OSARTIS®

PerOssal®

Clinical Cases

Release Statement

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PerOssal® Clinical Cases | Content

Preamble 3

Prof. Dr. med. Markus Rupp

1 Open fracture lower leg, left 4

2 Fracture-related infection tibial shaft, right 8

3 Tibial head fracture, right 12

Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss

4 Multifragmentary distal femoral fracture, right 16

5 Femoral neck fracture, right 20

6 Amputation femur, left 24

References 28

Clinical Cases online

A list with all clinical cases can be found online:

Scan:

Respectively under: https://osartis.de/en/perossal/clinicalcases

PerOssal® Clinical Cases | Preamble

PerOssal® is a synthetic, biodegradable and osteoconductive bone substitute material for restoration and filling of bone defects.

Composition:
51.5 % nanocrystalline hydroxyapatite
48.5 % calcium sulfate

PerOssal® is intended for the restoration of bone defects. After thorough surgical debridement and under systemic or local antibiosis, it may be also implanted in infected or contaminated areas. Its unique microporous structure ensures uniform uptake of liquid substances (such as antibiotics) and their controlled sustained release.

Dosage recommendations given by the manufacturer are based on in vitro results. The treating physician is responsible for the decision regarding the type and quantity of the corresponding antibiotic. The contraindications of the applied antibiotic have to be considered.

1

Case Study PerOssal®

Prof. Dr. med. Markus Rupp
Open fracture lower leg, left

Clinic	University Hospital Regensburg Department of Trauma Surgery Franz-Josef-Strauß-Allee 11 93053 Regensburg
Performed by	Prof. Dr. med. Markus Rupp
Date of surgery	14.11.2019
Patient	Age: 45 years Gender: male

History / reason for surgical intervention

- Open fracture of the left lower leg in motorcycle accident 1994
- 2-stage surgical treatment after accident
- 10 years free of complaints
- Since then recurrent swelling, redness and intermittent fistula formation

Products used	PerOssal® 50 pellets **Ratio 1:1**
Other products	Allograft chips
Antibiotics	Vancomycin - 0.4 g according to regimen

Microbiological findings

Staphylococcus aureus

Surgical history

Surgery 1

Resection of the soft tissue defect,
bony debridement,
PMMA chain insertion
(PMMA 40 g + 2 g meropenem
+ 2 g vancomycin, skin substitute for temporary wound covering)

Surgery 2

Removal of PMMA chains, debridement,
defect filling with PerOssal®/allograft chips,
plastic coverage by gracilis flap plasty

Preoperative

Chronic osteomyelitis Cierny Mader type III with fistula (FIG. 1-3)

FIG. 1

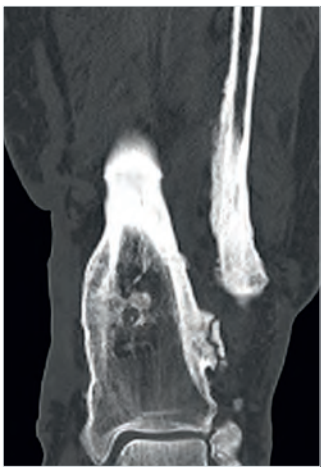


FIG. 2

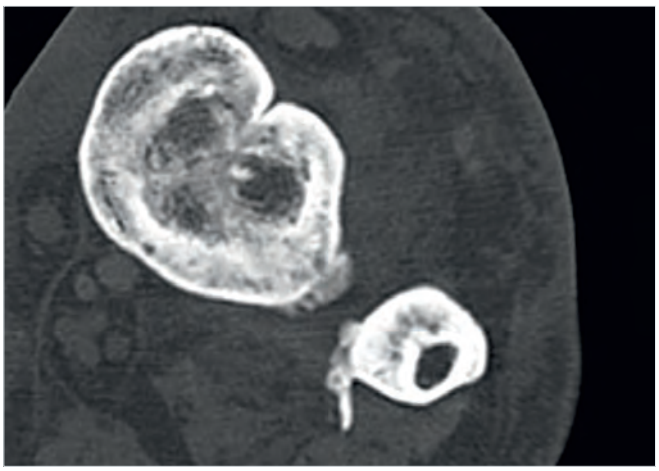


FIG. 3

Postoperative

After plastic coverage achieved bone consolidation (FIG. 4-5)

FIG. 4

FIG. 5

1 **Follow-up** according to the standard of care

3 months follow-up

Patient fully weight loaded, no further antibiotic therapy (FIG. 6-7)

FIG. 6

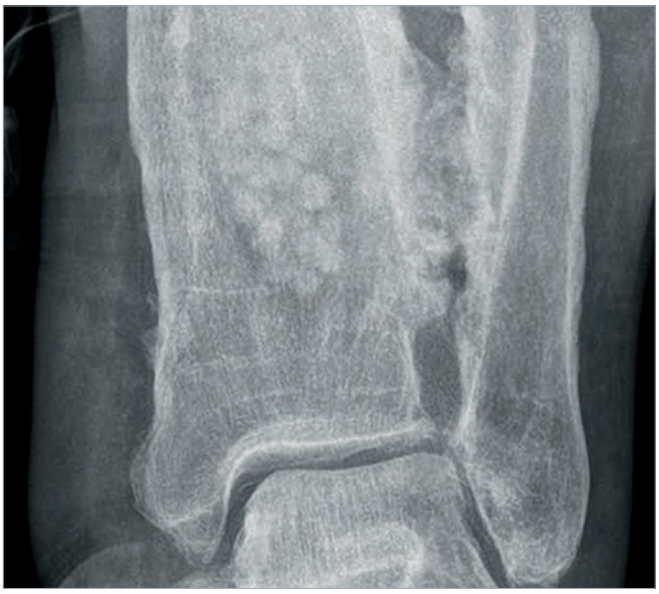


FIG. 7

6 months follow-up

Working capacity reached, patient runs without restrictions and is pain-free again, due to the distance to the hometown of >300 km no further control inhouse (FIG. 8-9)

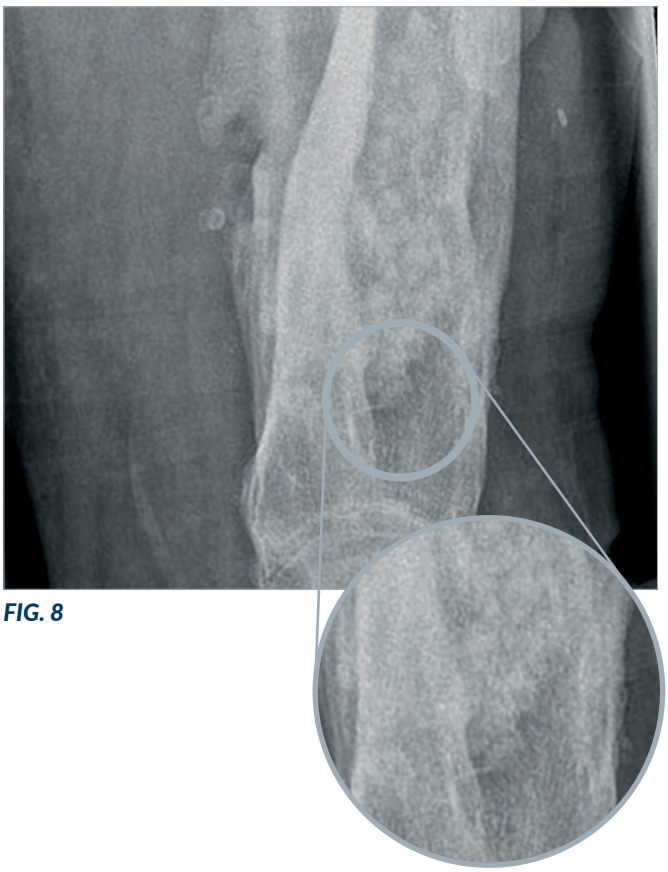


FIG. 8

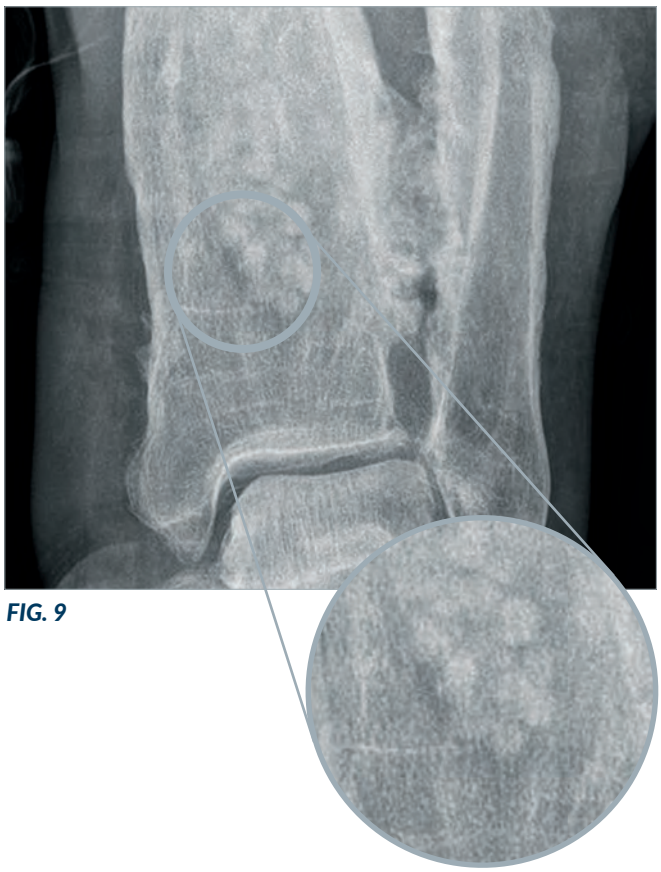


FIG. 9

Defect size to be filled	25 cm^3
Bone window to be covered	2 cm x 6 cm
Closure by	Bone chips
Intraoperative	Involucrum windowed
	2 cm x 6 cm, distance slushy putrid tissue in the medullary canal
Soft tissue situation	Poor
Soft tissue reconstruction	Gracilis free flap
Skin closure sufficient	Yes
Drainage	None
Complications / Concomitants	None

Results of the procedure Conclusions

Due to sufficent bone stock additional osteosynthesis could be avoided. Consolidation of the distal tibia after bone reconstruction by allograft/PerOssal® + 0.4 g vancomycin was achieved.

2

Case Study PerOssal®

Prof. Dr. med. Markus Rupp
Fracture-related infection tibial shaft , right

Clinic University Hospital Regensburg
Department of Trauma Surgery
Franz-Josef-Strauß-Allee 11
93053 Regensburg

Performed by Prof. Dr. med. Markus Rupp

Date of surgery 21.01.2021

Patient Age: 19 years
Gender: male

History / reason for surgical intervention

- Fracture-related infection of the tibial shaft after riding accident with lower leg fracture, intramedullary nail osteosynthesis
- Secondary compartment syndrome and fasciotomy
- Multiple debridements, then secondary wound closure
- Fracture-related infection
- One-stage exchange nailing from an uncoated nail to an antibiotic coated nail
- Due to infection persistence two-stage approach (Masquelet procedure)

Products used PerOssal® 12 pellets

Other products RIA from femur right

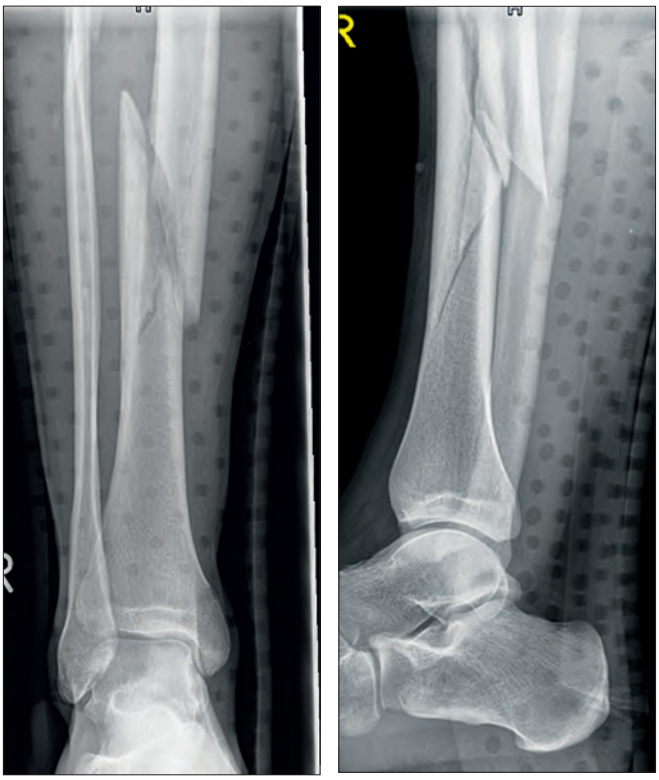
Antibiotics Vancomycin - 0.2 g according to regimen

Microbiological findings
Finegoldia magna, staphylococcus hominis

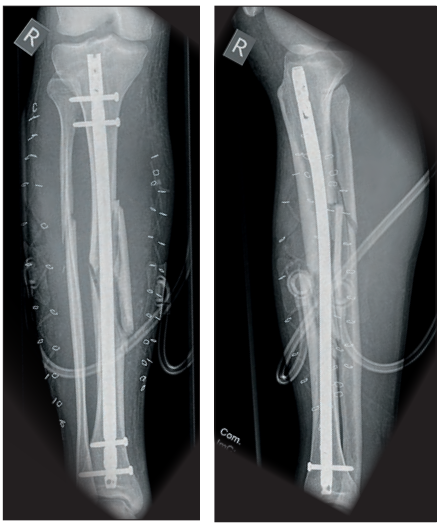
Surgical history

Surgery 1 & 2

Preoperative images from accident (08/2020)
Fracture-related infection after intramedullary nail osteosynthesis



Postoperative surgery 1 (08/2020)



Postoperative surgery 2 (09/2020)

Surgery 3

Resection of soft tissue defect, bony debridement, PMMA chain insert (PMMA 40 g + 2 g meropenem + 2 g vancomycin) skin substitute for temporary wound covering.

Postoperative surgery 3 (10/2020)

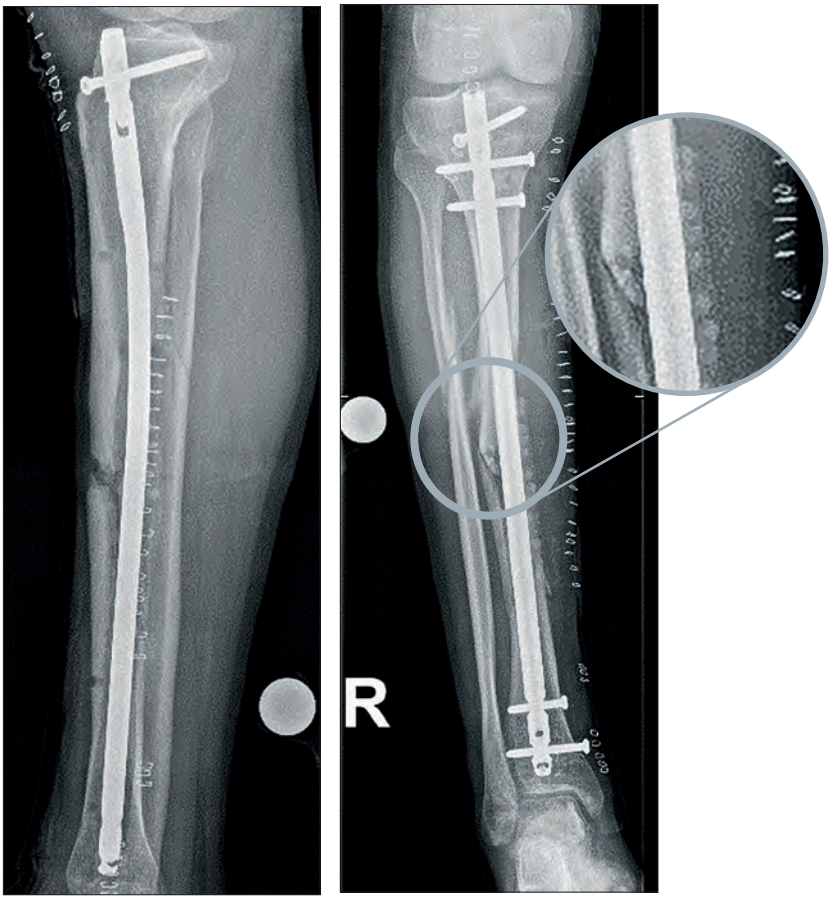
Semicircular medial defect after removal of a wedge fragment

Surgery 4

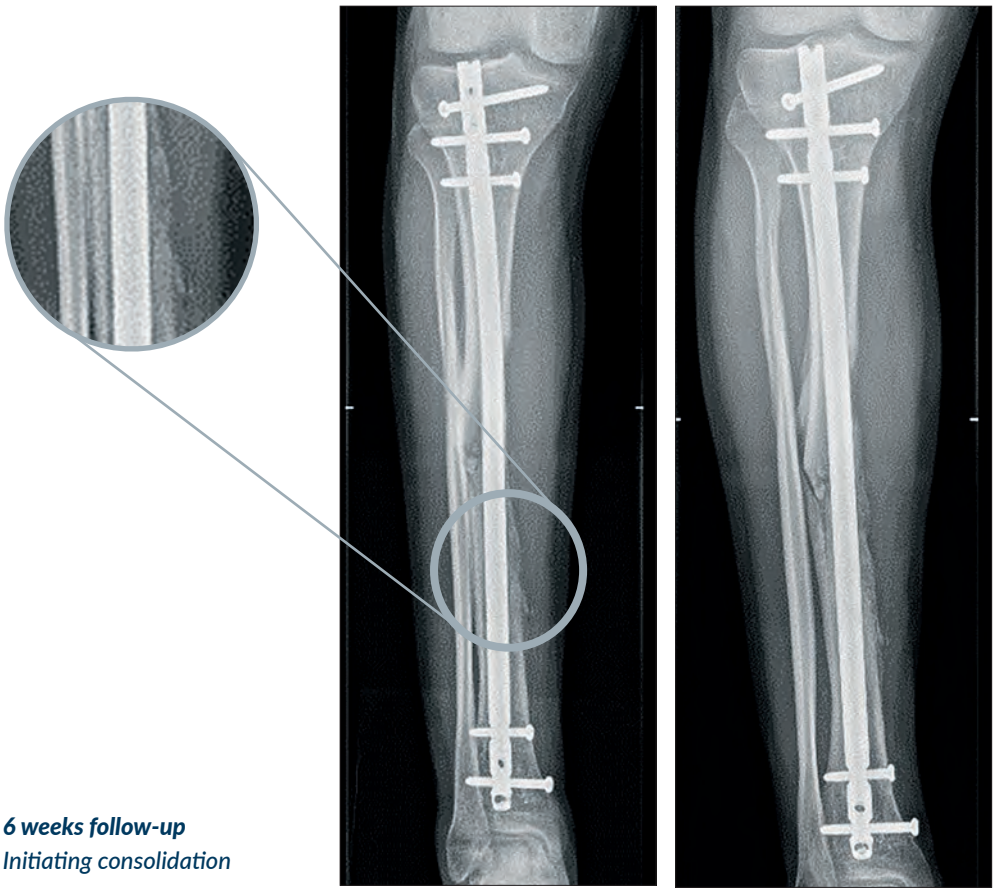
Removal of PMMA chains, debridement, defect filling with PerOssal®/allograft chips, plastic covering by gracilis free flap plastic.

Intraoperative surgery 4 (01/2021)

Postoperative

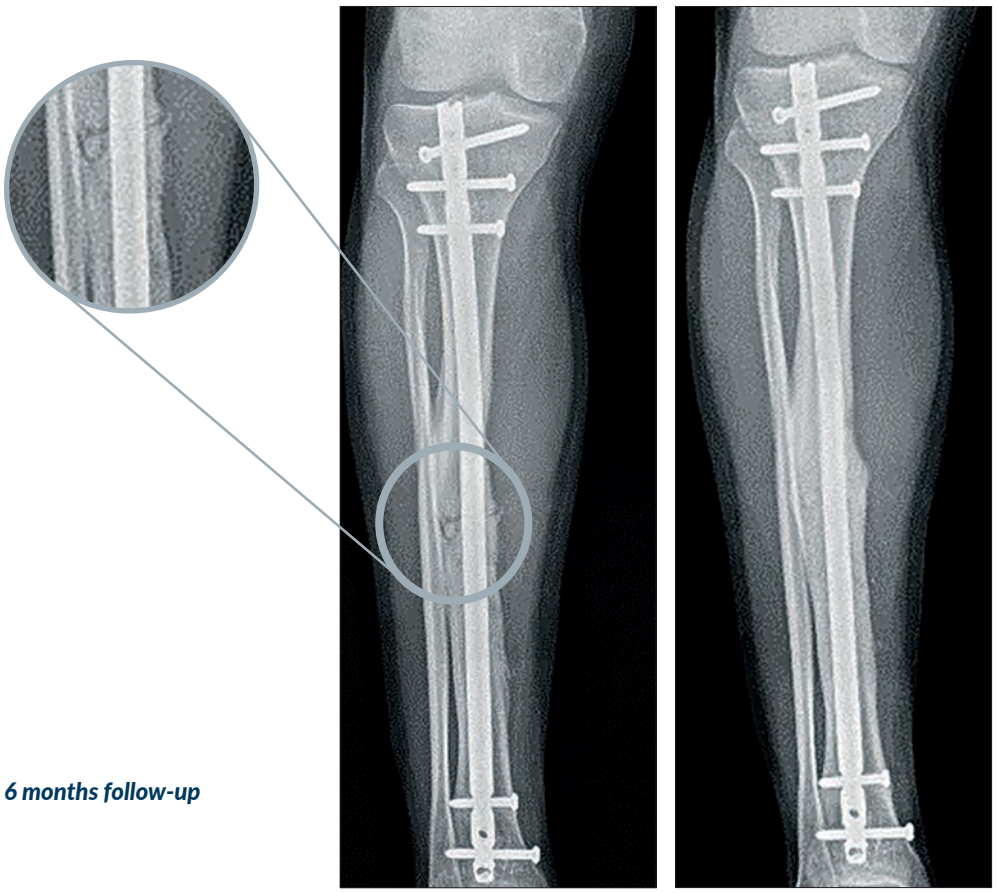


2 **Follow-up** according to the standard of care



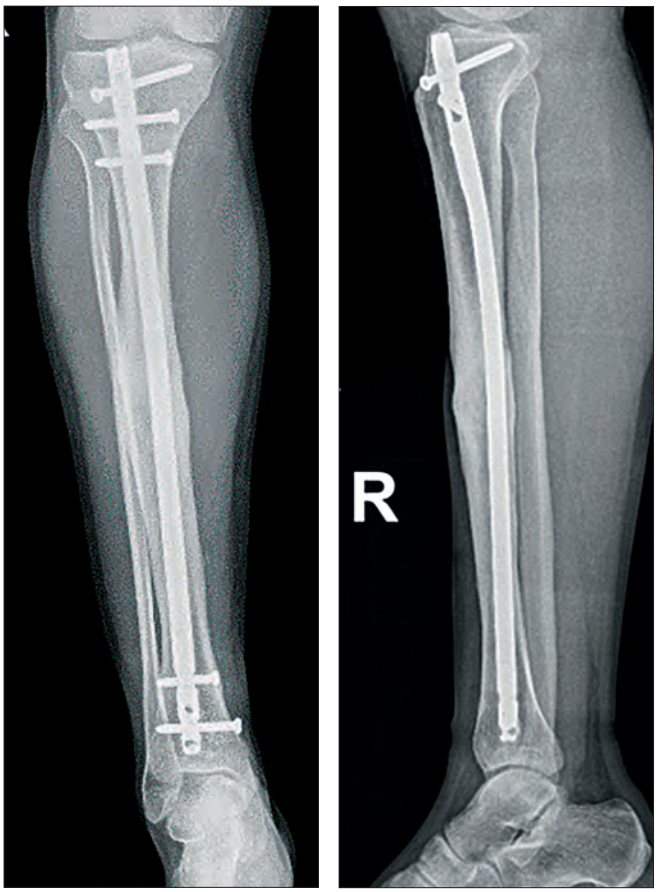
6 weeks follow-up
Initiating consolidation

12 weeks follow-up
Patient fully weight-bearing end of antibiotic therapy



6 months follow-up

12 months follow-up
Complete bone consolidation, the patient has no mobility restrictions



18 months follow-up
Complete bone consolidation and remodelling after 18 months

Defect size to be filled	25 cm^3
Bone window to be covered	3 cm x 9 cm
Closure by	The body's own Masquelet membrane was sutured
Soft tissue situation	Medium
Soft tissue closure	Layered wound closure
Skin closure sufficient	Yes
Drainage	None
Complications / Concomitants	None

Results of the procedure Conclusions

Consolidation was accomplished using the Masquelet technique in conjunction with defect reconstruction using RIA harvested autologous bone graft and 12 pellets of PerOssal® + 0.2 g vancomycin.

3

Case Study PerOssal®

Prof. Dr. med. Markus Rupp
Tibial head fracture, right

Clinic University Hospital Regensburg
Department of Trauma Surgery
Franz-Josef-Strauß-Allee 11
93053 Regensburg

Performed by Prof. Dr. med. Markus Rupp

Date of surgery 21.01.2021

Patient Age: 69 years
Gender: male

History / reason for surgical intervention

- Right tibia head fracture after ladder fall
- Temporary external fixation for emergency treatment, final fixation by double plate osteosynthesis
- After diagnosed acute FRI, debridement and implant retention (DAIR)
- Finally due to persistent infection implant removal and application of a hybrid fixator for Masquelet procedure has been performed
- After failure for the first bone defect reconstruction, again extensive debridement and a two-stage approach was performed
- One year after bone defect reconstruction removal of the hybrid fixator was possible

Products used PerOssal® 6 pellets

Ratio 1:10

Other products RIA harvested autograft
+ allograft chips

Antibiotics Surgery 3 – 1 g vancomycin
Surgery 5 – 1 g meropenem

Microbiological findings
Staphylococcus aureus

Surgical history

Surgery 1 (07/2020)

DAIR: Bone debridement, custom-made PMMA beads insertion (PMMA 40 g + 240 mg gentamicin + 2 g vancomycin), Epigard® coverage (FIG. 1-2)

FIG. 1: Surgery 1

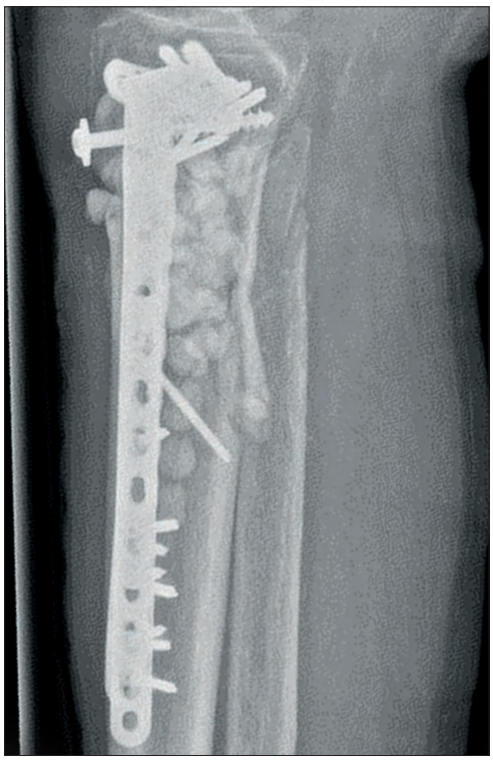


FIG. 2: Surgery 1

Surgery 2 (08/2020)

Removal of plate, screws and application of PMMA beads with gentamicin and clindamycin (FIG. 3-4)

FIG. 3: Surgery 2

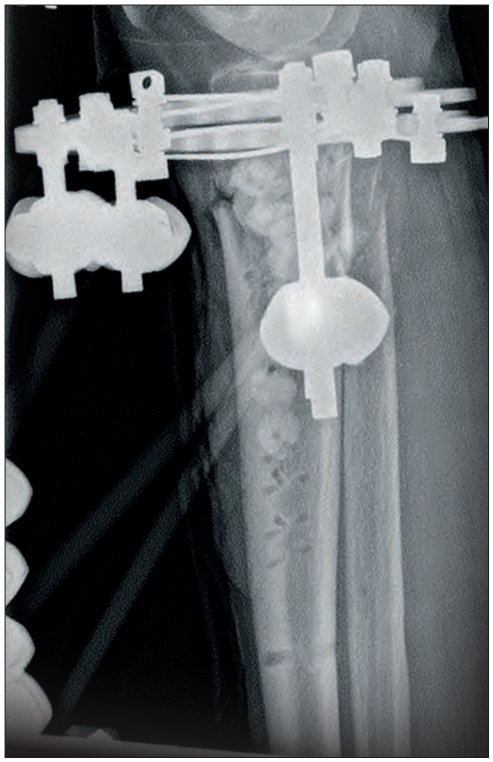


FIG. 4: Surgery 2

Surgery 3 (09/2020)

Defect filling with PerOssal® + 1 g vancomycin, autologous iliac crest bone graft, allograft chips, external fixation by hybrid fixator, additional plastic surgery covering by gracilis flap (FIG. 5-6)

FIG. 5: Surgery 3

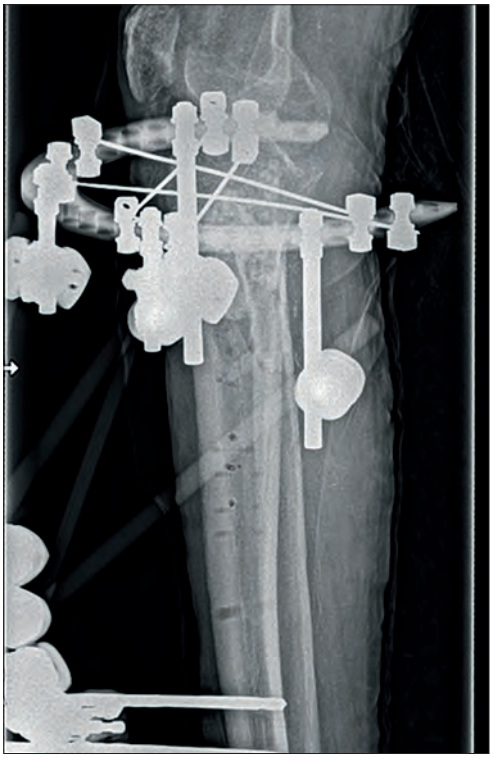


FIG. 6: Surgery 3

3 Surgical history

Surgery 4 (10/2020)

Resection of the soft tissue defect, bony debridement, PMMA spacer 80 g + 400 mg gentamicin + 4 g vancomycin + 300 mg amphotericin B, after reinfection (FIG. 7-8)

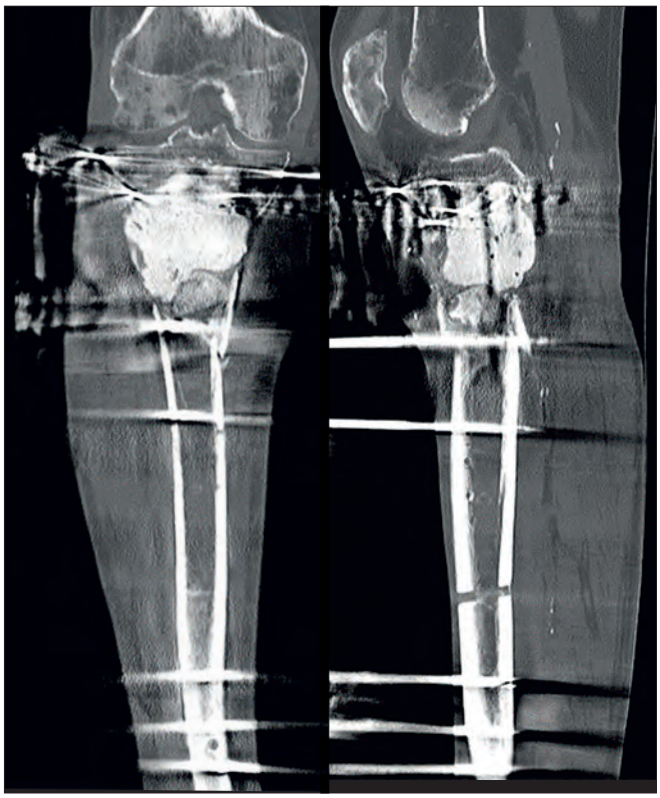


FIG. 7: Surgery 4

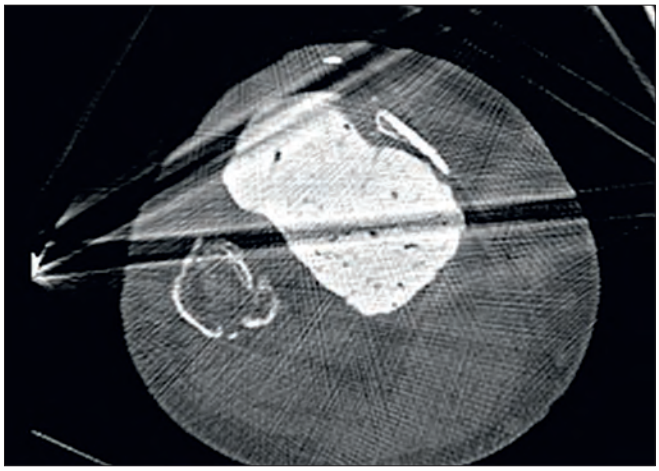


FIG 8: Surgery 4

Surgery 5 (02/2021)

Removal of the PMMA spacer, debridement, defect filling with PerOssal®, iliac crest bone autograft, allograft chips +1 g meropenem, local gastrocnemius flap (FIG. 9-10)

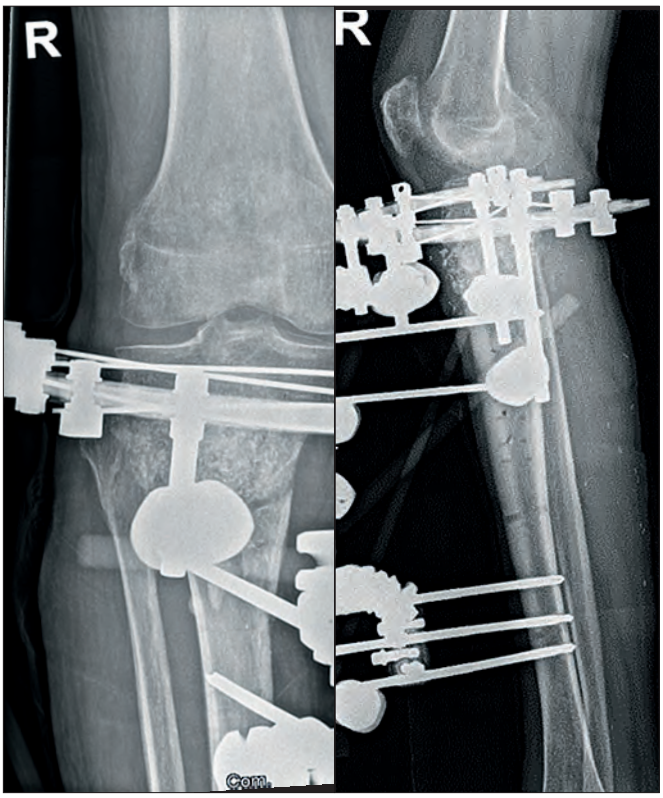


FIG. 9: Surgery 5

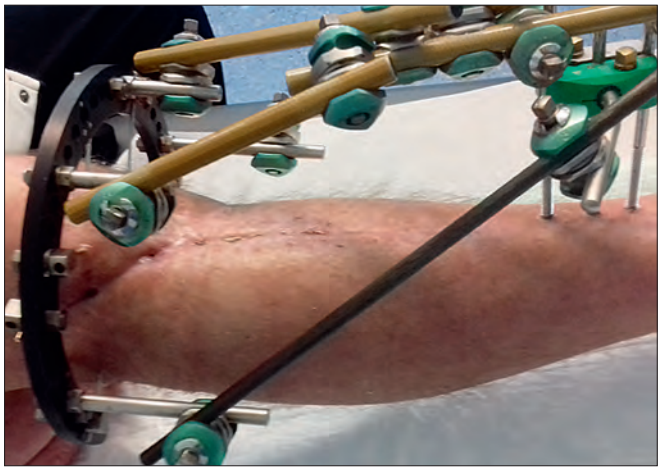


FIG. 10: Surgery 5

Follow-up according to the standard of care

7 months follow-up

Full weight-bearing was possible with the hybrid fixator, knee ROM E/F 0-0-100, proper consolidation, removal fixator (FIG. 11)

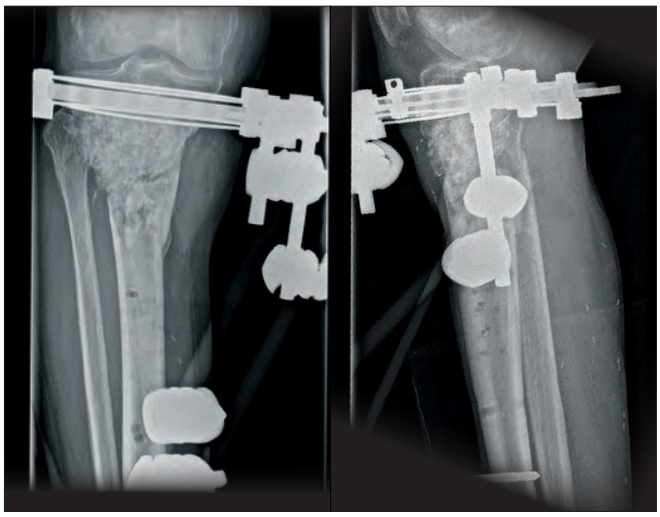


FIG. 11: 7 months follow-up (09/2021)

Defect size to be filled	120 cm^3
Bone window to be covered	3 cm x 2 cm
Closure by	Spongiosa
Soft tissue situation	Critical
Flap plastic	Gastrocnemius flap
Skin closure sufficient	Yes
Drainage	None
Complications / Concomitants	None after 5th surgery

20 months follow-up

Sufficient bone reconstruction of the proximal tibia was achieved allowing removal of the hybrid fixator (FIG. 12)

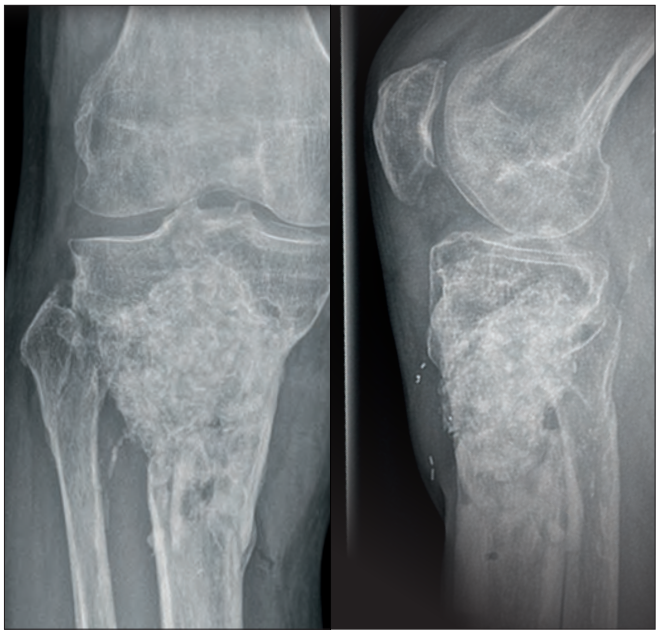


FIG. 12: 20 months follow-up (10/2022)

Results of the procedure Conclusions

Bone consolidation was successfully attained, leading to the preservation of the knee joint.
By addressing a significant bone defect, it was possible to avoid arthroplasty with replacing the proximal tibia with additional patellar tendon reconstruction.
Such an alternative surgical approach would carry a high risk of infection recurrence and probably a less favorable functional outcome. After a quite long treatment period of one year and eight months, the patient is able to walk several kilometers without assistance and is free from pain.

4

Case Study PerOssal®

Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss Multifragmentary distal femoral fracture, right

Clinic University Hospital Giessen GmbH
Department of Trauma, Hand and Reconstructive Surgery
Rudolf-Buchheim-Str. 7
35385 Giessen, Germany

Performed by Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss

Date of surgery 18.08.2009

Patient Age: 30 years
Gender: female

History / reason for surgical intervention

- The patient had presented herself in the emergency room as a polytraumatized patient with the ambulance and emergency doctor.
- She was hit as a pedestrian by truck and suffered various injuries.

Products used PerOssal® 1x50 pellets (two revisions – each time with 50 pellets)

Antibiotics Vancomycin - 200 mg per revision

Microbiological findings
Enterococcus faecium

Surgical sequences

Primarily, the patient was cared for by use of external fixator on the day of the accident. In the further course the patient was treated with an angle-stable plate for multifragmentary distal femoral fracture.
After 5 weeks, a procedure change was executed and a nail was implanted. Postoperatively, there was a wound infection of the right femur. Wound revision, debridement, jet lavage and the application of PerOssal® pellets were then carried out twice. After 14 weeks, the patient was free of infection.

Preoperative

Femur right in 2 levels: complex and multifragmentary femoral shaft fracture with a supracondylar component without involvement of the knee joint (stabilization with a fix. ex. FIG. 1)

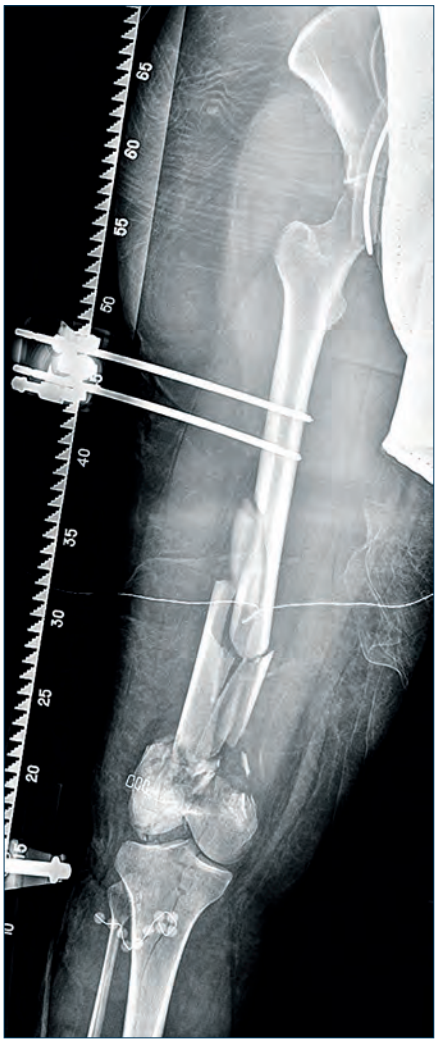


FIG. 1: Surgery 1
External fixator

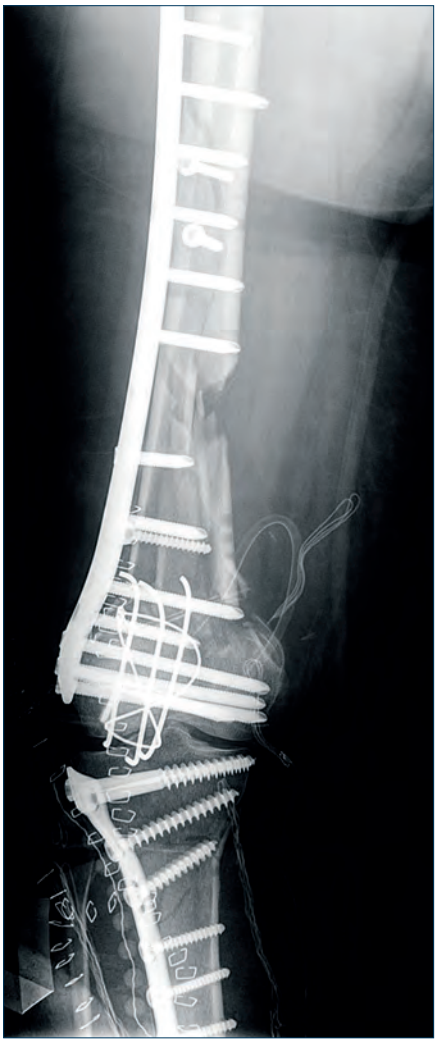


FIG. 2: Surgery 2
Osteosynthesis large-stable plates + PMMA beads

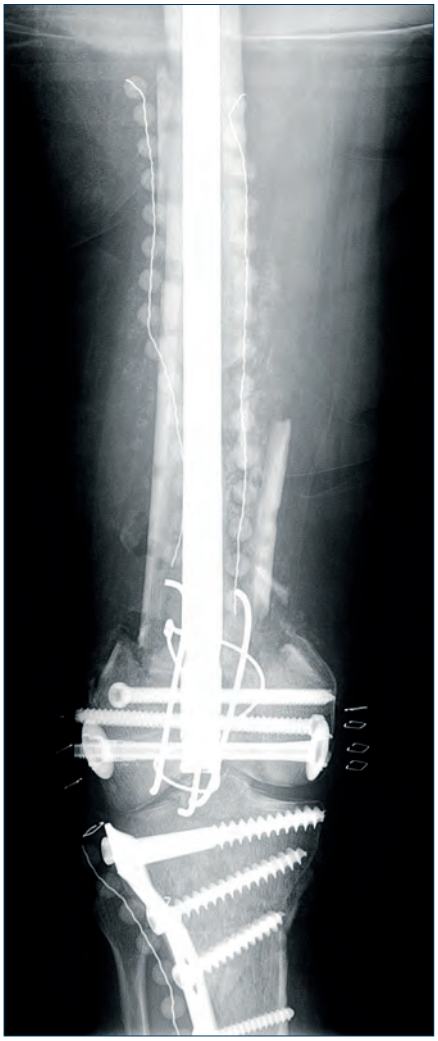


FIG. 3: Surgery 3
Femur nail + PMMA beads

4 Surgical sequences

Intraoperative

Bone defect medial side in the area of the femur right in a size of about 4 cm with signs of local infection (FIG. 4)

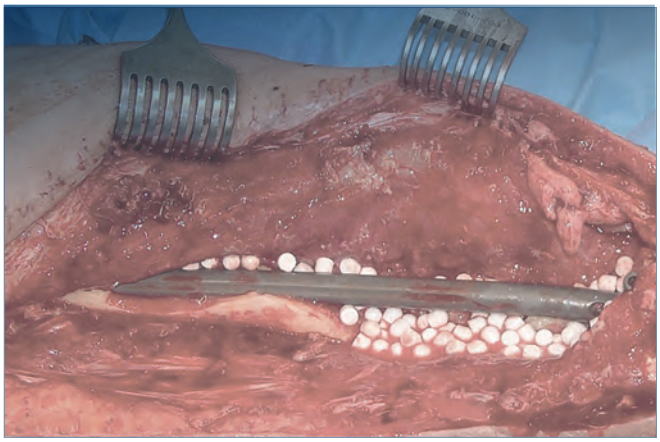


FIG. 4: Surgery 4
Due to wound infection debridement lavage
+ PerOssal® 50 pellets, near by the femur nail

Follow-up according to the standard of care

Postoperative surgery 4

After surgical revision of a complex and multifragmentary femoral shaft fracture with a supracondylar components, as well as application of locally acting antibiotic pellets around the fracture (FIG. 5-8)

3 months follow-up

No suspicion of a renewed infection,
increasing bony consolidation.

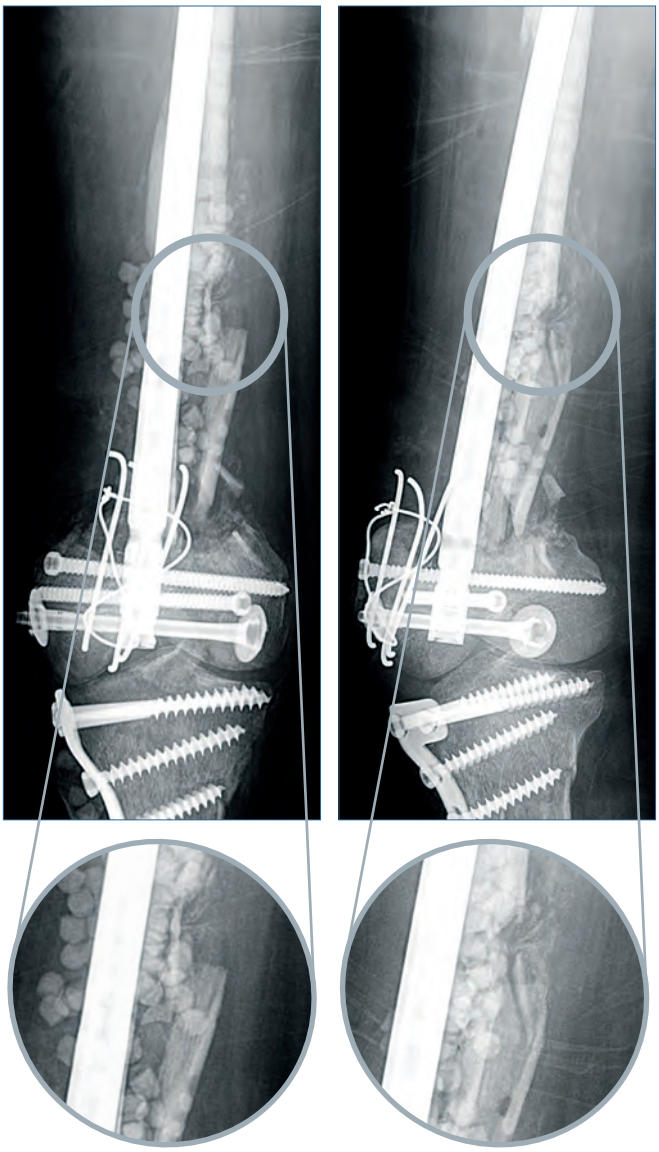


FIG. 5-6: 3 months follow-up

Defect size to be filled	4 cm^3
Bone window to be covered	4 cm
Soft tissue situation	Medium
Soft tissue closure	Layered wound closure
Skin closure sufficient	Yes
Drainage	Yes, at femur right, without vacuum
Complications / Concomitants	First and foremost, no complications were caused by the use of PerOssal® pellets.

12 months follow-up

Definitely no infection, complete bony consolidation, no signs of pseudoarthrosis, patient satisfied.

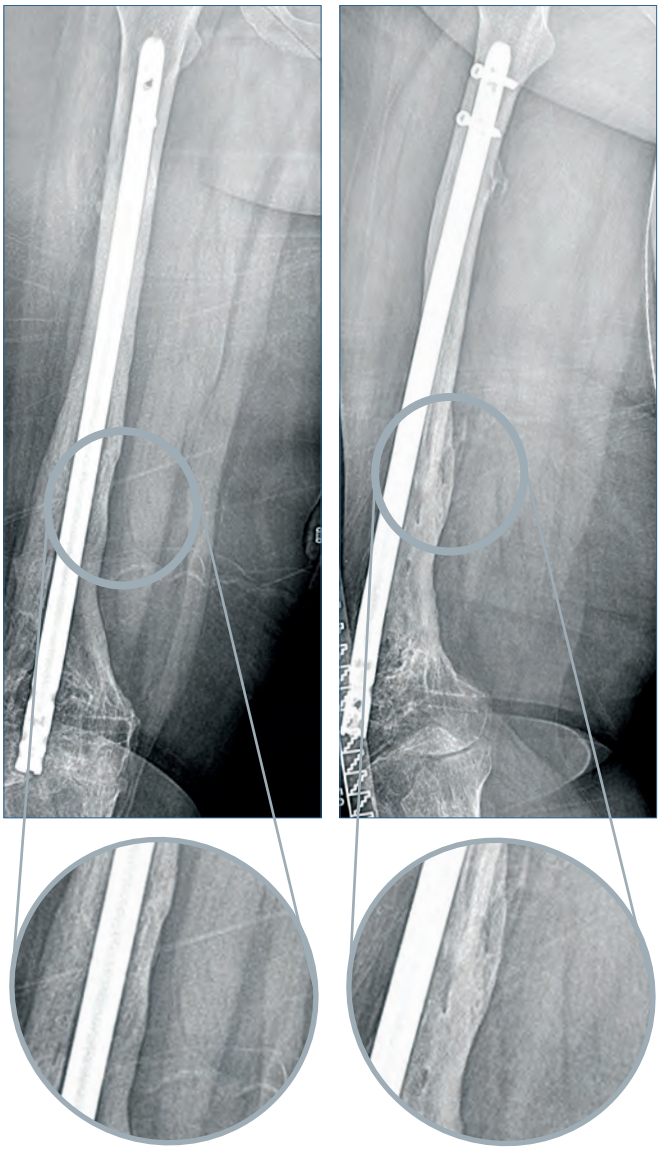


FIG. 7-8: 12 months follow-up

Results of the procedure Conclusions

In summary, a rapid and very effective performance of the implanted PerOssal® pellets took place. Fast and in this patient after 2 applications complete defeat of the germ.

5

Case Study PerOssal®

Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss
Femoral neck fracture, right

Clinic University Hospital Giessen GmbH
Department of Trauma, Hand and Reconstructive Surgery
Rudolf-Buchheim-Str. 7
35385 Giessen, Germany

Performed by Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss

Date of surgery 27.08.2009

Patient Age: 90 years
Gender: female

History / reason for surgical intervention

- The patient fell on 24.08.2009 on the street and fell on the right side of the body (right hip)
- A femoral neck fracture had been sustained
- Primary surgery with a cemented hip arthroplasty
- Postoperatively early signs of infection of the prosthesis so that the patient had to be revised on 17.09.2009

Products used PerOssal® 1x50 pellets (two revisions – each time with 50 pellets)

Other products Handmade cement spacer, PMMA beads

Antibiotics Vancomycin - 200 mg per revision

Microbiological findings
Proteus mirabilis,
hemolytic streptococci

Surgical sequences

The femoral neck fracture (right) was treated on 27.08.2009 with the implantation of a hip arthroplasty (duo head prosthesis). In the subsequent follow-up treatment in an other hospital, purulent effusion emptied from the scar.

First, the infected prosthesis was removed. The microbiological examination revealed the detection of hemolytic streptococci and proteus mirabilis.

For complete infection remediation, 3 revisions with insert/change of vancomycin-impregnated bone substitute pellets (PerOssal®) were carried out. In the end, the definitive implantation was carried out using a long-shaft prosthesis (Link).

Preoperative

Situation after implantation of hip prosthesis on the right without signs of dislocation or loosening (FIG. 1)
Condition after explanting hip-TEP right showing a multisegmental fracture with sharp cortical interruptions in the femoral shaft area and inserted PMMA antibiotic beads (FIG. 2)
Intraoperatively, there were no prutrid secretions, despite signs of loosening of the prosthesis. Here also starting 2 isolated bone sequesters. Due to persisting infection revision with PerOssal® pellets and spacer (FIG. 3)
A third revision led to no signs of infection so that a new hip-TEP could be implanted (FIG. 4)

FIG. 1: Hip arthroplasty

FIG. 2: Revision 1; Girdlestone-situation / PMMA beads

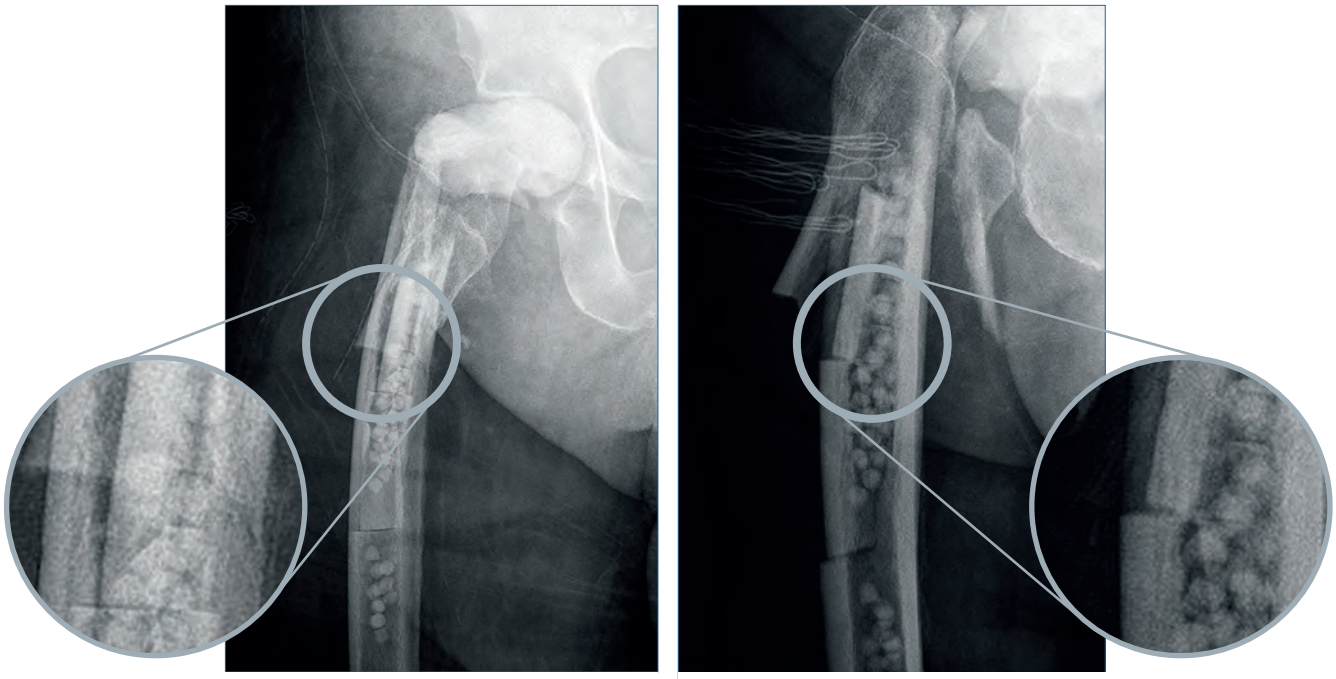


FIG. 3: Revision 2; PerOssal® pellets and spacer

FIG. 4: Revision 3; PerOssal® pellets and spacer

5 **Follow-up** according to the standard of care

3 months follow-up

After implantation of a long-shaft prosthesis right partially remaining antibiotic pellets, no signs of loosening (FIG. 5)

FIG. 5: 3 months follow-up
Long-shaft prosthesis - Link TEP
after revision with PerOssal® pellets

Bone window to be closed	None
Soft tissue closure	Layered wound closure
Skin closure sufficient	Yes
Drainage	Yes, at hip joint, without vacuum
Complications / Concomitants	No complications were reported

12 months follow-up

After implantation of a long-shaft prosthesis right completely absorbed antibiotic pellets, no signs of loosening (FIG. 6)

FIG. 6: 12 months follow-up

Results of the procedure Conclusions

Despite old age, after 3 revisions, the complete restoration of the infection as well as implantation of a prosthesis and final care of the patient.

6

Case Study PerOssal®

Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss
Amputation femur, left

Clinic University Hospital Giessen GmbH
Department of Trauma, Hand and Reconstructive Surgery
Rudolf-Buchheim-Str. 7
35385 Giessen, Germany

Performed by Univ.-Prof. Dr. med. Dr. h.c. Christian Heiss

Date of surgery 20.08.2021

Patient Age: 29 years
Gender: female

History / reason for surgical intervention

- After major amputation of the left femur on 26.07.2021 due to necrotizing fascitis after dog bite (surgery in Mexico).
- External presentation on 10.08.2021 due to the start of preparation for the prosthesis fitting.
- The scar showed swelling and redness at that time. The general infect situation of the patient went up and wound healing disorders were observed, the admission took place on 11.08.2021 at the University Hospital Giessen.

Products used PerOssal® 1x50 pellets (two revisions – each time with 25 pellets)

Antibiotics Vancomycin - 100 mg per revision

Microbiological findings
Methicillin-resistent staphylococcus aureus (MRSA)

Surgical sequences

Two-time surgical revision of the wound (left leg): revision of left femur shaft, post-resection, biopsies, drilling of the femoral canal, jet lavage, irrigation with granudacyn, insertion of PerOssal® pellets (25 pellets) due to thigh stump infection (MRSA) of the fulminant dog bite injury.
Second revision of femur left, pellets removal/exchange (Cave: only 25 pellets!).

X-ray, CT, MRI images for standardized documentation

Preoperative

MRI-Assessment: The finding is suspicious at elevated inflammatory parameters on an abscessing inflammation adjacent to the stump of the left femoral shaft with duct-like expansion into the adjacent muscles, as well as with slightly extensive osteomyelitis of the femoral shaft (FIG. 1-3)

FIG. 1

FIG. 2

FIG. 3

Intraoperative

There were signs of osteomyelitis and environmental reaction of soft tissues with necroid parts of the femur (FIG. 4-5)

FIG. 4

FIG. 5

6 Surgical sequences

Postoperative

Sharp settling margin of the femur after post-resection and perioperative vent inclusions of the soft tissues around the stump. Newly inserted antibiotic PerOssal® pellets in the medullary canal of the remaining femoral shaft as well as drainage material proximal at the hip joint.

Follow-up according to the standard of care

3 months follow-up

After thigh amputation antibiotic PerOssal® pellets almost absorbed. No signs of osteomyelitis (FIG. 6)

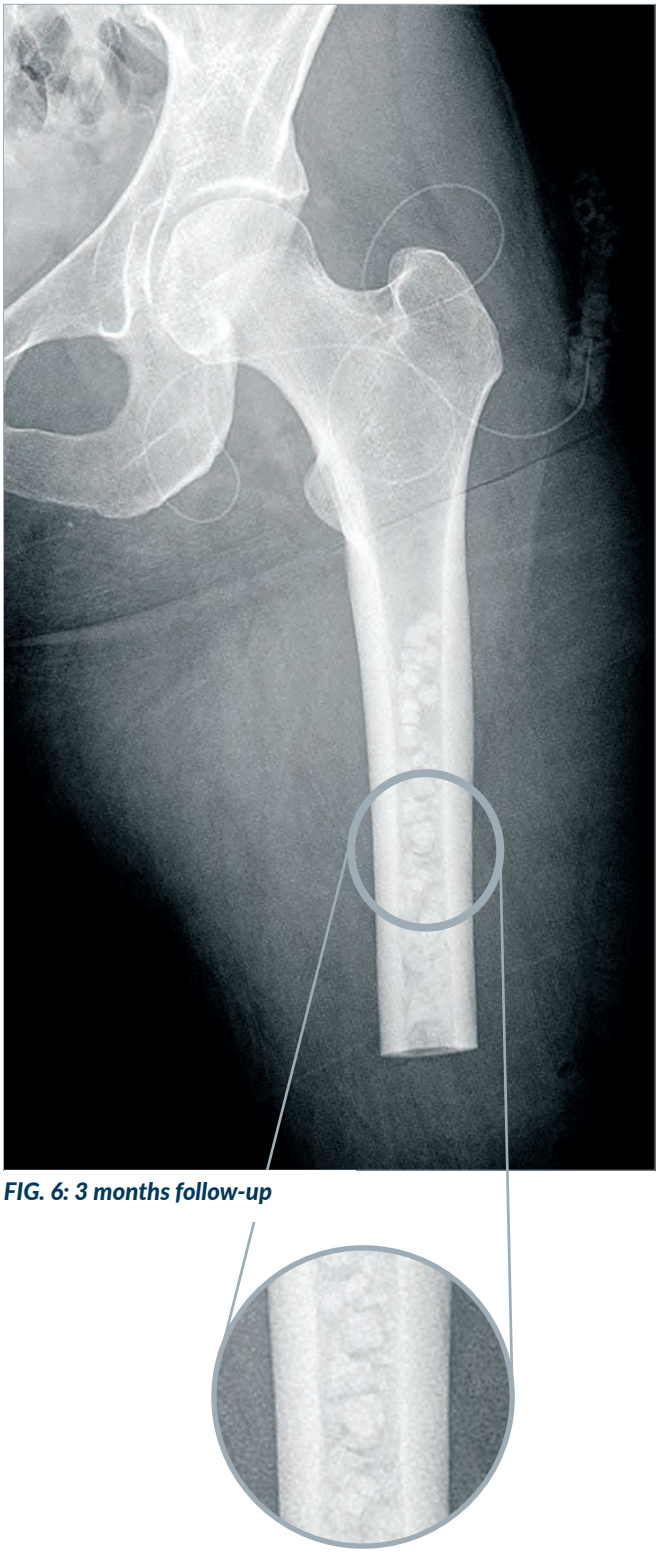


FIG. 6: 3 months follow-up

6 months follow-up

Stump functional, adapted prosthesis of the leg, no signs of infection (FIG. 7)

FIG. 7: 6 months follow-up

Soft tissue situation	Poor
Soft tissue closure	Layered wound closure
Skin closure sufficient	Yes
Drainage	Yes, at the stump, without vacuum
Complications / Concomitants	No complications and after 2 revisions the soothing of the soft tissues took place

Results of the procedure Conclusions

Rapid and very effective fight against MRSA infection.

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