



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER330
Topic:	Remote patient monitoring (RPM) with the robotic-assist knee balancing system for people undergoing total knee replacement arthroplasty.
Summary of findings:	<p>Health Technology Wales did not identify any published systematic reviews or randomised controlled trials that evaluated RPM when used with a robotic-assisted knee balancing system. We did identify one randomised trial that evaluated the accuracy of soft tissue balancing in total knee arthroplasty when compared to conventional measured resection. Three non-randomised primary studies were identified, although the studies did not evaluate RPM with a robotic-assist knee balancing system. One primary study aimed to validate the feasibility of a remote patient monitoring system for total knee arthroplasty, although the study did not produce any outcomes relating to clinical significance or how the application is used in adjunct to robotic-assist total knee arthroplasty.</p> <p>We identified a NICE clinical guideline that made recommendations to the care during and after a planned knee, hip, or shoulder replacement. The guidance made no specific reference or recommendations regarding RPM with a robotic knee balancing system or robotic-assist total knee arthroplasty. We identified a Health Technology Assessment (HTA) of scheduled procedures relating to the arthroplasty for osteoarthritis of the knee, although the document makes no specific reference to RPM and assist total knee arthroplasty.</p> <p>We did not identify any studies that evaluated the cost-effectiveness of RPM with a robotic knee balancing system or robotic-assist total knee arthroplasty.</p>

Introduction and aims

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of remote patient monitoring (RPM) with robotic-assist knee balancing system or robotic-assist total knee arthroplasty.

Remote patient monitoring (RPM) application is a digital platform for patients and surgeons, which is to be used with robotic-assist total knee arthroplasty. The technology can be used both before and after surgery. The RPM application would be introduced at the local hospital specialising in joint replacement, after a referral has been made by a GP. The RPM application populates the activity levels and patient reported outcome measures before and after the procedure. The data on knee soft tissue would be gathered intraoperatively by the balancing system and the healthcare professional would then determine whether the data would be available the patient. After the surgery, the RPM app would provide physiotherapy advice and continuous monitoring.

The RPM is a digital health technology and was determined to be a Tier C technology according to the [Evidence Standards Framework for Digital Health Technologies](#). Tier C evidence standards apply to digital health technologies that function as interventions. This includes technologies that are designed to self-manage or treat i.e., guides or provides treatment or allows people to self-manage a specified condition. For technologies of this classification, it is recommended that the best practice standard to demonstrate effectiveness would be to draw on randomised controlled studies carried out in a setting relevant to the UK health and social care system, comparing the digital health technology with a relevant comparator. The studies should demonstrate consistent benefit including clinical outcomes in the target population, in addition to using validated condition-specific outcome measures.

Evidence overview

Health Technology Wales did not identify any systematic reviews, economic evaluations or randomised controlled trials that evaluated the clinical or cost effectiveness of RPM in adjunct to robotic-assist total knee arthroplasty) when compared to manual total knee arthroplasty,

We did identify one study on the use of RPM with conventional knee arthroplasty. We also identified evidence on the robotic-assist knee balancing system for people undergoing total knee replacement arthroplasty, including one randomised controlled trail that evaluated the accuracy of soft tissue balancing in total knee arthroplasty when compared to conventional measured resection.

Evidence on RPM

Health Technology Wales identified one primary study Ramkumar et al. (2019), although the study does not evaluate RPM with a robotic-assist knee balancing system. This small pilot study (25 participants) aimed to validate the feasibility of a remote patient monitoring system for total knee arthroplasty, called Focus Ventures. The study analysed the frequency of data interruptions and patient acceptance. Postoperative outcome measures included step count (mobility), range of motion, patient-reported outcome measures (PROMs), opioid consumption and home exercise program (HEP) compliance. It is unclear from this study how well the RPM system can assist the robotic-assist total knee arthroplasty/balancing system, or how the application would compare to manual total knee arthroplasty.

Evidence on robotic-assisted total knee surgery

Guidance

Health Technology Wales identified relevant guidance relating to primary joint replacement in the hip, knee and shoulder (NICE 2020). The recommendation states that people should be given advice on preoperative rehabilitation such as exercises to do before and after surgery that will aid recovery. The guidance makes no specific reference or recommendations regarding robotic-assist total knee arthroplasty, robotic-assist knee balancing system or RPM.

Health technology assessment

We identified one health technology assessment (HTA) of scheduled procedures relating to the arthroplasty for osteoarthritis of the knee, published in 2014 by the Health Information and Quality Authority in Ireland (Health Information and Quality Authority 2014). The scope of the HTA was to recommend clinical referral and treatment thresholds to be used in the assessment, referral, and surgical management of patients for whom hip, or knee arthroplasty is being considered, although the HTA makes no specific reference or recommendations regarding robotic-assist total knee arthroplasty, robotic-assist knee balancing system or RPM.

Randomised controlled trials

One randomised trial in Korea analysed the accuracy of soft tissue balancing in total knee arthroplasty, comparing navigation gap balancing and conventional measured resection (Lee et al. 2010). However, the study did not evaluate the clinical or cost effectiveness of RPM in adjunct to this intervention and the cost effectiveness of the balancing system and/or RPM was not evaluated.

The study concluded that navigation-assist soft tissue balancing during total knee arthroplasty seemed to reduce postoperative alignment outliers when compared to conventional total knee arthroplasty, although the clinical outcomes between the two groups were similar.

Non-randomised primary studies

Two additional relevant primary studies were highlighted by the topic proposer relating to balanced total knee arthroplasty, although these studies do not evaluate the clinical or cost effectiveness of balanced total knee arthroplasty with RPM (Golladay et al. 2019, Shalhoub et al. 2019).

One primary study in the US aimed to compare satisfaction rates in 318 participants who underwent surgery using a robotic knee balancing system and those who underwent manual total knee arthroplasty (Golladay et al. 2019). In their results, 84% of patients (136 out of 162) were observed to have balanced knees, compared to 50% (86 out of 170) in the surgeon-guided (manual) group.

Another retrospective study in the US aimed to evaluate the ability of a robotic-assist gap-balancing technique to achieve a balanced knee (Shalhoub et al. 2019). The study found that over 90% of knees achieved mediolateral balance (129 participants).

Economic evidence

We did not identify any published economic evidence for RPM with the robotic-assist knee balancing system. The topic proposer highlighted a book chapter (Koenig & Plaskos 2019) that compared procedural costs for over the 90-day episode of care period were compared for patients undergoing either conventional or robotic-assisted total knee arthroplasty. The chapter could not be accessed by HTW researchers at the time of this topic exploration report, but the topic proposer reports that average total cost per episode was lower for patients receiving robotic-assisted surgery versus conventional surgery (\$28,943 versus \$31,028).

Areas of uncertainty

We did not find evidence evaluating the clinical or cost effectiveness of RPM with robotic-assist knee balancing system. The evidence identified includes a comparison of robotic knee balancing system to manual total knee arthroplasty, or a comparison of the satisfaction rates between the two procedures, or the feasibility of RPM for total knee arthroplasty and not necessarily with the robotic-assist knee balancing system. Based on limited clinical evidence found in this report, it is unclear whether use of RPM application with robotic-assisted knee balancing system leads to greater system benefits and improved outcomes when compared to standard practice in the UK.

Literature search results

Health technology assessments and guidance

NICE. (2020). Joint replacement (primary): hip, knee and shoulder [NG157]. UK: National Institute for Health and Care Excellence. Available at: <https://www.nice.org.uk/guidance/ng157> [Accessed 16 February 2022].

Health Information and Quality Authority. (2014). Health Technology Assessment of Scheduled Procedures: Arthroplasty for osteoarthritis of the knee. Available at: <https://www.hiqa.ie/reports-and-publications/health-technology-assessment/hta-scheduled-procedures-phase-iii> [Accessed 16 February].

Evidence reviews and economic evaluations

No evidence identified

Individual studies

Lee DH, Park JH, Song DI, et al. (2010). Accuracy of soft tissue balancing in TKA: comparison between navigation-assisted gap balancing and conventional measured resection. *Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA*. 18(3): 381-7. doi: 10.1007/s00167-009-0983-x <https://pubmed.ncbi.nlm.nih.gov/19924399/>

Ramkumar PN, Haeberle HS, Ramanathan D, et al. (2019). Remote Patient Monitoring Using Mobile Health for Total Knee Arthroplasty: Validation of a Wearable and Machine Learning-Based Surveillance Platform. *J Arthroplasty*. 34(10): 2253-9. doi: 10.1016/j.arth.2019.05.021 <https://www.sciencedirect.com/science/article/abs/pii/S0883540319304954>

Ongoing research

No evidence identified

Evidence supplied by topic proposer

Golladay GJ, Bradbury TL, Gordon AC, et al. (2019). Are Patients More Satisfied With a Balanced Total Knee Arthroplasty? *J Arthroplasty*. 34(7s): S195-s200. doi: 10.1016/j.arth.2019.03.036 <https://pubmed.ncbi.nlm.nih.gov/31079993/>

Koenig JA, Plaskos C. (2019). Total Knee Arthroplasty Technique: OMNIBotics. In: Lonner JH (ed.) *Robotics in Knee and Hip Arthroplasty: Current Concepts, Techniques and Emerging Uses*. Cham: Springer International Publishing. https://link.springer.com/chapter/10.1007/978-3-030-16593-2_17

Shalhoub S, Lawrence JM, Keggi JM, et al. (2019). Imageless, robotic-assisted total knee arthroplasty combined with a robotic tensioning system can help predict and achieve accurate postoperative ligament balance. *Arthroplast Today*. 5(3): 334-40. doi: 10.1016/j.artd.2019.07.003. <https://pubmed.ncbi.nlm.nih.gov/31516978/>

Date of search:	February 2022
Concepts used:	Ligament balancing, soft tissue balancing, remote patient monitoring (RPM) with robotic-assisted knee balancing system, robotic-assist total knee arthroplasty, knee replacement surgery