

Patent Owner's Demonstrative Exhibits

IPR 2013-00629

U.S. Patent 7,806,896

CLAIM 1

BSI Exhibit 2008
Smith & Nephew et al. v.
Bonutti Skeletal Innovations LLC
Trial: IPR2013-00629

CLAIM 1

1. A method ...
comprising the steps of:
... passing the cutting
guide through the incision
and on a surface of a
distal end portion of an
unresected femur, the
cutting guide secured to
the bone free of an
extramedullary or
intramedullary alignment
rod . . .

(Exh. 1001, '896 patent, claim 1)

Turner: extramedullary alignment rod

“49. In the technique described in Turner, the femoral cutting guide is mounted with an extramedullary alignment rod...

66. . . . The combination extramedullary rod and cutting guide that makes up Turner simply sits in between the condyles and extends up the center of the femur bone so that it generally aligns with the medullary canal of the femur. It is known as an extramedullary alignment rod because it is an alignment rod that is not located inside the medullary canal of the femur.”

(Exh. 2004, Schoifet Decl., pars. 49, 66)



(Exh. 1008, Turner, p. 181)

CLAIM 1

1. A method ...
comprising the steps of:
... passing the cutting
guide through the incision
and on a surface of a
distal end portion of an
unresected femur, the
cutting guide secured to
the bone free of an
extramedullary or
intramedullary alignment
rod . . .

(Exh. 1001, '896 patent, claim 1)

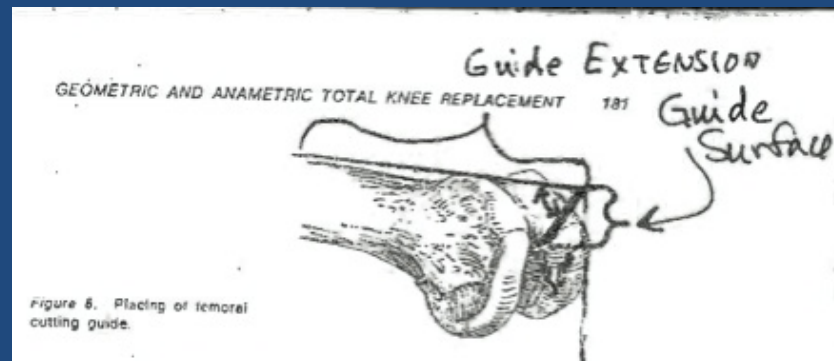
Turner: extramedullary alignment rod

“Q. And does what you first show as guide extension provide an extramedullary alignment for the cutting surface in the cutting guide of Figure 8?

MR. OYLOE: Objection to form.

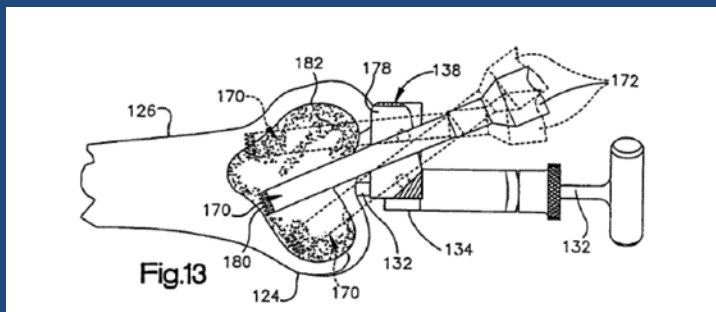
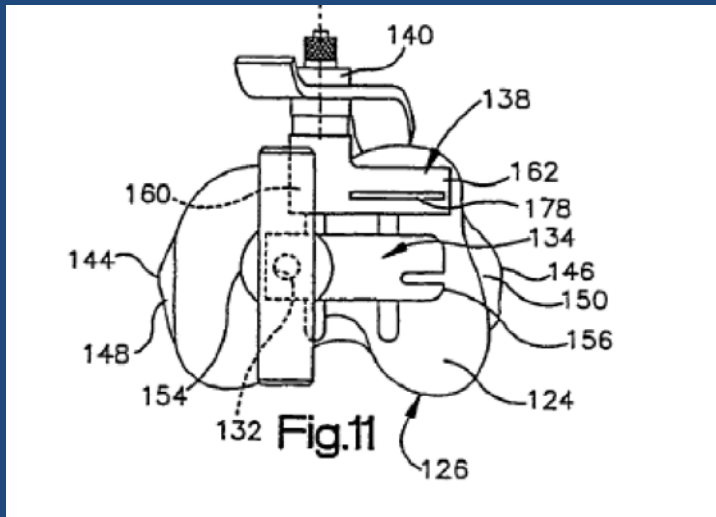
THE WITNESS: Yes. It is external to the intramedullary canal of the femur in this drawing.”

(Exh. 2003, Mabrey, Tr. , 72:6-12)

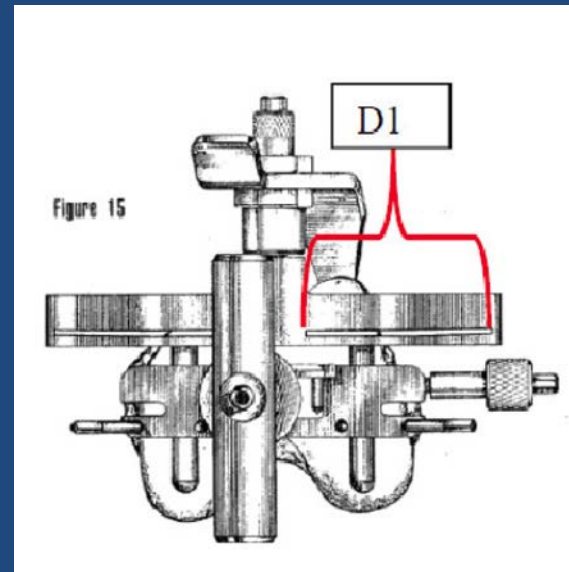


(Exh. 2001)

'896 Patent



Scorpio:



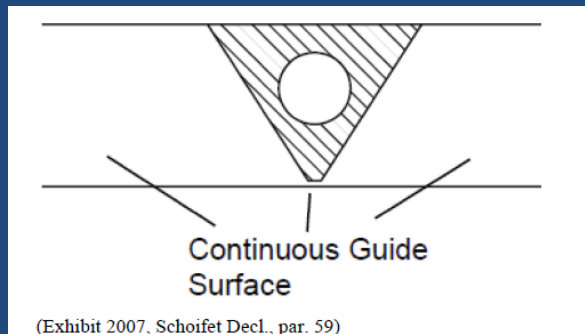
(Paper 3, Petition, p. 33)

CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:
making an incision . . . ;
. . . a guide surface on the cutting guide; and
. . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

Scorpio:



(Paper 17, PO Resp., pp. 20-21)

“the apex of the truncated triangle . . . is . . . approximately 1 mm wide by 0.5 mm deep”

(Exh. 1023, Mabrey Reply Dec., p. 12, Paper 22, Reply, p. 6, at n. 1)



(Exh. 1030, p. 10)

CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:
making an incision . .

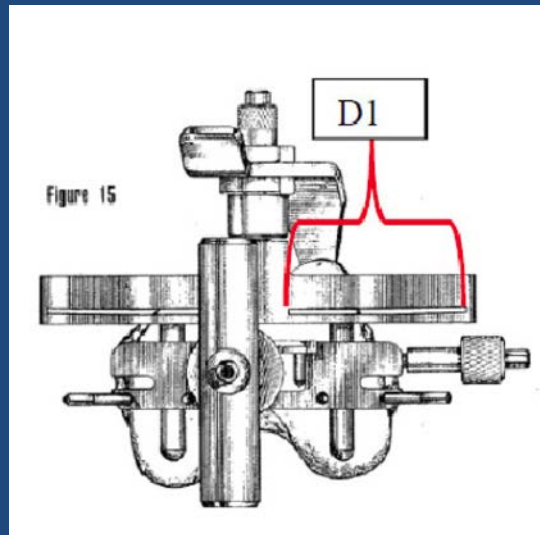
;

. . a guide surface on the cutting guide; and
. . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

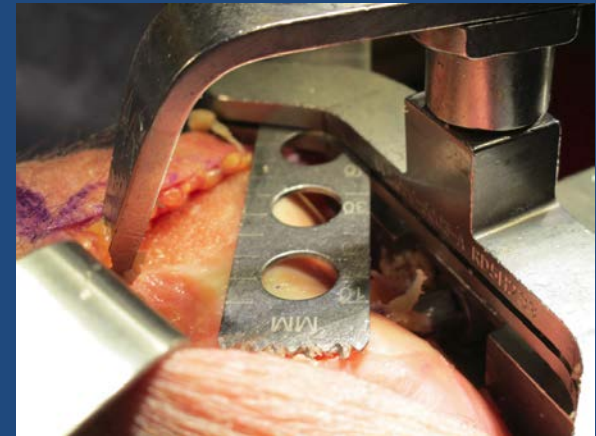
(Exh. 1001, '896 patent, claim 1)

Scorpio:

“the saw blade completely covers the medially resected bone without coming close to the central support of the guide. It is about 15 mm away from that central portion.” (Exh. 1023, Mabrey Reply Decl. p. 20)



(Paper 3, Petition, p. 33)



(Exh. 1023, Mabrey Reply Decl., p. 20)

- “I have a Scorpio device and have used such a guide in surgery. The dividing piece depicted in figures 15 and 18 . . . does not pass all the way to the bone side of the cutting guide surface.”
- “A space is left on the cutting guide surface between the end of the dividing metal piece and the bone side of the cutting guide surface, leaving a continuous guide surface from the lateral side to the medial side of the cutting guide surface.”
- “This space is necessary to allow the cutting blade to be angled enough to cut an entire condyle, i.e., to the trochlear groove side of the condyle.”
- “With this space, if a physician starts a cutting saw blade on one side he can run it right through to the other side of the bone.”



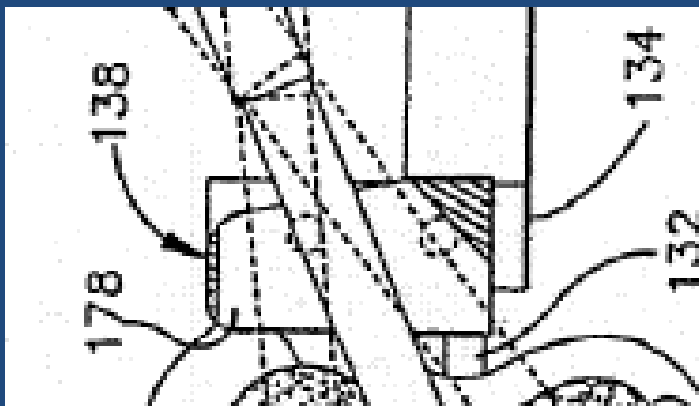
(Exh. 2004, Schoifet Decl. par 78)

“The de minimis space between the back edge of the divider and the back edge of the guide in the Scorpio Product—the space that in BSI’s view links the left to the right guide surfaces—does not guide the cutting instrument and therefore is not itself a “guide surface.”

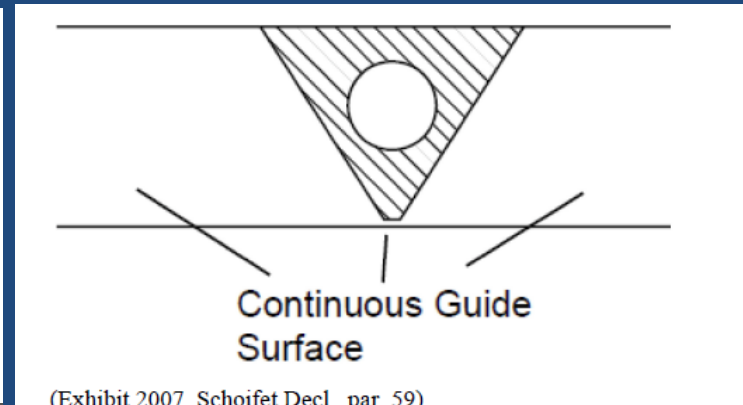
(Paper 22, Reply at pp. 6-7)

“Dr. Mabrey performed a test using the Scorpio product that demonstrated that the anterior resection cut can be performed using solely one of the two guide surfaces without the de minimis space behind the divider.”

(Paper 22, Reply at pp. 7-8)



(Exh. 1001, '896 patent, Fig. 13)



(Exhibit 2007, Schoifet Decl., par. 59)

(Paper 17, PO Resp. p. 20)

STULBERG: “accuracy”

“The reliability of techniques for total knee replacement (TKR) is still limited by the relative inaccuracy of instrumentation.”

(Exh. 1005, Stulberg. at p. 25 (Abst.)(Jan. 2000))

“Incorrect positioning or orientation of implants and improper alignment of the limb can lead to accelerated implant wear and loosening and suboptimal functional performance. A number of studies have suggested that alignment errors of greater than 3° are associated with more rapid failure and less satisfactory functional results of total knee arthroplasties.”

(Exh. 1005, Stulberg. at p. 25)

“Computer-based alignment systems have been developed to address the problems inherent in mechanical total knee instrumentation.”

(Exh. 1005, Stulberg. at p. 25)

STULBERG: “perpendicular”

“The goal of the total knee instrumentation procedure is to achieve cuts that are perpendicular to the mechanical axes of the femur and the tibia. The longevity of total knee arthroplasty is closely related to its intraoperative positioning. The computer-assisted procedure offers an effective and novel positioning method that improves the accuracy of the surgical technique of the TKR.”

(Exh. 1005, Stulberg. at p. 25)

CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:

making an incision . . . ;

. . . passing the cutting guide through the incision and on a surface of a distal end portion of an unresected femur . . .

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

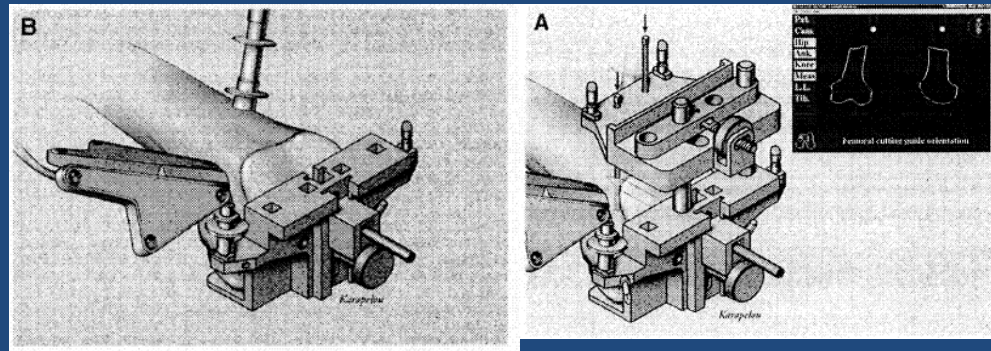
. . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

STULBERG: cutting guide

- Has a guide surface which is larger in the transverse dimension than the replacement femoral component.

(Paper 3, Petition, p. 45; Paper 10, Inst. Dec., p. 14, Paper 17, PO Response, p. 22, Exh. 2004, Schoifet Decl., par. 40)



CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:
making an incision . . .
.;
. . . a guide surface on the cutting guide; and
. . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

STULBERG: Does not discuss the size of the guide surface:

“Q:OK. Does Stulberg ever comment on the size of the cutting guides?”

THE WITNESS: As far as I can tell, from my reading of this article from 2000, he does not.

Q. And does Stulberg ever comment on the cutting surfaces on the cutting guide?

THE WITNESS: Again, I can't find a place where he does.

Q. So nowhere in Stulberg does it say surfaces of cutting guides are too large?

THE WITNESS: I don't see any passages relating to that.”

(Exh. 2003, Mabrey Tr. 51:25-:52:17)(Objections omitted)

(Paper 17, P.O. Resp., pp. 12,22,Exh. 2004, Schoifet Decl., par. 62)

DELP: accuracy

“Accurate alignment of knee implants is essential for the success of total knee replacement. Although mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations of this technology that will inhibit additional improvements. Various computer assisted techniques have been developed to examine the potential to install knee implants more accurately and consistently than can be done with mechanical guides.”

(Exh. 1003, Delp, p. 49, Abst.) (emphasis added).

“Even a small (2.5 mm) anteroposterior displacement of the femoral component has been shown to alter knee range of motion (ROM) as much as 20°.”

(Exh. 1003, Delp, p. 50).

“Even when using state of the art intramedullary alignment systems, surgeons find that it is difficult to install knee implants within 2° to 3° varus or valgus alignment.”

(Exh. 1003, Delp, p. 50).

CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:
 making an incision . . .
.;
 . . . a guide surface on the cutting guide; and
 . . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

Delp: Does not discuss the size of the cutting guide surface:

“Q. Does the Delp article discuss the size of the cutting guides?

THE WITNESS: I don't see any references to the size of the cutting block in the paper.

Q. Does it discuss the size of the cutting surface of the cutting guide?

THE WITNESS: And I don't see references to the size of the cutting surface.”

(Exh. 2003, Mabrey, Tr. 63:9-19) (Objections omitted)
(Paper 17, P.O. Resp., pp. 13, 46; Exh. 2004, Schoifet Decl., par 42)

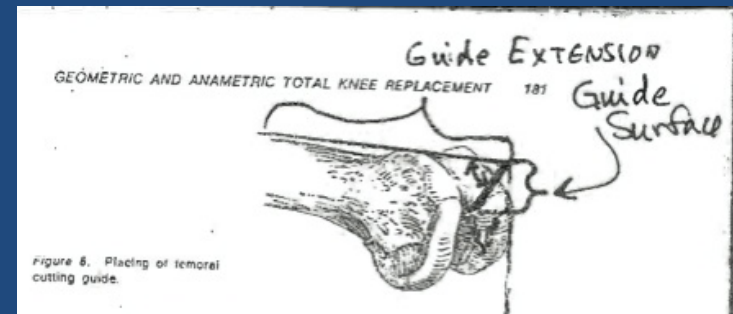
Turner: “eyeball cut”

“is nothing more than a handheld rod with a cutting guide edge that is so small that a cutting blade would pivot about the guide surface during a cut, even by an experienced physician. (Turner, Fig. 8, p. 181) Cuts like this are called freehand cuts or eyeball cuts.”

(Exh. 2004, Schoifet Decl., par. 69)

“would provide a far more imprecise cut than the techniques criticized in Delp and Stulberg. In the timeframe of 2000- 2003, a person of ordinary skill in the art would not consider using the femoral cutting guide of Figure 8 in a knee replacement surgery.”

(Exh. 2004, Schoifet Decl., par. 50)



Turner cut: “not perpendicular”

“Turner Cutting Guide makes a distal cut which is not perpendicular to the mechanical axis of the femur. This can be seen in Figure 9 of Turner. In contrast, the technique described in Stulberg, and all other techniques that I am aware of that were in use in the 2000-2003 timeframe require a distal cut that is perpendicular to the mechanical axis of the femur.”

(Exh. 2004, Schoifet Decl., par. 71)

“Q. [D]oes Figure 9 show the appearance of the femur after being cut with the cutting guide at Figure 8?

A. Figure 9 is the appearance of the femur after the cutting of the distal condyles.

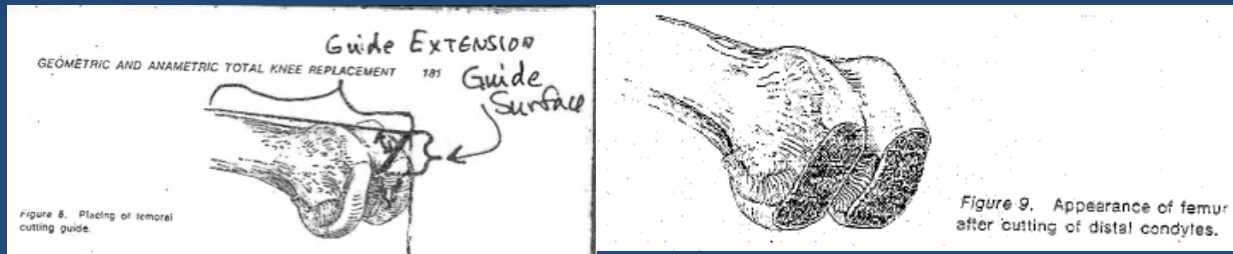
Q. And would you cut the distal condyles with the femoral cutting guide of Figure 8?

A. Yes, as described in the technique.

Q. Okay. Is that cut that's shown in Figure 9 perpendicular to the mechanical axis of the femur?

A. That cut is not perpendicular to the mechanical axis of the femur.”

(Exh. 2003, Mabrey Tr. 72:13-25)



Stulberg in view of Turner

Delp in view of Turner

Delp: “Even when using state of the art intramedullary alignment systems, surgeons find that it is difficult to install knee implants within 2° to 3° varus or valgus alignment.”

(Exh. 1003, Delp, p. 50).

“Stulberg also reports that while ‘m]echanical alignment guides have improved . . . Accuracy’ (id.), they are still unsatisfactory in that they have ‘fundamental limitations that limit their ultimate accuracy.’ (Id.).”

(Exh. 2004, Schoifet Decl., par. 38)

Stulberg in view of Turner

Delp in view of Turner

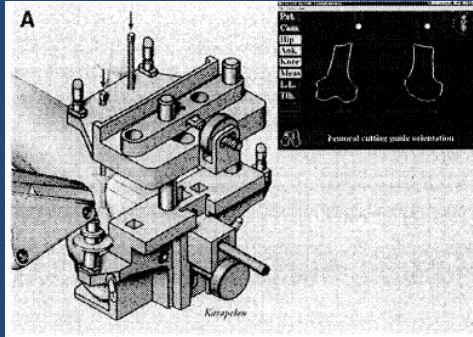
“I have known for decades of the geometric total knee replacement procedure discussed in Turner, and the femoral cutting guide shown in Figure 8 of Turner The geometric total knee replacement procedure was a primitive design with poor outcomes when compared to modern knees (post 1990). A person of ordinary skill in the art in 2000-2003 would not consider using either the Turner Cutting Guide, or the geometric total knee replacement procedure described in Turner.”

“[T] he proposed combination of Stulberg and Turner (or Delp and Turner) does not result in a more accurate surgical outcome. Turner is nothing more than a handheld rod with a cutting guide edge that is so small that a cutting blade would pivot about the guide surface during a cut, even by an experienced physician. (Turner, fig. 8, p. 181) The proposed combination of the teachings of Stulberg and Turner (or Delp and Turner) yields a less accurate surgical instrument, and thus, a less accurate surgical outcome. Using computer-assisted navigation to make an eyeball cut is not going to make the procedure any better.”

(Exh. 2004, Schoifet Decl., pars. 65, 73)

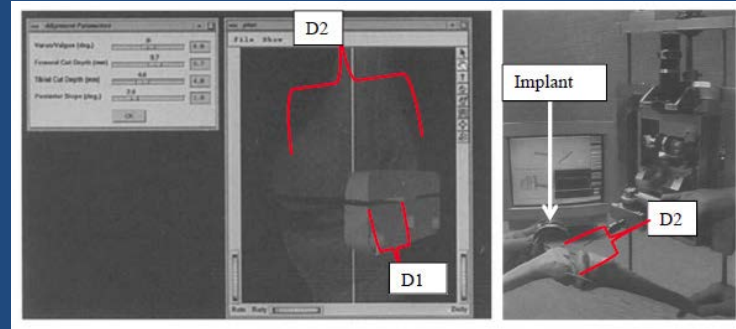
PETITIONER BEARS THE BURDEN OF PROVING UNPATENTABILITY 35 U.S.C. 316(e)

Stulberg in view of Turner

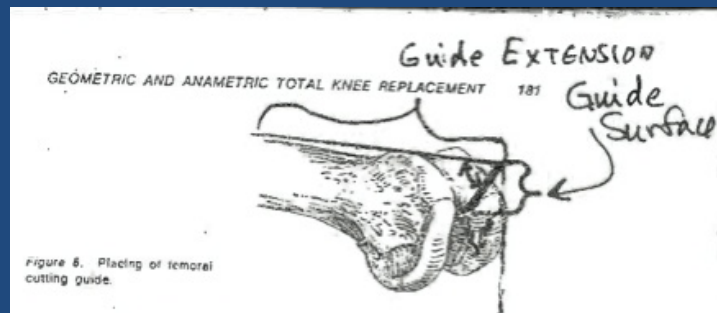


(Exh. 1005, Stulberg, Fig. 17A)

Delp in view of Turner



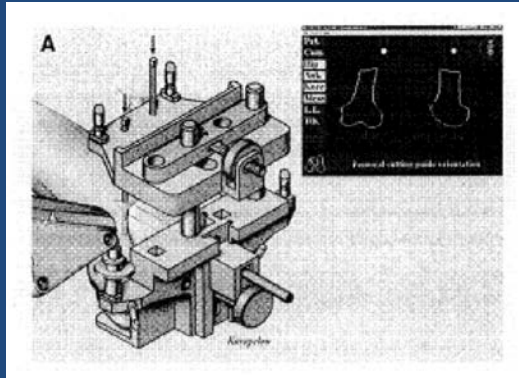
(Paper 3, Petition, p. 32)



(Exh. 2001)

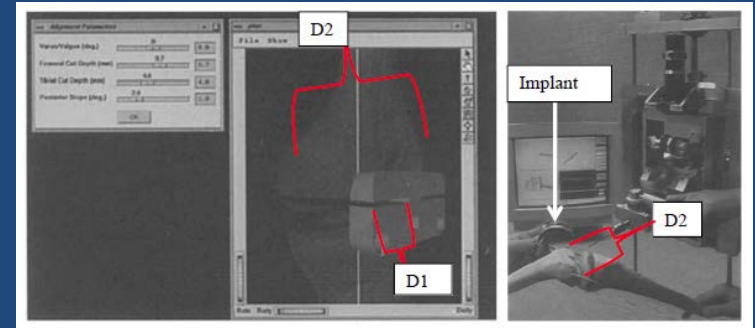
PETITIONER BEARS THE BURDEN OF PROVING UNPATENTABILITY 35 U.S.C. 316(e)

Stulberg in view of Scorpio

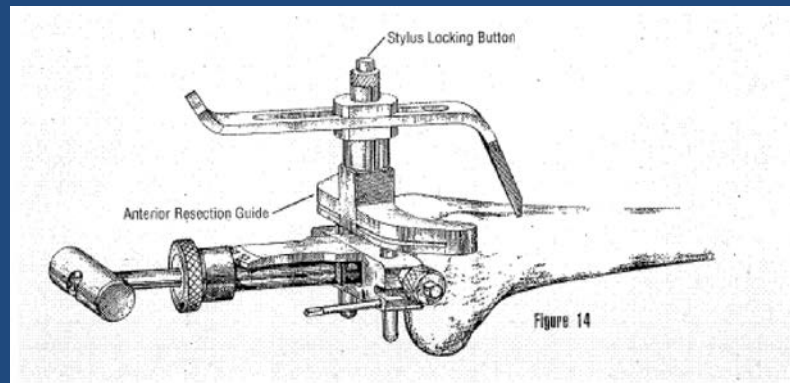


(Exh. 1005, Stulberg, Fig. 17A)

Delp in view of Scorpio



(Paper 3, Petition, p. 32)



(Exh. 1009)

“As Patentee admitted when arguing for patentability of a related application that claimed the same priority date as the challenged patent “[r]educing incision size is . . . **always a major motivation** for **any** surgical procedure.” File History for U.S. Patent No. 8,133,229 to Bonutti, June 18, 2009 Office Action Response (“’3229 File History”) at p. 20 (emphasis added) (Ex. 1024)”

(Paper 22, Pet. Reply, p.10)

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.

(Exh. 1024,p.20)

of the tibial cutting jig 1220, however, other methods of temporarily attaching the tibial jigs to the tibia 20 may be used without departing from the instant invention. The tibial jig 1220 is aligned using the same procedure that was used for the femoral jigs, using visual and aural feedback. The pin holes are drilled and surgical pins are inserted to fix the tibial jig 1220 to the tibia 20. The user then removes the CMM 670.

Turning now to FIG. 31, the patient's knee is now ready for bone resections. Tibial resection is performed in three steps, as reflected by block 1200. The three tibial resections all use a long burr, saw, and/or drill, and proceed in the following order: horizontal and vertical resections followed by creating a post hole by drilling or burring. The horizontal resection is made along the horizontal surface 1230 of the tibial cutting guide 1220 with either a saw or a long burring device. Vertical resection proceeds in the same manner along the vertical surface 1240 of the tibial cutting guide 1220. In an alternative embodiment, the user then places the post hole guide by inserting the pins on its body into the holes in the horizontal surface 1230 of the tibial cutting guide 1220. The user guides a drill or long burr through the holes to create the post hole.

As reflected by block 1200, femoral resection involves three different cuts. The posterior cut is made first with either a saw or long burr along the front face 1030 of the femoral docking jig 100. The user then inserts a drill or long burr through the first aperture 1040 to create the post hole. The distal and chondral resections are made by guiding a collared burr along the distal and chondral guide surfaces 1080 and 1090 of the contouring jig 1000. The depth of the burring is limited by the contact of the collar with the distal and chondral guide surfaces 1080 and 1090 of the contouring jig 1000.

In the preferred embodiment, as shown in FIG. 32, the surgeon next determines how close the resections are to intended resections that were defined in the surgical plan. First, as reflected by block 1250, the surgeon uses the CMM 670 to sample characteristic corners of the resections: for the femoral resections, these corners are the medial and lateral corners of the chondral/distal resection interface, and the medial and lateral corners of the chondral/posterior cut interface; for the tibial resections, the characteristic corners are the anterior and posterior corners of the horizontal/vertical cut interface. The procedure software uses the characteristic corner data to construct a three-dimensional model of the actual femoral and tibial resections, modeling the planes defined by the characteristic corners, as shown by block 1300. (The characteristic corners and the actual resections may be shown on the visual display means 790.)

The procedure software compares the intended resections with the actual resections, as reflected by block 1310, and determines whether and to what extent there exist variations between the pose of the actual resections and the pose of the intended resections, as reflected by block 1320. The procedure software then displays these variations on the visual display means 790, as reflected by block 1330.

Turning now to FIG. 33, in the preferred embodiment, the procedure software also permits the surgeon to compare the intended placement of the prosthesis, as defined in the surgical plan, with the actual placement of the prosthesis as represented by trial components. As reflected by block 1340, the surgeon installs trial components that each have three or more known points defined on their surfaces (i.e., the three-dimensional locations of the points relative to the geometry of the prosthetic components are located in the procedure software). The surgeon then samples these points

using the CMM 670, as reflected by block 1350. Next, as reflected by block 1360, the procedure software determines the pose of the actual femoral and tibial trial components from the sampled points. The procedure software then, as reflected by block 1370, compares the actual pose of the femoral and tibial prosthetic trial components with the intended pose of femoral and tibial prosthetic components 550 and 560, and determines whether and to what extent there are variations. The procedure software then displays these variations on the visual display means 790.

Turning now to FIG. 34, the next step is a trial reduction, as reflected by block 1375. The surgeon first selects the prosthetic components 550 and 560 recommended during the planning stage, as reflected by block 1380. The prosthetic components 550 and 560 then are inserted. The knee, with the prosthetic components 550 and 560 in place, is moved through its entire range of motion, and the stability and tension in the ligaments is tested, as reflected by block 1390. The thickness of the tibial articular surface 640 should be such that a maximal area of contact between the femoral articular surface 570 and tibial articular surface 640 exists, while not prohibiting a full range of motion.

Once the trial reduction is completed, and the surgeon is satisfied that the prosthetic components 550 and 560 properly fit, the prosthetic components 550 and 560 are cemented into place, and the incision closed in the usual manner, as reflected by block 1400. After the surgery is complete, the procedure computer 770 preferably displays on the visual display means 790 the amount of time the surgeon took to complete each step, and also may provide an inventory control for devices used during surgery, as reflected by block 1410.

The invention has several advantages over current mechanical instrumentation systems, surgical planning systems and computer-assisted surgical systems.

Mechanical instrumentation systems in use today rely on cutting jigs that align cuts using discrete metrics and visual means, which can introduce alignment errors. In addition, these systems require a large surgical exposure because the instrumentation is large, even for current UKA systems. The instrumentation is large because it needs to cover certain anatomical landmarks in order to align the cutting jigs.

The invention overcomes alignment problems by determining optimal alignment preoperatively and using computer guidance to help the surgeon achieve this alignment. The computer replaces large, complicated mechanical alignment systems, allowing smaller jigs to be used, and thus a smaller incision to be made. A smaller incision will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints.

Surgical planning systems have been introduced that help plan surgical procedures. Alignment of tools and prosthetic devices in relation to patient anatomy can be planned preoperatively using these systems, but many do not provide a means to implement the plan in the operating room. The invention not only allows detailed planning of a procedure, but also provides a method to implement the surgical plan.

The preoperative planning and intraoperative procedure systems of the instant invention provide also for better limb alignment and more accurate prosthetic component placement. This results in less prosthetic component wear and better prosthetic component fixation than is possible without these systems, thereby leading to longer lasting components requiring fewer revision surgeries, and better post-surgery joint functionality, thereby improving range of motion, knee function, and biomechanical performance. The instant invention also will help reduce revision surgeries.

The invention has several advantages over current mechanical instrumentation systems, surgical planning systems and computer-assisted surgical systems.

Mechanical instrumentation systems in use today rely on cutting jigs that align cuts using discrete metrics and visual means, which can introduce alignment errors. In addition, these systems require a large surgical exposure because the instrumentation is large, even for current UKA systems. The instrumentation is large because it needs to cover certain anatomical landmarks in order to align the cutting jigs.

The invention overcomes alignment problems by determining optimal alignment preoperatively and using computer guidance to help the surgeon achieve this alignment. The computer replaces large, complicated mechanical alignment systems, allowing smaller jigs to be used, and thus a smaller incision to be made. A smaller incision will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints.

Surgical planning systems have been introduced that help

(Exh. 1004)

CLAIM 1

1. A method of replacing at least a portion of a patient's knee, the method comprising the steps of:

making an incision in a knee portion of a leg of the patient;

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod;

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

forming at least an initial cut on the femur by moving the cutting tool along the guide surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

- “determining a position of a cutting guide using references derived independently from an intramedullary device”
- “positioning a cutting guide using the determined position, passing the cutting guide . . . on a surface of . . . an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod”
- “moving a cutting tool . . . into engagement with a guide surface on the cutting guide”
- “forming at least an initial cut on the femur by moving the cutting tool along the guide surface”
- “attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.”

CLAIM 1

1. A method of replacing at least a portion of a patient's knee, the method comprising the steps of:

... determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position,

passing the cutting guide through the incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod

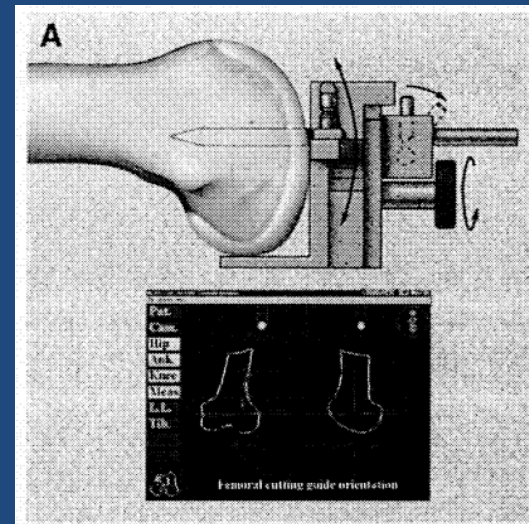
...

(Exh. 1001, '896 patent, claim 1)

STULBERG: cutting guide

- Positioned without intramedullary device
- Secured without intramedullary or extramedullary alignment rod

(Paper 3, Petition, p. 44, paper 10, Inst. Dec., pp. 11-12)



(Exh. 1005, Stulberg, Fig. 16a)

CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:
making an incision . . .
.;
. . . a guide surface on the cutting guide; and
. . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

DELP: Cutting Guide

LIKE STULBERG, DOES NOT DISCLOSE :

a cutting guide with a guide surface, where the replacement portion has “a transverse dimension that is larger than a transverse dimension of the guide surface.”

(Paper 10, Inst. Dec., p. 21, Paper 17, PO Response, pp. 45-46, Exh. 2004, Schoifet Decl., par. 89)

CLAIM 1

1. A method of replacing at least a portion of a patient's knee . . . comprising the steps of:
 making an incision . . .
.;
 . . . a guide surface on the cutting guide; and
 . . . attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

(Exh. 1001, '896 patent, claim 1)

Turner:

Does not discuss the size of the guide surface:

“There is no discussion of limiting incision sizes in Turner, and no indication that the relative size of the cutting surface of the cutting guide and the replacement component is of any interest.”

(Exh. 2004, Schoifet Decl., par. 51)

Stulberg in view of Turner

Delp in view of Turner

“Stulberg does not object to extramedullary or intramedullary alignment guides *per se*, but rather is concerned with more *accurate placement* of the cutting and alignment guides. Thus, for example, in its computer-assisted tibial procedure, an extramedullary alignment guide is used (Fig. 12), and the computer technique is used to more finely tune the position of the cutting guide. (Id., p. 29, final two pars.).

if a person of ordinary skill in the art were to combine the teachings of the femoral cutting guide of Figure 8 of Turner with Stulberg, there would be no apparent reason to abandon the extramedullary alignment feature of that cutting guide.”

(Paper 17, PO Response, p. 11, 31)

“Turner is an extramedullary aligned and mounted cutting guide. Assuming for purposes of argument that a person of ordinary skill in the art were to conclude that the Turner cutting guide can be used with the teachings of Delp, the only predictable result would be to use the computer imaging and probes of Delp to more accurately position the extramedullary mounting of the cutting guide, which is significantly different than the claimed invention.”

(Paper 17, PO Response, p. 52)