Abstract
The present invention discloses a trainer and kit thereof, for rehabilitating and treating incontinence, possibly post-operative incontinence. The trainer comprises an elongated, optionally curved effector suitable for being reversibly introduced into the rectum, via the anus of a human patient; the effector optionally comprising a penetration tip; and, handle which comprises a stopper preventing slippage of the effector into the body cavity; and optionally a at least one handle. The invention also presents a method of rehabilitating and treating incontinence and possibly post-operative incontinence. The method comprises steps of obtaining a trainer as defined above, and reversibly introducing the effector into the rectum, via the anus of a human patient.

Fig. 1
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— without international search report and to be republished upon receipt of that report
FIELD OF THE INVENTION

The present invention generally relates to a trainer for rehabilitating and treating continence and possibly post-operative incontinence and methods thereof.

BACKGROUND OF THE INVENTION

The present invention relates to a trainer for rehabilitating and treating continence and possibly post-operative incontinence.

Urinary incontinence is a significant health concern worldwide. Urinary incontinence can be developed in patients with neurological diseases such as Parkinson, Hemiparesis, Multiple Sclerosis. It is also found in elderly patients unable to control their muscles due to weakness and lengthy treatment with steroids, in patients during and after chemotropic treatments, in patients suffering from Irritable bowel syndrome, in patients with Constipation, in pregnant women, in patients with Osteoporosis, in athletes and after prostate operations.

In the urology field, needles, suture passers and ligature carriers are utilized in a variety of procedures, many of which are designed to treat incontinence. Moreover, various implantable devices, such as distensible medical devices, are known in which the distensible medical devices are implanted into the tissue of a human to treat urinary incontinence. These devices have typically relied upon restricting or constricting the urethra of the patient to maintain continence.

U.S. Pat. No. 4,733,393 to Haber et al. is an attempt at such a proposed device. U.S. Pat. No. 4,733,393 relates to a hypodermically implantable genitourinary prosthesis which provides an extensible, inflatable tissue expanding membrane to be located in proximal urethral tissue to add bulk to these tissues for overcoming urinary incontinence by localized increase in tissue volume.

U.S. Pat. No. 4,802,479 to Haber et al. is an attempt at an instrument for dispensing and
delivering material to an inflatable membrane of a genitourinary prosthesis within the tissues of a patient for overcoming urinary incontinence. U.S. Pat. No. 4,832,680 to Haber et al. relates to an apparatus for hypodermically implanting a genitourinary prosthesis comprising an extensible containment membrane for retaining a fluid or particulate matter which is injected from an external source.

U.S. Pat. No. 5,304,123 to Atala et al. relates to a detachable membrane catheter incorporated into an endoscopic instrument for implantation into the suburethral region of a patient. Also, U.S. Pat. No. 5,411,475 to Atala et al. discusses a directly visualized method for deploying a detachable membrane at a target site in vivo.

Once inflated, these devices maintain pressure on the urethra of the patient in an attempt to assist with continence. However, these devices are prone to being under or over inflated at time of implant, leading to undesirable postoperative results. For example, if the devices are overinflated it may cause the urethra to be restricted too tightly, and the patient is at risk for retention, a condition where the patient cannot pass urine. Such a condition could lead to kidney damage, necessitating major corrective surgery or at minimum use of self-catheterization to empty the bladder on a regular basis thus increasing the risk of urinary tract infection.

Furthermore, once these devices have been implanted within the patient, the only means of removing them in the event of a postoperative problem or device malfunction is through major surgery. Also, the devices are secured within the tissues of the patient, so there is the possibility of the devices migrating back along the pathway created in inserting them, a problem which has been noted with prior art devices.

Thus, there is a long felt need for an important medical need exists for an improved trainer for rehabilitating and treating urinary incontinence.

**DETAILED DESCRIPTION OF THE INVENTION**

It is in the scope of the invention wherein a trainer (100) for rehabilitating and treating continence and possibly post-operative incontinence is disclosed. The trainer comprises of (i) an elongated effector (10) suitable for being reversibly introduced into the rectum, via the anus of a human patient; said effector optionally comprising a penetration tip (11); and, (ii)
handle (20) comprising a stopper (21) preventing slippage of said effector into said body cavity; and optionally a at least one handle (22).

It is further in the scope of the invention wherein the aforesaid effector is of dimensions (i.e., diameter and length) that vary from about 4 to 25 mm and from about 30 to 150 mm, respectively.

It is further in the scope of the invention wherein the said effector and/or said penetration tip is made of conventional elastic or semi elastic, resilient material, especially rubber, silicon rubber, natural latex or alike biocompatible materials or combinations thereof.

It is further in the scope of the invention wherein the said effector is an elongated bladder characterized by an envelope and an inner portion comprising at least one compartment filled with flowing matter.

It is further in the scope of the invention wherein the said effector is included in a kit comprising of said trainer and disposable condom enveloping the same.

It is further in the scope of the invention wherein said flowing matter characterized by Shore A hardness of less than 5.

It is further in the scope of the invention wherein said flowing matter is selected from a group consisting of fluids, air, especially FDA approved gels, water, saline, glycerin, heat retaining materials, and flowing solids, especially fine particles, silica, silica gel, powders, aggregates or the like.

It is further in the scope of the invention wherein the wall thicknesses of said envelope are up to about 4 mm, especially 1.5 to 2.5 mm.

It is further in the scope of the invention wherein the effector is of high tear propagation resistance having a Shore A hardness of about 30 to 60.

It is further in the scope of the invention wherein the stopper is constructed from a semi-rigid material, especially a polymer or high durometer silicon or alike.

It is further in the scope of the invention wherein the penetration tip is constructed of a yieldable silicon material.

It is further in the scope of the invention wherein said handle is at least one hinged ring.
It is further in the scope of the invention wherein said handle is at least one inset beveled slot.

It is further in the scope of the invention wherein said effector is a massaging effector, interconnected to a power supply for causing said effector to vibrate and or oscillate, with or without an electronic module that may control timed vibrations and or oscillations that may be programmed by the physician to periodically simulate the patient to exercise the muscles.

It is further in the scope of the invention wherein said effector comprising means to facilitate the passage of fluids, medicaments, accessories, especially optic fibers and surgical tools.

It is further in the scope of the invention wherein said effector comprising means to facilitate the passage of diagnostic sensors into the patient body cavity, said sensors interconnected by wire or wirelessly with diagnostic apparatus.

It is further within the scope of the invention wherein an applicator is provided, including a bladder, perforated to facilitate controlled release of substances towards the rectal wall.

It is further within the scope of the invention wherein said applied substances are selected from a group consisting of fluids, medicaments, pastes, gels, lotions, creams, salves or combination thereof.

It is further within the scope of the invention wherein an extractor is provided, useful for removal of fecal samples especially for use in occult fecal blood examinations comprising of a plurality of protuberances located at the outer portion of the shaft and/or penetration tip.

It is further in the scope of the invention wherein said trainer is appropriately curved and adapted to treat a male patient. Alternatively, it is in the scope of the invention wherein said trainer is appropriately curved and adapted to treat a female patient.

It is further in the scope of the invention wherein said effector comprises of heating/cooling means.

It is further in the scope of the invention wherein said trainer is a heating/cooling device, wherein said heat/cool is provided by means selected from Pelletier device, electrical condenser, heated electrical element, pre-cooled or pre-heated materials or a combination thereof.

It is further in the scope of the invention to disclose a method of rehabilitating and treating post-operative incontinence. The method comprises of (i) obtaining a trainer as defined in any
of the above, and (ii) reversibly introducing said effector into the rectum, via the anus of a human patient.

It is further in the scope of the invention wherein the method additionally comprises of vibrating the effector to a predetermined measures of time, amplitude and frequency.

It is further in the scope of the invention wherein the method additionally comprises of heating and/or cooling the effector to a predetermined temperature, ranging from 4 to 42 degrees Celsius.

It is further in the scope of the invention wherein the method additionally comprises of administrating fluids, medicaments, accessories, especially optic fibers and surgical tools while said effector is deployed within the patient's body cavity.

Reference is now made to figure 1, schematically illustrating a trainer according to one embodiment of the invention. The trainer comprises of an elongated and curved shaft (effector 10) with a penetration tip (11). The shaft is at least temperately attached to stopper 20 having a defined rim 21. The stopper comprises of two handles 22.

Reference is now made to figures 2 and 3, illustrating a top view and side view of trainer 100. Figures 4 and 5 front view of two embodiments of eth invention, i.e., two handles (figure 4) and one handle (figure 5) versions.
CLAIMS

1. Trainer (100) for rehabilitating and treating incontinence, possibly post-operative incontinence, said trainer comprising:
   a. an elongated, optionally curved effector (10) suitable for being reversibly introduced into the rectum, via the anus of a human patient; said effector optionally comprising a penetration tip (11); and,
   b. handle (20) comprising a stopper (21) preventing slippage of said effector into said body cavity; and optionally a at least one handle (22).

2. The trainer according to claim 1, wherein said effector dimensions (i.e., diameter and length) are varies from about 4 to 25 mm and from about 30 to 150 mm, respectively.

3. The trainer according to claim 1, wherein the said effector and/or said penetration tip is made of conventional elastic, resilient material, especially rubber, silicon rubber, natural latex or combination thereof.

4. The trainer according to claim 1, wherein the said effector is an elongated bladder characterized by an envelope and an inner portion comprising at least one compartment filled with flowing matter.

5. A kit according to claim 1 comprising of said trainer and disposable condom enveloping the same.

6. The trainer according to claim 4, wherein said flowing matter characterized by Shore A hardness of less than 5.

7. The trainer according to claim 4, wherein said flowing matter is selected from a group consisting of fluids, air, especially FDA approved gels, water, saline, glycerin, heat retaining materials, and flowing solids, especially fine particles, silica, silica gel, powders, aggregates or the like.

8. The trainer according to claim 4, wherein the wall thicknesses of said envelope is up to about 4 mm, especially 1.5 to 2.5 mm.

9. The trainer according to claim 1, wherein the effector is of high tear propagation resistance having a Shore A hardness of about 30 to 60.

10. The trainer according to claim 1, wherein the stopper is constructed from a semi-rigid material, especially a polymer or high durometer silicon.
11. The trainer according to claim 1, wherein the penetration tip is constructed of a yieldable silicon material.

12. The trainer according to claim 1, wherein said handle is at least one hinged ring.

13. The trainer according to claim 1, wherein said handle is at least one inset beveled slot.

14. A vibrating trainer according to claim 1, wherein said effector is a massaging effector, interconnected to a power supply for causing said effector to vibrate.

15. An oscillating trainer according to claim 1, wherein said effector is a massaging effector, interconnected to a power supply for causing said effector to oscillate.

16. A vibrating and oscillating trainer according to claim 1, wherein said effector is a massaging effector, interconnected to a power supply for causing said effector to vibrate and oscillate.

17. A catheter according to claim 1, wherein said effector comprising means to facilitate the passage of fluids, medicaments, accessories, especially optic fibers, and surgical tools.

18. The trainer according to claim 1, wherein said effector comprising means to facilitate the passage of diagnostic sensors into the patient body cavity, said sensors interconnected by wire or wirelessly with diagnostic apparatus.

19. An applicator according to claim 4, wherein said bladder is perforated to facilitate controlled release of substances towards the rectal wall.

20. The applicator according to claim 17 wherein said substances are selected from a group consisting of fluids, medicaments, pastes, gels, lotions, creams, salves or combination thereof.

21. An extractor according to claim 1, useful for removal of fecal samples especially for use in occult fecal blood examinations comprising of a plurality of protuberances located at the outer portion of the shaft and/or penetration tip.

22. The trainer according to claim 1 curvature especially adapted to treat a male patient.

23. The trainer according to claim 1 curvature especially adapted to treat a female patient.

24. The trainer according to claim 1, wherein said effector comprises of heating/cooling means.
25. A heating/cooling trainer according to claim 14, wherein said heat/cool is provided by means selected from Pelletier device, electrical condenser, heated electrical element, pre-cooled or pre-heated materials or a combination thereof.

26. A method of rehabilitating and treating incontinence and possibly post-operative incontinence, comprising:
   a. obtaining a trainer comprising an elongated effector (10); said effector optionally comprising a penetration tip (11); and, handle (20) comprising a stopper (21) preventing slippage of said effector into said body cavity; and optionally a at least one handle (22);
   b. reversibly introducing said effector into the rectum, via the anus of a human patient.

27. The method according to claim 21, additionally comprising vibrating the effector to a predetermined measures of time, amplitude and frequency.

28. The method according to claim 21, additionally comprising oscillating the effector to a predetermined measures of time, amplitude and frequency.

29. The method according to claim 21, additionally comprising vibrating and oscillating the effector to a predetermined measures of time, amplitude and frequency.

30. The method according to claim 22, additionally comprising heating and/or cooling the effector to a predetermined temperature, ranging from 4 to 42 degrees Celsius.

31. The method according to claim 23, additionally comprising administrating fluids, medicaments, accessories, especially optic fibers and surgical tools while said effector is deployed within the patient's body cavity.