

All-in-one vs. a dedicated system

While other non-invasive brain treatment modalities claim parity with Leksell Gamma Knife®, no one can match the accuracy of Gamma Knife® surgery, which is supported by decades of experience and proven clinical outcomes. Constant innovation and development puts Gamma Knife® surgery decades ahead in terms of technology and effectiveness.

The Big Question:

Are radiotherapy systems 'good enough' to treat critical brain disorders?

The Answer:

No, according to compelling clinical tests and evidence.

The competition for medical equipment dollars is intense, so some equipment vendors are trying to convince hospitals they can get an "all-in-one" solution to treat the whole body with radiotherapy and also use it for brain surgery.

You should know:

Manufacturers and users of linac treatment systems will use Gamma Knife® treatment data as their own to justify their treatment efficacy. Gamma Knife® surgery is a totally different modality than linear accelerator treatments, and Gamma Knife® data isn't applicable or relevant.

These manufacturer claims are equivalent to saying a Hyundai performs as well as a Ferrari because both are cars with engines.

Key Points:

- **There is no other modality as safe and effective as Leksell Gamma Knife®.**
- **No other treatment modality has the proven clinical success and volume of clinical evidence as Elekta.**
- **Gamma Knife® surgery is the single most trusted and utilized solution for treating brain disorders without invasive surgery.**

The difference between radiosurgery and radiotherapy:

- **Radiosurgery is a single-session stereotactic procedure performed by a neurosurgeon-radiation oncologist team using radiation to destroy a target in the brain. Radiosurgery is preferred for the brain and spine because it is a precise, single-dose procedure.**
- **Radiotherapy is an extended treatment program using fractionated radiation over multiple sessions. It's the preferred solution for treating malignant tumors in the body.**
- **Elekta, manufacturer of Leksell Gamma Knife®, is a market leader in both radiosurgery and radiotherapy systems.**

Using radiation to treat cancer and other disorders

The biology of cancer cells makes them especially susceptible when using radiation therapy for treatment. However, the very nature of radiotherapy, which makes it an excellent treatment choice for the body, makes it questionable for precise delivery of radiation to well-delineated targets in the brain.

Radiosurgery for the Brain

Radiosurgery is the use of a number of precisely directed, highly focused beams of ionizing radiation to target a specific area. The purpose of radiosurgery is similar to a surgical procedure, namely to destroy or damage the volume of tissue within the target area. The treatment is designed to generate as large a therapeutic effect as possible within the target while minimizing radiation outside the target. A heterogeneous dose within the target is considered acceptable and sometimes advantageous over a homogeneous dose¹. The heterogeneous (focused) dose of radiation to the specific area being treated is its primary benefit.

Radiotherapy for the Body

Radiation therapy is a high dose of radiation commonly given over 10-35 low dose treatments. This treatment has been utilized for many decades as a standard treatment for cancer in the body. The ability to assure homogenous (uniform) doses of radiation to the areas being treated is one of the major tenets of modern external beam radiation therapy. In contrast to radiosurgery, radiotherapy often involves significant dose to larger tumor volumes, consequently involving more healthy tissue.

A Primer on Radiation Therapy

Radiation therapy (sometimes called radiotherapy, x-ray therapy or irradiation) is the treatment of disease using penetrating beams of high energy x-rays or electrons, both called radiation.

Radiation in high doses kills cells or keeps them from growing and dividing. Because cancer cells grow and divide more rapidly than most of the normal cells around them, radiation therapy can successfully treat many kinds of cancer. Normal cells are also affected by radiation but, unlike cancer cells, a higher percentage of them recover from the effects of radiation.

To protect normal cells, doctors carefully limit the doses of radiation and spread the treatment out over time. They also shield as much normal tissue as possible while they aim the radiation at the site of the cancer.

The goal of radiation therapy is to kill the cancer cells with as little risk as possible to normal cells. Radiation therapy can be used to treat many kinds of cancer in almost any part of the body. In fact, more than half of all people with cancer are treated with some form of radiation. For many cancer patients, radiation is the only kind of treatment they need. Thousands of people who have had radiation therapy alone or in combination with other types of cancer treatment are free of cancer.

Source: Excerpted from the National Cancer Institute/NIH

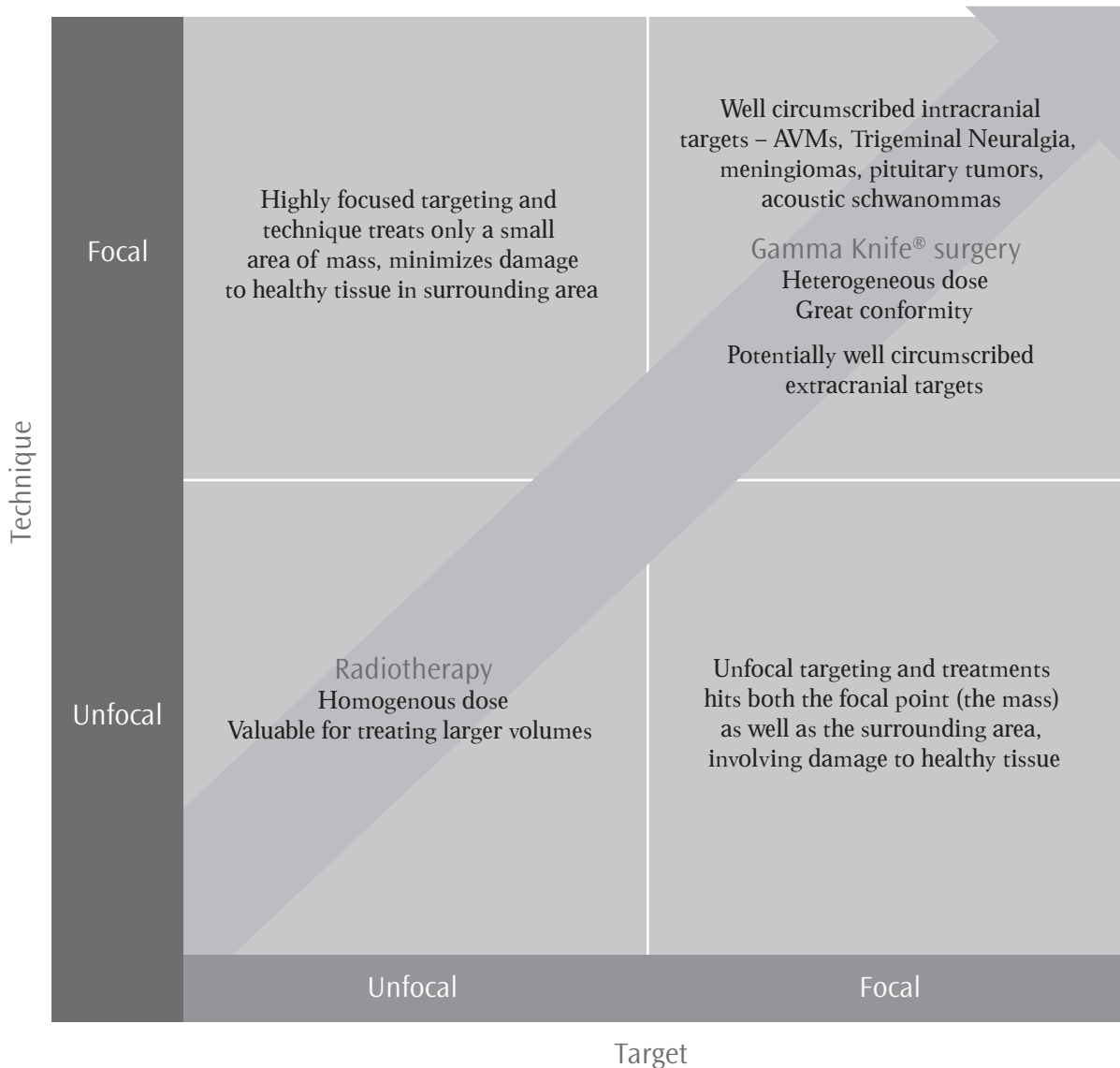
1. RTOG protocol 90-05.

Using radiation to treat cancer and other disorders *(continued)*

Choosing the Best Technique for the Target

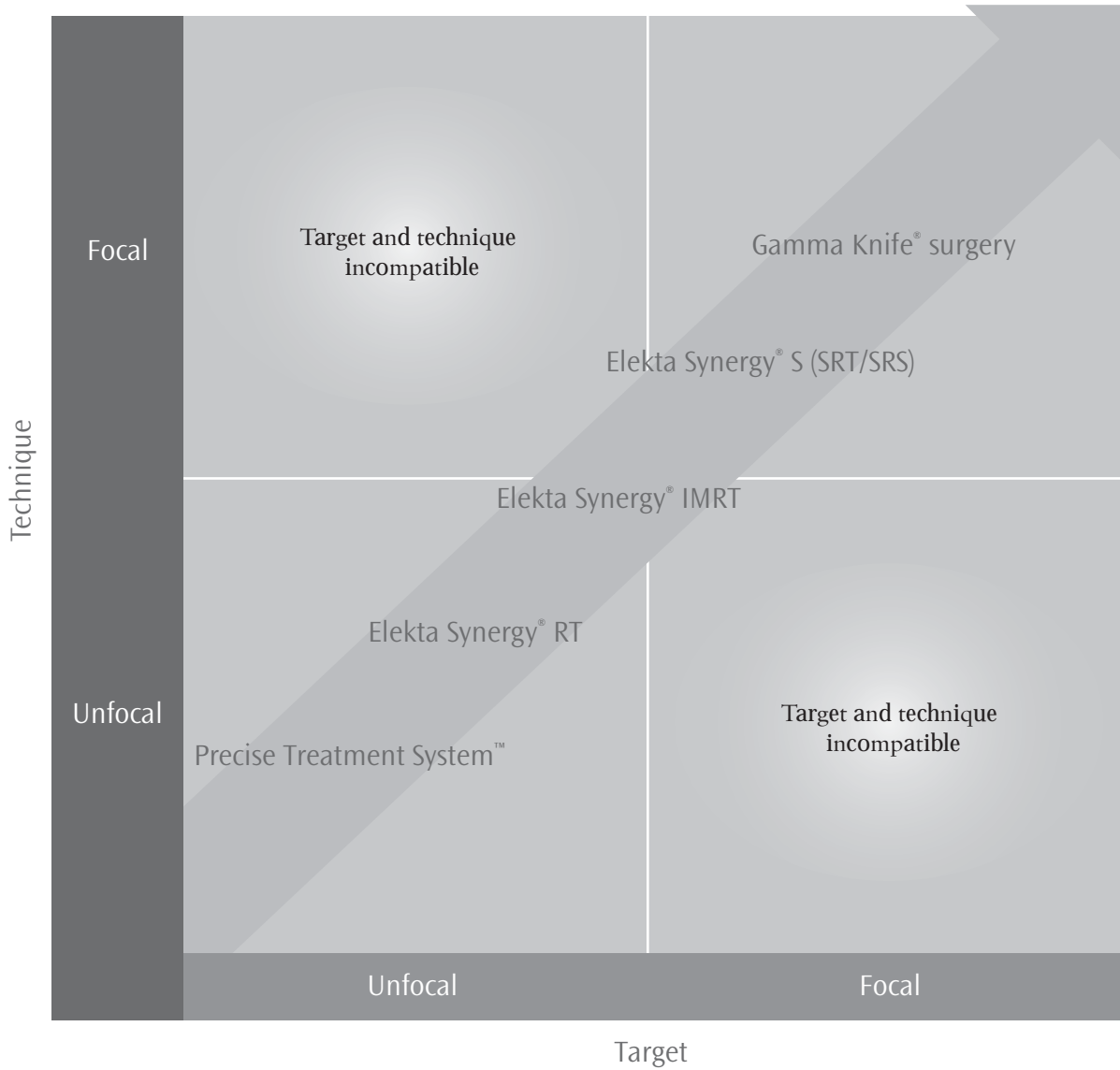
Consequences of using incompatible techniques for a target:

- 1) Inefficient – requires extra time to try to improve accuracy
- 2) Sub-optimal clinical outcome



Using radiation to treat cancer and other disorders *(continued)*

Elekta Solutions



Accuray CyberKnife

Accuray boasts of CyberKnife's leading edge technology, but in reality it is simply a linac that has been shrunk and put on a robotic arm. CyberKnife has the inherent limitations of a linac treatment system which are magnified by its low dose rate and lack of stability.

Attack

- The "compact" linac on CyberKnife can only deliver a low energy (6 MV).
- CyberKnife users must fractionate treatments because of the large volumes of healthy tissue which receive dose during treatment due to inaccuracies.
- The robotic arm moves the linac around the patient, but is limited in reaching certain areas and, because of safety concerns, cannot reach over the patient.
- CyberKnife uses a mask system abandoned by Elekta decades ago – not as effective or accurate as the stereotactic frame for radiosurgical targets (see Frame section for more details).
- Achieving even minimally acceptable results relies on the dedicated, individual expertise of the physician, physicist, dosimetrist and therapist. That expertise can take many years to develop and refine.

Counter Attack

CyberKnife says:

"The system's accuracy is comparable to that of Leksell Gamma Knife® and all other frame-based radiosurgical instruments."

The truth:

Of course it can be compared – it's just not equal to Gamma Knife® accuracy. Accuray researchers made accuracy claims in a 2003 Neurosurgery article (J Neurosurg. 1998 Aug;89(2):321-5.) used extensively in CyberKnife marketing. The measurements were made using head phantoms and are not relevant for three reasons:

- 1) head phantoms, unlike a real patient, do not move
- 2) the measurements do not include imaging error, essential in determining clinical accuracy
- 3) the article compares the CyberKnife to the Leksell Stereotactic System®, not to Leksell Gamma Knife®

Cyberknife accuracy is quoted in Neurosurgery, January 2003 as 1.1mm and in Neurosurgery June 1999 as 2.1mm. The 2.1mm accuracy statement includes the most clinically relevant data.

Only Elekta guarantees accuracy to at least 0.5mm for the life of the equipment. See the "Accuracy" section for more information.

Please see other sections for more information on CyberKnife, which has been one of the most vocal critics of Gamma Knife® surgery and has published the most erroneous information.

Counter Attack continued

CyberKnife says:

“It has the potential to treat tumors and lesions anywhere in the body.”

The truth:

CyberKnife lists a number of brain and neurological disorders in addition to other sites in the body. However, there is no published information on using the CyberKnife to treat these disorders.

Only Leksell Gamma Knife® has the depth of published clinical experience to prove and substantiate these treatments.

CyberKnife says of Leksell Gamma Knife®:

“Complete coverage of the targeted lesion requires the use of multiple isocenters. This necessitates multiple treatment steps, including patient repositioning, quality assurance, and treatment itself. This further complicates and prolongs treatment.”

The truth:

Leksell Gamma Knife® uses multiple isocenters in order to deliver the maximum amount of radiation during a single treatment while avoiding healthy surrounding tissue.

BrainLAB Novalis

BrainLAB's Novalis is a linear accelerator used for treating the whole body as well as the brain.

Attack

- There is little published literature on the efficacy of BrainLAB's Novalis for treating the brain despite eight years of clinical use.
- Achieving even minimally acceptable results relies on the dedicated individual expertise of the physician, physicist, dosimetrist and therapist. That expertise can take many years to develop and refine.
- The study comparing the accuracy of Novalis to Leksell Gamma Knife® (summary can be found on the Novalis website) was conducted using phantoms – not an accurate comparison methodology.

Counter Attack

BrainLAB says:

"Millimeter accuracy every time."

The truth:

Unlike BrainLAB, Leksell Gamma Knife® guarantees submillimeter accuracy, a level of refinement necessary for treating the brain.

BrainLAB says:

"Novalis achieves consistent, superior dose distribution, for a larger range of indications, in less time and with high precision."

The truth:

Novalis references one paper for this claim, and it does not focus on treating disorders of the brain. "Frighetto L., De Salles et al: First World Experience with Novalis Stereotactic Radiosurgery and Radiotherapy. The Book of Proceedings of the 12th World Congress of Neurosurgery, 2001."

BrainLAB says:

"The system's exceptional speed and high dose rate of 800 cGy/min. allow hospitals to treat up to four times more patients than possible on conventional linac or cobalt-based radiosurgery units."

The truth:

Because BrainLAB is a linac, it requires time-consuming fractionation. Therefore, even if the initial set-up speed for one treatment is less, patients may require multiple set-ups or must return up to 30 times for treatment. Gamma Knife® surgery is single session and requires less overall time commitment for both patients and physicians. The maximum dose rate of the Gamma Knife is 3000 cGy/min!

Varian Trilogy

The Trilogy system from Varian has only recently been placed into clinical use. However, one hospital was claiming superior accuracy based on a single measurement that may not be reproducible year after year.

Attack

- Trilogy has only recently been re-purposed for brain treatment – does a patient want to be one of the first when the brain is at risk?
- Trilogy is a linear accelerator that has been equipped with imaging capabilities, not purpose-built for treating the brain like Leksell Gamma Knife®.
- Trilogy's treatment and imaging systems revolve around the patient. Because the system is so new, the short- and long-term stability of the C-arm gantry supporting this additional heavy equipment is unknown.
- Achieving even minimally acceptable results relies on the dedicated, individual expertise of the physician, physicist, dosimetrist and therapist. That expertise can take many years to develop and refine.

Counter Attack

Trilogy says:

"This new Trilogy system allows for the most precise targeting of tumors or brain abnormalities, targeting the area within 0.4 of a millimeter, compared with the next best machine which targets within 0.75 of a millimeter."

The truth:

The total radiological accuracy of Leksell Gamma Knife® is guaranteed to be better than 0.5mm. After installation and reloading, and during regular service, this guaranteed accuracy is checked using film tests. After 332 measurements on 189 units that had been in service for periods ranging from six to 14 years, Elekta found the actual achievable radiological accuracy to be as high as 0.15mm. Varian does not state how their accuracy was determined or over what time period it can be relied on.

Trilogy says:

"Trilogy is the world's first image-guided radiation therapy system used for both brain and other tumors."

The truth:

Trilogy probably is the world's first IGRT system used for both brain and other tumors...because Elekta's IGRT system (Elekta Synergy®) is not used primarily for the brain. Elekta was the first manufacturer to start research on IGRT, the first to have systems in clinical use and the first to receive FDA approval. Elekta strongly believes that the unique demands of effectively treating the brain are so rigorous that only a specially designed system can offer the accuracy and assurance that patients and leading neurosurgeons demand.