An implantable rod can be bent three-dimensionally in an automated system, which is especially useful for pre-surgical formation of implantable spinal rods. When local and/or global feedback processing accompanies a series of shaping steps automatically imposed on a rod or other article being shaped into three-dimensional form, formation time may be expedited compared to manual creation, and shapes difficult or impractical to create manually may be constructed simply.
Figure 1A

Figure 1B

Thoracic vertebrae
Figures 9A, 9B, 9C, and 9D are shown with dimensions labeled. The slopes of cones are given as:

1 = 0.3
2 = 0.6
3 = 0.4
4 = 0.5
5 = 0.8
Data Store Data Store
Input Memory Memory
Iteration Data Store
Write

Constant Read

Figure 11

DAC
DS1104DAC_C4

Figure 11A
COMPUTER-AIDED THREE-DIMENSIONAL BENDING OF SPINAL ROD IMPLANTS, OTHER SURGICAL IMPLANTS AND OTHER ARTICLES, SYSTEMS FOR THREE-DIMENSIONAL SHAPING, AND APPARATUSES THEREFOR


DESCRIPTION

[0002] 1. Field of the Invention

[0003] The present invention is directed to computer-aided design and construction of medical implants and to surgical procedures, especially spinal surgery.

[0004] 2. Background of the Invention

[0005] Scoliosis affects about 2% of the population and is most commonly seen in children 10 years or older. The current clinical paradigm for designing and shaping the surgical corrective instrumentation is poorly resolved and highly personnel intensive. Corrective surgery typically involves the fixation of segments of the vertical column through the attachment of curved titanium rods to the spine through an arrangement of hooks and pedicle screws.

[0006] The shaping of spinal rods is generally effected manually by a surgeon during surgery with the patient’s spine exposed in a trial and error procedure and using hand tools for bending and cutting the rods. This part of a surgery may take up to several hours, and this process is both tiring to the surgeon and involves increased risks to the patient.

[0007] Conventionally, a (manual) rod bender has been used for bending a corrective spinal rod to be used in a surgical operation, such as corrective surgery to treat scoliotic deformity of the human vertebral column. An example of a manual rod bender used in manual shaping of a rod for a spinal implant is a three-point bender (called a “French bender”), in which bending pliers are manually operated to manipulate the rod. However, these manual rod benders have limitations for what shapes can be created, the amount of force and time required to bend a rod, and inability to precisely create a desired shape because of a material upon being released from the manual bending device not holding the bend. Such manual bending of spinal rods is a strenuous exercise.

[0008] Conventionally, there have been several rod benders (none of which is fully automated) used in spinal surgery. A conventional rod bender for spinal surgery is disclosed in U.S. Pat. No. 5,490,409 entitled “Adjustable Cam Action Rod Bender for Surgical Rods.” The surgeon manually imposes a series of local bends to achieve large-scale desired curvature and torsion. In addition to requiring significant physical effort, a successful transition from many small bends to a desired overall curvature requires significant experience. As local errors have long-range effects on the overall shape of the rod, after-the-fact corrections are often superposed on prior bends in a trial-and-error fashion thus reducing the accuracy of the bends and stressing the material.

[0009] See, e.g., U.S. Pat. No. 6,035,691, entitled “Adjustable rod bending device for a corrective spinal rod which is used in a surgical operation,” which discloses a device that uses a series of adjustable rollers to achieve the desired curvature and impose local bends on the rod by rotary motion. This only reduces the effort required by the surgeon in achieving the desired shape and results in a smoother final rod contour as compared to manual rod benders, and much work and time on the part of a surgeon still is needed. For example, this system offers no assistance to a surgeon in formulating a desired shape of the rod. At most, a computer may be used to calculate the “scale” of each roller that will generate the desired curvature. There is no automated imposition of curvature and torsion, and consequently this system is restricted to planar rods.

[0010] Another rod bender for surgical rods is disclosed in U.S. Pat. No. 6,644,087 issued Nov. 11, 2003 to Ralph et al. (assigned to Third Millennium Engineering, Summit, N.J.), for “Rod Bender for bending surgical rods.”


[0012] Some computer-aided shaping of spinal implants is described in “A pilot study on computer-aided optimal contouring of orthopedic fixation devices,” Comput Aided Surg. 1999, 4 (6):305-13, by Langlotz F, Liebschner M, Visarious H, Bourquin Y, Lund T, Nolte L-P. Langlotz et al.’s study uses a manual bending tool coupled to a computer system that prescribes required local curvature and torsion and monitors imposed local curvature and torsion. As an input mechanism, Langlotz et al. use photographic scanning as well as the use of a spatial locator. Langlotz et al. rely on manual effort to bend the rod. Langlotz et al.’s system is not designed to handle the large bends required for thoracolumbar rod implants. An interesting feature of Langlotz et al.’s system is that “at all times a computer display shows the differences between the current shape of the rod and the desired shape as determined by MODEL-SHAPE or OPTO-SHAPE” (page 309).

[0013] While some automated three-dimensional rod benders may be found in non-clinical settings, none are suitable for forming thoracolumbar rod implants. For example, U.S. Pat. No. 6,260,395, “Vertically oriented apparatus for bending tubing, and method of using same,” uses a computer for controlling the machine in one embodiment. Although this machine is capable of creating some three-dimensional bends, it does not address the imposition of large three-dimensional bends and clearance for the already bent portion of the rod that is necessary for the thoracolumbar rods. There may also be issues with the resolution of the machine, which refers to the typical distance between bends that the machine is designed to accommodate. Generally tubing is subjected to bending at a relatively few places to impose some typical angles, such as 90 degrees or 45 degrees. In such operations, the goal is not usually to create a smooth-looking curve, but rather to create a piecewise straight tube with long straight segments.

[0014] Another non-clinical rod bender is U.S. Pat. No. 6,434,995, “Method of bending small diameter metal pipe and its apparatus.” This automated bending device imposes local curvature and torsion through a sequence of feeding,
rotating, and bending commands, but does not address the imposition of large terminal three-dimensional bends and the required clearance for the long thoracolumbar rods.

[0015] A further example of a non-clinical rod bender is U.S. Pat. No. 6,318,424, “Multi-purpose hydraulic press, metal bending, and log splitting apparatus,” which configures a log splitter to work with other materials such as metal. This device uses a controllable hydraulic ram to achieve desired accuracy in the imposed bends.

[0016] Thus, conventional spinal surgery retains time-consuming manual components which have not been able to be reduced or eliminated. That result, although highly desirable, has not practically proved achievable before the present invention.

SUMMARY OF THE INVENTION

[0017] Computer-aided systems for on-the-fly design and automated manufacture of implants are provided by the invention. Significant treatment benefits and cost savings may be realized by using the inventive computer-aided systems, such as systems for on-the-fly design and automated manufacture of corrective instrumentation or scoliosis surgery. The invention in one embodiment provides a combination of manufacturing hardware and computer-aided design system to impose desired structure (such as desired curvature) on an actual article (such as a rod (such as, preferably, a surgical implant rod), plate, etc.) for surgical use, especially immediate surgical use. Inventive systems significantly reduce time and physical effort required of a surgeon during surgery in designing and shaping a spinal implant. Reducing time required for such surgical procedures reduces exposure to infection. Also, shaped articles (such as bent surgical rods, other bent rods, etc.) may be produced according to inventive automated systems with increased accuracy compared to manually shaped implants, thereby improving the likelihood of a desirable outcome of a spinal fixation surgery. The shaped article may be performed prior to surgery, completely eliminating a step during surgery of shaping an article to be implanted, such as, e.g., completely eliminating a step during spinal surgery of shaping a spinal rod.

[0018] The invention in one embodiment provides a way to accurately and automatically reproduce a three-dimensional shape of a spinal rod or other surgical implant rod for use in a surgical operation as conceived by medical personnel (such as a surgeon) onto an actual metallic implant. To do so, there may be used an integrated computer-aided design and manufacturing tool that translates a desired shape as specified by the surgeon or medical personnel into a series of actuator commands for imposing bending, such as for imposing local bends in arbitrary planes at discrete locations along the rod.

[0019] In another preferred embodiment the invention provides an automated system that bends a rod (especially, e.g., a surgical implant rod), comprising: an input mechanism for producing a desired three-dimensional deformed shape (such as, e.g., a three-dimensional bent shape); a translational control interface; and automated rod-bending hardware, wherein the automated rod-bending hardware imposes a series of local bends in the rod until the desired three-dimensional bent shape has been formed, such as, e.g., automated rod-bending systems; systems including after each imposition of a local bend, automated global feedback wherein an actual local bend imposed is automatically compared to the desired shape and instructions for remaining bending steps are automatically evaluated (with examples of kinds of automatic evaluation being local; global; local and global); systems including, after a first set of automated instructions for imposing a series of local bends has been formulated but in advance of implementing the first set of automated instructions, an automated screening of whether sufficient clearance is physically present to justify initiating the first set of automated instructions; automated systems wherein the input mechanism for producing a desired three-dimensional bent shape includes at least one of: in vivo medical imaging or in vivo biological imaging; automated systems wherein the hardware comprises a bending mandrel and a bending arm (such as, e.g., automated systems wherein the bending arm is disposed in a rolling sleeve); automated systems including (a) a motorized system responsible for forward movement of the rod including stopping according to a series of actuator commands, the actuator commands being computer-generated; or (b) a motorized system responsible for forward movement of the rod-bending hardware including stopping according to a series of actuator commands, the actuator commands being computer-generated; automated systems including (a) a motorized system responsible for rotary movement of the rod including stopping according to a series of actuator commands, the actuator commands being computer-generated; or (b) a motorized system responsible for rotary movement of the rod-bending hardware including stopping according to a series of actuator commands, the actuator commands being computer-generated; etc.

[0020] In another preferred embodiment, the invention provides an automated method of making an implantable rod, comprising: non-manual imposition of a series of local bends in an implantable rod, whereby a three-dimensional bent shape is non-manually formed; such as rod-making methods wherein following imposition of a local bend, at least one feedback loop (local or global) is operated, and with the feedback loop being machine-implemented and human-free; rod-making methods including at least one automated step of translating a desired bent shape into a series of actuator commands for machine-based rod-bending; rod-making methods including actuator command implementation, resulting in machine-imposed bending of the rod; rod-making methods including automated imposition of at least one three-dimensional bend approaching 180 degrees; rod-making methods including automated imposition of a sequence of bends whose combined effect is a three-dimensional bend approaching 180 degrees; rod-making methods including, after automated imposition of a local bend in the rod, operation of both automated local feedback and automated global feedback; rod-making methods wherein the three-dimensional bent shape is constructed before surgical exposure of the patient’s spine; rod-making methods including non-manually forming a customized bent rod shape corresponding to a spine of a particular patient having scoliosis; rod-making methods wherein rod-bending is entirely automated and the rod needs no manual shaping before being implanted in the patient; rod-making methods including: determining X-Y-Z coordinates of a desired rod shape, and integrated feedback processing a local bend that has been imposed; rod-making methods including operation of an automatic controller commanding operations per-
formed on the rod, the controller including: a feed command for feeding movement of the rod, a rotate command for rotating movement of the rod, and a bend command for bending movement of the rod; rod-making methods including measuring spring-back of the rod via an automatic sensor; rod-making methods including collecting spring-back measurements via an automatic sensor and automated processing of the spring-back measurements; rod-making methods including a step of computer-assisted design of a desired three-dimensional bent shape (such as, e.g., rod-making methods wherein the desired three-dimensional bent shape is actually constructed); rod-making methods including, as rod-bending progresses, performing a series of automated comparisons of the bent rod as actually-bent to the desired three-dimensional shape; rod-making methods wherein bends are imposed non-manually along the rod in one-direction progression without doubling-back; rod-making methods including an automated step in which is determined an end of the rod at which to begin imposing bends; rod-making methods including disposing the rod in an automated bending system and before bending is permitted to begin, an automated step is performed of processing a desired shape to be constructed to confirm or deny sufficient clearance for automated bending to successfully proceed; etc.

[0021] In a further preferred embodiment, the invention provides a method of making a rod (such as, e.g., an implantable rod, a three-dimensionally bent rod (such as, e.g., a three-dimensionally bent rod including at least one severe bend approaching 180 degrees, etc.), etc.), comprising: (a) an automated series of non-manual bending steps on a rod (such as, e.g., a rod made of titanium or a titanium alloy, a rod made of steel, a rod made of a shape-memory alloy, a rod having a diameter of less than about 1 cm, etc.), wherein each bending step imposes an actual bend on the rod; (b) after a bending step, (i) automatic local feedback processing wherein data representing the actual bend is processed for whether the actual bend is according to instruction or varies from instruction (which information then may be used to further impose bending actuation to reach the desired bending angle, either in a single step or in a sequence of steps, either by using an analytical estimate of the spring-back based on material properties or based on measurements from previous bends); and (ii) automatic global feedback processing wherein data representing the actual bend is processed for formulating at least one next instruction for a bending step downstream along the rod.

[0022] Herein, “global feedback” and “local feedback” have been referred to. In this invention, the meanings may be understood more particularly as follows, referring to a specific case of a rod (such as, e.g., a surgical implant rod) being bent. “Local feedback” is concerned with additional bends at the same location on the rod. “Global feedback” is concerned not with additional bends at the same location (that being the concern of “local feedback”) but only with subsequent bends downstream along the rod.

[0023] Another preferred embodiment of the invention provides an implantable-rod bending apparatus, comprising: a housing receiving an implantable-rod to which bending force is to be applied; and a fully-automated mechanical system that applies bending force to the rod disposed in the housing and that positions the rod disposed in the housing, including means for positioning, orienting and bending the rod into a three-dimensional bent shape, such as, e.g., apparatuses wherein the automated mechanical system that applies bending force can apply bending force approaching imposition of a 180 degree bend to the rod; apparatuses including a minimal clearance that is a void volume such that the rod may be as long as about 1 yard and may be bent while disposed in the apparatus into a three-dimensional bent shape; etc.

[0024] Also, the invention includes a preferred embodiment providing an automated rod-bending system, comprising: a housing receiving an implantable-rod to which bending force is to be applied; and a fully-automated mechanical system that applies bending force to the rod disposed in the housing and that positions the rod disposed in the housing, including means for positioning, orienting and bending the rod into a three-dimensional bent shape; a fully automated control system that delivers a series of computer-readable instructions to the fully-automated mechanical system that applies bending force and that positions the rod, such as, e.g., automated rod-bending systems including a sensor from which is obtained digitized information quantifying bending actually present in the rod; automated rod-bending systems including, after imposition of each bend, processing data from the sensor according to at least one or both of automated local feedback and automated global feedback; automated rod-bending systems including, after imposition of each bend, both automated local feedback and automated global feedback; etc.

[0025] The invention in another preferred embodiment provides a surgical method, comprising steps of: automated bending of a rod into a three-dimensional bent shape implantable in a patient; and surgical implantation into the patient of the three-dimensional bent shape, such as, e.g., methods wherein the three-dimensional bent shape is implanted in a spinal region of the patient; methods wherein the surgical implantation is for treating scoliosis; methods wherein the three-dimensional bent shape is constructed and ready for implantation before surgical exposure of the patient’s spine; methods including (in advance of surgical implantation) automated pre-screening of the three-dimensional bent shape, including a determination of placement in the patient of the three-dimensional bent shape with reference to cooperating hardware placed, or to be placed, in the patient; etc.

[0026] The invention also provides a method of making an implantable article, comprising steps of: automated shaping of an article, in a direction of a target design that is a three-dimensional bent shape implantable in a patient, including a series of automated shaping steps each imposing an actual local shape; after each automated shaping step wherein an actual local shape is imposed, automated global feedback wherein the actual local shape imposed is automatically compared to the target design and instructions for remaining shaping steps are automatically evaluated, such as, e.g., methods including automatic adjustment of instructions for at least one automated shaping step still to be performed; methods including automated local feedback wherein the actual local shape imposed is automatically compared to instructions given and additional actuation is imposed to the same local area of the article to improve the agreement between the desired local shape and the achieved local shape; methods wherein the implantable article is a rod; methods wherein the implantable article is formed in
less time via the automated shaping than could be accomplished by being manually formed; etc.

0027] In another preferred embodiment, the invention provides a pedicle screw cap, comprising an article having an opening which receives a pedicle screw, the article being biocompatible and of a medically-imageable material, such as, e.g., a pedicle screw cap having a shape that accentuates its position and orientation to surgical imaging apparatus; etc.

BRIEF SUMMARY OF THE DRAWINGS

0028] FIGS. 1A and 1B are schematic representations of an example that may be used in the invention of severe distal bends that may be used to anchor some thoracolumbar spinal implants in the sacrum. FIG. 1A is a front view; FIG. 1B is rotated 90 degrees (¼) and is a side view corresponding to FIG. 1A.

0029] FIG. 2 illustrates rod-bending hardware according to an embodiment of the invention, and which may be used to make, for example, bent surgical implant rods.

0030] FIGS. 3, 4 show details from FIG. 2, showing bending mandrel and sensor.

0031] FIGS. 5, 6 are respective schematic diagrams showing components in inventive system embodiments.

0032] FIG. 7 is a photograph of rod-bending hardware according to an embodiment of the invention and which may be used to bend, for example, surgical implant rods. Photographic FIG. 7 may be viewed in connection with diagrammatic FIG. 6. In FIG. 6, a rod R (such as a surgical implant rod) undergoes feeding in a linear direction. The rod R is in a housing. Bending is performed on the rod R. Sensors sample the rod R. All of the rod-feeding, sensors, rod-bending is powered, not manual.

0033] FIG. 8 is a photograph of a bending actuator according to an embodiment of the invention.

0034] FIG. 9 is an isometric view of an inventive pedicle screw cap 9 which screws onto a pedicle screw prior to imaging in an embodiment of the invention. FIG. 9A is a right view corresponding to FIG. 9; FIG. 9B is a front view corresponding to FIG. 9; FIG. 9C is a top view corresponding to FIG. 9. In FIGS. 9A, 9B, 9C, slopes are marked showing a particular example and the invention is not limited to a pedicle screw cap having the dimensions shown on FIGS. 9A-C.

0035] FIGS. 10, 10A, 10B, 10C, 10D, 10E show a rod-bending sequence according to an embodiment of the invention, which may be used, for example, for bending surgical implant rods. A rod-bending mechanism 10 acts on a rod R to bend the rod.

0036] FIGS. 11, 11A, 11B, 11C, 11D are control flow diagrams according to an embodiment of the invention. FIG. 11 shows exemplary main control. FIG. 11A shows rotary direction control. FIG. 11B shows feeding and rotation control. FIG. 11C shows a subsystem. FIG. 11D shows bending control. FIGS. 11-11D may be used, for example, for bending surgical implant rods.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

0037] There is provided an inventive automated system for constructing a three-dimensional bent article (such as a rod, a plate, etc., most preferably a rod (such as, e.g., a rod implantable in a patient)). A surgical implant rod is a most preferred example. In the invention, manual shaping (such as manual bending, etc.) of the article is minimized, preferably completely eliminated. Such automation is particularly advantageous when manual shaping of an article to be implanted in a patient can be minimized or avoided, especially when the manual shaping otherwise would be done by a surgeon, and most particularly when the manual shaping would be that of a spinal rod and otherwise would need to occur while the patient’s spine already has been surgically exposed.

0038] Shaping herein refers to force application that changes the shape of an article, such as, e.g., bending, twisting, etc., with bending being a preferred example, such as bending a surgical implant rod. A most preferred example of shaping an article according to the invention is rod-bending, especially bending an implantable rod (such as, e.g., a titanium rod; a titanium alloy rod; etc.). Examples of inventive rod-bending systems are, e.g., systems wherein implantation by the automated rod-bending hardware of the series of local bends in the rod (such as, e.g., a surgical implant rod), the automated rod-bending hardware provides higher repeatability than could be provided by a human operator manually attempting to execute a same series of local bends; systems including an automated cutting mechanism that reduces the rod to a desired length; systems in which prior to each imposition of a local bend according to a bend imposition instruction, an automated screening is performed of whether sufficient clearance is physically present to justify ordering execution of the bend imposition instruction; systems including an automated correction system which, when bend imposition has been proceeding along the rod (such as, e.g., a surgical implant rod) according to a first set of instructions for imposing local bends with the first set of instructions being only partially executed, the automated correction system 1) detects a point at which small errors in imposed bends have accumulated to a point where the first set of instructions cannot viably be completed as a matter of physical clearance and 2) revises the first set of instructions to a second set of instructions, wherein the second set of instructions can be viably completed as a matter of physical clearance; systems including real-time automated correction of local bends for spring-back; systems including a sensor operating at a region where a local bend has just been imposed, information from the sensor being subjected to at least one of a local feedback operation and a global feedback operation (such as, e.g., systems including information from the sensor being subjected to both a local feedback operation and a global feedback operation; systems wherein as a result of the feedback operation(s), a current sequence of applicable automated instructions for bending is automatically modified into a modified sequence of automated instructions for bending; systems wherein the rod (such as, e.g., a surgical implant rod) being bent is made of a material selected from the group consisting of: titanium; titanium alloy; steel and shape-memory alloys; etc.

0039] A preferred example of a rod to use in the invention is, e.g., a surgical implant rod. A preferred example of an implantable rod is an implantable spinal rod of a titanium or titanium alloy material, which are mentioned as examples, and the invention is not limited to such materials. A rod that is starting material for an implantable spinal rod may have
varying lengths, such as a length of about 6 inches to about 1 yard, which lengths are given as examples and not by way of limitation. An example of a diameter of an implantable spinal rod is about 8 mm, i.e., less than about 1 cm. However, the invention is not limited to dimensions that have been mentioned, and the dimensions for a starting material of an implantable rod may vary according to the patient. In designing an inventive rod-making machine, it is especially preferred to form openings specifically dimensioned for actual rods, and to have very small gaps between the rod and opening in the receptacle, to increase the accuracy of the bending operation.

[0040] A preferred example of a rod-bending device includes rod bending devices that impose subsequent and non-coplanar-large-angle bends (half a turn) at the terminal end of long rods (i.e., up to one meter) used to anchor thoracolumbar rods in the sacrum.

[0041] FIGS. 1A and 1B show an example of a rod (such as, e.g., a surgical implant rod) with severe distal bends that may be used to anchor some thoracolumbar spinal implants in the sacrum. Such bends as in FIGS. 1A and 1B may be imposed at the ends of rods (such as, e.g., a surgical implant rod), with the rods then being implanted to go about half the length of the spine. Implanted spinal rods are anchored into the pelvis (such as by screwing the rods to the pelvis).

[0042] It will be appreciated that the bends 100 in FIGS. 1A, 1B are severe bends in a titanium or titanium-alloy rod, i.e., are almost 180 degree bends. For a rod, it would not be physically possible to have an actual 180 degree bend. The net bend is achieved over a finite radius, possibly as a result of several smaller bends, but with the result that a half turn bend is imposed over a segment of the rod and possibly with several half-turn bends imposed in succession in the end part of the rod as would be necessary in the case of the rods anchored to the sacrum (see FIGS. 1A-1B).

[0043] By automated shaping of articles according to the invention, a variety of products (especially, most preferably, products including three-dimensional bent features) may be constructed. Examples of products constructed according to the invention include, e.g., three-dimensionally bent rods (such as, e.g., surgical implant rods), medical implants (such as, e.g., three-dimensionally bent spinal rods, disks, cages, etc.), dental implants, etc. Three-dimensionally bent spinal rods for medical implantation are a preferred example.

[0044] In the invention, at least one input system is used. Examples of an input system for use in the invention are, e.g., input systems comprising manually deforming an easily-deformable template rod (i.e., a “practice” rod of a more deformable material compared to the material of the actual rod to be shaped) into a desired three-dimensional bent shape followed by photographic scanning of that manually-deformed template rod to generate a virtual representation (which virtual representation can reside within interface software); input systems comprising operating a spatial locator to map a region where the desired three-dimensional bent shape is to be implanted; input systems comprising computer-aided design of a virtual rod; input systems comprising operating a surgical imaging apparatus; input systems comprising imaging pedicle screws to establish the desired three-dimensional bent shape (such as, e.g., optionally using a surgical fluoroscope during surgery to determine the position and orientation of the pedicle screw heads using inventive cooperating pedicle screw caps, with pedicle screw caps being provided by the present invention); an input mechanism as in Langlotz et al., supra; input systems comprising a virtual environment in which the three-dimensional shape of the rod is designed (especially in which the shape is designed prior to and/or during surgery); input systems comprising spatial locaters that may be used to generate a sequence of control points that define the three-dimensional shape of the article to be constructed; input mechanisms as in U.S. Pat. No. 6,578,280; input mechanisms as in U.S. Pat. No. 6,500,131 (titled “Contour mapping system applicable as a spine analyzer, and probe useful therein,” disclosing various embodiments of spatial locaters used in conjunction with computer software to locate the spinal vertebra through external palpation and to subsequently quantify the spinal geometry; other commercially available input systems; customized input systems; etc.

[0045] With regard to certain input systems comprising operating a spatial locator to map a region which have been mentioned for use in the present invention, examples of mapping can be, e.g., mapping of the vertebral column or mapping the pedicle screws already attached to the vertebral column. (With regard to working with pedicle screws, see also Inventive Example 2 below.) Another example of mapping is mapping a practice rod. For some such mapping examples (and for certain other examples of imaging), bending an implantable article during surgery would be likely to be required, only after the patient has been surgically exposed. Mapping according to the present invention may be particularly useful in the case of attaching multiple rods to a segment of the spine, because the attachment of the initial rod determines the final shape and the secondary rod is only required to support this shape rather than to further change this shape.

[0046] Examples of certain input systems having been discussed above, the input system more generally is now mentioned. In the various embodiments of the invention, the input system (also referred to herein as “input mechanism”) is used to provide computer-readable information to the translational control interface which then in turn communicates with the control software. The computer-readable information that the input system provides to the translational control interface represents a desired three-dimensional shape (such as a desired three-dimensional bent shape, etc.) to be formed by the automated hardware as commanded by the control software with which the translational control interface communicates.

[0047] For applying shaping force according to the invention, there is provided a motorized apparatus that holds the article to be shaped and includes an automated (i.e., non-manual) system for application of shaping force, such as an automated system for bending a rod. In the invention, the article is shaped non-manually, such as by operation of a series of computer-generated actuator commands, such as a series of actuator commands whereby a series of discrete local bends is imposed on a rod, with the local bends being imposed one at a time by a force-applying mechanism.

[0048] Preferably the rod is moved past the force-applying mechanism, with the rod being moved in a forward direction, being stopped as needed, but not being reversed, and with the force-applying mechanism stationary relative to the overall apparatus.
Alternately, the rod may be held stationary and a force-applying mechanism moved along the rod in a single direction and stopped to impose force.

It will be appreciated that in the invention any such movement (including stopping), whether of a rod or of a force-applying mechanism preferably are as computer-controlled as possible; as much as possible, with the movement (of the rod or of the force-applying mechanism) being motorized, not manual.

The structure of the force-applying mechanism is formed to coordinate with the article to which shaping force is to be applied. For example, in the case of bending a rod, an example of a structure of a force-applying mechanism is a structure having at least one circular opening through which the to-be-shaped rod fits snugly, such as being threaded through the circular opening(s). With such a structure for rod-bending, during motorized operation of the apparatus, the rod is moved in a “forward” direction until commanded to “stop” according to an automated control program. A motor is electrically connected to a rod-movement system which transports the rod according to a series of actuator commands for achieving rod movement. A controller is electrically connected to the motor responsible for linear rod movement (i.e., the controlled forward advancement and controlled stopping). Most preferably, movement of and stopping of the rod are controlled entirely by computer-generated instructions, i.e., during regular operation, the movement and stopping of the rod are completely free of human control (such as being completely free, during regular operation, of a human operating a knob, a keyboard, a joystick, a mouse, etc.).

It will be appreciated that the first “stop” of the rod, i.e., the first place on the rod where force will be applied, as a practical mechanical matter usually cannot be on the very tip or edge of the rod. For example, where a bend is wanted at an end of a rod, usually the starting rod includes an extra length that ultimately will be chopped-off, with the first bend applied at a mechanically practical first stop along the rod; the unneeded extra length of the rod is later removed (preferably, chopped). In the case of an implantable article, chopping is preferred over sawing. Selecting chopping operations, such as selecting which end(s) to chop, generally follow from the order in which the bends are imposed.

When the rod reaches a “stop,” the force-applying mechanism is then controllably activated to apply force to the article being shaped. At least one motor (which may be the same as, or different from, the motor used for driving the linear movement of the rod) is connected to the force-applying mechanism for operating application of force. A controller is connected to the motor that operates the force-application device, for controlling the motor that powers force-application. Preferably the number of motors and moving parts is minimized to the minimal number for accomplishing the desired application of force. Most preferably, force application is controlled entirely by computer-generated instructions, i.e., during regular operation, the force-application is completely free of human control (such as being completely free, during regular operation, of a human operating a knob, a keyboard, a joystick, a mouse, etc.).

The inventive motorized apparatus most preferably includes at least one automated rotating mechanism, such as, e.g., at least one of: a mechanism for motorized rotating of the article being shaped (such as an automated, computer-controlled rod-rotating system).

In a preferred example of rod feeding and movement, first the rod is fed through a circular slot in the force-applying mechanism, with the feeding being done by a linear actuator. The linear actuator need not be the same actuator as the force-applying actuator (herein called the bending actuator). After the rod is fed into the circular slot in the force-applying mechanism, the rod is rotated (with the rotation being automated rotation, not manual rotation) to permit determination of the plane in which the subsequent bend will be applied. The determination of the plane in which the subsequent bend will be applied is a non-manual operation. A rotary actuator may be used to achieve such rotation of the rod. The rotary actuator need not be identical to the feeding actuator or the bending actuator. After rotation of the rod, the bending actuator is called upon to impose a bend. After a bend is achieved satisfactorily (i.e., to the satisfaction of the computerized system), the cycle repeats.

In the preceding paragraphs, there has been discussed an inventive system in which the rod moves according to motorized movement as commanded by a series of computer-generated actuator commands, and in which the force-applying mechanism remains stationary compared to the overall system. In alternate embodiments, which parts are moving and which parts are stationary may be modified, such as, for example, a system in which the rod is held stationary relative to the entire system and it is the force applying mechanism that is moved along the stationary rod.

The inventive automated shaping system includes at least one sensor that measures the local geometry of the article being shaped, such as, e.g., a sensor measuring the local angle of a rod that has been locally bent. Most preferably, the sensor conducts its measurement continuously, so as to allow the controller to instruct the bending hardware to stop bending when a certain angle is reached. The sensor dispatches its measurement in computer-processible form to the control software, where the measurement information may be run through global feedback and/or local feedback operations or otherwise compared against the desired shape information. Sensor positioning is such that each actual bend imposed is measured. For simplicity it may be preferred to use a single sensor, but multiple sensors are not excluded. In a system where a rod is fed, rotated and bent, an example of a sensor used is an angular sensor. A separate sensor for rotary action can be avoided by using a rotary actuator that is a stepper motor with a built in sensor and because this rotary actuation requires no deformation of the rod and therefore can be achieved with arbitrary accuracy in a single step. Thus, a “sensor” mentioned herein refers to an angular sensor measuring a local region of the article being shaped.

The information from the sensor is subjected to local feedback and/or global feedback processing.

An example of a local feedback algorithm usable in the present invention is as follows. Suppose that a bend of an angle x degrees needs to be imposed. The control software calls upon the bending actuator to commence bending. The sensor continuously feeds information about the current angle. The control software may stop the bending when the desired angle is reached (as per the information
from the sensor) or when the desired angle has been exceeded by some predefined amount, dx1 degrees. In either case, as the bending actuator is restored to its original position, the rod springs back by some amount, sp1 degrees. If sp1 is known in advance, for example, based on an analytical formulation describing sp1 as a function of θ and the material properties, then the control software can be programmed to ensure that dx1=sp1 in which case the achieved bend is identical to x. In actuality, sp1 is not known in advance. Even if such an analytical formulation is available, it is only approximate and it is likely that dx1 is only approximately equal to sp1 resulting in a residual error. The control software may choose to use the deviation between the actual sp1 and that predicted by the analytical formulation to estimate the spring-back, sp2 degrees, that would result from an additional attempt to bend the rod at the same location, for example, by instructing the bending hardware to recompute bending and only stop bending once the sensor indicates that an angle x+dx2 has been reached in such a way that dx2=sp2, such that after the bending hardware is returned to its original position after the second bend the actual and desired bending angles agree more closely than before. This may be iterated several times until a desired local accuracy is achieved. Thus a methodology using an analytical formulation is provided.

An example of a clearance algorithm is as follows. Once you have computed the local bending and rotary actions, the rod-shaping action may be simulated in software while accounting for the physical shape of the hardware mechanism to ascertain whether all segments of the rod that have exited through the force-applying mechanism remain clear of the hardware. At each step of the simulation, the information about the location of all previously completed bends and the amount of rotation and bending achieved at these locations (as determined by the angular sensor) is used to reconstruct the global shape of the rod (which is straightforward three-dimensional geometry) and the spatial location of points on the rod are compared to the spatial regions where components of the hardware device reside. The simulation may be completed prior to any bending, as well as during bending to accommodate errors in local bends that were not anticipated prior to commencing bending.

Alternately, this methodology could be employed without the use of an analytical formulation, simply by setting dx1=0 and using the spring-back information from this and subsequent bends at the same location to achieve the desired location accuracy. Such an approach to local feedback may be based on extrapolation principles such as extrapolation principles used in the shaping of plates.

An example of a translational control interface for use in the invention is as follows. The information from the input mechanism is quantified in terms of spatial (x,y,z) coordinates of a discrete sequence of points along the rod. Consider any three successive points on the rod. These points are connected by two straight-line segments (in space, not necessarily on the actual rod) that lie in a plane. This is the bounding plane. The bending angle to be imposed at the middle of the three points is the angle between the two straight-line segments. Now consider any four successive points on the rod. The first three and the last three lie in two different bending planes. The middle two lie in both bending planes. The angle between the bending planes is the rotary angle to be imposed at the second of the four points.

An example of global feedback for use in the present invention is as follows. After a local bend has been achieved with sufficient accuracy, the angular sensor information about the achieved bending angles up to and including the last completed bend is used to locate in space the subsequent discrete point on the rod where the subsequent bend will be imposed. The global feedback uses this information coupled with the information about the desired location of all subsequent points (not including those points that have already passed through the force-applying mechanism nor the next point on the rod at which a local bend will be imposed) to recompute the sequence of rotations and bends (with the recomputation being as discussed above with regard to the translational control interface).

Preferably a clearance algorithm is included in systems for shaping an article, such as rod-bending systems. An example of a clearance algorithm is as follows. Once you have computed the local bending and rotary actions, the rod-shaping action may be simulated in software while accounting for the physical shape of the hardware mechanism to ascertain whether all segments of the rod that have exited through the force-applying mechanism remain clear of the hardware. At each step of the simulation, the information about the location of all previously completed bends and the amount of rotation and bending achieved at these locations (as determined by the angular sensor) is used to reconstruct the global shape of the rod (which is straightforward three-dimensional geometry) and the spatial location of points on the rod are compared to the spatial regions where components of the hardware device reside. The simulation may be completed prior to any bending, as well as during bending to accommodate errors in local bends that were not anticipated prior to commencing bending.

The inventive motorized apparatus for applying shaping force (such as an inventive automated rod-bender) has sufficient clearance to accommodate, during regular operation, the article during the procedure of the article being subjected to a series of applications of shaping force. For example, if the article being shaped is being moved as part of the force-application, the space through which the article is being moved needs to be free of any physical object or part. With reference to rod-bending, it can be appreciated that the automated rod bender needs to have sufficient void space (clearance) so that the first bend can be applied without the rod physically contacting any part of the automated rod-bender. Subsequent bends also will need to be applied without the rod physically contacting any part of the automated rod-bender. Where the automated rod bender is to be used for bending implantable spinal rods, the apparatus is configured so that two or more large three-dimensional bends each approaching 180 degrees (herein referred to as “severe” bending) can be imposed in the rod without a physical clearance problem occurring, i.e., without the rod encountering obstruction. For example, referring to FIGS. 1A, 1B, it can be seen that it is wanted not just to bend the spinal rod once into a sharp U (with the sharpness of the bend being a matter of preference, and could be achieved in a single bend, but more preferably is achieved in a sequence of bends resulting in a 180 degree bend over some finite radius), but to again bend the rod another time. Moreover, it is wanted to not be limited to a two-dimensional planar shape, such as an S shape, but rather, that the rod may be bent in three dimensions. To permit such three-dimensional bending of a rod, a sufficient void space is needed to be designed into the apparatus when the apparatus is made.

An angular sensor and feedback processing of information from the angular sensor has been mentioned above. The current actuator applies force until the sensor indicates that a stopping angle has been reached. The actuator transmission is used to control the amount of torque. By using an angular sensor in continuous sensing operation, and by operating global and local feedback, a desired bend can be accomplished without advance preprogrammed information about the amount of force needed to effect a particular bend (including springback behavior) of a particular material to be bent. Also, it may not be necessary to calibrate and recalibrate (here, referring to resorting to use of a different transmission to control the torque from the bending actuator) a machine according to a particular type of material to be received and bent. A stepper motor rather than
a servo motor could be used for the bending actuator. A stepper motor will bend until reaching a certain angle and will adjust the amount of torque without outside control. (Here, and elsewhere in this specification, a particular type of motor, such as a servo or stepper motor, is mentioned for example, and the selection of the type of motor is not considered significant, but rather, a question of cost or design choice.) In the invention, a single inventive motorized, computerized system with continuous angular sensing could receive a rod of a first material for bending, bend that rod, and immediately afterward without recalibration could receive a rod of a second different material for bending.

[0066] In a surgical context, rods generally are of the same diameter. However, if processing of a different diameter rod is wanted, the automated rod bending machine may be adjusted to accommodate a different diameter rod, such as by reconfiguring the slot through which the rod runs, and replacing the bending plate. In the clinical setting, preferably, rods of a same diameter are used in a single automated rod bending machine.

[0067] The inventive automated apparatus preferably provides as small a resolution as possible between two locations at which force is applied, while considering the fact that too small a bending radius may result in damage to the rod. Preferably bending takes into account available engineering data supporting recommended bending radii for different materials and rod radii. The minimum distance between bends will be determined by the geometry and mechanical characteristics of the apparatus, with about one inch being an example of a typical minimum resolution for an apparatus accommodating an 8 mm spinal rod. The minimum resolution is not required to be used, that is, the force-application mechanism is required to stop if no force-application is wanted, such as if the target design calls for the rod to remain straight the force-application mechanism proceeds without stopping until reaching a linear location at which force-application is called-for. By way of example, relatively short spinal rods are usually left almost straight with just a couple of bends; longer spinal rods generally are more carefully shaped to follow the desired contour of the vertebral column. For a typical spinal rod, 25 discrete bends which are non-manually imposed is an example of a relatively high but executable number for an automated rod-bender according to the invention to perform, and 5-15 discrete bends which are non-manually imposed is a preferred range of how many bends an automated rod-bender according to the invention may execute to construct a desired three-dimensional shape.

[0068] In regular operation of the automated shaping apparatus, the force application mechanism controllably moves in a linear direction, stopping according to automatic instructions, and applying force according to automatic instructions. So that the force application mechanism may so operate, there is included in the inventive apparatus or system a translational interface and control software.

[0069] Examples of a translational interface usable in the invention are, e.g., one or more of: a digital computer interface that converts digital photographs from the input system to a three-dimensional representation (such as, e.g., a three-dimensional representation of a spinal rod to be formed), a computer interface that for data received from the input system automatically computes (such as by applying methods of differential geometry or planar trigonometry) local curvature and local torsion of the desired shape (such as the desired bent-rod shape) and translates the computed values into a sequence of hardware operational commands (such as, e.g., a sequence of feeding, rotating and bending commands); a translational interface including real-time correction of local bends for spring back due to nonlinear elasticity and material hardening as well as for adjusting the desired local curvature and torsion of the as-of-yet unbent portions of the rod to retain global shape accuracy; a translational interface including correction for local bends using the analytic formulation for spring-back according to U.S. Pat. No. 6,035,691; a translational interface using other correction-for-spring-back methodology; etc.

[0070] Before automated rod-bending of the invention, spring-back could not accurately be corrected for when imposing a manual bend, because even if a formula was known for how much to bend so that the right spring-back was provided to ultimately end at a desired angle, a human operator could only be so accurate in applying the degree of bending force wanted to over-bend so that upon release, spring-back to the desired bend would occur. However, a strong advantage of the present invention is that by using a machine to bend a rod, the machine can bend the rod incrementally, according to a mathematical formulation. A human operator could not achieve the finesse of incremental bending that a machine can achieve.

[0071] Examples of control software useable in the invention are, e.g., one or more of: control software depicting a desired three-dimensional shape, such as, e.g., control software using a virtual representation of a patient's spinal rod to compute local curvature and torsion and to generate a sequence of actuator commands that will ensure satisfactory reproduction of the desired shape in the rod-bending hardware; control software that translates a desired target shape (received from the translational control interface) into a corresponding machine operation(s) such as, e.g., operation of an actuator or a motor; control software that processes actual measurement data from an angular-bend sensor and compares the actual measurement data to the desired target shape and, if needed, adjusts the sequence of actuator commands to ensure satisfactory reproduction of the desired shape (such as, e.g., control software that performs a local feedback operation; control software that performs a global feedback operation, etc.); etc.

[0072] In the case of rod-bending, an example of preferred control software used in the invention is control software which receives an actual angular bend measurement for a local bend just imposed, compares that actual angular bend measurement to the instruction that underlies that actual bend, and if the underlying instruction and actual angular bend measurement are at variance, reformulates the set of remaining bending instructions. For example, if the machine-based bending instruction was that the force-application mechanism was instructed to impose a 40 degree local bend, but the post-bend actual measurement received from the sensor for the local bend shows a 39 degree local bend actually was imposed, then the control software recognizes the discrepancy and recalculates the remaining force-application instructions to retain global accuracy and to achieve the desired shape. By doing so, advantageously in the present invention re-bending or placing bends on top of each other can be avoided.
[0073] The control software used in the invention preferably includes, for each material composition to be placed in the apparatus for shaping, at least one computer-readable table correlating each example of a desired angular bend to respective corresponding machine instructions for operating the force-applying mechanism to deliver the desired angular bend. That is, a titanium rod and a steel rod of the same diameter require different computer-readable tables of machine operation instructions because those different materials have non-identical elasticity or spring-back.

[0074] Optionally, there may be included in inventive systems and methods an automated pre-screening of the product being constructed. For example, in the case of a bent-rod medical implant which is to be connected to cooperating screws, there may be during construction of the bent-rod a step of confirming that imposition of a particular local bend in the rod will allow for cooperative placement of the screws. Another pre-screening example is of a pre-screening assessment of where a patient’s spine may receive attachment of the rod being constructed.

[0075] Making an automated rod-bending apparatus may be readily accomplished with reference to the above-mentioned regular operation of an automated shaping apparatus such as an automated rod-bender, and with reference to the figures, photographs and Examples included herein, and the following remarks.

[0076] For example, an inventive automated rod-bending machine may be constructed using a feeding/rotating/bending sequence of actuators (arranged in a structure so that desired local curvature and torsion can be imposed on a rod). For reference, Kataoka, U.S. Pat. No. 6,434,995, “Method of Bending Small Diameter Metal Pipe and its Apparatus” is mentioned. The rod-bending hardware, for example, may include three actuators: a stepper motor feeding actuator for correct positioning of the spinal rod relative to the bending mechanism; a stepper motor rotating actuator for correct orientation of the spinal rod relative to the plane of bending; and a motor (such as a servo motor or a stepper motor, preferably, a servo motor) bending actuator for imposing a desired bend of the spinal rod about the bending mechanism. For ensuring local accuracy, for the feeding and rotating action, open-loop controlled high-resolution stepper motors preferably are used. This is because the feeding and rotary actions do not work against the material but only reposition the material in space. No deformation occurs as a result. For the bending action, optionally closed-loop control is used. In that case, the bending actuation is transmitted from the servo motor to a bending arm through a 90 degree transmission. (The close-loop control is optional, not necessary.) The bending arm uses a rolling segment in contact with the actual rod to allow for non-concentric arc motion of the bending arm relative to the arc motion of the point of contact on the bent rod about the bending mechanism.

[0077] An example of a suitable angular sensor to use is one that detects the resultant bend and feeds this back to the control interface for appropriate action.

[0078] To achieve subsequent non-coplanar large angle bends (near half turn) at the terminal end of long rods (e.g., up to 1 meter) used to anchor thoracolumbar rods in the sacrum, the device may incorporate a displaced bending mandrel and sufficient clearance from the device casing. A sleeve may be used to support the unbent portion of the rod as bends are applied. It is over the bending mandrel that the rod is bent, with the bending arm doing the bending. The bending mandrel preferably uses a low friction (or, alternatively, rolling) segment in contact with the rod to allow for non-concentric arc motion of difference radius of the bending arm relative to the bent rod.

[0079] An example of a bending arm/bending mandrel mechanism is shown in FIG. 3. A bending mandrel 310 is shown perpendicular to a rod R. The rod R is sandwiched between the bending mandrel 310 and the bending arm 320. Looking at FIG. 3, the bending mandrel 310 appears “in front” of the rod R and bending arm 320 appears “behind” the rod R. The arm 320 rotates and pushes at the rod R, bending the rod R. The rod R gets pushed up against the mandrel 310. As shown, the arm 320 will not always push at the same point on the rod R, because the arm 320 makes a circular motion around the mandrel 310. One way of accomplishing the desired motion of the bending arm 320 is to form bending arm 320 as a rolling sleeve structure, such as a hollow cylinder that sits on the outside of the arm. The desired motion for the bending arm 320 is for the bending arm 320 that pushes at the rod R to be able to rotate along the rod R, like a rolling pin, rather than scrape along the rod R. The desired motion of the bending arm 320 may be accomplished by other structures, such as, e.g., by using bearings, etc., so that the bending arm 320 freely rotates as it rolls over the rod R so that when the rod R bends, it only bends, not scrapes. Thus, damage to the rod R can be avoided or at least minimized.

[0080] Most preferred for use as the input mechanism is software with which the surgeon can design the intended rod shape in a CAD environment. An alternative input mechanism is based on a photographic scanning of an actual, manually shaped template rod (i.e., a rod that is relatively much softer and formable than the ultimate rod to be shaped for use as the actual implant).

[0081] It is not particularly important to strictly distinguish between the translational interface and the control software, and whether a desired operation is present in one or the other. In actual implementation, certain algorithms or computer operations may reside in various locations.

[0082] A preferred example is, for the translational interface and control software, to use Matlab (commercially available) and Lab View (commercially available), applying customization as follows discussed with reference to FIG. 5 depicting computer-aided spinal instrumentation manufacture control flow: The three-dimensional shape information (in the form of X-Y-Z coordinates of desired rod shape 500) is received from the input mechanism and converted by the Lab View control program 510 with integrated feedback algorithm into a sequence of discrete control commands to the three hardware actuators, corresponding to a feeding distance along the rod between subsequent bends (feed command 512); a bending angle at each subsequent bend (bend command 516); and a rotational angle at each subsequent bend (rotate command 514). In this customization, the control software also includes a closed-loop, local feedback algorithm that achieves an acceptable local accuracy in the bending angle by addressing the spring-back exhibited by the metal rod after each bending motion. An angular sensor is used to provide information about the achieved bend. In this customization, the control software also includes a
closed-loop, global feedback algorithm that achieves an acceptable global accuracy in the curve shape by updating the subsequent control commands at the conclusion of each local bend to reflect the achieved bend.

[0083] Referring to FIG. 5, the feed command 512 operates feed stepper motor actuation 522 which operates feed linear actuator 532. The rotate command 514 operates rotate stepper motor actuation 524. The bend command 516 operates bend servo motor actuation 526 which operates mechanical bending mechanism 536 the result of which operation is measured by rod spring back sensor 540 which impacts bend servo motor actuation 526 and sends measurement information to Lab VIEW control program 510 with integrated feedback algorithm.

[0084] More generally, for constructing shaping apparatuses for acting on other shapes besides rods, a similar basic concept may be applied, with suitable adjustments for the geometry of the particular article being shaped. Three-dimensional considerations of physical clearance should be taken into account, and sufficient void space should be provided in the apparatus so that the article being shaped can move without encountering anything solid.

[0085] An inventive automated shaping apparatus thus is designed and constructed for accomplishing formation of at least one three-dimensional shaped article, preferably, more than one three-dimensional shaped article. However, advantageously, automated shaping apparatuses according to the invention are not limited to making only the three-dimensional shaped article or articles which they have been expressly constructed to make. By including a screening system including at least one sensor and at least one automated feedback system, inventive automated shaping apparatuses additionally permit manufacture of any other three-dimensional article which is not prohibited by its geometry, i.e., any other three-dimensional article the formation of which in the apparatus does not cause a physical clearance problem. Thus, the invention provides an “intelligent” manufacturing tool.

[0086] Herein many mentions and examples have been given referring to a rod, for simplicity. It will be appreciated that the invention is not limited to shaping a rod, and may be used for shaping bars, disks, plates, and other starting shapes (including regular or symmetric starting shapes, irregular starting shapes, asymmetric starting shapes, etc.).

[0087] The invention advantageously provides a system where repositioning can be avoided, and placing a second bend on top of a first bend can be avoided. The invention makes possible a series of sequential local bending steps occurring in a single direction and without needing traverse. This is made possible by real-time processing by the control software of angular measurements taken by sensor. For example, if the machine-based instruction was that the force-application mechanism was instructed to impose a 40 degree local bend and the post-bend actual measurement for the local bend shows a 39 degree local bend actually was imposed, then the control software recognizes the discrepancy and recalculates the remaining force-application instructions to retain global accuracy and to achieve the desired shape.

[0088] The following inventive Examples are mentioned, but it will be appreciated that the invention is not limited to the Examples.

**COMPARATIVE EXAMPLE 1**

[0089] A surgeon receives information from a computer, giving him bending instructions for a spinal rod, which he then manually bends.

**INVENTIVE EXAMPLE 1 (FULLY AUTOMATED ROD-BENDER)**

[0090] FIG. 2 shows an example of rod-bending hardware 200 in an embodiment of the invention. A rod R is disposed in the rod-bending hardware 200. Computer-aided design may be performed with the hardware of FIG. 2. In FIG. 2, a rotary actuator system 204 rotates and slides the rod. The rod R is inserted into the rotary actuator system 204. A linear actuator system 208 in the view shown in FIG. 2 is parallel to the rod R. Inside the linear actuator system 208 is a sliding magnet (not shown). The rotary actuator system 204 is attached to a bracket which slides on the linear actuator system 208. The actuator makes the magnet move and takes with the moving magnet anything on the rail, so that the rotary actuator system 204 rides on the linear actuator system 208. The rod R is thus attached to part of the linear actuator system 208. Another actuator 206 is shown at the front right of FIG. 2 near the sensor 202.

[0091] FIGS. 3 and 4 show details from FIG. 2, showing bending mandrel 300 and sensor 202. The rod R is bending up. As shown, the end of the rod R moves up and to the left. The sensor 202 collects information about the angle of the rod R. If a 180 degree bend is imposed, the rod R will almost bend back on itself in the rod-bending hardware 200 of FIG. 2.

[0092] FIG. 7 is a photograph of rod-bending hardware according to an embodiment of the invention. The rod-bending hardware used in this inventive Example consists of a feeding mechanism for correct positioning of the rod relative to the plane of bending, and a bending mechanism for imposed a desired bend of the spinal rod about the bending mandrel as well as a rotary mechanism for correct orientation of the bending plane.

[0093] FIG. 8 is a photograph of an actuator for a bending mechanism according to an embodiment of the invention.

[0094] The hardware of Example 1 may be used in an inventive system for automated rod-bending (such as shown in FIG. 5 or 6). The hardware of Example is useable in an integrated system for computer-aided rod bending for the automated impositions of a three-dimensional geometry on a corrective spinal rod to be used in a surgical operation, such as corrective surgery to treat scoliotic deformity of the vertebral column. Such integrated systems may, for example, consist of an input mechanism, a translational interface and control software, and automated rod-bending hardware for the discrete imposition of curvature and torsion on a spinal rod.

[0095] In the rod-bending machinery of the photographs, a spinal rod is subjected to motorized movement and a bending mechanism remains stationary. The rod is stopped and moved according to computerized commands for the actuator responsible for rod movement. Bending force is applied according to computerized commands for the actuator responsible for the rod-bending hardware.

[0096] With regard to Example 1 and the figures and photographs discussed therein, it will be appreciated that an
implantable rod can be bent three-dimensionally in an automated system, which is especially useful for pre-surgical formation of implantable spinal rods. When local and/or global feedback processing accompanies a series of shaping steps automatically imposed on a rod or other articles being shaped into three-dimensional form, formation time may be expedited compared to manual creation, and shapes difficult or impractical to create manually may be constructed simply. Thus, the embodiment of the present invention discussed with reference to Example 1 provides an improvement over conventional implant practices, and also constitutes a system-based approach to reproducing a desired shape as conceived by a surgeon onto a spinal rod implant.

Also, it should be appreciated that an inventive automated rod-bender such as in Example 1 can be used to put many more bends in a spinal rod than a human operator (such as a surgeon) can, and also to do so with more care and accuracy and repeatability compared to a human.

A rod bent using the inventive automated rod-bender of this Example may be processed by sterilization after shaping but prior to use in a patient, such as in an autoclave. The automated rod-bender of this Example is designed to impart no physical damage to the rod that other than the reshaping of its three-dimensional form.

In this inventive Example, to accommodate the cooperating fastening hardware, the translational control interface introduces points on either side of points corresponding to the location of the cooperating hardware and computes the necessary rotation and bending required to achieve the desired curve shape at these former points, thus ensuring that the rod passes through the positions of the cooperating hardware with the appropriate spatial direction.

In this example, there is nothing particular observed for large bends versus small bends. The same parts actuate the rod for these respective bends. It is advantageous from a material stress point of view, however, to not apply a large bend over too small a bending radius. Instead, as mentioned before, a sequence of smaller bends would be imposed to result in an accumulated large bend. The larger the bend, however, the more significant becomes the rolling sleeve on the bending mandrel which allows for the difference in radii and rotation center between the bending arm and bending mandrel and the rod. The bending arm structure that uses the rolling sleeve is particularly advantageous when working with surgical implant rods, to eliminate friction and to reduce possibility of damage to the rod surface during bending.

Notably, an inventive automated rod-bender such as that shown in Example 1 is able to establish the correct bend without needing the sort of backtracking that the surgeon might sometimes do when he manually bends a rod and he needs to backtrack and put new bends in regions already previously bent to compensate for errors resulting from previous bends. Rather, when the inventive machine bends several times at the same location, the bends are in immediate succession to achieve the desired local accuracy and account for spring back, and no backtracking is needed.

Even if a computer tells a surgeon what bend to put into a rod, if the surgeon has to manually bend the rod as in Comparative Example 1, the procedure is not particularly accurate, is time consuming, and will be fatiguing to the surgeon. The amount of force that a human can apply is relatively more limited than what a machine can deliver. By contrast, bending a spinal rod using the inventive technology of Example 1 avoids such problems and provides improved accuracy and other advantages.

INVENTIVE EXAMPLE 2

A preferred example of a use of the present invention is a method in which, in advance of surgical implantation, automated pre-screening of a three-dimensional bent shape is performed, including a determination of placement in the patient of the three-dimensional bent shape with reference to cooperating hardware placed, or to be placed, in the patient.

An example of cooperating hardware placed, or to be placed, in the patient is a pedicle screw, which is medical hardware conventionally in use, such as pedicle screw used in spinal surgery. An example of a three-dimensional bent shape is a bent spinal rod. The pedicle screws are used in attaching the spinal rod to the patient’s body. In the invention, placing the bent spinal rod in the patient may be assisted by an inventive article that cooperates with the pedicle screw, such as a cap for the pedicle screw. An example of an inventive pedicle screw cap is a pedicle screw cap, comprising an article having an opening which receives a pedicle screw, the article being biocompatible and of a medically-imageable material. See, for example, the inventive pedicle screw cap in FIG. 9.

The cones in the pedicle screw cap are used to provide enough information during imaging (such as imaging using a fluoroscope) to determine the position and orientation of the pedicle screw and thereby the desired location of points along the rod and the directions of the rod through these points. Features of the pedicle screw cap are formed so that these features may be imaged to provide the desired information. For example, in FIG. 9, the cones have different opening angles, so that from an image taken of the pedicle screw cap, it can be determined which cone is being viewed, and orientation thereby inferred. Preferably, the processing of the imaged cones is by processing using computer software, such as software detecting the shape of the screw cap and determining from the different opening angles of the cones the orientation that has been imaged.

A preferred shape of the pedicle screw cap is a shape that accentuates its position and orientation to commonly used surgical imaging apparatus (e.g., fluoroscopy), thus providing input to the translational control interface about the position and orientation of cooperating hardware and the desired position and orientation of corresponding points along the spinal implant rod for further processing and shaping by the hardware (with use of hardware according to the invention being preferred).

While the invention has been described in terms of its preferred embodiments, those skilled in the art will recognize that the invention can be practiced with modification within the spirit and scope of the appended claims.

What we claim as our invention is:

1. An automated system that bends a rod, comprising:
   - an input mechanism for producing a desired three-dimensional bent shape;
a translational control interface; and
automated rod-bending hardware, wherein the automated
rod-bending hardware imposes a series of local bends in
the rod until the desired three-dimensional bent shape has been formed.

2. The rod-bending system of claim 1, wherein the rod is
a medically implantable rod of less than about 1 cm diam-
eter.

3. The rod-bending system of claim 1, wherein the input
mechanism is selected from the group consisting of (1)
deforming a deformable template rod into the desired three-
dimensional bent shape followed by photographic scanning
of the deformed template rod; (2) operating a spatial locator
to map a region where the desired three-dimensional bent
shape is to be implanted; (3) computer-aided design of a
virtual rod; (4) operating a surgical imaging apparatus; and
(5) imaging pedicle screws to establish the desired three-
dimensional bent shape.

4. The rod-bending system of claim 1, including real-time
automated correction of local bends for spring-back.

5. The rod-bending system of claim 1, including a sensor
operating at a region where a local bend has just been
imposed, information from the sensor being subjected to at
least one of a local feedback operation and a global feedback
operation.

6. The rod-bending system of claim 5, including infor-
mation from the sensor being subjected to both a local
feedback operation and a global feedback operation.

7. The rod-bending system of claim 5, wherein as a result
of the feedback operation(s), a current sequence of applica-
tible automated instructions for bending is automatically
modified into a modified sequence of automated instructions
for bending.

8. The rod-bending system of claim 7, wherein feedback
is used to impose additional bending actuation at the same
location to achieve desired local bending accuracy.

9. The automated system of claim 1, wherein in position
by the automated rod-bending hardware of the series of
local bends in the rod, the automated rod-bending hardware
provides higher repeatability than could be provided by
a human operator manually attempting to execute a same
series of local bends.

10. The automated system of claim 1, including after each
imposition of a local bend, automated global feedback
wherein an actual local bend imposed is automatically compared to the desired shape and instructions for remain-
ing bending steps are automatically evaluated.

11. The automated system of claim 1, including an auto-
mated cutting mechanism that reduces the rod to a desired
length.

12. The automated system of claim 1, including, after a
first set of automated instructions for imposing a series of
local bends has been formulated but in advance of imple-
menting the first set of automated instructions, an automated
screening of whether sufficient clearance is physically
present to justify initiating the first set of automated instruc-
tions.

13. The automated system of claim 1, including, prior to
each imposition of a local bend according to a bend impos-
tion instruction, an automated screening of whether sufi-
cient clearance is physically present to justify ordering
execution of the bend imposition instruction.

14. The automated system of claim 1, including an auto-
mated correction system which, when bend imposition
has been proceeding along the rod according to a first set of
instructions for imposing local bends with the first set of
instructions being only partly executed, the automated cor-
rection system (1) detects a point at which small errors in
imposed bends have accumulated to a point where the first
set of instructions cannot viably be completed as a matter of
physical clearance and (2) revises the first set of instructions
to a second set of instructions, wherein the second set of
instructions can be viably completed as a matter of physical
clearance.

15. The automated system of claim 1, wherein the rod
being bent is made of a material selected from the group
consisting of: titanium; titanium alloy; steel and shape-
memory alloys.

16. The automated system of claim 1, including one of: (a)
a motorized system responsible for forward movement of
the rod including stopping according to a series of actuator
commands, the actuator commands being computer-generated;
or (b) a motorized system responsible for forward
movement of the rod-bending hardware including stopping
according to a series of actuator commands, the actuator
commands being computer-generated.

17. The automated system of claim 1, including one of: (a)
a motorized system responsible for rotary movement of the
rod including stopping according to a series of actuator
commands, the actuator commands being computer-generated;
or (b) a motorized system responsible for rotary
movement of the rod-bending hardware including stopping
according to a series of actuator commands, the actuator
commands being computer-generated.

18. An automated method of making an implantable rod,
comprising:

non-manual imposition of a series of local bends in an
implantable rod, whereby a three-dimensional bent shape is non-manually formed.

19. The rod-making method of claim 18, wherein follow-
ing imposition of a local bend, at least one feedback loop is
operated, with the feedback loop selected from the group
consisting of local feedback and global feedback, and with the
feedback loop being machine-implemented and human-
free.

20. The rod-making method of claim 18, including at least
one automated step of translating a desired bent-shape into
a series of actuator commands for machine-based rod-
bending.

21. The rod-making method of claim 20, including actua-
tor command implementation, resulting in machine-imposed
bending of the rod.

22. The rod-making method of claim 21, including auto-
mated imposition of at least one three-dimensional bend
approaching 180 degrees or automated imposition of a
sequence of bends whose combined effect is a three-dimen-
sional bend approaching 180 degrees.

23. The rod-making method of claim 18, including, after
automated imposition of a local bend in the rod, operation of
both automated local feedback and automated global feed-
back.

24. The rod-making method of claim 18, wherein the
three-dimensional bent shape is constructed before surgical
exposure of the patient’s spine.

25. The rod-making method of claim 18, including non-
manually forming a customized bent rod shape correspond-
ing to a spine of a particular patient having scoliosis.
26. The rod-making method of claim 18, wherein rod-bending is entirely automated and the rod needs no manual shaping before being implanted in the patient.

27. The rod-making method of claim 18, including:
   determining X-Y-Z coordinates of a desired rod shape;
   integrated feedback processing a local bend that has been imposed.

28. The rod-making method of claim 18, including operating an automatic controller commanding operations performed on the rod, the controller including:
   a feed command for feeding movement of the rod;
   a rotate command for rotating movement of the rod; and
   a bend command for bending movement of the rod.

29. The rod-making method of claim 18, including measuring spring-back of the rod via an automatic sensor.

30. The rod-making method of claim 18, including collecting spring-back measurements via an automatic sensor and automated processing of the spring-back measurements.

31. The rod-making method of claim 18, including a step of computer-assisted design of a desired three-dimensional bent shape.

32. The rod-making method of claim 31, wherein the desired three-dimensional bent shape is actually constructed.

33. The rod-making method of claim 31, including, as rod-bending progresses, performing a series of automated comparisons of the bent rod as actually-bent to the desired three-dimensional shape.

34. The rod-making method of claim 18, wherein bends are imposed non-manually along the rod in one-direction progression without doubling-back.

35. The rod-making method of claim 18, including an automated step in which is determined an end of the rod at which to begin imposing bends.

36. The rod-making method of claim 18, including disposing the rod in an automated bending system and before bending is permitted to begin, an automated step is performed of processing a desired shape to be constructed to confirm or deny sufficient clearance for automated bending to successfully proceed.

37. A method of making a rod, comprising:
   (a) an automated series of non-manual bending steps on a rod, wherein each bending step imposes an actual bend on the rod;
   (b) after a bending step, (i) automatic local feedback processing wherein data representing the actual bend is processed for whether the actual bend is according to instruction or varies from instruction; and (ii) automatic global feedback processing wherein data representing the actual bend is processed for formulating at least one next instruction for a bending step downstream along the rod.

38. The method of claim 37, wherein when the information from (b)(i) is used to further impose bending actuation to reach the desired bending angle, either in a single step or in a sequence of steps, either by using an analytical estimate of spring-back based on material properties or based on measurements from previous bends.

39. The rod-making method of claim 37, wherein the rod is an implantable rod.

40. The rod-making method of claim 39, wherein a three-dimensionally bent rod is formed.

41. The rod-making method of claim 39, wherein the rod is of titanium or a titanium alloy, and has a diameter of less than about 1 cm.

42. The rod-making method of claim 39, wherein the three-dimensionally bent rod includes at least one severe bend approaching 180 degrees.

43. An implantable rod bending apparatus, comprising:
   a housing receiving an implantable rod to which bending force is to be applied; and
   a fully-automated mechanical system that applies bending force to the rod disposed in the housing and that positions the rod disposed in the housing, including means for positioning, orienting and bending the rod into a three-dimensional bent shape.

44. The apparatus of claim 43, wherein the apparatus includes a minimal clearance that is a void volume such that the rod may be as long as about 1 yard and may be bent while disposed in the apparatus into a three-dimensional bent shape.

45. The apparatus of claim 43, wherein the apparatus includes a minimal clearance that is a void volume such that the rod may be as long as about 1 yard and may be bent while disposed in the apparatus into a three-dimensional bent shape.

46. An automated rod-bending system, comprising:
   a housing receiving an implantable rod to which bending force is to be applied; and
   a fully-automated mechanical system that applies bending force to the rod disposed in the housing and that positions the rod disposed in the housing, including means for positioning, orienting and bending the rod into a three-dimensional bent shape;
   a fully automated control system that delivers a series of computer-readable instructions to the fully-automated mechanical system that applies bending force and that positions the rod.

47. The automated rod-bending system of claim 46, including a sensor from which is obtained digitized information quantifying bending actually present in the rod.

48. The automated rod-bending system of claim 47, including, after imposition of each bend, processing data from the sensor according to at least one or both of automated local feedback and automated global feedback.

49. The automated rod-bending system of claim 48, including, after imposition of each bend, both automated local feedback and automated global feedback.

50. A surgical method, comprising steps of:
   automated bending of a rod into a three-dimensional bent shape implantable in a patient;
   surgical implantation into the patient of the three-dimensional bent shape.

51. The method of claim 50, wherein the three-dimensional bent shape is implanted in a spinal region of the patient.

52. The method of claim 51, wherein the surgical implantation is for treating scoliosis.

53. The method of claim 51, wherein the three-dimensional bent shape is constructed and ready for implantation before surgical exposure of the patient's spine.

54. The method of claim 50, including in advance of surgical implantation, automated pre-screening of the three-dimensional bent shape, including a determination of place-
A method of making an implantable article, comprising steps of:

automated shaping of an article, in a direction of a target design that is a three-dimensional bent shape implantable in a patient, including a series of automated shaping steps each imposing an actual local shape;

after each automated shaping step wherein an actual local shape is imposed, automated global feedback wherein the actual local shape imposed is automatically compared to the target design and instructions for remaining shaping steps are automatically evaluated.

The method of claim 55, including automatic adjustment of instructions for at least one automated shaping step still to be performed.

The method of claim 55, including automated local feedback wherein the actual local shape imposed is automatically compared to instructions given and additional actuation is imposed to the same local area of the article to improve the agreement between the desired local shape and the achieved local shape.

The method of claim 55, wherein the implantable article is a rod.

The method of claim 55, wherein the implantable article is formed in less time via the automated shaping than could be accomplished by being manually formed.

A pedicle screw cap, comprising an article having an opening which receives a pedicle screw, the article being biocompatible and of a medically-imageable material.

The pedicle screw cap of claim 60, wherein the screw cap has a shape that accentuates its position and orientation to surgical imaging apparatus.

The automated system of claim 1, wherein the input mechanism for producing a desired three-dimensional bent shape includes at least one of: in vivo medical imaging or in vivo biological imaging.

The automated system of claim 1, wherein the hardware comprises a bending mandrel and a bending arm.

The automated system of claim 63, wherein the bending arm is disposed in a rolling sleeve.