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Australia and New Zealand Horizon Scanning Network

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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Minimally invasive robot-assisted unicompartmental knee arthroplasty

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**Australian
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and Efficacy
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of New
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Procedures -
Surgical**



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PRIORITISING SUMMARY

REGISTER ID S000100

NAME OF TECHNOLOGY MINIMALLY INVASIVE ROBOT-ASSISTED UNICOMPARTMENTALISED KNEE ARTHROPLASTY

PURPOSE AND TARGET GROUP PATIENTS UNDERGOING UNICOMPARTMENTAL KNEE REPLACEMENT

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States		✓	
United Kingdom		✓	

IMPACT SUMMARY

Robot-assistance has the potential to improve the accuracy of unicompartmental knee arthroplasty (UKA) and is expected to result in substantial improvements to patient outcomes.

BACKGROUND

The primary indication for knee arthroplasty is to relieve pain caused by severe arthritis. Other indications include deformity or instability due to various causes such as accidents. Total knee replacement is typically the surgical procedure of choice, as it is

well established with proven efficacy. Partial knee replacement, also known as UKA has garnered increasing attention as the procedure requires a smaller incision and may result in faster recovery. In the United States, the total number of UKA implants has grown from 1% of all knee implants in 1997 to 6% of all implanted knee prostheses in 2000 (Millenium Research Group 2003). Unlike total knee replacement where all cartilage is removed from the knee joint and substituted with implants, UKA only replaces the most damaged areas. Advances in technology have also led to minimally invasive UKA (Conditt and Roche 2009).

However, despite the fact that UKA can achieve an overall reduction in soft tissue and bone trauma, minimally invasive UKA is not as accurate as open UKA (Pearle et al 2009). Furthermore, in comparison to patients who underwent total knee replacements, UKA patients appear to have inconsistent long-term survival, with revision rates ranging from 10% to 20% (Eickmann et al 2006, Swedish Knee Arthroplasty Register 2006). Research indicated that patient-specific factors such as age, weight and the presence of co-morbidities may play a major role in revision rates. Nevertheless, evidence indicated that correct alignment of the femoral and tibial components is the most objectively quantifiable factor (Pearle et al 2009). Using a minimally invasive approach with conventional instrumentation, studies have found that it is difficult to accurately align the tibial component in UKA on a consistent basis. Approximately 40% to 60% of components may be misaligned more than 2° from the preoperative plan, despite computer-assisted navigation (Cobb et al 2006, Keene and Kalairajah 2006). Computer navigation, although advantageous, is negatively influenced by the relatively imprecise mechanical tools (e.g. oscillating saw) that are performing the actual procedure.

The nature of joint arthroplasty procedures has typically meant that the robotic systems designed to date are not minimally invasive as the procedure requires immobilising the bones, exposure required to register surfaces to be cut and the general bulkiness of robotic systems. In recent years, technological advancements have led to two robotic systems capable of performing minimally invasive knee surgery with the promise of greater accuracy: 1) Tactile Guidance System (TGS) (MAKO Surgical Corp., Florida, United States) and 2) Acrobot system (The Acrobot Co. Ltd., London, United Kingdom). Both robotic systems are similar in the sense that they are both passive systems that utilise active constraints, which basically asserts resistive forces to the surgeon's hand in order to confine the UKA procedure to the "safe" zone. This allows for more accurate reproduction of preoperative plans for implant placement and overall alignment (Pearle et al 2009). However, there are some important differences between these systems. Unlike the Acrobot, the relatively newer MAKO TGS system does not rely on permanent or rigid fixation to the patient's bony anatomy as it is capable of dynamic tracking of the femur and tibia, while the robot movements are independent of the patient's position or movement. The developer of the MAKO TGS system claims that this should reduce the risk of infection, iatrogenic fractures and soft tissue injury (Pearle et al 2009).

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, knee arthroplasty is one of the top 10 surgical procedures performed on individuals with arthritis and musculoskeletal conditions between 2003 and 2004 (Australian Institute of Health and Welfare 2005). The number of knee arthroplasty procedures has increased over the years and the Australian Institute of Health and Welfare reported that from 2006 to 2007, a total of 29,941 knee replacement procedures and 1,629 knee replacements with bone graft to the femur or tibia were performed (Australian Institute of Health and Welfare 2007).

DIFFUSION

The MAKO Tactile Guidance System™ received FDA approval in January 2008 (K072806) for surgical knee procedures (Food and Drugs Administration 2008). The extent of diffusion within the United States is not clear but appears to be limited. The Acrobot system is not FDA approved and is primarily utilised in the United Kingdom. Both systems are not listed within the Australian Register of Therapeutic Goods and are therefore not cleared for use within Australia.

COMPARATORS

The main comparator to minimally invasive robot-assisted UKA is conventional UKA that is performed with or without computer-assisted navigation.

SAFETY AND EFFECTIVENESS ISSUES

Study description

Three studies on minimally invasive robot-assisted UKA were retrieved for inclusion. The randomised controlled trial by Cobb et al. (2006) compared the performance of the Acrobot System with conventional UKA surgery. Post-operative assessment blinding was performed; however the method utilised to randomise patients to both groups was not stated clearly. Both groups were comparable, with the exception of gender (fewer women in Acrobot group) and the fact that left knees were more common in the conventional UKA group. The procedure was clearly described for both patient groups. The primary outcome measure was the change in the tibiofemoral angle (difference between planned and achieved angles in the coronal plane). This data was transformed into dichotomous data (angles $\leq 2^\circ$ or $> \pm 2^\circ$). Secondary outcome measures include: American Knee Society Score (AKS) and Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index, all adverse events (particularly device or procedure related complications) and operating times. Patients were observed up to 3 months post-treatment.

The comparative study by Lonner et al (2009) examined the error and variance in tibial prosthesis alignment in UKA performed with the MAKO TGS system (n=31 patients) or with conventional manual instrumentation (n=27 patients). Retrospective data was utilised for the conventional UKA group, consisting of patients previously treated by the same surgeon. Radiographs were reviewed at 2 or 6 weeks to compare difference in preoperatively planned positions and postoperatively achieved positions for both patient

groups. The measured error for each technique of bone preparation was determined by comparing the preoperative planned position for each tibial component with the postoperative coronal and sagittal alignment achieved for each tibial component. The root mean square (RMS) was utilised to quantify alignment errors in order to avoid skewing of results. Patients were followed up for 3 months.

The case series study by Pearl et al (2009) presented results of 10 consecutive patients who underwent UKA with the MAKO TGS system. All operations were performed by the same surgeon and total follow-up duration was 6 weeks post-treatment.

Safety

Cobb et al. (2006) observed four minor adverse events. Three Acrobot group patients experienced mild cases of swollen leg, skin blister in peri-scar area and swollen ankle, respectively. Meanwhile, one patient from the conventional treatment group suffered bilateral swollen legs. Serious adverse events were evident in three patients, one from the Acrobot group (acute urinary retention) and two from the conventional group (perforated peptic ulcer and myocardial infarction). The investigators noted that all adverse events were likely to be related to the procedure, but none were considered to be directly related to the device itself.

Lonner et al. (2009) reported that there was one case of isolated tibial loosening in a patient who developed pain at 3 months and had tibial subsidence. Meanwhile, Pearle et al (2009) did not observe any adverse events at 6 weeks post-treatment and had uneventful wound healing. There were no technical failures or equipment specific problems during the procedure (Pearle et al 2009).

Efficacy

Utilising the Acrobot system, patients achieved tibiofemoral alignment in the coronal plane that were within 2° of the planned position with a mean of 0.65° (standard deviation SD: 0.59; range: -1.6° to 0.3°). For patients treated with conventional UKA, only 40% (6/15) of patients achieved this level of accuracy with a mean of -0.84° (SD: 2.75; range: -4.2° to +4.2°). The accuracy of the Acrobot system was significantly better compared to conventional UKA ($p=0.002$), therefore suggesting that the use of an active constraint robotic assistant improved the positioning of the prosthesis in the coronal plane. The investigators further demonstrated this difference in accuracy by superimposing planned and achieved position of the implants accompanied with assessment by a blinded investigator. AKS scores revealed that patients treated with conventional UKA had a wider spread, ranging from 3 to 83 compared to the Acrobot group, ranging from 38 to 107. Analysis of the data demonstrated that the mean increase in AKS score was twice as large in the Acrobot group (65.2 SD: 18.36) vs. 32.5 (SD: 27.45) while the median values were more than three times higher for Acrobot patients (62 vs. 19). This difference was statistically significant ($p=0.004$). However, there was no difference in WOMAC scores for pain, stiffness and physical function (Cobb et al. 2006). Overall mean operating time was greater in Acrobot patients (104[SD: 13.90] minutes vs. 97.3[SD: 18.1] minutes) but this was not statistically significant.

Comparison between the MAKO TGS system and conventional UKA demonstrated that the root mean square (RMS) error of the tibial slope was lower for the TGS group (1.9° vs. 3.1°). Furthermore, the variance using manual instruments in the conventional group was 2.6 times greater ($p=0.02$) compared to the TGS group. In the coronal plane, the average error of the tibial alignment was lower for the TGS group compared to conventional UKA which was more varus ($0.2^\circ \pm 1.8^\circ$ vs. $2.7^\circ \pm 2.1^\circ$, $p < 0.0001$). The varus/valgus RMS error was lower for the TGS group as well (1.8° vs. 3.4°) (Lonner et al 2009).

In the first 10 consecutive patients treated with TGS assisted UKA in the Hospital for Special Surgery (New York) the planned and subsequent intra-operative tibiofemoral angle in the coronal plane was within 1°. Post-operative long leg axis radiographs were within 1.6° to intra-operative measurements. The authors noted that setup time for the robotic system averaged 41 minutes with a specialised technician. The average time for the intra-operative registration process was 7.5 minutes (range: 6-13 minutes), and the average incision was 8cm. The duration of robot-assisted burring of the bone decreased with experience, from an average of 42.8 minutes in the first 5 cases to 27.3 minutes in the last 5 cases. Average hospital stay for this cohort was 2.2 days (Pearle et al 2009).

COST IMPACT

There are no cost-effectiveness studies on robot-assisted UKA. The randomised trial demonstrated that robot-assisted UKA is associated with an increase in surgical time, which may translate to higher procedural costs. In addition, ongoing servicing costs and the need for specialist technician support should be considered as well. As expected, there is also a substantial initial outlay to purchase the robotic system. Forbes noted that the MAKO robot costs US\$750,000 (Forbes 2006). In February 2009, MAKO Surgical Corp. issued a press release describing a new generation of the robotic system (Medgadget 2009). However the cost of this new system is not clear. We were unable to retrieve data on the total purchase cost of the Acrobot system.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

The randomised controlled trial by Cobb et al (2006) was funded by the manufacturer of the Acrobot system and the authors have received or will receive benefits for personal or professional use from a commercial party that is related directly or indirectly to the Acrobot system. In addition, it was disclosed that benefits have been or will be directed to a research fund, foundation, educational institution or other non-profit organisation which one or more of the authors are associated with.

One or more of the authors of the comparative study have received financial support from the MAKO Surgical Corp. Author Jess Lonner received payment as a consultant and is a stock holder of the company, while another author (Michael Conditt) receives compensation as Director of Clinical Research.

For the case series study, it is unclear if the authors received any compensation for their work from the manufacturer. The lead author, Dr. Pearle, has been cited to have no financial interests in MAKO Surgical Corp. in a 2008 article (MIT Technology Review 2008).

SUMMARY OF FINDINGS

Although some high level evidence is available on robot-assisted UKA, all of the included studies are limited by small patient cohorts and short follow-up periods. There is some evidence that minimally invasive robot-assisted UKA, with the Acrobot or TGS system, is more accurate compared to conventional UKA. However, the randomised trial demonstrated that despite improved accuracy, the utilisation of the Acrobot system did not confer substantial clinical benefits over conventional UKA at 3 months post-treatment. Further comparative studies are necessary to determine if the accuracy offered by these robotic systems translate to better patient outcomes over the long term, particularly revision rates. In addition, it would be prudent to observe differences in methodology and the robotic system utilised.

HEALTHPACT ACTION

Although the available evidence demonstrated that minimally invasive robot-assisted UKA is more accurate relative to conventional UKA, there is no evidence to suggest that this translates to better clinical outcomes. Long-term studies to determine revision rates and patient outcomes are necessary. Additional assessment of this technology is not necessary at this point in time.

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level II intervention evidence	1
Level III intervention evidence	1
Level IV intervention evidence	1

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SEARCH CRITERIA TO BE USED

Robotic*
Arthroplasty, Replacement, Knee/instrumentation
Unicompartmental knee arthroplasty
MAKO
Tactile guidance system
Acrobot