Only lazy person doesn’t criticize MoM bearings today

Hundred articles were dedicated to MoM systemic and local adverse reactions

April 2010 UK Medicines and Healthcare Products Regulatory Agency:
"… Medical device alert …"

May 2012 Health Canada:
" … Public health communication …"

Sept. 2012 Therapeutic Goods Administration of Australia:
" … Safety information …"

Last nail in MoM's coffin …

Jan 2013 FDA

" … Concerns about Metal on Metal Hip Implants …"

" ... Разные люди по разному реагируют на продукты износа металла. В настоящее время невозможно предугадать у кого проявится нежелательная реакция, в чем она будет состоять, когда она возникнет и насколько тяжелыми могут стать ее последствия ..."

How Did We Get Here?

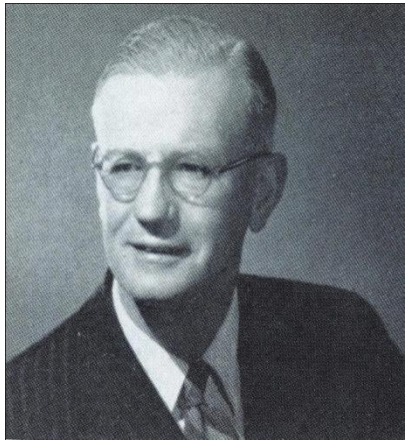
Hospital for Veterans of Wars

Metal–on-Metal: Large doesn't mean better

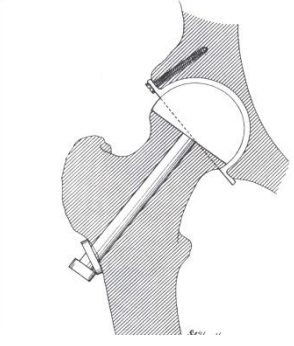
Vladimir Danilyak, M.D. Ph.D.

Yaroslavl – St. Petersburg 2013

Metal on Metal: from the first implantation to serial prostheses of the first generation

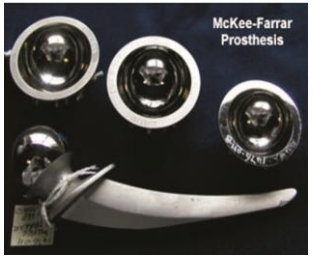


(Phillip W. Wales)
1899 – 1967



First implantation in 1938

George Kenneth McKee

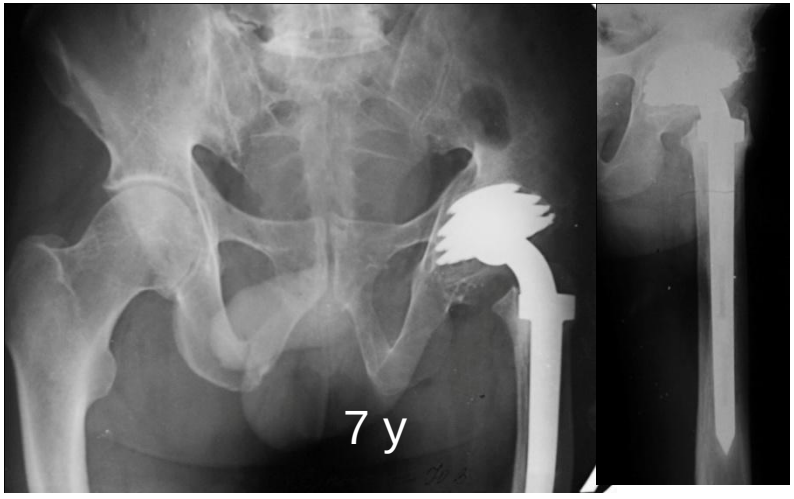


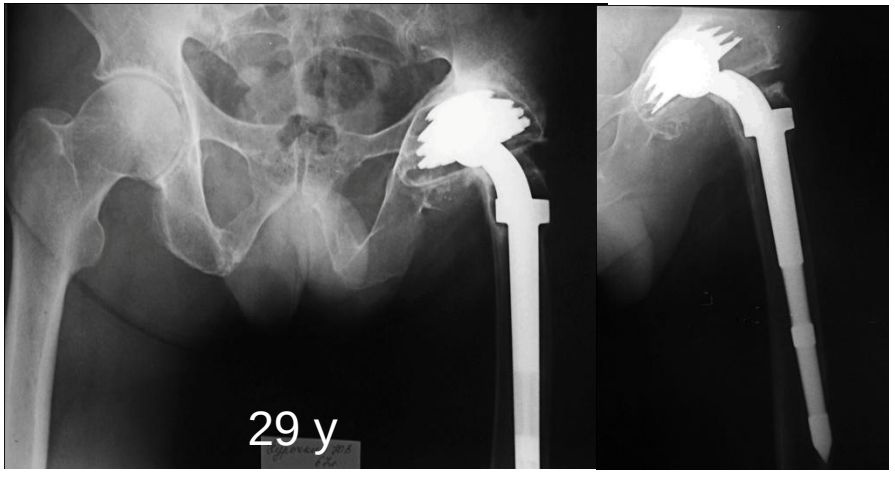
Ring, Ling, Aufranc,
Hagglers, Turner,
Amstutz, Muller

Konstantin Sivash

One piece
(constrained)
CoCrMo prosthesis

29 years result of Sivash implantation





No adverse soft tissue reaction and simple revision

- Primitive design
- Unsatisfactory fixation to the bone
- Underdeveloped manufacturing technology

But failures were not concerned with MoM bearings !

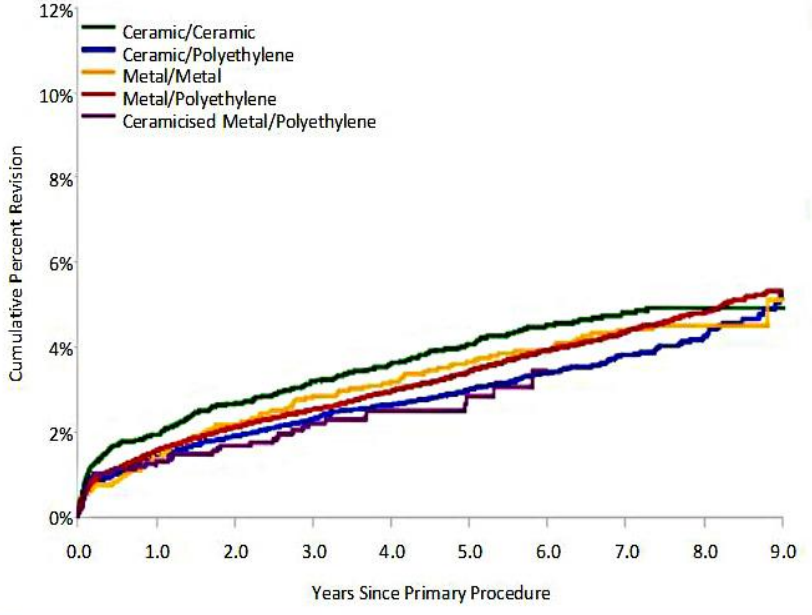
Metal-on-Metal of the II generation (middle of 80-th)

Bernard G. Weber

(Metasul – «sandwich»)

Protec, Sulcer, Mathys, Allopro, Endoprosthetic Plus, Zimmer

Yearly cumulative percent revision of primary THA by bearing surface (head diameter 28 mm)



Australian Register 2011

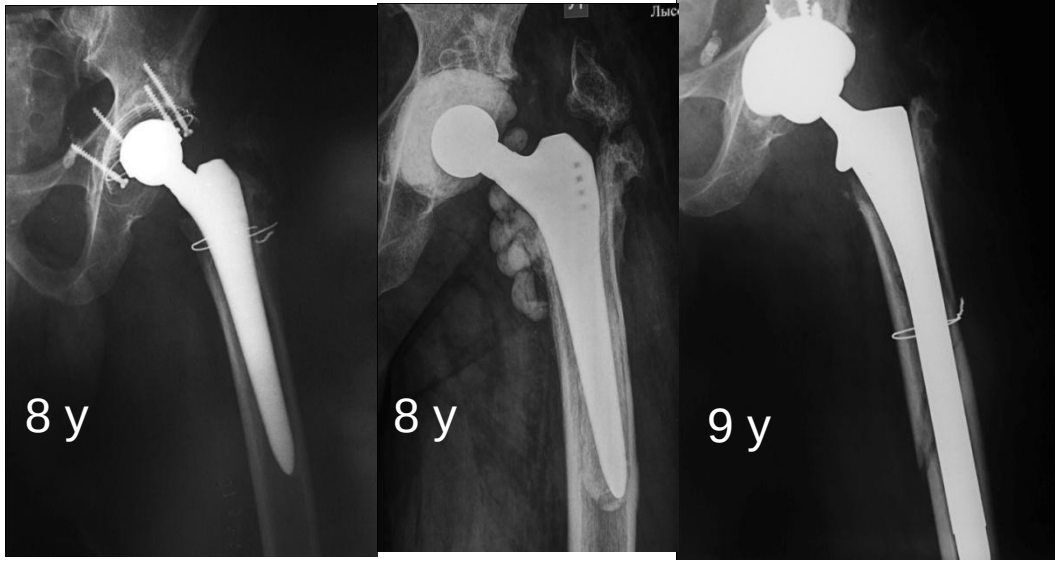
Our short cohort of MoM prostheses with 28 mm heads

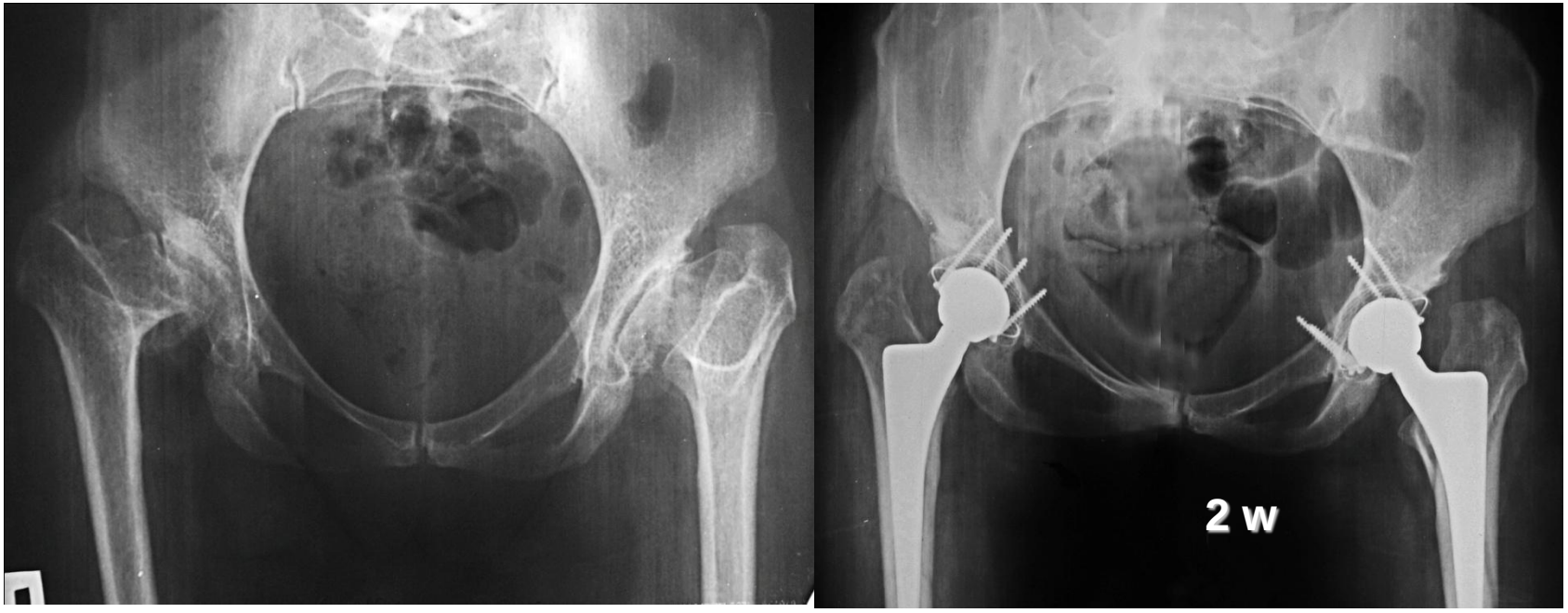
67 hips, 63 patients (4 – both sides)

Aged from 17 to 56 years (average 32.4)

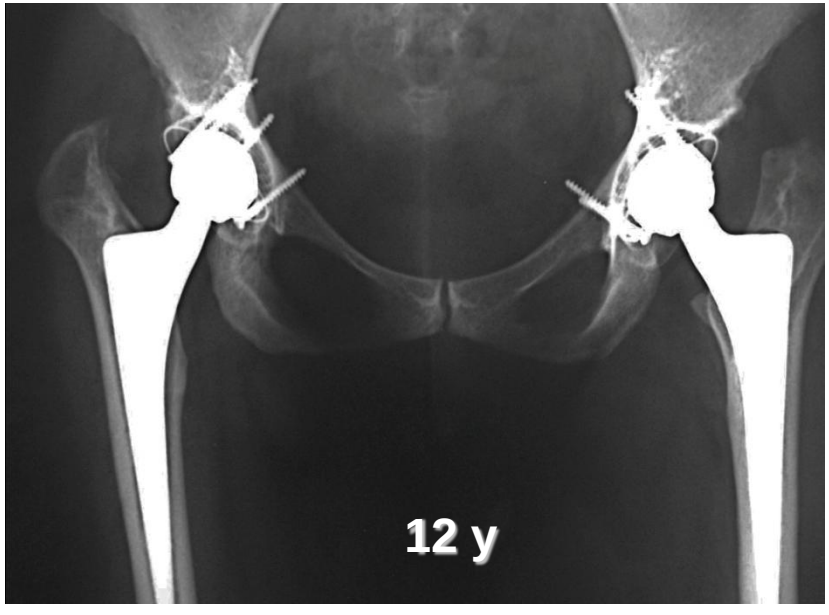
Follow-up period from 11 to 15 years

3 revisions – residual dislocation
- aseptic instability (after 7 years)
- infection (after 8 years)





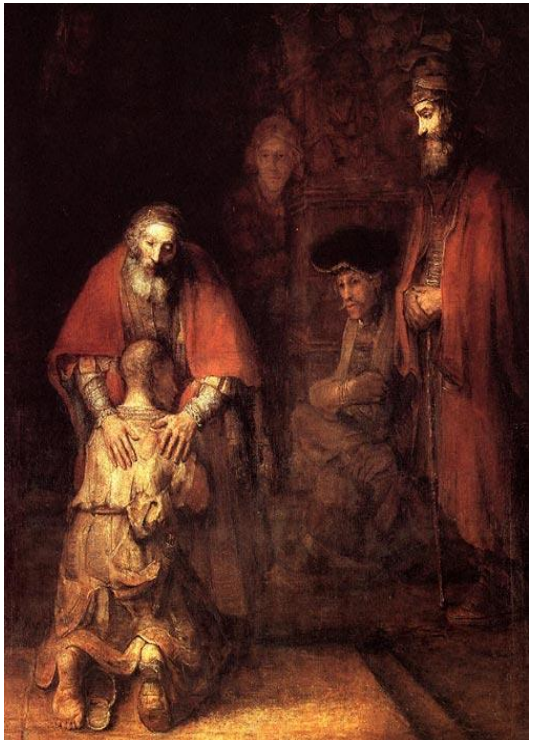
Crowe type III DDH



THA with met/met bearings

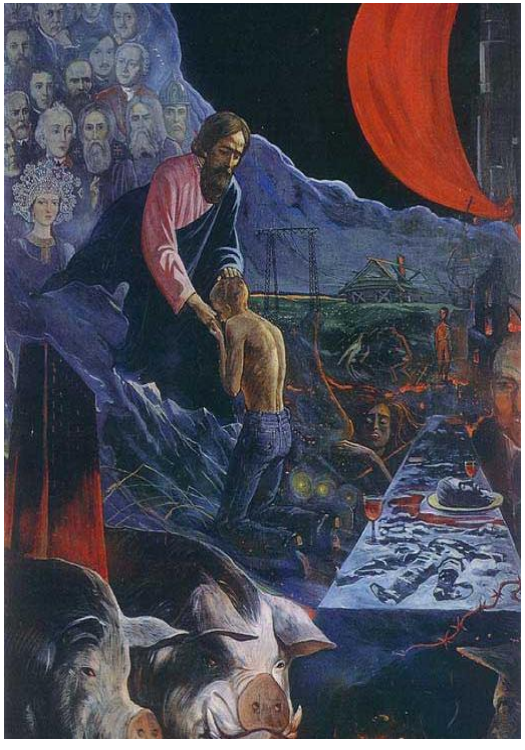
«The Return of the Prodigal Son»

Rembrandt van Rijn



MoM of the II generation,
Metasul,
Head diameter 28 mm & 32 mm

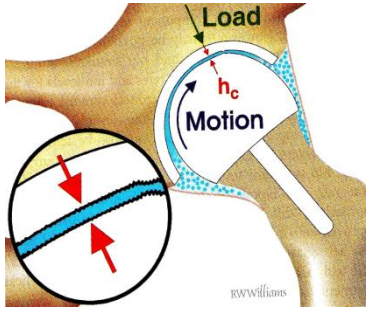
Iliya Glazunov



MoM of the III generation
Durom, M2a, BHR, Ultamet,
Head diameter 36 – 64 mm

XL-head MoM bearings

Experimental considerations



Prof. J. Fisher

- The increase of head diameter leads to decrease of volumetric wear in MoM bearings
- High gliding moment improved fluid film lubrication and decrease friction between moving surfaces
- From technical point it is possible to achieve equal narrow gap (clearance) between the head and the cup to avoid the solid – solid contact in all fazes of the gate
- The increase of head/neck ratio enlarges the range of motion of the hip
- The increase of head diameter improves joint stability and reduces rate of dislocations

XL-head MoM bearings

Clinical considerations

- Increasing number of young and active patients
- Solution of wear problems, osteolysis and dislocations
- Need the alternatives to MoP bearings
- disadvantages of the II generation CoC bearings (brittleness, noises)
- Bone preservation technologies (resurfacing)

XL-head MoM bearings

Patients of the 3-rd Millennium

Manufacturers

"Life without limitations and prohibitions …"

"XI-heads: the solution of all your problems"

Avalanche – like application of XL-head MoM prostheses

In 2008 -30% of all hip arthroplasties

Griffin W.L. AAOS Instruction Lectures, 2013.

Michael Morlock

Institute of Biomechanics

Hamburg University of Technology

“ … Unfortunately not each laboratory data can be confirmed by National Arthroplasty Registers. On the other hand the data of last ones not always correspond to the figures of individual hospitals …”

Personal communication

Yearly cumulative percent revision of primary THA by bearing surface and head diameter

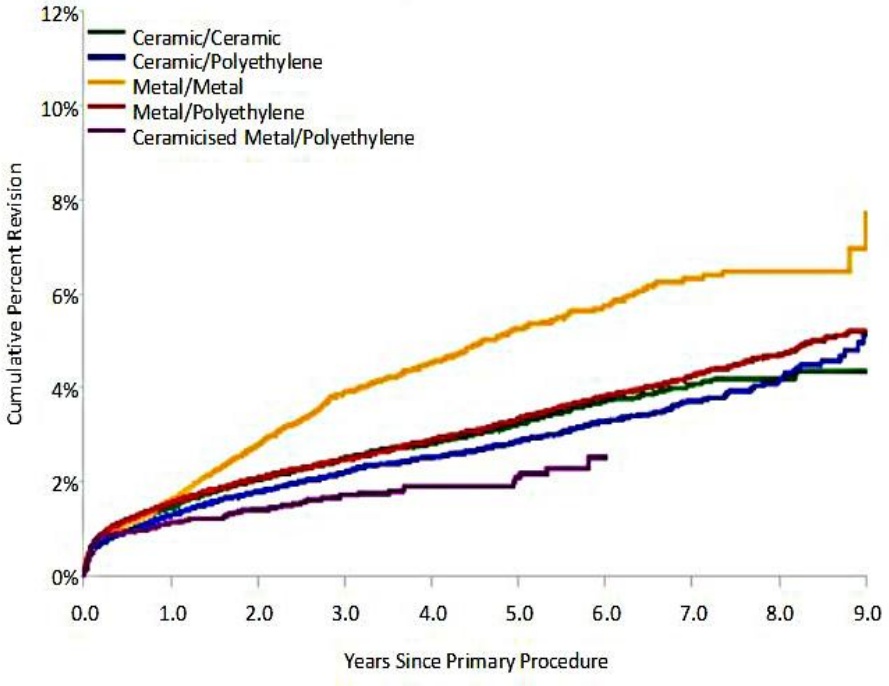


Table HT30: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Bearing Surface (Primary Diagnosis OA)

CPR	1 Yr	3 Yrs	5 Yrs	7 Yrs	9 Yrs
Ceramic/Ceramic	1.4 (1.3, 1.6)	2.5 (2.3, 2.7)	3.2 (3.0, 3.5)	4.0 (3.7, 4.4)	4.3 (3.9, 4.7)
Ceramic/Polyethylene	1.3 (1.1, 1.4)	2.2 (2.0, 2.3)	2.8 (2.6, 3.1)	3.7 (3.4, 4.0)	5.1 (4.4, 5.9)
Metal/Metal	1.6 (1.4, 1.8)	3.9 (3.6, 4.2)	5.2 (4.8, 5.7)	6.3 (5.7, 6.9)	7.7 (6.0, 9.7)
Metal/Polyethylene	1.5 (1.4, 1.6)	2.5 (2.3, 2.6)	3.3 (3.2, 3.5)	4.2 (4.0, 4.5)	5.2 (4.8, 5.5)
Ceramicised Metal/Polyethylene	1.1 (0.9, 1.4)	1.7 (1.4, 2.1)	2.1 (1.6, 2.6)		
Other (4)	2.2 (1.0, 4.5)	3.5 (1.8, 7.1)	3.5 (1.8, 7.1)	3.5 (1.8, 7.1)	

The liner wear of MoM bearings is very small

6 - 7 µm /year,

The quantity of particles is huge

up to 25^{12},

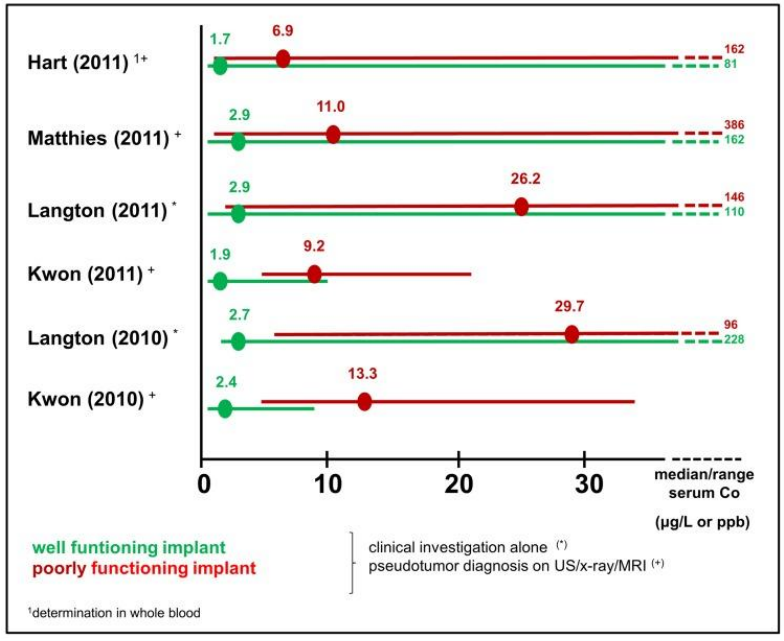
The sizes of titanium, chromium, cobalt and nickel particles are microscopic:

0,02 – 0,08 µm

The products of metal degradation are very aggressive:

CrPo4 Chromium Phosphates

Cobalt – Chromium wear particles and ions concerns



Hartmann A., Hannemann F., Lutzner J. et all Metal ion concentration in body fluids after implantation of hip replacement with MOM bearings. - Systemic review of clinical and epidemiological studies. - 2012

- Up to 500 times increase of wear particles (versus M0P)
- Dissolution of metal ions into surrounding tissues
- Elevated ion level in serum, urine and remote organs

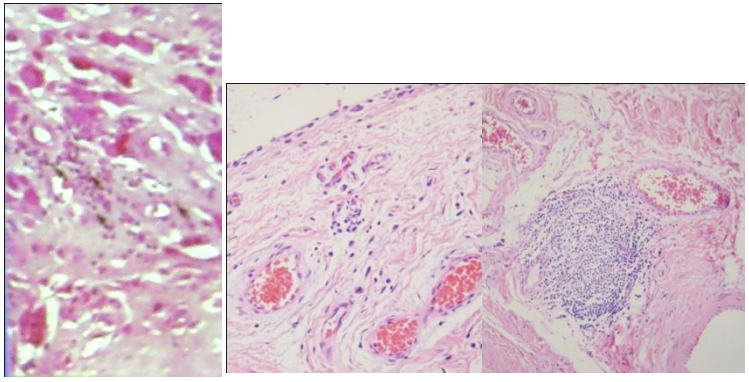
Pathogenesis of local and systemic adverse reactions to Co – Cr particles is uncertain

- Inflammatory response
- Delayed hypersensitivity (type IV)
- Cytotoxic response with tissue necrosis

Mahedrs G., et all. 2009

Hypersensitivity to metals

Aceptic
Lymphocyte
Vasculitis
Associated
Lesion



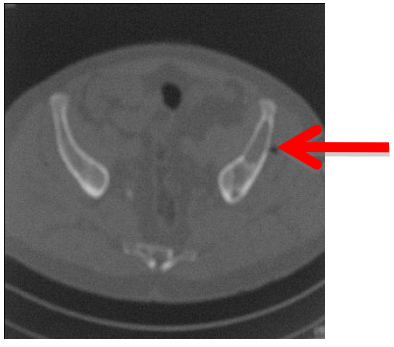
Perivascular Lymphocytic Infiltration (PVLI) is not specific histological finding

Ng V.Y., Lombardi A.V., Berend K.R. et all. Perivascular lymphocytic infiltration is not limited to Metal-on metal bearings. CORR. – 2011. – 469 (20). – P.523 -529.

Adverse Local Tissue Reactions

Type I Unexplained pain

Type II Osteolysis



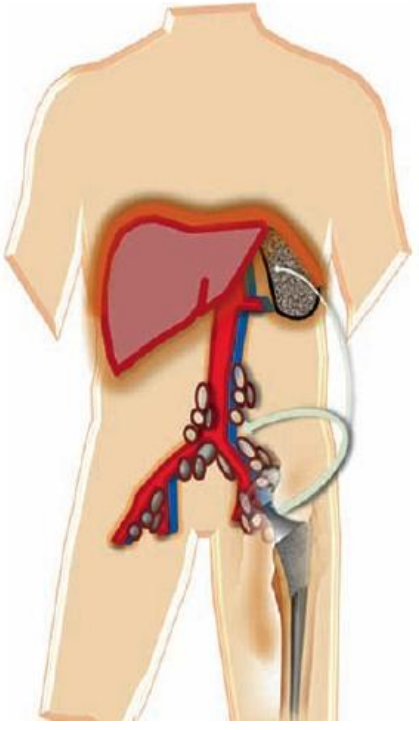
Type III Pseudotumor (extracapsular bursa)

Type IV Destruction of soft tissue adjacent to implant

Liddle A.D. et all. Patterns of failure in MoM hip arthroplasty and Implication for Revision. AAOS.- ICL.- San Francisco. - 2012

Systemic reactions to Cobalt and Chromium

- Cardiomyopathy
- Neurologic sensitive dysfunction
- Depression and cognitive dysfunction
- Renal failure
- Thyroid dysfunction
- Leucopenia
- Transplacental transfer of cobalt and chromium ions



Chromium

Cobalt

Concentration more than 7 ppb !!!!
(1:7.000.000 prml)

SOS !!!
Emergency revision

Slagis S.V. et all. Results of a Two-Year Prospective Controlled Study of Metal Ion Release following MoM Total Hip Arthroplasty. – AAOS Posters.- San Francisco. - 2012.

Sensitivity and specificity of serum Co – Cr ion level as the main indicator of MoM bearing failure

7 ppb
Sensitivity – 52%
Specificity – 89%

5 ppb
Sensitivity –63%
Specificity – 86%

- important but auxiliary test which can complete the assessment of patient and implant condition
- can not be used as the independent parameter to predict the revision surgery
- the direct correlation between Co – Cr ions level in blood, serum and synovial fluid and ALTR found at revisions was not proved

The level of ions depends upon:

Type and design of implant

- Monoblock or modular
- “Philosophy” of clearance (regular, irregular, contact at pole …)
- Perimeter of hemisphere, angle of covering, design of the edge …

Features of the material

- The way of manufacturing and processing of CoCrMo alloy
  - as cast
  - blanking with double heated treatment
  - isostatic forging
  - agglomeration
- Rigidity, strength, flexibility, forgeability (quan. of carbides)

Diameter of the bearing surface

Cup positioning

BHR
Smith & Nephew

Adept
Finsbury

Conserve Plus
Wright Medical

ReCap
Biomet

Different models with very different results …

Cormet 2000
Corin LTD &
Stryker

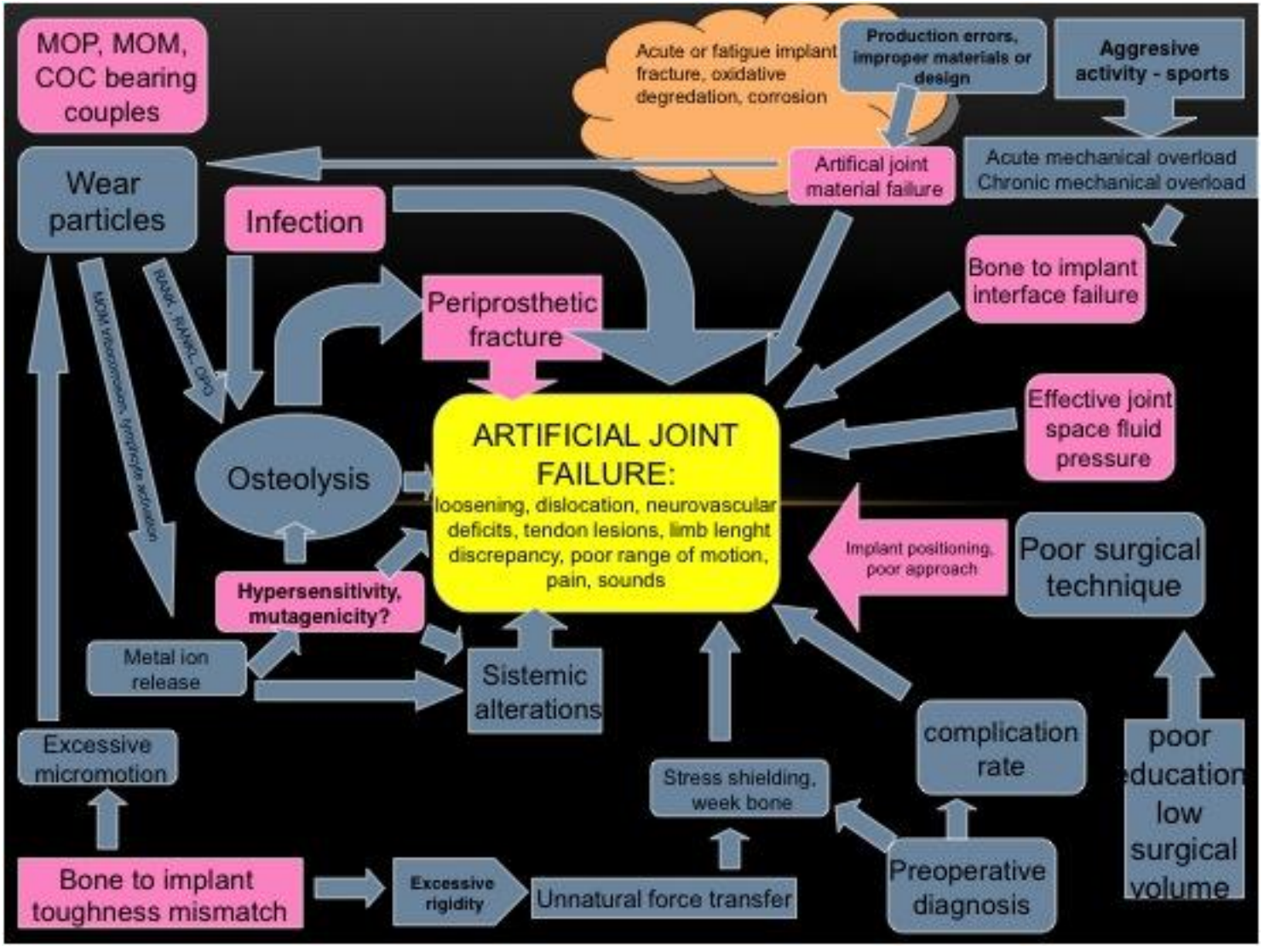
Durom
Zimmer

DynaMoM
Tornier

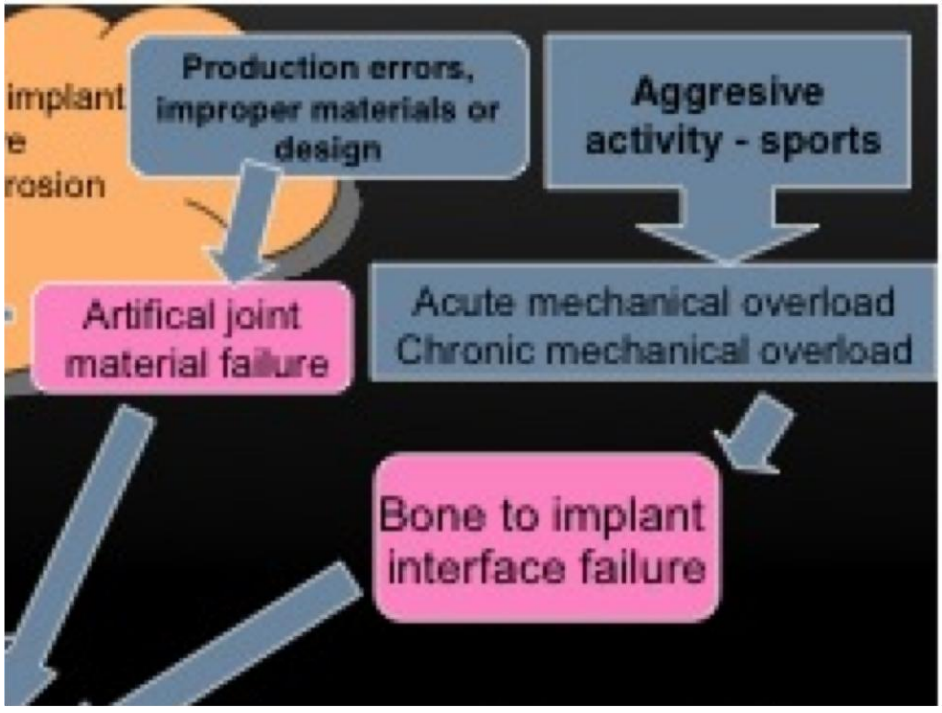
ASR
DePuy

Bionik
ESKA

Comprehensive scheme of artificial joint failure mechanism



Rihard Trebse, M.D., Ph.D. Valdoltra, Slovenia



Production errors,
Improper materials or design

↓

Artificial joint
materials failure

Large
heads

↓

High bearing
friction.
Taper stress
and failure

Aggressive activity,
sports

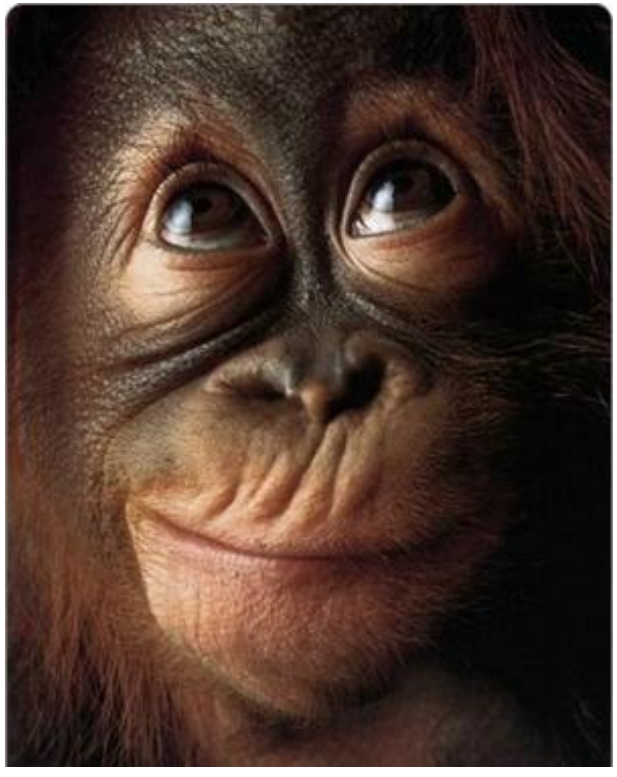
↓

Acute and chronic
mechanical overload

↓

Implant failure

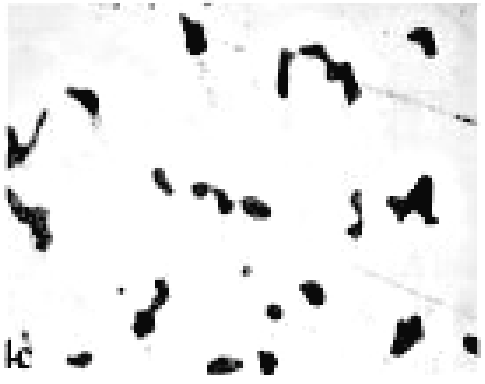
Why does ASR – XL head – Corail combination have so poor result?



My own hypothesis …

Metallurgy

BHR – “as cast”



Large blocks of hard materials (carbides – mix of carbon and CoCrMo alloy). This blocks can provide wear resistance.

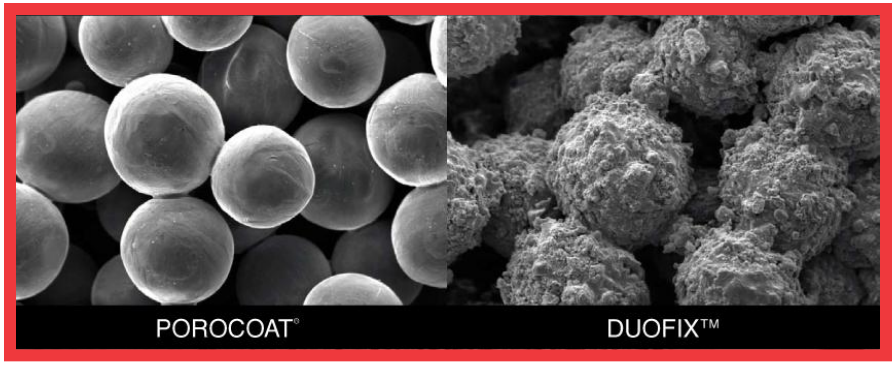
ASR – double heated treatment

Heat treating leads to dissolving of carbon into the metal. CoCrMo alloy looses wear resistance.

De Smet K. Birmingham Hip resurfacing versus Conserve Plus Metal-on-Metal Hip resurfacing. A surgeon’s perspective. – 2008. – 28 p.

Coating

Sintering balls of pure TiC with 200 µm porosity

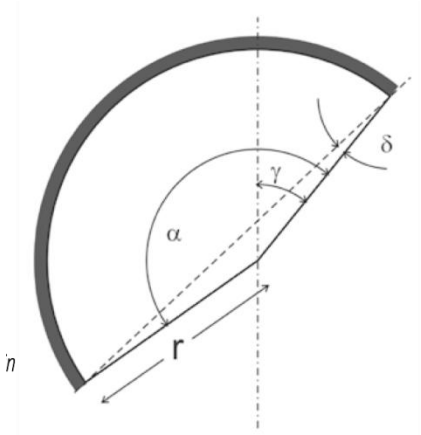


Coating of Porocoat with Hydrohilapatite powder

Bone growing-IN

Bone growing -ON

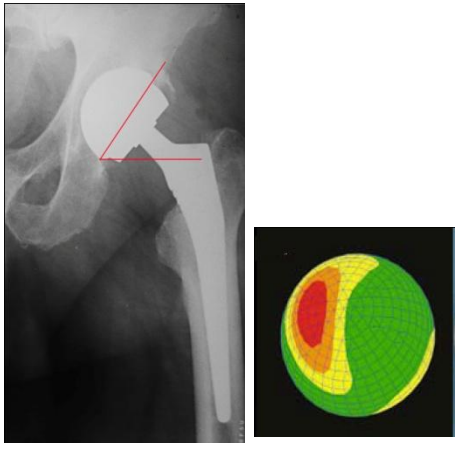
The angle of the head coverage by the cup



<α Conserve Plus = 170°
<α BHR = 164°
<α ASR = 156°

De Smet K. Birmingham Hip resurfacing versus Conserve Plus Metal-on-Metal Hip resurfacing. A surgeon's perspective. – 2008. – 28 p.

Critical abduction of ASR = 45°



Critical abduction of BHR = 52°

The difference between edge loading (ASR vs. BHR)
In the case of equal abduction

“Philosophy” of regular narrow clearance between ASR cup and head

Deformation of the edge in the cups of small sizes (≤52 mm)

A cup “catches” a ball

Characteristic property of the ASR cup edge

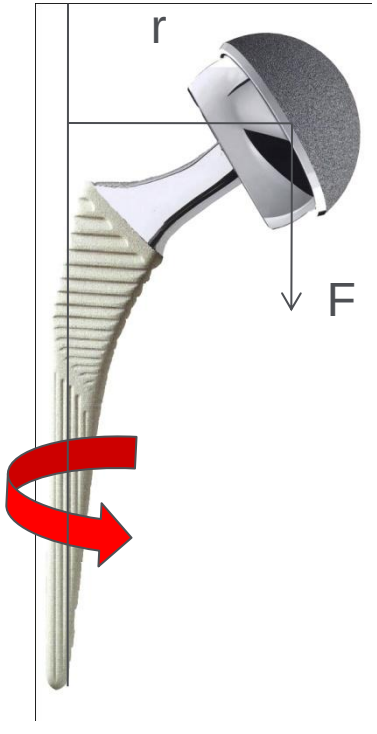
Technological round notch at the inner surface of the cup decreases it's strength and facilitates susceptibility to deformation (small sizes !!!)

Why does ASR – XL head – Corail combination have so poor result?

The volume of the head
$V = 4/3\ \pi\ R^3$

The mass of the head
$M = P \times V,$

Where P for CoCrMo alloy =
8,4 gram/sm^3



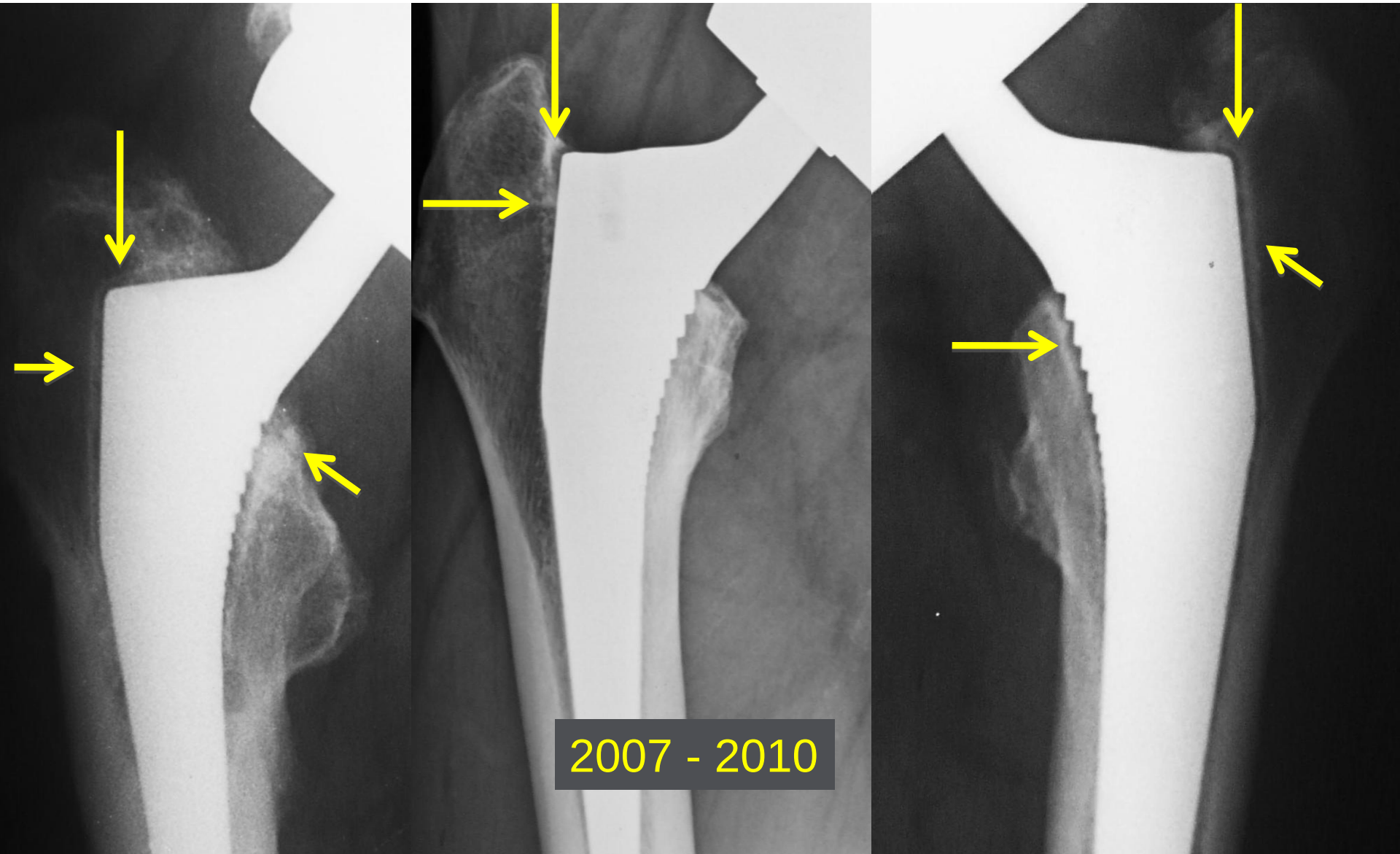
The mass of cored CoCrMo
50 mm ASR head is 340 grams
(= 4,5 times more than 28 mm ball !!).

➔ ➔ ➔
M = { r × F}

Where M – torque
r – lever arm (depend on the diameter)
F – the weight of the head

X-large heads are the real challenge for the stability of Corail HO stem !

28% reactive lines



Short taper and heavy XL-head

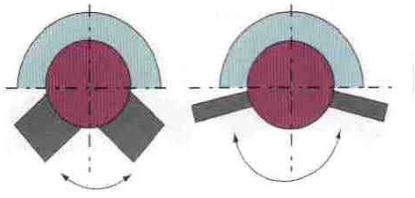
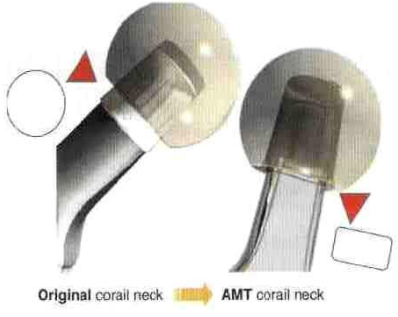
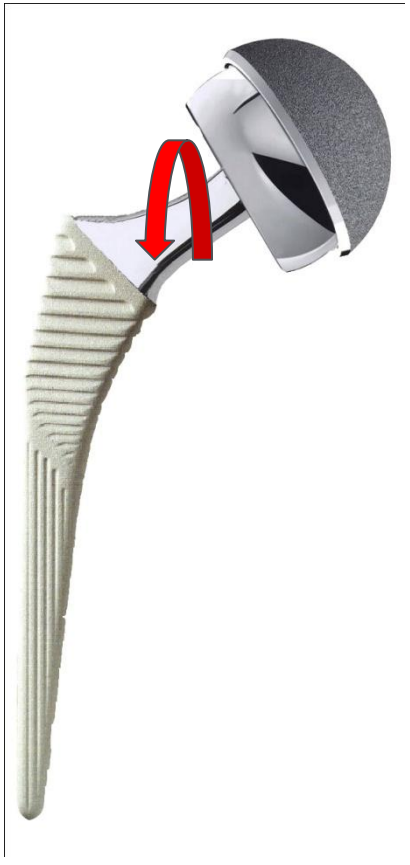


Fig. 2.14 Influence of femoral neck diameter

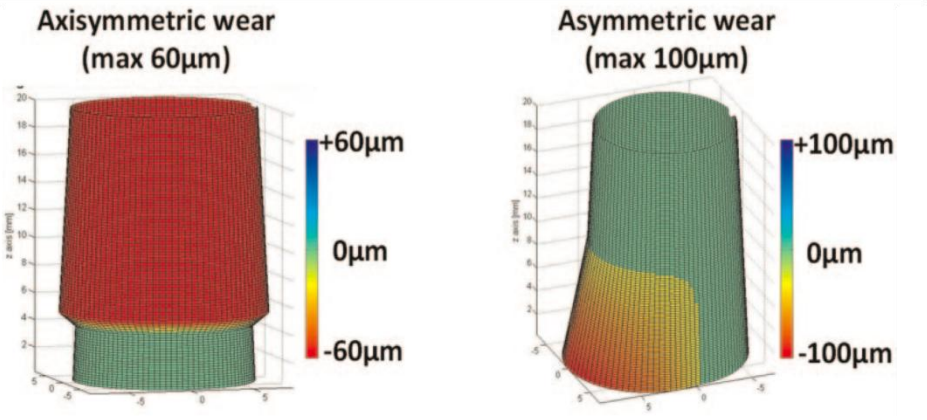


AMT for better adaptation of small ceramic heads

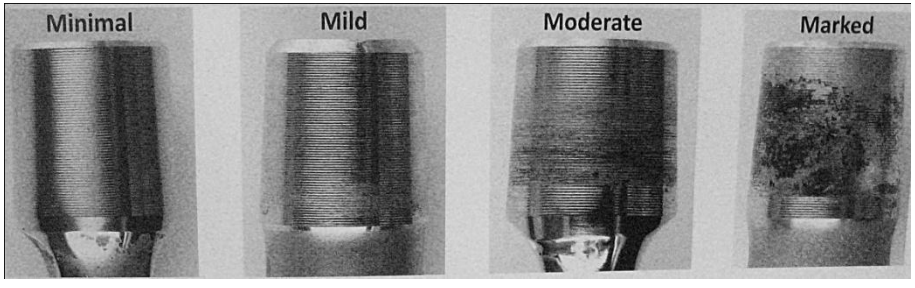


Probability of XL head rotation on a short Corail taper

Types of wear in central and eccentrical head placement

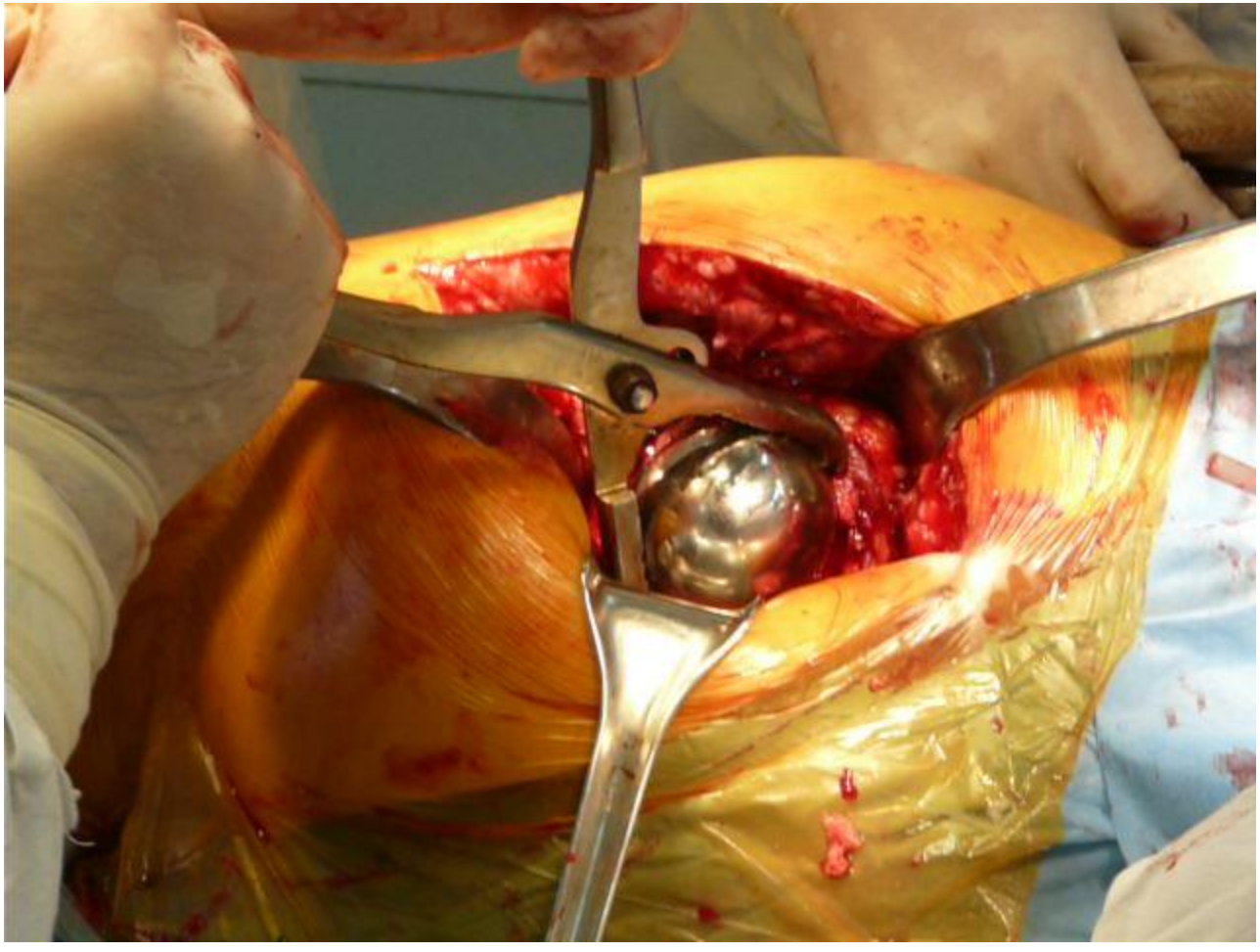


Bishop N., Witt F., Poursal R., Fisher A., Rutshi M., Michel M., Morlock M. Wear Patterns of Taper Connections in Retrieved Large Diameter Metal-on-Metal Bearings. – J. Orthop. Res. Month 2013



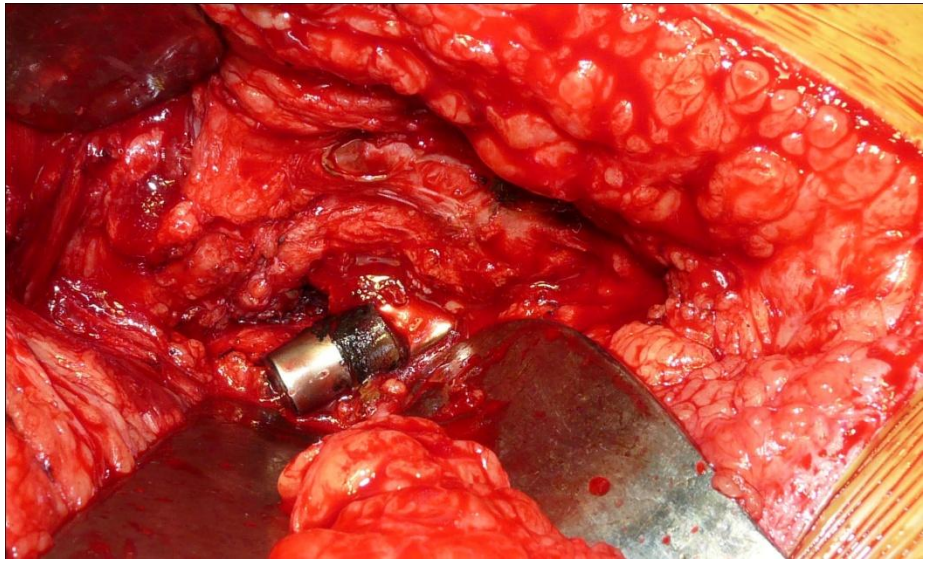
Corrosion of friction transforms to stress-corrosion.
The destruction of oxide protector films … “Taperosis”

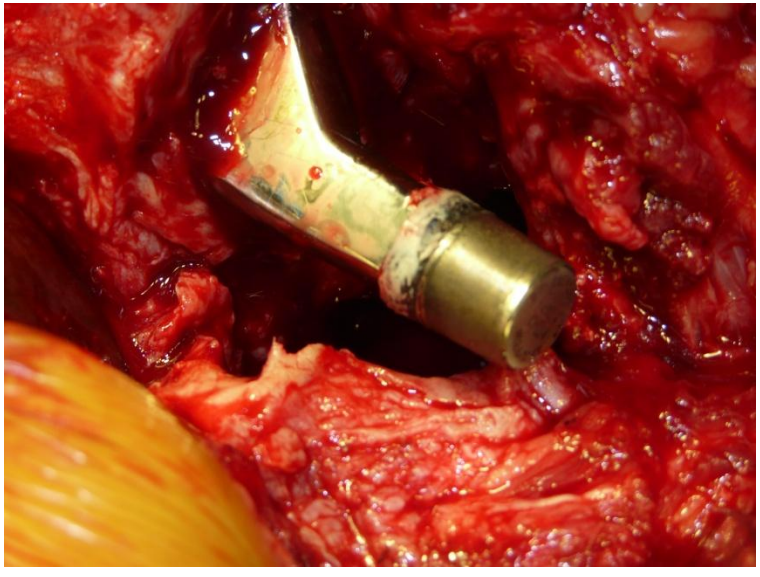
Good news



All ASR heads were firmly fixed at their tapers

Bad news





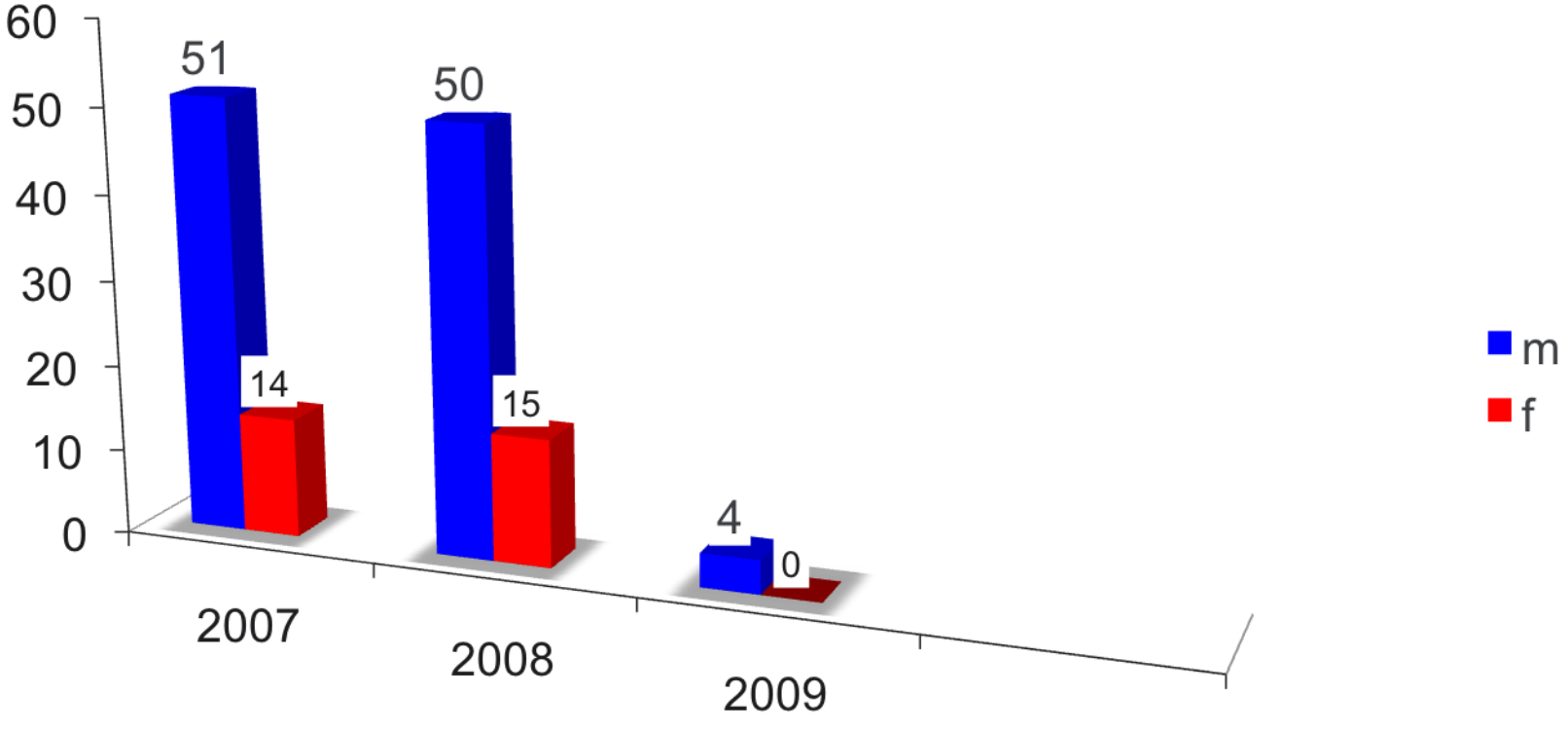
Severe
chemical reactions between
heads and stems
(titanium-CoCrMo galvanic couple)

119 patients

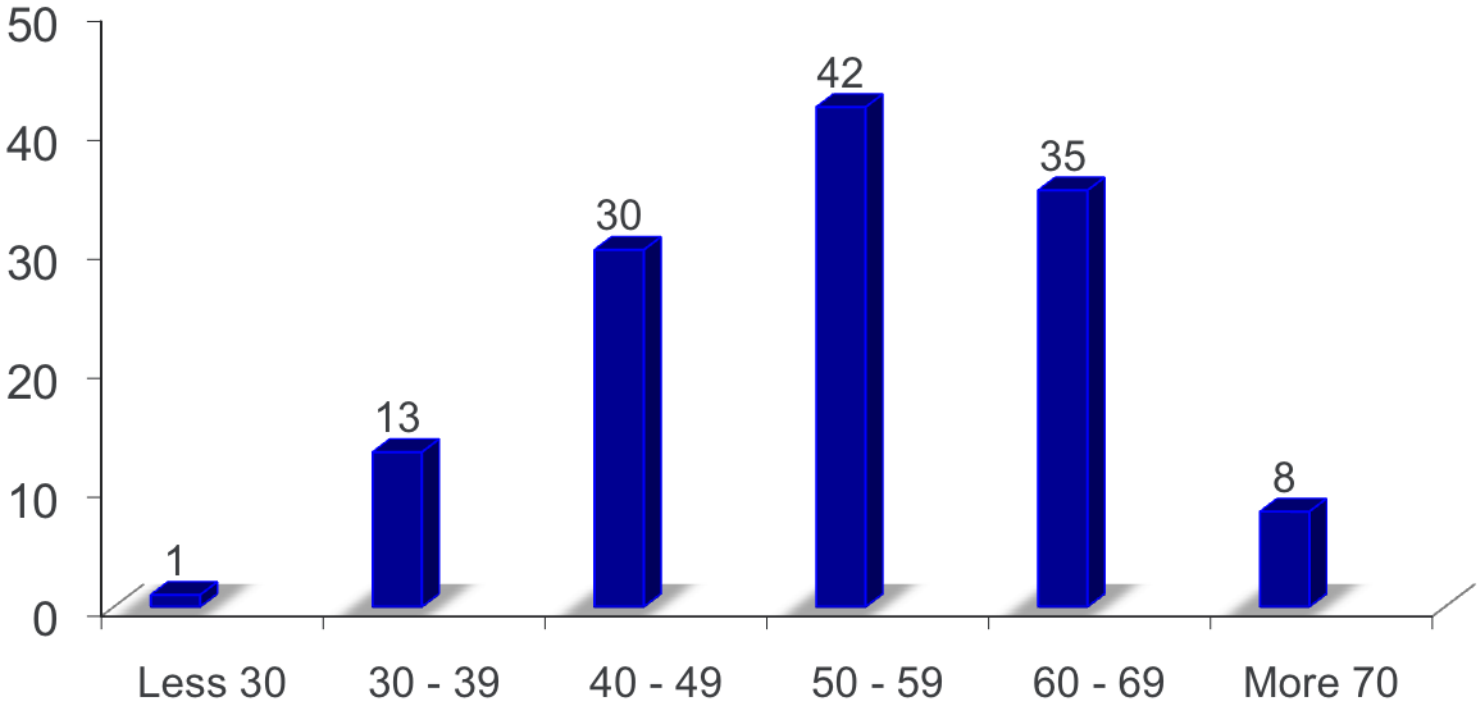
90 – m 29 - f

134 THA (15 – at both sides)

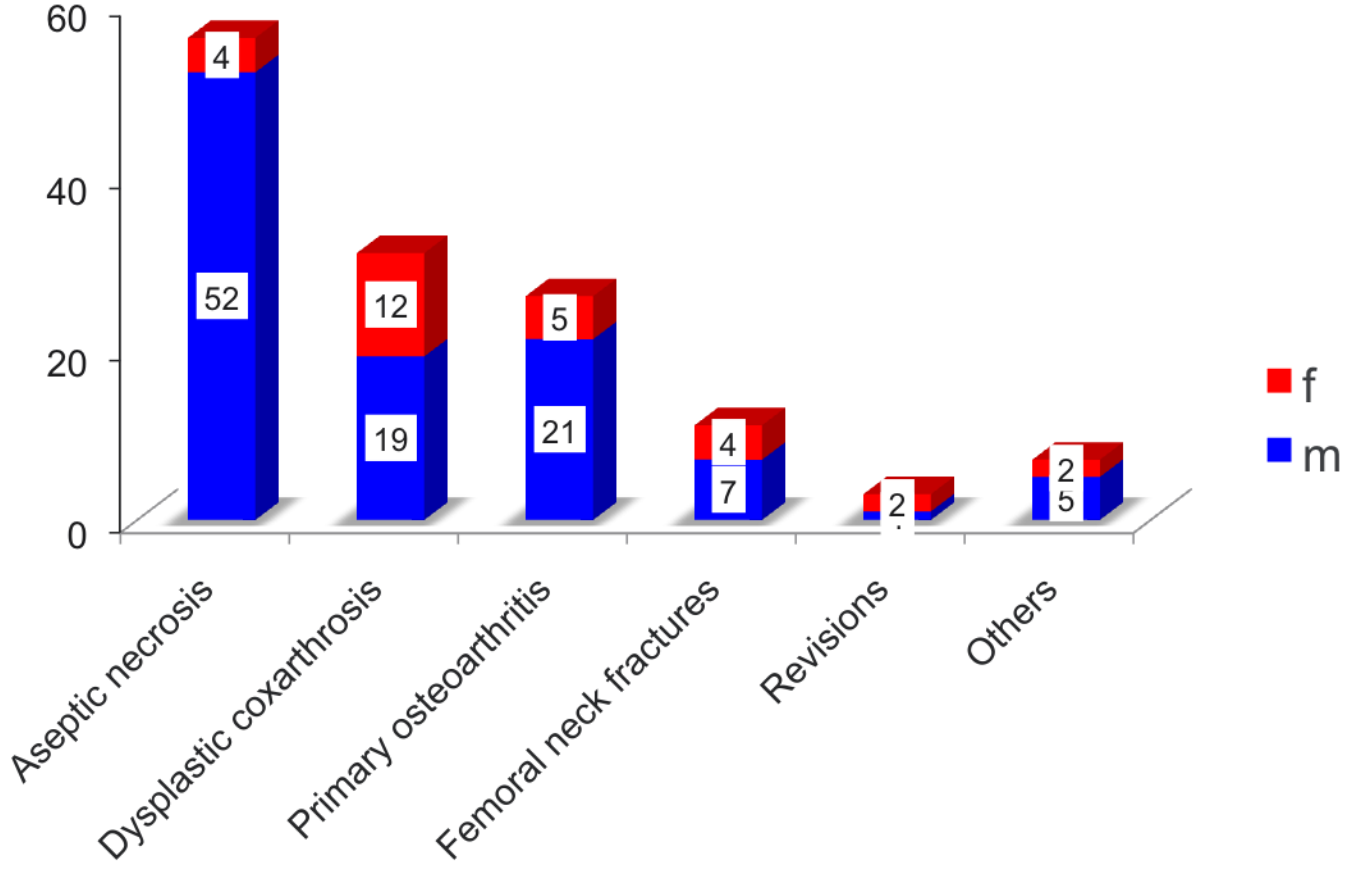
Distribution of surgeries



Age of the patients (n=119)



Indications for THA



Our results of ASR – XL – Corail total hip arthroplasties (119 patients, 134 hips)

Residual dislocation (mistake in cup orientation) - 1
Deep infection at 6 and 37 months - 2
Death because of cardio-vascular diseases (9 and 13 months) - 2

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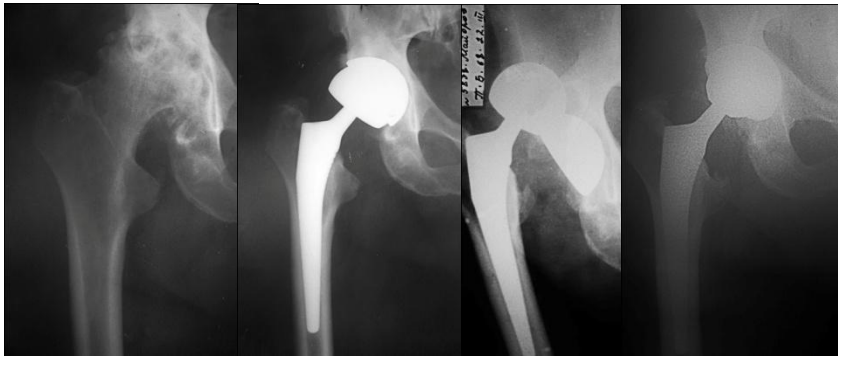
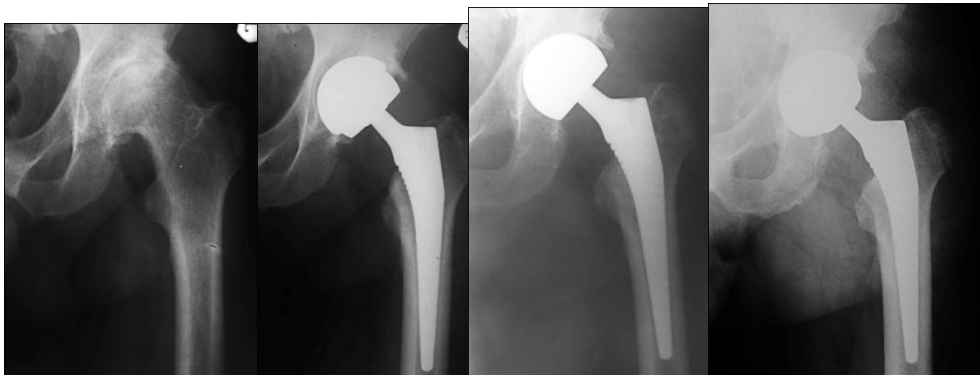
5 patients were excluded from the investigation



Residual dislocation.
Revision of the acetabular component.



Low grade infection after 37 months.
Two-stage revision through conversion arthroplasty

Our results of ASR – XL – Corail total hip arthroplasties

13 patients are still doing well and refuse to be followed (phone contacts)
6 patients changed their address and were lost

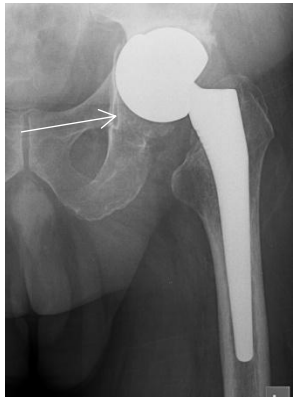
95 patients (106 hips) were investigated
Average time of follow–up was 65 ± 3 months

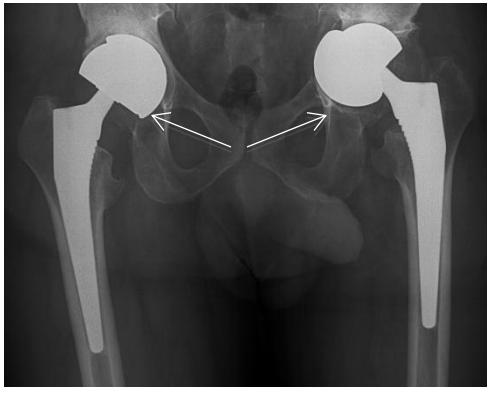
86 patients had good and excellent middle term results
(av. HHS – 89,2 points)

9 patients (10 hips) were not satisfied with the results
(groin and buttock pain, limping, limitations, cane …)
Average HHS – 65,7

MRI + ion level in serum

X-ray pathological signs





ASR cup instability – 4 patients (5 hips)

Throchanteric osteolysis - 2 patients (2 hips)

Siemens Magnetom Symphony (Siemens AG)
(1,5 Tesla; 64 MG)

MARS (Metal Artifact Reduction Sequences) program

Turbo Spin Echo (TSE) protocol

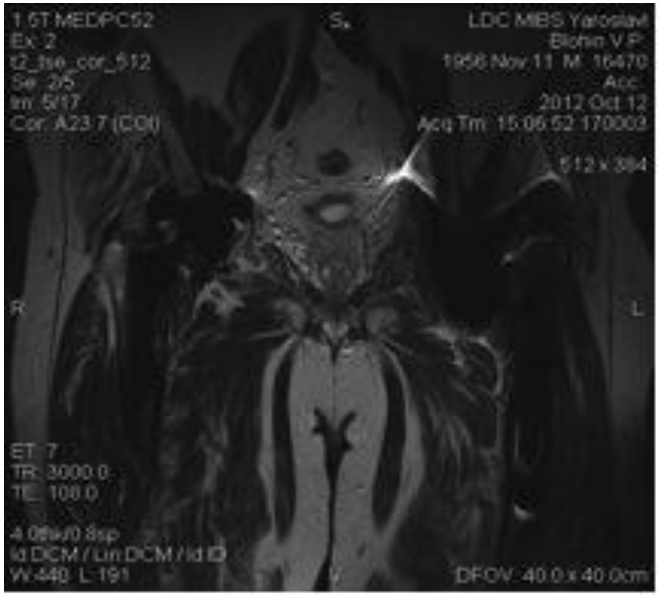
Main parameters of MRI settings

Seq	TR	TE	TI	Turbo factor	FA	BW	Dist. fac-tor	FOV	Matrix	Phaseres (%)	Phasedir	Avg
Loc	10	5	N/A	N/A	40	180	10/100 %	400	256	50	N/A	1
Ax T1	515	15	N/A	3	145	130	1/17 %	300	512	75	A>P	2
Ax T2	3000	67	N/A	7	150	70	8/20 %	400	384	75	AP	2
Cor T2 FS	3770	13	130	15	150	130	1/20 %	400	256	75	RL	1
Cor T2	3000	108	N/A	7	150	70	8/20 %	400	512	75	RL	2

MRI for the assessment of periprosthetic soft tissues

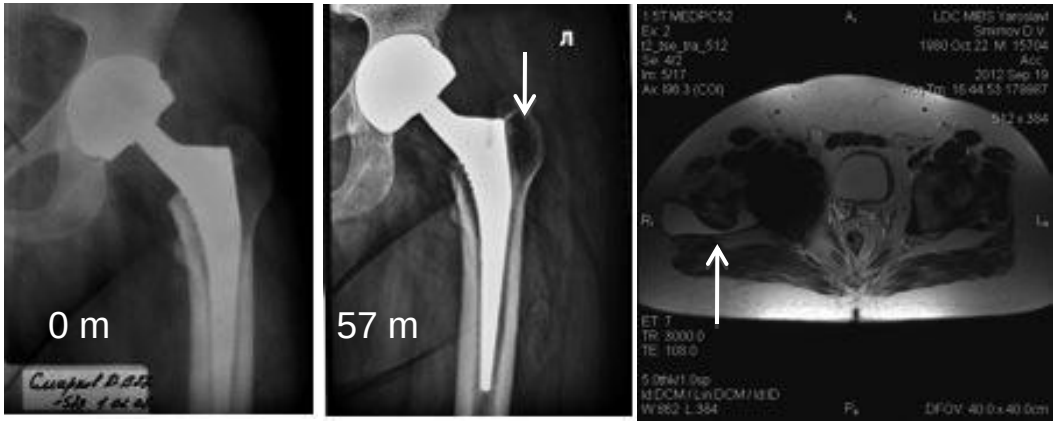
Metal Artifact Reduction Sequences

Standard setting



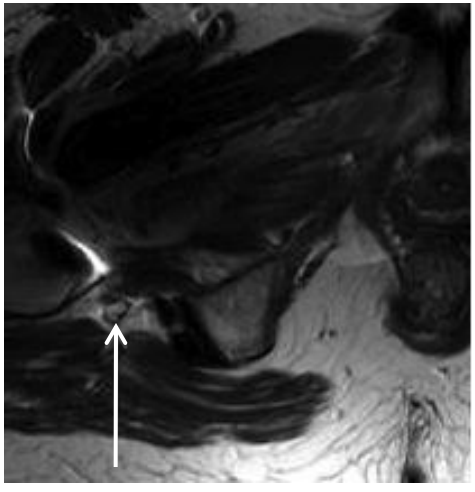
Modified setting

MRI for the assessment of periprosthetic soft tissues



X-ray signs of cup instability and throchanteric osteolysis.
Effusion around the prosthesis.

Multicompartment cyst and sclerotic zones
in the throchanter major



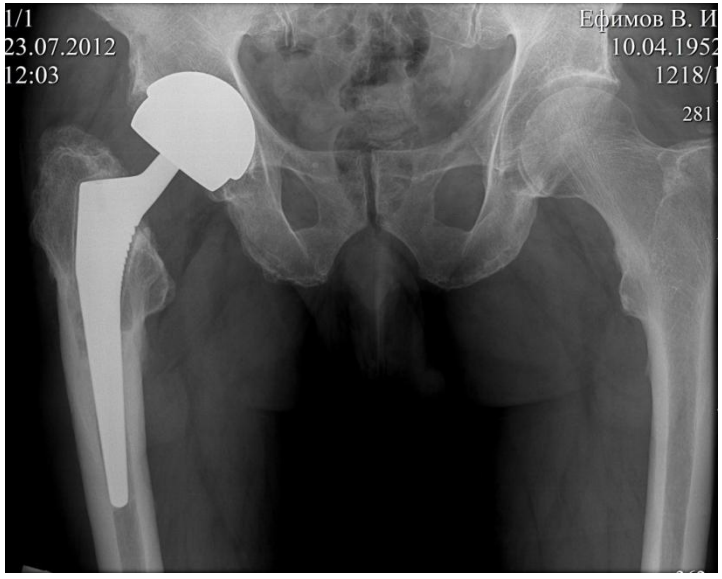
Sciatic nerve compression
In the scar tissue

Co and Cr ion level in serum of unsatisfied patients

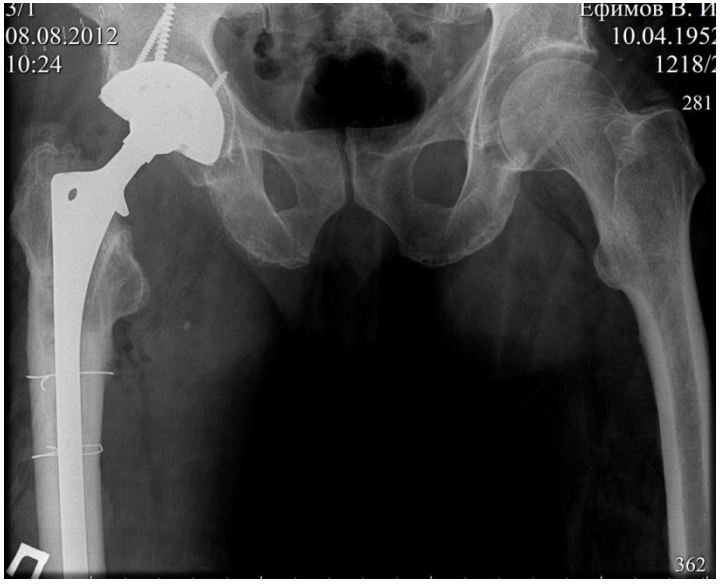
Patient	Cobalt	Chromium
M., female, 57 y.	3,6 ppb	5,3 ppb
E., male, 54 y.	5,21 ppb	2,53 ppb
E., male, 62 y.	8,0 ppb	1,11 ppb
T., male, 48 y.	3,7 ppb	3,85 ppb
B., male, 56 y.	3,9 ppb	2,52 ppb
S., male, 36 y.	2,18 ppb	2,19 ppb
S., female, 65 y.	5,12 ppb	3,69 ppb
T., male, 57 y.	1,88 ppb	2,5 ppb
T., male 42 y.	11,8 ppb	4,34 ppb

Indications for the revisions
(134 THA, 13 revisions for all reasons)

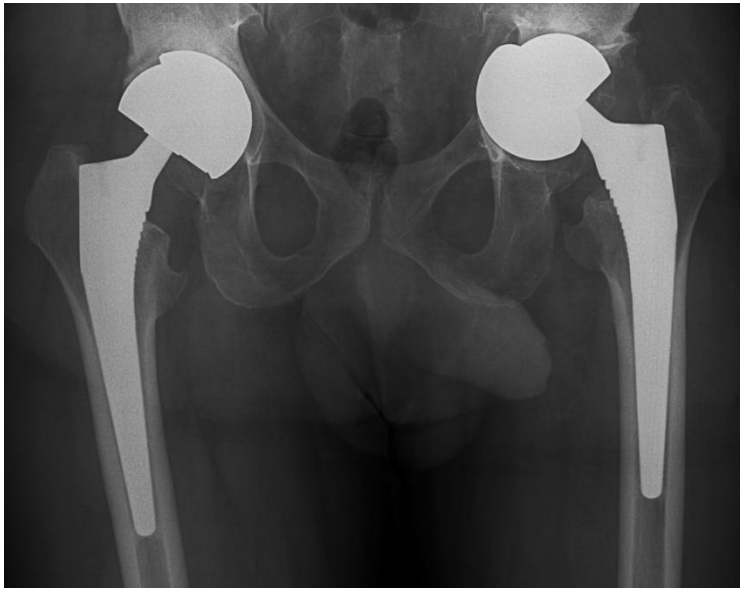
Reason	Number of surgeries
ASR cup instability	5
Pain	3
Osteolysis	2
Deep infection	2
Recurrent dislocation	1
TOTAL:	13



m., 59 y., THA with A
SR – XL head – Corail (2008).
Pain, limping after 3 years.



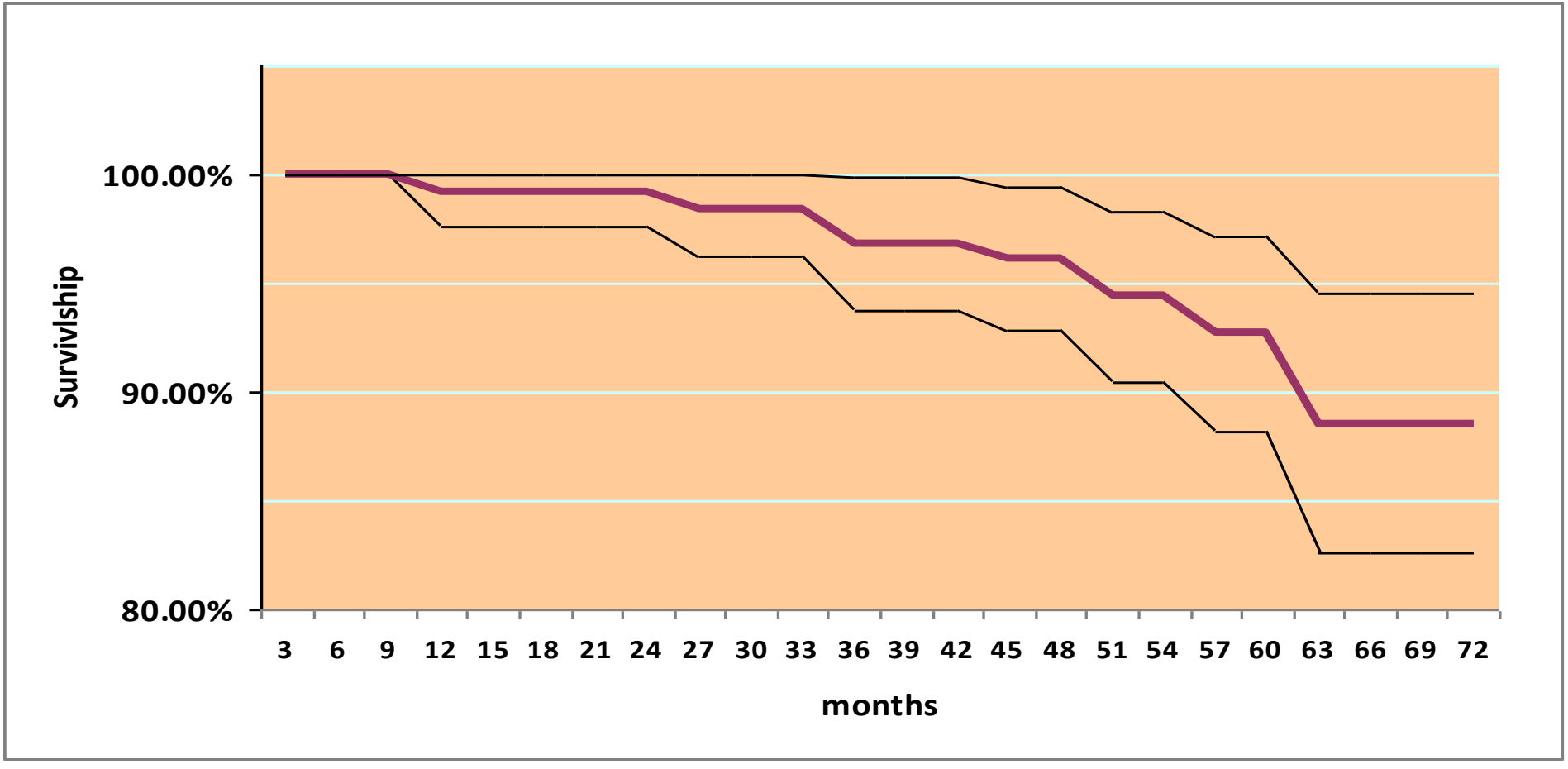
Corail was well fixed
distally. Lateral side
longitudinal osteotomy had
to be done for implant removal.



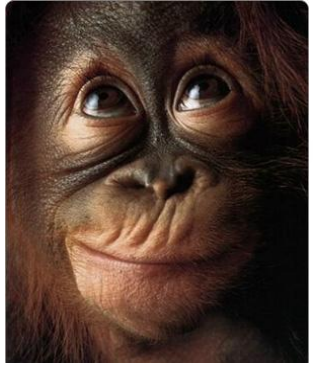
Both sides ASR cups instability

Both sides revision arthroplasty

Survivorship of 134 ASR-XL-CORAIL
(revisions for all reasons as an end point)



(p = 0,05)

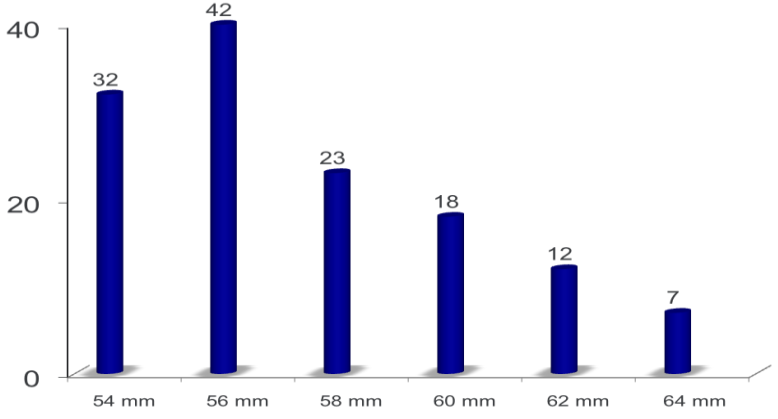


Why our results are “not very disappointed?”

(my own hypothesis …)

I. Male : female = 3 : 1
II. Aseptic femoral head necrosis – 41,7%

I. Big diameter of ASR cups



II. Diaphyseal (more rigid) type of Corail fixation


Arce


GJJ 317N

Спасибо !