

**Society of American Gastrointestinal and Endoscopic Surgeons
APPLICATION COVER SHEET FOR ENDOSCOPIC/LAPAROSCOPIC RESEARCH AWARD**

TITLE OF PROJECT: *Laparoscopic and Open Transversus Abdominis Release Offer Similar Reductions in Midline Fascial Closure Force*

PRINCIPAL INVESTIGATOR: **Eric M Pauli, MD:** The Pennsylvania State University, College of Medicine, Assistant Professor of Surgery, Director of Endoscopic Surgery (SAGES Member)

AMOUNT REQUESTED: \$27,883 **DUE DATE OF APPLICATION:** November 1, 2013

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UNIVERSITY/INSTITUTION:

The Pennsylvania State University, College of Medicine
Name: Stephanie Johnson Title: Director, Grants Administration
Address: Office of Research Affairs
500 University Drive, MC H138
City: Hershey State: PA Zip: 17033-0850 Phone: (717) 531-8495

START DATE OF PROJECT: July 1, 2014 **END DATE OF PROJECT:** June 30, 2015

CO-INVESTIGATORS:

Joshua S Winder, MD: The Pennsylvania State University, College of Medicine, Surgery Resident
Jerome R LynSue, MD FACS: The Pennsylvania State University, College of Medicine, Assistant Professor of Surgery

CHECK SHOULD BE MADE PAYABLE TO

Institution: The Pennsylvania State University
Attention: Tressa Jilek, Coordinator, Research & administrative Services
Address: 500 University Drive, G230
City: Hershey State: PA Zip: 17033-0850

STATEMENT OF FUNDS

Neither this, nor any related research projects are pending funds or have funding from at hand sources. Preliminary data were collected through division allocated research funds.

Summary

Recurrent incisional hernia formation following posterior component separation (PCS) herniorrhaphy is uncommon (~5% at 2 years). Our long-term goal is to understand the mechanisms by which PCS hernia repair reduces the rate of recurrent incisional hernias. The specific objective of this proposal is to compare the reduction in midline fascial approximation tension before and after release of the transversus abdominis muscle. The central hypothesis is that both open and laparoscopic transversus abdominis release (TAR) will result in similar, significant reductions in force necessary to approximate the midline fascia.

We formulated this hypothesis, in part, based on our strong clinical experience with the TAR method as well as our preliminary data that support our hypothesis. As presented in the preliminary data, we have found that midline tension is indeed reduced when laparoscopic or open release of the transversus muscle is undertaken. The rationale for the proposed research is that once it is known how laparoscopic and open TAR compare to one another, a novel method of laparoscopic component separation could be implemented clinically.

We will pursue this study in three specific aims utilizing a live porcine model.

Aim 1: We will determine the change in the amount of tension required to approximate various points on the anterior rectus fascia with the anatomic midline before and after open release of the transversus abdominis muscle and fascia.

Our working hypothesis for this aim is that open posterior component separation with transversus abdominis muscle release significantly reduces the force necessary for midline fascial approximation.

Aim 2: We will determine the change in the amount of tension required to approximate various points on the anterior rectus fascia with the anatomic midline before and after laparoscopic release of the transversus abdominis muscle and fascia.

Our working hypothesis for this aim is that laparoscopic posterior component separation with transversus abdominis muscle release significantly reduces the force necessary for midline fascial approximation.

Aim 3: We will compare the reductions in the amount of tension required to approximate various points on the anterior rectus fascia with the anatomic midline when the transversus abdominis muscle has been divided laparoscopically versus open.

Our working hypothesis for this aim is that there is no functional difference between open and laparoscopic posterior component separation with transversus abdominis muscle release.

The proposed work is innovative, because it capitalizes on the overall lack of data about the degree to which TAR alleviates tension on midline fascial closure. Moreover, no data exist about the differences between open TAR and laparoscopic TAR. At the completion of this project, it is our expectation that, the combination of work proposed in aims 1 and 2 will demonstrate significant and clinically relevant reductions in midline tension. We also expect that aim 3 will establish that laparoscopic TAR and open TAR are functionally equivalent procedures.

Background

Traditional methods of hernia repair have unacceptably high recurrence rates.¹⁻² Primary open suture repair of ventral hernias with simple fascial reapproximation results in recurrence rates in excess of 50 percent in long term follow up.³⁻¹¹ Fifty-five years ago, mesh herniorrhaphy was introduced.¹² The principle of a tension-free mesh-reinforced herniorrhaphy has undergone technical refinements since this time but is still considered to be the gold standard repair.^{2,13} Despite the widespread implementation of this 'gold standard,' the addition of mesh alone to open repairs still results in a long term recurrence rates as high as 32%.⁹⁻¹¹

In 1990, Ramirez and colleagues described a component separation hernia repair method which permitted greater medial fascial advancement and aided in definitive abdominal wall reconstruction.¹⁴ Component separation methods result in a lower rate of hernia recurrence, in part, by reducing tension across the midline closure through the surgical division of constraining myofascial planes.¹⁵⁻¹⁷ Numerous 'anterior' and 'posterior' methods of component separation have been described.

Posterior component separation (PCS) methods are based on the Rives-Stoppa-Wantz retro-rectus repair which utilizes the 6-8 cm wide potential space between the posterior rectus sheath and the rectus muscle to permit mesh positioning in a sublay fashion.¹⁸⁻²¹ Given its superior track record, this approach was deemed to be the gold standard method for open ventral hernia repair by the American Hernia Society in 2004.^{2,22} Although durable, the Rives-Stoppa-Wantz technique does not permit dissection beyond the lateral border of the posterior rectus sheath (the *linea semilunaris*), making it insufficient to permit a tension free midline re-approximation of larger abdominal wall defects.²¹⁻²² Numerous methods to extend this potential space have been described, including pre-peritoneal dissection and intra-muscular plane formation.²²⁻²⁶

More recently, Novitsky *et al* described transversus abdominis release (TAR) as a method of open PCS.²² Following takedown of the posterior rectus sheath, the transversus abdominis muscle and fascia are divided from costal margin through arcuate line by incising posteriorly (Figure 1). The avascular plane beneath the transversus muscle is then entered and bluntly dissected; laterally to the psoas, superiorly behind the xypoid process and inferiorly behind the pubic symphysis.²⁷ Utilizing the TAR method, Novitsky achieved a remarkably low recurrence rate of 4.7% with 26 months follow up.²² Despite these impressive results, no data exist about the degree to which TAR alleviates tension on the midline fascial closure.²⁸

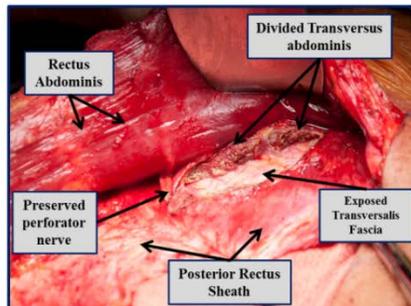
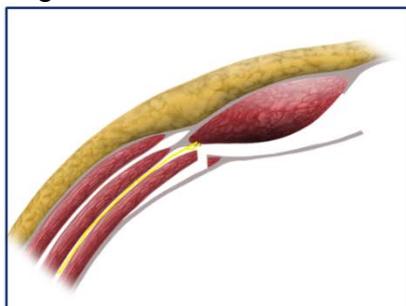


Figure 1: Division of the posterior rectus fascia just medial to the *linea semilunaris* and perforator nerves followed by division/release of the transversus abdominis muscle along its entire medial edge. From Novitsky *et al.*, *Am J Surg.* 2012; 204: 709–716.

Much has been published about the use of minimally invasive surgical techniques to perform an 'anterior component' separation through the division of the external oblique aponeurosis.²⁹⁻³⁰ This so called 'endoscopic component separation' does reduce the wound morbidity of traditional anterior component separation herniorrhaphy, but it is still used almost exclusively in conjunction with a subsequent open midline repair.²⁹⁻³⁰ There are several factors that have precluded the more widespread adoption of endoscopic component separation, among them is the need to create and navigate in an unfamiliar potential space within the muscles of the lateral abdominal wall.

Interestingly, the transversus abdominis muscle is readily visible and divisible from within the abdominal cavity; a space familiar to any laparoscopic surgeon (Figure 2). Despite this, the method has not been well described. Laparoscopic TAR may have the advantage of permitting reduced tension across the midline closure without the need to understand the complexities of an 'endoscopic component separation' release of the external oblique muscle. Moreover, laparoscopic TAR coupled with laparoscopic defect closure and mesh placement could eliminate the need for a fully open or hybrid (endoscopic/open) component separation hernia repair. The significance of a laparoscopic TAR herniorrhaphy would not only be in a return to the much lower surgical site infection rates seen with laparoscopic herniorrhaphy, but also in the return of a large population of hernia patients to the laparoscopic capable general surgeon from the plastic surgeons who routinely perform anterior component separation operations.



Figure 2: Laparoscopic view of the transversus abdominis muscle inserting on the posterior rectus sheath in a human patient.

Our preliminary data and clinical observations support the hypothesis that there is a substantial reduction in the force necessary to approximate various points on the midline fascia following open PCS. Force reductions as high as 30-50% were observed for specific locations on the abdominal wall. Moreover, laparoscopic TAR proved to be a straightforward endeavor without evidence of iatrogenic injury to additional layers of the abdominal wall (Figure 3). The intercostal motor nerves supplying innervation to the rectus abdominis muscle were identifiable between the internal oblique and transversus abdominis muscles and were able to be preserved during laparoscopic dissection (data not shown).

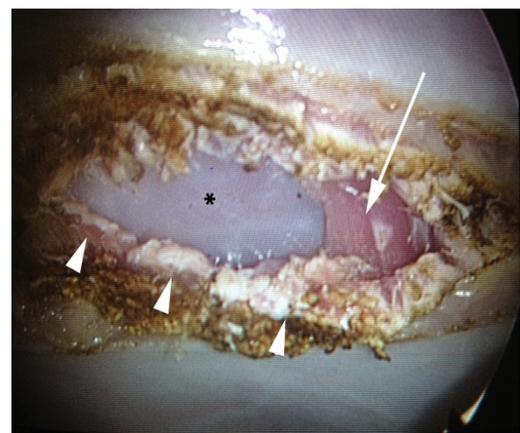


Figure 3: View of the abdominal wall following laparoscopic TAR. Cut lower edge of the transversus muscle (arrowheads), uncut transversus fibers (arrow) and intact internal oblique muscle (*) can all be seen.

Hypotheses

Hypothesis 1: Open posterior component separation with transversus abdominis muscle release reduces the force necessary for midline fascial approximation.

Prediction: There will be a significant reduction in the amount of force necessary for midline fascial approximation following open transversus abdominis release when compared to baseline.

Hypothesis 2: Laparoscopic posterior component separation with transversus abdominis muscle release reduces the force necessary for midline fascial approximation.

Prediction: There will be a significant reduction in the amount of force necessary for midline fascial approximation following laparoscopic transversus abdominis release when compared to baseline.

Hypothesis 3: There is no functional difference between open and laparoscopic posterior component separation with transversus abdominis muscle release.

Prediction: Both open and laparoscopic transversus abdominis release will demonstrate similar reduction in the amount of force necessary for midline fascial approximation compared to baseline.

Methods

Subjects:

Twenty 40 kg female domestic pigs (*Sus scrofa domestica*) will be utilized in this non-survival study. Sample size calculation follows below.

Pre-Operative Care:

Animals will be fed standard chow ad libitum during the required one week quarantine period. The animals will be kept without food (free access to water) beginning 24 hours prior to the procedure. All animals will be weighed prior to the induction of anesthesia.

For the surgical procedures, the animals will be anesthetized and monitored by the veterinary staff of the Penn State Department of Comparative Medicine. Anesthesia will be induced by an intra-muscular injection of telazol (500 µg/kg), medetomidine (70-80 µg/kg) and butorphanol (300 µg/kg). The animals will be intubated and anesthesia maintained with 1-2% isoflurane delivered in 100% O₂ with mechanical ventilation. An IV catheter will be placed in the marginal ear vein.

Neuromuscular-blocking agents and skeletal muscle relaxants will not be utilized at any point during the operation to eliminate their confounding effects on midline fascial tension. End-tidal CO₂, SpO₂, respiratory rate and pulse rate will be monitored throughout the procedure. Animals will be stabilized across the chest and pelvis to eliminate motion during force measurement.

Equipment Preparation:

Laparoscopic and open equipment will undergo high level disinfection with 2.4% glutaraldehyde (Cidex; Johnson and Johnson, New Brunswick, NJ) following use. Because this is a non-survival model, full aseptic technique will not be utilized during the procedures.

Operative Procedure:

Baseline Force Measurements: Following the satisfactory induction of anesthesia, a full midline laparotomy incision will be created. Bilaterally, the anterior rectus fascia will be exposed from 3 cm above to 3 cm below the umbilicus and from the midline to 5 cm laterally. This will be accomplished by dissecting the *cutaneous trunci* muscles off of the external oblique fascia to create a large lipocutaneous flap.

Force measurements across the abdominal wall will be taken using previously described methods.³¹ 2-0 nylon suture loops will be placed in the midline fascia at 15 locations per side. At 1 cm, 2 cm, 3 cm, 4 cm and 5 cm away from the midline, sutures will be placed 3 cm above, 3 cm below and at the level of the umbilicus (Figure 4). A digital force gauge (BFG200N (Slinfold, West Sussex, UK) will be hooked into each of the suture loops and measurements of the force taken to pull the base of the loop to the midline will be taken. The midline will be marked from xyphoid to pubis with a reference suture. Two measurements will be made at each location. In the event of discrepancy, a third measurement will be taken.



Figure 4: Nylon suture loops placed at one cm intervals from midline reference suture in lines 3cm above, 3cm below and at the umbilicus.

Laparoscopic TAR: Following baseline data collection, three laparoscopic trocars will be placed through the left abdominal wall lateral to the linea semilunaris. The midline will then be closed with skin staples and an occlusive drape (Incise Drape, 3M Corporation, USA). Pneumoperitoneum will be created utilizing a carbon dioxide insufflator (Electronic Laparoflator, Karl-Storz, Germany). Utilizing standard laparoscopic instrumentation and monopolar electrocautery, we will divide the right transversus abdominis muscle one centimeter medial to the *linea semilunaris*. The division will include the peritoneum, posterior transversus fascia, transversus muscle belly and anterior transversus fascia.

Open TAR: Following completion of the laparoscopic TAR the ports and occlusive drape will be removed. Utilizing previously described methods,²⁷ an open TAR will be performed on the left abdominal wall.

Repeat Force Measurements: Following the completion of the open TAR, the midline reference suture will be replaced. The digital force gauge will again be hooked into each of the nylon suture loops and measurements of the force taken to pull the base of the loop to the midline. As with baseline testing, two measurements will be made at each location.

Euthanasia:

At the conclusion of the procedure, animals will be euthanized by an overdose of pentobarbital sodium (>100 mg/kg i.v.). This method will be consistent with the recommendations of the 2013 Panel on Euthanasia of the American Veterinary Medical Association.³²

Necropsy:

Gross examination will evaluate for the adequacy of the release of the transversus abdominis muscle (uncut muscle fibers, fascial bands) as well as unintended injury to other abdominal wall structures including the *linea semilunaris*, the internal oblique muscle, the external oblique muscle and the rectus abdominis muscle.

Data Collection:

Physiologic Data will include cardio-pulmonary status (heart rate and pulse oximetry).

Operative Data will include anatomic descriptions of the starting point and ending point of the TAR (for both open and laparoscopic operations). Operative complications, including bleeding, iatrogenic injury to other structures (including unintended injury to abdominal wall structures) will also be noted.

Tension Data will be collected utilizing a Mecmesin BFG digital force gauge (BFG200N (Slinfold, West Sussex, UK). Baseline measurements of midline tension (before TAR) will be made 3 cm above, at and 3 cm below the umbilicus at one cm intervals away from/lateral to the midline (at midline, 1cm, 2cm, 3cm, 4cm, 5 cm). Following completion of the TAR, repeat measurements of midline tension will be made 3 cm above, at and 3 cm below the umbilicus at one cm intervals from the midline (at midline, 1cm, 2cm, 3cm, 4cm, 5 cm).

Data Analysis:

Students *t*-tests and paired samples *t*-tests will be conducted using SAS 9.3 (SAS Institute, Cary NC) with the assistance of the Division of Biostatistics and Bioinformatics. If needed, Wilcoxon signed-rank test may be utilized due to a small sample (< 30) that may not have a normal distribution. Continuous data monitoring will be used to ensure that no unnecessary operations are performed in the event that statistically-significant results are found earlier than anticipated.

Sample Size Calculation:

Assuming a 40-45% reduction in the force necessary to approximate the midline at the 2 cm marker following TAR, a significance level (α) of 0.05 and a power of 0.9, 20 laparoscopic and 20 open operations will be necessary to reject the null hypothesis. Because we plan one laparoscopic and one open side per animal, only 20 animals will be necessary for the study.

Anticipated Problems and Remediation Strategies:

1) *Discrepant force data.* If discrepant force is identified from one of the suture loop locations, a second independent observer will repeat the measurements and the average of the 2 data points in closest agreement will be utilized.

2) *Failure to complete the laparoscopic TAR.* In the event that the TAR cannot be successfully completed utilizing basic laparoscopic tools, more advanced tools may be utilized (advanced ultrasonic dissecting tools, curved or articulating laparoscopic tools).

3) *Failure to maintain pneumoperitoneum.* In the event that the occlusive dressing cannot adequately maintain the midline closure and permit sufficient pneumoperitoneum to perform the laparoscopic TAR, the midline skin and sub cutaneous tissues will be closed with suture. We will not suture the fascia to maintain pneumoperitoneum to avoid any confounding effects suturing may have on the tension measurements.

**SAGES RESEARCH GRANT APPLICATION
BUDGET SHEET**

Detailed budget for 12 month period from July 1, 2014 through June 30, 2015.

Dollar amount requested (Omit cents) \$ 27,883

Total for the grant request may not exceed \$30,000.

* Salary funds should be used for staff required to execute the study, but should not be used for salary support for the primary investigator. If salary support exceeds 50% of the project budget, then specific justification is required.

**Funds requests for travel for the presentation of a SAGES funded study should be limited to \$1,000.

NAME	POSITION TITLE	TIME/EFFORT		SALARY	FRINGE BENEFITS	SUB-TOTALS
		%	Hrs/ Week			
1. Eric Pauli, MD	Principal Investigator*	2	2			
2. Josh Winder, MD	Co-Investigator	10	4	\$ 5,382	(@36.5%) \$1,966	\$ 7,348
3. Jerome LynSue, MD	Co-Investigator	0.5	0.5			
5.						
	CONSULTANT COSTS					
	EQUIPMENT					
	(List all Items & Total Equipment Cost)					\$ 2,937
	SUPPLIES					
	(List all Items & Total Supplies Cost)					\$ 895
	TRAVEL**					
	For resident Co-Investigators (PI travel covered by institution)					\$ 6,354
	PATIENT CARE COSTS					\$ 925
	CONSORTIUM/CONTRACTUAL COSTS					\$ -
	OTHER EXPENSES					\$ -
	(List all Items & Total Cost)					\$ 9,424
	TOTAL DIRECT COSTS					\$ 27,883

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5. Flum DR, Horvath K, Koepsell T. Have outcomes of incisional hernia repair improved with time? A population-based analysis. *Ann Surg.* 2003;237:129–35.
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27. Pauli EM, Rosen MJ. Open ventral hernia repair with component separation. *Surg Clin North Am.* 2013;93:1111-1133.
28. Personal communication, Yuri W. Novitsky, October 2013.
29. Harth KC, Rosen MJ. Endoscopic versus open component separation in complex abdominal wall reconstruction. *Am J Surg.* 2010;199:342-6.
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31. Nahas FX, Ferreira LM. Cadaver as an experimental model to study abdominal wall tension. *Acta Cir Bras* [serial online] 2003 Vol 18 Special Edition.
32. AMVA Guidelines for the Euthanasia of Animals: 2013 Edition. Available at <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

Local/Institution Review Board

The Penn State University College of Medicine's Institutional Animal Care and Use Committee (IACUC) has received the proposed activity. It has been submitted as part of the Just-in-Time process.

Available Resources

The following resources are current available in our laboratory:

Equipment:

Laparoscopic Equipment

- Laparoscope: Storz Telecam (20212130; Karl-Storz Endoscopy, Tuttlingen, Germany)
- Video Monitor: Trinitron HR Monitor (PVM 1953MD; Sony Corp, Tokyo, Japan)
- Insufflator: Electronic Laparoflator (26012; Karl-Storz)
- Light Source: Xenon 300 (Karl-Storz)
- Fiber-Optic Cable: Karl-Storz
- Laparoscopic Lenses: 10 mm; 0°, 30°, 45° lenses (Karl-Storz)
- Laparoscopic Instruments: a variety of necessary laparoscopic instruments (graspers, dissectors, scissors, needle drivers) are available to perform the laparoscopic posterior component separation with transversus abdominis release.

Open Surgical Equipment

A standard variety of instruments for open large animal surgery are available through the Penn State Animal Resource Program. This includes all of the necessary tools for performing a posterior component separation with transversus abdominis release.

Data Recording Equipment

- Hardware:
 - 1) Dell Latitude laptop computer (D820; Dell Inc, Round Rock, TX)
 - 2) Sony Digital Handycam (DCR-VX2000; Sony Corp)
- Software:
 - 1) Pinnacle Studio Plus 700 USB real-time video capture (Version 10, Pinnacle Systems, Mountain View, CA)

Animal Care Facilities:

The Penn State Animal Resource Program is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All animal living conditions are consistent with standards required by AAALAC. Techniques courses are required by the Department of Comparative Medicine for all personnel (investigators, technicians, etc.) who work with the research animals. The facility provides appropriate housing for all animals pre- and post-procedure and has multiple fully functioning veterinary operating rooms with equipment sterilization capabilities. Necropsy rooms are available for post-mortem examination and the facilities' laboratory is capable of processing culture and histologic specimens.

Animal Care Staff:

Members of the full-time veterinary staff of the Penn State College of Medicine Department of Comparative Medicine are available 24 hours/day, 7 days/week. They provide pre- and post-procedure care for all animals in accordance with the above described protocol. Procedural anesthesia, monitoring, euthanasia anesthesia and gross necropsy assistance are provided by the veterinarians of the Department of Comparative Medicine.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Eric M. Pauli, MD		POSITION TITLE Assistant Professor Director of Endoscopic Surgery	
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.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
The University of Scranton, Scranton, PA	BA	05/00	Philosophy
The Pennsylvania State University, Hershey, PA	BS	06/04	Biology
Penn State Milton S. Hershey Medical Center, Hershey, PA	MD	06/05	Medicine
Penn State Milton S. Hershey Medical Center, Hershey, PA	Internship	06/05	Surgery
Penn State Milton S. Hershey Medical Center, Hershey, PA	Research Fellowship	06/08	Bariatric Surgery
Penn State Milton S. Hershey Medical Center, Hershey, PA	Residency	06/11	Surgery
University Hospitals Case Medical Center, Cleveland, Ohio	Clinical Fellowship	06/12	LaparoEndoscopic Surgery

A. Personal Statement

The goal of this project is to determine the extent to which laparoscopic and open posterior component separation with transversus abdominis release reduce the force required to approximate the midline fascia in a porcine model. I have been the principal investigator in other research projects requiring large animal surgery in a porcine model. I have a significant background in surgical research, most recently in the field of endoscopic surgery, with a demonstrated track record of successful and productive research projects and publications. My current clinical and research focus areas include laparoscopic and open abdominal wall reconstruction and I feel fully prepared to conduct this innovative project.

B. Positions and Honors

Positions and Employment

- 2007 – present Instructor, Simulation Development and Cognitive Sciences Laboratory, The Pennsylvania State University, College of Medicine, Hershey, PA
- 2011 – 2012 Instructor in Surgery, Milton S. Hershey Medical Center, Hershey, PA
- 2012 – present Director of Endoscopic Surgery, Penn State Hershey Medical Center, Hershey, PA
- 2012 – present Assistant Professor, Department of Surgery, The Pennsylvania State University, Hershey, PA

Other Experience and Professional Memberships

- 2000 – present Member, Alpha Sigma Nu (National Jesuit Honor Society)
- 2004 – present Member, Alpha Omega Alpha (National Medical Honor Society) Pennsylvania Eta Chapter
- 2005 – present Resident Member, The Gold Humanism Honor Society
- 2006 – 2012 Resident Member, American College of Surgeons
- 2012 – present Associate Fellow, American College of Surgeons
- 2006 – 2012 Candidate Member, Society of American Gastrointestinal and Endoscopic Surgeons
- 2007 – present Candidate Member, Association of Academic Surgeons
- 2007 – 2012 Trainee Member, American Society for Gastrointestinal Endoscopy
- 2012 – present Active Member, American Society for Gastrointestinal Endoscopy
- 2007 – present Resident Member, Society for Simulation in Healthcare
- 2008 – present Resident Member, The Society for Surgery of the Alimentary Tract

2008 – present Resident Member, The American Medical Association
2011 – 2012 Member, The Academy of Medicine of Cleveland and Northern Ohio
2012 – present Active Member, Society of American Gastrointestinal and Endoscopic Surgeons
2013 – present Member, American Hernia Society

Awards and Honors

1996 Valedictorian, Scranton High School
1998 Frank J. O'Hara Medal, College of Arts and Sciences, The University of Scranton
1998 Rose Kelly Award, College of Arts and Sciences, The University of Scranton
1998 Phi Lambda Upsilon (National Chemistry Honor Society), The University of Scranton
1998 Alpha Sigma Nu (National Jesuit Honor Society), The University of Scranton
1999 Francis P. Boland, M.D. Memorial Scholarship, The University of Scranton
2000 Alpha Epsilon Delta (National Premedical Honor Society), Pennsylvania Iota Chapter
2000 Phi Sigma Tau Inductee (National Philosophy Honor Society), Pen Tau Chapter
2000 *Summa Cum Laude* Graduate, The University of Scranton
2004 Alpha Omega Alpha Inductee, Pennsylvania Eta Chapter, Penn State College of Medicine
2004 Scholarship for Excellence in Surgery, Department of Surgery, Penn State College of Medicine
2005 Society of Vascular Surgery Resident Travel Award
2005 Department of Surgery Medical Student Teaching Award, Hershey Medical Center
2005 Arnold P. Gold Foundation Humanism and Excellence in Teaching Award, Penn State Milton S. Hershey Medical Center
2006 Pennsylvania Society of Colon and Rectal Surgeons Resident Travel Award
2007 Society of American Gastrointestinal and Endoscopic Surgeons Research Award
2007 - 2008 Outstanding Reviewer Award for Gastrointestinal Endoscopy
2009 AstraZeneca Endoscopic Research Award
2010 Arnold P. Gold Foundation Humanism and Excellence in Teaching Award, Penn State Milton S. Hershey Medical Center
2010 Resident Leader/Mentor in Surgery Award, Penn State Milton S. Hershey Medical Center
2011 Winner, Resident Competition in Innovation, Penn State Milton S. Hershey Medical Center
2011 – 2012 Outstanding Reviewer Award for Gastrointestinal Endoscopy
2012 – 2013 Outstanding Reviewer Award for Gastrointestinal Endoscopy
2012 – 2013 Penn State 'Hershey Hero' Service Excellence Award

C. Selected Peer-reviewed Publications

1. Moyer MT, **Pauli EM**, Haluck RS, Mathew A. The self-approximating transluminal access technique for potential use in NOTES: an ex vivo porcine model (with video). *Gastrointest Endosc.* 2007;66(5):974-8.
2. Mathews A, **Pauli EM**, Moyer MT, Haluck RS. Heller type cardiomyotomy using NOTES. *Endoscopy.* 2008;40:352.
3. Ionescu AM, **Pauli EM**, Rogers AM, Meier AH, Shope TR, Haluck RS. When is a Petersen's hernia not a Petersen's hernia. *J Am Coll Surg.* 2008;207(1):121-124.
4. **Pauli EM**, Haluck RS, Ionescu AM, Rogers AM, Shope TR, Moyer MT, Biswas A, Mathew A. Directed submucosal tunneling permits in-line endoscope positioning for transgastric natural orifice transluminal endoscopic surgery (NOTES). *Surg Endosc.* 2010;24(6):1474-81.
5. Moyer MT, Haluck RS, Gopal J, **Pauli EM**, Mathew A. Transgastric organ resection solely with the prototype R scope and the self-approximating transluminal access technique (STAT). *Gastrointest Endosc.* 2010;72(1):170-176.
6. Moyer MT, **Pauli EM**, Gopal J, Mathew A, Haluck RS The durability of the self-approximating transluminal access technique (STAT) for potential use in natural orifice transluminal surgery (NOTES). *Surg Endosc.* 2011;25(1):315-322.
7. Mathew A, Moyer MT, Gopal J, Ancrile BB, Haluck RS, Tomasko JM, **Pauli EM**. Reliability of gastric access closure with the self-approximating transluminal access technique or (STAT) for NOTES. *Surg Endosc.* 2011;25(8):2718-2724.

Program Director/Principal Investigator (Last, First, Middle): Pauli, Eric

No number Pauli (PI) 2/1/2008 – 5/31/2009

Natural Orifice Surgery Consortium for Assessment and Research

Title: Durability of the Self-approximating Transluminal Access Technique (STAT) for Transgastric Organ Resection

Project goal: The purpose of this study is to determine the feasibility of performing transgastric organ resection utilizing a tunneled gastrotomy and to determine the durability of the tunnel during the course of a transgastric organ resection in an *in vivo* porcine model.

Role: PI

No number Rogers (PI) 7/1/2008 – 6/30/2009

Surgery Feasibility (PSU, COM)

Title: The Self-approximating Transluminal Access Technique (STAT) for “Heller’s Myotomy” in a Porcine Model

Project goal: The purpose of this study is to determine the technical feasibility and short term morbidity of a per-oral transesophageal endoscopic cardiomyotomy in a porcine survival model.

Role: Co-Investigator

No number Erdahl (PI) 7/1/2008 – 6/30/2009

Surgery Feasibility (PSU, COM)

Title: Development of a “Home Box Laparoscopic Trainer” for the Acquisition of Laparoscopic Skills

Project goal: This study is designed to determine resident utilization of and to assess resident skill acquisition through the use of an at-home laparoscopic surgical simulator.

Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Joshua S. Winder		POSITION TITLE Surgical Resident	
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.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Brigham Young University, Provo, UT	B.S.	04/08	Exercise Sciences
University of Michigan Medical School, Ann Arbor, MI	M.D.	05/12	Medicine

A. Personal Statement

The goal of the project is to build on the growing knowledge of hernia repair in the surgical patient. Ventral and incisional hernias are a major source of morbidity in the post-surgical patient and present a challenging problem to the Surgeon. I came to understand the scientific process as an undergraduate at BYU. There I worked in the Neuroscience lab as an animal care provider and research assistant. I learned about data collection and the importance of strict adherence to project protocols. Furthermore, I learned the importance of eliminating bias and the proper use of controls. In medical school I found myself again working with animals in a surgical model. I learned how to be meticulously concerned with details as the slightest variation in our measurements made a tremendous effect on our outcome. My work experience as a Head Pyrotechnician taught me how to lead a group of workers to set up aerial displays in a safe and controlled manner. This required me to work closely with various parties including local police, fire crews, event coordinators, and clients. This experience was invaluable in teaching me how to coordinate efforts between multiple groups all while abiding to a strict time constraint. As a surgical resident I have come to see first hand the deleterious effects of ventral hernias in the patients that I treat. Furthermore, I have come to understand the need to provide these patients with a safe, effective repair. I have chosen Dr. Pauli and Dr. Haluck as research mentors for their expertise in the area of laparoscopic and endoscopic surgery and innovation. My past experiences have proven my ability to work hard and be task oriented and with their experience and mentorship in a research capacity I will familiarize myself with the tools and talents required to excel in academic medicine. The proposed study will show the feasibility of a laparoscopic transversus abdominus release in a porcine model. Such a procedure will provide me, and the surgical community at large, with a viable option in the treatment of ventral hernias.

B. Positions and Honors

Positions and Employment

08/2006 – 12/2006	Anatomy Laboratory Instructor, Human and Cadaver Laboratory, Brigham Young University, Provo, UT
08/2005 – 04/2008	Materials Management, Student Health Center, Brigham Young University, Provo, UT
05/2005 – 01/2008	Head Pyrotechnician, Fireworks West International, Logan, UT
2009 – 2010	Personal Assistant, to D. Lowell Fisher, Ph.D., Ann Arbor, MI
2012 – present	Surgical Resident, PGY2, The Pennsylvania State University, College of Medicine, Hershey, PA

Awards and Honors

May 2009 UMHS Center for Global Health grant recipient. Traveled to Brazil as visiting student to the Hospital das Clinicas in São Paulo.
April 2009 UMHS Summer Biomedical Research Program grant recipient.
BYU Dean's List and Full Tuition Scholarship recipient.

Presentations

November 5, 2009 UMHS Biomedical Research Conference, Poster presentation, *Treatment of Disuse Osteopenia with Bisphosphonates in Growing Bone- Differential Deposition and Healing in Cortical and Cancellous Bone.*
July 30, 2010 UMHS Department of Pediatrics, Oral presentation to Pediatric Newborn faculty and students on sudden infant death syndrome.
September 28, 2010 UMHS Department of Endocrine Surgery, Literature review of robotic assistance in General Surgery, presented to Endocrine Surgery faculty.
December 3, 2010 UMHS Department of Obstetrics and Gynecology, Oral presentation on scheduled cesarean section in multiple gestation pregnancies to faculty and students.

C. Selected Peer-reviewed Publications

None

D. Research Support

Ongoing Research Support

None

Completed Research Support

No number Picton (PI) 04/01/2011 – 05/01/2012
UMHS Department of Anesthesia
Title: Retrospective Review of one Medical Center's Outcomes for Carotid Endarterectomies
Project goal: Creating a database for all of the carotid endarterectomies performed at the University of Michigan Medical Center from 2005 to the current.
Role: Research assistant

No number Caird (PI) 02/01/2009 – 11/30/2009
UMHS Biomedical Research Program
Title: Treatment of Disuse Osteopenia with Bisphosphonates in Growing Bone- Differential Deposition and Healing in Cortical and Cancellous Bone
Project goal: Comparing the effects of bone remodeling in a model for disuse osteopenia in mice by creating burr-hole defects and comparing under micro-ct the trabecular and cancellous bone volumes with bisphosphonate therapy.
Role: Research assistant

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Jerome Lyn-Sue, M.D.	POSITION TITLE Assistant Professor of Surgery		
eRA COMMONS USER NAME (credential, e.g., agency login) jlynsue			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of the West Indies, Kingston, Jamaica	M.D.	07/96	Medicine
Royal College of Surgeons Edinburgh, Edinburgh, UK	MRCS	10/02	General Surgery
Howard University Hospital, Washington, DC	Residency	06/07	General Surgery
Johns Hopkins University Hospital, Baltimore, MD	Fellowship	06/08	Minimally Advanced and Bariatric Surgery

A. Personal Statement

I am a General Surgeon with subspecialty training in Advanced Laparoscopic and Bariatric Surgery. I am a clinician educator with special interest in obesity and its co morbidities. I have been on faculty at the Penn State Hershey Medical center in the department of Minimally Invasive Surgery and Bariatrics since 2010. Previously I was a General and Advanced Laparoscopic surgeon at Roper/ St Francis healthcare system in Charleston, South Carolina for 2 years.

The proposed project will measure the tension on midline closure after performing laparoscopic release of the transversus muscle for ventral hernia repair.

B. Positions and Honors

09/1991 – 07/1996	Medical School, University of the West Indies, Jamaica
07/1996 – 12/1997	Internship, Cornwall Regional Hospital, Jamaica
1/1998 -10/1999	General Surgery Resident, Cornwall Regional Hospital, Jamaica
10/1999 – 06/2002	General Surgery Resident, University Hospital of the West Indies, Jamaica
06/2002 – 06/2007	General Surgery Resident, Howard University Hospital, Washington, DC
07/2007 – 06/2008	Minimally Invasive Surgery Fellowship, Johns Hopkins Medical Institute, Baltimore, MD
08/2008 – 07/2010	General and Advanced Laparoscopic Surgeon, Roper St Francis Healthcare, Charleston SC
08/2010 – present	Assistant Professor MIS/ Bariatrics, The Pennsylvania State University, College of Medicine, Hershey ,PA

Professional Memberships and Other Experience

- American Society for Metabolic and Bariatric Surgery
- American College of Surgeons
- Society American Gastrointestinal Endoscopic Surgeons
- General Medical Council (United Kingdom)
- Member of the Royal College of Surgeons of Edinburgh
- Medical Council of Jamaica

Honors

- | | |
|------|---|
| 2005 | Gantt-Henderson Teaching Award (Howard University)2006 Instructor, Surgical Skills Lab, recipients of Kiernan-Matory Fellowship |
| 2007 | Howard University Hospital Medical Alumni Chief Residents Award |
| 2007 | Chairman's Award General Surgery |
| 2007 | AOA Honor Medical Society |
| 2007 | Outstanding Resident Award |

C. Selected Peer-reviewed Publications

1. Scarlett D, Cargill M, **Lyn-Sue J**, Richardson S, McCaw-Binns A. Breastfeeding prevalence among six-week-old infants at the University Hospital of the West Indies. *West Indian Med J*. 1996;45(1):14-17.
2. **Lyn-Sue J**, Siram S, Williams D, Mezgebe H. Epidemiology of trauma deaths in an urban level-1 trauma center predominantly among African Americans--implications for prevention. *J Natl Med Assoc*. 2006;98:1940-1944.
3. **Lyn-Sue J**, Steele K, Schweitzer MA, Magnuson T, Lidor A, Gupta A, Okolo P. Temporary covered stents for the treatment of anastomotic leaks following gastric bypass surgery. *Bariatric Times*. Apr 2008.
4. Gupta A, Chang D, Steele KE, Schweitzer MA, **Lyn-Sue J**, Lidor AO. Looking beyond age and comorbidities as predictors of outcomes in paraesophageal hernia repair. *J Gastrointest Surg*. 2008;2(12):2119-2124.
5. Gupta A, Schweitzer MA, Steele KE, Lidor AO, **Lyn-Sue J**. Surgical site infection in the morbidly obese patient: a review. *Bariatric Times*. Jun 2008.
6. Steele K, Schweitzer MA, **Lyn-Sue J**, Kantsevov SV. Flexible transgastric peritoneoscopy and liver biopsy: a feasibility study in human beings (with videos). *Gastrointest Endosc*. 2008;68(1):61-66.
7. **Lyn-Sue J**, Haluck R, et al. Quality of life outcomes after Heller Myotomy. *Surg Endoscopy*. 2011; in revision.

D. Research Support

Ongoing Research Support

None

Completed Research Support

Phase 4 clinical trial with use of intravenous (Caldolor) ibuprofen in post-operative patients. (Co-investigator)

Participation in SAGES

Eric M Pauli, MD: was a candidate member of SAGES from 2006-2012 and has been an active member since that time. He has attended the annual meeting 2006-2008 and 2010-2013. He is a member of the Flexible Endoscopy Committee (including the Video Atlas of Endoscopy subcommittee) and the Fundamentals of Endoscopic Surgery (FES) Committee. He has been an *ad hoc* reviewer for *Surgical Endoscopy* since 2011. He has participated in the following teaching/service activities for SAGES;

- 2006: Learning Center Faculty: Head-2-Head Laparoscopic Simulator (April 26-27)
- 2008: FES Beta tester; written exam
- 2012: FES Beta tester; skills exam
Faculty: SAGES Basic Endoscopy and Laparoscopy Course (May 3-4)
Faculty: Mini Med School (March 10)
- 2013: Lab Instructor: Ventral Hernia Repair (April 18)
Faculty: Mini Med School (April 20)
Reviewer: Video Abstracts (October).
Contributions to Video Atlas of Endoscopy; 50+ videos
- 2014: Co-Chair: SAGES/ASMBS Hands On Course Bariatric Endolumenal Treatments
Faculty: SAGES/AHS Postgraduate Video-based Course: Ventral Hernia Repair-
Technical Considerations in Challenging Scenarios (April 3)

In 2007 he was the principal investigator on a SAGES research grant entitled *Extended Submucosal Tunneling as a Means of Safe Peritoneal Access for NOTES Procedures*. He was a Co-Investigator on a 2012 SAGES grant entitled *Anti-scarring Therapy to Prevent Stricture Following Endoscopic Esophageal Mucosectomy* (PI Marks). He has the principal investigator of a 2008 NOSCART grant entitled *Durability of the Self-Approximating Transluminal Access Technique (STAT) for Transgastric Organ Resection*. He has authored 9 manuscripts in *Surgical Endoscopy* and presented 18 abstracts at SAGES meetings and 4 at NOSCART meetings. He is proudly one of the first FES and FLS certified members of the society.

Joshua S Winder, MD: is a second year surgical resident at The Pennsylvania State University, College of Medicine who has recently applied for SAGES Candidate Membership. He will be attending the 2014 meeting in Salt Lake City, Utah as his first SAGES meeting.

Jerome R LynSue, MD FACS: was a candidate member of SAGES from 2007-2008 and has been an active member since that time. He attended the annual meetings in 2007 and 2013. He has co-authored 6 abstracts at SAGES meetings and one manuscript in *Surgical Endoscopy*. He is FLS certified.