Polyurethane Paranoia Flexible Friend or Deadly Foe?
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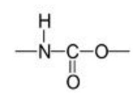
One of the most versatile of all materials used in medical devices has been under a cloud of suspicion for a few years, because of concerns about degradability and carcinogenicity. There is considerable confusion about the exact nature of polyurethanes and the extent of the problem. This article attempts to explain the essentials of polyurethane chemistry and put these concerns into perspective.

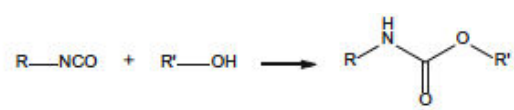
In the late 1930s, Carothers was developing at Du Pont the polyamides, or nylons, that would threaten to dominate the newly developing technologies of polymers and synthetic textiles. Meanwhile, Otto Bayer at I.G. Farbenindustrie in Germany came upon the urethanes, which soon became the basis for a whole new polyurethane business that would compete with the nylon. Little did Du Pont or Bayer realize then that approximately fifty years later these companies and materials would be at the forefront of controversies in the medical area. Leaving aside the Du Pont question for the moment, the current situation with polyurethanes, which has arisen as much from subjective speculation as objective technology, deserves comment. This article attempts to clarify the nature of polyurethanes and what they can and cannot do for the medical device technologist.

The nature of polyurethanes
One of the problems with polyurethane is that it is not one material but many. This is also one of its principal advantages, because the molecular structure can often be designer-made according to the desired properties.

Polyurethanes are polymers, the only mandatory distinguishing feature of which is the presence of a urethane linkage (see Formula 1).



Although there are many ways in which the urethane structure can be synthesized, it is easiest to consider it as the product of the interaction between an isocyanate and an alcohol, such as in Formula 2.



The versatility arises because

- there are many different kinds of isocyanate and alcohol that can be used in the reaction; that is, there are a wide range of possibilities for Rand R'
- the proportions of each constituent can be changed
- there are other constituents that can be added to modify the structures.

A few of the more important variables are as follows. If Rand R' are monofunctional, that is, able to bond to only one other group, then the urethane molecule would be small and simple. If they are difunctional, they would each be able to bond to something else and would form the basis of larger molecules, that is, linear polymers. If they are multifunctional, then each urethane group would not only be able to form linear polymers, but multidirectional polymers, or cross-linked polymers. There is, therefore, the possibility of urethane liquids corresponding to the first of these functional types; flexible polymers to the second type; and hard rigid cross-linked materials, such as those that form the basis of polyurethane paints and varnishes to the third type. Indeed, it is possible to vary the functionality to have some parts difunctional and some parts multifunctional so that a whole series of polymers of different flexibility or hardnesses can be produced.

Common difunctional precursors are the diisocyanates such as toluene diisocyanate (TDI) and 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. 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.