INDICATIONS ON WHEN TO USE SILVER

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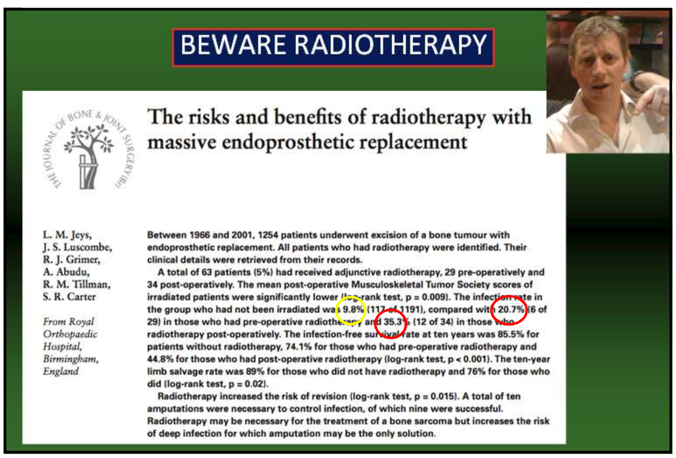
Arthroplasty Disaster Conference
September 20-22, 2018
MIAMI

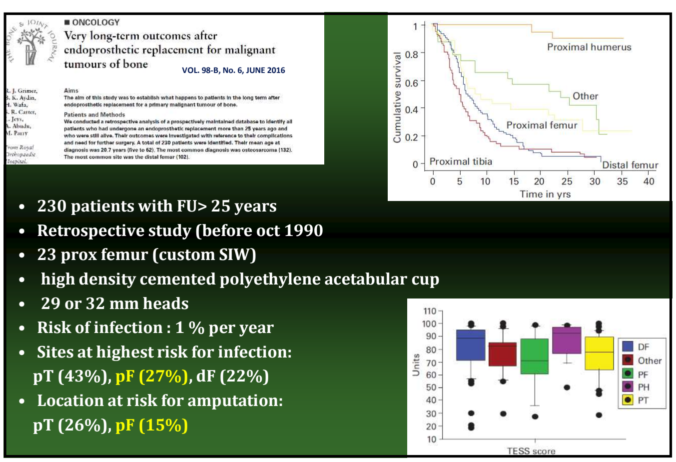
DISCLOSURE

- **IMPLANTCAST**

BONE TUMOUR: HIGH RISK OF INFECTION
BMJ open
Prophylactic antibiotic regimens in tumour surgery (PARITY): protocol for a multicentre randomised controlled study
SURVEY
High Infection Rate Outcomes in Long-bone Tumor Surgery with Endoprosthetic Reconstruction in Adults: A Systematic Review
Antonella Racano MSc, Theresa Pazionis MD,
Forough Farrokhyar PhD, Benjamin Deheshi MD, MSc, FRCS(C),
Michelle Ghert MD, FRCS(C)
8 - 20%



BEWARE RADIOTHERAPY
The risks and benefits of radiotherapy with massive endoprosthetic replacement
L. M. Jeys,
J. S. Luscombe,
R. J. Grimer,
A. Abudu,
R. M. Tillman,
S. R. Carter
From Royal Orthopaedic Hospital, Birmingham, England
Between 1966 and 2001, 1254 patients underwent excision of a bone tumour with endoprosthetic replacement. All patients who had radiotherapy were identified. Their clinical details were retrieved from their records.
A total of 63 patients (5%) had received adjunctive radiotherapy, 29 pre-operatively and 34 post-operatively. The mean post-operative Musculoskeletal Tumor Society scores of irradiated patients were significantly lower (log-rank test, p = 0.009). The infection rate in the group who had not been irradiated was 9.8% (117 of 1191), compared with 20.7% (6 of 29) in those who had pre-operative radiotherapy and 35.3% (12 of 34) in those who radiotherapy post-operatively. The infection-free survival rate at ten years was 85.5% for patients without radiotherapy, 74.1% for those who had pre-operative radiotherapy and 44.8% for those who had post-operative radiotherapy (log-rank test, p < 0.001). The ten-year limb salvage rate was 89% for those who did not have radiotherapy and 76% for those who did (log-rank test, p = 0.02).
Radiotherapy increased the risk of revision (log-rank test, p = 0.015). A total of ten amputations were necessary to control infection, of which nine were successful. Radiotherapy may be necessary for the treatment of a bone sarcoma but increases the risk of deep infection for which amputation may be the only solution.



ONCOLOGY
Very long-term outcomes after endoprosthetic replacement for malignant tumours of bone
VOL. 98-B, No. 6, JUNE 2016
Aims
The aim of this study was to establish what happens to patients in the long term after endoprosthetic replacement for a primary malignant tumour of bone.
Patients and Methods
We conducted a retrospective analysis of a prospectively maintained database to identify all patients who had undergone an endoprosthetic replacement more than 25 years ago and who were still alive. Their outcomes were investigated with reference to their complications and need for further surgery. A total of 230 patients were identified. Their mean age at diagnosis was 20.7 years (five to 62). The most common diagnosis was osteosarcoma (132). The most common site was the distal femur (102).
Proximal humerus
Other
Proximal femur
Proximal tibia
Distal femur
Cumulative survival
Time in yrs
230 patients with FU> 25 years
Retrospective study (before oct 1990
23 prox femur (custom SIW)
high density cemented polyethylene acetabular cup
29 or 32 mm heads
Risk of infection : 1 % per year
Sites at highest risk for infection:
pT (43%), pF (27%), dF (22%)
Location at risk for amputation:
pT (26%), pF (15%)
DF
Other
PF
PH
PT
Units
TESS score

SILVER IN TUMOUR PROSTHESIS?

SILVER IS SAFE!

Available online at www.sciencedirect.com
SCIENCE DIRECT
Biomaterials 25 (2004) 5547–5556
Biomaterials
www.elsevier.com/locate/biomaterials

Silver-coated megaendoprostheses in a rabbit model—an analysis of the infection rate and toxicological side effects

Georg Gosheger[a,*], Jendrik Hardes[a], Helmut Ahrens[a], Arne Streitburger[a], Horst Buerger[b], Michael Erren[c], Andreas Gunsel[d], Fritz H. Kemper[d], Winfried Winkelmann[a], Christof von Eiff[e]
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at www.sciencedirect.com
cienceDirect
ls 28 (2007) 2869–2875
Biomaterials
www.elsevier.com/locate/biomaterials

Lack of toxicological side-effects in silver-coated megaprostheses in humans

Jendrik Hardes[a,*,1], Helmut Ahrens[a,1], Carsten Gebert[a], Arne Streitbuerger[a], Horst Buerger[b], Michael Erren[c], Andreas Gunsel[d], Christian Wedemeyer[e], Guido Saxler[e], Winfried Winkelmann[a], Georg Gosheger[a]
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Received 26 January 2007; accepted 19 February 2007
Available online 3 March 2007

Journal of Surgical Oncology 2010;101:389–395

Reduction of Periprosthetic Infection With Silver-Coated Megaprostheses in Patients With Bone Sarcoma

JENDRIK HARDES, MD,[1]* CHRISTOF VON EIFF, MD,[2] ARNE STREITBUERGER, MD,[1] MAURICE BALKE, MD,[1] TYMOTEUS BUDNY, MD,[1] MARCEL P. HENRICHS, MD,[1] GREGOR HAUSCHILD, MD,[1] AND HELMUT AHRENS, MD[1]
[1] Department of Orthopedics and Tumor Orthopedics, Münster University Hospital, Münster, Germany
[2] Institute of Medical Microbiology, Münster University Hospital, Münster, Germany

- retrospective studies

- 29 silver coated Mutars proximal tibia EPR
- 41 non SC Mutars proximal tibia EPR (Titanium)

infection rate	SC : 6,9%	Non SC : 17,1%

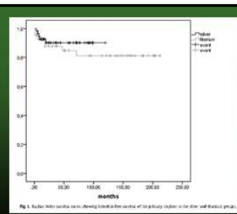
Contents lists available at ScienceDirect

The Journal of Arthroplasty

Revision Arthroplasty

Silver-Coated Megaprosthesis of the Proximal Tibia in Patients With Sarcoma

Jendrik Hardes, MD *, Marcel P. Henrichs, MD, Gregor Hauschild, MD, Markus Nottrott, PhD, Wiebke Guder, MD, Arne Streitbuerger, MD



- **98** patients with sarcoma or giant-cell tumour in proximal tibia
  - **titanium-implant (n=42)**
  - **silver-coated implant (n=56)**
- **16.7% infection rate** in titanium-group vs. **8.9%** in silver-coated group
- **5-year implant survival of 90%** in silver-coated group vs. **84%** in titanium group
- **In case of infection, patients with silver-coated implants had significantly better outcome**

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Levels of silver ions in body fluids and clinical results in silver-coated megaprostheses after tumour, trauma or failed arthroplasty

Guido Scoccianti *, Filippo Frenos, Giovanni Beltrami, Domenico Andrea Campanacci, Rodolfo Capanna

- **33 patients** receiving a modified silver-coated MegaC System megaprosthesis for
  - **previous infection (n=21)**
  - **high risk for infection (n=12)**
- **No further infection** in the "**infection high-risk**" group after 2 years
- **In two of 21 patients with previous infection, a periprosthetic infection recurred (9.5%)**
- **Silver ion-levels** between **0.41 and 5.33 µg/L** in **blood stream**, no significant change over time

Hindawi

Clinical Study

Silver-Coated Hip Megaprosthesis in Oncological Limb Savage Surgery

F. Donati,[1] G. Di Giacomo,[1] S. D'Adamio,[1] A. Ziranu,[1] S. Careri,[1] MA. Rosa,[2] and G. Maccauro[1]

- **68** patients treated with silver-coated (n=38) or non-silver-coated (n=30) tumour prostheses of proximal femur (MUTARS®)
- **Average follow-up** of **46.5 months**
- **Complications** requiring revision in 14 cases, with **8 infections**
- **Infection rate in silver-coated** group **7.9%** (n=3) vs. **16.7%** in non-silver-coated group (n=5)
- **Silver-coated prostheses** showed **significant degradation** of coating, especially in case of late infections

Hindawi Publishing Corporation
BioMed Research International
Volume 2013, Article ID 763096, 8 pages

Clinical Study

Measurement of the Silver Ion Concentration in Wound Fluids after Implantation of Silver-Coated Megaprostheses: Correlation with the Clinical Outcome

B. Hussmann,[1] I. Johann,[1] M. D. Kauther,[1] S. Landgraeber,[2] Marcus Jäger,[1,2] and S. Lendemans[1]

[1] Trauma Surgery Department, University Hospital Essen, Hufelandstraße 55, 45122 Essen, Germany
[2] Orthopaedic Department, University of Duisburg-Essen, Hufelandstraße 55, 45122 Essen, Germany

- **18** treated with silver-coated megaprostheses
- **31** patients with uncoated megaprosthesis (control group)
- **Silver ion levels** in **wound fluids** measured at days 7 and 14
- **Average silver ion** concentration in wound fluids of **0.08 ppm**
- **Lower infection rate** in group with silver-coated implants (5,6%) compared to control group (22 %) (p< 0.01)

■ ONCOLOGY

Retrospective evaluation of the incidence of early periprosthetic infection with silver-treated endoprostheses in high-risk patients

CASE-CONTROL STUDY

H. Wafa, R. J. Grimer, K. Reddy, L. Jeys, A. Abudu, S. R. Carter, R. M. Tillman

From The Royal Orthopaedic Hospital NHS Trust, Birmingham, United Kingdom

We conducted a case-control study to examine the merit of silver-coated tumour prostheses. We reviewed 85 patients with Agluna-treated (silver-coated) tumour implants treated between 2006 and 2011 and matched them with 85 control patients treated between 2001 and 2011 with identical, but uncoated, tumour prostheses.

In all, 106 men and 64 women with a mean age of 42.2 years (18.4 to 90.4) were included in the study. There were 50 primary reconstructions (29.4%), 79 one-stage revisions (46.5%) and 41 two-stage revisions for infection (24.1%).

The overall post-operative infection rate of the silver-coated group was 11.8% compared with 22.4% for the control group (p = 0.033, chi-square test). A total of seven of the ten infected prostheses in the silver-coated group were treated successfully with debridement, antibiotics, and implant retention compared with only six of the 19 patients (31.6%) in the control group (p = 0.048, chi-square test). Three patients in the silver-coated group (3.5%) and 13 controls (15.3%) had chronic periprosthetic infection (p = 0.009, chi-square test).

The overall success rates in controlling infection by two-stage revision in the silver-coated group was 85% (17/20) compared with 57.1% (12/21) in the control group (p = 0.05, chi-square test). The Agluna-treated endoprostheses were associated with a lower rate of early periprosthetic infection. These silver-treated implants were particularly useful in two-stage revisions for infection and in those patients with incidental positive cultures at the time of implantation of the prosthesis.

Debridement with antibiotic treatment and retention of the implant appeared to be more successful with silver-coated implants.

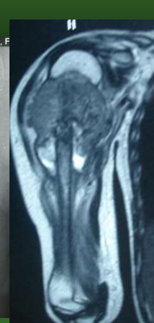
Cite this article: Bone Joint J 2015;97-B:252–7

- **85 patients TP / 85 patients Ag TP (DB 31 000 patients)**
- **106 m,64 f, mean age: 42,2 (18.4-90.4)**
- **Location: dF: 63, pT: 36, pF: 19, pelvis: 9, tF: 6,pH/6, dH: 2, d R :2, Diaph: 12**
- **50 primary reconstructions,**
- **79 one stage revisions, 41 two stage revisions**

Résults	Infection Primary recon	DAIR	Infection if cutures +	2 stage success
Silver	11%	70%	13,3 %	85%
Non Silver	22% p<0.01	30% p<0.01	40 % P<0.01	57,1% p< 0.01

INDICATION 1: PRIMARY TUMOURS

- 12 yo girl, EWING sarcoma
- Pathological fracture
- Open biopsy in the axillary region
- CT + recon with silver coated EPR
- Post op RT



PRIMARY TUMOURS
12 yo girl, EWING sarcoma

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- Post op RT

Arch Orthop Trauma Surg (2017) 137:149–153
DOI 10.1007/s00402-016-2584-8

CrossMark

ORTHOPAEDIC SURGERY

Lower limb reconstruction in tumor patients using modular silver-coated megaprostheses with regard to perimegaprosthetic joint infection: a case series, including 100 patients and review of the literature

J. Schmolders[1] · S. Koob[1] · P. Schepers[1] · P. H. Pennekamp[1] · S. Gravius[1] · D. C. Wirtz[1] · R. Placzek[1] · A. C. Strauss[1]

- 100 patients treated with SC prosthesis
- 31% primary bone tumours, 69% mets
- Median FU: 24 months (12-108)
- Prox. F: 52, distal F : 30, Total F: 14, Xpand : 3
- Infection rate: 10%

Injury, Int. J. Care Injured 47S (2016) S22–S28
Contents lists available at ScienceDirect
Injury
journal homepage: www.elsevier.com/locate/injury

ELSEVIER

Infective complications in tumour endoprostheses implanted after pathological fracture of the limbs

CrossMark

Andrea Piccioli[b], Fabrizio Donati[a,*], Giulio Di Giacomo[a,**], Antonio Ziranu[a], Silvia Careri[a], Maria Silvia Spinelli[a], Silvana Giannini[c], Giuseppe Giannicola[d], Carlo Perisano[a], Giulio Maccauro[a]

Division of Orthopaedic and Traumatology, Catholic University of the Sacred Heart, Rome, Italy
Oncologic Centre "Palazzo Baleani", Azienda Policlinico Umberto I, Rome, Italy
Department of Radiology "Villa Stuart", Rome, Italy
Department of Anatomical, Histological, Forensic Medicine and Orthopaedic Sciences, "Sapienza" University of Rome, Rome, Italy

- Retrospective study
- 30 patients with path.fr
- 17 silver coated
- 13 uncoated
- Mean age: 56 (12-78)
- Mean FU: 40.7 months

- Silver coated prosthesis : 11.8% of infection
- Uncoated prosthesis : 23.1 %
- No case of early infection (< 6 months) in SC group
- 66.7 % of early infection in uncoated group

- SC prosthesis : protective factor against early infection

INDICATION 2:METASTATIC DISEASE

- Pathological fracture
- Bone destruction
- Proximal femur +++

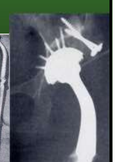



TUMOUR PROSTHESIS IN NON ONCOLOGIC INDICATIONS

LONG-TERM RESULTS OF PROXIMAL FEMORAL REPLACEMENT FOR NON-NEOPLASTIC DISORDERS

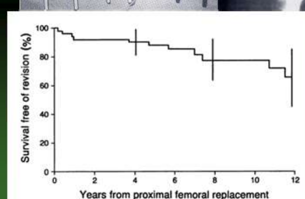
ARTHUR L. MALKANI, JEFFREY J. SETTECERRI, FRANKLIN H. SIM, EDMUND Y. S. CHAO, STEVEN L. WALLRICHS

From the Mayo Clinic and Mayo Foundation, Rochester, USA

- 30 patients
- Mean FU : 11.1 year
- Dislocation: 22%
- Infection : 6.3%
- Mean harris hip score:
  from 46 to 80 after operation

- Survival at 12 years : 64%
- (# 83% at 5 years)



J Bone Joint Surg [Br] **1995,77-B:351-6.**

Proximal Femoral Replacement in Patients with Non-Neoplastic Conditions

By Javad Parvizi, MD, FRCS, T. David Tarity, BS, Nicholas Slenker, BA, Frazier Wade, MD, Rachel Trappler, BS, William J. Hozack, MD, and Franklin H. Sim, MD

Investigation performed at the Rothman Institute of Orthopaedics at Thomas Jefferson University, Philadelphia, Pennsylvania, and the Department of Orthopedic Surgery, Mayo Clinic, Rochester, Minnesota

EXC : 19%
GOOD: 33%
FAIR: 23 %
POOR: 26%

- **48 patients (13 because of infection)**
- **Mean FU: 36.5 months**
- **10 reoperations**
- **Outcome Mean harris hip score: from 37.1 to 64.9**
- **Dislocation: 16%**
- **Infection: 1 patient (2%)**

- **Survivorship of the implant : 87% at 1 year**
  73% at 5 years

J Bone Joint Surg Am. 2007;89:1036-43


Contents lists available at ScienceDirect

The Knee

Review

A systematic review of endoprosthetic replacement for non-tumour indications around the knee joint

Muhammad T. Korim, Colin N.A. Esler, Venuthurla R.M. Reddy, Robert U. Ashford

- revue / 9 articles -> 241 EPR of the knee / non neoplastic conditions (mean age: 72 , mean FU : 3.3 years)
  - 58 % distal femur fractures
  - 15 % aseptic loosening
  - 16 % infection : success rate : 67 to 80 % (No silver coated implants in this series)

- Reoperation rate : 17 %
- Infection : 15 % at mean 3.3 years when used for salvage TKR for all indications
- aseptic loosening: 5 %
- Periprosthetic fractures : 5 %
- Mortality : 22 % (0 à 47 %)

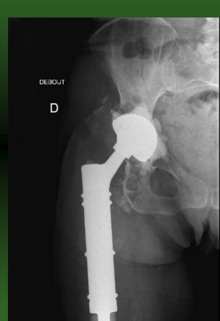
*** Korim MT & al Systematic Review of endoprosthetic replacement for non-tumour indications around the knee joint The Kne 2013**

Indication 3: revision surgery

- **Non septic complex revision**
- **Old lady**
- **85 yo**
- **Right THA**
- **Custom implant**
- **Implant rupture**

Revision surgery

- **Simple revision**
- **No bone graft**
- **Silver coated MUTARS**
- **Cemented dual mobility cup**
- **Happy at 2 years**



INDICATION 3 :TRAUMA and NON UNION

- **61 yo patient, car accident,**
- **BMI 32**
- **Bilateral fracture of the distal femur (open fracture on the left side)**
- **Non union at 1 year**
- **on the left side**
- **Pain**
- **No sign of infection**
- **normal CRP**

EPR distal femur

- **Silver coated Mutars**
- **Immediate stability**
- **Restauration of function**
- **Resumed walking**

- **Happy at 4 years**

INDICATION 4:SEPTIC REVISION SURGERY

- Complex cases
- Patients with prior multiple operations

- risk factors: diabetes, obesity, chronic renal failure, smoking, steroids…
- Associated disease (AS, Crohn disease, R A, psoriasis….)

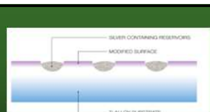
- Bone destruction
- Germs
- Soft tissue quality

OUR EXPERIENCE

- retrospective study.
- Patients were included in 2 university teaching hospital (CHU of Tours and CHU of Limoges) over a period of about 9 years.

- Multidisciplinary team
- Reference centres for complex osteo articular infections
- Systematic samples
- Systemic antibiotics
- 23 patients
- 2 stage revision surgery for 22 patients and
- 1 stage revision surgery for one patient.

OUR SERIES



- 18 Mutars® prostheses (ImplantCast, Germany)
- 5 Stanmore® prostheses (SIW, UK)

- Location:
  - proximal femur: 10
  - distal femur: 5
  - total femur: 4
  - knee arthrodesis : 2
  - lumic: 1
  - prox femur + lumic: 1

OUR SERIES

- n = 23
- 15 males, 8 females
- Mean age: 65,3 year (29-82)
- Mean FU : 62 months (10-138)

- flaps: 6
  - gastroc : 4
  - gluteus magnus: 2

Results

- Mean number of germs / patient :1.9 (1-10)
- 55% of the germs were *Staphylococcus spp*
- *Staphylococcus aureus:* 27,5 % (1 MRSA)
- *Coag neg Staphylococcus*: 27,5 %
- Other : *Bacillus, Pasteurella multocida, E.coli multi R, Proteus mirabilis, strepto constellatus, Clostridium perfringens+spp, E.coli, Entrobacter fecalis, Strepto constellatus, Strepto anginosus, Candida Fekir et Albicans, Bacteroides thetaiotaomicron,*

RESULTS

- Mean number of operations / patient : 5,3 (3-10) before the silver coated prosthesis was implanted
- 2 LR of infection at a 45 and 60 days (DAIR) free of infection at 36 and 38 months
- 4 chronic fistulas (3 total femurs)
- 1 patient dead with LR of infection
- 79 % succes at 62 months
- Mean MSTS scores : 24 (17-30)
  80% (56-100)

OUR EXPERIENCE
Silver coated tumour prosthesis in complex infection

- Short multicentric series (2 centres)
- Retrospective study, 23 patients
- 79 % succes at 5 years FU
- Complex infected cases
- Huge bone defects
- Efficient method of reconstruction
- for us : method of choice

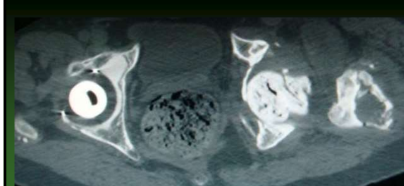
INDICATIONS
CASE DISCUSSION
INFECTION

COMPLEX 2 STAGE REVISION SURGERY
85% vs 57%

Résults	Infection Primary rec.	DAIR	Infection if cutures +	2 stage success
Silver	11%	70%	13,3 %	85%
Non Silver	22% p<0.01	30% p<0.01	40 % P<0.01	57,1% p< 0.01

CASE: COMPLEX THA INFECTION

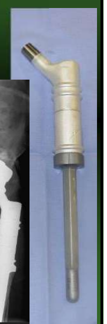
- 57 yo patient, left THA in 1982
- 8 operations on the left hip
- Infection With *Staphylococcus epidermidis*
- Vancomycin cement spacer
- Bipolar bone destruction
- 6 weeks of IV Antibiotics
- Hip aspiration: negative

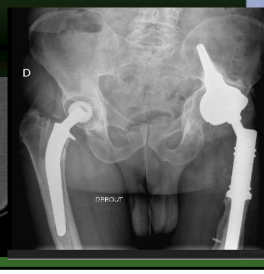


- Reimplantation at 8 weeks

- Silver coated LUMIC prosthesis +
- Silver Coated Mutars proximal Femur

- FU:
  - dislocation at 6 months
  - revision surgery with tripolar cup
  - no recurrence of infection at 7 years



COMPLEX INFECTION: 1 stage

64 yo woman

- Periosteal osteosarcoma left mid femur
- No mets
- 2011: Diaphyseal EPR (SC Mutars)

2011

- Did well in the begining
- Became painfull

2015

- Sharp pain in the thigh
- Local Staging (MRI, CT, X Rays)
- Chest CT, Pet scan: No LR,
- pulm mets: RFA + CT
- CRP: 9 mg/l

INFECTION

- Aspiration:
- *Staph Warneri,*
- *Staph Pastori,*
- *Staph capitis*

MANAGEMENT

- Staging
- 2 Pulm mets treated
- with RFA in October 15

- 1 or 2 stage?

- Diaphyseal EPR?
- Prox femur?
- Total femur

1 stage: SILVER COATED TOTAL FEMUR

- At 3 years
- Still alive
- No infection
- CRP < 5 mg/l
- Good function
- Walks with one stick
- Parker 9

DAIR
70% VS 30%

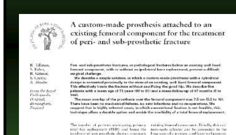
Résults	Infection Primary rec.	DAIR	Infection if cutures +	2 stage success
Silver	11%	70%	13,3 %	85%
Non Silver	22% p<0.01	30% p<0.01	40 % P<0.01	57,1% p< 0.01

DAIR
70% VS 30%

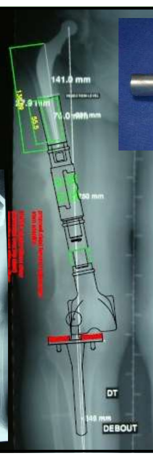
- 78 yo man
- Pathological fracture right mid femur under THA
- High grade spindle cell sarcoma of bone
- No mets
- CT
- Resection

SPECIAL DESIGN

- Use of an adaptor to connect with the stem of a THR
- Cemented silver coated prosthesis below


A custom-made prosthesis attached to an existing femoral component for the treatment of peri- and sub-prosthetic fracture

JBJS Br. 2006 Oct; 88(10):1299-302.



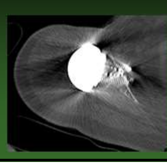
6 YEARS LATER

- Acute infection with staphylococcus gallalotycus
- DAIR changing all the silver coated modular parts
- Amoxicillin (12g/day)+ Ofloxacin for 6 weeks
- At 30 months, patient fine

Risk of infection in case of positive cultures: 13% vs 40%

Résults	Infection Primary rec.	DAIR	Infection if cutures +	2 stage success
Silver	11%	70%	13,3 %	85%
Non Silver	22% p<0.01	30% p<0.01	40 % P<0.01	57,1% p< 0.01

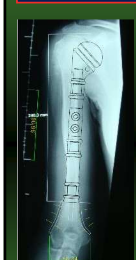
65 yo man , chondrosarcoma 20 years ago

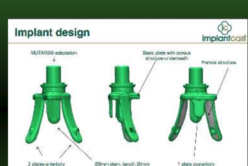


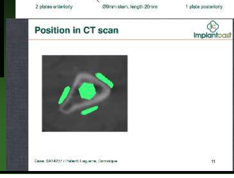
- Resection
- Reconstruction APC
- 7 operations later
- Loosening of inverse prosthesis

- Very painful
- Very limited range of motion
- Revision surgery?

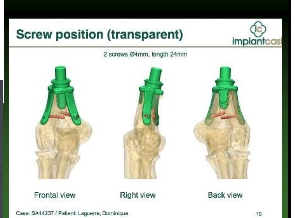
PLAN: CUSTOM MADE IMPLANT WITH EXTRACORTICAL PLATES







- Inverse Prox humerus
- Silver coated Implant
- Pectoralis major Myocutaneous flap

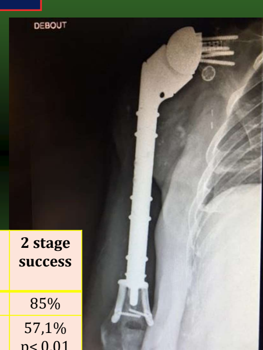


Positive cultures

- At 3 days post op
- Positive cultures : *Staphylococcus epidermidis*
- *What would you do??*

DON'T PANIC! MDT discussion:

- Silver coated implant
- AB 6 weeks
- Watch…….



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At 3years

- No fever
- Skin and flap perfect
- CRP < 5
- Chronic dislocation but
- no pain
- …

CONCLUSION

TAKE HOME 1: ONCOLOGIC INDICATIONS

YES! HIGH RISK PATIENTS !

- Primary bone tumours
- Metastatic disease
- Associated radiotherapy
- Location (P Tibia +++)

TAKE HOME 2:
Failed arthroplasty, trauma

- Revision surgery with major bone destruction (granuloma)
- Trauma : complex fracture with osteoporotic bone

TAKE HOME 3:
complex infected situations

1 stage
2 stage
DAIR

YES! EFFICIENT METHOD !

BIN THE BUGS!

USE SILVER!

THANK YOU FOR YOUR ATTENTION!