Orthotics and Prosthetics, Vol. 29, No. 1, pp. 23-32, March 1975

LOWER-LIMB MODULAR PROSTHESES[1] A STATUS REPORT

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The literal definition of "modular" is "*pertaining to a unit of measurement.*" The word has been used widely in this context in architectural circles for many years, but recent usage in electronics and other space-related technologies has given the word a meaning that connotes interchangeability within a system of components of the same or slightly different characteristics in order to effect a repair quickly or to change easily the characteristics of the overall system.

In recent years "modular" has crept into the language of prosthetics replacing "pylon" (which was also a poor choice of words) and has been used to describe a prosthesis made up of easily assembled and disassembled parts, sometimes interchangeable with parts providing slightly different function.

Some basic definitions concerning construction of limb prostheses developed and adopted at a conference sponsored by the Committee on Prosthetics Research and Development (CPRD) in 1971 (*2*) are:

Modular:	Having accessible a number of interchangeable components which can be assembled easily and quickly into a prosthesis.
Exoskeletal:	Used to describe a prosthesis where the supporting structure is outside of or external to the normal shape of the limb.
Crustacean:	Used interchangeably with "exoskeletal"—"crustacean" connotes "shell" whereas "exoskeletal" connotes "external support."
Endoskeletal:	Used to describe a prosthesis where the supporting structure is internal to the normal shape of the limb.
Endoprosthesis:	A prosthesis lying inside the body.

NOTE: A prosthesis may be entirely endoskeletal, such as the new Bock system, or may be partly endoskeletal and partly exoskeletal, such as the new Blatchford system.

The obvious objectives of modular systems are a reduction in the time required to provide the patient with a functional prosthesis and the possibility of trying out various combinations of components on each patient with a minimum expenditure of time and effort. Additional objectives of some designers have been to provide for adjustability of alignment throughout the life of the prosthesis and lighter weight. In any event it was hoped that the end result would be better service to the amputee at less expense.

The common approach to modular design is to use a metal tube, or pylon, to which feet, knee joints, sockets, and other components can be attached quickly with clamps, screws, or other devices. Cosmetic appearance is provided by use of a nonstructural cover. A tube not only provides an inexpensive structure with a high strength-weight ratio, but also permits easy adjustability in planes perpendicular to the long axis. Paré *(1)*, in the middle of the sixteenth century, offered this type of construction (Fig. 1), and Parmelee, in his suction-socket patent of

[1]From a paper presented at Prosthetics and Orthotics Symposium sponsored by the Department of Health, City of New York, in conjunction with the Metropolitan Prosthetic and Orthotic Association, New York, New York.

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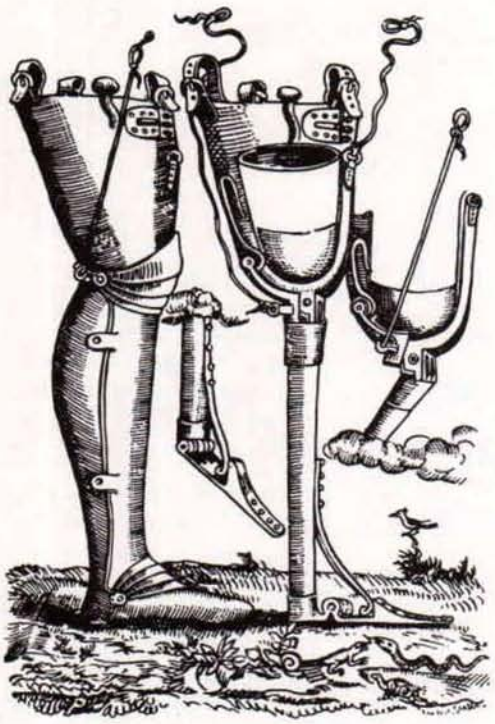


Fig. 1. Artificial leg invented by Ambroïse Paré (mid-sixteenth century). From A. Paré, *Oeuvres Completes*, Paris, 1940. From the copy in the National Library of Medicine.

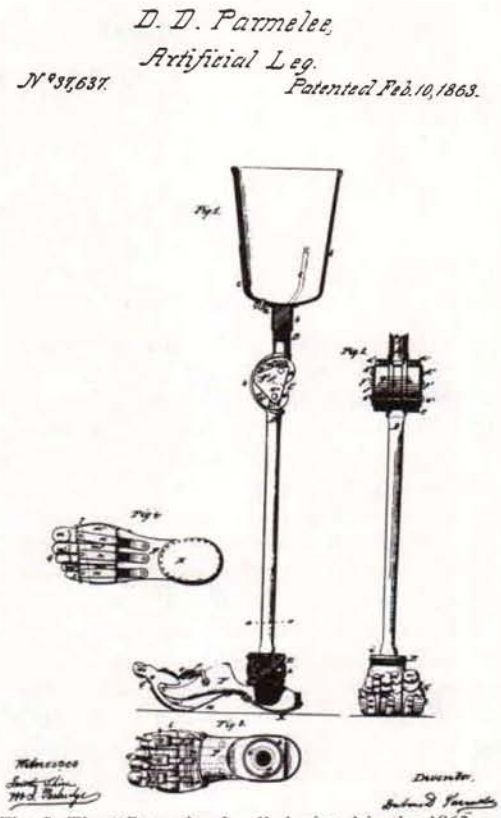


Fig. 2. The "Parmelee Leg" depicted in the 1863 patent covering the suction socket.

1863, proposed a pylon-type construction (Fig. 2). However, the crustacean type of construction has prevailed to this very day, in all probability because of the difficulty in providing a satisfactory cosmetic appearance.

In the early 1950s the University of California at Berkeley chose the pylon type of construction in designing the "adjustable legs" (Fig. 3) that have been used so successfully in arriving at a satisfactory alignment for each patient, to be transferred to and built into crustacean-type prostheses later (*9*). At the time of the original design, it was felt, correctly, that wide latitudes of adjustability were required and consequently the adjustable legs were too bulky for use other than for the time necessary to arrive at an adequate dynamic alignment, although an adaptation of the above-knee unit was made for use as a temporary prosthesis by the Veterans Administration Prosthetics Center.

The use of temporary prostheses was generally discouraged in the United States for many years because it was feared that ill-fitting, hastily devised sockets that might be prepared for temporary use would do more harm to the patient than good. However, in the early 1960s, after techniques had been developed for relatively quick fabrication of plastic-laminate sockets, interest in temporary limbs and fitting was revived and encouraged, and at least two devices—the so-called

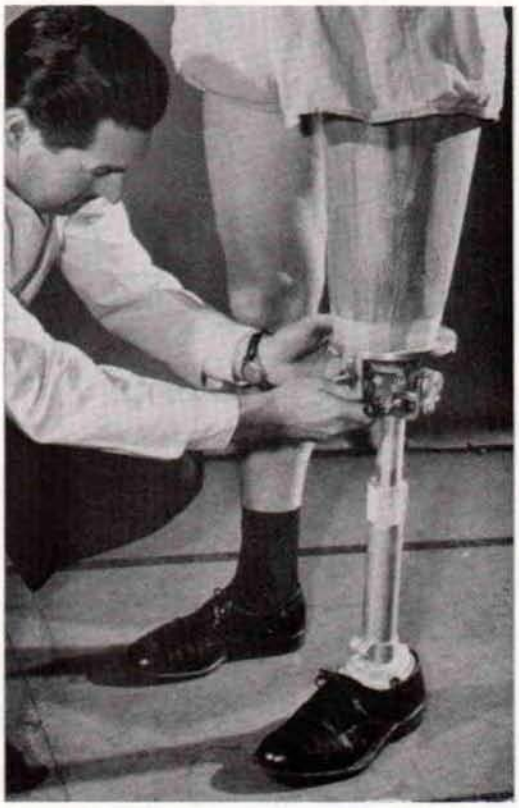


Fig. 3. The adjustable leg designed at the University of California, Berkeley, about 1950 for use in aligning above-knee legs.

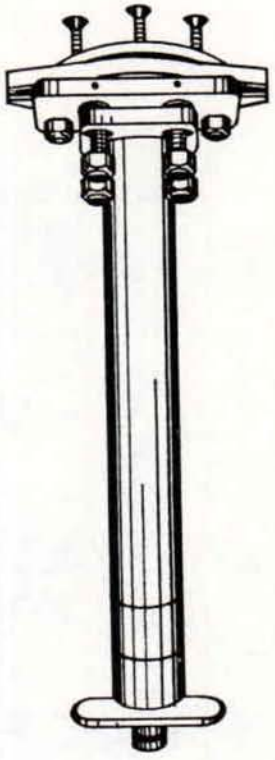


Fig. 4. The Northwestern Below-Knee Pylon, the first unit known to be designed for both temporary and definitive prostheses.

Northwestern adjustable below-knee pylon (Fig. 4)—and the Winnipeg system (Fig.5) (*1*) were designed to meet this need (*10*).

However, it remained for the introduction of immediate postsurgical fitting of prostheses to give full impetus to the development of the modular concept (Fig. 5) (*3*) (*7*) (*9*) (*10*) (*11*). The minimum requirements for a lower-limb prosthesis for use immediately after surgery are:

1. Adjustability of the socket in the flexion-extension plane.
2. Adjustability of the socket in the abduction-adduction plane.
3. Adjustability of the shank in the mediolateral plane.
4. Adjustability of the shank in the anteroposterior plane.
5. Adjustability of toe-in and toe-out of the foot.
6. Adjustability of the length of the shank.
7. Provision for quick connection and disconnection of the socket to and from the rest of the prosthesis.

For maximum ease in operation, it is desirable that each adjustment be independent of other adjustments, and an inexpensive method of providing cosmesis would be a welcome feature.

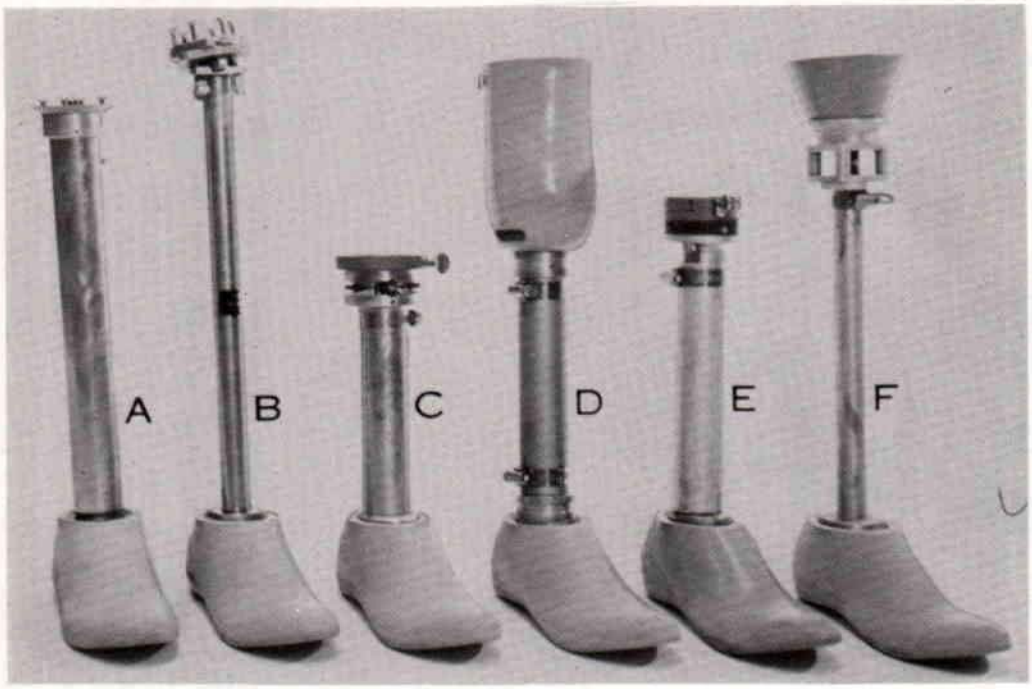


Fig. 5. Below-knee pylon-type prostheses that were available in 1968 for fitting prostheses immediately after surgery. *A*, Hosmer Postoperative Pylon; *B*, Northwestern Pylon (Hosmer); *C*, Veterans Administration Prosthetics Center (VAPC) "Standard" Pylon; *D*, Canadian "Instant" Prosthesis (Hosmer); *E*, United States Manufacturing Co. Pylon; *F*, Finnie-Jig (Arthur Finnieston Co.). Metal straps for attachment to a plaster-of-Paris socket are available, but not shown. *Courtesy of Veterans Administration Prosthetics Center.*

Better procedures for "bench alignment" permitted the reduction of the range of adjustments in comparison to the ranges provided by the original UC-B adjustable legs, and a number of very satisfactory pylon-type units were designed to meet the minimum criteria given above, and were made available commercially (Fig. 5) (*10*). These devices are used widely where immediate postsurgical fitting and early fitting procedures are carried out.

The minimum range of adjustments, set at a workshop on the subject sponsored by CPRD in 1971 (*2*), are:

Range of motion in flexion-extension plane	8 deg
Range of motion in adduction-abduction plane	8 deg
Horizontal movement in medio-lateral plane	20 mm
Horizontal movement in antero-posterior plane	20 mm

At the beginning of the immediate postsurgical fitting program, little attempt was made to provide good cosmesis, although the advantages that might accrue if it were feasible to leave the original unit in the definitive prosthesis were generally

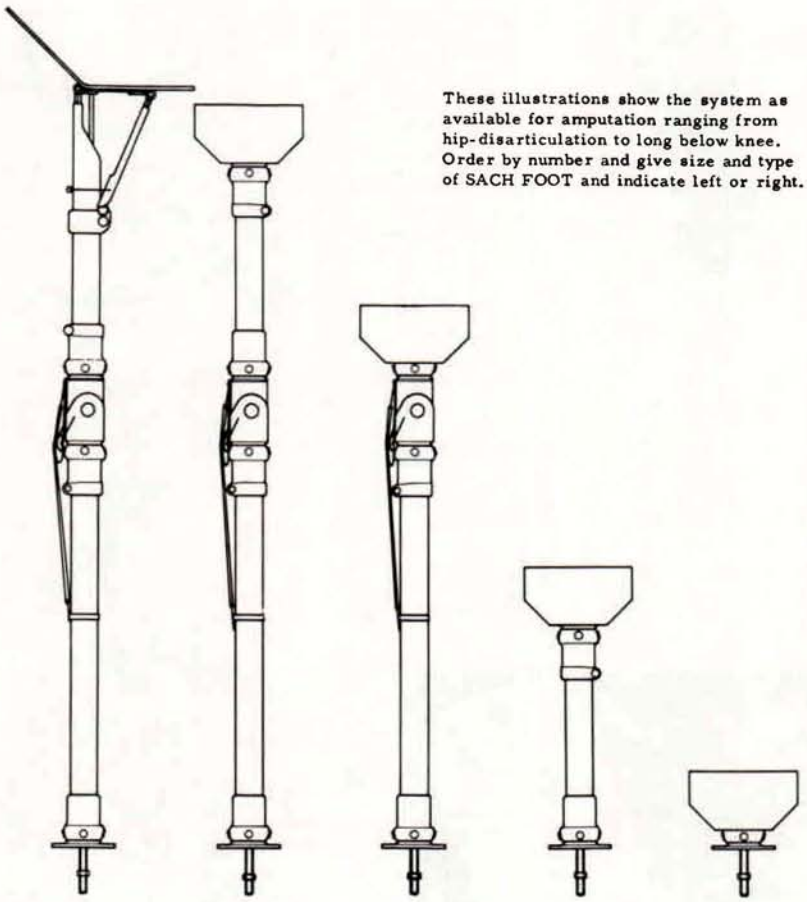


Fig. 6. Line drawings of the basic components of the Otto Bock modular system. From left to right, set-ups for hip-disarticulation, short above-knee, above-knee, below-knee, and Syme amputations.

recognized. It was felt by designers and prosthetists that the endoskeletal, modular concept offered an opportunity to provide a lighter weight prosthesis with improved cosmesis (to the eye and to the touch) at a lower cost. The obvious problem has been provision of adequate cosmesis, a problem pretty much independent of the mechnical design of the device itself.

A number of schemes to provide cosmesis have been investigated by private industry and by government-supported research groups, but the only method successful to date is the preformed resilient plastic foam that must be shaped and "fitted" by the prosthetist and for which a cosmetic cover, or skin, is needed.

All major manufacturers and suppliers in the United States offer one or more systems that include components for amputee types ranging from long below-knee to hip-disarticulation and hemipelvectomy.

The Otto Bock[3] (Figs. 6,7,8, and 9) and IPOS[4] systems (Figs. 10 and 11) are designed so that angular and linear adjustments can be made throughout the life of the prosthesis. The Kol-

[3]Manufactured by Otto Bock Orthopedic Industry, 3428 Duderstadt, W. Germany.

[4]Manufactured by IPOS Kommanditgesellschaft, 314 Luneburg, W. Germany. Available through Hosmer, Inc., 561 Division Street, Campbell, California 95008.

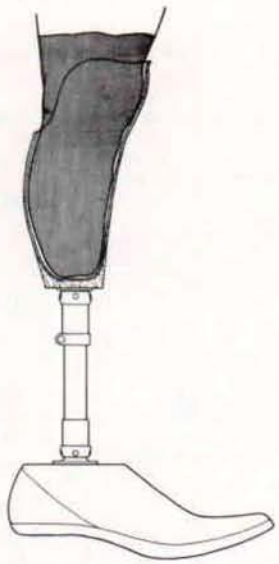


Fig. 7. Bock system used on below-knee patient. The cosmetic cover is not shown.

Fig. 8. The Bock system for an above-knee amputee showing the foam block that will be used to provide a cosmetic cover.

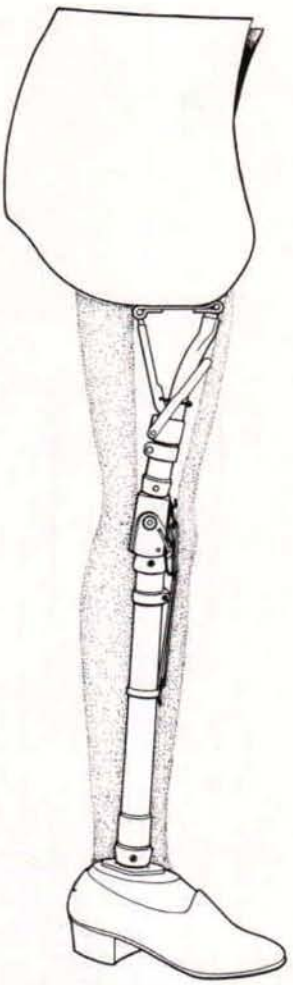


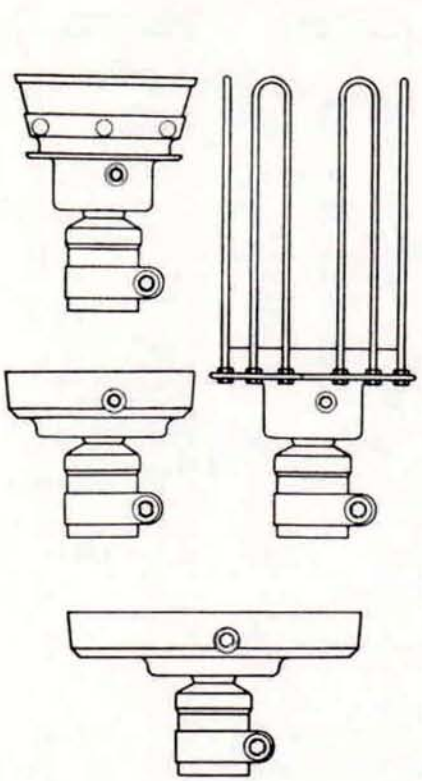
Fig. 9. The Bock system for the hip-disarticulation amputee.

man[5] system (Fig. 12) is simpler but does not provide adjustment in as many planes as the Bock and IPOS systems.

Various types of knee joints are available for use in the Bock, IPOS, and Kolman systems, but the Universal Multiplex Unit (Fig. 13) is the only design currently offering interchangeability of various popular fluid knee-control units.

The designers and manufacturers of the VAPC system recommend that the adjustable component be removed and replaced with solid parts.

[5]Manufactured by U.S. Manufacturing Company, 623 South Central Avenue, Glendale, California 91209.



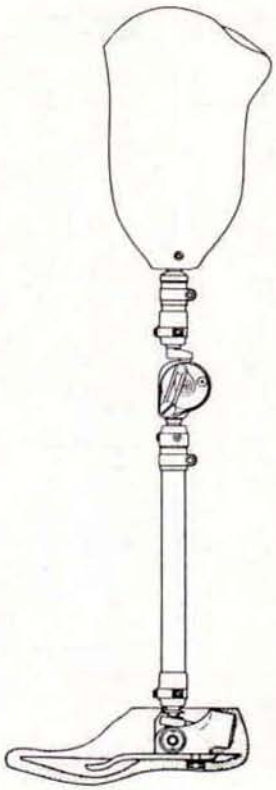


Fig. 10. The IPOS below-knee and above-knee components. Additional components for the hip-disarticulation case are also available.

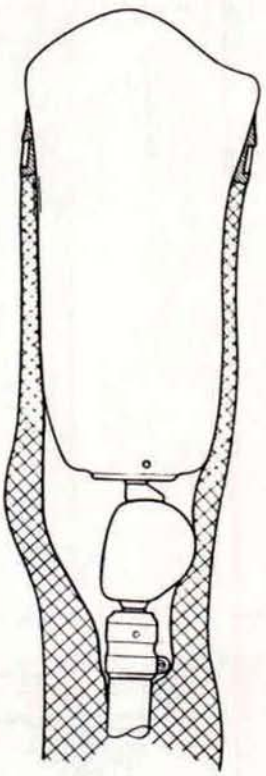


Fig. 11. Schematic view of the IPOS system for the above-knee amputee to show relationship between the cosmetic cover and the knee joint.

All systems use a plastic foam material to cover the mechanical parts (Fig. 8).

Three modular, endoskeletal systems are available for the hip-disarticulation case: the Otto Bock system (Fig. 9), the Kolman system (Fig. 12), and the IPOS system.

No formal clinical evaluation of any of these devices has been conducted in the United States because it has been felt that since no new function is provided the patient, such a program would be a waste of time and money. A research group at Strathclyde University did undertake a rather extensive evaluation project in 1971 involving 6 types of units and 23 subjects, each of whom were fitted with prostheses incorporating each unit. In all, there were 140 fittings involved. In an attempt to reduce the variables as much as possible, one prosthetist carried out all of the fittings. As might have been predicted, there seem to have been more variations within the prosthetist's contribution than there were from unit to unit. The report of this evaluation project has never been issued.

The government of Great Britain has sponsored, in cooperation with the International Society for Prosthetics and Orthotics, a series of international meetings (*4*) (*5*) (*6*) (*8*) to develop standards and bring about a certain amount of interchangeability of components for modular prostheses. The Blatchford[6] system has been adopted for use throughout Great Britain for an interim period until a distinctly improved model is developed.

[6]Blatchford & Sons Ltd., Artificial Limb Manufacturers, Lister Road, Basingstoke, Hants. RG 22 4AH, England.

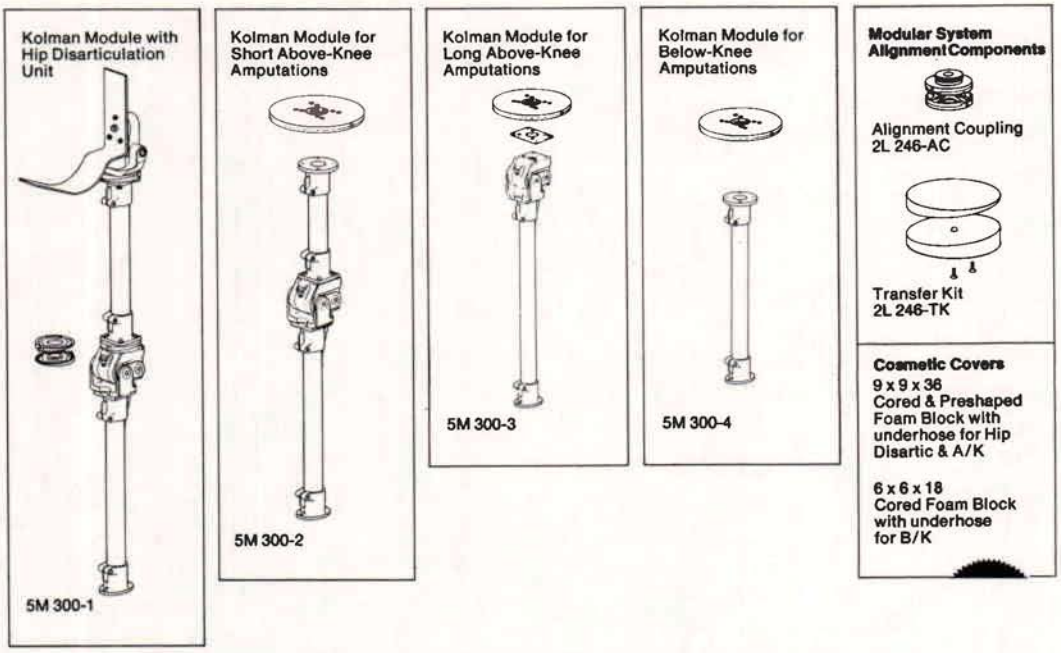


Fig. 12. Components for the Kolman system.

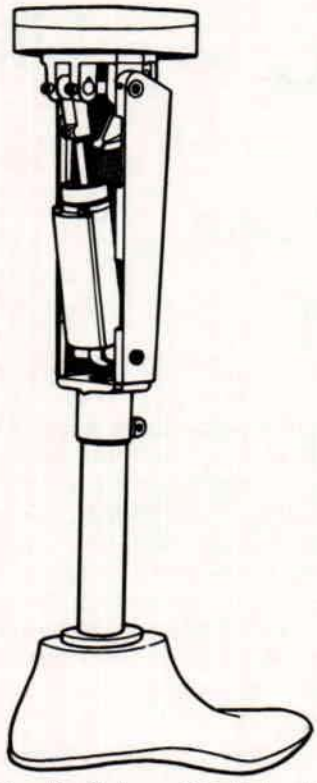


Fig. 13. Universal Multiplex Unit.

To get some idea of the use of modular prostheses in the United States, a limited survey was made by mail of 15 private limb facilities. Institutions not required to show a profit were excluded for obvious reasons. The questionnaire used is shown in Figure 14.

Very few patterns emerged from this survey. Modular prostheses are being used for immediate postoperative fitting and early fittings at all levels, but only the hip-disarticulation prostheses have found widespread acceptance for definitive prostheses.

It is clear that the differences between units designed for a given level are so small that such factors as availability and personal preference have as much to do with choice and selection as anything else.

CONCLUSIONS

Designers, manufacturers, and clinicians had hoped that the "modular" approach would yield better appearing prostheses that were lighter in weight and less expensive than the crustacean types in general use. However, modular prostheses for the below-knee and above-knee levels have been disappointing in this respect because

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MODULAR PROSTHESIS SURVEY

Name of Respondent_____

FREQUENCY OF USE

Type of Prosthesis and Components	Immediate Postoperative Fitting	Early Fitting	Definitive Fitting	Remarks
BELOW-KNEE				
1st Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	
2nd Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	
ABOVE-KNEE				
1st Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	
2nd Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	
HIP-DISARTICULATION				
1st Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	
2nd Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	
UPPER-LIMB AMPUTATIONS				
1st Choice Name_____	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	Never ___ Seldom ___ Often ___ Always ___	

Fig. 14. Questionnaire used in CPRD survey.

they are usually heavier than the corresponding crustacean model, and the time required to install the cosmetic filler and cover makes the modular prosthesis relatively expensive.

Nevertheless, the modular systems have proven to be valuable in the field of lower-limb prosthetics in early fitting and immediate post-surgical fitting at all levels. The hip-disarticulation systems are adopted widely for definitive prostheses, and the below-knee and above-knee systems seem to be used in definitive prostheses only when cosmesis is an unusually large factor to the patient and when hard use is not contemplated.

Work is being carried out to improve durability and to reduce the costs of achieving excellent cosmesis. In any event, the modular concept has already made a place for itself in lower-limb prosthetics.

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