Global Clinical Engineering Journal

Vol.7 Issue 1

Publisher International Medical Sciences Group, LLC

GlobalCE

open access

ISSN: 2578-2762

www.GlobalCE.org

Editor's Corner

Artificial Intelligence in Clinical and Biomedical Engineering: Opportunities and Challenges

Never has technology brought so much confusion. For some, AI is the savior of humanity; for others, it is an agent of destruction. The overwhelming fact is that AI is here to stay. But is AI good or bad, and what is its role in biomedical and clinical engineering? To answer this, we need to understand AI's capabilities, limitations, and evolution while also considering how we should participate in its development and responsible use.

AI, in a general sense, is an information system capable of replicating functions traditionally associated with the human brain. From the invention of writing to digital calculators and personal computers, AI has evolved into today's large language models—deep artificial neural networks capable of processing vast amounts of data and mimicking human language. Yet, AI remains a probabilistic computational engine that generates responses based on its training data. If a system lacks the correct data, it may still generate an answer—a phenomenon known as hallucination. This raises concerns, particularly in decision support, where AI should either provide evidence-based guidance or indicate the need for additional information.

AI's Potential in Clinical and Biomedical Engineering

While AI is still emerging in clinical engineering, several areas present significant opportunities:

- Decision Support Systems: AI can assist in procurement, maintenance scheduling, and calibration, improving efficiency and decision-making.
- Predictive Maintenance: AI-driven analytics can anticipate device failures, minimizing downtime and enhancing reliability.
- Inventory Management: AI can optimize medical device supply chains, ensuring timely access to critical equipment.
- Post-Market Surveillance: AI has the potential to enhance monitoring of medical device performance and early detection of malfunctions.
- Cybersecurity Measures: As medical devices become more connected, AI can detect and prevent cybersecurity threats.

Challenges and Considerations

Despite its promise, AI adoption in clinical engineering faces several challenges:

- Data Privacy and Security: Compliance with HIPAA and GDPR is essential to protect patient information.
- Algorithmic Bias: AI models must be trained on diverse datasets to avoid biases that could negatively impact healthcare outcomes. For instance, an AI system trained exclusively on maintenance data from a single manufacturer may yield recommendations that are inapplicable to other brands. Moreover, biases in patient datasets can lead to disparities in healthcare access and outcomes, making it crucial for clinical engineers to contribute to dataset diversification and validation.
- Environmental and Operational Context: AI models developed in high-resource settings may not perform effectively in low- and middle-income (LMI) environments, where infrastructure reliability varies. AI must be trained with data reflective of different operational contexts, including settings with limited electricity, refrigeration, and water supply. Clinical engineers play a vital role in ensuring AI models consider these variables to maintain relevance across diverse healthcare environments.
- Explainability and Transparency: AI systems should include interpretability layers so that engineers and healthcare providers understand the decision-making process.

- Workforce Adaptation: Clinical engineers must seek and receive AI training, including ethics and data governance, to oversee AI integration safely and effectively.

Future Directions and Recommendations

To leverage AI's potential in clinical and biomedical engineering, the following steps should be considered:

1. Develop AI-based decision support systems for maintenance, procurement, and calibration.
2. Implement cybersecurity frameworks to safeguard AI-driven medical device networks.
3. Diversify AI training datasets by including various patient populations and multiple medical device brands to mitigate algorithmic bias.
4. Ensure AI transparency by integrating explainability features to enhance trust and usability.
5. Explore AI applications in predictive diagnosis, early failure detection, and resource optimization.
6. Establish AI training programs for clinical engineers to promote ethical and effective implementation.
7. Develop domain-specific large language models (LLMs) tailored to clinical and biomedical engineering, ensuring AI recommendations are contextually appropriate.
8. Publish about best practices, and application of AI into Clinical Engineering practices. You may help many to avoid missteps shared in your publication.

Conclusion

AI presents a transformative opportunity for clinical and biomedical engineering, with the potential to enhance safety, efficiency, and decision-making. However, responsible AI adoption requires addressing data privacy, algorithmic bias, and transparency. By proactively engaging in AI development and governance, clinical engineers can play a pivotal role in shaping the future of healthcare technology management.

We must embrace our role as toolmakers, not just users, to shape AI into a force for good. Only through intentional development can we create ethical, intelligent systems that enhance efficiency, reduce risk, and improve the quality of life for both patients and technology users. AI is still in its infancy, and we must act as responsible teachers and stewards, guiding its evolution toward cooperation and progress. The alternative is too dangerous—without ethical oversight, unscrupulous corporations, negligent engineers, or uninformed users could steer AI toward harm rather than progress.

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CONTENTS

Received November 7, 2024, accepted January 6, 2025, date of publication January 15, 2025.

Review

Balancing Innovation and Safety in Digital Healthcare

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ABSTRACT

In an era of rapid digital transformation, patient safety is increasingly intertwined with technological advancements in healthcare. This article explores the dual nature of these innovations, where tools like telemedicine, artificial intelligence (AI), and electronic health records (EHRs) offer significant potential to enhance care delivery and introduce new risks such as algorithmic bias, cybersecurity threats, and challenges in minimizing patient risks. A balanced approach focusing on robust safety protocols and continuous learning is required to ensure technology enhancement without undermining patient safety. The paper aims to advance the discourse on integrating technology with patient-centric care, proposing future research and policy development strategies to sustain a high safety standard in an increasingly digital healthcare environment.

Keywords—*Digital health, Artificial intelligence, Telemedicine, Cybersecurity, Healthcare innovation, Patient safety.*

INTRODUCTION

Integrating digital technologies into healthcare supports enhancing patient outcomes, streamlining workflows, and making healthcare more accessible. Digital tools such as Electronic Health Records (EHRs), telemedicine, and artificial intelligence (AI) offer unprecedented opportunities to enhance patient care.[1,2] While these innovations have the potential to revolutionize patient care, they also pose significant risks if their implementation outpaces patient safety protocols.[3,4]

This intersection of technological innovation and patient safety has emerged as a critical area of focus. As the healthcare sector embraces digitalization and health systems become increasingly complex, these advancements hold the potential for both groundbreaking improvements and unintended risks. The challenge lies in ensuring that these technologies are implemented in ways that prevent inadvertent harm to patients.[4]

Digitized Healthcare systems must prioritize identifying and mitigating risks associated with new technologies.[2] The adoption of digital tools like AI and telemedicine should be viewed through a lens of sustainability, where the focus should be on developing resilient healthcare systems that can adapt to and mitigate emerging risks.[1] A proactive stance in technology integration could ensure patient safety is not compromised in pursuing technological progress.[4]

The challenges associated with new technological advancement in the healthcare sector are even more complex compared to other sectors. The nature of healthcare demands is different in different geographical regions. Further, there are disparities in how technology is implemented and accessed across different regions, particularly in low- and middle-income countries. These areas often face significant challenges in adopting advanced technologies due to resource limitations, which can exacerbate existing inequalities in patient safety outcomes.[5] Therefore, the benefits of digital tools that can enhance care delivery, are not universally experienced. Technological advancements must ensure equitable distribution and safe implementation across diverse healthcare settings and geographies.[6]

To address these disparities effectively, it is essential to integrate policy and organizational culture into the safe adoption of technology within healthcare systems. Policies must be adaptable and forward-thinking, balancing the promotion of technological advancements with the imperative to safeguard patient safety.[7] Equally important is fostering an organizational culture that prioritizes safety, encourages transparency, and supports continuous learning. Such a culture not only mitigates risks associated with new technologies but also empowers healthcare professionals to engage in proactive safety practices, thereby enhancing the overall resilience of the healthcare system.[8]

A balanced approach that prioritizes both innovation and safety is essential to harness the full potential of digital health. This requires a comprehensive understanding of how technologies influence various aspects of healthcare, along with a commitment to continuous learning and adaptation. Ensuring safety protocols keep pace with technological advancements is critical to mitigating risks and maximizing benefits.[2,4] By fostering a culture of safety, we can navigate the complexities of digital health and towards the future of robust healthcare systems. This paper aims to contribute to the ongoing discourse by offering insights that will help shape the future of patient safety in the digital age.[1,9] The paper explores the dualities, emphasizing the need for a balanced approach that maximizes the benefits of technology while safeguarding the fundamental principles of patient safety.[10]

METHODS

This study utilized a systematic literature review methodology to identify, evaluate, and synthesize peer-reviewed articles relevant to the intersection of patient safety and healthcare technologies, AI, telemedicine, and cybersecurity. The selection process was guided by the expertise of two highly qualified reviewers. One reviewer from the field of patient safety has extensive experience in identifying key issues in this field. The second reviewer specializes in quality control, focusing on integrating safety principles into healthcare systems. This dual expertise ensured a high evaluation standard, significantly enhancing the quality and reliability

of the selected studies for this review.

The review process began with a comprehensive search across four major academic databases: Scopus, Web of Science, PubMed, and Google Scholar, spanning publications from January 2014 to October 2024. A carefully curated search strategy was employed, utilizing thematic keywords designed to capture diverse terminologies and contexts associated with the study's themes. Terms such as "Artificial Intelligence", "Machine Learning", "Telemedicine", "Digital Health", "Healthcare Cybersecurity", "Health Disparities", and "Patient Safety" were included. Synonyms and alternative terms were explicitly incorporated to account for variability in terminology, such as "telehealth" alongside "telemedicine" and "electronic medical records (EMR)" alongside "electronic health records (EHR)". Boolean operators (e.g., AND, OR) and phrase searching were used to refine the search, while database-specific subject headings (e.g., MeSH terms in PubMed) further enhanced precision. This approach resulted in the retrieval of 234 articles, which were subsequently imported into reference management software for de-duplication.

After removing 28 duplicate records, 206 unique articles remained for title and abstract screening. Reviewers independently evaluated the articles based on predefined inclusion and exclusion criteria during this phase. Articles were included if they were empirical, peer-reviewed studies addressing healthcare technology, AI, telemedicine, or cybersecurity, published in English, and indexed in Scopus, Web of Science, or PubMed. Articles not meeting these criteria such as theoretical papers, non-peer-reviewed studies, or those unrelated to healthcare were excluded, leaving 87 articles for full-text review.

The full-text review phase, conducted by the same domain experts, excluded an additional 45 studies due to methodological limitations, irrelevance, or insufficient indexing. This process culminated in the selection of 42 articles for inclusion in the final review. These articles represented a diverse array of topics in the context of patient safety, including AI in healthcare (12 articles), telemedicine and digital health (10 articles), cybersecurity in healthcare systems (9 articles), digital divide (8 articles), and health disparities (3 articles). Geographically, the articles spanned studies conducted in North America, Europe, Asia, and Africa, providing a global perspective on the intersection of technology and healthcare.

The quality of the selected articles was validated through their indexing in major academic databases. Of the 42 articles, 38 (90.5%) were indexed in Scopus, 34 (81%) in Web of Science, and 30 (71%) in PubMed. Notably, 28 articles (66.7%) were indexed across all three databases, underscoring their multidisciplinary relevance and high scholarly standards. This systematic review methodology, characterized by a robust search strategy, precise selection criteria, and expert oversight, ensured the inclusion of high-quality, globally relevant studies. The synthesis focused on a qualitative narrative rather than a quantitative meta-analysis due to study heterogeneity.

LITERATURE REVIEW

The Key Challenges

Persistence of Medical Errors

Despite advances in medical technology, medical errors continue to plague healthcare systems worldwide, with around 33% of patients experiencing harm during healthcare delivery.[11] Studies have shown that the incidence of adverse events among hospitalized patients remains high globally despite increased digitalization in healthcare delivery.[12–14] This trend raises concerns about the effectiveness of current patient safety strategies and the disparity in resource allocation to safety initiatives compared to other medical priorities such as technology adoption.[15,16]

Health Inequities and the Digital Divide

While technology has the potential to reduce healthcare disparities, the digital divide continues to exacerbate health inequities, particularly for vulnerable populations,[17–19] Underprivileged communities may lack access to the necessary devices or internet connectivity to utilize telemedicine and remote monitoring technologies effectively.[20,21] These gaps in access further highlight the need for comprehensive policies and investment in digital infrastructure to ensure that advancements in

healthcare technology benefit all patients, regardless of socioeconomic status.[22,23]

Challenges of Telemedicine

The advent of telemedicine, particularly accelerated during the COVID-19 pandemic, presents both opportunities and challenges in healthcare delivery. While telemedicine enhances accessibility, it also increases the risk of miscommunication and missed diagnoses due to the lack of comprehensive physical examinations.[24–26] Moreover, technological illiteracy and inadequate access to digital devices exacerbate health disparities, especially in low-resource healthcare settings.[27–29] This highlights the importance of ensuring equitable access to telehealth services and addressing the underlying social determinants that hinder the effective use of such technologies.

Remote Monitoring

Remote monitoring technologies, particularly in managing chronic illnesses, have gained traction due to their ability to provide continuous data on patient health. However, these technologies are not without risks. Delays in healthcare provider responses or misinterpretation of remote data can lead to adverse patient outcomes.[30,31] Moreover, the effectiveness of remote monitoring depends on the accuracy and timeliness of the data collected. Underscoring the need for healthcare providers to carefully evaluate these technologies before implementation.[3,31,32]

Algorithmic Bias in AI

AI in healthcare holds the potential to improve diagnostic accuracy and optimize treatment plans. However, algorithmic bias remains a significant concern, particularly when AI models are trained on datasets that lack diversity.[33–35] Such biases can lead to inaccurate diagnoses and treatment recommendations that disproportionately affect marginalized populations.[36] For example, biased AI systems have been found to suggest less aggressive treatments for black patients compared to white patients, perpetuating health inequities.[37,38] Addressing this requires both, technological advancements and ethical considerations during the development and deployment of AI in healthcare.

Risks of Overreliance on Automation

The increasing automation of healthcare processes, while reducing human error in some cases, also poses risks. Overreliance on automated systems can lead to complacency among caregivers, diminishing their clinical judgment and decision-making capabilities.[39–41] Ensuring that healthcare professionals maintain their skills and remain critical of automated recommendations is essential for patient safety.[42] The balance between automation and clinical expertise is crucial to protect the medical proficiency of healthcare providers.

Cybersecurity Vulnerabilities in Healthcare Systems

The digitalization of healthcare has also introduced cybersecurity risks, which, if not properly addressed, can jeopardize patient safety.[43–45] Cyberattacks, including ransomware, disrupt healthcare services and compromise sensitive patient data.[46] The WannaCry ransomware attack, which targeted the UK's National Health Service (NHS), highlighted the potential for widespread disruption caused by inadequate cybersecurity measures.[47–49] As healthcare organizations increasingly adopt digital tools, governments and healthcare providers must prioritize cybersecurity investments and training to protect patient data and maintain uninterrupted care delivery.[50,51]

Thus, the extant literature highlights that digital technologies in healthcare hold promise but they also come with significant risks to patient safety, particularly in vulnerable populations and low-resource settings. To fully harness these technologies' potential, addressing issues such as cybersecurity, algorithmic bias, access disparities, and overreliance on automation is imperative. Ensuring patient safety in a digitalized healthcare environment requires a coordinated effort between healthcare providers, policymakers, and technology developers to mitigate these risks while advancing the quality of care.

RECOMMENDATIONS

Solutions to These Challenges

The solution to these challenges lies in the need for a balanced approach that embraces technological advancements and addresses the associated risks.

Integrating Technology with a Patient-Centric Approach

To mitigate the risks associated with digital technologies in healthcare, a patient-centric approach must be prioritized. This approach involves designing and implementing technologies that enhance patient safety while maintaining human oversight. For instance, AI algorithms should be developed with diverse datasets to avoid biases and ensure equity in healthcare outcomes.[52–54] Additionally, involving healthcare professionals in designing and deploying these technologies can bridge the gap between technological innovation and practical and safe application.[55–57]

Enhancing Interoperability of EHR Systems

One of the significant challenges with EHRs is the lack of interoperability between different systems, which leads to incomplete patient records and potential safety risks. To address this, healthcare organizations should adopt standardized data sharing and integration protocols across platforms.[58,59] This can be supported by government policies that mandate interoperability standards, ensuring that patient data can be accurately and securely accessed regardless of the system in use. The adoption of open-source solutions has shown promise in creating more adaptable and interoperable systems.[60]

Developing Robust Cybersecurity Frameworks

Given the increasing threats of cyberattacks on healthcare systems, developing and implementing robust cybersecurity frameworks is imperative. These should include regular updates to software systems, training for healthcare staff on recognizing and responding to cyber threats, and the adoption of advanced encryption methods to protect patient data. By investing in robust security systems, healthcare organizations can protect their patient's safety and operational integrity.[61]

Continuous Education and Training for Healthcare Providers

As digital technologies evolve, continuous education and training for healthcare providers are essential. This training should focus on using new technologies effectively and understanding their limitations and potential risks.[62,63] For example, training programs could include modules on the ethical implications of AI in diagnosis and treatment, emphasizing the importance of critical thinking and human oversight in automated processes.[64–66] Continuous professional development ensures that healthcare providers remain competent and confident in the face of rapidly changing technology.

Implementing Rigorous Evaluation and Feedback Mechanisms

To ensure that new technologies are safe and effective, healthcare systems should implement rigorous evaluation and feedback mechanisms. These mechanisms should involve continuous monitoring of technology performance, patient outcomes, and user experiences. Feedback from healthcare providers and patients should be systematically collected and used to refine and improve technologies.[67,68]

Suggestions for Policy and Regulatory Framework

The successful integration of digital technologies in healthcare requires robust policy and regulatory support. Policy makers and regulatory bodies should develop comprehensive frameworks that promote innovation while ensuring patient safety.

Setting clear guidelines for the ethical use of AI, mandating regular safety audits of EHR systems, and establishing protocols for responding to cybersecurity threats. These policies should be flexible enough to adapt to the fast-paced evolution of digital health technologies while maintaining stringent safety standards.[69,70]

Policymakers must create a comprehensive regulatory framework providing clear guidelines to healthcare institutions regarding the use of AI algorithms in healthcare, and must undergo rigorous testing and validation to prevent biases that could lead to unequal treatment outcomes.[66,71]

Stringent cybersecurity standards for all healthcare institutions, including mandatory encryption protocols, regular software updates, and comprehensive training for healthcare professionals on recognizing and responding to cyber threats. Additionally, there should be a legal requirement for healthcare organizations to report cyberattacks promptly, enabling a coordinated response and minimizing the impact on patient care.[62]

Government policies should also incentivize healthcare institutions especially in low- and middle-income regions to invest in advanced cybersecurity measures, such as AI-based threat detection systems, to protect patient data and ensure operational continuity.[72]

Setting national standards for data sharing and integration, ensuring that patient information can be seamlessly transferred across healthcare providers without compromising safety. Interoperability standards should be designed to support patient privacy while allowing healthcare professionals access to comprehensive patient histories, thus reducing the likelihood of medical errors.[73]

Policies should encourage the development of open-source EHR platforms that can be easily adapted to different healthcare settings, particularly in resource-limited environments.[74]

Establishing quality assurance programs to monitor and evaluate the effectiveness of remote healthcare services. These programs should include protocols for ensuring that telemedicine consultations are conducted with the same level of care as in-person visits. This could involve the development of standardized telemedicine practices, including guidelines for when physical examinations are necessary and protocols for ensuring accurate patient assessments.[75]

Scope for Future Research

Future research could focus on understanding and mitigating the biases inherent in AI systems used in healthcare. Researchers should explore the ethical implications of AI in healthcare, examining how these technologies can be designed to promote equity in treatment outcomes across different demographic groups.

There is a critical need for longitudinal studies assessing EHR systems' long-term impact on patient safety and healthcare outcomes. Future research could investigate how EHR-related issues, such as alert fatigue and data entry errors, evolve and what their implications are for patient safety.

Future research could focus on developing innovative cybersecurity solutions tailored to the healthcare sector. This includes exploring the use of AI for real-time threat detection and response and investigating new encryption technologies that can protect patient data without hindering legitimate users' access.

Studies could evaluate the effectiveness of telemedicine across different patient populations, particularly in rural and underserved areas. This includes studying the impact of telemedicine on healthcare access, patient outcomes, and satisfaction, as well as identifying barriers to effective telemedicine use.

DISCUSSION

The review illustrates that digital health technologies hold tremendous potential to improve patient care but also pose substantial risks that require ongoing evaluation, ethical considerations, and regulatory oversight. Ensuring patient safety in the digital age demands a multi-faceted approach involving continuous education, developing robust safety protocols, and establishing policies that foster both technological innovation and equity in healthcare delivery. This discussion reaffirms the need for healthcare systems to prioritize patient safety at every stage of technological integration, ensuring that digital health's benefits are realized without compromising care quality or exacerbating disparities.

The critical examination of the intersection of technological advancements and patient safety, offering insights into both the promise and perils of digital transformation in healthcare. While digital tools such as Electronic Health Records (EHRs), telemedicine, and AI have the potential to enhance care delivery, they also introduce significant risks that must be addressed proactively. Despite advancements in digital health, the persistence of medical errors underscores the complexity of ensuring patient safety in an increasingly digitized healthcare environment.

The rise of telemedicine, accelerated by the COVID-19 pandemic, represents a paradigm shift in healthcare delivery. However, its success is contingent upon equitable access and resolving inherent limitations, such as the absence of comprehensive physical examinations and technological illiteracy among vulnerable populations. These challenges illustrate that telemedicine can exacerbate existing health inequities rather than alleviate them without careful attention to implementation and infrastructure. Therefore,

policymakers must ensure that digital health solutions are accessible, effective, and tailored to diverse populations.

The review also highlighted the significant risks posed by algorithmic bias in AI systems, which can perpetuate health disparities if not properly addressed. AI's reliance on non-representative datasets can result in biased diagnoses and treatment plans, disproportionately affecting marginalized communities. Addressing this issue requires both technological advancements and ethical oversight to ensure that AI systems are trained on diverse and inclusive datasets. Furthermore, the risks of overreliance on automation, suggest the need for healthcare providers to maintain critical thinking and clinical judgment when interacting with digital tools.

In terms of cybersecurity, the digitalization of healthcare has made systems more vulnerable to cyberattacks, which can jeopardize both patient safety and data privacy. Robust cybersecurity frameworks and regular updates to software systems are essential to safeguarding patient data and ensuring the continuity of care. Additionally, training healthcare personnel to recognize and respond to cyber threats is critical in preventing disruptions in care delivery.

The analysis of remote monitoring technologies has revealed both the advantages and challenges of these tools in managing chronic illnesses. While remote monitoring offers the ability to continuously track patient health, the reliability of the data and the timeliness of healthcare responses are critical to ensuring positive patient outcomes. Delays in addressing essential health changes can result in adverse outcomes, underscoring the importance of healthcare providers carefully evaluating these technologies before widespread implementation.

CONCLUSION

While advancements like AI, EHRs, and telemedicine offer significant potential to improve healthcare, they must be deployed with strong safety protocols, attention to equity, and comprehensive regulatory oversight. There is an urgent need for a global, future-focused commitment to patient safety in the digital era. Without these safeguards, the risks—such as algorithmic bias, cybersecurity threats, and unequal access—can undermine the very goals of improving patient outcomes. This paper suggests a cohesive, patient-centric strategy that continuously evaluates emerging technologies to ensure they enhance, rather than compromise, the quality and safety of care.

AUTHOR CONTRIBUTIONS

Conceptualization, S.S.; Methodology, S.S.; Investigation, S.S.; Writing–Original Draft Preparation, S.S.; Writing–Review & Editing, M.S. and K.B.P.; Visualization, M.S. and K.B.P.; Supervision, M.S. and K.B.P.; Project Administration, M.S. and K.B.P.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not required.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not required.

CONSENT FOR PUBLICATION

Not required.

FURTHER DISCLOSURE

Not applicable.

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Received May 23, 2024, accepted December 19, 2024 date of publication January 20 2025.

Original Research Article

Research on Strategies for Improving Turnaround Time Efficiency through Automation Tools

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ABSTRACT

Background: Continuously monitor monthly laboratory turnaround time (TAT) data, analyzing the reasons for the continuous increase in TAT, and applying PDCA (Plan-Do-Check- Act, and automation tools for improvement, to enhance laboratory efficiency, and provide more accurate and efficient support for clinical diagnosis and treatment.

Methods: Analyzing data from November 2022 to April 2023, identifying risk points in biochemical sample TAT, sought root causes, formulated targeted improvement plans, and continuously tracked changes before and after improvement. The analysis group consisted of data from November 2022 to April 2023, and the improvement group from May 2023 to August 2023.

Results: Despite the gradual increase in laboratory sample volumes, the overall and segmented TAT for biochemical projects decreased after improvements.

Conclusion: Continuous monitoring of quality indicators within the laboratory is essential. Using PDCA tools to identify causes and automation tools can significantly improve TAT results, effectively help identify risk points and root causes, and enhance testing efficiency. This approach can be attempted to analyze and improve other indicators.

Keywords—*Biochemistry, Laboratory turnaround time, Automation, PDCA.*

INTRODUCTION

After the onset of the COVID-19 pandemic, nucleic acid testing gradually became a focal point of the laboratory department's work. As we enter the post-pandemic period, the volume of outpatient hospital visits has surged, and the number of samples in the laboratory department has increased accordingly. Testing quality directly affects patient diagnosis and satisfaction.[1] How to utilize automated and information-based assembly lines to improve work efficiency, achieve intelligent and intensive laboratory operations, optimize personnel arrangements, and provide accurate and efficient test reports to assist clinical work in differential diagnosis, thereby enhancing patient satisfaction, is a topic that the laboratory department needs to focus on continuously.

In the context of Diagnosis Related Groups (DRGs) reform, strengthening refined management is a new challenge and opportunity for laboratory medicine.[2] In 2017, the "Clinical Laboratory Quality Indicators" (WS/T496-2017)[3] was released, clearly defining 28 indicators closely related to the quality of the clinical laboratory. It proposed that the entire testing process spans from the clinical issuance of a test request to the patient receiving the test report, including pre-analytical, analytical, and post-analytical phases. Among these, efficiency-related quality indicators are pre-analytical turnaround time (TAT) and intra-laboratory TAT. TAT refers to when the laboratory receives the specimen to when the report is sent, encompassing the total time of the analytical and post-analytical phases.

Typically, biochemical and immunological samples are the focus of intra-departmental testing work and are significant sources of influence on the total TAT of the laboratory. Continuously analyzing the operational efficiency of the production line, monitoring changes in TAT data, early warning, and applying the PDCA cycle management method to analyze causes and implement improvements are effective methods to enhance the quality of testing and operational efficiency of the department, thereby providing better services to patients.

MATERIALS AND METHODS

General Information

The Dezhou People's Hospital Laboratory (Dezhou, Shandong Province, China) is equipped with a Power Express (PE) automation line (Beckman Coulter), connected to the AU5821 and DxI800. It is equipped with Remisol middleware for data transmission and analysis.

TABLE 1. Median TAT (min) data required by the standard.

Tertiary	Hospital	Minimum	Appropriate	Best
Emergency	Biochemistry	60	**45***	30
	Immunity	88	**60**	40
Routine	Biochemistry	150	**115**	80
	Immunity	225	**149**	100

According to the "Clinical Laboratory Quality Indicators" (WS/T496-2017)[3], the acceptable range for the laboratory's TAT is established, which meets the "appropriate" requirements in the "standards" (see Table 1).

*The data in bold means the laboratory TAT requirements recommended by the state, as stated in the above text.

Study Design

Following the PDCA cycle strategy, the improvement of TAT in the laboratory biochemical project is carried out based on Plan (discovering problems and defining causes), Do (formulating improvement plans), Check (tracking effects), and Act (continuous improvement plans).

Plan: Analyze the TAT data in the laboratory for projects conducted on the PE line from September 2022 to August 2023. It was found that the biochemical TAT fluctuated and increased, and indicated that the TAT showed too long and needed improvement. An improvement team was established, and the reasons affecting TAT were identified through interviews with relevant responsible personnel. A questionnaire survey was created, and the true influencing factors were identified through voting.

Do: Discuss within the group and formulate targeted improvement plans.

Check: Check the effect after rectification, regularly count the laboratory TAT indicators, compare the execution results with the target to be achieved, and determine whether there has been any improvement, and whether the target has been reached.

Act: Continuously monitor, and plan to use for other indicators.

According to the improvement plan and timeline differentiation statistics, the period from November 2022 to April 2023 is designated as the analysis group, and the period from May 2023 to August 2023 is designated as the improvement group.

Statistics Analysis

All the data were collected and analyzed through the automation tool named Remisol of the PE assembly line, and data processing was analyzed using Excel (2019, Microsoft, USA).

RESULTS

The Fluctuation in Biochemical TAT Had Increased and Needed Improvement

The monthly specimen quantity and TAT median of the analysis group for biochemical and immunological projects are as follows (see Table 2, Figure 1, and Table 3, Figure 2):

TABLE 2. Monthly statistics of biochemical samples (before improvement).

	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023
Total Samples (Number/Month)	19,269	26,313	37,022	42,045	44,326	40,462
Median TAT (min)	83.0	81.5	89.0	88.0	89.5	91.0

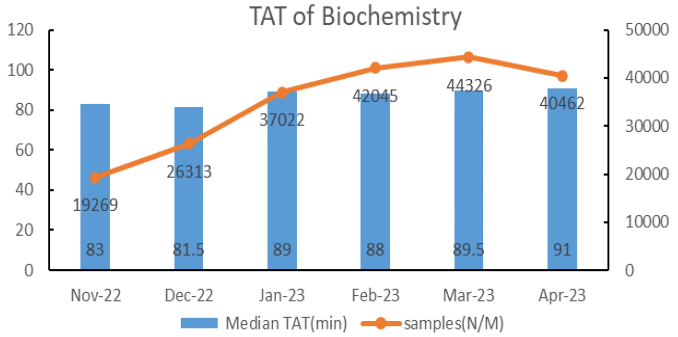

FIGURE 1. Trend of monthly median TAT of biochemical samples (before improvement).

TABLE 3. Monthly statistics of immunological samples (Nov. 2022–Apr. 2023).

	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023
Total Samples (Number/Month)	1,546	2,119	2,757	2,067	2,604	2,543
Median TAT (min)	81	58	47	46	69	71.5
Median TAT (min)	81	58	47	46	69	71.5

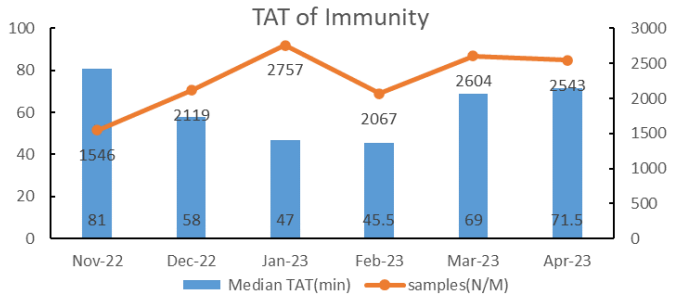

FIGURE 2. Trend of monthly median TAT of immunological samples (Nov. 2022–Apr. 2023).

The median TAT for biochemistry meets the "appropriate" requirement (< 115 min); the median TAT for immunology meets the "optimal" requirement (< 100 min). It is planned to improve the biochemical TAT, and based on the actual situation of the laboratory, taking into full consideration the increase in sample volume, the phased improvement target is set to reduce the median TAT for routine biochemical TAT to the average TAT median of the analysis group (< 84 min).

Personnel and Equipment are the Fundamental Reasons Affecting TAT

Referring to national quality management requirements, interview 20 members including laboratory members and manufacturer representatives. Review the factors affecting TAT, including personnel, equipment, management, and material. Invite participants to vote on the above factors, each selecting three items. Summarize and analyze the proportion of reasons. The data and analysis Pareto chart are shown in Table 4 and Figure 3.

TABLE 4. Reason analysis.

Categories	Entry	Quantity	Percent
Personnel	The laboratory member is limited, the sample number is large, and the result review time is lengthy.	16	26.7
	The personnel lacks a sense of timeliness, and the samples are not processed on the machine promptly.	12	20.0
Equipment	The automation level of equipment is insufficient, and the pre-treatment time is long.	16	26.7
	Instrument malfunction.	3	5.0
Material	Sample lost.	4	6.7
	The sample barcode is not clear.	2	3.3
Management	The process for handling abnormal sample results is complex.	1	1.7
	The process for handling critical values is complex.	5	8.3
Others	LIS malfunction.	1	1.7
All		**60**	**100**

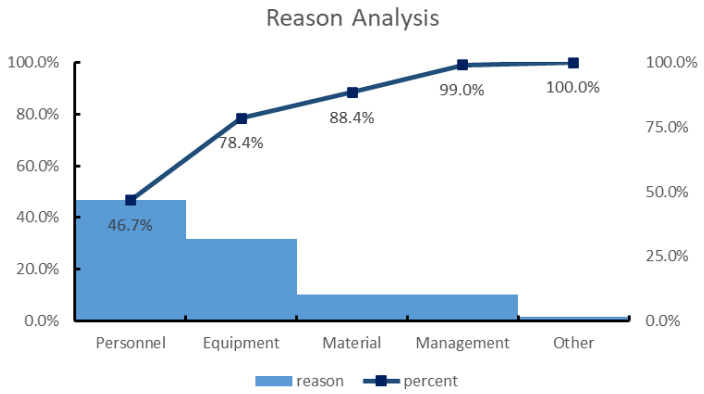

FIGURE 3. Reason analysis (Pareto principle).

According to the Pareto principle analysis, personnel and equipment are the main reasons for TAT in the laboratory. Specifically, the analysis shows: insufficient equipment automation level, long pre-processing time; personnel shortage, large sample volume, long result review time; lack of timeliness awareness among personnel, and samples not being processed promptly.

Formulate Improvement Plans

Improve the Automation Level of Equipment to Save the Quality Control Time of Pre-testing Processing

It is confirmed that the automation line meets the automatic quality control activation conditions. Prepare the necessary consumables and determine that each project will automatically start quality control testing at 6:00 AM and 4:00 PM daily. Train the responsible personnel to standardize the work content of the previous day, such as preparing reagents, instrument maintenance, project calibration, and quality control product archiving. Clearly state that the first task is to confirm that the quality control results have passed the next day, and then proceed directly to sample testing. Set the instrument parameters and conduct simulation experiments. After confirming that everything is correct, officially start.

Adjust the Automatic Review Rules to Increase the Approval Rate and Reduce the Pressure of Manual Reviews

Due to the number of department personnel cannot be increased quickly, an automated method was chosen to reduce the manual review of specimens. Data screening was conducted through the Remisol tools to analyze the specific reasons why the analysis projects did not pass the automatic review. Relevant department experts were invited to participate in discussions. Adding specialized logical rules and adjusting the review scope improved the automatic review pass rate. The sample validation confirmed a compliance rate of 100% before the official launch.

Organize Internal Departmental Training to Enhance Personnel's Attention and Reduce the Time Samples Spend on the Machine

At the departmental summary meeting, it was emphasized that the management of laboratory personnel should be standardized and gradually enhance their sense of work responsibility.

Improvement Effect Tracking

Sample Number and TAT Changes

The total volume of biochemical samples is rising, with the average sample volume for the analysis group being 34,906 units per month, and the average sample volume for the improvement group being 44,318 units per month, an increase of approximately 27.0%. The TAT has shown a fluctuating downward trend since May and meets the improvement targets. Data is shown in Table 5 and Figure 4.

TABLE 5. Monthly statistics of biochemical items (after improvement).

	May 2023	Jun 2023	Jul 2023	Aug 2023
Total Samples (Number/ Month)	43,647	42,643	43,943	47,037
Median TAT (min)	86	88.5	83.5	82

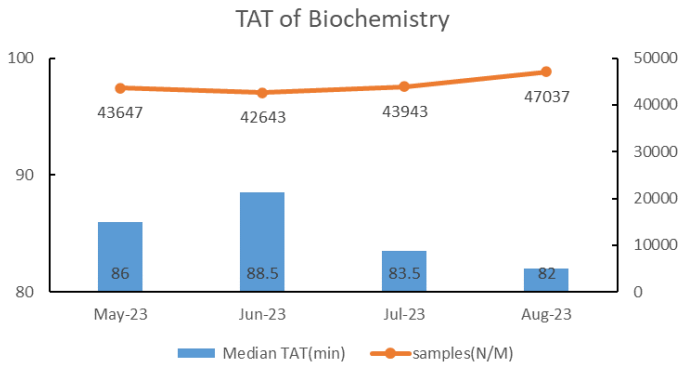

FIGURE 4. Trend of the monthly median turnaround time of biochemical samples (after improvement).

Select samples from March (before improvement) and August (after improvement), calculate the average TAT data for the time period for analysis. After improvement, the average decreased by 7 minutes compared to before improvement, with a statistically significant difference ($p < 0.01$). Data is shown in Figure 5.

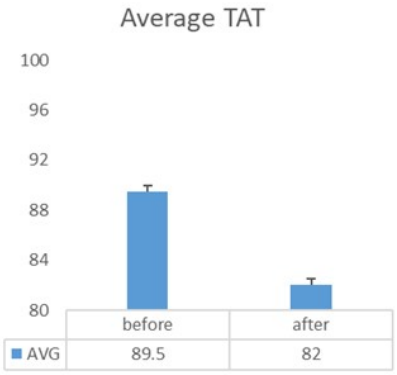

FIGURE 5. Comparison of median average TAT (turnaround time) (Control Group & Improvement Group).

Reduction in Pre-Processing Time for Biochemical Samples

Divide the overall TAT time into three segments, namely "Receive-to-Line", "Line-to-Machine", and "Machine-to-Upload". Through the analysis of pre-analytical processing using the Remisol tools, it was found that during the 7:00 AM–8:00 AM period, the "Reception-to-Line" time decreased from 24.5 minutes to 13.3 minutes, in a reduction of 45.7%, indicating that automatic quality control has a significant effect on shortening the pre-processing time during the

morning peak. During the 8:00 AM–1:00 PM period, the "Reception-to-Line" time decreased from 20 minutes to 10.8 minutes, in a reduction of approximately 46%, indicating a significant improvement in the timeliness of personnel operation. The results are shown in Figures 6 and 7.

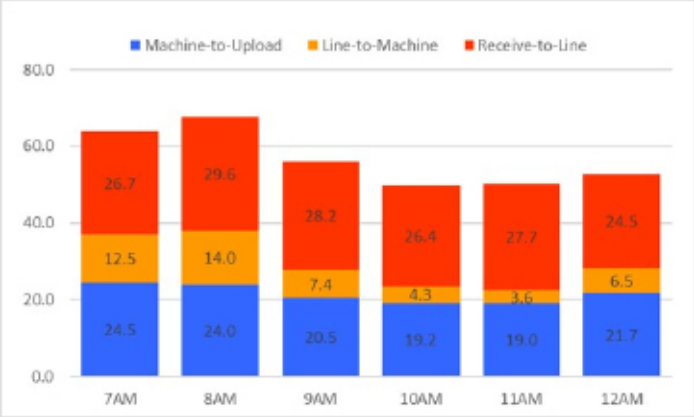

FIGURE 6. TAT data of biochemical sample segment (before improvement).

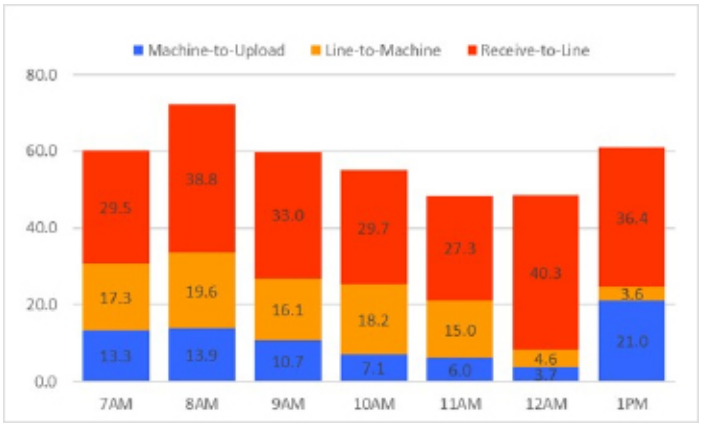

FIGURE 7. TAT data of biochemical sample segment (after improvement).

Note: The horizontal axis 7:00 AM represents the average time of all samples within the 7:00 AM–8:00 AM time interval.

Note: The horizontal axis 7:00 AM represents the average time of all samples within the 7:00 AM–8:00 AM time interval.

Randomly select the average "Receive-to-Line" time over 30 days for two groups for comparative analysis. The average time decreased from 23.2 minutes to 11.9 minutes, showing a statistically significant difference ($p < 0.001$). The results are shown in Figure 8.

FIGURE 8. Comparison of the average "Receive-to-Line" (Control group & Improvement group).

Increase in Automatic Review Pass Rate for Biochemical Samples

Through data analysis, the average automatic review pass rate for biochemical samples increased from 48.55% in the control group to 61.03% in the improvement group, as shown in Figure 9.

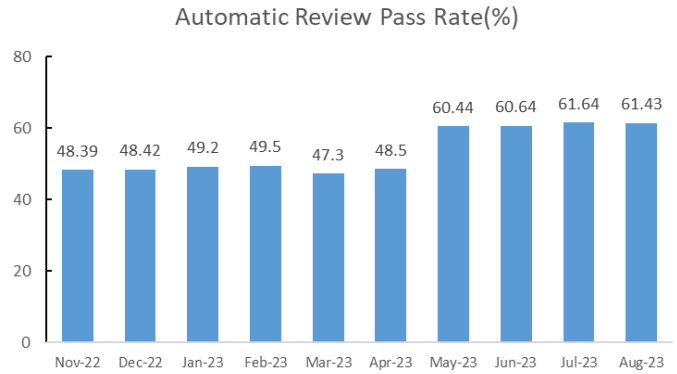

FIGURE 9. The automatic review pass rate of biochemical samples (Control group & Improvement group).

DISCUSSION AND CONCLUSION

The hospital's assembly line is connected to biochemical and immunological equipment, responsible for testing more than 90% of the laboratory's routine biochemical and immunological samples. Since its inception, it has focused on the efficiency of the assembly line and TAT. This study is based on the analysis of TAT based on the assembly line, noting the risk trend of fluctuating upward TAT for biochemical samples, and therefore decided to improve through PDCA tools. By initiating automatic quality control, the issue of prolonged waiting times for sample accumulation during peak hours was effectively solved, and the time of "Receive-to-Line" was reduced; by raising personnel awareness, samples were loaded onto the machine promptly after reception, simultaneously shortening the time of "Line-to-Machine"; by increasing the automatic review pass rate to reduce the pressure of manual review and improve review efficiency; the overall TAT returned to a better level despite the gradual increase in sample volume. The specific process is shown in Figure 10.

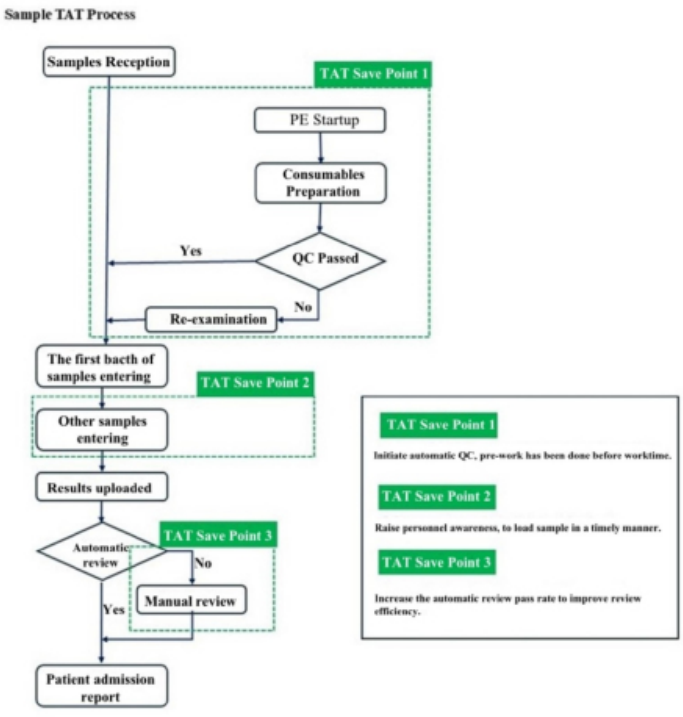

FIGURE 10. Sample of TAT process.

In 2009, the State Council began to promote the reform of public hospitals, gradually enhancing the requirements for refined management of public hospitals. In 2021, the General Office of the State Council issued the "Opinions on Promoting the High-Quality Development of Public Hospitals"[4], proposing that public hospitals should continuously improve the medical quality management system and standard system, and enhance the quality of medical services. As an important factor in measuring the management level of laboratories, the TAT of clinical laboratories is a crucial indicator affecting the quality of clinical laboratories.[5] In the ISO15189 laboratory accreditation requirement (2022)[6], the early warning role of "risk management" is mentioned multiple times and should be more widely applied in the management system of the laboratory department. The PDCA cycle is a quality management tool that helps to discover problems, find causes, and implement improvements.[7–9] In recent years, PDCA has been widely applied to managing various quality indicators in the laboratory department.[10–11] With the upward trend in the volume of samples in the laboratory department, the department needs to complete reports more efficiently and accurately, and optimize sample TAT times, to assist clinical departments in the dialectical treatment of patient conditions.

Data support is provided to improve TAT indicators through the comprehensive analysis of data information by the intelligent middleware system of the assembly line. A series of adjustments have improved the level of intelligence and efficiency of the laboratory. Therefore, strengthening data analysis is a prerequisite for improving various quality indicators in the laboratory. The laboratory can use various intelligent analysis software for regular monitoring and analysis of key quality indicators, explore the influencing factors of indicators, strengthen communication with clinical departments, determine the best improvement plans, gradually improve the quality and efficiency of laboratory work, provide efficient support for clinical departments, and provide high-quality services for patients.

AUTHOR CONTRIBUTIONS

Conceptualization, Z.Z. and J.J.; Methodology, C.Z.; Software, C.Z.; Hardware, C.Z.; Formal Analysis, F.L.; Investigation, L.Z.; Resources, L.Z.; Data Curation, L.Z.;

Writing–Original Draft Preparation, C.Z. and L.Z. and F.L.; Writing–Review & Editing, C.Z.; Visualization, L.Z.; Supervision, Z.Z.; Project Administration, J.J.

ACKNOWLEDGMENTS

We would like to thank Mr. Sun coming from Beckman Coulter for his technical assistance during the experiments.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received February 14 2024, accepted December 15, 2024, date of publication February 15 2025.

Original Research Article

A Study on the Legal Environment of Medical Devices and Enhancing the Regulatory System

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ABSTRACT

The regulation of medical devices is governed by the Law on Health, the Law on Medicines and Medical Devices, and the Law on Metrology. While these laws provide definitions of key terms, they lack detailed regulations. The Law on Health addresses issues related to special licenses, while the Law on Metrology covers metrological inspections. According to the "Methodology for Assessing the Consequences of the Implementation of Legislation", as approved by Appendix 6 of Government Resolution No. 59 of 2016, the implementation of these laws, including the Law on Medicines and Medical Devices, the Law on Health, and the Law on Metrology, has not fully aligned with reality. This misalignment has failed to regulate certain essential relationships, leading to negative societal impacts. Consequently, we assessed the implementation and consequences of these laws, considering the lag between social changes and legal developments. Additionally, comparing medical device regulations with the standard regulations of countries around the world revealed several differences, starting from the definitions of key terms. We concluded that there is a need to improve the legal and regulatory environment to establish unified policies and regulations for registration, quality, safety, optimal asset planning, and maintenance management, particularly for medical equipment.

Keywords—*Specialists, Consequences, Equipment, Medical devices, Medical supplies, Regulation.*

INTRODUCTION

The medical device market in Mongolia is small, which limits the potential for major manufacturers to establish businesses in the country. Mongolia does not produce any medical devices, except for disposable syringes and a few other minor items. As a result, nearly all medical devices are imported from various countries and manufacturers. This situation leads to many unregistered medical devices of uncertain quality. Supplying government hospitals with modern, high-quality, safe, and reliable equipment and ensuring regular preventive maintenance and repair services has been one of the biggest challenges in the Mongolian healthcare sector.

State budget investments in medical equipment have varied over the years: in 2019, USD 2.4 million were allocated; in 2020, USD 11.2 million; in 2021, USD 32.7 million; in 2022, USD 4.3 million; and in 2023, USD 3.5 million. Before 2017, the budget for medical equipment maintenance was included in the organization's operational expenditure. However, starting in 2018, the maintenance and service costs for major technologies, such as magnetic resonance imaging (MRI) scanners, computed tomography (CT) scanners, and angiography machines, were separately allocated within the state budget. In 2018, USD 0.7 million were dedicated to this purpose, followed by USD 0.8 million in 2019, USD 1.1 million in 2020, and USD 1.6 million in 2021. From 2022 onward, due to performance-based financing, a separate budget for these services is no longer allocated.[1]

Many developing countries today face similar challenges with medical devices due to their complex nature, as they combine mechanical, electronic, software, and chemical components. This complexity necessitates a higher level of safety and an improved regulatory system. Medical devices play a crucial role in diagnosing, preventing, monitoring, and treating diseases. Unlike drugs or biologics, medical devices can range from simple devices that pose little or no risk to the user (e.g., a suction pump) to life-sustaining devices (e.g., a pacemaker). The solution to these challenges lies in developing a comprehensive regulatory system for medical devices.

Regulatory systems for medical devices are generally less developed than those for other health products such as medicines or vaccines. A desk survey conducted in 2015–2016 revealed that 58% of World Health Organization (WHO) member states had some form of regulation for medical devices, even if limited.[2] Many governments, including Mongolia, that have drafted medical device regulations have made limited progress in implementing them.

In Mongolia, medical device regulatory systems are less developed than in other countries. Having an appropriate and comprehensive policy that guides medical equipment selection, procurement, and maintenance in compliance with international standards. While Mongolia has some ministerial orders and policy documents related to medical devices and health technology, there is still a need for improvement. Additional regulatory systems are required, including import control, product registration, classification, packaging and labeling, advertising, use, and disposal.

METHODOLOGY

We assessed the implementation of laws and regulations related to medical device regulation to identify areas for improving the regulatory system. We reviewed relevant articles, audit and evaluation reports, and other documents from authorized organizations to analyze the practical compliance of laws and regulations with their provisions and compare them with the most significant and influential international standards. Additionally, recommendations, documents, and standards from the WHO and international regulatory organizations were analyzed. Comparative studies were conducted on the regulations of other countries in relation to Mongolia's legal environment. Data collection involved meetings, discussions, and feedback exchanges using the following methods.

The descriptive study included audit, monitoring, assessment reports, news from authorized organizations, and recommendations, documents, standards, and regulations from the WHO and international regulatory organizations. Additionally, three focus group interviews were conducted, involving 26 participants divided into three groups: 9 medical equipment engineers from local healthcare facilities, 8 university faculties, and 9 medical equipment engineers from the private sector. The focus group interviews were analyzed using the content

analysis method to assess the implementation of legal documents related to medical equipment, the quality and accessibility of equipment, the capacity and adequacy of human resources, and the challenges encountered while implementing the laws.

RESULTS

The WHO defines "medical devices" as a broad category encompassing items ranging from small medical instruments and supplies to large diagnostic and therapeutic equipment.[3]

The International Medical Device Regulators Forum (IMDRF)/GHTF also defines "medical devices" as encompassing a wide range of products, from relatively simple non-implantable devices, such as tongue depressors, thermometers, blood pressure monitors, stethoscopes, scales, disposable gloves, wound dressings, hospital beds, and crutches, to highly advanced imaging diagnostic devices and implants. They recommend classifying medical devices to patients and medical professionals based on their risk level, with appropriate regulations tailored to each category.[4,5]

The IMDRF is a voluntary coalition of regulatory authorities that fosters international collaboration in regulating medical devices.

Established in 2011 as a part of the Global Harmonization Task Force (GHTF), the IMDRF aims to harmonize and enhance the global regulation of medical devices.

In the countries of the WHO Western Pacific Region, including Australia, Japan, Korea, China, and the Philippines, medical devices are classified based on the risk they pose to patients and medical professionals. These classifications include Categories A, B, C, and D, and Classes I, II A, II B, and III. Regulations are tailored to these classifications, with high-risk devices, such as those in Categories C, D, or Classes II B, and III, requiring registration, while lower-risk devices are listed separately.[6–10]

These classifications align with the "Global Model Regulatory Framework for Medical Devices" issued by WHO[11] and the general regulatory models provided by IMDRF.

In terms of the legislation in Mongolia, the regulation of medical devices is as follows: The Law on Health provides definitions of four terms: 3.1.13 "medical equipment", 3.1.14 "medical instrument", 3.1.15 "accessories for medical equipment", and 3.1.16 "prosthesis", and Article 19 of the law includes a group of provisions related to licenses to engage in healthcare activities. The Law on Medicines and Medical Devices defines two terms: 3.1.4 "diagnostic device" and 3.1.5 "medical device", and Article 8.1.1 of the Law on Metrology regulates them separately.

According to the descriptive study, within the framework of the above legislation, the following standards have been approved: Structure and Operation Standards-7, Medical Equipment Standards-16, Order of the Deputy Prime Minister of Mongolia-1, Order of the Minister of Health-14, and Order of the Director of the Mongolian Agency for Standard Metrology-2.

In a survey on implementing laws and regulations related to medical equipment, 86.1% of respondents said that a state inspection and regulatory system for medical equipment had not been established. 91.7% indicated that a legal framework for regulating medical equipment was absent. 91.9% reported no legal framework for ensuring the quality and safety of medical equipment. 91.7% said a legal framework for the optimal planning and regulation of medical equipment assets was not established. 97.3% indicated a legal framework for regulating medical equipment maintenance and service management was not in place. 75% of respondents said that a state inspection and regulatory system for medical equipment had been established, while 25% disagreed. A total of 25.7% felt that regulating medical equipment licenses was sufficient, while 74.3% believed it was insufficient.

Implementation of Legal Documents and Reflection of Stakeholders' Feedback

There is limited regulation related to medical equipment in sectoral laws, and existing regulations are scattered across individual laws. Although healthcare facilities follow Ministerial Order No. 439 of 2006, the implementation of this order varies depending on the hierarchy of healthcare facilities, with local areas facing particular challenges. It

is emphasized that human resources and room requirements are insufficient in these areas. In private healthcare facilities, regulations are created based on the internal rules and regulations of the institution, which prioritize customer requests. Since the rules and regulations concerning equipment regulation are separate, there is a recognized need for an integrated legal framework. This would involve consolidating and updating the existing regulations, including Ministerial Order No. 439 of 2006, Ministerial Order No. 404 of 2006, and MNS5097:2017 General Hospital Structure and Operation Standards.

Ministerial Order No. 439 of 2006 states that there should be 1 engineer for every 100 pieces of equipment. However, it is necessary to define which types of equipment should be included in the 100-piece count. Additionally, it should be clarified that one engineer should specifically be assigned to high-cost equipment, and there needs to be clear criteria for identifying what qualifies as high-cost equipment. Overall, an integrated legal regulation is needed, rather than relying solely on Ministerial Order No. 439 of 2006." (Engineer of the medical equipment, Healthcare facility)

"In the MNS5097:2017 standard, equipment is evaluated as either present or absent. For example, a hospital bed is considered 'present' even if it is broken. We would like to change this evaluation to a numerical system, where the condition of the equipment is assessed with plus or minus signs, rather than simply being counted as present or absent. A numerical evaluation would provide a more realistic assessment of the equipment's status." (Engineer of the medical equipment, Healthcare facility)

"It would be beneficial to include criteria for buildings, rooms, and human resources in the accreditation standards, so that these aspects can be properly evaluated." (Engineer of the medical equipment, Healthcare facility)

"In the future, the regulations should require the medical equipment manuals in a simplified format with two categories: user and engineering." (Engineer of the medical equipment, Pharmaceutical supply organization)[1]

Representatives from faculties and researchers have recently been involved in developing policy documents. However, representatives of engineers and technicians are not always included, and it is emphasized that the participation of other professionals is also crucial.

Equipment Quality, Availability, and Regular Maintenance

Investment and supply of medical equipment have improved due to the coronavirus pandemic. However, the lack of routine maintenance, inadequate funding planning, and the pressure to operate in high-demand conditions contribute to increased equipment damage.

While performance financing and management privatization have positively impacted equipment supply, some hospitals are forced to cut their maintenance budgets to remain profitable

"A hospital can only attract customers if it has both good equipment and skilled specialists." (Engineer of the medical equipment, Healthcare facility)

"Our hospital has a budget of USD 0.6 million for normal operations, covering everything from vehicles and buildings to computers. However, only about USD 500-600 are allocated for hospital equipment, which is insufficient even to cover the spare parts for a single device." (Engineer of the medical equipment, Healthcare facility)

"There is no stock of spare parts for the equipment, and availability is always uncertain. The order is constantly dependent on someone else. After the equipment is installed, if a failure occurs later, the spare parts may already be outdated, or the equipment may no longer be produced. As a result, we engineers are left with no choice but to resort to a 'Mongolian way' of handling it." (Engineer of the medical equipment, Supply organization)[1]

Medical equipment purchases are often organized by unqualified individuals without obtaining quotes based on technical specifications. As a result, the manufacturer is often unknown, and expensive, substandard equipment is frequently purchased.

"There was an instance where a company selling toys in the market won the tender to supply CPAP machines for infants, claiming there were no professionals available for the local tender. When the equipment was delivered, two salesmen—who were not professionals at all—came

to hand it over." (Engineer of the medical equipment, Healthcare facility)

"It is difficult to obtain spare parts for expensive equipment, and it would be beneficial if a certain percentage of the budget received from insurance were allocated specifically for spare parts." (Engineer of the medical equipment, Healthcare facility)[1]

It is believed that the equipment registration system needs to be updated.

Human Resource Capacity and Accessibility

Four universities train medical equipment engineers and technicians, with an employment rate of 95%. However, the high workload, part-time work, low salaries and benefits (which are set for non-medical professionals), and the lack of opportunities for postgraduate training and specialization contribute to a shortage of human resources, particularly in public hospitals and rural areas.

"There should be one engineer for every 100 pieces of medical equipment, but in reality, one engineer is responsible for 200–300 pieces of medical equipment." (University professor)

"Our hospital has over 600 pieces of medical equipment, and we have one engineer and two technicians working here. However, there are no engineers specifically responsible for CT, hemodialysis, and oxygen equipment, so three people are handling these tasks. Additionally, there is extra work related to Occupational Safety and Hygiene (OSH)." (Engineer of the medical equipment, Healthcare facility)

"We are performing tasks similar to surgeries, such as assisting with hemodialysis, and working with CT, yet we are paid at the Government Service (GS) level. Therefore, we want to be included in the GS of the Health Sector." (Engineer of the medical equipment, Healthcare facility)

"There are many people who don't fully understand the responsibilities of a medical equipment engineer or what their role should entail. They assign tasks to engineers simply because the work is related or similar." (Engineer of the medical equipment, Healthcare facility)

"We want to hire new specialists, but they are not coming to local areas. Students graduating from private universities are entering engineering fields, not medical technology. Additionally, graduates often lack the ability to distinguish between different types of equipment. Therefore, we need to focus on improving the quality of training." (Engineer of the medical equipment, Healthcare facility)[1]

Medical equipment engineers often have to take on various additional tasks due to the ambiguity of their responsibilities and are frequently employed as OSH staff. Medical equipment engineers can be compensated through the Health Sector Government Service (GS).

DISCUSSION

Based on the recommendations from the WHO and international regulatory bodies, as well as the legal frameworks related to the regulation of medical devices and other products in various countries, a wide range of products, from small medical instruments to large diagnostic and therapeutic equipment, are defined as "medical devices". These devices are then classified as A, B, C, and D, or Class I, Class II A, Class II B, and Class III, based on the level of risk they pose to patients and medical professionals. Regulations are being developed according to these categories, including the registration of high-risk products, such as those in categories C, D, or Class II B, and Class III, while other products are listed separately in the remaining categories.

The survey, conducted among medical equipment engineers, technicians, representatives of supply organizations, and faculties regarding the implementation of legislation, included 35–37 participants in each group. The findings indicate that the legal and regulatory framework concerning medical equipment is insufficiently developed, and state inspection and regulation are weak.

When comparing the regulations on medical equipment and other products included in major healthcare sector laws in our country with the standard regulations on "medical devices" in countries around the world, differences are evident, starting with the definition of the term. Establishing a legal framework for integrated policies and regulations covering medical equipment registration,

quality, safety, rational asset planning, and maintenance management is essential.

CONCLUSION

When comparing the regulations related to medical devices in Mongolia, particularly those concerning medical equipment, with the WHO recommendations, the IMDRF general regulatory models, and the regulations of countries such as Australia, Japan, Korea, China, and the Philippines significant differences emerge. These include discrepancies in the definitions of terms, the absence of a classification system for medical devices, a lack of post-market quality surveillance, and no regulations regarding packaging, labeling, advertising, or proper disposal. However, the regulations for importing medical devices through licensed suppliers are in line with the medical device regulations of the aforementioned countries and WHO recommendations.

AUTHOR CONTRIBUTIONS

Conceptualization, A.D., M-E.L., G-O.N. ;Methodology, A.D., M-E.L.; Formal Analysis, A.D., G-O.N.; Writing – Original Draft Preparation, G-O.N.; Writing – Review & Editing, A.D., M-E.L.; Supervision, A.D.; Project Administration, M-E.L.; Funding Acquisition, G-O.N.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study methodology was reviewed and approved by the Research Ethics and Monitoring Committee of the Mongolian National University of Medical Sciences during its meeting on January 21, 2022 (Approval No. 2022/3-01).

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Part of the findings from this study, titled "Assessment of the Implementation of Medical Equipment Policy in Mongolia", authored by Gerelt-Od Namdag, Munkh-Erdene Luvsan, and Amarsaikhan Dashtseren, was presented at the 5th International Clinical Engineering and Health Technology Management Congress (ICEHTMC), held from November 11 to 23, 2023.

Additionally, the abstract of this study was published in the Global Clinical Engineering Journal (GCEJ) Special Issue 5.

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Received July 5, 2024, accepted December 13, 2024, date of publication Feburary 27, 2025.

Review

Protocol for a Systematic Review on the Application of Robotics in Orthodontic Treatments

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ABSTRACT

Background and Objective: Robotics have multiple uses in dentistry, especially within the field of orthodontics, though the possible applications of these innovative systems are still not well defined. The objective of this systematic review protocol will focus on describing the steps to outline the role of robotics in orthodontic treatments and define its functionality and range within clinical applications.

Methods: To achieve this, peer-reviewed studies focusing on the employment of robotic systems in various aspects of orthodontic treatment will be incorporated, while literature reviews will be not considered. Data will be explored through Scopus, PubMed, Google Scholar and DOAJ. Potential for bias will be established using the ROBINS-E and certainty assessment with GRADE guidelines.

Results: The main results of the articles included will be tabulated in an Excel spreadsheet, and a detailed narrative summary and interpretation of the data will be produced and displayed based on its use in surgical and non-surgical orthodontic treatments.

Conclusion: This systematic review protocol aims to offer important perspectives on the application of robotic systems in orthodontic procedures, contributing to advancement in clinical practices and technological integration. The results may assist practitioners in adopting robotic systems to enhance treatment precision, efficiency, and overall patient care. The literature search will encompass studies from various regions worldwide. This study is self-funded and has been registered on the PROSPERO database under the registration number CRD42023463531.

Keywords—*Robotics, Orthodontics, Clinical application, Surgical orthodontics, Orthodontic wire bending, Systematic review, Dental technology, Innovative orthodontics.*

INTRODUCTION

The term "robot" originated in 1920 from Czech novelist Karel Čapek, while "robotics" represents an intelligent fusion of perception and action, spanning multiple fields like engineering and computer science.[1,2] In recent years, robotics has profoundly impacted various facets of modern life, from industrial manufacturing to healthcare, including significant advancements in dentistry. Emerging literature highlights robotics' capability to engage, investigate, and work alongside humans, transforming oral health services and assistance.[3,4]

The robotics industry has increasingly focused on autonomous technologies, enabling minimally invasive procedures in dental operations. A notable milestone occurred in 2017 with a robot's successful completion of full dental treatment, marking robotics' integration into diverse dental specialties.[5] While relatively new in orthodontics, robots are poised to streamline routine tasks, thereby enhancing orthodontists' workflow.[6]

Exploring the role of robotics in orthodontics is essential for redefining how treatments are conducted. Integrating robotic technology has the potential to enhance patient outcomes by optimizing treatment duration, reducing human error, and improving precision in procedures such as wire bending.[7,8] Additionally, incorporating robotics into orthodontic practice could help streamline workflows by addressing challenges related to efficiency and standardization. By automating repetitive and labor-intensive tasks, orthodontists may be able to dedicate more time to diagnosis and personalized patient care.[9,10]

Moreover, robotics could contribute to expanding access to orthodontic treatment and improving its overall quality. In regions with limited orthodontic specialists, robotic systems might help increase treatment capacity, ensuring faster and more precise care. Recognizing the significance of robotics in this field is fundamental to enhancing clinical efficiency and optimizing patient outcomes, ultimately reducing complications and expediting recovery. Currently, four primary categories of medical robots have been documented—robotic surgical systems, wearable robotic devices, assistive robots, and medical robots—highlighting their growing influence in healthcare services.[11,12]

To clarify the methods to be employed, a protocol for systematic review will be conducted to offer the scientific community accurate data on the implementation of robotics in orthodontics. This protocol addresses the current scarcity of literature by summarizing the role and scope of robotics in clinical practice within the orthodontics field.

METHODS

Statement Adherence

The PRISMA recommendations[13] will be followed in the elaboration of this review and this protocol is registered at the PROSPERO site with record number CRD42023463531, accessible at https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=463531.

Research Question

What are the steps for developing a systematic review on the role and scope of robotics in clinical orthodontic practice?

Inclusion Criteria, Data Variables, and Data Sources

An exhaustive search will be conducted in Scopus, DOAJ, PubMed, Google Scholar, ResearchGate: Academic networking platform and ProQuest Dissertations & Theses Global, excluding searches for unpublished or non-peer-reviewed literature. No restrictions based on age or language will be imposed for the publications. Eligibility criteria and data items will be stablished according the PICO tool[14]; detailed information will be displayed in Table 1, while Table 2 outlines the search strategy according to the data source.

Data Collection Process

The selection of documents will be carried out through a multi-step screening process, starting with the title, followed by the abstract, and ultimately the full text. Additionally, a manual search will be conducted by reviewing the reference lists of relevant manuscripts and documents that meet the inclusion criteria. During the review, several challenges may arise, such as inconsistencies in applying the inclusion and exclusion criteria, differing interpretations of data, or issues with retrieving relevant articles from certain databases. To address these challenges, the

TABLE 1. Eligibility criteria and data variables included within the study.

PICO Element	Inclusion and Exclusion Criteria	Data Variables
P (Problem)	Inclusion: All activity related to orthodontic practice Exclusion: Activities unrelated to orthodontics	Pertains to the dental specialty that the study concentrates on
I (Intervention)	Inclusion: Implementation of devices for functional purposes in orthodontics Exclusion: Original articles focused on Artificial intelligence applications in orthodontics	Focuses on the utilization of automated systems that support orthodontic procedures practitioners
O (Outcome)	Inclusion: Benefits and drawbacks of utilizing robotics in orthodontics Exclusion: Studies that do not show practical outcomes on the implementation of robotic technology in orthodontics	Results in employing innovative technological tools to aid orthodontic treatments
S (Study type)	Inclusion: Research studies, including published and unpublished original articles, doctoral dissertations, and master's theses Exclusion: Any documents not falling within the defined inclusion criteria	Studies considered to be included within results synthesis

search process will be performed concurrently by two independent authors, each reviewing the same data source. In case of disagreements, a third unbiased reviewer will be consulted to resolve discrepancies and reach a final consensus.

TABLE 2. Search strategy.

Source	Search Strategy
PubMed: U.S. National Library of Medicine	("robot technology" OR "robot-assisted" OR "robotic systems" OR "automation in robotics" OR "robotization" OR "robotic applications") AND ("orthodontics" OR "orthodontic treatments" OR "dental alignment" OR "braces therapy" OR "orthodontic procedures")
Google Scholar search engine	"robot-assisted" AND "orthodontics" AND "dentistry"
Scopus: Abstract and Citation Database	"robot-assisted" AND "orthodontic procedures"
DOAJ Directory of Open Access Journals	"robotic systems" AND "dental orthodontics"
ResearchGate: Academic networking platform	"robot-assisted technology" AND "orthodontic treatments"
ProQuest Dissertations & Theses Global: Global database of academic theses and dissertations	"robotics applications" AND "orthodontic care"

Data collection will be carried out by the researcher who will search the database and will be validated by O.T.O. and M.A.G.R. for consensus. Data collected by the authors will be arranged in an Excel worksheet and divided into the following sections: origin and journal impact level, authors, publication year, and country of study, type or name of the robotic technology, use in orthodontics (surgical or non-surgical), purpose of the study, study results, conclusions drawn, strength and drawbacks (Table 3).[15]

TABLE 3. Table format that will be employed for data extraction.

Origin and journal impact level	Authors, publication year, and country of study	Type or name of the robotic technology	Use in orthodontics (either surgical or non-surgical)	Purpose of the study	Study results	Conclusions drawn	Strengths	Drawbacks
1st included manuscript								
2nd included manuscript								
# included manuscript								

Evaluation of Potential Bias in the Study and Assessment of the Reliability of the Evidence

To avoid potential issues with missing data or low-quality studies, the potential risk for bias will be established trough the ROBINS-E tool, and individual and overall analyses will be performed. In the absence of data, the decision for article inclusion will be determined through collective agreement. For the certainty assessment, the GRADE approach will be applied to evaluate the quality of the evidence both individually and collectively.[16,17]

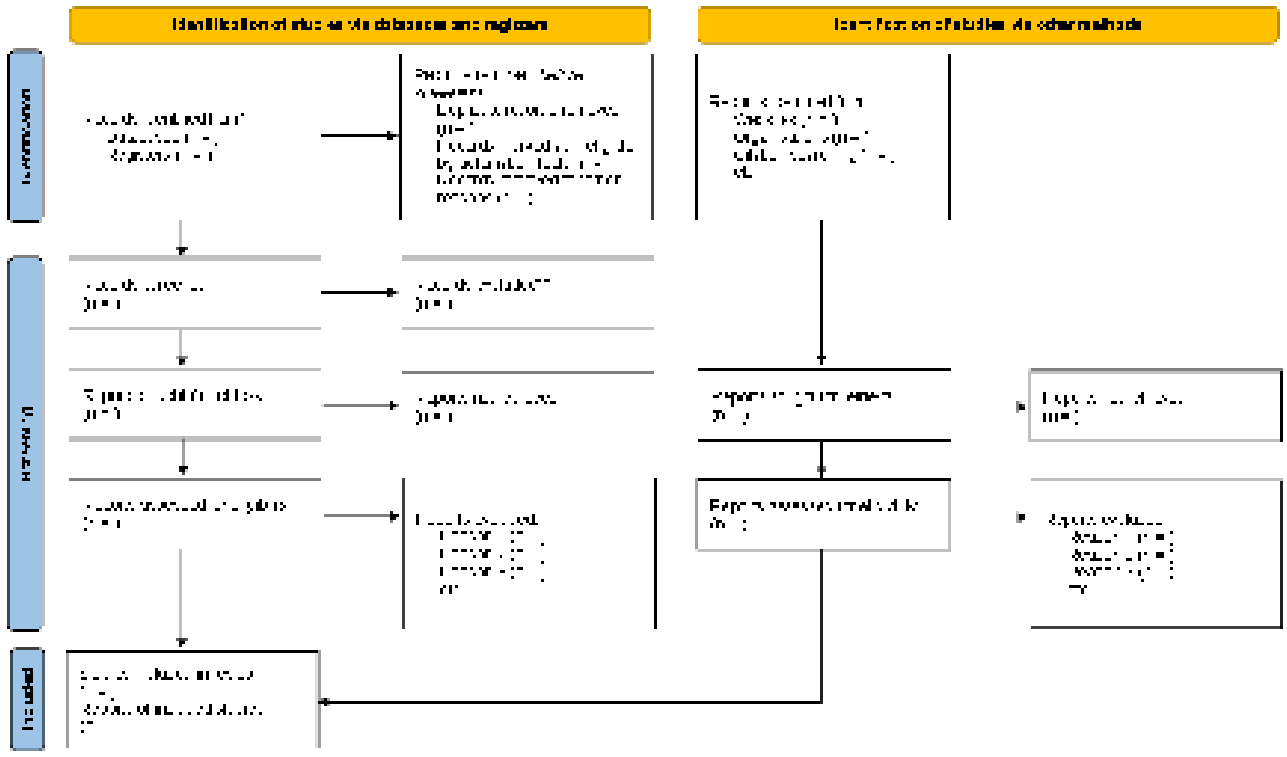

FIGURE 1. PRISMA flow selection diagram.

Approaches for Data Synthesis

A descriptive synthesis of the data will be carried out, organizing the information according to the use of robots in surgical and non-surgical orthodontic treatments. Heterogeneity will be assessed based on design of study and the specific application of robotics in orthodontics.[9]

RESULTS

This section will present the results after data collection and analysis. The flow selection will be represented with PRISMA flow diagram (2020 version)[18] for new systematic reviews, which include searches of databases, registers, and other sources, where identification, screening, and included manuscripts will be presented (Figure 1). The findings will be based on the use of robotics in surgical and non-surgical orthodontics.

Tables and figures will summarize key metrics and outcomes to facilitate comparison and interpretation. The risk of bias and certainty of evidence for each included study will be detailed.

DISCUSSION

This study aimed to summarize the methods employed for a systematic review of robotics applications in orthodontics. As a results, we obtained a comprehensive overview of the current methods and techniques used in orthodontics that incorporate robotics. The systematic review is expected to review how robotic technology is applied in orthodontic procedures, potentially providing insights into its effectiveness, precision, and impact on treatment outcomes. Additionally, it may highlight the challenges, benefits, and prospects of robotics in orthodontics, helping guide further research or development in this field.

This approach aligns with other researchers who have developed protocols for systematic reviews, aiming to clarify the methods used in emerging fields. By establishing clear and structured methodologies, these protocols help ensure that systematic reviews provide solid, reliable, and complementary research. This approach strengthens the evidence base and enhances the understanding of robotics applications in orthodontics, supporting future advancements in the field. Such systematic frameworks contribute to a more rigorous and standardized assessment of the technologies and techniques employed, ultimately benefiting clinical practice and ongoing research.[19–21]

While this review primarily focuses on robotics in orthodontics, it is important to consider complementary technologies that may synergistically enhance robotic applications. Artificial intelligence (AI), for instance, has the potential to revolutionize orthodontic treatments by improving diagnostic accuracy, treatment planning, and patient monitoring. AI can work in tandem with robotic systems, enabling more precise movements and personalized treatment strategies based on patient data.

Additionally, 4D printing, a technology that adds a temporal dimension to traditional 3D printing, could significantly impact orthodontic care by creating dynamic, self-adjusting devices that respond to the patient's anatomical changes over time. Integrating robotics with AI and 4D printing can provide a more holistic and future-proof approach to orthodontic treatments, enhancing both treatment outcomes and efficiency.

We will interpret the results in the context of existing literature, highlighting the implications for clinical practice in orthodontics. The advantages and limitations of using robotics in orthodontics will be critically evaluated. Additionally, this section will address the study's strengths and weaknesses, potential biases, and the generalizability of the findings.

CONCLUSION

This protocol is expected to contribute to elucidating a systematic review detailing robotics applications in orthodontics. It is anticipated that this protocol has been scientifically grounded, aiming to yield generalizable and valuable results to the scientific community.

AUTHOR CONTRIBUTIONS

Conceptualization: G.C.-V. and M.A.G.-R., Methodology: G.C.-V., O.T.O. and Y.L.L., Software: O.T.O. and Y.L.L., Validation: G.M.N.-R. and M.N. Á.-O., Formal Analysis: G.C.-V.

and K.J. H.-R., Investigation: G.C.-V., M.A.G.-R. and K.J.H.-R., Resources: M.N.Á.-O. and G.M.N.-R., Data Curation: O.T.O. and Y.L.L., Writing—Original Draft Preparation: G.C.-V. and M.A.G.-R., Writing—Review & Editing: G.C.-V., M.N.Á.-O. and G.M.N.-R., Visualization: Y.L.L. and K.J.H.-R., Supervision: M.A.G.-R. and M.N.Á.-O., Project Administration: G.C.-V., Funding Acquisition: M.N.Á.-O. and G.M.N.-R.

ACKNOWLEDGMENTS

The authors would like to express their gratitude to Frida Priscilla Bañuelos-Ruiz, DDS., and María José Mora-Reyna, DDS., for their support in the development of this protocol.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

A section of the present manuscript has been uploaded to the Open Science Framework (OSF) portal and is available for access at the following link: https://osf.io/tn6s2/?view_only=ac2622dc1b934089906da26d4352aa49. This repository provides access to relevant details of the research and can be consulted by those interested in exploring the methods and findings prior to formal publication.

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Received October 24 2024, accepted February 19, 2025, date of publication March 10 2025.

Original Research Article

Feasibility and Reliability of the My Jump 2 Smartphone Application in Measuring Peak Power, Flight Time and Jump Height in Physically Active Subjects during Two Different Jumping Tasks

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ABSTRACT

Muscle strength and power are often evaluated through jumping tasks. This study investigates the reliability of My Jump 2 (MJ2), a smartphone application (app) used for this assessment. Two commonly used jumps, the countermovement jump (CMJ) and squat jump (SJ), were analyzed. The study aimed to evaluate the reliability of MJ2 for assessing peak power, jump height, and flight time. **Materials and Methods:** Thirty-eight undergraduate students performed three jumps of each type in a randomized order. All jumps were executed on a contact mat and simultaneously recorded by the smartphone's slow-motion camera. Two independent researchers analyzed the video data by identifying take-off and landing frames to calculate flight time. The intra-class correlation coefficient (ICC), coefficient of variation (CV), and Lin's concordance correlation coefficient (CCC) were used for comparison. **Results:** Excellent reliability (ICC > 0.9) and high agreement were observed for flight time and jump height in both SJ and CMJ. Typical error and CV analysis indicated low variability for SJ, whereas CMJ jump height showed greater variability. However, peak power reliability and agreement were low (ICC < 0.5) for both jumps. **Conclusions:** The results suggest that MJ2 is a reliable and valid tool for assessing jump height and flight time, irrespective of the device used for data analysis. However, its power measurement capability differs from a contact platform's, likely due to the indirect methods used to estimate power. Based on these findings, the MJ2 app can be confidently used to measure flight time and jump height but should be used cautiously when assessing power.

Keywords—*Jumping, Reliability, Testing, Power, Countermovement jump, Squat jump.*

INTRODUCTION

In sports requiring continuous body movement, jumping is a fundamental task that relies on optimal lower-body coordination. These movements result from efficient energy transfer between lower limb joints,[1] and are essential for athletic success.[2] Vertical jumps are widely used to assess lower limb neuromuscular performance, as they correlate with injury risk prediction and athletic performance while serving as an indicator of power output.[3,4]

The squat jump (SJ) and countermovement jump (CMJ) are the most commonly analyzed jump types.[3] Jump height represents a key metric of neuromuscular performance. Mechanical power, a crucial component of sports performance, is often derived from jump height, as both SJ and CMJ require athletes to generate substantial mechanical work in a short duration.[3] This appears to be a critical factor in sports performance, distinguishing athletes by level,[5] experts vs. non-experts,[6] and related to sports performance characteristics, such as jumping.[7,8] As body weight is used to normalize power, it could be highlighted that individual power can significantly affect jump performance and, subsequently, reach jump height.[9]

Traditional instruments for assessing vertical jumps include force platforms, contact mats, linear position transducers, infrared cells, and optical systems.[10–12] However, these devices can be cumbersome, expensive, and require technical expertise, limiting accessibility for sports professionals.[4,13] Recent technological advancements have led to the increased use of mobile applications for real-time exercise assessment.[14] This type of assessment allows for increased familiarity for athletes (assessment at their training site), easy portability, and removes many constraints of time, space, and equipment/facilities required.[15,16] The high level of technology now available, combined with the ease of transport and use, emphasizes using mobile devices to assess physical exercise in real-time and store data for subsequent analysis.[17] Smartphone applications and wearables have been one of the most regular trends in the fitness industry in recent years[18] and present a cheaper alternative to other evaluation instruments. The My Jump 2 (MJ2) app was developed as a user-friendly, portable tool to accurately measure jumping performance.[19]

Several studies have validated MJ2 for jump height assessment in various populations, including active adults, children, elderly individuals, and athletes with cerebral palsy.[4,13,20–24] High intra-rater reliability has been demonstrated across multiple jumping types.[25,26] However, limited research has assessed the app's ability to measure power.

Yingling et al.[27] used the jump height data from the MJ2 app to assess peak power using Sayer's peak power equation.[28] The results reported were mixed, as they indicate excellent reliability for consistency between MJ2 and the force platform, but poor to excellent reliability for absolute agreement. According to the authors, the difference in the results could be explained by the fact that MJ2 uses time in the air for its calculations and does not consider the upper limb reach component of the jump, as measured by the force platform. Another study compared the MJ2 app and a force platform for assessing reactive strength index and mean power during a drop jump.[22] The results showed near-perfect levels of agreement for the reactive strength index, but a weaker agreement for mean power. According to the authors, this may be related to the different means of assessing power between MJ2 and the force platform. There is a lack of studies on the validity of power calculations derived from the MJ2 app. This means the data provided are still questionable and should be used cautiously.[29] To the best of our knowledge, no further studies have been conducted to assess other MJ2 app metrics, with most studies focusing on jump height.

Given the discrepancies in previous findings, further investigation is necessary. This study aims to analyze the validity, feasibility, and reliability of MJ2 for power measurement while providing additional evidence on its accuracy in measuring jump height and flight time.

METHODS

Participants

Sample size estimation was conducted based on the work of Donner et al.,[30] targeting a reliability of 0.8 with a minimum of 0.6, 90% power, a significance level of 0.05, and a 10% dropout rate, resulting in a required sample size of 36 participants.

A total of 38 undergraduate sports science students (34 males, 4 females; mean age: 21.84 ± 3.48 years; body mass: 69.24 ± 11.29 kg; height: 1.74 ± 0.09 m) volunteered. Inclusion criteria required participants to be free of lower extremity injuries or pain within the past three months. Written informed consent was obtained, and the study was approved by the Ethics Committee of the Polytechnic Institute of Leiria (CE/IPLEIRIA/22/2021), which considered the procedures mentioned in the Helsinki Declaration.[31]

Instruments

The study was conducted in a controlled laboratory setting. A Xiaomi Mi 11 Lite smartphone (version 14, Xiaomi, Beijing, China) recorded participants' feet in the frontal plane at a 1.5-meter distance[19] and a height of 30 cm using a tripod.[32] This position allowed for a clear view of the participant's lower extremities to ascertain take-off and landing moments. The smartphone's slow-motion camera recorded at 240 Hz with a 720-pixel resolution. Video data were exported for later analysis. Two independent evaluators analyzed the data: one using an iPad Mini-5 (version 16, CA, USA) (OBS-Ipad) and another using a MacBook Air M1 (version 15, CA, USA(OBS-Mac). A ChronoJump contact platform (version 1.9, ChronoJump Boscosystem, Spain) was used as the reference device for comparison. The validity of this platform has been previously established.[33]

Design and Procedures

This was an observational study, in which all data collection was conducted in a single session. The MJ2 app and contact platform simultaneously recorded all the jumps performed by the participants. Before data collection, the same evaluator took measurements of leg length and hip height at 90° knee flexion (distance from the greater trochanter to ground) since they are required for calculations in both the MJ2 app and Chronojump software.

Each participant completed a standard warm-up of dynamic stretching followed by three trial practices in total.[34] Participants performed three SJ and three CMJ trials, with a 30-second rest interval between each. The jump order was randomized, and verbal encouragement was provided. SJ required a squat position of ~90° of knee flexion, held for 2 seconds before jumping. Participants kept their hands on their hips for all jumps. Trials failing to meet the criteria were repeated. Subjects performed three SJ and three CMJ with a rest period of 30 s. between them. The order of jumps for each participant was randomized. All participants received verbal. All participants were required to refrain from vigorous physical exercise 24 hours before the testing and were properly dressed to perform the jumps. For safety purposes, there was a space of 1 m in front and sides of the contact platform. A whiteboard was placed in the back of the frame (Figure 1), with a specific coding, so that in the posterior analysis performed, observers could identify the subject and jump.

FIGURE 1. Data collection setup.

The same coding was used to record data on Chronojump software. Two evaluators with experience utilizing the MJ2 app independently assessed each of the 228 jumps (6 jumps for each of the 38 subjects), with a total number of 456 observations. Both observers have a Ph.D in sports science and previous experience working with strength and conditioning programs. For video analysis, observers manually determined take-off and landing frames, using the criteria for selecting video frames: both feet were off the ground (take-off) and at least one foot touched the ground (landing), as suggested earlier.[19] The videos were

not analyzed in any consistent order of participants or jumps. Data retrieved for comparison were flight time, jump height, and power. In the MJ2 app, peak power estimations were based on the work of Samozino et al.,[35] with the following equation $P\,(W) = (\frac{h}{hp0}+1)\sqrt{\frac{gh}{2}}$, with m the body mass, g the gravitational acceleration, $hp0$ the vertical push-off distance, and h the jump height. The contact platform estimated peak power with the Sayers equations.[28] $P\,(W) = 60.7 \times h + 45.3 \times m - 2055$.

Statistical Procedures

Descriptive statistics were presented as mean ± standard deviation. Shapiro-Wilk tests assessed normality. Systematic bias between observations was tested using paired t-tests, and effect sizes were calculated.[36] The highest scores of the three jumps in each technique were used for calculations. Standardized mean differences (95% confidence intervals; CI) and Hedges's g corrected effect size[37] were calculated to determine the magnitude of change and compare observations, where the effect size (ES) was considered trivial if g < 0.2, small (0.2–0.5), moderate (0.5–0.8), large (0.8–1.60), and very large (> 1.60).[38] Reliability was assessed through Intraclass Correlation Coefficient (ICC) calculations. For intra-rater observations, a two-way random effect absolute agreement single rater ICC (3, 1) was used; for inter-rater, a two-way random effect absolute agreement multiple rater ICC (3, k) was performed.[39] ICC values < 0.5 were considered indicative of poor reliability, values of 0.5–0.75 were indicative of moderate reliability, values of 0.75–0.90 were indicative of good reliability, and values > 0.90 suggested excellent reliability.[39] All these tests were performed using Statistical Package for Social Sciences (SPSS, v26, IBM Corp., Armonk, NY, USA).

Additionally, Typical Error (TE), expressed as the coefficient of variation (CV%), and the smallest worthwhile change (SWC; 0.2 of the between-subjects standard deviation) were calculated through the use of the Excel spreadsheet provided by Hopkins[40] to support reliability analysis. The formula used for CV% was $CV(\%) = 100e^{sd/100} - 1)$, where sd is the standard deviation and for TE was $TE = sd_{(diff)}/\sqrt{2}$.[41]

High reliability was determined if ICC > 0.90 and CV < 5%.[42] The usefulness of the test was defined as "Marginal" (TE > SWC), "OK" (TE = SWC), and "Good" (TE < SWC).[43]

The agreement was calculated using Lin's concordance correlation coefficient (CCC) using a custom-made Excel spreadsheet based on Lin's recommendations.[44–46] Values > 0.95 were deemed necessary to consider a good agreement.[43]

RESULTS

Table 1 presents the descriptive information regarding the participants, also used for MJ2 and the contact platform.

TABLE 1. Descriptive Statistics of Participants and Performed Measurements.

Variables	Total Subjects	Male Subjects	Female Subjects
Age (years)	21.84 ± 3.48	21.88 ± 3.51	21.50 ± 3.20
Weight (kg)	69.24 ± 11.29	71.47 ± 9.58	50.25 ± 5.31
Height (m)	1.73 ± 0.08	1.75 ± 0.07	1.58 ± 0.03
Leg length (cm)	102.68 ± 16.27	103.03 ± 17.06	99.75 ± 5.72
Height at 90° flexion (cm)	63.53 ± 6.50	63.59 ± 6.66	63.00 ± 4.85

Note: Values are expressed as mean ± SD.

Intra-observer and contact platform reliability results for CMJ and SJ flight time, height, and power, are presented in Tables 2 and 3. The ICC scores were > 0.90 in all cases, indicating good reliability.

Inter-rater reliability scores are presented in Table 4 for CMJ and Table 5 for SJ. In both the CMJ and SJ, flight time and height ICC scores were > 0.90, and CV was below 5% in all situations except OBS-Ipad vs. platform (CV =

8.8) and OBS-Mac vs. platform (CV = 8.7). Moreover, in CMJ and SJ, when testing for power, OBS-Ipad and OBS-Mac vs. platform ICC scores were < 0.50, indicating poor reliability, thus precluding further analysis.

Significant paired differences were observed in both observers and the platform results in the CMJ (p = 0.001) and SJ (p = 0.04). ES (g) results were, however, all trivial (< 0.2). As for usefulness, the CMJ results for flight time were rated as Good, and for the CMJ height they were rated as Marginal. In the SJ results, the flight time was rated as Good for OBS-Ipad vs. OBS-Mac and OBS-Ipad vs platform and Marginal for OBS-Mac vs. platform. In the SJ results, all observations were rated as Marginal in the height analysis.

All agreement results for CMJ and SJ indicate good agreement between observers and the platform (CCC > 0.95). Exceptions were verified for CMJ and SJ power analysis, where in all cases the CCC was < 0.15, thus reflecting no agreement when contrasted with the platform.

TABLE 2. Intra-observer and Contact Platform Reliability for Countermovement Jump Performance Variables.

Variables	OBS-Ipad		OBS-Mac		Contact Platform	
	Mean ± SD	ICC (95% CI)	Mean ± SD	ICC (95% CI)	Mean ± SD	ICC (95% CI)
Flight Time (ms)						
Jump 1	516.201 ± 54.067		515.528 ± 53.288		5,22.500 ± 52.639	
Jump 2	514.646 ± 48.469	0.921(0.871; 0.955)	517.112 ± 48.886	0.917 (0.864; 0.953)	5,22.921 ± 47.442	0. 912 (0.855; 0.950)
Jump 3	519.742 ± 47.899		519.447 ± 49.201		5,26.053 ± 47.467	
Height (cm)						
Jump 1	33.024 ± 6.523		32.930 ± 6.431		33.781 ± 6.422	
Jump 2	33.139 ± 5.997	0.920 (0.868; 0.954)	33.076 ± 6.038	0.917 (0.863; 0.953)	33.777 ± 5.917	0.911 (0.855; 0.950)
Jump 3	33.398 ± 5.952		33.377 ± 6.108		34.163 ± 6.010	
Power (Watts)						
Jump 1	1,592.916 ± 381.748		1,574.776 ± 385.070		9,46.045 ± 330.540	
Jump 2	1,594.180 ± 385.424	0.963 (0.937; 0.979)	1,582.117 ± 388.016	0.961 (0.934; 0.978)	9,49.240 ± 345.460	0.994 (0.990; 0.997)

ICC (95% CI): Interclass correlation coefficient with upper and lower confidence intervals.

TABLE 3. Intra-observer and Contact Platform Reliability for Squat Jump Performance Variables.

Variables	OBS-Ipad		OBS-Mac		Contact Platform	
	Mean ± SD	**ICC (95% CI)**	**Mean ± SD**	**ICC (95% CI)**	**Mean ± SD**	**ICC (95% CI)**
Flight Time (ms)						
Jump 1	506.151 ± 52.384		505.081 ± 52.458		510.921 ± 50.382	
Jump 2	508.442 ± 53.189	0.929 (0.868; 0.963)	507.540 ± 53.238	0.930 (0.965; 0.964)	514.684 ± 51.208	0.931 (0.866; 0.965)
Jump 3	518.440 ± 56.659		518.158 ± 56.724		523.947 ± 54.610	
Height (cm)						
Jump 1	31.742 ± 6.426		31.611 ± 6.416		32.274 ± 6.244	
Jump 2	32.036 ± 6.569	0.926 (0.860; 0.961)	31.926 ± 5.541	0.926 (0.855; 0.962)	32.756 ± 6.398	0.928 (0.857; 0.963)
Jump 3	33.342 ± 7.062		33.308 ± 7.083		33.996 ± 6.883	
Power (Watts)						
Jump 1	1488.335 ± 338.602		1506.616 ± 368.425		926.492 ± 334.469	
Jump 2	1504.804 ± 359.699	0.943 (0.892; 0.970)	1520.048 ± 369.943	0.947 (0.900; 0.973)	931.680 ± 331.032	0.994 (0.988; 0.997)
Jump 3	1562.984 ± 380.007		1579.455 ± 379.079		948.434 ± 338.721	

ICC (95% CI): Interclass correlation coefficient with upper and lower confidence intervals.

TABLE 4. Interreliability for Countermovement Jump Performance Variables.

	CMJ Flight Time (ms)			CMJ Height (cm)			CMJ Power (W)		
	OBS-Ipad vs OBS-Mac	**OBS-Ipad vs Platform**	**OBS-Mac vs Platform**	**OBS-Ipad vs OBS-Mac**	**OBS-Ipad vs Platform**	**OBS-Mac vs Platform**	**OBS-Ipad vs OBS-Mac**	**OBS-Ipad vs Platform**	**OBS-Mac vs Platform**
Paired diff. (cm) (95% CI)	0.30 (-1.51; 2.10)	−6.31 (−8.53; −4.01)*	−6.61 (−8.45; −4.76)*	0.02 (−0.20; 2.47)	−0.77 (−1.05; −0.48)*	−0.79 (−1.02; −0.56)*	−0.75 (−15.16; 13.67)	638.82 (512.27; 765.36)*	632.33 (505.64; 759.02)*
Paired ES (g)	0.01	0.13	0.14	0.01	0.13	0.13	0.01	1.84	2.7
ICC (95% CI)	0.99 (0.99; 0.99)	0.99 (0.93; 0.99)	0.99 (0.89; 0.99)	0.99 (0.99; 0.99)	0.99 (0.94; 0.99)	0.99 (0.91; 0.99)	0.99 (0.99; 0.99)	0.25 (−1.89; 0.594)	0.26 (−1.88; 0.601)
CCC (95% CI)	0.99 (0.08; 0.999)	0.98 (0.97; 0.99)	0.98 (0.97; 0.99)	0.99 (0.99; 0.999)	0.98 (0.98; 0.99)	0.99 (0.97; 0.99)	0.99 (0.99; 0.99)	0.14 (0.019; 0.261)	0.15 (0.022; 0.266)
TE (95% CI)	0.08 (0.06; 0.10)	0.10 (0.08; 0.13)	0.08 (0.07; 0.11)	0.18 (0.15; 0.23)	0.45 (0.37; 0.58)	0.44 (0.36; 0.57)			
CV (95% CI)	0.80 (0.6; 1.0)	1 (0.8; 1.2)	0.80 (0.7; 1.0)	4 (3.3; 5.2)	8.80 (7.2; 11.6)	8.70 (7.1; 11.4)			
SWC (cm)	1.1	1.35	1.12	0.14	0.17	0.14			
Rating	Good	Good	Good	Marginal	Marginal	Marginal			

* $P < 0.05$; CMJ: countermovement jump; ES: effect size; CI: confidence interval; ICC: intraclass correlation coefficient; TE: typical error; CV: coefficient of variation; SWC: smallest worthwhile change; (95% CI): Upper and lower confidence intervals.

TABLE 5. Interreliability for Squat Jump Performance Variables.

	SJ Flight Time (ms)			SJ Height (cm)			SJ Power (W)		
	OBS-Ipad vs OBS-Mac	**OBS-Ipad vs Platform**	**OBS-Mac vs Platform**	**OBS-Ipad vs OBS-Mac**	**OBS-Ipad vs Platform**	**OBS-Mac vs Platform**	**OBS-Ipad vs OBS-Mac**	**OBS-Ipad vs Platform**	**OBS-Mac vs Platform**
OBS-Mac	OBS-Ipad vs Platform	OBS-Mac vs Platform					2.94 (−22.62; 28.50)	636.70 (505.57; 767.82)*	634.85 (510.51; 759.20)*
Paired diff. (cm) (95% CI)	0.28 (−4.53; 5.09)	−5.26 (−10.27; −0.26)*	−5.72 (−7.25; −4.18)*	0.03 (−5.75; 0.64)	−6.33 (−1.23; −0.01)*	−0.69 (−0.88; −0.50)*	0.01	1.73	1.78
Paired ES (g)	0.01	0.09	0.1	0.01	0.09	0.1	0.99 (0.98; 0.99)	0.21 (−0.200 0.642)	0.29 (−1.95; 0.64)
ICC (95% CI)	0.98 (0.97; 0.99)	0.98 (0.97; 0.99)	0.99 (0.93; 0.99)	0.98 (0.97; 0.99)	0.98 (0.96; 0.99)	0.99 (0.93; 0.99)	0.99 (0.96; 0.99)	0.13 (0.002; 0.246)	0.13 (0.001; 0.252)
CCC (95% CI)	0.97 (0.94; 0.98)	0.96 (0.92; 0.98)	0.99 (0.98; 0.99)	0.97 (0.94; 0.98)	0.96 (0.92; 0.98)	0.99 (0.99; 0.99)	-	-	-
TE (95% CI)	1.02 (1.02; 1.03)	1.02 (1.02; 1.03)	1.01 (1.01; 1.02)	1.04 (1.03; 1.05)	1.04 (1.03; 1.05)	1.01 (1.01; 1.02)	-	-	-
CV (95% CI)	2 (1.6; 2.6)	2.10 (1.7; 2.7)	0.70 (0.6; 0.9)	4 (3.3; 5.2)	4.20 (3.4; 5.5)	1.30 (1.1; 1.7)	-	-	-
SWC (cm)	2.89	3	0.93	0.37	0.38	0.11	-	-	-
Rating	Good	Good	Marginal	Marginal	Marginal	Marginal	-	-	-

* $p < 0.05$; SJ: Squat Jump; ES: effect size; CI: confidence interval; ICC: intraclass correlation coefficient; TE: typical error; CV: coefficient of variation; SWC: smallest worthwhile change; (95% CI): Upper and lower confidence intervals.

DISCUSSION

This study had two primary objectives. The first was to assess the validity and reliability of the MJ2 app in evaluating neuromuscular performance through power measurements. The results demonstrated high intra-rater reliability (ICC > 0.91) across all studied variables in CMJ and SJ, consistent with prior research.[25,26] Furthermore, mean differences between observers and the contact platform for CMJ and SJ (< 0.1 cm) aligned with previous findings on MJ2 app validity in both male and female participants.[23,25,26] Yingling et al.,[27] highlighted the necessity of establishing confidence in MJ2 due to the potential bias introduced by manually selecting take-off and landing moments. The present study supports this confidence, as its intra-rater reliability findings align with previous research. Regarding inter-rater reliability, ICC scores exceeded 0.90 for flight time and jump height, with CV values below 5%, indicating strong reliability.[42] These results correspond with prior studies on MJ2 reliability.[24,26,44,45] Additionally, excellent agreement (CCC > 0.95) was found between MJ2 and the contact platform for both jumps and observers, consistent with Bogataj et al.,[23] who reported a high level of agreement between MJ2 and a photoelectric cell system.

CMJ height exhibited slightly higher variability (CV > 5%) when compared with the platform, while SJ height remained within acceptable limits. These findings contrast with previous studies that reported higher CV values for MJ2.[22,25] Differences in jump type, sample size, and equipment used for validation may account for these discrepancies.[22] For example, studies involving primary school children found higher variability in SJ height, likely due to a lack of experience executing the movement.[13,23]

Regarding test usefulness, as determined by the relationship between TE and SWC, flight time was rated as good (TE < SWC) for both CMJ and SJ, while jump height was rated as marginal (TE > SWC). A comparable study[23] reported similar findings, with a marginal rating for SJ height but not for CMJ height.

The primary focus of this study was the assessment of neuromuscular performance via peak power estimation with MJ2. Results indicated poor reliability (ICC < 0.5) when comparing MJ2-derived power measurements with those from the contact platform. Conversely, inter-rater reliability between observers was high (ICC > 0.98) for both jumps. These findings diverge from those of Haynes et al.,[22] who reported moderate ICC values (ICC = 0.67) when assessing mean power in drop jumps. Yingling et al.,[27] also found good reliability (ICC = 0.85) for peak power estimation, highlighting variability across studies. In the present study, peak power values obtained from the contact platform were lower than those estimated by MJ2. This discrepancy may be attributed to differences in sampling frequency, as the contact platform records at 1,000 Hz, while MJ2 video data is captured at 240 Hz. These variations in data acquisition may obscure crucial details required for accurate power estimation.

Although both MJ2 and the contact platform estimate neuromuscular performance via jump height, they employ different equations. The contact platform utilized an equation proposed by Fox and Mathews,[45] whereas MJ2 applied the Samozino et al.,[35] equation, which is more recent. Prior studies have reported moderate agreement for mean power[22] and good agreement for peak power[27] when evaluating MJ2's power estimation reliability. Differences in reference instruments and potential MJ2 estimation errors may explain these discrepancies. Notably, power estimation accuracy depends on the precision of jump height measurements, as flight time overestimation can amplify measurement error due to the squared nature of the variable. The disparity in data acquisition rates (1,000 Hz for the contact platform vs. 240 Hz for MJ2) may also contribute to higher flight time and jump height values in MJ2 assessments.

Carlos-Vivas et al.,[44] corroborated this observation, reporting a slight overestimation of jump height in their findings. Even minor overestimations can influence power estimation, thereby affecting agreement between MJ2 and the contact platform. These findings suggest that accurate and reliable force and power measurements require direct assessments rather than indirect calculations.

This is the first study to evaluate MJ2's reliability using two devices (tablet and computer) for video analysis. The results indicate that manual frame selection is a valid and

reliable method for assessing jump height and flight time, regardless of the device used for analysis. This minimizes the potential for bias and allows practitioners to use MJ2 across different screen sizes and environments. The study reinforces the reliability of MJ2 for assessing lower-body performance, offering a practical solution for practitioners.

A limitation of this study is the lack of information regarding participants' familiarity with the tested jump types. Although participants were active undergraduate sports science students, variations in the CMJ technique could have influenced the observed variability. Additionally, the findings are limited to the study sample and may not be generalizable to other populations. Future research should further investigate MJ2's power estimation capabilities by incorporating force platforms and alternative vertical jump tests (e.g., Abalakov) to enhance agreement, correlation, and mean difference assessments. Expanding the sample to include more female participants would also improve the generalizability of results.

Despite these limitations, the present study supports the use of MJ2 to measure jump height and flight time in an active young population. The increasing popularity, affordability, and technological advancements of smartphone applications suggest that tools like MJ2 will become integral to assessing physical fitness and health metrics.[47] These findings contribute to existing literature and enhance confidence in MJ2 as a rapid and reliable assessment tool for lower-body strength.

CONCLUSIONS

The results of the present study recommend using the MJ2 smartphone app as a valid, reliable, and useful tool for measuring jump height and flight time in active young adults. Due to its simplicity and practicability, it can be used by physicians, coaches, and other sports science practitioners to assess physical fitness, particularly lower-body performance.

AUTHOR CONTRIBUTIONS

Conceptualization, A.D. and D.T.; Resourses, M.S. and F.S.; Data collection, L.S. and P.M.; Data analysis P.P. and E.S.; Writing–Original Draft Preparation, A.D. and D.T; Writing–Review & Editing, M.E., M.S. and F.S.; Supervision, A.D.

ACKNOWLEDGMENTS

We would like to acknowledge all students who volunteer to participate in the present study.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

CONSENT FOR PUBLICATION

Written consent was obtained from all participants regarding publication of data and/or image, as long as the images maintain the anonymity of the participant.

FURTHER DISCLOSURE

Not applicable.

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Received February 8, 2024, accepted February 10, 2025, date of publication March 17, 2025.

Review

Effectiveness of Robotic Rehabilitation in the Management of Stroke Patients—A Literature Review

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ABSTRACT

Background and Objective: Stroke is considered a root cause of disability worldwide, adversely affecting movement and balance. It requires comprehensive rehabilitation to achieve maximum recovery. Gait training, including robot-assisted methods, is crucial in restoring independence among stroke survivors. Balance impairment leads to challenges that demand specialized interventions, while cognitive deficits add complexity to rehabilitation. Despite ongoing research, optimizing outcomes remains a challenge, urging innovation in trial design and intervention strategies to enhance the effectiveness during stroke rehabilitation. This literature review highlights the evidence regarding the uses and effectiveness of robotic rehabilitation amongst stroke survivors. **Methods:** The searches were performed on databases like PubMed, Scopus, and Google Scholar using keywords such as gait, balance, cognitive ability, and upper limb rehabilitation. The inclusion criteria were the studies published in English with a study design of randomized controlled trials focusing on stroke patients. The intervention included robotic rehabilitation. Qualitative data synthesis was gathered after screening the abstracts and full texts of the included articles. **Result:** This literature review found that robotic rehabilitation, including intensive and personalized sessions, targeted resistance, augmented feedback, and sensory inputs, yields significant improvements across multiple domains for stroke patients. These improvements include enhanced gait parameters, balance, cognitive abilities, and upper limb functionality. Robotic-assisted therapy can improve motor function, coordination, memory, attention, and sensory perception, ultimately contributing to better recovery and quality of life for individuals affected by stroke. **Conclusion:** This study concluded that combining robotic rehabilitation with other techniques can provide enhanced benefits compared to conventional rehabilitation. However, more studies are required to reach any firm conclusion.

Keywords—*Stroke, Gait, Robotic rehabilitation, Upper limb rehabilitation, Cognitive ability, Balance.*

INTRODUCTION

Stroke is the preliminary cause of disability observed amongst adults, leading to substantial financial consequences for victims, their families, and society as a whole. Following a stroke, disabilities are a hedge to healthcare and have several long-term counteraccusations on a person's capability to ambulate and maintain balance.[1] The unexpected reduction in brain conditioning causes weakness in one side of the lower extremities. Such individuals tend to depend more on the lower extremities, which are unaffected. They are more likely to have an inconsistent, unstable distribution of weight and a reduced gait cycle.[2] Thus, perfecting and recovering the capacity to walk is essential to gaining autonomy in day-to-day conditioning and perfecting daily life quality.[1] The general physical state and the strength, endurance, and coordination of their lower extremities amongst stroke survivors can be improved with gait training. Advancements in muscle tone normalization, balance, overall fitness and endurance, and functional skills are all included in the Barthel Index (BI) and Rivermead Mobility Index. These scales are accepted as suitable criteria to assess a stroke case's functional condition and are reliable labels of the effectiveness of the enforced therapy.[3]

Numerous strategies, including neurodevelopmental procedures, repeated task training, biofeedback, bodyweight-supported treadmill training, robot-supported training, and high-intensity physical therapy, have been used in neurorehabilitation programs to enhance balance and locomotor capabilities. Despite these initiatives, opinions on how well these approaches enhance balance and motor skills are still undiscovered.[1] One technique utilized to assist stroke victims in recovering their capacity to walk is robot-supported gait training. It enables the creation of walking movements continually, adding the number of gait cycles and step accuracy while requiring trainers to deliver the least amount of physical effort. An exoskeleton-assisted robot is generally used in robot-assisted gait training, which may be divided into two primary types: over-ground and treadmill-based exoskeleton robots.[4]

Amongst stroke victims, balance damage is a serious concern that can arise from several causes, including defined range of motion, muscular atrophy, sensitive abnormalities, and cognitive issues. This impairment makes movement delicate and raises the possibility of falling. The inability to integrate sensitive data from the vestibular, visual, and somatosensory systems is a major contributing factor. Balance is maintained by somatosensory signals from the lower extremities in healthy individuals, though stroke victims frequently do not receive this information. Balance requires central integration, which is the activation of substitute sensitive systems to make up for inadequacies. Balance capability can be enhanced using specialized training methods, like modifying sensory inputs or measuring balance with analytical equipment. However, studies on how stroke survivors' center of pressure movement and muscle activation are impacted by sensory integration.[5]

One of the most common physical impairments leading to stroke-related disability that affects the performance of daily living activities is gait disorder, which is a common clinical issue for stroke survivors. Therefore, a primary focus of post-stroke rehabilitation is gait disorder.[6]

Following a stroke, patients walk with coordinated lower extremities mass patterns instead of controlled movement of individual joints. Walking induces two kinds of synergistic patterns. While the hip, knee, and ankle dorsiflexors produce the mass flexion pattern during the swing phase, the quadriceps and gluteus maximus work in concert to produce a mass extension pattern during the stance phase. Basic deficits causing asymmetry include poor support for a single limb and uncontrollably moving forward. Reduced stance time and extended swing duration on the affected side make up the asymmetry. The gait cycle's regular pattern of symmetrical step length is absent, with the paretic side having a longer way.[7]

Post-stroke cognitive impairment is the term used to describe cognitive deficits that manifest three to six months following a stroke. The stroke itself can cause these deficits, or they can pre-exist. Aphasia, memory problems, and advanced-order cognitive dysfunctions similar to executive and visuospatial impairments are among these deficits; these frequently coincide with vascular cognitive impairment. Studies have demonstrated cognitive decline both before and after stroke, and vascular risk factors raise the threat of both stroke and cognitive decline.[8]

The need for stroke rehabilitation services is rising as strokes continue to be the primary cause of adult disability. Numerous large-scale intervention trials aimed at motor recovery report similar advancements in motor performance for both the intervention and control groups, though not always to the same degree. These indifferent outcomes could result from the tested interventions' lack of added benefit or the numerous difficulties in planning and carrying out extensive stroke rehabilitation trials. New approaches to patient selection, control interventions, and endpoint measures are strategies for enhancing the quality of trials. Rehabilitation techniques help stroke survivors recover their independence indeed, though research into stroke rehabilitation aims to enhance trials, interventions, and results.[9]

The main objective of this review study was to summarize robotic rehabilitation's effectiveness in managing stroke patients. This study provides valuable insight into the promising benefits of robot-assisted rehabilitation for improving the quality of life among individuals suffering from stroke.

METHODS

Search strategy: A comprehensive literature search was conducted across multiple databases, including keywords such as "robotic rehabilitation", "stroke", and "rehabilitation". The articles were searched in different databases including PUBMED, GOOGLE SCHOLAR, PEDRO, and COCHRANE LIBRARY.

Inclusion criteria: Inclusion criteria for study selection involved Randomized Controlled Trials and Pilot Studies published between 2017 and 2024.

Exclusion criteria: Exclusion criteria excluded systematic reviews, meta-analyses, and articles published before 2017.

Data extraction: Initial searches identified 87 relevant articles. These articles underwent screening, with 30 identified for this review study. The included articles compared outcomes of robotic rehabilitation interventions versus control groups in stroke patients. Data collection encompassed various parameters, such as the impact of robotic training on gait, balance, cognitive ability, and upper limb rehabilitation. Additionally, different components demonstrating the efficacy of robotic rehabilitation were reviewed.

RESULT

Effect of Robotic Rehabilitation on Gait

Kim et al. (2024) conducted a study titled "Simultaneous High-Definition Transcranial Direct Current Stimulation (HD-tDCS) and Robot-Assisted Gait Training in Stroke Patients".[10] The research utilized the Lokomat robotic device and involved 24 participants. These patients were split into the Real HD-tDCS set, and the Sham HD-tDCS set. In this Real HD-tDCS set, participants obtained robotic training alongside transcranial direct current stimulation, whereas the Sham HD-tDCS set underwent robotic drilling without the stimulation. Assessments using various measures such as the Functional Ambulation Category (FAC), Dynamic Gait Index (DGI), Fugl-Meyer Assessment (FMA), Timed-Up-and-Go (TUG) test, Berg Balance Scale (BBS), 10-Meter Walk Test (10MWT), Functional Reach Test, Visual Analog Scale (VAS), and Korean Modified BI (K-MBI) were conducted. The action spanned 10 sessions over four weeks. After four weeks, significant improvements were observed in all test parameters within the Real HD-tDCS set, whereas the Sham HD-tDCS set displayed no notable improvement. The Real HD-tDCS set exhibited multiple enhancements among physical functions, indicating the positive impact of combining robotic training with transcranial direct current stimulation.

Li et al., conducted a study titled "Effect of Robot-Assisted Gait Training on Motor and Walking Function in Patients with Subacute Stroke".[4] The research utilized the BEAR-H1 (wearable lower extremity exoskeleton robot) robotic equipment and included 36 patients aged 18 to 75. Patients were separated into two clusters: Cluster A, the experimental cohort, and Cluster B, the baseline cluster, which were delivered traditional therapy. Assessments were conducted using measures such as FAC, Mini-Mental State Questionnaire, Ashworth test, 6-Minute Walk assessment (6MWT), Functional Ambulatory Classification, Fugl-Meyer questionnaire for bottom extremity, and Modified Ashworth Scale. Both groups underwent exercises focusing on muscle strengthening, stretching, and balance for four weeks, twice a day for 1,800 seconds, five days

out of seven days. After four weeks, improvements were observed in motor abilities, gait performance, and walking endurance in patients treated with BEAR-H1 compared to those receiving conventional therapy. This proposes that Robot-acquired Gait Training is more effective for people with subacute stroke.[4]

Longatelli et al. conducted a study titled "Robotic Exoskeleton Gait Training in Stroke".[11] The study utilized robotic devices such as Ekso, Re-Walk, and Indego and included 29 contributors between 18–80 years old. Contributors were segregated into two bunches: The Control Bunch (CB), which received standard rehabilitation methods, and the Experimental Bunch (EB), which underwent a combination of conventional therapy and rehabilitation using an exoskeleton device. Assessments were conducted using the Modified Barthel Scale, Motricity Index, 10-meter walk test, 6-minute walk assessment, Functional Ambulatory Category, and Trunk Control Test. The intervention consisted of sessions conducted five times a week, each lasting 60 minutes, spanning over four weeks. Both groups demonstrated progress in their abilities (Capacity Score) after four weeks of intervention. The EB progress has been comparable to that of the CB after the experiment, with minor improvements observed in lower leg muscle activity during walking measurements.[11]

Maranesi et al. conducted a study titled "Robotic Intervention for Older Patients with Subacute Stroke".[12] The study incorporated the G-EO System which is a robotic and the end-effector device aiding in walking therapy. Over 152 subjects, 65 years and above, have been involved in research. The study comprised the control group and a technology-based experimental set. The control group underwent a standard rehabilitation program, while the intervention group engaged in a robotic rehabilitation program utilizing the G-EO system alongside their conventional therapy. Assessments were conducted using measures such as the FAC, Modified Ashworth test, Short Form-12 (SF-12), Performance-Oriented Mobility test, Motricity Index (MI), Mini-Mental State Test, Rivermead Assessment, Barthel Scale, Clinical Dementia Rating, Activities-specific Balance Confidence Scale (ABC), Participation in Autonomy and Domestic Life, and gait analysis along with instrumental postural analysis. The intervention comprised sessions conducted thrice a week, with each session lasting 30 minutes, spanning over seven weeks. Additionally, the intervention group received an extra 20 minutes of treatment with the G-EO System during each session. After seven weeks, participants in both groups demonstrated improvements in various aspects, including reduced risk of falling, increased walking speed, decreased fear of falling, improved mobility, and enhanced performance in daily tasks. Notably, the group utilizing the G-EO system experienced further advantages, such as improved walking speed, better balance, reduced fear of falling, and increased acceptance of technological aids.[12]

Alingh et al., conducted a study titled "Training for Improvement of Propulsion Symmetry and Gait Speed in Chronic Stroke Patients".[13] The study utilized the LOPES II, Demcon and MOOG BV, USA robotic devices. A total of 29 participants between 51–71 years old were interviewed for the research. The study consisted of a single group that received treatment using the LOPES II robotic device. Assessments were conducted using assessment tools such as the Hospital Anxiety and Depression Scale, Modified Ashworth Test, FMA, Functional Gait Assessment, Stroke Impact Assessment, Mini-Mental State Test, Medical Research Council (MRC) scale, 6-Minute Walk Test (6MWT), Star Cancellation Test, MI, and FAC. The exercise duration for the group was comprised of sessions conducted twice a week, with each session lasting 60 minutes and spanning over five weeks. After five weeks of treatment, participants experienced improved balance and coordination in walking, stronger leg movements, increased ankle flexibility on the weaker side, and enhanced overall walking speed, balance control, arm function, and cognitive abilities.[13]

Heng et al., in 2020, conducted a study titled "Changes in Balance, Gait, and Electroencephalography after Robot-Assisted Gait Training in Chronic Stroke Patients".[14] The study utilized the MRG-P 100 HIWIN Robotic Gait Training System, India and included 24 partakers between 35 and 80 years. The survey involved the Traditional Group and the Robot-Assisted Gait Training (RAGT) group. The Traditional Group received standard physiotherapy rehabilitation, whereas the RAGT group received standard physiotherapy and robotic gait training. Assessments were conducted using the Berg Balance Assessment and the Timed "Up and Go" test. The intervention for both groups consisted of sessions conducted four times a week, with every sitting lasting 30–45 minutes, spanning over four

weeks. Additionally, after the standard duration, the RAGT set acquired an extra 30 minutes of robotic gait exercise. After four weeks, the RAGT therapy resulted in a four-fold increase in balance improvements compared to usual care, indicating its superior effectiveness and potential added benefits in treating the condition.[14]

Kotov conducted a study titled "Robotic Restoration of Gait Function in Elderly Patients with Stroke".[15] The study utilized the ExoAtlet exoskeleton and Ortorent MOTO pedal trainer, Italy. A subtotal of 47 participants between the age of 52 and 74 were incorporated into the experiment. Participants were split into two bunches: ExoAtlet exoskeleton bunch, which received rehabilitation using the provided robotic device, and the Ortorent MOTO pedal trainer group, which underwent dynamic and ideal training for all extremities using the pedal trainer. Assessments were conducted using the MRC assessment, Modified Ashworth test, Berg Balance test, Hemiplegic Arm Shoulder Ability (HASA), 10-Meter Walk Test (10MWT), modified Rankin assessment, and BI. The exercise duration for both groups consisted of sessions conducted five days a week, each lasting 10–30 minutes, reliant on the participants' functional capacity, over two weeks. After two weeks, both groups experienced improvements in strength, balance, mobility, and walking pace. However, Group 1, utilizing the ExoAtlet exoskeleton, significantly improved more than Group 2. Group 1 also demonstrated reduced disabilities and increased daily function, which were more pronounced than those observed in Group 2. These findings suggest that both robotic training methods effectively improve gait and balance, with the ExoAtlet exoskeleton showing particular efficacy.[15]

Nolan et al., in the year 2020 conducted a study titled "Robotic Exoskeleton Gait Training During Acute Stroke Rehabilitation".[16] The study utilized a Robotic exoskeleton (Indigo Powered Exoskeleton) and involved 22 contributors within the customary age set of 59.6 years. The study comprised two groups of participants: the RE (Robotic Exoskeletons) +SOC (conventional Standard of Care) Group, which underwent robotic exoskeleton (RE) gait training as a component of their inpatient recovery program, and the conventional Standard of Care Set, which got standard rehabilitation treatments during their inpatient rehabilitation program. Assessments were conducted using the Modified Functional Classification, Modified Functional Evaluation, Walking Functional Classification, and Functional Independence Measure (FIM). The intervention consisted of sessions conducted thrice a week, each lasting 25 minutes, spanning over four weeks. Both groups demonstrated improvement in movement abilities after four weeks, but the RE+SOC group exhibited greater improvements than the SOC bunch. The RE+SOC bunch could engage in more intense walking practice without extending their training time, resulting in better recovery of their ability to perform daily tasks.[16]

Kim et al., conducted a study titled "Robotic-Assisted Gait Training for Balance and Lower Extremity Function in Patients with Infratentorial Stroke".[17] The study employed the Lokomat robotic orthosis and WALKBOT Mechanical-aided walking therapy and involved 19 participants with an average age of 47.4 years. Contributors have been divided into sets: Set A and Set B. Set A underwent four weeks of Resistance Agility Grappler Training combined with Cognitive Processing Therapy (CPT), after four weeks of CPT alone. In contrast, Set B received interventions oppositely: four weeks of CPT ensured by four weeks of RAGT combined with CPT. Conducted assessments using measures such as the Trunk Impairment Test, Fugl-Meyer Assessment for Lower Extremity (FMA-LE), Functional Electrical Stimulation (FES), 10-Meter Walk Test (10MWT), BBS Test, Scale for the Assessment and Rating of Ataxia (SARA), and FAC. The intervention consisted of sessions conducted five times a week, each lasting 30 minutes over four weeks. After a month, both groups demonstrated significant progress in maintaining balance while moving and standing still, lower body movement abilities (measured by FMA-LE), and coordination (measured by SARA). However, the group that underwent RAGT combined with conventional physical therapy (PT) showed a distinct advantage in maintaining balance while standing compared to the group receiving conventional PT alone. Additionally, while both groups showed improvements in walking ability (measured by FAC), the RAGT+CPT group showed more significant improvement in static balance (measured by BBS), and upper body movement abilities (measured by FMA-UE) improved slightly in both groups.[17]

Kim et al., examined the effects of "Effects of robot-assisted gait training for stroke patients"[18], utilizing

robotic devices including the Gait Trainer, Lokomat, Chicago, United States, and Morning Walk, Korea. The study comprised 25 participants, with a mean age of 57.7 years in the trial cluster and 60.4 years in the traditional cluster. The research compared two cohorts: The Morning Walk®, Korea Group, where participants underwent 30 minutes of Techno-assisted walking rehabilitation with Morning Walk® along with 60 minutes of conventional PT per session, and the traditional cluster, which solely got 90 minutes of traditional PT. Evaluation tools employed encompassed the Modified Barthel Scale, Rivermead Mobility scale, Functional Ambulatory Category score, 10 Meter Walk examination, Berg Balance test, and MI for lower extremities (Motricity Index-Lower). The exercise regimen entailed sessions five times a week, each spanning 60 minutes, over three weeks. After completing the three-week treatment, both groups exhibited significant enhancements across all measured parameters. Notably, the Morning Walk® group demonstrated more pronounced improvements in leg movement (quantified by the Motricity Index-Lower score) and balance (evaluated through the BBS) than the control group. Moreover, both cohorts displayed advancements in walking speed (indicated by increased pace in the 10 Meter Walk assessment) and balance (as evidenced by elevated scores on the BBS.[18]

Effect of Robotic Rehabilitation on Balance

Giovannini, et al., conducted a survey titled "Robotic-Assisted Rehabilitation for Balance and Gait in Stroke Patients".[19] The study utilized the Hunova Movendo Technology srl robotic device, Italy, robotic platform, end-effector RAGT, and robotic balance platform. A total of 24 partakers having a mean age of 65 years were collected in the investigation. The investigation involved The Investigative Cluster (IC) and Regulation Cluster (RC). The partakers in the IC underwent specialized balance disorder rehabilitation using a robotic platform in addition to standard care. At the same time, those in the RC received only traditional treatment as per their daily routine, without the robotic platform intervention. Assessments were conducted using measures such as Motricity Scale for lower extremity, Short Physical Performance Battery (SPPB), Berg Balance test, TUG test, ABC (Activities- specific Balance Confidence) Scale, Walking Handicap test, FAC, 10-Meter Walk Test (10MWT), 6-Minute Walk Test (6MWT), Barthel Index for Modified Kitchens (BIMK), EQ-5D-5L questionnaire (EQ-50), Modified Fatigue Impact Scale (MFIs), Fatigue Severity Scale (FSS), Frontal Assessment Battery (FAB), Symbol Digit Modalities Test (SDMT), Digit Cancellation Test, Trail Making Test (TMT), and Tinetti Assessment Measure. The duration of the exercises was thrice a week, for 45 minutes, spanning over four weeks. At the end of the four-week intervention, both groups demonstrated improved balance, fatigue levels, quality of life, and physical and mental abilities. It was anticipated that the group receiving robotic-assisted therapy and regular therapy (Investigative Cluster) would show greater effectiveness than the group receiving only regular therapy (Regulation Cluster).[19]

Li et al., investigated a trial on "Effects of a Brain-Computer Interface-Operated Lower Limb Rehabilitation Robot on Motor Function Recovery in Patients with Stroke".[20] In this study, Brain-Computer Interface (BCI) technology was employed. Twenty-eight patients were taken in the trial with an average age of three and seven decades. Two groups were established: the BCI cluster and the Sham cluster. The BCI cluster received robotic exercise, physiotherapy, and medical treatments, while the Sham group only received physiotherapy and medical treatment. Assessment tools such as Levels of Cognitive Functioning Test for Adults, FMA-UE (Fugl-Meyer Assessment for Upper Extremity), FAC, MBI (Modified BI), Serum Brain-Derived Neurotrophic Factor (BDNF) Levels, FMA-LE (Fugl-Meyer Assessment for Lower Extremity) and neurophysiological variables incorporating Motor Evoked Potential latency and amplitude were utilized. The exercise regimen consisted of sessions conducted six days a week, each lasting 30 minutes, spanning four weeks. After four weeks, the BCI group demonstrated significant improvements in various abilities for stroke recovery patients. Specifically, cognitive abilities showed enhancement, as evidenced by improved Levels of Cognitive Functioning Scale (LCFS) scores indicating better cognitive function. While both groups exhibited similar improvements in upper limb motor functions, gait, and balance, the positive effect of BCI, especially for cognitive ability improvement, was highlighted.[20]

Chen et al., conducted a study titled "Effect of Telerehabilitation on Balance in Individuals with Chronic Stroke".[21]

The study utilized various robotic devices, including the Kinect Sensor, RAGT (Microsoft Corporation, Redmond, WA, USA), with a Virtual Reality (VR) system, Virtual Reality System, Exergaming Telerehabilitation System, and Interactive Self-Rehabilitation Programs. A gross of 30 participants with a mean age of six decades were enrolled in the trial. The study comprised two sets: the Manipulated set, which participated in a VR intervention program, and the Sham Set, which received traditional PT treatment. Assessments were conducted using the Berg Balance test, TUG, MI, FAC, and Modified Falls Efficacy Scale. The duration of the exercise was six times for four weeks, for 2,400 seconds, spanning over a month. Within four weeks, both the Sham and Manipulated sets demonstrated measurable improvements in balance and walking. However, the Experimental Set exhibited superior balance improvements. Both sets showed enhancements in BBS scores, indicating improved balance, while the Manipulated group notably reduced their TUG test times, suggesting enhanced mobility. The Manipulated set's significant advancements in balance and walking measures compared to the Sham set establish its superiority. Specifically, the Manipulated set improvements in BBS scores and TUG test times signify enhanced balance and mobility, respectively.[21]

De Luca et al., investigated title "Dynamic Stability and Trunk Control Improvements Following Robotic Balance and Core Stability Training in Chronic Stroke Survivors".[22] The study utilized the robotic device Hunova. A sum of 15 partakers in the investigation, with an average age of 59 years old in the robotic squad and 63 years old in the experimental squad. The study consisted of two squads: The Experimental Squad, which underwent a rehabilitation program using robots, and the Control Squad, which underwent conventional rehabilitation sessions led by physical therapists. Assessments were conducted using the BBS, Mini-Balance Evaluation Systems Test (Mini-BESTest), and Trunk Impairment Scale. The exercise duration for both groups was six times for four weeks, for 2,700 seconds, spanning five weeks. After five weeks of exercise, both groups demonstrated enhanced balance, walking abilities, arm function, and cognitive performance. However, the control group only showed significant improvement in their ability to maintain balance when reacting to unexpected disturbances, while the Experimental Group maintained their balance improvements, as assessed by the BBS, over time. Specifically, for the Experimental Group, there was an enhanced ability to step forward and backward confidently, as indicated by the Mini-BES Test. Additionally, statistically significant improvements in balance as documented in Berg Balance Scale (BBS) persisted over time, along with increased trunk control and stability during activities.[22]

Castelli et al., conducted a study titled "Robotic-Assisted Rehabilitation for Balance in Stroke Patients (ROAR-S): Effects of Cognitive, Motor, and Functional Outcome".[23] The study utilized the robotic device Hunova® Movendo Technology, srl, Genoa, Italy, a cutting-edge robot designed to aid in rehabilitation for core stability, balance, and lower body functions. This robotic platform is specifically designed to assess and treat the trunk and lower limbs, providing personalized therapy. The study involved 24 participants with an approximate age of 77 years old in the Hunova Crew (HuC) and 76 years old in the Conventional Crew (CoC). HuC group received special treatment with the Hunova robotic platform for balance problems, on top of the usual treatment recommended by doctors. The CoC group served as a comparison and received only the usual treatment recommended by doctors. Assessments were conducted using measures such as the FAC, EuroQol-5D (EQ-5D), Modified Fatigue Impact Scale (MFIs), Fatigue Severity Scale (FSS), Functional Ambulation Battery, SDMT, TMT, Berg Balance test, SPPB, Modified BI (MBI), ABC scale, Walking Handicap Scale, and other cognitive and motor assessments. The duration of the exercise was thrice a week. Treatment outcomes for both groups showed improvements in clinical scales, cognitive performance, balance, mobility, quality of life, and fatigue. The HuC group demonstrated further enhancements in motor skills, cognitive function, and overall well-being compared to the CoC group. Both groups experienced shared improvements in gait, including enhanced ambulation, increased speed in the Timed Up & Go test, and improved walking and sit-to-stand abilities under the SPPB. Additionally, both groups showed strengthened balance, as indicated by improvements in the BBS and SPPB balance sub-score.[23]

Effect of Robotic Rehabilitation on Cognitive Ability

Zhao et al., conducted a study titled "Effects of Training with a Brain-Computer Interface Controlled Robot on Rehabilitation Outcome in Patients with Subacute Stroke".[24] The study employed a BCI-controlled robotic device and Newton's ring to elicit Steady-State Motion Visual Evoked Potentials. A total of 33 participants ages 32 to 68 years old were taken for the experiment. Two groups formation took place: the Sham cluster and the BCI cluster. The Sham cluster received conventional physiotherapy, while the BCI cluster received BCI-based intelligence in addition to conventional physiotherapy. Assessments were conducted using the LOCTA, Fugl-Meyer Testing for the Lower Limb, FAC, FMA for the Upper Limb, Modified Barthel testing, and Serum BDNF levels. Both groups received therapies for four weeks, 1 time a day for half an hour, 12 days of two weeks. After a month, improvements were observed in cognitive function, lower limb motor function, increased levels of BDNF, and ambulation abilities in patients treated with BCI and conventional therapy compared to the Sham cluster. These findings suggest a positive effect of BCI in patients with subacute stroke.[24]

Torrisi et al., organized a review on "The role of hand robotic rehabilitation plus VR in improving cognitive function".[25] In this study, the AMADEO Robotic device, USA was utilized. 48 participants, with a typical age of 54 years old, were incorporated. The candidates were fractioned into two bands: the Manipulated and the Standard bands. The Manipulated band received treatment from the AMADEO robot, while the Standard band underwent conventional PT (Physiotherapy). Assessment tools such as Mini-Mental State Questionnaire, TMT, Stroop Test, Clock Drawing Test, RAVLT (Rey Auditory Verbal Learning Test), FMA, ARAT (Action Research Arm Test), BBT, NHPT, Jebsen-Taylor Hand Function Test, BI, FIM, MoCA (Montreal Cognitive Assessment), mRS (modified Rankin Scale), NEADL (Nottingham Extended Activities of Daily Living) and SIS (Stroke Impact Scale) were utilized for testing. The duration of the exercise was not specified in the provided information. After the treatment, the study demonstrated that participants who received robotic hand therapy (RHT) experienced greater improvement in cognitive abilities compared to those who received conventional hand therapy. Specifically, AHT enhanced attention, executive function, and visual-spatial skills. However, hand function improvement was similar for both groups.[25]

Aprile et al., carried out a survey on "Robotic Rehabilitation to Improve Cognitive Functions in Subjects with Stroke".[26] In this study, three robotic models—Motore, Amadeo, and Diego (Tyromotion and Humanware)—along with a sensor-based instrument called Pablo, were utilized. The study comprised 51 partakers with an average age of 64 years. Various cognitive assessment tools were employed, including the Tower of London for Executive Functions, SDMT for Attention and Processing Speed, Digit Span Task for Memory, Oxford Cognitive Screen, FMA for Upper Extremity, and Rey-Osterrieth Complex Figure Test. Participants underwent 30 sessions lasting 45 minutes each, conducted five days a week. Following these sessions, improvements were observed in cognitive functions, upper extremity motor functions, and performance in daily activities. This suggests that the combined effect of robotics and cognitive exercises contributes to patient recovery.[26]

Manuli et al., conducted a study on "Robotic Rehabilitation plus VR affect cognitive behavioral outcome in patients with chronic stroke".[27] This study used Computer Assisted Reality, Lokomat Nanos, and Lokomat Pro robotic devices, USA. The review included a whole of 90 individuals, with 30 individuals allocated to each group. Three distinct groups were established: Team 1, comprising the "Robotic Rehabilitation team with VR"; Team 2, consisting of the "Robotic Rehabilitation without VR"; and Team 3, receiving "conventional therapy". Assessment tools utilized in the study included the Montreal Cognitive Assessment, FIM Cognitive Subscale, Motor Subscale, Weigl Test, Short Form-12 Health Survey Total (Mental and Physical), Beck Depression Inventory-II, TMT Form, Visual Search and FAB. Each participant underwent 40 sessions of their respective treatments, followed by 40 sessions of physiotherapy. After the completion of these sessions, improvements were observed across all three groups in cognitive functioning, mood, executive functions, and activities of daily living (ADL). Nevertheless, Team 1 receiving robotic rehabilitation and VR demonstrated impressive enhancements in shifting skills, quality of life, selective assessment, and cognitive flexibility. This

suggests that the combination of robotic rehabilitation and VR provides the most effective approach to cognitive rehabilitation.[27]

Effect of Robotic Rehabilitation on Upper Limb Management

Frisoli et al., conducted a study on "A randomized clinical control study on the efficacy of three-dimensional upper limb RE training in chronic stroke".[28] The study employed the Pnew-WREX, ARMin exoskeleton, and L-EXOS exoskeleton, Italy. Twenty-two people took part, segregated into two bunches: The Robotic bunch, which received treatment from the exoskeletons, and the CB, which underwent manual PT. Assessment tools such as BAT, FMA, and the Ashworth Scale were utilized. Exercise sessions were conducted thrice a week, each lasting 2,700 seconds, 6 times for four weeks. Following the 6-week period, the Robotic Group exhibited significant improvements in functional ability and task precision, indicating the positive effects of Robotic Rehabilitation compared to conventional therapy.[28]

Takebayashi et al., handled an analysis on "Robot-Assisted Training as Self-Training for Upper Limb Hemiplegia in Chronic Stroke".[29] The study focused on the use of the ReoGo-J upper limb extremity equipment, Brazil. The study involved 129 participants aged between 58 and 60. Three groups were established: the baseline assembly, who underwent basic physiotherapy techniques with self-improvement methodologies; the Robot Training (RT) assembly, which underwent robot-assisted training of ReoGo-J unit before standard occupational therapy; and the Movement Therapy (MT) Group, wherein participants engaged in occupational techniques based on Constraint-Induced Movement Therapy, task-oriented therapy, and robot-assisted therapy. Various assessment tools were utilized, including MAS, Performance Test for Upper Limb Functions, Motor Evaluation in Vascular Hemiplegia, Research Analysis of SIS, FMA, Action Research Arm Test, MI for Muscle Strength, Active Range of Joint Motion Assessment, SIS for Quality of Life. Exercise sessions were conducted thrice weekly, each lasting for an hour for two and a half months. After the intervention, RT assembly demonstrated the most significant improvement in FMA-UE scores, indicating the highest benefit. Additionally, the RT Group exhibited the greatest enhancement in upper limb function compared to the other groups.[29]

Budhota et al., conducted the following study on "Robotic Assisted Upper Limb Training in Stroke".[30] The study utilized the H-MAN robotic equipment, USA. Forty-four participants, encompassing a range of ages from 21 to 85, were encapsulated for investigation. Participants were fragmented into two squads: The robotic therapy squad, which received combined therapy of H-MAN robotic and conventional physiotherapy, and the conventional therapy (CT) squad, which received only conventional therapy. Assessment tools such as FMA, VAS, MAS, MMSE, LTA, CTA, ARAT, and GS were employed. The RT squad underwent 60 minutes of H-MAN training, after half an hour of traditional techniques, at the same time, the CT squad received one and a half hours of traditional techniques. Both squads participated in sessions lasting 90 minutes each, three sessions a week for one and a half months. After the 6-week experiment, participants in the RT squad showcased growth in motor function and movement smoothness compared to the CT squad. Additionally, combination therapy reduced the workload demand on therapists.[30]

Shi et al., conducted a study on "Effects of a Soft Robotic Hand for Hand Rehabilitation in Chronic Stroke Survivors."[31] The study utilized the VAEDA robotic device. Sixteen participants aged 56, were collected in the search, which consisted of a single group. Assessment tools such as BBT, MAS, FMA-UE, ARAT, and Maximum Voluntary Grip Strength test were employed. Exercise sessions were conducted seven days a week, with every session approximating 60 minutes, over six weeks. After a 6-week intervention, a significant improvement in test scores was observed, indicating the effectiveness of robotic exercises for hand rehabilitation in chronic stroke survivors.[31]

Li et al., conducted a study titled "Efficacy of Robotic Priming with Bilateral Approach in Stroke Rehabilitation".[32] The research employed the Bi-Manu-Trace robotic device and involved 31 participants having a mean age of 55. Two groups were formed: the Robotic Primed Mirror Therapy crew (RMT) and the Robotic Primed Bilateral Upper Limb Training crew (RBULT). RMT crew participants underwent robotic training and mirror therapy, whereas in the RBULT

group, participants received robotic training and bilateral upper limb training. Assessments were conducted using the robotic Neurological Severity Test, Chedoke Arm and Hand Activity Inventory, and accelerometer. The intervention consisted of sessions conducted six times in two weeks, with each training lasting 2,400 to 2,700 seconds over six weeks. After six weeks, the research findings indicated that the group receiving robotic priming with MT demonstrated a better outcome in motor function and arm use when matched to the crew receiving robotic priming with bilateral upper limb training. Therefore, combining robotic training with mirror therapy may improve motor function and arm functionality for stroke patients.[32]

Guillen-Climent et al., conducted a study titled "Use of MERLIN in Stroke Patients: A Robotic Device Based on Serious Games for Upper Limb Rehabilitation in Home Settings".[33] This study utilized the AA Robotic device, Italy, MERLIN robotic device, and Arm Assist robotic system. There were nine engagers between the ages of 41 and 84. The study comprised only one group, which received training from the MERLIN robotic system. Assessments using the Modified Ashworth Assessment and Fugl-Meyer scale were conducted. The exercise duration was thrice a week, for 30 minutes each session, spanning over three weeks. After three weeks, significant improvements were observed in upper limb coordination and overall motor function score.[33]

Ranzani et al., explored "Neurocognitive robot-assisted rehabilitation of hand function".[34] The study utilized the ReHapticKnob device. Thirty-three participants, covering ages from 18 to 19, were covered in the study, with 14 participants in the Robotic Group and 13 in the Control Group. Assessment tools such as FMA-UE, FMA-WH, FMA-SE, MAS, EmNSA-T, EmNSA-P, VAS, LCF-P, NIHSS, GoodGlass Kalpan Assessment, and Albert Test were employed. The Control Group underwent exercises 2–3 sessions a week for 30–45 minutes, whereas the Robotic Group engaged with set of 3, 2 times a week for 2,700 seconds. Both groups had kept track of assessments at 8 weeks and 32 weeks. The study concluded that robotic training yields outcomes comparable to Neurocognitive therapy, suggesting its potential as an alternative treatment approach for hand function rehabilitation.[34]

Aprile et al., executed a study, "Upper Limb Robotic Rehabilitation After Stroke".[35] In this study, various robotic devices were utilized: Motore, a robotic device facilitating assisted and unassisted flat motion of elbow and shoulder joints; Amadeo, supporting assisted and unassisted bending and straightening movements of fingers; Pablo, a sensor-based system enabling independent three-dimensional motion of wrist, shoulder, and elbow joints; and Diego, a device aiding three-dimensional, one/two-handed motion of the shoulder joint with arm weight assistance. The study encompassed a total of 224 members between the ages of 4 and 85, segregated in two sets: The Robotic set (RS), undergoing therapy with robotic devices targeting shoulder, elbow, hand, and wrist joints, and the Conventional set (CS), receiving traditional treatment focusing on upper limb function improvement, sensorimotor control restoration, and muscle stiffness reduction. Assessment tools such as FMA, MI, MRC, MAS, DN4, NRC, mRI, FAT, ARAT, SF 36-PCS, and SF-36-MCS were employed. Treatment comprised daily 45-minute episodes, five times a week, over the month, for both sets. Additionally, conventional rehabilitation sessions occurred six times a week, each lasting 45 minutes, during the same month. After four weeks of treatment, both the Robotic set and the Conventional set demonstrated improvement in several areas. The average FMA score increase was 8.50 for RS and 8.57 for CS, surpassing the clinically meaningful improvement threshold of 5 points. RG exhibited greater enhancement in upper extremity strength, as calculated by the Motricity Test, compared to CS, and maintained this advantage at the treatment's conclusion.[35]

Huang et al., reviewed "The comparison of the rehabilitation effectiveness of neuromuscular electrical stimulation robotic hand training and pure robotic hand training after stroke".[36] In this study, a variety of robotic devices were employed, including the Hybrid neuroprosthesis for the upper extremity, robotic hand, EMG-Driven robotic hand, EMG-driven neuromuscular electrical stimulation (NMES) robotic hand, and electromechanical wrist robot assistive system. Fifteen engagers represented the age of 57 for the experimental team and 6 decades for the pure team, were contained in the review. The study encompassed two participant cohorts: the NMES cohort, which

utilized a robotic hand controlled by electromyography (EMG)-driven NMES, and the Pure cohort, which utilized a robotic hand without additional NMES stimulation. Assessment tools such as FIM, MAS, ARAT, and FMA were employed. The exercise regimen consisted of sessions conducted thrice a week for 30 minutes over three months. After three months, it was observed that neuromuscular electrical stimulation (NMES) improved hand function in paralyzed patients when contrasted to a pure cohort without stimulation. NMES cohort exhibited a notable increase in hand function assessment scores (HFAS) and a substantial reduction in elbow, wrist, and finger muscle stiffness. The NMES group maintained these improvements in hand function, whereas the control group's hand function assessment score declined at the 12-week follow-up. The review emphasizes on upper limb function, particularly hand function, demonstrated significant benefits from NMES correlated to the control team.[36]

Franceschini et al., facilitated an examination on "Upper limb robot-assisted rehabilitation versus PT on subacute stroke patients".[37] In this study, robotic devices were employed, namely the InMotion2 robotic system and Planer end-effector robots. A total of 48 participants were involved, where the robotic crew is 74 years old and the conventional crew with an average age of 7. Involved parties were fragmented into two crews: The Experimental Crew, utilizing InMotion2 robotic system, Chicago for upper body rehabilitation, involving goal-based, two-dimensional reaching tasks, and the control crew, receiving conventional upper body PT. CT activities included stretching assistance, arm and shoulder training, and reaching activities with therapist guidance. Assessment tools such as FMA for upper extremity, lax range of motion, Modified Ashworth test for shoulder stiffness, and Modified Ashworth Scale for elbow stiffness were utilized. The exercise regimen consisted of sessions conducted five times a week, each lasting 45 minutes, spanning over six weeks. After six weeks, both crews illustrated improved upper extremity working, as assessed by the Fugl-Meyer measurement. Additionally, the Experimental Group improved shoulder and elbow stiffness (measured by the Modified Ashworth Scale) and arm flexibility (measured by passive range of motion). The Experimental Crew illustrated superior improvement in these areas compared to the Control crew, which only showed improvement in shoulder stiffness.[37]

Qian et al., conducted a study on "Early Stroke Rehabilitation of the Upper Limb Assisted with an Electromyography-Driven Neuromuscular Electrical Stimulation-Robotic Arm".[38] This study utilized various robotic devices, including the EMG-driven NMES robotic arm, Rehabilitation robot ARMin II, USA. Electromyography-driven robot, and electromechanical wrist robot-assisted system device. Twenty-four participants had a typical age of 54 for the exploratory cluster and 6.4 decades for the Control cluster. The study comprised two participant groups: the NMES-Robot Group, which underwent training using a robotic arm delivering NMES, and the Control cluster, which received conventional rehabilitation treatments focused on the upper limb. Assessment tools such as the Action Research Arm Examination, Function Independence Assessment, Modified Ashworth Scale and Fugl-Meyer Examination were employed. The exercise regimen consisted of sessions conducted five times a week, each lasting 40 minutes, spanning over four weeks. Following a month of drill, the exploratory cluster (NMES robot) and the control cluster exhibited substantial improvements in FMA, MAS, ARAT, and FIM. Nevertheless, the NMES-robot cluster demonstrated significantly grander improvements in FMA scores, particularly for the wrist and hand. This improvement has not been seen for control cluster, displaying superior efficacy of NMES-RT in enhancing wrist and hand function.[38]

DISCUSSION

The current literature review critically investigated 30 articles to highlight the effects of robotic rehabilitation on stroke. In addition to the basic impact of traditional physiotherapy in the form of manual techniques and a basic exercise program that was approved as an effective modality for the improvement of gait, balance, cognition and upper limb this study investigates for the beneficial effects of robotic rehabilitation for stroke survivors. Bruni et al.'s research highlighted significant improvements in gait parameters.[39] They emphasized the importance of patients engaging in more intense and repetitive training sessions, enhancing brain flexibility and supporting motor recovery. Task-Oriented Training through robotic

rehabilitation offers personalized sessions tailored to each patient's specific needs, focusing on enhancing particular motor skills and functional movements to improve overall mobility. Additionally, certain robotic systems provide augmented feedback, crucial in enhancing motor learning and performance by offering immediate feedback on movement quality and progress. As a result, robotic gait rehabilitation can effectively enhance walking speed, balance, and coordination, ultimately leading to improved gait function and greater independence in daily tasks.[39] Similarly, the reviewed articles examined various gait parameters, including step and stride length, gait speed, cadence, motor skills, and functional ability. Moreover, notable improvements were observed in gold-standard assessment scales such as the BBS, 10-Minute Walk Test, and Time-Up-and-Go test. Specific scales like the Fugl Mayer Assessment and DGI were also used to assess and track progress accurately. Zheng et al.'s research highlights the improvement in balance parameters, emphasizing that enhancing muscle strength is a key benefit of robot-acquired training for patients suffering from a stroke.[40] This training provides targeted resistance and controlled movements, enhancing balance function. Additionally, coordination improves as patients are guided through various tasks and exercises, helping them relearn and refine the motor skills necessary for balance control. The Recurring and work-oriented quality of training with robot-acquired training promotes neural plasticity, enabling the brain Restructure and establish fresh neural pathways, thereby aiding in balance function improvement during the recovery process. The therapy also offers patients a variety of sensory inputs, including proprioceptive and vestibular feedback, crucial for maintaining balance and spatial awareness.[40]

Moreover, postural control can be enhanced in stroke patients through robotic assistance, targeting specific muscle groups and adjusting their center of gravity, essential for maintaining balance during various activities. The aforementioned articles discussed balance parameters such as static and dynamic balance and ambulation. Additionally, improvements were noted in parameters like swing amplitude, center of pressure, and speed of oscillation. Significant improvements were observed in gold-standard scales such as the BBS and Fugl Meter Balance Scale. The research by Aminov et al., highlighted significant improvements in cognitive abilities, underscoring the potential advantages of robotic rehabilitation in enhancing cognitive function among stroke patients.[41] For example, VR interventions show promise in boosting cognitive function and memory by leveraging the connection between motor skills and cognitive capabilities. However, further in-depth investigations are necessary to fully understand the extent of these benefits and refine treatment plans for cognitive rehabilitation using robotic technology.[41]

The articles above discuss improvements in major components such as attention, visuomotor skills, memory, cognitive flexibility, executive functions, shifting skills, and enhancements in LOCTA score. Additionally, improvements in mood were also observed.

Bertani et al's research sheds light on the significant improvement in upper limb functionality.[42] They highlight how robotic therapy holds promise in enhancing motor function recovery in the upper limb, especially for individuals grappling with chronic strokes. Positive reorganization in the motor cortex can lead to better outcomes in arm function. Additionally, advanced robotics assisting in therapy through focused and repetitive exercises can greatly expedite recovery after a brain injury, improving upper limb function. Robotic technology can also enhance flexor synergies, coordination, and speed in the affected upper limb while improving the sense and understanding of the shoulder, arm, and forearm. Moreover, robotic-assisted therapy can alleviate joint pain in the upper limb, enhancing comfort and mobility during rehabilitation.[42]

The articles discussed above underscore improvements in various parameters of the upper limb, including motor functions, coordination, and sensory function. Significant enhancements were noted in gold-standard assessment scales such as the Fugl Meyer Assessment, Action Reach Arm Test, and Modified Ashworth Scale. Furthermore, additional scales such as the Biconical Activity test and MI were also utilized, highlighting the comprehensive evaluation of upper limb functionality.

Robotic rehabilitation for stroke patients has been extensively studied recently, with research post—2018 highlighting its feasibility and potential benefits. Feasibility studies have demonstrated the practicality of robotic

interventions in various settings. For instance, a 2018 pilot study evaluated the use of a robotic glove for hand rehabilitation in hemiplegic stroke patients at home. The findings indicated that the intervention was both feasible and safe, with 81% of participants completing the program. Significant improvements were observed in hand motor function, dexterity, and strength. Similarly, research from 2020 assessed the use of a single-joint Hybrid Assistive Limb (HAL-SJ) robot for upper limb rehabilitation in subacute stroke patients with varying severity levels. This study concluded that robot-assisted rehabilitation is feasible across different severity groups, with the most notable improvements in patients with moderate impairments.

The efficacy of robotic rehabilitation is further supported by studies integrating multiple therapeutic modalities. A 2021 study introduced the perSonalized UPper Extremity Rehabilitation (SUPER) program, which combined robotics, VR, and NMES. This program, tailored to individual functional levels, demonstrated feasibility and effectiveness, with 64% of participants showing clinically significant improvements in upper extremity function. Additionally, recent developments in neural interface technology, such as Neuralink's BCI trials, have explored controlling robotic arms through brain implants. While primarily targeting individuals with paralysis, this technology holds promising implications for stroke rehabilitation by enabling direct neural control of assistive devices.

This study has several limitations, including limited access to the databases, leading to the inclusion of fewer studies. Secondly, a quality appraisal of the included studies was not performed.

Future recommendations include high-quality randomized controlled trials to reach any firm conclusion regarding the effectiveness of robotic rehabilitation in the resolution of post-stroke survivors' symptoms.

CONCLUSION

In conclusion, recent research underscores the feasibility and safety of robotic rehabilitation for stroke patients, with significant functional improvements and high patient compliance. Advancements in integrating robotics with other modalities and neural interface technologies further enhance the potential of robotic rehabilitation in stroke recovery. The motive behind this study was to show that including robotic rehabilitation with other techniques can result in similar advantages to rigorous training. Analysis of the existing data indicates that robotic therapy can improve walking, balance, thinking, memory, coordination, daily tasks, motor abilities, and posture management. In the end, all of these areas may experience enhancements by implementing robotic rehabilitation. However, more studies are required to confirm the existing findings.

AUTHOR CONTRIBUTIONS

All the authors contributed equally in the conduct of the review study.

ACKNOWLEDGMENTS

Sincere thanks and gratitude towards the faculty members (Kriti Sachan and Baldev Negi) of Department of Physiotherapy, Sharda School of Allied Health Sciences, Sharda University, Greater Noida, Uttar Pradesh, India. They provided their valuable insights regarding the conceptualization of the topic, article selection, data analysis and final drafting of the manuscript.

FUNDING

This review has not received any funds through any agency.

CONFLICTS OF INTEREST

There is no conflict of interest as reported by the authors.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted in accordance with the ethical guidelines.

FURTHER DISCLOSURE

Not applicable.

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Received October 23, 2024, accepted February 21, 2025, date of publication March 20, 2025.

Letter

Navigating Thumb Ligament Pathology: From Injury to Recovery

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Dear Editor,

The metacarpophalangeal (MP) joint of the thumb functions predominantly as a hinge, facilitating flexion and extension while also allowing limited abduction–adduction and rotational movements. Both active and passive stabilizers contribute to its overall stability, with joint morphology playing a secondary role in this function.[1] The passive stabilizers include the volar plate (VP), which integrates two sesamoid bones, and the main and accessory collateral ligaments. The active stabilizers are classified into intrinsic muscles—abductor pollicis brevis (APB), flexor pollicis brevis (FPB), and adductor (ADD), and extrinsic muscles—long extensor of the thumb (LET), short extensor of the thumb (SET), and long flexor of the thumb (LFT).

The ulnar collateral ligament (UCL) of the thumb comprises two components: the primary and accessory ligaments. The primary ligament runs obliquely, from the dorsal side of the metacarpal head to the volar base of the first phalanx.[2] In contrast, the accessory ligament, which lies more superficially and volarly, merges with the volar plate and inserts at the base of the first phalanx. In extension, the accessory ligament becomes taut, while the primary ligament tightens during flexion, particularly around 30°. As the joint flexes, the accessory ligament slides proximally alongside the volar plate, allowing some degree of joint laxity—approximately 6° in extension and 12° in flexion during the varus–valgus stress test. The management of thumb ligament pathologies can significantly benefit from the integration of advanced clinical engineering technologies. These technologies offer tools to improve diagnostic accuracy, personalize treatment plans, and monitor recovery progress with greater precision. This document explores how advanced imaging, biomechanical modeling, and wearable devices can support the recovery process, enhancing diagnostic accuracy and therapeutic effectiveness.

Injuries to the MP joint frequently occur as a result of hyperabduction or hyperextension, often leading to UCL damage. Such trauma may also involve the dorsal capsule and volar plate, potentially causing volar subluxation of the joint. Chronic UCL insufficiency, because of its dorsal location relative to the joint's center of rotation, can result in a supination deformity of the first phalanx as it rotates around the intact radial collateral ligament (Figure 1).

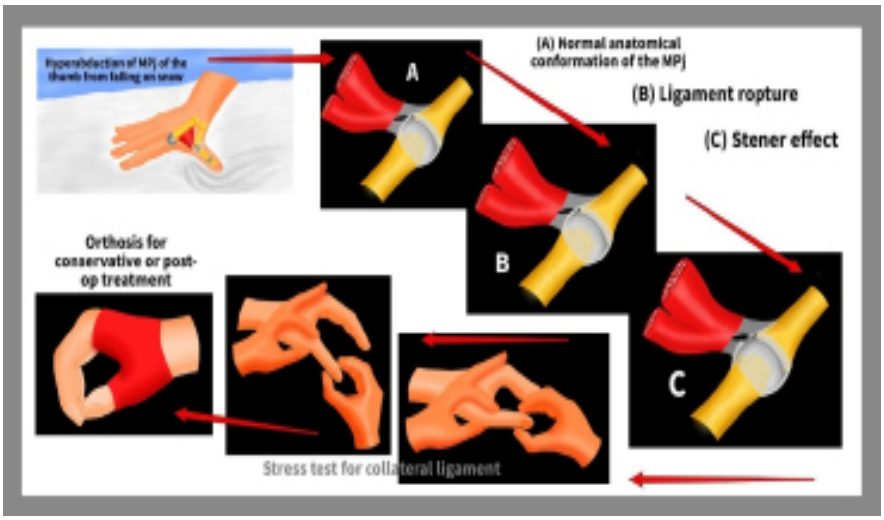

FIGURE 1. Management and evaluation of ulnar collateral ligament injuries of the thumb.

Hyperabduction of the thumb MP joint can result in UCL injuries, as shown in the series from normal anatomy (Figure 1A), through ligament rupture (Figure 1B), to the development of a stener lesion (Figure 1C). The figure also illustrates the use of an orthosis for conservative or postoperative care, alongside the proper technique for performing a collateral ligament stress test.

Ulnar collateral ligament injuries commonly involve its distal insertion, occasionally accompanied by an avulsion fracture at the base of the phalanx.[3] Injuries can also occur in the ligament's central or proximal regions. In case of ligament discontinuity, the interposition of the adductor aponeurosis between the torn ligament ends can prevent healing, leading to a Stener lesión.[4]

Clinical evaluation begins with an examination of the trauma history and physical appearance, where swelling and bruising are commonly observed. In severe cases, volar–radial subluxation of the first phalanx may be evident. Tenderness is typically present over the ulnar aspect of the MP joint.

The varus–valgus stress test is essential for determining ligament integrity. This test should always be compared with the contralateral hand and performed in both extension and 30° of flexion. Stabilization of the metacarpal neck is necessary while lateral stress is applied to the phalanx. Any phalanx rotation can obscure a ligament injury. Biomechanical modeling and simulation play a crucial role in understanding ligament stress in the thumb. Using Finite Element Modeling (FEM) techniques, researchers can digitally recreate anatomical structures and evaluate how the UCL responds to varying degrees of stress. These models support the planning of therapeutic, surgical, and conservative interventions by providing an accurate forecast of post-treatment joint stability. Laxity exceeding 30°, or more than 15°, compared to the unaffected side, strongly suggests UCL rupture. Laxity in flexion alone points to the involvement of primary ligament, while laxity in both flexion and extension indicates a more extensive injury to both ligament portions. Laxity only in extension may suggest an isolated volar plate injury.

Advanced imaging technologies, such as high-resolution ultrasound and three-dimensional (3D) magnetic resonance imaging (MRI), allow for a more precise evaluation of ligament structures. These tools can be paired with digital stress tests, which quantify the biomechanical response of the ligament. Such technologies, supported by 3D models, offer clinical engineers the opportunity to simulate specific thumb movements and predict ligament behavior under various stresses, thereby enhancing diagnostic assessments and reducing the risk of diagnostic errors.[5]

Ulnar collateral ligament injuries are categorized into three grades. Grade 1 involves ligament strain with no detectable laxity; Grade 2 presents with some laxity but a firm end point during the stress test, indicating a partial tear; and Grade 3 is characterized by significant laxity with a soft end point, suggesting complete rupture. Engineered orthoses represent an evolving therapeutic solution. With the development of adaptive designs and advanced materials, these orthoses can accommodate progressive changes in thumb stability, providing targeted support and comfort without restricting essential movements for rehabilitation. Advances in orthotic engineering allow for lighter and more durable devices that can be customized to support each stage of recovery. Looking forward, the integration of artificial intelligence (AI) algorithms with engineering technologies promises to further enhance the management of ligament injuries. Predictive systems powered by AI would identify individuals at the risk of injury and optimize rehabilitation plans by automatically monitoring patient progress. Such integrated approaches represent an exciting prospect for rehabilitation medicine and clinical engineering.

AUTHOR CONTRIBUTIONS

Conceptualization, P.B.; Validation, D.D.; Data Curation, P.B.; Writing–Original Draft Preparation, P.B.; Writing–Review & Editing, D.D. and R.T.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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