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HOW INDUSTRY 4.0 AFFECTED PROSTHESES MANUFACTURING

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A B S T R A C T

The rapid evolution of Industry 4.0 technologies, such as 3D printing, artificial intelligence (AI), the Internet of Things (IoT), and big data analytics, has introduced transformative opportunities in prosthetic manufacturing. This study evaluates the impact of these advanced technologies on improving manufacturing efficiency, enhancing product quality, fostering innovation, optimizing supply chains, and advancing healthcare delivery. This research demonstrates how Industry 4.0 technologies create highly customized, precise, and durable prosthetic devices that improve patient outcomes by conducting a comprehensive literature review and analyzing case studies. The findings reveal that while adopting Industry 4.0 offers significant benefits, including increased customization, reduced material waste, and improved regulatory compliance, it presents challenges such as high implementation costs, integration complexities, and data security concerns. The study contributes to the field by identifying strategies for overcoming these challenges and highlighting the potential of Industry 4.0 to drive sustainable advancements in prosthetic manufacturing, supporting global objectives for inclusive innovation and robust infrastructure.

1. INTRODUCTION

Orthopedic prostheses have been used since ancient times, as evidenced by Greek, Roman, and Egyptian artifacts. Today, the demand for prostheses is rising due to the aging population and advances in technology and medicine (Kulkarni et al., 2024). A prosthesis replaces a missing bodily part, like a joint, organ, or limb, to improve flexibility, functioning, or appearance. For those who have lost or injured body parts because of disease, trauma, or birth defects, prostheses are crucial in enhancing their quality of life. Various types of prostheses serve distinct needs: limb prostheses enable movement and physical activity, orthopedic prostheses replace joints to improve mobility and alleviate pain, dental prostheses restore dental function and aesthetics, and cosmetic prostheses primarily address appearance, such as artificial eyes or noses (Windrich, et al., 2016; Moisan et al., 2024). Advanced prostheses may incorporate sensors and electronics, allowing for more natural, responsive movements controlled by muscle or neural signals (Wolf et al., 2020). To satisfy patient requirements, prosthesis manufacturing involves designing, creating, and fitting artificial body components. Advanced materials, engineering concepts, and increasingly digital technologies like computer-aided design (CAD) and additive manufacturing are combined to create highly customized, useful, and biocompatible products (Barrios-Muriel et al., 2020).

Medical professionals treat numerous bone and tissue fractures daily, often caused by sports injuries, falls, and accidents. While most injuries are self-healing, aging reduces progenitor cells, impairing healing and increasing inflammation (Qian et al., 2024). To address these challenges, biocompatible materials are being

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developed, particularly in the form of metallic implants, which have significantly improved the quality of life, especially in aging populations. Advances in metals and alloys have enhanced the strength, durability, and resistance to fatigue and corrosion of these implants (Bandyopadhyay et al., 2023; Tang et al., 2017). Whether biodegradable or non-biodegradable, implants are critical for stabilizing fractures, with their design requiring a comprehensive understanding of mechanical properties and degradation patterns (Chandra & Pandey, 2020).Biomedical implants, such as screws and bone plates, play an essential role in supporting healing and restoring function, although they face challenges related to biocompatibility and immune response (Qian, et al., 2024).

Biocompatibility is a key consideration in the design and use of implants. Traditional definitions of biocompatibility emphasize non-toxicity and minimal immune response. However, as Buddy Ratner, a leading bioengineering expert, and professor of bioengineering and chemical engineering, argues, these materials should be classified as "biotolerable" rather than truly biocompatible (Mertz, 2013), as they provoke minimal inflammatory responses but do not fully integrate into the body. Ratner redefines biocompatibility to focus on a material's ability to guide healing, tissue integration, and reconstruction. His redefined concept of biocompatibility is informed by early observations from surgeon Harold Ridley, who noted that Perspex plastic used in eye lens implants remained inert within the body without causing adverse reactions, leading to the development of one of the first widely accepted biocompatible devices (Margo, 2017).

In this context, metallic implants, while essential in treating fractures, can face failure due to factors such as stiffness, corrosion, toxicity, and infection. Stiffness occurs when the implant does not match the bone's mechanical properties, resulting in stress shielding and bone resorption. Corrosion can lead to the release of toxic ions, damaging surrounding tissues, and infections can develop when bacteria colonize the implant, especially in porous areas. Despite these challenges, bone remodeling continues post-surgery to stabilize the implant. Non-cemented implants offer greater stability and require less bone removal compared to cemented implants, though infection risk remains a significant concern, particularly when bacteria adhere to the implant surface (Shayesteh Moghaddam, et al., 2016; Amirtharaj Mosas et al., 2022).

Innovations in prosthesis design have been made to enhance implant performance and address some of these challenges. For example, bone prostheses can feature a hollow interior chamber and a porous or mesh surface to connect to bone. Channels within the prosthesis allow for the injection of biomaterial that stimulates bone formation, enhancing the union between the prosthesis and the bone. Furthermore, joint prostheses are often made from carbon reinforced matrixes with carbon fibers, matching the elasticity of bone tissue to prevent loosening caused by tissue changes. Additionally, glass ceramic coatings improve adhesion, while sintered aluminum oxide layers on sliding surfaces reduce wear, contributing to the long-term success and functionality of the implant (Wang et al., 2023; Safavi et al., 2023; Yang et al., 2022).

1.1. Industry 4.0

Industry 4.0, launched by the German Federal Government in 2014, aims to transform manufacturing with smart factories that leverage advanced technologies like cyber-physical systems (CPS), AI, IoT, and cloud computing for enhanced data exchange and automation (Jamwal et al., 2021).

These four cardinal pillars drive the transformation: interoperability, virtualization, decentralization, and real-time. Interoperability enables seamless transfer of data among machines, individuals, and sensors through IoT and cloud computing. Virtualization through digital twins and real-time simulation enables predictive maintenance and process optimization. Decentralization enables self-organization of manufacturing systems, reducing the part played by man in decision-making. Lastly, real-time data processing enhances agility and enables manufacturing operations to respond dynamically to environments (Lu, 2017).

Interconnection between these pillars enables a transition from linear supply chains to network, adaptive networks where sharing of data, automation, and machine learning interact synergistically. For example, interoperability and real-time analysis enable continuous monitoring of prosthesis production to ensure correct selection of materials and optimal machining conditions. Virtualization enables digital prototyping of orthopedic implants to minimize errors before physical manufacture, while decentralized decision-making optimizes the efficacy of automated manufacturing lines (Friederichsen, et al., 2014; Koh et al., 2019).

This fourth industrial revolution integrates robotics, big data analytics, and machine learning to drive productivity and efficiency across sectors (Jamwal et al., 2021). Its impact is notable in the medical field, where innovations such as 3D-printed parts have improved precision and customization (Buj-Corral et al., 2020). Emerging tools like augmented and virtual reality, along with blockchain, are further enhancing Industry 4.0's reach, enabling interconnected and adaptive production environments (Jamwal et al. 2021).

The integration of the latest technology by Industry 4.0 has significantly transformed value chains by promoting self-organizing systems and creative products, as well as by increasing productivity and flexibility through end-to-end engineering. In intelligent orthopedics and prosthetic restorations, sensor-equipped devices collect real-time data that is analyzed using big data analytics and cloud computing (Javaid & Haleem, 2020).

Virtualization allows for digital twins of patient-specific prosthesis designs to be modelled before manufacture, thereby simplifying structural integrity and biomechanical functionality. Smart manufacturing decentralized decision-making will facilitate automated customization in which AI-enabled production lines adjust in real time to respond to patient-specific requirements. Interoperability between IoT-linked machines ensures accurate material application with less variability and more consistency in production (Koh et al., 2019; Sun et al., 2023).

This enables precise control over structural, technological, and material aspects to achieve high-quality results and exact dimensional tolerances (Dobrzański & Dobrzański, 2020). This degree of personalization boosts efficiency across healthcare settings by reducing errors, delays, and material waste, and improving patient comfort (Javaid & Haleem, 2020).

The research investigates how digital innovations are influencing the manufacturing of prosthetic devices. Manufacturers may now produce more accurate, effective, and tailored prostheses because Industry 4.0 integrates technologies including automation, real-time monitoring, and data analytics. Functionality, fit, and patient comfort are greatly improved by the design of intelligent devices that are customized to each patient's needs because of the transition from conventional mass production to data-driven, patient-centered approaches. Further enhancing access to high-quality prostheses and highlighting its potential to enhance the quality of life for those in need of prosthetic solutions, Industry 4.0 also lowers production costs and timeframes.

By integrating Industry 4.0 technologies, the manufacturing of prosthetics is transitioning from rigid mass production to highly flexible, data-driven, and patient-oriented processes. This not only reduces production costs and waste but also increases accessibility so that a greater diversity of patients can benefit from advanced, customized prosthetic solutions (Mobarak et al., 2023). As Industry 4.0 evolves further, its impact extends beyond production efficiency, transforming the entire value chain and consolidating the role of digitalization in precision medicine (Ahsan & Siddique, 2022).

Further, this technology shift is aligned with Sustainable Development Goal 9 (SDG 9) – Industry, Innovation, and Infrastructure, through ensuring resilient and sustainable industrialization. The implementation of digital twins, AI automation, and IoT manufacturing in the production of prosthetics not only boosts innovation but also enhances infrastructure resilience and fosters more sustainable industrial practices. By reducing wastage of material, optimizing use of energy, and enabling optimal supply chain management, Industry 4.0 is critical to sustainable production and universal access to quality healthcare solutions. By promoting these innovations, innovation continues, and prosthetic solutions are optimized for scalability and flexibility to respond to various patients' needs across the globe (United Nations. 2015).

This study aims to evaluate the integration of Industry 4.0 technologies in prostheses manufacturing and their impact on efficiency, product quality, innovation, supply chain optimization, and healthcare delivery, focusing on improvements in durability, precision, customization, and regulatory compliance.

1.2. Research Objectives

1.2.1. Industry 4.0 Technologies in Prostheses Manufacturing
1.2.2. Impact of Industry 4.0 on Prostheses Manufacturing
1.2.3. Challenges and Opportunities of Industry 4.0 Integration in Prostheses Production.

2. THEORETICAL FRAMEWORK

The study follows a theoretical framework, illustrated in Figure 1, to systematically achieve its goals and objectives. This framework outlines a structured approach, beginning with an extensive literature review and progressing through targeted analyses that align with each research objective. By following this organized methodology, the study ensures a thorough examination of prosthesis manufacturing within the Industry 4.0 landscape.

The study begins with a comprehensive literature review, drawing on academic sources from databases like Scopus, CORE, and Science.gov. Keywords such as "Industry 4.0", "prosthesis", "implant", "healthcare", and "manufacturing" were utilized to gather essential resources that establish a foundational knowledge base. Additional sources, including books and relevant websites, were also consulted to broaden the study's perspective. This extensive literature collection grounds the research in established knowledge, especially regarding the convergence of prosthesis manufacturing with advancements in Industry 4.0.

The authors then introduce fundamental concepts, providing an in-depth discussion on prostheses, their manufacturing methods, and the critical Industry 4.0 technologies applied in the field. This section also clearly defines the study's aims, objectives, and sustainability goals, situating the research within the larger context of technology and healthcare. This thematic overview establishes a framework for examining how Industry 4.0 technologies could improve the efficiency and customization of prosthesis manufacturing, benefiting both the industry and individual patient needs.

The framework systematically addresses each main objective of the study. The first objective involves identifying and describing the specific Industry 4.0 technologies relevant to prosthesis manufacturing, including tools such as automation, artificial intelligence, and digital twins. The second objective examines the effects of these technologies, focusing on improvements in precision, customization, and efficiency in producing prosthetic devices. The third objective explores the challenges associated with implementing Industry 4.0 within prosthesis manufacturing, particularly technical, financial, and regulatory issues that may hinder the adoption of advanced technologies in the healthcare manufacturing sector.

The concluding sections bring together the insights gained from each objective, offering suggestions for future research and development. The author explores potential advancements, stressing the need for ongoing innovation to enable patient-specific solutions and foster sustainable practices in prosthesis manufacturing within the Industry 4.0 framework. By following this structured methodology, the study delivers a thorough assessment of Industry 4.0's transformative impact on prosthesis manufacturing, addressing current challenges while highlighting opportunities for future growth.

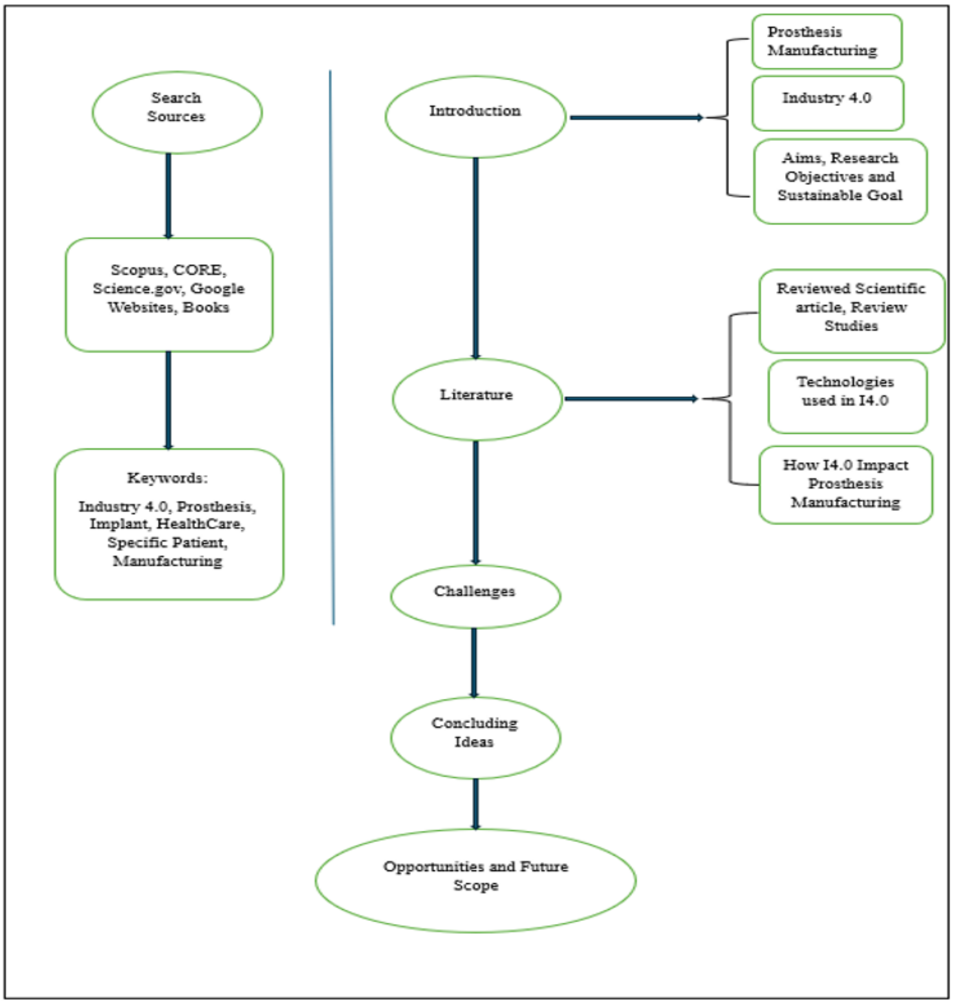

Figure 1. Theoretical framework

3. INDUSTRY 4.0 TECHNOLOGIES IN PROSTHESES MANUFACTURING

Prosthetic manufacturing in the era of Industry 4.0 leverages advanced technologies to improve efficiency, customization, and sustainability. Additive Manufacturing (AM), particularly techniques like Powder Bed Fusion, enables the creation of biocompatible, high-precision medical implants with minimal material waste (Raheem et al., 2021; Wang et al., 2016a). By producing intricate geometries, AM supports tailored solutions for orthopedic and dental needs. Despite its transformative potential, broader adoption is hindered by strict regulatory demands and the need for extended clinical validation (Bai et al., 2019; Pesode et al., 2023).

Big Data Analytics and Digital Twin technologies enhance manufacturing by streamlining production processes, predictive maintenance, and product customization. These tools enable personalized prosthetic designs and efficient supply chain management, ensuring high-quality outcomes (Wang et al., 2016).

Artificial Intelligence (AI) and Machine Learning (ML) facilitate defect detection, material optimization, and automated manufacturing, enabling cost-effective and precise prosthetic production (Lee et al., 2018). AI-driven adaptive systems and AR/VR applications further enhance real-time customization and healthcare training, contributing to superior therapeutic results (Saudagar et al., 2024). Augmented Reality (AR) and Virtual Reality (VR) technologies revolutionize prosthetic design by enabling advanced visualization, virtual prototyping, and remote fitting. These tools expedite development, reduce costs, and improve alignment accuracy. Additionally, AR and VR enhance patient rehabilitation through interactive and personalized therapy programs (Sun, 2022).

The Internet of Things (IoT) transforms prosthetic production through real-time monitoring, predictive maintenance, and resource optimization. IoT-enabled sensors improve supply chain management and facilitate early detection of manufacturing deviations. These technologies significantly improve prosthetic development by reducing production time and enhancing device performance (Xu et al., 2018; Abbas et al., 2025). Blockchain Technology strengthens data security and transparency in supply chains by providing immutable records of materials and processes. Smart contracts facilitate real-time updates, while improved inventory management reduces costs and inefficiencies (Leng et al., 2020; Li et al., 2018).

Automation and Robotics drive precision and scalability in prosthetic production, utilizing robotic machining, 3D printing, and adaptive systems to create highly personalized devices (Khanpara & Tanwar, 2019). Technologies such as smart microprocessors improve prosthetic functionality, while flexible and reconfigurable manufacturing systems accommodate market changes, reduce lead times, and lower production costs. These systems also promote sustainability by enabling localized, on-demand production that minimizes environmental impact (Khezri et al., 2019; Touzout & Benyoucef, 2019).

Cybersecurity is critical for safeguarding patient data and ensuring the reliability of smart prosthetic devices. Robust measures address vulnerabilities in wireless connectivity and software, ensuring compliance with regulatory standards and protecting device functionality. Comprehensive security protocols mitigate risks such as data breaches and operational disruptions, fostering trust in advanced prosthetic technologies (Lu, 2017; Ali & Mijwil, 2024).

Collectively, these innovations redefine prosthetic manufacturing, enabling highly customized, efficient, and sustainable solutions. By addressing regulatory, interoperability, and security challenges, Industry 4.0 technologies ensure continued advancement in personalized healthcare and production systems (Raschke, 2022; Jamwal et al., 2021).

4. IMPACT OF INDUSTRY 4.0 ON PROSTHESES MANUFACTURING

Industry 4.0 technologies, such as Design for Additive Manufacturing (DFAM), automation, Atomic Layer Deposition (ALD), and Selective Laser Melting (SLM), have transformed the manufacturing of bio-implants and prosthetics by improving their mechanical qualities, biocompatibility, and durability, particularly for specialized or high-end devices. The influence of these technologies, however, depends on the particular stage of the product lifecycle. SLM and DFAM allow for the development of complicated, customized prostheses during the design and Prototyping stages, but they might not be financially feasible for large-scale manufacturing. Although ALD performs well for precisely covering implants, it might not be an effective choice for expensive prosthetic devices (Jadhav et al., 2023). Although automation helps ensure consistency in bulk production, it is not very useful for producing highly customized prosthetics. Additionally, sophisticated prosthetics are more likely than simpler versions to employ computer simulations and smart sensors, which improve quality control and performance monitoring (Raschke, 2022). Finally, recycling and sustainability present major obstacles since the many materials utilized in bio-implants make end-of-life recycling procedures more difficult, expensive, and ineffective (Wiśniewska et al., 2023). Industry 4.0 also fosters collaboration among designers, manufacturers, and healthcare professionals, utilizing machine learning and big data analytics to refine design and production processes. The deployment of advanced technologies, such as Polyetheretherketone (PEEK) in 3D printing and digital workflows, results in customized, high-quality implants at the point of care, thereby reducing production times and ensuring regulatory compliance (Sharma, 2021). Modern approaches, including virtual reality (VR), augmented reality (AR), and digital twin technology, facilitate the creation of highly accurate, patient-specific implants while enhancing training and maintenance efficiencies (McKnight et al., 2020) The anticipated transition to Industry 5.0 emphasizes human-centricity, sustainability, and resilience in implant customization, leveraging AI, collaborative robotics, and smart sensors to create dynamic, adaptable implants and to enable continuous post-surgical monitoring (Grabowska et al., 2022; Zardawi, 2013). Collectively, these advancements in biomedical technologies are driving significant improvements in patient outcomes and healthcare efficiency (Sachenkov, 2022).

4.1. Major effect of I4.0 on prosthesis manufacturing

4.1.1. Efficiency Improvement

Industry 4.0 signifies a crucial evolution in manufacturing, emphasizing the enhancement of production efficiency and resource management in the context of globalization and competitive pressures (Jamwal et al., 2021). This shift encourages traditional sectors, including prosthetic limb manufacturing, to adopt innovative approaches. Key advancements such as automation through robotic systems and assembly lines have lowered costs while boosting productivity and precision (Dar et al. 2014). The implementation of Internet of Things (IoT) technology enables real-time data collection and monitoring, facilitating maintenance and ensuring product quality (Machado et al., 2020). Predictive maintenance practices, driven by sensor data and analytics, help anticipate equipment failures, reducing downtime and improving operational efficiency (Sang et al., 2020). Moreover, digital twinning technology allows for the creation of virtual representations of manufacturing systems, enabling simulations that optimize processes and result in considerable savings in time and resources (Jamwal et al., 2021).

4.1.2. Quality Enhancement

The enhancement of healthcare quality requires personalized and affordable medical services tailored to individual patient needs (Emelogu et al., 2016). The development of customized biomedical implants through advanced materials and additive manufacturing reflects this shift. Industry 4.0 fosters innovation and improves orthopedic practices by integrating software, sensors, and smart devices (Javaid & Haleem, 2020). This transformation has led to the creation of innovative materials, such as biocompatible substances and 3D-printable polymers, enhancing the aesthetics, functionality, and comfort of prosthetics. Additive manufacturing allows for precise customization of prosthetic components to match individual anatomies, improving overall comfort and performance (Ten Kate et al., 2017; Ventola, 2014). Additionally, the Internet of Things (IoT) enhances quality control in smart factories by utilizing real-time data to identify defects, ensuring higher product standards, and facilitating process improvements (Soori et al., 2023).

4.1.3. Innovation and Customization

Industry 4.0 technologies are reshaping the industrial sector by focusing on optimal production and efficient resource use through "smart manufacturing," which promotes extensive customization and flexibility (Jamwal et al., 2021). These advancements enable manufacturers to utilize virtual prototyping and CAD software to simulate prosthetic device functionality, allowing for rapid design iterations tailored to individual patient needs (Ten Kate et al., 2017). By incorporating patient-specific data and digital twin technologies, manufacturers can create personalized prosthetic solutions that enhance comfort and mobility. Additionally, additive manufacturing facilitates swift design refinement and prototype production, thereby driving innovation in prosthetic design (Soori et al., 2023; Chen et al., 2016).

4.1.4. Supply Chain Optimization

Industry 4.0 technologies—such as IoT, RFID (Radio-frequency Identification), automation, blockchain, machine learning, and big data analytics—are fundamentally transforming supply chain management. These innovations enable real-time product tracking, optimize inventory control, and reduce operational costs by improving efficiency and visibility across the supply chain. While these advancements minimize missed sales and lower inventory requirements, they also demand significant investment in digital infrastructure (Soori et al., 2023; Jamwal et al., 2021).

This digital evolution is particularly beneficial in the prosthetic limb supply chain, where it enables seamless data exchange and collaboration, thereby improving agility and coordination among suppliers and manufacturers (Ponomarenko et al., 2024). Blockchain technology further bolsters traceability by securely documenting the movement of goods, reducing the risk of fraud and supply chain disruptions (Zhang & Ling, 2022). Moreover, advanced analytics and artificial intelligence enhance demand forecasting and inventory management, empowering manufacturers to meet customer requirements more accurately, streamline production schedules, and make proactive, data-informed decisions (Jahin et al., 2024).

4.1.5. Impact on healthcare delivery

Industry 4.0 technologies are transforming healthcare by enabling personalized prosthetics, real-time monitoring, predictive maintenance, and enhanced collaboration (Raschke, 2022). Advanced techniques like CAD, 3D printing, and IoT allow for the customization of prosthetics, improving patient comfort, mobility, and quality of life (Chen et al., 2016). Real-time monitoring and AI-driven data analytics support timely interventions and proactive maintenance, while digital systems facilitate teamwork and continuous improvement. These innovations enhance rehabilitation by promoting independence and full participation in daily activities (Magbagbeola, 2022; Butpheng et al., 2020; Dias et al., 2024). However, challenges related to infrastructure, costs, and technology knowledge may limit equitable access, underscoring the need to address these barriers to ensure high-quality prosthetic care for all (Dias et al., 2024).

5. CHALLENGES AND OPPORTUNITIES OF INDUSTRY 4.0 INTEGRATION IN PROSTHESES PRODUCTION

5.1. Challenges Associated with Prosthesis Manufacturing

Industry 4.0 (I4.0), which integrates modern technologies like robotics, artificial intelligence (AI), and the Internet of Things (IoT), is significantly altering the prosthesis manufacturing industry. To ensure that new technologies are successfully used in the industry, several problems are also presented by these innovations.

5.1.1. High Initial Costs and Complex Integration

The high initial cost of implementation is one of the main issues with the use of Industry 4.0 technology in prosthesis manufacture. Robotics, artificial intelligence, and the Internet of Things are examples of advanced technologies that demand large expenditures in hardware and software infrastructure. Moreover, it can be difficult to integrate these technologies into current systems, requiring considerable adjustments to the manufacturing procedure. This integration often requires the reconfiguration of systems, specific training, and skilled labor, which raises the overall cost burden on manufacturers (Soori et al., 2023).

5.1.2. Data Security and Privacy Concerns

Significant threats to data security and privacy are introduced by the usage of linked devices and the sharing of private medical information. Protection of such data becomes crucial due to the nature of prosthesis production, which frequently involves sensitive health information (Dias et al., 2024) Adherence to data security regulations is crucial, particularly under laws such as the Health Insurance Portability and Accountability Act

(HIPAA), since any violations may have serious consequences for patients and manufacturers alike. This problem is further complicated by the potential weaknesses of IoT-enabled devices, which could be the target of data breaches or cyber-attacks (Soori et al., 2023; Sun et al., 2019).

5.1.3. Skilled Workforce Shortage

The lack of qualified personnel to oversee and run innovative production technology is another major issue. In the context of Industry 4.0, those who manufacture prostheses need to be skilled in fields like data analysis, robotics, and artificial intelligence. Maintaining production efficiency and quality requires hiring and educating staff that have both technical expertise and an understanding of biological engineering. Innovation might be hindered by a workforce that lacks the necessary skills to successfully implement new technologies (Soori et al., 2023).

5.1.4. Regulatory Compliance and Product Safety

To guarantee patient safety and effectiveness, prostheses are medical devices that must strictly adhere to regulatory criteria. Manufacturers are required to manage complex regulatory frameworks that differ between nations and regions. Materials, design, and testing methods are all governed by these rules. With the introduction of new materials and design possibilities via sophisticated manufacturing processes like additive manufacturing (AM), new prostheses must adhere to these safety criteria. Product safety is crucial since any prosthesis breakdown could have serious negative effects on the patient's health (Bandyopadhyay et al., 2023).

5.1.5. Supplier Cooperation and Resistance to Change

Strong collaboration between manufacturers and their suppliers is also essential for the effective implementation of Industry 4.0 technologies in prosthesis manufacturing (Nascimento et al., 2019). As the manufacturing of prostheses advances, it might be necessary to use specific materials or components that are not easily accessible or compatible with current systems. To satisfy the changing demands of manufacturers, suppliers must be prepared to adjust to new production techniques. Furthermore, because established supply chains and standard procedures are frequently deeply embedded in the sector, opposition to change from suppliers and employees can postpone the adoption of new technologies (Raut et al., 2020; Ito et al., 2021).

5.1.6. Reliability and Maintenance of Networked Devices

The use of networked sensors and devices to monitor and manage production processes is becoming more and more common in prosthesis manufacturing. Despite providing real-time data and insights, these devices' dependability and maintenance become serious problems. For production lines to continue operating and producing high-quality prostheses, these sensors and devices must operate continuously. Any problem or breakdown can cause delays, higher expenses, and lower-quality products by interfering with the manufacturing process. Therefore, to reduce operational downtime, networked devices require routine maintenance and timely replacement (Pearl, 2005; Resendes et al., 2025).

5.1.7. Biomechanical Variability and Customization Challenges

Individual differences in anatomy and biomechanics pose a basic barrier in prosthesis manufacturing. Patients' specific demands must be taken into consideration while constructing prostheses, especially when it comes to parts like prosthetic feet that need to strike a balance between comfort and flexibility. A major challenge is to create a universal design that is both aesthetically beautiful and operationally adaptable for each patient. Prosthetic solutions frequently fail to replicate the full range of motion and sensory feedback of native joints, which restricts their capacity to fully restore patients' mobility and function (Chadwell et al., 2020).

5.1.8. Long-Term Implantation Issues

Despite their short-term effectiveness, many orthopedic prostheses fail to fully restore function over time because of material degradation. When implanted prostheses deteriorate over time, it may cause pain and necessitate additional surgeries to replace or remove the devices. In addition to making patients more physically uncomfortable, this constant requirement for operations raises the entire expense of patient care. The advent of biodegradable implants, which progressively dissolve into the surrounding tissue, presents a viable way to address this issue, potentially reducing the need for follow-up procedures and enhancing patient outcomes going forward (Alluhydan et al., 2023).

5.1.9. Additive Manufacturing Defects and Material Limitations

Difficulties with material characteristics and mechanical behavior arise when prosthesis manufacture integrates additive manufacturing (AM). The use of powder bed fusion (PBF) in AM techniques can result in flaws such as anisotropy and inconsistent mechanical responses (van der Velden et al., 2025). The fine microstructures produced by the high heating and cooling rates inherent in AM methods might not be the best for creating strong, long-lasting prostheses. In-process optimization and defect mitigation strategies are key for producers looking to maximize the mechanical properties of AM materials. For prostheses made with AM to equal or surpass the mechanical qualities of standard materials and maintain their long-term performance and dependability, these material restrictions must be addressed (Lowther et al., 2019).

5.2. Challenges For The Next Generations

5.2.1. Improved biocompatibility and opportunity provided by 3D printing advanced prostheses design

Increasing the biocompatibility of modern prostheses with the human body is one of the main design difficulties. Promoting long-term stability and usefulness while lowering the risk of rejection and inflammation requires that prosthetic devices be well-tolerated by the body (Kulkarni et al., 2024). To enhance how the body responds to these devices, researchers are looking into new materials and surface treatment techniques. Innovative methods are being researched to promote tissue integration with the prosthesis and minimize negative reactions, including surface changes and bioactive coatings. Furthermore, 3D printing presents special chances to produce intricate structures that closely match each patient's anatomical and physiological requirements, improving biocompatibility and encouraging better integration with surrounding tissues (Li et al., 2025; Bose et al., 2018).

5.2.2. Enhanced durability

For prostheses to be practical and reduce the need for frequent replacements, they must be durable and capable of withstanding the stresses of regular use. This challenge has led to an exploration of advanced materials and production techniques that emphasize strength, resilience, and biocompatibility. Additive manufacturing and 3D bioprinting are central to this effort, enabling the creation of prosthetic structures that are not only robust but can also be customized to the unique needs of each patient. By integrating advanced bioprinting technologies, researchers aim to improve the longevity of prostheses while ensuring they maintain compatibility with human tissue over extended periods (Croes et al., 2020; Singh et al., 2019).

5.2.3. Better Integration with tissues

Ensuring effective integration between prosthetic devices and natural bone and tissue is essential for achieving lasting stability and optimal performance, ensuring functionality, comfort, and usability. Prosthetics should facilitate natural movement and load distribution, minimizing strain and enhancing mobility. A well-integrated design reduces discomfort, pressure points, and the risk of skin breakdown or infection, while maintaining structural integrity and alignment over time, minimizing the need for frequent adjustments. Ultimately, materials and design should foster a harmonious interaction with the body, prioritizing durability and user satisfaction (Alluhydan et al., 2023; Bai et al., 2024; Capsi-Morales et al., 2023). Researchers are exploring innovative surgical approaches, such as 3D bioprinting and computer- or robot-assisted techniques, to enhance osseointegration, the process by which a prosthesis bonds securely with surrounding bone and tissue. New materials and surface treatments are also being developed to encourage bone cell growth around the prosthetic implant, which further supports stability. These advancements allow for greater precision in both the design and implantation stages, leading to prostheses that are more seamlessly incorporated into the body's natural structure (Hu et al., 2019; Siebert et al., 2019).

5.2.4. Advanced sensory feedback

A major challenge in prosthesis innovation is enhancing sensory feedback, which is essential for restoring a sense of touch and body awareness (proprioception) to users. This feedback is crucial for precise control and helps users feel more natural when moving with a prosthetic limb. To address this, researchers are exploring advanced sensor technology and robotic systems that provide real-time feedback, making the device easier to control and feel more intuitive. These advancements aim to improve functionality, allowing users to interact with their surroundings in a way that closely resembles natural limb movement (Siebert et al., 2019).

5.2.5. Increased functionality

A key challenge in developing orthopedic prostheses is enhancing their functionality to more closely mimic the movement and flexibility of natural joints (Lee et al. 2020). Researchers are using advanced materials like shape memory alloys, along with robotic technologies, to create devices that can better restore mobility (Oreffo et al., 1999). 3D printing is instrumental in this process, as it enables the production of highly personalized designs tailored to the unique anatomical needs of each patient. This customization not only improves patient satisfaction but also reduces costs and increases efficiency in manufacturing, making prostheses more accessible and affordable (Wang et al. 2021).

6. CONCLUDING IDEAS

Industry 4.0 aims to meet individual needs through on-demand manufacturing, especially in orthopedics. It focuses on managing continuous treatment and creating patient-specific implants and equipment. Key technologies include big data, AI, IoT, 3D printing, and nanomedicine, offering real-time data, improved patient outcomes, and advanced treatment quality. Industry 4.0 enhances decision-making, technical support, and transparency with smart sensors, replacing traditional methods with faster, cost-effective automated systems. It accelerates research, development, and commercialization, and enhances education in the field, improving overall patient care and surgical techniques (Javaid & Haleem, 2020).

Global healthcare equity relies on producing high-quality, affordable medical devices and goods. Low-cost technologies reduce production costs and bring care facilities closer to patients, lowering travel expenses and removing barriers to accessing prosthetic clinics. The increasing affordability of 3D printing technology and the widespread use of smartphones for telemedicine enhance the ability to deliver advanced, portable, and affordable healthcare locally. This convergence of advancements enables more accessible and equitable healthcare, making sophisticated treatments available to a broader population (Raschke, 2022).

Industry 4.0, which offers opportunities for cost reductions, efficiency benefits, and customization, has had a significant impact on the manufacture of prostheses. Advanced digital modeling, scanning, and simulation techniques allow prosthetics to be tailored to each patient's needs, improving comfort, fit, and function. The use of additive manufacturing (3D printing) reduces waste and inventory costs. Automation and digitization of production processes also help to save costs and increase efficiency. Automated assembly lines and robotics enhance industrial processes, lowering labor costs and raising throughput. High-quality prosthetic devices are ensured for end users through the application of artificial intelligence, data analytics, and real-time monitoring of manufacturing factors. Rapid prototyping techniques like 3D printing and digital twin technologies accelerate prototype and iteration, reducing time-to-market and promoting faster innovation in prosthesis design.

IoT-enabled prosthetic devices make remote monitoring and maintenance easier. They are equipped with sensors to monitor the wearer's biometric data, performance indicators, and usage patterns. Early intervention in the case of issues or repercussions is made possible by the real-time communication of this data to medical specialists. Through the ability to view and interact with digital representations of their prostheses, virtual reality and augmented reality systems enhance patient experience and engagement. Because blockchain technology improves traceability and transparency in the prosthesis supply chain, it can reduce the risk of counterfeiting and boost supply chain visibility. The study findings suggest that the prosthesis manufacturing sector has been greatly affected by Industry 4.0, in which additive manufacturing (AM) or 3D printing are essential components. These advancements allow the production of individualized prosthetic devices that are more precise, quicker to make, and more affordable. Compared to traditional methods, which relied on manual labor, longer production times, and less efficient material usage, new technologies have significantly reduced manufacturing costs, making custom prosthetics more accessible than before (Raschke, 2022; Ten Kate et al., 2017; Zuniga et al., 2015; Prashar et al., 2023).

AM enables quick prototyping and the utilization of various materials, resulting in prostheses that are more practical and ergonomic. In general, Industry 4.0, particularly AM and 3D printing, has transformed the manufacturing process and enhanced patient results. Well-integrated design enhances comfort, prevents skin issues, and maintains structural integrity, reducing the need for adjustments. Durable materials and thoughtful design ensure seamless interaction with the body, prioritizing longevity and user satisfaction (Alluhydan et al., 2023; Bai et al., 2024; Capsi-Morales et al., 2023).

7. OPPORTUNITIES AND FUTURE SCOPE

Industry 4.0 has the potential to revolutionize prosthetics manufacturing by introducing advanced methods in patient care, production, and design. Future prosthetic limbs may closely replicate natural biomechanics and function, thanks to bio-inspired designs utilizing sophisticated computer modeling and simulation techniques (Raheem et al., 2021). Neural interfaces and brain-computer interfaces (BCIs) could enable amputees to control prosthetic devices directly with neural impulses from their brains, restoring dexterity and motor function. This technology promises significant advancements in the functionality and integration of prosthetic limbs, enhancing the quality of life for amputees (Raschke, 2022; Pulicharla & Premani, 2024).

Future prosthetics will benefit from smart materials and sensors, allowing them to adapt to changes in temperature, terrain, and user activity, thus enhancing stability, comfort, and effectiveness. Advances in bioprinting and tissue engineering will revolutionize limb replacement by enabling the creation of biocompatible scaffolds that support tissue integration and regeneration, leading to more natural and functional prosthetic solutions (Elcadi, 2023; Abbas & Zlopasa, 2025).

The integration of remote monitoring and telehealth platforms will enhance communication between users, healthcare providers, and prosthesis makers, optimizing design and rehabilitation plans. AI and machine learning will improve prosthesis performance and maintenance predictions. Virtual and augmented reality will offer personalized rehabilitation, boosting motivation and device adaptation. However, the ethical and societal implications of Industry 4.0 technologies remain a growing concern (Mikołajewska et al., 2024).

Industry 4.0 is transforming orthopedics by utilizing digital technologies for real-time data capture and communication. This will lead to innovative tools, reduced surgical risks, early disease prevention, and improved bioelectronics medicine. Robot-assisted surgeries will enhance patient care, providing new opportunities and innovative treatments (Javaid & Haleem, 2020).

Thanks also to advanced techniques like nanotechnology and multi-material 3D printing, prostheses are becoming stronger, lighter, and more biocompatible (Raschke, 2022). The integration of neuroprosthetics and Brain-Computer Interfaces (BCIs) is blurring the line between biological and artificial limbs, allowing for natural control over prosthetics (Pulicharla & Premani, 2024)

Furthermore, sensor-equipped prosthetic devices connected through the Internet of Things (IoT) facilitate real-time biomechanical data collection, enabling customization and data-driven optimization of prosthetic design to meet the unique needs of users (Haleem et al., 2019; Garcia-Rosas et al., 2020).

Telehealth and remote monitoring will make it possible for patients to get individualized care from any location, negating the necessity for in-person visits. Nonetheless, rules and norms will be required to guarantee safe implementation and accessibility, and ethical and regulatory issues will be critical. Innovation will be fueled by teamwork and multidisciplinary research to create comprehensive solutions for the complicated demands of prosthesis users (Dillon et al., 2024).

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