

Study on Digital Twin-Based Test Methods for Walking RACA Robots

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Summary

This study presents a novel test method for walking RACA (Rehabilitation, Assessment, Compensation, and Alleviation) robots using digital twin technology. Traditional physical testing based on ISO 5363:2024 and IEC 80601-2-78:2019 faces challenges due to high costs, resource limitations, and extended development cycles. To address these issues, we propose the integration of Medical Device Digital Development Tools (M3DT), leveraging digital twins for pre-validation and optimization before physical testing. Our research demonstrates that digital twin simulations can enhance compliance assessment, reduce development costs, and streamline validation procedures. This approach supports the standardization of digital testing protocols for rehabilitation robotics.

Introduction

Rehabilitation robotics has rapidly evolved, necessitating standardized test methods to ensure safety and performance. Walking RACA robots, governed by IEC 80601-2-78 [1] and ISO 5363[2], require comprehensive physical testing, which can be resource-intensive. Digital twin technology offers a promising solution to optimize evaluation methods.

Methods

We developed a digital twin framework within M3DT to simulate walking RACA robots' mechanical and functional behaviors (Figure 1). This system integrates computational modeling, finite element analysis, and gait cycle simulations. Comparative validation was performed using ISO 5363-compliant physical testing to assess the correlation between digital predictions and real-world results.

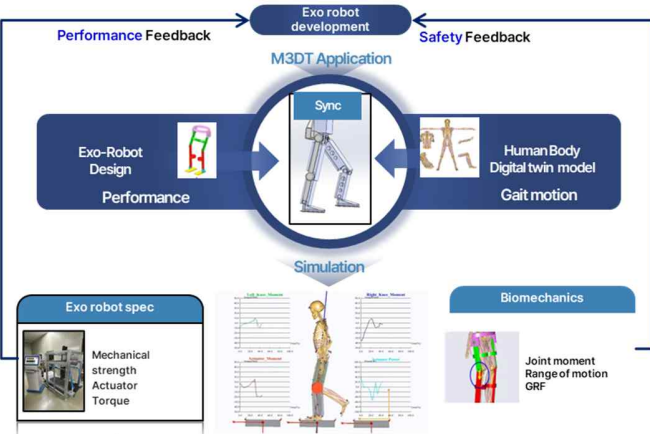


Figure 1: Concept of M3DT for Exoskeleton Rehabilitation Robots

Results and Discussion

The digital twin framework successfully predicted critical parameters, including push-off timing, torque generation, and structural integrity. Additionally, we evaluated the actuator performance required when a 100kg adult wears the RACA robot, assessing the maximum stress on each joint during the gait cycle [3] (Table 1). This method significantly reduced testing costs and time by eliminating unnecessary physical prototyping. Challenges in regulatory acceptance of digital validation were identified, highlighting the need for standardized digital test protocols within international standards.

Table 1: Maximum Stress at Each Joint

Gait cycle	Max stress (MP)	Hip (MP)		Knee (MP)		Ankle (MP)	
		L	R	L	R	L	R
Heel strike	1330	389	311	275	338	387	496
Mid Stance	686	271	271	130	85	91	33

Conclusions

Digital twin-based testing offers a viable alternative to traditional test methods for walking RACA robots, supporting more efficient compliance with ISO 5363 and IEC 80601-2-78. Further research should focus on formalizing digital validation procedures within regulatory frameworks to enhance standardization and industry adoption. Additionally, verification and validation (V&V) methods should be carefully considered to ensure the reliability and accuracy of digital twin simulations in compliance testing.

Acknowledgments

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References

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- [2] ISO 5363:2024. "Robotics — Test methods for exoskeleton-type walking RACA robot."
- [3] Li, M., et al. (2013). *IEEE Conference on Mobile Ad-hoc and Sensor Network*, 510-51