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Shedding light on erectile dysfunction: unveiling perspectives and pioneering new erectile assessments

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Part IV

Sensor development principals

Chapter 4

New methods for the monitoring of nocturnal erections

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Introduction

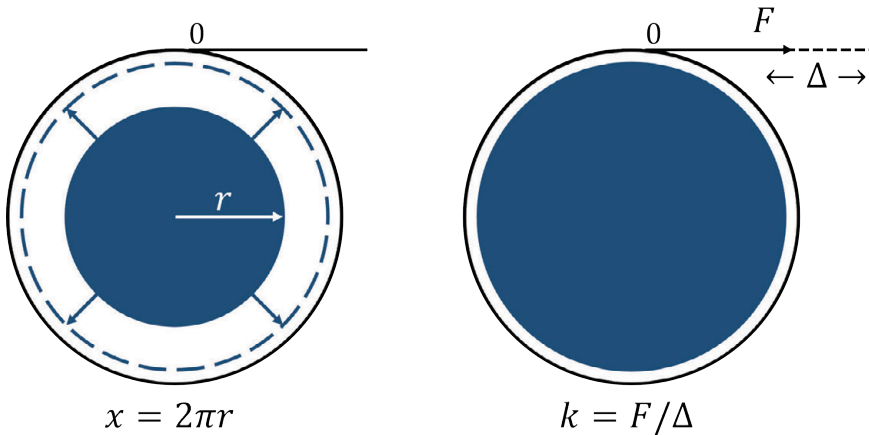
It is well known that the prevalence of erectile dysfunction (ED) increases with age, and ranges from 2 to 9% in men between 40 and 49 years old and increases up to 50–100% in the population older than 70 years [1]. According to the NIH Consensus Conference, ED is characterized as the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance [2]. Its cause can be either psychological, organic or mixed psychological and organic [1,2]. A method to distinguish between a psychological and organic cause is by measuring a patient's nocturnal erections [1,3]. Nocturnal penile erections are present in healthy men throughout their whole life and indicate an intact endocrine, vascular and neural supply as well as intact penile structures [1]. The golden standard for monitoring nocturnal erections and distinguish between psychogenic and organic causes is the RigiScan Plus (GoTop Medical, Minneapolis, MN, USA) [3]. Due to several drawbacks of this device, a novel user-friendly device for home monitoring of nocturnal erections is requested. Therefore, the goal of this perspective is to conceptualize a sensor that can be used at home for monitoring nocturnal erections. The mode of action of the golden standard RigiScan is first described, followed by new concepts to measure nocturnal erections in the future.

The RigiScan Plus

The RigiScan Plus is the most widely accepted and one of the most reliable tools to differentiate organic from psychogenic causes [3]. Nocturnal penile erections occur during periods of rapid eye movement (REM) sleep [4]. The absence of nocturnal erections indicates an organic cause of ED, and the presence of nocturnal erections indicates a normal penile function. The latter may imply a psychogenic cause [5]. The device registers the number and duration of nocturnal erections by monitoring the penile circumference and radial rigidity [6]. The apparatus is relatively big, uncomfortable and therefore disturbs a natural night of sleep. The sensor was developed in the previous century and its software is not updated to be compatible with the current operating systems on desktops, notebooks, tablets or smartphones. Therefore, new methods to measure and report nocturnal erections need to be developed. The RigiScan was developed by Bradley et al. for continuous measurement of nocturnal erections [7]. The device monitors penile rigidity and the tumescence of the penis expressed as circumference. The RigiScan consists of two non-elastic cable loops and a microcomputer for the processing of the data. The loop cables are attached to a position-sensing potentiometer and range from 5 to 15 cm circumference. Every fifteen seconds, the radial tumescence is measured by tightening the loops a little. This penile circumference is determined by the position-sensing potentiometer, which measures the change in x (Fig. 1). The change in the

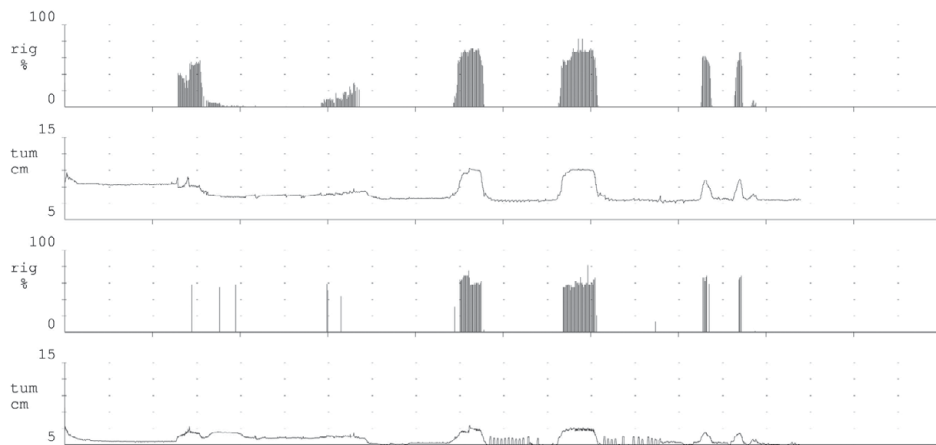
length of x relative to x_0 (the initial penile circumference) gives information about the actual penile circumference. A force of 1.1 N is sufficient for circumferential measurements [7].

Figure 1: Schematic view of loop cable to measure penile circumference and rigidity. The image on the left describes the calculation of the penile circumference by the position-sensing potentiometer. A change in x corresponds to a change in circumference ($X_0 =$ initial penile circumference). The image on the right shows how the relative rigidity is determined with the help of the spring constant (k), which is analogous to the circumferential stiffness. Figure is adapted from Bradley et al.[7].



Rigidity is monitored by means of the spring constant (k). A force (F) of 2.8 N results in a displacement (Δ) of the nonelastic loop cable. The spring constant (k) is analogous to the circumferential stiffness. The RigiScan device expresses the rigidity as a percentage relative to the spring constant of a semirigid rubber cylinder [7]. The material properties of this cylinder are not mentioned. We think they used a regular dildo to calibrate the RigiScan. We contacted GOTOP Medical, Inc. (Saint Paul, MN, USA) but our questions were not answered. A rigidity of 100% means that the penile rigidity is similar to the rigidity of the semirigid rubber cylinder [8]. A direct current torque motor pulls the loop cables every three minutes to determine the rigidity. When the penile circumference increases more than 3 mm, the rigidity sampling rate increases to once every 30 s [7]. The displacement of the loop is converted to a rigidity percentage. When the loop displaces ≥ 2.2 cm when a force of 2.8 N is applied, the rigidity is 0%. Zero displacement of the loop during a force of 2.8 N corresponds to a rigidity of 100%. For each 0.05 cm of loop displacement, the rigidity reduces by 2.3% [9]. Once connected to a computer with RigiScan Plus software a characteristic graphic is plotted. See Fig. 2 for the measurement and presentation of normal nocturnal erections.

Figure 2: Example of RigiScan data presentation during a nocturnal registration. The two graphs at the top are measured at the tip of the penis, and the two other graphs are measured at its base. On the x-axis, the time in hours is given. The y-axis of the first and third graph represent rigidity as a percentage. The y-axis of the second and fourth graph represent the tumescence in centimeters.



Possible measurable physiological changes during nocturnal erections

Arterial pulse

During nocturnal erections, dilation of the arteries in the early stage of erection reduces the vascular resistance and thereby increases the arterial flow into the corpora cavernosa. The flow increases from 2.5 ml/min in the flaccid state to 10–20 ml/min during the filling stage and decreases again when the intracavernosal pressure is increased [10]. This is accompanied by an increase in penile pulse amplitude, which is found by Bancroft et al. [11]. In most subjects, the increased penile pulse remained elevated throughout the increased penile circumference during erection. In other healthy subjects, however, the pulse amplitude declined during erection [11].

Rigidity

During maximal occlusion of the venous outflow, the intracavernosal pressure increases up to ~100 mmHg (the full erection phase). This pressure elevates further to the systolic blood pressure during maximal sexual arousal (the rigid-erection phase) [12]. The pressure in the corpus spongiosum, on the other hand, is only one-third to one half of the intracavernosal pressure [13]. This elevated outward pressure in the intracavernosal bodies results in an increased rigidity of the penile tissue. With an increased rigidity, the elasticity of the tissue decreases.

Circumference and length

A study of Promodu et al. shows that the mean penile base circumference of a flaccid penis increases from 9.14 cm to 11.5 cm in erect state. The mean penile length increases from ~8.21 cm to ~12.9 cm [14].

Temperature

Measurable elevations in skin temperature occur during sexual arousal caused by genital vasoconstriction [15]. A study in 1977 found a bigger change in temperature in the younger male population (19–30 years old), compared to males in the age of 48–65 years. The mean skin temperature increased from 33.8 to 36.2 °C ($\Delta 2.4$ °C) in the younger group and from 33.2 to 34.3 °C ($\Delta 1.1$ °C) among older men [16]. It is unknown whether the penis skin temperature depends on the thermal characteristics of the environment of the penis.

Oxygen saturation

In a study by Brow et al., saturation levels were monitored through a cavernosal blood gas analysis during a penile duplex ultrasonography in men with suspected impotence. They found a lower cavernosal PO₂ as an indicator for impotence [17].

Possible sensor concepts to measure physiological changes during nocturnal erections

When developing a new sensing system, several requirements need to be met. Sensor requirements can be divided into technical aspects and user aspects. Technical aspects include reproducibility, accuracy, validity, linearity, precision, influence of environment and sampling rate. User aspects include comfort, donning and doffing time, safety, data presentation and battery capacity. The new sensor should not disturb the natural sleep pattern. The donning and doffing time should be maximal several minutes. Besides, the system should be able to monitor for minimal one or two nights (i.e., 24 h) consecutively before charging. Next to that, the data should be presented as graphs (similar to the RigiScan Plus), which can be interpreted by the physician and patient without difficulty. The results are also presented in Table 1.

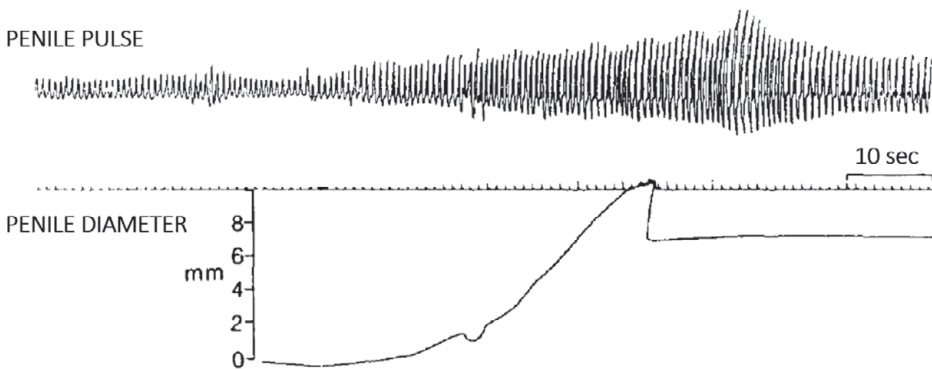
Table 1: Overview of consecutive physiological changes during erection, the accompanying non-invasive sensor principles and its advantages and disadvantages.

Physiological change	Non-invasive sensor principle	Advantages	Disadvantages
Neural innervation	Not available	X	X
Smooth muscle relaxation	Not available	X	X
Venous occlusion	Not available	X	X
Increase and decrease in arterial pulse	Photoelectric plethysmograph	<ul style="list-style-type: none"> - Can monitor small vessels. - Low cost. - High sensitivity. 	<ul style="list-style-type: none"> - Changes in penile pulse have only been studied in small populations. - Optimal site for sensor placement is unclear.
Increase in circumference	Radial strain gauge	<ul style="list-style-type: none"> - Data can be easily interpreted, since it is comparable to the RigiScan data presentation. - Provides information about duration and intensity of an erection. 	<ul style="list-style-type: none"> - Pressure on penile skin might disturb natural sleep.
Increase in length	Resistive or capacitive displacement sensor	<ul style="list-style-type: none"> - No pressure on penile skin is needed. - Different displacement sensors for medical applications already exist. 	<ul style="list-style-type: none"> - The influence of movement artefacts is unknown. - Too many movable layers beneath the skin, so fixation is not possible.
Increase in rigidity	Multiple radial strain gauges with a different stiffness	<ul style="list-style-type: none"> - Relation between percentage of rigidity and possibility of sexual intercourse is known [6]. - Data can be easily interpreted, since it is comparable to the RigiScan data presentation. - Provides information about duration and intensity of an erection. 	<ul style="list-style-type: none"> - Probably the least comfortable due to pressure on penile skin. - Maximal acceptable pressure is unknown.
Increase in cavernosal and skin temperature	Smart: thermocouple or thermistor Cavernosal: near infrared sensor seems an option	<ul style="list-style-type: none"> - Small size of the sensor. - Applicable for young men, $\Delta 2.4^{\circ}\text{C}$ of penile skin temperature. - Minimal sleep disturbance, since no pressure on penile skin is needed. 	<ul style="list-style-type: none"> Little is known about: - Influence of external thermal factors and penile conductivity. - Relation between temperature changes and duration and intensity of erection. - Optimal site for sensor placement is unclear.
Decrease in oxygen saturation	Tissue oxygenation sensor	<ul style="list-style-type: none"> - Small size of the sensor. - Minimal sleep disturbance. - Easy application. 	<ul style="list-style-type: none"> Little is known about: - Optimal site for sensor placement. - Sensor settings for depth measurement. - Relation between saturation levels and intensity of erection.

Plethysmography for arterial pulse

Bancroft et al. showed that photoelectric measurements of an increased arterial pulse amplitude from the dorsal penile artery are correlated with an increase in penile diameter, see Fig. 3. When maximal penile diameter is reached, the arterial pulse either remains constant or decreases [11]. A photoelectric plethysmograph consists of a light source and a light detector. The optical absorption of blood is higher than the absorption of the surroundings. Therefore, the incoming light has a higher attenuation when the blood volume is higher [18].

Figure 3: Arterial pulse during erection, measured by a photoelectric plethysmograph. Figure is modified from Bancroft et al. (1985) [13].



Displacement sensor for axial length

For monitoring changes in penile length, a measurement of the displacement is favored. Resistive sensors contain an elastic material and senses a change in resistance due to changes in diameter and length [19]. Capacitive sensors monitor displacement by changes in distance between two parallel plates [20]. An advantage of resistive and capacitive sensors is their capability of measuring small displacements and can therefore precisely monitor changes in penile length [19,20]. For measuring changes in penile length, a stretchable sensor is necessary.

Strain gauges for radial rigidity and circumference

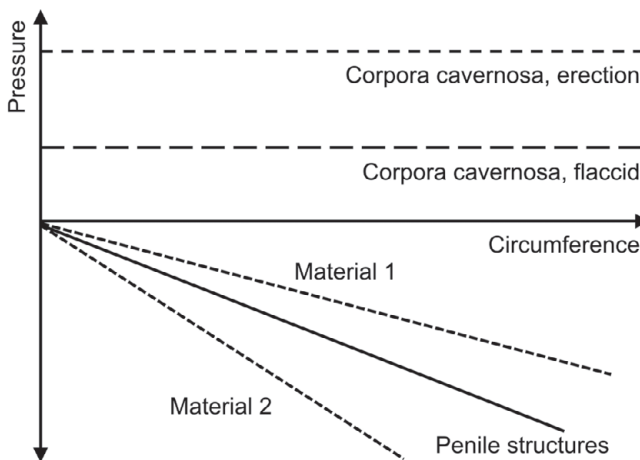
When simplified, the penis can be seen as a cylinder with two components: a blood reservoir (the corpora cavernosa) and the passive penile structures. During an erection, the outward pressure in the corpora cavernosa ($P_{\text{cavernosal}}$) and the inward pressure from the passive penile structures ($P_{\text{structures}}$) both increases, until the system is in equilibrium. An elastic band placed around the penis can be seen as an additional inward pressure (P_{elastic}). When the elastic band

stretches (thus an increase in circumference), the inward pressure increases as well. This extra pressure means that the equilibrium (the penile circumference at which the sum of the forces is zero) at the location of the elastic band shifts. See equation 1. Note that this equation describes a local equilibrium shift, and does not involve the entire penile length.

$$P_{\text{cavernosal}}(t) = P_{\text{structures}}(t) + P_{\text{elastic}}(t) \quad (1)$$

An elastic band with a strain gauge around the penile shaft is able to monitor penile circumference. A strain gauge works as a piezoresistive sensor [21]. One individual band with a certain elasticity will not provide information about the rigidity of the underlying tissue. Therefore, minimal two elastic bands with a different stiffness and thus two equilibria are recommended. Since the material properties of the elastic bands are known, information about the underlying tissue can be acquired. The relation between the change in penile diameter and accompanying pressure by the elastic bands provides information about the rigidity of the penile tissue. To visualize the interplay between the properties of the penile tissue and the strain gauges, a schematic representation is given in Fig. 4. Note that the relations given in this figure are linear, while in reality these relations might have a linear part but are not completely linear.

Figure 4: Schematic representation of the corpora cavernosa (dashed lines) and passive penile structures (solid line) relative to the elastic bands (dotted lines). The stiffness (i.e. slope) of material 2 is bigger than the stiffness of material 1. During an erection, the outward pressure (upper dashed line) is higher compared to flaccid state (lower dashed line). The sum of the inward pressures created by the elastic band and the penile structures must be equal to the outward pressure created by the corpora cavernosa. During an erection, the pressure inside the corpora cavernosa increases and thus leads to an equilibrium-shift to the right on the x-axis.



Skin and cavernosal temperature sensors

Penile skin temperature has a bigger time constant than penile circumference, during both increases and decreases in sexual arousal [15]. For skin temperature, a thermocouple or thermistor are suitable options [22]. It is important that the influences of environmental thermal characteristics, heat conductivity and artifacts are taken into account. Increased skin temperature is a consequence of increased temperature in the erected corpora cavernosa. Therefore, with adequate sensor depth settings also the temperature in the cavernosa should be measurable. The use of near-infrared (NIR) light can provide information about the temperature underneath the skin. Wearables are already being developed for infrared measurements [23]. This could be applied for penile tissue temperature measurements, especially in the corpora cavernosa.

Oxygenation sensor

Padmanabhan et al. studied the penile oxygen saturation in men with ED using a local tissue StO₂ sensor and showed a significantly lower corporal penile StO₂ in the flaccid penis. They made use of Optical Diffusion Imaging and Spectroscopy (ODIS) with the ODISey Tissue Oximeter [24]. With the use of a tissue StO₂ sensor with adequate depth settings, it should be possible to measure and visualize the saturation in the corpora cavernosa during flaccid state and during an erection.

Discussion

The current golden standard, the RigiScan, has several drawbacks. First of all, it causes physical discomfort and thereby disturbs natural sleeping patterns. Therefore, the results of the measured erections during REM sleep are less reliable. Other disadvantages are, for example, lack of updated software, lack of Bluetooth compliance, the enormous size of a simple mechanical sensor and difficult instructions for both physician and patient. Due to the working mechanism of the RigiScan, it is not possible to miniaturize the current system. For all further sensor concepts described in this perspective, smaller dimensions are achievable. In general, a stretchable sensor is necessary to minimize the level of discomfort.

When choosing the most suitable sensor principle for this application, considerations will have to be made. First, a fundamental consideration is the information that can be derived from the nocturnal measurements. For example, a basic sensor may indicate whether there is an erection or not. However, when more detailed information about the duration and intensity of erection is required, a more complex sensor is necessary. For a wide range of uses, information

about the duration and intensity of erections is favorable. With the available information, it is questionable whether the changes in temperature, arterial pulse and oxygen saturation can provide detailed information about the length and intensity of penile erections. Second, the data presentation should be taken into account as well. Urologists are familiar with the RigiScan and corresponding data presentation. Therefore, similar data presentation is favorable. The circumference and rigidity are physiological parameters with the same or a comparable data presentation, since these are the parameters measured by the RigiScan.

When looking at the penile anatomy, there are several layers between skin and the corpus cavernosa: skin, the superficial fascia, the deep fascia and the tunica albuginea [25]. When attaching a sensor to measure axial displacement during erection, the penile outer layers will move instead of the sensor itself. Because of movement of these layers relative to each other, it is impossible to attach a displacement sensor to a fixed point for axial length measurements. Moreover, these outer layers contribute to the tissue heat conductivity. The rate of increase and decrease of skin temperature depends on tissue conductivity and environmental temperature. Therefore, measuring the temperature inside the corpora cavernosa by a NIR temperature sensor provides more accurate information. However, little is known about the cavernosal temperature changes and its relation to the intensity and duration of an erection. Since these two components are important in the diagnostic process, cavernosal and penile skin temperature during erections should be studied thoroughly before it is put into practice.

Photoelectric plethysmography is suitable for peripheral vascular measurements and is sensitive to small amounts of pulsatile blood flow [18]. It is already being applied for continuous vascular monitoring in the evaluation of peripheral artery disease, for example in patients with atherosclerosis. The simplicity and low-cost of this method provide significant benefits to healthcare [26]. However, the changes in penile arterial pulse during tumescence and detumescence have not been studied in large populations. Nor is the exact location of the pulse sensor examined for application on the penis. Bancroft et al. [11]. found differences in the pattern of the penile pulse among 22 healthy subjects. In some subjects the penile pulse remained elevated during the full erection phase, while in others, the pulse amplitude lowered. Thus, further research on the changes in penile pulse during erection is needed.

Brow et al. described that cavernosal oxygen tension is lower in patients with arteriogenic and venogenic impotence compared to healthy individuals [17]. This might suggest that these patients have corporal fibrosis secondary to chronic ischemia [17]. Until today, little to nothing is known about oxygenation changes in cavernosal tissue during normal nocturnal erections. It is unknown whether physiologically normal nocturnal erections show a measurable decline in oxygenation of the corpora cavernosa during erection. A drawback of this method is the

fact that it is unknown what time it takes for the erected penis before a decrease in cavernosal oxygenation occurs. Therefore, a graphic presentation of oxygenation will show a delay between the actual start of the nocturnal erection and the measurable erection.

Among the concepts discussed in this paper, an arterial pulse, temperature or oxygenation sensor would exert the least pressure and tensile forces. For monitoring circumference and rigidity, a certain radial pressure is necessary. The pressure applied to the penile skin should be sufficient to obtain valuable information about the physiological parameter, but should not disturb the natural sleep pattern. An overview of the different sensor principles and its advantages and disadvantages is given in Table 1.

Conclusion

New methods for measuring nocturnal erections are necessary. We discussed several sensor concepts as a successor for the still important, but outdated RigiScan. Axial length measurements seem impossible because of movement of the skin relative to the cavernosa. Skin and cavernosal temperature, penile arterial pulse, radial circumference and rigidity measurements, and saturation of the cavernosa are potentially feasible for home monitoring of nocturnal erections. Whether a combination of these techniques is favorable or only one of them should be studied more thoroughly.

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