Historical pitfalls and actual situation - What have we learned & whar are current needs?



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Acknowledgement



Added substantial to present lecture





Historical pittfals





Region of

Southern Denmark

Boneloc Bone Cement (1992-1996)

Acta Orthop Scand. 1998 Oct;69(5):479-83.

Inferior performance of Boneloc bone cement in total knee arthroplasty: a prospective randomized study comparing Boneloc with Palacos using radiostereometry (RSA) in 19 patients.

Nilsson KG¹, Dalén T.







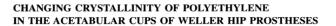






Hylamer polyethylene (1959, 1968, 1996)



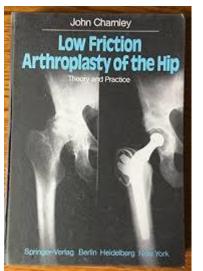


J. OTFINOWSKI, A. PAWELEC

From Jagiellonian University Medical College, Kraków, Poland







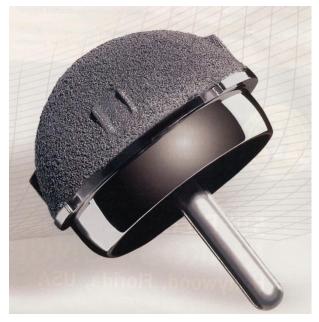


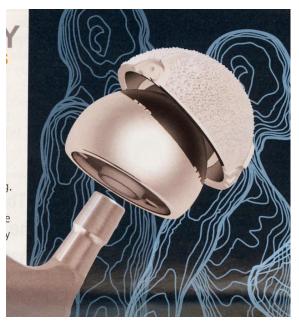




Metal-on-Metal Bearings

Large head THA / Resurfacing THA



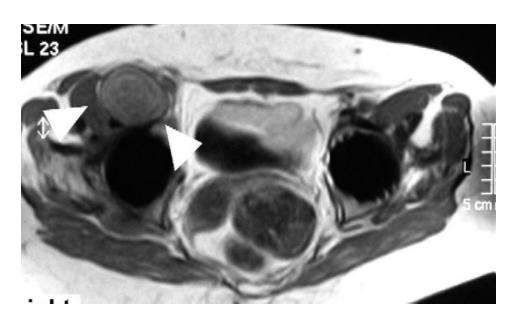








MoM – pseudo-tumor











Medical Device Alert

Device

All metal-on-metal (MoM) hip replacements

EMENT PATIENTS







SEVERE PAIN

MHRA

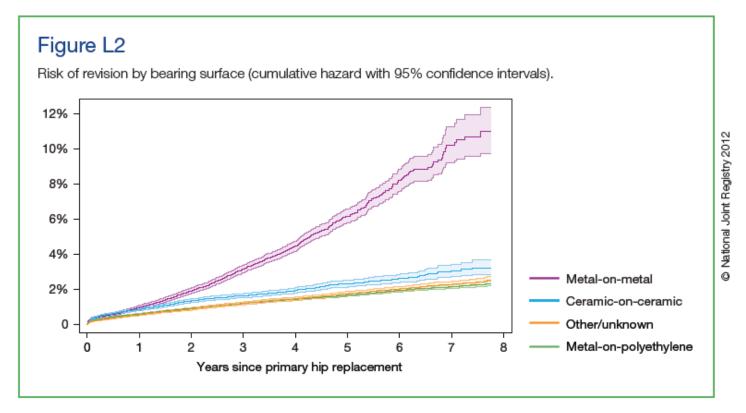
- HIP JOINT SWELLING
- BONE NERVE DAMAGE

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Southern Denmark

· CHESTINE STRUCKS

Outcome of MoM Bearings









European Recommendations MoM



Consensus statement "Current Evidence on the Management of Metal-on-Metal Bearings"

April 16, 2012

http://www.efort.org/communications/pdf/2012_05_10_MoM_Consensus_statement.pdf







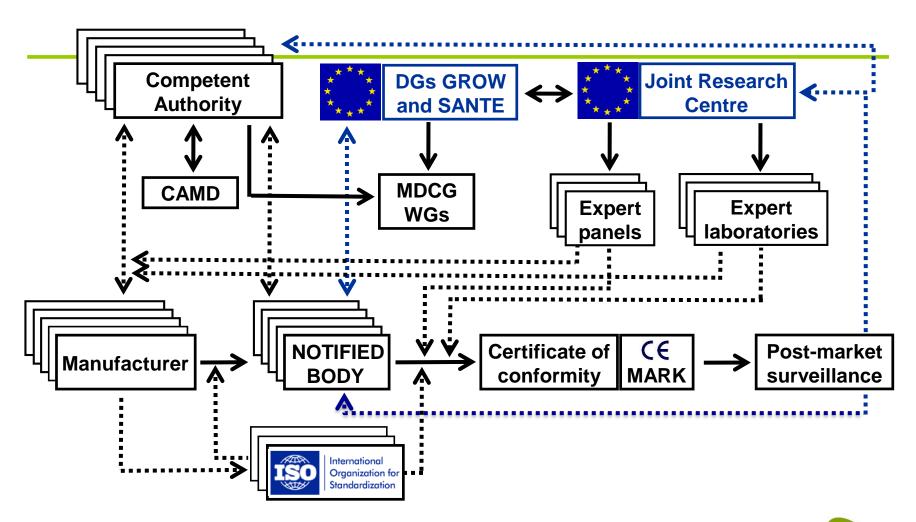
Actual Situation

NEW MDR





EU Medical Device Regulatory System







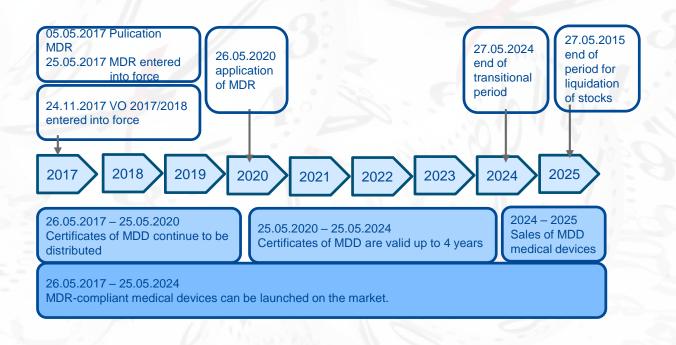
 Entry into force of the MDR May 2017 Full application of the MDR May 2020 Full application of the IVDR May 2022

Fig. 1 Timeline for implementation of the new regulations.





Timeline for MDR introduction







What have we learned?

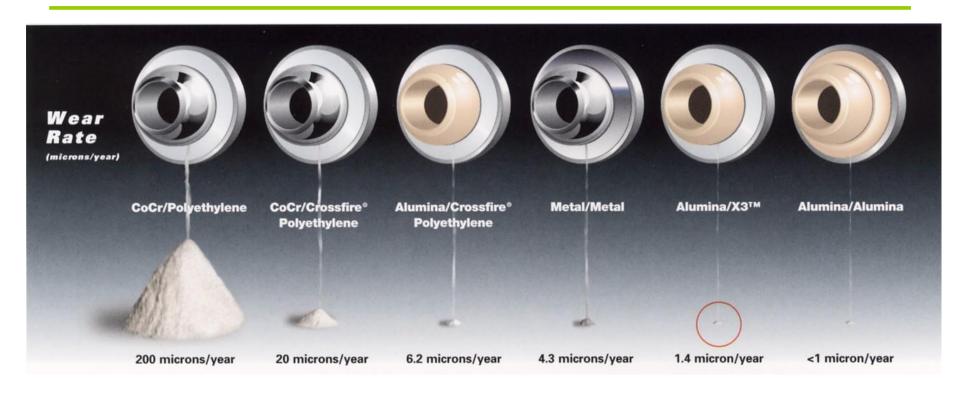




Region of Southern Denmark

Innovation is needed

Tribology







Failure will occur – also in future





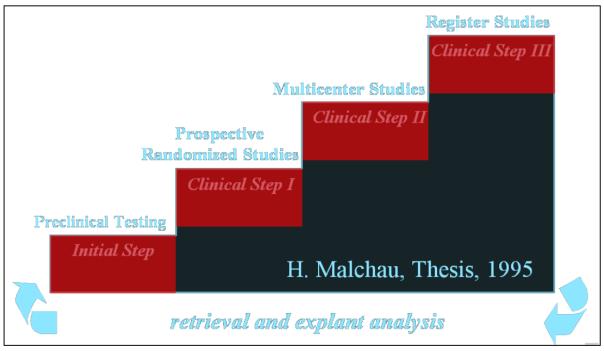






Vejle Sygehus en del af Sygehus Lillebælt

Step wise introduction (Malchau thesis 1995)



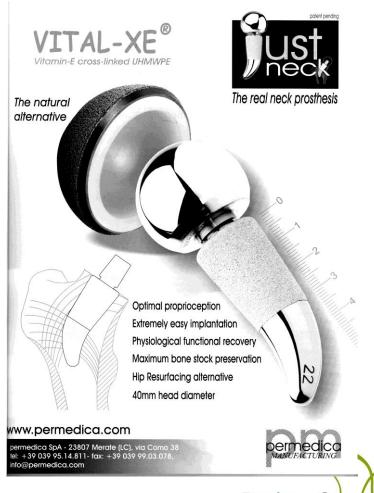






Experimental surgery – step-wise introduction







Se**verion Sygehips**and Knee



Experimental surgery – step-wise introduction



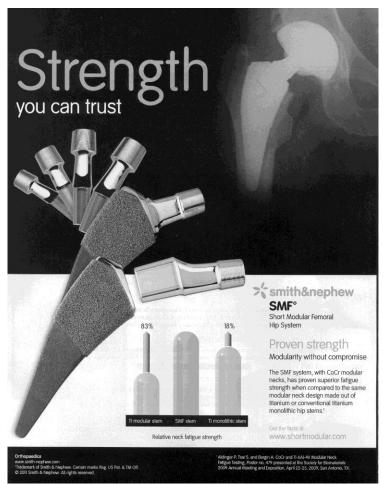






Experimental – step-wise introduction

Anatomical reconstruction

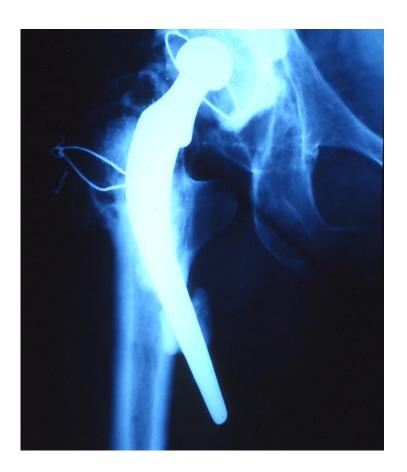




Southern Denmark



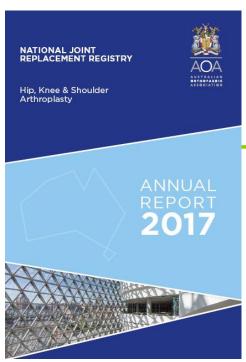
What are current needs?





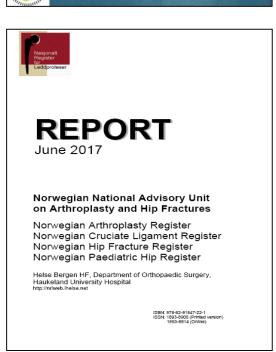


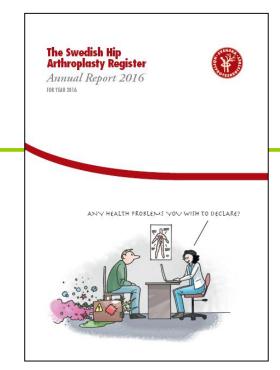
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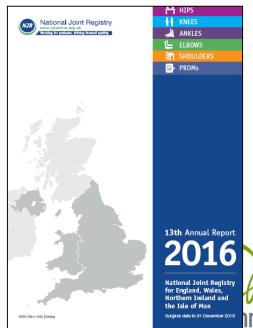












Close collaboration all stakeholders





































(A) SYNTHES













Disease-Specific Care











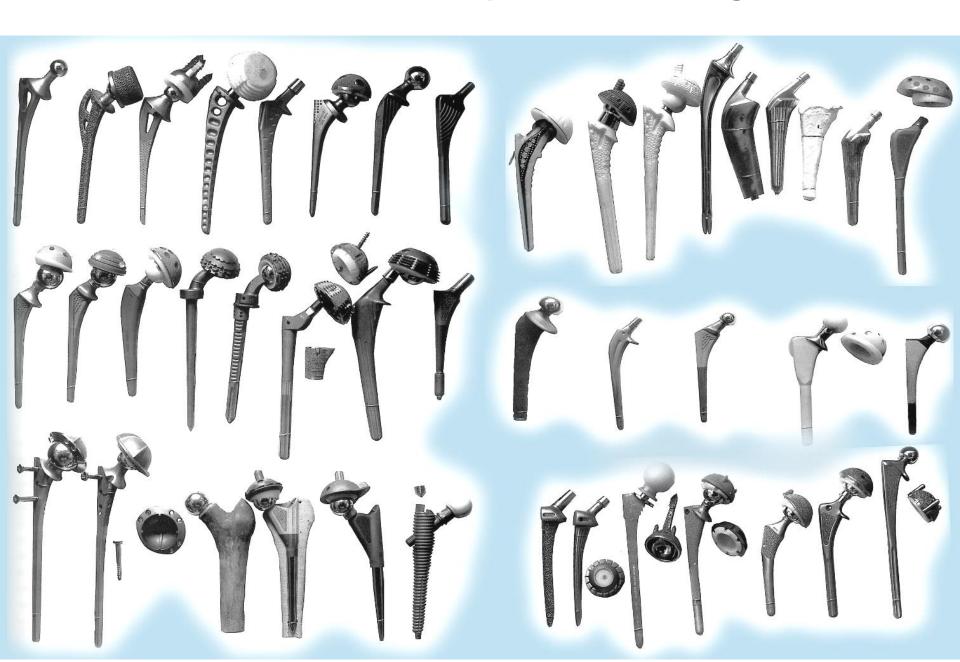




Se**verion Synchips**and Knee



We all look for safe implants – how to get it?



Education & training







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Thank you for your attention



Section for Hip & Knee Replacement, Vejle Hospital