

SCOTT M. As many in the medical community are aware, glioblastoma is one of the most vexing
LINDHORST: diagnoses within the field of neuro-oncology. And the standard of care has been set since around 2005 with the so-called Stupp regimen. The Stupp regimen that I described does have a proven overall survival benefit. But in the grade four setting, it is not nearly as great as we would like. And glioblastoma is still thought of as an incurable disease. And for that reason, additions to that standard of care regimen are necessary and beneficial.

And tumor treating fields can provide some of that benefit. The standard of care for most medical oncology, including neuro-oncology trials, is ideally an improvement in both progression free and overall survival. And that is something that we now see with tumor treating fields. And so their addition to the standard of care therapy by a novel mechanism that's not surgery and not radiation, not chemotherapy has proven to be beneficial for patients.

DAVID M. Tumor treating fields were approved by the FDA back in 2011. So they added another
CACHIA: therapeutic modality for our patient population. And back in 2011, it was approved for recurrent glioblastoma. A recent trial that was published last year was the F-14 trial. And this was a randomized trial where they randomized patients with newly diagnosed glioblastoma this time to either receive standard of care or standard of care plus the TF fields. And what they found was that those patients that wore the device, the median overall survival benefit was around five months over those that did not wear the device. So a few months ago, the FDA-- sorry, the NCCN guidelines included Nova TTF as a category one recommendation for the treatment of newly diagnosed glioblastoma.

And what the tumor treatment fields are doing, it's an alternating electrical field. And it is thought that this alternating electrical field disrupts cell division. Patients are given this device that they have electrodes placed on their head. They have to shave their hair. And they place these electrodes that are placed depending on where the tumor is. So it's built and is individualized according to the patient's MRIs to target, specifically, the area where the tumor is. And then those electrodes are attached to a battery pack, which is a very thin battery pack that the patient wears during the day.

SCOTT M. Initial studies for this device came out, first from Europe, and then across the world in about
LINDHORST: 2011. And we have been using the device at MUSC since roughly 2013. It has spread in its use across the states since then. But we are still the busiest center prescribing the device in

the state. And our experience in the MUSC Brain and Spine Tumor Center has reflected that which was achieved in the original studies in that there is an improvement in both progression free and overall survival on the order of about five months for most patients.

For the device to work, they have to turn it on and use it. So it is a commitment to patients, certainly in that fashion. And somewhat of a life altering commitment in that it becomes nearly a part of them all the time. To gain that survival benefit, we'll often need to see at least 18 hours minimum of use per day out of a 24 hour period. And ideally, closer to 22 hours per day. And what that means is, not only are the transducer arrays on their scalp during that time, but they are plugged in to the battery pack. And the battery pack is turned on during that time. And as a physician, we have a way to monitor that via a compliance report that is issued monthly by the sponsor of the device. So we can have educated discussions with patients as to how well the device is going for them and any toleration problems they may have.

Like all new therapies, this device was approved via evaluation and multi-center or clinical trials. And now that it is approved for both newly diagnosed and recurrent glioblastoma, its use is being explored in other settings as well. The device is being tested in lung cancer patients, patients who have had a brain metastases develop as a result of non-small cell lung cancer. This is anywhere from 1 to 10 brain metastases. The current standard of care is either whole brain radiation or selective stereotactic radiosurgery for these patients in addition to the systemic treatment of their disease. And the trial that is recently opened at MUSC is examining stereotactic radiosurgery versus stereotactic radiosurgery plus the use of the tumor treating fields device. And that's looking both at progression free survival and overall survival endpoints.

DAVID M. CACHIA: We're also working with other institutions around the country to use this device in lower grade gliomas. So gliomas that typically grow slower than glioblastoma, but at this point are still not something we can cure. So that's something that we're working on.

Any new technology, any new drug that is available for these tumors is something that moves our field forward. Obviously, we have steps to do to cure these tumors. And I think this adds and moves us closer to that ultimate goal.

SCOTT M. LINDHORST: Well, it's one more tool in our armamentarium to treat what is still an incurable disease. And for the committed patient who is used to have a slight alteration in their appearance that the device can require, it offers a way to extend their life in a relatively benign way without the side

effects of chemotherapy and radiation. And can also be incorporated simultaneously with any needed chemotherapy and radiation. So having that added therapeutic tool is very exciting.