A Prototyping of Penile Tumescence Continuous Observation Device

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Abstract In this study, we attempted to develop a wireless real-time continuous observation device for penile tumescence and/or stiffness for verification of nocturnal penile tumescence (NPT) and for diagnosis and classification of erectile dysfunction (ED). Unlike conventional mechanically wired method, the patient is not constrained by the device and is able to use the device by himself in his own living environment. A soft silicone ring that fits the penis is equipped with a built-in variable inductance, variable frequency oscillator and a one-time use micro-battery. The inductance (hence oscillating frequency) is responsible for the internal stress of the ring, which represents the tumescence and/or stiffness. A non-contact leakage flux coupled to the variable inductor allows proximity telemetry of the phenomenon overnight, or up to the battery life. Our prototype device was successful in a feasibility test using a desktop model and in a simulated ex vivo test. Now, preparation for pre-clinical trial in healthy volunteer(s) is underway.

Keywords: erectile dysfunction, tumescence, hardness, monitoring, device.


1. Introduction

1.1 Background of the study
Erectile dysfunction (ED) is a common and important “issue” for men. It may be age-dependent or caused by a variety of other reasons including iatrogenic cause and impendimental. Monitoring of nocturnal penile tumescence (NPT) [1] is a validated objective method for verification, diagnosis and classification of ED. To date, a de-facto standard device known as RigiScan(TM) or RigiScan-Plus(TM) has been used for this purpose in urological community [2, 3]. In this device, a set of sleeved tethers is wrapped around the concerned part of the penis, typically one at the annular groove and the other at the root, which extends to shift transducers located at a local measurement box fixed on the patient’s body. However, this “box-wired” method is unnatural and cumbersome for the patient. Another more serious issue for the medical/clinical community is that while this measurement is required for reporting to workers or traffic insurance bodies, the production of this device has been already discontinued, and hardware and software supporting services have also expired.

1.2 Problem statement
The purpose of this study was to develop and evaluate a new wireless real-time continuous observation device for penile tumescence and/or stiffness, which frees the patient from the “box-wired” method. We also aimed to develop a device that the patient can use by himself in his own living environment. Here we exclude the so called “postage stamp test” [4] and the “one time, result-only” measurement philosophy, and insist on real-time (or time series samples) continuous overnight observation of the phenomenon.

1.3 Prior arts of other researchers
A variety of methods and means have been proposed for overnight continuous monitoring-based objective measurement of ED. The majority of the measures include, but are not limited to, mechanical measurement for continuous monitoring of penile tumescence, length or stiffness (hardness, rigidity), or internal pressure. The elastic behavior of the penile tissue consisting mainly of tunica albuginea corporum cavernosorum is nonlinear. Therefore, these measurements are not simply have a linear correlation with each other, and the definition of the degree of erection is never straightforward, as in the case of durometry in rubber and similar soft material industry [5] or general biological soft tissue measurement [6]. However, for simplicity and easy understanding, each researcher or investigator adopts his/her own represent-
ing parameter in a heuristic or empirical manner. For examples, Barenea [7] measured the one-turn lateral resistance of conductive elastic ring over the penis. Leang and Brick [8] also measured the same resistance combined with a radial pressure/force sensor. Lavoisor [9] indirectly measured the internal pressure of the corpus cavernosum of the penis in a manner similar to the cuff-type blood pressure measurement. Adachi [10] utilized an ultrasonic distance meter across the penis shaft. Barbara et al. [11] proposed an axial rigidity measurement device involving a smashing action of hand-held force sensor, and claimed that their device provided qualitatively better measurements than circumference or tumescence measurement. However, none of these methods involve unconstrained, wireless, continuous monitoring of the phenomenon using a wearable device, which we attempted to develop in this study.

2. Materials and Methods

2.1 Method adopted in this study

The parameter used in our study was circumference measurement represented by lateral tension of a soft silicone ring applied to target the penis. We attempted to create a soft RTV-silicone [13] ring to fit to the target penis, having with a built-in variable inductance, variable frequency oscillator with and a one-time use micro-battery. The inductance of deformable variable inductor, and therefore the oscillating frequency, is responsible for the internal stress of the ring, which represents the target penis tumescence and/or stiffness. A leakage flux coupled to the oscillator inductor make allows proximity telemetry of target the phenomenon. The device works overnight or up to the battery life.

For the force- or displacement-sensitive variable inductance, we use a pair of serially connected coils (Figure 1), where total inductance depends on the distance between these coils.

2.2 The first prototype unit

First we made a proof-of-operation model unit as the first prototype unit. Figure 2 shows a close-up view of the two-coil section of the soft silicone ring. For this proof-of-operation model, we used an external breadboard oscillator circuit, as shown in Figure 3 for continuous wave (CW) oscillation of the coil pair. The oscillating frequency was about 2.2 MHz. As shown schematically in Figure 4, a 10-cm diameter probe coil was placed at a maximum distance of 30 cm, followed by a double super-heterodyne HF instrumentation receiver [14] in CW beat frequency detection mode, with a preselected fixed frequency local oscillator to yield a baseband audio signal for the frequency shift measurement. As shown in Fig. 4, the location and height of the probe coil are arbitrary except for the situation where the magnetic flux generated by the oscillating coil pair does not cross the probe coil.

2.3 The second prototype unit

Next, we made a second prototype unit aiming at real use, which consists of a 5 × 6 mm tiny oscillator circuit board stacked with a 4 mm diameter silver oxide battery, fitted next to the coil pair in the ring. The circuit board is a reproduction of the one used in our previous study for intracorporeal telemetry capsule [12]. Although the device temperature when attached to body surface during use is expected to be close to body temperature and sufficiently stable, NP0/C0G [17] class temperature compensated chip ceramic capacitors with temperature coefficient within ±30 ppm/deg.c temperature coefficient, is are used to ensure such stability. The ring material is RTV (room temperature vulcanizing) soft-silicone gel used for soft dye making to copy 3D shape of original

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**Fig. 1** Schematic presentation of our device. Variation of ring diameter causes change in distance between the coil pair, its total serial inductance, and hence oscillating frequency.

**Fig. 2** Close-up view of our first prototype coil pair ring and external breadboard oscillator.

**Fig. 3** Example of our oscillator circuit workable with the first and second prototype units.
This soft silicone material, when fully vulcanized, has hardness of about 30 measured by Shoer type-00 durometer. This is very close to the known hardness of biological soft tissues [18,19], and mechanical behavior matching the phenomena to be tested is expected. Figure 5 shows the close-up view. Figure 6 shows the relationship between the measured balloon pressure, ring size, and oscillating frequency of the second prototype unit. Figure 7 shows the setup for this measurement. Here a model penis is constructed using a large-size balloon catheter [16] to mimic the tunica albuginea. The manual pressure generator and pressure monitor are those for cuff-type blood pressure measurement device. The cross-section diameter of the ring decreases with size expansion caused by balloon pressure. We considered that the model reasonably simulates an actual erect penis, as it recreates the internal pressure of the corpus cavernosum caused by the peak arterial blood pressure at that time, most probably 100 mmHg or slightly higher (13.6 KPa or slightly higher).

2.4 In-vitro and quasi in-vivo tests

For the quasi in-vivo test, human (authors’) finger and penis are hired to test. Figure 8 shows the scheme for the quasi in-vivo test, but a dildo is used for illustration only. The instrumentation receiver continuously monitored in real-time the variation in diameter of the ring represented by the oscillating frequency. The beat frequency audio output of the instrumentation receiver is acquired by a PC (Macintosh) and analyzed for frequency spectrum-time chart using MATLAB [15].
3. Result

Figure 9a and b shows the signal beat frequency spectrum-time diagrams when the ring was inserted to the root of the middle finger (a), and to the root of a healthy volunteer’s penis (b). As seen in these spectrum-time diagrams, cardiac origin peripheral artery pulse wave is clearly seen in both observation locations using the ring. Figure 10 shows the beat frequency spectrum-time diagrams over 5 minutes, when the ring was placed at the middle part of the penis, while intermittent manual stimulation to the glans penis was made to cause tumescence for this study.

In case of Figure 9a and b, the pulsatile component is mm- or sub-mm-size peripheral artery in cm-size cross-section. In the case of Figure 10, however, almost all the observed cross-sections change size in step with erection. This causes the difference in deviation of oscillating frequency in these case; the former is only about 50 Hz while the latter is more than 1 KHz.

4. Discussion and conclusion

We proposed a realistic method and means for unconstrained, wireless, continuous observation of nocturnal penile tumescence in form of using a wearable sensor telemeter transmitter. Our prototype sensor ring successfully sensed size change of simulated penis in a desktop in vitro test, and peripheral artery pulse wave in a real-scale quasi-in vivo test at the finger and penis. After some minor preparation such as additional electrical insulation layer to exclude electrostatic loading to the oscillator coil pair and to make a protection layer for sterilization process, we will move to pre-clinical study in healthy volunteer(s).

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