Prosthetic Surgery in Urology

Asif Muneer
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Editors

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Foreword

It is a great pleasure to introduce this book on prosthetic surgery in urology. Asif, Ian and David are amongst the foremost leaders in the field of prosthetics in the UK, and between them they have commissioned an impressive group of authors, encompassing the whole field of the correction of functional disorders affecting the genitourinary tract.

The reader of this book will have access to the distilled wisdom of a number of the key opinion leaders in the field. I have no doubt that this book will provide an essential addition to any library, to provide the reader with a crisp, updated, user-friendly and relevant guide to the use of prosthetics in urology.

This is a challenging field of surgery which relies upon careful evaluation of patients, adequate counselling and meticulous surgical technique. Please recall the dictum: "A good surgeon knows what to do. A better surgeon knows when to do it. The best surgeon knows when not to do it." There is no other field within urology where this is more applicable.

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Preface

The use of man-made materials to replace or substitute the function of damaged or absent urogenital organs has been described for well over 5000 years. The Romans described using metal catheters to drain the bladder. Also wooden sticks placed within the male urethra or under the penile skin were the earliest documented examples of penile prostheses.

Whilst there are numerous examples of relatively crude forays into the realm of urogenital prosthetic surgery, it was not until the early twentieth century that advancements in biomaterials allowed the development of either functionally proficient or in the case of testicular prostheses, cosmetically acceptable prosthetics suitable for widespread patient application.

These biomaterial advances enabled both numerous and rapid developments in penile prostheses and artificial urinary sphincters and ultimately to functional restoration for men suffering with erectile dysfunction or urinary incontinence thus ensuring that the deleterious effects of surgical treatment for pelvic cancers or benign prostatic enlargement were able to be suitably and reliably addressed.

Prosthetic surgery for female urinary incontinence, a condition afflicting approximately 30 % of the female population, has been a major breakthrough, positively changing the quality of life for women across the globe who would have previously been reliant on containment products or long-term catheters.

Despite the undoubted success, all prosthetic devices are continually subject to ongoing modifications and developments aiming to enhance their acceptability, durability, ease of implantation and functionality whilst reducing their associated complications such as erosion and potential infection risk.

Future developments in urogenital prosthetic surgery and urology in general continue to excite and with ongoing research into new biomaterials, stem cells and tissue engineering, the boundaries both functionally and cosmetically continue to be pushed further and further.

This book covers the common prosthetic surgical procedures in urology and provides clinicians with an overview of the available prostheses as well as a step-by-step guide to the surgical procedures provided by experts in each field.

This is a valuable resource for established urologists and urology trainees with an interest in prosthetic surgery, as well as nursing staff and allied healthcare professionals involved in the perioperative management of these patients.

The editors are grateful to all of the contributors who have helped to create this unique and informative guide to prosthetic surgery in urology.

London, UK Asif Muneer
Manchester, UK Ian Pearce
London, UK David Ralph

Acknowledgements

The editors would like to thank all of the contributors who have given up their own time to skillfully put together their chapters. We would also like to thank everyone at Springer who has helped to finalise the project. Finally, to all our family, friends, colleagues and trainees – thank you for your patience.

A. Muneer
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D. Ralph

Contents

1 An Introduction to Prosthetic Devices

Asif Muneer and Ian Pearce

Abstract

The word “prosthesis” originates via New Latin from the Greek word “prostithenai” meaning to ‘add to’ or ‘in addition’. Although commonly used for external limb replacements, the term also encompasses surgical prostheses used in a wide range of surgical subspecialties.

Keywords

Prosthetic surgery • Biofilms • Stem cells • Tissue engineering

Prosthetic surgery is not new, the earliest recorded examples being that of a wooden toe in the New Kingdom of Egypt (1600–1100 BC) and an iron leg made for the warrior queen Vishpala, documented in the ancient Sanskrit poem collection of Rigveda, one of the four Vedas, or sacred texts of Hinduism, (circa 1500–1200 BC). These prosthetics however, had no function and were merely anatomical in nature, it was not until approximately 800 BC that a functioning prosthesis was discovered near Thebes in Egypt.

Urological surgery has always been at the forefront of innovative developments in surgery; from the development of endoscopy, the early adoption of laparoscopy and minimally invasive surgery to the utilisation of robot assisted surgery for pelvic cancers and more recently upper tract malignancy.

The male external organs of the urinary tract namely the penis and scrotal contents are areas of the body that have become synonymous over the years with masculinity, virility, power and fertility with the emphasis varying amongst different cultures and geographical regions. Hence any functional loss related to these organs either through traumatic injury or as a result of malignancy is often linked to a loss of quality of life and self-esteem together with a negative psychological impact. It is both relevant and interesting to note that some of the first medical prostheses were developed to replace either missing testicles or to restore function, either voiding or sexual to the penis. In modern urological practice, the major technological advances have been witnessed within the areas of penile prostheses and the artificial urinary sphincter through the use of improved biomaterials and design that have also

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Table 1.1 Properties of the ideal material for prostheses

1. Durable
2. Inert
3. Negligible particle migration
4. Low infective risk
5. Functionally resilient
6. Easy to handle
7. Cost effective

led to the evolution and improvement in ureteric stents, nephrostomy tubes and urinary catheters resulting in an increasingly wide and varied range available for practical use.

An ideal prosthesis requires components and materials which can either restore or reproduce the physiological function of an organ (Table 1.1). The rapid developments in material science have provided a vast array of potential materials which are inert and therefore suitable for use within the human body and have subsequently led to an increasing number of prostheses with more indications being available in urological practice.

However, as discussed later in this book, complications still exist as with any surgical intervention and the implantation of foreign material within the urinary tract will always be at a potential risk of prosthesis infection, device malfunction and erosion as well as particle migration. Careful as well as appropriate patient selection and preparation, is of paramount importance in order to reduce the patient morbidity and patient dissatisfaction.

Surgical specialities such as Trauma and Orthopaedic surgery where prosthetic surgery forms the major component of a surgeons workload necessitate a specific theatre set up and preparation and demand that all involved personnel are well versed in protocols aimed at reducing the risk of infection, and ensuring that the handling of the prosthesis itself is performed cleanly and efficiently with a minimal risk of contamination. In contrast prosthetic surgery in urology forms a small proportion of the surgical volume and overall workload focusing almost exclusively on either mainstream core procedures such as ureteric stenting and testicular prosthesis insertion and the more complex prosthetic surgery such as inflatable penile prosthesis insertion, artificial urinary sphincter insertion and neuromodulation. These more complex procedures tend to polarize to subspecialist centres such that high volume surgeons have the necessary equipment and theatre staff well versed in these procedures.

With penile prosthesis surgery the infection risk relates to the surgeons' case volume with lower rates of infection being witnessed in high volume centres. But how do we define a high volume centre? There is currently no evidence to suggest how many procedures should be performed in order to be deemed a high volume centre, indeed, defined values for the incidence of prosthesis infection or other morbidities does not exist and thus minimum numbers associated with such figures are impossible to extrapolate and delineate.

If we take the UK practice as an example, there are approximately 500 penile prostheses inserted per annum, which are performed in over 20 centres across the country with huge variation in numbers between centres. Some will perform 1 or 2 per year whilst the largest centre performs approximately 200 per year. The remaining centres therefore average approximately 15 prostheses per year if evenly distributed although amongst some of these there will be centres performing in excess of 30. Thus, it would seam reasonable to recommend an arbitrary minimum figure based on this average of 12–24 per year equating to at least one –two penile prosthesis implantations per month. This would enable surgeons, scrub teams and ward staff to maintain the necessary skills for prostheses surgery, in addition to facilitating a compromise between high volume centralization and geographical representation thus ensuring that patients nationally can be offered prosthetic surgery closer to home.

Although this may be a model suitable for primary prosthesis surgery, revision surgery is less common, more demanding and complex and carries with it an associated higher risk of infection. For instance the quoted infection risk for a primary inflatable penile prosthesis is 4 % with a reduction in the rate to 2 % in large volume centres. With revision surgery the infection rate doubles.

However, if a center is only performing 10 penile prostheses per annum and has a single case of prosthesis infection, the infection rate increases substantially to 10 % for that year. Revision surgery also requires specialized instruments, broader experience of prosthesis surgery as well as more sophisticated imaging interpretation and therefore there is a case for such surgery to be performed in the highest volume centres whereby a solitary infection amongst 100 procedures would amount to a mere 1 % infection rate. This of course must be balanced with clinical results and outcomes for each particular unit.

Clinicians and nursing staff in the field of urology routinely manage patients with various prosthetic devices on a daily basis which range from urinary catheters, stomas, ureteric stents to more complex prosthetic devices or injectables. With the more widely used prostheses such as catheters and stoma bags, very little training is often given, or indeed required in order to allow clinicians to manage complications and change or remove the prosthetic devices. However, more complex prostheses such as penile prostheses or artificial urinary sphincters do require more specialized and detailed training and this is often compounded by the relatively limited numbers of these cases performed compared to urinary catheters. In addition there is often a limited number of clinicians and nursing staff who have the required in depth knowledge or experience to troubleshoot peri and post-operative or late complications related to these devices.

In order to minimize complications when patients return to the community, it is imperative that patients undergo detailed pre-operative counseling regarding the device in order to ensure that expectations are realistic and that the patient understands the purpose of the prosthesis. In the case of sacral neuromodulation, inflatable penile prostheses and artificial urinary sphincters it is essential that the patient possesses both the mental capacity and dexterity to use the device appropriately. This aspect of a patient's care may be nurse led and aided by a standard proforma which should cover discussion of alternative options and documentation of which types of prostheses have been shown, demonstrated and discussed as potential treatment options. This also affords the opportunity to advise and optimise the patient pre operatively in terms of smoking cessation, screening for infection (urine, skin) and optimise control of their diabetes and other co-morbidities if present.

Research related to the role of biofilms has led to more interest in prophylactic measures in order to reduce the incidence of prosthetic infections by means of antibiotic coatings or developing surface materials which facilitate the absorption of antibiotics and other infection inhibiting agents. Prosthetic devices which are external such as urinary catheters will inevitably become colonized within 24 h at the latest and usually before. Although this is not problematic for short term indwelling catheters, patients with long term indwelling catheters with complicated or structurally abnormal urinary tracts often develop urosepsis if the catheters are mismanaged or, more commonly, neglected. Therefore, an understanding of biofilms has enabled researchers and clinicians to attempt to address these issues via a variety of innovations including the use of silver impregnated catheters for those who require intermittent self catheterization. The acceptance that a biofilm develops on a prosthetic device does have implications during revision surgery. Firstly the infection rate increases compared to the primary procedure and secondly, as in the case of penile prostheses and artificial urinary sphincters it is advisable to use antibiotic and antiseptic irrigants to reduce the risk of infection. In the case of penile prosthesis revision surgery, washout of the cavities with a combination of antibiotics and antiseptic agents is routinely performed, similar but not to the same extent as performing a salvage washout for an infected orthopaedic prosthesis.

There have been major advances in prosthetic surgery over the last four decades and this is likely to continue at an increasing pace as new materials are evolved and developed which have improved properties with respect to the major complications arising from such surgery.

Several exciting areas which are emerging include the use of tissue engineering to replace lost, damaged or dysfunctional tissue and to use as grafts to replicate areas within the urinary tract as well as 3D printing which offers a more personalized replacement of tissues and organs and facilitates the replication of function. Other innovations include prostheses which respond to nerve impulses thus enhancing their utility and acceptance amongst patients and surgeons alike. These technological advances combined with the rapid growth in stem cell technology will potentially allow replacement and reconstruction of a number of areas of the urinary tract and will continue to push the boundaries as we currently know them.

The History of Prosthetic Surgery in Urology

2

Sally Deverill and Dominic Hodgson

Abstract

There have been attempts to recreate the appearance and function of the genito-urinary tract with exogenous materials for millennia; but it is only within the last half century that real success has been achieved. This has been a result, to a large extent, of advancements in material science to provide inert yet pliable products. However, materials which are both resistant to infection and offer sustained functionality are still sought. In this chapter we explore how urologists worked in conjunction with industry to develop effective prosthetic solutions to: testicular absence or loss, erectile dysfunction, urinary incontinence, and strictures within the urinary tract.

Keywords

History • Urological prostheses • Artificial testicle • Artificial urinary sphincter • Penile prosthesis • Stent • Sacral neuromodulation

Although physicians have attempted to mimic the function of the urinary tract with exogenous materials for millennia, prosthetic urological surgery is more a modern phenomenon. Its development has been possible as a consequence of surgical innovation, collaboration across specialities and with industry, leading to the production of functional yet inert artificial devices.

Development of the Testicular Prosthesis

Testicular loss or absence occurs for a variety of reasons in both the paediatric and adult population. This may be as a result of unilateral orchidectomy (inguinal, scrotal or intra-abdominal) as a result of maldescent, malignancy, testicular trauma, infection, infarction or torsion, with bilateral orchidectomy mainly as a result of advanced prostate cancer or bilateral testicular tumours. In

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children, absence of a testicle may be as a result of testicular agenesis, intra-uterine torsion (vanishing testis), failure to descend (cryptorchidism). The loss or absence of a testicle may result in psychological distress for the individual, and therefore replacing the absent testicle with a prosthesis may lead to improved self esteem and quality of life. Prior to the introduction of synthetic materials, foreign bodies such as ivory had been used with limited success, however, the modern testicular prosthesis has undergone a number of innovative developments over the past 75 years.

The first synthetic testicular prosthesis procedure described in the literature [1] was performed by Ralph Bowers in 1940 for a patient with significant psychological distress following an orchidectomy as a result of trauma three years previously. In this case a hollow vitallium (an alloy of cobalt, chromium and molybdenum that had been successfully used in orthopaedic fixation) implant was used. After transient local oedema, the prosthesis was tolerated well and at one year follow-up the patient had no local reaction to the implant, but there was a cold metallic feel to it and considerable mobility of the artificial testicle in the scrotum. The patient's depression, however, was said to have resolved.

In the 1930s and 40s, polymethylmethacrylate (PMMA), a synthetic thermoplastic polymer which was a transparent, rigid plastic, was developed. It had been used as a substitute for glass in windows and skylights as well as signs and aircraft canopies. In 1943 Rea [2] described using PMMA (Lucite) as a testicular prosthesis, with the hope that it would produce a durable and more natural feeling product compared to vitallium. Subsequently, glass spheres [3], polyvinyl alcohol sponges and Dacron were also trialled but with little success. Interestingly, Gelfoam was also used as a filler following intra-capsular orchidectomy for metastatic prostate cancer [4].

In the 1940s silicone elastomers were developed by the chemical industry and revolutionised medical prosthetics. The first published report of these materials being implanted in humans was in 1946 when a Dr Lahey used silicone tubing for a bile duct repair [5] having obtained it from the experimental laboratory of the General Electric (GE) company. Following on from this, in 1948, Dr DeNicola used the same type of tubing to implant an artificial urethra [6] and in the 1950s, silicone was also used for creation of a ventriculo-atrial shunt for the management of hydrocephalus [7], with the aid of the other company involved in the evolution of silicone, Dow Corning. These early applications resulted in a substantial increase in interest from the medical field for both GE and Dow Corning, which led to the latter setting up a specific centre for medical research to supply scientists with research quantities of various silicone materials. In the early 1960s, as well as the production of orthopaedic implants, catheters, drains, shunts, heart valves and components in extra-corporeal technology such as haemodialysis and heart bypass machines, aesthetic implants started to also be developed. Silicone gel filled breast implants were first successfully implanted in 1963 [8]. Soon after, silicone artificial testes started to be implanted in 1964 [9]: the most significant subsequent innovation being a silicone gel filled, silicone-rubber prosthesis described by Lattimer et al. in 1973 [10]. This prosthesis was widely used until 1988 when a firmer, silicone-coated product became the standard until the mid-1990s.

The use of all silicone prostheses was called into question in 1992 in the US after the Food and Drug Administration (FDA) halted the use of gel-filled breast implants due to a number of concerns including the risk of connective tissue and autoimmune disorders, issues regarding mechanical instability and worries about the potential development of malignancy. Most of the evidence of harm was inconclusive; however, there was a perception that silicone particles migrated from the devices into the surrounding tissues. Robinson et al. analysed silicone breast implants removed from 300 consecutive patients and found that 64 % had some form of device disruption [11]. Barrett et al. also described leakage of small amounts of silicone into surrounding tissues from penile prostheses, a phenomenon known as "gel bleed" [12]. Despite this, no subsequent evidence ever found a link between the use of penile or testicular prostheses and the development of connective tissue disorders or an increased risk of malignancy.

However, as a result of the concern and controversy surrounding silicone breast implants, there was a voluntary withdrawal of silicone-gel filled testicular prostheses in the US in 1995 (although they have remained in use within the UK) and a new silicone composite shell, but saline-filled, prosthesis was introduced by Mentor Medical Systems and has been used from that year onwards. In 2004, Turek et al. published a multi-centre prospective case-controlled trial of this new prosthesis and found no complications after one year and concluded that saline-filled prostheses appeared safe and well-tolerated in the short-term [13].

There are now a number of companies producing and supplying testicular implants: Nagor Ltd (UK); Mentor Medical Systems, now Coloplast (USA); Osteotec Plastic Surgery (UK); and Silimed (Germany). Coloplast also produce a soft-solid reinforced silicone prosthesis as well as the saline-filled prosthesis (which is the only one currently licensed by the FDA for use within the US). The other companies produce silicone gel and elastomer versions. The majority of the prostheses have a suture loop to aid fixation of the implant within the scrotum (Fig. 2.1).

More recently there have been in vivo studies investigating the development of a hormone releasing testicular prostheses which has a dual function of providing a cosmetic replacement as well as physiological function.

Early Reports of Penile Prostheses

The earliest reports of penile prostheses described the use of wooden sticks placed in the urethra or under the penile skin [14]. Sadly, as with so many of the developments in surgery, it is injuries sustained during war that provided (and still provides) much of the necessity for invention. In the sixteenth century, the greatest of war surgeons, Ambroise Paré, describes using a piece of solid wood to replace a lost penis but emphasised its function was to allow the passage of urine rather than for intercourse: *"those*

Fig. 2.1 Five sizes of modern Silimed Silicone Elastomer Prostheses 2015

that have their yards cut off close to their bellies, are greater troubled in making of urine so that they are constrained to sit downe like women for their ease." Paré created what he termed *"an artificial yarde out of firm wood"* (Yarde being an Elizabethan term for the member) that served *"instead of the yarde in making of water."* [15, 16]. (Fig. 2.2)

The first recorded attempt to restore both voiding and sexual function was by the Russian surgeon Nikolaj A Borgaraz in 1936 (cited in Gee 1975) [17]. He used an abdominal tube graft and autologous rib cartilage with the aim of providing rigidity to allow coitus. This was akin to the *os penis* or *baculum* seen in lower order animals (Fig. 2.3).

Famously the Soviet Surgeon Frumkin further developed Borgaraz's autologous technique and also described releasing the penile suspensory ligament in order to increase length [18]. He reported successful intercourse in such patients and even achievement of orgasm. Others, however, reported frequent extrusion, erosion and penile curvature following surgery [19].

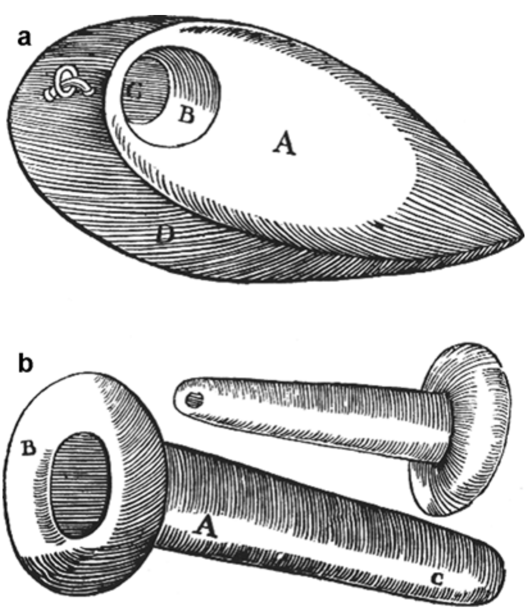

Fig. 2.2 (**a**) Urinal and (**b**) Artificial yard: examples of early incontinence and micturition devices according to Ambroise Paré (1564) [16]

Further Advancements in Penile Prostheses

The rapid post-war development in synthetic substances provided a vast array of prosthetic materials for implantation. Thus, in the 1950s stents made of acrylic materials (developed for rhinoplasties, artificial joints and testicular prostheses) were placed inside Buck's fascia but still outside the corpora cavernosa. However, many patients suffered extrusion as reported by Godwin and Scott [20].

In the late 1950s and early 1960s silicone rubber elastomers were better tolerated and less likely to induce infection when used for medical prosthetics. After being utilized for breast and testicular implants, silicone was first used in 1964 as a penile implant, using inlay methods borrowed from orthodontics, and described by Lash et al. [21]. This material provided flexibility as well as rigidity and durability with minimal tissue reaction and thus became the material of choice for future implants.

These rods were initially placed under Buck's fascia in the groove between the corpora but extrusion of the implants still remained problematic [22]. In 1972 Pearman reported an improvement by placing a single rigid silastic trimmable rod deep to the tunica albuginea (rather than Buck's fascia) dorsally between corona and suspensory ligaments [23]. This intra-cavernosal location has remained the preferred position of modern day penile prostheses.

In 1966 Beheri had also reported the use of intra-cavernosal placement of polyethene rods (an impressive 700 since 1958) [24]. However, Morales, who first reported the use of such rigid devices in the US, found that perforation and erosion were still a significant issue [25]. There was an attempt to improve on the devices by producing a larger implant filled with silicone gel, and whilst there were improved erosion rates, there was a significant risk of leaks and only a few of these were used.

In 1973 the Small-Carrion prosthesis was introduced with a silicone exterior and silicone sponge centre which permitted filling of the whole of the corpora with customized length [26].

Fig. 2.3 (**a**) Baculum- 59 cm Length (**b**) Racoon Baculum

This combination of silicone elastomer and the intra-cavernosal location proved ideal and such designs became the standard for malleable penile implants. Concealment, however, remained an issue and the Finney's Flexirod, Jonas, Omniphase and Duraphase prostheses aimed to improve this by allowing improved manipulation between the erect and flaccid state.

Although the majority of penile prostheses inserted are the inflatable devices, in certain circumstances malleable devices are preferred either for clinical reasons or cost related issues and therefore they continue to be manufactured.

Development of the Inflatable Penile Prostheses (IPP)

The charismatic Texan Urologist Brantley Scott first described an inflatable device in 1973, which consisted of two non distensible cylinders of Dacron-reinforced silicone elastomer together with a reservoir which was controlled by one pump for inflation and one for deflation [27]. This was manufactured and marketed by American Medical Systems (AMS). Such devices combined the function of non-inflatables whilst providing an acceptable appearance in the flaccid state and better concealment. This model was further modified (including a single inflation/deflation pump) and was implanted widely throughout the following decade (Fig. 2.4).

The AMS 700 model was used from 1983 to 1987 with several modifications including thicker cylinders and kink-resistant tubing (KRT). Wilson et al. reported a 61 % complication/revision rate with the first AMS device compared with a 13 % revision rate with the later AMS 700 [28]. A further modified AMS 700 CX (1987) had an outer silicone covered woven fabric which limited expansion of the cylinder (as opposed to the more elastic corpora previously) and reduced the risk of cylinder aneurysm. Subsequent improvements included colour coded KRT and pre-connected cylinder and pump tubing to decrease intra-operative time and simplify the operation. In 2007 Wilson reported a 60 % 15 year device survival rate from his institution [29].

The 700 Ultrex, was introduced in 1990 and had a middle fabric cylinder layer that expanded in diameter and length when inflated. This was further strengthened in 1993 to reduce the risk of tearing. The device was renamed the LGX (length girth expander) to emphasise the purpose of the modification. More recently the pump has been replaced with a "momentary squeeze" (MS) pump which results in device deflation in 3–4 s and has a built in lock out valve to prevent auto-inflation. At the time of Scott's death, in a plane crash in 1991, an estimated 100,000 had already been implanted.

Mentor (now Coloplast) introduced their three-piece prosthesis in 1983. Improvements have included a change in composition with the addition of polyurethane (which has improved tensile strength without compromising the biocompatibility), and reinforced tubing. In 1989 the Mentor Alpha-1 was a connector less, single pump IPP which again improved reliability and also the risk of connector leakage (Fig. 2.5).

In 2000 the Lock-out Valve ™ stopped the flow of fluid from the reservoir as a result of increased abdominal pressure thus eliminating the risk of auto-inflation. A study revealed a 1.3 % risk of auto inflation compared to 11 % with the unmodified device. An Alpha-1 narrow-base product also allowed smaller diameter cylinders to be placed in fibrotic or scarred corpora.

Since 2000, manufacturers have impregnated the devices with antibiotics. Thus, InhibiZone™ (Minocycline and Rifampicin impregnated into the external silicone surfaces) on the AMS device conferred an 82 % lower infection rate compared to the untreated device [30] (Figs. 2.6 and 2.7).

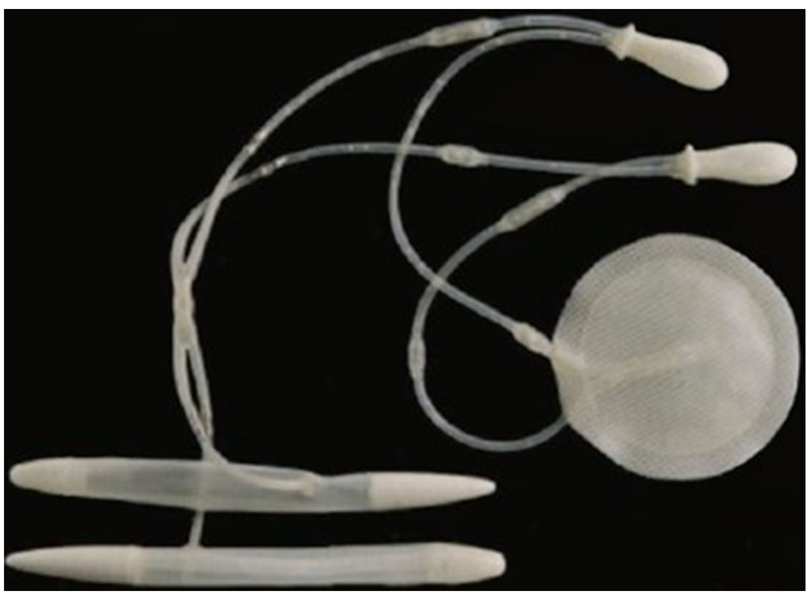

Fig. 2.4 The first inflatable penile prosthesis

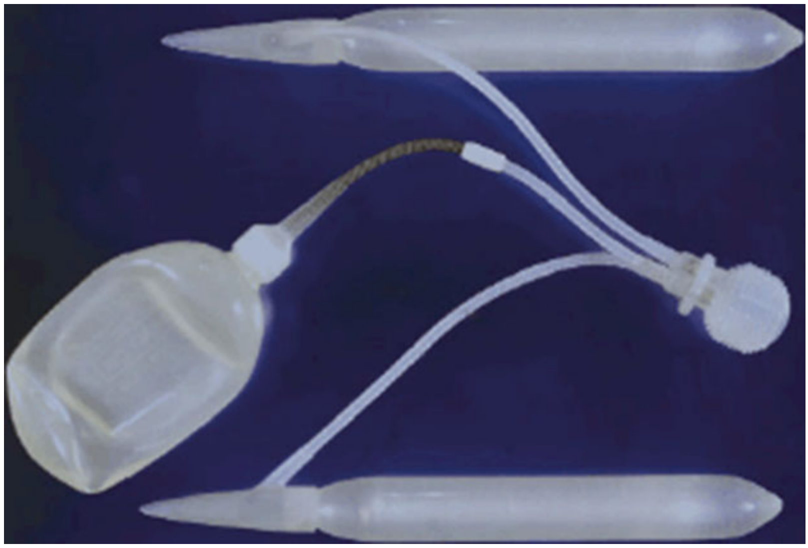

Fig. 2.5 Mentor Alpha-1 Inflatable Penile Prosthesis

Fig. 2.6 InhibiZone™ antibiotic eluting AMS IPP

Mentor's hydrophilic Titan coating was introduced in 2002, allowing absorption of antibiotics which the prosthesis is immersed in intraoperatively, with the advantage of allowing the surgeon to choose their own antibiotics. Studies have again shown a similar decrease in infection rates [31].

Further research into infections and combined with the improved knowledge of bio-films, has resulted in extensive lavage at the time of revision surgery to reduce the rate of infection.

Development of Prostheses for Urinary Incontinence

Ancient writings on urinary incontinence addressed cases of fistulae or overflow incontinence. Later there followed reports of the problem of postoperative incontinence after perineal lithotomy. The first surgical techniques to combat urinary incontinence originated with attempts at fistula repair. By the end of the nineteenth cen-

Fig. 2.7 Modern day Coloplast Titan inflatable penile prosthesis

tury procedures for stress incontinence were described, and in the late twentieth century procedures using prosthetics such as artificial urinary sphincters (AUS), prosthetic slings, bulking agents, and electro-stimulation had been introduced.

Artificial Urinary Sphincters (AUS)

The increase in the number of radical prostatectomy procedures for the management of localised prostate cancer in the latter decades of the twentieth century has had the consequence of an increase in male stress urinary incontinence. The introduction by AMS of the AUS in the early 1970s was a timely attempt to combat such male non-neurogenic stress incontinence. Its genesis was closely related to the development of the inflatable penile prostheses, borrowing many of the same technological advances, and in fact the IPP was a side-development from the AUS. The main indications for AUS insertion include: post prostatectomy incontinence; sphincter weakness incontinence due to neurogenic bladder dysfunction; intrinsic sphincter deficiency; failed female anti-incontinence surgery and rarer congenital causes of incontinence [32].

Although there have been descriptions of penile clamps to provide external compression of the urethra since the eighteenth century, the first description of an artificial urinary sphincter was credited to Foley in 1947 who described an inflatable cuff around the penile urethra controlled by a pump carried in the pocket [33]. In 1960, Vincent described the use of an externally worn belt and air-inflatable cushion to provide variable degrees of perineal compression.

The first prosthetic device in the modern era to increase urethral resistance was developed by Berry in 1961 [34]. He aimed to restore continence by using implanted acrylic blocks through the perineum in order to compress the bulbar urethra, but this technique was hindered by the implants moving and eroding into the urethra. In 1973, Kaufman described a gel filled disc shaped prosthesis designed to augment resistance by passive compression of the urethra [35].

The most significant development was in 1972 when Scott implanted the first AUS, the AMS721 (American Medical Systems, USA) [36]. This was a silicone prosthesis which consisted of an inflatable cuff for placement around the urethra or bladder neck together with separate inflation and deflation pumps and a reservoir, with valves controlling the direction of flow and the pressure within the system.

In 1978, Rosen produced an alternative sphincter consisting of a three-armed clamp, with one arm carrying a balloon attached to a reservoir bulb, and a release bulb, positioned in the scrotum. Compressing the reservoir bulb inflated the balloon which increased the urethral resistance in order to maintain continence. Failure was common as the pressure on the urethra could not be regulated and therefore the longest lasting prosthesis survived for only 26 months [37].

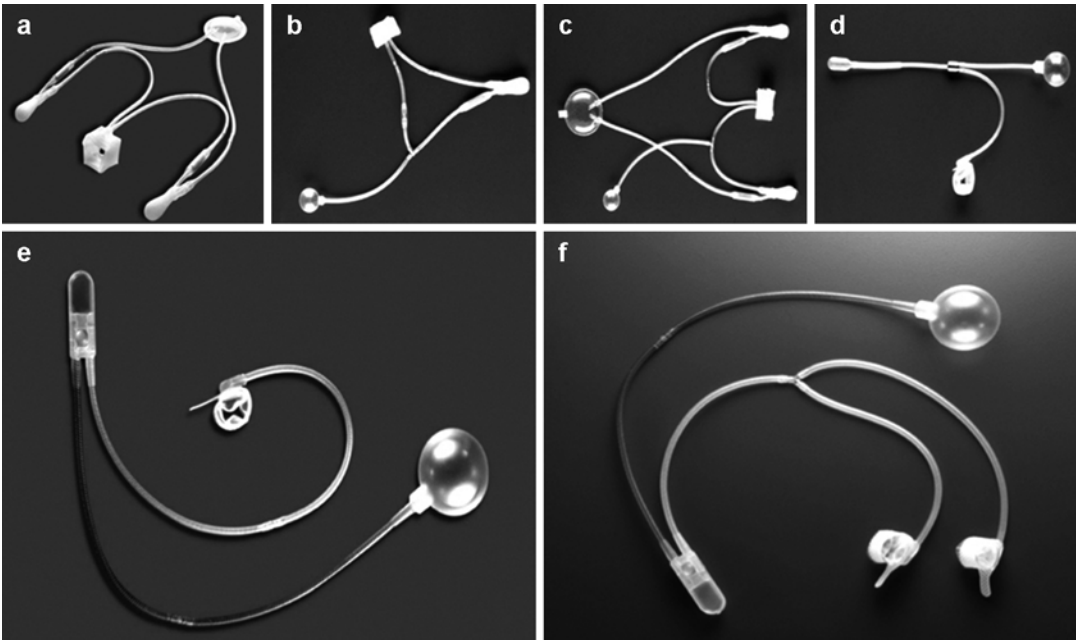

Fig. 2.8 Development of the AMS Artificial Urinary Sphincter: (**a**) 721 (1972–1979); (**b**) 742 (1974–1979); (**c**) 761 (1976–1977); (**d**) 791/2 (1977–1979); (**e**, **f**) 800 (1983/1986–)

Over the next decade and a half, the AMS model was modified to improve functionality and reduce mechanical failure. The most significant changes were the use of a balloon instead of valves to regulate the pressure, and a change to an automatic inflation device. Later models also saw the introduction of an entirely silicone based cuff instead of one of Dacron-reinforced silicone rubber. Additionally, silicone components were dip-coated to reduce the incidence of leakage, as a consequence of the concerns regarding silicone "bleed" from breast implants as previously mentioned. A deactivation button permitted periods of reduced direct urethral pressure in an attempt to prolong the life of the device, reduce mechanical fatigue and the incidence of erosion. Overall, there was a decrease in the number of components and connections, eventually leading to the currently used three-part AMS 800 AUS device. This was first introduced in 1982, reached maturity in 1987, and is still the most widely used AUS on the market, such that 25,000 had been implanted by the time of the inventor's death (Fig. 2.8).

With the increase in demand for the AUS in the last 20 years, there have been alternative devices developed to compete with the AMS 800, including the FlowSecure™ (FlowSecure, RBM-Med)[38], Zephyr ZSI 375 (Zephyr Surgical Implants, Switzerland) [39], ProACT (Uromedica) [40], Peri-urethral constrictor (Silimed, Brazil) [41], Tape Mechanical Occlusive Device (TMOD) [42] and the Versatile Automated Device [43].

Modified models and novel devices are still under investigation with innovations including the use of three smaller alternating sphincters with a microdrive control unit powered by a subcutaneous battery [44], and nanotechnology derived devices (utilising shape-memory alloys/electrically activated polymers).

Use of Sling Procedures for Urinary Incontinence

Autologus grafts for bladder neck sling procedures were first used in an attempt to restore continence in the early 1900s. Giordano used gracilis transposed beneath the bladder neck in 1907 [45]. Goebell, in 1910, described the use of pyramidalis [46] and Frangenheim in 1914 wrote of pyramidalis with overlying fascia [47]. Stoekel in 1917 combined this same muscle-fascial sling with a plication of the bladder neck [48]. In 1933, Price first described the use of fascia lata as a sling and there have been many modifications of this technique since [49]. The "Aldridge sling" became the standard procedure for much of the last century following his publication in 1942 [50].

In 1953 Armand J Pereyra described a vaginal needle suspension which introduced the concept of minimally invasive techniques for urinary incontinence [51]. Due to the morbidity associated with graft harvesting, toward the end of the century, non-autologous biological materials (allografts and xenografts) and synthetics (Mersilene and Goretex) were used. However, there were concerns about disease transmission with the former, and erosion and rejection with the latter.

Trans Vaginal Tape (TVT)

The innovator who revolutionised this area of surgery was the Danish Gynaecologist (working in Sweden), Ulf Ulmsten. He was a rigorous scientist and his "integral" theory [52] proposed that incontinence resulted from a deficient pubococcygeus muscle incapable of lifting the anterior vaginal wall close to the urethra. His mid-urethral sling aimed to reinforce this defective mechanism. He originally called this the intravaginal sling-plasty [53], but Johnson & Johnson changed the name to TVT when they bought the patent in 1997.

Since then there have been numerous attempts to improve the original design although it is questionable as to how successful these have been.

The Use of Bulking Agents for Incontinence

In 1938, Murless reported the injection of sodium morrhuate, a sclerosing agent, into the anterior vaginal wall of 20 patients, in an attempt to treat stress incontinence [54]. Following this, other sclerosing agents including paraffin and dondren were used but complicated by the development of pulmonary emboli. Teflon (polytetrafluroethylene) was trialled in the 1970s [55, 56] but there were concerns over microparticle migration and the development of inflammatory reactions and granuloma formation. The next development was the use of collagen by Shortliffe (1989)[57], and the first bulking agent to be US FDA approved in 1993 was a Glutaraldehyde cross-linked (GAX) bovine collagen 'Contigen'. Carbon coated zirconium beads in a water based carrier gel with beta glucan (Durasphere) have also been FDA approved [58]. In the 1990s, silicones were also introduced as bulking agents, although these were not FDA approved due to the previously mentioned concerns over silicone particulate migration. Of these, Macroplastique (polydimethylsiloxane elastomer implants) has also been used to treat vesico-ureteric reflux.

Sacral Neuromodulation Development

Robert Ultzmann (1842–1889) first described the use of electrophysiology in an attempt to stimulate the detrusor muscle and sphincter muscle, by way of inserting a catheter-like electrode into the bladder or prostatic urethra [59]. Subsequently Hopkinson and Lightwood introduced electrostimulation of the pelvic floor with plug-electrodes in the 1960s [60]. However, the development of permanent intracorporeal electrodes began in 1954 when Boyce et al. described the insertion of stimulating electrodes directly onto the bladder [61]. By 1967, Burghele attached stimulators to the pelvic splanchnic nerves and Habib attached them to the segmental sacral nerves [62, 63]. In the 1970s, sacral anterior root stimulators were developed concurrently by GS Brindley's team in the UK and also by a San Francisco based group. Initial experiments were performed on baboons and the first human sacral anterior root stimulator was implanted in London in 1976 but unfortunately this resulted in no useful micturition [64].