Patient-Specific TKA with the VELYS™ Robotic-Assisted Solution

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ABSTRACT

The VELYS™ Robotic-Assisted Solution (VRAS) (DePuy Synthes, Warsaw, Indiana) utilises new technology to accurately collect the bony anatomy and soft tissue envelope of the knee. This enables surgeons to use this information to intraoperatively plan anatomical placement of a total knee arthroplasty (TKA) with preservation of the soft tissues with the aim of restoring functional knee motion. The robotic-assisted saw delivers precise, accurate, and efficient delivery of this implantation plan.

This article describes the patient-specific TKA technique which maximises the full potential of VRAS; however, all TKA techniques and alignment philosophies can be accommodated with VRAS.

The first case was performed in late 2020. An early outcome study shows an improvement in knee function and pain with activity at discharge and six weeks and a neutral surgical time comparable with the author's extensive experience with patient-specific balanced TKA with navigation. Only a limited number of patients have one-year results. However, the data of this limited cohort demonstrates favourable outcome scores and high patient satisfaction.

INTRODUCTION

The first VELYS™ Robotic-Assisted Solution (VRAS) (DePuy Synthes, Warsaw, Indiana) total knee arthroplasty (TKA) was performed in Auckland, New Zealand in late November 2020. This article gives an overview of the new technologies, features, and benefits of this device for performing TKA and reports on the early results. Rather than the surgeon pre-planning their TKA with X-rays or (computed tomography) CT scans, VRAS accurately intraoperatively collects not only the bony anatomy but also the soft tissue envelope of the knee. This enables a surgeon to use this intraoperative assessment to help plan and execute the optimal placement of their TKA. VRAS is versatile and enables surgeons to choose their preferred surgical workflow and alignment philosophy. The patient-specific TKA technique described in detail in this article employs the full potential of the VRAS system.

Two early outcome studies comparing patient-specific VRAS TKA with the author's previous experience with patient-specific balanced TKA with the Brainlab® Knee3 Navigation system (Munich, Germany) will be presented.

VELYS™ ROBOTIC-ASSISTED SOLUTION OVERVIEW

The VRAS consists of an image-free operating room (OR) table bed-rail mounted robotic-assisted system, a high-speed 250Hz camera, hydrophobic optical reflectors, an optically tracked calibrated probe, and two touch screens (Fig. 1). Planes of resection, implant size, and optimal implant positioning are determined intraoperatively. Based on this intraoperative collection of the bony anatomy and soft tissue envelope of the knee, an initial surgical plan is generated. A graph is displayed on the graphical user interface to show the balance outcome of mechanical alignment positioning of the planned TKA. The medial and lateral gaps for this planned component position throughout the full range of motion are shown.

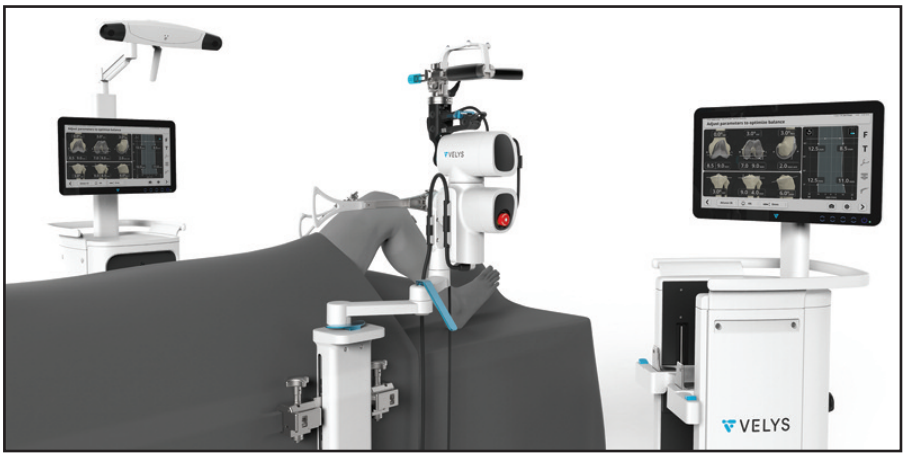

Figure 1. VELYS™ Robotic-Assisted Solution.

The surgeon then determines whether to accept the mechanical alignment plan with the projected balance, or if they should release the soft tissues, with real-time feedback on gap balance, or modify the component positioning to achieve optimal balance without any soft tissue releases. These options can also be used in combination to achieve desired balance and alignment.

Thus, the surgeon can choose their preferred surgical workflow, including femur first, tibial first, or hybrid workflows which can accommodate multiple alignment philosophies.

After planning is completed, the system positions an oscillating saw for the surgeon to perform resections of the bone with real-time cut-plane tracking to compensate for any leg movement. VRAS maintains the saw cut plane to help execute precise, reproducible surgeon-controlled cuts.[1] Due to the small footprint of the system, a surgical assistant can provide retraction from multiple positions, which aids in access and soft tissue protection. The system does not require any interaction with the screen during resection; therefore, attention is entirely focused on cut execution. After the cuts are completed, trials are inserted, allowing the surgeon to verify the balance and alignment of the knee prior to prosthesis implantation.

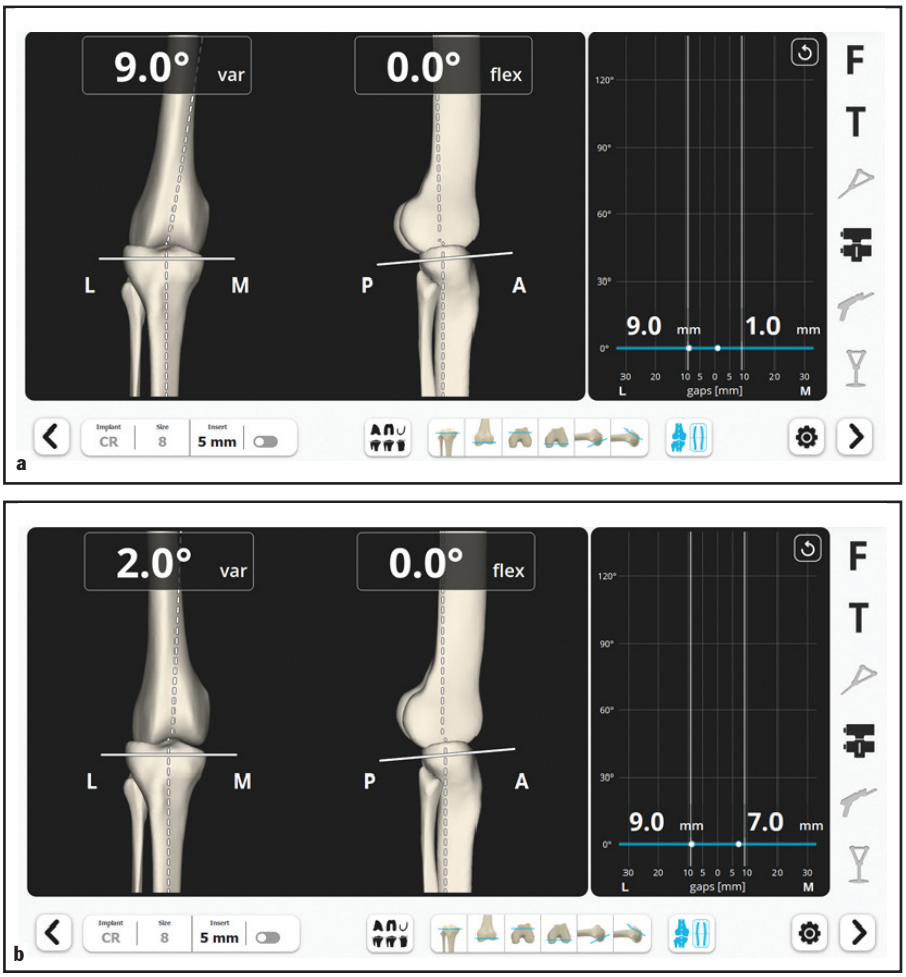

Figure 2. Two alignment screenshots of the knee. a) Arthritic alignment—The knee lies in 9° of varus. b) Corrected alignment—Applying a varus force after osteophyte removal corrects the alignment to 2° of varus and increases the medial extension gap to 7mm.

PATIENT-SPECIFIC TKA SURGICAL TECHNIQUE

This technique utilizes the intraoperative collection of the bony anatomy and soft tissue envelope of the arthritic knee to perform a bounded anatomical restoration of the knee which optimally balances the TKA through a full range of motion. Soft tissue releases are avoided so the TKA is implanted to function within its natural soft tissue envelope. A medial approach is made with only the deep mid-third capsular ligament (MCL) released and osteophytes tenting collateral ligaments removed. This is a critical step as this increases the correctability of the knee reducing the need for soft tissue releases. The arrays are inserted inside the incision on the bare area of the medial femur and in the anteromedial tibia

2cm below the knee joint. The knee landmark acquisition is performed by collecting the bony morphology of the knee and the centre of the hip and ankle. The lower limb alignment (Fig. 2a) and correctability (Fig. 2b) are then determined.

The soft tissue envelope is then evaluated by ranging the knee though a full range of motion in the existing and corrected positions. In the varus knee, a valgus force is applied in extension to determine the correctability of the medial side of the knee while in the valgus knee a varus force is applied in extension to determine the correctability of the lateral side of the knee. The soft tissue envelope in flexion is determined by flexing the knee to 90° and externally rotating the hip to tension the lateral side of the knee and internally rotating the hip to tension the medial side of the knee. VRAS will display the resultant graph that shows the balance consequence of mechanical alignment; whereas, a neutral tibial and femoral mechanical axis cut is planned with the femur externally rotated 3° to account for the average tibia being in 3° of varus (Fig. 3).

A virtual kinematic alignment (KA) placement of the implants is then performed whereby a true anatomic measured resection is planned with adjustments made to virtually restore the articular cartilage of the arthritic knee. The balance consequence of KA placement is then assessed using the planning screen (Fig. 4). The knee is then virtually optimized to be balanced. The balance philosophy is to have the MCL equally tensioned through a full ROM and to have more laxity laterally in flexion to allow lateral rollback of the femur thus replicating native knee kinematics. To achieve this, the medial and lateral extension gaps and the medial flexion gap are balanced while 2mm more laxity is applied to the lateral flexion gap. Small positional changes are made to the implant's placement to achieve this. The sequence is to first balance the extension gap by altering the varus or valgus tibial cut and or distal femoral cut. These cuts are bounded to 5° of varus or valgus for both the femur and tibia and for overall alignment. The second step is to balance the flexion gap by rotating the femoral component. The final step is to equalize the flexion and extension gap by changing the femoral component size, or if the femoral component size is optimal, the

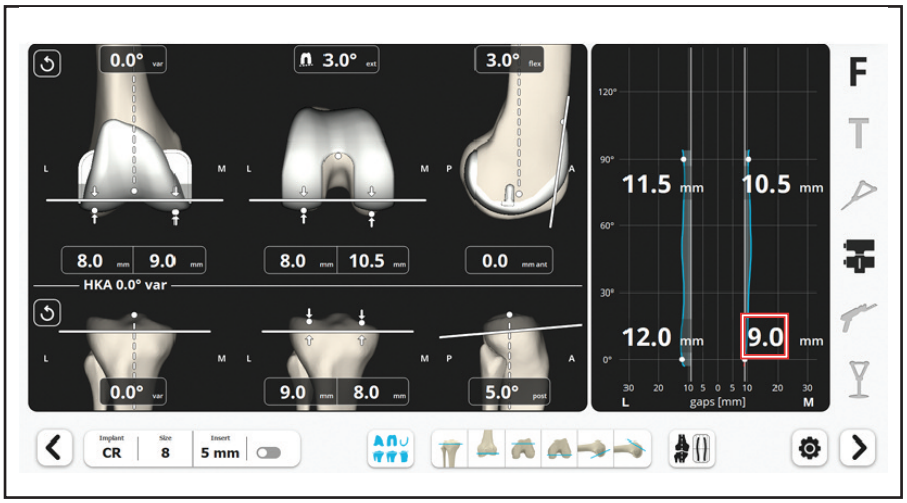

Figure 3. Implant planning and balance graph for mechanical alignment. The balance curve for mechanical alignment shows that the TKA will be too tight medially in extension (measured value 9mm, target value of 12mm).

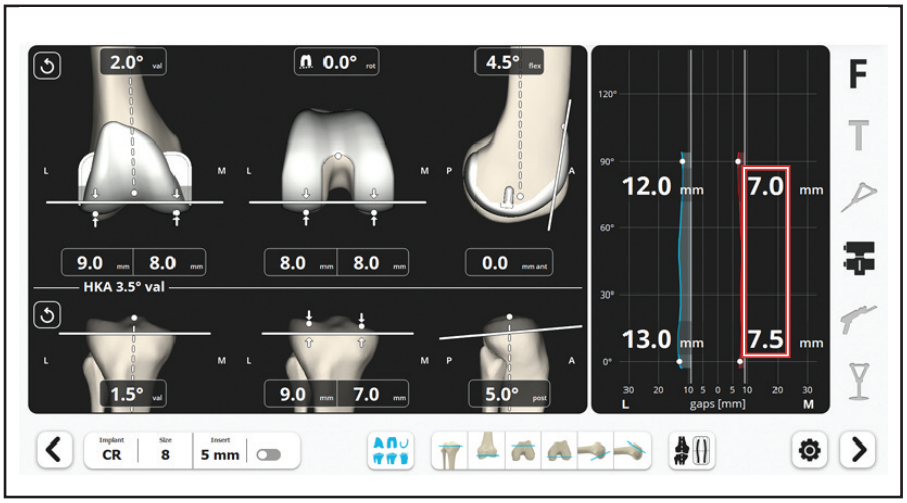

Figure 4. Implant planning screen and balance graph for kinematic alignment. This shows the anatomic placement of the TKA will be too tight medially in flexion and extension.

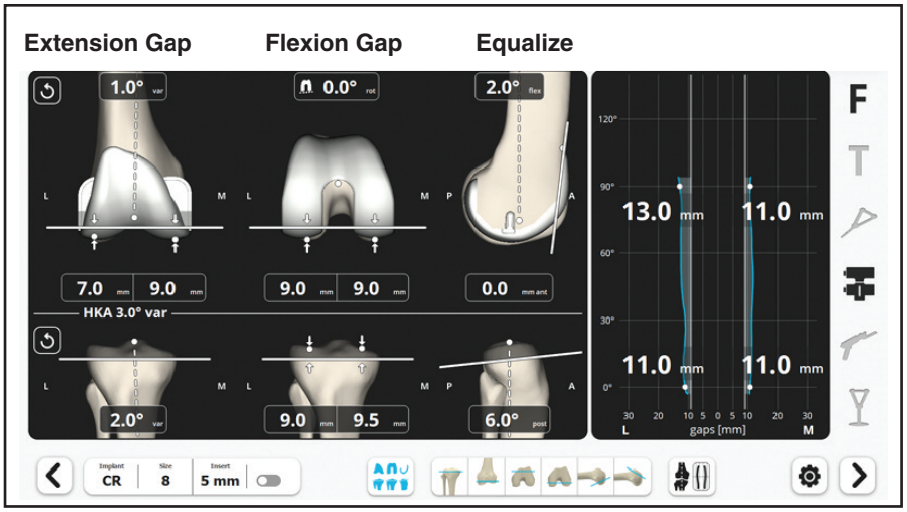

**Figure 5. Implant planning and balance graph for patient-specific TKA pre-tibial cut.
To balance the gaps, the tibia cut is modified to 2° of varus. The femoral cut is modified to 1° of varus and the femoral component is extended to 2° of flexion.**

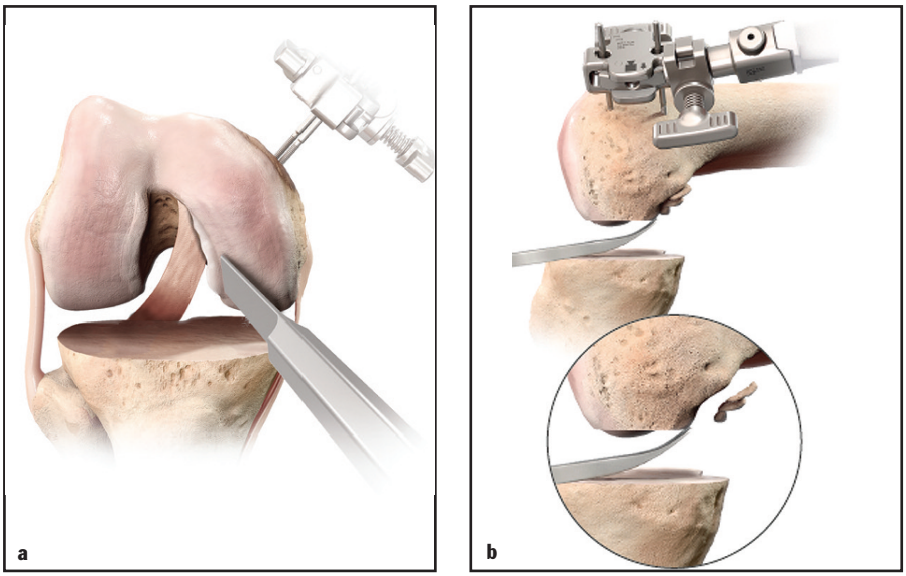

Figure 6. Posterior osteophyte removal post-tibial cut. a) Firstly, remove the osteophyte on lateral aspect of the medial femoral condyle with an osteotome. b) Use a bone hook to distract the femur and a curved osteotome to remove the posterior osteophytes.

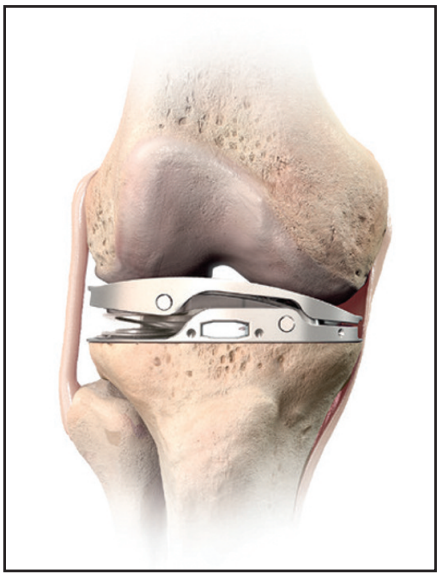

Figure 7. Ligament tensor.

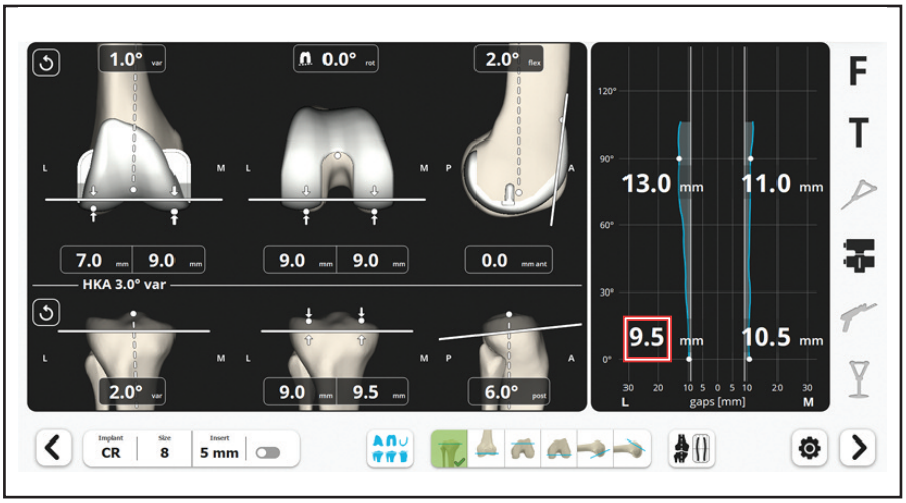

Figure 8. Femoral planning and balance graph post-tibial cut removal of posterior osteophytes and re-evaluating knee's soft tissue envelope. The lateral extension gap is too tight.

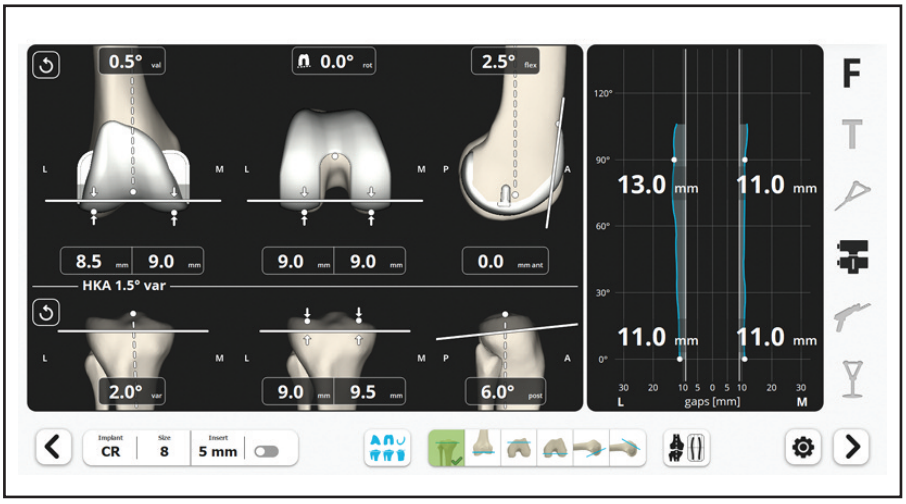

Figure 9. Femoral planning and balance graph after changing the femoral component position to balance the TKA. The femoral component position is modified to 0.5° of valgus to balance the extension gap. The flexion gap is already balanced. The flexion and extension gap is equalized by flexing the femoral component to 2.5° to provide optimal balance

flexion gap can be reduced by flexing the femoral component or the flexion gap can be increased by anteriorizing and extending the femoral component. This combined manoeuvre will prevent anteriorizing the femur and overstuffing of the patellofemoral joint (Fig. 5).

The sagittal tibial slope is cut at 6° which is within the manufacturer's recommendation for a cruciate-retaining (CR) component to enable optimal kinematics for the ATTUNE® implant (Johnson & Johnson Medical Devices, New Brunswick, New Jersey). The tibial cut is performed using the VRAS.

If present, posterior osteophytes are removed using a curved osteotome. This step is crucial, as these osteophytes tent the posterior capsule so they must be removed prior to planning the optimal femoral component position. This is easily achieved with a bone hook placed in the femoral notch to elevate the femur off the tibia to open up the flexion space. There is often a large osteophyte on the lateral aspect of the medial femoral condyle by the posterior cruciate ligament (PCL). Removing this first will aid access to the posterior condyle osteophytes (Fig. 6a and b). A computer-assisted surgery (CAS) ligament tensor (Fig. 7) is then inserted and the knee is ranged through a full range of motion (ROM) in the natural and corrected position. In a varus knee, ranging the knee in the natural position will tension the lateral side of the knee, while ranging the knee in the corrected position will tension the medial side of the knee. The reverse is true for a valgus knee. The

VRAS system produces the post-tibial resection femoral planning screen and balance graph (Fig. 8) from which the surgeon adjusts the femoral component position to enable a balanced knee through a full range of motion (Fig. 9).

Trial implants are inserted to confirm that the knee is well balanced and aligned. The PCL is released if the knee is tight in flexion. An anatomic patella is implanted. The patella component is rotated to match the rotation of the femoral component. This ensures that the anatomic patella is optimally rotated to match the trochlea groove of the femoral component. Thus, the positioning of the anatomic patella component matches the variable rotation of the femoral component (Fig. 10). Finally, the definitive prosthesis is implanted with cement with the knee held in full extension until the cement is hard.

A video of this surgical technique can be viewed on VuMedi.

STUDY METHODS AND RESULTS

Two prospective studies were initiated in November 2020 to evaluate the short-term and longer-term results of this new technology. The results were compared with the patient-specific balanced TKA technique using the Brainlab® KNEE3 Navigation system that the author developed in 2013 and has reported on previously.[2] This was the precursor to this VRAS patient-specific TKA technique. Over 1700 TKA procedures using this patient-specific navigation technique have been performed by the author. All procedures have been performed with the ATTUNE® CR fixed bearing cemented implant.

The first study compared the last 45 patients with osteoarthritis (OA) using navigation to the first 45 patients using VRAS. The surgical technique for these 90 patients was the same with the only difference being the technology used.

The parameters collected were:

1. Pain at discharge, two weeks and six weeks postoperative with a score of 0–10
2. Knee function score at two and six weeks postoperative with a score of 0–10
3. Range of motion preoperatively, at discharge, at two weeks and six weeks postoperative
4. Days to discharge
5. Skin-to-skin operation time

Statistical significance was assessed using a t-test.

VRAS showed significantly lower pain with activity scores at discharge and six weeks. There was no difference in the pain at rest scores or the two-week pain with activity scores (Table I). The VRAS function scores were significantly higher at two weeks and six weeks.

There was no difference in the preoperative, discharge, two-week, and six-week ROM. There was no difference in the surgical skin-to-skin time. The mean VRAS time for the second 10 cases was 10.7 minutes faster than the first 10 cases and was equivalent to navigation TKA time, indicating time neutral surgery with VRAS was quickly achieved. No adverse events or revisions occurred for either group.

The second study is a longer-term outcome study with a prospective collection of the following outcome scores: Oxford, all Knee Injury and Osteoarthritis Outcome Score (KOOS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, Forgotten Joint Score, normal score (subjects score 0–100 with 0 being no knee function and 100 being normal knee function), pain scores, patient satisfaction, and operation again. Data for

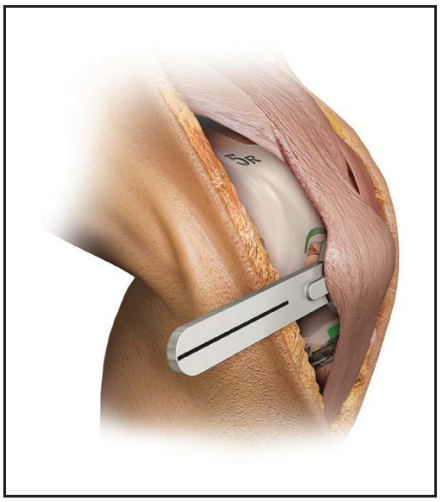

Figure 10. Anatomic patella positioning. The patella trial handle is rotated parallel to the trial femoral component lug holes to ensure the anatomic patella rotation matches the rotation of the femoral component.

Table I
First six-week study: ROM, pain, function, discharge days, and operation time

	VELYS	Navigation	Significance
Number of patients	**45**	**45**	
ROM			
Preop ROM	107°	109°	P=0.31
Discharge ROM	101°	98°	P=0.46
Two-week ROM	114°	114°	P=1
Six-week ROM	123°	122°	P=0.67
VAS Pain Score 0-10			
Discharge pain at rest	0.6	1.1	P=0.12
Discharge pain with activity	3.7	5.4	P=0.001
Two-week pain at rest	1.5	1.6	P=0.5
Two-week pain with activity	2.3	2.6	P=0.07
Six-week pain at rest	0.7	1.2	P = 0.09
Six-week pain with activity	1.5	2.1	P=0.04
Knee Function Score 0-10			
Two-week function	5.9	5.2	P=0.04
Six-week function	7.4	6.8	P=0.03
Discharge days	3.1	3.2	0.06
Operation Time	71.8 mins	70 mins	0.07
First 10 cases	80 mins		
Second 10 cases	69.3 mins		

Table II
One-year PROM and patient-satisfaction study

	VELYS	Navigation
Number of Patients	20 (first cases)	930
Oxford Knee Score	43	42
WOMAC	9	12
Forgotten Knee Score	68	63
KOOS – Joint Replacement	81	81
Normal Rating 0–100	87	79
Pain 0–100	9	14
Patient Satisfaction	100%	90%
Operation Again	100%	91%

this study was collected preoperatively and at one year. Only very early data is available with the first 20 VRAS cases compared with 930 navigation cases. No statistical analysis is possible due to the low number of VRAS cases with one-year follow up. However, VRAS patients did show a better mean Forgotten Joint Score, WOMAC score, pain score, normal score, operation again, and patient satisfaction. The Oxford and KOOS Joint Replacement scores were similar (Table II).

DISCUSSION

The technique described utilises a patient-specific technique which is a continuing area of focus and research in TKA.[3-5] This patient-specific technique with navigation has previously been shown to have improved clinical outcomes compared to a measured resection technique in an analysis of the New Zealand Joint Registry.[6] The equivalent or improvements in the early outcomes when executing the same technique with VRAS identified in this study is therefore encouraging. The reduction in pain and improvement in early function is consistent with findings of studies on other robotic-assisted TKA systems[7-9]; however, it is important to note that the baseline for those studies was manual instrumentation versus navigation, as in this case. The 100% satisfaction trend after one year, in combination with less pain and improved function early in the recovery, is encouraging and will be further monitored with greater sample sizes. This study found a subtle increase in surgical time in the first 10 cases, with time neutrality reached during the subsequent 10 cases—this is similar to the findings on other systems.[10] There were no adverse events or detrimental impact on clinical outcomes associated with adopting the technology on early outcomes despite this not only being the author's first cases but also the first VRAS cases worldwide with a learning curve for both the surgeon and those supporting this new technology.

CONCLUSION

The VELYS™ Robotic-Assisted Solution very accurately collects the bony anatomy and soft tissue envelope of the knee. The patient-specific technique described here enables the surgeon to use this intraoperative collection to plan anatomical placement of the implants with preservation of the soft tissues resulting in functional knee restoration. The robotic-assisted saw delivers precise, accurate and efficient bone cuts enabling neutral surgical time comparable with the author's extensive experience with navigation. Early outcome studies show an improvement in knee function and pain with activity at discharge and six weeks. Only a small number of patients have one-year data. The results on this limited cohort demonstrate favourable outcome scores and high patient satisfaction. STI

AUTHORS' DISCLOSURES

Dr. Clatworthy is a consultant for Johnson & Johnson De Puy Synthes.

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