Achalasia Treated with Laparoscopic Heller Myotomy and Fundoplication: Predictors of Postoperative Dysphagia
Statement of Funds

There are no pending external funds for this project. The University of Kentucky Department of Surgery will cover salary costs for Dr. Roth.
Achalasia is an idiopathic primary motility disorder of the esophagus, believed to be associated with infectious and/or autoimmune factors [1] Dysphagia with both solids and liquids, regurgitation, and chest pain are the most common symptoms of achalasia, and while available therapies do not change the underlying pathology of the disease, symptom palliation is possible [2]. Diagnosis of achalasia is suspected based upon clinical symptoms, barium radiographs and endoscopy, while the gold-standard for diagnosis is high resolution esophageal manometry (HRM). Essential features of the disease noted on barium esophagram are: “bird’s beak” appearance of the lower esophageal sphincter (LES) with incomplete opening, loss of primary peristalsis, and delayed esophageal emptying [1]. Characteristic features of achalasia from manometry include: aperistalsis of the esophageal body and incomplete or absent LES relaxation, with hypertensive LES pressure and low amplitude esophageal contractions providing additional supporting diagnostic information [1]. A systematic approach to evaluating esophageal motility based on HRM topographic plotting [3] has provided a classification system for achalasia pointing to three specific patterns of aperistalsis [4].

Surgical and non-surgical therapies for achalasia are available. Currently, cardiomyotomy via the laparoscopic approach is considered the gold standard of treatment. Symptom improvement following laparoscopic myotomy is thought to occur in as many as 89% of patients [5]. However, persistence or recurrence of dysphagia following laparoscopic myotomy with fundoplication creates a challenging situation for surgeon and patient alike. While response to treatment based on the different achalasia classifications has been described, how the various parameters attained across the preoperative workup, individually and in combination, affect clinical outcomes, specifically persistence or recurrence of dysphagia, is not understood and may allow improved treatment decision making.

The purpose of the proposed study is to review patient response to laparoscopic myotomy with fundoplication based on each parameter obtained from preoperative workup: manometry, upper endoscopy, and barium esophagram. This study will be accomplished by conducting a retrospective medical record review of all patients that underwent laparoscopic Heller myotomy with Dor or Toupet fundoplication by one surgeon over a seven year time period at our institution and combining that data with long-term follow up review of patient symptoms. The follow up data will be obtained by conducting a telephone survey with patients that are at least 12 months postoperative. The relationship between the long-term follow up survey responses and the specific findings from the individual patients’ preoperative workup will be measured in order to determine the relationship of each preoperative testing parameter on long-term postoperative symptoms. Information to be obtained from the medical record review will include patient demographics, medical and surgical history, prior treatment modalities, and the preoperative testing parameters. The telephone survey will be conducted to presence of absence of current symptoms, timing of onset of symptoms (in postoperative setting), any treatment or testing procedures since surgery, and time frame since surgery. This study is intended to provide preliminary data which would be used to substantiate a future multicenter prospective trial the aim of which would be to develop a predictive model of response to laparoscopic Heller myotomy with fundoplication based on each preoperative testing modality.
Background

1. The Problem
Achalasia, an idiopathic primary motility disorder of the esophagus, is characterized by absence of esophageal peristalsis and incomplete relaxation of the lower esophageal sphincter (LES) with swallowing [2]. Although not fully understood, the etiology of achalasia is thought to involve an autoimmune response to an unknown insult in genetically susceptible individuals [6]. Classic symptoms are dysphagia to solids and liquids with regurgitation of undigested food or saliva [1].

Diagnosis of achalasia is suspected based upon clinical symptoms, barium radiographs and esophagogastroduodenoscopy (EGD), while the gold-standard for diagnosis is high resolution esophageal manometry (HRM). Essential features of the disease noted on barium esophagram include: “bird’s beak” appearance of the lower esophageal sphincter (LES) with incomplete opening, loss of primary peristalsis, and delayed esophageal emptying. Also, dysmotility, spasm, dilated or sigmoid-like esophagus, and epiphrenic diverticula may be noted on barium esophagram, providing support for the diagnosis [1]. Essential features of achalasia from HRM include: aperistalsis of the esophageal body and incomplete or absent LES relaxation, with hypertensive LES pressure. Low amplitude esophageal contractions provide additional supporting information [1]. Three patterns of achalasia have been described from a systematic evaluation of HRM findings based on topographic plotting [4]. EGD is performed to rule out carcinoma simulating achalasia and short peptic strictures [7]. The most frequently noted features found on EGD with achalasia include: a patulous esophageal body with a tight LES that will not open with air insufflation, but opens relatively easily with gentle pressure of the endoscope against the GE junction [7].

Treatment does not change the underlying pathology of the disease, but allows palliation of symptoms. Non-surgical treatments include pharmacologic therapies and pneumatic esophageal dilation. Botulinum toxin injection is associated with high response rates at one month post-therapy, but the effect is known to wear off requiring repeat injection. Multiple injections have been shown to create an inflammatory reaction that may obscure the mucosal plane perhaps increasing the difficulty in subsequent surgical myotomy [1]. Pneumatic dilation is thought to be most effective for patients greater than 45 years old, females, narrow esophagus before dilation, and LES pressure after dilation < 10mm Hg [8].

Surgical treatment of achalasia includes cardiomyotomy achieved most frequently by laparoscopy. Laparoscopic Heller myotomy with fundoplication is associated with improvement of symptoms in as many as 89% of patients [5]; however, the resolution of symptoms is thought to decrease over the long-term [9]. Success of laparoscopic myotomy with fundoplication is thought to be dependent on severity of disease. Surgical morbidity, such as esophageal perforation, may be associated previous endoscopic treatment [10]. POEM, an endoscopic surgical treatment, was first described in 2008, [11], and has demonstrated durable symptomatic relief with a low rate of complications [12]; however, POEM is an evolving technology, and long-term postoperative reflux rates are not known as yet.

Although it is intuitive that increased disease severity may be associated with incomplete or lack of response to surgical treatment, and response to therapy based on manometric classification of
the disease has been reported, the specific parameters from all preoperative testing modalities, or groupings of parameters, that may be linked to persistence or recurrence of symptoms in the long-term are not fully understood.

2. Significance of the Problem
The incidence of achalasia is one in 100,000 individuals per year with a prevalence of ten in 100,000 [1]. Men and women are affected equally by the disease, and there is no racial partiality [5]. Using the National Inpatient Sample (NIS) to estimate the number of laparoscopic Heller myotomies performed in the United States from 1993-2005, Wang et al. reported a two-fold increase across the time period [13]. In 2005, it was estimated that 2,255 Heller myotomies were performed in the U.S., and shorter length of stay was noted at hospitals with increased number of procedures performed [13]. While long-term outcomes after surgical treatment are good, an estimated 10% to 20% of patients have persistence or recurrence of symptoms [14].

3. Prior Studies
Classification of achalasia into three subtypes based on HRM was reported in 2008 [4]. Type I is associated with lower basal LES pressure and diminished axial LES proximal movement after swallowing compared to the other two subtypes and is considered the classic definition of achalasia [4]. Type I patients have predominance of failed swallows. Type II is associated with significantly greater esophagogastric (EGJ) junction relaxation pressure compared with Type I. Type II patients experienced more swallows associated with compression. Type III patients have a dominant swallow pattern of spastic contraction. Based on the different variables, the authors compared treatment response and found Type II to be most predictive of positive treatment response and type III to be associated with negative treatment response [4].

In order to identify factors associated with success of pneumatic dilation for achalasia, Yamashita et al., evaluated specific manometry and clinical parameters at six and 12 months following pneumatic dilation therapy [15]. These authors found that older patients (47.1 years vs. 37.0 years) and residual LES pressures less than 15 mm Hg at six months post-procedure were most predictive of effective treatment [15].

While most studies concerning achalasia focus on LES pressures, the clinical implications of upper esophageal sphincter (UES) abnormalities in achalasia recently were evaluated [16]. In this retrospective review of 41 patients with achalasia, of the patients with UES abnormality (58.5%), nearly nine in ten patients reported poor treatment response; whereas fewer than 25% of patients without UES abnormality were noted to have poor response to treatment [16].

4. Preliminary Data
Previously at our institution a survey was conducted to follow up with patients having been treated with laparoscopic myotomy with partial fundoplication (n = 24), laparoscopic myotomy without fundoplication (n = 2), transthoracic myotomy with fundoplication (n = 1), transthoracic myotomy without fundoplication (n = 2) and open myotomy with fundoplication (n = 1) [17]. Across the different procedures, mean time to recurrence of mild dysphagia was found to be 21.3 months (SD = 5.8 months). Although improvement of symptoms was noted and patients reported enhanced well-being, specific preoperative parameters of any patient that reported recurrence of symptoms were not delineated [17].
**Hypothesis**

We hypothesize that clinical, manometric, endoscopic, and barium radiographic parameters, such as patient age, evidence of spastic swallows from both manometry and barium esophagram, previous treatment with botulinum toxin, previous treatment with pneumatic dilation, time of onset of symptoms to surgical treatment, individually or in combination, will demonstrate an association with persistence or recurrence of dysphagia.

To explore this hypothesis, the specific aim of the study is:

To compare patient and preoperative test variables with presence and severity of postoperative dysphagia, persistent or recurrent.

This study is exploratory, not confirmatory, in order to generate potential predictors of poor outcomes to be confirmed in a later multi-center trial.
Methods

This study will be a comparison of preoperative clinical and testing variables with long-term persistence or recurrence of symptoms for all patients that underwent laparoscopic Heller myotomy with fundoplication at the University of Kentucky (UK) healthcare system by one surgeon from January 1, 2009, through December 31, 2015. The project will consist of two phases, a retrospective review of medical records and a prospective telephone survey. The objective of the study is to identify preoperative variables most strongly associated with persistence or recurrence of symptoms in order to understand association of specific variables to treatment response.

Study Population:

We estimate that approximately 70 patients have undergone laparoscopic Heller myotomy with fundoplication (CPT code 43279) at the UK hospitals during the seven-year time period. The approximate average age of patients who would undergo these procedures is 50 years, with an approximately equal male to female ratio. This is an estimated number of cases from the time period described.

Study Design:

This is a two-phased study:

1) In order to identify potential cases, a review of the departmental surgical databases to identify patients that underwent laparoscopic Heller myotomy with fundoplication (CPT code 43279) within the UK healthcare system during the time period described will occur. Once the cases have been identified a retrospective review of existing electronic medical records will be done to obtain specific patient information for each patient.

2) As we are interested in understanding the long-term response to therapy, a prospective follow up telephone survey of patients identified from the database review will be conducted to discern patients’ current symptoms, severity of symptoms, timing of onset of symptoms (in postoperative setting), any treatment or testing procedures since surgery, and time frame since surgery.

Research Procedures:

A review of surgical databases will identify all patients that underwent laparoscopic Heller myotomy at our institution from January 1, 2009, through December 31, 2015. Once the cases are identified, from the medical record review we are interested in obtaining the following information from the medical records review: the specific procedure performed (CPT code(s)), type of fundoplication, length of hospitalization, surgical complications, hospital readmission, American Society of Anesthesiologists’ classification, comorbidity status, age, age at symptom onset, age at diagnosis, gender, body mass index, prior treatment modalities, duration of operative procedure in minutes. The following information will be recorded from the manometry report: basal LES and UES pressures, residual LES and UES pressures, distal wave amplitude,
percent peristaltic, simultaneous, and failed swallows, number of swallows evaluated, mean wave amplitude, Chicago classification.

Data to be obtained from preoperative barium esophagram report: presence or absence of: spasm, dilation of esophagus, bird’s beak appearance of the LES, dysmotility, and other notations of pertinence. From the preoperative EGD, evidence of patulous esophageal body, tight LES that opens with gentle pressure of the endoscope against the GE junction, and other notations of pertinence will be documented.

The second phase of the project will consist of a prospective telephone survey of patients that were identified in Phase One (patients that underwent laparoscopic Heller myotomy with fundoplication). The primary purpose of the telephone survey is to obtain information concerning current symptoms and severity. Also, patients will be queried as to care they have obtained for achalasia since surgical treatment. The data obtained from the two sources will be combined for analysis purposes.

Data Management: Data will be extracted from the medical record and entered directly into a password-secured and backed-up Research Electronic Data Capture (RedCAP) database designed for the study. RedCAP is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources [18]. Blinded data only will be extracted for the statistician to analyze. Data will be preserved for 7 years after the completion of the study, after which it will be deleted.

Statistical Analysis: Kaplan-Meier “survival” tables will be used to analyze the outcome recurrence of symptoms. Univariate log-rank tests will be performed to identify clinical variables influencing time to recurrence. For the outcome of symptom persistence, logistic regression models will be used to identify clinical variables influencing failure of the procedure to alleviate symptoms. The analysis is exploratory, factors predictive of either outcome at p < .25 will be noted and used for sample size calculations for the planned multicenter trial. All analyses will be performed with SPSS statistical software version 23 (IBM Corp., Armonk NY).

In this study we are seeking to generate hypotheses regarding risk factors not confirm hypotheses. Therefore; as it is an exploratory study, a power analysis is not appropriate.

Pitfalls: As the conduct of this study is based on retrospective review of existing medical records and telephone survey of patients, potential difficulties would include incomplete past medical records or out of date contact information for patients. Our research team has successfully completed projects with similar study design, and we are confident that we will have success with this patient population also.
## Budget

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<td>2. Margaret Plymale</td>
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<td>4. Daniel Davenport</td>
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<td>5. James T. Lee</td>
<td>Collaborator with no significant effort</td>
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**CONSULTANT COSTS**

| Items:                   |                                              |             |         |                 |             |

**SUPPLIES**

| Items: Office supplies   |                                              |             |         |                 |             |

**TRAVEL**

| Travel to SAGES meeting to present study findings |                                              |             |         | 1,000          |             |

**PATIENT CARE COSTS**

|                                              |                                              |             |         |                 |             |

**CONSORTIUM/CONTRACTUAL COSTS**

|                                              |                                              |             |         |                 |             |

**OTHER EXPENSES**

| Items                                      |                                              |             |         |                 |             |

**TOTAL DIRECT COSTS**

|                                              |                                              |             |         | 14,080          |             |
Budget Justification

The budget for this study will consist primarily of salary support for the co-investigator and the data coordinator. We are requesting salary support as the study will require considerable time for a data collection and telephone surveys, both of which will be completed by these two individuals.

Personnel

John Scott Roth, MD, FACS, Principal Investigator (2% effort): Dr. Roth, in his role as Principal Investigator and as the clinical expert for the study, has been responsible for study conception and will provide oversight across the conduct of the study. He will meet with the co-investigator and data coordinator on a bi-weekly basis to review study progress and will be available to answer questions. He will provide assistance with abstract and manuscript development and with clinical interpretation of study findings.

Margaret Plymale, DNP, RN, Co-Investigator (5% effort): Dr. Plymale will review surgical databases to identify potential cases for inclusion in the study. She will train and oversee the work of the data coordinator, be available for questions, and review all data collected and entered for accuracy. She will be primarily responsible for reporting findings through communication as requested with funding source, abstract and manuscript development.

TBD Data Coordinator: Once trained, the data coordinator will be responsible for developing spreadsheets, to the biostatistician’s approval, abstracting existing information from medical records for the retrospective review phase of the study, and conducting telephone calls for follow up portion of the study. An estimated 90-120 minutes will be required to abstract the data from the various electronic records for each case, and it is anticipated that a minimum of 70 cases for which data will need to be recorded will be identified. Data will be recorded with oversight for accuracy with both the collection and entry of data to electronic format. The second phase of the study, a prospective telephone survey, will require an estimated 60-90 minutes per case.

Daniel Davenport, PhD, MBA: Biostatistician (2% effort): Dr. Davenport has participated in study design and will provide statistical support. He will advise the co-investigator and data coordinator in best method of spreadsheet/data management in order to ease data analysis procedures. He will assist with reporting of findings and will be involved in development of future plans for prospective trial based on findings of the current study.

James T. Lee, MD: Collaborator with no significant effort: Dr. Lee, a radiologist, will collaborate with Dr. Roth and Dr. Plymale to develop a profile/checklist of findings to note from barium esophagram studies for this patient population. He will participate in review of the preoperative studies to note findings.

Travel: $1000 to travel to the annual SAGES meeting to present study findings.
References


Local/Institution Review Board

IRB approval is pending at time of proposal submission.
Available Resources

Office space with desktop computers are available to all study personnel. Microsoft Office software is available for all study personnel, and statistical software (SPSS) is available to the study biostatistician.
NAME: Roth, John Scott

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

POSITION TITLE: Professor of Surgery

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

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<th>INSTITUTION AND LOCATION</th>
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<th>Completion Date MM/YYYY</th>
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<td>College of William and Mary; Williamsburg, VA</td>
<td>B.S.</td>
<td>06/1989</td>
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<td>Medical College of Virginia, Va. Commonwealth University; Richmond, VA</td>
<td>M.D.</td>
<td>05/1993</td>
<td>Medicine</td>
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<td>University of Kentucky; Lexington, KY</td>
<td>Intern &amp; Resident</td>
<td>06/1998</td>
<td>General Surgery</td>
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<tr>
<td>University of Kentucky; Lexington, KY</td>
<td>Fellowship</td>
<td>06/1999</td>
<td>Minimally Invasive Surgery</td>
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A. Personal Statement
I am both the Chief of the Gastrointestinal Surgery Section and the Director of the Center for Advanced Training and Simulation. I specialize in advanced laparoscopic surgery with a focus in the areas of foregut surgery (hiatal and diaphragmatic hernias, gastroesophageal reflux (GERD), achalasia, gastric tumors) and abdominal hernias (ventral, incisional and inguinal hernias), abdominal wall reconstruction (endoscopic and posterior component separation) and solid organ surgery (spleen, adrenal, and pancreas). I am a nationally recognized leader in minimally invasive surgery. I have the specific clinical training and expertise in abdominal surgery, laparoscopic repair, and minimally invasive surgery, as well as the research experience in pre-clinical trials required for the proposed project. We have assembled an outstanding research team with the combined expertise and motivation required to be successful. I look forward to leading this project.

B. Positions and Honors

Positions and Employment
1998-1999 Clinical Instructor, Dept. of Surgery, University of Kentucky College of Medicine; Lexington, KY
2000-2004 Asst. Professor of Surgery, Brody School of Medicine at East Carolina Univ.; Greenville, NC
2004-2008 Asst. Professor of Surgery, University of Maryland School of Medicine; Baltimore, MD
7/08–9/08 Associate Professor of Surgery, University of Maryland School of Medicine; Baltimore, MD
10/08-06/14 Associate Professor of Surgery, University of Kentucky College of Medicine; Lexington, KY
10/08-present Chief, Gastrointestinal & Minimally Invasive Surgery, University of Kentucky; Lexington, KY
10/08-present Director, Center for Advanced Training & Simulation, University of Kentucky; Lexington, KY
11/09-present Adjunct Faculty, Fischell School of Biomedical Engineering, University of Maryland; College Park, MD
07/12-present Professor of Surgery, University of Kentucky College of Medicine; Lexington, KY
07/15-present Richard Schwartz Commonwealth Professor of Physician Leadership

Other Experience and Professional Memberships
1998-present Society of American Gastrointestinal and Endoscopic Surgeons
2000-present Fellow, American College of Surgeons
2001-present The Society for Surgery of the Alimentary Tract
2001-present American Hernia Society
2005-2008 Association of Program Directors in Surgery
2008-present Kentucky Chapter of the American College of Surgeons
2010-present Association for Academic Surgery
2014-present SAGES Advisor to the AMA CPT Editorial Panel
2014-present Member, SAGES Legislative Committee

Honors
1985 Salutatorian, Ridgewood High School
1989 Phi Sigma Biology Honor Society, The College of William and Mary
1997-1998 Vice President, House Staff Association
2002 The John Bernard Vick, MD Teaching Award, East Carolina University Department of Surgery (June 20, 2002)
2005 The Anthony Imbembo, MD Resident Teaching Award, University of Maryland Department of Surgery (June 17, 2005)
2010 University of Kentucky Department of Surgery Recognition of Excellence in Student and Resident Teaching
2015-present Richard Schwartz Commonwealth Professor of Physician Leadership

C. Contribution to Science

1. Surgical Outcomes: The primary goal of my research in this area is the assessment of surgical techniques, products, and tools how they can be applied to improving surgical outcomes.

a. Liang MK, Goodenough CJ, Martindale RG, Roth JS, Kao LS. External validation of the ventral hernia risk score for prediction of surgical site infections. Surg Infect (Larchmt) 2015; 16(1)36-40. PMID 4363797


2. Mesh Repair: Our studies in this area have investigated ways that mesh repair can be improved. These studies have included clinical applications as well lab-based studies.


3. Quality Control: I am an active member of the SAGES Guidelines Committee that develops practice standards for gastrointestinal surgeries based upon expert consensus.


4. Surgery Education: This area of research reflects my interest in surgery education.


D. Research Support

Ongoing Research Support

CR Bard, Inc. 4/8/16 – present
A Prospective, Multi-Center Trial of a Long-Term Bio-Absorbable Mesh with Sepra Technology in Challenging Laparoscopic Ventral or Incisional Hernia Repair
Role: Principal Investigator

Miromatrix Medical Incorporated. 12/1/2015-11/30/2017 $63,002
“A Prospective Post-Market Clinical Evaluation of Miromatrix Biological Mesh for Hiatal Hernia Repair”
Completed Research Support

Role: Principal Investigator

**CR Bard Inc.** 1/31/13-1/31/15 $128,000
A Prospective Observational Study Utilizing Phasix™ Mesh During Ventral and Incisional Hernia Repair Surgery
Role: Principal Investigator

**Musculoskeletal Transplant Foundation** 11/01/10-10/31/14 $192,076
“Feasibility study of the use of Flex HD® surgical implant in the closure of abdominal wall defects with component separation in clean or contaminated cases.”

**CR Bard, Inc.** 05/01/09-04/30/13 $51,095
“A Single Arm, Multi-Center, Retrospective Study with Prospective Follow-Up of Complex Ventral Hernia Repair Utilizing the AlloMax® Surgical Graft”
Role: Principal Investigator

**Miromatrix Medical Incorporated.** 7/1/2014-12/31/2015 $130,000
Comparison of Ventral Hernia Repair Using two different acellular allograft mesh
Role: Principal Investigator

**Society of American Gastrointestinal and Endoscopic Surgeons** April 2014-April 2015 $30,000
Effect of Matrix Metalloproteinase-2 Inhibitor Doxycycline on Incisional Hernia Recurrence Rates in an ADM or Polypropylene Mesh Implanted Rat Incision Hernia Model
Role: Principal Investigator

**LifeCell Incorporated** 3/1/2014-6/30/2015 $66,556
A Retrospective Analysis of Hospital Cost and Reimbursement Data for Follow-up Treatment and Complications in Patients who have undergone Ventral Hernia Repair
Role: Principal Investigator

**CR Bard Inc.** 3/1/2014-3/1/2015 $75,000
A prospective, multi-center study of Phasix™ Mesh for Ventral or Incisional Hernia Repair
Role: Principal Investigator

**W. L. Gore and Associates** 6/1/2015-present $38,220
“A Quality of Life Assessment after Hiatal Hernia Repair Using Bio-A Mesh”. Dates: June 2015 -Present
Role: Principal Investigator
A. Personal Statement

I am a clinical analytics PhD whose primary research involves assessing surgical risk and outcomes. I have a strong interest and publication record in hernia surgery outcomes and have collaborated frequently with Dr. Roth. The purpose of the proposed study is to predict patient response to laparoscopic myotomy with fundoplication based on the full set of data obtained from preoperative workup including manometry, endoscopy, and barium esophagram. The relationship between the long-term follow up survey responses and the specific findings from the individual patients’ preoperative workup will be measured in order to develop a predictive profile of findings from preoperative testing on long-term postoperative symptoms. Currently, an estimated 10% to 20% of patients have persistence or recurrence of symptoms requiring additional procedures. This is an important study as it has the potential to improve patient outcomes and decrease healthcare costs. I will be providing methodological, data design and measurement, biostatistical and outcomes assessment support for this grant. I do so regularly for a broad range of clinical trials and studies.

B. Positions and Honors

Positions and Employment

1992-1995
Division Administrator,
University of Kentucky Division of General Surgery, Lexington, Kentucky

1995-1997
Financial Analyst,
University of Kentucky Department of Surgery, Lexington, Kentucky

1997 – Present
Director, Department of Surgery Office of Decision Support,
University of Kentucky, Lexington, Kentucky

August 2006 – June 2008
Visiting Assistant Professor, University of Kentucky Gatton College of Business and Economics, Decision Sciences and Information Systems Area (Joint appointment in the College of Medicine, Department of Surgery)
July 2008 – June 2013 Assistant Professor, University of Kentucky College of Medicine, Department of Surgery (Joint appointment in the Gatton College of Business and Economics, Analytics Area)

July 2013 – Current Associate Professor (with tenure), University of Kentucky College of Medicine, Department of Surgery

Other Experience and Professional Memberships
2007-Present Member, Healthcare Information and Management Systems Society (HIMSS)
2007-2008 Member, Measurement and Evaluation Committee, American College of Surgeons National Surgical Quality Improvement Program
2010-Present American Medical Informatics Association (AMIA)

Honors
2003 Research Employee of the Year for the University of Kentucky College of Medicine

C. Contribution to Science

4. Hernia Surgery Outcomes: The primary mission of my research in this area is the assessment of surgical quality and risk assessment and how this can be applied to improving surgical outcomes in patients. We’ve done some early work on endoscopic component separation, octogenarian and functionally dependent patients and drain duration.


5. Cost Analysis: The cost of health care continues to increase and patients tend to live longer and remain active in their later years. Paramount in this era of rising costs and longer life is the idea of maximizing the value of health care dollars. Therefore, surgery cost analysis has become an important area for research.


6. Surgery Education: The educational process can be influenced in many ways including organization, student and resident counseling, faculty development, and program evaluation and development. As the Director of the Department of Surgery Office of Decision Support, in addition to working with other faculty, I work closely with medical students and residents, providing guidance in research methodology and design. The ways in which education, training, and communication can influence patient outcomes and hospital efficiencies is an area of great interest to me.


D. Research Support

**Ongoing Research Support**

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Competitive Renewal of “Renal Osteodystrophy: A Fresh Approach”

There is currently no established treatment regimen for chronic kidney disease (CKD) associated osteoporosis even though it is associated with early and frequent debilitating hip fractures which require costly surgery, result in reduced quality of life, high mortality and impose an enormous socioeconomic burden. The goal of the proposed controlled randomized study is to test the concept that CKD osteoporosis can be successfully treated.

Role: Co-investigator, 20% Effort

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“Biphosphonate Use and Bone Quality”

Role: Co-investigator, 5% Effort

**Completed Research Support**

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<th>Start Date – End Date</th>
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“In-Vivo Evaluation of the Safety and Efficacy of Extracorporeal Circuits”

Role: Co-investigator, 2% Effort
Musculoskeletal Transplant Foundation  
Roth JS (PI)  
11/01/2010-06/30/16  
“Feasibility Study of the Use of Flex HD Surgical Implant”  
Role: Co-investigator, 5% Effort

LifeCell,™ Inc.  
Roth JS (PI)  
10/1/2014 – 6/30/2016  
“A Retrospective Analysis of Hospital Cost and Reimbursement Data for Follow-up Treatment and Complications in Patients Who Have Undergone Ventral Hernia Repair”  
Role: Co-investigator, 5% Effort
NAME: Plymale Margaret A

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

POSITION TITLE: Clinical Nurse Coordinator

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

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>Lexington Technical Institute; Lexington, KY</td>
<td>A.D.N.</td>
<td>05/1980</td>
<td>Nursing</td>
</tr>
<tr>
<td>University of Kentucky; Lexington, KY</td>
<td>B.S.N.</td>
<td>12/1984</td>
<td>Nursing</td>
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<tr>
<td>University of Kentucky; Lexington, KY</td>
<td>M.S.N.</td>
<td>12/2000</td>
<td>Nursing</td>
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<tr>
<td>University of Kentucky; Lexington, KY</td>
<td>D.N.P.</td>
<td>05/2016</td>
<td>Nursing</td>
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A. Personal Statement
I am a doctor of nursing practice whose primary clinical practice over many years is general surgery and more specifically gastrointestinal minimally invasive surgery. My current research focuses on clinical outcomes. After a number of years involved in surgical educational research and surgical education, I joined Dr. Roth's clinical practice as coordinator in 2008. The purpose of the proposed study is to begin to gain an understanding to predict patient response to laparoscopic myotomy with fundoplication based on the full set of data obtained from preoperative workup including manometry, endoscopy, barium esophagram. The relationship between the long-term follow up survey responses and the specific findings from the individual patients' preoperative workup will be measured in order to develop a predictive profile of findings from preoperative testing on long-term postoperative symptoms. Currently, an estimated 10% to 20% of patients have persistence or recurrence of symptoms requiring additional procedures. This is an important study as it has the potential to improve clinical decision making and patient outcomes. I will provide training for the data coordinator and close oversight of the work of the data coordinator. I also will be primarily responsible for reporting to the funding source as requested and for reporting the findings via abstract and manuscript preparation.

B. Positions and Honors

Positions and Employment

<table>
<thead>
<tr>
<th>Dates</th>
<th>Position</th>
<th>Institution</th>
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<tbody>
<tr>
<td>08/1980 – 07/1982</td>
<td>Staff Nurse</td>
<td>Cabell Huntington Hospital; Huntington, WV</td>
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<td>08/1982 – 05/1990</td>
<td>Staff Nurse</td>
<td>University of Kentucky A.B. Chandler Hospital; Lexington, KY</td>
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<td>06/1990 – 11/1994</td>
<td>Staff Nurse</td>
<td>General Surgery Clinic; University of Kentucky, Lexington, KY</td>
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<td>12/1994 – 07/2000</td>
<td>Research Nurse Coordinator</td>
<td>Division of General Surgery; University of Kentucky, Lexington, KY</td>
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</table>
2000 – 11/2008
Nurse Coordinator
Department of Surgery - Education Office; University of Kentucky, Lexington, KY

12/2008 – Present
Program Coordinator, Minimally Invasive Surgery Service
Division of General Surgery, University of Kentucky, Lexington, KY

Other Experience and Professional Memberships
2000-Present  Member, Sigma Theta Tau International, Honor Society of Nursing
2015-Present  Member, American Nurses Association (ANA)
2016-Present  Member, Omicron Delta Kappa, Leadership Honor Society
2015-Present  Member, Kentucky Nurses Association
2016-Present  Member, American Hernia Society

Honors
2004  Department of Surgery Excellence Awards, Recipient of Education Award
2008  Trish Greene Quality of Life Award, University of Kentucky College of Medicine

C. Contribution to Science

7. Surgery Education: Competent nurse educators are crucial to preparing medical students and residents to become competent physicians and surgeons working in a multi-disciplinary environment as part of a healthcare team.


8. Development of Surgical Education Assessment Tools: The primary goal of my research in this area is the assessment of surgical education quality and how this can be applied to improving surgical competency.


9. **Education to Improve Surgical Outcomes**: Our studies in this area have shown that procedural standardization provides for more efficient and safe performance of surgical tasks and improves patient outcomes.


10. **Surgery Outcomes**: My most recent research focuses on procedural comparative analyses to achieve improved surgical outcomes.


**D. Research Support**

None.
Participation in SAGES

John Scott Roth is a long-standing member of SAGES. His current committee involvement includes: Acute Care Surgery Task Force, Advocacy and Health Policy, and Hernia Task Force.

Margaret Plymale has applied for Allied Health membership to SAGES.