The AMS 800

The AMS 800:

History, Techniques and Future

Edited by

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TABLE OF CONTENTS

FOREWORD

"Treatment of urinary incontinence by an implantable prosthetic urinary sphincter ", authored by F. Brantley Scott, William E Bradley and Gerald W. Timm, appeared in the January issue of the Journal of Urology in 1974, having been accepted for publication in December, 1973, presumably submitted earlier in that year. Also in January of that year, in the now defunct journal, investigative Urology, "Experimental evaluation of an implantable externally controllable urinary sphincter" was published, by the same three authors, with Timm as the first author and Scott as the senior author. The Journal of Urology article reported that the first prosthetic urinary sphincter actually was implanted by this group in June 1972, and, up to the time of the writing of the article, this prosthesis had been implanted in more than 34 patients for the treatment of urinary incontinence of various causes. The etiologies of the urinary incontinence in the 34 patients reported, ranging in age from 3-76 years, were neurogenic (19), stress (8), post prostatectomy (5), epispadias (1), and urethral trauma (reconstructed) (1). "Success" was reported in 27 patients, "failure "in 7, all of whom had a neurogenic etiology. Mechanical complications were noted 8 times in seven cases. In this first device, the AS 721, the urethral cuff pressure was regulated by a valve designed to avoid pressures above which tissue necrosis would occur. This was replaced in subsequent models by a pressure-regulating balloon. The current pressure regulated implantable prostheses represent further refinements of previous models. Although other types of devices have been developed, the artificial urinary sphincter remains the gold standard for comparison in individuals with moderate to severe urinary incontinence.

This book is an outgrowth of a consensus conference organized by Professor Corcos in 2015, specifically devoted to the artificial urinary sphincter AMS 800. The history portion recounts the development of the concepts and devices for controlling or containing urinary incontinence over the years. A large portion of the book is devoted to "practicalities": preoperative assessment and patient selection; preoperative challenges in special situations; implantation techniques; and postoperative care. Intraoperative and immediate postoperative complications are covered, including the management of incomplete continence after sphincter implantation. The book concludes with a look at the future of artificial sphincter devices and other ideas for the management of urinary

incontinence. The book is complete, an enjoyable read, and will be of special interest to those whose practice includes patients in whom such a device is a real consideration

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INTRODUCTION

It may seem strange for readers to hold in their hands a book on the artificial urinary sphincter, forty years after its introduction into the surgical arsenal of urinary incontinence treatment. We agree! However, our motivation to invite more than twenty specialists contributing to this book stems partly from our experience with this small and life-changing prosthesis for many of our patients, and also partly from the fact that, during its forty-year life span, the AMS 800 has not undergone any transformations nor faced serious competition. In fact, this book is at once a tribute to this small technological marvel and its inventors, an instruction manual for all urologists who use or will use it, and a summary of the results obtained or to be expected in both adult males, females, and children.

The decision to write this book now is based on the fact that we are at a turning point in the life of the AMS 800 which, although expected to be around for many years to come, may see some parts of its mechanism change, becoming more complex for potential better acceptability by patients.

The editors of this book also represent the life of the AMS 800: Dr Corcos, who began his career at the same time as the advent of the AMS 800 and has implanted hundreds of them, is ready to retire, and Dr Campeau, who is in the early phase of her career, will be a spectator and an actor in the changes that will be made to this prosthesis.

We have selected the authors based on their experience with artificial sphincters, their publications, their contribution to its development, mainly in men and obviously their availability to share in a timely fashion their knowledge and experience with the AMS 800.

We would like to warmly thank all authors, staff, fellows and residents who spent hours to write these very well written and instructive chapters.

We would like also to mention that, voluntarily, this book has been written in complete independence with the company selling the AMS 800, Boston scientific who did not contribute in any means to it publication.

Jacques Corcos and Lysanne Campeau

PART 1

HISTORY OF THE AMS-800

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Introduction

Over the years a large number of measures have been employed to treat urinary incontinence resulting from sphincter deficiency. (1) The treatments range from convenes, indwelling catheters and penile clamp devices to various surgical procedures involving reconstruction of the bladder neck and urethra, but also various slings. (2) Although these procedures may be very successful, there are particular groups of patients in whom an alternative strategy is required. Under such circumstances implantation of an artificial urinary sphincter (AUS) is a technique which may be utilized. More than 50 years ago the AS 721 (artificial sphincter model 721) was introduced. The design of this device has continuously evolved to its current form, the AMS-800™ (Boston Scientific, previously American Medical Systems). The AMS-800™ is the most widely used type of AUS in clinical practice, and more than 250.000 devices have been implanted worldwide. This chapter reviews the evolution of implanted devices for urinary incontinence and the development of the AMS-800 ™ from the first concepts to the actual model. Finally, the most recent refinements and alternative types of AUS will be discussed, including experimental devices.

Devices for Urinary Incontinence

One of the earliest descriptions of urinary incontinence, including the management with pads, is found in the ancient Egyptian Ebers Papyrus (1500 BC). (3) (**Figure 1**) The next practical approach, a portable

urine receptacle for incontinent males, was described in 1564 by the French physician Ambroise Paré. (4) (**Figure 2**) In 1682 the German Wilhelm Fabry (better known as Wilhelm Fabricius Hildanus (1560–1634) presented a urine receptacle made of the bladder of a pig and attached to the body with straps. (**Figure 3**) In 1739 the German physician Lorenz Heister (1683-1758) published an overview of different models of portable urinals for males with urinary incontinence. (**Figure 4**)

The oldest device for external compression of the male urethra was also a development by Lorenz Heister (1683-1758) and was published in 1747 (5) (**Figure 5**) He presented a removable penile clamp covered with leather, based on earlier work by Fabricius Hildanus. (6) With reference to his colleague Charles F Winslow from England, Heister also designed a belt that allowed perineal compression to the bulbar urethra. (**Figure 6**) However, Heister did not present an alternative for effective compressive treatment for female urinary incontinence.

In 1910, James H Cunningham introduced a 'modern' compression device, referred to as a penile clamp, initially developed to provide external urethral compression during retrograde urethrography. (7) Very soon after the introduction, the 'Cunningham clamp' was used to mitigate urethral leakage and this device is still in use for some male patients with urinary incontinence. (**Figure 7**) In 1975 George O Baumrucker from Chicago patented a 'new male incontinence clamp', based on the Cunningham design but aiming at half the pressure as compared to other clamps, because of the 2-point ventral urethral compression and the production of an S-curve to compress the penile urethra. (8) In recent years several alternative designs of circular and non-circular compression tools have been developed and commercialized, but overall, their clinical use remains limited.

The idea of perineal compression was revived in 1960 by Sage A Vincent from Philadelphia, using an air-inflatable cushion that was fixed to the perineum with a special belt and expanded manually via bellows to obstruct the male urethra. (9) (**Figure 8**)

Implanted Devices for Urinary Incontinence

Because of the lack of comfort and efficacy, but also the risk of complications with compression devices, implantable prosthetic devices for males and females have been researched as possible solutions for severe urinary incontinence from the second half of the 20th century on. The initial concept of an occlusive cuff to treat male urinary incontinence was already suggested in 1946, but established in 1947, by Frederick EB

Foley (1891-1966) from St Paul (Minnesota, USA), who also developed the modern balloon catheter. (10) (**Figure 9**) This predecessor of the AUS consisted of a cuff (pneumatic clamp) around the penile urethra and the corpus spongiosum that were divided form the corpora cavernosa and covered with skin. The clamp could be inflated with an external piston to achieve continence and deflated to allow for micturition, but there was no reported attempt to regulate cuff pressure, resulting in frequent cuff erosion into the urethra. (11)

As a further step to a real AUS, John L Berry from Albany (New York State, USA) described in 1961 an acrylic prosthesis that was conceived for implantation between the bulbous urethra and the bulbocavernosus muscles of the male. (12) This prosthesis saddled the urethra and was fixed in position by four wire sutures located at each corner of the prosthesis. The wires were anchored to the fascia of the ischiocavernosus and the ischial tuberosities. The increase in urethral resistance created in the area of the bulbus urethrae near the membranous urethra was sufficient to achieve continence, yet still allowed a free-flowing urinary stream during micturition. The early results with this prosthesis were encouraging, but late results were disappointing, primarily because of dislocation of the device. Implantation of a similar prosthesis for urethral compression, but in silicone rubber, has been reported in 1964 by James K Watkins form Cleveland, but no long-term results have been published. (13)

In the early 1970s, Joseph J Kaufman from Los Angeles, attempted to produce compression of the male bulbous urethra without using a prosthesis by detaching and crossing the penile crura over the bulbous urethra. (14) Subsequently, he found that it was better to leave the penile crura attached proximally, but mobilize and tie them together with a Marlex band over the bulbous urethra. (15) Later, pressure could be increased on the underlying bulbous urethra by inserting a wad of Marlex beneath the banded crura. As a further step to produce more effective compression, Kaufman developed a silicone gel prosthesis which was applied under the male bulbous urethra (the Kaufman III procedure). (16) (**Figure 10**) Straps from this prosthesis were wrapped around the crura, and later additional straps were stapled to the pubic rami. Although Kaufman initially aimed at avoiding the use of prosthetic material, it became obvious that the silicone gel prosthesis provided better control of urinary incontinence. Like other passive compression procedures, this prosthesis was designed to produce enough pressure against the bulbous urethra to achieve continence, yet allow the patient to empty his bladder. If insufficient pressure was applied, continence was not restored and too

much pressure prevented voiding, or could even cause necrosis of the underlying urethra. As a consequence of suboptimal control of the degree of compression, medium term results with the Kaufmann III procedure were rather disappointing.

As a next step Michael Rosen from Wollongong (New South Wales, Australia) described in 1976, a bulbous urethral compression device that could be inflated and deflated by the patient. (17) (**Figure 11**) This prosthesis was made of silicone elastomer and had an inflatable, oblong balloon which was implanted under the bulbous urethra. Attached to the balloon were two arms encircling the opposite side of the urethra. Tubing connected the balloon to a fluid reservoir pump which was implanted subcutaneously in the scrotum. To apply pressure against the urethra, fluid could be transferred to the balloon by squeezing the scrotal reservoir pump. A check valve held the fluid in place, but when the patient wanted to urinate, he had to apply pressure to unseat the check valve, allowing the fluid to return from the balloon to the reservoir pump. This prosthesis resembled the Kaufman silicone gel prosthesis, except that it could be inflated and deflated at will to permit easier micturition. It was limited to use in males and pressure in the balloon was not subject to precise control. In 1984 Udo Jonas from Hannover (Germany) presented an internal penile clamp that was implanted at the penoscrotal angle and could be opened for micturition by external compression from both sides through the skin. (18) For all these devices medium term results were poor and they caused multiple complications. Hence none of these devices was commercialized at larger scale.

The First Concepts of An Artificial Urinary Sphincter

In 1971the biomedical engineer Gerald Timm and the neurologist William Bradley (1925-1998), described an artificial urinary sphincter that was intended to be used in males as well as in females. (19) They had already published the year before on prototypical incontinence devices, including the first design of an inflatable occlusive cuff. (20) Timm and Bradley took their initial concept to the urologist Brantley Scott (1930-1991), (see separate biography), and worked with him to develop the AS 721, a hydraulic device constructed of medical-grade silicone elastomer and stainless steel, consisting of a circumferential sphincter cuff that could be implanted around the male or female bladder neck or alternatively around the male bulbous urethra. (**Figure 12**) This was the first real artificial urinary sphincter that was intended to be used in males as well as in females, and was patented in 1973 as the AS 721. (21) (**Figure 13**)

The urethral cuff of this artificial urinary sphincter was connected to inflation and deflation bulbs which were implanted subcutaneously in the right and left scrotum or labia majora. The inflation and deflation bulbs, in turn, were connected to a fluid reservoir which was implanted beneath one of the lower abdominal rectus muscles. The device was filled with isotonic saline or isotonic radiographic contrast fluid. The pressure in the sphincter cuff was controlled by a mechanical V-4 valve located above the deflation bulb to prevent over pressurization. To void, the patient squeezed the deflation bulb in the scrotum or labium majus. Fluid in the deflation bulb was returned to the fluid reservoir, and re-expansion of the deflation bulb withdrew fluid from the sphincter cuff. Repetitive squeezing and releasing of the deflation bulb transferred fluid from the cuff, back to the fluid reservoir. When the cuff was empty, the deflation bulb remained collapsed.

Following micturition, the patient reinflated the artificial sphincter by repeatedly squeezing and releasing the inflation bulb in the scrotum or labium majus. Each squeeze of the inflation bulb sended the fluid in the bulb to the sphincter cuff, and the bulb re-expanded by drawing fluid from the fluid reservoir. This process could be repeated indefinitely. When pressure in the cuff exceeded that set by the V-4 valve, the fluid returned to the fluid reservoir through the V-4 valve on the deflation side. With experience, the patient found the minimum number of squeezes of the inflation bulb, required for continence. To avoid tissue necrosis, pressure in the sphincter cuff was set by the V-4 valve below tissue perfusion pressures. This pressure-maintained continence in many circumstances, but significant physical activity could cause bladder pressure to exceed sphincter cuff pressure and cause urinary leakage. However, because the compressible fluid reservoir was implanted beneath the lower abdominal rectus muscles, pressure in the fluid reservoir could also raise with physical activity, thus preventing expression of fluid from the sphincter cuff into the reservoir.

The AS 721 prosthesis represented the first physiologic approach to the restoration of urinary continence. However, it became evident that the balloon could serve as both a pressure-regulating device and also as a reservoir for the cuff fluid during micturition. The balloon could also provide automatic refill of the sphincter cuff following micturition. These concepts were the basis for the development between 1974 and 1979 of the next model the AS 742, in which the fluid reservoir and the inflation bulb were integrated in one element. (**Figure 15**) (22)

Occasional failures of the AS 721 device indicated that the mechanical V-4 valve was critical to the success, and therefore the next model, the AS

761, was developed between 1976 and 1977. (**Figure 16**) This device introduced a pressure-regulating balloon between the cuff and the V-4 valve. Pressure in the balloon and in the sphincter cuff, was controlled by the thickness of the silicone elastomer wall of the balloon and by fluid volume in the balloon. Addition of a delay-fill resistor between the balloon and the sphincter cuff slowed return of fluid from the balloon to the cuff, thus giving the patient enough time to empty his bladder.

The development between 1977 and 1979 of the further models the AS 791 and the AS 792, represented a streamlining of the device. (**Figure 17**) The AS 791 was a bulbous urethral cuff implant, and the AS 792 was a bladder neck cuff implant. In both devices, the valves immediately above the deflation bulb and the delay-fill resistor were transferred to the interior of a stainless-steel assembly to which the balloon, the cuff, and the deflation pump could be attached. Tubes from the deflation bulb and the cuff were reduced from two to one in both. Furthermore, the silicone elastomer portions of the prosthesis were now being dip-coated to eliminate seams that might be prone to fluid leaks.

A shortcoming of these devices was their inability to be left in the permanently deflated or open cuff positions. To prevent bladder neck or urethral erosion in the immediate post implantation period, implantation with delayed activation was suggested in 1981. (23) With this adaptation of the implantation technique, the prosthetic components were implanted, but not connected, and after primary healing a second operation was performed to connect the balloon, pump, and cuff to activate the device. (24)

As a last major development, the need for two separate operations was eliminated by the development of the AS 800 device, the fifth generation of the AMS AUS. The AS 800 model received the CE-mark in June 1997 and was cleared by the FDA for marketing as a pre-amendments Class III device in 1983, and still is on the clinical market today as the AMS 800™ Artificial Urinary Sphincter (initially marketed by American Medical Systems, Minnetonka, Minnesota, USA, since 2015 by Boston Scientific, Marlborough, Massachusetts, USA). (25) (**Figure 18**)

The AMS-800

The AS 800 was identical in operative principle to the AS 791 and AS 792, but the valves and the delay-fill mechanisms had been moved to a housing attached to the top of the deflation bulb. Also present in this housing was a deactivation button. When the deactivation button was out, the device worked in the same manner as the AS 742, AS 791 and AS 792

models. Elimination of the stainless-steel assembly resulted in one fewer component to implant and only two tubing connections to be made. When the deactivation button was depressed, the AS 800 remained deactivated, and fluid could not flow from the balloon back into the cuff. To activate the device, the deflation bulb was firmly squeezed and the deactivation button popped out. Further improvements over the years have included a narrow-backed cuff, a kink-resistant tubing, quick connectors and Y-connectors.

With the AS 800 model, more than 90% of patients had continence restored, such that no external protection needed to be worn. The AS 800 was deceptively simple in number of components and connections, but at the same time applied controlled pressure to the bladder neck or the urethra while allowing pressure changes within the system during physical activity. To operate the device, the patient only needed to deflate the sphincter cuff for micturition, and fluid transfer back into the sphincter cuff for continence was automatic. Furthermore, the AS 800 could be deactivated and left open for an extended period without resorting to additional operations.

The materials in the AMS Sphincter 800™ Urinary Prosthesis are predominantly solid silicone elastomers. All the elastomers in the device are platinum-catalyzed, solid silicones and no silicone gel was used in the fabrication. Many of the materials used are the same as used in the AMS 700 series of Inflatable penile prosthesis, but some silicone elastomers not used in the fabrication of the penile prostheses are used in the construction of the balloon shell, cuff shell and fabric reinforced cuff backing of the AMS 800.

Since 1986 an AMS 800 was made available with two cuffs in tandem to treat patients that, after proper placement of an AUS, had persistent stress urinary incontinence, secondary to inadequate outflow resistance or in whom incontinence recurred as a result of tissue atrophy at the cuff site. (34) (**Figure 19**)

The traditional approach to AMS 800 implantation in adult males involved two incisions. In 2003 a single high trans-scrotal approach has been advocated, the benefits of this approach being ease of scrotal pump placement and excellent access to the bulbar urethra. (35) In the small series of 37 patients who underwent placement of the AUS via this approach, a complete continence rate of 66% was reported without increased incidence of complications compared to the standard approach. Furthermore, an alternative, ectopic placement of the balloon anterior to the transversalis fascia but beneath the abdominal muscles has been presented as a safe and effective alternative to placement of the pressure

regulating balloon in the retropubic space. Indeed, with the original transscrotal technique balloon placement could be difficult, as it required blind piercing of the transversalis fascia. (36) The single scrotal incision technique is quicker than the standard approach and offers the potential advantage of simultaneous placement of an inflatable penile prosthesis in those patients that presents with both erectile dysfunction and urinary incontinence after radical prostatectomy. This combined implantation is referred to as the AMS1500 procedure, comprising dual placement of the AMS800 AUS along with the AMS700 inflatable penile prosthesis. The AMS 1500 procedure is proven to be cost-effective and takes less time than implanting both prostheses separately (37). However, if early infection occurs with the AMS 1500 procedure, both devices have to be removed.

Over the years several adaptations of the cuff implantation technique have been described in order to manage urinary incontinence in the setting of a fragile urethra (after radiotherapy, after failed AUS implantation or previous urethroplasty), as this is associated with poorer functional outcomes and higher revision rates. (38) The techniques to minimize the risk of failure included cuff downsizing (39), insertion of 3.5 mm cuff (40), adjustment of the pressure regulating balloon (41) and transcorporal cuff placement (42).

Since 2006 the AMS 800 Urinary Control System with InhibiZone® is available. InhibiZone is a proprietary combination of the antibiotics Rifampin and Minocycline that is impregnated onto the surfaces of the occlusive cuff and the control pump of an AMS 800, and creates a zone of inhibition against bacteria commonly associated with prosthetic infections. In clinical studies however, the antibiotic coating of the AMS 800 seems not to have a significant impact on infection or explantation rates, contrary to what is noted in penile prosthetic implants. (43) (**Figure 20**)

Alternative Artificial Urinary Sphincters

In order to address some of the shortcomings of the AMS 800 device, the team of Tony Mundy from London (England, UK) presented in 2006 a proprietary AUS, the FlowSecure® (Sphinx Medical, Bellshill, UK) (44) The cuff of this AUS was molded from a curved template which was thought to reduce cracking of the cuff. The design also incorporated a second pressure-regulating balloon which rapidly could increase cuff pressure in response to increasing intra-abdominal pressure. This feature ultimately should have led to a lower rate of post-implantation stress urinary leakage. The overall pressure in the system was lower than that

found in the AMS 800, the putative advantage being lower risk of urethral erosion. Despite the initial enthusiasm and reasonable continence rates, this newly designed AUS was subsequently abandoned due to the high incidence of mechanical failures and need for revisions. (45)

In 2018 the VICTO® AUS (Promedon GMBH, Kolbermoor, Germany) was introduced on the European market. (46) (**Figure 21**) This device followed the basic principles of the FlowSecure® and included a self-sealing port allowing for in-office pressure adjustment. The second model (VICTOplus®) comprised a stress relief mechanism providing low resting occlusion pressure, with conditional increased urethral occlusive pressure during higher intra--abdominal pressures.

Another AUS model the ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) was designed in 2005 and introduced on the commercial medical market in 2009. (47) (**Figure 22**) It is a one-piece two-part device with a cuff and a pump unit with an integrated spring, and comes in one piece, pre-connected and pre-filled. There is no abdominal component in the ZSI 375, which along with its ready-to-implant configuration reduces the operating time. Furthermore, as there is no abdominal component, surgical interventions in the retroperitoneal space are not required. Previous surgeries, such as radical prostatectomy, may lead to post-operative scarring and fibrosis in the retroperitoneal space, and therefore avoiding dissection of retroperitoneal tissues avoids risks of surgical complications. Another advantage of the ZSI 375 model is the possibility to increase or decrease the pressure inside the device after implantation to meet the desired degree of occlusion. These adjustments particularly help to control continence in patients that develop post-implantation urethral atrophy or allow normal voiding if a poor urine flow or urinary retention is present after surgery. Adjustment of the pressure can be done in an outpatient setting by adding or removing sterile saline solution via a syringe through the scrotum.

In addition to the devices mentioned above, other new devices have been brought to market recently, such as the ContiClassic® and ContiReflex® AUS systems (Rigicon Inc., Ronkonkoma, USA). (48) (**Figure 23a**) (**Figure 23b**) In both models, sterile saline solution inside the system is used to generate pressure and compress the urethra. The urethral cuff is deflated manually by pressing the control pump that is placed in the scrotum and re-inflates automatically to refill the urethral cuff. The ContiClassic® has a similar design compared to the AS 800, but the ContiReflex® has a smart reflex balloon that constantly senses intra-abdominal pressure changes and simultaneously adapts the pressure on the

urethra, potentially helping patients stay dry more consistently f..e. during physical efforts.

Two other models of AUS have been developed, but never reached the clinical market. The Periurethral Constrictor (Silimed, Rio de Janeiro, Brazil) was designed in 1996 for implantation in pediatric patients with deficient urinary sphincter function and consisted of an adjustable cuff linked to an elliptical valve. (49) (**Figure 24**). This cuff could be implanted around the bladder neck or the bulbous urethra and the valve was placed in a space accessible by percutaneous puncture, usually in the subcutaneous space between the umbilicus and the iliac crest. Because of the high complication rate, this type of AUS was never commercialized. The second experimental AUS, presented in 2011, was the Tape Mechanical Occlusive Device (GT Urological LLC, Minneapolis, Minnesota, USA), a one-piece device consisting of an occlusive tape and a conduit, connected to a control mechanism that was manually controlled by the patient through on/off buttons. (50) However, also this experimental AUS was not brought to the clinical market.

History of the Future in Artificial Urinary Sphincters

The present AMS 800™ AUS has some limitations that can only be overridden by the emergence of a new AUS class. Indeed, the current AMS 800™ device has been marketed since 1983 and has never been submitted to major improvements since then. A total of nine hydro-mechanical or purely mechanical models of AUS have been reportedly developed, of which three have been implanted and studied in humans, but none has been directly clinically compared to the AMS 800™. (51) All these new models of AUS have limitations, and hence in recent history some new innovative concepts have been presented and studied.

As the functioning of the actual implants is purely hydromechanical, they apply circular constant pressure on the bulbous urethra. As a consequence, common reasons for device revision are insufficient cuff pressure with persistent leakage and with follow up in some patients, urethral atrophy, secondary to the permanent pressure on the urethral tissue. Furthermore, functioning requires some dexterity from the patient, limiting implantation in some patients. In 2014 a research group from Montreal presented a novel electronically controlled AUS which offers the possibility of remotely controlling the sphincter rapidly and without mechanical effort. (52) The implant's embedded software can also be updated remotely and its design eliminates the manual pump, making implantation easier in men and women. Furthermore, the remote-control

system is compatible with an implanted AMS 800™ AUS. The device has been tested in vitro and ex-vivo, but no human data have been published yet. (53) Other companies in cooperation with different clinical research groups are currently exploring different types of remotely controlled AUS. Examples are the UriControl® (Implantica AG, Vaduz, Liechtenstein) and the Artus device (Affluent Medical SA, Aix-en-Provence). (54) No clinical data have yet been presented.

Boston Scientific, the company that acquired the technology of the current AMS800™ AUS upon the dissolution of American Medical Systems, and that currently manufactures the device, has also a program to develop an electronically controlled AUS. The company reports they have made significant investments to develop the technology, and working prototypes of the eAUS have been manufactured and tested (54). Obviously, baseline information regarding the efficacy and safety of the current iteration of the device is fundamental to allow innovation in the current regulatory environment. A large-scale clinical trial has just completed enrollment, potentially in anticipation of setting parameters appropriate for eAUS trials and eventual approval in the United States.

Initial clinical results from a first in human implantation with a novel remotely controlled AUS, the UroActive™ (UroMems, Grenoble, France) have been presented at the ICS meeting in Toronto in 2023 (55) The UroActive™ is a smart active AUS powered by a MyoElectroMechanical System (MEMS), that can be programmed remotely. The urethral cuff is designed to be automatically controlled, based on the patient's activity, without the need for manual adjustments. This functionality allows for a greater ease of use for patients, and should provide a better quality of life than with current options. The expected benefit of the UroActive™ device is twofold. First, the urethral pressure can be increased when the patient is engaged in physical efforts, which is expected to improve continence during activity. Second, when the patient's activities do not require increased pressure, the compression on the urethral tissue can be limited, therefore potentially reducing the risk of erosion or tissue damage. In April 2024, at the 39th annual EAU congress in Paris, the preliminary, but promising results of the full cohort of patients implanted with the UroActive™ device were presented, and meanwhile a bid for FDA approval has been submitted. (56)

Conclusions

The first artificial urinary sphincter, the AMS721, was introduced in 1973 by the team of Brantley Scott to treat urinary incontinence due to sphincter

deficiency in males and females. After its clinical introduction, the basic design of the device changed to the fifth-generation model, the current AUS 800 that was commercialized as the AMS Sphincter 800™ from 1983 on. Despite its high success rate, but in order to decrease mechanical failure, numerous changes have been made to the various components of the AMS 800. However, its basic design and mode of operation have remained unchanged for over 40 years. New devices have been developed to overcome the drawbacks of the AUS 800, but have not resulted up to now in significantly higher success rates or less complications. Hence the golden standard in artificial urinary sphincter remains the AUS 800.

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Illustrations

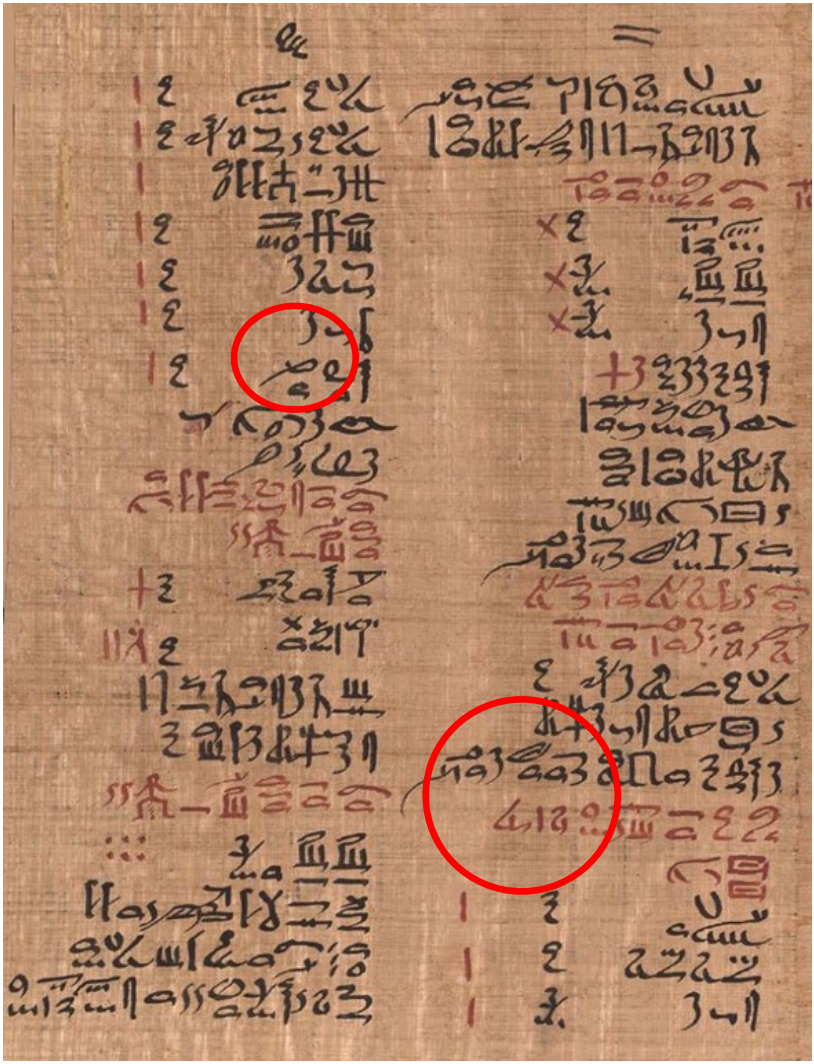
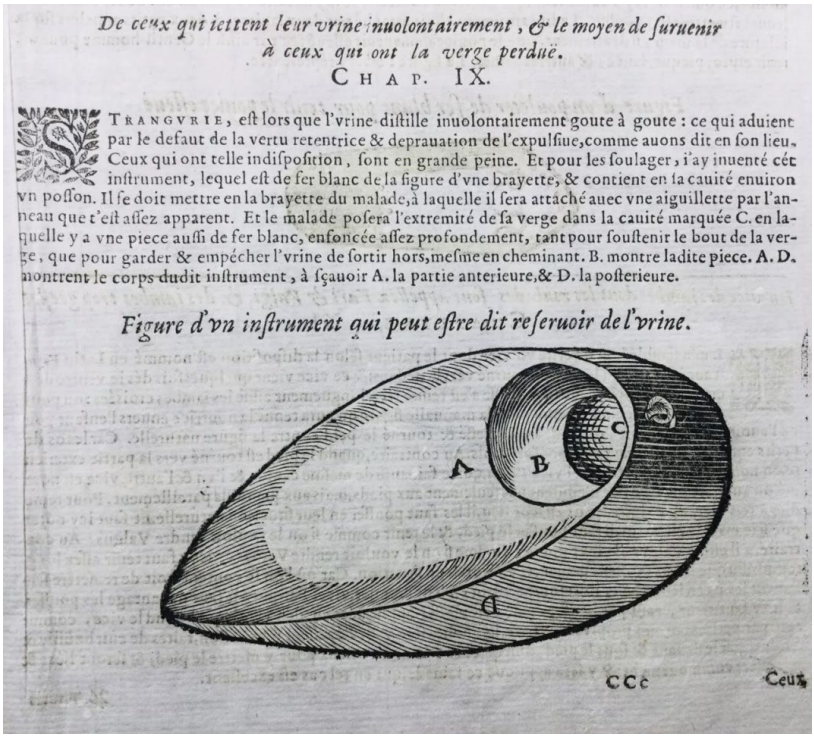


Fig. 1 Column 8 of the Ebers Papyrus indicating an erected penis with urinary leakage (probably due to neurogenic bladder dysfunction after spinal cord injury), Bibliotheca Albertina, Leipzig.



De ceux qui iettent leur vrine inuolontairement, & le moyen de ſuruenir à ceux qui ont la verge perduë.

CHAP. IX.

STRANGVRIE, eſt lors que l'vrine diſtille inuolontairement goute à goute : ce qui aduient par le defaut de la vertu retentrice & deprauation de l'expulſiue, comme auons dit en ſon lieu. Ceux qui ont telle indiſpoſition, ſont en grande peine. Et pour les ſoulager, i'ay inuenté cét inſtrument, lequel eſt de fer blanc de la figure d'vne brayette, & contient en ſa cauité enuiron vn poſſon. Il ſe doit mettre en la brayette du malade, à laquelle il ſera attaché auec vne aiguillette par l'anneau que t'eſt aſſez apparent. Et le malade poſera l'extremité de ſa verge dans la cauité marquée C. en laquelle y a vne piece auſſi de fer blanc, enfoncée aſſez profondement, tant pour ſouſtenir le bout de la verge, que pour garder & empécher l'vrine de ſortir hors, meſme en cheminant. B. montre ladite piece. A. D. montrent le corps dudit inſtrument, à ſçauoir A. la partie anterieure, & D. la poſterieure.

Figure d'vn inſtrument qui peut eſtre dit reſeruoir de l'vrine.

CCc Ceux

Fig. 2 Page from the 23rd book from «Les oeuvres d'Ambroise Paré» (edtion of 1614 with a portable urinal for incontinent males, as described in 1664 by Ambroise Paré, priv. coll.

Fig. 3 Urine receptacle made of the bladder of a pig and attached to the body with straps as described by Hildanus in 1682.

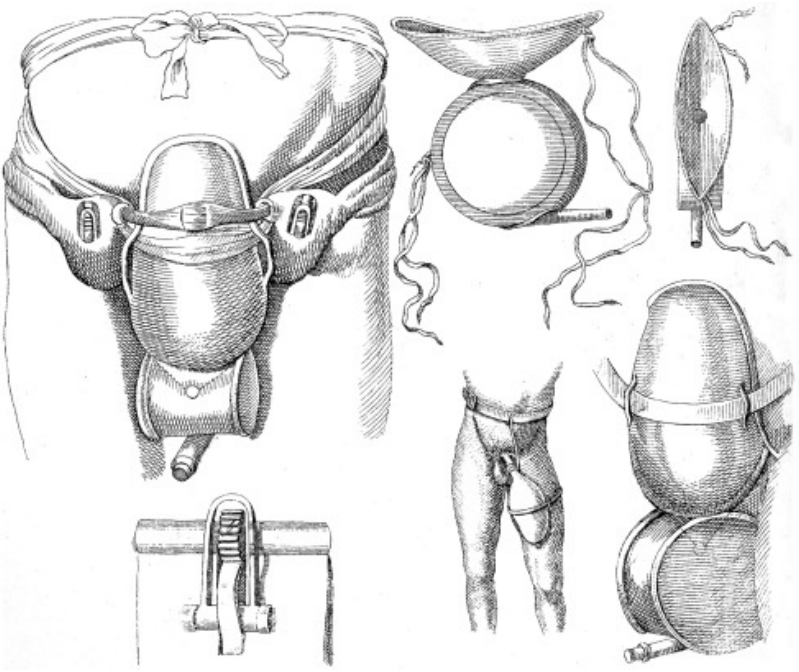


Fig. 4 Different models of portable urinals for males with urinary incontinence devices described by Lorenz Heister in 1739.

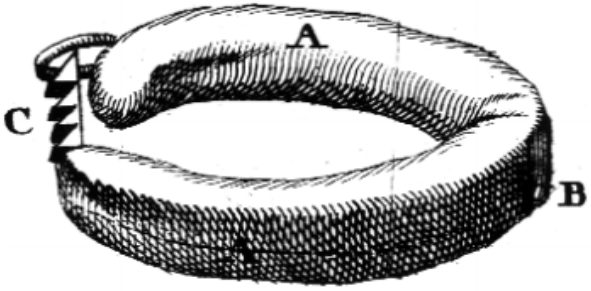


Fig. 5 Penile clamp covered with leather, according to Lorenz Heister (1747).

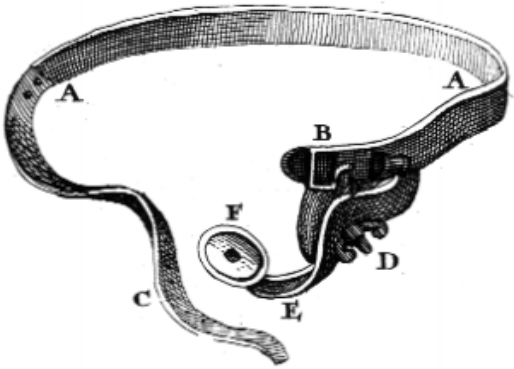


Fig. 6 Belt for perineal compression for the male bulbar urethra, according to Lorenz Heister (1747).

Fig. 7 A contemporary Cunningham type penile clamp (Bard company), collection of the authors.