Production and Use of Biomedical Devices – Its Relevance to India

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Abstract – *To achieve 'Health for All by 2000 AD.' India needs massive inputs of science and technology. Rupees 60,000 millions worth of medical supplies will be needed in India by 2000 AD. The supplies cover biomedical devices made from all classes of materials using precision light engineering techniques. Indian industry is wary of entering this field because of low perceived demand, unfair competition from imports, need for a strict Good Manufacturing Practice, and unrestricted availability of low cost, poor quality 'look-alikes'. Education of manufacturers and users, enactment of statutes regulating the making and use of these devices could be the answer.*

INTRODUCTION

India has declared its intention of achieving the WHO goal of 'Health for All by 2000 AD'. With a population close on 850 million, and only only about 60,000 hospital beds, India will have to go in for a massive programme of Science and Technology inputs into health care delivery if the goal of universal health has to become anything more than a mere slogan.

Much of modern health care delivery depends directly or indirectly on engineering. In specialised areas like cardiology, nephrology, and neurology, the diagnosis and treatment of diseases would be impossible without the use of advanced electromedical equipment for endoscopy, angiography, EEG, ECG, ultrasound imaging, and many others. Even recent advances in science and technology like ceramic superconductors are being pressed into service for health care systems!

The entire field of biomedical technology encompassing (a) biomaterials, (b) medical instrumentation, and (c) biomedical engineering, is usually ignored or relegated to the background whenever national priorities are being set up. There are two major reasons for this:

- There is a lack of hard data on the needs in this area, and
- The total tonnage requirement is perceived to be very small when compared to the needs in other key sectors.

Unfortunately, it is not often realised that the social significance, the improvement in the quality of life, and better health care delivery to larger numbers of people have a value far greater than the mere money value. When the problem is studied closely, even the money value is seen to be considerable.

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A survey carried out by Sree Chitra Tirunal Institute for Medical Sciences and Technology in 1985 indicated that a substantial current consumption of biomedical devices with a large annual growth rate of 15 to 20 per cent existed.

Most of this demand is met through import of biomedical devices at a high cost. The devices are available only to a small number of patients in select hospitals while the rest of the requirement remains unfulfilled and suppressed. Today, there is probably only one biomedical device of an acceptable international standard being made in the country, that too subsequent to 1985.

This paper takes an overview of the country's requirements for biomaterials and devices, the problems facing manufacturers and strategies relevant to India.

Consumption in India

There is a lack of awareness in this country regarding the importance of biomaterials and devices in health care delivery. This is because there is very little data available on the consumption of biomaterials in India. There is a general feeling that the consumption is too small for serious consideration during planning.

Sree Chitra Tirunal Institute for Medical Sciences and Technology conducted a pilot survey in 1985 to establish some figures on the consumption of biomedical devices. This survey indicated that the term annual consumption was of Rs. 3,500 millions worth of medical supplies in India with an annual growth rate of 15 to 20 per cent. This would represent a gross demand of Rs. 35,000 to 60,000 millions by 2000 A.D. These figures exclude the entire field of electromedical instrumentation and the requirements of the armed forces.

IMPLANTS CONSUMPTION IN INDIA
Results from 1985 Survey
Unpublished Data

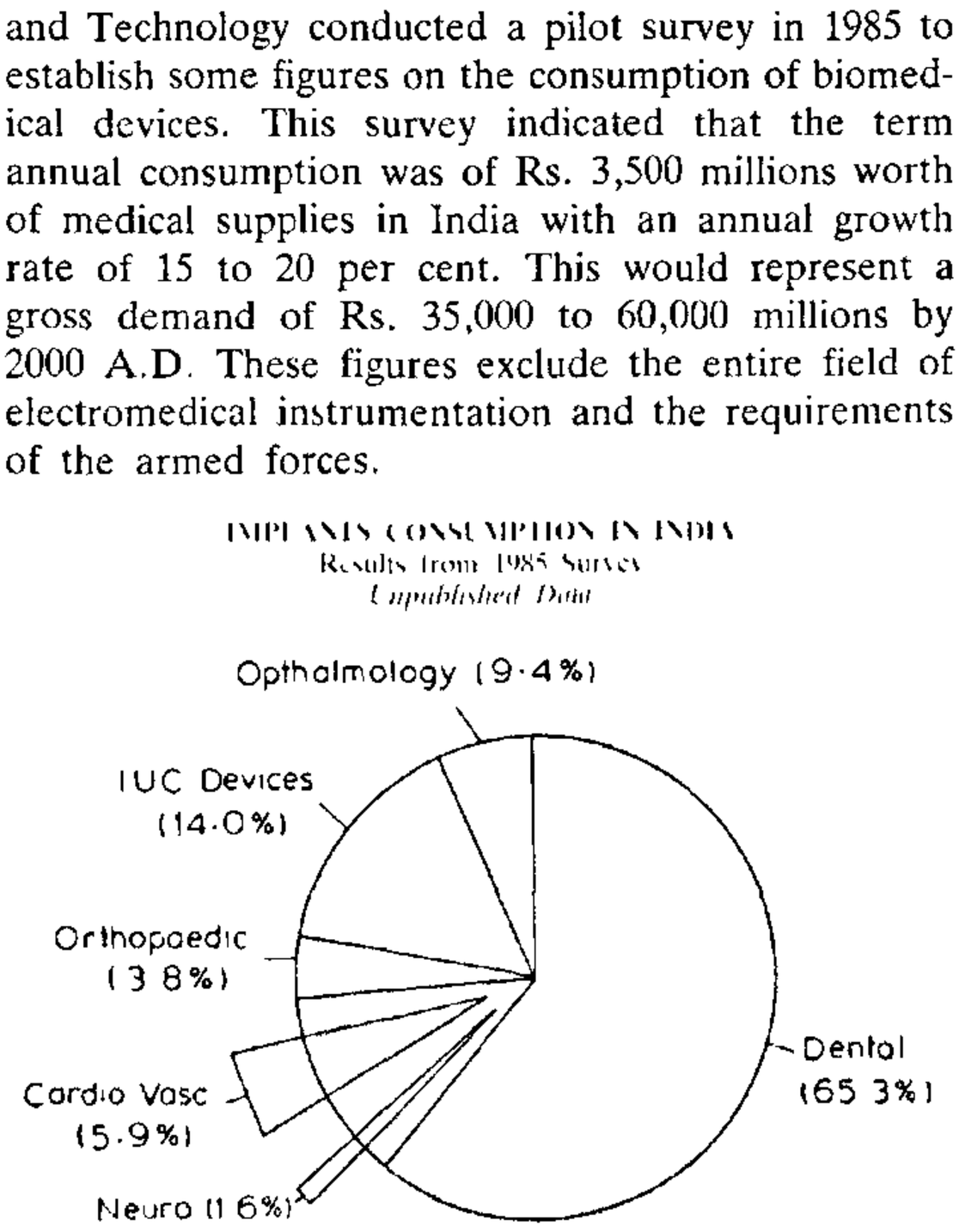

FIGURE 1 Demand for Implantable Devices.

CRITICAL USE EXTRA CORPOREAL DEVICES
Results from 1985 Survey

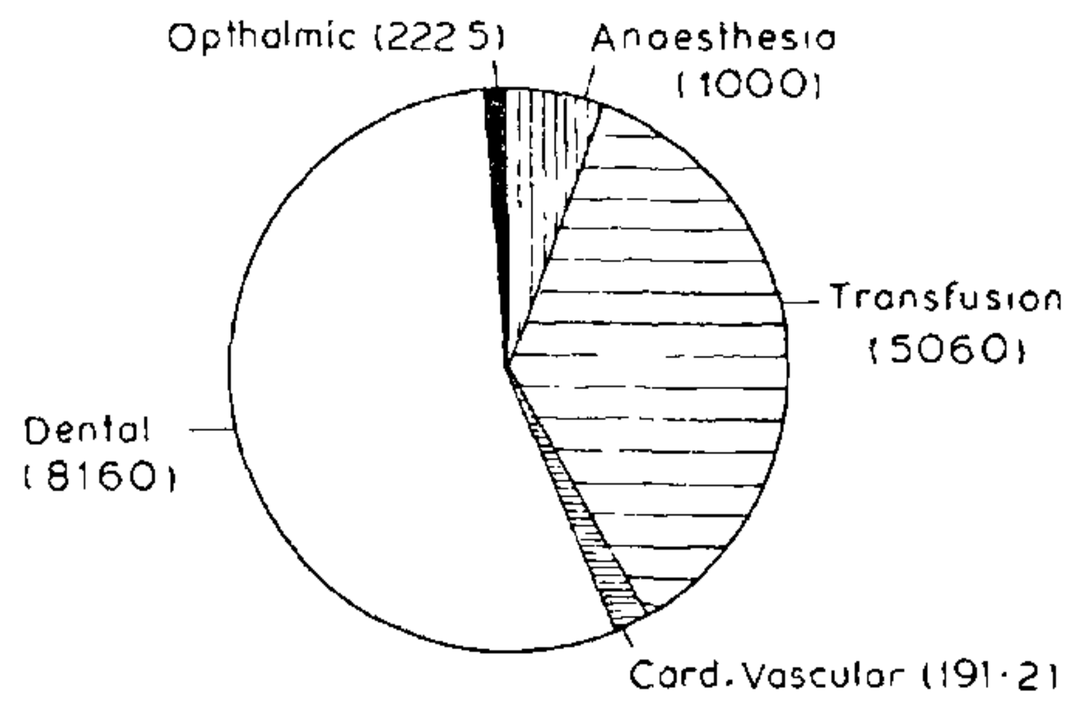

FIGURE 2 Demand for Extra-Corporeal Devices.

Figure 1 gives the values for implantable devices while Figure 2 gives those for extra-corporeal devices. These cover a whole gamut of materials with representation from metals, ceramics, polymers, and composites.

The criteria for suitability of a material for biomedical applications vary with the severity of the intended use. Implantable materials have to pass the most stringent tests while non-contact ones like components of medical equipments need mainly to pass the engineering specifications.

Table 1 gives a list of medical applications of materials. The list is arranged in descending order of stringency with implantables at the top and non-contact applications as components of medical equipments at the end.

TABLE 1. Medical Applications of Biomaterials

Application
• Implantables
• Disposables
• Hospital use articles
• Medical packaging
• Components of medical equipments

Table 2 gives a list of forms or shapes in which materials are used in medicine. It must be noted that different classes of materials (e.g. metals, ceramics, polymers) could be used in each shape (e.g. sheet, fabric, etc).

TABLE 2. Shapes of Biomaterials

Forms	Forms
1. Fibres, fabrics	6. Cements
2. Films	7. Coatings
3. Membranes	8. Moulded shapes
4. Tubes	9. Containers
5. Powders	

What distinguishes biomaterials from others is the requirement of biocompatibility. Biocompatibility relates to two issues, materials-tissue interaction, and biodegradation. Table 3 covers these criteria. Table 4 sets out tests to be passed by biomaterials. Not all these tests are valid for all applications.

TABLE 3 Biocompatibility Requirements

Medical-tissue Interactions

Tissue Damage
- Acute damage
- Chronic damage

Biodegradation of Materials
- Corrosion and failure
- Fatigue failure
- Loss of strength

TABLE 4. Evaluation of Biocompatibility

***In Vitro* Procedures**
- Tissue culture
- Inhibition of cell growth
- Haemolysis assay

***In Vivo* Procedures**
- Intra-dermal irritation test
- Acute systemic toxicity test
- Intra muscular implantation test
- Histo-pathological tests of implantation site

There is a wide scope for the use of biomaterials for therapy. There is hardly any disease or any vital organ whose repair has not benefited from materials.

However, materials are rarely used as such in medicine. They are fabricated as devices of various kinds to suit specific applications. It is in this that problems arise.

BIOMEDICAL DEVICES

Biomedical Devices and Regulations

- High tech, low volume products like artificial heart valves and heart assist devices.
- Medium tech, medium to large volume products like oxygenators, hydrocephalus shunts, blood bags, and angiography catheters.
- Low tech high volume products like urine bags, various tubings and catheters, giving sets, and fluids.

More than 90 per cent of the demand for biomedical devices in the country relate to the low tech and medium tech devices. These include central and orthodontic devices, blood bags, disposables for extra-corporeal circulation, and various forms of catheters, giving sets and fluids.

The interesting point about the manufacture of most of these devices is that the technology is one of any precision light engineering production. The materials used are drawn from virtually every source used by existing engineering manufacturing units.

It is then a matter for enquiry why there is no local manufacture of biomedical devices in India with its strong infrastructure for precision light engineering. The reason lies in the need for a strictly administered Good Manufacturing Practice (GMP).

Just as biocompatibility is the common criterion for materials intended for medical applications, GMP is the common requirement for biomedical devices. GMP represents an elaborate code of manufacturing conduct which encompasses the production environment, worker health and hygiene, quality control and assurance of the products, and mandatory testing for biological safety. Packaging and labelling, failure analysis of defective products, and the procedure for the recall of failed products are also within the purview of GMP.

In all developed countries GMP is enforceable by law. Considerable checks and balances are provided to ensure that the patient and the clinicians have the guarantee that the devices used are tested and safe. Mechanisms exist for forcing the recall of defective batches.

Unfortunately, this is not true in India. There is no legislation regulating the manufacture and use of biomedical devices. Nor are the manufacturers too keen that such regulations should be passed.

It is essential that India enacts a suitable 'Biomedical Devices Act' soon, as developed countries have done. This would ensure that only products conforming to international standards are made following applicable GMP. Unscrupulous manufacturers will be prevented from marketing spurious, untested, 'look-alike' products in unfair competition with reputed manufacturers.

The lack of regulations, paucity of raw materials, and unrestricted import of finished products all conspire to daunt an intending manufacturer of biomedical devices.

PROBLEMS OF PRODUCTION

The problems facing an Indian manufacturer of biomedical devices are many.

Most of the financing institutions are unaware of the social and commercial importance of indigenous manufacture of medical devices. They are reluctant to fund what are perceived as high-risk-low-return projects.

Because of the high cost of imports the existing demand for biomedical devices is low, at least for the medium and high tech products. At the same time the market for the lower end disposables is vitiated by the unbridled manufacture of devices without any concern for GMP.

The rate of growth of the market for health care products is decreasing in the developed countries, while it is increasing faster in the developing nations. This has led to a situation where the West has to look to the developing countries for a market for its wares. To forestall indigenous competition many foreign manufacturers resort to dumping and other unfair trade practices. Because of life-saving implications the Indian government is hesitant to impose restrictions on import without a proven indigenous manufacturing base.

The Indian clinical community is averse to using devices of Indian manufacturers because of uncertain standards and lack of quality assurance.

The market is flooded with non-standard Indian 'look-alike' products which are sold at very low prices.

Both the manufacturers and the users are unfamiliar with the concept of GMP. This leads to a lack of accountability and even traceability at all levels.

The major constraint appears to be the low perceived demand. The single largest contributing factor for this is probably the developing world penchant for re-use. Even strictly disposable devices like fluid administration sets, stopcocks, tubings, and cathcters are re-used. What is not fully understood by the bulk of the Indian health care machinery, starting from the clinicians going down to the nursing staff, is that there is a considerable cost for such re-use. These costs obviously include the direct costs involved in cleaning and resterilising. The greater costs concern the extended hospital stay, and charges for the treatment of infections engendered by devices inadequately prepared for re-use.

CONCLUSION

There appears to be a large potential for the indigenous production of health care devices. But the Indian industry seems to be unwilling to take to this area because of imports, problems of GMP, and poor present demand.

There is a growing awareness that biomedical devices are essential to achieve universal health. The growing market in developing countries is also seen as an export potential.

Biomedical devices find use in various areas from non-contact applications in equipments, to critical implanted active devices.

They are made from virtually all categories of materials with the additional requirement of bio-compatibility. The devices have to be made using appropriate GMP. They have to conform to the standards set by both the country of origin and the country of consumption.

There appears to be considerable ignorance even in the user community regarding GMP, quality assurance, standards, and problems in re-use. This leads to the manufacture of sub-standard products which compete unfairly with good quality products. This is because implementation of standards in India is largely voluntary.

The following approach can ensure the proper production and use of biomedical devices:

- Enacting and enforcing regulations controlling the manufacture and use of devices. These should also cover the conduct of controlled clinical trials.
- Setting up internationally accepted standards for the devices. These would include performance evaluation protocols.
- Establishing norms for the Good Manufacturing Practice applicable to each category of devices.
- Convincing the manufacturers through user response, and academic form that all can win only if everyone conforms to standards.
- Convincing the users through an awareness programme by the enforcing agency, and manufacturers committed to GMP that the Indian alternative should always be chosen provided that internationally accepted production and evaluation protocols have been followed.

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