

# Chance observation leads to new evaluation

An accidental discovery reaps much-needed diagnostic improvements.



**L**ouis Pasteur once said that where observation is concerned, chance favours only the prepared mind. Today, a mind has to be prepared for almost anything. Take, for example, bladder disease.

Who would have thought that a piglet peeing on a table would revolutionize the way we measure bladder function? Thankfully, some doctors did, and today, UroDynamix Technologies has developed a basic prototype that uses NIRS (near infrared spectroscopy) to assess exactly what is going on with the bladder.

The accidental discovery arose from a collaboration between a pediatrician, Dr. Andrew Macnab, and a research technician, Dr. Roy Gagnon, and later, a urologist, Dr. Lynn Stothers, at the University of British Columbia. The story goes that they were looking at spinal cords using NIRS when the animal they were studying peed on the table. The NIRS device detected this bladder activity and ultimately, the physicians changed their area of study.

It could represent a much-needed improvement to diagnosing bladder function. Conventional diagnostic procedures — the very invasive dual catheterization — aren't fun.

"Conventional urodynamic evaluation often involves an invasive, somewhat embarrassing procedure," says Craig Pamplin, Director of Corporate Development and Communications for UroDynamix Technologies Ltd. "Compliance is low, and often patients don't show up for these referrals."

The technology being developed could change all that. Basically, it involves a sensor and a transmitter. A large patch is placed on the abdomen over the bladder. Energy from light is shone through the tissue and the amount of oxygenation (among other things) is measured.

"It's significant because it provides a clearer picture of what is going on inside the tissue, and whether the bladder is working correctly. It's also a totally non-invasive, painless exam," says Pamplin.

UroDynamix has identified at least three potential markets for this technology: primary care for women, including the evaluation

of urinary incontinence; primary care for men, including the diagnosis of prostate-related conditions; and acute care urology.

These are all huge markets. Just look at the numbers. An estimated three million Canadians and 25 million Americans, mostly women, suffer from urinary incontinence. Direct and indirect costs of UI in Canada are about \$2.6 billion a year (more than \$26 billion in America). Perhaps even more disturbing is the fact that UI is one of the top three reasons for individuals to be transitioned into long-term care facilities.

Or for men, look at lower urinary tract symptoms (LUTS), including benign prostatic hyperplasia (BPH), a non-cancerous enlargement of the prostate gland. Commonly occurring in men over 50, LUTS affects an estimated 30 million men in North America.

"Thousands of patients undergo uncomfortable, invasive and humiliating bladder function tests that involve catheterization of the urethra and rectum to obtain an indirect measure of bladder function," says Pamplin. "We believe that data from this rapid, non-invasive, user friendly procedure could take a lot of guesswork out of diagnosing bladder dysfunction. The device could be used as an adjunct or replacement for invasive methods to increase patient compliance and subsequent treatment of the underlying conditions. It could represent a new gold standard for evaluating bladder disorders."

Based on sophisticated electronics, NIRS uses energy from different wavelengths of light to diffuse through blood and tissue. These absorb light differently and the light bounces back to the sensor patch where it is measured and analyzed to monitor changes in physiology.

Part of UroDynamix's plan is to improve upon its PC-based prototype and possibly develop a portable monitor, which, says Pamplin, is still a long way away. But the technology does make it a definite possibility that a physician could conduct this test in her office.

"The premise is that yes, if she wanted to, she could," says Pamplin. "In a primary

care setting, she could offer the procedure, with less risk that the patient would run away screaming."

Earlier this year, UroDynamix completed the technology in-licensing agreement, established proof of the technology, and resolved IP issues. Now, it is focused on ongoing design controls and verification. By the end of 2006, the company hopes to be well underway with its clinical trials and regulatory preparation.

"By the end of 2007," says Pamplin, "we hope to have regulatory clearance with FDA and Health Canada, partnerships with other companies in hand, and a product ready for launch."

In September 2006, the company initiated the first US-based clinical study to assess the effectiveness of its NIRS urodynamics device for measuring bladder function in male subjects with LUTS. It is the first of several studies planned using its newest prototype, which the company has equipped with advanced features including automatic laser attenuation control, analog and digital signal processing and an integrated data management system to make the device more effective and user-friendly.

The future looks bright.

"We are optimistic that key players in urology markets will express an interest in our technology," says Pamplin. "Obviously there are large medical device companies out there that are interested in providing primary-care physicians with relevant, informative data that will allow them to effectively evaluate men with symptoms of prostate disease. Others may be more focused on primary care for women, or applications in acute care. We intend to take our core technology, commercialize it, and develop partnerships as required to address each of these key markets." ●

**For more information on UroDynamix and the company's technology go to [urodynamix.com](http://urodynamix.com) or call 604-694-7770.**

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