White Paper Series: *Efficiency and Vision During Laparoscopic Surgery*

Decreased Need to Interrupt Surgery to Clean the Laparoscope During Laparoscopic Cholecystectomy using the FloShield™ System

Abstract: A prospective randomized trial was performed in 28 patients to identify whether FloShield™ would reduce the need to interrupt surgery to clean the lens even in a routine and rapid laparoscopic procedure. In this limited analysis study FloShield™ produced a 90% reduction in the need to interrupt the procedure to clean the lens.

The Problem

The insertion of a cold laparoscope into the abdominal cavity results in condensation on the end of the scope obscuring vision. Heat will also conduct up through the shaft of the steel laparoscope resulting in fogging even though initially a warm scope was introduced into the cavity. Debris floating within the inflated abdominal cavity, and especially mist or smoke generated by energy cutting or cautery devices will also result in deposition on the lens and a diminished view.

The problem is currently managed in a variety of ways, none of which are effective at keeping the lens clean without interruption. Hot water may be used to warm the lens to inhibit fogging, but this requires that the scope be rapidly reintroduced. If the trocar seal then needs cleaning, the cycle must be repeated over again. Anti-fog liquids have surface properties that may prevent condensation, but will not work effectively unless the are allowed to dry on the lens surface before the lens is introduced, which wastes time

Debris on the lens may be cleaned off by wiping the end against abdominal viscera, but this may frequently result in a "smear" on the end of the lens. A surgeon may keep working through the resultant "haze," just to keep the operation proceeding. Alternatively, the lens may of course be removed, cleaned, re-warmed, and then reinserted. An experienced OR team may make quick work of that transition, but camera holders that are less experienced may find that task time consuming. Finally, it is common for trocar seals to deposit debris on the end of the laparoscope during re-introduction, which OR staffs find particularly irritating.

Study Premise

FloShield™ is a disposable device that prevents debris or fog from attaching to the end of the laparoscope by creating an invisible air-curtain effect at the terminus of the scope. This paper considers the ability of the device to decrease interruption of the surgical procedure for cleaning during routine and rapid laparoscopic cholecystectomy.

Study Design

28 patents were randomized to use of FloShield™ or not. Exclusion criteria were limited to previous upper abdominal surgery. The study was IRB approved and all patients consented. A dedicated observer measured the duration of surgery and the number of times the procedure was interrupted to clean off debris or remove fog. All surgeries were performed by two different surgeons (randomized to both) at Riverside Methodist Hospital in Columbus, OH.

Results

25 patients had evaluable data, 14 without the use of FloShield™ and 11 with the device. Three patients were excluded due to open conversion based upon intraoperative findings. Surgery with FloShield™ was interrupted for cleaning an average of 0.25 times, or once every four surgeries. Without the device surgery was interrupted an average of 2.43 times per surgery. Duration of surgery was the same in each group and averaged 29 minutes.

Analysis

FloShield™ is a device intended to decrease the need to interrupt surgery to clean the lens, which is commonly performed by lens removal, or in some cases, by wiping the lens against abdominal viscera. In other analysis, such as laparoscopic gastric bypass, the device has been demonstrated to produce OR time savings.

FloShield™ is anticipated to be of benefit in complex laparoscopic procedures such as gastric bypass, colon resection, Hysterectomy, and Nephrectomy, among others. In this analysis gall bladder surgery was chosen to rapidly accumulate data and see if even in a relatively simple procedure whether the device would decrease the need to remove the lens. It deceased lens removal, but did not impact the overall time of a procedure that averaged only 29 minutes.

Conclusion

FloShield™ functions by producing an invisible curtain of air over the surface of the distal end of a laparoscope to prevent fogging and deflect aerosolized particles from attaching to the lens. In this analysis of patients undergoing L/S cholecystectomy it decreased the need to interrupt surgery to clean the lens by 90%