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A total knee replacement is considered medically necessary when there is radiographic evidence of advanced joint disease and BOTH of the following conditions are met:

- persistent pain despite an appropriate course of nonsurgical management (e.g., nonsteroidal anti-inflammatory agents [NSAID's], analgesics, light exercise, assistive device, bracing, viscoelastic supplementation)
- functional limitation resulting in impaired, age-appropriate activities of daily living

A revision of total knee replacement is considered medically necessary when ANY of the following conditions are met:

- recurrent disabling pain, stiffness and functional limitation that has not responded to appropriate nonsurgical management
- fracture or dislocation of the patella
- instability of the components or aseptic loosening
- infection
- periprosthetic fractures

A unicompartamental (i.e., partial) knee arthroplasty is considered medically necessary when ALL of the following conditions are met:

- severe osteoarthritis is limited to a single compartment (i.e., medial or lateral compartment)
- knee examinations demonstrate good alignment and ligamentous stability
- persistent pain despite an appropriate course of nonsurgical management (e.g., NSAIDs, analgesics, light exercise, assistive device, bracing, viscoelastic supplementation)
- functional limitation resulting in impaired, age-appropriate activities of daily living, secondary to the knee

The following are considered experimental, investigational or unproven and thus not medically necessary:

- minimally invasive approaches to knee arthroplasty
- computer assisted knee arthroplasty
- unicondylar interpositional spacer (e.g., UniSpacer®)
- unicompartamental patellofemoral knee arthroplasty

General Background

The knee joint functions as a complex hinge system to allow flexion and extension movement, in addition to rotation and gliding movement. The knee joint is made up of three compartments: the lateral, medial and patellofemoral. Medical conditions such as osteoarthritis, ligament instability and trauma result in symptoms such as knee pain, stiffness of joints, locking of the joint or giving way of the joint. Nonoperative treatment often consists of activity modification, exercise programs, weight loss, knee braces, orthotics, anti-inflammatory medications and injections. Surgical treatment options include knee arthroscopy, osteotomy, partial knee replacement, and total knee replacement (TKR).

Osteotomy is usually preferable in young, heavy or active patients, especially males who do not have significant disease in the opposite compartment. Partial knee replacement (unicompartmental knee arthroplasty) is employed for the treatment of early, nonadvanced stages of osteoarthritis that are confined to a limited area. The unicompartmental implant is designed to replace either the medial or the lateral compartment of the knee. Another alternative proposed by some authors is a metallic tibial hemiarthroplasty, using an implantable prosthetic device such as the UniSpacer[®] (Sulzer Orthopedics, Austin, TX) for the treatment of isolated, medial unicompartmental arthritis. Metallic tibial hemiarthroplasty may be considered for patients for whom osteotomy is contraindicated due to early opposite compartment disease or poor range of motion, as well as for patients considered too young, too heavy or too active for total knee arthroplasty. The UniSpacer does not require any bone resection for implantation and has no bone fixation. Total knee replacement, also referred to as total knee arthroplasty, is performed for severe degeneration of the knee joint resulting from osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, osteonecrosis, and other types of inflammatory arthritis. It is one of the most common orthopedic procedures performed. The TKR procedure consists of resection of the diseased articular surfaces of the knee and resurfacing, with the addition of prosthetic components (e.g., metal or plastic), involving two or three compartments of the knee.

Authors have evaluated the success of standard TKR based on Knee Society scores with review of radiograph parameters, long-term implant performance and low revision scores. Standard surgical approaches to TKR allow for greater visibility and safe mobilization of the tissues. Minimally invasive surgical (MIS) approaches have been proposed for both total knee arthroplasty and unicompartmental arthroplasty, involving two developments: a smaller incision and a new technology approach (Vail, 2004). Evaluation of MIS TKR emphasizes short-term goals, such as shorter hospitalization, less pain, more rapid return of function, and less use of assistive devices (Vail, 2004). As with any new technology, the new surgical approach should be scientifically compared to standard surgical approaches, and reported patient outcomes should be equivalent to or better than those reported with conventional methods. Minimally invasive surgical approaches include smaller incisions, the use of navigational equipment, and other techniques beyond the conventional approach. While less invasive knee surgery seems promising, patient outcomes that are better than or equivalent to previously reported outcomes have not been established. Data comparing long-term outcomes of the minimally invasive approach with the standard approach for TKR are not available in the published literature, nor does the published evidence provide strong conclusions related to improved functional outcomes.

The main outcomes of TKR are the relief of pain and restoration of function. A technology assessment prepared for the Agency for Healthcare Quality and Research (AHQR) (Kane, et al., 2003) reported that both TKR and TKR revision are associated with improved function, with the strongest evidence existing over a follow-up of two years, although the studies that extend 5–10 years show positive results as well. Long-term results have been documented in the literature with 94–98% survivorship of prosthetic implants at 15 years (Meek, et al., 2004).

The existing evidence supports the safety and efficacy of TKR and unicompartmental knee replacement for medial or lateral compartment disease in improving patient outcomes, including the alleviation of pain and improvement of function. Failure rates vary and are often related to malalignment and loosening of the prosthesis. Some patients require revision of the TKR or unicompartmental replacement to correct mechanical and rotational alignment, to alleviate recurrent pain and to improve joint function.

U.S. Food and Drug Administration (FDA)

Artificial joints, such as the knee joint prosthesis, are regulated by the FDA as Class II devices. Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance.

The UniSpacer was determined to be substantially equivalent to previously approved knee prostheses and was granted marketing approval by the FDA via the 501(k) process on January 4, 2001. The UniSpacer is intended for uncemented use in the treatment of moderate degeneration of the medial compartment of the knee (grade III–IV chondromalacia) with no more than minimal degeneration (grade I–II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments. This device is an implantable prosthetic device described as a cobalt, chromium, asymmetric, kidney-shaped device, designed to mimic the shape of the medial tibial condyle.

According to the 510(k) summary, the UniSpacer was developed as an alternative to arthroscopy, high tibial osteotomy and knee arthroplasty for situations where limited degeneration/joint destruction exists. The treatment allows for placement of the metallic spacer into the joint space above the affected medial tibial plateau. The femur articulates against the polished, curved surface of the device. It is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures. The surgical procedure to implant the device takes place in two stages. The posterior horn of the meniscus is debrided and resected arthroscopically. The device is then inserted into the joint space above the affected medial tibial plateau via open surgical implantation. Similar devices that have received more recent FDA 510(k) approval include the Knee Interpositional Spacer (Osteoimplant Technology, Hunt Valley, MD) and the Knee Interpositional Mini-Repair System (Imaging Therapeutics, Inc., San Mateo, CA).

On February 4, 2004, Zimmer, Inc. received 510(k) approval for the Minimally Invasive Solutions™ Osteotomy Guide Instrument, an electrosurgical cutting and coagulation device, intended for use during minimally invasive surgeries. Minimally invasive surgery, however, is a procedure and as such is not regulated by the FDA.

Total Knee Replacement (TKR)

Conventional TKR has been performed through various surgical approaches, including median parapatellar, lateral parapatellar, midvastus and subvastus. The incision most frequently used is the median parapatellar with separation of the rectus femoris from the vastus medialis muscle and eversion of the patella (Laskin, et al., 2004). All standard approaches involve disruption of the quadriceps muscle and/or eversion of the patella. Conventional methods result in an incision that extends 8–10 inches in length directly over the knee, followed by extensive soft tissue dissection and eversion and lateral dislocation of the patella. Patients who elect TKR are typically between ages 60 and 75, although the range has broadened to include more elderly and younger patients.

According to the National Institutes of Health (NIH) Consensus Development Panel on Total Knee Replacement (NIH, 2003), primary TKR is most commonly performed for knee joint failure caused by osteoarthritis (OA); other indications include rheumatoid arthritis (RA), juvenile rheumatoid arthritis, osteonecrosis, and other types of inflammatory arthritis. The aims of TKR are relief of pain and improvement in function. Candidates for elective TKR should have radiographic evidence of joint damage, moderate-to-severe persistent pain not adequately relieved by an extended course of nonsurgical management, and clinically significant functional limitation resulting in diminished quality of life. An extended course of nonsurgical management typically includes nonsteroidal anti-inflammatory agents (NSAIDs), analgesics, light exercise, assistive device, bracing and viscoelastic supplementation. Reported patient outcomes of decreased pain and improved function and mobility associated with traditional replacement have been good (Kane, et al., 2003; Satku, 2003; NIH, 2003). The disadvantages of TKR include sometimes long and painful recovery periods, and the return to activities of daily living can be a challenge for some patients.

Contraindications to TKR include, but are not limited to, recent or recurrent sepsis, ongoing infection, extensor mechanism discontinuity or severe dysfunction, recurvatum deformity secondary to muscular

weakness, and the presence of a painless, well-functioning knee arthrodesis (Crockarell and Guyton, 2003).

Prostheses are generally very durable; however, in some cases failure does occur, requiring a revision of the TKR. When assessing the need for revision TKR, conditions such as disabling pain, stiffness, and functional limitation which are unrelieved by appropriate nonsurgical management and lifestyle changes should all be considered. Evidence of progressive and substantial bone loss alone is considered sufficient reason to consider revision in advance of catastrophic prosthesis failure; furthermore, fracture or dislocation of the patella, instability of the components or aseptic loosening, infection, and periprosthetic fractures are also common reasons for total knee revision (NIH, 2003).

Partial Knee Replacement (PKR)

Medial or Lateral Compartment : Partial knee replacement has been proposed as an alternative to TKR for patients with disease limited to a single compartment (i.e., medial or lateral), with the proposed advantages being less pain, quicker recovery and better long-term results. In comparison to TKR, a partial replacement may provide more physiological function, better range of movement, easier salvage in case of failure, and a quicker recovery (Meek, et al., 2004). Patients with disease limited to a single compartment tend to be younger (< age 55) and therefore may not be considered ideal candidates for TKR, as they generally desire better function and quicker recovery than older patients with more advanced disease. A unicompartmental knee replacement requires a smaller and less invasive incision that does not interrupt the main muscle controlling the knee (American Academy of Orthopaedic Surgeons [AAOS], 2006).

Contraindications for a unicompartmental arthroplasty include but are not limited to inflammatory arthritis, a flexion contracture of five degrees or more, a preoperative arc of motion of less than 90 degrees, angular deformity of more than 15 degrees, significant cartilaginous erosion in the weight-bearing areas of the opposite compartment, anterior cruciate ligament deficiency, and exposed subchondral bone beneath the patella (Crockarell and Guyton, 2003).

Published literature confirms that reported long-term outcomes associated with unicompartmental replacement approach those of primary TKR in selected patients (Dabov and Perez, 2003). Clinical studies have shown that patients treated with unicompartmental knee arthroplasties have more functionality and greater range of motion than patients treated with total knee arthroplasties (Rougraff, et al., 1991; Newman, et al., 1998). Authors have also reported on the survival rate of prostheses, most of which approach at least 10 years (Murray, et al., 1998; Berger, et al., 1999). In addition, it is possible that in later years a patient could wear out the initial knee replacement, thus requiring a second procedure (i.e., revision). Research has shown that a unicompartmental knee implant can be revised more easily than a total knee replacement.

Patellofemoral Compartment: A patellofemoral knee replacement, similar to a unicompartmental replacement, replaces only the worn articular surface underneath the patella and its articulating trochlear surface. Authors have proposed that it is indicated for patients with arthritis limited to the patellofemoral areas who have failed more conservative management. Alternative treatment options for a severely degenerated patellofemoral joint include osteotomy, patellectomy, and for elderly less active patients, TKR. Some authors have reported favorable results; however, isolated patellofemoral replacement is still undergoing investigation. The use of a custom-designed patellofemoral prosthesis has been proposed by some authors, versus off-the-shelf designs, as a method of improving clinical outcomes. Nonetheless, evidence in the published scientific literature does not lead to strong conclusions and remains controversial. There are few well-designed clinical trials evaluating safety and efficacy, and patient selection criteria are not well-defined.

Sisto and Sarin (2006) conducted a retrospective case series evaluating the clinical results of a patellofemoral arthroplasty utilizing a custom-designed prosthesis (i.e., Kinemad) in patients under age 50. Twenty-five patellofemoral arthroplasties were performed in 22 patients with isolated patellofemoral arthritis of the knee, and as noted by the authors on both sides of the articulation. The custom-designed prosthesis is made using computed tomography modeling technology to achieve a custom fit to the patient's femoral anatomy. All patients were evaluated using the Knee Society functional and objective rating scales. A score of > 90 points was considered by the authors to be excellent; a score of 80–90 was

considered a good outcome. The authors reported 18 excellent and seven good results at a mean of 73 months postoperatively. All implants were in reportedly in place and functioning well. The mean Knee Society functional score was 89 points (preoperative score was 49 points), and the mean Knee Society objective score was 91 points (preoperative score was 52 points). The authors reported no infections and no clinical findings of patellar subluxation or dislocation. No progressive radiolucent lines or other radiolucencies measuring > 2 mm in width were found around the implants in any knee. Furthermore, it was reported that the results of their study compared favorably with those of TKR performed in similar, but older groups of patients. The authors concluded that a custom patellofemoral arthroplasty appeared to be safe and effective, although additional follow-up is necessary to assess long-term efficacy. The results of this study are limited by short-term follow-up and a small study population.

Ackroyd and Chir (2005) conducted a prospective study evaluating patients continuously added to a registry/database and reported on 306 patellofemoral arthroplasties performed in 240 patients between 1997 and 2004. Eight-month follow-up was available for 170 knees; two-year follow-up was available for treatment of 124 knees; and five-year follow-up was available for treatment of 33 knees. There was no deterioration in pain or function with follow-up to five years. Sixteen patients had early complications, all of which were resolved satisfactorily. There were no late complications reported. Disease progression of the tibiofemoral joint occurred in 16 knees (i.e., 5%), 11 of which required a revision TKR (i.e., 3.6%). The median Bristol pain score improved from 15 points (out of 40 maximum) to 35 at two years and 38 at five years. The mean range of motion improved at five years from 114° to 120°. The median Melbourne score improved from 10 points (out of 30 maximum) to 26 points at two years, and 27 points at five years. The median Oxford score improved from 19 points (out of 48 maximum) to 38 at two years, and 40 at five years. Persistent anterior knee pain was reported in 14 knees. While this study is encouraging, it is limited by relatively short-term follow-up (i.e., five years) and lack of comparison groups.

Cartier et al. (2005) retrospectively reviewed patients who had patellofemoral arthroplasties between 1975 and 1991. The authors were able to clinically re-evaluate 50 patients. Twenty patients were contacted by telephone, completed a questionnaire, and after sending radiographs were used for survivorship analysis. Thirty-three patients were lost to follow-up, and five patients died. The authors reported that 75% of the prostheses were still functioning at a minimum of six years and an average of 10 years after the implantation. Furthermore, Knee Society scores were 77% excellent, 14% fair, and 9% failures. The Function scores were 72 % excellent, 19% fair, and 9% failures. The patients reported 47 knees as pain-free and 12 knees as moderate or worse pain. The pain was caused by tibiofemoral deterioration, which led to TKR in eight patients. Three cases of lateral patellar pain in flexion led to two iterative lateral releases; one patient had secondary pain because of a high tibial fracture that compromised the result, and the pain was not believed to be related to the arthroplasty. Five cases required minor surgery and essentially consisted of releasing of lateral patellar retinaculum for lateral patellar pain. The results of this study are promising; however, it is limited by poor study design (e.g., no comparison group, self-reported evaluations), small population and high loss to follow-up.

Leadbetter and colleagues (2005) conducted a literature search and evaluated 12 studies published between 1979 and 2005 on the results of patellofemoral arthroplasty. Overall, reoperation was done on 24% of all knees treated. The mean duration of follow-up was 5.7 years. Revision surgery was most often related to extensor malalignment with prosthetic instability, progression of arthritis, prosthetic malpositioning, mechanical prosthetic-related symptoms, and prosthetic type. The overall patient age range was 19 to 90 years. The highest failure rates were in patients with progression of osteoarthritis in other compartments or persistence of congenital or surgically uncorrected malalignment. The authors of this review suggest the age limitation for patellofemoral arthroplasty have not been defined, and recommend extensive evaluation of other compartments preoperatively to identify the isolated patellofemoral treatment group. This publication is limited by the small number of cases reviewed, the small number of patients available for review, and limited data, as some studies had significant loss to follow-up. In addition, none of the studies reviewed consisted of randomized trials.

According to the AAOS clinical guideline on osteoarthritis of the knee, "For isolated patellofemoral arthritis, a patient who is not young or very active may be a candidate for total knee arthroplasty. A patellofemoral arthroplasty may also be considered, but the role for this surgical procedure is not well defined and indications are limited" (AAOS, 2003).

Some authors have proposed patellofemoral arthroplasty for patients with isolated patellofemoral arthritis, although patient selection criteria are not clearly defined in the published scientific literature or textbooks. The reported outcomes vary and are generally short-term to mid-term, extending on average to approximately 5–6 years, and in few publications > 6 years. Progression of osteoarthritis in the remaining compartments, persistent pain, malalignment and instability, as well as component loosening, have been reported in the literature. In addition, results vary according to surgical technique and the prosthetic design. The long-term safety and efficacy of patellofemoral arthroplasty is currently unproven. There is insufficient evidence to support improved patient outcomes from a unicompartmental patellofemoral arthroplasty when compared to TKR.

Minimally Invasive Techniques

MIS approaches to TKR have been investigated with the intention of limiting surgical dissection without compromising the surgical procedure or patient outcomes. The MIS TKR incision is 4–6 inches long (AAOS, 2005). The main difference between a traditional approach and the MIS approach is the method in which the surgeon exposes and gains access to the joint—a minimally invasive approach has a smaller incision and avoids patella eversion and quadriceps muscle splitting. Modifications of the medial parapatellar, subvastus and midvastus approaches applying MIS techniques have been published in the literature (Scuderi, et al., 2004).

Surgical techniques for minimally invasive approaches have been facilitated by the use of smaller instrumentation; nonetheless, choice of prosthetic type is limited. In addition, MIS methods involve the risk of inaccurate implant positioning and possible additional complications, due to a restricted operative field. Incorrect positioning or orientation of implants during TKR, poor soft tissue balancing, and improper alignment of the limb can lead to accelerated wear, loosening and decreased overall performance of the implant (DiGioia, et al., 2004). Methods of improving accurate positioning of knee replacement with computer-guided instruments (i.e., computer navigational systems) have been proposed by some authors, although potential benefits and associated risks have not been well established. Recently, Seon and Song (2006) conducted a prospective randomized trial evaluating navigation assisted less invasive TKR compared to conventional TKR and concluded that the navigation assisted methods had fewer prosthetic alignment outliers. Authors have also reported longer operative times for MIS TKR than for the standard approach (Kolisek, et al., 2007; Tria and Coon, 2003), although not significantly longer (Haas, et al., 2004). Consequently, increased length of surgery may lead to a higher rate of complications (e.g., thromboembolism, infection) in some patients. Additionally, some authors have reported decreased length of hospitalization stays in patients who have undergone MIS TKR (Shankar, 2006), while others have reported minimal differences in length of stay (Kolisek, et al. 2007). In a prospective randomized study (n=80) conducted by Kolisek, et al. (2007) evaluating safety and efficacy of MIS TKR, the authors reported that at 12 weeks follow-up there was no difference in mean Knee Society objective and functional scores and that early radiographic and clinical results were indistinguishable. The authors concluded that for short-term outcomes, there was no demonstrated improvement over a standard approach to TKR. According to Whitehead (2006), “Recent efforts to shorten the incision in total knee arthroplasty have added significant risk, but little benefit.”

Minimally invasive surgical techniques are difficult to evaluate in the scientific literature because of the multiple definitions describing the techniques and lack of reported long-term data. According to the American Association of Hip and Knee Surgeons (AAHKS), less invasive surgery encompasses both small incision techniques and minimally invasive techniques. Less invasive incisions are smaller than conventional incisions. Minimally invasive knee replacement surgery uses not only a smaller incision but also a new exposure technique (AAHKS, 2004). These techniques typically include minimal interruption and dissection of neurovascular tissue, muscles, tendons and ligaments, minimal resection of bone in some cases, and a minimal surgical incision. Most authors suggest that a minimally invasive approach to the knee should not violate the extensor mechanism or the suprapatellar pouch (AAHKS, 2004; Haas, et al., 2004; Tria and Coon, 2003). Patient selection criteria are not well established. Less invasive surgical implants (e.g., unicompartmental knee arthroplasty) use different components and incision methods and should be evaluated as a separate type of less invasive surgery.

Evidence in the published literature reveals promising short-term results, but long-term patient outcomes are not proven for the MIS approach when utilized for TKR or unicompartmental replacement. In a case series conducted by Tria and Coon (2003), the authors reported on 70 patients who had minimally

invasive total knee arthroplasties completed during a nine-month period. The patients had less intraoperative blood loss, shorter hospital stays and increased range of motion when compared to a group of patients who underwent standard arthrotomy technique. The results of this study, however, are short-term, and further studies evaluating long-term outcomes are required. Minimally invasive TKR remains investigational, and long-term function and durability have not been established.

Fisher et al. (2003) conducted a retrospective radiographic analysis of implant position in minimally invasive unicompartmental knee arthroplasty (i.e., 3–4 inch parapatellar arthrotomy without dislocating the patella, n=88), open unicompartmental arthroplasty (i.e., performed through a total knee arthrotomy, n=64) and total knee arthroplasty (n=54). Radiographic analysis included standing bilateral anterior-posterior (AP) and a lateral radiograph with the knee flexed 60 degrees. The authors reported that the TKR group had the least variation and greatest accuracy of implant placement and limb alignment. The postoperative limb alignment was 3.5°, 4.3° and 4.5° of tibiofemoral valgus for groups 1, 2 and 3 respectively. The variance in each was also significantly different with the least variance observed in the total knee group and the most variance observed in the minimally invasive group. There was no difference in AP or lateral position of the femoral implant between groups 1 and 2 (average AP 95.8°), although compared to group 3 (AP 95.2°), there was a significant difference. For lateral position of the femoral component the average for groups 1 and 2 were 86.8° compared to 89.5° for group 3. The difference in tibial implant position was significant for each group, although when comparing AP tibial implant position, the minimally invasive group demonstrated a greater standard deviation of 2.8 compared to the open unicompartmental arthroplasty standard deviation of 2.1 and 1.7 for the TKR group. The authors concluded that, based on their study, unicompartmental arthroplasty does not seem to be as accurate or reproducible as TKR when assessing implant position and postoperative limb alignment. In addition, the use of minimally invasive techniques may further alter the accuracy and reproducibility for unicompartmental arthroplasty.

Muller et al. (2004) compared postoperative functional outcome and accuracy of implant position in 38 cases after unicompartmental knee arthroplasty using a standard open approach to 30 cases with a minimally invasive approach. With the minimally invasive approach, tipping of the patella or incision of the quadriceps femoris tendon was not required. The patients all had primary degenerative osteoarthritis of the medial compartment of the knee. Follow-up was conducted one year after surgery. The authors reported that patients with the minimally invasive approach had significantly better functional outcomes, with average Hospital for Special Surgery scores of 92 compared to 78 for the open group. Although not significant, the minimally invasive group demonstrated better range of motion one year postoperatively (113° vs. 107°). The minimally invasive approach in this group did not have a negative effect on positioning of the prosthesis. The authors concluded that, in their opinion, the minimally invasive approach was the method of choice for treatment of anteromedial osteoarthritis utilizing unicompartmental knee arthroplasty. This study is limited by its retrospective review, small population, short-term outcomes, and lack of randomization.

Laskin et al. (2004) conducted a retrospective cohort review comparing 32 total knee replacements performed through a minimally invasive approach with 26 total knee replacements conducted through a standard medial parapatellar approach. Patients were evaluated immediately post-surgery and at six weeks and three months postoperatively. Estimated total blood loss for the minimally invasive group (713 ml) was greater than for the standard group (573 ml). Patients in the minimally invasive surgery group demonstrated significantly higher passive flexion than the standard group. The change in Knee Score was statistically higher in the minimally invasive surgery group, while the average visual analog pain score and total amount of pain medication were lower. Nonetheless, reported patient outcomes are short-term and do not establish strong conclusions regarding long-term efficacy.

Haas and associates (2004) conducted a controlled cohort study between September 2001 and September 2002 to evaluate the short-term functional results of MIS TKR compared with a traditional TKR using a medial parapatellar exposure. The outcomes of 40 consecutive MIS TKRs were compared to those for a control group of 40 TKRs through a standard medial parapatellar arthrotomy and a standard-length skin incision. Evaluations conducted preoperatively and postoperatively at six weeks, 12 weeks, six months and one year consisted of Knee Society scores, range of motion (ROM), and function scores. Patients in the MIS TKR group achieved motion faster and had greater mean flexion compared to the TKR group. Improved ROM was also seen at one year postoperatively. Total operative time for the MIS

TKR group was longer, although not significantly so. At one year postoperatively, the MIS TKR group had higher knee scores. The authors reported use of the same type of knee prostheses in both groups and did not believe that technique would alter the long-term durability of the implant, although long-term follow-up studies are required. The authors concluded that the MIS TKR approach resulted in a more rapid functional recovery and improved range of motion without compromising positioning of the implant. Haas et al. (2006) reported similar outcomes on a much larger group of patients (n=335, including the first 40 previously reported), who underwent the same MIS TKR technique between 2001 and 2004, with similar results.

Bonutti and colleagues (2004) reported their clinical experiences with minimally invasive surgical approaches to total knee arthroplasty. In one study, the authors evaluated 166 consecutive patients who underwent knee replacement with a minimally invasive approach at two years and four years. The authors used regional anesthesia, an incision of 6–10 cm, minimal splitting of quadriceps and placement of components without patellar eversion. The authors concluded that, in the short-term, the functional outcomes of total knee arthroplasty with a minimally invasive approach were comparable to those with the standard approach.

In 2005, Laskin reported on 100 primary unilateral total knee arthroplasties performed on 100 patients using a mini-midvastus capsular incision. The mean follow-up period was 2.4 years. One patient was lost to follow-up after the one-year visit. The mean basal metabolic index (BMI) of the group was 31.2. The surgical approach could not be used in patients with a BMI > 40 (n=6) or in those with severe fixed valgus deformity (n=2). The length of the skin incision varied from 8 to 15 cm, with an average of 10.5 cm. A continuous passive motion machine was used in the post-anesthesia care unit, with the flexion arc being increased daily. Patients were allowed to bear full weight on the leg beginning the day after surgery using external support for balance. The mean hospital stay was 4.2 days. Range of motion was measured by a member of the physical therapy department at various times throughout the evaluation period. Knee Society Scores at four weeks, three months, one year and two years were 88, 93, 94, and 95, respectively, and the mean function scores were 52, 65, 68, and 73, respectively. Radiographs were taken to determine alignment at one month, one year, and two years after surgery. At two years' follow-up, one patient had tibial components with bone cement lucencies, and one patient had tibial radiolucency. The authors reported there was no malpositioning of implants, and there was no coronal or sagittal imbalance. The implant and polyethylene used in the current study were the same as those used previously for implantation, using a standard median parapatellar incision for which excellent clinical and radiograph results had been obtained. The results of this study suggest that a limited exposure method, avoiding patellar eversion, can be successful and that minimally invasive surgery can allow correct positioning of implants and ligamentous balancing. However, limitations of the study design and short-term follow-up preclude the ability to draw general conclusions.

Dalury and Dennis (2005) conducted a retrospective review of two groups of patients with osteoarthritis who underwent total knee arthroplasty. Group A consisted of 30 patients who had a mini-incision (4–5 inches in length), and Group B consisted of 30 patients who had a standard length incision (8–10 inches). The groups were matched for age, weight, preoperative range of motion, and preoperative radiographic deformity. The midvastus approach was used in a total of 44 patients, and the standard medial parapatellar approach was used in the remaining patients. In patients with shorter than average femurs, and excess fat or muscle tissue, the midvastus approach could not be used. The standard postoperative protocol included continuous passive motion, cryotherapy, early ambulation, and physiotherapy that allowed the patients to progress as tolerated. All patients were discharged to home or a rehab center three days postoperatively. The groups were compared for surgical time, tourniquet time, perioperative complications, perioperative pain, medication, blood loss, radiograph postoperative alignment, range of motion, and Knee Society scores. The 12-week radiographs showed no difference in femoral alignment among the two groups; however, four patients in Group A had tibial component varus malalignment, and three patellae had mild tilting but no subluxation. Group A had longer perioperative tourniquet time and less total surgical time, although the differences were not significant. Both groups had moderate ecchymosis and similar blood loss. Neither group had major complications. The patients in Group A used less pain medication than Group B. Range of motion was slightly greater in Group A three days postoperatively, although not significantly different, and at six and 12-week follow-up, there was no difference, nor were there differences in Knee Society scores. Although encouraging, the study is limited by small patient population, and did reveal a high incidence of tibial component malpositioning.

Malalignment is a leading cause of TKA failure. The authors concluded that, while the minimally invasive approach may provide some early advantages, minimal incisions can impede a surgeon's vision and may influence component alignment and possibly compromise long-term outcome.

Early results of a multicenter, randomized prospective study suggest that minimally invasive total knee arthroplasty may be an acceptable alternative to standard techniques. Authors reported on a trial conducted by six surgeons that included 80 patients who were randomized to a minimally invasive surgery group or a standard surgery group. The published results showed similar functional and objective outcomes for both groups at 12 weeks; both groups had similar pain levels, rehabilitation needs and functional levels (Kolisek, et al., 2007). However, this study was limited by short-term follow-up and did not show any greater benefit of the MIS approach versus a standard approach.

Hamilton and colleagues (2006) reported the results of a retrospective cohort of 221 consecutive patients with medical compartment osteoarthritis of the knee treated with a minimally invasive, medial unicompartmental arthroplasty between 2001 and 2003. The 221 patients were compared to 557 knees that underwent medial unicompartmental arthroplasties between 1984 and 2001 using a standard arthrotomy and routine patellar eversion. The authors reported a total reoperation rate of 11.3% in the MIS group compared to 8.6% in the standard arthrotomy group. The rate of aseptic loosening in the MIS group was reported to be 3.7% compared to standard group of 1.0%. The results suggest the MIS approach did not compare favorably to the standard approach in this report.

The National Institute for Clinical Excellence (NICE) issued a procedural guidance regarding mini-incision surgery for total knee replacement (March, 2005). The Institute concluded that current evidence on the safety and efficacy of mini-incision surgery for total knee replacement does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. Furthermore, they concluded that more evidence is required on the long-term safety and efficacy of the procedure and that clinicians should submit data to the National Joint Registry (NICE, 2005).

Unicondylar Interpositional Spacer (UniSpacer®)

Hallock and Fell (2003) published results of one- and two-year data of 71 UniSpacer implants in 67 patients (four patients had bilateral implants). The mean age and weight of the patients were 54 years and 207 pounds, respectively. After one year, 63 patients (66 knees) continued to have the implant in place. All knees were evaluated using the Knee Society clinical rating system, Lysholm scoring scale, radiographic limb alignment and range of motion. Mean scores after one and two years showed improvement in all measures. Five implants were revised to total knee arthroplasties, and 10 implants were revised to another UniSpacer implant. The authors concluded that early results suggest the UniSpacer is a viable treatment option for osteoarthritis in the younger patient. This study involved small numbers of patients, however, and did not provide long-term outcome data.

Sisto and Mitchell (2005) reported the experience of one surgeon with Unispacer arthroplasty in the treatment of isolated medial compartment arthritis of the knee. From April through November 2002, 37 Unispacer arthroplasties were performed in 34 patients with a median age of 55. A prior arthroscopic meniscectomy had been performed in 12 patients. The mean preoperative Knee Society function score was 60 points (range, 40–80 points) and the mean preoperative Knee Society objective score was 62 points (range, 40–76 points). At a mean follow-up of 26 months, there were no excellent, 10 good, 15 fair and 12 poor results. The mean postoperative total function score was 69 points (range 40–82 points), and the mean Knee Society objective score was 72 points (range, 45–88 points). Six of the 12 poor results were in knees that had dislocation of the UniSpacer. All 12 knees were revised to a total knee arthroplasty. The authors concluded that, based on this experience, they do not recommend UniSpacer arthroplasty for the treatment of degenerative arthritis of the medial compartment of the knee.

There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of the UniSpacer. While the device may provide short-term improvement for osteoarthritis of the medial or lateral knee compartment, long-term durability of the device is not known. There are no available data that compare metallic tibial hemiarthroplasty with the UniSpacer to conservative treatment or traditional surgical approaches of osteotomy, unicompartmental arthroplasty and total knee arthroplasty. In a review of the UniSpacer published in 2003, R.D. Scott concluded that the eventual role of the UniSpacer is

uncertain and that the procedure is technically demanding and sensitive, making its widespread success unlikely.

Professional Societies/Organizations

The American Academy of Orthopaedic Surgeons (AAOS, 2003) guideline on minimally invasive surgery states, “The American Academy of Orthopaedic Surgeons believes that 'Minimally Invasive Surgery' for total joint replacement is a promising, but evolving surgical technique that requires additional scientific evidence to validate its short and long-term safety and effectiveness, in comparison to conventional joint replacement methods.”

Advisory statements regarding minimally invasive and small incision joint replacement surgery by the American Association of Hip and Knee Surgeons (AAHKS, 2004) indicate that same or better long-term outcomes have not been validated with less invasive knee replacement surgery, and there is not a great deal of significant scientific proof to support its use at this time.

Summary

Total knee replacement (TKR) and unicompartmental knee replacement (UKR) for medial or lateral compartment joint disease is supported with sufficient clinical evidence in the published scientific literature as safe and effective in relieving pain and improving joint function. There is insufficient evidence to support safety, efficacy, and improved long-term outcomes with unicompartmental patellofemoral replacement.

Minimally invasive surgical (MIS) TKR seems promising in providing outcomes similar to those of standard TKR. Early evidence suggests that MIS TKR reduces postoperative pain, shortens length of hospital stay and improves functional outcomes; however, patient outcomes were not evaluated long-term, and short-term outcomes were not statistically significant. The published, peer-reviewed scientific literature does not provide strong evidence that the MIS approach to TKR provides patient outcomes that are comparable to a standard approach. Using current standard TKR techniques, 90–95% of knee replacements should last 15 years or longer (American Academy of Orthopaedic Surgeons [AAOS], 2005). Long-term function and durability have not been proven with the minimally invasive technique. To date, only one unpublished multicenter, randomized clinical study comparing MIS to TKR has been identified. Further well-designed clinical studies are required to document long-term effectiveness, durability and improvement in functional outcomes.

Metallic tibial hemiarthroplasty with the UniSpacer and other similar devices has been proposed as an alternative to the traditional surgical techniques of osteotomy, unicompartmental arthroplasty and total knee arthroplasty in the treatment of unicompartmental arthritis of the knee. Published evidence is limited, and consists of small case series with limited follow-up and mixed results. The long-term safety and efficacy of unicondylar interpositional spacers have not been established in the published medical literature.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

When medically necessary:

CPT®* Codes	Description
27440	Arthroplasty, knee, tibial plateau;
27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment

27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; one component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component

HCCPS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
136.9	Unspecified infectious and parasitic diseases
711.86	Arthropathy associated with other infectious and parasitic diseases, lower leg
715.16	Primary localized osteoarthritis, lower leg
715.26	Secondary localized osteoarthritis, lower leg
715.36	Localized osteoarthritis not specified whether primary or secondary, lower leg
717.6	Loose body in knee
718.86	Other joint derangement, not elsewhere classified, lower leg
719.46	Pain in joint, lower leg
719.56	Stiffness of joint, not elsewhere classified, lower leg
719.96	Unspecified disorder of lower leg joint
822.0	Closed fracture of patella
822.1	Open fracture of patella
836.3	Closed dislocation of patella
836.4	Open dislocation of patella
V43.65	Knee joint replacement by other means

Experimental/Investigational/Unproven/Not medically necessary:

CPT* Codes	Description
27437	Arthroplasty, patella; without prosthesis
27438	Arthroplasty, patella; with prosthesis
27599 [†]	Unlisted procedure, femur or knee
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)
0056T	Computer assisted musculoskeletal surgical navigational orthopedic procedure, image-less (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

[†] Experimental /investigational or unproven and not medically necessary when used to report either unicondylar interpositional spacer (UniSpacer) or a minimally invasive knee arthroplasty surgical approach.

*Current Procedural Terminology (CPT®) © 2006 American Medical Association: Chicago, IL.

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