



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

VectorVision® computer-assisted minimally
invasive stereotactic surgery platform for
orthopaedic and nasal procedures

July 2005
(Updated June 2006)



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

July 2005

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Name of Technology:

VectorVision® computer-assisted minimally invasive stereotactic surgery platform for orthopaedic and nasal procedures.

Purpose and Target Group:

VectorVision® (BrainLAB, Inc.) is a hardware platform developed to launch an array of BrainLAB software designed to facilitate frameless, image-guided stereotactic surgery. The BrainLAB software currently in use includes: VectorVision® uni-knee, computed tomography (CT)-free knee, Fluoro3D, cranial, Ear-Nose-Throat (ENT), hip, trauma, anterior cruciate ligament (ACL), and the frameless biopsy system. By generating a real time three-dimensional image of the patient's anatomy, the VectorVision® software assists in the operative planning and navigation of a wide range of minimally invasive knee, hip, cranial, spinal, joint and ENT surgery. VectorVision® is approved by the U.S. Food and Drug Administration (FDA) for any patient requiring stereotactic surgery, where a rigid anatomical bone structure reference can be identified through fluoroscopy, CT or magnetic resonance imaging (MRI) (<http://www.fda.gov/cdrh/pdf/k003589.pdf>). While computer-assisted neuronavigation has been widely employed for more than a decade, the use of VectorVision® for orthopaedic and nasal surgery is a relatively recent indication.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

The VectorVision® system is listed in the Australian Register of Therapeutic Goods (ARTG) (ARTG number: 71087).

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
Germany		✓	
U.S.A.		✓	
U.K.		✓	

Impact Summary:

Background

VectorVision® is a 'line of sight' infrared beam directed system which generates real time three-dimensional images of patient anatomy and instrument tracking. Three-dimensional imaging can be mapped either through preoperative CT and fluoroscopic images (CT-based), or through the intraoperative registration of anatomical landmarks (CT-free) (Bäthis *et al.* 2004). The system utilises a free-hand probe linked to wireless passive marker spheres attached to the patient and a variety of surgical instruments, which can be employed as pointers during surgery (Gumprecht *et al.* 1999). Real time intraoperative data is transmitted by these markers, and subsequently converted into a digital image output by the VectorVision® platform (Muacevic *et al.* 2000).

In the past, mechanical frames and two-dimensional X-ray, CT and MRI images have traditionally been used as navigational aids for orthopaedic surgery and neurosurgery. Image-guided technologies such as VectorVision® aim to increase the accuracy, safety, reliability and reproducibility of surgical techniques by enabling surgeons to continuously track and anticipate the location and orientation of instruments and anatomical features as they work (Stulberg *et al.* 2002).

Computer-assisted neurosurgery has existed in Australia for the last 12 years and has become a standard practice for most neurosurgical procedures (BrainLAB Australia Pty Ltd., *Personal communication*, February 24, 2005). However, the application of computer-assisted stereotactic surgery to orthopaedic and nasal procedures is still a fairly novel concept (BrainLAB Australia Pty Ltd., *Personal communication*, February 24, 2005). The earliest reports of computer-navigated surgery outside the neurosurgical field began to appear in the literature in 1998, following the first cases of computer-assisted knee surgery (Bäthis *et al.* 2003).

Clinical Need and Burden of Disease

Computer-navigated surgery has been routinely useful in the neurosurgical field, enabling improved surgical outcomes and limiting damage to healthy tissue. There exists a similar need for precision and improved outcomes in orthopaedic surgery. Knee and hip replacements are particularly popular surgical procedures in Australia, with 50 000 implants performed in 2001-02 alone

(<http://www.theage.com.au/articles/2002/12/11/1039379869617.html>). Given Australia's ageing population and the high burden of disability from skeletal disorders such as arthritis, it is likely that this figure will rise into the future. Considering that errors in alignment of $>3^\circ$ impair the lifespan and performance of knee implants, the precision and reduced incision size achieved with computer-assisted surgery offers potential clinical and economic benefits (Stulberg *et al.* 2002).

Disability from back pain also presents a high burden of disease, currently affecting 5.4% of the Australian population, or about 1 million people (Australian Institute of Health and Welfare 2003). Minimally invasive computer-assisted surgery for the repair of spinal injury and back pain

reduces the risk of tissue injury and improves recovery when compared to open spinal surgery (Cleary *et al.* 2002). These advantages are also relevant to ears, nose and throat surgery, which requires a high degree of precision and small incision size.

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

Developed by the German company BrainLAB, the VectorVision® system was first employed by the University of Vienna in 1990. The system was subsequently approved in 1997 by the FDA for commercial use in the U.S. (www.brainlab.com/). By 2002, BrainLAB had installed 750 navigation systems worldwide (Versweyveld 2003). VectorVision® is currently marketed in Australia by BrainLAB Australia Pty Ltd. It is listed by the Therapeutic Goods Administration (TGA) under the Australian Register of Therapeutic Goods number (ATGN) 71087, product number 136141.

Computerised navigation systems similar to VectorVision® have also been widely used in neuronavigation over the last decade, and a number of studies into the efficacy of computer-assisted orthopaedic surgery have employed these other systems. Currently, platforms such as Orthopilot®, SurgiGate® and Regulus® are being used in orthopaedic and nasal surgery in a similar capacity to VectorVision®.

Existing Comparators

- Conventional frame-based stereotactic orthopaedic surgery
- Preoperative planning with conventional CT/X-ray/MRI imaging

Estimated Cost Impact

Costs associated with this product for orthopaedic surgery in Australia are not currently listed under the Medicare Benefits Schedule (MBS). However, stereotactic neuronavigation is presently subsidised under the MBS. The reimbursement fee for stereotactic anatomical localisation on the head is \$541.95 (MBS item number 40800), while the reimbursement fee for computer-assisted functional stereotactic procedures is \$1 481.25 (MBS item number 40801). According to the Health Insurance Commission, a total of 26 claims were processed between July 2003 and June 2004 for computer-assisted functional stereotactic procedures.

Given that many Australian hospitals are currently equipped with VectorVision® or a similar system for neurosurgical procedures, the major cost factor will be the price of purchasing image-guided software pertinent to orthopaedic surgery. The commercial retail cost of VectorVision hardware and software in Australia has decreased over time. In 2002, a single VectorVision® system trialled at the Brisbane QEII Jubilee Hospital for knee arthroplasty was priced at \$500 000 (<http://www.theage.com.au/articles/2002/12/11/1039379869617.html>). Today, VectorVision compact hardware retails in Australia for approximately \$120 000, and VectorVision software has a commercial value of about \$60 000 (Dr. David Morgan, *personal communication*, 15 May 2005). It is probable that initial purchase costs will be offset in the long-

term by savings from reduced hospital stay, improved surgical outcomes, and prolonged joint implant lifespan.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	8*
Non-randomised comparative studies	4
Case series studies	3
Case reports	1

*Note: BrainLAB is currently undertaking a trial using the compact VectorVision system for Birmingham Hip Resurfacing surgery with a surgeon in Lippstadt, Germany (Dr. David Morgan, *personal communication*, 15 May 2005).

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from two non-randomised comparative studies and two case series studies have been selected for inclusion in this summary.

There is some evidence for the efficacy of computer-assisted minimally invasive orthopaedic and nasal surgery using VectorVision®. However, no studies specifically comparing the efficacy of the VectorVision® system to frame-based or traditional surgical techniques were identified in the literature.

No statistical difference was found between CT-free models and the older CT-based model in guiding total knee arthroplasty (TKA). In a non-randomised comparative study (n=100), B athis *et al.* (2003) recorded a slight, though insignificant improvement in the accuracy of CT-free over CT-based models, with 92% (46/50) of surgical cases in the CT-based group reaching the optimum leg axis (between 3° valgus* and 3° varus†), compared to 96% (48/50) of cases in the CT-free group. In another comparative study (possible patient overlap), B athis *et al.* (2004) again reported no statistical difference in leg axis deviation between these two groups. Sixty out of 65 (92%) TKAs in the CT-based group were within optimum leg axis range, compared to 63/65 (97%) in the CT-free group. However, sagittal alignment was notably lower in the CT-based group (5.0±2.4°) than the CT-free group (7.1±3.5°) (B athis *et al.* 2004). The authors (B athis *et al.* 2004) attributed these differences to the intra-operative determination of ligament balancing and leg axis offered by the CT-free model, which is not available with the CT-based model.

Two case series studies demonstrated the high efficacy of VectorVision® in endonasal surgery and in pedicle screw placement in the cervical and cervico-thoracic spine. Khan *et al.* (2003) reported favourable system accuracy for VectorVision® in 60 patients undergoing endonasal surgery, achieving a mean of within 1.9 mm of all landmarks. Special landmarks could be approached in 83.3% of all cases with the VectorVision® system. Richter *et al.* (2004) reported that 31/31 (100%) cervical pedicle screws, 10/10 (100%) high thoracic pedicle screws and 20/22 (91%) transarticular screws were successfully implanted with VectorVision® guidance.

* 'Valgus' meaning "turned outward; especially of a deformity in which part of a limb is twisted away from the centre of the body." (Hyperdictionary 2005. <http://www.hyperdictionary.com/>).

† 'Varus' meaning "turned inward; especially of a deformity in which part of a limb is twisted toward the centre of the body." (Hyperdictionary 2005. <http://www.hyperdictionary.com/>).

Few serious errors or complications were reported in VectorVision® case series studies. Khan *et al* (2003) recorded system-dependent complications arising from view loss. This was remedied in 54/60 (90%) cases by correcting the pointer and/or position of the camera (Khan *et al.* 2003). A special pointer was also developed in this study to improve navigation when working tangentially (Khan *et al.* 2003). Richter *et al.* (2004) noted that an image intensifier was needed for the placement of transarticular screws in C1/2, due to a failure of VectorVision® in registering these vertebrae. The authors recommended that surgeons should manually verify that the correct vertebrae are instrumented, rather than relying solely on the feedback of computer-assisted technology in spinal procedures (Richter *et al.* 2004).

Mean operation time was slightly less for CT-free groups in both of these comparative studies. Balthis *et al.* 2003 reported a mean operation time of 81 [standard deviation of 16] minutes for the CT-based group, compared to 78[12] minutes for the CT-free group. In their subsequent paper, Balthis *et al.* 2004 reported a mean operation time of 81[15] minutes for the CT-based group, and 76[13] minutes for the CT-free group.

Evidence on the safety of VectorVision® was particularly sparse. Richter *et al* (2004) was the only study to report a possible safety issue, with a single case of cervical pedicle screw perforation (1.6 mm) (Richter *et al* 2004). A deep wound infection was also observed in 1/22 (5%) patient who had rheumatoid instability in C0/C2 (Richter *et al* 2004). No intraoperative complications or vascular injury resulted, and no postoperative neurological deterioration was observed. It is unclear whether the use of VectorVision® played a role in these complications (Richter *et al.* 2004). The lack of safety data may be an indication of a good safety profile, or it may show that the safety of VectorVision® for orthopaedic and nasal surgery has not been widely investigated.

2006 update

Safety and efficacy

A search of relevant databases, online journals and the Internet was conducted in May 2006, following the recommendation in July 2005 that VectorVision be monitored for assessment in 12 months time. One new source of evidence on the safety and efficacy of VectorVision was identified.

Total number of studies	1
Case series	1

A prospective clinical study evaluating the accuracy and safety of conventional technique and computer assisted surgery (VectorVision) in pedicle screw placement (cervical spine, C3-C6) revealed that overall accuracy was better in the VectorVision group (Richter *et al.* 2005) (see table below):

	Group 1	Group 2	Group 3
Conventional	85/93 (91.4%)	8/93 (8.6%)	0/93 (0%)
VectorVision	162/167 (97%)	5/167 (3%)	0/167 (0%)

** Group 1 – Correct screw placement without pedicle perforation or with pedicle perforation < 1mm; Group 2 – Pedicle perforation > 1mm without the need for screw revision; Group 3 – Pedicle perforation > 1mm with the need for screw revision because of irritation or injury of roots or the spinal cord, or because of reduced biomechanical stability.

Both treatment groups did not experience any complications related to pedicle perforation and there was no necessity for screw revision. Richter *et al.* (2005) concluded that conventional insertion of transpedicular cannulated screws in the cervical spine and cervicothoracic junction is safe and accurate. However, the use of VectorVision can offer significantly better accuracy and safety. Despite this advantage, surgeons are warned to be wary of the limitations of computer assisted surgery whereby software or hardware failure can occur during the surgical procedure. In addition, the authors highlighted the need for surgeons to manually identify the correct vertebra for instrumentation due to the fact that vertebrae can have very small spinous processes and similar posterior surfaces, factors that can effect computer assisted identification of vertebrae (Richter *et al.* 2005).

2006 Recommendation

The use of VectorVision in orthopaedic and nasal surgery has not garnered significant interest in the past year. Based on the information available, it is recommended that the following is conducted.

Horizon Scanning Report Full Health Technology Assessment
 Monitor Archive

Reference

Richter M, Cakir B, Schmidt R. Cervical pedicle screws: Conventional versus computer-assisted placement of cannulated screws. *Spine* 2005;30(20): 2280-2287.

Ethical Issues

No issues were identified from the retrieved material.

Cultural or Religious Considerations

No issues were identified from the retrieved material.

Other Issues

No issues were identified from the retrieved material.

HealthPACT recommendation:

Long-term safety and efficacy data specific to VectorVision® from randomised controlled trials may be required before this device can be widely accepted for use in orthopaedic or ENT surgery. Due to the limited high level evidence available on this particular device, it is recommended that the following be conducted:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

References:

Australian Institute of Health and Welfare. Disability Prevalence and Trends. AIHW cat. no. DIS 34. 2003.

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Bäthis H, Perlick L, Tingart M, Luring C, Perlick C, Grifka J. Radiological results of image-based and non-image-based computer-assisted total knee arthroplasty. *International Orthopaedics* 2004;28:87-90.

Cleary K, Clifford M, Stoianovici D, Freedman M, Mun S, Watson V. Technology improvements for image-guided and minimally invasive spinal procedures. *IEEE Transactions on Information Technology in Biomedicine* 2002;6:249-61.

Gumprecht H, Widenka D, Lumenta C. BrainLab VectorVision neuronavigation system: technology and clinical experiences in 131 cases [instrumentation and application]. *Neurosurgery* 1999;44:97-104.

Khan M, Ecke U, Mann WJ. The application of an optical navigation system in endonasal sinus surgery. *HNO* 2003;51:209-15.

Muacevic A, Uhl E, Steiger H, Reulen H. Accuracy and clinical applicability of a passive marker based frameless neuronavigation system. *Journal of Clinical Neuroscience* 1999;7:414-8.

Pan H-C, Wang Y-C, Lee S-D, Chang N-F, Yang D-Y. A modified method to perform the frameless biopsy. *Journal of Clinical Neuroscience* 2002;10:602-5.

Porter ML, Gambhir AK, Pradhan N. Image-guided surgery for total knee replacement [letters to the editor]. *The Journal of Bone and Joint Surgery* 2004;86A:1096.

Richter M, Mattes T, Cakir B. Computer-assisted posterior instrumentation of the cervical and cervico-thoracic spine. *European Spine Journal* 2004; 13: 50-59.

Stulberg SD. S.D. Stulberg replies [letters to the editor]. *The Journal of Bone and Joint Surgery* 2004;86-A:1096-7.

Stulberg SD, Loan P, Sarin V. Computer-assisted navigation in total knee replacement: results of an initial experience in thirty-five patients. *The Journal of Bone and Joint Surgery* 2002;84-A:90-8.

Versweyveld, L. BrainLAB offers higher accuracy for total knee replacements using CT-free image-guided surgery. *Virtual Medical Worlds Monthly*. Last updated 25-11-2003.

<http://www.hoise.com/vmw/03/articles/vmw/LV-VM-12-03-21.html> [Accessed February 2005].

Sources of Further Information:

Porter ML, Gambhir AK, Pradhan N. Image-guided surgery for total knee replacement [letters to the editor]. *The Journal of Bone and Joint Surgery* 2004; 86-A: 1096.



Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in February 2005.

Search terms used were: 'vectorvision'; 'vector vision'; 'navigated surgery'; 'image guided trauma software'; 'brainlab'; 'computer-assisted surgery'; 'frameless stereotactic surgery'.

This Horizon Scanning Prioritising Summary was prepared by Miss Pauline McLoughlin from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).