GID-HTE10043 – Robotics in orthopaedics: Early Value Assessment – Addendum 1

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Background

During the evaluation of the technologies included within the Final Scope for 'GID-HTE10043 Robotics in orthopaedics: early value assessment' no information was provided by the Company and the EAG included information available in the public domain in its Final report. During public consultation for the topic, MicroPort (manufacturer of SkyWalker) submitted evidence in confidence for consideration by the Committee.

The information in this document will be used to advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The document forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

New evidence for SkyWalker

Technology

The SkyWalker system is indicated for total knee arthroplasty (TKA). This technology requires a preoperative CT scan for planning. It uses an arm-based cutting tool attached to a moveable base station and uses indirect cutting. The system has CE certification and is classified as class IIb. [redacted] Full technology characteristics, components and training requirements are described in Table 1.

Table 1 - Summary of SkyWalker (MicroPort MedBot) technology characteristics, components and training requirements

Technology characteristics	
Device indication	TKA
Contraindications	• Hip pathology with significant bone loss (e.g., avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum) • Hip pathology severely limiting range of motion (e.g., arthrodesis, severe contractures, chronic severe dislocation) • Active infections of the knee joint area

	• Knee replacement revision surgery • Presence of strong infrared sources or infrared reflectors in the vicinity of the devices • Implants that are not compatible with the system • Contraindications for the implant as given by the implant manufacturer
Requires pre-op imaging	CT
Open/closed	Closed - compatible with the Evolution Medial-Pivot Knee Implant.
Deployment of robot	Arm: moveable base station
Cutting type	Indirect
Technology components	
System components (dimensions)	1x Robotic arm trolley, 1x Surgical console consisting of camera, 1 surgeon screen, 1 operator screen, 1 operator console
Instrumentation kits	Cables, a foot pedal, a Knee Kit with trackers (for the femur, tibia, base, calibration and cutting block), and probes (blunt and pointed), and disposable pins, nails, and drapes
Tracking reference arrays and fixation method	The femur and tibia trackers are used to track the position of the bones. They are attached to fixation components and then attached to the bone using disposable bone pins. Bone pins and trackers must remain stable and steady to be identified by the Optical Tracking Device and complete surgery. The installation position is suggested as 10cm below the tibial tubercle for the tibia, and 10cm above the superior edge of the patella for the femur as described in the instructions for use. Two bone pins (standard or long) are drilled into femur and another 2 pins (standard or long) into tibia with a drill through the tunnel guide outside the incision. Drill through first hole, then drill through third hole preferably, or the surgeon can select the second hole. After the bone pins are driven in, the fixation components are screwed onto bone pins.
Types of data collected	[redacted]
Device lifetime	[redacted]
Planned updates to technology	[redacted]
Training requirements	

Surgeon	Mandatory certification is required from the surgeon to use SkyWalker Total Knee System
Nurse/theatre team	Staff will be also trained at the surgeon's facility by a manufacturer supplied team of experts on surgical workflow, assembly, and operation of sterile and disposable instrumentation
Sterile service	None explicitly stated

Abbreviations: TKA, total knee arthroplasty; CT, computed tomography

Clinical evidence

The manufacturer submitted 5 pieces of evidence to NICE during the consultation period (see Appendix A for summary of evidence and reasons for exclusion or deprioritisation). The EAG extracted outcomes from 1 study (Yang et al. 2023) which was prioritized based on relevance to the decision problem.

Yang et al (2023) was a retrospective propensity matched cohort study in total knee arthroplasty (TKA) with the conventional arm data taken from procedures conducted by the same surgeon at the same hospital as the intervention arm. The study reported the same trial registration (ChiCTR2100054391) as the previous study included in the EAG report (He et al. 2022), with slight overlap in recruitment dates (He et al. 2022; n=60 recruited between June 2019 and December 2020; Yang et al. 2023; n=52 robotic cases recruited between October 2020 and January 2021, matched to n=104 cases conventional assumes same recruitment period, but not explicitly reported). Yang et al. (2023) reported on several outcome measures in both arms, but did not report the mean differences between arms:

- Reported no evidence of a statistical difference in the Western Ontario and McMaster Universities (WOMAC) patient reported outcome measure, at 3 months (p=0.73), Table 3Table 2. The authors emphasised that these PROMs reported were for short-term follow-up only.

- Reported no evidence of a statistical difference in intraoperative blood loss between robotic and conventional surgery (p=0.46), Table 3. The authors propose that the minimal difference in blood loss was due to a tourniquet being used in both surgeries. Yang et al. 2023 also reported a significant difference in haemoglobin reduction between the arms at both day 1

(p<0.001) and day 3 post surgery (p<0.001), both lower in the robotic arm, Table 3Table 4. The authors propose that the similar intraoperative blood loss across both arms combined with a smaller haemogloblin decrease indicates a lower risk of “hidden” blood loss (for example hematoma) which may have clinical implications.

- Reported a statistical difference for both operation time (robotic: 130.1 ± 26.9 min, conventional: 108.8 ± 22.9 min; p<0.001) and tourniquet time (robotic: 96.1 ± 15.1 min, conventional: 69.6 ± 17.9 min; p<0.001); both longer in the robotic arm, using the Robotic-assisted surgery than conventional surgery, Table 4Table 5.

- Did not report on learning curve or revision surgery which were primary outcomes listed in NICE Final Scope.

- Reported on secondary outcomes including alignment (statistical differences in lateral tibial component angle between robotic and conventional, p<0.001; with the authors reporting that the robotics arm was closer to the ideal angle of 87°, and statistically fewer outliers when considering deviations in other alignment angles), and length of hospital stay (no statistical difference between arms, p<0.750), Table 6.

The Yang et al. (2023) paper contributes to the evidence base, Table 7, however does not change any of the evidence generation questions in the original EAG report.

Table 2: Study summary

[Note: Ages reported in years, BMI in kg/m2, both reported as mean (SD) or median [Q1,Q3 or range, as stated]]

Author (journal, year); country (N number of centres)	Study design [duration of follow-up]	Procedure	Intervention (n patients allocated)	Comparator (n patients allocated)	Demographics (intervention arm)	Demographics (comparator arm)	Outcomes extracted
Yang (Int J Surg, 2023; 1552-1560); China (N=1)	Retrospective 1:2 propensity score matched (age, sex, left and right, BMI, preoperative HKA) cohort with historical comparator – same surgeon and hospital [procedural, 3 day, WOMAC 3 months]	TKA (primary)	SkyWalker (n=52)	Conventional (n=104)	Age: 66.1 (7.9) Male: 21% BMI: 26.0 (4.2)	Age: 63.9 (6.6) Male: 22% BMI: 25.6 (3.3)	PROMs (WOMAC) Complications (intraoperative bleeding, haemoglobin (Hb) decrease at 1, 3 days post-surgery) Operating time Tourniquet time Length of hospital stay Alignment

Abbreviations: BMI, body mass index; NR, not reported; PROM, Patient Reported Outcome Measure; TKA, total knee arthroplasty

Table 3: Summary of SkyWalker studies which reported PROMs

PROM	Timepoint	Author (year); country	Study design	Procedure	Intervention (SkyWalker) Mean (SD)	Comparator (Conventional) Mean (SD)	p-value
WOMAC	3 months	(Yang et al., 2023) China	Retrospective propensity matched cohort	TKA	11.7 (8.2)	11.2 (7.1)	0.73

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty; WOMAC, Western Ontario & McMaster Universities Score

Table 4: Summary of SkyWalker studies which reported complications

Author (year); country	Study design	Procedure	Key results
(Yang et al., 2023) China	Retrospective propensity matched cohort	TKA	Intraoperative blood loss, ml: mean (SD) of 193.5. (36.1) in robotic arm and 198.6 (42.8) in conventional arm; p=0.462
(Yang et al., 2023) China	Retrospective propensity matched cohort	TKA	Haemoglobin decrease at day 1, g/l: mean (SD) of 9.6 (9.1) in robotic arm and 16.7 (9.6) in conventional arm; p<0.001 Haemoglobin decrease at day 3, g/l: mean (SD) of 22.9 (13.6) in robotic arm and 31.8 (12.2) in conventional arm; p<0.001

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty;

Table 5: Summary of SkyWalker studies reporting operating time

Author (year); country	Study design	Procedure	Operating/tourniquet time, minutes, mean (SD), Length of hospital stay, days, mean (SD)	p-value
(Yang et al., 2023) China	Retrospective propensity matched cohort	TKA	Operation time: SkyWalker: 130.1 (26.9) Conventional: 108.8 (22.9) Total tourniquet time: SkyWalker: 96.1 (15.1) Conventional: 69.6 (17.9)	<0.001 <0.001

Abbreviations: SD, standard deviation; TKA, total knee arthroplasty;

Table 6: Summary of SkyWalker study reporting secondary outcomes

Author (year); study design	Procedure	Key findings Mean (SD)
(Yang et al., 2023) Retrospective propensity matched cohort	TKA (primary)	Alignment: statistical difference in mean (SD) lateral tibial component (LTC) angle between robotic and manual arms post-operatively (86.7 (2.3) and 80.9 (3.6) respectively; p<0.001). The authors reported that the robotic arm was closer to the ideal LTC of 87°. No statistically significant difference in mean (SD) between robotic and manual arms post-operatively: • Hip-knee-ankle (HKA) angle: 180.4 (1.9) compared with 180.1 (SD 3.9); p=0.526 • Frontal femoral component (FFC) angle: 89.6 (1.5) compared with 89.8 (2.8); p=0.654 • Frontal tibial component (FTC) angle: 90.0 (1.3) compared with 89.8 (2.0); p=0.445 • Lateral femoral component (LFC) angle: 88.5 (2.3) compared with 89.2 (3.6); p=0.131. Statistical differences in absolute deviations between angles post-operatively and targets were reported between arms, and smaller in the robotics arm for HKA (p<0.001), FFC (p<0.001), FTC (p=0.001) and LTC (p<0.001) deviations. No evidence of a statistical difference was reported in absolute deviation in LFC (p=0.225). Statistically fewer outliers were reported in the robotic arm in HKA (p<0.001), FFC (p=0.001), FTC (p=0.018), LFC (p=0.004), and LTC (p<0.001). Length of hospital stay, mean (SD) day: no statistical difference between robotic and conventional (8.5 (3.2) and 8.7 (1.1) respectively, p=0.750.

Abbreviations: FFC, frontal femoral component angle; FTC, frontal tibial component angle; HKA, hip-knee-ankle angle; LFC, lateral femoral component angle; LTC, lateral tibial component angle; SD, standard deviation; TKA, total knee arthroplasty

Table 7: Availability of evidence for primary outcomes across studies

Device: procedure	PROMs	Complications	Learning curve	Revision Surgery	Operating time
SkyWalker: TKA (primary)	**GREEN**	**GREEN**	**RED**	**RED**	**GREEN**

Key: **GREEN** RCT or comparative observational study with matched baseline characteristics (or single-arm study for learning curve outcome only); **AMBER** comparative observational study with unmatched baseline characteristics. **RED** single-arm only or no evidence. Abbreviations: TKA, total knee arthroplasty

Costing information

The EAG was supplied with costs for the SkyWalker technology. The EAG transformed these (Table 7) into a similar format to enable comparison with costs provided by the other manufacturers (as reported in the original EAG report).

[redacted]

Table 8: Costs supplied for SkyWalker

Parameter	SkyWalker (capital purchase option)	SkyWalker (monthly rental option)
Annual procedure volume	250	250
Lifetime of system, years	[redacted]	[redacted]
Device costs (assuming procedural volume and lifetime of robot above), per patient	[redacted]	[redacted]
Consumable costs for TKA, per patient	[redacted]	[redacted]
Implant costs for TKA, per patient	[redacted]	[redacted]
CT imaging costs (pre-procedure), per patient	[redacted]	[redacted]
Service plan, per patient (assuming not applied in first year and included in 12-month warranty, so service charge applied is over one less year than the lifetime)	[redacted]	[redacted]
Optional extras, per patient	[redacted]	[redacted]
Total costs (TKA)	[redacted]	[redacted]
Total costs (with optional extras)	[redacted]	[redacted]

The EAG has not repeated the base case (capital purchase) economic analysis for SkyWalker because the cost of the technology lies within the range of costs per patient for the other technologies, and the total per patient cost over the time horizon of the model would therefore also lie within the range of results for the other technologies, that is, Skywalker RAS is dominated by conventional TKA. In the original EVA report, the EAG did sensitivity analysis only for the Mako technology, so has also run no other economic analysis using the costs supplied for SkyWalker.

Summary

The new clinical evidence (propensity matched retrospective cohort) does show potential benefit for SkyWalker in some clinical outcomes but there are uncertainties associated and need for prospective studies with the robotic systems remain lacking. The new costing information provided for SkyWalker does not change the conclusions of the original EAG report.

Appendix A: Summary of the evidence submitted by MicroPort during public consultation

Title	Study design (number of participants)	Reason for exclusion or deprioritisation
Lei, Kai et al. 2021 Lei K, Liu L, Yang P, Xiong R, Yang L, He R, and Guo L., 2022 titled "Robotics versus personalized 3D preoperative planning in total knee arthroplasty: a propensity score-matched analysis."	Retrospective cohort study with propensity score matched comparator (n=156)	Compares device to surgical technique with 3D-preoperative planning, not considered standard care in NHS
Ping et al., titled "Efficacy of the newly designed 'SkyWalker' robot compared to the MAKO robotic system in primary total knee arthroplasty: a one-year follow-up study"	Retrospective cohort study with propensity score matched comparator (n=75)	Compares device to another RAS device – out of scope
Yang et al., titled "Clinical evaluation of the first semi-active total knee arthroplasty assisting robot made in China: a retrospective propensity score-matched cohort study."	Retrospective cohort study with propensity score matched comparator (n=156)	Prioritised study
He, Rui et al. titled “Semiactive robotic-arm system versus patient-specific instrumentation in primary total knee arthroplasty: Efficacy and Accuracy"	Retrospective cohort study with age and gender matched comparator (n=90)	Less robust study design than prioritised study and no additional primary outcomes reported
Karachalios, T. titled “A prospective randomized control study on Skywalker with a Medial Pivot Knee vs conventional Medial Pivot knee”	Randomised controlled trial (n=142)	Conference presentation with inadequate information to assess data

Appendix B: Study characteristics of Yang et al. (2023)

Author (year); Funding	Design and intervention(s)	Participants & Setting	Outcomes	EAG comments
Yang (Int J Surg, 2023; 1552-1560) [ChiCTR2100054391] *Funding:* National Key R&D Program of China *Declaration of interests:* authors reported no conflicts of interest	*Study design:* Retrospective [1:2] propensity score matched (age, sex, left and right, BMI, preoperative HKA). *Procedure:* TKA (primary) *Intervention:* SkyWalker (n=52) with Advance medial-pivot knee system (MicroPort). **GREEN** *Comparator:* Conventional (n=104 matched) with LEGION Total Knee System posterior stabilised prosthesis (Smith & Nephew, Memphis, TN, US) **AMBER**	*Inclusion:* osteoarthritis patients aged between 45 and 80 years old; unilateral TKA required; able to cooperate in the follow-up with good compliance; volunteered to participate in this study and signed written informed consent. *Exclusion*: previous replacement of major joints (hip, knee) on the same side of the lower extremity; knee varus or knee valgus deformity greater than 15°; ankylosing deformity of the hip or ankle joints, known or suspected allergy to polyethylene or metal materials and other contraindications to receiving implants; prosthesis cannot be fixed in the subject due to disease; those who have participated in clinical trials of other investigational drugs or devices within 3 months; other circumstances deemed unsuitable for the clinical study by the investigators. *Recruitment period:* SkyWalker between October 2020 and January 2021. Comparator: NR *Follow-up:* 3 months *Setting:* China (N=1 centre, same surgeon)	Alignment, blood loss, operative time, tourniquet time, complications, length of stay, PROMs (WOMAC)	Different implant system used in the comparator arm. Statistically powered to detect difference in malalignment rates between arms (previously reported as 2% with robotics and 18% without).