Patient Warmings' Role in Orthopedic Infection Reduction

Becker's ASC 2017

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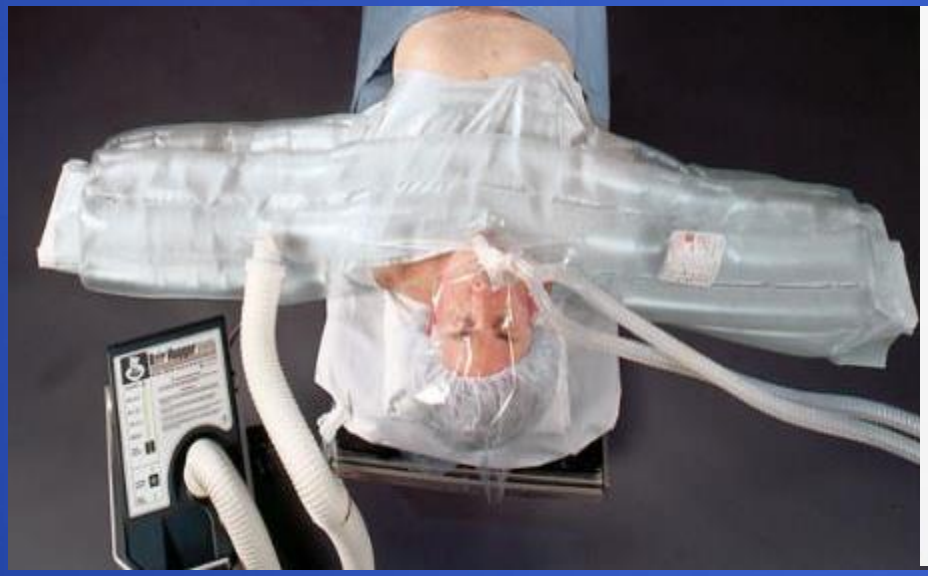
Disclosure Statement of Financial Interest

I, Scott Augustine, do have financial interest/arrangement or affiliation with one or more organizations that may be perceived as an apparent conflict of interest in the context of the subject of this presentation; these include:

Affiliation/Financial Interest	Name of Organization
Owner	Augustine Temperature Management
Equity Position	

Conflict of Interest Disclosure



Bair Hugger® Warming

Augustine Medical Inc.
Arizant/3M

1000 watts, 40 CFM air

HotDog® Patient Warming

Augustine Temperature Management LLC.

200 watts, 0 CFM air

Learning Objectives

This presentation will enable participants to:

1. Understand the benefits of patient warming in preventing soft tissue infections.
2. Understand the difference between soft-tissue infections and periprosthetic joint infections.
3. Understand the consequences of periprosthetic joint infections.
4. Understand the CDC warning: Do not use *any* equipment that blows air in the OR.

Learning Objectives

5. Understand how operating room ventilation is designed to prevent bacteria from rising from the floor and contaminating the surgical field.
6. Understand how convection currents of waste forced-air warming heat disrupt OR ventilation airflow, contaminating the sterile surgical field and increasing the risk of PJI.

Periprosthetic joint infections and how anesthesia equipment is causing them.

Importance of Patient Warming

- Warm patients do better than cold patients!
- The benefits of patient warming include:
  - Reduced wound infections (soft tissue)
  - Reduced blood loss
  - Reduced cardiac events
  - Lower mortality rates
  - Shortened hospital stays
- Active warming is now the "standard" set by: Medicare, SCIP, PQRS (US), NICE (UK)

Common Patient Warming Methods

- Water-based systems
  - *History*
- Forced-Air Warming (FAW)
  - *Soon to be history*
- Electric warming
  - *The future*

Normothermia's Role in Preventing SSIs (Soft-Tissue Infections)

- Kurz et al reported a 66% reduction in wound infections during colon surgery, when the patients were warmed to normothermia with FAW (compared to 2°C hypothermic, non-warmed control patients). *NEJM*
- Warm patients have fewer soft tissue infections.
- Corroborated by Melling (breast and hernia)

Different Kinds of Infections "SSI" vs. "PJI"

- Common mistake: lumping the varieties of infection together—causes confusion
- The term "SSI" is reserved for soft-tissue infections
- SSI must be differentiated from Periprosthetic joint infections ("PJI")* that can occur after total joint replacement surgery

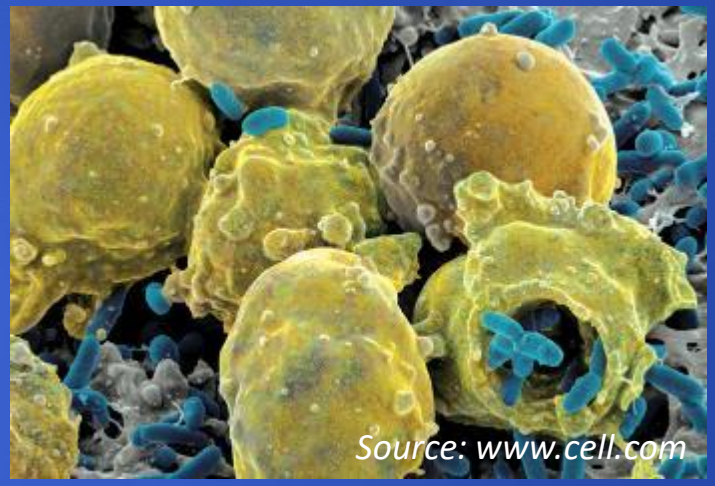
*Also known as Deep Joint Infections ("DJI")

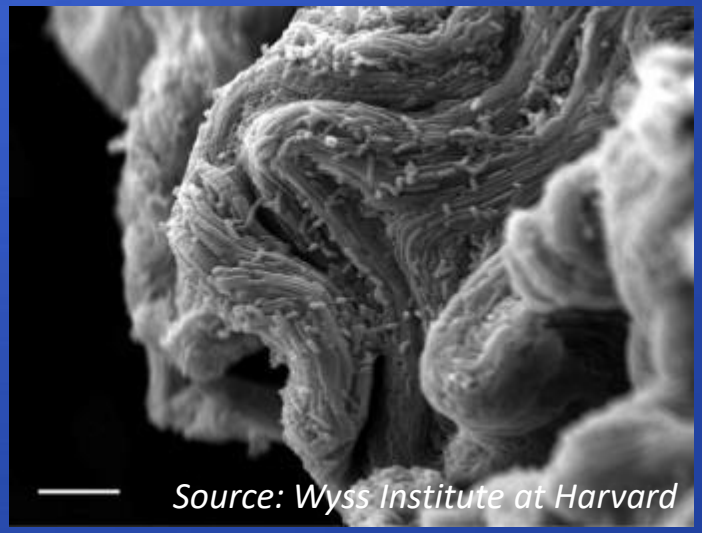
The Infectious Process

- Implanted foreign materials fundamentally change the pathophysiology of the infectious process:
  - An inoculum of more than one million bacteria are required to cause an SSI.[7]
  - A *single* bacterium can cause a PJI, and it usually enters the wound as *airborne* contamination.[8-10]

How can 1 germ cause a PJI?

- It's all about *biofilm*.[11]
- In the presence of an implanted foreign material, the bacterium produces a coating of exopolysaccharide material.
- Biofilm effectively protects it from antibodies and antibiotics.





No Biofilm in Soft-Tissue

- In contrast, bacteria cannot produce effective biofilm in soft tissue.
- Exposed to both antibodies and antibiotics.
- Since it takes more than a million bacteria to cause a soft tissue SSI, the airborne contamination in the operating room is virtually irrelevant for soft tissue SSIs.

SSI vs PJI

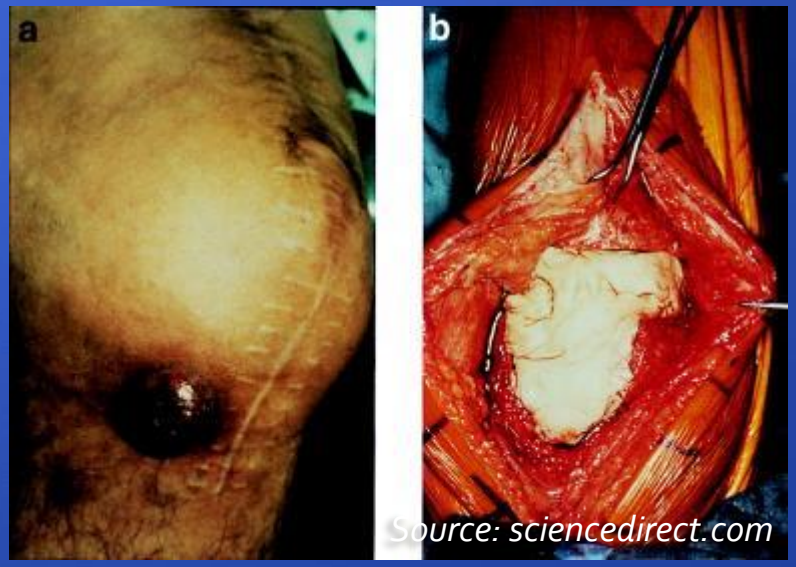
- SSI generally an easily treatable complication
- PJI is a catastrophic complication:
  - Often requires explantation of the joint and weeks of antibiotics.
  - Patients never regain full capacity and frequently cannot accomplish the activities of daily living.
  - 12% of patients rate their life after surviving a PJI as "worse than death."[12]

Periprosthetic joint infections (PJI)

- PJI after total joint replacement: Relatively common complication (1-2%).
  - Medicare says 2% in primary hips and knees.
  - → 20,000 per year in the US.

SSI vs PJI -- cost

- **SSI: generally cheap to treat**
- **PJI: a very expensive complication:**
  - Costs $100,000 - $150,000 each.
  - Not reimbursed by Medicare.

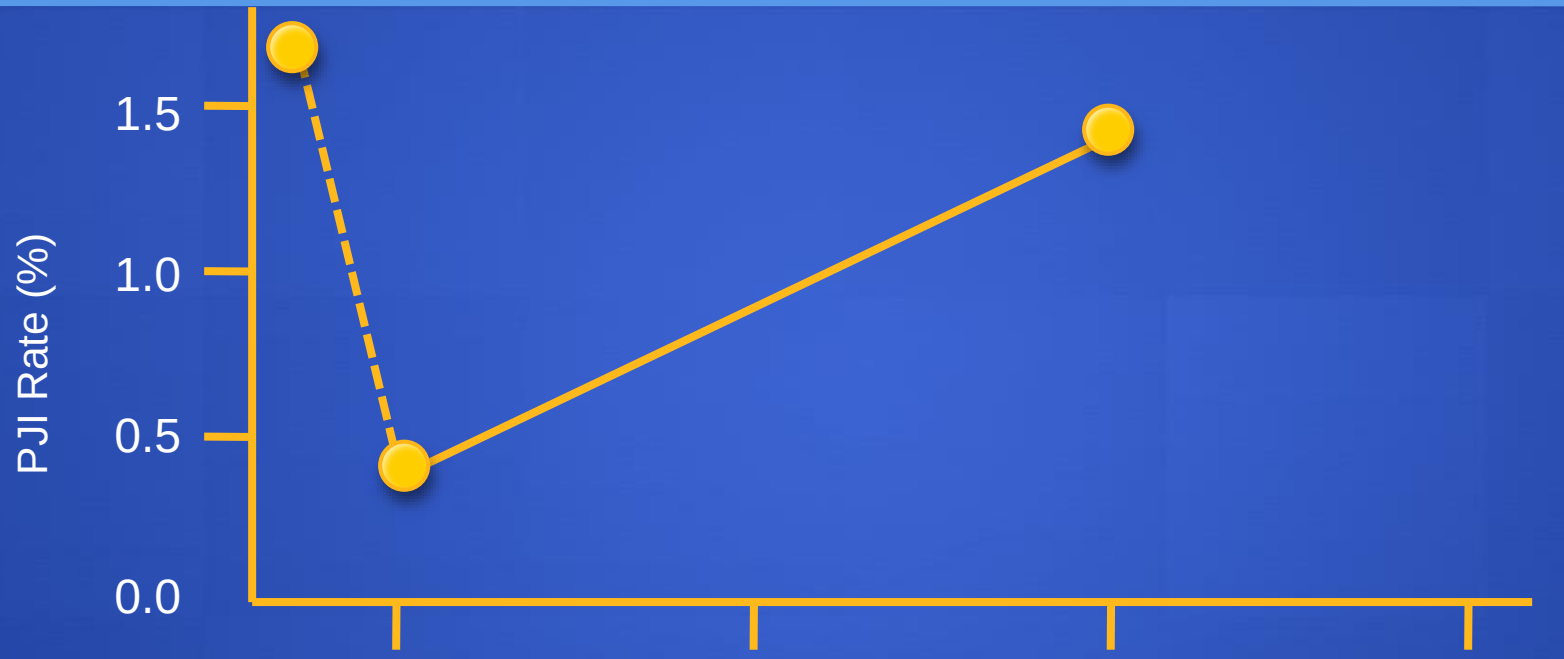


Source: sciencedirect.com

Periprosthetic joint infections due to anesthesia equipment

- Evidence to date: The unintended consequence of my invention (FAW) is that it may be causing 75% or more of PJIs.
- PJI is the most common serious anesthetic complication?

Studies:
Joint Sepsis (PJI) vs. OR Ventilation



Lidwell, O.M. (UK)

- Multicenter
- Excellent ventilation
- Followed protocol
- + Antibiotics

Brandt, C. (Ger)
Knobben, B. (Hol)

- Multicenter
- Excellent ventilation
- Followed protocol
- + Antibiotics

US Operating Room Ventilation Standards

- **ASHRAE Standard 170: *ceiling-to-floor, clean-to-dirty*:**
  1. **Section 7.1.1.a: "Design of the ventilation system shall provide air movement that is generally from clean to less clean areas."**
  1. **Section 7.4.1.a: "The airflow shall be unidirectional, downwards..."**
  1. **Ventilation must be filtered at an efficiency of >90% for the removal of germ sized particles**

Causes of ventilation disruption

- Ventilation obstructions (e.g.: surgical lights)
- Personnel movement
- Blowing air
  - Any new sources of blowing air introduced to the OR between the late '80's and 2000's? FAW (40-50 CFM)
- Heat (creates convection currents of rising air)
  - Any new sources of heat introduced to the OR between the late '80's and 2000's?
  - FAW! 1000 watts of waste heat vented near the floor since 1989.

Heat and Flow Obstructions

Forced-Air
Heat OFF

Forced-Air
Heat ON

Heat and Surgical Lights

Forced-Air Heat OFF

Forced-Air Heat ON

Heat and Surgeon

Heat and Mayo Stand

Heat and Ether Screen

Research

- Video evidence supported by 10 published studies[44-48, 65, 67]

Legg, A.J.; Hammer, A.J. Forced-air patient warming blankets disrupt unidirectional airflow. *B&JJ*, March 2013 vol. 95-B no. 3 407-410

- 2,000 times more contaminant particles were found in the air over the wound with FAW than with air-free conductive warming.

217,400% Increase!

Table I. Particle entrainment concentration

Warming scenario	Concentration (particles/m^3)
Control	2000
Radiant warming	1000
Forced-air warming	2 174 000

Belani, K; et al. Patient Warming Excess Heat: Effects on Orthopedic Operating Room Ventilation Performance. *A&A*. 2013 Aug;117(2):406-11

- "… exhaust from forced-air warming generated hot-air convection currents that mobilized 'bubbles' over the anesthesia drape and into the surgical site."

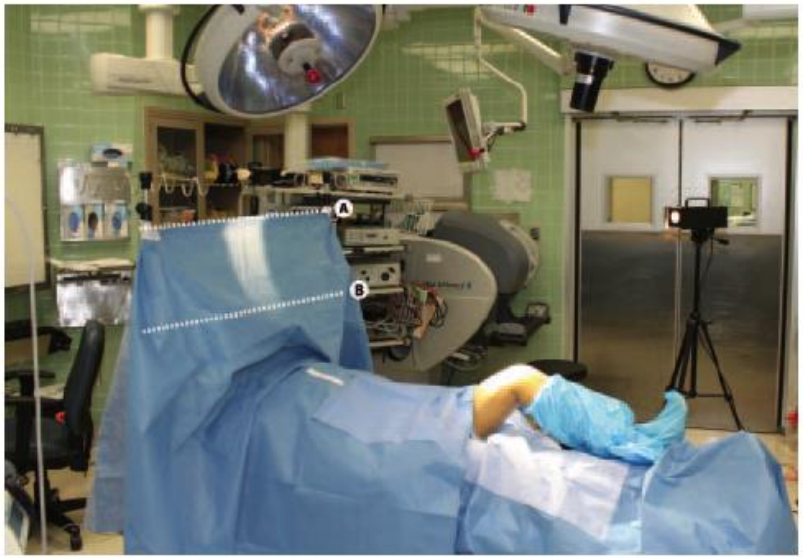
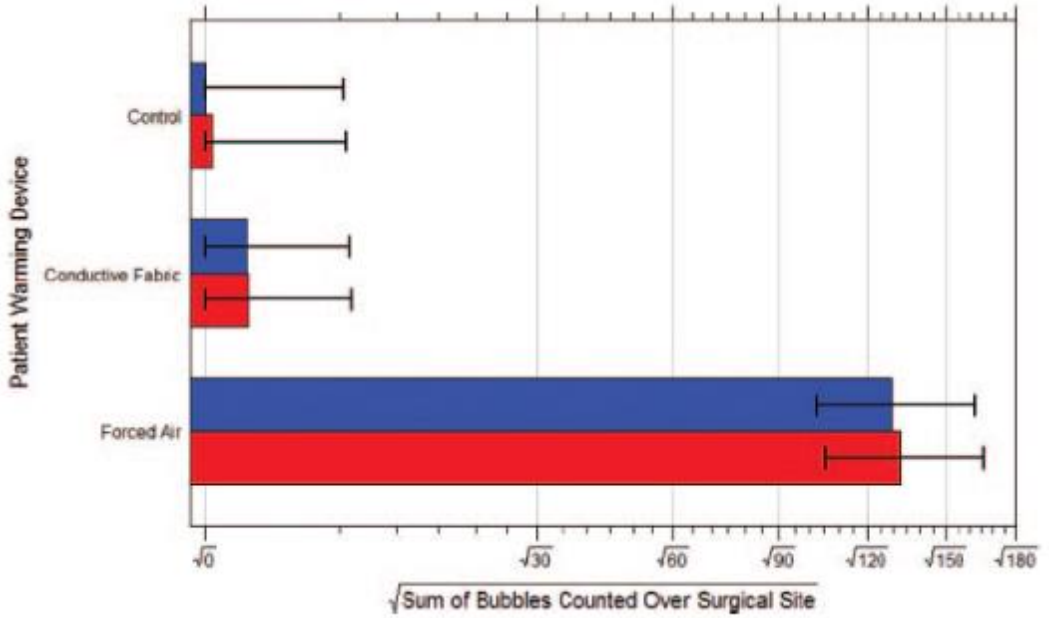
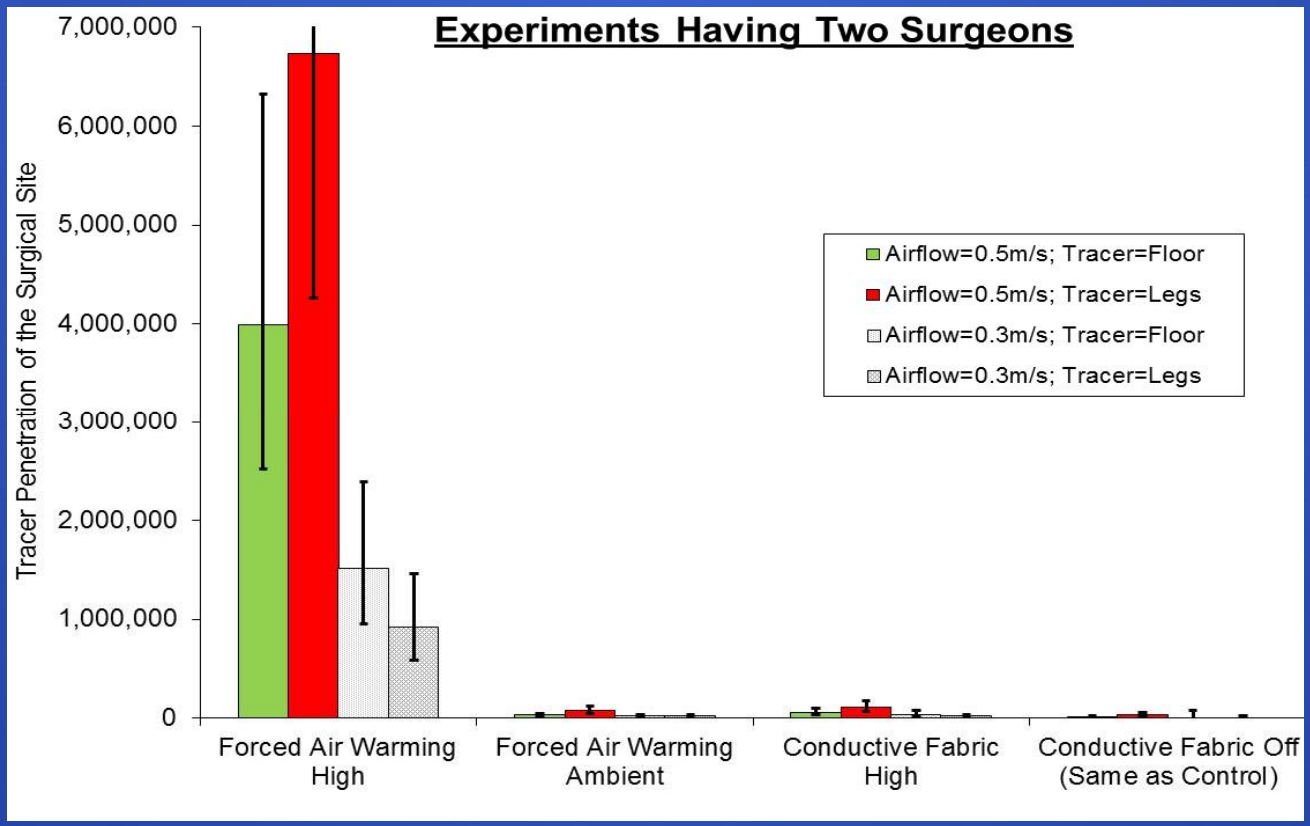


Figure 1. Total knee replacement setup showing high anesthesia drape position (A) and low anesthesia drape position (B).



Increased ventilation velocity ➔ increased contamination

- 0.3 vs 0.5 meters/sec. laminar flow velocity



Reed M, McGovern P et al. FAW vs. CFW – An evaluation of laminar operating room ventilation disruption. (Unpublished)

"Infection control hazards associated with the use of forced-air warming in operating theatres" --- *J Hospital Infection*, 2014 [66]

- SSI experts including DJ Leaper, Chair SSI Comm. (NICE)
  - "Many studies suggest that disruption of ultra-clean ventilation air flow by FAW is significant…"
  - "We conclude that FAW does contaminate ultra-clean ventilation…"
  - "…we recommend that surgeons should at least consider alternative patient-warming systems in areas where contamination of the operative field may be critical."

CDC warns against blowing air in the OR!

- Investigation of *Mycobacterium* heart valve infections
- Genetically linked to *Mycobacterium* growing in the water of Heater-Cooler Devices (HCD)
- The *Mycobacterium* are aerosolized in the cooling air blowing from the HCD
- Healthcare Infection Control Practices Advisory Committee (HICPAC) of the CDC: "Nothing that blows air should be in an operating theater, if possible." [69]

CDC warns against blowing air in the OR!

- **The CDC investigating Heater-Cooler Devices (HCD)**
- **"Nothing that blows air should be in an operating theater, if possible." and "…it is important not to blow air in the operating theater."[69]**
- **"Until more detailed evidence is available regarding this issue…devices that generate drafts should be banned from the operating room."[70]**
- Warning against blowing air is clearly *not* limited to HCDs
- Forced-air warming: the worst offender of all air-blowing equipment in any operating room

- Healthcare Infection Control Practices Advisory Committee (HICPAC) of the Centers for Disease Control and Prevention (CDC)

November 2015

FAW blowers identical to HCDs

- **6 studies: bacteria and mold aerosolized from FAW blowers[34,35,68]**
- **Bair Hugger filters 63.8% efficient (vs. HEPA 99.97%)**
- **Reed: 100% of blowers internally contaminated[34]**
  - **Aerosolizing 300 million bacteria-sized particles per hour**
  - Emitted particle count 40x greater than the intake count = bacteria and mold were *grown inside* the blower and aerosolized
- Hamilton: blower bacteria cultured from the skin of 10% of patients[68]

CDC warns against blowing air in the OR!

- **The CDC warning to healthcare providers shifts the "Burden of Proof"**
  - Blowing air in the OR is an *unacceptable risk until proven otherwise*
  - *You have to prove FAW safety*
- **Continuing to use FAW after a CDC warning:**
  - May shift liability to the provider (vs. the product)
  - Should be disclosed during *informed consent*
- **ZERO outcome studies showing FAW safety in orthopedics**

FAW Contaminates the Sterile Surgical Field

- **Undisputable: Waste FAW heat rises mobilizing infectious contaminates from the floor up into the sterile surgical field.** [44-49, 63-66]
  - "Gotcha" response: "The heat may cause contamination, but prove to me that it causes infections!"
    - The "burden of proof" has shifted with the CDC warning, the provider must now prove safety—prove that the contamination does not cause infections.
  - Even if FAW is never *proven* to cause infections, how can anyone justify willfully contaminating the sterile surgical field?

Contaminated air = increased infection risk

- Basic logic (If A=B and B=C then A=C)

A. Waste FAW heat rises mobilizing infectious contaminates from the floor up into the sterile surgical field. [44-49, 63, 64, 65]

B. The concentration of airborne contaminates correlates directly with the concentration of contaminates in the wound. [2-4,51-57]

C. Concentration of contaminates in the wound correlates with the risk of PJI. (only need one bacterium) [8-10]

- A=C, therefore FAW logically increases PJI risk

Research Results: McGovern et al. *Journal of Bone and Joint Surgery-br*

- Deep joint infection rates:
  - 9/’ 08 – 6/’ 10, Forced-air warming: 3.1% (1066 cases)
  - 7/’ 10 – 1/’ 11, HotDog warming : 0.81% (371 cases)
- Discontinuing the use of forced-air warming resulted in a 74% reduction in joint implant infections (p=0.024).
- Retrospective outcome study
- Contrast: ZERO outcome studies showing FAW safety

Research Results: McGovern et al. *Journal of Bone and Joint Surgery-br* [44]

- Discontinued FAW and switched to HotDog air-free warming in total joint replacement surgery.
- "[Forced-air] Patient warming ventilation disruption was associated with a significant increase in deep joint infections, as demonstrated by an elevated infection odds ratio (3.8, p=0.028) for the forced air versus conductive fabric patient groups (n=1437 cases, 2.5-year period)."

Research Results: Retrospective PJI Outcome Study[71]

- A medium-sized independent regional healthcare network:
- Baseline PJI rate: FAW ($t_{baseline}$ = 1 yr):
  - 1.55% 388 cases
- Study PJI rate: air-free conductive fabric electric warming (t_{study}=2 yr):
  - 0.29% 677 cases

- Decrease in PJI rate: 81% (p = 0.027)

Research Results: Retrospective PJI Outcome Study[71]

- An independent orthopedic and sports institute:
- Baseline PJI rate: FAW ($t_{baseline}$ = 1 yr):
  - 2.29% 175 cases
- Study PJI rate: air-free conductive fabric electric warming (t_{study}=1 yr):
  - 0.00% 218 cases

- Decrease in PJI rate: 100% (p= 0.031)

Research Results: Retrospective PJI Outcome Study[71]

- A medium community hospital:
- Baseline PJI rate: FAW ($t_{baseline}$ = 1 yr):
  - 1.57% 382 cases
- Study PJI rate: air-free conductive fabric electric warming (t_{study}= 6 mo):
  - 1.03% 194 cases

- Decrease in PJI rate: 34% (p = 0.045)

Research Results: Retrospective PJI Outcome Study[71]

- Multicenter pooled results 3 hospitals:
- Baseline PJI rate: FAW ($t_{baseline}$):
  - 1.7% 945 cases
- Study PJI rate: air-free conductive fabric electric warming (t_{study}):
  - 0.4% 1089 cases

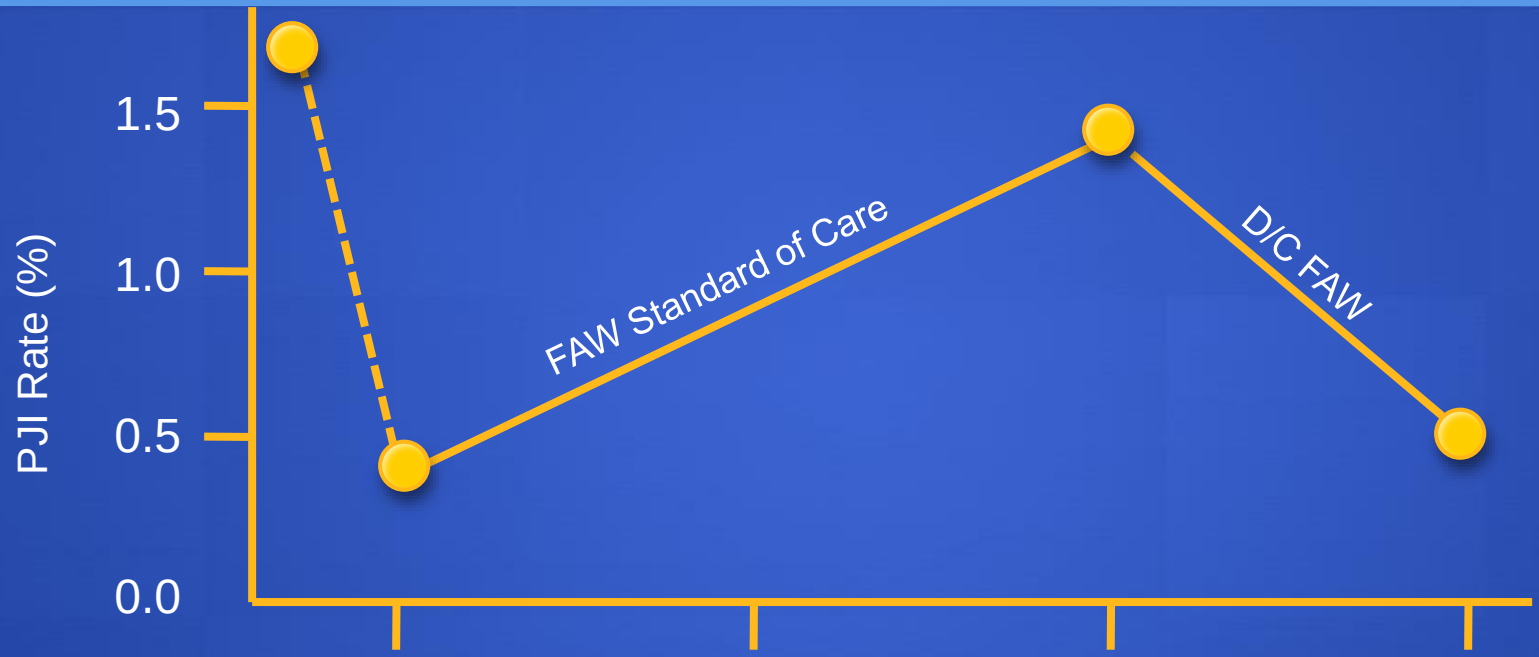
- Decrease in PJI rate: 78% ($p < 0.002$)

Research Results: Retrospective PJI Outcome Study (unpublished)

- A large general hospital:
- Baseline PJI rate: FAW ($t_{baseline}$ = 1 yr):
  - 3.2% 667 cases
- Study PJI rate: air-free conductive fabric electric warming (t_{study}=20 mo):
  - 0.9% 1097 cases

- Decrease in PJI rate: 72% (p=0.00041)

Studies:
Joint Sepsis (PJI) vs. OR Ventilation



1980's	2000's	2010's
Lidwell, O.M. (UK)	Brandt, C. (Ger) Knobben, B. (Hol)	McGovern, P.D. (UK) Augustine S (US)
• Multicenter	• Multicenter	• Multicenter
• Excellent ventilation	• Excellent ventilation	• Excellent ventilation
• Followed protocol	• Followed protocol	• Followed protocol
• + Antibiotics	• + Antibiotics	• + Antibiotics
• No forced-air warming	• + forced-air warming	• No forced-air warming

Today's lesson in summary

- The waste heat from FAW contaminates the sterile surgical field with bacteria, significantly increasing the risk of PJI.
- Therefore: PJI is the most common serious *anesthetic* complication.

And?

Litigation follows complications

Litigation

- Mass tort product liability action against a forced-air warming manufacturer started mid-August '15.
- > 100 law firms advertising for plaintiffs.
- TV advertising across the country.
- MDL certified in Mpls Federal Court. Dec. '15
- ≈4,000 lawsuits so far against defendant FAW mfr.
- Expect more than 20,000 plaintiffs? (30,000 metal-on-metal hips)

Why should clinicians care?

- Catastrophic injuries → Permanent disability
- With 20,000 PJIs per year (x6 years SOL); plenty of potential plaintiffs…and billions in potential damages.
- Product liability → Medical Malpractice? (exact same fact-set)
  - More deep pockets needed for tens of billions of dollars of liability.

"Learned intermediary" defense

- The defendant's response to the Court: the "learned intermediary" defense.
- Who/what is a "Learned Intermediary"?
  - It's you…and the surgeon and the anesthesiologist…and the hospital.
- Defendant: The hospital and the providers knew the risks of using FAW and used it anyway so it's their fault, not the manufacturer.
- When defendant says FAW is "safe," don't believe it. They are already blaming you and they would love to have you share liability.

Litigation: Inside story

- *"[Defendant] is not aware of any study that shows waste heat from a FAW device contaminating the sterile field." - Press Release July 14, 2017*
- **Al Van Duren is Defendant's Director of Science Affairs and Education, and the designated corporate spokesperson for science [their 30(b)(6) witness] in their Multi-District Litigation, in sworn deposition testimony:**
  - ***every single study shows that FAW causes contamination of the air of the sterile surgical field.***

Litigation: Inside story

- Defendant: "There is absolutely no evidence—not one scientific study—that shows the [defendant's FAW] system causes or contributes to surgical site infections."
- Al Van Duren, defendant's Director of Science Affairs and Education, in an internal email commenting on the companies marketing statements regarding infection risks says:
  - *"Actually, there is evidence that [forced-air warming] use increases risk—this evidence was the motivation for Dr. Memarzadeh's work."*

What should providers do?

- Switch to an air-free patient warming technology for all implant surgery. (Follow the CDC's recommendation)
- If the *hospital* refuses to switch (contracts for example):
  - Demand that the hospital *indemnify* you against liability *in writing*.
  - Add a discussion of the CDC warning and current FAW infection/contamination research to your standard *informed consent*.
- If *you* refuse to switch: remember, the "*burden of proof*" is on you to *prove* FAW safety. *Informed consent* is a must.

Take-away Message About Litigation

With 20,000 lawsuits predicted—plenty of opportunity for you to be involved….

Distance yourself!

Thank you!

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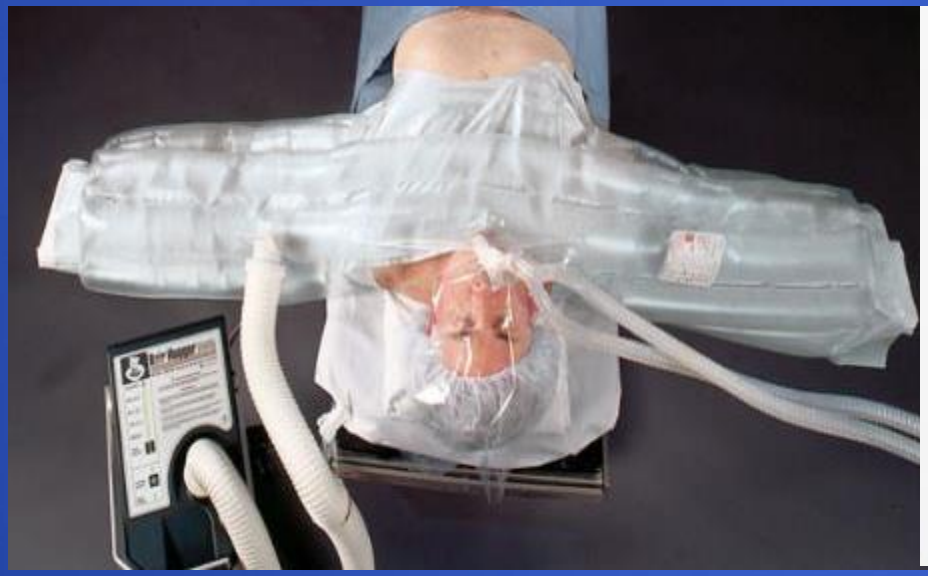
FAW vs. Conductive Fabric Warming



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