

FORCED-AIR WARMING IN ORTHOPEDIC SURGERY: BENEFIT OR DANGER?

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Do popular forced-air warming (FAW) devices used during surgery increase or decrease the risk of deep infection following orthopedic implant procedures? What does the published research reveal?

This analysis is specific to orthopedic implant surgery because of the difference between soft-tissue surgical site infection (SSI) and peri-prosthetic joint infection (PJI). The implantation of foreign material in the body fundamentally changes the pathophysiology of the infectious process. An inoculum of more than one million bacteria is required to cause a soft-tissue SSI, and the bacteria usually enter the wound from the adjacent skin or cut bowel.¹ In sharp contrast, it has been shown that a single bacterium can cause a PJI, and it usually enters the wound as airborne contamination.² A detailed explanation of the difference between SSI and PJI, and the role of biofilm, can be found at stopsurgicalinfections.org.³

No research has ever been conducted regarding the benefit (if any) of FAW in orthopedic implant surgery. The research cited by 3M, manufacturer of Bair Hugger, does not address orthopedic risks, yet it continues to be used to defend safety. Five recently published studies, on the other hand, have specially addressed the risks created by FAW convection currents.

Interest in this safety topic is intensifying. ECRI Institute released a guidance stating that the convection currents created by FAW were “especially concerning” during orthopedic implant surgery.⁴ Law firms are soliciting patients that have suffered infections following joint-replacement surgery, and one Texas patient has already sued 3M/Bair Hugger for causing his devastating hip infection. This analysis examines the research cited by each side of the argument.

EVIDENCE CITED BY 3M TO PROVE FORCED-AIR WARMING SAFETY:

Proving safety would require establishing that Bair Hugger is *never* unsafe during orthopedic implant surgery. At minimum, the manufacturer must do a large randomized controlled trial (RCT) that proves no negative effects in joint replacement surgery.

Instead, 3M and other advocates of FAW routinely cite to the following six studies:

1. Kurz, *NEJM*, 1996⁵

This is the seminal study showing that patient warming reduces soft-tissue wound infections. Kurz showed a 3x reduction in SSI rates for patients warmed versus not warmed during colorectal surgery. This study does not address the risk in orthopedic implant surgery.

Once again, soft tissue infections, such as those following colorectal surgery, have vastly different mechanisms for infection than those involving implanted foreign material. These infection types can not be compared.

2. Melling, *Lancet*, 2001⁶

This study only examined the effects of prewarming the patient or the surgical site prior to short surgeries. It does not include intraoperative warming, much less orthopedic implant surgery. The study is simply irrelevant to the issue of safety in orthopedics.

3. Barie, *Surgical Infections*, 2001⁷

This review article merely cites the previous two articles by Kurz and Melling. Because the two studies summarized are irrelevant, so is this article.

4. Huang, *Critical Care*, 2003⁸ and

5. Moretti, *J Hospital Infection*, 2009⁹

Both studies are culture plate studies that look at a single spot in the operating room at two points in time. The hot air thermals produced by FAW waste heat that carry contaminants from the floor are variable and may not be in the single location being measured. The same is true of the floor-level contamination that may be aerosolized. Testing at a single location can easily produce a false negative. Culture plate results do not equate to wound contamination or infections.

6. Sessler, *A&A*, 2011¹⁰

The deficiencies of this study are many and complex. A full analysis may be found at hotdog-usa.com. In short:

- The authors did not add tracer particles to the waste heated air. Absent particles, the waste heated air couldn't possibly be detected by a particle counter.
- The surgical set-up was manipulated to vent waste heat to an area where researchers did not measure particles.
- The authors did not follow the DIN standard as they reported (only 1 of 6 tests was completed and not the appropriate ones).
- Section 6.8 of the DIN standard specifically forbids the use of devices that cause convection currents in a laminar flow OR [forced-air warming].

EVIDENCE SHOWING THE DANGER OF FORCED-AIR PATIENT WARMING:

In order to prove that a device is unsafe, one simply has to show that the device *sometimes* puts patients at unnecessary risk. The burden of proof to show *risk* is very low. Five peer-reviewed, published studies show that FAW contaminates the sterile surgical field with bacteria-laden floor air:

1. McGovern, *JBJS-Br*, 2011 ¹¹

Orthopedic surgeons studied the effects of FAW and conductive fabric warming during hip replacement and lumbar spinal procedures.

“Excess heat from FAW resulted in the development of hot-air convection currents between the surgeon’s body and the operating table, that transported [contaminated] floor-level air upwards and into the surgical site.”

Discontinuing the use of FAW resulted in a 74% reduction in peri-prosthetic joint infection rate (3.1% → 0.8%) p=0.024, 1437 patients, 2.5 years.

2. Legg and Hamer, *Bone and Joint Journal*, 2013 ¹²

In knee replacement surgery, orthopedic surgeons found that the “...waste heat from the poorly insulated forced-air warming blanket increased the air temperature on the surgical side of the drape by >5°C. This created convection currents that rose against the downward unidirectional airflow, causing turbulence over the patient.”

The convection currents increased the particle concentration 2000-fold (2,174,000 particles/m³ for FAW vs

1,000 particles/m³ for air-free conductive fabric warming) by drawing potentially contaminated particles from below the operating table into the surgical site.

“...[FAW]...can significantly disrupt unidirectional air flow and draw particles from the potentially contaminated area below the sterile field. This is a concern.”

3. Legg, *JBJS-Br*, 2012 ¹³

“[FAW] resulted in a significant mean increase in the temperature (1.1°C vs 0.4°C) and the number of airborne particles (1038.2 vs 274.8) over the surgical site when compared to radiant warming [or control], which raises concern as bacteria are known to require particles for transport.”

4. Belani, *A&A*, 2012 ¹⁴

“[FAW] was found to establish convection currents that mobilized resident air from the nonsterile areas upward and into the surgical site. The clinical concern is that convection currents may mobilize underdrape contaminants into the surgical site...”

5. Dasari, *Anaesthesia*, 2012 ¹⁵

“With [FAW], mean temperatures were significantly elevated over the surgical site vs those measured with the conductive blanket (+2.73 (0.7)°C...”

“We conclude that [FAW] generates convection current activity in the vicinity of the surgical site.”

CONCLUSION

Showing that a device is unsafe is a much lower hurdle than proving safety: if a device *sometimes* puts patients at unnecessary risk, it is unsafe in those situations. In contrast, standards are much higher for proving that a device is universally safe. Given that all of the studies cited by 3M are either irrelevant or poorly designed, it is impossible for FAW to claim safety in orthopedic implant surgery. Although there is only one study positively linking FAW to infection, five studies clearly prove increased airborne contamination of the sterile surgical field when FAW is used. Increased airborne contamination has been linked to increased PJIs for decades. Due to the pathophysiology of the infectious process in surgeries involving implanted foreign materials—where airborne contaminants significantly increase the risk of developing complicated infections—FAW is unsafe and should not be used. Air-free warming alternatives do not present the same risks.

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