

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): P. Bonutti

Confirmation No.: 6375

Application No.: 10/722,102

Attorney Docket No: 780-A03-012C

Filed: November 25, 2003

Group Art Unit: 3733

For: KNEE ARTIHOPLASTY METUOD

Examiner: P. Philogene

**RESPONSE TO OFFICE ACTION**

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In reply to the Office Action mailed January 30, 2007, and Interview conducted April 10, 2007, please enter this Response into the file of the above-entitled application.

In accordance with USPTO practice, each section of this Response begins on a separate sheet. Applicant submits, these amendments and remarks serve to clarify the present invention, and are independent of patentability.

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**In The Specification**

Please replace paragraph [0001] with the following:

This application is a continuation of U.S. patent application Serial No. 10/191,751 filed July 8, 2002. This application is also continuation-in-part of U.S. patent application Serial No. 09/976,396 filed October 11, 2001. This application is also continuation-in-part of U.S. patent application Serial No. 09/941,185 filed August 28, 2001. This application is also a continuation-in-part of U.S. patent application Serial No. 09/566,070. This application is also a continuation-in-part of U.S. patent application Serial No. 09/737,380 filed December 15, 2000. This application is also a continuation-in-part of U.S. patent application Serial No. 09/569,020 filed May 11, 2000. This application is also a continuation-in-part of U.S. patent application Serial No. 09/483,676 filed January 14, 2000. This application is also a continuation-in-part of U.S. patent application Serial No. 09/798,870 filed March 1, 2000 ~~2001~~. This application is also a continuation in part of U.S. patent application Serial No. 09/526,949 filed on March 16, 2000. This application is also a continuation-in-part of U.S. patent application Serial No. 09/789,621 filed February 21, 2001.

#### **Amendments to the Claims**

1. (Original) A method of performing surgery on a patient's knee including a femur and a tibia, the method comprising the steps of:
  - making an incision in a knee portion of a leg of the patient;
  - positioning a cutting guide through the incision and on a side surface of a distal end portion of the femur;
  - moving a cutting tool through the incision into engagement with a guide surface on the cutting guide;
  - cutting the femur by moving the cutting tool along the guide surface,
  - wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod.
2. (Original) The method of claim 1 wherein the side surface is a medial side of the distal end portion of the femur.
3. (Original) The method of claim 1 wherein the side surface is a lateral side of the distal end portion of the femur.
4. (Original) The method of claim 1 wherein a computer navigation system is used in the positioning step.
5. (Original) The method of claim 1 wherein the positioning step includes removably attaching the cutting guide to the side surface of the distal end portion of the femur.
6. (Original) The method of claim 5 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the femur.

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7. (Original) The method of claim 1 wherein the guide surface comprises a plurality of straight guide segments.

8. (Original) The method of claim 7 wherein the plurality of straight guide segments comprises:

- a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the femur and extends through lateral and medial condyles of the femur;

- an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

- a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

- an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

- a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

9. (Original) The method of claim 1 further comprising the step of removing at least a portion of the side surface prior to positioning the cutting guide such that a flattened section of the side surface is created and abuttingly engaged by a major side surface of the cutting guide when the cutting guide is positioned thereon.

10. (Original) The method of claim 1 wherein said step of cutting the femur includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the femur, and completing the cut in the femur while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the femur.

11. (Original) The method of claim 10 wherein the cutting guide is positioned on the side surface of the distal end portion of the femur during completion of the cut.

12. (Original) The method of claim 10 wherein the cutting guide is removed from the side surface of the distal end portion of the femur after making the initial portion of the cut and before completion of the cut.

13. (Original) A total knee replacement cutting guide for forming a cut surface on a bone in preparation to receive a total joint replacement component comprising:

a guide member having a body configured and dimensioned for attachment to a side surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod; and

at least one guide surface extending from one side of the guide member to an opposite side of the guide member, the at least one guide surface configured and dimensioned for engagement with a cutting tool to thereby direct the cutting tool in making only a portion of the cut surface.

14. (Original) The total knee replacement cutting guide of claim 13 wherein the guide member attaches to either a medial or lateral side surface of the end portion of the bone.

15. (Original) The total knee replacement cutting guide of claim 13 wherein the at least one guide surface includes a distal end surface having opposite ends spaced apart by a distance which is less than a distance that the total joint replacement component extends across the bone when implanted.

16. (Original) The total knee replacement cutting guide of claim 15 wherein the guide member has an aperture for receiving a pin to thereby secure the guide member to the bone.

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17. (Original) The total knee replacement cutting guide of claim 16 wherein the at least one guide surface includes:

- an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

- a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

- an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

- a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

18. (Original) The total knee replacement cutting guide of claim 16 wherein the cutting guide is a non-captured cutting guide.

19. (Original) A method of performing surgery on a joint in a patient including a first bone and a second bone, the method comprising the steps of:

- making an incision proximal to the joint in the patient;

- positioning a cutting guide through the incision and on a side surface of an end portion of the first bone;

- moving a cutting tool through the incision into engagement with a guide surface on the cutting guide;

- cutting the first bone by moving the cutting tool along the guide surface,

- wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod.

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20. (Original) The method of claim 19 wherein the side surface is a medial side of the end portion of the first bone.

21. (Original) The method of claim 19 wherein the side surface is a lateral side of the end portion of the first bone.

22. (Original) The method of claim 19 wherein a computer navigation system is used in the positioning step.

23. (Original) The method of claim 19 wherein the positioning step includes removably attaching the cutting guide to the side surface of the end portion of the first bone.

24. (Original) The method of claim 23 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the first bone.

25. (Original) The method of claim 19 wherein the guide surface comprises a plurality of straight guide segments.

26. (Original) The method of claim 25 wherein the plurality of straight guide segments comprises:

- a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the first bone;

- an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

- a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the first bone; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

27. (Original) The method of claim 19 further comprising the step of removing at least a portion of the side surface prior to positioning the cutting guide such that a flattened section of the side surface is created and abuttingly engaged by a major side surface of the cutting guide when the cutting guide is positioned thereon.

28. (Original) The method of claim 19 wherein said step of cutting the first bone includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the first bone, and completing the cut in the first bone while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the first bone.

29. (Original) The method of claim 28 wherein the cutting guide is positioned on the side surface of the end portion of the first bone during completion of the cut.

30. (Original) The method of claim 29 wherein the cutting guide is removed from the side surface of the end portion of the first bone after making the initial portion of the cut and before completion of the cut.

31. (New) The method of claim 1, wherein said incision is between about seven and about thirteen centimeters.



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32. (New) The method of claim 1, where said positioning step further includes the step of using light beams.

33. (New) The method of claim 1, wherein in said step of making an incision, said incision is offset from the center of said knee area.

34. (New) The method of claim 13, wherein said at least one guide surface includes a guide surface corresponding to each guide surface required by said joint replacement component.

35. (New) The method of claim 19, wherein after said step of cutting, further including the steps of:

removing said cutting guide; and,

guiding said cutting tool using cuts formed in said cutting step to complete said cuts.

36. (New) The method of claim 19, wherein in said step of positioning, said cutting guide is sized smaller than said side surface.

37. (New) The method of claim 19, wherein after said step of positioning, further including the step of:

aligning said cutting guide using markings on said side surface.

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### Remarks

Claims 1-37 are presented for the Examiner's review and consideration. In this response, claims 31-37 have been added. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

### Interview

An Applicant Initiated Telephonic Interview with the Examiner was conducted on April 10, 2007. In accordance with MPEP §713.04, the substance of the interview was as follows:

- A) No exhibits were shown or demonstrations conducted.
- B) Claims 1, 13 and 19 were discussed.
- C) Prior art reference Masini (6,500,179) was discussed.
- D) It was agreed that Masini was not directed to a cutting block positioned on a side surface of the femur, and that Masini required Intra and Extramedullary alignment means, particularly with respect to the initial resection of the distal end of the femur, requiring IM means, and EM means 120, 124, 160. Accordingly, it was agreed that the reference was overcome. It was further agreed that the next Office Action would not be Final since no claim amendments were necessary in order to overcome the rejection.
- E) Arguments were substantially as described for item "D", above.
- F) No other pertinent matters were discussed with respect to this application. Other applications were discussed during the interview, the substance of which will be detailed in responses in the respective applications.
- G) Results were as described in "D", above.
- H) The interview was not conducted by email.

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35 U.S.C. §102(e) Rejections

Claims 1-30 were rejected under 35 U.S.C. §102(e) as being anticipated by Masini (6,500,179) ("Masini"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

The rejection states that Masini shows a guide having a body configured and dimensioned for attachment to a side surface of an end portion of a bone 130. Applicant respectfully submits that cited reference 130, shown in Fig. 1, refers to the whole bone, generally. In the specification, and in all of the figures of Masini, the guide is shown and described as being attached to the end of the bone only. Accordingly, this element of the claimed invention is not met by the disclosure of Masini.

Further, the rejection states that Masini shows at least one guide surface (106,108,110,112) extending from one side of the guide member to an opposite side of the guide member. However, in the specification and in all of the figures of Masini, the guide slots do not extend from one side of the guide to the other; rather none of the guide slots extend through the center portion of the device. Accordingly, this element of the claimed invention is also not met by the disclosure of Masini.

Masini discloses a device incorporating a plurality of cutting guides, wherein at least one of the guides is used to resect or otherwise modify a bone to receive a prosthetic element... (Col. 1, lns. 50-52). ...the guides take the form of parallel, spaced-apart slots extending through at least a portion of the body... (Col. 2, lns. 3-4). ...With reference to fig. 1 of Masini, the device 102 optionally further includes a posterior gauge 120 coupled to a member 122, and an anterior gauge 124 coupled to a member 126. (Col. 3, lns. 17-19). With reference to fig. 2 of Masini, the members 122 and 126 preferably interlock within the body of the block 104, with a manually operated fastener 128 being used to compress the gauges while compressively urged against respective protrusions of a bone 130. (Id).

With reference to fig. 3 of Masini, ...the guide block preferably features a smooth, planar backside 330, enabling the device to be positioned against a previously prepared surface such as a resected distal surface. (Col. 3, lns. 49-51). To assist in positioning, subtle adjustments may be achieved by moving the guide body with a fine control knob 140 which, as shown in fig. 2 of Masini, couples to a rod 242 and toothed element 244. (Col. 3, lns. 57-60). The element 244, in turn, interacts with teeth 246 to move the entire block [up--?] and down relative to the bone when held in place by gauges 120 and 124 upon being tightened using fastener 128. (Id). Readouts 150 and 152 may be provided for a visual indication of element size selection, and/or one or more additional "feeler gauges" such as element 160 may be used to make contact with an appropriate portion of the bone indicative of a particular implant size. (Col. 3, ln.67 – Col. 4, ln. 4).

Thus, Masini does not disclose or suggest a guide member free of extramedullary or intramedullary alignment means. Rather, Masini discloses anterior and posterior gauges extending from the block and interlocking within the block, operative with a fine control knob and gear. There is not suggested other means by which the block is positioned. Moreover, the block of Masini is positioned against a flat distal end of the bone, which in the prior art, requires an intramedullary device for its creation.

Additionally, as discussed above, Masini does not disclose or suggest a guide member positioned on a side surface of an end portion of a bone, nor does Masini disclose or suggest a guide surface extending from one side of the guide member to an opposite side of the guide member.

In contrast, the present invention relates to a new and improved method of performing surgery, and instruments, implants, and other surgical implements that can be used in surgery. (Background). Regardless of the type of surgery to be performed, a limited incision may advantageously be utilized. (Id). The incision 114 is movable relative to the distal end portion 124 of the femur 126 to maximize exposure of the femur through the limited length of the incision. (§[0174]). ...the minimally invasive surgical instruments, implants, systems, and methods disclosed herein represent a significant deviation from those used in open surgical procedures... (§[0714]).

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Although any one of many known surgical procedures may be undertaken through the limited incision, down sized instrumentation for use in the making of cuts in a femur and/or tibia may be moved through or part way through the incision. (§[0013]) The down sized instrumentation may be smaller than implants to be positioned in the knee portion of the patient. (Id).

With reference to Fig. 54 of the present invention ...a femoral cutting guide 800 is illustrated as being mounted on a lateral surface 802 of the femur 126. (§[0494]). However, the femoral cutting guide 800 could be mounted on the medial surface of the femur 126 if desired. (Id).

It is contemplated that the down sized instrumentation may have cutting tool guide surfaces of reduced length. (§[0014]). The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. (Id). A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool. (Id).

As such, the present invention provides a means for cutting bone, where the guide member is free of extramedullary or intramedullary members. As noted above, Masini fails to disclose a guide member free of extra or intramedullary members, a guide used on a side surface of a bone, or a guide with a surface extending from one side of the guide to an opposite side.

Claim 1 recites, *inter alia*, A method of performing surgery on a patient's knee including a femur and a tibia, the method comprising the steps of: making an incision in a knee portion of a leg of the patient; positioning a cutting guide through the incision and on a side surface of a distal end portion of the femur; moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; cutting the femur by moving the cutting tool along the guide surface, wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod.

Claim 13 recites, *inter alia*, a total knee replacement cutting guide for forming a cut surface on a bone in preparation to receive a total joint replacement component comprising: a guide member having a body configured and dimensioned for attachment to a side surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod; and at least one

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guide surface extending from one side of the guide member to an opposite side of the guide member, the at least one guide surface configured and dimensioned for engagement with a cutting tool to thereby direct the cutting tool in making only a portion of the cut surface.

Claim 19 recites, *inter alia*, a method of performing surgery on a joint in a patient including a first bone and a second bone, the method comprising the steps of: making an incision proximal to the joint in the patient; positioning a cutting guide through the incision and on a side surface of an end portion of the first bone; moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; cutting the first bone by moving the cutting tool along the guide surface, wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod.

Accordingly, applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Masini. As claims 2-12 depend from claim 1; claims 14-18 depend from claim 13; and claims 20-29 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Masini for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejection.

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Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$350 is believed to be due for 7 additional dependent claims. A credit card payment form is being submitted herewith. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Paul Bianco", with a stylized flourish at the end.

Paul Bianco, Reg. #43,500

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Electronic Patent Application Fee Transmittal				
Application Number:		10722102		
Filing Date:		25-Nov-2003		
Title of Invention:		Knee arthroplasty method		
First Named Inventor/Applicant Name:		Peter M. Bonutti		
Filer:		Paul David Bianco/Dinah Fuentes		
Attorney Docket Number:		780-A03-012C		
Filed as Large Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	7	50	350
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				



Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				350

Electronic Acknowledgement Receipt	
EFS ID:	1726939
Application Number:	10722102
International Application Number:	
Confirmation Number:	6375
Title of Invention:	Knee arthroplasty method
First Named Inventor/Applicant Name:	Peter M. Bonutti
Customer Number:	33771
Filer:	Paul David Bianco/Dinah Fuentes
Filer Authorized By:	Paul David Bianco
Attorney Docket Number:	780-A03-012C
Receipt Date:	30-APR-2007
Filing Date:	25-NOV-2003
Time Stamp:	11:08:57
Application Type:	Utility

**Payment information:**

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 350
RAM confirmation Number	1895
Deposit Account	

**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
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