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Active or semi-active robotic arm-assisted versus manual knee arthroplasty: benefits and risks

Hermodsson J, Bäckman L, Hongslo Vala C, Jivegård L, Mohaddes M, Petzold M, Saari T, Stålfelt F, Svanberg T, Svensson M, Bernhardsson S.

Active or semi-active robotic arm-assisted versus manual knee arthroplasty: benefits and risks

[Aktiv eller semiaktiv robotassisterad knäplastik jämfört med manuell knäplastik: nytta och risker]

Hermodsson J[1*], Bäckman L[2], Hongslo Vala C[3], Jivegård L[3], Mohaddes M[1], Petzold M[3], Saari T[1], Stålfelt F[1], Svanberg T[2], Svensson M[3], Bernhardsson S[3].

[1]Region Västra Götaland, Sahlgrenska University Hospital, Dept of Orthopaedics, Gothenburg, Sweden

[2]Medical Library, Region Västra Götaland, Sahlgrenska University Hospital, Gothenburg, Sweden

[3]HTA-centrum of Region Västra Götaland, Gothenburg, Sweden.

[*]Corresponding author

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1. Abstract

Background

The most common surgical treatment for end stage knee osteoarthritis is total or unicompartmental knee arthroplasty. In Region Västra Götaland, implant revision rates are 4.5% and 16% after total and unicompartmental knee arthroplasty, respectively. Robotic arm-assisted active (robot-driven surgery) or semi-active (surgeon-driven, robot provides tactile feedback) knee arthroplasty has been developed to improve surgical accuracy and patient outcomes.

Question at issue

Is active or semi-active robotic arm-assisted total (rTKA) or unicompartmental (rUKA) knee arthroplasty for patients in need of surgery better than manual total (mTKA) or unicompartmental (mUKA) knee arthroplasty regarding mortality, function, revision, complications, implant positioning, health-related quality of life, pain, length of stay, operation time, learning curve, and patient experiences?

Methods

During May 2021 two authors performed systematic searches in five databases, selected studies, assessed abstracts, and made a first selection of full-text articles. All authors read and then decided in consensus which articles finally should be included. These articles were critically appraised, and data were extracted by one author and checked by another. When possible, data were pooled and subjected to meta-analysis. Certainty of evidence was assessed using the GRADE approach. We identified published values for minimal important difference.

Results

Eight randomised controlled trials (RCTs) (11 articles, 1,921 patients), and 15 cohort studies (up to 755,350 patients each) were included. Four RCTs evaluated active rTKA, two RCTs and eight cohort studies semi-active rTKA, and two RCTs and two cohort studies semi-active rUKA. Remaining studies did not specify system. The RCTs generally suffered from some or serious study limitations and serious imprecision, and the cohort studies from some study limitations, some indirectness, and uncertain precision.

<u>Patient-reported function</u> was assessed using seven different validated scales. There may be little or no important difference in short and intermediate-to-long term knee function between active rTKA and mTKA (GRADE ⊕⊕◯◯). For semi-active rUKA, short-term (within 1 year) knee function is probably slightly improved compared with mUKA, while there is probably no difference in intermediate-to-long term function (GRADE ⊕⊕⊕◯).

<u>Revision rate:</u> There may be no difference in intermediate-to-long-term revision rates between active rTKA and mTKA, although the confidence interval includes both lower and higher revision rate for rTKA (GRADE ⊕⊕◯◯). For semi-active rTKA versus mTKA, there may be no difference in short-term revision rate, although the confidence interval includes both higher and lower revision rate for rTKA, while intermediate-term revision rate may be lower for rTKA (GRADE ⊕⊕◯◯). For semi-active rUKA, short-term (within < 90 days) revision rate may be lower than with mUKA (GRADE ⊕⊕◯◯). For long-term revision rate, it is uncertain whether there is any difference between rUKA and mUKA (GRADE ⊕◯◯◯).

Complications were generally not predefined. The results suggest that there are no major differences in complications between the rTKA/UKA and mTKA/UKA.

Implant positioning may be improved with active rTKA compared with mTKA (GRADE ⊕⊕◯◯), and is probably improved with both semi-active rTKA and rUKA compared with mTKA and mUKA, respectively (GRADE ⊕⊕⊕◯).

Length of hospital stay: There may be little or no difference in length of stay between active rTKA and mTKA (GRADE ⊕⊕◯◯), as well as between semi-active rUKA and mUKA (GRADE ⊕⊕◯◯).

Pain: There is probably little or no difference in long-term pain for rTKA versus mTKA, nor in short- or long-term pain for semi-active rUKA versus mUKA (GRADE ⊕⊕⊕◯).

Health-related quality of life: There may be little or no difference in short- or long-term for active rTKA versus mTKA (GRADE ⊕⊕◯◯), and there is probably little or no difference in long-term health-related quality of life for semi-active rUKA versus mUKA (GRADE ⊕⊕⊕◯).

Operating time may be longer for active rTKA than for mTKA. There may be little or no difference in operating time between semi-active rTKA and mTKA (GRADE ⊕⊕◯◯). Available data suggest a learning curve for semi-active rTKA regarding operating time, but not regarding implant positioning (certainty of evidence not assessed).

Costs: Additional costs for robot arm-assisted knee arthroplasty are difficult to estimate but amount to approximately 1-2 million SEK/year depending on robot system, implying an estimated additional cost per patient of 4,000-99,000 SEK (for annual case volume 250 and 20, respectively). The current average cost for mTKA and mUKA is 98,000 SEK and 68,000 SEK, respectively.

Conclusions

This HTA report shows that although both rTKA and rUKA probably improve implant positioning, no long-term patient benefits could be identified concerning the patient-related outcomes knee function and health-related quality of life, for any robotic arm-assisted technique in comparison to manual knee arthroplasty. However, intermediate-term revision rate may be lower with semi-active rTKA than with mTKA and short-term revision rate may be lower after rUKA than after mUKA. Knee function within one year is probably improved after rUKA compared with mUKA, but not after rTKA compared with mTKA.

2. Populärvetenskaplig sammanfattning – Plain language summary in Swedish

Bakgrund

Den vanligaste kirurgiska behandlingen för svår knäartros är knäprotesoperation omfattande ena eller både inre och yttre ledytan i knät. I Västra Götalandsregionen behöver operationen göras om för 4,5 % respektive 16 % av patienterna efter total respektive partiell proteskirurgi. Robotarm-assisterad aktiv (robotdriven kirurgi) eller semi-aktiv (roboten ger taktil återkoppling till kirurgen) knäprotesoperation har utvecklats i syfte att förbättra operationsnoggrannhet och resultat.

Fokuserad fråga

Är aktiv eller semi-aktiv robotarm-assisterad total (rTKA) eller partiell (rUKA) knäproteskirurgi bättre än manuell total (mTKA) respektive partiell (mUKA) knäproteskirurgi avseende mortalitet, funktion, revisionsfrekvens, komplikationer, implantatpositionering, hälsorelaterad livskvalitet, smärta, vårdtid, operationstid, upplärning av kirurgteamet och patienterfarenheter?

Metod

I maj 2021 gjorde två av författarna systematiska sökningar i fem databaser, valde ut studier, bedömde abstrakt och gjorde ett första urval av fulltextartiklar. Alla författare läste sedan och beslutade i konsensus vilka artiklar som slutligen skulle inkluderas. Dessa artiklar granskades kritiskt och data extraherades av en och kontrollerades av en annan författare. När så var möjligt poolades data och metaanalyserades. Resultatens tillförlitlighet utvärderades enligt GRADE. Vi identifierade publicerade värden för minsta kliniskt viktiga skillnad.

Resultat

Åtta RCT:er (11 artiklar, totalt 1 921 patienter) och 15 kohortstudier (med upp till 755 350 patienter vardera) inkluderades. Fyra RCT:er utvärderade aktiv rTKA, två RCT:er och åtta kohortstudier semi-aktiv rTKA, och två RCT:er och två kohortstudier semi-aktiv rUKA. Resterande studier specificerade inte system. RCT:erna hade generellt vissa eller allvarliga begränsningar i studiekvalitet och allvarliga begränsningar i precision, medan kohortstudierna hade vissa begränsningar i studiekvalitet och överförbarhet samt osäker precision.

Patientrapporterad funktion bedömdes med sju olika validerade skalor. Det kan finnas liten eller ingen betydelsefull skillnad i funktion på kort och lång sikt mellan aktiv rTKA och mTKA (GRADE ⊕⊕◯◯). Knäfunktionen är troligen något bättre efter semi-aktiv rUKA jämfört med mUKA på kort sikt (inom 1 år), medan det sannolikt inte är någon skillnad på medellång och lång sikt (GRADE ⊕⊕⊕◯).

Revisionsfrekvensen kan vara oförändrad vid aktiv rTKA jämfört med mTKA på medellång till lång sikt, men konfidensintervallen inkluderar både en högre och en lägre frekvens för rTKA. För semi-aktiv rTKA kan revisionsfrekvensen vara oförändrad på kort sikt (inom <90 dagar) jämfört med mTKA, men konfidensintervallen inkluderar både en högre och en lägre frekvens för rTKA. På medellång till lång sikt kan revisionsfrekvensen vara lägre för semi-aktiv rTKA än för mTKA. För semi-aktiv rUKA kan revisionsfrekvensen på kort sikt vara lägre än för mUKA (GRADE ⊕⊕◯◯).

Komplikationer var i allmänhet inte fördefinierade. Resultaten antyder att det inte föreligger några större skillnader vad gäller komplikationer mellan rTKA/UKA och mTKA/UKA.

Implantatpositionering kan förbättras med aktiv rTKA jämfört med mTKA (GRADE ⊕⊕◯◯) och förbättras troligen med både semi-aktiv rTKA och rUKA jämfört med manuell knäplastik (GRADE ⊕⊕⊕◯).

Vårdtiden kan vara oförändrad mellan aktiv rTKA och mTKA (GRADE ⊕⊕◯◯), liksom mellan semi-aktiv rUKA och mUKA (GRADE ⊕⊕◯◯).

Smärta: Det är troligen liten eller ingen skillnad i smärta på lång sikt mellan rTKA och mTKA, eller i smärta på kort och lång sikt för semi-aktiv rUKA jämfört med mUKA (GRADE ⊕⊕⊕◯).

Hälsorelaterad livskvalitet kan vara oförändrad på kort och lång sikt mellan aktiv rTKA och mTKA (GRADE ⊕⊕◯◯) och det är troligen liten eller ingen skillnad på lång sikt mellan semi-aktiv rUKA och mUKA (GRADE ⊕⊕⊕◯).

Operationstiden är troligen längre för aktiv rTKA jämfört med mTKA (GRADE ⊕⊕⊕◯). Det kan föreligga liten eller ingen skillnad i operationstid mellan semi-aktiv rTKA och mTKA (GRADE ⊕⊕◯◯). Tillgängliga data tyder på en inlärningskurva för semi-aktiv rTKA avseende operationstid, men inte avseende implantatpositionering (tillförlitligheten ej bedömd).

Förväntade tillkommande kostnader för robotarm-assisterad knäledsplastik är svåra att uppskatta men uppskattas till cirka 1-2 miljoner SEK/år beroende på robotsystem, vilket skulle leda till en uppskattad merkostnad per patient på 4 000 – 99 000 SEK (för årliga operationsvolymer på 250 respektive 20 ingrepp). Aktuell genomsnittlig kostnad för mTKA och mUKA är 98 000 respektive 68 000 SEK.

Sammanfattande bedömning

Denna HTA-rapport visar att även om både rTKA och rUKA troligen förbättrar implantatpositioneringen så kunde ingen långsiktigt förbättrad nytta avseende de patientrelaterade utfallen knäfunktion och hälsorelaterad livskvalitet identifieras för någon av de robotarm-assisterade teknikerna jämfört med motsvarande manuell teknik. Däremot kan behovet av revisionsoperation på medellång sikt vara lägre efter semi-aktiv rTKA än efter mTKA och på kort sikt efter rUKA än efter mUKA. En förbättrad knäfunktion inom ett år observerades för rUKA jämfört med mUKA, men inte för rTKA jämfört med mTKA.

The above summaries were written by representatives from the HTA-centrum. The HTA report was approved by the Regional board for quality assurance of activity-based HTA. The abstract is a concise summary of the results of the systematic review. The plain language summary in Swedish is intended for decision makers.

Christina Bergh, Professor, MD

Head of HTA-centrum of Region Västra Götaland, Sweden, 2 May 2022

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DDS Doctor of dental surgery

MD Medical doctor

PhD Doctor of Philosophy

OD Odontology doctor

PT Physiotherapist

RN Registered Nurse

3. Summary of findings

PICO 1: Active robotic arm-assisted vs manual total knee arthroplasty

Outcomes	**Study design Number of tudies (patients)**	**Relative effect (95% CI)**	**Absolute effect (SD or 95% CI)**	**Certainty of evidence GRADE*** significance /direction
		Critical outcomes		
Mortality	NR			
Function	1 RCT (n=60) 4 RCTs (n=1,491)		*Short term* KSS rTKA: 152.1 (SD 25.19) mTKA: 152.6 (SD 21.43) MD -0.50 (-12.38 to 11.38) *Intermediate-to-long term* KSS WMD -1.01 (-1.92 to 0.10) WOMAC WMD -1.10 (-2.38 to 0.17)	⊕⊕◯◯[1] ns ⊕⊕◯◯[2] ns
Revision	3 RCTs (n=143) 4 RCTs (n=1,491)	*Intermediate-to-long term* RR 1.09 (0.54 to 2.16)	*Short term* rTKA: 0/111 mTKA 0/109 *Intermediate-to-long term* rTKA: 16/835 (1.92%) mTKA: 14/833 (1.66%)	⊕◯◯◯[3] ⊕⊕◯◯[4] ns
		Important outcomes		
Implant positioning	3 RCTs (n=220)	Mechanical axis outliers RR 0.06 (0.01 to 0.33)	Mechanical axis outliers rTKA: 0/111 (0%) mTKA: 23/109 (21.1%)	⊕⊕◯◯[5] Favouring rTKA
Length of stay	1 RCT (n=60)		rTKA: 5.2 days (SD 2.3) mTKA: 5.8 days (SD 3.8) between-group difference: 0.6 (ns)	⊕⊕◯◯[6] ns
Pain	1 RCT (n=1,348)		*Long term (13 ± 5 years)* rTKA no pain: 85% mTKA no pain: 82% rTKA mild pain: 13% mUKA mild pain: 16% rTKA severe pain: 2% mUKA severe pain: 2% ns	⊕⊕⊕◯[7] ns

Health-related quality of life	1 RCT (2 articles) (n=60)		*Short term* 6 months SF-36 Physical Component Score: rTKA: 46.2 (9.1) mTKA: 46.7 (11.6) MD 0.5 (95% CI -5.9 to 4.9) SF-36 Mental Component Score: rTKA: 57.0 (8.8) mTKA: 52.6 (9.7) MD 4.5 (95% CI -0.3 to 9.2) *Intermediate-to-long term* 24 months SF-36 Physical Component Score: rTKA:50.3 (7.0) mTKA: 46.2 (13.9) MD 4.1 (-1.7 to 9.8) SF-36 Mental Component Score: rTKA: 59.3 (9.8) mTKA: 54.7 (10.3) MD 4.6 (-0.8 to 9.9)	⊕⊕◯◯[8] ns ⊕⊕◯◯[8] ns
Operating time	4 RCTs (n=1,668)		WMD 19.1 minutes (95% CI 5.3 to 32.8)	⊕⊕◯◯[9] Favouring mTKA

CI: Confidence interval; MD: Mean difference; mTKA: Manual total arthroplasty; NR: Not reported; ns: Not significant; RCT: Randomised controlled trial; rTKA: Robot-assisted total arthroplasty; WMD: Weighted mean difference

KSS: Knee Society Score (range 0–200, higher better, MID 13.6)
WOMAC: Western Ontario and McMaster Universities Arthritis Index (range 0-96, higher worse, MID 10 points)
SF-36: Short form, 36 items (Score range 0-100, higher better, MID 10 points)

[1] Downgraded one level for serious study limitations and one level for serious imprecision
[2] Downgraded one level for serious study limitations and one level for some uncertainties regarding directness and precision
[3] Downgraded one level for serious study limitations and two levels for very serious imprecision
[4] Downgraded one level for serious study limitations and one level for serious imprecision
[5] Downgraded one level for serious study limitations and serious imprecision
[6] Downgraded one level for serious study limitations and one level for serious imprecision
[7] RCT downgraded one level for some study limitations and some uncertainty regarding directness and precision
[8] Downgraded one level for serious study limitations and one level for serious imprecision
[9] Downgraded one level for serious study limitations and one level for uncertainties regarding indirectness, inconsistency and precision

PICO 2: Semi-active robotic arm-assisted vs manual total knee arthroplasty

Outcomes	Study design Number of studies (patients)	Relative effect (95% CI)	Absolute effect (SD or 95% CI)	Certainty of evidence **GRADE*** significance/direction
Critical outcomes				
Mortality	1 cohort study (n=198,371)		rTKA: 0.39% (0.19 to 0.59) mTKA: 0.30% (0.27 to 0.32) Absolute risk reduction: 0.09% (-0.11 to 0.30)	⊕◯◯◯[1]
Function	2 cohort studies (n=7,969)		*Short term* KOOS-JR WMD -2.40 points (95% CI -5.39 to 0.58) PROMIS-PH rTKA: (n=67/290): 48.62 (variance 53.07) mTKA: (n=170/900): 49.43 (variance 77.56) ns FJS rTKA: (n=42/367) 20.55 (SD 20.56) mTKA: (n=404/6,442) 26.50 (SD 23.51) MD -5.95; p-value NR	⊕◯◯◯[2]
	1 cohort study (n=6,809)		*Intermediate-to-long term* FJS rTKA (n=41/367): 38.27 (SD 24.74) mTKA (n=436/6,442): 41.83 (SD 27.1 MD -3.56; p-value NR KOOS-JR rTKA (n=55/367): 67.17 (SD 15.2) mTKA(n=673/6,442): 70.65 (SD 15.65 MD -3.48; p-value NR	⊕◯◯◯[2]
Revision	1 RCT (n=30)	*Short term*	*Short term* rTKA: 0/15 mTKA: 0/15	⊕⊕◯◯[3] ns
	2 cohort studies (762,159)	RR 1.14 (0.85 to 1.53)	rTKA: 44/5,595 (0.79%) mTKA: 5,505/756,564 (0.73%)	
	1 cohort study (755,350)	*Intermediate-to-long term* OR 0.83 (0.70 to 0.97)	*Intermediate-to-long term* rTKA: 151/5,077 (2.97%) mTKA: 25,060/725,062 (3.46%)	⊕⊕◯◯ Favouring rTKA

Important outcomes				
Implant positioning	2 RCTs (n=90)	Mechanical axis outliers rTKA: 1/32 (3.1%) mTKA: 8/28 (28.6%) p=0.019	Error of mechanical axis rTKA: mean 1.8 (SD 1.2) mTKA: mean 3.0 (SD 2.4) p=0.019 Error in planned limb alignment rTKA: 1.2 RMSE (SD 0.7) mTKA: 3.1 RMSE (SD 1.3) p<0.001	⊕⊕⊕◯[4] Favouring rTKA
Length of stay	9 cohort studies (n=1,586,216)		WMD 0.7 days (-0.7 to 2.0)	⊕◯◯◯[5]
Learning curve	2 cohort studies (n=729)		Operating time Significantly lower in last 20 vs first 20 cases of rTKA. No difference between last 20 cases of rTKA and mTKA.	Not assessed
Pain	1 cohort study (n=492)		*Short term* Postoperative pain (0-4 days) (0-10 VAS) rTKA: mean pain levels 5.4-5.5 mTKA: mean pain levels 5.1-5.8; ns	⊕◯◯◯[6]
Health-related quality of life	NR			
Operating time	1 RCT (n=30) 4 cohort studies (n=2,581)		rTKA: mean 62.4 (SD 3.4) min mTKA: mean 64.1 (SD 3.1) min between-group difference: 1.0; ns WMD -2.0 min (95% CI -11.6 to 7.6)	⊕⊕◯◯[7] ns

CI: Confidence interval; MD: Mean difference; mTKA: Manual total arthroplasty; NR: Not reported; ns: Not significant; RCT: Randomised controlled trial; RMSE: Root Mean Square Error; rTKA: Robot-assisted total arthroplasty; WMD: Weighted mean difference

FJS: Forgotten Joint Score (range 0-100, higher better, MCID 13.7)
KOOS-JR: Knee Osteoarthritis Outcome Score, Joint Replacement (range 0-100, higher better, MID: 6.8 points)
PROMIS-PH: Patient-Reported Outcomes Measurement Information System, Physical Health (range 0-100, higher better, MCID 32.5)
SF-12: Short form, 12 items (range 0-100, higher better)
VAS: Visual analogue scale (range 0-100, higher better); WMD: Weighted mean difference

[1] Downgraded one level for serious imprecision
[2] Downgraded one level for serious study limitations, uncertain precision
[3] RCT downgraded one level for some study limitations and some indirectness, and one level for serious imprecision
[4] Downgraded one level for some study limitations, some inconsistency, some indirectness and some imprecision
[5] Downgraded one level for some study limitations, some inconsistency and serious imprecision
[6] Downgraded one level for some study limitations and some imprecision
[7] RCT downgraded one level for some study limitations, some indirectness and some imprecision, cohort studies downgraded one level for some inconsistency and serious imprecision

PICO 3: Semi-active robotic arm-assisted vs manual unicompartmental knee arthroplasty

Outcomes	Study design Number of studies (patients)	Relative effect (95% CI)	Absolute effect (SD or 95% CI)	Certainty of evidence GRADE* significance/ direction
Critical outcomes				
Mortality	NR			
Function	2 RCTs (n=202)		*Short term* KSS WMD 14.48 (95% CI 2.76 to 26.19) OKS rUKA: median 35 (Q1 29, Q3 41) mUKA: 33 (Q1 23, Q3 38) between-group difference 2 (ns) FJS WMD 11.97 (95% CI 4.26 to 19.67 (favouring rUKA).	⊕⊕⊕◯[1] Favouring rUKA
	1 RCT n=136/109		*Intermediate-to-long term* FJS rUKA: median 55.2 (Q1 23.3, Q2 81.8) mUKA: median 54.1 (Q1 37.0, Q2 79.2) between-group difference 0.9 (ns) OKS rUKA: median 40 (Q1 32, Q3 44) mUKA: 39 (Q1 33, Q3 44) between-group difference 1 (ns)	⊕⊕⊕◯[1] ns
Revision		*Short term*	*Short term*	⊕⊕◯◯[2] Favouring rUKA
	1 RCT (n=129)	rUKA: 0/64 mUKA 0/65		
	1 cohort study (n=35,061)	RR 0.21 (0.12 to 0.36)	rUKA: 14/13,617 (0.10%) mUKA: 107/21,444 (0.50%)	
		Intermediate-to-long term	*Intermediate-to-long term*	⊕◯◯◯[3]
	2 RCTs (n=180)	RR 0.74 (95% CI 0.05 to 10.51)	rUKA: 1/91 (1.11%) mUKA 2/89 (2.25%)	
	3 cohort studies (n=48,211)	RR 0.35 (0.20 to 0.60)	rUKA: 207/16,931 (1.22%) mUKA 1,185/31,497 (3.76%)	
Important outcomes				

Implant positioning	1 RCT (n=120)		Lower RMSE and lower median errors in all component parameters (p<0.01)	⊕⊕⊕◯[4] Favouring rUKA
Length of stay	1 RCT (n=129) 1 cohort study (n=738)		MD -0.5 days; ns rUKA: mean 1.8 days mUKA: 2.0 days MD -0.2 (p=0.0047) favouring rUKA	⊕⊕◯◯[5] Little or no difference
Pain	1 RCT (2 papers) (n=136/112)		*Short term* Median pain at 8 weeks (VAS) 55.4% lower after rUKA than after mUKA (p=0.040) Median pain at 3 months (VAS) rUKA: 8 (IQR 2-21) mUKA: 9 (IQR 4-28) between-group difference 1.0 (ns) Median pain at 12 months (VAS) rUKA: 4.5 (IQR 2-18) mUKA: 5.0 (IQR 1-23) between-group difference 0.5 (ns) *Long term* Median pain at 24 months (VAS) rUKA: 3.0 (IQR 1.0-26.0) mUKA: 5.0 (IQR 2.0-16.8) between-group difference 2.0 (ns)	⊕⊕⊕◯[6] Little or no difference ⊕⊕⊕◯[6] ns
Health-related quality of life	1 RCT (n=112)		*Intermediate term* 12 months (SF-12) . SF-12 Physical Component Score rUKA: 46.8 (9.8) mUKA: 44.6 (9.8) MD 2.2 (95% CI -1.09 to 5.49) SF-12 Mental Component Score: rUKA: 54.9 (8.3) mUKA:54.6 (8.3) MD 0.3 (95% CI -2.67 to 3.27)	⊕⊕⊕◯[6] ns
Operating time	NR			

CI: Confidence interval; MD: Mean difference; rUKA: Robot-assisted unicompartmental arthroplasty; mUKA: Manual unicompartmental arthroplasty; NR: Not reported; ns: Not significant; RCT: Randomised controlled trial; RMSE: Root Mean Square Error; WMD: Weighted mean difference

FJS: Forgotten Joint Score (range 0-100, higher better, MCID 13.7)
KSS: Knee Society Score (range 0–200, higher better, MID 13.6)
OKS: Oxford Knee Score (range 0-48, higher better, MCID: 7.4)
VAS: Visual analogue scale (range 0-100, higher better); WMD: Weighted mean difference

[1] Downgraded one level for some study limitations and some imprecision
[2] RCT downgraded two levels for very serious imprecision. Cohort study downgraded one level for some study limitations and some imprecision, and upgraded one level due to large magnitude of effect (OR<0.5)
[3] RCTs downgraded one level for some study limitations and some inconsistency, two levels for very serious imprecision; cohort studies downgraded one level for some study limitations and some indirectness

[4] Downgraded one level for some study limitations and uncertain precision
[5] RCT downgraded one level for some study limitations and uncertain precision and one level for inconsistency with the cohort study
[6] Downgraded one level for serious imprecision

*) Certainty of evidence High certainty ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty ⊕⊕⊕◯	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty ⊕⊕◯◯	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty ⊕◯◯◯	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

4. Abbreviations/Acronyms

AKSS	American Knee Society Score
CI	Confidence Interval
FJS	Forgotten Joint Score
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HRQoL	Health-related Quality of Life
HSS	Hospital for Special Surgery
HTA	Health Technology Assessment
IQR	Interquartile range
KSS	Knee Society Score
KOOS-JR	Knee Osteoarthritis Outcome Score – Joint Replacement
MD	Mean Difference
MCID	Minimal Clinically Important Difference
MID	Minimal Important Difference
mKA	Manual Knee Arthroplasty
mTKA	Manual Total Knee Arthroplasty
mUKA	Manual Unicompartmental Knee Arthroplasty
ns	not significant
OKS	Oxford Knee Score
OR	Odds Ratio
PROMIS-PH	Patient-Reported Outcomes Measurement Information System, Physical Health
PROM	Patient-reported Outcome Measure
Q1/3	Quartile
RAS	Robotic arm-assisted surgery
RCT	Randomised Controlled Trial
RMSE	Root mean square error
RR	Risk ratio
rKA	Robotic-assisted Knee Arthroplasty
rTKA	Robotic-assisted Total Knee Arthroplasty
rUKA	Robotic-assisted Unicompartmental Knee Arthroplasty
SD	Standard deviation
SF-12/36	Short Form Health Survey
SU	Sahlgrenska University Hospital (Sahlgrenska universitetssjukhuset)
TKA	Total Knee Arthroplasty
UCLA	University of California Los Angeles activity-level rating scale
UKA	Unicompartmental Knee Arthroplasty
VAS	Visual Analogue Scale
VGR	Region Västra Götaland (Västra Götalandsregionen)
WMD	Weighted Mean Difference
WOMAC	Western Ontario and McMaster Universities Arthritis Index

5. Background

Disease/disorder of interest and its degree of severity

Most patients who are candidates for joint arthroplasty suffer from osteoarthritis, a disease that affects joint cartilage in both large and small joints, predominantly knee and hip. Less common indications for knee arthroplasty include posttraumatic osteoarthritis, osteo-necrosis, and with a declining incidence rheumatoid arthritis. Besides causing pain, gait difficulty and reduced function, at variable severity, osteoarthritis may entail an increased risk for cardiovascular disease and excess cardiovascular death rates which may be assuaged with total joint arthroplasty (Turkiewicz et al., 2019, Ravi et al., 2013).

Prevalence and incidence

Osteoarthritis affects nearly 7% of the global population and was the 15th highest cause of years lived with disability, with a total global share of 2% of all years lived with disability and with a higher share in developed countries. The prevalence in high income countries is around 15% (Global Burden of Disease, 2019). One in four Swedes over the age of 45 suffer from osteoarthritis, and the prevalence is predicted to increase (Englund et al., 2014). The challenge in defining the aetiology and diagnosis of osteoarthritis makes assessments of its prevalence more difficult. People with knee osteoarthritis have an almost twofold increased risk of sick leave compared with the general population and account for about 2% of all sick days in Sweden (Hubertsson et al., 2013).

Normal pathway for patients with osteoarthritis through the healthcare system and current wait time for medical assessment/treatment

Patients are most often referred from primary care to orthopaedic specialists in hospital settings. Patients are listed to undergo surgery after a consultation with the specialist, who confirms the diagnosis, assesses the degree of symptom burden and quality of life, considers the patient’s general health and fitness for surgery, and establishes whether further conservative treatment is a viable alternative to surgery. The waiting times in Region Västra Götaland (VGR) range from 4-5 weeks to 13 months or more, depending on potential complicating factors to surgery (SKR 2022). Currently (February 2022) waiting times exceed 12 months for nearly 50% of patients listed to undergo elective primary knee arthroplasty at the Sahlgrenska University Hospital (SU) (internal hospital records). However, this is a unique situation due to the Covid-19 pandemic.

Present treatment

Osteoarthritis is a chronic condition with a complex and elusive aetiology and the difficulty in finding medical treatments likely depends on the biomechanical component of osteoarthritis, where prevention through avoidance of joint trauma and weight loss have gained general acceptance as the only sufficiently evidence-merited interventions (Johnson et al., 2014). Many patients will, however, attain adequate symptom relief with analgesics and/or physiotherapy/ exercise.

Treatment of “end stage disease”, whereby symptoms and radiological findings indicate that conservative treatment is no longer successful in managing symptoms, is surgical treatment. There are different surgical treatments for osteoarthritis of knee. The most common surgical treatment for osteoarthritis of the knee is total knee arthroplasty (TKA), which together with total hip arthroplasty are two of the most common surgical treatments in orthopaedics.

The knee joint is divided into three different compartments usually affected at different severities as the disease progresses. This provides an opportunity to replace only one compartment by means of a unicompartmental knee arthroplasty (UKA), which is considered a less invasive procedure than a TKA.

10-15% of patients who undergo knee arthroplasty report that they are not fully satisfied with the procedure, and nearly 20% report difficulties with their gait (SKAR, 2020, Noble et al., 2006). In recent years the ten-year implant survivorship rates of TKA approach 95% in Sweden (SKAR, 2020). The rate of patients requiring revision or reoperation of their TKA is 1.5% at one year, 3% at three years, and 4.5% after ten years in VGR. The corresponding frequencies for UKA are 3% at one year, 7% at three years, and 16% at ten years. The recovery from UKA is faster than for TKA, as the surgical trauma to the knee joint and surrounding soft tissues is less extensive prompting proponents of the technique to consider it a minimally invasive and vital ligament-preserving procedure.

Especially UKA requires precise positioning of the implant and studies show that placement of the implant affects the implant performance to a much higher degree than for, e.g. TKA and partial or total hip arthroplasty (Aleto et al., 2008, Tsai et al., 2016). Implant positioning does, however, play an important role in preventing wear, bone attrition, and dislocation also in the latter three procedures (Sharkey et al., 2002). Suboptimal knee implant positioning, i.e. malalignment, is associated with prosthetic loosening (Bonner et al., 2011) and an axis deviation of more than 3° significantly increases the risk of TKA failure (Liu et al., 2016). Correct knee implant positioning has also been associated with improved knee function (Choong et al., 2009, Gøthesen et al., 2014, van Lieshout et al., 2019). The positioning of a knee implant is determined and planned using preoperative radiographs but may also be adjusted intraoperatively. A preoperative plan may be compared with a postoperative radiograph to ascertain precision of implant placement in different planes as well as of the limb alignment.

The average length of hospital stay at SU in 2019 was approximately 2.5 days for TKA and 1.7 days for UKA (internal hospital records). Most patients operated with a primary knee arthroplasty rehabilitate in their home with some requiring short-term care home stay and others seeking assistance from a physiotherapist in primary care. Rehabilitation times vary and may take up to a year, with most patients not recovering their quadriceps strength after six months, although UKA patients seem to improve faster than those operated with a TKA (Friesenbichler et al., 2018).

Number of patients per year who undergo current treatment regimen

At present around 17,000 patients are treated with a primary knee arthroplasty each year in Sweden. This is a figure that is projected to increase by around 20% in the coming decade (Nemes et al., 2015). At SU, around 400 primary TKA and between 10-20 primary UKA procedures are performed each year (internal hospital records). Around 3-4% of patients undergoing knee arthroplasty at SU receive a UKA. The corresponding national figure is around 10-11% (Swedish Knee Arthroplasty Register, 2020). Some centres in Sweden perform this procedure in around 20% of cases. The reluctance to use UKA may be due to historically high revision rates, which incur high costs on the hospital as well as on patient wellbeing. A low surgical case volume is at the same time predictive of high revision and complication rates (Jolbäck et al., 2019).

Present recommendations from medical societies or health authorities

Swedish national guidelines recommend patient education and exercise as first line treatment for patients with osteoarthritis, if relevant combined with a weight loss regime (Socialstyrelsen, 2021). When needed, medication is recommended as an adjunct treatment. Surgery is only suggested for patients with persistent pain or disability that is not alleviated by first-line or adjunct treatments. These recommendations are reinforced in the recent guideline developed by the national work group for knee osteoarthritis (Nationellt kliniskt kunskapsstöd, 2022)

There are presently no recommendations concerning use of robotic-assisted or manual arthroplasty in Sweden.

6. Health technology at issue: Robotic arm-assisted knee arthroplasty

Technological advancements in orthopaedic surgery include computer-assisted orthopaedic surgery, navigational techniques, patient-specific instrumentation, sensors and robotic arm-assisted surgical (RAS) systems. The systems employ different or converging sets of technologies with the intent of improving surgical accuracy. The elements and features that set them apart are sometimes not distinct.

Newly developed orthopaedic RAS systems are generally mobile stand-alone units that utilise already existing hospital infrastructure for maintenance and use. Incorporated technologies vary between different systems but often include sensors and arrays for navigation and real time limb-tracking, 3D-modelling software, robotic-arm stabilisation and haptic feedback. They either combine pre-operative radiology imaging with mapped and calibrated sensory data gathered during surgery, or make full use of the latter for limb tracking. A pre-operative plan made according to the individual patient's anatomy is combined with sensory data gathered during the surgery. This is used for performing bone-cuts, making decisions on the angle and size of the implants and provides a measurable way of balancing the soft tissues around the joint.

RAS systems are commonly categorised into active, semi-active or passive, based on the surgeon's involvement. Today, active systems are used for TKA, semi-active systems can be used for both TKA and UKA. Active systems perform bone-cuts independently where the surgeon monitors the pre-planned action. Semi-active systems by contrast, give the surgeon haptic, visual, and auditory feedback in real-time and stabilise movements when performing bone-cuts. This provides accurate navigation according to the intended plan while allowing for adjustments in response to measurements obtained during the surgery. Passive systems, which also include navigation and computer-assisted systems, provide real-time guidance while the surgeon has full control over the surgical instruments used to perform bone-cuts. By comparison of example, the Da Vinci surgical system, employed by soft tissue surgeons, uses enhanced inputs from the surgeon for remote telemanipulation. RAS systems in arthroplasty are also distinctly different from those employed in orthopaedic spinal surgery. The earliest RAS system for arthroplasty was an active system developed in the 1980’s and approved for total hip arthroplasty in 1992. Further development and approval from regulatory authorities have varied across the world. Only semi-active systems have received approval for knee arthroplasty by the Food and Drug Administration in the United States and active systems have been used mostly in Asia for knee arthroplasty although they have received approval by European regulatory agencies. The use of RAS systems varies globally today with nearly 30% of US hospitals utilising robotic assistance in joint arthroplasty in 2015 and 35% of UKA being performed using RAS in Australia in 2020 (Boylan 2018, AOANJRR annual report 2021). No system has ever been sold or used in Sweden, but robotic-assisted knee arthroplasty is used more and more frequently globally (Boylan et al., 2018, AOANJRR annual report 2021); Finland has three robot systems for hip and knee arthroplasty installed and the manufacturer of the MAKO system, which is the most frequently occurring system in the studies of this review, reports over 850 systems installed in 29 countries worldwide.

While a number of systematic reviews on robot-assisted knee arthroplasty have been published in recent years, most examined only one type of procedure (TKA or UKA) and not all clinical and patient-important outcomes, while we aimed to provide a comprehensive review of all available robotic systems and both procedures, and several clinical, radiological and patient outcomes. None of the identified reviews combine a systematic review with organisational and economic aspects as done in the present Health Technology Assessment (HTA) report. Combining these perspectives provides a comprehensive picture of potential risks and benefits with the technology. The HTA was initiated by the Department of Orthopaedic Surgery at SU in view of a possible introduction of robotic-assisted knee arthroplasty, with the intention of increasing the ratio of patients operated using the less invasive UKA procedure.

7. Focused question

Is active or semi-active robotic arm-assisted TKA or UKA for patients in need of knee arthroplasty better than manual TKA or UKA regarding mortality, patient-reported outcomes and experiences, revision, complications, implant positioning, length of stay, operation time, and learning curve?

PICO: P= Patients, I= Intervention, C= Comparison, O= Outcome

P	Patients in need of elective primary knee arthroplasty
I1 **I2** **I3**	Robotic arm-assisted total knee arthroplasty using active systems (rTKA) Robotic arm-assisted total knee arthroplasty using semi-active systems (rTKA) Robotic arm-assisted unicompartmental knee arthroplasty using semi-active systems (rUKA)
C1 **C2** **C3**	Manual total knee arthroplasty (mTKA) Manual total knee arthroplasty (mTKA) Manual unicompartmental knee arthroplasty (mUKA)
O	**Critical for decision-making** Mortality Patient-reported function, measured with validated instruments Revision Complications **Important for decision-making** Implant positioning Length of stay Patient-reported pain, measured with validated instruments Patient-reported health-related quality of life, measured with validated instruments Operation time Learning curve Patient experiences

Eligible study designs were randomised controlled trials of any size and cohort studies (non-randomised controlled studies) with ≥ 200 patients in each group, published from 2010. Systematic reviews published from 2018 were searched for only for commenting on in the discussion. Publications in English, Swedish, Norwegian, and Danish were eligible.

8. Methods

Systematic literature search (Appendix 1)

During May 2021 two authors (TSv, LB) performed systematic searches in Medline, Embase, the Cochrane Library, Cinahl and AMED. The websites of the Swedish Agency for Health Technology Assessment and Assessment of Social Services and the Norwegian Public Health Institute were visited. Reference lists of relevant articles were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are presented in Appendix 1. These authors conducted the literature searches, selected studies, independently assessed the obtained abstracts, and made the first selection of full-text articles for inclusion or exclusion. All abstracts were screened using the Rayyan tool. Any disagreements were resolved in consensus. The remaining articles were sent to all the participants of the project group. All authors read these articles independently and it was finally decided in a consensus meeting which articles should be included in the assessment.

Critical appraisal and certainty of evidence

Included studies, their design and characteristics are presented in Appendix 2. Excluded studies and the reasons for exclusion are presented in Appendix 3.

The included randomised controlled trials (RCTs) and cohort studies were critically appraised using checklists for quality assessment from the Swedish Agency for Health Technology Assessment and Assessment of Social Services, modified by HTA-centrum.

Certainty of evidence was assessed using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach (Atkins et al., 2004; GRADE Working group). With the GRADE approach, certainty of evidence is assessed as high, moderate, low or very low. RCTs are assessed as having high certainty as a starting point, and can be downgraded one to three levels for study limitations (risk of bias), indirectness, inconsistency, imprecision, or publication bias. Cohort studies are assessed as having low certainty as a starting point, and can be downgraded one level for study limitations (risk of bias), indirectness, inconsistency, imprecision, or publication bias. They can also be upgraded one or two levels if, e.g. the magnitude of the effect is large. Conclusions are formulated according to standard GRADE recommendations.

A summary result per outcome and the associated certainty of evidence are presented in Summary-of-Findings tables (page 9).

Data extraction and analysis

Data were extracted by one author and checked for accuracy by another. The results of each article were tabulated per outcome in Appendix 4. When possible, data were pooled and subjected to meta-analysis using a random effects model in Stata and presented as forest plots. When mean and 95% confidence interval (CI) were not reported, we converted median values and range to means and standard deviations (SD). For the outcome function measured with the Knee Society Score (KSS), we summated the subscales KSS Function and KSS Knee, for both study data and minimal important differences (MID) collected from the literature. Because the instruments used in the included studies measured somewhat different aspects of function, we did not pool data from different instruments. SD was calculated based on range when not reported. Point estimates are presented as risk ratios (RR) with 95% CI for binary data and as weighted mean differences (WMD) with 95% CI for continuous data. When meta-analyses were performed, we used unadjusted data reported in the included studies. When adjusted data were reported in the studies, we present these data in the results section, as specified under each outcome.

Definitions

Different follow-up points were categorised into short term or intermediate-to-long term, depending on the clinical relevance of the time period, as decided in consensus by the authors. For the outcome revision, short term was defined as up to 90 days and intermediate-to-long term was defined as over three months to 15 years. For the outcome patient-reported function, short term was defined as less than 12 months and intermediate-to-long term was defined as 1-13 years.

For the outcome implant positioning, variability in reporting methods was large. Several studies reported absolute angular values of implant component positions without distinctly referencing target values. These were not included in our analysis due to difficulties in interpreting achieved accuracy, but are reported in Appendix 4.2. Studies that analysed outliers from the mechanical axis were included for analysis as were implant positions analysed postoperatively in comparison to a reported preoperative plan. We only included implant positioning reported up to three months in the analysis, as longer measuring periods entail a risk for data reflecting aseptic loosening rather than implant positioning at time of surgery.

Outcome measures for patient-reported function

Patient-reported function was reported using the validated scales KSS, Oxford Knee Score (OKS), AKSS (American Knee Society Score), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Knee Osteoarthritis Outcome Score Joint Replacement (KOOS-JR), Patient-Reported Outcomes Measurement Information System, Physical Health (PROMIS-PH), Forgotten Joint Score (FJS), HSS (Hospital for Special Surgery), SF-12/36 (Short Form Health Survey), and UCLA (University of California Los Angeles activity-level rating scale). We searched for published values for MID and minimal clinical important difference (MCID) for the various scales in the literature. We used anchor-based MID/MCID values because this method takes into account the patient perspective. If more than one value was found, we averaged those values.

The following MID/MCID values were used (the terms were used as reported by the respective authors). When results are presented in this report, the term important difference is used when the difference exceeds the MID.

TKA

KSS Knee/function: MCID average 13.6 points (summated for the two subscores) (Lizaur-Utrilla et al., 2020, Lee et al., 2017)

FJS: MCID 13.7 points (confounder adjusted; anchored to satisfaction) (Clement et al., 2021)

WOMAC: MCID 10 points for total scale (regression analysis adjusted for confounders) (Clement et al., 2018)

OKS: MCID 4.7 to 10 points, 7.4 points average (Maredupaka et al., 2020)

KOOS-JR: MCID 6.8 points (Khalil et al., 2020)

PROMIS-PH: MCID 32.5 points (Khalil et al., 2020)

SF-36: MCID 10 points (Escobar et al., 2007)

SF-12: MCID 1.5-1.8 for PCS and MCS, respectively (Clement et al., 2019)

VAS: MCID 22.6 mm (Danoff et al., 2018)

UKA

FJS: MCID 12.5 points (Longo 2021)

AKSS: 13.6 points average (Lee et al., 2017)

HSS: 5.41 points (Fan et al., 2021)

Patient involvement

Comments on the PICO were provided by a patient representative, and were considered in the formulation of the PICO. The patient representative also read and commented on the final report.

Ongoing research

A search in Clinicaltrials.gov (2021-10-29) using the search terms (knee AND (robot OR robotic OR robotics OR mako OR rosa OR robodoc OR bluebelt navio) identified 207 trials. A search in WHO ICTRP (2021-10-29) using two separate search strings: (knee AND robot*) and

(mako OR robodoc OR bluebelt navio) identified 139 trials. In total 264 unique ongoing trials were identified.

9. Results

Search results and study selection (Appendix 1)

The literature search identified 901 articles after removal of duplicates. After reading the abstracts 737 articles were excluded by two authors. Another 30 articles were excluded by these two authors after reading the articles in full text. The remaining 108 articles were sent to all participants of the project group, and 26 articles were finally included in the assessment (Appendix 2). Eleven articles reported outcomes from 8 RCTs and 15 articles reported cohort studies.

Included studies

A total of 23 studies were included, of which eight were RCTs (reported in 11 papers) and 15 were cohort studies. Because sufficient data on complications were available in the large cohort studies, no case series were included. The RCTs were performed in France, the United Kingdom, Korea, Singapore, and India, and involved a total of 1921 patients. Of the cohort studies, 13 were from the United States, one from Australia and one from Belgium. Most cohort studies were large register studies, each including between 280 and 755,350 patients.

Four of the included RCTs evaluated rTKA using active robot systems, two RCTs and eight cohort studies evaluated rTKA using semi-active systems, and two RCTs and two cohort studies evaluated rUKA using semi-active systems. Remaining studies did not specify system used but studies conducted in the US were assumed to report on semi-active systems as no active system has received approval for knee arthroplasty by the Food and Drug Administration.

The RCTs generally suffered from some or serious study limitations (mainly lack of blinding, baseline differences) and serious imprecision (mainly due to small study sizes and few events). Limitations in the cohort studies included some or serious study limitations (including baseline differences, uncertainties regarding confounders, low response rates), some indirectness, and some uncertainties regarding precision.

Results per comparison

PICO 1: Active robot arm-assisted vs manual total knee arthroplasty

<u>Outcomes critical for decision-making</u>

Mortality (Appendix 4.1)

Mortality was not reported for this PICO.

Patient-reported function (Appendix 4.2)

<u>Short term:</u> One RCT (n=60) (Liow 2014) reported function measured with the KSS at short term (6 months) for active rTKA versus mTKA. The study had serious study limitations and serious imprecision. The study showed no difference in short-term KSS score between rTKA and mTKA; mean 152.1 points (SD 25.19) vs 152.6 (SD 21.43), mean difference (MD) -0.50 (95%

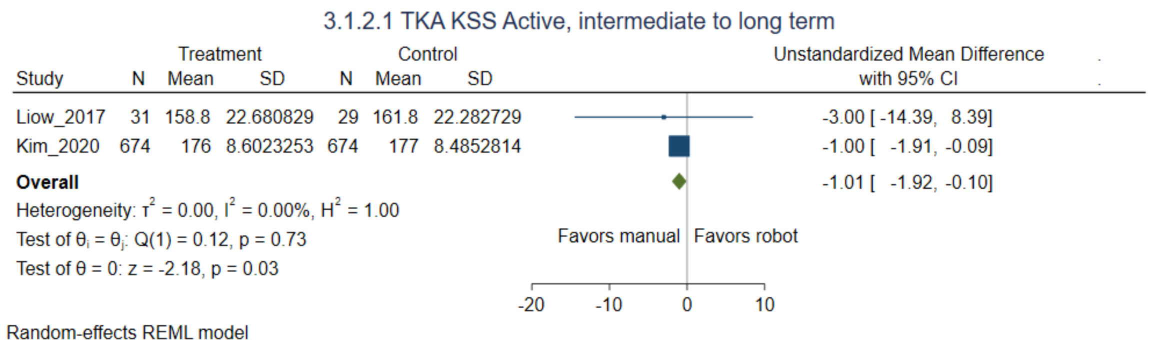
CI -12.38 to 11.38). The combined KSS score ranges from 0-200, with higher values indicating better function. MID for the combined KSS score is 13.6 points.

<u>*Conclusion:*</u> There may be no important difference in short-term knee function measured with KSS between active rTKA and mTKA (GRADE ⊕⊕◯◯).

<u>Intermediate-to-long term:</u> Four RCTs (n=1,491) (Kim 2020, Liow 2017, Song 2011, Song 2013) reported intermediate-to-long term (1-13 years) function measured with KSS, WOMAC or HSS for active rTKA. The studies had serious study limitations and some uncertainties regarding directness and precision.

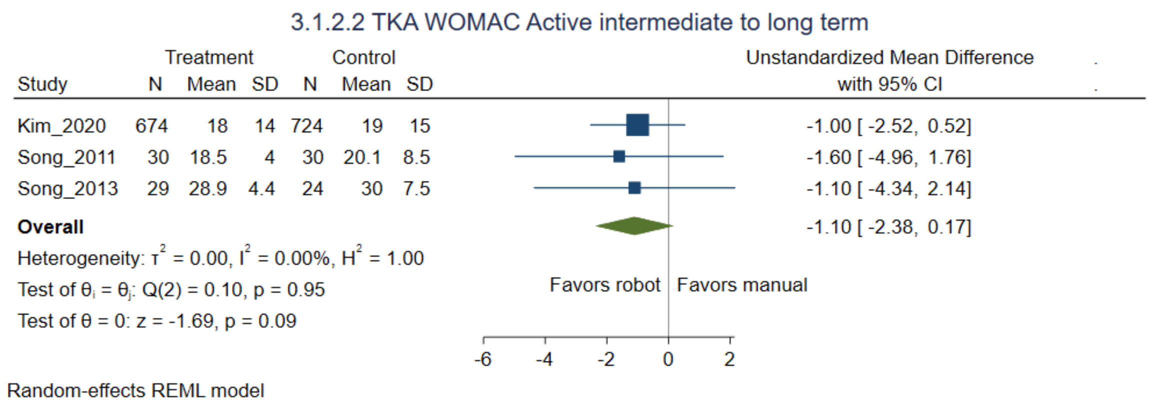
The RCTs that reported KSS scores (Kim 2020, Liow 2017) showed a statistically significant, non-important difference in function between rTKA and mTKA at 24 months' and 13 years' follow-up (WMD -1.01 points; 95% CI -1.92 to -0.10) (MID for the combined KSS score: 13.6 points).

Fig. 1 Intermediate-to-long term function measured with KSS for active rTKA versus mTKA



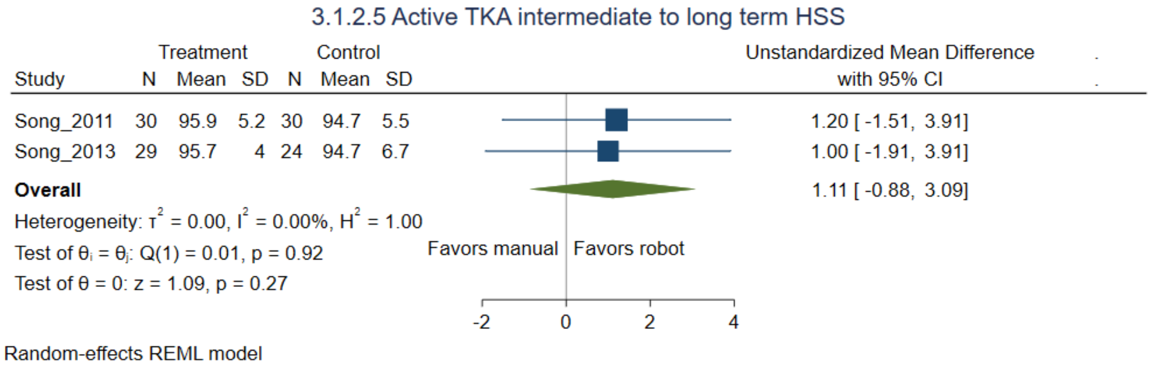
The three RCTs that reported WOMAC scores did not show any important difference between rTKA and mTKA at 12 months to 13 years (WMD -1.10 points (95% CI -2.38 to 0.17; ns). The WOMAC score ranges from 0-96 points with higher score indicating *worse* functional limitation (MID for WOMAC: 10 points).

Fig. 2 Intermediate-to-long term function measured with WOMAC for active rTKA versus mTKA



The two RCTs that reported HSS scores did not show any important difference between rTKA and mTKA at 12 to 36 months (WMD 1.11 points (95% CI -0.88 to 3.09; ns). The HSS score ranges from 0-100 points with higher score indicating better function (MCID for HSS is 5.41 points).

Fig. 3 Intermediate-to-long term function measured with HSS for active rTKA versus mTKA



UCLA scores were reported in Kim 2020, the median was 7 (95% CI 5 to 10) for rUKA and 7 (95% CI 5 to 10) for mUKA at 12 months; between-group difference 0; ns. MCID: 4.7 to 10 points.

<u>*Conclusion:*</u> There may be little or no important difference in intermediate-to-long term knee function between active rTKA and mTKA (GRADE ⊕⊕◯◯).

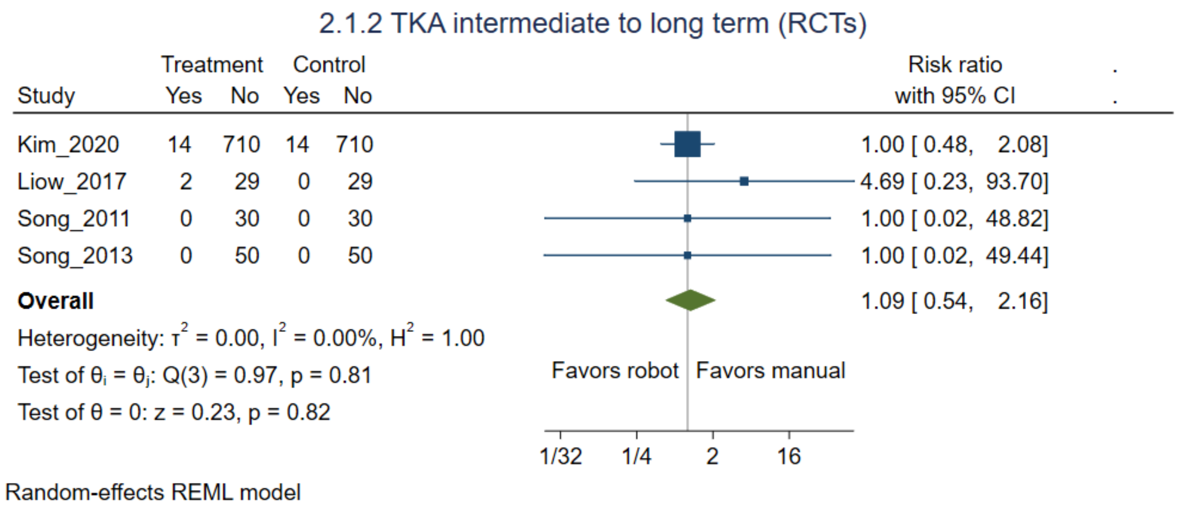
Revision (Appendix 4.3)

<u>Short term:</u> Three RCTs (n=143) (Liow 2017, Song 2011, Song 2013) reported revision rates at short term (90 days) for active rTKA versus mTKA. The studies had serious study limitations and very serious imprecision. No revisions were reported in any of the studies; the combined revision rate was 0/111 in the rTKA groups and 0/109 in the mTKA groups.

<u>*Conclusion*</u>*:* It is uncertain whether short-term revision rate differs between active rTKA and mTKA (GRADE ⊕◯◯◯).

<u>Intermediate-to-long term:</u> Four RCTs (n=1,491) (Kim 2020, Liow 2017, Song 2011, Song 2013) reported intermediate-to-long term revision rates (6 months to 15 years) for active rTKA. All RCTs had serious study limitations and serious imprecision. The combined revision rate was 16/835 (1.92%) in the rTKA groups versus 14/833 (1.68%) in the mTKA groups, RR 1.09 (95% CI 0.54 to 2.16).

Fig. 4 Intermediate-to-long term revision rates for active rTKA versus mTKA



Conclusion: There may be no difference in intermediate-to-long term revision rate between active rTKA and mTKA, although the confidence interval includes both higher and lower revision rate for rTKA (GRADE ⊕⊕◯◯).

Complications (Appendix 4:4)

Complications after active rTKA versus mTKA were reported in three RCTs (n=1,461) (Kim 2020, Liow 2014/2017, Song 2013). The studies had some or severe study limitations, uncertainty or problems concerning precision, and uncertainty concerning directness. Complications were generally not reported in a systematic way in the included studies, e.g. complications were not predefined, not stratified according to severity, and only a few studies reported mechanical complications and procedure-related complications. Complication rates were not possible to determine, as most studies reported number of complications rather than number of patients in whom complications occurred. This precluded any meaningful comparison between rTKA and mTKA.

The most commonly reported complications were aseptic loosening, surgical site infection, and deep vein thrombosis. The largest study (Kim 2020), with 1,348 patients, reported complications up to 13 years after surgery and showed an equal number of complications in each group (15 aseptic loosenings, 4 superficial wound infections). The other studies reported similar results in both groups. Indirect indicators of complications such as readmissions were not included in this assessment.

Although differences in complication rate between active rTKA and mTKA were not possible to quantify with any certainty due to inadequate reporting, no major differences in complication rates were noted.

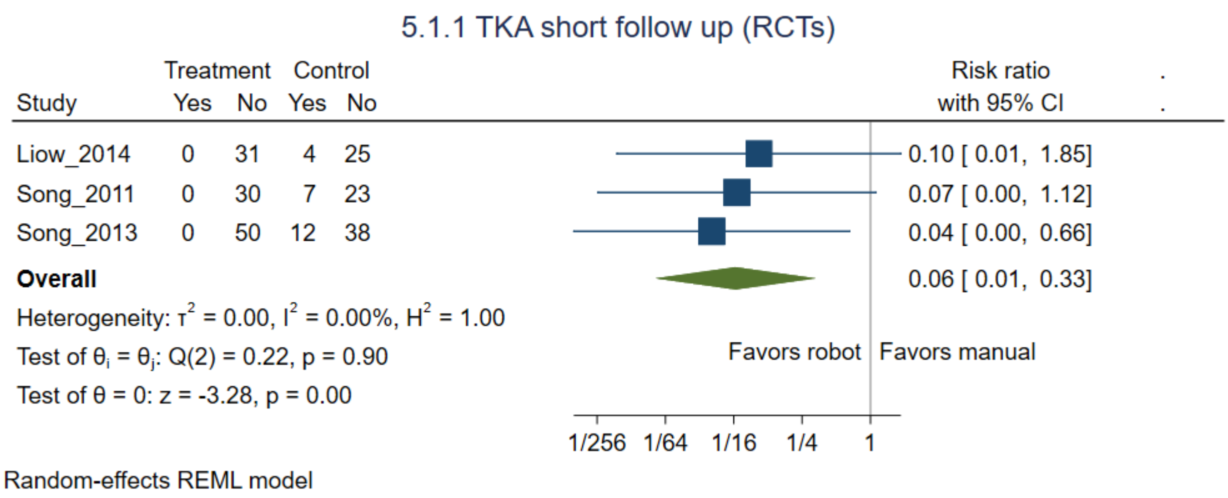
Conclusion: Based on the available data it is difficult to draw any firm conclusions regarding complication rates in active rTKA vs mTKA, but the included studies suggest that there are no major differences in complications between the two procedures.

Outcomes important for decision-making

Implant positioning (Appendix 4:5)

Implant positioning after active rTKA versus mTKA measured as mechanical axis outliers (> ± 3 degrees from neutral) was reported in three RCTs (n=220) (Liow 2014, Song 2011, Song 2013). The outcome was measured postoperatively or at one month. The studies had serious study limitations, some uncertainty regarding directness and serious imprecision. The combined rate of mechanical axis outliers was 0/111 (0%) in the rTKA groups vs 23/109 (21.1%) in the mTKA groups, RR 0.06 (95% CI 0.01 to 0.33).

Fig. 5 Short-term mechanical axis outliers for active rTKA versus mTKA



Footnote: Long-term (13 +/- 5 years) implant position was also reported in Kim 2020, but was not included in this analysis because we do not consider a change in mechanical axis after such a long time period as being a consequence of positioning of the implant at the time of surgery, but rather a loosening or instability of the implant due to ligament insuffiency or implant wear. However, the study showed significantly fewer outliers in the rTKA group than in the mTKA group; 14% (101/724) vs 26% (188/724), p= 0.035, which supports the short-term results.

Conclusion: Implant positioning may be improved with active rTKA compared with mTKA (GRADE ⊕⊕◯◯).

Length of stay (Appendix 4:6)

Length of stay after active rTKA versus mTKA was reported in one RCT (n=60) (Liow 2014). The study reported no statistically significant difference in length of stay between rTKA and mTKA (5.2 (SD 2.3) vs 5.8 (SD 3.8); MD 0.6, ns). The study had serious study limitations and serious imprecision.

Conclusion: There may be little or no difference in length of stay between active rTKA and mTKA (GRADE ⊕⊕◯◯).

Learning curve (Appendix 4:7)

This outcome was not reported for this PICO.

Patient-reported pain (Appendix 4:8)

Long term: Pain at 13 ± 5 years was measured in one RCT for active rTKA versus mTKA (Kim 2020; n=1,348) and reported as proportion of patients with no, mild or severe residual pain. The study had some study limitations and some uncertainty regarding directness and precision, and showed that 85% of rTKA patients vs 82% of mTKA patients reported no residual pain; 13% rTKA vs 16% mTKA reported mild pain; 2% in both groups reported severe pain (no statistically significant differences between the groups).

Conclusion: There is probably little or no difference in long-term pain between active rTKA and mTKA (GRADE ⊕⊕⊕◯).

Patient-reported health-related quality of life (HRQoL) (Appendix 4:9)

Short term: HRQoL after active rTKA versus mTKA was measured at 6 months in one RCT (n=60) (Liow 2014/Liow 2017) using SF-36. The study had serious study limitations, some uncertainty regarding directness, and serious imprecision. The study reported no statistically significant difference in HRQoL between rTKA and mTKA. MID for SF 36 is 10 points (Escobar 2006).

SF-36 Physical Component Score: 46.2 (9.1) vs 46.7 (11.6); MD 0.5 (95% CI -5.9 to 4.9)

SF-36 Mental Component Score: 57.0 (8.8) vs 52.6 (9.7); MD 4.5 (95% CI -0.3 to 9.2)

Conclusion: There may be little or no difference in short-term HRQoL between active rTKA and mTKA (GRADE ⊕⊕◯◯).

Intermediate-to-long term: HRQoL at 24 months was reported in one RCT (n=60) (Liow 2017) using SF-36. The study reported no statistically significant difference in HRQoL between rTKA and mTKA.

SF-36 Physical Component Score: 50.3 (7.0) vs 46.2 (13.9); MD 4.1 (−1.7 to 9.8)

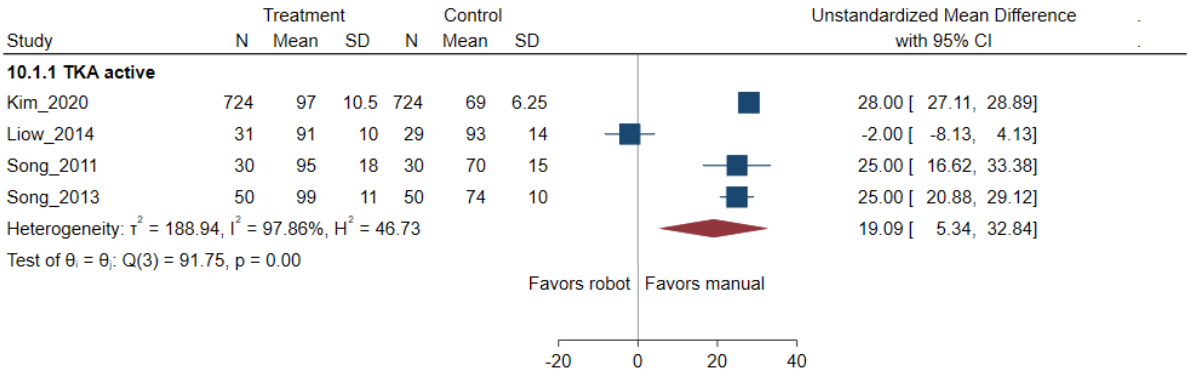
SF-36 Mental Component Score: 59.3 (9.8) vs 54.7 (10.3); MD 4.6 (−0.8 to 9.9)

Conclusion: There may be little or no difference in long-term HRQoL between active rTKA and mTKA (GRADE ⊕⊕◯◯).

Operating time (Appendix 4:10)

Operation time for active rTKA versus mTKA was reported in four RCTs (n=1,668) (Kim 2020, Liow 2014, Song 2011, Song 2013). The studies had serious study limitation, and some uncertainties concerning indirectness, inconsistency and precision. Pooled data from the four studies showed that operating time was statistically significantly longer for active rTKA than for mTKA: WMD 19.1 minutes (95% CI 5.3 to 32.8).

Fig. 6 Operating time (minutes) for rTKA versus mTKA



Conclusion: Operating time may be substantially longer for active rTKA compared with mTKA, although the magnitude of the difference is uncertain (GRADE ⊕⊕◯◯).

Patient experiences

No study was identified that reported patients' experiences of active rTKA.

PICO 2: Semi-active robotic arm-assisted vs manual total knee arthroplasty

Outcomes critical for decision-making

Mortality (Appendix 4.1)

Mortality within 90 days of the index operation was reported in one cohort study (n=198,371) (Shah 2021) comparing semi-active rTKA with mTKA. The study had some study limitations and serious imprecision.

There was no statistically significant difference in mortality rate between rTKA and mTKA (0.39% (95% CI 0.19 to 0.59) vs 0.30% (95% CI 0.27 to 0.32); MD 0.09% (95% CI -0.11 to 0.30).

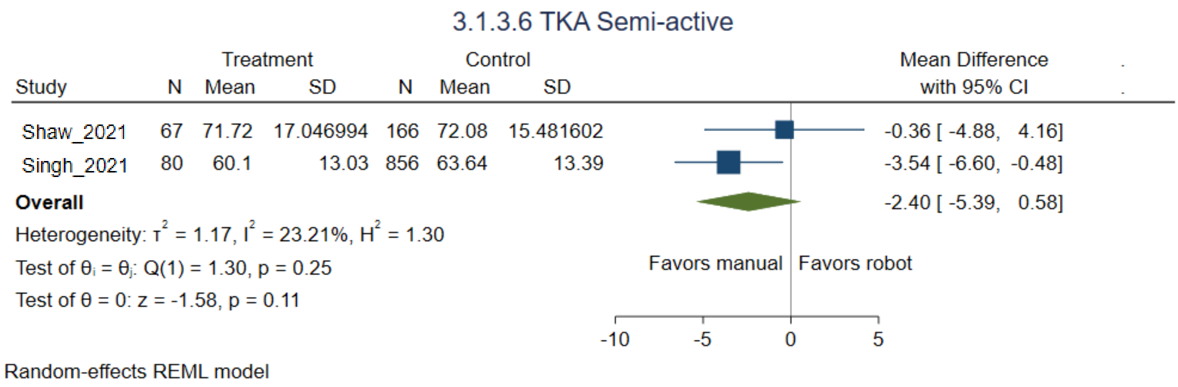
Conclusion: It is uncertain whether 90-day mortality differs between semi-active rTKA and mTKA (GRADE ⊕◯◯◯).

Patient-reported function (Appendix 4.2)

Short term: Two cohort studies (n=7,969) assessed short-term (<12 months) function after semi-active TKA versus mTKA using KOOS-JR (Shaw 2021, Singh 2021), PROMIS-PH (Shaw 2021) and FJS (Singh 2021), respectively. Both studies had serious study limitations (baseline differences, low response rate) and uncertain precision. Shaw 2021 collected Patient-reported Outcome Measure (PROM) data through voluntary tablet data entry at in-clinic follow-ups as per the surgeons' routine practice, with a drop-out rate of 77% in the intervention group and 87% in the control group. Singh 2021 collected PROM data entered voluntarily in the hospital's mobile patient engagement app at highly varying rates preoperatively and during follow-up. The studies showed no important differences between groups, when measuring function with KOOS-JR, PROMIS-PH and FJS.

The studies that reported KOOS-JR scores (Shaw 2021, Singh 2021) showed no statistically significant difference in function between rTKA and mTKA (WMD -2.40 points; 95% CI -5.39 to 0.58) (MID for KOOS-JR: 6.8 points).

Fig. 7 Short-term function measured with KOOS-JR for semi-active rTKA versus mTKA



For PROMIS-PH, Shaw 2021 reported 48.62 points (variance 53.07; n=67/290) in the rTKA group vs 49.43 (variance 77.56; n=170/900) in the mTKA group at 4-8 months; ns (MCID for PROMIS-PH: 32.5).

FJS measurements were reported in Singh 2021 at three months with 20.55 points (SD 20.56; n=42/367) and 26.50 points (SD 23.51; n=404/6442) in the rTKA and mTKA group, respectively. No p-values relating robotic-assisted and "no technology assisted" surgery were reported in Singh 2021 (MCID for FJS: 12.5)

Conclusion: It is uncertain whether there is any difference in short term function between semi-active rTKA and mTKA (GRADE ⊕○○○).

Intermediate-to-long term: One cohort study (n=7,096) (Singh 2021) assessed intermediate-to-long-term (12 months) function using FJS and KOOS-JR. The study had serious study limitations (baseline differences, low response rate) and uncertain imprecision.

The study showed no important difference and reported no statistically significant differences between groups. FJS scores at 12 months were 38.27 points (SD 24.74; n=41/367) in the rTKA group vs 41.83 points (SD 27.16; n=436/6442) in the mTKA group. The KOOS-JR scores in the rTKA group were 67.17 points (SD 15.2; n=55/367) vs 70.65 points (SD 15.65; n=673/6442) in the mTKA group. No p-values relating robotic-assisted and "no technology assisted" surgery were reported in the study.

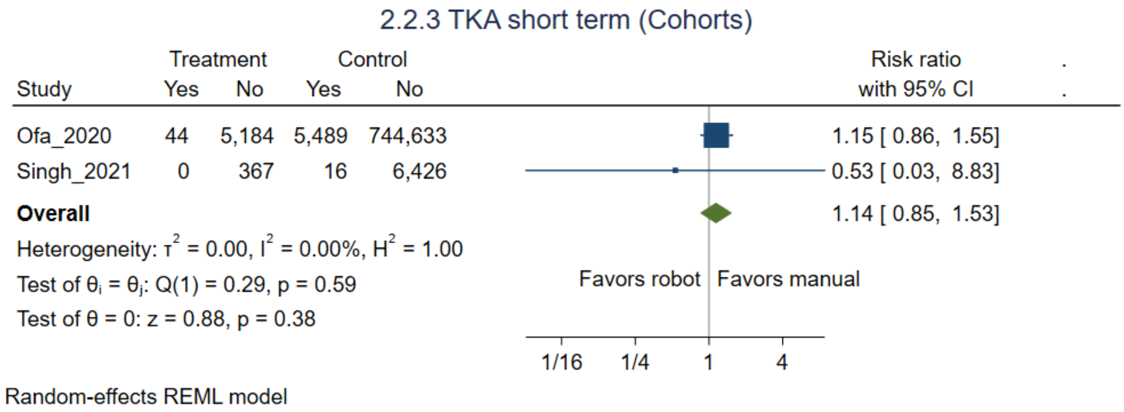
Conclusion: It is uncertain whether there is any difference in intermediate-to-long term function between semi-active rTKA and mTKA (GRADE ⊕○○○).

Revision (Appendix 4.3)

Short term: One RCT (n=30) (Kayani 2021) and two cohort studies (n=762,159) (Ofa 2020, Singh 2021) reported short term revision rates (90 days) for semi-active rTKA versus mTKA. The RCT had some study limitations, some indirectness, and serious imprecision. No revisions were reported in any of the groups; 0/15 in the rTKA group and 0/15 in the mTKA groups.

Both cohort studies had some study limitations and uncertain precision. The combined revision rate was 44/5,595 (0.79%) in the rTKA groups vs 5,505/756,564 (0.73%) in the mTKA groups, RR 1.14 (95% CI 0.85 to 1.53).

Fig. 8 Short-term revision rates for semi-active rTKA versus mTKA



Conclusion: There may be no difference in short term revision rate between semi-active rTKA and mTKA, although the confidence interval includes both higher and lower revision rate for rTKA (GRADE ⊕⊕◯◯).

Intermediate term: One cohort study (n=755,350) (Ofa 2020) reported intermediate term revision rates (six months to two years) for semi-active rTKA versus mTKA. The study had some study limitations, but no imprecision. The reported revision rate was 151/5,228 (2.89%) in the rTKA group vs 25,060/750,122 (3.34%) in the mTKA group (adjusted OR 0.83; 95% CI 0.70-0.97).

Conclusion: Intermediate-term revision rate may be lower after semi-active rTKA compared with mTKA (GRADE ⊕⊕◯◯).

Complications (Appendix 4:4)

Complications after semi-active rTKA versus mTKA were reported in four large cohort studies (n=958,299) (Grosso 2021, King 2021, Ofa 2020, Shah 2021). The studies had some or severe study limitations, uncertainty or problems concerning precision. Complications were generally not reported in a systematic way in the included studies, e.g. complications were not predefined, not stratified according to severity, and only a few studies reported mechanical complications and procedure-related complications. Complication rates were not possible to determine, as most studies reported number of complications rather than number of patients in whom complications occurred. This precluded any meaningful comparison between rTKA and mTKA.

The studies reported similar results in both groups. The most commonly reported complications included anaemia, acute renal failure, urinary tract infections, deep vein thrombosis, pulmonary embolism, and cerebrovascular events. Indirect indicators of complications such as readmissions were not included in this assessment.

Differences in complication rate between semi-active rTKA and mTKA were not possible to quantify with any certainty, due to inadequate reporting. No major differences in complication rates between the two procedures were noted.

Conclusion: The reported frequencies of complications after semi-active rTKA vs mTKA varied considerably among the included studies. Based on the available data it is difficult to draw any firm conclusions regarding complication rates, but the included studies suggest that there are no major differences in complications between the two procedures.

Outcomes important for decision-making

Implant positioning (Appendix 4:5)

Implant positioning after semi-active rTKA versus mTKA was measured postoperatively and compared to set targets in two RCTs (n=90) (Kayani 2021, Vaidya 2020). The studies had some study limitations and some uncertainties regarding inconsistency, indirectness and precision. The studies reported implant positioning using several different measures, including malalignment in the sagittal, coronal and axial planes of the femoral and tibial component, as well as mechanical axis outliers.

Kayani 2021 reported the error in planned limb alignment as root mean square error (RMSE) 1.2 (SD 0.7) after rTKA vs 3.1 (SD 1.3) (p<0.001) after mTKA. Lower RMSE indicates more accurate alignment. For the tibial and femoral component in the coronal and sagittal axis, RMSE ranged between 1.0-1.4 (SD 0.4-1.0) for rTKA vs 3.1-3.9 (SD 0.8-1.1) for mTKA. All differences were statistically significant in favour of rTKA (p<0.001).

Vaidya reported the mean error of the mechanical axis to be 1.8 (SD 1.2) after rTKA group and 3.0 (SD 2.4) after mTKA (p=0.019). The number of outliers of >3 degrees from the planned mechanical axis was 1/32 (3.1%) after rTKA and 8/28 (28.6%) after mTKA (p=0.019). Mean implant errors was reported to be 1-6.4 (SD 0.7-2.9) for rTKA vs 1.5-6.3 (SD 0.8-3.2) for the tibial and femoral component in different axes. Mean differences were statistically significant for femoral coronal rotation (p=0.03) and tibial coronal alignment (p=0.04), but not for other axes.

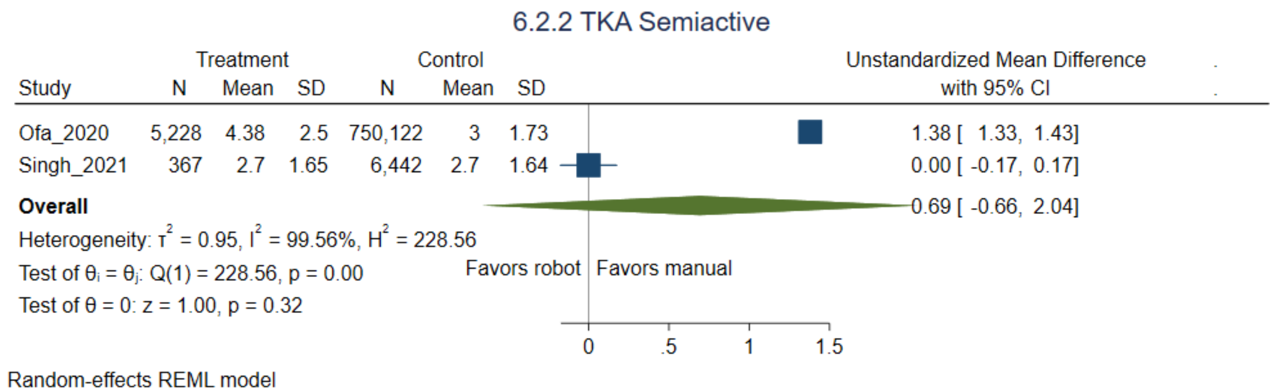
Conclusion: Implant positioning is probably slightly improved with semi-active rTKA compared with mTKA (GRADE ⊕⊕⊕◯).

Length of stay (Appendix 4:6)

Hospital length of stay after semi-active rTKA versus mTKA was reported in nine cohort studies (n=1,586,216) (Cool 2019a, Emara 2021, Grosso 2021, King 2020, Mont 2021, Ofa 2020, Pierce 2020, Shah 2021, Singh 2021).

Two of the studies reported SD and could be pooled for meta-analysis (Ofa 2020, Sing 2021). The studies had some study limitations, inconsistency and serious imprecision. The meta-analysis showed no statistically significant difference between semi-active rTKA and mTKA (WMD 0.7 days, 95% CI -0.7 to 2.0).

Fig. 9 Length of stay for semi-active rTKA and mTKA



The studies that could not be pooled (King 2020, Mont 2021, Pierce 2020, Shah 2021, Cool 2019a) all reported significantly shorter length of stay with rTKA, with a range of 1.8-2.3 days for semi-active rTKA and 2.0 to 2.7 days for mTKA. Grosso 2021 reported no significant difference between semi-active rTKA and mTKA (MD 0.02 days; 95% CI -0.12 to 0.15). Emara 2021 pooled UKA and TKA over the study period and reported 2.0 (SD 1.4) days for semi-active robotic arm-assisted knee arthroplasty and 2.5 (SD 1.8) days for manual knee arthroplasty (p<0.001). All studies had serious study limitations and uncertain precision.

Conclusion: It is uncertain whether there is any difference in length of stay after semi-active rTKA compared with mTKA (GRADE ⊕◯◯◯).

Learning curve (Appendix 4:7)

Learning curve was reported for semi-active rTKA versus mTKA in two cohort studies (n=729) (Sodhi 2018, Vermue 2020). The studies had some study limitations and uncertainty regarding precision. Operating time for the first 20 cases was compared with the last 20 cases.

Both studies reported a learning curve associated with operating time. Sodhi 2018 reported that operating time of Surgeon 1 in the first 20 robotic-assisted cases was 81 (71–104) minutes vs 70 (52–121) minutes for the last 20 robotic-assisted cases (180 cases between the first 20 and last 20 cases). In comparison, 20 historical manual cases were reported to take 68 (50–106) minutes (p < 0.005 for the first 20 and ns for the last 20). Surgeon 2's first 20 robotic-assisted cases took 117 (74–142) minutes and the last 20 robotic-cohort cases took 98 (67–123) minutes (p<0.05), with 60 cases between the first 20 and last 20 cases. This compared to 20 manual cases: 95 minutes (71–142) (p < 0.005 for the first 20 and ns for the last 20).

Vermue 2020 reported a median of 22 (min: 11, max 43; n= 3/6 surgeons) cases to reach infliction point in operating time. Initial 10 cases for six surgeons were compared to the last 10 robotic cases where the latter were matched to a cohort of manually performed cases by each surgeon.

Differences in the last 10 rTKA cases versus mTKA were only significantly higher for one surgeon (76.3 (SD 11.7) for rTKA versus 63.9 (SD 15.7); p<0.01). Vermue 2020 also reported no learning curve with respect to implant positioning after not resulting in an inflexion point in a CUSUM analysis of implant component angles measured at different planes. However, the learning curve for implant position was not compared to a conventional control.

This outcome was not graded because learning curve for mTKA was not reported.

Conclusion: Available data indicates that there is a learning curve for semi-active rTKA with respect to operating time, but not with respect to implant positioning.

Patient-reported pain (Appendix 4:8)

Short term: Postoperative pain, 0-4 days post-surgery, for semi-active rTKA versus mTKA was reported in one cohort study (n=492) (King 2020). The study reported mean pain levels at 0 to 4 days postoperatively ranging from 5.4-5.5 with rTKA vs 5.1-5.8 with mTKA on a 0-10 VAS, ns. The study had some study limitations and some imprecision.

Conclusion: It is uncertain whether there is any difference in post-operative pain between semi-active rTKA and mTKA (GRADE ⊕◯◯◯).

Patient-reported health-related quality of life (HRQoL) (Appendix 4:9)

This outcome was not reported for this PICO.

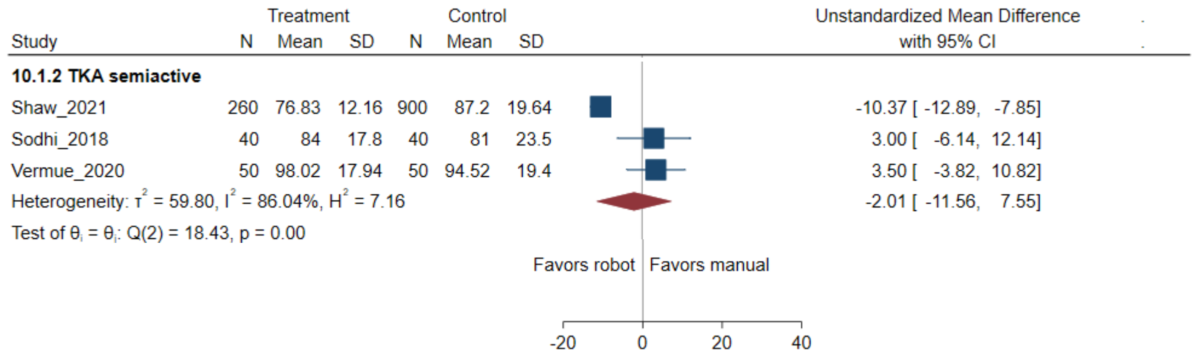
Operating time (Appendix 4:10)

Operating time for semi-active rTKA versus mTKA was reported in one RCT (n=30) (Kayani 2021) and four cohort studies (n=2,581) (King 2020, Shaw 2021, Sodhi 2018, Vermue 2020).

The RCT showed a mean operating time of 62.4 (SD 3.4) minutes in the rTKA group and 64.1 (SD 3.1) minutes for mTKA (between-group difference: 1.0; ns). This study had some study limitations and some uncertainty regarding directness and precision.

Data from three of the cohort studies (Shaw 2021, Sodhi 2018, Vermue 2020) could be pooled; operating time did not differ statistically significantly between semi-active rTKA and mTKA (WMD -2.0 minutes; 95% CI -11.6 to 7.6).

Fig. 10 Operating time (minutes) for semi-active rTKA versus mTKA



The fourth cohort study (King 2020) showed a 9.3 minutes shorter operating time with mTKA; 76.5 min for rTKA vs 67.2 min for mTKA (p<0.001) (neither SD or range reported).

All cohort studies had some inconsistency and serious imprecision.

Conclusion: There may be little or no difference in operating time between semi-active rTKA and mTKA, although the confidence interval includes both higher and lower revision rate for rTKA (GRADE ⊕⊕◯◯).

Patient experiences

No study was identified that reported patients' experiences of semi-active rTKA.

Outcomes critical for decision-making

Mortality (Appendix 4.1)

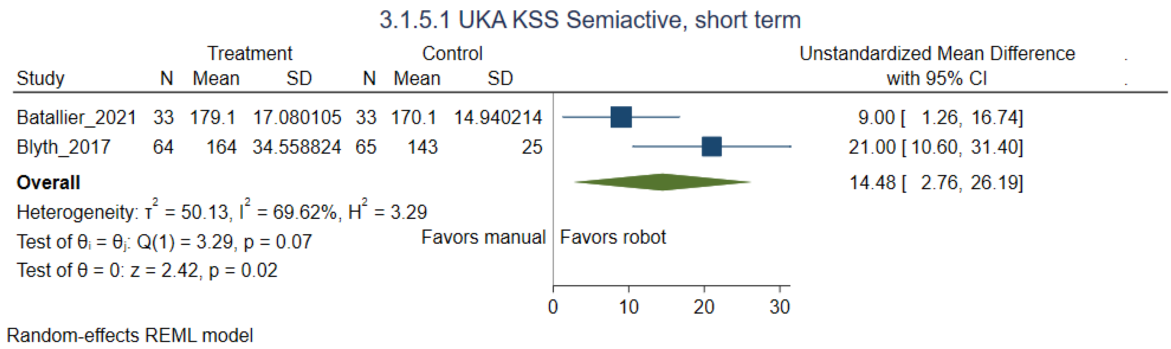
Mortality was not reported for this PICO.

Patient-reported function (Appendix 4.2)

Short term: Two RCTs (n=202) (Batailler 2021, Blyth 2017) assessed short-term function for semi-active rUKA versus mUKA, using KSS and FJS. Both RCTs had some study limitations and some uncertainty regarding precision. One RCT (Blyth 2017) also assessed short-term function using OKS.

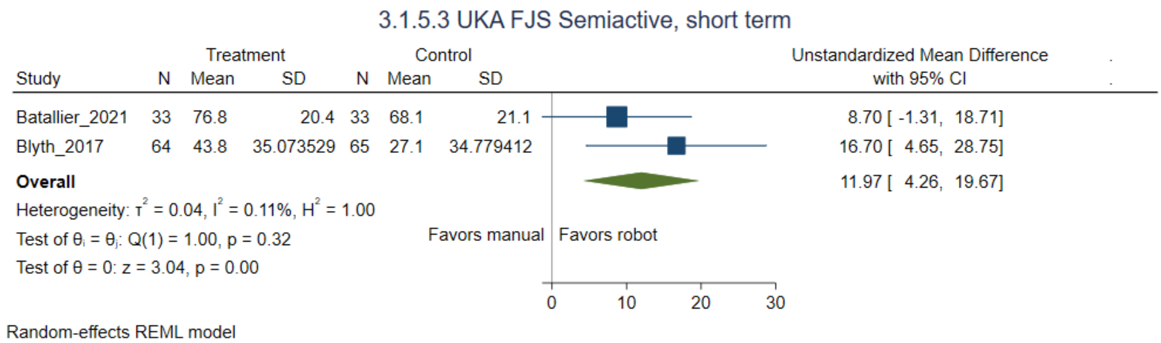
For KSS scores, the short-term WMD between rUKA and mUKA was 14.48 points (95% CI 2.76 to 26.19) in favour of rUKA (MID for combined KSS score: 13.6 points).

Fig. 11 Short term function measured with KSS for semi-active UKA versus mUKA



For FJS scores, the short-term WMD was 11.97 points (95% CI 4.26 to 19.67) (MCID for FJS: 12.5 points).

Fig. 12 Short-term function measured with FJS for semi-active UKA versus mUKA



For OKS scores, the median was 35 points (Quartile (Q)1 29, Q3 41) for rUKA and 33 (Q1 23, Q3 38) for mUKA at three months; between-group difference: 2; ns (MCID: 7.4 points).

Intermediate-to-long term: One RCT (Blyth 2017/Gilmour 2018) assessed intermediate-to-long-term function for semi-active rUKA versus mUKA using FJS, AKSS, OKS and UCLA. The RCT had some study limitations and some uncertainty regarding precision.

AKSS scores at two years were reported in Gilmour 2018: median 168.0 points (Q1 141.0, Q3 191.0) for rUKA vs median 173.0 (Q1 162.3, Q3 185.5 for mUKA; between-group difference 5; ns).

For OKS scores at two years, the median was 39.0 points (Q1 32.8, Q3 45.0) for rUKA and 40.0 (Q1 33, Q3 44) for mUKA at 24 months; between-group difference: 1; ns (MCID: 7.4 points).

For FJS scores at two years, the median was 55.2 points (Q1 23.3, Q32 81.8) for rUKA vs median 54.1 (Q1 37.0, Q2 79.2) for mUKA at 24 months; between-group difference 0.9; ns).

UCLA scores at 12 months were reported in Blyth 2017 (supplementary material), the median was 5 (Q1 4, Q3 6) for rUKA and 5 (Q1 4, Q3 7) for mUKA at 12 months; between-group difference 0; ns. MCID: 4.7 to 10 points.

Conclusion: Short-term knee function is probably slightly improved while there is probably no difference in intermediate-to-long term knee function after semi-active rUKA compared with mUKA (GRADE ⊕⊕⊕◯).

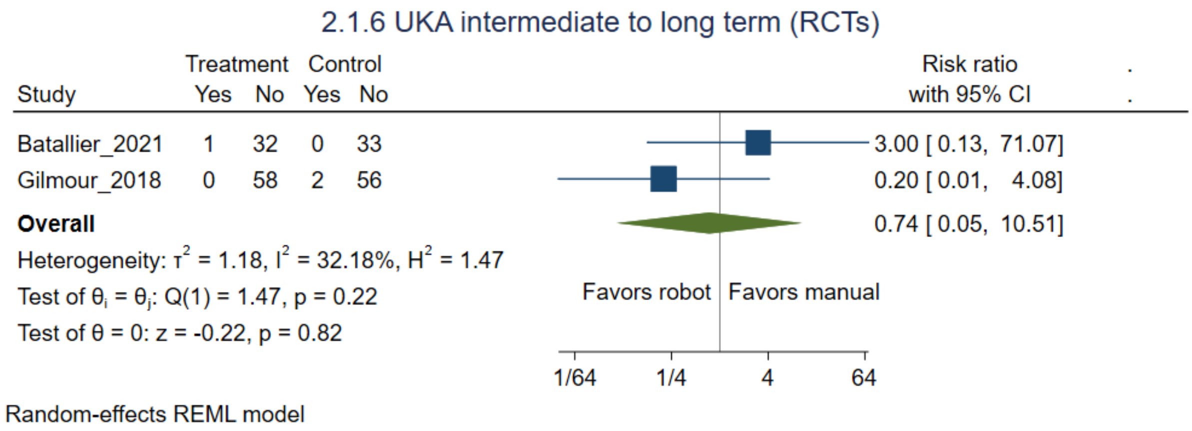
Revision (Appendix 4.3)

Short term: One RCT (n=129) (Blyth 2017) and one cohort study (n=35,061) (Vakharia 2021) reported short term revision rates (0-90 days) for semi-active rUKA versus mUKA. The RCT had some study limitations and very serious imprecision. The revision rate was 0/64 in the rUKA group and 0/65 in the mTKA group. The cohort study had some study limitations and some imprecision, but demonstrated a large effect magnitude (RR<0.5). The revision rate was 14/13,617 (0.10%) in the rTKA group vs 107/21,444 (0.50%) in the mUKA group (RR 0.21; 95% CI 0.12 to 0.36). (Data estimated from a graph in the publication).

Conclusion: Short-term revision rate may be lower with semi-active rUKA than with mUKA (GRADE ⊕⊕◯◯).

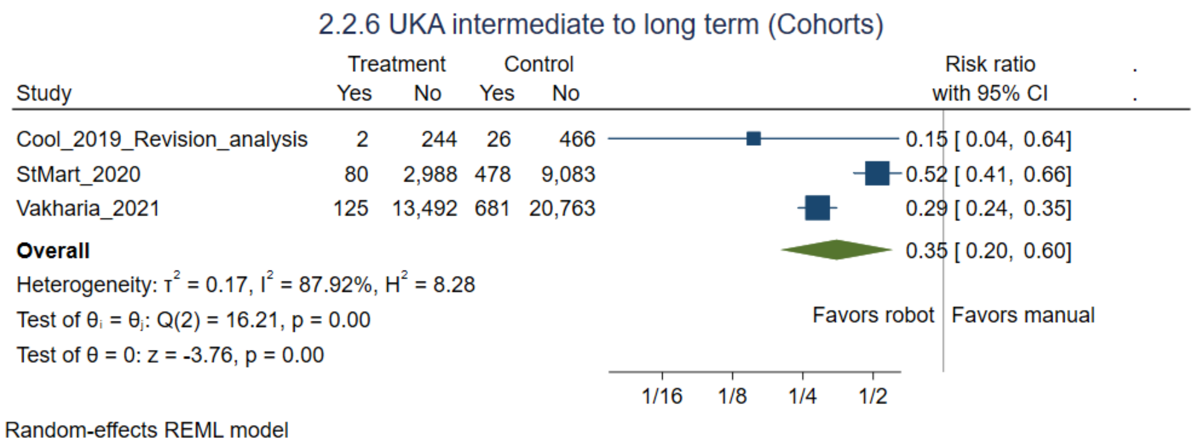
Intermediate-to-long term: Two RCTs (n=180) (Batailler 2021, Gilmour 2018) and three cohort studies (n=48,211) (Cool 2019b, St Mart 2020, Vakharia 2021) reported intermediate-to-long term revision rates (six months to five years) for semi-active rUKA versus mUKA. Both RCTs had some study limitations, some inconsistency, and very serious imprecision. The combined revision rate was 1/91 (1.10%) in the rUKA groups vs 2/89 (2.24%) in the mUKA groups, RR 0.74 (95% CI 0.05 to 10.51).

Fig. 13 Intermediate-to-long term revision rates for semi-active UKA versus mUKA



The three cohort studies had some study limitations, some indirectness, but no imprecision. The combined revision rate was 207/16,931 (1.22%) in the rUKA groups vs 1,185/31,497 (3.76%) in the mUKA groups, RR 0.35 (95% CI 0.20 to 0.60).

Fig. 14 Intermediate-to-long term revision rates for semi-active UKA versus mUKA



Conclusion: It is uncertain whether intermediate-to-long term revision rate differs between semi-active rUKA and mUKA (GRADE ⊕○○○).

Complications (Appendix 4:4)

Complications after semi-active rUKA versus mUKA were reported in two RCTs (n=195) (Bataillier 2021, Blyth 2017/Gilmour 2018) and two cohort studies (Emara 2021, St Mart 2020). The studies had some study limitations. The RCTs had some or serious imprecision. One of the cohort studies had some imprecision and uncertainty regarding directness. Complications were generally not reported in a systematic way in the included studies, e.g. complications were not predefined, not stratified according to severity, and only a few studies reported mechanical complications and procedure-related complications. Complication rates were not possible to determine, as most studies reported number of complications rather than number of patients in whom complications occurred. This precluded any meaningful comparison between rTKA and mTKA.

In Batailler 2021 minor complications after rUKA (stiffness, pain) and none after mUKA were reported. In Blyth 2017/Gilmour 2018), reported complications included stitch abscess (2 after rUKA, 12 after mUKA), suspected wound infection (3 after rUKA, 9 after mUKA) wound leakage (13 after rUKA, 16 after mUKA). The cohort studies reported a number of complications, similar as for semiactive rTKA. Indirect indicators of complications such as readmissions were not included in this assessment.

Differences in complication rate between semi-active rUKA and mUKA were not possible to quantify with any certainty, due to inadequate reporting. However, fewer complications were seen in the RCTs after rUKA than after mUKA.

Conclusion: Based on the available data it is not possible to draw any firm conclusions regarding complication rates in semi-active rUKA vs mUKA.

Outcomes, important for decision-making

Implant positioning (Appendix 4:5)

Implant positioning for semi-active rUKA versus mUKA was measured at three months postoperatively as implant component position in the sagittal, coronal, and axial planes and compared to a pre-operative plan in one RCT (n=120) (Bell 2016). The study had some study limitations and uncertain precision.

Bell reported statistically significant lower RMSE and lower median errors in all component parameters ($p < 0.01$) for the rUKA group compared to mUKA. Statistically significantly higher proportion of patients with component implantation within two degrees of the target position the rUKA group compared with the mUKA group was reported for femoral component sagittal position (57% vs 26%, p = 0.0008), femoral component coronal position (70% vs 28%, p = 0.0001), femoral component axial position (53% vs 31%, p = 0.0163), tibial component sagittal position (80% vs 22%, p = 0.0001), and tibial component axial position (48% vs 19%, p = 0.0009).

Conclusion: Implant positioning is probably improved with semi-active rUKA compared with mUKA (GRADE ⊕⊕⊕◯).

Length of stay (Appendix 4:6)

Length of stay for semi-active rUKA versus mUKA was reported in one RCT (n=129) (Blyth 2017) and one cohort study (n=738) (Cool 2019b). The RCT reported no statistically significant difference in length of stay between rUKA and mUKA (MD -0.5, ns). The study had some study limitations and uncertain precision. The cohort study reported an average length of stay of 1.8 days after rUKA vs 2.0 days after mUKA (MD -0.2, p=0.0047). The study had some study limitations.

Conclusion: There may be little or no difference in length of stay between semi-active rUKA and mUKA (GRADE ⊕⊕◯◯).

Learning curve (Appendix 4:7)

This outcome was not reported for this PICO.

Patient-reported pain (Appendix 4:8)

Short term: Short-term pain for semi-active rUKA versus mUKA was reported in one RCT (n=136) (Blyth 2017). The study had some study limitations and serious imprecision. Median pain levels postoperatively were reported as decreasing from 60 to 19 points (VAS 0-100) from day 0 to day 5 postoperatively after rUKA. The corresponding decrease after mUKA was from 48 to 45 points. At 8 weeks post-operatively, the median pain scores for the rUKA group were 55.4% lower than after mUKA (p=0.040).

At three months, median pain level was reported as 8 (Inter Quartile Range (IQR) 2-21) for rUKA vs 9 (IQR 4-28) for mUKA; between-group difference 1.0 (ns). At 12 months median pain level was reported as 4.5 (IQR 2-18) for rUKA vs 5.0 (IQR 1-23 for mUKA); between-group difference 0.5 (ns).

Conclusion: There is probably little or no difference in short-term pain between semi-active rUKA and mUKA (GRADE ⊕⊕⊕◯).

Long term: Long-term pain was reported in one RCT for semi-active rUKA (Gilmour 2018; n=112). The study had some study limitations and serious imprecision. Median pain level at 24 months was reported as 3.0 (IQR 1.0-26.0) for rUKA vs 5.0 (IQR 2.0-16.8) for mUKA; between-group difference 2.0 (ns).

Conclusion: There is probably little or no difference in long-term pain between semi-active rUKA and mUKA (GRADE ⊕⊕⊕◯).

Patient-reported health-related quality of life (HRQoL) (Appendix 4:9)

Intermediate-to-long term: HRQoL for semi-active rUKA versus mUKA was measured at 12 months in one RCT (n=136) (Blyth 2017), using SF-12. The study had some study limitations and serious imprecision. The study reported no statistically significant difference in HRQoL between rUKA and mUKA. MCID for PCS and MCS is 1.5-1.8, respectively (Clement et al., 2019).

SF-12 Physical Component Score: 46.8 (9.8) vs 44.6 (9.8); MD 2.2 (95% CI -1.09 to 5.49)

SF-12 Mental Component Score: 54.9 (8.3) vs 54.6 (8.3); MD 0.3 (95% CI -2.67 to 3.27)

Conclusion: There is probably little or no important difference in long-term HrQoL between semi-active rUKA and mUKA (GRADE ⊕⊕⊕◯).

Operating time (Appendix 4:10)

This outcome was not reported for this PICO.

Patient experiences

No study was identified that reported patients’ experiences of rUKA.

10. Organisational aspects

Time frame for the putative introduction of the new health technology

The time frame for a putative introduction of robot-assisted knee arthroplasty is one to two years. Regulatory requirements pertaining to national legislation would need to be met before any introduction of a robot system into routine health care. Before a new system could be introduced, it would need to undergo a process of procurement, and investments would need to be made in necessary equipment. No other investments nor infrastructure changes would be necessary.

Present use of the technology in other hospitals in Region Västra Götaland

Robot arm-assisted joint arthroplasty is currently not performed anywhere in Sweden. However, robotic surgery within soft tissue is a tangential technology that is in use, at SU and other hospitals in VGR, as well as elsewhere in Sweden.

Consequences of the new health technology for personnel

Adoption of new technologies in healthcare settings requires adequate competence and acceptance by staff and the organisation. Examples from soft tissue robotic surgery include the introduction of Registered Nurse First Assistants. If robotic arm-assisted knee arthroplasty were to be introduced at SU, it could lead to career advancement opportunities for operating room staff. System-specific training of qualified surgeons is generally provided by the system manufacturer. A 2-day cadaveric training course is required for surgeons for qualification in robotic surgery (Stryker, Smith-Nephew). Other operating room staff would also require training, which could be managed through agreements with manufacturers. Manufacturers generally require or supply support staff throughout an introductory period or while the robotic system is being operated at a site. This competence might be provided by the hospital organisation in the future through hiring or training of staff.

Consequences for other clinics or supporting functions at the hospital or in Region Västra Götaland

The RAS systems that are available on the market today are relatively small and light weight, and designed to utilise already existing hospital infrastructure, for example power, sterilisation, and information technology integration. Manufacturers require the establishment of service contracts for technical services that fall outside of the competencies of hospital staff.

Some systems require pre-operative radiology to be performed with a computed tomography (CT) scan with a special protocol supplied by the manufacturer. Normal radiographic evaluation before knee arthroplasty includes a weight-bearing knee x-ray usually performed in primary care, along with a standing long leg x-ray normally ordered prior to surgery in conjunction with the first out-patient visit, which may be replaced by the CT scan. The addition of a CT evaluation, depending on surgical volumes and arrangements between clinics, would incur additional costs. A single image-based RAS system would add between 200-400 CT scans per year. The likely longer initial operating times with a robot system would require adjustments to operative planning and possibly cause displacements of other surgeries during a “learning curve” period.

11. Economic aspects

Present costs of currently used technologies

Based on the cost per patient database (VEGA) from interventions performed at SU (2019-2020), the mean cost per patient for mUKA was 67,600 Swedish kronor (SEK) (based on code NGB19) and 98,400 SEK for mTKA (based on code NGB49).

Expected costs of the new health technology

Expected costs of RAS are difficult to estimate. No system is currently available in Sweden, and costs would vary substantially depending on system type and configuration. The main cost of implementing rTKA/rUKA is the fixed annual leasing and service costs for the robot technology. Some minor instruments and additional CT scan costs (approximately 3,000 SEK per operation) are disregarded in the analysis. The annual total cost per robot unit is assumed to be between 1 and 2 million SEK, depending on system (there is no current investment cost data to use). The additional cost per case will depend on both robot system cost and case volume, approximately as follows:

	Case volume per year				
	20/year	50/year	100/year	200/year	250/year
Robot-specific cost per case (thousand SEK)	50-99	20-40	10-20	5-10	4-8

Total change in costs

If there are no changes in revision rates or length of stay, rTKA/rUKA will lead to increased costs of about one to two million SEK per unit and year. If rTKA/rUKA substantially reduces revisions and length of stay, the technology could be cost-neutral. Below is shown the 10-year revision rates that would be required for rTKA/rUKA to be cost-neutral (assuming no change in length of stay and an investment cost per year between 1 and 2 million SEK):

	TKA	UKA
	Current revision rate: 4.5%	Current revision rate: 16%
Case volume/year	The revision rate needs to be reduced to:	
20	Cannot be cost-neutral	Cannot be cost-neutral
50	Cannot be cost-neutral	2 to 9%
100	Cannot be cost-neutral	9 to 12%
200	0.9 to 2.7%	12 to 14%
250	1.7 to 3.1%	13 to 15%

Possibility to adopt and use the new technology within the present budget

It is necessary that rTKA/rUKA reduces revision rates and/or length of stay substantially to be able to be implemented in the present budget without displacing other health care. It is also required that a decent case volume is achieved, which would require that the currently low case volumes of UKA are increased substantially.

Available economic evaluations or cost advantages/disadvantages

Findings from the studies that included economic analyses (excluding systematic reviews that also considered costs) are summarised in the table below. The relevant studies identified are from a US or United Kingdom (UK) healthcare setting. The observational cost-comparison studies, all from the US setting, generally point to rTKA being cost-saving compared to mTKA. This is primarily driven by fewer readmissions, shorter length-of-stay and fewer inpatient rehabilitations.

The studies have attempted to control for potential selection bias by matching procedures or regression analyses including patient characteristics as covariates/controls, but may not have identified all relevant confounders.

The cost-effectiveness studies are all Markov-cohort models that simulate cost and health outcomes by synthesising secondary data. Generally, several of the studies indicate that the cost per gained quality-adjusted life-year with rTKA compared to mTKA is low and rTKA is considered as cost-effective in clinics with a case volume of at least 100 patients per year and if rTKA reduces the revision rate by 50% or more. An exception was the study by Vermue et al. (2020) that indicated that the case volume needs to be at least 253 patients/year for rTKA to be considered cost-effective. Note that the assumption that rTKA reduces revision rates by half is not supported by the findings in this report (Appendix 4:2), which would imply that the cost-effectiveness results from these studies exaggerate the health economic benefits of rTKA.

Author	Time period	Country	Type of study	Main result (rTKA/rUKA vs mTKA/mUKA)
Cool et al.	2016-2020	US	Observational cost-comparison	rTKA was less expensive (USD2,391/patient) due to fewer readmissions.
Emara et al.	2008-2018	US	Observational cost-comparison	rTKA had (slightly) lower costs compared to mTKA
Pierce et al.	2016-2017	US	Observational cost-comparison	rTKA was less expensive (USD 4,049/patient) due to fewer readmissions and inpatient rehabilitation.
Shah et al.	2017	US	Observational cost-comparison	rTKA was less expensive (USD 600/patient) due to shorter length of stay and fewer post-op. admissions.
Month et al.	2016-2017	US	Observational cost-comparison	rTKA was less expensive (USD 2400/patient) due to fewer readmissions and health home visits.
Cotter et al.	2015-2017	US	Observational cost-comparison	rTKA was less expensive (USD 2100/patient) due to fewer readmissions and shorter length-of-stay.
Burn et al.	Secondary data from varying years	UK	Markov-model cost-effectiveness	Modelling results show that if rTKA reduce revisions by 50%, costs are reduced (and health outcomes improved).
Clement et al.	Secondary data from varying years	UK	Markov-model cost-effectiveness	If rTKA reduces revisions by 50%, both health outcomes and costs are higher with rTKA, but the cost per gained quality-adjusted life-year was deemed reasonable and cost-effective.
Moschetti et al.	Secondary data from varying years	US	Markov-model cost-effectiveness	Assumed rUKA vs mUKA reduces revisions from 1.5% to 0.5% per year. If this holds true, it still increases total costs, but deemed reasonable cost-effectiveness if case volume >100 patients per year.
Nherera et al.	Secondary data from varying years	UK	Markov-model cost-effectiveness	rUKA vs mUKA modelled to increase costs but if case volume>100 patients/year, the cost per gained quality-adjusted life-year was deemed reasonable (2800 GBP per gained QALY).
Vermue et al.	Secondary data from varying years	Unclear	Markov-model cost-effectiveness	rTKA was generally not considered cost-effective. Reasonable cost-effectiveness (cost per QALY <50,000 USD) if case volume at least 253 patients/year.
Yeroush-almi et al.	Secondary data from varying years	UK/US	Markov-model cost-effectiveness	rUKA vs mUKA modelled to increase costs for the typical clinic and assumed to reduce revisions (HR assumption=0.2). The increased cost per avoided revision modelled to be $14,737. rUKA cost-neutral if case volume at least 431 patients/year.

12. Ethical aspects

This HTA report shows that robotic arm-assisted techniques compared with manual knee arthroplasty probably improves implant positioning. Short-term revision rate for rUKA may be lower than for mUKA, but it is uncertain whether there is any long-term difference. For semi-active rTKA, intermediate-to-long-term revision rate may also be lower. However, no long-term patient benefits could be identified concerning patient-related outcomes such as knee function or health-related quality of life.

The robotic arm-assisted techniques increase the costs of surgery. The increased costs for robotic arm-assisted compared with manual surgery might affect other care at the hospitals in VGR as hospital budgets are limited.

Although several small RCTs and some very large cohort studies that have examined revision and complication rates were included in this HTA, there is still a paucity of adequately powered studies with low risk of bias reporting risks and benefits of RAS. Reporting of risks with RAS compared with manual surgery was suboptimal, but available data suggest that there are no major differences.

Malalignment of implants entails a risk of component wear, detrimental joint dynamics and revision. This HTA shows that the frequency of malalignment probably decreases when using RAS compared with conventional surgery. Malalignment has in previous studies been associated with higher revision rates. In the present HTA report we conclude that there may be no difference in intermediate-to-long term revision rates between active or semi-active rTKA and mTKA. Revisions are relatively rare after knee arthroplasty. A revision is detrimental to the patient, requiring new surgery, long postoperative recovery, and often entails a decreased quality of life.

Osteoarthritis is a disease that can be severe in its end stage and knee arthroplasty, both robotic-assisted and manual, improves quality of life in patients who have suffered long from pain and disability. Surgical treatment is effective in the long term but entails a significant surgical trauma and long recovery times.

Given the higher cost of surgery for RAS compared with manual knee arthroplasty, establishing a positive risk-benefit ratio is important. Hospital stay, revision rates, complication and readmission rates are examples of outcomes that may be deemed cost-modifiers as well as indirect indicators of patient well-being. Ensuring that patients are not exposed to increased direct risks by introducing the new technology is of primary importance. Displacement due to cost increases and jeopardised operation room scheduling pose risks to patients who will not receive prompt treatment of their condition and may be considered a risk to patient well-being. Uncertainty of long-term outcome of some cost-modifiers translates into some uncertainty in economic projections.

13. Discussion

Summary of main results

The aim of this HTA report was to compare clinical, radiographic and economic outcomes of RAS with conventional manual surgery in patients undergoing elective knee arthroplasty. The different systems, active and semi-active, as well as operation types (TKA and UKA), have different characteristics and were therefore analysed and presented separately. Key findings are not applicable to all RAS systems and may not serve as evidence base for specific systems in a fast changing and technologically diverse area of arthroplasty.

The main findings comparing UKA and TKA using semi-active RAS systems are:

- It is uncertain whether there is any difference in short- or long-term function between rTKA and mTKA. For rUKA there is probably a clinically important improvement in short-term function compared to manual surgery, but there is probably no difference in the long term.
- Intermediate-to-long term revision rates may be lower for rTKA than for mTKA. For rUKA, short-term revision rates may be lower compared to mUKA, while it is uncertain whether there is any difference in intermediate-to-long-term revision rate.
- The accuracy of implant positioning is probably improved in a clinically important way when using RAS for both TKA and UKA compared with manual surgery.
- There may be little or no difference in operating time between rTKA and mTKA (this outcome was not reported for rUKA). Operating time in rTKA is in two cohort studies reported to be reduced to times comparable to manual surgery after an initial learning curve.
- There is probably little or no difference in long-term HrQoL between RAS and manual knee arthroplasty, nor in short- and long-term pain between rUKA and mUKA.
- There may be little or no difference in length of stay between RAS and manual knee arthroplasty.
- It is uncertain whether complications rates differ between RAS and manual knee arthroplasty.

Overall completeness and applicability of evidence

The main perceived advantage of robotic assistance from a clinical perspective is the increased surgical precision. This has led to several studies on the accuracy of implant positioning showing favourable results for RAS over manual surgery. Malalignment of implants have been implicated in failure of both TKA and UKA (Hernigou et al., 2004, Emerson and Higgins, 2008, Collier et al., 2006).

The reported improvements in early functional outcomes for rUKA might be attributed to earlier recovery due to an increased precision in cutting and soft tissue balancing, resulting in less extensive surgical trauma. However, this short-term effect on function was not sustained in the intermediate-to-long term for rUKA, and it is uncertain whether there is any difference in short- and long-term function between semi-active rTKA and mTKA.

For active systems, the possible increased accuracy did not seem to result in any significantly improved functional outcomes or changes in revision rates. There was no evidence that supported differences in pain, HrQoL, length of stay or complications. The operative time may be longer for rTKA compared with mTKA.

There are several limitations to this report. The majority of the RCTs were small and investigated different robotic systems and types of knee arthroplasty. The included RCTs were mostly single-centre, often single-surgeon, studies, and a few studies included different implants in the robotic- and conventional surgery groups. The surgeon's volume and experience are predictive of outcomes after arthroplasty, as is the hospital where the surgeries are performed (Jolbäck et al., 2019, Badawy et al., 2017). The included cohort studies were generally large register studies with many using data from large Medicare or insurance registries in the US, implying potential risks of data source bias.

Another limitation was the intricacy in categorising different robotic systems. Outcome reporting was also heterogenous, with studies using different PROMs, heterogenous reporting of implant alignment, complications, assessment intervals, and statistical analysis. Few outcomes could be meta-analysed due to these variations. Most studies reported findings on a per-protocol basis. Revision events were few with revised patients excluded from follow-up, and thus revision had no impact on cumulative functional or HrQoL measurements. Robotic assistance is generally expensive, and many studies are funded by the manufacturers of RAS systems, with several authors also receiving royalties.

Agreements and disagreements with other studies and reviews

We identified 28 published systematic reviews on RAS, published from 2018 to 2021 (Appendix 1). Consistent with our findings, heterogenous reporting in studies, difficulties in pooling data, lack of long-term data, inadequate randomisation, risk of commercial bias, lack of stratification between systems and technologies, consideration for technology maturation, inadequate reporting on implant type and different implants in examined groups, and small sample sizes for some outcomes have been reported as limitations in several reviews (e.g. Kort et al., 2021, Zhang J et al., 2021). Recent reviews generally concur with our findings regarding implant positioning and effects on PROMs. Revision rates and complication rates are generally reported as uncertain but similar between RAS and conventional surgery, or slightly in favour of RAS. Operating time differs depending on the robotic system used but are generally longer for all systems (Kort et al., 2021, Zhang J et al., 2021, Negrin et al., 2021, Chin et al., 2020). Vermue et al. (2020a) reported a learning curve of between six to 36 cases for rUKA and rTKA with semi-active systems, with operating times comparable to that of conventional surgery at the end.

In our analysis, improved implant positioning with robot arm-assisted unicompartmental knee arthroplasty did not manifest in long-term functional improvements. Earlier secondary analysis in randomised studies have shown a correlation (observational data) between accurate implant positioning and patient-reported knee function, but also these findings have been at short-term follow-up (up to one year) (Choong et al., 2009, Gøthesen et al., 2014, van Lieshout et al., 2019). Long-term function also is influenced by several other factors, and many patients who suffer from poor implant positioning undergo revision surgery and are therefore not included in long-term follow-ups.

Implications for research

In line with the suggested potential benefit of an increased precision in arthroplasty surgery, long-term studies on both revision rates and functional outcomes are needed. As revisions are rare events and often encompass many potential confounders, a well-designed and adequately powered RCT would be a considerable and costly undertaking. Further follow-up in well maintained registers is needed. An RCT of semi-active rTKA is planned to start at SU and

Örebro University during 2022, followed by an RCT of semi-active rUKA planned to start during 2023.

14. Future perspectives

Scientific knowledge gaps

The HTA identified a need for well-designed, adequately powered, long-term studies on revision rates and functional outcomes. RCTs that are powered to examine long-term function may also examine optimal alignment in the mechanical axis. Capture and storage of peri-operative data may also enable studies on the soft-tissue balance performed by the surgeon and its implication on functional outcomes. Further research on outcomes of patients with large deformities or high activity demands are merited. There may be a need for consensus classifications to accommodate a diverse market of RAS systems. Grants funding of studies may be needed to avoid industry bias, to accommodate high procurement rates of RAS systems. There are many ongoing trials, as described below.

Ongoing research

A large number of studies are currently being conducted and are expected to be published in the years to come, mainly in 2023. The search in the Clinicaltrials.gov database and the World Health Organization ICTRP portal identified 207 and 57 ongoing clinical trials, respectively. Of these, 40 studies were considered relevant according to the PICO of this report, and are listed in Appendix 5. The studies are conducted in Thailand, Russia, Canada, United States, Poland, United Kingdom, France, Belgium, China, Ireland, Australia, Hong Kong, New Zealand, and Norway.

None of the identified ongoing trials have mortality as outcome. Nine have outcome revision, 34 have outcome function, seven have outcome complications, 26 have outcome implant positioning, three have outcome length of stay, 12 have outcome pain, 13 have outcome HRQoL, five have outcome operation time, and one have outcome learning curve.

Of the 40 identified studies, none have been registered as terminated and one is listed as completed (NCT04307251) (the World Health Organization database does not provide this information). The study was published in November, 2021 (Thiengwittayaporn et al., 2021). The study is not included in this report, but corroborates our findings of rTKA yielding better accuracy of knee alignment and component positioning than mTKA.

15. Participants in the project

The question was nominated by

Anna Nilsdotter, Associate Professor, Consultant Orthopaedic Surgeon, Head of the Department of Orthopedic Surgery, Sahlgrenska University Hospital, Mölndal, Sweden

Participating healthcare professionals

Jacob Hermodsson, PhD student, MD, Orthopedic Surgery Resident
Maziar Mohaddes, Associate Professor, Consultant Orthopaedic Surgeon
Tuuli Saari, PhD, Consultant Orthopaedic Surgeon
Frans Stålfelt, Biomedical engineer, PhD Student, MSc, Research Assistant
All from Sahlgrenska University Hospital, Mölndal, Sweden

Participants from HTA-centrum

Susanne Bernhardsson, PT, Associate Professor
Cecilie Hongslo Vala, Osteologist, PhD
Lennart Jivegård, MD, Associate Professor
Max Petzold, Statistician, Professor
Mikael Svensson, Health economist, Professor
All from Region Västra Götaland, HTA-centrum, Gothenburg, Sweden

Participants from the Medical Library

Therese Svanberg, Librarian
Linda Bäckman, Librarian
Both from Region Västra Götaland, Medical Library, Sahlgrenska University Hospital, Gothenburg, Sweden

Administrative support

Pernilla Rönnholm, project coordinator, Region Västra Götaland, HTA-centrum, Gothenburg, Sweden

Patient participant

Kerstin Nilsson

External reviewers

Eva Haglind, MD, Professor, Department of Surgery, Sahlgrenska University Hospital/Östra, Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden
Ola Samuelsson, MD, Associate professor, Region Västra Götaland, Department of Nephrology, Sahlgrenska University Hospital, Gothenburg, Sweden

Declaration of conflicts of interests

J Hermodsson is a co-investigator in a planned multi-centre study on robotic-arm assisted surgery which is partially funded by Stryker but does not receive any remuneration from the funder.

M Mohaddes is principal investigator in a multicentre study on robot-assisted surgery in total knee arthroplasty financed by Stryker. No financial compensation is paid to M Mohaddes from Stryker.

T Saari is principal investigator in a knee total arthroplasty study financed by DePuy and co-investigator in a multicentre study on robot-assisted surgery in total knee arthroplasty financed by Stryker, but does not receive any financial compensation.

S Bernhardsson, L Bäckman, C Hongslo Vala, L Jivegård, M Petzold, F Stålfelt, T Svanberg, and M Svensson declare no conflicts of interest.

Project time

The HTA was accomplished during the period of 20 May 2021 – 23 Feb 2022.

Literature searches were made on 28 May 2021.

Appendix 1: PICO, study selection, search strategies, and references

Question at issue:

Is active or semi-active robotic arm-assisted TKA or UKA for patients in need of knee arthroplasty better than manual TKA or UKA regarding mortality, patient-reported outcomes and experiences, revision, complications, implant positioning, length of stay, operation time and learning curve?

PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

P	Patients in need of elective primary knee arthroplasty
I1 **I2** **I3**	Robotic arm-assisted total knee arthroplasty using active systems (rTKA) Robotic arm-assisted total knee arthroplasty using semi-active systems (rTKA) Robotic arm-assisted unicompartmental knee arthroplasty using semi-active systems (rUKA)
C1 **C2** **C3**	Manual total knee arthroplasty (mTKA) Manual total knee arthroplasty (mTKA) Manual unicompartmental knee arthroplasty (mUKA)
O	Critical for decision-making Mortality Patient-reported function, measured with validated instruments RevisionComplications Important for decision-making Implant positioning Length of stay Patient-reported pain, measured with validated instruments Patient-reported health-related quality of life, measured with validated instruments Operation time Learning curve Patient experiences

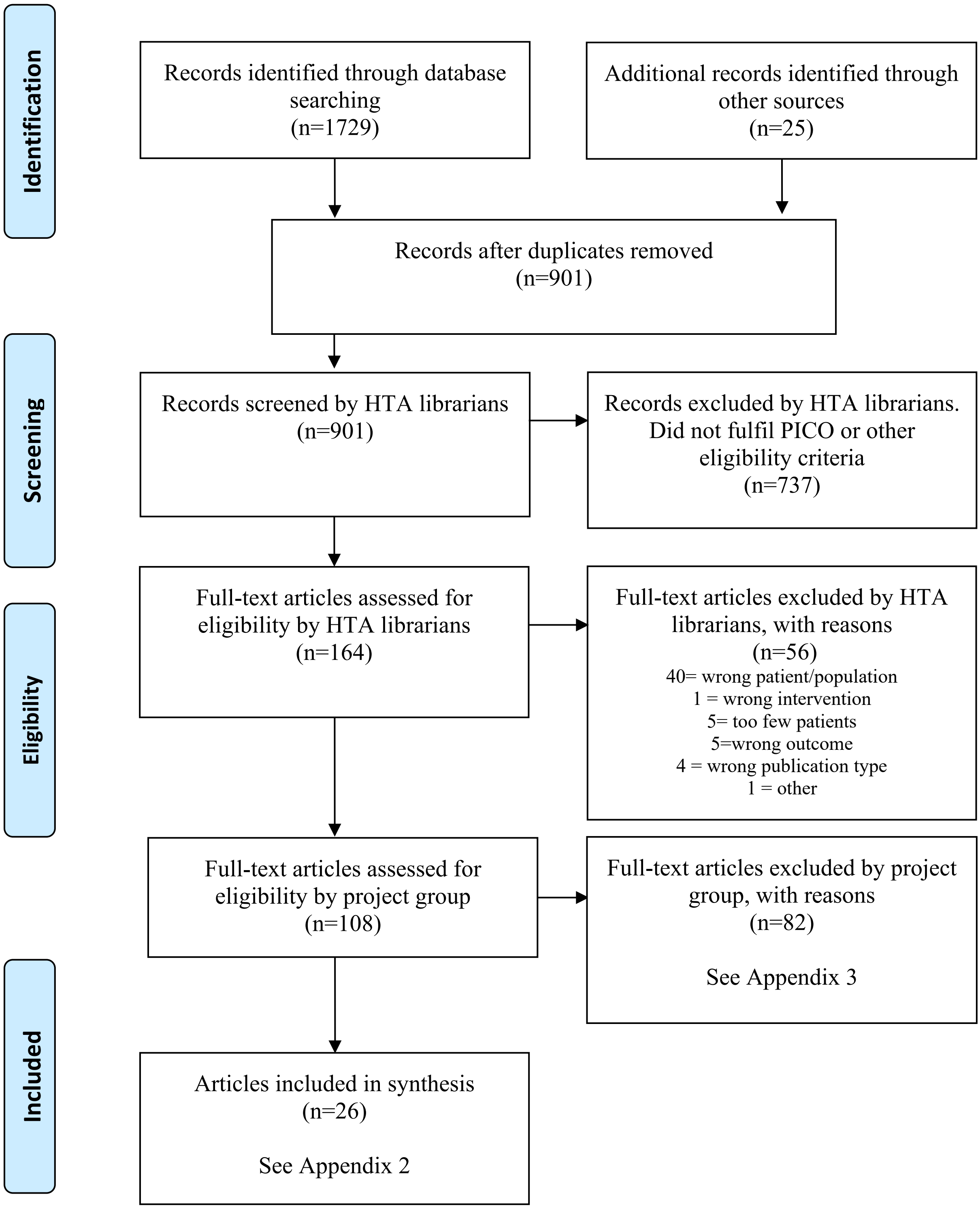
Eligibility criteria

Study design:
Randomised controlled trials
Non-randomised controlled studies with ≥ 200 patients in each group
Systematic reviews published from 2018 (only for commenting on)

Language:
English, Swedish, Norwegian, Danish

Publication date: 2010-

Selection process – flow diagram



Modified from Moher et al., 2009

Database: Ovid MEDLINE(R) ALL (OvidSP)
Date: 28 May 2021
No. of results: 639 ref

#	Searches	Results
1	exp arthroplasty, replacement, hip/ or exp arthroplasty, replacement, knee/ or exp hemiarthroplasty/	50741
2	exp hip prosthesis/ or exp knee prosthesis/	34683
3	(UKA or TKA or THA or THR or TKR).ab,kf,ti.	50931
4	1 or 2 or 3	98944
5	exp hip joint/ or exp knee joint/	87481
6	exp hip/ or exp knee/	25847
7	(knee or hip).ab,kf,ti.	276225
8	5 or 6 or 7	299678
9	(arthroplas$ or replace$ or implant$ or prosthes$).ab,kf,ti.	896244
10	Joint Prosthesis/	10367
11	"Prostheses and Implants"/	47133
12	9 or 10 or 11	914865
13	8 and 12	91318
14	4 or 13	128255
15	Robotics/	21844
16	Robotic Surgical Procedures/	9802
17	robot$.ab,kf,ti.	52096
18	(mako or rosa or robodoc or bluebelt navio).ab,kf,ti.	3438
19	15 or 16 or 17 or 18	60242
20	15 or 16 or 17	56971
21	14 and 19	897
22	limit 21 to yr="2010 -Current"	664
23	**limit 22 to (danish or english or norwegian or swedish)**	**639**

Note: All literature searches were devised and performed at a stage in the project when the population of interest was patients in need of knee and/or hip arthroplasty. This was later (but before data extraction had begun) changed to only knee arthroplasty.

Database: Embase 1974 to 2021 May 27 (OvidSP)
Date: 28 May 2021
No. of results: 759 ref

#	Searches	Results
1	exp knee arthroplasty/ or exp hip arthroplasty/	56088
2	exp total knee arthroplasty/	12629
3	exp hemiarthroplasty/ or exp hip replacement/ or exp knee replacement/	26550
4	joint prosthesis/ or exp hip prosthesis/ or exp knee prosthesis/	64619
5	(UKA or TKA or THA or THR or TKR).ab,kw,ti.	62649
6	1 or 2 or 3 or 4 or 5	143043

7	hip/	51410
8	knee/	67245
9	(knee or hip).ab,kw,ti.	353763
10	7 or 8 or 9	370508
11	exp arthroplasty/ or exp replacement arthroplasty/	83970
12	joint prosthesis/	11085
13	prosthesis/	32130
14	(arthroplas$ or replace$ or implant$ or prosthes$).ab,kw,ti.	1173142
15	11 or 12 or 13 or 14	1198494
16	10 and 15	117465
17	6 or 16	173369
18	exp robotics/	42079
19	exp robotic surgical device/	3577
20	exp robot assisted surgery/	13809
21	robot$.ab,kw,ti.	79386
22	(mako or rosa or robodoc or bluebelt navio).ab,kw,ti.	5052
23	18 or 19 or 20 or 21 or 22	93869
24	17 and 23	1176
25	limit 24 to (embase or medline)	1065
26	limit 25 to yr="2010 -Current"	793
27	**limit 26 to (danish or english or norwegian or swedish)**	**759**

Database: The Cochrane Library
Date: 28 May 2021
No. of results: 62 ref
Cochrane Reviews (0)
Other Reviews (0)
Trials (62)
Methods Studies (0)
Technology Assessments (0)
Economic Evaluations (0)
Cochrane Groups (0)

ID	Search	Hits
#1	MeSH descriptor: [Arthroplasty, Replacement, Hip] explode all trees	1908
#2	MeSH descriptor: [Arthroplasty, Replacement, Knee] explode all trees	2575
#3	MeSH descriptor: [Hemiarthroplasty] explode all trees	55
#4	MeSH descriptor: [Hip Prosthesis] explode all trees	1121
#5	MeSH descriptor: [Knee Prosthesis] explode all trees	722
#6	(UKA or TKA or THA or THR or TKR):ti,ab,kw (Word variations have been searched)	5673
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6	8739
#8	MeSH descriptor: [Hip Joint] explode all trees	1006
#9	MeSH descriptor: [Knee Joint] explode all trees	3380
#10	MeSH descriptor: [Hip] explode all trees	425
#11	MeSH descriptor: [Knee] explode all trees	822

#12	(knee OR hip):ti,ab,kw (Word variations have been searched)	50539
#13	#8 OR #9 OR #10 OR #11 OR #12	50565
#14	MeSH descriptor: [Joint Prosthesis] explode all trees	1900
#15	MeSH descriptor: [Prostheses and Implants] explode all trees	17603
#16	(arthroplas* or replace* or implant* or prosthes*):ti,ab,kw (Word variations have been searched)	80034
#17	#14 OR #15 OR #16	85881
#18	#13 AND #17	16349
#19	#7 OR #18	17118
#20	MeSH descriptor: [Robotics] explode all trees	908
#21	MeSH descriptor: [Robotic Surgical Procedures] explode all trees	296
#22	(robot*):ti,ab,kw (Word variations have been searched)	5216
#23	(mako or rosa or robodoc or bluebelt navio):ti,ab,kw (Word variations have been searched)	394
#24	#20 OR #21 OR #22 OR #23	5576
#25	#19 AND #24	132
#26	(clinicaltrials or trialsearch):so	364015
#27	**#25 NOT #26**	**78**
Limit search to 2010-2021		**62**

Database: CINAHL & AMED (EBSCOhost)
Date: 28 May 2021
No. of results: 269

#	Query	Results
S7	**S3 AND S4** **Limiters - Published Date: 20100101-20211231** **Expanders - Apply related words; Apply equivalent subjects** **Narrow by Language: - english** **Search modes - Find all my search terms**	**269**
S6	S3 AND S4 Limiters - Published Date: 20100101-20211231 Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	286
S5	S3 AND S4	358
S4	robot*	16,747
S3	S1 OR S2	50,632
S2	(knee or hip) AND (arthroplas* or replace* or implant* or prosthes*)	49,415
S1	UKA or TKA or THA or THR or TKR	14,199

The websites of **SBU** and **Folkehelseinstituttet** were visited on 28 May 2021.
Nothing relevant to the question at issue was found.

Reference lists
A comprehensive review of reference lists brought 25 new records.

Reference lists

Included studies:

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Project: Robotic arm-assisted knee arthroplasty

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of follow-up	Study groups; Intervention vs control (System)	Patients (n)	Mean age (years)	Men (%)	Outcome variables (measures) (Appendix)
Batailler 2021 France	RCT	6 months	I = rUKA C = mUKA (NAVIO[1])	66 I = 33 C = 33	I = 65.6 C = 67.1	I = 36.4 C = 63.6	Revision (4.2) Function (IKS, FJS) (4.3) Complications (4.4) Implant positioning (4.5)
Bell 2016 UK	RCT	Postoperative	I = rUKA C = mUKA (MAKO[2])	139 I = 70 C = 69	I = 62.5 C = 61.7	I = 17 C = 29	Implant positioning (4.5)
Blyth 2017 UK	RCT (same RCT as above)	12 months	I = rUKA C = mUKA (MAKO)	126 I = 64 C = 62	NR	NR	Revision (4.2) Function (AKSS, OKS, FJS, UCLA activity scale) (4.3) Complications (4.4) Pain (VAS) (4.8) HRQoL (SF-12) (4.9)
Gilmour 2018 UK	RCT (same RCT as above)	24 months	I = rUKA C = mUKA (MAKO)	112 I = 58 C = 54	I = 61.8 C = 62.6	I = 23 C = 8	Revision (4.2) Function (OKS, AKSS, FJS, UCLA activity scale) (4.3) Complications (4.4) Pain (VAS) (4.8)
Kayani 2021 UK	RCT	28 days	I = rTKA C = mTKA (MAKO)	30 I = 15 C = 15	I = 67.9 C = 68.7	I = 40 C = 47	Revision (4.2) Implant positioning (4.5) Operating time (4.10)

Project: Robotic arm-assisted knee arthroplasty

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of follow-up	Study groups; Intervention vs control (System)	Patients (n)	Mean age (years)	Men (%)	Outcome variables (measures) (Appendix)
Kim 2020 Republic of Korea	RCT	13 years (+/-5)	I = rTKA C = mTKA (ROBODOC[3]) (one surgeon)	1406 I = 700 patients, 750 knees C = 706 patients, 766 knees	I = 60 C = 61	I = 24.3 C = 27.2	Revision (4.2) Function (KSS, WOMAC, UCLA activity score) (4.3) Complications (4.4) Implant positioning (4.5) Pain (4.8) Operating time (4.10)
Liow 2014 Singapore	RCT	6 months	I = rTKA C = mTKA (ROBODOC)	60 I = 31 C = 29	I = 67.5 C = 68.3	NR	Function (KSS, OKS) (4.3) Complications (4.4) Implant positioning (4.5) Length of stay (4.6) HRQoL (SF-36) (4.9) Operating time (4.10)
Liow 2017 Singapore	RCT (same RCT as above)	2 years	I = rTKA C = mTKA (ROBODOC)	60 I = 31 C = 29	I = 67.5 C = 68.3	NR	Revision (4.2) Function (KSS, OKS) (4.3) Complications (4.4) HRQoL (SF-36) (4.9)
Song 2011 Republic of Korea	RCT	12 months	I = rTKA C = mTKA in contralateral knee (ROBODOC)	30 patients (60 knees) I = 30 C = 30	67	0	Revision (4.2) Function (HSS, WOMAC) (4.3) Implant positioning (4.5) Operating time (4.10)
Song 2013 Republic of Korea	RCT	3 years	I = rTKA C = mTKA (ROBODOC)	100 I = 50 C = 50	I = 66.1 C = 64.8	I = 8 C = 10	Revision (4.2) Function (HSS, WOMAC) (4.3) Complications (4.4) Implant positioning (PCL tension) (4.5) Operating time (4.10)

Project: Robotic arm-assisted knee arthroplasty

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of follow-up	Study groups; Intervention vs control (System)	Patients (n)	Mean age (years)	Men (%)	Outcome variables (measures) (Appendix)
Vaidya 2020 India	RCT	Postoperative	I = rTKA C = mTKA (NAVIO)	60 I = 32 C = 28	I = 62.2 C = 59.9	I = 25 C = 14.2	Implant positioning (4.5)
Cool 2019a USA	Cohort study	90 days	I = rTKA C= mTKA (MAKO)	3,114 I = 519 C = 2,595	NR	I = 42.8 C = 41.8	Length of stay (4.6)
Cool 2019b USA	Cohort study	2 years	I = rUKA C = mUKA (MAKO)	738 I= 246 C = 492	NR	I = 46.3 C = 42.7	Revision (4.2) Length of stay (4.6)
Emara 2021 USA	Cohort study	Between 2008 and 2018	I = rUKA C = mUKA (NR[4])	365,812 I = 72,916 C = 292,896	NR	NR	Complications (4.4) Length of stay (4.6)
Grosso 2021 USA	Cohort study	90 days	I = rTKA C = mTKA (NR[4])	4,086 I = 581 C = 3,505	I = 67 C = 67.1	I = 37.0 C = 37.0	Complications (4.4) Length of stay (4.6)
King 2020 USA	Cohort study	90 days	I = rTKA C = mTKA (MAKO)	492 I=202 C = 290	I = 68 C = 66	I = 35 C = 40	Complications (4.4) Length of stay (4.6) Pain (VAS) (4.8) Operating time (4.10)
Mont 2021 USA	Cohort study	90 days	I = rTKA C = mTKA (NR, but study design indicates MAKO)	249,320 I = 519 C = 248,801	NR	I = 42.8 C = 41.8	Length of stay (4.6)

Project: Robotic arm-assisted knee arthroplasty

Appendix 2 – Characteristics of included studies

Author Year Country	**Study design**	**Length of follow-up**	**Study groups; Intervention vs control (System)**	**Patients (n)**	**Mean age (years)**	**Men (%)**	**Outcome variables (measures) (Appendix)**
Ofa 2020 USA	Cohort study	Postoperative in-hospital 90 days 1 year	I = rTKA C = mTKA (NR[4])	755,350 I = 5,228 C = 750,122	NR	I = 50.3 C = 57.7	Revision (4.2) Complications (4.4) Length of stay (4.6)
Pierce 2020 USA	Cohort study	Postoperative	I = rTKA C = mTKA (MAKO)	2,124 I = 357 C = 1,785	NR	I = 51.6 C = 49.6	Length of stay (4.6)
Shah 2021 USA	Cohort study	Postoperative 90 days	I = rTKA C = mTKA (NR[4])	198,371 I = 4,351 C = 194,020	Total = 72.8	Total = 38.5	Mortality (4.1) Complications (4.4) Length of stay (4.6)
Shaw 2021 USA	Cohort study	4 weeks 6 months	I = rTKA C = mTKA (MAKO)	1,160 I = 260 C = 900	I = 67.2 C = 67.1	I = 32.3 C = 30.4	Function (KOOS-JR, PROMIS) (4.3) Operating time (4.10)
Singh 2021 USA	Cohort study	3 months 1 year	I = rTKA C = mTKA (MAKO and NAVIO)	6,809 I = 367 C = 6,442	I = 68.5 C = 66.2	I = 28.6 C = 31.1	Revision (4.2) Function (FJS, KOOS-JR) (4.3) Length of stay (4.6)
Sodhi 2018 USA	Cohort study	NR	I = rTKA C = mTKA (MAKO)	280 I = 240 C = 40	NR	NR	Learning curve (4.7) Operating time (4.10)
St Mart 2020 Australia	Cohort study	3 years	I = rUKA C = mUKA (MAKO)	12,412 I = 2,851 C = 9,561	I = 65.7 C = 65.2	I = 56.4 C = 57.8	Revision (4.2) Complications (4.4)

Project: Robotic arm-assisted knee arthroplasty

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of follow-up	Study groups; Intervention vs control (System)	Patients (n)	Mean age (years)	Men (%)	Outcome variables (measures) (Appendix)
Vakharia 2021 USA	Cohort study	5 years	I = rUKA C = mUKA (NR[4])	35,061 I = 13,617 C = 21,444	NR	I = 42.6 C = 47.6	Implant survivorship Revision (4.2)
Vermue 2020 Belgium	Cohort study	Postoperative	I = rTKA C = mTKA (MAKO)	649 I = 386 C = 263	I = 70.4 C = 70.0	I = 34.7 C = 37.3	Learning curve (4.7) Operating time (4.10)

AKSS: American Knee Society Score; C: control; CT: Computer tomography; FJS: Forgotten Joint Score; HRQoL: Health-related quality of life; I: Intervention; IKS: International knee society score; KOOS: Knee Osteoarthritis Outcome Score for Joint Replacement; LOS: Length of stay; mTKA: Manual total knee arthroplasty; mUKA: Manual unicompartmental knee arthroplasty; NA: Not available; NR: Not reported; OKS: Oxford Knee Score: PROMIS: Patient-Reported Outcomes Measurement Information System Global Health Measures of Physical Health (PH) and Mental Health (MH); rUKA: Robot-assisted unicompartmental knee arthroplasty; rTKA: Robot-assisted total knee arthroplasty; RCT: Randomised controlled trial; UCLA: University of California Los Angeles activity-level rating scale

1. NAVIO: Semi-active system
2. MAKO: Semi-active system
3. ROBODOC: Active system
4. Type of system not reported. Assumed to be semi-active system when from the US, since only semi-active systems have received approval for knee arthroplasty by the Food and Drug Administration.

Project: Robotic arm-assisted knee arthroplasty
Appendix 3 - Excluded articles

Author	Year	Reason for exclusion
Agarwal	2020	SR
Banger	2020	Wrong outcome: knee anatomy
Batailler	2020	SR
Battenberg	2020	Case series
Beldame	2010	Case series
Bhimani	2020	Cohort study with fewer than 200 patients/group
Bouche	2020	SR
Burger	2019	Case series
Burger	2020a	Case series
Burger	2020b	Case series
Burn	2020	Cohort study with fewer than 200 patients/group
Chin	2020	SR
Cho	2019	Cohort study with fewer than 200 patients/group
Chun	2011	Case series
Clement	2019	Markov study, only used in economic analysis
Clement	2020	SR
Cotter	2020	Cohort study with fewer than 200 patients/group
Fournier	2021	Cohort study with fewer than 200 patients/group
Fu	2018	SR
Gao	2020	SR
Gaudiani	2020	SR
Gordon	2021	Case series
Greiner	2020	Cohort study with fewer than 200 patients/group
Hasan	2020	SR
Held	2021	Cohort study with fewer than 200 patients/group
Iturriaga	2020	SR
Kamalapathy	2021	Wrong intervention: navigation-assisted system
Karunaratne	2019	SR

Project: Robotic arm-assisted knee arthroplasty
Appendix 3 - Excluded articles

Author	Year	Reason for exclusion
Khlopas	2020	Cohort study with fewer than 200 patients/group
Kleeblad	2017	Case series
Kleeblad	2018a	Case series
Kleeblad	2018b	Case series
Kort	2021	SR
Kunze	2021	SR
Lei	2021	SR
Lin	2020	SR
Lonner	2019	Case series
Luan	2020	Case series
Malkani	2020a	Wrong intervention: manipulation
Malkani	2020b	Case series
Mancino	2020	SR
Mannan	2018	SR
Marchand	2018	Case series
Marchand	2019	Case series
Marchand	2020	Cohort study with fewer than 200 patients/group
Marchand	2021	Case series
Matassi	2021	Case series
Mergenthaler	2020	Cohort study with fewer than 200 patients/group
Mofidi	2014a	Case series
Mofidi	2014b	Case series
Moschetti	2016	Markov study, only used in economic analysis
Motesharei	2018	Wrong outcome: gait analysis
Naziri	2018	Wrong control: computer navigated
Naziri	2019	Case series
Negrin	2021	SR
Nherera	2020	Markov study, only used in economic analysis

Project: Robotic arm-assisted knee arthroplasty
Appendix 3 - Excluded articles

Author	Year	Reason for exclusion
Nodzo	2020	Case series
Ollivier	2016	Wrong intervention: PSI
Onggo	2020	SR
Pearle	2017	Case series
Plate	2017	Case series
Ponzio	2016	Wrong population (not primary arthroplasty), wrong outcome (tibial resection)
Ren	2019	SR
Robinson	2019	SR
Sephton	2020	Cohort study with fewer than 200 patients/group
Shalhoub	2019	Case series
Shatrov	2020	SR
Smith	2019	Cohort study with fewer than 200 patients/group (also wrong intervention: CAS)
Smith	2021	SR
Tandogan	2021	SR
Wakelin	2021	Case series
Vermue	2020a	SR
Vermue	2021	Markov study, only used in economic analysis
Yeroushalmi	2021	Markov study, only used in economic analysis
Yim	2013	Case series
Zambianchi	2019	Case series
Zambianchi	2020a	Case series
Zambianchi	2020b	Case series
Zhang F	2019	SR
Zhang P	2021	SR
Zhang J	2021a	Cohort study with fewer than 200 patients/group
Zhang J	2021b	SR

SR: Systematic review

Note: At inclusion meeting, it was decided to exclude all case series due to a number of very large cohort studies that reported complications

Project: Robotic arm-assisted knee arthroplasty

* + No or minor problems ? Some problems - Major problems

Appendix 4.1
Outcome variable: Mortality

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				Robotic	Manual					
PICO 1: Active rTKA vs mTKA										
NR										
PICO 2: Semi-active rTKA vs mTKA										
Shah 2021 USA	Cohort study	198,371 I = 4,351 C = 194,020	n/a	0.39% (95% CI 0.19 to 0.59)	0.30% (95% CI 0.27 to 0.32) Between-group difference: 0.09% (-0.11 to 0.30); ns	System not specified. Assumed to be semi-active TKA, as only semi-active systems have received approval for knee arthroplasty by the Food and Drug Administration. Mortality was defined as death occurring within 90-days of the index operation. Data from risk-adjusted multivariable analysis.	+/?	?	-	
PICO 3: Semi-active rUKA vs mUKA										
NR										

C: control, I: intervention, mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; n/a: not applicable; NR: not reported; ns: not significant; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
PICO 1: Active rTKA vs mTKA										
Kim 2020 Republic of Korea	RCT	1406 I = 700 patients, 750 knees C = 706 patients, 766 knees	I= 26 patients, 26 knees C= 32 patients, 42 knees	**13 years** KSS (1989) 93 (5) 95% CI 0.8 to 2.4 WOMAC 18 (14) 95% CI 16 to 22 UCLA Median 7 95% CI 5 to 10	**13 years** KSS (1989) 92 (6) ns Between-group difference: 1; ns WOMAC 19 (15) ns Between-group difference: 1; ns UCLA Median 7 CI 95% 5 to 10 ns	ROBODOC TKA KSS (1989) is an older version of KSS. WOMAC consists of 24 items divided into 3 subscales pain, stiffness and physical function (17 items). possible score range of 0-20 for Pain, 0-8 for Stiffness, and 0-68 for Physical Function. Usually a sum of the scores for all three subscales gives a total WOMAC score, 0-96 points. Higher score = worse functional limitation. UCLA is a single-item 10-level-scale, range 1-10, with 1 representing a patient who is dependent on others and unable to leave home and 10 representing a highly physically active patient.	?	?	?	+
Liow 2014 Singapore	RCT	60 I = 31 C = 29	0	**6 months** KSS Function 71.3 (18.5) KSS Knee 80.8 (17.1)	**6 months** KSS Function 70 (15.6) ns KSS Knee 82.6 (14.7) ns	ROBODOC TKA	?	-	?	?

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic** Mean (SD), unless otherwise stated	**Results: Manual** Mean (SD), unless otherwise stated	**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary outcome***
				KSS Function/Knee* 152.1 (25.19) OKS 18.8 (5.7)	KSS Function/Knee* 152.6 (21.43) ns OKS 19.6 (6.8) ns	*) KSS Function and KSS Knee scores were summated for the meta-analysis.				
Liow 2017 Singapore	RCT	60 I = 31 C = 29	0	**24 months** KSS Function 77 (17.1) KSS Knee 81.8 (14.9) KSS Function/Knee* 158.8 (22.68) OKS 18.3 (7.0)	**24 months** KSS Function 73.9 (19.6) ns KSS Knee 87.9 (10.6) ns KSS Function/Knee* 161.8 (22.28) ns OKS 17.7 (4.2) ns	ROBODOC TKA *) KSS Function and KSS Knee scores were summated for the meta-analysis.	?	-	?	
Song 2011 Republic of Korea	RCT	30 60 knees I = 30 C = 30	0	**3 months** HSS 91.1 (6.7) WOMAC 36.8 (12.0)	**3 months** HSS 90.5 (6.6) ns WOMAC 36.4 (12.4) ns	ROBODOC TKA Hospital for Special Surgery (HSS) Knee Score The HSS Knee Score is based on a total of 100 points. The score is divided into seven categories, which include pain, function, range of motion, muscle strength, flexion deformity, instability, and subtractions. The knee is initially given a score of 0, and additions or subtractions are made according to specific criteria. Approximately 50% of the				

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

*	
+	No or minor problems
?	Some problems
-	Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				6 months HSS 93.4 (6.5) WOMAC 28.1 (11.0) **12 months** HSS 95.9 (5.2) WOMAC 18.5 (4.0) **12-20 months** HSS 95.2 (4.0) WOMAC 11.0 (4.5)	**6 months** HSS 93.5 (5.9) ns WOMAC 27.9 (10.1) ns **12 months** HSS 94.7 (5.5) ns WOMAC 20.1 (8.5) ns **12-20 months** HSS 94.7 (5.0) ns WOMAC 13.0 (6.6) ns	score is based on a patient interview and the remaining on physical exam. Higher value=better. 12-20 months definition is average of 16 months (SD 3.2)				
Song 2013 Republic of Korea	RCT	100 I = 50 C = 50	I = 21 C = 26	**36 months** HSS	**36 months** HSS	ROBODOC TKA				

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				95.7 (4.0) WOMAC 28.9 (4.4)	94.7 (6.7) ns WOMAC 30 (7.5) ns					
PICO 2: Semi-active rTKA vs mTKA										
Shaw 2021 USA	Cohort	1,160 I = 260 C = 900		**Preoperative** KOOS-JR (n=259) 48.25 (13.17) Min, max: 0, 84.6 PROMIS-PH (n=259) 41,36 (6.77) **2-4 weeks** KOOS-JR (n=231) 60.11 (variance 142.75) PROMIS-PH (n=229) 44.34 (variance 46.21)	**Preoperative** KOOS-JR (n=894) 48.03 (13.58) Min, max: 0, 100 ns PROMIS-PH (n=899) 41,98 (6.8) ns **2-4 weeks** KOOS-JR (n=689) 61.72 (variance 128.36) ns PROMIS-PH (n=667) 43.47 (variance 44.22) ns	MAKO KOOS-JR is a validated "knee health" instrument specifically designed to address the most relevant issues in patients with end-stage knee osteoarthritis undergoing TKA. The score range is 0-100, with 0 representing complete knee disability and 100 representing perfect knee health. PROMIS-PH is a validated physical health measure (part of PROMIS-Global Health) that measures physical function and other physical health domains. Score range is 20-80. Higher value = better global mental/physical health.				

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				4-8 months KOOS-JR (n=67) 71.72 (variance 290.6) PROMIS-PH (n=67) 48.62 (variance 53.07)	**4-8 months** KOOS-JR (n=166) 72.08 (variance 239.68) ns PROMIS-PH (n=170) 49.43 (variance 77.56) ns					
Singh 2021 USA	Cohort	6,809 I = 367 C = 6,442		**Preoperative** KOOS-JR (n=40) 43.39 (13.44) **3 months** KOOS-JR (n=80) 60.1 (13.03) FJS (n=42) 20.55 (20.56) **12 months** KOOS-JR (n=55) 67.17 (15.2)	**Preoperative** KOOS-JR (n=985) 45.23 (13.85) NR **3 months** KOOS-JR (n= 856) 63.64 (13.39) NR FJS (n=404) 26.50 (23.51) NR **12 months** KOOS-JR (n=673) 70.65 (15.65) NR	Statistical significance only specified when no technology assisted surgery is compared to both navigation and robotic-assisted surgery. No values available for comparison with robotic-assisted surgery only.	+	?	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				FJS (n=41) 38.27 (24.74)	FJS (n=436) 41.83 (27.16) NR					
PICO 3: Semi-active rUKA vs mUKA										
Batailler 2021 France	RCT	66 I = 33 C = 33	0	**6 months** IKSS Function 87.2 (13.7) Min, max: 35, 100 IKSS Knee 91.9 (10.2) Min, max: 65, 100 IKSS Function/Knee* 179.1 (17.08) FJS 76.8 (20.4) Min, max: 31, 100	**6 months** IKSS Function 81.3 (12) Min, max: 51, 100 ns IKSS Knee 88.8 (8.9) Min, max: 66, 100 ns IKSS Function/Knee* 170.1 (14.94) ns FJS 68.1 (21.1) Min, max: 11, 100 ns	I = Navio UKA Journey II Uni C = Conventional UKA Journey II Uni Secondary outcome. IKS Score comprises a function score and a knee score, each on a scale 0-100 that can be summated to a total score, 0-200. Higher value = better function. *) KSS Function and KSS Knee scores were summated for the meta-analysis. FJS is a joint-specific, self-report questionnaire that measures the patient's ability to "forget" about their problematic joint after treatment. Scale 0-100, higher value = better (greater patient satisfaction and better outcomes; less awareness of the affected joint when performing daily activities).	+	?/-	-	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
Blyth 2017 UK	RCT	139 I = 70 C = 69	3 I = 3 C = 0	**Preoperative** AKSS 105 (27) OKS 20.9 (8.1) **3 months** AKSS Median 164 Q1, Q3: 131, 178 OKS Median 35 Q1, Q3: 29, 41 FJS Median 43.8 Q1, Q3: 20.5, 68.2 **12 months** AKSS Median 171 Q1, Q3: 153, 179	**Preoperative** AKSS 102 (27) ns OKS 20.5 (7.5) ns **3 months** AKSS Median 143 Q1, Q3: 132, 166 p = 0.041 OKS Median 33 Q1, Q3: 23, 38 ns FJS Median 27.1 Q1, Q3: 15.2, 62.5 ns **12 months** AKSS Median 164 Q1, Q3: 144, 182	I = MAKO Restoris MCK UKA C = Conventional Oxford Phase 3 UKA The AKS score is comprised of two parts, one completed by healthcare personnel after a patient interview and physical examination, and one by the patient itself. It has two components, a knee score and a function score, which summated ranges 0-200. Higher values = better knee condition. The knee component has four items that add points (pain, flexion, mediolateral stability, and anteroposterior stability) and three items that subtract points (malignment, flexion contracture and extension lag). In the functional component, two items add points (walking and stairs) and one item removes points (use of a walking aid). The Oxford Knee Score: 12 items are scored 0-4, for a total of 0-48 points. Higher value = better. OKS power 3 months (%) 99.9 in post hoc power analysis Underpowered for AKSS in post hoc power analysis	+	?	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

*	
+	No or minor problems
?	Some problems
-	Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				<u>UCLA</u> Median 5 Q1, Q3: 4, 6 <u>OKS</u> Median 40 Q1, Q3: 32, 44	ns <u>UCLA</u> Median 5 Q1, Q3: 4, 7 ns <u>OKS</u> Median 39 Q1, Q3: 33, 44 ns	UCLA is a single-item 10-level-scale, range 1-10, with 1 representing a patient who is dependent on others and unable to leave home and 10 representing a highly physically active patient.				
Gilmour 2018 UK	RCT	139 I = 69 C = 70	27 I = 11 C = 16	**Preoperative** <u>AKSS</u> 105 (27) <u>OKS</u> 20.9 (8.1) <u>UCLA</u> Median 3.0 Q1, Q3: 3.0, 4.5 **24 months** <u>AKSS</u> Median 168.0	**Preoperative** <u>AKSS</u> 102 (27) ns <u>OKS</u> 20.5 (7.5) ns <u>UCLA</u> Median 4.0 Q1, Q3: 3.0, 6.0 ns **24 months** <u>AKSS</u> Median 173.0	I = MAKO Restoris MCK UKA C = Conventional Oxford Phase 3 UKA Underpowered for AKSS in post hoc power analysis UCLA is a single-item 10-level-scale, range 1-10, with 1 representing a patient who is dependent on others and unable to leave home and 10 representing a highly physically active patient.	+	?	? ?/-	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.2
Outcome variable: Function

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD), unless otherwise stated	Results: Manual Mean (SD), unless otherwise stated	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				Q1, Q3: 141.0, 191.0 <u>OKS</u> Median 39 Q1, Q3: 32.8, 45 <u>FJS</u> Median 55.2 Q1, Q3: 23.3, 81.8	Q1, Q3: 162.3, 185.5 Between-group difference: 5; ns <u>OKS</u> Median 40 Q1, Q3: 35.8, 44 Between-group difference: 1; ns <u>FJS</u> Median 54.1 Q1, Q3: 37.0, 79.2 Between-group difference: 0.9; ns					

AKSS: American Knee Society Score; C: control; FJS: Forgotten Joint Score; HSS: Hospital for Special Surgery Knee-Rating Scale; I: intervention; IKSS: International Knee Society Score; KOOS-JR: Knee Osteoarthritis Score-Joint Replacement; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; NR: not reported; ns: not significant; OKS: Oxford Knee Score; PROMIS-PH: Patient-Reported Outcomes Measurement Information System, Physical Health; Q: quartile; RCT: randomised controlled trial; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty; SD: Standard deviation; UCLA: University of California Los Angeles activity-level rating scale; WOMAC: Western Ontario and McMaster Universities Arthritis Index

Navio: Semi-active system
MAKO: Semi-active system
ROBODOC: Active system

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.3
Outcome variable: Revision

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results**		**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				Robotic Time Revision_rate Cases/n (%) (unless otherwise specified) (95% CI)	**Manual Time Revision_rate Cases/n (%) (unless otherwise specified) p-value if available**					
PICO 1: Active rTKA vs mTKA										
Kim 2020 Republic of Korea	RCT	1406 I = 700 (750 knees) C = 706 (766 knees)	I = 26 (26 knees) C= 32 (42 knees)	**15 years** Implant survival 98% (95% CI 94-100)	**15 years** Implant survival 98% ns	I: ROBODOC TKA C: Manual TKA Both: Duracon® posterior cruciate-substituting total knee prosthesis, patellar resurfacing 10 knees each group, cemented, single surgeon	?	?	?	+
Liow 2017 Singapore	RCT	60 I = 31 C = 29	0	**90 days** 0/31 (0.00%) **24 months** 2/31 (6.45%)	**90 days** 0/29 (0.00%) n/a **24 months** 0/29 (0.00%) NR	I: ROBODOC TKA C: Manual TKA Both: Zimmer NexGen LPS-Flex PS, single surgeon	?	-	?	
Song 2011 Republic of Korea	RCT	30 (bilateral knees) I = 30 C = 30	0	**90 days** 0/30 (0.00%) **16 months** 0/30 (0.00%)	**90 days** 0/30 (0.00%) n/a **16 months** 0/30 (0.00%) n/a	I: ROBODOC TKA C: TKA contralateral knee Both: Zimmer NexGen PS, cemented, single surgeon	?	?/-	?	
Song 2013 Republic of Korea	RCT	100 I = 50 C = 50	47 I = 21 C = 26	**90 days** 0/50 (0.00%)	**90 days** 0/50 (0.00%) n/a	I: ROBODOC TKA C: TKA contralateral knee Both: Zimmer NexGen CR, cemented, single surgeon	?	?/-	?	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.3
Outcome variable: Revision

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic Time Revision_rate Cases/n (%) (unless otherwise specified) (95% CI)**	**Results: Manual Time Revision_rate Cases/n (%) (unless otherwise specified) p-value if available**	**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				36 months 0/50 (0.00%)	**36 months** 0/50 (0.00%) n/a					
PICO 2: Semi-active rTKA vs mTKA										
Kayani 2021	RCT	60 I = 15 C = 15	0	**28 days** 0/15 (0.00%)	**28 days** 0/15 (0.00%) n/a	I: MAKO TKA C: Manual TKA Both: Triathlon cruciate-retaining knee system, asymmetrical component patellar resurfacing.				
Ofa 2020 USA	Cohort	755,350 I = 5,228 C = 750,122	n/a	**90 days** 44/5,228 (0.84%) **12 months** 151/5,228 (2.89%)	**90 days** 5,489/750,122 (0.73%) ns **12 months** 25,060/750,122 (3.34%) Significant, p-value NR	I: Semi-active (System not specified) TKA C: Manual TKA	+/?	?/-	+	
Singh 2021 USA	Cohort	6,809 I = 367 C = 6,442	n/a	**90 days** 0 /367 (0.00%)	**90 days** 16/6,442 (0.20%) ns	I: MAKO TKA C: Manual TKA	+	?	?	
PICO 3: Semi-active rUKA vs mUKA										
Batailler 2021 France	RCT	66 I = 33 C = 33	0	**6 months** 1/33 (3.00%)	**6 months** 0/33 (0.00%) ns	I: Navio UKA C: Manual UKA Both: Journey II Uni (Smith and Nephew®, Andover UK), fixed bearing, cemented	+	?/-	-	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.3
Outcome variable: Revision

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Risk of Bias*	Precision*	Precision, primary
				Robotic Time Revision_rate Cases/n (%) (unless otherwise specified) (95% CI)	**Manual Time Revision_rate Cases/n (%) (unless otherwise specified) p-value if available**					
Blyth 2017	RCT	129 I = 64 C= 65	0	**3 months** 0/64 (0.00%)	**3 months** 0/65 (0.00%) n/a	I: MAKO Restoris MCK, fixed bearing C: Manual UKA Oxford Phase 3, mobile bearing				
Gilmour 2018 UK	RCT	139 I = 69 C = 70	27 I = 11 C = 16	**24 months** 0/58 (0.00%)	**24 months** 2/56 (3.45%) NR	I: MAKO Restoris MCK, fixed bearing C: Manual UKA Oxford Phase 3, mobile bearing	+	?	?/-	
Cool 2019b USA	Cohort	738 I = 246 C = 492	n/a	**24 months** 2/246 (0.81%)	**24 months** 26/492 (5.28%) p=0.0017	I: MAKO UKA C: Manual UKA	+/?	?/-	+	
St Mart 2020 Australia	Cohort	12,412 I = 2,851 C = 9,561	n/a	**Cumulative 3 years** 80/3,086 (2.60%)	**Cumulative 3 years** 478/9,561 (5%) NR	I: MAKO UKA C: Manual UKA mixed implants	?	?	?	
Vakharia 2021 USA	Cohort	35,061 I = 13,617 C = 21,444	n/a	**90 days** 14/13,617 (0.1%) **Cumulative 5 years** 125/13,617 (0.92%)	**90 days** 107/21,444 (0.5%) ns **Cumulative 5 years** 681/21,444 (3.18%) p=0.003	I: Semi-active (System not specified) UKA C: Manual UKA Revision rate estimated from graph of survival data in the publication.	+	?	?	

C: control, I: intervention, mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; n/a: not applicable; NR: not reported; ns: not significant; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time period n, type of complication	Results: Manual Time period n, type of complication	Comments	Directness*	Risk of bias*	Precision*	Precision, primary utcome*
PICO 1: Active rTKA vs mTKA										
Kim 2020 Republic of Korea	RCT	1406 I = 700 patients, 750 knees C = 706 patients, 766 knees	58 I = 26 C = 32	**13 years** 15 aseptic loosenings 4 superficial wound infection	**13 years** 15 aseptic loosenings 4 superficial wound infections 4 stiffness		?	?	?	+
Liow 2014 Singapore	RCT	60 I = 31 C = 29	0	**6 months** 1 deep vein thrombosis (soleal vein) 1 superficial wound site infection	**6 months** 1 post-operative delirium 1 deep vein thrombosis (peroneal vein)	All complications were managed non-surgically				
Liow 2017 Singapore	RCT	60 I = 31 C = 29	0	**24 months** 1 superficial wound site infection 2 venous thromboembolisms 1 septic arthritis of the implanted knee leading to revision 1 pain leading to revision	**24 months** 1 venous thromboembolism 1 post-operative delirium (systemic complication)		?	-	?	
Song 2013 Republic of Korea	RCT	100 I = 50 C = 50	47 I = 21 C = 26	**36 months** 2 superficial wound infections 1 pin site seroma 2 patellar tendon abrasions 1 skin rash 1 lymphatic edema	**36 months** 2 Superficial wound infections 3 pleural effusions 1 incisional skin sloughing 2 gastrointestinal 1 TIA/CVA		?	-	-	+

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time period n, type of complication	Results: Manual Time period n, type of complication	Comments	Directness*	Risk of bias*	Precision*	Precision, primary utcome*
				1 crepitus 2 arrythmias 1 pleural effusion	2 foot numbness					
PICO 2: Semi-active rTKA vs mTKA										
Grosso 2021 USA	Cohort	4,086 I = 581 C = 3,505		**90 days** 11 complications	**90 days** 11 complications	Complications not specified				
King 2021 USA	Cohort	492 I= 202 C = 290		**Postoperative** 0 manipulation under anesthesia within 30 days 0 deep or organ space SSI 0 superficial infection **30 days (ED)** 1 syncope/AMS 1 leg swelling 2 dressing problems 1 chest pain or shortness of breath 1 fall 2 medication problem 1 GI bleed 1 disc herniation 0 urinary retention	**Postoperative** 6 manipulations under anesthesia within 30 days 0 deep or organ space SSI 1 superficial infection **30 days (ED)** 3 syncopes/AMS 7 leg swelling 0 Dressing problem 5 chest pain or shortness of breath 2 falls 2 medication problems 1 GI bleed 0 disc herniation 1 urinary retention	AMS – Altered Mental Status ED – Emergency Department GI – Gastrointestinal SSI – Surgical Site Infection				

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* + No or minor problems
? Some problems
- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic** **Time period n, type of complication**	**Results: Manual** **Time period n, type of complication**	**Comments**	**Directness***	**Risk of bias***	**Precision***	**Precision, primary utcome***
				90 days (Readmission) 1 GI bleed 0 strokes 1 pulmonary embolism 0 femoral neck fracture 0 urinary retention 1 disc herniation	**90 days (Readmission)** 1 GI bleed 1 stroke 0 pulmonary embolisms 1 femoral neck fracture 1 urinary retention 0 disc herniation					
Ofa 2020 USA	Cohort	755,350 I = 5,228 C = 750,122		**Postoperative** 15 deep vein thromboses 8 altered mental status 7 pulmonary embolism 613 anaemias 38 acute renal failures 5 myocardial infarction 18 cerebrovascular events 7 pneumonias 15 respiratory failure 43 urinary tract infection **90 days** 101 deep vein thromboses 27 altered mental status 28 pulmonary embolisms 135 anaemias 46 acute renal failures 14 myocardial infarctions 64 cerebrovascular events 46 pneumonias	**Postoperative** 5,345 deep vein thromboses 3,111 altered mental status 4,026 pulmonary embolisms 179,851 anaemias 1,5987 acute renal failures 1,620 myocardial infarctions 5,310 cerebrovascular events 4,086 pneumonias 6,914 respiratory failures 13,477 urinary tract infections **90 days** 23,274 deep vein thromboses 6,298 altered mental status 9,203 Pplmonary embolisms 49,227 anaemias 13,049 acute renal failures 3,104 myocardial infarctions 10,827 cerebrovascular events 9,261 pneumonias		+/?	?/-	+	

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time period n, type of complication	Results: Manual Time period n, type of complication	Comments	Directness*	Risk of bias*	Precision*	Precision, primary utcome*
				19 respiratory failures 143 urinary tract infections 2 prosthetic dislocations 25 prosthetic joint infections 2 aseptic loosenings 88 manipulations under anesthesia **12 months** 3 prosthetic dislocations 39 Prosthetic joint infections 9 Aseptic loosenings 88 manipulations under anesthaesia	6,022 respiratory failures 34,869 urinary tract infections 159 prosthetic dislocations 4,637 prosthetic joint infections 300 periprosthetic fractures 182 aseptic loosenings 19,139 manipulations under anesthesia **12 months** 248 prosthetic dislocations 7,221 prosthetic joint infections 676 periprosthetic fractures 1,212 aseptic loosenings 25,059 manipulations under anesthaesia					
Shah 2021 USA	Cohort	198,371 I = 4,351 C = 194,020		**Postoperative** 165 complications	**Postoperative** 6353 complications	Merged data extraction from Bundled Payment for Care Improvement (BPCI) and non-BCPI categories				
PICO 3: Semi-active rUKA vs mUKA										
Batailler 2021 France	RCT	66 I = 33 C = 33	0	**6 months** 2 stiffness 1 pain	**6 months** No complications	Complications not pre-defined.	+	?/-	-	

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* +	No or minor problems
?	Some problems
-	Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time period n, type of complication	Results: Manual Time period n, type of complication	Comments	Directness*	Risk of bias*	Precision*	Precision, primary utcome*
Blyth 2017	RCT	129 I = 64 C= 65	0	**24 months** 0 deep infections 0 MUA 2 stitch abscess/minor wound breakdowns 5 redness/swelling in a dry wound 0 wound leakages (negative cultures) 0 revised	**24 months** 0 deep infections 0 MUA 12 stitch abscess/minor wound breakdowns 5 redness/swelling in a dry wound 5 wound leakages (negative cultures) 0 revised					
Gilmour 2018 UK	RCT	139 I = 69 C = 70	27 I = 11 C = 16	**24 months** 13 wound leakages 3 suspected wound infections treated with antibiotics 1 stitch abscess, resolved without antibiotics	**24 months** 16 wound leakages 9 suspected wound infections treated with antibiotics 1 stitch abscesses, resolved without antibiotics 1 persistent numbness 1 wound dehiscence, required surgery 1 dislocated polyethylene bearing, required surgery 5 radiographic lucent lines, under observation only 1 revision to TKA for pain 1 revision to TKA for aseptic loosening		+	?	? ?/ -	

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* + No or minor problems ? Some problems - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time period n, type of complication	Results: Manual Time period n, type of complication	Comments	Directness*	Risk of bias*	Precision*	Precision, primary utcome*
Emara 2021 USA	Cohort	365,812 I = 72,916 C = 292,896		**Between 2008 and 2018** 389 implant-related mechanical complications 105 mechanical loosenings 60 dislocations of prosthetic joint * prosthetic joint implant failures 59 periprosthetic fractures * articular-bearing surface wears 155 unspecified/other mechanical 17,308 procedure-related nonmechanical complications 98 hematomas/seromas 19 disruptions of wound 614 infections 20 postoperative infections * infections/inflammatory reactions 584 urinary tract infections 20 cellulitis/abscess 12,213 acute posthemorrhagic anaemias 35 pulmonary embolisms with/without infarction 85 lower extremity DVTs * pulmonary insufficiency 816 transfusions of blood and products 140 central nervous system 5374 cardiac * peripheral vascular 185 respiratory	**Between 2008 and 2018** 7,161 implant-related mechanical complications 3,619 mechanical loosenings 1,354 dislocations of prosthetic joint 170 prosthetic joint implant failures 566 periprosthetic fractures 245 periprosthetic osteolyses 255 articular-bearing surface wears 1,682 unspecified/other mechanical 83,109 procedure-related nonmechanical complications 20 postoperative shocks 477 hematomas/seromas 223 disruptions of wound 3,646 infections 203 postoperative infections 49 infection/inflammatory reactions 3,274 urinary tract infection 242 cellulitis/abscess 58,338 acute posthemorrhagic anemia 343 pulmonary embolism with/without infarction 694 lower extremity DVT 68 pulmonary insufficiency 9,963 transfusion of blood and products	Revisions not reported	+	?	+	Comp: +

Project: Robot arm-assisted knee arthroplasty
Appendix 4.4
Outcome variable: Complications

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic** Time period n, type of complication	**Results: Manual** Time period n, type of complication	**Comments**	**Directness***	**Risk of bias***	**Precision***	**Precision, primary utcome***
				* Not available	799 central nervous system 23695 cardiac 143 peripheral vascular 932 respiratory					
St Mart 2020 Australia	Cohort	12,412 I = 2,851 C = 9,561		**Postoperative** 10 revisions due to loosening 8 revisions due to progression of disease 1 revision due to fracture 18 revisions due to infection 3 revisions due to pain 3 revisions due to instability 1 revision due to malalignment 1 revision due to patellofemoral pain 2 other	**Postoperative** 114 revisions due to loosening 64 revisions due to progression of disease 25 revisions due to bearing of dislocation 26 revisions due to fracture 25 revisions due to infection 16 revisions due to pain 8 revisions due to instability 8 revisions due to malalignment 3 revisions due to prosthesis dislocation 3 revisions due to incorrect sizing 2 revisions due to patellofemoral pain 1 revision due to implant breakage tibial 1 revision due to lysis 1 revision due to mental related pathology 1 revision due to osteonecrosis 1 revision due to synovitis 2 other	Only complications leading to revisions were reported.	?	?	?	

C: control; I: intervention; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; RCT: randomised controlled trial; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**	**Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**	**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
PICO 1: Active rTKA vs mTKA										
Kim 2020 Republic of Korea	RCT	1,406 I = 700 patients, 750 knees C = 706 patients, 766 knees	58 I = 26 patients, 26 knees C = 32 patients, 42 knees	**13 years** <u>Femoral coronal component position (alignment)</u> Mean (SD, Min-Max): 98 (2, 94-102) <u>Femoral sagittal component position (alignment)</u> Mean (SD, Min-Max): 3 (1, 1-4) <u>Femorotibial angle (standing) (degrees)</u> Mean (SD, Min-Max): 2 (2, 0-6) <u>Rotational alignment femoral (external)</u> Mean (SD, Min-Max): 5 (4, 3-7) <u>Rotational alignment tibial (external)</u> Mean (SD, Min-Max): 6 (7, 5-8)	**13 years** <u>Femoral coronal component position (alignment)</u> Mean (SD, Min-Max): 97 (2, 91-101) ns <u>Femoral sagittal component position (alignment)</u> Mean (SD, Min-Max): 2 (2, 0-4) ns <u>Femorotibial angle (standing) (degrees)</u> Mean (SD, Min-Max): 3 (3, 0-8) ns <u>Rotational alignment femoral (external)</u> Mean (SD, Min-Max): 5 (5, 4-7) ns <u>Rotational alignment tibial (external)</u> Mean (SD, Min-Max): 6 (8, 5-9) ns	I: ROBODOC TKA C: Manual TKA Standing AP hip-to-ankle radiographs, supine AP and lateral radiographs, and skyline patellar radiographic were made. The radiographs were evaluated to determine the limb anatomic axis, component alignment, joint line, posterior femoral condylar offset, and the presence and location of radiolucent lines. All radiographs were made under fluoroscopic guidance to control knee rotation. Loosening was defined as change in the position of the components and assessed using plain radiographs, osteolysis using CT scans at the latest follow-up visit, and component and limb alignment on mechanical axis radiographs.	?	?	?	+

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**	**Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**	**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				<u>Tibial coronal component position (alignment)</u> Mean (SD, Min-Max): 90 (1, 87-94) <u>Tibial sagittal component position (alignment)</u> Mean (SD, Min-Max): 87 (2, 84-93) <u>5 degree outliers femorotibial angle (standing)</u> % (cases/n) 4 (29/724) <u>3 degree outliers femoral coronal</u> % (cases/n) 11 (80/724) <u>5 degree outliers femoral coronal</u> % (cases/n) 3 (22/724) <u>3 degree outliers femoral sagittal</u> % (cases/n) 12 (87/724)	<u>Tibial coronal component position (alignment)</u> Mean (SD, Min-Max): 89 (2, 86-92) ns <u>Tibial sagittal component position (alignment)</u> Mean (SD, Min-Max): 86 (3, 78-91) ns <u>5 degree outliers femorotibial angle (standing)</u> % (cases/n) 6 (43/724) ns <u>3 degree outliers femoral coronal</u> % (cases/n) 21 (152/724) p= 0.028 <u>5 degree outliers femoral coronal</u> % (cases/n) 5 (36/724) ns <u>3 degree outliers femoral sagittal</u> % (cases/n) 21 (152/724) p= 0.043					

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary *
				<u>5 degree outliers femoral sagittal</u> % (cases/n) 4 (29/724) <u>3 degree outliers tibial coronal</u> % (cases/n) 11 (80/724) <u>5 degree outliers tibial coronal</u> % (cases/n) 5 (36/724) <u>3 degree outliers tibial sagittal</u> % (cases/n) 11 (80/724) <u>5 degree outliers tibial sagittal</u> % (cases/n) 6 (43/724) <u>3 degree outliers femorotibial angle (standing) (degrees)</u> % (cases/n) 14 (101/724)	<u>5 degree outliers femoral sagittal</u> % (cases/n) 6 (43/724) ns <u>3 degree outliers tibial coronal</u> % (cases/n) 20 (145/724) p = 0.045 <u>5 degree outliers tibial coronal</u> % (cases/n) 6 (43/724) ns <u>3 degree outliers tibial sagittal</u> % (cases/n) 20 (145/724) p= 0.041 <u>5 degree outliers tibial sagittal</u> % (cases/n) 7 (51/724) ns <u>3 degree outliers femorotibial angle (standing) (degrees)</u> % (cases/n) 26 (188/724) p=0.035					

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results**		**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	**Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**					
Liow 2014 Singapore	RCT	60 I = 31 C = 29	0	**1 month** AP femoral flexion Mean (SD): 95.5 (1.3) AP tibial angle Mean (SD): 89.7 (1.1) Joint line difference (modified Kawumara) Mean (SD): 1.9 (1.1) Joint line post-op (modified Kawumara) Mean (SD): 10.8 (2.9) LAT femoral flexion Mean (SD): 2.2 (1.9) LAT tibial angle Mean (SD): 84.9 (2.0)	**1 month** AP femoral flexion Mean (SD): 97 (1.9) p=0.001 AP tibial angle Mean (SD): 89.1 (1.8) ns Joint line difference (modified Kawumara) Mean (SD): 3.5 (2.8) p=0.010 Joint line post-op (modified Kawumara) Mean (SD): 14.6 (3) p=0.000 LATfFemoral flexion Mean (SD): 2.3 (2.4) ns LAT tibial angle Mean (SD): 85 (3.5) ns	I: ROBODOC TKA C: Manual TKA Weight bearing radiographs (anteroposterior, lateral, skyline, long-leg films) were performed at one-month follow up.	?	-	?	?

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary *
				Mechanical axis Mean (SD): 1.3 (0.9) Joint line shift outliers (> 5 mm deviation) % (cases/n) 3.2 (1/31) Coronal plane MA outliers (mal-alignment > 3°) % (cases/n) 0 (0/31) Cases with anterior femoral notching % (cases/n) 0 (0/31)	Mechanical axis Mean (SD): 1.8 (1.2) ns Joint line shift outliers (> 5 mm deviation) % (cases/n) 20.6 (6/29) p=0.049 Coronal plane MA outliers (mal-alignment > 3°) % (cases/n) 19.4 (4/29) p=0.049 Cases with anterior femoral notching % (cases/n) 10.3 (3/29) ns					
Song 2011 Republic of Korea	RCT	30 patients 60 knees I = 30 C = 30	0	**Postoperative** Femoral coronal alignment (°) Mean (SD): 89.2 (1.3) Femoral sagittal alignment Mean (SD): 0.8 (0.8)	**Postoperative** Femoral coronal alignment (°) Mean (SD): 90.1 (1.7) ns Femoral sagittal alignment Mean (SD): 1.0 (0.6) p=0.004	I: ROBODOC TKA C: TKA contralateral knee Radiographic measurements with regard to changes in mechanical axes and the inclinations of femoral and tibial components were checked with consistent distance according to the Knee Society Roentgenographic	?	?/-	?	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**	**Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**	**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				Mechanical axis (°) Mean (SD): 0.2 (1.6) Tibial coronal alignment Mean (SD): 90.0 (1.3) Tibial sagittal alignment Mean (SD): 85.2 (1.4) Femoral coronal within 2 degrees % (cases/n) 76.67 (23/30) Tibial sagittal within 2 degrees % (cases/n) 66.67 (20/30) Tibial coronal within 2 degrees % (cases/n) 90 (27/30)	Mechanical axis (°) Mean (SD): 1.2 (2.1) p=0.035 Tibial coronal alignment Mean (SD): 90.7 (1.1) ns Tibial sagittal alignment Mean (SD): 85.7 (2.7) ns Femoral coronal within 2 degrees % (cases/n) 50 (15/30) p=0.008 Tibial sagittal within 2 degrees % (cases/n) 33.33 (10/30) p=0.001 Tibial coronal within 2 degrees % (cases/n) 80 (24/30) ns	Evaluation System. In addition, radiographic measurements were accurately measured using PACS (Picture Archiving and Communication Systems).				

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary *
				<u>3 degree outliers femoral coronal</u> % (cases/n) 0 (0/30) <u>3 degree outliers femoral sagittal</u> % (cases/n) 0 (0/30) <u>3 degree outliers tibial coronal</u> % (cases/n) 0 (0/30) <u>3 degree outliers tibial sagittal</u> % (cases/n) 6.7 (2/30) <u>3 degree outliers mechanical axis</u> % (cases/n) 0 (0/30) <u>Mechanical axis within 2 degrees</u> % (cases/n) 93.3 (28/30)	<u>3 degree outliers femoral coronal</u> % (cases/n) 26.7 (8/30) p=0.008 <u>3 degree outliers femoral sagittal</u> % (cases/n) 10 (3/30) ns <u>3 degree outliers tibial coronal</u> % (cases/n) 0 (0/30) ns <u>3 degree outliers tibial sagittal</u> % (cases/n) 50 (15/30) p=0.001 <u>3 degree outliers mechanical axis</u> % (cases/n) 23.3 (7/30) p=0.001 <u>Mechanical axis within 2 degrees</u> % (cases/n) 50 (15/30) p=0.001					

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary *
				Femoral sagittal within 2 degrees % (cases/n) 90 (27/30)	Femoral sagittal within 2 degrees % (cases/n) 70 (21/30) ns					
Song 2013 Republic of Korea	RCT	100 I = 50 C = 50	47 I = 21 C = 26	**Postoperative** Femoral coronal alignment Mean (SD): 89.5 (0.7) Femoral sagittal alignment Mean (SD): 1.1 (0.7) Mechanical axis Mean (SD): 0.5 (1.4) Tibial coronal alignment Mean (SD): 90.1 (0.9) Tibial sagittal alignment Mean (SD): 85.6 (3.4)	**Postoperative** Femoral coronal alignment Mean (SD): 88 (1.3) p<0.001 Femoral sagittal alignment Mean (SD): 1.1 (1.1) ns Mechanical axis Mean (SD): 1.2 (2.9) ns Tibial coronal alignment Mean (SD): 90.7 (1.8) p=0.04 Tibial sagittal alignment Mean (SD): 86.1 (4.6) ns	I: ROBODOC TKA C: Manual TKA Radiographic assessments performed preoperatively and at latest follow-up according to The Knee Society Roentgenographic Evaluation System, which included measurements of the coronal mechanical axis and sagittal and coronal inclinations of femoral and tibial components. Radiographic measurements were made using a PACS.	?	-	-	+

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary *
				3 degree outliers femoral coronal % (cases/n) 0 (0/50) 3 degree outliers femoral sagittal % (cases/n) 0 (0/50) 3 degree outliers tibial coronal % (cases/n) 0 (0/50) 3 degree outliers tibial sagittal % (cases/n) 2 (1/50) 3 degree outliers mechanical axis % (cases/n) 0 (0/50)	3 degree outliers femoral coronal % (cases/n) 4 (2/50) ns 3 degree outliers femoral sagittal % (cases/n) 4 (2/50) ns 3 degree outliers tibial coronal % (cases/n) 6 (3/50) ns 3 degree outliers tibial sagittal % (cases/n) 6 (3/50) ns 3 degree outliers mechanical axis % (cases/n) 24 (12/50) ns					
PICO 2: Semi-active rTKA vs mTKA										
Kayani 2021 UK	RCT	30 I = 15 C = 15	0	**Postoperative** Planned limb alignment RMSE: 1.2 (SD 0.7)	**Postoperative** Planned limb alignment RMSE: 3.1 (SD 1.3) p<0.001	I: MAKO TKA C: Manual TKA Weight bearing plain radiographs/HKA at discharge and 4 weeks after surgery.	?	?	?	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary*
				Tibial coronal alignment RMSE: 1.3 (SD 0.9) Tibial sagittal alignment RMSE: 1.0 (SD 0.4) Femoral coronal alignment RMSE: 1.1 (SD 0.5) Femoral sagittal alignment RMSE: 1.4 (SD 1.0)	Tibial coronal alignment RMSE: 3.9 (SD 0.8) p<0.001 Tibial sagittal alignment RMSE: 3.1 (SD 1.1) p<0.001 Femoral coronal alignment RMSE: 3.8 (SD 1.1) p<0.001 Femoral sagittal alignment RMSE: 3.2 (SD 1.0) p<0.001	Accuracy of achieving planned limb alignment and component positioning was assessed using root mean square error (RMSE) values for these outcomes by comparing values achieved in the postoperative lateral and long-leg radiographs to their respective planned values with each alignment technique. Femoral and tibial axes were used as reference markers.				
Vaidya 2020 India	RCT	60 I = 32 C = 28	0	**Postoperative** Femoral component rotation Mean (SD, Min-Max): 2.3° (2.9, -3.1 to 6.5) Femoral coronal rotation Mean (SD, Min-Max): 1.1° (0.8, -1 to 2.7) Femoral sagittal rotation Mean (SD, Min-Max): 3.1° (0.7, 1.7-5.1)	**Postoperative** Femoral component rotation Mean (SD, Min-Max): 1.8° (3.2, -3.8 to 7.2) ns Femoral coronal rotation Mean (SD, Min-Max): 2° (1.9, -6.6 to 5.6) p=0.03 Femoral sagittal rotation Mean (SD, Min-Max): 2.9° (0.8, 1.2-4.4) ns	I: Navio TKA C: Manual TKA	?	?	?	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Risk of Bias*	Precision*	Precision, primary
				Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE					
				Joint line deviation Mean (SD, Min-Max): 0.9 mm (0.9, 0.1-3.7) Mechanical axis deviation Mean (SD, Min-Max): 1.8 mm (1.2, 0-6.1) Tibial coronal alignment Mean (SD, Min-Max): 1° (0.9, -2.7 to -3.4) Tibial sagittal alignment Mean (SD, Min-Max): 6.4° (1.4, 2.3-8.5) 3 degree outliers femoral coronal % (cases/n) 0 (0/32) 3 degree outliers tibial coronal % (cases/n) 3.13 (1/32)	Joint line deviation Mean (SD, Min-Max): 3.5 mm (1.6, 0.9-6.1) p<0.001 Mechanical axis deviation Mean (SD, Min-Max): 3.0 mm (2.4, 0-8.8) p=0.019 Tibial coronal alignment Mean (SD, Min-Max): 1.5° (1.3, -3.3 to -4.5) p=0.04 Tibial sagittal alignment Mean (SD, Min-Max): 6.3° (1.6, 3.8-9.7) ns 3 degree outliers femoral coronal % (cases/n) 21.43 (6/28) p-value NR 3 degree outliers tibial coronal % (cases/n) 17.86 (5/28) NR					

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary*
				3 degree outliers mechanical axis % (cases/n) 3.13 (1/32)	3 degree outliers mechanical axis % (cases/n) 28.57 (8/28) p=0.019					
PICO 3: Semi-active rUKA vs mUKA										
Batailler 2021 France	RCT	66 I = 33 C = 33	0	**6 months** Femoral mechanical axis (°) Mean (SD, Min-Max): 92 (1.8, 87-95) HKA angle (°) Mean (SD, Min-Max): 177.1 (2.3, 172-181) Tibial baseplate alignment (°) Mean (SD, Min-Max): 0 (2.4, -7.4-8) Tibial mechanical axis (°) Mean (SD, Min-Max): 87.2 (1.7, 84-90) Tibial slope (°) Mean (SD, Min-Max): 85.7 (2.6, 77-90)	**6 months** Femoral mechanical axis (°) Mean (SD, Min-Max): 92.6 (1.7, 88-97) ns HKA angle (°) Mean (SD, Min-Max): 176.9 (2.5, 171-182) ns Tibial baseplate alignment (°) Mean (SD, Min-Max): -1.3 (2.3, -6.5-3.4) p=0.05 Tibial mechanical axis (°) Mean (SD, Min-Max): 86.2 (2.6, 82-96) ns Tibial slope (°) Mean (SD, Min-Max): 84.6 (3.6, 76-93) ns	I: Navio UKA C: Manual UKA Radiographic examination was performed before and 6 months after surgery and consisted of weightbearing antero-posterior and lateral knee radiographs, a patellar axial view, and full-length standing radiographs.	+	?/-	-	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results**		**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	**Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**					
				Tibial slope < 82° % (cases/n) 6.1 (2/33)	Tibial slope < 82° % (cases/n) 15 (5/33) ns					
Bell 2016 UK	RCT	139 I = 70 C = 69	19 I = 8 C =11	**3 months** Femoral axial within 2 degrees % (cases/n) 53 (37/70) Tibial sagittal within 2 degrees % (cases/n) 80 (56/70) Tibial coronal within 2 degrees % (cases/n) 58 (41/70) Tibial axial within 2 degrees % (cases/n) 48 (34/70) Femoral coronal within 2 degrees % (cases/n) 70 (49/70)	**3 months** Femoral axis within 2 degrees % (cases/n) 31 (21/69) p=0.0163 Tibial sagittal within 2 degrees % (cases/n) 22 (15/69) p<0.0001 Tibial coronal within 2 degrees % (cases/n) 41 (28/69) ns Tibial axis within 2 degrees % (cases/n) 19 (13/69) p=0.0009 Femoral coronal within 2 degrees % (cases/n) 28 (19/69) p=0.0001	I: MAKO Restoris MCK C: Manual UKA Oxford Phase 3 A CT scan was performed on a single scanner at three months postoperatively using a standard protocol. The accuracy of component positioning was determined using postoperative CT by comparing the target positioning values in the preoperative plan with the actual values achieved postoperatively. Accuracy was therefore determined by the degree of deviation from the preoperative planned target values rather than by the absolute values of the component position.	+	?	?	

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results**		**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	**Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE**					
				<u>Femoral sagittal within 2 degrees</u> % (cases/n) 57 (40/70) <u>Tibial coronal implantation error</u> Median (Q1-Q3): 1.6 (0.8-3.0) RMSE: 2.58 <u>Tibial sagittal implantation error</u> Median (Q1-Q3): 1 (0.7-1.8) RMSE: 1.64 <u>Femoral coronal implantation error</u> Median (Q1-Q3): 1.4 (0.6-2.3) RMSE: 2.09 <u>Femoral sagittal implantation error</u> Median (Q1-Q3): 1.9 (0.8-2.9) RMSE: 3.35	<u>Femoral sagittal within 2 degrees</u> % (cases/n) 26 (18/69) p=0.0008 <u>Tibial coronal implantation error</u> Median (Q1-Q3): 2.7 (1.6-3.7) p=0.0089 RMSE: 3.71 <u>Tibial sagittal implantation error</u> Median (Q1-Q3): 3.7 (2.3-5.6) p<0.0001 RMSE: 4.43 <u>Femoral coronal implantation error</u> Median (Q1-Q3): 4.1 (1.8-5.8) p<0.0001 RMSE: 5.09 <u>Femoral sagittal implantation error</u> Median (Q1-Q3): 3.9 (2.0-7.8) p<0.0001 RMSE: 6.87					

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.5
Outcome variable: Implant positioning

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Results: Manual 1: Median (Q1-Q3) or 2: Mean (SD, Min-Max) If available RMSE	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary *
				Femoral axial implantation error Median (Q1-Q3): 1.9 (1.1-3.3) RMSE: 2.7 Tibial axial implantation error Median (Q1-Q3): 2.2 (1.1-3.4) RMSE: 2.97	Femoral axial implantation error Median (Q1-Q3): 3.6 (2.0-5.9) p<0.0001 RMSE: 5.78 Tibial axial implantation error Median (Q1-Q3): 5.4 (2.8-9.3) p<0.0001 RMSE: 7.95					

AP: Anterioposterior; C: control; I: intervention; LAT: Lateral; HKA: Hip-Knee-Ankle; MA: mechanical axis; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; NR: Not reported; ns: not significant; SD: standard deviation; RCT: randomised controlled trial; RMSE: Root Mean Square Error; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty; UKA: unicompartmental knee arthroplasty

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.6
Outcome variable: Length of stay

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Days (SD if available) (unless otherwise specified)	Results: Manual Days (SD if available) (unless otherwise specified)	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
PICO 1: Active rTKA vs mTKA										
Liow 2014 Singapore	RCT	60 I = 31 C = 29		5.2 (2.3)	5.8 (3.8) ns	ROBODOC	?	-	?	?
PICO 2: Semi-active rTKA vs mTKA										
Cool 2019a USA	Cohort	3,114 I = 519 C = 2,595		1.84	2.53 p<0.0001	MAKO	?	?/-	+	Readmission: ?
Emara 2021 USA	Cohort	365,812 I = 72,916 C = 292,896		2.0 (1.4)	2.5 (1.8) p<0.001	System not specified	+	?	+	Comp: +
Grosso 2021 USA	Cohort	4,086 I = 581 C = 3,505		Multivariate analysis estimate: 0.019 (95% CI -0.12 to 0.15)		System not specified	+	?	+/?	SF-12: ?
King 2020	Cohort	492 I = 202 C = 290		2.3	2.6 p=0.001	MAKO	+	-	-	
Mont 2021	Cohort	249,320 I = 519 C = 248,801		1.84	2.53 p=0.0001	System not specified (study design indicates MAKO)	?	-	?	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.6
Outcome variable: Length of stay

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Days (SD if available) (unless otherwise specified)	Results: Manual Days (SD if available) (unless otherwise specified)	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
Ofa 2020 USA	Cohort	755,350 I = 5,228 C = 750,122		4.38 (2.5)	3 (1.73) p<0.001	System not specified	+/?	?/-	+	
Pierce 2020 USA	Cohort	2,124 I = 357 C = 1,785		1.8	2.72 p=0.0001	System not specified (study design indicates MAKO)	+	?/-	+	
Shah 2021 USA	Cohort	198,371 I = 4,351 C = 194,020		1.9	2.3 p<0.001	System not specified	+/?	?	?	
Singh 2021 USA	Cohort	6,809 I = 367 C = 6,442		2.7 (1.65)	2.7 (1.64) ns	MAKO + Navio	+	?	?	
PICO 3: Semi-active rUKA vs mUKA										
Blyth 2017	RCT	129 I = 64 C = 65		Difference: 0.54 days shorter	p = 0.07	I: Navio UKA C: Manual UKA Both: Journey II Uni (Smith and Nephew®, Andover UK), fixed bearing, cemented	+	?/-	-	
Cool 2019b USA	Cohort	738 I = 246 C = 492		1.77	2.02 MD -0.25, p=0.0047	MAKO	+/?	?/-	+	

C: control; I: intervention; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; ns: not significant; RCT: randomised controlled trial; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty; UKA: unicompartmental knee arthroplasty

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.7
Outcome variable: Learning curve

* + No or minor problems ? Some problems - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Operating time, minutes mean (SD, range) Other as specified	Results: Manual Operating time, minutes mean (SD, range) Other as specified	Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
PICO 1: Active rTKA vs mTKA										
NR										
PICO 2: Semi-active rTKA vs mTKA										
Sodhi 2018 USA	Cohort	280 I = 240 C = 40	n/a	<u>Surgeon 1</u> First and last robotic cohort: 81 (71–104) vs 70 (52–121) minutes (p < 0.05) First 20 robotic-assisted cases: 81 (71–104) minutes Last 20 robotic-assisted cases: 70 (52–121) minutes. <u>Surgeon 2</u> First and last robotic cohort: 117 (74–142) vs 98 (67–123) minutes (p < 0.05) First 20 robotic-assisted cases: 117 (74–142) minutes Last 20 robotic-cohort cases: 98 (67–123) minutes	<u>Surgeon 1</u> 20 manual cases: 68 (50–106) minutes (p < 0.005) 20 manual cases: 68 (50–106) minutes (ns) <u>Surgeon 2</u> 20 manual cases: 95 minutes (71–142) (p < 0.005) 20 manual cases: 95 (71–142) minutes (ns)	Manual cases selected at random from each surgeon's cases 3 months prior to initiation of robotic surgery.	?	?	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.7
Outcome variable: Learning curve

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Operating time, minutes mean (SD, range) Other as specified	Results: Manual Operating time, minutes mean (SD, range) Other as specified	Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
				Robotic assisted last combined 40 cases Mean (range) 84 (52–123)	40 manual cases combined Mean (range) 81 (50–142)					
Vermue 2020 Belgium	Cohort	649 I = 386 C = 263 Implant alignment: I = 108 C = 0	n/a	Surgeon 1, 46 cases First 10 cases 101.6 (18.8) Last 10 cases 89.7 (20.6) Surgeon 2, 9 cases First 10 cases NA Last 10 cases NA Surgeon 3, 111 cases First 10 cases 103.1 (18.83) Last 10 cases 76.3 (11.7) Surgeon 4, 22 cases First 10 cases 139.0 (18.83) Last 10 cases 124.2 (21.8) Surgeon 5, 120 cases First 10 cases 129.7 (26.3) Last 10 cases 91.5 (15.9)	Surgeon 1 Manual cases 82.0 (18.7) ns Surgeon 2 Manual cases NA p= NA Surgeon 3 Manual cases 63.9 (15.7) p= <0.01 Surgeon 4 Manual cases 125.5 (16.2) ns Surgeon 5 Manual cases 92.6 (17.1) ns	Six surgeons participated, with 5-32 years of practice and low, medium and high surgical volume. The dropout-rate for surgeons were 3 for surgical time and 0 for implant positioning. Patients who underwent conventional TKA surgery by the same group of surgeons in the second half of 2017, prior to the introduction of the surgical robot, were included as a control group. Identical inclusion and exclusion criteria were used. All surgeons contributed > 25 cases to the control group. RA TKA was associated with a learning curve of 11–43 cases for operative time (p < 0.001). This learning curve was significantly affected by the surgical profile (high vs. medium vs. low volume). A complete normalisation of operative times was seen in four out of five surgeons.	+	?	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.7
Outcome variable: Learning curve

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Operating time, minutes mean (SD, range) Other as specified	Results: Manual Operating time, minutes mean (SD, range) Other as specified	Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
				<u>Surgeon 6, 74 cases</u> First 10 cases 174.9 (44.4) Last 10 cases 108.4 (19.7) Cases to reach infliction point in operative time: n= 3 Min, max: 11, 43 Median 22 Average deviation of measured postoperative angle from the preoperative plan <u>mLDFA</u> 0.2° (SD 1.4) <u>MPTA</u> 0.7° (SD 1.1) <u>HKA</u> 1.2° (SD 2.1) <u>PDFA</u> 0.2° (SD 2.9) <u>PPTA</u> 0.3° (SD 2.4)	<u>Surgeon 6</u> Manual cases 108.6 (29.3) ns					

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.7
Outcome variable: Learning curve

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
				Robotic Operating time, minutes mean (SD, range) Other as specified	Manual Operating time, minutes mean (SD, range) Other as specified					

PICO 3: Semi-active rUKA vs mUKA
NR

C: control; I: intervention; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; ns: not significant; n/a: not applicable, NA: not available; mLDFA: mechanical lateral distal femoral angle, MPTA: Medial proximal tibial angle, HKA: Hip-Knee-Ankle, PDFA: Posterior Distal Femur Angle, PPTA: Posterior proximal tibial angle; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.8
Outcome variable: Patient-reported pain

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time Measurement scale Measurement unit	Results: Manual Time Measurement scale Measurement unit	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary
PICO 1: Active rTKA vs mTKA										
Kim 2020	RCT	1,406 I = 700 patients, 750 knees C = 706 patients, 766 knees	58 I = 26 patients, 26 knees C = 32 patients, 42 knees	**13 years (± 5)*** Proportions of patients with residual pain No pain: 85% (573/674) Mild pain: 13% (88/674) Severe pain: 2% (13/674)	**13 years (± 5)*** Proportions of patients with residual pain No pain: 82% (553/674) Mild pain: 16% (108/674) Severe pain: 2% (13/674) ns	*) Outcomes were assessed at 3 months and 1 year postop. and every 2 to 3 years thereafter, up till 13 years postoperatively. Assessment was made using VAS 0-10. Pain was categorised based on VAS as no, mild or severe. It is unclear when pain was assessed, as the article states "pain at latest follow-up".				
PICO 2: Semi-active rTKA vs mTKA										
King 2020 USA	Cohort	492 I= 202 C = 290	n/a	**Postoperative pain** 0 days Mean 5.4 1 day Mean 5.4 2 days Mean 5.6 3 days Mean 5.5	**Postoperative pain** 0 days Mean 5.2 ns 1 day Mean 5.7 ns 2 days Mean 5.8 ns 3 days Mean 5.1 ns	VAS pain score 0-10; higher value = worse pain SD not reported	+	-	-	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.8
Outcome variable: Patient-reported pain

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Time Measurement scale Measurement unit	Results: Manual Time Measurement scale Measurement unit	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary
				4 days Mean 5.5	4 days Mean 5.1 ns					
PICO 3: Semi-active rUKA vs mUKA										
Blyth 2017 UK	RCT	139 I = 70 C = 69	3 I = 3 C = 0	**Postoperative pain** Day 0 Median 61 Day 1 Median 29 Day 2 Median 40 Day 3 Median 32 Day 4 Median 20 Day 5 Median 19 **First 8 weeks** 55.4% lower median pain scores than controls **3 months** Pain, VAS score Median (Q1-Q3)	**Postoperative pain** Day 0 Median 48 Day 1 Median 50 Day 2 Median 60 Day 3 Median 53 Day 4 Median 50 Day 5 Median 45 **First 8 weeks** p=0.040 **3 months** Pain, VAS score Median (Q1-Q3)	Visual analogue scale (VAS): 0-100; higher value = worse pain.	+	?	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.8
Outcome variable: Patient-reported pain

* + No or minor problems
? Some problems
\- Major problems

Author year country	**Study design**	**Number of patients n=**	**Withdrawals - dropouts**	**Results: Robotic** Time Measurement scale Measurement unit	**Results: Manual** Time Measurement scale Measurement unit	**Comments**	**Directness***	**Risk of Bias***	**Precision***	**Precision, primary**
				8 (2-21) **12 months** <u>Pain, VAS score</u> Median (Q1-Q3) 4.5 (2-18)	9 (4-28) Between-group difference 1.0; ns **12 months** <u>Pain, VAS score</u> Median (Q1-Q3) 5.0 (1-23) Between-group difference 0.5; ns					
Gilmour 2018 UK	RCT	139 I = 69 C = 70	27 I = 11 C = 16	**24 months** <u>Pain, VAS score</u> Median (Q1-Q3) 3.0 (1.0-26.0)	**24 months** <u>Pain, VAS score</u> Median (Q1-Q3) 5.0 (2.0-16.8) Between-group difference 2.0; ns	Pain Visual Analogue Scale: 0-100; higher value= worse pain.	+	?	? ?/-	

C: control; I: Intervention; n/a: not applicable; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; ns: not significant; RCT: randomised controlled trial; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty; SD: Standard deviation; VAS: Visual analogue scale

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.9
Outcome variable: Patient-reported Health-related quality of life (HRQoL)

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD)	Results: Manual Mean (SD) Mean difference (95% CI)	Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
PICO 1: Active rTKA vs mTKA										
Liow 2014 Singapore	RCT	60 I = 31 C = 29	0	**6 months** SF-36 data reported in more detail in Liow 2017	**6 months** SF-36 data reported in more detail in Liow 2017					
Liow 2017 Singapore	RCT (same as above)	60 I = 31 C = 29	0	**Preoperative** SF-36 Physical Component Score 32.4 (9.6) SF-36 Mental Component Score 53.9 (8.2) **6 months** SF-36 Physical Component Score 46.2 (9.1) SF-36 Mental Component Score 57.0 (8.8)	**Preoperative** SF-36 Physical Component Score 29.1 (9.2) ns SF-36 Mental Component Score 50.0 (12.6) ns **6 months** SF-36 Physical Component Score 46.7 (11.6) MD 0.5 (95% CI −5.9 to 4.9) ns SF-36 Mental Component Score 52.6 (9.7) MD 4.5 (95% CI −0.3 to 9.2) ns	SF-36 has eight domains (physical functioning, social functioning, role physical, bodily pain, mental health, role emotional, vitality and general health) which were recorded individually and transformed into two summary scores: the physical component summary (PCS) and mental component summary (MCS). All scores were recorded as whole numbers. Score range 0-100, higher score=better health.	?	-	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.9
Outcome variable: Patient-reported Health-related quality of life (HRQoL)

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD)	Results: Manual Mean (SD) Mean difference (95% CI)	Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
				24 months SF-36 Physical Component Score 50.3 (7.0) SF-36 Mental Component Score 59.3 (9.8)	**24 months** SF-36 Physical Component Score 46.2 (13.9) MD 4.1 (95% CI −1.7 to 9.8) ns SF-36 Mental Component Score 54.7 (10.3) MD 4.6 (95% CI −0.8 to 9.9) ns					
PICO 2: Semi-active rTKA vs mTKA										
NR										
PICO 3: Semi-active rUKA vs mUKA										
Blyth 2017 UK	RCT	139 I = 70 C = 69	3 I = 3 C = 0	**Preoperative** SF-12 Physical Component Score 32.8 (7.7) SF-12 Mental Component Score 54.2 (10.6)	**Preoperative** SF-12 Physical Component Score 32.5 (8.3) ns SF-12 Mental Component Score 53.1 (10.5) ns	SF-12 is a 12-item, patient-reported survey of patient health. It is a reduced size version of the SF-36, produces similar results for physical and mental health scores. Score range 0-100, higher score=better health. Mean difference (MD) and 95% CI calculated when not reported.	+	?	?	

Project: Robotic-arm assisted knee arthroplasty
Appendix 4.9
Outcome variable: Patient-reported Health-related quality of life (HRQoL)

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robotic Mean (SD)	Results: Manual Mean (SD) Mean difference (95% CI)	Comments	Directness	Risk of Bias	Precision *	Precision, primary outcome*
				12 months SF-12 Physical Component Score 46.8 (9.8) SF-12 Mental Component Score 54.9 (8.3)	**12 months** SF-12 Physical Component Score 44.6 (9.8) MD 2.2 (95% CI -1.09 to 5.49) ns SF-12 Mental Component Score 54.6 (8.3) MD 0.3 (95% CI -2.67 to 3.27) ns					

C: control; I: Intervention; MD: Mean difference; ns: not significant; mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; n/a: not applicable; NR: not reported; ns: not significant; RCT: randomised controlled trial; SD: standard deviation; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.10
Outcome variable: Operating time

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robot-assisted Mean operating time, minutes (SD) Range	Results: Manual Mean operating time, minutes (SD) Range	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
PICO 1: Active rTKA vs mTKA										
Kim 2020 Republic of Korea	RCT	1406 I = 700 patients, 750 knees C = 706 patients, 766 knees	58 I = 26 C = 32	97 (10.5) 81-123	69 (6.25) 56-81 Between-group difference: 28; p<0.001	SD calculated for this analysis as IQR/4	?	?	?	+
Liow 2014 Singapore	RCT	60 I = 31 C = 29	0	91 (10) NR	93 (14) NR Between-group difference: -2.0; ns		?	-	?	?
Song 2013 Republic of Korea	RCT	100 I = 50 C = 50	47 I = 21 C = 26	99 (11) NR	74 (10) NR Between-group difference: 25; p<0.001		?	-	-	+
Song 2011 Republic of Korea	RCT	60 I = 30 C = 30	0	95 (18) NR	70 (15) NR Between-group difference: 25; ns		?	?/-	?	

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.10
Outcome variable: Operating time

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results: Robot-assisted Mean operating time, minutes (SD) Range	Results: Manual Mean operating time, minutes (SD) Range	Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
PICO 2: Semi-active rTKA vs mTKA										
Kayani 2021 UK	RCT	30 I = 15 C = 15	0	62.4 (3.4) NR	61.4 (3.1) NR Between-group difference: 1.0; ns		?	?	?	
King 2020 USA	Cohort	492 I=202 C = 290	0	76.5 (Not stated) NR	67.2 (Not stated) NR Between-group difference: 9.3; p<0.001		+	-	-	
Shaw 2021 USA	Cohort	1,160 I = 260 C = 900	0	76.8 (12.2) 22-120	87.2 (19.6) 43-297 Between-group difference: -10.4; ns		+/?	?	?	
Sodhi 2018	Cohort	280 I = 240 C = 40	0	84 (17.75) 52–123	81 (23) 50–142 Between-group difference: 3; ns	Comparison of robotic-assisted cases and manual cases performed by the same surgeon. Manual cases from 3 months prior to the introduction of robotic technology were used as controls. Reported operative times are of last 20 cases in the study, i.e. after learning curve SD calculated for this analysis as IQR/4				

Project: Robotic arm-assisted knee arthroplasty
Appendix 4.10
Outcome variable: Operating time

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Risk of Bias*	Precision*	Precision, primary outcome*
				Robot-assisted Mean operating time, minutes (SD) Range	Manual Mean operating time, minutes (SD) Range					
Vermue 2020	Cohort	649 I = 386 C = 263	0	98.2 (17.92) NR	94.52 (19.4) NR Between-group difference: 3.68; ns	Reported operative times are of last 10 cases in the study, i.e. after learning curve	+	?	?	
PICO 3: Semi-active rUKA vs mUKA										
NR										

C: control; I: Intervention; IQR: interquartile range;mTKA: manual total knee arthroplasty; mUKA: manual unicompartmental knee arthroplasty; n/a: not applicable; NR: not reported; ns: not significant; RCT: randomised controlled trial; SD: standard deviation; rTKA: robotic arm-assisted total knee arthroplasty; rUKA: robotic arm-assisted unicompartmental knee arthroplasty

Appendix 5 Ongoing trials

Author **Country**	**Titel**	**Estimated completion date**	**Study design**	**Study groups**	**Estimated patients (n)**	**Outcomes**
Satit Thiengwittayaporn Thailand	Comparative Outcomes Between Imageless Robotic-assisted and Conventional Total Knee Arthroplasty	February 25, 2021	RCT	I: Navio™ Robotics-assisted Surgical System C: Manual TKA	168	Mechanical axis Knee Society and Knee Society function score Range of motion of knee Oxford knee score
Andrey Gritsyuk Russia	Total Knee Arthroplasty Using an Active Robotic System	August 1,2025	RCT	I: Active robotic system C: Manual TKA	300	Quality of life and knee function assessment Quality of life assessment Spielberger test Overall health score assessment Quality of life assessment (mental, physical assessment) Quality of life assessment (the condition of patients) Pain assessment Quality of life assessment
Anthony Adili Canada	Robot-Assisted Partial Knee Replacement Versus Standard Total Knee Replacement	December, 2022	RCT	I: Robot-assisted partial knee arthroplasty C: Manual TKA	64	Return to function questionnaire Oxford knee score Forgotten joint score Gait walking mechanics analysis Quality of life- EQ-5D Persistent post-surgical pain (PPSP) Patient global impression of change score Healthcare resource use (for cost-effectiveness) Rage of motion (ROM) Knee alignment Adverse events Short-term implant survival

Todd Borus United States	Clinical and Economic Comparison of Robot Assisted Versus Manual Knee Replacement	November, 2021	Observational Model: Cohort Time Perspective: Prospective	I: Procedure: MAKO® Robot Assisted Medial Knee Arthroplasty Device: RESTORIS Multicompartmental Knee System Device: Depuy Knee Replacement System Device: Stryker® Knee Replacement System C: Manual TKA	150	Reduced WOMAC Knee injury and Osteoarthritis Outcome Score EQ-5D Forgotten Joint Score Length of Stay Time to physical therapy discharge Timed Up and Go 6 Minute Walk Test (6MWT) Stair Ascend/Descend Test Return to Driving Time Return to Work Time
Herbert John Cooper United states	Navio Robotic Versus Conventional Total Knee Arthroplasty	December 31, 2022	RCT	I: Device: Navio™ Robotics-assisted Surgical System C: Non robotics-assisted Surgical System	86	Score on WOMAC Score on the Timed Up and Go Test (TUG) Score on Short-Form 12 Health Questionnaire (SF-12) Score on New Knee Society Scores (2011 KSS) Score on Global Rating Score of Knee Function (GRS)

Bartosz M. Maciąg Poland	Robotic-assisted Total Knee Arthroplasty vs. Conventional One	December 1, 2022	RCT	I: Active Comparator: Robotic-assisted total knee arthroplasty C: Conventional total knee arthroplasty	30	Oxford Knee Score (OKS) Oxford Knee Score Activity & Participation Questionnaire (OKS_APQ) Forgotten Joint Score (FJS) UCLA (University of California) score Changes in knee range of motion Changes in pain medication Arthroplasty related complications Arthroplasty revision surgeries Walking abilities Length of hospital stay Biomechanical 3D motion and emg walking outcomes Radiological outcome on CT scans 6- minute walking abilities Biomechanical stair climbing outcomes Biomechanical static balance outcomes Biomechanical dynamic balance outcomes Leg muscle strength outcomes
Ian J Leslie United States	Comparison of Alignment Achieved Using the VELYS Robotic-Assisted Solution Versus Manual Instrumentation in Total Knee Arthroplasty	December 15, 2023	Non-Randomized	I: Robotic-Assisted Arm C: Manual Arm	200	Learning curve EuroQol 5-Dimension 5-Level (EQ-5D-5L) - Change from baseline Forgotten Joint Score (FJS-12) Knee Injury and Osteoarthritis Outcome Score (KOOS) - Change from baseline Subject Satisfaction with Knee Replacement Pain - Change from baseline

Fares S Haddad United Kingdom	Inflammatory Response Conventional Total Knee Replacement Versus Mako Total Knee Replacement	December 31, 2021	RCT	I: Robotic arm-assist TKA C: Conventional TKA	30	Serum CRP level C-reactive Protein (CRP) Interleukin-1 beta (IL1 beta) Interleukin-6 (IL6) Tumour necrosis Factor alpha (TNFalpha) Creatine Kinase (CK) Creatine Phosphokinase (CPK) Full blood count (FBC) Erythrocyte sedimentation rate (ESR) Myoglobin (MG) Lactate dehydrogenase (LDH) Urea and Electrolytes (U&Es) IL-6 Interleukin-8 (IL-8) TNFalpha Thermal response to inflammation Soft tissue injury prior to implantation of femoral and tibial prostheses Operating time Time to discharge Pain in knee Analgesia requirements Oxford knee score (OKS) Short form health survey of 12 items (SF-12 Knee injury and osteoarthritis outcome score (KOOS) Western Ontario and Mcmaster Universities Arthritis Index (WOMAC) European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D)
Jeremy Reid United States	A Prospective Study to Evaluate Robot Assisted Total Knee Replacement Outcomes	December 31, 2023	RCT	I: Robot Assisted Total Knee Replacement C: Traditional Total Knee Replacement	248	Patient reported Forgotten Joint Score (FJS) Patient reported Knee injury and Osteoarthritis Outcome Score (KOOS) Patient reported Veterans Rand 12-item Health Survey Score (VR-12) The mechanical alignment of the post-operative limb

Régis Pailhé France	Total Knee Arthroplasty Robot Assisted With MAKO™ Robotic System Compared to the Conventional Total Knee Arthroplasty by Mechanical Ancillary	September 23, 2020	RCT	I: Total knee arthroplasty with the Stryker's MAKO™ system C: Total knee arthroplasty with mechanical ancillary	60	Difference between the actual HKA angle obtained postoperatively and the planned HKA angle preoperatively Mechanical axis between the conventional surgery group and the MAKO™ assisted surgery group Angles accuracy of inclination and rotation in the 3 planes of the space (frontal, sagittal and axial) to accomplish the preoperative planning Operative time between the conventional surgery group and the MAKO™ assisted surgery group Conversion rate in conventional method for patients in the MAKO™ assisted surgery group Blood loss during the procedure between the conventional surgery group and the MAKO™ assisted surgery group Time needed to reach the hospital discharge criteria Functional results between the conventional surgery group and the MAKO™ assisted surgery group Intraoperative complication rates between the conventional surgery group and the MAKO™ assisted surgery group Results of early (<1 months) and late (≥ 1 month) postoperative consultations between the conventional surgery group and the MAKO™-assisted surgery group Operating times for surgical installation, bone preparation and implant placement

Sebastien Lustig France	Evaluation Protocol of the Installation of Knee Unicompartmental Prosthesis (Journey (Smith & Nephew)) With Mechanical Ancillary Versus Robotic Assisted (Navio System)	April 2022	RCT	I: Internal PUC implanted with robotic assistance C: internal PUC implanted with mechanical ancillary	66	Proportion of patients with Angle Hip Knee Ankle (HKA) (lower limb axis) restitution at 178 ° +/- 2 ° when the foot is touched with the floor and during the single support phase Radiological positioning of implants Cmparison of the means of the International Knee Society (IKS) overall score between the groups Comparison of the Forgotten Joint Score
Jan Victor Belgium	Evaluation of Robot-assisted Total Knee Arthroplasty With Automatic Balancing	December 1, 2024	RCT	I: Robot-assisted TKA C: Conventional TKA	60	Knee Laxity Knee Injury and Osteoarthritis outcome score Knee Society Score EuroQoL Pain Catastrophizing Scale Forgotten Joint Score Alignment Knee laxity anteroposterior Knee kinematics in 3D after squat, knee flexion/extension, stair ascend and descend
Wang Lydia (contact) China	Robotic-assisted Versus Conventional Total Knee Arthroplasty	December 31, 2022	RCT	I: TKA assisted with ROSA® Knee System C: TKA with conventional surgical instrumentation	156	Mechanical axis alignment Coronal Lower Limb Alignment
Not stated United States	Post-Market Study of Robotic-Arm Assisted Total Knee Arthroplasty	June 2019	Non-Randomized	I: Robitic arm total knee replacement C: Manual instrument total knee replacement	400	Component alignment

Iain McNamara Ireland	A Comparison of Patients Receiving a Total Knee Replacement With Robotic Assistance or With Conventional Instrumentation	January 30, 2025	RCT	I: Robotic-Total Knee Replacement (R-TKR) (NAVIO) C: Conventional-Total Knee Replacement (C-TKR)	420	Oxford Knee Score (OKS) Oxford Arthroplasty Early Recovery Score (OARS) Oxford Arthroplasty Early Change Score (OACS) Short-Form 12 Health Questionnaire (SF-12) EuroQol Five-Dimensional Five-Level (EQ-5D-5L) EuroQol Visual Analogue Scale (EQ-VAS) Visual Analogue Score (VAS)-PAIN Timed Up and Go (TUG) Test 6-Minute Walk (6MW) Test Tibial Sagittal Alignment Femoral Sagittal Alignment Coronal Alignment Mechanical Axis Alignment Radiographic Assessment
Iain McNamara Ireland	A Comparison of Patients Receiving a Unicompartmental Knee Replacement With Robotic Assistance or With Conventional Instrumentation	May 30, 2025	RCT	I: Robotic-Unicompartmental Knee Replacement (R-UKR) (NAVIO) C: Conventional-Unicompartmental Knee Replacement (C-UKR)	420	Oxford Knee Score (OKS) Oxford Arthroplasty Early Recovery Score (OARS) Oxford Arthroplasty Early Change Score (OACS) Short-Form 12 Health Questionnaire (SF-12) EuroQol Five-Dimensional Five-Level (EQ-5D-5L) EuroQol Visual Analogue Scale (EQ-VAS) Visual Analogue Score (VAS)-PAIN Timed Up and Go (TUG) Test 6-Minute Walk (6MW) Test Tibial Sagittal Alignment Femoral Sagittal Alignment Coronal Alignment Mechanical Axis Alignment Radiographic Assessment

Babar Kayani United Kingdom	RCT: Mako Medial Unicondylar Knee Arthroplasty vs Oxford Unicondylar Knee Arthroplasty	December 31, 2022	RCT	I: Mako medial UKA C: Oxford media UKA	140	Accuracy of component positioning Lower limb alignment Femoral implant alignment Tibial implant alignment Operating time Time to discharge Oxford Knee Score (OKS) Short form SF-12 Western Ontario and McMaster Universities Arthritis Index (WOMAC) Knee injury and Osteoarthritis Outcome Score (KOOS) Osteoarthritis Outcome Score (KOOS) European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D) Mobilisation distance (metres) Use of mobility aids Range of movement Complications
Jan Victor Belgium	Evaluation of Standard and Robot Assisted Total Knee Arthroplasty With a Bicrucatie Retaining Prosthesis	January 1, 2023	RCT	I: Stabilized with robot-assistance Bicruciate retaining TKA without robot-assistance Bicruciate retaining TKA with robot-assistance C: Posterior Stabilized TKA without robot-assistance	60	Knee Injury and Osteoarthritis outcome score Knee Society Score EuroQoL Pain Catastrophizing Scale Forgotten Joint Score

Kacy Arnold United States	A Randomized Controlled Trial for Partial Knee Arthroplasty	December 2024	RCT	I: Robotic-Assisted UKA C: Traditional/Conventional UKA	180	Accuracy of implant position Evaluation of Patient safety Evaluation of range of motion Evaluation of Instability Patient Reported Outcome Measure (Oxford Knee Score) Patient Reported Outcome Measure (KOOS-12) Numeric Pain Rating Scale (NPRS) Subject Satisfaction
Astrid Yung Australia, China, Hong Kong, New Zealand	Study to Evaluate the Safety and Effectiveness of the REAL INTELLIGENCE™ CORI™ in Total Knee Arthroplasty (TKA) Procedure	July 30, 2024	RCT	I: CORI TKA C: Conventional TKA	140	Post-operative Leg Alignment Component Alignment Radiographic Assessment 2011 Knee Society Score (KSS) Oxford Knee Score (OKS) Forgotten Joint Score (FJS) EuroQol Five-Dimensional Five-Level (EQ-5D-5L)
Not Stated United States	UKA Manual Versus UKA MAKO Robotic	February 2, 2022	Observational	I: Robotic UKA Arm C: Fixed and Mobile UKA Arm Total Knee Arthroplasty	486	Post Op EOS measurements for alignment
Matthew P Abdel United States	RCT Comparing Robotically-Assisted vs. Manually-Executed Total Knee Arthroplasties	January 2022	RCT	I: Total Knee Robotically-Assisted C: Total Knee Manual-Executed by Surgeon	142	Radiographic Parameters

Ove Furnes Norway	Robotized Navigation Compared to Conventional Technique in Total Knee Replacement	December 31, 2031	RCT	I: Robotic TKA (Navio) C: Conventional TKA	214	Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) high responders Radiostereometric migration Knee injury and osteoarthritis outcome score (KOOS) Knee society score (KSS) EQ-5D Visual analogue scale (VAS) Forgotten Joint Score (FJS) Maximum climb-up test Anchor questions Timed 40 meters walking test Chair test 30 seconds
Astrid Yung Australia, China, Hong Kong, New Zealand	Study to Evaluate the Safety and Effectiveness of REAL INTELLIGENCE™ CORI™ in Unicondylar Knee Arthroplasty (UKA) Procedures	June 30, 2023	RCT	I: Unicondylar knee arthroplasty (UKA) treated with CORI C: Conventional unicondylar knee arthroplasty (UKA)	140	Component Alignment Radiographic assessment 2011 Knee Society Score (KSS) Oxford Knee Score (OKS) Forgotten Joint Score (FJS) Five-level EuroQol five-dimensional (EQ-5D-5L) VAS and index scores
Records below are from the WHO register – less information provided						
	A prospective, multicenter, randomized and parallel controlled study of unicondylar knee arthroplasty (UKA): safety and efficacy of MCK			I: MAKO group:Orthopedic surgical navigation system C: Oxford group:Conventional UKA		HSS score Adverse events Complications Oxford Knee Score SF-12 score WOMAC score Radiological evaluation Survivorship of prosthesis
	A prospective comparative study of safety and validity of new unicondylar knee with robotic interactive orthopedic system			I: UKA with RIO C: Manual UKA		HSS Score Oxford Knee Score SF-12 WOMAC Radiological evaluation Survival rate

	A prospective comparative study on the safety and validity of Robotic Interactive Orthopedic system in total knee arthroplasty (TKA)			I: TKA with RIO C: Manual TKA		Femorotibial angle Survival rate KSS Score Oxford Knee Score SF-12 WOMAC Score Radiologic Evaluation
	Superior component position during robotic-assisted Oxford unicompartmental knee arthroplasty (UKA) compared with conventional technique: a 5-year follow-up study			I: Robotic-assisted surgery C: Conventional technique		KSP scores KSF scores KSC scores
	Comparation of traditional total knee arthroplasty and robot-assisted total knee arthroplasty in safety and efficacy			I: Robot-assisted total knee arthroplasty C: Traditional total knee arthroplasty		Angle of femoral component in sagittal plane Angle of tibial component in sagittal plane Coronal plane femoral component Angle Coronal plane tibial component Angle Range of motion of the knee KSS score VAS Score
	Clinical outcomes and gait analyses after robot-assisted total knee arthroplasty versus conventional TKA: a prospective randomized controlled study			I: Robot-assisted total knee arthroplasty C: conventional TKA		Gait analyses Clinical outcomes Functional outcomes
	Clinical trial of Joint robots for knee arthroplasty			I: Joint robots independently for knee arthroplasty C: Conventional knee arthroplasty		the reconstructed mechanical axes bone resection angles on the coronal and sagittal KSS score WOMAC score Visual Analogue Scale

	Manual versus Robotic-arm assisted Total Knee Replacement			I: Robotic-Arm Assisted Total Knee Arthroplasty (RATKA): C: Manual or Jig-Based TKA Patients undergoing simultaneous bilateral total knee replacement surgery, will be RANDOMIZED to receive Robot-arm assisted TKR one side/knee and conventional/manual TKR on the other knee.		Visual Analogue Scale for Pain (VAS Pain) Morphine-Equivalents (ME) Distance walked in 3 minutes (in meters) Forgotten Joint Score (FJS) Range of Motion (ROM) Knee Society Score Limb alignment Oxford Knee Score (OKS) Use of aids to walk WOMAC
	Robotic-assisted versus manual total knee arthroplasty – a non-invasive prospective randomized controlled trial (NIS)			I: Manual Implantation of a total knee arthroplasty C: robotic-assisted version (Stryker MAKO® surgical robot)		Accuracy of implantation KSS (Knee Society Score) Oxford Knee Score

	Manual versus Robotic Unikondylar Knee Arthroplasty. A prospective pair matched trial.			I: Implantation of a Unikondylar Knee Arthroplasty Operation method: robotic-assisted version (Stryker MAKO® surgical robot) C: Implantation of a Unikondylar Knee Arthroplasty Operation method: manual implantation Intervention		Accuracy of implantation KSS (Knee Society Score) Oxford Knee Score
	Short-term results after knee TEP implantation in valgus gonarthrosis regarding subjective patient satisfaction and function after robotic-assisted and manual surgical techniques			I: Robotic assisted (NAVIO) C: Manual		Forgotten Joint Score (FJS) Knee Scociety Score (KKS) Oxford Knee Score (OKS) Radiologic difference
	A comparison of standard versus robotic total knee replacement			I: Robotic total knee replacement (TKR) (MAKO) C: Manual TKR		Forgotten Joint Score (FJS) Mean pain intensity Estimated blood loss Morphine Equivalent Hours from surgery to hospital discharge Oxford Knee Score (OKS) EQ5D-5L PROMIS Pain Intensity Scale Satisfaction with the knee replacement measured using a five-point Likert scale questionnaire Number of re-operations

	A comparison between robotic and orthosensor-assisted total knee replacement and standard total knee replacement surgery			I: Robotic assisted knee replacement C: Conventional manual knee replacement		WOMAC Oxford Knee Score (OKS) Forgotten Joint Score (FJS) Satisfaction after total knee replacement EQ-5D-3L Cost-effectiveness Gait patterns and balance
	Comparison of haptic assisted versus non-assisted uni-compartmental knee arthroplasty			I: MAKOplasty® unicondylar knee arthroplasty, using the RESTORIS implant and the MAKO RIO® Robotic Arm C: OXFORD® Partial Knee Arthroplasty		Mechanical knee alignment (tibiofemoral angle, degrees) Oxford Knee Scores (OKS) American Knee Society Score (AKSS) Pain Visual Analogue Score (VAS) SF-12 Canadian Occupational Performance Score (COPM) UCLA activity scale Hospital Anxiety and Depression (HAD) score Operation time Complications Knee angles during functional tasks Frequency/type of activity Gait velocity, knee angles and moments
	Comparison of Oxford unicompartmental knee arthroplasty outcomes in osteoarthritic knee patients; cemented vs cementless vs hybrid fixation			I: Robotic assisted UKA C: Conventional UKA		Survivorship Revision Complication rate Rate of infection Fracture and dislocation
	Robotic assisted vs conventional unicompartmental knee arthroplasty: A prospective randomized trial			I: Robotic assisted UKA C: Conventional UKA		Revision Knee function Oxford knee score Complication Number of infections Fracture, loosening and dislocation

Innehållsdeklaration

Denna HTA-rapport är baserad på följande moment:

- ✔ Metodbeskrivning
- ✔ PICO
- ✔ Uttömmande litteratursökning
- ✔ Flödesschema
- ✔ Urval relevans
- ✔ Kvalitetsgranskning
- ✔ Tabelldata
- ✔ Sammanvägning av resultat
- ✔ Metaanalys
- ✔ Evidensgradering enligt GRADE
- ✔ Sammanfattning
- ✔ Ekonomi
- ✔ Organisation
- ✔ Etik
- ✔ Pågående studier
- ✔ Exkluderade artiklar
- ✔ Expertgrupp deltar
- ✔ Extern granskning
- ✔ Kunskapsluckor identifierade
- ✔ Jävsdeklaration inhämtad från projektdeltagarna

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA

HTA

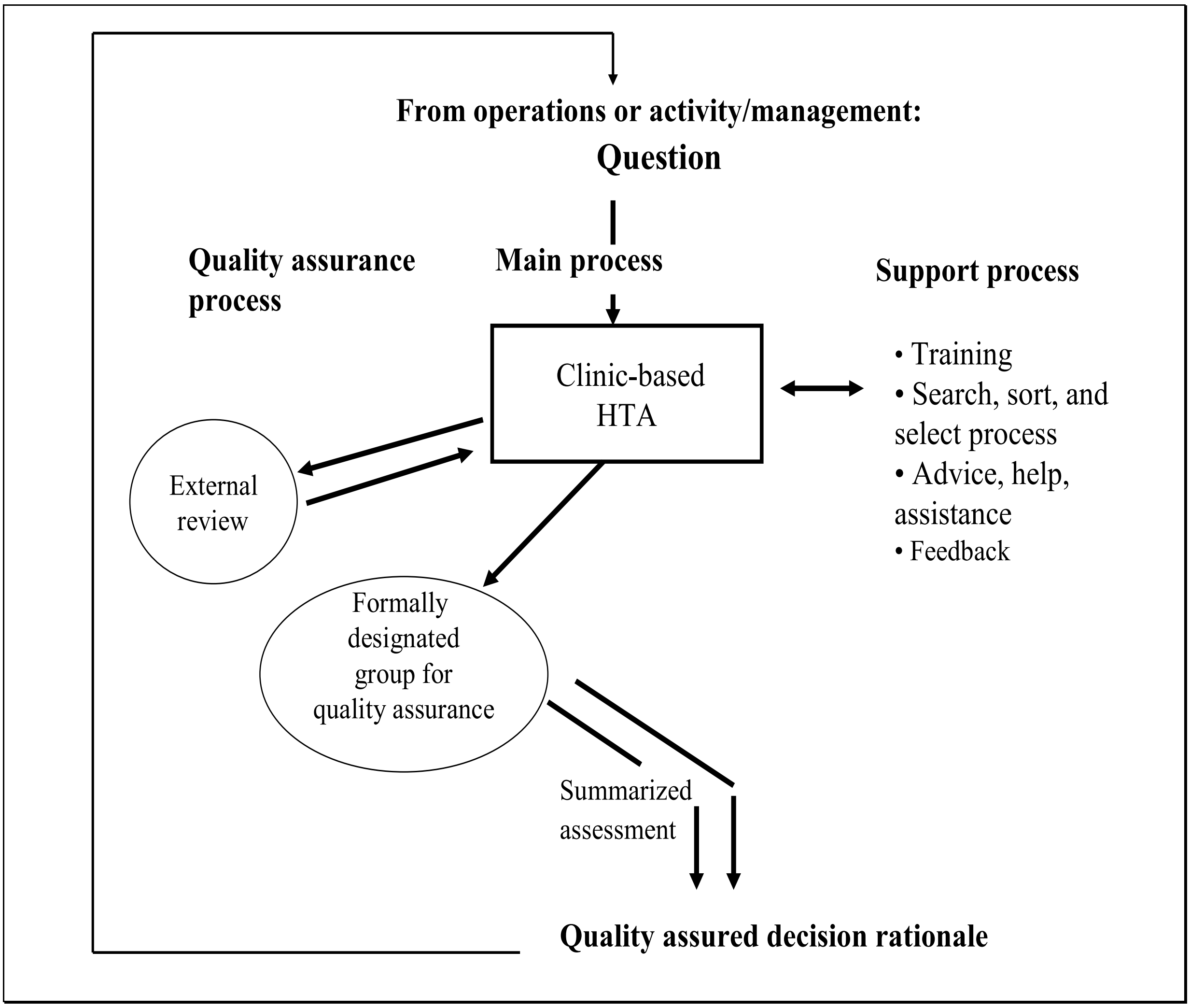
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the certainty of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High certainty of evidence	= (GRADE⊕⊕⊕⊕)
Moderate certainty of evidence	= (GRADE ⊕⊕⊕O)
Low certainty of evidence	= (GRADE ⊕⊕OO)
Very low certainty of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either "strong" or "weak". This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh
Professor, MD
Head of HTA-centrum



From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

VÄSTRA
GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Sahlgrenska Universitetssjukhuset, HTA-centrum
Röda Stråket 8, 413 45 Göteborg
www.sahlgrenska.se/htacentrum