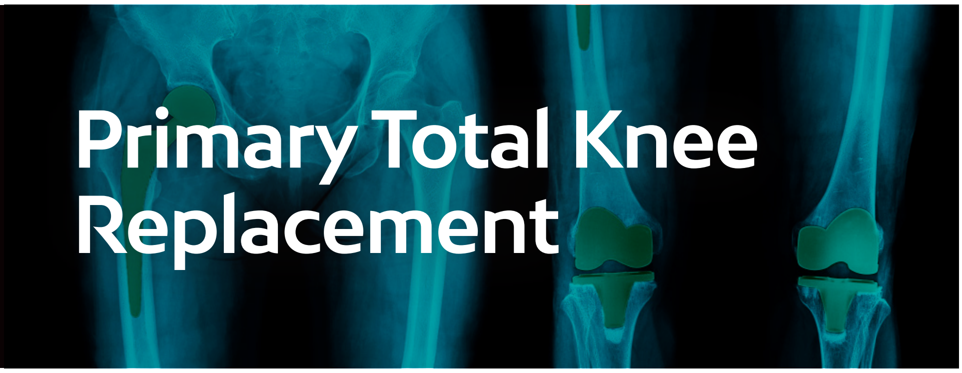

# Primary Total Knee Replacement

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## About the Experts


### Simon Young

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Simon Young is an orthopaedic surgeon specialising in surgery of the knee. After completing orthopaedic surgical training in New Zealand Simon went on to work in the USA, completing a Sports Medicine fellowship at Stanford University and an Arthroplasty fellowship at the Mayo Clinic. Simon is a Consultant Surgeon at North Shore Hospital, where he serves as Director of Research and is a Senior Lecturer in Orthopaedics at Auckland University. Simon is regularly invited to speak nationally and internationally on knee and shoulder topics and has more than one hundred research publications in the orthopaedic literature. He is heavily involved in researching new technologies in knee replacement, currently leading the first randomised trial of robotic-assisted knee replacement in Australasia.

### Mark Clatworthy

**MB ChB (Otago); FRACS (Orth), MD**

Mark Clatworthy is one of New Zealand's most experienced orthopaedic knee surgeons. He trained initially in New Zealand then worked under leading knee surgeons in the US, Canada, the UK, and Australia. Mark has been practicing in Auckland for 25 years and has a consultant position at Middlemore Hospital and in private at Ascot Hospital with satellite clinics on the North Shore and in West Auckland. Mark is actively involved in clinical research and has published many research articles, reviews, and book chapters which he presents internationally. He has been involved in pioneering computer-guided knee surgery and is developing arthroscopic and knee replacement techniques, which he teaches globally. He is a member of four international societies who meet to pioneer and progress knee surgery and is past president of the ACL Study Group, which is an international group of the world's leading sports knee surgeons. Mark is on the Board of ISAKOS, the International Knee Society, and is past chairman of the Arthroscopy and Sports Knee committees.



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Total knee replacement is an effective surgical intervention, demand for which has been driven by an ageing population and growing rates of obesity. This review discusses primary total knee replacement with a focus on different surgical approaches and technologies that aim to achieve improved patient outcomes. This review is sponsored by an educational grant from DePuy Synthes.

## Background

Total knee replacement (TKR) surgery is one of the most commonly performed musculoskeletal surgical procedures.[1] The main indication is advanced osteoarthritis of the knee joint with intolerable pain and unacceptable functional limitation with the loss of valued activities of daily living.[2]

Resection of the degenerating joint and replacement with an implant, which reconstructs the worn joint surface, allows pain-free mobilisation leading to improved quality of life.[1,3] Cost-effectiveness analyses estimate the ratio of incremental costs to health gain (quality-adjusted life-years) from TKR to be in the range considered representative of good value for money.[1]

Overall mean implant survivorship for TKR surgery is 95.7% at 10 years and 92.1% at 20-years follow-up based on NZ Joint Registry data.[4] Following implantation, a 65-year-old patient has a 7% lifetime risk of requiring revision surgery; however, this risk increases substantially with younger age groups.[1] The most common reasons for revision surgery are infection, implant loosening, pain, and instability.[1,5]

## Prevalence of knee replacement

More than 95% of knee joint replacements are done for osteoarthritis.[1] Although the average age of people undergoing knee replacement is about 65 years, increasing numbers of knee replacement surgery are done in younger patients.

A total of 119,109 conventional total knee arthroplasties were performed in NZ between 1999 and 2019 according to the NZ Joint Registry,[4] with osteoarthritis (113,108 of diagnoses; 95%) being the main reason for knee replacement surgery.[4] Other reasons for knee replacement include arthritis (2,451 of diagnoses; 2.1%), post fracture (1,258; 1.1%), and post ligament disruption (1,068; 0.9%).

With age and obesity being major risk factors for osteoarthritis, the prevalence of knee osteoarthritis has been increasing due to lengthening life expectancy and the growing prevalence of obesity.[6,7] Consistent with these demographic trends the number of knee replacements performed per year in NZ has increased gradually since 1999 (**Figure 1**), although rate appears to have stabilised in recent years with the 8,431 implants in 2019 being similar to the 8,392 implants in 2018.


**Figure 1.** Number of primary knee replacement surgeries performed in NZ by year for the period January 1999 to December 2019.[4]

## Total versus partial knee replacement

Knee replacement can be either partial (PKR) or total (TKR), depending on the degree of joint disease. Although most patients receive a TKR, approximately 8% of cases receive a PKR.[1] According to the Australian Joint Registry, PKR accounted for just 7.7% of all knee replacement procedures performed in 2019.[8] Medical unicompartmental knee replacement is the most common type of primary PKR, accounting for 92.8% of all PKR procedures in Australia in 2019.[8]

Outcomes for TKR and PKR surgery are thought to be similar;[9] however, partial replacement tends to be associated with fewer medical complications, shorter postoperative length of stay, less pain during the recovery period, and fewer re-admissions.[1,9]

However, a major reason why PKR has not been more widely adopted as an alternative to TKR is the higher revision rate reported in nearly all national registry reports.[1] For example, the 2020 Australian Joint Registry reported 10- and 15-year cumulative revision rates of 14.3% and 22.1%, respectively, for PKR compared with rates of 6.5% and 13.1 for TKR.[8] Revision surgery for unicompartmental knee replacement usually involves a conversion to TKR, with outcomes that are comparable with revisions after TKR.[10]

Additionally, although PKR leaves more of the original knee intact, for the remaining parts of the knee to develop arthritis and require replacement in the future.[9]

## Surgical aspects of total knee replacement

A goal of TKR is to obtain symmetric and balanced flexion and extension gaps.[11] Prerequisites for a favourable clinical outcome after TKR are proper implant alignment, sizing, and rotation, as well as adequate soft-tissue balancing.[12,13] Improperly balanced TKRs are at increased risk for complications including residual pain and/or instability, which may require correction by a revision surgery.[14]

## Measured versus balanced resection

Measured resection and gap balancing are widely used surgical techniques to implant the TKR prothesis and to determine the rotational alignment of the components.[12,13]

The measured resection technique relies on bone landmarks (e.g., trans epicondylar, anterior-posterior, or posterior condylar axes) to determine proper femoral component rotation and subsequent gap balance.[11] The gap balancing technique involves positioning the femoral component parallel to the resected proximal tibia, and each collateral ligament equally tensioned to obtain a rectangular flexion gap.

In theory, measured resection is performed before soft tissue balancing.[13] However, in the gap balancing technique, soft tissue balancing is performed before femoral bone cutting. The differences in these approaches may affect femoral component rotation and change in joint line position. The optimal method for achieving appropriate soft tissue balancing and femoral component rotation, with minimal joint line position change, remains controversial.[13,15]

According to a recent meta-analysis, synthesized data from prospective clinical trials comparing measured resection technique with gap balancing technique for primary TKR indicate that both techniques achieve similar clinical and functional outcomes and with no difference in terms of revision surgery, aseptic loosening, or implant infections.[15] There was no difference between the two techniques in the alignment of mechanical axis and femoral rotation and no difference between the medial and lateral gaps during knee motion. In an earlier meta-analysis that synthesised data from retrospective comparison studies, the gap balancing and measured resection techniques yielded similar soft tissue balancing and minimal differences in femoral component rotation and joint line position change.[13]

## Developments in total knee replacement

With life expectancy increasing and a tendency for people to have a joint replacement earlier in life, efforts to improve implant survival and clinical outcomes are ongoing, either by altering implant design to minimise mechanical wear or by enhancing implant fixation.[1,3] However, despite most patients having a good clinical outcome after TKR, evidence suggests that up to 15–20% of patients are dissatisfied with their outcome in terms of quality of life, pain relief, and function.[1]

Increasingly, it is being recognised that improved patient outcomes can be achieved via better implantation methods and more recent development efforts have focussed on technologies that aim to achieve more natural kinematics and more precise implant positioning.[3]

## Technology options

Manually controlling lower leg alignment, component positioning, and soft tissue balancing during TKR can pose difficulties for the orthopaedic surgeon.[16,17] Since tighter control over these surgical variables by surgeons is assumed to lead to improvements in clinical outcomes, such as patient-reported outcomes and implant survival, patient-specific instrumentation (PSI) and computer-navigation and robotic-assisted intraoperative systems have been developed. Additionally, PSI and computer navigation can help less experienced, lower-volume surgeons to achieve greater precision and accuracy.[1]

### Patient-specific instrumentation

PSI, in which preoperative imaging (plain radiographs, computed tomography (CT), or magnetic resonance imaging [MRI]) and proprietary software is used to create cutting guides specific to a patient's anatomy, was introduced with the aim of achieving better anatomical and functional outcomes with TKR.[18,19] PSI also avoids practical issues related to the high cost and complexity of navigation and robotic systems.[20]

According to two comprehensive meta-analyses of randomised controlled trials (RCTs) that compared knee replacement using PSI versus conventional instrumentation, PSI was associated with statistically significant reductions in operating time and blood loss.[21,22] One of these meta-analyses also found that knee function was significantly improved with PSI and that MRI-based PSI favoured reduced operating time and risk of malalignment of mechanical axis versus CT-based PSI according to sub-group analysis.[21]

### Computer-navigation and robot-assisted systems

Computer-navigation systems have an interface that allows entry of anatomical data and provides surgeons with feedback on positioning of instruments and implants and overall alignment of the knee, but cannot be programmed to perform tasks.[3,17] Computer-assisted gap balancing can be used to assist with soft-tissue balancing to increase the accuracy of mechanical alignment and improve the precision of balancing flexion and extension gaps.[14]

Data from well-designed clinical studies indicate that computer-navigation systems improve the accuracy and precision of component positioning in TKR, with promising results for early clinical outcomes.[16,23] Emerging medium-term implant survival data show small benefits compared with manual surgery, with the benefit being more pronounced in patients aged <65 years.[17] However, conclusive evidence of superiority in terms of improved patient-reported outcomes and lower cumulative revision rates in the long term is lacking.[16,23] All published studies evaluating computer navigation have aimed to implant the TKR with a neutral mechanical axis, which very few patients have. So, if every knee is different and mechanical axis computer-navigated TKR makes them more the same, it is no surprise that these studies have not shown an improvement in clinical outcomes.

Robotic systems represent an extension of navigated joint replacement.[3,17,24] In general, they provide additional intraoperative feedback that assists with restoring knee kinematics and soft tissue balance, offer more comprehensive planning, and can be programmed to assist positioning instruments or control the function of tools to ensure that bone resection matches the pre-surgical planning.

Similar to computer navigation, robotic systems can improve lower leg alignment, component positioning, and soft tissue balancing in TKR,[16,17] and early results suggest a similar small benefit in patient-reported outcomes compared with manual TKR.[17] In terms of surgical efficiency, a retrospective study found that there was decreased navigation time, malalignment, and duration of hospitalisation associated with the use of a robotic system compared with computer navigation among patients undergoing TKR.[25] As with computer navigation, however, evidence of improved clinical outcomes and revision rates over the long term with robotic-assisted surgery is lacking.[16,17]

## Alignment philosophies

### Mechanical alignment

Mechanical alignment has historically been considered the standard alignment strategy for TKR, whereby the hip, centre of the reconstructed knee, and the ankle are in neutral alignment.[1,26] Recently, questions arising about the quality of the data supporting that status and an increased understanding of native knee motion have resulted in the optimal alignment strategy for TKR being revisited.[26]

Mechanically-aligned TKR aims to achieve a neutral mechanical alignment of the limb as well as a varus–valgus alignment of the tibial and femoral components, perpendicular to the limb mechanical axis.[27] However, despite improvements in implant design and the precision of surgery (due to navigation systems, PSI, and robotics), it is clear that traditional mechanical alignment does not restore normal 'native' lower limb alignment or optimal soft tissue balance for many patients. Some experts argue that this difference from 'natural' alignment in some patients may lead to a poorer functional outcome and lower patient satisfaction.

### Kinematic alignment

Kinematic alignment has been proposed as an alternative approach to implantation.[1,26,27] This procedure aims to restore more natural kinematics by replicating the pre-arthritis femur and tibial articular surface orientation.[1,27] Kinematic alignment involves returning the arthritic deformity to the native or pre-arthritic alignment by positioning the tibial, femoral, and patellar components with respect to the three axes of rotation of the knee (**Figure 2**), as well as the native distal and posterior joint lines.[26,28] Kinematic alignment can be performed with the assistance of navigation, PSI, or manual instrumentation (via the measured resection technique).[29]

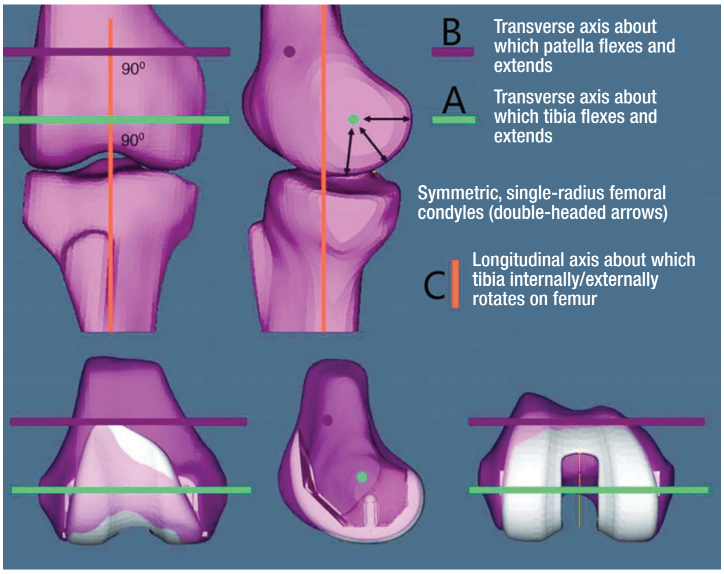


**Figure 2.** Schematic showing the parallel and perpendicular relationships between the three kinematic axes of the knee.[28]

In terms of the performance of non-mechanically aligned TKR, the findings of a recent meta-analysis of RCTs comparing kinematic alignment and mechanical alignment in TKR are mixed.[30] Some trials report that kinematic alignment is associated with better pain relief and knee function than mechanical alignment; however, other trials report no difference.[31] In another meta-analysis of RCTs that evaluated early outcomes after kinematic alignment in TKR, cumulative survivorship was 97.4% at 38 months' follow-up.[32] A key question is whether 'alternative' alignment techniques will compromise survivorship of the implants due to altered loading. While long-term data is lacking, current evidence suggests that medium-term survivorship between kinematically-aligned and mechanically-aligned implants are similar.[33]

A case series study of 222 knees treated with TKR aligned kinematically with PSI reported 5-year and 10-year implant survivorship rates of 98% and 97.5%, respectively (**Figure 3**).[20] A limitation of the case series is that it is unlikely to represent the full range of preoperative deformities and native alignments. An observational study of data from the Australian and NZ joint replacement registries found that kinematically-aligned TKR using PSI has a revision rate similar to that of all other TKRs.[34] Of 20,512 TKR procedures recorded, 416 were performed using PSI kinematic alignment. The cumulative revision rate at 7 years was 3.1% in the kinematically-aligned TKR using PSI cohort compared with 3.0% in the computer-assisted surgery and conventionally-instrumented TKR cohort.

Because the kinematic-alignment approach to TKR is reliant on a three-dimensional understanding of the three key kinematic axes of knee rotation (**Figure 2**) and their correct implementation,[26,27] the implementation of these axes using conventional instruments is complex.[27] Techniques such as PSI, navigation, and robotics may improve understanding in the area and optimise balancing in the future.[20]

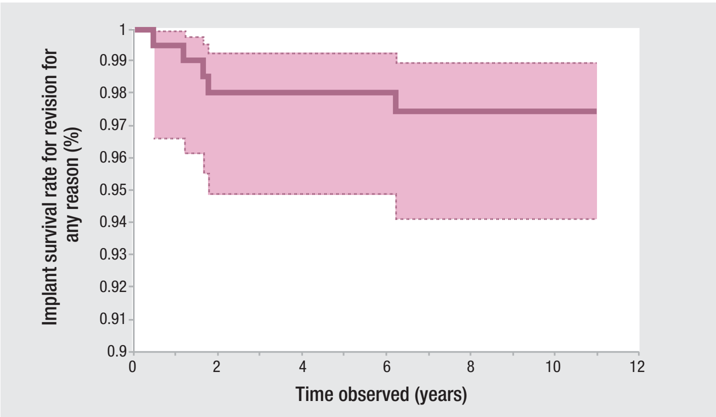


**Figure 3.** Kaplan-Meier survivorship curve (solid red line) with 95% confidence intervals (dotted red lines) for the endpoint of revision for any reason following kinematic-alignment TKR with PSI.[20] Five-year survival rate was estimated at 98.0% (95% CI: 94.8–99.5) and the 10-year survival rate was estimated at 97.5% (95% CI: 94.5–99.0).

## Functional alignment

Computer navigation and robotic-assisted systems aid 'virtual' positioning of the components in TKR and intra-operative assessment of ligament balancing prior to any bony cuts being made.[35] This allows resection thickness, joint gaps, and limb alignment to be assessed during surgery, and changes to be made virtually to optimise component positioning. The technique incorporates elements of both measured resection and gap-balancing techniques, and can be used to make small adjustments to traditional mechanical or kinematic alignment targets to achieve balance. This can prevent or minimise the need for soft tissue release.

## Patient-specific alignment

Although TKR surgery aims for a neutral mechanical axis, with a tibial cut and joint line perpendicular to the mechanical axis, there is evidence of marked variability in knee anatomy whereby the tibia is in more varus and the femur is in more valgus than neutral alignment.[36] Only one in 1,000 patients were shown to have both neutral femoral and tibial alignment.

The aim of patient-specific alignment is for a bounded anatomical resurfacing of the knee to replicate the native anatomy of the knee. Small positional modifications are made to enable a stable TKR through a full range of motion. To avoid soft tissue releases, the TKR is implanted to function within its natural soft tissue envelope. Replicating the natural joint line of the knee is associated with improved soft tissue balance,[37] and improved functional outcomes.[38]

Excessive internal and external rotation of the femoral component has been associated with poor patient satisfaction and clinical outcomes with a measured-resection neutral mechanical alignment TKR.[39,40] The technique assumes that every tibia is in 3° of varus so the femoral component is placed in 3° of external rotation relative to the posterior condylar axis to enable a balanced flexion gap. However, the assumption that the tibia is always in 3° of varus is incorrect as there is wide variability in the bony anatomy and soft tissue envelope of the knee so flexion imbalance may occur.[41,42]

The patient-specific alignment navigated balanced technique involves using bony anatomy and the soft tissue envelope of the knee to guide the optimal placement of the TKR. Either computer navigation or robotic technology enables the surgeon to evaluate the balance consequence of how a TKR is implanted. The bony surface anatomy of the knee is morphed to give a three-dimensional model of the knee. The surgeon uses this to initially place the TKR in its pre-arthritic position (kinematic alignment). The technology provides a balance curve to evaluate how well balanced the TKR will be in its kinematic position. Often, the TKR will not be well balanced so small positional changes are made to the tibial and femoral component to enable TKR to be optimally balanced within its natural soft tissue envelope.

Use of a ligament tensor device to match the flexion gap to the extension gap to enable the TKR to be balanced through a full range of motion can result in variable rotation of the femoral component, including internal rotation.[29,43] To assess patients' clinical outcomes according to the variable femoral component rotation using a patient-specific alignment navigated balanced technique, a prospective single-surgeon case-series study on 287 consecutive varus osteoarthritic knees was performed with 2 years of follow-up.[43] The key finding was that patient functional outcomes and satisfaction were not altered by variable femoral component rotation when a patient-specific alignment navigated balanced TKR technique was performed in varus knees.

### Expert comment on patient-specific alignment – Mark Clatworthy

Most knee arthroplasty surgeons globally aim for a neutral mechanical axis. They use a measured resection technique whereby the femur and tibia are cut independently with the hope they will marry up. This is often not the case so the surgeon has two choices: leave the soft tissue of the knee intact and have a poorly balanced TKR or release the soft tissue envelope of the knee and as a result change the kinematics of the knee. As the native knee rarely has a neutral mechanical axis, the kinematic alignment technique was developed to insert the TKR to replicate the bony anatomy of the knee. Because a TKR does not replicate the native kinematics of the knee due to the different shape of the TKR implant to the variable bony shape of the knee and the effect of removing the anterior cruciate ligament and meniscus, kinematic alignment often does not result in a well-balanced knee. In response to this, a Patient-Specific Technique was developed to enable a balanced TKR to be performed every time with small positional changes in the true anatomic positioning of the TKR.

## EXPERT'S CONCLUDING COMMENTS – SIMON YOUNG

During the development of TKR in the 1980s, the driving focus was on improving implant survival with early designs suffering from a high failure rate. Achieving a 'neutral' mechanical axis was seen as the key to longevity, and the relationship between the prosthesis and the mechanical axis of the limb was the priority. With modern implants and fixation techniques, early failure is now uncommon and the emphasis has shifted to the relationship between the prosthesis and the soft tissue envelope. This is the focus of kinematic alignment and its derivatives, in the hope of improving functional outcomes for patients without compromising longevity. While clinical data is currently lacking, newer technologies have enabled advances in surgical technique and accuracy that show considerable promise.

## EXPERT'S CONCLUDING COMMENTS – MARK CLATWORTHY

With the advent of soft-tissue balancing, computer navigation, and robotics, the patient-specific alignment ligament-guided technique is increasing in popularity. Surgeons have seen reduced pain, early restoration of motion, and improved outcomes and patient satisfaction. As this technology is recent, many studies evaluating patient-specific alignment have been presented but are yet to be published.

## TAKE-HOME MESSAGES

- TKR results in successful clinical outcomes and excellent long-term implant survival; however, a proportion of patients continue to report dissatisfaction.
- Incremental changes in implant design do not appear to have achieved substantial improvement in outcome and patient satisfaction.
- Additional efforts are required to improve implantation methods and enhance patient-reported outcomes.
- Evidence suggests that mechanical alignment measured resection and gap balancing techniques achieve similar clinical and functional outcomes, with no difference in terms of revision surgery.
- PSI, computer navigation systems, and robotics aim to enhance the precision and accuracy of knee replacement surgery and improve patient outcomes.
- Computer navigation and robotic-assisted TKR improves surgical variables and mechanical axis accuracy and implant positioning versus manual control but evidence of superiority in long-term functional outcomes is currently lacking.
- The optimal alignment philosophy for TKR has yet to be established.
- Kinematic alignment aims to restore native alignment and result in knee motion similar to the native knee.
- Excellent clinical outcomes as well as survivorship for kinematic alignment with up to 10 years' follow-up have been demonstrated in retrospective analyses but have yet to be reproduced in RCTs.
- Evidence suggests that a kinematic strategy has at least equivalent clinical outcomes compared with a mechanical strategy, without increased risk of implant failure in the medium term.
- Functional alignment has been proposed as a method for allowing mechanically-sound, soft tissue-friendly alignment targets to be identified intra-operatively.
- The concept of patient-specific alignment was developed because the mechanical alignment technique assumes that every knee is the same, which is not the case. There is wide variability in the bony anatomy and soft tissue laxity of the knee. This personalised technique uses computer navigation or robotic technology to place the TKR as anatomically as possible within the patient's natural soft tissue envelope so that the TKR can function optimally.

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