

GENERAL SURGERY NEWS

Solving the Costly, Deadly Issue of Indwelling Catheter Infections

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This article seeks to provide a solution to the following question: What's new in medicine to solve the costly, deadly issue of indwelling catheter infections?

Hospital-associated infections (HAIs) are the most common and preventable complications in healthcare today. Each year, \$28 billion to \$48 billion is spent on HAIs in the United States alone (Infect Drug Resist 2018;11:2321-2333). For patients who are immunocompromised or have organ failure, this all-too-common complication often proves fatal. Compounding the problem is the increased use of antibiotic and fungal medications, leading to the emergence of new pharmacologic-resistant organisms, which increases mortality for all of society. In fact, antibiotic resistance is now the third-leading cause of death worldwide.

Fortunately, the COVID-19 pandemic has catalyzed a paradigm shift from in-hospital and clinic care to in-home care with telemedicine assistance, increasing the number of medical professionals advocating for telemedicine assistance for their practice and patients. One critical step forward has been the recent relevant legislative changes.

For example, in 2019, an executive order, "Advancing American Kidney Health Initiative," created the goal of having 80% of end-stage renal disease (ESRD) patients either be on home dialysis or receive an organ transplant by 2025 (<https://trump-whitehouse.archives.gov/presidential-actions/executive-order-advancing-american-kidney-health/>).

The push to have patients treated at home, along with new telemedicine regulations, allows for the needed expansion of doctor/patient access. However, the shift to in-home care will not succeed if the risk for catheter-associated infections is not reduced. These infections place unacceptable stress on the medical system financially and on patients' quality of life. This problem cannot continue.

Critical Challenges for the Healthcare Provider

Some of the key challenges currently facing healthcare providers, particularly those who treat patients with ESRD, are listed here:

- Each year, there is an increased number of people with organ failure, specifically ESRD patients who require multiple types of indwelling catheters.

- There are unacceptably long transplant waitlist times. For example, over the past decade, Utah has seen an increase in wait times for a kidney transplant from less than two years to more than four years.

- Organs are now shared nationally to help equalize wait times for transplants, which increases the length of time patients are on dialysis in many parts of the country, thereby increasing the risk for infection.

- Due to COVID-19, dialysis centers have become a petri dish for multiple infections.

- The Centers for Medicare & Medicaid Services (CMS) has imposed significant financial penalties for HAIs, yet there is no readily available infection prevention technology.

- For peritoneal dialysis (PD) catheters and tunneled dialysis lines, the question is not if, but when patients will get infected.

- The ESRD population is aging, with accompanying comorbidities, consequently increasing the prevalence of central venous catheter utilization.

- Increasing incidence of acute kidney injury leads to ESRD, and therefore increases the prevalence of central venous catheter utilization.

Is Visible Light-Based PhotoDisinfection Technology The Answer?

Technology Review

- The Light Line PhotoDisinfection System (System), developed by Light Line Medical, Inc., uses visible light (violet/blue, not ultraviolet [UV]) to disinfect catheters, thereby reducing pathogens that cause PD and hemodialysis catheter-associated infections, urinary tract infections, bloodstream infections, and ventilator-associated pneumonia. As shown in the Figure, the System consists of a reusable light engine that delivers visible light to a fiber optic placed in an off-the-shelf catheter. The fiber optic, which is modified pursuant to a proprietary process, disinfects the catheter by precisely emitting light inside and outside the treatment area of the catheter. Light Line is completing testing in preparation for the device's FDA clearance, first in a PD catheter, to be followed by urinary, respiratory and vascular catheters.

- Visible light requires longer durations of time than UV light to kill pathogens; however, its unique mechanism of action allows consistent dosing over extended periods for infection prevention across the device's lifetime. Significantly, unlike UV light, visible light is a safe option because it does not harm human tissue and does not compromise the structural integrity of catheter materials.

- Light Line Medical is currently investigating the delivery of high-intensity energy for shorter durations (as few as 15 minutes) in a simulated PD catheter environment. The light is delivered while the patient is draining fluid from the abdomen, prior to replacing it with new fluid. This shorter duration for the PD patient is important because it would avoid adding any more time to the patient's treatment.

Evidence Review

Visible light's (405 nm) antimicrobial efficacy has been established for decades. Its effectiveness inside a catheter has been empirically demonstrated by Light Line Medical both in vitro in the laboratory and in vivo experiments via two small animal studies in swine and ovine models. Light Line Medical has achieved statistically

significant bacterial reduction in the following five species: *Streptococcus pneumoniae*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *S. epidermidis*, with results from four of these species published in two peer-reviewed journals (*Lasers Surg Med* 2016;48[3]:311-317; *J Surg Res* 2016;206[2]:316-324). Light Line Medical has even killed 100% of some microbes, including *E. coli*.

Light Line Medical recently achieved a significant milestone by verifying the antifungal effectiveness of its PD PhotoDisinfection System. Tests conducted by a GLP [Good Laboratory Practice]-certified laboratory using the System in a simulated PD environment resulted in the complete killing of *C. albicans*—the hardest microbe to kill—in only 35 minutes.



The Light Line Peritoneal Dialysis PhotoDisinfection System



Summary Benefits of the Light Line PhotoDisinfection System

This technology:

- If successful at reducing air and touch contamination, it stands to reason it will provide proactive line protection for catheters (PD, urinary/Foley, central venous lines, endotracheal tubes and more);
- If successful at reducing air and touch contamination, it stands to reason it will reduce infection, thereby extending the indwelling life of catheters (it may ultimately treat infections, but Light Line's current focus is on prevention);
- Reduces or eliminates the need for costly prophylactic protocols that replace catheters based on dwell time;
- Eliminates fear and increases confidence of patients and medical providers of home ESRD treatments by reducing infections and extending the life of catheters;
- Helps avert the growing antibiotic resistance crisis that is now the third-leading cause of death worldwide;
- Reduces healthcare costs associated with all of the above;
- Ultimately saves lives by creating a safe at-home medical environment, especially for patients waiting on the list for organ replacement therapy; and
- Increases confidence of patients, which may alleviate psychological barriers to the use of home dialysis.

Conclusion

The Light Line PhotoDisinfection System is game-changing technology, positioned to revolutionize how the global healthcare system prevents and treats catheter-associated infections. Visible light is harmless to the patient, lengthens the catheter's lifespan, and successfully kills bacteria and fungi that cause catheter-associated infections. As a consequence of the COVID-19 pandemic, medical professionals have begun to recognize the significant benefits for patients and the reduction in costs that a shift to home care and telemedicine can bring. However, this shift will only be successful if healthcare providers have confidence that the systems ensuring patient safety standards at home rival or surpass those in a medical facility.

This paper asserts that one pathway to achieve this goal is the Light Line PhotoDisinfection System. It is a safe, inexpensive and user-friendly technology, with numerous studies demonstrating it will significantly decrease infections.

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Dr. Campsen reported that he serves as an un-paid clinical advisor to Light Line Medical, Inc.