LCS MULTICENTER WORLDWIDE OUTCOME STUDY

James B. Stiehl, MD

Karl Hamelynck,MD

Paul Voorhorst, MS

INTRODUCTION:

Mobile bearings were originally introduced with the Oxford knee in 1977 which sought to improve articular congruity for improved wear characteristics using a spherical, congruous articulation while diminishing implant constraint with a floating surface.[1] The Low Contact Stress (L.C.S.) knee prosthesis (Depuy, Warsaw), the subject of this outcome study was a mobile bearing design with modifications of the tibial component to allow for posterior cruciate retention (meniscal bearing) or sacrifice (rotating platform). From the outset, it was recognized that a long term experience would be needed to prove the experiment that mobile bearings would solve the issues of fixation and wear through a favorable, high area of contact, wear surface and nonconstrained moveable bearings.[2]

An interesting point of comparison with other fixed bearing prosthetic designs is the fact that over the years, the LCS components have remained identical in geometry from the outset of original implantation in 1977. In contrast, most implant systems have undergone substantial design changes over a period of time, thus adding complexity to any conclusions about potential long term durability. With keen interest of current prosthetic designers in the mobile bearing concept, it is important to evaluate these implants over the long term to determine which factors may predispose to late clinical failure.

This chapter will present the existing knowledge on the clinical efficacy of the LCS total knee system. We will evaluate peer reviewed publications regarding the LCS prosthesis analyzing the long term outcome and clinical performance of the femorotibial articulation, patellar resurfacing, and various issues of surgical technique such as cruciate retention or sacrifice, tibial axis alignment method of bone resection, cement versus cementless, and the lateral approach in valgus deformed knees. These results will be compared with outcome studies of total knee arthroplasty in general. We will then present the results of a multicenter outcome study evaluating the survivorship results from surgeons around the world who have extensive experience with the LCS knee.

LCS CLINICAL EXPERIENCE (Literature Review):

Buechel and Pappas presented their 10 year experience with the LCS knee replacement of the first 357 total knee arthroplasties in 1989.[3] There were 72 bicruciate retaining meniscal bearing implants, 49 posterior cruciate retaining meniscal bearing implants, and 137 posterior cruciate sacrificing rotating platform implants, with 80 revision arthroplasties. Of the entire group, there were 231 excellent results and 87 good results with 89% of the total in these categories and the remaining in fair or poor categories. In regards to complications specific to mobile bearings, there were 7 rotating platform dislocations(3.2%) and 1 traumatic meniscal bearing dislocation(0.7%). Most of the revision arthroplasties were rerevision of difficult revision cases where there was flexion instability. Factors predisposing to mobile bearing complications such as dislocation were stated to be malrotation of the tibial component allowing a meniscal bearing to sublux, late rupture of the posterior cruciate ligament, flexion/extension gap instability, and traumatic twisting of the knee joint. Three tibial components loosened (2.0%) in very heavy patients where the component poorly covered the proximal tibia. There were no femoral implant loosenings.

Buechel, et.al. reported their 11 year experience with the LCS metal-backed, rotating-bearing patellar prosthesis in 515 total knees of which 331 had greater than 24 month followup.[4] The overall postoperative fracture rate was 0.58% with avacular necosis seen in 0.38%. There was one patellar dislocation of the entire group and no polyethylene dissociations, no polyethylene wear through and no implant loosenings. It was postulated the deep femoral groove engagement prevented dislocation and allowed high contact, even with subluxation.

Buechel, et.al. studied 373 LCS total knee replacements of their initial series surviving a minimum of 10 years.[5] Of this group, 97.9% had good or excellent with the posterior cruciate retaining meniscal bearing implant, 100% with the cemented rotating platform, and 97.9% with the cementless rotating platform. Meniscal bearing dislocation occurred in 2.5% while 5% required meniscal bearing exchange for wear at an average of 10.1 years. Rotating bearing dislocation was seen in 1.2% and there were three rotating platforms revised for wear of the overall group. Kaplan-Meier survivorship for noninfected LCS total knee replacements and mechanical loosening for any reason was 83% at 16 years for the cementless meniscal bearing group, 97.7% for the cemented rotating platform group, and 98.3% at 18 years for the cementless rotating platform group.

Stiehl, et.al. reported the results of the American FDA clinical trial in 147 meniscal bearing and 44 rotating platform total knees done with a cementless technique at an average of 68 months followup.[6] Pain was absent in 94% of meniscal bearing and 93.2% of the rotating platform knees. Range of motion averaged 120º for the meniscal bearing and 108º for the rotating platform knees ($p<.001$). The overall New Jersey Orthopaedic Score was 93.2 for the meniscal bearing knees and 87.6 for the rotating platform knees ($p<.001$). The overall survivorship was 98.1% at 7 years. The overall meniscal bearing complication rate was 0.6% with one fracture and one extrusion. No rotating platform problems bearing spinouts were noted. The patellar complication rate was 1%.

Jordan, et.al. evaluated 473 cementless cruciate retaining meniscal bearing LCS total knees with 2-10 year followup (average 5 years).[7] Mechanical failure occurred in 3.6% with meniscal bearing fracture and dislocation in 2.5%. In 1%, there was tibial subluxation resulting from ligamentous instability. Kaplan-Meier survivorship for mechanical revision for any reason was 94.6% at 8 years.

Sorrels reported the results of 525 cementless rotating platform total knees with up to 13 years followup.[8] The revision rate of this entire group was 5%, and tibial component exchange rate for polyethylene wear or instability was 2%. The survivorship for mechanical component failure was 92.9%(95% CI: 83-100%) at 13 years. Sorrels, et.al. reported a subgroup of this experience with 117 patients younger than 65 years (average 56 years). With average followup of 8.5 years, the average knee score was 91 points and pain score was 27 (with a possible 30). The survivorship with revision for any reason was 88% at 14 years. The revision rate was 7% with four malpositioned implants, one infection, and one case of osteolysis. Bearing dislocation or "spin out" occurred in one case at three weeks following surgery.

Callaghan, et. al. studied 114 cemented LCS rotating platform total knees with 9-12 year followup.[9] The average Knee Society clinical and functional score was 90 and 75 at final followup. The average active range of motion was 102º at final followup. In this series, there were no cases of periprosthetic osteolysis, implant dislocation, or evidence of implant loosening and none of the patients available for followup have been revised.

Stiehl and Voorhorst evaluated factors affecting range of motion with the LCS total knee evaluating the posterior cruciate retaining or sacrificing technique in 782 total knees.[10] Postoperative motion averaged 115º for the meniscal bearing and 104º for the rotating platform ($p<.05$) but the preoperative range was significantly lower for the rotating platform. The greatest gains in motion occurred in patients with less than 90º of preoperative motion and improvement in motion was greater in patients without prior surgery.

Keblish, et.al. compared resurfaced LCS total knees versus non-resurfaced LCS total knees, in 52 patients with bilateral total knee arthroplasties with an average followup of 5.24 years.[11] Comparing the group overall, there was no significant difference with subjective preference, performance on stairs, or the incidence of anterior knee pain. However, they recommended nonresurfacing in cases with a small patella under 19 millimeters thickness or the younger active patient and resurfacing with the very large patella and in the workmen's compensation case.

Keblish, et.al. reviewed their experience with the lateral parapatellar approach for the valgus deformed total knee arthroplasty in 53 patients who had undergone an LCS total knee arthroplasty.[12] The results were good/excellent in 94% of cases, and there were no failures from patellar maltracking or implant instability. They stated the a lateral release which is need in most of these cases is a part of the approach allowing the medial blood supply to be preserved. More recently, a coronal z-plasty has been recommended where the lateral retinacular dissection is more lateral in the superficial and then dissects medially through the synovium and fat pad allowing for a significant lateral based soft tissue mass that allows for a water tight lateral closure.

LCS WORLDWIDE SURVIVORSHIP ANALYSIS:

Materials and Methods:

This study included the results of ( ) surgeons from around the world with extensive experience with the LCS. The surgical technique of the LCS is standardized with a tibial cut first method utilizing instrumentation described in other chapters. Without exception, all surgeons included here utilized the recommended method. Inclusion criteria were all primary total knee arthroplasties performed before January 1, 1997 with a minimum of 5 year follow-up. Exclusion criteria were unicondylar knee replacements, revision total knee arthroplasties, and the use of all polyethylene tibial components, a recent addition to the LCS system.

Data collection included those parameters required for the survivorship anaylsis including the dates of the operative procedure and status at last follow-up with death or revision as drop out criteria. Demographic data included age, sex, diagnosis, involved extremity, and history of previous surgery. The type of device utilized was noted whether meniscal bearing or rotating platform, and fixation which was either cementless or cemented. Pain, walking, or functional outcome questions were not recorded as these are not recorded in a standardized method. Range of motion, however, was recorded as this is considered to be quantifiable and routinely performed in most centers.

Statistical analysis focused on survivorship using life table methods. Dorey and Amstutz suggested that survival estimates be reported as only when the effective sample size is greater than 20 cases and that guideline is followed in this chapter. Relationship of patient's age, diagnoses, previous knee surgeries, device configuration, cement status, and range of motion on survival were assessed using Cox proportional hazard methodologies.

Results:

There were 4743 TKR's performed between February , 1981, and January , 1997. The averaged followup was 5.7 years (Range: 5 to 18 years). There were 1437 males, and 3306 females. There were 324 bicruciate retaining implants; 2165 posterior cruciate retaining implants and 2254 rotating platform implants inserted. By diagnosis, 77.3% were osteoarthritic, 19% rheumatoid, 2.6% post traumatic, and 1.1% other. The overall average age at surgery was 68 years. The mean age for the posterior cruciate retaining and rotating platform patients was 68 while that for bicruciate retaining was 62 years. By diagnosis, the mean age was 69 for osteoarthritics, 64 for the other group, and 62 for post traumatic and rheumatoid patients. The knee was right sided in 52.2% and 47.8% left.

Overall, 69% of all knees had cementless fixation while 31% had at least one component, either femur or tibia fixed with cement. Similiarly, the patella was fixed cementless in 77% of cases. By diagnosis, for osteoarthritics, 78% of posterior cruciate retaining knees were cementless while 61% of rotating platform. In the rheumatoid arthritis group, 88% of the bicruciate retaining implants were cementless. Similiarly, 95% of bicruciate retaining patellar implants were inserted cementless. By implant type, 86% of patella were cementless with bicruciate retaining; 74% posterior cruciate retaining; and 80% rotating platform. The overall range of motion at last followup examination was 110° and was similar for each of the implant types. For the "other" group, the final range of motion was 118° for the rheumatoid group, and 98° for the rotating platform group.

With failure defined as revision for any reason, the survivorship was 79% (95% C.I.: 74% to 84%) at 16 years followup. This included a total of 259 (5.4%) of the entire cohort of patients. The survivorship for aseptic loosening was 95% (C.I.: 91%-98%) The overall survivorship for osteoarthritic patients was 80% at 15 years while that for rheumatoid patients was 85%. By implant type, the 14 year survivorship for bicruciate retaining implants was 79%; posterior cruciate retaining implants was 82%; and rotating platform was 87%. When we look at the survivorship rates at 10 years followup, the comparison is 89% for bicruciate retaining, 91% for the posterior cruciate retaining, and 94% for the rotating platform implants. The overall 14 year survivorship for cementless fixation was 83% and cemented fixation, 84%. The survivorship of knees who had patellar resurfacing when considering all causes of failure was 80% at 14 years, while in the unresurfaced patellar group, survivorship was 91% at 13 years. The survivorship of the patella implants for only revision of patella related complications was 98% at 15 years.

The most common cause of revision was bearing related issues including chronic instability, bearing subluxation, bearing dislocation, or bearing failure in 1.3% of all patients. This was followed by implant loosening in 1.1% of cases and wear related issues in 0.8% of cases. Chronic pain and revision for undetermined causes was noted in 0.7% of cases and sepsis was seen in 0.5% overall. Finally, patella related causes of failure was noted in 0.5% of cases.

DISCUSSION:

Total knee arthroplasties with well designed fixed-bearing prostheses have provided long-term fixation with prosthetic survival rates of 95 to 97 percent at ten to fifteen years.[9] Recent studies have failed to show substantial differences of variables such as cemented or cementless fixation; posterior cruciate retention, substitution or sacrifice; or specific prosthetic design issues such as flat on flat condylar geometry versus a more dished fixed bearing design, or the type of posterior stabilizer used in a posterior substituting design. Robertsonn, et.al. have reported the most recent update of the Swedish Knee Arthroplasty Register in 1999 indicating that the overall revision rate for total knee arthroplasty is about 1% per year.[13] From that study, it was difficult to isolate the performance of particular tricompartmental fixed bearing total knees as being superior or inferior due to the divergence of confidence intervals. Patellofemoral failures have been exaggerated in prior studies due to poorly designed metal backed components, patellar complications such as fracture or subluxation, and more subtle problems such as patellar "clunk". These reports have indicated an incidence of problems in 4 to 21% of cases.[14] Polyethylene wear related osteolysis is another failure mechanism causing the need for revision with certain problematic designs noted from 16 to 30% in certain series.[15,16]

How then can we define a prosthetic design that performs better than average and has a greater expectation of longevity and durability. In the first place, the implant must perform at least as well as the “gold standard” in terms of mechanical loosening, osteolysis, overall revision rate, and the absence of glaring issues such as patellar clunk or polyethylene failure. There must adequate experience with a specific prosthetic design over an extended period of time. Two logical criticisms can be made of recent retrospective reports. The implants of a long-term follow-up series are commonly modified during the period of study or are no longer in vogue. Secondly, a specific problem is identified and then data analysis segregates out that data subset from the overall conclusions of the experience. The suggested implication is that the newer improved version of an implant design is better than original due to the evolutionary changes. The clinical performance of an implant is then compared by certain favorable aspects such as mechanical loosening or absence of the need for lateral release. These conclusions may be true for the most part but realistic conclusions regarding overall outcome are called for. For example if the revision rate for a particular total knee implant is 10% due to a poor patellar design and resulting osteolysis, the statement of favorable performance from a low mechanical femorotibial loosening rate and a survivorship of 98% is disingenuous. A better approach would be to compare the overall revision rate or survivorship for any reason.

The LCS total knee experience is unique in several regards. Most importantly, this implant has remained successful though unmodified in nearly 25 years of continuous use. There have been some minor changes such as altering the meniscal bearing polyethylene design when it was shown that minor subluxation could cause edge fracture of the implant. The basic implant geometry continues to be considered satisfactory and evolutionary from a design standpoint. Finally, the surgical technique of the tibial axis alignment method with the tibia cut first has continued to remain the standard method of implant insertion, though several instrument improvements have been made over the years.

Outcome studies of the designer have the longest clinical followup and continue to show successful performance. It would be pointed out however, that the incidence of bearing failure and fracture with the meniscal bearings has proven significantly greater than that of the rotating platform after ten years though the overall revision rate continues to be about 1% per year. Buechel, et.al. noted bearing dislocation in 2.5% of meniscal bearings while only of 1.2% of rotating platforms dislocated.[5] This was unexpected, as the meniscal bearing was projected to have greater potential for long term performance while the rotating platform was reserved for more complex and difficult cases. The contemporary view is that the rotating platform will show the greatest long term durability though some surgeons remain enthralled with the better clinical function of meniscal bearing implants. All studies compared have shown greater range of motion with the meniscal bearings and posterior cruciate retention compared to the rotating platform with posterior cruciate sacrifice.

Non-designer studies have shown similar long-term results with survivorship, revision rates, and bearing failures. It is interesting to note that the long term studies quoted in this report include primarily the initial experience of the original surgeon study group. All surgeons including Buechel, Sorrels, Keblish, and Jordan participated in the FDA Investigational Device Exemption study initiated in 1984. Sorrels has pointed out that nearly 50% of the mechanical failures in his study were related to early surgeon error due to prosthesis malalignment and ligament imbalance, mistakes that could be avoided with improved surgical technique and the availability of more implant sizes.

The current worldwide survivorship study has provided some interesting data that we believe confirm our overall opinion of the clinical durability of the LCS system. As we had an overall revision rate of 5.4% at average followup of 5.7 years, this would easily fall below the rough 1% per year revision rate of that large experience. The bearing failure rate fell under 2% of the overall group, which is typical of all other reports with the LCS. Finally, while we have seen evidence of long term polyethylene wear, the occurrence of clinically significant osteolysis is virtually nonexistent in this study.

When looking at the various subgroups of this study, there was a slight advantage of cemented fixation over cementless fixation at the longest followup. Over 10 years, the rotating platform was clearly better than the posterior cruciate retaining or the bicruciate retaining implants. The results of patellar resurfacing were extremely favorable with an overall complication rate of 0.5% and a 15 year survivorship of 98.5%. We attribute this to a variety of factors including the favorable anatomical shape of the femoral component with deepened intercondylar sulcus, the tibia cut first technique which optimizes femoral component external rotation, and the highly conforming mobile patellar implant that optimizes both wear issues and function. Other issues will be further discussed below.

We believe the results of this study are unique for several reasons. In the first place, this study was not performed predominantly by a small trial of surgeons from university settings but more likely in community settings by high volume practicing orthopaedists. From our knowledge, neither the technique nor the implant has changed in any major way during the entire 18 year study. By including failure for any reason, we were not segregating our data to focus on some particular strength of the system at the expense of the overall experience.

Perhaps the most outstanding clinical performance of the LCS prosthesis has been the paucity of patellofemoral complications and satisfactory outcome with patella nonresurfacing. From all LCS clinical series noted to date including the current worldwide outcome study, the overall patellar resurfacing complication rate is about 1% despite the longterm use of a metal backed patellar component. The LCS patella is unique in several aspects, allowing high conformity for improved wear yet allowing near anatomical patellar kinematics as shown by recent kinematic fluoroscopy studies.[17] Patellar component loosening is virtually nonexistent and this may be attributed to the uncontrained mobility allowed by the implant as well as the physiological positioning allowed by the deepend intercondylar groove of the femoral component. The clinical experience with the unresurfaced patella has been equal to that of resurfacing and would be the recommended technique of many European surgeons.

One of the reasons cited for improved mobile bearing performance has been improved polyethylene wear related to the high conformity and low surface contact stresses of the articulation. Long term clinical follow-ups certainly support this design objective as cases of overt osteolysis are virtually nonexistent. Collier evaluated the one case identified by Sorrels, et.al. finding substantial polyethylene inclusions and oxidation in that particular implant. Collier has also stated that retrieval analysis of a large number of LCS implants have revealed few of the findings typical of fixed bearing retrievals such as pitting and delamination wear. This was noted despite the prevalence of gamma in air sterilzation in most of these retrievals, which is known to cause surface oxidation and much higher wear rates.[18]

The tibial axis alignment method of implant insertion with tibial cut first technique continues to be the method of choice by most LCS users. Stiehl, et.al. has shown that the transepicondylar axis has a perpendicular relationship anatomically to the long axis of the tibial shaft.[19] As the transepicondylar axis closely approximates and parallels the axis of knee flexion, the tibial axis alignment method makes the initial cut perpendicular to the shaft of the tibia and thusly parallel to the transepicondylar axis. LCS surgeons have found that bearing dislocation is most likely related to flexion gap instability or imbalance.[20] Thusly, the surgical technique focuses on perfect flexion gap balance, which is achieved as the first step in femoral bone preparation. Overall ligament balancing must be done early in the case, certainly before completing the posterior and distal femoral cuts. Surgeons have found that some mild ligamentous laxity in extension may be tolerated but the avoidance of flexion gap instability is inviolate. Once the flexion gap is created, it cannot be altered by subsequent ligament release.

Keblish developed the lateral approach to the valgus deformed knee as early lateral ligament balancing is facilitated by a primary direct approach.[12] This is important as most tight structures requiring release in the valgus knee are on the lateral side. Furthermore, a lateral release is required in virtually all valgus knees due to the tight lateral retinaculum which must be released when femorotibial malalignment is corrected. The lateral approach is quite useful in cases of chronic patellar dislocation as this also will require patellar realignment and extensive lateral release with medial ligament reefing. Recent modifications to the lateral approach are the coronal z-plasty described by Keblish(personal communication) and the lateral tibial tubercle osteotomy popularized by Muller. The coronal z-plasty simplifies the initial dissection and facilitates water tight closure at the end of the case. The tibial tubercle osteotomy enhances exposure by allowing easier patellar eversion.[21]

The clinical performance of the LCS total knee prosthesis remains exemplary based on long term clinical outcome studies. The incidence of bearing complications remains low, particularly with the posterior cruciate sacrificing rotating platform implant. Osteolysis and patellar problems are extremely low compared to the general total knee experience and can be cited as a primary reasons for favoring the LCS implant. Surgical technique remains an important element of success with mobile bearing implants and tibial axis alignment continues to be the preferred method of implant insertion.

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