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Handheld navigation in total knee arthroplasty

Edwin P. Su, MD[a,b,*]

[a]*Clinical Orthopaedic Surgery, Weill Cornell Medical College, 535 E 70th St, New York, NY 10021*
[b]*Adult Reconstruction and Joint Replacement Division, Hospital for Special Surgery, New York, NY*

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ABSTRACT

Handheld navigation is now available for use in total knee arthroplasty, allowing for precision cuts of the distal femur and proximal tibia. By using inertial sensors and accelerometers, the handheld navigation unit is able to provide real-time, intraoperative information about alignment without additional incisions or arrays, line-of-sight issues, or the large capital expense associated with large console navigation systems. This handheld navigation unit reduces alignment outliers commonly seen with conventional guides, potentially leading to benefits in knee function and implant longevity.

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1. Introduction

Alignment in total knee arthroplasty (TKA) is considered to be an important factor in the function, longevity, and ultimate success of the operation, but it is debatable to what extent. At one side of the spectrum is the opinion that it is critically important to perform bony resections at the proper angle so that the implant knee prosthesis is aligned within a tight window, thereby optimizing function and implant survival. At the other end of the spectrum, the opinion is that the importance of alignment has been overstated, and there is a paucity of studies that links it to function or implant survival. In fact, some studies have found that implant alignment had no effect upon longevity [1] or function [2,3].

Most surgeons would concede that alignment of the femoral and tibial bone cuts, and overall composite alignment of the knee, is of *some* importance in how well a TKR performs. Therefore the question is: how best to achieve this goal, given the context of its questionable effect on TKR success? In other words, should surgeons spend a lot of time and money on a technique that may not translate to any benefit? Traditionally, surgeons have used simple cutting guides and jigs, in conjunction with intraoperative bone landmarks, to achieve resections perpendicular to the mechanical axis of the tibia and femur. We present a newer device consisting of a handheld navigation unit to more precisely create such cuts, with a significant reduction in the presence of outliers, without the expense and time requirements of other forms of computer navigation.

2. Alignment in TKA

One of the principles of performing bone resections in TKA is to make them perpendicular to the mechanical axis, creating a neutral mechanical alignment to the knee. One of the key benefits of this technique is that the forces upon the implant are normalized, reducing shear stresses upon the bone–implant interface. Theoretically, this should help enhance implant longevity.

Disclosures: The author, Edwin P. Su, MD, wishes to disclose that he has stock options in OrthAlign, Inc, the manufacturer of the KneeAlign 2 device.

* *Correspondence address*: Adult Reconstruction and Joint Replacement Division, Hospital for Special Surgery 535 East 70th Street New York, NY 10021.

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To achieve a neutral mechanical alignment, the tibia is resected perpendicular to its anatomic long axis, which is coincident with its mechanical axis. The femur is resected perpendicular to its mechanical axis, which typically deviates 3–7° from its anatomic axis. Taken together, these two cuts will give a composite femoral–tibial angle of approximately 3–7°. Berend et al. [4] have shown that if the tibial resection and implant position are in varus relative to the mechanical axis, there is a greater incidence of tibial loosening. Out of over 3000 TKR, they found that there were 41 tibial failures (1.3%) at a mean 5-year follow-up. Tibial component position of more than 3° of varus had a 17.2 × greater risk of failure as compared to if the component was neutrally aligned. If an additional factor such as a BMI $>$ 40 kg/m^2 was added to varus implant position, then the relative risk for tibial loosening increased to 168 [4].

Femoral alignment has not been as clearly linked to failure, but Ritter et al. [5] demonstrated that a femoral component in $>$8° valgus relative to the mechanical axis, had a greater rate of failure due to instability of the TKR. Therefore, there is evidence to support the importance of aligning a TKR within a certain window.

A conventional femoral cutting guide uses an intramedullary rod inserted into the femoral canal as a reference, and then a bushing with a variable angle to achieve the desired cut. Many surgeons use an angle of 4°–6° as a general rule, assuming that this will account for the difference between the anatomic and mechanical axes of the femur. However, Nam et al. [6] found that 30% of patients have a distal femoral mechanical–anatomic angle outside of 5° ± 2°; therefore, if the standard bushing angle is used with a conventional guide, 30% of femoral implants will be outside the desired neutral window.

Contrary to studies demonstrating the importance of implant alignment, Parratte et al. [1] compared the revision rate at 15 years between a group of well-aligned TKR (within 3° mechanical axis) vs poorly aligned knees ($>$3°outside of mechanical axis) and found no difference in the revision rate. A limitation of this study, however, is that they pooled both varus and valgus malalignment together, so it is possible that there was insufficient power to distinguish a difference.

3. Background on computer navigation

Computer navigation was developed in the early 2000s as a method to guide a surgeon to make precise bone cuts during TKA. Typically, computer navigation is imageless, meaning it does not require the use of radiography, rather relying on a process of intraoperative registration of bone landmarks and infrared cameras. The infrared cameras are mounted on overhead arrays, relying on line-of-sight to visualize reflective markers on the surgical field. The actual navigation computer is a separate unit with a display screen, positioned within the room to provide information to the surgeon, and is operated by a non-gowned person, or with a foot pedal. Because of the size of the unit and array, it is typically called "large console navigation."

Large console navigation is not commonly used in the United States, because of the high initial cost to hospitals of purchasing the unit and software. Additionally, surgeons were frustrated with the workflow of the navigation process, finding that additional incisions were needed to place reference arrays and the procedure was time consuming. Therefore, the promise of a technique that would make TKR more precise, but remain unobtrusive, was yet to be realized.

There has also been the development of newer navigation systems that incorporate robotic haptic guidance to the surgical procedure. With the addition of a robotic arm and a requirement for preoperative three dimensional imaging studies, the expense of robotic navigation systems is even greater.

4. Results of computer navigation

Multiple studies have demonstrated the reproducibility of computer navigation in reducing the incidence of outliers [2,3,7,8]. A meta-analysis examining alignment in 29 studies of computer assisted vs conventionally performed TKR, found alignment within ±3° neutral mechanical axis in 91% vs 68% [9]. Prospective-randomized trials have also found similar results, with approximately one-third of conventionally performed TKR found to be outliers, whereas only about 10% of navigated TKR are outliers [2,10].

Studies examining function and satisfaction of navigated vs conventional TKR, however, have not found significant differences. Knee society scores, satisfaction scores, and assessments on recovery have not been found to be different at either 2-year [3] or 10-year followup [2].

A recent study examining the use of computer navigation in a national joint registry has suggested that navigated TKR has a lower revision rate at 9 years [11]. In the Australian National Joint Registry, over 14% of all TKR are performed with computer navigation, and the overall 9-year revision rate was 4.6% vs 5.2% in the non-navigated cohort. This effect was further increased in the younger patient $<$65 years old, with a 6.3% vs 7.8% revision rate, leading to a hazard ratio of 1.13 for conventionally performed TKR.

5. Handheld navigation

With the advent of miniaturization of electronics, accelerometers and inertial sensors have been integrated into smartphones. This same technology has been incorporated into a handheld unit called KneeAlign 2 ("KA2," OrthAlign Inc, Aliso Viejo, CA), which consists of a sensorized display box that communicates with another small sensor (Fig. 1). These two units have been designed to attach to cutting guides, very similar to conventional guides, to navigate the distal femoral and proximal tibial cuts. Because of the integration of the handheld unit with the cutting guides, KA2 is able to provide real-time information about the position of the guides. These cutting guides are easily adjustable, allowing a surgeon to decide upon the desired resection angles intraoperatively. KneeAlign was released in a phased fashion, first available for tibial navigation only in 2010. In the next phase, distal femoral navigation was incorporated, and hence named KneeAlign 2.

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