Aesculap Orthopaedics Clinical Evidence

Columbus Total Knee Endoprosthesis





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Rationale

Rationale

One aim of a Total Knee Arthroplasty (TKA) is to restore the functionality of the knee by reconstructing its physiological mobility. Various types of knee implants have been designed in the last decades to achieve this goal.

Fixed-bearing knee prostheses have been used for more than 20 years with highly successful clinical results and very good survival statistics¹⁻⁵.

The experience gained with these fixed-bearing implants has been incorporated into the design of the Columbus knee system, which was launched in 2003.

The Columbus knee prosthesis offers some several distinguishing features:

The length of the posterior femoral condyles has been reduced and they have a particularly small radius. As a result, the intrinsic flexion of the implant is improved, allowing a range of motion of up to 140°.

The femoral condyle of the implant is designed to ensure that the surface of the patella always has the same distance to the rotational center of the femur. Herewith, ligamentary tension remains constant for all flexion angles, ensuring an even pressure on the patella.





Columbus is a modular knee system that offers a wide range of implant components and grants a high degree of flexibility. It gives the surgeon the opportunity to adjust to the individual patient's anatomy and to follow his or her own implantation philosophy. Following prosthesis designs with adapted polyethylene gliding surfaces are offered:

For normal ligamentary conditions, the posterior cruciate ligament retaining designs are suitable: Columbus CR and, for a more secure knee flexion guidance, the deep dish (DD) gliding surface

For stable ligamentary conditions, the rotating version (RP) can be used. With this implant, the posterior cruciate ligament is retained

Also for stable conditions, the ultra congruent (UC) gliding surface is available, sacrificing the posterior cruciate ligament

For unstable posterior ligamentary conditions, the posterior stabilized (PS) gliding surface is suitable. This also sacrifices the posterior cruciate ligament.

Indication	Prosthesis
normal ligamentary conditions, functional posterior cruciate ligament	Columbus CR, Columbus DD
stable ligamentary conditions, functional posterior cruciate ligament	Columbus RP
stable ligamentary conditions, sacrificed PCL	Columbus UC
unstable ligamentary conditions, no functional posterior cruciate ligament	Columbus PS

For minimally invasive surgery, the Columbus MIOS system is available. The clearly shortened tibial stem facilitates a smaller and less traumatic approach.

For revision cases or other difficult cases of insufficient bone quality, a tibial augmentation plateau is available. The plateau can be combined with tibial extension stems and hemispacers for secure fixation.

Rationale

The Columbus modular knee system: Prosthesis design and possible combinations



For long-term results, the alignment of the knee implant is of high importance. Due to higher forces, malaligned knee prostheses lead to higher failure rates of the polyethylene inlay and of the bone-implant interface and are referred to as the main reason for aseptic loosening. Stable ligamentary conditions are equally important for a well-balanced and secure knee in both flexion and extension, and for an anatomical functionality of the joint.

The CT-free OrthoPilot navigation system allows for accurate surgery and precise alignment of implants. It provides the surgeon with information about the medio-lateral soft-tissue balance and the congruence of flexion and extension gaps.

In minimally invasive surgery, navigation is particularly important for good alignment. Combining the Columbus MIOS system with OrthoPilot navigation results in a comprehensive solution for minimally invasive surgery. While generally a navigated TKA offers more secure and reproducible outcomes, Columbus can also be implanted manually, with dedicated instruments granting a precise use of the cutting blocks and sawblades.



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Clinical Evidence

Most published studies use the Knee Society Score (KSS)⁶ to measure outcome after TKA. The KSS can be divided into two parts - a 'knee' score and a 'function' score. Both measures allow possible outcome scores of 0 to 100 (where 100 is the best). In the following, the KSS results have been cumulated from these publications.

The average preoperative KSS knee score (table 1) is 32 points (range 29-46). After 3-6 months it increases to 79 points (range 74-84) and 12 months after the operation Dries et al. [2007]⁸ have a score of 84 points.

KSS Clinical	preop	3–6 months postop	12 months postop
Lampe et al. 2006 [7]	29	74	
Dries et al. [8]	29		84
Lampe et al. 2007 [10]	29	80	
Stulberg et al. 2006 [12]	46	84	

Table 1: KSS knee

The KSS function score (table 2) is starting with an average of 52 points (range 49-54). At 3-6 months postoperatively, it is 74 (range 63-82) and after 12 months Dries et al. [2007]⁸ have a result of 86 points. The functionality is clearly improving with time.

KSS Functional	preop	3–6 months postop	12 months postop
Lampe et al. 2006 [7]	49	78	
Dries et al. 2007 [8]	49		86
Lampe et al. 2007 [10]	54	82	
Stulberg et al. 2006 [12]	54	63	

Table 2: KSS function

Oxford	preop	6 week postop	3–6 months postop	12 months postop
Lampe et al. 2006 [7]	41		25	
Dries et al. [8]	41			23
Lampe et al. 2007 [10]	40		24	
Picard et al [13]	43	28		

of 12 is the best possible outcome. A score of 60 is the worst, reflecting severe pain and limitations in every day life. Starting with an average of 41 points (range 40-43) preoperatively, the score shows a steady improvement over the follow-up period.

The Oxford Score for patient self-assessment (table 3) also

has been reported in most publications. An Oxford Score

Three studies showed good results with scores of 23, 24 and 25 points. Only Picard et al. [2006]¹³ have slightly inferior results, probably because the Oxford Score was re-assessed after a very short postoperative interval of just 6 weeks.

Table 3: Oxford Score



Key Messages

Columbus is a modular system that enables the surgeon to react with considerable flexibility to the condition of each patient as well as allowing him or her to follow any personal preferences in surgery

Columbus patients experience a high range of motion (Lampe et al.⁷, 2006; Stulberg et al.¹², 2006)

OrthoPilot navigated Columbus TKA ensures precise implant alignment (Manili and Fredella¹⁴, 2004)

The OrthoPilot navigation system allows accurate positioning of the implant and balancing of soft tissue in minimally invasive TKA, without increasing complication rates (Lampe et al.¹⁰, 2007)





Results after TKA with fixed vs. rotating platform – A prospective, randomized study

Lampe F, Dries S, Sufi-Siavach A, Hille E, Stulberg DS⁷ German Orthopaedic and Trauma Congress. 2006. Berlin.

Mobile components in TKA are supposed to reduce wear of polyethylene and to improve clinical and functional results. However, there is yet a lack of studies according to the criteria of evidence based medicine and a clear clinical advantage of mobile bearing TKA has not been validated so far.

METHODS: Lampe et al.compared in a prospective, randomized study the results of 50 patients receiving a fixed inlay implant (Columbus CR, cemented) with 50 patients receiving a rotating platform implant (Columbus RP, cemented). Primary endpoint was a clinically significant difference between the CR and the RP group.Clinical relevance was defined as a 10-point difference in the KSS or Oxford Score. Secondary endpoint was to show a significant improvement in patient satisfaction and knee score after TKA for both types of implant. Inan intermediate evaluation, Lampe et al. assessed patients after 6-7 months. They compared outcomes of 27 patients who had the fixed inlay (CR) with 23 patients who had the rotating platform implant (RP). Their clinical and functional results were assessed with the Oxford Score (patient self-assessment), the KSS, range of motion (RoM) and by radiological outcome.

RESULTS: The postoperative Oxford scores were 23 in the CR group and 26 in the RP group. RoM was 117 in the CR group and 119 in the RP group. KSS function scores were 79 (CR)and 76 (RP) and KSS knee scores were 71 (CR) and 76 (RP) respectively. Statistical testing (Student's t-test) showed no significant differences between the two groups in any of the scores. There were also no statistical differences in the radiological outcomes, with results being very similar in both groups.

CONCLUSION: The two designs of knee prostheses showed no differences in knee or function scores and both demonstrated good short-term results. Navigation allowed precise alignment in both groups. Preliminary results of a prospective randomized study – Fixed vs. mobile bearing computer assisted total knee arthroplasty.

Dries SPM, Sufi-Siavach A, Lemke KU, Bohlen KE, Hille E, Lampe F⁸ CAOS 2007, Heidelberg

One year after Lampe et al.⁷ published their interim assessment, Dries et al. published their results on the same patients after 12 months.

METHODS: The Oxford Score, the KSS and radiological outcomes were used to look for differences between the two groups in the postoperative period.

RESULTS: There were 32 patients in the CR group and 28 patients in the RP group. They showed a KSS knee score of 86 and 81, respectively. KSS function scores were 86 and 86. Self-assessment scores (Oxford) were 21 and 25. Again the Student's t-test revealed no statistical significant differences between the groups, confirming the short-term results previously published by Lampe et al. [2006]⁷. Radiological results showed precise implant alignment in both groups.

CONCLUSION: Both the CR and RP designs demonstrate good outcomes without any significant differences in the scores. A significant improvement compared with the preoperative status was achieved in both groups. This study revealed no clear advantage of one prosthesis design over the other.

Quality of implant alignment and results in minimally invasive navigated total knee arthroplasty

Bohlen KE, Dries SPM, Sufi-Siavach A, Hille E, Lampe $F^{\scriptscriptstyle 9}$ CAOS 2006, Montreal

Minimally invasive surgery potentially offers reduced pain, a faster functionality of the knee and a shorter hospitalization. On the other hand, concerns regarding an increase in general complications, malaligned prostheses and a not correctly managed soft tissue-balancing are existing. The aim of this study was to evaluate the risks and benefits of minimally invasive and conventional approaches in navigated TKA.

METHODS: Of 50 patients treated with a navigated, cemented Columbus CR TKA, 25 had a conventional approach (CMP) and 25 had a mini-midvastus split (MMS) approach. The primary endpoint was to evaluate whether minimally invasive navigated TKA is associated with a higher incidence of malalignment. The secondary endpoint was to see if there were differences in the functional or clinical results between the CMP and MMS groups. Range of motion (RoM) and pain (visual analogue scale) scores were analyzed daily for the first 10 postoperative days. The KSS and the Oxford Score (patient self-assessment) were also documented. For this publication intraoperative parameters (length of skin incision, intraoperative mechanical leg axis and blood loss) and pain and (ROM) in the first 10 postoperative days were compared between the conventional and the minimally invasive group.

RESULTS: The length of the skin incision was significantly shorter in the minimally invasive MMS group (11 \pm 1 cm) compared to the conventional CMP group (18 \pm 2 cm). Post-operative RoM scores were significantly higher and pain was significantly less intense in the minimally invasive group. Rates of blood loss and complications in both groups were similar.

CONCLUSION: The minimally invasive MMS group showed better results with respect to RoM and pain in the first postoperative days. The authors emphasize that the technically more demanding minimally invasive technique should always be performed with the support of navigation.

Accuracy of implant alignment and early results after minimally invasive vs. conventional OrthoPilot navigated Columbus TKA.

Lampe F, Bohlen K, Dries SPM, Sufi-Siavach, Hille H¹⁰ Orthopedics. 2007; 30 (10) Suppl.: 107-111

In this study, Lampe and colleagues analyzed the results obtained by Bohlen et al. 2006⁹. They evaluated their results at 3–6 months follow-up and assessed the clinical, functional and radiological outcomes of both groups.

RESULTS: As shown previously by Bohlen et al. the minimally invasive (MMS) group showed significantly less pain than the conventional (CMP) group in the first 10 postoperative days. Further, the daily gain in mobility (as assessed by RoM) was significantly higher in the MMS group than in the CMP group. Radiological assessment showed no significant difference between the minimally invasive and conventional implantation groups, however both groups showed well-aligned implants and stable and well-balanced joints. This assessment found no significant differences in the postoperative scores. The KSS function score in the MMS group improved by 32 points between preoperative and postoperative assessments; in the CMP group it improved by 23 points. The KSS knee score improved by 55 points in the MMS group and 47 points in the CMP group. The Oxford Score improved by 18 and 14 points in the MMS and CMP groups, respectively. All scores improved significantly between preoperative and postoperative assessments. No differences in perioperative complications were observed (both groups had one case of minor femoral notching). Similarly there were no differences in postoperative complications (in the MMS group there was one case of uncomplicated revision for hematoma and in the CMP group there was one case of uncomplicated deep vein thrombosis).

CONCLUSION: These results show that, compared with a conventional approach, minimally invasive TKA produces accurate implant positioning, allows soft-tissue balancing and results in comparable complication rates when a navigation system is used to compensate for the limited view of the anatomic field. In the first 10 postoperative days after minimally invasive surgery, functional results are superior and patients experience less pain.

A five-year experience with OrthoPilot navigated Columbus total knee replacement.

Hakki S¹¹ CAOS. 2008. Hong Kong

Hakki evaluated results of OrthoPilot navigated TKA with the Columbus cruciate-ligament-retaining knee prosthesis. The Columbus femoral component has a high curvature that provides a high degree of flexion and a stabilized knee in flexion (preventing posterior dislocation of the knee). This evaluation aimed to assess the value of this design.

METHODS: This was a retrospective study on 200 TKA procedures in 182 patients. Both clinical and radiological results were evaluated. Clinical results were assessed after 3, 12 and 24 months. Radiological assessments were made between 1 year and 5 years (after 2 years on average). The clinical outcome was evaluated using the Knee Society Score (KSS), the range of motion (RoM) and knee stability testing. In all cases, surgery was performed with the OrthoPilot navigation system. No patellae were resurfaced. All cruciate ligaments were retained.

RESULTS: The KSS improved significantly in the first 12 months compared to the preoperative score. RoM improved from 118° preoperatively to 130° postoperatively. Assessment of knee stability with the leg in extension revealed a mean varus and valgus deflection of 1.43° of the 180° mechanical axis (range 4° varus to 4° valgus). Analysis of the radiological results showed 23 cases with radiolucent lines, of which 20 measured less than 1 mm in width. In 18 cases the radiolucent lines were found to be located around the medial tibial stem. None of these lines were deemed to be progressive. The postoperative mechanical axis showed a mean of 180° (\pm 0.11°). Patella tilting was grouped into two categories: tilting of 0° to 4° was observed in 72 %, and tilting of 5° to 17° was observed in 28 %. The patella was displaced laterally in 11 % of patients, but this was by less than 3 mm and there were no associated symptoms. Some patients (3.5 %) reported patella pain when climbing stairs or getting out of a chair. No implant-related complications or revisions were reported.

CONCLUSION: The Columbus knee prosthesis showed good intermediate clinical and radiological results, with no major implant-related complications.

Computer-assisted surgery versus manual total knee arthroplasty: A case-controlled study

Stulberg SD, Yaffe MA, Koo SS¹² J Bone Joint Surg. 2006; 88-A (4): 47-54

Computer-assisted TKA is associated with better overall limb and implant alignment and fewer outliers compared with manual TKA. This study aimed to determine if the improved accuracy in alignment is also associated with superior clinical and patient-perceived functional outcomes.

METHODS: A total of 78 consecutive cemented TKA were assessed to compare clinical and patient-perceived functional and radiological results of manual TKA with computer-assisted surgery. Of these, 40 were manual cases and 38 were assisted by OrthoPilot navigation. All patients received the Columbus CR prosthesis. Examinations were performed at 4 weeks and 6 months postoperatively, with assessment by the KSS.

RESULTS: No significant differences between functional and clinical scores were found at 4 weeks or 6 months postoperatively. RoM scores improved from 114° preoperatively to 116° 6 months postoperatively in the manual group, and from 112° to 117° in the navigated group. The KSS knee score improved from 48 to 85 and the KSS function from 57 to 62 points in the manual group. In the navigated group, the knee score improved from 45 to 83 points, and the function score from 50 to 64. The pain score improved from 12.8 preoperatively to 39.5 6 months postoperatively in the manual group, and from 12.0 to 36.5 in the navigated group. Radiological results in both groups were comparable. CONCLUSION: No significant differences in radiological, functional or clinical results were found between the two groups. This suggests that implant design and manual instrumentation are well advanced and allow for accurate TKA procedures. Also, the improvements in manual techniques may be due to extensive use of computer-assisted surgery over the last few years.

Computer-assisted dynamic total knee arthroplasty using Whiteside's line alignment

Picard F, Gregori AG, Dean F, Mennessier A, Dillon J¹³ Orthopedics. 2006; 29 (10) Suppl.: 104 -107

The literature reveals several references to measurement of the rotational alignment of the femoral component in TKA. However to date no technique has been proven as superior –different techniques produce highly variable rotational alignments.

METHODS: This study followed 71 patients. They were treated with cemented Columbus retaining and sacrificing prostheses, by navigated implantation procedures. The rotational femoral alignment was analyzed using the Whiteside line for orientation. In addition to the radiological outcome, Oxford Score and RoM were used for assessment. The outcome was evaluated 6 weeks postoperatively.

RESULTS: The mean external femoral rotation was 2.06° (-1° to 5°). Patients were divided into three categories according to femoral rotations of -1° to 0° (group A), 1° to 2° (group B) and 3° to 5° (group C). Group B displayed the best results, showing a neutral alignment in flexion. Group A tended to valgus, and group C tended to varus alignment in flexion. The Oxford Score improved from 42 preoperatively to 28 after 6 weeks, with a slight decrease in flexion from 120° preoperatively to 118° postoperatively. No prosthesis-related complications occurred (there were two renal impairments, one deep vein thrombosis, two superficial hematomas and one delayed wound healing).

CONCLUSION: The results of this study support the value of Whiteside's line as a reference for an individually adapted femoral component rotation.

Navigation through OrthoPilot in total knee prosthesis: Advantages and significance

Manili N, Fredella N¹⁴ CAOS 2004

Navigation in TKA is an important assistance to perform the correct tibial and femoral bone cuts and to restore the mechanical axis. It is especially valuable in minimally invasive surgical techniques, where there is a reduced window into the operating field. The objective of this study was to evaluate the accuracy of the OrthoPilot navigation system in minimally invasive TKA using the Columbus prosthesis.

METHODS: 25 patients treated with navigated minimally invasive surgery (MIS) were compared to 23 patients with a traditional approach and navigated surgery (CON). Operating time, postoperative blood loss, complications during and after the operation and range of motion (RoM) were assessed. Radiological results included evaluation of the mechanical axis.

RESULTS: The average length of follow-up was 14 months (range 6 to 26). Operating time was 55-120 minutes in the CON group and 65-140 minutes in the MIS group. The average postoperative blood loss was 550 mL in the CON group and 500 mL in the MIS group. No complications were reported in either group and no flexion contraction was seen in any patient. A flexion of 120° was reached by 15 patients (65 %) in the CON group and by 17 patients (68 %) in the MIS group. The mechanical axis was $180 \pm 3^\circ$ in the CON group and $180 \pm 4^\circ$ in the MIS group.

CONCLUSION: The clinical results were slightly better in the minimally invasive group, particularly with respect to the range of motion. This may be attributable to the lower level of damage to the quadriceps in the minimally invasive group. The use of the OrthoPilot navigation system in minimally invasive TKA reduces the risk of malpositioning and intraoperative complications associated with conventional MIS.

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Aesculap AG

Am Aesculap-Platz 78532 Tuttlingen Germany Phone +49 7461 95-0 Fax +49 7461 95-2600 www.aesculap.de

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