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(54) Title: PROCESS FOR PRODUCING AN EXTERNAL FIXATION DEVICE, PARTICULARLY AN ILIZAROV FIXATOR

(57) Abstract: A method of producing components of an external fixation device for treatment on a living body, particularly an Ilizarov external fixator is disclosed. A high performance engineering polymer is used in the injection molding process for the production of rings, plates, rods or arches of an external fixation device.
PROCESS FOR PRODUCING AN EXTERNAL FIXATION DEVICE,
PARTICULARLY AN ILIZAROV FIXATOR

Technical Field of the Invention
5 The present invention relates to a process for producing body components of an external fixation device, particularly an Ilizarov External Fixator wherein polymer based materials, particularly thermosets or thermoplastics are used as the base material in an injection moulding process. The present invention aims to eliminate major material related drawbacks of metal and composite fixation devices to provide a light and durable fixation device having x-ray permeability.

Background of the Invention / Prior Art
Various external fixation devices exist in the market. These, and particularly Ilizarov fixators are either made of metal or carbon-fiber composites. The Ilizarov external fixator was first developed in Russia by Gabriel A. Ilizarov in 1950s. Ilizarov's method is a system consisting of rings and rods used to fix the bone externally. He developed not only a mechanical external fixator, but also achieved distraction osteogenesis, a technique to produce longitudinal bone growth. Use of this technique has progressed over the last several years to include correction of angular deformities, congenital abnormalities, leg and arm length inequalities, soft tissue contractures, and recently the treatment of acute complicated periarticular fractures. The use of the external fixator has a steep learning curve and is technically very demanding, both from an operative perspective and its labor-intensive postoperative management.

25 The present invention proposes a new production process for manufacturing rings, foot rings, arches, plates and the like used in a typical Ilizarov system. Accordingly, components of the Ilizarov system are made of polymeric materials, preferably thermoplastics or thermosets, which eliminate major drawbacks of existing fixation devices that are made of either metal or composites or a combination thereof. These drawbacks include high weight of the final product, x-ray impermeability and high cost of the end product.

As an example, all classical fixation devices made of stainless steel appears on X-ray films and block partially or totally the view of the bone, or especially the fracture zone on the bone at which the orthopedist is applying the treatment. A second drawback of classical external fixators arises from the fact that the fixation device in some cases
has a considerable weight, which inadvertently affects treatment on rather larger bones. In order to eliminate this latter problem associated with the weight of an external fixator, lightweight metals are employed in the production of the same. These however still accompany the disadvantage of X-ray impermeability and in some cases, corrosion.

Recently, major components of the Ilizarov fixation devices, such as rings, foot rings, arches, and plates are produced from some composite materials such as carbon fibers due to their lower weight and radio lucent properties. Despite these advantages, fixation devices made of carbon fiber composites still have important drawbacks such as their high cost, difficult manufacturing process and non-reliable operative nature. In order to fix the components to each other, holes, bolts and nuts are essential elements in an external fixation system. As apparent to those skilled in the art, fibers are broken during drilling of holes in a component. Since a large number of broken and cracked fibers exist in the region of a drilled hole, these constitute a potential risk of an infection around that region. Particles that break from a drill position any time during operation may contact its vicinity and lead to an infection on the patient body.

**Objects of the Invention**

An object of the present invention is to provide a process for the production of an external fixation device, particularly an Ilizarov external fixator, made of a lightweight and non-corrosive material.

Another object of the present invention is to provide a process for the production of an external fixation device, particularly an Ilizarov external fixator, having components such as rings, foot rings, arches and plates that are radiolucent on X-Ray films.

A further object of the present invention is to provide a process for the production of an external fixation device, particularly an Ilizarov external fixator, in which the problem of cracks around holes or separation of small particles are eliminated to avoid infection risks.

Still a further object of the present invention is to provide a low-cost external fixation device, particularly an Ilizarov external fixator, which can be re-sterilized at an elevated temperature upto 150°C.
Summary of the Invention
The objects of the invention are achieved through use of thermoplastic or thermoset plastic materials in an injection moulding process in the production of basic components of an external fixation device, such as an Ilizarov fixator which is used for lengthening the bones such as femur, tibia, humerus, ulna and radius in short-statured people, in post-traumatic reconstructions, for the treatment of osteomyelitis of the long bones, acute fractures, correction of angular deformities, congenital abnormalities, leg and arm length inequalities, soft tissue contractures and acute complicated periarticular fractures.

Major disadvantages of the metallic and fiber composite materials in the existing fixator systems are eliminated through the use of polymer materials in the production of components such as rings, foot rings, arches, plates and rods. Thermoset and thermoplastic polymers bring the advantages of non-corrosive, radiolucent, lightweight and smooth surface properties. Unlike the classical fixators made of metals and composites, the manufacturing process does not involve drilling or machining tools, which result in chippings or cuttings. Instead, all components are molded as ready for use.

The present invention also proposes a process, which enables rapid and mass production of components of an external fixation device, thus enabling considerable reductions in the cost of an end product. Injection molding is also a rapid production process enabling all products to be in a standard size.

Brief Description of the Figures
Accompanying figures are given solely for the purpose of schematically exemplifying the principle products of the present invention.

Fig. 1 represents a ring produced according to the present invention using thermoset or thermoplastic materials.

Fig. 2 similarly represents a foot ring produced with same process and the same materials.

Fig. 3 shows an arch made of thermoplastic or thermoset materials in a plastic injection method.
Fig. 4 shows a plate made of again thermoplastic or thermoset materials in a plastic injection process.

Fig. 5 is a schematic illustration of an injection-molding machine used in the production of an external fixation device proposed by the present invention.

**Detailed Description of the Invention**

Ilizarov external fixator devices are widely used for various purposes such as lengthening the bones such as femur, tibia, humerus, ulna and radius in short-statured people, in post-traumatic reconstructions, for the treatment of osteomyelits of the long bones, acute fractures, correction of angular deformities, congenital abnormalities, leg and arm length inequalities, soft tissue contractures and acute complicated periarticular fractures as explained above. Main components of these fixation devices are rings, foot rings, arches and plates, which have been until present produced of generally stainless steel, aluminum alloys and carbon fiber composites.

The present invention proposes a process to production of major components of an external fixation device for treatment on a living body. Metallic or composite components may also be used in combination to high performance polymeric components of the present invention. Since all parts of such a fixation device do not necessarily be fully made of a single material, the present invention proposes a method for production of components on the body of a fixation device. These include rings, foot rings, arches, plates and rods.

An Ilizarov ring produced of a thermoplastic material is shown in fig. 1. Rings are half ring shaped and served in various diameters. There are holes (1.1) on the rings lined up in the axis of the ring to fit the rods and fixing bolts. For the two rings to be on the same plane when assembled, the end of the rings is shaped in a step design (2.1). Rings in various sizes can be designed according to thickness and width (3.1) of the products. The dimensions or the number of holes can easily be changed on desire.

Figure 2 shows a foot ring produced of thermoplastic material. These components are used when fixation of the posterior aspect of the foot is required. Foot rings are designed to fit the shape of the foot and work in accordance with the other components of the system. The number of holes (1.2), thickness, and width of the foot rings (2.2) are increased proportionally with the diameter in order to fit different sizes.
An arch produced of thermoplastic material is shown in Fig 3. Arches (3.3) are produced in different diameters and lengths and are designed to fit the rods and bolts located on the different components of the Ilizarov system. Schanz screw can be connected to bone from any place (1.3) throughout the arch as the holes (2.3) are formed in various positions. These arches are used together with Schanz screw especially on proximal femur and pelvis.

Figure 4 shows a plate (2.4) produced of thermoplastic material. The plates can be manufactured in different sizes and the holes (1.4) are designed to fit the rods and bolts and also to be used with the other components of the system. These plates are used to connect rings in different diameters and to form different shapes like foot components.

As explained above these products had a number of problems such as corrosion, high weight, X-ray impermeability and machining/drilling chips, which pose major drawbacks in the treatment of a patient. The present invention aims to eliminate these drawbacks by way of employing a new process for the production of external fixation devices, particularly an Ilizarov fixator utilizing polymers in the manufacturing.

Preferably, all components like arches, plates and rods in an external fixation device according to the present invention are made of thermoset or thermoplastics groups of polymers. As well known in the related industry, these materials are radio lucent, lightweight and non-corrosive materials, which can also provide smooth surfaces in a molding process. As the process does not require machining or drilling the holes, the components do not carry the risk of infectious particles breaking from machined surfaces. According to the present invention, details like notches, threads on a component of the fixation device are formed integrally with the component during the molding process.

Even with aluminum alloy products coated by surface anodizing, reports show traces of corrosion after several sterilization processes. Components of an external fixation device according to the present invention, however, pose absolutely no risk of corrosion as they are produced of polymers.

Granulated thermoset or thermoplastic material is collected in a tank (11) in which it is heated to the material’s damp removing temperature. It is then injected into a funnel
of an injection machine e.g. one as shown in fig. 5 and pushed towards the heating cylinder (13) by a piston (12). With the effect of heating in the cylinder and the friction forces among the granules under elevated pressure, the plastic material softens passing through an adjustable valve and comes into the injection nozzle. The female part of the mold which is fixed on a moving plate (15) is then pushed by a mold-closing piston (21), which is guided on coupling rods (16). A mold adjustment tool (19) ensures that the male and female parts of the mold perfectly fit to each other. Injection is started with the full stroke of the mold-closing piston (21) until the male and female parts of the mold fully engage. The molten material heated in the heating cylinder (13) is then injected in between the male and female molds through a nozzle. After filling the molds, the molten plastic material starts to cool down and takes the shape of the internal volume in between the male and female parts guided on a coupling rod (16). The product solidifies as it cools down and is taken out of the molds after clamps of the molds are unfastened following the solidification. A control panel (17) is used to monitor the operation parameters of the injection machine.

As fixation devices are used after sterilization at an elevated temperature, generally around 120°C, the polymer to be used in such a moulding process shall be resistant to heat-related effects such as deformation in shape. Glass transition temperature of the polymer used in such a process shall be more than 150°C. As the temperature drops, the material passes through the glass transition temperature and its mechanical properties change from those of a rubber to those of a brittle material, like glass.

Example 1

An Ilizarov fixator system, comprising a number of ring, foot ring, arch and plate, is produced using Polyetherimide (PEI) resin as raw material in a plastic injection process. Table-1 below shows process parameters of the Polyetherimide resin, which is represented by the general formula C_{27}H_{24}O_6N_2.
Table 1: Injection Moulding Polyetherimide

<table>
<thead>
<tr>
<th>Process Parameter</th>
<th>Typical Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amorphous density (at room temp.)</td>
<td>1.3 g/cm³</td>
</tr>
<tr>
<td>Drying Temperature</td>
<td>150°C</td>
</tr>
<tr>
<td>Drying Time</td>
<td>4 – 6 hrs.</td>
</tr>
<tr>
<td>Maximum Moisture Content</td>
<td>0.02 %</td>
</tr>
<tr>
<td>Melt Temperature</td>
<td>370 – 410°C</td>
</tr>
<tr>
<td>Nozzle Temperature</td>
<td>360 – 410°C</td>
</tr>
<tr>
<td>Hopper Temperature</td>
<td>80 – 120°C</td>
</tr>
<tr>
<td>Mold Temperature</td>
<td>140 – 180°C</td>
</tr>
</tbody>
</table>

Polyetherimide (PEI) is a high performance engineering thermoplastic resin. PEI's characteristics include high strength and rigidity at elevated temperatures, long term heat resistance, dimensional stability and good electrical properties. Like other amorphous, high temperature resins, PEI has outstanding dimensional stability and is inherently flame retardant. PEI does resist chemicals such as hydrocarbons, alcohols, and halogenated solvents. Moreover, PEI resins are cost effective and colorable.

Damp removing temperature of the granulated raw material was 150°C whereas the molding temperature ranged between 140°C to 180°C. Injection temperature of the molten polymer in this case was determined to be between 350°C and 420°C. Glass transition temperature of PEI is 216°C.

The injection-molding machine reduces pelletized PEI resin and colorants into a hot liquid. This "melt" is forced into a temperature adjustable mold under tremendous pressure. After the material solidifies, the mold is unclamped and a finished part is ejected. Injection molding offers the lowest piece prices available. Using different molds, the shape of the produced components of the Ilizarov fixator may be changed. The unit clamps the mold in a closed position during injection, opens the mold after cooling, and ejects the finished part made of PEI resin.
Claims:

1. A process for producing components of an external fixation device for treatment on a living body, and particularly an Ilizarov fixator, which comprises the steps of:
   a-) heating a thermoplastic or a thermoset type polymer up to the melting point of the same,
   b-) pressurizing the molten polymer and moving the same into an injector,
   c-) injecting the molten polymer into a space formed between at least one male and female part of a mold,
   d-) cooling molten polymer and allowing the same to solidify,
   e-) separating the parts of the mold and retrieving a component of said fixation device.

2. A process for producing components of an external fixation device according to claim 1 wherein said polymer has a glass transition temperature, which is more than 150°C.

3. A process for producing components of an external fixation device according to claim 1 wherein said polymer material has a melting point more than 150°C.

4. A process for producing components of an external fixation device according to claims 1-3 wherein the polymer is pre-heated to a damp removing temperature prior to being heated to its melting temperature.

5. A process for producing components of an external fixation device according to any of the preceding claims wherein said polymer material is Polyetherimide.

6. A component of an external fixation device for treatment on a living body, produced according to a process of any of the claims 1 to 5.

7. An Ilizarov fixator whose ring, arch, plate or rod is produced according to a process of any of the claims 1 to 5.