How a retrieval lab can help when things go wrong

Michael M. Morlock and co-workers

bmh
Institute of Biomechanics
TUHH Hamburg University of Technology

TUHH
Hamburg University of Technology

What do implant retrieval studies tell us?

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

Example 1

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Example 2

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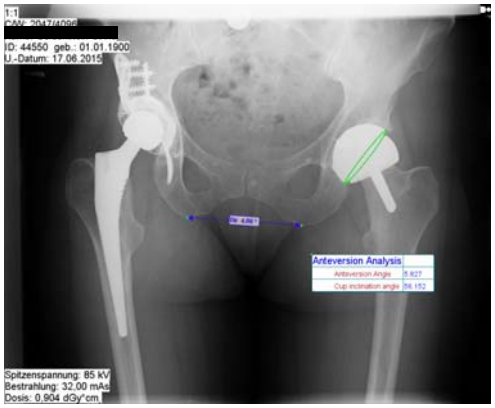

Example 2

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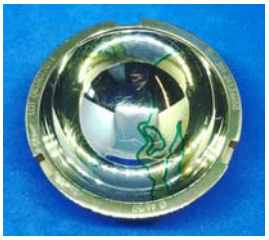
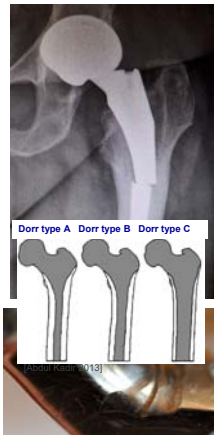
Co 93.1 µg/l



Example 3

2.8 years



Example 4

6,5 years

What do implant retrieval studies tell us?

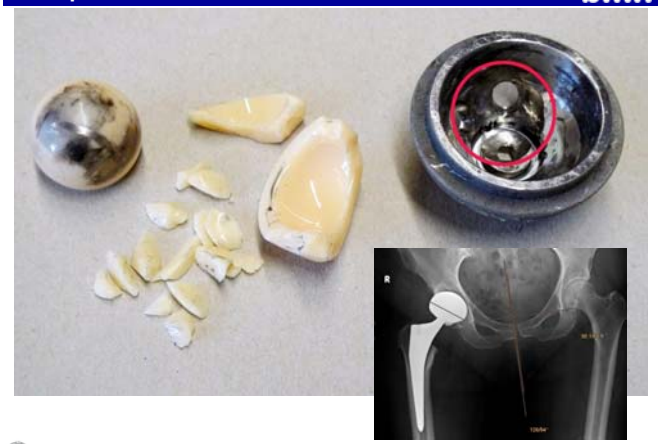
- It didn't work and had to be replaced
- Best case: failure can directly be related to observations made from the implant

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

What do implant retrieval studies tell us?

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

Example 6



What do implant retrieval studies tell us?

- It didn't work and had to be replaced
- Best case: failure can directly be related to observations made from the implant
- Normal case: Not conclusive
- Supplemental quantitative information on
  - surgical procedure,
  - loading in the patient, and
  - registry data (single or system problem)

  are needed to speculate on the causes
- Otherwise: Bias towards the implant

The real question

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

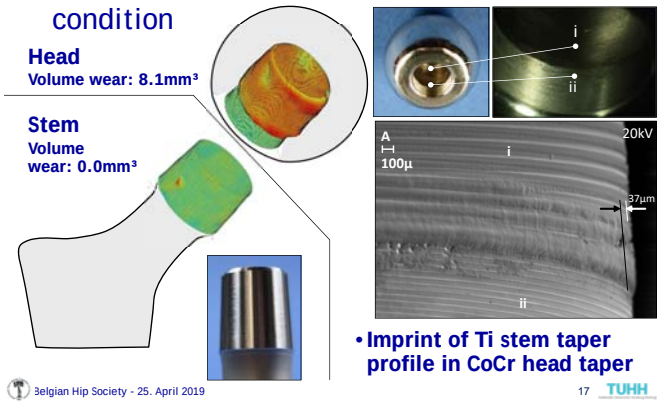
Introduction

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 really standardized, transfer of knowledge after training courses not assured (CME credit for physical presence)
- Patient: …..

Retrieval analysis

- Multiple quantitative methods to document condition



- **Imprint of Ti stem taper profile in CoCr head taper**

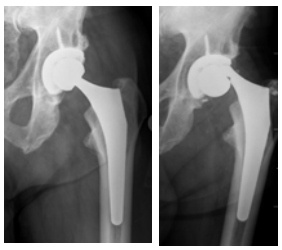
Retrieval analysis

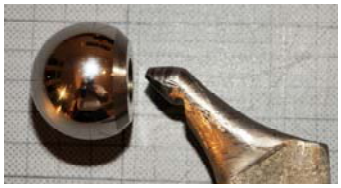
- Multiple quantitative methods to document and describe condition
- Difficult to conclude, what exactly caused it, especially if only single retrievals are available

-> look for many!

Corrosion/Fracture/GTF

- **Active patient**
- **9 years in situ**
- **Dislocated without warning**
- **Taper „problem“ – what caused it?**
- **Some patients show ARMD before GTF**





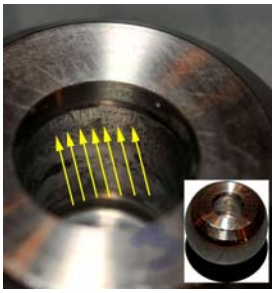
Material

- 10 Accolade® TMZF® stems from dis-association cases (n=9) or fracture (n=1)
- 31 LFIT™ CoCr heads (Ø 36 mm and larger)
- Time-in-situ, patient gender and patient age

Methods

Material loss:

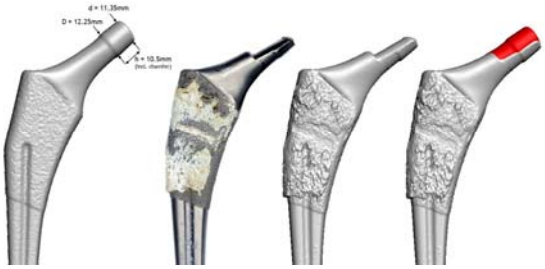
- Head: Estimate material loss from undamaged areas



Methods

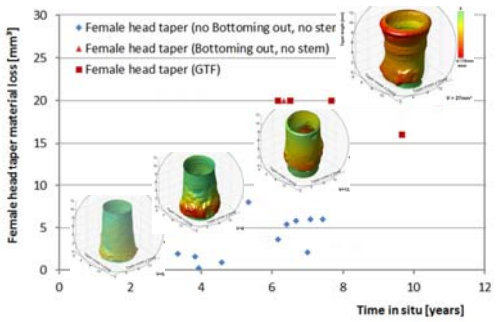
Material loss:

- Stem: Estimate material loss from original geometry (intact stems)



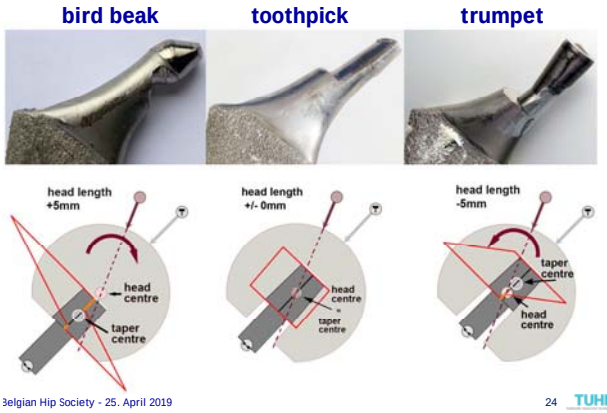
Results

- Female head taper material loss increases with time (r^2=0.49, p<0.001)



Results

The 3 GTF patterns



Discussion

Why does it happen frequent (>95% of the cases reported in the literature) with a V-40 taper made from TMZF?

n=21

n=30

n=30

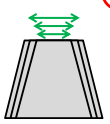
Model

Hypothesized failure mechanism:

(1) Larger micromotion at taper interface for small tapers

Taper designs

	14/16	12/14	V-40
Taper angle:	5°43'30'	5°43'30'	5°40'
Taper diameter:	14.5mm	12.4mm	11.5mm



Hypothesized failure mechanism:

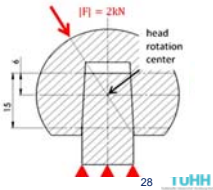
(2) Larger micromotion at taper interface for small tapers, softer materials

Stem

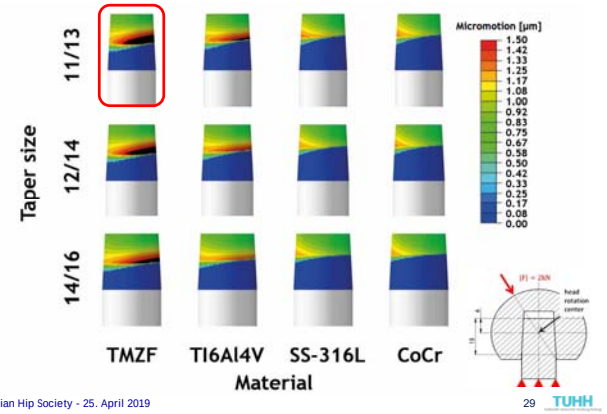
Taper angle	5.72°
Taper length	15mm
Proximal taper diameter	11.5mm for V40 taper 12.4mm for 12/14 taper 14.5mm for 14/16 taper
Material stiffness	CoCr 220 GPa 316L 200 GPa Ti6Al4V 110 GPa TMZF 80 GPa

Head

Taper angle	5.78°
Material	CoCr



Micromotion vs. taper design & material



Retrieval analysis – what did we learn?

- **Metals corrode in the physiological environment**
- **Concerned implants and material are not commercially available anymore**
- **Recalls/withdrawals initiated by**
  - **retrieval studies**
  - **publications (case and series)**
  - **registry data**
- **Little evidence, WHAT differentiates between success and failure of the respective implants**

- **Failure patterns need to be reproduced in the lab to validate suspected failure mechanisms**
- **Registries are essential to estimate the extend of the problem. They need to include patient and surgeon data.**
- **Without „quantitative“ information on patient & procedure, retrieval analysis will always focus on the only factor with detailled and quantitative information – the implant.**
- **It might be the time to think about solutions to improve the situaion beyond implant design…..**

Thank you for your attention!

bmh