Radiofrequency Ablation in Radiation Naïve Patients for Palliation of Osseous Metastases: An OPuS One Sub-analysis

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DISCLOSURES

OPuS One was sponsored by Medtronic.

Author	Entity	Relationship
Jason Levy, MD FSIR	Medtronic Varian Sirtex	Consulting/Advisory, Speaker Consulting
Shannon Song, MS	Medtronic	Employment
Eric Grovender, PhD	Medtronic	Employment
Sandeep Bagla, MD	Prostate Centers USA IMBiotechnologies Boston Scientific Medtronic Terumo Cook Medical	Employment Stock Honoraria, Research Funding Honoraria, Consulting/ Advisory, Research Funding Honoraria, Research Funding Research Funding

PURPOSE

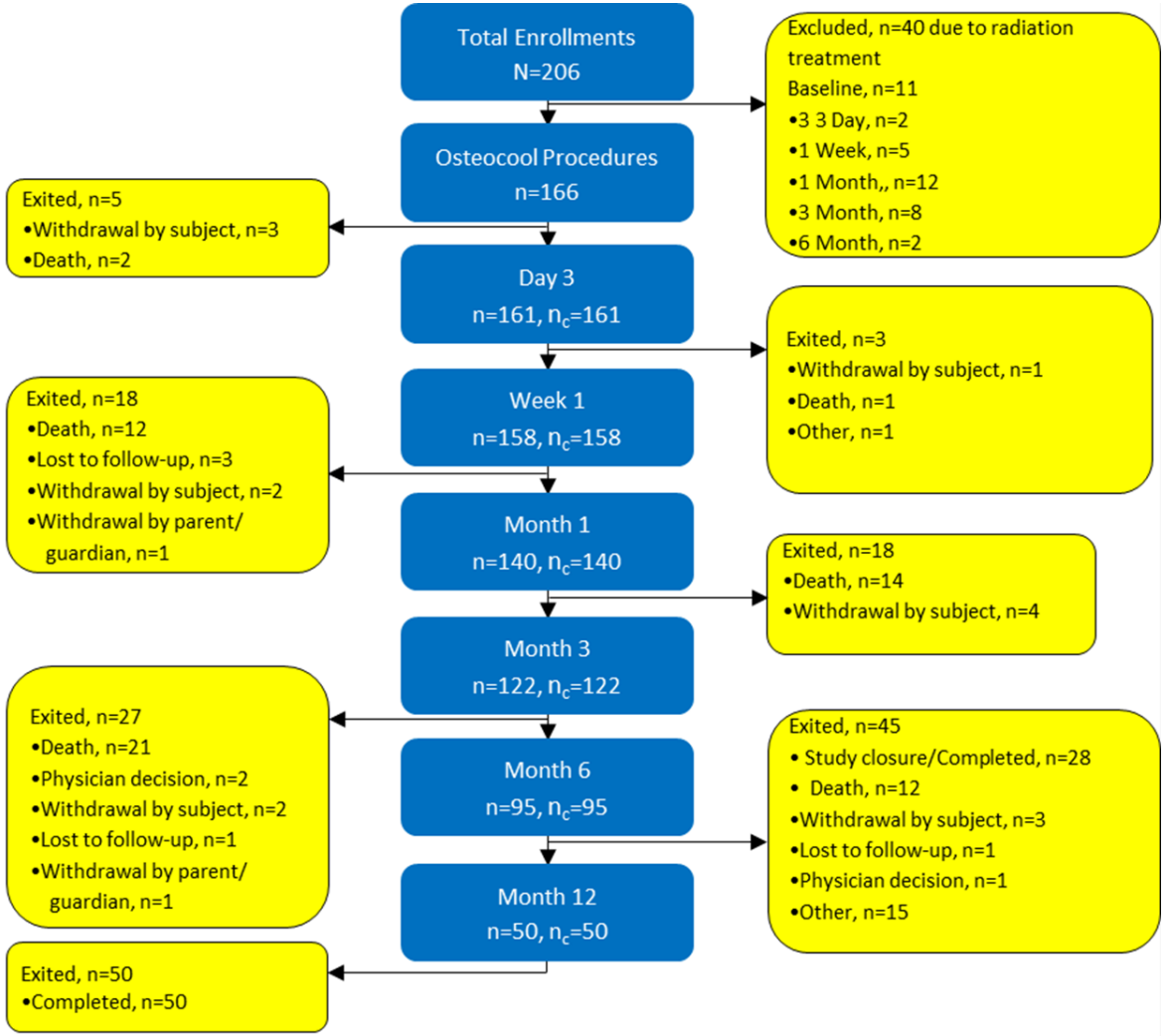
To report the results from a prospective multicenter study (OPuS One) of radiofrequency ablation (RFA) for the palliation of painful bone metastases for subjects that did not receive radiation therapy at the index site of RFA before or after RFA treatment

STUDY DESIGN: OPuS ONE

- Prospective, multicenter, post-market, non-randomized, single-arm, non-comparative, open-label, 12 months follow-up
- RFA for treatment of painful bone metastases
- For details, see: Levy, et al. *J Vasc Interv Radiol.* 2020;31:1745–1752.

SUBJECT DISPOSITION & ANALYSIS COHORT

81% of RFA-treated subjects were free from radiation therapy (166/206).



Note: n in the blue boxes represents the number of subjects who were followed at the visit or at a later visit. n_c is the number of subjects who completed the visit.

PATIENT POPULATION

Patient Characteristic	Value
No. of patients enrolled	206
No. of patients receiving RF ablation	166
Sex	
Female	92 (55.4%)
Male	74 (44.6%)
Age, years; mean (range)	63.5 (21-90)
Top primary cancer	
Lung	39 (23.5%)
Breast	36 (21.7%)
Kidney	17 (10.2%)
Procedure sites per subject	
One metastatic location	123 (74.1%)
Two metastatic locations	42 (25.3%)
Three metastatic locations*	1 (0.6%)

PROCEDURE DATA

RFA Procedure	Value
Ablations	
Total	210
Single	158 (75.2%)
Multi	52 (24.8%)
Procedure time, hours; mean (range)	1.1 (0.3-3.5)
Technical success	
Yes	209 (99.5%)
No	1 (0.5%)
Cement augmentation	
Yes	204 (97.1%)
No	6 (2.9%)
Lesion location	
Thoracolumbar spine	148 (89.2%)
Posterior Elements*	11/57 (23.4%)
Posterior Wall*	26/57 (55.3%)
Pelvic and/or sacrum	13 (7.8%)
Mixed (Thoracolumbar, pelvic, and/or sacrum)	5 (3.0%)

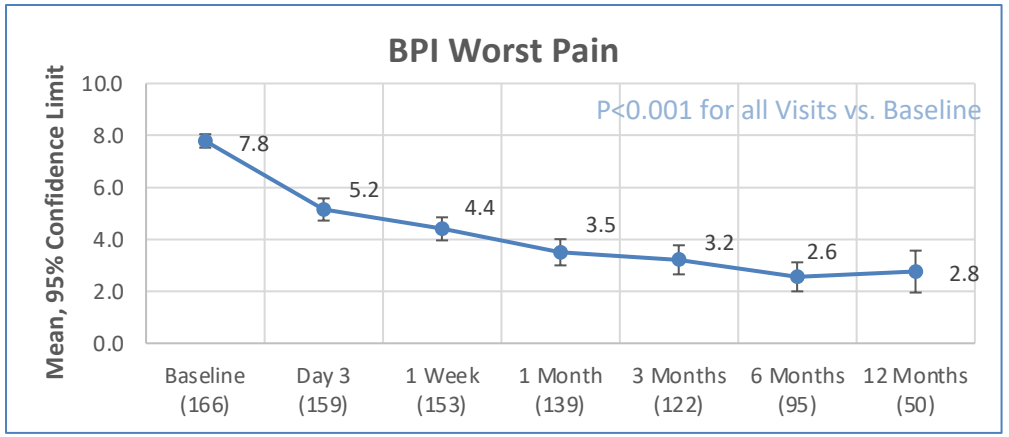
*Tumor images evaluated at baseline, if available.

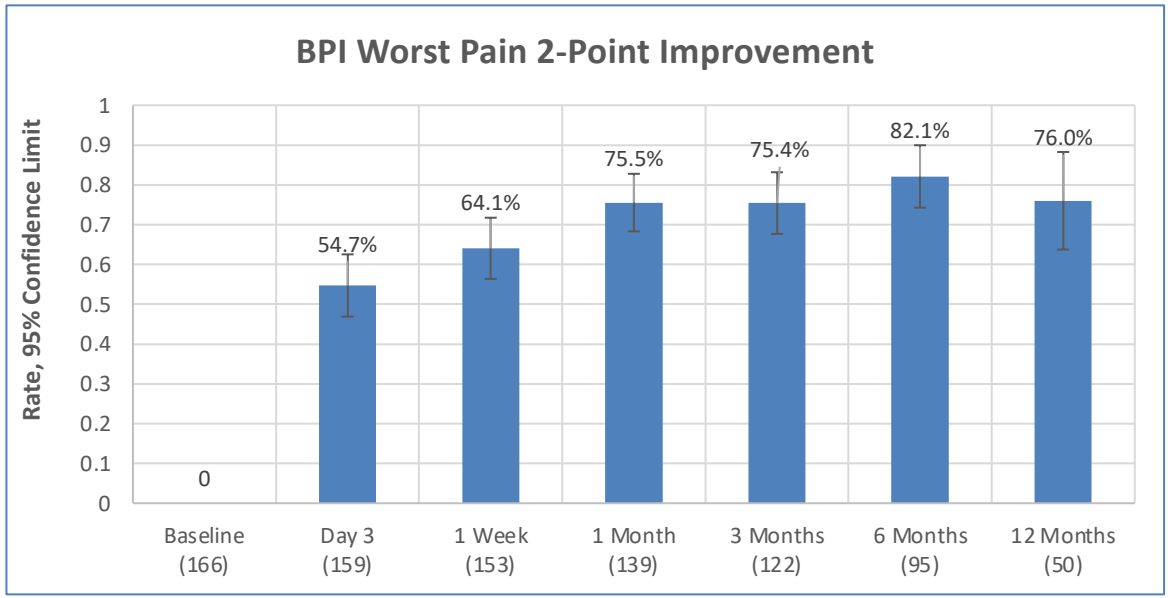
RESULTS: RAPID, SIGNIFICANT, AND SUSTAINED

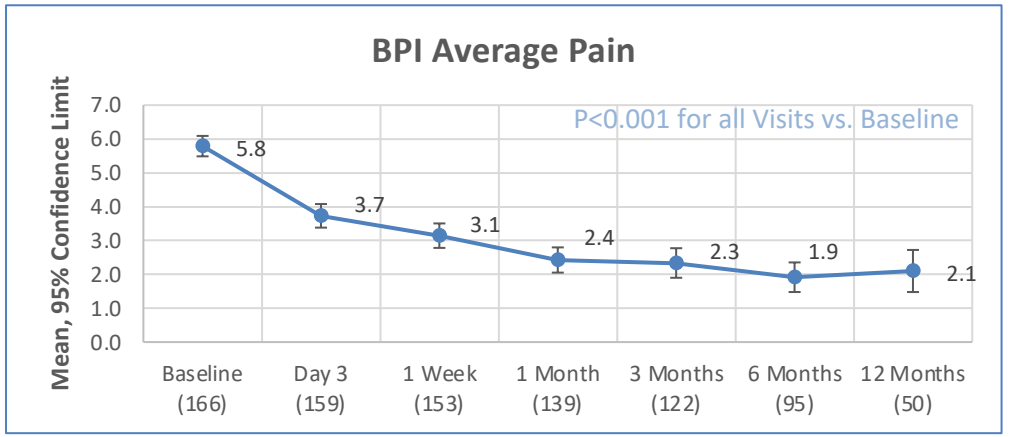
PAIN RELIEF

Patients treated with RFA achieved significant improvements in pain relief (worst pain, average pain) at all visits

- Rapid as early as 3 days post RFA
- Sustained up to 12 months post RFA
- Clinically meaningful (≥ 2-point change)







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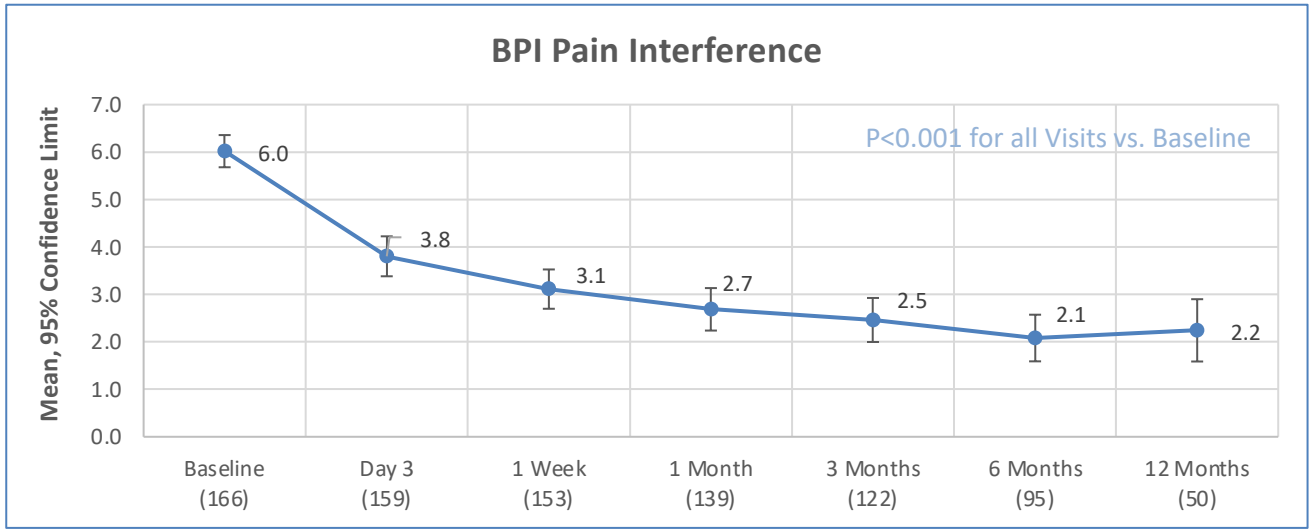
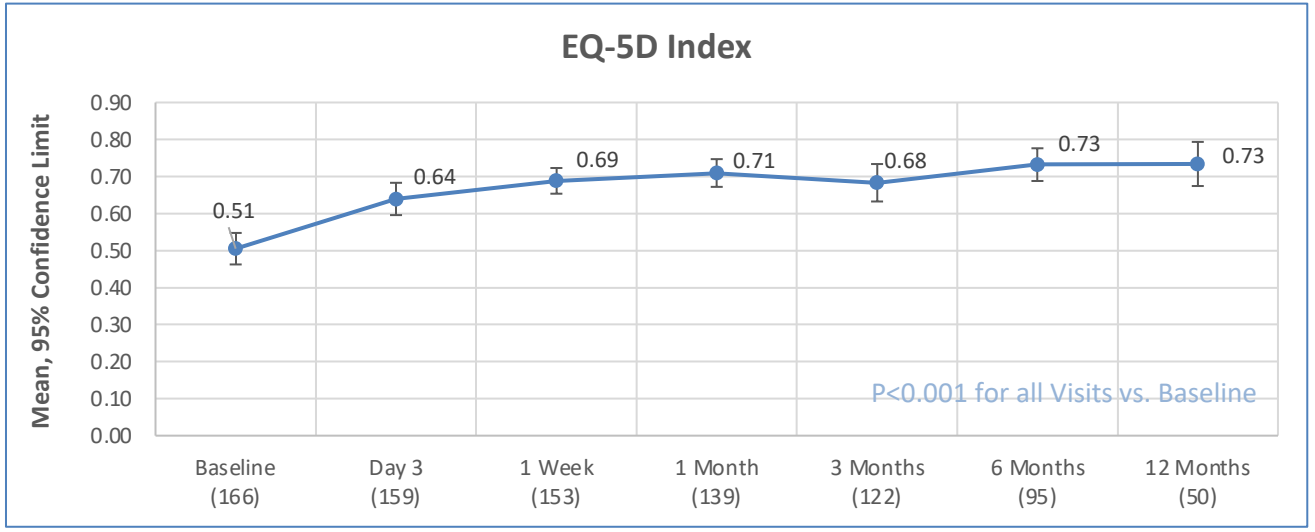
RESULTS: RAPID, SIGNIFICANT, AND SUSTAINED

QOL IMPROVEMENT

Patients treated with RFA achieved significant improvements in pain interference and quality of life (EQ-5D) at all visits

- Rapid as early as 3 days post RFA
- Sustained up to 12 months post RFA





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SAFETY

- 6-device, therapy, and/or procedure-related adverse events in 6 patients (3.6%; 6/166) were reported. Three of these were serious: intra-abdominal fluid collection, pneumonia, respiratory failure.
- 62 deaths (37.3%; 62/166) were reported in this cohort, but all were attributed to an underlying malignancy by an independent Clinical Events Committee.
- No neurologic injuries or delayed skeletal-related events (including fractures) were reported.

CONCLUSION

The results of this subgroup analysis from the OPuS One clinical study show swift and significant pain reduction and improved quality of life for up to 12 months after RFA treatment for metastatic bone disease, without radiation therapy.