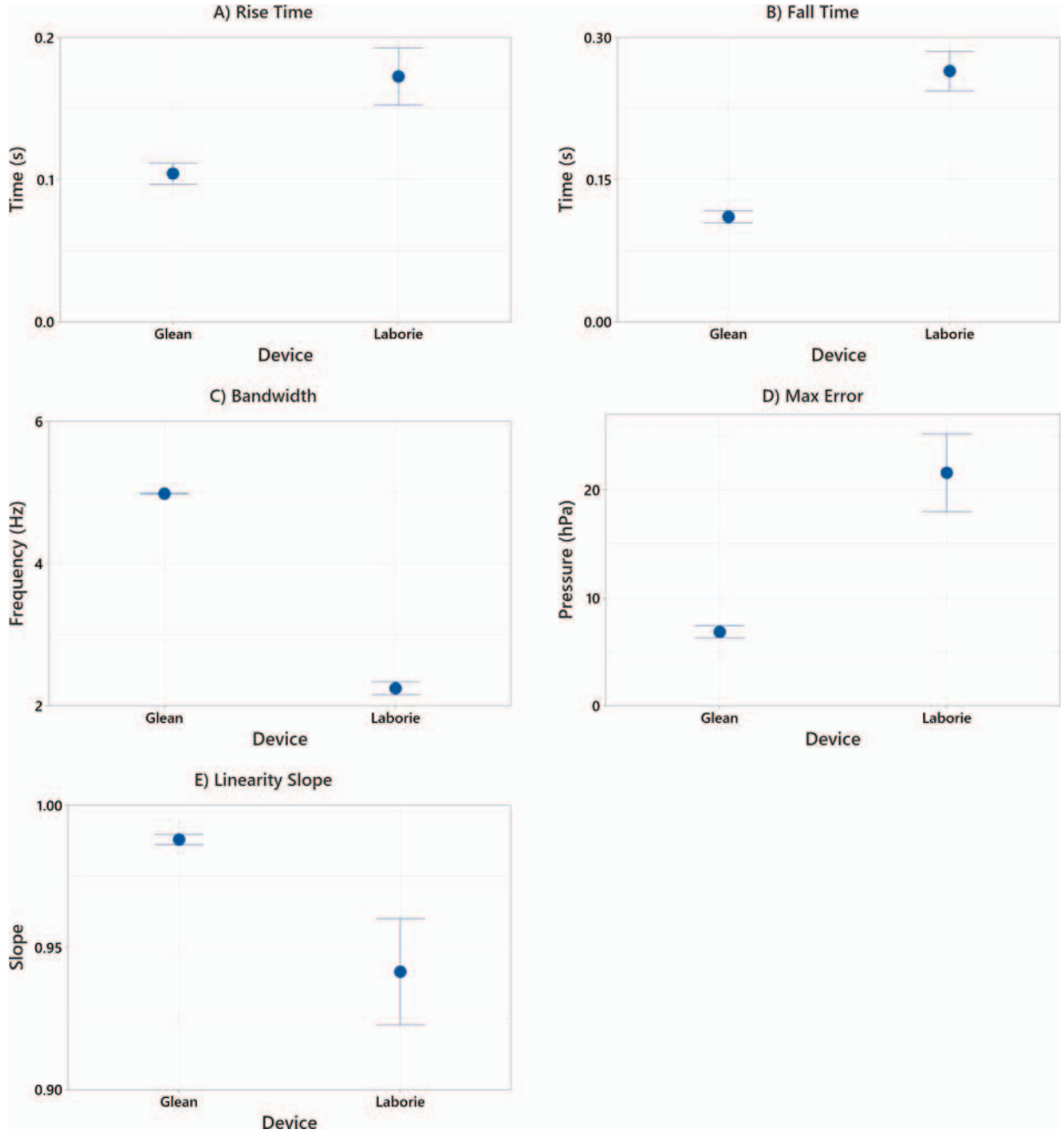


**FIG. 3.** Interval plots of analytic metrics. Interval plots with 95% CI for the mean for **(A)** rise time, **(B)** fall time, **(C)** bandwidth, **(D)** maximum error, and **(E)** linearity slope. The Y-axis in plots **(C)** and **(E)** has been truncated to enhance visualization of between-group differences. hPa = hectopascals; Hz = Hertz; s = seconds; CI = confidence interval.

pressure step from the time the device starts to respond. Fall time was defined as the time it takes the device to decrease from 100% to 10% of the applied unloading (downwards) pressure step, starting from the time the system starts to drop.

Frequency bandwidth. Test devices were subjected to a sine wave of changing frequency (1–5 Hz over 2 minutes for the full range of 0–320 cm $H_2O$). Bandwidth is computed by applying the Fast Fourier Transform (FFT) to the time series data from the sensor and then evaluating the magnitude of detected frequencies for each device. A rolling average is used to reduce noise from test artifacts, with the window size being based on the sample rate of each dataset. Bandwidth is defined as the frequency at which the recorded pressure amplitude drops below approximately 3 decibels of the applied pressure.

Maximum error. For each measurement taken by the test device, the closest preceding and anteceding measurement on the reference were used to calculate the linearly interpolated reference value, representing the true value of the HBM pressure chamber. Error was calculated using the following formula:

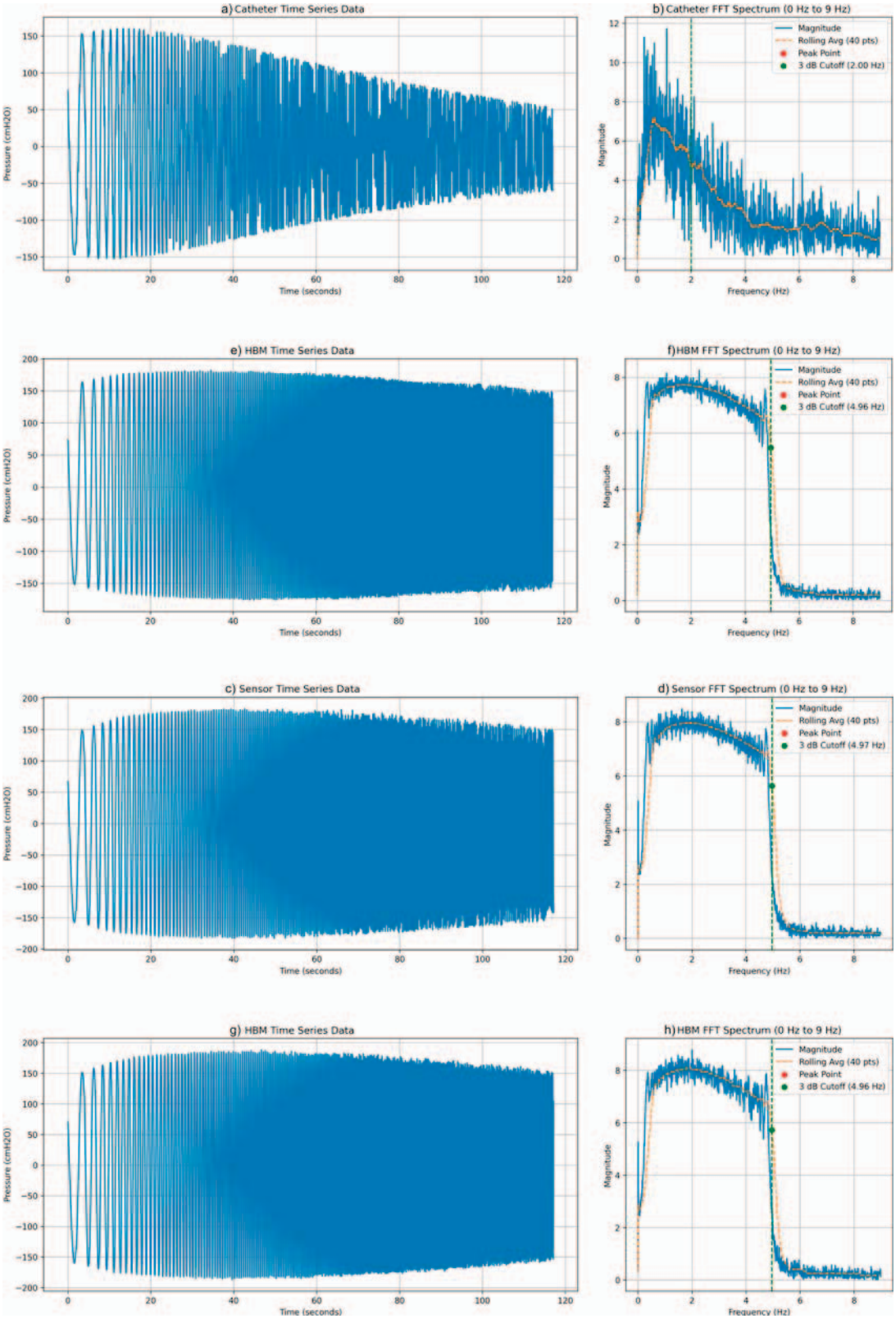


**FIG. 4.** Sample results of a sinusoidal pressure sweep. The bottom plots show the raw pressure signals **(E** and **G)** and the corresponding Fast Fourier Transform (FFT) **(F** and **H)** from the human bladder model reference pressure sensor, which converts the time-domain signal to the frequency domain. The 3 decibel (dB) point is approximated by finding the frequency at which the rolling average magnitude drops below 0.707 of the peak frequency. As the frequency increases, the air-charged catheter **(A** and **B)** fails to capture pressure amplitude, resulting in reduced spectral magnitude in the FFT, whereas the Glean intravesical pressure sensor **(C** and **D)** closely tracks the reference across the full test range, indicating a bandwidth of at least 0–5 Hz. Avg = average; cm $H_2O$ = centimeters of water; dB = decibel; HBM = human bladder model; Hz = Hertz.

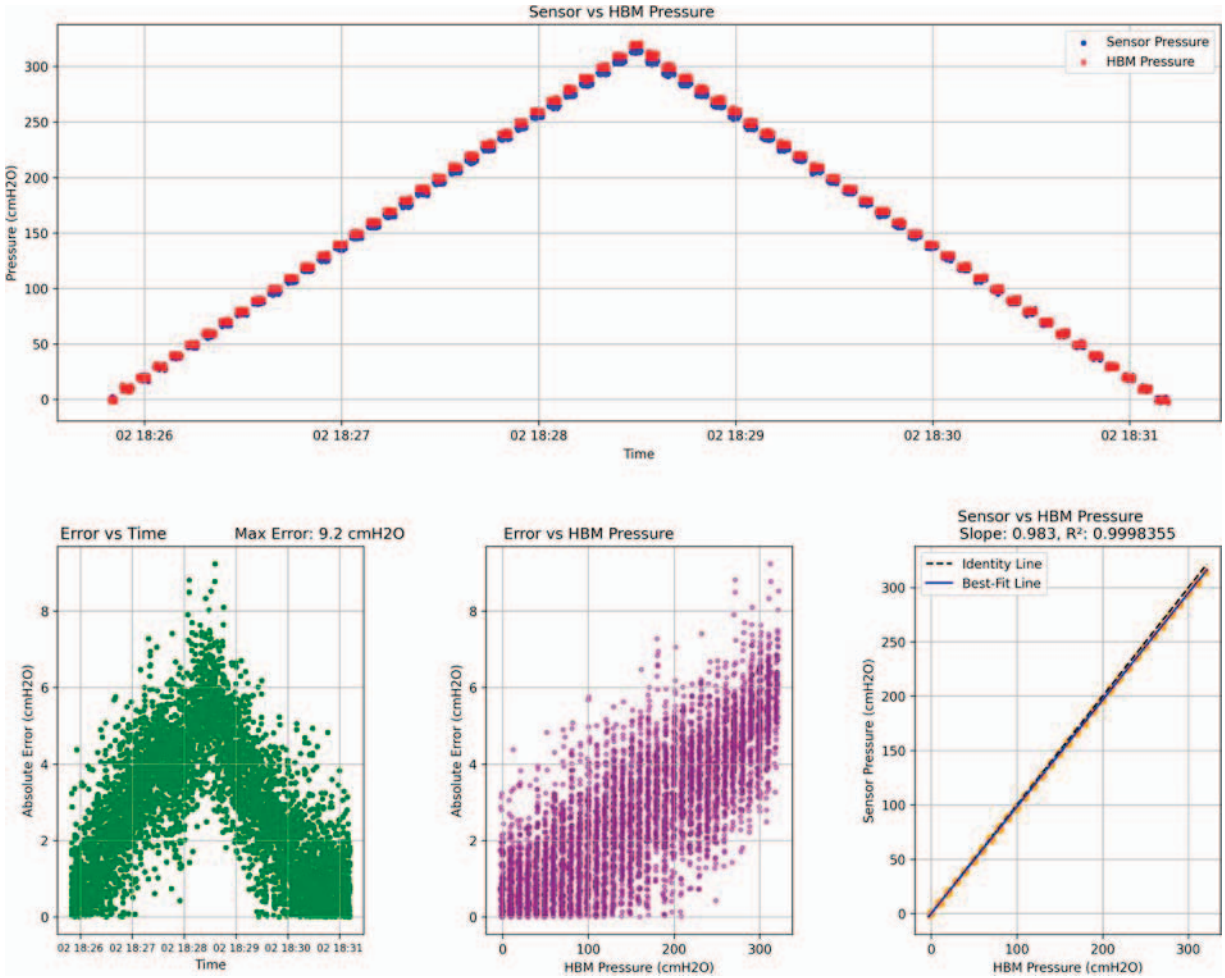


**FIG. 5.** Sample results of a ramp pressure test. This figure shows a ramp pressure test for a single Glean intravesical pressure sensor. The top plot shows the full set of test data (after filtering out nonsteady state data). The bottom plots show error *vs* time (left), error *vs* the human bladder model reference pressure sensor (center), and an identity line between the reference pressure sensor and the pressure reported by the Glean sensor (right). The maximum error shows that through the entire test, the Glean sensor never deviated from the reference measurement by more than 9.2 cm $H_2O$. cm $H_2O$ = centimeters of water; HBM = human bladder model.

$$Error = \left|P_{reference} - P_{measured}\right|$$

Maximum error was defined as the greatest distance between the measured and reference pressure values across the full range of recordings.

Linearity. Simple linear regression was performed between the measured and reference pressure values, where an R-squared closer to 1.00 indicates a better fit (or linearity). The slope of the regression line was also determined to show any bias in output values.

### *Statistical analysis*

This study was not powered for hypothesis testing; therefore, no formal sample size calculation was performed. Pressure data from the HBM and comparator were converted from cm $H_2O$ to hectopascals (hPa) for comparison with the Glean Urodynamics System using a conversion factor of 1 cm $H_2O$ to 0.980665 hPa. All data were normalized to zero.

Data analyses were conducted in Minitab (Minitab, LLC; State College, PA), Python (Python Software Foundation; Wilmington, DE), or SPSS® Statistics (IBM® Corporation; Armonk, NY). All analyses were performed relative to the reference pressure sensor of HBM and then compared. Analyses excluded data points that were erratic, missing, or visually identified as outliers. Data are presented as means, standard deviations, and 95% confidence intervals of between-group differences. Two sample *t*-tests were used to evaluate statistically significant differences between groups, defined as a p-value of less than 0.05. Data are displayed using interval plots and time-series plots.

## Results

Summary data are presented in Table 1 and displayed in Figure 3. All data from the 30 (100%) Glean intravesical pressure sensors were included in analyses. In contrast, select data points from three (10%) of the conventional air-charged catheters were excluded from analyses because of erratic behavior (Table 1). The Glean sensor exhibited significantly

($p < 0.001$) faster rise time (mean, 0.104 seconds) and fall time (mean, 0.111 seconds) than the air-charged catheters mean, 0.172 and 0.264, respectively. The bandwidth of the Glean sensor (mean, 4.978 Hz) was close to the maximum frequency tested of 5 Hz, whereas the catheters displayed a significantly lower bandwidth (mean, 2.250 Hz; $p < 0.001$ between groups). Figure 4 shows sample results from a sinusoidal pressure sweep. As frequency increases, the air-charged catheter under-captures pressure amplitude, resulting in reduced spectral magnitude in the FFT. In contrast, the Glean intravesical pressure sensor closely tracks the reference across the full test range, indicating a bandwidth of at least 0 to 5 Hz. The maximum error (mean, 6.882 hPa) of the Glean sensor was significantly lower than the error of the catheters (mean, 21.549 hPa; $p < 0.001$ between groups). Figure 5 shows sample results from a ramp pressure test. Across the entire test, the maximum error indicates that the Glean sensor did not deviate from the reference pressure sensor measurement of HBM by more than 9.2 cm $H_2O$. The Glean sensor and the catheters both showed highly linear relationships between the applied and measured pressures, although R-squared was not significantly different between groups ($p = 0.305$). All individual Glean sensor results were 1.00, whereas the catheter results ranged from 0.98 to 1.00 (Supplementary Table). The catheters exhibited a slope significantly farther from the ideal (1.00) compared with Glean ($p < 0.001$), with mean slopes of 0.941 and 0.988, respectively.

## Discussion

This study demonstrated equivalent or superior performance of the wireless, catheter-free Glean Urodynamics System intravesical pressure sensor compared with the conventional Laborie Goby air-charged catheters under simulated pressure conditions using a bench-top HBM. The Glean sensor had faster rise and fall times and was more sensitive to a larger range of frequencies (bandwidth) than the air-charged catheters. Faster response times and a higher bandwidth suggest improved fidelity in quickly capturing rapid pressure changes representing the dynamic changes of the bladder.[14] Given that the bandwidth evaluation was limited to a frequency of as much as 5 Hz, it is possible that the Glean sensor's true bandwidth may be higher, thus being better at capturing high-frequency events overall. The lower maximum error of the Glean sensor relative to the reference indicates a more accurate representation of pressures across the bladder's functional range. Similarly, the linear relationship between applied and measured pressures strongly agreed, showing the Glean sensor recorded pressure values closer to the truth than the air-charged catheters. Linearity results also indicated that both devices behaved linearly, with the Glean sensors performing significantly better than the catheters.

The Laborie Goby conventional UDS with air-charged catheters was an appropriate comparator, as it has the same intended use and measures the same urodynamic parameters using established pressure-based technology. In this study, the conventional UDS system did not consistently acquire accurate and reliable pressure measurements. Data collected from three conventional catheters were deemed erratic and unreliable and were therefore excluded from the relevant analyses, whereas the Glean Urodynamics System consistently produced accurate and reliable data. The conclusions from this study did not change when data from these conventional UDS tests were included (data not shown), as the average performance of that system became measurably worse. Although this study only compared one UDS system and catheter type (air-charged) to evaluate the performance of the Glean Urodynamics System, it is anticipated that similar catheter-based UDS systems would perform comparably with those evaluated in that study. Prior studies, however, have demonstrated that different catheter types are not directly equivalent in performance.[16–18] Future studies are needed to further establish the performance of the Glean Urodynamics System relative to conventional and other ambulatory urodynamic systems.

There are several limitations to this study. It was neither designed nor powered for hypothesis testing. The number of test devices may have limited statistical power and precision, increased sensitivity to outliers, and reduced confidence that the results are representative of overall device performance. The metrics chosen for comparison may not have provided a comprehensive assessment of device performance and accuracy. Reliance on a custom-built HBM without validated accuracy limits reproducibility and may have introduced potential bias by inadvertently favoring certain device designs. There may also have been slight variation in testing environments, as three (albeit designed the same) HBMs were used in this study, which may have affected results. It is unclear if the multiple devices in the chamber affected device readings, as three Glean sensors were tested at one time, where testing the devices independently may have provided higher confidence in the results; however, one-way analysis of variance did not demonstrate statistically significant run-to-run differences (data not shown). In addition, this study was performed in a controlled, laboratory setting for which the HBM may not have accounted for physiological characteristics such as bladder filling and voiding. A study of a similarly designed intravesical pressure sensor found a mean difference in simultaneous conventional and ambulatory UDS pressure measurements of less than 1 cm $H_2O$ and an R-squared of 0.87 in six patients with overactive bladder.[11] Future studies comparing these results to water-filled *in vivo* validation will be important to fully interpret their significance. Ongoing studies are underway to further assess the performance and accuracy of the Glean Urodynamics System compared with conventional UDS systems in patients with lower urinary tract symptoms.[19]

## Conclusion

The Glean Urodynamics System is a wireless urodynamics platform that provides accurate and reliable measurements, making it a modern alternative to traditional catheter-based systems. By demonstrating consistent technical performance under differing testing conditions and analytical equivalence to the conventional Laborie Goby UDS system, the Glean Urodynamics System satisfies the essential criterion for clinical success. These findings support the conclusion that wireless UDS can be performed without compromising diagnostic capability, while potentially reducing procedural complexity and patient burden, and thus, positioning the Glean Urodynamics System as a meaningful advancement in the assessment of lower urinary tract function.

### Acknowledgment

Katherine Kacena, PhD for statistical consultation and analysis.

### Authors' Contributions

M.H.: Investigation, formal analysis, and writing—original draft preparation. T.M.: Investigation and writing—review and editing. A.P.: Investigation and writing—review and editing. B.N.: Investigation and writing—review and editing. H.S.: Investigation and writing—review and editing. B.U.C.: Formal analysis and writing—original draft. T.T.: Formal analysis and writing—review and editing. D.F.: Investigation and writing—review and editing. H.W.: Investigation and writing—review and editing.

### Data Availability Statements

Data are not publicly available.

### Author Disclosure Statement

M.H., T.M., A.P., B.N., H.S., B.U.C., T.T., D.F., and H.W. are current or former paid employees of Bright Uro, Inc. M.H., T.M., A.P., B.N., H.S., B.U.C., T.T., D.F., and H.W. hold stock or stock options in Bright Uro, Inc. T.M., B.N., and H.S. are listed as inventors on patents held, planned, or pending by Bright Uro, Inc. T.M. is a paid consultant of EndoQuest Robotics.

### Funding Information

Bright Uro, Inc.

### Supplementary Material

Supplementary Table S1

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**Abbreviations Used**

cm $H_2O$ = centimeters of water
F = French
FDA = Food and Drug Administration
FFT = Fast Fourier Transform
HBM = human bladder model
hPa = hectopascals
Hz = hertz
UDS = urodynamics