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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: P. Bonutti

Confirmation No.: 3567

Application No.: 10/684,904

Attorney Docket No: 780-A03-012B

Filed: October 14, 2003

Group Art Unit: 3733

For: KNEE ARTHROPLASTY METHOD

Examiner: M. Hoffman

RESPONSE TO OFFICE ACTION

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

Dear Sir:

In response to the Final Office Action mailed March 18, 2009, 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.

**S&N EXHIBIT 1024
S&N v. BSI
IPR2013-00629**

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For: KNEE ARTHROPLASTY METHOD

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RESPONSE TO FINAL OFFICE ACTION
AND REQUEST FOR CONTINUED EXAMINATION
PURSUANT TO 37 C.F.R. §1.114

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

Introductory Comments

Dear Sir:

In response to the Office Action mailed March 18, 2009, and Advisory Opinion mailed June 30, 2009, Applicant requests continued examination pursuant to 37 C.F.R. §1.114. Please enter the following amendments and remarks into the file for the above-identified application. This response replaces the response filed June 18, 2009.

In accordance with USPTO practice, each section of this Response begins on a separate sheet. Applicant submits, this response serves to clarify the present invention, and is independent of patentability.

Amendments to the Claims:

1. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg having a length not more than 13 cm;
displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward; and
positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg and cutting bone of the leg while the patella is maintained offset from a normal position and not everted.

2. (Canceled)

3. (Previously presented) The method of claim 1, further comprising:

expanding the incision by applying a force against opposite edge portions of the incision, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision.

4. (Original) The method of claim 1, further comprising cutting an end surface of at least one of the upper or lower portions of the leg.

5. (Previously presented) The method of claim 4 comprising:

moving at least one implant through the incision while the patella is offset from the normal position with the inner side of the patella facing inward; and
connecting the at least one implant with the cut end portion of at least one of the upper or lower portions of the leg.

6. (Original) The method of claim 1, further comprising connecting a guide member to at least one of the upper or lower portions of the leg.

7. (Original) The method of claim 6, wherein the guide member is connected to the upper portion of the leg, the upper portion being a femur, the guide member including a first end portion in engagement with a lateral condyle of the femur, the first end portion offset medially from a lateral edge portion of the lateral condyle, and a second end portion in engagement with a medial condyle of the femur, the second end portion offset laterally from a medial edge portion of the medial condyle.

8. (Original) The method of claim 7, further comprising cutting the lateral and medial condyle of the femur.

9. (Previously presented) The method of claim 8, further comprising:
moving at least one femoral implant through the incision while the patella is offset from the normal position with inner side of the patella facing inward; and
connecting the at least one femoral implant with the cut lateral and medial condyle of the femur.

10. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:
making an incision in a knee portion of the leg ~~having a length not more than 13 cm~~;
displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;
positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;
and
connecting a guide member to at least one of the upper or lower portions of the leg; wherein the guide member is connected to the lower portion of the leg, the lower portion being a tibia;
cutting a bone of the knee portion of the leg, while the patella is maintained in the offset position, and while no bone of the knee extends to pass outside the patient's body through said incision, until cut and removed from the joint.

11. (Original) The method of claim 10, further comprising cutting an end surface of the tibia.

12. (Original) The method of claim 11, further comprising:
moving at least one tibial implant through the incision while the patella is offset from the normal position with the inner side of the patella facing inward; and
connecting the at least one tibial implant with the cut end portion of the tibia.

13. (Original) The method of claim 1, further comprising:
moving a guide member into the incision, the guide member including opposite ends spaced apart by a distance which is less than a distance between a lateral epicondyle and a medial epicondyle on a femur;
positioning the guide member on the femur in the leg of the patient with the opposite ends of the guide member aligned with an axis through the lateral and medial epicondyles;
positioning the cutting tool on the guide member; and
moving the cutting tool along a guide surface on the guide member to cut the lateral and medial epicondyles on the femur.

14. (Previously presented) The method of claim 13, further comprising:
moving at least one femoral implant through the incision while the patella is offset from the normal position with the inner side of the patella facing inward; and
connecting the at least one femoral implant with the cut lateral and medial epicondyles of the femur.

15. (Previously presented) The method of claim 13, further comprising:
cutting the inner side of the patella in the knee portion of the leg, wherein the inner side of the patella faces towards a posterior portion of the knee portion of the leg and includes removing at least a portion of the inner side of the patella.

16. (Currently amended) A method of performing a joint arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg;

displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;

~~positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;~~

positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool;

cutting the inner side of the patella, using the guide assembly, in the knee portion of the leg, prior to resecting the femur or the tibia, wherein while the inner side of the patella faces towards a posterior portion of the knee portion of the leg, and includes removing at least a portion of the inner side of the patella; ~~and~~

~~positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool.~~

17. (Original) The method of claim 16, wherein positioning the guide assembly comprises extending a first parallel arm under a superior aspect of the patella and a second parallel arm under an inferior aspect of the patella, such that the guide surface is aligned with the patella.

18. (Original) The method of claim 15, further comprising:

moving at least one patella implant through the incision; and

connecting the at least one patella implant to the cut inner side of the patella.

19. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg ~~having a length not more than 13 cm;~~

displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;

positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;
cutting the inner side of the patella in the knee portion of the leg, wherein the inner side of the patella faces towards a posterior portion of the knee portion of the leg and includes removing at least a portion of the inner side of the patella, while no bone of the joint extends to pass outside the body through said incision, until cut and removed from the joint; and
wherein the inner side of the patella is cut prior to displacing the patella from the normal position to the offset position.

20. (Original) The method of claim 19, further comprising:

moving at least one patella implant through the incision prior to displacing the patella from the normal position to the offset position; and
connecting the at least one patella implant to the cut inner side of the patella prior to displacing the patella from the normal position to the offset position.

21. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg;
displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward; and
positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;
and
supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position with the inner side of the patella facing inward.

22. (Original) The method of claim 1, further comprising:
moving a leading end of an endoscope through the incision to a posterior portion of the knee portion of the leg of the patient; and
inspecting the posterior portion of the knee portion of the leg, including viewing the posterior portion of the knee portion through the endoscope.

23. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:
making an incision in a knee portion of the leg having a length not more than 13 cm;
displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;
positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg, and cutting bone of the leg while the patella is in the offset position;
moving a leading end of an endoscope through the incision to a posterior portion of the knee portion of the leg of the patient;
inspecting the posterior portion of the knee portion of the leg, including viewing the posterior portion of the knee portion through the endoscope; and
moving the leg of the patient between a flexed condition and an extended condition, wherein the posterior portion of the leg is viewed, at least partially, during movement of the leg of the patient between the flexed and extended conditions.

24. (Previously presented) The method of claim 1, further comprising:
initiating a cut with the cutting tool along an end portion of at least one of the upper or lower portions of the leg to define a cutting surface; and
completing the cut while guiding the cutting tool along the cutting surface formed during making of the initial cut in an end portion of at least one of the upper or lower portions of the leg.

25. (Currently amended) A method of performing a knee arthroplasty surgery on first and second portions of a leg of a patient, comprising:

- making an incision in a knee portion of the leg having a length not more than 13 cm, the length shorter than the combined width of said first and second portions of the leg;
- displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;
- positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;
- exposing the first portion of the leg through the incision and performing surgery on the first portion;
- effecting relative movement between the upper and lower portions of the leg, thus exposing the second portion of the leg through the incision, thereby enabling surgery cutting bone of the leg on the second portion through the incision while maintaining the patella in the offset position.

26. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

- making an incision in a knee portion of the leg having a length not more than ~~13 cm~~ about twice the length of the patella;
- displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;
- positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;
- ~~and~~
- providing an output signal which is a function of tension in a ligament extending between bones in the leg of the patient; and
- cutting bone of the leg while maintaining the patella in the offset position.

27. (Original) A method as set forth in claim 26, wherein providing the output signal comprises:

- positioning a transducer between the ligament and a bone in the knee portion of the leg; and

providing an output signal which varies as a function of variations in force applied against the transducer during relative movement between the upper and lower portions of the leg.

28. (Original) The method of claim 1, wherein making the incision in the knee portion of the leg comprises making the incision adjacent to a medial edge portion of the patella.

29. (Original) The method of claim 1, wherein making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters.

30. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg having a length not more than 13 cm;
displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;
positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg;
and

wherein displacing the patella from the normal position to the offset position comprises moving the patella laterally relative to the knee portion of the leg; and
cutting bone of the knee portion of the leg while maintaining the patella in the offset position.

31. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg of the patient having a length not more than ~~13 cm~~ a distance between, about the proximal end of the tibia to about the epicondylar notch on the distal end portion of the femur;

displacing the patella from the normal position to an offset position with an inner side of the patella facing inward; and

cutting an inner side portion of a patella in the knee portion of the leg, the patella being ~~disposed in a normal position relative to the knee portion of the leg; and~~ maintained in the offset position

~~displacing the patella from the normal position to an offset position with an inner side of the patella facing inward.~~

32. (Original) The method of claim 31, further comprising:
moving at least one patella implant through the incision; and
connecting the at least one patella implant to the cut inner side of the patella.

33. (Original) The method of claim 32, wherein the at least one patella implant is connected to the patella prior to displacing the patella from the normal position to the offset position.

34. (Original) The method of claim 31, further comprising positioning a cutting tool proximal to at least one of the upper and lower portions of the leg.

35. (Original) The method of claim 34, further comprising cutting an end surface of at least one of an upper and lower portions of the leg.

36. (Original) The method of claim 35, further comprising:
moving at least one implant through the incision while the patella is offset from the normal position with the inner side of the patella facing inward; and
connecting the at least one implant with the cut end portion of at least one of the upper and lower portions of the knee portion of the leg.

37. (Original) The method of claim 35, wherein the upper portion of the leg is a femur and lateral and medial condyles of the femur are cut.

38. (Original) The method of claim 37, further comprising:

moving at least one femoral implant through the incision while the patella is offset from the normal position with the inner side of the patella facing inward; and

connecting the at least one femoral implant with the cut lateral and medial condyles of the femur.

39. (Original) The method of claim 35, wherein the lower portion of the leg is a tibia and an end portion of the tibia is cut.

40. (Original) The method of claim 39, further comprising:

moving at least one tibial implant through the incision while the patella is offset from the normal position with the inner side of the patella facing inward; and

connecting the at least one tibial implant with the cut end portion of the tibia.

41. (Original) The method of claim 31, wherein the inner side of the patella is cut prior to displacing the patella from the normal position to the offset position.

42. (Original) The method of claim 31, wherein displacing the patella from the normal position to the offset position comprises moving the patella laterally relative to the knee portion of the leg.

43. (Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising the steps of:

making an incision in a knee portion of the leg having a length not more than ~~13 cm~~ about twice the length of the patella;

cutting an inner side portion of a patella in the knee portion of the leg, the patella remaining in a normal position relative to the knee portion;

moving a patella implant through the incision;

connecting the patella implant to the cut inner side portion of the patella;

displacing the patella from the normal position to an offset position with the cut inner side portion of the patella facing inward;

cutting an end portion of at least one of an upper or a lower portion of the leg;
moving at least one implant through the incision while the patella is offset from the normal position with the cut inner side portion of the patella facing inward; and
connecting the at least one implant with the cut end portion of at least one of the upper or lower portions of the leg.

44. (Original) The method of claim 43, further comprising moving the patella into the normal position, wherein the inner side portion of the patella facing towards a posterior portion of the knee portion;

45. (Original) The method of claim 44, wherein the patella implant is connected to the cut inner side portion of the patella after moving the patella into the normal position from the offset position.

46. (Original) The method of claim 43, wherein the patella implant is connected to the cut inner side portion of the patella prior to displacing the patella from the normal position to the offset position.

47-50. (Canceled)

51. (Previously presented) The method of claim 30, further comprising the steps of:
forming an opening in a bone of the leg; and
positioning a portion of an intramedullary alignment device within said opening.

52. (Previously presented) The method of claim 30, further comprising the step of:
positioning an extramedullary alignment device proximate a bone of the leg.

53. (Previously presented) The method of claim 30, further comprising the step of:
supporting at least the lower portion of the leg on a supporting member including actuating and controlling means, operative to move the lower portion of the leg.

54. (Previously presented) The method of claim 30, further comprising the step of: viewing at least a portion of the interior of the leg during surgery using viewing instrumentation selected from the group consisting of: endoscope, fluoroscope, magnetic resonance imaging unit (MRI).

55. (Previously presented) The method of claim 30, further comprising the step of: performing at least part of the surgery using a robotic device.

56. (Previously presented) The method of claim 30, further comprising the step of: generating and projecting an image on a bone of the leg using a computer, said image operative to guide cutting of the bone.

57. (Previously presented) The method of claim 30, further comprising the step of: implanting an implant including a plurality of layers, at least one of said layers including at least one material selected from the group consisting of: fetal cells, bone cells, embryonal cells, stem cells.

58. (Previously presented) The method of claim 30, further comprising the steps of: sequentially passing portions of an implant through said incision; and, affixing at least two of said implant portions, one to the other, within the leg, in association with one side of the knee joint.

59. (Previously presented) The method of claim 30, further comprising the steps of: replacing at least a portion of a single condyle with an implant; and, replacing at least a portion of a trochlear groove with an implant.

60. (Previously presented) The method of claim 30, wherein the cutting tool is fabricated at a lower cost than a reusable cutting tool by being designed to be used in a single procedure and thereafter discarded.

61. (Previously presented) The method of claim 30, further comprising the step of:
positioning said cutting tool proximal to a side surface of the distal end of the femur to
guide cutting the bone of the leg.

62. (Previously presented) The method of claim 30, further comprising the steps of:
making a second incision in a knee portion of the leg;
inserting at least one item through said second incision selected from the group consisting
of: visualization instrument, inflatable balloon, part of a multi part implant, and surgical
instrumentation.

63. (Withdrawn – Currently amended) A method of repairing a patella on a leg of a patient,
comprising:

making an incision in a knee portion of the leg having a length not more than ~~13 cm~~ a
distance between, about the proximal end of the tibia to about the epicondylar notch on the distal
end portion of the femur;

cutting the patella while the patella is not everted, forming an elongated channel or
projection on the patella, the patella cut without first resecting the femur or tibia; and

sliding a patellar implant, having a channel or projection mateably engageable with the
channel or projection formed in the patella, onto the patella, from a medial or lateral approach to
the patella, thereby affixing said implant onto the patella;

whereby the patella may be cut, and the implant engaged, without a requirement of
substantial subluxation of the patella.

64. (Withdrawn) A method of repairing a patella on a leg of a patient, comprising:
making an incision in a knee portion of the leg having a length not more than 13 cm;
passing a guide wire through the incision;
attaching the guide wire to the patella;
passing a cutting tool along the guide wire, to contact and cut the patella while the patella is
not everted, preparing the patella for a patellar implant; and

affixing a patellar implant to the patella, upon the cut portion of the patella, from a medial, lateral, or retrograde approach to the patella;

whereby the patella may be cut, and the implant engaged, without a requirement of substantial subluxation of the patella.

65. (Withdrawn – Currently amended) A method of performing surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg having a length not more than ~~13 cm~~ a distance between, about the proximal end of the tibia to about the epicondylar notch on the distal end portion of the femur;

disconnecting one of a medial or lateral collateral ligament;

hinging open the joint space, thereby moving the patella medially or laterally without substantially stretching the patellar ligaments;

performing a surgical procedure within the joint space; and

reconnecting the disconnected collateral ligament;

whereby when the patella is moved, an accessible area within the joint space is increased, thereby facilitating the surgery, without a requirement of substantial subluxation of the patella.

66. (Withdrawn – Currently amended) A method of performing a knee arthroplasty surgery on a leg of a patient, comprising:

making an incision in a knee portion of the leg having a length not more than 13 cm;

cutting the patella while the patella is not everted;

attaching at least one transducer operative to indicate a force transmitted between the patella and the femur; and

attaching at least one inflatable bladder to the patella, operative to change a force transmitted between the patella and the femur;

whereby one or both of said transducer or bladder may be left inside the body after surgery, and

whereby patellar tracking may be corrected by inflating the at least one inflatable bladder, based on a force indicated by said at least one transducer.

67. (Withdrawn – Currently amended) A method of performing surgery on knee of a patient, comprising:

making an incision adjacent to a side surface of the patella of the knee, ~~having a length not more than 13 cm~~ extending between, and having a length no longer than a distance between, about the proximal end of the tibia to about the epicondylar notch on the distal end portion of the femur;

positioning a guide, comprising two parallel arms and a saw guiding surface, in contact with the patella, by inserting the arms through the incision, one arm positioned under a superior aspect of the patella, and another arm under an inferior aspect of the patella, thus aligning the saw guiding surface with a portion of the patella to be cut;

cutting a surface of the patella using the saw guiding surface,

affixing a patellar implant to the patella, upon the cut portion of the patella, from a medial, lateral, or retrograde approach to the patella;

whereby the patella may be cut, and the implant engaged, without a requirement of substantial subluxation of the patella.

REMARKS

Claims 1, 3-46 and 51-67 are presented for the Examiner's review and consideration. In this response, claims 1, 10, 16, 19, 21, 23, 25-26, 30-31, 43, and withdrawn claims 63 and 65-67 have been amended. Claims 63-67 were deemed to be constructively non-elected in the Office Action mailed March 18, 2009, and were therein withdrawn. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Election / Restrictions

A restriction was required between Inventions (I): claims 1, 3-46, and 51-62; (II): claims 63-65, and 67; and (III): claim 66. A constructive election of Invention (I) was declared, and claims 63-67 were withdrawn. For reasons set forth below, Applicant respectfully submits that the restriction and constructive election should be withdrawn.

Claims 63-67 include, or have been amended to include, subject matter relating to joint arthroplasty, incision size, a non-everted or non-subluxed patella, and cutting the patella, all subject matter of the original claims. Claims 63-67 add additional elements, further defining the invention.

As such, Applicant respectfully submits that the Restriction Requirement is no longer applicable, and in light of the foregoing, Applicant respectfully requests that the Requirement for Restriction and Constructive Election be withdrawn.

35 U.S.C. §103 Rejection

Claims 1, 4-12, 16-21, 24-25, 28-46, 51-52 and 57-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) ("Johnson") in view of Waddell (U.S. Patent No. 6,174,314) ("Waddell");

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell further in view of Howell (U.S. Patent No. 6,019,767) ("Howell");

Claims 22-23, 54-56 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell further in view of Wang et al. (U.S. Patent No. 6,102,850) ("Wang");

Claims 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell, further in view of Gustilo (U.S. Patent No. 5,733,292) ("Gustilo");

Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell, further in view of Whitt (U.S. Patent No. 4,373,709) ("Whitt");

Claims 1, 4-21, 24-25, 28-46, 51-52 and 57-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines (U.S. Patent No. 5,643,272) ("Haines") in view of Waddell;

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Wang;

Claims 22-23, 54-56 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Wang;

Claims 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Gustilo. Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Gustilo; and,

Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell further in view of Whitt.

For reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

Initially, Applicant respectfully notes that previous Office Actions failed to provide adequate reasoning or citations within the prior art for assertions of disclosures therein. This delays prosecution, and prejudices the Applicant. In addition, the Office Actions do not meet the requirements of MPEP §§707.07, 2142, and 2143.01(IV), and 37 C.F.R. §§1.104 (particularly 1.104(c)(2)) and 1.113. Applicant respectfully requests, in order to expedite and advance prosecution of this application, that the requisite supporting citations and rationale are provided in future Office Communications *at the time the Communication is issued*.

Discussions of Johnson and Haines were provided in a previous response, and in the interests of brevity, those discussions are incorporated by reference herein.

Waddell

In Waddell, "a method and apparatus for resectioning a human patella in a normal anatomic position during a total knee arthroplasty is disclosed". (Col. 5, ln. 60-62). Using an adapter base such as base 12 or 212, the guide 10 is mounted directly on a component of the total knee

system, such as the femoral or tibial trial. (Col. 6, ln. 28-30). Typically, the knee should be held in a flexed position from 0 to 90 degrees, with 60 degrees being the preferred position. (Col. 7, ln. 49-51). Waddell additionally states "...the patellar surface and adjacent component surfaces are determined with the patella in its non-everted anatomical alignment with the femur and tibia. First, the femoral trial, tibial trial, and any other final components are installed and the knee is held in the desired position." (C3L17-22, see also C7L32-42). "When mounted on the medial side 322 of the femoral trial 320, as shown by example in FIGS. 4 and 5, there is access through the standard medial parapatellar incision." (C7L59-61).

Thus, in Waddell, the patella is not cut until at least the femur is cut, and a trial implant or total knee system has first been placed on the femur. Further, in order to use the cutting guide of Waddell, a standard parapatellar incision is made.

Reduced Incision, Cutting Bone with Offset Patella

Claims 26 and 43 recite, *inter alia*, "making an incision in a knee portion of the leg having a length not more than about twice the length of the patella". Claim 25 recites, *inter alia*, "making an incision in a knee portion of the leg having a length not more than 13 cm, the length shorter than the combined width of said first and second portions of the leg". Claims 1, 23, 30, 64, and 66 recite, *inter alia*, "making an incision in a knee portion of the leg having a length not more than 13 cm". Claim 31 recites, *inter alia*, "making an incision in a knee portion of the leg of the patient having a length not more than a distance between, about the proximal end of the tibia to about the epicondylar notch on the distal end portion of the femur". Claim 67 contains a similar recitation.

All of the previously cited claims additionally contain recitations pertaining to:

- displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward;
- cutting bone of the knee while the patella is offset position and facing inward; and
- knee arthroplasty surgery.

The Rejection admits that the references do not disclose making an incision having a length between about seven and thirteen centimeters, i.e. not more than 13 centimeters, but states that it would have been obvious to one of ordinary skill in the art at the time. Applicant respectfully disagrees.

At the time of the cited references, the well known prior art parapatellar incision (referred to in Waddell) was sufficient long to enable complete exposure of the distal femur and proximal tibia. Such an incision is inherently longer than twice the width of the patella (claims 1, 23, 43), 13 cm (claims 25 and 30), or a distance between the proximal tibia and the epicondylar notch (claims 31 and 67). There is no suggestion or teaching in any of the cited references to employ a reduced size incision as claimed in the instant invention.

As to whether, in the absence of a suggestion in the prior art, it would be obvious to employ a reduced size incision, Applicant further respectfully disagrees.

Substantially reducing incision size is clearly not a matter of routine skill for at least the following reasons. Incision size directly correlates, at least, to the problems of disfigurement, tissue necrosis, prolonged recovery time, nerve damage, circulation damage, and opportunity for infection. Reducing incision size is therefore always a major motivation for any surgical procedure, and therefore it can be assumed that a known procedure is already using the shortest possible incision. Accordingly, a reduction in incision size may be presumed to involve a non-obvious change in the procedure, otherwise the improvement may be expected to already have been carried out.

The inventor has detailed the motivation for a reduced sized incision in an affidavit filed May 9, 2008, in U.S. Patent Application Serial No. 11/170,969. The relevant portion is repeated as follows:

“An incision of less than 13 cm offers a number of extremely important benefits not available prior to my invention. In particular:

a) Incisions in the skin of the knee necessarily involve cutting skin or cutaneous nerves, or denervating portions of the skin extending laterally to the incision, and thus there is a loss of sensation. This loss of sensation can cause simple movements, such as kneeling wearing clothes (pants), to be difficult to execute. In addition, affected areas of skin are not protected by nerve sensation, and being thus insensate, are vulnerable to damage, such as by puncture or burn, including burns by hot water [see Johnson DF, Love DT, Love BR, Lester DK, *Dermal Hypoesthesia after Total Knee Arthroplasty*, Am J Orthop, 2000 Nov; 29(11):863-6]. Traditional incisions for TKA

surgery before the invention were typically in the range of 20 to 30 cm. A reduced size incision, particularly an incision of less than 13 cm, thus presents a substantially reduced potential for denervation, and an increased potential for better limb function.

b) Incisions in the skin of the knee necessarily involve cutting blood vessels, or devascularizing portions of the skin extending to either or both sides of the incision. Blood flow in the area of the incision is often reduced. A more serious problem arises in instances of revision surgery, where a subsequent operation in the same area is necessary. In this instance, a subsequent incision offset from the original incision can create an area of skin that potentially has a reduced or deficient blood supply. In this instance, areas of skin can become necrotic, with attendant serious consequences. By creating a reduced size incision in the initial surgery, particularly an incision of less than 13 cm, there is greater opportunity to create a subsequent incision during revision surgery which does not bound an area of skin between the incisions, and thus the possibility for skin necrosis is greatly reduced.”

As Johnson, Haines, and Waddell do not suggest, teach, or disclose a reduced size incision as recited in the claims of the instant application, and as there was significant motivation to do so, as outlined above, it cannot be said to be obvious. In contrast, the instant invention discloses performing a knee arthroplasty, through a smaller incision than suggested or taught in the prior art. Some claims further recite that the patella is maintained in a non-everted position. Maintaining the patella in a non-everted position has, at least, the benefits of reducing damage to the patellar tendons and quadriceps mechanism, and facilitates performing a knee arthroplasty through a small incision relative to the prior art, and particularly relative to the standard parapatellar incision of the prior art.

Suspended Leg

With respect to claim 21, the rejection states that Johnson and Haines each disclose “positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position”. No citations

are provided within Johnson or Haines in support of this position. Applicant has carefully reviewed the references, and respectfully submits that the references simply do not disclose the claimed subject matter.

The Remarks section of the Office Action states: “supporting the patient with the lower portion of the leg suspended from the upper portion of the leg (inherent, as the lower and upper knee portions are never completely severed from each other);”. Applicant respectfully submits that suspension is not inherent, in that it is tantamount to stating that a limb portion is suspended until it is severed. Suspended is defined as to “hang from somewhere” (AskOxford.com), or “to hang something from above, especially so that it can swing freely” (MSN Encarta). When a patient is in a prior art prone or supine position on an operating table, the lower leg is simply not hanging freely, and therefore cannot be deemed to be suspended. The instant invention discloses a suspended, or hanging limb, at least in paragraphs [0142], [0161], [0184], and [0205], and in Fig’s. 2-3, and 8-9. Accordingly, claim 21 is patentable over the cited references for at least these reasons.

Bone Not Extending Through Incision

Claim 10 recites, *inter alia*, “cutting a bone of the knee portion of the leg, while the patella is maintained in the offset position, and while no bone of the joint extends to pass outside the body through said incision, until cut and removed from the joint”. Claim 19 recites, *inter alia*, “cutting the inner side of the patella in the knee portion of the leg, wherein the inner side of the patella faces towards a posterior portion of the knee portion of the leg and includes removing at least a portion of the inner side of the patella, while no bone of the joint extends to pass outside the body through said incision, until cut and removed from the joint”.

As described above, the prior art relies on a large incision and complete exposure of the bones of the knee (see, e.g., Fig. 5 of Waddell, Fig’s. 11-12 of Johnson, or Fig’s. 1, 2 or 6 of Haines). In contrast, the instant invention performs knee arthroplasty through a reduced size incision, with the patella in an offset position with an inner side of the patella facing inward. Claims 10 and 19 specifically recite that no bone of the joints extends to pass outside the body through the incision. There is no teaching or suggestion in the cited references to perform a knee arthroplasty through a reduced size incision, without extending the bones of the joint outside the body through the incision; rather, a standard parapatellar incision is disclosed, and thus the prior

art teaches away from the aforementioned recitations of claims 10 and 19 of the instant invention.

Cutting the Patella Prior to the Femur

Claim 16 recites, *inter alia*, displacing a patella to an offset position with an inner side of the patella facing inward, and “cutting the inner side of the patella in the knee portion of the leg, prior to resecting the femur or the tibia, wherein the inner side of the patella faces towards a posterior portion of the knee portion of the leg”. In Waddell, “First, the femoral trial, tibial trial, and any other final components are installed and the knee is held in the desired position...” (C3L17-22, see also C7L32-42). Thus, in Waddell, cutting of the femur and tibia are accomplished by performing a standard parapatellar incision, and no benefit of space is achieved by cutting the patella first.

In one embodiment of the instant invention, the patella is cut first, creating space for cutting the femur and tibia through a reduced size incision, and without a requirement for everting the patella. The instant invention additionally uses a “guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool”, and cuts the inner side of the patella “while the inner side of the patella faces towards a posterior portion of the knee portion of the leg”. In this manner, incision size may be reduced, and damage to the patellar tendons and quadriceps mechanism is minimized.

Accordingly, Applicant respectfully submits that claims 1, 10, 16, 19, 21, 23, 25-26, 30, 31, 43, and 63-67 are patentable over a combination of the cited references. As claims 3-9, 13-15, 18, 22, 24, and 28-29 depend from Claim 1; 11-12 from 10; 17 from 16; 20 from 19; 27 from 26; 51-62 from 30; 32-42 from 31; and 44-46 from 43, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references for the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the section 103 rejections.

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

Applicant: P. Bonutti
Application No.: 10/684,904
Examiner: M. Hoffman

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 \$810 is believed to be due for an RCE, and \$1,110 for a 3 month extension. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-012B).

Respectfully submitted,

/ Paul D. Bianco /

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