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CarboJet®

Bone Preparation

Apr2019

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What is Important to Your Hospital?

- Patient Outcomes and Revision Rates
- Patient Experience
- Being a “State of the Art” provider

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How Kinamed Adds Value

1. Patient Outcomes
   - Aseptic loosening is the leading cause of knee arthroplasty revision

2. Patient Experience
   - Recovery
     - Pain and Return to Function after knee arthroplasty
   - Complications
     - Fat Embolism from knee arthroplasty can impair cardiac, pulmonary, and cerebral function

3. “State of the Art” Treatment Center
   - The best available clinically validated method to clean and dry bone surfaces

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About Kinamed

- Established in 1987

- Global medical device Company
  - Products sold in >30 countries

- Focus on Bone & Joint Applications

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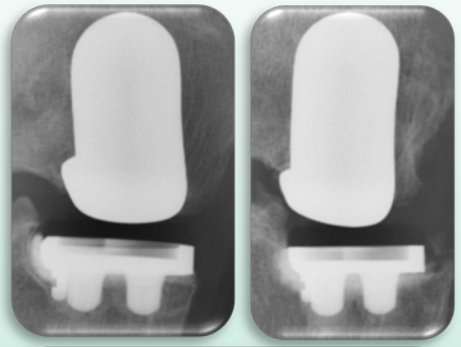
Clinical Applications



CarboJet®

KineMatch®

SuperCable®

NeuroPro®

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CarboJet Bone Preparation

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CarboJet Bone Preparation

1. **What is the clinical relevance?**
2. What is it?
3. What does it do?
4. What is the clinical evidence?

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Clinical Relevance: Patient Outcomes

- Knee arthroplasties primarily fail due to loosening

The Journal of Arthroplasty 28 Suppl. 1 (2013) 116–119

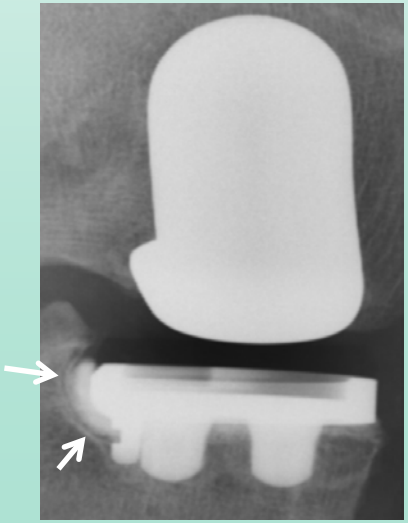
Contents lists available at ScienceDirect

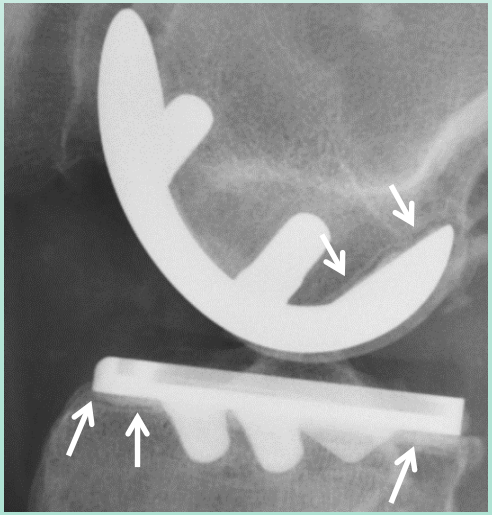
The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Why Are Total Knees Failing Today? Etiology of Total Knee Revision in 2010 and 2011

William C. Schroer, MD [a], Keith R. Berend, MD [b], Adolph V. Lombardi, MD [b], C. Lowry Barnes, MD [c], Michael P. Bolognesi, MD [d], Michael E. Berend, MD [e], Merrill A. Ritter, MD [e], Ryan M. Nunley, MD [f]





Mechanism of Failure Over Time.

All Patients	844	100.0%
Aseptic Loosening	263	31.2%
Instability	158	18.7%
Infection	137	16.2%
Poly Wear	84	10.0%
Arthrofibrosis	59	7.0%
Malalignment	56	6.6%
Isolated Patella Revision	35	4.1%
Periprosthetic Fracture	27	3.2%
Other	13	1.5%
Extensor Mechanism	10	1.2%
AVN patella	2	0.2%

“Early failure mechanisms are primarily surgeon dependent”

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Clinical Relevance: Patient Outcomes

- Knee arthroplasties primarily fail due to loosening

Mechanism of Failure Over Time.

			<2 Years		2–5 Years		5–15 Years		>15 Years	
All Patients	844	100.0%	298	35.3%	210	24.9%	249	29.5%	87	10.3%
Aseptic Loosening	263	31.2%	56	18.8%	82	39.0%	99	39.8%	26	29.9%
Instability	158	18.7%	75	25.2%	39	18.6%	40	16.1%	4	4.6%
Infection	137	16.2%	68	22.8%	35	16.7%	29	11.6%	5	5.7%
Poly Wear	84	10.0%	3	1.0%	1	0.5%	38	15.3%	42	48.3%
Arthrofibrosis	59	7.0%	38	12.8%	15	7.1%	5	2.0%	1	1.1%
Malalignment	56	6.6%	24	8.1%	16	7.6%	15	6.0%	1	1.1%
Isolated Patella Revision	35	4.1%	15	5.0%	9	4.3%	8	3.2%	3	3.4%
Periprosthetic Fracture	27	3.2%	7	2.3%	5	2.4%	12	4.8%	3	3.4%
Other	13	1.5%	7	2.3%	4	1.9%	1	0.4%	1	1.1%
Extensor Mechanism	10	1.2%	5	1.7%	4	1.9%	1	0.4%	0	0.0%
AVN patella	2	0.2%	0	0.0%	0	0.0%	1	0.4%	1	1.1%

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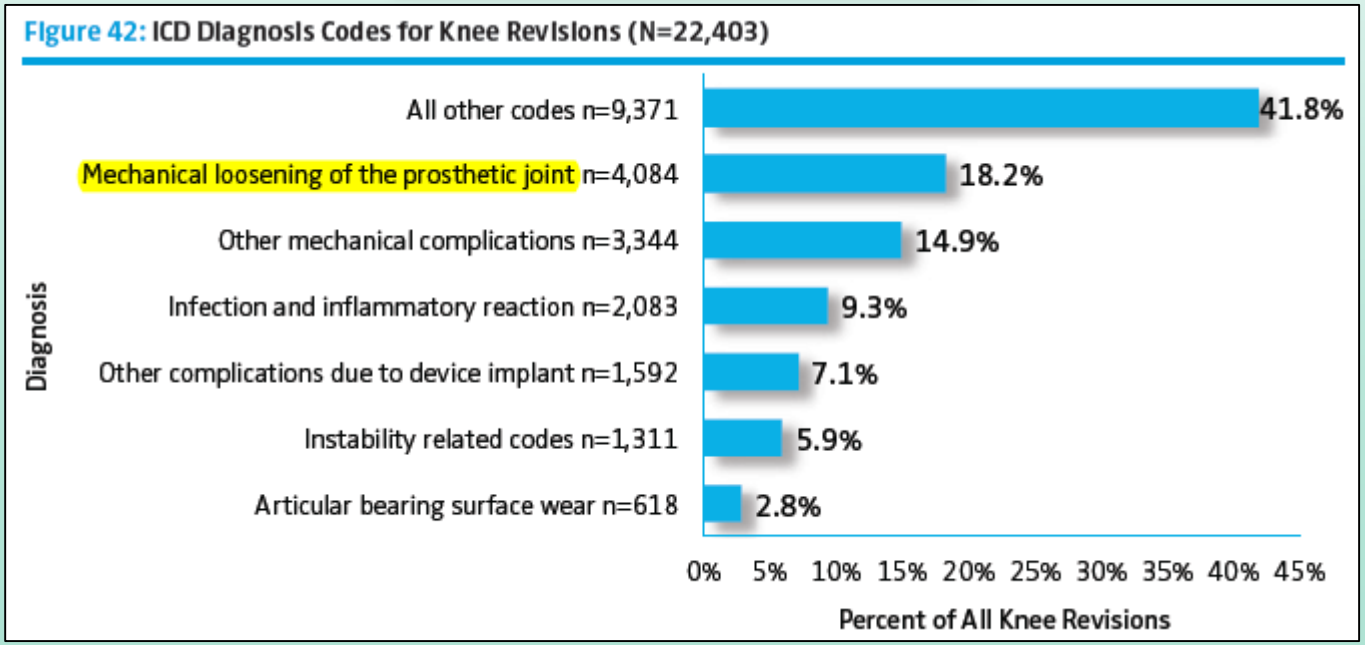
Clinical Relevance: Patient Outcomes

- Knee arthroplasties primarily fail due to loosening

AJRR American Joint Replacement Registry — Improving Orthopaedic Care Through Data — 2016



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Clinical Relevance: Revisions

Clinical Medicine Insights: Arthritis and Musculoskeletal Disorders

Libertas Academica
FREEDOM TO RESEARCH

PERSPECTIVE

Clinical and Economic Burden of Revision Knee Arthroplasty

Mohit Bhandari[1], Jon Smith[2], Larry E. Miller[3,4] and Jon E. Block[4]

Clin Orthop Relat Res (2010) 468:45–51
DOI 10.1007/s11999-009-0945-0

SYMPOSIUM: PAPERS PRESENTED AT THE ANNUAL MEETINGS OF THE KNEE SOCIETY

The Epidemiology of Revision Total Knee Arthroplasty in the United States

Kevin J. Bozic MD, MBA, Steven M. Kurtz PhD, Edmund Lau MS, Kevin Ong PhD, Vanessa Chiu MPH, Thomas P. Vail MD, Harry E. Rubash MD, Daniel J. Berry MD

“The average LOS for revision TKA was 5.1 days, and the average total charges were $49,360”

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Clinical Relevance: Patient Experience

- Patients want a rapid return to function after knee arthroplasty

422 *Acta Orthopaedica* 2014; 85 (4): 422–426

Faster recovery without the use of a tourniquet in total knee arthroplasty

A randomized study of 70 patients

Ashir Ejaz[1,2,3], Anders C Laursen[1,2,3], Andreas Kappel[1], Mogens B Laursen[1,2,3], Thomas Jakobsen[1,3], Sten Rasmussen[1,2,3], and Poul Torben Nielsen[1]

"Several randomized controlled trails and meta-analyses have detailed adverse effects of tourniquet use. Disadvantages of tourniquet use include: thigh pain, nerve palsy, ischemia, soft tissue damage, thromboembolic complications, poor wound healing, and patella mal-tracking. Recovery may be delayed due to reduced muscle strength, reduced knee ROM, and increased pain. Increased pain and impaired ROM up to 1 year after surgery."

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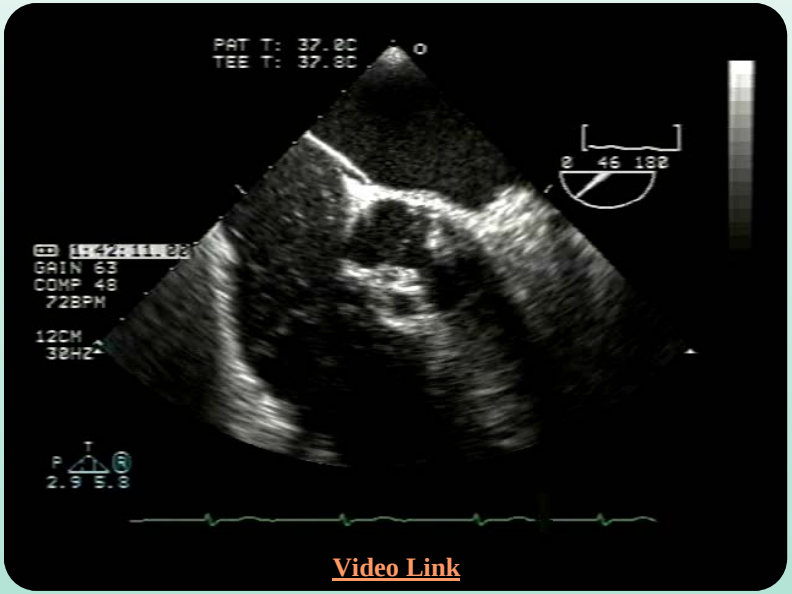
Clinical Relevance: Patient Experience

- We all want to avoid intra-operative and post-operative complications



Video Link

ClinicoEconomics and Outcomes Research — Dovepress
open access to scientific and medical research

Open Access Full Text Article — REVIEW

Review of the cost of venous thromboembolism

Cost per pulmonary embolism hospitalization averaged $8,764 in 2010.

"Costs for VTE treatment are considerable and increasing faster than general inflation for medical care services, with hospitalization costs being the primary cost driver."

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Clinical Relevance: State of the Art

- Kinamed offers cost-effective, clinically validated technologies

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CarboJet Bone Preparation

1. What is the clinical relevance?

2. **What is it?**

3. What does it do?

4. What is the clinical evidence?

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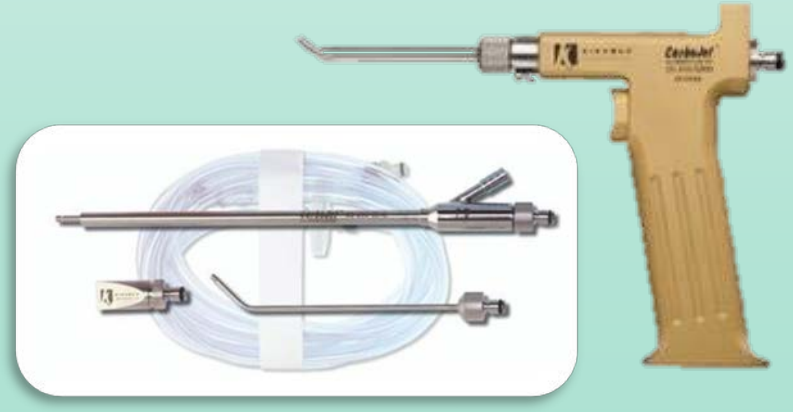
What is CarboJet?

- An FDA-cleared, clinically validated system for delivering sterile, dry, pressurized medical-grade carbon dioxide gas to bone surfaces

- It's purpose is to deep clean and dry the bone bed for increased cement penetration and bond strength

- Fast and simple to use



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What is CarboJet?

- FDA cleared
- Used in >150,000 surgeries in 30 countries to date
- CarboJet quickly and efficiently removes lipids/fatty marrow elements for improved cement bond strength

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CarboJet Bone Preparation

Compressed gas is effective at cleaning and drying…

… for the dentist, before applying amalgam or a crown

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CarboJet Bone Preparation

Compressed gas is effective at cleaning and drying…

… in machine shops, for clearing away cutting fluids and debris

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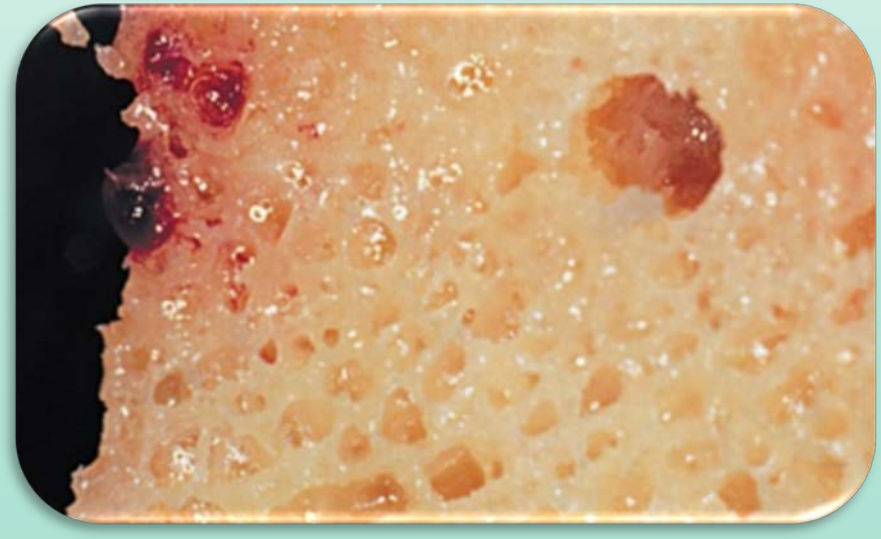
CarboJet Bone Preparation

Compressed gas provides a more effective and efficient way to clean and dry the bone in preparation for cemented fixation

After pulsatile saline



After CarboJet cleaning

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CarboJet Bone Preparation

1. What is the clinical relevance?

2. What is it?

3. **What does it do? How does it Work?**

4. What is the clinical evidence?

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What does *CarboJet* do?

1. Increases Cement Penetration in TJA
2. Increases Bone-Cement Interface Strength
3. Reduces Opportunity for Micro-Emboli
4. Facilitates Tourniquet-free TKA, which Reduces Pain and Opiate Use
5. Improves cleaning of osteochondral allograft

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How does *CarboJet* work?

- Bone cleaning is typically performed with saline irrigation

- "Oil and Water don't mix"
  - Irrigation clears blood and particulates, but is not effective at removing viscous fatty marrow debris/ **lipids**.
  - Irrigation leaves behind a wet bone surface

- A pressurized gas jet effectively displaces fluid and lifts away lipids/ fatty marrow debris
  - A cleaner bone surface results in improved cement penetration
  - A drier bone surface results in improved cement adhesion

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Surgical Video

- CarboJet in TKA and Tourniquetless TKA 

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CarboJet Bone Preparation

1. What is the clinical relevance?
2. What is it?
3. What does it do?
4. **What is the clinical evidence?**

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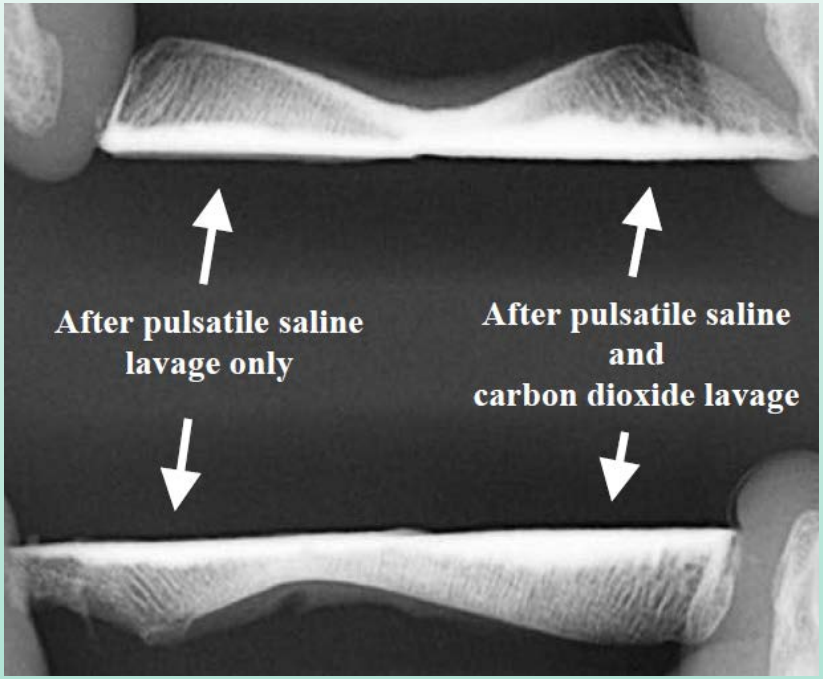
What is the Clinical Evidence?

1. Increases Cement Penetration

Goldstein (2007) Improvement of cement mantle thickness with pressurized carbon dioxide lavage. ISTA. Paris, France.

- ***CarboJet* resulted in a 35% increase in cement penetration depth versus use of pulsatile saline lavage alone**

"This improvement is thought to be due to the displacement and removal of residual fluid and fatty material that remains in cancellous bone after conventional pulsed saline irrigation and suction."



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What is the Clinical Evidence?

1. Increases Cement Penetration – even without a Tourniquet

Meneghini et al (2019) The Effect of Tourniquet Use and Sterile Carbon Dioxide Gas Bone Preparation on Cement Penetration in Primary Total Knee Arthroplasty. The Journal of Arthroplasty (2019).

- ***Bone prepared with CO2 gas showed significantly more cement penetration in 3 zones with greater cancellous bone. The results suggest that use of CO2 gas bone preparation may achieve greater cement penetration than using a tourniquet with lavage only.***

A major challenge with Tourniquetless TKA is achieving an optimal “cement technique” because of the additional fluid debris present in the bone and at the implant interfaces. CarboJet addresses this challenge and enables surgeons to perform TKA without a tourniquet without compromising their cement technique.

This study compared a group with CarboJet and no tourniquet versus a group without CarboJet and with tourniquet. Results show that, by adopting CarboJet and eliminating the tourniquet, cement penetration can actually be improved.

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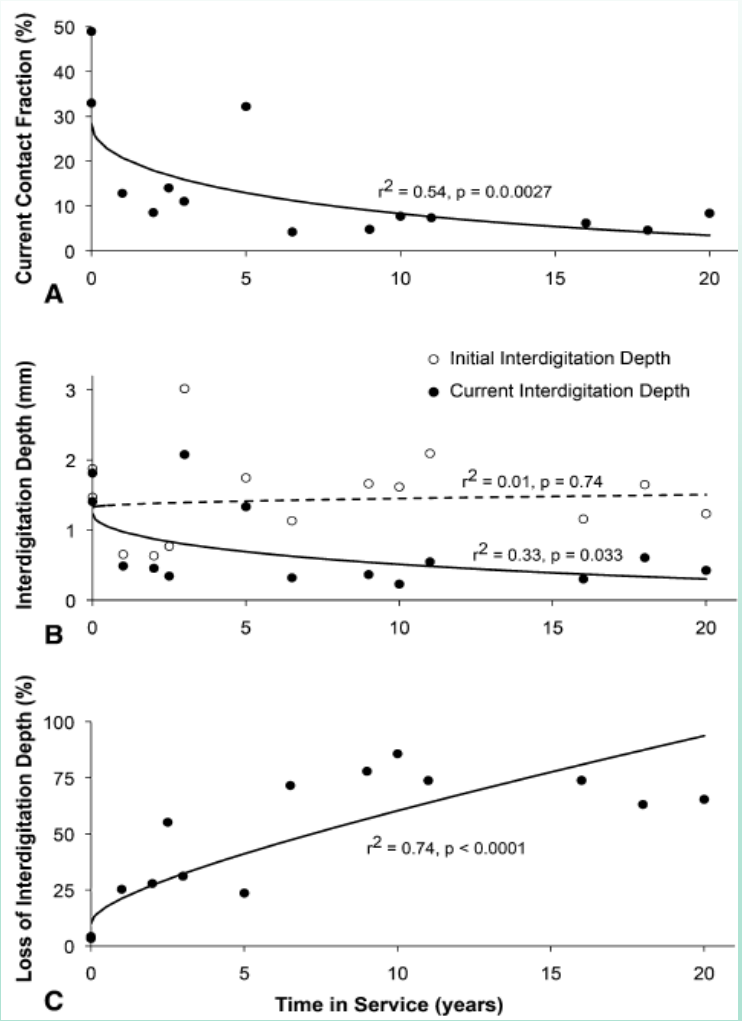
Why this matters

Increased cement penetration counters bone resorption over time

Miller et al (2014) Loss of Cement-bone Interlock in Retrieved Tibial Components from Total Knee Arthroplasties. Clin Orthop Relat Res 472:304-313.

- **Maximum initial interdigitation is critical because bone at the interface resorbs over time**



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What is the Clinical Evidence?

2. Increases Bone-Cement Interface Strength

Stanley (2010) Bone-Cement interface strength in distal radii using two medullary canal preparation techniques. Hand Surg 15:95.

- ***CarboJet*** **resulted in 58% higher cement plug push-out strength versus a saline lavage technique (median 581N vs. 366N)**

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Why this matters

Infiltration of lipids in the cement interface significantly reduces tibial fixation strength

Mason et al (2018) AAOS Scientific Exhibit #15.

- ***"Aseptic tibial loosening remains the leading cause of total knee arthroplasty (TKA) failure. Studies implicate cement technique as a factor for loosening."***

CarboJet **removes lipids/marrow elements from the bone bed <u>prior to</u> cementation**

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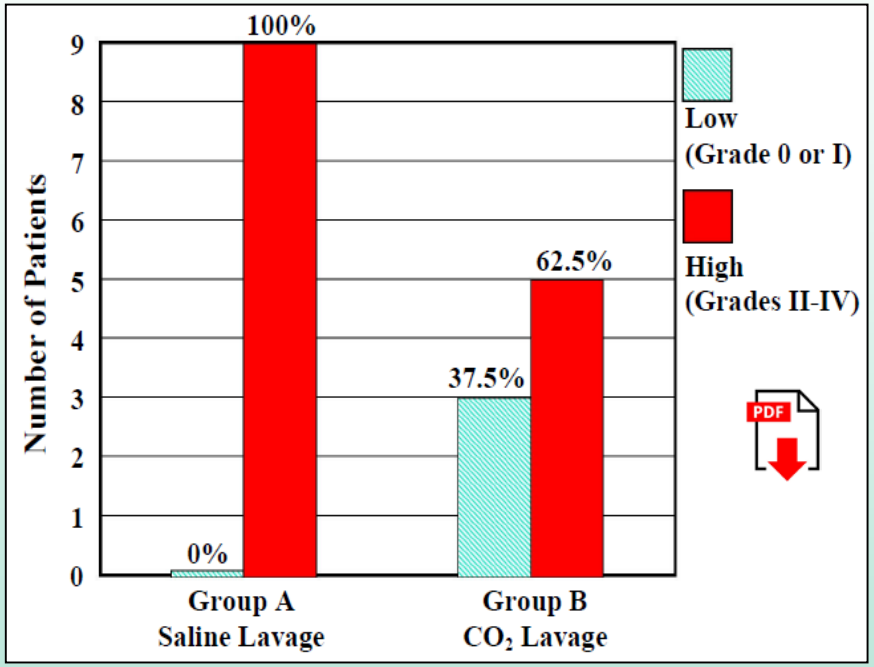
What is the Clinical Evidence?

3. Reduces Micro-Emboli

Lassiter (2010) Intraoperative embolic events during TKA with use of pulsatile saline versus carbon dioxide lavage. ORS. New Orleans, USA.

Duke University School of Medicine



- **CO_2 preparation reduced the number & size of intraoperative cardiac emboli during cemented total knee arthroplasty**

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What is the Clinical Evidence?

4. Facilitates a Tourniquetless TKA technique

- ***CarboJet*** **allows Tourniquetless TKA to be performed without compromising the cement technique**

Tourniquetless TKA Reduces Opiate Use in Women

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Primary Arthroplasty

Tourniquetless Total Knee Arthroplasty With Modern Perioperative Protocols Decreases Pain and Opioid Consumption in Women

Michael M. Kheir, MD [a], Mary Ziemba-Davis, BA [b], Julian E. Dilley, BS [c], Mark J. Hood Jr., MD [a], R. Michael Meneghini, MD [a, b, *]

[a] Department of Orthopaedic Surgery, Indiana University School of Medicine, Indianapolis, IN
[b] Indiana University Health Physicians Orthopedics and Sports Medicine, IU Health Saxony Hospital, Fishers, IN
[c] Department of Orthopaedic Surgery, Indiana University School of Medicine, Indianapolis, IN

INDIANA UNIVERSITY SCHOOL OF MEDICINE

"In contemporary TKA using multi-modal pain protocols and TXA, not using a tourniquet resulted in less pain and lower narcotic consumption in the first 24 hours after surgery for women, but not for men."

"…Median pain in the first 24 hours was significantly lower for women without a tourniquet (1.9 vs. 2.7, p = 0.002). This corresponded to significantly less opioid consumption in the first 24 hours among women without tourniquets (18.8 vs. 42.8 Me, p < 0.0001)."

Tourniquetless Total Knee Arthroplasty with Modern Perioperative Protocols Decreases Pain and Opioid Consumption in Females

Michael M. Kheir MD, Mary Ziemba-Davis BA, Julian E. Dilley BS, Mark Hood Jr. MD, R. Michael Meneghini MD
Indiana University School of Medicine, Indianapolis, IN, USA

Background: Studies have observed that tourniquet use results in greater pain in the immediate postoperative period. Two of three studies noted a related increase in analgesia consumption. We examined the relationship between tourniquet use and pain and opioid consumption in the early postoperative period following TKA performed with modern perioperative pain protocols.

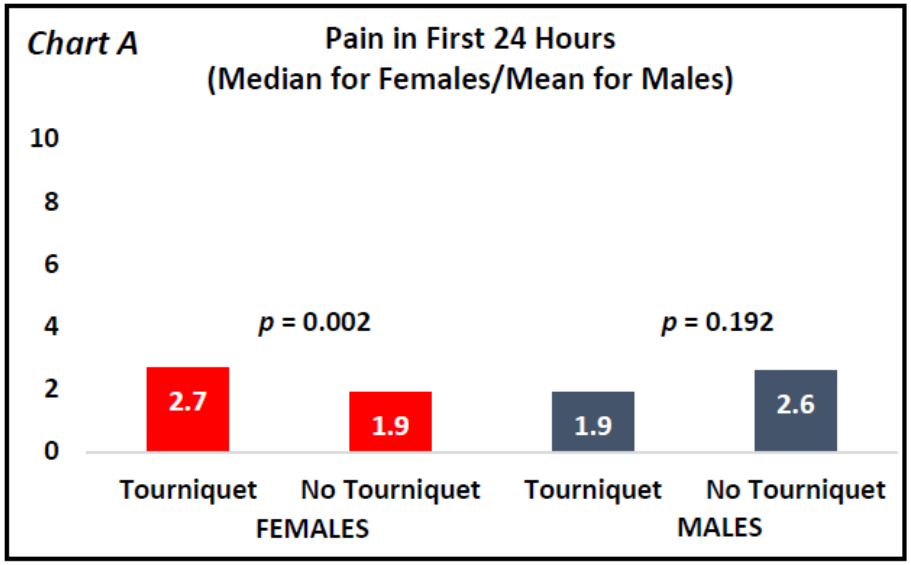
Methods: Retrospective study of 203 consecutive primary unilateral cemented TKAs performed by a single surgeon at a single academic institution between Jan 2016 and Mar 2017. *Inclusion Criteria:* secondary to primary, traumatic, or inflammatory osteoarthritis. *Exclusion Criteria:* antiplatelet medications except aspirin, clotting disorder, unplanned tourniquet disruption, or preexisting periarticular hardware. The same surgical approach, computer-aided navigation, implants, and modern perioperative pain, clinical, and rehabilitation protocols implemented in all cases. *Tourniquet Group* (n = 93): Inflated at 250 mm Hg from incision to sterile dressing. *No Tourniquet Group* (n = 91): Tourniquet not inflated during cementation. Cement mantle optimized with CO2 gas compression. Patient-reported pain scores on a 10 point scale (none to severe) recorded every four hours by nursing staff were averaged to derive an overall pain score during the first 24 hours following surgery. Narcotics consumed during the first 24 hours were recorded and standardized to morphine milligram equivalents.

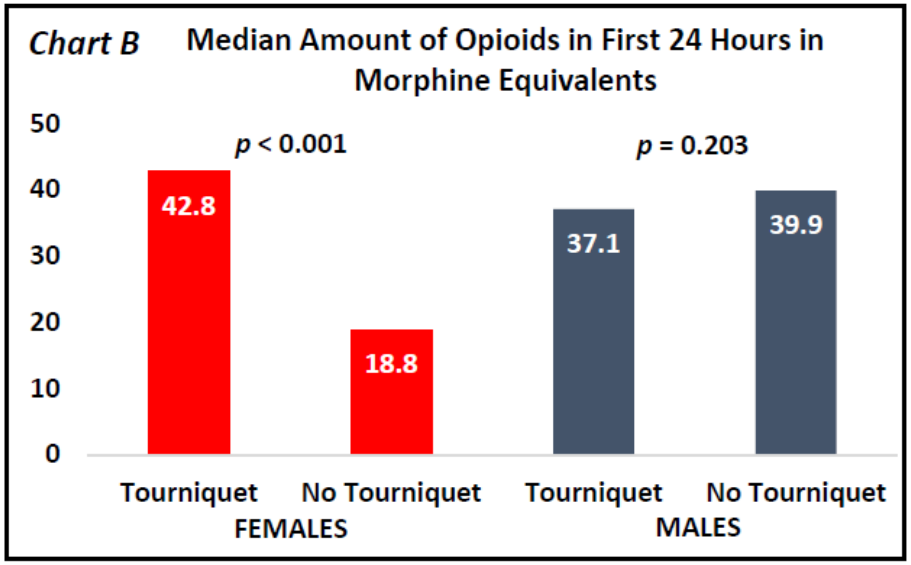
Results: Analysis was performed separately for females and males because the tourniquet group had significantly more females than the no tourniquet group ($p = 0.019$). Demographics and covariates are presented in Table 1. *Chart A:* Females with a tourniquet reported more post-operative pain in the first 24 hours after surgery than females without a tourniquet (2.7 vs. 1.9, $p = 0.002$). Pain scores did not differ in either group based on the presence of depression ($p \geq 0.245$). *Chart B:* Females with a tourniquet consumed significantly more opioids in the first 24 hours following surgery than females without a tourniquet (42.8 vs. 18.8 morphine equivalents, $p < 0.001$). There were no differences in pain (Chart A) or amount of opioids consumed (Chart B) among males with and without a tourniquet.

The project described was supported by the Indiana University Health – Indiana School of Medicine Strategic Research Initiative

Poster P0683 presented at the 2018 Annual Meeting of the AAOS (New Orleans, LA, USA)

Table 1	FEMALES			MALES		
	Tourniquet	No Tourniquet	*p*	Tourniquet	No Tourniquet	*p*
N	**76**	**60**		17	31	
Mean Age in years	66.9	67.2	0.844	71.3	66.7	**0.046**
Mean BMI kg/m^2	33.5	33.8	0.788	33.5	34.4	0.664
Median Procedure Time in Minutes	74.0	74.5	0.833	77.3	85.2	**0.023**
Mean Limb Ischemia Time in Minutes	70.1	0.0		72.9	0.0	–
% with Lumbar Spine Disease	18.4	15.0	0.651	41.2	22.6	0.201
% with Fibromyalgia or SLE	7.9	6.7	1.000	0.0	0.0	
% with Depression	27.6	45.0	**0.047**	0.0	16.1	0.146
% without Preoperative Narcotic Use	65.8	71.7	0.724	64.7	67.7	0.968





Conclusion: Tourniquet use has been associated with increased postoperative pain but the effect on opioid consumption and modulating factors such as patient sex is not well known. We observed that female patients with tourniquets compared to those without tourniquets reported significantly higher pain and opioid consumption in the first 24 hours after surgery. Pain and opioid consumption did not vary based on tourniquet use in male patients. Avoiding tourniquet use for females may be a relatively risk-free adjunct to minimize opioid consumption during hospitalization. Further study is warranted to elucidate the factors accounting for different outcomes in females and males.

The project described was supported by the Indiana University Health – Indiana School of Medicine Strategic Research Initiative

Poster P0683 presented at the 2018 Annual Meeting of the AAOS (New Orleans, LA, USA)

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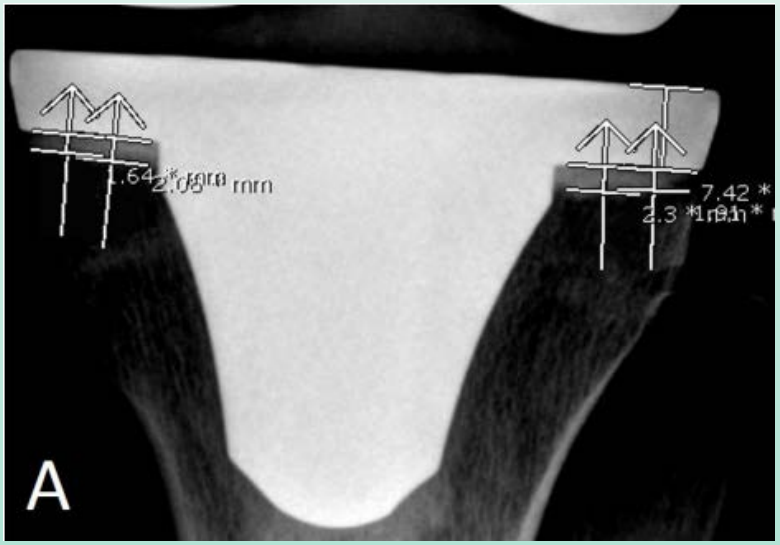
What is the Clinical Evidence?

4. Facilitates a Tourniquetless TKA technique *(continued)*

Cement penetration in Tourniquetless TKA with CarboJet → **Greater than** → **Cement penetration in Standard (Tourniquet) TKA without CarboJet**

Meneghini et al (2019) The Effect of Tourniquet Use and Sterile Carbon Dioxide Gas Bone Preparation on Cement Penetration in Primary Total Knee Arthroplasty. The Journal of Arthroplasty (2019).

This study compared a group with CarboJet and no tourniquet versus a group without CarboJet and with tourniquet. Results show that, by adopting CarboJet and eliminating the tourniquet, cement penetration can actually be improved.



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What is the Clinical Evidence?

5. Improves cleaning of osteochondral allograft

Effectiveness of Lavage Techniques in Removing Immunogenic Elements from Osteochondral Allografts

Cartilage
1–5

DOI: 10.1177/1947603516681132

RUSH UNIVERSITY MEDICAL CENTER

Maximilian A. Meyer[1], Mark A. McCarthy[1], Matthew E. Gitelis[1], Sarah G. Poland[1], Atsushi Urita[1], Susan Chubinskaya[2], Adam B. Yanke[1], and Brian J. Cole[1]

PDF

- Remaining marrow elements have been shown to stimulate an immune response in the host that may affect graft survival
- High-pressure carbon dioxide gas more effectively clears marrow elements from osteochondral allografts than saline alone

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Value Proposition

- Hospital
  - Improved patient outcomes, improved patient satisfaction, state of the art clinical care
- Patients
  - Improved clinical result and higher patient satisfaction
- Surgeons
  - State of the art surgical techniques and improved clinical results

Literature Summary

The CarboJet CO2 Bone Preparation system offers important benefits that are not available through the use of any other product. These benefits include:

1. The improved ability to perform total knee arthroplasty (TKA) without the use of a tourniquet *(see study by Jones).* The tourniquetless TKA technique is associated with a reduction in post-op pain and opioid consumption (*see published study* and *AAOS abstract by Meneghini),* as well as other clinical benefits. There is widespread availability of scientific literature describing the adverse effects of tourniquet use in TKA, including the following linked studies:

   - Faster recovery without the use of a tourniquet in total knee arthroplasty
   - Does Tourniquet Use in TKA Affect Recovery of Lower Extremity Strength and Function?
   - Effects of tourniquet use on quadriceps function and pain in total knee arthroplasty

   A major challenge with Tourniquetless TKA is achieving an optimal "cement technique" because of the additional fluid debris present in the bone and at the implant interfaces. *CarboJet* addresses this challenge and enables surgeons to perform TKA without a tourniquet without compromising their cement technique. In fact, by adopting *CarboJet* and eliminating the tourniquet, cement penetration can actually be improved, as described in a recent *Journal of Arthroplasty* study which compared a group with no tourniquet and with *CarboJet* versus a group with tourniquet and without *CarboJet* (*see 2019 study by Meneghini et al*).

2. A demonstrated increase in cement penetration into the cancellous bone matrix in TKA as compared to pulsatile saline lavage (*see studies by Meneghini et al* and *Goldstein et al)* as a result of effective removal of lipids/ fatty marrow, blood, and saline from the bone bed. Aseptic loosening was shown in a recent study to be the number one cause of knee arthroplasty failure *(see study by Schroer et al). Also see the White Paper on Aseptic Loosening (linked here), which discusses some of the numerous studies showing similar results over the last decade. Below are links to some of these studies:*

   - Why are total knee arthroplasties being revised?
   - Why are total knee replacements revised?: analysis of early revision in a community knee implant registry.
   - Revision total knee arthroplasty in the young patient: is there trouble on the horizon?

3. A demonstrated increase in the bone-cement interface strength *(see study by Stanley et al).* In this study, bone-cement interface strength was shown to be 58% higher with *CarboJet* cleaning versus saline.

4. The ability to gain access in the posterior regions of the knee to achieve bone bed cleaning and drying in both TKA and UKA (unicompartmental knee arthroplasty) (see technique vignette by Dr. Dennis McGee) . It is extremely difficult to gain access to the posterior femoral bone cuts in TKA, and particularly UKA with its small incision, for adequate cleaning and drying of the bone bed using saline methods.

5. A demonstrated decrease in large intraoperative cardiac emboli as evidenced by reduced cardiac echogenic load *(see study by Lassiter et al).* The embolization of fat and marrow contents into the vascular tree is a very serious issue that demands our best efforts to mitigate.

6. A demonstrated improvement in the removal of immunogenic elements from Osteochondral Allografts (OCA) (see study by Cole et al). Given that postoperative antibody development may impact graft integrity and longevity in OCA surgery, there is tremendous interest in decreasing the amount of antigenic cellular material present in osteochondral allografts.

7. Improved 10-year survivorship rates for hip resurfacing arthroplasty *(see study by Amstutz & Le Duff).* This long-term, large-cohort study showed that the addition of CarboJet to the author's hip resurfacing technique improved 10 year survivorship rates.

In summary, by addressing these important issues, *CarboJet* contributes to our shared mission to provide the highest standard of patient care.

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Thank You!

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