2013 SAGES Research Grant Application Cover Sheet

Title: Marginal ulcer prophylaxis following laparoscopic Roux-en-Y gastric bypass for morbid obesity: A randomized, blinded, placebo-controlled pilot study

Principal Investigators (SAGES members): Drs. Timothy Jackson and Allan Okrainec

Amount Requested: $27,350
Application Date: November 1, 2013

Primary Mailing Address:
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Phone: 416-581-8639
Fax: 416-603-6458
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Projected Start Date: April 1, 2014       Projected End Date: June 30, 2015

Co-Investigators:

Dr. Ahmad Elnahas
Minimally Invasive Surgery Fellow
Toronto Western Hospital, University Health Network

Dr. Fady Saleh
Minimally Invasive Surgery Fellow
Toronto Western Hospital, University Health Network

Jane Lui
Pharmacist, Investigational Pharmacy Services
Toronto Western Hospital, University Health Network
A. Statement of Funds

Funding for this project is not pending or on hand through other sources.
B. Summary

Purpose: To compare the effect of postoperative daily oral pantoprazole therapy for 90 days versus placebo on the proportion of patients with marginal ulcers (MU) diagnosed within 6 months following laparoscopic Roux-en-Y gastric bypass (LRYGB)

Population: Patients ≥ 18 years undergoing LRYGB for morbid obesity at Toronto Western Hospital

Design: Randomized, blinded, placebo-controlled, pilot study

Intervention: Fifty patients will be randomized in equal proportions between pantoprazole and placebo, receiving either a once daily, oral dose (40 mg) of pantoprazole for 90 days starting on postoperative day (POD) one or daily oral placebo (identical in size, shape, and color) for 90 days starting on POD one.

Regimen: An independent pharmacist will oversee the randomization and send the corresponding treatment bottle to the research coordinator the day after surgery. Bottles will be identical and labeled only by the study identification number. The research coordinator will administer a bottle containing oral pantoprazole or placebo to the patient the day after surgery while in hospital. Trial participants, healthcare providers, outcome assessors, data collectors and data analysts are not allowed to receive information about the group allocation.

Outcomes: The feasibility measures for this pilot study will be the recruitment and retention rates. These percentages will be used to improve the enrollment period and sample size calculation estimates for the main study. In addition, costs accrued during the pilot study will be analyzed to estimate future trial expenses. The primary outcome of the main study will be the presence of MU diagnosed within 6 months of surgery. The secondary outcomes of the main study will be the presence of MU diagnosed within 12 months of surgery and the presence of clinical upper gastrointestinal (GI) bleeding (i.e. episode of hematemesis, coffee-ground emesis or melena) within 12 months of surgery.

Timeline: The expected pilot study enrollment period is 5 to 7 weeks. The baseline patient characteristics and recruitment rate will be assessed during the preoperative visit. The retention rate and presence of upper GI bleeding will be assessed from routine clinic visits at 1, 3, 6, and 12 months along with hospital charting. The main study’s primary outcome will be assessed by an esophagogastroduodenoscopy (EGD) at 6 months following surgery or earlier if upper GI symptoms (i.e. epigastric pain, dyspepsia, dysphagia, emesis, or upper GI bleeding) are present. An additional EGD will be performed to evaluate any upper GI symptoms present 6 to 12 months following surgery.
C. Background

The ulcerogenic potential of gastric bypass procedures has been a longstanding concern for bariatric surgeons [1]. The jejunum, unlike the native duodenum, does not possess an innate acid buffer, which contributes to the development of marginal ulcers (MU) after the creation of a gastrojejunostomy [2]. A MU is defined as mucosal erosion adjacent to the gastrojejunal anastomosis, typically on the jejunal side and represents as many as 52% of postoperative complications following gastric bypasses [3]. The documented incidence of MU is quite variable, ranging from 0.6% to 16% [2,4]. However, the true incidence is likely higher than reported, since documented ulcers represent only those diagnosed on endoscopy and many may be treated medically based on symptoms without any endoscopic evaluation.

Bariatric patients diagnosed with MU typically present postoperatively with epigastric pain, emesis or upper gastrointestinal (GI) bleeding, which may be gross or occult [1]. However, 62% to 92% of patients with MU can remain asymptomatic and risk developing acute complications such as perforation and bleeding [5]. Accordingly, some authors have advocated routine upper endoscopy for all postoperative gastric bypass patients to rule out ulcer disease [4,6]. Interestingly, studies have shown a decreasing prevalence of MU with time from surgery [2]. The proportion of MU presenting by 6 and 12 months after surgery is 83% and 95%, respectively [7-8]. However, the incidence falls between 0.3% and 1% in patients followed for more than a year after surgery [4,9].

Risk Factors

Both operative and patient-related factors have been identified as two classes of risk factors for MU. Operative factors include gastric pouch size, anastomotic orientation, anastomotic tension and presence of foreign bodies (e.g. nonabsorbable sutures and staples). Better data exists for patient-related risk factors, which include diabetes, \textit{H. pylori} infection, chronic anticoagulation, smoking, alcohol use, nonsteroidal anti-inflammatory drug (NSAID) use and lack of proton pump inhibitor (PPI) prophylaxis [1-2,5,7]. These risk factors contribute to ulcer formation through several mechanisms such as mucosal disruption, ischemia, and increased gastric pouch acidity [7]. With respect to etiology, very early MU have been attributed mostly to technical problems at the gastrojejunostomy site, type of suture, inflammatory reaction, use of electrocautery, and local tissue injury [2, 4]. However, later ulcers have been associated more with excess acid, enlarged gastric pouch, NSAID use, \textit{H. pylori} infection, and staple line dehiscence [4,9].

Therapy and Prevention

Although proton pump inhibitor (PPI) therapy for MU is successful in 68% to 88% of cases, up to one third of patients eventually require surgical revision [2,5]. Even with successful revisional surgery, MU can recur in up to 8% of patients and pose a difficult problem for bariatric surgeons [5]. The challenge in treating intractable MU disease has prompted the use of several preventative strategies. Surgical techniques have been modified to reduce the risk of MU such as creating smaller gastric pouches, using absorbable sutures, and avoiding staples [7]. Other prophylactic measures include elimination of patient-related risk factors and inhibition of gastric acid secretion with postoperative PPI therapy [1].
Study Rationale

Bariatric surgeons are commonly using postoperative PPI therapy in order to decrease the risk of MU [10]. However, there is no high quality level of evidence demonstrating the effectiveness of PPI therapy and supporting current practice. In addition, the associated costs and potential adverse risk of lengthy PPI therapy has made some bariatric surgeons reluctant to prescribe PPI prophylaxis for their patients. Articles comparing prophylactic PPI therapy with placebo on the proportion of MU are scarce and a variety of regimens have been studied such as Omeprazole 20 mg daily for 30 or 60 days, H2-blockers for 90 days, Famotidine for 60 days and Lansoprazole for 30 days [6,10, 12-13]. A study by Gumbs et al. found a decreased proportion of MU associated with PPI use (p = 0.006), but only in a subgroup of patients with positive preoperative H. pylori serology [1]. Another study by Wilson et al. found that PPI therapy after LRYGB was associated with a 67% relative risk reduction (p = 0.04) of MU [7]. However, the clinical application of this finding is limited since this was a retrospective analysis of different PPI therapy at variable doses during the postoperative period [7]. Therefore, a prospective study is needed to determine whether PPI prophylaxis is truly an effective strategy for reducing the proportion of MU after gastric bypass.

Rationale for Assessing Feasibility

Implementation of a large, multi-center randomized controlled trial is a very resource-intensive undertaking that requires a high level of institutional organization. Therefore, a pilot study needs to be conducted initially to assess feasibility. The objective of this pilot study is primarily to provide estimates on the recruitment and retention rates of participants. Patients will be randomized in two arms and participate in the study protocol in order to provide preliminary data on the proportion of MU in both groups. These estimates will better inform the sample size calculation for the future multi-center trial. Provided there are no major changes with study protocol, the pilot data will be used in the main trial to increase efficiency. In addition, costs accrued during the pilot study will be analyzed to estimate future trial expenses.

Institutional Data

A recent survey of 13 bariatric surgeons at the University of Toronto Collaborative Bariatric Surgery Program found that 11 out of 13 surgeons (85%) prescribe postoperative PPI therapy. Of those who prescribe PPI therapy, 3 (27%) suggest it for 1 month and 8 (73%) for 6 months. A retrospective analysis of 212 patients that underwent LRYGB at Toronto Western Hospital between 2009 and 2011 was performed to evaluate the occurrence of MU. The results showed that only symptomatic patients were referred for EGD and that 19 patients (8.9% of study population) were diagnosed with MU all within their 1-year follow-up period. Twelve of the 129 (9.3%) who received prophylactic PPI therapy developed MU compared to 7 of the 83 patients (8.4%) in the control group (p = 0.829).
D. Objectives and Hypothesis

Feasibility Objectives (Pilot Study):
- To measure the recruitment rate
- To measure the retention rate
- To analyze costs accrued during the pilot study

Main Study Primary Objective:
- To compare the effect of postoperative daily oral pantoprazole therapy for 90 days versus placebo on the proportion of patients with MU diagnosed within 6 months following LRYGB.

Main Study Secondary Objectives:
- To compare the effect of postoperative daily oral pantoprazole therapy for 90 days versus placebo on the proportion of patients with MU diagnosed within 12 months following LRYGB.
- To compare the effect of postoperative daily oral pantoprazole therapy for 90 days versus placebo on the proportion of patients with clinical upper gastrointestinal bleeding (i.e. episode of hematemesis, coffee-ground emesis or melena) within 12 months following LRYGB.
- To evaluate the patient and operative variables associated with the development of MU in the overall study population.

Hypothesis:
- Postoperative daily oral pantoprazole therapy for 90 days is superior to placebo in reducing the proportion of MU within 6 months following LRYGB.
E. Methods

**Pilot Study Setting:** Bariatric program at the Toronto Western Hospital (TWH)

**Eligibility Criteria:**
Patients eligible for the study must comply with all of the following at randomization:

- Age ≥ 18 years
- Diagnosis of morbid obesity (body mass index ≥ 35)
- Treatment with laparoscopic Roux-en-Y gastric bypass

Exclusion criteria include the following:

- Allergy or intolerance to pantoprazole
- Proton Pump Inhibitor (PPI) use within 1 month of study enrollment
- History of peptic ulcer disease or gastritis
- Previous bariatric surgery
- Chronic use (> 1 month) of steroids, non-steroidal anti-inflammatories, or anticoagulants at study enrollment

**Intervention:** Patients will be randomized in equal proportions between pantoprazole and placebo, receiving either a once daily, oral dose (40 mg) of pantoprazole for 90 days starting on postoperative day (POD) one *or* daily oral placebo (identical in size, shape, and color) for 90 days starting on POD one. Pantoprazole was chosen since it is the PPI of choice at TWH. There is no Level I evidence to suggest one type of PPI is more effective than another. The research coordinator will administer an oral pantoprazole or placebo bottle to the patient while the patient is in hospital.

**Modifications:**

- **Adverse Events:** In the event of a diagnosed PPI side effect, the trial medication will be withdrawn after other causes have been ruled out. Study participants will be retained in the trial and analyzed using intention-to-treat.
- **Marginal Ulcers:** In the event of a diagnosed marginal ulcer, the trial medication will be withdrawn and the study participant will start on a 90-day course of oral pantoprazole and sucralfate suspension. An endoscopic evaluation will also be arranged at the end of the treatment course. An intention-to-treat analysis will be performed.

**Adherence:** A face-to-face adherence reminder session will take place during the initial product dispensing and at the 1-month follow-up clinic visit. The session will include:

1. The importance of following study guidelines and adherence
2. Instructions about how to take the study pill including dose, timing, storage and what to do in the event of a missed dose
3. Notification that pills in the bottle will be counted and recorded at the first two clinic visits (i.e. 1 and 3-month follow-up) to assess compliance
4. Reinforcement that study pills may be pantoprazole or placebo
5. Importance of calling the bariatric clinic if experiencing problems possibly related to study product such as symptoms or lost pills
6. Reminder to present to TWH for any Emergency Department visits
Outcomes:

Specific Feasibility Measures (Pilot Study):

- Recruitment rate to estimate enrollment period for the main study.
- Retention rate to guide the future follow-up protocol and sample size calculation. Reasons for dropout will also be explored.
- Study cost analysis to provide an accurate estimate of the total costs for the main study.

Primary Outcome of Main Study:

- Presence of MU within 6 months of surgery
  - Marginal ulceration will be defined as a mucosal break adjacent to the gastrojejunal anastomosis identified by EGD.
  - An adjudication committee consisting of two outside general surgeons will meet at 3-month intervals after the end of enrollment to review photographs of suspected MU to confirm the diagnosis.

Secondary Outcomes of Main Study:

- Presence of MU within 12 months of surgery (see above)
- Presence of clinical upper gastrointestinal (GI) bleeding (i.e. episode of hematemesis, coffee-ground emesis or melena) within 12 months of surgery

Timeline: At TWH, approximately 10 patients are consented for a LRYGB per week and operating rooms can accommodate up to 10 surgeries per week. Assuming an 80% to 100% recruitment rate, the pilot study enrollment-period should last 5 to 7 weeks. The baseline patient characteristics and recruitment rate will be assessed during the preoperative visit. The retention rate and presence of upper GI bleeding will be assessed from routine clinic visits at 1, 3, 6, and 12 months along with hospital charting. The main study’s primary outcome will be assessed by an esophagastroduodenoscopy (EGD) at 6 months following surgery or earlier if upper GI symptoms (i.e. epigastric pain, dyspepsia, dysphagia, emesis, or upper GI bleeding) are present. An additional EGD will be performed to identify MU if any upper GI symptoms are present 6 to 12 months following surgery.

Sample Size: The pilot study population will be limited to approximately 10% of the expected sample size \( (n = 50) \). This sample size will provide enough information with respect to recruitment and retention rates. Once the pilot study is completed, participating research personnel will have the logistical experience to conduct the larger, multi-center trial. The sample size calculation for that trial is described below:

The proportion of MU after gastric bypass ranges from 0.6% to as high as 16% [1-2]. However, these proportions likely underestimate the true frequency of MU since reports are usually based on exclusively symptomatic patients [12]. Therefore, the high end of this range (16%) will be used to estimate the proportion of MU for patients in the placebo group. A 50% relative risk reduction or minimal clinical difference of 8% in the proportion of MU between groups would be deemed clinically relevant. In order to reject the null hypothesis that the proportion of MU in both groups are equal with a power of \( 1-\beta = 0.80 \) and a level of statistical significance of \( \alpha = 0.05 \), 258 subjects will be required in both groups for a total of \( 2 \times 258 = 516 \). An uncorrected chi-squared statistic will be used to evaluate this null hypothesis. Based on the retention rate and outcome estimates from the pilot study, this sample size may be modified.
Recruitment: In the past, research projects conducted at the TWH Bariatric Program achieved enrollment rates near 100%. As well, the duration of the study is short and the follow-up protocol would be no different than routine post-operative care. Previously high enrollment rates have been attributed to the extensive and mandatory education patients receive preoperatively. Patients also receive thorough screening with the support of a psychiatric team and other ancillary staff to select highly motivated patients.

A research coordinator will interview eligible patients after their preoperative consultation with the surgeon. A verbal and written explanation of the study using clear and common language will be presented to the patient. Consent will be obtained only after the consent for surgery has been signed to avoid any sense of obligation. The consent form will also have prior Institutional Review Board approval. The risk of adverse effects and the option of voluntary withdrawal from the study will be emphasized in the consent form. The principal investigator, research coordinator and Ethics Board contact information will be provided to the participants in the consent form.

Allocation: Participants will be randomly assigned after surgery to either the control or experimental group with a 1:1 allocation as per a computer generated randomization schedule using permuted blocks of random sizes. The randomization list will be kept by an independent pharmacist.

Implementation: All consented patients that fulfill the inclusion criteria will be randomized. After the LRYGB has been completed, a member from the surgical team will request randomization from the research pharmacist. The corresponding treatment bottle will be given to the patient via the research coordinator the day after surgery. Bottles will be identical and labeled only by the study identification number. Trial participants, healthcare providers, outcome assessors, data collectors and data analysts will not be allowed to receive information about the group allocation.

Blinding: The patient, surgeon and research coordinator will all be blinded to treatment allocation. Both pantoprazole and placebo pills inside the bottle will be identical in size, shape and color. Unintentional concealment of study pills by the patient will be unlikely since pantoprazole has a low side effect profile. As well, any symptom relief in patients with prior reflux problems could be attributed to the surgery and not the study intervention.

The patient’s surgeon will be the assessor for both the primary and secondary outcomes. However, a blinded and independent adjudication committee will meet to confirm the endoscopic assessments. The research coordinator will input data on baseline patient characteristics, including relevant findings from clinic visits and endoscopy reports into a datasheet developed by the study statistician. The research pharmacist will create a separate datasheet consisting of all patient identification numbers and their corresponding group allocation in code. This will ensure the study statistician is blinded during the analysis.

Blinding will be broken only in exceptional circumstances when knowledge of the actual treatment is essential for further management of the patient. If unblinding is deemed necessary, the healthcare provider will directly contact the independent pharmacist.
**Data Collection & Management:** The research coordinator will be trained to collect relevant baseline patient characteristics, such as age, body mass index, smoking status, alcohol use, history of diabetes, history of reflux disease, operating surgeon and anastomotic technique. All patient charts will be reviewed to obtain relevant information from clinic visits (1, 3, 6 and 12 months) and endoscopy reports. Data will be entered into an electronic dataset and stored in a secure location. The patient’s surgeon will arrange an EGD at 6 months or earlier from surgery to evaluate for evidence of marginal ulceration. The surgeon will also arrange a diagnostic EGD for any patient with upper GI symptoms 6 to 12 months after surgery. Endoscopic photographs will be taken of suspected ulcers and sent to an adjudication committee to review and confirm the diagnosis at 3-month intervals. The research coordinator will be notified of all final decisions.

The research coordinator will directly contact study participants with missed appointments to improve follow-up. Reasons for missing data will be recorded for future reference. If there is a systematic reason for the missing data, this will be reported to the principal investigator and collection methods will be modified accordingly.

**Statistical Methods:** With respect to the pilot study, the recruitment rate will be calculated based on the number of consents obtained over the number of patients informed about the study. The retention rate will be calculated based on the number of patients with primary outcome data over the number of study participants. The total study cost will include all expenses related to the pilot study. A power analysis adjusted for the recruitment, retention and primary outcome rates in the pilot study will then be performed to modify the proposed sample size for the main study.

The intervention arm (pantoprazole) will be compared against the control (placebo) for all analyses. An “intention-to-treat” analysis will be performed to avoid selection and attrition bias. Therefore, all participants, regardless of protocol adherence will be analyzed based on their randomized allocation. Descriptive statistics will be computed and a chi-squared test will be used to compare categorical variables and a t-test to compare continuous variables. A relative risk (RR) with a corresponding 95% confidence interval will be calculated for both the primary and secondary outcomes. A secondary analysis will be performed to identify any predictors for the development of MU in the overall study population. A sensitivity analysis will also be conducted to assess the study results under different methods of handling missing data. For all tests, a 2-sided p-value with alpha <0.05 level of significance will be used. An up-to-date version of SAS (Cary, NC) will be used to conduct analyses.

**Data Monitoring:** An independent data monitoring committee (DMC) will be set up consisting of a data analyst and a general surgeon as a field expert. The priority of this committee is to ensure patient safety with respect to adverse events such as serious postoperative complications, reoperations, and mortality. The committee will meet before study enrollment to decide on operational roles.

An independent data analyst will review the data collected by the research coordinator and perform an interim analysis at 6 months from the end of enrollment. The analyst will then report to the DMC any suspicious or relevant findings. In the event of patient safety concerns, the DMC will have unblinded access to all data and immediately inform the study investigators and the institution’s central ethics committee.
# F. Budget Sheet

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G. References


H. Local/Institution Review Board

An application to the institutional review board was submitted on June 27, 2013 and has been approved in principle. It is understood that documented IRB approval must be provided prior to obtaining funding.
I. Available Resources

Participating sites for the future multi-center trial will include five academic hospitals affiliated with the University of Toronto Collaborative Bariatric Program. A total of 16 bariatric surgeons operate on approximately 1500 patients annually. An average of 20 patients visit the TWH Bariatric Program every two weeks and an average of 8 to 10 bariatric operations are performed every week. The comprehensive psychosocial program consists of five surgeons, three nurse practitioners, one clinical nurse specialist, three social workers, two psychiatrists, three psychologists, four dieticians, one nurse manager, one data entry clerk and one data manager.

There is an established investigational pharmacy available at TWH, which is fully staffed with pharmacists and capable of administering study drug and placebo bottles. Baseline costs for pharmacy participation and pharmaceutical services have been included in the attached budget.

The Temerty/Chang International Centre for Telesimulation and Innovation in Medical Education will act as a dedicated laboratory space, providing the necessary work-space and resources to complete data storage and analysis. It is a dedicated lab with two full-time research coordinators, one full-time data analyst and two research fellows.
J. Curriculum Vitae

Co-Principal Investigator: Timothy Jackson

BIOGRAPHICAL SKETCH

<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION TITLE</th>
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<tbody>
<tr>
<td>Timothy Jackson</td>
<td>General Surgeon, Department of Surgery, University Health Network</td>
</tr>
<tr>
<td></td>
<td>Assistant Professor, Department of Surgery, University of Toronto</td>
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EDUCATION/TRAINING  (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

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<td>Harvard Medical School, Massachusetts General</td>
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<td>Minimally Invasive Surgery</td>
</tr>
<tr>
<td>Hospital Advanced Laparoscopic Surgery Fellowship, Boston, MA, USA</td>
<td>06/10</td>
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A. PERSONAL STATEMENT

My research interest is in surgical education and outcomes with a focus on minimally invasive and bariatric surgery.

B. POSITIONS AND HONORS

Hospital:
July 1, 2009-June 30, 2010: Assistant in Surgery, Massachusetts General Hospital, Boston, MA

July 1, 2010-present: Staff Surgeon, University Health Network, Toronto Western Hospital, Toronto, ON

January 1, 2011-present: Surgeon Champion, ACS-NSQIP Program, University Health Network, Toronto, ON
University:
July 1, 2009-June 30, 2010: Clinical Instructor, Harvard University, Boston, MA
July 1, 2009-present: Assistant Professor, Department of Surgery, University of Toronto, ON
July 1, 2010-present: Adjunct Research Fellow, Codman Center for Clinical Effectiveness in Surgery, Massachusetts General Hospital, Boston, MA

Other Experience and Professional Memberships:
2007-2008 McMaster University, Co-Liaison, Residence and Associate Society of American College of Surgeons
2008-2009 Laparoscopy Committee Resident Representative, Canadian Association of General Surgeons
2010-2011 Medical Director, Bariatric Surgery Program, University Health Network
2010-2011 Bariatric Liaison and Research Committee Member, Society of American Gastrointestinal and Endoscopic Surgeons
2011 Surgical Oncologist Search Committee Member, University of Toronto
2011-2012 Communications Committee Member, American Society of Bariatric and Metabolic Surgeons
2011-2012 Member, American College of Surgeons Bariatric Advisory Committee
2012 Update in General Surgery 2013 Planning Committee Member
2010-present Co-Chair, Bariatric Surgery Research Committee, University of Toronto
2012-present Committee on Metabolic and Bariatric Surgery – Division of Patient Safety and Optimal Patient Care and Accreditation and Quality Improvement Program, American College of Surgeons
2012-present Governing Council Member, Young Fellows Association of the American College of Surgeons
2012-present Board of Directors, Ontario Association of General Surgeons

Awards and Honors:
Society of American Gastrointestinal and Endoscopic Surgeons, Career Development Award 2010
Canadian Association of General Surgeons/Covidien Teaching Excellence Award 2008 & 2009
McMaster University, General Surgery Resident Research Award 2006 & 2007
Margaret and Charles Juravinski Surgical Research Fellowship 2005 - 2006
Canadian Institutes of Health Research, Professional Student Research Award 2002 - 2003
Heart and Stroke Foundation of Ontario Medical Student Research Scholarship 2002 - 2003
Canadian Association of Gastroenterology Research Initiative Award 1997 & 1999
Crohn’s and Colitis Foundation of Canada Summer Student Scholarship 1998
The McMaster University Governors’ Scholarship 1996 - 1999
Carter Scholarship & Elliot Memorial Scholarships 1996
C. SELECTED PEER-REVIEW PUBLICATIONS:


**D. RESEARCH SUPPORT:**


4. Implementation of a Comprehensive Surgical Quality Improvement Program into an Ontario Academic Hospital. **Jackson TD**, Urbach DR, Rotstein L, Okrainec AO: Academic Health Sciences Centre Alternate Funding Plan Innovation Fund. ($200,000 2011-2013)


Co-Principal Investigator: Dr. Allan Okrainec

BIOGRAPHICAL SKETCH

NAME
Allan Okrainec, MD, MHPE, FRCSC, FACS

eRA COMMONS USER NAME (credential, e.g., agency login)

POSITION TITLE
General Surgeon, Department of Surgery, University Health Network
Assistant Professor, Department of Surgery, University of Toronto

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>MM/YY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>McGill University, Montreal, Quebec</td>
<td>MD</td>
<td>06/00</td>
<td>Medicine</td>
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<tr>
<td>McMaster University, Hamilton, Ontario</td>
<td>FRCSC</td>
<td>06/05</td>
<td>General Surgery</td>
</tr>
<tr>
<td>McGill University, Montreal, Quebec</td>
<td>Fellowship</td>
<td>06/06</td>
<td>MIS</td>
</tr>
<tr>
<td>University of Illinois at Chicago, Chicago, IL</td>
<td>MHPE</td>
<td>06/09</td>
<td>Med Education</td>
</tr>
</tbody>
</table>

A. PERSONAL STATEMENT

My research interest is in surgical education and outcomes with a focus on minimally invasive and bariatric surgery.

B. POSITIONS AND AWARDS

Hospital:
Apr 2009-present: Deputy Head, Division of General Surgery, University Health Network

July 2006-present: Staff Surgeon, University Health Network, Toronto Western Hospital, Toronto, ON

Apr 2009-present: Site Head, Division of General Surgery, Toronto Western Hospital, Toronto, ON

Apr 2011-present: Director, Temerty/Chang Telesimulation Centre, Toronto Western Hospital, Toronto

University:
July 2010-present: Director, Minimally Invasive Surgery Fellowship Program, University of Toronto, Toronto, ON

July 2010-present: Academic Director, University of Toronto Collaborative Bariatric Surgery Program, Toronto, ON
July 2009-present: Assistant Professor, Department of Surgery, University of Toronto, ON

July 2005-June 2009: Lecturer, Department of Surgery, University of Toronto, Toronto, ON

Oct 2007-present: Clinician Educator Researcher, The Wilson Centre for Research in Education, Faculty of Medicine, University of Toronto, Toronto, ON

Awards and Honors:
2009: **Ross Fleming Surgical Educator Award**, University Health Network, Toronto, ON
2009: **Winner Best paper**, University of Illinois at Chicago, Annual conference
2007: **Frank Mills Award for Excellence in Teaching by a General Surgery Faculty Member**
University Health Network, Toronto, (ON)

C. SELECTED PEER-REVIEWED PUBLICATIONS:


**D. RESEARCH SUPPORT ($462, 285 total as PI, $5,110,940 as collaborator)**


Co-Investigator: Dr. Ahmad Elnahas

**BIOGRAPHICAL SKETCH**

<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmad Elnahas</td>
<td>Minimally Invasive Surgery Fellow, Department of Surgery, University Health Network</td>
</tr>
</tbody>
</table>

eRA COMMONS USER NAME (credential, e.g., agency login)

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

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<th>FIELD OF STUDY</th>
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<tbody>
<tr>
<td>McMaster University, Hamilton, Ontario</td>
<td>BHSc</td>
<td>06/05</td>
<td>Health Sciences</td>
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<tr>
<td>McMaster University, Hamilton, Ontario</td>
<td>MD</td>
<td>06/08</td>
<td>Medicine</td>
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<td>McMaster University, Hamilton, Ontario</td>
<td>FRCSC</td>
<td>06/13</td>
<td>General Surgery</td>
</tr>
<tr>
<td>University of Toronto, Toronto, Ontario</td>
<td>MSc (candidate)</td>
<td>N/A</td>
<td>Clinical Epidemiology</td>
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</table>

A. PERSONAL STATEMENT

I am currently a minimally invasive surgery research fellow and completing my Master’s degree in the clinical epidemiology program at the University of Toronto. I will use my knowledge of biostatistics and clinical trial methodology to assist with the data analysis as well as study protocol.

B. POSITIONS AND AWARDS

Employment:
July 2013-Present: Minimally Invasive Surgery Fellow, University of Toronto

Professional Memberships:
Ontario Medical Association (OMA)
Canadian Medical Association (CMA)
Canadian Association of General Surgeons (CAGS)
Ontario Association of General Surgeons (OAGS)
Awards and Scholarships:
2005 Dean’s Honour List
2004 McMaster University Entrance Honour Award
2004 Health Sciences Summer Research Scholarship
2004 University Senate Scholarship
2002 Governor's General Academic Medal
2002 Rotary Club of Hamilton Award

C. SELECTED PEER-REVIEWED PUBLICATIONS


Co-Investigator: Dr. Fady Saleh

BIOGRAPHICAL SKETCH

NAME
Fady Saleh

POSITION TITLE
Minimally Invasive Surgery Fellow, Department of Surgery, University Health Network

eRA COMMONS USER NAME (credential, e.g., agency login)

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

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<tbody>
<tr>
<td>York University, Toronto, Ontario</td>
<td>BSc</td>
<td>05/01</td>
<td>Applied Mathematics</td>
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<tr>
<td>University of Toronto, Toronto, Ontario</td>
<td>MD</td>
<td>06/05</td>
<td>Medicine</td>
</tr>
<tr>
<td>Harvard University, Boston, Massachusetts</td>
<td>MPH</td>
<td>06/08</td>
<td>Public Health</td>
</tr>
<tr>
<td>McMaster University, Hamilton, Ontario</td>
<td>FRCSC</td>
<td>06/10</td>
<td>General Surgery</td>
</tr>
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</table>

A. PERSONAL STATEMENT

With a background of a Masters of Public Health from Harvard School of Public Health, I have the qualifications to contribute to this project as a co-investigator. Having had specific training in conducting randomized controlled trials during my studies, I feel prepared to contribute to the design and conduct of this trial.

B. POSITIONS AND AWARDS

Employment:
July 2013-Present: Minimally Invasive Surgery Fellow, University of Toronto

June 2012-June 2013: General Surgery Research Associate, Toronto Western Hospital, University Health Network, Toronto, Ontario

Mar 2012-Aug 2012: General Surgery Locum, Oakville Trafalgar Hospital, Oakville, Ontario
Aug 2010-Dec 2012: General Surgery Locum, Winchester District Memorial Hospital, Winchester, Ontario

Sep 2010-Jan 2012: General Surgery Locum, Cornwall Community Hospital, Cornwall, Ontario
Jan 2011-Sep 2011: General Surgery Locum, Headwaters Health Care, Orangeville, Ontario
Sep 2011-Oct 2011: General Surgery Locum, Qikiqtani General Hospital, Iqaluit, Nunavut

**Professional Memberships:**
- 2010 – present: Member, Ontario Medical Association (OMA)
- 2010 – present: Member, Canadian Medical Association (CMA)
- 2005 – present: Member, Canadian Association of General Surgeons (CAGS)
- 2005 – present: Member, Ontario Association of General Surgeons (OAGS)

**Awards and Scholarships:**
- 2007: Harvard School of Public Health Admission Scholarship, Harvard University
- 2003: Faculty of Medicine Summer Research Scholarship, Faculty of Medicine, University of Toronto
- 2001: Alice Turner Award for Academic Achievement, Faculty of Applied Science, York University
- 2001: Chair’s Honour Roll, Faculty of Applied Science, York University
- 2001: Natural Sciences and Engineering Research Council Research Scholarship, Faculty of Applied Science, York University
- 2000: Natural Sciences and Engineering Research Council Research Scholarship, Faculty of Applied Science, York University
- 1998-2000: Continuing Students Scholarship, Faculty of Applied Science, York University
- 1999: Faculty of Applied Science Student Scholarship, Faculty of Applied Science, York University
- 1998: Entrance Scholarship, Faculty of Applied Science, York University

C. SELECTED PEER-REVIEWED PUBLICATIONS

NAME
Jane Lui

POSITION TITLE
Pharmacist, Investigational Pharmacy Services

eRA COMMONS USER NAME (credential, e.g., agency login)

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

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</thead>
<tbody>
<tr>
<td>University of Toronto, Toronto, Ontario</td>
<td>BSc</td>
<td>06/03</td>
<td>Toxicology</td>
</tr>
<tr>
<td>University of Toronto, Toronto, Ontario</td>
<td>BPharm</td>
<td>06/07</td>
<td>Pharmacy</td>
</tr>
</tbody>
</table>

A. PERSONAL STATEMENT

As a pharmacist at the investigational pharmacy services at Toronto Western Hospital, University Health Network, I have experience in coordinating, collaborating and providing expertise in support of clinical investigational drug trials. I can provide the appropriate guidance for this pilot clinical trial. I would act as a liaison between the study team and the pharmacy, briefing the pharmaceutical team on the study. I provide accurate and efficient dispensing of medication. I would be the primary contact if there are any concerns with the use of the PPI in this study.

B. POSITIONS AND AWARDS

April 2012-Present  Pharmacist, Investigational Pharmacy Services
Sept 2007-April 2012  Clinical Pharmacist, Cardiology
Aug 2008- Present  Part-time Pharmacist
K. Participation in SAGES

Timothy Jackson

Submitted SAGES Abstracts

1. Is next-day discharge following laparoscopic Roux-en-Y gastric bypass safe in select patients? Analysis of short-term outcomes. Ahmad Elnahas, David Urbach, Allan Okrainec, Fayez Quereshy, **Timothy D Jackson**

2. Is Bariatric Surgery Safe in Patients with Cirrhosis? An Analysis of Short-Term Outcomes. Andrew Smith, Ahmad Elnahas, Allan Okrainec, Fayez Quereshy, **Timothy Jackson**

Peer Reviewed Papers Read at SAGES Meetings


4. Wannaes JJ, **Jackson TD**, Lancaster RT, & Hutter MM. Does a Fellow’s involvement in advanced laparoscopic procedures improve outcomes? *(submitted to Surgical Endoscopy).*


Oral Presentations at SAGES Meetings


Poster Presentations at SAGES Meetings

1. Wannaes JJ, **Jackson TD**, Lancaster RT, & Hutter MM. Does a Fellow’s involvement in advanced laparoscopic procedures improve outcomes? *(submitted to Surgical Endoscopy).*

**Committees**
1. SAGES Research and Career Development Committee 2010
2. SAGES Bariatric Liaison Committee 2010

**SAGES Grant**

**Allan Okrainec**

**Submitted SAGES Abstracts**

2. Defining the Learning Curve: Early Experience of Laparoscopic Roux-En-Y Gastric Bypass from a Bariatric Centre of Excellence. Andrew Smith, Ahmad Elnahas, Timothy Jackson, Fayez Quereshy, Todd Penner, David Urbach, **Allan Okrainec**

**Peer Reviewed Papers Read at SAGES**


Poster Presentations


6. Orzech N, Palter V, Aggarwal R, Okrainec A, Grantcharov T: Assessment of intracorporeal suturing skills - a comparison of four tools using the FLS task model. Surgical Association of Gastrointestinal and Endoscopic Surgeons – Annual Meeting,


Invited Visits at SAGES Annual Meetings


Committees
1. SAGES Board Member 2013 - present
2. SAGES leadership retreat 2007, 2009, 2010
3. Co-chair Conflict of Interest Task Force: 2009 - present
5. Fundamentals of Laparoscopic Surgery committee. 2007 – present
6. Go Global committee. 2008 - present
7. International Relations Committee. 2008 – present
9. SAGES Internet Task Force. 2007 – present

Previous SAGES Grant
   Project update: Study completed, results published in Surgical Endoscopy, 2010

   Project update: Study completed, results submitted to SAGES Meeting 2012

International FLS Courses
1. FLS course coordinator: Botswana, Africa: 2007
2. FLS course instructor: Ghana, Africa: 2008
3. FLS course coordinator: Colombia: 2008
5. FLS course coordinator: Jamaica: 2009
6. FLS course coordinator: Guyana: 2009
7. FLS course coordinator: Hungary 2009
8. FLS course coordinator: Rwanda 2010
9. FLS course coordinator: China 2010
10. FLS course coordinator: Ghana 2010
11. FLS course coordinator: Ethiopia 2011
12. FLS course coordinator: Ukraine 2011
Ahmad Elnahas

Submitted SAGES abstract

1. Is next-day discharge following laparoscopic Roux-en-Y gastric bypass safe in select patients? Analysis of short-term outcomes. Ahmad Elnahas, David Urbach, Allan Okrainec, Fayez Quereshy, Timothy D Jackson

Peer Reviewed Papers Read at SAGES Meetings


Oral Presentations at SAGES Meetings