High-Performance Total Knee Replacement

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Abstract

The concept of a high-performance total knee replacement has gained prominence because of continued technological improvements by implant manufacturers and the changing expectations of an increasingly younger, more active patient population. Improvements in surgical technique, instrumentation, implant design, biomaterials, and implant fixation have occurred in recent years. The literature is inconclusive whether novel approaches can lead to improvements in patient satisfaction rates, address objectively measured parameters, and improve implant survival rates, while doing so in a cost-efficient manner.

Total knee replacement has been shown to be cost effective in improving health-related quality of life. The concept of a high-performance total knee replacement has gained prominence because of continued technological improvements by implant manufacturers and the changing expectations of an increasingly younger, more active patient population. Mont and coworkers described that the features of a high performance joint replacement are four-fold: 1. the joint must “feel” normal, 2. it may allow participation in activities, such as high impact sports, 3. it should allow participation in certain activities, such as squatting, kneeling, and allow for deep knee flexion, and 4. it must be durable for many years. Changing demographics and perceived success of the total knee replacement—improved functional status, pain relief, and low perioperative morbidity and mortality—have expanded demand among all population segments and increased patient expectations for their postoperative function. Simultaneously, patient expectations and activity have increased with the improved success of the operation. The unintended effect of the increased popularity and the broadening indications may affect the excellent long-term survivorship, which has reached almost 90% at 20 years with conventional implants.

Despite the popularity of TKA, the outcomes remain to be clearly defined. In some studies, up to a third of subjects failed to match improvements in functional outcome scores with increases in subjectively measured parameters. Although management of patient expectations with regard to postoperative limitations, the length and the difficulty of the recovery period play a major part in shaping patients’ perception of a successful outcome. The role of the physician in addressing the less conventional criteria for success may be underestimated. Purely subjective outcome scores have been proposed, but validation of those assessment scales remains to be seen. The purpose of this paper is to review recent advances in surgical technique and implant design in an attempt to improve the subjective and objective outcomes of total knee replacement.

Surgical Approach

Advances in the total knee surgical technique, postoperative rehabilitation protocols, and implant design have been proposed to aid patient recovery from surgery as well as improve long-term performance and implant durability. Some of the recently introduced improvements have focused on utilization of minimally invasive surgical approaches (MIS), careful handling of the soft tissues, employing smaller surgical instrumentation, and the use of computer navigation. The distinguishing features of the MIS total knee techniques include a smaller incision, working “through a mobile window,” avoidance of patella eversion, and lack of anterior tibiofemoral joint dislocation. Some investigators have
described incisions as small as 6 cm. The proponents of minimally invasive surgery cite faster recovery time, reduced pain, blood loss, and improved cosmesis as the main advantages of a smaller incision. However, there is a lack of clinical evidence demonstrating these benefits in clinical practice. Advantages that may exist are confined to the early postoperative period, and no long-term improvements in functional outcome scores with any specific technique have been clearly defined.

Despite this lack of demonstrable improvement, attempts at creating a more functional total knee through a more minimally invasive approach have continued. The use of minimally invasive techniques is safe and effective in experienced hands and may have benefits in the early recovery period. However, these approaches may increase the risk of complications for some patients. Soft tissue balancing and component positioning in obese patients or those with a significant soft-tissue or bony pathology is more challenging. In addition, wound complications are more likely to develop in patients who are obese, smoke, or have medical comorbidities such as diabetes or vascular insufficiency. Finally, the learning curve may present a challenge, and the use of MIS techniques has been shown to be an independent risk factor for early failure.

Quadriceps muscle strength exhibits a marked decline after a total knee arthroplasty, and the recovery of postoperative knee function is closely correlated to the recovery of quadriceps muscle strength. Consequently, approaches designed to minimize quadriceps disruption have proliferated. In contrast with the standard parapatellar approach, the mid-vastus, sub-vastus, and the vastus medialis oblique (VMO) snip approaches attempt to preserve the attachment of the VMO while allowing adequate joint exposure. Some investigators have shown that quad-sparing approaches decrease the postoperative pain and lead to an earlier return of quadriceps function and the range of motion. Maintaining the attachment of the VMO may also improve patellar tracking and decrease the need for a lateral release. However, many other studies have been less enthusiastic about the vastus sparing approaches and have demonstrated the transient nature of any functional improvement or results equivocal to the standard parapatellar approach at the expense of decreased surgical exposure. A decreased exposure during a limited approach may lead to increased intraoperative blood loss and surgical errors. Little evidence exists to support one quad-sparing approach over another, and currently, the choice depends on the surgeon’s familiarity and personal preference.

Instrumentation and Technique
Since its introduction in the 1970s, total knee arthroplasty instrumentation has become physically smaller, more accurate, and easier to use. It has given more flexibility to the extension and flexion gap balancing and optimizing of the patellar tracking. Early evidence from knee simulator studies and finite element analysis models suggested that a malalignment of greater than 3° resulted in abnormally high forces on the tibial component, and several technological advancements designed to decrease outliers have been developed. Computer navigation was introduced with the goal of achieving an even more accurate implant position and helping with ligament balancing. With its potential to avoid the use of intramedullary instrumentation, computer navigation may have a secondary benefit of decreasing the rates of pulmonary emboli and minimizing intraoperative blood loss. The challenges facing computer assisted surgery include the added surgical time, with its potential to increase the infection rate, the increased cost and complexity, which may make any improvements less cost-effective, and the learning curve. Recent Norwegian registry data showed...
a slightly increased revision rate at 2 years when computer navigation was used with one type of total knee implant.\(^5^0\)

In recent analyses of the computer navigated and conventional total knee arthroplasty, both techniques led to a statistically similar mechanical alignment, although computer navigation decreased the rate of significant deviation beyond 3° in the coronal plane.\(^5^1,5^2\) However, navigation also increased the duration of surgery and showed no difference with respect to functional outcomes or complication rates. In an 8-year follow-up of 421 total knees, Ritter noted no significant increase in failures in the knees implanted in valgus but noted that the knees in the varus group had an increased rate of revisions and radiographic loosening.\(^5^3\) A recent study by Parratte and colleagues has cast doubt on the deleterious effect of alignment outside of the 3° of normal.\(^5^4\) Over a 15 year period, they noted no difference in survival rates between the total knees implanted within 3° of normal and the knees that were more than 3° in either varus or valgus.

The use of custom cutting blocks, based on preoperative MRI or CT scans, was introduced with the goal of increasing the accuracy of bone cuts as well as, potentially, decreasing the surgical time. The technology aims to optimize bony resection while helping with ligamentous balancing thus leading to closer restoration of patient’s anatomy. Early reports of this technology showed conflicting results regarding operating room efficiency and the potential for restoring the knee mechanical axis, which could be important in determining the long-term implant survivorship.\(^5^5,5^6\)

Although the technology has generated some interest among patients and orthopaedic surgeons, further clinical outcome and cost-effectiveness outcome research is needed prior to more widespread acceptance of the technology.\(^5^7,5^8\)

### Implants

The second major area of focus for achieving a high performance total knee has been implant design. The most frequent reasons for total knee revisions remain infection, instability, polyethylene wear, and component loosening.\(^5^9\) Although infection and instability are patient and surgeon centric issues, implant design and polyethylene wear characteristics can have an important impact on the longevity of the total knee arthroplasty. New manufacturing and processing methods of polyethylene have been developed with the goal of improving wear characteristics to minimize osteolysis and implant loosening.

### Materials

The repetitive axial and shear stresses in the total knee lead to the well described wear patterns on the implant surfaces that are difficult to replicate in the laboratory. Joint simulators have been developed that permit rigorous preclinical evaluation of artificial joints in a controlled environment. They allow independent assessment of multiple variables, such as implant geometry, kinematics, and materials. Although good at predicting wear properties of materials, simulators are less accurate in measuring wear that will occur in a total knee arthroplasty, where in-vivo shear and axial loads acting on the complex geometry of the implants is more complex leading to increased wear or even catastrophic forms of failure, such as polyethylene fracture.

The manufacturing process of polyethylene is complex and proprietary. Variables that are implicated in determining wear characteristics and mechanical properties of the polyethylene include formation of the polyethylene form from resin, sterilization via radiation, or exposure to certain chemicals, as well as packaging. Formation of free radicals during the manufacturing process, in storage, or after implantation may lead to oxidation which in turn may lead to accelerated wear and even catastrophic failure.\(^6^0\)

Ultra-high molecular weight polyethylene (UHMWPE) has been introduced to increase wear resistance. However, the irradiation during the manufacturing process leads to the creation of free radicals, which predispose UHMWPE to oxidation. Post-processing techniques, such as remelting and annealing, have been introduced to reduce the potential for in-vivo oxidation after implantation but are not always effective.\(^6^1,6^2\) While the risk of catastrophic failure due to oxidation may be reduced if the UHMWPE is re-melted or annealed prior to implantation, those methods lead to a reduction of mechanical properties, such as yield, ultimate stress and fatigue propagation resistance, which increases fracture risk.

The supporting evidence for UHMWPE has come from simulator studies where it has been demonstrated to achieve an up to 80% reduction in wear rates.\(^6^3,6^4\) Synovial fluid aspirated from the knees implanted with UHMWPE showed a decreased number of particles compared to the joints implanted with conventional polyethylenes.\(^6^5\) The few available retrieval studies demonstrated early preservation of machine marks on the surface of the poly, perhaps suggestive that any surface changes post-implantation were not a result of material removal.\(^6^6,6^7\) Although highly-cross-linked polyethylene appears to be safe with no evidence for increased early catastrophic failure, more long term studies are needed to support its clinical efficacy.\(^6^6,6^8,6^9\)

Vitamin E infused polyethylene has been introduced as an alternative technique to reduce oxidation and improve polyethylene performance. Vitamin E is an anti-oxidant and reacts with oxygen and oxidized lipids, stabilizing them against further oxidative degradation reactions. In wear simulator studies, vitamin E infused polyethylene demonstrated an improvement in mechanical properties with resisted delamination and bending fatigue while providing appropriately high wear resistance.\(^7^0,7^1\) Presence of vitamin-E has also been shown to decrease the aging process due to oxidation. Given its effect of reducing cross-linking efficiency during the irradiation process, by applying different concentrations of vitamin E to the surface and the core, some investigators have shown the ability to create
an implant that is highly cross-linked on the surface with high wear characteristics while maintaining higher fatigue strength in the deeper layers. Therefore, it may be a better future alternative due to decreased oxidation compared with conventional poly with improved mechanical properties compared with highly cross-linked polyethylene.

Development of hard-on-hard articulations has remained a challenge in total knee replacement, where high contact stresses that require significant mechanical performance have prevented the use of most available biomaterials. Although the design of early all-metal hinged total knees diminished the unconstrained contact stresses, the high failure rates of those implants pointed toward the need to look for better hard-on-hard couples. Therefore, the use of alternative materials has been explored, and the focus has been on the development of low-friction surfaces, such as ceramics. Compared to metal alloys, ceramics have an inherently high resistance to abrasion, better wettability and lubrication. They may also present advantages in patients with metal hypersensitivity. The incidence of metal hypersensitivity has been estimated to be present in up to 15% of the general population.

Newer manufacturing techniques aimed at addressing the problem of brittleness by decreasing the ceramic powder grain size and using combinations of alumina, with its high wear resistance, and zirconia, with its high toughness. Improved ceramic formulations have led to a wide-spread acceptance of all-ceramic total hips, beginning in the 1990s, but experience is limited in TKA. Most experience with ceramic total knees comes from Japan, where it has been used since the early 1980s.

The potential benefits of ceramic femoral components have been supported by knee simulator studies. In the study by Tsukamoto and colleagues, ceramic femur on conventional polyethylene showed a four-fold decrease in wear compared to conventional couplings. Wear of highly-cross-linked polyethylene on a ceramic femur was undetectable, after more than five million cycles. Clinical experience with purely ceramic total knees is sparse. In a study out of Japan, by Koshino and colleagues, 90 all ceramic total knees were followed for 5 years. The investigators noted significant improvements in knee society scores while complications included three cases of bony femoral fracture, but no ceramic fractures.

Oxinium was introduced as an alternative to all-ceramic total knees. It is prepared by subjecting a metallic zirconium alloy to a thermally driven oxidation process. Although the 5 µm to 10 µm thick layer of oxidized zirconia that is created is not as hard as a true ceramic surface, it is thought to be much harder and more scratch resistant than a conventional cobalt chrome alloy. Lower wear rates have been demonstrated in simulator studies, with an up to eight-fold reduction. Ten-year clinical survival rates of the oxinium total knee implants are as high as 96% without complications that could be attributed to the implants, such as wear, osteolysis, aseptic loosening, or component failure. However, concerns over durability of the oxinium layer remain, with several investigators reporting damage observed in retrieved femoral head implants, which can lead to accelerated wear.

**Fixation**

Alternative component fixation has also been explored to achieve better performance. Multiple fixation methods of cementless tibial trays have been introduced, including pegs, screws, stems, as well as extensive porous coating. Although a number of studies showed promising survival rates at 10 years, longer follow-ups revealed increasing failure rates of cementless tibias and especially metal-backed patellar components. Patients experienced failure secondary to screw osteolysis, failure of ingrowth and loosening. In a study by Berger and colleagues, at an 11 year follow-up, 48% of the metal-backed patellar components and 8% of the press-fit tibial trays had to be revised for aseptic loosening.

The success of cementless total knee techniques needs to be examined against the excellent results achieved with the conventional cemented implants, which have been shown to achieve 20 year survivorship rates of 90% and higher by some investigators. Most of the patients in these studies were older and led sedentary lifestyles. Although some studies have supported similar success rates in younger patients, other studies are less enthusiastic. A study by Odland and colleagues that looked at younger patients, who underwent a total knee replacement at an average age of 48, showed a 16% rate of aseptic loosening and osteolysis at 10 years. In those patients, substituting an implant-cement interface for biologic fixation, with its potential to remodel in response to stress, may provide a longer lasting alternative.

Long-term outcome studies with cementless total knee replacements are needed, but the ability of cementless fixation to respond to physiologic stress may be attractive in the younger, active patient. New materials, such as porous tantalum, have shown high in-growth potential in revision scenarios and may be useful in primary cementless total knees. Current designs of porous tantalum for orthopedic implants maintain a high volumetric porosity (70% to 80%), low modulus of elasticity (3 MPa), and high frictional characteristics, making this metal conducive to biologic fixation. Hydroxyapatite coatings have been shown to increase the shear strength of these uncemented implants by up to a factor of three, and newer bearing surfaces may minimize the problem of osteolysis. Applications of newer biomaterials and novel implant designs will continue in the future. The greatest challenge will be to demonstrate the clinical superiority of the newer implants over the highly successful and cheaper conventional alternatives.

**Implant Design**

In addition to changes in bearing materials, implant geometry of total knee implants has continued to evolve in search of a perfect balance between the increased conformity, with its lower contact stresses, and the need to allow the high
degree of freedom present in the normal human knee. For example, mobile-bearing total knee arthroplasty was developed with the goal of achieving a longer-lasting and "more natural" feeling alternative. Knee kinematics may be more closely approximated in the designs that allow independent flexion and rotation. The native tibiofemoral joint is a modified hinge that allows for some rotation when flexed. Conventional "fixed-bearing" designs rely on the rotation in the tibiofemoral joint by decreasing the degree of constraint between the polyethylene and the femoral component. This may increase point stresses and potentially, lead to increased wear of the bearing surfaces. By allowing independent rotation between the tibial tray and the polyethylene, mobile-bearing designs allow more conforming articulations, which simulator studies have shown to decrease point contact stresses throughout the arc of motion.\(^8^8\)

As the increased sizing options make modularity a virtual necessity in conventional implants, tibial tray locking mechanisms remain a complex interface that can generate debris through micromotion of the poly on the metal baseplate. Another advantage of mobile bearing designs is that they eliminate the need for a locking mechanism by introducing a controlled articulation through a much easier-to-manufacture smooth surface between the polyethylene and the tibial tray. Increasing the degrees of freedom from pure rotation, to rotation with anterior-posterior translation, to a completely unconstrained polyethylene insert also has the potential of transferring greater amounts of implant-bone stresses to the soft tissues. Decreased stresses at the implant-bone interface may potentially lead to a longer lasting implant.

Despite these theoretical advantages, establishing superior efficacy of the mobile-bearing implants has proven to be difficult even in biomechanical studies. In a study by Otto and colleagues, who used a biomechanical simulator as well as a finite element model to study the behavior of mobile bearings under physiologic loads of the gait cycle, the investigators confirmed the high-conformity of the implant.\(^9^9\) However, they also noted the high-frictional forces between the polyethylene and the baseplate, which may explain why some of the mobile-bearings fail to rotate in-vivo. In a wear simulator study by Grupp, mobile-bearing designs showed a significantly decreased wear rates per unit area.\(^9^0\) However, because the unit area was also greatly increased in the highly conforming designs, there was no significant decrease in the overall wear rates.

Mobile-bearing designs have many design derivatives. In a recent attempt by the FDA to classify the mobile-bearing designs, 46 different designs were identified, of which five were available in the United States. In addition, less conventional designs, such as meniscal bearing, have been developed. Some investigators have even proposed an option of preserving both the ACL and the PCL, when they are well functioning, to more closely mimic the 4-bar-link biomechanics of the native knee and provide better proprioception.\(^9^1,9^2\)

The variety of the available mobile-bearing implants has made drawing encompassing conclusions difficult. A number of complications specific to these designs have been reported. In their analysis of meniscal-bearing implants, Hartford and colleagues looked at implants of 14 different designs and noted a 4% incidence of polyethylene fracture and 0.8% rate of polyethylene dislocation.\(^9^3\) The risk factors for these complications included a failure to achieve good ligamentous balancing or correct a varus or valgus instability. A recent meta-analysis of 14 studies that compared the mobile-bearing and the conventional implants showed no statistically significant difference with respect to functional knee scores or range of motion.\(^9^4\) In a separate meta-analysis of 19 studies that examined the survivorship of mobile-bearing implants, Carothers and colleagues noted a 15 years survival of 96.4% for the rotating-platform designs and 86.5% for meniscal-bearing implants. They also noted a decreased rate of complications after 1995, perhaps secondary to improved understanding of implants and surgical techniques.\(^9^5\) Data from the Australian National Joint Replacement Registry published in 2009 showed an increased rate of failure with mobile-bearing implants when compared to conventional total knees. Therefore, it is unclear whether the theoretical biomechanical benefits and the potential to reduce wear justify the increased cost of these implants.

The expectations of the increasingly younger patient population have placed an increased emphasis not only on the longevity but also on the actual performance of the implants. Recent design directions aimed at achieving multiple goals from the more objective parameters, such as the range of motion and biomechanics, to the purely subjective determinants, such as the “natural feel” of the native knee.

High-flexion total knee replacement has been introduced with the goal of restoring an increasingly large range of motion that may be needed for specific functional activities. Whereas the typical arc of motion after a total knee replacement rarely exceeds 115°, some cultural and religious activities may require knee flexion of up to 165°.\(^9^6,9^7\) Design changes aimed at increasing the range of motion included smaller posterior femoral condyle radii, altered polyethylene geometry to avoid patellar impingement, and to facilitate better roll-back, as well as alterations of the tibial post to delay its contact with the femoral cam at higher degrees of flexion.

However, these innovations also introduced new specific problems, such as a potential for accelerated wear when the thinner posterior polyethylene or the patella are exposed to high-contact stresses inherent with deep flexion. Decreased articular conformity of the design and a relative collateral ligament laxity, inherent with increased amounts of flexion, could produce flexion instability. Changes in the femoral design often necessitate increased bone resection from the posterior condyles or the trochlea, which become problematic in smaller femora. In some studies, patients who underwent a high-flex total knee replacement and achieved
a higher degree of flexion, especially with weightbearing in that position, had higher rates of complications with aseptic loosening and the need for revision.

In a review of literature by Murphy and colleagues, five of the nine studies showed an increased range of motion with high-flexion designs. However, only two of the studies looked at culturally specific activities, and only one found an increase in the ability to squat. Almost half of those patients could not get up without assistance, and all of the patients reported that they did not squat in their daily activities. There were no differences in the reported functional outcome scores at the longest follow-up of 35 months. In a different meta-analysis by Luo, high-flex total knees offered no improvements in the final range of motion or knee society scores. Several recent randomized controlled studies similarly failed to show any clinical benefit to the high-flexion designs.

Even if increased range of motion is achieved, its potential to affect functional outcomes remains unclear. Miner and colleagues compared a questionnaire-based assessment, the WOMAC score, and the objective measurement of the knee range of motion in their accuracy of predicting the postoperative satisfaction and quality of life improvement. They noted a significant worsening in the WOMAC pain and function scores in patients who achieved less than 95° of flexion. Only the WOMAC scores were predictive of the patient satisfaction and the perceived improvement in the quality of life. Although it may be inferred that a restricted motion may have a negative influence on the outcomes, there is little evidence to support that an exceedingly high range of motion provides a tangible benefit in terms of functional outcome scores. Devers examined whether increasingly high flexion improved patient satisfaction, perception, and function after a conventional total knee replacement. Although increased knee flexion had a significant correlation with achievement of expectations, restoration of a more “normal” knee and functional improvement, overall satisfaction after surgery did not increase. A possible explanation is that, given a high rate of pain and functional improvement after a total knee replacement in a typical patient, the marginal benefit derived from high-flexion was too small to measure, suggesting the difference is not clinically significant. As a result of these findings, some of the recent advances in total knee arthroplasty have focused on reproducing native knee kinematics to achieve a more normal feel in the knee rather than purely examining flexion.

Both the posterior stabilized and cruciate retaining conventional total knees fail to recreate the physiologic rollback, as the femur shows paradoxical anterior subluxation in flexion. Medial pivot total knee design aims to prevent anterior subluxation by increasing the congruency of the medial compartment, which creates a ball-in-a-socket articulation and allows the lateral side to roll back further in a fashion similar to the native knee joint. Fluoroscopic studies have demonstrated that the medial condyle position stays constant with flexion, while the lateral side rolls back in these designs. Patellar tracking and quadriceps function is also optimized by maintaining the quadriceps level arm.

However, similar to other advancements, the medial pivot design is a relatively new procedure and long-term literature supporting its use is lacking. A few clinical series have demonstrated a near 100% survival of the implants at an average of 5 to 7 years and significant improvements in the functional measurements that were equivalent to the results with the conventional implants. However, it is unclear whether the more physiologic knee kinematics translates into a clinically important observable benefit. Pritchett looked at 492 patients who underwent a staged bilateral total knee arthroplasty with five different designs, with each patient receiving two different implants. In addition to the conventional implants, the study included the medial pivot, mobile-bearing, and ACL/PCL preserving total knee designs. Patients in the study preferred the ACL/PCL retaining and the medial pivot implants, although no clear reason for their preference was identified. The investigator postulated it could have been related to the differences in proprioception, the subjective sense of stability, or the sagittal plane kinematics, but further research is needed.

### Conclusion

Introduction and use of expensive new medical devices and implants has been identified as one of the key factors contributing to the rapidly rising medical costs in the United States. The efforts to contain medical expenses will place an increasing emphasis on examining the cost-effectiveness of every new treatment. A recent study by Gioe and colleagues examined whether the premium implants provided added benefit that would justify an increase in cost sometimes exceeding $1,000. In their total knee arthroplasty group, they compared 3,400 conventional total knees to 2,800 premium implants, defined as mobile-bearing, high-flexion, oxidized zirconium, and those using moderately cross-linked polyethylenes. There were no differences in the revision rates at the final follow-up of 8 years. Further research is needed to determine if the premium implants provide benefits at longer follow-up or lead to improvements in functional outcomes.

Although total knee arthroplasty has proven to be one of the most successful surgical procedures, it is likely that patients will expect even more from their joints in the future. The question remains whether novel approaches can lead to improvements in patient satisfaction rates, address objectively measured parameters, and improve implant survival rates while doing so in a cost-efficient manner. Proving a clear benefit to new surgical and rehabilitation techniques and technological advancements will continue to be a challenge, but this evidence should be sought before adoption of changes to this highly successful procedure. Large scale registry data, randomized trials, and cost-effectiveness analyses may assist in this endeavor. Until substantial evidence is available, patients and surgeons will continue to
rely on personal experiences and preferences when making decisions regarding surgical technique, rehabilitation protocols, and implant choice.

**Disclosure Statement**

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