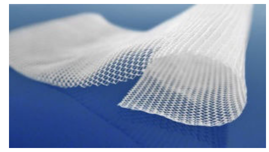

Below the Belt: The Technology of Incontinence
Medical Device Technology
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David Williams

At a time when advances in so many areas of medicine and surgery mean that hitherto catastrophic diseases can be prevented, diagnosed, or treated with amazing precision and efficiency, the urinary track remains relatively ignored by molecular biology and medical technology. This article addresses some of the reasons underlying this phenomenon and points to major technical and commercial opportunities in this neglected area.

Defining the problem

The dictionary [1] defines incontinence as the "quality or state of being incontinent." Apart from the rather unfortunate connotation with quality, which with reference to life, is what incontinence sufferers clearly do not have, this definition does not aid in providing an understanding of what is involved. In turning to the word incontinent, this is defined as "not continent," qualified by an unfortunate phrase, "lacking in self-restraint." Continent is held to mean exercising continence and continence is described as the state of self-restraint from yielding to impulse or desire. None of this appears to reflect the serious nature of a huge problem, and one begins to wonder if this is a subject that is not supposed to be talked about, let alone discussed in language that displays an understanding of the problem.

Why should that be? Everybody knows what incontinence really means, but although most people are content to talk all about their other ailments and proverbial scars, urinary incontinence remains taboo; as well as literally, it is deemed by many to be metaphorically below the belt. Even cancer, for so long the unmentionable disease, is now the subject of discussion in the public forum; it is not yet the case for urinary incontinence. However, it is estimated that approximately two million people suffer from some form of incontinence in the UK alone. Note that this is an approximate estimate because, by definition, there is little information on the subject.

Two important issues follow from the above in the context of medical devices. First, the general lack of communication on this subject appears to extend to the professions because urology is certainly not considered to be a contender when it comes to the glamour of clinical disciplines and to attracting the interests of passing bioengineers. Second, the reference to a lack of self-restraint, although being offensive to those who are incontinent, successfully alludes to the fact that the problems usually lie within the mechanisms that control muscular activity of sphincters; however, most treatment regimes concentrate on minimizing the consequences of this lack of control, rather than optimizing the control.

Essential urology

Using the specific situation of urinary incontinence as an introduction, this article will explore the urological problems that could be better addressed by medical devices. It is usual to consider the urinary system in two halves. In the upper tract, urine is formed by filtration of blood in the kidneys that flows down the tubular ureters. In the lower tract, the urine is received by, and stored in, the bladder, which is then emptied through the urethra at convenient intervals. For the purposes of this article, only the lower tract will be considered. This does not imply that there are no problems with the upper tract and indeed the main work of the urologist is often the maintenance of kidney function. Management of diseases associated with the formation of kidney stones remains a formidable task, although the impact of minimally invasive techniques and associated devices, particularly with lithotripsy, is quite considerable.

The bladder is an easily distensible balloon. As urine is produced, typically at 1 mL per minute, the bladder expands to accommodate this production, normal capacity varying from 300 to 600 mLs. Urine is retained in the bladder as long as the outflow into the urethra is closed. This is achieved by the action of the urethral sphincter. Because the bladder wall is extensible, the pressure in the bladder is normally kept low, typically at less than 15 cm water. The closing pressure of the muscle that constitutes the sphincter is normally between 60 and 80 cm water so that there should be a reasonably large safety margin.

There are three main problems that affect this part of the anatomy. First, the bladder may have a considerably reduced capacity, possibly related to hyperactivity or sensitivity. This is not easy to treat, although surgical augmentation of the bladder involving a segment of the small or large intestine may be employed. In passing it should be noted that total reconstruction of the bladder may be required after resection for malignant disease, a segment of the bowel being used for this purpose. Second, there may be an obstruction to the outflow of the bladder, particularly in relation to the prostate, which may require relief. Third, and most significantly, there may be some dysfunction of the urethral sphincter resulting in the urinary incontinence. This may be associated with chronic and irreversible damage, in which case there is absolutely no control and urine simply passes through the bladder and into the urethra with little or no resistance. More commonly, it is some deficiency in the closure mechanism that causes the sphincter to open under lower than normal pressures. This may mean that patients have to empty their bladder at very frequent intervals or that the sphincter opens unexpectedly when pressure in the bladder is temporarily raised, for example during sneezing or coughing. This so-called stress incontinence is particularly troublesome and is, of course, aggravated by the associated psychological disturbance.

Urological medical device technology

Because so many people suffer from one of the above conditions, it would be logical to assume that a vast effort is being expended in solving these problems. Much has been done, but a search for solutions remains fairly low in R&D priorities and clinical services. At a time when there are materials suitable for use in tissue or organ reconstruction all over the body, the replacement of bladder, ureter, or urethra with prosthetic materials has remained stubbornly resistant to such developments. The relief of chronic obstruction of the bladder outflow is still difficult and although the use of catheters and stents have made some improvements, there is still a long way to go.

It is not surprising, however, that the treatment of urinary incontinence provides most cause for concern. As always when the uses of medical technology are contemplated, the preference for prevention or pharmacological control must be respected. However, if it is assumed that there is no way of preventing such conditions occurring and that pharmacological control of the urethral sphincter is unlikely, it is vital to consider advances in materials technology and device design that could benefit these patients.

Currently, the options are limited to attempts at sphincter-muscle stimulation or augmentation in an extremely small cohort of patients, the long term catheterization of patients with multiple disorders who are severely affected, and the use of collection devices and appliances for the vast majority. However water-absorbing a material may be, there is something inherently wrong with a strategy that serves only to minimize the discomfort of a physiological failure rather than address the real origin.

There are two technical/material issues here. Muscles vary in their power and in their efficiency all over the body, and the medical profession is just coming to terms with the tremendous possibilities in harnessing muscles and redirecting or controlling their behavior. As noted, the basis of the problem of urinary incontinence is the lack of muscular power where it matters and when it matters. There are some implantable electronic stimulators and perhaps these will become more widespread in their application, but at this stage they are interesting curiosities. Elsewhere in the body, functional electrical stimulation is achieving very interesting results and it is uncertain whether all avenues are being explored with regard to possible urological applications. In the treatment of certain cardiovascular deficiencies, much attention is being paid to the transposition of skeletal muscle (specifically the latissimus dorsi) to wrap around part of the heart or aorta and to transform its fast-acting but fatigue susceptible action to the fatigue-resistance, consistent action that is required for cardiac assistance. This has required a significant input of medical technology at the most sophisticated level.[2] It is to be hoped that such interest can be directed towards the movement of unsociable urine as well as fashionable blood.

In defense of all those who have worked for years in the search for materials that are compatible with the urinary tract, the interface between synthetic materials and urine is as complex as any, and the encrustation of urinary catheters and other such devices is a hallmark of bioincompatibility. Urine is a super-saturated solution of minerals and macromolecules in a bacterially-laden aqueous fluid, the intended action of which, it would seem, is to deposit as much of its solutes as possible on any biomaterial that comes near it.

The process of encrustation is complex, but currently it is still unclear what factors control its mechanisms. Surface energy may be modified, and surfaces may be made antibacterial, but considerable materials development is needed if progress is to be made with the successful exploitation of technology in the minimization of encrustation, either through some form of reconstruction or catheterization. The issues involved here include the need to resist bacterial contamination, colonization, and migration associated with foreign materials placed in the urinary system. There have been attempts to use bactericidal coatings on catheters, for example with silver, or to use antibiotics. These are only partially successful solutions, however, because the use of such adjuncts often serves only to alter the nature and balance of the bacterial flora rather than eradicate it entirely.

The so-called biofilm that forms on materials in contact with biological solutions is particularly significant in this area and the control of wettability and surface charge appear sensible options, although again no clear consensus has emerged on the optimal surface conditions to control these events.

Following biofilm formation there is the process of nucleation and growth of crystalline deposits on, and in, the film and a number of options could be explored with respect to these processes.

All of these factors are not necessarily unique to the urinary tract, but they appear together and with greater severity. This is clearly a major factor in explaining why there is still a long way to go in resolving these problems.

The future

If it is true that professional interests in medical conditions vary according to the risk of being affected personally, there should be a tremendous activity in the search for better treatment modalities for incontinence. But that large population group has not led to any major advances in the treatment of the lower urinary track nor an obvious investment in research. Indeed, with oversight of a number of medical funding bodies, this author has seen minimal interest in this type of development. Perhaps it is time to be more constructive and proactive in the search for a better quality of life for those who suffer in this way.

References

1. "Dictionary of the English Language," Longman, London (1984).
2. L. Callewaert et al., "Programmable Implantable Device for Investigating the Adaptive Response of Skeletal Muscle to Chronic Stimulation," Medical & Biological Engineering and Computing, 29,548 (1991)