Biomed Tech 2013; 58 (Suppl. 1) © 2013 by Walter de Gruyter · Berlin · Boston. DOI 10.1515/bmt-2013-4223

AN INTRAVESICAL MEASUREMENT SYSTEM FOR CATHETERLESS LONG-TERM URODYNAMICS

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Abstract: *The urodynamics is considered as a standard diagnostic test for urinary incontinence. For this test, transurethral catheter tip sensors are used to measure the pressure inside the bladder. The measurement takes about 25 minutes, and often it is not possible to monitor pathological changes of pressure during this period. Additionally, different psychological factors could affect the results of standard urodynamics. We have developed a new system for catheterless urodynamic measurement. The system consists of an implantable intravesical capsule that measures the pressure for a period of more than 72 hours. It needs no components outside the human body, so an outpatient treatment is possible, which allows measurements under conditions of the patient's daily routine.*

Keywords: *Standard urodynamics, intravesical pressure measurement*

Introduction

The urodynamics is considered as a diagnostic test for urinary incontinence using catheter tip sensors to measure the pressure inside the bladder. Many urological patients present clinical symptoms, however most of them do not show any pathological findings during the conventional urodynamics. Standard urodynamics measurement takes 20-30 minutes, so this measurement shows only a short period in which the pathological change of pressure often cannot be detected. Additionally, different psychological factors could affect the results of standard urodynamics. The insertion of a transurethral catheter is embarrassing to the patient and may influence urodynamic results.

In this paper we describe a new system for catheterless urodynamic measurement. Catheterless pressure measurement is generally of great interest for many medical applications such as intracranial pressure measurement [1] or real-time blood pressure measurement [2]. Some devices have been designed especially for intravesical pressure measurement [3-6], but they are too large to insert them through a cystoscope, or the operating time is not sufficient for long-term urodynamics. Furthermore, no satisfying solution for a fixation inside the bladder is given.

The system, we have developed, measures the pressure inside the bladder for a time of up to 72 hours. To prevent an expulsion out of the bladder during micturition, the capsule is C-shaped. The measurement capsule with moulded electronics is shown in Figure 1. The capsule is flexible and can be straightened to push or pull it through a cystoscope for implanting. In straightened state the capsule is approx. 45 mm long and 5 mm in diameter, therefore it fits the inner diameter of a cystoscope.

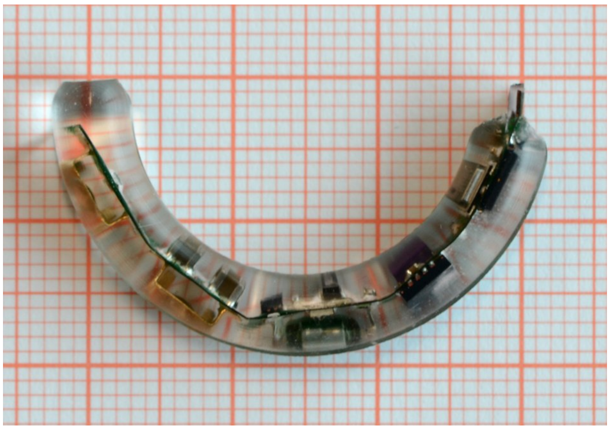

Figure 1: Measurement system for intravesical pressure measurement (on scale paper)

Methods

The new measurement capsule consists of a MEMS pressure sensor, an EEPROM for storing the measured time and pressure data, a microcontroller, a battery based power supply and a non-tactile, magnetically driven on-switch.

The supply current, especially of the microcontroller, strongly depends on the operating frequency and the supply voltage, so the system is operated at 1 MHz and 2.5 V. The lowest possible voltage is limited by write operations of the EEPROM.

The electronics is soldered on a double-sided flexible printed circuit board encapsulated in silicone, as it can be seen in Figure 1.

Because the whole electronics is moulded in silicone, a non tactile switch is needed for switching on the system. A P-channel MOS transistor separates the battery from the circuitry. It is opened either by an externally switched reed (the non-tactile, magnetically driven switch) or by an output pin of the microcontroller. This allows it to test the battery charge or the system's functionality after sterilization process without switching the system on for measurement.

Results

The electronics has been built up and tested. The accuracy of the pressure sensor is 2.5 mbar (cm H_2O) with a resolution of 0.2 mbar. The sensitivity of the moulded pressure sensor has been measured inside a pressure chamber as nearly 1 mbar/mbar (Fig. 2), so there is practically no reduction of pressure sensitivity due to moulding.

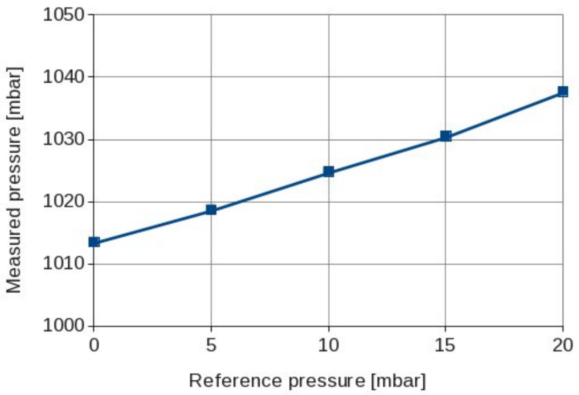

Figure 2: Sensitivity of the moulded pressure sensor

To detect fast pressure changes, as they occur due to pathological spasms or cough, the sample rate of the pressure measurement is 4 Hz. For effective utilization of the EEPROM, a new pressure value is only stored in memory if it differs from the former stored value by a given threshold, or if the time to the last stored measurement value is 60 s.
The maximum operating time results from battery capacity (8 mAh for used coin cell type 337) and mean current consumption of the measurement system. The current has been measured as voltage over a 100 Ω resistance in series to the battery via an instrumentation amplifier with an amplification of 5.

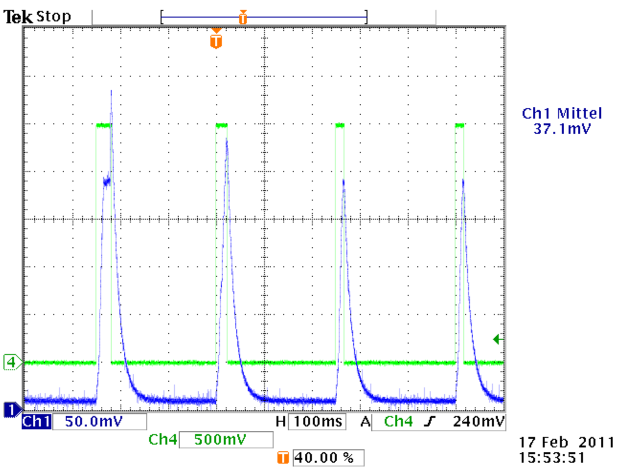

Figure 3: Measured current consumption (blue) of the system; green: active-flag of the microcontroller

The results of current measurement are shown in Figure 3. The green signal shows the active-time flag of the microcontroller, and the blue signal shows the current consumption which is proportional to the measured voltage. The mean current can be calculated from the mean voltage as

$$I_q = \frac{U_q}{a \cdot R_m} = \frac{37.1\,\mathrm{mV}}{5 \cdot 100\,\Omega} = 74.2\,\mu\mathrm{A} \ . \qquad (1)$$

From the battery capacity and the mean current consumption, calculated in (1), a theoretical operating time of 107 hours results. Measurements have ensured an operating time of 84 hours. The usable battery capacity depends on the output current, therefore the measured operating time is smaller than the calculated.
Cytotoxicity investigations, made at BMP GmbH in Aachen, have been passed successfully in November 2012, further tests of biocompatibility are ongoing currently. In February 2013 we have made first in-vitro tests of the C-shaped measurement capsule inside a bladder model at University Hospital of Cologne. The insertion of the capsule through a cystoscope works fine, handling of the capsule inside the bladder has appeared a little bit delicate, therefore the shape of the capsule will be modified to allow a better handling.

Discussion

We have developed a new measurement system for long-term urodynamic measurement. The measurement capsule can be implanted into the patient's bladder through a cystoscope and measures the pressure for a period of more than 72 hours, so the measurement can take place at home for about three days during the patient's normal daily routine. The proper functionality of the moulded pressure sensor has been proven. First in-vitro tests inside a bladder-model have been preponderantly successful, some modifications of the capsule shape will be made to enhance the handling inside the bladder. Extensive in-vitro tests are planned for summer 2013, the results will be presented at the DGBMT conference in September.

Acknowledgement

This work is supported by the German Federal Ministry of Research and Education (BMBF grant 01KN1106):

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