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SPECIAL REPORT

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Technology assistance in primary total knee replacement: hype or hope?

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ABSTRACT

Introduction: Total knee replacement (TKR) reduces pain, it increases quality of life and it generally lasts a long time with revision rates of less than 5% at 10 years. Some authors have suggested that outcomes may be further improved by technology assistance.

Areas covered: Technology assistance in primary TKR includes technologies such as navigated TKR, patient specific instrumentation TKR and robotic TKR.

Expert opinion: In general, technology assistance results in higher accuracy of component positioning and alignment, but this is likely not clinically relevant as no clinically important difference in clinical outcomes, quality of life and complications such as revisions has been demonstrated in meta-analyses of randomized controlled trials. As technology assistance in primary TKR is increasingly used to capture patient and surgeon data, surgeons have an increasingly important role in protecting their patients' data and their own data. Real world evidence of implant registries has shown that TKR without technologically assistance can achieve perfectly acceptable outcomes. Although there is a genuine hope that technology-assisted TKR may further improve these outcomes, this hope is based on promises rather than solid evidence. At the same time, technology assisted TKR is heavily promoted including direct patient marketing, which are aspects of a hype.

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1. Introduction

Total knee replacement (TKR) is a very successful surgical treatment for symptomatic end-stage osteoarthritis of the knee joint. It reduces pain, it increases quality of life and it generally lasts a long time with revision rates of less than 5% at 10 years for some modern TKR [1]. Despite this impressive track record, approximately 10% of the patients are dissatisfied with their TKR [2]. Some authors have suggested that many revision procedures are related to the biomechanical aspects of the surgical procedure that can be adjusted by the surgeon, such as implant position and alignment [3]. In order to improve implant position and alignment technology assistance for TKR has been developed such as navigation, patient specific instrumentation (PSI) and robotic systems [4–7]. While the use of such technology assistance in general improves the accuracy of component positioning and leg alignment in TKR, such improved accuracy may not translate into actual benefits for patients in terms of better outcomes or less revisions, see Table 1 [5–7].

2. Body

2.1. Navigated TKR

Navigated TKR uses sensors to localize surgical tools relative to bone anatomy and landmarks. This provides the surgeon with feedback on a computer monitor as to the spatial location of the surgical cutting tools [4]. Navigation has been shown to provide better accuracy for component positioning and alignment [7,8]. However, despite better accuracy, there seems to be no clinically relevant difference in functional outcomes, quality of life or revision rates [7,8].

Navigated TKR often requires extra pins to be attached to the bone. Such extra pins are not necessary for conventional TKR. These extra pins could lead to complications in navigated TKR that are not seen in conventional TKR, such as: fractures of bones around the pin sites, multiple pin insertion attempts, pin loosening resulting in conversion of navigated TKR to conventional TKR, hematoma, infection and nerve injury [8]. Navigated TKR is also associated with a learning curve and longer operative time [7].

Contrary to conventional TKR, navigated TKR does not require intra-medullary instrumentation. In cases of TKR where conventional intra-medullary alignment is not possible, e.g. due to hardware in the intra-medullary canal or altered bone anatomy after fractures, navigated TKR may prove a valuable solution [8]. Reducing or eliminating intramedullary canal instrumentation may reduce fat and morrow embolization, which could be an advantage for navigated TKR with potentially decreases in postoperative confusion, respiratory thromboembolic events of venous thromboembolism. However, such decreases have not been demonstrated [8].

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Article highlights

- Technology assistance in primary total knee replacement (TKR) includes navigated TKR, patient specific instrumentation TKR and robotic TKR.
- As technology assistance in primary TKR is increasingly used to capture patient and surgeon data, surgeons have an increasingly important role in protecting their patients' data and their own data.
- Technology assistance does not require intra-medullary canal instrumentation, which may be beneficial in cases where conventional intra-medullary alignment is not possible.
- Technology assistance may require extra pins to be attached to the bone, which could lead to complications around these pin sites: fractures, hematoma, infection and nerve injury.
- In general, technology assistance results in higher accuracy of component positioning and alignment.
- Meta-analyses of randomized controlled trials have not shown clinically important differences for technology assistance TKR compared to conventional TKR in clinical outcomes, quality of life and complications such as revisions.

Table 1. Mean difference in functional outcomes according to type of technological assistance.

	NAV vs non-NAV [7] Mean difference [95%CI]	PSI vs non-PSI [5] Mean difference [95%CI]	ROB vs non-ROB [6] Mean difference [95%CI]
WOMAC	−0.4 [−2.2 to 1.3]	0.9 [−1.9 to 3.8]	−0.4 [−0.8 to 4.3]
KSS	0.5 [−0.6 to 1.6]	0.7 [−0.3 to 1.7]	−0.9 [−2.0 to 1.2]
ROM	−0.4 [−2.1 to 1.3]	1.5 [−0.4 to 3.4]	0.7 [−6.0 to 7.5]

NAV = navigated TKR.
PSI = Patient Specific Instrumentation TKR.
ROB = Robotic TKR.
WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index (points).
KSS = Knee Society Score (points).
ROM = Range of Motion (degrees).

2.2. Patients specific instrumentation TKR

Patient Specific Instrumentation (PSI) in TKR uses pre-operative imaging such as CT or MRI for the fabrication of patient specific cutting jigs. These jigs are used intra-operatively to make the preplanned bone cuts [4,9]. While PSI TKR is associated with improved accuracy of component positioning and alignment [9], there do not seem to be any clinically relevant differences in functional outcome, quality of life, revision rates or other complications compared to non-PSI TKR [5]. Interestingly, a recent systematic review and meta-analyses has shown publication bias in favor of PSI for randomized controlled trials (RCTs) comparing PSI with non-PSI TKR. This publication bias was time dependent with earlier publications showing a more positive effect for PSI compared to non-PSI TKR, whereas later studies found the opposite [5.]

Similar to navigated TKR, PSI TKR does not require intra-medullary canal instrumentation, which may be beneficial in cases where conventional intra-medullary alignment is not possible.

2.3. Robotic TKR

Robotic TKR uses optical tracking and/or haptic feedback to help surgeons performing bone cuts according to the pre-operative planning [4]. The body of high-level evidence on robotic TKR is less extensive than for navigated TKA and PSI TKR. However, a recent systematic review and meta-analysis suggests that robotic TKR likely results in higher radiologic accuracy, but that this may not be clinically relevant as there is probably no clinically important difference in clinical outcomes between robotic TKR and conventional TKR [6]. The evidence for revision rates and complications was deemed inconclusive due to insufficient evidence [6].

Robotic TKR does not require intra-medullary canal instrumentation, which may be beneficial in cases where conventional intra-medullary alignment is not possible. Similar to navigated TKR, robotic TKR often requires extra pins to be attached to the bone. These extra pins may lead to complications around the pin site that are not seen in conventional TKR such as: fractures, hematoma, infection and nerve injury [10]. Robotic TKR is also associated with a learning curve and longer operative time [6].

Despite no clear evidence that robotic TKR is superior to conventional TKR, it is used in ever increasing number of cases to such an extent that approximately 25% of senior orthopedic residents felt that robotics negatively compromised their training with traditional instrumentation according to a study from the United States [11]. If the use of robotic TKR were to increase further, there is a risk that surgical skills for conventional TKR could be lost, making orthopedic surgeons dependent on robotic TKR. The same study revealed that more than half of the residents (53%) agreed that robotic TKR is used primarily for marketing purposes and 42% agreed or strongly agreed that financial conflict of interests influence a surgeon's decision to use robotic TKR [11]. Another study has found that nearly all studies comparing robotic TKR to conventional TKR involve authors with financial conflict of interests [12]. The same seems to be true for Total Hip Replacement and Unicompartimental Knee Replacement [12]. Studies with financial conflict of interests were more likely to report favorable results for robotics than non-conflicted studies and studies with favorable results for robotics had a higher number of conflicted authors and a higher mean industry payment per author [12].

On top to these worrisome observations, direct patient marketing for robotic TKR has been initiated. This may not be a problem by itself as long as the information provided in the adds is free from manipulation and selection and that the adds give an accurate and up-to-date interpretation of the evidence base. However, such unbiased information seems to be missing from the adds: no results from high quality systematic reviews or meta-analyses are mentioned and in particular there is no mentioning that there is probably no clinically important difference in clinical outcomes between robotic TKR and conventional TKR [6]. In the past, there have been direct patient marketing campaigns for instance with the 'sport hip' which had a metal-on-metal articulation. This has led to widespread use of meta-on-metal total hip implants that turned out to be disastrous by exposing patients to higher risks of revision surgery and possibly higher risks of mortality [13,14]. While robotic TKR does not seem to be a disaster, it has also not been shown to be superior in terms of clinical benefits for patients [6].

A disadvantage of robotic TKR is that it may not be compatible with all TKR implants, which means that in order to use a particular robotic TKR system the orthopedic surgeon is limited in the choice of implants and possibly has to start using implants that he or she has not used before. This could introduce a learning curve to get familiar with the new implant on top of the learning curve of the robotic TKR system [15].

Robotic TKR generates patient data during the pre-operative imaging phase (if an imaging-based system is used) and patient and surgeon data during surgery. This patient and surgeon data may be used to gain insight into the surgical procedure, and surgeons could learn from it when this data is stored and owned by the patient and orthopedic surgeons. However, this data may also be used and owned by medical device companies with patients and surgeons having to ask medical device companies to get access to their own data. Moreover, this data may be used for commercial reasons such as development of artificial intelligence algorithms for e.g. pre-planning software. While this may sound as future issues, there are medical device companies that already store patient and surgeon data associated with robotic TKR. Some companies even openly mention on their websites that their databases contain over a million patient records and over a 100 million actionable data points. With robotic TKR centering around the capture and use of data, it is becoming increasingly important that surgeons are familiar with best practice on data governance to act as guardians not only for their own but also for their patients' data [16]. Lack of financial conflicts of interest is crucial for this role.

3. Conclusion

Technology assistance in primary TKR includes navigated TKR, PSI TKR and robotic TKR. In general, these technologies result in higher accuracy of component positioning and alignment, but this is likely not clinically relevant as no clinically important difference in clinical outcomes, quality of life and complications such as revisions has been demonstrated in meta-analyses of randomized controlled trials.

4. Expert opinion

As technology assistance in primary TKR is increasingly used to capture patient and surgeon data, surgeons have an increasingly important role in protecting their patients' data and their own data [16]. This particularly important for robotic TKR where the question arises: should patients and surgeons give up their data to medical device companies without any clear clinical benefit?

In the next 5 years, high quality randomized controlled trials on clinically relevant outcomes are needed to determine the relevance of technologically assistance in primary TKR, if any. These RCTs should take up the challenge of adequately addressing blinding of caregivers and patients especially when dealing with subjective outcomes such as patient reported outcomes or pain. For PSI TKR and robotic TKR, a pre-operative CT or MRI scan is often necessary. When only patients in the intervention group and not patients the conventional TKR groups receive such a scan pre-operatively, it is already clear before surgery what treatment the patient will receive. This lack of blinding could lead to overly optimistic results in the PSI or robotic TKR group. Other aspects that should be addressed in order to achieve adequate blinding are the additional incisions in navigated or robotic TKR that are often required for the insertion of extra pins for the sensors. These incisions are not necessary in conventional TKR, so it is apparent to patients and caregivers what treatment the patient has received by the presence or absence of extra incisions, which could lead to biased results.

The way the TKR is performed, e.g. alignment method, may be more important than the accuracy of TKR, given the lack of clinically relevant improvement for technologically assisted primary TKR compared to conventional TKR in clinical outcomes, quality of life and complications, such as revisions.

Key areas for improvement in primary TKR are improvement of patient outcomes by reducing the number of dissatisfied patients and increasing the life span of the implants resulting in lower revision rates and lower revision burden. With TKR approaching its technological limit, it will be increasingly difficult for new technologies to improve those outcomes. At the same time, the risk of worse outcomes may increase with introducing new technologies as it is not guaranteed that their outcomes will match the outcomes of well-established implants and surgical methods [17,18]. There are several examples where newly introduced technology resulted in bad outcomes, which include implant material, modular necks and metal-on-metal hip implants [13,19,20]. Critical assessment of new technologies is therefore of paramount importance.

Since technology alone will probably not be the answer, it is worth considering patient selection and selection on successful TKR implants for improvement of outcomes. For instance, it has been shown that patients with severe radiographic osteoarthritis have a better prognosis in physical functioning after TKR [21]. Similarly, it has been shown that joint replacement registries reduce the burden of revision surgeries [22]. Joint replacement registries use a variety of analyses to identify well performing implants and poor performing implants. This information guides orthopedic surgeons in choosing the optimal treatment and implant. This leads to revision rates that decrease in time [1].

Real world evidence of implant registries has also shown that TKR without technologically assistance can achieve perfectly acceptable outcomes [1]. Although there is a genuine hope that technology assisted TKR may further improve these outcomes, this hope is based on promises rather than solid evidence. At the same time, technology assisted TKR is heavily promoted including direct patient marketing, which are aspects of a hype.

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