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STAR: die neue Generation in der Wirbelsäulenmetastasenbehandlung

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Knochenmetastasen: Ein wachsendes, unzureichend versorgtes Patientenklientel

Knochenmetastasen sind unter vielen Tumorarten weit verbreitet

Primärtumor	Fünf-Jahres-Auftreten[1]	Entwicklung von Knochenmetastasen[2]
Myelom	144.000	70% - 95%
Niere	480.000	20% - 25%
Melanom	533.000	14% - 45%
Schilddrüse	475.000	60%
Lunge	1.394.000	30% - 40%
Brust	3.860.000	65% - 75%
Prostata	1.555.000	65% - 75%

1 Ferlay J, Bray F, Pisani P, Parkin DM. GLOBOCAN 2000: Cancer incidence, mortality and prevalence worldwide, version 1.0. IARC CancerBase No. 5, Lyon, IARCPress, 2001 Available at: http://www.dep.iarc.fr/globocan/cdrom.htm. Accessed February 26, 2004.

2 Coleman RE. Metastatic bone disease: clinical features, pathophysiology and treatment strategies. Cancer Treat Rev 2001:27:165-176

3 Coleman RE. Skeletal complications of malignancy. Cancer 1997:80 (suppl):1588-1594

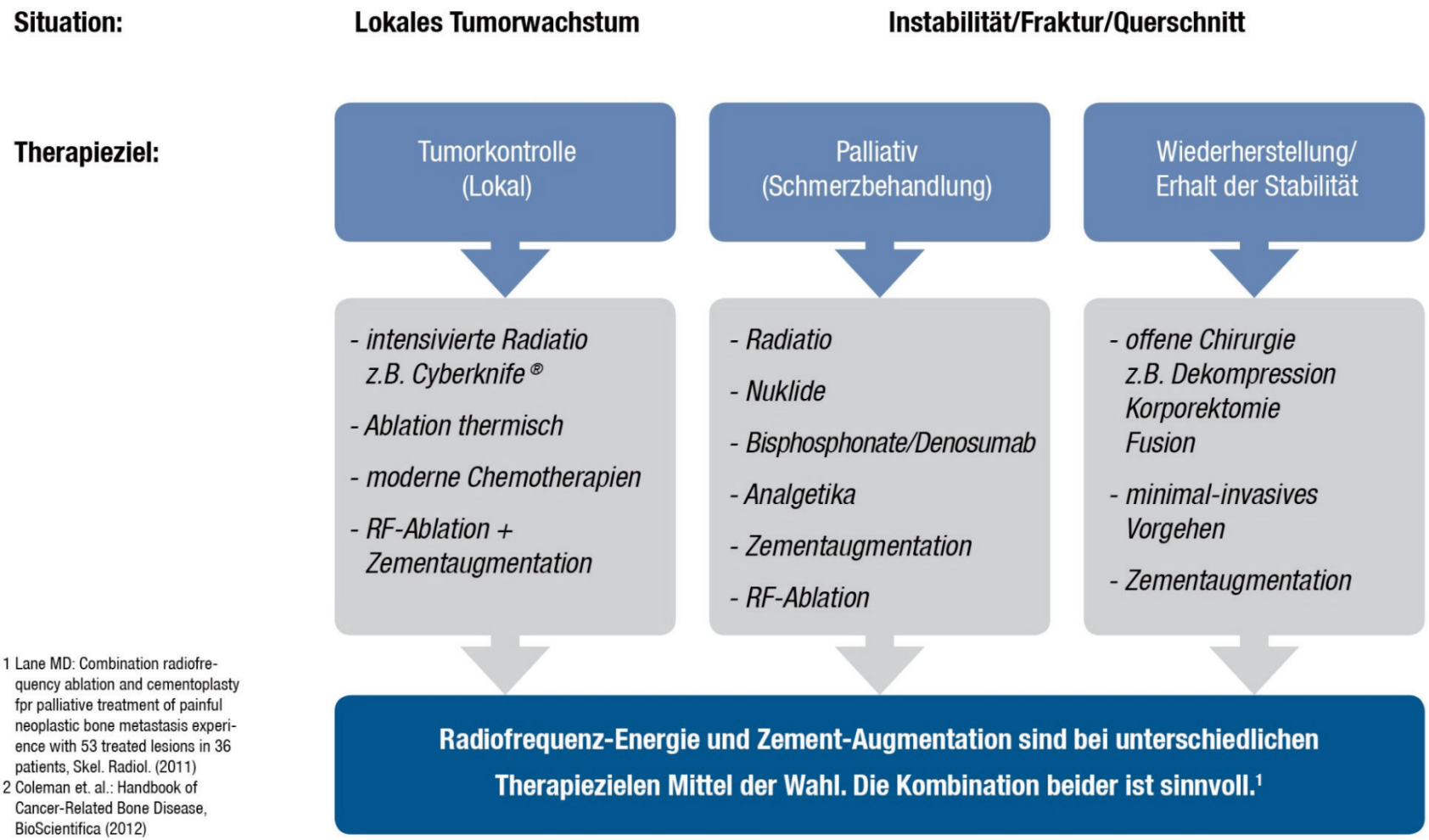
Charakteristika

Art und Vorkommen der Läsion	Anzahl der Fälle	Prozentuales Auftreten
Osteoblastisch	45	8,0%
Osteolytisch	**399**	**70,9%**
Mischtypen	**119**	**21,1%**
1 Wirbelkörper betroffen	77	13,4%
> 1 Wirbelkörper betroffen	**486**	**86,3%**
Läsion des gesamten Wirbels	81	14,4%
Läsion des Wirbelkörpers	252	44,8%
Läsion des posterioren Wirbelbogens	228	40,5%

Metastasen der Wirbelsäule sind häufig osteolytischer Natur und betreffen mehrere Wirbelkörper. Ausgewertet wurden 600 Fälle von Wirbelkörpermetastasen, wovon 563 charakteristische Merkmal von Knochenläsionen auswiesen. Hierbei wurde nach klinischen Gesichtspunkten, dem Typus des Primärtumors, Läsionsort und Überlebensrate analysiert. Behandelt wurden bis auf 7 alle Patienten.

Constans, JP. et al. Spinal metastases with neurological manifestations. J. Neurosurg 1983

Magnetresonanztomographie-gesteuerte fokussierte Ultraschalltherapie?



1 Lane MD: Combination radiofrequency ablation and cementoplasty fpr palliative treatment of painful neoplastic bone metastasis experience with 53 treated lesions in 36 patients, Skel. Radiol. (2011)
2 Coleman et. al.: Handbook of Cancer-Related Bone Disease, BioScientifica (2012)

NCCN Guidelines Version 2.2016
Adult Cancer Pain

NCCN Principles of Cancer Pain Management [1]	Targeted tumor ablation supports NCCN Principles [2,3]
There is increasing evidence in oncology that **survival is linked to symptom control and that pain management contributes to broad quality-of-life improvement.** To maximize patient outcomes, pain management is an essential part of oncologic management.	t-RFA provides clinically significant pain relief to patients suffering from metastatic spinal lesions and improves quality of life.
Goals of pain management are improved comfort, function, and **safety**.	t-RFA is a safe and effective treatment option.
Prevention of expected analgesic side effects… is key to effective pain treatment.	Over 50% of those treated with t-RFA decreased usage of pain medications.[2]

Interventional Strategies recognized by NCCN for local bone pain include:

- *vertebral augmentation*
- *vertebroplasty*
- *radiofrequency ablation*

National Comprehensive Cancer Network. Adult Cancer Pain (Version 2.2016)
AnchalaPR et al. Pain Physician 2014; 17:317-327
Bagla S et al. Cardiovasc Intervent Radiol 2016 v39 p1289-1297

Was ist das Ziel?

„Debulk“/Komplettablation der RF

Stabilisation des WK

Minimimal invasives Vorgehen

Lokale Tumorkontrolle

Schmerzreduktion

ASCO 2013 Annual Mtg. J ClinOncol31, 2013, (Suppl;Abstr10585)

STAR Ablation

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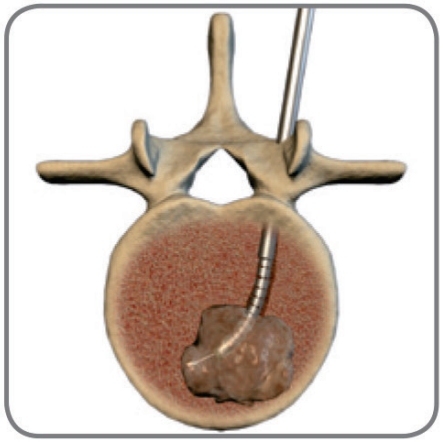
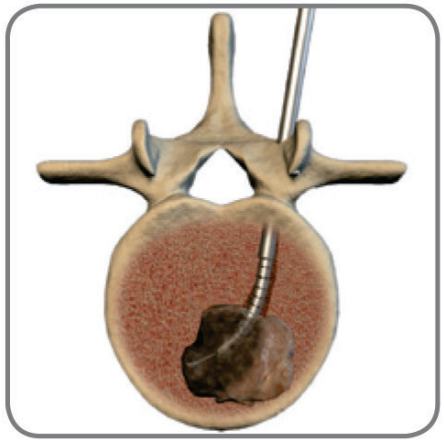
Das SpineSTAR™ Ablationsinstrument, eine Komponente des STAR™ Systems, ist ein kleines, navigierbares Gerät, das in den Wirbelkörper eingeführt wird, um gezielt RF-Energie in den Tumor abzugeben.

RF-Energie erhitzt und zerstört metastatische Tumorzellen, während Temperatursensoren innerhalb des SpineSTAR™ die Temperatur kontinuierlich messen und anzeigen, um das Risiko für den Patienten so gering wie möglich zu halten.



Platzierung der Ablationselektrode



Abgabe von Radiofrequenz-Energie

Abladierter Tumor im Wlrbelkörper

Zementauffüllung

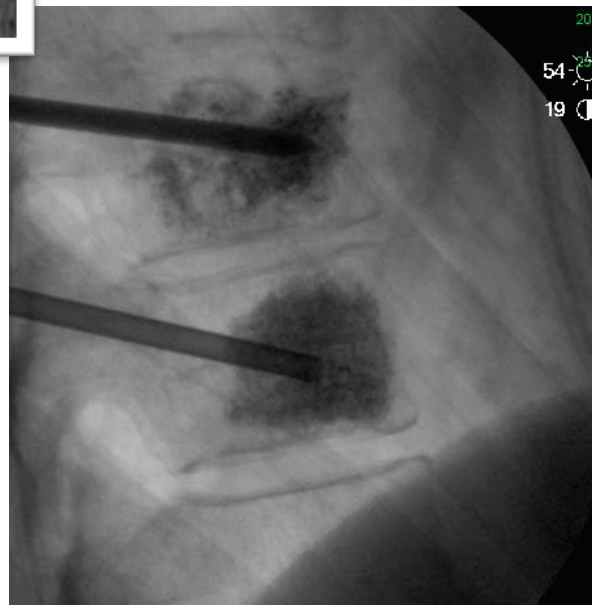
Quelle: Merit Medical (Dfine, Mannheim, Germany)

Warum nicht nur Zement?

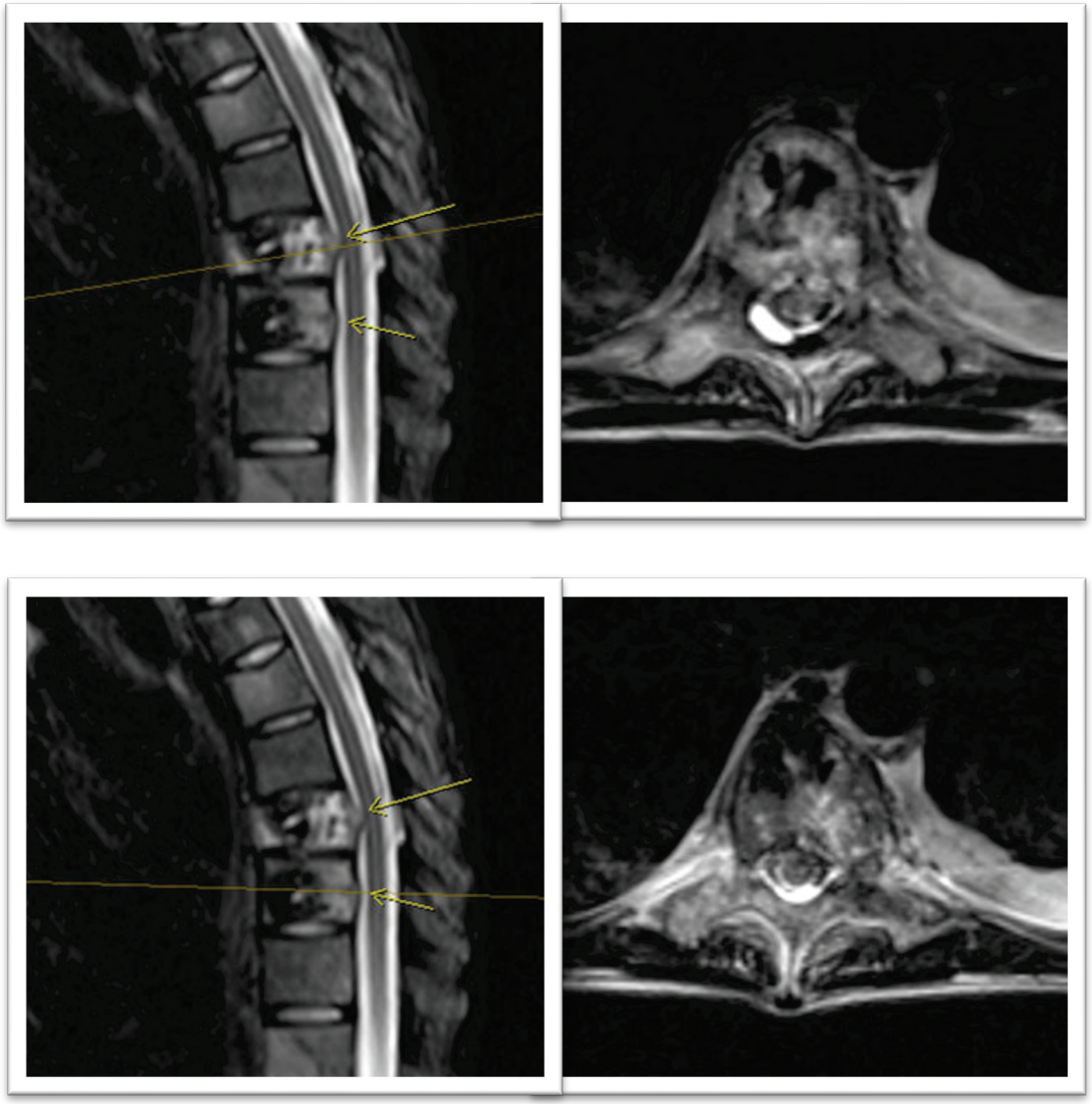
- Keine komplette Auffüllung des Wirbelkörpers möglich um dem Tumor die Basis für weiteres Wachstum zu entziehen
- Zementmasse verdrängt Tumormasse (Archimedes)

1 P. C. Gerszten and E. A. Monaco, "Complete percutaneous treatment of vertebral body tumors…," Neurosurg Focus 27 (6) : E9 (2009)

2 Anselmetti GC: Temperature Measurement during polymerization of bone cement in percutaneous vertebroplasty, Cardiovasc Intervent Radiol (2009)


20
54
19

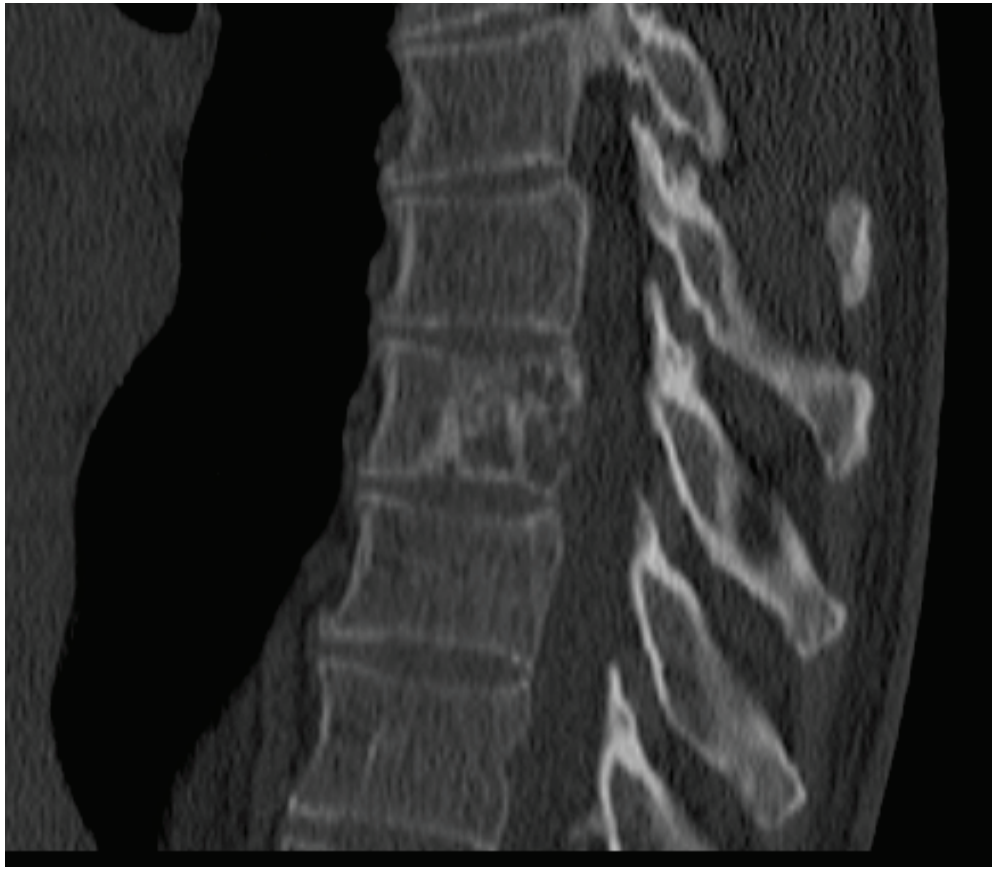
3 Monats-Kontrolle



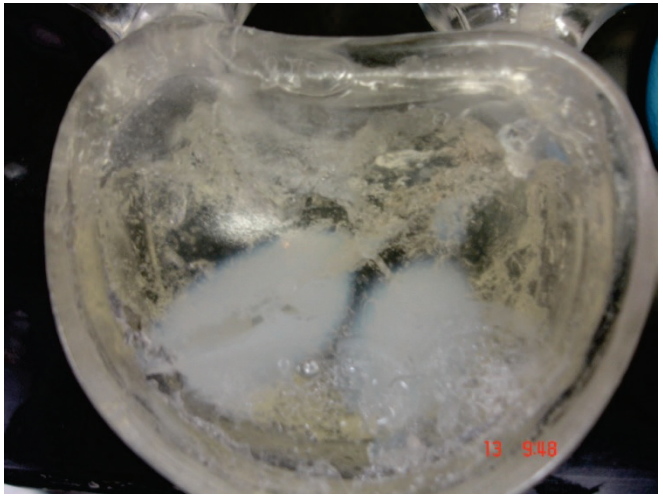
J. Jennings, M.D., St. Louis, USA: MammaCa with painfull metastases in Th10,11. Filling and stabilization with bone cement.

J. Jennings, M.D., St. Louis, USA: MammaCa with painfull metastases in Th10,11. Follow-Up after 4 months. Recurring tumor growth into the spinal canal.

RFA



RFA und Zement



MetaSTAR™ RF Generator

- Aktive Temperaturmessung
- Kontrollierte Energieabgabe
- Anzeige aller relevanten Informationen in Echtzeit

SpineSTAR™ Ablation Instrument

- Ausfahrbare, navigierbare Elektrode ermöglicht unipedikulären Zugang und Schaffung multipler Ablationszonen
- Bipolares Design

Markierung am Thermoelement

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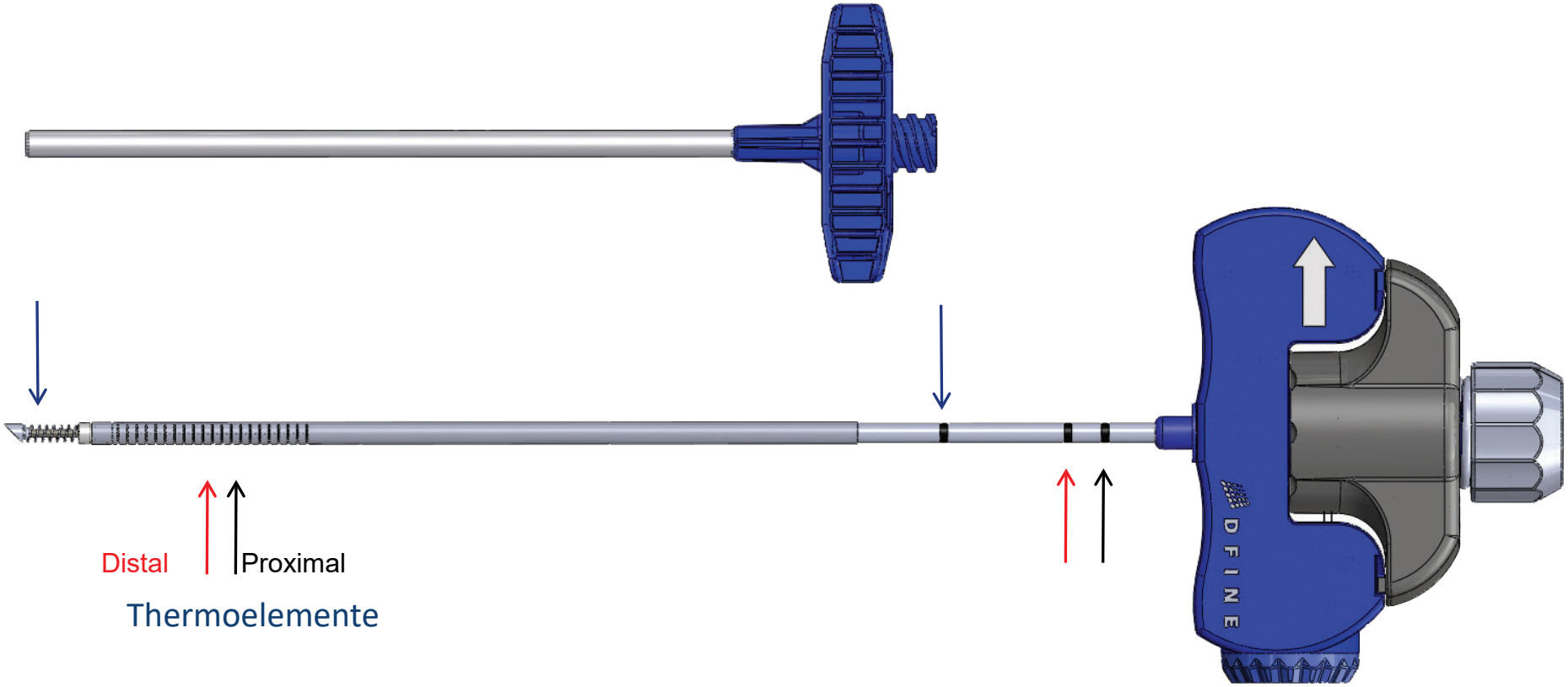
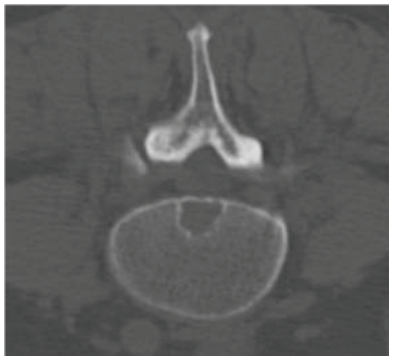
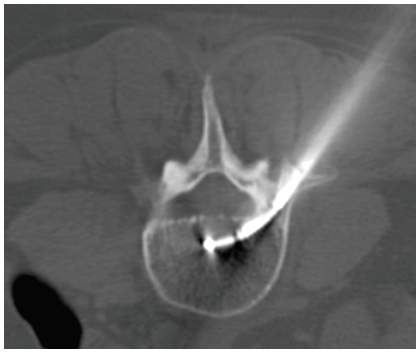
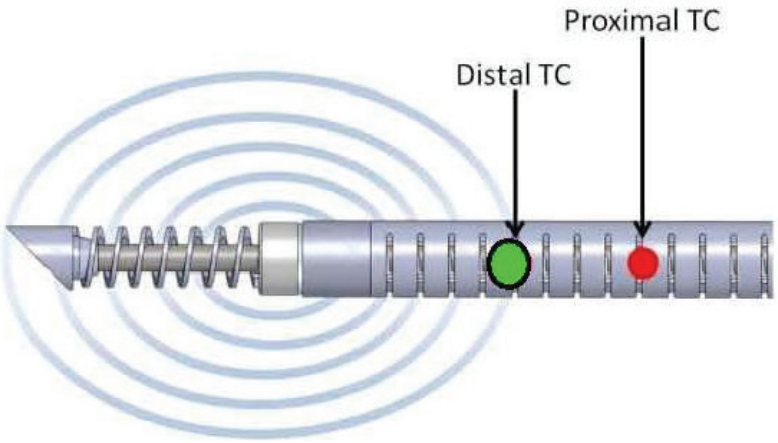
1. distales Ende der Arbeitskanüle
2. distales TE nach dem Ende der AK
3. proximales TE nach dem Ende der AK

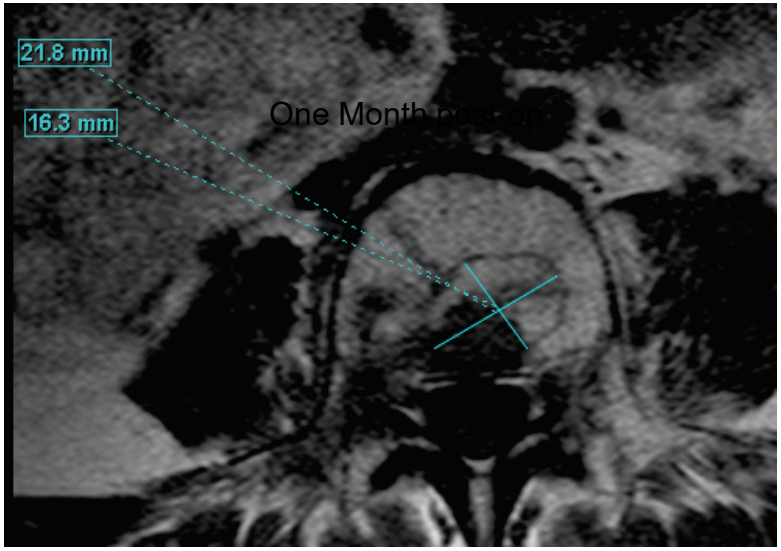


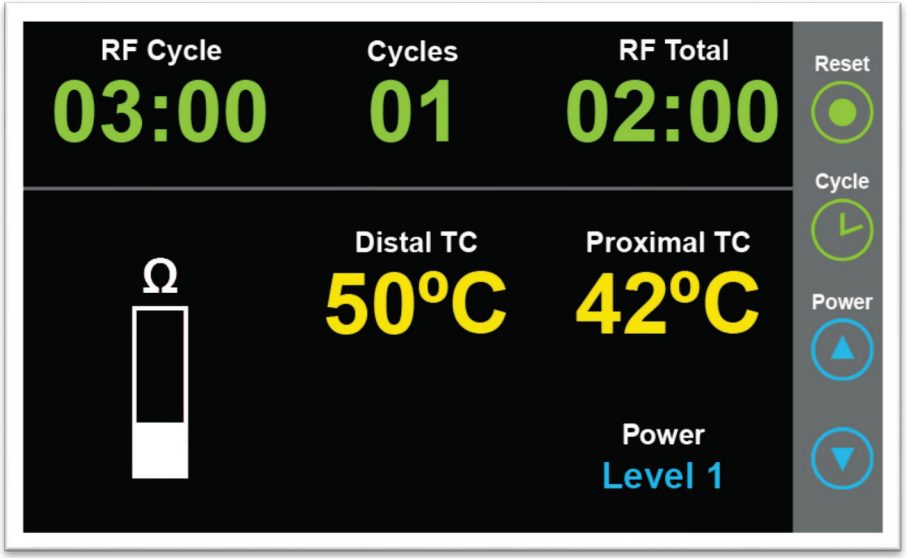
Quelle: Merit Medical (Dfine, Mannheim, Germany)











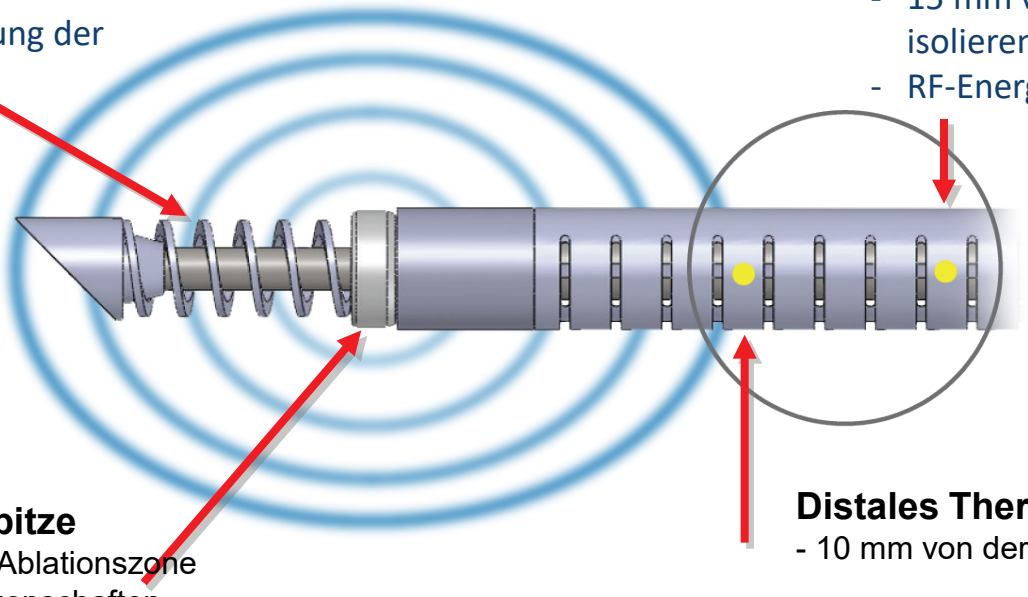
Quelle: Merit Medical (Dfine, Mannheim, Germany)

Aktive Navigation ermöglicht die Festlegung situsspezifischer Ablationszonen im gesamten Wirbelkörper über einen monopedikulären Zugang

Temperaturüberwachung in Echtzeit: zur Abschätzung der Wärmeausbreitung und als intraoperative Entscheidungshilfe

Aktive Ablationselektrode
- Schräge Spitze - für die Navigation im Knochen
- Ausfahrbar zur Erweiterung der Ablationszone

Proximales Thermoelement
- 15 mm von der isolierenden Spitze
- RF-Energie stoppt bei 50 ºC



Gelenkiges Segment
- Navigation im Knochen

Isolierende Spitze
- Mittelpunkt der Ablationszone
- Für bipolare Eigenschaften

Distales Thermoelement
- 10 mm von der isolierenden Spitze

Quelle: Merit Medical (Dfine, Mannheim, Germany)

Klinische Anwendung

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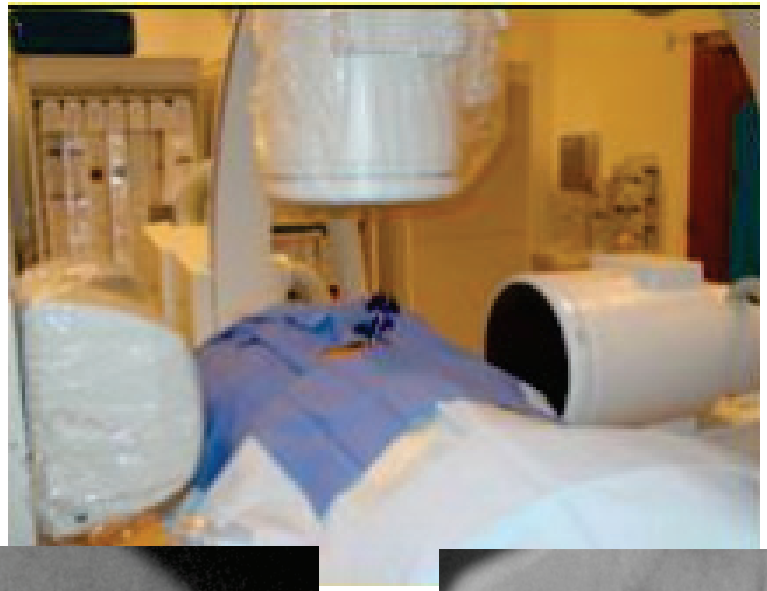
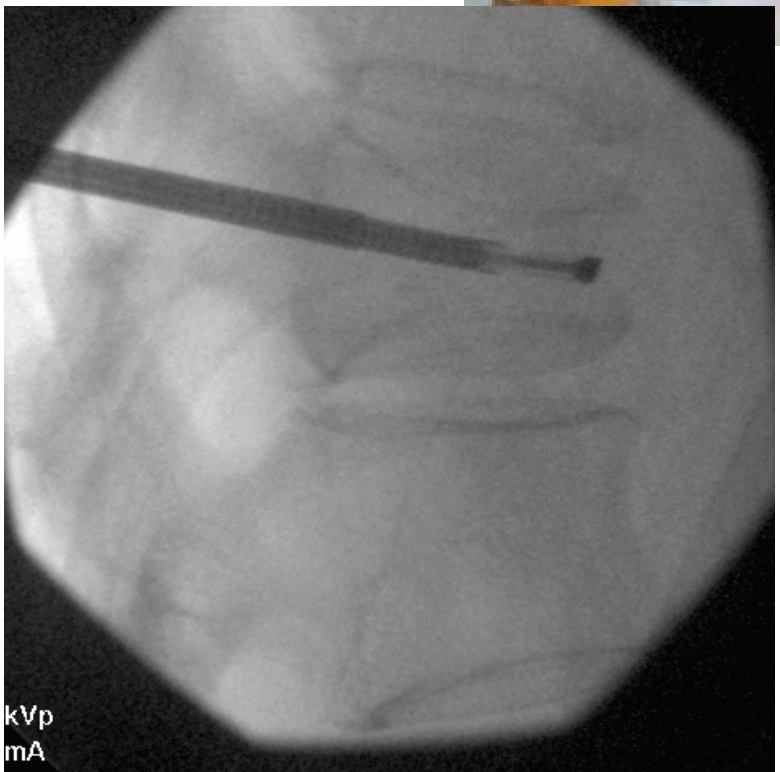
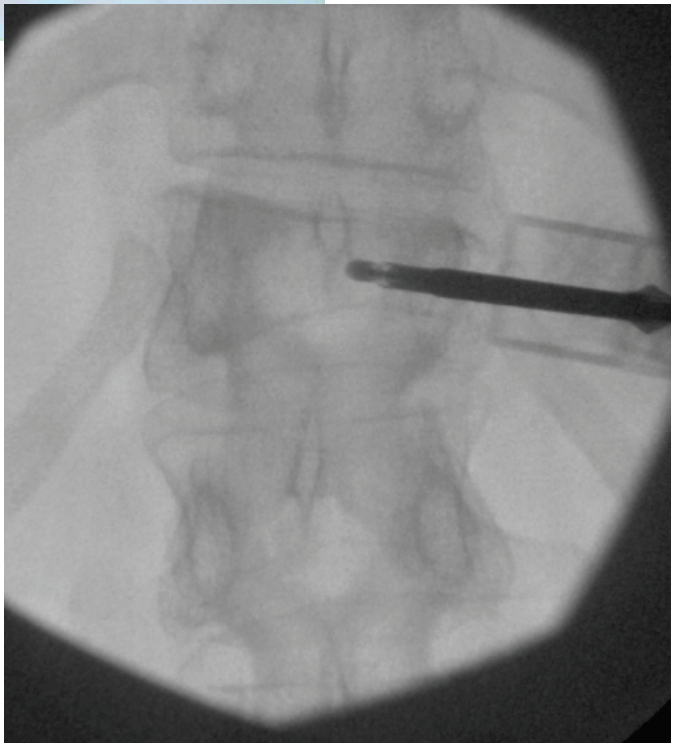
STAR Eingriffe	➢4.000
Behandelte Läsionen	> 5.000 Läsionen in >700 Zentren
Läsionsort	T2 - L5, sacrum, ilium, acetabulum, sternum, rib, femur, tibia
Art des Tumors	Breast, Lung, Lymphoma, Myeloma, Colon, Leiomyosarcoma, Renal cell, Epithelioid hemangioendothelioma, Liposarcoma, Liver-HCC, Pancreas, Prostate, Thyroid, Bladder, Melanoma, Osteoid osteoma, Squamous cell carcinoma
# of Ablationen /level	1- 5 Ablationszonen
Total Ablation Time*	1:00 – 20:00 minutes (ø = 6 min)
Zugangsart	> 95% Unilateral
Augmentation	>98%
Klinische Resultate	Signifikante Schmerzreduktion bei allen Patienten. Keine Komplikationen. VAS reported in two series at SIR 2013: • Ryu: 8.9 pre - 2.7 @ 4d post • Jennings: 7.0 pre - 3.1 @1wk, 1.75 @6mo post

Quelle: Merit Medical (Dfine, Mannheim, Germany)

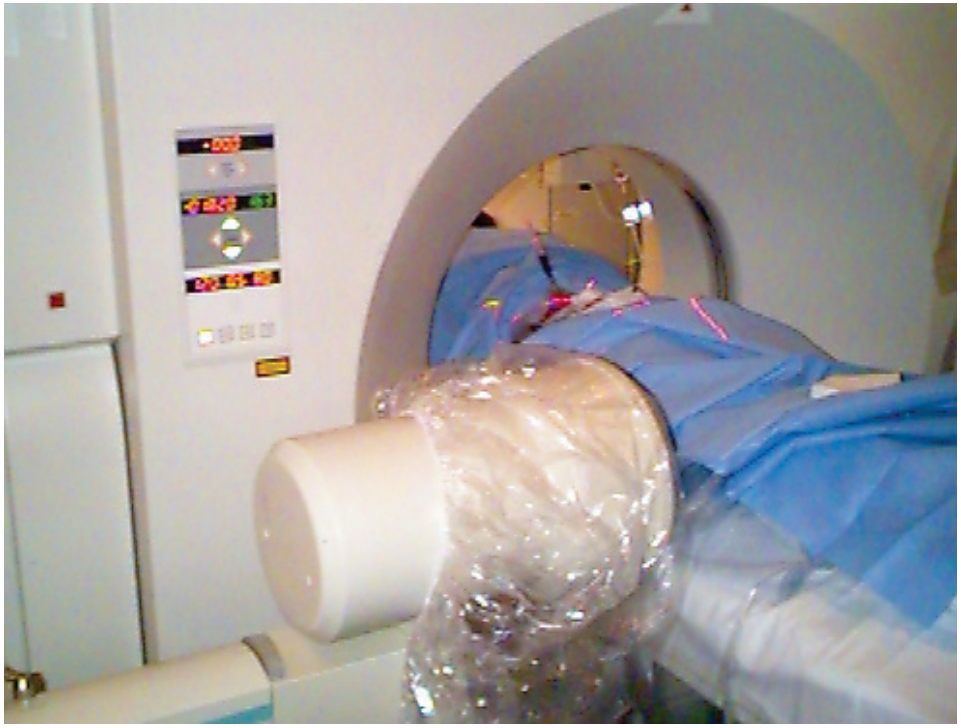



kVp
mA



Aufbau

Durchführung der mittels einer Kombination aus Durchleuchtung und Computertomographie



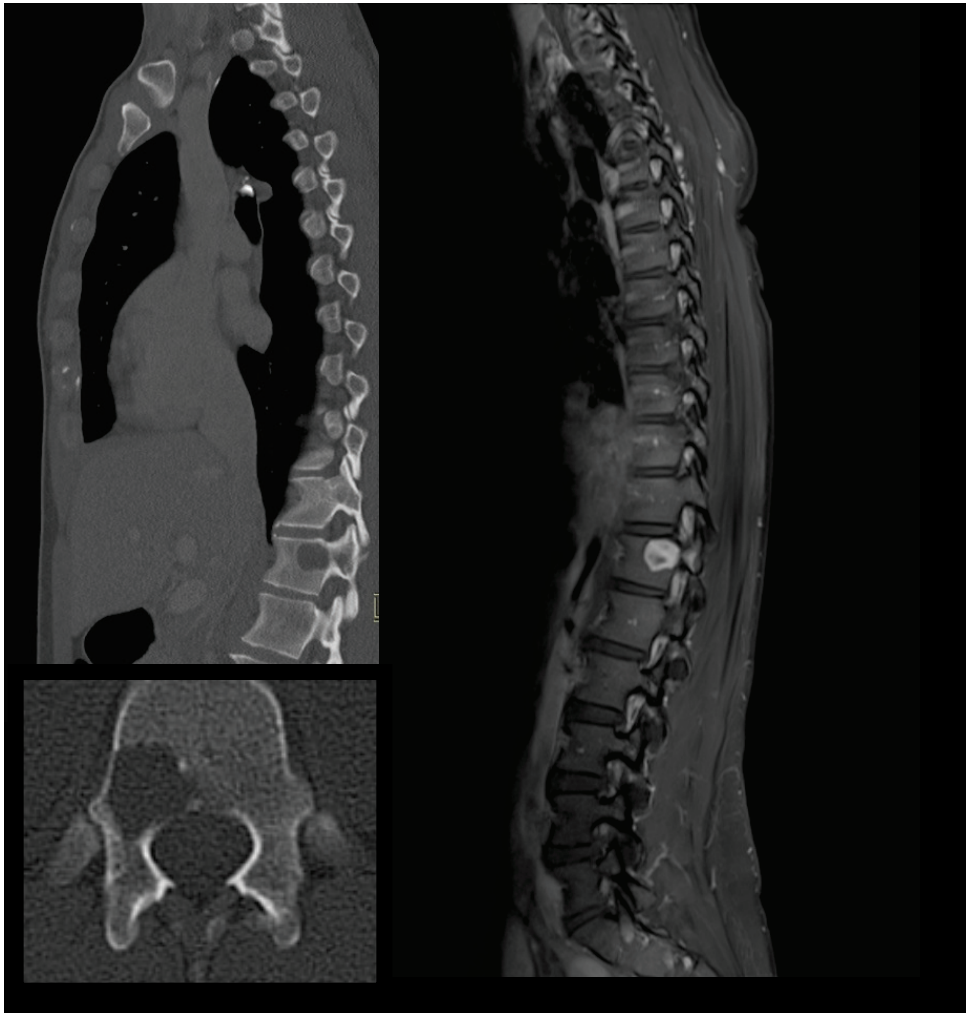
<u>Vorteil:</u>
Exaktere Punktion und Ablation und dann Applikation von Zement möglich

Frühzeitige Diagnostik von Leckagen

• Multizenter-Studie (Bonn, Magdeburg, Frankfurt, Strassburg)
Einschluss von 45 Patienten insgesamt

• 1-2 Wirbelkörper mit pathologischer Fraktur mit isolierter Pedikelbeteiligung ohne epidurale Beteiligung oder Kompression des Myelons mit pathologischer Fraktur.
• Knochenmetastasen, kein Osteosarkom, kein Plasmozytom.
• Ausgeschlossen sind auch Patienten, die kürzer als 2 Monate eine Strahlentherapie erhalten haben, oder bei denen eine Strahlentherapie 2 Wochen nach Ablation geplant ist.
• Lebenserwartung über 6 Monate
• Normale Ein- und Ausschlusskriterien für eine Ablation
• Schmerzwert > 4 auf einer numerischen Rating Skala.

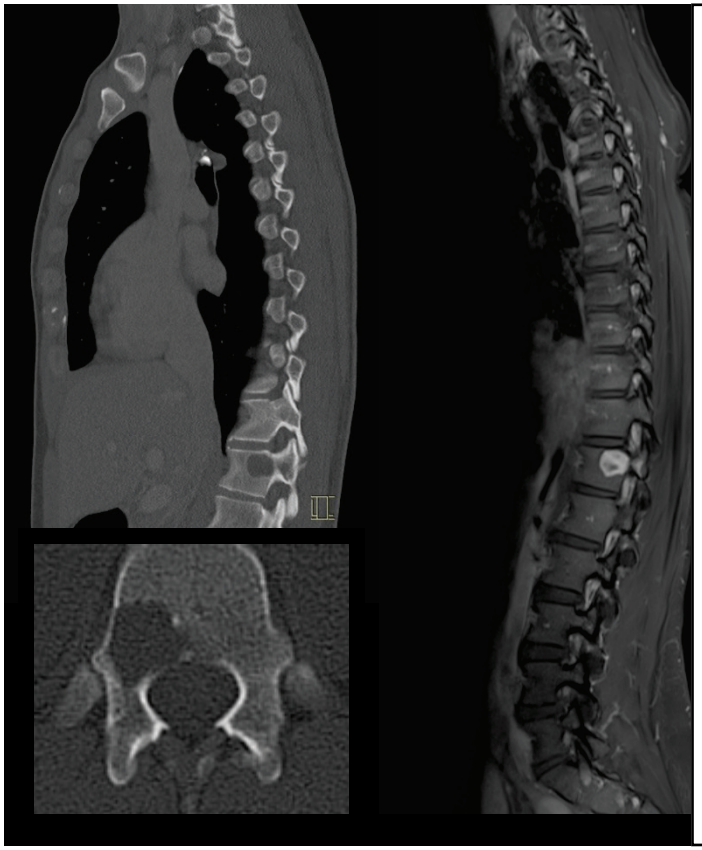
EU-STAR Ablation Case



38-jährige Patientin

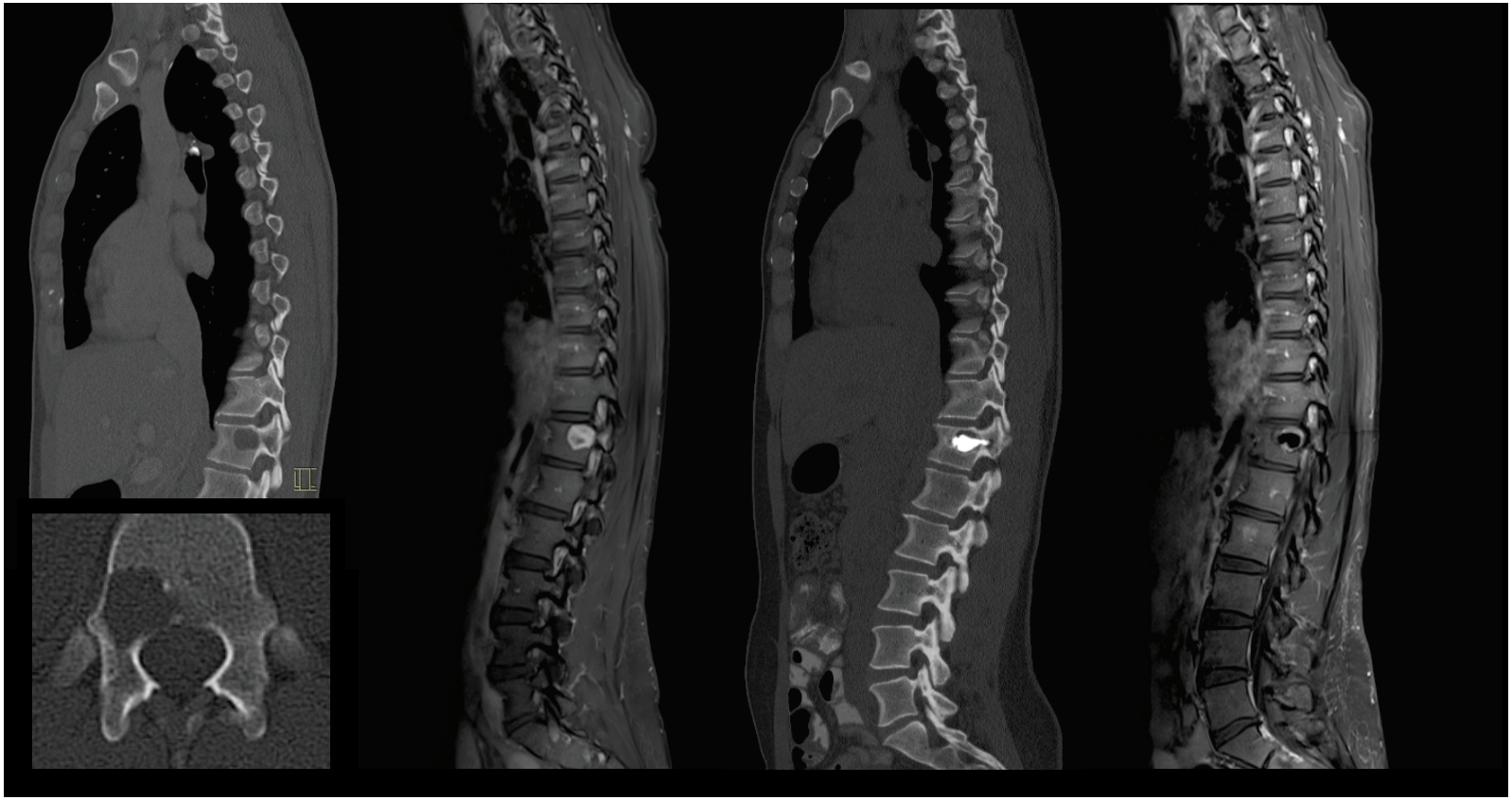
- Diagnose:
- Malignes Melanom am Rücken
- Solitäre Metastase TH12
- LK im Bereich des kleinen Beckens
- Rückenschmerz: level 4 [VAS]

EU-STAR Ablation Case: MR-imaging pre-op

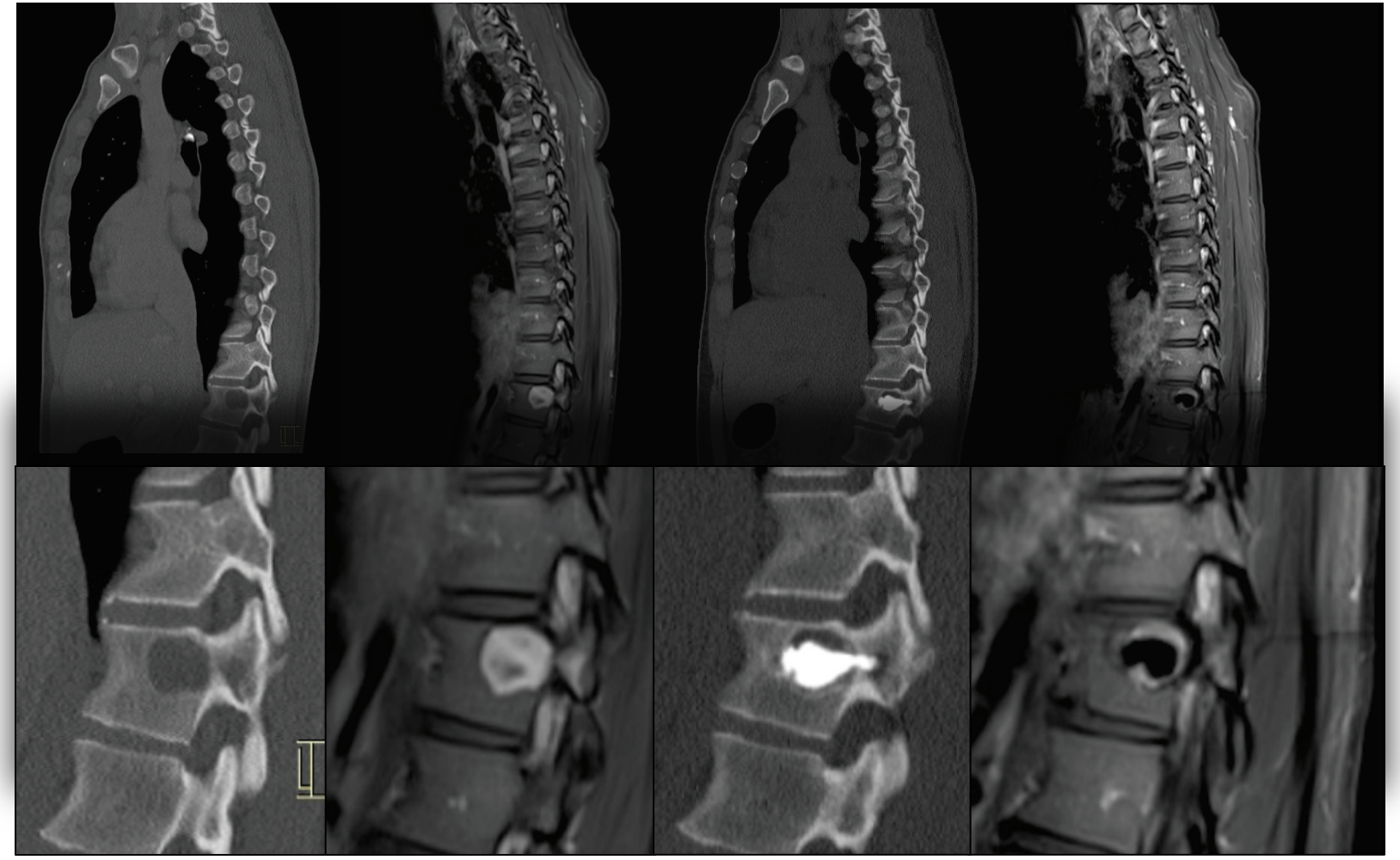


EU-STAR Ablation Case: Interventional Procedure

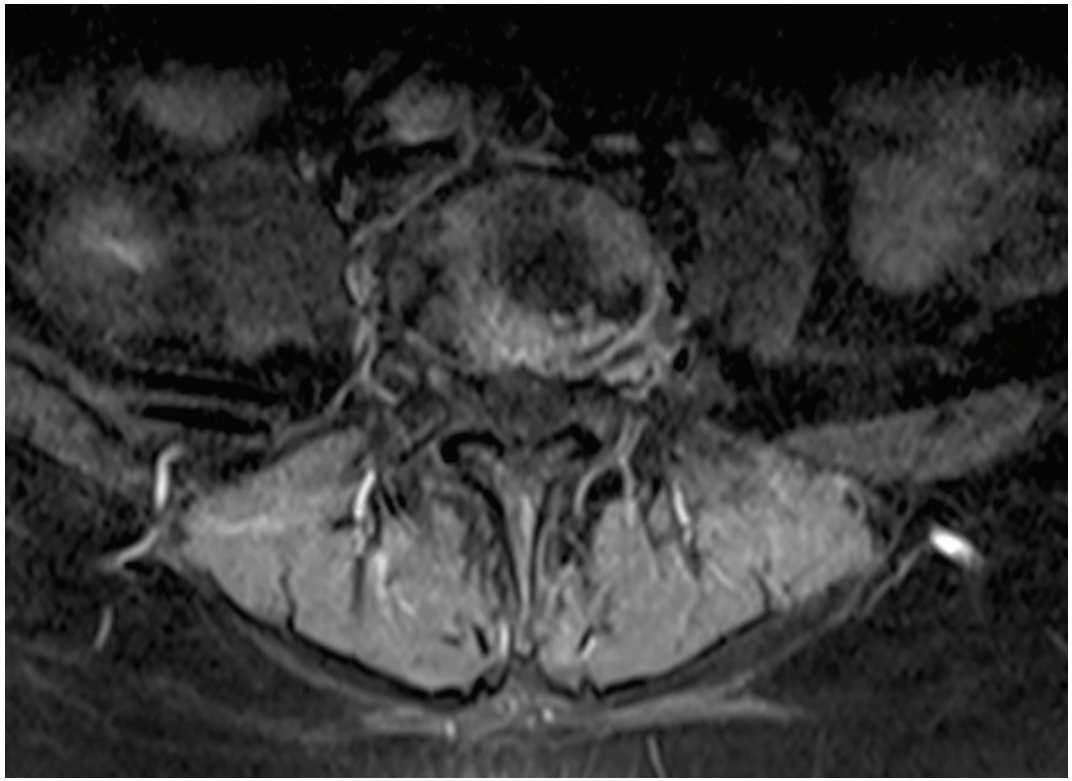
EU-STAR Ablation Case: 6 Month Follow-Up



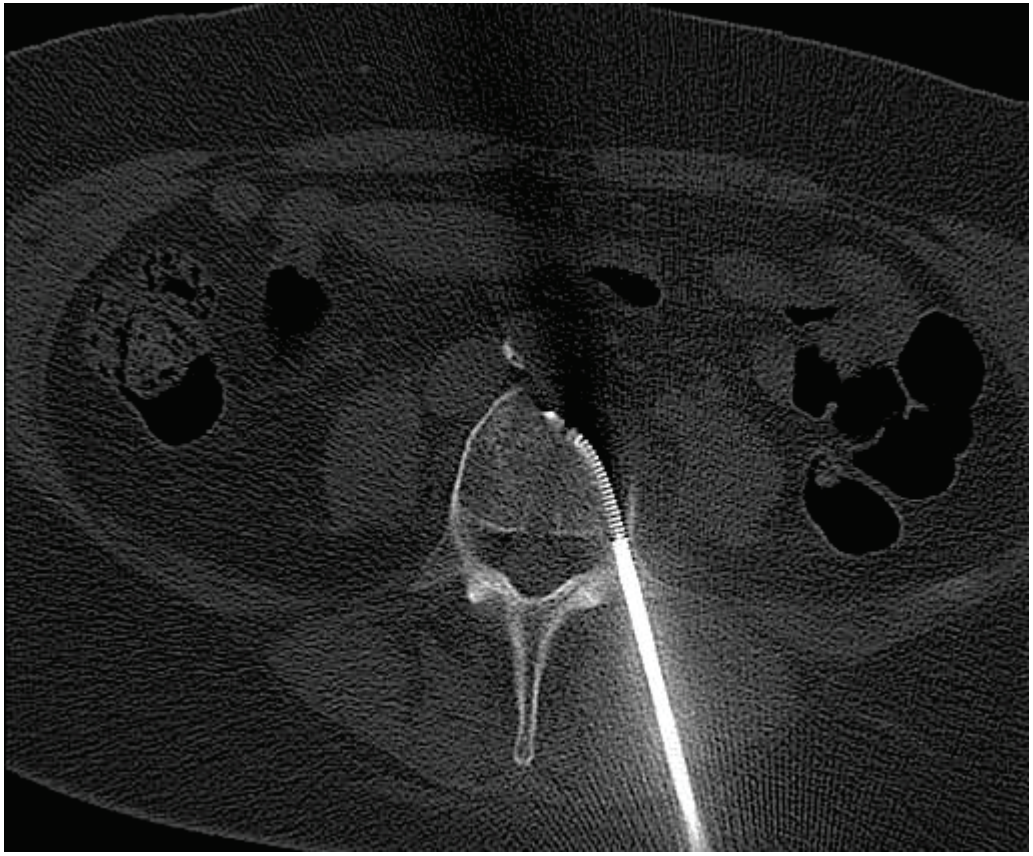
EU-STAR Ablation Case: 6 Month Follow-Up



Patientin-Nr: 2

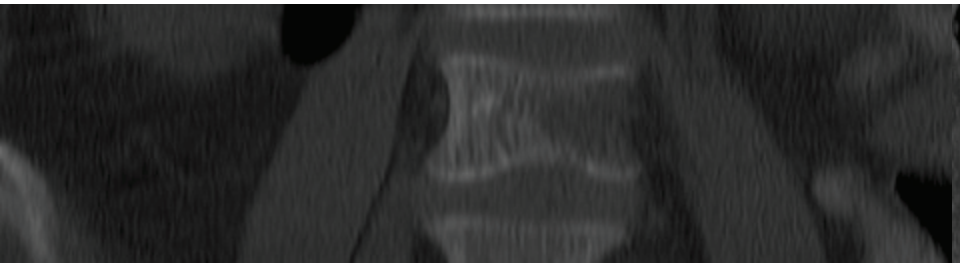
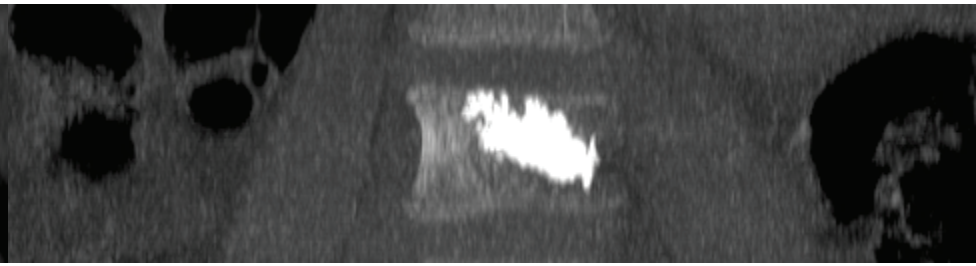
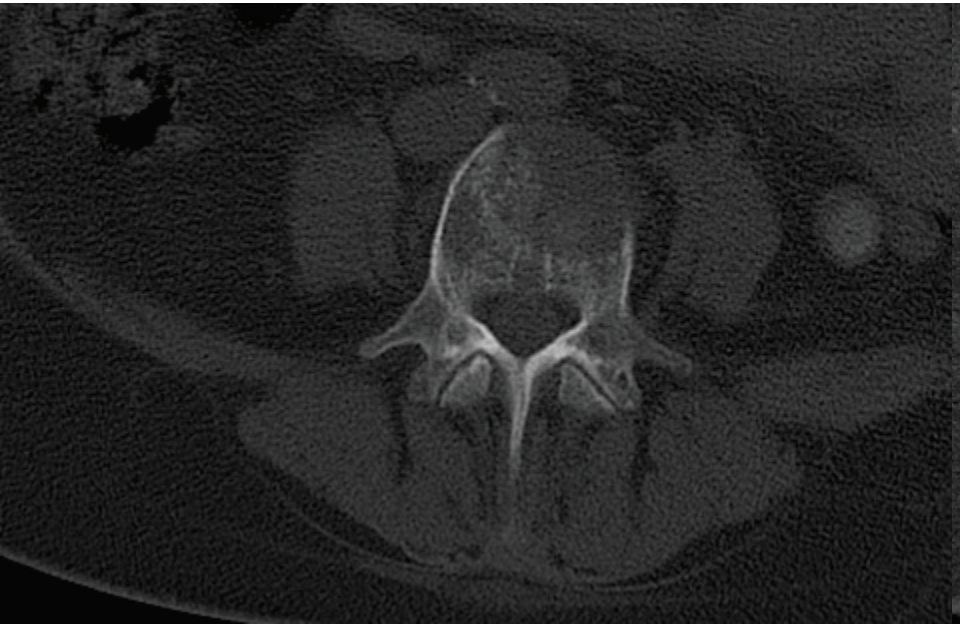
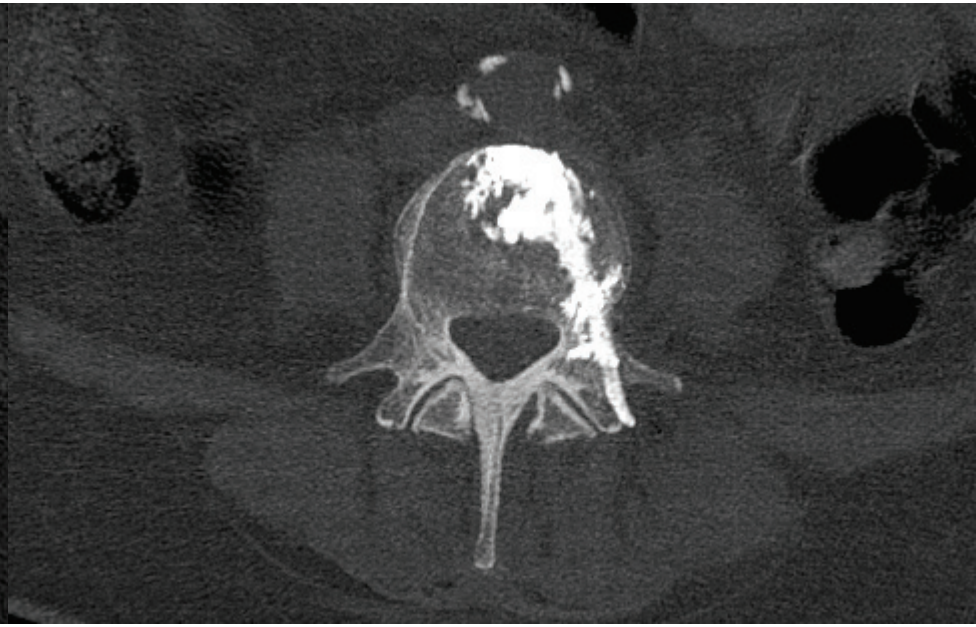
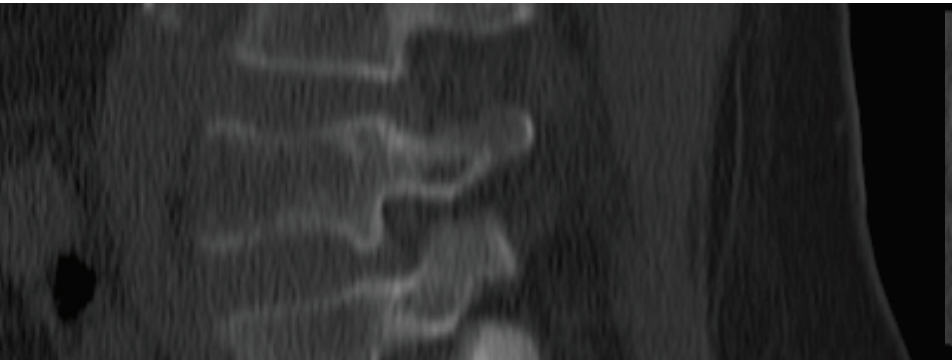
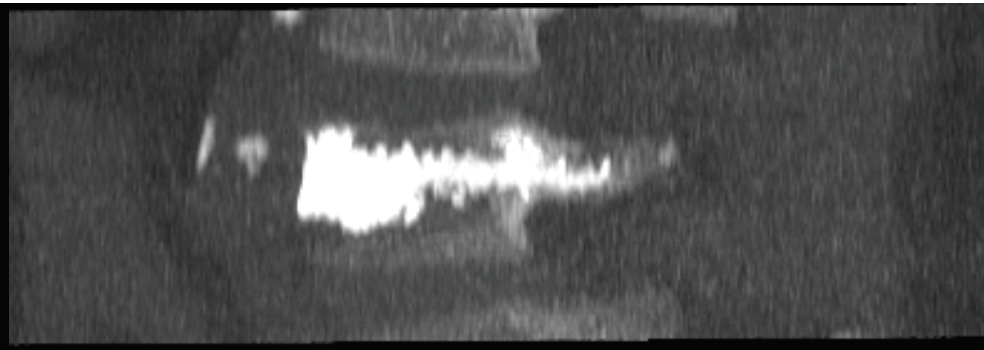


Patientin-Nr: 2

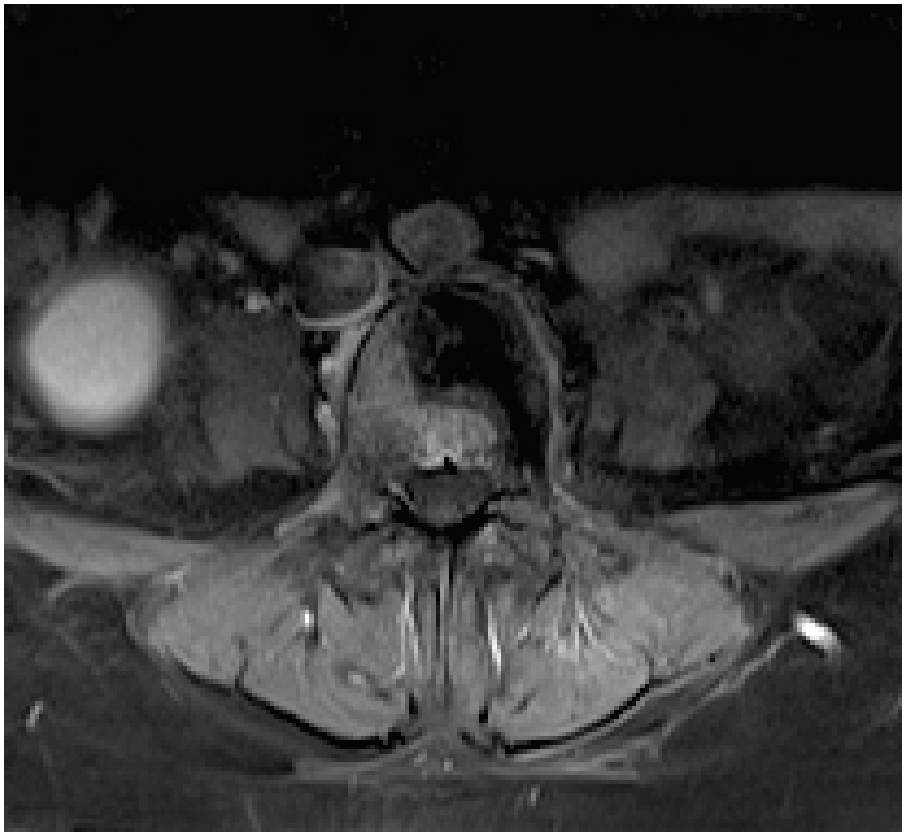


58-jährige
Patientin mit ED
Bronchial-CA,
schlechter AZ

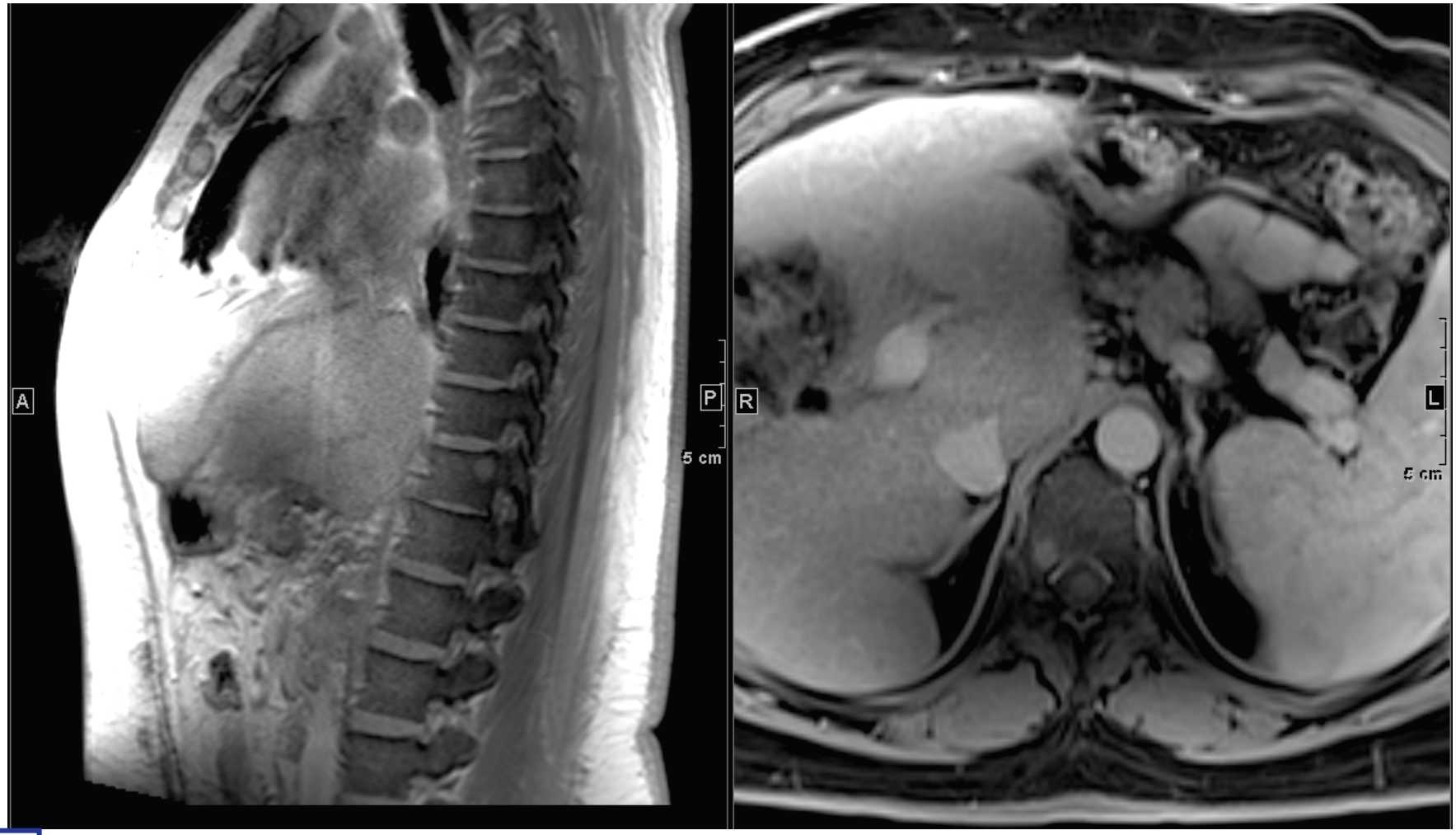
Ablation von 4:50 sec
Maximale Temp: 62°C
von 5 Watt
4 ml Zement

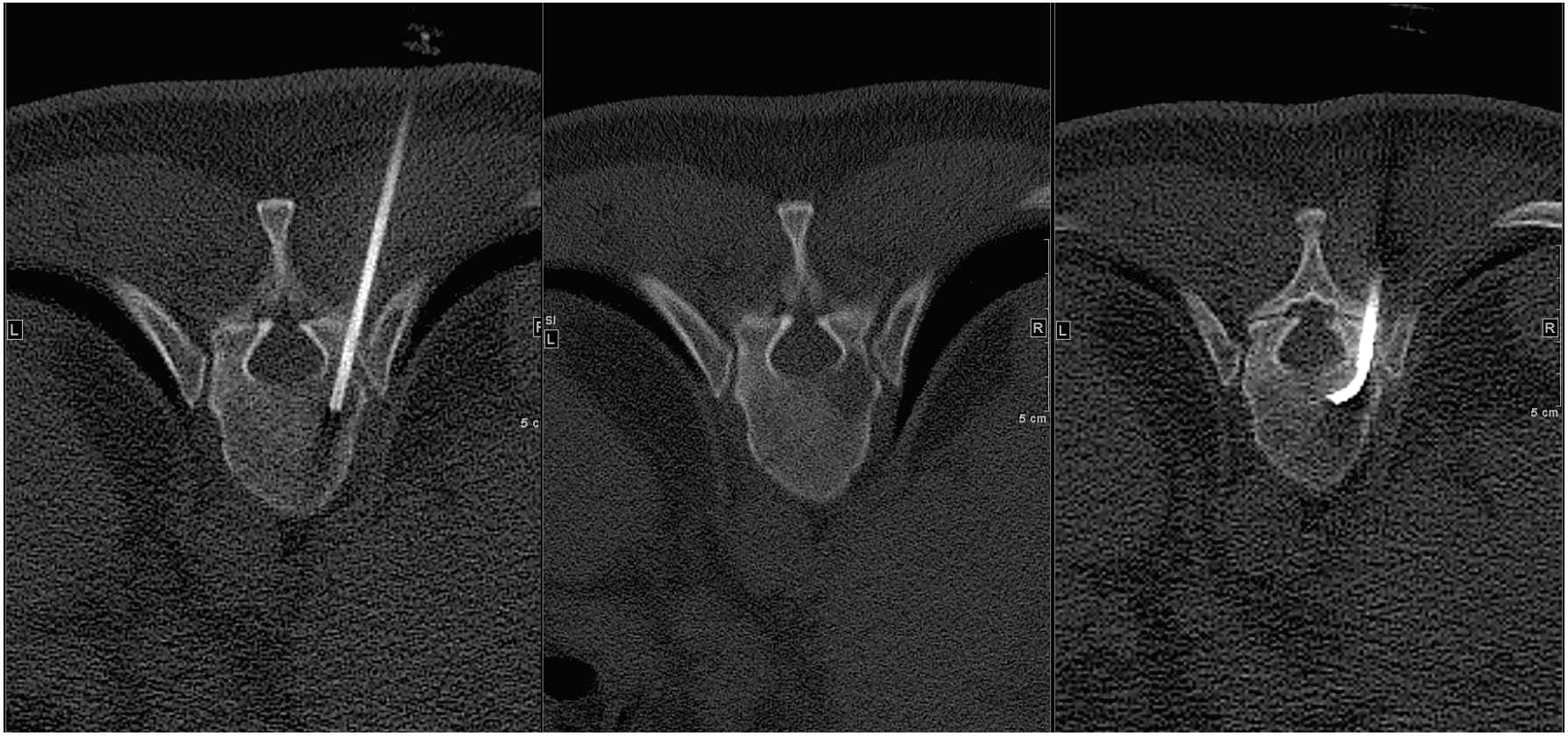







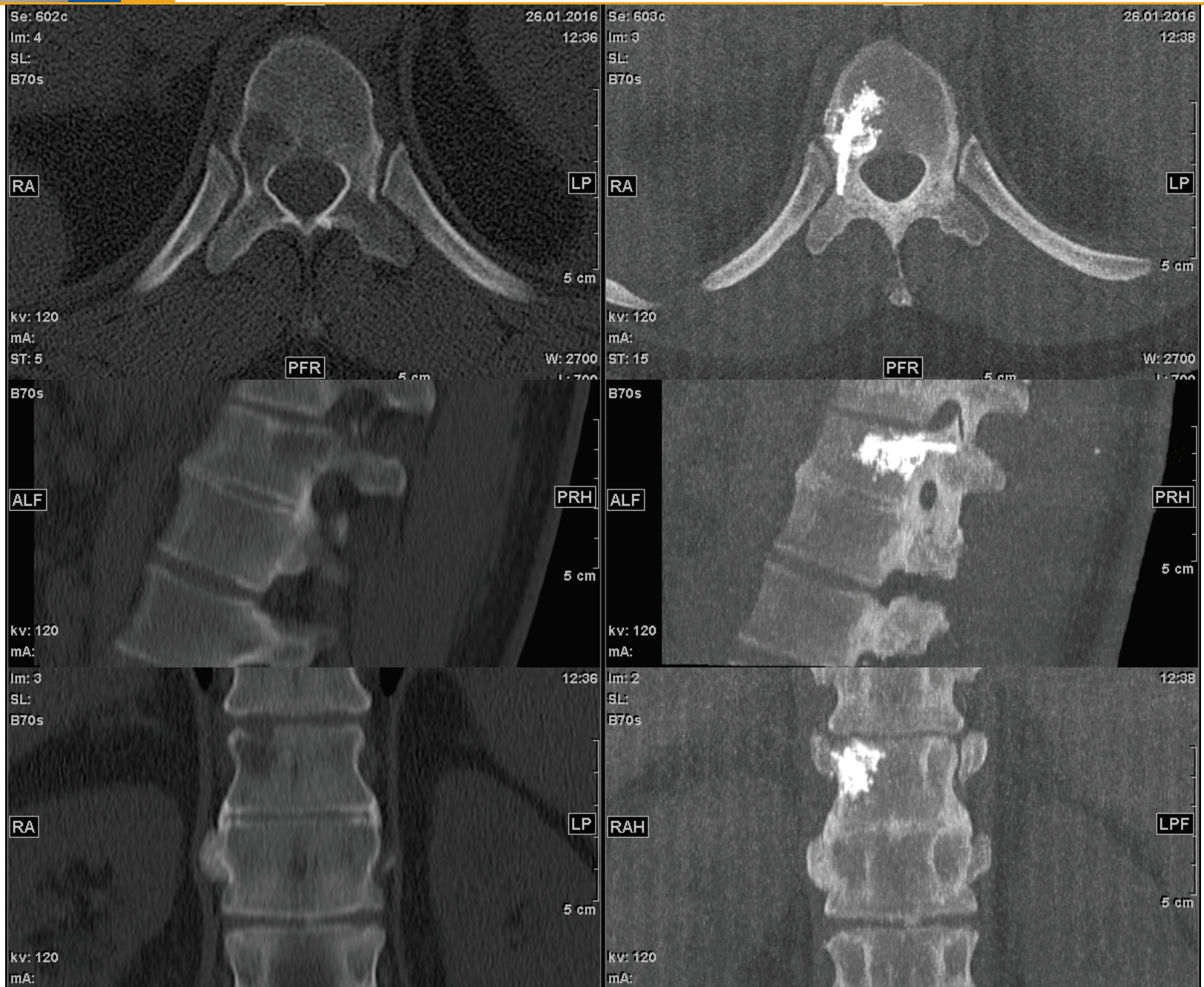
Patientin-Nr: 2



Patient-Nr. 3: 40 Jahre, histologisch gesichertes CCC




L
R
5 cm


Se: 602c
Im: 4
SL:
B70s
26.01.2016
12:36
RA
LP
5 cm
kv: 120
mA:
ST: 5
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W: 2700
Se: 603c
Im: 3
SL:
B70s
26.01.2016
12:38
RA
LP
5 cm
kv: 120
mA:
ST: 15
PFR
W: 2700
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kv: 120
mA:
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mA:
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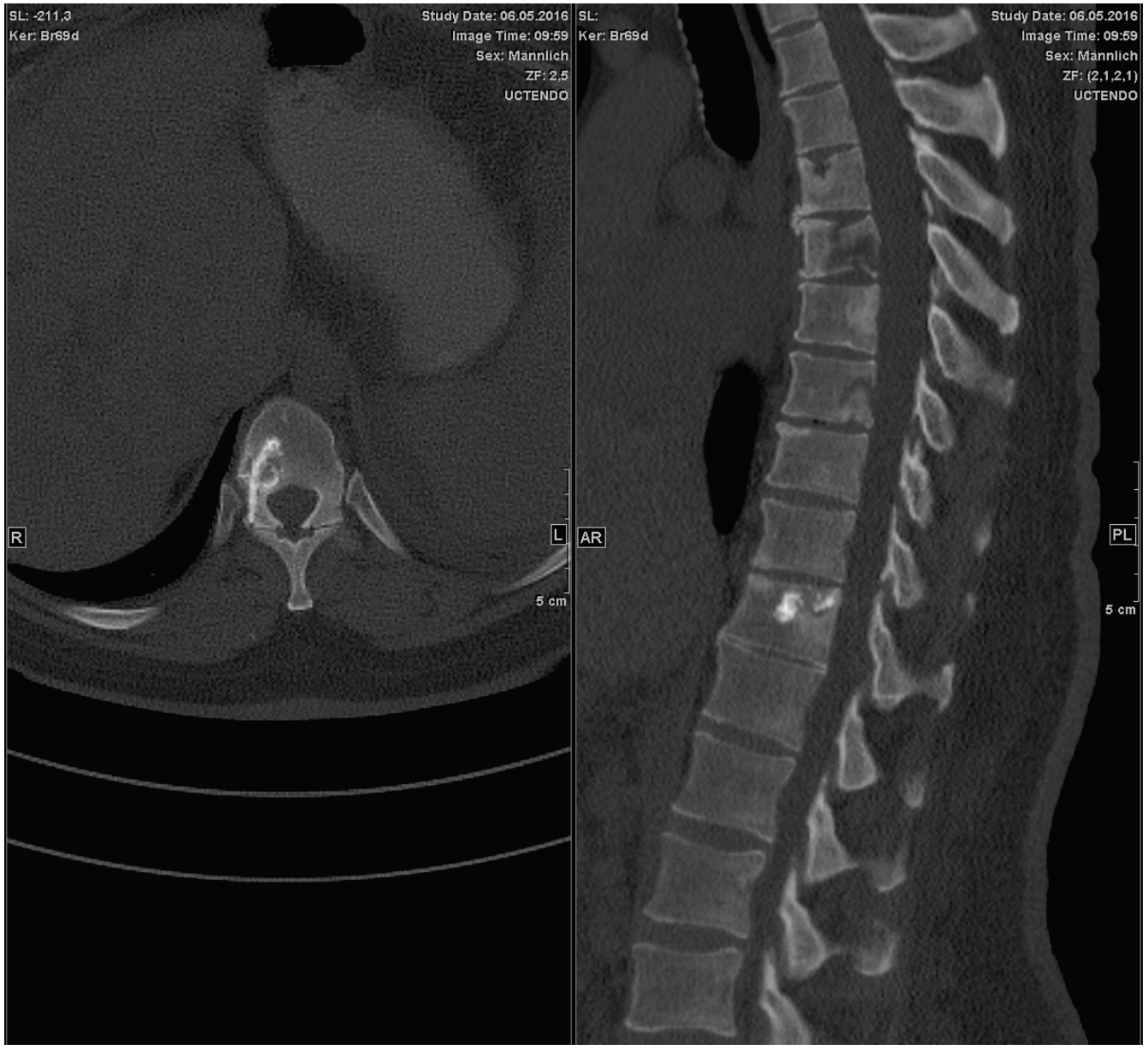
SL: -211,3
Ker: Br69d
Study Date: 06.05.2016
Image Time: 09:59
Sex: Männlich
ZF: 2,5
UCTENDO
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5 cm
SL:
Ker: Br69d
Study Date: 06.05.2016
Image Time: 09:59
Sex: Männlich
ZF: (2,1,2,1)
UCTENDO
AR
PL
5 cm

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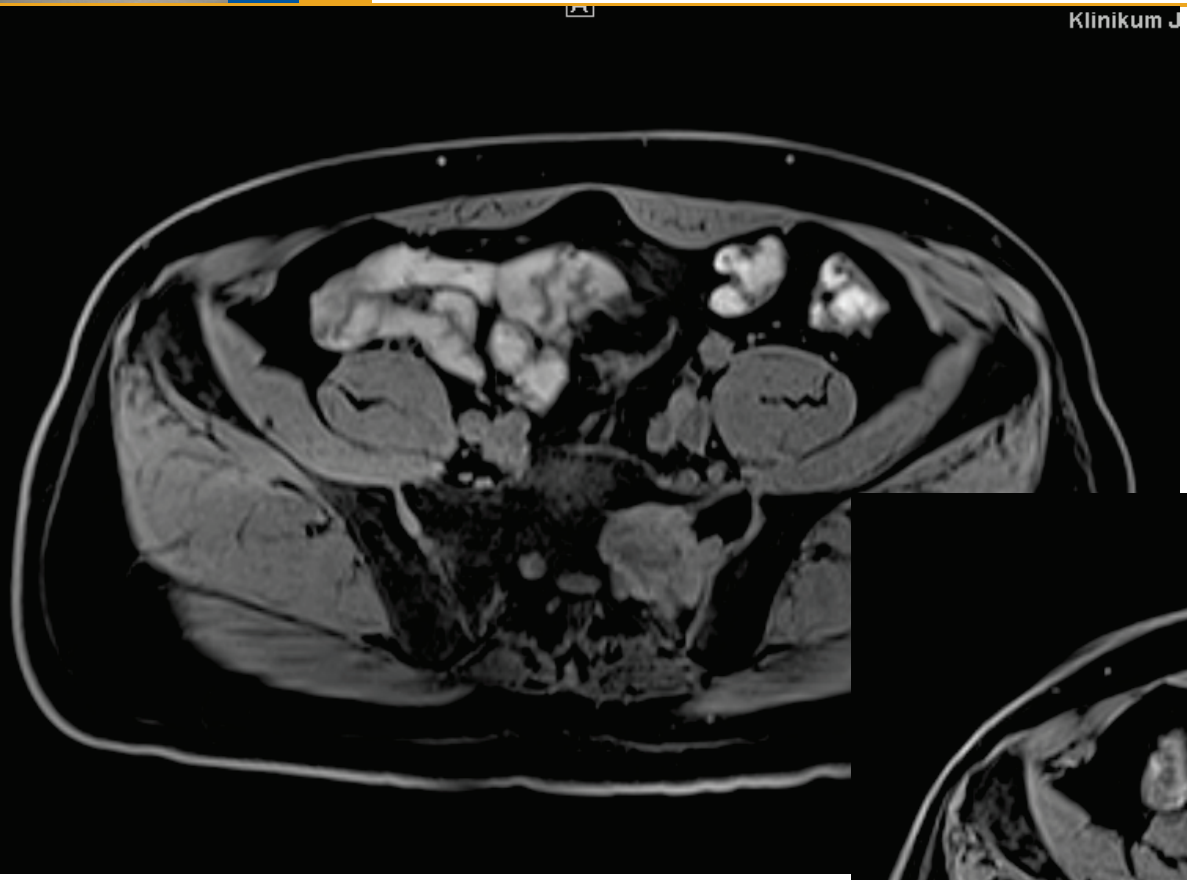
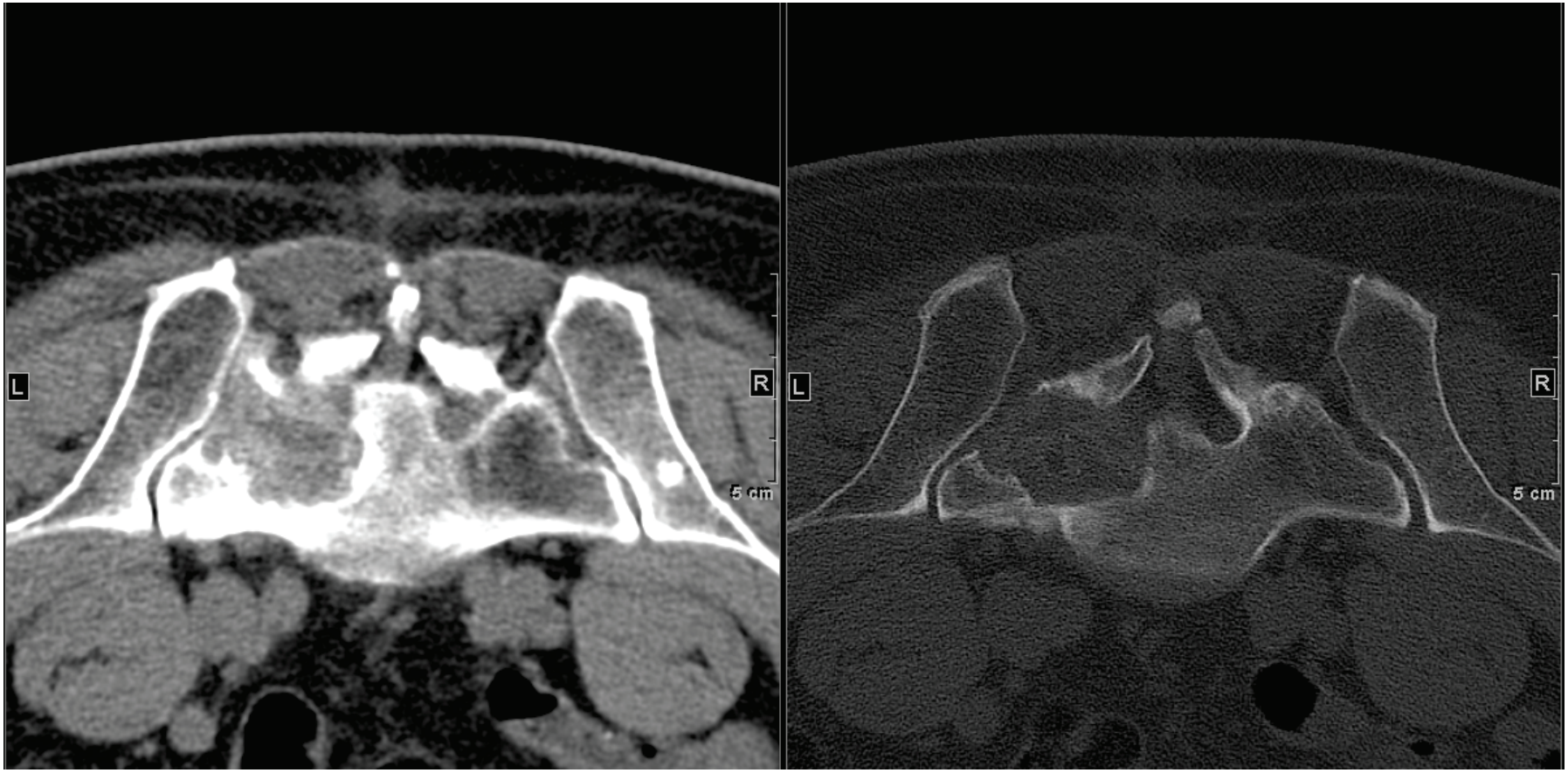


Patient mit Metastase eines Nierenzell-Karzinoms in S1 und S2, Z.n. Radiatio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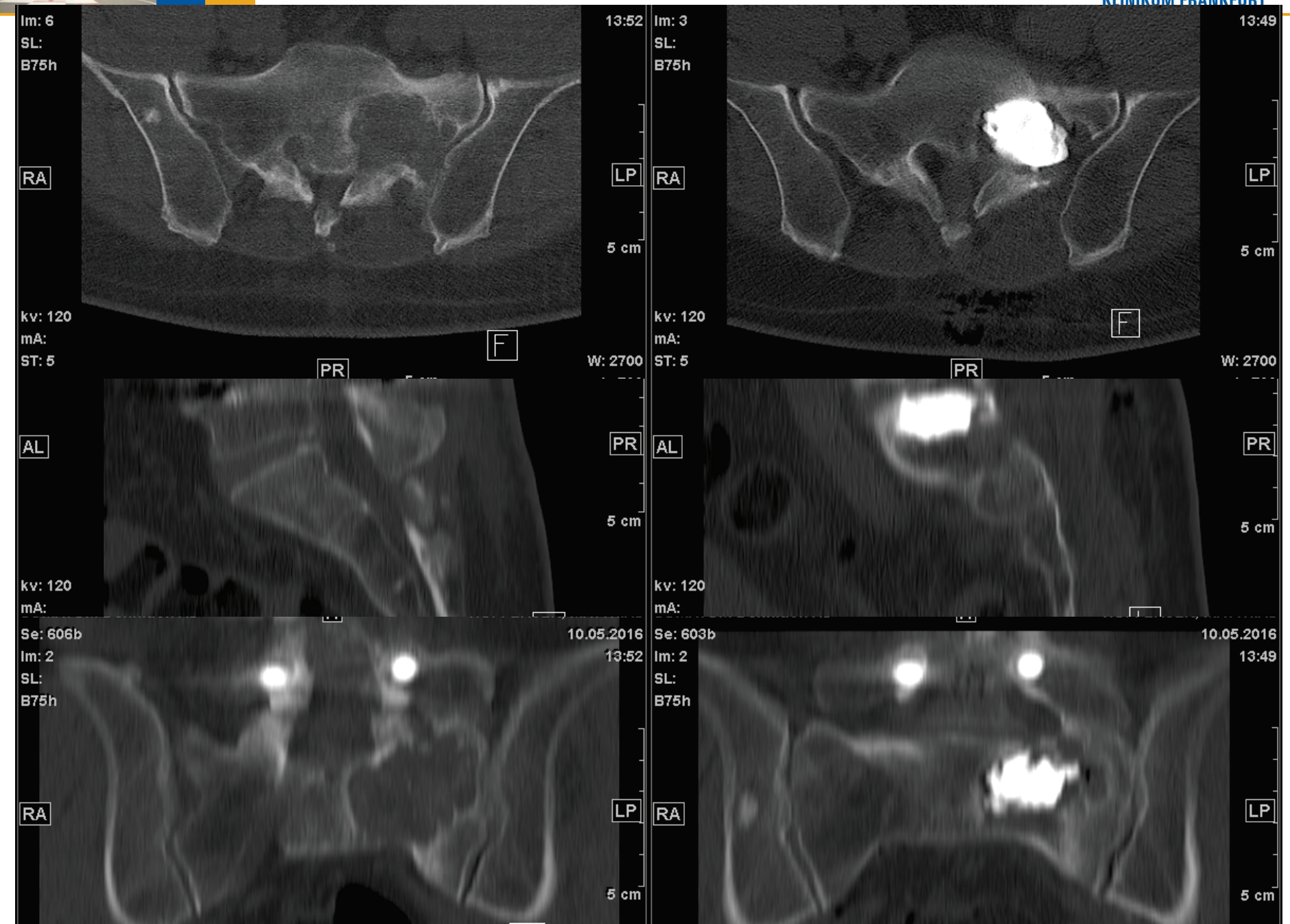
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10.05.2016
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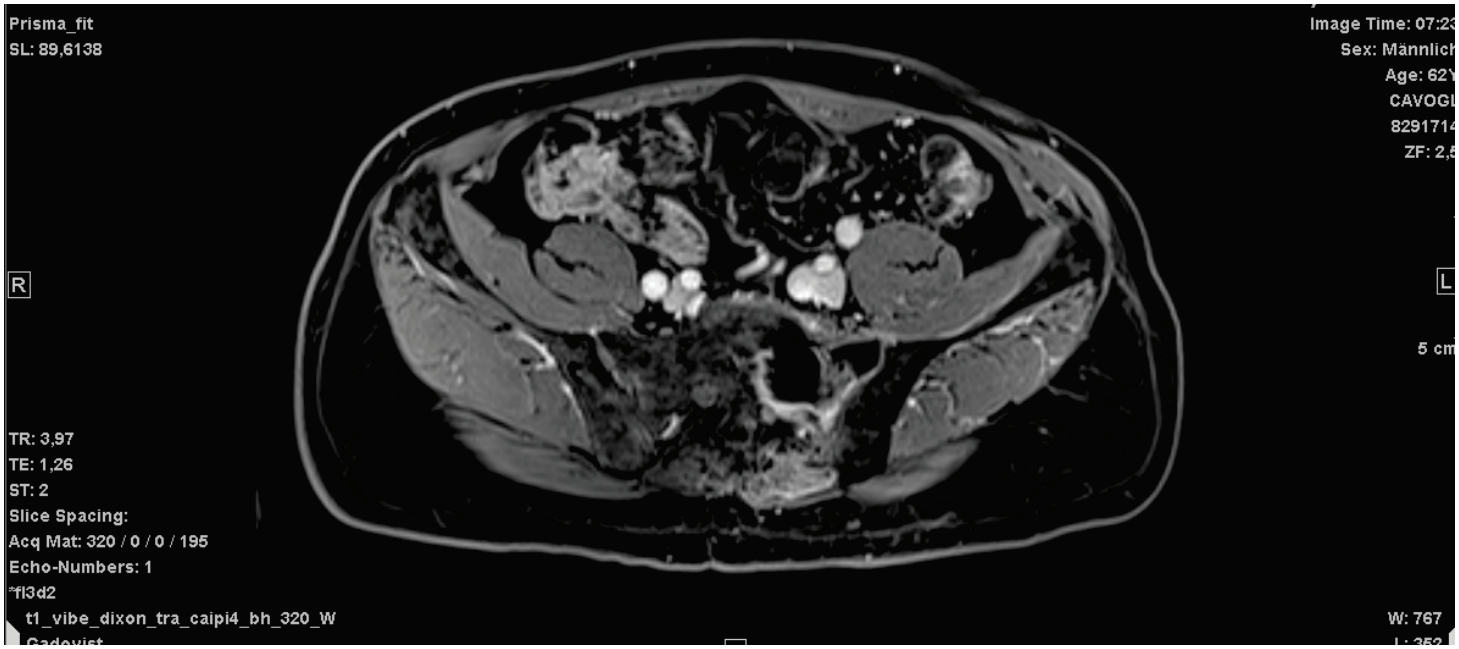
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L
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TR: 3,97
TE: 1,26
ST: 2
Slice Spacing:
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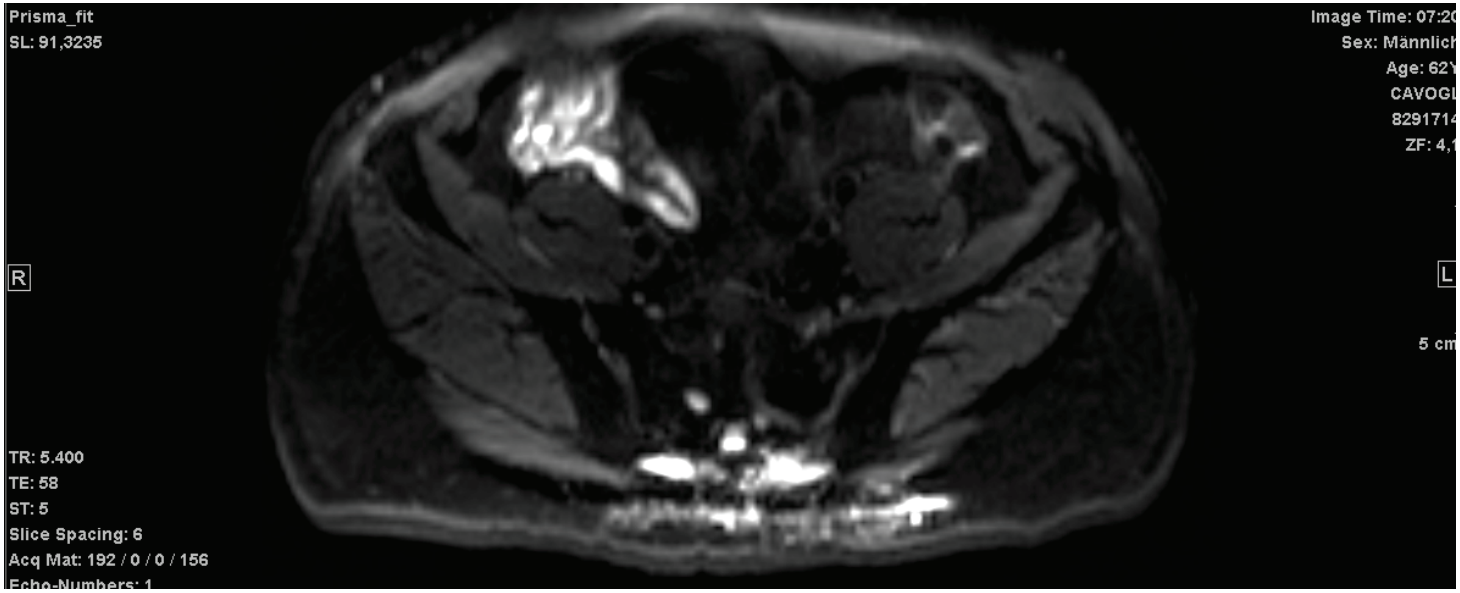
Gadovist
W: 767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R
L
5 cm
TR: 5.400
TE: 58
ST: 5
Slice Spacing: 6
Acq Mat: 192 / 0 / 0 / 156
Echo-Numbers: 1

Literaturübersicht

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Authors	N	Description	t-RFA method	Results
Howard &Hampton, Interventional Oncology 2015	**1**	Case report of STAR treatment of alveolar soft part sarcoma (ASPS). Patient received SBRT to L2 to L5 vertebras. Residual tumor in L4 and persistent pain	STAR ablation instrument inserted into L4	Debalking of the tumor. Pain score decreased from 8 pre-procedure to 5 postprocedure and to 0 after 2 months. Patient is still pain free at 6 months after the intervention
Hillen et al., Radiology 2014	**26**	Retrospective study on 26 cancer pts. Most common primary type tumor (27%) was lung 9/26 pts received radiotherapy prior to RFA	STAR ablation used in 47 posterior vertebral bodies tumors	Post procedural pain VAS score (1 week and 1 month) statistically significantly lower than pre procedural score 50% of pain medications usage No major complications (as thermal nerve injuries) occurred; 4 pts had radicular nerve pain, all resolved
Anchala et al, Pain Physician 2014	**92**	Multicenter retrospective study on 128 bone mets identified in 92 pts	STAR ablation used in all 92 pts with a total of 96 procedures. 92/96 (96%) underwent vertebral augmentation	No complications or thermal injuries; VAS score significantly decreased at 1 week, 1 month and 6 months post procedure in all lesions; 54% of pts had a decrease in pain medications. MRI and PET/CT confirmed necrosis of the lesions
Malusa et al, Neuro-Oncology SIG pub 2013	1	Case study of patient with prostate cancer who underwent prostatectomy, but developed spinal lesions treated with targeted tx first and RT after,	STAR was used in T11 lesion first and others later	Pain decreased from a VASA score of 7-8 to 2-3 and patient had a considerable QOL improvement
Hillen et al., Semin Musculoskelet Radiol 2013	-	Review paper on image-guided intervention of tumors	STAR curve probe listed among RFA methods	Multidisciplinary team importance highlighted as well as the knowledge of indications/contraindications of methods.
Proschek et al., Journal of bone	6	Animal study in white rabbits, whose local bone tumors were	6 STAR ablations were performed	Mean time of ablation was 6 min and the average temperature used was 55 C. MRI

Anchala et al. 2014

Treatment of Metastatic Spinal Lesions with a Navigational Bipolar Radiofrequency Ablation Device: A Multicenter Retrospective Study

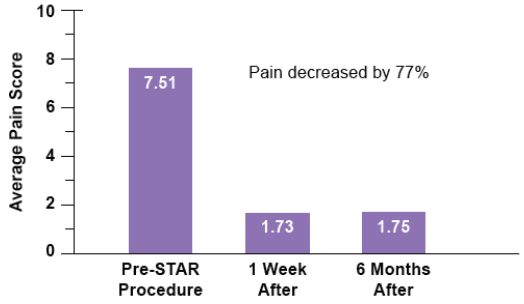
Pain Physician 2014; 17:317-327 • ISSN 1533-3159

Retrospective Study

Treatment of Metastatic Spinal Lesions with a Navigational Bipolar Radiofrequency Ablation Device: A Multicenter Retrospective Study

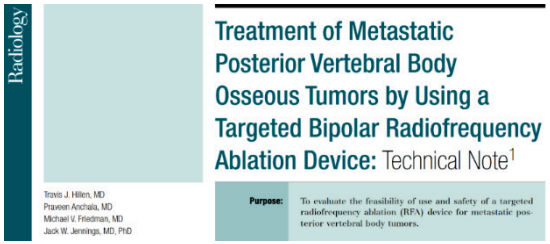
Praveen R. Anchala, MD[1], Winston D. Irving, MD[1], Travis J. Hillen, MD[1], Michael V. Friedman, MD[1], Bassem A. Georgy, MD[2], Douglass M. Coldwell, MD, PhD[3], Nam D. Tran, MD[4], PhD, Frank D. Vrionis, MD, PhD[4], Allan Brook, MD[5], and Jack W. Jennings, MD, PhD[1]

- Retrospective study on 128 bone mets identified in 92 pts who underwent a total of 96 procedures
- t-RFA resulted to be safe (no complications or thermal injuries) and effective (VAS score significantly decreased at 1 week, 1 and 6 mo post procedure) in all these lesions; 54% od pts had a decrease in pain medications
- Post ablation MRI and PET/CT confirmed size of ablation with necrosis of the targeted tissue
- Vertebral augmentation was successfully performed in 92/96 (96%) treated lesions, proving the safety and efficacy of the combined approach
- Follow-up imaging demonstrated no further growth of the treated tumor



Hillen et al. 2014

Treatment of Metastatic Posterior Vertebral Body Osseous Tumors by Using a Targeted Bipolar radiofrequency ablation Device: Technical Note[1]


Radiology

Treatment of Metastatic Posterior Vertebral Body Osseous Tumors by Using a Targeted Bipolar Radiofrequency Ablation Device: Technical Note[1]

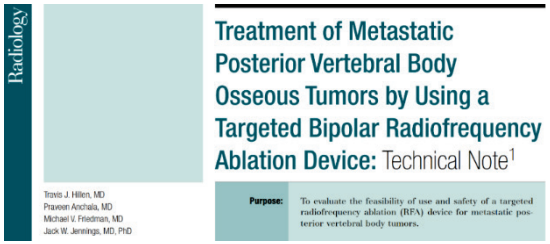
Travis J. Hillen, MD
Praveen Anchala, MD
Michael V. Friedman, MD
Jack W. Jennings, MD, PhD

Purpose: To evaluate the feasibility of use and safety of a targeted radiofrequency ablation (RFA) device for metastatic posterior vertebral body tumors.

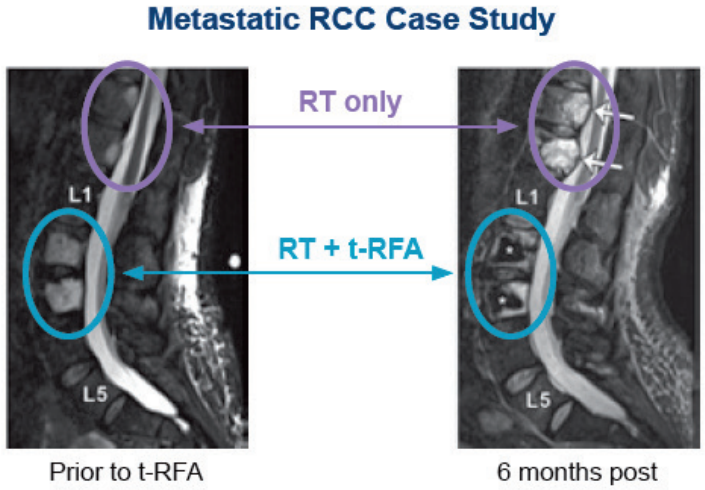
- Retrospective study on 26 pts using image-guided t-RFA (STAR Tumor Ablation System, DFINE) in 47 posterior vertebral body tumors
- 9/26 (35%) pts received RT in the same tumors
- Different numbers of ablation zones, times and temperatures were used but the same articulating device strategy was used
- Post procedural pain VAS score (1 week) decreased by 64% and 50% of pts decreased their use in pain medications
- No major complications (as thermal nerve injuries) occurred; 4 pts had radicular nerve pain, all resolved
- RFA represents a safe and effective method of ablation of posterior vertebral body tumors, difficult to access with other ablative devices or who could not undergo RT

Hillen et al. 2014

Treatment of Metastatic Posterior Vertebral Body Osseous Tumors by Using a Targeted Bipolar radiofrequency ablation Device: Technical Note[1]



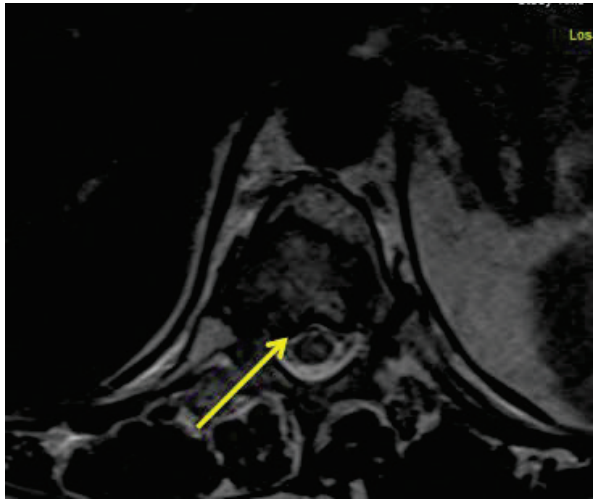
- The study was not supposed to show any difference between vertebrae treated with RT only vs those treated with RT + RFA
- However vertebrae treated with RT only functioned as internal control
- RFA may provide an alternative therapy for tumors resistant to RT

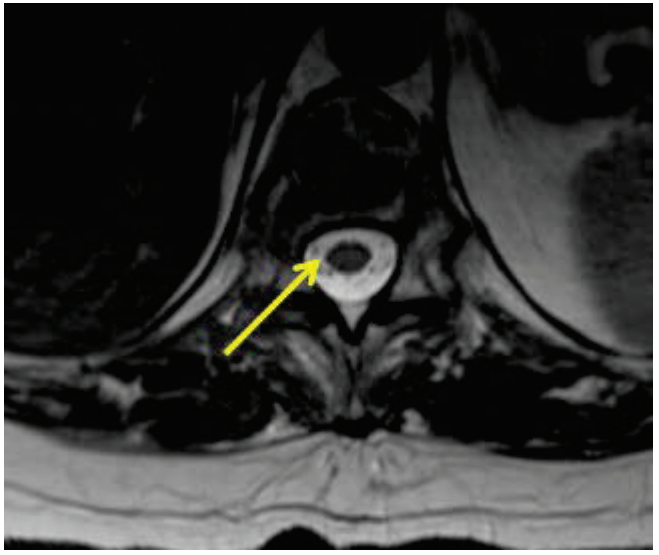


Wallace et al.. AJNR 2016

MRI control of spinal metastases with percutaneous RFA and vertebral augmentation

55 lesions treated with STAR Tumor Ablation System
Excluded those also treated with RT
Median f/u 34 wks
(interquartile range, 15-89 weeks)
local tumor control
- 89% at 3 mos
- 74% at 6 mos
- 70% at 1 year





Zusammenfassung:

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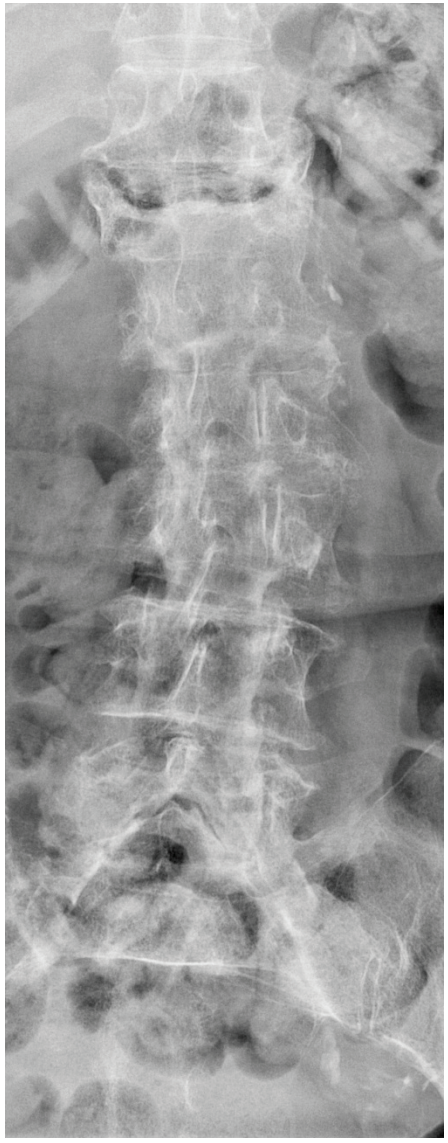
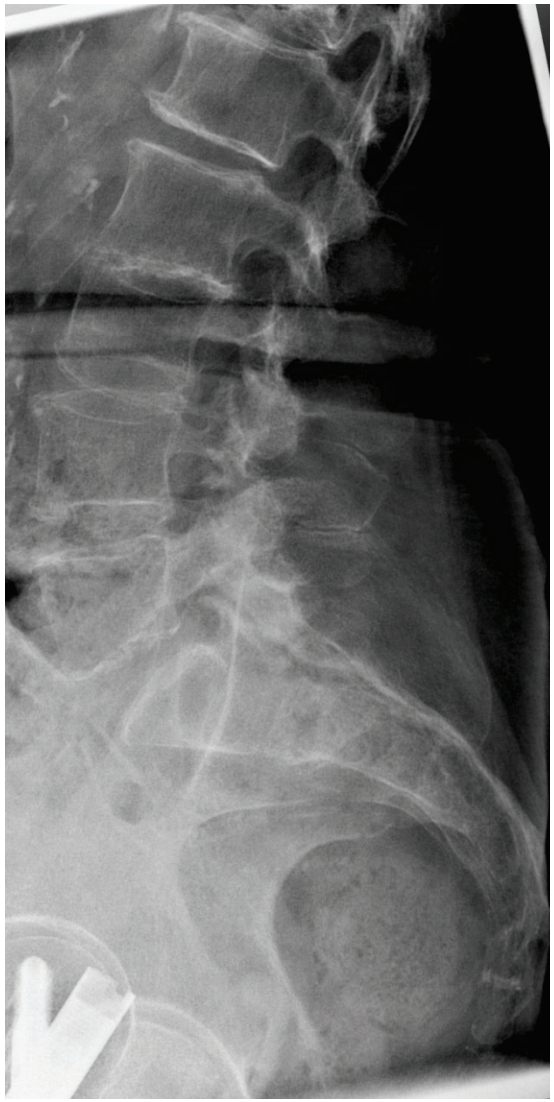
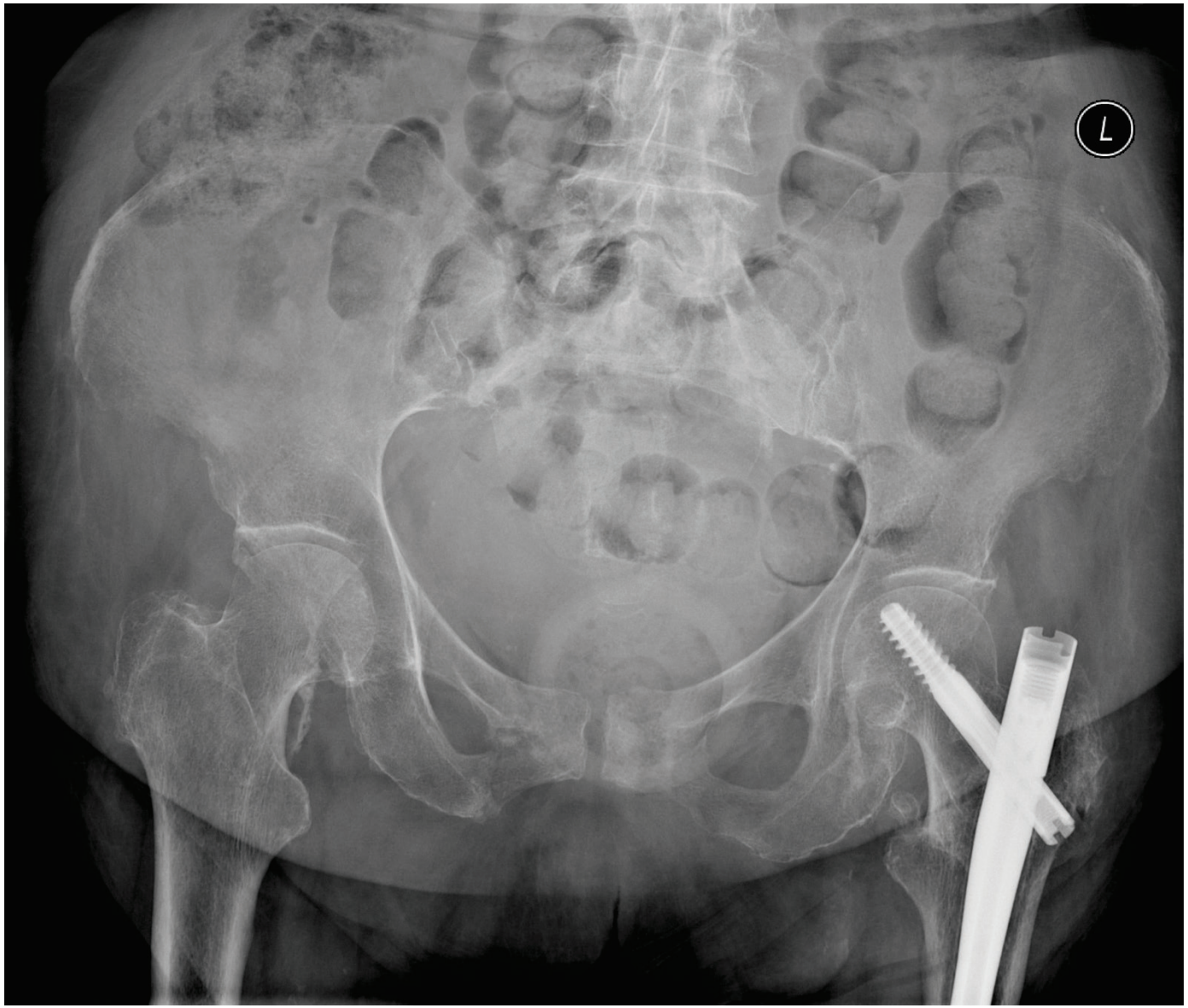
- Minimal-invasives Verfahren mit der Möglichkeit der Tumormassereduktion
- Schnelle Schmerzlinderung (vor einer gegebenenfalls notwendigen Strahlentherapie)
- Ermöglicht die zielgerichtete Behandlung von strahlenresistenten Tumoren
- Neue Therapieoption bei Erreichung der Strahlendosisgrenze
- Kompatibel mit aktuellen Behandlungsalgorithmen
- Verbesserung der Lebensqualität

Vielen Dank für Ihre Aufmerksamkeit



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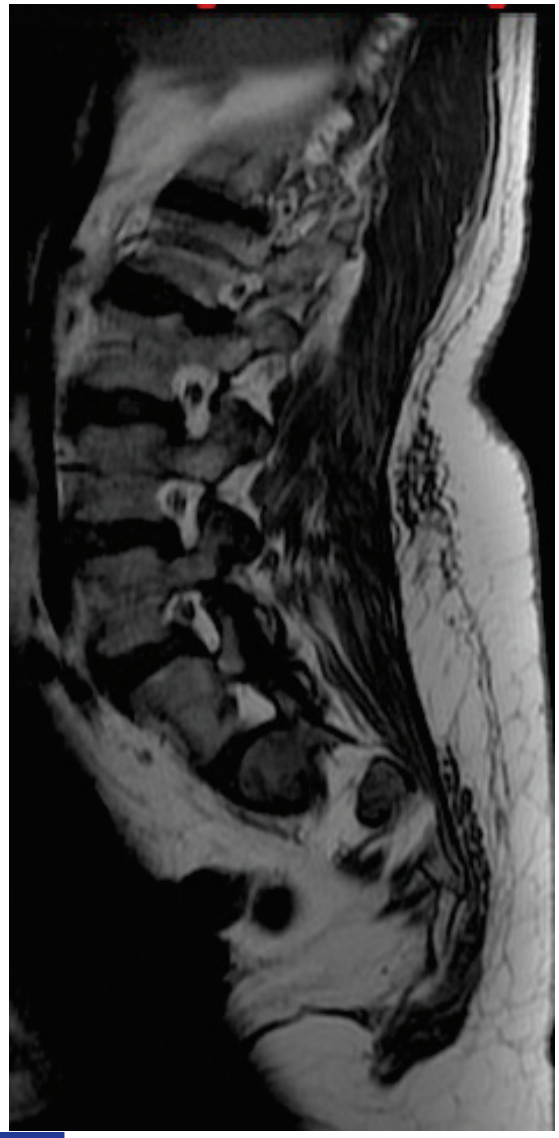

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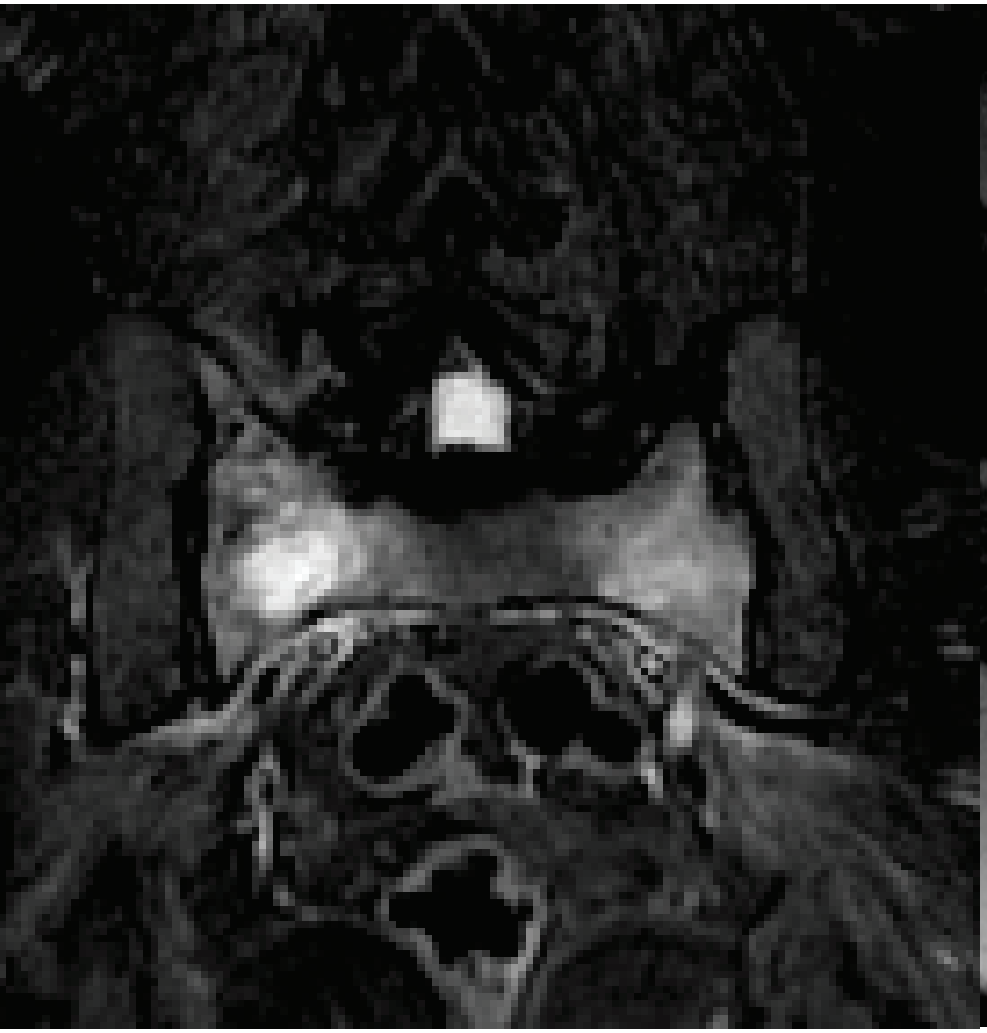

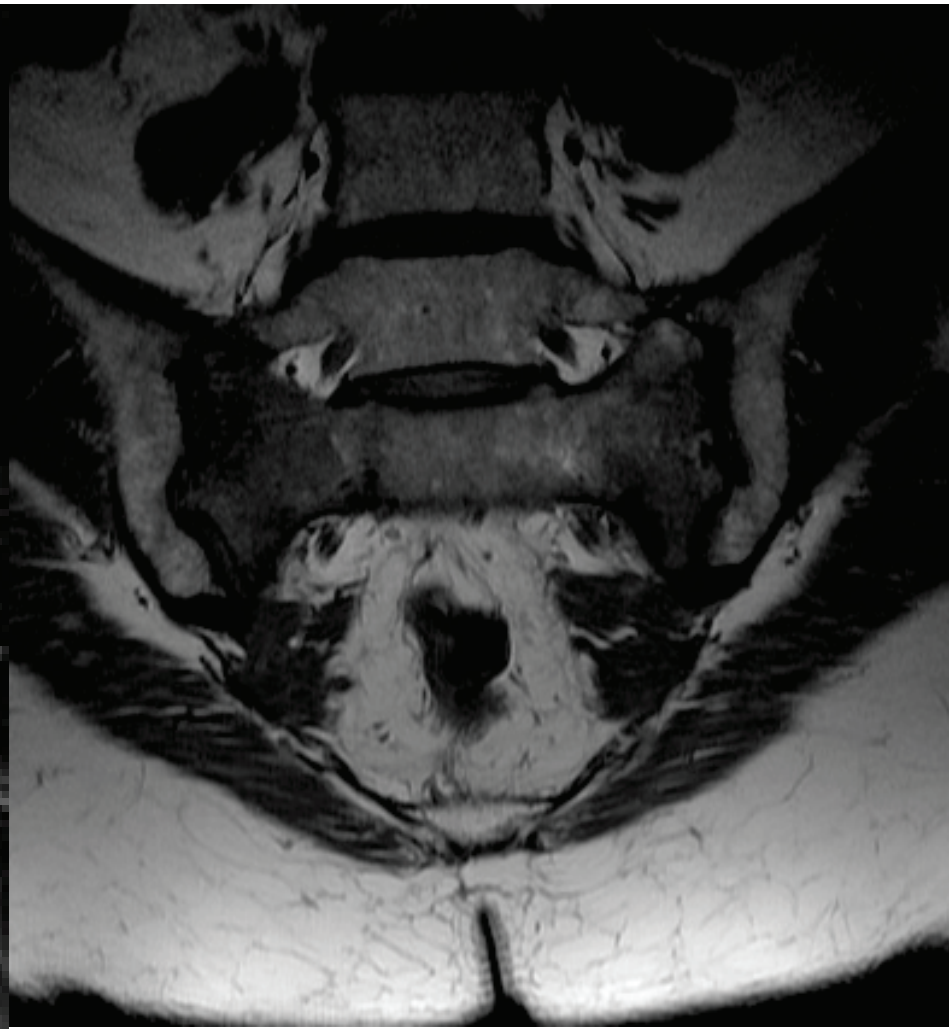

Institute of diagnostic and interventional radiology, Goethe university, Frankfurt, Germany

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Injury. 2015 Feb;46(2):315-9. doi: 10.1016/j.injury.2014.10.050. Epub 2014 Oct 22.

Significance of clinical examination, CT and MRI scan in the diagnosis of posterior pelvic ring fractures.

Nüchtern JV[1], Hartel MJ[2], Henes FO[3], Groth M[3], Jauch SY[4], Haegele J[5], Briem D[2], Hoffmann M[2], Lehmann W[2], Rueger JM[2], Großterlinden LG[2].

Author information

Abstract

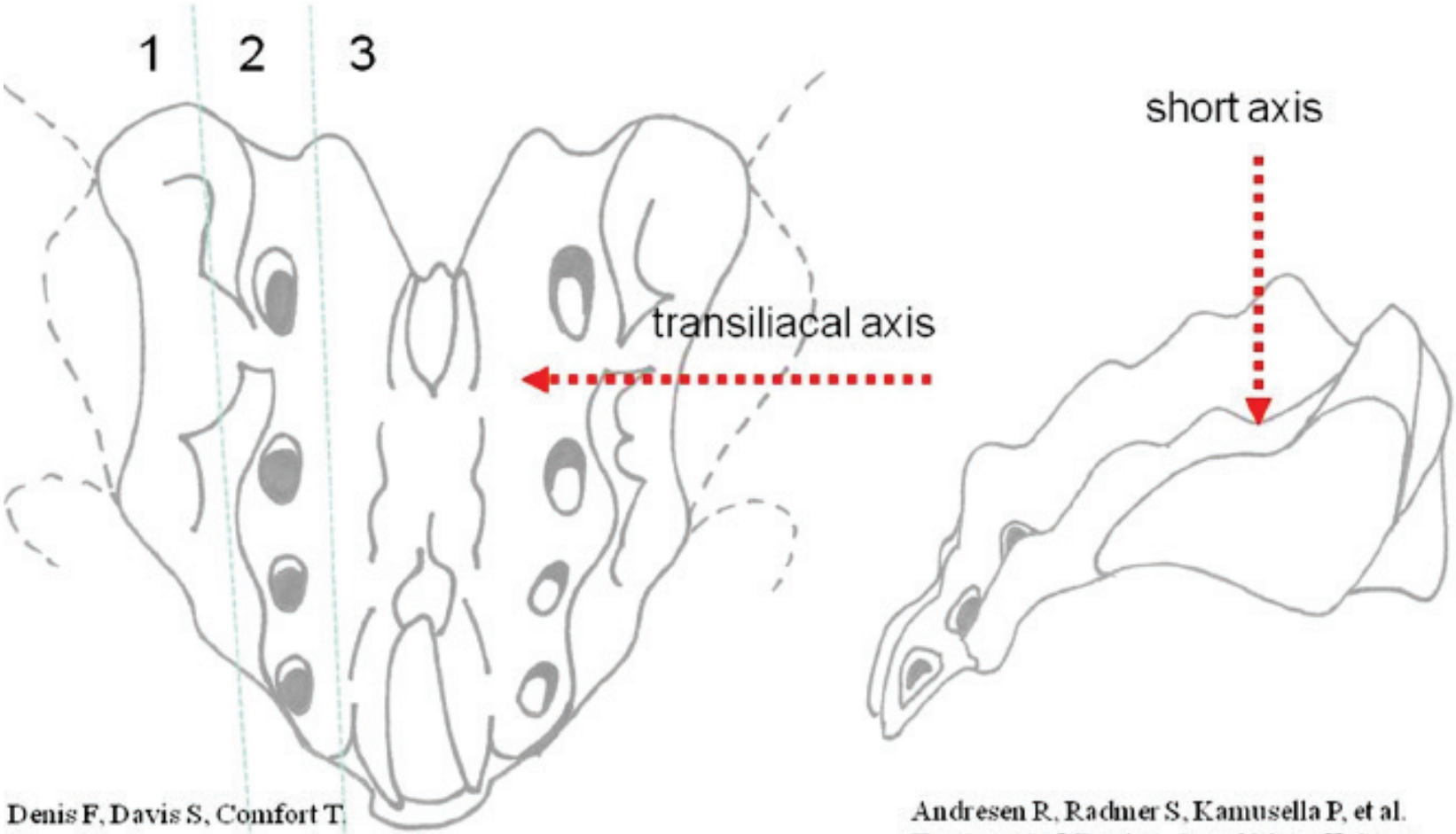
INTRODUCTION: Patients with a fracture in the anterior pelvic ring often simultaneously demonstrate pain in the posterior pelvic ring. The aim of the present prospective study was to assess the sensitivity of CT, MRI and clinical examination in the detection of fractures in the posterior pelvic ring in patients with fractures of the anterior pelvic ring diagnosed in conventional radiographs.

METHODS: Sixty patients with radiographic signs of an anterior pelvic ring injury were included in this prospective analysis. Following a focused clinical examination of the posterior pelvis, all patients underwent both a CT and then a MRI scan of their pelvis. Two board certified radiologists evaluated the CT and MRI scans independently. To estimate the presence of osteoporosis the Hounsfield units of the vertebral body of L5 were measured in each case.

RESULTS: Fifty-three women and seven men, with a mean age of 74.7+/-15.6 years were included into the study. A fracture of the posterior pelvic ring was found in fourty-eight patients (80%) patients using MRI. Fractures of the posterior pelvic ring would have been missed in eight cases (17%), if only CT had been used. Eighty-five percent of the patients with a posterior fracture had an osteoporosis. The majority of the cases suffered from a low energy trauma. Thirty-eight patients (83%) with positive clinical signs at the posterior pelvic ring actually had a fracture of the posterior pelvic ring in the MRI. The clinical examination proved to be equally effective to CT in detecting posterior pelvic ring fractures.

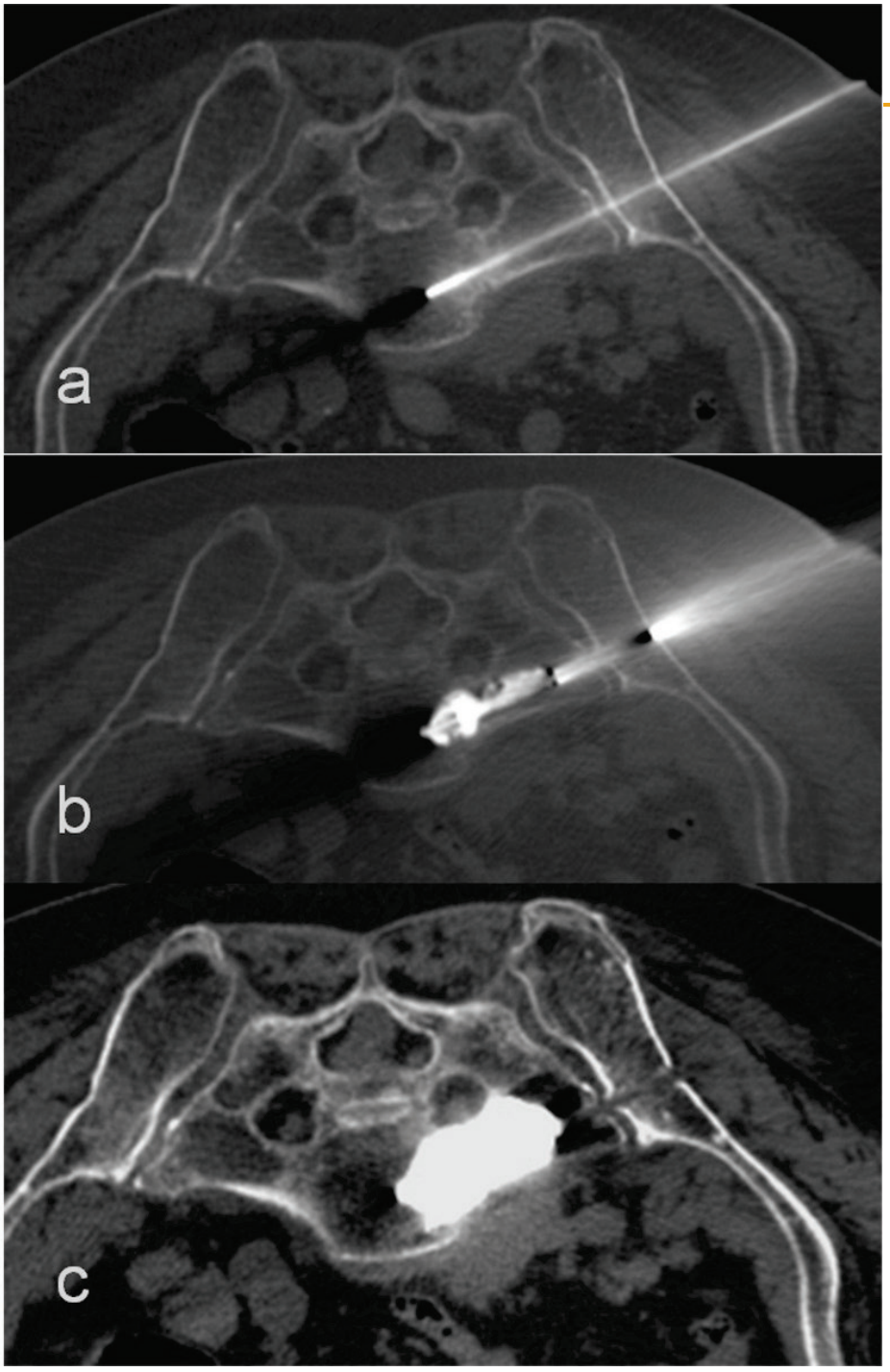
CONCLUSION: The significance of both, clinical examination and CT was confirmed in the detection of fractures in the posterior pelvic ring. MRI examination of the pelvis however, was found to be superior in detecting undislocated fractures in a cohort of patients with a high incidence of osteoporosis. Using MRI may be beneficial in select cases, especially when reduced bone density is suspected.

KEYWORDS: CT; Clinical examination; Elderly; MRI; Osteoporosis; Pelvic ring fractures

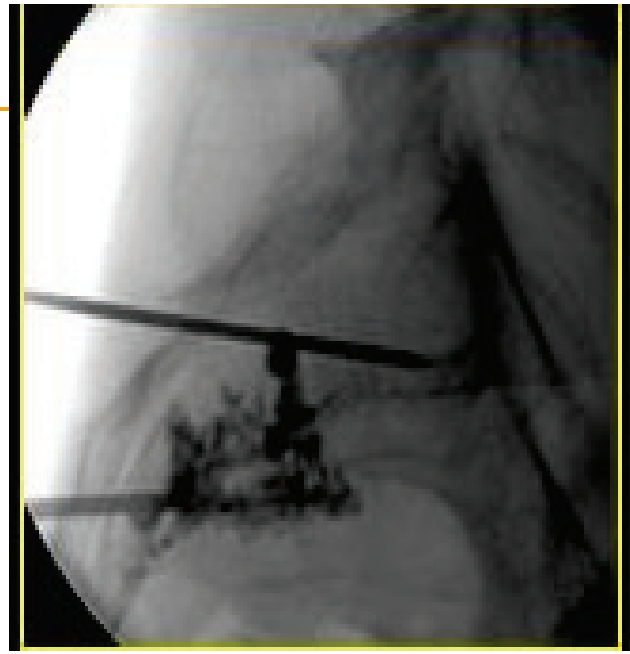


Denis F, Davis S, Comfort T.
Sacral fractures: an important problem.
Retrospective analysis of 236 cases.
Clin Orthop Relat Res 1988; 227: 67–81

Andresen R, Radmer S, Kamusella P, et al.
Treatment of Denis 1, 2 and 3 insufficiency
fracture zones of the os sacrum.
Osteol 2012; 21: 168 -173

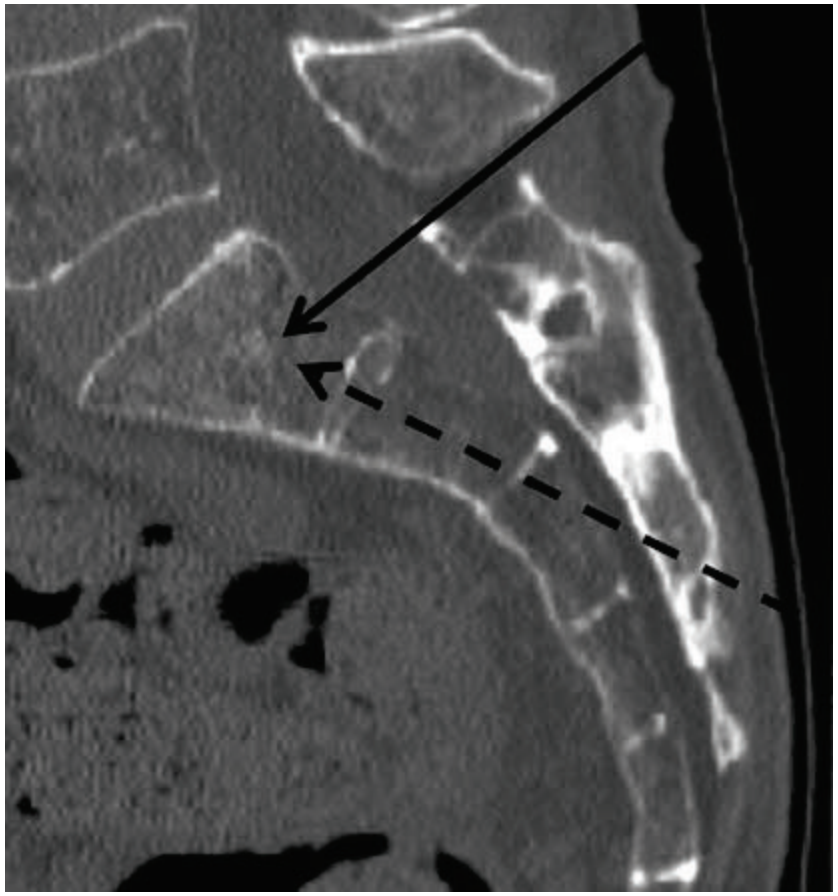


P-0095
Andresen et al.
ESSR 2012



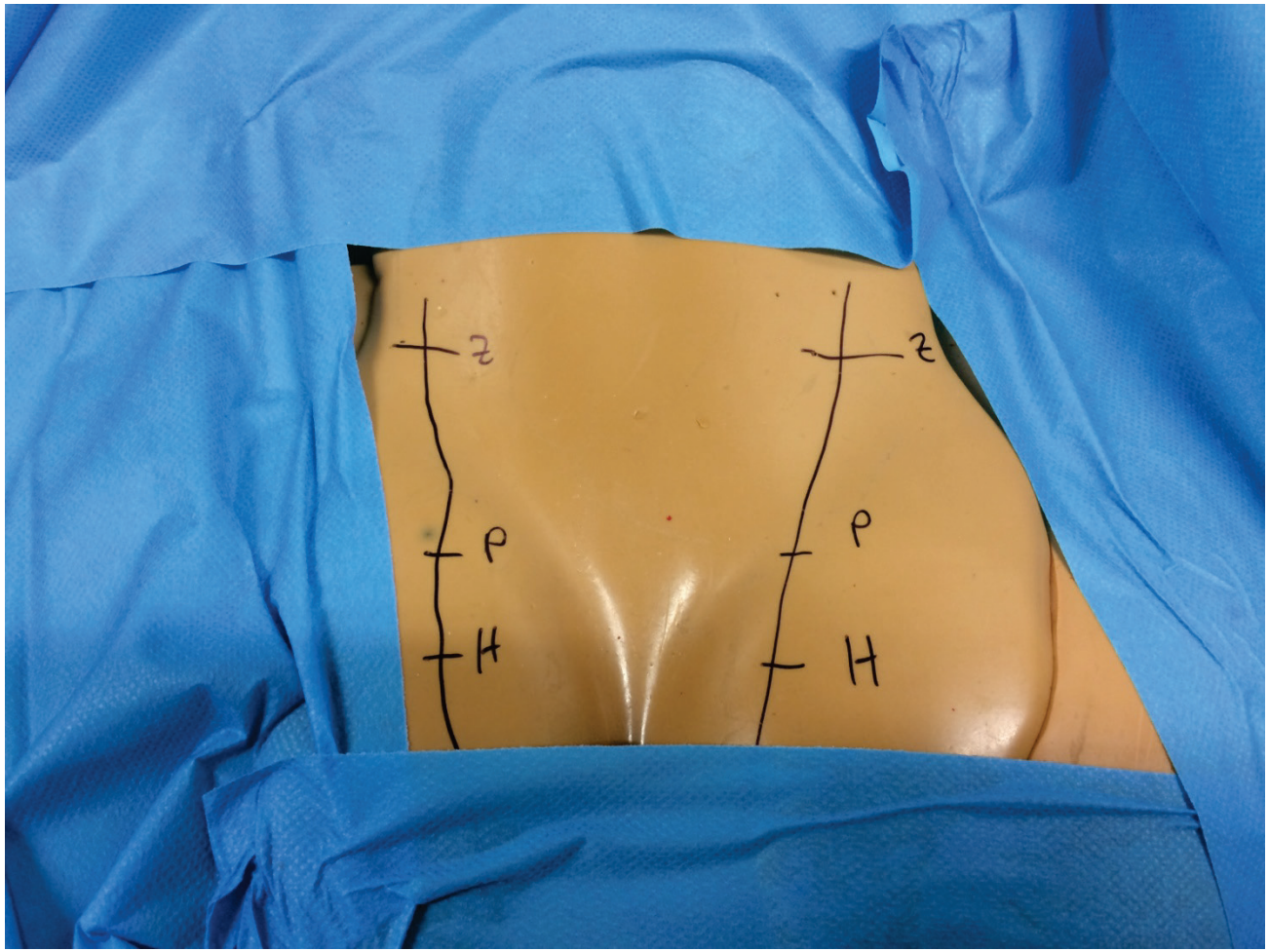
Majdi Radaideh, MD
Northwestern University

Zugangswege



Eigenes Patientengut

- Durchschnittsalter: 81 Jahre
- 21 Patienten
- 18 Frauen und 3 Männer
- Assigned from traumatology, internal medicine and gynecology
- Zementeingabe von 1.5-6 ml pro Seite
- Bauchlage, RR, HF und O2 Kontrolle, Lokalanästhesie
- 4 Tage stationärer Aufenthalt, aber auch ambulant möglich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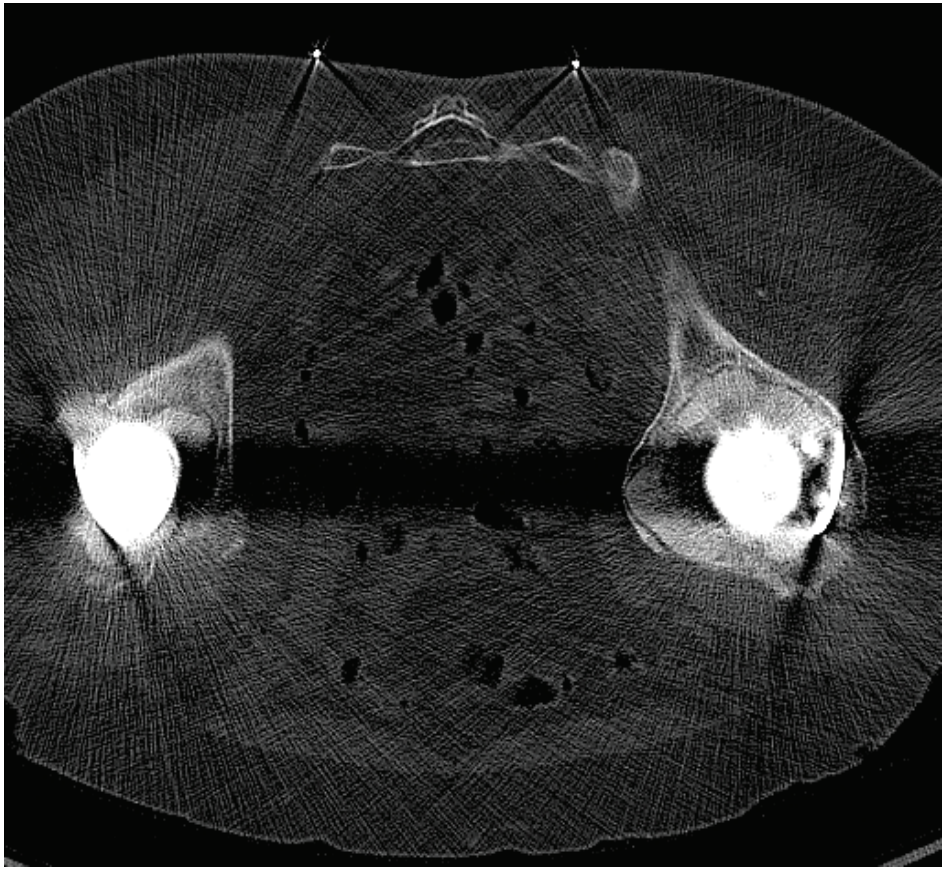

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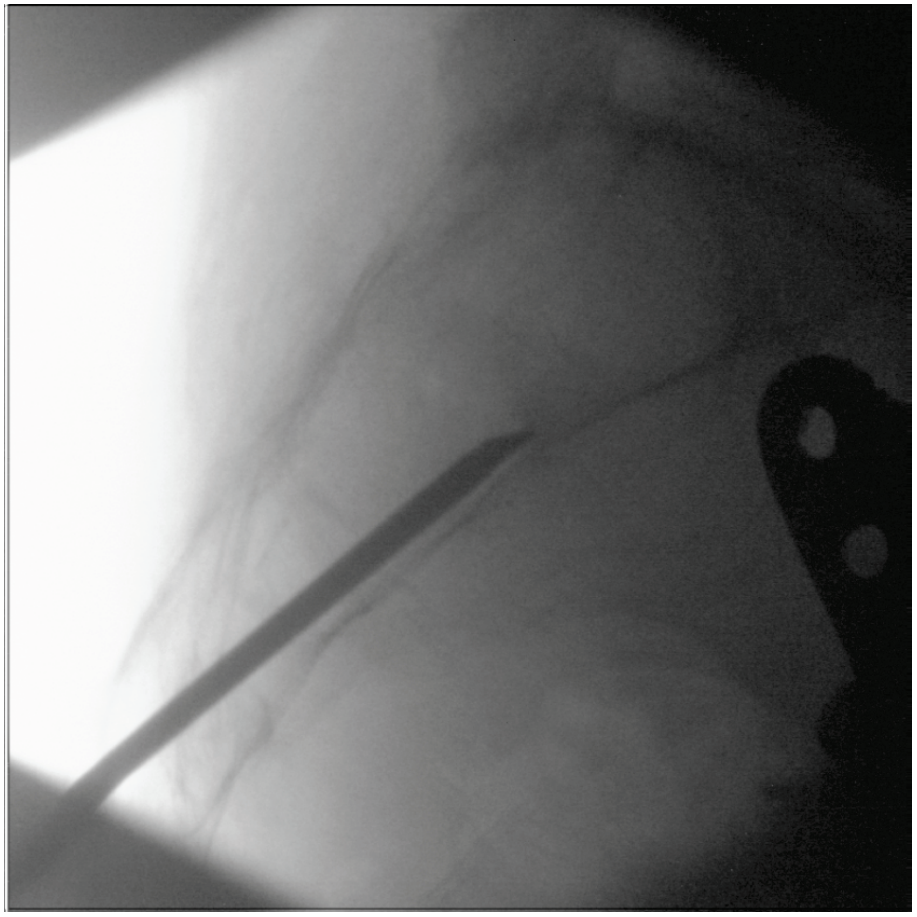

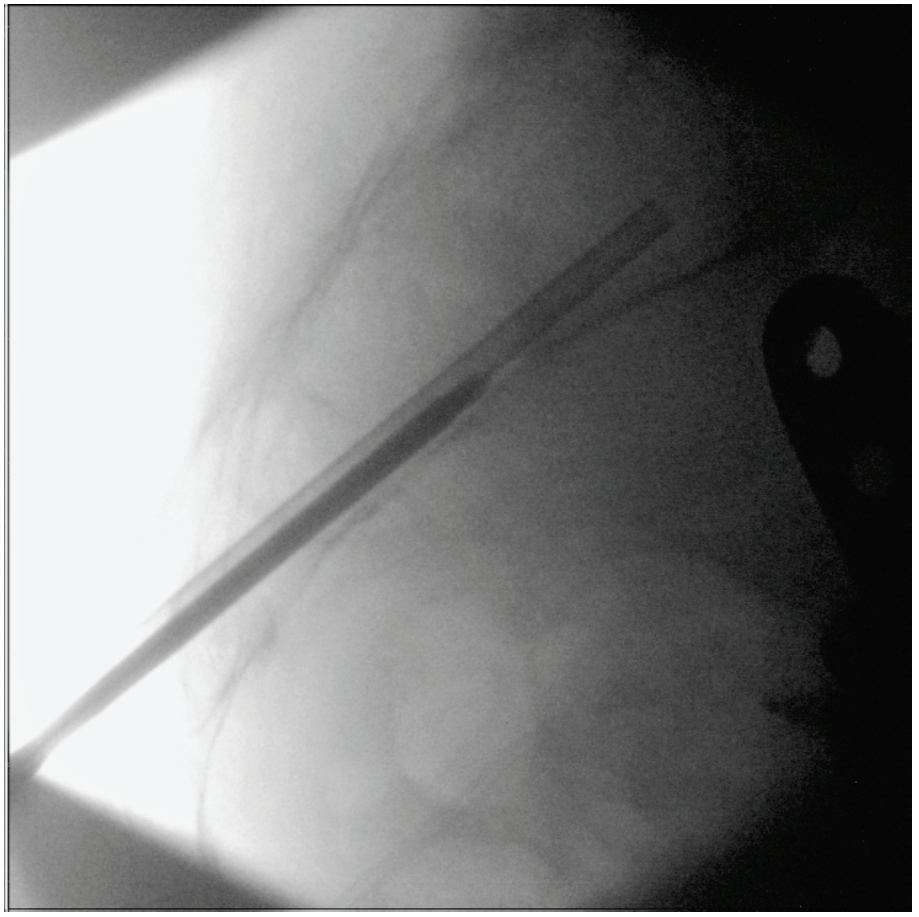

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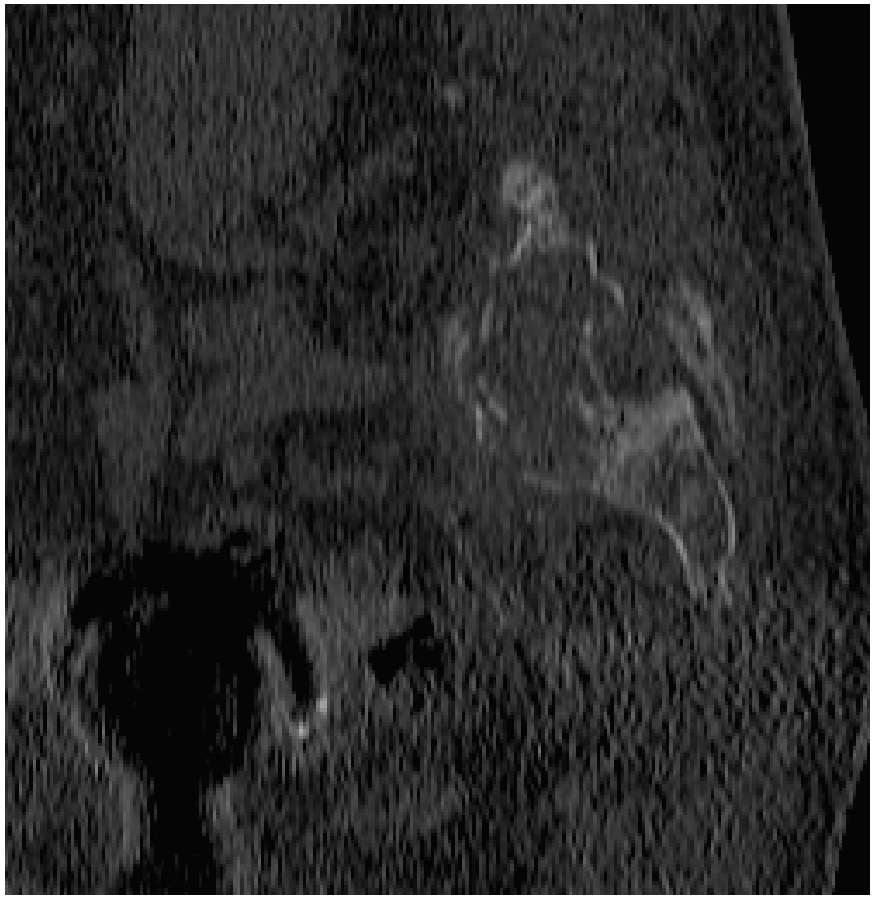

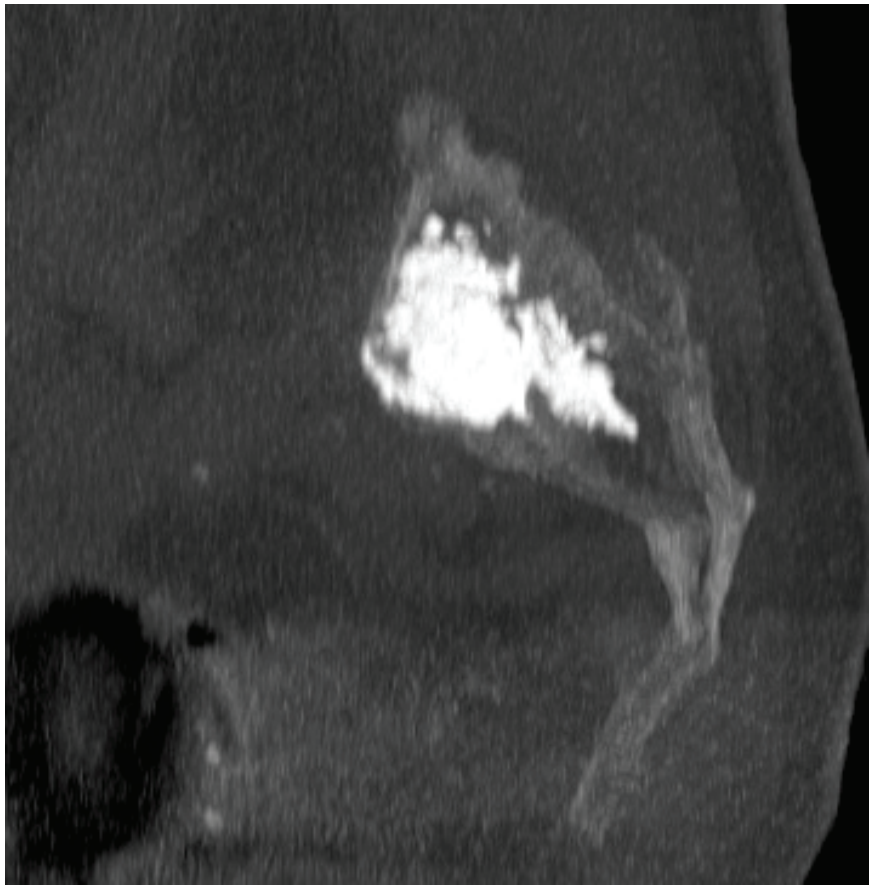

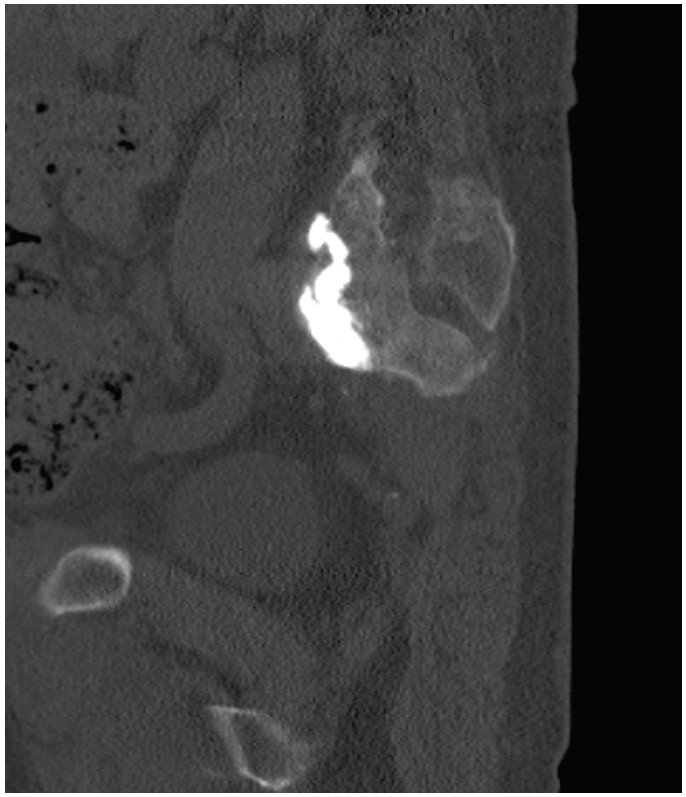

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Ergebnisse

- Mobilisaton nach 2 h möglich
- Leakage Rate von 2.5%
- VAS preinterventional 7 ± 1.9 (range, 5 to 10).
- VAS postinterventional und 4 Tage post 3 ± 1.2, range, 1 to 7
- 3-Monats follow-up 2.2 ± 1.1, range, 1 to 5
- Ein Patient verstorben innerhalb des Follow-ups (HI)