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(54) **INJECTABLE FASTENER SYSTEM AND METHOD**

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(51) **Int. Cl.**

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(58) **Field of Classification Search**

None

See application file for complete search history.

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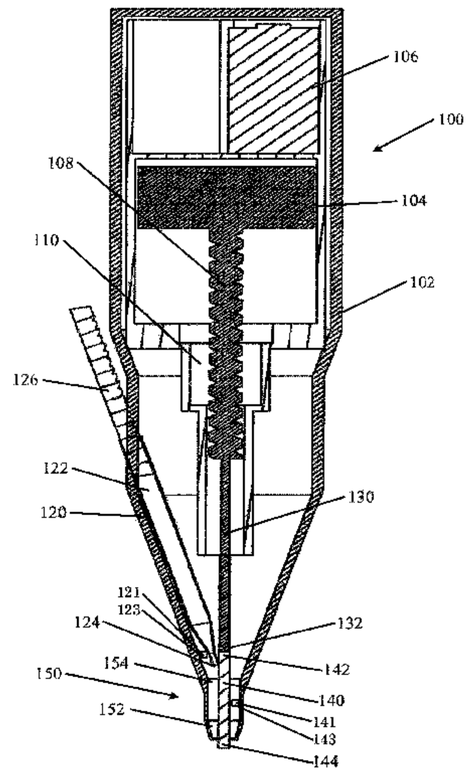
(57) **ABSTRACT**

Methods and devices are shown for forming polymer fasteners into bone by expelling the polymer from a cannula. Devices and methods shown allow a user to form multiple fasteners of various sizes without re-loading a device. Devices and methods shown further provide temperature profiles during fastener formation that reduce or eliminate thermal necrosis. Devices and methods shown further provide fasteners with increased strength.

48 Claims, 4 Drawing Sheets



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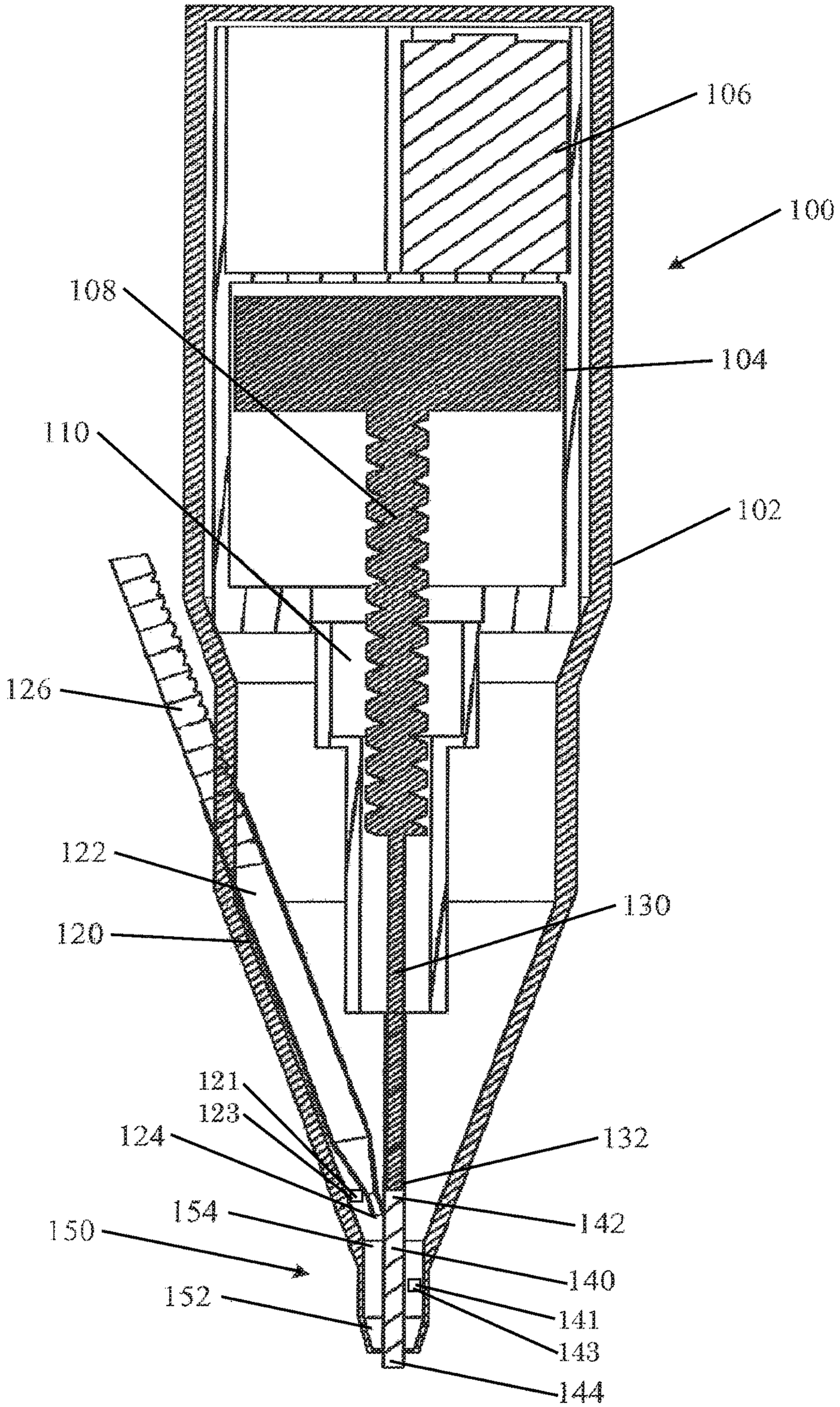

FIG. 1

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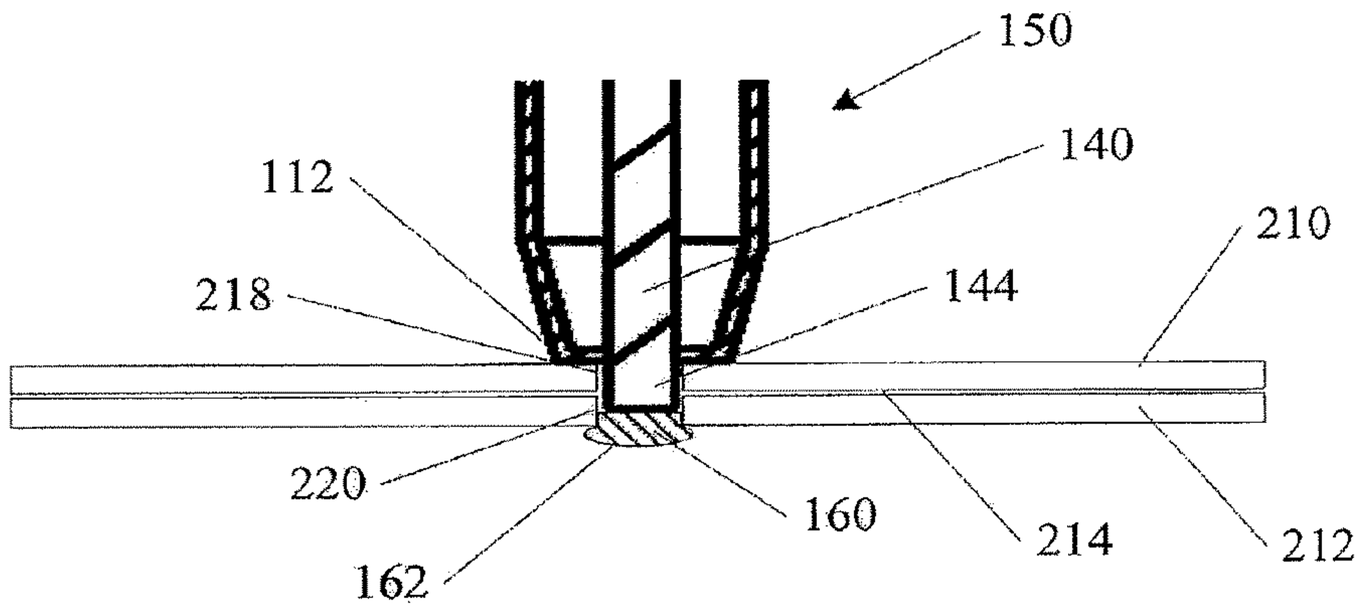

FIG. 2

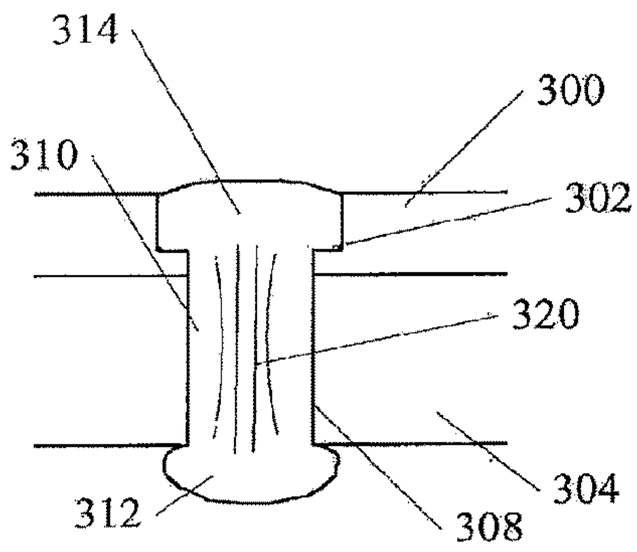

FIG. 3

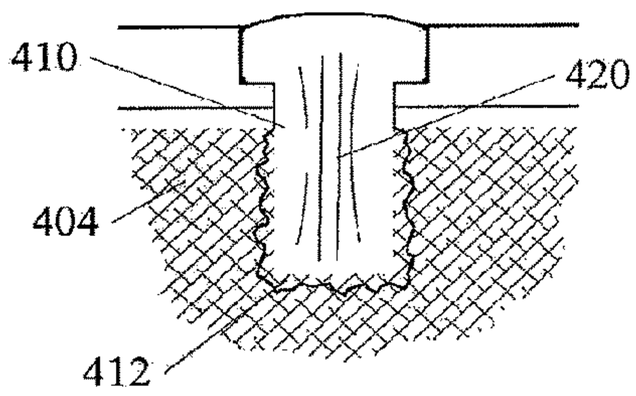

FIG. 4

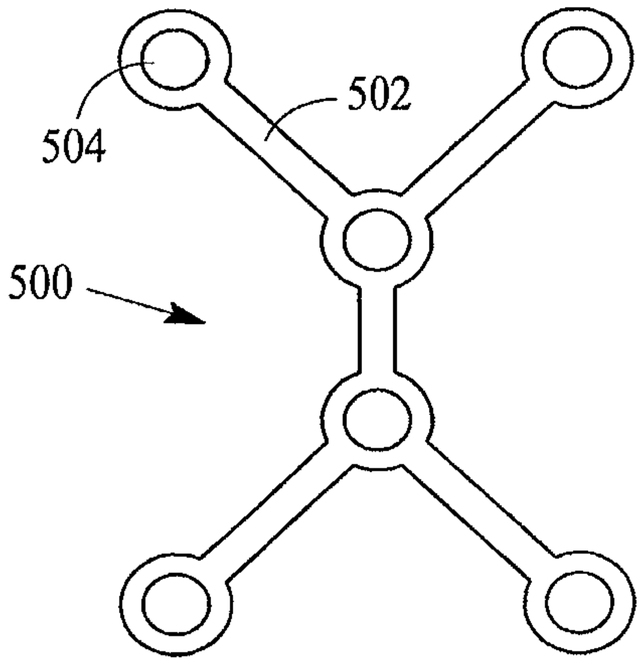

FIG. 5

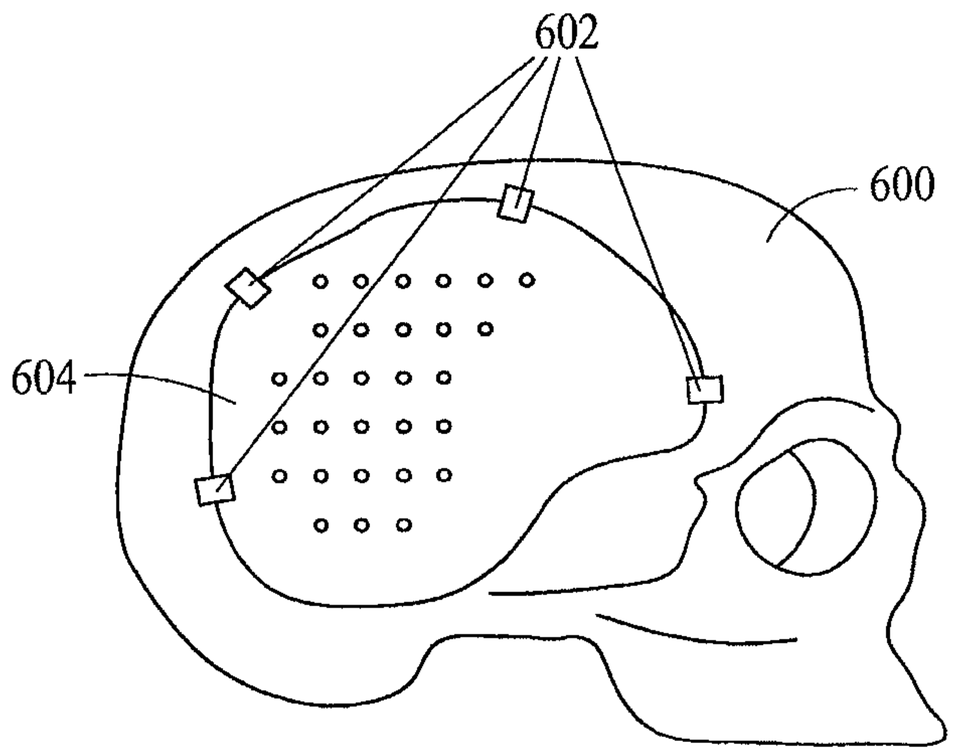

FIG. 6

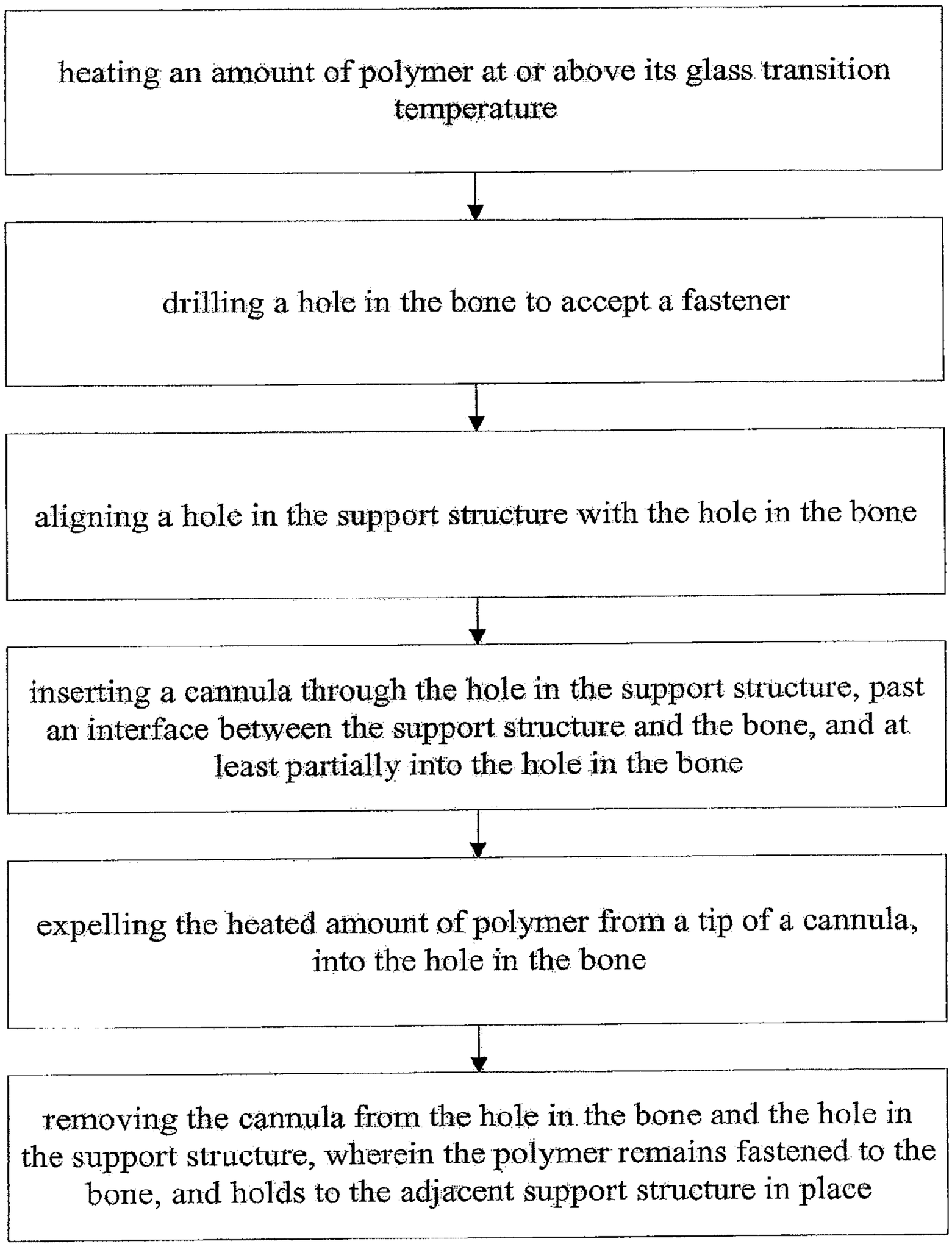
heating an amount of polymer at or above its glass transition temperature
drilling a hole in the bone to accept a fastener
aligning a hole in the support structure with the hole in the bone
inserting a cannula through the hole in the support structure, past an interface between the support structure and the bone, and at least partially into the hole in the bone
expelling the heated amount of polymer from a tip of a cannula, into the hole in the bone
removing the cannula from the hole in the bone and the hole in the support structure, wherein the polymer remains fastened to the bone, and holds to the adjacent support structure in place

FIG. 7

INJECTABLE FASTENER SYSTEM AND METHOD

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a *reissue application of U.S. Pat. No. 8,641,722, issued Feb. 4, 2014, which is a* continuation of U.S. patent application Ser. No. 11/959,675 filed Dec. 19, 2007, *now U.S. Pat. No. 8,197,491,* which claims priority to U.S. Provisional Application No. 60/870,757 filed Dec. 19, 2006, all of which are incorporated herein by reference in their entireties.

BACKGROUND

The present invention relates to methods for attaching plates to bone. Specific examples include attaching bioresorbable plates to bone using bioresorbable fasteners.

One current methods for attaching bioresorbable plates to bone fragments is bioresorbable screws inserted with a screwdriver either manually or powered. In order to insert a screw, a threaded hole must be made into the bone. Threading or tapping is very technique sensitive and if done incorrectly the screw will not properly hold the plate to the bone. In addition, using a manual screwdriver can cause surgeon fatigue if the case requires more than a few screws to be inserted. Using a powered screwdriver speeds insertion and reduces surgeon fatigue, but can strip screws or torque off the screw head if not handled properly. The strength of standard bioresorbable screws is also in need of improvement, particularly for load bearing applications. Methods to improve the strength of resorbable screws through drawing exist, but require additional manufacturing processes and require that each screw is individually machined which is more time consuming than injection molding of standard screws. Even with these processes, the shear strength of a screw is diminished since only the minor root diameter of the threads impart the load carrying capacity. A screw that is marketed as 1.5 diameter actually only has the strength of a 1.1 diameter pin since the threads do not impart strength, but only pull out resistance.

Another method for attaching plates is using tacks or rivets. Inserting a tack is very technique sensitive. If the hole is drilled slightly oversized, a tack will not have sufficient holding power. Even if the hole is of the proper size, a tack generally does not have the same pull out resistance as screws since no threads are formed into the bone.

Eaves et al in U.S. Pat. No. 6,080,161 describe a cannulated pin that is inserted into a hole, heated and deformed in place. This method obviates the need to tap the hole and provides a means to accommodate slight variations in the diameter of the hole that is drilled. However each fastener must be individually heated adding additional time to the operative procedure. Also, the heat required to deform the fastener can add the risk of thermal necrosis to the surrounding tissue.

A relatively new method of fastener insertion is an ultrasonically inserted pin inserted using a sonotrode. This method is relatively simple, does not require tapping and requires only a minimal amount of training. The high temperatures created during insertion may induce thermal necrosis. This risk is especially pronounced at the interface of the polymer and the bone since this is where the heat is generated during insertion. Also, the molten polymer can be extruded under the plate and away from the hole during insertion since the hole that is drilled is smaller than the diameter of the fastener. Also, the fastener will often melt to the plate making removal of one individual fastener from the plate difficult.

In all of the above listed methods, the instrument must be reloaded after each fastener is inserted. This can be a time consuming process and the fastener is at times unintentionally disengaged from the instrument during this handling process. In addition, multiple lengths and diameters of fasteners must be on hand to complete each case. These fasteners are packaged in bulky packages and significant space is required to house this inventory.

A need exists for an improved fastener and method that addresses these and other concerns.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section of an example bone support attachment device according to an embodiment of the invention.

FIG. **2** illustrates a stage in a fastening operation according to an embodiment of the invention.

FIG. **3** illustrates another stage in a fastening operation according to an embodiment of the invention.

FIG. **4** illustrates another stage in a fastening operation according to an embodiment of the invention.

FIG. **5** illustrates an example bone support structure for use according to an embodiment of the invention.

FIG. **6** illustrates a number of example bone support structures in place on a skull according to an embodiment of the invention.

FIG. **7** is a flow diagram of an example method according to an embodiment of the invention.

DETAILED DESCRIPTION

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown, by way of illustration, specific embodiments in which the invention may be practiced. In the drawings, like numerals describe substantially similar components throughout the several views. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention. Other embodiments may be utilized and minor deviations may be made without departing from the scope of the present invention.

FIG. **1** shows an example of a bone support attachment device **100**. In one embodiment, an amount of polymer is heated to a temperature to provide desired properties such as a temperature high enough to flow, and low enough to limit or prevent necrosis of tissue. The flowable polymer is expelled from an end of the bone support attachment device **100**, and hardens in place to form a bone fastener. In one embodiment, the polymer includes a bioresorbable polymer. Selected details and advantages are discussed in more detail below.

A body **102** forms the structure of the bone support attachment device **100**. At one end of the device **100** is located an injection cannula **140**. A plunger **130** is configured to pass through the injection cannula **140** and expel an

amount of polymer from the injection cannula **140**. The plunger **130** shown in the embodiment of FIG. **1** enters the injection cannula at a first end **142** of the injection cannula **140**, which in turn expels an amount of polymer from a second end **144** of the injection cannula **140**.

In one embodiment, the plunger is driven with respect to the cannula using a motor **104**. One example of a plunger driving system includes a threaded member **108** coupled to the motor **104**, although the invention is not so limited. Other examples of plunger driving systems include, but are not limited to manual operation, pneumatic operation, a controlled chemical reaction or explosion.

A battery **106** is illustrated in FIG. **1** to power aspects of the bone support attachment device **100**, including the motor **104**. One example of a battery **106** includes a lithium ion battery. Other battery examples include nicad, alkaline, lead acid and nickel metal hydride. The batteries **106** can either be of the disposable or rechargeable type. In alternate embodiments the power source is an AC to DC power supply that energizes the motor via a cable.

A polymer supply inlet **124** is shown coupled to a side of the injection cannula **140**. In operation, when a tip **132** of the plunger **130** travels from the first end **142** toward the second end **144** of the injection cannula **140**, the supply inlet **124** is cut off as the tip **132** passes by. When the tip **132** is returned to the first end **142** of the injection cannula, the supply inlet **124** is again exposed and available to refill the injection cannula **140**.

In one embodiment, a chamber **120** is included to house a block of polymer. In one example the chamber **120** includes a cannula, or other cylindrical chamber, although the invention is not so limited. FIG. **1** shows a block of polymer **122** located within the chamber **120**. Using a chamber, and a supply of polymer **122**, multiple fasteners can be formed without reloading the bone support attachment device **100**. Additionally, fasteners of varying dimensions can be formed from a single polymer supply. For example a fastener with a larger diameter for additional strength, or a fastener with a longer length to accommodate a thicker bone support plate can be formed.

To form multiple fasteners, fasteners of varying dimensions, etc., the plunger **130** is withdrawn into a selected location within the injection cannula **140**. Heated polymer is flowed into the injection cannula **140** through the polymer supply inlet **124**. In one embodiment a local region of the chamber **120** near the inlet **124** is heated to a sufficient temperature to flow the polymer. A mechanical feed system, manual feed, or other system provides pressure to inject the liquid polymer at the inlet **124** into the injection cannula **140**.

In one embodiment, a starting position of the tip **132** of the plunger **130** is varied to adjust a volume of the injection cannula available for polymer. The flowing polymer will fill the size hole as will be described in more detail below, while the volume of polymer necessary to form the fastener is selected by moving the starting location of the tip **132**.

In an alternate embodiment, the volume of material that is transferred into the injection cannula **140** is controlled by the displacement of cartridge plunger **126**. The displacement of this cartridge can be controlled by any means, including, but not limited to a variable displacement mechanism or motor. The means of adjusting the displacement can be user controlled either through a knob, lever, or switch.

In certain procedures, few fasteners are utilized and thus a volume of polymer that can delivery approximately 5 fasteners may be sufficient. In other cases, such as in a craniosynostosis case, more than **150** fasteners may be utilized. In these cases a volume of polymer that could deliver **20** or more fasteners would be beneficial to reduce the number of times that the cartridge needs to be replaced during the procedure. The number of fasteners that can be delivered from each chamber **120** is dependent on the volume of the final fastener and the volume of polymer within the chamber **120**.

The diameter of the chamber **120** can be modified to suit the requirements for size, heat transfer, the size of fastener desired and the number of fasteners per cartridge. In the preferred embodiment, the chamber diameter is between 2 and 4 mm and is between 30 and 50 mm long to deliver up to approximately 20 fasteners. However, invention is not so limited.

In one embodiment, the polymer **122** is heated within at least a portion of the chamber **120**. It is desirable to heat the polymer to a temperature where the polymer flows, but at a temperature that is not so high as to cause necrosis of tissue. In one example the polymer **122** is substantially non-flowable at room temperature or physiological temperatures (i.e. 15-37° C.). The polymer **122** or portions of the polymer are heated to a temperature of at least the glass transition temperature (T_g), where the material is rendered sufficiently flowable to be expelled from the chamber **120**. In one embodiment, the polymer **122** and chamber **120** are coordinated together as a cartridge. In other embodiments, the polymer **122** is refillable by itself, and inserted into a chamber **120** that is part of the bone support attachment device **100**.

For one example bioresorbable polymer, the T_g is approximately 55° C. While this describes the minimum temperature required to be render the material at least partially flowable, it may be advantageous to increase the temperature to a temperature up to or even above the melting point of the polymer to reduce the force required to expel the material from the injection cannula **140**. In one embodiment this temperature is between 130 and 180° C., but temperatures between 50 and 250° C. could be utilized. It is, however, advantageous not to excessively heat the polymer **122**. Excessive heat will degrade the polymer, consume additional power from the internal power source, heat the instrument itself and create an injected polymer that can cause thermal necrosis.

In certain embodiments, the temperature of the polymer **122** within the chamber **120** may not be homogeneous, but rather incorporate a gradient from a higher temperature adjacent to the polymer supply inlet **124** to a lower temperature where polymer flow is not necessary. This gradient can be incorporated to optimize the expulsion force while minimizing the issues associated with excessive heat in the polymer addressed above. Certain embodiments may only actively heat the region adjacent to the polymer supply inlet **124** to provide this gradient.

The method of producing heat in the preferred embodiment is through electrically resistive elements *121* that are powered by the battery or batteries **106**. Materials that these electrically resistive elements *121* can be manufactured from include, but are not limited to, nickel chromium wire, conductive plastics, ceramics, quartz, etc. In alternative embodiments, the methods of producing heat may include, but are not limited to, induction, radio frequency, vibrational, ultrasonic, microwave, frictional, exothermic chemical reactions and infrared. The temperature can either be controlled actively or passively. Any known method of active temperature control could be utilized including sensing the temperature through a temperature sensor and utilizing this to control the amount of power going to the heater

123 (*shown schematically*). Resistive heating elements *121* that have a resistance that increases with increasing temperature (positive temperature coefficient or PTC) can provide a means of self regulating their temperature actively without additional controls. In alternate embodiments the temperature is controlled passively without active regulation.

In one embodiment, the polymer includes a thermoplastic polymer **122**. On example of a thermoplastic polymer includes a bioresorbable aliphatic polyester. Aliphatic polyesters that can be used in this device include, but are not limited to, homo- and co-polymers of polylactic acid, polyglycolic acid and polycaprolactone. These polymers have been used for a number of years in orthopedic devices and are generally regarded as biocompatible and bioresorbable. In the preferred embodiment the polymer is substantially non-crystalline, but at least partially crystalline polymers could be used. Other biocompatible but non-resorbable polymers could be used in instances where the resorbability was undesirable. Non-resorbable polymers that could be used include, but are not limited to, acrylic, polycarbonate, PEEK, polypropylene, and polyethylene.

In one embodiment, the thermoplastic polymer **122** is compounded with an agent to increase radiopacity, osteoconductivity, osteoinductivity or deliver a therapeutic agent. Possible radiopacifiers include, but are not limited to, barium sulfate, zirconium oxide, titanium oxide, titanium dioxide, calcium, tantillum and iodine. Agents to increase osteoconductivity include, but are not limited to, hydroxyapatite, calcium phosphate and calcium sulfate. Agents to increase osteoinductivity include, but are not limited to, bone morphogenic proteins and growth factors. Therapeutic agents include, but are limited to, antibiotics, antiseptics, analgesics, chemotherapeutics, and pain medications.

As mentioned above, in one embodiment the chamber **120** and polymer **122** are coordinated together as a replaceable cartridge. This configuration provides a disposable delivery vessel for the polymer to obviate the need to clean the internal mechanisms and chambers of the injection device. One example chamber **120** in a cartridge embodiment is constructed of a heat resistance metal such as stainless steel or aluminum or of a heat resistant, biocompatible polymer such as PEEK, polysulphone, Radel, or polycarbonate.

In selected polymer cartridge embodiments, the cartridge further includes a cartridge plunger **126** that expels the polymer when advanced. In one embodiment the cartridge plunger **126** is integral to the polymer cartridge and is disposed of along with the polymer cartridge. In alternative embodiments, the cartridge plunger **126** is a part of the bone support attachment device **100** and separated by a seal from the polymer **122**. The advancement of the cartridge plunger **126** is controlled by the bone support attachment device **100** as described in more detail below.

In an alternate embodiment the polymer **122** is provided in discrete sections that are not heated in the chamber **120**. The volume of each section would correspond to the desired volume of each fastener. In this embodiment the unheated sections are individually transferred to the injection cannula through a mechanism, or manually. They are then individually heated in the injection cannula **140**. In one embodiment, they are stacked in a linear or circular array. Alternately, they could be transferred individually into the injection cannula by the user without the aid of an internal mechanism or cartridge.

In one embodiment, one or more heating elements *141* are provided at a tip region **150** surrounding the injection cannula **140**. The heating elements *141* in the tip region provide further control of the polymer temperature as it comes into contact with tissue and forms a fastener.

In one embodiment the injection cannula **140** is actively heated in the entire region from the first end **142** to the second end **144**. In one embodiment at least part of the heat for the injection cannula is generated through an actively regulated heater *143* (*shown schematically*) in order to maintain consistent temperatures. Once the cannula exits the distal tip, it is exposed to variable thermal conditions (i.e. dry bone, wet bone, room temperature, physiological temperature). Active temperature regulation will help to maintain a consistent temperature profile in the cannula. In one embodiment, a thermal gradient is provided in the injection cannula **140** where the polymer **122** is at a higher temperature in a proximal region **154** of the tip than at a distal end **152** of the tip **150**. The higher temperature at the proximal end **154** facilitates improved flow characteristics, while the lower and more tightly controlled temperature at the distal end **152** reduces the possibility of necrosis in tissue. In one embodiment, multiple heating elements *141* and/or thermal control circuits are used to control the temperature gradient.

FIG. **2** shows a close of view of the tip **150** of the bone support attachment device **100** during formation of a fastener. A cross section view of a bone support structure **210** is shown located adjacent to a portion of bone **212**. A hole **218** is included through the bone support structure **210** and a corresponding hole **220** is included in the bone **212**.

In one embodiment, the bone support structure **210** includes a plate, although other forms of support structures are within the scope of the invention. In one embodiment, the bone support structure **210** is formed from a bioresorbable material such as a bioresorbable polymer. In one example, the bone **212** is a thin layer of bone, such as a portion of a skull, although the invention is not so limited. An interface **214** is formed between the bone support structure **210** and the bone **212**. As shown in the Figure, frequently a gap is included at the interface **214**.

In one embodiment, a depth gauge **112** is included near the tip **150** of the bone support attachment device **100**. An example of a depth gauge includes a static shelf that butts against the bone support structure **210** and limits a depth that the injection cannula **140** travels within the holes **218** and **220**. The depth gauge **112** determines where in the holes **218** and **220** the second end **144** of the injection cannula **140** is located. In one embodiment, the desired depth of the second end **144** is through the hole **218** in the bone support structure **210**, past the interface **214** and partially into the hole **220** in the bone. By passing the interface with the second end **144**, a possibility of polymer being extruded into a gap at the interface **214** is reduced or eliminated.

Extrusion of polymer between any gap at the interface is undesirable for a number of reasons. Any polymer that is accidentally extruded at the interface is not available to form structural portions of the fastener, therefore strength of the fastener is lessened by extrusion into a gap at the interface. Further, any extrusion at the interface tends to open any existing gap further.

In one embodiment, the depth gauge **112** is dynamic. For example, in one embodiment, once a predetermined volume of polymer is extruded into the holes **218**, **220**, the depth gauge is moved to retract the second end **144** of the injection cannula **140** from the holes **218**, **220**.

In selected embodiments, the position of the depth gauge **112** is user selectable to adapt to plates of various thicknesses and holes of different depths. In one embodiment the depth gauge **112** is larger than the hole **218** or any countersunk area around the hole **218** in the bone support structure

210. This allows the surgeon to compress the bone support structure **210** against the tip **150** against the bone **212**. In an alternate embodiment the depth gauge **112** is slideably attached, and the second end **144** of the cannula **140** protrudes only when the instrument is compressed against the bone support structure **210**. This feature would protect the second end **144** except when injection is about to take place. In one embodiment the second end **144** of the cannula **140** seals against a portion of the tip **150** so as to not allow extraneous fluid and matter to enter the inside of the injection cannula **140** or between the cannula and tip **150**.

In one embodiment, the outer diameter of the second end **144** of the cannula **140** is slightly smaller than the hole **220** in the bone **212**. Without implying limitation, this diameter would generally fall within the range of 1.3 to 3.5 mm at the most distal point. This is to allow the cannula **140** to enter the hole **220** in the bone **212** with minor resistance. In one embodiment, the hole **220** in the bone **212** is tapered or stepped to allow for a larger opening for entry of the cannula **140** and a smaller hole to minimize the amount of material required to fill the entire opening.

FIG. **2** further shows a volume of expelled polymer **160**. The process of expelling a polymer in contrast to heating in place has an advantage of forming a cooled profile across the volume of expelled polymer **160**. A surface **162** of the expelled polymer cools first on contact with tissue or other external surfaces. The interior of the expelled polymer remains flowable, and tends to form a desirable shape similar to blowing up a balloon. The balloon shape helps to form a mechanical bond in the bone **212** similar to a rivet. Additionally, the cooled surface **162** is far less likely to cause thermal necrosis with tissue it comes into contact with. In contrast, for example, polymer that is heated through sonic vibration in a hole in bone is hottest at the interface between the bone and the polymer.

In one embodiment, the plunger **130** has a slight clearance fit relative to the inner walls of the injection cannula **140**. The clearance is generally within the range of 2 to 200 μm. The clearance should be small enough as to not allow polymer to flow past the distal tip of the plunger yet large enough as to not create mechanical interference. In one embodiment the plunger **130** rotates as it translates to create additional friction as it travel within the cannula **140**. This friction produces heat which reduces the viscosity of any polymer which flows between the cannula **140** and plunger **130**. This rotation can be achieved through the attachment of the plunger **130** to the rotating lead screw **108**. In one embodiment the clearance is eliminated at the second end **144** of the cannula **140** and an interference fit is achieved. An interference fit helps to sever any polymer from the plunger **130** and cannula **140** at the end of the cycle.

In one embodiment, the entire plunger **130** or at least the distal end of the plunger **130** is manufactured from or coated with a non stick material such as silicone or PTFE. This prevents polymer from adhering to the plunger **130** after a formed fastener is completed.

As discussed above, in one embodiment, the temperature profile of injection cannula **140** is controlled to allow the polymer to remain sufficiently flowable yet not induce thermal necrosis into the bone at the second end **144**. Thermal necrosis in living tissue is a complex time and temperature dependent relationship, but is often considered to begin when the tissue reaches 48° C. Additionally, the bone support device **210** or plate may begin to deform under thermal stress. If, for example, a polylactide/polyglycolide polymer is used, a suitable range around a glass transition temperature of 48-55° C. is used for the injection cannula **140**.

The rate at which the polymer cools within the cannula is dependent upon the rate at which it travels. Thus a lower temperature of the cannula at the distal end could be permitted if the polymer travels at a high enough rate such that it does not have sufficient time to equilibrate with the temperature of cannula itself.

In one embodiment the tip **150** of the bone support attachment device **100** acts as a heat sink and dissipates the heat from distal portion of the cannula **140** allowing for reduced temperature. This dissipating effect can be optimized through the use of thermally conductive materials and designs to accentuate heat transfer through conduction and convection. Such materials include, but are not limited to, aluminum, aluminum filled polymers, copper, brass, conductive metal, silver, and thermally conductive polymers or ceramics. Designs to promote heat transfer include, but are not limited to fins, vanes, ribs, pins, and spikes, etc. Active cooling could also be incorporated including, but not limited to, syringe irrigation, gases (N_2, air or CO_2), liquid nitrogen, peltier effect devices, vortex chillers, pumped saline, fans and recirculating chilled liquids. These methods of cooling the second end **144** of the cannula **140** can also be used to cool the polymer head once it has been formed as disclosed below.

As the polymer exits the second end **144** of the cannula **140** and into the bone **212**, it begins to flow and interdigitate into any pores within the bone **212**. FIG. **3** illustrates the flow anticipated when a hole **308** is in relatively non porous material and the hole extends through the bone **304**. In this case, the polymer expands on the far cortex and forms a bulbous tip **312** with a diameter larger than the hole created **308**. This provides for a rivet-like effect with additional pullout resistance.

FIG. **3** further illustrates a strengthening property that is unique to an extrusion process as described in the present disclosure. During extrusion, through a plate **300** and into bone **320**, polymer molecules **320** are stretched and aligned along a long axis of the fastener **310**. The alignment of the polymer molecules provides significant increases in fastener strength. In selected embodiments, strength of the fastener is increased by up to at least 75% over non-extruded polymer. A number of process variables such as the temperature at or around the glass transition temperature during extrusion contribute to alignment of polymer molecules.

FIG. **4** illustrates the flow anticipated when a fastener **410** is injected into porous or cancellous bone **404**. In this case the polymer can flow into the interstices **412** of the bone **404** and interdigitate with it. This also provides pullout resistance. The embodiment shown in FIG. **4** also illustrates alignment of molecules **420** and strengthening of the fastener **410**.

Referring again to FIG. **3**, the head **314** that is formed by the fastener is allowed to substantially fill a countersink recess **302** in the plate **300**. This provides locking of the fastener **310** to the plate **300** yet allows rotational motion. If locking in rotation is also desired, the countersunk recess can be incorporate grooves or other surface irregularities that the polymer can flow into. The injected polymer and fixation device can also be bonded together if melted.

FIG. **5** illustrates an example of a bone plate **500**. As discussed above, bone plates **500** are included in the category of bone support structure, however additional bone support structures other than plates are included within the scope of the invention. Holes **504** are shown to accept

polymer fasteners as described in embodiments above. Other plate portions **502** form structure between the holes **504**.

FIG. **6** illustrates one example use of bone plates in conjunction with polymer fasteners as described in embodiments above. A skull **600** is used as an example portion of bone. A first plate **604** is shown secured to the skull **600** using a number of bone plates **602** and polymer fasteners as described in selected embodiments above.

FIG. **7** illustrates an example method according to an embodiment of the invention. An amount of polymer is heated heating to a temperature at or above its glass transition temperature. A hole is drilled in a bone to accept a fastener. The hole in the bone is aligned with a hole in a support structure, such as a bone plate. A cannula is inserted through the hole in the support structure, past an interface between the support structure and the bone, and at least partially into the hole in the bone. As discussed above, the insertion of the cannula to this location helps prevent extrusion of polymer at the interface. Insertion of the cannula further aids in alignment of the holes. The heated amount of polymer is then expelled from a tip of a cannula, into the hole in the bone, and the cannula is removed from the hole in the bone and the hole in the support structure. The polymer left in the holes forms a fastener, as described in selected embodiments above.

While a number of example embodiments and advantages of the invention are described, the above examples are not exhaustive, and are for illustration only. Although specific embodiments have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that any arrangement or method which is calculated to achieve the same purpose may be substituted for the specific embodiment shown. This application is intended to cover any adaptations or variations of the present invention. It is to be understood that the above description is intended to be illustrative, and not restrictive. Combinations of the above embodiments, and other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention includes any other applications in which the above structures and methods are used. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

The Abstract is provided to comply with 37 C.F.R. § 1.72 (b) to allow the reader to quickly ascertain the nature and gist of the technical disclosure. The Abstract is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

What is claimed is:

1. A bone support attachment device, comprising:

an injection cannula sized to hold an amount of polymer to form a single fastener;

a polymer supply inlet coupled to a side of the injection cannula;

a plunger having a tip disposed at a first end of the injection cannula such that, when actuated, the plunger expels the amount of polymer from a second end of the injection cannula upon the plunger reaching the second end of the injection cannula; **[**and**]**

a chamber sized to house a block of polymer sufficient to form a plurality of fasteners, the chamber having a first end having a chamber polymer supply inlet and a second end distal the first end and connected to the polymer supply inlet to sequentially provide the amount of polymer to form a single fastener from the chamber**[**,**]**; *and,*

[the chamber including an actively regulated**]** *a* chamber heater, *adjacent the chamber and* configured to *actively regulate the chamber so as to* maintain a temperature profile from a first end of the chamber to the second end of the chamber, wherein the temperature profile comprises a temperature gradient from the first end of the chamber to the second end of the chamber and wherein the temperature gradient is warmer at the second end of the chamber than at the first end of the chamber.

2. The bone support attachment device of claim **1**, wherein the **[**actively regulated**]** chamber heater comprises multiple heating elements.

[3. The bone support attachment device of claim **1**, wherein the actively regulated chamber heater comprises multiple thermal control circuits.**]**

4. A bone support attachment device of claim **1**, further comprising **[**an actively regulated**]** *a* cannula heater *disposed at a tip region of the device* configured to *actively regulate the injection cannula so as to* maintain a consistent temperature profile from the first end of the *injection* cannula to the second end of the *injection* cannula, wherein the temperature profile comprises a temperature gradient from the first end of the injection cannula to the second end of the injection cannula and wherein the temperature gradient is warmer at the first end of the injection cannula than at the second end of the injection cannula.

5. The bone support attachment device of claim **4**, wherein the **[**actively regulated**]** cannula heater comprises multiple heating elements.

[6. The bone support attachment device of claim **4**, wherein the actively regulated cannula heater comprises multiple thermal control circuits.**]**

7. The bone support attachment device of claim **4**, wherein the **[**actively regulated**]** cannula heater is configured to raise a temperature of the polymer within the injection cannula to a melting point of the polymer and is configured to actively control the temperature of the polymer at the second end of the injection cannula to a temperature that is low enough to not cause necrosis when the polymer is discharged from the injection cannula to contact tissue.

8. The bone support attachment device of claim **4**, wherein the **[**actively regulated**]** cannula heater is configured to raise a temperature of the polymer within the injection cannula to between 50° C. and 250° C.

9. The bone support attachment device of claim **8**, wherein the **[**actively regulated**]** cannula heater is configured to raise the temperature of the polymer within the injection cannula to between 130° C. and 180° C.

10. The bone support attachment device of claim **1**, further comprising a depth gauge proximate the second end of the injection cannula**[**, the depth gauge configured to move relative to the second end of the injection cannula once a predetermined volume of polymer is expelled from the second end of the injection cannula**]**.

11. The bone support attachment device of claim **10**, wherein the depth gauge is **[**positionable**]** *configured as a static shelf and positioned* at a **[**selectable**]** *proximal* distance from the second end of the injection cannula.

[12. The bone support attachment device of claim **10**, wherein the second end of the injection cannula is configured to extend a selectable distance from the depth gauge.**]**

13. The bone support attachment device of claim **[12]** *11*, wherein the **[**selectable**]** *proximal* distance is greater than a thickness of a bone support such that when the bone support is engaged with **[**a static shelf of**]** the depth gauge, the second end of the injection cannula extends completely through the bone support.

14. The bone support attachment device of claim **1**, wherein the **[**actively regulated**]** chamber heater is configured to raise a temperature of the polymer within the chamber to a melting point of the polymer and is configured to actively control the temperature of the polymer at the second end of the chamber to a temperature that **[**is low enough to not cause necrosis when the polymer is discharged from the injection cannula to contact tissue**]** *permits the polymer to flow into the polymer supply inlet.*

15. The bone support attachment device of claim **1**, wherein the **[**actively regulated**]** chamber heater is configured to raise a temperature of a portion of the polymer within the chamber to between 50° C. and 250° C.

16. The bone support attachment device of claim **15**, wherein the **[**actively regulated**]** chamber heater is configured to raise a temperature of a portion of the polymer within the chamber to between 130° C. and 180° C.

17. The bone support attachment device of claim **1**, wherein a temperature at the second end of the injection cannula is controlled in a range within approximately 37° C. to 55° C.

18. The bone support attachment device of claim **1**, wherein a starting plunger location is variable to provide a variable volume in the injection cannula that corresponds to a selectable amount of polymer to form fasteners of various sizes.

19. The bone support attachment device of claim **1**, further comprising a chamber plunger configured to expel polymer from the chamber into the injection cannula when actuated.

20. The bone support attachment device of claim **1**, wherein at least a portion of the plunger is configured to reduce adhesion of polymer to the plunger.

21. The bone support attachment device of claim **1**, further comprising an actuator configured to advance the plunger at a rate sufficient for at least a portion of the polymer expelled from the *injection* cannula to interdigitate within a bone into which the injection cannula is extended.

22. The bone support attachment device of claim **1**, further comprising an actuator configured to advance the plunger at a rate sufficient to form a bulbous polymer tip proximate a point distal to the second end of the injection cannula, the point distal to the second end of the injection cannula being defined by an inner cortical bone surface that is opposite a cortical bone surface upon which a bone support is positioned when the injection cannula is extended through the bone support during operation of the bone support attachment device.

23. The bone support attachment device of claim **1**, wherein the plunger, when actuated, cuts off the supply inlet.

24. A bone support attachment device, comprising:

an injection cannula sized to hold a first amount of polymer to form a single fastener;

a polymer supply inlet coupled to a side of the injection cannula;

a plunger having a tip disposed at a first end of the injection cannula such that, when activated, the plunger expels the first amount of polymer from a second end of the injection cannula upon the plunger reaching the second end of the injection cannula;

a chamber sized to house a second amount of polymer sufficient to form a plurality of fasteners, the chamber having a first end having a chamber polymer supply inlet and a second end distal the first end and connected to the polymer supply inlet to sequentially provide the first amount of polymer to form a single fastener from the chamber; and,

a chamber heater, adjacent the chamber and configured to actively regulate the chamber so as to maintain a temperature profile from a first end of the chamber to the second end of the chamber, wherein the temperature profile comprises a temperature gradient from the first end of the chamber to a the second end of the chamber and wherein the temperature gradient is warmer at the second end of the chamber than at the first end of the chamber.

25. A bone support attachment device, comprising:

an injection cannula sized to hold an amount of polymer to form a single fastener;

a polymer supply inlet in fluid communication with a side of the injection cannula;

a plunger having a tip disposed at a first end of the injection cannula such that, when activated, the plunger expels the amount of polymer from a second end of the injection cannula upon the plunger reaching the second end of the injection cannula;

a chamber sized to house a supply of polymer sufficient to form a plurality of fasteners, the chamber having a first end having a chamber polymer supply inlet and a second end distal the first end and in fluid communication with the polymer supply inlet to sequentially provide the amount of polymer to form a single fastener from the chamber; and,

a chamber heater, adjacent the chamber and configured to actively regulate the chamber so as to maintain a temperature profile from a first end of the chamber to the second end of the chamber, wherein the temperature profile comprises a temperature gradient from the first end of the chamber to a the second end of the chamber and wherein the temperature gradient is such that the polymer is warmer at the second end of the chamber than at the first end of the chamber.

26. A bone support attachment device for forming fasteners from a polymer composition, the bone support attachment device comprising:

an outer device body having a proximal portion, a distal end, and a distal tip portion located proximally from and adjacent to the distal end, the outer device body having a bore located at the distal end;

an injection cannula extending through the bore and having a first end located within the outer device body and a second end located distally from the bore of the device body, the injection cannula also having a polymer supply inlet through a side of the injection cannula;

a polymer supply chamber having an inlet end and a discharge end in fluid communication with the inlet end and with the injection cannula through the polymer supply inlet;

a plunger having a plunger tip configured to be disposed within the injection cannula and to be movable within the injection cannula from the first end to the second end; and

a chamber heater adjacent the polymer supply chamber configured to actively maintain a rising temperature gradient for a polymer composition within the polymer supply chamber, wherein the rising temperature gradient is such that a temperature of the polymer composition at the inlet end is less than a temperature of the polymer composition at the discharge end of the polymer supply chamber.

27. The bone support attachment device of claim 26 wherein the injection cannula has a proximal portion adjacent the first end and wherein a maximum outer dimension

of the plunger tip is from 2 to 200 μm less than a minimum inner dimension of inner walls of the injection cannula at the proximal portion of the injection cannula.

28. The bone support attachment device of claim 27, wherein the injection cannula has a distal portion adjacent the second end and wherein the plunger tip forms an interference fit with inner walls of the injection cannula at the distal portion of the injection cannula.

29. The bone support attachment device of claim 26 further comprising a quantity of a thermoplastic polymer composition that is non-flowable at room temperature located within the polymer supply chamber.

30. The bone support attachment device of claim 29 wherein the thermoplastic polymer composition comprises an aliphatic polyester.

31. The bone support attachment device of claim 30 wherein the aliphatic polyester comprises a homo- or co-polymer of polylactic acid, polyglycolic acid, or polycaprolactone.

32. The bone support attachment device of claim 29 wherein the thermoplastic polymer composition comprises polylactide/polyglycolide.

33. The bone support attachment device of claim 32 wherein the rising temperature gradient is sufficient to transition the thermoplastic polymer composition from a non-flowable state to a temperature up to or above the melting point of the thermoplastic polymer composition.

34. The bone support attachment device of claim 29, wherein the thermoplastic polymer composition includes a therapeutic agent.

35. The bone support attachment device of claim 34, wherein the therapeutic agent comprises an antibiotic.

36. A bone support attachment device for forming fasteners from a polymer composition, the bone support attachment device comprising:

an outer device body having a proximal portion, a distal end, and a distal tip portion located proximally from and adjacent to the distal end, the outer device body having a bore located at the distal end;

an injection cannula extending through the bore and having a first end located within the outer device body and a second end located distally from the bore of the device body, the injection cannula also having a polymer supply inlet through a side of the injection cannula;

a polymer supply chamber having an inlet end and a discharge end in fluid communication with the inlet end and with the injection cannula through the polymer supply inlet;

a plunger having a plunger tip configured to be disposed within the injection cannula and to be movable within the injection cannula from the first end to the second end;

a cannula heater disposed at the distal tip portion configured to actively maintain a decreasing temperature gradient for a polymer composition within the injection cannula, wherein the decreasing temperature gradient is such that a first temperature of the polymer composition at a first position of the second end of the injection cannula is lower than a second temperature of the polymer composition at a second position located proximally from the first position within the injection cannula; and,

means for dissipating heat from a distal portion of the injection cannula.

37. The bone support attachment device of claim 36 wherein the injection cannula has a proximal portion adjacent the first end and wherein a maximum outer dimension of the plunger tip is from 2 to 200 μm less than a minimum inner dimension of inner walls of the injection cannula at the proximal portion of the injection cannula.

38. The bone support attachment device of claim 37, wherein the injection cannula has a distal portion adjacent the second end and wherein the plunger tip forms an interference fit with inner walls of the injection cannula at the distal portion of the injection cannula.

39. The bone support attachment device of claim 36 further comprising a quantity of a thermoplastic polymer composition that is non-flowable at room temperature located within the polymer supply chamber.

40. The bone support attachment device of claim 39 wherein the thermoplastic polymer composition comprises an aliphatic polyester.

41. The bone support attachment device of claim 40 wherein the aliphatic polyester comprises a homo- or co-polymer of polylactic acid, polyglycolic acid, or polycaprolactone.

42. The bone support attachment device of claim 39 wherein the thermoplastic polymer composition comprises a polylactide/polyglycolide polymer.

43. The bone support attachment device of claim 42 wherein the decreasing temperature gradient is sufficient to maintain the thermoplastic polymer composition in a flowable state.

44. The bone support attachment device of claim 39, wherein the thermoplastic polymer composition includes a therapeutic agent.

45. The bone support attachment device of claim 44, wherein the therapeutic agent comprises an antibiotic.

46. A bone support attachment device for forming fasteners from a polymer composition, the bone support attachment device comprising:

an outer device body having a proximal portion, a distal end, and a distal tip portion located proximally from and adjacent to the distal end, the outer device body having a bore located at the distal end;

an injection cannula extending through the bore and having a first end located within the outer device body and a second end located distally from the bore of the device body, the injection cannula also having a polymer supply inlet through a side of the injection cannula;

a plunger having a plunger tip configured to be disposed within the injection cannula and to be movable within the injection cannula from the first end to the second end;

a polymer supply cartridge containing an amount of thermoplastic bioresorbable polymer, the polymer supply cartridge being removably attached to the outer device body and having a distal discharge opening in fluid communication with the injection cannula;

a heater located proximate the distal tip portion of the outer device body, wherein the heater is configured to actively regulate the temperature of the thermoplastic bioresorbable polymer in the injection cannula so as to maintain a temperature profile within the injection cannula;

wherein the temperature profile comprises a decreasing temperature gradient such that a first temperature of the thermoplastic bioresorbable polymer at a first position at the second end of the injection cannula is lower than a second temperature of the thermoplastic biore-

sorbable polymer at a second position located proximally from the first position within the injection cannula.

47. The bone support attachment device of claim 46, wherein the thermoplastic bioresorbable polymer comprises an aliphatic polyester.

48. The bone support attachment device of claim 47, wherein the aliphatic polyester comprises a homo- or co-polymer of polylactic acid, polyglycolic acid, or polycaprolactone.

49. The bone support attachment device of claim 48, wherein the co-polymer is polylactide/polyglycolide.

50. The bone support attachment device of claim 46, wherein the thermoplastic bioresorbable polymer includes a therapeutic agent.

51. The bone support attachment device of claim 50, wherein the therapeutic agent comprises an antibiotic.

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