



The PJI Diagnosis and Treatment

Thorsten Gehrke



ENDO Clinic Hamburg

51 Years ago



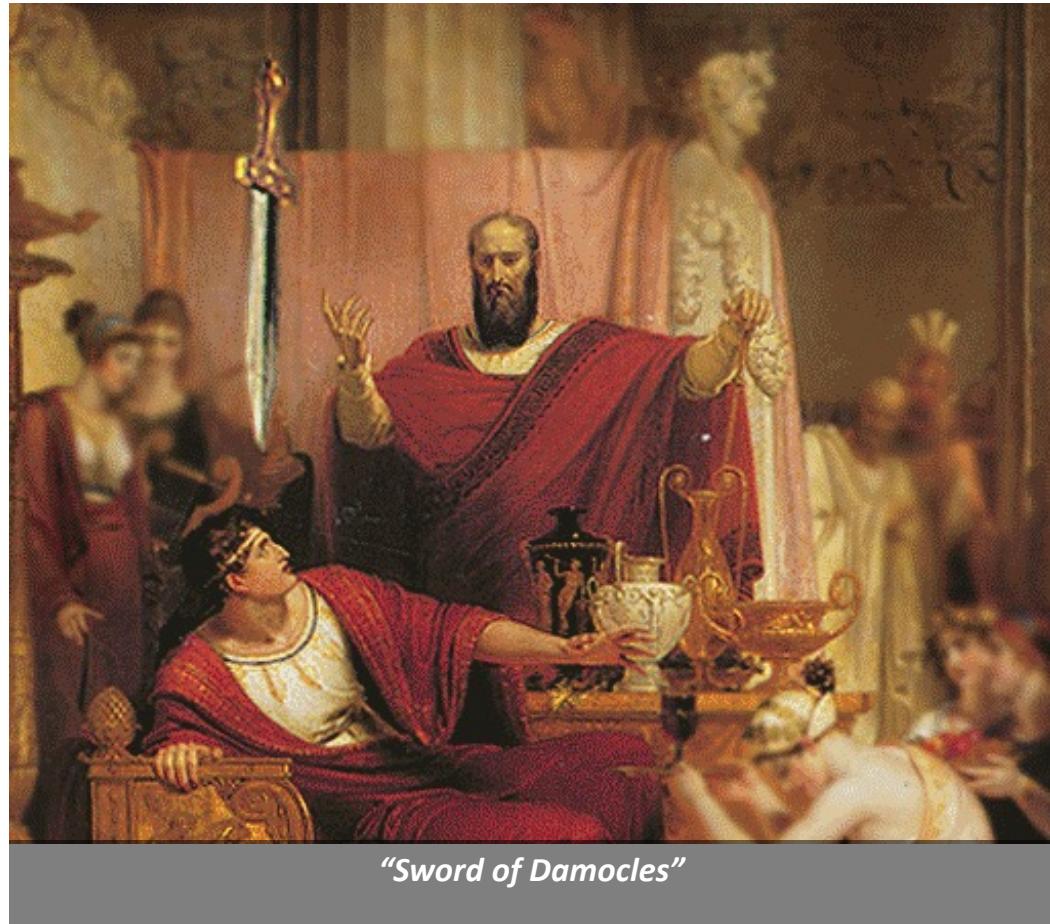
“The greatest challenge of THA is to eliminate PJI completely.”

Sir J. Charnley , CORR, 1972



ENDO Clinic Hamburg

PJI – An ever present danger!



Courtesy: S. Jones

Multiple Definitions

TABLE 3 Proposed definitions for prosthetic joint infection^a

Criterion	Definition of prosthetic joint infection ^b		Infectious Diseases Society of America	
	Musculoskeletal Infection Society	International Consensus	Definitive evidence	Supportive evidence
Sinus tract communicating with the prosthesis		x		x
Identical microorganisms isolated from 2 or more sites		x		x
Purulence surrounding the prosthesis	x			x
Acute inflammation upon histological examination of periprosthetic tissue	x		x	x
Single culture with any pathogen	x		x	
Single culture with a high index of suspicion	x			x
Elevated synovial fluid white blood cell count	x		x	
Elevated synovial fluid neutrophil percentage	x		x	4
Elevated serum ESR and/or CRP	x		x	

^a The MSIS definition requires 2 supportive criteria; the International Consensus Meeting definition requires 3 supportive criteria. Data are from references 60, 61, and 251. ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

^b The International Consensus Meeting definition also includes a “++” result on the leukocyte esterase strip.

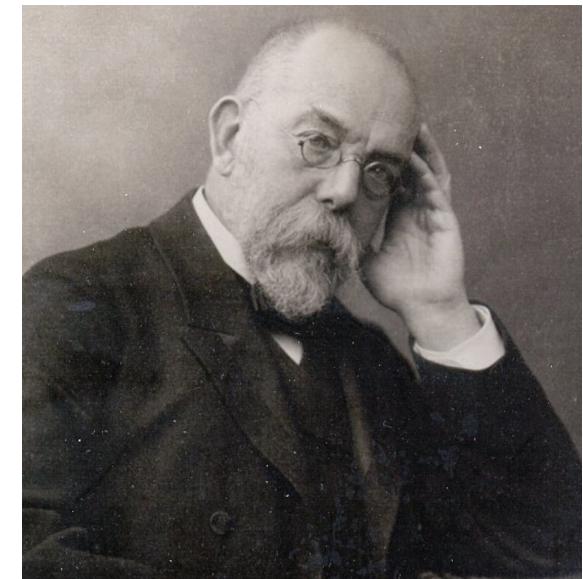
Diagnosis of PJI is difficult

Current Pathogen Identification Methods

Culture = “Gold standard?”

- 1886 technology
- Imperfect
- Technique / Lab-dependent
- Time to lab / # Samples
- Duration incubation
- Many more

Koch



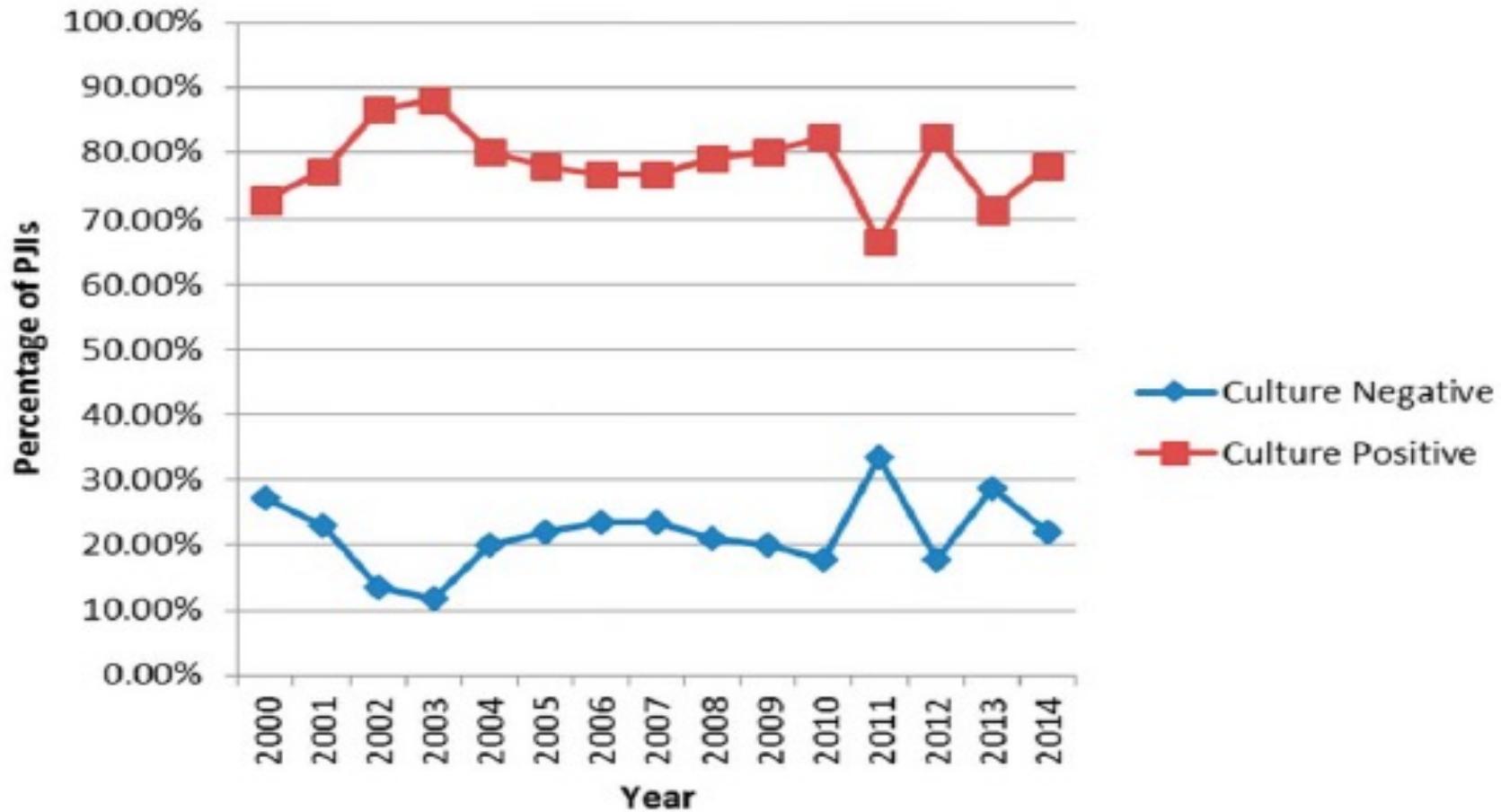
Main advantage culture



Able to test the susceptibility of bacteria for different antibiotics



How often do we have Culture Negative results



Tan TL et al. *JBJS open access* 2018; 3(3).

Laboratory Tests sometimes used

JOURNAL OF
MEDICAL MICROBIOLOGY

Volume 68, Issue 6

Research Article | Free

Serum C-reactive protein relation
pathogens in the diagnosis

Niklas Unter Ecker¹ , Eduard

Nael Hawi², Mustafa

„Approximately 15 % of infected PJI
cases have normal CRP values“

387 PJI cases

386 Cases of aseptic revision

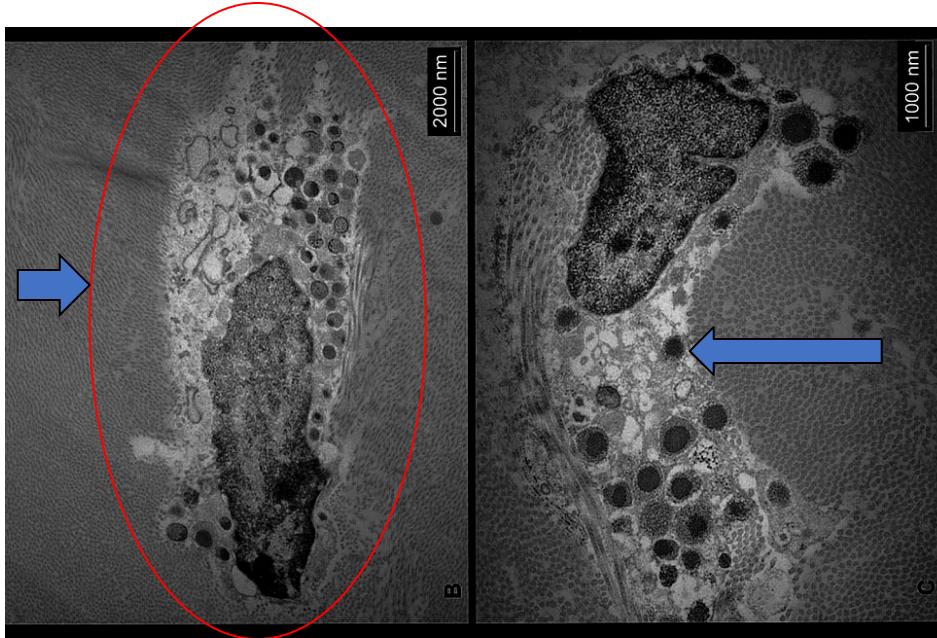


Here is no doubt!



Intracellular *S. aureus* in Periprosthetic Tissue

Osteoblast



S. aureus

European Cells and Materials Vol. 25 2013 (pages 341-350)

ISSN 1473-2262

INTRA-CELLULAR STAPHYLOCOCCUS AUREUS ALONE CAUSES INFECTION *IN VIVO*

Therwa Hamza^{1,2}, Matthew Dietz¹, Danh Pham¹, Nina Clovis¹, Suzanne Danley¹ and Bingyun Li^{1,2,3,4,*}

¹Department of Orthopaedics, School of Medicine, West Virginia University, Morgantown, WV 26506, USA

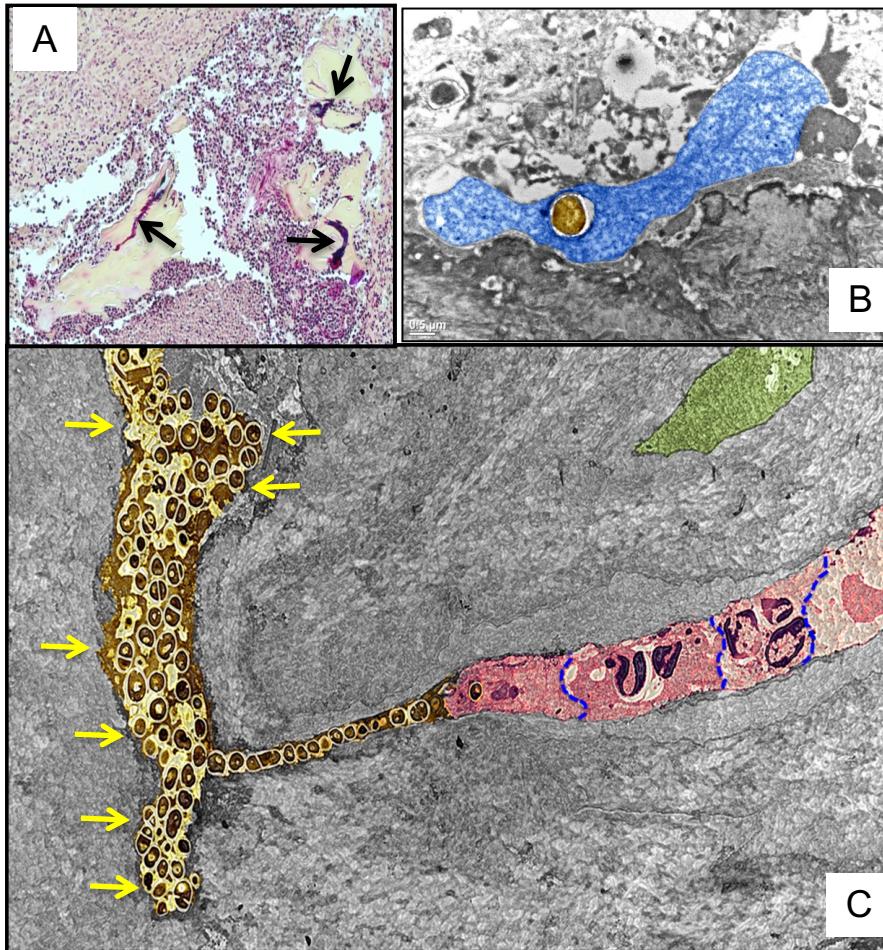
²Department of Basic Pharmaceutical Sciences, School of Pharmacy, West Virginia University, Morgantown, WV 26506, USA

³WVNano Initiative, Morgantown, WV 26506, USA

⁴Mary Babb Randolph Cancer Center, Morgantown, WV 26506, USA

Parham S et al, Clin Infect Dis 2006

S. aureus in Bone Canaliculi



Colonized Osteocytic-
Canalicular Networks are
the Major Reservoirs of
S. aureus in Chronic
Osteomyelitis.

Courtesy of Edward Schwarz

ICM Algorythm (2018)

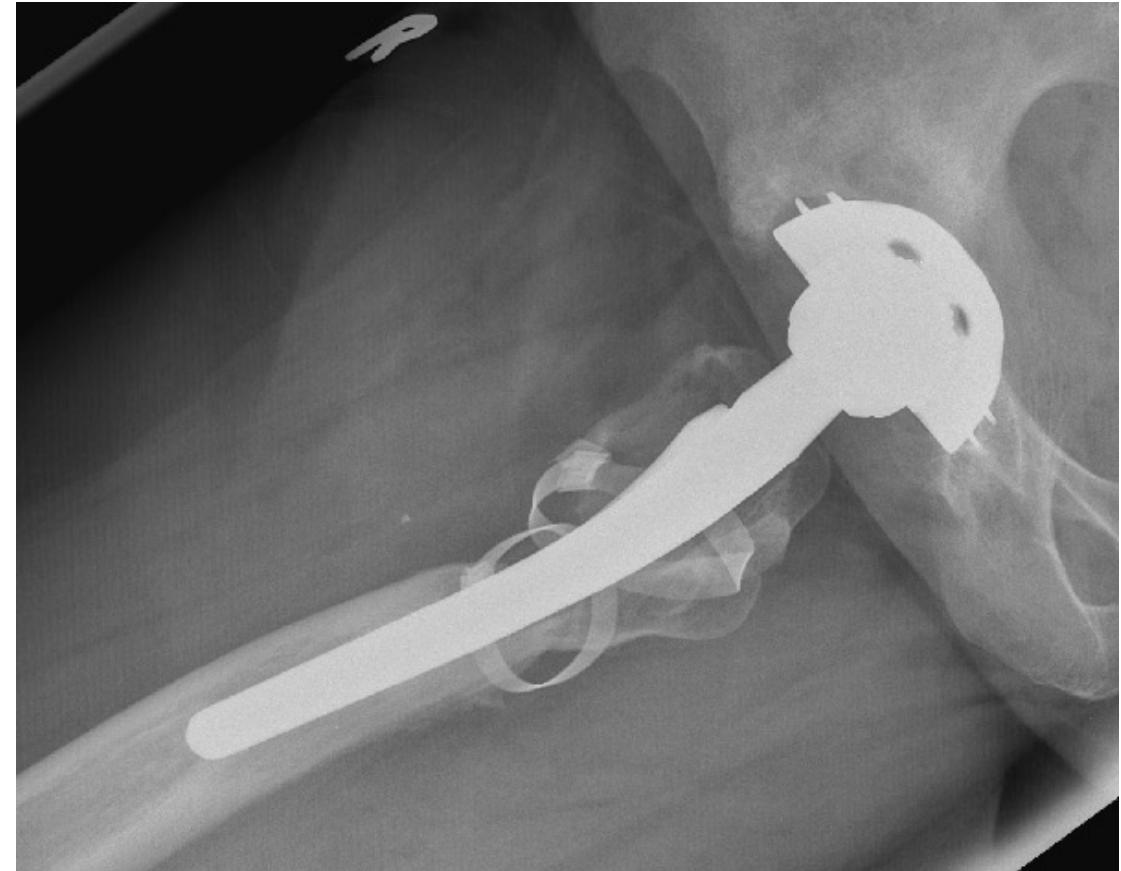
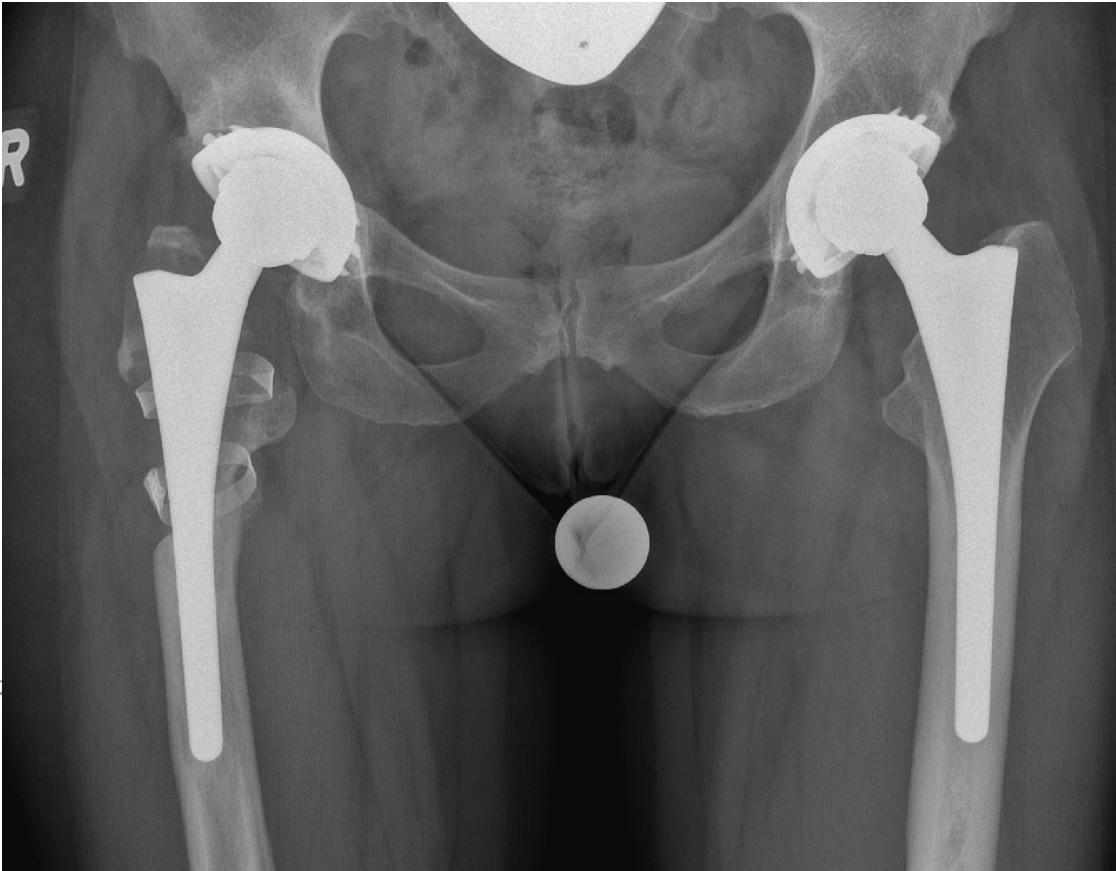
Second INTERNATIONAL
CONSENSUS MEETING (ICM)
on MUSCULOSKELETAL INFECTION



Major criteria (at least one of the following)	Decision
Two positive growth of the same organism using standard culture methods	Infected
Sinus tract with evidence of communication to the joint or visualization of the prosthesis	

Minor Criteria	Threshold		Score	Decision
	Acute [€]	Chronic		
Serum CRP (mg/L)	100	10	Combined preoperative and postoperative score: ≥6 Infected 4-5 Inconclusive* ≤3 Not Infected	
<i>or</i>	Unknown	860		
D-Dimer (ug/L)				
Elevated Serum ESR (mm/hr)	No role	30		
Elevated Synovial WBC (cells/µL)	10,000	3,000		
<i>or</i>				
Leukocyte Esterase	++	++		
<i>or</i>				
Positive Alpha-defensin (signal/cutoff)	1.0	1.0		
Elevated Synovial PMN (%)	90	70		
Single Positive Culture			2	
Positive Histology			3	
Positive Intraoperative Purulence [¥]			3	

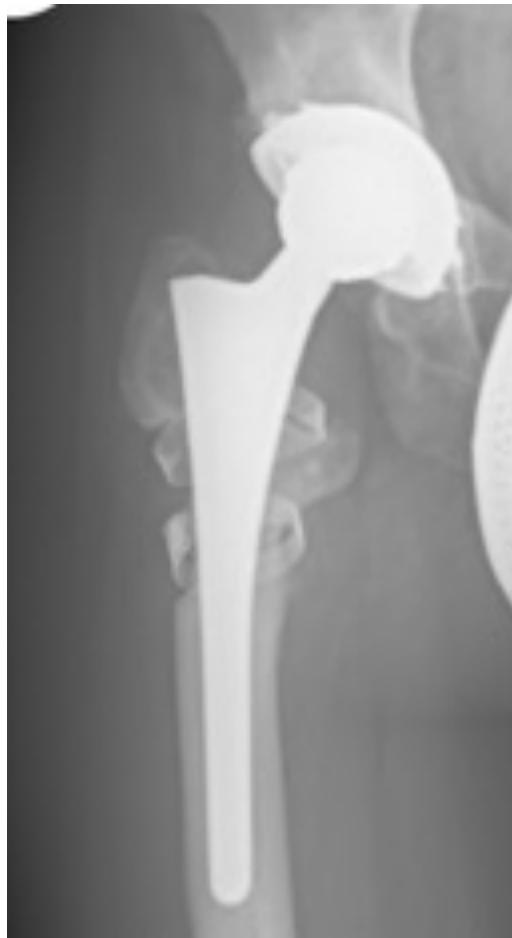
Paul, 60 Years



06/2019



09/2013



05/2014

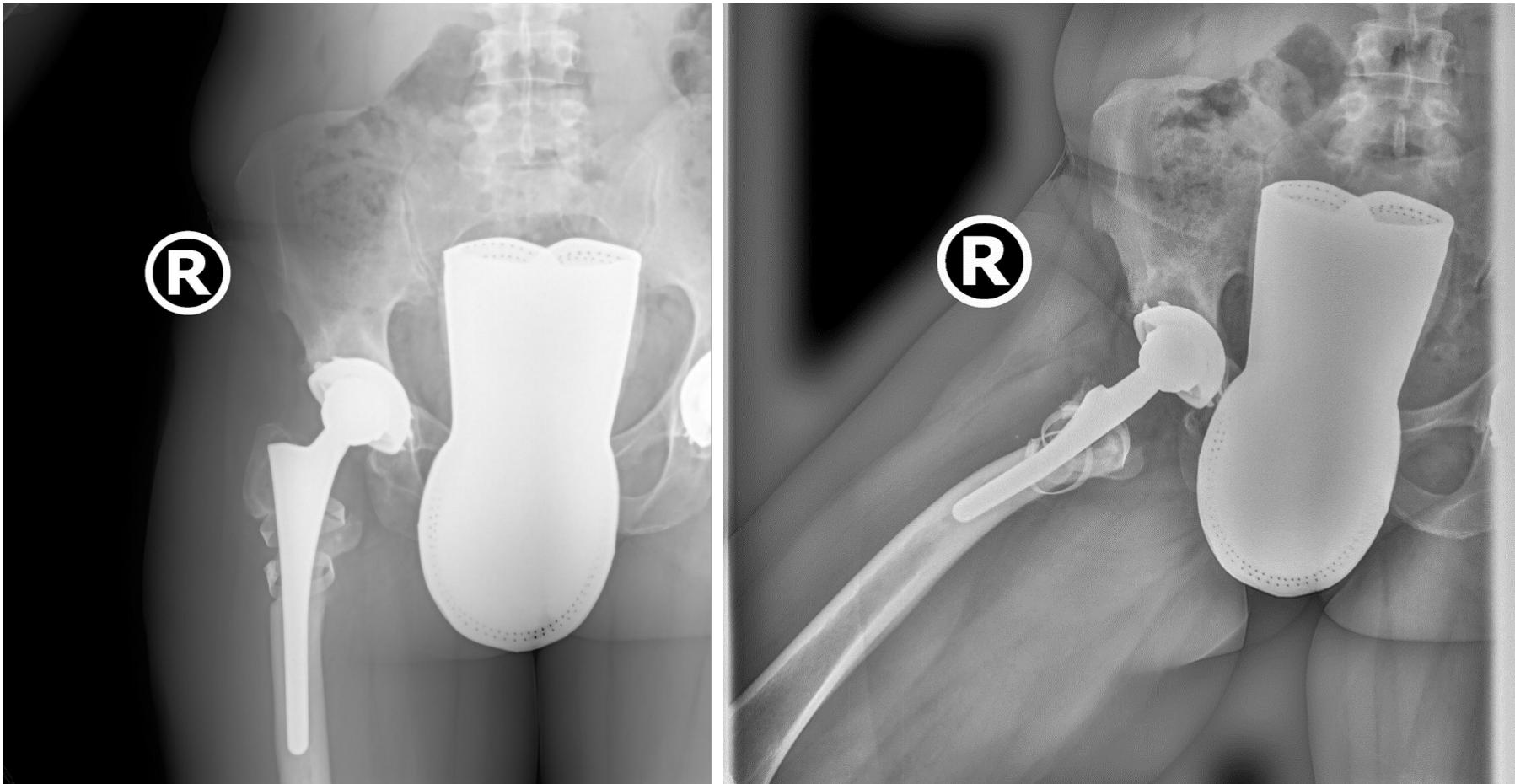


06/2019



01/2020

06/2020



27.05.24

Massive pain right hip

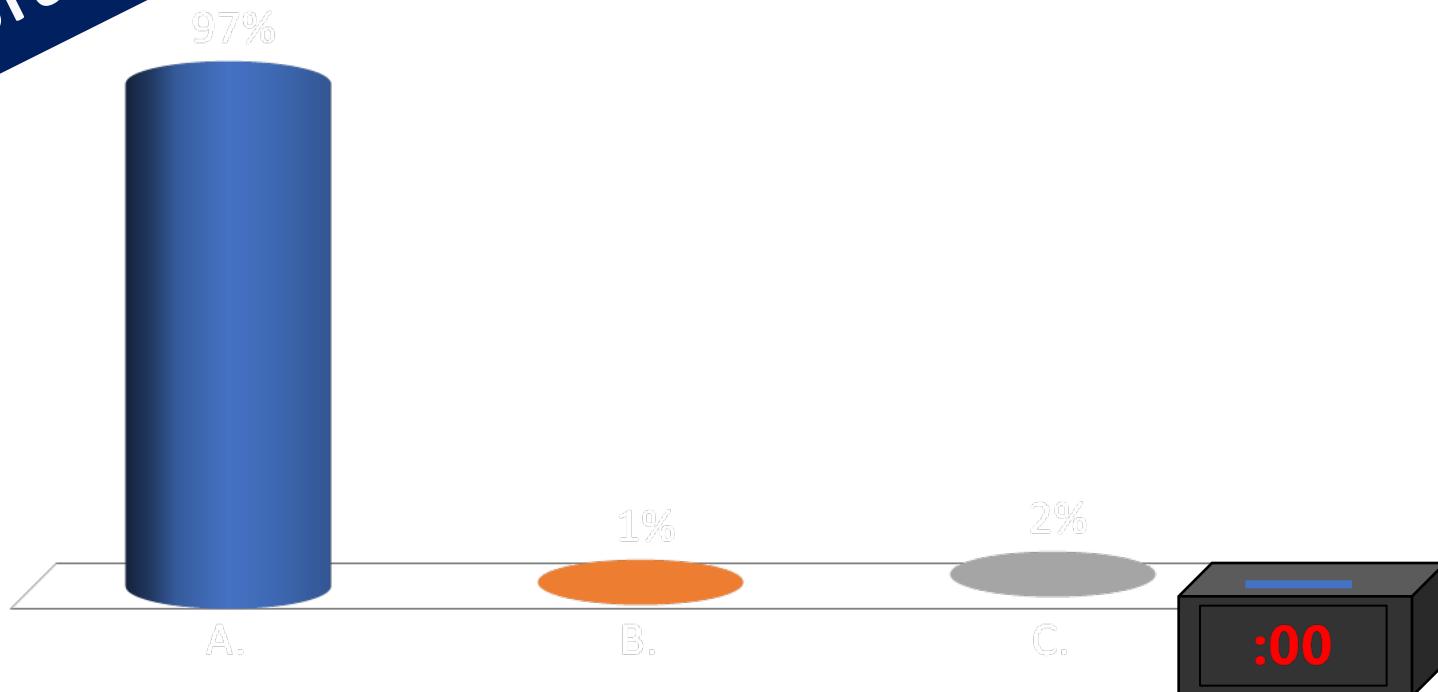


Recommendation: A painful prosthetic joint is the **most sensitive but least specific clinical finding in PJI**. Signs of deep tissue involvement (sinus tract, purulence, abscess or extensive necrosis) are the most specific signs. It is important to note that clinical findings differ notably based on the type of joint involved (hip or knee) as well as to the timing of presentation of PJI (early postoperative, acute hematogenous, and chronic).

Level of Evidence: Moderate

- A. Agree
- B. Disagree
- C. Abstain

Pain: Most sensitive, but least specific

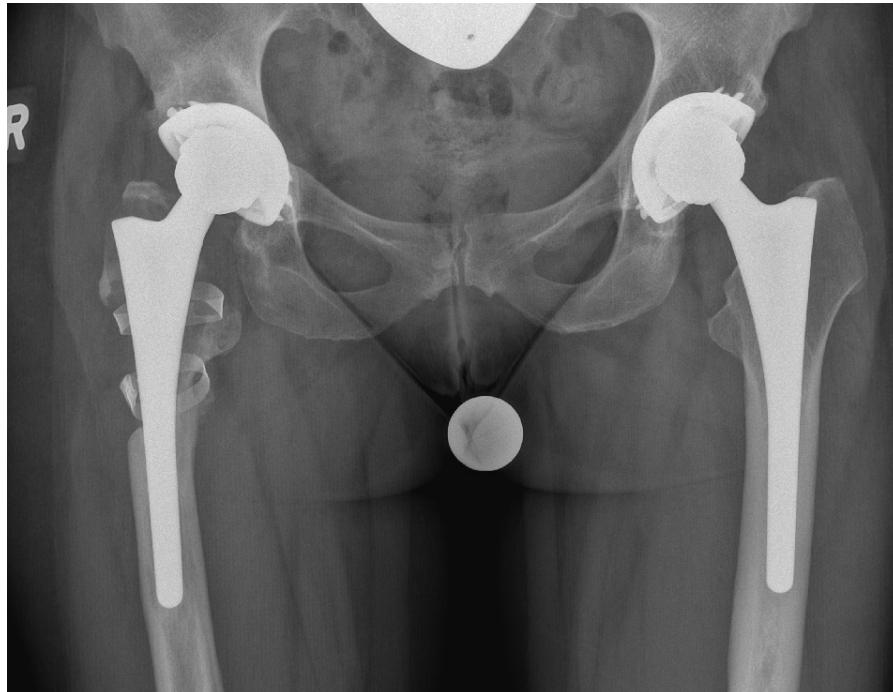


The Aspiration



Minor Criteria	Threshold		Score	Decision
	Acute [€]	Chronic		
Serum CRP (mg/L)	100	10	2	Combined preoperative and postoperative score: ≥6 Infected 4-5 Inconclusive* ≤3 Not Infected
<u>or</u> D-Dimer (ug/L)	Unknown	860		
Elevated Serum ESR (mm/hr)	No role	30	1	
Elevated Synovial WBC (cells/µL)	10,000	3,000	3	
<u>or</u> Leukocyte Esterase	++	++		
<u>or</u> Positive Alpha-defensin (signal/cutoff)	1.0	1.0		
Elevated Synovial PMN (%)	90	70	2	
Single Positive Culture			2	
Positive Histology			3	
Positive Intraoperative Purulence [¥]			3	

Should we aspirate both sides?



06/2019

THE BONE & JOINT JOURNAL
EST. 1948

■ ARTHROPLASTY

Periprosthetic joint infection in patients with multiple arthroplasties

AN UPDATE ON METACHRONOUS PERIPROSTHETIC JOINT INFECTION

**R. Sangaletti,
L. Zanna,
M. Akkaya,
N. Sandiford,
S. Ekhtiari,
T. Gehrke,
M. Citak**

From HELIOS ENDO-Clinic, Hamburg, Germany

Aims
Despite numerous studies focusing on periprosthetic joint infections (PJIs), there are no robust data on the risk factors and timing of metachronous infections. Metachronous PJIs are PJIs that can arise in the same or other artificial joints after a period of time, in patients who have previously had PJI.

Methods
Between January 2010 and December 2018, 661 patients with multiple joint prostheses *in situ* were treated for PJI at our institution. Of these, 73 patients (11%) developed a metachronous PJI (periprosthetic infection in patients who have previously had PJI in another joint, after a lag period) after a mean time interval of 49.5 months (SD 30.24; 7 to 82.9). To identify patient-related risk factors for a metachronous PJI, the following parameters were analyzed: sex; age; BMI; and pre-existing comorbidity. Metachronous infections were divided into three groups: Group 1, metachronous infections in ipsilateral joints; Group 2, metachronous infections of the contralateral lower limb; and Group 3, metachronous infec-

02/23

Methods

Group 1
SAME-SIDE



Group 2
CONTRALATERAL



Group 3
UPPER AND LOWER
LIMB



ENDO Clinic Hamburg

Results

	Non-Metachronous PJI	Metachronous PJI	p-value
Number of patients	588	73	
Average age at first septic revision (SD)	68.6 (12.4)	73.4 (17.0)	0.27
Average BMI (SD)	29.6 (6.1)	28.6 (5.7)	0.30
>2 prosthesis (%)	128 (19.4)	19 (26)	0.10
Difficult to treat primary PJI	10.5 %	8.2 %	0.54
History of neoplasia	0.7 %	1.4 %	0.52
Immune-modulating therapy	0.4 %	1.4 %	0.22
Rheumatoid arthritis	6.1 %	5.5 %	0.49
Renal Insufficiency	8.3 %	8.2 %	0.97
Polymicrobial primary PJI	4.6 %	28.8 %	<0.05
Enterobacter	0.3 %	5.5 %	<0.05
Diabetes mellitus	17.9 %	27.4 %	<0.05



Where should we perform the aspiration?



How do you perform the aspiration?



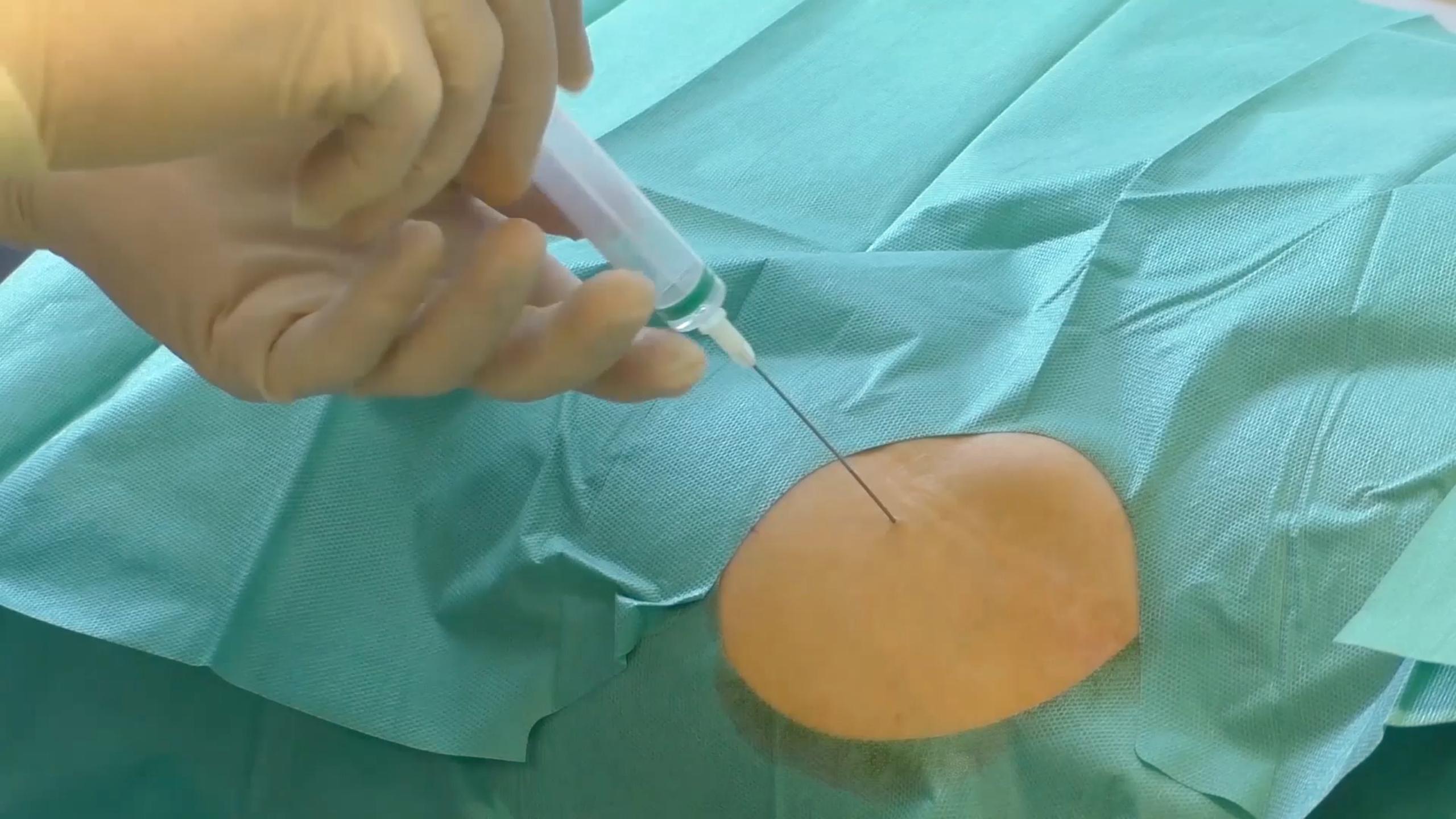
CT-Guided



Ultrasound guided



Fluoroscopy guided



Criteria	Aspiration right hip	Aspiration left hip
Sinus tract	-	-
Culture 2x	-	-
Cell count	17.020 (3.000)	457
Neutrophilpercentage	86,5% (70%)	35 (70%)
Leukocyteseserase-Test	+++	
Alpha-Defensin	6,7 (1,0)	0,1 (1,0)
Histology		
Serum CRP	25	25
Culture	Neg.	Neg.
Positive Purulence	-	-
(Sonication)		
Points (ICM)	7	0

Cell Count Studies

Study	Published (y)	Cutoff CC/ μ L	Cutoff PMN %	Joint
Mason et al [11]	J Arthroplasty (2003)	2500/ μ L	60%	Knee
Trampuz A et al [10]	Am J Med (2004)	1700/ μ L	57%	Knee
Della Valle CJ et al [7]	J Arthroplasty (2007)	2500/ μ L	58%	Knee
Ghanem E et al [12]	J Bone Joint Surg Am. (2008)	2500/ μ L	64%	Knee
Schinsky MF et al [13]	J Bone Joint Surg Am. (2008)	2500/ μ L	80%	Hip
Shukla SK et al [14]	J Arthroplasty (2010)	2500/ μ L	79%	Hip
Lee SC et al [15]	Orthopedics (2010)	2500/ μ L	89%	Knee
Kusuma SK et al [16]	Clin Orthop Relat Res (2011)	3000/ μ L	80%	Knee
Cipriano CA et al [17]	J Bone Joint Surg Am. (2012)	3450/ μ L	78%	Hip and knee
Dinneen A et al [18]	Bone Joint J (2013)	1590/ μ L	65%	Hip and knee
Zmistowski BM et al [19]	J Arthroplasty (2014)	640/ μ L	62%	Hip and knee (no specific joint)
Gallo J et al [20]	Univ Palacky Olomouc Czech Republ (2017)	3450/ μ L	74.6%	Hip and knee

ICM Cutoff: 3000/ μ L

Cell Count Cut-Off values

640/ μ L – 3600/ μ L



Complications - Infection

How Reliable Is the Cell Count Analysis in the Diagnosis of Prosthetic Joint Infection?

Akos Zahar, MD, PhD ^{a,*}, Christian Lausmann, MD ^a, Camila Cavalheiro, MD ^{a,b},
Anoop C. Dhamangaonkar, MS, DNB, D Ortho, FCPS Ortho ^{a,c},
Tommaso Bonanzinga, MD ^d, Thorsten Gehrke, MD ^a, Mustafa Citak, MD, PhD ^a

Joints	LE Test	Cell Count			<i>P</i> Value
		THA and TKA	THA and TKA	TKA	
Cutoff level	++ and +++	2582/ μ L	1630/ μ L	3063/ μ L	
Sens.	80.5%	80.6%	83.6%	78.1%	.607
Spec.	92.7%	85.2%	82.2%	80.0%	.043
PPV	88.0%	78.3%	70.8%	77.0%	
NPV	87.7%	86.9%	90.7%	81.0%	
Overall accuracy	87.8%	83.4%	82.7%	79.1%	.233

What Is the Impact of Automated Synovial Cell Counting on Different Aseptic Causes and Periprosthetic Conditions Associated with Revision THA?

Hussein Abdelaziz MD¹, Alaa Aljawabrah MD¹, Markus Rossmann MD¹, Calvin Shum Tien MD¹, Mustafa Citak MD, PhD¹, Till Orla Klatte MD, PhD², Thorsten Gehrke MD¹

Table 2. WBC count of different aseptic revision causes of THA and periprosthetic conditions

Variable	Mean ± SD
Revision cause (n)	
Aseptic loosening (475)	3520 ± 2796
Recurrent dislocation (113)	1200 ± 796
Polyethylene wear (42)	1821 ± 1167
Implant fracture (13)	
Iliopsoas impingement (12)	
Periprosthetic fracture (11)	
Elevated metal ions (6)	
Periprosthetic condition (n)	
Wear-induced synovitis (83)	4464 ± 3620
Osteolysis (33)	3565 ± 3555
Metallosis (47)	3103 ± 4063

Data presented as mean ± SD.

Table 3. Percentage (PMN%) of different aseptic revision causes of THA and periprosthetic conditions

Variable	PMN%
Revision cause (n)	
Aseptic loosening (475)	35 ± 21
Recurrent dislocation (113)	34 ± 23
Polyethylene wear (42)	42 ± 23
Implant fracture (13)	31 ± 25
Iliopsoas impingement (12)	44 ± 25
Periprosthetic fracture (11)	28 ± 25
Elevated metal ions (6)	41 ± 24
Periprosthetic condition (n)	
Wear-induced synovitis (83)	34 ± 23
Osteolysis (33)	35 ± 22
Metallosis (47)	45 ± 25

Data presented as mean ± SD.

CC is elevated in most of the aseptic revisions,
PMN% not!

Criteria	Aspiration right hip	Aspiration left hip
Sinus tract	-	-
Culture 2x	-	-
Cell count	17.020 (3.000)	457
Neutrophilpercentage %	86,5% (70%)	35 (70%)
Leukocyteserase-Test	+++	
Alpha-Defensin	6,7 (1,0)	0,1 (1,0)
Histology		
Serum CRP	25	25
Culture	Neg.	Neg.
Positive Purulence	-	-
(Sonication)		
Points (ICM)	7	0

Determining Diagnostic Thresholds for Acute Postoperative Periprosthetic Joint Infection

Kamolsak Sukhonthamarn, MD, Timothy L. Tan, MD, Chi Xu, MD, Feng-Chih Kuo, MD, Mel S. J. Mustafa Citak, MD, PhD, Thorsten Gehrke, MD, Karan Goswami, MD, and Javad Parvizi, MD

TABLE II Diagnostic Performance of Each Marker by Time Period After Arthroplasty*

Time Period and Marker	Threshold	Sensitivity	Specificity	LR+ Value	AUC*
90 days	Synovial fluid WBC count 6,130 cells/ μ L	0.864	0.932	0.884	0.96 (0.93 to 0.99)
	Synovial PMN percentage 79.5%	0.897	0.732	0.900	0.79 (0.69 to 0.88)
	Serum CRP 14.9 mg/L	0.821	0.893	0.889	0.94 (0.90 to 0.99)
	ESR 45 mm/hr	0.727	0.674	0.737	0.705
45 days	Synovial fluid WBC count 6,130 cells/ μ L	0.864	0.891	0.884	0.875
	Synovial PMN percentage 79.5%	0.909	0.609	0.69	0.875
	Serum CRP 14.9 mg/L	0.818	0.891	0.878	0.837
	ESR 45 mm/hr	0.727	0.674	0.681	0.721
180 days	Synovial fluid WBC count 10,170 cells/ μ L	0.846	0.952	0.943	0.870
	Synovial PMN percentage 87%	0.897	0.643	0.700	0.871
	Serum CRP 50.7 mg/L	0.821	0.905	0.889	0.844
	ESR 48.5 mm/hr	0.667	0.714	0.684	0.698

*The values are given as the AUC, with the 95% CI in brackets.

PMN% is the Best in acute



ELSEVIER

Contents lists available at [ScienceDirect](#)

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org



Complications - Infection

The 2018 International Consensus Meeting Minor Criteria for Chronic Hip and Knee Periprosthetic Joint Infection: Validation From a Single Center



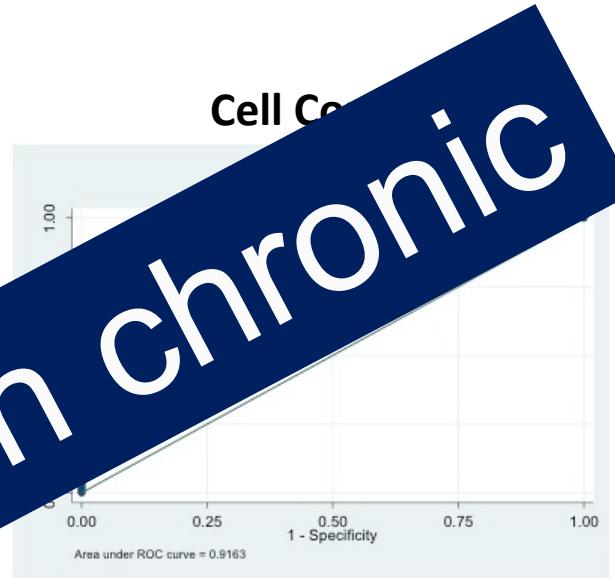
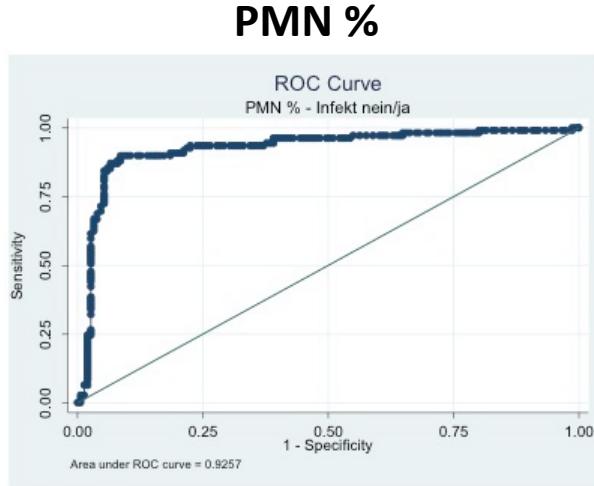
Check for updates

Hussein Abdelaziz, MD ^{a,*}, Kristof Rademacher, MD ^{a,b}, Eduardo M. Suero, MD ^c,
Thorsten Gehrke, MD ^a, Christian Lausmann, MD ^a, Jochen Salber, MD, PhD ^b,
Mustafa Citak, MD, PhD ^a

^a Department of Orthopaedic Surgery, Helios ENDO-Klinik, Hamburg, Germany

^b Department of Surgery, Ruhr-University Hospital, Bochum, Germany

^c Department of Trauma and Reconstructive Surgery, Ludwig-Maximilians-University, Munich, Germany



Diagnostic performance of Predictive Tests ranked in descending order:

PMN% is the best in chronic sinusitis = 345

1. PMN% (0.926)
2. Alpha-Defensin (0.922)
3. Cell count (0.916)
4. LE-test (0.861)
5. Serum CRP (0.860)

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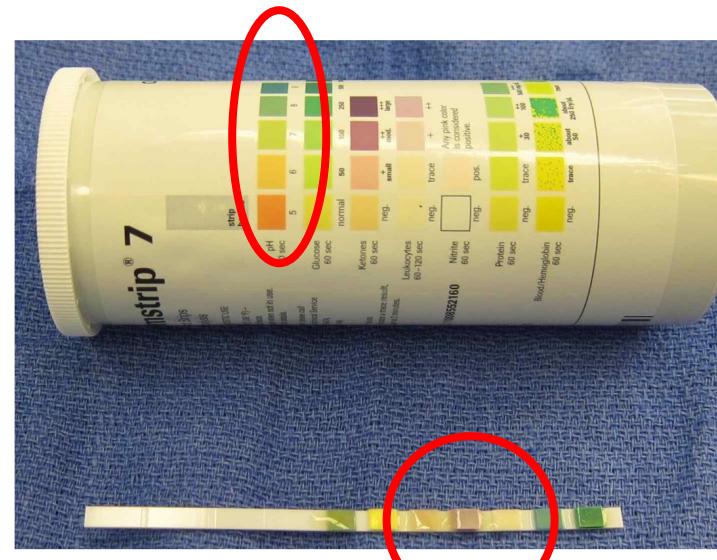
Leukocyte-esterase (LE) – Urinary Strips

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Diagnosis of Periprosthetic Joint Infection: The Utility of a Simple Yet Unappreciated Enzyme

Javad Parvizi, MD, FRCS, Christina Jacovides, BS, Valentin Antoci, MD, PhD, and Elie Ghanem, MD

Investigation performed at the Rothman Institute of Orthopedics at Thomas Jefferson University Hospital, Philadelphia, Pennsylvania



- **Parvizi J, Jacovides C, Antoci V, Ghanem E:** Diagnosis of periprosthetic joint infection: the utility of a simple yet unappreciated enzyme, JBJS-Am 2011, 93(24): 2242-8
- **Aggarwal VK, Tischler E, Ghanem E, Parvizi J:** Leukocyte esterase from synovial fluid aspirate: a technical note, J arthroplasty 2013, 28(1): 193-5

- cheap
- quick
- easy to carry out

Sensitivity: 85.7 %
Specificity: 88.3 %

> *J Arthroplasty*. 2021 Aug;36(8):2942-2945.e1. doi: 10.1016/j.arth.2021.03.006

Epub 2021 Mar 5.

Leukocyte Esterase Versus C-reactive Protein in the Diagnosis of Periprosthetic Joint Infection

Emanuele Chisari¹, Stefano Sartori¹,

Javad Parvizi¹

Affiliations

Published:

July 2021

We suggest using the cutoff of LE1+ (result = negative or trace) as a point of care test to exclude infection, whereas LE at 2+ threshold has near absolute specificity for the diagnosis.

Criteria	Aspiration right hip	Aspiration left hip
Sinus tract	-	-
Culture 2x	-	-
Cell count	17.020 (3.000)	457
Neutrophilpercentage	86,5% (70%)	35 (70%)
Leukocyteseserase-Test	+++	+
Alpha-Defensin	6,7 (1,0)	0,1 (1,0)
Histology		
Serum CRP	25	25
Culture	Neg.	Neg.
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Points (ICM)	7	0

Alpha Defensin – Multicenter-Study



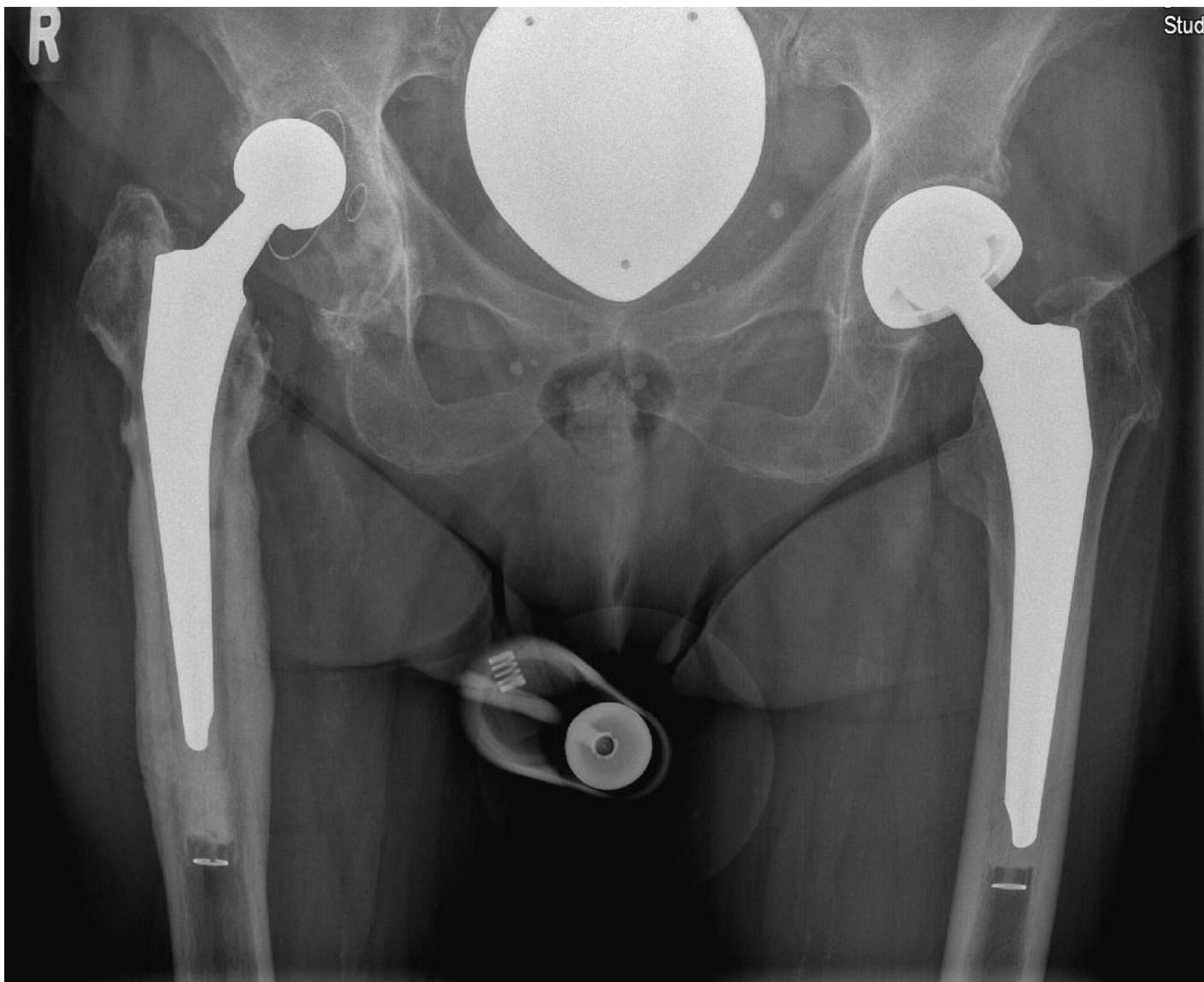
Institution	N	Gold Standard	Sensitivity	Specificity
Rothman Institute	149	MSIS Criteria	97% (3637)	96% (107/112)
Mayo Arizona	61	MSIS Criteria	100% (33/33)	95% (83/87)
Cleveland Clinic	111	MSIS Criteria	100% (24/24)	98% (53/54)
ENDO Klinik	156	MSIS Criteria	97% (28/29)	97% (123/127)
Cleveland Florida	70	MSIS Criteria	97% (34/35)	97% (34/35)
Combined	547		98.1% (95%CI: 95-100%)	96.4% (95%CI: 94-98%)

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Histology		
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Culture	Neg.	Neg.
Positive Purulence	-	-
(Sonication)		
Points (ICM)	7	0

7 Points = Infected

Major criteria (at least one of the following)			Decision	
Two positive growth of the same organism using standard culture methods			Infected	
Sinus tract with evidence of communication to the joint or visualization of the prosthesis				
Minor Criteria	Threshold		Score	Decision
Serum CRP (mg/L) or D-Dimer (ug/L)	100 Unknown	10 860	2	Combined preoperative and postoperative score: ≥6 Infected 4-5 Inconclusive* ≤3 Not Infected
Elevated Serum ESR (mm/hr)	No role	30	1	
Elevated Synovial WBC (cells/ μ L) or Leukocyte Esterase	10,000 ++	3,000 ++	3	
Positive Alpha-defensin (signal/cutoff)	1.0	1.0		
Elevated Synovial PMN (%)	90	70	2	
Single Positive Culture			2	
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Positive Intraoperative Purulence [¥]			3	

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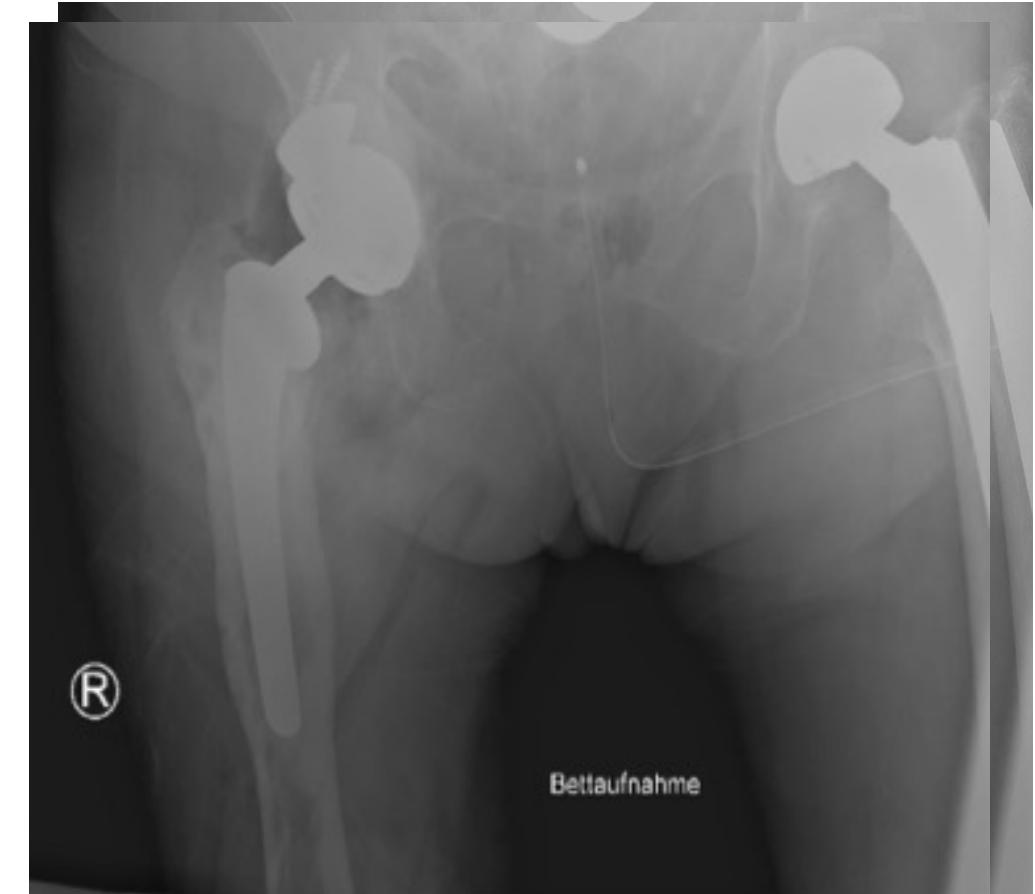
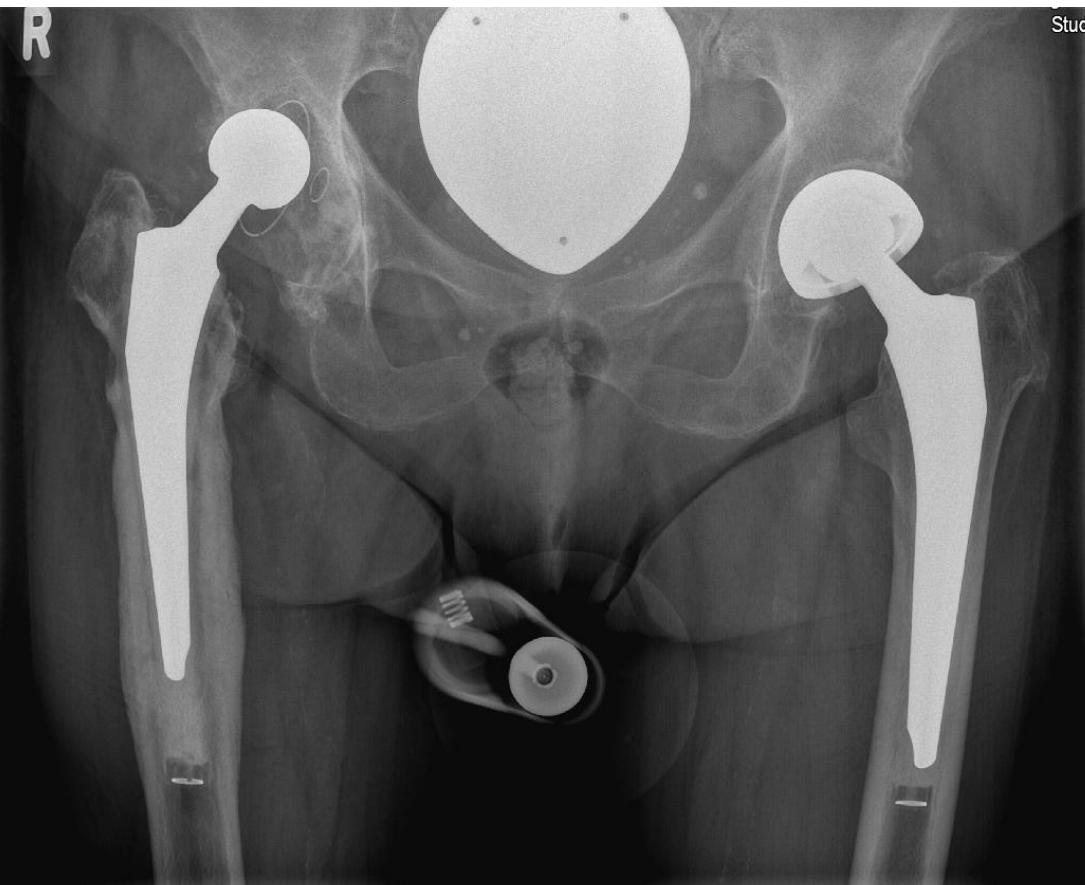
PJI right hip



Example

Joint	Date	Bacteria	LE-Test	Elevated Synovial WBC	Elevated Synovial PMN (%)	Alpha-Def	Serum CRP (mg/L)
Hip right	03.11.2020	No bacteria found	+++	32247/ μ l	95,3	6,1	17,5
Hip left	03.11.2020	No bacteria found	invalid	invalid	invalid	<0,1	17,5
Knee left	03.11.2020	No bacteria found	-	413/ μ l	49,7	<0,1	17,5
Hip right	24.11.2020	Streptococcus mutans	+++	78606/ μ l	92,7	6,0	

One Stage Exchange



No Germ



Biopsy (open)



Diagnostic utility of open biopsy in patients with two culture-negative aspirations in the diagnostic work-up of periprosthetic joint infection

Ianiv Klaber^{1,2} · Fabian Scholz¹ · Mustafa Citak¹ · Akos Zahar³ · Thorsten Gehrke¹ · Carl Haasper⁴ · Nael Hawi⁵ · Christian Lausmann¹ 

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Results 126 patients were included in this study. 62 (49.2%) patients had prior revisions, 48 of them due to PJI. The sensitivity and specificity of OB was 69.4% and 89.1%, respectively. The OB procedure led to the identification of the causative germ in 50 out of 126 (40%) cases so they could undergo one-stage (septic) exchange.

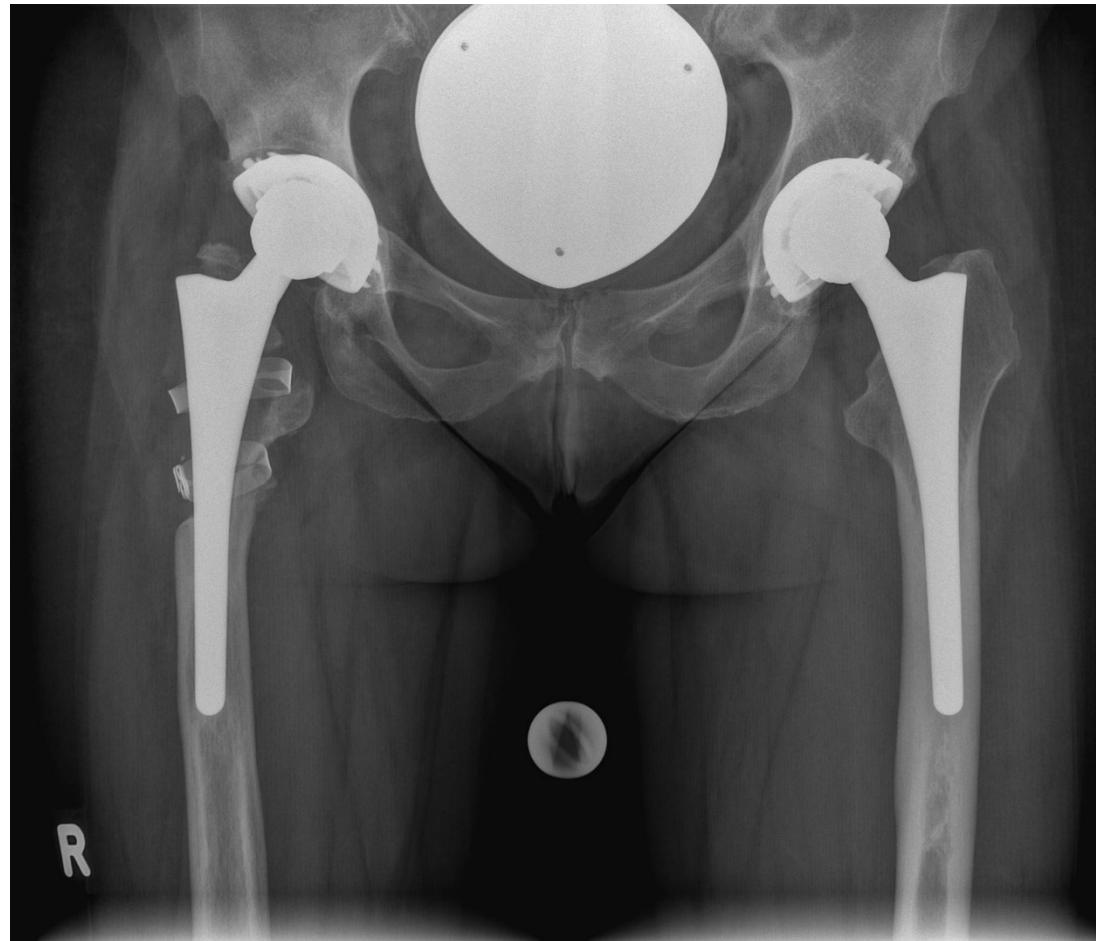
Conclusion The OB is a valuable resource if preoperative synovial fluid cultures are negative, a high suspicion of infection persists and a one-stage procedure is preferred. It intends bacteria identification and allows surgeons to evaluate prosthetic complications for further surgical procedures.

Criteria	Aspiration right hip	Aspiration left hip	Open Biopsy
Sinus tract	-	-	
Culture 2x	-	-	
Cell count	17.020 (3.000)	457	
Neutrophilpercentage	86,5% (70%)	35 (70%)	
Leukocyteserase-Test	+++	+	
Alpha-Defensin	6,7 (1,0)	0,1 (1,0)	
Histology			Low Grade Infection
Serum CRP	25	25	
Culture	Neg.	Neg.	Staph. Warneri, Cutibact. acnes
Positive Purulence	-	-	
(Sonication)			
Points (ICM)	7	0	10

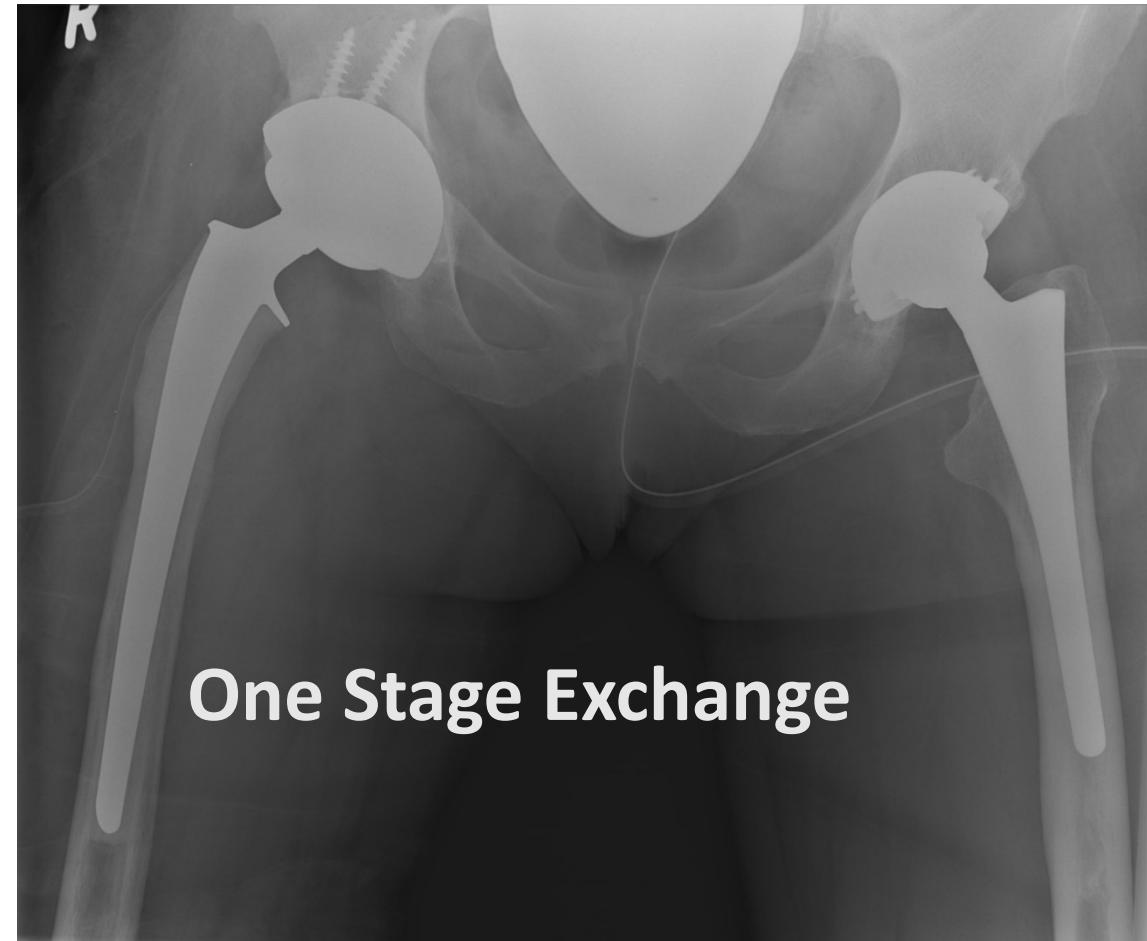
12 Points = Infected

Major criteria (at least one of the following)			Decision
Two positive growth of the same organism using standard culture methods			Infected
Sinus tract with evidence of communication to the joint or visualization of the prosthesis			
Minor Criteria		Threshold	Score
		Acute [€]	Chronic
Serum CRP (mg/L)		100	10
or			
D-Dimer (ug/L)		Unknown	860
Elevated Serum ESR (mm/hr)		No role	30
Elevated Synovial WBC (cells/ μ L)		10,000	3,000
or			
Leukocyte Esterase		++	++
or			
Positive Alpha-defensin (signal/cutoff)		1.0	1.0
Elevated Synovial PMN (%)		90	70
Single Positive Culture			2
Positive Histology			3
Positive Intraoperative Purulence ^x			3
			Combined preoperative and postoperative score:
			≥ 6 Infected
			4-5 Inconclusive*
			≤ 3 Not Infected

Tantal Revision + Double Mobility Cup



preoperative



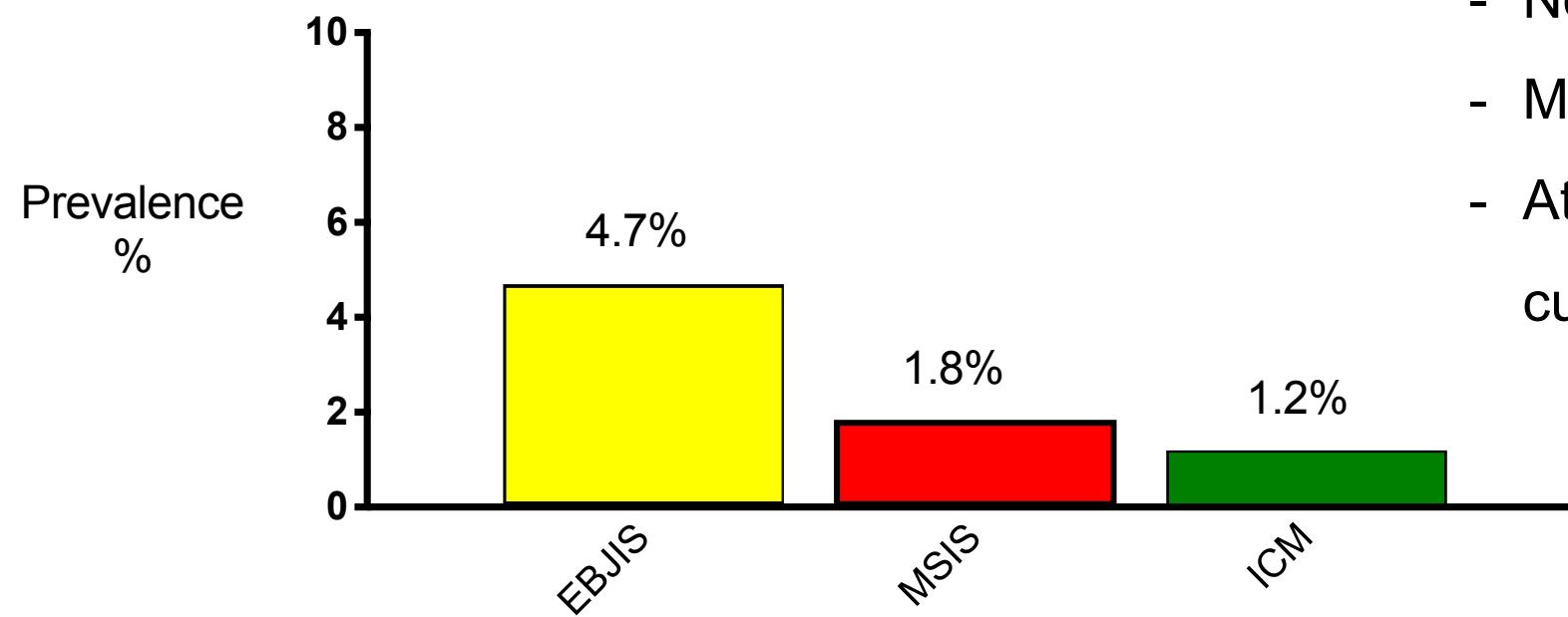
One Stage Exchange

postoperative

Molecular Testing



Indication: culture negative PJs



COHORT:

- No prior antibiotic treatment
- Minimal incubation time 9 days
- At least 4 intra-operative tissue cultures obtained

Most common molecular techniques

- Broad range 16S PCR
- Multiplex targeted PCR
- Next generation sequencing
- Targeted PCR for one specific microorganism

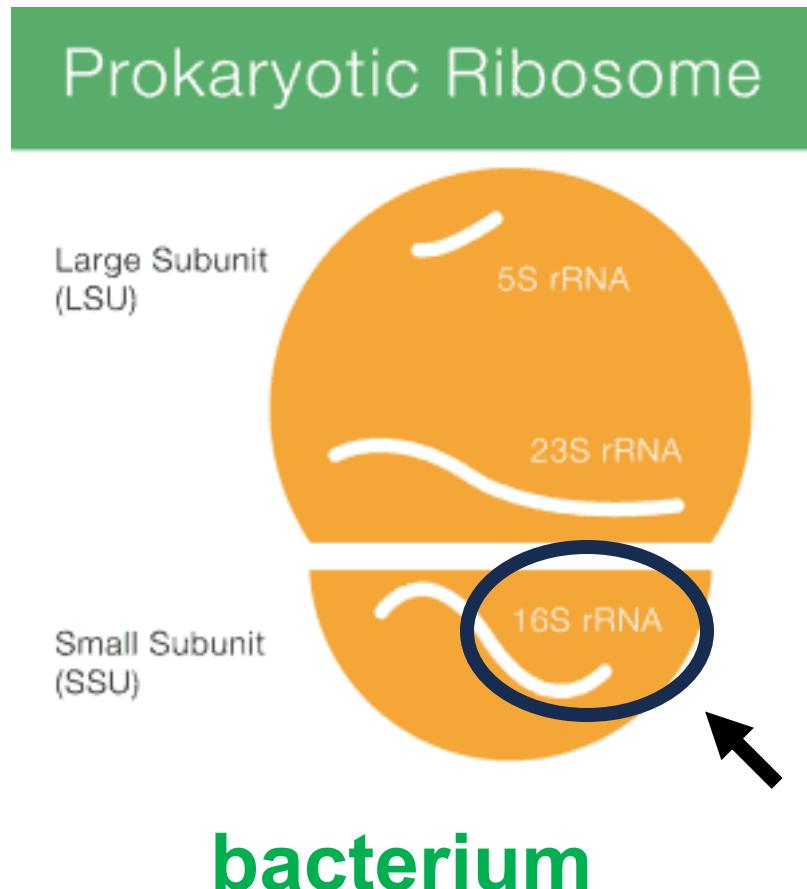
Most common molecular techniques

- Broad range 16S PCR
- Multiplex targeted PCR
- Next generation sequencing
- Targeted PCR for one specific microorganism

Targeted:

Specifically designed to
detect a predefined
bacterial species

Broad range 16S PCR



Advantages

- Available in most microbiology laboratories
- Cheap
- Can detect all types of bacterial species

Disadvantages

- Only detects 1 bacterial species that is most abundantly present
(not suitable to detect polymicrobial infections)
- Less sensitive than targeted PCR

Indication 16S PCR: monomicrobial infections



late acute (hematogenous)



Late chronic (without a sinus)

Multiplex targeted PCR

BIOFIRE® JOINT INFECTION (JI) PANEL MENU

1 TEST. 39 TARGETS. ~1 HOUR

GRAM-POSITIVE BACTERIA (15)

Anaerococcus prevotii/vaginalis
Clostridium perfringens
Cutibacterium avidum/granulosum
Enterococcus faecalis
Enterococcus faecium
Finegoldia magna
Parvimonas micra
Peptoniphilus
Peptostreptococcus anaerobius
Staphylococcus aureus
Staphylococcus lugdunensis
Streptococcus spp.
 Streptococcus agalactiae
 Streptococcus pneumoniae
 Streptococcus pyogenes

GRAM-NEGATIVE BACTERIA (14)

Bacteroides fragilis
Citrobacter
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Kingella kingae
Klebsiella aerogenes
Klebsiella pneumoniae group
Morganella morganii
Neisseria gonorrhoeae
Proteus spp.
Pseudomonas aeruginosa
Salmonella spp.
Serratia marcescens

YEAST (2)

Candida spp.
 Candida albicans

ANTIMICROBIAL RESISTANCE GENES (8)

Carbapenemases
IMP
KPC
NDM
OXA-48-like
VIM

ESBL
CTX-M

Methicillin Resistance
mecA/C and MREJ

Vancomycin Resistance
vanA/B

Advantages

- Most common microorganisms for PJI included
- Can detect polymicrobial PJs
- Can detect resistance genes
- More sensitive than 16S PCR
- Rapid

Disadvantages

- CoNS and *C. acnes* missing
- More expensive than 16S PCR

Indication multiplex PCR



late acute (hematogenous)

Indication multiplex PCR



Early post-surgical and chronic
PJIs:

CoNS and *C. acnes* not
included

late acute (hematogenous)

Next generation sequencing (NGS)



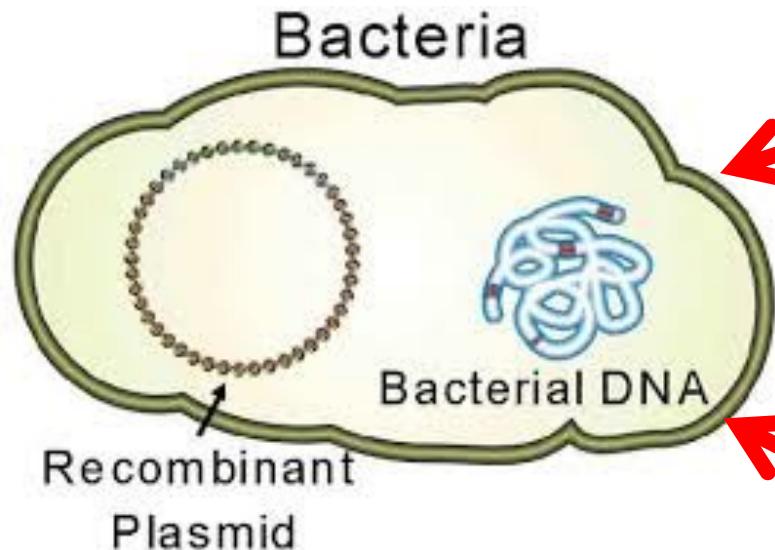
Advantages

- Can detect all types of bacterial species
- Can detect polymicrobial infections
- Can detect resistance genes

Disadvantages

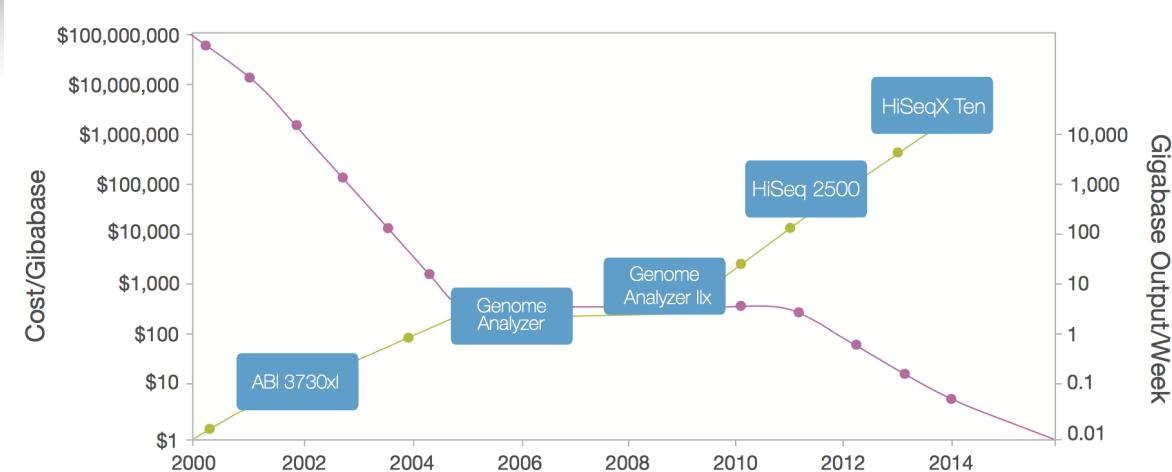
- Not available in every center
- Expensive
- Clinical relevance of detections not always clear

NGS vs. PCR



PCR- Panel of
Microbes (8-30)

NGS- 30,000
species



OrthoKey Based on the ICM Algorythm

Original

MICROGEN DIAGNOSTICS					
2002 W LOOP 289, SUITE 116 LUBBOCK, TX 79407 FAX: 1 - 407 - 204 - 1401 PHONE: 1 - 855 - 208 - 0019					
PATIENT DOB	Biomarkers, Test1 01/01/1987	SPECIMEN RECEIVED	LT KNEE 11/13/2020	PHYSICIAN PHONE	Physician, Incomplete -
PATIENT ID	BIOMARKERS01011987	COMPLETED	11/14/2020 11:07 AM	FAX	-
GENDER	Male	ACCESSION	440	COLLECTED	11/12/2020

RESULT DETAIL

Figure 1 2018 ICM Definition

MAJOR CRITERIA (AT LEAST ONE OF THE FOLLOWING)			DECISION
Two positive cultures of the same organism Since tract with evidence of communication to the joint or visualization of the prosthesis			Infected
PREOPERATIVE DIAGNOSIS	MINOR CRITERIA	POSSIBLE SCORE	PATIENT SCORE
Serum	Elevated CRP or D-Dimer*	2	
Serum	Elevated ESR*	1	
Synovial	Elevated synovial WBC count or LE	3	3
Synovial	Positive alpha defensin	3	
Synovial	Elevated synovial PMN (%)	2	2
Synovial	Elevated synovial CRP	1	1
*Serum values should be incorporated into the cumulative score by the physician			
INTRAOPERATIVE DIAGNOSIS	INCONCLUSIVE PRE-OP SCORE or DRY TAP	POSSIBLE SCORE	PATIENT SCORE
Preoperative Score		-	
Positive Histology		3	
Positive Purulence		3	
Single Positive Culture		2	
Positive NGS *		2	2
CUMULATIVE PATIENT SCORE		8	INFECTED

The above table was developed at the 2018 International Consensus Meeting. Bolded tests are included in the MicroGenDX OrthoKey and can contribute up to 8 points to the patients cumulative score satisfying the criteria for evidence-based diagnosis of PJI. As these criteria were not designed to include molecular methods such as quantitative PCR and Next Generation Sequencing, these tests have been included in the MicroGenDX OrthoKey and contribute the same diagnostic points as a single positive culture in the criteria.

qPCR TESTS FOR BACTERIA		FUNGI	STIs	RESISTANCE GENES
Enterococcus faecalis	Klebsiella pneumoniae	Streptococcus agalactiae	Candida albicans	None
Streptococcus pyogenes	Enterococcus faecium	Pseudomonas aeruginosa		Vancomycin Extended-Spectrum Beta-Lactamase Aminoglycoside Carbapenem Quinolone
Staphylococcus aureus	Cutibacterium acnes			Methicillin Beta-lactam Tetracycline Macrolide Bacitracin

DISCLAIMER: (i) This test was developed and performance characteristics have been determined by Southwest Regional PCR Laboratory dba MicroGenDX. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA); however, the FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. Its use should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) as qualified to perform high complexity clinical laboratory testing. (ii) A negative result does not rule out the presence of PCR inhibitors, or DNA extraction inhibitors such as lidocaine, in patient's specimens or microbial DNA concentrations below the level of detection of the assay. (iii) This test is performed pursuant to an agreement with Roche Molecular Systems, Inc. (iv) Relative quantitation of swabs refers to analyte load levels of <10³, 10³ to 10⁴, and >10⁴ for low, medium and high respectively. Southwest Regional PCR Laboratory dba MicroGenDX license no. CLIA 43D106539 and CAP 7214171.



To help you better interpret the enclosed results of Next Generation Sequencing, please visit <https://icmphilly.com/ortho-applications/>

Original

MICROGEN DIAGNOSTICS					
2002 W LOOP 289, SUITE 116 LUBBOCK, TX 79407 FAX: 1 - 407 - 204 - 1401 PHONE: 1 - 855 - 208 - 0019					
PATIENT DOB	Biomarkers, Test1 01/01/1987	SPECIMEN RECEIVED	LT KNEE 11/13/2020	PHYSICIAN PHONE	Physician, Incomplete -
PATIENT ID	BIOMARKERS01011987	COMPLETED	11/14/2020 11:07 AM	FAX	-
GENDER	Male	ACCESSION	440	COLLECTED	11/12/2020

RESISTANCE GENES DETECTED

None

LEVEL 2 NGS REPORT

COMPREHENSIVE IDENTIFICATION NEXT-GEN DNA SEQUENCING RESULTS with PRIOR PCR RESULTS.

COMPLETE (NGS & PCR RESULTS)	DNA copies per mL	Gram Stain	ANTIMICROBIALS FOR CONSIDERATION									
			PO	PO	PO	IV	PO	PO	PO	PO	PO	IV
BACTERIAL LOAD	Medium											
	10 ⁵ -10 ⁷											
Escherichia coli	NGS	75%	-	FAn	✓	✓	✓	✓	✓	✓	✓	✓
Enterococcus faecalis	NGS	24%	+	FAn	✓	✓	✓	✓	✓	✓	✓	✓
Cutibacterium acnes	1.63 x 10 ⁹	+ An	✓									✓

FUNGI DETECTED

%

ANTIFUNGALS FOR CONSIDERATION	
None	

DNA copies per mL
(NGS) = Detected by Next-Gen Seq. Only
Bacterial Load: <10³ = LOW
10³ to 10⁴ = MED
>10⁴ = HIGH

Gram Stain:
[+] = Positive
[-] = Negative
[V] = Variable
[U] = Not Applicable
[U] = Unknown

Respiration:
[A] = Aerobic
[An] = Anaerobic
[FAn] = Facultative anaerobic
[Un] = Unknown

Antimicrobial:
[✓] = Proven to be effective.
[R] = Recommended empirically.
[I] = Empiric Fomite disease Unknown.
[PO] = Available in Oral formulations.
[IV] = Intravenous; [TP] = Topical.

REVIEW ARTICLE

Diagnostic Value of Next-Generation Sequencing in Periprosthetic Joint Infection: A Systematic Review

Yuchen Tang, MD[†] , Dacheng Zhao, MD[†], Shenghong Wang, MD, Qiong Yi, MD, Yayi Xia, PhD, Bin Geng, PhD

Department of Orthopaedics, Lanzhou University Second Hospital, Orthopaedic Key Laboratory of Gansu Province, Orthopaedic Clinical Research Center of Gansu Province, Lanzhou, China

while in three studies it was lower than 50% (range from 9% to 31%). Also, the detection rate of NGS for PJIs with antibiotic administration history ranged from 74.05% to 92.31%. In conclusion, this systematic review suggests that NGS may have the potential to be a new tool for the diagnosis of PJI and should be considered to be added to the portfolio of diagnostic procedures. Furthermore, NGS showed a favorable diagnostic accuracy for culture-negative PJI patients or PJI patients with antibiotic administration history. However, due to the small sample sizes of studies and substantial heterogeneity among the included studies, more research is needed to confirm or disprove these findings.

An Enhanced Understanding of Culture-Negative Periprosthetic Joint Infection with Next-Generation Sequencing

A Multicenter Study

Karan Goswami, MD, Samuel Clarkson, MD, Caleb D. Phillips, PhD, Douglas A. Dennis, MD, Brian A. Klatt, MD, Michael J. O'Malley, MD, Eric L. Smith, MD, Jeremy M. Gililand, MD, Christopher E. Pelt, MD, Christopher L. Peters, MD, Arthur L. Malkani, MD, Brian T. Palumbo, MD, Steven T. Lyons, MD, Thomas L. Bernasek, MD, Jon Minter, DO, Nitin Goyal, MD, James F. McDonald III, BS, Michael B. Cross, MD, Hernan A. Prieto, MD, Gwo-Chin Lee, MD, Erik N. Hansen, MD, Stefano A. Bini, MD, Derek T. Ward, MD, Noam Shohat, MD, Carlos A. Higuera, MD, Dennis Nam, MD, Craig J. Della Valle, MD, and Javad Parvizi, MD, FRCS, on behalf of the Orthopedic Genomics Workgroup

Results: The overall cohort included 301 patients who met the ICM criteria for PJI. Of these patients, 85 (28.2%) were culture-negative. A pathogen could be identified by NGS in 56 (65.9%) of these culture-negative patients. Seventeen species were identified as common based on a study-wide incidence threshold of 5%. NGS revealed a polymicrobial infection in 91.1% of culture-negative PJI cases, with the set of common species contributing to 82.4% of polymicrobial profiles. *Escherichia coli*, *Cutibacterium acnes*, *Staphylococcus epidermidis*, and *Staphylococcus aureus* ranked highest in terms of incidence and study-wide mean relative abundance and were most frequently the dominant organism when occurring in polymicrobial infections.

Next generation sequencing (NGS)



Moleculaire diagnostiek (PCR) :

16S-23S rDNA NGS analyse

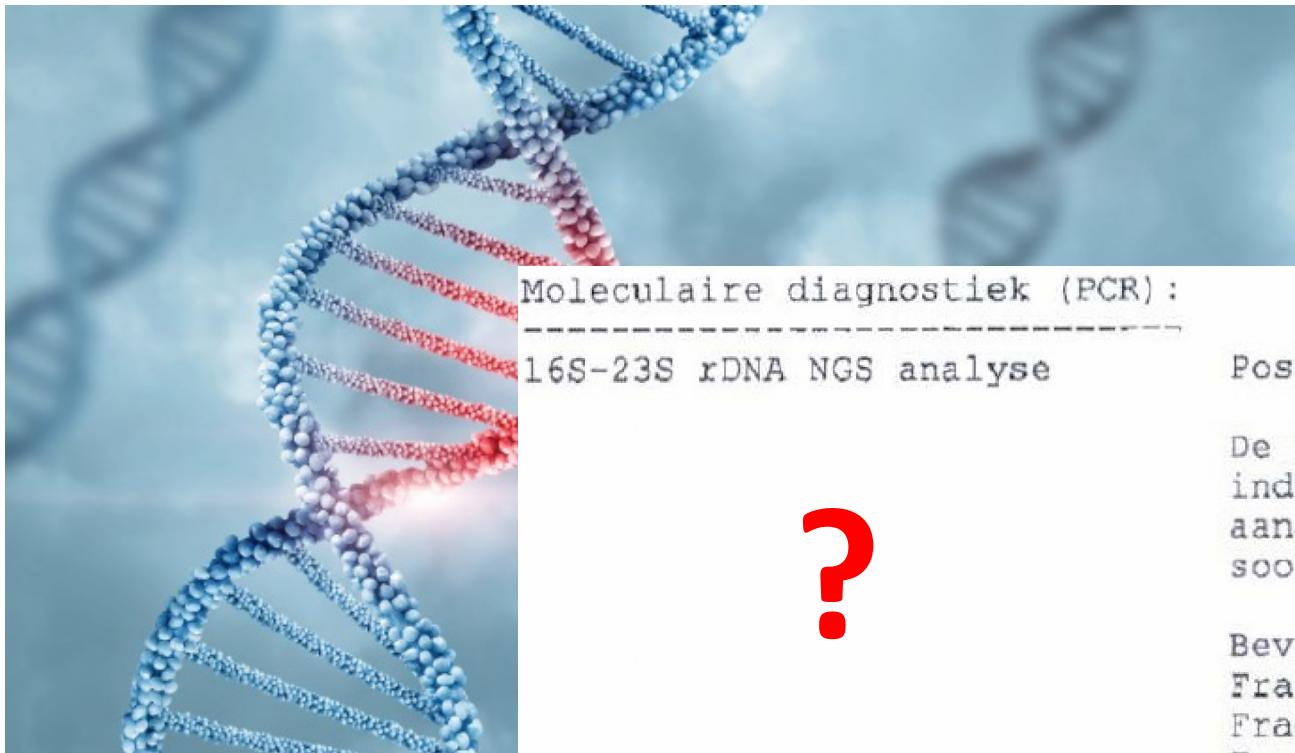
Positief: (Ct37)

De fractie (uitgedrukt in percentage) geeft een indruk van de relatieve hoeveelheid van het aangetoonde 16S-23S rDNA van de verschillende soorten in het monster.

Bevindingen:

Fractie 70%: *Enterococcus faecalis*
Fractie 8%: *Staphylococcus* spp.
Fractie 8%: *Staphylococcus hominis*
Fractie 5%: *Cutibacterium acnes*
Fractie 9%: Background

Next generation sequencing (NGS)



Positief: (Ct37)

De fractie (uitgedrukt in percentage) geeft een indruk van de relatieve hoeveelheid van het aangetoonde 16S-23S rDNA van de verschillende soorten in het monster.

Bevindingen:

Fractie 70%: Enterococcus faecalis
Fractie 8%: Staphylococcus spp.
Fractie 8%: Staphylococcus hominis
Fractie 5%: Cutibacterium acnes
Fractie 9%: Background

Indication NGS: all type of PJIs



late chronic



late acute (hematogenous)



early postsurgical

Therapy



ENDO Clinic Hamburg

Multidisciplinary Approach

Surgeon

Microbiologist

Infection Disease Department

Histology

General Medicine

Prerequisite for any kind of septic revision

■ HIP

A multidisciplinary team approach to two-stage exchange for the infected hip

■ KNEE

■ A minimum five-year follow-up study

M. S. Ibrahim, S. Raja, M. A. Khan, F. S. Haddad

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BJO

■ ARTHROPLASTY

Improving outcomes in acute and chronic periprosthetic hip and knee joint infection with a multidisciplinary approach

M. Biddle,
J. W. Kennedy,
P. M. Wright,
N. D. Ritchie,
R. M. D. Meek,
B. P. Rooney

From Queen Elizabeth University Hospital, Glasgow, UK

RESEARCH ARTICLE

Open Access

High cure rate of periprosthetic hip joint infection with multidisciplinary team approach using standardized two-stage exchange

Doruk Akgün^{1,2*}, Michael Müller¹, Carsten Perka¹ and Tobias Winkler¹



rg

„Golden Standard“

Two stage

- - Identification of the infecting organism
- Appropriate adjustment about surgical implantation technique
- (cem./cementless) depending on bone defects and quality
- Adequate debridement of necrotic or infected tissues
- plus a greater flexibility in reconstructive options
- - Use of allografts for acetabular and femoral reconstruction in
- aseptic condition



Anagnostakos et al., 2006, Dairaku et al., 2009

What makes you nervous about a 1 stage ?

Lower infection control rate ?

Limited ability to deliver high dose antibiotic cement ?

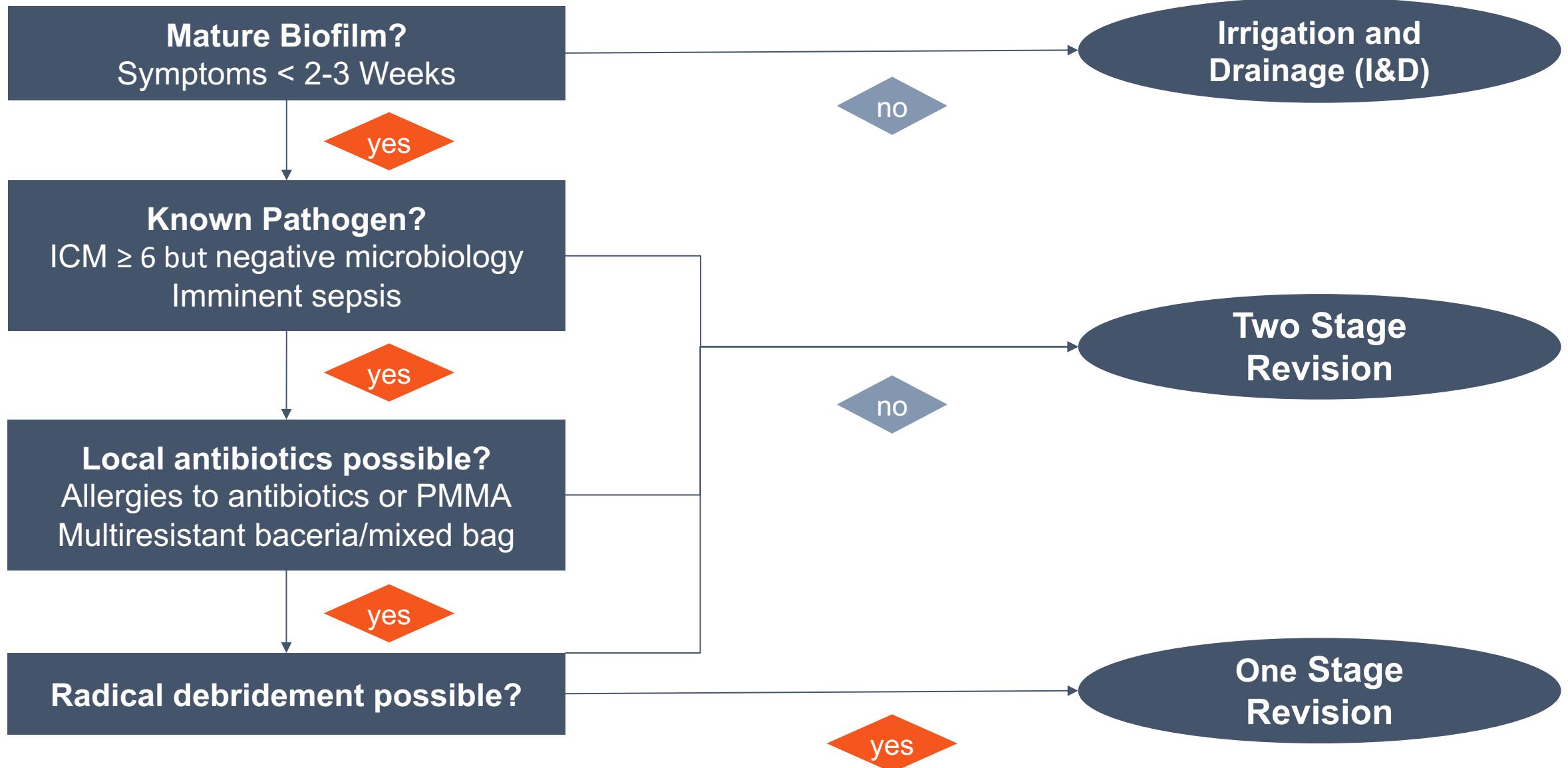
Difficulty of revision?

Necessitates use of antibiotic loaded cement?

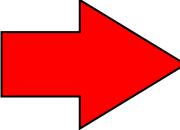
Resource intensive for that procedure?

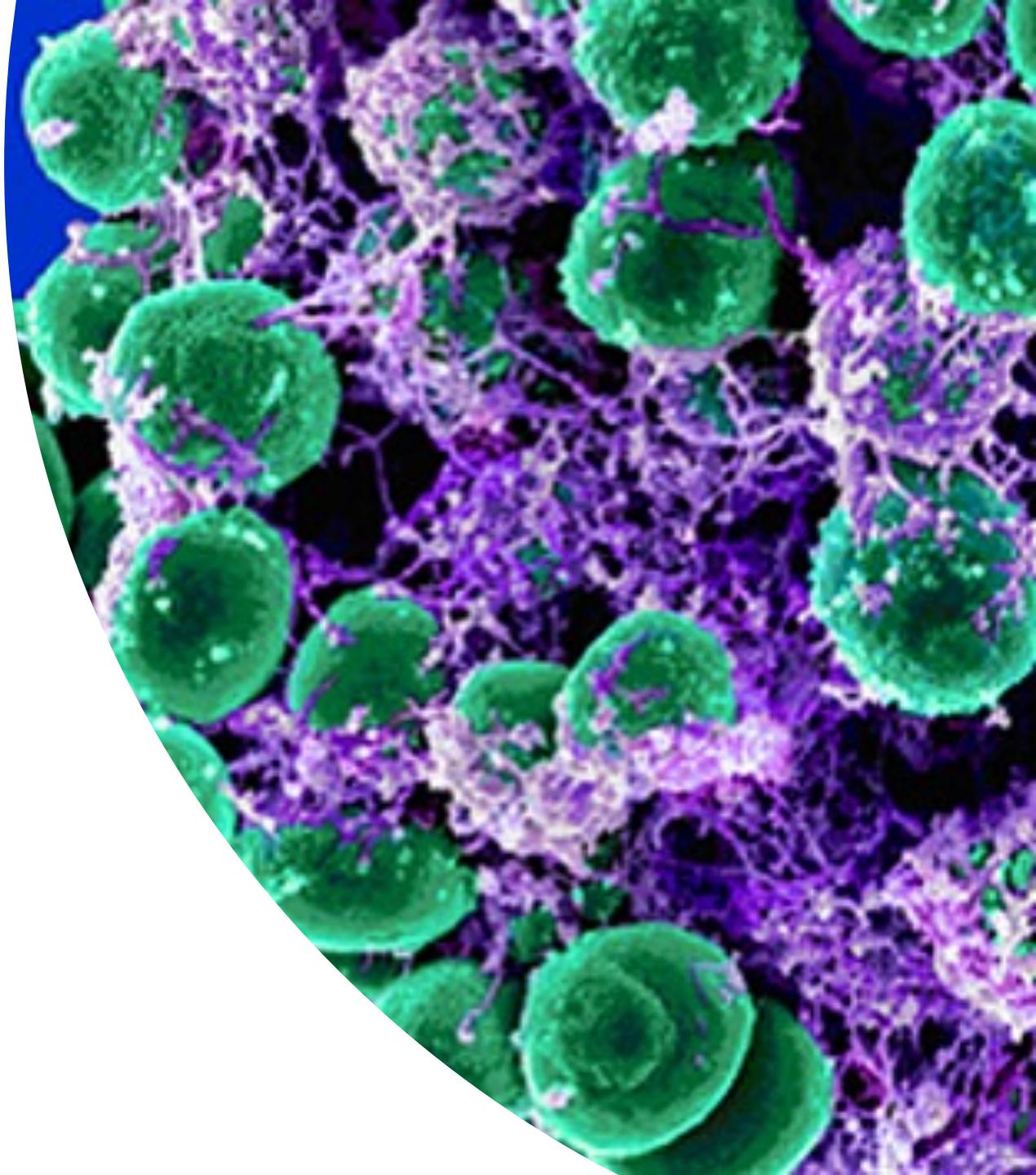


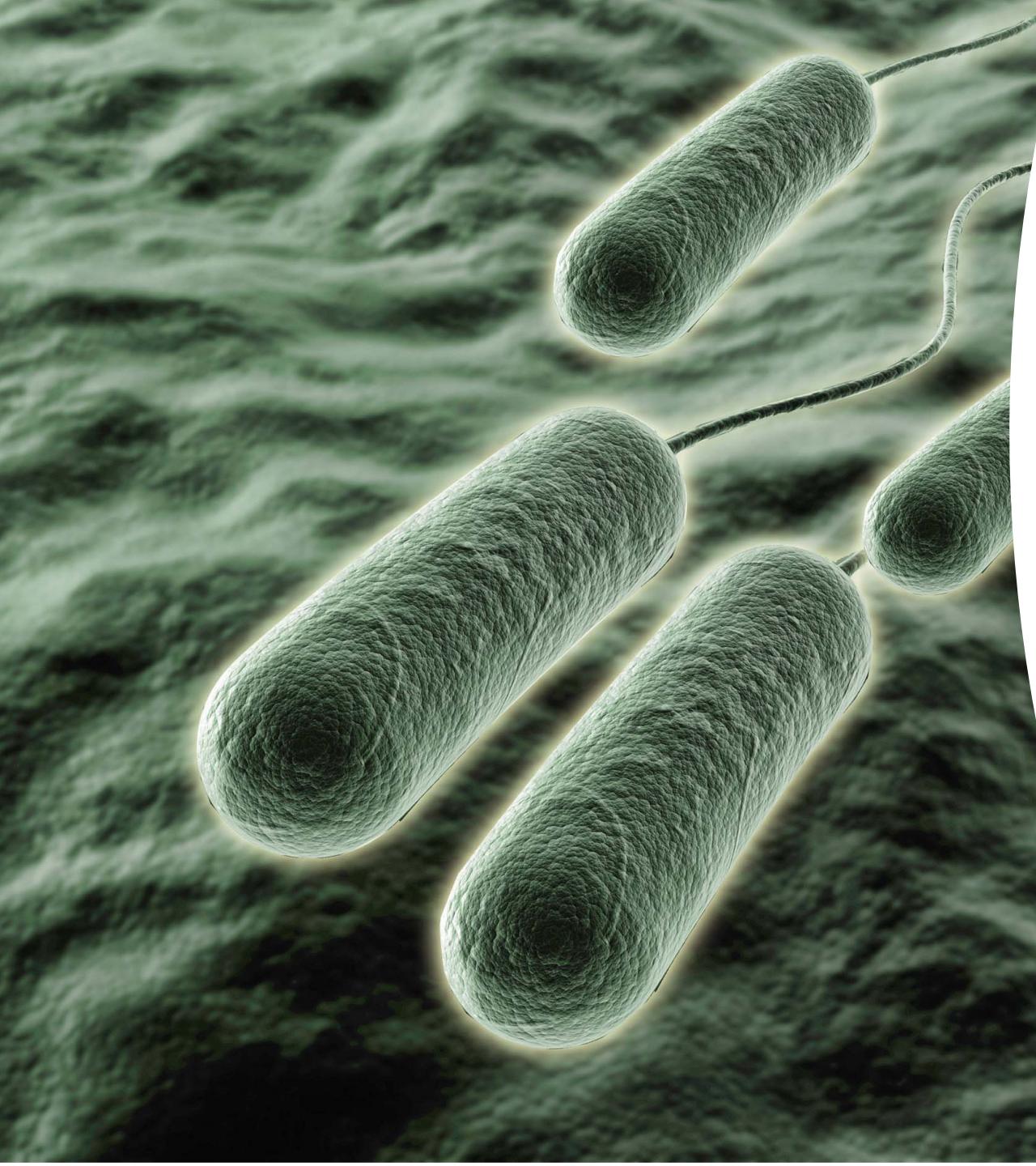
Algorithm of ENDO-Klinik



The key of success in one stage

- Preoperative diagnostics
-  find the bugs
- Which germs are responsible for the PJI?
 - Susceptibility of the germ?
 - What is the best therapy option?



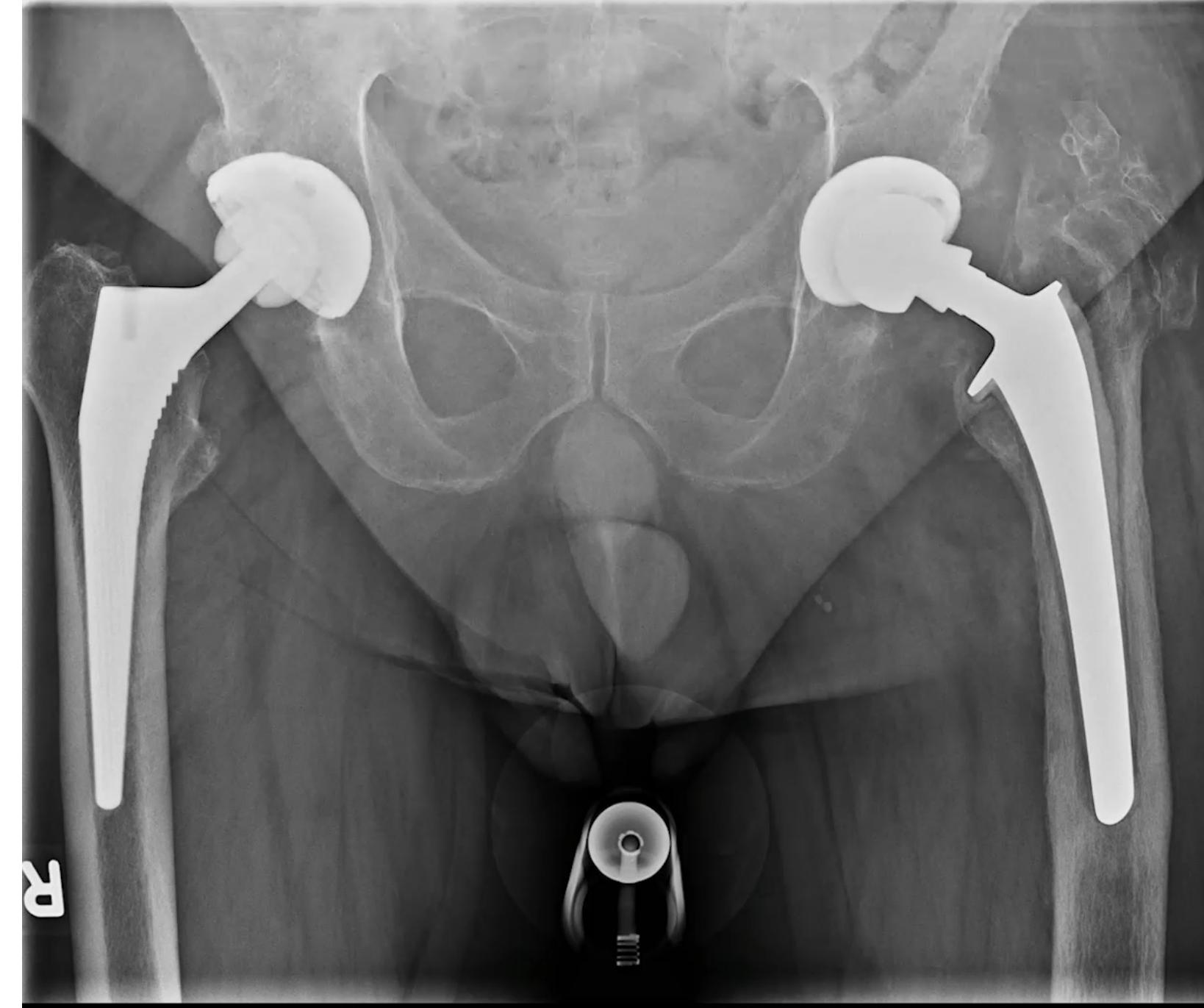
A close-up, microscopic image showing several green, rod-shaped bacteria (likely Escherichia coli) against a dark, textured background. The bacteria have a slightly granular surface texture and appear to be moving or attached to a surface.

One stage or two stage?

- **Known** germ & susceptibility
 - One stage septic exchange (90-91%)
- **Unknown** germ
 - Two stage septic exchange (9-10%)
with spacer

The Surgery

1. Debridement and Implant removal



L
liegend
axial

R

The Surgery

2. Starting the Systemic Antibiotic Therapy

Daptomycin Hikma 500 mg
Daptomycin

500 mg

i.v.

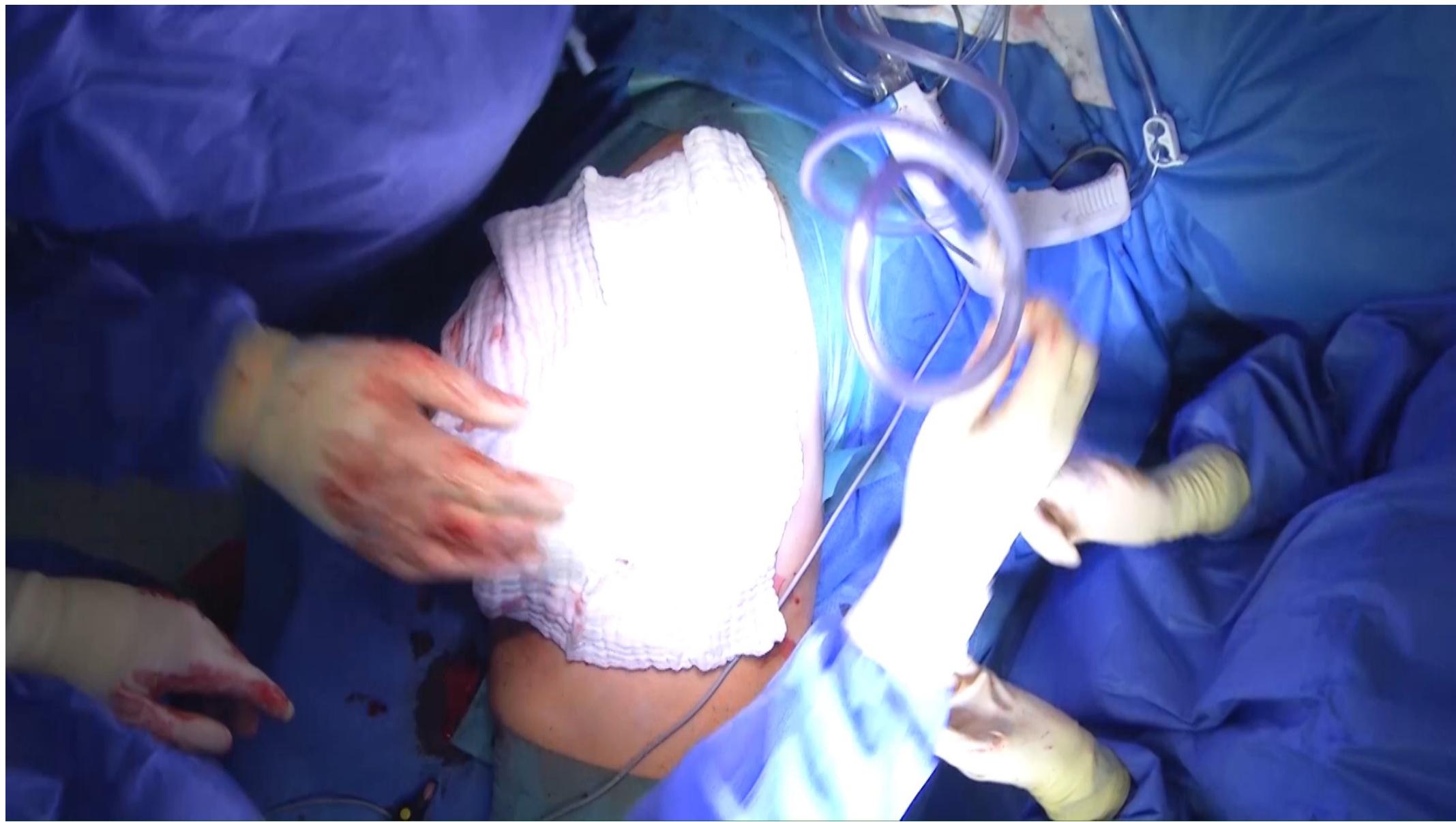
Pulver zur Herstellung einer
Injektions-/Infusionslösung.

Hikma

13006277-A

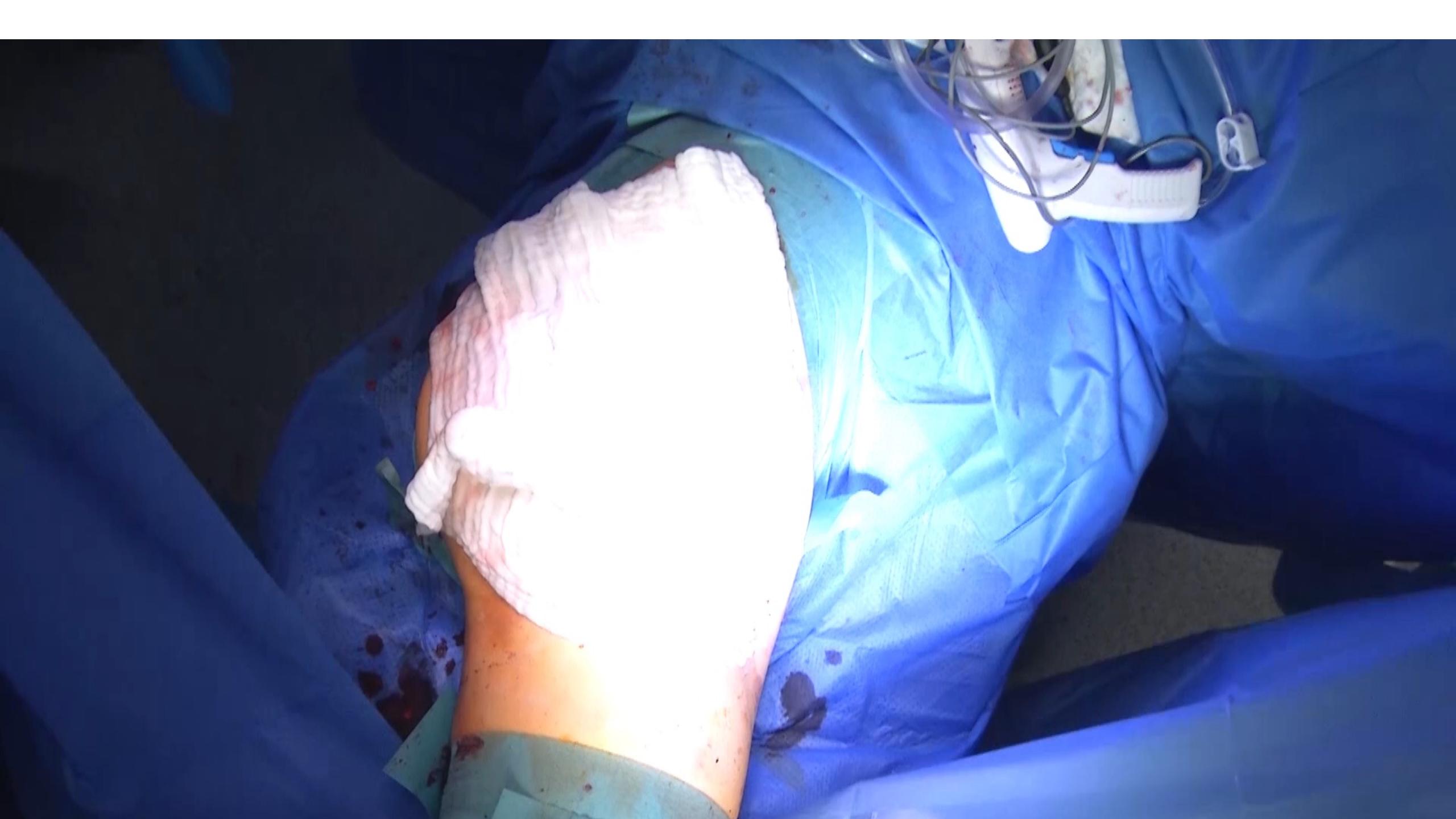
The Surgery

3. Mixing the Bone Cement
and Antiseptic Irrigation



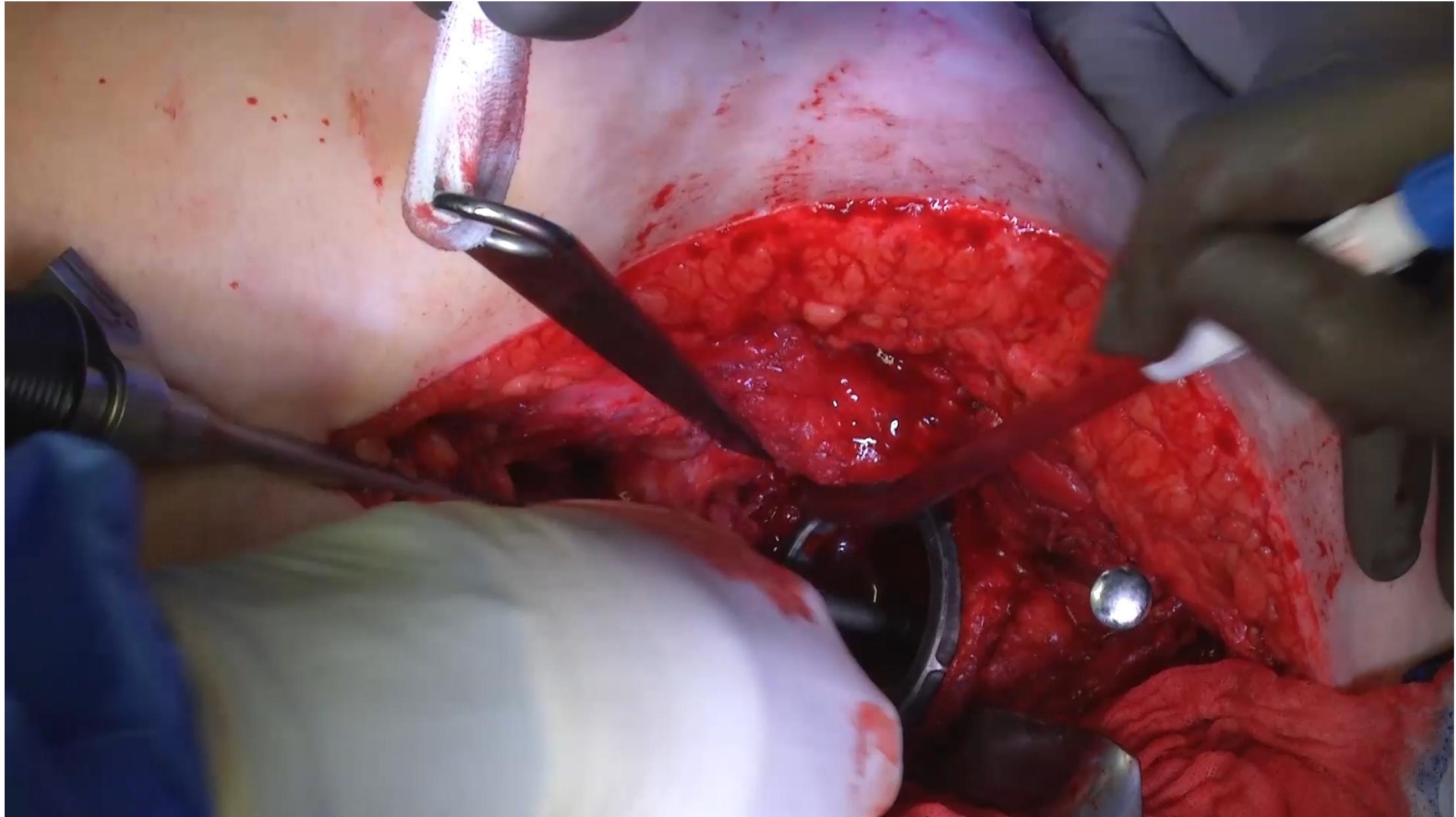
The Surgery

4. Exchange of the Drapes,
Gloves, Instruments etc.



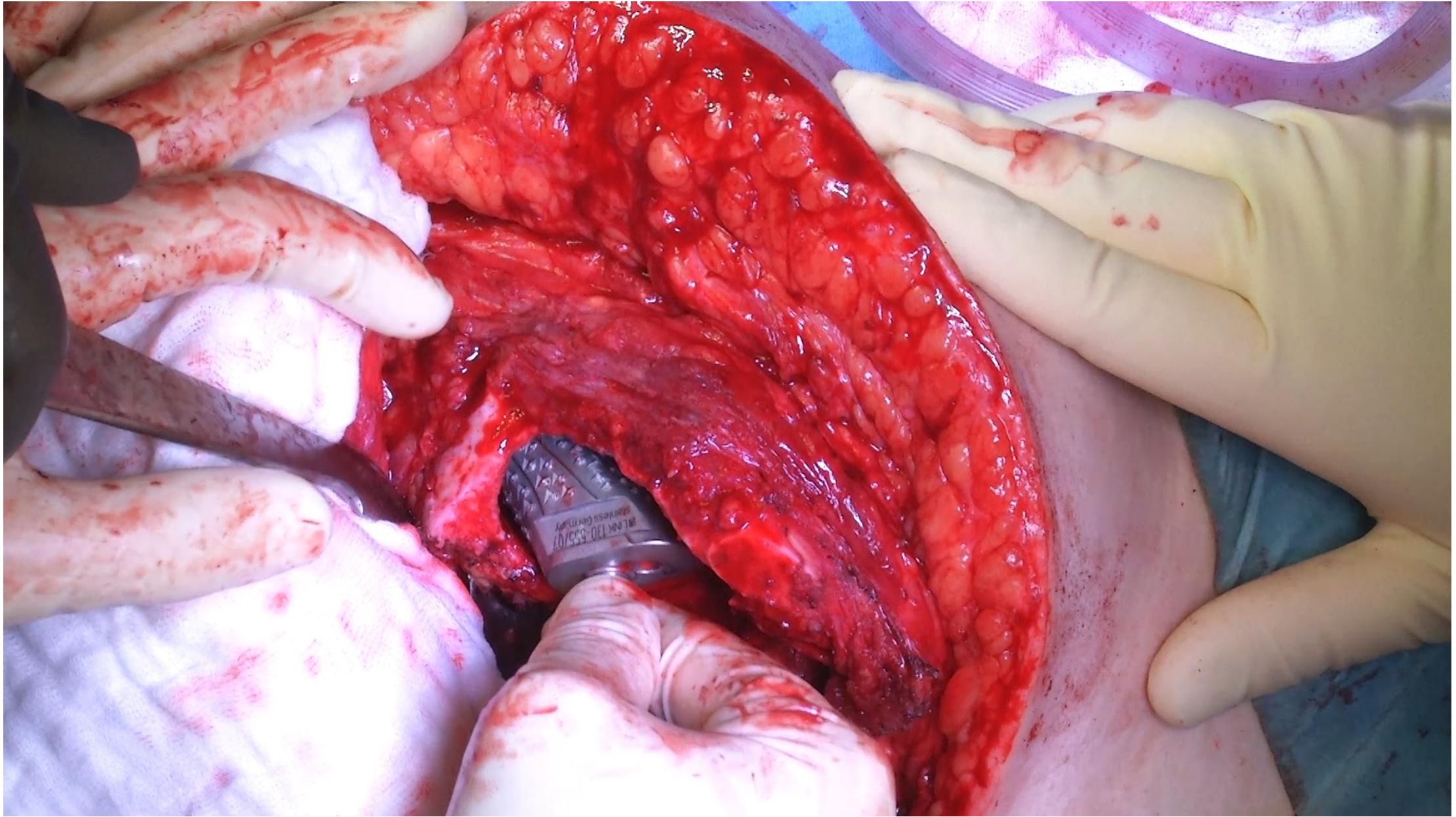
The Surgery

5. Reimplantation of the Cup
- usually TM Revision Cup + cemented
Dual Mobility Cup -



The Surgery

6. Reimplantation of the cemented Stem



Post-operative Treatment

- **Septic 1-stage revision of hip/knee**
 - One night stay on intermediate care
 - Early mobilisation on day 1 (full weight-bearing)
 - i.v. antibiotic therapy for 14 days (including day of surgery)
 - Switch to oral antibiotic therapy on day 14 (testing of tolerability)
 - Discharge from hospital on day 15
 - Oral antibiotic therapy from 4 weeks (*Cutibacterium*) to 6 weeks
 - Outpatient appointment after 12 months

Results

■ KNEE

Outcomes of single- and two-stage revision total knee arthroplasty for chronic periprosthetic joint infection

LONG-TERM OUTCOMES OF CHANGING CLINICAL PRACTICE IN A SPECIALIST CENTRE

H. E. Matar,
B. V. Bloch,
S. E. Snape,
P. J. James

From Nottingham City Hospital, Nottingham, UK

ORIGINAL PAPER

One-stage revision total knee arthroplasty: outcome of 39 consecutive cases

Theodore G. Hatzakos¹ · Michael J. Lafferty¹ · Peter Emil Ochsner³ · Bernhard Kessler² · Martin Clauss³

ORIGINAL ARTICLE

Evaluation and Management of Periprosthetic Joint Infection—an Inter-

Saseendar Shanmugam^a
Patrick S. Sussmann, MD · Ma

aff, MD,
ly, MD



70



CrossMark

in Comment



CrossMark

One-Stage Revision Arthroplasty Using Cementless Stem for Infected Hip Arthroplasties

Guillem Bori, MD, PhD^{a, c}, Ernesto Muñoz-Mahamud, MD^{a, c}, Jordi Cuñé, MD^{a, c}, Xavier Gallart, MD, PhD^a, David Fuster, MD, PhD^{b, c}, Alejandro Soriano, MD, PhD^{c, d}

They all show better results

Two Stage Exchange

1495

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A commentary by Thomas J. Blumenfeld, MD,
is linked to the online version of this article
at jbjs.org.

The Fate of Spacers in the Treatment of Periprosthetic Joint Infection

Miguel M. Gomez, MD, Timothy L. Tan, MD, Jorge Manrique, MD, Gregory K. Deirmengian, MD, and Javad Parvizi, MD, FRCS

Investigation performed at the Rothman Institute at Thomas Jefferson University, Philadelphia, Pennsylvania

ABSTRACT

Background: Two-stage exchange arthroplasty remains a popular surgical treatment for patients with chronic periprosthetic joint infection (PJI). Patients who do not receive reimplantation were largely overlooked in the current literature. We aimed at investigating the clinical outcomes of these patients.

Methods: Our institutional PJI database was retrospectively reviewed to identify 616 patients (237 hips, 379 knees) who were treated with an intended 2-stage exchange. Of them, 111 (18%) did not receive reimplantation within a minimum follow-up of 1 year. Chart review and targeted interviews were performed to elucidate the cause of attrition. Patients were considered to have failed treatment in the absence of reimplantation if they remained medically unfit for reimplantation, underwent a salvage procedure, or died during the study period.

Results: Of the 111 patients without reimplantation, 29 (26.1%) did well with their retained spacer and were unwilling to proceed with reimplantation, 23 (20.7%) underwent salvage procedures, and the remaining 59 (53.2%) were considered medically unfit for reimplantation, with 34 of them dying within 1 year of initial spacer insertion. The overall success rate for 2-stage exchange cohort at 2 years was 65.7% when treatment failure without reimplantation was taken into account. Several factors associated with increased risk of treatment failure without reimplantation were identified using a multivariate regression model.

Conclusion: Almost 1 in 5 patients may never receive the intended reimplantation. Among many reasons for attrition, mortality appears to be a relatively common event. The current definition of treatment success does not take into account the attrition group and thus inflates the relative success of 2-stage exchange arthroplasty.

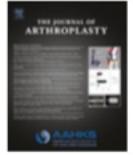
The Journal of Arthroplasty 34 (2019) 2749–2756



Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org



Complications - Infection

Two-Stage Exchange Arthroplasty for Periprosthetic Joint Infection: The Rate and Reason for the Attrition After the First Stage

Qiaojie Wang, MD ^{a,b}, Karan Goswami, MD, MRCS ^a, Feng-Chih Kuo, MD ^{a,c},
Chi Xu, MD ^{a,d}, Timothy L. Tan, MD ^a, Javad Parvizi, MD, FRCS ^{a,*}



Almost 1 in 5 patients may never receive the intended reimplantation. Among many reasons for attrition, mortality appears to be a relatively common event.

The overall success rate for 2-stage exchange cohort at 2 years was 65.7% when treatment failure without reimplantation was taken into account.



ENDO Clinic Hamburg

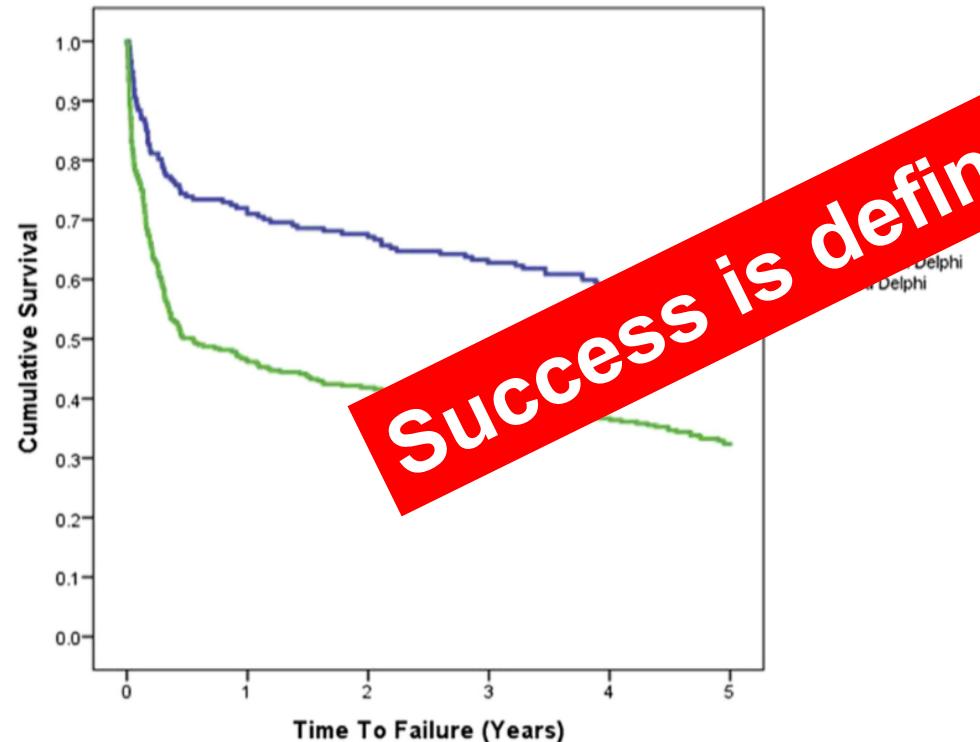


Complications - Infection

Defining Treatment Success After 2-Stage Exchange Arthroplasty
for Periprosthetic Joint Infection

Check for updates

Timothy L. Tan, MD ^a, Karan Goswami, MD ^a, Yale A. Fillingham, MD ^a,
Noam Shohat, MD ^{a, b}, Alexander J. Rondon, MD, MBA ^a, Javad Parvizi, MD, FRCS ^{a, *}



Success is defined as reimplantation

1

International multidisciplinary
Delphi consensus success

2

Medline consensus

3

Organism success

4

Implant success

5

Surgical success

Lack of the following:

- (a) The presence of a sinus tract, an unhealed wound drainage, pain, or infection recurrence caused by the same organism strain.
- (b) Subsequent surgical intervention for infection after reimplantation surgery.
- (c) Occurrence of PJI-related mortality.

Lack of the following:

- (a) The presence of a sinus tract, an unhealed wound or drainage, or infection recurrence caused by any organism strain.
 - (b) Any unplanned surgical intervention (reimplantation not counted).
 - (c) Occurrence of mortality of any cause.
 - (d) Reimplantation surgery.
- Considered no recurrence of any organism regardless of whether it was present at the time of the first stage.

Considered patients who were reimplanted.

Defined by no additional surgeries except planned surgeries (ie, other than reimplantation). Unplanned spacer exchanges or interim surgeries such as irrigation and debridement were considered a failure.

2 prospective randomized studies



INFORM Study

The only prospective randomised study

RESEARCH

Clinical and cost effectiveness of single stage compared with two stage revision for hip prosthetic joint infection (INFORM): pragmatic, parallel group, open label, randomised controlled trial

N = 140

Ashley W Blom,^{1,2} Erik Lenguerrand,¹ Simon Strange,¹ Sian M Noble,³ Andrew D Beswick,¹ Amanda Burston,¹ Kirsty Garfield,^{3,4} Rachael Goberman-Hill,^{1,2} Shaun R S Harris,^{3,4} Setor K Kunutson,^{1,2} J Athene Lane,^{3,4} Alasdair MacGowan,⁵ Sanchit Mehendale,⁶ Andrew J Moore,¹ Ola Rolfsen,⁷ Jason C J Webb,¹ Matthew Wilson,⁸ Michael R Whitehouse,^{1,2} on behalf of the INFORM trial group

Conclusions

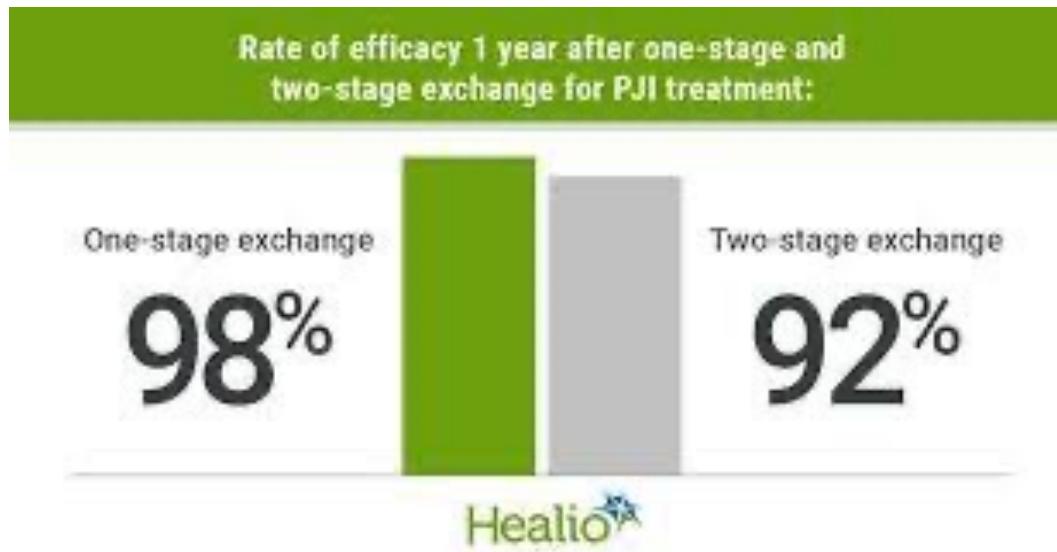
At 18 months, single stage revision compared with two stage revision for prosthetic joint infection of the hip showed no superiority by patient reported outcome. Single stage revision had a **better outcome** at three months, **fewer intraoperative complications**, and was **cost effective**. **Patients prefer early restoration of function, therefore, when deciding treatment, surgeons should consider patient preferences and the cost effectiveness of single stage surgery.**



ENDO Clinic Hamburg

Prospective randomized Study US

One Stage vs. Two Stage



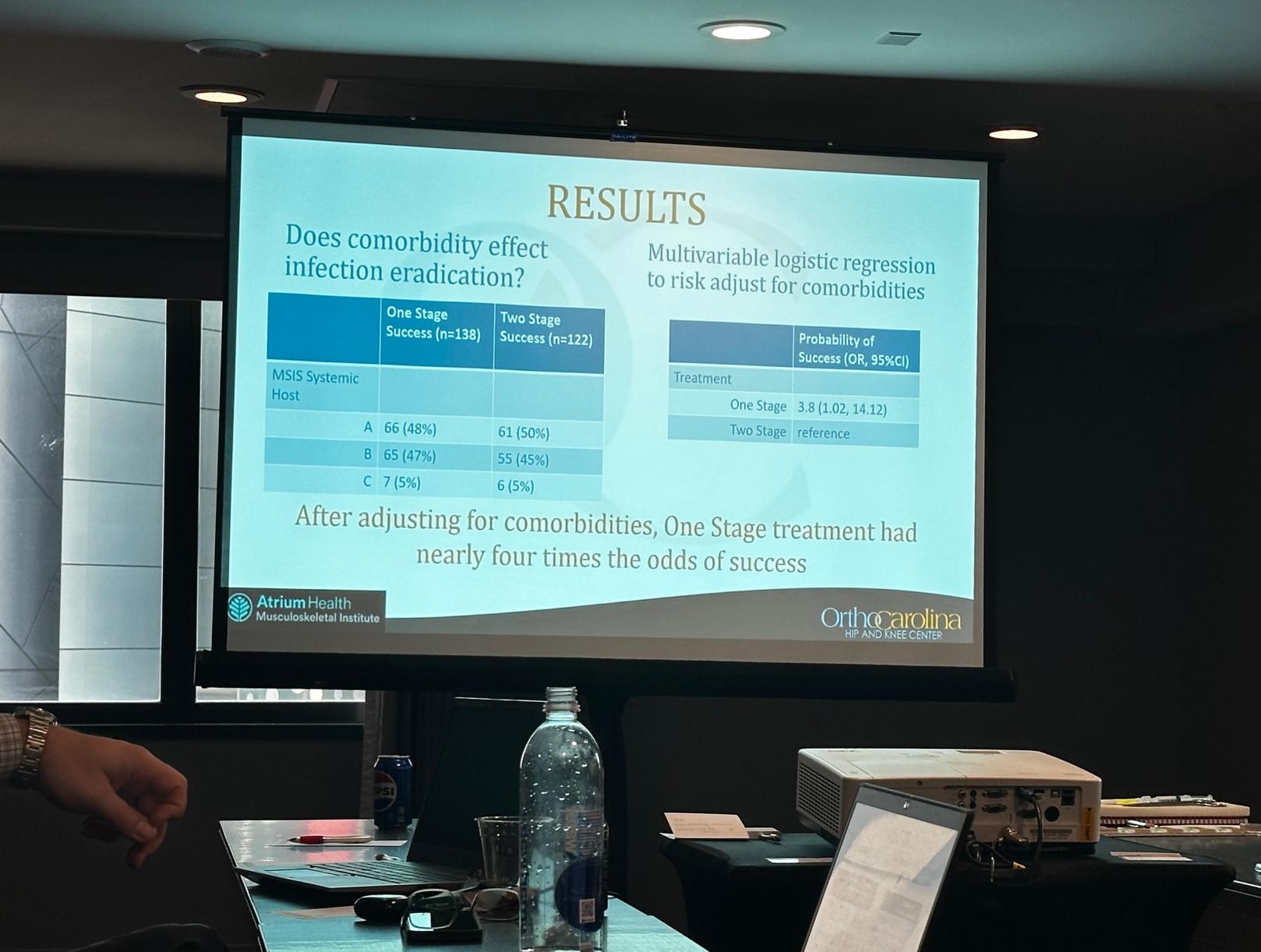
N=273

American Knee Society Meeting 2023,
AAHKS 2023

Tom Fehring



ENDO Clinic Hamburg



RESULTS

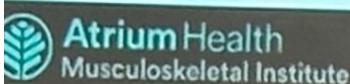
Does organism resistance effect infection eradication?

Resistance	One Stage Success (n=138)	Two Stage Success (n=145)
Non-resistant	92 (67%)	72 (59%)
Resistant	27 (20%)	27 (22%)
Multi Non-resistant	3 (2%)	10 (8%)
Multi Resistant	3 (2%)	0 (0%)

Multivariable logistic regression to risk adjust for organism resistance

Treatment	Probability of Success (OR, 95%CI)
One Stage	3.79 (1.0, 14.356)
Two Stage	reference

After adjusting for organism resistance, One Stage treatment had nearly four times the odds of success



RESULTS

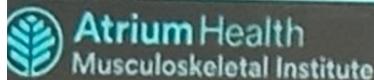
Does a draining sinus effect infection eradication?

	One Stage Success (n=138)	Two Stage Success (n=122)
Draining Sinus		
Yes	16 (12%)	23 (19%)
No	122 (88%)	99 (81%)

Multivariable logistic regression
to risk adjust for draining sinus
OR 95%CI

	Success
Treatment	
One Stage	3.55 (.94, 13.47)
Two Stage	reference

After adjusting for draining sinus, One Stage treatment had nearly 3.5 times the odds of success



Is two-stage revision surgery for infected hip arthroplasty worth the suffering, resources and results compared to one-stage?

Dimitrios Sotiriou, Hampus Stigbrand and C

HIP International
1–8
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Interpretation: Revision total hip arthroplasty for PJI with vancomycin-loaded impaction bone grafting is a safe method that achieves both the restoration of bone stock and resolution of the infection. This single-stage procedure could therefore be the new gold standard for treatment of non-complicated PJI in the hip.





Elb- Philharmonie Hamburg