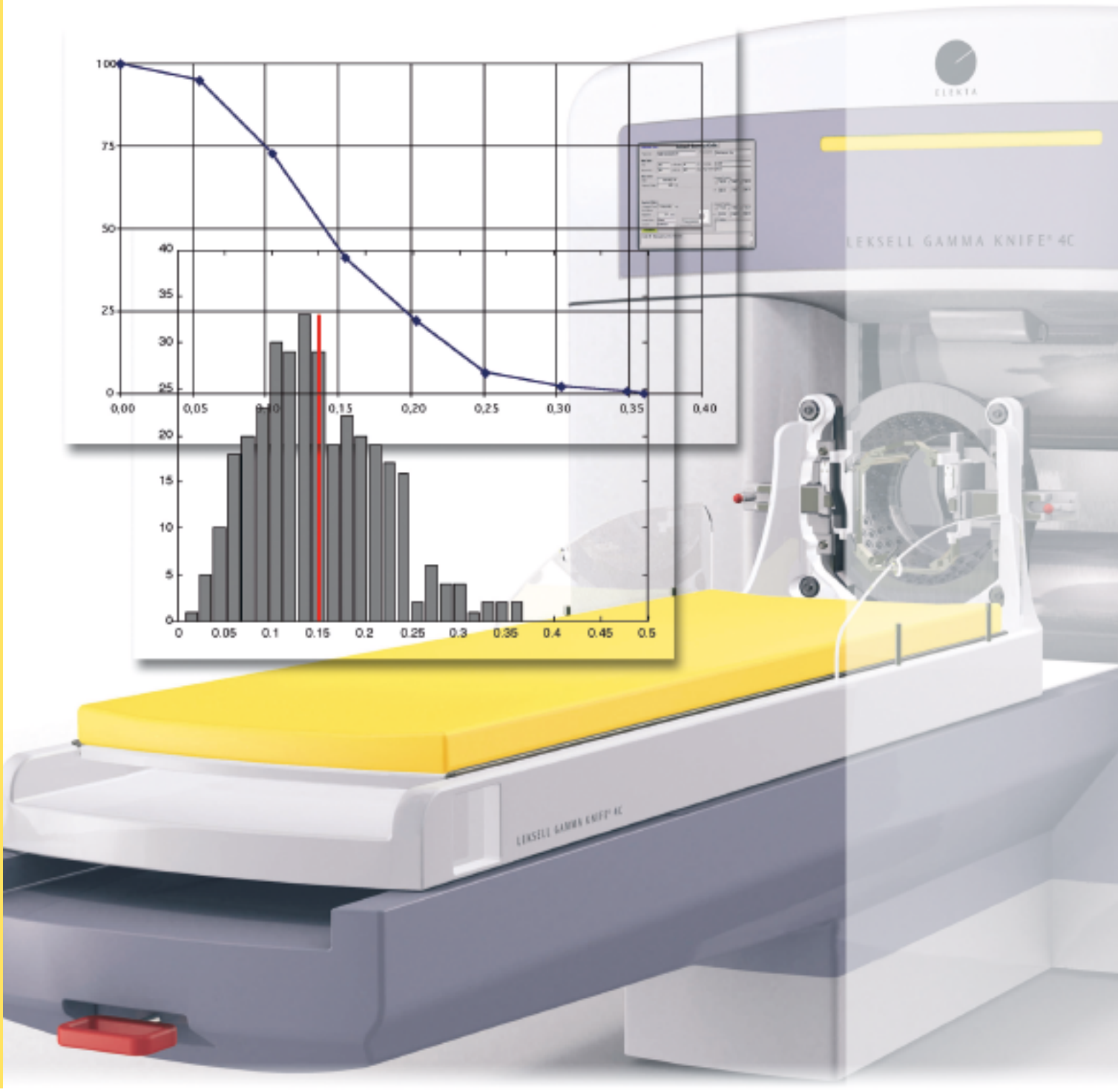
Leksell Gamma Knife®



Accuracy report

ELEKTA

Assessing the accuracy of Leksell Gamma Knife®

Accuracy means results

Gamma Knife® surgery is based on the principle of converging multiple, narrow static beams; all beams are aimed at a target that is reliably fixed to the treatment device. The idea was developed by the late Professor Lars Leksell to overcome handling and accuracy problems associated with contemporary Linac and proton devices. A key component in Gamma Knife® surgery is the stereotactic frame that secures the patient's head to the radiation unit; a feature that contributes to the superior, unmatched stability and accuracy.

How is accuracy defined?

When discussing the accuracy of one system compared with another, it is important that there is a common understanding and definition of "accuracy". Accuracy is a measure of the difference between the desired or planned outcome and a measurable outcome. Accuracy in the procedure of intracranial radiosurgery is a sum of a number of different – and more or less independent – "accuracies" that all have to be taken into account, such as imaging (e.g. MRI and CT), dose planning, patient positioning, radiological and mechanical accuracy. All of these different "accuracies" must be accounted for in the only relevant "accuracy" – the final *clinical accuracy*. This report presents the results from the analysis of two sets of measurements; one set is based on data from the measurements performed regularly on all installed systems, and the other set of data is from an external, clinical study, conducted by Gamma Knife® users. The report aims to explain the different accuracy entities and answers the question: How accurate is Gamma Knife® surgery?

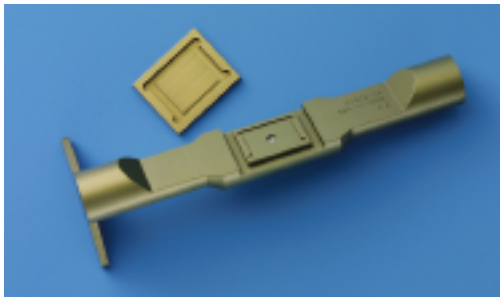


Fig 1: The measuring tool. The tool holds a piece of radiological film that is pierced with a small hole in the center (representing the focus point in the mechanical positioning system).

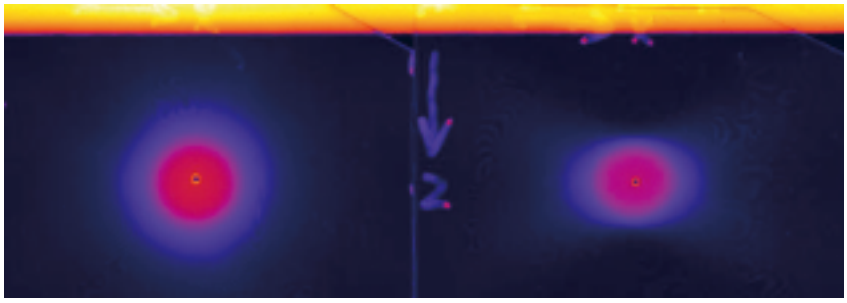


Fig 2: Radiological accuracy is determined by measuring the distance between the hole in the film and the edge of the dose distribution. According to the results presented in this report, the average value for Leksell Gamma Knife® is 0.15mm.

Radiological accuracy

Radiological accuracy is in general terms a measure of how well the mechanically positioned target point aligns with the radiation focus. Elekta guarantees that the Gamma Knife® system will perform with a total radiological accuracy of 0.50 mm: an achievement in itself. However, as will be shown here, the actual result is much better. Elekta's analysis is performed on 332 measurements of the radiological accuracy. These were all conducted in connection to new Leksell Gamma Knife® installations, source reload from systems ranging from 6-14 years old, and service activities. A total of 189 distinct systems were assessed. **The analysis of these measurements gave an average radiological accuracy of 0.15mm. This means that Leksell Gamma Knife® has a radiological accuracy of, on average, 0.15mm.** See below how the measurement was done.

Clinical accuracy

The main quantity of importance for the clinician is clinical accuracy, which is the sum total of the accuracy contributions from the entire treatment procedure, i.e. imaging, patient positioning, dose planning as well as the radiological and mechanical accuracy. Elekta cannot control the accuracy of the imaging steps but a recent study

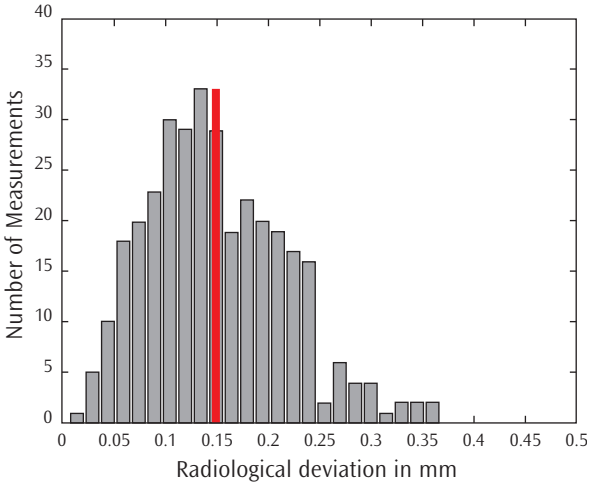


Fig 3: The graph shows the number of measurements and the deviation in millimeters, including statistical standard deviation.

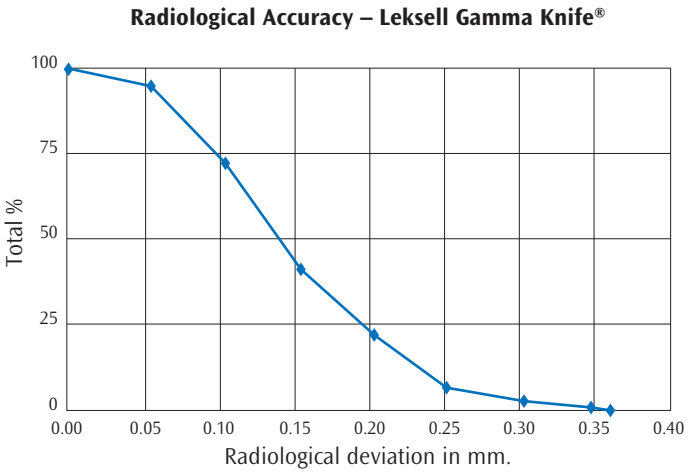
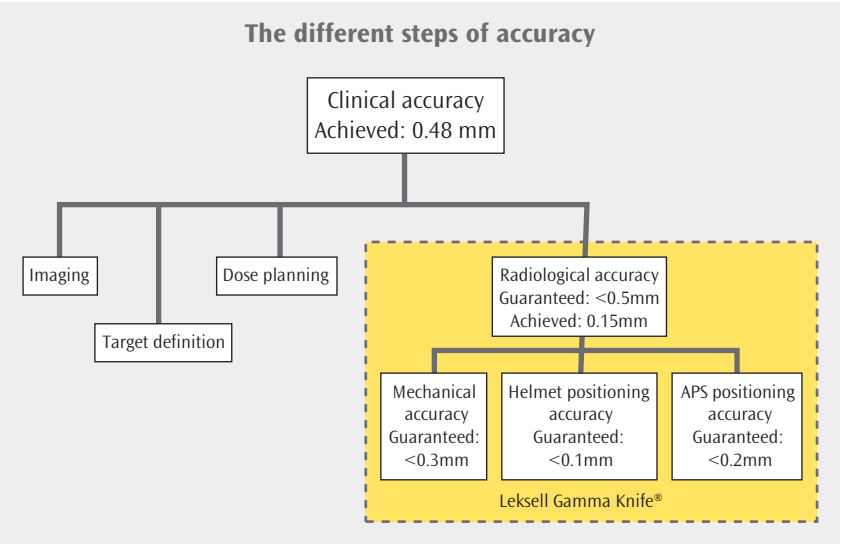


Fig 4: The graph shows that approximately 75 % of all units measured gives an accuracy of 0.20 mm or better.

by Drs Mack and Kreiner in Munich, Germany, covering 170 measurements of the entire Gamma Knife® surgery procedure over 5 years **showed an average clinical accuracy of 0.48mm.** The major part of the difference in achievable radiological accuracy (0.15mm) and clinical accuracy (0.48mm) is explained by imaging inaccuracies.



Mechanical accuracy: *The sum of all mechanical tolerances.*

Radiological accuracy: *System accuracy including mechanical accuracy plus beam delivery accuracy.*

The methods

Radiological measurement

The radiological accuracy of Leksell Gamma Knife® is assessed by measuring the distance between the point where 201 radiation beams intersect and the mechanically positioned target point. A special tool, a small film holder, is used to determine the geometrical location of the radiation focus. The tool contains a small space where a film can be placed, and a sharp, spring-loaded needle. The film holder is fixed in the collimator helmet so that the position of the needle tip coincides with the mechanical isocenter.

After the film is exposed in the treatment unit, the distance between the needle mark and the 50 % isodose contour can be measured and the radiological accuracy thus determined. (Fig. 2)

The readings were taken from 332 measurements over a period of two years, including 189 installed systems. The average value of the total deviation is 0.15 ± 0.07mm. The experimental uncertainty of the dosimetry procedure is approximately 0.1 – 0.2 mm and is related to the setup of the measurement and the collection of data from the films. (Fig. 3)

Studying the whole procedure

The study by Mack et. al. "Quality assurance in stereotactic space. A system for verifying the accuracy of aim in radiosurgery" was published in Medical Physics 29(4), April 2002. The aim with the study was twofold; first, the chain of steps in terms of a complete patient simulation should be followed and second, the stereotactic MR image data should be verified against a reference, in this case stereotactic radiographic projection images. A phantom with a marked radiochromic film was used. After imaging and planning, the phantom was adjusted and irradiated. The measured distance between the planned target point and the spot on the radiosensitive film is a measure of the clinical accuracy. The results, evaluating 170 system tests within 5 years, show that the average deviation of the complete system is 0.48 mm ± 0.23 mm. Given the high radiological accuracy of Leksell Gamma Knife®, it is clear that optimizing the imaging, in terms of accuracy, gives the highest payback in terms of final clinical accuracy.

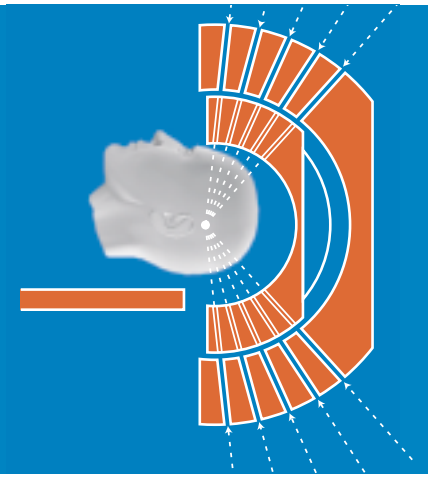
Leksell Gamma Knife® – accuracy and results

Accuracy is crucial to intracranial surgery. Leksell Gamma Knife® does not compromise – it is safe, reliable and clinically proven. The studies in this document show that Leksell Gamma Knife® has a life-long, repeatable radiological accuracy with an average value of 0.15 mm. Even when the whole treatment procedure is taken into account, i.e. when the clinical accuracy is assessed, the result is below 0.50 mm. This underlines Gamma Knife® surgery as one of the most viable stereotactic radiosurgical procedures today.

The system has been in clinical use for more than 30 years and has treated over a quarter of a million patients, with the clinical results being reported in more than 2,000 peer-reviewed articles.

How Gamma Knife® surgery works

Gamma Knife® surgery is a unique method that delivers extremely focused radiation beams to targets in the brain. 201 individual radiation sources (cobalt 60) are positioned in a hemisphere so that the beams converge at a single focal point. The shape of the dose distribution is optimized to cover only the target, while minimizing the effect on the surrounding healthy tissue.



Type of accuracy	Definitions	Leksell Gamma Knife®
Mechanical Accuracy	The sum of all mechanical tolerances	<0.3mm (Guaranteed)
Radiological Accuracy	Accuracy of the system, including mechanical accuracy plus beam delivery accuracy	<0.50 (Guaranteed) 0.15mm (Average)
Total Clinical Accuracy	Radiological accuracy plus imaging inaccuracies	0.48mm (Average)

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