THE INTERNATIONAL STANDARDS ORGANIZATION

TECHNICAL COMMITTEE ON SURGICAL IMPLANTS

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INTRODUCTION

Implants have been defined as "objects or devices which are surgically placed in the body either temporarily or permanently for diagnostic or therapeutic purposes". This is indeed a broad definition. Practically every surgical procedure thus involves the use of an implant.

There is need for surgical implant standards and assurance of their quality control. The achievements of ISO's technical committee (TC150) on Implants for Surgery, are described.

SURGICAL IMPLANTS

Recent innovations in almost every branch of surgery have been accompanied by, and often were dependent upon, remarkable new materials and composites derived from the fields of metallurgy, chemistry, textiles and bio-ceramics. Processed materials of biological origin must also be included. The surgeon, who is untrained in the materials and engineering sciences, is justifiably bewildered by the confusion, particularly in the polymer field, between chemical and generic names. He is unaware of the different properties engendered by variations in chemical formulation, molecular weight and methods of fabrication and sterilization. He may be unaware that "nylon" is a trade name for polyamide and that there are many variations in type. Or that a cobalt-chromium or titanium alloy may have excellent qualities in tension or bending but is less satisfactory in tension, torsion and bending--the typical forces that exist when inserting a bone screw. He may not know, for instance, that polyamides (such as nylon) lose tensile strength in the tissues, and incorrect grades will degrade. PTFE (Teflon) is hystiocytic when abraded. Dissimilar metals, if both implanted, produce an electromotive force and reaction. If incorrect catheter materials are selected for intravascular and intracardiac
use, the result may be embolization due to fragments of material, or cardiac rupture. Often he is unversed in the formulation and composition, details of fabrication, effects of sterilization and of in-service conditions on these materials, and in other important technological details. He thus accepts implants in blind faith.

Implants vary in the service expected of them, and this also must be taken into consideration. For instance a bone plate and screws have served their purpose once the fracture has united, whereas the components of a hip replacement or vascular graft must last the life-span of the patient. Should infection occur then the whole problem of implant compatibility and performance is altered, as is the success of the exercise.

Surgical implants form only a proportion of expenditure compared to the 1984 world-wide assessment of $90 billion turnover in the pharmaceutical industry, but this proportion is not minor. Often manufacturers of implants also make instruments as a further profitable outlet. Ancillary items, such as disposable drapes, syringes, drains, catheters, bandages, transfusion sets, telemetric devices and many others, add to commercial potential.

One could quote figures such as over 500 000 total joint replacements per year worldwide or 250 000 cardiac pacemakers, or that an annual market for internally applied surgical staples in Western countries could be $220 million, in 46 million operations and external skin staples $200 million. Or that basic components and cements in an average total hip joint replacement may vary between $250 to $1000. Or that country X spends 5.6% of its gross national product on health care, and country Y only 2%. Trade figures are not always accurate in detail. Country Z may import $50 million of surgical goods, but these could include $10 million of bedpans and $30 million of bandages. Detailed breakdowns of imports and exports are difficult to obtain, but the potential volume of the implant market is enormous, particularly with the increasing industrialization of developing countries.

MATERIALS

The use of stainless-steel, chromium-cobalt and titanium alloys for orthopaedic implants is a well-established major industry. Composition and mechanical properties continue to improve in quality. These contain varying amounts of Ni and Cr as dictated by properties required. Ceramics and carbon composites also have application.

The four dominant medical polymers are polyvinyl chloride, polycarbonates, polyesters and methyl methacrylate, but growing use of fluoro polymers, cellulosic materials and silicone rubbers is increasing, as is the use of composites. Ultra high molecular weight polyethylene has proved an essential component in joint prostheses.