Male and Female: Residents and Attending Obstetrician teams
used Polyurethane tipped retractors verses standard Kelly
retractors: a comparison of maximum forces during simulated
cesarean sections to the Bowel and soft tissues

Theodore M. Hale*, Vasiliy Stankovich, Gomez-Roberts, Hunter, Crystal Santiago, Isaac C. Boyack

*Lead corresponding author:

Dr. Theodore M. Hale, MD, MA North Central Bronx Hospital, Department of OBGYN 3424 Kossuth Avenue ,Bronx, New York ,10467

Telephone: 718-519-5000 E-mail: <u>Halet@nychhc.org</u>

Department of Obstetrics and Gynecology, Lincoln Medical Center, Weill Medical College of Cornell University, New York, NY, USA

Abstract

Background: The basis of this Safety study is discovering whether decreased maximum forces were applied when Male and Female, Resident and Attending Obstetrician teams—applied simulated retraction to the Bowels, Pelvic Sidewall, Liver and Bladder—with the use of a less rigid honeycomb attached retractor tip—as compared to bare standard. Kelly retractor. Our hypothesis was that a Silicone—Honey Comb tipped—retractors compared to Kelly, Deaver, Balfour—Stainless steel retractor alone—would generate less force and maintain—a fixed space between the tip of the blades to the Psoas muscles, Pelvic side wall, Bowel, Bladder, Liver, Major Blood Vessels and Nerves

Objective: To test a new honeycomb Kelly retractor ,Honey Comb tipped attachment for maximum force generated and compare it against a standard abdominal steel retractor maximum force generated during a simulated Cesarean Section.

Methods: After designing a polyurethane honeycomb retractor tip, we used a pelvic manikin model to simulate an Obstetrics Laparotomy Pfannensteil incision. Force and load sensors were attached to the distal inner aspect of the Kelly retractors. A Tekscan 201 (accurate for measuring 0–25 pounds of force) 0.375 inches flexible printed circuit was used that measured contact forces. A calibrated sensor recorded the force generated between the retractor and the pelvic sidewall.

Results: The mean maximum mechanical force applied to the pelvic sidewall was 1.90 pounds [range 1.3-2.8] for the retractor with a honeycomb polyurethane attachment versus 10.56 pounds [range 7.5-14.9] for the steel retractor [P=0.0029].

Conclusion: The polyurethane honeycomb attachment Tip applied 82% less overall mechanical force to the pelvic sidewall compared to steel retractors in a maximum Retraction during a simulated Cesarean section.

Introduction

Manual retraction or fixed retractors are used to improve exposure, Retract Bowel, bladder, Cecum, and further open wound site incisions applied to the pelvic side walls during cesarean sections. The Ideal safety condition is to retract under visualization by the assistant but some sometimes this is done blindly, even in best circumstances. Bare Stainless steel retractors are inserted within the abdominal incisions during Cesarean Laparotomy to forcibly enlarge the area of incision and facilitate access within the abdomen or Bladder. Rigid metal Kelly, Balfour or Deaver retractors and Balfour retractors formed from stainless steel are well known, having the advantage of being durable as well as easy to sterilize for repeated surgical procedures. The association of intraoperative neurologic injuries and Bowel Lacerations with surgical procedures is well established [7]. During typical use, Stainless steel retractors are placed at opposing edges of a linear incision and are opposed from each other to effectuate incision expansion. Metal retractors can be a cause for concern due to risk of trauma resulting in intraoperative compression, Stretch, entrapment and transection have all been implicated in the genesis of postoperative neuropathies, Ileus, Urine retention and even Bowel and Bladder perforations within soft tissue with its abundant network of vessels and nerves. Upper and lower extremity neuropathies are generally associated with patient and retractor positioning, while anterior abdominal wall and pelvic nerve injuries are more often associated with direct surgical trauma. Risk factors associated with persistent neuropathy include prolonged Labor ,Cesarean Hysterecomy , Abruptions , Obsterical Hemorrhage , Severe Preeclampsia, Hellp Syndrome , Macrosomia, Adhesions Intraluminal Appendix Fibrosis, Fibroids, steep Trendelenburg position, low or high BMI, and a history of smoking. Prospective data suggest the incidence of peripheral nerve injury ranges between 1.5% and 11.6%.[9-11].

Catastrophic injury during and after Cesarean Section have been reported with Rupture of Glisson's capsule 1 in 2000 patients [13], Rupture of Caecal (Ogilvie's syndrome) incidence in colonic pseudo obstruction is 3-40 percent with mortality from rupture of 40-50 percent [14]. The most common sites of potential catastrophic injury during a cesarean section is: Severe Ileus leading to Olivigues syndrome, Liver rupture Hemmorhage, and Bowel obstruction,

Femoral nerve injury during surgery is associated with fixed and hand held retractor. The pelvic blades of the retractor may exert compression on various nerves. Weakened muscles suggest that the nerve compression occurred intrapelvically [8]. Injury to the femoral nerve arising from L2 and L4 during laparotomy can cause significant complications from The femoral nerve compressed from the Retractor Blade in between Soft tissue and Boney tissues . femoral nerve injury and wound infections .

are the anterior surface of the psoas muscle Femoral nerve injury along the psoas muscle usually is attributable to direct compression of the femoral nerve from the blades of a self-retaining retractor. Illioinguinal and Iliohypogastric nerve injury has been reported in up to 3.7% of Gynecologic procedures performed through a Pfannenstiel incision [].Lower extremity neuropathies result from injury to branches of the lumbosacral nerve plexus. These include the ilioinguinal, iliohypogastric, lateral femoral cutaneous, femoral, genitofemoral, and obturator nerves. Of these, the femoral and obturator nerves have significant motor components. The femoral nerve, formed by the ventral rami of L2-L4, provides motor innervation to the anterior compartment of the thigh and sensation to the anterior thigh and medial leg. Femoral nerve injury during Cesarean procedures is believed to result from nerve compression by the lateral blades of self-retaining or even fixed retractors sometimes used .

The objective of this study is to test a new Flexible Abdominal Retractor for maximal force generated to the Pelvic side wall during a simulated Cesareans and to compare this to a similar shaped steel retractor. Decreasing pelvic sidewall pressure may help decrease pelvic nerve injuries. This abdominal retractor attachment is configured for maintaining access to the abdomen and pelvis during intra-abdominal surgery while minimizing excessive forces to the surrounding soft tissue, nerves and vessels

Materials and Methods

A simulated cesarean section was performed using an OB manikin model with a pelvic/abdominal incision [2]. For Maintaining equal testing conditions during cesarean simulation, a self-retaining Bookwalter retractor system was used with and without a honeycomb polyurethane attachment Hneycomb tips .The Lincoln Medical and Mental Health Center ObGyn Department staff performed the simulated surgeries. This was a prospective double-blinded study. The Cesarean Kelly blades were covered with surgical draping to keep participants blind. Each participant applied maximum force to the pelvic sidewall, using the same The Using a Bookwalter retractor ring to create an equal testing ground. The force was applied to the Cesarean Kelly Retractors for a timed 5 seconds using 4 fingers (not including the thumb) to the same side of the user side retractor and all force towards the base of each retractor blade. A sensor was used to determine the force generated [3]. The maximum force generated with the two retractors was

measured and recorded. Significance was calculated by Welch's two-tailed T-test for P value with confidence intervals.

The silicone consisted of a retractor blade shaped tip with an elongated flexible hexagonal honeycomb configuration, which was freely compressible and moldable to the shape of the surface with which it contacted [1, 4, 5, Fig C

Flexi force sensors were used to determine the amount of force generated. Flexi-force sensors are ultra-thin and have a flexible printed circuit [3, Fig B]. The active sensing area is 0.375 inches (9.53 mm) diameter at the end of the sensor. The sensors are constructed of two layers of substrate composed of polyester film. On each layer a conductive material (silver) is applied followed by a layer of pressure sensitive ink. The linearity is defined as the sensor's response (digital output) to the applied load over the range of the sensor. Error is less than +/-3% and drift was less than 5% per logarithmic time scale. Sensors were conditioned before calibration and testing, which helps lessen the drift [3]. Sensors were attached at the inner tips of the honeycomb retractor surface. The resistance was read by connecting a multimeter to the outer two pins, then applying a force to the sensing area. Five real-time recordings were made of simulated surgeries and were recorded on a digital movie program. An 8-bit application was used that was compatible with Microsoft Windows Tekscan ELF [3] and that was capable of storing the force data [Fig A].

Results

The results of force testing are shown in Table 1. The polyurethane honeycomb retractors mean maximum traction force at the pelvic sidewall was 1.9 pounds (1.3-2.8). The steel retractors mean maximum traction force at the pelvic sidewall was 10.56 pounds (7.5-14.9). The polyurethane retractor sample had a variance of 0.425 and stainless steel sample had a variance of 9.913. The difference was significant by T-testing P = 0.0029 with a polyurethane honeycomb absorption pad retractor 95% confidence interval of 1.09-2.71, and a stainless steel retractor 95% confidence interval of 6.65-14.47.

Table 1 Results of comparative forces generated by polyurethane and steel retractors

Polyurethane retractor	Stainless steel retractor
1.8	7.5
1.3	10.6
1.3	7.6
2.3	12.2
2.8	14.9

Discussion

The polyurethane honeycomb attachment pad applied 82% less overall mechanical force to the pelvic sidewall compared to steel retractors in a simulated pelvic surgery. By distributing the force over a greater surface area, pressure points are reduced or eliminated when the force is applied or exerted on the flexible surgical retractor with honeycomb pressure absorption Honeycomb tip. Accordingly, damage or injury to the underlying delicate tissues in the incision site subject to retractor force is likely reduced

A comparison of the variance of force generated between the two subsets studied showed a polyurethane retractor variance of 0.425 and a stainless retractor variance of 9.913. It is possible that the polyurethane honeycomb retractor decreases the wide range of forces applied by different surgeons as seen in the stainless steel retractor data set. Further analysis shows a gender discord solely within the stainless steel retractor study group; which further supports the idea that the polyurethane honeycomb retractor decreases the variance in forces applied by various surgeons regardless of gender or experience when using maximal force.

Intraoperative compression, stretch, entrapment, and transection of peripheral nerve fibers have all been implicated in the genesis of postoperative neuropathies. Upper and lower extremity neuropathies are generally associated with patient and retractor positioning, while anterior abdominal wall and pelvic nerve injuries are more often associated with direct surgical trauma..Prospective data suggest the incidence of peripheral nerve injury ranges between 1.5% and 11.6%.

Lower extremity neuropathies result from injury to branches of the lumbosacral nerve plexus. These include the ilioinguinal, iliohypogastric, lateral femoral cutaneous, femoral, genitofemoral, and obturator nerves. Of these, the femoral and obturator nerves have significant motor components. The femoral nerve, formed by the ventral rami of L2-L4, provides motor innervation to the anterior compartment of the thigh and sensation to the anterior thigh and medial leg. Femoral nerve injury during abdominal procedures is believed to result from nerve compression by the lateral blades of self-retaining or fixed retractors. Therefore, the shortest lateral blades should be used that allows a space between the tip of the blade and the psoas muscle. Surgical towels between the retractor and the anterior abdominal wall is needed to further elevate the blades in very thin patients, Therefore the provider should check if the tips of the lateral Blades were not resting on the Psoas muscles Unfortunately The use of moist laps have been reported to move during surgery .[9-11]

Three major factors that predispose to neurologic injury at the time of surgery are 1) the improper placement or positioning of self-retaining or fixed retractors, particularly those with deep lateral retractor blades; 2) improper positioning of patients in lithotomy position preoperatively; and 3) radical surgical dissection resulting in autonomic nerve disruption. Level I data strongly implicate the self-retaining or fixed retractors as the most common cause of femoral nerve injury arising in association with abdominal surgical procedures [7, 8]. The Honey Comb Tip generated less force in this study. It is important to consider the Silicon tips to improve safety in the Obstetrical patient when consider the complications of ruptured bowel, Liver Hemmorhage, and post op neuropathy, that to easily can occur in Obstetrics

References

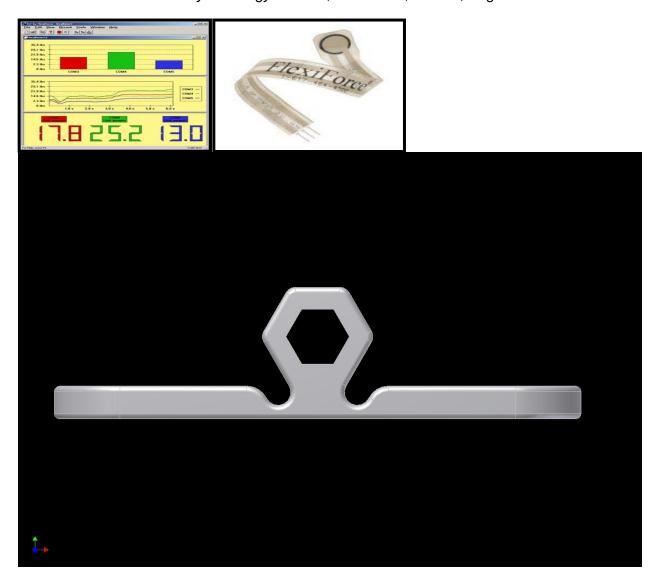
- [1] Hale: Flexible Surgical Retractor with collapsible Internal Chamber US Patent 8,529444B2 Obstetrical Retractor :September 2013
- [2] Obstetrics and Gynecology Manikin http://www.Similaids.com, 16 Simulaids Drive, Saugerties, NY 12377
- [3] Tekscan FlexiForce Standard Model A201; Tekscan FlexiForce Economical Load and Force Measurement (ELF)
- [4] Cad Model 1: Sidney Hale.
- [5] Cad Model 2: Rapid Die & Engineering, Inc, 2031 Calvin Ave, S.E. Grand Rapids, MI 49507.
- [6] Craig Prototypes: Definitive Design, 105 Corporate Dr, Langhorne, PA 19047.
- [7] Irvin W, Andersen W, Taylor P, Rice L. Minimizing the risk of neurologic injury in gynecologic surgery. Obstet Gynecol. 2004 Feb;103(2):374-82.
- [8] Maneschi F, Nale R, Tozzi R, Biccire D, Perrone S, Sarno M. Femoral nerve injury complicating surgery for gynecologic cancer. Int J Gynecol Cancer. 2014 Jul;24(6):1112-7.
- Irvin W, Anderson W, Taylor P, Rice L. Minimizing the risk of neurologic injury in gynecologic surgery. Obstet Gynecol 2004;103:374–82
- [9]. Bohrer JC, Walters MD, Park A, et al. Pelvic nerve injury following gynecologic surgery: a prospective cohort study. Am J Obstet Gynecol 2009;201:531.e1-7.
- [10]Bradshaw AD, Advincula AP. Postoperative Neuropathy in Gynecologic Surgery. Obstet Gynecol Clin N Am 37 (2010) 451–459
- [11] Rahn DD, Phelan JN, Roshanravan SM, et al. Anterior abdominal wall nerve and vessel anatomy: clinical implications for gynecologic surgery. Am J Obstet Gynecol. 2010 Mar;202(3):234.e1-5.

[12] AUJayaram P, Mohan M, Lindow S, Konje. JPostpartum Acute Colonic Pseudo-Obstruction (Ogilvie's Syndrome): A systematic review of case reports and case series. SOEur J Obstet Gynecol Reprod Biol. 2017;214:145. Epub 2017 May 2.

[13[] S, Dessole · G, Capobianco · P, Virdis Hepatic rupture after cesarean section in a patient with HELLP syndrome: a case report and review of the literature .Arch Gynecol Obstet (2007) 276:189–192

[14] Matthew D. Laskin, Karen Tessler, Sari Kives Cecal Perforation Due to Paralytic Ileus Following Primary Caesarean Section

Journal of Obstetrics and Gynaecology Canada, Volume 31, Issue 2, Pages 167-171



- Fig. A: This is the computer dashboard that recorded and graphed all pressure readings in pounds.
- Fig. B: The Tekscan flexi force sensor.
- Fig. C polyurethane honeycomb pelvic retractor cushion