



Scanning the Horizon

Informing Decision Makers About Emerging Medical Technologies

Interest in positron emission tomography (PET) remains high across Canada. In this issue of the *Health Technology Update*, we present an article about a new diagnostic tool that combines the molecular imaging of PET with mammography. PET mammography, or “positron emission mammography,” can detect lesions in the breast that are two to three times smaller than lesions that can be detected with whole-body PET. (Stay tuned for our January 2008 issue, which will bring you an update on PET scanners in Canada and on developments in the licensing of the radiopharmaceuticals used in the scans.)

New and emerging technologies for the treatment of knee osteoarthritis, gastroesophageal reflux disease, hypertension, refractory angina pain, and newborn brain injury are also featured in this issue. We hope you will find the articles informative and useful.

In this Issue

- ② **PET mammography:** Also called “positron emission mammography,” this nuclear medicine technology is an adjunct to conventional breast cancer imaging.
- ③ **OrthoGlide™:** A new metallic knee implant offers a less invasive alternative to total knee replacement for younger patients.



Aerial view of Vancouver, British Columbia.

Photo courtesy of Tourism Vancouver.

- ④ **Plicator™:** This device tightens the valve at the junction of the stomach and esophagus to act as a natural barrier in gastroesophageal reflux disease.
- ⑤ **RESPeRATE®:** A new biofeedback approach guides users through controlled breathing exercises to lower blood pressure.
- ⑥ **Implantable spinal cord stimulators for angina:** Electrical stimulation of nerve fibres in the spinal cord may reduce chest pain in individuals with severe, intractable angina.
- ⑦ **Cool-Cap®:** A new head-cooling device induces mild hypothermia in newborns at risk of brain damage due to oxygen deprivation during birth.
- ⑧ **New and emerging health technology reports:** Links to recent publications from CADTH and other health technology assessment agencies.

Your feedback on the newsletter is always welcome, as are suggestions for new technologies to review in future issues. Please send comments to: Catherine Allison, Editor.

E-mail: catherinea@cadth.ca

Positron Emission Tomography (PET) Mammography: A New Diagnostic Tool

Positron emission tomography (PET) mammography incorporates PET technology into a mammography unit that can detect lesions as small as 2 mm; this is two to three times smaller than lesions that can be detected by whole-body PET.¹

How It Works

PET is a nuclear medicine technology best known for its role in cancer imaging. A small amount of a radioactive sugar molecule, 18 fluoro-2-deoxyglucose (FDG), is injected into the bloodstream and a scanner is used to detect and generate images that indicate areas of high-FDG uptake. Many cancers require more energy than normal cells and the FDG tracer preferentially accumulates in these cells. This allows cancers to be seen as “hot spots” on the PET scan. PET also guides therapy by assessing treatment response.

How It Fits Into Current Practice

PET mammography is also called positron emission mammography or PEM. Like whole-body PET imaging, it is an adjunct to conventional breast cancer imaging for disease staging or restaging, surgical planning, and for treatment evaluation. It is not intended for breast cancer screening or for assessing lymph node status. PET mammography is proposed for women who have breast lesions that are difficult to characterize, especially women with dense breast tissue and those at

high risk for multi-focal or aggressive disease.¹

Regulatory Status

The PEM Flex™ Solo II unit (Naviscan PET Systems, Inc.) received US Food and Drug Administration clearance in 2003 for general-purpose imaging. Unlike whole-body PET units, dedicated PET mammography units are not yet licensed in Canada. Toronto-based IMAGIN Diagnostic Centres, Inc. holds the Canadian distribution rights for PEM Flex.

Evidence

Currently, there is limited published evidence available. However, dedicated PET mammography is more sensitive than whole-body FDG PET imaging for detecting small lesions.¹ One prospective, non-randomized clinical trial with 77 patients reported that PET mammography had an overall accuracy of 88% to 92% compared with 71% for conventional imaging ($p < 0.001$).² This was largely due to PET mammography performing better for very early-stage breast cancer that had not spread beyond the site of origin.

Cost

The cost of the PEM Flex Solo II unit was unavailable. The cost for each PET mammography scan will likely be similar to the cost of a whole-body PET scan since the infrastructure and radio-pharmaceutical costs will be similar.

In Canada, the total cost for each whole-body FDG PET scan ranges from \$1,231 to \$7,869, depending on patient volumes, the cost of the FDG radiopharmaceutical dose, physician fees, capital infrastructure costs, operational costs, and the regulatory costs of a clinical trial application for FDG products that have not received a notice of compliance from Health Canada.³ For out-of-province residents, Alberta and Manitoba charge approximately \$1,250 and BC charges \$1,500 per FDG PET scan. Private Canadian PET facilities charge patients approximately twice this amount. Physician professional fees range from \$200 to \$300 per case.

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The Naviscan PEM Flex™ Solo II images the breast at the molecular level.

Photo courtesy of Naviscan.

OrthoGlide™ May Offer a Smooth Ride for Knees

OrthoGlide is a new implant that replaces worn cartilage inside the knee, offering patients younger than 55 years a less invasive alternative to total knee replacement.

The knee joint has three compartments: medial (inside), lateral (outside), and patellofemoral (front, or knee cap). Knee osteoarthritis due to cartilage breakdown often starts in the medial compartment.¹ Patients slowly become bow-legged, which increases pressure and causes pain on the inside of the knee.²

How It Works

OrthoGlide is a metallic, wedge-shaped device that is inserted into the knee's medial compartment to relieve pressure, restore proper joint alignment, redistribute the load more evenly to the outside of the knee, and increase stability by tightening loose ligaments. The mobile (uncemented) device rests on top of the tibia, and is held in place by gravity and a small lip at the back designed to prevent it from slipping forward and out of position.²

Patients receive general anesthesia or a spinal block and the OrthoGlide device is inserted through a 5-cm to 7-cm incision during a 45- to 60-minute operation. Patients can often go home the same day, with minimal post-operative restrictions.³

The device may allow total knee replacement to be delayed until patients are older and less likely to require a second knee replacement.³

Who Might Benefit

About 3,000 Canadians under the age of 54 underwent total knee replacement in 2004–2005.⁴ OrthoGlide is indicated for patients under 55 years of age with moderate knee osteoarthritis involving only the medial compartment, pain primarily on the inside of the knee, minimal or no degeneration in the lateral or patellofemoral compartments, intact ligaments, and bow-leggedness on x-ray.³ Fewer than 1% of patients with knee osteoarthritis are appropriate candidates for OrthoGlide⁵ and all conservative treatment options should be tried first, including medication, injections, and exercise.³ OrthoGlide may be an alternative for obese patients, who are often poor candidates for other knee surgeries.

Regulatory Approval

OrthoGlide™ (Advanced Bio-Surfaces, Inc.) was licensed by Health Canada and by the US Food and Drug Administration in 2006.

Evidence

There are no published trials of OrthoGlide. The evidence to support its use is based on studies of similar devices, such as the UniSpacer® (Zimmer, Inc.). Two brief reviews of the literature on the UniSpacer device concluded there was insufficient evidence to establish long-term safety and efficacy.^{6,7}

Cost

The Canadian cost for the OrthoGlide device is unavailable, but the US price is US\$4,500. According to the manufacturer, 220 patients have received OrthoGlide implants, although the implant has not been used in any Canadian patients to date.



OrthoGlide™ Medial Knee Implant.

Image courtesy of Advanced Bio-Surfaces, Inc.

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The Plicator™: A Non-Surgical Treatment for Gastroesophageal Reflux Disease

The Plicator procedure is an endoscopic treatment for gastroesophageal reflux disease (GERD) – a chronic condition that occurs when the lower esophageal sphincter relaxes, allowing the contents of the stomach to flow back into the esophagus.

How It Works

The Plicator device is inserted through the mouth and down the esophagus with the help of an endoscope. The device grasps, folds, and fixates tissue with a pre-tied suture at the junction of the stomach and esophagus. This tightens the valve that acts as a natural barrier to gastric reflux.¹ Patients receive intravenous conscious sedation during the 20- to 30-minute procedure and return home the same day.

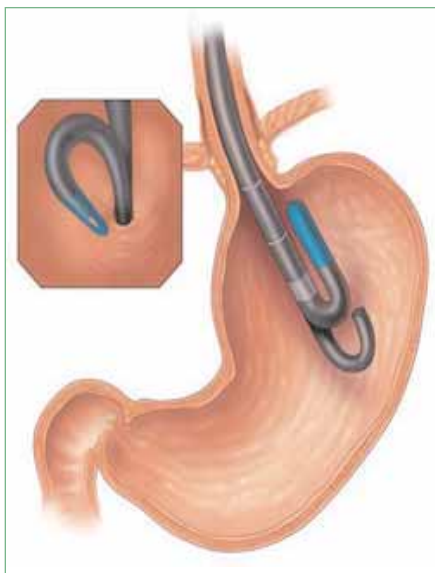


Photo courtesy of NDO Surgical Inc.

The Plicator is positioned at the junction of the stomach and esophagus.

Who Might Benefit

About 13% of Canadian adults experience moderate to severe GERD symptoms at least weekly.² Common GERD symptoms include heartburn and regurgitation. The Plicator is intended for individuals with chronic GERD who would otherwise be treated with drugs, particularly proton pump inhibitors (PPIs), or by surgical fundoplication. While PPI therapy is largely effective, some patients experience intolerable side effects or persistent regurgitation.³

Regulatory Approval

The Plicator™ (NDO Surgical Inc., Mansfield, MA) received US Food and Drug Administration clearance in April 2003. It is not yet licensed in Canada.

Evidence of Effectiveness

A randomized controlled trial of 159 patients compared the Plicator against a “sham” treatment. In the Plicator group, health-related quality of life was significantly greater at three-months follow-up and more patients were able to cease PPI therapy (50% versus 24%, $p < 0.001$) compared with those in the sham group. Esophageal acid exposure also improved compared with the sham group.³

In an open label trial, 36 of 53 patients (68%) who had been using PPIs daily had stopped taking this medication 12 months after the Plicator procedure.⁴ At 36-months follow-up, 14 of 28 patients (50%) had discontinued PPIs.⁵ Health-related quality of life scores remained significantly improved ($p < 0.001$) compared with baseline values.⁵

No randomized trials have compared the Plicator treatment with PPIs, surgery, or other endoscopic anti-reflux devices.⁶ Evidence that it is better than, or at least as good as, medical therapy is still needed.⁶

Safety

The most commonly reported adverse effects with the Plicator procedure include sore throat, radiating shoulder pain, and abdominal pain, which resolve without intervention.^{3,4} Long-term adverse events were not observed in the open-label trial.^{4,5} In the randomized trial, four of 78 persons (5%) in the treatment arm required hospitalization after the procedure, and another person had the plication suture removed and a fundoplication performed three months after the Plicator procedure.³

Cost

According to the manufacturer, the capital cost of the Plicator instrument is US\$15,000. A single-use tissue retractor and implant cartridge cost US\$1,800 per patient.

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RESPeRATE®: Lowering Blood Pressure By Synchronizing Breathing With Melody

RESPeRATE is a portable biofeedback device that guides users through specialized breathing exercises designed to slow breathing, which, in turn, lowers blood pressure.

How It Works

The battery-operated device resembles a personal CD player and consists of a breathing sensor, a computerized panel, and headphones. The belt-like sensor wraps around the chest to analyze breathing patterns, which are then converted into a personalized two-tone melody: one tone for inhaling and another for exhaling. As breathing synchronizes with the tones, the device gradually prolongs the exhalation tone and guides the user to a slower respiratory rate with prolonged exhalation. The goal is to reach a “therapeutic zone” of 10 breaths per minute.

Focused slow breathing, with an emphasis on prolonged exhalation, is believed to calm the autonomic nervous system, allowing small blood vessels to dilate so that blood flows more freely.¹ Fifteen-minute sessions of “therapeutic zone” breathing are recommended three or four times weekly.¹

Hypertension in Canada

Approximately one-fifth of Canadians have hypertension.² Elevated blood pressure increases the risk of developing heart disease, heart failure, stroke, and kidney disease.^{1,3}

Regulatory Status

RESPeRATE (InterCure Ltd.) was licensed by Health Canada in March 2004. It is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological or non-pharmacological interventions.

Evidence

The California Technology Assessment Forum reviewed the evidence on RESPeRATE reported in seven published studies involving 357 individuals.⁴ All studies, including two randomized controlled trials (RCTs), showed moderate reductions in systolic and diastolic blood pressure. In one RCT with 65 patients, systolic blood pressure was reduced by an average of 15.2 mm Hg and diastolic blood pressure by 10.0 mm Hg in those using RESPeRATE for 10 minutes per day for eight weeks.⁵ This compared to reductions of 11.3 mm Hg ($p=0.14$) and 5.6 mm Hg ($p=0.008$) in those listening to quiet music on a Walkman. Another RCT with 149 patients found that for those who used RESPeRATE for more than 180 minutes over eight weeks, systolic blood pressure decreased by a mean of 15 mm Hg ($p<0.001$) versus a 7.3 mm Hg reduction ($p=0.005$) for those using the device for less than 180 minutes.³ There was a 9.2 mm Hg reduction ($p=0.012$) in



Photo courtesy of InterCure Ltd.

The portable computerized electronic device guides users through therapeutic breathing sessions.

the control patients who simply measured their blood pressure. The California assessment concluded that daily use of RESPeRATE met their technology assessment criteria for safety, effectiveness, and improvement in health outcomes for otherwise healthy, non-pregnant individuals.⁴

Cost

According to the Canadian distributor’s web site, the RESPeRATE device costs approximately \$300.

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Implantable Spinal Cord Stimulators for Refractory Angina Pain

During spinal cord stimulation (SCS), also called dorsal column stimulation or neurostimulation, electrical impulses stimulate nerve fibres in the spinal cord, thereby inhibiting pain signals to the brain.

SCS was first used for angina in 1987. The launch of a recent US trial may indicate a renewed interest in the use of this technology for the treatment of intractable angina pain.

How It Works

A small generator, similar to a heart pacemaker, is surgically implanted, usually in the abdomen. Percutaneous leads connect to electrodes implanted in the epidural space of the spine. The implant is intended to be permanent, but it can be removed, if necessary. The physician programs the levels of stimulation and the patient uses a hand-held controller to activate the generator and adjust the intensity, as needed. The rechargeable batteries require replacement about every nine years.

Who Might Benefit

For angina treatment, SCS is an option for individuals with severe refractory disease that cannot be managed with anti-anginal drugs or revascularization procedures such as angioplasty or coronary artery bypass surgery. An estimated 483,000 Canadians have angina.¹ Based on US estimates, 10,000 Canadians may have refractory angina.²

Regulatory Status

Several implantable spinal cord stimulation systems are licensed by Health Canada for the broader indication of chronic pain. These include the Itriel 3[®] System, Synergy™ system, and RestoreADVANCED™ (all from Medtronic Inc.); the Genesis™ Neurostimulation System (Advanced Neuromodulation Systems/St. Jude Medical); and the Precision™ SCS System (Advanced Bionics/Boston Scientific).

Evidence

In 2004, an industry-sponsored review of the evidence from 830 patients in 11 controlled and uncontrolled studies concluded that there is some evidence that SCS has positive, symptomatic, long-term effects on refractory angina pain. The review also concluded that larger, longer-term controlled studies are still needed.³

The UK National Institute for Health and Clinical Excellence (NICE) is currently assessing spinal cord stimulation for chronic neuropathic or ischemic pain, with publication expected in November 2008.



The spinal cord stimulator consists of an epidural lead, an extension wire, and a pulse generator.

A clinical trial of the Genesis™ Neurostimulation System began recently in the US.⁴ Medtronic suspended the STARTSTIM trial of SCS in 2006; these study results have not yet been published.

Adverse Events

Infection and lead displacement or breakage are common complications of SCS.³ Additional surgery may be required to reposition the leads or remove the stimulator. Several studies report that for many patients, pain relief from SCS appears to reach a plateau over time.^{5,6}

Cost

In Canada, SCS devices range in price from \$10,000 to \$26,000.

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Keeping a Cool Head May Prevent Brain Injuries in Newborns

A new head-cooling device aims to prevent or reduce the severity of hypoxic-ischemic encephalopathy (HIE) – a potentially fatal brain injury in the newborn caused by inadequate blood flow or by oxygen deprivation during labour or delivery.

How It Works

The Olympic Cool-Cap® device uses selective head cooling to lower the body temperature by three degrees Celsius and induce a state of mild hypothermia. Cold water circulates through a fitted cap, while the newborn is kept under a radiant warmer to maintain a rectal temperature of 34°C to 35°C.¹

Cooling is thought to help prevent the neurological damage that continues to occur over a period of hours or days following oxygen deprivation. Brain cooling must be initiated within six hours of the initial injury and maintained for 72 hours.

Who Might Benefit

An estimated one to two babies per 1,000 term live births are at risk of HIE.¹ About 25% to 30% of babies who survive HIE will be left with lifelong disabilities, such as cerebral palsy, seizure disorder, and cognitive disability.² No other current

therapies exist to improve the outcome from HIE, beyond supportive care and anticonvulsants for seizure control.³

Regulatory Status

The Olympic Cool-Cap is manufactured by Olympic Medical Corporation, a subsidiary of Natus Medical Incorporated, in San Carlos, California. Cool-Cap was licensed by Health Canada in October 2006. It received US Food and Drug Administration pre-market approval in December 2006 for use in full-term infants with clinical evidence of moderate to severe HIE.

Evidence

An industry-sponsored, randomized controlled study of 234 full-term infants with moderate to severe HIE and an abnormal amplitude-integrated electroencephalogram (aEEG) compared the effects of head cooling for 72 hours against a non-cooled group who received supportive care.¹ Of 108 infants treated with Cool-Cap, 59 died or suffered severe disability by the time they were 18 months old, compared with 73 of 110 infants in the control group. This corresponded to an 11% absolute rate reduction in death or major disability, which was not statistically significant ($p=0.10$). However, in a predefined subgroup analysis, when 46 infants with the most severe aEEG changes were removed from the analysis, head cooling resulted in a statistically significant, 18% absolute rate reduction of death or disability in 172 infants with less severe aEEG abnormalities ($p=0.009$).

Longer-term outcomes, such as cognitive function at school age, are currently



Photo courtesy of Natus Medical Incorporated.

Olympic Cool-Cap® System.

unknown. Several studies investigating the use of whole body cooling for the treatment of HIE are now underway.^{4,5}

Adverse Events

With Cool-Cap treatment, temporary scalp swelling, slowed heart rate, and a modest rise in plasma glucose occurred, but these were not clinically significant.¹

Cost

Neither the capital cost for the Cool-Cap device, nor the cost for single-use caps and temperature sensors, were available at the time of writing this article.

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New and Emerging Health Technology Reports

Recent Reports from CADTH and Other HTA Agencies

These reports are available without cost at the web sites shown below:

Agence d'évaluation des technologies et des modes d'intervention en santé (AÉTMIS)

📖 Three-wheel and four-wheel scooters: alternatives to powered wheelchairs? [English summary, full report in French].

Available: <http://www.aetmis.gouv.qc.ca/site/index.php?aid=1001>

Australia New Zealand Horizon Scanning Network (ANZHSN)

📖 USCOM: ultrasound cardiac output monitor for patients requiring haemodynamic monitoring.

Available: [http://www.health.gov.au/inter.net/horizon/publishing.nsf/Content/30948B2D5B54C4BDCA25715C000223DE/\\$File/HSR%20-%20USCOM%20Final.pdf](http://www.health.gov.au/inter.net/horizon/publishing.nsf/Content/30948B2D5B54C4BDCA25715C000223DE/$File/HSR%20-%20USCOM%20Final.pdf)

📖 Genetic testing for congenital long QT syndrome to identify individuals at high-risk of sudden cardiac death.

Available: [http://www.horizonscanning.gov.au/inter.net/horizon/publishing.nsf/Content/8F86C8B4D8513895CA25715C0005D972/\\$File/Genetic%20testing%20for%20Long%20QT%20syndrome%20to%20identify%20individuals%20at%20high-risk%20of%20sudden%20cardiac%20death%20June2006.pdf](http://www.horizonscanning.gov.au/inter.net/horizon/publishing.nsf/Content/8F86C8B4D8513895CA25715C0005D972/$File/Genetic%20testing%20for%20Long%20QT%20syndrome%20to%20identify%20individuals%20at%20high-risk%20of%20sudden%20cardiac%20death%20June2006.pdf)

Canadian Agency for Drugs and Technologies in Health (CADTH)

📖 Intra-articular hyaluronic acid (viscosupplementation) for hip osteoarthritis.

Available: http://www.cadth.ca/media/pdf/E0024_viscosupplementation_cetap_e.pdf

📖 Nuchal translucency measurement in first trimester Down syndrome screening.

Available: http://www.cadth.ca/media/pdf/E0021_Nuchal_Translucency_cetap_e.pdf

UK National Horizon Scanning Centre (NHSC)

📖 Ultrafiltration for acute decompensated heart failure.

Available: http://pcpoh.bham.ac.uk/publichealth/horizon/PDF_files/2006reports/December06/Ultrafiltration.pdf

📖 MySkin™ for wound healing (epithelialisation phase).

Available: http://pcpoh.bham.ac.uk/publichealth/horizon/PDF_files/2006reports/December06/Myskin.pdf

📖 Myocardial stress perfusion magnetic resonance imaging (MRI) assessment of myocardial blood flow in coronary artery disease.

Available: http://pcpoh.bham.ac.uk/publichealth/horizon/PDF_files/2007reports/April2007/Myocardial_stress_perfusion_CAD.pdf

US Blue Cross Blue Shield Association (BCBS)

📖 Microvolt T-wave alternans testing to risk-stratify patients being considered for ICD therapy for primary prevention of sudden death.

Available: <http://www.bcbs.com/betterknowledge/tec/vols/21/microvolt-t-wave-alternans.html>

US California Technology Assessment Forum (CTAF)

📖 Artificial disc replacement for degenerative disc disease of the lumbar spine.

Available: <http://www.ctaf.org/content/general/detail/686>

📖 Low dose spiral computerized tomography (LDCT) screening for lung cancer.

Available: <http://www.ctaf.org/content/general/detail/687>



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600-865 Carling Ave.
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Tel: (613) 226-2553

Fax: (613) 226-5392

Web site: www.cadth.ca

Editor/Writer: Catherine Allison

Contributing Writers: Sandor Demeter, David Hailey, Andra Morrison, Leigh-Ann Topfer

Information Specialists: Monika Mierzwinski-Urban, Andra Morrison, Sarah Normandin

Copy Editor: Kinneret Globerman

Layout and Design: Nathalie Charron, Matt Kulka

Web Designers: Martha Hodgson-Oram, Paul Ting

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