Orthotics and Prosthetics, Vol. 28, No. 1, pp. 12-20, March 1974.

VACUUM FORMING OF PLASTICS IN PROSTHETICS AND ORTHOTICS

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The first reference to vacuum forming of plastics applied in orthotics appeared in 1968, in an article in "Orthopaedics: Oxford" by Dr. Gordon Yates of England (14). In this well-illustrated article, he described the end products, lower-limb orthoses of polypropylene and ABS (acrylonitrile-butadiene-styrene) but left much to the imagination concerning the fabrication procedure. Included were Helfet heel-cups (similar to the University of California at Berkeley shoe inserts) (6) (7) (9), ankle-foot orthoses (AFO), and knee-ankle orthoses (KAO).

Inspired, apparently, by Yates, the Ontario Crippled Children's Centre and the George Brown School of Applied Arts and Technology, both of Toronto, Canada, began in 1970 a program in the application of vacuum-forming techniques in orthotics, at all levels, and to some degree in limb prosthetics (1) (2) (8). The result of this program was the design and development of a machine especially suited to needs of orthotists and prosthetists (Fig. 1). Eventually machines of this type were made available commercially by VAF Industries, Ltd.[2] also of Toronto.

In 1969 Snelson and Mooney of Rancho Los Amigos Hospital, Downey, California, received a grant from the Social and Rehabilitation Service, Department of Health, Education, and Welfare to develop a practical method for fabrication of a transparent socket. Methods of making clear sockets had been developed previously but none was sufficiently practical, even for use in research programs. After some experimentation, Snelson and Mooney turned their attention to vacuum-forming polycarbonate sheet stock in spite of being told by suppliers of the materials that "it won't work." The result was a method of producing plastic sockets, both clear and otherwise, using very simple equipment (Fig. 2) (10) (13). Further experience has shown that this simple method is also suitable for production of AFOs. Success with this method of production has persuaded Orthomedics, Inc.[3] to make a simple compact machine available commercially (Fig. 3).

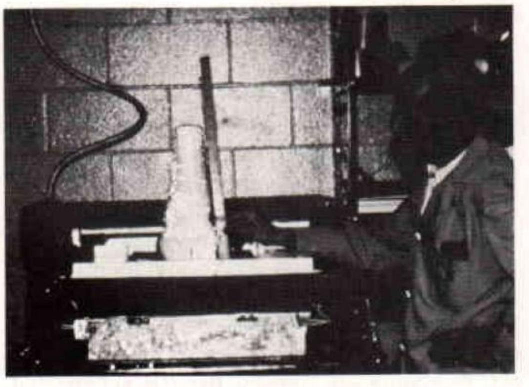

Fig. 1. Front view of the vacuum-forming machine developed at the Ontario Crippled Children's Centre. The male model is forced upward into the semimolten plastic sheet by a compressed air actuator.

In 1969 the Arkansas Cerebral Palsy Equipment Center began the use of individually molded wheelchair-seat inserts for severely involved cerebral palsied patients (3). The first sixty units were laid up in the conventional manner using fiberglass and resin, but since 1972, the seat inserts have been produced by vacuum-forming ABS over a mold using a machine commercially available from the EMC Co.[4] for fabrication of plastic signs and other items. By use of the vacuum-forming technique, the production rate has been increased about 300 percent. In addition to the cerebral palsied patients, the Center is providing seat inserts for paraplegic and quadri-

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[4] P.O. Box 9331, Dallas, Texas.

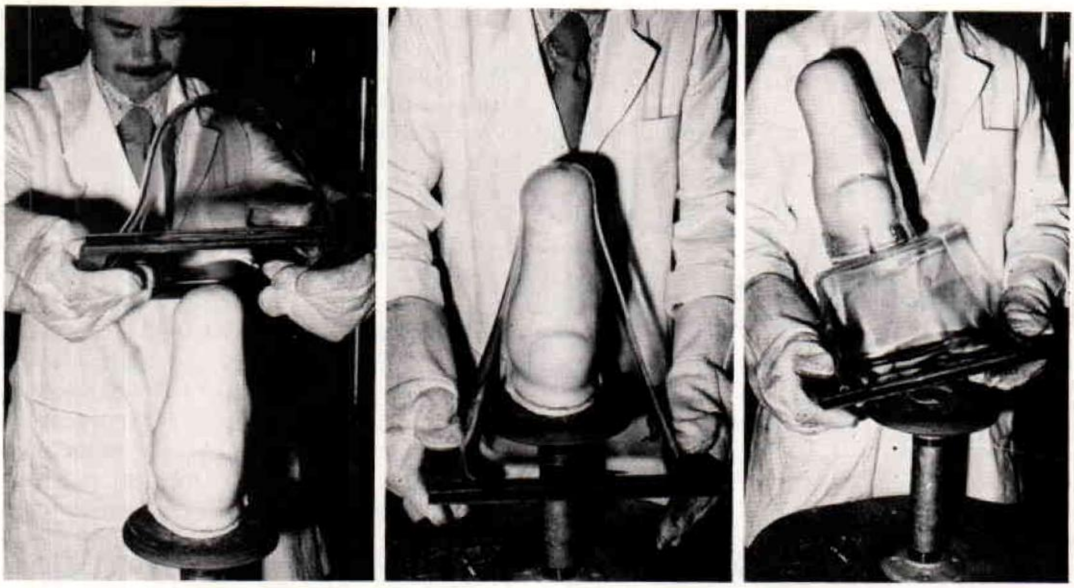

Fig. 2. Snelson's original manual technique to make transparent sockets for artificial limbs. *Left,* the Lexan sheet, placed in a metal frame, has been heated to a semimolten state; *center,* it is drawn down over the male model and, after air has been drawn out through the central pipe, the Lexan is pulled in until it conforms to the male model. *Right,* the gross casting is being removed from the machine.

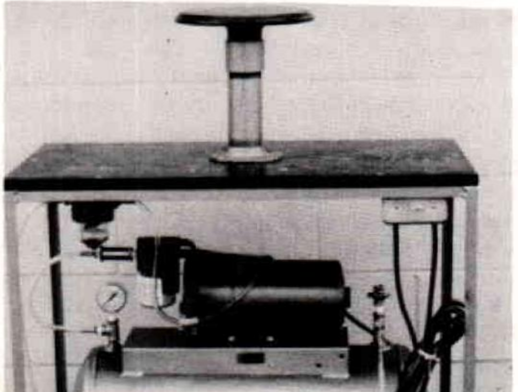

Fig. 3. The commercial version of the Snelson machine. A rectangular platen is substituted for the round one when most orthoses are to be formed.

plegic patients in order to spread the load over the weight-bearing areas when the patient is seated.

(An interesting facet of the Arkansas procedure is the method used for taking the impression, which consists of the revival of dilatancy (11), a process also employing the use of vacuum, and one which has been tried from time to time in taking impressions of amputation stumps. It may be time to initiate new experiments in dilatancy in view of the new knowledge gained and new processes developed over the years.)

As part of its evaluation program, the Committee on Prosthetics Research and Development ordered a prototype machine from VAF (Fig. 4) and sent it to the Veterans Administration Prosthetics Center for trials. Primarily because of electrical problems, it was difficult to obtain experience sufficient to evaluate either the equipment or the process. Meanwhile, Moss Rehabilitation Hospital in Philadelphia, because they could not obtain early delivery from VAF, purchased a large commercially available machine from Plastic Vac, Inc.,[5] primarily to make lower-limb orthoses (Fig. 5).

[5] P.O. Box 5543, Charlotte, North Carolina.

Fig. 4. The VAF machine. This model accommodates a 3-ft. sq. sheet of plastic.

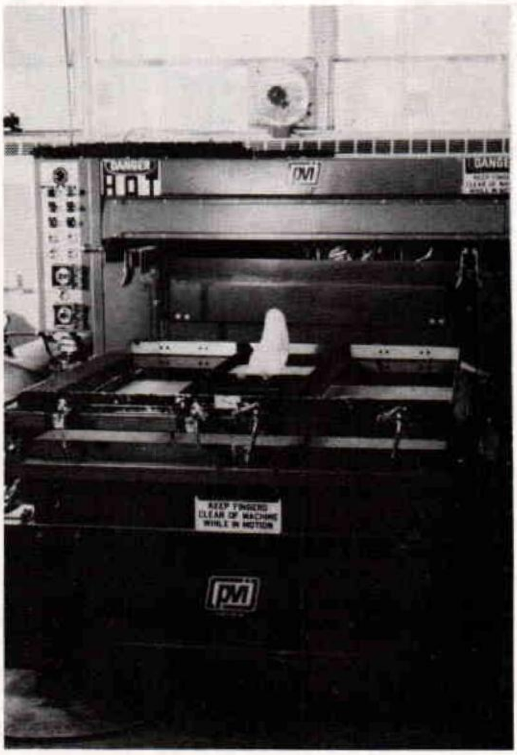

Fig. 5. The Plastic VAC machine. This model accommodates a 4-ft. sq. sheet of plastic.

Later the J.A. Pentland Co. and Rancho Los Amigos Hospital purchased VAF machines similar to one bought by CPRD.

Natresources, as a consultant to NOPCO, designed a special machine for prosthetics and orthotics practice for use in Boston, Massachusetts. Others, including a group in Winnipeg, were experimenting with vacuum forming.

Because it seemed beneficial to bring the various groups together and exchange information and then develop recommendations for future work, CPRD convened a meeting of representatives of all groups in North America known to have experience in vacuum forming of components for prostheses and orthoses at Moss Rehabilitation Hospital, June 3, 1973 (4).

It was the consensus of the participants that vacuum forming of plastics offers great potentials for improving not only prosthetics and orthotics services, but also should be very useful in educational programs.

It was also the consensus that not enough is known about materials and techniques. While general knowledge exists in industry where plastic shapes are mass-produced for a large variety of products, specialized knowledge is needed in tailoring special shapes in the prosthetics and orthotics field. In order to assure satisfactory results, there is a need to determine specifics in process variables for different materials and end products. Until the variables unique to the fabrication of prosthetic and orthotic components are documented, the process cannot be taught effectively.

The participants from educational institutions felt that equipment and processing details for vacuum-forming orthotic components such as lower-limb appliances were not well enough defined to consider opening courses immediately. Teaching the vacuum forming of larger components, such as spinal or other torso-fitting configurations, was even further off in time.

The state of the art in vacuum-forming sockets, however, appeared to be ready for use in formal educational programs. Accordingly, it was proposed that a two-day instructional course be convened in Downey, California. Orthomedics agreed to teach the course without reimbursement. It was held July 2 and 3, 1973, and was attended by representatives from New York University, Northwestern University, University of California at Los Angeles, and the University of Washington.

METHODS AND MATERIALS

There are many methods of using air-pressure differential to form heated plastics in sheet form into a given shape. In some instances, female molds are used; in others, male molds, and elaborate schemes have been developed for the mass production of items to provide uniform wall thickness and intricate shapes (Figs. 6-9). For prosthetics and orthotics, the use of the method known as "drape" molding, or forming (Fig. 9), seems to be the most appropriate, although it is

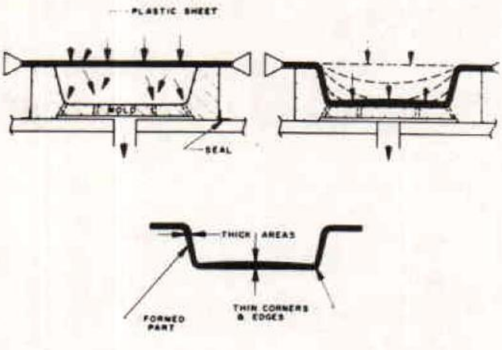

Fig. 6. Straight vacuum forming.

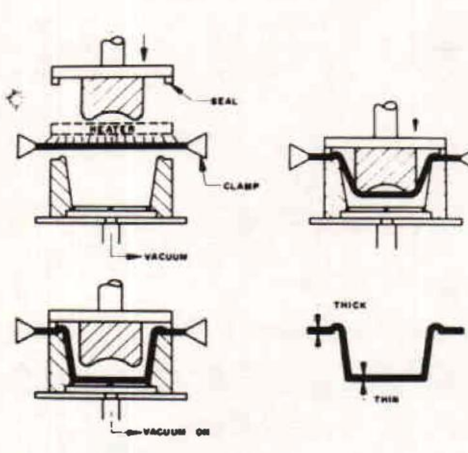

Fig. 7. Plug-assist vacuum forming.

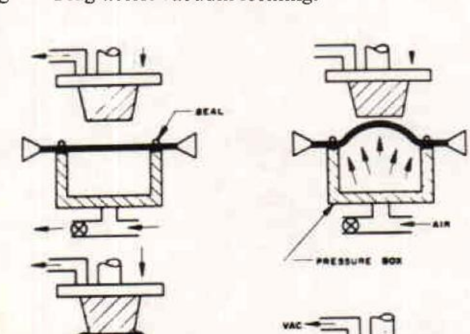

Fig. 8. Pressure-bubble immersion forming.

sometimes difficult to obtain uniform wall thickness by drape forming. All of the machines used in prosthetics and orthotics to date use the drape method.

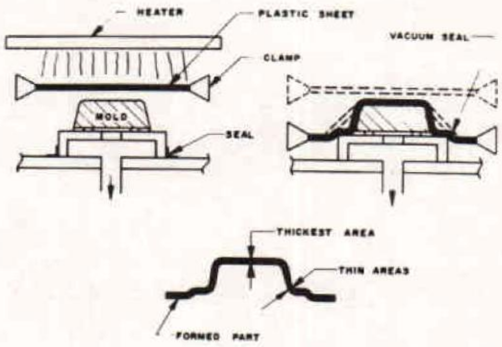

Fig. 9. Drape forming.

Five materials have proven to be useful in prosthetics or orthotics: polycarbonate, acrylonitrile-butadiene-styrene, cellulose acetate butyrate, polypropylene, and polyethylene. Their physical characteristics are shown in Table 1.

No single material has an ideal set of properties for use in prosthetics and orthotics. Polycarbonate is transparent and has high impact resistance, but its fatigue strength is low and the cost is high. ABS seems to be the preferred material for spinal supports and seats because of its rigidity. CAB is used rarely because of certain properties such as rate of elongation, but should not be overlooked for special cases. Polypropylene's resistance to fatigue and its low cost makes it very useful for limb orthoses, although it is not available in a transparent form. Polyethylene shows a lot of promise because when formed over a layer of Plastazote, which is itself expanded polyethylene, a perfect bond is formed. This readily permits the installation of a cushion between the soft tissues and the external supporting structure when necessary.

Other materials, new and old, are being tried at various places in an effort to find even more suitable materials for each application.

STATE OF THE ART

The use of vacuum forming in prosthetics and orthotics is increasing progressively. The following examples are those known to the author, but by no means include all that are being used in North America.

At the OCCC, vacuum forming is used routinely in the supply of virtually all lower-limb orthoses, back panels for orthoses, and in many seating and support devices. Polypropylene is generally used for limb orthoses, polycarbonate

TABLE 1
PROPERTIES OF PLASTICS FOR VACUUM FORMING

Characteristics	Units	Polycarbonate	Acrylontrile Butadene Styrene	Cellulose Acetate Butyrate	Polypropylene	Polyethylene
Tensile Strength	P.S.I.	8500	6000	5000	4900	4200
Elongation	%	115	15.0	75	390	500
Tensile Modulus	10^5P.S.I.	3.25	3.80	2.25	2.20	1.30
Compressive Str.	P.S.I.	10500	9000	—	7200	2900
Flexural Yield Str.	P.S.I.	12500	11000	5000	7000	—
Impact Str. (12OD)	ft.lb/in Not.	15.0	4.50	—	2.00	1.50
Hardness (Rockwell)	R.	120	110	70	95	95
Flexural Modulus	10^5P.S.I.	3.30	3.50	—	2.30	1.80
Compressive Modulus	10^5P.S.I.	3.45	2.20	—	2.10	—
Specific Heat	CAL/°C/gm-R.T.	0.29	0.35	0.35	0.46	0.55
Thermal Expansion	10^{5}/in/in/°C	6.60	7.0	14.0	7.30	12.0
Continuous Heat Res.	°F	250	200	190	230	230
Deflection Temp.	°F	270	235	220	200	200
Clarity	—	Trans.	—	Trans.	Opaque	Opaque
Transmittance	%	85	33.3	88	60	50
Haze	%	3.0	100	<1	2.0	3.0
Water Absorp. (24 hours)	%	0.16	.30	1.10	<.01	<.01
Burning Rate	in./min.	Self. Ext.	Slow	Slow	Slow	Slow
Effects of:						
Sunlight		Slight	None	Slight	Crazes	Crazes
Weak Acids		None	None	Slight	None	None
Strong Acids		Slowly	Attacked	Attacked	Slowly	Slowly
Weak Alkalies		Slowly	None	Slight	None	None
Strong Alkalies		Attached	None	Soluble	None	None
Organic Solvents		Soluble	Soluble	Soluble	None	None
Other Properties:						
Draw Ratio	Height to Base	2:1	4:1	3:1	2:1	2.5:1
Linear Mould Shrinkage	in./in.	0.006	0.006	.005	.015	.035
Specific Gravity	lb./cu.in.	1.20	1.05	1.19	.904	.940
Specific Volume	cu./in./lb.	23.0	27.0	23.0	30.4	28.3
Machining Qualities		Excellent	Good	Good	Good	Good

for back panels, and ABS for seating and support devices (Figs. 10-12).

At Orthomedics, polycarbonate sockets are used routinely as check sockets in lower-limb prosthetics, and polypropylene lower-limb orthoses are used widely (Fig. 13) (5).

At the Veterans Administration Prosthetics Center approximately 75 percent of the ankle-foot orthoses are being vacuum-formed of polypropylene. Experiments to develop practical methods of fabricating knee-ankle orthoses, orthoses for the upper limb, and limb prostheses are under way.

In Arkansas the Cerebral Palsy Center is routinely providing vacuum-formed seat inserts of ABS for cerebral palsy patients and patients with spinal-cord injuries.

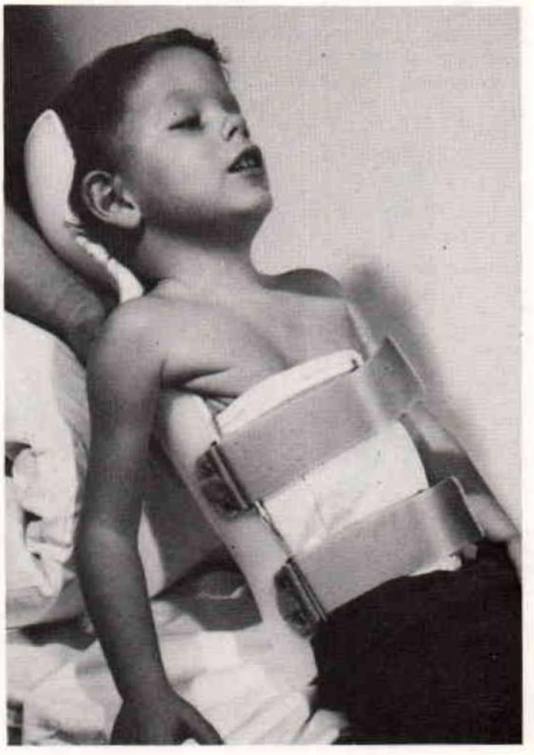

Fig. 11. Plastic back panel provided at OCCC.

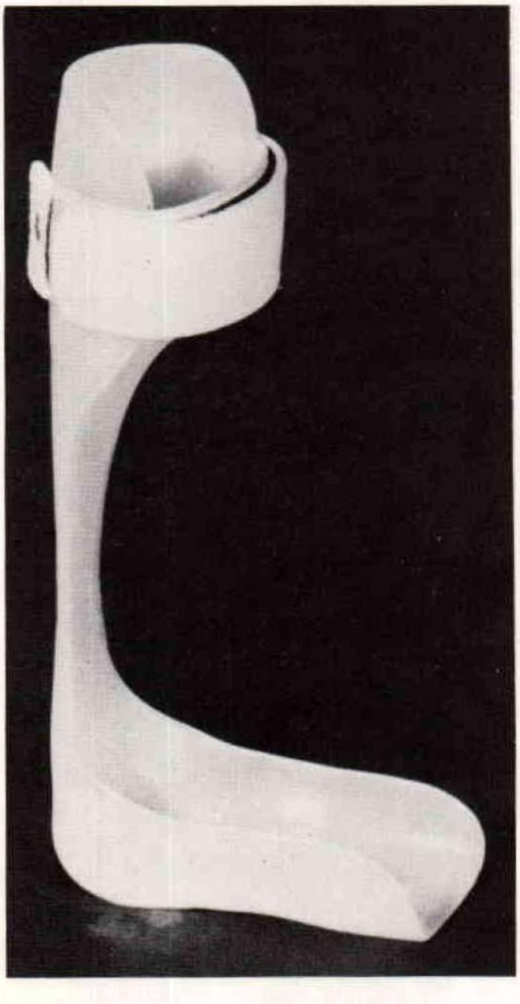

Fig. 10. Plastic knee-ankle orthosis provided at OCCC.

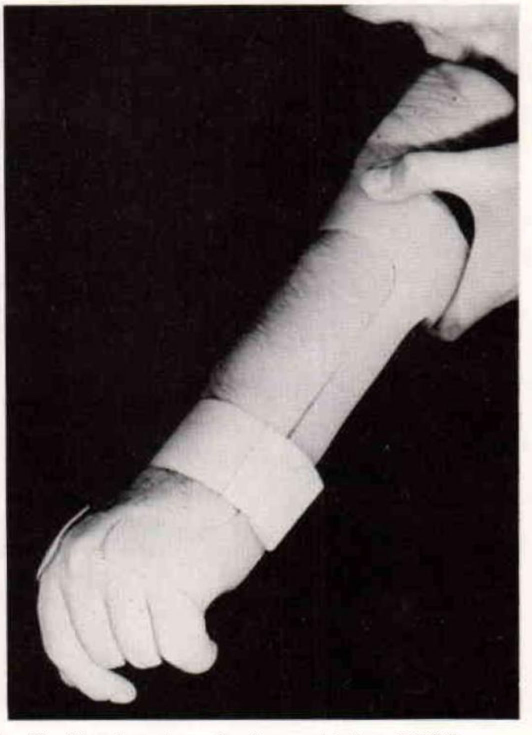

Fig. 12. Plastic wrist orthosis provided at OCCC.

Moss Rehabilitation Hospital is providing on a routine basis lower-limb orthoses molded from polypropylene and is experimenting with other materials. This group at MRH is also developing methods to check the performance of any given orthosis in order to develop a method for correlation of prescription, fabrication, and fitting (Figs. 14-16).

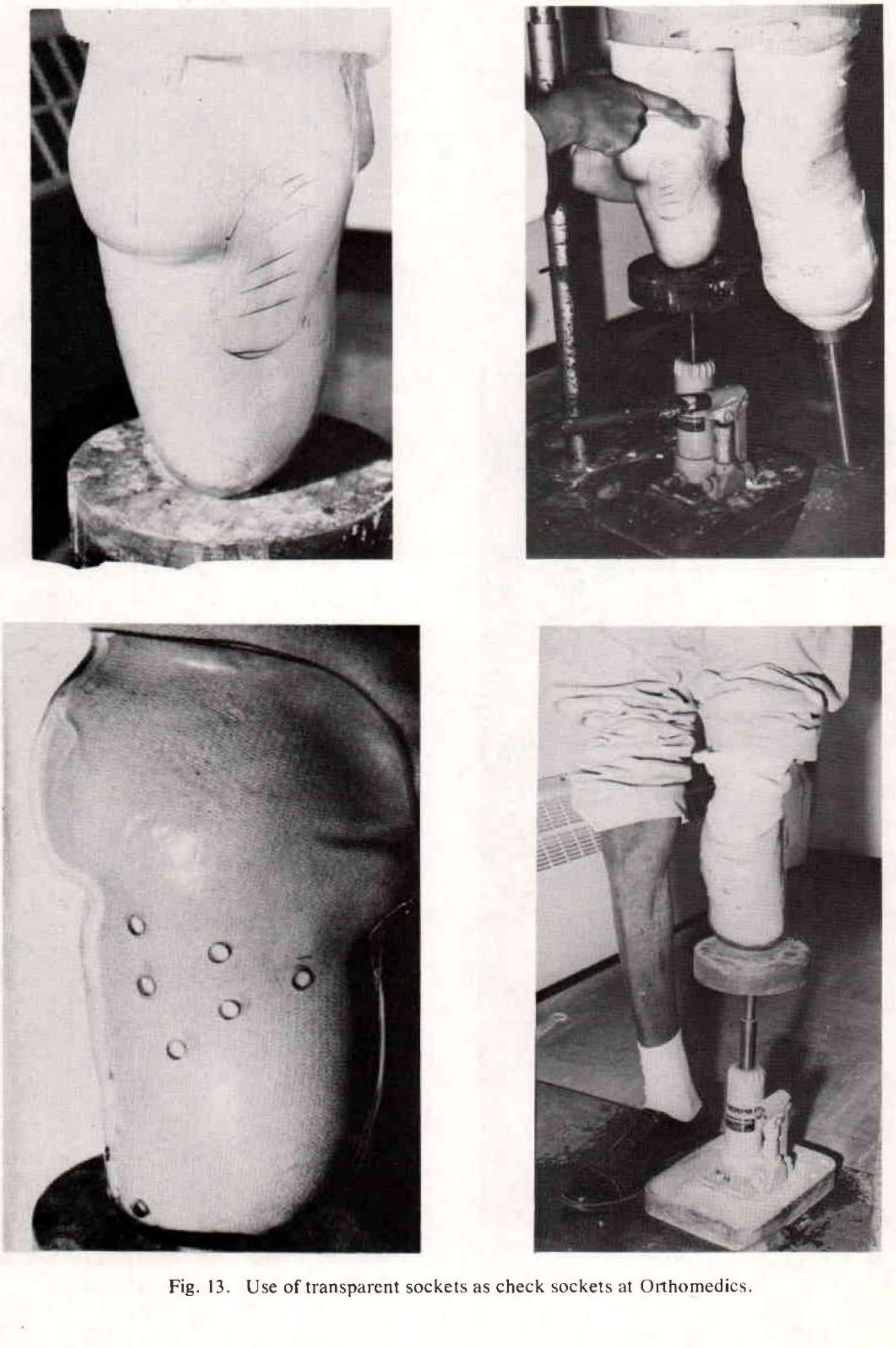

Fig. 13. Use of transparent sockets as check sockets at Orthomedics.

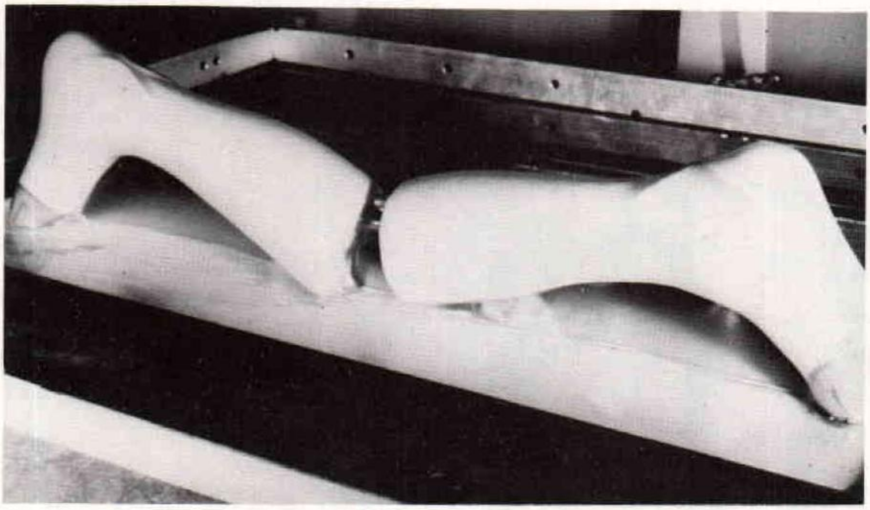

Fig. 14. Two AFOs being molded of polypropylene simultaneously on the plastic VAC machine at Moss Rehabilitation Hospital.

The Prosthetics Education Program at the University of Washington is using the Orthomedics technique in their prosthetics education program. Clear sockets have been found to be very useful for laboratory instruction.

A firm, Plasthetics, Inc.,[6] has been established to provide vacuum-forming services, especially for prosthetists and orthotists.

ADVANTAGES AND DISADVANTAGES

At this point, it appears that vacuum forming of sheet plastics offers prosthetists and orthotists an opportunity to provide improved, more functional prostheses and orthoses more rapidly than can be done with present practice. Orthoses, especially, can be tailored to fit the needs of the patients more adequately with thermoplastics than with either metal or plastic laminate. The cosmetic factors should not be overlooked. Color, even transparency, and snugly fitting orthoses provide less conspicuous devices.

Vacuum forming has the potential of providing the clinical prosthetist prompt service when required, especially for patients fitted for the first time. The use of check sockets (5) in lower-limb prosthetics becomes practical. Needed to be developed are simplified means for coupling the vacuum-formed socket to a pylon for extended use.

For the first time now, research groups have an inexpensive way of forming sockets, transparent as well as translucent, so that extensive experiments in casting techniques, heretofore considered to be too costly, can be carried out. At the present time, just such an experiment is being conducted jointly by Rancho Los Amigos Hospital and CPRD in determining the relative differences between the conventional technique for casting a below-knee stump and two other recently developed methods.

It would seem that vacuum-formed sockets, especially transparent ones, would prove to be extremely valuable in an education program.

Present-day prosthetist students do not go to

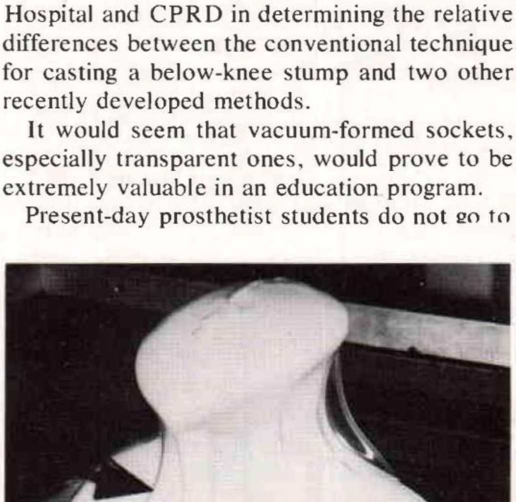

Fig. 15. Cervical collar formed at Moss Rehabilitation Hospital.

[6]5640 Enterprise Drive, Lansing, Michigan 48910.

Fig. 16. Polypropylene AFO provided by Moss Rehabilitation Hospital.

school to learn lamination, yet they must laminate sockets over casts they have taken and modified in order to determine if they have taken the cast and modified it satisfactorily. The use of vacuum forming to provide sockets would permit the students to spend their time more fruitfully than making a lay-up.

THE FUTURE OUTLOOK

At this time, it appears that vacuum forming has a great future in prosthetics and orthotics. There is reason to believe that materials with even more appropriate physical properties will be emerging from the plastics industry, and ingenious prosthetists, orthotists and engineers will devise practical means of taking the maximum advantage from these new materials.

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