

Prospective, Randomized Comparison of the Use of the FloShield® System versus Clearify™ Visualization System (D-HELP) during Laparoscopic Surgery to Evaluate the Operative Interruption for Lens Cleaning

Tayyab S. Diwan, M.D.¹, Juan Carlos Verdeja, M.D.², K. Warren Volker, M.D.³

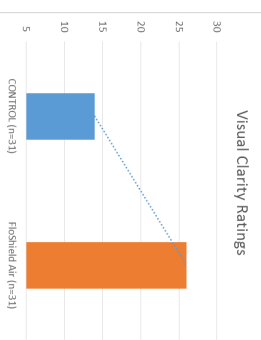
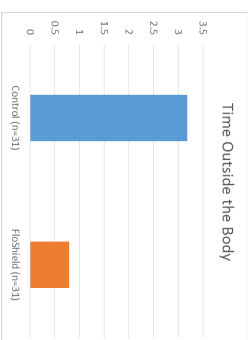
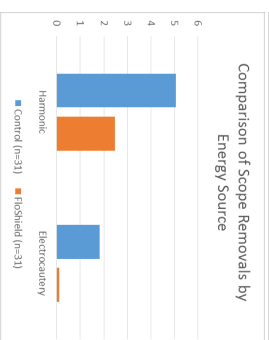
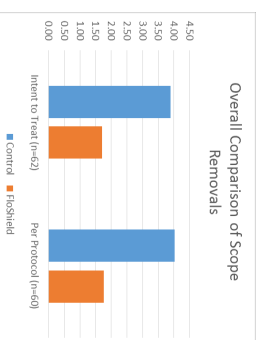
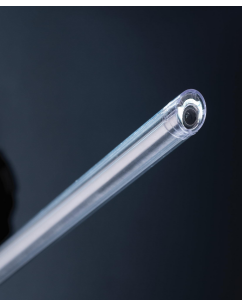
¹University of Cincinnati, Division of Transplantation; ²South Miami Hospital; ³Centennial Hills Medical Center

OBJECTIVE OF THE FLOSHIELD DEVICE:

- Facilitate intra-operative defogging and deflection of debris from the lens of a laparoscope.
- Significantly reduce laparoscope removals for cleaning/defogging, therefore minimizing surgical interruptions.

DESCRIPTION OF THE TECHNOLOGY AND METHOD OF USE

- A multi-lumen sheath assembly that mounts over shaft of laparoscope.
- Pre-connected tube set connects device to existing CO₂ insufflation circuit.
- CO₂ is directed through device and forms a vortex of gas in front of the scope lens - preventing significant accumulation of condensation.
- Continuous flow and velocity of CO₂ across the lens helps deflect smoke and surgical debris from the lens during surgery.



PRELIMINARY RESULTS USING FLOSHIELD

- Statistically significant reduction in laparoscope removals in both the Intent To Treat and Per Protocol populations (56.4% reduction, p = 0.0207) (56.2% reduction, p = 0.0194) vs. control.
- Statistical significance regardless of energy type used; 95% reduction (p = 0.0035) in scope removals with electrocautery, and a 51% reduction (p = 0.0482) with harmonic.
- Scope was outside the body an average of 2.39 minutes less with FloShield than control (statistically significant, p = 0.0294).
- On a scale from 1 to 5 (1=poor, 5=excellent) surgeons rated FloShield as a 5, 1.9 times more often than control when looking at these factors collectively:
 - overall video clarity
 - consistency of video clarity
 - ability to see tissue planes

CONCLUSION

FloShield significantly reduced the need to remove the laparoscope during surgery for purposes of cleaning/defogging as compared to a commonly used defogging device. The reduction in laparoscope removals with FloShield has the potential to increase OR efficiency through reducing surgical interruptions and improving video clarity.

