Health Policy Advisory Committee on Technology

Technology Brief Update

STAR™ Tumor Ablation System

March 2017

HealthPACT
emerging health technology
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This Brief was commissioned by Queensland Health, in its role as the Secretariat of the Health Policy Advisory Committee on Technology (HealthPACT). The production of this Brief was overseen by HealthPACT. HealthPACT comprises representatives from health departments in all States and Territories, the Australian and New Zealand governments and MSAC. It is a sub-committee of the Australian Health Ministers’ Advisory Council (AHMAC), reporting to AHMAC’s Hospitals Principal Committee (HPC). AHMAC supports HealthPACT through funding.

This brief was prepared by Dr Meegan Vandepeer from Research & Evaluation, incorporating ASERNIP-S.
2017 Summary of findings

Two new studies were identified on the effect of targeted radiofrequency ablation (t-RFA) using the STAR Tumor Ablation System for patients with spinal metastases. Both were case series studies: one was in the form of a conference abstract. Both studies used vertebral augmentation in conjunction with t-RFA.

The regulatory status and usage of the STAR Tumor Ablation System remains unchanged since the original Brief. This device is not listed on the Australian Register of Therapeutic Goods, and there is still no evidence to suggest that the STAR Tumor Ablation System or any other t-RFA system is being used in Australia.

No major complications, including thermal injuries, occurred in the 4-week follow-up periods of either study. The only adverse event reported by one study was radicular pain. Both studies reported significant reductions in pain following t-RFA. In a subgroup of patients with moderate to severe pain prior to treatment, one case series study reported increased activity levels in 50 per cent of these patients and lower pain medication use in 31 per cent. The level of increased activity was not reported.

Two other radiofrequency ablation electrodes have been developed specifically for the treatment of vertebral metastases. At the time of writing this Update only pre-clinical studies were identified on these devices.

In summary, the literature on t-RFA for relief of pain in patients with spinal metastases is still limited to case series data. Whilst the treatment appears to be relatively safe, with no major complications reported, the question as to whether the pain relief reported is due to t-RFA or vertebral augmentation, or whether they have a synergistic effect on pain relief, is still unclear from the studies included in this update.

2017 HealthPACT Advice

It is unclear whether the modest patient benefits reported in the current evidence base is due to the effect of the STAR Tumor Ablation System alone, or if this effect is augmented by radiotherapy delivered to patients during the same course of treatment. There is no evidence describing outcomes in patients treated with the STAR Tumor Ablation System compared to those treated with radiotherapy or analgesics alone. As such, this technology should not be considered for use as a first line treatment but may have a place as a second line treatment if radiation treatment for pain palliation has failed. In addition, it is unclear whether or not the pain associated with spinal metastases is caused by mechanical forces or by tumour growth. Studies comparing bone stabilisation to RFA would clarify this issue.

There is currently insufficient evidence to support the use of this technology; however, the collection of prospective data should be encouraged. HealthPACT does not support public investment in this technology in clinical practice at this time, except under the auspices of a clinical trial conducted in a centre of excellence.
Technology, Company and Licensing

Register ID WP196
Technology name The STAR™ Tumor Ablation System
Patient indication Patients with metastatic spinal lesions

Reason for assessment
In 2016 a Technology Brief investigated the use of the STAR™ Tumor Ablation System, a targeted radiofrequency ablation (t-RFA) device for the palliative treatment of spinal tumours. As only case series evidence was available, HealthPACT recommended that the evidence for the STAR Ablation System, and similar systems, be reviewed again in 12 months. In line with this recommendation, the purpose of the current Update is to consider the evidence that has emerged since 2016 and to determine whether this new evidence may provide additional information to inform policy decisions.

Description of the technology
The STAR™ Tumor Ablation System (DFINE, Inc., California, United States of America [USA]) is a minimally invasive t-RFA device used for the palliative treatment of spinal tumours. It consists of an ablation instrument (SpineSTAR™ Ablation Instrument) and a generator (MetaSTAR™ RF Generator), which has a 5 and 10 watt power setting. The ablation instrument has a flexible tip that contains a bipolar electrode and a heat sensor.¹

![Figure 1 The STAR Tumor Ablation System](image)

The ablation procedure is performed under fluoroscopic or computed tomography (CT) guidance with the patient lying face down. The tube (introducer) containing the electrode is passed through a small puncture in the skin and correctly positioned at the tumour site. Radiofrequency energy is then delivered through the electrode to heat and destroy (ablate) the spinal tumour. The heat sensor monitors the temperature at the edge of the ablation zone in real time, allowing the physician to adjust the level of energy being delivered² and to minimise damage to the surrounding healthy tissue.¹,³ Following ablation the introducer may be removed or it may be used to deliver cement to strengthen the spinal vertebrae.
(vertebral augmentation) in cases where the patient had a vertebral fracture or when spinal instability is a concern.\textsuperscript{1} The introducer can also be used to take tissue biopsies.\textsuperscript{4}

The entire ablation procedure reportedly takes less than 90 minutes and is performed on an outpatient basis using a local anaesthetic and moderate sedation. The STAR Tumor Ablation System is indicated for patients with painful metastatic spinal tumours and is contraindicated in patients with pacemakers or other electronic implants, or who have tumours in the cervical spine.\textsuperscript{2} Patients treated with the STAR Tumor Ablation System can continue their systemic cancer treatments without interruption.

One of the key advantages of the STAR Tumor Ablation Systems is the articulating bipolar extensible electrode tip. This tip can be curved up to 90 degrees, allowing the interventional radiologist to navigate the probe into areas of the vertebral body that are typically difficult to access. Attached thermocouples allow real-time monitoring of the ablation zone volume, to assist avoiding thermal injury to the spinal cord and exiting nerve roots of the spine. The use of bipolar electrode enables the ability to deliver a focused treatment and avoid the use of a grounding pad. Finally, the STAR Tumor Ablation System allows the interventional radiologist to perform both RFA and vertebral body augmentation (Personal Communication, St. Andrew’s War Memorial Hospital).

The manufacturer (DFINE, Inc.) also market products for vertebral augmentation. Their system is called the StabiliT\textsuperscript{®} Vertebral Augmentation System. Vertebral augmentation is traditionally associated with the treatment of vertebral compression fractures. However, it can also be performed in addition to tumour ablation. During the procedure, a small tube is placed into the fractured vertebra and a cavity is created. Bone cement is used to fill the cavity and it infiltrates the surrounding bone to stabilise the fracture. DEFINE, Inc., also market a bone cement the StabiliT\textsuperscript{®} ER2 Bone Cement.\textsuperscript{5}

**Company or developer**

STAR™ Tumor Ablation System, DFINE, Inc., California, United States of America.

**2017 Stage of development in Australia**

- Yet to emerge
- Experimental
- Investigational
- Nearly established
- Established
- Established *but* changed indication or modification of technique
- Should be taken out of use

**2017 Licensing, reimbursement and other approval**

The licensing status of the STAR Tumor Ablation System remains unchanged since the original Brief; it has United States Food and Drug Administration approval (510(k) K091310)\textsuperscript{6} and a CE mark\textsuperscript{7}, but it does not have approval from the Therapeutic Goods Administration.
2017 Australian Therapeutic Goods Administration approval

☐ Yes  ARTG number(s) NA
☒ No  Not applicable

2017 Diffusion of technology in Australia

No evidence was identified to suggest that the STAR Tumor Ablation System or any other t-RFA system is being used in Australia.

2017 International utilisation

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States of America</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

2017 Evidence and Policy

Safety and effectiveness

Two retrospective case series studies (level IV interventional evidence) were identified for inclusion in this Update; one was in the form of a conference abstract. Details of the included studies are reported in Table 1.

Table 1  Details of included studies

<table>
<thead>
<tr>
<th>Study details/Location</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Number of patients, length of follow-up and losses to follow-up</th>
<th>Conflicts of interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Georgy et al 2015</td>
<td>Patients with metastatic spinal lesions*</td>
<td>NR</td>
<td>N = 74  Length: 2 to 4 weeks  Losses to follow-up: NR</td>
<td>NR</td>
</tr>
<tr>
<td>Wallace et al 2015</td>
<td>Patients who underwent RFA of osseous metastases between April 2012 and July 2014†</td>
<td>Metastases that were entirely osteoblastic, associated with pathologic compression fracture with spinal instability or causing metastatic spinal cord</td>
<td>N = 72  Length: 4 weeks  Losses to follow-up: 6/72 (8.3%)§</td>
<td>One of the authors is a speaker panellist and consultant for DFINE, Inc.</td>
</tr>
<tr>
<td>Study details/Location</td>
<td>Inclusion criteria</td>
<td>Exclusion criteria</td>
<td>Number of patients, length of follow-up and losses to follow-up</td>
<td>Conflicts of interest</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>---------------------------------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Single centre USA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NR: not reported RFA: radiofrequency ablation
*Patients had cement augmentation in addition to targeted radiofrequency ablation
†Vertebral augmentation was performed after 95% of ablations
‡Some patients (it is not stated how many) were treated with RFA for local control; these patients are only included for complication rate assessment
§Patients died prior to the 4-week follow-up

Georgy et al 2015

This retrospective, multicentre case series, published as a conference abstract, investigated the use of t-RFA with the STAR Tumor Ablation System to treat 106 spinal metastatic lesions in 74 patients. No information was reported on the number of patients per site, or if they were consecutively enrolled. Patients had cement augmentation in addition to radiofrequency ablation. Visual analogue scores (VAS) and Oswestry Disability Index (ODI) scores were measured before and two to four weeks after treatment. Losses to follow-up were not reported.

Safety

No complications or thermal injuries were observed.

Effectiveness

Mean VAS scores improved significantly from 8.1 pre-procedure to 3.5 post-procedure ($p<0.0001$), as did the mean ODI scores (from 29.3 pre-procedure to 18.4 post-procedure; $p<0.0001$).

Wallace et al 2015

Wallace et al reported a retrospective case series study on 72 consecutive patients who underwent t-RFA with the STAR Tumor Ablation System for 110 spinal metastases at a single institution between April 2012 and July 2014. In addition to the inclusion criteria listed in Table 1, treated patients: could not receive radiation therapy; had persistent or recurrent pain despite radiation therapy; and were treated with combination radiation therapy, t-RFA and vertebral augmentation when tumour radiation-resistance was anticipated. Some patients were also treated with t-RFA for local control (number not reported); these patients were only included in the case series for complication rates.

Forty-nine per cent (54/110) of treated tumours were located in the thoracic spine and 51 per cent (56/110) were located in the lumbar spine. Vertebral augmentation was performed after 95 per cent (105/110) of ablations. Thirty one per cent (22/72) of patients also received radiation therapy within six weeks of t-RFA.
The outcomes assessed included pain relief at one and four weeks post-treatment, assessed using the Numeric Pain Rating Scale (NPRS) (Table 2), and post-procedure complications. Pre- and post-procedure pain scores were compared in patients with pre-procedure NPRS scores of ≥4. Subgroup analyses were performed on: patients not treated with radiation therapy within six weeks of t-RFA therapy; patients who did not receive radiation therapy six weeks prior to t-RFA therapy or an epidural or nerve root corticosteroid injection within two weeks of t-RFA therapy; patients who underwent treatment of a single vertebra; and patients who underwent treatment of multiple vertebrae. The percentage of patients that had partial (≥2-point reduction in NPRS score) or complete pain relief (post-procedure NPRS score ≤1) at one and four weeks post-procedure was calculated. At four weeks post-treatment patients were also interviewed about any changes in their pain medication use and activity level.

Table 2 Numerical Rating Scale for pain self-assessment

<table>
<thead>
<tr>
<th>Rating</th>
<th>Pain level</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No pain</td>
</tr>
<tr>
<td>1-3</td>
<td>Mild pain (little interference with ADL)</td>
</tr>
<tr>
<td>4-6</td>
<td>Moderate pain (significant interference with ADL)</td>
</tr>
<tr>
<td>7-10</td>
<td>Severe pain (unable to perform ADL)</td>
</tr>
</tbody>
</table>

ADL: activities of daily living

Safety

No major complications occurred in the four-week follow-up period. Four patients (4/72; 6%) reported post-procedure radicular pain, which resolved after one or two transforaminal nerve root corticosteroid injections. There were no cases of symptomatic cement leakage (extravasation). Sixty per cent (3/5) of the treated vertebrae that were not augmented fractured within 12 months.

Effectiveness

Significant reductions in median NPRS pain scores were reported at one and four weeks post-procedure in all patients with an NPRS score of at least 4, as well as in two of the four patient subgroups (p<0.0001) (Table 3): patients who had a single vertebra treated and patients who had multiple vertebrae treated, although these differences were not analysed statistically. The degree of change in median pain scores at one or four weeks post-procedure was not significantly different between patients who received treatment of a single vertebra and those who had multiple vertebrae treated (p>0.05).

Results on post-treatment pain relief, pain medication usage and activity levels in all patients and in two of the subgroups are presented in
Table 4. Four weeks post-procedure, pain medication usage decreased in 31 per cent of all patients and activity levels increased in 50 per cent of all patients. The level of increased activity was not reported. The proportion of patients with partial and complete pain relief was 78 and 45 per cent, respectively. In general, the percentage of patients with partial and complete pain relief in the two subgroups was not as high as for all patients at four weeks post-procedure. The greatest proportion of patients who decreased their pain medication use at four weeks post-procedure were those who did not receive radiation therapy six weeks prior to t-RFA therapy or an epidural or nerve root corticosteroid injection within two weeks of t-RFA therapy.

Table 3  Comparison of pre- and post-procedure median NPRS scores in patients with pre-procedure NPRS scores ≥4

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Median NPRS score</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure (N = 64)</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>1 week post-procedure (N = 64)</td>
<td>3.25</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>4 weeks post-procedure (N = 58)†</td>
<td>2.75</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subgroup of patients who did not receive radiation therapy 6 weeks prior to t-RFA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure (N = 43)</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>1 week post-procedure (N = 43)</td>
<td>3.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>4 weeks post-procedure (N = 43)</td>
<td>2.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subgroup of patients who did not receive radiation therapy 6 weeks prior to t-RFA or an epidural or nerve root corticosteroid injection within 2 weeks of t-RFA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure (N = 22)</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>1 week post-procedure (N = 22)</td>
<td>5.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>4 weeks post-procedure (N = 22)</td>
<td>4.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subgroup of patients who underwent treatment of a single vertebra</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure (N = 39)</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>1 week post-procedure (N = 39)</td>
<td>2.0</td>
<td>NR</td>
</tr>
<tr>
<td>4 weeks post-procedure (N = 39)</td>
<td>2.5</td>
<td>NR</td>
</tr>
<tr>
<td>Subgroup of patients who underwent treatment of multiple vertebrae</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure (N = 27)</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>1 week post-procedure (N = 27)</td>
<td>4.0</td>
<td>NR</td>
</tr>
<tr>
<td>4 weeks post-procedure (N = 27)</td>
<td>3.0</td>
<td>NR</td>
</tr>
</tbody>
</table>

*Six patients died prior to 4 week follow-up; NR: not reported; NPRS: Numeric Pain Rating Scale; t-RFA: targeted radiofrequency ablation.
Table 4  Pain relief, pain medication usage and activity level reported by patients with pre-procedure NPRS scores ≥4 (N = 64)*

<table>
<thead>
<tr>
<th>Group</th>
<th>Partial pain relief n/N (%)</th>
<th>Complete pain relief n/N (%)</th>
<th>Decreased pain medication usage 4 weeks post-procedure n/N (%)</th>
<th>Increased activity level 4 weeks post-procedure n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>1 week pp: 45/64 (70)</td>
<td>1 week pp: 15/64 (23)</td>
<td>18/58 (31)</td>
<td>29/58 (50)</td>
</tr>
<tr>
<td></td>
<td>4 weeks pp: 45/58 (78)</td>
<td>4 weeks pp: 26/58 (45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subgroup 1†</td>
<td>1 week pp: 33/43 (77)</td>
<td>1 week pp: 11/43 (26)</td>
<td>12/39 (31)</td>
<td>18/39 (46)</td>
</tr>
<tr>
<td></td>
<td>4 weeks pp: 21/39 (54)</td>
<td>4 weeks pp: 16/39 (41)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subgroup 2‡</td>
<td>1 week pp: 14/22 (64)</td>
<td>1 week pp: NR</td>
<td>14/20 (70)</td>
<td>7/20 (35)</td>
</tr>
</tbody>
</table>

Note: In all but one row for each group the numerators (partial pain relief plus complete pain relief) do not add up to the denominator, these discrepancies were not explained by the author.

*Six patients died prior to 4 week follow-up, †Patients who did not receive radiation therapy six weeks prior to t-RFA therapy
‡Patients who did not receive radiation therapy six weeks prior to t-RFA therapy or an epidural or nerve root corticosteroid injection within two weeks of t-RFA therapy, NR: not reported; NPRS: Numeric Pain Rating Scale; pp: post-procedure; t-RFA: targeted radiofrequency ablation

2017 Economic evaluation
No economic evaluation studies were identified.

2017 Ongoing research
Four clinical trials were identified on the STAR Tumor Ablation System from a search of Clinicaltrials.gov and ANZCTR.org.au. All four trials are sponsored by the manufacturer (DFINE Inc.) Details of the trials are described in Table 5.

Table 5  Registered clinical trial characteristics on the STAR Tumor Ablation System

<table>
<thead>
<tr>
<th>Trial ID; location</th>
<th>Study design</th>
<th>Estimated enrolment</th>
<th>Intervention(s)</th>
<th>Outcome measure(s)</th>
<th>Status</th>
<th>Estimated completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02225223 USA</td>
<td>Non-randomised comparative Multicentre</td>
<td>64</td>
<td>t-RFA with the STAR Tumor Ablation System and radiofrequency-targeted vertebral augmentation in patients with no previous radiotherapy versus patients who have not responded to or refused further radiotherapy</td>
<td>Pain relief, quality of life, change in function, change in pain medication</td>
<td>Recruiting</td>
<td>June 2017</td>
</tr>
<tr>
<td>NCT02217150 USA</td>
<td>Case series Multicentre</td>
<td>50</td>
<td>t-RFA with the STAR Tumor Ablation System</td>
<td>Change in pain, change in quality of life</td>
<td>Active, not recruiting</td>
<td>March 2016</td>
</tr>
<tr>
<td>NCT02419703 USA</td>
<td>Case series Multicentre (registry data)</td>
<td>1000</td>
<td>t-RFA with the STAR Tumor Ablation System</td>
<td>Pain relief, change in quality of life</td>
<td>Recruiting</td>
<td>December 2018</td>
</tr>
<tr>
<td>NCT02081053 France, Germany, Italy</td>
<td>Case series Multicentre</td>
<td>40</td>
<td>t-RFA with the STAR Tumor Ablation System and targeted vertebral augmentation</td>
<td>Pain relief, change in function, change in quality of life, change in pain medication</td>
<td>Recruiting</td>
<td>December 2016</td>
</tr>
</tbody>
</table>

t-RFA: targeted radiofrequency ablation
2017 Other issues

Merit Medical Systems, Inc. (Utah, United States of America) acquired DFINE, Inc., the developer of the STAR Tumor Ablation System, in July 2016.

One of the authors on the Wallace et al\textsuperscript{8} study is a speaker panellist and consultant for DFINE, Inc. However, no mention was made of conflicts of interest in the conference abstract.

As noted in the original Brief, most of the patients in the two studies included in this Update also received vertebral augmentation. Consequently, it is not clear whether the observed reductions in pain, increased activity levels and reduced usage of pain medication were a result of the t-RFA, the vertebral augmentation procedure or both. It is also unclear how the degree of pain relief after t-RFA, with or without augmentation, compares with other therapies such as external beam radiation, as no comparative studies have been done.

A second retrospective case series study by Wallace et al on the use of the STAR Tumor ablation system for spinal metastases was identified.\textsuperscript{10} This study included patients from the same database and time period as Wallace et al\textsuperscript{8}, but t-RFA was performed to achieve local control and, in most cases, pain relief. As the focus of this Update is the effect of the STAR System on the palliation of spinal cancer symptoms (pain and reduced activity) rather than tumour control, this study was not eligible for inclusion in this Update.

Research into this technology identified the full publication\textsuperscript{11} of the conference abstract published by Bagla et al (2015)\textsuperscript{12}. Although this later publication included slightly higher follow-up numbers, it did not report and additional or different results. Consequently the full study was not included in this Technology Brief Update.

In addition to the STAR Tumor Ablation System, two other radiofrequency ablation electrodes have been developed specifically for the treatment of vertebral metastases: the OsteoCool\textsuperscript{™} RF Ablation System (Medtronic, Minnesota, USA) and a helical coil ablation electrode developed in Ontario, Canada.\textsuperscript{13} Medtronic acquired OsteoCool from Baylis Medical Company Inc. (Quebec, Ontario) on 16 December 2015.\textsuperscript{14} Only pre-clinical studies were identified on these two devices. No approvals were identified for the helical coil ablation electrode, whereas the OsteoCool System received United States Food and Drug Administration 510(k) approval (K152057) in November 2015.\textsuperscript{15}

2017 Number of studies included

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies: 2
Total number of Level IV studies: 2
Date searched
23/11/2016

2017 References


Technology name: The STAR™ Tumor Ablation System

Patient indication: Patients with metastatic spinal lesions

Description of the technology

The STAR™ Tumor Ablation System (DFINE, Inc., California, United States of America [USA]) is a minimally invasive targeted radiofrequency ablation (t-RFA) device used for the palliative treatment of spinal tumours. It consists of an ablation instrument (SpineSTAR™ Ablation Instrument) and a generator (MetaSTAR™ RF Generator), which has a 5 W and 10 W power setting. The ablation instrument has a flexible tip that contains a bipolar electrode and a heat sensor.\(^1\)

The ablation procedure is performed under fluoroscopic or computed tomography (CT) guidance with the patient lying face down. The tube (introducer) containing the electrode is passed through a small puncture in the skin and correctly positioned at the tumour site. Radiofrequency energy is then delivered through the electrode to heat and destroy (ablate) the spinal tumour. The heat sensor monitors the temperature at the edge of the ablation zone in real time, allowing the physician to adjust the level of energy being delivered\(^2\) and to minimise damage to the surrounding healthy tissue.\(^1,3\) Following ablation the introducer may be removed or it may be used to deliver cement to strengthen the spinal vertebrae (vertebral augmentation) in cases where the patient had a vertebral fracture or when spinal instability is a concern.\(^1\) The introducer can also be used to take tissue biopsies.\(^4\)

The entire ablation procedure reportedly takes less than 90 minutes and is performed on an outpatient basis using a local anaesthetic and moderate sedation. The STAR Tumor Ablation System is indicated for patients with painful metastatic spinal tumours and is
contraindicated in patients with pacemakers or other electronic implants, or who have tumours in the cervical spine. Patients treated with the STAR Tumor Ablation System can continue their systemic cancer treatments without interruption.

The use of bipolar electrode enables the ability to deliver a focused treatment and avoid the use of a grounding pad. Additionally, the use of thermocouples facilitates the real-time temperature monitoring and control of the growth of the lesion.

The manufacturer (DFINE, Inc.) also market products for vertebral augmentation. Their system is called the StabiliT® Vertebral Augmentation System. Vertebral augmentation is traditionally associated with the treatment of vertebral compression fractures. However, it can also be performed in addition to tumour ablation. During the procedure, a small tube is placed into the fractured vertebra and a cavity is created. Bone cement is used to fill the cavity and it infiltrates the surrounding bone to stabilise the fracture. DEFINE, Inc., also market a bone cement the StabiliT® ER2 Bone Cement.

Company or developer
The STAR Tumor Ablation System was developed by DFINE, Inc., California, USA.

Reason for assessment
The STAR Tumor Ablation System provides a new treatment for use in the palliative care of patients with spinal metastases.

Stage of development in Australia
- ☒ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established but changed indication or modification of technique
- ☐ Should be taken out of use

Licensing, reimbursement and other approval
The STAR Tumor Ablation System received Food and Drug Administration (FDA) 510(k) (K091310) approval in August 2010 and a CE mark in October 2013.

Dfine, Inc. has filed a patent for STAR Tumor Ablation System in Australia (AU2013240565) in 2013.
Disease description and associated mortality and morbidity

Metastatic spinal tumours are lesions located in the vertebrae and are the most common form of bone metastases in patients with cancer. Bone metastases are a major cause of chronic pain and the long term outlook for cancer patients with spinal metastases is poor. Patients with spinal metastases have a median survival of 10 months. By this point the cancer is at an advanced stage and treatment of spinal metastases is primarily focused on controlling pain and preserving function. Bone metastases can also cause vertebral fractures and spinal cord compression, leading to urinary and bowel incontinence, limb weakness and excess calcium in the blood (hypercalcaemia).

Number of patients

Cancer is a major contributor to disease burden in Australia. It is was estimated that 123,920 people were diagnosed with cancer and 45,780 people died from cancer in 2014. Although it is not clear how many people with cancer have, or will experience spine metastases, some data is available regarding palliative care provided in the hospital setting. In 2012-13 there were 34,379 hospitalisations in Australia for palliative care relating to cancer. Palliative care was recorded as the intended mode of care for 74 per cent of these cases, and secondary site cancer was the most common reason for palliative care hospitalisation. New Zealand data from 2006 indicate that cancer and vascular blood disorders were the leading causes of health loss at the condition group level (17.5% each), and that cancer was responsible for 8,254 deaths in 2006.

Although the total number of patients with metastatic cancer is unknown, lesions of the vertebral column have an incidence of between 30 and 70 per cent at autopsy. Of symptomatic lesions about 70 per cent are found in the thoracic spine, while the remainder are found in the lumbar region (20%) and the cervical spine (10%). More than 50 per cent of patients with spinal metastases have tumours at multiple sites in the spine.
**Impact**

**Additive and substitution technology**

Targeted radiofrequency ablation of spinal metastases is a new palliative treatment for painful spinal metastases. It may be used instead of existing radiotherapy or surgical techniques for pain relief.

**Current technology**

The type, location and extent of spinal metastases determine the method of symptom control and treatments may be used in combination. Patients with spinal metastases generally experience localised pain, radiating (radicular) pain with or without back pain.

Painful spinal metastases are generally treated with external-beam radiation, surgical intervention or analgesics including nonsteroidal anti-inflammatory drugs, neuropathic agents and opioids. In terms of achieving pain control, external-beam radiotherapy is considered the standard of care\(^3\) as painful spinal disease is often unresponsive to chemotherapy or hormonal therapy.\(^3, 9\) External-beam radiotherapy achieves at least partial pain relief in 40 to 70 per cent of patients.\(^3, 16\) Pain relief from radiotherapy may be delayed for up to two weeks and may be inadequate in some cases.

With advances in hardware and software, highly focussed radiation therapy (stereotactic radiotherapy) is another potential treatment option. One to four doses can provide very high biological dose of radiation to the tumour with a low dose to the surrounding tissue. Multiple studies demonstrate a high local tumour control rate (between 70 – 90 per cent).\(^17, 19\) However, some patients may reach the maximal tolerated dose of radiation precluding further treatment.

For patients with back pain, medication in combination with physiotherapy can be helpful, and neuropathic drugs may be used for nerve root pain.\(^3, 16\)

Surgery is generally not suitable for patients with spinal metastases because of their short life expectancy and the risk of complications.\(^16\) Some minimally invasive techniques may be helpful, including percutaneous (needle-puncture of the skin) vertebral augmentation procedures such as vertebroplasty, kyphoplasty and skyphoplasty. However, these procedures are not yet a mainstay of treatment in this patient population.\(^16\)

Radiofrequency ablation with vertebral augmentation of the bone tumour sites, including the vertebrae, has been reported in the literature prior to the development of the STAR Tumor Ablation System.\(^20-24\) However, the role of this treatment in the standard care of spinal metastases, both internationally and within Australia, is unclear.

Other radiofrequency ablation systems for treating spinal metastases may also exist. For example the FDA recently approved the OsteoCool® V-2 RF Ablation System (Baylis Medical Company Inc., Mississauga, Canada).\(^25\)
Diffusion of technology in Australia

No evidence was identified to suggest that the STAR Tumor Ablation System or any other t-RFA system is used in Australia.\(^\text{16}\)

International utilisation

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States of America</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Cost infrastructure and economic consequences

No cost information regarding the system was identified. Similarly no cost information regarding associated vertebral augmentation systems was available. However, in terms of cost considerations there may be:

- costs associated with the disposables used with the t-RFA probe
- costs associated with vertebral augmentation (bone cement, fluoroscopic imaging, surgical consumables)
- the cost of the ablation instrument and generator
- day patient facility costs
- specialist fees
- costs associated with imaging.

Ethical, cultural, access or religious considerations

No cultural, religious or access considerations for t-RFA were identified.

Evidence and Policy

Safety and effectiveness

Three retrospective case series studies and four conference abstracts were selected for inclusion in this technology brief (level IV interventional evidence). It is important to note that there may be patient overlap across the included studies and conference abstracts. Many of the conference abstracts share common authors and do not report recruitment periods. Similarly, it is likely that the patients reported by Hillen et al 2014 are also included in the multicentre study by Anchala et al 2014. A summary of the included literature is provided in Table 1.
### Table 1  Included study characteristics

<table>
<thead>
<tr>
<th>Study/design</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Length of follow-up &amp; number of patients</th>
<th>Conflicts of interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchala et al 2014&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Patients receiving t-RFA with or without concurrent vertebral augmentation</td>
<td>NR</td>
<td>6 months N=92 Losses to follow-up = NR</td>
<td>Two authors are consultants and speakers for DFINE, Inc.</td>
</tr>
<tr>
<td>Hillen et al 2014&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Patients receiving t-RFA for posterior vertebral body tumours</td>
<td>NR</td>
<td>1 month N=26 Losses to follow-up = NR</td>
<td>Two authors received compensation for supervising training with the device. One author received compensation for participating on a DFINE, Inc. speaker panel</td>
</tr>
<tr>
<td>Bagla et al 2015&lt;sup&gt;20&lt;/sup&gt;</td>
<td>Patients with painful spine metastases treated with t-RFA</td>
<td>NR</td>
<td>3 months N=50 Losses to follow-up = NR</td>
<td>NR</td>
</tr>
<tr>
<td>Greenwood et al 2015&lt;sup&gt;21&lt;/sup&gt;</td>
<td>Patients with spine metastatic lesions treated with t-RFA</td>
<td>NR</td>
<td>1 month N=91 Losses to follow-up = NR</td>
<td>NR</td>
</tr>
<tr>
<td>Georgy et al 2015&lt;sup&gt;22&lt;/sup&gt;</td>
<td>Patients with spinal metastatic lesions treated with t-RFA</td>
<td>NR</td>
<td>NR NR</td>
<td>NR</td>
</tr>
<tr>
<td>Dhand et al 2013&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Patients with symptomatic vertebral body metastatic tumours who failed conventional chemotherapy and radiation therapy and received t-RFA</td>
<td>NR</td>
<td>Up to 10 days N=10 Losses to follow-up = NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

1-RFA: targeted radiofrequency ablation *with the STAR Tumor Ablation System*; NR: not reported; N: number; USA: United States of America.

Anchala et al 2014<sup>1</sup>

Anchala et al (2014) reported the technical success and pre- and post-procedure pain scores (1 week, 1 month and 6 months) for patients with spinal lesions who were treated with t-RFA at five centres between March 2012 and March 2013. All patients were treated with the STAR Tumor Ablation System and there were 128 treated lesions in 92 patients (96 procedures). The retrospective study included patients who had t-RFA with or without concurrent or subsequent vertebral augmentation, but it was not clear how many patients in total underwent vertebral augmentation. Two of the procedures were performed under general anaesthesia and 94 were performed under conscious sedation.
The most common types of primary tumours were lung cancer (27%), breast cancer (16%) and sarcoma (9%). Detailed procedural and demographic data, such as patient age, gender, location of lesions and prior therapies, were only available from the largest centre included in the study (34 patients, 70 lesions). This institution reported that patients had a mean age of 60 years (range, 35-84 years) and were predominantly women (62%). The institution treated 70 lesions; 50 per cent of these lesions were in the thoracic spine, 39 per cent were in the lumbar spine and 11 per cent were in the sacrum. Vertebral augmentation was performed in 94 per cent of the 70 patients.

**Effectiveness**

All ablations were technically successful and resulted in statistically significant reductions in visual analogue scale (VAS) pain scores. The mean pre-procedure VAS score for 92 patients was 7.5 (standard deviation [SD] 2.46). The mean VAS scores after the procedure were 1.7 (SD 2.28, \( p < 0.0001 \)) for 56 patients (61%) at one week, 2.3 (SD 2.44, \( p < 0.0001 \)) for 83 patients (90%) at one month, and 1.8 (SD 2.62, \( p = 0.009 \)) for 9 patients (10%) at six months. It was not clear whether patients were lost to follow-up or died before the six month data collection.

Cement augmentation of the vertebrae was successfully performed in 92 of the 96 procedures through the same working cannula used for t-RFA. Asymptomatic leakage of cement occurred in two patients. Among the four patients who did not receive vertebral augmentation, three had subsequent fractures that required augmentation.

The largest contributing centre, which treated 34 patients, reported an average ablation time of 361 seconds (range, 55-653 seconds), with each lesion being treated with an average of 4.3 overlapping ablation zones. A decrease in pain medication use was observed in 18 of the 33 patients (54%) for whom change in pain medication was reported. No change in pain medication was observed in 10 patients (30%) and an increase in the use of pain medication was seen in six patients (16%). Postoperative magnetic resonance imaging performed on 13 of the 34 patients showed stable or improved metastatic disease in 10 patients (at an average of 92 days post-procedure) and progression in three patients (after an average of 82 days). Two of the patients with progression underwent a second t-RFA procedure. The third patient had diffuse, increased metastatic progression after 16 days and was treated with systemic therapy.

**Safety**

The study reported that all lesions were treated without complications or thermal injury. No further information regarding safety was provided.

Hillen et al 2014

This retrospective study reported the results of t-RFA with the STAR Tumor Ablation System in 26 patients (47 tumours) treated at a single institution from June 2012 to June 2013. The
authors report pre- and post-procedural VAS pain scores, changes in pain medication usage and other technical results relating to t-RFA. The study included 14 women (54%) and 12 men (46%) and the mean age was 62 years (range, 44-85 years). The primary tumours included lung cancer (27%), renal cell carcinoma (19%), sarcoma (19%), breast cancer (8%) and melanoma (8%). Treated tumours ranged in size from 1.2 cm to tumours involving the whole vertebral body. Conscious sedation was used in all cases, and no patient required conversion to general anaesthesia. Vertebral augmentation following t-RFA was performed on 23 patients (88%). The VAS pain scores were taken on the day of the procedure and analgesic use histories were recorded by a nurse coordinator. Follow-up analgesic use histories and VAS scores were obtained by telephone at one week and one month after the procedure. Complication data were collected by telephone and chart review.

**Effectiveness**

The mean VAS score, which was 7.8 before the procedure, was reduced to 2.8 after one week and 3.3 after one month ($p<0.001$ for both comparisons). Pain medication use was reduced in 13 patients (50%), unchanged in six patients (23%) and increased in 7 patients (27%). Two of the seven patients who reported a medication increase indicated that the increase was for reasons other than back pain.

Post-procedure imaging was performed in 13 patients, showing disease progression in three patients. The mean ablation time was 420 seconds (range, 93-565 seconds) per treatment.

**Safety**

The authors reported no major complications. Four patients (15%) experienced radicular nerve pain that resolved after treatment with transforaminal nerve blocks.

**Bagla et al 2015**

This conference abstract reported the interim results of clinical trial NCT02217150 (see ongoing research), a prospective multicentre case series study evaluating pain relief after t-RFA. Between August 2013 and September 2014, 50 patients were enrolled and treated with t-RFA at eight centres in the USA. Included patients had pain in a thoracolumbar vertebral body and were evaluated at baseline, prior to discharge and at 3, 7, 30 and 90 days after treatment. The following scales were used at each follow-up point: the Numerical Pain Rating Scale (NPRS), the Oswestry Disability Index, the Functional Assessment of Cancer Therapy-7 and the Quality of Life Measurement in Patients with Bone Pain. Patients had a mean age of 60 years (SD 12.3) and the study included 26 men and 24 women. Breast, lung and renal cancer were the main types of primary tumours. All procedures were successful and vertebral augmentation was performed in 94 per cent of treated levels. There was significant improvement ($p<0.05$) in all measures from baseline to each follow-up interval (Table 2). The authors reported no major adverse events.
Table 2  Interim results of trial NCT02217150

<table>
<thead>
<tr>
<th>Time point*</th>
<th>Mean Numerical Pain Rating Scale (NPRS) score</th>
<th>Mean Oswestry Disability Index score</th>
<th>Mean Functional Assessment of Cancer Therapy-7 score</th>
<th>Mean Quality of Life score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (50)</td>
<td>5.7</td>
<td>53</td>
<td>10.8</td>
<td>35.8</td>
</tr>
<tr>
<td>Discharge (46)</td>
<td>3.5</td>
<td>42.8</td>
<td>15.4</td>
<td>24.4</td>
</tr>
<tr>
<td>Day 3 (41)</td>
<td>3.3</td>
<td>45.1</td>
<td>16.2</td>
<td>23.8</td>
</tr>
<tr>
<td>Day 7 (41)</td>
<td>3.5</td>
<td>44.3</td>
<td>15.0</td>
<td>24.0</td>
</tr>
<tr>
<td>Day 30 (31)</td>
<td>3.0</td>
<td>37.7</td>
<td>15.8</td>
<td>22.0</td>
</tr>
<tr>
<td>Day 90 (24)</td>
<td>1.4</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR: not reported
*There was significant improvement in all measures from baseline to each interval


Effectiveness and safety

The mean change in pain scores reported by the three conference abstracts is provided in Table 3. All three reports stated that no complications were observed.

Table 3  Mean VAS scores pre- and post-procedure

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of patients (lesions)</th>
<th>Mean VAS pain score at baseline</th>
<th>Mean VAS pain score at follow-up</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up</td>
<td></td>
<td>Mean VAS pain score at baseline</td>
<td>Mean VAS pain score at follow-up</td>
<td>p-value</td>
</tr>
<tr>
<td>Dhand et al 201329</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=10 (12)</td>
<td></td>
<td>8.8 (range, 5-10)</td>
<td>2.6 (range, 0-6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean 3.8 days (range, 0-10 days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Georgy et al 201528</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=65 (95)</td>
<td></td>
<td>7.8 (SD 2.4)</td>
<td>3.5 (SD 2.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Range, 2 to 4 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greenwood et al 201527</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=91 (119)</td>
<td></td>
<td>6.6</td>
<td>4.3 (1 week)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1 week and 1 month</td>
<td></td>
<td>3.3 (1 month)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n: patient; SD: standard deviation; VAS: visual analogue scale

Greenwood et al (2015) also reported reductions in opioid usage and changes in general activity. At one month after treatment, opioid usage was decreased in 46 of 91 patients (51%), unchanged in 24 patients (26%) and increased in 21 patients (23%). The general
activity level was increased in 61 patients (67%), unchanged in 14 patients (15%) and decreased in 16 patients (18%).

Economic evaluation
No economic evaluation studies were identified.

Ongoing research
A search of ClinicalTrials.gov and the Australian and New Zealand Clinical Trials Registry identified four trials involving the STAR Tumor Ablation System that were either recruiting or due to start (Table 4).

Table 4  Registered clinical trial characteristics

<table>
<thead>
<tr>
<th>Study Location</th>
<th>Design</th>
<th>Number of patients</th>
<th>Intervention</th>
<th>Primary outcomes</th>
<th>Trial status</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02419703, Unknown</td>
<td>Case series study (registry)</td>
<td>1,000</td>
<td>STAR Tumor Ablation System</td>
<td>Pain relief (measured by Numerical Pain Rating Scale [NPRS])</td>
<td>Active, not recruiting</td>
</tr>
<tr>
<td>NCT02217150*, USA</td>
<td>Multicentre case series study</td>
<td>50</td>
<td>STAR Tumor Ablation System</td>
<td>Change in pain (from baseline worst pain score to one month with NPRS)</td>
<td>Recruiting (September 2015)</td>
</tr>
<tr>
<td>NCT02225223, USA</td>
<td>Multicentre case series study</td>
<td>64</td>
<td>STAR Tumor Ablation System and the StabiliT® Vertebral Augmentation System**</td>
<td>Pain relief (Measured by Brief Pain Inventory worst pain score)</td>
<td>Recruiting (June 2016)</td>
</tr>
<tr>
<td>NCT02081053, France, Germany, Italy</td>
<td>Multicentre case series study</td>
<td>40</td>
<td>STAR Tumor Ablation System and the StabiliT® Vertebral Augmentation System**</td>
<td>Pain relief (Measured by the NPRS)</td>
<td>Recruiting (May 2016)</td>
</tr>
</tbody>
</table>

*The interim results of this trial were reported by Bagla et al 2015
** StabiliT® Vertebral Augmentation System (DFINE, Inc., San Jose, California, United States of America [USA])

Other issues
All of the published literature and clinical trials have links to the manufacturer DFINE, Inc. Additionally, many of the conference abstracts and published studies share common authors and recruitment periods, making it difficult to ascertain the extent of possible patient overlap across the included studies.

The study findings and conference abstracts concluded that t-RFA provides significant pain reduction for patients with spinal metastases, a patient population in whom symptom control is very important. However, none of the included studies compared other interventions for pain control in this population. In addition, it appears that most patients
also received vertebral augmentation. It is not clear whether the observed reductions in pain scores were driven primarily by the ablation procedure or the vertebral augmentation procedure. It is also unclear as to how the pain relief associated with t-RFA, with or without augmentation, compares with other therapies such as external-beam radiation. DFINE, Inc. additionally manufacture a vertebral augmentation system.

The included literature reports that there were no safety issues; however, two cases were reported of cement escaping the bony compartment. The authors do not comment on the potential complications of cement augmentation more broadly, or the types of adverse events that may be encountered if the procedure is performed more broadly.

Of the preliminary literature investigating RFA for bone or spinal metastases (published prior to development of the STAR Tumor Ablation System) most included less than five patients or included patients with metastases outside of the spinal column. One study was identified which included 10 patients with spinal metastases. This study included patients treated between November 1999 and January 2001. Radiofrequency ablation was performed with a 50 W radiofrequency generator connected to an expandable electrode catheter (Rita Medical System, Inc., California, USA). At follow-up (up to 5.8 months), 9 of 10 patients reported reduced pain (average VAS pain score reduction was 74%); no complications were reported.

**Number of studies included**

All evidence included for assessment in this technology brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies: 6

Total number of Level IV studies: 6 (including four conference abstracts)

**Search criteria to be used (MeSH terms)**

- Catheter Ablation/instrumentation*
- Spinal Neoplasms/secondary*

**Literature search date:**

1st September 2015
References


