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Development and analysis of filament holder for fused filament fabrication 3D printer using Python programming language

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Abstract. The work aimed to analyse and develop a 3D printer coil holder using the Python programming language. The methodology included a coil holder designed using computer-aided design (CAD) software, namely Autodesk Fusion 360. External libraries and plug-ins such as Stress Analysis and Generative Design were used for optimisation. The suitability of the developed design for improving the feeding of strings and reducing their tangling when printing on a 3D printer was determined. The operation of the coil holder with different types and coil sizes was analysed. The developed spool holder successfully passed 97% of the tests for printing models using PLA, ABS and PETG. Testing the measurements of the coil holder with a PROTESTER WDF-30 digital dynamometer revealed several essential observations: Teflon tubing added additional friction, increasing both the minimum and maximum forces by approximately 0.2 N, and slightly reducing the range between the minimum and maximum values; plastic coils showed lower minimum forces, ~0.4 N, due to reduced friction, but a more extensive range, ~0.5 N, due to their greater mass, and cardboard coils had higher minimum forces, ~0.5 N, but a smaller range, ~0.3 N; no tension significantly reduced both minimum, ~0.2 N, and maximum, ~0.3 N, forces, as well as the range between them, ~0.1 N, and this condition increased the risk of coil entanglement; the effect of the Teflon tube was more pronounced under proper tension conditions, approximately 0.2-0.3 N; the high-tension setup showed significantly higher minimum, ~0.8 N, and maximum, ~1.1 N, forces compared to the developed holder (minimum ~0.5 N, maximum ~0.8 N), but the range of acceptable values was similar, the increased minimum force in the high-tension setup could potentially lead to insufficient extrusion and increased extruder wear. The developed coil holder reduces the printer's extruder mechanism load by maintaining an optimal tension in the range of 0.5 to 0.8 N. This can significantly extend the life of critical components, reducing the cost of maintaining the 3D printer

Keywords: 3D printing; filament holder; dynamometer; Matplotlib; data visualisation

Introduction

The advancement of additive manufacturing, primarily through Fused Filament Fabrication (FFF) technology, has led to innovative approaches for creating complex geometries from various materials. A critical component of this technology is the filament holder, which plays a key role

in ensuring consistent filament control during the printing process. Despite progress in 3D printing, unresolved filament management challenges can lead to inefficiencies and mechanical failures. Research into filament holder design, incorporating mechanical analysis, sustainability

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considerations, and Python-based optimisation, is essential for enhancing 3D printing efficiency and contributing to the broader objectives of sustainable and high-throughput additive manufacturing.

Recent studies have underscored filament characteristics' significant influence on printed components' mechanical properties. For instance, F. Calignano *et al.* (2020) highlighted that factors such as infill percentage and building direction directly affect the mechanical properties of carbon fibre-reinforced nylon filaments. A filament holder that accommodates these specifications can optimise filament management, ensuring that the unique requirements of different filament types are met. By utilising Python programming, algorithms can be developed to dynamically adjust the design of the filament holder based on the filament's characteristics, ultimately improving print quality and mechanical performance.

Similarly, Q. Wang *et al.* (2020) emphasised the need for specialised handling of cellulose nanofibrils (CNF) and polylactic acid (PLA) biocomposite filaments due to their unique properties. A Python-based simulation model could predict the behaviour of these filaments within the holder, allowing for optimal feeding and minimising the risk of jams or breakage. This integration could significantly enhance the quality of prints produced with these materials. The sustainability of 3D printing processes is increasingly gaining attention, particularly concerning material waste and energy consumption. Researchers J. Kechagias & D. Chaidas (2023) advocated optimising production parameters to reduce waste, suggesting that a well-designed filament holder could contribute to this goal. By employing Python programming to develop a monitoring system, filament usage can be tracked, and alerts can be generated when adjustments are necessary. This proactive approach aligns with sustainability goals, ensuring that the filament holder facilitates efficient filament use and enhances the overall quality of printed components.

Moreover, the findings from H. Bakhtiari *et al.* (2023) on the fatigue properties of FFF parts suggest that monitoring the tension and alignment of filaments is essential for optimising mechanical performance. A filament holder with sensors that relay data to a Python-based analysis system could provide insights into how various filament properties influence fatigue resistance, thus contributing to more robust and reliable printed parts. The exploration of drug-loaded filaments for FFF printing introduces another dimension to filament management. As B. Shaqour *et al.* (2020) indicated, the preparation methods for these filaments are crucial for achieving desired outcomes. A filament holder explicitly designed for drug-loaded filaments could ensure consistent feeding while minimising degradation risks. Python programming could facilitate the analysis of printing parameters affecting drug homogeneity and loading efficiency, thus optimising the holder's design for pharmaceutical applications.

Innovative materials, such as cholesteric hydroxypropyl cellulose (HPC) filaments, also require specialised

handling strategies. C.L.C. Chan *et al.* (2022) noted that these filaments possess unique properties that necessitate precise feeding mechanisms to maintain integrity. Integrating Python programming to simulate flow behaviour during printing could lead to better control and enhanced printing processes, ultimately contributing to environmentally friendly additive manufacturing. Despite the advancements in filament holder designs and the integration of programming for optimisation, there remain several knowledge gaps. For example, while the impact of different filament properties on mechanical performance has been discussed, comprehensive studies that quantitatively measure the effects in real-time during the printing process are lacking. Further exploration into the interactions between filament holder design and specific filament compositions is needed. Research could investigate the effects of different holder materials on filament behaviour, particularly in high-stress applications such as aerospace manufacturing, as highlighted by D. Martinez *et al.* (2022). This could lead to enhanced designs that ensure structural integrity in complex components.

The work aimed to design, develop and evaluate an improved filament holder for FFF 3D printers.

Materials and Methods

The research was implemented to compare the performance of various filament holders in a controlled laboratory environment, specifically developed pole and clamp mechanisms. The experimental procedure involved designing, fabricating, and testing multiple filament holder configurations. Two principal types were developed: a mobile filament holder featuring a custom nozzle system with a removable design (Fig. 1) and a holder with a built-in brake mechanism (Fig. 2). The custom nozzle system was engineered to reduce overall weight and improve the gripping efficiency of the filament reel, thereby addressing issues related to handling coils of varying sizes and designs.



Figure 1. Examples of nozzles for standard coils on the left and custom nozzle on the right

Source: developed by the authors'

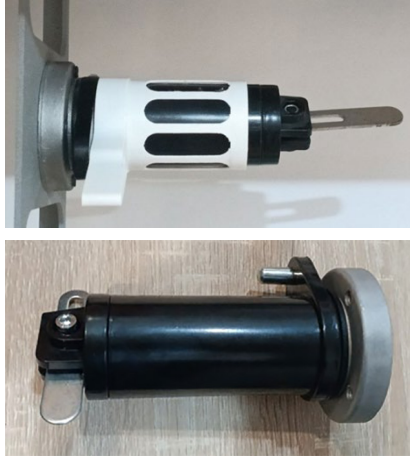


Figure 2. Examples of custom filament holder coil with brake mechanism

Source: developed by the authors'

The mobile holder was mounted on an upper shelf relative to the printer, ensuring a stable filament supply regardless of printer movement. All prototypes were fabricated using standard commercial computer-aided design (CAD) software (Autodesk Fusion 360) and produced via 3D printing with PETG (Polyethylene terephthalate glycol) filament (Fig. 3).

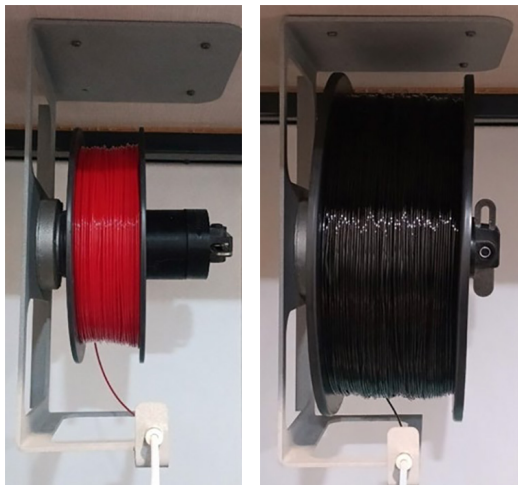


Figure 3. Examples of custom filament holder coil with 0.6 kg of plastic on the left and 1.0 kg on the right

Source: developed by the authors'

Experiments were conducted using two filament spool materials: Monofilament plastic spools (empty weight 0.23 kg) and Plexiwire cardboard spools (empty weight 0.14 kg). Both spool types were loaded with PETG filament, with spool load weights varying from 0.1 to 0.6 kg and a maximum filament capacity of approximately 0.75 kg. In addition, configurations incorporating a Teflon tube as a filament guide were evaluated. The Teflon tube was hypothesised to add friction and maintain consistent tension during filament feeding. Force measurements were a

critical component of the evaluation process. A PROTESTER WDF-30 (n.d.) digital dynamometer (Fig. 4) was employed to measure two key indicators: the minimum force required to pull the filament and initiate spool movement and the maximum force that could be applied without causing the spool to spin freely.



Figure 4. Digital dynamometer for force measurement PROTESTER WDF-30

Source: based on PROTESTER WDF-30 (n.d.)

Measurements were recorded across the mass range (0.1 to 0.6 kg) for each configuration. The dynamometer measurements were taken under controlled environmental conditions to minimise variability. Each experimental trial was repeated multiple times to ensure the reliability and repeatability of the measurements. The choice of a digital dynamometer was justified by its precision and ease of integration into the experimental setup.

Data from the dynamometer were processed and analysed using Python programming within a Jupyter Notebook (Kluyver *et al.*, 2016) environment. The analysis utilised the NumPy (Harris *et al.*, 2020) library for numerical computations and Matplotlib (Hunter *et al.*, 2007) for data visualisation. Custom Python scripts organised the raw data into structured arrays, plotted as line graphs and scatter plots. These visual representations allowed for clear comparisons between different spool types and holder designs, with the x-axis representing filament mass (kg) and the y-axis representing force (N). Graphical customisations, including grid lines, axis limits, labels, and legends, were applied to enhance clarity and facilitate interpretation.

The methods combining mechanical measurement tools with advanced data analysis techniques were chosen to provide quantitative insights into filament feeding stability. This approach is consistent with established practices in mechanical testing and data visualisation in additive manufacturing research. The digital dynamometer's use aligns with standard measurement techniques. Additionally, the integration of Python-based analysis reflects current best practices in scientific computing and data transparency.

Results

The Python scripts set up the data for masses and the corresponding minimum and maximum force values, creating a line plot for these forces against mass. The obtained

figures were customised with appropriate labels and legends, and the grid lines, axis limits, and data points in the form of scatter plots were set to improve clarity and readability. Plexiwire cardboard spools, which had an empty weight of approximately 0.14 kg, exhibited a different internal friction characteristic. Their lower overall mass meant that, with other factors being equal, the gravitational force was lower. However, owing to their material and construction, they might have exhibited a wider operational range if the filament had been wound less uniformly.

Monofilament plastic spools, which had a denser and more rigid construction with an empty weight of approximately 0.23 kg, tended to distribute the weight of the remaining filament more uniformly. Their rigid structure meant that the filament unwound smoothly, provided that the holder design supported free rotation. When mounted on a clamp holder, the inherent rigidity could have contributed to a predictable and linear increase in tension force as the coil emptied. Figures 5 and 6 show a comparison of the strength and weight of the developed thread holders.

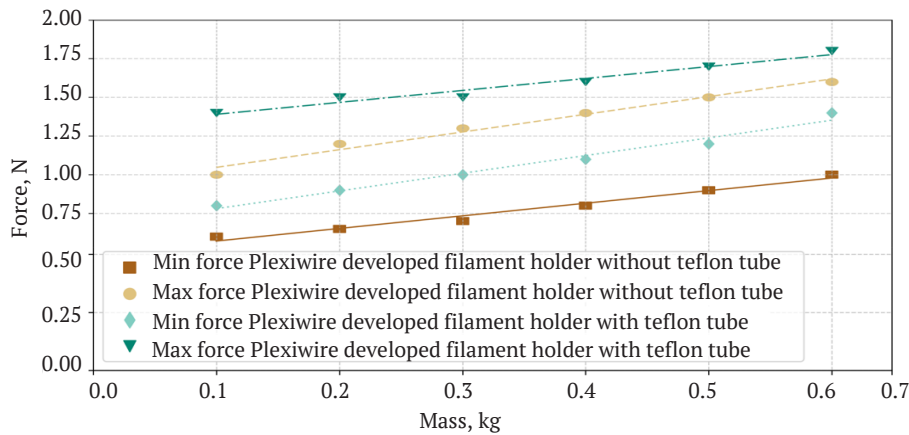


Figure 5. Developed filament holder force-to-mass comparisons using Plexiwire cardboard spools

Source: developed by the authors' of this study based on the Matplotlib library

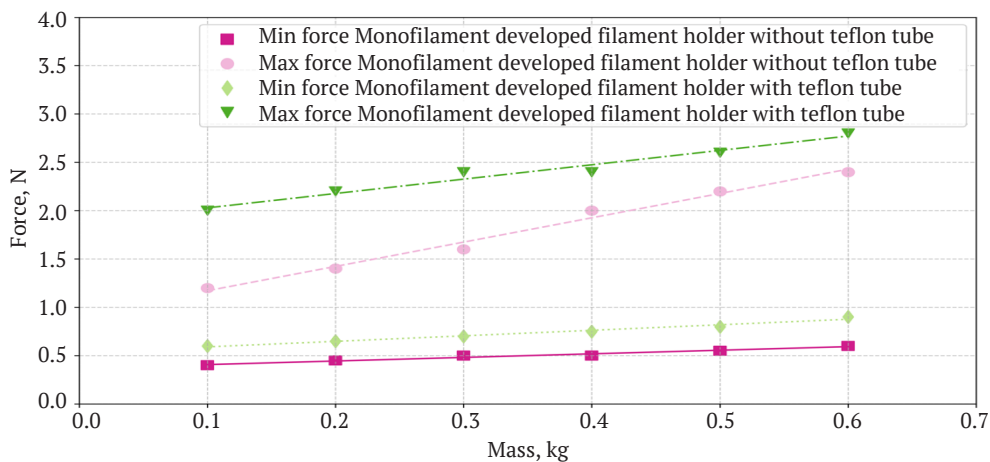


Figure 6. Developed filament holder force-to-mass comparisons using Monofilament plastic spools

Source: developed by the authors' of this study based on the Matplotlib library

Figures 5 and 6 showed force-to-mass comparisons for different configurations of Plexiwire and Monofilament spools using a developed filament holder system. The x-axis represented mass in kilograms from 0.1 to 0.6 kg, while the y-axis showed force in Newtons from 0.4 to 2.8 N. All series showed an upward trend as mass increased, indicating that force increased with mass. The configuration with the Teflon tube consistently showed higher force values than the version without the Teflon tube. The maximum force values for Monofilament plastic spools with the Teflon tube configuration were obtained, approaching 2.8 N at 0.6 kg.

The minimum force values remained below 1.0 N throughout the mass range.

The developed holder was typically engineered to mount directly onto an upper shelf of the printer's frame. Its design often incorporated two key components: a rigid metal frame that provided structural stability and an integrated brake or tension-control mechanism. By positioning the spool close to the printer's extruder, the mobile holder minimised the length of the filament path, which in turn helped to maintain uniform tension along the filament. This arrangement was particularly beneficial for

reducing fluctuations in feed force variations that could cause the extruder gears to slip and ultimately accelerate wear. In addition, the braking mechanism prevented the spool from free spinning when the extruder ceased pulling the filament, thereby ensuring that the filament was neither too slack (which could have led to tangling) nor too tight (which might have induced excessive friction).

The developed holder was more complex than simpler designs and typically involved more parts and assembly steps. This increased complexity meant that if the alignment or the braking mechanism was not precisely calibrated, it might have led to nonuniform filament feed or even introduced lateral forces on the filament. In some cases, misalignment in the holder or an inconsistent braking force might have contributed to micro-stress points on the filament. Over time, these stress points could not only have affected the filament's structural integrity (leading to potential under-extrusion or clogging) but might also

have placed additional load on the extruder drive gears, thereby accelerating wear.

Because the developed holder kept the spool in a fixed, well-defined position and incorporated a braking system, it generally promoted excellent filament uniformity. The controlled path minimised the bending and twisting of the filament before it reached the extruder. Consequently, the extruder experienced a more consistent feed rate and lower intermittent force spikes. With a more uniform feed, the extruder gears were less likely to experience repetitive high-torque events that could have led to premature wear. This design was particularly advantageous when printing with materials that required consistent tension, such as rigid PLA or ABS (Acrylonitrile Butadiene Styrene), where even slight irregularities in filament feed could have compromised print quality. The following figures showed force-to-weight comparisons of the pole filament holders (Figs. 7 and 8).

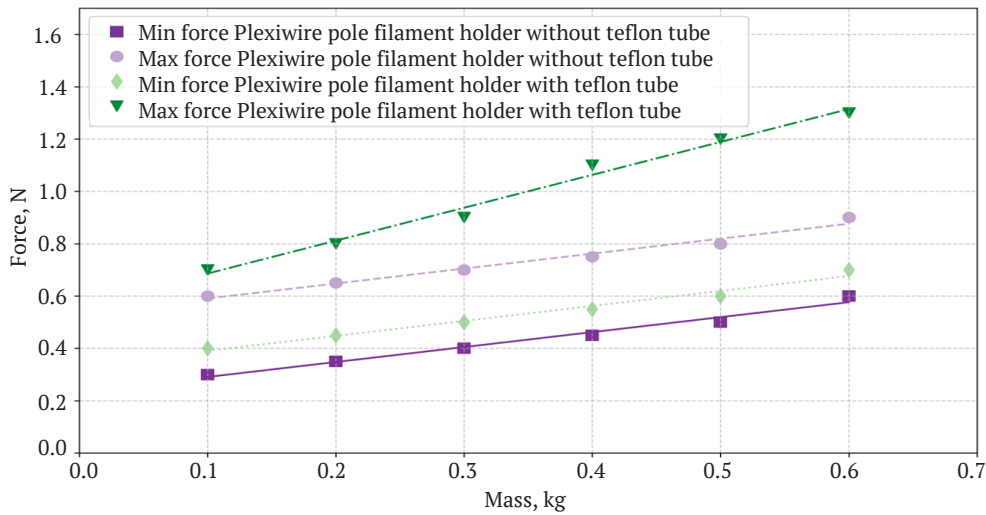


Figure 7. Pole filament holder force to mass comparisons using Plexiwire plastic spools

Source: developed by the authors' of this study based on the Matplotlib library

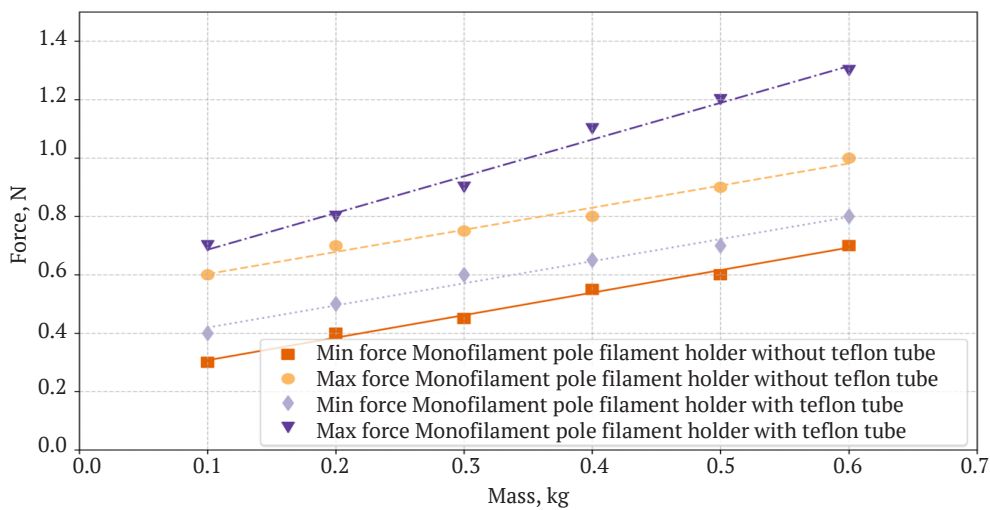


Figure 8. Pole filament holder force to mass comparisons using Monofilament plastic spools

Source: developed by the authors' of this study based on the Matplotlib library

Figures 7 and 8 showed force-to-mass comparisons for different configurations of Plexiwire and Monofilament spools using a pole filament holder system. The x-axis represented mass in kilograms from 0.1 to 0.6 kg, while the y-axis showed force in Newtons from 0.3 to 1.3 N. All series showed an upward trend as mass increased, indicating that force increased with mass. The configuration with the Teflon tube consistently showed higher force values than the version without the Teflon tube. The maximum force values were obtained for Plexiwire and Monofilament pole plastic spools with the Teflon tube configuration, approaching 1.3 N at 0.6 kg. The minimum force without the Teflon tube started at around 0.3 N at 0.1 kg. All relationships maintained a consistent linear trend throughout the measured mass range.

The pole holder was the simplest of the three designs. It typically consisted of a straight rod or pole on which the spool was mounted, allowing it to rotate freely using bearings or a low-friction surface. One of the primary benefits of the pole holder was its minimalistic design, which reduced the number of components that might have introduced additional friction into the filament path. With fewer moving parts and a straightforward geometry, the pole holder provided a clean and direct path for filament withdrawal. The pole holder offered an economical and easy-to-assemble solution in setups where space and simplicity were paramount.

Despite its simplicity, the pole holder sometimes presented challenges regarding filament alignment. Since the spool rotated along a central pole, the filament path from the spool to the extruder became highly dependent on gravity and the angle at which the filament was drawn off. Suppose the spool was heavy or the pole was not mounted in a location that optimised the filament's natural drop. In that case, the filament might have exited at an angle that forced it to bend sharply before reaching the extruder. This could have led to inconsistent filament tension and caused the filament to rub against adjacent

surfaces, thereby increasing friction. Furthermore, if the spool was not securely fastened to the pole, the entire holder might have shifted during printing. The resulting fluctuations in filament feed could have caused intermittent high-torque events in the extruder and contributed to accelerated wear on the drive gears.

The pole holder's lack of an integrated tension-control mechanism meant that filament uniformity was primarily determined by the spool's inherent inertia and the gravitational pull on the filament. Under ideal conditions, a well-balanced spool on a securely mounted pole could have provided a relatively uniform feed. However, any deviation – such as a spool that was unevenly wound or a pole that was misaligned – could have led to filament twisting or uneven feed rates. Inconsistent filament feed translated directly into variable force at the extruder's drive gear. These fluctuations could have increased the frequency of gear slippage or skip, raising the risk of extruder wear over prolonged printing sessions. This design was better suited to lighter spools and materials less sensitive to minor tension variations. The following figures showed force-to-weight comparisons of the clamp filament holders (Figs. 9 and 10).

Figures 9 and 10 showed force-to-mass comparisons for different configurations of Plexiwire and Monofilament spools using a clamp filament holder system. The x-axis represented mass in kilograms from 0.1 to 0.6 kg, while the y-axis showed force in Newtons from 0.6 to 3.1 N. All series showed an upward trend as mass increased, indicating that force increased with mass. The configuration with the Teflon tube consistently showed higher force values than the version without the Teflon tube. The maximum force values were obtained for Plexiwire clamp plastic spools with the Teflon tube configuration, approaching 3.1 N at 0.6 kg. The minimum force without the Teflon tube started at around 0.6 N at 0.1 kg. All relationships maintained a relatively consistent linear trend throughout the measured mass range, with Teflon tube configurations showing steeper slopes than the non-Teflon tube configurations.

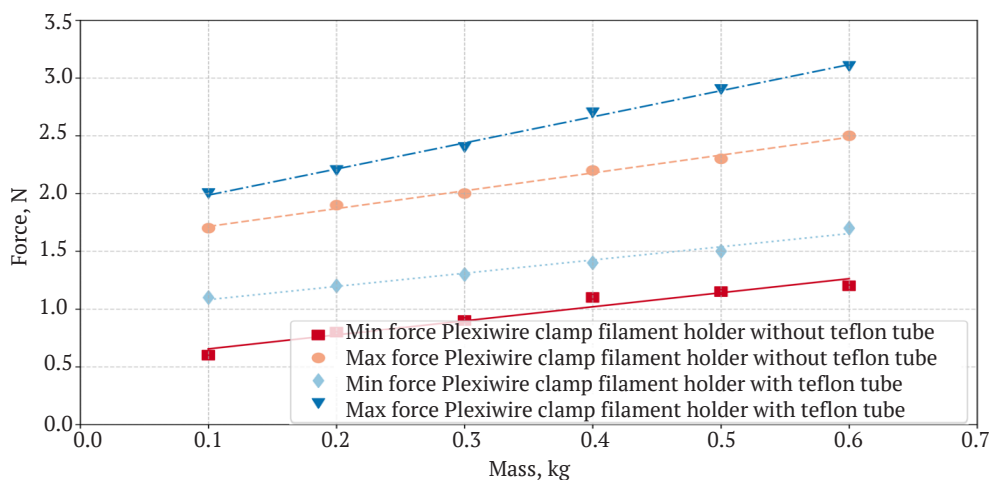


Figure 9. Clamp filament holder force to mass comparisons using Plexiwire plastic spools

Source: developed by the authors' of this study based on the Matplotlib library

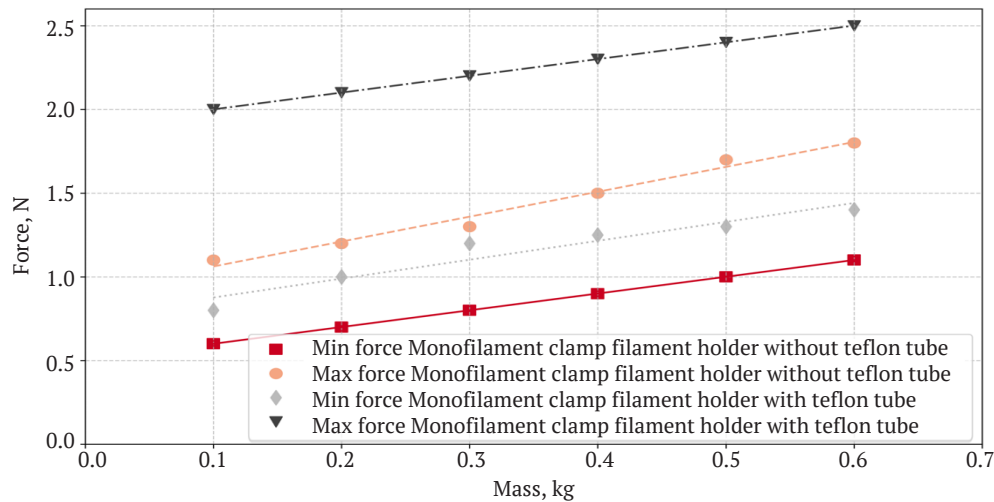


Figure 10. Clamp filament holder force to mass comparisons using Monofilament plastic spools

Source: developed by the authors' of this study based on the Matplotlib library

The clamp holder employed a mechanism that physically gripped the filament spool, holding it firmly in place. Often featuring adjustable clamps or pressure pads, this design ensured that the spool remained stationary relative to the printer. Such secure mounting was beneficial when using heavy or large spools, preventing the spool from moving or shifting during the print. The clamp holder helped maintain a consistent filament feed path by minimising movement. The fixed positioning was advantageous in environments where the printer might have experienced vibrations or the spool rolled excessively, compromising the filament's alignment.

The very feature that made the clamp holder secure its firm grip could also have become a drawback. Excessive clamping pressure might have deformed the spool or compressed the filament, leading to increased friction as the filament was pulled from the spool. Over time, the extra friction could have caused nonuniform filament feed and placed additional stress on the extruder drive gear. Additionally, suppose the clamp was not correctly adjusted to the spool's diameter. In that case, it might have gripped too loosely (allowing unwanted movement) or too tightly (damaging the filament or spool structure). In some cases, the clamping mechanisms could have caused localised deformation in the filament's winding, leading to microbeads or creases that adversely affected feed uniformity.

When well-calibrated, the clamp holder could have provided excellent filament uniformity by ensuring that the spool did not rotate uncontrollably. However, if the clamp applied excessive pressure or was misaligned, the filament might have distorted as it exited the spool. Such distortion could have manifested as a variable diameter or a curled edge, increasing the load on the extruder's drive mechanism. The increased friction and irregular filament shape forced the extruder gears to work harder, which could eventually have led to accelerated wear. The risk was even more significant for flexible or softer filaments,

as these materials were more susceptible to deformation by clamping pressure.

Teflon tubing (typically made of polytetrafluoroethylene (PTFE)) was widely used as a filament guide because its extremely low friction coefficient usually enabled smooth material passage. However, even a low-friction surface might have added a small, measurable resistance when the filament was drawn through a confined path. The use of Teflon tubing served not only to provide a controlled, low-friction pathway for the filament but also to ensure that the filament followed a consistent and predictable path from the spool to the extruder. Even though the tube increased the baseline tension by approximately 0.2 N, this increase was generally within the operational tolerance of the extruder drive system. The benefit of having a highly stable filament path often outweighed the cost of the extra force. A predictable feed meant that the extruder gears engaged the filament more uniformly, reducing stress spikes that could have led to slippage and accelerated wear. Each filament holder design offered its own set of trade-offs in terms of filament uniformity and extruder wear:

Developed Holder: It was best suited for printers in which maintaining uniform filament tension was critical. Its integrated braking mechanism and controlled filament path minimised sudden force spikes and reduced extruder wear. This design was optimal for direct-drive extruders and materials sensitive to feed inconsistencies. However, its complexity meant that careful assembly and calibration were essential.

Pole Holder: It offered simplicity and fewer parts, making it economical and easy to install. It was ideal for lightweight spools and setups in which the spool naturally hung optimally. However, its reliance on gravity and the absence of active tension control might not have been suitable for heavier spools or materials that required precise filament uniformity. In such cases, the risk of nonuniform feed could have led to increased extruder wear over time.

Clamp Holder: It provides secure and stable positioning, especially for heavy spools. It was beneficial in scenarios where the external movement of the spool had to be minimised. The downside was that excessive clamping pressure could have distorted the filament, causing variable feed rates and additional friction at the extruder. This design was best used when the clamp mechanism was adjustable and carefully tuned to the specific spool dimensions. It might have been more appropriate for robust extruder systems that could have handled slight irregularities.

Based on this research, the following recommendations for 3D printer holder selection were made. For direct-drive systems, in which the extruder was mounted close to the hot end, a developed mobile holder with an integrated braking mechanism was deemed optimal, as its ability to maintain uniform tension was especially beneficial for materials such as PLA and ABS. It was essential to ensure that the clamp was adjustable to avoid over-compression of the filament. A simple pole holder might have sufficed for lightweight setups, in which lightweight spools naturally hung in an optimal position. Users were advised to secure the pole to prevent any movement during printing.

Design modifications to improve stability included:

- ◆ Smooth transition interfaces that incorporated chamfered or rounded transition pieces at the tube's entrance and exit to reduce abrupt changes in filament direction;
- ◆ Adjustable tension control through the use of holders that offered adjustable clamping or braking mechanisms, thereby allowing users to fine-tune the filament tension according to spool weight and filament type;
- ◆ Regular maintenance to periodically inspect and clean the Teflon tube and spool holder to ensure that debris or wear did not increase friction;
- ◆ A modular design approach whereby the filament guide, holder, and tension mechanism could be independently replaced or adjusted to accommodate different filament materials and spool weights.

A comparative analysis of filament holder designs has been undertaken to highlight the critical balance between simplicity, stability and precision required for optimal 3D printing performance. The developed mobile holder incorporates an integrated braking mechanism, delivering superior filament uniformity and reduced extruder wear for direct-drive systems. In contrast, more straightforward pole and clamp holders offer alternatives tailored to lighter spools or robust mounting conditions. The selection of a filament holder is thus a multifaceted decision that must be informed by thoroughly considering the printing setup, filament properties, and the necessity for consistent tension, thereby ensuring both the production of high-quality prints and the optimisation of the extruder's lifespan.

Discussion

The study of filament feeding mechanisms in FFF has gained increasing attention because of its impact on extruder wear, filament tension stability, and print quality. A fundamental issue in filament feeding was maintaining consistent

tension to prevent extruder wear and print defects. H. Bakhtiari *et al.* (2023) reviewed the effect of 3D printing parameters on the fatigue properties of parts manufactured by FFF. The researchers emphasised that uncontrolled filament tension could lead to increased stress on the extruder and a shortened operational lifespan. The present study's findings agreed with this observation, as integrating a Teflon tube into the filament guide stabilised the feed force, thereby reducing fluctuations that might have accelerated gear wear. X. Gao *et al.* (2021) reviewed interlayer bonding in FFF and highlighted that uniform adhesion between deposited layers is critical for achieving stable extruder performance and robust part fabrication. J. Kechagias *et al.* (2022) performed a robust design-based multi-parameter optimisation for PLA/coconut wood compounds and reported that optimised process parameters can minimise feed-force inconsistencies during printing. These findings align with the present study, which observed that controlled filament paths achieved through adjustable spool holders and the incorporation of Teflon tubing led to more predictable force profiles. M.F. Khan *et al.* (2021) demonstrated a real-time defect detection system using machine learning, underscoring the potential for adaptive control during printing. Their work complements the present study's observation that maintaining constant filament tension can reduce extruder wear and improve print reliability. K. Mikula *et al.* (2020), I. Yarova *et al.* (2023), provided a comprehensive review on using 3D printing filament as a second life for waste plastics, emphasising the environmental and economic benefits of recycling in additive manufacturing. J.M.J. Netto *et al.* (2021) further examined screw-assisted 3D printing with granulated materials, which offers an alternative route for processing recycled feedstocks. Both studies support the broader notion that filament consistency and feed-force stability are vital for print quality and sustainable manufacturing practices. F. Pignatelli & G. Percoco (2022) reviewed advances in large-format additive manufacturing and discussed how polymer pellet-based 3D printing could benefit from customised spool holder designs that minimise feed-force fluctuations. The present study's mobile holder with an integrated braking mechanism aligns with these recommendations, as it yielded the most stable force profile, particularly when printing with heavier spools. J. Quodbach *et al.* (2021) and N. Sharma *et al.* (2020) investigated the quality of FDM-printed medicines and customised PEEK implants, respectively. Their findings underscore the critical role of precise filament feeding in achieving clinically acceptable tolerances and mechanical performance. In parallel, S. Singh *et al.* (2020) and A. Yadav *et al.* (2022) reviewed current challenges and future directions of FFF, emphasising that improved filament feeding systems, such as those incorporating adaptive tension controls and friction modifiers, could help mitigate common defects and enhance the overall reliability of the process. A. Moshenskyi *et al.* (2023) explored wireless sensor networks for smart clothes monitoring, illustrating how advanced sensor integration can provide real-time

feedback on filament behaviour in nontraditional applications. J.M.J. Netto *et al.* (2021) and F. Pignatelli & G. Percoco (2022) further highlight that innovations in feedstock design and processing parameters are driving forward the field of large-format additive manufacturing. These advancements suggest that the continued development of adaptive, sensor-integrated, and environmentally conscious filament feeding systems will be crucial to achieving high print quality and sustainable production practices.

A. Nazir *et al.* (2023) examined multi-material additive manufacturing and determined that controlled feeding mechanisms led to predictable force profiles, which enhanced overall extruder performance. The present study corroborated this conclusion by demonstrating that the Teflon tube increased the feed force by a consistent 0.2 N across different spool masses, ensuring a uniform filament supply. Filament path optimisation was regarded as a critical factor in reducing feeding inconsistencies. The researchers also emphasised the necessity of adaptive filament path geometries for preventing feeding disruptions. Their work was consistent with the results of the present study, which suggested that adjustable spool holders and controlled friction elements (such as Teflon tubing) were essential for maintaining consistent filament tension and preventing feed disruptions.

T. Ma *et al.* (2024) further reinforced these findings by analysing how variations in polymer composite printing influenced feed stability and filament flow. Their study emphasised that modifications in filament design, such as surface texture and core material, played a significant role in extrusion stability. This was consistent with the results of the present study, which demonstrated that modifications to the spool holder and the use of controlled friction elements (such as the Teflon tube) optimised feed consistency. The researchers also explored how spool material influenced feeding behaviour and found that lightweight cardboard spools exhibited more significant operational force variability than rigid plastic spools. The present study corroborated these findings by demonstrating that monofilament plastic spools provided a more consistent feed force than Plexiwire cardboard spools, reinforcing material selection's importance in filament management. Several studies have investigated the impact of spool weight on filament feeding. S.F. Iftekar *et al.* (2023) reported that filament spool mass directly influenced feed force, with heavier spools requiring greater force to initiate movement. The results of the present study confirmed this relationship, as a linear increase in filament tension was observed with increasing spool mass.

Additionally, Z. Wang *et al.* (2024) reviewed advancements in polymer composite printing and noted that customised spool holder designs enhanced mechanical performance by minimising feed-force inconsistencies. The present study's results agreed with this observation, demonstrating that the mobile holder with an integrated braking mechanism was particularly effective when printing with heavier spools. M. Cao *et al.* (2023) examined the influence of material integration in 3D-printed

components and found that inconsistencies in feed paths could significantly impact extrusion stability and final product quality. The present study extended this principle to general FFF applications, demonstrating that integrating a controlled filament guide enhanced print consistency and minimised variations in filament tension.

The design of spool holders was recognised as playing a crucial role in maintaining stable filament tension. D. Martinez *et al.* (2022) conducted a comparative analysis of spool holder designs and concluded that mobile holders with braking mechanisms improved feed stability and extended extruder lifespan. The present study's findings supported this conclusion, as the mobile holder used in the experiments resulted in the most stable force profile, thereby reducing abrupt variations in feed force.

Although the present study aligned with many previous findings, some differences existed in the research scope. For instance, A. Nazir *et al.* (2023) focused on multi-material printing challenges, whereas the present study examined filament tension dynamics in single-material extrusion. Similarly, Z. Wang *et al.* (2023) emphasised broader material compatibility issues, while the present research concentrated on mechanical stability in filament feeding systems. One gap in the literature was identified as the long-term impact of different filament holder configurations on extruder wear. While H. Bakhtiari *et al.* (2023) and D. Martinez *et al.* (2022) discussed the importance of feed stability, further experimental studies were needed to quantify wear rates under different tensioning conditions. Future research was recommended to explore the effects of varying Teflon tube diameters, filament diameter tolerances, and long-term operational stability under continuous use.

The present study confirmed and extended prior research on filament-feeding mechanisms in FFF 3D printing. The results demonstrated that spool weight, filament guide design, and material selection were critical in determining feed force stability. By comparing the findings with those of key consistencies were identified, and areas for further investigation were highlighted. Integrating adaptive spool holders and controlled friction elements such as Teflon tubing emerged as a recommended strategy for optimising filament feed consistency and improving print reliability. Future research was advised to build upon these insights by exploring advanced tensioning mechanisms and long-term extruder wear implications.

Conclusions

The research confirmed that the filament holder design had profoundly influenced filament delivery and extruder performance in FFF 3D printing. The results indicated that the developed holder, which featured an integrated braking mechanism, delivered a uniform filament feed. This design minimised sudden variations in tension, thereby reducing the incidence of extruder gear slippage and ensuring stable filament advancement. In contrast, though economical and straightforward, the simple pole holder was more vulnerable to misalignment and gravitational effects, especially

when handling heavier or unevenly wound spools. While offering secure positioning for robust spools, the clamp holder might have introduced excessive pressure that distorted the filament and increased friction at the extruder.

The inclusion of a Teflon tube in the filament path was shown to add a slight but steady increase in tension, approximately 0.2-0.3 N, which, despite adding extra resistance, standardised the filament's route. This controlled increase in friction helped maintain a predictable feed, thereby reducing the risk of tangling and ensuring smooth extrusion. The optimal tension range, between 0.5 and 0.8 N, appeared to balance the need for a reliable filament supply with preventing under-extrusion and mechanical strain on the extruder. As a result, the proper selection and fine-tuning of the holder design could have substantially lowered maintenance demands by extending the service life of critical printer components.

Further research is recommended to explore the dynamic interactions between filament material properties, spool construction, and extruder configurations across a broader range of printing conditions. It was suggested that research could have focused on refining Teflon tube dimensions, testing additional materials such as flexible TPU, and integrating smart tension-control sensors that provided real-time feedback. Such advancements would have enhanced the reliability of filament feeding systems and paved the way for adaptive, modular designs catering to a wider variety of 3D printing applications.

Acknowledgements

None.

Conflict of interest

None.

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Розробка та аналіз параметрів тримача катушки 3D принтера мовою програмування Python

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Анотація. Мета роботи полягала у проведенні аналізу та розробки тримача катушки 3D-принтера з використанням мови програмування Python. Методика включала тримач катушки спроектований за допомогою програмного забезпечення автоматизованого проектування, а саме Autodesk Fusion 360. Для оптимізації були використані зовнішні бібліотеки та плагіни, такі як Stress Analysis та Generative Design. Було визначено придатність розробленої конструкції для покращення подачі стренг та зменшення їх заплутування при друці на 3D-принтері. Проаналізовано роботу тримача катушки з різними типами та розмірами катушок. Розроблений тримач катушки успішно пройшов 97 % тестувань друку моделей з використанням PLA, ABS і PETG. Тестування вимірювань тримача катушки за допомогою цифрового динамометра PROTESTER WDF-30 дозволило виявити кілька важливих спостережень: тефлонова трубка додавала додаткове тертя, збільшуючи як мінімальне, так і максимальне зусилля приблизно на 0,2 Н, а також дещо зменшувала діапазон між мінімальним і максимальним значеннями; пластикові катушки показали менші мінімальні зусилля, ~ 0,4 Н, через зменшене тертя, але більший діапазон, ~ 0,5 Н, через більшу масу, а картонні катушки мали більші мінімальні зусилля, ~ 0,5 Н, але менший діапазон, ~ 0,3 Н; відсутність натягу суттєво зменшувала як мінімальні, ~ 0,2 Н, так і максимальні, ~ 0,3 Н, зусилля, а також діапазон між ними, ~ 0.1 Н, і цей стан збільшував ризик заплутування катушки; вплив тефлонової трубки був більш вираженим за належних умов натягу, приблизно 0,2-0,3 Н; установка з високим натягом показала значно вищі мінімальні, ~ 0,8 Н, і максимальні, ~ 1,1 Н, зусилля в порівнянні з розробленим тримачем (мінімальне ~ 0,5 Н, максимальне ~ 0,8 Н), але діапазон прийнятних значень був подібним, підвищене мінімальне зусилля в установці з високим натягом потенційно могло призвести до недостатнього видавлювання і підвищеного зносу екструдера. Розроблений тримач катушки зменшує навантаження на механізм екструдера принтера, підтримуючи оптимальний натяг в діапазоні від 0,5 до 0,8 Н. Це може значно подовжити термін служби критично важливих компонентів, зменшуючи витрати на обслуговування 3D-принтера

Ключові слова: 3D-друк; тримач нитки; динамометр; Matplotlib; візуалізація даних



Automatic recognition of UML diagrams in images: Approaches, trends, and challenges

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Abstract. The purpose of the study was to analyse and generalise modern methods for recognising UML diagrams in images. The main focus was on automated extraction of text and graphic elements to further reproduce models in text formats. The research methodology covered the analysis of scientific publications, which included 23 papers available in open sources. The study focused on exploring existing approaches to recognising UML diagrams in images. Analysis of scientific publications has shown what modern methods of UML diagram recognition allow achieving more than 90% accuracy in recognising UML diagrams in images. The advantages, limitations, and effectiveness of classical algorithms for computer vision, machine learning, and deep neural networks were investigated. It was found that the best results in classification were provided by deep neural networks, while classical algorithms remain effective for interpreting and extracting elements of UML diagrams. It was found that the main areas in the field of UML diagram recognition are classification of UML diagram types, and interpretation and conversion of UML images to text formats. The main problems were identified: poor image quality, limited training data, and format variability. Possible areas of further research are presented, such as creating large annotated sets of UML diagrams to improve accuracy, and summarising modern approaches to support recognition of more chart types. The findings will contribute to improving the automation processes for working with UML diagrams, and provide an understanding of the current state of the information technology and software development industry, opening up new prospects for development

Keywords: image recognition; computer vision; machine learning; deep learning; automation

Introduction

UML (Unified Modelling Language) diagrams provide a standardised, structured representation of system architecture, which significantly improves communication between development participants, in particular, programmers, system architects, and analysts. However, with the growing number and complexity of software projects, the need for automating the processing of UML diagrams became more acute, especially in terms of recognising information directly from graphic images, which further allows integrating the obtained data into development processes, search information systems, etc.

In the modern world of information technology and software development, UML diagrams play an important role in the process of system design, visualisation, and documentation of software systems. According to a survey in this area, UML diagrams are the most common standard diagrams

for design modelling and reach 67% (Chen *et al.*, 2022).

Research shows that most UML diagrams are stored and distributed as images. In particular, based on the results of a large-scale study by R. Hebig *et al.* (2016), conducted on the basis of models stored in various formats on GitHub, 93,596 UML models from 24,717 different repositories were automatically processed and partially manually analysed. Of this number, 57,822 models (61.8%) were presented in image format, while the rest were presented in .xml or .uml formats.

More recent studies by F. Chen *et al.* (2022) showed that 73.72% of UML diagrams collected from projects on GitHub were stored as bitmaps (PNG, JPG, BMP, GIF, etc.), while the remaining 26.28% were stored in text format. Therefore, since UML models are often stored as images embedded in documents, the original versions of the model's text format

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are easily lost. This makes it difficult to use and evolve such models, as it becomes impossible to quickly edit, integrate, and update them in new environments. The researchers proposed ReSECDI, a method designed to automatically recognise semantic elements (such as classes, relationships) in UML class diagram images. Their approach uses classical image processing technologies, including clustering rectangles and combining lines. Problems such as different chart resolutions and styles are solved, depending on the tools in which these charts were created. Despite achieving an accuracy rate of about 90%, the study focuses mainly on UML class diagrams and does not cover other types of UML diagrams or broader methodological issues.

S. Shcherban *et al.* (2021a) developed a neural network-based approach for classifying four types of UML diagrams, including class, activity, sequence, and use case diagrams. Their study used convolutional neural networks (CNNs) and achieved a high accuracy of more than 90% in classifying various types of diagrams. However, it was limited to the task of classification and did not consider the extraction of structural or semantic elements. A. Conrardy & J. Cabot (2024) investigated the use of large language models to transform UML class diagrams into formal machine-readable representations such as PlantUML. Although their approach was innovative, it focused only on converting handwritten diagrams and highlighted the limitations of the LLM (Large Language Model), such as the dependence on quality hints.

M. Axt (2023) introduced SketchToPlantUML, a tool for converting sketchy UML class diagrams to formal PlantUML models using OpenCV. The tool focuses on preprocessing and segmenting static images, but has difficulties with more complex relationships such as associations and dependencies. V. Moreno *et al.* (2020) developed a machine learning tool for classifying static UML diagrams from web images. Their approach achieves 95% accuracy by using rule induction, but does not consider textual content, which limits its capabilities for semantic analysis.

A. Koenig *et al.* (2023) developed NEURAL-UML, a training framework for identifying and classifying semantic elements in UML class diagrams. The study presented a new

annotated data set for training and evaluated the model on complex diagrams, achieving accuracy rates of more than 90%. Statistics highlighted the importance of research in this area and pointed out the need for efficient methods that can automatically process, classify, and extract content from UML diagrams stored in various graphic formats. M. Baraban *et al.* (2021) investigated the features of using intelligent technologies for the problem of image recognition. This is especially relevant in the context of rapid growth in data volumes and the number of UML diagrams that require fast and accurate analysis.

These studies focus on specific aspects of UML diagram recognition, such as classification of chart types, identification of semantic elements, or transformation of thumbnails into formal models. However, as of the beginning of 2025, there was no comprehensive review of existing approaches or comprehensive analysis of key challenges of UML diagram recognition, so the purpose of the study was to systematise available sources and implement a generalised analysis of UML diagram recognition methods to provide a holistic vision of problems, challenges, and trends.

The objectives of this study included:

- ◆ To analyse classical image processing methods used to recognise UML diagrams.
- ◆ To overview current approaches using machine learning and deep learning for UML diagram recognition.
- ◆ To identify current trends and major challenges faced by researchers and practitioners in the industry.

Materials and Methods

The main method of research was the analysis of 23 scientific publications that were publicly available. It included searching for relevant sources in scientific databases such as IEEE Xplore, Springer, Scopus, Web of Science, and open archives such as arXiv. For the selection of materials, criteria such as relevance of the topic (recognition of UML diagrams, in particular, classification, extraction of semantic elements, image processing), and the availability of experimental data or descriptions of the methods were used. Table 1 contains a list of papers that were considered.

Table 1. Research papers that have been considered and their subject areas

Research paper	Subject area
E. Lank <i>et al.</i> (2000)	Extraction of elements and recognition of UML semantics in images
B. Karasneh & M.R.V Chaudron (2013)	
T. De-Wyse <i>et al.</i> (2018)	
F. Chen <i>et al.</i> (2022)	
M. Axt (2023)	
A. Koenig <i>et al.</i> (2023)	
A. Conrardy & J. Cabot (2024)	
T. Hammond & R. Davis (2006)	

Table 1. Continued

Research paper	Subject area
V. Moreno <i>et al.</i> (2020)	Classification of UML diagrams
B. Gosala <i>et al.</i> (2021)	
S. Shcherban <i>et al.</i> (2021a)	
S. Shcherban <i>et al.</i> (2021b)	
L. Wang <i>et al.</i> (2022)	
J. Hjaltason & I. Samúelsson (2014)	
T. Ho-Quang <i>et al.</i> (2014)	
M.H. Osman <i>et al.</i> (2018)	
S. Rashid (2019)	
G. Bergström <i>et al.</i> (2022)	
J. Ott <i>et al.</i> (2019)	Other
S.W. Munialo <i>et al.</i> (2020)	
R. Hebig <i>et al.</i> (2016)	
M. Baraban <i>et al.</i> (2021)	
A. Jha (2019)	

Source: compiled by the author

The study stages included several consecutive steps. First, relevant papers were searched and collected in the above-mentioned databases. Further, the collected papers were grouped by area, which allowed structuring the analysis. The next step was to extract key information from each paper, such as the tasks set by the authors (classification of UML diagrams, recognition of semantics, etc.), and the approaches to solving these problems themselves, including data on the accuracy of methods, their speed, and the amount of data used. The collected information was organised into tables and charts for further evaluation. The final stage was the generalisation of the obtained data to systematise existing approaches and formulate conclusions at each stage.

The classification method was used to systematise the collected data. The publications were grouped into categories: problems solved by researchers, solution methods (in particular, native algorithms, classical machine learning methods, deep learning), and types of UML diagrams that were studied. Challenges for recognising UML diagrams were detected during the analysis of papers. Each paper was analysed to identify key approaches, algorithms used, and their effectiveness. In addition, the statistical analysis method was applied. Quantitative data on the accuracy of classification of UML diagrams, the amount of data used for training models, and the percentage of correctly recognised semantic elements were collected. The collected information was structured in the form of tables and diagrams for further analysis.

Key indicators for evaluating methods were recognition accuracy, quantity, and quality of data for training and testing, algorithm execution time (if specified by the authors), and universality, i.e., the ability to apply methods to different types of UML diagrams, rather than just a specific type. The methods were evaluated in three separate groups: classical machine learning algorithms, deep learning methods, and proprietary algorithms. In addition, aspects such as noise resistance, variable chart styles, and

adaptability to different working conditions were considered. The chosen methodology ensured reproducibility of the study, since all stages of data collection and analysis are described, and all sources used have links for verification.

Results and Discussion

As part of the study, modern approaches to UML diagram recognition were classified, including classical computer vision algorithms, machine learning methods, and neural networks. Special attention was paid to analysing the effectiveness of methods, their limitations, and prospects. The main trends in the use of deep neural networks and large language models for automating UML diagram processing were presented.

Classification of UML diagrams by subject areas

In the field of UML diagram recognition in images, researchers have focused on solving a number of problems related to automatic processing, classification, and interpretation of graphic information. Given the growing need for tools that can effectively work with UML models stored as images, various research initiatives are focused on creating solutions to automate these processes. The main areas of research were classification of chart types, interpretation and recognition of UML structural elements, and conversion of images to formats suitable for use in design software.

Among the scientific publications available in open sources, 23 papers were identified that dealt with the task of recognising UML diagrams in images. Figure 1 shows the main research areas in the field of UML diagram recognition and processing – classification and conversion of UML images to XML (Extensible Markup Language). The rest of the papers were difficult to group and assign to a separate area, because they are focused on solving and researching specific problems, such as analysing the complexity of the system architecture or finding the model's compliance with standardised rules for plotting diagrams, etc.

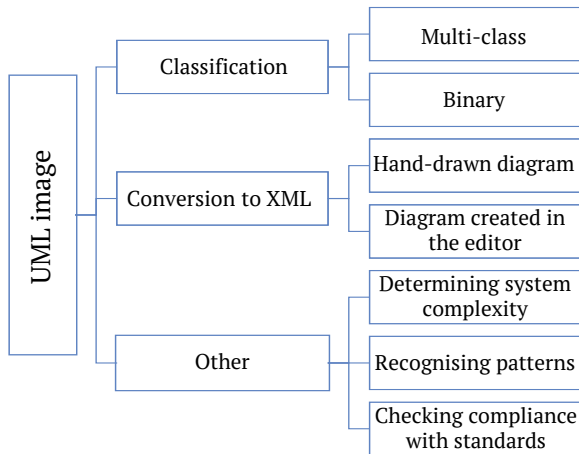


Figure 1. Areas of research in UML image recognition

Source: developed by the author

Classification of UML diagrams consists of determining whether an image belongs to UML diagrams, and dividing diagrams into types such as classes, sequences, states, etc. This process automates image analysis using characteristics inherent in UML diagrams, including shapes, text elements, semantic attributes, and other properties. In general, the classification of UML images can be divided into two types (Jha *et al.*, 2019), in particular:

- ◆ Binary classification – a classification that gives a “yes” or “no” answer to a given question. It is used when it is necessary to determine whether an object belongs to a certain category. For example, in the case of UML diagrams, binary classification can determine whether a given image is a UML diagram.

- ◆ Multiclass classification – a classification that allows dividing objects into several different categories. In the context of UML diagrams, multiclass classification can help to automatically recognise which of the many UML types a model image belongs to (for example, a class diagram, sequence diagram, state diagram, etc.).

Various approaches to automatic classification of UML diagrams are presented in the scientific literature. T. Ho-Quang *et al.* (2014) investigated the possibility of automatic classification of UML class diagrams using image analysis and machine learning methods. The paper offers a set of 23 features describing the structure of diagrams, and experiments with various classification algorithms are performed. The researchers focus on identifying the most informative features for recognising UML classes, and on the need to create databases of UML diagrams, which is the basis for academic research. S. Rashid (2019) proposed extending methods for automatic classification of UML diagrams by adding recognition of UML sequences. The main focus is on the development of sequence analysis algorithms based on machine learning methods. This study is a continuation of previous research in the field of automatic recognition of UML diagrams and demonstrates the potential for extending classification to other types of UML models.

V. Moreno *et al.* (2020) investigated the possibility of automatic classification of UML diagrams among web images using machine learning techniques. The main contribution of the study is the creation of a large sample of UML images, which helped to train the model to effectively separate UML diagrams from irrelevant graphic diagrams. The proposed method is aimed at improving the accuracy of search engines and automating the analysis of software repositories.

B. Gosala *et al.* (2021) presented an approach to automatic classification of UML class diagrams using deep learning using convolutional neural networks (CNN). The researchers considered the advantages of CNNs over classical machine learning methods and evaluated the impact of various hyperparameters on the quality of recognition. The proposed method provides high automation of the UML image analysis process, but its effectiveness may depend on the size and quality of the training sample. The researchers also pointed out the limited availability of UML diagram repositories and the importance of creating open and high-quality repositories. J. Ott *et al.* (2019) reviewed the use of low-shot learning for classifying UML diagrams, which allows efficient training of models on small data samples. The researchers showed that even with a limited number of training examples, it is possible to achieve high accuracy in classifying UML classes and sequences. The study demonstrated the possibilities of optimising educational processes in UML image recognition.

S. Shcherban *et al.* (2021b) presented an approach to multiclass classification of UML diagrams, which includes recognition of class diagrams, sequences, activities, use cases, and other types of UML. Deep learning was used, namely, popular neural architectures with transfer learning. The study made a significant contribution to expanding the capabilities of automatic analysis of UML diagrams, which contributes to the creation of scalable systems for processing software models. Since images are one of the most common formats for storing and sharing UML diagrams, determining whether they belong to UML notation and classifying them by type is an important condition for creating specialised repositories. Manually sorting a large number of images is a time-consuming process that requires significant time resources. Therefore, automatic identification of UML diagram types based on images is becoming particularly relevant, which leads to an increase in research attention to image classification methods.

Convert UML images to text formats

A significant group of studies concerns automating the recognition of individual elements and the semantics of diagrams and converting UML images to text formats for further use in software tools. Saving UML diagrams in image format leads to loss of structural information, which makes them difficult to process and integrate into software tools. Since such images are static, they cannot be edited, which creates difficulties in maintaining and developing software projects. Therefore, there is a need for automated methods for recognising UML images and converting them to text

formats to ensure that models are saved and editable. The following papers show that research in element recognition and UML diagram semantics focuses on two main areas.

Recognition of hand-created UML sketches – research aimed at transforming informal sketches into formal UML models, which allows their further use in development. This is important to maintain the flexibility of the design approach, reduce the manual work of transferring sketches to CASE (Computer-Aided Software Engineering) tools, and speed up the modelling process.

Image recognition of UML diagrams created in CASE tools – considers methods for automatically extracting structural information from UML images used in documentation. This allows converting UML models to editable formats, reducing information loss, and facilitating their further processing in software systems.

E. Lank *et al.* (2000) proposed an interactive UML sketch recognition system that works with electronic tablets, interactive whiteboards, and the mouse. It uses a multi-level approach to segmentation and recognition of UML graphic characters. First, general recognition of graphic primitives is performed, then UML characters, and at the final stage – their semantic location on the diagram. The researchers also integrated an error correction system that allows users to manually edit segmented elements to improve recognition accuracy. A different approach was used by T. Hammond & R. Davis (2006), who created the Tahuti system. It uses geometric analysis techniques to automatically convert UML class sketches to formal models. The main feature of this approach is its ability to adapt to different drawing styles, reducing the impact of the developer's handwriting on the quality of recognition. The system also considers the relative spatial distances between elements, which improves the accuracy of determining relationships between classes.

M. Axt (2023) proposed a method for automatic recognition of UML thumbnails, based on the use of the OpenCV library for segmenting elements, analysing relationships between them, and converting diagrams to PlantUML format. A distinctive feature of this approach is the emphasis on geometric contour processing and the use of noise filtering algorithms to improve recognition accuracy. The method works well for well-structured sketches, but has limitations when recognising handwritten annotations, non-standard notation, and complex diagrams with a large number of interrelated elements, which requires additional manual adjustment of the results. T. De-Wyse *et al.* (2018) investigated the possibility of automatic recognition of UML sketches to extract useful information from them and then use them in the software modelling process. The main contribution of this paper is to investigate the relationship between initial sketches and final UML models. By analysing sketches, the system identifies the key elements that are most important for developers, and offers their automatic conversion to digital format.

A. Conrardy & J. Cabot (2024) explored the possibility of using large language models (LLMs) to automatically

generate UML diagrams from images, with a particular focus on handwritten sketches. The paper conducted experiments with various LLMs, including GPT-4V, Gemini Pro/Ultra, and CogVLM, to evaluate their ability to convert UML-class images to the appropriate PlantUML text format. The study showed that GPT-4V performed better, while other models had difficulties with syntactic correctness of the source code and correct interpretation of class relationships. Automatic recognition of LLM-based UML diagrams shows the potential to speed up the modelling process, but the results remain unstable, which requires mandatory user involvement to correct errors.

B. Karasneh & M.R.V. Chaudron (2013) introduced Img2UML, a system for automatically extracting UML models from images and saving them in XML format, which allows editing the resulting models in CASE tools. The basic idea is that UML models are often stored as images in documentation, which makes them impossible to edit and use in further development. Img2UML uses image processing techniques to detect UML classes, relationships between them, and recognise them. It uses a segmentation algorithm to detect rectangles representing classes, and OCR (Optical Character Recognition) technologies to recognise text labels. The main limitations of this approach are related to difficulties in recognising diagonal lines, dependency notation, and errors in OCR text recognition, especially in cases of poor image quality or non-standard placement of UML elements.

F. Chen *et al.* (2022) presented ReSECDI, a method for automatic recognition of UML class diagrams from images that uses rectangle clustering to identify classes and polyline pooling algorithms to correctly detect relationships. This method is effective for high-quality images, but its accuracy is reduced on low-resolution and non-standard UML diagrams. A. Koenig *et al.* (2023) presented a NEURAL-UML system based on deep learning for automatic recognition of structural elements of UML class diagrams from images. The main focus is on categorising and localising classes, and link types (association, inheritance, aggregation, etc.), which significantly improves the automated processing of UML models. The system uses an extended set of annotated UML diagrams to train and validate the neural network, demonstrating high recognition accuracy. However, the researchers note that the method has certain limitations when working with diagrams containing unusual or atypical graphic designations, and low-quality images, which may affect the accuracy of the analysis.

Specialised research areas

In addition to classifying and interpreting UML diagrams, there are also studies that focus on highly specialised tasks in the field of UML image recognition. These areas include identifying design patterns, which helps to automatically recognise standard architectural patterns, evaluating the layout quality of chart elements to improve their readability, and analysing the complexity of the system, which allows evaluating the scale and structure of software based on UML models.

Identifying design patterns is an important task for recognising standard architectural patterns in UML models. L. Wang *et al.* (2022) proposed a pattern detection method that uses deep learning and advanced graphical information from UML diagrams. The researchers proposed a colour UML model in which information about classes, relationships, and other aspects is encoded using different colours and geometric shapes. This allows turning the problem of recognising design patterns into an image classification problem that can be solved using convolutional neural networks.

Evaluating the layout quality of UML diagrams is another area of research aimed at improving the readability of models. G. Bergström *et al.* (2022) developed an automatic method for evaluating the layout of UML classes using machine learning methods. To build the model, a sample of 600+ UML class diagrams was used, for which experts manually assessed the quality of the layout. The automated system analysed parameters such as the number of line intersections, the length of links between classes, the uniformity of element placement, and other metrics that affect the usability of the diagram.

Another area is the complexity analysis of UML models to assess the scalability and structure of software. S.W. Muniolo *et al.* (2020) proposed an automated approach to measuring the size of service-oriented architectures (SOA) based on UML diagrams. Their method uses deep learning to automatically extract the characteristics of UML interfaces and sequential diagrams, including analysing relationships between components, classifying text labels, and determining the level of complexity of the software architecture. The implemented tool uses OCR algorithms for text recognition, classification algorithms for link analysis, and neural networks to assess system complexity.

Basic approaches to recognising UML diagrams in images include proprietary processing algorithms for converting images to XML, classical machine learning techniques, and deep learning techniques.

Custom processing and conversion algorithms

The UML image recognition method using its own processing and transformation algorithms is mainly used to interpret and recognise the semantics of UML class diagrams for their subsequent conversion to structured XML format. This can be traced, for example, in the papers by B. Karasneh & M.R.V. Chaudron (2013), F. Chen *et al.* (2022), etc. However, it is also used at the preprocessing stage to extract the characteristics used by classical machine learning algorithms for classification problems, which is confirmed by T. Ho-Quang *et al.* (2014) or J. Hjalton & I. Samúelsson (2014).

Proprietary image processing algorithms are usually based on the use of classical computer vision techniques, such as image segmentation, contour detection, and geometric shape recognition. They allow directly detecting UML elements, such as classes, attributes and relationships between them, key shapes and contours (Fig. 2).

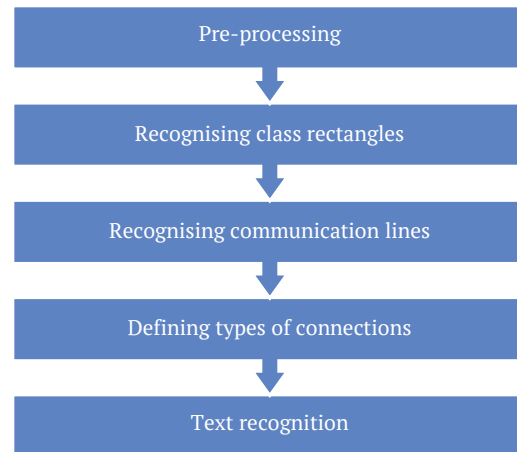


Figure 2. General algorithm of the UML class diagram recognition software

Source: developed by the author

The implementation details and algorithms used at each individual stage differ in different research papers. However, diagram 2 describes typical steps of the UML class diagram recognition algorithm, which can be considered as a generalised approach. At the first stage, the image is pre-processed to eliminate noise that may interfere with the accuracy of element recognition. The second stage focuses on identifying rectangles that represent classes. Each class can have one or more rectangles to indicate the name, attributes, and methods. To classify rectangles as components of a single class, clustering methods are used, where rectangles are distributed in a hierarchy: the class name is at the top, attributes are in the middle, and methods are at the bottom.

Once classes are detected, all rectangles are removed from the image to avoid interference when recognising link lines. The method of combining polygonal lines recognises different types of link lines: straight and diagonal. This helps to pinpoint the source and target class for each link. Character recognition is used to define link types, such as dependency, implementation, and aggregation. This includes identifying geometric shapes that represent the type of connection (for example, triangles for generalisation or rhombuses for aggregation). At the final stage, text recognition is performed in all class rectangles. This process allows getting class names, attribute names, and method names. After text recognition, the information is combined with class rectangles to form a complete class with its characteristics.

During the analysis of papers that specialised in building their own recognition algorithms, data from the experimental results of these studies were extracted, and Table 2 was compiled. According to each paper, the table contains information about the accuracy of class recognition, linking, and text processing. It is worth noting that the table contains only data from three studies, since other studies did not provide results confirming the effectiveness of their algorithms.

Table 2. UML chart element recognition accuracy indicators

	B. Karasneh & M.R.V. Chaudron (2013)	F. Chen <i>et al.</i> (2022)	M. Axt (2023)
Classes	100%	98.62%	92%
Connections	97%	93%	84%
Text and symbols	85%	not specified	not specified

Source: developed by the author

Notably, the study by M. Axt (2023) could have had lower accuracy indicators, since the problem was solved by recognising sketches of diagrams that are created in an informal form (for example, by hand or on a blackboard). This approach had significant problems due to the uncertainty and non-standard styles of elements in such diagrams. Instead, B. Karasneh & M.R.V. Chaudron (2013) and F. Chen *et al.* (2022) recognised diagrams created in specialised editors, which greatly facilitated the process and improved recognition accuracy due to a well-defined element structure.

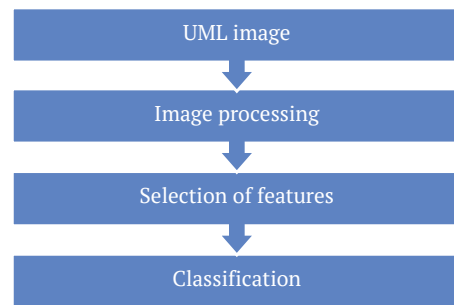
In addition, B. Karasneh & M.R.V. Chaudron (2013) provided accuracy metrics tested on only 10 sample charts created in a specific editor, which may limit the generalisation of the results. However, it is worth noting that among the methods considered, only the study by B. Karasneh & M.R.V. Chaudron (2013) contained data on the accuracy of text character recognition, which is an important aspect in preserving the semantics of UML diagrams. In contrast, the accuracy specified by F. Chen *et al.* (2022) was tested on 598 sample diagrams found in various open source projects. This provides more grounds for generalising the results obtained and demonstrates the stability of the methodology using real-world examples of UML diagrams.

Classical machine learning methods

Classical machine learning methods are widely used to classify UML diagrams. A common feature of classical machine learning algorithms is that they are based on the use of predefined features to classify UML diagrams. Each of these methods relies on extracted graphical characteristics such as shapes, contours, element sizes, distances between them, and their spatial location, helping to clearly identify UML classes, relationships, and other components. This approach ensures good interpretability of the model, since the classification process can be tracked and explained based on the selected features.

In the research papers mentioned in Table 1 and specialising in classification using classical machine learning

methods, a common pattern that the authors use when solving the problem of classifying UML diagrams can be distinguished. Figure 3 shows a general approach to UML classification experiments for class diagrams. The first step of the process is to get an input image of the UML class diagram. At the next stage, image processing is performed to identify contours and shapes, recognise horizontal and vertical lines, and identify rectangles and link lines, which is the basis for UML connections. To avoid delays in processing complex images, images are pre-checked before basic processing. Next, special attributes or metrics are defined (for example, size, area, etc.). These attributes are calculated based on the objects identified in the previous step and presented as numeric values. Selected features are fed to the input of a machine learning algorithm, such as SVM (Support Vector Machine), which was trained based on these features to classify UML class diagrams.

**Figure 3.** Experimental classification process

Source: developed by the author

The classical machine learning algorithms most commonly used for UML diagram classification problems are SVM, LR (Logistic Regression), RF (Random Forests), DT (Decision Tables), and J84 (a subspecies of Decision Tree). Some studies use RI (Rule Induction) and K-NN (K-Nearest Neighbours). Table 3 shows the machine learning methods whose accuracy data was taken from the relevant studies.

Table 3. UML diagram recognition accuracy in various studies

	J48	LR	DT	RF	SVM	RI	K-NN
T. Ho-Quang <i>et al.</i> (2014)	90%	91%	89%	93.1%	89%		
J. Hjaltason & I. Samúelsson (2014)	88.65%	91.1%	89.4%	91.9%	91.5%		
S. Rashid (2019)					90.8%		
V. Moreno <i>et al.</i> (2020)						94.4%	
M.H. Osman <i>et al.</i> (2018)	88.6%	88.9%	88.3%	90.7%	87.28%		89.1%
L. Wang <i>et al.</i> (2022)					91.9%		

Source: developed by the author

Comparative analysis of the classification accuracy of UML diagrams between different studies was not performed due to differences in experimental conditions, such as the set of classification features, image quality, chart type, and volume of training data. However, the Random Forests algorithm stands out in three papers with accuracy results of 93.1%, 91.9%, and 90.74%, which indicates its high efficiency in classifying UML diagrams. The highest results of classification accuracy among all the considered papers were achieved by V. Moreno *et al.* (2020), who showed that their Rule Induction method, with the correct set of rules, achieves an accuracy of 94.4%. This demonstrates the advantage of the Rule Induction method in the context of classifying UML diagrams, although its use may be specific to the conditions of this experiment. In general, all the considered algorithms provide a fairly high accuracy, reaching about 90%, so under the appropriate conditions they can be successfully used for classification problems of UML diagrams.

Deep learning methods and neural networks

With the development of new neural network architectures, such as CNN (Convolutional Neural Network), RNN (Recurrent Neural Network), Transformers, etc., there has been a noticeable interest among researchers in applying these methods to UML diagram recognition problems. Their advantage over classical machine learning algorithms is the ability to automatically extract relevant features from UML diagrams and adapt to different formats and styles.

J. Ott *et al.* (2019) investigated the possibility of using low-shot learning to classify UML diagrams using CNN and the VGG (Visual Geometry Group) architecture as a basic comparison. However, the VGGNet method showed low accuracy in this paper (about 50%), which did not exceed random guessing due to the excessive number of parameters and the complexity of training. Instead, using a smaller CNN with four convolutional layers allowed achieving 70% accuracy already with 100 training examples and almost 90% with several hundred. This highlights the effectiveness of low-shot learning in cases of limited data for training. B. Gosala *et al.* (2021) applied CNN to automatically classify UML-class diagrams, investigating the effectiveness of CNN using regularisation techniques to improve model accuracy.

In classification problems, the use of deep learning helped to rapidly move from binary classification to multiclass classification, which expanded the ability to recognise various types of UML diagrams and elements in them. S. Shcherban *et al.* (2021a) experimented with MobileNet, DenseNet (Densely Connected Convolutional Network), NasNet (Neural Architecture Search Network), ResNet (Resident Network), Inception, and its own architecture for the multiclass classification problem. In the paper S. Shcherban *et al.* (2021a), the researchers indicated the accuracy of algorithms when solving the problem of multiclass classification of UML diagrams. Among the tested models, DenseNet showed the highest accuracy – 94.44%, followed by MobileNet with 94.22%, while

ResNet reached 93.50%. The NasNetMobile architecture showed lower accuracy compared to other models – 90.21%. This suggests that DenseNet and MobileNet are more efficient for this task, probably due to their ability to use parameters efficiently and store important information during deep learning.

In general, the performance indicators of these neural network methods are quite high for UML diagram recognition tasks. On average, they recognise UML in images in more than 90% of cases. However, the researchers demonstrated that native neural network architectures designed specifically for a specific task provide even better results for recognising UML diagrams in images and can reach up to 95%. However, native architectures had significantly fewer parameters (2.4 million) and demonstrated the fastest classification time (0.0135 s/image) (Shcherban *et al.*, 2021a). Moreover, the researchers point out that the disadvantage of building own neural network architecture is its complexity. Developing a specialised architecture to perform a specific task, such as UML diagram recognition, requires considerable effort in designing and configuring the model, and a deep understanding of the task features and the data being processed.

By interpreting UML semantics, researchers can recognise individual diagram elements such as classes and types of relationships, which helps to automate software architecture analysis. However, there are currently no papers that solve the problem of completely converting UML images to XML format using deep learning, which indicates a potential area for future research. A. Koenig *et al.* (2023) developed a system for recognising structural elements in UML class diagrams using YOLOv8 (You Only Look Once) for semantic analysis of UML diagram images. YOLO provides high performance for the task of recognising individual UML elements of a class diagram, which averages 94.11%, and the accuracy of recognising class elements reaches 98.69%.

The ability of deep learning methods to generalise and automatically identify features for problem solving allows researchers to go beyond typical problems. Therefore, in addition to the problems of classifying and converting UML images to XML, they also explore such areas as, for example, determining the complexity of the system architecture (Munialo *et al.*, 2020). It is difficult to perform a comparative analysis of all architectures together, because they are used in separate studies and often solve different problems. In addition, in each individual paper, the authors have their own set of training data, and separate experimental conditions in which the tests were conducted.

Advantages and limitations of UML recognition methods

After considering each approach separately, it can be concluded that each has its own advantages and limitations (Table 4). Deep neural networks have shown the best results in recognising different diagrams of different types and formats. However, they have significant computational costs and also require a sufficient amount of marked-up

data to train the model. Classical machine learning methods may be the best choice in situations where there are limited resources for training neural networks, but higher accuracy and interpretability of the model is required,

since the layout works according to a clearly defined set of characteristics. Proprietary algorithms remain relevant for fast and easy processing of standard UML diagrams without significant complexity in their structure.

Table 4. Advantages and limitations of UML recognition approaches

Approach	Advantages	Disadvantages
Custom processing algorithms	High processing speed, easy implementation	Low adaptability to complex UML diagrams
Classical machine learning	Good balance between performance and adaptability	Requires manual selection of attributes
Deep learning	High accuracy and ability to summarise new data	Requirements for computing resources, the need for a large amount of data

Source: developed by the author

The analysis showed that deep neural networks are slightly superior to classical machine learning methods in the accuracy of recognising UML diagrams in the classification problem, achieving 94-95% accuracy in the case of DenseNet, MobileNet, ResNet, while the best classical algorithms (Random Forest, Rule Induction, SVM) show results in the range of 91-94%. However, classical methods have the advantage of processing speed and explanatory solutions, while deep neural networks provide better generalisation capabilities and recognise more complex UML diagrams with variable representation styles. Thus, the choice of UML classification approach depends on the trade-off between accuracy, processing speed, and available computing resources, but the general trend indicates the advantage of deep learning in automatic UML recognition tasks.

It was found that for the tasks of recognising individual elements and semantics of UML diagrams in images, among the various approaches to automatic recognition of UML diagrams, only NEURAL-UML uses deep neural networks, while other studies are based on conventional image processing methods and computer vision algorithms (Koenig *et al.*, 2023). The resulting accuracy for recognising various elements using NEURAL-UML varies between 92.62-96.09%, while Table 2 shows the recognition rates of native algorithms, the accuracy of which varies in the range of 93-98.62% in the study by F. Chen *et al.* (2022). Although ReSECDI and similar classical methods may show slightly higher accuracy rates for individual

elements, NEURAL-UML has a number of important advantages. Firstly, the neural network approach is more resistant to the diversity of UML diagram styles, in particular, to changes in fonts, element positions, and circuit structural features. Secondly, NEURAL-UML works better with UML diagrams that contain low-quality artefacts, such as distortion, blurring, or poor contrast, which is a common problem in UML images stored in bitmap format. Thirdly, the method demonstrates a higher generalisation ability, which allows it to work effectively with UML diagrams created in various software environments without the need for significant refinement. Thus, while conventional algorithms can show high accuracy under certain controlled conditions, it is deep neural networks that provide greater reliability, scalability, and adaptability for automatic UML diagram recognition.

Challenges and trends for further research

Current research on recognising UML diagrams from images faces a number of technical challenges that become obstacles to achieving full automation and accuracy. Despite this, the development of new approaches and methods allows gradually expanding the possibilities of analysing and automating work with UML. Among the analysed papers (Table 1), several problems of UML diagram recognition can be distinguished, which are most often solved by the researchers. Figure 4 shows those that were mentioned more than once.

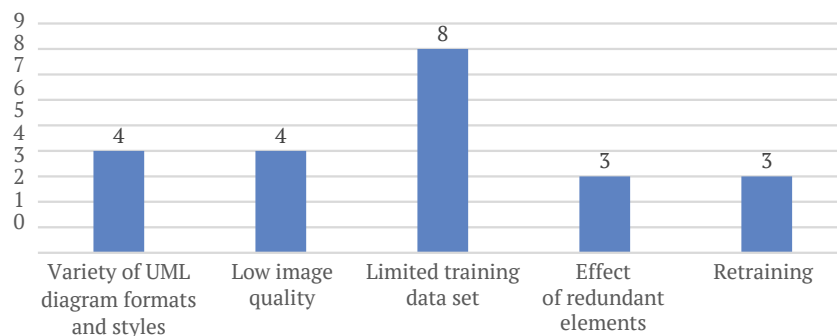


Figure 4. The most frequently mentioned problems with UML diagram recognition

Source: compiled by the author

In different UML software projects, diagrams may differ not only in content, but also in styles, fonts, colours, and element placement. This makes automatic recognition difficult, as the systems used for classification are often trained in standard styles. For example, diagrams can have different types of arrows to indicate dependencies or associations, or they can be created in different tools, which adds variability that is not provided for in training models. Effective recognition requires additional algorithms that can adapt to different styles or standardise the diagrams themselves.

The quality of UML diagram images significantly affects the performance of recognition algorithms. Low resolution, blurry borders, background noise, or other artefacts can cause important details to be lost. In the case of blurry or low-quality images, the model may not correctly recognise text names, roles, or relationships between elements. This causes the need for image preprocessing, such as improving contrast, eliminating noise, or even image reconstruction.

One of the most serious limitations is limited access to large data sets containing various UML diagrams. The small amount of training images limits the ability of models to generalise, which increases the likelihood of errors when working with new or unusual UML diagrams. There is also often a problem of uneven distribution between UML chart types (for example, more class diagrams, less sequential ones), which can affect the accuracy of classification.

Real UML diagrams often contain additional elements that may not be important for recognising a particular type or pattern, such as comments, markers, or other graphic labels. Such elements can “clog” the image, complicating model analysis and reducing classification accuracy. Algorithms often require first removing or ignoring such elements, which, however, requires additional resources.

Overfitting occurs when the model performs well on the training set, but shows low accuracy on new data. This is especially problematic with a limited data set, because the model can “learn” the specifics of specific diagrams, but cannot generalise knowledge to new images. Regularisation techniques are often used to solve the problem, and data augmentation strategies, but this requires additional computational resources.

Modern research on UML diagram recognition shows a clear evolution of methods and approaches covering the period from classical image processing algorithms to deep learning and the use of large language models. Early approaches were based on geometric techniques and optical character recognition (OCR) algorithms that made allowed extracting UML elements from scanned or digital images (Lank *et al.*, 2000). In the following years, the researchers integrated machine learning techniques to classify UML diagrams based on features extracted from graphical objects. Since 2014, there has been an active development of methods for automatic classification of UML diagrams using machine learning technologies, in particular SVM and Random Forest (Hjaltason & Samúelsson, 2014). In 2018, the first papers appeared using deep neural networks to

recognise UML diagrams, including convolutional neural networks (CNN) to extract semantic structures (Osman *et al.*, 2018). Recent trends in UML diagram research are related to the integration of large language models (LLM), which allow automatic conversion of UML thumbnails into formal models (Conrardy & Cabot, 2024).

In addition, there is an active introduction of low-shot learning methods, which allows training models on limited data sets, as an attempt to reduce the need for large marked-up datasets (Otts *et al.*, 2019). The low-shot learning method has become an effective approach for teaching UML diagram recognition models based on limited samples of training data. The researchers proved that even with 100 training examples, 70% accuracy can be achieved, and with several hundred – almost 90%. The study showed that a compact CNN with four convolutional layers showed significantly better performance in small samples than the large VGGNet model, which highlights the importance of adapting the architecture to the specifics of the task.

An important area is also the combination of conventional machine learning and deep learning methods, which helps to improve the accuracy of recognising UML elements in complex diagrams (Koenig *et al.*, 2023). The use of CNN allowed researchers to automatically extract key graphical features of UML elements, such as class forms and relationships between them, while SVM was used for final classification and verification of the obtained characteristics, in particular, recognition of text elements (class names, attributes, and methods).

Most classification studies focused on only one type of UML diagram, but noted the need to improve methods for recognising other types. In such studies, classical machine learning algorithms were most often used, in particular, SVM (Rashid, 2019), Random Forest (Osman *et al.*, 2018), logistic regression (Ho-Quang *et al.*, 2014). However, the use of deep neural networks, such as different CNN architectures, allowed achieving a generalised approach that covers the classification of various UML diagrams within a single model by automatically extracting characteristics, which reduced the need for manual feature design. Thus, studies of UML diagram classification are gradually shifting the focus from highly specialised approaches based on classical algorithms to generalised solutions based on deep learning. The development of UML diagram recognition goes through several stages—from basic geometric algorithms to modern hybrid methods that combine deep neural networks, large language models, and adaptive approaches to limited samples. Further research is likely to focus on improving the accuracy, adaptability, and efficiency of UML diagram recognition in real-world software environments.

Conclusions

The study confirmed the relevance and effectiveness of various methods of automatic recognition of UML diagrams, especially for tasks of classifying, extracting elements, and converting UML images to text format. An analysis of

23 publications showed that 53% of studies are devoted to classifying UML diagrams, 33% to extracting elements and converting them to text format, and 14% to other areas.

In UML diagram classification problems, neural networks show the highest accuracy – up to 95%, while classical machine learning methods, such as SVM, reach 94%. Studies show that the Random Forest method is one of the most effective for classifying UML diagrams, reaching 93.1%, 91.9%, and 90.74% in various experiments.

In problems of extracting individual elements of UML diagrams, proprietary computer vision algorithms show accuracy in the range of 93-98.62%, while deep neural networks show accuracy in the range of 92.62-96.09%. Despite the high accuracy of conventional algorithms under controlled conditions, it is deep neural networks that provide greater reliability, scalability, and adaptability when automatically recognising UML diagrams. The main problems in this area remain the poor quality of input images, the limited number of annotated data sets, and the significant variability of UML chart formats. There is also a problem integrating recognised UML diagrams into CASE tools, as many of them do not support editing UML images without first converting them to text format.

Among the promising areas of further research are low-shot learning methods, the use of large language models) for UML diagram recognition, and combined approaches that combine classical machine learning algorithms with deep neural networks. Most often, researchers point out the need to create large-scale open repositories of UML diagrams for training models, improve algorithms for converting sketches into formal UML diagrams, and develop new methods for automatic semantic interpretation of UML models. Additionally, based on the results obtained, appropriate areas for further research are the development of self-learning methods to improve the accuracy of recognising UML diagrams without the need for a large amount of annotated data, ways to reduce the computational complexity of algorithms for real use in resource-dependent environments, and the development of methods for automatic detection of anomalies in UML diagrams to identify potential errors in models.

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Conflict of Interest

None.

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Автоматизоване розпізнавання UML діаграм на зображеннях: підходи, тенденції та виклики

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Анотація. Мета дослідження полягала в аналізі та узагальненні сучасних методів розпізнавання UML-діаграм на зображеннях. Основна увага була приділена автоматизованому вилученню текстових і графічних елементів з метою подальшого відтворення моделей у текстових форматах. Методика дослідження охоплювала аналіз наукових публікацій, що включав 23 роботи, доступних у відкритих джерелах. Дослідження зосереджувалося на вивченні існуючих підходів до розпізнавання UML-діаграм на зображеннях. Аналіз наукових публікацій показав, які сучасні методи розпізнавання UML-діаграм дозволяють досягти точності понад 90 % у розпізнаванні UML-діаграм у зображеннях. Досліджено переваги, обмеження та ефективність класичних алгоритмів комп'ютерного зору, машинного навчання та глибоких нейронних мереж. Встановлено, що найкращі результати у класифікації забезпечують глибокі нейронні мережі, тоді як класичні алгоритми залишаються ефективними для інтерпретації та вилучення елементів UML-діаграм. З'ясовано, що основними напрямками у сфері розпізнавання UML-діаграм є класифікація типів UML-діаграм, а також інтерпретація та перетворення UML-зображень у текстові формати. Виявлено основні виклики: низьку якість зображень, обмеженість навчальних даних і варіативність форматів. Наведено можливі напрямки робіт для подальших досліджень, такі як створення великих анотованих наборів UML-діаграм для підвищення точності, узагальнення сучасних підходів для підтримки розпізнавання більшої кількості типів діаграм. Результати роботи сприятимуть вдосконаленню процесів автоматизації роботи з UML-діаграмами, а також забезпечать розуміння сучасного стану галузі інформаційних технологій та розробки програмного забезпечення, відкриваючи нові перспективи для розвитку

Ключові слова: розпізнавання зображень; комп'ютерний зір; машинне навчання; глибоке навчання; автоматизація



Optimising productivity and automating software development: Innovative memory system approaches in large language models

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Abstract. This study explored innovative approaches to enhancing memory systems in large language models to improve efficiency and automate software development. The primary focus was on optimising memory systems that enable long-term context storage and facilitate model adaptation to evolving interaction conditions. The research analysed contemporary methods of data storage and processing that enhance the ability of models to handle large volumes of information efficiently. This included the utilisation of specialised algorithms and memory mechanisms that improve the accuracy and adaptability of large language models in executing complex tasks. A secondary focus of the study examined the capabilities of large language models in automating software development. It assessed how these models can generate code, optimise it, and perform error detection. Particular attention was given to analysing the impact of automation on software quality and development time. In this context, the study investigated the use of large language models for automating repetitive tasks, generating tests, and implementing best programming practices. The findings indicated that enhancing the memory systems of large language models significantly improves their efficiency in tasks requiring long-term interaction. Integrating such models into software development processes has been shown to reduce both time and resource expenditures while enhancing product quality. The practical significance of this study lies in the formulation of recommendations for the optimal utilisation of large language models in the field of information technology

Keywords: contextual processing; algorithm optimisation; code generation; intelligent agents; big data processing; automation; interaction modelling

Introduction

The modern development of artificial intelligence (AI) is opening up new opportunities across various domains, including software development. Large language models (LLMs) occupy a central role in this process due to their ability to analyse, generate, and adapt to changing conditions. A crucial factor influencing the performance of these models is the memory system. Through memory optimisation, LLMs can interact effectively with users, preserve context, and adapt to new data. This study aims to explore innovative approaches to the utilisation of memory systems in LLMs, as well as to analyse the potential for automating software development using these models.

One of the key challenges in the operation of large language models is the preservation of long-term context

when processing vast amounts of data. Traditional approaches to information processing often face limitations in speed and accuracy, which impact the adaptability of these models. W. Zhong *et al.* (2024) proposed the MemoryBank system, which enhances the long-term memory of language models by enabling more efficient context storage and retrieval. This significantly improved the accuracy and stability of models when handling lengthy texts. Innovative methods such as hierarchical memory structures, dynamic context windows, and compression algorithms have facilitated more efficient data storage. Q. Wu *et al.* (2020) introduced Memformer, an extended memory transformer that allows models to manage complex dependencies while optimising memory usage.

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Another important aspect is the integration of memory with big data storage and processing. The use of distributed memory systems, cloud computing, and specialised hardware solutions can significantly enhance model performance. For example, W. Kwon *et al.* (2023) proposed PagedAttention, a method for efficient memory management, which reduced latency and increased the speed of real-time data processing. S. Sagi (2024) explored optimisation techniques for graphics processing units (GPUs) aimed at improving the performance of LLMs, enabling the modelling of more complex problems while reducing computational costs. Innovations in memory technology also create new opportunities for the development of intelligent agents. With improved memory systems, such agents can not only analyse data in real time but also make informed decisions based on accumulated experience.

The automation of software development is another promising application of large language models. By leveraging automation capabilities such as code generation, optimisation, and verification, developers gain powerful tools to reduce development time and enhance software quality. M. Schäfer *et al.* (2023) investigated the use of LLMs for automated testing, demonstrating how these models generate test scripts and verify component compatibility. Beyond code generation, LLMs are also capable of optimising code. For instance, B. Liu *et al.* (2024) examined the potential of automatic software refactoring using LLMs, highlighting their contribution to improving development efficiency and quality. Moreover, ensuring high-quality software solutions throughout their lifecycle is essential for enhancing the efficiency of LLMs. As A. Shantyr (2024) states, the use of combined quality models not only facilitates the assessment of software system efficiency but also ensures compliance with established criteria throughout the entire development process.

LLMs are capable of automatically generating code based on specifications provided by developers. For example, X. Jiang *et al.* (2024) proposed a self-scheduling approach to code generation, enabling models to solve complex problems with minimal user intervention. Another significant area is automated code testing. F.F. Xu *et al.* (2022) examined the effectiveness of LLMs in generating test scenarios, highlighting their ability to detect errors at an early stage. Additionally, Z. Zheng *et al.* (2025) investigated the role of LLMs in software engineering tasks, focusing on their capacity to automate complex processes such as design and testing. Their findings underscored the importance of advancing memory systems in LLMs to enhance performance and adaptability. By integrating modern memory technologies and data processing algorithms, these models become more effective in tasks requiring long-term context retention and flexible interaction with users. This has created significant opportunities for software development automation, allowing for substantial reductions in the time and resources required to produce high-quality software products.

The aim of this study was to develop and evaluate innovative approaches to the utilisation of memory systems in LLMs, with the objective of improving their performance and adaptability to evolving interaction conditions. Additionally, the study explored the potential of these models for automating software development.

Materials and Methods

To achieve the research objective, a comprehensive experimental approach was developed, incorporating innovative memory mechanisms in LLMs to optimise their performance. The primary focus was on testing and comparing different memory management methods, including MemoryBank, Memformer, and PagedAttention, to enhance the efficiency and accuracy of models in software development automation scenarios. The experiments were conducted on a high-performance computing infrastructure comprising clusters equipped with NVIDIA A100 graphics processors, enabling efficient data processing through parallel computing. The Amazon Web Services (AWS) cloud platform was utilised to scale resources, integrated with local servers. This setup facilitated the creation of a flexible environment for handling large datasets and various model configurations.

The three selected memory mechanisms were integrated into the foundational architecture of GPT-like models:

- ◆ MemoryBank, designed for long-term context storage through a hierarchical data structure, allowing for efficient information retention and retrieval when performing complex tasks. The memory access operation can be formalised as:

$$m_t = \alpha \times m_{t-1} + (1 - \alpha) \times h_t + \sum_{l=1}^L \beta_l \times c_{t-l} \quad (1)$$

where $\alpha \in 0.1$ – memory decay rate, β_l – layer-specific weights ($\sum_{l=1}^L$), c_{t-l} – context vectors from l -th layer, h_t – current hidden state.

- ◆ Memformer, a transformer with extended memory, capable of managing complex dependencies between tokens, thereby improving generation accuracy and analytical capabilities. The Memformer extends standard attention with (2):

$$\begin{aligned} \text{Attention}(Q, K, V, M_t) &= \\ &= \text{softmax}((QK^T + QM_t^T) / \sqrt{d_k}) \times [V; M_t], \end{aligned} \quad (2)$$

where M_t is the persistent memory at time t , updated according to (3):

$$M_{t+1} = f(M_t, X_t, A_t), \quad (3)$$

where f being a learnable update function, X_t the current input, and A_t the attention matrix.

- ◆ PagedAttention, a dynamic memory management approach that loads only relevant contextual data, optimising processing speed. The paged attention mechanism computes attention scores as:

$$A_{ij} = (e^{(q_i \times k_j) / \sqrt{d}}) / (\sum_{i \in P(i)} e^{(q_i \times k_j) / \sqrt{d}}), \text{ if } j \in P(i) 0, \text{ otherwise}, \quad (4)$$

where $P(i)$ represents the set of token indices in pages relevant to token i , determined by a relevance function such that (5):

$$P(i) = j \vee \text{relevance}(i, j) > \theta, \quad (5)$$

where θ being a configurable relevance threshold.

To evaluate effectiveness, a test dataset comprising 10,000 diverse queries was created. This dataset included: generating text responses to short queries; creating large code segments in Python and C++; long-term interaction tasks where the query context exceeded 10,000 tokens. The performance and efficiency of the models were assessed using the following metrics: latency, measured in milliseconds to determine model response speed; tokens per Second (TPS), which assessed the number of tokens processed

per second; accuracy, measuring the proportion of correct responses or generated code that met predefined requirements; memory Usage, indicating the amount of memory consumed by the model during task execution.

The experimental procedure comprised three main stages. At the first stage, the models were provided with a technical specification detailing functional and non-functional requirements. The task was to generate code that fully met these specifications from the outset. At the second stage, automated testing was conducted, where the models generated test scripts to verify the code, assessing their ability to detect logical and syntactic errors. At the third stage, existing code bases were refactored to identify duplication, detect complex logical conditions, and optimise the overall structure (Fig. 1).

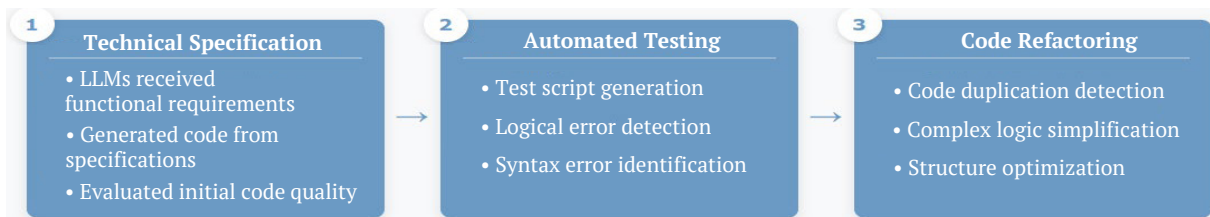


Figure 1. Experimental procedure for model evaluation

Source: compiled by the author

The results of the experiments were analysed using statistical tests, including the t-test to compare the mean values of performance metrics across different memory configurations. The t-test statistic was calculated using (6):

$$t = (\bar{x}_1 - \bar{x}_2) / \sqrt{[(s_1^2/n_1) + (s_2^2/n_2)]}, \quad (6)$$

where \bar{x}_1 and \bar{x}_2 are the means of the compared memory configurations, s_1^2, s_2^2 are their variances, and n_1, n_2 are the sample sizes. Results were considered statistically significant at $p < 0.05$, representing a 95% confidence level. Additionally, a qualitative analysis of long-term interactions was carried out, involving manual error coding and an evaluation of the contextual relevance of responses. The proposed methodology enabled a comprehensive assessment of the impact of innovative memory mechanisms on the efficiency of large language models, providing a foundation for their further optimisation and practical application in software development automation.

Results and Discussion

The impact of advanced memory systems on LLM performance. The findings of this study indicate that innovative memory mechanisms significantly enhance key performance metrics of LLMs. During the experiments, three approaches to memory organisation – MemoryBank, Memformer, and PagedAttention – were tested against the baseline model, which did not incorporate additional optimisations. The evaluation focused on four key parameters: response time (Latency) in seconds, throughput (Tokens per Second, TPS), where $\text{TPS} = \text{NumberOfTokens}/\text{Time}$, accuracy (Accuracy) percentage, which shows the correct answers, and total memory consumption (Memory Usage). The results demonstrated a clear advantage for models equipped with advanced memory mechanisms. Table 1 presents the average performance metrics for the baseline LLM configuration alongside each of the three approaches.

Table 1. Comparative performance indicators of LLM with different memory systems

LLM configuration	Latency (Mc)	TPS	Accuracy (%)	Memory usage (GB)
Basic	145	1,800	82	12
MemoryBank	100	2,200	88	10
Memformer	90	2,400	90	11
PagedAttention	85	2,500	91	9

Source: created by the author

As can be seen from Table 1, PagedAttention showed the best results: the model with this mechanism had the lowest response time (Latency = 85 ms) and the highest

accuracy (91%). Memformer was a close competitor, showing a slightly higher response time (90 ms) and TPS at 2,400. At the same time, MemoryBank showed an

improvement compared to the baseline version, but was still slightly inferior in speed to the other two options.

The next step was to study long-term interaction, when the query context exceeded 10,000 tokens. This scenario simulates situations in which the model has to “remember” a large amount of information from previous messages or code fragments. The results showed an advantage for all three improved memory systems. PagedAttention again showed the highest efficiency, reducing the time to search for relevant context by 35% compared to the baseline method. Memformer and MemoryBank also proved to be significantly more efficient, providing 20-30% faster response times. At the same time, PagedAttention was distinguished by dynamically “loading” only those pages of context that are needed for current processing, which gave it an advantage over hierarchical or segmented methods. In addition to quantitative indicators, the quality of the models’ responses in the long-term mode was evaluated. PagedAttention demonstrated the highest rate of correct reference to the previous context (92%), as well as error-free consideration of changes made to the original data. Memformer had about 89% of correct responses, while in certain scenarios losing small details implicitly mentioned in previous queries. MemoryBank (85%) showed a good ability to combine different data segments in complex questions, but sometimes mistakenly ignored secondary information if it was located outside the main “window” of memory.

Thus, these new methods not only accelerated data processing but also enhanced the ability of models to maintain and update long-term context – an essential factor in tasks involving a large number of interconnected steps. Contemporary research indicates that the integration of extended memory mechanisms significantly improves the performance of LLMs, influencing both inference speed and response quality. By preserving intermediate states during data processing, models can rapidly revisit previously obtained results and refine them without the need to recompute all steps from the beginning.

U. Antero *et al.* (2024) highlighted that LLMs equipped with sufficient memory capacity can perform automatic code generation and verification more effectively, as they retain logical connections and can reuse previously generated fragments. This capability is particularly valuable when tasks require an analysis of a long history of changes or the broader context of a project. Similarly, B. Kim *et al.* (2024) noted that reducing memory access latency is a critical factor in determining overall model performance. Optimising memory architecture enables reduced processing time, even in scenarios involving a high degree of parallel operations. Furthermore, Z.R.K. Rostam *et al.* (2024) demonstrated that a well-configured memory system can significantly accelerate both training and inference, which is especially crucial for resource-intensive models.

Additionally, D. Nguyen *et al.* (2024) proposed an approach in which the use of larger mini-batches, combined with optimised GPU allocation procedures, enhances

training efficiency. They emphasised that memory mechanisms play a crucial role in preventing the duplication of effort when processing similar fragments. Another strong argument in favour of extended memory is its ability to accurately track logical dependencies within code. R. He *et al.* (2024) highlighted that such an approach is particularly important in the development of complex software solutions, where each module depends on data or logic from preceding components. Similarly, G. Marvin *et al.* (2024) noted that effective prompt engineering is directly influenced by the model’s capacity to retain context. The greater the relevance and accuracy of recalled information, the more precise and coherent the responses.

However, I. Ozkaya (2023) warned that if a model’s memory becomes cluttered with unnecessary or irrelevant information, accuracy may decline. Therefore, implementing a mechanism for filtering or selectively “forgetting” redundant data is essential. Many contemporary approaches incorporate memory-cleaning algorithms or recursive refinement techniques to ensure that only the most relevant details remain in focus. Finally, G. Dolcetti *et al.* (2024) emphasised the importance of feedback from testing and static analysis. They argued that if a model retains the outcomes of previous attempts and learns from them, it can iteratively improve code generation accuracy and accelerate error correction. This further underscores the critical role of well-structured memory mechanisms in enabling LLMs to operate effectively in complex scenarios.

Software development automation: Results of innovative approaches. The second phase of the study focused on analysing the impact of advanced memory systems on the ability of LLMs to automate software development. A series of experiments was conducted in which the models generated code in Python and C++, automatically created test scripts, and refactored existing modules in accordance with best practices.

Initially, each model was provided with a technical specification detailing both functional and non-functional requirements. The task was to generate fully functional code based on these specifications. To evaluate the results, two key criteria were considered. The time (in seconds) required to generate a working prototype. The percentage of generated code that met all requirements without further corrections. To facilitate comparison, a graph was constructed in which the bars represent the proportion of correctly generated code, while the line indicates the generation time (Fig. 2).

In the field of software engineering, advanced LLM memory enables a significant increase in automation across all stages of development – from the initial formulation of requirements to the refactoring of large code bases. To effectively interact with code or technical documentation, a model must be capable of “understanding” and maintaining focus on the context of multiple diverse files, sometimes even across different programming languages.

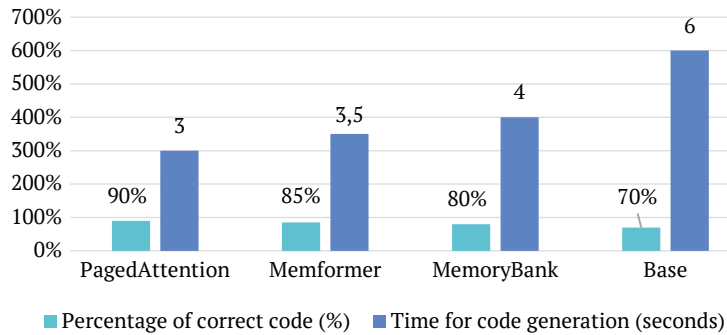


Figure 2. Comparing the efficiency of code generation with different memory systems

Source: created by the author

According to the findings of M.K. Görmez *et al.* (2024), LLMs equipped with advanced memory systems can rapidly generate prototypes while simultaneously producing test scenarios that cover the most critical aspects of functionality. This capability allows for the early detection and resolution of vulnerabilities during development. Additionally, R. He *et al.* (2024) observed that memory support enhances the model’s ability to resolve conflicts between different project components, particularly in cases where modifications to one module may introduce issues in another. If an LLM retains an understanding of the logic and structure of all modules, it becomes significantly more effective in identifying compromise solutions. At the same time, G. Dolcetti *et al.* (2024) emphasised the effectiveness of feedback mechanisms: when a detected error is recorded in the model’s memory, it is accounted for in subsequent code generation attempts, thereby substantially reducing the recurrence of similar shortcomings. Another crucial aspect is the ability of LLMs to generate unit tests and

integration tests. As part of the experiment, the models were tasked with independently developing test scripts to verify the compliance of the source code with its specifications. In addition to evaluating the speed of test generation, the experiment measured the percentage of detected logical and syntactic errors that had been intentionally introduced into the source code. The results showed that PagedAttention successfully generated adequate tests for 94% of functions, detecting 87% of errors. Memformer achieved comparable results, with 90% of tests deemed adequate and 85% of defects detected. Meanwhile, MemoryBank demonstrated slightly lower performance, with 87% of adequate tests and an 82% error detection rate. The baseline LLM configuration, in contrast, identified only 75% of artificial errors and required significantly more time to generate test scripts. Beyond test generation, the models also analysed existing projects for code duplication, complex logical checks, and anti-patterns. Table 2 presents a summary of the refactoring results.

Table 2. Comparing code refactoring results

LLM configuration	Duplication reduction (%)	Complexity optimisation (number of reduced conditions)	Recommended patterns (pcs.)
Basic	15	8	2
MemoryBank	30	13	5
Memformer	35	15	6
PagedAttention	40	18	7

Source: created by the author

PagedAttention proved to be the most effective in reducing code duplication (by 40%) and in suggesting design patterns, while Memformer and MemoryBank also significantly outperformed the baseline model. This result can be attributed to the extended memory capabilities, which allow the model to retain a larger portion of the code in focus, quickly analyse its structure, and propose improvements without losing context. Refactoring often requires consideration of global dependencies between modules, and in this regard, PagedAttention demonstrated the greatest flexibility, as it dynamically loaded only the relevant “pages” of data.

Contextual extension also plays a crucial role. A.N.T. Dieu *et al.* (2024) demonstrated how a model can dynamically access the history of interactions, including past testing and code reviews. This capability is particularly useful for quickly adapting to changes in requirements or resolving logical inconsistencies. Similar approaches have been proposed by K. Wu (2024), and J. Park & H. Sung (2023), who focused on runtime optimisation. Their research highlights that during GPU-based code generation, the model can load only the relevant portion of the context, thereby improving processing speed and reducing memory overhead. Meanwhile, Y. Bajaj & M.K. Samal (2023) suggested

using LLMs for semi-automatic test generation, where the model, by retaining an understanding of the code structure, can immediately identify common logical pitfalls.

This approach is particularly relevant for Continuous Integration/Continuous Delivery (CI/CD) pipelines. According to X. Hou *et al.* (2024), an LLM integrated into CI/CD workflows can validate key functional components with each new commit, referencing the history of successful and failed results to enhance software reliability. In turn, S. Jalil (2023) highlighted that such automated scenarios are becoming increasingly important in complex projects characterised by a high frequency of changes. The integration of memory enables LLMs to retain key contextual information and adapt more rapidly to evolving conditions. This approach, as emphasised by N. van Viet & N. Vinh (2024), forms the foundation for intelligent systems capable of independently determining development or testing priorities.

Finally, R. Hoda *et al.* (2023) introduced the concept of “Augmented Agile”, in which an LLM with an advanced memory mechanism effectively becomes part of the development team, assisting in operational decision-making related to task distribution and code structure. This marks a significant shift in software development, reducing the burden on engineers by automating routine error detection and resolution. Overall, the findings from the second phase of the study confirmed that optimised memory systems substantially enhance the capabilities of LLMs in automating software development – from code generation and testing to comprehensive refactoring. This opens up the prospect of integrating such models into Continuous Integration (CI) and Continuous Delivery (CD) pipelines, where they could autonomously handle a significant portion of routine tasks, thereby accelerating release cycles and reducing the risk of errors.

Comparative analysis and prospects for use. Based on the data obtained, several general conclusions can be drawn regarding the effectiveness of each of the examined approaches and their potential applications in real-world conditions. First, all three memory systems – MemoryBank, Memformer, and PagedAttention – demonstrated superior performance compared to the baseline LLM. According to the metrics presented, these systems achieve 30-40% faster data processing and 6-9% higher accuracy, which is particularly critical for scenarios requiring stable handling of large contexts or long-term interaction with users.

Among these systems, PagedAttention exhibited the best balance between speed and accuracy. Due to its ability to dynamically “load” context pages, it achieved the lowest latency while maintaining high accuracy (91%). It also outperformed other approaches in refactoring tasks, as it efficiently analysed complex project structures and suggested design patterns. Memformer proved particularly effective in complex, multi-layered scenarios, where projects contain multiple levels of logical dependencies and large datasets. Its hierarchical model scales effectively while maintaining high accuracy (90%), though its

implementation is more complex and may be excessive for simpler applications. Conversely, MemoryBank is most suitable for medium-sized or segmented projects. While it lags slightly behind the other two approaches in overall performance, it stands out for its ease of implementation and flexibility in managing individual data blocks. This makes it an ideal choice for small teams or projects requiring rapid deployment without unnecessary complexity.

Comparing MemoryBank, Memformer, and PagedAttention with the baseline LLM, all three memory mechanisms demonstrate significant improvements in performance and accuracy, particularly when handling large contexts or highly interconnected tasks. However, each approach has distinct advantages, making it more suitable for specific scenarios. PagedAttention dynamically “loads” only the necessary pages of information, optimising efficiency and reducing processing overhead. Memformer scales effectively in complex scenarios involving multiple logical dependencies. MemoryBank is easier to implement and well-suited for small to medium-sized projects that require flexible memory management.

It is worth noting that X. Hou *et al.* (2024) highlighted the versatility of long-term memory mechanisms, noting that they are beneficial not only for code generation but also for adaptive documentation analysis and project history management. According to S. Jalil (2023), LLMs that account for previous changes and specifications serve as integrators between different development team departments, facilitating better cross-team collaboration. Meanwhile, N. van Viet & N. Vinh (2024) observed that the scaling and advancement of memory architectures has paved the way for self-optimising systems capable of monitoring design changes and autonomously suggesting improvements. F. Chalumeau *et al.* (2024) further described how innovative memory methods are particularly valuable for addressing combinatorial explosion problems, where the model must track and manage multiple intermediate states simultaneously.

Further efficiency gains are also linked to advancements in hardware solutions. L.A.S. Julien *et al.* (2023) highlighted the emergence of enhanced chips and memory devices, which have simultaneously reduced power consumption and accelerated data processing. J. Cheng *et al.* (2021) emphasised the importance of efficient memory allocation in multi-threaded code synthesis environments, where multiple program segments may need to access shared memory areas within the model. According to M. Alenezi & M. Akour (2025), these advancements offer not only technical but also economic benefits, enabling companies to release updates more quickly and reduce long-term maintenance costs. It is also worth noting how memory mechanisms facilitate applications beyond text-based tasks. M. Zhu *et al.* (2019) demonstrated that in generative image modelling (DM-GAN), dynamic memory improves the alignment between textual descriptions and visual outputs. By analogy, in software engineering, similar concepts enable the integration of diverse data types,

including code fragments, UML diagrams, and technical documentation, thereby enhancing project coherence and facilitating multi-modal processing.

Additionally, J. Cruz-Benito *et al.* (2019) observed that extended memory mechanisms significantly enhance the accuracy of code autocompletion. When a model can reference the global structure of a project, the number of logical errors and incorrect recommendations is substantially reduced. Concluding the review, Z. Lyu *et al.* (2025) introduced the Top Pass technique, which combines ranking of the best results with a memory mechanism. This approach enables the model to rapidly filter potential answers, discarding the least relevant options and refining its outputs more effectively.

Thus, the prospects for integrating innovative memory systems into LLMs are extensive, ranging from enhancing productivity and accuracy to improving integration within development workflows. By retaining and adaptively managing context, these models become more flexible and versatile, enabling them to handle increasingly complex tasks in dynamic and continuously evolving environments. The findings of this study confirm that innovative memory systems significantly enhance both the performance and flexibility of large language models. With improved long-term context management, LLMs are evolving into powerful tools for automating software development, capable of independently generating code, testing it, and suggesting optimisations. Among the tested approaches, PagedAttention delivered the best overall performance, though the choice of a specific memory mechanism depends on factors such as project scale, complexity, speed requirements, memory constraints, and ease of implementation. Looking ahead, these technologies are poised to become industry standards, fostering more effective collaboration between humans and AI and laying the groundwork for further innovations in software engineering.

Conclusions

The findings of this study confirmed the high efficiency of innovative memory management approaches in LLMs, particularly MemoryBank, Memformer, and PagedAttention. Each of these mechanisms significantly enhanced model performance and accuracy, which is especially critical for tasks requiring long-term context retention and

handling a large number of interconnected actions. The implementation of MemoryBank improved long-term context processing through its efficient hierarchical memory structure, leading to reduced latency and greater accuracy in complex tasks. Memformer demonstrated high effectiveness in scenarios involving complex dependencies between tokens, enabling deeper context analysis and more precise generation. PagedAttention, in turn, outperformed other approaches in key metrics, achieving the highest data processing speed and optimal memory usage by dynamically loading only relevant data.

In the domain of software development automation, the study highlighted the potential of LLMs in executing a broad spectrum of tasks, from code generation and test script creation to refactoring existing software modules. The integration of advanced memory mechanisms significantly reduced development time while improving code quality, minimising both logical and syntactic errors. The use of PagedAttention in CI/CD processes proved particularly promising, as its dynamic context management optimised the code testing and verification pipeline.

Overall, the study confirmed that enhancing memory systems not only improves the performance and accuracy of large language models but also expands their potential applications. Further research in this field could explore the integration of LLMs into multi-component systems that support decision-making across various sectors, from medicine to financial analytics. In particular, advancements in technologies similar to PagedAttention could lay the foundation for new solutions prioritising scalability, adaptability, and efficiency. Innovative memory management approaches have the potential to become the de facto industry standard, enabling fast, precise, and efficient problem-solving across a wide range of complexities. These developments could fundamentally reshape the way data is processed and software is developed, unlocking new opportunities for automation, personalisation, and seamless integration into existing workflows.

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Conflict of Interest

None.

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Оптимізація продуктивності та автоматизація розробки програмного забезпечення: інноваційні підходи до системи пам'яті у великих мовних моделях

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Анотація. Це дослідження розглядало інноваційні підходи до вдосконалення систем пам'яті у великих мовних моделях для підвищення ефективності та автоматизації розробки програмного забезпечення. Основна увага приділялася оптимізації систем пам'яті, які забезпечують довготривале зберігання контексту та полегшують адаптацію моделі до мінливих умов взаємодії. У дослідженні проаналізовано сучасні методи зберігання та обробки даних, які підвищують здатність моделей ефективно обробляти великі обсяги інформації. Це включало використання спеціалізованих алгоритмів і механізмів пам'яті, які підвищують точність і адаптивність великих мовних моделей при виконанні складних завдань. Другим напрямком дослідження було вивчення можливостей великих мовних моделей в автоматизації розробки програмного забезпечення. Оцінювалося, як ці моделі можуть генерувати код, оптимізувати його та виявляти помилки. Особливу увагу приділено аналізу впливу автоматизації на якість програмного забезпечення та час розробки. У цьому контексті дослідження вивчало використання моделей великих мов для автоматизації повторюваних завдань, генерації тестів та впровадження найкращих практик програмування. Отримані результати свідчили про те, що покращення систем пам'яті великих мовних моделей значно підвищує їхню ефективність у задачах, що потребують довготривалої взаємодії. Показано, що інтеграція таких моделей у процеси розробки програмного забезпечення дозволяє скоротити витрати часу та ресурсів при одночасному підвищенні якості продукту. Практична значущість цього дослідження полягає у формулюванні рекомендацій щодо оптимального використання моделей великих мов у сфері інформаційних технологій

Ключові слова: контекстна обробка; оптимізація алгоритмів; генерація коду; інтелектуальні агенти; обробка великих даних; автоматизація; моделювання взаємодії



Qualification studies at SAT acceptance stage of the pharmaceutical containers washing machine

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Abstract. In pharmaceutical practice, glass containers are subject to mandatory cleaning before filling. The presence of dust, microorganisms or other contaminants significantly affects the quality of the medicinal product, in particular, reducing its effectiveness. Proper preparation of containers ensures the safety of medicines and their preservation throughout the entire shelf life. The purpose of the study was to evaluate the effectiveness of glass vial preparation on an automatic washing machine as part of qualification tests to confirm its compliance with production standards. The preparation of vials for bottling included disinfection, soaking, rinsing, washing, drying, depyrogenation, and sterilisation using automated washing machines. Site Acceptance Tests ensured that the equipment worked properly after installation. They included an analysis of the technical documentation, parameters of communication systems and control units of the washing machine. Residual contaminants such as sodium chloride, alkalis, and riboflavin were tested to assess the efficiency of the washing process. Based on the results, a seven-step procedure was defined, which included ultrasonic cleaning, rinsing with purified water, and a final rinse with injection water. These cycles have proven to be effective in the preparation of sterile drug containers. Recommendations for optimising process parameters, such as duration, temperature, chemical composition, and mechanical action, have helped to maximise productivity and minimise maintenance costs. A modern approach in compliance with international ISO standards ensured the high quality of vial preparation. The automated washing machine proved its efficiency, optimised the cleaning process, reduced the risk of contamination, and guaranteed the reliability of packaging preparation for sterile medicines

Keywords: glass containers for pharmaceutical use; bottle washing machine; site acceptance tests (SAT); user requirement specification (URS); fluorescence test for cleanability

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Introduction

Modern pharmaceutical developments are focused on ensuring the safety and high quality of parenteral medicines and biopharmaceuticals. One of the key stages in this process is the preparation of containers for sterile products. Proper treatment of the containers helped to reduce the risk of contamination and ensure that the quality of the products is maintained throughout their shelf life. In the context of the implementation of GMP principles and cost optimisation in the Ukrainian pharmaceutical industry, the study of validation and qualification of equipment for washing, drying, and depyrogenising containers has become particularly relevant. However, the scientific literature insufficiently covers the aspects of acceptance testing (AT), which leads to gaps in theoretical knowledge and practical application.

Innovative developments in the pharmaceutical industry use processes such as aseptic manufacturing to ensure the safety and high quality of parenteral products and biopharmaceuticals for patients with various medical conditions. K. Sampathkumar & B.A. Kerwin (2024) noted that to accelerate development, ensure compatibility between formulation and storage container, and reduce production costs, pharmaceutical companies can use predefined container/sealant systems that are compatible and prequalified for use with filling lines at manufacturing sites. S. Panighello & G. Pintori (2024) highlighted that the pharmaceutical industry depends on reliable and efficient packaging to ensure the integrity, safety and efficacy of its products, and glass packaging has long been a key material in pharmaceutical packaging. In pharmaceutical practice, glass containers must be washed before being filled with the drug. The presence of dust, pathogens, and other contaminants can significantly affect the quality of the medicinal product, reducing its effectiveness. The proper preparation of pharmaceutical containers should ensure the safety and quality of the product throughout the entire shelf life.

S. Yoneda *et al.* (2021) noted that containers supplied by manufacturers, even if they are manufactured to high quality standards, may contain various particles that need to be removed before filling. Therefore, containers intended for sterile products are handled differently depending on the material and type of product being prepared. F. Liu & R. Hutchinson (2024) highlighted that the presence of particles, endotoxins, and chemical contaminants in parenteral medicinal products (PMPs) poses a significant risk to the safety and efficacy of the product. Even if containers are manufactured to high standards, they may still contain particles that need to be removed before filling. These contaminants, if not removed properly, can lead to serious adverse reactions in patients. Therefore, sterile product containers must be handled with great care, considering factors such as the material and type of product being prepared. Effective removal of particles is essential to ensure the safety of both humans and animals, which underlines the need for strict quality control in the preparation and handling of these products.

Researchers F. Jameel *et al.* (2021) also noted that additionally, during the drying and depyrogenation stages of vial preparation and washing, static charges can form on the surface of vials, potentially affecting dosing during filling, mechanical visible and invisible particles, surface changes in curved glass vials, coating failure, alkali depletion in the glass structure, and alkali ingress into the drug product environment.

Researcher W.G. Lindboe (2021) studied the evolution of approaches to container preparation inspection in the pharmaceutical industry. He noted that these approaches have undergone significant changes, from conventional methods to innovative solutions driven by advances in technology and the type and level of contamination of containers. In his paper, W.G. Lindboe described in detail the stages of vial preparation, which may include disinfection, soaking, rinsing, washing, drying, depyrogenation, and sterilisation. The researcher paid special attention to the use of automated washing machines, which significantly increase the efficiency and accuracy of these processes.

The selection of appropriate pharmaceutical equipment for the preparation of sterile product containers and the proper qualification of washing machines are necessary steps to ensure and guarantee the quality of sterile and parenteral medicines and biopharmaceuticals for patients with various medical conditions. Washing and sterilisation (depyrogenation) machines for containers are among the pharmaceutical equipment that requires qualification – documentary evidence that a particular equipment works correctly, reproducibly, and produces the expected results.

The authors O.O. Saliy *et al.* (2019) emphasised that the pharmaceutical industry, where GMP principles are mandatory, is also gradually moving to lean manufacturing. In the context of the current Ukrainian economy, this approach is aimed at reducing operating costs while maintaining the proper quality of medicines. Y. Chen *et al.* (2023) also noted that the development of a combined and optimisation approach to minimise energy consumption while maintaining product quality will lead to improving energy efficiency and reduce the cost of qualification studies without adversely affecting production or product quality. According to FDA recommendations, “containers and closures for drugs must be clean and, if required by the nature of the product, sterilised and treated to eliminate pyrogenic properties to ensure fitness for intended use” (U.S. Food and Drug Administration, 2024).

Site Acceptance Tests (SAT) are a critical quality management stage conducted “on-site.” Testing occurs when a washing machine is accepted at its site. These final tests are essential as they confirm the washing machine’s performance after installation and adjustment, ensuring it is functional as a complete unit. Scientific literature has scarcely covered approaches, best practices, results, and challenges in qualification testing of pharmaceutical equipment, including washing, sterilisation, and depyrogenation machines for glass containers,

particularly at the SAT acceptance stage at pharmaceutical production sites.

The purpose of this study was to conduct SAT qualification studies for a pharmaceutical vial washer designed for sterile formulations.

Materials and Methods

The study was conducted at a pharmaceutical enterprise Ukraine equipped with a new line for washing, sterilising, and depyrogenating glass vials for sterile formulations manufactured by Ambica Pharma Machines Pvt. Ltd, India. The line included a vial washing machine and a sterilisation/depyrogenation tunnel. Depyrogenation methods, such as heating tunnels, address pyrogenicity issues, but residual particles, endotoxins, and chemical contaminants may cause adverse reactions in humans or animals. Therefore, vial washing machines are identified as critical devices, and validation qualification studies, conducted according to available guidelines such as EU GMP Annex 15 (European Commission, 2013-2014), are essential for their effective and compliant operation.

Studies on SAT stage:

Visual inspection. The analysis of the documentation included a check Design specifications, Electrical Wiring Diagrams, Installation Instructions, Operation Manual and Functional Specifications, Maintenance Instructions, Material Certificates, IQ Protocol, OQ Protocol, FAT Protocol and Report, SAT Protocol, Instructions for Key Machine Components, Functional Specification, Equipment Design Specifications, Supplier test documents, Cleaning Instructions. The enterprise carried out a check of the connection of systems and identification of control points to confirm compliance of the equipment with technical specifications (EU guidelines for good manufacturing practice..., 2015). Acceptance criteria: Compliance with user requirements specification (URS) and purpose of application (Shoturma, 2024).

Qualification studies were performed on an automated linear continuous-motion washing machine, where vials undergo various cleaning stages, including pre-washing, main washing, and rinsing. ISO 8362-1 Type I 100R glass vials with a 20 mm neck diameter, manufactured by Bormioli Pharma S.p.A., Italy, were used for tests.

Washing and preparation process for vials for sterile formulations. The automatic vial washing machine was designed for external and internal cleaning of glass cylindrical containers with volumes of 50 and 100 ml. Vials, packed in polyethylene wrapping, were transported to a "D"-class cleanroom where the washing machine and sterilisation/depyrogenation tunnel were installed. Vials were unpacked and placed on the feed tray/conveyor of the washing machine, from where they were transported to the washing zone and underwent all stages of cleaning including: Ultrasonic cleaning; Washing with recirculated water; Washing with purified water (PW); Final rinsing with water for injection (WFI). The vials were unloaded from the washing machine and transported via a conveyor to the

sterilisation/depyrogenation tunnel, where they underwent the following sterilisation stages: preheating – wet vials were preheated and dried; sterilisation/depyrogenation: the vials were exposed to high temperatures to ensure sterility and the removal of pyrogens; cooling: the vials were cooled to 20°C.

Considering the martial law in Ukraine, the conduct of FAT tests online, and the impossibility of conducting SAT tests in the presence of specialists from the equipment manufacturer, as part of the SAT acceptance, tests for soluble substances were conducted to confirm that the equipment can function as intended. Qualification studies included testing for the absence of contaminants on the surfaces of vials and inside them after completing a washing cycle in the machine. For these tests, a predetermined amount of each contaminant was applied to test vials, and the number of residues was determined after the washing cycle. The reduction in contaminants was used to evaluate the machine's performance.

Sodium chloride challenge test (soluble substances). A 30% aqueous solution of sodium chloride was prepared, and 0.1 ml was applied to the inner surface of 10 test vials. The vials were rotated to coat their inner surfaces and allowed to air-dry at room temperature. The test vials were marked and loaded into the washing machine along with uncontaminated vials. The test vials were placed at the beginning, middle, and end of the washing cycle. After washing cycle, the vials were carefully removed to avoid environmental contamination.

The vials were rinsed with distilled water, and the residual amounts of sodium chloride in the rinses were examined by a qualitative reaction. 0.2 ml of 1.0 M silver nitrate and 1 ml of dilute nitric acid were added. The procedure was repeated for flushes from containers not contaminated with sodium chloride. Acceptance criteria: all vials should be free of sediment, opalescence, or turbidity. The amount of chloride ions was determined by direct argentometry with potentiometric determination of the equivalence point (Pearson & Elstob, 1970). Acceptance criteria: absence of sodium chloride in the rinses from the inner surface of the vials after washing.

Test for the absence of chemicals (with alkali). An aqueous solution of alkali of known concentration was prepared and 10 vials were contaminated, subjected to a washing cycle, and the wash water was collected similarly to the test with sodium chloride. The alkali content of the wash water was determined by titration with a standard solution of sulphuric acid until the colour of the phenolphthalein indicator changed (Dhoke, 2023). Acceptance criteria: absence of alkali in the rinses from the inner surface of the vials after washing.

Chemical contamination (riboflavin testing). The use of fluorescent riboflavin allowed for clear visualisation of areas that were difficult to clean (edges, corners, etc.) (Salo et al., 2008). An aqueous solution of riboflavin (Hubei Guangji Pharmaceutical Co., Ltd., China) was prepared at a concentration of 0.2 g/L as a test residue of the chemical. The aqueous solution was applied to the surface of 10 test vials

to be loaded into the washing machine. Riboflavin is highly soluble in water and has an ultraviolet fluorescence at 385-395 nm. The contamination had a fluorescent yellow colour that was easily visualised (VDMA, 2007). The test vials were placed between the other vials so that they would enter the washing machine at the beginning, middle, and end of the washing cycle. After the washing cycle, the test vials were carefully removed to avoid other contamination from the environment. The cleaning efficiency was evaluated based on the presence of any residual contamination by visual assessment and under UV light at 360 nm to detect any signs of riboflavin contamination by fluorescence. The criterion

for machine compliance was the absence of riboflavin fluorescence on the inner surfaces of the vials after washing.

Results and Discussion

The washing and preparation machine for sterile vials is a relatively simple device used to clean containers during pharmaceutical manufacturing. The first acceptance test (SAT) was conducted at the pharmaceutical enterprise. During SAT acceptance, only installation qualification (IQ) and operational qualification (OQ) of the machine were performed, as no regulatory requirements explicitly specify that washing machine performance must be qualified.

Table 1. Documentation review for proper installation and operation of the vial washing machine

No.	Parameter	Available or not?		
		Yes	No	Undetermined
1.	Design specifications (DS) Drawings of the general location	+		
2.	Electrical Wiring Diagrams	+		
3.	Installation Instructions	+		
4.	Operation Manual and Functional Specifications (FS)	+		
5.	Maintenance Instructions	+		
6.	Material Certificates	+		
7.	IQ Protocol	+		
8.	OQ Protocol	+		
9.	FAT Protocol and Report	+		
10.	SAT Protocol	+		
11.	Instructions for Key Machine Components	+		
12.	Functional Specification	+		
13.	Equipment Design Specifications	+		
14.	Supplier test documents such as welder qualifications, welding records, roughness checks	+		
15.	Cleaning Instructions	+		
16.	Original Instructions and Qualification Certificate for Key Components	+		

Source: based on authors' own research

The SAT included documentation review, system connectivity verification, and control point identification. The results are summarised in Table 1. Documentation was critical for successful commissioning and verification.

The analysis of the documentation for the installation and operation of the vial washing machine revealed that most of the necessary materials were available, ensuring that the machine could be properly installed, operated, and maintained. Key documents, such as the Design Specifications (DS), including the general layout drawings, were present, providing the foundational framework for the installation. The availability of Electrical Wiring Diagrams ensured proper electrical connections, which is crucial for ensuring safe operation.

Additionally, Installation Instructions were available, detailing the setup process for the machine, while the Operation Manual and Functional Specifications (FS) provided guidance on how to operate the machine and its expected performance. Maintenance instructions were also included, helping to ensure the longevity of the

equipment and its proper upkeep. The presence of Material Certificates guaranteed that the materials used in the construction of the machine met the required quality standards. Furthermore, the IQ Protocol (Installation Qualification) and OQ Protocol (Operational Qualification) documents were available, which were essential for verifying that the machine was correctly installed and functions as intended.

Cleaning Instructions is also critical, as proper cleaning procedures are necessary to maintain hygiene standards, particularly in environments dealing with pharmaceutical or medical equipment. Without these documents, certain aspects of the installation and operation may not fully comply with regulatory standards or best practices. The machine's design and functional characteristics met the User Requirements Specification (URS). Table 2 shows the results of the verification of the electrical system parameters of the sterile vial washer machine. It lists the parameters required to ensure the proper installation and operation of the vial washer.

Table 2. Verification of utility supply systems parameters of the vial washing machine for sterile forms

No.	Parameter	Expected Result		
		Accept	No	Undetermined
1.	Total power load 15.7 kW (380 V, 50 Hz, 3 phases, 5 wires)	√		
2.	Compressed air 50 [L/min] at 6-7 [bar]	√		
3.	WFI pressure [bar] 3-4 [bar]	√		
4.	WFI temperature [°C] 70-80 [°C]	√		
5.	WFI consumption [m ³ /h] 1.0 [m ³ /h]	√		
6.	Length (mm) To be specified on site	√		
7.	Width (mm) To be specified on site	√		
8.	Height (mm) To be specified on site	√		
9.	Weight (kg) To be specified on site	√		

Source: based on authors' own research

The table lists the various electrical systems and physical characteristics that need to be verified. For each parameter, the expected result is given and the verification status is indicated as “Accept”, “No” or “Undetermined”. The parameters are critical to the operation of the machine, especially in a sterile environment where precise conditions are required. Compressed air is a critical utility for the functioning of the washing machine, typically used to power certain components or assist with the cleaning process. The expected flow rate is 50 L/min at a pressure of 6-7 bar. The WFI system is used to provide water of the highest purity, necessary for sterilisation processes. The expected pressure range for WFI is 3-4 bar. The machine’s WFI pressure has been verified as within the expected range. The temperature of WFI is critical for ensuring effective sterilisation. The expected temperature range for WFI is between 70-80°C. The consumption of WFI is expected to be 1.0 m³/h. This is an important metric for determining water usage and efficiency.

The verification results for most of the utility supply parameters indicate that the vial washing machine is in compliance with the expected specifications. All key utilities, such as total power load, compressed air, WFI

pressure, temperature, and consumption, have passed the verification, showing that the machine can function as intended within the provided operational environment. The location environment of the bottle washing machine was also checked, namely the available space in the production room (the room plan was assessed), the available ceiling height, the requirements for drains (pH neutralisation, wastewater cooling), and the maximum noise level allowed (dBA). The verified parameters confirm that the Installation Qualification (IQ) has been successfully completed. The automated vial washing and preparation machine has been installed as specified in the URS, and the utility systems were sufficient to support its operation and ensure proper functionality of the equipment.

Verification of Control Units for the Vial Washing Machine for Sterile Forms provides a comprehensive overview of the control systems and safety parameters for the vial washing machine. Table 3 lists various operational conditions and failure scenarios, specifying whether the system is set to display, stop, signal, or reset (either manually or automatically) in response to each condition. The parameters are critical for ensuring the machine’s safe operation, particularly in a sterile manufacturing environment.

Table 3. Verification of control units for the vial washing machine for sterile forms

No,	Parameter	Requirements						Result	Remarks
		Customise	Display	Stop	Signal	Manual reset	Automatic reset		
1.	Performance and applications	◆	◆					+	
2.	Low compressed air pressure		◆	◆	◆	◆		+	
3.	Low pressure WFI		◆	◆	◆	◆		+	
4.	Low recycled water pressure		◆	◆	◆	◆		+	
5.	Vials min. accumulation at the power supply station		◆	◆	◆		◆	+	

Table 3. Continued

No.	Parameter	Requirements						Result	Remarks
		Customise	Display	Stop	Signal	Manual reset	Automatic reset		
6.	Pump overloading		◆	◆	◆	◆		+	
7.	Low water level		◆	◆	◆		◆	+	
8.	Low water temperature		◆	◆	◆		◆	+	
9.	Engine overloading		◆	◆	◆	◆		+	
10	Feed from the next machine is blocked or malfunctioning		◆	◆	◆		◆	+	

Source: based on authors' own research

The system is appropriately configured to address a wide range of fault scenarios and operational issues that could occur during the machine's use. Each fault condition is set to activate the necessary safety measures, including display alerts, stoppage of operation, signalling the issue, and automatic resets where applicable. These safety measures are crucial in ensuring the machine operates within the required standards, preventing any potential damage or failure.

The configuration ensures comprehensive monitoring of vital processes such as air pressure, water levels, pump and engine load, and any potential malfunctions related to the feed from the next machine. The automatic reset feature in many cases is particularly valuable in maintaining continuous operation and reducing the need for manual intervention.

The control units for the vial washing machine have been properly configured to address a variety of operational faults and performance issues. The system's comprehensive

safety and alert mechanisms, including display, stop, signal, and automatic reset functions, provide adequate protection for both the machine and the process. The verified results demonstrate that the machine's control systems are fully prepared to ensure safe and efficient operation in a sterile production environment. Washing Cycles and Utilities Systems Applied to the Sterile Vial Washer provides an overview of the various washing cycles involved in the operation of the sterile vial washer, along with the corresponding utility systems required for each cycle.

Therefore, the results of the site acceptance test (SAT), which included installation qualification (IQ), were satisfactory and can guarantee that the washing machine, once installed and configured, will perform according to URS design parameters and the prepared containers will meet expectations for cleanliness, identity, safety and quality. Based on the results of the SAT acceptance, the vial washing cycles were determined, as shown in Table 4.

Table 4. Washing cycles and utilities systems applied to the sterile vial washer

No. of washing cycle	Cycles	Utilities systems
1	Ultrasonic cleaning	Compressed air + tap water
2	Pre-washing of vials	Recycled water (recycled water)
3	Vial blowing	Compressed air, tap water
4	Washing of vials	Purified water (WP)
5	Vial blowing	Sterile compressed air
6	Rinsing vials	Water for injection (WFI)
7	Drying of vials	Sterile compressed air

Source: based on authors' own research

Each row represents a distinct step in the vial washing process, specifying the cycle type and the utility systems used during that step. The utility systems include compressed air, tap water, recycled water, purified water (WP), sterile compressed air, and Water for Injection (WFI), all of which play a critical role in ensuring the effectiveness of each washing step. As can be seen from Table 4, the preparation of compressed air and its supply to the vial washing machine has a significant impact on meeting the requirements for the preparation of non-sterile primary packaging. Cleanliness is achieved by the machine's option of inverting the container under the influence of gravity and the use a filtered compressed air for cleaning process.

The table below shows that a variety of utility systems are employed across different cycles, each serving

a specific purpose in the cleaning and sterilisation process. The washing cycles outlined in Table 4 demonstrate a well-structured and efficient approach to vial cleaning, with careful consideration of the utility systems required at each stage. The use of appropriate utilities, such as recycled water for pre-washing and WFI for final rinsing, ensures both cost-effectiveness and compliance with the highest standards of sterility. The combination of compressed air and sterile compressed air for drying and blowing also contributes to maintaining the vials' cleanliness and sterility throughout the process. Overall, the system is well-designed to meet the stringent requirements of sterile vial washing in pharmaceutical manufacturing.

Test vials were prepared and vial washing cycles were performed. The riboflavin test is designed to provide a

preliminary demonstration that the proposed wash cycles clean the vials. The results of the evaluation of the cleaning

and preparation of pharmaceutical containers after the washing cycle are presented in Table 5.

Table 5. Results of qualification tests for cleaning and preparation of pharmaceutical containers after the washing cycle

Qualification tests	Total number of vials	Number of test vials	Number of contaminated vials	
			Visual assessment	Evaluation under ultraviolet light
Sodium chloride challenge test (soluble substances)	300	30	Not detected	-
Test for the absence of chemicals (with alkali)	280	28	Not detected	-
Chemical contamination (riboflavin testing)	300	30	Not detected	Not detected

Source: based on authors' own research

This successful run of a full cleaning cycle demonstrated that all systems were functioning correctly and confirmed that all sensors and probes were calibrated, operational, and compliant with the requirements outlined in the URS. Contaminant testing had been conducted on both the surfaces and interiors of the vials post-wash cycle, with predetermined amounts of various contaminants applied to test vials prior to washing. Post-cycle evaluations detected no residual contaminants, highlighting the high performance of the machine. Additionally, riboflavin testing was employed to identify critical cleaning points that could have posed hygiene risks or structural defects. Based on these results, the Operational Qualification (OQ) was successfully completed.

Glass remains the preferred primary packaging material for parenteral medicines, primarily due to its chemical resistance, inertness, strength, and transparency (Schaut et al., 2014). The most commonly used glass vials are ISO 8362-1 type I 6R, 10R and 100R with 20 mm diameter elastomeric stoppers coated with fluoropolymer. These vials are available in baths, pre-washed and depyrogenated, ensuring that they are treated in the same way as during drug manufacturing. The stoppers are also available pre-washed and ready to be sterilised before use, which minimises the necessary preparation steps and brings them closer to the manufacturing process (Teska et al., 2016). The use of fluoropolymer-coated stoppers guarantees the integrity of the vials and prevents contamination from external sources, making them ideal for sensitive pharmaceutical products.

In pharmaceutical practice, glass containers must be washed before filling with the drug. The presence of dust, pathogens and other contaminants can significantly affect the quality of the medicine, reducing its effectiveness. Proper preparation of pharmaceutical containers ensures the safety and preservation of products within the established shelf life (Kuzmina & Strokan, 2013). According to the authors, even minor traces of contamination can lead to instability of the dosage form, which can negatively affect its therapeutic efficacy. Therefore, ensuring that containers are thoroughly cleaned is a critical step in the pharmaceutical manufacturing process.

Mechanical visible and invisible particles, surface changes in curved glass vials, coating breakdown, alkali

depletion in the glass structure and release of alkali into the drug product environment (Ditter et al., 2018). The research highlights the crucial role of maintaining the integrity of glass containers to avoid interactions between the packaging and the pharmaceutical product. Even small changes to the glass surface, such as alkali release, can alter the chemical composition of the medicinal product, affecting its safety and efficacy. Therefore, proper washing protocols are essential to prevent such problems and ensure product quality.

Scientific publications provide data on the regulatory framework governing laboratory equipment and metrological qualification work, and also propose approaches to the classification of equipment for determining the scope of qualification work. M.M. Nesterchuk et al. (2009) discussed the need to develop clear qualification standards to ensure that laboratory equipment, including cleaning systems, performs in accordance with established regulatory requirements. They emphasised the importance of periodic testing and certification of equipment to minimise the risks associated with non-compliance and to maintain consistency in the production process. This approach is critical to meeting the stringent safety and quality standards required in the pharmaceutical industry.

V.K. Yakovenko et al. (2015) identified key features and opportunities for qualification of spectrophotometric equipment in pharmaceutical analytical laboratories. The researchers focused on the importance of proper qualification of spectrophotometric equipment to ensure accurate measurements in pharmaceutical analysis. Their study illustrated how qualification procedures for such equipment can improve the accuracy of analytical results, which is essential for the safe production of pharmaceutical products. Proper qualification of analytical equipment ensures that measurements are consistent and reliable, thereby supporting the overall quality control process.

Reviews of vial and rubber stopper washers include tests for insolubles, solubles, and endotoxins by S.J. Shinde et al. (2014) emphasised the importance of testing cleaning solutions for impurities that may contaminate pharmaceutical products. In their study, the researchers emphasised that the water quality and purity of the chemicals used in the washing process are vital to maintaining

the safety and stability of the final medicinal products. The researchers recommended comprehensive testing protocols to detect endotoxins and other contaminants that may be present in cleaning solutions, ensuring that the cleaning process does not result in the release of harmful substances into the packaging.

P. Lopolito *et al.* (2017) demonstrated how process parameters such as time, temperature, chemical composition, coating, and mechanical action affect the performance of automated vial washing systems. The researchers found that optimising these parameters led to a significant increase in cleaning efficiency and a reduction in the risk of contamination. They also emphasised that variations in these parameters can affect the quality of the cleaning process, highlighting the importance of careful control of the washing conditions. Their study illustrated how fine-tuning process variables in automated systems can minimise the need for manual intervention, thereby improving productivity and safety in pharmaceutical manufacturing.

In summary, qualification studies of pharmaceutical equipment are limited, but in the rapidly evolving global pharmaceutical market, understanding the basics of cleaning helps optimise automated systems and avoid common mistakes that reduce cleaning efficiency, productivity and increase maintenance costs. The results of these studies contribute to ongoing efforts to refine cleaning procedures, improve automation systems, and ensure safe pharmaceutical production. Proper equipment qualification and process optimisation play a key role in achieving high standards of purity and ensuring the long-term stability of medicines.

Conclusions

Based on the results of the on-site acceptance testing (SAT-acceptance), including documentation review, system connections, and control unit verification, it has been established that the equipment, its configuration, and spare parts comply with the technical specifications outlined in the contract. Key documents, such as the Design Specifications (DS), including the general layout drawings, were present, providing the foundational framework for the installation. The availability of Electrical Wiring Diagrams ensured proper electrical connections, which is crucial for ensuring safe operation. The equipment meets the

preselected design parameters. The results obtained are satisfactory and confirm that, after installation and setup, the washing machine will function properly, ensuring that the washed and prepared containers meet expectations for cleanliness, identity, safety, and quality.

The communication systems and washing/preparation cycles for pharmaceutical vials intended for sterile medicinal forms have been defined. All key utilities, such as total power load, compressed air, WFI pressure, temperature, and consumption, have passed the verification, showing that the machine can function as intended within the provided operational environment. The verified parameters (the room plan), the available ceiling height, the requirements for drains (pH neutralisation, wastewater cooling), and the maximum noise level allowed (dBA) were confirmed that the Installation Qualification (IQ) has been successfully completed. It is confirmed that the system control units is appropriately configured to address a wide range of fault scenarios and operational issues that could occur during the machine's use. Each fault condition is set to activate the necessary safety measures, including display alerts, stoppage of operation, signalling the issue, and automatic resets where applicable.

Contaminant testing on vial surfaces and interiors after the machine's washing cycle, using test contaminants such as soluble substances (sodium chloride), chemical agents with alkali, and riboflavin, followed by post-wash evaluations, confirmed the absence of contaminants. This indicates the high performance of the machine and the effectiveness of the selected washing cycle. Further research is also focused on optimising testing protocols for evaluating the machine's performance in removing biological contaminants under varying operational conditions and container specifications. Additionally, studies evaluating the effectiveness of the washing cycle on non-standard or challenging vial geometries, and testing for the removal of biological contaminants and endotoxins, would provide a more comprehensive validation of its capabilities.

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Conflict of Interest

None.

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Кваліфікаційні дослідження на стадії SAT приймання машини для миття та підготовки фармацевтичних контейнерів

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Анотація. У фармацевтичній практиці скляні контейнери підлягали обов'язковому миттю перед розливом препарату. Наявність пилу, мікроорганізмів або інших забруднень суттєво впливає на якість лікарського засобу, зокрема зменшуючи його ефективність. Належна підготовка контейнерів забезпечує безпеку препаратів і їх збереження протягом усього терміну придатності. Дослідження було спрямоване на оцінку ефективності підготовки скляних флаконів на автоматичній мийній машині в рамках кваліфікаційних випробувань для підтвердження її відповідності виробничим стандартам. Підготовка флаконів до розливу включала дезінфекцію, замочування, ополіскування, миття, сушіння, депірогенізацію та стерилізацію із використанням автоматизованих мийних машин. Гарантію належної роботи обладнання після встановлення забезпечували приймальні випробування (Site Acceptance Test – SAT). У їх межах проводили аналіз технічної документації, параметрів систем комунікації та вузлів контролю мийної машини. Для оцінки ефективності миття тестували залишкові забруднення, такі як хлорид натрію, луги та рибофлавін. На основі отриманих результатів визначили семистадійну процедуру, що включала ультразвукове очищення, промивання очищеною водою та остаточне промивання водою для ін'єкцій. Ці цикли підтвердили свою ефективність у підготовці контейнерів для стерильних лікарських засобів. Рекомендації щодо оптимізації параметрів процесу, таких як тривалість, температура, хімічний склад і механічна дія, дозволили досягти максимальної продуктивності та мінімізувати витрати на обслуговування. Сучасний підхід із дотриманням міжнародних стандартів ISO забезпечив високу якість підготовки флаконів. Автоматизована мийна машина підтвердила свою ефективність, оптимізувала процес очищення, знизила ризики забруднення та гарантувала надійність підготовки упаковки для стерильних лікарських засобів

Ключові слова: скляні контейнери для застосування у фармації; машина для миття флаконів; приймальні випробування на місці (ПВМ); специфікація вимог користувача (СВК); флуоресцентний тест для перевірки здатності до очищення



Analysis of the current state of computer systems in the field of virtual healthcare

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Abstract. The purpose of this study was to develop a conceptual model for the integration of modern digital technologies in the healthcare sector with adaptation to Ukrainian conditions and the creation of a single national medical ecosystem. The study was based on a systematic analysis of literature sources using content analysis and a systematic approach. Publications, review papers, and official documents available in leading scientific databases (PubMed, Scopus, and Web of Science) over the past five years were used to collect data. The research algorithm included preliminary selection of sources according to the criteria of relevance, reliability, and scientific significance, further analysis of technological solutions in the areas of telemedicine, artificial intelligence and virtual reality, and assessment of their integration compatibility with existing electronic health systems. The analysis covered the economic, ethical, and legal aspects of implementing innovative technologies. The results showed that telemedicine contributes to improving access to health services in remote regions, but its implementation is limited due to imperfect infrastructure and the lack of uniform regulatory standards. Analysis of artificial intelligence algorithms has shown their high potential in diagnosing and predicting diseases, which indicates the need to adapt technologies to local conditions. Research on the possibilities of virtual reality has confirmed its effectiveness in therapy, rehabilitation, and medical education, although implementation is accompanied by technical difficulties. The developed conceptual model considers both technical and organisational factors of digitalisation of healthcare, which can become the basis for strategic planning of further experimental implementations in the national health system. Thus, the analysis identified the main trends and problem areas of digital technology implementation that contribute to improving the quality of medical services and optimising resources. The results of the study form the scientific basis for developing practical measures and strategies for digitalisation adapted to the conditions of Ukraine

Keywords: telemedicine; virtual reality; artificial intelligence; privacy of medical data; digital transformation

Introduction

21st century medicine is at the stage of comprehensive digital transformation, which involves the active introduction of telemedicine, artificial intelligence (AI) and virtual reality (VR) in various areas of healthcare. These technological solutions not only improve the accuracy of diagnosis and effectiveness of treatment, but also significantly expand the possibilities of rehabilitation and remote monitoring of patients, especially in remote regions.

Thus, E. Donnellan & A. Watts (2024) noted that telemedicine has proved extremely important in times of crisis and emergency situations due to timely remote consultations and automated patient monitoring systems. In their publication, the researchers detailed the experience of using

telemedicine solutions during disasters and epidemics, showing how they help to ensure continuity of medical care. The paper also emphasised the positive impact of such technologies on optimising resource allocation and improving interaction between doctors. However, W. Febriyani *et al.* (2023) emphasised that the lack of uniform data security standards and regulation of the legal framework hinders the large-scale spread of such solutions. The researchers proposed the development of unified information exchange protocols to strengthen patient privacy protection and prevent confidential data leakage. In addition, they stressed the importance of international cooperation in the harmonisation of legislative requirements and relevant ethical standards.

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Artificial intelligence algorithms are becoming increasingly important in the medical field, because they can quickly process large amounts of data and detect pathologies with high accuracy. V. Pillai (2024) drew attention to the fact that platforms like PathAI speed up diagnosis, but there is a question of transparency of the “black box” – difficulties in understanding exactly how the algorithm makes decisions in specific clinical cases. The researcher also suggested integrating explanatory AI techniques to increase trust on the part of doctors and patients and make the decision-making process clearer. N. Shah (2024) saw the need for clear standardisation of approaches and certification of AI tools, so that the results of their study are reproducible in various medical institutions. The researcher compared the available standards and proposed creating unified criteria for evaluating the accuracy and reliability of AI solutions. The researcher also noted that constant monitoring of algorithms and updating their models is a prerequisite for maintaining a high quality of medical services.

An equally important role was played by virtual reality, which opens up new prospects in therapy and rehabilitation, providing manageable conditions for training patients with various diagnoses. K. Moulai *et al.* (2024) pointed out the effectiveness of VR platforms in dealing with post-traumatic stress disorder and the consequences of neurological damage, as patients are able to safely handle stressful situations or restore lost skills. The study noted that regular use of VR technologies contributes not only to improving clinical indicators, but also to increasing the motivation of patients to actively participate in their own rehabilitation. Moreover, interactive simulations have become useful for medical education, as they provide close to real-world clinical scenarios where students and doctors can hone their professional competencies (Schiza *et al.*, 2019). The researchers noted that such training significantly improved the skills of teamwork, decision-making in stressful conditions and mastering emergency protocols. It was based on simulating various situations in a virtual environment that participants were able to quickly respond to complications and mistakes, without exposing real patients to risks.

The next level of digital medicine is associated with building a single integrated environment where all stakeholders interact – from healthcare institutions and insurance organisations to patients themselves. According to S.S. Albouq *et al.* (2022), the fragmentation of available solutions and the lack of agreed protocols complicate data exchange and interoperability of systems, and therefore hinder the development of an integrated digital ecosystem. The researchers emphasised that the introduction of generalised standards can minimise duplication of processes and speed up the provision of health services at all levels. Instead, creating a shared information space could increase the effectiveness of therapy, optimise costs, promote better communication between doctors and patients, and simplify the implementation of synergy between AI, VR, and telemedicine services (Morita-Jaeger *et al.*, 2024). Researchers studying this topic emphasised that a single integrated

platform can provide comprehensive support for clinical solutions and speed up administration processes. Attention has increased to ethical issues related to the confidentiality of personal data, and the distribution of responsibility for errors that can be made by automated systems. Therefore, the purpose of the theoretical research was to thoroughly investigate the available digital solutions and develop a conceptual model outlining scientifically based approaches to their implementation in broad clinical practice.

Materials and Methods

The study focused on the development and theoretical substantiation of a conceptual model that integrates key digital technologies and their interaction mechanisms in a single healthcare ecosystem. At the first stage of the study, a comprehensive analysis of scientific publications, review papers and official documents covering the implementation of telemedicine, artificial intelligence technologies, and virtual reality in various clinical settings was carried out. This approach helped to identify common patterns and the main challenges that arise when integrating individual digital solutions into medical practice. The accumulated information about real cases and implemented developments formed the basis for building a conceptual model.

In the process of forming the model, general scientific methods of data analysis, synthesis, and systematisation were used. Initially, the available sources were divided into thematic blocks covering specific areas of healthcare digitalisation. After summarising the results obtained, a search was carried out for logical connections between various technological solutions, which helped to identify critical nodes of the ecosystem that should be given special attention to ensure compatibility and scalability of the system. Special emphasis was placed on integrating electronic health records with a common database, which ensures continuous exchange of information between all components of the model. The analysis considered both technical and organisational aspects that contribute to the creation of an effective digital ecosystem in the context of modern clinical processes. To test the viability of the developed concept, an additional theoretical analysis of modern technological solutions used in medical institutions and research centres was carried out.

The study covered data encryption, security of information exchange, and effective integration of various information systems into a single digital healthcare platform (Pawar *et al.*, 2024). Special attention was also paid to the investigation of the possibilities of creating virtual environments for rehabilitation activities and training simulations.

A conceptual model has been developed that describes a complex architecture in which telemedicine, AI, and VR can interact through a single centralised data ecosystem. This model has been expanded with a more detailed description of information flows and possible connection points for other compatible technologies, such as Internet of Things systems for continuous monitoring of health indicators. Based on this, a number of recommendations were proposed to optimise the integration process, in

particular, to strengthen the security of data exchange, improve the compatibility of various electronic systems, and create common standards.

Results and Discussion

Overview of digital technologies in healthcare:

Essence, significance, and key aspects

During 2014-2024, digital technologies were considered as a fundamental catalyst for the transformation of

the healthcare industry, as they allowed expanding the horizons of diagnosis, therapy, and prevention. However, their massive development was accompanied by a number of challenges covering both legal and ethical issues, including the need to adapt infrastructure and improve the digital literacy of patients and healthcare professionals. Table 1 provides a comparative description of the main digital technologies that were actively used in medicine in 2024 and their key advantages.

Table 1. Key digital technologies in healthcare: features and advantages

Technology	Description	Features and advantages
Telemedicine	Video consultations and remote medical care.	1. Provides access to medical services without physical contact. 2. Facilitates access for patients in remote regions. 3. Reduces the burden on inpatient departments and hospitals.
Artificial intelligence	Use of algorithms and machine learning to analyse medical data.	1. Improves the accuracy of diagnostics, in particular, in oncology and cardiology. 2. Can analyse large amounts of data to detect patterns and anomalies. 3. Automates routine tasks and improves the efficiency of healthcare professionals.
VR	Use of simulations for therapeutic or rehabilitation purposes.	1. Helps patients with mental disorders through exposure therapy (for example, schizophrenia, post-traumatic stress disorder). 2. Used in rehabilitation after injuries and strokes. 3. Creates opportunities for training medical personnel through simulations of complex clinical situations

Source: compiled by the author based on D.K Pawar et al. (2024)

However, the large-scale integration is still accompanied by financial, technical, and personnel obstacles. If it is possible to develop more affordable equipment, uniform standards for testing effectiveness, and train the necessary

specialists, virtual reality may well become an integral part of modern medicine. Table 2 summarises the main factors that facilitate or, conversely, restrain the introduction of digital technologies.

Table 2. Factors of introduction of digital technologies in medicine

Factor	Impact on implementation	Detail
Technical standards	Lack of uniform standards can complicate integration and interaction between different technologies and platforms	1. Need to develop a single protocol for data exchange between medical institutions. 2. Importance of creating standards to ensure compatibility between different hardware and software solutions.
Legal aspects	Need to develop legal norms for the protection of medical data and define the limits of responsibility for their processing	1. Defining the legal framework for processing patients' medical data, especially in the context of telemedicine and AI. 2. Need to create rules for informed consent of patients to use their data for AI training.
Digital patient literacy	Low levels of digital literacy limit patients' access to new technologies and can become a barrier to their implementation	1. Patients who are not familiar with digital technologies may have difficulty accessing online counselling or health services 2. Problems with teaching patients the basics of using technologies such as video communication, online consultation platforms
Financing and investment	The need for large investments to create and maintain medical technologies, which may limit their implementation in some countries.	1. Develop infrastructure for digital medical platforms, including hardware, software, and staff training. 2. Government or private sector support is required to finance projects that reduce the cost of technology
Training of medical personnel	Regular training and retraining of healthcare professionals is required to effectively use new digital tools	1. Without proper training, doctors will not be able to effectively use new technologies, which will lead to their inefficiency. 2. Organisation of advanced training courses for medical professionals, which will ensure the correct use of technologies.
Social acceptability	Importance of cultural, social, and psychological aspects for the successful adoption of new technologies by patients and doctors	1. Patients, especially the older generation, may not be ready to use digital technologies such as video consultations 2. Consideration of socio-cultural features in the development of platforms and ensuring access to technologies for different groups of the population

Source: compiled by the author

As evidenced by the experience of India and South Korea, given in the papers by N. Viswanadham (2021) and H.Y. Lee et al. (2023), comprehensive implementation of solutions is possible only with an interdisciplinary approach and coordinated actions of government agencies,

medical institutions, IT companies, and insurance organisations. India has demonstrated an example of centrally combining hospitals, insurance companies and pharmaceutical suppliers into a single network that facilitates data access and treatment coordination. This model is especially

valuable for regions with uneven distribution of resources, where there are not enough specialists and modern equipment. South Korea focuses on personalised strategies where Internet of Medical Things (IoMT) devices continuously collect vital data and transmit it to the shared medical space. Due to this, doctors can quickly respond to minor deviations, which reduces the number of exacerbations and hospitalisations and increases patient comfort.

The combination of telemedicine, AI, and VR in a single platform forms the basis for future medicine based on continuous information exchange, personalisation of therapeutic programmes, and a multidisciplinary approach. As noted by W. Huang *et al.* (2023), AI systems can speed up the processing of laboratory tests, minimise errors, and support more efficient use of clinic resources. However, telemedicine and VR open up new formats of rehabilitation, when patients are given the opportunity to perform exercises remotely or undergo training scenarios. Despite their high potential, the integration of these tools largely depends on the degree of interaction between the state and the private sector, the willingness to invest in infrastructure and implement data protection measures. In addition, the lack of uniform industry standards and clear legal norms complicates the exchange of medical information, increases the risk of abuse or cyber-attacks, and undermines patient trust.

It is indisputable that digitisation of the medical sector has both social and economic consequences. South Korea's experience shows that the development of telemedicine and IoMT reduces barriers to access to qualified care, especially for remote regions or low-mobility patients (Lee *et al.*, 2023). This helps to improve public health indicators and allows doctors to focus on more complex clinical situations. From an economic standpoint, automating processes (such as laboratory research) using AI increases productivity and reduces the cost of manual work (Huang *et al.*, 2023). Telemedicine reduces the number of face-to-face visits, which reduces the need to expand the physical network of hospitals and allows doctors to serve more patients online. However, the success of such models is impossible without initial investment in equipment, training, and support for network infrastructure, and for poorer countries, these costs can be excessively high without external funding.

In addition, digital medicine can deepen social inequality if some people do not have access to high-speed Internet or the necessary level of technical skills. Therefore, state and international programmes of "digital inclusion" are becoming very important, aimed at ensuring that the most vulnerable categories of the population are not left out of medical innovations. Digital technologies in healthcare (telemedicine, AI, VR, and IoMT) have huge potential to improve the efficiency, accessibility, and personalisation of healthcare services. However, their large-scale implementation faces a number of obstacles – from the lack of unified technical standards and legal mechanisms to the problem of insufficient digital literacy. Successful integration of these technologies into the real medical ecosystem requires:

1. Systematic approach that considers telemedicine, AI, VR, and IoMT as an interconnected ecosystem. All components must be compatible with each other and based on agreed standards for storing, sharing, and analysing medical data.

2. Interdisciplinary interaction that attracts specialists in the fields of medicine, computer science, engineering, and social sciences. This helps to assess the impact of digital solutions on different regions and health systems, considering economic, cultural, and legal characteristics.

3. Legal and ethical grounds. Clear regulatory norms and mechanisms of responsibility in case of errors or abuses are needed, in particular, regarding the processing of personal data and explaining the results of AI systems.

4. Comprehensive training programmes for doctors and patients, and digital inclusion efforts to avoid the gap between "technologically trained" and vulnerable populations.

5. Financial incentives and public-private partnerships to cover high initial costs and further scale pilot projects to the level of national programmes.

If these principles are followed, digital innovations can move from the category of auxiliary or "crisis" tools to a full-fledged basis for the development of modern healthcare. In the long run, this can ensure better provision of medical services, save resources, and develop truly patient-centred medicine, where everyone receives the necessary care on time and in a convenient format.

Telemedicine: Integration in the modern healthcare system

In the period 2015-2024, telemedicine became particularly important as one of the most promising tools for modernising the healthcare sector. It significantly reduced the physical distance between the patient and the doctor, providing virtual consultations, diagnostics, and real-time monitoring. According to M. Hägglund *et al.* (2023), in the context of the COVID-19 pandemic, the introduction of video consultations in the Swedish primary care system has reduced the burden on inpatient departments and reduced the risk of infection of people from high-risk groups. However, such a rapid transition required not only the installation of technical equipment, but also a significant restructuring of infrastructure, which in some regions was not properly developed. In addition, information campaigns were conducted to dispel patients' scepticism about the safety and effectiveness of online interaction.

L. Kupczik *et al.* (2022) and M.S. Khan *et al.* (2019) noted that video consultations are only the initial stage in the development of telemedicine. A promising area is the widespread introduction of remote sensors that can transmit real-time data on the patient's physiological state (blood pressure, pulse, oxygen saturation, etc.). This format allows quickly identifying deviations and adjusting therapy, which is especially important for patients with chronic diseases (cardiovascular, respiratory, etc.). However, the researchers warn about the risks of leakage of confidential information, since data transmission can take place through different platforms with different levels of protection. This makes it

difficult to form a unified picture of the course of the disease and disrupts the continuity of patient monitoring. An equally important aspect is the development of universal technical protocols that allow integrated data exchange between medical institutions. Unification of formats and standards facilitates interaction between doctors, reduces barriers to patient performance transmission, and improves treatment coordination. It is necessary to clearly distribute the levels of access to medical records to protect personal data and prevent unauthorised use of information. The imperfection of the legal framework in this area often becomes a serious obstacle to the development of telemedicine, even despite the obvious advantages of such a model.

As noted by Y. Sofia *et al.* (2022), telemedicine also carries socio-cultural challenges. Remote consultations have greatly facilitated access to a doctor for those who live in remote regions or have limited mobility. However, older adults and patients with low levels of digital literacy may have significant difficulties adapting to technological innovations. To overcome this barrier, comprehensive educational initiatives, training programmes on the use of telemedicine services, and the involvement of social workers to help set up video communications and explain what data the doctor needs are offered. All this shows that for the full integration of telemedicine into the healthcare system, it is necessary not only to improve the technical base, but also to build patient trust and ensure the protection of personal data. In general, telemedicine is turning from an “emergency” tool into a full-fledged component of modern medical care. Its greatest potential is manifested in epidemiological threats, when it is important to minimise contacts in hospitals and simultaneously maintain the continuity of service provision to a wide range of the population. The history of remote consultations and access to digital patient cards greatly facilitate the work of various specialists, because all information is available in a centralised format. However, the ultimate success of spreading such models depends on the availability of clear technical solutions, public confidence in online doctors, and high-quality support for patients who need help using new services.

Artificial intelligence in medicine: Application and problems

AI is rapidly integrating into medical practice, as it can process big data, identify hidden patterns, and improve diagnostic accuracy. According to the observations of O.C. Oguine & K.J. Oguine (2022) and J. Li *et al.* (2024), deep learning algorithms are very effective in recognising the first signs of cancer in medical images. This is extremely important for oncology, since early detection of the disease allows choosing the optimal therapy in time and thereby increasing the chances of recovery. Based on AI, doctors can reduce the impact of the human factor and pay more attention to complex clinical decisions, rather than routine verification of results.

A. Amjad *et al.* (2023) highlighted the growing efficiency of AI through its combination with IoMT.

This integrated environment allows continuously monitoring patients’ vital signs and instantly signalling deviations from the norm. This paves the way for a preventive model of medicine, where exacerbations can be avoided or postponed to a later date due to timely treatment adjustments. However, the effective implementation of these ideas requires the unification of information platforms and security protocols to protect sensitive data and eliminate duplication of information in different databases (Mohammed *et al.*, 2022).

M.S. Khan *et al.* (2019) focused on the compatibility of different information systems, without which AI algorithms will not be able to form a holistic view of the patient’s condition. Disparate databases, lack of a consistent format for storing information, and duplication of records increase the risk of clinical errors and delay treatment decisions. Therefore, the inclusion of AI in the infrastructure of medical institutions requires not only technical, but also organisational training, including the establishment of procedures for the exchange of medical information. The phenomenon of the “black box” remains particularly controversial, when the decision-making process of a neural network is incomprehensible to users. According to D. Apage (2023), this opacity creates distrust on the part of doctors and patients who do not know what factors influenced the diagnosis or recommendation. The answer to this problem is the explicable AI paradigm, which allows explaining how the algorithm came to a certain conclusion (Patil *et al.*, 2021). However, the introduction of such solutions requires additional developments and new methodologies for interpreting complex machine learning models.

From a legal standpoint, the question of liability for AI errors remains open. When the algorithm assumes inaccuracies in a complex clinical case, it is not clear who should be responsible – the doctor who trusted the technology, the software developer, or the institution that implemented it. Such aspects are actively discussed by legal experts, and relevant regulators who are trying to adopt rules for the use of AI. Thus, the success of AI in medicine depends not only on the quality of algorithms and the amount of data, but also on creating transparent rules and safety standards that establish a framework of responsibility and protect the interests of patients.

Virtual reality: Therapy, rehabilitation, and training

VR has opened up new approaches to treatment and rehabilitation, offering the creation of interactive environments that are as close as possible to real conditions. With VR, patients can “immerse themselves” in controlled scenarios that mimic social interactions, therapeutic exercises, or even critical situations that are not available for safe playback in a clinic setting. According to D. Kruk *et al.* (2020), the use of VR therapy has shown positive results in patients with psychiatric disorders, in particular, schizophrenia. This format allowed tracking reactions in more detail and gradually correcting pathological representations, avoiding excessive stress or risky contacts.

The study by M.M.T.E. Kouijzer *et al.* (2023), which was based on the North American Society for the Sociology of Sport (NASSS) Framework, highlighted several barriers to introducing VR into everyday practice. First, there are not enough specialists who have a thorough knowledge of clinical medicine and understand the development of virtual environments. Second, high equipment costs (helmets, controllers, powerful computers) hinder large-scale implementation. Third, the lack of proper facilities and the lack of understanding of the potential of VR by the management of institutions also make it difficult to integrate the technology. Z. Liu *et al.* (2022) summarised areas where VR has already demonstrated tangible positive effects: treatment of post-traumatic stress disorder (PTSD), treatment of various phobias (A&F), chronic pain management (PM), and dynamic neuromuscular stabilisation (DNS). The key advantage is the possibility of gradual exposure of the patient to trigger situations and the development of game scenarios that increase the motivation of patients for rehabilitation. However, the researchers emphasised the lack of unified methods for evaluating the effectiveness of VR therapy, which makes it difficult to compare the results of different research groups.

According to F. Ferreira-Brito *et al.* (2022), gamification is an important factor in increasing the attractiveness of VR

applications. In virtual “gaming” environments, patients feel more involved and follow rehabilitation instructions more easily. However, the spread of such solutions is still hindered by the high cost of the hardware complex, the need for a high-speed Internet connection and the availability of technical personnel responsible for the correct operation of VR systems. Thus, despite the great prospect, VR continues to be a technology that requires further improvement and adaptation to the real conditions of various clinics. Overall, the analysis of these studies shows that VR can significantly expand the available therapy formats, increase patient motivation to collaborate with a doctor, and complement conventional treatment and rehabilitation methods.

Conceptual model for integrating digital technologies into the healthcare system

Based on the analysis and collected literature, a conceptual model for integrating digital technologies into the healthcare system was developed, which provides for the creation of a single integrated environment. This environment combines telemedicine services, artificial intelligence tools, virtual reality technologies, and other digital solutions, ensuring their synergistic interaction to improve the efficiency of medical services. The structure and interaction of system components is shown in more detail in Figure 1.

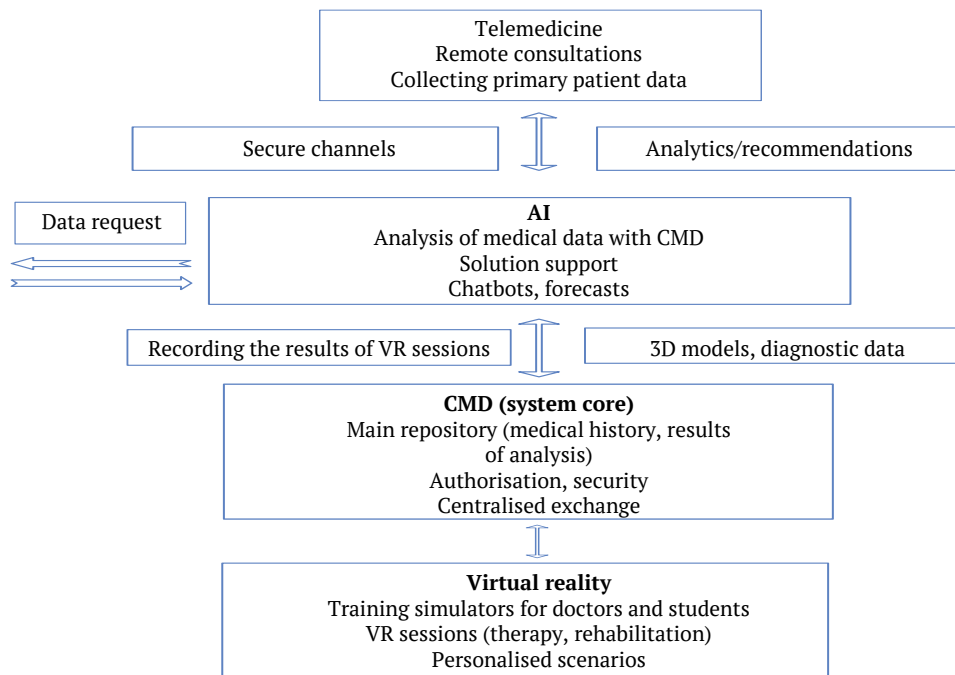


Figure 1. Integrated medical ecosystem: telemedicine, AI, VR, and centralised database

Source: compiled by the author

The basis of this integration is a centralised ecosystem of medical data that combines information from a variety of sources, including electronic medical records, data from telemedicine consultations, test results, and metrics collected using Internet of Medical Things. Such an ecosystem provides a continuous stream of data that is analysed

using AI algorithms to support clinical decision-making, risk prediction, and treatment personalisation. The use of AI allows automating routine tasks, improving the accuracy of diagnostics and optimising treatment processes. For example, deep learning algorithms can quickly and accurately detect abnormalities in medical images, which

significantly speeds up the process of making a diagnosis and choosing the optimal therapy.

An important aspect is the use of VR technologies for patient rehabilitation and training of medical personnel. VR environments create a controlled and adaptive therapy environment, allowing patients to safely handle stressful situations or restore physical skills. For medical personnel, VR provides the ability to train in simulated clinical scenarios, which increases their professional competence and readiness for various clinical situations. For example, virtual simulations can help doctors to practice complex surgical procedures without risking patients, and patients with mental disorders can safely process their emotions in a controlled environment.

Telemedicine plays a key role in ensuring the availability of health services for patients in remote regions and for those with limited mobility. Remote monitoring of physiological parameters in combination with teleconferences allows doctors to constantly monitor the condition of patients and quickly respond to changes in their health. This not only improves the quality of medical services, but also reduces the burden on hospitals and medical institutions. For example, patients with chronic diseases can regularly receive remote consultations and monitoring, which allows them to adjust the treatment process in a timely manner and prevent complications.

Integration of digital technologies also involves considering regulatory aspects and issues of confidentiality of medical data. The implementation of common security standards and data exchange protocols is an important component for ensuring the protection of patients' personal information and responsibility for its processing. Regulating the legal framework promotes trust in digital medical solutions and their widespread adoption. For example, the creation of regulations on the collection, storage, and transmission of medical data, and defining the responsibility of the parties in the event of violations, is a necessary step to ensure the safety and effectiveness of digital medical systems.

The social and organisational aspects of digital integration include increasing digital literacy among patients and medical staff, and creating conditions for smooth interaction between different participants in the medical ecosystem. This includes conducting training programmes, information campaigns, and creating intuitive interfaces for users of different ages and social groups. Increasing digital literacy allows patients to use telemedicine services more effectively, and healthcare professionals to successfully integrate new technologies into their daily practices. For example, organising training sessions for doctors on the use of AI and VR can significantly improve the quality of medical services and increase patient satisfaction.

The integration of digital technologies into the healthcare system also requires consideration of economic aspects. High initial investment in equipment procurement, software development, and staff training can be a significant barrier for many healthcare facilities. However, the long-term benefits of implementing digital technologies,

such as reducing the cost of maintaining physical infrastructure, improving the productivity of healthcare workers, and improving the quality of healthcare services, make this investment justified. For example, automating laboratory processes using AI can reduce the cost of processing tests and improve the accuracy of results, which, in turn, improves the efficiency of medical institutions.

Overall, the integration of digital technologies into the healthcare system provides a comprehensive approach that combines technical innovation, regulatory, social adaptation, and organisational support. This helps to create a flexible, efficient and safe medical ecosystem that can meet modern challenges and provide a high level of medical services for all categories of the population. Based on this integration, it is possible to achieve a more flexible, personalised and patient-oriented medicine that is able to quickly adapt to changes in the medical field and provide high-quality care regardless of the geographical location or socio-economic status of patients.

Challenges, prospects, and ethical aspects of implementing digital technologies in the medical sector of Ukraine

The introduction of digital tools in Ukrainian medicine faces a number of fundamental obstacles, while opening up significant prospects for improving the quality and accessibility of medical care. One of the most important factors that complicate the implementation of these processes is the lack of funding. Against the background of military operations, the country is forced to allocate limited resources primarily to the needs of the defence complex and the provision of urgent social programmes. As a result, funds aimed at modernising medical infrastructure and developing/implementing the latest software are often not enough. This situation directly affects the availability and quality of telemedicine services. According to the latest statistics, only 8% of doctors use specialised official telemedicine platforms that require a paid subscription or installation of additional applications. But the popular free messengers Viber, Telegram, and WhatsApp have become widespread. As noted by V. Poberezhets *et al.* (2022) despite their convenience and accessibility, these unofficial services do not provide the proper level of personal data protection and are not adapted to the systematic maintenance of electronic medical records. Accordingly, cyber risks and the likelihood of leakage of sensitive patient information are increasing, which is especially critical under martial law.

The second difficult problem is the insufficient level of digital literacy among both doctors and patients. It is interesting that experienced doctors with more than 10 years of experience in some aspects are more adaptive to the use of certain digital tools, compared to the younger generation of specialists, which, at first glance, should be more "technologically savvy". In particular, older doctors are more likely to master remote monitoring using blood glucose meters or pulse oximeters, while young specialists are often less knowledgeable in the field of telemedicine

and need specialised training (Kotsarenko *et al.*, 2023). This paradox is explained by the fact that traditional educational programmes for doctors in previous years could offer separate modules or courses related to the introduction of telemedicine technologies, while current university graduates do not always have the opportunity to receive such training in the proper amount. Therefore, the establishment of a programme of additional trainings, webinars, and courses for different age groups of health workers becomes a necessary condition to increase the overall level of digital competence and move the process of digitising healthcare from its place.

The third key aspect remains the lack of a proper regulatory framework. Despite the gradual progress, Ukraine still lacks clear legislative provisions that would regulate the collection, processing, and dissemination of medical data, and define standards for secure electronic document management. International law and European Union (EU) legislation in this area provide for rather high requirements for compatibility of IT systems, data encryption methods, and interaction procedures between different institutions. However, as of today, Ukrainian regulations do not always meet these requirements, creating legal uncertainty and holding back the potential for digitalisation. M. Kotsarenko *et al.* (2023) emphasised that without clear rules for the protection of medical records and without agreed mechanisms that would regulate the work with personal data, significant progress in the field of telemedicine remains problematic.

The use of the latest technologies, which include artificial intelligence and virtual reality, opens up unique prospects for reforming domestic medicine. Based on the conclusions of M. Kotsarenko *et al.* (2023), the use of AI has significantly improved the process of diagnosis and monitoring of patients' condition: automation of X-ray analysis, ultrasound diagnostics or computed tomography (CT) examinations simplifies and accelerates the detection of pathologies, and predicting the risks of complications allows the doctor to adjust treatment in time. This approach not only optimises time and financial costs, but also improves the accuracy of diagnoses, which is especially valuable during armed conflict, when the number of wounded and patients with serious injuries increases. VR technologies, in turn, prove their effectiveness in the rehabilitation of military and civilian victims of military operations. The ability to create interactive simulations allows performing recovery procedures remotely or speeding up the return to normal life after injuries. In addition, VR technologies can be integrated into the training system for future doctors: creating virtual clinical cases and training scenarios allows students to acquire practical skills without risks for real patients.

International cooperation is of great importance for accelerating the digital transformation of Ukrainian medicine. Organisations such as the World Health Organisation (WHO), the World Bank, and the United States Agency for International Development (USAID) actively support modernisation projects in countries in conflict or with

limited resources (Kruk *et al.*, 2020). Attracting external grants and technical assistance allows purchasing the necessary equipment for remote diagnostics, improving local telemedicine platforms, and organising large-scale training programmes for staff. Partnership with European states and organisations encourages the harmonisation of Ukrainian legislation with EU standards. This refers to personal data protection policies, cryptography, and information transfer protocols. All this generally increases the confidence of patients and doctors in innovative technologies, and creates a solid foundation for the legal use of digital tools. In the end, the international exchange of experience helps to find and adapt best practices from states that have already passed similar challenges, in particular, in the organisation of remote rehabilitation or psychological support for the population affected by military operations. Research has confirmed that the synergy of local specifics and global innovations allows quickly and effectively integrating advanced medical solutions into the reality of Ukrainian healthcare (Kotsarenko *et al.*, 2023).

However, along with these economic, organisational, and technical challenges, it is important to pay due attention to the ethical aspects of using digital tools in the medical field. Protecting patient privacy and privacy is becoming increasingly critical as the use of artificial intelligence, telemedicine, and robotic therapeutic technologies significantly increases the volume and speed of medical information processing. E. Chandrakar & A. Dahiya (2024) emphasised that it is necessary to create an effective legal framework that would clearly regulate the rules of access to data and prevent possible abuse by commercial structures or third-party organisations. They noted that the patient's informed consent to data processing and transparency of these processes are the cornerstone of trust in new technologies. Patients should know how and for what purpose their information is used, and be able to revoke permission to process it if necessary.

It is also important to ensure reliable cybersecurity in the field of robotic therapy and virtual psychotherapy. According to L. Grosman-Rimon & P. Wegier (2024), these industries collect particularly sensitive information related to mental and physical health, making it a potential target for cyber-attacks. The researchers stressed that technical security tools should be combined with clear incident response procedures to quickly identify the problem and minimise damage in the event of a data leak. They also stressed the importance of creating instructions that are accessible to patients themselves, so that the latter understand how their data is stored and who has access to it. The introduction of security standards for developers and providers of medical technologies, according to researchers, will help to prevent the implementation of unfair practices and strengthen the security of private information.

There are concerns about the depersonalisation of medical care, where excessive reliance on AI and digital algorithms can displace direct human contact. S.O. Hansson & B. Fröding (2024) warns that reducing the time a doctor

spends communicating with a patient can negatively affect the quality of treatment and the patient's emotional state. Socio-cultural factors also play a significant role: in different regions and among different population groups, the attitude to technology in medicine may differ significantly. Therefore, the introduction of AI should be accompanied by training programmes for doctors that explain the ethical and cultural aspects of using innovative solutions to prevent a decrease in the level of empathy and trust on the part of patients.

According to I.O. Bogomazova (2024), some of the problems related to the preservation of privacy can be solved by legislating the procedure for informed consent to the use of medical data for research or commercial purposes. Anonymisation of information that is necessary for training machine learning algorithms becomes particularly relevant. Care should be taken to ensure that anonymisation preserves the usefulness of data for researchers and does not interfere with scientific progress. The researcher pointed out that it is advisable to create independent regulatory bodies or structures that would conduct security audits and monitor compliance with established standards on the part of developers and suppliers of digital medical solutions. This approach will help maintain trust in medical institutions and individual specialists who directly use technological tools for treatment and diagnosis.

Thus, the Ukrainian healthcare system faces a number of fundamental challenges – from limited finances and uncoordinated legislation to a lack of digital literacy among doctors and patients. Despite this, the potential of technologies, in particular, telemedicine, AI and VR, remains extremely large. In the context of military operations and the difficulties associated with them, these solutions can serve as a basis for optimising resources, expanding access to quality medical care, and restoring the health of military personnel and civilians. However, the real benefit from the introduction of digital tools is possible only with systematic support from the state and active international cooperation aimed at forming the necessary legal, financial and educational foundations. An equally important component is ethical – the protection of confidential data and the preservation of the human face of medicine, where technology supports the doctor, and does not replace them. Only such an integrated approach will ensure an effective and secure digital transformation of the Ukrainian medical industry and help to strengthen its potential on the way to integration into the global medical space.

Key recommendations for digitalisation of healthcare

Considering the results of the study, a number of recommendations are proposed for further integration of digital technologies into the healthcare system, which will create a unified, efficient, and safe medical ecosystem. First, it is necessary to implement unified technical standards for the collection, storage, and exchange of medical data. Creating a single protocol will ensure compatibility between different information systems and devices, reduce the risk

of data duplication, and facilitate prompt clinical decision-making. Second, legal regulation in the field of digital medicine should be strengthened. The development of clear regulations on the protection of personal information, defining mechanisms for liability for violations and setting standards for electronic document management will help not only to protect patients' data, but also strengthen the trust of both medical professionals and patients themselves in digital solutions. Third, special attention should be paid to improving digital literacy among medical personnel and users of medical services. The organisation of regular trainings, seminars, webinars, and courses on the use of digital technologies will help to reduce barriers to the introduction of innovative tools, allow doctors to use the capabilities of telemedicine, artificial intelligence, and virtual reality more effectively, and patients will be more confident in navigating new services.

An important component of the strategy is the promotion of interdisciplinary collaboration. Joint projects involving specialists in medicine, IT, engineering, and social sciences will contribute to the development and implementation of adapted innovative solutions that meet the specifics of modern healthcare challenges. Ultimately, financial support remains a critical factor. Actively attracting public resources, private investment, and international grant programmes will allow implementing large-scale projects to modernise medical infrastructure, ensure the purchase of modern equipment, and support constant software updates. An integrated approach, which includes the unification of technical standards, legal regulation, digital literacy, interdisciplinary interaction, and financial support, will become the basis for further digital transformation of healthcare and will contribute to the creation of a modern patient-oriented health care system.

Conclusions

As part of the study, a comprehensive analysis of digital technologies in the healthcare sector was carried out and a comprehensive conceptual model was developed that combined telemedicine solutions, artificial intelligence, virtual reality, and IoMT devices. Systematic study of scientific literature, detailed familiarisation with current innovations and methodological analysis of the collected data helped to achieve the declared goal. In the course of research, the advantages of each technological area were considered, key difficulties associated with their implementation were identified, and specific recommendations were formulated for optimising the interaction of all components within a single digital ecosystem.

The results confirmed that digital reform of the medical industry opens up new opportunities for improving diagnostics and treatment, in particular, through the active use of remote patient monitoring and automation of routine operations based on machine learning algorithms. The proposed conceptual model illustrates how a combination of telemedicine services, AI-based platforms, and virtual reality tools can improve the quality of healthcare

delivery by ensuring continuous data exchange between all healthcare participants. The practical value lies in creating a methodological basis for further implementation of integrated digital solutions both in clinical activities and in the modernisation of information systems of medical institutions. The proposed options for solving the problems of technology compatibility, legal regulation, and improving digital literacy provide the basis for more effective implementation of innovative approaches in the work of healthcare institutions. Further study involves conducting pilot projects to test the viability of the developed

model in practice, and developing security standards and data transmission protocols. This will improve the concept itself, adapting it to the specifics of medical institutions in different regions, and guarantee reliable protection of personal information and stable quality of medical services.

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Conflict of Interest

None.

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Аналіз сучасного стану комп'ютерних систем в сфері віртуальної охорони здоров'я

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Анотація. Метою даного дослідження була розробка концептуальної моделі інтеграції сучасних цифрових технологій у сфері охорони здоров'я з адаптацією до українських умов та створення єдиної національної медичної екосистеми. Дослідження базувалося на систематичному аналізі літературних джерел із застосуванням контент-аналізу та систематичного підходу. Для збору даних використовувались публікації, оглядові статті та офіційні документи, доступні у провідних наукових базах даних (PubMed, Scopus, Web of Science) за останні п'ять років. Алгоритм дослідження включав попередній відбір джерел за критеріями актуальності, достовірності та наукової значущості, подальший аналіз технологічних рішень у напрямках телемедицини, штучного інтелекту та віртуальної реальності, а також оцінку їх інтеграційної сумісності з існуючими електронними системами охорони здоров'я. Аналіз охоплював економічні, етичні та правові аспекти впровадження інноваційних технологій. Отримані результати свідчили про те, що телемедицина сприяє покращенню доступу до медичних послуг у віддалених регіонах, проте її впровадження обмежене через недосконалу інфраструктуру та відсутність єдиних нормативно-правових стандартів. Аналіз алгоритмів штучного інтелекту засвідчив їх високий потенціал у діагностиці та прогнозуванні захворювань, що вказує на необхідність адаптації технологій до локальних умов. Дослідження можливостей віртуальної реальності підтвердило її ефективність у терапії, реабілітації та медичній освіті, хоча впровадження супроводжується технічними складнощами. Сформована концептуальна модель враховувала як технічні, так і організаційні чинники цифровізації охорони здоров'я, що може стати основою для стратегічного планування подальших експериментальних впроваджень у національну систему охорони здоров'я. Отже, проведений аналіз дозволив виявити основні тенденції та проблемні зони впровадження цифрових технологій, що сприяють підвищенню якості медичних послуг та оптимізації ресурсів. Результати дослідження формують наукову базу для розробки практичних заходів і стратегій цифровізації, адаптованих до умов України

Ключові слова: телемедицина; віртуальна реальність; штучний інтелект; конфіденційність медичних даних; цифрова трансформація



Development of a chitosan polymer based composite haemostatic agent and a method for evaluation of performance

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Abstract. The aim of this study was to develop an in vitro method for evaluating the hemostatic efficacy of composites and to investigate the factors influencing the hemostatic efficacy of polymer composite materials based on chitosan using the developed method. Existing contact haemostatic composite materials based on zeolites and chitosan polymer were reviewed. For research and quality control work with haemostatics, it was required to test their haemostatic performance. Conducting in vivo studies required intervention in a living organism and is undesirable for ethical reasons. A generally accepted system for assessing the efficacy of hemostatic agents in vitro does not exist. A methodology for analyses to

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determine the haemostatic properties of composites has been developed. The main quality attributes of haemostatics, such as gel formation time and permeability, were determined. The composition and method for producing the finished haemostatic composite material were developed. The composite contains a salt of chitosan and lactic acid, polyethylene glycol 4,000. The effect of carboxylic acids and surfactants on the properties of the composite was studied. Chitosan with a molecular weight of at least 80,000 Dalton and a degree of deacetylation of 85-95% was selected. The “active” and “inactive” forms of chitosan, which affect the haemostatic properties of the composite, were studied. The process for obtaining the “active” form of chitosan from the “inactive” form by redeposition, which consists in the interaction of chitosan with carboxylic acid to obtain a soluble salt and subsequent alkali precipitation, was developed. The influence of the following factors on the properties of the resulting product was studied: solvent in the salt synthesis reaction; molar ratio of lactic acid and chitosan; particle size of the haemostatic powder. The resulting haemostatic is effective in binding water and blood into a fixed gel-like clot. The product has sufficient permeability and haemostatic performance. The clot formed by binding liquids is stable for 24 hours

Keywords: lactic acid; polyethylene glycol; composite polymeric materials; gel formation; permeability; *in vitro*

Introduction

The issue of first aid is extremely important. According to statistics, blood loss is the main cause of death of the wounded soldiers in combat and emergency situations. For example, R.K. Latif *et al.* (2023) state that a large number of casualties die from bleeding, often before they can be treated. N.P. Charlton *et al.* (2021) describe that tactical medicine protocols focus on the effective use of haemostatic agents (haemostatics) such as powders, bandages, and applicators. The most common products include gelatine sponge; collagen plate; oxygenated regenerated cellulose; combined preparation with fibrin glue. However, the Tactical combat casualty care guidelines (2024) state that these topical haemostatic agents cannot stop bleeding from large arteries and veins on their own. They must be used in combination with other methods of stopping bleeding.

Celox Medical (2025) report a dramatic change in mortality statistics with the use of contact haemostatics for massive bleeding, especially in areas where tourniquets are not available (buttocks, armpits, neck). P. Yu & W. Zhong (2021) state that two main groups of contact haemostatics have a great advantage in stopping bleeding – chitosan-based composite materials (e.g. Celox®, ChitoGauze®) and kaolin-based materials (QuikClot®), which can stop almost any bleeding in a matter of seconds. The advantages of this type of haemostat include hypoallergenicity due to the fact that a physical reaction-absorption occurs in the contact zone and induce a local sharp rise in temperature.

Y. Zheng *et al.* (2023) state in their work that typical production technologies for inorganic hemostatics include 3D printing, freeze-drying, electrospinning, and vacuum filtration, which provide materials in the form of three-dimensional scaffolds, porous masses, soft membranes, or hydrogels. Chitosan serves as the foundational material for an alternative class of contact haemostatics. The advantages of chitosan-based composites include their properties: their performance does not decrease at low temperatures; the performance does not depend on impaired blood clotting factors; the presence of the composite in the wound provides the effect of gluing damaged soft tissues and prevents the resumption of bleeding during transport.

D. Tripathi *et al.* (2021) report that chitosan-modified gauze achieved a hemostatic effect nearly threefold faster than standard gauze, and facilitated more rapid wound closure.

D. Alemu *et al.* (2023) emphasised the widespread use of chitosan in various industries, including medicine and pharmacy. D. Yan *et al.* (2021) and A. Guarnieri *et al.* (2022) reported that the unique features of chitosan-based composites include antibacterial activity against gram-positive and gram-negative bacteria, which reduces the risk of wound infection and ensures faster healing without the massive use of antibiotics. The haemostatic mechanism of action of chitosan-based composites is that the latter, having a positive charge, binds negatively charged red blood cells and platelets in the blood, thus, forming a dense blood clot. J. Bar *et al.* (2017) reported that chitosan-containing haemostatics work effectively independently of coagulation factors without affecting the natural coagulation cascade.

Chitosan is completely biodegradable under the influence of microbial enzymes such as chitinases and chito-biases. Chitosan is characterised by mucoadhesive properties, i.e. the ability to adhere to mucous membranes, the ability to absorb biological fluids and help regenerate tissues (Liu, 2022). Modified forms of chitosan in the form of composite materials have been used in the form of various haemostatic products (Das *et al.*, 2024; Zeng *et al.*, 2025). Chitosan does not exhibit a pronounced gel formation property when in contact with liquids (except for acid solutions) and has weak haemostatic properties (Gheorghită *et al.*, 2023). Chitosan has free amino groups and is able to form salts with acids that have stronger haemostatic properties, such as salts of lactic, succinic, acetic acids and some other organic acids with a short carbon chain (Pieklarz *et al.*, 2021). Bicarboxylic and tricarboxylic acids can form intermolecular ionic cross-links between the amino groups of adjacent chitosan chains, which allows for a three-dimensional “mesh” of chitosan molecules.

Chitosan derivatives are a promising class of haemostatic agents. Thus, the study and optimisation of methods for the synthesis of haemostatic chitosan-based composite materials is an urgent task that will improve user properties and reduce the level of blood loss in wounds. Research

work with haemostatics requires that they be tested for haemostatic performance (Rezabeigi *et al.*, 2022; Zhang *et al.*, 2022). At present, there is no generally accepted system for evaluating the efficacy of haemostatics *in vitro*, and *in vivo* studies require intervention in a living organism, which is not desirable for ethical reasons (Kiani *et al.*, 2022). Existing *in vitro* methods for evaluating the efficacy of hemostatic materials are complex to implement and resource-intensive for quality control, being more suitable for the development stage of a hemostatic agent (Nativel *et al.*, 2024). Therefore, the search for simple but effective *in vitro* methods remains relevant for testing haemostatics.

The aim of the work was to develop an *in vitro* method for the evaluation of the haemostatic efficacy of chitosan-containing composites and to study the factors influencing the haemostatic performance of polymeric composite materials based on chitosan using *in vitro* methods.

Materials and Methods

Chitosan is an aminosaccharide, a derivative of a linear polysaccharide, macromolecules consist of randomly linked β -(1-4) D-glucosamine units and N-acetyl-D-glucosamine (Aranaz *et al.*, 2021). Chitosan is a solid substance in the form of scales with a particle size of no more than 10 mm or powder of various degrees of grinding. White to off-white, often with yellow or grey tint. Odourless. Insoluble in

water, alkalis, solvents. It is soluble in dilute solutions of some organic and inorganic acids. Chitosan is a natural polymer with a molecular weight of several thousand to hundreds of thousands of Dalton (Fig. 1) (PubChem. Chitosan, n.d.). To perform the study, 6 samples of chitosan produced by Zhengzhou Delong Chemical Co., Ltd. (China) with different viscosities and degrees of deacetylation were used (Table 1). Other starting components used to produce haemostatic composites are lactic acid, sodium hydroxide, ethyl alcohol, polyethylene glycol. Lactic acid (α -oxypropionic, 2-hydroxypropanoic) is a monobasic oxycarboxylic acid, a light yellow to dark yellow liquid. It is soluble in water and alcohols. In the study, lactic acid was used from PURAC bioquímica s.a. (Spain). Sodium hydroxide is a white crystalline substance, highly hygroscopic, and highly soluble in water. It has strong alkaline properties. In this study, sodium hydroxide was used from Merck KGaA (Germany). Ethyl alcohol is a single-atom alcohol, a colourless volatile liquid with a characteristic odour and burning taste. It is a good solvent for other organic substances. The study used 96% alcohol produced by Lopatyn Distillery LLC (Ukraine). Polyethylene glycol (PEG) is a water-soluble polymer, a non-ionic surfactant. Depending on the average molecular weight of the polymer, it is a viscous liquid, gel-like or solid substance. PEG 4,000 manufactured by Clariant Product (Deutschland) GmbH (Germany) was used in the study.

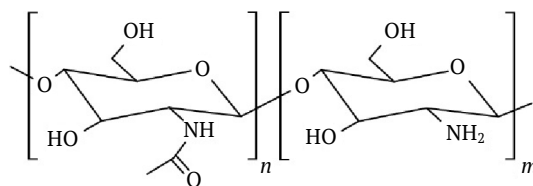


Figure 1. Chitosan molecule

Source: developed by the authors of this study

Table 1. Characteristics of the original chitosan

Parameters from the certificate of quality	Chitosan					
	X1	X2	X3	X4	X5	X6
Viscosity, cPs	7	13	44	54	80	170
Degree of deacetylation, %.	91	90	95	95	85	85

Source: developed by the authors of this study based on certificates of analysis from the chitosan manufacturer

Preparation of “active” chitosan. The method of producing “active” chitosan is based on precipitation, i.e., the production of salt from chitosan and lactic acid, followed by alkaline precipitation of chitosan. Water is loaded into the mixer and chitosan is added while stirring. Small portions of lactic acid are added to the suspension in terms of 1 mol/mol of chitosan. The addition of acid significantly increases the viscosity of the reaction mass. A viscous mass is formed with particles of undissolved chitosan. The mass is kept under stirring for 1 hour. During the holding time, a slight decrease in the

viscosity of the mass is observed, as well as the dissolution of chitosan particles (Fig. 2, a). After the aging is completed, an aqueous solution of sodium hydroxide in the amount of 0.95 mol per 1 mol of chitosan is added to the reaction mass in small portions. During the reaction, the formation of fibrous chitosan is observed (Fig. 2, b). After the addition of alkali, a suspension is formed consisting of a liquid phase (water and sodium lactate) and fibres of “active” precipitated chitosan. The precipitated active chitosan is filtered and washed first with water and then with ethanol.

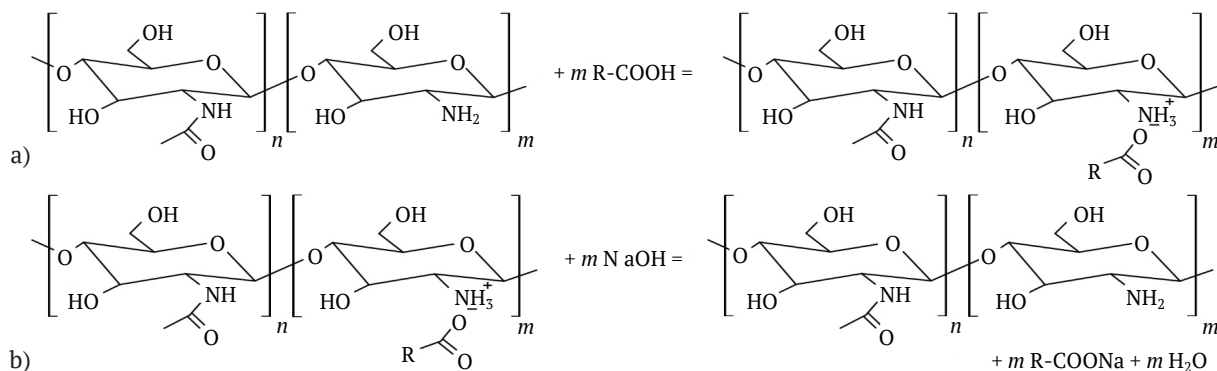


Figure 2. Reactions of chitosan redeposition,

where a – obtaining a carboxylic acid salt; b – precipitation of “active” chitosan

Source: developed by the authors of this study

Preparation of a solid haemostatic composite. The method for obtaining the haemostatic composition is the reaction of “active” chitosan (m.w. 50-200 kDa) with lactic acid at room temperature, followed by mixing with a surfactant. It is planned to use different chitosans for synthesis, in particular, chitosans with different degrees of deacetylation and different molecular weights. The method of producing haemostatic composites consists in the production of a composite material based on a carboxylic acid salt and chitosan (Fig. 3). Ethyl alcohol and water in a ratio of 7:3 wt% are loaded into a mixer. Next, lactic acid is added

under vigorous stirring in the amount of 0.5 mol per 1 mol of chitosan. Then, a surfactant, polyethylene glycol 4,000, is added to the reaction mass. The mass is kept under stirring for 1 hour. As a result, a viscous mass is obtained with the inclusion of insoluble chitosan particles. The solvent is removed from the resulting mass under vacuum, then dried with flowing air at a temperature not exceeding 60°C. The composite is dried to a moisture content of no more than 5% by weight. The resulting fibrous films of the haemostatic composite are crushed and calibrated. A fraction of not more than 0.8 mm is used.

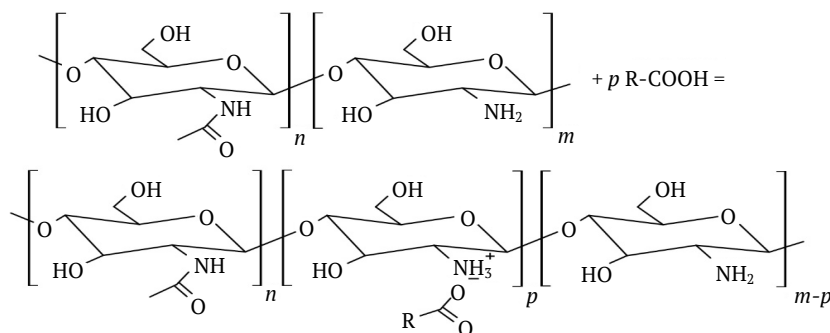


Figure 3. Reaction for the preparation of chitosan salt

Source: developed by the authors of this study

In vitro method for the evaluation of haemostatic performance. The development of *in vitro* method for the evaluation of haemostatic performance was carried out using the ready-made haemostatic composite Celox® as a reference agent. *In vitro* parameters of the method were chosen for the following reasons:

- ◆ take water R as the Quality Control (QC) medium;
- ◆ the process of formation of a fixed gel (hereinafter referred to as gel formation) when the composite is in contact with liquids should be as fast as possible, therefore the time of formation of a fixed gel plug is an important parameter;
- ◆ the composite should have permeability limits when in contact with liquids, as there is a risk of: the formation of a gel layer of insufficient depth and, as a result,

strength; or in the second case, too high permeability of the liquid through the composite layer and the inability to stop bleeding.

The properties of the haemostatic composite material were studied by evaluating the gel formation time and permeability.

Gel formation time. Added 40 ml of water R into a 50 ml chemical beaker with an internal diameter of 38±2 mm, and added 2.0 g of the drug at a time, spreading it evenly over the surface of the liquid in a circular motion from the walls to the centre of the beaker. A gel-like mass should form within no more than 180 seconds, which remains stationary when the beaker is turned 180°. The resulting gel should retain its consistency for at least 24 hours (Fig. 4). At least 2 parallel tests are carried out.

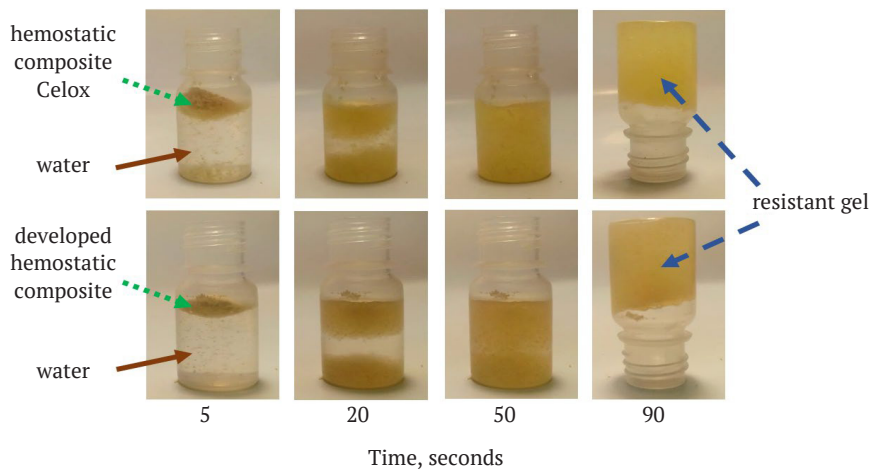


Figure 4. Gel formation during testing of Celox and the developed haemostatic composite

Source: developed by the authors of this study based on the findings of experimental research

Permeability and wetting. Added 5 ml of a 0.25% solution of Ponceau 4R food colourant (E-124) in *water R* in a test tube with a diameter of 13-14 mm, and quickly added 2.00 g (m) of the composite at a time. After 1 minute, performed the following steps:

- 1) measure the value of the wetted gel-like layer in mm;
- 2) pour out the remaining dry weight of the drug, weigh it (m_1) and calculate % moisture content using formula (1):

$$\% \text{ wetting} = (m - m_1) / m \times 100, \quad (1)$$

where m – the weight of the drug to be tested, g; m_1 – the residual dry weight of the drug after the test, g.

Note: The value of the gel layer should be at least 5 mm. % moisture content should be between 35.0 and 70.0%.

Results and Discussion

Evaluation of haemostatic performance of the reference product “Celox®”. *Water R* was chosen as *in vitro* blood substitute to develop *in vitro* haemostatic performance method. The first stage of the method development was carried out using the reference composite Celox®.

The parameters “Gel formation time” and “Permeability and wetting” were studied and developed to test the reference product for haemostatic performance. As a result of the studies, it was found that the gel formation parameters depend on: the quantitative ratio of gestatic composite – water; the amount of haemostatic (and, accordingly, water) (Table 2); the size of the vessel in which the test is carried out (Table 3). As a result of the studies, a threshold ratio of 20:1 was established at which water could still be completely bound by the haemostatic composite to form a stable gel. At higher ratios, no gel clot was observed. Taking into account that water and blood have different nature and properties, the haemostatic composition was tested on blood with a ratio of 20:1 and 25:1. The results were reproduced for water and blood. Thus, the use of *water R* as a QC medium can be considered acceptable for the *in vitro* method, therefore water in the ratio of 20:1 was chosen for further tests. During the gel formation studies, it was observed that in some cases the time of complete water binding differs from the time of formation of a fixed gel. From the results of the studies, it was found that the time indicators depend on the size of the vessel in which the test is performed (Table 2).

Table 2. Dependence of the time of water binding and gel formation on the diameter of the vessel, 0.5 g of powder, 10 g of water

Parameter	Diameter of a cylindrical vessel with a flat bottom, mm							
	12	14	17	20	22	25	30	40
Time of complete water binding, s	-	300	80	70	55	50	35	15
Gel formation time, s	90	70	70	70	70	50	40	40

Source: developed by the authors of this study based on the findings of experimental research

As the vessel diameter increases, the area of contact between the haemostatic and the liquid increases, and the height of the liquid column decreases, which contributes to faster wetting of the haemostatic, water binding and gel formation. At small vessel diameters, the composite forms a gel layer, which allows all the water to

penetrate the powder, and for vessels with larger diameters, the powder absorbs water quickly, but the limiting process is gel formation. For further gel formation tests, a 38 mm inner diameter chemical beaker was chosen. For this vessel, the effect of increasing the gel weight was tested (Table 3).

Table 3. Dependence of water binding and gel formation time on powder weight, vessel diameter 38 mm

Parameter	Weight of composite / water, g			
	0.5 / 10.0	1.0 / 20.0	2.0 / 40.0	3.0 / 60.0
Time of complete water binding, s	15	35	45	180
Gel formation time, s	40	70	90	110
Gel retention time, h	> 24	> 24	> 24	2.1

Source: developed by the authors of this study based on the findings of experimental research

As the amount of haemostatic composite and water increases, the height of the liquid column also increases, leading to an increase in the time of water binding and gel formation. After gel formation, the beakers were inverted and the gel mobility was observed. For powder weights of up to 2 g, the resulting gel remained stationary for at least 24 hours, while for a 3 g composite weight, the immobility lasted about 2 hours, after which the gel flowed out of the beaker. This observation can be explained by the too large weight of the gel, which did not allow the adhesive and cohesive bonds to hold it in the glass. Therefore, for *in vitro* method, the amount of the composite was chosen to be 2.0 g. This amount of the composite also correlates well with the commercially available Celox® in the amount of 2 g, which is designed for household use.

Taking into account the studied cases when all the water has not yet been bound by the haemostatic composite during testing in a narrow vessel, and the top layer is already stationary, there is a need to study the permeability of water through the powder. From observations, it was found that the optimal height of the column of the resulting gel should be at least 15-25 mm for wide vessels (25-40 mm in diameter) and at least 5 mm for narrow vessels (12-14 mm in diameter). Gels obtained from composites with lower permeability values have low strength and can collapse under the pressure of the liquid. Based on the data obtained, *in vitro* methods for evaluating the haemostatic performance of chitosan-based composite materials were developed.

Study of the influence of carboxylic acid and solvent type and amount on composite synthesis. To solve this problem, haemostatic composites using chitosan and various organic acids were obtained. The low efficiency of the composites formed with succinic and citric acids was

found. Succinates and citrates of chitosan quickly form a gel upon contact with water (20-45 s), but their stability time does not exceed 30-50 minutes, which does not allow obtaining a composite material with effective haemostatic properties. The study of the gel formation properties of chitosan salts and monobasic carboxylic acids showed a slightly longer gel formation time (1-3 min) and significantly better stability of the formed gels – up to 24 hours. It was found that the length of the carbon chain in the range of C₁...C₃ does not significantly affect the properties of the obtained composites. For the further development of a solid haemostatic composite material, lactic acid was chosen among organic carboxylic acids due to its sufficient haemostatic performance and safety for the human body, as it is naturally formed in the body. Lactic acid also acts as a plasticiser in the composite. As a result of the work performed, it was determined that the properties of the composite are affected by the ratio of chitosan to acid in the formed salt. With an increase in the acid content, the gel formation efficiency increases. At acid content of 0.6 mol/mol or more, a gel unstable for 24 hours is formed (Table 4).

In the course of the work, the possibility of using different solvents for the synthesis of haemostatic composite material was studied. It was found that the nature of the solvent significantly affects both the process parameters and the haemostatic performance of the obtained composites. It has been established that salts of organic acids and chitosan exhibit better gel formation properties when water-alcohol solvents are used for their synthesis. The aqueous-alcohol solvent has process advantages: the reaction mass has a lower viscosity, which simplifies the mixing conditions; it evaporates more easily and quickly. It was found that haemostatic performance is affected by the concentration of alcohol in the solution used as a solvent (Table 5).

Table 4. Dependence of water binding and gel formation time on the molar ratio of chitosan: acid

Parameter	Molar ratio acid: chitosan						
	0.25:1	0.30:1	0.40:1	0.50:1	0.60:1	0.75:1	1:1
Water binding time, s	90	65	55	50	50	45	40
Gel formation time, s	-	140	110	90	90	85	80
Gel retention time, h	-	> 24	> 24	> 24	18	8	1.5

Source: developed by the authors of this study based on the findings of experimental research

Table 5. Dependence of water binding and gel formation time on the concentration of ethanol in the solvent

Parameter	Alcohol concentration in the solvent, % wt.					
	40	50	60	65	70	75
Time of complete water binding, s	55	70	60	70	50	-
Gel formation time, s	125	110	110	95	90	-

Source: developed by the authors of this study based on the findings of experimental research

The best results of haemostatic performance are demonstrated by the samples obtained using 70% (w/w) ethanol. With a decrease in the concentration of alcohol in water, the viscosity of the reaction mass increases during the preparation of the haemostatic composition, which necessitates an increase in the amount of solvent. In addition, the properties of the haemostatic, in particular, the gel formation time, deteriorate. When using a more concentrated alcohol solution than 70%, the formation of a haemostatic composition is impossible, because in this case chitosan does not react with acids.

Study of the effect of surfactant amount and preparation method of “active” chitosan. To improve haemostatic performance, the composite can contain a medically acceptable surfactant. In this study, polyethylene glycol 4,000 was used. It can also serve as a plasticiser and is safe for the human body. The results of the study showed that the presence of 1.0% polyethylene glycol 4,000 in the haemostatic composite reduces the time of water binding and gel formation due to faster water permeability (Table 6). Further increase in the content of PEG-4,000 above 1.0% does not improve the performance of the composite.

Table 6. Dependence of water binding and gel formation time on the content of PEG 4,000 in the composite

Parameter	PEG-4000 content in the composite, % wt.						
	0.00	0.25	0.50	0.75	1.00	1.25	1.50
Water binding time, s	60	60	55	55	50	50	50
Gel formation time, s	105	100	100	95	90	90	90

Source: developed by the authors of this study based on the findings of experimental research

The presence of a surfactant in the haemostatic composite can significantly improve the efficiency of gel formation with blood, since blood has a much higher viscosity and lower permeability compared to water. In the course of the work, it was found that the haemostatic composite

material which contains chitosan lactate and PEG 4,000 meets the established requirements and has satisfactory efficiency for both water and blood tests. Studies have shown that the use of chitosans of different grades/viscosities to produce composites has produced inconsistent results (Table 7).

Table 7. Performance of haemostatic composites of different brands/manufacturers of chitosans

Chitosan	Viscosity, cPs	Baseline chitosan “activity”	Tests of chitosan haemostatic samples	
			Permeability	Gel formation efficiency
X1	7	-	-/-	-/-
X2	13	-	-/-	-/-
X3	44	-	-/+	-/-
X4	54	-	-/+	-/-
X5	80	+	+	+
X6	170	-	-/+	-/+

Note: test results are for two states of chitosan – “inactive” and “active” except for sample X5.

Source: developed by the authors of this study based on the findings of experimental research

Thus, haemostatic properties can be influenced by the characteristics of the original chitosan, in particular, molecular weight (viscosity), degree of deacetylation and chitosan “activity”. It has been suggested that the phenomenon of unstable results for different chitosans may be due to the presence of chitosan in the “active” form, i.e. when the shape and arrangement of polymer molecules does not facilitate uniform access of acid molecules to them, and the “inactive” form, which does not provide uniform access of acid molecules to amino groups. C. Carrera *et al.* (2023) in their work consider modifications of chitosan with different surface characteristics and the possibility of creating a variety of individual chitosan adapted to different applications. In view of the above, it became necessary to establish the possibility of using “inactive” chitosan for the production of haemostatics. The “active” form of chitosan was obtained by synthesising a chitosan salt followed by precipitating the

active chitosan through interaction with an alkali. Thus, the chitosan samples X1, X2, X3, X4 and X5 were redeposited.

The composites obtained from chitosans X1 and X2 showed low permeability and gel formation efficiency both in the initial state and after “activation”. Composites based on X3 and X4 showed low permeability and gel formation efficiency in the initial state. After “activation”, the permeability values are normal. The gel formation efficiency improved, but beyond the normal range. The composite based on X5 showed good results of permeability and gel formation efficiency in the initial state (without additional “activation”). The composite with X6 showed low permeability and gel formation efficiency in the initial state. After “activation”, the sample meets the testing standards. Of the 6 different chitosans, only one is suitable for use in the synthesis of composite haemostatics according to the redeposition-free scheme. The other chitosans do not produce compositions

that meet the requirements without activation. It was found that even in the case of chitosan precipitation, not all of them can be used to prepare a haemostatic composite – chitosan must have a molecular weight of at least 80,000.

Study of the particle size distribution of a haemostatic composite. The dependence of the efficiency of composites on the size of powder particles was studied (Table 8).

Table 8. Dependence of water binding and gel formation time on the particle size of the composite

Parameter	Fraction or mixture of fractions, mm									
	0-0.08	0.08-0.25 (A)	0.25-0.5 (B)	0.5-0.63	0.63-0.8	0-0.8	10% A + 90% B	20% A + 80% B	30% A + 70% B	40% A + 60% B
Water binding time, s	-	40	55	80	90	50	50	50	55	60
Gel formation time, s	-	70	80	105	140	90	70	70	85	90

Source: developed by the authors of this study based on the findings of experimental research

The results showed that the best gel formation efficiency was achieved with a fraction of up to 0.5 mm. At the same time, it was found that composites with a particle size of less than 0.5 mm have low permeability. Thus, the

optimal particle size distribution of the haemostatic was selected – up to 0.8 mm. The IR spectra of the haemostatic composite material based on chitosan were obtained in the course of the study (Fig. 5).

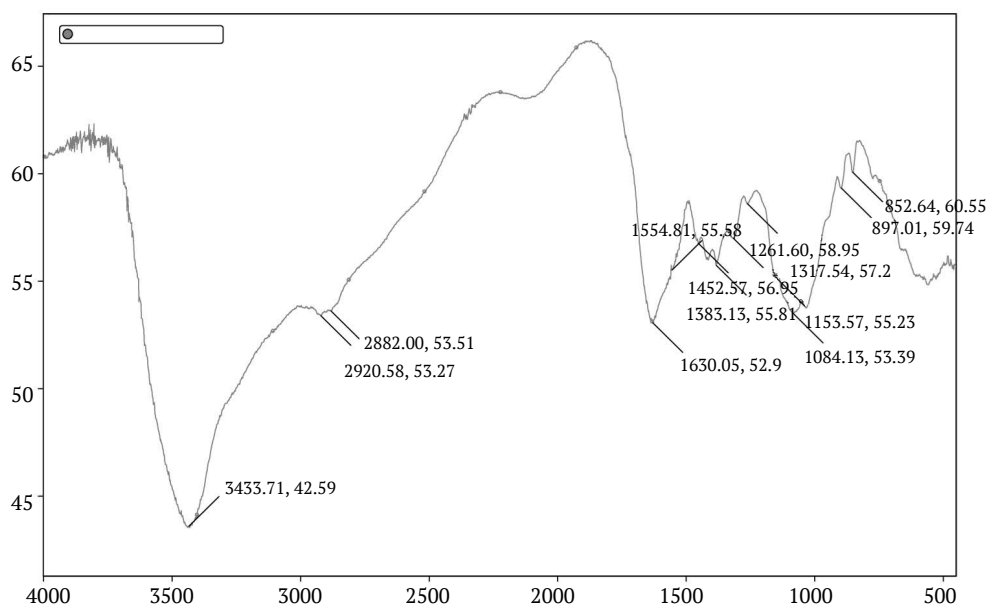


Figure 5. IR spectrum of haemostatic composite material

Source: developed by the authors of this study based on the findings of experimental research

Thus, during the development of the method, an optimal polymer composition was established, containing chitosan lactate (molar ratio 0.5:1) and polyethylene glycol in an amount of 1% wt. It is proposed to use a 70% wt. water-alcohol solution as a solvent. The solid composition has a particle size of no more than 0.8 mm. The resulting haemostatic composite demonstrates high haemostatic properties. In this work, the authors have for the first time proposed an approach to developing *in vitro* quality control methods for chitosan-based haemostatic composites that do not require *in vivo* intervention. Celox Medical (n.d.) relies on *in vivo*

studies for their haemostatic composite, but information on *in vitro* gelation effectiveness studies is absent. The available general information from the manufacturer correlates with the obtained *in vitro* research results. For example, Celox Medical (n.d.) states that the haemostatic composite effectively absorbs blood, forms a gel in no more than 5 minutes, can be used in wounds of any shape, and is simple to apply and remove. The *in vitro* method developed by the authors allows for the quantitative assessment of the gelation effectiveness of the haemostatic composite – how much liquid the composite can absorb, how quickly, and

how long the gel can be retained. The method accurately reproduces results for both the QC environment and blood.

The method developed by the authors allowed for the study of the influence of factors on the gelation properties of composites based on modified chitosan. A. Das *et al.* (2024) demonstrate in their work various methods for obtaining chitosan-based composites. Modified chitosan show significant differences in composite properties compared to the original chitosan. The chitosan lactate obtained by the authors of this work demonstrates a high gelation capacity, unlike regular chitosan. K. Piekarczyk *et al.* (2021) in their work describe a method for obtaining chitosan lactate by physically mixing chitosan with acid using crosslinking agents. In contrast to the described synthesis method, the method proposed by the authors has advantages. The use of water-alcohol solvents for synthesis instead of water is proposed. A water-alcohol solvent has technological advantages: the reaction mass has lower viscosity, which simplifies mixing conditions; it evaporates more easily and quickly, and the resulting composite exhibits better hemostatic properties. The method proposed by the authors for obtaining a hemostatic composite based on chitosan lactate does not require the use of additional agents for crosslinking molecules. The authors' work shows the influence of the ratio of chitosan and lactic acid during the synthesis of chitosan lactate salt. The influence of surfactants on the composition is also additionally studied.

During the development of the method for obtaining a hemostatic composite, it was found necessary to pre-treat some chitosan samples that have an "inactive" form. Of the 6 different chitosans studied, only one is suitable for use in the synthesis of a composite hemostatic agent according to the scheme without redeposition. Other chitosans without activation form compositions that do not meet the requirements. C. Carrera *et al.* (2023) in their work consider methods of influencing the surface activity of chitosan at the synthesis stage. This method does not allow changing the properties of existing chitosan after its synthesis stage. To solve this problem, a method for obtaining the active form of chitosan by obtaining a salt of chitosan and acid with subsequent precipitation of active chitosan upon interaction with alkali is proposed. The proposed method made it possible to expand the choice of initial chitosans, but it was found that not all redeposition chitosans can be used to prepare a hemostatic composite – chitosan must

have a molecular weight of at least 80,000. This requires careful selection of chitosan depending on its properties, which necessitates further research to develop a method for determining the initial activity.

Conclusions

This paper presents the results of the development of an *in vitro* method for the evaluation of the haemostatic performance of chitosan-based composites using *water R* as a QC medium, including gel formation and permeability tests. The results of studies of the properties of chitosan and chitosan lactate are presented. It was found that to obtain a haemostatic, it is necessary to use chitosan with a molecular weight of at least 80,000 Dalton and a degree of deacetylation of 85-95%. It was found that the "active" and "inactive" forms of chitosan affect the properties of the composite. A method for obtaining the "active" form of chitosan from the "inactive" form was developed, which consists in redeposition: the interaction of chitosan with acid to obtain a soluble salt, followed by alkali precipitation. A method for obtaining the finished haemostatic composite material was developed, in particular, the acid and surfactant were selected. Lactic acid was used as a carboxylic acid because it provides high haemostatic performance. Polyethylene glycol 4,000 in the amount of 1% was used as a surfactant. The influence of various factors on the properties of the resulting composite was determined: the solvent used in the salt synthesis reaction; the molar ratio of lactic acid and chitosan; and the particle size of the haemostatic powder. The research results showed that 70% ethanol is the optimal solvent. The ratio of chitosan to acid should not be more than 0.6 mol/mol of chitosan. The haemostatic powder should have particles not larger than 0.8 mm. The properties of the obtained haemostatic composite were studied. The developed haemostatic composite is effective in binding water and blood into a stationary gel-like clot that is stable for 24 hours. The composite can be used for the production of haemostatic products in the form of applicators, tapes or bandages, which are more convenient for use in the field.

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None.

Conflict of Interest

None.

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Розробка композиційного гемостатичного засобу на основі полімеру хітозану та методу оцінки ефективності

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Анотація. Метою дослідження було розробити *in vitro* методику оцінки гемостатичної ефективності композитів та вивчити фактори впливу на гемостатичну ефективність полімерних композиційних матеріалів на основі хітозану за допомогою розробленої методики. Розглянуто існуючі контактні гемостатичні композиційні матеріали на основі цеолітів та полімеру хітозану. Для проведення досліджень та контролю якості роботи з гемостатиками необхідно тестувати їх гемостатичну ефективність. Проведення досліджень *in vivo* вимагає втручання в живий організм і є небажаним з етичних міркувань. Загальноприйнятої системи оцінки ефективності гемостатиків *in vitro* не існує. Розроблено методику проведення аналізів для визначення гемостатичних властивостей композитів. Визначено основні показники якості гемостатиків – час гелеутворення та проникність. Розроблено склад та методику отримання готового гемостатичного композиційного матеріалу. Композит містить сіль хітозану та молочної кислоти, поліетиленгліколь 4000. Досліджено вплив карбонових кислот та поверхнево-активних речовин на властивості композиту. Підібрано хітозан з молекулярною масою не менше 80000 Дальтон та ступенем деацетилювання 85-95 %. Досліджено «активну» та «неактивну» форми хітозану, що впливають на гемостатичні властивості композиту. Розроблено технологію отримання «активної» форми хітозану з «неактивної» шляхом переосадження, що полягає у взаємодії хітозану з карбоною кислотою

з отриманням розчинної солі та наступним висадженням лугом. Досліджено вплив факторів на властивості отриманого продукту: розчинник в реакції синтезу солі; мольне співвідношення молочної кислоти та хітозану; розмір часток порошку гемостатика. Отриманий гемостатик є ефективним в зв'язуванні води та крові в нерухомий гелеподібний згусток. Засіб має достатню проникність та гемостатичну ефективність. Згусток, що утворюється внаслідок зв'язування рідин, є стійким протягом 24 годин

Ключові слова: молочна кислота; поліетиленгліколь; композиційні полімерні матеріали; гелеутворення; проникність; *in vitro*



Computer modelling of LoRa network parameters using the FLoRa simulator

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Abstract. The purpose of this study was to investigate and compare the results of calculating the parameters of the LoRa network obtained by computer modelling with the results of experimental measurements. To fulfil this purpose, the methods of computer modelling of signal loss were used. Specifically, the study described a modification of the FLoRa simulator to estimate signal losses during propagation, perform computer simulations in FLoRa, and compare the findings obtained with the data obtained during the experiment. In addition, the RSSI values obtained in the simulation were compared with the experimental values. The functionality of the FLoRa software simulator was extended by adding signal power loss values to the simulation results table. Using the FLoRa software, the study simulated the signal power loss along the propagation path at frequencies of 433 MHz, 868 MHz, and 2.4 GHz. A comparative analysis revealed that the simulation results for different spreading factors and different signal frequencies correspond to the experimental data. It was found that the received signal power values are represented in the software as RSSI values. The signal power at the input does not correspond to the RSSI values and depends on the concrete type of receiver chip, and therefore the RSSI calculation methodology should be adjusted. It was confirmed that the results table should display both the signal strength at the receiver input and the RSSI value. To improve the accuracy of the FLoRa computer model, specifically, the calculation of RSSI values, it was proposed to consider the specific features of measuring these values by different types of LoRa receiver chips. The obtained findings can be used to improve the accuracy of modelling and, accordingly, the quality of designing networks based on LoRa technology

Keywords: Long Range; computer simulators; Framework for LoRa; Received Signal Strength Indicator; signal power loss; distribution factor; simulation parameters

Introduction

LoRa (Long Range) technology is widely used in modern sensor networks to ensure reliable communication between nodes. The advantages of this technology are long data transmission distances, high noise immunity, and minimal power consumption. With the rapid growth in the need to transmit data from many sensor nodes to remote servers, the relevance of optimising the parameters of LoRa networks is becoming critical.

Computer simulation provides powerful tools for modelling the behaviour of LoRa networks under various conditions and the ability to evaluate performance, identify potential problems, and test new solutions without the need to deploy expensive and time-consuming networks. D. Capriglione *et al.* (2012) found that by modelling different network scenarios, parameters such as signal propagation loss, interference level, data rate,

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received signal power, and energy consumption can be analysed in detail.

According to M.A.M. Almuhaaya *et al.* (2022), one of the most widely used tools for modelling LoRa networks is simulation software. They provide researchers with the flexibility to configure network parameters and enable them to simulate a variety of scenarios that factor in the specifics of the network. This allows identifying potential problems, developing and testing optimisation strategies, which helps to improve the efficiency of the LoRa network in real-world conditions. In this regard, the relevance of computer modelling of LoRa network parameters, considering the features of the hardware, is undeniable.

Previous research has highlighted a series of key aspects related to LoRa transmission parameters. T. Rasic *et al.* (2021) investigated the effects of parameters such as the expansion ratio, bandwidth, and transmit power on communication efficiency and energy consumption using a FLoRa (Framework for LoRa) simulator. The study found that changing the distance between the node and the gateway considerably affects transmission stability and energy consumption. S. Francisco *et al.* (2021) proposed an improved LoRaSim (Long Range Simulator) model that improves the accuracy of reproducing real-world conditions through adaptive simulation parameters. O.A. Nahorniuk (2024) focused on methods for automatically determining the parameters of LoRa radio signals and focused on the peculiarities of modelling using MATLAB, which helped to improve the accuracy of measurements. However, there are still unresolved issues related to the reliability of simulation models compared to real experimental data, especially in scenarios where the distance between nodes changes substantially or where there is considerable interference.

S. Bertoldo *et al.* (2019) noted that the choice of a suitable signal propagation model is critical for accurately predicting LoRa network parameters. Their study demonstrated that the use of empirical models, such as Motley-Keenan or COST 231 Multi-Wall, can greatly improve the accuracy of predictions for sensor networks in indoor environments. This confirms the need for additional analysis and adaptation of simulators such as FLoRa to more accurately reproduce real-world operating conditions (FLoRa, n.d.).

M.G. Campos *et al.* (2024) noted the lack of representativeness of some simulator configurations when network parameters are varied. This points to the need for further research that validates simulation models in a wider range of conditions.

The purpose of this study was to analyse and compare the results of calculations of LoRa network characteristics obtained by computer simulation with the results of experimental studies.

To fulfil the purpose of the study, the following tasks were set:

1. Modify the FLoRa simulator software to display the values of signal propagation losses.

2. Conduct a computer simulation in FLoRa to obtain values of signal loss as a function of distance.

3. Compare the findings of the simulation with the data obtained from the visual experiment and the RSSI (Received Signal Strength Indicator) values obtained from the simulation with the values obtained from the experimental measurements.

Materials and Methods

The study employed a computer modelling method that allows predicting the parameters of the LoRa network based on theoretical models and experimental data. The key method for estimating signal propagation losses was the Fris model, which is widely used for calculations in urban environments. This model captures the random effects of shadowing due to natural and artificial obstacles such as hills, trees, buildings, and is known as the ordinary shadowing model. The Fris model was chosen because it is suitable for estimating losses in densely populated and built-up areas, which are typical conditions for LoRa network deployments. The model parameters, such as γ and X_σ , were chosen considering the specifics of the LoRa network and the environment in which the experiments were conducted. Using the Fris model, the path loss as a function of the communication distance d can be described as follows (Rappaport, 1996):

$$L_{pl}(d) = L_{pl}(d_0) + 10\gamma \log\left(\frac{d}{d_0}\right) + X_\sigma, \quad (1)$$

where $L_{pl}(d)$ is the path loss in dB; $L_{pl}(d_0)$ is the loss at the reference distance d_0 ; γ is the path loss exponent; $X_\sigma \sim N(0, \sigma^2)$ is the deviation of a normal distribution with zero mean; and σ^2 is the variance to account for shadowing.

Losses at a reference distance d_0 when signals propagate without obstacles between the transmitter and receiver are equal:

$$L_{pl}(d_0) = 20 \log_{10}\left(\frac{4\pi f d_0}{c}\right).$$

At the same time, the losses on the way to distribution can be written as follows:

$$L_{pl} = P_{tx} + G_{tx} + G_{rx} - P_{rx}, \quad (2)$$

where P_{tx} is the strength of the transmitted signal; G_{tx} , G_{rx} are the antenna gains, P_{rx} is the signal strength at the receiver input.

The signal power at the receiver input P_{rx} , can be expressed as follows:

$$P_{rx} = RSSI + K,$$

where K is the offset, which depends on the characteristics of the transceiver chip used, the frequency, and the chosen technology and its features (in this case, LoRa and SF), or

$$P_{rx} = P_{tx} + G_{tx} + G_{rx} - L_{pl}, \quad (3)$$

Therefore, signal losses along the way can be expressed in terms of RSSI:

$$L_{pl}(d) = P_{tx} + G_{tx} + G_{rx} - RSSI - K. \quad (4)$$

Thus, based on the RSSI values obtained experimentally or as a result of simulation, it is possible to estimate the level of network losses at different distances. The relationship between RSSI and losses, expressed through the K-factor, is unique to each type of LoRa chip and was investigated by Yu. Onykienko *et al.* (2022).

This study used the FLoRa simulator based on the OMNeT++ platform. Running simulations using FLoRa helped to simulate various environments based on the data obtained and preserve the conditions of the experiment, which makes the simulation results comparable to real measurements.

The receivers and transmitters used in the experiment (Fig. 1) were designed according to the modern element base. For measurements at 433 MHz, the study used the LoRa Ra-02 transceiver developed by Shenzhen Ai-Thinker Technology Co., Ltd (China), based on the SX1278 chip manufactured by Semtech Corporation (USA). For measurements at 868 MHz, the study used the TTGO LORA32 868/915 Mhz ESP32 LoRa OLED module created by the LILYGO team (China), based on the SX1276 chip from the same company Semtech Corporation (USA). Measurements at 2.4 GHz were performed using the E28-2G4M12S module developed by Chengdu Ebyte Electronic Technology Co., Ltd (China), based on the SX1280 chip manufactured by Semtech Corporation (USA).

The transmitter settings were changed during measurements via the built-in Wi-Fi channel of the ESP32 microcontroller. The receiver settings were changed via the LoRa channel. All the antennas are omnidirectional and vertically polarised, which minimised signal loss and helped to evaluate the network parameters in real-world conditions where interference from multidirectional objects often occurs. The data was transmitted in packets of 100 units with a payload of ten bytes and a 12-character preamble at each distance. The received RSSI values of each packet were recorded in the receiver’s memory for

further analysis of the effect of the SF spreading factor, which was set to 7, 9, and 12, and the distance at 433 MHz, 868 MHz, and 2.4 GHz. The initial data for modelling and calculations are presented in Table 1.

Node parameters, such as transmitter power, receiver sensitivity, and other characteristics, are configured according to chip specifications. For simulations, FLoRa uses a class-based signal propagation model, namely LoRaLogNormalShadowing, which factors in the characteristics of urban buildings, including reflection, attenuation, and other factors. A series of simulations were performed for various scenarios that reproduced the experimental conditions (different distances, frequencies, and other parameters). Each simulation included a certain number of data transmissions between nodes to collect statistically significant results. Thus, by means of experimental measurements and computer simulations, data were obtained that allow estimating the level of losses in the signal transmission path based on RSSI for different distances.



Figure 1. LoRa modules used in the experiment (in the white case – a transmitter at a frequency of 868 MHz, in the black case – a transmitter at 433 MHz and 2.4 GHz)

Source: developed by the authors of this study

Table 1. Input data for modelling

Frequency		433 MHz	868 MHz	2.4 GHz
σ		2.65		
γ		2.2		
$Lpl(d0)$, dB		45.2	51.2	60.0
K	SF = 7	49	47	24
	SF = 9	54	50	25
	SF = 12	54	50	26
Frequency band, kHz		125	125	812.5
Coding rate		4/5	4/5	4/5
Output power, dBm		17	17	10
Antenna gain, dBi		2.5	2	3

Source: developed by the authors of this study based on Yu. Onykienko *et al.* (2022)

Results

OMNeT++ provides the infrastructure and tools for running simulations. One of the fundamental features of this infrastructure is the architecture of components for simulation models. Models are assembled from many

components called modules. Modules can be connected to each other using gateways and combined into composite modules. The depth of nesting of modules is not limited. Modules communicate through message passing, where

messages can contain arbitrary complex data structures that can transmit messages along predefined paths through gateways and connections or directly to a destination; the latter is useful, e.g., for wireless simulations. Modules may have parameters that can be used to configure behaviour and/or to parameterise the model topology. The modules at the lowest level of the hierarchy are called simple modules, and they encapsulate the behaviour of the model. Simple modules are programmed in C++ and use the simulation library. OMNeT++ simulations can be run in a variety of user interfaces. Graphical user interfaces with animations are very useful for demonstration and debugging, while command line interfaces are best suited for batch execution.

FLoRa (n.d.) (Framework for LoRa) is a software library for end-to-end modelling of LoRa networks that provides support for the LoRa physical layer model, considering collisions and capture effects. It enables simulations with one or more gateways, provides accurate end-to-end modelling of the transport network, and provides statistics on network energy consumption. FLoRa is based on the INET framework, which is an open-source set of OMNeT++ models for wired, wireless, and mobile networks. The OMNeT++ environment and simulator allows creating LoRa networks with LoRa node, gateway, and network server modules. The parameters of the system elements are set in the initial simulation settings file. Figure 2 shows a fragment of the LoRa network simulation window.

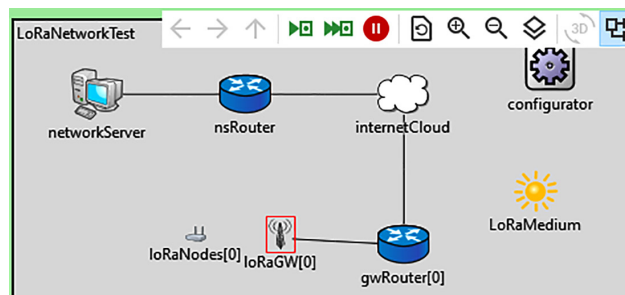


Figure 2. FLoRa simulation window

Source: developed by the authors of this study

The FLoRa package has all the necessary elements and their graphical representation to simulate both the network and server parts of the system, namely:

- ◆ A graphical representation in the LoRaNetworkTest plane of the network server (networkServer), router (nsRouter), network cloud (internetCloud), gateway (gwRouter), and LoRa node module (LoRaGW – transmitter, LoRaNodes – receiver);
- ◆ The duration of the simulation process is determined by the value set in the initialisation file. The results of the

simulation are recorded in the results.anf file, which has the form of a table;

- ◆ Two signal propagation models LoRaHataOkumura and LoRaLogNormalShadowing can be used in the simulation;
- ◆ The simulation results, as well as the input data of the simulation, are entered into the table (Fig. 3). The parameters Vector of RSSI per node (RSSI value) and Vector of Pass Loss per node (loss value) are used to estimate the signal loss depending on the distance.

Browse Data

Here you can see all data that come from the files specified in the Inputs page.

All (4 005 / 4 005) Parameters (2 576 / 2 576) Scalars (1 074 / 1 074) Histograms (90 / 90) Vectors (265 / 265)

experiment filter measurement filter replication f module filter

Experiment	Measur...	Re...	Module	Name	Count	Mean	StdDev	Variance
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.eth[0].r	queueBitLength:vector	84	0 b	0 b	0 b ²
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.eth[0].r	txPk:vector(packetBytes)	84	64	0	0
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.eth[0].mac	rxPkOk:vector(packetBytes)	84	64	0	0
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.eth[0].mac	passedUpPk:vector(packetBytes)	84	64	0	0
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.ethernet	decapPk:vector(packetBytes)	84	46	0	0
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.udp	packetReceived:vector(packetBytes)	88	35	0	0
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.app[0]	Vector of SNIR per node	89	195.282367	182.871582	33,442.015409
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.app[0]	Vector of RSSI per node	89	-108.414612	3.452556	11.920146
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.app[0]	Vector of Pass Loss per node	89	129.414612	3.452556	11.920146
General	\$0="avg"	#0	LoRaNetworkTest.LoRaNodes[0].LoRaNic	receptionState:vector	352	0.534091	0.563846	0.317923
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.app[0]	Received Sequence number	88	43.500000	25.547342	652.666667
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.app[0]	Calculated SNRmargin in ADR	4	192.664751	30.083020	904.988117
General	\$0="avg"	#0	LoRaNetworkTest.networkServer.udp	packetSent:vector(packetBytes)	4	24	0	0
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.ppp[0].queue	incomingPacketLengths:vector	4	352 b	0 b	0 b ²
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.ppp[0].queue	incomingDataRate:vector	864000	0.016296 bps	7.573821 bps	57.362764 bps ²
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.ppp[0].queue	queueingTime:vector	4	0 s	0 s	0 s ²
General	\$0="avg"	#0	LoRaNetworkTest.nsRouter.ppp[0].queue	outgoingPacketLengths:vector	4	352 b	0 b	0 b ²

Figure 3. A fragment of the modelling results table with the output of signal loss values along the propagation path

Source: developed by the authors of this study

The FLoRa simulator calculates signal propagation losses but does not display them in a table with the results. In many cases, when designing a network, it is more convenient to use the loss values. Therefore, the program code has been modified, and the obtained values are displayed in the table after the RSSI values.

In Figure 4, the curves showing the dependence of signal loss on distance, different SFs, and frequency are modelled

using formula (1) and calculated from experimental data using formula (4). The curve L, which shows the total signal loss with distance, is obtained as a result of modelling. The *min* and *max* curves indicate the minimum and maximum values of signal loss obtained during the simulation. The other curves, SF7, SF9, and SF12, respectively, represent the results of path loss calculations using formula (4), where the experimentally obtained RSSI and K values were applied.

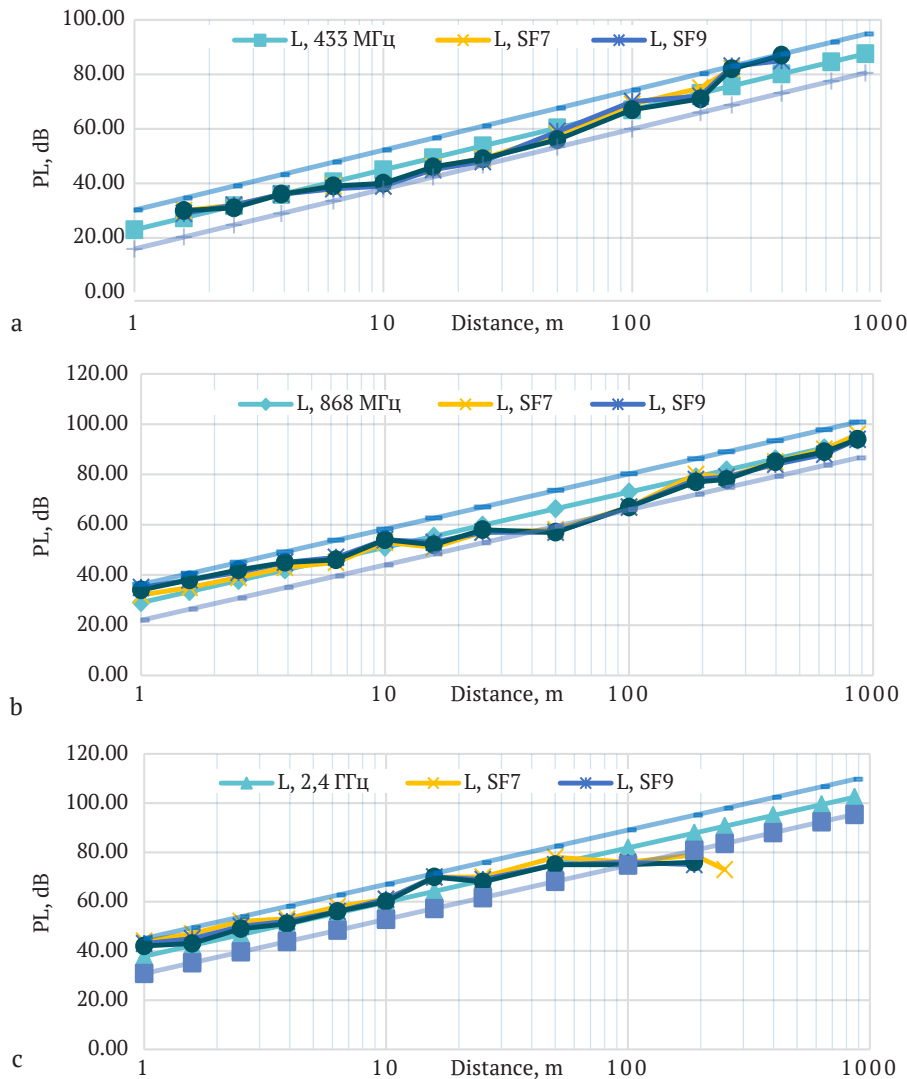


Figure 4. Dependence of signal loss at different frequencies on distance and distribution factor

Note: a – 433 MHz, b – 868 MHz, c – 2.4 GHz

Source: developed by the authors of this study

The simulation and calculation results for the 433 MHz frequency are presented in Figure 4a. Clearly, the signal propagation loss obtained from calculations based on experimental data is within the maximum and minimum values obtained during simulation. The graphs show that the installed power and the selected antenna limit the range in the 433 MHz band to about 400 m. During reception at longer distances, a considerable increase in the number of errors was observed.

The graph for the 868 MHz frequency (Fig. 4b) shows that the signal loss obtained experimentally is within the range of theoretical calculations at most distances. Notably, at a distance of 50 metres, an additional signal reflection was observed during the experiment, and therefore the loss value at this point is lower than at the neighbouring ones. As a result, the theoretical models can be adjusted and improved based on real data to increase the accuracy of predictions and improve network planning processes.

Figure 4c shows signal loss versus distance at 2.4 GHz. The graphs show that the range in the 2.4 GHz band reaches approximately 250 m. At this point, reception errors became noticeable, which led to a considerable difference in the RSSI value calculated by formula (4) compared to neighbouring points. Achieving the specified distance is possible only if the distribution coefficient $SF = 7$ is used. For values of the spreading factor, such as $SF = 9$ and $SF = 12$, the maximum range in the 2.4 GHz band does not exceed 160 m. This confirms that lower SF values provide the maximum communication range of LoRa technology and increase interference immunity at analogous values of channel bandwidth and coding rate.

To estimate the signal power loss as a function of distance, the FLoRa software uses RSSI values for each endpoint. Considering that for LoRa networks, RSSI values depend on both the type of transceivers used and the SF distribution factor, the present study evaluated the consideration of these factors when performing calculations in the FLoRa simulator. Figure 5 presents the results of comparing the RSSI values obtained in the experiment conducted by Yu. Onykienko *et al.* (2022) and those calculated in the FLoRa simulator as a function of distance at 868 MHz for different values of the SF distribution factor. Also presented in Figure 5 is the dependence of the signal power P_{rx} at the receiver input on the distance, calculated using formula (3).

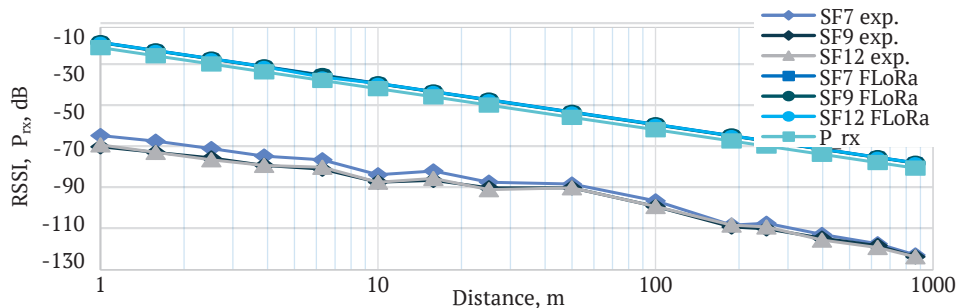


Figure 5. RSSI values obtained experimentally and in the FLoRa simulator at 868 MHz for different SFs at different distances and input power values P_{rx}

Source: developed by the authors of this study

Figure 5 shows that the RSSI values calculated in the FLoRa simulator with the parameter settings listed in Table 1 are significantly different from those obtained in the experiment. There is also no effect of the SF distribution factor. On the other hand, the simulation results almost coincide with the input power levels for the endpoint calculated by formula (3). Thus, in FLoRa, the received signal power values are represented as RSSI values. This approach is not entirely correct, since RSSI values depend on the concrete type of receiver chip. Therefore, the method of calculating RSSI in FLoRa should be adjusted. It would also be advisable to display both the signal value at the receiver input and the RSSI value in the results table.

Discussion

The findings of this study confirmed the significance of choosing the right spreading factor (SF) in LoRa networks to ensure the best performance. This is in line with the findings of S. Mnguni *et al.* (2021), who demonstrated that lower SF values (e.g., SF7) provided lower power consumption and faster data transmission, but could cause more packet collisions due to channel congestion. In the study, a modified version of the FLoRa simulator also showed high accuracy in assessing the impact of SF on signal loss and energy performance. Furthermore, this study expanded the FLoRa functionality by adding signal power loss modelling for different frequencies (433 MHz, 868 MHz, and 2.4 GHz). This helped to compare the simulation findings with experimental data and confirm that the choice of parameters,

such as SF and transmit power, greatly affects network performance, including power consumption, latency, and throughput. However, the study found that the RSSI values presented in FLoRa need to be adjusted to consider the hardware characteristics of the receivers. This complemented the findings of S. Mnguni *et al.* (2021), indicating the need to further adapt the model to more accurately estimate the physical parameters of the network. The findings revealed the significance of optimising the spreading factors (SF) to ensure a balance between energy consumption, reliability, and transmission range in LoRa networks. It is also consistent with the findings of C. Bouras *et al.* (2021), who demonstrated that the use of machine learning can significantly improve energy efficiency and transmission reliability in LoRa networks through adaptive SF selection. In contrast to the approach of the researchers, the present study focused on modelling signal loss and estimating RSSI parameters using a modified version of FLoRa. At the same time, the findings confirmed that SF plays a critical role in network performance, especially in the context of multifactorial influences such as signal frequency, transmission medium, and distance to the gateway. C. Bouras *et al.* (2021) also pointed to the promise of integrating machine learning into simulators such as FLoRa for automated parameter tuning.

G. Premsankar *et al.* (2020), who used linear programming to find the optimum SF and TP parameters in dense urban networks, achieved an increase in the delivery ratio of up to 8% compared to previous algorithms and ensured a fair distribution of radio resources between nodes.

In contrast to the methodology of G. Premsankar *et al.* (2020), which focused on optimising real networks by modelling spatial configurations and the mutual influence of nodes, the present study is aimed at simulating the analysis of influence factors such as signal loss and RSSI values using the FLoRa tool. Nevertheless, the key findings of the researchers can be integrated into further research, specifically to improve ADR algorithms that have limitations in terms of their setup time. Furthermore, the approach demonstrated that the use of optimisation tools such as linear programming can be integrated with simulation platforms to enable rapid testing of different network configuration scenarios. This opens the prospect for future research on dynamic optimisation of LoRa parameters, which can increase the adaptability and efficiency of FLoRa.

At the same time, R. Serati *et al.* (2022) proposed a new ADR-Lite algorithm that optimises the settings of transmission parameters such as SF, TP, CF, and CR to achieve prominent flexibility and performance even in mobile environments. Unlike standard ADR, the ADR-Lite algorithm operates independently of received packet history, using a binary search to determine the optimum transmission parameters. This substantially reduces computational complexity, which is critical for the scalability of IoT networks. Simulations showed that in a mobile environment with high channel noise, ADR-Lite achieved a 2.8 times improvement in packet delivery ratio (PDR) compared to standard ADR and outperformed other algorithms by 35%. The present study highlighted the significance of including additional transmission parameters such as CF and CR in the optimisation process, which is also relevant for extending the functionality of the FLoRa simulator. The lack of dependence on the previous transmission history opens the prospect of integrating ADR-Lite into scenarios with dynamically changing channel conditions. Thus, the approach proposed by R. Serati *et al.* (2022) can form the basis for further research, including the use of machine learning to find the best transmission parameters without reducing PDR.

A considerable contribution to the understanding of LoRa technology was made by M.A. Kamal *et al.* (2023), which offered a detailed analysis of LoRa specifications, implementation history, simulation tools, as well as the principal technical and operational challenges. The researchers highlighted the key advantages of LoRa, such as wide range, low power consumption, and the availability of the technology due to the use of unlicensed frequencies. Among the technical challenges outlined in the study, special attention was paid to connection management, resource allocation, ensuring stable communication, and security in LoRa networks. Particularly interesting was the discussion of parameters that affect network performance, such as spreading factor (SF), bandwidth (BW), and bitrate calculation. The researchers presented a formula for determining the data rate depending on the selected parameters, which is useful for simulation experiments. The study also highlighted that despite the wide range of solutions, some issues are still unresolved. The discussion of

simulation tools also provided a useful context for extending the functionality of FLoRa. The inclusion of new parameters, such as the effects of network topology or environmental changes, can substantially improve modelling accuracy and make simulations more realistic.

A.I. Griva *et al.* (2023) presented a comparative analysis of the performance of LoRa networks in rural, urban environments, and a car park scenario. The researchers used the OMNeT++ simulation environment with the open-source FLoRa framework. In rural areas, an increase in node density significantly degraded network performance, which was less noticeable in urban scenarios due to the better location of gateways and other infrastructure features. It was also found that increasing the expansion factor (SF) from SF 11 to SF 12 increased energy consumption by 50.76%. It was also emphasised that optimisation of parameters such as antenna height, transmit power, and number of gateways is a vital factor for efficient deployment of LoRa networks. Popular signal fading models, such as Okumura-Hata and Oulu, were used for modelling, which helped to evaluate the network performance in various conditions. The findings revealed that the correct choice of the signal fading model and technical parameters greatly affects the quality of communication and energy efficiency of the network. The researchers also emphasise the necessity of experimental studies to confirm the findings.

R.P. Centelles *et al.* (2024) considered a new Distance-Vector Routing Protocol (DV RP) for LoRa Mesh networks. The proposed approach aimed to extend the capabilities of the conventional LoRaWAN star topology by using a more flexible mesh topology. The principal innovation was the Time on Air (ToA) metric, which accommodated the possibility of using different spanning factors (SFs) for efficient routing in networks with heterogeneous topologies. The advantages of using multi-SF included the use of different SFs, while allowing for optimised data transmission, especially in cases of high loads, improving network performance. The protocol is optimised for limited node computing resources, making it suitable for low-power devices. In simulations using FLoRa based on OMNeT++, the study demonstrated better packet delivery ratio (PDR), goodput, and latency compared to other known routing strategies in heterogeneous topologies. This study is a valuable contribution to the development of LoRa Mesh networks by showing the potential of multi-SF routing to solve real-world problems in challenging environments. In the future, the researchers plan to implement the developed protocol on real devices for field trials, which emphasises the practical orientation of the study. The findings revealed that the correct choice of the signal fading model and technical parameters considerably affects the quality of communication and energy efficiency of the network.

Y. Sarr *et al.* (2019) proposed the deployment of a street lighting control system based on LoRaWAN technology for smart cities. The system, which operates on the principle of 'smart lighting', allows solar lights to dynamically adjust the level of illumination depending on environmental

conditions and the state of energy supply. The study showed that the use of a single gateway causes a large loss of packets due to collisions, which confirmed the need for multiple gateways to improve network performance. The simulation results showed that multiple gateways considerably reduce packet loss and collisions (up to 20%), which indicates the value of network scalability for the best results.

E.F. Silva *et al.* (2023) proposed the SlidingChange mechanism, which helps to dynamically adjust these parameters depending on the network conditions and provides an opportunity to reduce the number of configuration changes in the network. This approach, compared to other methods such as InstantChange and LR-ADR, revealed a significant improvement in Signal-to-Noise Ratio (SNR) and Bit Error Rate (BER). At the same time, by using a sliding window to smooth out short-term changes, it reduced the need for frequent network reboots. Overall, the use of techniques such as SlidingChange can greatly improve the efficiency of a LoRa network by reducing the number of frequent frequency and configuration changes, which reduces energy consumption and increases network stability. This is especially significant for large IoT networks where many devices need to communicate with the network with minimal energy consumption and high data reliability.

G. Yascaribay *et al.* (2022) focused on evaluating the effectiveness of communication systems for IoT in agriculture, specifically the use of LoRaWAN. In this study, based on simulations using Omnet++ and the FLoRa library, the performance of LoRaWAN in rural areas was evaluated using the example of Ecuador. The researchers showed that by using two gateways and activating Adaptive Data Rate (ADR) technology, the packet delivery ratio can be considerably increased without increasing the power consumption of network nodes. These findings demonstrated the potential of LoRaWAN to solve the problem of providing reliable communication in an agricultural environment, where the distance between nodes can reach great values and energy-saving features are vital for the long-term operation of devices. Importantly, the study also highlighted the need to develop additional mechanisms to improve network scalability, such as the introduction of multiple communication channels to reduce packet collisions, which is a prominent issue when there are a considerable number of nodes in the network. Such aspects still require further study, as existing protocols do not provide optimised traffic management in situations where the number of gateways and nodes increases significantly.

Conclusions

The analysis of the simulation results using FLoRa software revealed that the obtained results of modelling the signal loss along the propagation path correspond to the experimental data. For frequencies of 433 MHz, 868 MHz, and 2.4 GHz, the signal losses obtained in the simulation were within the experimental values, which confirmed the high accuracy of the simulation model for predicting signal propagation losses. Specifically, this confirmed that the model can correctly account for various factors that affect the nature of signal propagation in real-world conditions, including environmental changes, obstructions, and interference. Particular attention should also be paid to the consideration of various propagation factors (SF) and different signal frequencies, which were also accurately modelled, helping to assess the effects of these parameters on signal loss.

The comparison of simulation and experimental data confirmed that the computer modelling methods employed in this study are effective in predicting the characteristics of LoRa networks. The results of simulations performed using the FLoRa software revealed high agreement with experimental measurements within the permissible errors, which suggests the accuracy of the model for predicting signal loss and other parameters such as delay and interference. This opens new opportunities for the development of adaptive models that accommodate both hardware and environmental factors when selecting SF. Thus, the use of machine learning can be a logical step in improving FLoRa to predict network parameters more accurately.

The FLoRa software simulator proved to be a powerful tool for modelling systems based on LoRaWAN technology. The openness of the software source code helped to adapt the simulator to the concrete conditions and needs of various studies, considering the environment.

In the future, a valuable area is to improve the FLoRa simulation programme to more accurately calculate the RSSI output values, specifically by considering additional factors such as hardware features of the system implementation and changes in the propagation coefficients (SF) during the simulation.

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None.

Conflict of Interest

None.

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Комп'ютерне моделювання параметрів мережі LoRa з використанням симулятора FLoRa

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Анотація. Метою статті було дослідження та порівняння результатів обчислень параметрів мережі LoRa, отриманих за допомогою комп'ютерного моделювання, з результатами експериментальних вимірювань. Для досягнення мети було використано методи комп'ютерного моделювання втрат сигналу. Зокрема, у статті описано модифікацію симулятора FLoRa для оцінки втрат сигналу під час його поширення, виконання комп'ютерних симуляцій у FLoRa та порівняння отриманих результатів з даними, здобутими в ході експерименту. Також проведено порівняння значень RSSI, отриманих у процесі симуляції, з експериментальними значеннями. Розширено функціональні можливості програмного симулятора FLoRa шляхом додавання значень втрат потужності сигналу до таблиці результатів симуляції. З використанням програми FLoRa виконано симуляцію втрат потужності сигналу на шляху поширення на частотах 433 МГц, 868 МГц та 2,4 ГГц. Порівняльний аналіз показав, що результати симуляції для різних коефіцієнтів розподілення) та різних частот сигналу відповідають експериментальним даним. Встановлено, що в програмі значення потужності отриманого сигналу представлені як значення RSSI. Потужність сигналу на вході не відповідає значенням RSSI і залежить від конкретного типу мікросхеми приймача, тому методика розрахунку RSSI має бути скорегована. Підтверджено, що було б доцільно виводити в таблицю результатів як значення сигналу на вході приймача, так і значення RSSI. Для підвищення точності комп'ютерної моделі FLoRa, зокрема обчислення значень RSSI, запропоновано враховувати особливості вимірювання цих значень різними типами мікросхем приймачів LoRa. Отримані результати можуть бути використані для підвищення точності моделювання і відповідно якості проектування мереж на основі технології LoRa

Ключові слова: Long Range; комп'ютерні симулятори; Framework for LoRa; Received Signal Strength Indicator; втрати потужності сигналу; коефіцієнт розподілення; параметри симуляції

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