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## EDITORIAL

Dr John O'Neill MD, FRACP

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EDITOR, PROCEEDINGS

**T**his 19th Issue of *Proceedings* incorporates seven articles from separate disciplines within the Clinic.

With our ageing population, it is common for surgery to be required on patients with vascular co-morbidities including those which require the use of anticoagulant medication. The time at which anticoagulation medication should be ceased before and commenced after various surgical procedures is now a common problem facing general practitioners, anaesthetists and surgeons. The important topic of management of anticoagulant medication in the peri-operative period is discussed in the article by Drs Omari and McGrath, Vascular Physicians.

In his article, Dr Richard Gallagher, ENT Surgeon, describes the use of endoscopic procedures for surgical lesions involving the anterior skull base.

A Positron Emission Scanner (PET) was introduced into the Nuclear Medicine Department of the Clinic early this year. It has been extensively utilised and Dr Lyn Chan, Nuclear Medicine Physician explains the value of this investigative tool particularly with respect to the diagnosis and management of lung cancer.



Associate Professor Bernie Haylen provided an update on developments in Urogynaecology in the 2000 Issue of *Proceedings*. This Issue highlights further advances in that field over the ensuing seven years.

Robotic surgery was introduced to St Vincent's Campus in 2005. It is now being utilised in cardiac, gynaecological and urological surgery. Dr Raji Kooner and Associate Professor Phillip Stricker highlight new modalities available for the treatment of prostatic cancer, including the use of robotic-assisted laparoscopic radical prostatectomy.

Technological advances in joint replacement have led to the creation of artificial discs which can now be inserted into the cervical or lumbar spine regions of those patients who previously required disc replacement surgery and fusion (with its resultant immobility of the spinal segments adjacent to that which was fused). Dr Tim Steel, Neurosurgeon, discusses the surgical management of spinal degenerative disease highlighting the new disc replacement technology and his own personal experience with disc replacement.

Dr Doug Fenton-Lee, Upper Gastrointestinal Surgeon, highlights the advantages of endoscopic surgery and the St Vincent's experience in endoscopic surgery for management of certain upper gastrointestinal conditions especially reflux and gastro-oesophageal malignancy.

On page 23 of this Issue is the list of St Vincent's Clinic Foundation Grants awarded during 2007. These totalled \$640,000. There were 2 major grants of \$100,000. One of these was to Professor Robert Graham to investigate the possible use of adult stem cells to stimulate neovascularisation in patients with ischaemic heart disease. The other, The Ladies' Committee Sr Mary Bernice Research Grant (recognising the vital continuing fundraising activities of The Ladies' Committee of St Vincent's Private Hospital and St Vincent's Clinic) was to Professor Terence Campbell to investigate drugs which may suppress potentially life threatening cardiac arrhythmias.

On page 37 of *Proceedings* is an application form for persons who may wish to make a donation to assist with the continuing research work supervised by St Vincent's Clinic Foundation.



Dr Abdullah Omari  
Dr Michael McGrath

# Peri-operative warfarin anticoagulation



## INTRODUCTION

The need for patients on warfarin anticoagulation therapy to undergo invasive procedures or surgery presents a problem for their treating doctors. There is a balance between the risk of thromboembolic events when anticoagulant therapy is interrupted and the risk of bleeding associated with the invasive procedure when warfarin is continued or a substitution therapy is used. Unfortunately, little consensus exists on the optimal peri-procedural management for such patients.<sup>1</sup> Much of the uncertainty stems from the lack of randomized controlled trials or large rigorous cohort studies.

## WHAT ARE THE RISKS OF THROMBOSIS OFF WARFARIN?

The risk for a patient developing an arterial or venous thrombosis off warfarin varies. Factors that influence this risk include the:

- reason for anticoagulation
- associated risk factors (e.g. atrial fibrillation, prior deep vein thrombosis)
- intervention being performed
- duration off anticoagulation

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- degree of anticoagulation reversal

Jaffer and colleagues<sup>2</sup> have defined three risk categories for thromboembolism: low, intermediate and high (Table 1).

### Special situations:

#### a. Atrial fibrillation:

In patients with chronic non-valvular AF the risk of stroke is <5 per cent.<sup>3</sup> Factors such as advanced age (>65), previous cardio-embolic event and impaired left ventricular function increase the risk of thrombotic complications.

#### b. Prosthetic heart valves:

Depending on the location of the heart valve, the nature of the valve itself (mechanical or tissue) and the type of valve used (Starr-Edwards, St. Jude, etc) the risk of thrombotic complications vary.

Older type valves (e.g. Starr-Edwards) and those in the mitral position carry the highest thrombotic risk.

Importantly, individuals with both atrial fibrillation and prosthetic valves pose a high risk of thrombotic complications. Patients with a history of stroke are also at high risk.

#### c. Venous thromboembolic (VTE) disease

In the absence of anticoagulation the risk of recurrent VTE is highest in the first month after the first thrombotic event.<sup>4</sup> Estimated to be approximately one per cent per day off anticoagulation<sup>1</sup>, this risk declines after the initial four week period. Therefore, if possible, this indicates that elective surgery should be delayed one month after the episode of VTE when the risk off warfarin decreases. However, if urgent surgery is required, patients with a high risk of developing thromboembolic complications if anticoagulation is discontinued may require the insertion of an inferior vena cava filter.

#### d. Spinal or epidural anaesthesia

Concern exists regarding the risk of epidural haematoma formation among patients who undergo spinal or epidural anaesthesia in the setting of anticoagulation. Depending upon the anticoagulant used (unfractionated or low molecular weight heparin) it would be advised to with-hold unfractionated heparins at least six hours prior to the anaesthetic procedure or 18-24 hours in the case of low molecular weight heparins. In the elderly, individuals with renal impairment, thrombocytopenia or anaemia the delay may need to be increased.

#### e. Minor surgical procedures

There are some procedures which entail a low risk of bleeding and so do not require interruption to warfarin therapy if the INR is within the therapeutic range e.g. due to the likelihood of bleeding being infrequent and controllable, simple dermatological excisions and repairs may be performed without altering warfarin usage.<sup>5</sup>

#### f. Dental procedures:

In the majority of dental procedures the requirement to vary the degree of anticoagulation in preparation for the procedure is not warranted. For example, uncomplicated extractions, restorations, and periodontal treatment usually require no cessation of warfarin therapy.<sup>6</sup> Complicated extractions or gingival surgery on the other hand, may require anticoagulation cessation. Importantly, discussion with the dentist is required to determine bleeding risk.

#### g. Gastrointestinal endoscopic procedures:

Depending on the procedure performed the risk of bleeding may be low or high. Upper endoscopy, flexible sigmoidoscopy and colonoscopy; all with or without biopsy are low risk<sup>7</sup> and anticoagulation therapy may not need to be ceased. Procedures including polypectomy, treatment of varices or biliary sphincterotomy pose a higher risk of bleeding and necessitate cessation of warfarin therapy prior to the

Risk	Examples
<b>Low</b> 1-year risk of arterial embolism < 5 per cent, or 1-month risk of venous thromboembolism <2 per cent	Atrial fibrillation (AF) with no cerebrovascular events or risk factors for emboli; Single episode of venous thromboembolism >6 months earlier
<b>Intermediate</b> 1-year risk of arterial embolism 5-10 per cent, or 1-month risk of venous thromboembolism 2-10 per cent	Atrial fibrillation with no history of cerebrovascular episodes but with other risk factors for embolism (e.g. age >65, abnormal echocardiogram); Venous thromboembolism 3-6 months earlier
<b>High</b> 1-year risk of arterial embolism >10 per cent, or 1-month risk of venous thromboembolism >10 per cent	Older type prosthetic valves (esp. in mitral position), atrial fibrillation & history of cerebrovascular episode; very recent thromboembolism (<3 months)

**Table 1.** Risk and examples for thrombosis (adapted from Jaffer et al<sup>2</sup>)

intervention.<sup>7</sup> Additionally, bowel preparation for colonoscopy may increase the patient's sensitivity to warfarin. However, disagreement exists regarding anticoagulation use and cessation in relation to endoscopic procedures and therefore assessment of each patient on a case by case basis is required especially when the nature of the endoscopic procedure to be performed is unclear and the extent of the intervention will be determined at the time of endoscopy.

### Procedure for cessation of oral anticoagulation.

Generally, cessation of warfarin five days prior to the procedure should be sufficient to reduce the international normalised ratio (INR) to safe levels for surgery.<sup>8</sup> An INR of 1.5 is generally considered not to increase the risk of perioperative bleeding.<sup>1</sup> Examples of the surgical procedures that require cessation of warfarin are listed in **Table 2**. Importantly, with some interventions (e.g. neurosurgical procedures where bleeding may have catastrophic complications) an INR level closer to 1.0 may be advisable. Practically, an INR performed the day before the procedure is essential to ensure that adequate anticoagulation reversal has been achieved.

Even though lower INRs tend to be associated with thromboembolic complications and higher INRs associated with haemorrhagic complications, an INR on the day of the intervention has been found not to predict the occurrence of a complication<sup>9</sup> which suggests that local factors play an important role perioperatively.

## BRIDGING ANTICOAGULATION

### a. Low molecular weight heparin (LMWH):

Enoxaparin (Clexane) is a commonly used bridging anticoagulant because of the predictable effect, ease of use (subcutaneous preparation in pre-filled syringes) and lack of monitoring required. In comparison to unfractionated heparins, LMWH are as

effective and safe.<sup>10</sup> This is vital since surgical patients are more frequently being admitted closer to their time of surgery making outpatient anticoagulation bridging therapy more important.

### b. Intravenous unfractionated heparin (UFH):

The use of intravenous UFH once frequently used in the hospital setting is significantly decreasing. The ease of use and increasing requirement for outpatient use of LMWH has resulted in the shift away from UFH. Historically, among individuals with mechanical valves who had undergone valve insertion, UFH was used for anticoagulation as a bridge until the patient's INR was therapeutic. However, a paucity of data has existed in relation to the safety of LMWH in the setting of bridging anticoagulation. In recent times evidence has emerged that LMWH appears effective, safe, and feasible in individuals with prosthetic valves.<sup>10</sup>

### c. Suggested Clexane bridging protocol

Many different protocols exist regarding what is appropriate bridging anticoagulation in the perioperative period. Medical evidence is lacking in relation to which regimen provides the

most effective and safest pathway that minimises both thrombotic events and bleeding complications. Currently, we use a protocol that in our clinical practice has been both easy to follow and effective (**Table 3**).

Importantly, there are some key points in relation to the information presented in Table 3. They are:

- The last dose of warfarin is five days before the scheduled procedure.
- An INR is performed five days before and the day before the scheduled procedure.
- As a guide we usually commence Clexane at a dose of 1mg/kg once daily. For example a patient who is 60 kg will receive Clexane 60 mg administered at 6pm daily starting day -4 until day -2. In individuals who are obese, underweight, anaemic, thrombocytopenic, have renal impairment or a medical condition that may interfere with Clexane the dose may need to be adjusted.
- No anticoagulation is administered the day before or on the day prior to the procedure. However, this may be altered depending upon the thrombotic risk (e.g. individuals with prosthetic heart valves) where

Orthopedic surgery	
	Hip
	Knee
	Shoulder
Abdominal surgery	
	Digestive tract
Urology	
	Prostatectomy
	Transurethral resection of prostate (TURP)
Neurosurgery	
Vascular surgery	
Thoracic surgery	
	Coronary artery bypass graft
	Lobectomy
	Valve surgery

**Table 2.** Surgery requiring discontinuation of warfarin

anticoagulation, utilising intravenous unfractionated heparin for example, may be administered closer to the time of the procedure.

- Depending on the procedure performed and the surgeon, anticoagulation may be recommenced after the procedure that day with the dose of anticoagulant being determined by the nature of the surgical procedure.

Regardless of which bridging anticoagulation regimen is used, it is vital that clear communication with the patient's surgeon and general practitioner are maintained so that errors in anticoagulation use do not occur. Also, the protocol used should be easy to understand so that both patient and doctor are able to follow it without likelihood of error.

## POST-PROCEDURE ANTICOAGULATION

Depending on the procedure, the surgeon's wishes and the degree of haemostasis, post-procedure anticoagulation will vary. As soon as practical and safe, low dose anticoagulation should be recommenced and gradually increased as appropriate. In the post-operative setting, anaemia may increase an individual's risk of bleeding and therefore close monitoring of haematological parameters is required. It may be appropriate that prophylactic

doses of anticoagulation are used in the post-operative period until it is safe for full anticoagulation to be undertaken. Also, non-pharmacological measures such as early mobilisation, graduated compression stockings and intermittent pneumatic sequential calf compressors be utilised to minimise the risk of VTE. Duplex ultrasound surveillance of the lower limb deep veins may also be indicated at five to seven days following the surgery in selected high risk patients.

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DAY	DATE (insert date)	INR (when to check)	WARFARIN Dose	CLEXANE Dose
-5		X	Last dose	Nil
-4			Nil	1mg/kg once daily administered in the afternoon
-3			Nil	1mg/kg once daily administered in the afternoon
-2			Nil	1mg/kg once daily administered in the afternoon
-1		X	Nil	Nil
0	PROCEDURE		Nil	To be advised
1			To be advised	To be advised

**Table 3.** Clexane bridging anticoagulation regimen



## INTRODUCTION

The traditional approach to malignant tumours of the anterior skull base is the craniofacial resection involving a combined bifrontal craniotomy and transfacial approach. These procedures evolved in the 1960s.<sup>1</sup>

The introduction of endoscopes in the 1970s for the examination and surgery of the nose and paranasal sinuses has led to a revolution in the management of diseases of the anterior skull base. The Hopkins' rod rigid nasal endoscope provides brilliant illumination of the surgical field combined with good contrast and a wide field of view. Telescopes are available with varied angles of view (0°, 30°, 45°, 70°) enabling the surgeon to look around corners and into areas which could only previously have been reached by open approaches. Functional endoscopic sinus surgery (FESS) was popularised in the mid-1980s by Stammberger and Kennedy. Today it is the standard surgical approach to diseases of the paranasal sinuses. Improvements in surgical technology and techniques have enabled extended surgical procedures to include CSF leak repair, resection of encephalocoeles, and optic nerve decompression.

The management of tumours however is more controversial. Most benign tumours are now removed endoscopically. Increasingly surgeons have pushed the boundaries and demonstrated that endoscopic resection of malignant tumours is possible with low morbidity and good short term survival rates.<sup>2</sup>

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# Endoscopic Surgery for Malignant Tumours of the Anterior Skull Base



## ANATOMY OF THE ANTERIOR SKULL BASE

The anterior skull base is formed by the ethmoid complex, frontal and sphenoid bones. The ethmoid sinuses, ethmoid plate, cribriform plate and planum sphenoidale form the central skull base. The roof of the ethmoid sinuses and orbits is formed by the frontal bone which has variable pneumatization.

The important relationships superiorly are the dura, olfactory bulbs and frontal lobes. Laterally are the orbits and more posteriorly the optic nerves,

internal carotid arteries and cavernous sinuses. Also of note is the blood supply to the nose and sinuses by the sphenopalatine and ethmoid arteries.

## IMAGING OF THE ANTERIOR SKULL BASE

To successfully manage tumours both computed tomography (CT) and magnetic resonance imaging (MRI) are required. High resolution CT bone images in three planes demonstrate complicated sinus anatomy and relationships, tumour extent and bone erosion. MRI provides superior soft tissue

images to determine exact tumour extent and will distinguish tumour from inflamed mucosa or secretions. The surgeon can determine if dura or periorbita is involved or if there is gross breach of the anterior skull base.

## SURGICAL TECHNIQUE

The technique for resection of tumours can be classified as endoscopic, endoscopic with endoscopic craniotomy, endoscopic assisted craniofacial resection or open craniofacial resection. The choice of approach is determined by the tumour extent and pathology.

All cases are performed under general anaesthetic. The nose and sinuses are vasoconstricted in a standard fashion. Tracheotomy is not routinely performed and a lumbar drain is not placed. The tumour is approached in a circumferential and preoperatively planned fashion. Vascular control is achieved with bipolar diathermy or titanium clips as access to the entry points of the sphenopalatine, anterior and posterior ethmoid arteries into the nasal fossa and sinuses is reached. The lamina papyracea is almost always

removed. Periorbital tissue may be resected and repaired with fascia lata. Removal of bone of the ethmoid roof and cribriform plate is performed as required. Dura is resected and the olfactory bulb can be removed. Frozen sections are performed to enable precise and complete tumour removal. Repair of the skull base defect depends on the amount of resection. To achieve a water tight closure several layers are required. A synthetic dural replacement such as Duragen is placed into the defect as an underlay graft. Fascia lata is then placed over this again as an underlay graft. If a mucosal rotation flap is available this covers the whole skull base defect. Layers of surgicel are applied. The operative site is covered in a synthetic fibrin glue (Duraseal). The nasal cavity is packed with BIPP coated vazgauze which is left in place for one week.

## ILLUSTRATIVE CASES

### Case 1

A 60 year old man presented with a decreased level of consciousness and headache following an iatrogenic injury to the whole of the left skull base. A large encephalocoele was identified on

imaging (**Figure 1**). The encephalocoele was resected endoscopically and the skull base repaired with fascia lata (**Figure 2**). The patient suffered no long term neurological sequelae. Previously such an extensive defect would have been approached via a bifrontal craniotomy. It demonstrates that very large defects can be closed endoscopically.

### Case 2

A 38 year old woman presented with left nasal obstruction, mild epistaxis and Eustachian tube dysfunction. Endoscopic examination revealed a mass arising from the left olfactory fossa. This was confirmed on imaging. Biopsy demonstrated esthesioneuroblastoma. An endoscopic resection with endoscopic craniotomy and removal of the left olfactory bulb was performed. The skull base defect was 2 x 3cm and was repaired with fascia lata and a large right septal mucosal flap (**Figure 3**). There were no postoperative complications. Olfactory function although diminished was preserved. Adjuvant radiotherapy was performed. This patient was spared the traditional morbidity of an open craniofacial resection with associated complete anosmia.



**Figure 1: (top left)** Soft tissue CT in coronal plane demonstrating a breach in the roof of the left ethmoid sinus and consequent encephalocoele

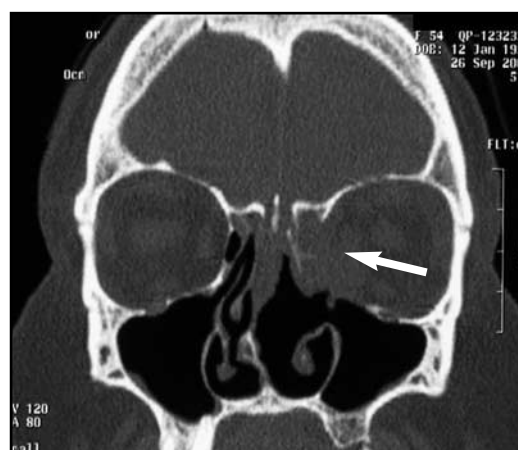
**Figure 2: (bottom left)** Bone window CT in coronal plane 6 months after surgical repair of encephalocoele



**Figure 3: (top right)** Bone window CT in coronal plane 12 months after surgery. The bony skull base defect is easily seen and the right olfactory fossa is intact



**Figure 4: (bottom right)** Bone window CT in coronal plane demonstrates tumour involving the ethmoid sinus with erosion of the lamina papyracea and periorbital involvement





### Case 3

A 58 year old woman presented with a delayed diagnosis of SCC of the left ethmoid sinus (**Figure 4**). The patient was consented for possible orbital exenteration and underwent endoscopic resection with endoscopic craniotomy and resection of dura. Tumour at the orbital apex was resected preserving the eye with resultant expected loss of vision. The skull base defect was 5 x 5cm. This was repaired with Duragen and fascia lata (**Figure 5**). The patient suffered no postoperative complications and proceeded onto adjuvant radiotherapy. This case illustrates several points. Very large defects can be created and repaired endoscopically without postoperative CSF leak. Also orbital exenteration was avoided however visual loss was accepted.

### Case 4

A 68 year old woman presented with right nasal obstruction and epistaxis. Tumour filled the right nasal fossa (**Figures 6 & 7**) and was biopsy proven esthesioneuroblastoma. The patient was consented for endoscopic resection and endoscopic craniotomy. At surgery although the tumour was very large it arose from a discrete 1cm area at the

posterior end of the middle turbinate. The tumour was completely resected without the need for endoscopic craniotomy. Favourable pathology has meant adjuvant radiotherapy was not required. In this case the patient would have proceeded to open craniofacial resection which as demonstrated was found to be endoscopically unnecessary.

## DISCUSSION

There has been a natural progression over the past 20 years in the surgical management of sinonasal tumours from exclusively open to endoscopic procedures. Two important benchmarks have enabled this to occur: firstly, development of endoscopic repair of CSF leaks and encephaloceles; and secondly, the recognition that benign tumours such as inverting papilloma can be resected completely by endoscopic approaches.<sup>3</sup>

Malignancy of the anterior skull base is rare and the histopathology is variable. Most large series are dominated by adenocarcinoma, squamous cell carcinoma and esthesioneuroblastoma.<sup>4</sup> The behaviour of these tumours is highly variable. They can be locally aggressive. Regional and distant metastatic disease is generally a late phenomenon.

The introduction of endoscopic resection for selected cases means a significant number of patients can be spared the traditional morbidity of craniofacial resection (transfacial incisions, lateral rhinotomy, osteotomies, bifrontal craniotomy and frontal lobe retraction). Resultant morbidity included nasal and facial deformity, complete anosmia, postoperative confusion, memory impairment, personality change and epilepsy.

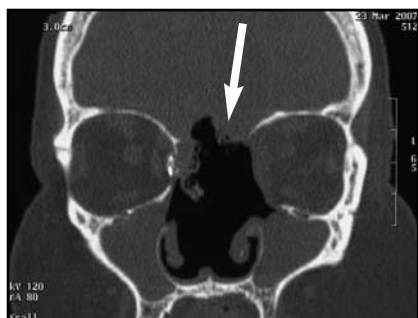
The endoscopic approach enables a better assessment of the origin and spread of the tumour which cannot be appreciated with a headlight. Large tumours will often be found to arise from a limited discrete base. It may be that the site of origin is well clear of the skull base and entry intracranially can be avoided. In an open approach such a scenario cannot be appreciated until the tumour is delivered.

It is emphasized that endoscopic resection does not mean minimal surgery. It provides a different approach with less morbidity to achieve the same goal of complete tumour removal. Gross involvement of the anterior cranial fossa and frank invasion of brain are considered contraindications to a purely endoscopic approach.

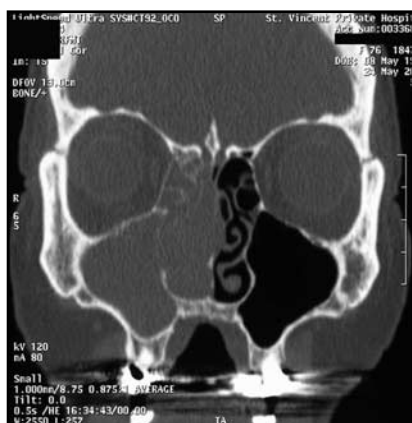
It is too early in the development of endoscopic management to comment meaningfully about patient survival. This heterogeneous group of tumours will in most cases require adjuvant treatment with radiotherapy and in select cases chemotherapy.

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**Figure 5: (top left)** Bone window CT in coronal plane performed 3 months postoperatively demonstrating the extent of skull base resection. The soft tissue thickening on the right is due to crusting of mucous secondary to surgery and radiotherapy



**Figure 6: (left)** Bone window CT in coronal plane demonstrates tumour filling the entire right nasal fossa and opacification of sinuses

**Figure 7: (right)** Gadolinium enhanced MRI in the coronal plane demonstrating tumour filling the nasal fossa. Note the tissue in the maxillary antrum does not enhance helping to differentiate tumour from normal lining/secretions



## INTRODUCTION

Positron emission tomography (PET) is the most important advance in lung cancer imaging since the introduction of computed tomography (CT) scanning. Functional information derived from PET is complementary to the high resolution structural imaging data available from such modalities as CT and magnetic resonance imaging (MRI). St Vincent's Hospital has recently purchased an integrated PET/CT scanner and this article is intended to provide an overview of its indications and advantages in the investigation of pulmonary nodules and staging of lung cancer.

## PRINCIPLES AND INDICATIONS FOR PET

The basic principles of PET are based on the detection of photons emitted from the patient after the intravenous injection of a short-lived radiopharmaceutical (fluorine-18 fluorodeoxyglucose or 18F-FDG, a glucose analogue). These photons are detected by the PET scanner and allow the reconstruction of a three dimensional image of glucose metabolism in the body. The ability to image glucose metabolism non-invasively is important, because most malignant tumours exhibit a high glucose metabolic activity.

18F-FDG PET currently is indicated for the characterisation of lung lesions, staging of non-small cell lung carcinoma (NSCLC), detection of distant metastases and diagnosis of recurrent disease. Furthermore many institutions have found significant value in 18F-FDG PET for treatment monitoring.

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# PET Evaluation of Pulmonary Nodules and Lung Cancer



## MEDICARE REBATABLE INDICATIONS FOR PET IN AUSTRALIA

PET imaging of the lungs is currently rebatable in Australia under Medicare as stipulated below:

- Whole body FDG PET study, performed for evaluation of a solitary pulmonary nodule where the lesion is considered unsuitable for transthoracic fine needle aspiration biopsy, or for which an attempt at pathological characterisation has failed.
- Whole body FDG PET study, performed for the primary staging of proven non-small cell lung cancer, where curative surgery or radiotherapy is planned.

## ADVANTAGES OF PET/CT

The limited anatomic information yielded by PET can be overcome by fusing functional PET data with

morphological CT data. Accurately fused functional and morphologic data sets are now generated by recently available dual modality PET/CT imaging systems. In addition to enhancing accuracy, PET/CT systems facilitate reduced examination times – by up to 30 per cent – by basing attenuation correction on the CT data.

Among the diagnostic advantages of PET/CT in imaging lung cancer are: exact demarcation of the primary tumour, detection of tumour invasion into adjacent tissue; exact demarcation of tumour in atelectasis; precise localization of mediastinal lymph node metastases; and precise localization and classification of extrathoracic lesions, even when no morphologic changes are identified with CT.

PET/CT also offers advances in surgical management, including: the ability to guide surgical mediastinal biopsy to small lymph-node metastasis, thus improving the accuracy of surgical mediastinal staging; and the ability to guide the biopsy of extrathoracic metastasis, thus reducing anatomic misses.



PET/CT also offers a number of advantages in radiation therapy, including: a minimized dose of ionizing radiation to nontarget organs; and definition of radiation treatment field of tumour in atelectasis.<sup>1</sup>

## PET IN SOLITARY PULMONARY NODULE

A solitary pulmonary nodule (SPN) is a rounded opacity <3cm diameter, completely surrounded by pulmonary parenchyma, not associated with lymphadenopathy, atelectasis or pneumonia.<sup>2</sup> There are nearly 80 causes including granulomas, cancer, hamartoma and vascular malformations.<sup>3</sup> The two most common underlying pathologies of SPNs are primary lung carcinomas and benign granulomas, which constitute more than 80 per cent of pulmonary nodules with equal distribution of about 40 per cent in each category.

SPNs may be detected incidentally on CXR/CT. The cause may remain unknown despite clinical and anatomical assessment. Further investigation may be indicated despite CT/fine needle aspiration (FNA) if there is a suspicion for malignancy. PET allows cost effective non-invasive functional/ metabolic assessment.<sup>4</sup> **Figure 1** illustrates an intense focus of glycolytic metabolism in left lung mid zone of a 62 year old male smoker which is highly suspicious of a primary lung malignancy.

PET may detect other indicators of malignancy including occult mediastinal and extra-thoracic metastases. Furthermore PET may detect other pathology including an unexpected simultaneous primary malignancy potentially affecting patient management.

In a recent meta-analysis, FDG-PET imaging was found to have cumulative sensitivity of 97 per cent and specificity of 78 per cent for identifying malignant lung nodules and masses.<sup>5</sup> A negative FDG-PET study represents less than five per cent probability for cancer in an SPN.

**Figure 1:** Intense focus of glycolytic metabolism in left lung mid zone of 62 year old male smoker, highly suspicious of a primary lung malignancy.

PET imaging for the diagnosis of pulmonary lesions is more useful in patients with an intermediate probability of lung cancer as estimated by considering symptoms, risk factors and radiographic appearances. A PET scan is also warranted when there is discordance between the pretest probability of cancer and the appearance of the nodule on CT.<sup>6</sup>

False negative findings may occur in malignancies with low metabolic activity eg bronchioloalveolar-cell carcinoma and carcinoid; and small nodules (<1cm).<sup>7</sup> False positive FDG uptake is seen in inflammatory conditions such as bacterial pneumonia, pyogenic abscess; and granulomatous diseases such as tuberculosis, sarcoidosis and histoplasmosis.

## PET IN THE STAGING OF LUNG CANCER

PET has been applied to the staging of non small cell (NSCLC) and less commonly small cell lung cancer. Accurate staging guides therapy and prognosis. The most important decision is between those patients who are candidates for surgical resection and those who are judged to be unresectable for cure but will benefit from chemotherapy, radiotherapy, or both.

The staging of malignancies with the TNM system was created to provide consistency in communication of the extent of disease, to provide a basis for the selection of therapy, and to help determine prognosis. The important decision in using this system is whether



the disease is resectable. The T status classifies the features of the primary tumour. The N status classifies the presence or absence of regional lymph node involvement. The M status classifies the presence or absence of extrathoracic metastasis.

## T STAGING

PET is a useful tool for differentiation between tumoral and peritumoral atelectasis. This is particularly important for radiotherapy planning in patients with lung cancer associated with atelectasis. The information provided by PET results in a change in the radiation field in approximately 30 to 40 per cent of patients.<sup>8</sup> With integrated PET/CT-based radiotherapy planning, the radiation field can be exactly defined. The dose of ionizing radiation to non-target organs can be reduced.

## N STAGING

PET has proven to be a very effective staging modality for mediastinal nodal staging. Integrated PET/CT is becoming the new standard of radiologic mediastinal staging. Surgical biopsy by mediastinoscopy remains the gold standard for mediastinal staging. However mediastinoscopy is not perfect and is surgeon dependent. Integrated PET/CT guides surgical mediastinal biopsy to small lymph-node metastasis, thus improving the accuracy of surgical mediastinal staging.<sup>9</sup>

Of major clinical importance is the good negative predictive value of PET in lymph node staging, so mediastinal PET-negative patients may be adequately staged without invasive procedures and proceed directly to thoracotomy.

The positive predictive value is reasonable, but false-positive results can be obtained in infection or granulomatous disorders. In these patients, confirmation of N2 or N3 disease by mediastinoscopy is mandatory to ensure that no patient with resectable N0 or N1 disease is denied the chance of curative surgery.<sup>10</sup>

**Figure 2:** Contralateral left lung and left adrenal metastatic lesions in patient with known right lower lobe lung carcinoma, rendering the patient stage 4.

## M STAGING

Whole-body FDG-PET is an excellent method to use in screening for extrathoracic metastases. PET detects unexpected extrathoracic metastases in 10 to 20 per cent of patients with NSCLC, and changes therapeutic management in about 20 per cent of these patients.

PET is more accurate than CT in the evaluation of adrenal metastases. A study of adrenal lesions demonstrated a sensitivity of 100 per cent, a specificity of 94 per cent and an accuracy of 96 per cent for detecting metastasis. **Figure 2** illustrates contralateral left lung and left adrenal metastatic lesions in a patient with known right lower lobe lung carcinoma, therefore rendering the patient stage 4.

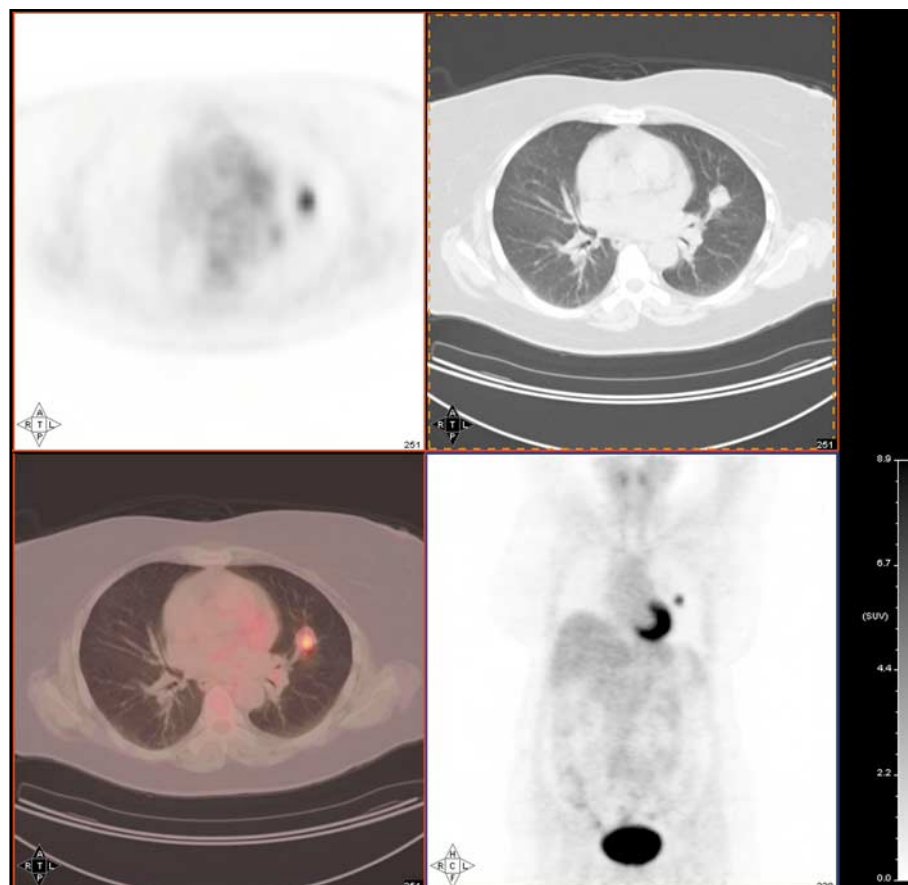
PET has a higher specificity (98 per cent versus 61 per cent) and a slightly lower sensitivity than bone scintigraphy in detecting bone metastasis. FDG uptake is increased only transiently at fracture sites and therefore is less likely to cause false-positive results.<sup>11</sup> PET appears to have the advantage of detecting osteolytic lesions, whereas bone scintigraphy has the advantage of detecting osteoblastic lesions.

The evaluation of liver metastases by PET is less well studied. At present ultrasound (US) and/ or CT remain the standard imaging techniques for the liver. Additional diagnostic information is provided by PET combined with CT, namely in the differentiation of hepatic lesions that are indeterminate on conventional imaging.

PET is less effective than CT or MRI for the detection of cerebral metastases.<sup>12</sup> The sensitivity of PET is low (60 per cent) due to the high glucose uptake of normal surrounding brain tissue.

## IMPACT OF PET ON SURGICAL PLANNING

The PET in Lung Cancer Staging Trial concluded that the addition of PET to conventional radiologic staging workup (CWU) prevented unnecessary surgery in one of five patients with suspected NSCLC. In addition the staging of disease was increased for 27 per cent of patients. The researchers believed that the negative predictive value of PET for mediastinal lymph node involvement was sufficiently high to avoid mediastinoscopy for noncentral tumours.<sup>13</sup> Accurate preoperative staging is therefore required to reduce the



number of futile surgeries and other interventions. Across several patient series, a change in management has been reported in 25 to 52 per cent of patients.<sup>14</sup> Mainly, treatment intent (curative versus palliative) was altered.

In surgically managed lung cancer patients, the degree of standardized uptake value (SUV) on the initial PET images proved to be highly predictive of overall survival after resection.<sup>15</sup> Therefore the maximum SUV of lung cancer lesions may be an accurate predictor of prognosis and outcome.

### IMPACT OF PET ON RADIATION THERAPY PLANNING

Limiting treatment to the tumour spares non-target tissue, allowing an increase in dose to target tissues and a reduction in toxicity to non-target tissues. Peritumoral collapse/atelectasis may limit the ability of CT in differentiating tumour from non-tumour opacification. PET may alter the size of radiation portals by excluding atelectasis or including unsuspected lymph node disease.<sup>14</sup>

### PET IN PLEURAL DISEASE

Differentiating between benign and malignant effusion is important in determining resectability and use of radiotherapy. PET has been found to be useful in the evaluation of suspected malignant pleural effusions. The high negative predictive value of PET in pleural effusions may be of help in reducing the number of repeat thoracenteses or thoroscopic biopsies in patients with negative PET findings and benign effusion.

### PET IN MONITORING RESPONSE TO TREATMENT

Morphologic response (CT) is relatively delayed compared to metabolic response (PET), potentially resulting in unnecessary treatment. PET may differentiate residual viable tumour from therapy-induced fibrosis.<sup>16</sup> The decrease in metabolic response by PET correlates with the pathologic response in the

tumour. PET derived tumour response after treatment is a better predictor of survival than that obtained by CT.<sup>17</sup>

### PET IN DETECTION OF RECURRENT DISEASE

Approximately 50 per cent of patients with resected NSCLC present with a recurrent tumour during the course of the disease. PET can detect local recurrences of previously treated lung carcinomas with a sensitivity of 98 per cent and specificity of 87 per cent, substantially superior to those of other imaging modalities.<sup>18</sup>

### FUTURE DIRECTIONS

Future avenues of investigation include improving the coregistration of lung tumours on PET/CT and determination of the potential benefit of other PET radiotracers.

### CONCLUSION

PET is useful in the assessment of SPNs and in the staging of NSCLC patients who are considered to be candidates for radical treatment. The technique should not be used in patients with, for example, metastatic lymph nodes at clinical examination or when a simple US study demonstrates diffuse hepatic metastases.

The main additional benefit of PET is its ability to assess locoregional lymph node spread more precisely than CT, to detect metastatic lesions that would have been missed on conventional imaging and to help in the differentiation of lesions that are equivocal after conventional imaging.

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## INTRODUCTION

Urogynaecology is the area of gynaecology and female urology that involves the assessment and treatment of lower urinary tract (bladder and urethra) and pelvic floor problems including uterine and vaginal prolapse. The prevalence of urogynaecological problems overall is high. Thirty-four per cent of Australian women experience urinary incontinence, with a third of these women's symptoms of a severe nature. Forty per cent of women aged between 45 and 85 at their routine gynaecological examination will have significant uterine and/or vaginal prolapse.

It is important to clarify the six main urogynaecological diagnoses, some of which have changed in the last seven years (when they were outlined in an earlier edition of these *Proceedings*<sup>1</sup>), before discussing the key advances in this subspecialty.

# An Update on Key Issues in Urogynaecology



## THE SIX MAIN DIAGNOSES

**A: Urodynamic Stress Incontinence (USI):** Previously known as genuine stress incontinence, this condition is diagnosed after urodynamics (specialised studies of bladder function). It refers to female urinary incontinence due to bladder neck or urethral sphincter weakness, most often associated with the symptom of stress incontinence (involuntary loss of urine with coughing, jumping etc). The prevalence of USI in urogynaecology patients is around 72 per cent.<sup>2</sup>

**B: Detrusor Overactivity (DO):** Previously known as detrusor instability, this diagnosis is also made after urodynamics where abnormal contractions of the bladder (detrusor) musculature are noted. Symptoms associated with this condition are urinary frequency (more than seven voids per day), nocturia (more than one void per night), urgency (compelling desire to void which is difficult to defer), urge incontinence and nocturnal enuresis. The prevalence of DO in urogynaecology patients ranges widely between practices from 13 per cent<sup>2</sup> to 40 per cent.<sup>3</sup>

**C: Sensory Urgency (SU):** This diagnosis is in the same spectrum of bladder dysfunction as detrusor overactivity<sup>4</sup>, with similar symptomatology, though no detrusor contractions are noted at the time of urodynamic diagnosis. Rather, the findings are an early first desire to void (under 100mls), an increased overall sensation to void and a reduced capacity of under 400mls (as opposed to the normal capacity of around 500mls in a Caucasian female population). The prevalence of sensory urgency in urogynaecology patients is around 10-13 per cent.<sup>4</sup>

**D: Voiding Difficulty:** This diagnosis<sup>2</sup>, which again requires urodynamics, refers to abnormally slow and/or incomplete micturition, as judged by an abnormally slow urine flow and/or an abnormally high postvoid residual (PVR). The prevalence of voiding difficulty in urogynaecology patients is up to 39 per cent.<sup>2</sup>

**E: Uterovaginal Prolapse (Prolapse):** A diagnosis by clinical examination, it refers to abnormal descent towards (Grade 1), to (Grade 2) or through (Grade 3/4) the vaginal introitus, of any or all of the uterus, bladder (cystocele), rectum (rectocele) or vaginal vault. The prevalence of some degree of

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prolapse in urogynaecology patients is 65 per cent.<sup>2</sup>

#### **F: Recurrent Urinary Tract Infections:**

This diagnosis can be defined as at least two symptomatic and medically documented urinary tract infections in the previous 12 months. At times, previous pathology results are not available and the diagnosis has to be made on history. The prevalence of women describing two or more and three or more urinary tract infections in the prior 12 months are 21 per cent and 13 per cent respectively.<sup>5</sup>

## KEY ISSUES IN UROGYNÆCOLOGY

The following questions will be addressed:

1. **Suburethral (e.g. tension-free vaginal) tapes:** Have they continued to revolutionize the surgical treatment of female stress urinary incontinence without major problems?
2. **Drug therapy for detrusor overactivity:** Has an ideal one been found?
3. **Prolapse surgery:** What are the current trends in native tissue repairs? Is mesh the way forward?
4. **Complications of prostheses and grafts in urogynaecological surgery:** The need for a classification is being addressed.

### **SUBURETHRAL TAPES – Have they continued to revolutionize the treatment of female stress urinary incontinence without major problems?**

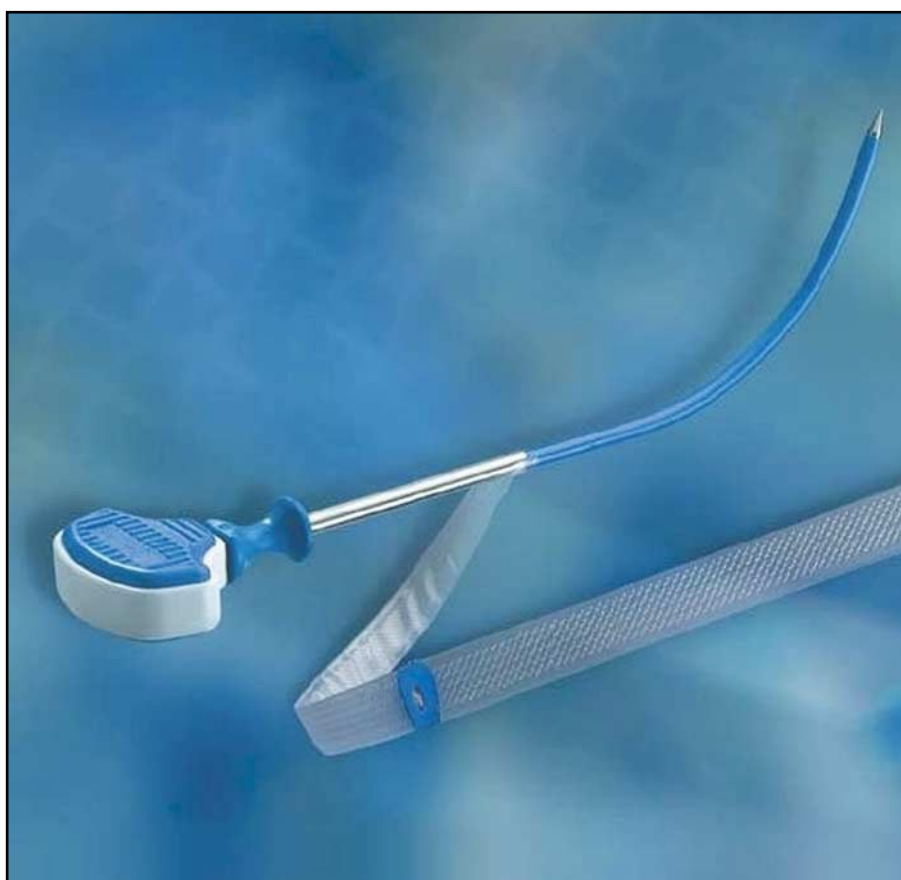
The answer in general is definitely yes. The major benefit of the suburethral synthetic tapes has been to convert continence surgery from a laparotomy or challenging laparoscopic procedure to a minimally invasive procedure. Only three small incisions of around 1cm each are required, one vaginally, two above the pubis (retropubic tapes) or in the upper thigh (transobturator tapes). Total theatre time is under one hour with hospitalization of one to two days maximum generally. Cure rates should be around 90 per cent or more. Side-effects are minor with some possible

slowing of voiding, persistence of any urgency symptoms (despite cure of stress incontinence) and local bruising or bleeding. In experienced hands, there should be no major complications. Combination with prolapse surgery is excellent, allowing concomitant cure of prolapse and stress urinary incontinence. The prolapse surgery will, however, extend the length of hospitalization.

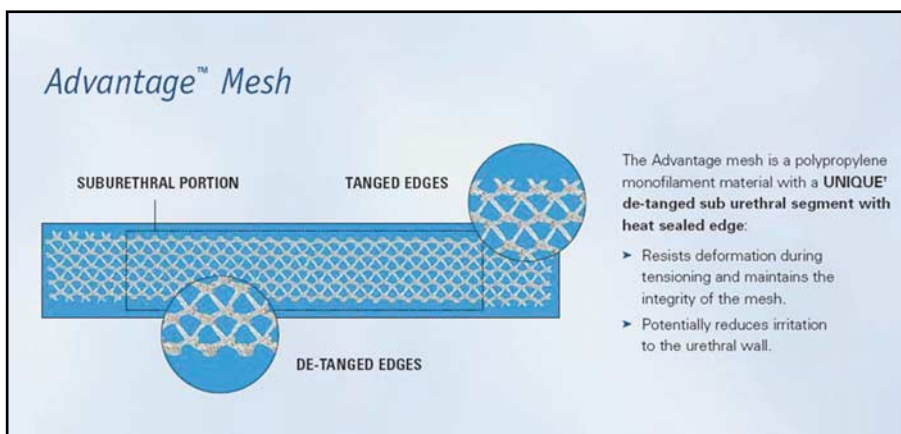
The original tension-free vaginal tape (TVT)<sup>6</sup> developed by Johnson and Johnson Medical has been well-researched. It has been followed by a legion of different tapes generally with a paucity of scientific data. The TVT and

most current tapes use low weight, large pore, monofilament (generally prolene) mesh of 20 per cent to 35 per cent elasticity. This type of mesh has generally served well with no significant mesh healing issues e.g. infection.<sup>7,8</sup> Tape insertion issues, due to the use of a trocar, are still possible. These include bleeding, bladder perforation or vaginal exposure.

Modifications such as the total enclosure of the tape in a plastic sheath until its suburethral placement and heat-sealing the suburethral section of the tape (e.g. Advantage – Boston Scientific – **Figures 1A, 1B**) have reduced the



**Figure 1: (A)** “Advantage” (Boston Scientific) tape and trocar



**Figure 1: (B)** “Advantage” (Boston Scientific) mesh.

chances of fraying or narrowing of the tape during insertion, which might contribute to unsuccessful surgery or postoperative voiding difficulty.

The lateral (transobturator) route was developed in an attempt to reduce overall complications whilst maintaining success rates in all groups. There is no convincing evidence that either goal has been achieved. The complication profile of the transobturator approach is slightly different (thigh pain is one side effect more commonly reported) but still at a low overall prevalence. There is increasing evidence that the success rates for women with more severe stress incontinence are lower with the transobturator approach than the retropubic approach. Attempts at miniaturizing the tape surgery, at this stage, are not showing results comparable with the retropubic approach.

#### DRUG THERAPY FOR DETRUSOR OVERACTIVITY – Has an ideal one been found?

The search for an ideal medication for detrusor overactivity, one that is highly efficacious with few side-effects is probably the current medical “holy grail” of urogynaecology. Unfortunately the “grail” has yet to be discovered. Drug therapy is often necessary in more severe detrusor overactivity or where behavioural therapies such as bladder training have proved ineffective.

Australia’s range of medications for detrusor overactivity remains restricted compared to most other countries. Additional drugs, alternate dosages or administration routes (e.g. patches) have been very slow to be approved and marketed. In 2000, only two anticholinergics were available on PBS, Propantheline (Probanthine) and Oxybutynin (Ditropan). Dry mouth was the main side-effect of these medications. Regulatory and other issues delayed the introduction of Tolterodine (Detrusitol) till 2004, which then, as now, is still not on the PBS. A reduction of the dry mouth side-effect with Tolterodine was beneficial though cost (\$55-\$80) is a factor for some patients. In general, individual preference after trial of the different anticholinergics will determine the final medication chosen. Longer term compliance (at best 50 per cent after six months) remains an issue for most medications.

In late 2006, two medications marketed as antimuscarinics were introduced to the Australian market, neither on the PBS. The antimuscarinics aim at more specific targeting on the M3 and M5 receptors in the bladder, hopefully to reduce the overall side-effect profile. The first of these Solifenacin (Vesicare) has been strongly marketed as having a 60 per cent reduction in urge incontinent episodes with only 10 per cent women having dry mouth as a side-effect. It takes an individual practitioner much time to glean whether that is the experience with his or her own patients, or whether alternate side-effects might arise. The once daily dose should be an advantage in terms of compliance. Overall experience with this medication in Australia is relatively short. The alternate antimuscarinic is Darifenacin, which has not been heavily marketed at this stage. **Figure 2** shows a range of currently available medications for detrusor overactivity.

From August 2007, Oxytrol patches will be marketed, allowing the skin absorption of oxybutynin as a twice weekly application. The transdermal administration shows a comparable incidence of dry mouth to placebo though itching at the site of application is experienced in around 10 per cent to 16 per cent patients.

For cases of detrusor overactivity recalcitrant to drug treatment, intravesical Botulinum Toxin (BTX)

injections over most of the bladder continues to gain an established place.<sup>9</sup> This treatment bridges a wide gap within the therapeutic armamentarium between non drug treatment and more invasive treatments, such as sacral neuromodulation (wires inserted in the spine attached to electrical stimulation boxes) or augmentation cystoplasty (replacing part of the bladder with a bowel segment).

Ever since the publication by Schurch et al,<sup>10</sup> who pioneered the application of BTX-A in neurogenic detrusor overactivity, there is now increasing evidence that BTX, specifically the A serotype, is effective at improving or restoring continence in 50 per cent to 90 per cent patients, with either neurogenic DO and idiopathic DO. The results from several large trials are awaited to confirm the ideal safe dosing and dosing intervals, to evaluate its longer term efficacy.

#### PROLAPSE SURGERY – What are the current trends?

First time (primary) repairs for prolapse using a patient’s own tissues (native tissue repair) in experienced hands can be most effective. Prolapse of the anterior vaginal wall (cystocele), uterus, posterior vaginal wall (rectocele) or, following hysterectomy, the vaginal vault (enterocele) generally don’t occur in isolation. Surgical success will generally depend on all components of the prolapse being addressed



**Figure 2:** A selection of oral medications for detrusor overactivity.

concomitantly. A three or four part prolapse repair is most often required involving anterior and posterior vaginal walls, vaginal hysterectomy (if the uterus is present and prolapsing) as well as some vaginal vault fixation. Attempts to bypass any of these components will end up in higher rate of recurrence often within an earlier timeframe.

In terms of the often necessary aspect of vaginal vault support, this author maintains his preference for a sacrospinous ligament (hitch) as offering a fixation point with the highest pull-out strength of the possible reattachment sites in reconstructive pelvic surgery.<sup>11</sup> Other effective sites/ procedures for stabilizing the vaginal vault are (a) the sacrum (sacrocolpopexy) via laparoscopy or laparotomy (b) the uterosacral ligaments within the pelvis via a challenging vaginal procedure. In comparison with these procedures, the sacrospinous hitch (i) can be used in all anatomical circumstances of prolapse (a universal option); (ii) most conveniently combines with other vaginal prolapse surgery; (iii) adds only around 20 minutes on average to the operating time; (iv) effectively stabilizes the vagina, a favourable factor if concomitant continence surgery is to be performed. Medium term success rates of 90 per cent or more can be achieved with an up to 25 per cent recurrent cystocele rate reduced if this area is aggressively repaired at the time of the first surgery.<sup>12</sup>

In terms of prolapse, there has been at times a surgical "holy grail" mentality, a quest to achieve a prolapse repair with as close to 100 per cent efficacy and reduce the long-term re-operation rate of 29 per cent for prolapse surgery.<sup>13</sup> There has been the widespread use of mesh with repairs without scientific justification. Anatomical perfection may be quite different from functional acceptability for the patient. "Kits" have been introduced for all types of prolapse repairs, again involving the use of different materials with different fixation devices or trocars. Few papers on such procedures have met the scientific criteria for randomized prospective trials. In addition to "kits", the same materials have been also been independently laid in place or fixed with surgical sutures. The use of prostheses or grafts has progressed questionably in some areas from an indication for recurrent prolapse to that of using them in primary procedures.<sup>14</sup>

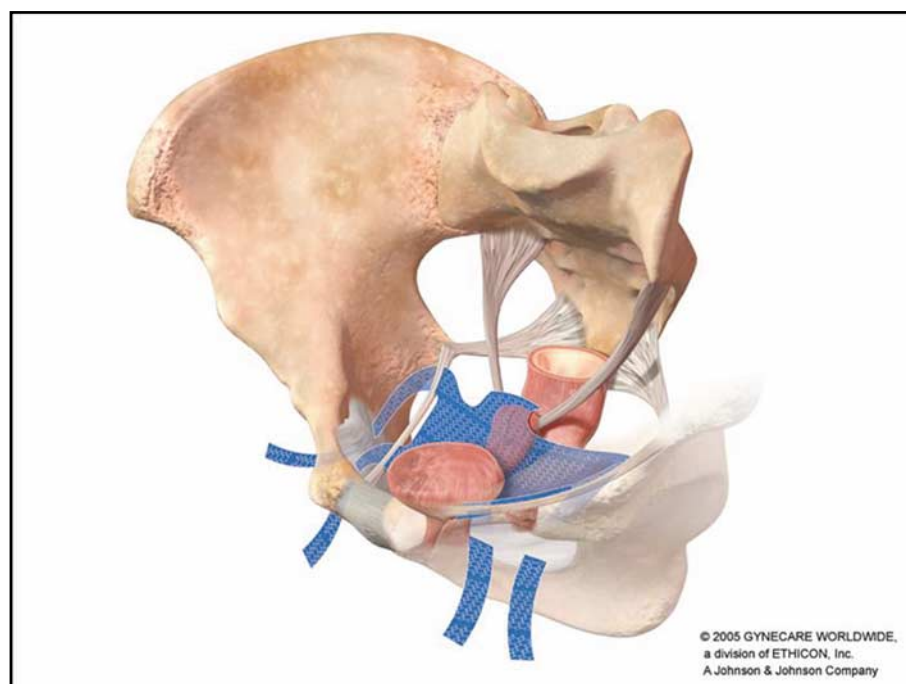
Surgical history witnesses operations "coming and going". The main reasons for a procedure being discontinued are (i) lack of efficacy; or (ii) complications (above). Native (patient's own, not an autologous graft) tissue repairs are not without complications. Prostheses or grafts potentially add to the above complication profile the aspects of (i) trauma of insertion; (ii) reaction of the body to the prosthesis in terms of inflammation, infection and/or rejection; (iii) the stability of the prosthesis over time.

Synthetic meshes, applied intra-abdominally have been used for post-hysterectomy vaginal vault prolapse for 40 years<sup>15</sup> and are now also well-established.<sup>16,17</sup> Both of these areas have been subject to prospective randomized trials and prospective published series.<sup>18</sup> The place of different meshes, implants and grafts in vaginal surgery for pelvic organ prolapse has not been definitely proven. The author, in line with many of his urogynaecological colleagues, would support the use of mesh in the difficult circumstances of a recurrent cystocele, where adequate support with native tissue repairs is difficult to obtain. **Figure 3** shows a diagram of the Prolift (Gynecare/ Johnson & Johnson) anterior vaginal mesh repair.

#### COMPLICATIONS OF PROSTHESES (MESHES, TAPES, IMPLANTS) AND GRAFTS IN UROGYNAECOLOGICAL SURGERY – The need for a classification is being addressed.

One key precept in the Hippocratic oath, often quoted in Latin, is "primum non nocere" (first, to do no harm). Surgeons need to know the possible complications that their surgeries might cause and when and where they might occur. Such information might be generated from a table of complications, personal, multi-centre, a national registry or industry-coordinated, classified according to three aspects: category, time and site. Only with this information can: (i) a surgeon know the value and risk of a certain procedure (and fulfil this key ideal outlined by Hippocrates); (ii) is he/she able to counsel a woman so that she is properly informed as to whether she should embark on that procedure; (iii) if the procedure involves a prosthesis supported by industry, then that group needs to have feedback on the value and complications of that procedure. Should the overview in terms of complications be sufficiently adverse, the procedure and/or the prosthesis or graft should be abandoned.

This author was pleased to be asked by the International Urogynaecological Association to be the prime developer (in conjunction with their Standardization and Terminology Committee) of the first ever classification of complications from the insertion of prostheses (meshes, tapes,



**Figure 3:** Prolift (Gynecare/Johnson and Johnson) Anterior Vaginal Mesh Repair.



implants) and grafts in urogynecological surgery.<sup>19</sup> That work (Figure 4) has been submitted for publication. The classification table (See table) is included for interest. Terminology has been carefully selected and defined. Every anticipated complication can then be classified with a code involving three letters and three or four numerals relating to the category (C) or type of complication, the time (T) the complication occurred (in relation to the time of surgery) and the site (S) of the complication.

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**Table 2: A CLASSIFICATION OF COMPLICATIONS DIRECTLY RELATED TO THE INSERTION OF PROSTHESES (MESHES, IMPLANTS, TAPES) OR GRAFTS IN UROGYNECOLOGICAL SURGERY**

CATEGORY					
General Description		Notes	A	B	C
1	Vaginal: no epithelial penetration	e.g. subepithelial mesh, implant, tape or graft prominence or excessive contraction	1A: Asymptomatic abnormal mesh finding or unusual pain / tenderness on clinical examination	1B: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	1C: Infection (suspected or actual). C1 = Abscess Formation
2	Vaginal: epithelial penetration	No vaginal epithelial separation	2A: Asymptomatic	2B: Symptomatic	2C: Infection
3	Vaginal: smaller exposure	≤ 1 cm vaginal epithelial separation	3A: Asymptomatic	3B: Symptomatic	3C: Infection
4	Vaginal: larger exposure (including extrusion)	> 1 cm vaginal epithelial separation or mesh, implant, tape or graft extrusion	4A: Asymptomatic	4B: Symptomatic	4C: Infection
5	Urinary Tract: compromise or perforation		5A: Minor intraoperative defect e.g. bladder perforation 5A1: Urinary retention requiring surgical intervention	5B: Other lower urinary tract complication or compromise	5C: Ureteric or upper urinary tract complication or compromise
6	Rectum or Bowel: compromise or perforation		6A: Minor intraoperative defect (rectal or bowel)	6B: Other rectal injury or compromise	6C: Other bowel injury or compromise
7	Patient compromise		7A: Bleeding complication including haematoma	7B: Major degree of resuscitation or intensive care*	7C: Mortality * *(additional complication - no site applicable - S0)

TIME (clinically diagnosed)

T1: Intraoperative	T2: up to 24 hours post - op	T3: 24 hours to 2 weeks post - op	T4: 2 weeks to usual post - op review (6 to 12 weeks)	T5: Post - op review to 12 months	T6: over 12 months post - op
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SITE

S1: Vaginal: area of suture line	S2: Vaginal: away from area of suture line	S3: Vaginal Vault	S4: Trochar passage Exception: Intra-abdominal (S6)	S5: Trochar exit	S6: Intra-abdominal
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N.B. 1. Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.  
2. The highest final category for any single complication should be used (e.g. Table 3: patient number 888).  
3. Urinary tract infections and functional issues (apart from 5A1) have not been included.

CODE

-

T

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S

**Figure 4: A classification of complications directly related to the insertion of prostheses and grafts in urogynaecological surgery.**



## Dr Raji Kooner A/Prof Phillip Stricker

### INTRODUCTION

Prostate cancer is a major health issue in Australia, being diagnosed in over 18,000 patients per year and killing over 3,000 men each year. Early detection and aggressive local therapy hold the promise of decreasing the death rate and suffering from this condition. There are many treatments available now for localised prostate cancer and the St Vincent's Urology Department has the largest experience in treating prostate cancer in the country. Already it has the largest experience in radical prostatectomy, low dose rate brachytherapy, high dose rate brachytherapy, active surveillance and hormone therapy. Over the last two years, it has introduced two new forms of treatment for localised prostate cancer: robotic assisted laparoscopic radical prostatectomy (R.A.L.R.P.) and high intensity focused ultrasound (HIFU). This provides patients with the widest selection of therapies in any one institution in the country.

### ROBOT-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY FOR LOCALISED PROSTATE CANCER

There is a strong trend in the United States of America for RALRP to be performed with an estimated 6 per cent of radical prostatectomies this year done robotically, as opposed to only about 5 per cent in 2004. St Vincent's Private Hospital became the centre for the fourth commissioned robot in practice

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# New Technologies for Prostate Cancer – Robotic Radical Prostatectomy and High Intensity Focused Ultrasound



in Australia (other centres being in Melbourne and Adelaide) and the only centre in NSW. RALRP commenced at St Vincent's in February 2006. To date, the authors have now undertaken RALRP in over 150 patients.

RALRP uses recent advances in robotics to allow a minimally invasive method of carrying out radical prostatectomy. This minimally invasive surgery is performed through small keyholes with the da Vinci surgical system (**Figure 1**). This is a computer enhanced master/slave system with the surgeon in control. The surgeon initially sets the robotic arms in positions and then scrubs. The surgeon then operates at the console with the assistant surgeon next to the patient (**Figure 2**). There are two cameras present which allow the computer to marry these images and provide a three dimensional view. The surgeon is immersed in a three dimensional image of the surgical field with ten times magnification. There are a variety of surgical instruments that can be used (similar to open surgery). These

are small and fit through keyhole incisions. Da Vinci instruments move like a wrist within the patient allowing increased dexterity, manoeuvrability and precision as opposed to traditional laparoscopic instruments which are straight and do not bend. The surgeon places his hand in special devices that direct the instrument movement. The robot system cannot make any movements without the surgeon moving. It mimics the surgeons' movement and it is likened to becoming a miniature person suspended in the patient, operating with small flexible hands with ten times magnification. There is the extra advantage of an additional arm that is used to act as an additional surgeon would. The assistant's task is to change instruments on the robotic arm, suck and irrigate to give a clear view of the field, introduce sutures as required and apply haemostatic clips etc.

In short, the da Vinci system offers several advantages over laparoscopic surgery:

- A wrist that allows 60 of movement.
- A telescope with 2 vision channels to provide a 3-D image.
- Magnification of up to ten times.
- A scaling function to reduce hand and wrist movement.
- Motion tremor filter to avoid tremor.
- Surgeons control of the camera.

The disadvantages of the da Vinci system are a lack of tactile feedback, the initial capital outlay and the cost of disposables. Currently, the patient bears no additional costs as a consequence of robotic versus open prostatic surgery.

Selection criteria for RALRP are virtually the same as for those for open radical prostatectomy. Large prostate size, morbid obesity and extensive abdominal surgery can make this procedure more difficult but do not preclude it.

Available data on RALRP versus open approaches show that RALRP is consistently associated with decreased blood loss. Many articles suggest that, with RALRP, there is less post-operative pain and a shorter hospital stay.

It appears that oncological outcomes are very similar between experienced robot surgeons and experienced open surgeons.<sup>1</sup> Oncological outcomes can be assessed by the incidence of positive surgical margins which appear similar in most series of RALRP and open radical prostatectomy. In very extensive cancers (PT3 and PT4) there has been some suggestion that oncological outcomes may be slightly better with experienced open surgeons rather than with experienced surgeons.<sup>2</sup>

As to functional outcomes, it appears that results for post-operative urinary continence and potency are similar in experienced units performing robotic surgery when compared to experienced units performing open radical prostatectomy.

Post-operative continence depends on obtaining a good length of urethra plus an accurate water tight anastomosis of the bladder neck to the urethra. This is facilitated by the 60 of freedom of the robotic needle holders, together with a high resolution, 3-D magnified image that is provided by the da Vinci Robot. Menon et al and Patel et al have reported greater than 95 per cent of patients achieving full continence by a year after robotic surgery.<sup>3, 4</sup> This is similar to the results of Scardino et al and Walsh et al in open series.<sup>5, 6</sup>

Essential for the return of erectile function after radical prostatectomy is the preservation of the neurovascular bundles. These run in close proximity to the prostate. The high resolution magnified view with the robot facilitates the accurate dissection of the fascial layers essential in separating the neurovascular bundle from the capsule of the prostate. The dissection needs to be cautery free to minimise damage to the nerve plexus. In expert hands either by open or robotic means, greater than 75 per cent of young potent patients return their erections.

At St Vincent's, the initial 150 patients have had excellent results. Over 95 per cent of patients have been discharged within three days; blood loss has been minimal with no transfusions; return to normal activities has been rapid, usually within two to three weeks; positive margin rates have been excellent with approximately 5 per cent positive margin rate in tumours



**Figure 1:** Set up of Da Vinci Equipment. Surgeon working in console and working arms operating on patient with assistant surgeon.



**Figure 2:** Viewing section of Da Vinci machine and surgeon operating device with master controls.



contained within the prostate and 25 per cent positive margin rates for tumours extending outside the prostate.<sup>7,8</sup>

Continence has been excellent with rapid return of urinary control. Over 75 per cent of patients did not require a pad beyond three months and in those patients followed more than six months, almost 90 per cent of patients are pad-free with the anticipation that greater than 95 per cent of patients should be pad-free by 12 months. Early data on sexual function show outcome at least as good as for open radical prostatectomy. Further improvement might be expected with the new Vip Patel retrograde nerve sparing technique introduced by us in March 2007.

The St Vincent's Urology Department is increasingly using robotic radical prostatectomy as we believe that it offers significant advances over conventional open surgical radical prostatectomy. As in the USA, it is expected that robotic surgery will increase in Australia as the technology becomes more widely available.

### HIGH INTENSITY FOCUSED ULTRASOUND IN THE TREATMENT OF PROSTATE CANCER

HIFU (high intensity focused ultrasound) has become a potential method of treating localised prostate cancer. Over 10,000 patients have been treated with this technology in over 13 countries over 15 years, mainly in Europe. There are currently two HIFU devices available to treat patients with prostate cancer and these are the Ablatherm and Sonablate systems. The Ablatherm machine has been available for fifteen years and the Sonablate for approximately five years. The majority of published information and the longest follow-up is with the Ablatherm machine, developed in France (**Figure 3**). The first treatment of a human was conducted on the Ablatherm device in 1993 in Lyons. At St Vincent's, in October 2005, we introduced the Ablatherm machine and it is the only hospital in Australia which carries this device. All other units have used the Sonablate device which is a less tested system internationally.

HIFU treatment should be considered particularly in slightly older patients (over 65 years of age) with less aggressive cancers which are localised to the prostate when surgery or radiotherapy are unsuitable or if the patient refuses these options. Another group of patients suitable for this treatment are those who have previously had radiotherapy and the cancer has returned in the prostate.

HIFU means that the prostate cancer will be treated by focusing non-invasive ultrasound waves into the prostate tissue by means of a rectal probe. This method kills the prostate cancer cells by heating the prostate tissue. The treatment involves two procedures which are performed under the same anaesthetic. The first is an inspection of the bladder and shaving of the central section of the prostate to open the channel through the prostate (TURP). The HIFU treatment then follows and this takes between one to three hours. The HIFU treatment is delivered via an ultrasound probe placed in the rectum. The device is enclosed in a cooling balloon that acts to maintain rectal temperature within a pre-defined range. A safety monitor is placed onto the skin to protect any positional change. Ultrasound waves are then focused onto the prostate. The temperature at the focal point and prostate tissue immediately surrounding the area increases to a level that is not compatible with the survival of the tissue. This causes the prostate cells to die. The HIFU machine continuously repeats this procedure until the entire

prostate is treated. Although the prostate is completely treated, it does not disappear and a small prostate remnant is left, composed of scar tissue.

The particular advantages of this procedure are that it is minimally invasive, there is no radiation, a short hospital stay, treatment is performed in one session and the treatment is repeatable. Other therapeutic alternatives can still be considered in cases of incomplete results and the outcome of treatment can be assessed very quickly in three months, with a biopsy and prostate-specific antigen (PSA). There is a low risk of side-effects and the risk of incontinence is particularly low. The risk of impotence is comparable to any radiotherapeutic treatment available and can be minimised by avoiding damage to the erectile nerves.

The disadvantages of the procedure are its cost as it is currently not covered by Medicare and the lack of long-term data as it is a relatively new technology. Furthermore, there is a significant risk of complications in the first three months after treatment due to the passage of necrotic prostatic tissue which can result in infection or blockage.

International results suggest that this is a treatment associated with acceptable side-effects and durable intermediate cancer control. A multi-centre European study, using the Ablatherm device, shows that five years after the procedure



**Figure 3:** Ablatherm HIFU machine with patient being treated by surgeon at working table.

93 per cent of patients have negative biopsies and 87 per cent have a PSA level of <1.<sup>7</sup> A further study of 402 patients in a European multi-centre study conducted by Prof. Turoff, reported in the *Journal of Endo-Urology*, using the Ablatherm device, yielded a 92 per cent negative biopsy rate in low-risk patients, 86 per cent in intermediate risk and 82 per cent in high risk patients.<sup>8</sup> More recently, Professor Turoff has presented his own first 1,000 patients using the Ablatherm device and in the low and intermediate risk group of patients, he found that 80 per cent of patients, at ten year actuarial follow-up, (median follow-up six years) had a low and stable PSA, suggesting the likelihood of cure.

Only one centre in Europe has reported results of HIFU using the Ablatherm device after previously failed radiotherapy. This group reported an 80 per cent negative biopsy rate.<sup>9</sup> The cure rate, however, after previous failed radiotherapy is as yet unknown in the long-term, but at five years of follow-up, approximately 30-40 per cent of patients appear likely to be cured. This is similar to the cure rate of salvage surgery and cryotherapy in this similarly difficult group of patients.

At St Vincent's we have now treated over 60 patients and almost all have been discharged home 1 – 2 days after the procedure. All patients have had their catheters removed, generally between four and 14 days post-operatively. At the end of the three months, all patients have had PSA levels and/or repeat biopsy, to ensure that all cancer has been eradicated. There has been two repeat treatments of the prostate cancer at this stage. Results to date have been excellent, with >90 per cent achieving a negative biopsy and a PSA of under 0.5. Side-effects have been minimal in those patients who have not previously had radiotherapy. In those patients who have been followed for more than six months, five per cent of patients have mild incontinence and 95 per cent have no incontinence.

As virtually all patients have been treated with a non-nerve sparing technique, impotence rates have been very high in this patient group with over 80 per cent of patients confirmed to be impotent after the treatment. It must be remembered, however, that 30 per cent

of patients were impotent prior to the treatment. There have been no cases of severe complication and, in particular, there have been no cases of rectal injury. There has been a 10 per cent incidence of scarring, either in the prostate or in the urethra, which required a second procedure to dilate this area. A further 10 per cent of patients have required removal of debris from the prostate cavity within the first three months after the procedure as it was causing difficulty passing urine. Urinary tract infection has occurred in approximately 10 per cent of patients within the first three months. Urinary frequency has been common in the first three months, but then resolved after that.

In our first 10 men who have had salvage HIFU after previous radiotherapy, we have had a high negative biopsy rate, but only approximately 50 per cent have maintained a low PSA. The side-effect profile in this very high-risk group of patients has been high, with a 30 per cent incidence of ongoing moderate to severe incontinence.

HIFU therefore, has an established role in a select group of patients where the more established treatments are not suitable or have been rejected by informed patients.

## CONCLUSION

With the addition of RALRP and HIFU, St Vincent's Urology Department is able to further tailor treatment to patients with localised prostate cancer by offering a wide selection of therapies in the management of localised prostate cancer.

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# 2007 St Vincent's Clinic Foundation Grants

## **The Ladies' Committee Sr Mary Bernice Research Grant – \$100 000**

A/Prof Katherine Samaras (St Vincent's Hospital)

*"The role of adipocyte-derived inflammatory cytokines in the pathogenesis of diabetes, dyslipidaemia, atherosclerosis, non-alcoholic liver disease and gastro-oesophageal reflux disease: the effects of medical and surgical weightloss"*

## **Tancred Research Grant – \$50 000**

Dr John Moore (St Vincent's Hospital)

*"Assessment of the Common Lymphoid Progenitor (CLP) in allogeneic stem cell transplantation using the OP9 thymic cell line"*

## **K&A Collins Cancer Research Grant – \$50 000**

Dr Ron Bova (St Vincent's Hospital and Victor Chang)

*"p16 gene epimutations and risk of cancer"*

## **Froulop Vascular Research Grant – \$25 000**

Dr Abdullah Omari ( St Vincent's Hospital)

*"Natural history of calf vein thrombosis in post-operative hip and knee replacement patients after treatment with short-term anticoagulation"*

## **Annual Grant 1 – \$25 000**

Prof Terry Campbell (St Vincent's Clinic School)

*"Protein trafficking defects as a cause of congenital Long QT syndrome"*

## **Annual Grant 2 – \$25 000**

Prof Peter McDonald (St Vincent's Hospital)

*"The nature of endothelial progenitor cell subsets in vitro: A study of EPCs from 'normal' donors and patients with chronic ischaemic heart disease"*

## **Annual Grant 3 – \$25 000**

Prof David Ma & Dr Bojiang Shen (St Vincent's Hospital)

*"The differentiation of autologous bone marrow mesenchymal stem cells into intervertebral disc cells for tissue repair by bone morphogenetic proteins and transforming growth factor- $\beta$ 3"*

## **Travelling Scholarship – \$10 000**

Dr Anthony Chambers – Clinical Fellowship in Surgical Oncology at the University of Calgary

## **Multi-disciplinary Patient Focussed Research Grants – \$25 000 per project**

### **St Vincent's Private Hospital**

Prof Kim Walker

*"A multi-disciplinary model of care to improve Warfarin Anticoagulation"*

# Spinal Disc Replacement: Disc Arthroplasty

## INTRODUCTION

Spine surgery has undergone major refinements in the last two decades. Endoscopic and minimally invasive (“key hole”) techniques that allow surgical access to the spinal column with minimal exposure-related morbidity have been developed. Fixation systems with polyaxial screws for cervical and thoraco-lumbar fusion have been developed that allow rigid fixation without the need for extensive fusion surgery.

Frameless stereotactic navigation systems allow more accurate and safer insertion of spinal instrumentation. Progress in bone graft substitutes and orthobiologics are replacing the need for bone grafting procedures.

The development of total disc replacement or “spine arthroplasty” also promises to expand the surgeon’s armamentarium for treating spinal pathology. In this procedure the injured or degenerative disc material is removed and an artificial disc is implanted in the spine. This avoids the necessity for performing a fusion procedure in the spine.

Just as the management of degenerative disease in the hip and knee require the use of prosthetic implants, now the management of selected patients with degenerative discs may be revolutionised with the use of artificial discs prostheses. Performing total disc replacement can help spine surgeons achieve the previously unattainable goal of neural decompression while maintaining mobility to preserve spinal balance. The initial experience of total disc arthroplasty at St Vincent’s Hospital is presented.

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## FUNDAMENTALS OF DEGENERATIVE DISC DISEASE

**A**fter reaching skeletal maturity at around age 20, changes in the structure of the intervertebral disc begin and these progress and continue throughout life. The disc becomes dehydrated. Changes in the synthesis and metabolism of proteoglycans occur.

Progressive axial loading causes the discs to lose height. Cracks and fissures develop in the posterior section of the annulus fibrosis. If healing fails to occur the nucleus may migrate through the

tear. If a disc fragment is extruded or a significant disc protrusion occurs, symptoms of nerve compression i.e. brachialgia or sciatica may occur. If stretching of the annular layers of the disc occur this can lead to neck or back pain without associated symptoms of nerve compression. Changes ensue in the vertebral endplates with oedema and sclerosis. Subchondral sclerosis reduces the porosity of endplates interfering with the transfer of fluids, nutrients and metabolites. The accumulation of these substances creates an environment which in combination with an inflammatory reaction and the release of chemical mediators may cause pain.

## CAUSES OF SPINAL PAIN AND SURGICAL MANAGEMENT

Sources of spinal pain include the intervertebral discs, facet joints, ligaments, muscle and nerve roots. Spinal pain caused by degenerative disc disease is a multifactorial condition induced by various pathological changes in these anatomical structures. In treating these conditions surgeons must analyse meticulously each possible source of pain, and its relative contribution to the patient's overall clinical symptoms.

In general, the vast majority of surgical procedures carried out in the spine are performed for the relief of nerve compression and these surgical procedures do not usually involve the removal of all disc material. A cervical and lumbar microdiscectomy is the removal of only the portion of disc material that is compressing the adjacent nerve or spinal cord. The majority (95 per cent) of the parent disc material is left intact. Surgical procedures that involve total removal of the disc up until now necessitated a subsequent fusion procedure as the total removal of the disc could lead to instability of the involved segment. Hence an anterior cervical discectomy was followed by an anterior cervical interbody fusion. This involved the harvesting of bone usually from the patient's iliac crest ("hip") and inserting it into the disc space. A plate was inserted anterior to the graft to prevent migration of the bone graft (**Figure 1**). This is an anterior cervical discectomy and fusion (ACDF).

For the treatment of cervical disc disease the ACDF procedure has been well accepted since the 1950s.<sup>1</sup> Although these procedures are very effective in alleviating symptoms and improving neurological outcomes the adverse long term effects of interbody fusion procedures have been the subject of considerable debate.<sup>2</sup> It is widely accepted that the relative immobility of the fused spinal segments leads to increased motion at the adjacent levels leading to increased stress in the adjacent unfused segments.<sup>3,4</sup> This stress loading of the adjacent segments causes an acceleration of the degenerative process that occurs in the disc leading to "adjacent segment degeneration". (**Figure 2**).

**Figure 1.** Lateral x-ray of cervical spine. C4/5 ACDF has been performed. An anterior plate is fixed to the C4 and C5 vertebral bodies.



**Figure 2:** Sagittal T2 MRI scan of cervical spine. Adjacent segment degeneration. Previous C4 to 6 anterior cervical fusion has been performed. Significant degeneration at the discs above and below the fusion causing spinal cord compression is seen.



Long term follow up studies conducted after interbody fusion procedures have shown up to 92 per cent of patients demonstrating adjacent level degeneration on radiographs.<sup>5,6</sup> Clinical symptoms however do not always correlate with the severity of the degenerative changes seen on the x-ray films.<sup>5</sup>

Clinically, long term deterioration after ACDF has been documented in several studies. In one study of 374 patients who had undergone ACDF, patients developed new radiculopathic symptoms at an adjacent level at 2.9 per

cent per year with a cumulative rate of 25 per cent over a 10 year period.<sup>7</sup> Two-thirds of these patients required additional cervical surgery.

In another report of almost 10 year follow-up, adjacent segment degeneration was reported in 50 per cent of patients following cervical fusion, with 19 per cent requiring further surgery.<sup>8</sup> In many long term studies the repeated operation rate for anterior cervical fusion is around 6-7 per cent following ACDF.<sup>4</sup> This is in contrast to the repeated operation rate of one per cent for posterior cervical procedures



(microdiscectomy, microforamenotomy) in which segmental motion is preserved.<sup>4</sup>

The natural progression of disc degeneration can be easily demonstrated. Typical features of disc degeneration can be seen on x-ray, CT and MRI scans and these tend to progress with age leading to the characteristic appearances of cervical spondylosis.

The available literature indicates that adjacent segment degenerative disc disease is affected by both natural history and the biomechanical stress of fusion. It is clear that as many as one in five patients undergoing a cervical fusion will require another procedure over a long term follow up.<sup>1</sup> Despite the immediate gratification of good results following ACDF long term clinical deterioration leaves room for improvement.

Motion sparing implants offer theoretical advantages over fusion procedures by maintaining physiological movement at the surgically operated spinal segment. The compensatory stress loading with adjacent segment degeneration should not occur. Furthermore there are other drawbacks to fusion surgery. Alterations to spinal biomechanics, graft and hardware complications and donor bone harvest site pain may occur.

## TREATMENT GOALS FOR TOTAL DISC REPLACEMENT

The aim of total disc replacement is to decompress the neural elements, remove the disc and yet maintain mobility in the functional spinal unit so that the spine remains in an adaptive sagittal balance. In contrast with fusion surgery, total disc replacement preserves mobility in the operated segment and mimics physiological conditions. Reconstructive non-fusion surgery has the potential to replace fusion procedures in a significant number of patients who would otherwise receive an anterior cervical or lumbar fusion procedure.

## HISTORY OF DISC REPLACEMENT SURGERY

Since the 1950s there have been many implants designed to restore the

function and motion of the intervertebral disc.<sup>4</sup> The majority of these focused on the lumbar spine rather than the cervical region.

Several factors have influenced the slow progress of spine arthroplasty. In contrast to the hip and knee joints in which the muscles and ligaments are of prominent importance in maintaining joint stability, in the spine the disc itself is of major structural importance. Disc arthroplasty must also ensure the facet joints are balanced whilst maintaining the axis of rotation in the posterior portion of the disc space.<sup>4</sup> The disc material must be able to withstand 30 to 50 years of strain in which time the device will undergo anywhere between 10 and 30 million cycles of flexion. (The spine undergoes approximately 100 million cycles of flexion in a lifetime).

Early attempts at arthroplasty were met with failure. In 1966 Fernstrom reported his experience with 125 patients.<sup>4</sup> He used a prosthesis shaped like a ball bearing which he implanted into both the lumbar and cervical spine. In the majority of patients this spherical prosthesis created segmental hypermobility with subsidence and migration into the adjacent superior bony endplate. Attempts at cervical arthroplasty were subsequently abandoned in favour of cervical fusion procedures for many years.

In the 1980s there was a resurgence of interest in spine arthroplasty specifically in the lumbar spine. The SB Charite prosthesis was designed in 1982 and first implanted in 1984. Problems with migration and fatigue fractures led to the abandonment of the first two versions. In 1987 the Link SB Charite 3 became commercially available and more than 5000 implants have now been undertaken worldwide. In long term follow-up studies good outcomes have been reported in more than 70 per cent of patients.<sup>9, 4, 10</sup>

In the 1980s a rubber lumbar disc was devised however concerns about the carcinogenic potential of the rubber as well as failure of the rubber component on subsequent testing caused the withdrawal of the device.<sup>4</sup>

The Pro Disc was first introduced for the lumbar spine in 1989. Good and excellent outcomes have been reported

in more than 70 per cent of patients after follow-up periods of between seven and 11 years.<sup>4</sup> In 1999 the Pro Disc 2 featuring design improvements was introduced. The first patients receiving a lumbar disc arthroplasty at St Vincent's Hospital have received the Pro Disc 2. In the USA prospective multi-centre randomised trials were initiated in 2000 for the SB Charite and 2001 for the Pro Disc. The Charite was given FDA approval for use in June 2004.

With the reported success of lumbar arthroplasty devices, renewed enthusiasm emerged for cervical disc replacement. The first trial of a two piece stainless steel metal on metal ball and socket configuration with anchoring screws called the Cummins-Bristol disc was commenced in 1991. Between 1991 and 1996, 22 discs were inserted. In 1996 follow up was reported.<sup>4</sup> Sixteen individuals demonstrated continued joint motion of five degrees in flexion and extension. Adjacent segment degeneration was not observed. Complications of screw pull out, a broken screw and joint subluxation were observed. The technique was modified to strengthen the bone screw interface with partial success. Unfortunately dysphagia developed in all patients attributed to the high profile of the implant in the pre vertebral tissues.

A new device was designed and a two year pilot study of this disc was published in 2002<sup>11</sup> fifteen patients prone to adjacent segment degeneration were enrolled. At two years post-implantation cervical motion was preserved and no settling or dislocation had occurred. In a prospective randomised fashion the authors compared adjacent segment motion after implantation of the new disc with a one level cervical fusion. The fusion group demonstrated a significant increase in adjacent segment motion of five per cent at six months and 15 per cent at one year. Overall adjacent level movement for the group receiving the disc replacement device was not affected. These results had been predicted by previous biomechanical studies.<sup>4</sup>

In August 2000 the first prospective randomised trial comparing cervical arthroplasty with iliac crest autographed fusion using the Prestige disc was initiated at multiple centres. The preliminary results presented at the

Annual Meeting of the North American Spine Society in October 2003 reported favourable outcomes in the arthroplasty group with preservation of motion and lack of progression in adjacent segment disease.

In contrast to the metal on metal design of the Prestige disc, a metal on plastic design called the Bryan disc emerged in the late 1990s. The disc consisted of a polyurethane core that articulates between two titanium alloy shells that included convex porous surfaces that allow for bone ingrowth (**Figure 3**). Clinical trials were initiated in January 2000. Australian trials have been ongoing since 2001. No significant complications have been reported with its use although paravertebral ossifications have been noted in approximately 30 per cent of cases. These have not affected overall clinical outcomes. Success rates at two years were as high as 90 per cent. Motion was maintained at each level averaging more than seven degrees. No device failure or subsidence was noted in any patient.



**Figure 3:** The Bryan cervical disc.

The Pro Disc C used at St Vincent's Hospital was first implanted in 2004 and launched in Australia in February 2005. It consists of two cobalt chromium molybdenum endplates with a central core of ultra high molecular weight polyethylene (UHMWPE) compound found in hip and knee arthroplasties (**Figure 4**).

The prosthesis is anchored to the vertebral bodies by a central keel. The porous surface coating facilitates bone ingrowth. Bone integration generally occurs shortly after implantation. This helps ensure rigid fixation of the disc minimising the risk of subsidence or migration. Both in the cervical and lumbar region, the Pro Disc permits rotation in all planes. The constrained

(fully seated) design minimises anterior/posterior sheer forces at the facet level and protects the facet joints from further degeneration while permitting full rotation at the operative segment. The range of motion allowed by the Pro Disc mimics normal physiological motion in the lumbar and cervical spine. The lumbar Pro Disc permits 13 degrees of flexion and seven degrees of extension. It permits 10 degrees of lateral bending. There is no restriction on axial rotation. The cervical Pro Disc C allows 17.2 degrees of flexion/extension and 17.2 degrees of lateral bending which is the normal physiological range. Axial rotation is also limited only by anatomical structures and not by the prosthesis.

### TECHNIQUE OF DISC REPLACEMENT SURGERY

Disc arthroplasty is performed by an anterior approach either in the cervical or lumbar region. The approach is minimally invasive. After a routine anterior disc removal, trial implants are inserted initially. The implant is subsequently inserted under direct vision with the aid of image intensifier guidance. Midline positioning with sagittal alignment of the implant is vital for successful implantation.

### PERSONAL EXPERIENCES OF DISC REPLACEMENT SURGERY

With increasing age spondylotic changes occur throughout the spine leading to progressive ankylosis and reduction of movement. For this reason



**Figure 4:** The Pro Disc C cervical disc replacement

disc replacement is generally advocated for patients less than 60 years. I have been using cervical disc arthroplasty as an alternative for anterior cervical fusion, for patients under 60 years old with significant spinal cord or nerve root compression, since January 2005. Patients with single level symptomatic lumbar degenerative disc disease have been considered as candidates for lumbar disc arthroplasty with the Pro Disc L.

At the time of writing I have performed total disc arthroplasty on 16 patients. Thirteen patients have received a single level cervical or lumbar disc replacement and three patients have received a two level cervical disc arthroplasty. All patients receiving cervical disc replacement had symptomatic and radiographically proven spinal cord compression. All patients had progressive symptoms that had failed to respond to non-surgical treatment. The average duration of symptoms prior to surgery was greater than 12 months. All patients had pre operative x-ray, CT and MRI scans.

All patients had extensive discussions on the rationale for placing a disc arthroplasty compared to a fusion procedure. All patients underwent an anterior discectomy using minimally invasive techniques. Lumbar disc arthroplasties were performed in conjunction with Dr Tony Grabs, vascular surgeon at St Vincent's Hospital.

One patient, a 42 year old Asian female had the attempted insertion of a cervical disc in early 2005. Because of her small stature the disc prosthesis (Bryan Cervical Disc) was unable to be placed into the intervertebral space. A cervical fusion was performed. Since this time a smaller prosthetic disc targeted at the Asian market has been introduced. This patient has not been included in this study.

The patients' ages ranged from 20 to 49 years. There were 10 males and 6 females. All three patients receiving a two level arthroplasty were male. Follow-up now ranges from three to 30 months. The 16 patients underwent 16 surgical procedures with the insertion of 19 disc prostheses. There were no intra-operative complications. There were no post-operative wound infections. There have been no new neurological deficits. No patients have required revision



surgery and there has been no evidence of post-operative implant migration. All patients were discharged home under five days following the surgery. All patients receive 12 monthly clinical and radiographic follow-up.

All patients have had relief of their pre-operative neurological symptoms and signs. No patient has significant neck or back pain. The average post-operative Visual Analogue Scale (VAS) Pain Score is 1.0 out of 10. One patient reported new onset right S1 distribution pain following an L5/S1 disc replacement which has responded to targeted cortisone injections. All patients have shown preservation of physiological movement at the level of the disc prosthesis on post operative imaging studies. No patients have developed symptoms or signs of adjacent segment degeneration.

## ILLUSTRATIVE CASES

### Case 1.

A 31-year-old male, presented with a six week history of progressive C7 myeloradiculopathy. He had progressive pain with sensory loss and weakness in his left arm and leg secondary to a large left C6/7 disc protrusion causing spinal

cord compression (**Figure 5a and 5b**). An anterior cervical disc removal and C6/7 disc arthroplasty with a Pro Disc C was performed with immediate resolution of his symptoms. Six weeks following the surgery his strength had returned to normal. Post-operative cervical spine x-rays show optimal positioning of the implant with physiological range of movement (**Figure 6a and 6b**).

### Case 2

A 45-year-old male, presented with a two year history of progressive neck pain with bilateral radicular pain and gait disturbance. He reported increasing difficulty walking with stiffness. On examination he had a myelopathy with increased tone and hyperreflexia in his lower extremities. Cervical MRI scans showed C5/6 and C6/7 cervical cord compression secondary to diffuse disc protrusions at both levels (**Figure 7**). There was no sensory disturbance. A two level anterior cervical decompression and disc replacement was performed. He noticed immediate improvement in his radicular symptoms and in his walking. He was discharged home five days following the surgery. Six weeks after the operation his myelopathy had resolved. Post-operative imaging studies showed

physiological range of movement. (**Figure 8a and 8b**).

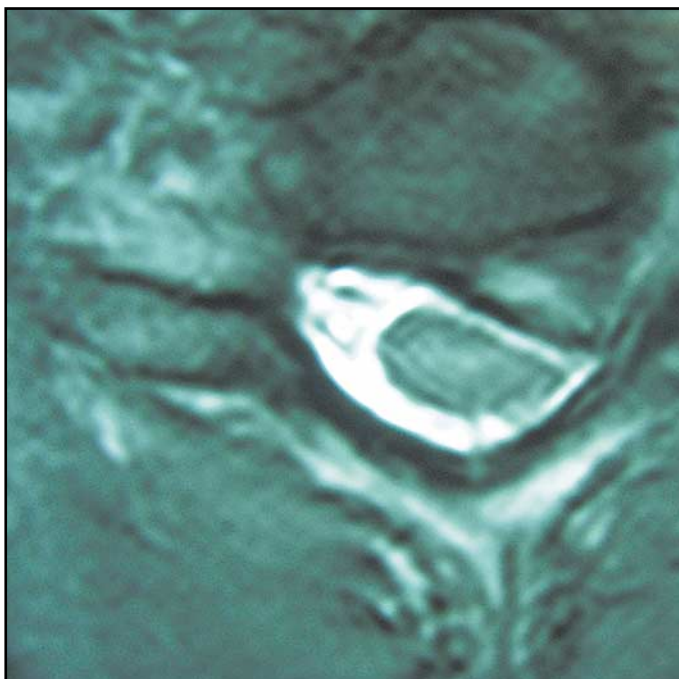
### Case 3

A 35 year old female, presented with an 18 month history of severe low back pain and left S1 radicular symptoms. Her pain had become progressively more severe. Her MRI scan showed significant L5/S1 disc degeneration with a slight retrolisthesis and Modic Type 3 paravertebral endplate changes (**Figure 9**). At the time of her surgery she was on multiple medications. Her pain was rated as 10/10 on a VAS. She obtained partial relief from a transforaminal steroid injection at the L5/S1 level, however this relief only lasted two weeks. At operation an anterior lumbar exposure was performed. The L5/S1 disc was identified and completely removed. A Pro Disc L arthroplasty was inserted (**Figure 10a and 10b**). She noticed immediate improvement in her left leg and lower back lumbar symptoms and resolution of her left leg pain. She was discharged five days after her surgery. On her return visit six weeks following the procedure she had discontinued her opiate analgesia.



**Figure 5a: (left)** Patient 1 – Large disc protrusion extending posteriorly from C6/7 disc space causing spinal cord compression. Degenerative changes are seen at the C5/6 disc.

**Figure 5b: (below)** Patient 1 – Axial T2 MRI scan showing large left C6/7 disc protrusion causing spinal cord compression.





## DISCUSSION

Total disc arthroplasty represents the latest technological innovation available in spine surgery. The technology has been available for some years in Europe but is still in trial stages in the United States of America. As with any new technology or surgical technique caution must be applied to its use. While lumbar disc prostheses have been widely available for more than 20 years cervical disc prostheses have a shorter follow-up available for assessment. As a result the long term sequelae and possible complications that may ensue are not yet proven. In Australia single level lumbar disc arthroplasty was given

Medical Benefits Schedule approval (MBS) in November 2006. Trials of cervical disc arthroplasty are still being carried out in Australia including this series of patients. The application to have cervical disc replacement receive MBS approval was rejected by the Medical Advisory Council until longer term results of its outcome were available.

## CERVICAL DISC ARTHROPLASTY

With the increasing sophistication of minimally invasive spine procedures around 80 per cent of cervical spine

surgery can now be performed by a posterior approach e.g. microdiscectomy, microforamenotomy and partial laminectomy. These procedures in most cases allow for decompression of the neural elements without the morbidity and muscle disruption that occurs with extensive cervical laminectomies. Central spinal cord compression however still requires an anterior exposure as it is not amenable to posterior cervical cord decompression due to the relative immobility of the cervical spinal cord. These patients have traditionally received anterior decompression, removal of disc material



**Figure 6a:** Patient 1 – Post operative x-rays showing Pro Disc C inserted. Dynamic views in extension



**Figure 6b:** Patient 1 – Flexion views show motion is preserved.



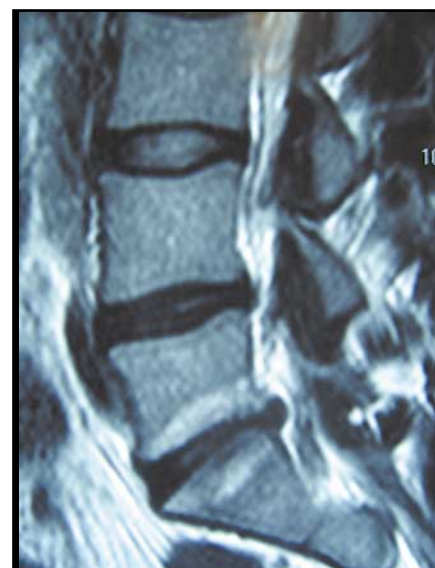
**Figure 7:** Patient 2 – Significant disc protrusions are seen at C5/6 and C6/7 causing spinal cord compression. Signal change in the spinal cord is seen.



**Figure 8a:** Patient 2 – Extension position.



**Figure 8b:** Patient 2 – Flexion showing physiological range of motion of C5/6 and C6/7 disc prosthesis.



**Figure 9:** Patient 3 – Sagittal T2 MRI scan showing advanced L5/S1 disc degeneration with L5/S1 disc protrusion, signal change in the vertebral endplates (Modic changes) indicate active disc degeneration. The L3/4 disc appears normal. The L4/5 disc shows mild degenerative changes with loss of signal and very slight disc protrusion.

and cervical fusion. It is for young patients with spinal cord compression that the insertion of a total disc arthroplasty is indicated.

With respect to cervical disc arthroplasty by maintaining the physiological range of motion at the surgical level it seems intuitive that reduction of stress loading and hence a reduction in adjacent segment degeneration will occur. All studies performed so far have shown anterior cervical disc replacement is identical to anterior cervical fusion in initial clinical outcomes of pain relief, decompression of neural elements, discharge from hospital and return to work.<sup>4</sup> No study to date has shown that disc replacement is superior over anterior cervical fusion procedures however as patient series such as this one evolve over time it is expected that the superior performance of the disc replacement will be demonstrated. So far, none of the patients in this series have developed symptoms from adjacent segment degeneration in the cervical spine. Longer term follow-up with this study and others will be required before longer time superiority over fusion is proven.

In order to maintain spinal balance, placement of the prosthesis in the midline and in a favourable position within the disc space is an essential part of the surgical technique. One of the criticisms of the Bryan disc prosthesis

was a tendency to kyphotic angulation which may occasionally occur as a result of intra-operative lordotic distraction.<sup>12</sup> This is one of the primary reasons that I now choose Pro Disc C as it does not have the same tendency towards kyphotic angulation. None of the patients with a Pro Disc C has developed post-operative kyphosis.

## LUMBAR DISC ARTHROPLASTY

While anterior cervical approaches to the spine are relatively common, anterior lumbar approaches have been considerably less so. Most lumbar pathology is approached posteriorly with procedures such as lumbar microdiscectomy, laminectomy, and pedicle screw fusion.<sup>13,14</sup> The indications for anterior lumbar approaches are relatively rare. Most surgical procedures in the lumbar spine require nerve root or cauda equina decompression and there is no doubt that this is best performed by a posterior exposure.<sup>13,14</sup> Anterior interbody approaches offer only a limited view of the neural elements and hence a limited opportunity to achieve adequate and safe decompression. With our increasing use of endoscopic techniques in the spine this may change in the future.<sup>15</sup>

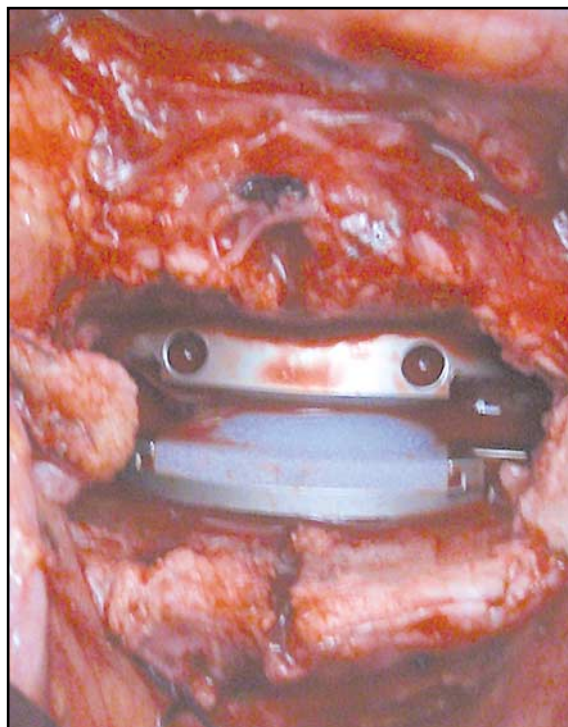
A relatively small number of patients with symptomatic lumbar degenerative disc disease will benefit from an anterior

lumbar interbody fusion and it is for these patients that lumbar disc arthroplasty may be indicated. Patients with high grade spondylolisthesis, acute infection or a tumour are contraindicated for the insertion of a lumbar prosthesis. Careful patient selection, as is the case with all surgical spinal procedures is mandatory to achieve a successful outcome in the lumbar spine.

For degenerative disc disease at L4/5 and at L5/S1 both the clinical outcome and the incidence of major neurological complications following the insertion of an artificial disc was found to be equivalent to those observed following a single level anterior lumbar interbody fusion 2 years following surgery.<sup>16,17,18</sup> The range of flexion and extension was restored and maintained with the artificial disc.

In a prospective study of total lumbar disc replacement with three year results of 92 patients better functional outcomes were obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation.<sup>13</sup>

Improvements were achieved for both monosegmental and bisegmental disc replacements. However patients who had bisegmental interventions had significantly inferior results at 12 and 24 months follow-up.<sup>13</sup> In a prospective study of 36 patients undergoing lumbar



**Figure 10a: (right)** Patient 3 – Intra-operative photograph showing the Pro Disc L positioned into the L5/S1 interspace.



**Figure 10b: (below)** Patient 3 – Post-operative lateral x-ray of L5/S1 Pro Disc L in position



total disc replacement using a Pro Disc L significant benefits in reduction of VAS for low back and leg pain were reported.<sup>17</sup> Scores were reduced from 7.5 and 4.7 to 3.0 and 1.2, respectively. At a minimum follow up of two years the lumbar total disc replacement showed excellent clinical and radiographic outcomes without any significant complication.<sup>17</sup>

One criticism of early studies of lumbar disc replacement has been that a significant number of disc prostheses spontaneously fused. As motion preservation is the driving force behind total disc replacement technology the post operative range of movement measurement is an important part of follow-up. In all our cases a range of movement of greater than five degrees has been observed indicating that motion preservation has been attained. Accurate midline placement of the disc prosthesis is paramount in achieving and ensuring mobility.

## ANTERIOR LUMBAR EXPOSURE

The anterior approach to the thoracic and lumbar spine is used for various indications. With the advent of prosthetic intervertebral disc replacements its use has become even more frequent. Serious vascular complications have been reported due to injury to arterial and venous structures while attempting to insert lumbar disc prostheses. The aortic bifurcation lies anterior to the vertebral body of L4. The vena cava arises at the level of the L5 vertebral body.

There is a significantly higher risk of vascular injury when the L4/5 segment is approached. The surgical exposure of the L5/S1 interspace is relatively safer as it involves less mobilisation of the major vascular structures. The anterior approach to the lumbar spine requires the assistance of an experienced vascular surgeon.

Sexual dysfunction after anterior lumbar fusion surgery is a relatively rare but much feared complication of the exposure. This is thought to occur due to damage of the pre-sacral nerves at the L5/S1 level. Literature reports an incidence of retrograde ejaculation of up to four per cent following anterior lumbar surgery. In one study of sexual

function in men and women after anterior surgery for chronic low back pain the surgically treated patients were found to have a significantly better sex life than those non-surgically treated. Improved sex life was associated with a reduction in back pain.<sup>19</sup> To help reduce the risk of pre-sacral nerve dysfunction we employ a nerve preserving technique in dissecting the pre-sacral fascia. All male patients are counselled extensively prior to consideration of surgery. No incidences of sexual dysfunction have so far been reported.

## CONCLUSIONS

The historic progression of cervical arthroplasty is based on the clinical success encountered with hip, knee and subsequently lumbar arthroplasties. Despite the positive short term outcomes with cervical fusion, up to 25 per cent of patients who undergo ACDF will require another surgery within 10 years primarily for adjacent segment disease. Preserving and restoring natural motion of the cervical spine is intuitively desirable in the treatment of cervical disc disease. If primary clinical outcomes from the use of cervical arthroplasty can match or surpass those of cervical arthrodesis a new treatment standard for cervical disc disease will have emerged.

Total disc replacement holds the promise of achieving the goals of decompression of neural elements, removing the pain source whilst maintaining mobility to preserve and maintain spinal balance. There are numerous types of disc prostheses in design, under study or in development, so that well designed prospective randomised control trials are needed before approval or widespread application of this technology can be used. My initial results indicate that the use of the Prod Disc C and the Pro Disc L is safe and biocompatible and demonstrates excellent results in human short term studies. The patients have shown a rapid return to normal function with maintenance of physiological movement, decompression of neural elements and relief of pain. Longer term clinical studies are necessary and are in progress.

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# Advances in the Role of Laparoscopic Surgery in Upper Gastrointestinal Surgery

## INTRODUCTION

Laparoscopic cholecystectomy was the procedure performed by Dr Mouret in 1987 two decades ago which sparked a revolution in gastrointestinal surgery. Since that seminal operation surgeons throughout the world have attempted and successfully performed almost all abdominal operations laparoscopically.

The controversy of the benefits of laparoscopic over open surgery still rages for many of the routine and not so common operations in spite of the mounting evidence in the literature of the benefits of minimally invasive surgery. The advantages so often cited in the literature are less pain, quicker recovery and earlier return to normal activity. This is a result of the small incisions which are required to perform laparoscopic surgery. What is not mentioned is the clear, well illuminated and magnified view of the operative field which the surgeon

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enjoys. In the upper abdomen many operations which were performed by surgeons using touch are now operations in which we can clearly visualise the structures which we are operating upon.

The advancement of complicated laparoscopic surgery has in the main been in the domain of the upper gastrointestinal surgeon, though other specialties have now included laparoscopic techniques in their surgical armamentarium. At St Vincent's Hospital we provide a comprehensive advanced upper gastrointestinal

laparoscopic service to patients referred from other specialist units within the hospital such as the heart/lung transplantation, gastro-enterology, endocrinology and haematology units and we also receive outpatient referrals for advanced laparoscopic surgery. The types of procedures we have performed are listed in Table 1.

In this brief overview of our experience with laparoscopic surgery I am going to limit further discussion to some of the oesophagogastric operations in which laparoscopy has significant advantages over open surgery.

## ANTIREFLUX SURGERY

The oesophagus and stomach have traditionally required large thoracic and abdominal incisions respectively to access these organs for surgery.

Following cholecystectomy the next condition that was enthusiastically treated by laparoscopic surgeons was reflux disease. We saw a ten fold increase in this type of surgery performed in the early 1990s only to see a decrease over time with the ready availability of proton pump blockers and a question as to the durability of the operation when

assessed at ten years. However in those patients with large volume reflux or symptomatic type II (paraesophageal) and type III hiatus hernias, laparoscopic antireflux surgery has been invaluable in management. Type II and III hiatus hernias sometimes require the use of a biosynthetic mesh to repair the defect in the diaphragm in order to reduce the recurrence rate.

St Vincent's has a large heart and lung transplantation programme which for lung transplantation was initiated in 1986. The 5 year survival figures for the programme have been in the order of 60%. The major obstacle for long term survival is the development of

bronchiolitis obliterans syndrome (BOS), the definition of which is a persistent decrease in FEV1 relative to the best post-transplant FEV1. Once present the condition is irreversible. The cause of this is thought to be multifactorial but there is a higher incidence of BOS in patients with gastro-oesophageal reflux. Injury to the lung is thought to occur with aspiration of gastric contents which becomes more common following transplantation surgery. Patients who have had a lung transplant are often asymptomatic for typical reflux symptoms. Therefore we now routinely investigate patients with BOS for reflux disease and more recently screen all patients following lung

### Oesophagogastric

**Benign**

- Excision of duplication cysts
- Antireflux surgery
- Heller's myotomy for achalasia
- Pyloroplasty for gastroparesis
- Gastric banding, bypass and sleeve gastrectomy for obesity

**Malignant**

- Staging of oesophago-gastric malignancy
- Oesophagectomy
- Partial and total gastrectomy +/- D2 lymphadenectomy
- Prophylactic gastrectomy( E-caderin gene abnormality)
- Gastroenterostomy for gastric outlet obstruction

### Pancreatic-Biliary

**Benign**

- Cholecystectomy
- Choledochotomy and transcystic exploration and removal of common bile duct calculi
- Cyst-gastrostomy ( drainage of pancreatic pseudocyst)

**Malignant**

- Staging of periampullary malignancy
- Distal pancreatectomy

**Liver**

- Management of liver cysts, including hydatid cyst
- Wedge resections for haemangiomas and fibronodular hyperplasia (FNH)

**Spleen**

- Splenectomy

**General Surgery**

- Groin hernia repair
- Incisional hernia repair
- Small bowel resection
- Appendicectomy
- Division of adhesions in small bowel obstruction

**Table 1:** Upper gastrointestinal and some general laparoscopic procedures performed at St. Vincents Hospital.

	Pre-NF	Post-NF
Total acid exposure% (normal <4%)		
Mean (SEM)	10.4(2.45)	1.14 (1.02)
Range	3.3-18.3	0-5.2
FEV1 (Litres) mean (SEM)	2.12 (0.13)	2.18(0.15)

**Table 2:** Results of oesophageal acid exposure and FEV1 pre and post Nissen fundoplication(NF)

transplantation for reflux. This is so that prophylactic antireflux surgery can be performed before the development of BOS. We now have the largest experience of laparoscopic antireflux surgery in lung transplant patients in Australia.

We have presented our experience of 30 lung transplant patients who underwent laparoscopic antireflux procedures over a 2 year period between May 2004 – May 2006 out of a total of 75 patients who underwent laparoscopic antireflux surgery on the campus. The outcome measures included 24hr pH monitoring and assessment of post-operative lung function.<sup>1</sup>

In **Table 2** the results of repeat pH probe testing showed a significant reduction in overall acid exposure post-NF ( $p=0.006$ ). There was an overall stabilisation in lung function with a mean increase in 60ml in FEV1 at 3 months post-NF ( $p=0.02$ ). There was a decline in the rate of fall of lung function post-NF in a subgroup of patients with early BOS. We are now of the view that routine surveillance and early management of gastro-oesophageal reflux disease may lead to improved long-term allograft function.

## OESOPHOASTRIC MALIGNANCY

Oesophogastric malignancy is an uncommon malignancy in Australia and its incidence is around 1:10,000 population. The majority of patients present with advanced disease and the overall 5 year survival is in the order of 20 per cent.

Staging of the disease is extremely important in order to prevent unnecessary surgery. Staging modalities include: CT scan; positron emission tomography scanning (which uses radiolabelled glucose to identify increased cellular proliferation); endoscopic ultrasound, especially useful for assessing T-stage (depth of invasion of the tumour) and fine needle aspiration biopsy to assess regional lymph node involvement. At St Vincent's hospital we have been using routine laparoscopic staging, which involves direct inspection of peritoneal and organ surfaces, biopsy of suspicious nodules, obtaining peritoneal cytology and laparoscopic ultrasound.

The staging modalities are complimentary however with laparoscopic staging we are able to detect an additional 30 per cent of patients with inoperable metastatic disease not detected by the other modalities. **Table 3** shows data from individual studies looking at the utility of laparoscopic staging and was presented at the Sydney Upper Gastrointestinal Surgical Society.<sup>2, 3, 4, 5</sup>

Obtaining peritoneal cytology at the time of laparoscopic staging adds to the sensitivity of staging. Positive peritoneal cytology for malignant cells should be considered as indicating metastatic disease. **Table 4** illustrates that the incidence of positive peritoneal cytology increases with the depth of tumour invasion into the wall. Even patients who appear to have early stage gastric cancer according to T staging may be found to have positive peritoneal cytology. Interestingly some patients with obvious peritoneal metastases do not necessarily have detectable positive peritoneal cytology.<sup>5, 6, 7</sup>

Laparoscopic surgery for upper gastrointestinal cancer is performed in only a few centres and this is due to the technical difficulty in performing these procedures and concern by some as to the adequacy of the surgery to meet oncological principles. There are two randomised trials which support the benefit of laparoscopic over open surgery for both early and advanced cancer.<sup>8, 9</sup>

At St Vincent's we have audited our initial experience of laparoscopic gastrectomy with a D2 lymphadenectomy and found that the oncological principles such as tumour free resection margins and an adequate number of nodes harvested was comparable with patients undergoing open surgery. The benefits of less operative blood loss, decrease in postoperative pain and a faster recovery were benefits which were evident in our patients as in previous reports. The time taken to perform laparoscopic resection was significantly longer than with open surgery as is seen with most new procedures but this has decreasing with experience. The data summarised in **Table 5** was presented at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) meeting in Las Vegas 2006.<sup>10</sup>

## GASTROINTESTINAL STROMAL TUMOURS (GIST)

These are uncommon tumours of the gastrointestinal tract which are characterised by the expression of the c-Kit gene which distinguishes them from smooth muscle tumours which are predominantly benign and sarcomas.

	Burke et al 1997	Possik et al 1986	Hunerbein et al 1998	Fenton-Lee 2005
Patients	104	352	389	26
Unresectable	24	123	141	10
Potentially Resectable	71	222	248	16
Resected	65	111	233	14
Correctly Predicted	91	50	94	88
Avoid Laparotomy	24 (23%)	123 (34%)	141 (36%)	10 (38%)

**Table 3:** Patients with gastric cancer were classified into unresectable and potentially resectable based upon findings at staging laparoscopy. Those that underwent resection were the true negatives and a correct predictive value could be calculated based on the false negative rate. The constant finding is the true positive rate of 30% ie those patients with metastases diagnosed only at laparoscopy and thus avoiding unnecessary surgery.



They occur throughout the GI tract but are most commonly found in the stomach (60 per cent). They metastasise via the bloodstream to lung, liver and bone but rarely to lymph nodes. Local excision with clear margins is adequate treatment. We have treated a number of patients with wedge excision and partial gastrectomy depending upon the size of the lesion. The larger the GIST and the more mitotic figures per high power field the more likely the tumours will behave in a malignant manner.

## FAMILIAL GASTRIC CANCER

There is a group of patients with a rare familial condition which predisposes them to developing cancer of the stomach. These patients carry an abnormality of the E-caderin gene which leads to the development of gastric cancer in 80 per cent of carriers. The difficulty in managing these patients is that we are unable to predict which patients will develop the cancer. The risk of developing the cancer increases with age and most patients will develop cancer by the age of 40 years. Also these patients may develop aggressive submucosal cancers which may metastasise whilst being enrolled in a surveillance programme. The recommended treatment is prophylactic gastrectomy before the tumour becomes advanced and cure is compromised. Patients have been reluctant to undergo major prophylactic surgery but less so if laparoscopic surgery is available knowing that the laparoscopic approach offers a less painful and quicker recovery. The first laparoscopic prophylactic gastrectomy for this condition in Australia was performed at St Vincent's Hospital in 2006.

## OTHER UPPER GASTROINTESTINAL CONDITIONS PARTICULARLY AMENABLE TO LAPAROSCOPY

Oesophagogastric duplication cysts are uncommon but require resection when they become symptomatic. These cysts are unlikely to involve the mucosal

layer and can be dissected out without breaching the lumen of the gut and therefore alimentary intake can be recommenced shortly after surgery allowing early discharge from hospital. Thorascopic and laparoscopic resection are excellent techniques for removing these benign lesions with minimal morbidity.

Achalasia has for many years been treated by non-operative means, primarily endoscopic balloon dilatation and more recently by botulinum toxin injections into the lower oesophageal sphincter. They produce good symptomatic relief but recurrence rates are high and the risk of perforation of the oesophagus is a significant risk with repeated dilatation. Surgery that requires laparotomy has never been popular but laparoscopic Heller's myotomy together with an antireflux procedure is the procedure of choice for the treatment of achalasia especially in younger patients and produces good long term symptomatic relief.

## BARIATRIC SURGERY

Bariatric surgery has been revolutionised by laparoscopic surgery and is the fastest growing discipline within surgery of the alimentary tract. Obesity is in epidemic proportions in western countries resulting in an increased incidence of diabetes mellitus, hypertension, reflux, osteoarthritis, sleep apnoea and a host of other co-morbidities. Surgery has been proven to be the most effective treatment for long term weight loss and as a result leads to the resolution of these co-morbidities and results in increased life expectancy.<sup>11</sup> The two most common

procedures performed in the world are laparoscopic adjustable gastric banding and laparoscopic gastric bypass. Here in Australia the most widely performed procedure is the band and in the U.S it is the bypass procedure but this is gradually changing as the band has become FDA approved in the U.S. There is no doubt that the laparoscopic placed band has 10 times less mortality than the bypass procedure and also avoids the problems of vitamin and mineral malabsorption which can occur with the latter procedure. In the U.S the health insurance agencies and government bodies have made accreditation of both institutions and surgeons compulsory in order to reduce the mortality rate of the bypass procedure. The banding procedure is a much easier procedure to perform and therefore has not alarmed the public with its rate of morbidity and mortality. The results of the band versus the bypass procedure in terms of weight loss and reduction in the co-morbidities are similar. The definition of success is a weight loss of greater than two thirds of the patients excess body weight. We have performed over 200 laparoscopic band procedures with no mortality and a success rate of 80 per cent. I think that there is a place for both procedures depending upon individual circumstances and preference but I emphasise to patients that the band is a safer procedure with morbidity that can be more easily managed than that arising from the bypass procedure.

## THE FUTURE

We have already seen the use of robotics to assist surgeons with laparoscopic surgery. As the cost of

	Bentrem 2005 Positive cytology(%)	Kodera Y 2002 Positive cytology (%)	Fenton-Lee 2005 Positive cytology (%)
T1		1/68 (1.5)	0/3 (0)
T2	4/176 (2)	3/52 (5.8)	0/0(0)
T3		25/55 (46)	1/11 (9)
T4	19/181 (10)	6/14 (43)	0/2 (0)
Peritoneal metastases	(59)	18/26 (69)	3/10 (30)

**Table 4:** The stage of tumour invasion(T1-4) and the presence of peritoneal metastases was correlated with finding malignant cells in peritoneal fluid(positive cytology) in these three separate studies.

robotic surgery decreases and with development of the next generation of easier to use robots we may well see them being used on a routine basis in upper gastrointestinal surgical procedures.

The other exciting development is in a field called natural orifice trans-enteric surgery (NOTES). Access to the abdominal cavity is gained by puncturing a hole in the stomach or other viscera with an endoscopic instrument and performing procedures in the abdominal cavity which results in scarless surgery. The instruments which are being developed for NOTES will also allow surgeons to perform procedures from within the lumen of the gut such as endoscopic Nissen fundoplication and removal of mucosal lesions which are currently too large to be removed with current endoscopic surgery.

The technological advances which are occurring with optical systems, magnification and instrumentation will enable a new generation of minimally invasive procedures to be performed.

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	Laparoscopic N=10	Open N=13
Age Median(Range) yrs	72(38-82)	70(43-80)
Sex M:F	9:1	10:3
Operation: Total gastrectomy Subtotal	4 6	9 4
Total time in theatre Median(Range) mins	446(385-703)	276(235-500)
Intraoperative Complications/ Conversions	Nil	Nil
Postoperative Complications	1 Radiological leak	Nil

**Table 5:** Comparison of laparoscopic versus open gastrectomy performed by author at St Vincent's Hospital 2005-2006.



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- Pain
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- Alzheimers Disease
- Adult stem cell research

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