Running head: Surgical navigation in canine total knee replacement

Full Title: Surgical Navigation Improves the Precision and Accuracy of Tibial Component Alignment in Canine Total Knee Replacement

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ABSTRACT

Objective -- The goal of the current study was to determine whether computer-assisted surgical navigation improves the accuracy of tibial component alignment in canine TKR.

Study design – Retrospective radiographic review and prospective ex-vivo study.

Sample population -- Seventeen sets of canine total knee replacement (TKR) radiographs were reviewed to determine the incidence and magnitude of tibial component malalignment. A cadaveric study was then performed in 12 canine stifle joints.

Methods -- Tibial component alignment was compared after either standard ("surgeon-guided") component placement or computer-assisted ("navigation-guided") placement. Results were compared against the current recommendations of a neutral (0° varus-valgus) ostectomy in the frontal plane and 6° of caudal slope in the sagittal plane.

Results – Malalignment of greater than 3° in the frontal and sagittal planes was identified in 12% and 24% of radiographs respectively. Surgical navigation reduced both the mean error (p=0.007) and the variability in frontal plane alignment (p<0.001) as compared with surgeon-guided procedures. The mean error in sagittal plane alignment was not significantly different (p=0.321) but variability in alignment was significantly lower when navigation was used (p=0.008).

Conclusions -- Surgical navigation significantly improves accuracy and decreases variability in tibial component alignment in canine TKR. Clinical trials would be required to determine whether these improvements in surgical accuracy lead to better clinical outcomes in terms of joint function and a reduction in long-term implant wear.

INTRODUCTION

Until relatively recently, treatment options for end-stage canine stifle disease have been limited to medical management, arthrodesis, or amputation. The presence of bilateral disease often makes these options less feasible due to contralateral stifle pathology. Total knee replacement (TKR) is now an established treatment option for dogs with severe osteoarthritis secondary to multiple primary pathologies [1]. The primary goals of TKR are to relieve pain and to improve stifle joint function. Approximately 350 canine TKR procedures have been performed around the world to date (personal communication, BioMedtrix LLC).

The long-term outcome of TKR depends on careful preparation of the articular surfaces. The accuracy of conventional ("surgeon-guided") operative technique is largely dependent on three factors: experience of the surgeon, quality of instrumentation, and the inherent anatomy of the patient. In humans, it has been suggested that the most common cause of revision TKR is surgical error [2]. An estimated 10% of TKR procedures result in errors in tibial and femoral alignment of >3° even when performed by highly experienced surgeons [2]. Errors in tibial component positioning are associated with an increased risk of implant wear, mechanical loosening and pain [3,4]. In an attempt to improve surgical accuracy, some surgeons have turned to the use of computer-assisted surgical navigation systems that use three-dimensional motion capture and optical tracking technologies to collect real-time data on bone and joint alignment in the operating room.

Surgical navigations systems can be broadly classified into image-based systems and image-free systems. With image-based systems, pre-operative imaging (typically MRI or CT) or intra-operative imaging (fluoroscopy) are used to generate a three-dimensional model of the patient's unique anatomy [5, 6]. With image-free navigation systems, the patient's anatomy is determined through measurements of anatomic landmarks and joint kinematics in three dimensions [7]. For reasons of cost and convenience, image-free navigation systems have become the most common navigation technique and will be the focus of the work that we are presenting.

Image-free systems utilize anatomic mapping of the joint through calculation of algorithms based on specific anatomic reference points [8]. The anatomic reference frames are based around the mechanical axes of the bones that make up the joint. In the case of the knee (or stifle) joint, the positions of the femur and tibia are recorded in real-time through the use of optical marker arrays that are rigidly fixed to the diaphysis of the bone and tracked by a camera. The mechanical axis of the femur is determined by locating the center of the femoral head, by circumduction of the femur and identification of the point in space around which the femur rotates, and the center of the stifle joint, through use of a digitizing stylus to identify anatomic landmarks on the distal femur and proximal tibia. The tibial mechanical axis is defined proximally by the center of the stifle joint (identified as above) and distally as the mid-point between the medial and lateral malleoli. Once these axes have been determined, and the relationship of the marker arrays to these axes has been identified, the surgeon is able to obtain real-time data relating to angulation and position, allowing accurate planning of instrument placement and bone preparation [8, 9].

While the utility of surgical navigation has been confirmed in laboratory and clinical studies on human total knee replacement [10-12], objective data relating to the relationship between component malalignment and implant failure are currently lacking in canine TKR, but it is logical and reasonable to make every effort to optimize the accuracy with which implants are positioned, with an expectation that this will reduce the risk of implant-related complications and extend the working life of the implant. In a recent cadaveric study, we demonstrated that frontal plane malalignment of 3 degrees or more results in significant alterations in the loading of the medial and lateral compartments of the tibial component in dogs [13]. The specific goal of the current study was to build on these earlier data and to explore the feasibility and utility of using computer-assisted surgical navigation in canine TKR. We hypothesized that use of computer-assisted navigation would improve both the precision (reproducibility) and accuracy of tibial component alignment.

MATERIALS & METHODS

Cadaveric Tissue Specimens

Retrospective data on tibial component alignment were collected from a series of 17 cadaveric TKR procedures performed by board-certified surgeons participating in a surgical training workshop. These surgeons had experience in performing total joint replacements but had not performed TKR prior to the training workshop. Tissues for a prospective cadaveric study were then collected from 12 skeletally mature dogs that were euthanized for reasons unrelated to this study. The pelvic limbs were disarticulated at the hip and then radiographed (standard caudocranial and mediolateral stifle series plus a full-length craniocaudal view of the femur) to rule out the presence of pre-existing bone or joint pathology, and to allow for the measurement of limb axes (see later). A 10-cm magnification marker was included in the radiograph to allow for pre-surgical templating and selection of an appropriate implant size.

Radiographic Determination of the Mechanical Axes of the Pelvic Limb

The mechanical axis of the femur was defined as a line connecting the center of the femoral head proximally to the center of the intercondylar notch distally [9]. The mechanical lateral distal femoral angle was defined as the angle formed between the mechanical axis of the femur and the distal femoral joint surface in the frontal plane [9]. The mechanical axis of the tibia was defined as a line connecting the center of the intercondylar eminence proximally to a point mid-way along the distal intermediate tibial ridge (Figure 1A) [14]. The mechanical medial proximal tibial angle (mMPTA) was defined as the angle formed between the mechanical axis of the tibia and the proximal tibial joint surface in the frontal plane (angle MPTA in Figure 1A) [10]. The sagittal axis of the tibia was defined as a line joining the mid-point of the two apices of the two tibial intercondylar eminences proximally and the center of a circle created by the talus distally (Figure 1B) [15]. Finally, tibial slope (also referred to as the mechanical caudal proximal tibial angle, mCPTA, or the tibial plateau angle) was defined as the angle formed between the sagittal axis of the tibia and a line connecting the cranial and caudal margins of the articular surface of the medial tibial plateau (angle CPTA in Figure 1B) [16].

Digitization and Real-time Tracking with the Surgical Navigation System

The procedures used for establishing surgical navigation on the canine stifle joint are illustrated in Figure 2. The 12 cadaveric pelvic limbs were instrumented with retro-reflective optical trackers rigidly attached to Ellis pins implanted into the diaphyses of the femur and tibia (Figure 2A). Anatomic coordinate systems were established for the femur and tibia, similar to the methods we have described previously in navigated human TKR [17]. The three-dimensional positions of these marker arrays were tracked in real time using a custom navigation system comprised of a Polaris Spectra camera (NDI, Waterloo, Ontario, Canada) that was controlled by MATLAB (MathWorks Inc., Natick, MA) and LabVIEW (National Instruments Corporation, Austin, TX) software. According to the manufacturer, the measurement error associated with tracking tools with this system is 0.3 mm root mean square (RMS). The anatomical landmarks for digitization of the femur were: the center of the femoral head; the most proximal extent (roof) of the intercondylar notch (Figure 2B); the medial and lateral epicondyles; and the distal articular surfaces of the medial and lateral femoral condyles. Landmarks for the tibia were: the medial and lateral margins of the edges of the proximal tibial articular surface; the center of the intercondylar eminence; the deepest points within the medial and lateral tibial condyles; and the medial and lateral malleoli distally.

Surgical Procedure – Total Knee Replacement

Following digitization of the anatomic landmarks, the stifle was extended and the extramedullary tibial alignment guide (ETAG) positioned against the tibia as per current clinical guidelines [1]. The ETAG is a telescoping tubular instrument equipped with a cutting block at its proximal end. For the **surgeon-guided procedure**, the ETAG was positioned by eye and then secured to the proximal tibia with pins. The final alignment of the cutting block relative to the mechanical axis (frontal plane) and the tibial axis (sagittal plane) was then recorded with the surgical navigation system. The final slope of the tibial cut is always parallel to that of the top surface of the tibial cutting block, so the orientation of the cutting block provides a surrogate marker for final alignment of the tibial component. A flat, thin-bladed tracking tool (Figure 2E) was placed on the top surface of the tibial cutting block to record its orientation in the frontal and sagittal planes. It was therefore not necessary to resect the tibia, making it possible to "re-use" the tibia for the second procedure (**navigated procedure**), in which real-time output from the navigation system was used to determine the optimal alignment of the ETAG/tibial cutting block. At the end of the second TKR procedure, the tibia was resected and a flat, spatula-like tracker was used to measure the frontal and sagittal plane alignment of the ostectomized surface of the tibia. The stifle joints were then radiographed to allow measurement of tibial component alignment (see earlier description for greater detail).

Radiographic Determination of Tibial Component Alignment

Caudocranial and mediolateral radiographs were made following completion of the TKR procedure in the specimens from the cadaveric workshop and the twelve instrumented cadaveric stifles (see later). Alignment of the tibial component was measured in both the frontal plane and in the sagittal plane. In the frontal plane, varus-valgus angulation of the tibial component was determined by measuring the angle formed between the mechanical axis of the tibia and a line drawn along the ostectomized surface of the tibia (Figure 3A). Sagittal plane alignment was determined by measuring the angle formed between the ostectomized surface of the tibia and the sagittal axis of the tibia (Figure 3B). As per clinical guidelines [1], the optimal orientation of the tibial component was defined as neutral varus-valgus angulation (i.e. 90 degrees relative to the mechanical axis of the tibia) and six degrees of caudal slope (i.e. 84 degrees relative to the sagittal axis of the tibia) [1].

Comparison of Mechanical Axes – Radiography versus Surgical Navigation

Since accurate alignment of TKR components depends upon accurate identification of the mechanical axes of the pelvic limb, it was important to determine whether the computer-assisted tracking system was capable of accurately identifying the mechanical axes of the pelvic limb. Values derived from the computer-assisted system were compared against those derived by direct measurement on the cranio-caudal radiographs.

Statistical Analysis

The relationship between radiographic and navigation-assisted measurements of the mechanical axes of the tibia was determined by linear regression analysis. Absolute errors in cutting block alignment, relative to the gold standards of 0° varus-valgus angulation and 6° caudal slope, were measured by the computer and data from the two approaches (navigated, non-navigated) were compared by both paired t-test (to compare mean values) and Levene's test (to compare variances). Intra-observer variability in the measurement of tibial component alignment was determined by calculating the coefficient of variation for ten repeated measurements performed by a single investigator on one set of radiographs. Inter-observer variability was calculated as the coefficient of variation from twelve sets of radiographs that were reviewed by three independent evaluators. A significance level of $p<0.05$ was used throughout.

RESULTS

Retrospective Analysis of Tibial Component Alignment

In a series of 17 cadaveric TKR procedures, the tibial component was implanted at an average of 90.2° (range 85° to 95°) relative to the mechanical axis in the frontal plane, with 2 cases (12%) falling outside the 3° error threshold (Figure 4A). In the sagittal plane, the tibial component was implanted at an average of 82.4° (range 78° to 86°) relative to the tibial axis, with 4 cases (24%) falling more than three degrees outside the optimal 6° alignment that is recommended clinically [1] (Figure 4B). Inter-observer reproducibility was good, with a coefficient of variation of 0.54% for alignment in the frontal plane and 1.16% in the sagittal plane. Inter-observer variability was also low, with a mean coefficient of variation of 1.14 % (range 0 to 2.21 %) for alignment in the frontal plane and 1.97 % (range 0.70 to 2.52 %) in the sagittal plane.

Use of Navigation to Determine Tibial Mechanical Axes

The mean (±SD) angle formed between the tibial mechanical axis and the proximal tibial joint surface was measured at 91.2°±2.2° by radiography and at 91.6°±3.5° by surgical navigation. There was a statistically significant relationship between radiographic and navigation estimates of the tibial mechanical axis (r^2=0.866, $p<0.001$)(Figure 5).

Use of Navigation to Align the Tibial Cutting Block

Under surgeon-guidance, the tibial cutting block was placed with a mean varus-valgus angulation of 1.24° (range -2.35° to +1.93°) in the frontal plane and a mean sagittal slope angulation of 7.08° (range +2.23° to +10.81°). With computer-assisted navigation, cutting blocks were placed with a mean varus-valgus angulation of 0.41° (range -0.71° to +0.81°) and a mean sagittal slope angulation of 6.46° (range 5.13° to 7.59°). When the mean values from the two techniques were compared using a paired t-test, a statistically significant improvement in alignment was identified for the frontal plane (p=0.007) but not the sagittal plane (p=0.321). The data from the navigated procedures were less scattered than the data from the non-navigated procedures (Figure 6), and this effect was confirmed as being statistically significant by Levene's test for equality of variances for both the frontal plane ($p<0.001$) and the sagittal plane ($p=0.008$).

DISCUSSION

The results from this *ex-vivo* study allow us to draw two important conclusions regarding surgical accuracy in canine TKR. First, alignment errors of 3 degrees or greater were seen in a significant proportion of TKR procedures performed by surgeons performing TKR for the first time. Second, surgical navigation reduced inaccuracy and improved the precision of tibial component positioning in a cadaveric canine TKR model. Taken as a whole, these data support the potential value of integrating surgical navigation into both the training and the clinical practice of canine TKR.

Although it could be argued that the results from a surgical training workshop may not mirror those from surgeons with more experience in TKR, it is the relatively inexperienced TKR surgeon who would likely benefit most from computer-assisted surgical navigation and so we felt that it was reasonable to use this population of surgeons as the sample population for the screening portion of this study. It is highly likely that surgical accuracy increases as surgeons develop more experience with the procedure, but it is also likely that experienced surgeons will take on more challenging cases, making surgical navigation an appealing option, even if only as an objective "back-up" to confirm the verify the accuracy of the procedure.

The second step of this project involved a head-to-head comparison of tibial component positioning in TKR procedures performed without surgical navigation ("surgeon-guided") or with computer-assisted navigation. All of the procedures were performed by the same investigator [redacted] who had been trained in the TKR procedure by the senior author, who has performed >145 canine TKR procedures in vivo. Although the results from this study confirm that a traditional surgical approach (without navigation) generally results in alignment that is within the recommended guidelines, the variability of implant alignment is high. With surgeon-guided block placement, 1 of 12 dogs was aligned outside the 3° threshold. With navigation, none of the 12 tibial components was malaligned in either the frontal or the sagittal plane. Blocks placed using navigation were closer to the ideal alignments in both planes. Navigation also dramatically reduced the variability in both the frontal and sagittal planes, with standard deviations in the navigated group being approximately one-third of that in the hand guided group. This effect may be especially important in cases where the normal anatomy is significantly deviated as a result of intra- or extra-articular pathology or deformity [18].

Results from human TKR have revealed that navigation systems provide more reliable and reproducible mechanical axis alignment, and consistently show fewer outliers and increased accuracy of alignment in navigated groups when compared to traditional methods [19]. Our data from canine TKR support and parallel these findings in humans. Interestingly, in addition to reducing the risk of altered joint loading, navigation has been shown to improve the kinematics of total knee replacements immediately after surgery [20]. It would be of interest to determine whether a similar benefit can be realized in canine TKR. Improvements in joint kinematics will positively impact the patient, both in terms of restoration of joint function (and a faster or more complete return to activities of daily living) and by reducing the risk of implant wear and wear-related complications such as osteolysis [21] and implant loosening [22].

Despite the proven advantages of computer-assisted navigation in human total joint replacement, the technique has yet to be universally adopted by arthroplasty surgeons. Some of the resistance relates to financial concerns over the one-time cost of equipment purchase [23] and the difficulty in securing appropriate reimbursement of these costs within an increasingly constrained healthcare model. The system that we used in this study was custom built and significantly less expensive than a commercial system, with a total cost of approximately $60,000. A second source of concern relates to the risk to the patient and the increase in operating room time needed for tracker placement and joint registration. To date there have been minimal complications with the use of computer-assisted navigation in human TKR [24] and the available data suggest the slight increase in operative time is outweighed by the improvements in surgical precision that result from navigation [25, 26]. The most significant obstacle to the routine use of navigation lies in the general attitude of experienced arthroplasty surgeons who report clinically acceptable results using non-navigated procedures. For these surgeons, the case for using navigation to improve their already excellent results is less clear. However, with ongoing concerns regarding medical malpractice, the potential for documenting the accuracy of the procedure in real-time, in an electronic format that can be audited and objectively assessed after the procedure, is potentially very appealing.

In the context of potential veterinary applications, there are opportunities for using surgical navigation both as a teaching tool and in clinical practice. As a training tool, navigation has the potential to allow surgeons to learn the spatial relationships between hand, instrument and patient within a more controlled setting. Good examples where navigation could be very helpful would include acetabular reaming during total hip replacement, or osteotomy alignment for the correction of angular limb deformity. Over time, one would anticipate that the need for navigation will dissipate as trainees develop greater confidence in their abilities, but navigation should allow surgeons to progress up the learning curve with greater speed and with less risk to the patient, since the chances of a clinically impactful error in implant placement will be reduced.

As a clinical tool, navigation offers potential advantages as a means of enhancing surgical accuracy and decreasing the risk of potentially problematic clinical outliers. It is widely recognized in human total joint replacement that clinical results from surgeons with a low annual total joint caseload are not as good as are those from surgeons with a high caseload [27, 28]. With a much lower overall TKR caseload in dogs, navigation could help to ensure the quality of the procedure is consistent regardless of the interval between cases. Navigation also allows for objective documentation of implant positioning; these data could then be used in prospective studies assessing the relationship between implant alignment, joint function and implant longevity.

Given the caudal slope of the canine knee, as compared with the relatively flat tibial plateau in humans, it is likely that the canine knee is more tolerant of small errors in component angulation in the sagittal plane. This is supported by results from a recent study by Baker et al. in which the authors showed that joint kinematics and medial collateral ligament strains were similar in tibial components implanted at 8 degrees and at the recommended 6 degrees [29]. In contrast, our data on the effects of frontal plane malalignment confirm that stifle loading is sensitive to errors in this plane [13]. Taken as a whole, we conclude that the greatest value of navigation will likely be seen in optimizing frontal plane alignment.

In conclusion, surgical navigation has the potential to reduce the number of malaligned outliers by improving the accuracy and reproducibility of implant alignment. Clinical studies would be required to determine whether the improvements in implant alignment translate into improved clinical outcomes and implant survival in canine TKR. Additionally, it will be important to determine how the accuracy of bone and joint registration is influenced by the presence of osteoarthritic changes such as osteophytosis and joint collapse. Further studies are now planned to address these issues, as well as to evaluate the efficacy of surgical navigation in other veterinary orthopedic procedures, including total hip replacement, total elbow replacement and angular limb correction.

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FIGURE LEGENDS

Figure 1. Mechanical axes and joint angles of the canine tibia in the frontal (A) and sagittal (B) planes. The descriptions of the mechanical axis and the joint lines are based on those from [9] and [10] and are described more completely in the text.

Figure 2. Schematic illustration of the steps involved in surgical navigation for total knee replacement in the dog. The initial step involves implantation of rigid trackers into the femur and tibia (A). The hip is then circumducted to enable identification of the center of the femoral head, and anatomic landmarks on the distal femur (B), proximal tibia and distal tibia (C) are visually identified and marked with a tracked stylus. With the mechanical axes of the femur and tibia identified, the surgeon is able to use real-time outputs from the navigations system to ensure accurate alignment of the tibial cutting block in both frontal and sagittal planes (D). In this study, navigation was also used to document the final alignment of the tibial ostectomies in procedures that were performed without navigation assistance.

Figure 3. Radiographic determination of the accuracy of tibial preparation in the sagittal plane (A) and frontal plane (B) .

Figure 4. Variability in tibial component alignment in the frontal (A) and sagittal (B) planes. Data were collected from 17 cadaveric TKR procedures performed in surgical workshops. Red boxes identify outliers greater than 3 degrees beyond the clinically recommended alignment.

Figure 5. Relationship between tibial mechanical axis measurements derived from surgical navigation and radiography. Regression analysis (r^2=0.866, p<0.001) confirmed the validity of navigation as a means of measuring limb axis alignment.

Figure 6. Effects of surgical navigation of tibial component alignment in the frontal (A) and sagittal (B) planes. Dashed line represents the ± 3 degrees of error that were

considered clinically acceptable. Data represent mean (SD) for N=12 cadaveric samples. Statistically significant differences between navigated and non-navigated groups are denoted by asterisks comparisons of means by paired t-test (* $p<0.05$ or ** $p<0.01$) and by letters for comparisons made using Levene's test for equality of variances (a represents $p<0.05$ and b represents $p<0.01$).