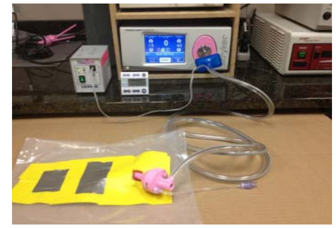
Unique Laparoscopic Access Port For Improving Gas Delivery, Quality and Surgical Outcomes

Douglas E. Ott, MD, MBA, Adjunct Professor Biomedical Engineering
Mercer University School of Engineering, Mercer University, Macon, GA

Background: Laparoscopic surgery is done with minimal access. This creates challenges for device safety, efficiency and design. To create a safe operating space in the abdomen carbon dioxide (CO_2) gas is instilled under pressure and flow restrictions. CO_2 is used because of its safety profile: being relatively inert, non-toxic, colorless, soluble in blood, cleared through the lungs and non-flammability. The gas is delivered at 20 degree (o) Centigrade (C) and bone dry having only 200 parts per million of water. Normal physiologic parameters are 37o C and wet. The surgical consequences of dry cold gas insufflation are: hypothermia, tissue desiccation, increased pain and inflammation and longer post-operative recovery. Humidifying and warming the gas to more normal physiologic conditions reduces these problems. The conventional method to fill a surgical space with gas is to use cannulas or hollow cylinders whose walls are continuous, smooth and uninterrupted top to bottom. This cannula design increases pressure drops and has a unidirectional delivery pattern with high velocity gas flow. These long standing problems and unmet needs to have laparoscopic gas delivered that maintains normal conditions of humidity and warmth with the lowest pressure drop, low velocity gas flow; radial dispersion without loss of cannula function is achieved with the Insuflow Synergy Port manufactured by LEXION Medical. This paper is a comparative analysis of traditional cannulas with a new perforated port design and the effects on gas flow dynamics, gas distribution, pressure drop and time to create a pneumoperitoneum.


Traditional trocars/cannulas tested and Synergy

Pressure drop testing



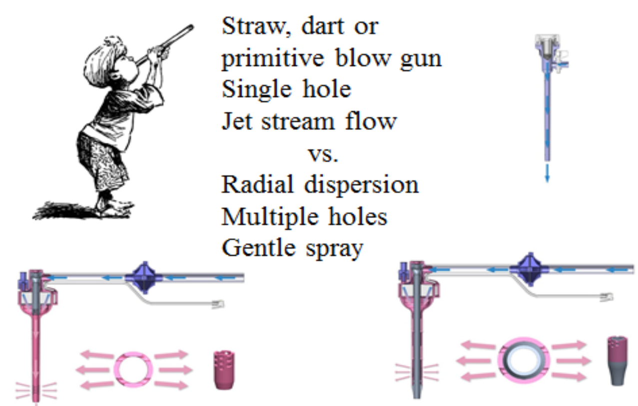

Gas dispersion analysis

Methods: The newly designed cannula was compared in laboratory and laparoscopic procedures with currently available conventional trocar/cannulas for performance and clinical outcomes. Performance tests were flow rate (filling rate and pressure drop), gas velocity, valve pressure leak test (no instrument vs. instrument presence), insertion force, instrument drag, fascial penetration force, facial retention and gas dispersive pattern. Dispersion pattern, percent area coverage of the pneumoperitoneum dome, pressure drop, digital mass flow and time to create a pneumoperitoneum were measured. A dispersion pattern was determined using aerosolized dye in a gas stream and evaluating the covered area in a pneumoperitoneum dome and percent area stained determined. Pressure drop testing involved testing each trocar connected to a regulated carbon dioxide gas source, linked to a rotometer and a digital mass flow sensor to measure flow in liters per minute. Time to create a pneumoperitoneum was determined by introducing the insufflation systems into a mock peritoneal cavity and timed filling to 3.5 liters (L).

Comparative analysis of an unobstructed conventional 5 millimeter (mm) cannula to a 5 mm cannula containing an instrument at a 3 L per minute flow rate changed terminal gas velocity from 6 to 25 meters per second (14 to 56 miles per hour). Flow rate was similarly decreased from 9.2 with an open cannula to 0.06 L per minute with an instrument in the cannula. The same evaluations with the newly perforated design cannula showed a statistically significant improvements ($p<0.01$) with higher flow rates (up to 78% improvement, 11.5 L per minute to 7.8 L without an instrument in the cannula and 11.5 L to 1.95 L with an instrument present), lower pressure drop (up to 70% improvement), higher pressure to prevent seal failure (84% improvement), higher max flow (up to 42% improvement), time to create a pneumoperitoneum (up to 84% improvement), and gas terminal velocity (up to 35% lower). The gas distribution pattern of conventional trocars was circular, uni-directional, constricted and covered less than 2 % of a 180^o pneumoperitoneum dome area. The perforated port covered 92% of the 180^o radius. This was done using three different insufflators and twelve different trocar/cannula devices to the Insuflow Synergy Port. Clinical evaluations compared intra-operative temperature drop (hypothermia), tissue desiccation, post-operative pain and post-operative recovery time were evaluated. This was done using three different insufflators and twelve different trocar/cannula devices to the Insuflow Synergy Port. Clinical evaluations compared intra-operative temperature drop (hypothermia), tissue desiccation, post-operative pain and post-operative recovery time were evaluated.

Results: The Insuflow Synergy port exceeded laboratory performance characteristics compared with conventional trocar/cannulas for filling rate, reduced pressure drop, lower gas velocity, valve pressure leak test (no instrument vs. instrument presence) and gas dispersive pattern. Other parameters were comparable. The Insuflow Synergy Port had statistically significant improved clinical outcomes compared to conventional trocar/cannula and insufflators. These include less hypothermia, less tissue desiccation and damage, decreased inflammatory response, decreased pain, less pain medication use, shorter recovery room time and less time until feeling normal again.

Interpretation: Carbon dioxide moisture and temperature characteristics effect clinical outcomes in laparoscopy. Delivering gas at 35^{o}C and 95% relative humidity improve clinical outcomes. Cannula design determines gas flow characteristics. Conventional trocar/cannulas result in increased pressure drops, restricted gas distribution in the pneumoperitoneum and longer time to create a pneumoperitoneum when compared to the Insuflow Synergy Port. The new port design with distal cannula perforations and internal channels has lower pressure drops, quicker surgical cavity fill time, almost complete pneumoperitoneum gas dispersion distribution, and the incorporation of a humidification warming means in the port has beneficial utility with significant improved clinical benefits for the patient.



You can see the difference
The peritoneum feels the difference
The patient experiences the difference




Summary: Changing gas quality to wet and warm and cannula design improves clinical outcomes by improving physical and mechanical restrictions for gas distribution pattern, flow rate, pressure drop and terminal velocity.