Improving Safety during Laparoscopic Surgery – A New Device to Minimize Exposure to COVID-19, HPV, and Carcinogens

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Introduction

Background:

- Particles may escape patients' bodies through trocar ports during laparoscopic procedures.
- COVID-19, HPV, and carcinogens are some of many hazardous particulates that may be aerosolized during procedures.
- Interactions between surgical instruments and trocar ports create additional gas leakage, suggesting a need for improved trocar sealing to further protect OR personnel.

Objective:

- Understand potential gas leakage during simulated surgical scenarios using commercially available trocars and instruments.
- Assess performance of novel technology to minimize gas leakage.

Concept

Design:

- The innovative Vulcan device incorporates a multiaxial dynamic seal inside of an adaptive elastic housing. The seal also adapts to instruments of various diameters/sizes.
- The versatile design enables Vulcan to reduce gas leakage seen by various instrument-trocar combinations (sizes & OEMs).

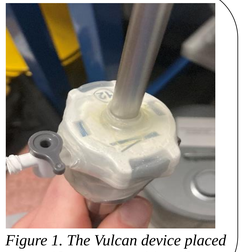


Figure 1. The Vulcan device placed over a 12mm trocar with a 10mm scope.

Conclusions

Results show that the Vulcan embodies notable versatility and adaptability with current OR instrumentation. Anticipated modifications on future prototypes look to offer substantial improvements to generate an even safer surgical environment for OR personnel.

Methods

Insufflation Testing:

- To measure the amount of leakage in commercially available trocars, a benchtop setup was used to simulate an insufflated surgical cavity.
- Four different trocars (5mm and 12mm Applied Medical and Ethicon), along with three scopes (one 5mm Stryker, and one 5mm and one 10mm Karl Storz), were tested for a total of 10 setup combinations. 3 setup combinations were tested with Vulcan to establish early efficacy data.
- Two repeatable testing scenarios were performed for each setup: a static "best-case" scenario (i.e. uncompromised seal and stationary instruments) and a dynamic "real-life" scenario (i.e. compromised seal and moving instruments).
- Each testing scenario was performed three times for each combination of instruments and the results were averaged.

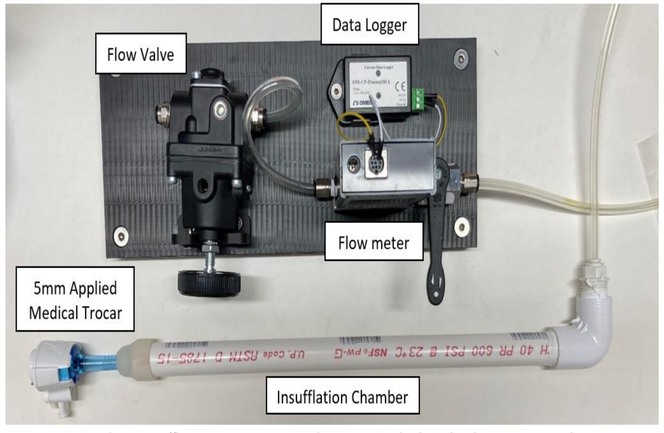


Figure 2. Benchtop insufflation testing setup with a 5mm Applied Medical trocar inserted.



Figure 3. 10mm Karl Storz scope undergoing static testing inside a 12mm Ethicon trocar with Vulcan attached.

Results

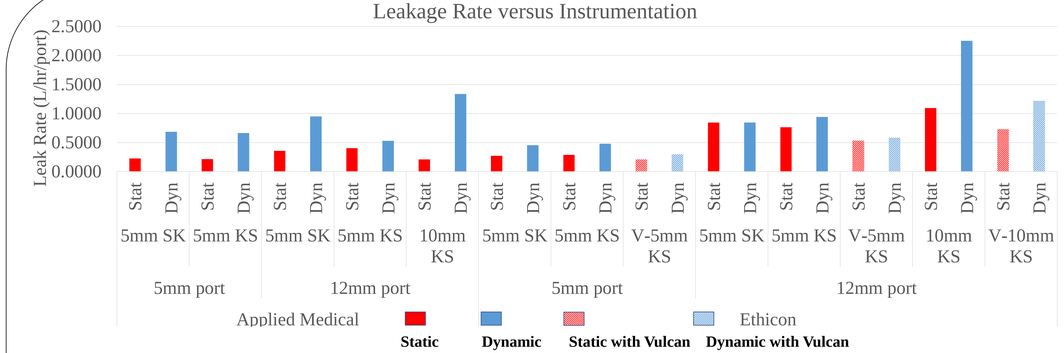


Figure 4. Insufflation Testing Data for various instrument-trocar combinations

- Data from the graph above shows larger leak rates in larger trocars independent of instrument sizes.
- Vulcan (V) was tested on three configurations and shows notable leak mitigation performance.

	Vulcan/ No Vulcan Ratios		Vulcan Leak Reduction (%)	
Configuration	***Static/ Static***	***Dynamic/ Dynamic***	***Static***	***Dynamic***
Eth, 5mm- KS, 5mm	0.71	0.63	28.56	37.47
Eth, 12mm- KS, 5mm	0.69	0.62	30.52	38.05
Eth, 12mm- KS, 10mm	0.67	0.54	33.12	45.87

Table 1. Insufflation Testing results for Vulcan versus non-Vulcan for three scenarios.

- Vulcan reduced gas leak rates by nearly 30%+ in each use case, with particularly more impressive leak reduction when used in conjunction with larger instruments/ports.