Over the past two decades there have been several attempts to develop an artificial bladder. To a large extent appropriate results for the use of alloplastic materials have been mentioned in lectures, but have not been published so far. The reason for this was, on the one hand, the lack of development of suitable materials, and on the other a lack of ideas for realistic, active concepts.

As a clinical user of bladder substitute systems, urology supports at present, operative processes in which the use of a separated segment of intestine play the main role.

Clinical indications for the use of bladder substitutes are shrunken bladders as a result of infection or radiation damage, or in seldom cases of congenital bladder malformation. The main areas for substitute bladders are tumours of the bladder.

There are approximately 18,000 cases of tumours of the bladder each year in Germany alone. Approximately double so many men are affected (12,500 cases) as women (5,100 cases). The number of women affected is rising dramatically, however, most probably due to the fact that the number of women smokers is becoming larger.

The radical cystectomy in women, i.e., a continent urinary diversion as a substitute for their own bladder presents a challenge because the female does not have the sphincter muscle that the male has. The bladder is the 4th most frequent localisation of cancer in men, and the 8th most frequent in women.

The frequency of the urothel carcinoma in Europe in 1990 was 66,518 (men: 52,213, women: 14,305), corresponding to a frequency of 28,5/100,000 in men and 5,2/100,000 in women. The highest rate of males was recorded in Italy and Spain, whereas in Great Britain and Sweden the highest rate of females was recorded. The lowest rate for men was in Ireland and for women in Luxembourg. In USA approximately 55,000 new cases are recorded each year.

In our part of the world all themes associated with urology are tabu, whereas in Anglo-American countries the scientific and social aspects are openly discussed and information is given.

Articles for incontinence are often sold in Germany under the counter, but in USA and Canada one comes across products in advertising and on the internet and the discussion of their use and merits is regarded as one of the most normal things in the world.

Themes of research and development are often categorized according to their social status.

It was a message in Canadian internet that „Incontinence may destroy your life“, accompanied by a disturbing picture, that stimulated us to research openly and intensively, against the general tabus in society and to research for a solution.
In the majority of cases the substitute bladder entails the integration of parts of the large and small intestine in order to allow for the development of a urinary reservoir and for urinary diversion. So far there is no alternative construction, so that these variable intestine systems are considered the "golden standard". These processes, however, have considerable possibilities of complication and a high rate of follow-up problems.

An operative urinary diversion, uses considerable parts of the intestine that are cut off from the natural intestinal continuity, or modify the configuration of the intestine. Considering the burden of the operation on the patient, the post-operative recovery and the morbidity rate as a result of the process, the use of the artificial substitute bladder instead of the above methods could have considerable advantages.

Purely biological substitute systems, e.g. the xenograft transplants of the pigs' bladder, or that of the ape, or rather the transplantation of human or animal "acellular matrix", are hardly likely to be realised clinically because of the numerous, in particular, immunological and functional problems. According to those acting in this field, it is not certain if a clinical substitute will be possible.

A new realistic conversion for the development of an alloplastic substitute bladder that operates when it is adapted to the physiology gains, on the one hand, from the availability of new biocompatible materials, and on the other hand from the miniaturising successes with actuators (pumps, closing and locking systems) as well as efficient TET, i.e. transcutaneous energy-transfer and supply systems.

The medical wishes and needs of such an artificial system are easily defined: an alloplastic semi-elastic capsule, that is energetically self-sufficient, telemetry and able to be coded and controlled externally. It must also be individually adaptable as a module and can be implanted as a whole.

This may be a short definition, but it represents an enormous technical challenge. Ten years of interdisciplinary, intensive research and development have taken place with the financial support of the Ministry for Education and Research and with support from the industry, in particular from the owner of the ESKA Holding, Dr. Hans Grundei.

What makes the concept of the implant geometrically, electromechanically and electronically so unique?

All the actuating and energy-technical parts have to be integrated into the hard part of the capsule of this new product, i.e., an active technical sub-system may not be found outside the capsule. Neither a supply connection nor any other system component may protrude through the outer skin. The system is not visible after the operation. The only elements that are implanted subcutaneously are: an energy transfer element necessary for the control of transmission, an information system for the amount in the bladder, and an individually codable chip for the commencement of the emptying process.

The only sign of the presence of an artificial device in the abdomen and pelvis is the charging and control display that is attached to a belt which must be applied manually. There are already technical solutions for the signal and transfer element used elsewhere in the medical-technical field of substitute organs.

However, a 1:1 takeover of such products is not possible in particular because of the special urological demands on such devices. These
Urinary Diversion System

Fig. 9: Sequential scheme for a typical cycle of emptying and filling, and the electric supply of the implanted artificial bladder.
include: high density of energy, permissible and compatible frequencies, coding and dislocation corrections.

The solutions to the developments – already begun in 1992 in the above-mentioned fields – are superior to the American concepts.

Success in the in vivo functional test

The idea of an implantable capsule was developed in 1995 and 1996 as a result of integration and adaption work on corpses and segments of corpses. This work took place in the Institute of Pathology and Anatomy of the MUL in many iterative steps and it produced many valuable impulses. Numerous hollow cavities were developed, manually injected and spun and optimized again and again (see fig. 2).

It caused great consternation when both doctors and technicians realised that although after much hard work, the forms that had been developed were well-suited to the topology of corpses but not at all suitable for implantation in the living organism. All our work was futile, and we, including our medical partner, Prof. Dr. Dieter Jocham, Director of the Urology Clinic of the University of Lübeck, were thrown back many months. Pioneer work can lead down painfully wrong tracks.

The really decisive sophistication, and with it the new lead in invention occurred with the geometric definition. This new position was produced out of biocompatible material with a functional pattern, and fitted into the living body during an operation (fig. 1). The result is reported in the German patent registration No. DE 199 12 472.8 and in the international registration No. WO 00/56246.

These include the details of a main function, by means of 6th grade polynomials described in their optimum form.

The innovative process results from the fact that during an operation, in a first step a dummy (made up of three different sections) has to be fitted optimally. The dummy can be re-used after sterilisation. In a second phase the real implant, which has been formed from selected modules is fitted. This process is easier for the patient and requires less resources.

Work on the detrusor function

The assessment of the mechanical detrusor process in order to empty an artificial bladder can be illustrated by a spindle with the aid of compressing bellows in time-lapse process.

The experiment using spherical precision spindles and bellows made out of polyurethane 1303 ended after approximately 88,000 cycles. This meant that the aim of approximately 85,000 cycles was more than reached. This represents a duration of use of approximately 15 years (see fig. 4).

The so-called U8/U4 experiments are in automatic continuous operation. Polyurethanes, silicones, pumps and valves using artificial urine, and natural human urine, kept at body temperature are tested (fig. 5).

Further emptying technologies, in particular with regard to efficiency, safety and ergonomy were tested and compared within the research work supported by the BMBF (fig. 6).
that was previously closed for safety is released. After several cycles of miction, e.g. after two days, especially when a visit to the Oktoberfest was included, the rundown batteries have to be recharged. The capacity of the batteries can be read on the LED display.

The next step is to establish proof of the prototype’s ability to function in animals and in clinical trials. We have already had many inquiries about, and requests for the artificial bladder. When the trials are successful these people can be helped.

Further technical experiment installations

It would be possible to add to the list of successful experiments. The following two results are particularly interesting:

1. Polyurethane bellows: mechanical, electric and electronic components of the pneumatic experimental installation, including control have reached the number of 5,2 mio. cycles with no remarkable damages (see fig. 8). The additional important insight gained by this, concerning the form and folds, and employing diverse polyurethanes, guarantees the success of the product.

2. The FHM and the MUL developed three movement tables for simulation of movement in the urological area. These all function in the same manner, but are technically different so that they represent the possibilities of speed and movement in the pelvis. These movement tables have been developed according to the investigations of the ETH Zurich and the corresponding algorithms (see our patent registration No. DE 199 12 473.6). These so-called hip-movement tests also covered the question of the artificial aging of the materials by means of thermic over-heating (see fig. 7).

In order to understand the function of the implanted substitute bladder we should imagine in fig. 9 that the tissue is transparent and that one can only see the pelvis and the spine. When the contents of the bladder have reached a certain level there is a vibratory alarm, that can also be acoustic or optical by choice. Having been to the toilet the patient gives his own personal code into the device.

The recharged batteries (shown green) supply the energy for the control, for the pump function and for the use of the valves. The emptying process occurs quite normally as with the natural bladder, either standing or sitting. When the bladder is completely empty the antireflux valve

Contact:

Prof. H. Wassermann

Munich University of Applied Sciences
Faculty of Elektrotechnik und Informationstechnik
Lothstr. 34
D-80335 München
Germany
Tel. +49-(0)89/1265-2903
Fax +49-(0)89/1265-2930
email: wassermann@ee.fhm.edu