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# PROTOTYPE OF NEW INSTRUMENTATION FOR NON-INVASIVE URODYNAMICS IN MALES: PRELIMINARY RESULTS

Hypothesis / aims of study

Nowadays, clinical investigations to understand the functionality of the lower urinary tract (LUT) are based on invasive techniques (e.g. use of catheters) for measuring intra-bladder pressure and flowmetry through urethra. These techniques can lead to significant discomfort and possible complications to patients; moreover, they represent for the health agencies an economic burden in terms of costs associated with supplies, and above all they require a great deal of personnel's time; finally, current techniques are inadequate for urodynamic analysis in pediatric subjects.

This project expands the work previously carried-out by the same research team on the analysis of the hydraulic behavior of bladder-urethra system. The research is based on a physical model specifically designed and assembled in our laboratory and experiments on water jets issuing from elastic tubes with similar behavior to the urethra and the development of mathematical models suitable to represent the complex phenomena that occur in the LUT in physiological and pathological conditions.

Based on the previous results, a new instrumentation for non-invasive urodynamic diagnostic was developed. This instrumentation does not have any parts in contact with the human body, moreover it is characterized by the same diagnostic reliability of the current techniques in use.

The basic concept arises from considering the LUT similar to a hydraulic system consisting of a pressure feed tank (bladder) and an outlet elastic duct (urethra) whose physical behavior is governed by the laws of fluid mechanics. Starting from the knowledge of the physical quantities of the urinary jet measurable outside of the urethra it is possible to model the LUT internal urodynamic characteristics.

In this report, we present the preliminary results of a clinical trial with healthy male volunteers designed to test and calibrate the diagnostic reliability of the new equipment.

Study design, materials and methods

The prototype (Figure 1), developed in the Laboratory of River And Lagoon Hydraulics And Bio-fluid-dynamics of the Department of Civil and Environmental Engineering of the University of our city, consists of a bearing structure of iron L-section bars which has the task of supporting a deflector and a funnel, as in a classic wall urinal; the funnel conveys the fluid in a vessel placed on a digital precision scale. A digital camera is placed on the right side; both instruments have been positioned on supports connected to the bearing structure. The prototype has overall external dimensions of 70x56x133 cm (WxDxH).

The data acquisitions of the scale and the camera operate in a synchronous way at a frequency of 5.5 Hz. Both the acquisition and processing are carried out in a totally automatic way, without the need for any intervention by the medical staff, who only needs to input the patient's personal data before the beginning of the test. The patient has to urinate first positioning his feet on a ground mark and then starting the urinary flow horizontally. At the end of the flow a final report with the test's results is automatically printed.

The flow rate (Q) was evaluated from the vessel weight variation over time, assuming an average value of 1020 kg/m$^3$ of the urine density.

The detrusorial pressure ($P_{det}$) was estimated from a series of tests, carried out on our laboratory physical model of the LUT, which relates the output speed of the jet with the detrusorial pressure in healthy people. The jet velocity was calculated from the images of the trajectory taken with the digital camera.

In this first stage, as we have no information regarding the abdominal pressure, we assume $P_{det}$ equal to intravescical pressure.

Results

The tests were carried out on 57 healthy male volunteers, aged between 25 and 30 years. Below, Table 1 shows a summary of the performed tests with the corresponding maximum and minimum recorded values, where $T_{tot}$ is the total voiding time, $V_{tot}$ the total voided volume, $Q_{peak}$ the maximum flow, $P_{det}@Q_{peak}$ the bladder pressure recorded in the same time of maximum flow; moreover, well-known urodynamic index OCO (obstruction coefficient), BCI (bladder contraction index) and BOOI (bladder outlet obstruction index) have been evaluated.

Note that only the trials with $V_{tot}$ between 150 and 500 ml were analyzed.

Interpretation of results

The evaluation of the results was performed by plotting our data in the Schäfer's nomogram and then analyzing OCO, BCI and BOOI.

Figure 2 shows the results of our tests on Schäfer's nomogram (currently used in Pressure/Flow Study), where each red cross represents the urinary maximum flow and the associated bladder pressure; it appears that the test results are all in the areas of the chart where the flow is considered not-obstructed (0 and I) and the estimated bladder contractility is considered good (N and ST). Note that the chart area was extended to show maximum flows higher than 25 ml/s.

Also, urodynamic parameter analysis gives encouraging results: none of the volunteers shows a clear outlet obstruction (OCO less than 1 and BOOI less than 15) and the bladder contractility is for all normal or strong (BCI more than 100).

| *Test #* | *$T_{tot}$ (s)* | *$V_{tot}$ (ml)* | *$Q_{peak}$ (ml/s)* | *$P_{det}@Q_{peak}$ (cm $H_2O$)* | *OCO* | *BOOI* | *BCI* |
|---|---|---|---|---|---|---|---|
| *57* | 10.6 ÷ 58.4 | 160.5 ÷ 476 | 13.2 ÷ 41 | 14.6 ÷ 63.2 | 0.19 ÷ 0.67 | -49 ÷ 14 | 102 ÷ 239 |

*Table 1: Results from volunteers' tests.*

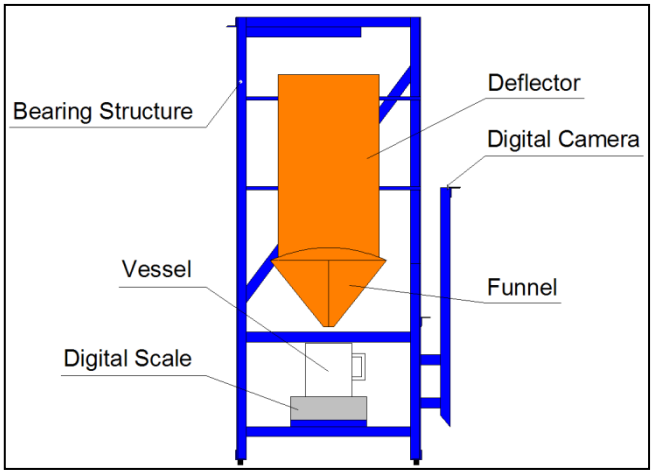


*Figure 1: Sketch of the new instrumentation.*

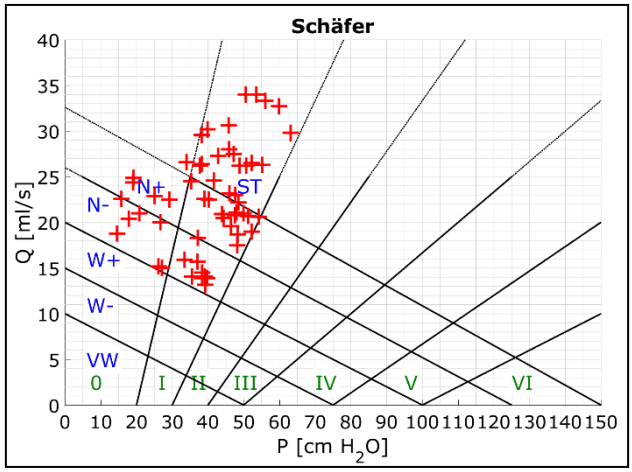


*Figure 2: Results obtained with the new instrumentation plotted in the Schäfer's nomogram*

Concluding message

A prototype of a new instrumentation able to assess the functionality of the LUT in a totally non-invasive way, was developed. The instrumentation, based on the analysis of the hydrodynamic characteristics of the urinary flow, was tested on 57 healthy male volunteers aged between 25 and 30. The results show the capability of the present system to investigate the functionality of the LUT.

Future development will focus on the comparison between the results of Pressure/Flow Study with those from our new instrumentation.

Disclosures

**Funding:** none **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** not required **Helsinki:** Yes **Informed Consent:** Yes