Development of an Intra-Vaginal Sensor

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Numerous women suffer from pelvic floor disorder, which can generate, amongst others, stress urinary incontinence (SUI) [1]. However, the pathophysiology of SUI is not well understood but pelvic floor muscle (PFM) dysfunction is suspected [1]. Based on the lack of suitable commercially available instrumentation, two novel, chemically disinfectable intra-vaginal sensor prototypes were developed and successfully tested for measuring PFM activity, strength and movement characteristics.

Introduction

SUI is a particularly prevalent type of incontinence that is defined as the "complaint of involuntary urine leakage on effort or exertion, or on sneezing or coughing" [1]. Several theories have attempted to explain female urinary continence mechanisms emphasizing the importance of the PFM in urethral closure for maintaining continence [1]. Nevertheless, the lack of suitable commercially available instrumentation to assess PFM activity remains a significant diagnostic problem and prevents physiotherapists and medical doctors from understanding the pathophysiology of SUI.

Materials and Methods

In order to provide a better understanding of the mechanisms of PFM contraction and its influence on SUI, two chemically disinfectable intra-vaginal sensors were developed. These sensors allow complex measurements such as static and dynamic PFM strength in the transverse plane, rate of force development, electromyogram measurement, and three-dimensional position and orientation changes of the probe during a PFM contraction. The intra-vaginal sensor prototype I (Fig. 1) is composed of four measurement units, each equipped with a force measurement platform based on thin film strain gauge technology and a pair of bipolar electrodes, while the intra-vaginal sensor prototype II (Fig. 2) is a light-weight version composed of only two measurement units. Orientation and position of both sensors within the vagina is tracked by a six degrees-of-freedom electromagnetic tracking device (trakSTAR, Ascension Technology Corporation).

Results

Preclinical tests on a few healthy subjects showed that the developed probes are complementary: while the intra-vaginal sensor prototype I, in some cases, might prevent practitioners from studying functional contractions during physical activities (walking, climbing stairs, etc.), the intra-vaginal sensor prototype II provides less functionality but a better stability due to its reduced weight and improved design.

Discussion

The results suggest that these investigational devices fully meet the defined user and system requirements and are ready for human use. Approvals from the competent Ethics Committee and Swissmedic are pending.

References

[1] M. Morin et al., "Pelvic floor muscle function in continent and stress urinary incontinent women using dynamometric measurements." Neurourology and urodynamics, vol. 23, no. 7, pp. 668–74, 2004.

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Fig. 1: Intra-vaginal sensor prototype I
(Image source: arteplus.ch)

Fig. 2: Intra-vaginal sensor prototype II
(Image source: arteplus.ch)