Extrusion Blow Molded Orthotic Devices

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Introduction

With current technology in orthotic devices, the parts are extremely costly. This is mostly due to the size of injection molding machine that is required to create these parts. In an effort to create a better product for those who are differently-abled. Instead of injection, molding these large hollow parts it may be more cost effective to use an extrusion blow molding technique. This will allow for current supportive and realigning braces of most of the human body to be created in a less expensive fashion.

These braces may also be a candidate to replace the current technology of plaster and gauze cast materials to set a broken bone. The same braces can be utilized; in many cases, very few safety mechanisms would be required to be attached in order to obtain the same level of immobilization. The great advantage of this side use is to give doctors access any surface wounds that the patient may have while still keeping the user in their cast to heal.

A third application with minor modification in the program of the person would be a military application in body armor that is lighter weight and less cumbersome for the soldier. This also allows the soldier to carry his or her own personal medical brace system wherever they go.

Application of Blow Molding

Braces that are in current production are parts of large projected area and constant wall thicknesses. These parts are currently injection molded using several molding machines with assembly processes occurring later within the process line. In an effort to create a viable replacement part, more efficiently considering machine costs blow molding is the best option. Using blow molding every part of a given device can be molded simultaneously. While these braces will still require assembly and an added step of trimming, they provide for the use of one machine to create a part rather than several. Using less machinery to create these parts will save money in the cost of production. This savings can either be translated into profits or can be passed on to the end user.

Orthotic braces are always custom fit to the end user. This is a three-stage process beginning with a casting of the body part of the user. The casting is made at the orthotics shop. From that casting, a mold is created. Out of this system of molds, a single brace is created. This brace is then assembled and finally fit to the user by a professional. This procedure takes weeks from beginning to end and several visits with the orthotics professional. This fact makes the mass production of these braces impossible.

By utilizing a blow, molded part a general mold can be created to fit many people. A professional would still be required to fine-tune the brace, but by utilizing different methods of fitting the part a better fit as well as a less expensive part can be created. The same molds can be used to create casts for use with broken bones. When using an injection molded brace the molded part still has to be a relatively close fit to the user. The doctor or orthotics specialists can then trim and fine-tune the brace to fit perfectly. If an extrusion blow molded part were to be used the part can be annealed at low temperatures, and with a boundary layer of cotton between the brace and the wearer’s skin, can be hot
fit. This hot fit brace will always be a perfect match to the wearer and remain comfortable for the life of
the device. This process should take one fitting or one measuring then a fitting. It should be relatively
quick from prescription to fitting for the wearer, since the general sizes can be stocked by the provider,

While the base material of braces should not change extrusion blow molding offers an efficient
means of lining the brace with a softer material. While speaking with current users of orthotic devices
the chief complaint was that, the brace could stand to be more form fit as well as a softer material to
interface with is desired. The form fitting is solved by hot fitting the part. The softer feel can be solved
by means of co-extrusion. In using co-extrusion the current ballistic nylon shell material is still utilized
however the inner material should be a thermo-plastic elastomer with a durometer similar to that of
human skin (on the shore scale this should be around 40 to 45). This soft inner material should create a
more comfortable brace that the end user will be more comfortable in the said device. This softer
material should be more comfortable as well as cut down on blisters, calluses, pressure sores, and
undue wear to the users’ skin that is in contact with the device. To create the same part using injection
molding a two shot mold is required adding complexity and costs to the already costly injection molded
part. This would also take more time to create in the injection molding process.

For military applications, these same braces can be used as lighter weight rigid body armor. A
blow-molded part would provide for quicker production of protective wears. This also produces a full
bracing system for our men and women in the field that can be used to cut down on what supplies are
needed by the field hospitals. Fewer supplies that are required for cast materials can translate to more
supplies that are vital to saving lives.

Design Details

In order to keep similar strength to weight ratios within orthotic braces a ballistic nylon should
be used. This presents some difficulties concerning melt strength, however if an accumulator system is
utilized this difficulty should be small. The mold itself should be slightly textured in order to allow for
venting. If additional vents are required, the optimal placement should be where the part is to be
trimmed in subsequent operations.

In a full production, setting it is important to have several sizes of mold for a given brace. This
concept gives the ability to fit nearly everybody. Fewer custom molds will drive the price of orthotics
down while keeping the quality of the device high. The multiple sizes create a standard for fitting while
at the same time providing for the likelihood that a standard size exists for most people. It is also
important to remember that each brace will be form fit to the wearer so a perfect fit right out of the
molding machine is not required. The life expectancy of the current technology bracing is less than five
years less for braces with movable joints. This ensures that bracing is a renewable resource industry and
has longevity for an industry. The new technology will extend this somewhat however there will still be a
need for replacements due to wear and tear. The comfort, cost, and variety of function of the basic
blow-mold technology are the reasons to explore the option of new technology.
The shapes of the parts being a casing of the human body tend to provide for a natural draft within the tooling. This can aid in ejection of the part. The blow ratios usually at about 1. These blow ratios vary based on which brace is being produced as well as the draft that is naturally provided.

The utilization of co-extrusion to place a softer material in contact with the wearer will help cut down on pressure sores as well as undue wear of the skin that is in contact with the device. While this process is possible with injection molding it requires specialty machinery or the softer layers are assembled afterward-adding substantial thickness to the part.

Mold and Tooling

The tooling for this family of products is rather simple. A basic blow mold made of steel for longevity should suffice. The extrusion blow-molding machine requires an accumulator in order to compensate for the low melt strength of the ballistic nylon. All operations should take place in a clean room, which for some molders could pose a problem. Most of the specialty in the part itself is the secondary operations of cutting the blow-molded part into its separate components and attaching the strapping mechanisms to attach the part to the user.

If these braces become commonplace as a replacement to plaster casts in order to heal a broken bone the strapping mechanisms can be interchanged with a locking mechanism. This is to protect the user from taking off the “cast” prematurely. The advantages of using these parts as casts is that it allows the wearer to bathe regularly without having to protect their cast from moisture. It also allows doctors easy access to the limb in question if there are lacerations that are to be treated. This ease of access can allow any covered wounds to heal more quickly and efficiently than they could have if covered by plaster and gauze. This easily removable casting system will avoid epidermal and dermal infections that can occur in a standard casting system when other injuries are present.

Manufacturing Details

The parts themselves will have the seams to be cut at molded in. This molded in seam will mean that the trimming operation will create a part that is statistically identical as every other until it becomes hot fit. Once the part is cut into the separate pieces of the brace; the straps that fasten the brace to the wearer can be attached. The straps would still utilize the same rivets that are in current use. This hollow part is then ready to be packaged and shipped to a hospital to begin the service life and help another human being.

In the event that the braces become used as a replacement to plaster casts for the mending of broken bones, new jobs will be created for the United States of America. This process may also have a global impact as the idea of using a blow molded part as a common medical device catches on throughout the world. In a global market, this part has the potential to bring jobs and money into the United States while keeping operating costs relatively low.
The only major issue is the use of co-extrusion. This makes it rather difficult and nearly impossible to recycle the trimming. This can be considered negligible, as medical parts commonly require that only virgin material be used.

While the material that is scrap may not be able to be reused, the old braces themselves can. After proper sterilization a brace can be reused and refit to a new wearer. This process can increase the longevity of the part beyond a single broken bone thus making the medical field more efficient. This also provides an outlet for mission work. This mission work can change the life of a person who would not normally be able to afford one of these life-changing devices.

Blow molding processes create hollow parts more efficiently than most other processes. When creating orthotic braces, which are essentially hollow tubes, this process proves invaluable. This process seems a perfect fit to the given application, and yet historically orthotic devices have been only injection molded. It is time for a change; not only in how the supportive and realigning braces are made, but the design features that they provide as well.

**Drawings**

The following pages include drawings with standard three view drawings and isometric pictures.
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