Burdenko's Journal of Neurosurgery
2026, No. 2, pp. 70–74
https://doi.org/10.17116/neiro20269002174

Primary clinical experience of Vivostat autologous fibrin glue for neurosurgery in Kazakhstan and Central Asia

© E.N. Kuanyshev, B.S. Syzdykova, D.K. Teltayev, K.H. Mustafin

National Center of Neurosurgery, Astana, Kazakhstan

ABSTRACT

Background. Watertight dural closure and skull base reconstruction remain key challenges in neurosurgery. Autologous fibrin sealant Vivostat, produced from the patient's own blood, provides high biocompatibility, elasticity, and reliable adhesion. The absence of clinical data on its use in Central Asian countries highlights the relevance of the present study.

Objective. To evaluate the clinical efficacy and safety of autologous fibrin sealant Vivostat for dural sealing and skull base reconstruction.

Material and methods. This retrospective-prospective study included 110 patients operated on at the National Center of Neurosurgery (Astana, Kazakhstan) between August 2024 and September 2025. The sealant, derived from autologous blood using the Vivostat system, was applied for dural defect sealing and fixation of reconstructive grafts. The primary outcomes were the incidence of postoperative cerebrospinal fluid (CSF) leakage, infectious complications, and the need for reoperation.

Results. The mean patient age was 48.9±14.7 years; 60% were women. An endoscopic transnasal approach was used in 65 patients, craniotomy in 35, and other approaches in 10. Polymerization occurred almost instantly, reaching maximal strength within 1—2 minutes. Successful sealing was achieved in 109 (99.1%) patients, while 1 (0.9%) patient required reoperation due to nasal CSF leakage and epistaxis. No infectious, allergic, or thromboembolic complications were observed.

Conclusion. The use of autologous fibrin sealant Vivostat demonstrated high efficacy and safety for dural sealing and skull base reconstruction. The method reduced the risk of postoperative CSF leakage and reoperation. This study presents the first clinical experience with Vivostat in Central Asia.

Keywords: *autologous fibrin sealant, dural sealing, skull base reconstruction, neurosurgery, cerebrospinal fluid leakage, clinical efficacy.*

INFORMATION ABOUT THE AUTHORS:
Kuanyshev Y.N. — https://orcid.org/0009-0008-2819-2549
Syzdykova B.S. — https://orcid.org/0009-0003-4379-5309
Teltayev D.K. — https://orcid.org/0000-0002-4990-8410
Mustafin Kh. — https://orcid.org/0000-0003-3984-9565
Corresponding author: Kuanyshev Y.N. — e-mail: kuanysheverbol@gmail.com

TO CITE THIS ARTICLE:
Kuanyshev YN, Syzdykova BS, Teltayev DK, Mustafin Kh. First clinical application of autologous fibrin sealant Vivostat for neurosurgery in Kazakhstan and Central Asia. *Burdenko's Journal of Neurosergery*. 2026;90(2):70–74. https://doi.org/10.17116/neiro20269002170

Introduction

Dural defect closure is still a key challenge in neurosurgery. Despite various synthetic and biological adhesive systems, fibrin adhesives are still the «gold standard» [1]. Their efficacy in neurosurgery was confirmed by numerous clinical studies [2]. Recent systematic reviews show that fibrin sealants in reconstructive skull base surgery are associated with lower incidence of postoperative cerebrospinal fluid leakage and complications [3, 4, 18, 20].

Commercial fibrin-thrombin glues (Tisseel and Evicel) are effective in neurosurgery. However, they are produced from donor plasma or contain aprotinin that is associated with risk of immune reactions [5, 6]. These sealants provide high elasticity, adhesion and reproducible properties regardless of fibrinogen level in donor plasma [7, 8, 12, 19].

Synthetic adhesives, including BioGlue, are described in the literature as causing severe inflammatory reactions [9—11]. In contrast, autologous fibrin glue (Vivostat system, Vivostat A/S, Denmark) is prepared from autologous blood in the operating theater. This minimizes theoretical risk of infection and allergic reactions. Its mechanical properties are comparable or superior to some traditional fibrin glues [12—14].

Historically, there were attempts to use official fibrin glues derived from donor plasma (CryoSeal system) in Kazakhstan. Subsequently, production and supply of consumables were discontinued, and its use in clinical practice was discontinued. This adhesive demonstrated effectiveness but had several limitations: the need for thrombin, short-term shelf life and reliance on regular supplies of consumables. Recent reviews indicate that official fibrin adhesive systems

face some technological and biochemical limitations related to stability, polymerization rate and biocompatibility [11].

The need for effective and safe sealing materials is increasing with greater number of high-tech neurosurgical interventions requiring skull base and dura mater reconstruction. Central Asian countries lack own production of such systems, so clinical practice is entirely dependent on imports. This creates risks. Indeed, supply disruptions or quality inconsistencies can lead to difficulties in scheduling admissions and surgeries. This is critical for large-volume hospitals.

Until 2024, the National Center for Neurosurgery primarily used industrial adhesive systems (BioGlue), but these systems were accompanied by limitations related to safety and dependence on external suppliers. In 2024, the Center's Transfusiology Department became the first in the region to implement a technology for obtaining autologous fibrin glue using Vivostat System.

This study is the first report on clinical efficacy and safety of Vivostat autologous fibrin glue for neurosurgery in Kazakhstan and Central Asia.

The purpose of the study was to evaluate clinical efficacy and safety of Vivostat autologous fibrin glue for brain and skull base surgeries at the National Center for Neurosurgery in Kazakhstan.

Material and methods

A retrospective-prospective study included 110 patients who underwent surgery at the National Center for Neurosurgery between August 2024 and September 2025. Vivostat autologous fibrin glue was used. The process involved patient blood harvesting (120 ml), automated processing and obtaining 5—6 ml of adhesive composition. In 2024, this technique was piloted in 10 patients. In 2025, it was introduced into routine practice and used in 100 patients.

Inclusion criteria: age >18 years, dura mater or skull base defect requiring repair, informed consent. Patients with severe coagulopathy, sepsis or local infection before surgery, refusal to participate and insufficient blood volume to obtain autologous fibrin glue were excluded. We additionally considered physiological limitations recommended by the Vivostat manufacturer: hemoglobin >95 g/L, fibrinogen >1 g/L, platelet count $\geqslant 140 \cdot 10^9$/L, body weight >35 kg. This was necessary to obtain stable and high-quality fibrin glue.

Autologous fibrin glue was applied using a pneumatic applicator included in device complex. We used fibrin glue for closure of dura mater and skull base defects, prevention of cerebrospinal fluid leakage, fixation of grafts and flaps. This technical solution allowed surgeons to select optimal adhesive application mode and use it for 8 hours without losing functional properties.

To integrate this technology into clinical practice, we developed and approved appropriate document at the medical facility level. Official permission was obtained from the Ministry of Health of the Republic of Kazakhstan. Standard procedures were implemented in the Transfusiology Department, medical personnel were trained, and special registry was created to ensure full traceability of each procedure according to donor-patient principle. Particular attention was paid to process safety and adaptation.

Quantitative data are presented as median and interquartile range, categorical variables – as absolute numbers and percentages. Descriptive analysis was aimed to summarize clinical experience.

Table 1. **Demographic characteristics and surgeries (*n*=110).**

Variable	Value
Age, years	48.9±14.7 (19—76)
Women/men, *n* (%)	66 (60)/44 (40)
Transnasal approach, *n* (%)	65 (59.1)
Craniotomy, *n* (%)	35 (31.8)
Other approaches, *n* (%)	10 (9.1)

Table 2. **Characteristics of autologous fibrin glue.**

Variable	Value (data)
Polymerization rate	Fast (maximum strength within 1—2 min)
Adhesive properties	High (uniform distribution over surface, no excess leakage)
Compatibility with additional materials	High (combination with tachocomb, artificial dura mater, autologous fat)
Ease of use for dura mater defect closure	High (pneumatic glue delivery system, various applicators and modes)
Intraoperative side effects	Not registered

Results

The study included 110 patients who underwent surgery with autologous fibrin glue. Mean age was 48.9±14.7 years (range 19—76). Women predominated (60%). Endoscopic transnasal approach was the most common (65 patients), open craniotomy was used in 35 patients, other procedures — in 10 patients **(Table 1)**.

The glue polymerized almost instantly with maximum strength after 1—2 min. Autologous fibrin glue demonstrated favorable adhesive properties with even coating the surface, not leakage and good interaction with additional plastic materials. This provided additional strength and sealing, as well as enhanced hemostatic effect in endoscopic procedures. Intraoperative characteristics of autologous fibrin glue are presented in **Table 2**.

Autologous fibrin glue provided effective closure of dura mater and skull base defects in 109 (99.1%) out of 110 patients. In one case (0.9%), nasal cerebrospinal fluid leakage with epistaxis occurred postoperatively and required redo surgery. There were no infectious complications, allergic reactions or thromboembolic events **(Table 3)**.

Table 3. **Clinical efficacy (*n*=110).**

Complication	*n*	Incidence, %
Nasal cerebrospinal fluid leakage with epistaxis	1	0.9
Infectious complications	0	0
Allergic reactions	0	0
Thromboembolic events	0	0

Discussion

Autologous fibrin glue (Vivostat system) is an effective and safe method for dura mater and skull base defect closure in neurosurgery. In our sample (*n*=110), the incidence of cerebrospinal fluid leakage was 0.9%. This value is significantly lower than that reported in most publications on industrial adhesives (5—10%) [3, 4, 18].

Our findings are consistent with some reports demonstrating efficacy of Vivostat in neurosurgery and other fields. According to available data, Vivostat is an effective method for hemostasis and additional sealing during craniotomies and spinal procedures with low rate of allergic reactions and infectious complications [8, 12, 14]. Vivostat was successfully used as a component of multilayer reconstruction for intraoperative defects and nasal cerebrospinal fluid leakage in otolaryngology and endoscopic skull base reconstruction [15, 16, 18, 20].

Thus, our data are consistent with international findings and confirm effectiveness of this method. Our sample demonstrates an extremely low rate of postoperative cerebrospinal fluid leakage (comparable or better than that in some historical series devoted to industrial adhesive systems). These results demonstrate potential economic benefits (lower rate of redo surgeries and risk of infectious complications, as well as shorter hospital stay).

Economic models in other surgical fields have already shown that lower complication and redo surgery rate can fully offset the costs of expensive local hemostatic/sealing agents. Economic studies (including analyses based on aggregated resource data) have demonstrated a positive budgetary impact with rational use of modern fibrin products [16, 17]. Nevertheless, pharmacoeconomic assessment of Vivostat in neurosurgery requires a separate analysis taking into account local prices for consumables, cost of redo surgeries and daily costs of hospital-stay.

This is the first report on Vivostat autologous fibrin glue for neurosurgery in Central Asia. Until now, reports on Vivostat were only European without regional experience. Introduction of this technology in Kazakhstan opens up opportunities for scaling up in other clinics and countries in the region.

Importantly, autologous adhesive has unique advantages. Unlike industrial analogues (e.g., Tisseel, BioGlue), there is no risk of infection transmission or immune reactions due to excellent biocompatibility [10, 12, 13]. Furthermore, Vivostat technology enables intraoperative production of standardized-quality adhesive that simplifies surgery and reduces dependence on official adhesive systems [5, 13, 15].

Our data demonstrate not only clinical efficacy but also organizational feasibility of this method (standard operating procedures, patient registry and support for transfusion service).

An advantage of our study is consistent use of technology with gradual increase of sample size (from 10 patients in 2024 with assessment of primary results to 100 patients in 2025 as routine practice). No complications related to autologous fibrin glue is also important.

Study limitations are single-center design, no control group and short-term follow-up. Nevertheless, our results demonstrate advantages of this method and consistency with international data. Finally, patient sample was quite homogeneous (predominant surgeries for skull base tumors and pituitary adenomas). This complicates extrapolation of data to other neurosurgical interventions.

According to our experience, widespread implementation of this technology can reduce the incidence of postoperative complications, improve quality of life and reduce treatment costs.

Thus, Vivostat can become a standard for dura mater and skull base defect closure in Kazakhstan and potentially throughout the entire Central Asian region.

Conclusion

Vivostat autologous fibrin glue demonstrated high efficacy and safety in dural and skull base defect closure. Postoperative cerebrospinal fluid leakage was observed in only 0.9% of cases, and there were no infectious, allergic or thromboembolic complications. The glue polymerized quickly, provided uniform surface coverage, combined well with reconstructive materials and enhanced intraoperative hemostasis and density of repair.

Vivostat technology reduced dependence on imported official fibrin glues, ensured predictable and sustainable surgical results.

In the future, prospective controlled studies including formal economic evaluation would be advisable to confirm long-term clinical and financial benefits of Vivostat autologous fibrin glue in neurosurgical practice.

Ethical aspects

The study was conducted in accordance with the Declaration of Helsinki and standards of institutional and national ethics committees. We patients signed an informed consent for the use of autologous blood and anonymized clinical data for scientific purposes. Patient personal information was not disclosed. Observational study did not include interventions beyond standard surgical practice, and additional approval from the ethics committee was not required in accordance with current national regulations.

Funding. This study received no external funding. All materials and resources were provided by the National Center for Neurosurgery as a part of institutional research and innovation activities.

Acknowledgment. The authors acknowledge the management of the National Center for Neurosurgery for supporting this initiative and creating conditions for implementation of innovative technologies. Special thanks go to the management of the Scientific Production Center for Transfusiology for assistance and expert guidance throughout all stages of implementing the autologous fibrin glue technology. The authors also thank the staff of the Transfusiology Department of the Burdenko Neurosurgery Center (Moscow, Russia) for sharing their experience, consulting and methodological support.

International collaboration between leading centers in Moscow and Astana was a key factor in successful implementation of Vivostat technology in Kazakhstan.

Author contribution:
Concept and design of the study — Kuanyshev E.N., Syzdykova B.S.
Collection and analysis of data — Kuanyshev E.N., Syzdykova B.S., Teltayev D.K.
Statistical analysis — Kuanyshev E.N.
Writing — Kuanyshev E.N.
Editing — Syzdykova B.S., Teltayev D.K., Mustafin Kh.A.

The authors declare no conflicts of interests.

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Received 13.11.2025
Accepted 30.01.2026

COMMENT

The authors present own experience of autologous fibrin glue in neurosurgical procedures. The advantage of this technique is ex tempore production of fibrin glue from the patient's whole blood. Autologous fibrin glue has advantage of complete biocompatibility and no risk of blood borne infections. Importantly, Vivostat system allows for fibrin glue harvesting from autologous blood and donor plasma (single-donor fibrin glue) and has the advantage of no residual excess thrombin. As we know, the last one can induce cell apoptosis and negatively impact regenerative process. Fibrin glue harvesting based on Vivostat system differs fundamentally from mechanism of other fibrin glue compositions. Unlike thrombin releasing fibrinopeptide A and B from the NH2-terminal domains of the Aα and Bβ chains of fibrinogen, batroxobin releases only fibrinopeptide A and has narrow specificity of action. Batroxobin does not affect other components of blood clotting cascade, does not activate factor XIII and does not cleave fibrinopeptide B from fibrinogen. Batroxobin catalyzes release of soluble fibrin I acids from plasma fibrinogen. The last one, upon application, polarizes at neutral pH to form a natural cross-linked fibrin II clot (fibrin glue). This technique for fibrin glue synthesis in neurosurgery is far from new. It has been used for over 25 years. Danish cardiac surgeon Hans Kristian Kjaergard developed this procedure. The Burdenko Neurosurgery Center has had positive experience with autologous fibrin glue since 2021, when appropriate equipment was registered in the Russian Federation. The number of patients who have received the procedure has reached 5.000.

The authors present a retrospective-prospective study of 110 neurosurgical patients who underwent intraoperative dura mater repair with autologous fibrin glue. No glue-related complications confirm high clinical efficacy. This study can be viewed primarily as a process for validating the technique for wider application, developing a standard procedure and implementing into clinical practice.

Despite numerous studies of biological and synthetic adhesive compositions, it is still unclear how subtle differences in fibrin sealant formulations relate to their clinical efficacy and safety. Further research is needed. Widespread autologous fibrin glue is determined by patient-focused nature of healthcare, as it provides a personalized treatment approach.

Kvan O.K. (Moscow)