e. Quality control and testing
f. Marketing

2. Considerable uncertainty surrounds the business of gauging market size and reception for a new product.

3. However well an object sells, the field of prosthetics and orthotics can hardly be said to constitute a mass market of sizable proportions.

4. Experience has repeatedly shown that it takes three years to achieve a profitable volume of sales once a new product is introduced.

The result of these facts is that the manufacturers of items for use in the prosthetic and orthotic market are confronted with the need to make sizable initial investments for a rather small market that is oftentimes slow to adopt new products of even the greatest merit. Considerable uncertainty surrounds the decision to make the investment and it can take many years for a return on the investment to be realized and the decision to be vindicated. Given these facts, it is understandable that manufacturers differ from developers and their backers about the utility and acceptability of many developments, and that they are slower to adopt new products than others might wish.

Flexible Prosthetic Socket Techniques

H.R. Lehneis, Ph.D., CPO*, Don Sung Chu, M.D.*, Howard Adelglass, M.D.*

The continuous development and availability of new materials of various kinds, e.g., elastomers, copolymer thermoplastics, and composite materials have brought a potentially revolutionary development in the design, configuration, and fitting principles of prosthetic sockets, especially for above-knee prostheses. All of this may result in greater patient comfort, physiological, and psychological advantages.

Improvements in socket comfort with concomitant physiological and psychological benefits are not only due to the materials themselves, but rather, the inherent characteristics of the various materials used permit socket configurations heretofore not possible. For example, socket fenestrations over selected or entire stump surface areas are now possible. The desirability and principle of permitting greater flexibility over muscular areas than is possible in a rigid, laminated socket were appreciated more than 25 years[1] ago in the fitting and design of the "Flexicage" socket[2] which consisted of nylon cords strung between the proximal brim and the distal end of the socket. McCollough, et. al.,[3] as early as 1968, attempted fenestrations over selected socket areas. These attempts, however, were not generally successful because of the potential and real problems with window edema and the properties of the material used. These problems now have been overcome through the availability of materials which can be used as elastic or semi-elastic inserts, preventing window edema, yet permitting removal of the outer rigid socket shell in selected areas.[4,5]

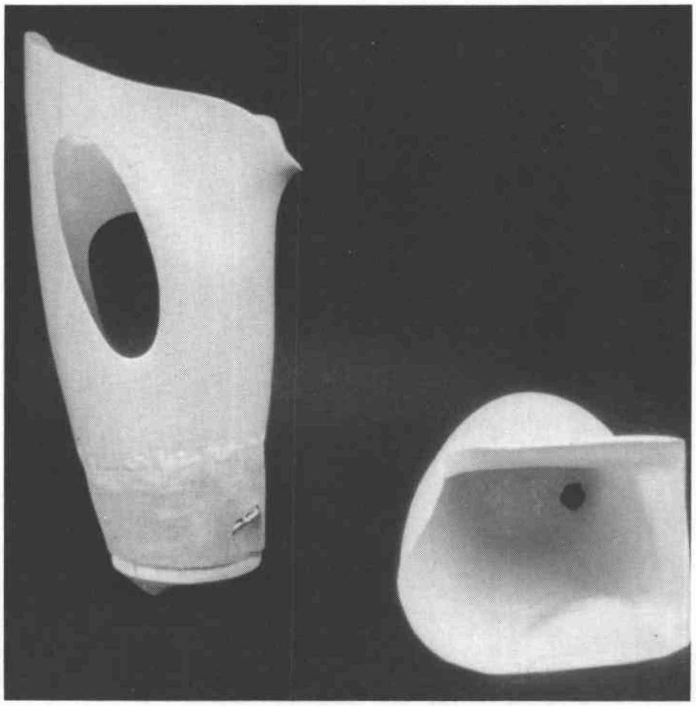

Figure 1.

Below are described several approaches allowing flexible or semi-flexible stump containment, while maintaining the essential biomechanical characteristics required for interface stability to transfer body weight through the prosthesis to the ground, and for dynamic and safe control of the prosthesis.

Two systems are curently used at the Institute of Rehabilitation Medicine at NYU Medical Center (IRM-NYU) to provide the characteristics described above. The first system consists of an inner socket laminated of Perlon fiber and silicone elastomer contained in a rigid plastic laminated socket (Figure 1). The laminated silicone elastomer has nearly perfect memory and permits fenestrations of the rigid outer socket over the posterior area (Figure 2), rectus femoris (Figure 3) and the adductor group, without causing window edema. This design permits greater muscle expansion than the designs described below because of the elasticity of the silicone material. It also provides enhanced sensory feedback, particularly when sitting, i.e., the patient is able to feel the surface of the chair or seat. The soft liner is also a boon to improved comfort, particularly in geriatric amputees and those with a history of general socket discomfort.

The second design utilized at IRM-NYU is a Surlyn™ inner socket (Figure 4) which permits removal of even more of the hard outer laminated socket (Figure 5). The reason larger areas of the hard socket can be removed is the lesser flexibility of Surlyn™. Thus, more rigid material can be eliminated without compromising the integrity of known biomechanical principles (Figure 6).

A more recent design developed in Iceland and further refined in Sweden and at New York University, known as the ISNY socket, consists of a medical rigid frame only, leaving the rest of the polyethylene socket semi-flexible.

For below knee amputations, similar systems have been developed at IRM-NYU and in Belgium by Van Rolleghm

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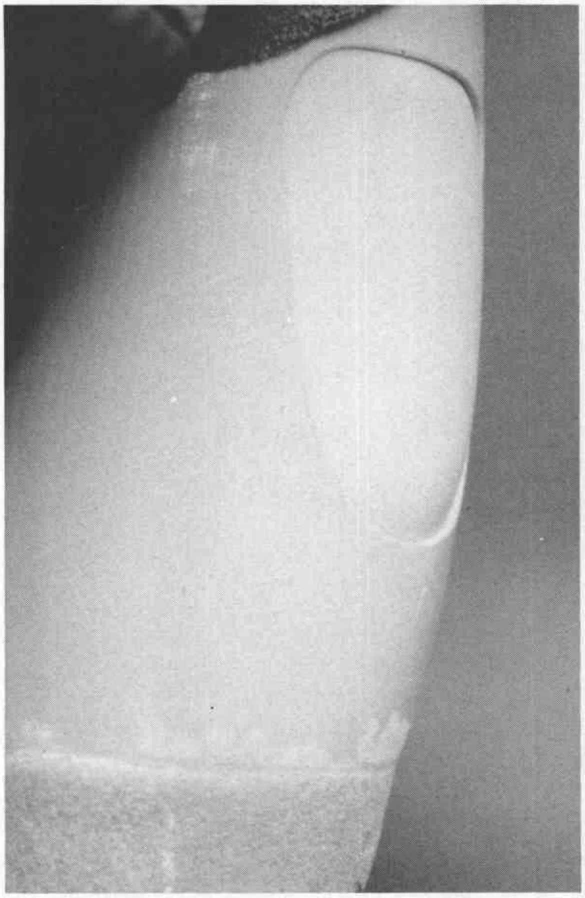

Figure 2.

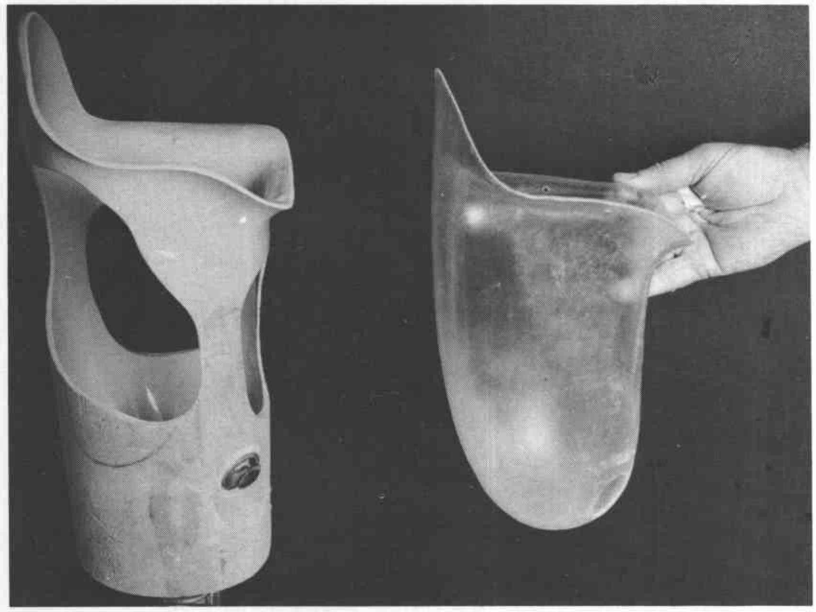

Figure 4.

of CEBELOR.[6] In the IRM-NYU system, a Surlyn™ inner socket permits removal of material in the outer laminated socket over bony or pressure sensitive areas (Figure 7). This permits easy inspection of these areas and ease of adjustment by heating the inner socket to further relieve painful areas.

The CEBELOR consists of a silicone laminated soft socket insert for the SP-SC below-knee prosthesis. Thus, it is self-suspending, provides improved comfort, and permits selected fenestration over pressure sensitive

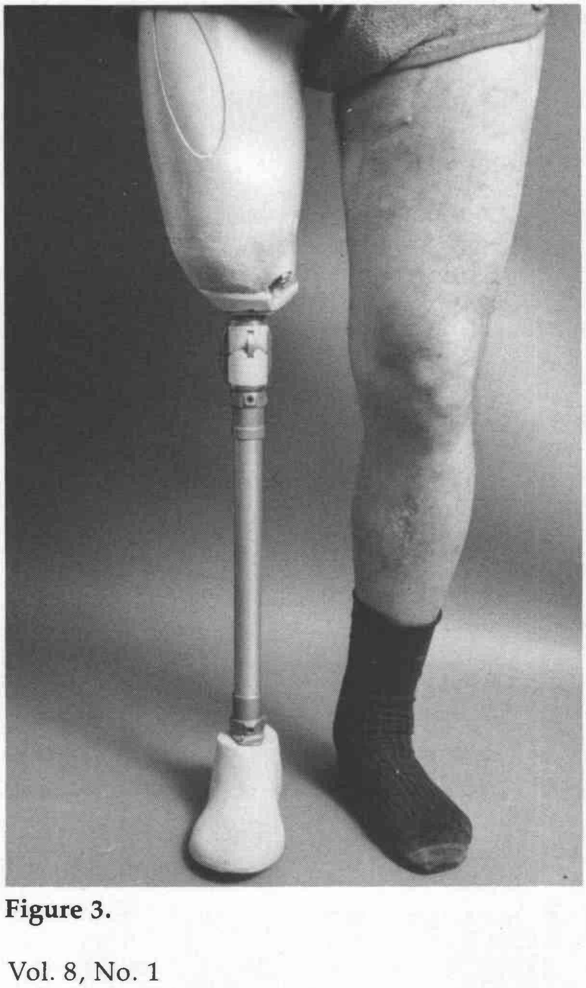

Figure 3.

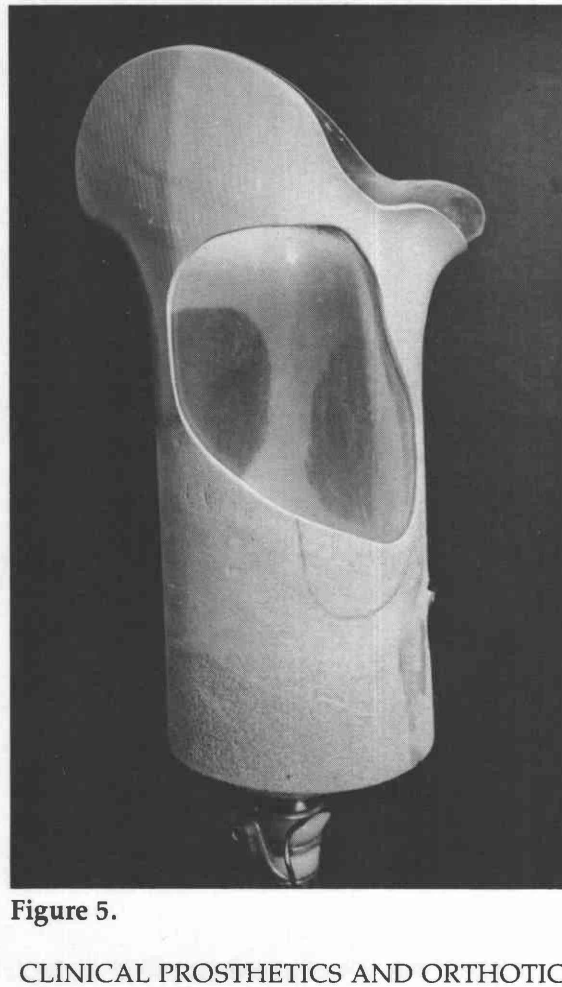

Figure 5.

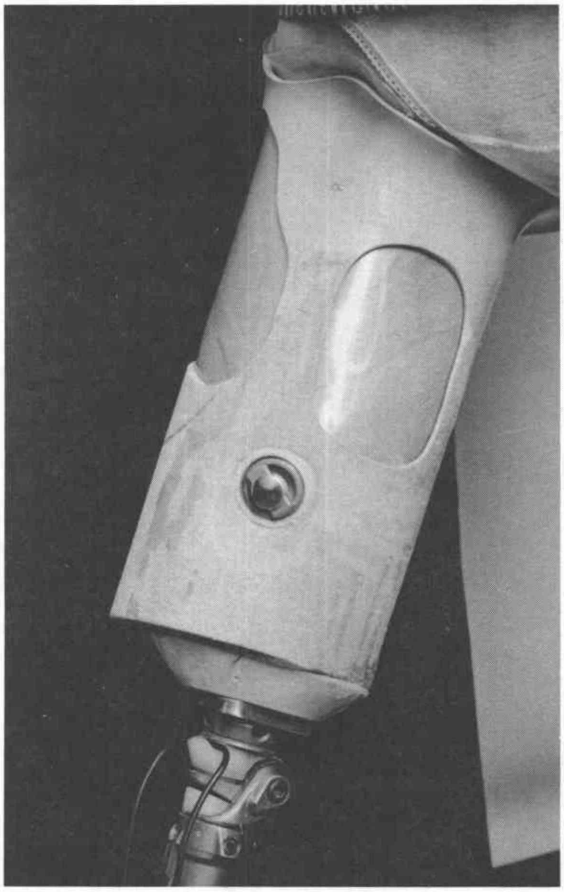

Figure 6.

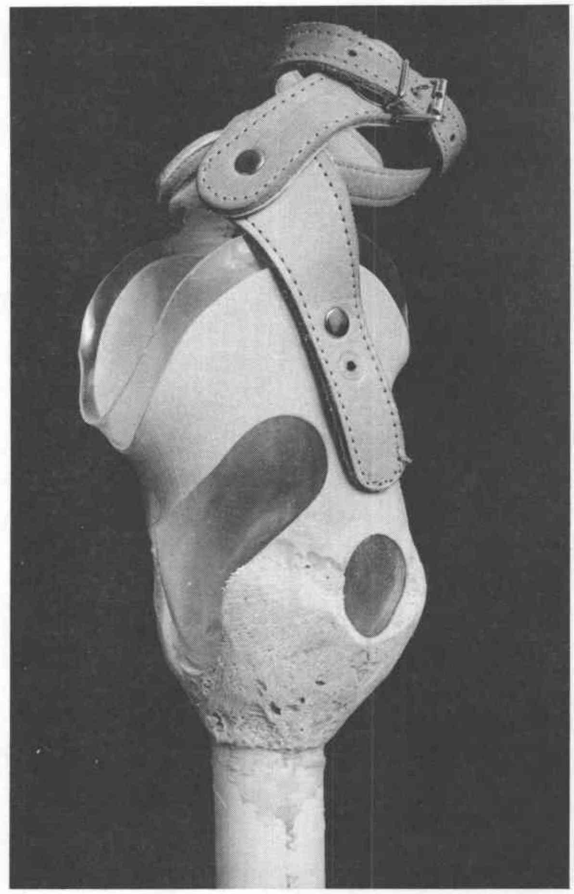

Figure 7.

areas, e.g., head of the fibula, distal end of the tibia. To prevent slippage and rotation of the inner silicone socket, distal and posterior plugs are laminated as an integral part of the soft socket to fit into female counterparts in the plastic laminated socket.

Summary

While the various systems described above employ different materials and socket configurations, certain characteristics are common to all systems. These are: improved muscle physiology due to greater socket flexibility; enhanced sensory feedback; quicker heat dissipation due to thinness of the flexible stump containment material; and improved comfort, especially in the IRM-NYU and CEBELOR systems with the soft silicone liner.

All these are important improvements which were made possible through the use of flexible or semi-flexible materials. Yet, the biomechanical principles of providing stump containment, weight transfer, and control of the prosthetic limb are not compromised. In the ISNY System, however, it is not clear how lateral and anterior/posterior stability of the femur is achieved, since there are no structural components in areas conventionally considered to provide such stability. This question, however, will be addressed in studies to be conducted in the near future.

Acknowledgments

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AOPA Regions VII, VIII, X, and XI Combined Meetings held May 25–28, 1983 in San Antonio, Texas has been awarded seven (7) hours of credit in the Academy Continuing Education Program.