A new treatment option for patients with metastatic spinal tumors

Metastatic disease in the skeleton may occur in up to 85% of patients with the three most common types of cancer—breast, prostate and lung.¹

The spine is the most common site for bone metastasis, where it commonly affects multiple vertebral levels.²

For patients, this can cause debilitating pain, numbness, and even paralysis as these tumors impinge on neurologic tissue and weaken the structure of the vertebrae.

Targeted Radiofrequency Ablation (t-RFA) with the STAR™ Tumor Ablation System was developed to provide these patients a new, minimally invasive treatment option to alleviate pain.

Intelligent Energy Delivery

The MetaSTAR™ RF Generator displays real-time feedback to the physician including RF cycle time, active impedance measurements, and current temperatures at multiple locations within and at the periphery of the ablation zone.

Access and Navigation in 3 dimensions

The STAR Tumor Ablation System is designed and purpose-built for the palliative treatment of metastatic vertebral body lesions.

With active steering capabilities, the SpineSTAR™ Ablation Instrument enables physicians to create site-specific ablation zones throughout the vertebral body from a unipediculate approach, thereby minimizing the number of times instrumentation must pass the spinal canal while still providing 3-dimensional access to the vertebral body.

The unique bipolar design of SpineSTAR's extendable electrode tip allows the instrument to serve as both an osteotome and an ablation electrode.

Controlled Ablation Zone

The STAR Tumor Ablation System offers controlled thermal distribution that produces a consistent and predictable ablation zone.

The steep thermal gradient produced by the SpineSTAR Ablation Instrument is designed to minimize impact to vital structures adjacent to the ablation zone.

The unique electrode design maximizes edge effects and RF energy delivery to the targeted tissue while minimizing charring and impedance shut-offs.

Expanding the range of treatment options

With its use of targeted RF energy, the STAR System improves the physician’s ability to offer acute pain relief through the use of a single, minimally invasive procedure that is compatible with both chemo and radiation therapy.

- Minimally invasive, targeted procedure
- Rapid pain relief
- Compatible with current treatment algorithms
- Alternative for patients who have reached their cumulative toxicity limit
- Potential treatment for radio-resistant lesions
- Pain reduction prior to radiotherapy

Unlike other conventional ablation instruments, with SpineSTAR the thermocouples are located at the periphery of the ablation zone in a configuration designed to monitor margins and temperatures within the kill-zone and provide an added margin of safety for adjacent vital structures.
DFINE

DFINE is the developer of minimally invasive radiofrequency (RF) targeted therapies for the treatment of vertebral pathologies. Our devices are built on an extensible RF platform that currently covers two procedural applications: The treatment of vertebral compression fractures (VCFs) with the StabiliT Vertebral Augmentation System, and the palliative treatment of metastatic vertebral body lesions with the STAR Tumor Ablation System. Both systems represent generational advancements in the minimally invasive treatment of vertebral pathologies.

DFINE is dedicated to relieving pain and improving the quality of life for patients suffering from vertebral pathologies through innovative, minimally invasive therapies.

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>PRODUCT DESCRIPTIONS/SPECIFICATIONS</th>
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<tbody>
<tr>
<td>3192</td>
<td>SpineSTAR™ Ablation Instrument</td>
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<td>Specifications:</td>
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<tr>
<td></td>
<td>41mm Articulating Tip</td>
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<td></td>
<td>Full articulation allows for up to 28mm reach from SpineSTAR shaft</td>
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<td></td>
<td>5mm extension of Ablation Electrode</td>
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<tr>
<td>3383</td>
<td>STAR™ Tumor Ablation Kit</td>
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<td></td>
<td>SpineSTAR™ Ablation Instrument</td>
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<td>StabiliT™ Introducer (Bevel tip and Diamond tip)</td>
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<td>VertecoR® Straightline Cement Staging Osteotome 3.0-11.5</td>
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<td>3195</td>
<td>MetaSTAR™ RF Generator</td>
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<td>Dimensions: 18”(L) x 11”(W) x 6”(H)</td>
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**Risks Statement**

Targeted RF Ablation (t-RFA) is designed to provide a minimally invasive therapy for palliative treatment of metastatic lesions. As with most surgical procedures, adverse events that may be serious can occur. Such events that may occur include: damage to surrounding tissue through iatrogenic injury, hemothorax or pneumothorax, unintended puncture wounds, pulmonary embolism, hemorrhage, hematoma, infection, pain, and/or nerve injury leading to radiculopathy, paresis, or paralysis.
Targeted Radiofrequency Ablation (t-RFA) of Spinal Tumors using a Novel Bipolar Navigational Device: Initial Multicenter Clinical Experience

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1) Washington University, St. Louis, MO, USA .  2) University of California, San Diego, CA, USA.
3) University of Louisville, Louisville, KY, USA.  4) Albert Einstein College of Medicine, New York, NY, USA.

Purpose:
Osseous metastatic lesions are the most frequent complication of malignant tumors, reported to be seen in up to 85% of patients at the time of death and associated with severe pain and pathologic fractures. (1,2) The use of radiofrequency ablation (RFA) first described by Rosenthal et al. (3) has been limited in spinal metastatic disease due to requirement of targeted ablation in close proximity to neural elements and challenges to navigate the unique anatomy of the spine. The early clinical experience and procedural feasibility using an innovative, bipolar, navigational RF ablation device for targeted treatment of such malignant spinal lesions is reported in this limited feasibility multicenter review.

Materials and Methods:
78 spinal lesions in 55 patients were treated at four academic centers. Image guided t-RFA was performed with the STAR Tumor Ablation System which includes a robust articulating, navigational bipolar electrode containing two active thermocouples (TC) positioned to permit real time monitoring of the peripheral edge of the ablation zone to determine size of ablation. Pre-procedural planning was performed based on cross-sectional imaging to determine number of targeted ablations based on lesion size & thermal distribution curves. Treatment was controlled by adjusting power while monitoring TC temperature in-situ. Special neural thermal protection techniques involving epidural or neuroforaminal TC and injection of CO2 or cooled fluid were used in some cases. Cement augmentation using RF warmed high viscosity cement was performed via the same guiding cannula when required. In select cases, post-procedural contrast enhanced magnetic resonance imaging (MRI) was performed to assess ablative zone and post-op metastatic lesion status. In a subset of patients at one institution, pain was assessed by Visual Analogue Scale (VAS) and function by Oswestry Disability Index (ODI).

Fig 1. STAR (Spinal Tumor Ablation with Radiofrequency) System Components:
A. SpineSTAR Instrument, 10 g, articulated, extendable bipolar electrode.
B. Distal end of SpineSTAR containing two thermocouples (red dots), located at 10 and 15 mm from center of ablation zone which permit real-time monitoring of peripheral edge of ablation zone.
C. MetaSTAR Generator Display: proprietary RF generator with impedance and temperature controlled algorithm.
Results:

- Fluoroscopic and CT guided RFA procedures were successfully performed in all 78 lesions. Cement augmentation was performed in the majority of the 78 lesions in the presence of compression fracture.
- Lesion etiology included a wide variety of metastatic lesions (e.g. lung, renal cell, breast, thyroid, atypical carcinoid, leiomyosarcoma, liposarcoma, epithelioid hemangioendothelioma) & multiple myeloma involving T2 to S2 & ilium.
- Post-ablation MRI's demonstrated discrete ablation zones consistent with thermal monitoring by TCs during the ablation. Ablation zone morphology was typically 3:2 length to width aspect ratio.
- TCs on the ablation device were used to confirm re-establishment of physiologic temperature in-situ post ablation prior to cement augmentation. Cement augmentation following RF ablation through same coaxial working cannula was efficient and resulted in predictable cement filling.
- All patients reported pain relief. Average VAS improved from 7.0 pre to 4.7 post t-RFA and ODI improved from 25.8 pre to 18.0 post t-RFA, which represents improvement from moderate to minimal disability. (4)
- No device related adverse events.

Conclusion:

The STAR Tumor Ablation System, an innovative bipolar RF device, purpose built for targeted ablation of spinal malignant lesions, was safely and effectively used in the navigation and targeted RFA of spinal malignant lesions. Post-ablation MRI's confirmed lesions were included in the ablation zone with necrosis of the lesion. The ablation zone size was accurately determined by temperature monitoring of TCs on the bipolar articulating electrode and the morphology was very similar to that extrapolated from pre-clinical thermal distribution curves. The navigational ability of the STAR System allowed for easy access to posterior vertebral body lesions, previously difficult to access with other ablation devices. In vertebral bodies with pathologic fractures or at risk of fracture, high viscosity cement was delivered after ablation via the same working cannula. In many cases, this technique allowed for treatment of individual lesions not controlled by systemic or radiation therapy.


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Fig 2. 50 year old female with history of retroperitoneal leiomyosarcoma with PET positive L4 metastatic lesion unresponsive to prior stereotactic radiation therapy with continued progression of lesion size and pain:

A. L4 - Axial CT with destructive, posterior vertebral body lesion.
B. Articulation of SpineSTAR instrument allows navigation to center of metastatic lesion in posterior aspect of vertebra.
C. One month post procedure T1 weighted MRI images demonstrated the lesion was included within a discrete ablation zone.
D. One month post procedure: Post-contrast T1 weighted images demonstrate ablation zone (thin arrows) & necrosis of lesion with peripheral rim enhancement.
E. Six month follow-up PET/CT showing no FDG uptake within the lesion
Targeted Radiofrequency Ablation (t-RFA) of Malignant Spine Lesions using a Bipolar Navigational Device: Initial Clinical Experience

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1) University of California, San Diego, CA, USA. 2) University Medical Center Mainz, Mainz, Germany. 3) University of Louisville, Louisville, KY, USA. 4) Albert Einstein College of Medicine, New York, NY, USA. 5) Washington University, St. Louis, MO, USA

Background and Purpose:
Musculoskeletal metastatic lesions are the most frequent complication of malignant tumors, reported to be seen in up to 85% of patients at the time of death and associated with severe pain and pathologic fractures. (1,2) The use of radiofrequency ablation (RFA) first described by Rosenthal et al. (3) has been limited in spinal metastatic disease due to requirement of targeted ablation in close proximity to neural elements and challenges to navigate the unique anatomy of the spine. The early clinical experience and procedural feasibility using an innovative, bipolar, navigational RF ablation device for targeted treatment of such malignant spinal lesions is reported in this limited feasibility multicenter review.

Materials and methods:
26 spinal lesions in 20 patients were included. Lesion etiology and location included a variety of metastatic malignant solid tumors and multiple myeloma in T2- S1, sacral ala and ileum. The STAR™ Tumor Ablation System (Fig 1) includes a robust, navigational, articulating osteotome which serves as a bipolar electrode containing two active thermocouples (TC) positioned along the length of the device to permit real time monitoring of the peripheral edge of the ablation zone. Treatment is controlled by adjusting power while monitoring TC temperature. Pre-op planning used CT and thermal distribution curves. Cement augmentation via the same guiding cannula was performed when required.

Fig 1. STAR (Spinal Tumor Ablation with Radiofrequency) System Components:

SpineSTAR Instrument (left): 10 g, bipolar, articulated, extendable electrode containing two thermocouples, 10 and 15 mm from center of ablation zone. Permits real time monitoring of peripheral edge of ablation zone.

MetaSTAR Generator Display (right): proprietary RF generator with an impedance and temperature controlled algorithm.
Results:

- Fluoroscopic and CT guided RFA procedures were successfully performed in all 26 lesions. Cement augmentation was performed in 24 of the 26 lesions in the presence of compression fracture.
- Mean ablation time was 6 minutes and 23 seconds.
- Post ablation-MRI imaging in non-augmented lesions demonstrated discrete ablation zones consistent in size with temperatures registered by the thermocouples (and displayed on the Generator monitor).
- Ablation zone morphology was typically 3:2 length to width aspect ratio.
- The TC on the ablation device was used to confirm re-establishment of physiologic temperature in-situ post ablation prior to cement augmentation. Cement augmentation following RF ablation through same coaxial working cannula was efficient and resulted in predictable cement filling.
- No device related adverse events, consistent cement augmentation post ablation.

**Fig 2.** 50 year old female with history of retroperitoneal leiomyosarcoma with PET positive L4 metastatic lesion unresponsive to prior stereotactic radiation therapy with continued progression of lesion size and pain:

A. Axial CT of L4 with destructive, posterior vertebral body lesion. Pre-op CT images used to plan access, size and shape of desired ablation zone.

B. Articulation of SpineSTAR instrument allows navigation to center of metastatic lesion in posterior aspect of vertebra.

C. One month post procedure MRI images demonstrated the lesion was included within a discrete ablation zone.

D. One month post procedure: Post-contrast T1 images demonstrate ablation zone (thin arrows) and necrosis of lesion with minimal enhancement posteriorly.

Conclusion:

These human feasibility data demonstrate a novel RF ablation device reduced to clinical practice. The STAR Tumor Ablation System, the first purpose-built, bipolar RF device for targeted ablation of spinal malignant lesions, functioned as designed. Malignant lesions were easily accessed, regardless of location. Proximal and distal thermocouples allowed accurate monitoring of temperature inside the vertebral body, and at the periphery of the increasing ablation zone, to avoid complications of nearby vital structures. High viscosity cement could be delivered after ablation from the same guiding cannula.