



ortho
The Hip Preservation Society

BHS
The Hip Society



ISHA
The Hip Preservation Society

**The ASR problem
... a personal experience**
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AZ Herentals





ASR ... a personal experience

- 1995 visit Mc Minn in Birmingham
- Not convincing
- I was a non believer
 - Resurfacing is a total hip: mimicking the hip joint
 - Less resection on the femur, but more on the acetabular site
 - Big operation, big approach
 - Repeating failures of history


ASR ... a personal experience

- Resurfacing was really hip
- The pressure to have it in the portfolio for the patients who asked for it...
- The promising results BHR and some excellent publications
- One colleague who helped me and so I started....




ASR ... a personal experience

- BHR
- Recap
- ASR
- Mitch Per
- 8/2010 Complete stop following registries UK & Australia
- 10/2010 ASR Recall
 - ASR users in meeting with company
- 11/2010 Mediasstorm




ASR ... a personal experience

- Mediasstorm
- 86 ASR hips
- Patients are calling
- 5 calls very long
- Every patient seen in the office
- 4 are very anxious and it takes more than one hour each
- Most understand the problem, angry on the company not on the surgeon



ASR ... a personal experience

- X-ray, Ultrasound, Cr Co in serum
- If positive: MRI (MARS protocol)
- Decision to revise on preceding examinations and clinical picture



ASR ... a personal experience

- 86 hips
- 6/2009
 - ASR stop
 - 5 revisions
 - 2 fractures, 2 cup loosening, 1 infection??
- 4/2019: 28 revisions



ASR ... a personal experience

- 4/2019: 28 revisions
 - Mean time: 4,8 y postop
 - 21 Metallose +/- Pseudotumour
 - 2 fractures
 - 3 cup loosening
 - 2 infections?



ASR ... a personal experience

- Recall...
 - The surgeon
 - Stressfull
 - Change a system you believed
 - Guilty
 - Time consuming
 - Towards the company:
 - Angor - Distrust



ASR ... a personal experience

- Recall...
 - The patient
 - Anxious
 - Towards the company angor
 - Towards the surgeon: help me!



ASR ... a personal experience

- Recall...
 - The Company
 - Correct but few information to the patient
 - All costs of examinations were paid
 - All revision surgery and related costs has been paid
 - Sometimes long story, depending on the company and the patient
 - One trial



ASR ... a personal experience

- Recall...
 - The Company
 - One trial
 - Male 51 y surgery 2007
 - Groin pain
 - Infiltrations: no effect
 - Ultrasound, MRI, CT negative
 - Co 2,5
 - Cr 3,5



ASR ... a personal experience

- Recall...
 - Hip arthroscopy with biopsy
 - Revision
 - Femoral fracture
 - Wires
 - Infection
 - Spacer
 - Revision



ASR ... a personal experience

- Personal conclusions
 - I have chosen for the wrong implants believing that all resurfacing were similar
 - 30 % revisions of one implant is a huge (personal) disaster
 - See all the patients yourself if there is a recall
 - MOM, keep on following them



ASR ... a personal experience

- Conclusion
 - Recall for the surgeon
 - Guilty
 - Stressfull
 - Time consuming
 - Recall for the patient
 - Anxious
 - Angor



ASR ... a personal experience

- Conclusion
 - Believe in registries and follow them
 - Total hip has excellent results, lets keep them
 - Before changing a winning team....



ASR ... a personal experience



Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies

OPEN ACCESS

Marc J Nieuwenhuijse research fellow ICOR and FDA^{1,2}, R G H H Nelissen professor¹, J W Schoones information specialist³, A Sedrakyan associate professor³

Objective

To determine the **evidence of effectiveness and safety** for introduction of **five** recent and ostensibly high value implantable devices in major joint replacement to **illustrate the need for change** and inform guidance on evidence based introduction of new implants into healthcare.



ASR ... a personal experience



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Study selection

The five selected innovations comprised three in total hip replacement (**ceramic-on-ceramic bearings**, **modular femoral necks**, and **uncemented monoblock cups**) and two in total knee replacement (high flexion knee replacement and gender specific knee replacement).



ASR ... a personal experience

Conclusion:

thebmj

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New technologies are being introduced to the commercial market without sufficient high quality evidence for improved benefit over existing, well proven, and safe alternative implant solutions.

Combined with recent disasters actions should be undertaken by all stakeholders to prevent patients from being further exposed to new device related technologies without proper evidence of improved clinical benefit and safety.



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ASR ... a personal experience

- Is the access to the market of new implants too easy?
- Let the debate start.....

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