

A WIRELESS SURGICAL CAMERA ELIMINATES RISKS ASSOCIATED WITH HIGH INTENSITY LIGHT SOURCES & FIBER OPTIC CABLES USED FOR VISUALIZATION IN MINIMALLY INVASIVE SURGERY

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BACKGROUND

Minimally invasive surgery (MIS), performed through a natural orifice or several small incisions, is associated with decreased pain, shorter hospital stays, and improved accuracy. The success of MIS is dependent on visualization of the surgical field. A traditional system for visualization consists of an endoscope, camera, and a LED illumination source that transmits light to the camera via a fiber optic cable. The inefficiency of LED light transmission through fiber optic cables has historically required the use of a high intensity light source to provide adequate illumination. At least 80% of this light is lost during transmission, released as thermal energy, and creating a fire or burn risk to patients and medical personnel.

MATERIALS & METHODS

To examine risks encountered during MIS where the surgical drape is exposed to high intensity light via a fiber optic cable, several scenarios were examined at the Computational Fire Dynamics (CFD) Lab at Case Western Reserve University (CWRU). The setup consisted of a Stryker L9000 300-Watt LED Light Source (100% brightness), Stryker Clear Case Fiber Optic Light Cables, an Arthrex 4mm 30° Arthroscope, and Cardinal Health Three-Quarter Sheet folded into 4 layers (surgical drape). An NI 9211 thermocouple input module with K-Type 0.51mm Omega SCASS-020G-6 thermocouples measured temperatures every 0.5 seconds. Lastly, the traditional system was compared to the ArthroFree Wireless Surgical Camera.

RESULTS

TRADITIONAL MIS SYSTEMS

Layout 1 measured the maximum temperature attainable by a high intensity light source using an Aluminosilicate Refractory Ceramic Fiber Board as an insulating material, preventing heat dissipation. A fiber optic light cable was held vertically, in direct contact with a thermocouple and fiber board to measure the temperature at the tip. The temperature at the tip increased to to 60°C within 0.5 s and 90 °C within 1.0 s, increasing at a maximum rate of 62°C/s. The temperature continued to increase at a logarithmic rate until reaching 369 °C, where it begins to taper (**Figure 1**).

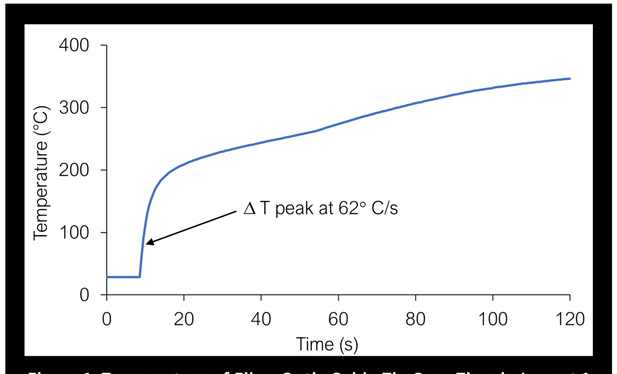


Figure 1. Temperature of Fiber Optic Cable Tip Over Time in Layout 1

Layout 2 examined temperatures achieved when the fiber optic cable is connected to a rigid arthroscope at a 30° angle, with the tip of the arthroscope in contact with a surgical drape on a ceramic fiber board (non-refractory). A thermocouple found temperatures at the tip of the arthroscope to be significantly lower than the fiber optic cable **(Figure 2)**.

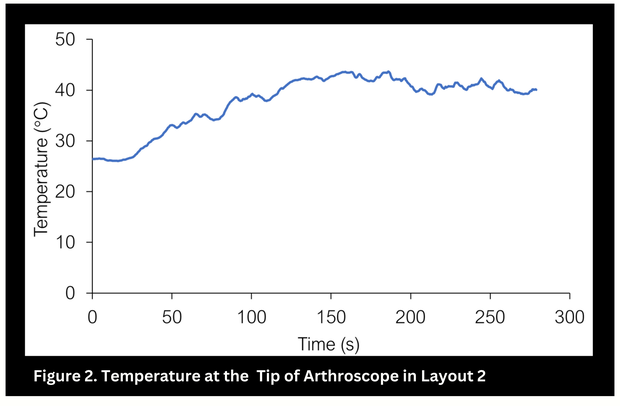


Figure 2. Temperature at the Tip of Arthroscope in Layout 2

Layout 3 examined a "worst-case" scenario where a fiber optic cable was held vertically, with the tip in direct contact with a surgical drape. Two thermocouples were attached to the outside of the cable: one 5 mm away from the tip (TC1) and the other, 10-12 mm further away (TC2). The temperature rises at a logarithmic rate with the temperature at TC2 found to be significantly lower than the temperature at TC1 (**Figure 3, left**). Additionally, **Figure 3 (right)** shows the damage inflicted to a drape and ceramic fiberboard ("representative of tissue") by direct exposure to the tip of the fiber optic light cable. All four layers of surgical drape were melted, and the heat further penetrated the ceramic fiberboard beneath.

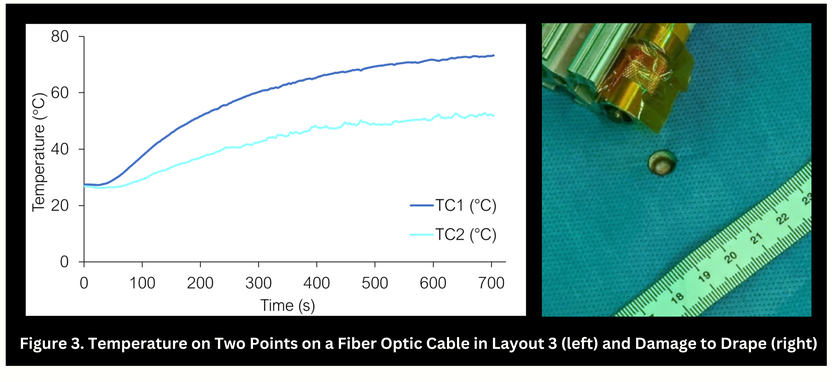


Figure 3. Temperature on Two Points on a Fiber Optic Cable in Layout 3 (left) and Damage to Drape (right)

ARTHROFREE WIRELESS SURGICAL CAMERA

A fully charged battery pack was inserted into the ArthroFree handheld camera device. Temperature probes were placed on to the surface in four locations (light source, C-mount camera connector, battery compartment, and body of the handheld device). Temperatures were recorded in 10 minutes intervals for the duration of the time required to deplete two fully charged batteries. Testing was repeated with three devices. The maximum overall temperature reached anywhere on the surface of the ArthroFree System was 43.0 °C, reached after 130 minutes (**Figure 4**).

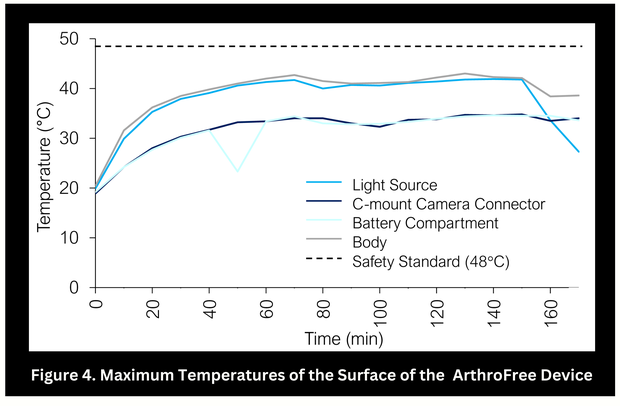


Figure 4. Maximum Temperatures of the Surface of the ArthroFree Device

CONCLUSIONS

The risks presented by use of a traditional MIS System are woefully understated by medical device manufacturers in printed warnings and device documentation. Several studies have examined these risks and concluded that extensive education and training is the best approach to reducing them. Policies and procedures intended to address these risks have been established in hospitals and surgery centers, however, this approach is not comprehensive and does not take the likelihood of human error in consideration.

According to ISO 60601-1 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), the maximum temperature allowable for medical electrical equipment that comes into skin contact for >1 minute is 48 °C. This study demonstrated multiple scenarios where temperatures exceed these limits. Once the light source has been activated, the tip of the cable can quickly exceed 350 °C with the housing exceeding 75 °C, creating fire or burn risks in the operating room. Such scenarios are most likely to occur due to surgeon error, if the fiber optic light cable were placed on top of the patient while switching instruments or moving to the next step in a procedure.

Furthermore, this study demonstrated that unlike the high intensity light sources of traditional MIS systems, the ArthroFree Wireless Surgical Camera System never reaches temperatures high enough to damage human tissue or surgical drapes and offers a much safer alternative to the systems currently in use.