

Framing the question

The stereotactic frame, which is integral to the accuracy of Gamma Knife® surgery, is often criticized by makers of mask-based devices, and can also be a source of anxiety for patients.

The Big Question:

Is a frame necessary?

The Answer:

Yes, if you want to ensure the highest accuracy.

If the patient moves, the target is lost. With Leksell® Coordinate Frame, the patient's head is totally immobilized and basically becomes part of the machine. The combination of a stationary (fixed source) radiation delivery system with a frame that securely fastens onto the equipment itself creates a highly stable system that facilitates accuracy.

Key Points:

- **The accuracy provided by the frame is well documented in more than 1,000 peer-reviewed published clinical papers.**
- **Patients report discomfort is minimal.**
- **Face masks – used with “frameless” systems – are uncomfortable and claustrophobic for patients.**

Compared to linac systems

The stereotactic frame accomplishes two things – first, it fixates the head so there is no movement during treatment. Second, it offers tracking metrics which facilitate accurate treatment planning and delivery.

You should know:

- The face mask system was tried and discarded by Elekta decades ago
- The face mask serves only for fixation...no inherent aid in targeting
- Frame-based radiosurgery does not require fractionation to compensate for errors in positioning and patient movement

Benefits:

- **Frame provides exact MR and CT correlation from planning to delivery in 3D**
- **Allows neurosurgeon to completely avoid movement artifacts, thereby providing best image quality**
- **Treatment images are mechanically tied to Gamma Knife® coordinates for highest accuracy**
- **Gamma Knife's® full MRI compatibility avoids series of potential sources of error from having to fuse multiple sets of images**

Countering the competition's claims

When manufacturers begin making claims about efficacy and accuracy, it can be difficult to sort out fact from fiction. The following information should help in explaining why Gamma Knife® surgery is the best choice (*Attack*) as well as provide factual corrections to misinformation about Leksell Gamma Knife® (*Counter Attack*).

Attack

- Fixed objects are going to provide more stability, and therefore more accuracy.
- The mask is very uncomfortable and claustrophobic – essentially the patient's head is shrink-wrapped to the treatment table.
- Despite the shrink-wrapping, head movement is still possible.
- With the linac delivery system also moving, it's like trying to play paddle ball – everything is moving, the target and the machine!
- Patients agree – when it comes to their brain, they welcome the frame because it ensures better accuracy.

Counter Attack

CyberKnife says of Leksell Gamma Knife®:

“Accurate targeting requires an invasive stereotactic head frame fixed to the patient's skull, an uncomfortable and traumatic experience for patients.”

The truth:

“Invasive” is relative...puncturing the skin with small screws is extremely minimal. And CyberKnife's “non-invasive” treatment is a claustrophobic aquaplastic mask, and for other parts of the body involves surgically implanting fiducials.

Patients repeatedly state that the stereotactic head frame was slightly uncomfortable but they readily accept minor discomfort to ensure high accuracy.

CyberKnife says of Leksell Gamma Knife®:

“Fractionated treatments are rarely performed due to the limitations and difficulties associated with repeat fixation (patient immobilization and target localization).”

The truth:

There is no need for fractionation with the powerful Leksell Gamma Knife®, which can achieve its full dose delivery in one treatment. Fractionation is an unnecessary inconvenience to the patient. With the stereotactic frame, patient immobilization is never an issue and target localization is actually improved with MRI vs. CyberKnife's CT scans.

CyberKnife says of Leksell Gamma Knife®:

“Correlation of target within the reference system is confirmed only once, prior to treatment.”

The truth:

The target position is confirmed 10 times per second during Gamma Knife® surgery, rather than once every 10 seconds as it is during CyberKnife treatment. To minimize radiation exposure from multiple x-ray shots and to speed up treatments, that number is often reduced, CyberKnife physicians report. (See following section, “Where the competition fails”.)

Where the competition fails

What companies state are the best practices for treating patients can vary from what actually occurs during treatments. The following information offers background on CyberKnife's imaging during treatment to adjust for patient movement.

You should know:

Patient tracking on the CyberKnife does not continuously update patient position, thus the beam may be directed away from the intended target if the patient moves during treatment.

Before the CyberKnife radiation is turned on, the CyberKnife updates the patient position using an X-ray camera system. This means that patient movements taking place after the X-ray camera measurement and before the actual radiation delivery are not registered, potentially resulting in significant errors.

Studies suggest that with CyberKnife, the patient position is updated every 10 seconds to account for patient movement. This may result in clinically significant errors in the accuracy of radiation delivery, considering the amount of patient movement that can occur during 10 seconds.

Moreover, in clinical use, this tracking may be significantly less frequent than 10 seconds. According to the Korean Cancer Center Hospital, the patient is not imaged before every radiation delivery because the X-rays used for patient positioning contribute to the cumulative therapeutic dose. The number of images are therefore reduced to approximately one tenth because of this dose issue, resulting in further opportunities for errors in radiation delivery from patient movement.

On site visits, observers have reported that CyberKnife treatments were inter-operatively stopped several times because of patient movement that could not be compensated for by the system. Also, a direct relationship was observed between the number of tracking samples per minute and the frequency of interrupted treatments due to patient movement. A higher sample rate for tracking dramatically increases the number of interruptions, thereby extending treatment time. Because the patient is not efficiently tracked by the system, radiation may end up at the wrong coordinates due to patient movement.

Using a frame fixation system eliminates this opportunity for error. Elekta believes one of the major reasons for the unmatched accuracy and clinical results with Gamma Knife® surgery is its simplicity; stationary source of radiation, stationary target. This compares to a CyberKnife's moving target and simultaneously moving source of radiation.

Background - Leksell® Coordinate Frame

Leksell® Coordinate Frame is a key component to ensure accuracy, and was designed based upon the Leksell Stereotactic System®. This three-dimensional reference system allows the surgeon to accurately localize and treat the pathological area with the highest accuracy.

Ever since Elekta's founder, the late professor Lars Leksell, revolutionized the design of head frames in 1949, the system has occupied a front-line position in stereotactic surgery worldwide. Renowned for its exceptional accuracy, simplicity and versatility, its applications include diagnostic, therapeutic, functional and stereotactic microsurgery, and it serves as the model for the Coordinate Frame used in Gamma Knife® surgery.

The widely used Leksell Stereotactic System® is comprised of the coordinate frame as well as a semicircular arc. Various instruments such as biopsy needles, cannulas and electrodes can be mounted on the arc. The modular, compact design, unique components and range of optional accessories offer the surgeon an easy-to-learn and easy-to-use solution.

- All-around access and exchangeable front pieces for maximum flexibility
- Fast, easy localization and target mapping
- Compatible with all types of imaging modalities, including CT, MR and X-ray — one frame, one setting and the patient is ready for any scanning technique
- Images of different modalities easily compared using the same target coordinates
- Access to all intracranial areas for choice of optimal trajectory
- Largest user group in the world with more than 1,300 systems in use
- More than 1,000 peer-reviewed clinical papers published
- Dedicated training programs in cooperation with reputable neurosurgical clinics

What to tell patients

The appearance of the head frame may cause apprehension in patients, which is inflated by the alarmist materials published by competitors. The following information may be helpful in developing information for patients. You may also want to elicit quotes from your patients – these are particularly powerful when videotaped and included in an informational presentation.

- Acknowledge their apprehension – the frame can be a source of anxiety
- Assure them that it is an absolute necessity to ensure accuracy during treatment.
- Made of a lightweight aluminum alloy that only weighs 1.8 pounds.
- Frame can be seen on the imaging equipment, providing treatment team with an exact set of coordinates so that a lesion or tumor is precisely targeted.
- Patient receives a local anesthetic to numb the locations where the frame will be attached to the head. The injections are slightly uncomfortable and are given just under the skin.
- There is no pain during the placement of the frame but the patient may experience a feeling of pressure or tightness that will disappear in about 15 minutes.
- This guiding device will stay on the patient's head until the Gamma Knife® treatment is completed.
- Patients have stated they feel no pain, only some pressure, during this procedure.
- The four pins used to secure the frame onto the head penetrate only a small amount of the outer skull.

Step-by-step – mask:

- Patient comes to the center one or more days prior to the treatment
- A pliable substance is applied to the face, hardened, then removed
- The day(s) of treatment the mask is placed on the patient's face completely covering it for the entire duration of the treatment (which may last for hours)
- The mask and the patient's face are shrink-wrapped to the treatment table

Quotes from patients:

“I thought the funniest thing was this birdcage they put on my head. I was wishing I had a picture of what I looked like with this birdcage on my head! It didn't hurt, just a little heavy. They put me into the room with the Gamma Knife®, I think there was music playing, it was very pleasant. I don't think it took even 20 minutes. Very fast and painless. I had something to eat, watched my video, and that was it...I went home.”

Doris Heroupolis
Trigeminal neuralgia patient

“I slept about half the time while being treated. They watched me for about an hour, then said my wife could take me home. By then I was waking up more. They put a Band-aid on each of the wounds on the front of my head, but didn't bother with the back. I rested and slept that afternoon, had dinner with my family. I felt a little ache at the wound site, but didn't require any medication. I was able to drive the next day and on Monday, I had normal office hours and performed one surgery that had been scheduled.

Dr. Russell Miller (*orthopedist*)
Acoustic neuroma patient