OrthAlign

The Smart Technologies Company

Clinical Efficacy of OrthAlign® Technology

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"Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it."

- H. James Harrington

Introduction

Joint replacement in the Unites States continues to increase in numbers and patient variability. Today there are over a million joint replacements performed each year in the US with expectations that this will exceed 4 million by 2030[1]. In addition, the mean age of patients receiving joint replacement is decreasing, resulting in a more active patient population[2]. With decreasing age of patients and therefore increasing activity loads, implant longevity is and kinematics are stretched to levels beyond the total joint replacement of years past.

Implant testing frequently utilizes optimal loading conditions in order to maximize reproducibility and results. In order to reproduce the optimal loading conditions in vivo, implants must be implanted as similar to the testing conditions to support the patient demographics that are now receiving them. Objective, quantifiable metrics of success in joint replacement are tied to implant placement as measured in the post-operative x-ray.

Research continues to refine the definition of optimal implant placement, and, through that, technologies have emerged to implement these narrow targets and provide valuable, quantitative feedback to surgeons in real-time. Smart technologies enable these repeatable results across the patient population.

Sensor Based Technology

Technological offerings that support this goal have evolved in orthopedics in the same way they have evolved in other technologies that we use in our day to day lives. Computers were once large, costly, slow, and inaccessible to the broad population. Similarly, large console navigation and robotic systems for orthopedic surgery are large, costly, slow and require specialized training and a long learning curve. These tools primarily rely on optical sensors in order to track the bones in space and require space-consuming equipment to operate. Much like computers and mobile phones, a small, concise device, OrthAlign, has emerged to provide value in a minimal footprint package.

"Literally the rocket science mathematics [combined] with the sensors and you've got the means to make a very cost effective very precise and reproducible device for alignment in orthopedic surgery"
-Nick Van der Walt

Sensor based applications in orthopedics allow for technology in the operating room to be small, cost effective, fast, easy to use, and accessible to surgeons across the globe without requiring specialized training. OrthAlign provides sensor based handheld devices for total knee, unicompartmental knee, and total hip arthroplasty. These smart devices utilize multiple sensors, wireless communication, and simple mechanical instruments with an intuitive user interface to provide accurate and clinically valuable measurements in joint arthroplasty, much like a smartphone provides a simplified, hand-held computer for every-day use. The primary disposable unit (navigation unit) houses all the applications needed for total knee, partial knee, and total hip replacement procedures regardless of implant or technique.

Knee Arthroplasty

"What I like is every single x-ray I take post-op looks exactly the same"
-Michael Ast, MD

The KneeAlign® application measures the major angles of all bony resections that serve as the foundation for implant alignment in total knee arthroplasty (TKA). It utilizes patient-specific bony landmarks to generate measurements based on individualized, sensor-derived anatomic planes for optimal alignment. Alignment has been shown to impact implant survivorship, rate of revision, and patient satisfaction[3, 4]. Short-term benefits include preserving the intramedullary canal for decreased blood loss and its potential for decreased infection rates.[14]

Clinical Impact

Accuracy:
The KneeAlign application utilizes sensors that are accurate within half of a degree. The accuracy has been proven through numerous clinical publications from around the globe and the product is utilized at world renowned institutions[5-8].

With standard intramedullary (IM) instrumentation, the accuracy of the femoral resection angles relies on averages without accounting for each patient's specific anatomy. Nam showed that when using a fixed angle to guide femoral resection the overall mechanical alignment is neutral within 2 degrees only 63.1% of the time[10]. The KneeAlign application gathers patient specific inputs to directly identify the femoral mechanical axis from the center of the hip through the knee for each individual patient. This results in improved overall accuracy as demonstrated by data showing alignment within 2 degrees 94.9% of the time with KneeAlign[5] (Figure 1).

Compared to standard instrumentation the KneeAlign application has demonstrated significant improvement in tibial component accuracy in the coronal and sagittal planes. In a randomized controlled trial, the KneeAlign group achieved tibial alignment within 2 degrees of the mechanical axis 95.7% of the time compared to only 68.1% in the standard instrumentation group[6] (Figure 2).

Intramedullary Canal Preservation:
KneeAlign does not require violation of the intramedullary canal to guide femoral mechanical alignment. This may minimize risk of deep vein thrombosis and inflammation associated with pressurization of the canal using standard IM instrumentation[9].

Use of navigation has also been shown to significantly reduce introduction of fatty emboli into the bloodstream as compared to standard instrumentation[9]. This may, in turn, decrease risk of post-operative complications such as deep vein thrombosis. In addition, preservation of the canal may decrease blood loss[14].

Blood Loss:
The effect of mitigating blood loss has significant clinical implications. By potentially reducing the need for transfusion there may be improvements in recovery, decreased length of stay, and lower risk of infection[11, 12]. In addition to these implications for patient outcomes, mitigating need for transfusion carries economic benefits. Nichols used a model to determine that the incremental total hospital cost of transfusion in primary TKA is $2,477[13]. KneeAlign has been proven to statistically significantly decrease blood loss in primary TKA versus conventional instrumentation (Figure 3).[14]

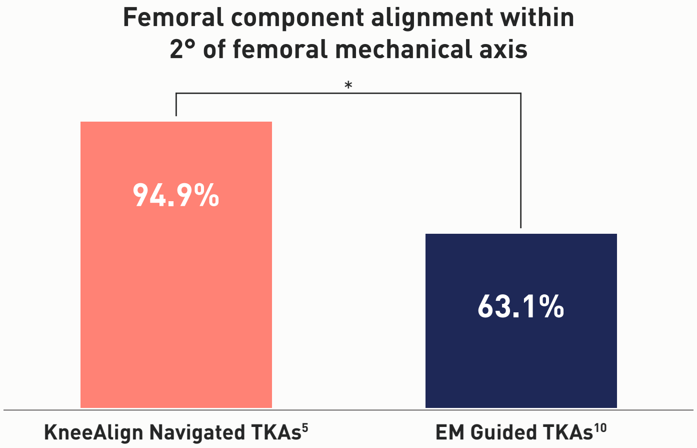

Figure 1: Comparison of femoral component alignment in patients who received a TKA using KneeAlign vs manual instrumentation.

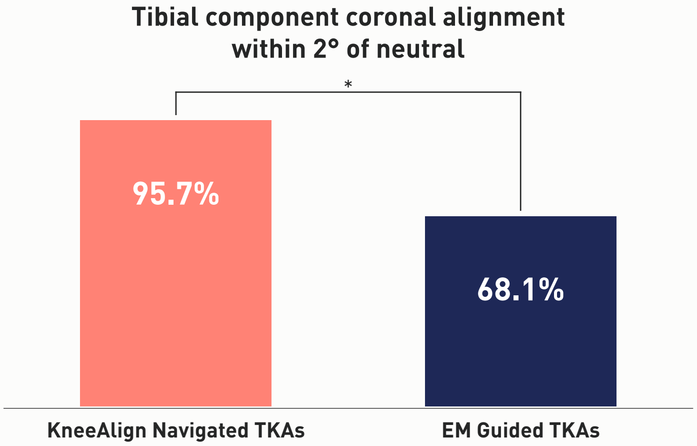

Figure 2: Comparison of tibial component placement in patients who received a TKA using KneeAlign vs manual instrumentation approach (IM rod).

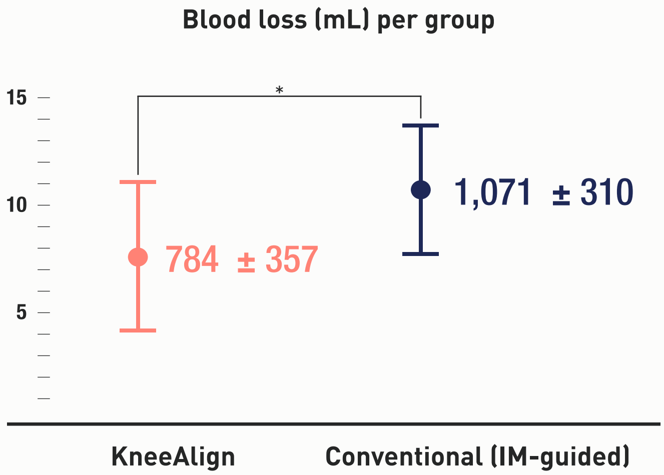

Figure 3: Comparison of blood loss in patients who received a TKA using KneeAlign vs a manually instrumented approach (IM rod).

Pin Sites:
Extra-articular pin sites in long bones have been associated with infection, fracture, and pain[15-17]. KneeAlign instrumentation, uniquely, does not require the use of pins outside of the wound in the diaphysis of the bone.

Partial Knee Arthroplasty:
The UniAlign® application delivers sensor technology to unicompartmental knee arthroplasty (UKA). The most frequent mode of failure for fixed-bearing UKA is aseptic loosening[18] which is most likely to stem from malalignment of the tibial component[19]. By facilitating careful control of the tibial resection on both the coronal and sagittal planes, the use of UniAlign may prevent complications and improve implant survivorship. UniAlign utilizes the same proven technology for the tibial alignment as KneeAlign safely navigating the tibial resection in UKA in both the sagittal and coronal planes (Figure 3, Figure4).

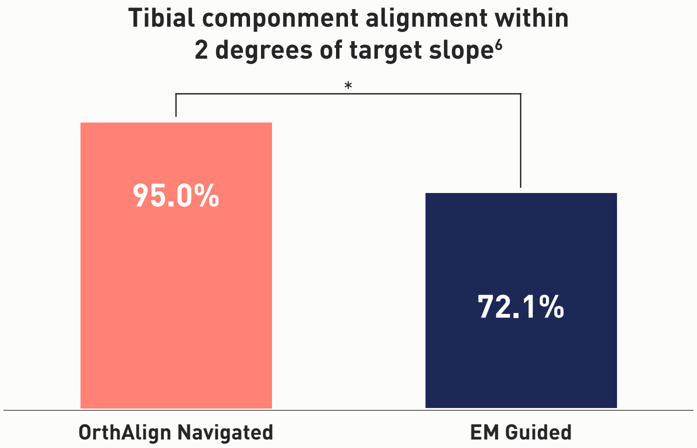

Figure 4: Comparison of tibial component alignment in patients who received an OrthAlign vs manual instrumentation.

Hip Arthroplasty

The HipAlign® application navigates acetabular component angles and measures changes in leg length. The technology adapts accelerometer and gyroscope sensors and a laser module to digitize critical anatomic landmarks and create reference frames. As with the KneeAlign application, the landmarks used and the reference frames created provide valuable clinical information that has been proven to correlate with post-operative images to yield consistent, predictable results. Through the improvement in accuracy these features may improve short- and long-term clinical outcomes such as dislocation and component wear, respectively.

Accuracy:
The HipAlign application yields marked improvements in targeted cup placement. In a randomized controlled trial, the conventional instrumentation group achieved cup placement within the target zone 67% of the time, consistent with previous reports[20, 21]. The HipAlign group achieved target in 93% of cases[20]. Similarly, another clinical data set showed 95% of cups placed within the target zone when using HipAlign in direct anterior approach THA as compared to 73% of cups within the target zone in fluoroscopy-guided direct anterior THA[21, 22] (Figure 5, Figure 6). In addition, the HipAlign application has been proven to match post-operative images within 1.5 degrees for the acetabular angles and within 2mm for changes in leg length with 90% confidence[23].

Cup Placement:
Literature has shown that outliers in cup placement exceed 30% when using conventional techniques[21]. Poor implant placement has been linked to dislocation[24], polyethylene wear[25] and revision[26]. The use of technology has been proven, not only to improve cup placement accuracy, but also, to decrease dislocations[27] and may

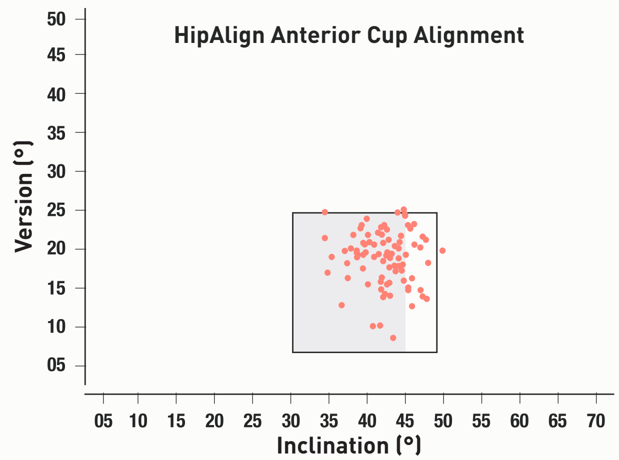

Figure 5: HipAlign-Guided Cup Placement. Black box denotes Lewinnek Safe Zone. Grey shading denotes Callanan safe zone.

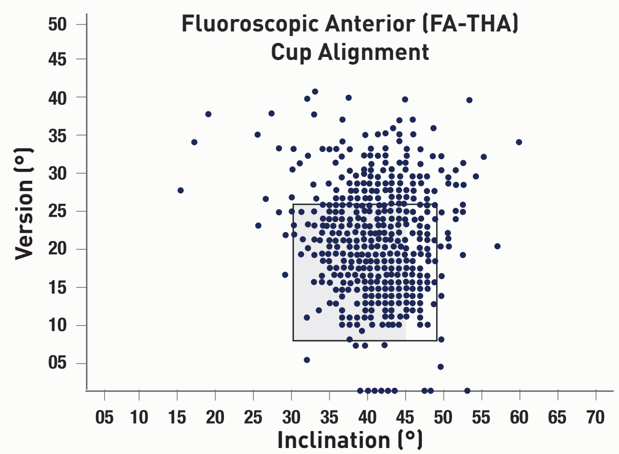

Figure 6: Fluoro-Guided Cup Placement, DA THA (Domb). Black box denotes Lewinnek Safe Zone. Grey shading denotes Callanan safe zone.

impact the clinical and economic burden of the associated unplanned readmission following THA. Bosco reported that the median cost of unplanned readmission within the first 30 days after THA can exceed $11,000[28].

Leg Length Restoration:
In addition to targeted acetabular component placement, successful hip arthroplasty is measured by resultant leg length equality. Leg length inequality has been linked to pain, limping, and can negatively impact patient satisfaction[21,29]. Patients can perceive a leg length discrepancy as small as 6mm[30]. Leg length discrepancy continues to be amongst the more frequent reasons for litigation in orthopedics[29]. The use of technology can quantify this metric to provide valuable intraoperative information and improve patient satisfaction.

Reduction in Fluoroscopy:
The use of fluoroscopy is common in total hip arthroplasty performed through a direct anterior approach. While there are benefits to the additional visualization it provides, it comes with drawbacks. First, it is limited in the added accuracy it can provide. The use of fluoroscopy does not eliminate outliers in component placement[21]. It introduces radiation exposure to the surgeon, patient, and operating room staff. The operative use of fluoroscopy requires the added cost of an additional specialist in the OR which can also impact space and operative time. Proper machine alignment to capture the needed image may add time to the overall procedure.

The use of HipAlign can reduce fluoroscopy time and may reduce operative time overall. Lutes tracked his fluoro time and overall OR time before and after introduction of HipAlign into his workflow. Compared to cases with the use of conventional instruments, fluoro time was reduced by 68% and OR time by over 12 minutes[31].

Efficiency of Sensor Based Technology

Sensor based technology, developed by OrthAlign, delivers simplicity that fits into large scale hospitals as well as smaller institutions. The applications seamlessly integrate into the workflow and operations of the surgeon and the hospital. They are designed to minimize disruption and operative time. Applications range from adding 10 minutes of OR time, on the high side, to saving OR time. This contrasts with complex technological systems that increase OR time 20 or even 30 minutes[32].

OrthAlign applications require no capital cost, maintenance, special storage or system upgrades. Each disposable unit contains the latest hardware, electrical and software updates. This makes the economics of OrthAlign applications simple and transparent, without concern for devices becoming obsolete or requiring servicing.

In addition to updates and maintenance requirements, large console navigation systems and robotic systems were not designed to be pragmatically employed in a hospital setting with multiple surgeons and multiple ORs in simultaneous use unless large capital purchases are made to put a system in each OR. This adds unnecessary burden to scheduling and logistics without ultimately allowing for scale. The OrthAlign Plus unit is the only device with applications for total knee arthroplasty, partial knee arthroplasty, and total hip arthroplasty that can be used in all these orthopedic procedures, simultaneously, with a simple, linear cost model.

Conclusion

Technology in orthopedics has evolved in parallel with technology outside the operating room towards becoming small, affordable, portable, and easy to use. Inertial sensors have traditionally been used in drones and missile-guidance systems and now have been imparted into surgical applications. OrthAlign provides sensor based technology in a single-use, handheld device. The multi-application platform enables use in the most common orthopedic procedures for any implant or surgical technique. Sensor based smart technologies deliver a combination of economics, operational efficiencies and clinical outcomes, finally offering the most attractive platform for building technology into orthopedic operating rooms now and into the future.

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