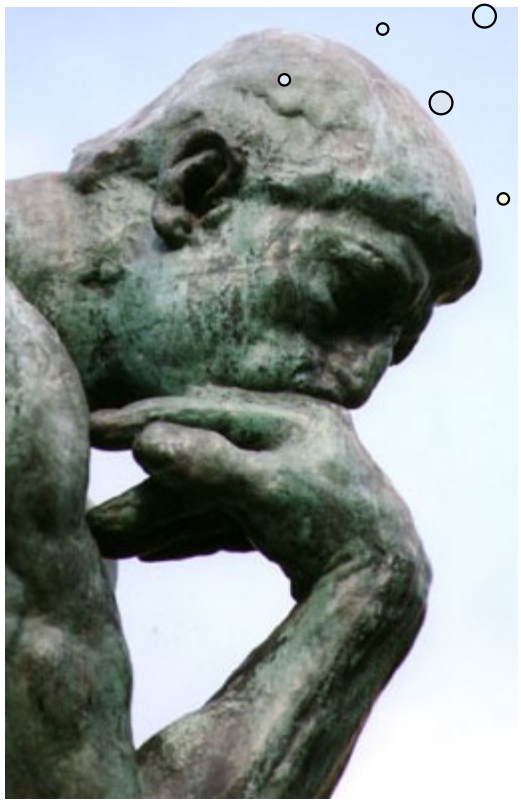
CENTER OF ORTHOPAEDICS AND TRAUMATOLOGY
UNIVERSITY HOSPITAL BRANDENBURG / HAVEL

BRANDENBURG
MEDICAL SCHOOL

The role of bearing surface: wear, type of PE and potential allergy

ROLAND BECKER

Materials used in TKA



1. Wear patterns in TKA

2. Modern polyethylene

3. Allergy in TKA ??

Wear patterns

Adhesive wear: *High surface pressure cause forcer stronger than the marterial*

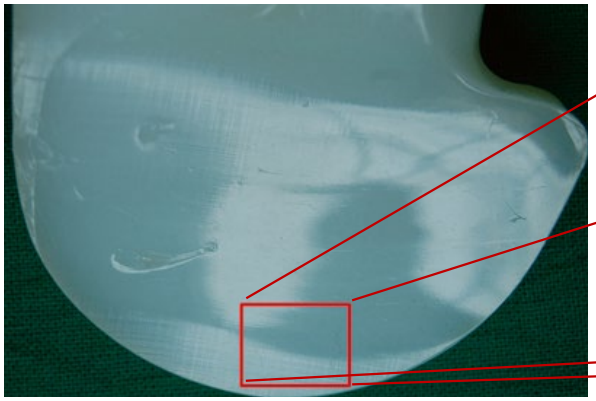
Abrasive wear: *1) Harder and rougher surface articulates against a softer surface*
2) Hard particles between two surfaces

Surface fatigue: *Material near to the surface is weakened by cyclic shear stress*

Tribo-chemical wear: *Process with chemical basis at the interface between surfacces*

Wear patterns - femoral component and liner

Burnishing: Contact area are polisehd due to abrasive and adhesive wear



Polyethylene liner of a TKA

smoothened area

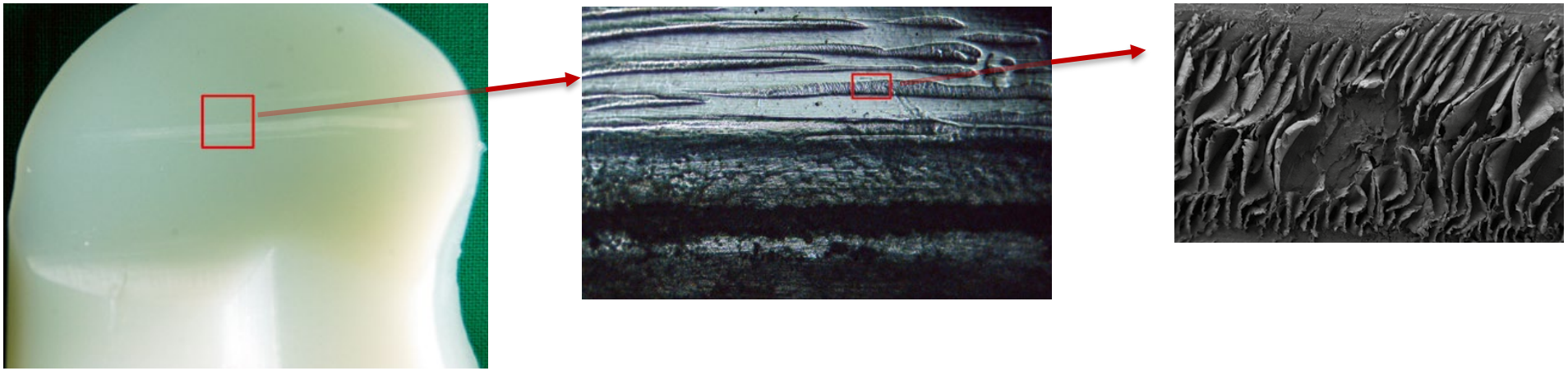
Horizontal manufacturing related characteristics of the polyethylene

particles in size of submicrometer

Tissue reaction → activation of macrophages → osteolysis at implant-bone-interface

Wear patterns - femoral component and liner

Scratching: Damage is caused by abrasion. Differences in roughnes and hardness of articular partner causes plowing of the surface



Most common form of backside wear

Wear patterns - femoral component and liner

Scratching: Damage is caused by abrasion. Differences in roughnes and hardness of articular partner causes plowing of the surface

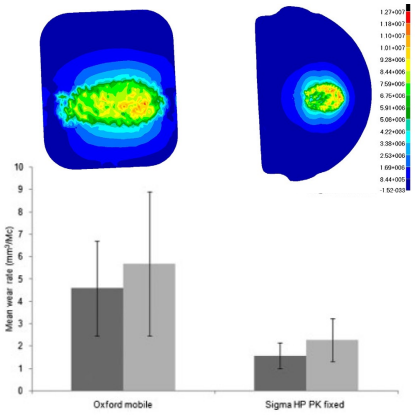
Introduction of the mobile bearing concept in UKA in 1978

- Increasing congruency
- Polyethylene wear

?

Wear rate /10^6 cycles	medial	lateral
Mobile bearing	10.7 ± 0.59 mg	5.38 ± 0.63
Fixed bearing	7.51 ± 0.29	3.04 ± 0.35

Experimental setting



Brockettt, J of Engineering in Medicine 2012, Kretzer Acta Biomaterial 2011

Wear patterns - femoral component and liner

No difference between fixed and mobile bearing TKA under **clinical conditions** using conventional polyethylene

	Fixed bearing – PS 18 Pts.	Mobile bearing – PS 18 Pts.
Particle number	$1.6 \pm 1.9 \times 10^7$	$2.2 \pm 2.6 \times 10^7$
Particle size	$1.5\mu m \pm 0.2$	$1.5\mu m \pm 0.3$

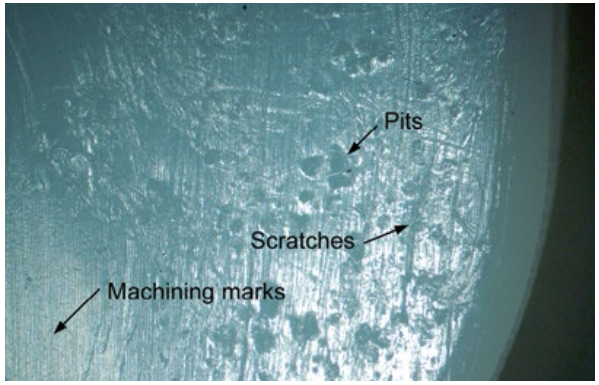
Minoda Y et al. KSSTA 2016

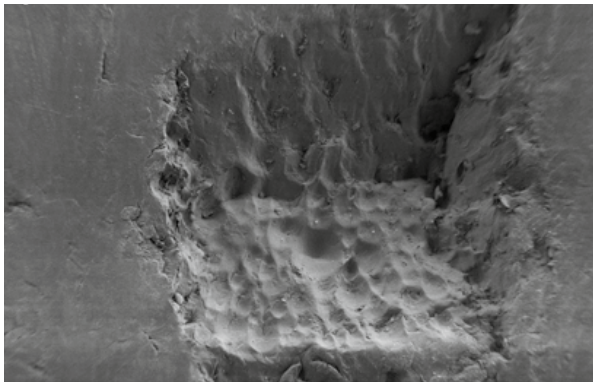
Wear patterns - femoral component and liner

Pitting: Most frequent type of surface alteration caused by maximum contact stress

Cracks at the bearing surface

Expansion in the UHWMPE





Wear patterns - femoral component and liner

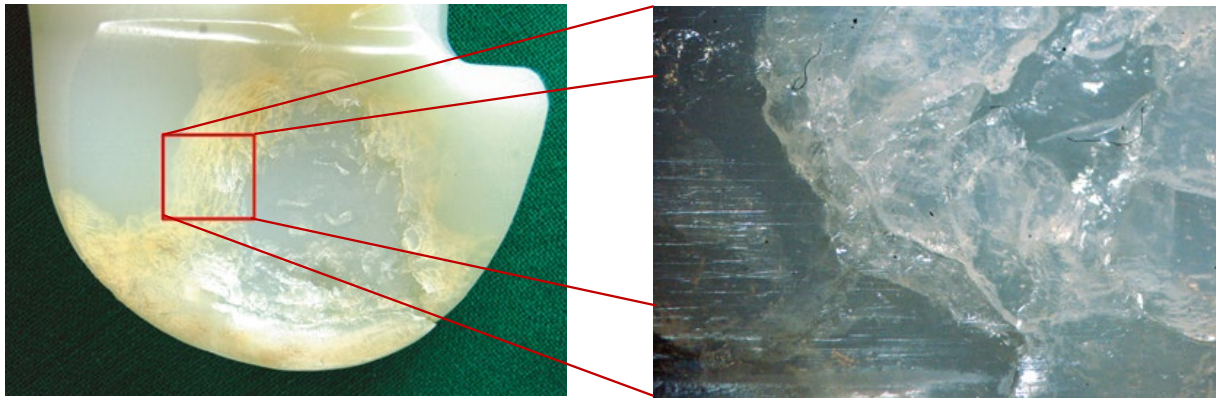
Delamination: Elastic deformation of the UHMWPE due to rolling and sliding

Wreak subsurface cracks

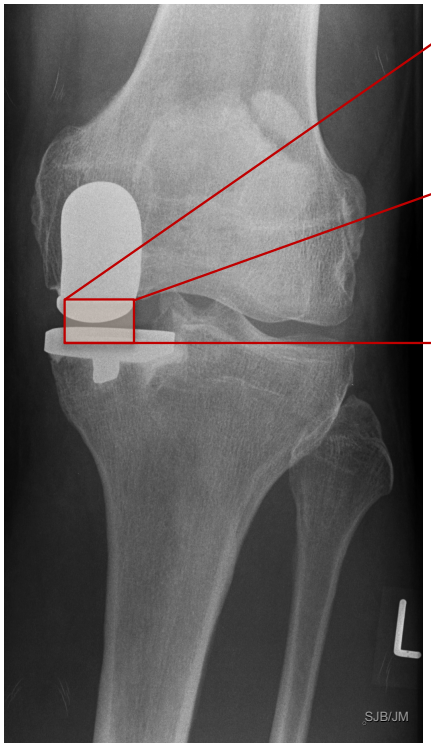
Shear off of UHMWPE flakes

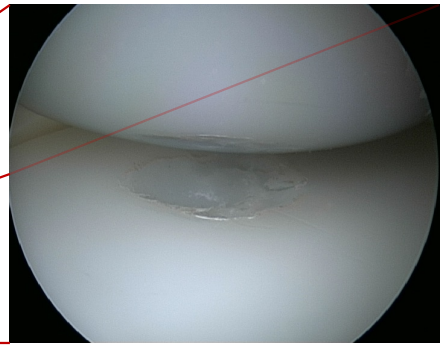
Subsurface oxidation

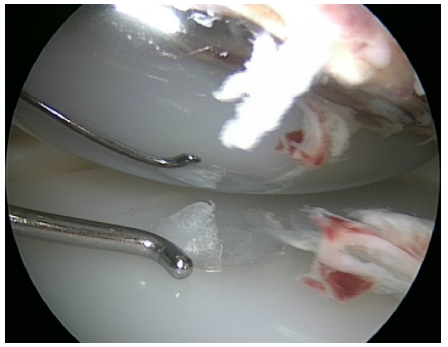
During the sterilization process (gamma irradiation in ear) may lead to subsurface degradation of the PE)



Wear patterns - femoral component and liner







57 yrs old male Pat.

- UKA 7’ 2011
- Persistend effusion

- Arthroscopy 11’ 2011
- Exchange of the liner 11’2011

- Re-evaluation 12’2021
- F/E: 125°-0°-0°, no pain

Modern polyethylene

Ultra-High-Molecular-Weight Polyethylene - Polymerer molecules consist of long chain hydrocarbons

Highly Cross-Linked Polyethylene - Better wear performance, BUT reduced strength and fatigue resistance

Re-melted Highly Cross-Linked Polyethylene - Reduction in free radicals and wear

Annealed Highly Cross-Linked Polyethylene - Better mechanical properties due to preservation of the Crystallinity

Sequentially irradiated and Annealed Polyethylene – Gamma irradiation and annealing in a repetitive manner, lowest rate of wear

Vitamine E Highly Cross-Linked Polyethylene - Replaces the remelting process and thus prevents loss of crystallinity, prevention of loss of fatigue strength

Chakravarty R, J Knee Surg 2015, 370-375

List of standards for TKA

MHB
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Standard	Name	Used for
ISO 7207-1 & 2	Implants for surgery—Components for partial and knee joint prostheses	D, R, T
ISO 10993-1 to 18	Biological evaluation of medical devices	R, T
ISO 13485	Medical devices—Quality management systems—Requirements for regulatory purposes	D, R, T
ISO 14243-1 & 2	Implants for surgery—Wear of total knee joint prostheses	T
ISO 14283	Implants for surgery—Fundamental principles	D, R, T
ISO 14630	Non-active surgical implants—General requirements	D, R, T
ISO 14879-1	Implants for surgery—Total knee joint prostheses—Determination of endurance properties of knee tibia trays	T
ISO 14971	Medical devices—Application of risk management to medical devices	R
ISO 16142	Medical devices—Guidance on the selections of standards in support of recognized essential principles of safety and performance of medical devices.	D, R, T
ISO 17853	Wear of implant materials—Polymer and metal wear particles—Isolation, characterization, and quantification	T
ISO 21536	Non-active surgical implants—Specific requirements for knee joint replacement implants	D, R, T
IEC 62366	Medical devices—Application of usability engineering to medical devices	D, R, T
ASTM F 1223	Standard Test Method for Determination of Total Knee Replacement Constraint	T
ASTM F 1800	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacement	T
ASTM F 2052	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	T
ASTM F 2083	Standard specification for Total knee prosthesis	D, R, T
ASTM F 2182	Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging	T
ASTM F 2724	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation	T
ASTM F 2777	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion	T

Modern ultra high polyethylene

Vitamin E-infused highly cross-linked polyethylene (E1) versus conventional polyethylene (CP)

	E1	CP
Totel number of particles obtained after 3.4 years	$6.9 \pm 4.0 \times 10^7$	$2.2 \pm 2.6 \times 10^7$
Particle size	$0.5\mu m \pm 0.1$	$1.5\mu m \pm 0.3$

Orita K, Bone Joint J 2020

Knee loading

- No association between alignment within ± 3° and wear characteristic after TKA,

Parrate S JBJS-Am 2010

- Malalignment of the component of >5° varus significant effect on wear characteristics

Collier MB JBJS-AM 2007

- Joint line elevation of more than 5mm increases wear

Pang HN J Arthroplasty 2014

Allergy

Allergy: Overreaction of the immunesystem against agends

Type of immunreaction:

Type 1: Free antigens ⟶ IgE transmitted early type

Type 2: Cell associated antigen: ⟶ antiody related cytotoxic type

Type 3: Antibody related immuncomplex type of reaction

Type 4: Cell mediated type, antibody related type (late type)

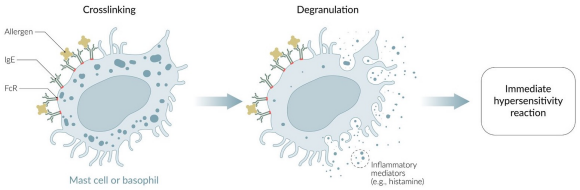
(Lymphocyts, CD4 supporter cells)

Allergy

Allergic reaction involves **type I hypersensitivity**:

- Prevalence of type I hypersensitivity to metal = **10-15%** (f/m=15%/2%)

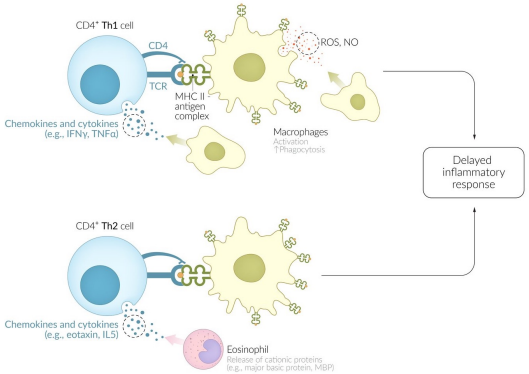
acute IgE antibody mediated response



Metall implants may cause delayed **type IV hypersensitivity**

Cell mediated reaction

- Prevalence of symptoms to metal **< 0.1%**



Usage of coated implants in: Germany = 4%
England = 1.2%

Allergy

Peripheral T-Lymphocytes

T_{H1} cells become active

Release of TNF-α, IFN-α, IFN-γ

Recruitment of macrophages

PROINFLAMMATORY MILIEU

Allergy

Test for metal hypersensitivity

- Lymphocyte transformation test (LTT)
- Modified lymphocyte stimulation test (mLST)
- Leukocyte migration inhibition test (LMIT)

Hypersensitivity in 113 patients

Cement components	No. of patients with reaction	Percentage
Gentamicin	19	16.8
Benzolperoxide	9	8
Hydrochinon	3	2.7
2-Hydroxy-ethyl-methylacrylate	2	1.8
Copper(-II) sulfate	0	
Methylmethacrylat (MMA)	1	0.9
NN-Dimethyl-p-Toluidin	0	
One or more bone cement components	28	24.8
Metal and bone cement components	11	9.7

Basics in primary knee arthropladsty 2022, Chapter 56, Thomas P et al. Orthopäde 20081

Allergy

Symptoms after TKA
- Joint effusion +/-
- Pain +/-
- Dermatitis +/-
- Reduced range of motion +/-

Clinical examination (Effusion, ROM, anteroposterior and mediolateral stability)

Laboratory testing (CrP, Leukocyte)

Radiography (ap, lat. view)
Long leg weight bearing view
Computertomography

Instability +/-

Stiffness +/-

PAIN +/-

Synovitis +/-

Loosening +/-

Symmetrical or asymmetrical mismatch of the extension and/or flexion gap

5 Biospies

aseptic

septic

Wear +/-

Aseptic loosening +/-

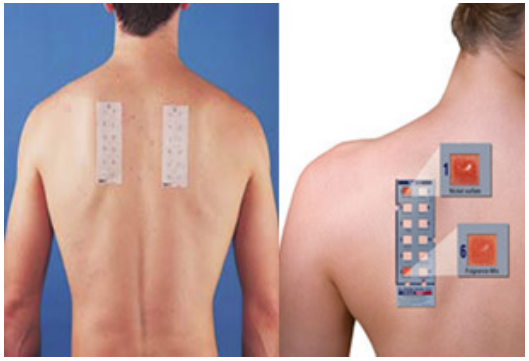
Chronic synovitis +/-

Infection

Patch -Test + LTT +/-

+

Immune response



Problem

Allergic skin reaction does not need to be related to the implanted metall

40 Hip revisions
- 9 patients showed positiv epicutaneous test
- No difference in histology of periprothetic tissue

Milavec-Puretic AOTS 1998

Danish hip register
- 18700 patients received epicutaneous test
- RESULTS: no increase in revision rate
- no increase in complication rate

Thyssen Acta Orthop 2009

ALTERNATIVES

Coverage of the surface: Ti(Nb)N – Titan (niob) nitrit

Oxinium: Zirconium + Niob
Nickel content of 0.0035%

Ceramic: Aluminiumoxid or Circoniumoxid

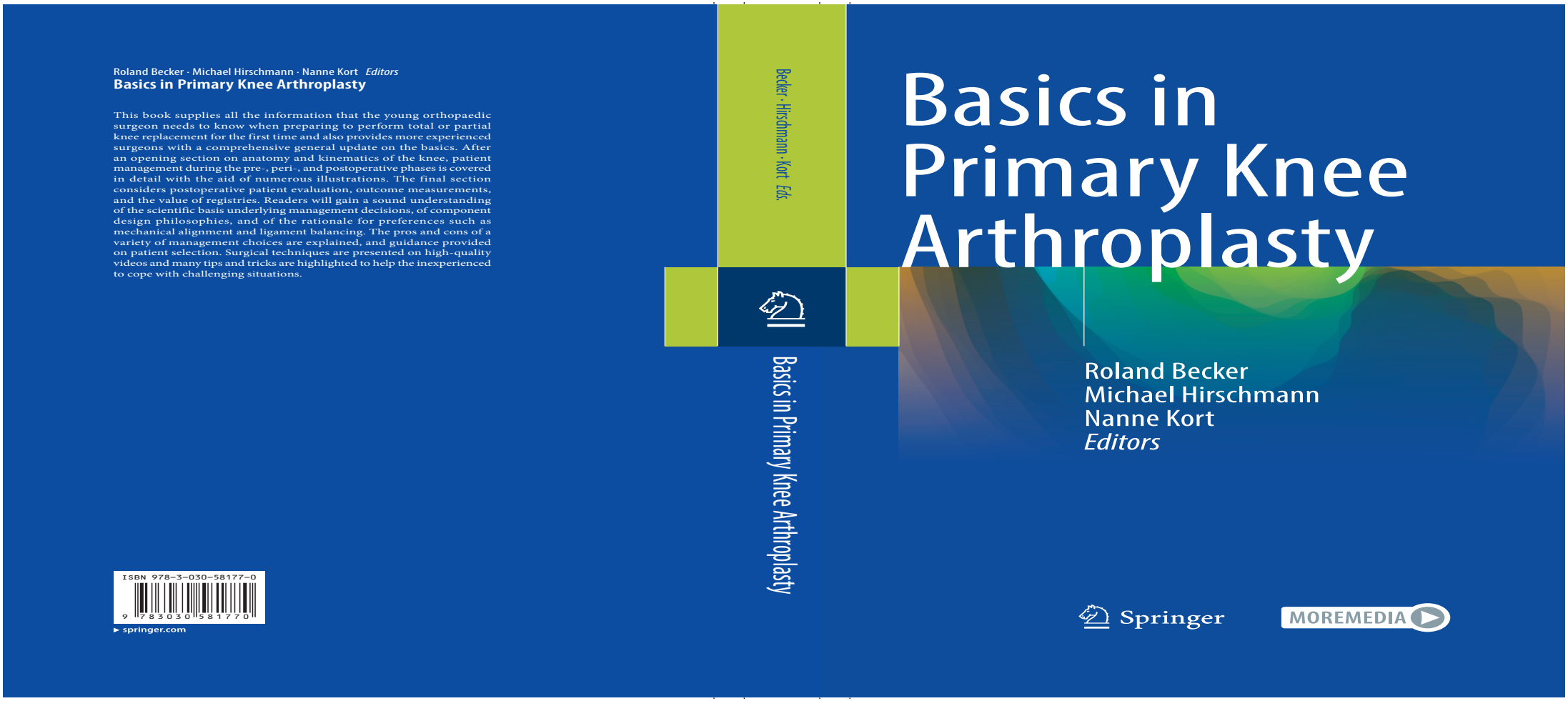
Bader Orthopäde 2008

Summary

1. Correct terminology is **hypersensitivity** and not **allergy**
2. Hypersensitivity after total joint replacement very rare (0.6%)
3. No correlation between epicutaneous test, lymphocyte proliferation test and hypersensitivity
4. Increase in positive epicutaneous tests after total joint replacement – BUT no correlation
5. Hypersensitivity after total joint replacement is an exclusion diagnosis

Low allergy implants (Ceramic) used in Germany for legal reasons,

Thank You


Roland Becker · Michael Hirschmann · Nanne Kort Editors
Basics in Primary Knee Arthroplasty
This book supplies all the information that the young orthopaedic surgeon needs to know when preparing to perform total or partial knee replacement for the first time and also provides more experienced surgeons with a comprehensive general update on the basics. After an opening section on anatomy and kinematics of the knee, patient management during the pre-, peri-, and postoperative phases is covered in detail with the aid of numerous illustrations. The final section considers postoperative patient evaluation, outcome measurements, and the value of registries. Readers will gain a sound understanding of the scientific basis underlying management decisions, of component design philosophies, and of the rationale for preferences such as mechanical alignment and ligament balancing. The pros and cons of a variety of management choices are explained, and guidance provided on patient selection. Surgical techniques are presented on high-quality videos and many tips and tricks are highlighted to help the inexperienced to cope with challenging situations.
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