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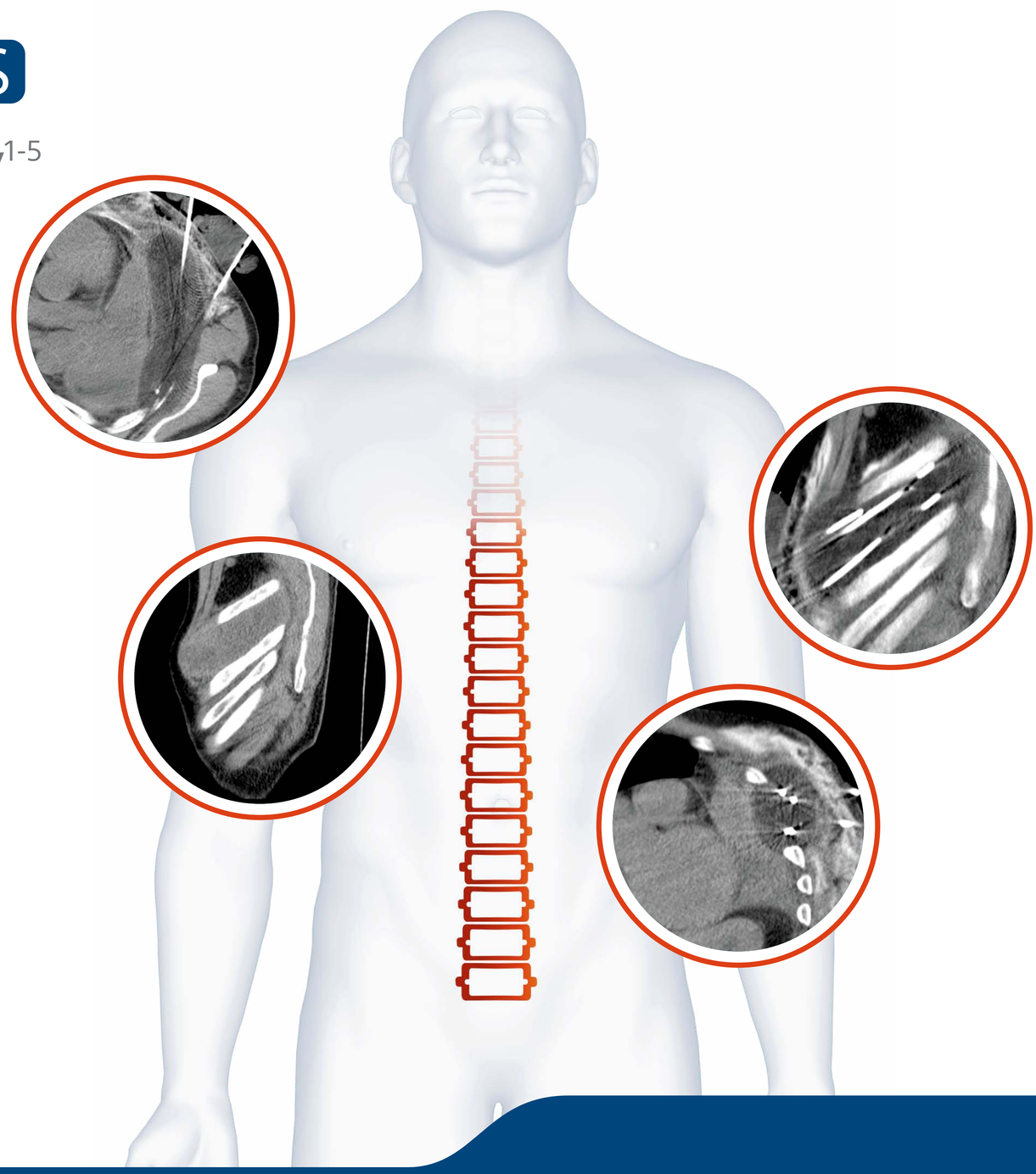
PALLIATIVE CRYOABLATION BONES

Safe, effective and durable therapy[1-5] of bone metastases



Click to select a topic

Images courtesy of Dr Julien Garnon
University Hospital Strasbourg, France

1 Overview of Palliative Bone Cryoablation

A SAFE, EFFECTIVE AND DURABLE THERAPY

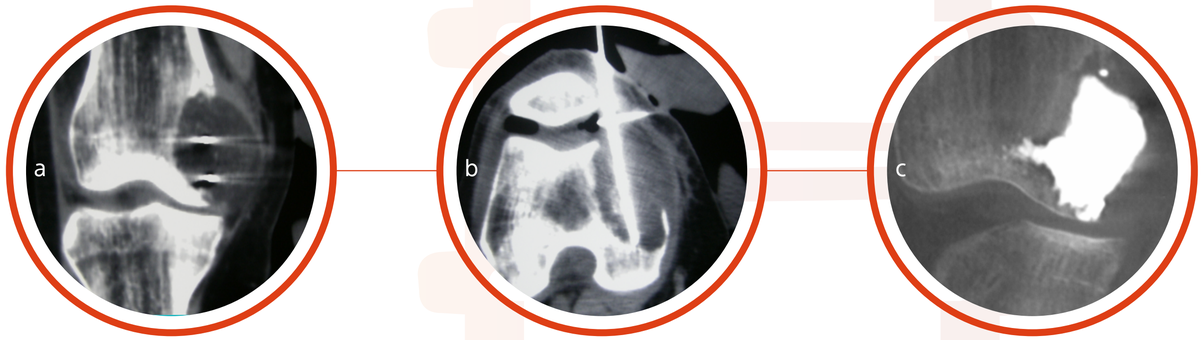
Bone metastases have significant impact on quality of life and their prevalence is increasing as survival rates for cancer patients improve[5-8]. Studies show that effective palliative treatment of bone metastases:

- Improves quality of life and functional status.[1-3]
- May prevent debilitating skeletal-related complications.[2,8]
- Reduces the use of pain medication, including opioids.[2,3]

> *Bone metastases are a major cause for morbidity, characterized by severe pain, impaired mobility, pathologic fractures, spinal cord compression, bone marrow aplasia and hypercalcemia.*
>
> **Macedo F et al. 2017[6]**

> *Pain, especially bone pain, is the most common symptom in malignancy patients, which seriously affects the life quality of patients with cancer.*
>
> **Zhu XC et al. 2015[7]**

CRYOABLATION OF BONE METASTASIS
Clear visualisation of the ablation zone during cryoablation of knee (a and b), followed by cement injection to stabilise joint (c)



Images courtesy of Professor Afshin Gangi, University Hospital Strasbourg, France

1 Overview of Palliative Bone Cryoablation (cont.)

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IN COMPARISON: CRYOABLATION VERSUS ...

... CONVENTIONAL THERAPIES

- Effectiveness is independent of tumour histology.[5]
- Suitable for patients refractory to medication/radiation or at limit of radiation dose.[2,3]
- Repeatable therapy with faster palliative impact than radiation.[2,5]
- Allows monitoring and modifications based on motor-evoked neural response.[9]
- Radiation may exacerbate structural frailty and instability.[8]
- Lower morbidity and faster recovery than surgery.[2]
- Avoidance of drug-related side-effects.[2]
- Can be combined with stabilisation, fixation and reconstruction techniques.[2,8]

> *Percutaneous ablation of MSK metastases may result in significant pain palliation, prevention of morbidity from skeletal-related events, and local tumor control. This minimally invasive approach has unique advantages compared with surgery or radiation therapy.*
>
> **Kurup AN et al. 2017[2]**

> *Of all ablative techniques, cryoablation is the least painful modality, probably due to the intrinsic analgesic properties of ice.*
>
> **Auloge P et al. 2019[5]**

... RADIOFREQUENCY ABLATION

- Ability to sculpt the ice to specific lesion shapes and to treat larger tumours.[4,8]
- Real-time control and monitoring minimise risk of damage to adjacent nerves or structures.
  - Tolerability under conscious sedation allows patient participation in monitoring neural response during iceball creation, and appropriate adjustments.[9]
  - Visualisation of iceball allows “sculpting” to desired ablation zone while avoiding peripheral anatomy.[1,3,8]
- Lower intra-procedural and post-procedural pain[4], with associated reductions in narcotics and length of hospital stay.[10]
- Improved complete local response rate.[11]
- Excellent safety profile.[5]

> *The role of image-guided thermal ablation techniques for the non-operative local management of painful osseous metastatic disease has expanded during recent years, and several advantages of cryoablation in this setting have emerged.*
>
> **Prologo JD et al. 2014[4]**

> *Radiation therapy is the standard treatment of palliation of pain from MSK metastases. However, this treatment may be applied only in areas that have not reached the limit of radiation tolerance for normal tissues.*
>
> **Kurup AN et al. 2017[2]**

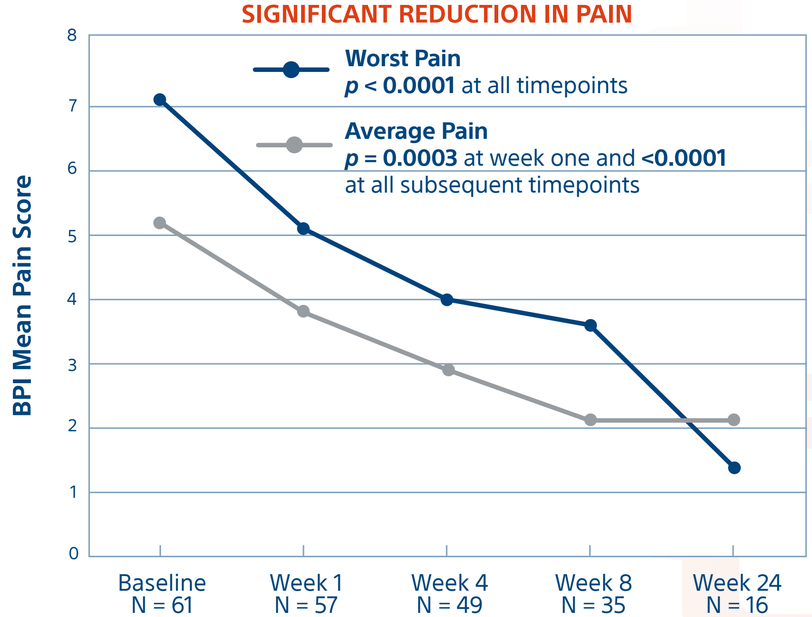
2 Clinical Results

PERCUTANEOUS IMAGE-GUIDED CRYOABLATION OF PAINFUL METASTASES INVOLVING BONE: MULTICENTER TRIAL

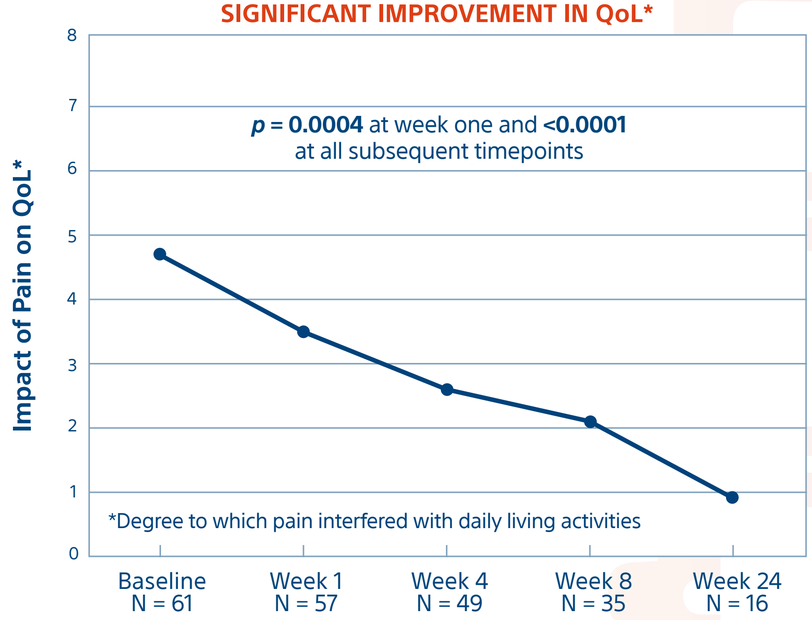
Callstrom MR et al. 2013[1]

- N = 61 patients/69 tumours.
- Mean treated tumour diameter 4.8 cm.
- Single major complication – treatment site infection (successfully managed).
- No significant difference in pain scores between patients who had/had not received previous EBRT.

SIGNIFICANT REDUCTION IN PAIN



SIGNIFICANT IMPROVEMENT IN QoL*

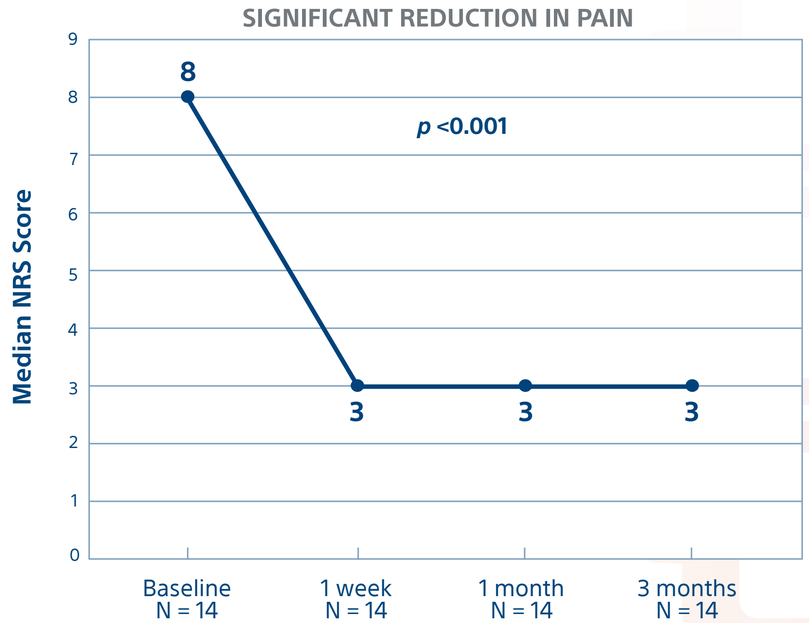


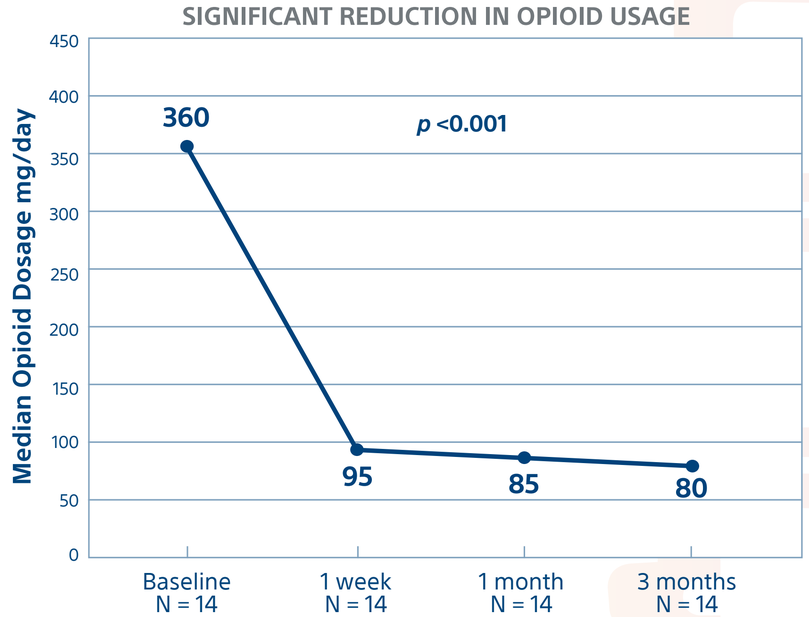
2 Clinical Results (cont.)

SPINE CRYOABLATION: PAIN PALLIATION AND LOCAL TUMOR CONTROL FOR VERTEBRAL METASTASES

Tomasian A et al. 20163

- N = 14 patients/31 vertebral tumours.
- Patients' pain not previously controlled by radiation, chemotherapy or analgesics.
- Local tumour control achieved in 97% of tumours (mean follow-up of 10 months).
- No major complications.





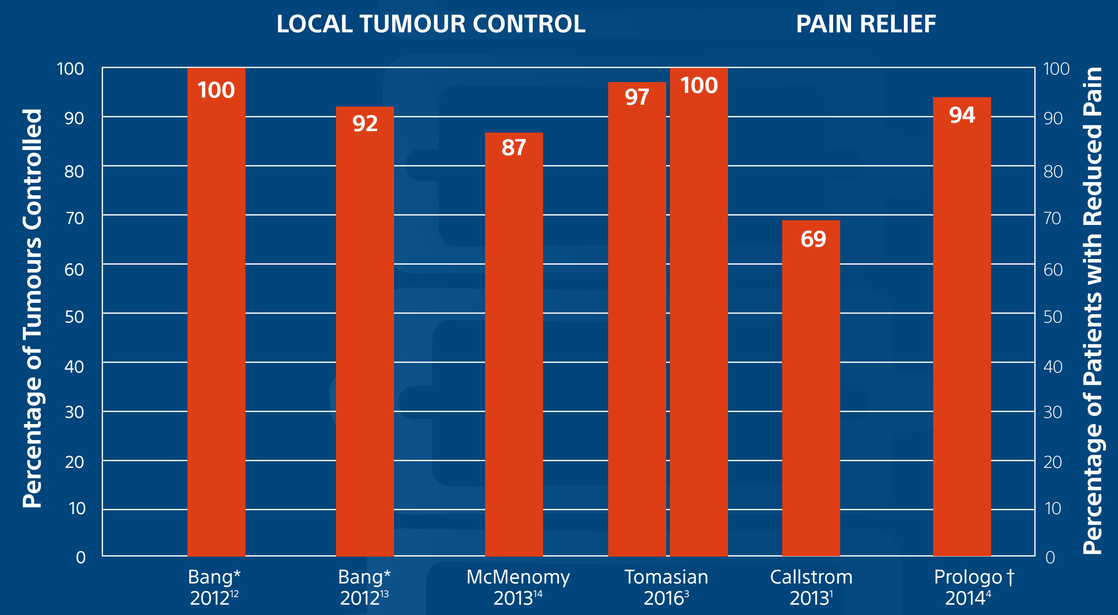
2 Clinical Results (cont.)

CRYOABLATION OF BONE AND MSK METASTASES: EFFICACY DATA

Five-Year Survival after Cryoablation of Stage 1 Non-Small Cell Lung Cancer in Medically Inoperable Patients

Moore W et al. 2015

- Retrospective, single-centre study to evaluate 5-year survival, cancer-specific survival and progression-free survival
  – 45 patients/47 NSCLC tumours (T1a: n=14; T1b: n=33)
  – Mean follow-up time: 51 months (+/- 10)
- 5-year overall survival: 67.8%
  – 5-year cancer-specific survival: 56.6%*
  – 5-year progression-free survival: 87.9%*
- Procedure did not impact pulmonary function
- Average length of hospital stay: 1.6 days (median 1.0 day, range 1-16)
- Survival rates compare favourably with those published for sublobar resection, lobectomy, VATS and stereotactic radiation therapy



Tumour histology	NSCLC	RCC	MIXED	MIXED	MIXED	MIXED
Number of patients (tumours)	6 (10)	7 (13)	40 (52)	14 (31)	61 (69)	50 (54)**
Follow-up period, months	11	16	21	10	6	3
Mean tumour diameter, cm	4.3	4.8	2.0	NR	–	–
Mean pain score change	–	–	–	8 to 3 (5/10)	7.1 to 1.4 (5.7/10)	8 to 3 (5/10)
Grade >3 complications	2**	0	2	0	1	1

* Both studies by Bang et al included a variety of metastases. Bone metastases data only has been used here.
** Includes one death within 30 days of treatment which authors deem unrelated to treatment.
† Study included bone (72%) and other MSK (28%) metastases.

2 Clinical Results (cont.)

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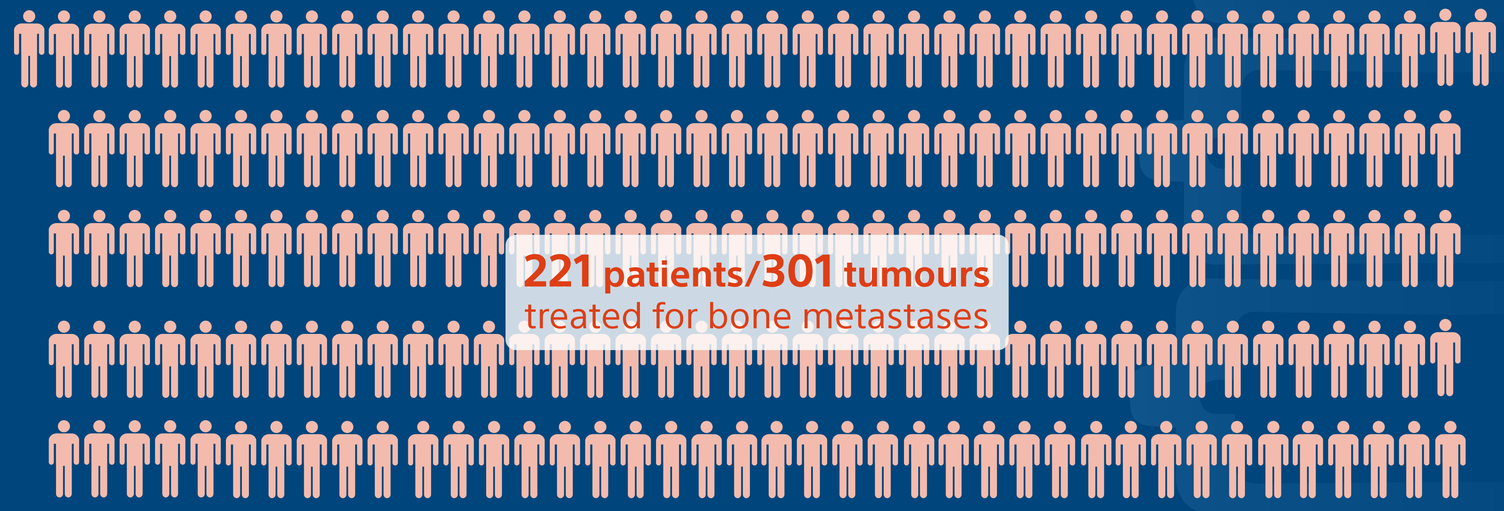
CRYOABLATION OF BONE METASTASES: 10-YEAR SAFETY DATA

"Bone tumour cryoablation is a safe procedure with a very low rate of major complications."

Auloge P et al. 2019. University Hospital of Strasbourg, France[5*]



Overall complication rate **8.6%**

2.7% Major complication rate†

† Major complications associated with: Age >70 years; Use of >3 cryoablation needles
* This study included 18 patients treated for primary bone cancer or benign bone tumours. Boston Scientific Corporation does not promote cryoablation for primary bone cancer; information presented here is for metastatic bone tumours only.

3 Cryoablation Needles: Isotherm Data 37° Gel

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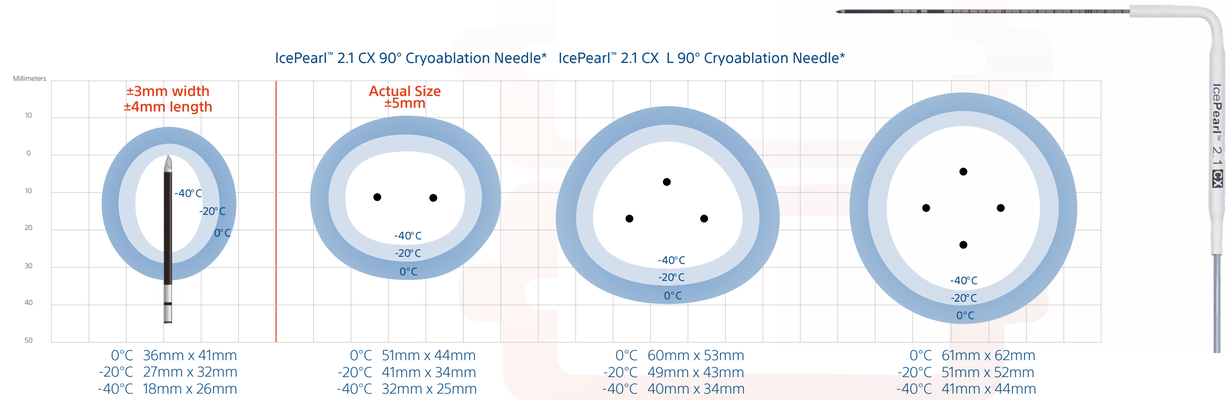
> *The advantage of this technique [cryoablation] is the use of several needles at the same time, making possible to carve the size and the shape of the ice …*
>
> **Mastier C et al. 2018[8]**

ICEPEARL™ 2.1 CX FAMILY

Optimal spacing: 1.0–1.5 cm

*Track Ablation: Radial width 2.1mm; Length 13mm

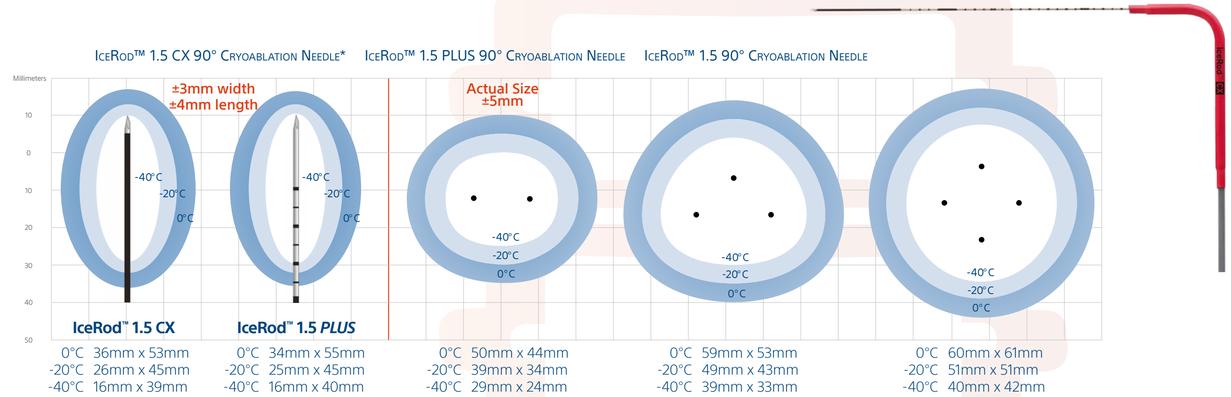


> *Although effective at reducing pain, RFA has important limitations, including nonvisualization of the ablation margin with CT, pain associated with the procedure, and, frequently, increased pain during the immediate posttreatment period.*
>
> **Tomasien A et al. 2016[3]**

ICEROD™ 1.5 FAMILY

Optimal spacing: 1.0–1.5 cm

*Track Ablation: Radial width 2.1mm; Length 13mm

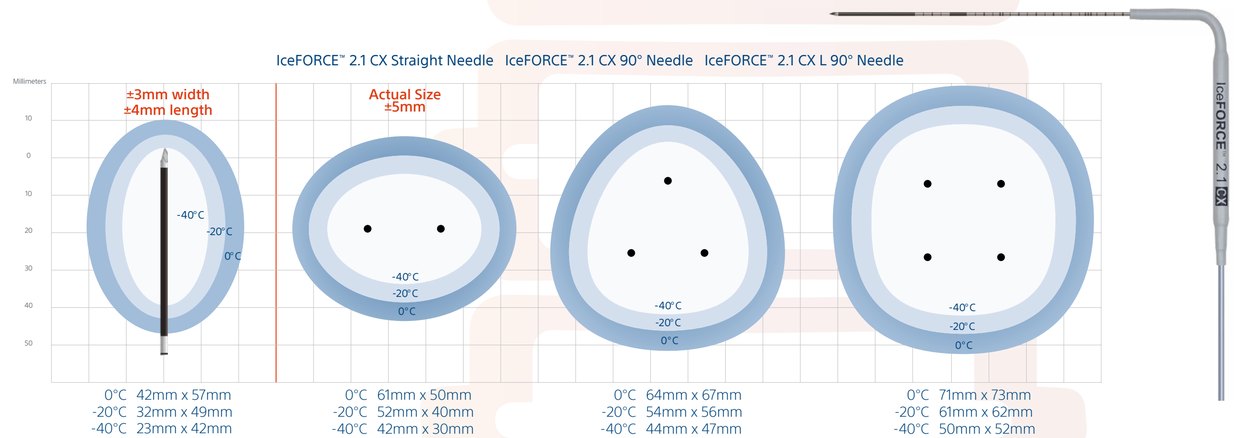


> *Intraprocedural MEP monitoring helps predict neural injury and may improve patient safety during cryoablation of perineural musculoskeletal tumors.*
>
> **Kurup AN et al. 2014[9]**

ICEFORCE™ 2.1 CX FAMILY

Optimal spacing: 1.5–2.0cm

*Track Ablation: Radial width 2.5mm; Length 29mm



1 Quote refers to cryoablation with primary and metastatic tumours

FOR MORE INFORMATION ON CRYOABLATION
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PI-919109-AA- Printed in Germany by medicalvision.

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