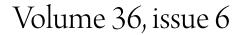
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# Canadian Journal of Surgery Journal canadien de chirurgie

Vol. 36, No. 6, December 1993/décembre 1993

- Pediatric Free Tissue Transfer
- New Cardiac Surgery Program
- Cemented and Noncemented Knee Prostheses



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# Canadian Journal of Surgery Journal canadien de chirurgie

Vol. 36, No. 6, December/décembre 1993 ISSN 0008-428X

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*CJS* is printed by RBW Graphics, Owen Sound, Ont. and published every 2 months (February, April, June, August, October, December). Postage is paid at Owen Sound. Publications mail registration no. 5375. US 2nd-class postage paid at US Office of Publication: Champlain, NY (USPS no. 762–530).

Annual (1994) subscription rates for Canada: Canadian Association of General Surgeons. Canadian Orthopaedic Association. Canadian Society for Vascular Surgery, Canadian Society of Cardiovascular and Thoracic Surgeons and Canadian Society of Surgical Oncology members \$25 (included in annual membership fee); Royal College of Physicians and Surgeons of Canada \$25; nonmembers \$60 (\$33 for trainees in surgery in Canada only); for all other countries \$65 (US). Single copies (current issue) \$10, back issues \$11. (Note: in Canadian \$ to Canadian addresses and in US \$ to all other addresses.) Canadian orders are subject to 7% GST.

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Le *JCC* est imprimé par RBW Graphics, Owen Sound (Ont.) et publié aux 2 mois (février, avril, juin, août, octobre, décembre). Port payé à Owen Sound. Courier de publications nº 5375. Tarif postal 2º classe US; port payé au bureau de publication aux États-Unis : Champlain, NY (USPS nº 762–530).

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# Is the Increasing Frequency of Laparoscopic Bile Duct Injury Justifiable?

Roger G. Keith, MD, FRCSC

Chairman, Department of Surgery, University of Saskatchewan, Saskatoon, Sask. Coeditor, Canadian Journal of Surgery

n this issue (pages 509 to 516) Roy and colleagues report on 21 cases of serious bile duct injuries managed at two Canadian University centres between June 1991 and June 1993. During that time the majority of general surgeons in the two catchment areas changed from open to laparoscopic cholecystectomy as the procedure of choice for biliary tract disease. Because the population at risk is indeterminate for this study, a true incidence of bile duct injury during laparoscopic cholecystectomy could not be assessed. None the less, this report has merit in identifying a problem of increasing frequency.

Girard and Morin<sup>1</sup> studied over 10 000 open cholecystectomies accrued between 1971 and 1990 at one of the university centres contributing to the present report. Twenty-four (0.26%) bile duct injuries occurred in 9339 patients having cholecystectomy alone; however, only 7 (0.07%) of the injuries involved transection or resection similar to those reported by Roy and colleagues. Extrapolation of the higher injury frequency to average accrual for Girard and Morin's series would yield 1.26 injuries in 492 open cholecystectomies per year.

The number of bile duct injuries reported by Roy and colleagues is 10.5 per annum. To recognize an incidence comparable to that for open cholecystectomy, it would require that 4100 laparoscopic cholecystectomies be performed annually in the catchment area served by the authors. If the data of Deziel and associates,<sup>2</sup> who reported on 77 604 laparoscopic cholecystectomies performed in the United States at hospitals with over 50-bed capacity, were taken into consideration, Roy and colleagues would require that all bile duct injuries from laparoscopic cholecystectomy in 60 hospitals be referred to the two reporting centres.

Whether the incidence of biliary injury has plateaued or is increasing is debatable. Regardless, the combined rate of early and late biliary injuries is higher than that which became tolerable for open cholecystectomy during the past decade.

In 1991, Cuschieri and associates<sup>3</sup> reported a 0.33% rate of bile duct injury from seven European centres of excellence for laparoscopic cholecystectomy. Other good results<sup>2,4-6</sup> report incidences of up to 0.6%. Recently, Moosa and colleagues,<sup>7</sup> Adams and associates<sup>8</sup> and Davidoff and associates<sup>9</sup> have reported an alarmingly high frequency of bile duct injuries after laparoscopic cholecystectomy. Wexler and colleagues,<sup>10</sup> in a Canadian survey, noted that injuries occurred beyond the learning curve.

As Roy and colleagues indicate in their paper, the nature of bile duct injuries associated with laparoscopic cholecystectomy is more serious than that with the open technique. Frequently the bile duct is resected, the proximal injury is high and the duct diameter is small. The high failure rate after attempted primary duct-to-duct anastomosis must be emphasized because the subsequent repairs will be at the level of the hilum or above. Recurrent stricture, biliary cirrhosis and transplantation can be avoided by technically expert biliary enteric reconstruction when the injury is first repaired. Referral should not be considered an admission of inability but rather evidence of wise judgement.

The responsibility of surgical departments during the new era in health care delivery will include critical audit as part of the changes engendered by quality management. Lowered incidence of biliary injury associated with laparoscopic cholecystectomy will be expected as part of continuous quality improvement. In order to comply, it will be necessary to record accurately the frequency of injury per case volume per surgeon, institution and region. Prospective data collection may yield true figures for purposes that are not necessarily aligned with clinical research. It is justifiable to report, within the profession, the concerns expressed by Roy and colleagues so that the surgical community will recognize the need for self-modulation without legislation.

#### QUILL ON SCALPEL

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# MacLean-Mueller Prize

Jonathan L. Meakins, MD, FRCSC; Roger G. Keith, MD, FRCSC

Coeditors, Canadian Journal of Surgery

The Editorial Board of the Canadian Journal of Surgery (CJS) and the Director of Publications of the Canadian Medical Association take pride in announcing the creation of the MacLean-Mueller Prize. This award will be presented annually for the best manuscript written by a resident or fellow from a specialty program affiliated with one of the five sponsoring associations and societies of the CJS.

The prize recognizes the contributions made by Drs. C. Barber Mueller and Lloyd D. MacLean during their terms as coeditors of the Journal. They have been responsible for sustaining broad support and contributions to the Journal from the Canadian surgical specialty societies, which currently contribute in financial terms, through scholarly editorial input and submission of papers. It is fitting that this award will be presented for the work of residents who are contributing to surgery through publication, a medium to which these two pillars of Canadian surgery made a lifelong commitment.

The Canadian Medical Association, as publisher of the *CJS*, has established an award of \$1000, and the prize winner will also receive a certificate. At the time of submission of the manuscript, the resident or fellow must not have completed training nor have assumed a faculty position. Deadlines for each calendar year will be in keeping with those of annual meetings or resident research presentations of the specific societies, but papers must be in the Journal's Saskatoon office by Oct. 1, 1994, for the first competition. Papers should be submitted through the sponsoring society. The winning paper will be published in the first issue of the *CJS* of the succeeding year.

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### CORRESPONDENCE CORRESPONDANCE

#### Anterior Mediastinal Masses After Cancer Therapy: Recurrences or Benign Lesions?

To the editors. The development of an anterior mediastinal mass in the follow-up of a patient treated for malignant disease is always worrisome for the clinician. Although recurrent malignant disease is always a possibility, an increasing number of reports have raised the possibility of a benign lesion of the thymus. Recently, we have seen two cases of thymic lesions, in patients treated for lymphomatous disease.

#### **Case Reports**

#### Case 1

A 40-year-old woman was first seen in November 1989 for investigation of an enlarged cervical node and lower-limb edema. A complete work-up, including computed tomography (CT) of the chest and abdomen, gallium scanning and bone marrow and cervical node biopsies revealed a nonHodgkin's lymphoma of the mixed diffuse and nodular type, classified as stage IIIA (the National Panel Working Formulation classification<sup>1</sup>). Over a 6-month period, this woman received seven cycles of combination chemotherapy, including cyclophosphamide, vincristine, prednisone, bleomycin, Adriamycin and procarbazine (COP-BLAM). Follow-up CT of the chest and abdomen in May 1990 showed no abnormalities. However, repeat follow-up CT 1 year later revealed a large mass in the anterior mediastinum measuring

 $5 \times 3 \times 2$  cm. The patient was asymptomatic. Gallium scanning showed an abnormal uptake in the upper chest. Sternotomy with thymectomy revealed a massive thymic hyperplasia with no evidence of malignant disease.

#### Case 2

A 17-year-old previously healthy patient was admitted in September 1990 for investigation of a right supraclavicular mass and an enlarged mediastinum. There were no other palpable lymph nodes. After a complete work-up, which included lymphangiography, CT of the chest and abdomen, gallium scanning, a bone marrow biopsy and a biopsy of the supraclavicular mass, a diagnosis of stage IIA Hodgkin's disease of the sclerosing nodular type, with "bulky mediastinal disease" was made. The patient received six cycles of combination chemotherapy, including, mechlorethamine, vincristine, procarbazine, prednisone, Adriamycin, bleomycin, vinblastine (MOPP/ABV) followed by mediastinal and cervical irradiation over a 25-day period for a total of 36 Gy.

Follow-up CT of the abdomen and thorax in July 1991 showed a large mass, 7 cm in dimension, in the anterior mediastinum. Gallium scanning gave negative results. The mass was excised and found to be a combination of thymic involution scarring and multiple retention cysts. As of September 1992 he was free of disease.

#### Comment

When masses develop after therapy for cancer, recurrence of the

malignant disease has to be ruled out first. If the mass is in the anterior mediastinum, thymoma is a possibility, although most of the cases followed immunosuppression with cyclosporine in experimental animals and in transplant patients.2 Thymic hyperplasia was reported after chemotherapy in children and adolescents as a rebound phenomenon.3 Some authors4,5 have postulated that the development of thymic hyperplasia after treatment of malignant disease is a good prognostic sign because it indicates restoration of the host's immunity. Surgery in these cases was required in the early experience from the M.D. Anderson Hospital in Houston, Tex., but in the later cases a steroid test eliminated the need for biopsy.6 In adults, most of the cases have been reported after treatment for lymphomas or germ cell tumours,7,8 and in most cases, surgery was performed through a thoracotomy or a sternotomy to excise the abnormal mass. Gallium scanning in these situations is not helpful because abnormal uptake is seen both in recurrence and thymic hyperplasia. Recognition of the possibility of thymic hyperplasia and steroid testing will eliminate unnecessary surgery.4,6 In fact, as Ford and associates6 showed, these patients should be treated with predisone, orally, at a dosage of 60 mg/m<sup>2</sup> daily for 7 days if the initial diagnosis is not steroid-sensitive leukemia or lymphoma. If the mediastinal changes regress, the patient should be followed up by serial chest radiography. If the mass remains unchanged or enlarges, then an open biopsy of the mass should be performed.

### HOW I DO IT COMMENT JE M'Y PRENDS

# Beware of the Trendelenburg Position During Prolonged Laparoscopic Procedures

Josée Gagnon MD; Eric C. Poulin MD, FRCSC

**M** any laparoscopic surgical procedures are currently being evaluated. Some, like laparoscopic sigmoid resection, require placement of the patient in the Trendelenburg position to maintain the small bowel above the pelvic rim and to improve exposure during surgery. This increases the possibility of brachial plexus injury during prolonged surgery, as our recent experience demonstrated.

#### **Case Report**

A 48-year-old woman underwent an uncomplicated 3-hour laparoscopic sigmoid resection for recurrent diverticulitis. The next morning it was obvious that she had sustained a left brachial plexus injury. She had a flaccid and numb left arm and forearm and a partial Horner syndrome with complete involvement of the plexus. Her condition resolved completely over a period of 5 months.

#### Comments

The patient's positioning had been standard for a general surgical procedure. Her head had been centred and her upper extremities placed at 80° on armboards with a locking mechanism to forestall hyperextension.

The cause of most peripheral nerve injuries in anesthetized patients is ischemia of the vasa nervorum. This results from stretching of a nerve and then compression of that already vulnerable nerve. Injuries occur more readily during general anesthesia when muscle tone is diminished and when the unconscious patient cannot respond to postural insults. Nerve palsy can be produced within 30 minutes if the patient is in an unfavourable position.

The brachial plexus is the most susceptible of all nerve groups to damage from malpositioning during anesthesia. It has a long, mobile, superficial course in the axilla between two firm points of fixation the vertebrae and the axillary fascia. It also lies close to a number of freely movable bony structures. Damage is produced by any factor that increases the distance between the points of fixation. The plexus may be depressed caudally by being stretched over the head of the humerus with the extremity abducted when the patient is in the Trendelenburg position (Fig. 1). Five situations are then especially hazardous:1

• When the patient's head is in dorsal extension and lateral flexion to the opposite side. This widens the angle between the head and the shoulder and stretches the plexus.

• When the upper extremity is abducted from the table at an angle of more than 90°. The plexus is then stretched by the head of the humerus and coracoid process, especially if the extremity is externally rotated and dorsally extended.

• When shoulder braces are

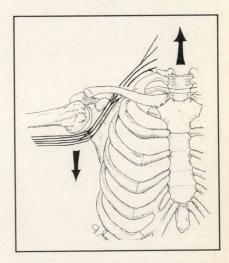


FIG. 1. Diagram of relationship between brachial plexus and surrounding bony structures. Arrows indicate directions of pressure applied.

From the Department of Surgery, Hôpital du Saint-Sacrement, Université Laval, Québec, Que.

Accepted for publication June 14, 1993

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used and placed too medially. In this situation they depress the clavicle caudally and posteriorly, compressing and stretching the plexus.

• When shoulder braces are placed too laterally, pushing the humeral head downward, carrying the plexus with it.

• When the patient is held by wristlets. In this case the humeral head is pulled downward, carrying the plexus with it.

Other factors that enhance the

risk of nerve injury include the following: abnormal anatomy (hypertrophy of the scalenus muscles, cervical rib), pre-existing metabolic conditions such as diabetes, atherosclerosis, anemia, blood dyscrasias and anticoagulant therapy, hypothermia, hypotension and the duration of malposition.<sup>2</sup>

After decades of use of the Trendelenburg position for diagnostic laparoscopic procedures in gynecology, brachial plexus injury was not

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even mentioned as a complication in a 1982 survey of 125 560 laparoscopic sterilizations.<sup>3</sup> The explanation may be that this procedure is of shorter duration or that in the gynecologic setting armboards are seldom used. In general surgery, since we cannot avoid using the Trendelenburg position for some laparoscopic procedures, special precautions should be taken.

• The upper limbs should be kept at the patient's side, with the palms down or facing the thighs and a draw-sheet extending well above the elbows to hold the position. Wristlets should not be used to restrain the extremity.

• Shoulder braces should not be used to prevent the patient from sliding on the operating table. If the mattress is held firmly to the operating table, the patient seldom slides on the mattress. If braces are used, they must be placed over the acromia, and they should never be used with an abducted upper extremity.

• The patient's head should remain in the midline.

• The extreme Trendelenburg position should be avoided.

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### ORIGINAL ARTICLES ARTICLES ORIGINAUX

# Bile Duct Injury During Laparoscopic Cholecystectomy

André F. Roy, MD, FRCSC;\* Ronald B. Passi, MD, FACS, FRCSC;\* Réal W. Lapointe, MD, FRCSC;† Vivian C. McAlister, MD, FRCSC, FRCSI;\* Michel H. Dagenais, MD, FRCSC;† William J. Wall, MD, FRCSC\*

*Objective:* To determine the nature of bile duct injuries during laparoscopic cholecystectomy, the treatment of these injuries and patient outcome.

Design: Case series review.

Setting: Two tertiary care hospitals.

Patients: Twenty-one patients (average age 37 years) who sustained bile duct injuries during laparoscopic cholecystectomy over a 2-year period. Two groups were analysed: patients whose injury was recognized intraoperatively (9 patients) and patients in whom it was diagnosed postoperatively (12 patients).

*Interventions:* Laparoscopic cholecystectomy, duct-to-duct repair over a T tube, Roux-en-Y hepaticojejunostomy, endoscopic cholangiopancreatography (ERCP), percutaneous transhepatic cholangiography (PTC).

*Results:* Misidentification of the common duct during laparoscopic cholecystectomy, resulting in accidental division or resection of a portion of the duct, and obstruction of the duct by hemoclips were the most common types of injury. Pain, jaundice and bile collections were the typical presenting features of injuries that became evident after laparoscopic cholecystectomy. ERCP and PTC accurately defined the injuries. Immediate duct-to-duct repair over a T tube was associated with a high failure rate. Twenty of the 21 patients required Roux-en-Y hepaticojejunostomy for definitive treatment. There were no deaths.

*Conclusions:* Proper identification of the pertinent anatomy will prevent the majority of these injuries. Prompt radiographic visualization of the biliary tract is indicated in patients who have pain, jaundice and bile collections postoperatively. A hepaticojejunostomy is the procedure of choice for repair of these bile duct injuries.

*Objectif :* Déterminer la nature des lésions du cholédoque qui surviennent durant une cholécystectomie laparoscopique, comment ces lésions sont traitées et avec quels résultats.

Conception : L'examen d'une série de cas.

Contexte : Deux hôpitaux de soins tertiaires.

*Patients* : Vingt-et-un patients (âge moyen, 37 ans) qui, au cours d'une période de 2 ans, subirent des lésions du cholédoque durant une cholécystectomie laparoscopique. Deux groupes ont été analysés : les patients dont les lésions furent reconnues durant l'intervention (9 patients) et ceux chez qui elles furent diagnostiquées en postopératoire (12 patients).

Interventions : Cholécystectomie laparoscopique, réparation bout à bout sur tube en T,

hépaticojéjunostomie de Roux en Y, cholangiopancréatographie endoscopique (ERCP), cholangiographie transhépatique percutanée (CTP).

*Résultats* : Les lésions les plus fréquentes étaient reliées à une mauvaise identification du cholédoque durant la cholécystectomie laparoscopique, résultant en une division ou une résection accidentelle d'une partie du canal, ou à l'obstruction du canal par une pince hémostatique. Douleur, ictère et collections de bile représentaient les signes cliniques caractéristiques des lésions qui se manifestèrent après l'intervention. Une ERCP et une CTP permirent de définir les lésions avec précision. Une réparation immédiate bout à bout sur un tube en T donna le plus haut taux d'échec. Vingt des 21

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#### Accepted for publication Oct. 4, 1993

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patients nécessitèrent une hépaticojéjunostomie de Roux en Y comme traitement définitif. Il n'y eut aucun décès.

*Conclusions :* Une bonne identification anatomique permettrait de prévenir la majorité de ces lésions. Une visualisation radiographique immédiate est indiquée chez les patients qui présentent de la douleur, de l'ictère ou des collections biliaires en postopératoire. Une hépaticojéjunostomie est l'intervention de premier choix pour réparer ces blessures du cholédoque.

ver the past 3 years, laparoscopic cholecystectomy (LC) has replaced open cholecystectomy (OC) as the preferred surgical management for symptomatic gallstones. The distinct advantages of LC for patients in terms of short hospital stay, minimal pain and quick recovery have been amply and convincingly demonstrated.<sup>1-4</sup> An overall complication rate of approximately 5% has been reported, and most complications are minor.1,5,6 The most serious complication of LC, excluding death, is injury to the bile duct. During the era of OC. large surveys reported injury to the common duct in 1 to 2 cases per thousand cholecystectomies.7-9 It has become evident that the incidence of common duct injuries is several times higher with LC.1 Although some reports document that injury of the duct tends to be more common earlier in a surgeon's experience with the operation,1,10 a recent Canadian survey suggests that the incidence may not decrease with experience.<sup>11</sup> Regardless of whether injuries of the duct will become less frequent, it is important to document how they occur and how they are managed. Only through this type of analysis will it be understood how bile duct injuries are best avoided during LC and, just as importantly, what is the ideal way to manage the injuries when they occur.

We report on 21 patients who sustained injury to the bile duct during a 2-year period and were referred for management to University Hospital, London, Ont., and to the Hôpital Saint-Luc, Montreal, Que.

#### Patients

Twenty-one patients (18 women, 3 men) underwent LC between June 1991 and June 1993. The mean age was 37 years (range from 22 to 53 years). All operations were elective. Dissection was done with electrocautery in every instance. None of the patients was excessively obese.

The patients were divided into two groups. In nine patients an injury to the bile duct was recognized during LC (group 1). In the remaining 12 patients the injury was diagnosed postoperatively (group 2). For a classification of the level of the injury to the common duct, we adopted the Bismuth classification12 of strictures of the common duct: type I — hepatic duct stump more than 2 cm long, type II - hepatic duct stump less than 2 cm long, type III — no hepatic duct but confluence intact, type IV right and left duct separated and type V - involvement of sectorial right duct with or without injured common duct.

#### Findings

#### Group 1 (Table I)

In none of these cases was the LC described as difficult, and there was no indication that anomalies were present to confuse the anatomy. In seven patients injury of the bile duct resulted because the common duct was erroneously identified as the cystic duct. Only after the bile duct had been clipped and divided or a portion of it had been excised was the injury recognized. A frequent observation was persistent bile staining of the operative field or visualization of a "second duct" after division of what had been interpreted as the cystic duct. In two patients perforation of the bile duct occurred as a result of the application of electrocautery with the dissecting hook. The perforations were recognized when continued bile leakage was noted in the operative field.

In three patients who had accidental resection of a portion of the common duct, a drain was placed when the injury was recognized, and they were transferred the same day for management of the injury. Each patient had a laparotomy and underwent a Roux-en-Y hepaticojejunostomy within 24 hours. Operative identification of the proximal bile duct was not difficult with these fresh injuries. The patients recovered without complication and were well at follow-up 2, 8 and 23 months later.

Four patients had conversion of the LC to a laparotomy and a duct-to-duct anastomosis over a T tube. The operative notes indicated that the ducts were uniformly small in calibre, and the anastomosis was often described as being under slight tension. In two of the four patients, leakage of contrast material at the site of the anastomosis was seen on the initial postoperative T-tube cholangiogram. In each of these four patients the duct-toduct repair failed, and strictures developed between 6 weeks and 6 months after the initial repair. The patients became jaundiced, and percutaneous transhepatic cholangiography (PTC) demonstrated type III strictures in two patients and type IV strictures in two patients. In each patient the duct-to-duct repair was revised with a hepaticojejunostomy, and they were well at followup 3, 4, 16 and 22 months after reconstruction.

The two patients with electrocautery injuries had the LC converted to a laparotomy, and a T tube was inserted in the common duct. One patient (Table I, no. 5) was well 11 months later, and the other patient (Table I, no. 7) had a type I stricture 6 weeks after LC and required a hepaticojejunostomy. He was well 4 months after repair.

Eight of the nine patients in this group either initially or ultimately had a hepaticojejunostomy to repair the bile duct injury.

#### Group 2 (Table II)

Ten of the 12 patients in whom the bile duct injury was diagnosed after LC presented within the 1st postoperative week. Jaundice was present in seven of them, upper abdominal pain in five, bile collections in five and fever in three. Of the two patients who presented after the 1st postoperative week, one presented with jaundice 2 weeks after LC and the other with pruritus and jaundice 3 months after LC.

In 7 of the 12 patients, the operative notes revealed nothing of concern noted by the surgeon during LC to suggest that an injury to the bile duct had occurred. The operations were considered to have been straightforward. In four patients, however, troublesome bleeding had been encountered during LC; the bleeding was controlled by the application of between one and two dozen hemoclips. In two of the four, the surgeon noted that severe inflammation of the gallbladder had made the LC difficult. In the remaining patient (Table II, no. 19), bile was noted in the right upper quadrant at the end of LC, and for that reason a drain was left in place.

The patients were referred as early as 3 days after LC, when it was evident there was a problem, and as late as 3 weeks after the onset of signs or symptoms. Endoscopic retrograde cholangiopancreatography (ERCP) was attempted in all patients; it was successful in nine patients. It showed complete biliary obstruction with visualization of the distal bile duct only in seven patients and partial obstruction of the common duct with some filling of the proximal duct in two patients. In 11 patients PTC demonstrated the proximal biliary tree and the level of obstruction. Extravasation of contrast medium into the subhepatic space was noted in three patients.

Eight of the 12 patients had a Roux-en-Y hepaticojejunostomy as primary repair of the injuries, and the procedure was successful in 7 of them. One patient (Table II, no. 17) subsequently required resection of the right hepatic lobe for a recurrent intrahepatic stricture of the right hepatic duct. The biliary reconstructions were performed from 4 days to 5.5 months after LC. When the reconstruction was performed within 1 or 2 weeks of LC, the operative findings were usually clear enough to determine what mishap had occurred during LC. It was evident that there had been extensive dissection both on and to the left of the common duct, and in

					Treat	ment	
Patient no.	Age, yr	Sex	Injury (level)	Cause of injury	First repair	Second repair (mo after LC)	Outcome (mo)
1	30	F	Segment of common duct excised (II)	Misinterpretation of anatomy	Same day hepaticojejunostomy	Not required	Well (23)
2	32	F	Segment of common duct excised (III)	Misinterpretation of anatomy	D–D anastomosis over T tube	Hepaticojejunostomy (4)	Well (4)
3	36	F	Division of common duct (III)	Misinterpretation of anatomy	D–D anastomosis over T tube	Hepaticojejunostomy (1.5)	Well (22)
4	25	F	Segment of common duct excised (IV)	Misinterpretation of anatomy	D–D anastomosis over T tube	Hepaticojejunostomy (6)	Well (16)
5	35	F	Perforation of right hepatic duct (V)	Electrocautery	T-tube insertion	Not required	Well (11)
6	22	F	Excision of common duct confluence (IV)	Misinterpretation of anatomy	Same day hepaticojejunostomy	Not required	Well (8)
7	52	М	Burn and perforation of common duct (I)	Electrocautery	T-tube insertion	Hepaticojejunostomy (1.5)	Well (4)
8	26	F	Segment of common duct excised (I)	Misinterpretation of anatomy	Same day hepaticojejunostomy	Not required	Well (2)
9	46	F	Division of proximal common duct (IV)	Misinterpretation of anatomy	D–D anastomosis over T tube	Hepaticojejunostomy (6)	Well (3)

two patients the lateral aspect of the portal vein had been exposed. Segments of the common duct were missing or, especially when bleeding had been encountered during LC, many hemoclips had been applied to the common duct and periductal tissues. When reconstruction was not performed until several weeks after LC, considerable inflammation and scarring were always present, with hemoclips embedded in the scar and in strictured segments of the common duct.

Patient no. 13 (Table II) had a laparotomy 5 days after LC when an ERCP showed complete obstruction of the common duct by two hemoclips. The two clips intended for the cystic duct were found encroaching on the common duct near the junction of the two ducts. The clips were removed, and the patient

was referred for hepaticojejunostomy 7 months later when a stricture developed at the site. Presumably, the clips had produced enough of a crush injury that healing of the duct by fibrosis was the result. Two patients (Table II, nos. 14 and 19) had bilomas drained externally without further investigation. The bile drainage ceased, but both patients had common duct strictures 3.5 and 5.5 months later requiring hepaticojejunostomy. One patient (Table II, no. 15) underwent exploration of the common duct, and a T tube was inserted for a type II stricture that was evident 3 months after LC. The stricture recurred, and revision to a hepaticojejunostomy was necessary at 13 months.

All 12 patients in this group required a hepaticojejunostomy either as the primary method of repair or for revision of a failed initial treatment.

#### **Illustrative Cases**

#### Patient 1, Group 1

During LC on this 30-year-old woman the surgeon clipped and divided what was believed to be the cystic duct. As the dissection progressed additional tissue in the area of Calot's triangle was clipped and divided, and the gallbladder was removed. Gross inspection of the gallbladder showed that a segment of common duct was attached to the cystic duct. The surgeon realized that a portion of the common bile duct had been resected, and the operation was terminated. After awaking from the anesthetic, the

			Problem		Type of	Treatm	ient		
Patient no.	Age, yr	Sex	encountered during LC	Postoperative complications (d)	obstruction/ stricture*	First repair (d after LC)	Second repair (mo after LC)	Outcome (mo)	
10	23	F	Many clips for bleeding	Jaundice (5)	III	Hepaticojejunostomy (42)	Not required	Well (19)	
11	37	F	Many clips for bleeding	Pain, jaundice (4)	II	Hepaticojejunostomy (35)	Not required	Well (15)	
12	36	М	Many clips for bleeding — difficult procedure	Jaundice (3)	1	Hepaticojejunostomy (4)	Not required	Well (13)	
13	40	F	Nothing noted	Pain, jaundice (3)	1	Laparotomy, removal of clips (5)	Hepaticojejunostomy (7)	Well (15)	
14	40	F	Nothing noted	Pain, fever, biloma (3)	III	External drainage (12)	Hepaticojejunostomy (5.5)	Well (13)	
15	41	F	Nothing noted	Pruritus, jaundice (90)	II	ECBD, T-tube insertion (3)	Hepaticojejunostomy (13)	Well (2)	
16	45	F	Many clips for bleeding — difficult procedure	Jaundice (14)	IV	Hepaticojejunostomy (14)	Not required	Transient bile leak, well (9)	
17	53	F	Nothing noted	Fever, pain, peritonitis, biloma (3)	V	Hepaticojejunostomy (14)	Right lobectomy and hepaticojejunostomy to left duct (14.5)	Well (6)	
18	30	F	Nothing noted	Biloma (7)	V	Hepaticojejunostomy to left duct, right lobectomy (84)	Not required	Well (2)	
19	36	F	Bile noted, drain placed	Biloma, fever, jaundice (7)	IV	External drainage	Hepaticojejunostomy (3.5)	Well (1)	
20	27	М	Nothing noted	Pain, jaundice (3)	II	Hepaticojejunostomy (17)		Well (2)	
21	22	F	Nothing noted	Jaundice, biloma (3)	III	Hepaticojejunostomy (11)	Not required	Well (2)	

patient was immediately transferred for repair of the injury. At laparotomy about 4 hours later, the proximal bile duct was identified, disclosing a type II injury. A Roux-en-Y hepaticojejunostomy was performed. The postoperative course was uncomplicated, and the results of liver function tests 23 months postoperatively were normal.

#### Patient 2, Group 1

A 32-year-old woman underwent LC for symptomatic gallstones. During the surgery, what was believed to be the cystic duct was clipped and divided. After the cystic artery was divided, a third structure was identified as the cystic duct. The surgeon realized that the common bile duct had been divided, and a laparotomy was performed. A type III injury was found with a gap of about 1 cm in the common duct. Duct-to-duct reconstruction over a T tube was performed, and the anastomosis was described as being under slight tension. An intraoperative T-tube cholangiogram showed good passage of dye into the duodenum and a leak of contrast material at the anastomosis (Fig. 1). The patient was referred postoperatively for continued management. The bile leak closed after 2 weeks, and the T tube was removed 3 months later. Four months after LC the patient

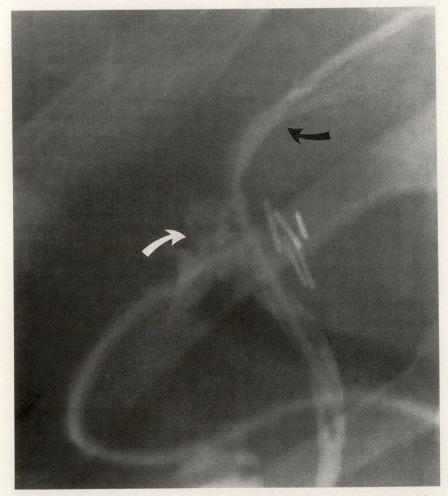


FIG. 1. Patient no. 2, group 1. Operative T-tube cholangiogram shows leak of dye from anastomosis (white arrow). Because proximal limb is in left hepatic duct (black arrow), there is no opacification of right hepatic duct.

became jaundiced, and ERCP and PTC disclosed a type IV stricture. A hepaticojejunostomy was performed and she was well 4 months after repair.

#### Patient 10, Group 2

During LC on a 23-year old woman, bleeding was encountered and controlled by the application of approximately 15 hemoclips. Progressive, painless jaundice and itch developed postoperatively. Five days after LC, the serum alkaline phosphatase level was elevated at 488 U/L (normal 18 to 113 U/L) and the serum bilirubin level was also elevated at 186 µmol/L (normal 3.4 to  $17.1 \,\mu mol/L$ ). Ultrasonography revealed dilated intrahepatic bile ducts. The patient was referred 3 weeks postoperatively at which time an ERCP disclosed complete bile duct obstruction by numerous hemoclips (Fig. 2). PTC demonstrated a type III injury (Fig. 3). She underwent a Rouxen-Y hepaticojejunostomy 6 weeks after the LC. The patient remained asymptomatic, with normal results of liver function tests 19 months after surgery.

#### Patient 14, Group 2

A 40-year old woman with symptomatic gallstones had LC. An intraoperative cholangiogram appeared normal. Three days later, right upper quadrant pain and fever developed. Ultrasonography showed a fluid collection, and a biloma was drained percutaneously 12 days after the LC. This resulted in clinical improvement. ERCP and PTC were attempted without success. A laparotomy was performed 2 weeks after the drainage procedure when the patient's clinical condition worsened. Bile peritonitis with dense adhesions was found. The leak was coming from a divided common

#### ROY ET AL

duct. Because of the local inflammation and the instability of the patient, a catheter was inserted into the proximal bile duct to create a controlled external biliary fistula. Cholangiography through the catheter demonstrated a type III injury. A Roux-en-Y hepaticojejunostomy with separate anastomoses to the right and left hepatic ducts was performed 5.5 months after the LC. The postoperative course was complicated by thrombosis of the right subclavian vein and spontaneous hemopericardium after anticoagulation. She recovered after 7 weeks in hospital and was well, with normal liver function, at follow-up 7 months after biliary reconstruction.

#### Discussion

The danger of injury to the common duct during cholecystectomy can never be eliminated, whether the gallbladder is removed by the laparoscopic or the open technique. The training of surgeons in the Halstedian tradition plus a century

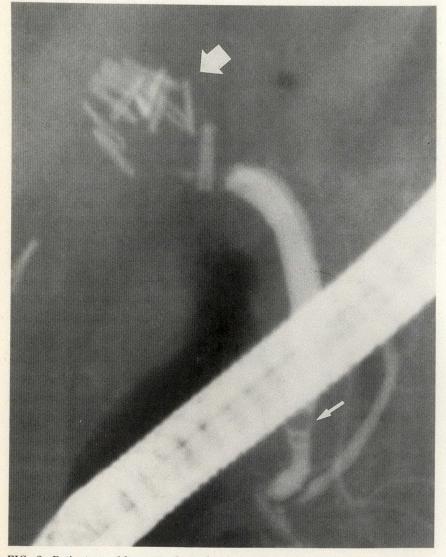


FIG. 2. Patient no. 10, group 2. Endoscopic retrograde cholangiography shows complete occlusion of common bile duct by multiple hemoclips (large white arrow). Air bubbles are seen in lower bile duct (small white arrow).

of experience in biliary tract surgery established OC as a technically safe operation. As OC is replaced by LC, injury of the common duct has emerged as a serious problem. Although some series record a very low incidence of common duct injury during LC, others report an incidence ranging from 0.6% to 1%, several times higher than that expected with OC.13-16 The tendency for accidents to be frequent early in a surgeon's experience with LC is best exemplified by the study of Davidoff and associates.<sup>10</sup> In that report, 10 of 12 bile duct injuries during LC occurred within the referring surgeon's first dozen laparoscopic procedures. A similar finding was reported by the Southern Surgeons Club.1

The injuries in our series demonstrated several characteristic features. When the injury was recognized during LC, the error that was most commonly responsible was misinterpretation of the common duct for the cystic duct. This mistake was the most frequent cause of injury in other reports too.10,17 Hunter18 has emphasized the importance of proper orientation of Calot's triangle in setting up the operative field to avoid this error. Lateral and inferior rather than upward retraction on Hartmann's pouch opens up Calot's triangle and increases the angle between the cystic and common ducts. This manoeuvre avoids cephalad tenting of the common bile duct, making it less likely to be mistaken for the cystic duct. The use of the 30° angle scope also permits a more en face view of Calot's triangle and provides better distinction between the relative positions of the cystic duct and the common duct. Only after the cystic duct and artery have been both dissected should either structure be clipped and divided. Precise adherence to the surgical principle of correct identification of the anatomy would have avoided injury in most of these cases. Persistent bile staining of the operative field and visualization of a "second duct" after division of what was identified initially as the cystic duct were common operative findings during LC that pointed to an injury of the bile duct.

The second commonest cause of injury during LC was dissection on and around the common duct that included the application of hemoclips to the common duct and the tissues surrounding it. The position of the common duct relative to the other structures should be constantly used as a reference point, but it is neither necessary nor desirable to actually dissect out the common duct. It was evident in this series of patients that extensive dissections had frequently occurred along the right side of the hepatoduodenal ligament, a manoeuvre that immediately puts the common duct at risk. Dissection in this area also increases the risk of bleeding by trauma to the hepatic artery or its right branch. This invites the next commonest mechanism of injury, namely the application of many hemoclips near the common duct to stop bleeding. The danger of applying many hemoclips has been reported recently, with a recommendation that only six hemoclips be used during LC and that more clips be applied only with caution and justification.19 If enough hemorrhage occurs that the position of the common duct is obscured, the repeated application of hemoclips to stop the bleeding is hazardous. The bleeding may result from direct injury to a specific

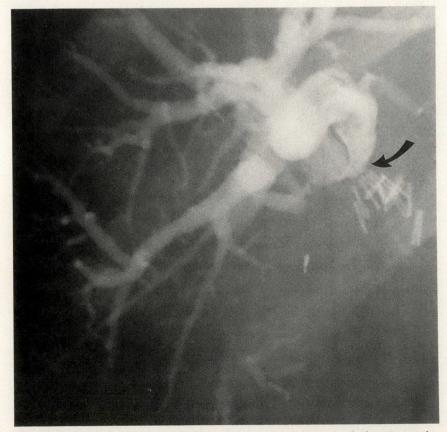


FIG. 3. Patient no. 10, group 2. Percutaneous transhepatic cholangiography shows Bismuth type III stricture with intact confluence but absence of hepatic duct (arrow).

vessel or it may be due to a severely inflamed or scarred gallbladder. Regardless of the cause, such a situation calls for a critical assessment of the need to convert the LC to an OC to avoid a bile duct injury.

Electrocautery injury of the bile duct was the least common mechanism of injury in this series. Vigorous use of electrocautery anywhere close to the common duct must be avoided. Thermal injury may create a hole that is immediately apparent, or the area of burn may heal by fibrosis and ultimately result in a stricture weeks or months later.<sup>10</sup>

When the common duct is inadvertently divided or a portion of it is resected, and the injury is recognized during LC, a duct-to-duct anastomosis over a T tube may seem the easiest, most expeditious solution. This type of repair is reported to have a high failure rate,<sup>20</sup> however, and this was demonstrated in our patients. Circumferential loss of length of the common bile duct or common hepatic duct, or both, is common, limiting the feasibility of a good duct-to-duct anastomosis without tension. In addition, the dissection during LC and burn from the electrocautery may have impaired the blood supply to the ends of the bile duct. The duct is usually nondiseased and small, permitting only a narrow calibre anastomosis that is predisposed to stenosis. Our preference for primary repair of a divided bile duct recognized during LC would be an immediate Roux-en-Y hepaticojejunostomy. The loop always has a good blood supply, the anastomosis is without tension and the long-term results with this type of reconstruction are good.<sup>21</sup> Although years of follow-up are necessary before declaring success with any type of biliary reconstruction, none of the patients in this series who underwent a hepaticojejunostomy either for immediate primary repair or for secondary reconstruction has so far needed a revision. If the surgeon performing the LC is not prepared to perform a reconstruction with a Roux-en-Y loop, immediate referral should be made to a centre where a hepaticojejunostomy can be performed within 24 hours of injury. A catheter may be left for interim drainage of bile to the exterior during the transfer. Insertion of a T tube may be appropriate treatment if there has been just a partial laceration of the bile duct.

Right upper quadrant pain, jaundice and a bile collection within days of an LC are a suggestive triad. Patients presenting with this symptom complex demand immediate investigation to exclude a bile duct injury. It is not adequate to drain a postoperative bile collection and await events. As shown in this series, patients with an injured bile duct will have serious signs and symptoms within several days after LC. A prompt diagnosis would allow reconstructive surgery soon after the injury, before sepsis and infected bile collections create adverse systemic and local conditions. Abdominal ultrasonography will often show dilatation of the intrahepatic biliary tree, but the most important test is a contrast study of the ducts. Our preference is an ERCP, because it will be diagnostic for a bile duct injury and it may be therapeutic if jaundice is due to a retained stone or if a nasobiliary catheter is required to control leakage of bile from a cystic duct stump. When the ERCP shows obstruction to the common duct the precise anatomy of the proximal duct is essential in planning reconstructive surgery. An ERCP may detail the proximal anatomy when the obstruction is incomplete, but a PTC is usually necessary to determine the exact level of injury and in particular whether the confluence of the right and left hepatic ducts is

intact. This information is needed to ensure that all obstructed ducts will be adequately drained at the time of reconstruction. Placement of a percutaneous transhepatic catheter in the proximal bile duct immediately before reconstruction may make identification of the duct easier at the time of surgery.<sup>22</sup> The best chance at repair of an injured duct is the first attempt, and factors that are important in the ultimate outcome after biliary reconstruction include the level of the stricture and prior attempts at reconstruction.<sup>23</sup>

More than half the patients in this series were in their third or fourth decade of life, and in more than half of them the injury or stricture was high (type III or above). Collectively, they will have many decades to test the effectiveness and durability of their biliary repairs. This underscores the key message, namely, that prevention has to be regarded as the real solution to bile duct injuries during LC.

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### Use of the External Fixation Apparatus for Percutaneous Insertion of Pins in the Distal One-Third of the Radius: an Anatomic Study

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*Objective:* To assess the risk of soft-tissue injury during percutaneous placement of external fixation pins in the proximal radius.

Design: An anatomic study with embalmed cadaver limbs.

Setting: Hand and upper limb centre at a university-affiliated hospital.

Interventions: Two 4-mm Hoffman half pins were percutaneously placed along the dorsoradial ridge of the radius, four finger breadths proximal to the radial styloid process.

Main Outcome Measures: Injuries to soft tissues including tendons, nerves and vessels were noted. Results: Nerve or tendon injuries occurred in 7 of 26 forearms. Three pins transfixed either the superficial branch of the radial nerve or lateral antebrachial cutaneous nerves. Tendon injuries included the brachioradialis in two forearms, the extensor carpi radialis brevis in three forearms, and the extensor carpi radialis longus an <sup>th</sup>e abductor pollicis longus in one forearm each. Conclusions: Percutaneous pin placement in the distal radius is unsafe. The authors recommend open pin placement for fractures of the distal radius.

*Objectif :* Évaluer le risque de blessure des tissus mous durant l'insertion percutanée d'une tige de fixation externe du radius proximal.

Conception : Une étude anatomique utilisant des membres embaumés de cadavres. Contexte : Le centre du traitement des mains et les membres supérieures, dans un hôpital universitaire. Interventions : Deux demi-tiges Hoffman de 4 mm ont été insérées par voie percutanée le long de la crête dorsoradiale du radius, à quatre largeurs de doigt de l'apophyse styloïde du radius.

Principaux effets mesurés : Les lésions des tissus mous incluant tendons, nerfs et vaisseaux furent notées.

*Résultats* : Des lésions des nerfs ou des tendons sont survenues dans 7 avant-bras sur 26. Trois tiges ont traversé soit la branche superficielle du nerf radial, soit les nerf brachiaux cutanés internes latéraux. Les blessures tendineuses comprennent des lésions du brachioradialis dans deux avant-bras, de l'extensor carpi radialis brevis dans trois avant-bras, et de l'extensor carpi radialis longus et de l'abductor pollicis longus dans un avant-bras chacun.

*Conclusions :* L'insertion percutanée de tige dans la partie distale du radius n'est pas sûre. Les auteurs proposent la pose ouverte de tiges dans les fractures du radius distal.

**D** istraction of the wrist with ligamentotaxis provides a good method of stabilizing comminuted or unstable fractures of the distal radius. This can be accomplished with pins and plaster<sup>1,2</sup> or with an

external fixator.<sup>3,4</sup> Although the complication rate associated with the use of an external fixator is lower than that with pins and plaster,<sup>1,3</sup> use of an external fixator can cause complications. These include

pin infection, loosening, fracture of the radius, nerve injury, neuroma and tendon injury.

The purpose of this study was to assess the risk associated with percutaneous pin placement in the ra-

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#### Accepted for publication July 19, 1993

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dius and to determine whether a safe zone exists.

#### Methods

Twenty-six forearms (13 right and 13 left) from different cadavers were used. Two 4-mm self-tapping Hoffman (Howmedica Inc., Rutherford, NJ) half pins were placed into the radius with a universal hand drill. Cooney<sup>5</sup> has recommended placement of the first pin four finger breadths proximal to the radial styloid process. Therefore, the first pin was placed 8 cm proximal to the radial styloid. The second pin was placed 2 cm proximal to the first. The pins were placed percutaneously along the dorsoradial ridge of the radius parallel to the coronal plane of the forearm. No stab incisions or predrilling was used. After pin placement, skin and subcutaneous tissues were dissected with 3.5-loupe magnification over an area extending from the midaxial line of the dorsum of the forearm to the flexor carpi radialis tendon. The

lateral antebrachial cutaneous nerve (LACN) and the superficial branch radial nerve (SBRN) were preserved. Measurements of the following distances were made: arm length from the radial styloid to the elbow flexion crease, the distance from the radial styloid to the SBRN at its exit from beneath the brachioradialis tendon, the distance from the radial styloid to each pin, and the distance from the SBRN and the LACN to each pin. Injuries to soft tissues, including tendons, nerves and vessels, were noted and photographed. The distance from the radial styloid to the SBRN was compared to the arm length from the radial styloid to the elbow flexion crease to determine if there was a safe zone for percutaneous pin placement that would protect the SBRN from injury.

#### Findings

The SBRN was identified within the dissection field (Fig. 1) in all 26 specimens, and the LACN was simi-

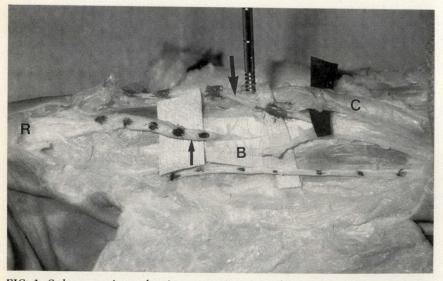


FIG. 1. Cadaver specimen showing anatomic points of interest in placement of pins for percutaneous external fixation of radial fractures. In this specimen elbow is to right and wrist to left. Distal external fixation pin is placed 8 cm proximal to radial styloid (R). Cephalic vein (C) is seen, with branch of lateral antebrachial cutaneous nerve (large arrow) passing in close proximity to pin. Superficial branch of radial nerve (small arrow) is seen exiting from beneath brachioradialis tendon (B).

larly identified in 8 specimens. The distance measurements are shown in Table I. The average distance from the SBRN to pin 1 was 7 mm (range from 0 to 18 mm) and to pin 2 was 9 mm (range from 4 to 14 mm). The average ratio of the distance from the radial styloid to the elbow crease and the distance from the radial styloid to the exit of the SBRN from under the brachioradialis tendon was 0.35 (range from 0.28 to 0.44). The SBRN was transfixed by pin 1 (the distal pin) twice. The average distance from the LACN to pin 1 was 6 mm (range from 3 to 10 mm) and to pin 2 was 6 mm (range from 0 to 11 mm). The LACN was transfixed once by pin 2.

Three tendons were transfixed by the pins. The abductor pollicis longus and the extensor carpi radialis longus were transfixed by pin 1. The extensor carpi radialis brevis (ECRB) was transfixed by pin 2. Four tendons sustained partial tendon lacerations. The ECRB was injured by both pins, and the brachioradialis was injured twice by pin 1.

The point of nerve emergence from beneath the brachioradialis varied in relation to the arm length, from 28% to 44% of total arm length. In other words, it could emerge anywhere from the midforearm to the distal one quarter of the forearm.

Overall, 7 (27%) of 26 arms sus-

	Distance, mm		
Measurement	Average	Range	
Pin 1 to SBRN	7	0 - 18	
Pin 1 to LACN	6	3 - 10	
Pin 2 to SBRN	9	4 - 14	
Pin 2 to LACN	6	0 - 11	
Radial styloid to SBRN	88	70 - 112	
Arm length	251	212 - 285	

tained soft-tissue injuries. Three nerve (12%) and seven (27%) tendon injuries were noted.

#### Discussion

Complications associated with use of the external fixator apparatus can be clinical, equipment related or multifactorial.6 Clinical complications can be from soft-tissue or osseous damage. Pin complications include infections and loosening. Clinical soft-tissue injuries during pin insertion include damage to nerves, vessels, muscles and tendons. These complications can be avoided with proper insertion technique, for which intimate knowledge of forearm anatomy is essential. Attempts have been made to make percutaneous pin insertion safe by delineating safe, hazardous and unsafe corridors. Safe corridors without musculotendinous units and neurovascular structures occur only in the scapula, ulna and metacarpals in the upper limb. Hazardous corridors contain musculotendinous units but no important neurovascular structures. The radius and humerus are concentric bones in which no safe corridors exist. Pin placement here ideally occurs through corridors in which musculotendinous units are present without neurovascular structures.6

In regard to external fixation of the radius, complications involving tendon and nerve damage range from 5%<sup>5</sup> to 11%<sup>7</sup> to 18%.<sup>8</sup> Cooney<sup>5</sup> believed that the radial sensory nerve is not at risk if pins are placed four finger breadths or more from the radial styloid. He stated that in the 10% of his cases in which the radial sensory nerve or tendons were considered to be at risk, an open technique was appropriate. Others<sup>9,10</sup> have reported that proximal pin placement through small stab incisions avoids sensory neuromas. Seitz, Putnam and Dick<sup>10</sup> believed that small stab incisions with a drill sleeve to protect the soft tissues can avoid injury. The use of blunt dissection and drill sleeves is easily accomplished in metacarpal pin placement but can be difficult in radial pin placement. To date no study has defined risk factors or external landmarks that predict the location of the SBRN.

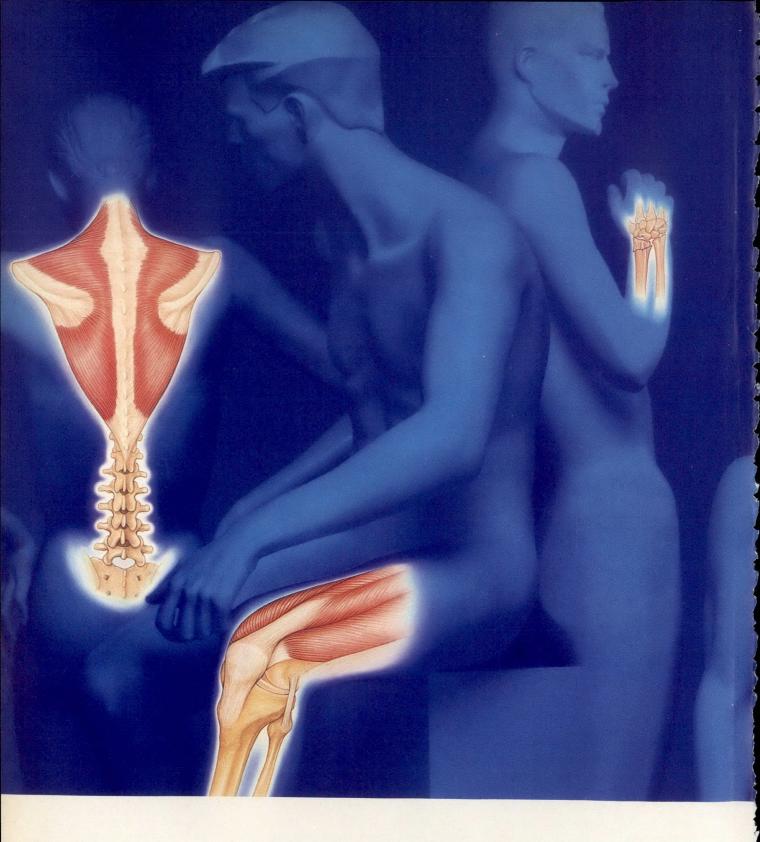
In our anatomic study we showed that percutaneous pin placement was associated with soft-tissue injury in 27% of forearms studied. Varying degrees of tendon injury occurred, but all injuries involved less than 50% of the tendon substance. Although there were no complete tendon lacerations, the subsequent scarring may affect rehabilitation. The incidence of nerve injury was 12%. This correlates well with reported clinical complication rates. Due to the well-established degree of overlap<sup>11</sup> between the LACN and the SBRN, injury to either nerve will give similar symptoms, and in our opinion both these nerves are at risk. We were unable to identify external landmarks that determined a safe zone for percutaneous pin placement. The anatomy of the SBRN and the LACN is highly variable. Our data show that both these nerves are at risk when pins are placed anywhere into the distal half of the radius. Because of the high rate of nerve and tendon injuries recorded, we recommend open pin placement in this region of the radius. Open pin placement allows visualization and protection of nerves and tendons and will decrease the number of soft-tissue complications.

#### Conclusions

On the basis of cadaver dissection, a safe zone for percutaneous placement of fixation pins in radial fractures could not be established. Injury to both nerves and tendons is common after percutaneous pin placement in the radius.

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### Emergency Medicine<sup>22,23,57</sup>

Renal colic Low back pain Sprains and strains

### Orthopedic Surgery<sup>4-9,48,55</sup>

Total hip or knee replacement Open reduction and fixation of long bone fractures Meniscectomy

### Trauma<sup>9,22</sup>

Fracture pain Acute trauma pain Contusions and lacerations

# TORADOL IM Providing highly effective non-narcotic analgesia for relief of moderate to severe acute pain.

In clinical trials, Toradol IM (ketorolac tromethamine) has been shown to be as effective as narcotics in treating a variety of acute pain conditions, including post-operative pain.<sup>4,9,52,55,56,57</sup> One Toradol 30 mg IM injection has been proven as effective as morphine 12 mg IM and meperidine 100 mg IM.<sup>10</sup>

Toradol IM offers an improved side effect profile compared to narcotics.<sup>5,16</sup> Patients generally experience a lower incidence of nausea, vomiting, constipation, drowsiness, and respiratory depression.<sup>5,22,55,57</sup> As a result, Toradol patients usually benefit from a faster return to normal activities and earlier discharge.<sup>13</sup>

Toradol tablets provide effective and generally well-tolerated analgesia when used alone or as follow-on therapy to Toradol IM.

By class, Toradol belongs to the nonsteroidal anti-inflammatory drug (NSAID) family. However, unlike conventional NSAIDs, it is a potent analgesic with minimal anti-inflammatory and antipyretic activity.

As with all NSAIDs, the most common side effects with Toradol involve the G.I. tract. Toradol is contraindicated in patients with peptic ulcer, active inflammatory disease of the G.I. system and patients who display hypersensitivity to the drug itself, ASA, or other NSAIDs.<sup>2</sup>

A highly effective<sup>4-10</sup> therapy, Toradol IM gives patients the advantages of non-narcotic analgesia in the short-term treatment of moderate to severe acute pain.

### General Surgery<sup>4-9,59-61</sup>

Cholecystectomy Gastric bypass Thoracotomy Hernia repair

### Gynecological Surgery<sup>9,38,39,46,59</sup>

Abdominal hysterectomy Vaginal hysterectomy Laparotomy Post-partum uterine cramping



## Acute Abdominal Emergencies in Patients on Long-Term Ambulatory Peritoneal Dialysis

James L. Wellington, MD, CM, FRCSC, FACS; Kelly Rody, RN

*Objective:* To review intercurrent abdominal emergencies in patients receiving long-term peritoneal dialysis on an ambulatory basis.

Design: A chart review.

Setting: Tertiary care referral centre.

*Patients:* Seven patients receiving long-term peritoneal dialysis, who suffered an acute abdominal emergency during a 7-year study period.

Interventions: Laparotomy with appropriate management depending on the findings. Antibiotic therapy and dialysate culture.

*Results:* In all patients the acute abdominal process involved the colon: five patients had perforated diverticulitis and two had ischemic colitis. The death rate overall was 57%. Peritonitis in these patients was difficult to differentiate from the peritonitis that occurs commonly in patients on long-term peritoneal dialysis. As a result there was a delay in the initiation of therapy ranging from 2 to 27 days. *Conclusions:* Coincidental abdominal emergency should be considered when patients receiving long-term peritoneal dialysis on an ambulatory basis present with peritonitis that does not respond to established antibiotic protocols and when culture results show evidence of multiple enteric organisms.

*Objectif :* Étudier les urgences abdominales intercurrentes qui surviennent chez les patients soumis à une dialyse abdominale de longue durée administrée en ambulatoire.

Conception : Une étude rétrospective des dossiers d'hôpitaux.

Contexte : Un centre d'acheminement pour soins tertiaires.

*Patients :* Sept patients sous dialyse péritonéale de longue durée qui ont présenté une urgence abdominale aiguë au cours d'une période de 7 ans.

*Interventions :* Une laparotomie accompagnée des soins appropriés aux observations. Antibiothérapie avec culture du dialysat.

*Résultats* : Dans tous les cas, l'abdomen aigu était relié à une atteinte du côlon: cinq patients avaient une diverticule perforée et deux, une colite ischémique. La mortalité a été de 57 %. Chez ces patients, il était difficile de différencier ce type de péritonite des péritonites fréquemment observées chez les patients sous dialyse péritonéale de longue durée. En conséquence, on compte un délai de 2 à 27 jours avant de débuter le traitement.

*Conclusions :* On doit envisager la possibilité d'une urgence abdominale intercurrente quand un patient sous dialyse péritonéale de longue durée administrée en ambulatoire présente une péritonite qui ne cède pas aux protocoles d'antibiothérapie établis et quand les cultures indiquent la présence de multiples entérobactéries.

The role of chronic (long-term) ambulatory peritoneal dialysis (CAPD) in the treatment of chronic renal failure is rapidly expanding. Exogenous infection resulting in peritonitis is the commonest late complication in most CAPD programs. Such infections are usually due to a single organism and respond to established treatment pro-

tocols. However, when peritonitis develops because of unrelated intraabdominal disease of the gastrointestinal tract, the diagnosis may be uncertain, and this may lead to

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Accepted for publication Mar. 15, 1993

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ABDOMINAL EMERGENCIES AND PERITONEAL DIALYSIS

delay in emergency operation and contribute to a high surgical death rate. Our experience with seven such patients on CAPD, who had coincidental emergency surgical conditions, is reported.

#### **Patients and Methods**

Between May 1984 and October 1991, seven patients (five men, two women) on CAPD were recognized as suffering from acute abdominal surgical conditions (Table I). The diagnosis was verified at operation in six and at autopsy in one. Many patients were elderly (mean age 69 years, range from 57 to 83 years). They had been on peritoneal dialysis for periods ranging from 1 to 106 months. Five of the seven patients had had peritonitis.

Clinically, the patients with gastrointestinal complications could not be differentiated from the usual patient with CAPD peritonitis. Radiologic investigations were not helpful, most patients showing nonspecific bowel distension compatible with ileus. No patient had evidence of free intraperitoneal air. When an acute abdomen developed, treatment was initiated with a standard antibiotic protocol consisting of cefazolin 1 g, tobramycin 40 mg and vancomycin 1 g infused intraperitoneally. Antibiotic therapy was modified depending on the culture results.

#### Results

In this series, specimens of dialysate were sent for Gram's staining in six of the seven patients. Two of these specimens gave negative results, but the remainder grew gramnegative bacilli. Cultures of the dialysate from six of the seven patients grew mixed enteric organisms, including *Bacteroides fragilis* in two and a solitary growth of *Escherichia coli* in one.

At operation or autopsy, all patients were noted to have conditions affecting the large intestine. Five patients had perforated sigmoid diverticulitis with either paracolic abscess or frank peritonitis, and two suffered from ischemic infarction of the large bowel. Six patients underwent some form of colonic resection: primary anastomosis in one and fecal diversion in five. Four (57%) of the seven patients died. The cause of death was myocardial infarction in two and sepsis in two.

Patient no.	Sex	Age, yr	Duration of CAPD, mo	Previous episodes of peritonitis, no.	Results of Gram's staining	Results of culture	Duration from onset to surgery, d	Findings	Procedure	Outcome	Length of hospital stay, d
1	Μ	63	106	1	Negative	MEO (Bacteroides fragilis)	2	Perforated diverticulitis	Local resection and anastomosis	Survived	21
2	Μ	83	1	0	Gram- negative bacilli	MEO	5	Perforated diverticulitis with pericolic abscess	Sigmoid resection, colostomy	Survived	79
3	Μ	69	3	0	Negative	Escherichia coli	3	Infarction right colon	Right hemi- colectomy, ileostomy	Died (MI)	8
4	M	57	16	2	Gram- negative bacilli	MEO (Bacteroides fragilis)	. 27	Perforated diverticulitis with pericolic abscess	Sigmoid resection, colostomy	Died (sepsis)	87
5	F	66	45	2	Gram- negative bacilli	MEO	5	Ischemic colitis with perforation	Total colectomy, ileostomy	Died (sepsis)	46
6	М	77	27	2	Gram- negative bacilli, gram- positive cocci	MEO	No surgery	Perforated diverticulitis with pericolic abscess (autopsy)	No surgery	Died (MI)	4
7	F	69	34	6	N/A	MEO .	6	Perforated diverticulitis with peritonitis	Sigmoid resection, colostomy	Survived	23

Three of the six patients who underwent surgery died for an operative death rate of 50%.

The delay from the time of presentation to surgery varied from 2 to 27 days. In four of the six patients treated surgically, the delay was longer than 5 days. One patient (no. 6) died on the 4th day after admission and did not undergo operation.

The length of stay from admission to discharge or death varied from 4 to 87 days (mean 38 days).

#### Discussion

Since it was introduced in 1976,1 CAPD has been used with increasing frequency as the preferred method of home dialysis in patients with end-stage renal failure. As experience with the technique has increased, the incidence of complicating peritonitis has fallen. However, peritonitis remains the main complication in these patients, with a reported incidence of approximately 1.3 episodes per patient per year.2 Our incidence of peritonitis at the Ottawa General Hospital is lower, being 0.45 episodes per patient per year with a current peritoneal dialysis population of 166 patients.

CAPD peritonitis is usually caused by normal skin bacteria, notably coagulase-negative staphylococci.<sup>3</sup> However, gram-negative bacteria may be responsible for as many as one-third of all cases of peritonitis associated with CAPD.<sup>4</sup> The presence of anaerobes or polymicrobial peritonitis should raise the suspicion of bowel perforation. In a series of patients reported by Spence and colleagues,<sup>5</sup> no patient without multiple enteric organisms required laparotomy. Conversely, 6 of 10 patients with multiple enteric organisms recovered without surgery.

Peritonitis secondary to bowel perforation may be difficult to differentiate clinically from that of peritonitis associated with CAPD. Similar findings were reported by both Spence and colleagues<sup>5</sup> and Moffat, Deitel and Thompson.<sup>6</sup> The presence of severe pain, especially when initially localized, should raise the suspicion of an intercurrent acute abdominal condition. Such conditions are frequently associated with muscle guarding and absent bowel sounds, which are infrequent features of the type of peritonitis commonly occurring in CAPD patients. Certainly, pain that persists after institution of the usual treatment protocol should alert the physician to the possibility of peritonitis caused by gastrointestinal complications.

In our series, all patients suffered from colonic conditions. Perforated diverticulitis was the commonest complication, followed in frequency by ischemic bowel disease. Delay in necessary surgery was almost invariable, inviting a poor outcome and high mortality. Our operative death rate of 50% was identical to that reported by Moffat, Deitel and Thompson<sup>6</sup> who cited nutritional depletion as a factor contributing to the poor outcome.

The cause for delayed intervention in our series was related to prolonged medical treatment for what was interpreted as acute sigmoid diverticulitis without perforation. Surprisingly, patients in the series of Spence and colleagues<sup>5</sup> had an average delay of 7.5 days before they underwent operation, and all survived. These authors believed that longer intraperitoneal administration of antibiotics, by producing therapeutic serum levels, might have been responsible for the increased survival in the treatment of patients suspected of having CAPD peritonitis.

#### Summary and Conclusions

Peritonitis remains the commonest complication of CAPD for patients with chronic renal failure. When such patients present with peritonitis that, on culture, demonstrates multiple enteric organisms and does not respond to standard treatment protocols, a bowel perforation should be suspected. Delay in surgery is likely to lead to increased surgical complications and mortality. Our experience with seven such patients, all with disease affecting the large bowel, resulted in an operative mortality of 50%.

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# Pediatric Free Tissue Transfer: an Evaluation of 99 Cases

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*Objective:* To evaluate the results of free tissue transfers in children who undergo reconstructive surgery.

Design: Case series chart review. Mean follow-up longer than 2 years.

Setting: Two tertiary care pediatric hospitals.

Patients: Consecutive sample of 99 children.

Interventions: Free tissue transfers for reconstruction of a variety of defects.

Main Outcome Measures: Indications, operations, complications, survival.

*Results:* The most common indications were for restoration of muscle function and for difficulties with soft-tissue coverage. Multiple donor sites were used, with the gracilis muscle, fibula, latissimus dorsi and groin flaps predominating. The overall survival rate was 99.0%. Complications were common, with an overall rate of 59.6%; most were graded as minor or moderate.

*Conclusions:* Meticulous planning is paramount in achieving a successful outcome. Complications are common but do not include vascular spasm. Free tissue transfers can be successfully completed in small children despite the dimensions of the tissues.

*Objectif :* Évaluer les résultats des transferts de tissu libre chez les enfants qui subissent une chirurgie de reconstruction.

Conception : Une revue d'une série de cas. Le suivi moyen dépasse 2 ans.

Contexte : Deux hôpitaux de soins pédiatriques tertiaires.

Patients : Un échantillonnage de 99 patients consécutifs.

Interventions : Les transferts de tissu libre pour la reconstruction de diverses lacunes.

Principaux effets mesurés : Indications, opérations, complications, survie.

*Résultats* : Les indications les plus courantes étaient liées au rétablissement de la fonction musculaire ou à des difficultés de recouvrement des tissus mous. On eut recours à de multiples zones de prélèvement de greffons, avec prédominance des muscles droit interne de la cuisse, péroné et grand dorsal, de même qu'à des lambeaux d'aines. La survie fut de 99 %. Les complications étaient fréquentes, leur taux atteignant 59,6 %; la plupart de celles-ci furent considérées bénignes ou modérées. *Conclusions* : Une planification méticuleuse est de première importance pour obtenir de bons résultats. Les complications sont fréquentes mais ne comprennent pas le spasme vasculaire. Le transfert de tissu libre peut être réalisé avec succès chez le petit enfant malgré la faible dimension des tissus.

**T** he ability to transfer viable, functional units of tissue about the body has greatly enhanced the capabilities of reconstructive surgery. The techniques are no better

applied than in children, a population in which there is an interesting array of congenital deformities and acquired defects. Harii and Ohmori<sup>1</sup> were the first to report on free tissue transfer in children. They used free groin-flap transfer in two 4-year-old children to cover open wounds of the ankle. Free tissue transfer has been under-

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#### Accepted for publication Aug. 3, 1993

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taken in children as young as 3 months.2 To date there are two large series describing free tissue transfer in children. Parry, Toth and Elliott3 reviewed 22 cases in children ranging from 2 to 14 years of age. All but one case was for the coverage of soft-tissue defects, and 15 had massive lower-extremity trauma with exposed bone. In their series of 21 patients under 20 years of age (mean age, 10.6 years) who underwent free tissue transfer, Serafin and Barwick<sup>4</sup> reported on 22 free flaps used for a variety of problems. There was one failure. They felt that there were problems related to vessel size in small children. Further, Banic and Wulff<sup>5</sup> described injuries to the lower limbs of 15 children from 3 to 9 years of age that were treated by immediate reconstruction with latissimus dorsi musculocutaneous flaps. Iwaya, Harii and Yamada6 recommended the groin flap as the preferred donor site for coverage of traumatic defects on the dorsum of the foot and ankle in seven children. Expanded parascapular free skin flaps were used by Moghari and colleagues7 in four children, with direct closure of the donor wound. Superior gluteal flaps of fascia lata, muscle and fat and, in one case, skin were used to reconstruct hemifacial microsomia by La Rossa and associates.8 Other reports have included a high proportion of children but in small numbers.9-13

In reviewing the first 99 free tissue transfers undertaken at two large pediatric centres we hope to indicate the breadth of surgery that can be undertaken and the relative safety of these procedures.

#### **Patients and Methods**

The first 99 consecutive free tissue transfers undertaken in children at the Hospital for Sick Children in Toronto (70 cases) and the Children's Hospital Medical Center in Boston (29 cases) were reviewed. Half of these children were operated on in the first decade of life (mean age at operation, 10.8 years, range from 17 months to 19 years). The hospital charts were reviewed in all cases to identify any complications in the perioperative period. Further recall visits were not feasible. The mean follow-up was 25.1 months with a maximum follow-up of 6.5 years.

#### Results

#### Indications for Operation

The most common indication for operation was restoration of facial (20 children) or forearm (9 children) animation (Table I). Facial animation was undertaken in most cases for congenital facial palsy or Möbius' syndrome. Forearm animation was indicated after Volkmann's ischemic contracture as a result of a supracondylar fracture of the humerus. Soft-tissue reconstruction was undertaken in the head and neck (11 children), the upper limb (4 children) and the lower limb (13 children). Hand reconstruction with replacement of congenitally absent

Indication	Patients, no.		
Facial reconstruction	20		
Soft-tissue cover			
Lower limb	13		
Head and neck	11		
Upper limb	4		
Digital reconstruction	12		
Forearm animation	9		
Pseudarthrosis	9		
Bony reconstruction	9		
Soft-tissue contour	8		
Burn-scar alopecia	1		
Cutis aplasia congenita	1		
Shotgun injury	1		
Ovary preservation	1		
Total	99		

or traumatically damaged structures was undertaken in 12 children. Pseudarthrosis of the tibia was treated with free fibular transfer in nine cases. There were an additional nine cases of bony reconstruction and eight cases of soft-tissue contour treatment without a cutaneous defect.

#### Planning for Operation

Extensive planning was undertaken in all cases. A two-team approach was usually used, one team to prepare the donor tissue and the other to prepare the recipient site. Both teams reviewed the cases preoperatively in the planning phase. Angiography was undertaken in 50% of cases to evaluate either the donor site anatomy, as is commonly required in free fibular transfers, or the recipient vascular anatomy, as in trauma cases. Models and templates were frequently used.

#### Variety of Operations

The gracilis muscle was the most common donor tissue used (30 children), in many cases for functioning muscle transfer (Table II). The fibula was used in 17 children and is the preferred bone for microvascular transfer in children because the

Table II. Donor Tissues Used				
Donor tissues	Patients, no.			
Gracilis	30			
Fibular	17			
Latissimus dorsi	16			
Groin	11			
Second toe	7			
First toe	5			
Temporoparietal fascia	3			
Posterior calf	2			
Scapular	2			
Forearm	1			
Rectus abdominus	1			
Dorsalis pedis	1			
Scalp	1			
Ovarian	1			
Omentum	1			
Total	99			

dissection is straightforward, can be done under tourniquet control and provides a long segment of bone for reconstruction. It was extremely well suited for microsurgical reconstruction of pseudarthrosis of the tibia (nine children). The latissimus dorsi was used to cover large defects (16 children). The groin flap, known to be a difficult dissection, was used less commonly (11 children). It is reserved for selected cases of soft-tissue contour deformities. First and second toes were used in hand reconstruction with the second toe often used for congenital deformities of the ulnar side of the hand.

All patients received increased intravenous fluid infusions intraoperatively, and one and one-half their normal maintenance requirements postoperatively. The fluids were tapered gradually over 5 to 7 days. The transfusion rate was 60% and included packed red cells, plasma, albumin and coagulation factors.

Postoperative anticoagulation was not routine, being used in only 13 of the 70 children in Toronto and 20 of the 29 in Boston.

#### Complications (Table III)

Complete necrosis of the transferred flap was documented in only one case, giving an overall flap survival rate of 99%. There were

Complication	Patients, no					
Bulk or scar						
necessitating revision	23					
Recipient wound problems	17					
Infection	14					
Systemic	10					
Donor wound problems	9					
Partial or complete flap						
necrosis	5					
Vascular compromise						
necessitating						
re-exploration	4					
Hypertrophic scar	2					
Poor function	2					
Total	86					

three late deaths, all of which were related to recurrence of the original condition (rhabdomyosarcoma), and there were no operative deaths.

Complications were classified as minor, moderate or severe. Minor complications (in 28% of the patients) were those that did not require reoperation, such as infection or delayed healing, and did not prolong the hospital stay. Moderate complications were seen in 38% of cases: more than one-half of these were revisions to the flap to correct contour or bulk. In some cases it was not possible to provide a definitive sizing for the flap at the original surgery, thus necessitating this reoperation. Severe complications, all occurring in groin flap transfers, were seen in 3% of patients and consisted of loss of a significant portion, but not all, of the flap.

Major systemic complications, such as pulmonary embolism or respiratory failure, were not seen. Lesser systemic complications included pulmonary problems related to prolonged procedures, antibiotic sensitivity and fluid and electrolyte problems, which were seen in 10 patients. In total 86 complications were seen in 59 patients, an overall complication rate of 60%.

#### Discussion

The indications for free tissue transfer in children differ from those in adults in that congenital anomalies and the specific diseases of childhood account for a large group of cases. They include the reconstruction of congenital hand deformities,<sup>14</sup> congenital pseudarthrosis of the tibia,<sup>15</sup> hypospadias<sup>16</sup> and tumours such as rhabdomyosarcoma. The vascular anatomy may also vary in congenital anomalies. The normal arches of the hand may not be present in cleft hands or radial ray deformities. Abnormal vascular anatomy has been noted by Fisher and Jackson<sup>9</sup> in patients with hemifacial microsomia, in whom the carotid bifurcation may be low and the external carotid system abnormal.

More delicate technique is reguired in small children because the structures are smaller than those in adults.<sup>2-4,10</sup> The vessels may not be smaller in proportion to the child's size but are often more delicate. Masquelet and colleagues<sup>10</sup> dissected the vascular pedicle in posterior arm flaps without difficulty but found that it was less than 1 mm in diameter in the two youngest children (aged 3 and 6 years) in their series. In their opinion the size of the vascular pedicle is directly related to the age of the patient. Parry, Toth and Elliott<sup>3</sup> noted that the vessels were slightly smaller than in comparable flaps in adults. Serafin and Barwick<sup>4</sup> recommended that elective microsurgical procedures should be performed after the child has reached 3 to 4 years of age since the histologic appearance of the blood vessels becomes more like that of the adult. The vessels may be particularly small in hypoplastic tissues.8,9,13 Vascular spasm was not a problem in our series or those of others.3

The common features of adult and pediatric free tissue transfer bear emphasis because a successful outcome depends on them. The planning required in carrying out these procedures cannot be overemphasized. All the details of the procedure should be worked out in advance by a microvascular team. Anesthetists who are familiar with the requirements of children undergoing extended procedures should be involved in the planning process. Small vessels require appropriately fine instruments and sutures. Postoperative monitoring of fluid status and flap perfusion must be undertaken by experienced nursing and

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medical personnel. Shapiro, Akbarnia and Hanel<sup>17</sup> recommended hydration with twice the usual maintenance fluids for 12 hours before and 5 days after surgery. We recommend one and one-half times the usual maintenance fluids.

Complication rates were high in our series as in other pediatric<sup>17</sup> and adult experiences. Morrison, O'Brien and MacLeod<sup>18</sup> reported a complication rate of 38% and noted that thrombosis was the most serious problem.

Given the possible complications of transfusion therapy, the transfusion rate of 60% in our series raises concern. The risk of giving albumin may be extremely small but is considered none the less.

The postoperative need for anticoagulation, including heparin. dextran or acetylsalicylic acid, remains extremely controversial. Banic and Wulff<sup>5</sup> used anticoagulants in 2 of 15 cases after revision of the arterial anastomosis. Parry, Toth and Elliott<sup>3</sup> related their two complications (bleeding into the donor site) to the use of lowmolecular-weight dextran, and they used dextran only if there was a technical problem with the anastomoses. Acetylsalicylic acid was used by Shapiro, Akbarnia and Hanel17 in all cases for 2 weeks, but they acknowledged that there are no data to support this practice. Our approach is to consider anticoagulation if there are problems with the vascular anastomoses or perfusion of the flap. The intra-arterial infusion of streptokinase and heparin has been suggested for the salvage of vascular repairs in children,<sup>19</sup> but we have no experience with these agents.

#### Conclusions

Both pediatric and adult microsurgical procedures must be carefully planned and meticulously executed. In children, the vessels, although smaller, are still of adequate size for reliable anastomosis. There is no lower age limit for these procedures. Vascular spasm is not a problem. Intraoperative complications have been reduced with the establishment of appropriate anesthetic protocols. Anomalies of the recipient vasculature are often found to be critical at surgery.

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# Blunt Traumatic Liver Injury Associated With Clostridial Infection of Early Onset

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Hepatic clostridial infections associated with blunt abdominal trauma are rare. Generally they occur from 2 weeks to 3 months after injury and are thought to result from the growth of normal enteric organisms, which are carried to the liver by the portal venous system and infect devitalized tissue. The authors describe two patients in whom the hepatic infection became established in less than 24 hours after injury and was due to *Clostridium* spp. The patients were successfully treated by hepatic resection and combination antimicrobial therapy. Hyperbaric oxygen was used as an adjunct in one case.

Les infections hépatiques à clostridies liées aux traumatismes abdominaux fermés sont rares. Elles surviennent généralement de 2 semaines à 3 mois après la blessure et l'on croit qu'elles résultent de la multiplication de bactéries intestinales normales, lesquelles migreraient vers le foie par le système porte pour aller infecter le tissu dévitalisé. Les auteurs décrivent deux patients chez qui une infection hépatique à *Clostridium* spp s'est établie moins de 24 heures après la blessure. Les patients ont bien répondu à une résection hépatique et à une antibiothérapie d'association. L'oxygène hyperbare fut utilisé comme traitement d'appoint dans un des cas.

**P** yogenic liver abscess is uncommon. It is reported to occur in approximately 0.03% of all hospital admissions.<sup>1</sup> Blunt trauma to the abdomen and lower chest is the third most common cause after primary biliary tract infection and direct contiguous infection.<sup>2</sup> In recent years anaerobic organisms have been more frequently implicated as causative organisms, although *Clostridium* spp. have been isolated.

We present two cases of rapidly occuring clostridial hepatic infection after blunt abdominal trauma seen at the Vancouver General Hospital between August 1990 and November 1991. The limited experience with clostridial hepatic infection after blunt abdominal trauma is reviewed, and the principles of therapy are discussed.

#### **Case Reports**

#### Case 1

A 29-year-old man was involved in a roll-over motor vehicle accident in a remote area of the province. He was not wearing a seat belt. At the scene of the accident his blood pressure and heart rate were reported to be 80 mm Hg systolic and 110 beats/min respectively. The patient was awake and alert. Transfer to the nearest hospital took approximately 3 hours during which time the patient received 5 L of crystalloid solution. Upon admission the patient was in respiratory distress with a blood pressure of 110 mm Hg systolic and a heart rate of 100 beats/min. A flail segment of ribs four to seven was noted on the right side. Right tube thoracostomy was performed, and the patient was intubated. A chest film revealed a large right pulmonary contusion. The findings on abdominal examination with the patient awake and apparently nonobtunded was considered to be normal: however, a contusion measuring 10 cm in diameter was noted over the right upper quadrant. Although the patient appeared to be in stable condition, he was transferred to the Vancouver General

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Accepted for publication May 25, 1993

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Hospital, which is the level I trauma centre for British Columbia.

The patient arrived at the Vancouver General Hospital approximately 10 hours after injury. He had been intubated, and paralysed and sedated for transfer. His blood pressure was 100 mm Hg systolic. and he had a tachycardia of 125 beats/min. His body temperature was 38°C. On admission the patient had received 8 L of crystalloid solution. A right chest tube was in place. A large right pulmonary contusion with fractures of ribs four to seven on the right side was confirmed by chest radiography. Abdominal examination revealed a contusion of the right upper quadrant. Diagnostic peritoneal lavage was grossly positive for blood. The hemoglobin value was 94 g/L (140 g/L before transfer). The leukocyte count was depressed at  $3.3 \times 10^9$ /L (normal 4.5 to  $11 \times$  $10^9/L$ ), with a shift to the left. Prothrombin time was prolonged at 16.5 s (normal 12 to 14 s), with a plasma fibrinogen level of 0.77 g/L (normal 2 to 4 g/L). The serum aspartate aminotransferase level was elevated at 1448 U/L (normal 7 to 40 U/L) and the total serum bilirubin elevated at 106 µmol/L (normal 0 to 22  $\mu$ mol/L.

After receiving 2 g of ceftizoxime, the patient underwent a midline laparotomy, which revealed a splenic hilar laceration, requiring splenectomy. There was a foul odour from the liver, and exploration revealed a large laceration (10 cm in dimension) extending to the portal hilum. The majority of the right lobe was soft, yellowish and necrotic and was the source of the foul odour. No obvious gas was present. Intraoperative Gram's staining revealed gram-positive bacilli. A formal right hepatic lobectomy, with an inflow occlusion time of 47 minutes, was performed. Resection margins were negative for

bacteria. A no. 32 French chest tube connected to closed suction was used as a subdiaphragmatic drain along with two smaller flat Jackson-Pratt drains. The patient was given penicillin G, 30 million units/d and imipenem, 500 mg every 6 hours. Microscopic examination of the liver showed extensive areas of coagulative necrosis with large numbers of gram-positive, spore-bearing rods (Fig. 1). Tissue cultures identified a *Clostridium* sp. that could not be grown out for subtyping.

Six hours postoperatively the patient remained tachycardic and febrile, so hyperbaric oxygen therapy was instituted. Five dives at 2.5 atmospheres for 90 minutes each were undertaken over the next 3 days. The patient was returned to the operating room on the 2nd postoperative day for evacuation of a right subdiagphragmatic hematoma. Cultures of this material showed no bacterial growth. Antibiotics were continued for 12 days at which time the patient was afebrile and had a normal leukocyte count. He suffered no further complications and was discharged from the hospital 21 days after his accident.

### Case 2

A pedestrian, a 31-year-old man who was intoxicated, was struck by a motor vehicle in a remote area of the province. About 4 hours after the accident he was seen in the emergency department of the local hospital, complaining of abdominal pain. The blood pressure was 120/50 mm Hg, the heart rate was 98 beats/min and the body temperature was 38.2°C. Physical examination revealed a markedly tender abdomen especially in the right upper quadrant. A chest film showed a right pulmonary contusion, fractures of the eighth rib on the left side and fractured transverse processes of lumbar vertebrae 2 and 3. His transfer to the Vancouver General Hospital was delayed for 10 hours because of adverse

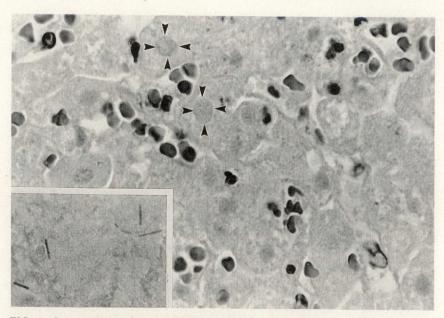


FIG. 1. Case 1. Excised necrotic liver showing preservation of architecture with pyknotic nuclei (arrowheads) (hematoxylin-eosin, original magnification  $\times$  100). Insert shows gram-positive rods typical of *Clostridium* organisms (Gram's stain, original magnification  $\times$  400).

weather conditions. On arrival, his body temperature was 38.5°C, his heart rate was 117 beats/min and his blood pressure 110/60 mm Hg. He was awake and alert. A chest film confirmed the right pulmonary contusion but also showed some consolidation of the lower lobe of the right lung with mild loss of volume. The presence of the previously noted fractures was also confirmed. Abdominal examination elicited marked tenderness in the right upper quadrant. There was frank hematuria. The hemoglobin level was 146 g/L and the leukocyte count was  $16 \times 10^9/L$  with a marked shift to the left. The serum aspartate aminotransferase level was 417 U/L with an elevated total serum bilirubin level of 50 mmol/L. Triple-contrast computed tomography and retrograde cystography were carried out. The retrograde cystogram revealed an intact bladder with mild, right, renal contusion. There was no evidence of pedicle injury. A large amount of intraperitoneal fluid, and a hepatic contusion and laceration corresponding to hepatic segments six and seven were noted (Fig. 2). Consolidation of the lower lobe of the right lung was again noted. Preoperatively, blood samples were drawn for culture.

After receiving a loading dose of 2 mg/kg of gentamicin and 750 mg of clindamycin the patient underwent laparotomy. A right subcostal incision with midline extension to xiphisternum revealed a frank hemoperitoneum with a foul odour from the right lobe of the liver. There was a minimal right retroperitoneal hematoma, but the retroperitoneal portion of the duodenum appeared normal. Mobilization of the right lobe of the liver revealed a laceration 6 to 8 cm long in hepatic segments 6 and 7. The surrounding liver tissue was soft, yellowish and malodorous. Gas was present in the tissue along with some pus and a marked bile leak. Nonanatomic resectional débridement was carried out until uninvolved hepatic parenchyma was reached. A visible lacerated segmental bile duct was ligated. An intraoperative dose of 6 million units of penicillin G was given. A no. 32

French chest tube connected to closed suction was used in addition the standard Jackson-Pratt to drains to provide maximal drainage of the subdiagphragmatic space. Postoperatively, the patient was given penicillin G 20 million units/d. clindamycin 750 mg four times daily and gentamicin 80 mg three times daily. Cultures of both blood and resection tissue grew Clostridium sp., but as in case 1 the culture could not be successfully grown out for subtyping. A moderate bile leak resolved spontaneously after 3 days, at which time the drains were removed. The hematuria resolved spontaneously. Antibiotics were discontinued on postoperative day 8 after the patient had shown no signs of sepsis for 72 hours. The patient was discharged from hospital 11 days after operation.

### Discussion

Blunt abdominal trauma with hepatic infection has been reported, but in most instances the temporal relationship of the trauma to the development of the infection has ranged from 2 weeks to 3 months after the inciting event.3 In our cases hepatic infection with Clostridium sp. was well established within 16 hours of injury. The pathogenesis of hepatic infection after trauma has yet to be delineated. Eng. Tecson-Tumang and Corrado<sup>3</sup> have postulated that in normal circumstances organisms from the gastrointestinal tract are carried through the portal circulation and cleared by the Kuppfer cells of the liver. When hepatic trauma occurs these organisms multiply in the hepatic hematoma or devitalized tissue. They may then elaborate cytotoxins that produce further necrosis and extending infection.

The only other reported case of

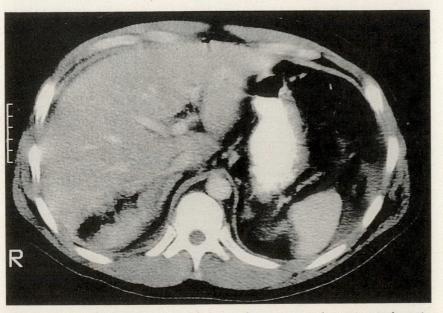


FIG. 2. Case 2. Computed tomography scan demonstrating laceration in hepatic segments 6 and 7, with gas.

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clostridial hepatic infection after blunt abdominal trauma is that described by Nachman and colleagues.<sup>4</sup> A 6-year-old child with abdominal trauma and hepatic laceration of the right lobe was managed conservatively, an approach that is often successful in children. A hepatic infection with *Clostridium bifermentans* developed on the 3rd day after injury. The infection was successfully treated by resection and combination antimicrobial therapy.

Standard surgical treatment of clostridial infections includes débridement of involved tissue and appropriate antibiotics. This may be combined with hyperbaric oxygen therapy. This protocol also appears applicable to traumatic clostridial liver infection as well. Mixed anaerobic bacteria have been the causative organisms cultured from many hepatic infections, although in some instances no organisms could be demonstrated or cultured.<sup>5</sup> Because of the possibility of a mixed infection in our cases we elected to use antibiotic coverage appropriate for this eventuality. If the mechanism of hepatic infection is via the portal venous drainage system, then antibiotic coverage of enteric anaerobes appears prudent in every instance.

Although the use of hyperbaric oxygen therapy remains controversial, its use in all cases of clostridial infection following full débridement and appropriate antibiotic coverage is favoured.6 The cases we have described illustrate that hepatic clostridal infection after blunt abdominal trauma can be early in onset and difficult to diagnose preoperatively. On the basis of our experience and the few reports in the literature we suggest that traumatic hepatic clostridial infection be diagnosed by the operative findings of foul odour and liver necrosis,

confirmed by Gram's staining of tissue and fluid and treated by resectional débridement or formal resection to eliminate nonviable tissue along with combination antimicrobial therapy. Hyperbaric oxygen therapy may be a useful adjunct.

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# SESAP VII Question / Question SESAP VII

### Item 241

Iatrogenic vascular injuries that result in permanent disability are chiefly related to

- (A) the location of the injury
- (B) delayed surgical intervention
- (C) preexisting atherosclerotic disease
- (D) the type of instrument causing the injury
- (E) extravasation of material around the injury site

For the incomplete statement above select the one completion that is best of the five given.

For the critique of Item 241 see page 550.

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# Unusual Isolated Common Bile Duct Injury After Blunt Trauma

Peter C.W. Kim, MD, PhD; Thomas Gilas, MD, FRCSC; Michele F.M. Brulé, MD

Isolated injury to the extrahepatic biliary tree after blunt trauma is rare. The authors describe the case of a 17-year-old boy who suffered such an injury after falling over the handlebar of his motocycle. Ultrasonography, computed tomography and abdominal paracentesis were used to make the diagnosis. At laparotomy there was a partial tear of the common bile duct at its junction with the cystic duct. A cholecystectomy was performed and a T tube inserted. The patient recovered without complication. The authors emphasize that only awareness of the condition and diagnostic confirmation by computed tomography and abdominal paracentesis and treatment. The choice of surgical repair must be individualized according to the clinical findings and the nature of the injury.

Suite à un traumatisme fermé, il est rare d'observer une lésion isolée des voies biliaires extrahépatiques. Les auteurs décrivent le cas d'un garçon de 17 ans qui subit une blessure de ce type après avoir été projeté contre le guidon de sa motocyclette. L'échographie, la tomographie par ordinateur et la parencentèse abdominale furent toutes utilisées pour le diagnostic. On découvrit à la laparotomie une déchirure du cholédoque à sa jonction avec le canal cystique. Une cholécystectomie fut pratiquée avec insertion d'un tube en T. Le patient se rétablit sans complication. Les auteurs soulignent que ce n'est qu'en gardant cette possibilité à l'esprit et en recherchant une confirmation diagnostique au moyen de la tomographie par ordinateur et par paracentèse abdominale que l'on peut hâter le diagnostic et le traitement. Le traitement chirurgical doit être choisi en fonction du tableau clinique individuel et de la nature de la lésion.

**I** solated injury to the extrahepatic biliary tree by blunt trauma is rare.<sup>1-5</sup> The diagnosis is usually made when the injury is found incidentally during an urgent abdominal exploration or as a late presentation in the form of obstructive jaundice, resulting from stricture formation.<sup>1,2</sup> The following case report illustrates an early diagnosis, an unusual site of injury and a rational plan for surgical management.

### **Case Report**

A 17-year-old boy presented to

our emergency room with moderately severe, vague, epigastric discomfort of less than 2 hours' duration, after falling over the handlebar of a motorcycle. His body temperature was 38.2°C, the pulse rate was 92 beats/min, the respiratory rate was 35/min, and the blood pressure was 157/55 mm Hg. Findings on initial physical examination were unremarkable except for a moderate degree of tenderness to deep palpation in the epigastrium. The hemoglobin level was 147 g/L, leukocyte count was  $12.4 \times 10^9$ /L with the differential of lymphocytes 73% and granulocytes 21%; the serum amylase level was 135 U/L, serum aspartate aminotransferase level 400 U/L, serum alkaline phosphatase level 172 U/L, serum creatine phosphokinase level 209 U/L and serum bilirubin (direct/total) level  $2/6 \ \mu$ mol/L. The initial chest x-ray film and a flat plate of abdomen were normal.

Repeat examination of the patient 6 hours after initial presentation demonstrated persistent tenderness in the epigastrium without any signs of peritoneal irritation. Repeat laboratory evaluation revealed a leukocyte count of  $15.7 \times 10^9$ /L with the differential of lymphocytes 12% and granulocytes 83%. Ultrasonography of the abdomen demonstrated

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Accepted for publication Oct. 20, 1992

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a significant amount of free fluid in the abdomen. The computed tomography scan of the abdomen demonstrated a moderate amount of free fluid in subhepatic, pericholecystic and right paracolic gutter spaces (25.5 Housefield units) (Fig. 1). Abdominocentesis was performed, and a bilious fluid with a bilirubin (direct/total) content of  $119/473 \mu$ mol/L and an amylase content of 38 U/L was obtained.

Laparotomy through an upper abdominal midline incision 18 hours after the initial injury revealed 500 mL of free bilious fluid in the abdomen. There was a substantial retroperitoneal collection of bilestained fluid. The only injury discovered after a careful laparotomy with special attention to duodenum was an isolated partial tear involving about 25% of the circumference of the common bile duct at its junction with the cystic duct (Fig. 2). A cholecystectomy was performed, and a no. 10 French T tube was inserted into the common bile duct at the site of the injury by extending the laceration distally. Intraoperative cholangiography was performed (Fig. 3). The abdomen was closed, and a closed drain was left at the operative site.

The patient's postoperative course was uncomplicated. T-tube cholangiography on the 7th postoperative day (Fig. 4) gave essentially normal results with good flow into the duodenum. At the time of discharge on postoperative day 7, the patient's leukocyte count was  $5.6 \times 10^9/L$  with the differential of lymphocytes 30% and granulocytes 60%, the serum aspartate aminotransferase level was 130 U/L, the serum alkaline phosphatase level was 133 U/L, the serum amylase

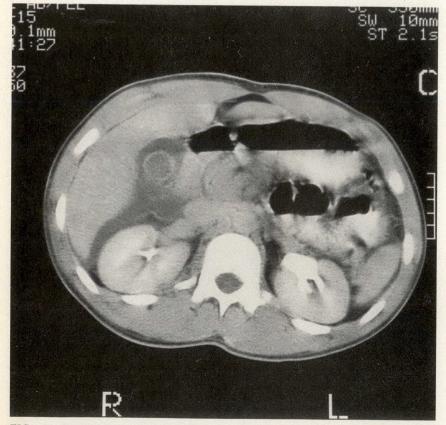


FIG. 1. Preoperative computed tomography scan of abdomen demonstrating significant subhepatic and pericholecystic free fluid.

level was 114 U/L and the serum bilirubin (direct/total) level was  $3/10 \,\mu$ mol/L. At the time of discharge the patient's T tube was clamped.

# Discussion

Injury to gallbladder and extrahepatic bile duct is uncommon. In a recent multicentre review, Cogbill and associates<sup>6</sup> reported that an associated injury to the gallbladder and to extrahepatic bile duct after blunt trauma was found in only 5% and 3% of cases respectively. Isolated injury to the extrahepatic biliary tree after blunt trauma is rare. Only 126 cases have been reported in the literature since 1799.<sup>1-5.7</sup> The low incidence has been attributed to the location and relative size of the extrahepatic biliary tree.<sup>2.3</sup>

The usual site of injury in these cases is at the superior border of the pancreas, and the injury usually results in a complete transection of the common bile duct.<sup>2,3</sup> The transmission of maximum stress from a lateral shearing force of blunt trauma is thought to occur at the superior border of the pancreas due to the relative fixity of the intrapancreatic portion of common bile duct.<sup>2,3</sup> In addition, traumatic decompression of the gallbladder into the common bile duct and the resultant ductal distension may render the biliary tree more susceptible to a lateral shearing force.1-3 Only four cases have been reported in the

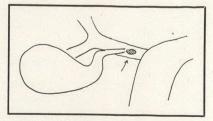


FIG. 2. Schematic diagram of extrahepatic biliary system, demonstrating site and extent of injury.

literature involving disruption of the common bile duct occurring at its junction with the cystic duct.<sup>3,8</sup> We suspect that the injury in our patient resulted from an avulsionshearing type of force applied cranially and medially to the distended common bile duct at its junction with the cystic duct, when the liver was displaced by the motorcycle handlebar.

Isolated injury of the extrahepatic biliary tree from blunt trauma presents a unique diagnostic challenge. The delay between clinical presentation and surgical intervention in the literature averaged 18 to 24 days.<sup>1-3</sup> The lack of overt peritoneal irritation by noninfected bile, the rarity of the injury and the insufficient indications all have been thought to contribute to the delav.<sup>1-3</sup> Several radiologic modalities, including intravenous cholangiography. HIDA scanning and angiography have been suggested to aid in early diagnosis.<sup>2,3,8</sup> Although sufficient reports do not yet exist to document that, we agree with the suggestion by Michelassi and Ranson<sup>3</sup> that ultrasonography and computed tomography of the abdomen followed by a radiologically guided abdominal paracentesis may be the most valuable diagnostic procedures in making an early diagnosis. Elevated serum amylase levels in the paracentesis fluid may represent a confounding variable. However, in the hands of those experienced in ultrasonography or computed tomography, the diagnostic confusion should be minimized.

The literature on isolated injury to the extrahepatic biliary tree by blunt trauma is scarce and provides no data on which to make a general recommendation for surgical treatment.<sup>1-5</sup> Therefore, the choice of surgical repair must be individualized according to the clinical scenario and the nature of the injury. There appears to be a consensus on the treatment of a completely transected common bile duct.1-3 Choledochoenteric reconstructions have provided the best long-term results by significantly reducing morbidity and mortality associated with stricture formation.<sup>1,3,8</sup> Simple axial or lateral tear, or common bile duct disruption less than 25% of its circumference as in our patient can be successfully repaired primarily, without significant morbidity and mortality, with placement of a T tube and external drainage of the subhepatic area.<sup>3,8</sup> Given the high incidence of stricture formation (up to 55%) and mortality (up to 40%) attributed to primary end-to-end anastomosis, any significant bile duct disruption after blunt trauma should be repaired with choledochoenteric reconstruction.1,3

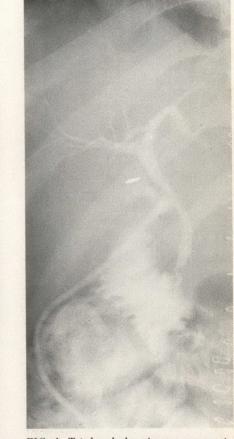


FIG. 4. T-tube cholangiogram on postoperative day 7, demonstrating intact extrahepatic biliary tree with good flow into duodenum.

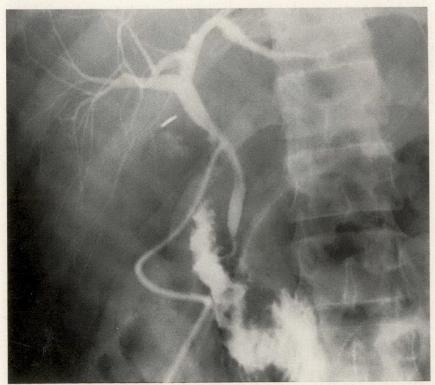


FIG. 3. Intraoperative cholangiogram through T tube immediately after repair.

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The development of a benign cystic lesion in the thymus after radiotherapy for Hodgkin's disease has also been reported.<sup>9</sup> The lesion is usually well-circumscribed with an attenuation value close to that of water, and gallium scanning is usually negative. The cyst seems to originate from successful radiotherapy to a thymus previously involved with lymphoma. With these findings most patients can be followed up without lymphoma therapy or biopsy.

Recent studies to evaluate the frequency of thymic changes after chemotherapy indicated that the problem is more common than previously thought.4,10 With modern imaging techniques in the follow-up of cancer patients, the clinician will face more cases of thymic changes. If thymic hyperplasia and benign thymic cysts are considered in the differential diagnosis of a mediastinal mass recurring after the successful treatment of a malignant lesion by chemotherapy or radiotherapy, some patients could be saved unnecessary suffering. Moreover, these two conditions should be excluded before treatment with either chemotherapy or radiotherapy. $^{5}$ 

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# **P**rognostic Factors in Metastatic Nonseminomatous Germ Cell Tumours

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*Objective:* To determine predictors of prognostic significance for patients with nonseminomatous testicular cancer (NSTC) who have advanced disease at the time of presentation.

Design: A chart review with a mean patient follow-up of 5.5 years (range from 0.75 to 13 years). Setting: University hospitals in Halifax.

Patients: All patients with NSTC, stages II-B, II-C and III. Patients were excluded if the follow-up status at the time the study closed could not be determined. Thirty-three patients were included in the study. Current patient status was determined from the clinical charts and personal communication with the patients or their physicians.

Interventions: All patients received cisplatinum-based chemotherapy. The extent of the disease was assessed by chest radiography or lung tomography, bone scanning, abdominal computed tomography or lymphangiography.

Main Outcome Measures: Correlation between levels of  $\beta$ -human chorionic gonadotropin (BHCG) and  $\alpha$ -fetoprotein (AFP), comparison of duration of symptoms before initial treatment, response to treatment and survival, and relationship between stage, tumour volume and survival.

*Results:* The 3-year overall survival rate was 76%. Seven of 18 patients with symptoms for more than 16 weeks died of disease (p < 0.01). Overall complete response was seen in 27 of 33 patients. All initial nonresponders died. A survival rate of 93% was seen among initial complete responders (p < 0.01). All seven patients with persistent elevation of BHCG levels (p < 0.001) and the two patients with persistent elevation of AFP levels (p < 0.01) after the second course of chemotherapy died.

*Conclusions:* A symptomatic interval of more than 16 weeks, poor response to initial treatment, bulky retroperitoneal disease, larger volume lung disease and persistently elevated levels of BHCG and AFP were all indicators of poor prognosis.

*Objectif* : Établir quels sont les indicateurs prévisionnels possédant une signification pronostique pour les patients atteints d'un carcinome testiculaire non séminomateux (CTNS) dont la maladie est déjà à un stade avancé lorsqu'ils consultent pour la première fois.

*Conception :* Une étude des dossiers de patients avec une période de surveillance moyenne de 5,5 années (écart de 0,75 à 13 ans).

Contexte : Les hôpitaux universitaires d'Halifax.

*Patients :* Tous les patients porteurs de CTNS de stades II-B, II-C et III. Furent exclus de l'étude, les patients dont l'évolution de la maladie n'avait pu être établie à la fermeture de l'étude. Trente-trois patients furent inclus. L'état actuel des malades fut déterminé à partir des dossiers médicaux et d'une communication personnelle des médecins avec leurs malades.

*Interventions :* Tous les patients avaient reçu une chimiothérapie comprenant du cisplatine. L'étendue de la maladie fut évaluée par radiographie thoracique ou tomographie des poumons, scintigraphie osseuse, tomographie abdominale par ordinateur ou lymphangiographie.

Principaux effets mesurés : La corrélation entre les taux de  $\beta$ -gonadotrophine chorionique humaine (BGCH) et ceux d' $\alpha$ -foetoprotéine (AFP), la comparaison entre la durée des symptômes précédant le

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Accepted for publication July 19, 1993

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traitement initial, la réponse au traitement et la durée de la survie, et le rapport entre le stade d'évolution, le volume de la tumeur et la survie.

*Résultats* : Le taux de survie global à 3 ans a été de 76 %. Sept des 18 patients ayant eu un intervalle symptomatique de plus de 16 semaines sont morts de la maladie (p < 0,01). Pour l'ensemble, une réponse fut obtenue chez 27 des 33 patients. Tous les patients qui n'ont pas répondu initialement au traitement sont décédés. On a observé un taux de survie de 93 % chez les patients qui ont eu une réponse initiale complète (p < 0,01). Les sept patients qui ont présenté des taux élevés de BGCH (p < 0,001) et les deux patients qui ont eu des taux élevés persistants d'AFP après un second cycle de chimiothérapie sont décédés.

*Conclusions :* Un intervalle symptomatique de plus de 16 semaines, une réponse insatisfaisante au traitement initial, une masse rétropéritonéale importante, des atteintes pulmonaires de volume important et la persistance de taux élevés de BGCH et d'AFP sont tous indicateurs d'un mauvais pronostic.

Datient survival after treatment for advanced nonseminomatous testicular cancer (NSTC) has improved greatly with recent advances in treatment.<sup>1,2</sup> The mortality, however, remains at 25% to 30%.<sup>1,2</sup> The extent of the disease is universally accepted as being the single most important prognostic factor.<sup>1-5</sup> There is no consensus as to which other factors may identify a patient as having a poor prognosis. In an effort to determine if other predictors of survival could be found, we reviewed the charts of all patients with advanced NSTC treated between 1980 and 1990 at Dalhousie University hospitals in Halifax. The following factors were considered: duration of symptoms before initial treatment, response to treatment, retroperitoneal tumour volume, extent of pulmonary metastases, and  $\beta$ -human chorionic gonadotropin (BHCG) and  $\alpha$ -fetoprotein (AFP) levels at the time of diagnosis and after treatment.

### Patients and Methods

The charts of the 33 patients with NSTC, stages II-B (dimension of retroperitoneal tumour involvement of 2 to 10 cm), II-C (dimension of retroperitoneal tumour involvement greater than 10 cm) and III (tumour spread beyond retroperitoneal lymph nodes),<sup>6</sup> were reviewed. The mean age of the pa-

tients was 29.7 years (range from 19 to 57 years). The mean duration of symptoms was the time from the day that a patient became aware of symptoms to the day of presentation to a physician, rounded off to the nearest week. The extent of the disease was assessed by physical examination, chest radiography or lung tomography, or both, bone scanning and abdominal computed tomography or lymphangiography. or both. The mean duration of follow-up was 5.5 years (range from 0.75 to 13 years). Table I shows the histologic type of the tumours. Serum AFP and BHCG levels were measured at the time of initial presentation and at the start of each treatment cycle. All patients received chemotherapy (Table II) with cisplatin-based drug regimens in standard 3-week cycles until tumour-marker levels had normalized and there was radiologic evidence that the tumour had regressed or disappeared or until the degree of regression plateaued. The response

Table I. Histologic Types of Advanced           Nonseminomatous Testicular Cancer           (NSTC) in 33 Patients			
Histologic type	Patients no. (%)		
Embryonal cancer	12 (36)		
Embryonal cancer +			
choriocarcinoma	10 (30)		
Teratoma	5 (15)		
Teratoma + choriocarcinoma	3 (9)		
Pure choriocarcinoma	3 (9)		
Total	33 (100)		

to chemotherapy was graded as follows: complete (disappearance of all clinical, radiologic and biochemical evidence of disease for at least 1 year), partial (a 50% decrease in tumour volume and normal AFP and BHCG levels for at least 6 months) and no response (all other types of response).

Student's *t*-test was used for statistical analysis.

### Results

The overall 3-year survival rate was 76%. Initially, 27 (82%) patients had a complete response to chemotherapy (Table III), and 6 (18%) patients had no response or a partial response; all 6 died of disease within 2 years. Nine (33%) of the 27 patients with initial complete response had a subsequent relapse

Table II. Chemotherapy Regimens Used on           33 Patients With NSTC Between 1980 and           1990				
Chemotherapy regimen	Patients, no. (%)			
Cisplatin, vinblastine, bleomycin	24 (73)			
Cisplatin, cyclophosphamide, vinblastine, bleomycin Cisplatin, vincristine, methotrexate, bleomycin, actinomycin D,	6 (18)			
cyclophosphamide, etoposide Cisplatin, cyclophosphamide, vinblastine, actinomycin D, bloomycin	2 (6)			
bleomycin Total	1 (3) 33 (100)			

after 1 year. Of these, seven (78%) had a complete response to salvage chemotherapy or surgery, or both, and at the closing date of this study had not had a relapse. A survival rate of 93% (25 of 27 patients) was observed in those with a complete response to initial chemotherapy.

A comparison of mean duration of symptoms, treatment response and survival revealed that 7 (39%) of 18 patients with symptoms for longer than 16 weeks died compared with 1 (7%) of 15 patients with symptoms for less than 16 weeks (p < 0.01).

The relationship between stage,

metastatic tumour volume and survival is shown in Table IV. Three deaths (27%) occurred in 11 stage II patients with aggregate retroperitoneal disease of 5 cm or more in diameter: in contrast, no deaths occurred in the nine stage II patients with an aggregate retroperitoneal tumour diameter of less than 5 cm (p < 0.01). A 3-year survival rate of 100% was seen in patients with unilateral lung metastases less than 2 cm in diameter, whereas only one (17%) of six patients with bilateral lung metastases less than 2 cm survived (p < 0.01).

No significant correlation be-

		Initial response		pse	Respon salvage che and su	motherapy	3-yea surviv	
Response	No.	0/0	No.	0/0	No.	0/0	No.	0/0
Complete	27	82	9/27	33	7/9	78	25/27	93
Partial	2	6	_	_	0/2	0	0/2	C
None	4	12	-	-	0/4	0	0/4	C
Total	33	100	9/27	33	7/15	47	25/33	76

		Patient	survival
Factor	Patients, no.	No.	0/0
Clinical stage	and the second second		
IIB	15	15	100
lic	5	4	80
	13	6	46
Retroperitoneal tumour bulk, cm			
Stage II $< 5$	9	9	100
> 5	11	8	73
Pulmonary metastases, cm			
Unilateral < 2	3	3	100
Bilateral < 2	4	1	25
> 2	6	1	17

		Patient survival		
Tumour marker levels	Patients, no.	No.	0/0	
$\alpha$ -fetoprotein, ng/mL				
5 - 100	16	12	75	
101 – 999	4	4	100	
>1000	5	4	80	
$\beta$ -human chorionic gonadotropin, ng/mL				
2 – 100	11	10	91	
101 - 999	6	4	67	
1000 - 9999	5	4	80	
> 10 000	2	1	50	

tween the degree of initially elevated AFP or BHCG levels and survival was noted (Table V). However, 6 (21%) of 28 patients with persistently elevated AFP levels after one cycle of chemotherapy died of disease. All patients with elevated AFP or BHCG levels, or both, after two cycles of chemotherapy died (p < 0.001). No patient with normal levels of AFP or BHCG after two cycles of chemotherapy died of disease (p < 0.05).

# Discussion

Several authors have identified prognostic factors in advanced NSTC that may identify a patient as a poor risk.<sup>1,2,5</sup> All agree on the importance of tumour bulk at the time of diagnosis. However, there is no general agreement as to which other prognostic factors are truly significant.

Among the factors found significant in our patients was the correlation between duration of symptoms and survival. This has been demonstrated for advanced NSTC patients in other studies.<sup>7-12</sup> The increased mortality seen with delays in diagnosis reinforces the importance of self-examination programs.

Several authors<sup>13-16</sup> have studied the effect of different chemotherapy regimens on "poor-risk" groups. There was no consensus on the constituents of a "poor-risk" group in these studies; therefore, it is impossible to compare the results accurately. No agreement on the chemotherapeutic treatment of "poor-risk" groups has emerged from these and other studies.

Other factors such as retroperitoneal tumour volume, AFP levels, number of pulmonary metastases and visceral organ involvement have been suggested as characteristics defining poor-risk patients. Initial complete response rates of up to

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94% have been found in patients considered to be "poor risk" by one set of criteria but "good risk" by another.<sup>17</sup> Retroperitoneal tumour volume, number of pulmonary metastases and AFP and BHCG levels have all been demonstrated to be significant in other studies.<sup>3,4,13,18-22</sup> We found that persistently elevated AFP and BHCG levels after two courses of chemotherapy were predictive of a worse prognosis than when the levels normalized.

Large prospective studies using multivariate analysis of prognostic factors are needed to spare goodrisk patients from potentially toxic chemotherapy and to identify a definitive poor-risk group. This study has helped to provide the basis for eligibility criteria for such groups.

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# The Cardiac Surgery Program at the Royal Columbian Hospital: Review of the First Fiscal Year

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From a budgetary viewpoint, the authors summarize the operative experience of the cardiac surgery program at the Royal Columbian Hospital during its first fiscal year of operation. The program was funded for 250 cardiopulmonary bypass (CPB) procedures: \$16 800 per CPB procedure (\$4.2 million for the program). The 250 CPB procedures were performed on 248 patients. The 30-day operative mortality was 2%. Thirty patients (12.1%) underwent a second operation for complications or delayed primary closure of the sternum, or both; the complications included aortic prosthetic perivalvular leaks in 2 patients. Eight patients (3.2%) required insertion of an intra-aortic balloon pump preoperatively to stabilize their condition; 10 others (4.0%) required intra-aortic balloon pump insertion at surgery to correct low-cardiac-output syndrome. Blood products were needed for 149 (59.6%) of the 250 CPB procedures. The average hospital stay was 10.4 days for noncoronary procedures and 9.0 days for coronary procedures.

Les auteurs résument au plan budgétaire les résultats d'exploitation du programme de chirurgie cardiaque du Royal Columbian Hospital durant son premier exercice financier. Le programme a reçu des fonds pour 250 pontages aortocoronariens (PAC) : 16 800 \$ par malade ou 4,2 millions de dollars pour l'ensemble du programme. Les 250 PAC furent effectués chez 248 patients. La mortalité opératoire à 30 jours fut de 2 %. Trente patients (12,1 %) subirent une seconde opération pour des complications ou pour défaut de soudure primaire du sternum, ou pour les deux; parmi les complications, on a constaté des fuites périvalvulaires de la prothèse aortique chez deux patients. Huit patients (3,2 %) ont nécessité l'insertion d'une pompe à ballonnet intra-aortique (PBIA) en préopératoire pour stabiliser leur état; 10 autres (4,0 %) ont nécessité la PBIA durant l'intervention pour corriger un syndrome de faible débit cardiaque. Des dérivés sanguins furent requis pour 149 (59,6 %) des 250 PAC. Le séjour hospitalier moyen fut de 10,4 jours pour les interventions non coronariennes et de 9,0 jours pour les interventions coronariennes.

**B** ecause of increasing demand, three new cardiac surgery units were established in Canada in 1990 and 1991. One of these, at the Royal Columbian Hospital in New Westminster, BC, was established to provide community service rather than a new teaching program.

In conjunction with the increasing demand for cardiac surgical services there is a demand for greater fiscal responsibility by all levels of health care personnel. The goal for the new heart unit set by the Ministry of Health of British Columbia was to provide 250 cardiopulmonary bypass (CPB) procedures in the first fiscal year, with an operating budget of \$16 800 per procedure (including bridge funding) — a total of \$4.2 million. The goal of the Royal Columbian Hospital was to provide this care with a mortality of less than 2%, in a way that would have minimal impact on the function of other services in the institution.

We report on the 250 CPB proce-

dures completed between Apr. 1, 1991 and Mar. 31, 1992 — the first fiscal year of the new cardiac unit.

# Background

A number of factors affected the provincial government's decision to open a heart unit at the Royal Columbian Hospital. An apparent increase in the elective waiting list for open heart surgery was of increasing concern.<sup>1</sup> For several

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### Accepted for publication July 9, 1993

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months before the government's decision, the medical staff had worked zealously to draw attention to the particular needs of the patients at the Royal Columbian Hospital and the advantages to government in locating the heart surgery unit there. The provincial government had carried out an independent review of the needs for open heart surgery in the province of British Columbia; this review identified the establishment of a cardiac unit at the Royal Columbian Hospital as an ideal solution to the need for further cardiac service in the province. A nursing strike and severe shortage of perfusion personnel thwarted the provincial ministry of health's efforts to increase the caseload through additional funding in the province's existing heart units. The increased expenditures did not reduce the waiting list or increase the number of procedures performed. These factors created a climate of scepticism on the part of both the Ministry of Health of British Columbia and the medical community and led to the requirement that the 1st year's operation of the new unit must provide evidence of the ability to achieve mutually acceptable goals.

The inaugural year was also expected to attract intense scrutiny from the medical staff of the Royal Columbian Hospital. They had given unanimous approval to the hospital's medical administration to establish an open heart surgery program that would function within an established budget and not create demands on the underfunded critical care areas of the hospital. The medical community in the greater referral area was also expected to monitor the surgical outcome of the inaugural caseload out of genuine concern for the patients. For these reasons, and to provide reassuring statistics to the general community, it was decided to apply

stringent case exclusion criteria for the inaugural period.

# **Exclusion** Criteria

These criteria essentially excluded patients with known risk factors that would adversely affect their surgical outcome. They included patients requiring heart transplants, procedures on the thoracic aorta, repeat cardiac procedures, procedures for major congenital cardiac deformities, emergency procedures other than cardiac catheterization and patients who had associated critical systemic, pulmonary, renal, cerebrovascular or hemopoietic disorders. Verbal agreements made with established cardiac units in British Columbia allowed easy referral of these higher-risk patients.

# Results

Between Apr. 1, 1991, and Mar. 31, 1992, 250 CPB procedures were performed on 248 patients (Table I); 2 required a repeat procedure with cardiopulmonary bypass before discharge from hospital after the initial operation. Patients were categorized by age, sex and admission status (Tables II and III). Times spent by the patients on the various nursing units and mean hospital stays were also recorded. Fifteen patients underwent multiple or miscellaneous operations.

# Death Rate

Five (2.0%) of the 248 patients

died within 30 days of operation (Table IV).

# Complications

Patients were returned to the operating room on 30 occasions because of complications or for further management. In 16 cases reopening of a recent sternotomy was required because of bleeding or tamponade. Thirteen patients were returned to the operating room for delayed primary closure of an open sternotomy in the management of low-output syndrome. One patient was returned to the operating room for removal of a foreign body (a piece of chest tube). In two patients who underwent aortic valve replacement, suture line disruption at the site of the first valve insertion necessitated repeat valve replacement with CPB. One of these patients was the recipient of a double valve implant at the first procedure.

Intra-aortic balloon pumps were used on 18 patients (7.2%) to enhance myocardial and systemic perfusion. In eight cases (3.2%), the patient arrived in the operating room with the intra-aortic balloon pump in situ after it was inserted in the catheterization laboratory to stabilize the patient's condition for emergency coronary artery bypass grafting. This practice provided a smooth transition for the patient from the catheterization laboratory to the operating room, allowing for organized operative intervention. The remainder of the intra-aortic balloon pumps were placed intraop-

Table I. Summary of Cardiopulmonary Bypass at the Royal Columbian H	Procedures Performed During t ospital, New Westminster, BC	the First Fiscal Yea
Type of procedure	No.	0/0
Coronary artery bypass grafting	196	78.4
Aortic valve	25	10.4
Mitral valve	10	4.0
Atrial septal defect	4	1.6
Combined and miscellaneous	15	6.0
Total	250	100.0

# NEW CARDIAC SURGERY PROGRAM

eratively to manage low-output syndrome and facilitate weaning from cardiopulmonary bypass.

One patient had a prolonged hospitalization because of dehiscence of a leg incision. Two patients were readmitted for sternal wound infection, which required open sternotomy, operative débridement and prolonged hospitalization with healing by secondary intention (0.8% infection); neither of these patients had delayed primary closure of the sternum.

## Blood Bank Use

During the fiscal year, blood transfusions were required during 149 (59.6%) of the 250 CBP procedures (Table V). Overall, 160 (64.5%) patients required two or less units of blood (99 [39.9%] of them required no transfusion at all).

## Hospital Stay

The average length of hospital stay was 10.4 days for noncoronary procedures and 9.0 days for CBP procedures. This compared with a national average of 14 days (HMRI data).

### Discussion

Our cardiac unit consists of two

fully equipped operating rooms, which were used on alternate days to complete these procedures and ensure that the new equipment was functional in both theatres, a cardiac surgery intensive care unit (CSICU) with four beds and a ward component consisting of six patient beds. The national average of 14 days from HMRI data was used to budget for length of stay. We planned for an operative death rate of 2% or less in our lst year, based on our case exclusion criteria. The 30-day death rate was precisely 2%.

Funds were made available for the open heart surgery program at the Royal Columbian Hospital in its first fiscal year from the Ministry of

		Se	Sex		Admission category		Mean stay	Mean stay	Mean	
	Mean age, yr	M	F	E	U	EI	in CSICU, d	on ward, d	hospital stay, d	
1	8	60.7	4	4	2	4	2	3.87	5.37	9.42
2	26	60.7	20	6	2	15	9	3.07	5.42	8.49
3	50	63.3	38	12	2	44	4	3.48	5.38	8.76
1	55	65.6	38	17	3	48	4	3.38	5.63	9.01
5	37	65.5	29	8	3	31	3	3.62	5.43	9.05
6	17	63.1	16	1	2	14	1	3.64	5.70	9.34
7	2	64.5	2	Ö	ō	1	1	3.50	5.50	9.00
8	1	68.0	1	Ő	0	1	0	3.00	6.00	9.00
Total/mean	196	63.9	148	48	14	158	24	3.45	5.56	9.01

Principal procedure						Admission category		Mean stay	Mean stay	Mean
	No. of patients	Mean age, yr	M	F	E	U	EI	in CSICU, d	on ward, d	hospital stay, d
Mitral valve	1. N. C. S. M.									0.00
Repair	3	45.0	0	3	0	0	3	2.33	7.33	9.66
Tissue								11 50	0.00	14.50
replacement	2	80.5	1	1	1	1	0	11.50	3.00	14.50
Mechanical									5.04	11 50
replacement	13	57.6	3	10	1	11	1	5.69	5.84	11.53
Aortic valve										
Tissue				14					0.00	10.00
replacement	3	74.6	1	2	0	3	0	4.00	8.33	12.33
Mechanical							_	1.07	0.00	10.20
replacement	26	66.5	21	5	1	18	7	4.07	6.23	10.30
Repair of										
atrial septal								0.05	4.00	6.45
defect	4	50.0	2	2	0	0	4	2.25	4.20	0.45
Removal of								0.00	5.00	0.00
тухота	1	67.0	0	1	0	0	1	3.00	5.00	8.00
Total/mean	52	63.0	28	24	3	34	15	4.69	5.70	10.39

Health of British Columbia (\$15 077 per CPB procedure) and from bridge funding provided by the Royal Columbian Hospital (\$1800 per CPB procedure). The total of \$16 800 per procedure was the total program budget available for the 1st year of operation and amounted to \$4.2 million. Careful cost-centre analysis of the actual money spent during the first fiscal year indicated that the program had an operating surplus of \$164 887 or \$659 per procedure. (Cost centres had been established within each hospital department to evaluate the inaugural year of open heart surgery experience.) The program was managed on a month-to-month basis by a program management committee, representing key areas of the hospital administration, and by the open heart surgery team. The program management committee was concerned that as case

exclusion criteria were withdrawn, the narrow operating surplus would likely preclude a balanced operating budget for the program. From a hospital accounting viewpoint, however, the first year's results were obtained with the expenditure of \$16 141 per procedure of the \$16 800 funded for each CPB procedure.

Review of our findings invites a discussion of the principles of case selection. It had been our intention to provide emergency surgery only to patients who encountered misadventure during angioplasty procedures and that other patients identified for urgent or emergent surgery would be transferred to the other institutions that had supported the catheterization laboratory at the Royal Columbian Hospital. Within a few months of the program's initiation, however, the scope of emergency support was broadened to

Table IV. Details of Operative Deaths					
Patient no.	Diagnosis	Procedures performed	Postop. survival, c		
1	Critical aortic and mitral stenosis, ischemic heart				
	disease	AVR, MVR, CABG X 3	11		
2	Rheumatic valvular heart				
	disease	AVR, MVR	15		
3	Severe mitral insufficiency	MVR	2		
4	Aortic root aneurysm with		-		
	aortic insufficiency	Bentall procedure	20		
5	Severe aortic stenosis and mitral regurgitation,	p.000000	20		
	ischemic heart disease	AVR, MVR, CABG X 3	18		

include any patients resident in the Royal Columbian Hospital whose anatomy had been defined and who did not have multisystem disease. Our intention to avoid repeat surgery similarly had to be disregarded. Four repeat procedures were, for various reasons, undertaken in the 1st year. As the program gained momentum, the intention to avoid combined procedures was also disregarded, and complicated multipleprocedure cases were included, accounting for 6% of the total.

Nevertheless, patient selection was quite strictly applied to the candidates for surgery through the 1st fiscal year. The cooperation of the referring cardiologists at the Royal Columbian Hospital and the surgeons working in established programs at other centres, which permitted this case selection, must have acted favourably on the overall results in terms of morbidity and mortality. The relatively low use of intra-aortic balloon pump support (4.0%) in patients not identified as candidates for surgery from the catheterization laboratory also indicates the favourable effect of case selection. This effect is reflected in the overall length of patient stay in the unit, and also in the CSICU, the costs for which were well below the budgeted target for the program that had been based on HMRI standards.

Review of the complications re-

	No. (%) of		Blood product, mean units/procedure				
Procedure	No. of patients	procedures with blood products	RBCs	Platelets	FFP	Cryo.	
CABG	196	112 (57.1)	2.22	0.23	0.62	0.21	
AVR	25	15 (60.0)	4.64	2.24	1.92	0.21	
MVR	10	6 (60.0)	4.20	2.80	2.40	2.60	
Atrial septal		- ()	neo	2.00	2.40	2.00	
defect repair	4	1 (25.0)	0.25				
Combined and		1 (20.0)	0.20			-	
miscellaneous							
procedures	15	15 (100.0)	6.00	2.00	9.60	1.00	
		. ,	0.00	2.00	9.00	1.00	
Total/mean	250	149 (59.6)	2.74	0.63	1.34	0.32	

quiring repeat operative intervention revealed that of the 30 occasions on which this was required, 13 procedures were for delayed primary closure of the sternotomy, which had been electively packed open either at the time of the initial procedure due to low-output syndrome or at the time of emergency sternotomy for hemorrhage or for management of diffuse nonspecific bleeding. It has been our experience in many patients requiring intraaortic balloon counterpulsation for low-output syndrome that hemodynamics are markedly improved by a decision to delay sternal closure. It has also been our experience that patients returned to the operating room because of hemorrhage or tamponade in whom the bleeding site is not identified are best treated by packing the sternal incision and delaying sternal closure for 24 to 36 hours. This technique has not been associated with an increased incidence of infection, and we believe it helped to keep our operative mortality at the expected 2%.

In the two patients who did have deep sternal wound infection, the sternum was closed primarily in one instance. The other patient had been treated by delayed closure. Surgical treatment of both cases was accomplished by immediate reopening of the entire sternotomy wound allowing débridement, irrigation and packing in the operating room. Over the following 2 to 3 weeks' stay in the Royal Columbian Hospital, these patients were managed by repeated replacment of the packing three times a day with sponges soaked in quarter-strength Dakin's solution. The patients were then transferred to another institution for long-term sternal wound care before being discharged home to allow healing by secondary intention.

Reoperation for periprosthetic aortic valve leak was required in

two patients, both of whom had rheumatic valvular heart disease with severe annular calcification. The leaks occurred despite the use of pledgeted sutures and care taken to control decalcification of the heavily calcified annulus.

Sixty-four percent of our patients could have been managed without the use of any blood bank products if there had been a mechanism in place for preoperative personal blood donation and storage of two units. The overall effect of such a mechanism would have been a net donation to the blood bank. It is hoped that such a procedure can be provided in the future at our hospital.

During the 1st fiscal year of operation of the new cardiac surgery program, approximately twothirds of the patients identified by the cardiac catheterization laboratory at the Royal Columbian Hospital as candidates for open heart surgery were referred to other institutions. Some of these referrals were arranged as we attempted to meet our case exclusion criteria, but the bulk of referrals were required because of the overall ceiling on the program of 250 funded CPB procedures. The strains created in the Department of Cardiac Sciences by referring two-thirds of the surgical caseload were considerable, and the members of the Department will continue to work with the hospital administration to expand the program as additional ministry of health funding is secured.

## Conclusions

The inaugural fiscal year of the open heart surgery program has been viewed as successful by the Ministry of Health of British Columbia, the hospital administration and the medical staff both within and referring to the Royal Columbian Hospital. The new unit demonstrated that it could function within a budget (250 procedures budgeted, 250 procedures completed). The staff in the program were able to control the demands for emergency procedures and function within the program budget. The program operated without interfering with scheduled cases on the main operating room slate and with little impact on the medical and surgical intensive care units or the coronary care unit. The professional staff directly involved with the program were able to work together as a team and provide morbidity and mortality results that would inspire the confidence of colleagues and the community.

Reflection on the principles involved in planning for a new open heart unit at the Royal Columbian Hospital reinforces that case exclusion criteria, even if not 100% applicable, were important in achieving the program's goals. Other decisions, including recruitment and employment of experienced personnel responsible for the initial phase of the program, must be viewed as another factor responsible for success. The decision to manage the funding as a separate program outside the hospital global budget gives the opportunity to measure success in financial terms, namely a balanced budget. As daunting as the prospect may be for the personnel handling the initial caseload, the anxiety felt by patients having surgery in an untested unit must be even greater. If the experience at the Royal Columbian Hospital were to be followed in opening other new units, the patients should be reassured of a satisfactory outcome.

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TORADOL® (ketorolac tromethamine) 10 mg tablets

TORADOL® IM (ketorolac tromethamine injection) 10 mg/mL, 15 mg/mL or 30 mg/mL intramuscular injection

### THERAPEUTIC CLASSIFICATION: Analgesic Agent

### ACTION

ACTION: Toradol (ketorolac fromethamine) is a non-steroidal anti-inflammatory drug (NSAID) that exhibits analgesic activity mediated by peripheral effects. Ketorolac inhibits the synthesis of prostaglandins through inhibition of the cyclo-oxygenase enzyme system. At analgesic doses, it has minimal anti-inflammatory and antipyretic activity. Pain relief is comparable following the administration of ketorolac by intramuscular or oral routes. The peak analgesic doses of the administration of ketorolac by intramuscular or oral routes. The peak and difference over the recom-mended dosage range. The greatest difference between large and small doses of Toradol administered by either route is in the duration of analgesia. Ketorolac tromethamine is rapidly and completely absorbed when administered by either the oral or the intramuscular route. The pharmacokinetics are linear following single and multiple dosing. Steady state plasma levels are attained after one day of Q.I.D. dosing. Following oral administration, peak plasma concentra-tions of 0.7 to 1.1 µg/mL occurred at an average of 44 minutes after a single 10 mg dose. The terminal plasma elimination half-life ranged between 2.4 and 9.0 hours in healthy adults, while in elderly subjects (mean age = 72 years), it ranged between 4.3 and 7.6 hours. A high fat meal decreased the rate, but not the extent, of absorption of ral ketorolac tromethamine. The use of an antacid had no effect on the pharmacokinetics of ketorolac. Following intramus

The use of an antacid had no effect on the pharmacokinetics of ketorolac. Following intramus-cular administration, peak plasma concentrations of 22 to 3.0 µg/mL occurred an average of 50 minutes after a single 30 mg dose. The terminal plasma half-life ranged between 3.5 and 9.2 hours in young adults and between 4.7 and 8.6 hours in elderly subjects (mean age = 72 years). hours in young adults and between 4.7 and 8.6 hours in elderly subjects (mean age = 72 years). In renally impaired patients there is a reduction in clearance and an increase in the terminal half-life of ketorolac tromethamine (see table below). The primary route of excretion of ketoro-lac tromethamine and its metabolites (conjugates and the p-hydroxy metabolite) is in the urine (91.4%) with the remainder (6.1%) being excreted in the feces. More than 99% of the ketorolac in plasma is protein bound over a wide concentration range. The hemodynamics of anaes-thetized patients were not altered by parenteral administration of Toradol.

# THE INFLUENCE OF AGE, LIVER AND KIDNEY FUNCTION ON THE CLEARANCE AND TERMINAL HALF-LIFE OF TORADOL IM<sup>1</sup> AND ORAL<sup>2</sup>

		or rolo bound ?	THE OIGH	
TYPES OF SUBJECTS		LEARANCE /h/kg) <sup>3</sup>	TERMINAL HALF-LIFE (in hours)	
	IM MEAN (range)	ORAL MEAN (range)	IM MEAN (range)	ORAL MEAN (range)
Normal Subjects IM (n=54) Oral (n=77)	0.023 (0.010-0.046)	0.025 (0.013-0.050)	5.3 (3.5-9.2)	5.3 (2.4-9.0)
Healthy Elderly Subjects IM (n=13), Oral (n=12) (mean age = 72, range = 65-78)	0.019 (0.013-0.034)	0.024 (0.018-0.034)	7.0 (4.7-8.6)	6.1 (4.3-7.6)
Patients with Hepatic Dysfunction IM and Oral (n=7)	0.029 (0.013-0.066)	0.033 (0.019-0.051)	5.4 (2.2-6.9)	4.5 (1.6-7.6)
Patients with Renal Impairment IM and Oral (n=9)(serum creatinine 1.9-5.0 mg/dL)	0.014 (0.007-0.043)	0.016 (0.007-0.052)	10.3 (8.1-15.7)	10.8 (3.4-18.9)
Renal Dialysis Patients IM (n=9)	0.016 (0.003-0.036)		13.6 (8.0-39.1)	

<sup>1</sup> Estimated from 30 mg single IM doses of ketorolac tromethamine

Estimated from 10 mg single oral doses of ketorolac tromethamine <sup>3</sup> Litres/hour/kilogram

### INDICATIONS:

Oral Route: Orally administered Toradol (ketorolac tromethamine) is indicated for the shortterm management of mild to moderately severe pain, including post-surgical pain (such as general, orthopaedic and dental surgery), acute musculoskeletal trauma pain and post-partum uterine cramping pain.

Intramuscular Route: Intramuscular injection of Toradol is indicated for the short-term man-agement of moderate to severe pain, including pain following major abdominal, orthopaedic and gynecological operative procedures.

### CONTRAINDICATIONS

Hypersensitivity: Like other non-steroidal anti-inflammatory drugs, Toradol (ketorolac tromethamine) has been associated with hypersensitivity reactions. Toradol should not be used when there is a known or suspected hypersensitivity to the drug. Because of the possibility of cross-sensitivity. Toradol should not be used in patients with the complete or partial syndrome of nasal polyps, angloedema, bronchospastic reactivity (e.g. angloedema and gic manifestations to acetylsalicylic acid (ASA) or other non-steroidal anti-inflammatory drugs. Severe and fatal anaphylactoid reactions have occurred in such individuals.

Gastrointestinal: As with other NSAIDs, Toradol also should not be used in patients with peptic ulcer or active inflammatory disease of the gastrointestinal system. Severe and fatal reactions have occurred in such individuals.

### WARNINGS

The long-term administration of Toradol (ketorolac tromethamine) is not recom-mended. The most serious risks associated with NSAIDs including Toradol are:

Gastrointestinal Ulcerations, Bleeding and Perforation: Serious gastrointestinal toxicity, such as bleeding, ulceration, and perforation, can occur at any time, with or without warning symp-toms, during therapy with non-steroidal anti-inflammatory drugs. To date, studies with NSAIDs have not identified any subset of patients not at risk for developing peptic ulceration and bleeding. Post-marketing experience with Toradol suggests that there may be a greater risk of gastrointesti-nal ulcerations, bleeding, and perforation in the elderly, and most spontaneous reports of fatal gastrointestinal events are in the aged population.

LONG-TERM USE OF TORADOL: The oral use of Toradol 10 mg QID on a long-term basis is associat-ed with more gastrointestinal tract adverse effects than is ASA 650 mg QID. In a clinical trial in 823 patients with chronic pain states comparing Toradol tablets 10 mg QID (553 patients) with ASA 650 mg QID (270 patients), during the first week there was a 2.4% dropout rate because of upper GI complaints in the Toradol tablets treated patients as compared with 0.4% rate in the ASA treated group. After the first 2 weeks, the dropout rates due to GI pain or discomfort were comparable in both treatment groups. The time-adjusted percentages, which are not statistically significantly different, of patients who developed ulcers or upper GI bleeding are as follows:

	CUMULATIVE OCCURRENCE	
INTERVAL	KETOROLAC	ASA
≤ 3 months	0.69*	0*
≤ 6 months	1.59*	0.73*

\*There was no statistically significant difference between ketorolac and ASA at either of the intervals tested

PHYSICIANS SHOULD CAREFULLY WEIGH THE POTENTIAL RISKS AND BENEFITS OF USING TORADOL TABLETS ON A LONG-TERM BASIS. PATIENTS SHOULD BE INSTRUCTED TO WATCH FOR SIGNS OF SERIOUS GI ADVERSE EVENTS AND THEY SHOULD BE MONITORED MORE CLOSELY THAN IF THEY WERE ON ANOTHER NSAID

Renal Toxicity: The following renal abnormalities have been associated with Toradol and other drugs that inhibit renal prostaglandin biosynthesis: acute renal failure, nephrotic syndrome, interstitial nephritis, renal papillary necrosis

Haemorrhage: Postoperative haematomas and other symptoms of wound bleeding have been reported in association with the perioperative use of intramuscular Toradol. If Toradol is to be administered to patients who have coagulation disorders or who are receiving drug therapy that interferes with haemostasis, careful observation is advised

Hypersensitivity Reactions: The possibility of severe or fatal hypersensitivity reactions should be considered, even for patients with no known history of previous exposure or hyper-sensitivity to Toradol or other NSAIDs. As with other NSAIDs, patients should be questioned for history of allergy to NSAIDs or ASA or for the syndrome consisting of nasal polyps. ASA allergy and asthma before being prescribed Toradol. Asthmatic patients with thad asthma (the syndrome of nasal polyps, asthma and hypersensitivity to ASA or other NSAIDs) may be at particular risk for severe hypersensitivity reactions.

Other NSAIDs: Ketorolac tromethamine is not recommended for concurrent use with other NSAIDs because of the potential for additive side effects.

Use in Pregnancy and Lactation: The administration of ketorolac tromethamine is not recom-mended during pregnancy or lactation. After 1 day at 10 mg QID. oral dosing. Toradol has been defected in the milk of lactating women at a maximum concentration of 7.9 ng/mL.

Use in Labour: Ketorolac tromethamine is not recommended for use as an obstetrical preoperative medication or for obstetrical analgesia because of the known effects of NSAIDs on uterine contraction and fetal circulation

Use in Children: Safety and efficacy in children have not been established. Therefore, Toradol is not recommended for use in children under age 16.

Use in the Elderly: Because ketorolac is cleared somewhat more slowly by the elder-ly (See PHARMACOKINETICS) who are also more sensitive to the gastrointestinal and renal effects of NSAIDs (See WARNINGS and PRECAUTIONS), extra caution and the lowest effective dose (See DOSAGE AND ADMINISTRATION) should be used.

#### PRECAUTIONS:

Physicians should be alert to the pharmacologic similarity of Toradol (ketorolac tromethamine) to other non-steroidal anti-inflammatory drugs that inhibit cyclo-oxygenase. Toradol is not an anesthetic agent and possesses no sedative or anxiolytic properties.

Gastrointestinal Effects: Close medical supervision is recommended in patients prone to gastrointestinal tract irritation, particularly those with a history of peptic ulcer, diver-ticulosis or other inflammatory disease of the gastrointestinal tract. In these cases, the physician must weigh the benefits of treatment against the possible hazards. Patients taking any NSAID including ketorolac tromethamine should be instructed to contact a physician Install including kerorolac fromerinamine should be instructed to contact a physician immediately if they experience symptoms or signs suggestive of peptic ulceration or gastroin-testinal bleeding. These reactions can occur at any time during the treatment. If peptic ulcer-ation is suspected or confirmed, or if gastrointestinal bleeding occurs, ketorolac tromethamine should be discontinued and appropriate treatment instituted with close patient monitoring.

Renal Effects: As with other drugs that inhibit prostaglandin biosynthesis, elevations of blood urea nitrogen (BUN) and creatinine have been reported in clinical trials with (ketoro-lac tromethamine). Since ketorolac tromethamine and its metabolites are excreted primarily Icc tromethamine). Since ketorolac tromethamine and its metabolites are excreted primarily by the kidney, the following precautions are indicated for patients with: Severely impaired renal function (serum creatinine values greater than 5 mg/dL, 442 µmol/L): Toradol is not rec-ommended; Moderately impaired renal function (serum creatinine values ranging from 1.9 to 5.0 mg/dL, 168 to 442 µmol/L) - The total daily dose of ketorolac tromethamine should be reduced the for the activative the total daily dose of ketorolac tromethamine should be to approximately half. In these patients the rate of ketorolac tromethamine clearance was reduced to approximately half of normal. Patients who are volume depleted may be dependent on renal prostaglandin production to maintain renal perfusion and, therefore, glomerular filtration rate. In such patients, the use of drugs which inhibit prostaglandin synthesis has been associa-ted with the dependent on ted with further decreases in renal blood flow. Predisposing factors include sepsis, impaired renal function, heart failure, liver dysfunction, diuretic therapy, and advanced age. Caution is advised if ketorolac fromethamine is used in such circumstances. Close monitoring of urine output, serum urea and serum creatinine is recommended until renal function recovers.

Hepatic Effects: Meaningful elevations (greater than 3 times normal) of serumtransami-nases (glutamate pyruvate (SEPT or ALT) and glutamic oxalacetic (SEOT or AST)), occurred in controlled clinical trials in less than 1% of patients. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), ketoro-lac tromethamine should be discontinued. Patients with impaired hepatic function from cirtho-lac have any clinically impacting to hepatic purchase. But of the theorem is a constrained by the second s is do not have any clinically important changes in ketoralact memory and the clearance. Studies in patients with active hepatitis or cholestasis have not been performed.

Fluid and Electrolyte Balance: Fluid retention and edema have been observed in patients reated with Toradol. Therefore, as with many other NSAIDs, the possibility of precipitating con-gestive heart failure in elderly patients or those with compromised cardiac function should be considered. Toradol should be used with caution in patients with cardiac decompensation, hypertension or other conditions which cause a predisposition to fluid retention.

Hematologic Effects: Ketorolac tromethamine inhibits platelet function and may prolong Hematologic Effects: Ketorolac fromethamine inhibits platelet function and may prolong bleeding time. It does not affect platelet count, prothrombin time (PT) or partial thromboplas-tin time (PT). Unlike the prolonged effects from ASA the inhibition of platelet function by ketorolac tromethamine is normalized within 24 to 48 hours after the drug is discontinued. Patients on full anti-coagulation therapy (e.g. heparin or dicumarol derivatives) may be at increased risk of bleeding if given Toradol concurrently. Thus, the benefit should be weighed against this risk. The concomitant use of Toradol and heparin (5000 U s.c. BID) appears to be associated with less risk (see DRUG INTERACTIONS). In patients receiving anticagulants, the risk of intramuscular haematoma formation from Toradol IM injections may be increased. In post-marketing experience, postoperative wound haemorrhage has been reported with the use of Toradol. Therefore, caution should be exercised when strict haemostasis is critical. Toradol IM is not recommended as a pre-operative or intra-operative medication because of the risk of excessive bleeding. Blood dyscrasias associated with the use of NSAIDs are rare, but could occur with severe consequences.

Infection: In common with other non-steroidal anti-inflammatory drugs, ketorolac tromethamine may mask the usual signs of infection.

#### DRUG INTERACTIONS:

Protein Binding: Toradol (ketorolac tromethamine) is highly bound to human plasma protein (mean 99.2%) and binding is independent of concentration. As ketorolac tromethamine is a highly potent drug and present in low concentrations in plasma, it would not be expected to displace other protein-bound drugs significantly. Therapeutic concentrations of digoxin, warfarin, acetaminophen, phenytoin, and tolbutamide did not alter ketorolac tromethamine protein binding.

Anticoagulant Therapy: Prothrombin time should be carefully monitored in all patients Anticcagulant Therapy: Prothrombin time should be catefully monitored in all patients receiving oral anticcagulant therapy concomitantly with ketorolac tromethamine. Toradol IM given with two doses of 5000 U of heparin to 11 healthy volunteers resulted in a mean tem-plate bleeding time of 6.4 min (3.2-11.4 min) compared to a mean of 6.0 min (3.4-7.5 min) for heparin alone and 5.1 min (3.5-8.5 min) for placebo. The *in vitro* binding of warfarin to plasma proteins is only slightly reduced by ketorolac tromethamine (99.5% control vs. 99.3%) at plasma concentrations of 5 to 10 µg/mL.

Digoxin: Ketorolac tromethamine does not alter digoxin protein binding.

Salicylates: In vitro studies indicated that, at therapeutic concentrations of salicylates (300 µg/mL), the binding of ketorolac tromethamine was reduced from approximately 99.2% to 97.5% representing a potential two-fold increase in unbound Toradol plasma levels.

Enzyme Induction: There is no evidence, in animal or human studies, that ketorolac tromethamine induces or inhibits the hepatic enzymes capable of metabolizing itself or other drugs. Hence, it would not be expected to alter the pharmacokinetics of other drugs due to enzyme induction or inhibition mechanisms.

Probenecid: Concomitant administration of ketorolac tromethamine and probenecid results in the decreased clearance of ketorolac and a significant increase in ketorolac plasma levels (approximately three-fold increase) and terminal half-life (approximately two-fold increase)

Furosemide: Ketorolac tromethamine reduces the diuretic response to furosemide by approximately 20% in normovolemic subjects

Lithium: Some NSAIDs have been reported to inhibit renal lithium clearance, leading to an increase in plasma lithium concentrations and potential lithium toxicity. The effect of ketorolac tromethamine on lithium plasma levels has not been studied.

Methotrexate: The concomitant administration of methotrexate and some NSAIDs has been reported to reduce the clearance of methotrexate, thus enhancing its toxicity. The effect of ketorolac tromethamine on methotrexate clearance has not been studied.

Morphine: Intramuscular Toradol has been administered concurrently with morphine in several clinical trials of postoperative pain without evidence of adverse interactions.

ADVERSE EVENTS:

TORADOL TABLETS: Short-Term Patient Studies - The incidence of adverse reactions in 371 TORADOL TABLETS: Short-lerm Patient Studies - The Incidence of doverse feactions in 37 patients receiving multiple 10 mg doses of Toradol (ketorolac tromethamine) for pain resulting from surgery or dental extraction during the post-operative period (less than 2 weeks) is listed below. These reactions may or may not be drug related. Incidence between 4 and 9%: Nervous system - somnolence, insomnia; Digestive system - nausea. Incidence between 2 and 3%: Nervous system - nervousness, headache, diziness; Digestive system - diarrhea, dyspep-376: Nervous system - nervousness, neodacne, atziniess; bigestive system - alarned, ayspep-sia, gastrointestinal pain, constipation. Body as a whole - fever. Incidence 1% or Less: Nervous system - abnormal dreams, anxiety, dry mouth, hyperkinesia, paresthesia, increased sweating, euphoria, hallucinations; Digestive system - anorexia, flatulence, vomiting, stomatitis, gastritis, gastrointestinal disorder, sore throat; Body as a whole - asthenia, pain, back pain; cardioarge.uke weter weredilation, ended the anorexia back pain; Cardiovascular system: vasodilatation, palpitation, migraine, hypertension; Respiratory system cough increased, rhinitis, dry nose; Musculo-skeletal system - myalgia, arthralgia; Skin and Skin and appendages - rash, urticaria; Special senses - blurred vision, ear pain; Urogenital system:

Long-Term Patient Study - The adverse reactions listed below were reported to be probably related to study drug in 553 patients receiving long-term oral therapy (approximately 1 year) with Toradol. Incidence between 10 and 12%: Digestive system - dyspepsia, gastrointestinal pain

Incidence Between 4 and 9%: Digestive system - nausea, constipation; Nervous system - headache. Incidence Between 2 and 3%: Digestive system - diarrhea, flatulence, gastrointesti-nal fullness, peptic ulcers; Nervous system - Dizziness, somnolence; Metabolic/Nutritional disorder - edema. Incidence 1% or Less: Digestive system - eructation, stomattilis, vomiting, anore-la, duodenai ulcer, gastritis, gastrointestinal haemorrhage, increased appetite, melena, mouth ulceration, rectal bleeding, sore mouth; Nervous system - abnormal dreams, anxiety, depression, dry mouth, insomnia, nervousness, paresthesia; Special senses - tinnitus, taste perversion, abnormal vision, blurred vision, deafness, lacrimation disorder; Metabolic/Nutritional disorder abnormai vision, biurred vision, deatriess, lacrimation disorder; Merabolic//wiliminond disorder Weight gain, alkaline phosphatase increase, BUN increased, excessive thirst, generalized edema, hyperuricemia; Skin and appendages - pruritus, rash, burning sensation skin: Body as a whole - asthenia, pain, back pain, face edema, hernia; Musculo-skeletal system - arthral-gia, myalgia, joint disorder; Cardiovascular system: chest pain, chest pain substernal, migraine; Respiratory system - dyspnea, asthma, epistaxis; Urogenital system - hematuria, increased urinary frequency, oliguria, polyuria; Hemic and lymphatic - Anemia, purpura.

TORADOL IM: The adverse reactions listed below were reported in Toradol IM clinical efficacy trials. In these trials patients (n=660) received either single 30 mg doses (n=151) or multiple 30 mg doses (n=509) over a time period of 5 days or less for pain resulting from surgery.

These reactions may or may not be drug related. Incidence Between 10 and 13%: Nervous System - somnolence; Digestive system - Nausea. Incidence Between 4 and 9%: Nervous sys-System - somnolence; Digestive system - Nausea. Incidence Between 4 and 9%: Nervous sys-tem - headache; Digestive system - vomiting; Injection site - injection site pain. Incidence Between 2 and 3%: Nervous System - sweating, dizziness; Cardiovascular system - vasodilata-tion. Incidence 1% or Less: Nervous system - insomnia, increased dry mouth, abnormal dreams, anxiety, depression, paraesthesia, nervousness, paranoid reaction, speech disorder, euphoria, libido increased, excessive thirst, inability to concentrate, stimulation. Digestive sys-tem - flatulence, anorexia, constipation, diarthea, dyspepsia, gastrointestinal fullness, gastroin-testinal haemorrhage, gastrointestinal pain, melena, sore throat, liver function abnormalities, rectal bleeding, stomatitis; Cardiovascular system - hypertension, chest pain, tachycardia, haemorrhage, palpitation, pulmonary embolus, syncope, ventricular tachycardia, pallor, flush-ing: Injection site - injection site reaction; Body as a whole - asthenia, fever, back pain, chills, pain, neck pain; Special senses - taste perversion, tinnitus, blurred vision, diolopia, retinal haemorrhage; Musco-skeletal system - myalgia, twitching; Respiratory system - asthma, cough increased, dyspnea, epistaxis, hiccup, thinitis; Stin and appendages - pruritus, rash, sub-cutaneous hematoma, skin disorder; Urogenital system - dysuria, urinary retention, oliguria. cutaneous hematoma, skin disorder: Urogenital system - dysuria, urinary retention, oliguria, increased urinary frequency, vaginitis; Metabolic/nutritional disorders - edema, hypokalemia, hypovolemia Hemic and lymphatic system - anemia, coagulation disorder, purpura.

Post-Marketing Experience: The following post-marketing adverse experiences, although rare (1% or less), have been reported for patients who have received either formulation of Toradol.

Renal events - acute renal failure, flank pain with or without haematuria and/or azotemia; Hypersensitivity reactions: bronchospasm, laryngeal edema, hypotension, flushing, rash, and anaphylactoid reactions, such reactions have occurred in patients with no prior history of hypersensitivity. Gastrointestinal events - gastrointestinal hemorrhage, peptic ulceration, gastrointestinal perforation; Hematologic events - postoperative wound haemorthage, rarely requiring blood transtusion (see PRECAUTIONS), thrombocytopenia; Central nervous system-convulsions, abnormal dreams, hallucinations, hyperkinesia, hearing loss; Cardiovascular pulmonary edema; Dermatology - Lyell's syndrome, Stevens - Johnson syndrome, exfoliative dermatitis, maculopapular rash

OVERDOSAGE: The absence of experience with acute overdosage precludes characterization of sequelae and assessment of antidatal efficacy at this time. In a gastroscopic study of healthy subjects, daily doses of 360 mg given over an 8-hour interval for each of five consecutive days (3 times the highest recommended dose) caused pain and peptic ulcers which resolved after discontinuation of dosing.

### DOSAGE AND ADMINISTRATION:

Adults: Dosage should be adjusted according to the severity of the pain and the response of the patient. **Ordi**: The usual oral dose of Toradol (ketorolac tromethamine) is 10 mg every 4 to 6 hours for pain as required. Doses exceeding 40 mg per day are not recommended. Toradol is recommended for short-term use only, i.e., for a maximum of a few weeks.

Parenteral: The recommended usual initial dose is 30 mg. Subsequent dosing may be 10 mg to 30 mg every 4-6 hours as needed to control pain. It is recommended that the administration of Toradol IM be limited to short-term therapy (not over 5 days) and the total daily dose should not exceed 120 mg

This is because the risk of toxicity appears to increase with longer use at recommended doses (see WARNINGS and PRECAUTIONS). The administration of continuous multiple daily doses of Toradol IM has not been extensively studied. There has been limited experience with intramuscular dosing for more than 3 days since the vast majority of patients have transferred to oral medication or no longer required analgesic therapy after this time. In the initial post-operative period, more frequent dosing (e.g. every 2 hours) may be employed but the total daily dosing should not exceed 120 mg/day. If supplementary analgesia is required, a concomitant low dose of opiate can be used.

Patients under 50 kg, over age 65 years, or with less severe pain at baseline: the lower end of the dosage range (10-15 mg 4 times a day) is recommended.

Impaired Renal Function - Moderate - In patients with impaired renal function (serum creatinine values ranging from 1.9 to 5.0 mg/dL or 168 to 442 µmol/L), the total daily dose of Toradol should be reduced by half;

Severe - In patients with severely impaired renal function (serum creatinine values greater than 5 mg/dL, or 442 µmol/L) Toradol is not recommended.

Conversion from Parenteral to Oral Therapy: Toradol tablets may be used either as monotheraconversion from Parentera to Oral interapy: fordato liables may be used entities as infollotted py or as follow-on therapy to parenteral ketorolac. Toradol IM should be replaced by an oral analgesic as soon as feasible. When Toradol tablets are used as a follow-on therapy to par-enteral ketorolac, the total combined daily dose of ketorolac (oral + parenteral) should not exceed 120 mg on the day the change of formulation is made. Subsequent oral dosing should not exceed the recommended daily maximum of 40 mg.

not exceed the recommended daily indxitruit of 40 tilg. Directions for Use of the Prefilled Syringes: Insert the plunger into the syringe barrel and thread if onto the screw. WITHOUT REMOVING THE NEEDLE GUARD, apply quick, firm pressure to the plunger to break the inner seal. (You will feel it let go). Pull back on the plunger slightly to relieve pressure. Remove the needle guard by twisting as you pull. Use the unit as you would a normal syringe. Dispose of properly. Single use only. Discard Unused Portions. Parenteral drug products should be inspected visually for particulate material and discoloration prior to use. Toradol (ketorolac tromethamine) is a Schedule F drug

### Stability and Storage Recommendations:

Toradol Tablets: Store at room temperature with protection from light.

Toradol IM: Store at room temperature with protection from light. Availability of Dosage Forms: Toradol (ketorolac tromethamine) is available as 10 mg white Availability of busgle Politics. Totacing ketorolac fromethamine, microcrystalline cellulose, lac-tose and magnesium stearate with one side printed in red with TORADOL inside bold T and other side with Syntex. Toradol (ketorolac fromethamine) 10 mg tablets are available in bottles of 100 and 500 tablets.

Toradol IM is available in 1 mL ampoules (trays of 10) containing 10 or 30 mg/mL. Toradol IM is also available in 1 mL syringes (1/box) containing 15 or 30 mg/mL.

Product Monograph available on request.

Product Monograph available on request. References: 2. TORADOL Product Monograph, Syntex Inc., Dec. 1992. 3. Rooks WH II. Pharmacother 1990;10(6 Pt 2):30S-32S. 4. Yee JP et al. Pharmacother 1986; 6(5):253-61. 5. Brown CR et al. Pharmacother 1990; 10(6 Pt 2):45S-50S. 6. O'Hara DA et al. Clin Pharmacol Ther 1987; 41:556-61. 7. Fragen RJ. Data on File, Syntex Inc., Document Cl3837, 1987. 8. Cherry C et al. Data on File, Syntex Inc., Document Cl3835, 1987. 9. Stanski DR et al. Pharmacother 1990; 10(6 Pt 2):40S-44S. 10. Data on File, Syntex Inc., Document #90027-1, 1989. 13. Stanligren L. Data on File, Syntex Inc., Document RS-37619, 1991. 16. Data on File, Syntex Inc., Document #90027-2, 1988. 17. Forbes JA et al. Pharmacother 1990;10(6 Pt 2):77S-93S. 18. Forbes JA et al. Pharmacother 1990; 10(6 Pt 2):49S-105S. 21. Data on File, Syntex Inc., Document #90027-3, May 1990. 22. Mehlisch D et al. Data on File, Syntex Inc., Document Cl3686, 1986. 23. Oosterlinck W et al. J Clin Pharmacol 1990; 30: 336-41. 24. Cutting CJ et al. Data on File, Syntex Inc., Document Cl3686, 1986. 23. Oosterlinck W et al. Clift Pharmacol 1990; 30: 336-41. 24. Cutting CJ et al. Data on File, Syntex Inc., Document Cl3648, 27. Herrera JMC et al. Syntex Inc., Document Cl3648, 1980. 27. Herrera JMC et al. 1990. 26. Molinie J et al. Data on File, Syntex Inc., Document CL4624, 1988. 27. Herrera JMC et al. Data on File, Syntex Inc., Document CL4886, 1989. 30. American Pain Society. *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain*, 3<sup>rd</sup> edition, 1992. 36. Hutteman Analgesic Use in the Treatment of Acute Pain and Cancer Pain, 3<sup>IIC</sup> edition, 1992. 36. Hutterman
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Toradol Information Line: 1-800-561-5481.

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# Thoracoscopic Intracavitary Drainage for Pneumothorax Secondary to Bullous Emphysema

John D. Urschel, MD, FRCSC; William J. Dickout, MD, FRCPC

Most patients with spontaneous pneumothorax secondary to bullous emphysema are successfully managed by chest-tube drainage. Occasionally a very large air leak prevents full lung expansion. The authors report on a patient in whom thoracoscopic intracavitary drainage of a leaking bulla led to rapid resolution of the pneumothorax and obliteration of the bulla. A large bronchopleural fistula was converted to a controlled bronchocutaneous fistula. The authors conclude that when conventional management fails to provide full lung expansion in cases of pneumothorax secondary to bullous emphysema, thoracoscopic intracavitary drainage is useful.

La plupart des patients qui subissent un pneumothorax spontané secondaire à un emphysème bulleux sont traités avec succès par drainage thoracique. Occasionnellement, une fuite d'air très importante va empêcher l'expansion complète du poumon. Les auteurs décrivent un cas de ce genre où un drainage intracavitaire par thoracoscopie de la bulle responsable de la fuite a résulté en une résolution rapide du pneumothorax et en l'élimination de la bulle. Une importante fistule bronchopleurale fut transformée en une fistule bronchocutanée contrôlée. Les auteurs concluent que, quand le traitement traditionnel ne suffit pas à permettre l'expansion complète du poumon dans les cas de pneumothorax secondaire à un emphysème bulleux, le drainage intracavitaire par thoracoscopie est utile.

C losed chest-tube drainage is the treatment of choice for patients with pneumothorax secondary to bullous emphysema. We describe a patient in whom we used a thoracoscopic modification of an old technique to manage the pneumothorax. We discuss the place of this modified technique, intracavitary drainage, in the management of pneumothoraces that do not respond to conservative treatment.

# **Case Report**

An 84-year-old man with a histo-

ry of smoking and chronic obstructive pulmonary disease presented with chest pain and dyspnea. Chest radiography showed a left pneumothorax and a bulla in the lower lobe of the left lung (Fig. 1). Insertion of a chest tube resulted in only transient lung expansion. A massive air leak, subcutaneous emphysema and collapse of the lung required insertion of a second chest tube. Pleurodesis with tetracycline was unsuccessful. After 12 days of chest-tube drainage, the pneumothorax and air leak persisted.

Left thoracoscopy was performed under general anesthesia. A rup-

tured bulla was found in the lower lobe of the left lung. Because of the size of the bulla, intracavitary drainage was favoured over endoscopic stapling. The bulla was "pursestringed" with an absorbable suture, and a large Foley catheter was inserted. Two pleural chest tubes were inserted, and the bulla was brought up to the chest wall by gentle traction on the inflated Foley catheter. Air leak from the pleural tubes ceased within 24 hours, and a postoperative radiograph showed lung expansion. A large air leak was noted from the intracavitary Foley catheter. The pleural tubes

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Accepted for publication July 20, 1992

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# THORACOSCOPIC INTRACAVITARY DRAINAGE

were removed after several days (Fig. 2). Despite the presence of a persistent small air leak from the intracavitary tube, it was removed on the 10th postoperative day because pleural symphysis was as-

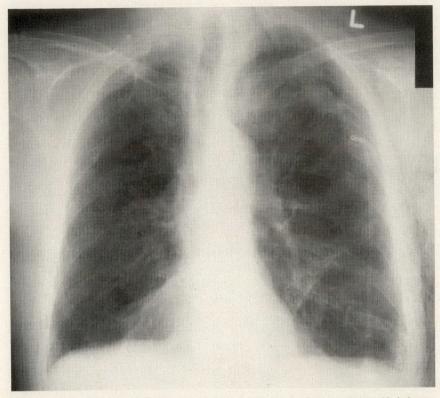


FIG. 1. Chest film showing left pneumothorax and bulla in lower lobe of left lung. Small chest catheter, inserted on emergency basis, was replaced by chest tube.

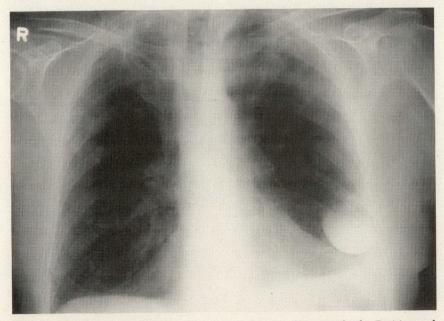


FIG. 2. On 7th postoperative day pneumothorax has resolved. Position of intracavitary drainage tube is shown by balloon filled with contrast material.

sumed to be present. The bronchocutaneous fistula quickly closed, and the pneumothorax did not recur.

# Discussion

Most pneumothoraces secondary to bullous emphysema resolve with a combination of chest-tube drainage and patience. If the lung cannot be expanded by pleural drainage, surgical intervention is necessary. Many of these patients are elderly and have poor pulmonary function so they are not candidates for thoracotomy and excision of the bullae. Minimally invasive thoracoscopic techniques are preferred. These techniques include ligation of the bullae.1 laser or cautery ablation of the bullae<sup>2,3</sup> and endoscopic stapling. Thoracoscopic approaches to pleural symphysis, such as pleural abrasion, pleural cautery or laser pleurodesis,4 pleurectomy1 and talc poudrage,<sup>5</sup> are useful if the lung can be expanded.

Thoracoscopic intracavitary drainage is a modification of Monaldi's two-stage procedure for tuberculous cavities.6 Intracavitary drainage has proved successful in the elective treatment of selected symptomatic patients with bullous lung disease.7 In the case we have described, intracavitary drainage resulted in prompt resolution of the pneumothorax and obliteration of the bulla. A large bronchopleural fistula was converted to a controlled bronchocutaneous fistula. This allowed lung expansion and facilitated the development of pleural symphysis. The bronchocutaneous fistula closed spontaneously after removal of the intracavitary tube.

When conventional methods of management fail, thoracoscopic intracavitary drainage is a useful option in the treatment of selected patients with pneumothorax sec-

# URSCHEL AND DICKOUT

ondary to bullous emphysema. Large bullae are particularly suitable for intracavitary intubation.

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# SESAP VII Critique / Critique SESAP VII

### Item 241

Iatrogenic vascular injuries are an increasingly common event in hospital practice. Invasive diagnostic and therapeutic interventions create situations in which vascular disruption or thrombosis can create acute ischemia, hemorrhage, or neurologic deficit. Although the location of the vascular injury and the presence of preexisting atherosclerotic disease may complicate the repair, a delay in surgical intervention is the dominant factor in predicting permanent disability. That permanent disability is usually a result of the peripheral ischemic neurologic deficit. Prompt reversal of the peripheral ischemia lessens the likelihood of permanent neurologic damage.

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# **P**ica in the Mentally Handicapped: a 15-Year Surgical Perspective

Chris J. Decker, MD, FRCSC

*Objective:* To review the general surgical management of mentally handicapped persons with pica. *Design:* A study of hospital records and a review of the current literature.

Setting: A community hospital.

*Patients:* Thirty-five patients from a large institution for the mentally handicapped were treated for well-documented pica on 56 occasions at the Orillia Soldiers Memorial Hospital between 1976 and 1991.

Interventions: Endoscopy and laparotomy for the removal of foreign bodies or to close perforations. *Results:* Fourteen (25%) cases of pica were managed by observation only, but 42 (75%) cases required surgical intervention. There were 34 laparotomies. The complication rate was 30% and the death rate 11%.

*Conclusions:* Pica is a serious health risk for mentally handicapped patients. Diagnosis and postoperative care can be difficult. Pica should be suspected in mentally handicapped patients with gastrointestinal symptoms.

*Objectif :* Revoir le traitement chirurgical des handicapés mentaux souffrant de pica. *Conception :* Une étude des dossiers d'hôpitaux et une revue de la littérature actuelle. *Contexte :* Un hôpital communautaire.

Patients : Trente-cinq patients d'un important établissement pour handicapés mentaux furent traités pour une pica bien établie, en 56 occasions, au Orillia Soldiers Memorial Hospital, entre 1976 et 1991. Interventions : Des endoscopies et des laparotomies effectuées pour retirer des corps étrangers ou pour refermer des perforations.

*Résultats* : Quatorze cas (25 %) de pica furent traités par simple observation mais 42 cas (75 %) nécessitèrent une intervention chirurgicale. Il y eut 34 laparotomies. Le taux de complications fut de 30 % et la mortalité, de 11 %.

*Conclusions :* La pica représente une menace sérieuse pour la santé des handicapés mentaux. Le diagnostic et les soins postopératoires peuvent présenter de grandes difficultés. La pica doit être soupçonnée chez les handicapés mentaux qui présentent des symptômes gastro-intestinaux.

**P** ica is a pathologic craving for normal food constituents or for substances not commonly regarded as food. First defined by Ambrose Paré in the 16th century, pica is the Latin word for magpie, a bird known for its proclivity to pick up multiple things to satisfy its hunger or curiosity.<sup>1</sup> Pica may be seen in four sets of circumstances: nutritional disorders, social or cultural mores, mental illness and mental handicap. The major nutritional disorder is iron deficiency anemia, which results in the ingestion of many unusual substances such as ice, clay, starch or lead.<sup>2</sup> Cultural practices may involve geophagia (earth eating), which is endemic throughout the world and is valued as an adjunct to religious or magical beliefs in some areas.<sup>3</sup> Among mentally ill people, long-term schizophrenics or those with marked personality disorders may indulge in pica.<sup>4</sup>

Pica is said to be the most fre-

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Accepted for publication Apr. 6, 1993

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quently seen eating dysfunction in the mentally handicapped. Danford and Huber<sup>5</sup> studied 991 institutionalized patients over a 2-year period and found a 25% incidence of pica. It became less frequent as age increased and the level of retardation decreased. Food pica was most frequently found in borderline retarded patients, whereas non-food pica increased with the severity of retardation.

The practice of pica was deliberate in every case, and in 56% specific items such as cigarette butts were preferentially sought. Some researchers believe that pica is related to a patient's inability to discriminate between edible and inedible items, with an infantile hand to mouth response.<sup>6</sup> A small group of patients may suffer from specific brain disorders in the left temporal lobe or amygdala, and this can cause faulty eating patterns.<sup>1</sup>

Patients confined to large institutions for the mentally handicapped provide an opportunity to study this behaviour. Nearby community general hospitals are called upon to provide surgical care. Orillia Soldiers Memorial Hospital (OSMH) provides surgical services to the Huronia Regional Centre (HRC), a large institution for the mentally and physically handicapped. In this paper we report our experience with pica in patients from HRC.

### **Patients and Methods**

A retrospective study of OSMH records from Jan. l, 1976, to Dec. 31, 1991, identified those patients who presented from HRC with documented pica, foreign bodies in the gastrointestinal tract, bowel obstruction, peritonitis or perforation with transfer from another institution. Patients who underwent laparotomy after transfer from another institution were also reviewed. Excluded from analysis were patients who presented with aspiration of foreign bodies and normal pediatric patients with foreign bodies. The HRC records of patients with pica transferred to OSMH were also analysed.

Numerous patients from HRC presented to the emergency department of OSMH with an acute abdomen. Although many were suspected of pica they were excluded from the study if the pica was not clearly documented radiographically, if foreign bodies were not recovered or if ingestion was not witnessed. The data assessed included sex, age, clinical presentation, hemoglobin level and leukocyte count, radiologic findings, operative findings, type of operation, postoperative complications or death, other diagnoses, time from clinical onset to surgery and time of year treated.

# Findings

From 184 cases identified, 56 cases of documented pica in 35 different patients (31 male, 4 female) were treated at OSMH; 21 patients had repeat incidents. The patients ranged in age from 15 to 48 years (median 23 years). All patients were moderately to severely retarded and were usually physically handicapped also. Sixteen patients (46%) were epileptic and were taking antiepileptic medications. Two had Down's syndrome, and one each had microcephaly, tuberous sclerosis, Prader-Willi syndrome and congenital rubella. None was anemic. In eight cases (14%) the patient presented with impaction in the oropharynx or esophagus. The presenting signs were excessive salivation with choking or agitation. In 5 cases (9%) there was gastric outlet obstruction and in 22 cases (39%) there was small-bowel obstruction.

In nine cases (16%) the patient had peritonitis from acute perforation of the gastrointestinal tract: five in the small bowel, three in the large bowel and one in the stomach (Table I).

Five patients had asymptomatic large foreign bodies in the stomach. These were removed when the foreign body failed to pass after a minimum of 5 to 7 days' observation or if the foreign bodies were too large to be removed endoscopically.

Twenty (36%) of the 56 cases of pica occurred in August and September.

Fourteen (25%) cases were treated nonoperatively. In nine cases there was incomplete small-bowel obstruction. In two cases, the patients were seen to ingest foreign bodies but had no symptoms, and in two other cases, asymptomatic patients were found to have foreign bodies on the x-ray film. One patient presented in septic shock and died.

In three cases foreign bodies were removed from the posterior oropharynx or hypopharynx laryngoscopically. In another five cases esophagoscopy was required for removal of foreign bodies.

Thirty-four laparotomies were carried out: 9 involved simple gastrotomy and removal of foreign bodies and 12 involved enterotomy or colotomy, or both. In three cases,

Table I. Clinical Presentation of Pica $(N = 56)$		
Diagnosis	Cases, no. (%)	
Impaction in esophagus or hypopharynx Gastric outlet or small-bowel	9 (16)	
obstruction Perforation Asymptomatic, failure of	27 (48) 9 (16)	
foreign-body passage Observed pica, asymptomatic Gastrointestinal hemorrhage	5 (9) 4 (7) 1 (2)	
Intestinal mass Total	1 (2) 56 (100)	

foreign-body perforation of the intestine was treated by simple closure. In seven (21%) of the laparotomies the patient required bowel resection for removal of long-standing foreign bodies that could not be removed by simple enterotomy, for gross perforation of the intestine and, in one case, for removal of a mass of unknown nature, proven on later pathological examination to be a foreign body. In two cases, the patient required partial gastrectomy, for bleeding in one case and for perforation in the other. In one case, the patient had lysis of adhesions and milking of a foreign body into the large bowel. The foreign body then passed with no further complication.

The types of foreign bodies removed were variable, but plastic was the most common, being recovered in 26 cases (46%) (Table II).

There were 17 in-hospital complications or deaths (30%). Four patient died (11%). One sustained a massive upper gastrointestinal hemorrhage after endoscopic removal of a piece of leather. Autopsy revealed erosion of a pulmonary artery causing exsanguination. Two patients died of septic shock after free perforations and generalized peritonitis. The fourth patient who died was moribund on arrival in the Emergency Department and died there. Autopsy revealed acute bowel obstruction and acute tubular necrosis of the kidneys. There were four cases of prolonged ileus bevond 7 days. There were four in-

Table II. Fo	oreign Bodies Recovered
Branches	Pieces of cloth
Canvas	Raw potatoes
loves	Rings
lair rollers	Shoelaces
lard plastic	Stones
ar tops	Styrofoam
Keys	Toothpicks
Marbles	Towels
Metal foil	Wooden balls
Plastic bags	Wooden spatula

hospital wound infections, two cases of postoperative urinary tract infection, two cases of pneumonia and one seizure. Four cases of small-bowel obstruction developed from 7 days to 4 months postoperatively.

## Discussion

The gastrointestinal tract has a remarkable ability to pass most objects that enter it: 80% to 90% of all foreign bodies will pass, given time.<sup>7</sup> Although the HRC has 668 patients, over a 15-year period only 56 cases of documented pica reguired assessment or treatment at OSMH. If estimates of 25% incidence are correct, then far more pica takes place at chronic care institutions than is encountered at acute care hospitals. Since foreign bodies were recovered endoscopically in only 9 (16%) of the 56 cases. the other objects, some of which were very large (towels, gloves, plastic bags), passed uneventfully through the esophagus and in some cases the pylorus also.

The gastroesophageal junction, pylorus, distal ileum and rectosigmoid are the narrowest areas in the gastrointestinal tract,<sup>8</sup> but these were not the only areas of obstruction noted, probably because of the size or sharpness of some of the objects.

In addition to mental handicap, the patients in this study, exhibited multiple skeletal deformities and motor and sensory impairment, and were taking numerous medications, so history taking and physical examination could be extremely difficult. Illness is suspected when symptoms of vomiting, distension, prolonged constipation, irritability and fever are noted. Attendants who know the patient are crucial to the assessment. Patients can be combative, irritable or show no response to stimuli that would make normal patients extremely uncomfortable. Symptomatology does not always correlate with the advanced condition sometimes encountered. The physician must rely on laboratory and radiologic data for diagnosis. However, of the 34 cases in which laparotomy was performed, foreign bodies could be seen in only 12 (35%) of the plain x-ray films. In 19 patients the development of symptoms preceded laparotomy by more than 24 hours. Although in five cases the patient was observed to see if the foreign body would pass, 14 (41%) laparotomies were delaved because of some doubt about diagnosis. Aerophagy is common in the mentally handicapped, hence presentation of patients in the emergency department with abdominal distension, vomiting and air fluid levels demonstrated radiologically is encountered relatively frequently.

The complication and death rate was 30%. Most complications were relatively minor but did point out the difficulties with these patients in the postoperative period. Their lack of cooperation resulted in nasogastric tubes and intravenous catheters being removed by the patient. Chest physiotherapy can be impossible. Most of our patients were young and did recover, but the death rates of 11% in this series, 25% reported by Voitk9 and 33% reported by Teimourian, Cigtav and Smyth<sup>10</sup> emphasize that pica is a significant complication in this population.

Although anemia is a known causal factor in pica, no evidence of this was found in the HRC patients, the mean hemoglobin level being 144 g/L (range from 122 to 191 g/L). Sixty percent of patients were on antiepileptic medication, but this has never been implicated as a cause of pica in patients of normal intelligence.

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Although institutional staff attempt to prevent pica by placing high-risk patients in special wards, it is virtually impossible to prevent all cases.

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# BOOKS RECEIVED LIVRES REÇUS

This list is an acknowledgement of books received. It does not preclude review at a later date.

Cette liste énumère les livres reçus. Elle n'en exclut pas la critique à une date ultérieure.

Anterior Cervical Spine Surgery — Principles and Techniques in Spine Surgery. Series Editor: Robert G. Watkins. Edited by Thomas S. Whitecloud III and Stewart B. Dunsker. 145 pp. Illust. Raven Press, New York. 1993. \$95 (US). ISBN 0-7817-0050-7

Biological, Material and Mechanical Considerations of Joint Replacement. Bristol-Myers, Quibb/Zimmer Ortho Symposium Series. Edited by Bernard Morrey. 470 pp. Illust. Raven Press, New York. 1993. \$98 (US). ISBN 0-7817-0008-6 Color Atlas of Microsurgery. Edited by Sun Lee. 388 pp. Illust. Ishiyaku EuroAmerica Inc., St. Louis. 1993. \$145 (US). ISBN 0-912791-64-0

Diagnosis and Management of Pathologic Fractures. Edited by Joseph M. Lane and John H. Healey. 176 pp. Illust. Raven Press, New York. 1993. \$110 (US). ISBN 0-7817-0062-0

Erythopoietin — Molecular Physiology and Clinical Applications. Edited by C. Bauer, K.M. Koch, P. Scigalla and L. Wieczorek. 496 pp. Illust. Marcel Dekker, Inc, New York. 1993. \$99.75 (US). ISBN 0-8247-9139-8

Minimal Access Medicine and Surgery. Principles and Techniques. Edited by David Rosin. 279 pp. Illust. Radcliffe Medical Press Ltd., Oxford. 1993. Price not stated. ISBN 1-870905-67-9 Surgery for Spinal Cord Injuries. Principles and Techniques in Spine Surgery. Series editor: Robert G. Watkins. Edited by Steven R. Garfin and Bruce E. Northrup. 311 pp. Illust. Raven Press, New York. 1993. \$120 (US). ISBN 0-7817-0075-2

Surgery of the Cranial Nerves of the Posterior Fossa. Edited by Daniel L. Barrow. 323 pp. Illust. The American Association of Neurological Surgeons, Washington, DC. 1993. \$80 (US). ISBN 1-879284-02-2; Neurological Topics ISBN 0-9624246-6-8

Thoracolumbar Spine Fractures. Edited by Yizhar Floman, Jean-Pierre C. Farcy and Claude Argenson. 507 pp. Illust. Raven Press, New York. 1993. \$130 (US). ISBN 0-7817-0049-3

# Noncemented Stem Tibial Component in Total Knee Replacement: the 2- to 6-Year Results

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*Objective:* To determine if the addition of a stem to the tibial component in noncemented total knee replacement affects sinkage of that component or micromotion.

Design: A cohort of 176 consecutive cases with no exclusions. Follow-up ranged from 2 to 6 years. Setting: A university-affiliated institution specializing in elective orthopedic surgery.

*Participants:* All 176 patients had arthritis of the knee, mainly osteoarthritis. All agreed preoperatively to prolonged postoperative follow-up.

Intervention: Noncemented total knee replacement with the Tricon M long-stem tibial component. Main Outcome Measures: Hospital for Special Surgery rating system for clinical results and degree of tibial sinkage and stem lucency seen radiologically.

*Results:* Eight (4.5%) of the 176 prostheses required revision, none for sinkage. Of the remaining 168 knees, 156 (92.9%) scored good or excellent, 6% fair and 1.2% poor. Sinkage occurred in 3%, but was not of sufficient severity to require revision. No lucency was visible in 33.8% of stems, partial lucency in 62%, complete lucency with the lines being parallel to the stem in 3.5% and complete lucency with divergent lines, indicating a loose implant, in 1.7%. Lucency, when present, was seen mainly in the lateral view, seldom in the anteroposterior view. There was no correlation between radiologic results and clinical results.

*Conclusions:* The addition of a metaphyseal stem reduces the incidence of sinkage of the tibial component in total knee replacement. The stem largely solves the problem of mediolateral micromotion but does not completely prevent anteroposterior micromotion.

Objectif : Déterminer si l'addition d'une tige à la partie tibiale d'une prothèse totale non cimentée du<br/>genou affecte l'affaissement de la partie tibiale de la prothèse ou les micromouvements du tibia.Conception : Une cohorte de 176 cas, sans exclusions. La période de surveillance s'étend sur 2 à 6 ans.Contexte : Un établissement universitaire spécialisé en chirurgie orthopédique non urgente.Participants : Les 176 patients souffraient tous d'une atteinte arthritique du genou, principalement<br/>d'arthrose. Tous avaient accepté avant l'opération de participer à un suivi prolongé.Intervention : Arthroplastie totale non cimentée du genou avec la composante tibiale Tricon M à<br/>longue tige.

Principaux effets mesurés : Évaluation des résultats cliniques à l'aide du système «Hospital for Special Surgery» et degré d'affaissement du tibia et d'espacement de la tige visible à la radiographie. *Résultats* : Huit (4,5 %) des 176 prothèses ont nécessité une révision, aucune pour affaissement. Des

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Accepted for publication Apr. 6, 1993

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168 autres genoux, 156 (92,9 %) ont donné des résultats bons ou excellents, 6 % des résultats moyens et 1,2 %, de mauvais résultats. Un affaissement est survenu dans 3 % des cas mais il ne fut jamais assez important pour nécessiter une révision. Aucun espacement n'est apparu pour 33,8 % des tiges, un espacement partiel a été vu dans 62 % des cas, un espacement complet avec parallélisme des lignes avec la tige dans 3,5 % des cas, et un espacement complet avec divergence des lignes indiquant une prothèse flottante dans 1,7 % des cas. L'espacement pouvait être visualisé surtout en vue latérale, rarement en vue antéropostérieure. On n'a noté aucune corrélation entre les résutats radiologiques et cliniques. *Conclusions :* L'addition d'une tige métaphysaire réduit la fréquence de l'affaissement de la partie tibiale d'une prothèse totale du genou. La tige résolut en grande partie le problème des micromouvements médiolatéraux mais ne prévient pas totalement les micromouvements antéropostérieurs.

N oncemented total knee replacement is now well established, although the majority of reported studies have a short follow-up.1-5 Some concern exists about fixation of the noncemented tibial component.6.7 It has been shown experimentally with micromotion studies8 and pressure-sensitive-plate film studies9 and clinically in one roentgen stereophotogrametric analysis of a small number of cases<sup>10</sup> that the addition of a stem to the tibial component significantly increases initial stability. This in turn may reduce the incidence of tibial sinkage and the extent of micromotion. which is a potent cause of failure of bone ingrowth into porous metal components.1

Tibial sinkage in noncemented total knee replacement usually occurs within 2 years and most often in the first 6 months to 1 year.<sup>11</sup> We believed that there were enough cases of a noncemented ingrowth stem tibial component with a follow-up longer than 2 years to allow meaningful examination of tibial sinkage.

Micromotion is difficult to study on clinical x-ray films. Unless an image intensifier is used to ensure an edge-on shot of the tibial base plate, radiolucency, which is an indicator of micromotion, is always underestimated: a variation in the beam angle of only 3° will obscure a radiolucent line.<sup>12</sup> Radiolucency surrounding a stem prosthesis, as for example a hip stem, is not nearly as sensitive to minor changes in beam angle and rotation. Micromotion of the stem of the tibial component can occur in three planes: rotation, anteroposterior toggle and medial lateral toggle. By a comparison of anteroposterior and lateral x-ray films of the stem tibial component we felt useful information could be obtained about the relative incidence of anteroposterior and medial lateral micromotion.

Therefore, all Tricon M (Richards Manufacturing Co., Memphis, Tenn.) long-stem total knee replacements carried out by the senior author (H.U.C.) were studied prospectively. We believed that this approach would eliminate variables in surgical technique and postoperative management.

## Patients, Materials and Methods

The 202 patients ranged in age from 47 to 83 years (mean, 69.5 years). Eight patients had rheumatoid arthritis, two had post-traumatic arthritis, three had Paget's disease<sup>13</sup> and one had avascular necrosis. The remainder had primary osteoarthritis.

There were 212 knees: bilateral replacements were done with an identical knee (Tricon M prosthesis) in 10 patients and with another type of knee in 56 patients. All numbers will refer to knees with Tricon M replacements only and bilaterality will be ignored.

Thirty-six knees (17.0%) were

lost to follow-up; 10 (27.8%) of them were placed in patients who died within 2 years of replacement.

Of the remaining 176 knees, 134 were replaced in women and 42 in men. Thirty-seven knees (21.0%) had been operated on previously (22 high tibial osteotomies, 6 total knee revisions, 2 unicompartmental knee replacements, 2 Girdlestone procedures, 2 fusions, 1 procedure for supracondylar fracture, 1 for supracondylar osteotomy and 1 Maquet procedure (elevation of tibial tubercle). The replaced knees were evaluated at 3 months and 6 months after placement and annually thereafter. They were rated according to the Hospital for Special Surgery rating system.<sup>14</sup> Patients were examined radiographically by 1-m standing anteroposterior, lateral and skyline views of the knee.

The follow-up ranged from 2 to 6 years (mean, 3.5 years).

## The Prosthesis

The Tricon M prosthesis, a porous coated total knee replacement, is designed for use without bone cement. The stem design chosen was wide in the sagittal plane to resist medial lateral loads. It was cut in the shape of an I-beam to minimize bone resection. It was designed to approach the posterior tibial endosteal cortex to prevent anterior sinkage of the tibial component. It was highly polished to prevent osseointegration.

Initially, the stem was straight

posteriorly, but five crack fractures of the posterior tibial cortex occurred in the 1st year of use. (These cases have been included in this study.) Thereafter, the stem was bevelled to slide down the posterior cortex, and no further fractures have occurred (Fig. 1).

### Insertion Technique

The tibial plateau was cut at right angles to the long axis of the tibia and the distal femur in  $7^{\circ}$  of valgus. The ligaments were carefully balanced, releasing the structures in the concave side of the deformity. The tibial components trials were sized and positioned to give maximum tibial coverage, and when trial reductions were complete, the hole for the central tibial stem was punched out.

Most patients were allowed immediate, full weight bearing. Those with tibial crack fractures or bone grafts larger than 2 cm<sup>2</sup> were restricted to touch weight bearing for 4 to 6 weeks.

All patellae were resurfaced.

### Evaluation of the Prosthesis

Sinkage was measured on serial anteroposterior x-ray films. A vertical line was drawn on the long axis of the tibia and a horizonal line to some recognizable feature, usually the top of the fibular head. Another line was drawn along the base of the metal tibial tray, and the difference between these two lines measured. After several measurement sessions on serial x-ray films, we decided that only sinkage of more than 3 mm could be measured reliably.

The stem was examined radiologically in anteroposterior and lateral views. Any bone change, a visible lucent line or a linear increase in bone density adjacent to the stem was counted as lucency, except for changes at the absolute stem tip. Lucency was divided into partial lucency, when the lucent line was only seen around part of the stem, and complete lucency, when the lucent line extended around the whole stem. Note was made of whether the complete lucent line

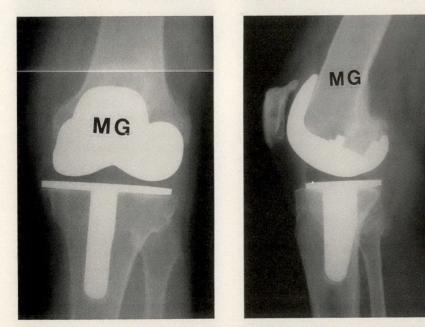


FIG. 1. Stem on this tibial component is bevelled to slide down posterior tibial cortex, giving added resistance to anterior sinkage of tibial component. Stem is wide in sagittal plane to give medial lateral resistance.

was parallel to or divergent from the stem. The lucent line was graded after the fashion of Engh<sup>15</sup> as modified by Dorr for noncemented total hip replacement:<sup>16</sup> type IA represents no lucency; type IB represents partial lucency (Fig. 2); type II represents complete lucency with the lucent lines parallel to the stem; and type III represents complete lucency with the lucent lines divergent from the stem (i.e., the tibial component exhibits macromotion and is therefore loose [Fig. 3]).

### Results

Of the 176 knees available for 2-year follow-up, 8 (4.5%) were revised. The reasons for revision were as follows: sepsis in four knees (three early and one late), lost skin and subcutaneous tissue over the anterior aspect of the knee and subsequent dislocation of the knee in one patient, sticking of the original stem of the prosthesis before complete seating in one knee, patellar wear in one knee and patellar and tibial wear in one knee.

Of the remaining 168 knees, 127 (75.6%) knees scored excellent, 29 (17.3%) scored good, 10 (6%) scored fair and 2 (1.2%) scored poor. There were no femoral loosenings. Tibial sinkage occurred in five (3.0%) knees. Sinkage was less than 5 mm in all cases and none was of sufficient severity to require revision. Sinkage of the patella occurred in two (1.2%) cases and reflex sympathetic dystrophy in four (2.4%) cases. With use of the original stem, there were five crack fractures of the tibial cortex at the time of stem insertion. Screws were inserted in two cases, but the others were simply ignored, and the patient was limited to touch weight bearing for 6 weeks. All fractures healed without complication. This problem did not occur with the

bevelled stem. Wear of the tibial component occurred in two knees. one of which was revised, and in three patellae, two of which were revised. In one case the patellar tendon was reinforced with wires at the time of the initial replacement. The wires were removed later. A stress fracture of the tibia of one knee was treated conservatively. One patient had early sepsis and the knee was treated with débridement. Although this knee continued to function 2 years later, both tibial sinkage and patellar sinkage were demonstrated, suggesting an ongoing low-grade infection.

According to the modified Engh-Dorr classification, 33.8% of tibial components were type IA, 62% were type IB, 3.5% were type II and 1.7% were type III. Stem lucency in the anteroposterior x-ray film appeared complete in 5.2% of cases, partial in 6.5% and absent in 88.3%. On the lateral x-ray film, lucency was complete in 14.3%, partial in 51.9% and absent in 33.8%.

## Discussion

It has been pointed out<sup>11</sup> that wear of the plastic component is unlikely to be noted before 3 to 4 years of follow-up and revision is unlikely to be needed before 6 years from the time of placement. Because the mean follow-up in this study was 3.5 years, no reliable conclusions could be drawn regarding wear other than to point out that it does exist in both the patellar and tibial components.

Sinkage associated with noncemented components usually occurs

in the first 6 months after placement of the prosthesis and is nonprogressive.11 Sinkage of the noncemented tibial component of such severity as to require revision is uncommon in the short term.1-5 Sinkage occurred in five knees (2.8%) in this series, and one of them was probably infected. In no case was sinkage of sufficient severity as to require revision, even though 5% of cases had tibial bone grafting to some degree. These sinkage rates are superior to those obtained with the flat-plate version of this knee prosthesis, suggesting that the stem does indeed aid in initial stability.

There seem to be few disadvantages to the use of a stiff metaphyseal stem. Undoubtedly more bone is sacrificed, but this is mostly poor-quality subsurface bone. Use of a bevelled stem has resolved the



FIG. 2. Arrows on stem indicate radiolucent line, which does not extend completely around stem. Small arrow indicates radiolucency under base plate anteriorly.



FIG. 3. If undersurface of tibial component only is examined, no lucency will be seen because beam angle is couple of degrees off. This implant might, therefore, be regarded as stable. If stem is examined, however, radiolucent lines surrounding it are found to be divergent (i.e., Type III). This stem is toggling, indicating that implant is loose.

problem of crack fractures of the posterior cortex, which occurred with the original stem in five cases. No case of end-of-stem pain was encountered.

Although the task of seeking radiolucency under the tibial plate is difficult, radiolucency of the stem is easy to identify. In our series 1.7% of knees could be classified as radiologically loose, although there was no clinical correlation and x-ray films of the base plate did not reflect this. Of more significance was that the plane of micromotion could be identified. In the anteroposterior x-ray film, 88.3% of knees showed no lucency, indicating that tibial fixation with beads, pegs and stem is sufficient to stop micromotion in that plane. However, lucency was absent in only 33.8% in the lateral x-rays, indicating that micromotion was still occurring in the anteroposterior plane. The most likely reason for this is that the bone of the anterior tibial plateau is very soft.

It could be argued that symptomless micromotion is of little significance. However, micromotion may prevent bone ingrowth into porous materials since the acceptable level of micromotion is very low, less than 100  $\mu$ m.<sup>17</sup> If bone ingrowth is the goal, research into design changes should be done to further decrease micromotion at the implant-bone interface.

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# Noncemented, Porous Ingrowth Knee Prosthesis: the 3- to 8-Year Results

Hugh U. Cameron, MB, ChB, FRCSC;\* Young B. Jung, MD†

*Objective:* To determine the principal long-term problems encountered in noncemented total knee replacement.

*Design:* A cohort of 252 consecutive cases of total knee replacement with no exclusions. Follow-up ranged from 3 to 8 years.

Setting: A university-affiliated institution specializing in orthopedic surgery.

*Participants:* All 252 patients had arthritis of the knee, mainly osteoarthritis. All agreed preoperatively to prolonged postoperative follow-up.

*Intervention:* Noncemented total knee replacement with the Tricon M prosthesis, which has a metal-backed patella.

Main Outcome Measures: The Hospital for Special Surgery rating system for clinical results and the radiologic results, including reasons for revision surgery.

*Results:* Thirty-five prostheses were revised: 11 prostheses because of patellar wear only; in 13 prostheses the tibial component (mainly a 6-mm unit) and patella were revised because of wear; 6 prostheses were revised for sepsis, 4 for reflex sympathetic dystrophy and 1 only for sinkage of the tibial component. Of the remaining 217 prostheses, 88% scored good or excellent, 6% fair and 6% poor. *Conclusions:* The single most common cause of failure was polyethylene wear. This was associated with the metal backing of the patella and the use of thin, polyethylene tibial components.

*Objectif :* Identifier les principaux problèmes rencontrés à long terme dans les arthroplasties totales non cimentées du genou.

*Conception :* Une cohorte de 252 cas consécutifs d'arthroplastie totale du genou, sans exclusions. Le suivi va de 3 à 8 ans.

Contexte : Un établissement universitaire spécialisé en chirurgie orthopédique.

*Participants :* Les 252 patients souffraient tous d'arthrite du genou, principalement d'arthrose. Tous avaient accepté avant l'opération de participer à un suivi de longue durée.

Intervention : Arthroplastie totale non cimentée du genou avec la prothèse Tricon M qui possède une rotule avec armature de métal.

Principaux effets mesurés : L'évaluation des résultats cliniques à l'aide du système «Hospital for Special Surgery» et résultats radiologiques, incluant les raisons des révisions chirurgicales.

*Résultats :* Trente-cinq prothèses durent être révisées : 11 pour usure de la rotule seulement, 13 pour usure de la partie tibiale (principalement une partie de 6 mm) et de la rotule, 6 pour infection de prothèse, 4 pour dystrophie sympathique réflexe et 1 seulement pour affaissement de la partie tibiale.

Des 217 autres prothèses, 88 % donnèrent de bons ou excellents résultats, 6 % des résultats moyens et 6 %, de mauvais résultats.

*Conclusions :* La cause la plus fréquente d'échec a été l'usure du polyéthylène. Celle-ci est reliée à l'armature métallique de la rotule et à l'utilisation d'une partie tibiale de polyéthylène mince.

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Accepted for publication Apr. 6, 1993

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• he noncemented ingrowth type I of total knee replacement prosthesis was introduced about a decade ago.<sup>1,2</sup> The clinical results, although short-term, have been reasonably good.3-6 However, there is concern about fixation of the tibial component<sup>7,8</sup> and wear of the patellar component.9,10 Sinkage of noncemented components may be an early phenomenon, wear is not. There are two main components to plastic wear: abrasive wear due to cement particles and bony impingement, which may occur at a relatively early stage; and delamination, which is the main producer of wear debris particles and seldom occurs within the first few years.11

Knee replacement is done mainly in elderly patients. Thus, it is difficult to obtain sufficient numbers of long-term survivors for study. However, we believed that a sufficient number of 3- to 8-year survivors existed for a meaningful study. Replacements done by a single surgeon only were followed so that variations in technique and management could be eliminated.

The objective of this study was to evaluate sinkage and wear in patients who received a Tricon M (Richards Manufacturing Co., Memphis, Tenn.) noncemented total knee prosthesis. This is a porous coated ingrowth knee prosthesis. Initial fixation of the components is by ridged plastic pegs driven into undersized holes in the bone.<sup>5</sup> Long-term fixation comes from tissue ingrowth into the implant.

### **Patients and Methods**

Two hundred and fifty-two knees (85 in men and 167 in women) replaced with the Tricon M prosthesis by one surgeon (H.U.C.) had a minimal follow-up of 3 years. The patients ranged in age from 36 to 87 years (mean, 68.5 years). Most knees were osteoarthritic: 8 (3%) had rheumatoid arthritis, 3 (1%) had post-traumatic arthritis and 1 (0.4%) had avascular necrosis. Thirty-nine knees (16%) had previously been operated on: tibial osteotomy in 29 (12%), unicompartmental knee replacement in 6 (2%), total knee replacement in 3 (1%) and a Maquet procedure (elevation of the tibial tubercle) in 1 (0.4%).

The tibial cut was made at right angles to the long axis of the tibia and the distal femoral cut in 7° of valgus with respect to the femur. Ligament balancing was carefully carried out, with release of the soft tissues on the concave side of the knee until equal tension was achieved. All patellae were resurfaced with an ingrowth metalbacked component (Fig. 1). All patients were allowed to bear weight immediately.

Follow-up was at 3 months, 6 months and annually, and the knees were rated clinically according to the Hospital for Special Surgery (HSS) rating system.<sup>12</sup> They were examined radiographically from a 1-m, standing, anteroposterior x-ray film, a lateral view and a skyline view. Serial x-ray films were compared to assess sinkage and wear. After several trials, it was concluded that sinkage of less than 3 mm could not be measured reliably.

No attempt was made to look for radiolucency. Variation in the beam angle of 3° obscures lucency. Unless an image intensifier is used to ensure an edge-on shot, an impossible task in the review of a sizeable number of patients, radiolucency is always so underestimated that the findings are useless.

## Findings

Revision was required for 35 (14%) knees. Of the remaining 216 knees, 75% scored excellent, 13%

good, 6% fair and 6% poor (i.e., 88% good or excellent according to the HSS rating system).

The reasons for revision included pain and chronic effusion due to patellar wear in 11 knees and patellar and tibial wear in 13 knees. This figure is somewhat inflated because it has recently become the practice of H.U.C. to change the tibial component if there is the slightest sign of wear when the patella is being revised. Revision for tibial component wear was carried out an average of 6.2 years after the initial replacement. One knee (0.4%) was revised for tibial sinkage. Six knees were revised for sepsis, two early, one intermediate and three late. The knees requiring late revision for sepsis showed significant wear of the tibial component and had a wear debris synovitis. Four knees were revised for reflex sympathetic dystrophy before knowledge that this condition existed. Three patients required additional surgery other than revision, two (0.8%) for patellar subluxation, which was treated by soft-tissue repair, and one for patellar tendon rupture, which was treated by wiring.

Of the 217 knees not revised, 14 (6%) showed evidence of wear of the tibial component and 10 (5%) had patellofemoral squeak indicating patellar wear. Twenty (9%) showed nonprogressive sinkage of the tibial component (i.e., sinkage was noted within 2 years but did not change further) (Fig. 1). Three knees only, including the revised knee, showed sinkage of more than 5 mm.

Nine (4%) knees demonstrated reflex sympathetic dystrophy; revision was done in four of them, as already noted.

Prior tibial osteotomy is thought to influence the outcome of total knee replacement.<sup>13</sup> Of 29 such knees, only 16 (55%) scored good or excellent and 13 (45%) scored fair or poor. Seven (24%) of these

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29 knees required revision and four (14%) had reflex sympathetic dystrophy.

Most knees were within 3° and 9° of valgus. Even the 10% that fell outside this range did so only by a few degrees. Alignment did not correlate with clinical scores or with wear.<sup>6</sup>

# Discussion

The use of standard clinical x-ray

films to measure sinkage is not ideal. The sinkage rate of 9% refers only to patients who showed sinkage of more than 3 mm. We could not reliably measure sinkage of less than this. In keeping with other published series,<sup>3–6</sup> however, the revision rate for sinkage of noncemented tibial components was low, being only 0.4% in our series. Other series of porous coated and even press fit prostheses have had similar results.<sup>14</sup> Indeed, the only series evaluating noncemented prostheses

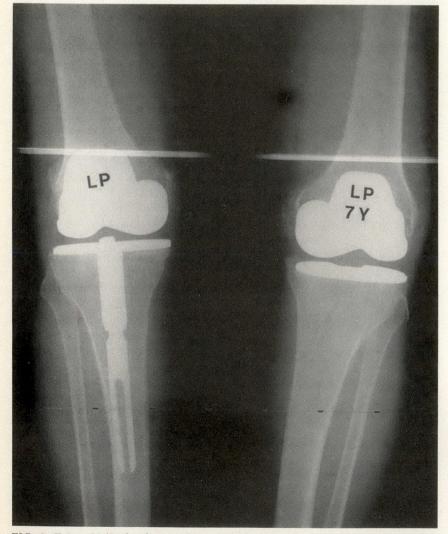


FIG. 1. Tricon M (Richards Manufacturing Co., Memphis, Tenn.) tibial component in this bilateral total knee replacement (right) shows 3 mm of medial sinkage, which was noted 1 year after replacement and was unchanged thereafter. Knee continued to be perfectly functional. Newest version of this knee was inserted on left side. Stiff metaphyseal stem with flexible diaphyseal stem extension appears (in first 2 years) to have stopped any angular sinkage.

that showed significant revision for sinkage was Albrektsson and Herberts' series of press fit in all polyethylene components.<sup>4</sup>

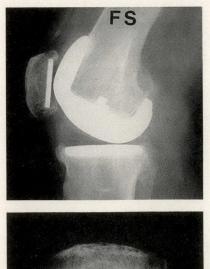
In our series, sinkage occurred within 6 to 12 months of operation and was nonprogressive.

The main problem leading to revision was pain and swelling due to polyethylene wear. Wear of metalbacked patellae has been reported previously, and it is generally recommended that the use of metalbacked patellar components be discontinued.9,10 Due to the small contact area of the patella, the service loads theoretically exceed the load capacity of the plastic so that wear is inevitable. For some reason yet to be explained, little has appeared in the literature on wear of non-metalbacked patellae, although this must occur. The theoretical advantage of metal backing has in practice turned out to be a disadvantage, perhaps by reducing polyethylene thickness.15

The prosthetic patella in this series was inset into the bone, in distinction to customary onset patellae (Fig. 2). The fact that the metal is below the surface of the patellar bone should have prevented metal-to-metal contact. Unfortunately, the advantage of sinking the metal backing well below the level of the bony patella was not recognized early in this series. Patellae that were deeply sunk have not as yet required revision. In another study, however, which had a 2-year longer follow-up, the durability of an identical inset, snap fit, purely plastic patella was compared with that of a metal-backed patella. Only one knee had to be revised for patellar wear.16 Because it can be difficult to sink the metal backing deeply into an eroded patella and because the results of the purely polyethylene component are just as good, use of the metal-backed patella should be discontinued.

Few other noncemented series have commented on significant tibial component wear. This is almost certainly a function of time since delamination is not seen until after several years of service.<sup>11,17</sup> Revision for tibial component wear in our series was carried out an average of 6.2 years after the index operation, and short-term studies therefore are unlikely to demonstrate significant wear.

Twenty-seven tibial components showed evidence of wear, and 13 were revised. This figure is inflated because many of these tibial components could have lasted several more years. Nevertheless, this incidence of wear is a cause for concern. The location of wear in these cases was posterior, and significant



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FIG. 2. Tricon M patella was designed to be inset into bony patella. Surrounding bone protects plastic from wear-through because there is some rim contact. Outlines of plastic pegs that give initial fixation to components can dimly be seen. cold flow occurred. With one exception all the components were 6 mm in thickness. Given that the metal back was 3 mm thick, this means that the actual thickness of polyethvlene at its thinnest was only 3 mm. This was clearly a design error. Bartel and colleagues<sup>18</sup> and Racherman and colleagues14 have demonstrated that the minimum polyethylene thickness should be 6 mm. In other words, the minimum total component thickness should be 9 mm when metal backing is used. This means that the thickness of the tibial cut would have to be increased, and the component would rest in poorer quality bone, which in turn may affect sinkage rates.

One interesting observation is



FIG. 3. This knee shows significant wear of plastic 5 years after initial placement. There is no tibial sinkage. Main reason for accelerated wear in this case was use of small tibial component, which reduced area contact between femur and tibia. Four years into this study femoral component was replaced by component that was wider in coronal plane and gave increased surface area. Patient remained mainly asymptomatic for 1 year after this film was obtained, then knee developed an acute late infection necessitating revision.

that an earlier tibial component with identical surface geometry had no cruciate gap and none of these components have required revision for wear. Similarly, wear has not been a major problem with the original total condylar prosthesis, which also did not have a cruciate gap. All the tibial components in this series had a large cruciate gap, suggesting that such a gap results in lack of support of the posterior part of the tibial component, possibly accelerating cold flow. Of course, the original noncruciate gap implant was not metal backed and therefore had 6-mm thick polyethylene, so that the cruciate-gap factor cannot be seen in isolation.

Polyethylene wear on the tibial component does not seem to give rise to pain until the polyethylene is worn through to expose metal. Even then, pain may not be a striking feature.

When significant wear is first noted on routine x-ray films, the patient is usually asymptomatic. Two to 3 years later the knee becomes chronically swollen. Even this may not be particularly painful, and it is difficult to convince a patient who is largely asymptomatic to accept a revision. The danger of delay, however, is that acute late infection superimposed on a wear debris synovitis may develop, as in three knees in this series (Fig. 3).

Another problem is osteolysis. If this condition is ignored, the wear debris synovitis may develop into a granuloma at the metal-bone junction.<sup>19</sup> This has been well described in hips.<sup>20</sup> In our series the main area of erosion was the posterior femoral condyles. This erosion can be difficult to see on x-ray films because a plate of bone usually remains in place. Fortunately the grip of the bone to the distal end of the prosthesis so far has been sufficient for implant stabilization and bone grafting. Bone grafting has

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not been required, and no loosening of the femoral component has been seen.

One interesting finding in our series was the very poor results following tibial osteotomy. For some time it has been the senior author's practice to reosteotomize the tibia before total knee arthroplasty as an interval procedure when the extra-articular deformity is greater than 15°.21 In spite of the ability to gain correction and mechanical stability, however, the results are much worse than those reported by Amendola and associates,13 who found reduction in range of motion to be the main problem. A large percentage (14%) of knees subjected to high tibial osteotomy did develop reflex sympathetic dystrophy, which suggests that perhaps the reflex sympathetic dystrophy was unrecognized and predated the total knee replacement.

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### Angiotensin Converting Enzyme Inhibitor INDICATIONS AND CLINICAL USE

VASOTEC<sup>®</sup> is indicated in the treatment of essential or renovascular hypertension: usually administered in association with other drugs, particularly thiazide diuretics. Consider the risk of angioedema (see WARNINGS). Normaly used when a diuretic to teta-blocker was ineffective or associated with unacceptable adverse effects. Can also be tried as initial agent where a diuretic and/or beta-blocker is contraindicated or could cause serious adverse effects.

Oral enalapril is also indicated in the treatment of congestive heart failure, as adjunctive therapy in patients not responding adequately to digitalis and diuretics.

# Use of ACE inhibitors during the second and third trimesters of pregnancy can cause injury or death of a developing fetus. When pregnancy is detected, discontinue VASOTEC® as soon as possible (see WARNINGS; Use in Pregnancy).

VASOTEC® I.V. (enalaprilat) is an active metabolite of enalapril; the onset of action after administration occurs within 15 minutes, with the maximum effect within 1 to 4 hours.

VASOTEC® IV. is indicated for the treatment of hypertension when oral therapy is not practical. VASOTEC® IV. has been studied with only one other antihypertensive agent, furosemide, which showed additive effects on blood pressure. Due to insufficient experience in the treatment of acceler-ated or malignant hypertension, VASOTEC® IV. is not recommended in such situations (see DDSAGE and ADMINISTRATION).

### CONTRAINDICATIONS

Hypersensitivity to any component; history of angioneurotic edema related to ACE inhibitor therapy.

### WARNINGS

Angioedema, with laryngeal edema and/or shock, have been reported Any development, will laylige elema and/or shock, have been reported and may be fatal. In such cases, discontinue drug promptly and observe patient until swelling subsides. Swelling confined to the face, lips, and mouth usually resolves without treatment, although antihistamines may be useful in reliving symptoms. However, where there is involvement of the tongue, glottis and larynx, likely to cause airway obstruction, prompt administration of subcutaneous adrenatine (0.5 mL 1:1000) may be indicated. Patients with a history of angioedema, unrelated use, may be at increased risk (see CONTRAINDICATIONS) unrelated to ACE inhibitor

Symptomatic hypotension has occurred, usually during initial therapy or when the dose was increased, and is more likely in patients who are volume-depleted. In patients with severe congestive heart failure, excessive hypotension may be associated with oliguria and/or progressive azotemia. hypotension may be associated with oliguria and/or progressive azotemia. For patients in whom the excessive hypotension could result in severe or fatal complications, i.e. those with severe congestive heart fature, ischemic heart or cerebrovascular disease – start therapy under close medical supervision, usually in a hospital. Such patients should be followed closely for the potential fall in blood pressure during first two weeks of therapy or when enalapril or a diuretic is increased. If hypotension occurs, place patient in supine position and in exeded, administer IV initision of normal saline. A transient hypotensive response is not a contraindication to further doses of enalapril or enalaprilat.

Neutropenia/agranulocytosis and bone marrow depression have been caused by ACE inhibitors. Current experience with enalapril shows incidence to be rare. Consider periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease.

Use of ACE inhibitors in pregnancy can cause feta and neonatal morbidity and mortality. When pregnancy is detected, discontinue VASOTEC® as soon as possible. Barely, no alternatives to an ACE inhibitor VHSITLEV as solution and mothers should be apprised to the polential hazards to will be found and mothers should be performed to assess fetal development, well-being and volume of amnitotic fluid. If oligohytdramnics is observed, discontinue VASOTEC® unless lifeaving for the mother. A non-stress test and/or a biophysical profiling may be appropriate however, if concerns persist, a contraction stress testing should be considered. Oligo-butdramnics may only anopar after faith pipes curveling directible pipe. hydramnios may only appear after fetus has sustained irreversible injury. Closely observe infants exposed in utero to ACE inhibitors for hypotension, oliguria and hyperkalemia, and initiate appropriate corrective medical procedures.

Human Data: Exposure to ACE inhibitors during second and third trimesters has been associated with hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure and death of the fetus. Oligohydramnios, associated with hypotension, neonatal skull craniofacial deformation, and hypoplastic lung development also has been reported. Prematurity and patent ductus arteriosus also reported but unknown it due to ACE inhibitor use. It is not known whether exposure limited to the first trimester can adversely affect fetal outcome. PRECAUTIONS

Impaired renal function: Renal function should be assessed before initiating therapy with enalapril or enalaprilat. Patients with renal insufficiency may require reduced or less frequent doses, and their renal function must be monitored appropriately (see DOSAGE). Renal failure, which has been reported mainly in patients with severe congestive heart failure or underlying renal disease including renal artery stenosis, is unequire mergine when the disease including renal artery stenosis, is usually reversible when treated promptly.

Some hypertensive patients with no apparent renal disease have developed increases in BUN and creatinine while on concurrent diuretic/ enalapril therapy. Dosage reduction or discontinuation of one or both drugs may be required

Hyperkalemia: In clinical trials, hyperkalemia (>5.7 mmol/L) was observed in approximately 1% of hypertensive patients, and caused discontinuation of therapy in 0.28% of such patients. Risk factors for hyperkalemia development may include renal insufficiency, diabetes mellitus, and concomitant use of agents to treat hypokalemia (see ADVERSE REACTIONS)

Valvular Stenosis: Theoretically, patients with aortic stenosis, who do not develop as much afterload reduction, might be at risk of decreased coronary perfusion when treated with vasodilators.

Surgery/Anaesthesia: During major surgery or anaesthesia with hypotensive agents, enalapril blocks angiotensin II formation secondary to compensatory renin release. Hypotension that develops due to this mechanism can be corrected by volume expansion.

Impaired liver function: Hepatitis, jaundice (hepatocellular and/o Imparted liver function: Hepatitis, jaundice (nepatocentrial autor) cholestatic), elevation of liver enzymes and/or serum bilinythin, which have occurred in patients with or without pre-existing liver abnormalities, were usually reversed on discontinuation of enalapril or enalaprilat. For any unexplained symptoms, particularly within the first months of treatment, a full set of liver function tests and other necessary investigations are recom-mended. Consider discontinuation of enalapril or enalaprilat when scenaristic. Her enclosed is conclosed with particular existing in patients appropriate Use enalogni or enalogniata with particular caution in patients with pre-existing liver abnormalities. Obtain baseline liver function tests before initiating drug and monitor response and metabolic effects closely.

Cough: A dry, persistent cough has been reported, which usually disappears after withdrawal or lowering the dose of enalapril or enalaprilat. Nursing mothers: Enalapril and enalaprilat are secreted in human milk in

trace amounts therefore, nursing should be interrupted.

Pediatric use: This use is not recommended because enalapril and have not been studied in children.

enalginal have not been studied in clinitien.
Hemodialysis patients: Anaphylacioid reactions have been reported with high-flux membranes (eg. polyacrylonitrile [PAN]) and treated concomitantly with an ACE inhibitor. If symptoms such as nausea, abdominal cramps, burning, angioedema, shortness of breath and severe hypotension occur, stop dialysis immediately. The symptoms are not relieved by antihistamines and the use of a different type of dialysis membrane or class of antihypertensive agent should be considered.

#### Drug Interactions

Hypotension - Patients on Diuretic Therapy: Particularly when diuretics recently initiated, patients occasionally experience hypotension after initiating therapy with enalapril or enalaprilat. To minimize the hypotensive effects, discontinue the diuretic or increase the salt intake prior Injusticative effects, obsciming of a control of the discrete statistical of the discrete statistical of the discrete statistical supervision for at least one hour after the initial dose of enalaprilat (see WARNINGS).

Agents Increasing Serum Potassium: Since enalapril and enalaprilat decrease aldosterone production, elevation of serum potassium may occur. Diuretics such as spironolactone, triamiterene or amiloride, or potassium supplements should be given cautiously for documented hypokalemia only and should be monitored frequently. Potassium containing salt substitutes bloud be used with caution. should be used with caution.

Agents Causing Renin Release: Diuretics, for example, augment the antihypertensive effect of enalapril and enalaprilat.

Agents Affecting Sympathetic Activity: Ganglionic blocking agents or adrenergic neuron blocking agents, for example, may be used with caution. Beta-adrenergic blockers add some further antihypertensive effect to enalapril

I ithium Salts: Lithium clearance may be reduced: therefore, monitor serum lithium levels carefully if they are administered.

### ADVERSE REACTIONS

VASOTEC®: In controlled clinical trials involving 2314 hypertensive VASOTEC®: In controlled clinical trails involving 2314 hypertensive patients and 363 heart failure patients, the most severe adverse reactions were: angioedema (0.2%), hypotension (2.3%) and renal failure (5 cases). In hypertensive patients, hypotension occurred in 0.9% and syncope in 0.5%, with a discontinuation rate of 0.1%. In heart failure patients, hypotension occurred in 4.4% and syncope in 0.8%, with a discon-tinuation rate of 2.5%. The most frequent clinical adverse reactions in controlled clinical trials were: headache (4.8%), dizziness (4.6%) and fatigue (2.8%). Discontinuation of therapy was required in 6.0% of the 2677 natients 2677 patients.

	Hypertension	Heart Failure
	% (2314 Patients)	(363 Patients)
CARDIOVASCULAR Hypotension Chest Pain Palpitations Myocardial Infarction, Acute Myocardial Infarction, Recurre	0.9 0.9 0.6 0.2	4.4 1.7 0.3 0.6 0.3
GASTROINTESTINAL Nausea Vomiting Dysphagia Diarrhea Abdominal pain	1.4 0.8 0.1 1.4 0.7	1.1 1.7 3.0 1.4
RENAL Renal failure Oliguria Proteinuria†	0.1 1 case 0.1	0.6
DERMATOLOGIC Rash Pruritus	1.4 0.4	1.9 1.4
NERVOUS SYSTEM Headache Dizziness Insomnia Nervousness Somnolence Paresthesia	5.2 4.3 0.5 0.6 0.6 0.6	2.2 6.6 0.3 
ALLERGIC Cough Angioedema	1.3 0.2	1.4
HEMATOLOGIC Anemia Leukopenia	0.1 1 case	Ξ
MISCELLANEOUS Muscle cramps Dyspnea	0.6 0.6	0.3 1.1

### MISCELLANEOUS (cont'd)

1ypermulusis	0.1	
mpotence	0.4	0.3
	3.0	1.4
aste disturbance	0.4	0.3
Defined as >1 g/24h or >0.5 g/12h at least one month apart.	on two consecutive	measur

### ABNORMAL LABORATORY FINDINGS

Hyperkalemia: (see PRECAUTIONS).

Creatinine, Blood Urea Nitrogen: Increases were reported in about Creatimme, Duogo urea entrogen: increases were reported in about 20% of patients with renovasoular hypertension and about 2.2% of patients with essential hypertension on enalapril alone. Increases, which usually were reversible upon discontinuation of enalapril or concomitant therapy, were reported in 9.7% of heart failure patients who were receiving diuretics and/or digitalis.

ements

Hemoglobin and Hematocrit: Decreases (mean approximately 0.34 g% and 1.0 vol%, respectively) occurred frequently, but were rarely of clinical importance. In clinical trials, less than 0.1% of patients discontinued therapy due to anemia.

Hepatic: Elevations of liver enzymes and/or serum bilirubin have occurred (see PRECAUTIONS).

#### ADVERSE REACTIONS REPORTED IN UNCONTROLLED TRIALS AND/OR MARKETING EXPERIENCE

With an incidence of 0.5 to 1%: Insomnia, impotence, renal dysfunction, renal failure and oliguria

#### With an incidence < 0.5%:

Cardiovascular: Myocardial infarction or cerebrovascular accident. Cardiovascular: Myocardial infarction of cereorovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS); cardiac arrest; pulmonary embolism; rhythm disturbances; angina pectoris. **Gastrointestinal**: Anorexia; ileus; pancreatitis; dysepesi; constipation. **Hempopeitic**: Neutropenia; thrombocytopenia; bone marrow depression. **Hepatic**: Liver function abnormalities; hepatitis; bone marrow depression. Hepatic: Liver function abnormalities; hepatics; jaundice (hepatocellular and/or cholestatic). Nervous System/ Psychiatric: Vertigo; depression; confusion; ataxia. Respiratory: Bronchospasm/asthma; rhinorrhea. Other: Erythema multiforme; exfoliative dermatitis; Stevens-Johnson syndrome; toxic epidermal necrosis; urticaria; photosensitivity; alopecia; flushing; tinnitus; hearing impairment; glossitis; blurred vision. A symptom complex has been reported which may include fever; serositis, vasculitis, myalgia, arthraligi/arthritis, a positive ANA, elevated erythrocyte sedimentation rate, eosinophilia and leukorytosis. Rash, photosensitivity or other dematologic manifestations may occur. These symptoms have disap-peared after discontinuation of therapy.

### LABORATORY TEST FINDINGS: Hyponatremia

LABORATORY TEST FINDINGS: hyponatremia VASOTEC® I.V.: Since enalaprii is converted to enalapriia, those adverse reactions associated with VASOTEC® tablets might also be expected to occur: with VASOTEC® I.V. The incidence of symptomatic hypotension is 3.4% with VASOTEC® I.V. Other adverse experiences occurring in greater than 1% of patients were headache (2.9%) and nausea (1.1%). Adverse reactions occurring in 0.5 to 1.0% of patients in controlled clinical trials include myocardial infarct, fatigue, dizziness, fever, rash and noneticative. constipation

### SYMPTOMS AND TREATMENT OF OVERDOSAGE

Limited human data are available. The most likely manifestation of overdosage would be hypotension, which can be treated by I.V. infusion of normal saline solution. Enalaprilat may be removed from the general circulation by hemodialysis.

### DOSAGE AND ADMINISTRATION VASOTEC® FOR ORAL ADMINISTRATION ONLY

Dosage must be individualized. The absorption of enalapril maleate is not affected by food.

#### HYPERTENSION

Initiation of enalapril requires consideration of extent of blood pressure elevation, salt restriction and recently used antihypertensive agents, the dosage of which may need to be adjusted.

The recommended initial dose of enalapril maleate in patients not on The recommended initial dose of entagin initiate in plantation in diverses in the divertice is 5 mg once a day. Adjust doseg according to blood pressure response; the usual range is 10 to 40 mg daily, in a single dose or divided in two doses. Some patients on once-daily dosage may have diminished antihypertensive effect toward the end of dosing interval and require an increase in dosage, or twice daily administration. If blood pressure is not controlled, a divertic may be added. Raising the daily dose above 40 mg is not concorded because adverse reactions may be increased. not recommended because adverse reactions may be increased

Occasionally symptomatic hypotension may occur following the initial dose, more likely in patients currently taking a diuretic. Therefore, if possible, discontinue the diuretic two to three days before initiating enalapril therapy (see WARNINGS). If the diuretic cannot be discontinued, use an initial dose of 2.5 mg.

In the absence of sufficient experience in the treatment of accelerated or malignant hypertension, enalapril is not recommended in such situations.

Dosage in the Elderly (over 65 years): Start at 2.5 mg daily. Some elderly patients may be more responsive than younger patients. Dosage Adjustment in Renal Impairment: (see PRECAUTIONS -

Hemodialysis patients)

Guidelines for reducing doses in hypertensive patients:

Renal Status	Creatinine Clearance mL/min(mL/s)	Initial Dose mg/day
Normal renal function	>80 mL/min (>1.33 mL/s)	5 mg
Mild impairment	≤80>30 mL/min (≤1.33>0.50 mL/s)	5 mg
Moderate to severe impairment	≤ 30 mL/min (≤ 0.50 mL/s)	2.5 mg
Dialysis patients		2.5 mg on dialysis days*

Enalaprilat is dialysable. Dosage on nondialysis days should be adjusted depending on the blood pressure response. CONGESTIVE HEART FAILURE

Use in conjunction with a diuretic and digitalis. Initiate therapy under close medical supervision, usually in a hospital. Monitor blood pressure and renal function before and during treatment with enalapril, because severe more blow and blow hypotension, and more rarely, consequent renal failure have been reported (see WARNINGS and PRECAUTIONS). When initiating enalapril consider the recent diuretic therapy and possibility of severe salt/ volume depletion. Before beginning enalapril reduce diuretic therapy if possible.

The recommended initial daily dose is 2.5 mg. While managing symptomatic hypotension, increase dose gradually, depending on individual response, to the usual maintenance dose of 10-20 mg daily. given in a single dose or divided in two doses. This dose titration may be performed over a two- to four-week period, or more rapidly if indicated by residual signs and symptoms of heart failure. The maximum daily dose is 40 mg

### VASOTEC® I.V. FOR INTRAVENOUS ADMINISTRATION ONLY

VASOTEC® LV, vials should be inspected visually and should not be used if particulate matter or discoloration is observed.

VASOTEC® I.V. may be administered intravenously as supplied, or mixed with up to 50 mL of one of the following diluents:

- 5% Dextrose Injection
- 0.9% Sodium Chloride Injection 0.9% Sodium Chloride Injection in 5% Dextrose 5% Dextrose in Lactated Ringer's Injection
- Diluted solutions should be used within 24 hours.

The dose is 1.25 mg every 6 hours administered intravenously over at least 5 minutes. A clinical response is usually seen within 15 minutes. Peak effects after the first dose may not occur for up to four hours after dosing. The peak effects of the second and subsequent doses may exceed those of the first

No dosage regimen for VASOTEC<sup>®</sup> I.V. has been clearly demonstrated to be more effective in treating hypertension than 1.25 mg every 6 hours. However, in controlled clinical studies in hypertension, doses as high as 5 mg every 6 hours were well lolerated for up to 36 hours. There has been inadequate experience with doses greater than 20 mg per day.

In studies of patients with hypertension, VASOTEC® I.V. has not been administered for periods longer than 48 hours. In other studies, patients have received VASOTEC® I.V. for as long as 7 days.

The dose for patients being converted to VASOTEC® IV from oral therapy for hypertension with enalapril maleate is 1.25 mg every 6 hours administered intravenously over at least 5 minutes. For conversion from intravenous to oral therapy, the recommended initial dose of VASOTEC® tablets is 5 mg once a day with subsequent dosage adjustments as necessary. necessary.

#### Patients on Diuretic Therapy

For patients on diuretic therapy, the recommended starting dose for hypertension is 0.625 mg administered intravenously over at least 5 minutes. A clinical response is usually seen within 15 minutes. Peak effects after the first dose may not occur for up to 4 hours after dosing, although most of the effect is usually apparent within the first hour. If after 1 hour there is an inadequate clinical response, the 0.625 mg dose may be repeated. Additional doses of 1.25 mg may be administered at 6 hour intervals.

For conversion from intravenous to oral therapy, the recommended initial dose of VASOTEC® tablets for patients who have responded to 0.625 mg of enalaprilat every 6 hours is 2.5 mg once a day with subsequent dosage adjustment as necessary

### Dosage Adjustment in Renal Impairment

The usual dose of 1.25 mg of enalaprilat every 6 hours is recommended for patients with a creatinine clearance >30 mL/min [> 0.50 mL/s] (serum creatinine up to approximately 3 mg/dL (265.2 µmol/L)). For patients with creatinine clearance 300 mL/min [< 0.50 mL/s] (serum creatinine 23 mg/dL (265.2 µmol/L)), the initial dose is 0.625 mg (see WARNINGS). If after 1 hour, there is an adequate clinical response, the 0.625 mg dose

may be repeated. Additional doses of 1.25 mg may be administered at 6 hour intervals. For dialysis patients, the initial dose should be 0.625 mg every 6 hours. (see PRECAUTIONS - Hemodialysis patients).

(See PRECKOTOR's - Reindulaysis patients). For conversion from intravenous to oral therapy, the recommended initial dose of VASOTEC<sup>®</sup> is 5 mg once a day for patients with creatinine clearance >30 mL/min [<0.50 mL/s] and 2.5 mg once daily for patients with creatinine clearance <30 mL/min [<0.50 mL/s]. Dosage should then be adjusted according to blood pressure response.

### AVAILABILITY OF DOSAGE FORMS

Barrel-shaped, biconvex tablets, engraved with code number on one side and VASOTEC on other.

VASOTEC® 2.5 mg - yellow, scored, engraved 14.

VASOTEC<sup>®</sup> 5 mg - white, scored, engraved 712.

VASOTEC® 10 mg - rust-red, engraved 713.

VASOTEC® 20 mg - peach, engraved 714.

All strengths available in bottles of 100 tablets.

 $\mathsf{VASOTEC}^{\otimes}$  I.V. 1.25 mg per mL, is a clear, colourless solution and is supplied in vials containing 2 mL.

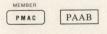
# PRODUCT MONOGRAPH AVAILABLE ON REQUEST

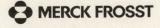
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5527, 5959, 5974, 6657





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# ABSTRACTS RÉSUMÉS

# The Canadian Society for Surgery of the Hand: Abstracts 1993

ASSESSMENT OF UPPER EXTREMITY FUNCTIONAL ABILITY IN RELATION TO RESTRICTION OF THE RANGE OF JOINT MOTION. Kevin M. Rumball and Alan A. Giachino. Department of Surgery, Ottawa General Hospital, Ottawa, Ont.

The purpose of this study was to assess the disability that occurred from restriction of upper extremity joint motion and to show which joints when freed of restrictions would (a) improve performance on objective tests and (b) most restore independence in the activities of daily living. For 5 days, 15 healthy subjects wore right-upper-limb splints with comparable restrictions of shoulder, elbow, wrist and metacarpophalangeal joint motion. Objective and subjective scores were recorded with all joints restricted and after alternately freeing of one of the four joints. Performance and independence were most improved with the metacarpophalangeal joints free.

# JACCOUD'S ARTHROPATHY. Lisa M. Ronback and Carolyn L. Kerrigan. Division of Plastic Surgery, Royal Victoria Hospital, Montreal, Que.

Jaccoud's arthropathy is a non-erosive, deforming arthropathy seen in systemic lupus erythematosus, rheumatic fever and vasculitis. Typical deformities include ulnar drift, swan neck, limited metacarpophalangeal joint extension, boutonnière and "Z" deformities. Changes appear to arise from periarticular inflammation. The literature concerning surgical treatment of this arthropathy is extremely limited, but suggested options include metacarpal shortening and Silastic arthroplasties. In this paper the authors review the literature on Jaccoud's arthropathy and discuss three clinical cases. The charts of patients in the authors' systemic lupus erythematosus registry are reviewed to establish the prevalence of Jaccoud's arthropathy in that population.

### CARPOMETACARPAL ARTHROSIS: A QUESTION OF LENGTH? Stephen Southerland, Geoffrey H.F. Johnston. Department of Orthopedic Surgery, Royal University Hospital, Saskatoon, Sask.

Osteoarthritis commonly affects the thumb carpometacarpal (CMC) joint, although the reason for this is unclear. Biomechanically, longer lever arms create greater forces across adjacent joints. The relationship between first metacarpal length and thumb CMC arthrosis has not been studied. The authors tested the hypothesis that a long first metacarpal predisposes its CMC to degenerative change. Measurements of thumb metacarpal and phalangeal length from 500 randomly selected radio-graphs were compared to similar measurements from 50 radiographs in patients with thumb CMC osteoarthritis. Results revealed remarkable consistency in thumb, index and long finger-length relationships. Skeletal length ratios in hands with thumb CMC arthritis were no different from those of the controls.

DESIGN RATIONALE FOR A NEW ANATOMIC METACARPO-PHALANGEAL JOINT PROSTHESIS. Pierre Beaumont, Sylvain Gagnon, Jean-M. Pagé, Yves A. Ratron. Department of Orthopedic Surgery, Hôpital du Sacré Coeur, Montreal, Que.

The authors described a design for a prototype metacarpophalangeal (MCP) joint prosthesis that would restore joint kinematics and balanced hand function. Using data from previous studies at the Mayo Clinic on MCP joint kinematics, the authors designed a metal-polyethylene, uncemented, low constraint, resurfacing prosthesis, which required preservation or reconstruction of the capsuloligamentous mechanism. Anatomic factors, such as volar displacement of the instant centres of rotation in flexion, contact surface profiles and freedom of movement, as well as intra-articular forces involved in normal and pathologic function, were taken into account. The new implant concept reproduced the anatomy of the MCP joint, with the theoretical advantages of lower constraint, increased durability, less loosening and better biocompatibility than silicone.

ASSESSMENT OF PROXIMAL POLE VASCULARITY IN SCAPH-OID NONUNION: A PRELIMINARY REPORT USING LASER DOPPLER FLUOMETRY. Douglas C. Ross, Stuart D. Patterson, James H. Roth, Susan E. Vokey. Department of Surgery, University of Western Ontario, London, Ont.

Proximal pole vascularity of the ununited scaphoid has been assessed by radiography, measurement of intraoperative bleeding and magnetic resonance imaging (MRI). Intraoperative laser Doppler fluometry was used in five patients with established nonunion. Flow to proximal and distal poles was measured with the tourniquet inflated and after deflation. The average value per 100 g of tissue for proximal pole flow was 0.93 mL/min with the tourniquet inflated and 3.80 mL/min after deflation. The ratio of distal pole to proximal pole flow was 1.72. One patient with avascularity on MRI exhibited flow by laser Doppler, and union was subsequently achieved. The authors conclude that laser Doppler fluometry may be a sensitive indicator of proximal pole perfusion.

### EARLY RESULTS OF MODIFIED SCAPHOLUNATE ADVANCED COLLAPSE WRIST RECONSTRUCTION. Gary R. McGillivary. Department of Surgery, Dalhousie University, Halifax, NS

Twenty-six consecutive patients with scapholunate advanced collapse (SLAC) underwent a modified reconstruction consisting of scaphoid excision and four-corner fusion with correction of carpal collapse. All patients were then independently evaluated for grip strength, pain and range of motion. In 19 patients the follow-up was long enough (range

Abstracts of papers presented at the annual meeting of the Canadian Society for Surgery of the Hand, Montreal, Que., May 30, 1993

from 8 to 38 months, mean 20 months) to permit evaluation. Postoperative grip strength was 74% of normal. On average, preoperative range of motion was maintained. All but two patients (89%) were pain free. This modified reconstruction for SLAC is an excellent alternative to wrist arthrodesis.

RESULTS OF WRIST ARTHODESIS WITH PLATE FIXATION AND ILIAC CREST BONE GRAFT. Robin R. Richards, Dorcas E. Beaton, Thomas A. Barnhill. Division of Orthopedic Surgery, St. Michael's Hospital, Toronto, Ont.

In a prospective study the authors examined the fusion rate and incidence of complications when a plate and bone grafting were used to perform wrist arthrodesis in 60 patients: 50 with osteoarthritis, 8 with neurologic disorders and 2 with rheumatoid arthritis. The mean age of the patients was 32 years and the mean follow-up was 23 months. Each wrist was fused in the desired position without subsequent procedures. There were no iliac crest complications and no infections. One patient had reflex sympathetic dystrophy. Two sustained distal radial fractures at the plate-bone junction. Fifteen had plate removal for distal plate tenderness. Fourteen had slight flexion contracture of the third metacarpophalangeal joint. In conclusion, this technique is reliable, assures fusion in the desired position and has a low complication rate.

HISTOLOGIC AND MECHANICAL CHARACTERIZATION OF RHEUMATOID WRIST EXTENSORS. Martine J. Breault, David R. Pichora, Sandip S. Gupta, Carolyn Small, Tim Bryant. Department of Surgery, Queen's University, Kingston, Ont.

Implants were once used to treat wrist rheumatoid arthritis, but because implants migrate and dislocate arthrodesis is now preferred. Wrist implant failure may be due to soft-tissue imbalance related to changes in the tissue histologic and mechanical properties. A standardized protocol was developed for testing wrist extensors harvested from patients who underwent wrist arthrodesis. Specimens were examined under light and scanning electron microscopy and were tested in a senohydraulic Instron Universal Machine (Instron Canada Ltd., Burlington, Ont.). Histologic and viscoelastic properties were significantly different between normal and rheumatoid tissue for the 23 specimens tested. This finding has clinical significance for soft-tissue reconstruction during wrist surgery and stresses the importance of developing improved methods of fixation.

FLEXOR CARPI RADIALIS TO EXTENSOR DIGITORUM COMMU-NIS TENDON TRANSFER TO RESTORE METACARPOPHALAN-GEAL JOINT EXTENSION. Robin R. Richards, Dorcas E. Beaton, Alan R. Hudson. Division of Orthopedic Surgery, St. Michael's Hospital, Toronto, Ont.

The results of ulnar transfer of flexor carpi radialis to extensor digitorum communis were reviewed with a minimum follow-up of 12 months (mean 20.6 months). Twenty-five patients (mean age 39 years) who had no active extension of the metacarpophalangeal joint (MCPJ) due to neural injury (8 brachial plexus, 7 radial nerve and 10 posterior interosseous nerve) underwent transfer. All recovered active MCPJ extension, and patient satisfaction was universal. With the wrist in the neutral position, 21 had no extensor lag. Mean grip strength was 18.8 kg. Functional testing revealed deficits when compared with the noninjured side (Jebsen 50.6%; Minnesota Rate of Manipulation Test 34.7%). No patient had wrist radial or ulnar deviation. The FCR can be considered as an alternative method for restoration of MCPJ extension.

RESTORATION OF METACARPOPHALANGEAL EXTENSION IN THE RHEUMATOID THUMB. Claude Manueddu, David E. Hastings, Earl R. Bogoch. Division of Orthopedic Surgery, Wellesley Hospital, Toronto, Ont.

The authors studied rerouting of the extensor pollicis longus muscle by the Hastings method to restore active extension to the thumb in 10 patients with rheumatoid arthritis who had extensor lag and an intact metacarpophalangeal joint. Other methods have previously been reported to be unsuccessful. Of the 10 patients, 6 had full active extension of the thumb, 2 retained an extensor lag of 23° and 30° but were improved from their preoperative state of  $-30^\circ$  and  $-40^\circ$  and 2 had a fixed flexion deformity of 30° and 20° respectively. Preoperative fixed flexion deformity is a contraindication to this procedure, and loss of cartilage dorsally in the joint lessens the chances of success.

### A BIOMECHANICAL ANALYSIS OF PERCUTANEOUS PINNING FOR UNSTABLE EXTRA-ARTICULAR FRACTURES OF THE DIS-TAL RADIUS. James Collicut, Gary R. McGillivary, Michael Gross. Department of Surgery, Dalhousie University, Halifax, NS

Percutaneous pinning is advocated for the treatment of unstable distal radial fractures. Few guidelines exist for the optimal placement of pins. In this study eight pinning configurations were assessed in vitro in 40 embalmed cadaver radii. Rigidity of intact specimens under axial and bending loads in the coronal and sagittal planes was determined. A transverse metaphyseal osteotomy was performed, and rigidity was reassessed after reconstruction with 0.062-in Kirschner wires. Significant reductions were measured in the axial and bending rigidities of the reconstructed specimens. No significant differences were observed between the rigidity of the four, three and two crossed-pin configurations. Single-pin configurations were grossly unstable.

ABSORBABLE IMPLANTS FOR INTRA-ARTICULAR HAND FRAC-TURES. Mahmud Kara, Douglas C. Ross, James H. Roth, Robert S. Richards. Department of Surgery, University of Western Ontario, London, Ont.

The use of absorbable poly-*p*-dioxanone pins has been secently described for both large- and small-bone fractures. The autors evaluated this technique prospectively in six patients with intra-articular fractures of the hand with significant displacement (three proximal interphalangeal joint [PIPJ]; three metacarpophalangeal joint [MCPJ]). The average follow-up was 20 weeks. The mean range of movement for the PIPJ injuries was good to excellent but was less satisfactory for MCPJ injuries. There were no mechanical failures of the implants, and there was no evidence of allergic or inflammatory reaction. The authors conclude that poly-*p*-dioxanone pins in the treatment of intra-articular fractures can provide stable fixation and are a useful adjunct in the treatment of these fractures.

### DYNAMIC TRACTION SPLINTING FOR PROXIMAL INTER-PHALANGEAL JOINT INJURIES. Kenneth A. Murray. Department of Surgery, St. Boniface General Hospital, Winnipeg, Man.

The proximal interphalangeal (PIP) joint is important in the overall function of the digit. Injury to this joint can severely affect hand function. Early active motion, as with other joint injuries, is important in ensuring a good range of motion and functional outcome. The author reviews experience of dynamic traction splinting at the PIP joint with a variety of injuries. The benefits of this traction system are that it allows early, active motion, traction that can aid in reduction of fragments and provide a marked decrease in pain. This encourages patient compliance, gives early range of motion and an enhanced result.

### CANADIAN SOCIETY FOR SURGERY OF THE HAND

THE MANAGEMENT OF METACARPOPHALANGEAL AND PROXI-MAL INTERPHALANGEAL JOINT ARTICULAR FRACTURES USING DYNAMIC SKELETAL TRACTION AND IMMEDIATE MO-BILIZATION. Stuart D. Patterson, Shrikant Chinchalkar, Douglas C. Ross, Carol Weekes, James H. Roth. Department of Surgery, University of Western Ontario, London, Ont.

Twelve patients with joint articular fractures (10 proximal interphalangeal, 1 thumb metacarpophalangeal, 1 fifth digit metacarpophalangeal) ranging in age from 8 to 65 years, were treated with dynamic skeletal traction and immediate mobilization. All fractures were analysed under image intensification, and the distraction force required for reduction was determined. A mean force of 329.17 g (range from 200 to 450 g) was applied. Active range of movement and tendon gliding were undertaken for 6 weeks, resisted motion at 8 to 10 weeks and unrestricted use at 12 to 14 weeks. At a minimum follow-up of 6 months, pain-free motion was present in 11 patients. Mean range of movement for the proximal interphalangeal joints was 95.5°, for the thumb metacarpophalangeal joint 80° and for the fifth digit metacarpophalangeal joint 40°. Complications included two pintract infections, one mild scissoring and one volar plate contracture.

### EVALUATION OF A NEW ANCHORING DEVICE IN THE DISTAL PHALANX. Robert J. Feibel. Department of Surgery, Ottawa General Hospital, Ottawa, Ont.

Stainless steel wire (26 gauge) was secured to fresh frozen human cadaver distal phalanges by (a) a dorsal tie-over button, (b) a 2-mm self-tapping Luhr screw or (c) the Mitek Mini-GII (Mitek Industries, Norwood, Mass.) suture anchoring device. The fixation systems were stressed to failure along the phalangeal axis. All button tie-over wires failed through the wire (mean force of 157.9 N). Screws and Mini-GII anchors failed by pullout from bone (mean loads of 83.5 N and 82.3 N respectively). There was no significant difference between results with the Luhr screw and with the Mini-GII. The Mitek device should be considered for repair of an avulsed flexor digitorum profundus, suture of a collateral ligament or active Hunter tendon rod to bone and may also be used for volar plate arthroplasty for dorsal fracture-dislocations of the proximal interphalangeal joints.

### OCCUPATIONAL EXPOSURE TO HAND VIBRATION IN NORTH-ERN ONTARIO GOLD MINERS. Philip P. Narini, Chris B. Novak, Susan E. MacKinnon, Cathy Coulson-Roos. Division of Plastic Surgery, Sunnybrook Health Science Centre, Toronto, Ont.

Nineteen underground gold-mine drillers (mean age 35.4 years) who operated vibration equipment and a control group of 16 gold mill workers (mean age 31.0 years) who did not were evaluated with static and moving two-point discrimination, vibration and cutaneous pressure thresholds. Provocative tests, including Tinel's, pressure and Phalen's sign, were also performed. The mean duration of vibration exposure was 14.3 years. Numbness, pain and weakness were reported in 12 miners and 1 control subject. Vibration white finger was reported in 16 miners and three control subjects. Miners had a higher incidence of positive provocative tests at both carpal and cubital tunnels and higher cutaneous pressure thresholds than controls. Significantly higher vibration thresholds were found in miners (p < 0.05). A correlation relationship between years of vibration exposure and vibration threshold was found (r = 0.7).

### SAFE AND EFFECTIVE BRACHIAL PLEXUS BLOCKS BY SUR-GEONS. Daniel S. Thomas, Carolyn L. Kerrigan. Division of Plastic Surgery, Royal Victoria Hospital, Montreal, Que.

A quality assurance study was undertaken to establish the safety and effectiveness of brachial plexus blocks performed by surgeons for emergency and elective hand surgery. Forty-five consecutive patients received an axillary block consisting of 1% mepivacaine and lidocaine hydrochloride. Safety was assessed by electrocardiogram pulse oximetry and blood-pressure monitoring. Effectiveness was judged by a pain questionnaire and neurologic testing. Eighty-two percent (37 of 45) of blocks were completely successful. Supplemental local injections at the operative site provided sufficient anesthesia for all other cases. Two-thirds of patients judged the block procedure to be less or equal to the pain of an intravenous insertion. This experience indicates that hand surgeons can perform safe and effective brachial plexus blocks.

PALMAR CUTANEOUS SENSORY BRANCH OF THE MEDIAN NERVE PASSING THROUGH THE PALMARIS LONGUS TENDON: A CADAVERIC STUDY. Robert S. Richards, Paul Dowdy, Robert M. McFarlane. Division of Plastic and Reconstructive Surgery, University of Western Ontario, London, Ont.

The relationship of the palmar cutaneous branch of the median nerve to the palmaris longus tendon was studied in 52 wrists from 27 preserved cadavers. In three wrists the palmaris longus tendon was absent. The palmar cutaneous branch arose from the median nerve at a mean of 4.0 cm proximal to the wrist crease. In two wrists, the palmar cutaneous branch passed through the palmaris longus tendon 1.0 cm and 1.5 cm proximal to its insertion into the palmar aponeurosis. When this anomaly is present, the palmar cutaneous sensory branch of the median nerve may be injured during harvesting for tendon grafting if transection is not proximal to the insertion into the palmar aponeurosis.

TENOSYNOVIAL CHANGES IN PATIENTS WITH ACTIVITY-ASSOCIATED SYMPTOMS OF CARPAL TUNNEL SYNDROME. Linda Mrkonjic, Peter T. Gropper, Brent A. Graham. Division of Orthopedic Surgery, University of British Columbia, Vancouver General Hospital, Vancouver, BC

Activity-associated changes in carpal canal pressures may be secondary to dynamic variations in the volume of the flexor synovium. Samples of flexor tenosynovium were collected from 21 patients who underwent carpal tunnel release. Twelve cadaveric specimens, from individuals with no history of carpal tunnel syndrome or inflammatory disease, formed a control group. A blinded pathologist graded the histologic findings. Synovial fibrosis was the most common histologic factors, indicated that patients with symptoms associated with strenuous upper extremity activity were more likely to have significant synovial fibrosis than patients not engaged in repetitive or vigorous hand use or cadaveric controls. The authors conclude that flexor tenosynovial fibrosis in the carpal canal may be important in the development of activity-associated carpal tunnel syndrome.

### RICHE-CANNIEU CONNECTION IN MEDIAN NERVE INJURIES. Michelle M. Carr, J. Brian Boyd, C. Vaughan A. Bowen. Department of Surgery, Toronto General Hospital, Toronto, Ont.

The Riche–Cannieu connection between the deep branch of the ulnar nerve and the recurrent motor branch of the median nerve was described 100 years ago. It has been considered rare and unimportant in the interim. Electrophysiologists have recently shown that this connection occurs in the majority of normal people and accounts for a variable proportion of motor response in the thenar musculature. The authors describe two cases of median-nerve injuries proven by operative exploration, both with intact thenar function. They postulate that this anomalous clinical presentation is due to the Riche–Cannieu connection and present supportive clinical evidence. Such unusual clinical situations emphasize the need for careful evaluation of nerve injuries. A COMPARATIVE STUDY OF STEINDLER AND PECTORALIS MAJOR FLEXORPLASTY. André Dumont, Dorcas E. Beaton, Alan R. Hudson, Robin R. Richards. Division of Orthopedic Surgery, St. Michael's Hospital, Toronto, Ont.

The functional outcomes of two types of elbow flexorplasty performed with shoulder arthrodesis for patients with brachial plexus injuries were compared. Of 14 patients assessed, 5 had a pectoralis major tendon transfer and 9 a modified Steindler flexorplasty. All patients had brachial plexus lesions that were irreparable or unresponsive to neurolysis, repair or grafting. Average follow-up was 60 months.

	Modified Steindler flexorplasty (n = 9)	Pectoralis major transfer (n = 5)	Normal extremity (n = 14)
Elbow flexion, °	117	116	138
Extension, °	20	26	1
Isometric strength, kg			
Flexion at 45°	33.6	45.9	200.4
Flexion at 90°	26.8	42.7	230.0
Flexion at 110°	11.8	22.7	176.8
Isotonic power (engals)			
Elbow flexion	994	1347	3852
Patient satisfaction* Activities of daily living	9/10	9/10	NA
score	12/30	8/30	30/30

In the patient requiring stabilization of the shoulder and flexorplasty, the pectoralis major tendon transfer is at least equivalent, if not superior, to the modified Steindler flexorplasty in terms of range of motion, strength and subjective measures.

### NEUROLOGIC LESIONS WITH SUPRACONDYLAR FRACTURE OF THE ELBOW IN CHILDREN. Marc Isler, Constantin Stanciu. Department of Orthopedic Surgery, Hôpital Sainte-Justine, Montreal, Que.

Supracondylar fracture of the elbow in children has a significant frequency of neurovascular complications. A prospective study was made of 92 supracondylar fractures. Eighteen cases (20%) were complicated by neurologic lesions. All fractures were of the extension type, grade 2b or 3 (Gartlan classification). All lesions healed completely in an average time of 20 weeks. The most frequently involved nerves were the radial and median, with an equal incidence. The second most frequent pattern was either the ulnar nerve, all three nerves or the anterior interosseus nerve, with equal frequency. All other combinations were less frequent. Results demonstrated excellent neurologic recovery.

### PRIMARY MALIGNANT TUMOURS OF THE HAND. Narayana Nandagopal, Alok Shah, Derek Younge. Department of Surgery, King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia.

Thirteen noncutaneous tumours of the hand were studied retrospectively. Eleven tumours arose from soft tissues and 2 from bone. Four tumours were located in the fingers and nine in other regions. Two cases were staged as IIA, seven as IIB and four as III (metastases on presentation). Five patients underwent amputation, four patients had wide excision and another four patients underwent biopsy alone. Radiotherapy was given to four patients and palliative chemotherapy to another four. At follow-up, which ranged from 6 months to 10 years, seven patients were alive and disease free and six had died of metastatic disease. Functionally, radiotherapy was not detrimental. Wide resection followed by radiotherapy may salvage proximal hand tumours, providing reasonable function without compromising patient survival. IF IT ISN'T TENNIS ELBOW, WHAT MIGHT IT BE? Donald A. Ranney, Richard Wells, Anne Moore. Department of Kinesiology, University of Waterloo, Waterloo, Ont.

The musculoskeletal health of 146 female workers in five industries characterized by repetitive upper limb activity was assessed clinically at the work site and subsequently correlated with a number of ergonomic factors. Data were collected on 288 extensor regions and 290 flexor regions. Tenderness was found in the lateral epicondyle or common extensor tendon, or both, in 26 workers and in the extensor muscle bellies in 35. Tenderness was found in the medial epicondyle or common flexor tendon, or both, in 12 workers and in the flexor muscle bellies in 23. Radial tunnel syndrome and pronator syndrome could explain the forearm pain in some cases but not in the majority. Muscle ischemia from prolonged static contraction was a more likely possibility and evidence for this is presented.

### EVALUATION OF RADIAL BOWING IN ULNAR CLUB HAND. Jean Rousseau, Constantin Stanciu, Benoit Morin. Department of Orthopedic Surgery, Hôpital Sainte-Justine, Montreal, Que.

Ulnar hypoplasia is a rare congenital defect. The hand is stable on the distal radius but syndactyly and absent rays are frequent. The radial head is often dislocated or fused to the distal humerus. Radial bowing is increased, but the natural history is unknown. Ulnar anlage resection is recommend by some authors. Radial bowing was measured in eight untreated patients with nine ulnar club hands at a mean follow-up of 5 years. The radial bowing did not progress in any patient whether the radial head was dislocated or fused to the distal humerus. In five of nine forearms a slow regression of radial bowing was seen. It was concluded that prophylactic release of ulnar anlage is not indicated in ulnar club hand.

### FRACTIONAL FLEXOR TENDON LENGTHENING FOR SEVERE METACARPAL FLEXION CONTRACTURE IN THE RHEUMATOID HAND. David R. Pichora. Department of Surgery, Queen's University, Kingston, Ont.

Six patients with severe (90° to 120°) metacarpophalangeal joint flexion contractures had Zancolli flexor tendon lengthening with standard metacarpal osteotomy and intrinsic release during Swanson arthroplasty. At a mean 11-month follow-up, a mean active range of movement arc of 61° and a mean passive range of motion arc of 86° were noted along with an actual mean active range of motion arc of 4° to 63° of flexion. Because of its simplicity and lack of complications, fractional flexor tendon lengthening is a successful procedure to correct severe flexion deformity in the rheumatoid metacarpophalangeal joint and obviates the need for excessive metacarpal resection.

### TUBERCULOSIS OF THE HAND. Mohammed Al Qattan, C. Vaughan A. Bowen. Department of Surgery, Toronto General Hospital, Toronto, Ont.

Three patients with tuberculosis of hand are described. The first presented with recurrent carpal tunnel syndrome with rice bodies associated with tuberculous synovitis. The other two patients presented with wrist pain and bony destruction with sinuses and successfully underwent wrist fusion. A review of the literature is presented and a classification for tuberculosis of the hand described. The authors conclude that since tuberculosis of the hand is now rarely seen, the correct diagnosis is usually delayed. Awareness of the presenting features will help in making an earlier and more effective diagnosis and in early treatment.

# BOOK REVIEWS CRITIQUES DES LIVRES

KNEE MENISCUS: BASIC AND CLINICAL FOUNDATIONS. Edited by Van C. Mow, Steven P. Arnosky and Douglas W. Jackson. 204 pp. Illust. Raven Press, New York. 1992. \$89 (US). ISBN 0-88167-895-3

It is ironic that a structure that has been considered to be a functionless remnant of muscle origin, subject to quick excision at the mere mention of a knee problem now has a book dedicated to its structure and function. It seems, however, that the days of little respect for the meniscus are now officially gone. In this book, a well-organized attempt is made to demonstrate why the meniscus is such an important structure and how it functions. The editors have recruited contributors who have the most experience in the various aspects discussed in the book.

The material is well presented. The text starts with the basic scientific elements, including gross and microscopic anatomy with reference to the biochemical and physiologic features and the engineering principles. This section is strong. The information given is based on excellent research that has been done in this field. The clinical sections of the book, although well written, do not solve many of the difficult meniscal problems seen in clinical practice. Perhaps this is a reflection of how little we know and can do with such problems and how much more work is necessary in this area.

It is unfortunate that the information provided in this text was not available at the time when meniscectomy was a popular treatment for knee problems. This text should be mandatory reading for anyone who deals with knee disorders, and the information contained therein should at least be understood. Fellows and residents in orthopedics as well as orthopedic researchers interested in the meniscus will want this book as a reference source. The orthopedic surgeon in clinical practice will not find this book helpful in handling clinical problems. Overall, however, this text is well written, easy to understand and teaches some important lessons about the knee meniscus and its function. More importantly, it serves as a reminder that nothing is without purpose and that before excision of any anatomic structure the potential complications of such excision must be considered.

Anthony Miniaci, MD, FRCSC Division of Orthopedic Surgery University Hospital 339 Windermere Rd. London, ON N6A 5A5

HIGH TECH UROLOGY. TECHNO-LOGIC INNOVATIONS AND THEIR CLINICAL APPLICATIONS. Joseph A. Smith. 362 pp. Illust. W.B. Saunders Co., Philadelphia. 1992. \$107 (US). ISBN 0-7216-3053-7

Rapid technologic advances in urology and the flood of new information on molecular biology have made it difficult for the academic urologist to remain up to date in all aspects of the specialty and have greatly challenged the community urologist. Furthermore, with knowledge acquired from lay publications, patients seek reassurance that they are being treated appropriately and in the most up-to-date fashion. Recognizing the need for an evaluation of new technology, Joseph A. Smith has edited this excellent text, which contains contributions from leaders in the field in the United States. Theoretical and practical aspects are covered, and there is recognition that all that is new is not necessarily beneficial.

Stone disease illustrates the farreaching management changes in urology over the past decade. The chapter on extracorporeal shock-wave lithotripsy covers the principles of shock-wave physics and the design of the lithotripter. The second- and third-wave lithotripters are compared and assessed against the record of the original Dornier HM3 lithotripter. An efficiency quotient is proposed, but stone-free rates are also dependent on the action of caliceal contractions as well as shock-wave generation. The biologic effects of shock waves are dealt with, and the status of biliary lithotripsy is reviewed.

The chapter on ureteronephroscopy is excellent and covers all aspects of the intelligent use of both solid and flexible instruments. Therapeutic indications for the techniques are described. The importance of inserting a safety guide wire before the procedure is stressed. The risks of using the stone basket, even under ureteroscopic control, are emphasized; the authors prefer a three- or four-pronged grasper, because the stone can be released if it proves too large to remove intact.

It would have been logical to follow these sections with the chapters on percutaneous techniques and urologic accessory devices, but these chapters are placed later in the book. The anatomy and methods of percutaneous renal puncture are well described, and the explanation of multiple caliceal puncture by a Y-tract technique is commended. In addition, a method of retrograde percutaneous nephrostomy is described. Complementary medical management of stones is also given consideration. Endopyelotomy is discussed, and the reasons for the small number of failures are detailed. A method for percutaneous management of simple renal cysts is described.

The physics of lasers and their application to urology is contained in a valuable chapter, which brings the reader up to date on this expensive technology.

Urologists are generally poorly instructed in the use of ultrasonography and interpretation of the findings, so the section on ultrasonography is particularly welcome. It explains the fundamentals and physical principles. The section on imaging of the prostate gland is especially useful. The subject of urodynamics is covered concisely, and another chapter clarifies the prodigious capabilities of the flow cystometer.

The chapter on male infertility attempts to place the practising urologist back in the forefront of management by providing an understanding of recent highly specialized techniques of investigation. Especially welcome is the excellent chapter on immunology and molecular biology, which will update and solidify the urologist's understanding of this rapidly developing science. The book concludes with chapters on the practical aspects of stapling devices, laparoscopy in urology and innovations in pediatric urology.

The editor is to be congratulated on producing such a timely work that is stimulating and easy to read.

Norman W. Struthers, ChM, FRCSC Division of urology St. Michael's Hospital 30 Bond St. Toronto, ON M5B 1W8

ATLAS OF TRANSVAGINAL SUR-GERY. Shlomo Raz. 262 pp. Illust. W.B. Saunders Company, Philadelphia. 1992. \$158. ISBN 0-7216-2431-6

I began my review of this book with considerable scepticism because it is a common belief that transvaginal surgery should be performed only by gynecologists. However, Dr. Raz, a urologist, has demonstrated that this belief is incorrect.

The book begins with a description of the anatomy of pelvic support and its relation to stress incontinence. This is followed by a description of the instrumentation required and the complications of vaginal surgery. These chapters are extremely well written. They contain the fundamental information required by all vaginal surgeons and are well illustrated, providing easy understanding of the complex anatomy and physiology of this region. A wide variety of surgical conditions are discussed. Conventional gynecologic conditions such as cystocele, rectocele, enterocele, vaginal prolapse, uterine prolapse and vaginal wall cysts are covered in detail. Conventional lower urinary tract conditions such as vesicovaginal fistula, urethral diverticula, infected Skene gland and urethral caruncle are also thoroughly discussed.

The chapter on treatment of urinary incontinence, for which the author is well known, provides great detail; surgical photographs and schematic diagrams are used for increased understanding. This chapter should be particularly interesting to gynecologists since they have probably not been exposed to many of the surgical techniques described.

Only a few reference books have been written on transvaginal surgery, and most have been written by gynecologists. This book provides an entirely different approach and should therefore be of great interest to the gynecologist.

This should be the reference text of choice on transvaginal surgery for both gynecologists and urologists.

Stephen S. Im, MD, FRCSC, FACOG Department of Obstetrics and Gynecology St. Michael's Hospital 30 Bond St. Toronto, ON M5B 1W8

ENDOSCOPIC PARANASAL SINUS SURGERY. 2nd edition. Dale H. Rice and Stephen D. Schaefer. 256 pp. Illust. Raven Press Ltd., New York. 1992. \$115 (US). ISBN 0-88167-946-1

Limited access surgery has attracted much attention in all the surgical specialties. With appreciation of the significance of previously described physiology of the paranasal sinuses and the advent of coronal computed tomography (CT) in the evaluation of sinus disease, the application of limited access surgery has led to important advances in the management of acute and chronic sinus conditions. The authors cannot be credited with the increased interest in this branch of rhinologic surgery, which has had a strong following in Europe for over a decade. They nevertheless produced the first comprehensive review of the subject in the initial edition of this book.

The second edition covers every aspect of the anatomy, physiology and evaluation of patients who may benefit from endoscopic sinus surgery. There is a detailed account of surgical technique. At present there are two recognized approaches, the first popularized by Messerklinger, who proposed an anterior to posterior procedure primarily for the ostiomeatal complex with persisting disease of frontal, anterior ethmoidal and maxillary sinuses. Wigand proposed a posterior to anterior approach for diseases of the sphenoid and posterior ethmoid system. This text shows how these techniques may be applied after assessment of the patient from the history, endoscopic examination and interpretation of the CT scan.

One of the strengths of this edition and the first one has been the photographs of fresh cadaver dissections, which are photographed from both the best anatomic perspective and the endoscopic view. The photographs are interpreted by clear line drawings, allowing an excellent appreciation of the paranasal sinus anatomy.

There are numerous CT scans, which show not only the normal anatomy but also the commonly seen pathologic features.

The title suggests that this text describes primarily the operative procedure. However, the approach to the subject is balanced with chapters on the management of pediatric sinus disease, a comprehensive account of medical management and a review of complications, which are relatively uncommon to well-trained surgeons but which can lead to significant morbidity and have given rise to medicolegal concerns. The authors have been ably helped by five experts who have provided contributions with respect to the radiologic aspects, the medical management and the accompanying diagrams.

Each chapter either gives specific references or lists cited publications.

The book contains only 256 pages,

### **BOOK REVIEWS**

and although many of these are taken up with well-reproduced photographs and diagrams the text is comprehensive and has probably already established itself as the pre-eminent reference for those wishing to further their knowledge in this expanding area of otorhinolaryngology.

This book is a virtual necessity for rhinologic surgeons, and all otolaryngologists will find it extremely interesting. Although no text can take the place of good training, the inclusion of a chapter on the selection of instruments and the descriptions of operative techniques will enable otolaryngologists to apply this surgery to their practice. Neurosurgeons and respirologists will likely find it of interest since many of the procedures described are applicable to their patients.

This is a clearly written, excellently illustrated text that can be highly recommended.

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### MECHANICS OF HUMAN JOINTS — PHYSIOLOGY, PATHOPHYSIOLO-GY AND TREATMENT. Edited by Verna Wright and Eric L. Radin. 480 pp. Illust. Marcel Dekker Inc., New York. 1993. \$185 (US). ISBN 0-8247-8763-3

This book is coedited by two recognized experts in the field of biomechanics. Verna Wright is from the University of Leeds, England, and Eric Radin is from the Henry Ford Hospital in Detroit. Contributions have been made by a team of authors — anatomists, bioengineers, biologists, orthopedic surgeons and physicians. The text is subdivided into major sections that include the physiology of joints, mechanics, neurophysiology, pathophysiology and treatment. The book is well illustrated and referenced. Interestingly, there no sections written by Verna Wright.

The anatomy and function of joints is described in great detail in the mechanics section. Jacqueline Perry's description of the mechanics of gait is excellent. However, only normal gait is described, which is disappointing since orthopedic surgeons deal primarily with disorders characterized by abnormal gait. This is particularly relevant in reconstructive surgery where abnormal gait can affect implant loading. The energy cost of walking is discussed with reference to oxygen consumption during abnormal gait but is not discussed in detail.

The chapter on knee-ligament reconstruction gives emphasis to the anterior cruciate ligament and provides a good general review of the topic but is lacking in specifics. The lack of illustrations in this chapter is a major omission. I enjoyed reading this section but did not feel that it helped to resolve the uncertainty associated with the management of isolated injuries of the anterior cruciate ligament.

There is a superb chapter by Anthony Unsworth in which he describes the lubrication of the human joints. A natural extension of this section would have been an analysis of wear mechanisms in artificial joints.

The section describing the properties and physiologic functions of synovial fluid in health and disease is excellent and should be of particular interest to orthopedic surgeons. The chapters relating to muscle physiology, electromyelography and joint innervation are also valuable.

There is an interesting chapter on the pathophysiology of intervertebral disc herniation. It describes the effect of vibration on joints and the relation between occupation and spinal problems. The theories of vibration are presented, but they are complex and may be difficult for the average reader to understand.

Finally, the treatment section is divided into two areas: the principles of joint prostheses, by J.D. Blaha, and physiologically based treatments, by P. Maquet. The joint replacement portion is disappointingly brief. Little information is provided about joint wear and implant failure. Maquet's description of physiologically based treatments, however, provides the reader with a wellillustrated description of the treatment of osteoarthritis of the hip and knee by osteotomy and soft-tissue release procedures. The biomechanical principles involved are clearly described and well illustrate the biomechanical principles involved in treatment.

The preface indicates that this book is intended for physicians, orthopedic surgeons, rehabilitationists and fundamental scientists. Overall, there is too much detail in some sections and not enough in others to make the book of compelling interest to practising orthopedic surgeons. Residents in orthopedic surgery may find it useful as a musculoskeletal basic science reference text, but its main appeal. I suspect is for those involved in research. The book is a suitable addition to a hospital library, but regrettably I think it has limited interest for the average orthopedic surgeon.

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ORTHOPAEDIC TRAUMA PROTO-COLS. Edited by S.T. Hansen Jr. and M.F. Swiontkowski. 393 pp. Illust. Raven Press, New York. 1993. \$150 (US). ISBN 0-88167-994-1

This book is edited by two orthopedic surgeons with extensive experience in the management of orthopedic and multiple trauma. They have used their experience at the Harborview Medical Center in Seattle, Wash., to put together a comprehensive text on the management of orthopedic trauma.

The book is divided into two main sections. The first, 75 pages long, details general considerations in the management of trauma. These include musculoskeletal traumatology, the role of the trauma surgeon in the management of orthopedic trauma, nursing standards (to which considerable attention is given), anesthesia and rehabilitation. All of these chapters are succinctly written for the treating surgeon rather than for the appropriate nonphysician health care provider. However, the section on nursing is excellent for the non-nursing health care provider.

The second main section of the text is devoted to regional fracture management. The editors have selected a group of contributors with recognized expertise in the management of musculoskeletal trauma in the specific body parts to be discussed. The depth and breadth of the program at Harborview Medical Center is reflected in that all of the contributors work at this centre. Each chapter is well illustrated with both line drawings and appropriate radiographs; because a single person provided all the illustrations, the quality greatly exceeds that found in most multiauthored books. The surgical technique, where appropriate, is well described, with excellent preoperative and postoperative examples. The references for each chapter are appropriate but not excessive.

This book will be of considerable value to both orthopedic surgeons and nonorthopedic surgeons involved in trauma care. For the orthopedic surgeon the book provides a succinct reference manual for many specific fracture types; it is also an excellent source of reference material and illustrations. The book will be of particular value to residents in orthopedics for fracture classification and treatment. For nonorthopedic surgeons involved in the management of polytrauma patients with musculoskeletal injuries, this text provides excellent topical suggestions with respect to appropriate fracture management.

The editors are to be congratulated on producing a topical, well-illustrated uniform text. I predict that this will be a standard fracture textbook for many years to come.

James P. Waddell, MD, FRCSC Director, Trauma Services St. Michael's Hospital 30 Bond St. Toronto, ON M5B 1W8

LASERS IN HEAD AND NECK SUR-GERY. Edited by Edward C. Weisberger. 293 pp. Illust. Igaku-Shoin Medical Publishers Inc., New York/HBJ-Holt-Saunders Distribution Services, Toronto. 1991. \$87. ISBN 0-89640-181-2

This text provides an overview of the current usage of lasers in the management of benign and malignant lesions in the head and neck. Although the book concentrates primarily on the proven modalities of argon, carbon dioxide and neodymium : yttrium-aluminum-garnet lasers, the potential of new lasers such as the potassium-titanyl-phosphate (KTP), Excimer, gold vapour and tunable dye lasers is also discussed.

The introductory chapters contain descriptions of the physical characteristics of surgical lasers and the interaction of tissue with a variety of laser wavelengths. This section is clear and concise without the inclusion of complex mathematical formulae. There is an excellent summation of the advantages and disadvantages of various modes of operation: continuous, pulsed and Q-switching. Following this section are detailed descriptions of the necessary safety precautions and special anesthetic requirements.

The book continues with a detailed discussion of laser use in specific areas of the head and neck. Individual chapters are devoted to lasers in dermatologic surgery, rhinologic and paranasal sinus surgery, surgery of the oral cavity and pharynx, otologic and laryngologic surgery, surgery on the tracheobronchial tree and surgery for palliation of esophageal carcinoma.

The final two chapters cover the

possible future applications of lasers in photodynamic therapy in head and neck cancer, and in microvascular laser welding of blood vessels and nerves.

As with most multiauthored books there is some repetition. A major oversight is the absence of any discussion of lasers in ophthalmic surgery. Aside from these shortcomings, this book is an excellent introduction to current laser use. The contributors are to be commended for their detailed recommendations on laser type, power settings, mode of operation and spot size in dealing with specific lesions, a very valuable resource for the reader with limited previous experience.

This book would be a valuable addition to the library of all surgeons who deal with lesions in the head and neck as well as their colleagues in anesthesia and dermatology.'

Ralph R.F. Ruby, MD, FRCSC, FACS Department of Otolaryngology/Audiology St. Joseph's Health Centre The University of Western Ontario Third Floor 900 Richmond St. London, ON N6A 5B3

SURGICAL DECISION MAKING. 3rd edition. Edited by L.W. Norton, G. Steele Jr. and B. Eiseman. 342 pp. Illust. W.B. Saunders Company/Harcourt Brace Jovanovich, Inc., Philadelphia. 1992. \$75 (US). ISBN 0-7216-6498-5

This edition of *Surgical Decision Making* follows a similar pattern to the two previous editions in that individual surgeons have been asked to provide their personal approaches to a multiplicity of surgical problems. In this edition, the authors have been asked to justify their choices not only on the basis of their experience and current published information but also on the basis of cost and outcome.

This edition has been expanded by the inclusion of sections on transplantation surgery and perioperative manage-

# **BOOK REVIEWS**

ment; more than one-third of the authors are making their "first appearance" in this textbook.

The text is divided into a section on surgery in general, followed by sections on head and neck, cardiopulmonary, gastrointestinal, breast, endocrine, vascular, pediatric and transplantation surgery. Subspecialty interest is seen in sections on urology, gynecology and fracture management. Under each of these headings a specific topic is approached by a short narrative section that is accompanied on the facing page by an algorithm that is referenced to the text. Therefore, in the narrative on the left-hand page a specific paragraph will be labelled with a letter that can be found in the algorithm. Review of the

algorithm allows the reader to get an overview of the problem and the thinking behind the author's problem-solving exercise: the thinking for each step in the algorithm can be obtained from the narrative. Although this may result in some oversimplification of complex problems, the editors point out that this text is not intended to be definitive on the problems discussed but to help the reader understand the logic of the approach used by recognized experts with respect to each condition covered.

The value of this writing technique is immediately evident when the reader peruses unfamiliar specialty sections. By reading the short narrative text, reviewing the algorithm and returning to the narrative text, the reader can,

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within a few minutes, get a good grasp of the basic steps in dealing with many common surgical problems.

This text will be of great value to trainees in surgery and to surgeons who are occasionally required to care for patients with problems that are outside that surgeon's area of expertise. It will be a valuable addition to the library of any hospital in which surgical procedures are performed.

James P. Waddell, MD, FRCSC Professor of surgery University of Toronto St. Michael's Hospital 30 Bond St. Toronto, ON M5B 1W8

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