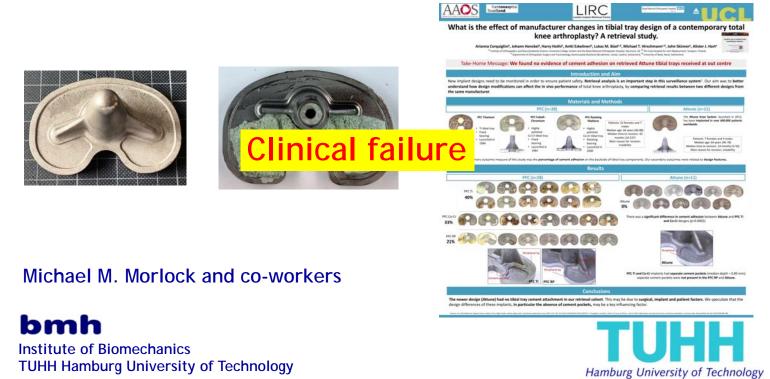
# Failure analysis: practice and future challenges



Institute of Biomechanics TUHH Hamburg University of Technology



## Failure analysis: practice and future challenges



- It didn't work and had to be replaced
- Main question: material failure or clinical failure?
- Best case scenario: failure can directly be related to observations made from the implant

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## Example 1





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## Example 1

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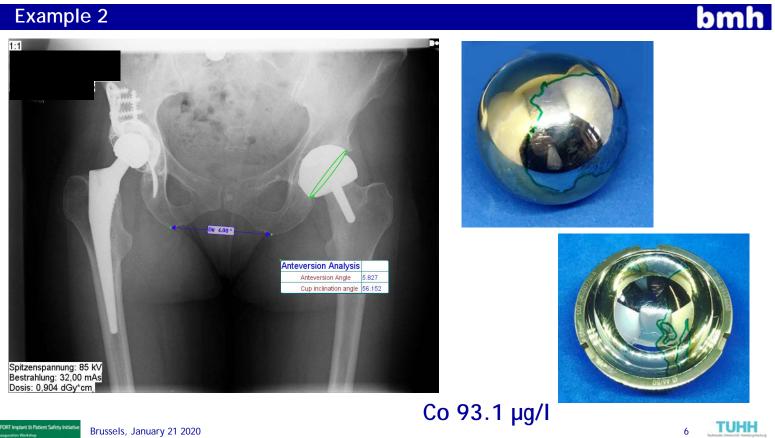


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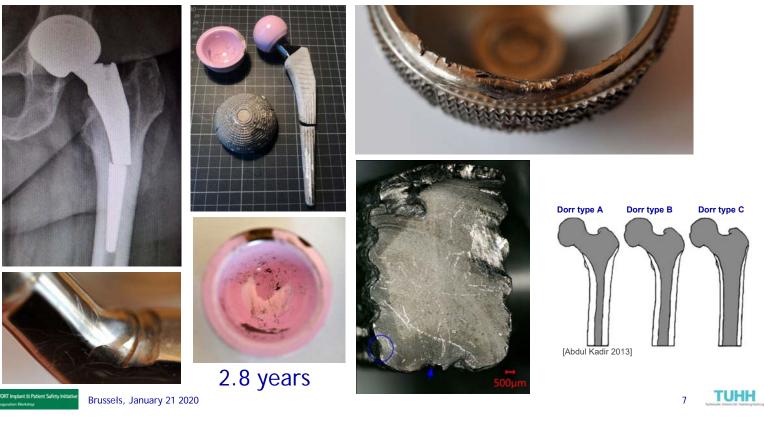
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#### Example 2



## Example 3

## bmh



## Example 3

## 6.5 years







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#### Example 6

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#### Primary 08.10.2006 +8mm head







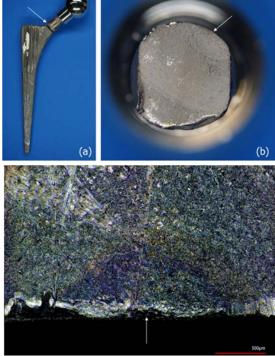




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#### Example 6



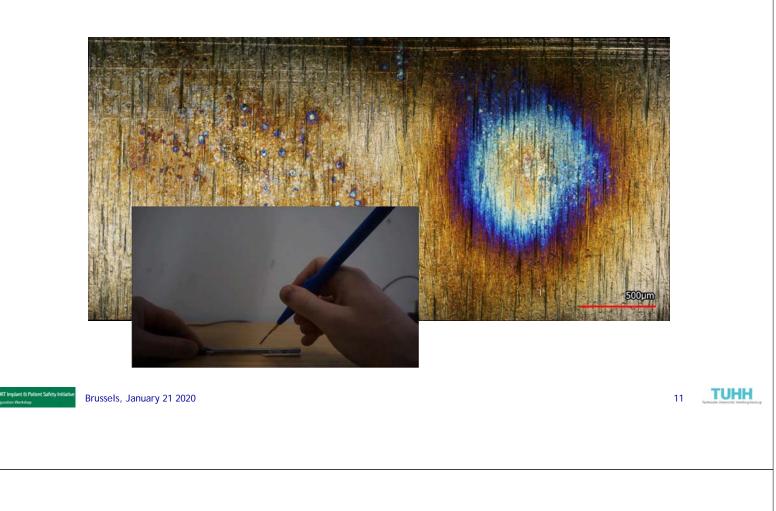


..... the combination of a CLS stem and a DePuy head with a neck length of **more than 8 mm** is an unauthorized combination, which is not released by Zimmer (see www. product-compatibility. zimmer.com).....

Implant & Patient Safety Initiative don Workshop 10 **TUHH** 

#### **Sparc Transition**

## bmh



#### What does retrieval analysis tell us?

- It didn't work and had to be replaced
- Best case scenario: failure can directly be related to observations made from the implant

All examples (also previous talk) from court cases in which manufacturer was accused

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# Normal situation •

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#### **Example 7 - Liner dislocation**

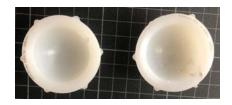
This damage has been documented before: NJR 0.1% (Jameson et al., 2013) DePuy 0.06% Peer reviewed studies 0.17%, 0.32%, 0.77%, 0.82% (in total 12 publications)



- It didn't work and had to be replaced
- Best case scenario: failure can directly be related to observations made from the implant



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## Example 8 - Ceramic Inlay fracture

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## Example 11 - Stem taper failure



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#### What does retrieval analysis tell us?

### Little -

without supplemental quantitative information on:

- surgical procedure,
- loading in the patient, and
- registry data (single or big problem)

is required to speculate on the "causes" for revision

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#### Registry

 
 Table HT15
 Primary Total Conventional Hip Replacement by Reason for Revision (Primary Diagnosis OA)

2.122.212		
Reason for Revision	Number	Percent
Loosening	2975	25.6
Prosthesis Dislocation	2506	21.6
Fracture	2265	19.5
Infection	2055	17.7
Lysis	266	2.3
Pain	219	1.9
Leg Length Discrepancy	169	1.5
Malposition	154	1.3
Instability	125	1.1
Implant Breakage Stem	119	1.0
Metal Related Pathology	118	1.0
Implant Breakage Acetabular Insert	102	0.9
Wear Acetabular Insert	98	0.8
Incorrect Sizing	90	0.8
Implant Breakage Acetabular	76	0.7
Implant Breakage Head	39	0.3
Other	234	2.0
TOTAL	11610	100.0

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded

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Table HT15		Total Conventional Hip Replaceme on for Revision (Primary Diagnosis	
Reason	for Revision	Number	Percent

## Direct material/design related: 3.7%

TOTAL	11610	100.0
Other	234	2.0
Implant Breakage Head	39	0.3
Implant Breakage Acetabular	76	0.7
Wear Acetabular Insert	98	0.8
Implant Breakage Acetabular Insert	102	0.9
Implant Breakage Stem	119	1.0

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded

#### Failure Analysis

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He crashed twice...

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#### The real question

# "What are the factors to make an implant successful in some but fail in other patients?"

#### The situation



## What do we know?

- Implant: CE-certified, fullfills all specifications required by the notified body (most contolled factor....)
- Surgeon: Trained (University, Hospital, Training courses). Not standardized, transfer of knowledge after training courses not assured (CME credit for physical presence)
- Patient: .....

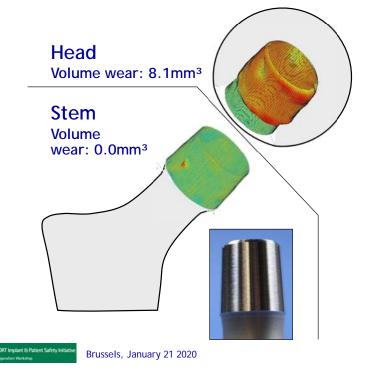
Predominantly the implant is "identified" as the reason for revision, since we only look at the implant (predominantly)

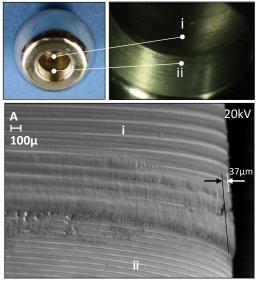
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#### The situation

• Multiple quantitative methods to document condition





 Imprint of Ti stem taper profile in CoCr head taper

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# The situation Multiple quantitative methods to document condition Very difficult to conclude, what exactly caused the condition (in most cases), especially if only single retrievals are available Gross product failure vs. Interface failure -> look for frequency of occurence in registries! TUHH Brussels, January 21 2020 24 Take Home bm Failure analysis: practice and future challenges **Practice** Sophisticated descriptive methods to document situation

- Little gain of knowledge, what differentiates between failure and success
- Difficult to establish causality (missing info flight recorder?)
- Material problems vs.



tness)

#### Take Home



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## *Failure analysis: practice and future challenges* Future challenges

 Obtain "complete" data: Manufacturer (technical data) Surgeon (procedure) Patient (loading) Registry (single - many)

- Report to authorities, manufacturer, original surgeon, laboratory - <u>do not throw away!</u>
- Design a simple process of reporting and providing explants together with the additional information without scaring the surgeons away by too much paper.
- Most important: dare to address all "real" problems! Brussels, January 21 2020 28