TREATMENT OF MALE URINARY INCONTINENCE AND SEXUAL DYSFUNCTION

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ABSTRACT

Methods and devices to diagnose and treat male urinary incontinence and sexual dysfunction are provided. A multiple sensor-enabled catheter for rectal insertion in a male patient allows for the visualization and manipulation or positioning of the bladder. A multiple sensor-enabled catheter for rectal insertion in a male patient allows for the visualization and implementation of efficient and effective exercises to strengthen pelvic floor muscles.
TREATMENT OF MALE URINARY INCONTINENCE AND SEXUAL DYSFUNCTION

BACKGROUND

[0002] The present embodiments relate to the devices, diagnosis, and treatment of male urinary incontinence and sexual dysfunction. The diagnosis and treatment may involve the use of a multiple sensor-enabled catheter capable of providing real-time data regarding the patient's anatomy and physiology, such as muscular function of the pelvic floor and rectal sphincter, as well as the position and movement of the catheter within the patient.

[0003] Human males may experience urinary incontinence (UI), which is the unintentional loss (accidental leakage) of urine, as well as sexual dysfunction, which is a problem during the phase of the sexual response cycle that prevents the man or couple from experiencing satisfaction from sexual activity. Reports indicate that urinary incontinence can occur in 11% of the male population whereas male sexual dysfunction can occur in 31% of the male population. Weak or damaged pelvic floor muscles (hypotonia), overactive pelvic floor muscles (hypertonia), certain prostate conditions, and nerve damage are some of the possible underlying causes of urinary incontinence in men. Different types of urinary incontinence in men include stress incontinence, urge incontinence, and overflow incontinence. Some men may experience more than one type of incontinence. Diagnosis of urinary incontinence in men typically involves a medical history and physical exam, and may include keeping a bladder diary. Diagnosis of sexual dysfunction in men typically involves a self-reporting questionnaire. Therapy for urinary incontinence in men may include behavioral modification such as like bladder training and Kegel exercises, medication, surgery, or a combination of these therapies.

[0004] Sexual dysfunction is the inability to have satisfactory sexual activity. This definition depends on each person's own interpretation of satisfactory sexual activity. Typically, male sexual dysfunction includes erectile dysfunction (ED), or impotence, and ejaculation problems such as premature ejaculation. ED is the inability to acquire or maintain a satisfactory erection. The prevalence of erectile dysfunction varies according to the patient's age. About 18% of men from 50 to 59 years of age and 37% of those aged 70 to 75 years will suffer from erectile dysfunction. Ejaculation problems involve the improper discharge of sperm, prostatic, and seminal vesicle fluid through the urethra. Premature ejaculation is the most common of the ejaculatory disorders; approximately 20% to 30% of men will have premature ejaculation. As with incontinence, sexual dysfunction in males is often associated with, or caused by, pelvic floor dysfunction.

[0005] Pelvic floor muscle training (PFMT, or Kegel exercises), includes a series of exercises designed to rehabilitate the musculature of the pelvic floor. For example, PFMT can help strengthen and tone the muscles under the bladder, and bowel (large intestine), and thus aid those who have problems with urine leakage, bowel control or sexual dysfunction. A current problem with PFMT is that the individual is often unable to visualize or attain the proper muscle position and control to carry out an efficient and effective exercise regimen required to rehabilitate the pelvic floor muscles.

SUMMARY

[0006] The embodiments described herein relate to the diagnosis and treatment of male UI and male sexual dysfunction. In one embodiment, diagnosis and treatment involves the use of a multiple sensor-enabled catheter capable of providing real-time data regarding the patient's anatomy and physiology, such as muscular function of the rectal sphincter or pelvic floor, as well as the position and movement of the catheter within the patient. In one embodiment, the device may be a pressure sensor-enabled catheter.

[0007] In one embodiment, the multiple sensor-enabled catheter may include at least one sensor capable of providing real-time data of one or more types selected from the group consisting of position, movement, pressure, and flow. In this regard, a sensor may have a single measurement and reporting capability, or may have multiple measurement and reporting capabilities.

[0008] The present embodiments also provide for methods for the diagnosis or treatment of male UI, comprising positioning a multiple sensor-enabled catheter in a male patient's rectum and determining the anatomical state of the patient, which treatment is capable of relieving or ameliorating incontinence. The anatomical state may be the relative position of the bladder neck and urethra. The anatomical state may also be the sphincteric and supportive functions of the pelvic floor. The method of diagnosis or treatment may also include manipulating the patient to relieve the incontinence. The manipulation may be performed by the health care provider or the patient. The manipulation may include achieving a particular anatomical position of the bladder neck relative to the urethra or achieving a particular muscular function of the pelvic floor.

[0009] The present embodiments also include a method for the diagnosis or treatment of male sexual dysfunction, comprising positioning a multiple sensor-enabled catheter in a male patient's rectum and determining the anatomical state of the patient, which treatment is capable of relieving or ameliorating a sexual dysfunction. For example, the treatment if capable of achieving efficient and effective control of pelvic floor muscles to relieve the sexual dysfunction.

[0010] The present embodiments contemplate the real-time position and movement tracking as described in U.S. Pat. No. 8,805,472. In this regard, the real-time position and movement tracking may include sensing the position of the bladder relative to a fixed reference point within the patient's body, by providing a catheter enabled with a sensor and capable of providing positional or movement data. The fixed reference point within the body may be the pubic bone, the coccyx, the bladder, the urethra, the prostate, or the rectum. The method may be performed in real-time, for example, during an operation. In another embodiment, the method may be performed...
at multiple time intervals. The multiple time intervals may occur, for example, pre- and post-event, wherein the event may be injury or surgery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 depicts a view of an example probe device comprising a multiple sensor-enabled catheter.

DETAILED DESCRIPTION

[0012] All patents, applications, and other publications identified are expressly incorporated herein by reference for the purpose of describing and disclosing, for example, the devices methodologies described in such publications that might be used in connection with the present invention. These publications are provided solely for their disclosure prior to the filing date of the present application. Nothing in this regard should be construed as an admission that the inventors are not entitled to antedate such disclosure by virtue of prior invention or for any other reason. All statements as to the date or representation as to the contents of these documents are based on the information available to the applicants and does not constitute any admission as to the correctness of the dates or contents of these documents.

[0013] As used herein and in the claims, the singular forms include the plural reference and vice versa unless clearly indicated otherwise by context. Throughout this specification and claims, unless otherwise indicated, “comprise,” “comprises” and “comprising” are used inclusively rather than exclusively. The term “or” is inclusive unless modified, for example, by “either.” Other than in the operating examples, or where otherwise indicated, all numbers should be understood as modified in all instances by the term “about.”

[0014] Unless otherwise defined, scientific and technical terms used herein shall have the meanings that are commonly understood by those of skill in the art. The terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention, which is defined solely by the claims.

[0015] One embodiment described herein provides for methods for the diagnosis or treatment of male urinary incontinence, comprising positioning in the rectum of a male patient a multiple sensor-enabled catheter, visualizing the anatomical state of the patient, and manipulating the patient’s body to a position capable of relieving the incontinence. In an additional embodiment, the anatomical state is the relative position of one or more internal anatomical reference points selected from the pubic bone, the coccyx, the bladder, the urethra, the prostate, and the rectum. In one other embodiment, the anatomical state is the muscular function of the bladder or rectal sphincter.

[0016] Another embodiment described herein provides for methods for the diagnosis or treatment of male sexual dysfunction, comprising positioning in the rectum of a male patient a multiple sensor-enabled catheter, visualizing the anatomical state of the patient, and manipulating the patient’s body to a position capable of strengthening pelvic floor muscles. In an additional embodiment, the male sexual dysfunction is erectile dysfunction or premature ejaculation.

[0017] An additional embodiment provides for a method of rehabilitating the pelvic floor musculature, comprising positioning in the rectum of a male patient a multiple sensor-enabled catheter and visualizing the anatomical state of the patient, wherein the patient manipulates the catheter as a method of exercising control of sphincter or pelvic floor muscles.

[0018] In the present embodiments, for example, a catheter is enabled with at least one sensor capable of providing real-time data of at least one data type selected from the group consisting of position, movement, pressure, and flow. In this regard, a sensor may have a single measurement and reporting capability, or may have multiple measurement and reporting capabilities. The data obtained by the multiple sensor-enabled catheter may be reported in any number of ways know in the art, including the transmission to, and visualization on, a graphical user interface. For purposes of the embodiments, “real-time” may include instantaneous as well as delayed observation, reporting, or recording of an event as it elapses.

[0019] Advantageously, by viewing a real-time image of where the bladder and urethra are located in a patient relative to one or more other anatomical reference points during a procedure, a health care provider may manipulate the patient such that the patient’s bladder and the urethra are in a position capable of relieving or ameliorating incontinence. In other instances, a patient himself may visualize his own anatomical state using the multiple sensor-enabled catheter, and may manipulate his body such that his bladder and the urethra are in a position capable of relieving incontinence. Additionally, the patient himself may visualize his anatomical state using the multiple sensor-enabled catheter, and may manipulate his body to a position capable of controlling his pelvic floor muscles to relieve incontinence.

[0020] In addition, by viewing a real-time image of where the bladder and urethra are located in a patient relative to one or more other anatomical reference points during a procedure, a health care provider may manipulate the patient such that the patient is in a position capable of strengthening his pelvic floor muscles. In other instances, the patient himself may visualize his anatomical state using the multiple sensor-enabled catheter, and may manipulate his body to a position capable of strengthening his pelvic floor muscles. In either instance, the visualization allows the health care provider or the male patient to achieve the efficient and effective exercising of his pelvic floor muscles to control pelvic floor musculature and relieve sexual dysfunction.

[0021] A multiple sensor-enabled catheter provides a valuable study or diagnostic tool for a health care provider as well as a patient, particularly when the patient is considering surgery that may result in UI or sexual dysfunction as a side effect or post-surgical complication. For example, a health care provider may provide the patient with an in-office procedure that determines a baseline position or relative mobilization of the bladder (baseline), before possible damage to his pelvic floor that might occur, for example, during prostate or colorectal surgery; such that if surgical repair is subsequently performed, his bladder can be repositioned to the original, pre-incontinence anatomical position. Surgery could also be performed on patients with a surgically correctable structural defect, using the multiple sensor-enabled catheter to provide positioning data. Such procedures may involve a male sling, placement of an artificial bladder sphincter, bulking, or ultimately urinary diversion.

[0022] A multiple sensor-enabled catheter can also be used as a diagnostic tool where the position of the bladder needs to be adjusted surgically to correct a urinary problem, such as that involving male prostatic hypertrophy causing a stricture of the urethra. The multiple sensor-enabled catheter may also
be used after male prostatectomy to help determine the optimal positioning of the urethra and bladder neck, or the pressure exerted by the bladder sphincter. Another use for a multiple sensor-enabled catheter would be to correct male fecal incontinence.

[0023] The multiple sensor-enabled catheter may incorporate at least one sensor capable of measuring or reporting data of various types, including position, movement, pressure, or flow. A multiple sensor-enabled catheter with more than one individual sensor may be arrayed as depicted in FIG. 1, or it may incorporate a single sensor that has multiple measuring and reporting capabilities.

[0024] The position or movement data may be of the sort measured or reported by any number of sensor devices, including accelerometer, gyroscope, inductive non-contact position sensor, string potentiometer, linear variable differential transformer, potentiometer, capacitive transducer, Eddy-current sensor, Hall effect sensor, optical proximity sensor, piezo-electric transducer, or photodiode array sensor devices. The position or movement data may also include magnetic, electromagnetic, microelectromechanical, radio frequency, ultrasound, or video data.

[0025] The pressure or flow data may be of the sort measured or reported by any number of sensor devices, including force collector types, such as piezo-resistive, capacitive, electromagnetic, piezo-electric, optical, potentiometric, or other types, such as resonant, thermal, ionization, ultrasonic, or density (mass and index of refraction) sensor devices.

[0026] For example, an embodiment of a multiple sensor enabled catheter comprising a firm tip, which may be about ½ inch in length to guide the catheter through the rectum. The number and precise placement of an individual sensor may vary depending on the type of positional, movement, pressure or flow measurement or reporting system employed. An individual sensor may have a single function or be multifunction (such as positional tracking combined with pressure and flow sensing). The multiple sensor-enabled catheter may also embody a video observation or recording device as well as an illumination source to facilitate such video capture. The precise placement of the sensor(s) and video capture component(s) are not pre-defined, and may be configured according to the requirements of the desired application.

Examples

[0027] As described herein, catheters useful in the present embodiments may embody at least one sensor capable of measuring and reporting at least one data type, including position, movement, pressure, and flow. These include, but are not limited to, magnetic, electromagnetic, microelectromechanical, radio frequency, ultrasound, and video. One example of a multiple sensor-enabled catheter, as shown in FIG. 1, is a probe or catheter 100 containing multiple sensors arranged in an array 102. The probe or catheter 100 may be constructed of a silicon or other material suitable for medical use in or on a patient's body. The probe or catheter 100 may include a distal probe or catheter tip 101, which may be constructed of a material with sufficient hardness or rigidity to facilitate the ease of insertion of the probe or catheter 100 into a patient's rectum. The probe or catheter 100 may also contain a proximal portion with a connector/handle 104 to facilitate positioning or movement of the probe or catheter 100 by the patient or health care provider. A sensor, such as a pressure sensor 103, may be contained in the proximal portion of the probe or catheter 100 to facilitate the assessment of rectal sphincter strength and/or control when the probe or catheter 100 is inserted into the patient's rectum.

[0028] In other embodiments, the sensor(s) may be positioned in the probe or catheter 100 without a particular spatial relationship to any other sensor(s). The probe or catheter 100 may contain a microelectromechanical (MEMS) device(s), a 3-axis accelerometer, a roll/pitch gyroscope and a yaw rate gyroscope, and a pressure and flow transducer. The devices may also be mounted on a small flexible printed circuit board (PCB) and then attached to the probe or catheter. The 3-axis accelerometer may track translation of the probe or catheter in three directions. The gyroscopes are utilized to account for gravitational rotation, allowing real-time movement to be tracked.

[0029] In one embodiment, a PCB may be prepared with the three MEMS devices mounted thereon. Soft leads trail the MEMS devices to supporting devices, including, for example, a data acquisition card which may be used for transforming analog signals to digital signals. The PCB is set within the wall of the probe or catheter. The location of the probe or catheter may be determined by the output signals of the MEMS devices.

[0030] The multiple sensor enabled catheter may be linked via data cable 105 to a transmitter 106, which can provide a wireless data signal (such as Bluetooth) to a device 107 (computer, tablet, smartphone, or similar device) capable of receiving the transmission of data collected by the sensors. The connection of the data cable 105 to the catheter or probe 100 may be achieved through a mating interface with connector/handle 104. Alternatively, the transmitter may be contained within the probe/catheter or probe/catheter handle. The linked device 107 may process the data or provide a graphical user display, or transmit such information to another device(s) to accomplish similar tasks. In another embodiment, the probe or catheter 100 may transmit a wireless data signal directly to the device 107.

[0031] The patient may be asked to reiterate maneuvers that induce incontinence at the same time that the parameters for the location/pressure/flow/visualization of the urethra and bladder are determined.

[0032] The urethra and bladder are manipulated to the position where muscular pressure is optimized and urine flow is returned to normal physiological control. These positions for the urethra and bladder neck may be displayed in real-time on a graphical user interface and/or recorded.

[0033] In the case of surgical intervention, if no pre-incontinence position is known, the urethra and bladder neck are positioned based on data collected from a cohort of patients with similar UI history or profile. Where pre-incontinence data is available (e.g., the positions of the urethra and bladder neck are based on patient information from an earlier date), then at the time of surgery the urethra and bladder neck are repositioned to the location where the patient was previously determined to be continent.

[0034] Following examination using the multiple sensor-enabled catheter, a health care provider may conclude that rehabilitation is an efficacious option for the patient. In this regard, the measurements provided by the multiple sensor-enabled catheter may be recorded to facilitate appropriate patient instructions on performing Kegel exercises in an optimal manner using the visual (on-screen) information provided by the catheter in real-time. Once engaging the proper muscular style has been successfully demonstrated to the patient during a medical office visit, the patient may be sent home.
with the instructions to perform Kegel exercises five to six times daily, for example. Four to six weeks later the patient may return for another examination using the multiple sensor-enabled catheter to evaluate rehabilitative treatment effectiveness, which may allow a health care provider to advise the patient about the prospects for restoring complete continence or alleviating sexual dysfunction with a continued rehabilitative regime or a surgical procedure.

[0035] Detailed embodiments are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the claimed invention that may be embodied in various forms. It will be appreciated that many modifications and other variations that will be appreciated by those skilled in the art are within the intended scope of this invention as claimed below without departing from the teachings, spirit, and intended scope of the invention.

What is claimed is:

1. A method for the diagnosis or treatment of male urinary incontinence comprising inserting into the rectum of a male patient a multiple sensor-enable catheter, visualizing the anatomical state of the patient, and manipulating the patient’s body to a position capable of relieving the incontinence.

2. The method of claim 1, wherein the anatomical state is the relative position of one or more patient anatomical reference points selected from the group consisting of the pubic bone, the coccyx, the bladder, the urethra, the prostate, and the rectum.

3. The method of claim 1, wherein the anatomical state is the muscular function of the bladder sphincter.

4. The method of claim 1, wherein the anatomical state is the muscular function of the rectal sphincter.

5. The method of claim 1, wherein the anatomical state is the muscular function of the pelvic floor.

6. The method of claim 5, wherein the manipulating is done by the patient.

7. A method for the diagnosis or treatment of male sexual dysfunction comprising inserting into the rectum of a male patient a multiple sensor-enable catheter, visualizing the anatomical state of the patient, and manipulating the patient’s body to a position capable of strengthening pelvic floor muscles.

8. The method of claim 7, wherein said dysfunction is erectile dysfunction.

9. The method of claim 7, wherein said dysfunction is premature ejaculation.

10. The method of claim 7, wherein the manipulating is done by the patient.