Non- Invasive Urinary Incontinence Control Device

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ABSTRACT

Urinary incontinence is affecting a large number of men and women around the world and it lowers the quality of life dramatically. A large number of treatments have been introduced, but they require invasive surgeries associated with infections and loss of privacy.

In this paper a novel device is introduced which is designed for permanent or temporary treatment of incontinence in men and women, providing more convenience and control.

This design provides a urethral stent having a magnetically controlled valve for patients suffering from incontinence due to diseases like bladder sphincter dyssynergia and neurogenic bladder. The new device provides an effective way for controlling the urination time and voiding the bladder, with a simple design, easy to insert, remove and operate.

In this paper first a review on the urinary system diseases causing incontinence is presented, and then treatment options, indications for their use, and relevant clinical observation are discussed. Finally the new device is introduced and its characteristics and applications are addressed.

Keywords: Urinary incontinence, Urethra, Stent, Catheter, Magnetic valve.

1. INTRODUCTION

Urinary incontinence is “uncontrollable leakage of urine" either continuous or intermittent, as defined by the Standardization Committee of the International Children’s Continence Society (ICCS) [1]. It is the inability to hold urine in the bladder because voluntary control over the urinary sphincter is either lost or weakened.

An analysis of examination survey data of 17,850 adults (20 years old or older) in a period of 7 years in the United States showed that standardized prevalence of urinary was 51.1% in women and 13.9% in men. This study shows increase of prevalence in both women and men from 2001 to 2008 [2]. Approximately one in every ten women in the

United States undergoes surgery for urinary incontinence or pelvic organ prolapse, and sizable minority of women bear the cost of pads, medications, and nonsurgical therapies. While urinary incontinence (UI) is widely thought of as a condition affecting women, it also affects men of all ages, with the prevalence shown in table 1. The male-to-female ratio is about 1:2 [3].

Table 1- Prevalence of UI by age and gender [3]

Group	Range (%)	Mean (%)
Older Women	17- 55	34
Younger Women	12- 42	25
Older Men	11-34	22
Younger Men	3-5	5

Urinary incontinence has been categorized differently by different organizations and researchers, as in [4,5]. The three main groups include: stress incontinence, urge incontinence, and overflow incontinence. When the pelvic floor muscles are weakened and cannot keep the urethra completely closed, stress incontinence occurs. It can be caused by age, pregnancy, childbirth, menopause, hysterectomy, and obesity. It is the most common type of incontinence among women [4].

Urge urinary incontinence is a sudden and intense urge to void, followed by an involuntary leakage of urine. Urge incontinence happens when the person's bladder contracts prematurely, commonly before it is full, usually diagnosed as overactive bladder syndrome. Cystitis, neurogenic problems and benign prostatic hyperplasia can cause urge incontinence.

Overflow incontinence happens when there is an obstruction or blockage to the bladder. The patient may not be able to empty the bladder completely after urination; pressure builds up behind the obstruction, causing leakages. Prostatitis, urinary stones, and constipation may cause an obstruction.

2. CURRENT INCONTINENCE TREATMENTS

Treatment for urinary incontinence depends on the type of incontinence, the severity of the problem and the underlying cause. Options for treating incontinence include lifestyle changes, physical therapy, medical devices, medications, and surgery [6]. In most cases, the least invasive treatments are suggested first, such as behavioral techniques and physical therapy, and other options are used only if these techniques fail. Behavioral techniques include bladder training; scheduled toilet trips, fluid and diet management, and physical therapies include pelvic floor muscle exercises and electrical stimulation. Often, medications are used in conjunction with behavioral techniques.

There are also some medical devices available such as urethral inserts which is small tampon-like disposable device inserted into the urethra and act as a plug to prevent leakage.

When the above treatments aren't working, several surgical procedures have been developed for urinary incontinence, such as sling procedures, bladder neck suspension, and artificial urinary sphincter (Fig.1).

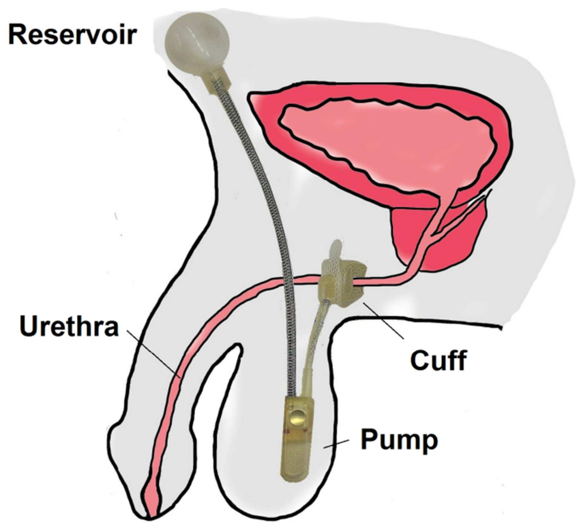


Figure 1- Currently available artificial urinary sphincter (AMS800)

The artificial urinary sphincter (AUS) which is currently implanted in men is a device made of silicone, and has an inflatable cuff that fits around the urethra. A reservoir regulates the sphinctering pressure of the cuff, and a pump controls inflation and deflation of the cuff. The reservoir is surgically placed within the pelvic area, and the control pump is placed in the scrotum. For deflating the cuff the pump should be squeezed and released. This action pulls the fluid out of the cuff and sends it to the reservoir, allowing urine to drain out. Minutes after the bladder is empty, the fluid automatically returns from the reservoir to the cuff and closes the urethra.
The main problem with this procedure is its invasiveness (pump in scrotum, balloon reservoir in pelvic area, cuff around the urethra, and connecting tubing). If the device fails, another surgery will be required to remove the failed system and re-implantation. Van der Aa et al. [7] have performed an analysis that shows AUS has had an average rate of 8.5% in infection or erosion, 6.2% in mechanical failure, 7.9% in urethral atrophy and 26.0% in reoperation in the past 25 years,. In addition, due to its invasiveness it is employed only for severe cases of incontinence and the patient should also have hand dexterity.

Catheterization is used as a temporary or permanent treatment of incontinence. Catheters are broadly used in the treatment of different bladder problems, providing a hollow lumen between bladder and a drainage bag (Fig. 2). Catheters are not preferred as a permanent solution for incontinence because of the drainage bag, attached to the leg or bed side. Also, the insertion and removal processes are painful and furthermore patients lacking manual dexterity may require assistance.

Other problems with incontinence catheters are urinary tract and kidney infections, because they connect the internal body tissues to external means. They also might cause pain in the urinary tract by being contacted or pulled or pushed.

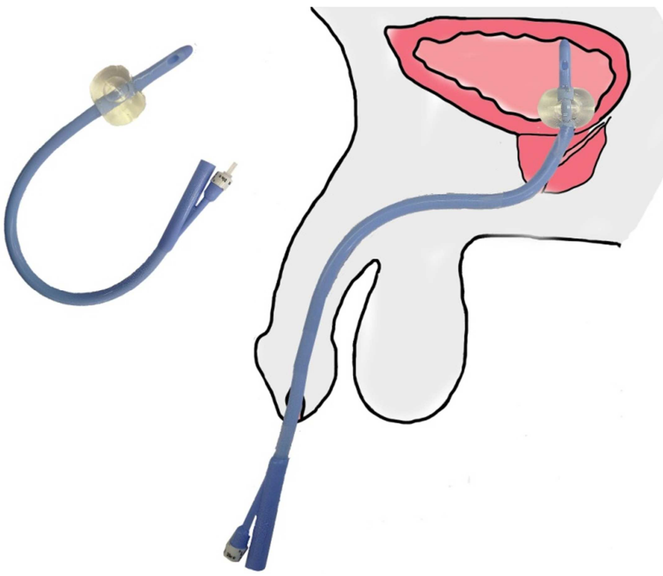


Figure 2- Foley Catheter (Dover 26 Fr)

These problems are behind the motivation to design a simple device for the treatment of urinary incontinence in both males and females.

3. URETHRAL STENTS

Urethral Stents (so called prostatic stents) have been used since the 1980s [8] for treating the bladder outlet obstruction problems like benign prostatic hyperplasia (BPH), and their main function is to keep the urethra open. In this indication the patient still has self-controlled urination and their external sphincter is operational.

Urethral stents are typically made of a metal alloy or polymeric or biodegradable material in a variety of designs that are rigid enough to maintain urethral patency [9].

These stents are usually placed in the urethra between the internal and the external sphincter. In some new designs they could penetrate inside the bladder like catheters.

Indications for urethral stent placement include urethral stricture disease, BPH, detrusor-sphincter dyssynergia (DSD), and bladder outlet obstruction secondary to locally advanced prostate cancer [8,9].

An ideal urethral stent should be easy to insert, easy to remove, biocompatible, radiopaque (to facilitate stent insertion using fluoroscopy and confirm position during follow up radiography), rigid enough to relieve urethral obstruction, resistant to encrustation and infection even after prolonged indwelling times, resistant to migration, comfortable, allow for internal lumen to be large enough to alleviate the obstruction and to facilitate cystoscopy if needed [9].

4. NEW INCONTINENCE CONTROL DEVICE

The present device (Fig. 3) essentially is a urethral stent having a magnetic valve, which is operated from outside of the body magnetically. The device main duty is to empty the bladder with full control of urination time for patients, which is completely different from the current stents. Current stents are designed to prevent the obstruction of the prostate. The design of the device provides an effective way for controlling the urination time and having only one moving part without surgery or using electrical parts.

This device includes a biocompatible flexible tube with a pouch-shaped balloon on the top, a valve, and an anchoring part at the bottom. The flexible tube, like a Foley catheter, defines a lumen which takes the shape and curvature of patient's urethra after insertion and also keeps it open. The length of the tube must be selected according to the patient body size and gender.

The anchoring balloon rests on the bladder neck and provides maximum voiding capacity. The balloon material could be PET, Nylon, Polyurethane or Silicone, and has a diameter of 30 to 40 mm depending on the tube French size, and inflates with 5 to 10 ml of water. Its conical design allows complete emptying of a bladder, because the tube urine entrance hole is located at the bottom of the balloon. In other designs, there is a large spherical-shaped balloon inside the bladder which places the urine drainage eyes of the tube at top of the bladder and makes a reservoir for bacteria colonization, which plays an essential role in the pathogenesis of catheter or stent-associated infections.

In addition, the expandable and collapsible nature of the tube allows for easy insertion and removal of the stent within the urethra of patients. An anchoring part is designed to prevent stent migration into the bladder.

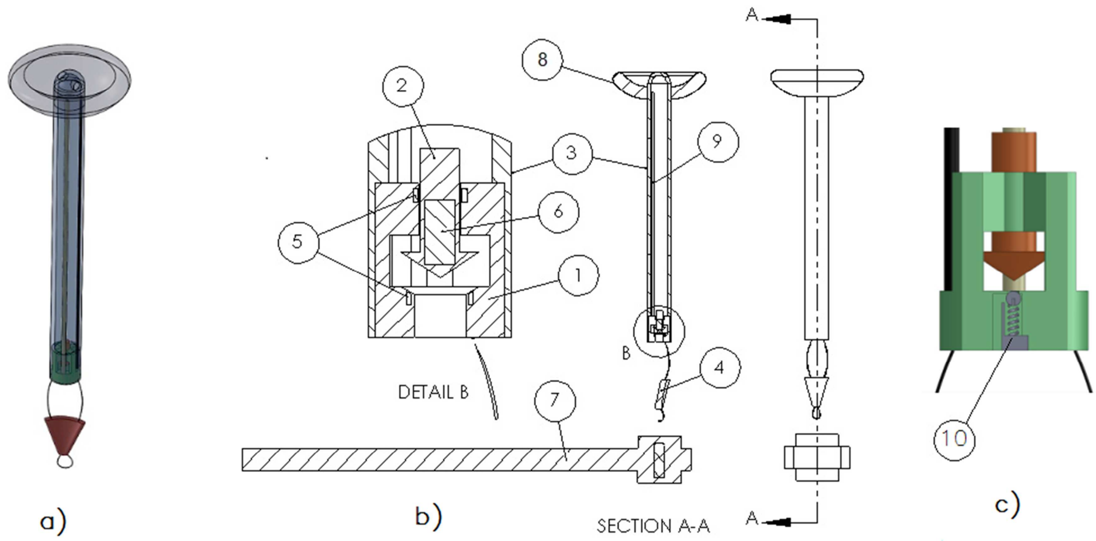


Figure 3- a) 3D view b) The new device details: 1) control valve block 2) control valve piston 3) tube 4) anchoring part 5) upper and lower metallic rings 6) valve piston magnet 7) external magnet 8) anchoring balloon 9) balloon saline way 10) safety valve c) Safety valve section view (in gray)

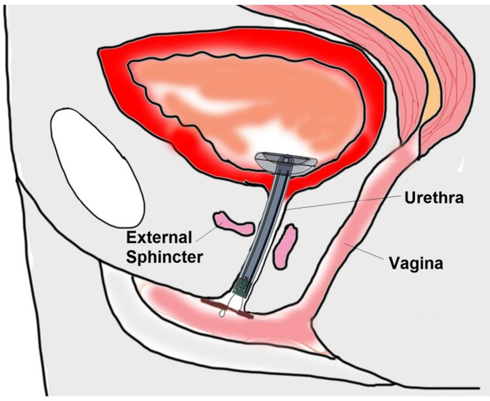
A magnetically driven valve is located at the bottom of the device, which is operated by an external (out of body) magnet by the patient. Permanent magnets have been used inside the body in different applications [10–12] and no harm or complication has been reported. There are two metallic rings inside the valve block and one magnet inside the piston. In the closed position the conical head of the piston sits on the valve outlet, and remains closed due to gravity and magnetic attraction to the lower ring. In the open position, the back of conical head rests on the upper section of valve block and stays open due to magnetic attraction to the upper ring.

For safety reasons, a miniature relief valve (part 10) is located inside the control valve block. When the bladder pressure reaches a certain threshold, this valve opens the urine path. This part comes to operation only if the patient fails to urinate on time, and it protects the bladder and kidneys from undergoing high pressures.

5. METHODS: NEW DEVICE APPLICATIONS

Insertion Procedure:

The covered and crimped stent is to be inserted into the urethra by an introducer. When the stent reached the inside of the bladder, 5 to 10 ml of saline water is injected into the balloon (Figs. 4 and 5). Afterwards, the introducer is pulled out of the body and the anchoring part (part 4) opens to prevent migration of stent inside the bladder. The device is radiopaque because of the internal magnet and metallic rings, thus a plain x-ray can confirm the position of the device and whether the device is open or closed.



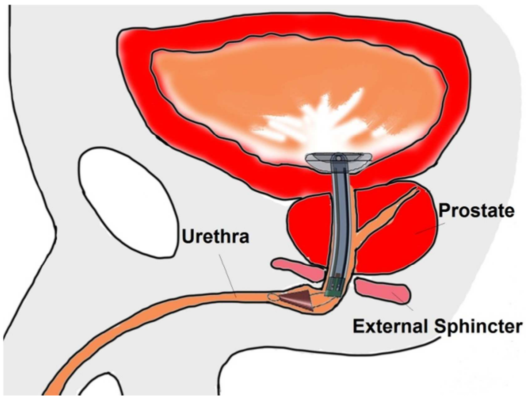


Figure 4- The new device in place for women Figure 5- The new device in place for men

Removal Procedure:

There is a small thread loop connected to the anchoring part for an easy removal. For men, a hook is designed which attaches to the cystoscope head. Using the hook, the thread loop is pulled and opens a plug in the balloon and allows it to drain. Then the stent is ready to be pulled out (Fig. 6-b).

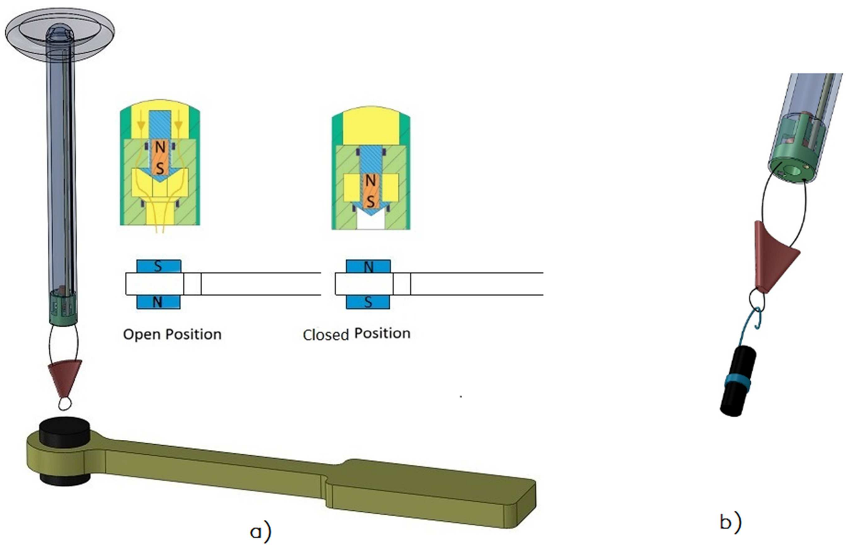


Figure 6- a) Device operation procedure, b) device removal in men (the hook placed is on a cystoscope tip)

Operation Procedure:

For initiating urination, patient introduces the S-pole of the external magnet to the device (Fig. 6-a). This action opens the internal valve. Valve's piston moves up due to magnetic repulsion and stays there due to magnetic attraction to the upper metallic ring (part 5). A this point, urination can be initiated by detrusor muscle attractions. After urination, the patient introduces the N-pole of the external magnet to the device to close the internal valve. Valve's piston moves down due to magnetic attraction to the external magnet and stays there due to magnetic attraction to the lower metallic ring.

6. RESULTS

The device could be manufactured in different size categories. In order to get an estimate of different forces involved in the operation, the following calculations are presented for a typical size:

ρ_s : steel density = 7800 kg/m^3

ρ_{sr} : silicon rubber density = 1200 kg/m^3

D_m : internal magnet dia. = 6 mm

h_m : internal magnet height = 10 mm

D_{1p} : piston cylindrical section dia. = 6.4 mm

h_{1p} : piston cylindrical section height = 8 mm

D_{2p} : piston conical section dia. = 7 mm

h_{2p} : piston conical section height = 4 mm

There are four forces acting on the piston which include three resistive forces and one operating force. The resistive forces are the piston weight, urine pressure, and the magnetic attraction of the magnet inside the piston to the upper or lower metallic ring. The operating force is the attraction or the repulsion force between the internal magnet and the external magnet, when the patient applies the external magnet.

6.1. Resistive Forces Analysis

Piston Weight

The volumes of internal magnet and piston are, respectively:

$$V_m = \frac{\pi}{4} D_m^2 h_m = 282.7\ mm^3 \qquad (1)$$

$V_p = \frac{\pi}{4} D_{1p}^2 h_{1p} + \frac{\pi}{12} D_{2p}^2 h_{2p} = 308.7\ mm^3$ (2)

Therefore the total weight of piston would be:

$W_p = (V_p - V_m)\rho_{sr} + V_m \rho_s = 2.2\ gr$ (3)

Pressure Force

Urine pressure at the urethra during urination is around 60 cm of water. Before urinating, this pressure is almost zero, because detrusor muscle is not in contraction. Before detrusor contraction, bladder pressure could reach to 25-30 cm of water. Therefore, maximum possible pressure on the piston is 30 cm of water, and the corresponding force is:

$F_{pr} = 0.3\ m.1000 \frac{kg}{m^3} \frac{\pi}{.4} D_{2p}^2 = 11.5 gr$ (4)

Magnetic Attraction Forces between Internal Magnet and Metallic Rings

The magnetic attraction between lower ring and internal magnet in closed position is 5 gr, to make sure that piston remains in closed position in different body angles and patient's activities. This force in open position is almost zero. The magnetic attraction force between upper ring and internal magnet is 10 gr to make sure the valve remains open during urination. This force in closed position is almost zero. Therefore:

$F_{LR} = 5gr, F_{UR} = 10gr$ (5)

Total Resistive Force on the Piston

The total force on the piston in closed position is:

$F_C = W_p + F_{pr} + F_{LR} = 19gr$ (6)

This force will maintain the valve in a closed configuration. For opening the valve, external and internal magnets repulsion force must overcome this force. Total holding force on the piston in open position is:

$F_O = F_{UR} - W_p = 8gr$ (7)

This force makes the valve remain open during urination. For closing the valve, external and internal magnets attraction forces must overcome this force.

6.2. Operative Forces Analysis

For opening and closing the valve, magnetic force between the internal and the external magnets should overcome the total resistive forces calculated above. Analytical modeling of the magnets is usually complicated and tedious. Among the several approaches that have been proposed [13], in this research, we used a simplified formulation to calculate the forces between the two cylindrical magnets [14].

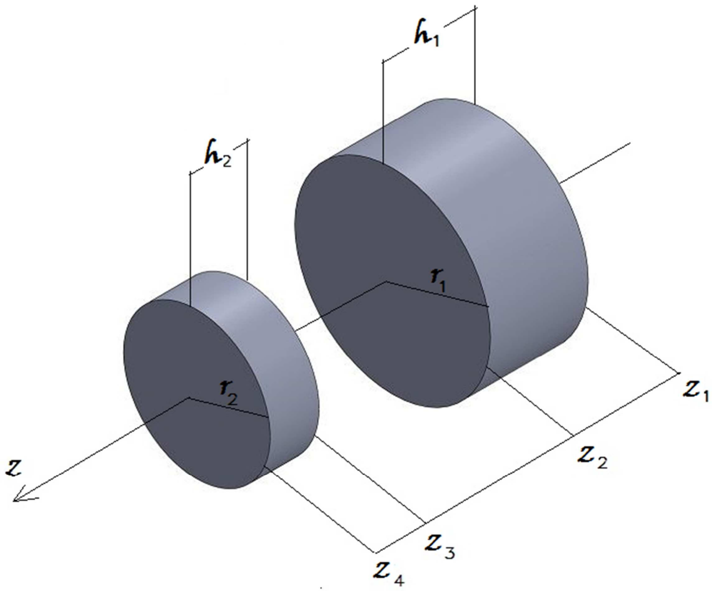


Figure 7- Coaxial magnets and geometric parameters

The axial force between the two coaxial cylindrical magnets with the geometry shown in the Fig. 7 can be calculated from the following equation:

$$F_z = \frac{J_1 J_2}{2\mu_0} \sum_{i=1}^{2} \sum_{j=3}^{4} a_1\, a_2 a_3 f_z [-1]^{i+j} \qquad (8)$$

Where J_1 and J_2 are the magnets magnetization in Tesla in the positive direction of the *Z* axis, $\mu_0 = 4\pi \times 10^{-7}\ \mathrm{NA}^{-2}$ is the magnetic constant and f_z is given by:

$$f_z = K(a_4) - \frac{1}{a_2} E(a_4) + \left[\frac{a_1^2}{a_3^2} - 1\right] \Pi\left(\frac{a_4}{1-a_2}, a_4\right) \qquad (9)$$

Where $i = \sqrt{-1}$ and *K(a)*, *E(a)*, and *Π (a, b)* are the complete elliptic integrals of the first, second and third kind, respectively. Also:

$$a_1 = z_i - z_j \qquad (10)$$
$$a_2 = \frac{[r_1 - r_2]^2}{a_1^2} + 1 \qquad (11)$$
$$a_3 = [r_1 + r_2]^2 + a_1^2 \qquad (12)$$

$$a_4 = \frac{4r_1 r_2}{a_3^2} \quad 0 < a_4 \leq 1 \qquad (13)$$

We have used a set of rare earth magnets of grade N=45 of sizes 6x10 mm and 40x20 mm as internal and external magnet, respectively. The magnetization can be calculated from the grade number in Tesla from the following equation:

$$J = 2\sqrt{\frac{N=45}{100}} = 1.341\ T \qquad (14)$$

A MATLAB code incorporates the above equations to find the force for different distances between the two magnets. The results are shown in Fig. 9.

FE analysis also has been performed using COMSOL Multiphysics to verify the theoretical solution. Figure 8 shows the 2D axisymmetric model, where the distance between the magnets is 20 mm.

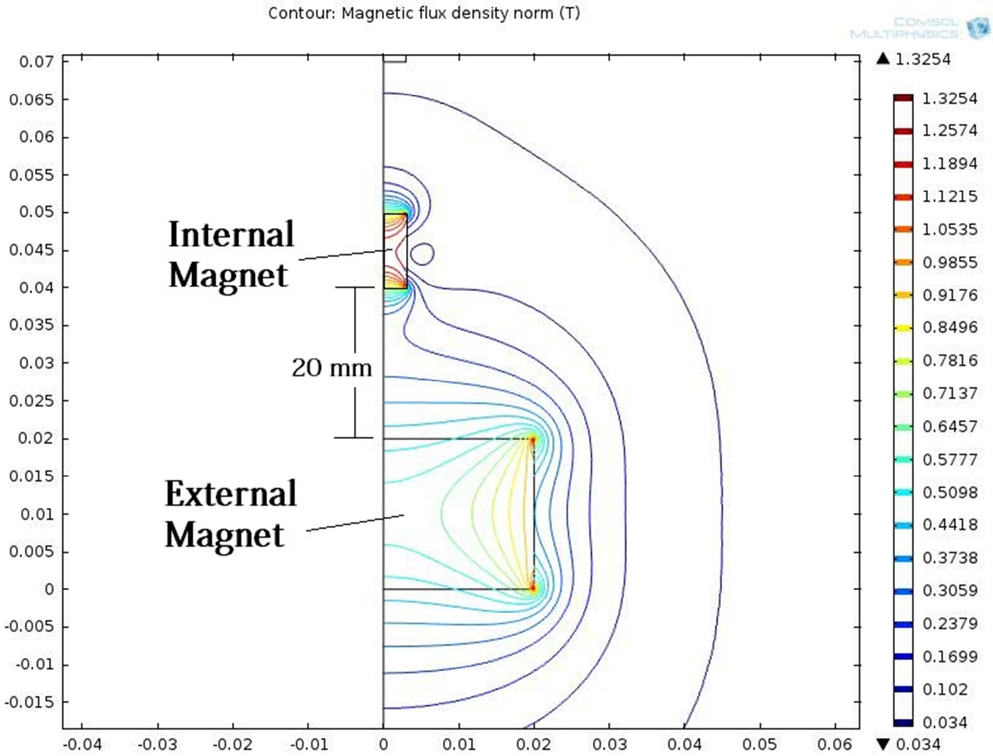


Figure 8- COMSOL model: magnetic flux density norm

Using a parametric solution, the force between the magnets in different distances has been calculated. The results are plotted in Fig 9. As it can be seen, the analytical solutions and FEA are in a very good agreement.

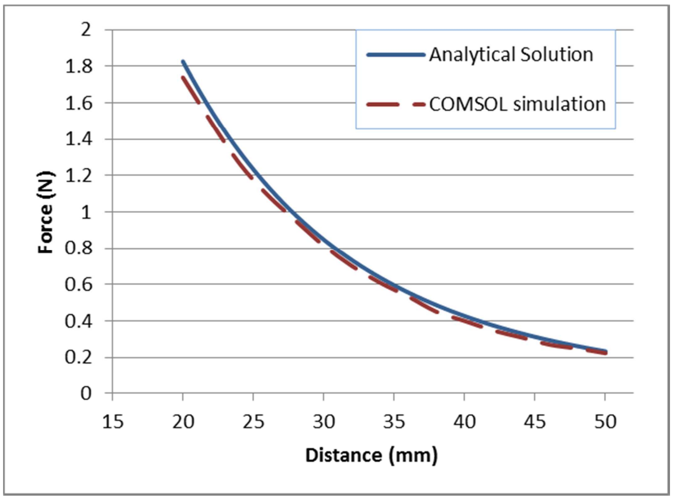


Figure 9- Magnetic force between the internal and external magnet: analytical solution, and COMSOL simulation

The piston working course is 5 mm. So, for example for this set of magnets, the distance between the two magnets could vary from 20 to 25 mm or from 40 to 45 mm, depending on the patient's size. Table 2 compares the resistance forces to the operating (magnet) forces for each case.

Table 2- Comparison between resistance and operating forces acting on the piston

	Resistive force (gr)		Operating force (gr)	
Working Range	Opening	Closing	Opening	Closing
20-25 mm	19	8	180	123
40-45 mm	19	8	42	31

As shown in this table, for short distance working ranges the operation forces are sufficient, however for longer distances, larger magnets should be employed. Other limitation includes patient's hand dexterity enough to be able to apply the external magnet.

7. CONCLUSION

Urinary incontinence is a worldwide problem which lowers the quality of life directly. The current treatments for urinary incontinence need to be revised and more research is needed in this area.

In this paper a new device for permanent or temporary treatment of urinary incontinence is presented. This device can be inserted in the urethra in a few minutes like a Foley catheter and immediately provides the patient with continence control over urination and voiding. Operating the proposed device does not need high dexterity, and its removal is easy and fast as well. The chance of urinary system infections is minimal because of its design with no connectivity to outside of the body. Depending on the patient size, the best fit should be chosen.

The future work is the development of the product, prototyping and initiating the process of obtaining FDA approval for product realization.

NOMENCLATURE

ρ_s	steel density, kg/m^3
ρ_{sr}	Silicone rubber density column, kg/m^3
D_m	Internal magnet diameter, m
h_m	Internal magnet height, m
D_{1p}	Piston cylindrical section diameter, m
h_{1p}	Piston cylindrical section height, m
D_{2p}	Piston conical section diameter, m
h_{2p}	Piston conical section height, m
V_m	Internal magnet volume, m^3
V_p	Total piston volume, m^3
W_p	Total piston weight, N
F_{pr}	Force on top of the piston due to urine pressure, N
F_{LR}	Force between lower ring and internal magnet in closed position, N
F_{UR}	Force between upper ring and internal magnet in open position, N
F_C	Total resistance force on the piston in closed position, N
F_O	Total resistance force on the piston in open position, N
F_z	Magnetic attraction or repulsion force between magnets, N

J Magnetization, Tesla

N Magnet grade

REFERENCES

[1] Neveus T., Gontard A. von, Hoebeke P., Hjälmås K., Bauer S., Bower W., Jørgensen T. M., Rittig S., Van de Walle J., and Yeung C., 2007, “The standardization of terminology of lower urinary tract function in children and adolescents: Report from the standardization committee of the International Children’s Continence Society (ICCS),” Neurourology and Urodynamics, **26**(1), pp. 90–102.

[2] Markland A. D., Richter H. E., Fwu C.-W., Eggers P., and Kusek J. W., 2011, “Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008,” The Journal of Urology, **186**(2), pp. 589–593.

[3] Pearle M. S., Calhoun E. a, and Curhan G. C., 2005, “Urologic diseases in America project: urolithiasis.,” The Journal of Urology, **173**(3), pp. 848–857.

[4] Parsons M., and Cardozo L., 2003, “The classification of urinary incontinence,” Reviews in Gynaecological Practice, **3**(2), pp. 57–64.

[5] Mangera A., and Chapple C. R., 2011, “Urinary incontinence in adults,” Surgery (Oxford), **29**(6), pp. 254–259.

[6] Carpenter D. a, and Visovsky C., 2010, “Stress urinary incontinence: a review of treatment options.,” AORN journal, **91**(4), pp. 471–8; quiz 479–81.

[7] Van der Aa F., Drake M. J., Kasyan G. R., Petrolekas A., and Cornu J.-N., 2013, “The artificial urinary sphincter after a quarter of a century: a critical systematic review of its use in male non-neurogenic incontinence,” European Urology, **63**(4), pp. 681–689.

[8] Appleyard D., and Makar A., 2005, “Prostatic Stents as a Treatment for Benign Prostatic Hyper trophy,” BUSINESS BRIEFING: EUROPEAN PHARMACOTHERAPY, pp. 85–89.

[9] Duvdevani M., Chew B. H., and Denstedt J. D., 2006, “Urethral Stents: Review of Technology and Clinical Applications,” Interventional Management of Urological Diseases, Springer, pp. 191–206.

[10] Harrison M. R., Gonzales K. D., Bratton B. J., Christensen D., Curran P. F., Fechter R., and Hirose S., 2012, “Magnetic mini-mover procedure for pectus excavatum III: safety and efficacy in a Food and Drug Administration-sponsored clinical trial,” Journal of Pediatric Surgery, **47**(1), pp. 154–159.

[11] Kim M.-K., Park I.-Y., Song B.-S., and Cho J.-H., 2006, “Fabrication and optimal design of differential electromagnetic transducer for implantable middle ear hearing device,” Biosensors and Bioelectronics, **21**(11), pp. 2170–2175.

[12] Crescini D., Sardini E., and Serpelloni M., 2011, “Design and test of an autonomous sensor for force measurements in human knee implants,” Sensors and Actuators A: Physical, **166**(1), pp. 1–8.

[13] Ravaud R., Lemarquand G., Babic S., Lemarquand V., and Akyel C., 2010, "Cylindrical magnets and coils: fields, forces, and inductances," Magnetics, IEEE Transactions on, **46**(9), pp. 3585–3590.

[14] Robertson W., Cazzolato B., and Zander A., 2011, "A simplified force equation for coaxial cylindrical magnets and thin coils," Magnetics, IEEE Transactions on, **47**(8), pp. 2045–2049.

Figure Captions List

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Fig. 4 The new device in place for women

Fig. 5 The new device in place for men

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Fig. 7 Coaxial magnets and geometric parameters

Fig. 8 COMSOL model: magnetic flux density norm

Fig. 9 Magnetic force between the internal and external magnet: analytical solution, and COMSOL simulation

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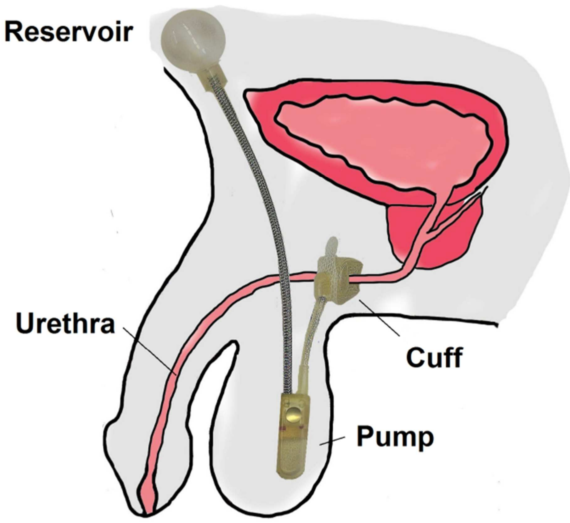

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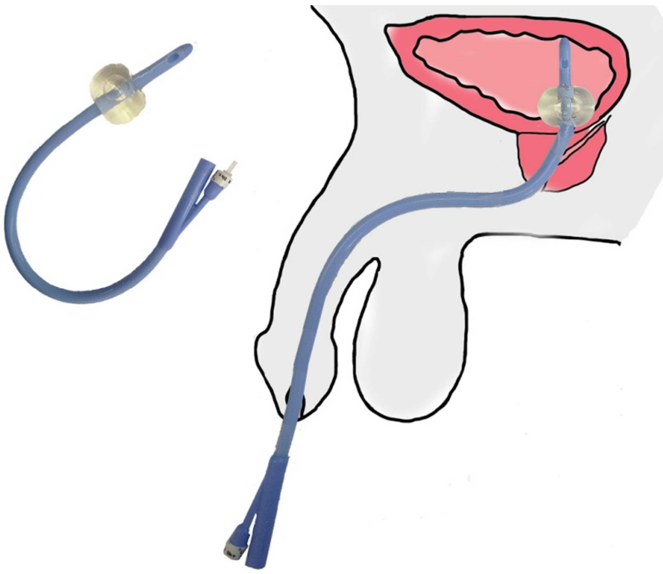

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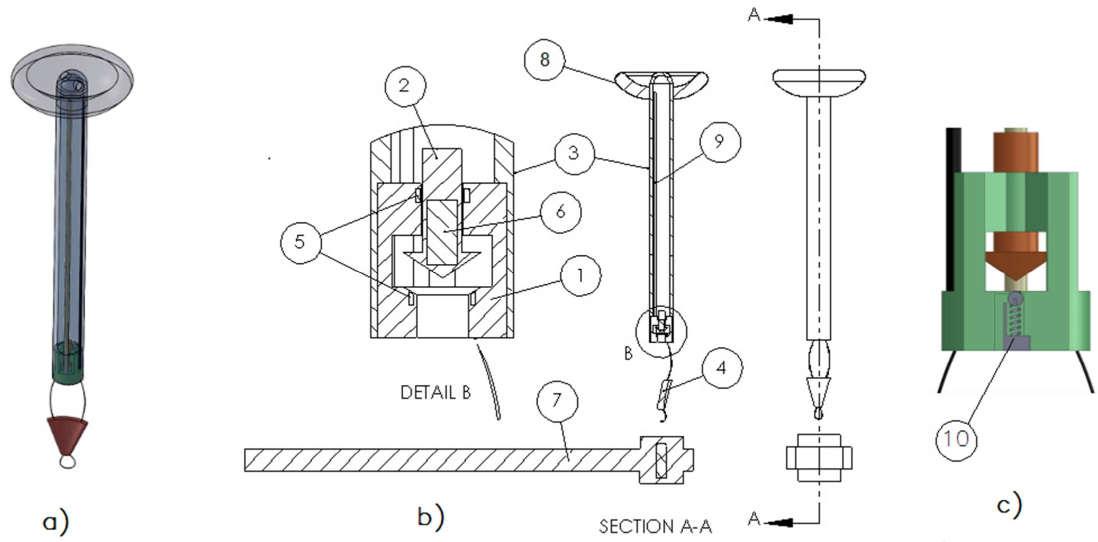

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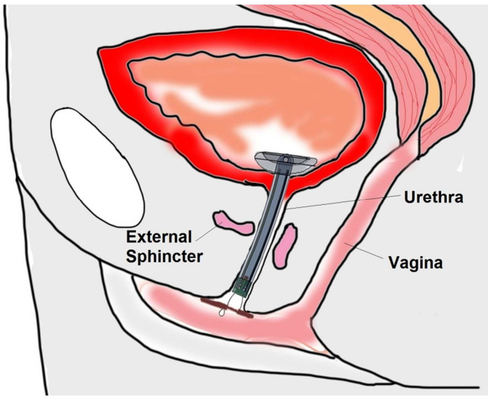

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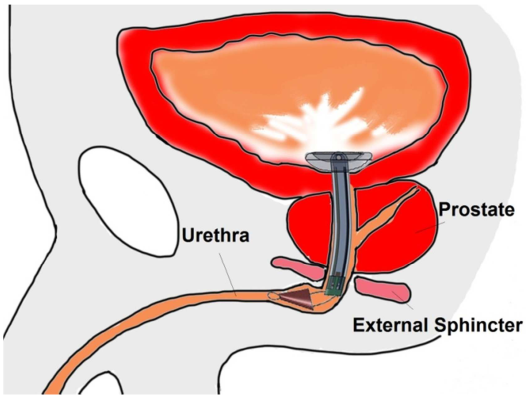

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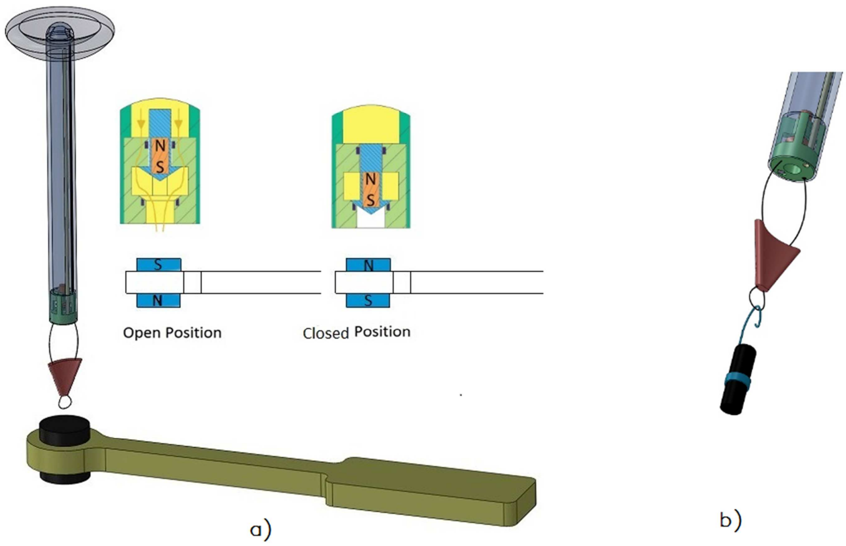

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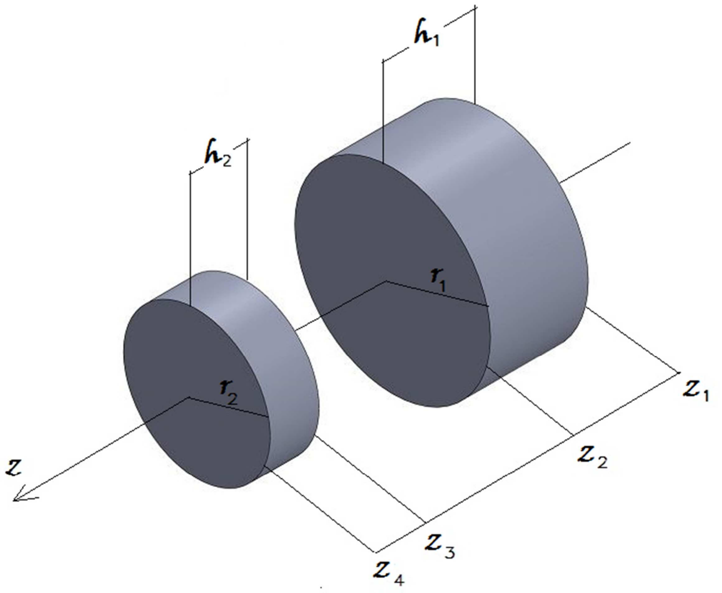

fig7.eps

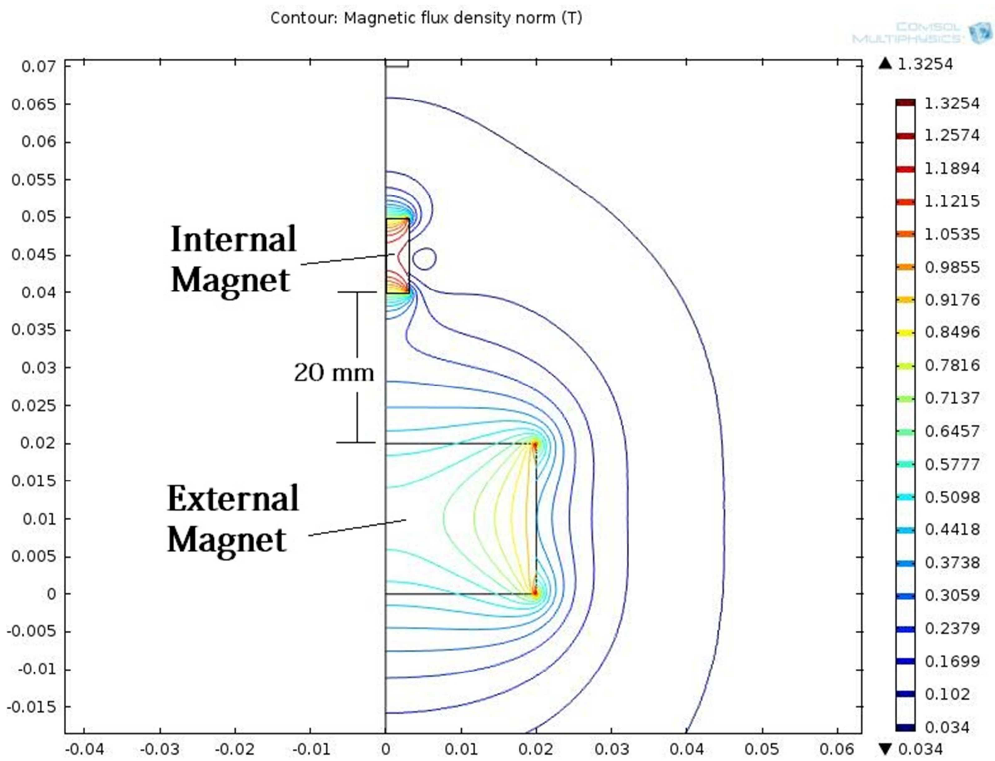
Contour: Magnetic flux density norm (T)
Internal Magnet
20 mm
External Magnet
▲ 1.3254
1.3254
1.2574
1.1894
1.1215
1.0535
0.9855
0.9176
0.8496
0.7816
0.7137
0.6457
0.5777
0.5098
0.4418
0.3738
0.3059
0.2379
0.1699
0.102
0.034
▼ 0.034

fig8.eps

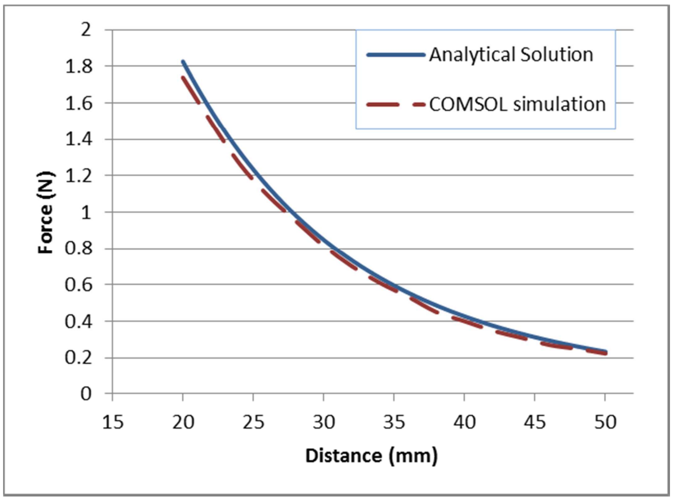
Analytical Solution
COMSOL simulation
Force (N)
Distance (mm)
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
15
20
25
30
35
40
45
50

fig9.eps