

DOCKET NO: 0286868-00188
'896 PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW INC., WRIGHT MEDICAL GROUP, INC. AND WRIGHT
MEDICAL TECHNOLOGY, INC.
Petitioners,

v.

BONUTTI SKELETAL INNOVATIONS, LLC
Patent Owner of U.S. Patent No. 7,806,896

Trial No. IPR2013-00629, Consolidated

**REPLY DECLARATION OF DR. JAY D. MABREY, MD, MBA
REGARDING
U.S. PATENT NO. 7,806,896**

S&N EXHIBIT 1023
S&N v. BSI
IPR2013-00629

I, Jay D. Mabrey, declare as follows:

1. My name is Jay D. Mabrey. I am the same Jay D. Mabrey who signed and submitted a declaration on September 25, 2013 in IPR2013-00629. I also note that my declaration was submitted in IPR2014-00354 and I understand that that proceeding has been joined with IPR2013-00629. My background and credentials are detailed in my prior declaration.

2. In addition to the documents I reviewed to prepare my first declaration, I reviewed the following additional documents:

- Decision on Institution of *Inter Partes* Review IPR2013-00629
- Patent Owner's Response
- May 30, 2014 Declaration of Dr. Schoifet, Exhibit 2004
- Exhibits 2001-2007
- August 25, 2014, Deposition of Dr. Scott Schoifet
- Exhibits 1022 and 1024-1031
- Exhibit 1013, U.S. Patent No. 4,502,483 ("Lacey '483")
- Lacey Condylar Total Knee System Surgical Procedure ("Lacey Technique Guide" (Ex. 1032))

- “Minimally Invasive Solution: The M/G Unicompartmental Knee Minimally Invasive Surgical Technique” (Zimmer, Inc. 2000) (“Zimmer Guide” (Ex. 1034));
- P.M. Bonutti and M.A. Kester, “Unicompartmental Knee Arthroplasty: a US Experience” *in* Unicompartmental Knee Arthroplasty pp. 260-66 (Ph. Cartier *et. al* eds. 1997) (“Bonutti 1997” (Ex. 1035));
- Aaron A. Hofmann, Rodney L. Plaster, and Louis E. Murdock, “Subvastus (Southern) Approach for Primary Total Knee Arthroplasty,” *Clinical Orthopaedics and Related Research*, Vol. 269 (Aug), 1991: pp. 70-77 (“Hofmann” (Ex. 1036));
- Matthew D. Skolnick, Mark B. Coventry, and Duane M. Ilstrup, “Geometric Total Knee Arthroplasty,” *The Journal of Bone and Joint Surgery*, Vol. 58-A, No. 6 (Sept.), 1976: pp. 749-53 (“Skolnick” (Ex. 1029));
- Steven H. Stern, “Surgical Exposure in Total Knee Arthroplasty,” *in* *Knee Surgery* Vol. 2: pp. 1289-1302 (Freddie H. Fu *et. al* eds. 1994) (“Stern” (Ex. 1033)).

3. In my opening declaration, I provided my opinion that claim 1 of the '896 patent was obvious over the combinations of Stulberg with Turner or Scorpio and Delp with Turner or Scorpio. This declaration is submitted in response to

arguments raised by Bonutti Skeletal Innovations, LLC in its response, or factual inaccuracies articulated by Dr. Schoifet in his May 30, 2014 declaration.

The Disclosed Benefits Of the Methods In the '896 Patent Were Known

4. Throughout Dr. Schoifet's declaration, he alleges that prior to 2000 the state of the art of total knee arthroplasty ("TKA") involved invasive procedures that used large incisions, created additional cuts in the quadriceps, and required patellar eversion "because it was common practice." Schoifet Decl. ¶ 64 (Ex. 2004). As an initial matter, I understand that none of these aspects of TKA surgical techniques is relevant to whether or not claim 1 of the '896 patent is obvious, because none of these features is claimed. Moreover, a person of skill in the art would have understood that there were previously known techniques that avoided the need for large incisions, patella eversion, and that would preserve the quadriceps mechanism. Dr. Schoifet's implied assertion that TKA always had involved long incisions and patellar eversion is, therefore, incorrect.

5. More particularly, Dr. Schoifet asserts that the state of the art in TKA during the 2000-2003 timeframe "was invasive and involved a relatively long incision." Schoifet Decl. ¶ 17 (Ex. 2004). He alleges that "[l]arge incisions, such as 12 to 16 inches, were simply accepted whether the procedure involved computer-assisted navigation or not." Schoifet Decl. ¶ 18 (Ex. 2004). This is not correct.

6. As early as 1985, more than a decade earlier than the date of the '896 patent, there were minimally invasive TKA devices and procedures. U.S. Patent No. 4,502,483 to Lacey discloses instruments and a method of TKA performed through “[a]n anterior 5” to 6” (127 mm to 152 mm) midline incision [that] is made with the knee flexed to 90 degrees.” Lacey '483, col. 7, ll. 56-58 (Ex. 1013). The patented Lacey system was eventually marketed and sold to doctors for use in patients. Lacey Technique Guide (Ex. 1032). Accordingly, TKA through a small incision was known 15 years before the earliest possible priority date of the '896 patent.

7. Dr. Schoifet also asserts that the large incisions also required that the quadriceps muscle would need to be “split” in TKA prior to 2000. Schoifet Decl. ¶ 18 (Ex. 2004). However, this ignores that there were known TKA incision techniques that spared the quadriceps, at least one of which was known as far back as the 1930's. Stern, p. 1291 (Ex. 1033); *see also* Hoffman, p. 70 (Ex. 1036). A subvastus incision for TKA was used to spare the quadriceps by approaching the internal structure of the knee from the “south,” making an L-shaped incision to the side of the knee:

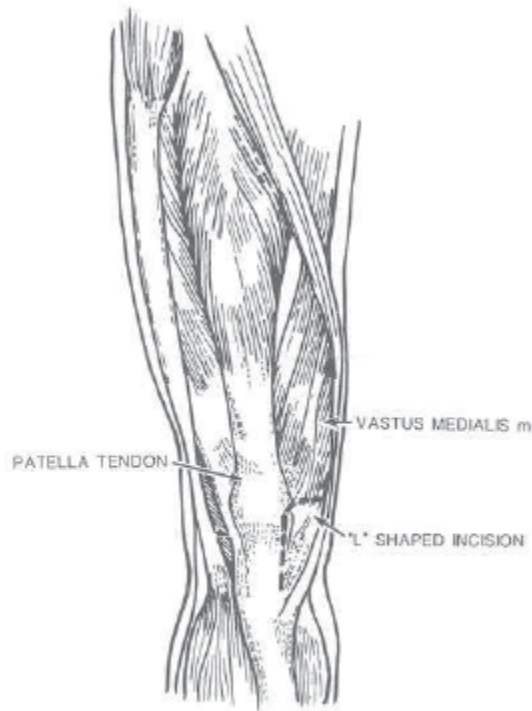


FIG. 1. L-shaped deep capsular incision used in the subvastus approach.

Hofmann, p. 71 (Ex. 1036). This approach preserved “[t]he vascularity to the patella and extensor mechanism” of the quadriceps, and was believed to be “associated with less postoperative pain and a stronger extensor mechanism.” *Id.* at 70 (Ex. 1036). Dr. Schoifet’s view that the quadriceps muscle was necessarily “split” ignores preexisting techniques that preserved the quadriceps.

8. Dr. Schoifet also asserts that it was common practice for a person of skill in the art to “evert the patella.” Schoifet Decl. ¶ 64 (Ex. 2004). This again ignores that there were known knee repair techniques that would avoid patella eversion. Before the priority date of the ’896 patent, unicondylar knee replacement techniques were being performed without everting the patella. Indeed, *the sole*

inventor of the '896 patent previously acknowledged that *not* everting the patella could “allow for faster recovery time as less exposure is required for single compartment.” Bonutti 1997, p. 266 (Ex. 1035). Further, it was also known that in certain cases standard TKA could be performed without the patella everted. Stern, p. 1290 (Ex. 1033). Therefore, performing knee arthroplasty without everting the patella was nothing new at the time of filing for the '896 patent.

9. At bottom, the motivation of every orthopedic surgeon, and indeed every doctor, is first to do no harm. Accordingly, a doctor chooses the techniques that will minimize any and all side effects (including associated surgical trauma and cosmesis) while still providing the best possible outcome for the patient. Therefore, the motivation of a person of skill in the art of orthopedic surgery is always to design/develop the most effective and least invasive technique possible to achieve the desired outcome. This was true well before 2000, and it is true today. Contrary to Dr. Schoifet’s assertions, the methods claimed in the '896 patent do not in any way improve the then-current state of the art with respect to the invasiveness of TKA. Instead, the disclosed benefits of small incisions, sparing quadriceps, and non-eversion of the patella, (that is, “improved cosmetic results, improved rehab, less dissection of muscle and soft tissues, and preservation of the quadriceps mechanism”) were already known to the person of ordinary skill in the

art and were readily obtainable through the simple combination of known techniques. '896 patent, col. 15, ll.15-18 (Ex. 1001).

Scorpio

10. On May 13, 2014, I was deposed by BSI's counsel about my first declaration. At that time, I was asked a number of questions about the Scorpio reference, and the fact that the "bone side" of the device was not visible in the picture. Specifically, I was asked whether the person of skill in the art would know that the solid metal portion that divided the two cutting surfaces extended completely through to the bone side thereby creating two separate guide surfaces. As I discussed in my first declaration and at my deposition, the person of skill in the art would understand from the Scorpio technique guide that there are two separate, distinct guide surfaces that make up the Scorpio anterior resection guide and that the femoral implant used in the Scorpio procedure has a transverse dimension that is larger than the transverse dimension of each one of the guide surfaces. *See* Sep. 25, 2013, Declaration of Jay Mabrey M.D., ¶ 70 ("Mabrey Decl." (Ex. 1002)).

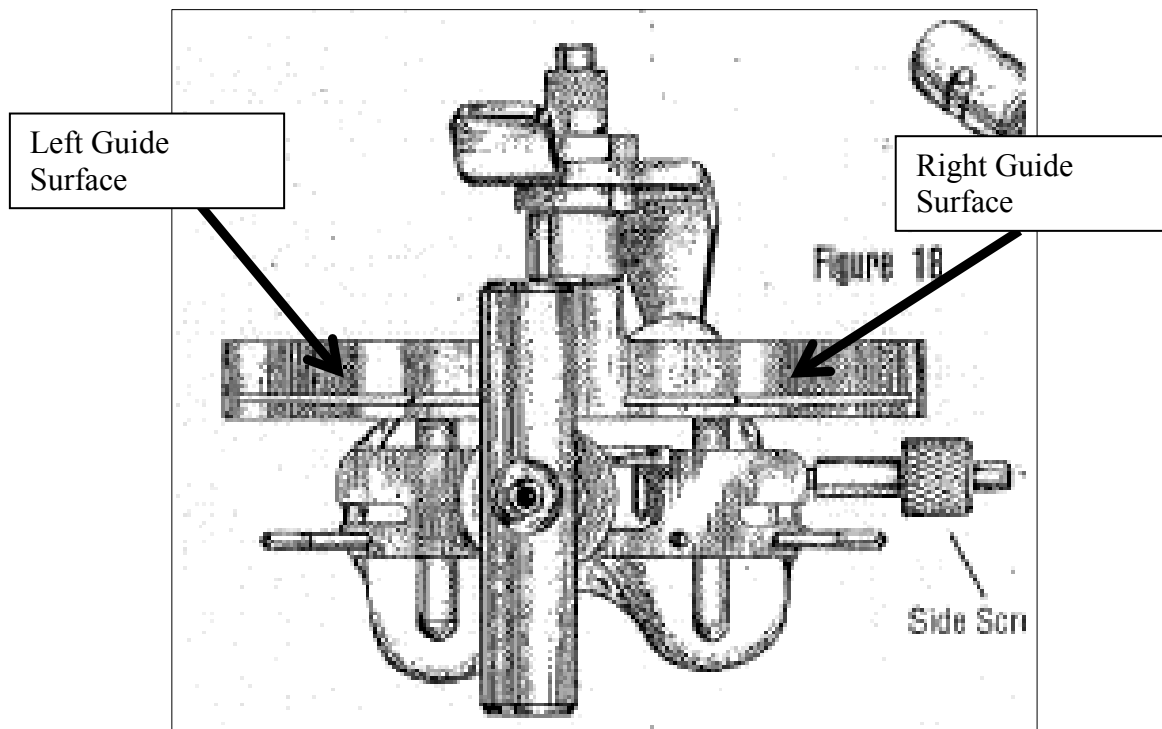
11. Since my deposition, I have reviewed Dr. Schoifet's declaration, reviewed pictures of the Scorpio device Dr. Schoifet relies on, inspected an actual Scorpio device, and used that device on a cadaveric knee. As discussed further below, my opinion remains unchanged—the Scorpio reference shows two separate,

distinct guide surfaces, each of which is less than the width of the implant as required by claim 1 of the '896 patent.

12. Dr. Schoifet alleges that the person of skill in the art at the relevant priority date for the '896 patent would have understood that the Scorpio device depicted in Ex. 1009 has a “single continuous guide surface that extends across the entire cutting guide” based on a guide he purportedly used in 2003. Schoifet Decl. ¶ 59 (Ex. 2004) (emphasis in original). This is not so, for at least three reasons. First, as I described in my opening declaration, the Scorpio guide consists of two separate cutting slots with two separate guide surfaces. These two slots are designed to cut different anatomy. Second, the portion of the cutting guide that rests at the apex of the solid metal piece at the division of the two separate guide surfaces is not a “guide surface.” Third, I have performed a test of the Scorpio device and confirmed that this apex portion of the cutting guide has no impact whatsoever on the function of the device.

The Scorpio Device Has Two Guides Surfaces

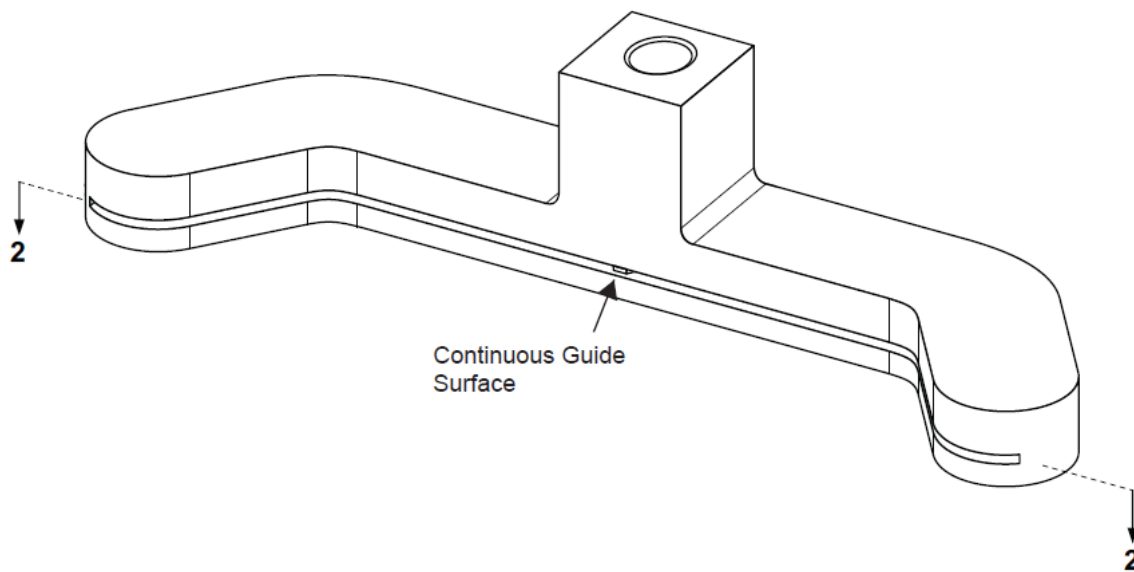
13. As discussed at paragraph 70 of my opening declaration, the anterior resection cutting guide shown in, for example, Fig. 18 of Ex. 1009 has two guide surfaces (highlighted with arrows) that are separated by a solid metal portion in the middle of the device:



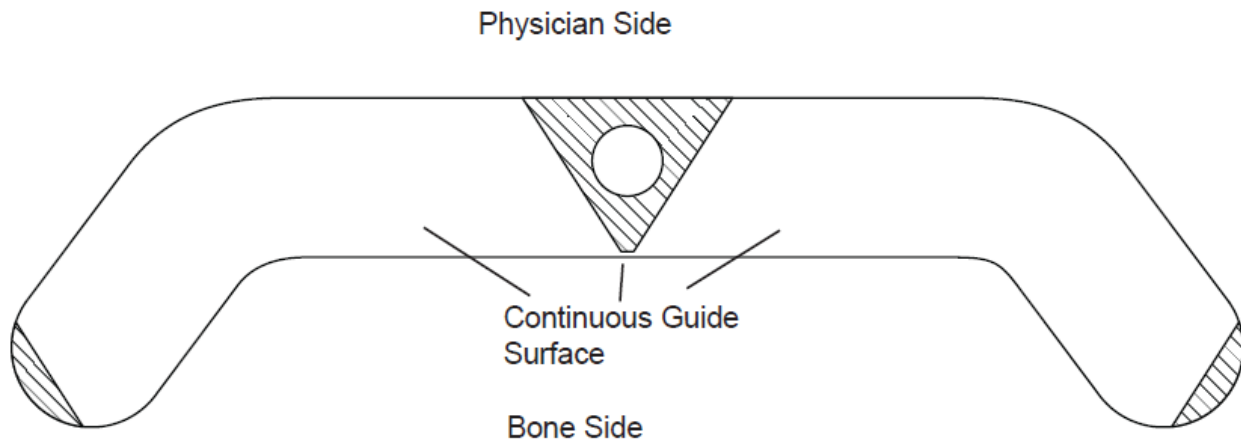
Scorpio, p. 11 (Ex. 1009); Mabrey Decl. ¶ 70 (Ex. 1002). There is no dispute that the two guide surfaces are separated by a solid metal portion. The person of skill in the art would know this is true because he could not move his saw blade from the farthest right side of the device to the farthest left side of the device without first removing the blade from one slot and placing it in the other slot. The reason for two guide surfaces is to allow the surgeon to use the same device for both the left and right knee, because as the Scorpio technique guide states, it “is designed for use on either the left or the right knee.” Scorpio, p. 6 (Ex. 1009). Therefore, a person of skill in the art reading the Scorpio technique guide and using the device would not view these two separate guide surfaces as a single continuous guide surface, but as two different guide surfaces for two different cuts.

Dr. Schoifet Has Not Identified a Continuous Guide Surface

14. In his declaration, Dr. Schoifet alleges that the Scorpio guide actually has a single continuous guide surface that runs across the entire length of the anterior resection cutting guide. He states that “[t]he guide surface [is] narrowed and widened from one side of the cutting guide to the other, but it [is] extended as a single continuous surface throughout.” Schoifet Decl. ¶ 59 (Ex. 2004) (emphasis in original). In support of this opinion, he references two drawings:



Drawing Alleged To Depict the Back Side Of the Scorpio Guide

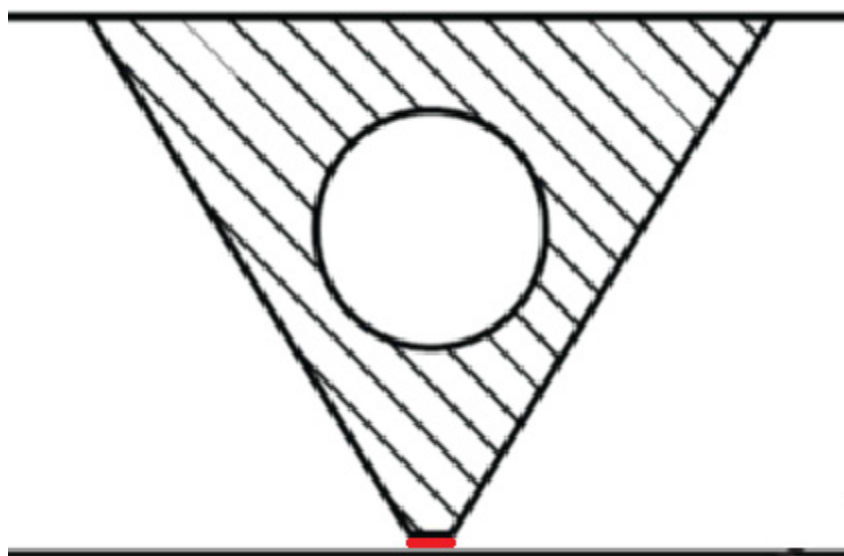


Drawing Alleged To Depict a Cross Section View Through the
Central Portion Of the Scorpio Guide

BSI Drawings, p. 2 (Ex. 2007). Dr. Schoifet indicates that a small portion of the cutting guide at the apex of the truncated triangle (which in actuality is only approximately 1 mm wide by 0.5 mm deep) is “guide surface” and that its presence means the Scorpio cutting guide has a continuous guide surface across its entire width. Schoifet Decl. ¶ 78 (Ex. 2004). I disagree.

15. The Board has defined the term “guide surface” to mean “a surface that guides a cutting instrument.” Decision on Institution at 27, Smith & Nephew, Inc. v. Bonutti Skeletal Innovations, LLC, IPR2013-00629 Paper 9 (“Decision on Institution”). Therefore, the only parts of a cutting guide that can be a “guide surface” are those that guide a cutting instrument. Under the Board’s construction, the Scorpio device plainly has two guide surfaces. Dr. Schoifet’s claims that the

small portion of the Scorpio device at the apex of the truncated triangle that divides the two guide surfaces (shown in red in the enlarged portion of Dr. Schoifet's diagram below) is also "guide surface" and that, therefore, the Scorpio device has one continuous guide surface are incorrect:



16. Dr. Schoifet's view is flatly inconsistent with the Board's construction that a "guide surface" must guide a cutting instrument, as the portion of the Scorpio device on which Dr. Schoifet relies does not do so. When a surgeon performs the anterior resection cut described in the Scorpio technique guide, the blade is inserted into one slot and is guided by resting it on the flat surface of the cutting guide. The cutting instrument is never "guided" by the truncated portion at the apex of the metal divider of the device.

Anterior Resection of Human Cadaveric Knee Using the Scorpio Cutting Guide

17. Dr. Schoifet also asserts that the metal portion in the center of the Scorpio guide cannot extend all the way to the bone side of the guide surface because “if it did a physician would not be able to cut the entire condyle portion of the bone.” Schoifet Decl. ¶ 77 (Ex. 2004) (emphasis in original). Dr. Schoifet states that “[t]his 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.” Schoifet Decl. ¶ 78 (Ex. 2004).

18. In order to demonstrate that Dr. Schoifet is incorrect, I performed an anterior resection on a human cadaveric knee with 50% of the femoral and tibial bones and with no previous surgery. I used a Scorpio anterior resection guide that is functionally identical to that which is described in Ex. 1009. I followed the procedure outlined in the Scorpio technique guide, and have documented the procedure in the paragraphs below.

19. Description of the procedure:

- a. I identified the anatomical landmarks on the left knee, specifically the medial and lateral sides, the patella, and the tibial tubercle:



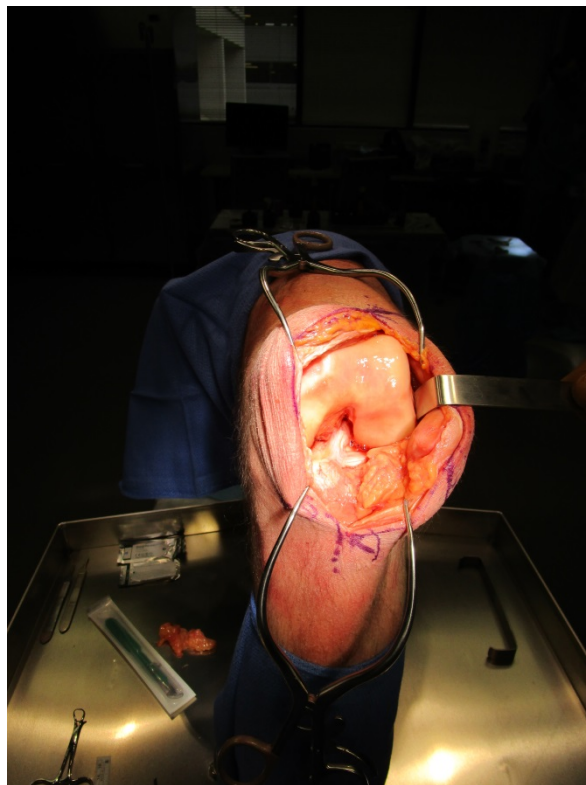
Scorpio Demonstration Photos, p. 13 (“Scorpio Photos” (Ex. 1030)).

- b. Then, with the leg in extension, I laid out a medial parapatellar incision of 13 cm. *See Scorpio Guide, p. 3 (Ex. 1009).*



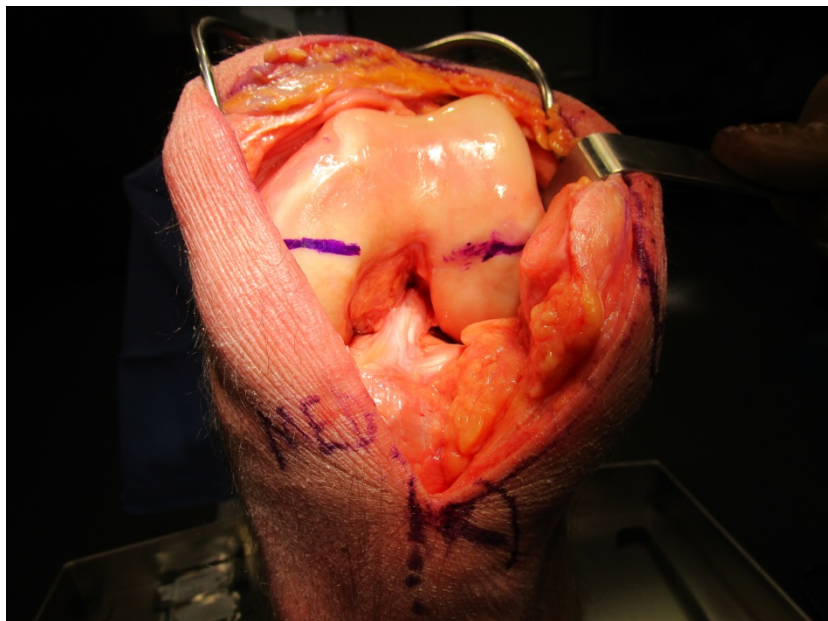
Scorpio Photos, p. 14 (Ex. 1030).

- c. I then made the incision and lateralized the patella but did not evert it
in order to expose the knee.



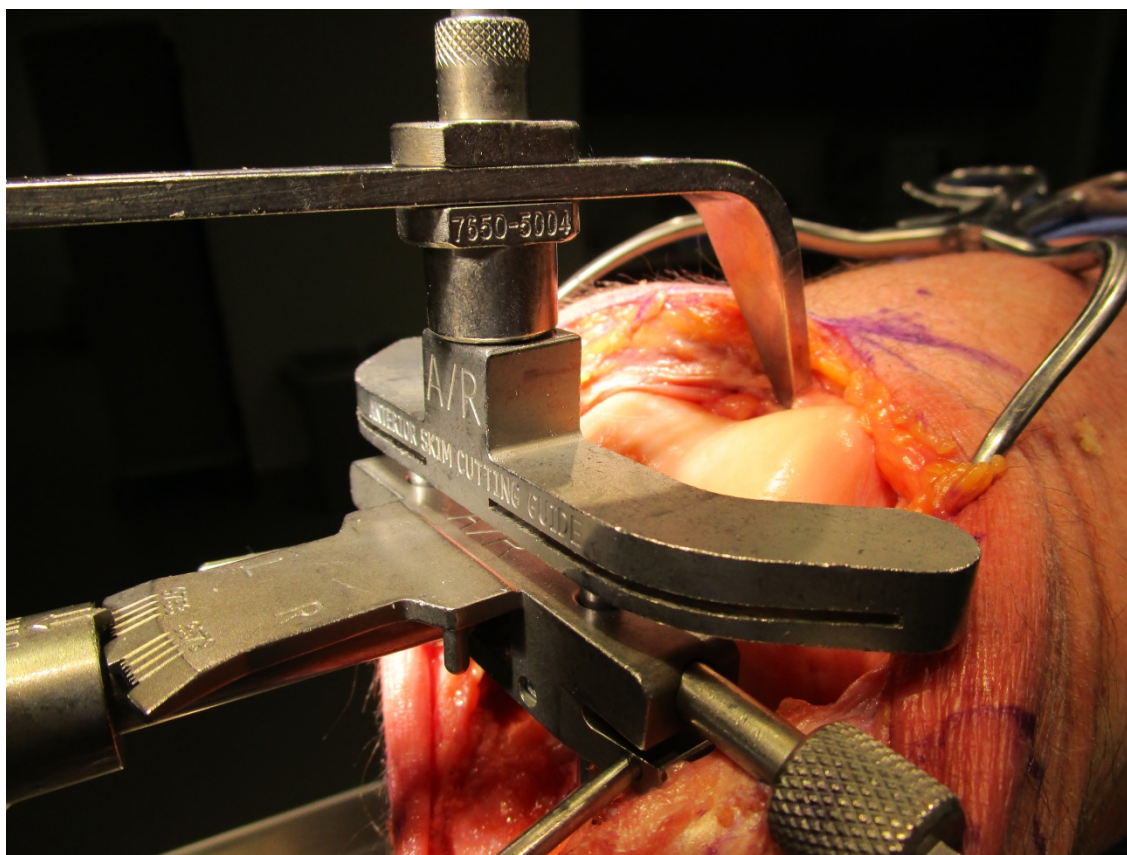
Scorpio Photos, p. 17 (Ex. 1030).

- d. I drew a line linking the medial and lateral epicondyles of the femur (the “transepicondylar line”). *See* Scorpio Guide, p. 5 (Ex. 1009).



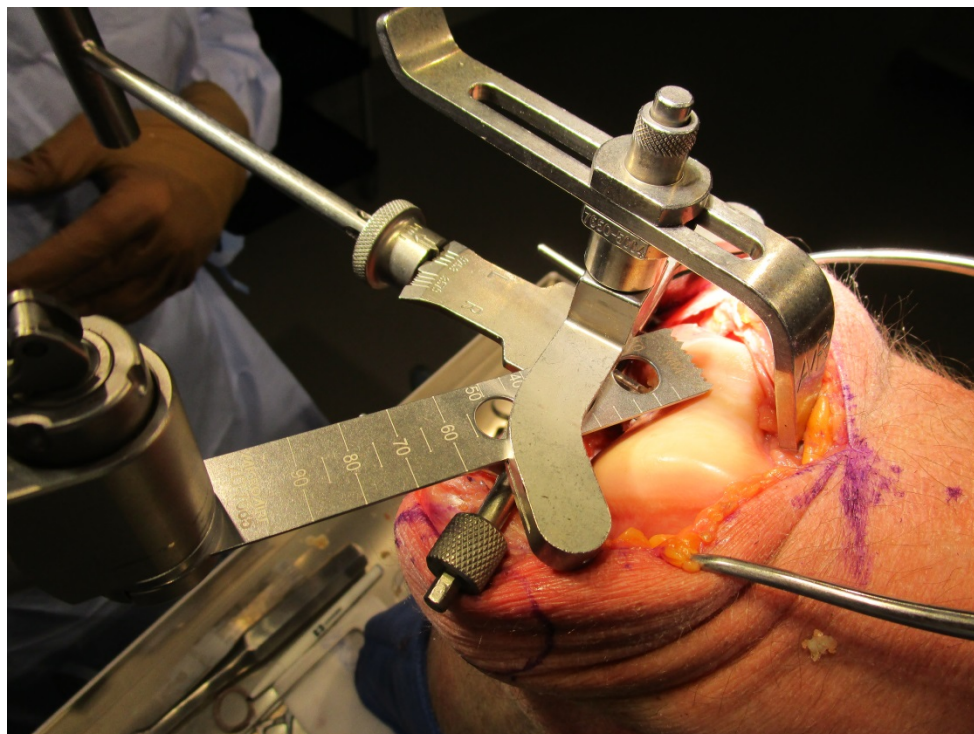
Scorpio Photos, p. 20 (Ex. 1030).

e. I drilled a 1/4 inch hole through the femur and inserted the intramedullary rod through the Scorpio Femoral Alignment Guide. I then pinned the Femoral Alignment Guide in place to stabilize the guide. I then placed the anterior resection guide in the two holes on the Femoral Alignment Guide, and placed the anterior depth gauge on the highest point of the anterior femur to set the depth of the cut. *See* Scorpio Guide, pp. 6-8 (Ex. 1009).



Scorpio Photos, p. 25 (Ex. 1030).

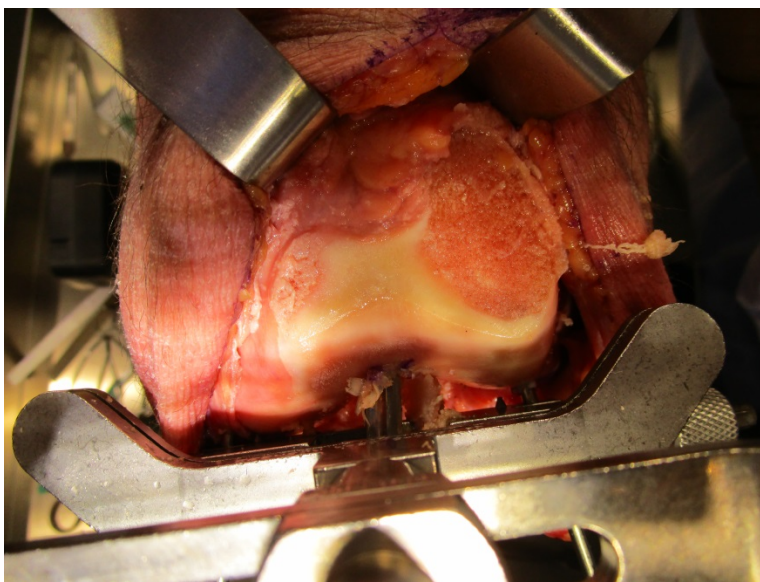
- f. Using a standard width oscillating saw blade, I confirmed the proper placement of the guide and verified that I could complete the resection using only one of the guide surfaces. *See Scorpio Guide p. 9-10 (Ex. 1009).*



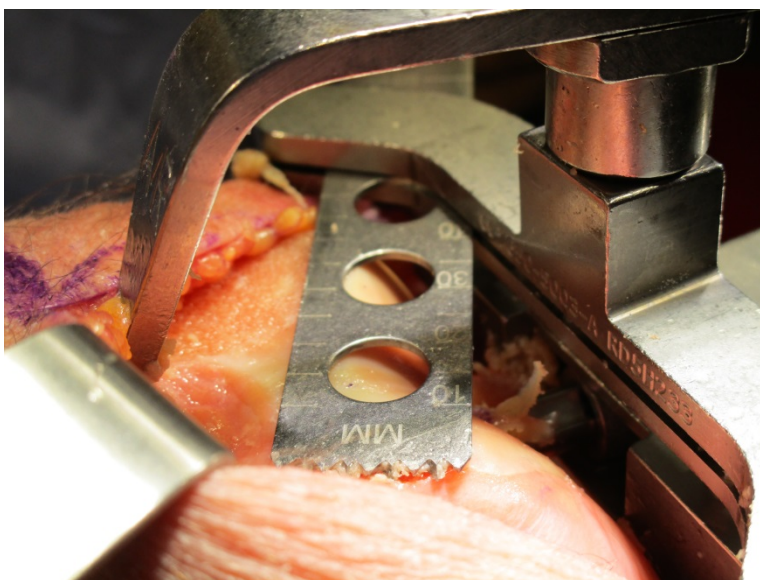
Scorpio Photos, p. 27 (Ex. 1030).

- g. I then cut the anterior bone with the saw by sweeping the oscillating blade from side to side. The central portion of the cutting guide that connects the two guide surfaces at the knee was not guiding the cutting blade during my cut. The picture below depicts the completed cut and the saw blade extending from the distal side cutting the medial portion of the knee. *See Scorpio Guide, p. 9-11 (Ex. 1009).* In

addition, note that 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.



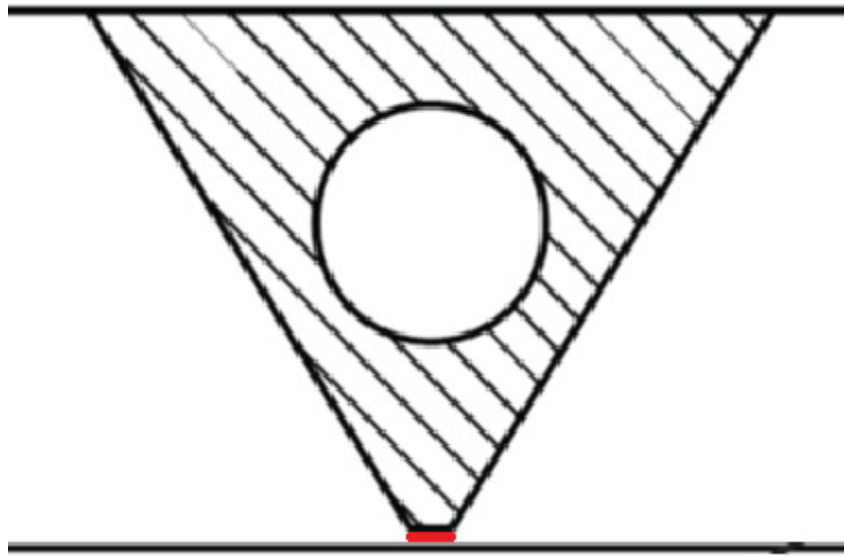
Scorpio Photos, p. 40 (Ex. 1030).



Scorpio Photos, p. 29 (Ex. 1030).

20. As shown above, the anterior resection cut needed to complete a Scorpio TKA replacement was done using only one side of the Scorpio anterior resection guide. A person of ordinary skill at the time using the Scorpio anterior resection guide would have observed this directly and would have known that only one of the Scorpio's two guide surfaces was needed to make the anterior cut on the femur.

21. Further, contrary to Dr. Schoifet's opinion, a person of ordinary skill would not be prevented from making the entire anterior cut if the solid portion of the guide were to extend a few fractions of a millimeter further to the bone side of the device. Dr. Schoifet testified that if the red portion of the cutting guide cross-section shown below were to be solid metal (in other words the metal were to extend completely to the bone side, then the Scorpio guide may be a "non-functioning" cutting guide (Schoifet Dep. at 142:7-143:8; 144:4-11; 152:25-154:2; 154:21-156) (Ex. 1031):



I disagree, the red portion of the guide is not used during the procedure, nor does it guide a cutting blade. Accordingly, if it were metal it would have no impact on the ability of a surgeon to perform the anterior resection. I observed during my resection that the cutting blade did not contact the small area at the tip of the support triangle. This is consistent with the fact that the person of skill in the art would understand that this part of the cutting guide is not used at any point during the anterior resection.

Downsizing an Instrument System is Obvious

22. As I discussed in my opening declaration, it would be obvious to a person of skill in the art before the priority date of the '896 patent to downsize standard instrumentation for performing TKA. Mabrey Decl. ¶ 70 (Ex. 1002). It would have been obvious to do so because reducing the size of cutting guides was

a known method of minimizing the size of the incision. Specifically, Delp '018 states that "[t]he computer replaces large, complicated mechanical alignments systems, allowing smaller jigs to be used, and thus a smaller incision to be made." U.S. Patent No. 5,871,018 ("Delp '018"), col. 22, ll. 45-50 (Ex. 1004). Dr. Schoifet states that this motivation does not indicate that the size of the guide surface would be reduced. *See* Schoifet Decl. ¶ 97 (Ex. 2004). I disagree. Delp '018 clearly contemplates making cutting jigs that do not "align cuts using discreet metrics and visual means." Delp '018, col. 22, ll. 36-37 (Ex. 1004). Further, the instrumentation used by the Delp '018 system can be smaller because it does not need to "cover certain anatomical landmarks" to align the cutting jigs. Delp '018, col. 22, ll. 40-41 (Ex. 1004). Dr. Schoifet's opinion ignores that Delp '018 teaches that the jigs themselves can be smaller. Making a cutting jig smaller relative to the anatomy of the knee necessarily means that a person of skill in the art would make all aspects of the guide smaller, including the guide surfaces. Because the cuts needed to perform a TKA are the same, a surgeon using smaller guide surfaces of a smaller jig would necessarily use them to perform larger, accurate cuts for TKA. Therefore, as I discussed in my opening declaration, the Delp '018 patent provides the motivation to use smaller cutting jigs with reduced guide surfaces to accommodate smaller incisions. Mabrey Decl. ¶ 82 (Ex. 1002).

23. In sum, Dr. Schoifet's opinion that the Scorpio device has one continuous guide surface is incorrect. It has two distinct guide surfaces, each of which is smaller than the width of the implant that is installed during the Scorpio TKA procedure.

Turner

24. Dr. Schoifet articulates his views on the relevance of the Turner article to the state of the art of TKA prior to the filing date of the '896 patent at paragraphs 64-68 of his declaration. As discussed more fully below, I disagree with Dr. Schoifet's opinions regarding the teachings of Turner. Further, none of his opinions address the fact that Turner discloses the use of a small guide surface to make a cut for a larger implant.

25. Dr. Schoifet's opinion is that the geometric knee is "a primitive design with poor outcomes when compared with modern knees (post 1990)" and that, as a result, a "person of ordinary skill in the art in 2000-2003 would not consider using [the Turner Cutting Guide or procedure]." Schoifet Decl. ¶ 65 (Ex. 2004) (emphasis omitted). I disagree. Dr. Schoifet ignores what the geometric knee represents to the development of TKA. The geometric knee was a widely used and successful TKA device in the patient population it was designed to treat—severely arthritic patients with high levels of pain and significantly reduced mobility. These patients had significant pain, lack of mobility, and arthritic deformity. For these

patients, an implant life of 8 to 10 years (*i.e.*, a 69% chance that the implant will last 10 years) represented a significant increase in the quality of life for those years. Thus, in a two year follow-up study published when the geometric knee was widely used, it was noted that “[r]elief of pain was the primary goal of surgery for 84 per cent of the cases” where 96% of the patient population had significant pain. Skolnick, pp.749, 752 (Ex. 1029). At the two-year follow-up timeframe 92% of these patients had “little or no pain.” *Id.* at 752. This represents significant success for these patients.

26. Further, more of these patients could walk better, with decreased use of walking aids, and for further distances than were possible prior to the surgery. *Id.* The geometric knee, using the procedure outlined in Turner, was therefore a very successful TKA system.

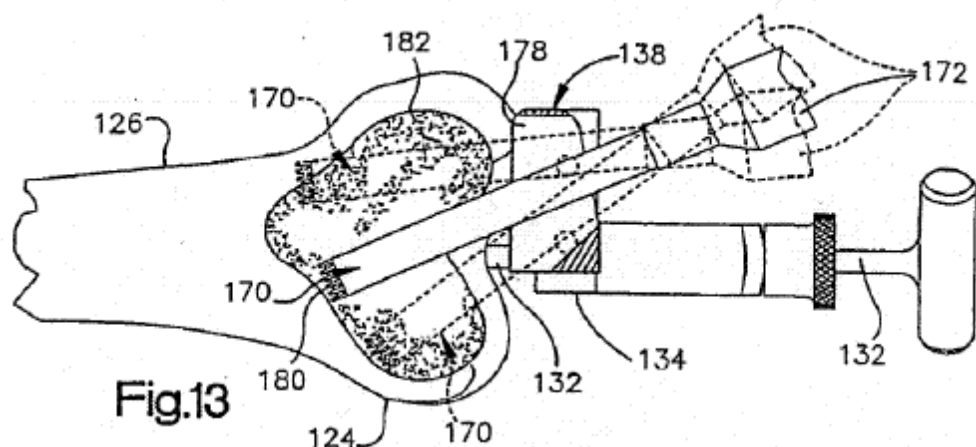
27. The geometric knee also was the harbinger of many current and successful total knee designs. Its highly congruent design not only contributed to stability, but reduced the effects of wear caused by metal rubbing against polyethylene. It led to the development of the duopatellar knee and eventually the Insall-Burstein total knee, each of which was built on the success of the geometric knee design and technique. Later TKA systems owe their success to the Turner knee.

28. Dr. Schoifet states that the teachings of Turner should be ignored because while the design of the geometric knee was purportedly governed by the desire to maximize stability in extension, it was later discovered that stability in flexion [the opposition functionality] was the more critical parameter. Schoifet Decl. ¶ 67 (Ex. 2004). I disagree. Turner states that “although stability in flexion [as the knee flexes] may be sacrificed somewhat with spherical surfaces, the requirements for stability in flexion are not nearly as significant functionally as are the requirements for stability at or near full extension.” Turner, p. 174 (Ex. 1008). Turner does not say that stability in flexion is unimportant, but rather that a knee replacement design will function better if the stability is maximized at or near full extension. This means that the patient will have greater, more reliable, function of the knee joint if stability in full extension is maintained (as is necessary for a stable heel to toe gait progression).

29. Dr. Schoifet’s also states that prior to 2000 it was well understood that shortening the width of a guide surface “would reduce precision because it would not allow the entire cut of the femur to be guided as precisely.” Schoifet Decl. ¶ 98 (Ex. 2004). He states that the Turner guide surface is “so small that a cutting blade would pivot about the guide surface during a cut.” *Id.* at ¶ 90. I disagree with both statements. A person of skill in the art is trained to handle saw blades and guide them accurately using a smaller guide surface. A person of skill in the art would

be able to use the guide surface to make an accurate cut on the distal femur. There is no indication in the Turner reference, or elsewhere, that the Turner cutting guide failed to make an accurate cut.

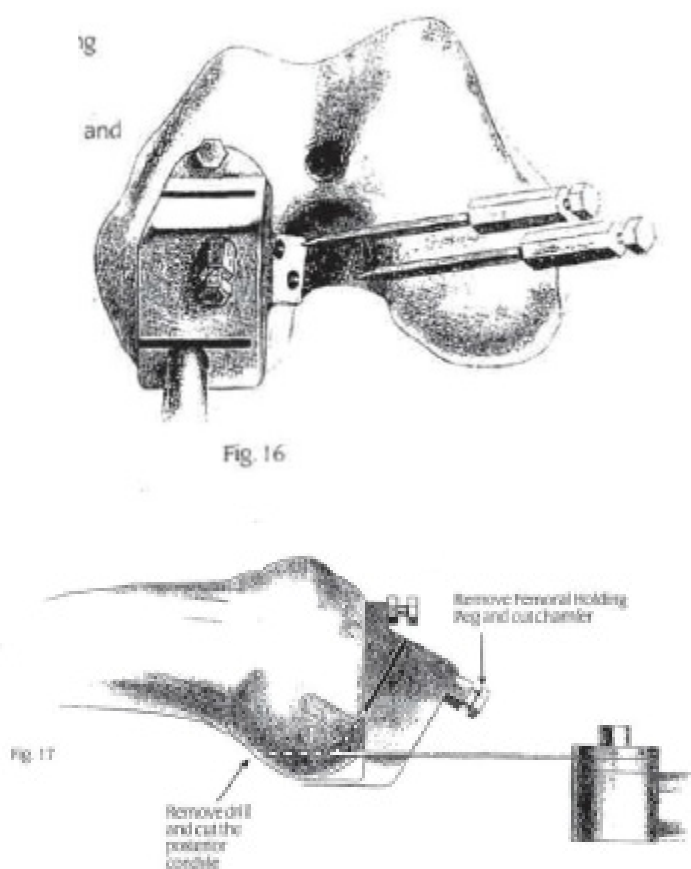
30. Second, I disagree that narrower guide surfaces necessarily result in reduced precision. The bone resection blades used to perform resections in TKA, both prior to 2000 and today, are relatively stiff and often fairly wide. They were designed to rest on relatively narrow-width cutting surfaces and remain straight in order to perform an accurate cut, even if that cut is relatively far from the guide surface. For example, Figure 13 of the '896 patent illustrates how a narrow guide surface can allow for a precise cut at a significant distance from the guides surface itself:



'896 patent, Figure 13 (Ex. 1001). As shown above, in my tests with the Scorpio device this was also true. Therefore, I disagree with Dr. Schoifet that narrow guide surfaces necessarily result in less accurate cuts. A person of skill in the art at the

time would have known that large, accurate cuts could be made with smaller guide surfaces using long flat blades to install implants larger than the transverse dimension of the guide surface.

31. In addition, smaller guide surfaces have been used to make accurate cuts in unicondylar knee arthroplasty (“UKA”). For example, Zimmer’s M/G Unicompartmental MIS system (“M/G System”) included “guides for accurate and reproducible alignment, sizing, and resection.” Zimmer Guide, p. 2 (Ex. 1034). The guide surfaces used in the M/G System are very small relative to the size of the cuts being made. The portion of the cutting block that is used to cut the posterior condyle is small and the surgeon is able to make a much larger accurate cut:



Zimmer Guide, p. 15 (Ex. 1034). The fact that UKA systems used small guide surfaces to create larger, accurate cuts demonstrates that a reduced guide surface does not create an inherent inaccuracy of the cut.

32. In summary, it is incorrect to label the geometric knee as a failure or to claim that it had poor outcomes. More importantly, the mere fact that the geometric knee was replaced by newer knee systems does not diminish what the Turner article teaches—that smaller guide surfaces can be used to make the required cuts for larger implants.

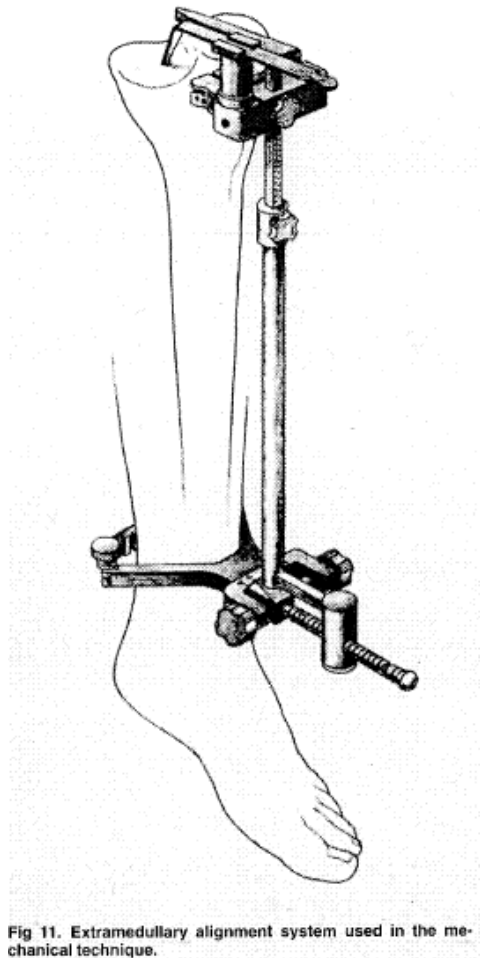
The Cutting Guide in Turner Does Not Have an Extramedullary Alignment Rod

33. Dr. Schoifet asserts that the cutting guide in Turner uses an extramedullary alignment rod “because it is an alignment rod that is not located inside the medullary canal of the femur.” Schoifet Decl. ¶ 66 (Ex. 2004). This is incorrect.

34. A person of ordinary skill would understand that an extramedullary alignment rod is a mechanical alignment device that is external to the body and relies on fixed anatomical markers in order to properly align cuts or implants. For example, Stulberg describes how the extramedullary rod accomplishes alignment:

The proximal portion of the tibial instrumentation system is placed in such a way that the intramedullary or extramedullary rod intersects the proximal medial-lateral midpoint of the tibial plateau. An ankle clamp helps position the distal portion of an extramedullary rod over the midportion of the talus. This point represents the medial-lateral midpoint of the ankle joint.

Stulberg, p. 29 (Ex. 1005). This can also be clearly seen in Fig. 11:



Stulberg, p. 32, Fig. 11 (Ex. 1005). The rod that is outside the skin (and therefore external to the medullary canal) is aligned in relation to two anatomical markers (the proximal medial-lateral midpoint of the tibial plateau and the medial-lateral midpoint of the ankle joint) to properly align the cutting block for the tibial resection.

35. In contrast, the Turner cutting guide is inserted into the suprapatellar pouch and the cutting guide surface itself is aligned with the condyles. The Turner

cutting guide is an angled piece of metal with a narrow flat guide surface that is used to guide the cutting device. The longer piece of metal that rests on the anterior femur is only for stabilization of the guide surface to help ensure the surgeon can make an accurate cut. Therefore, the anatomic landmarks used for aligning the cutting surface are the femoral condyles, not the femoral or tibial shaft as would be the case for a standard extramedullary alignment rod.

36. Therefore, the handle of the Turner cutting guide is not an extramedullary alignment rod as understood by a person of ordinary skill in the art.

Stulberg and Turner Are Combinable

37. Dr. Schoifet states that “a person of skill in the art would find no motivation to combine the teachings of Turner with a computer-assisted technique, such as Stulberg’s (or Delp’s)” for the following reasons:

- The Turner guide is “very crude” and “would not be suitable” for use in knee replacement surgery;
- The femoral cutting guide of Turner serves a different function (*i.e.*, makes a different cut) than the cutting guide of Stulberg;
- The combination of Stulberg with Turner would not result in a more accurate surgical outcome and would be difficult to use.

Schoifet Decl. ¶¶ 68-74 (Ex. 2004) (emphases omitted). As I stated in my previous declaration, a person of ordinary skill in the art would combine the teaching of positioning small cutting guides as taught by Turner, with computer-assisted systems taught in Stulberg in order to “overcome the deficiencies of standard mechanical measuring techniques, such as the inability to locate crucial alignment landmarks, the presumption that bone geometry is standardized, and the reliance on visual inspection to verify proper alignment of the implant.” Mabrey Decl. ¶ 92 (Ex. 1002). I have been involved in the development and use of computer-assisted surgical techniques, including techniques for TKA, since the mid-1990’s. Moreover, from 2000-2003, I was specifically involved with the development of a computer-assisted TKA system that would eliminate mechanical alignment. I have performed over 500 computer assisted TKA surgeries. In my experience, the combination of any cutting guide system, including Turner, with computer-assisted alignment techniques would be nothing more than the “predicable use of prior art technology according to its established function to achieve [the] predictable result.” *Id.* Specifically, the result of this combination is that the cutting guide is more accurately aligned with the anatomy of the specific patient than it would have been had mechanical alignment been used, and it thereby creates a more accurate surgical outcome.

38. Accordingly, I disagree with Dr. Schoifet's opinions for at least three reasons. First, the Turner cutting guide is neither crude nor would its use result in what he calls a "free hand" or "eyeball cut." The Turner cutting guide provides guide surface that directs the blade during the cut. Specifically, the "femoral osteotomies are made with a power or hand saw parallel with the guide which is approximately 30 degrees to the long axis of the femur." Turner, p. 181 (Ex. 1008). This cut is not imprecise. A free hand cut is just that, a cut that does not use a guide surface to direct the cut, but rather relies only on the physician's skill in cutting. Instead, Turner teaches a person of skill in the art that larger, precise cuts can be made with fairly narrow guide surfaces—exactly the teaching that renders the invention of claim 1 obvious.

39. Second, it is irrelevant that Turner and Stulberg used guides designed to make different cuts in the femur. What Turner teaches is that guide surfaces smaller than the implant can be used to make cuts sufficient for larger implants. Stulberg teaches that all mechanical cutting guides can be improved by eliminating their mechanical alignment devices and replacing them with computer-assisted positioning on the femur. A person of skill in the art would know that you could combine the concept of smaller cutting guides from Turner and improve the accuracy by using the techniques of Stulberg regardless of what cut was being made on the femur.

40. Third, the combination of Turner and Stulberg would not result in a less accurate surgical outcome, nor would that combination be difficult to use. As stated above, the Turner guide provides sufficient guide surface to make an accurate cut in order to install a larger femoral implant. Further, Stulberg provides a computer-assisted technique that could be adapted to any cutting guide to eliminate any mechanical alignment, including the alignment of the Turner guide in the intercondular notch. Because the Turner guide could be aligned based on “the correct location of crucial alignment landmarks,” it would necessarily be a more accurate technique. Stulberg, p. 25 (Ex. 1005). Moreover, it would be as simple to use Turner with Stulberg as it would be to use the cutting guide described in Stulberg: the doctor would simply insert the guide in the suprapatellar pouch and then align it with the disclosed computer-assisted method.

41. Contrary to Dr. Schoifet’s incorrect characterizations, the person of skill in the art would therefore be motivated to combining the teachings of Turner and Stulberg to achieve the predictable result of more accurate surgical outcomes.

Stulberg and Scorpio Are Combinable

42. Dr. Schoifet states that “a person of skill in the art would not consider combining the teachings of Stulberg (or Delp) with Scorpio” for the following reasons:

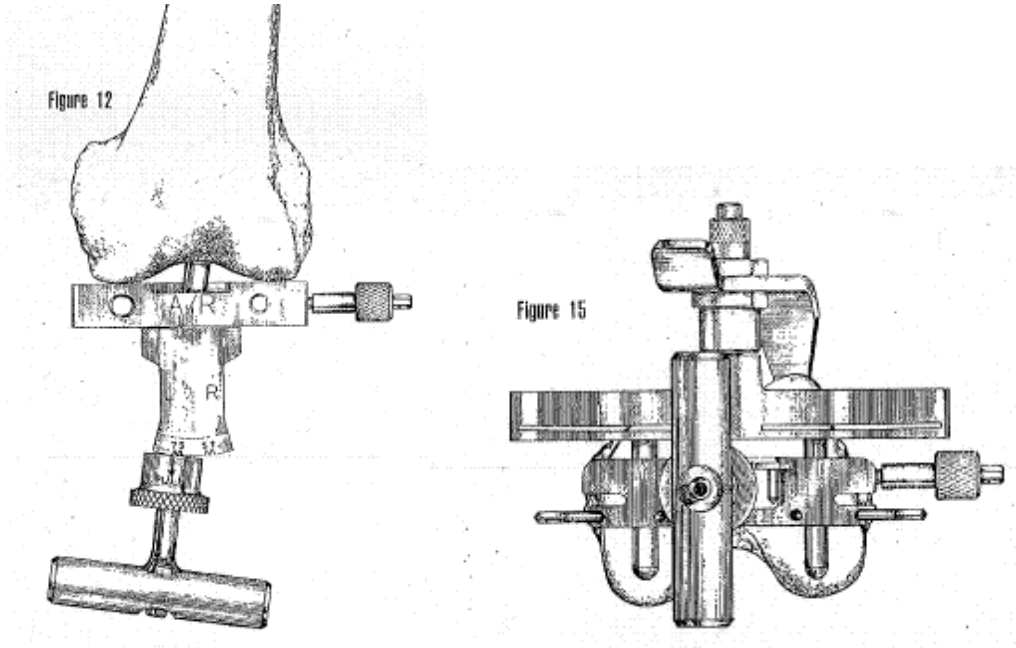
- A person of skill in the art would have difficulties performing computer-assisted navigation with Scorpio because it is “so large and would be unstable without positioning and mounting assistance of the intramedullary rod of Scorpio”; and
- The cutting guide used in Scorpio serves a different function (*i.e.*, makes a different cut) than the cutting guide of Stulberg.

Schoifet Decl. ¶¶ 81-82 (Ex. 2004).

43. As I stated in my previous declaration, a person of ordinary skill in the art would combine the teaching of positioning small cutting guides as taught by Scorpio with computer-assisted systems taught in Stulberg in order to “overcome the deficiencies of standard mechanical measuring techniques, such as the inability to locate crucial alignment landmarks, the presumption that bone geometry is standardized, and the reliance on visual inspection to verify proper alignment of the implant.” Mabrey Decl. ¶ 92 (Ex. 1002). The combination of any mechanical cutting guide system, including Scorpio, with the computer-assisted alignment techniques would be nothing more than the “predicable use of prior art technology according to its established function to achieve [the] predictable result” of a more accurate surgical outcome. *Id.*

44. Accordingly, I disagree with Dr. Schoifet’s opinions. The Scorpio device is modular. The alignment is not done with the entire device, but with a

small portion of the device. As shown in Figures 12 and 15 below, the actual anterior resection cutting guide is held in place by a smaller Femoral Alignment Guide:



Scorpio Guide, p. 7-9 (Ex. 1009). This smaller Femoral Alignment Guide, roughly half the size of the cutting guide, is aligned with the IM alignment rod and is held in place with bone pins. *Id.* at p. 6. The IM rod of Scorpio could be replaced with a bone pin identical to the bone pin used in the guide of Stulberg (*e.g.*, Figure 16), and properly positioned with the computer-assisted technique. Stulberg, p. 35 (Ex. 1005). The size and shape of Scorpio have no effect on the ability to apply computer-assisted techniques to the device, and thereby eliminate the IM rod.

45. Second, the fact that the cutting guides of Scorpio and Stulberg are designed to make different cuts does not mean that the movements required to use

computer-assisted techniques cannot be performed with Scorpio. A person of skill in the art could use the computer assisted techniques of Stulberg with the Femoral Alignment Guide of Scorpio. As shown above, the Scorpio alignment guide is positioned initially on a central IM rod. It freely rotates about this axis until it is properly pinned in place with bone pins. The technique in Stulberg also contemplates that the cutting guide is fixed at one point and then adjusted before being pinned in its final position. *See* Stulberg, p. 30 (Ex. 1005). The fact that different cuts are being made is irrelevant to the fact that computer-assisted techniques could be applied to the Scorpio technique.

46. Contrary to Dr. Schoifet's incorrect characterizations, the person of skill in the art would therefore be motivated to combining the teachings of Scorpio and Stulberg to achieve the predictable result of more accurate surgical outcomes.

Delp and Turner Are Combinable

47. Dr. Schoifet states that “[f]or the same reasons I discussed [] regarding Stulberg and Turner, a person of ordinary skill in the art in the 2000-2003 timeframe would never consider using the Turner Cutting Guide in the computer-assisted techniques discussed in Delp.” Schoifet Decl. ¶ 90 (Ex. 2004). Specifically, Dr. Schoifet reiterates his view that the Turner guide is “small and unstable,” and would not be combined with Delp because it is “contrary to what Delp is trying to achieve, namely accuracy.” Schoifet Decl. ¶ 90 (Ex. 2004). This

is incorrect. First, the fact that the Turner guide is “small” is precisely the point.

The small Turner guide allows the surgeon to make a much larger cut to accommodate the larger implant. Second, as stated above, the Turner guide is not an inaccurate or unstable cutting guide. It creates an accurate cut that allows for the proper placement of the femoral implant that is used for geometric knee replacement—a successful TKA system. Finally, also as discussed above, Delp is also associated with improving accuracy of the surgical outcome and this would be accomplished if Delp was applied to the teachings of Turner.

48. Therefore, for the same reasons discussed with respect to the combination of Stulberg and Turner, and as stated in my original declaration, the combination of Delp and Turner “would have been obvious to a person of ordinary skill in the art to augment the mechanical instruments in Turner or Scorpio with measurement probes [of Delp] to achieve predictable benefits such as the ability to align prosthetic components more accurately. Doing so is no more than the predictable use of prior art elements according to their established functions.”

Mabrey Decl. ¶ 72 (Ex. 1002)

Delp and Scorpio Are Combinable

49. Dr. Schoifet states that “[f]or the same reasons I discussed [] regarding Stulberg, a person of ordinary skill in the art in the 2000-2003 timeframe would never consider using Scorpio in the computer-assisted techniques discussed

in Delp.” Schoifet Decl. ¶ 92 (Ex. 2004). Specifically, he argues that a person of skill in the art would not have combined the teachings of Scorpio and Delp for the following reasons: the Scorpio guide “is so large and would be unstable without the positioning and mounting assistance of the intramedullary rod;” and the guides in Scorpio and Delp make different cuts that would require different adjustments, such that “there is no way to use computer navigation to properly position the Scorpio anterior [resection] guide.” Schoifet Decl. ¶ 92 (Ex. 2004). As stated above, the Scorpio anterior resection guide is not large and the portion of the cutting guide that is actually positioned is the much smaller Femoral Alignment Guide. A person of skill in the art would be able to place and properly adjust the alignment guide of Scorpio using computer-assisted techniques (*i.e.*, without an IM alignment rod) regardless of the fact that the cuts being made are different from the cuts made by the guide in Delp.

50. Therefore, for the same reasons discussed above, and as stated in my original declaration, the combination of Delp and Scorpio “would have been obvious to a person of ordinary skill in the art to augment the mechanical instruments in Turner or Scorpio with measurement probes [of Delp] to achieve predictable benefits such as the ability to align prosthetic components more accurately. Doing so is no more than the predictable use of prior art elements according to their established functions.” Mabrey Decl. ¶ 72 (Ex. 1002).

Availability for Cross-Examination

51. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

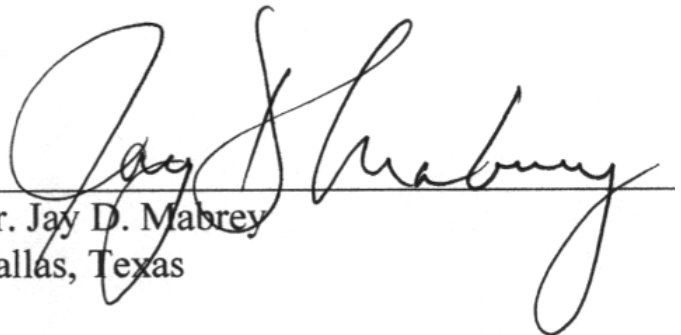
Right to Supplement

52. I reserve the right to supplement my opinions in the future to respond to any arguments that Patent Owner raises and to take into account new information as it becomes available to me.

Jurat

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: September 3, 2014



Dr. Jay D. Mabrey
Dallas, Texas