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A LOW COST VACUUM-FORMING SYSTEM[1]

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Vacuum-forming is an excellent method for molding sheets of plastic into complicated shapes. It is just beginning to be used in the field of rehabilitation medicine where the need to make devices that fit the human form is great. This article describes a new, inexpensive apparatus which enables orthotists and prosthetists to use the vacuum-forming process in their work with a very small outlay of capital. Very little training is required to use the apparatus, and it is now being made available in limited quantities.

In the vacuum-forming process a sheet of hot, pliable plastic is drawn either into or around a mold with the use of suction provided by a vacuum pump. When the plastic cools and hardens, it retains the shape caused by the mold. An example of the usefulness of a molded orthosis is shown in Figure 1.

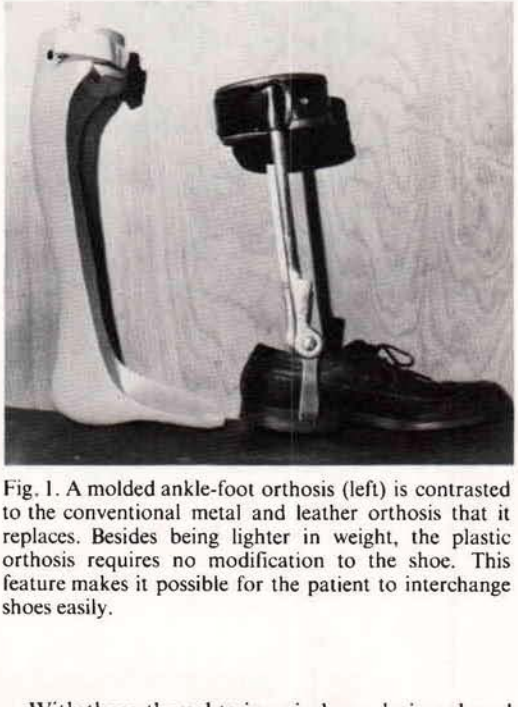

Fig. 1. A molded ankle-foot orthosis (left) is contrasted to the conventional metal and leather orthosis that it replaces. Besides being lighter in weight, the plastic orthosis requires no modification to the shoe. This feature makes it possible for the patient to interchange shoes easily.

The process, though simple, when adapted to the needs of mass-production, requires very expensive machinery. Until recently only industrial vacuum-forming equipment was available, with prices ranging from $4,000 to over $125,000. Because of the large investment in money and space required to obtain and use the machines designed for mass production, very few medical facilities have made use of the vacuum-forming process.

For mass-production expensive equipment results ultimately in low unit costs. But for the specialized, one-of-a-kind world of rehabilitation, expensive equipment does not necessarily justify itself, and a low-volume, low-cost, non-automated system seems much more suited to the needs of orthotists and prosthetists. Such a machine is feasible when the inherent simplicity of the vacuum-forming process is fully exploited.

With these thoughts in mind we designed and built a vacuum-forming apparatus called the "Bracemaker" (Fig. 2), which is simple, functional, versatile, and, above all, inexpensive. In accordance with the terms of the federal grant which provided part of the funds for this work, we are making the design of the "Bracemaker" available to the medical community.

Why should orthotists and prosthetists be interested in vacuum-forming, when they already have many conventional techniques to use? The advantages of plastics are part of the reason. Plastics are often found in rehabilitation devices where light weight, cosmesis, flexibility, durability, and close fit are needed. Until recently, it has been necessary to form plastics by hand, a process that requires considerable skill, and often repeated attempts, to achieve good results on any but the simplest shapes. With vacuum forming very little skill is needed, results can be quite

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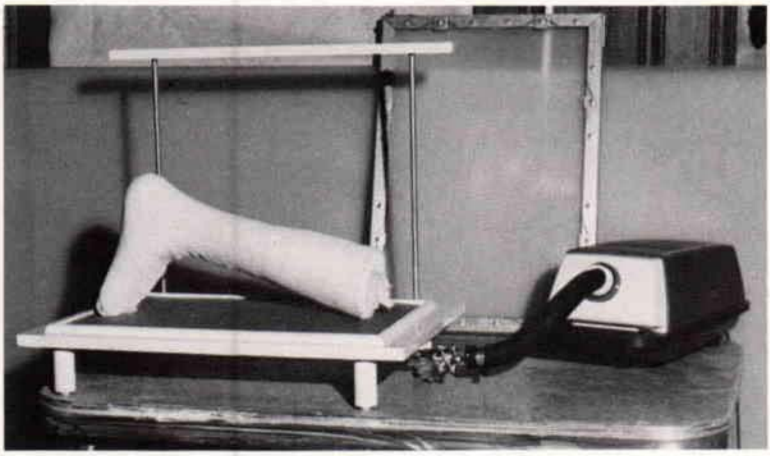

Fig. 2. The "Bracemaker." The vacuum cleaner is used for the pump to evacuate air through the table top from the space between the plastic sheet and the table. Note the two upright guides at the rear edge of the table. The rack, or frame, for holding the plastic sheet during heating and forming is shown in the rear.

consistent, and parts can be formed which cannot be done at all by hand. Moreover, the technique can be used with a large variety of plastics—almost all of the thermoplastics. This eliminates the need for special, low-temperature forming plastics, and opens up a wide range of new plastics that are extremely useful in the provision of rehabilitation devices.

THE PROCESS

The type of vacuum-forming most useful in prosthetics and orthotics can be broken down into six distinct steps:

1. *Mold Preparation*—A mold in the shape of the part to be formed must be prepared. In prosthetics and orthotics plaster-of-Paris is usually

Fig. 3. The molten plastic sheet being removed from the oven prior to placement over the male model. Note the special frame, or rack, for holding the plastic sheet around the periphery.

the material of choice. The mold is placed on a special table (Fig. 2), and supported for the best wrapping action of the plastic.

2. *Heating*—The plastic sheet must be brought to a temperature that makes it soft and pliable, yet leaves it strong enough to resist tearing (Fig. 3).

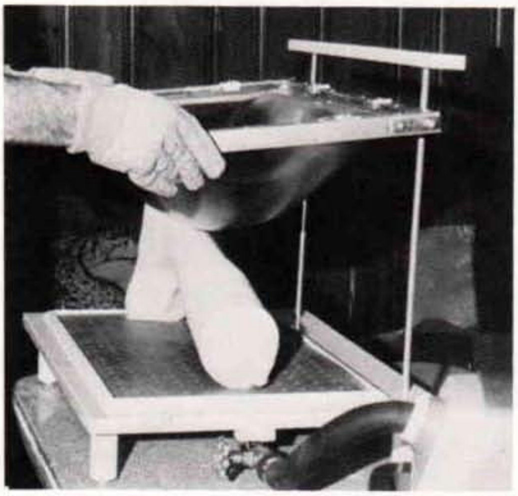

Fig. 4. The plastic sheet is draped over the mold. The uprights are used to assist the operator in keeping the molten plastic sheet aligned with the table.

3. *Draping*—The plastic sheet must be draped over the mold and then sealed at its edges, so that the mold is totally enclosed (Figs. 4 and 5).

4. *Drawing*—The air underneath the plastic is pumped out, allowing the pressure of the atmosphere to wrap the soft plastic around the mold, taking its shape (Fig. 6).

5. *Cooling*—The plastic is allowed to cool while the vacuum is maintained. The plastic hardens and regains its normal properties.

6. *Extraction*—The finished part (Fig. 1, left) is cut out of the plastic. (Unfortunately, the excess plastic is waste which can rarely be reclaimed, even though it is inexpensive relative to other materials). The mold may also be removed at this time. Usually it can be removed intact, but occasionally it must be broken and removed in pieces.

THE BRACEMAKER

The basic elements of the "Bracemaker" vacuum-forming system (Fig. 2) are:

1. an oven, for heating the plastic
2. a rack, for handling the plastic
3. a vacuum table, to support the mold and seal the plastic against air leakage during drawing
4. a vacuum pump, for withdrawing the air

Fig. 5. The plastic sheet and frame are brought in contact with the vacuum table so as to seal the enclosed area with respect to the atmosphere.

Fig. 6. The air underneath the plastic is pumped out and the plastic follows the form made by the model and table. The form is retained faithfully by most sheet plastics upon cooling.

The oven is an ordinary household oven, either gas or electric. Because they are mass-produced, these ovens are far less expensive than the acceptable alternatives. Yet, they are just as adequate as laboratory and industrial ovens are for this purpose. One can often be bought new for $200.00 or less.

The rack (Fig. 7) has been designed especially for the vacuum forming process, and it holds the plastic sheet firmly about its perimeter even when the plastic is in the molten stage. Its special clamping devices, or "traps" (Figs. 8 and 9), are designed to permit easy insertion and removal of the plastic, and to obviate the need for special

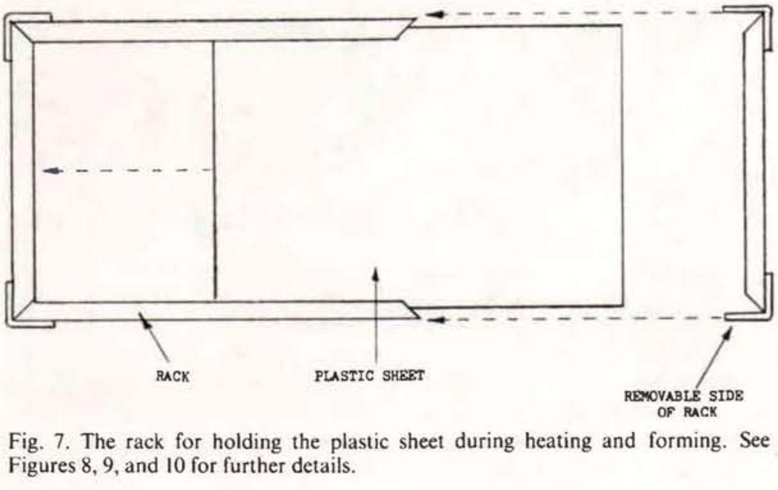

Fig. 7. The rack for holding the plastic sheet during heating and forming. See Figures 8, 9, and 10 for further details.

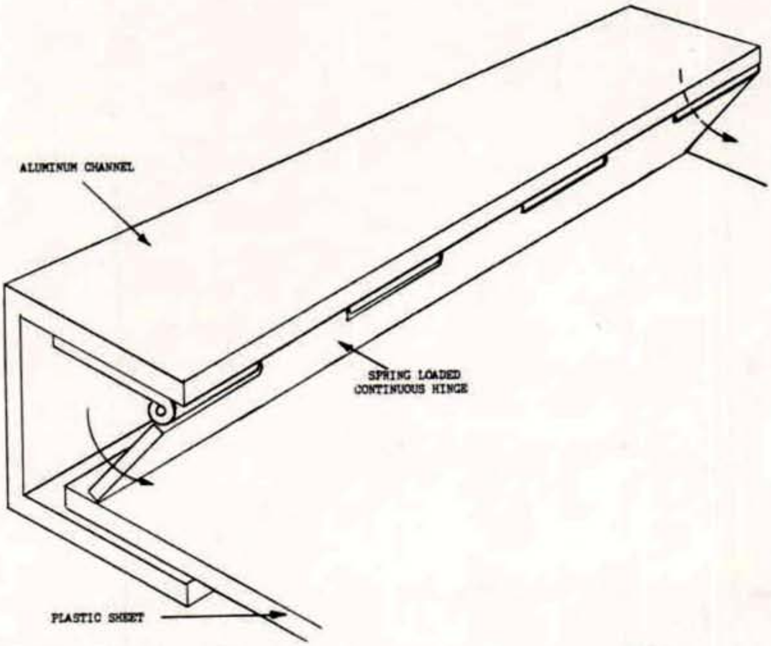

Fig. 8. Details of the trap in the frame to hold the plastic sheet during heating and forming.

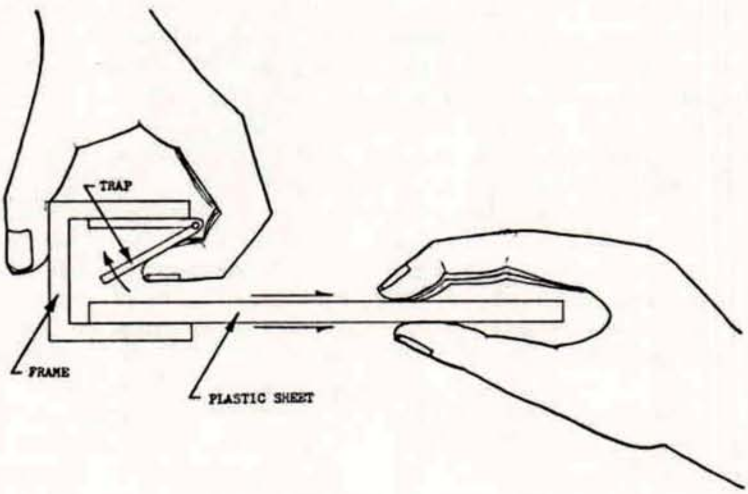

Fig. 9. The plastic can be removed from the rack only when the hinge-traps are released.

preparation of the plastic, such as drilling holes for bolts or pins. The spring-loaded continuous hinge digs into the plastic when tension is applied to pull it out. The traps must be released by hand, as shown in Figure 8, in order to free the plastic sheet. One end of the rack is removable to permit insertion of the sheet. To heat the plastic, the rack can be placed in an oven instead of one of the regular wire shelves. This arrangement makes it possible for the plastic to be placed in the oven, removed, and carried to the vacuum table without the need for handling the plastic itself. Because

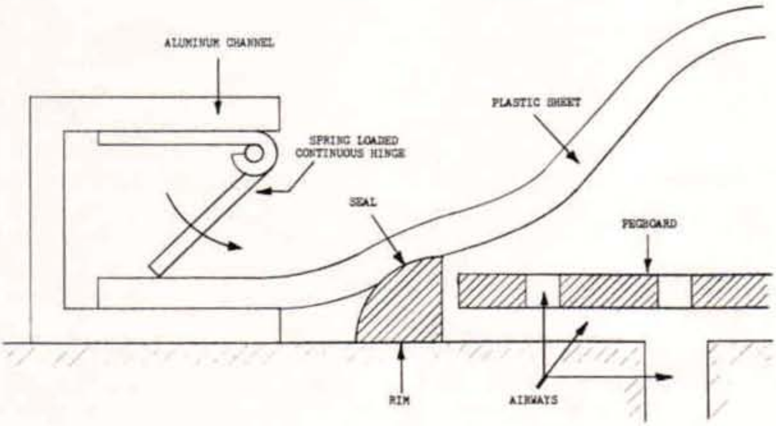

Fig. 10. Cross-section view of plastic sheet, rack, and vacuum table during a forming operation.

the plastic sags several inches when heating, and becomes sticky and pliable, this handling ability is quite necessary for success.

The vacuum table, also a special piece of equipment, is the basic work-surface of the "Bracemaker." It is a low table, designed to sit atop a workbench. It incorporates a perforated surface on which the mold is placed and through which the air is withdrawn, a rim or vacuum seal which provides a seal against leakage (Fig. 9), a valve to control the rate at which the plastic is drawn around the mold, and a set of guides to aid in draping the plastic over the mold.

The vacuum pump is nothing more than a simple household vacuum cleaner with fittings to attach the suction hose to the vacuum table. Surprisingly, it is more than adequate for the job, and in fact is far better than vacuum pumps costing four to twenty times as much because a vacuum cleaner pump has a far greater tolerance for leakage than most other pumps, while still being able to draw the vacuum needed.

The peripheral equipment needed varies with the raw material used and the end product desired. Tools for cutting out sheets of raw plastic, smaller cutting tools for extraction work, cast cutters, finishing tools, are all needed to some extent in vacuum-forming. But there are many different tools which can do these jobs, and most shops have a number of suitable tools already. For this reason such items are not supplied with the "Bracemaker," but recommendations as to what is needed and what can be used are available.

OPERATION

A good example of the use of vacuum forming in orthotics is the procedure used to make an ankle-foot orthosis (AFO). Figure 1 shows a conventional steel-and-leather orthosis on the right and a vacuum-formed plastic orthosis on the left. This type of plastic orthosis is, to date, the most widely used and highly developed of the vacuum-formed appliances.

The ankle-foot orthosis is usually made out of polypropylene sheet, most often 3/16 in. thick. Polypropylene is often called an "engineering plastic," and is noted for its ability to stand up to constant flexure, its resistance to "creep," its strength, its springiness, and its low cost. These are all useful properties for the AFO. Other useful available plastics are Lexan, ABS, and polyethylene. The cost of plastic for each brace varies with material and supplier, but, at the time of this writing the average cost in the Boston area for polypropylene for one orthosis is $4.00.

To make the mold for the AFO, a plaster cast of the patient's lower leg and foot is taken, using standard techniques. The cast is then cut down the anterior wall with a cast cutter, and removed from the patient. It is then dusted thoroughly inside with talcum powder, sealed again usually with strips of plaster bandage, and filled with plaster of Paris.

When the plaster has cured, the cast is stripped away, to reveal a positive model of the patient's lower leg and foot. This model is finished to remove rough spots, and then trimmed at the toe and shin so that it will stand heel upwards on the vacuum table (Fig. 2). The mold is then covered with cotton stockinet, and placed on the vacuum table.

A sheet of plastic is placed in the rack. The rack and plastic sheet are then inserted in the oven, which has been holding at 500°F. The rack should be placed in the top of the oven, with plenty of clear space underneath to permit the plastic to sag as it is heated. Within five minutes the plastic will begin to turn clear and sag. In two or three more minutes it will be clear all the way to the edges of the rack, and it will have sagged six to eight inches in the center. At this point it is ready to be removed from the oven (Fig. 3).

The vacuum pump is turned on, and the vacuum control valve is opened to one quarter-turn. The rack containing the heated plastic is removed from the oven, carried to the vacuum table, lifted high over the mold, and draped smoothly down over it (Fig. 4). The rack is pressed down onto the table (Fig. 5), stretching the plastic over the rim which surrounds the vacuum surface, and forming the vacuum seal (Fig. 9). The plastic will begin to draw down over the mold, and the rate of draw can be adjusted by further opening or closing the vacuum valve. Once the plastic is properly drawn down, the valve should be adjusted so that it does not draw further, but still remains tight on the mold (Fig. 6). The vacuum is left on until the plastic hardens—in two or three minutes.

Once the plastic has cooled thoroughly, it can be removed from the rack. The orthosis can then be rough-cut out of the plastic, and the mold removed. (The mold can normally be re-used, should that be necessary.) The orthosis is then finished to the proper shape, but left a little oversize at the ankle. The ankle area is where the orthosis flexes the most, and the size of this section is critical to the corrective force the orthosis provides to the patient. It is necessary to leave the ankle stiffer than is thought to be necessary, so that material can be trimmed away during patient trials until the correct amount of stiffness has been reached.

A strap with a Velcro closure is riveted at the top of the orthosis, so it can be fastened to the patient's leg (see Figure 1). The lower part of the orthosis inserts into the patient's shoe as if it were part of his foot. No other attachments are necessary.

Should the patient find the orthosis to be irritating at some point, or some other flaw is discovered, minor changes in the orthosis can be made. Small areas of the plastic can be re-heated with an electric heat gun or a propane torch, and bent by hand to a new configuration. However, major modifications by this method are rarely successful, and usually a new molding is required.

The final finishing of the orthosis should include fire-polishing. This process extends the life of the orthosis by removing microscopic cracks left on its edges by previous finishing operations. These cracks are where the stresses in the plastic become highest, and where breakage is most likely to start. Playing the blast (but not the actual flame) from a propane torch along the edges of the brace will cause a small amount of plastic to melt there. When the melted plastic cools it forms a smooth bead, which should be devoid of cracks.

PROJECT STATUS

In May of 1974 we began the distribution of a small number of pre-production "Bracemakers" to hospitals and brace shops in the New England region and in New York. The object was to test the machine in the field and to gain a base of experience outside of our own facilities. As of this writing we have had machines in the field and in operation for over a year, with encouraging results. We estimate over three hundred orthoses have been made on our machines. Most of these have been AFO's, but a number have been experimental orthoses of other varieties. The private orthotics facilities using our machine have shown a definite ability to custom-manufacture plastic orthoses.

Our future plans for the "Bracemaker" project aim at the development of a self-perpetuating technology. This includes the development of a production model of the "Bracemaker," the distribution of machines to facilities throughout the country, and the establishment of a clearinghouse for the assembly and distribution of information on vacuum-forming. In addition, we intend to continue our research into new uses for vacuum-formed parts in rehabilitation medicine.