Pee Xylophone: A Novel Non-Invasive Bladder Pressure Measurement System

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Background

- **Lower urinary tract symptoms** (LUTS) refer to a group of medical conditions that **affect the bladder and urethra**, causing problems with urination. (Fig. 1)
- They affect over 80% of men above the age of 60.
- LUTS are **caused by either an obstruction** in the urethra **or a weak detrusor muscle**. Treating LUTS requires distinction between these two diagnosis.
- The maximum flow rate achieved during a void (Q_{max}) and the pressure inside the bladder at Q_{max} (P_{det}) is plotted on **Fig. 2 to identify this distinction** and the subsequent diagnosis.
- **Urodynamics** (UDM) (Fig. 3), is an extremely **invasive test** (the industry standard) that **measures bladder pressure** by inserting pressure sensors in the bladder through the urethra.
- Though UDM may identify potentially life-threatening complications, men are hesitant to get the test done due to the pain it causes.

Storage Phase Symptoms	
Name	Description
Increased daytime frequency	Patient voids frequently during the day
Nocturia	Patient wakes one of more times at night to void
Urgency	Sudden and difficult to defer desire to pass urine
Urinary incontinence	Involuntary urine leakage
Voiding Phase Symptoms	
Name	Description
Slow stream	Perception of slow urine flow
Splitting or spraying	Urine stream splits into multiple streams or sprays
Intermittent stream	Urine flow stops and starts on one or more occasions
Hesitancy	Difficulty initiating a stream
Straining	Muscular effort used to initiate, maintain, or improve the stream
Terminal dribble	Flow slows to a trickle/dribble and the final part of voiding is prolonged
Post Voiding Symptoms	
Name	Description
Feeling of incomplete emptying	Sensation of urine remaining in the bladder
Post micturition dribble	Involuntary loss of urine immediately after finished voiding, usually after leaving the bathroom or rising from the toilet.

Fig. 1: Description of various lower urinary tract symptoms

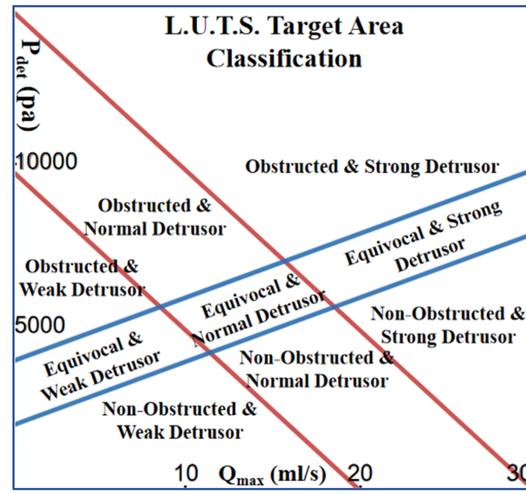


Fig. 2: LUTS Target Area Classification Chart

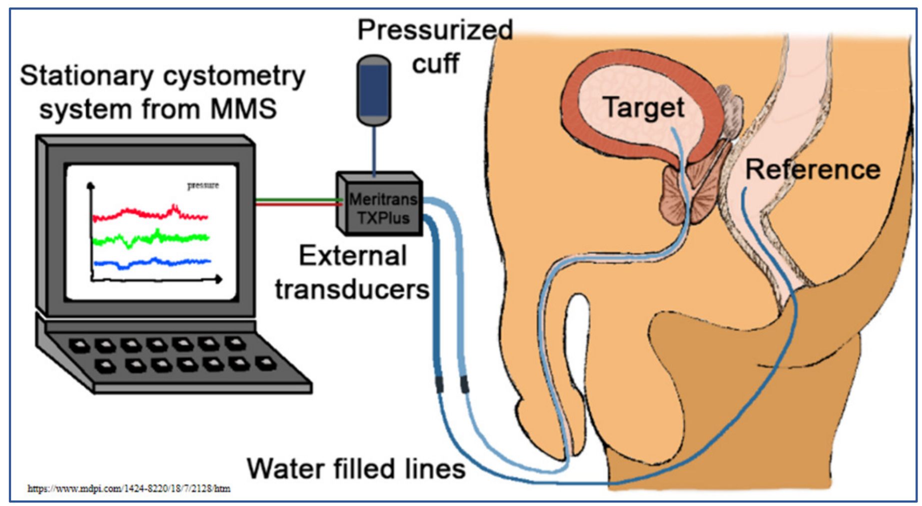


Fig. 3: Urodynamics test procedure visual

Pee Xylophone: An Overview of Invention and Discovery Process

While experimenting with sonouroflowmetry, a **relationship between bladder pressure and the final range of urine** was observed. Unable to relate the two using prior work, the **problem was solved in two parts**.

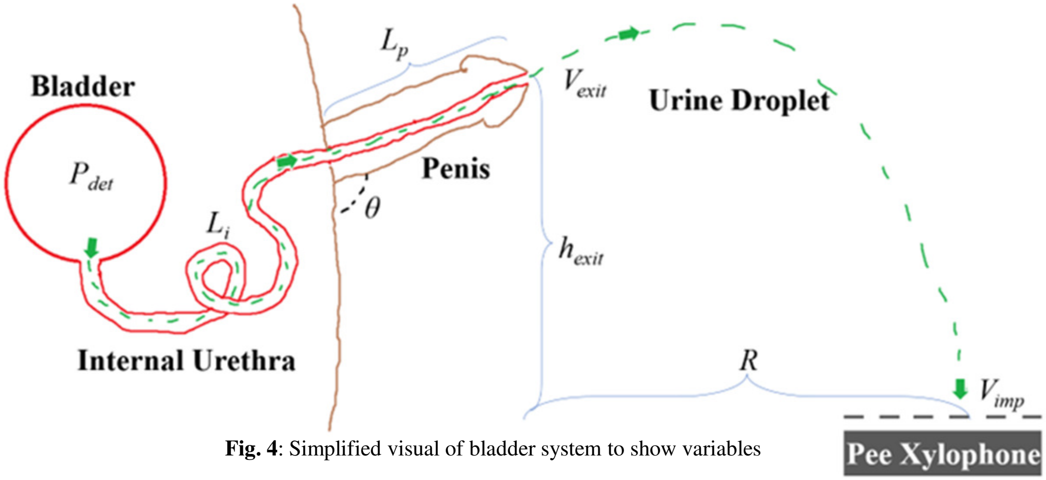


Fig. 4: Simplified visual of bladder system to show variables

Variable Reference (Fig. 4)

P

$\boldsymbol{P_{det}}$: Bladder pressure at Q_{max} (Pa)
$\boldsymbol{\Theta}$: Angle of urine release (°)
$\boldsymbol{V_{exit}}$: Urine exit velocity (m/s)
$\boldsymbol{R}$: Range urine travels (m)
$\boldsymbol{Q}$: Volumetric flow rate of urine (L/s)
$\boldsymbol{L_i}$: Length of internal urethra (m)
$\boldsymbol{L_p}$: Length of external urethra (m)
$\boldsymbol{h_{exit}}$: Height of urine release (m)
$\boldsymbol{V_{imp}}$: Impact velocity of urine (m/s)

Order of Experiments

Relating P_{det} to V_{exit}

1. Applying Bernoulli's principle

   Problem : Confusion about urine velocity in the bladder and external pressure.

2. Estimating energy loss

   Problem: Cannot measure physiological features due to invasiveness of measurement

Calculating V_{exit}

1. Simple kinematics

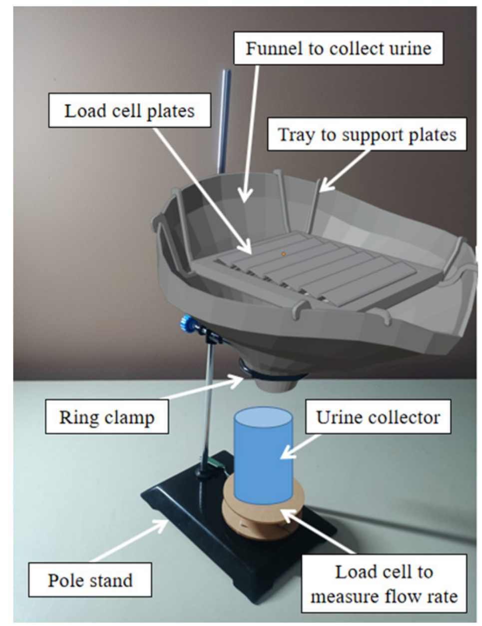
   Problem: Assumed θ was 0°

2. Substituting V_{imp} for θ

   Problem: Kinematics became too complicated; Had to use Newton's Method for solution

3. Energy conservation solution

Result



Finding Urine Exit Velocity: The Iterative Solution

Initially, it was assumed that the patient can urinate perfectly horizontally, resulting in θ equalling 0°. Therefore, there can only be one V_{exit} that can produce a measured R. However, feedback warned against this assumption as the anatomy of some men would not allow for horizontal urination.

- When assuming $\theta = 0°$, all energy possessed by a urine droplet at exit is converted to achieve horizontal displacement.
- When $\theta \neq 0°$, **not all initial energy is converted for horizontal displacement**, **some is left and can be measured as impact force.**
- Because both V_{imp} and R contain θ and V_{exit} in their kinematic relation, θ can be replaced.

Order of Derivation

$$R = \frac{V_{exit}\cos\theta\left(V_{exit}\sin\theta + \sqrt{(V_{exit}\sin\theta)^2 + 2gh_i}\right)}{g}$$

Solve for θ

$$\theta = \tan^{-1}\left(\frac{V_{exit}^2 \pm \sqrt{V_{exit}^4 - R^2g^2 + 2h_i g V_{exit}^2}}{Rg}\right)$$

Substitute

$$V_{imp} = \sqrt{(\sin\theta\, V_{exit})^2 + 2gh_i}$$

The following function returns 0 when the correct value of V_{exit} is inputted (Fig. 5):

$$f(V_{exit}) = \sqrt{\left(V_{exit}\sin\left(\tan^{-1}\frac{V_{exit}^2 \pm \sqrt{V_{exit}^4 - R^2g^2 + 2h_i g V_{exit}^2}}{Rg}\right)\right)^2 + 2gh_i} - V_{3y}$$

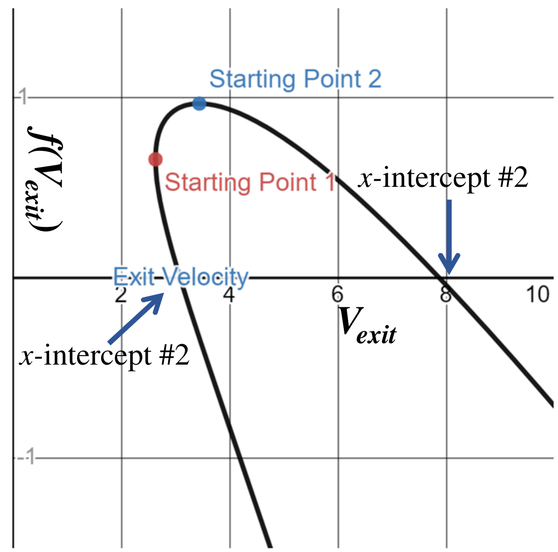


Fig. 5: $f(V_{exit})$ graph showing the starting points for Newton's Method and intercepts

- The **lowest *x*-intercept of the function is the correct V_{exit}.**
- The function is too difficult to solve however.
- Newton's Method, an iterative method to estimate *x*-intercepts was used to find the exit velocity.

Finding Urine Exit Velocity: The Iterative Solution

- As shown in Fig. 5 on the previous page, there are 2 x-intercepts, however, only the lowest is correct.
- Newton's Method has the potential to return either depending on where it initially starts.
- **Two different starting positions on the $f(V_{exit})$ graph were tested** to identify the starting position that most reliably returned the lowest x-intercept.
- Tests included many different height, angle, and velocity configurations. Care was taken to ensure a realistic range of input parameters.
- As seen (Fig. 6 & 7), **Starting Point 1 is far more reliable than 2.**
- However, there is **still some error** with Starting Point 1 and Newton's Method required 10+ iterations to arrive at the x-intercept.

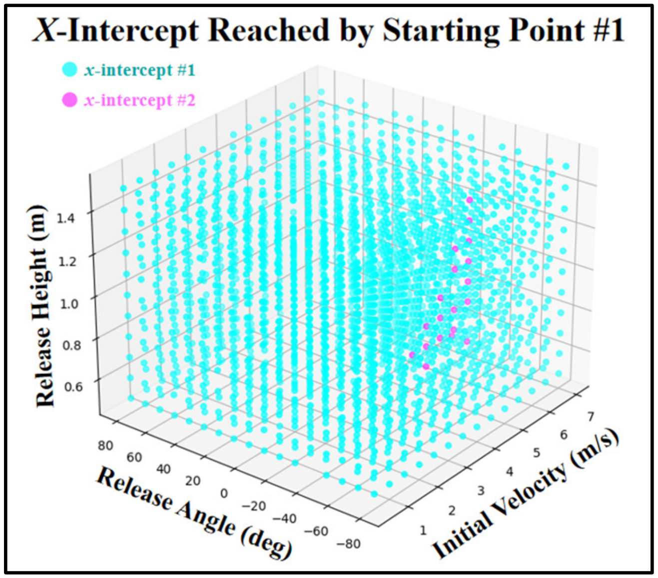


Fig. 6: Intercepts Starting Point 1 reaches

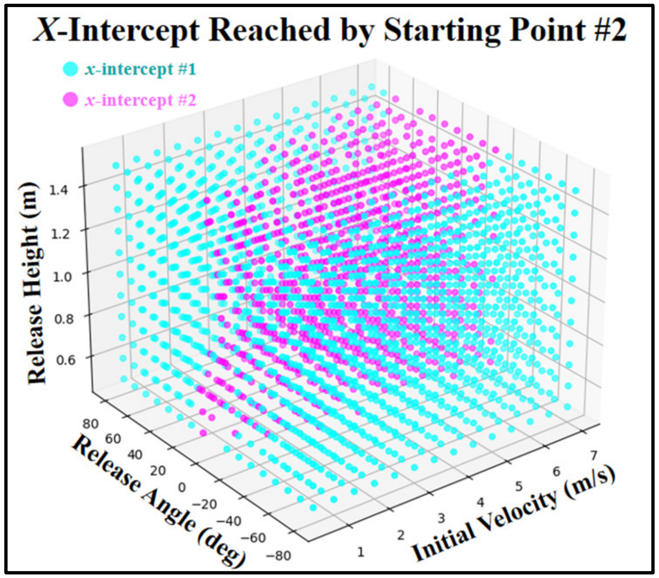


Fig. 7: Intercepts Starting Point 2 reaches

Starting Position 1

$$V_{exit} = \sqrt{g}\sqrt{\sqrt{h_i^2 + R^2} - h_i}$$

Starting Position 2

$$V_{exit} = \frac{Rg}{\sqrt{2gh_i}}$$

Finding Urine Exit Velocity: The Definitive Solution

- Because Starting Point 1 sometimes returns the wrong V_{exit} and Newton's Method is computationally intensive, **a direct relation between V_{exit} and R & V_{imp} is needed.**
- Instead of using kinematics to solve this problem, energy conservation principles were used to derive the following relation (Eq. 1).

$$V_{exit} = \frac{\sqrt{2}\sqrt{2h_{exit}^2V_{imp}^2 - 4gh_{exit}^3 - R^2gh_{exit} + R^2V_{imp}^2 - R^2\sqrt{V_{imp}^4 - 2V_{imp}^2gh_{exit}}}}{2h_{exit}}$$

Eq. 1

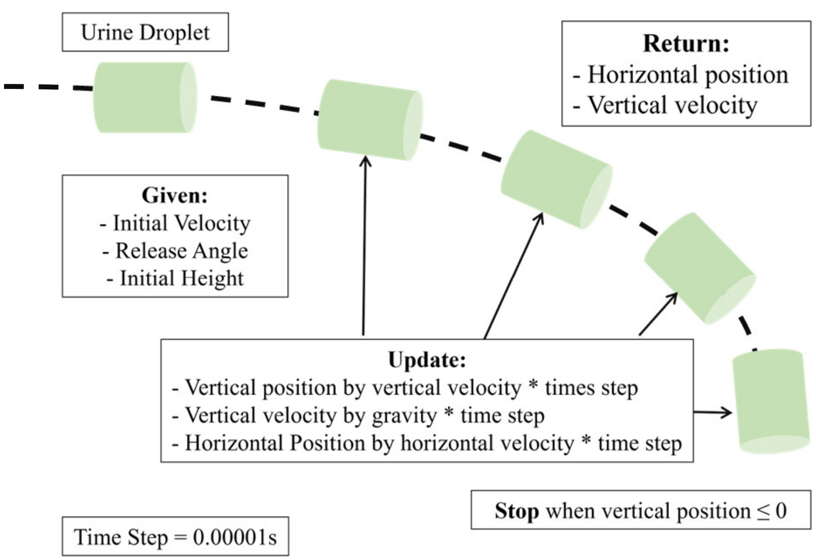


Fig. 8: Simulation visual description

```
V2 = 10 #m/s
θ = 5 #deg
h = 1 #m

TIME_STEP = 0.00001 #s

y_pos = h
x_pos = 0

x_vel = V2 * cos(θ)
y_vel = V2 * sin(θ)

g = -9.81

while y_pos > 0:
  x_pos += x_vel * TIME_STEP
  y_pos += y_vel * TIME_STEP
  y_vel += g * TIME_STEP

R = x_pos #final position
V3 = y_vel #final downwards velocity

print("The calculated V2 is: ")
print(newtons_method(f(R, g, h, V3))
```

- A **simulation was used to verify** Eq. 1 and conduct the experiments related to the starting position of Newton's Method.
- Eq. 1 is the final relation used to calculate V_{exit} in the Pee Xylophone device.
- It does not require the user urinate in a fixed position, is not computationally expensive, and is a perfect relation.

Finding Bladder Pressure: Applying Bernoulli's Principle

- After calculating urine exit velocity, the Pee Xylophone must use it to calculate internal bladder pressure.
- An observed relationship exists between P_{det} and V_{exit} but it's hard to describe mathematically due to the complexity of the bladder system.
- For Bernoulli's principle to be applied across the urethra, **the following conditions must be met:**
  1. **Urine must be inviscid**
  2. No energy must be lost from the bladder to the tip of the urethra
  3. **Urine's flow must be laminar**
- **Urine** at 37° C is less viscous (0.8293 cSt) than water at 20° C (1 cSt) and **is therefore inviscid**.
- Reynold's Number (*RE*) can be calculated for an average urine flow to determine the nature of it's flow:
  - *RE* for urine of dynamic viscosity of 0.8293 cSt and a density of 1017 kg/m^3 flowing through a 3 mm radius urethra at 0.6 m/s is around 2000.
  - *RE* under 3000 is **considered laminar**.
- **Confusion arises when relating variables** needed for Bernoulli's equation with the bladder system:
  - If the velocity of urine in the bladder (V_{det}) is assumed to be 0 m/s, could the accelerating urine's exit velocity be dependent upon how long it is accelerating (length of urethra)?
  - Could external pressure (P_{ext}) be assumed to equal air pressure?
- Different permutations of said assumptions were used to create modified Bernoulli's equations (Fig. 8).
- These models were tested to understand **which set of assumptions accurately applies to the urethra**.

Assumption	Modified Bernoulli's equation
$V_{det} \neq 0$	Cannot relate P_{det} with V_2 without knowing V_1
$P_{ext} \neq P_{air}$ and $V_{det} = 0$	$P_{det} = \frac{1}{2}\rho V_2^2\left((dA)^{-1} + 1\right)$ Eq. (2) *d* is urethra length & *A* as cross-sectional urethra area
$P_{ext} = P_{air}$ and $V_{det} = 0$	$P_{det} = \frac{1}{2}\rho V_2^2$ Eq. (3)

Fig. 8: Table of modified Bernoulli's equations with corresponding assumptions

Finding Bladder Pressure: Applying Bernoulli's Principle

- To simulate the flow of urine out of a bladder, 27° C water (same viscosity as urine at 37° C) was stored and released from three containers suspended at different h_i meters above the ground.
- The **pressure responsible for the release of water is proportional to the height of water** in the container *(h_1)*.
- Containers had 1/8" and 1/4" diameter release holes to simulate different urethra-cross sectional areas while the 3rd container had a straw attached to the release hole to simulate different urethra lengths.
- Three cameras were positioned to record h_i, R, & θ of the set-up over time. (Fig. 9)
- The expected range derived using the known pressure from h_1 was compared to the measured range using the video footage.
- **Eq. 3 was more accurate** as it's curve (Fig. 10) resembled the observations. External pressure is air pressure, and internal urine velocity is 0 m/s.

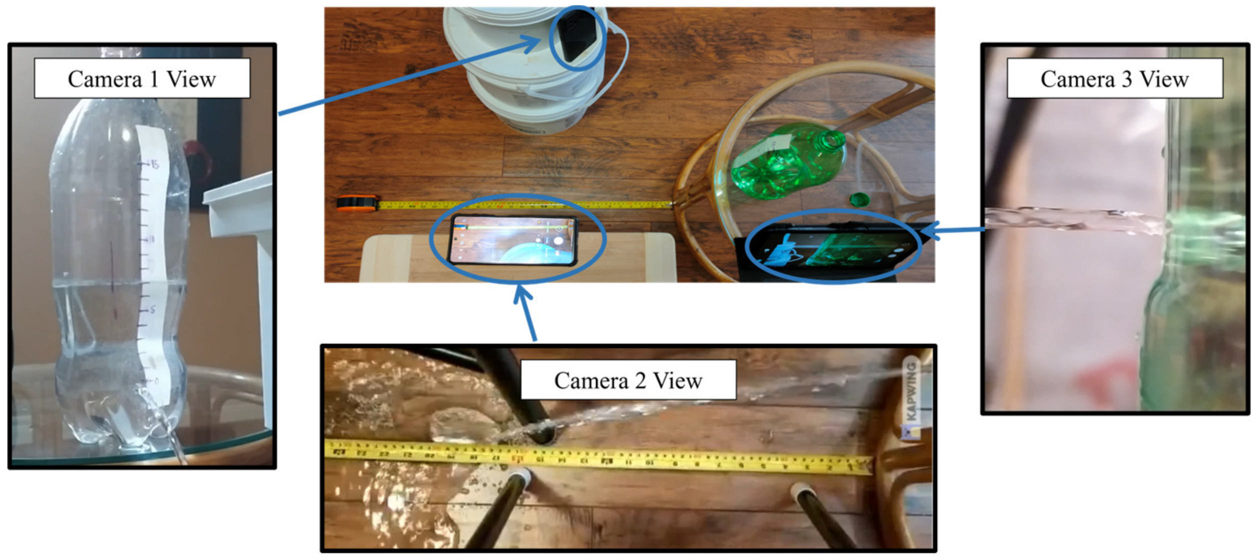


Fig. 9: Bernoulli's assumptions experiment setup

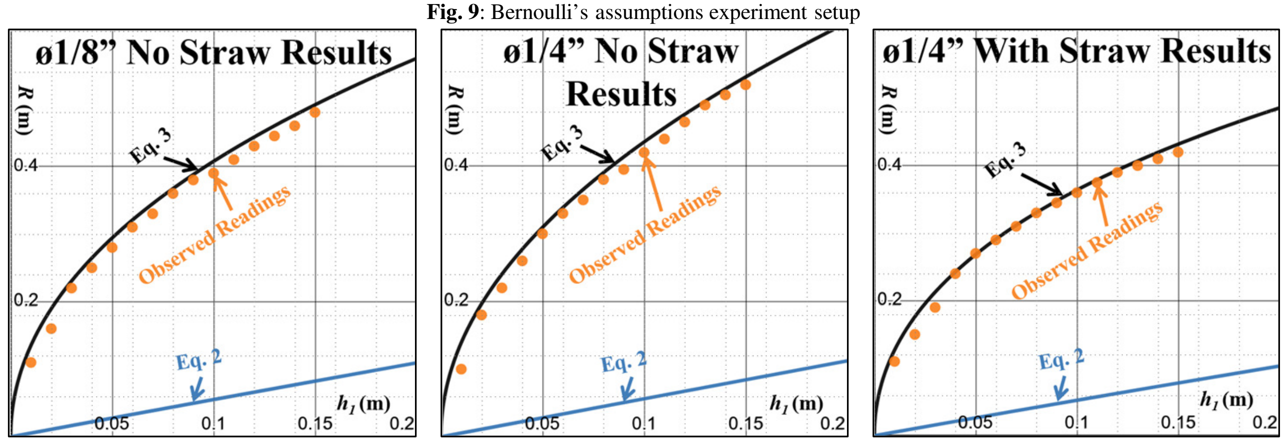


Fig. 10: Bernoulli's assumptions results

Finding Bladder Pressure: Calculating Energy Loss

- Applying Bernoulli's Principle requires condition 2 of no energy loss to be met. However, the complexity of the urethra and bladder system undoubtably **introduces energy loss**.
- This renders the existing relation to calculate bladder pressure using exit velocity inaccurate.
- To increase device accuracy, the energy loss must not be standardized for all patients, however, the energy loss for each patient depending must be determined based on their attributes.
- The following Bernoulli's relation incorporates energy loss:
  - h_i: Minor head loss (energy lost due to the expansion/contraction of the urethra and it's curved nature) (unitless)
  - f: Friction factor (dependent on the roughness of the urethra walls) (unitless)
  - γ: Specific gravity of urine (N/m^3)

$$P_{det} = P_{air} + \gamma L_p \tan\theta + \frac{\gamma V_{exit}^2}{2g} + \frac{\gamma f \left(L_i + L_p\right) \pi V_{exit}^3}{2Qg} + \gamma h_i \quad \text{Eq. (4)}$$

- ***L_i, f*, and *h_i*, must be known for each patient in order to calculate energy loss**, however, these variables are **extremely difficult to measure** due to the invasive nature of the measurement methods.
- If these values are known for a large number of test patients alongside each patient's easily measurable physical attributes (EMPA) (height, weight, blood pressure, race), then a relationship between the EMPAs and L_i, f, and h_i can be determined. This relationship can be used to predict the L_i, f, and h_i values of a new patient given that patients EMPAs.
- However, L_i, f, and h_i cannot be measured even for the test patients.
- If P_{det} and all other required variables other than L_i, f, and h_i are measured for test patients, then a novel bounded regression analysis technique can be used to determine the relationship between L_i, f, h_i and EMPAs.

Finding Bladder Pressure: Calculating Energy Loss

The analysis technique proposes the following:

1. Try all L_i, f, and h_i values in a chosen range at a defined interval in Eq. 4 for all patients. Error is the difference in calculated and measured pressure.
2. For all error values (for each patient), the error will be bound by a bounding function ($-e^x$, max(x, a)…).
3. The sum of all bounded error values will determine the error for one set of L_i, f, and h_i values.
4. All L_i, f, and h_i combinations that result in a bounded error sum under a predefined threshold value will be chosen for examination.
5. The averages of the EMPAs for all of the patients will be calculated using the bounded error value as each patient's weight factor in the average.
6. This will output a set of EMPAs with corresponding L_i, f, and h_i values.
7. A new patient can be related to this set using nearest neighbour of nearest-k neighbour techniques to estimate L_i, f, and h_i values.

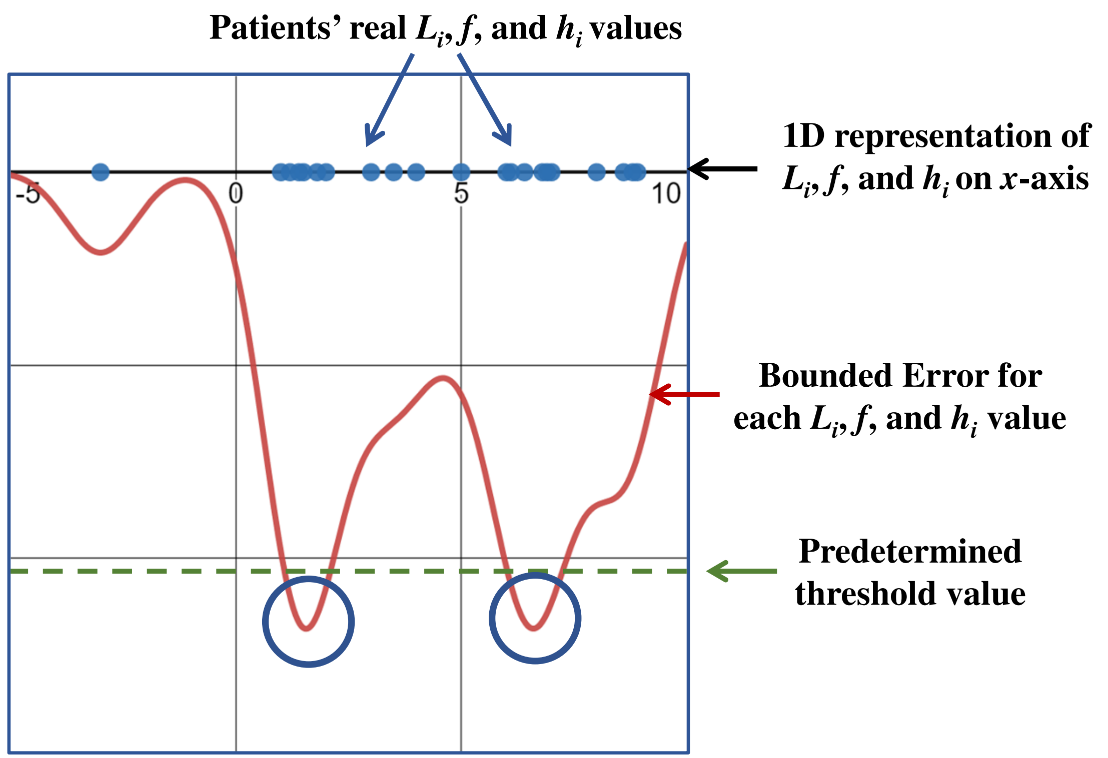


Fig. 11: 2D representation of the proposed analysis method

Weighted average EMPAs will be calculated for the circled local minima

Finding Bladder Pressure: Calculating Energy Loss

- Because the ethics approval procedure to start testing on patients is very time consuming (3-4 months), patient testing has been postponed.
- However, **the proposed analysis technique has been verified** through a patient trial simulation where random EMPAs were related to L_i, f, and h_i values for 500 patients. Error was introduced to the relation between the EMPAs and L_i, f, and h_i values to emulate reality.
- The proposed analysis method was able to successfully deduce the nature of the random EMPA to L_i, f, and h_i relationships.
- Though a large patient study is the holy-grail for error reduction, a through prior-art search was conducted to **determine relationships between L_i and various EMPAs and h_i was discovered to be nominal**.
- Because urine has laminar flow in the urethra, Darcy-Weisbach's principle says that friction factor can accurately be assumed to be 60/*RE*.
- Using these revelations, **error due to energy loss in the urethra was reduced**.
- The Pee Xylophone used the range of urine as well as it's impact velocity to calculate the exit velocity of urine, which it then relates to the internal bladder pressure for accurate LUTS cause diagnosis.
- It does this **non-invasively and with minimal error**.
- **This device is now patent-pending**. U.S. Patent Application Serial No. 63/362,158 under the name "SYSTEM, DEVICE AND METHOD TO MEASURE THE INTERNAL PRESSURE OF A PRESSURIZED CONTAINER".

References

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