# Novel Positioning System for Vantage Stereotactical Frame Enabling Accurate and 2 Hands Frame Placement

***Andrius Radziunas[1], Tamasauskas Sarunas[1], Tamasauskas Arimantas[1], Eidukynas Darius[2], Jurenas Vytautas[2], Ostasevicius Vytautas[2]***

■ BACKGROUND: **Accurate placement of stereotactic frames, such as the Leksell Vantage frame, is crucial for optimal stereotactic procedures. Conventional mounting methods for the Vantage frame, often involving adhesive straps, can be imprecise, complicated, time-consuming, and require at least 2 medical staff members. This study aimed to design and investigate a novel, universal positioning system suitable for the Vantage frame.**

■ METHODS: **A prototype of a positioning system was developed, consisting of inflatable silicone cushions with a composite structure, fixation edges, and direct connection to hand pumps. The prototype was tested in a clinical environment at the Lithuanian University of Health Sciences Neurosurgery department with 20 patients, divided into 2 groups with 10 patients in each group. Group A had the frame applied using the manufacturer's recommendations, while Group B used the new prototype. The procedure time and personnel involved were recorded.**

■ RESULTS: **The study demonstrated that the newly developed prototype enabled successful stereotactic frame placement with the participation of only 1 neurosurgeon, compared to the 2 required with the standard method. Furthermore, the average procedure time was significantly shorter when using the prototype (6 minutes and 20 seconds) compared to the standard procedure time (8 minutes and 34 seconds). The prototype was also found adaptable to various head sizes.**

■ CONCLUSIONS: **The experimental evaluation indicates that the novel 3-dimensional positioning system for the Leksell Vantage frame effectively reduces the number of personnel needed and shortens the frame placement procedure, potentially leading to more efficient use of neurosurgeons' time and reduced stress for both patients and surgeons.**

## INTRODUCTION

There are 100,000 radiosurgical procedures and around 12,000 deep brain stimulation implantations carried out worldwide each year using stereotacic frames.[1] Moreover, intracranial lesion biopsies and stereotactic electroencephalography electrode placement also are done by using a frame-based technique. For optimal stereotactical magnetic resonance imaging, appropriate frame positioning on the patient's head is mandatory. The stereotactic frame must be accurately placed on the patient's head to ensure that the images are aligned correctly with the treatment plan. Incorrect placement can lead to final target coordinates calculation errors.

Conventional Leksell G and Vantage frame mounting methods are based on usage of ear bars,[2] over-the-head Velcro or mounted bar,[3] additional plates for supine placement,[3,4] or bite bars.[5]

Most of these methods are suitable for Leksell G frame, however not for a Vantage frame which was presented for clinical use 6 years ago.[6]

The Vantage frame was designed to be more comfortable for patients and for surgeons and its composition improved imaging capabilities. Frame placement is manual, and for initial stability during alignment phase, the user manual recommends to use adhesive straps (**Figure 1**), and then the frame is finally fixed with titanium studs to the skull bone. Such an attachment is not precise and is quite complicated, requires at least 2 medical

**Key words**
- Frame fixation
- Leksell Vantage frame
- Positioning system

**Abbreviations and Acronyms**
3D: 3-dimensional

*From the [1]Lithuanian University of Health Sciences, Medical Academy, Neurosurgery Department, Kaunas, Lithuania; and [2]Kaunas University of Technology, Institute of Mechatronics, Kaunas, Lithuania*

*To whom correspondence should be addressed: Andrius Radziunas, M.D., Ph.D. [E-mail: andrius.radziunas@lsmuni.lt]*

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staff, and the attachment time is quite long and stressful for the patient and doctor. Uncooperative patients or patients with uncontrolled movements with frame placement make it even more complicated.

The objective of this study is to design and investigate a novel, universal 3-dimensional (3D) positioning system of a stereotactic frame, which is suitable to be used with Leksell Vantage frame.

## TECHNICAL NOTE

During the project, initial numerical modeling of cushions with a composite structure was performed to determine the rational shape and rigidity characteristics. Based on the results obtained, cushions with a larger contact width with the patient's head were modeled, having a composite structure—a cast reinforcing frame, which increases not only the rigidity of 1 actuator cushion but also has a significant impact on the overall rigidity of the stereotactic frame positioning system. For more convenient insertion of the cushions into the frame and more reliable adherence to it during the procedure, additional fixation edges were designed, eliminating the potential spontaneous fallout of the cushion or the use of additional fastening elements, such as Velcro straps, during the procedure. Taking into account the results of testing the prototype of the original stereotactic frame 3D positioning system in a clinical environment, the newly designed cushion is connected to the hand pump directly, through one channel without additional connectors and valves, thus simplifying the overall structure and use of the positioning system, and eliminating the contact of the hand pumps with the patient's head. The results of theoretical research were validated in practice by manufacturing pilot cushions of the updated design and experimentally testing their rigidity and tightness in laboratory conditions (Figure 2).

**Figure 1.** Leksell Vantage frame with adhesive straps for primary alignment (image Elekta group used with permission).

During experimental studies, an updated 3D positioning system prototype of a stereotacic frame used in radiosurgery was produced, consisting of 2 pieces of inflatable soft, silicone cushions with a composite structure, an additional fixation edge, and direct connection of a hand pump, eliminating the use of additional fastening elements and the contact of the pumps with the patient's head during the procedure. The updated prototype was tested in practice (Figures 3 and 4) at the Lithuanian University of Health Sciences Kauno klinikos Neurosurgery department with 10 different patients.

The results obtained showed that using the prototype of the developed system, it is possible to successfully place a stereotacic frame with the participation of only 1 doctor in the process. This stereotacic frame positioning-fixation prototype is easy to manufacture, suitable for heads of various sizes and shapes, suitable for patients with movement disorders and very sensitive patients, and the use of this stereotacic frame fixation (positioning) method is easily adaptable. Patients of the Lithuanian University of Health Sciences Kauno klinikos Neurosurgery

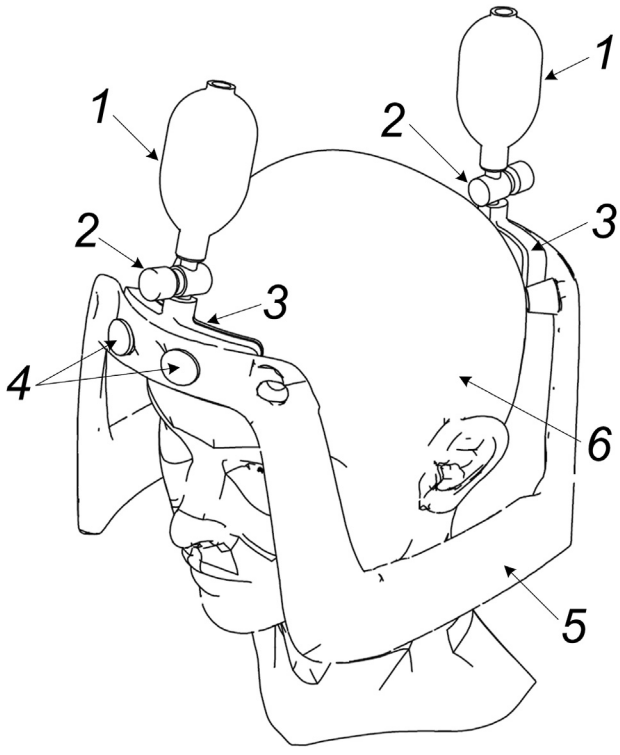


**Figure 2.** A novel 3D positioning system of a stereotactic frame: 1: hand pump, 2: discharge valve, 3: air distributor, 4: inflatable bladder, 5: Leksell Vantage frame, and 6: patient's head. 3D, 3-dimensional.

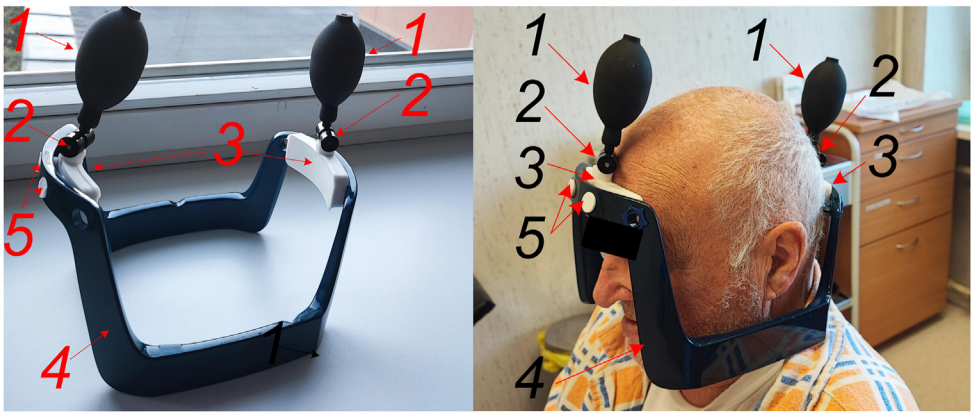


**Figure 3.** View of a novel 3D positioning system of a stereotactic frame: version 2: left side: prototype and right side: mounted on patient's head. Here: 1: hand pump, 2: discharge valve, 3: inflatable bladder, and 4: Leksell Vantage frame. 3D, 3-dimensional.

department, for whom treatment using the stereotacic Leksell Vantage frame from Elekta (Sweden) was indicated, were randomly divided into 2 groups: Group A (10 patients): the stereotacic frame was applied using the manufacturer's recommendations and tools; Group B (10 patients): the stereotacic frame was applied using a prototype of a new type of stereotacic frame 3D positioning system (temporary fixator). The stereotacic frame application procedure was performed by 2 neurosurgeons who had performed more than 200 such procedures. Each neurosurgeon performed frame applications on an equal number of patients in groups A and B. Using the developed prototype (group B patients), all procedures were successfully performed with the participation of only 1 neurosurgeon (**Video 1**), while in group A patients using the standard frame fixation method, a second neurosurgeon was required to accurately apply the frame, who performed the work of the supporting personnel fixing the frame in the target position. In the case of high workload of neurosurgeons, the use of the newly developed prototype allows for more efficient use of doctors' time and easier planning of the frame placement procedure.

Video

*Video available at www.sciencedirect.com*

Due to the convenient design of the stereotacic frame positioning system prototype, intuitive use options, and a more easily manipulated fixation system, the procedure time is shortened. The standard procedure lasted an average of 10 minutes and 34 seconds ± 2.24 (standard deviation), and using the frame positioning system prototype, an average of 5 minutes and 20 seconds ± 1.72 (standard deviation). Due to the shorter procedure time and more convenient use, less stress was found for patients and the surgeon.

Using the newly developed frame positioning system prototype, a shorter procedure time, a smaller number of participating personnel, and a smaller need for adjustments were achieved, which made it easier to implement the frame position desired by the neurosurgeon.

Proposed positioning system consists of 2 or 4 inflatable, soft, silicone bladders, 2 hand pumps with discharge valves, and 2 adjustable air distributors and adhesive ("velcro" type) straps (**Figure 5**) for additional fixation if needed for certain size of patient's head.

Inflatable bladder designed to be used in version 2 can have different configurations made of different colors in thickness and height depending on patient's head size. Principal scheme of designed bladder and different configurations of bladders are presented in **Figure 3**.

## DISCUSSION

Accurate and stress-free stereotactic frame placement is a crucial part of the daily practice for neurosurgeons working with stereotactic frames. The Leksell Vantage frame was designed to enhance imaging capabilities and patient comfort. However, the removal of the possibility to use earplugs in the Vantage frame, as was the case with the previous version of Leksell frame G, to decrease patient discomfort, led to a decrease in the stability of the frame during positioning. The Velcro straps suggested by the manufacturer do not ensure the necessary stability during the placement procedure. Moreover, achieving accurate frame placement for patients with movement disorders or those who are anxious presents even more significant challenges. In response to these challenges, our technical modeling has led to the development of an innovative tool. This tool is designed to facilitate accurate Vantage frame placement, particularly for these patients, while maintaining our commitment to patient comfort and safety.

The findings of this technical modeling and prototype application in clinical settings demonstrate the feasibility and benefits of a novel 3D positioning system designed for the Leksell Vantage stereotactic frame. The experimental evaluation conducted with real patients showed significant advantages over the

**Figure 4.** Top view of a novel 3D positioning system of a stereotactic frame: back outer pins are shorter and not resting on patients head. 3D, 3-dimensional.

conventional frame mounting methods recommended by the manufacturer. One of the most notable outcomes was the reduction in the number of medical personnel required for frame placement.

The newly developed prototype enabled successful frame application with the participation of only 1 neurosurgeon, whereas the standard method necessitated 2. This is particularly significant considering the potential for more efficient use of neurosurgeons' time and easier scheduling of the frame placement procedure, especially in situations with high workload.

## CONCLUSION

Experimental evaluation of the prototype of the stereotactic Leksell Vantage frame positioning system was conducted with real patients in the Hospital of Lithuanian University of Health Sciences Kauno klinikos. Obtained results showed that it is possible to use a novel 3D positioning system, presented above—the number of personnel to perform the procedure is reduced and the procedure is performed faster due to shorter preparation and procedure time, especially if the patient is restless or has uncontrolled movements.

## CRediT AUTHORSHIP CONTRIBUTION STATEMENT

**Andrius Radziunas:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Conceptualization. **Tamasauskas Sarunas:** Methodology, Conceptualization. **Tamasauskas Arimantas:** Writing – review & editing. **Eidukynas Darius:** Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Conceptualization. **Jurenas Vytautas:** Writing – review & editing, Conceptualization. **Ostasevicius Vytautas:** Writing – review & editing, Conceptualization.

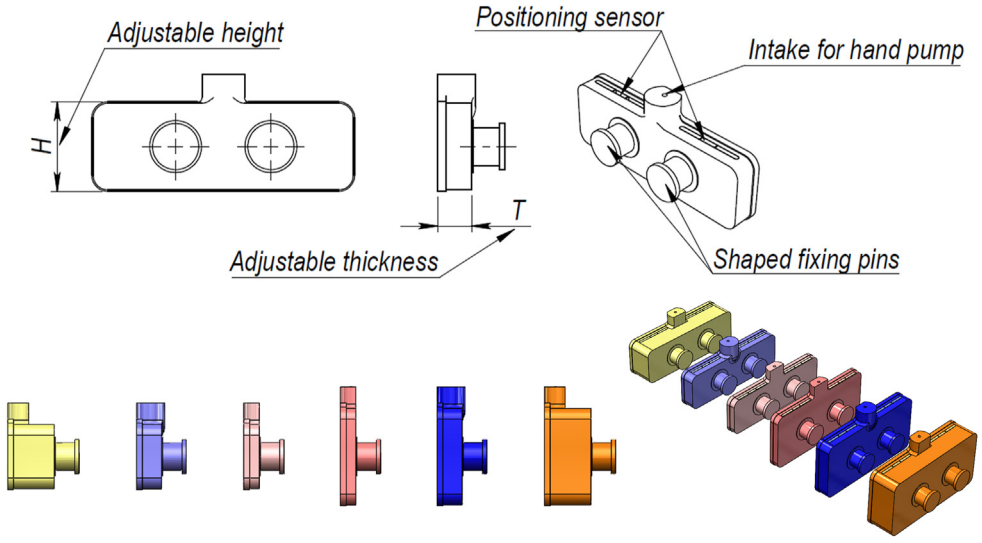


**Figure 5.** Inflatable bladder: above: principal scheme and below: 3D model view of different configurations in height and thickness. 3D, 3-dimensional.

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