PLM Strategy Definition in Product Development: Case Study on Lower Limb Sockets

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Abstract

The main objective of the research project was to define PLM strategy in the process of developing lower limb prostheses sockets. The present study used different reference framework for PLM strategy configuration. This research was carried out to define the socket design development process by implementing virtual technologies, low-cost additive manufacturing and PLM strategy. The strategy definition was focused on the first three lifecycle stages: ideation, definition, conceptualization and process areas such as product requirements, configuration and changes, product design, product manufacturing and testing. Workflows, activities and roles were subsequently defined with a collaborative work scheme in PLM. This study was intended to meet quality standards and good practices during the product development process, manage resources in an efficient way, integrate technologies, and improve information management as well as communication between all the stakeholders. Finally, the research will allow a future implementation of this strategy in case studies with the aim of comparing traditional socket fabrication processes with the proposed PLM strategy. The study is proposed for the design of lower limb socket development process. A strategy will be set in order to develop transtibial and transfemoral socket cases. This comparison will make it possible to analyse the results obtained from the product development process in aspects such as time, product quality and information management.

Keywords: Product Lifecycle Management, sockets, technology integration, development process

1. Introduction

Manufacturing companies are constantly changing environments in order to effectively respond to opportunities, improve customer satisfaction and compete on the market (Hachani, Gzara, & Verjus, 2013). Companies need to develop new value propositions and save money by implementing different strategies to improve industrial activity and business processes (Bosch-Mauchand *et al.*, 2013). One of the strategies implemented by companies is Product Lifecycle Management (PLM). This strategy improves productivity, efficiency and industrial flexibility in the product development process (Demoly *et al.*, 2012). Due to the demand for personalized articles adapted to specific needs, it is important to implement PLM strategy for integration and exchange of transparent, reliable and relevant information (Borsato, 2014). The demand for specific orthopedic products has increased due to longer life expectancy in recent years (Díaz Lantada, 2013). However, the lack of specialized knowledge and limited development and production of new medical products has been evidenced (Songkajorn & Thawesaengskulthai, 2014). The development of medical devices requires to update data, take a traceability process and integrate software tools, which facilitate information exchange between roles, processes and communication tools (Díaz Lantada, 2013). Lower limb prostheses are orthopedic medical devices that allow amputees to recover partial functioning of their lost limb (Tzeng, Hsu, & Chang, 2015). The socket is the interface between stump and prosthesis; it is a personalized product that must be adapted to the stump anatomy, and therefore, it is the most important part of the prosthesis (Colombo *et al.*, 2013).

Currently, socket manufacture is carried out using two techniques: the traditional way and technology implementation. The success of the traditional technique depends on the technicians' experience, who take stump measurements and moulds to then manufacture the sockets (Sengeh *et al.*, 2016). Nevertheless, there have been identified technique problems such as time (Saverio Frillici & Rotini, 2013), measurement mistakes and no adaptation between socket and stump (Hsu *et al.*, 2010); which affect the socket development process. On the other hand, the technology implementation technique shows successful results (Hsu *et al.*, 2010), with the use of virtual technologies and additive manufacturing such as reverse engineering (Dhokia *et al.*, 2017), CAD software (Doubrovski *et al.*, 2015) rapid prototyping (Vitali, Rizzi, & Regazzoni, 2017). However, it is important and necessary to integrate different software and systems (Colombo *et al.*, 2010). Accordingly, there is the need to integrate different low-cost technologies with the purpose of manufacturing more precise sockets at affordable prices (Colombo *et al.*, 2010), causing the reduction in the number of physical stump models, operations by technicians (Colombo *et al.*, 2013), and at the same time, saving time and money. The strategy will allow integration and accessibility to technologies and information generated in development stages.

2. Purpose

2.1 Background

Previous studies that have been conducted in order to develop lower limb prostheses are the baseline for this research. These are oriented to socket development through the integration of reverse engineering technologies (Machuca, 2015), the design of adaptable sockets to changes in stump volume (Moreno, 2016), and the design process for obtaining sockets through digital

manufacturing (Solano & Bravo, 2018). The studies allowed us to establish a preliminary process for socket development, and define some roles and technologies in design and manufacturing stages. However, it was identified the need to manage all the information, technology integration and role supervision during the product lifecycle stages. In the first place, information management is insufficient because it is a specialized product and it depends on the tacit knowledge of a specific role (Colombo *et al.*, 2018). Secondly, there are barriers to technology interoperativity and software tools and equipment high cost (Vitali *et al.*, 2017). Therefore, it is required to find solutions in order to create robust and reliable design methods that involve low-cost technology and define workflows aimed at meeting quality, safety and efficiency criteria. Finally, it is important to guarantee the transfer of organizational knowledge with the objective of guiding and supervising the performance of each role.

2.2 PLM

Product Lifecycle Management (PLM), is defined as a strategy that integrates information, people, processes and technologies in all the stages of a product lifecycle, from its design, manufacture, implementation and maintenance, and ending in the withdrawal from service and final disposition (Grieves & Tanniru, 2008). PLM strategy has been implemented in aerospace (Brandao & Wynn, 2009), textile (Hribernik *et al.*, 2019) and automotive industries (Nascimento & Cessa, 2019), however, only a few studies have been done in the field of orthopaedic medicine. The studies done in this sector are mainly focused on osteosynthesis implants (Murillo, López, & Martínez, 2017; Ngo, Bernard, & Belkadi, 2017). For some years, medical device manufacturers have achieved benefits by integrating product design, technical transfer and manufacture process planning (Scott, McDonnell, & Burkett, 2009).

2.3 Need for PLM implementation

The industry has done research on PLM strategy, especially in BOL (Beginning of Life) and MOL (Middle of Life) stages, as well as on the implementation of systems such as PDM and Computer-Aided Technologies (CAx) (Demoly *et al.*, 2012). On the other hand, process differentiation for specific product development has not been addressed in terms of developing platforms or engineering products on demand, as well as lifecycle innovation and production (Borsato, 2014). Information needs to be traced up during the development process in order to guarantee compliance with the requirements and the implementation of the established processes (Garro, 2016). Different problematic situations in technology implementation techniques for socket development were identified through the literature review. Problems are mainly focused on information management, integration of different software and systems (Colombo et al., 2010). There is an evidenced need to create guidelines for prosthetics designers or technicians to emulate the traditional technique by implementing virtual technologies (Vitali et al., 2017). According to the above mentioned, PLM strategy definition and subsequent implementation will allow information traceability and security about each product, design reuse in a database and resource management of the product development process (Pinna et al., 2018). Likewise, technology integration will improve processes, support the roles of the design and manufacturing areas, reduce physical prototype manufacturing, costs and development process times (Colombo *et al.*, 2013).

The objective of this study was to define a framework to implement PLM strategy in the healthcare industry, according to lower limb socket development requirements. The

methodological basis for PLM strategy definition was the construction methodology of the strategy established by Stark (2016) and the visualization model and process areas definition proposed by Martínez *et al.*, (2014). The objectives for configuring PLM strategy were defined hereafter: Define a technology integration model based on low-cost technologies for socket design and manufacturing process. Define a reference framework that integrates stages, process areas, technologies and roles. Provide better interaction and communication between the different roles of design and manufacturing teams.

3. Methodology

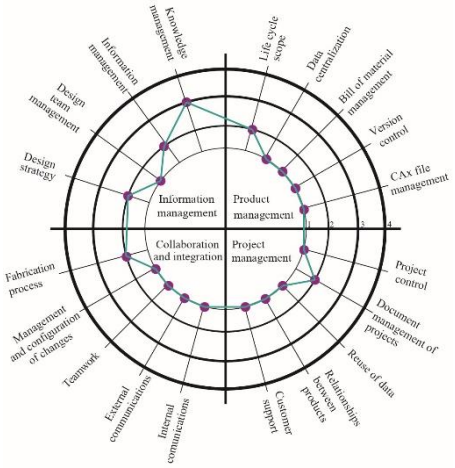
The methodology was divided into six stages for the strategy definition. In the first stage, the product life cycle management diagnosis was made in order to identify the laboratory state. In the second stage, the strategy framework construction was proposed. In the third stage, the KPIs process was identified and defined. In the fourth stage, the technologies to be integrated are selected. In the fifth stage, workflows and visualization models were defined and finally, the PLM strategy was presented.

4. Results

4.1 Product Lifecycle Diagnosis

The objective of this self-diagnostic tool is to review the laboratory current situation on product lifecycle management and the possibility of implementing PLM strategy ("Herramienta de Autodiagnóstico de la Gestión del Ciclo de Vida del Producto," 2010). The diagnosis is divided into 4 chapters: Business Management, Product Management, Project Management, and Collaboration and Integration. According to the total sum of the situations found, the result obtained was a low management level (26 points). The score from each question can be observed in Fig. 1, highlighting weaknesses from each area.

Figure 1: Product Lifecycle diagnosis results



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4.2 Framework creation

Four areas proposed by Schuh *et al.*, (2008) were taken into account in order to configure the strategy: Data Management, File Management, Project Data Management, Business Administration and System Integration. In product data management, tools are implemented in document storage, configuration and change management, and file management. For file management, one needs to select a platform in order to manage of the development process and have software tools to create and edit documents. In the project management area, formats were designed for planning, quality evaluation and compliance with product requirements. The business management area is related to the traceability and documentary integrity, change control, KPIs, access types and workflows. Finally, the collaboration and integration area, where systems are needed to be joined in a single interface in order to store and exchange data.

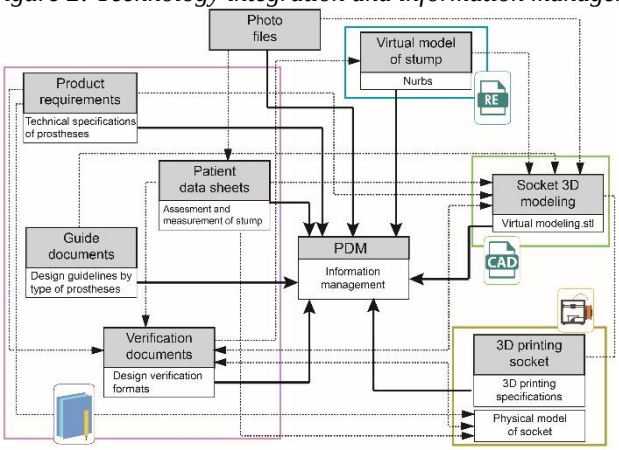
4.3 KPIs definition

The following performance indicators were defined for this research, which will allow us to evaluate categories in the development process. They were classified according to three main categories: Time, Information Management and Quality.

4.4 Technology selection

According to the studies mentioned in the background section, different virtual and additive manufacturing technologies were defined for lower limb socket design and manufacture. Different software types were identified: public software, open source, educational software, demo and commercial software. The technologies selected to implement and integrate should allow file edition, CAD volume visualization and CAx file creation. They were also needed to be interoperable in order to manage and share the different data generated in each product development stages, and besides, software tools had to be low-cost type. For PDM platform selection, the choice made was a software tool addressed to storage, configuration and changes of generated files in device development process, data management and material storage for knowledge transfer. The following technologies were selected regarding the above mentioned: RE (Reverse Engineering) for obtaining virtual models, Sense 3D scanner and KScan3D software. For socket design activities, Rhinoceros® CAD software. In the case of documents such as formats and design guides, Microsoft Office® tools. The FDM printer (Fused Deposition Modelling) with PLA material and CURA software for socket 3D impression. Finally, the PDM selected for technology integration and information management were ARAS Innovator®, see Fig. 2.

Figure 2: Technology integration and information management



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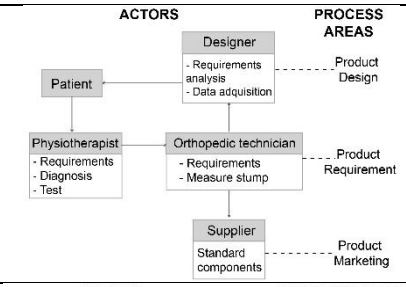
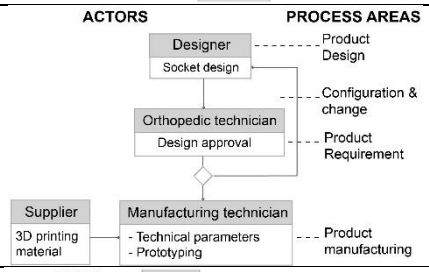
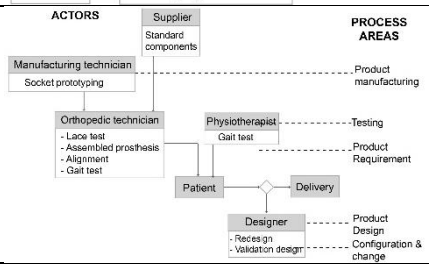
4.5 Workflow and visualization models

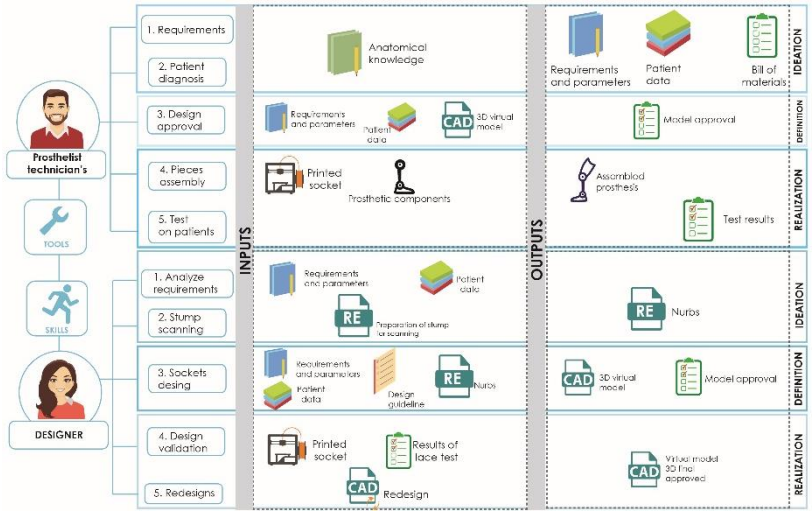
This stage involves the description of the two main roles Fig. 3 shows the visualization model of the prosthetist technician's role, and the designer's role. Both of them present the activities performed by these roles in each of the stages along with their corresponding inputs and outputs. Likewise, the interaction of the different roles in each stage: Ideation, definition and realization, as well as the process areas involved in each stage of the product lifecycle Table 1.

Table 1: Interaction between roles in each stage

Stage	Description	Interaction between roles in the stage
Ideation	The roles interact with the aim of performing diagnosis activities and patients' preliminary evaluation, obtaining the stump reference model, and defining product requirements and performing patients' tests	
Definition	The roles interact with each other to facilitate socket design and manufacture	
Realization	The roles from interact to perform the socket assembly with the prosthesis components, fitting and walking tests with the patient using the prosthesis, product quality evaluations and reports	

Source: Authors

Figure 3: Prosthetist technician's and Designer's role

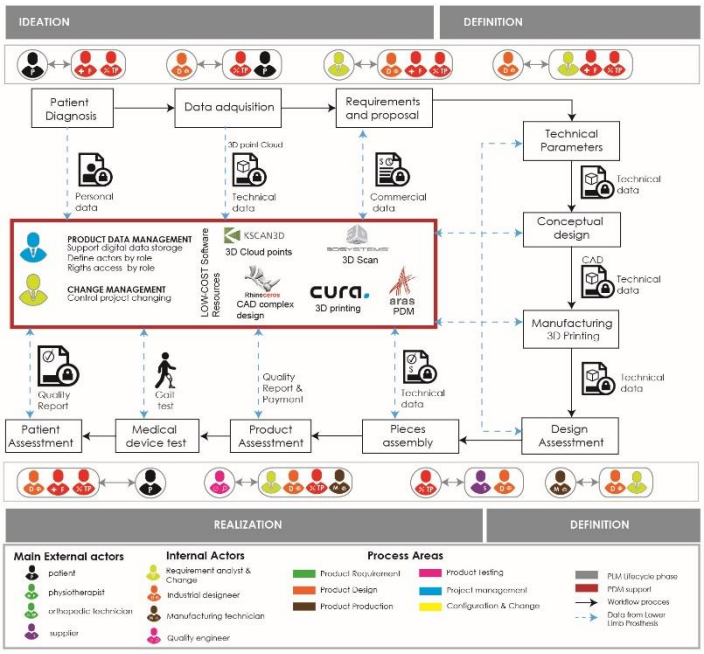


Source: Authors

4.6 PLM strategy

The strategy reference framework was defined regarding experiences from the case studies described above, which were based on the visualization model of (Martínez *et al.*, 2014) and the general process introduced by (Ngo et al., 2017). The strategy configuration was focused on the first three stages of the product lifecycle: ideation, definition and implementation. Likewise, the process areas to implement were defined according to the stages mentioned above. There was an integration of workflows, roles and information types regarding active process areas in each stage of product lifecycle development. All the information generated and shared in each of the activities was managed, stored and shared by implementing a PDM platform, in which data can be edited and visualized by different actors. A process within PLM strategy framework was proposed based on digital manufacturing, is a SoS RE, CAx and 3DP. The process flow defined for lower limb socket development is described in Fig. 4. This process starts with reverse engineering with the collection of input data by means of a 3D scanner, for the generation of the stump virtual reference model. Subsequently, based on the prosthetist technician's specifications, requirements are defined and the traditional emulation technique for obtaining the mould is performed. In this way, the socket is designed in CAD software based on this reference model. Finally, sockets modelled in 3D are taken to 3D printing. In order to carry out the verifications of socket design and manufacture, and besides, there should be fitting and walking tests with the patient. The strategy will be set in order to develop transtibial and transfemoral socket cases.

Figure 7: PLM strategy framework



Source: Adapted from (Martínez, López, Murillo, & Garnica, 2019)

5. Conclusions

In the present study, technology evaluation allowed us to identify and select technological tools, based on the vision of (Schuh et al., 2008), about technological contributions to the PLM implementation objective. Important processes, roles, and activities were defined. According to the above mentioned, the costs of implementing the strategy are important, and therefore, low-cost technologies are crucial, as well as the reduction of development times and costs to guarantee applicability, especially in initial development stages where the organization has greater control. With the strategy configuration, the implementation of case studies will be carried out, the design process will be evaluated and the traditional socket manufacturing technique will be contrasted. It is intended to compare development time, product quality and information management.

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References

Borsato, M. (2014). Bridging the gap between product lifecycle management and sustainability in manufacturing through ontology building. *Computers in Industry*, *65*(2), 258–269. https://doi.org/10.1016/j.compind.2013.11.003

Bosch-Mauchand, M., Belkadi, F., Bricogne, M., & Eynard, B. (2013). Knowledge-based assessment of manufacturing process performance: Integration of product lifecycle management and value-chain simulation approaches. *International Journal of Computer Integrated Manufacturing*, *26*(5), 453–473.

Brandao, R., & Wynn, M. (2009). Improving the New Product Development Process through ICT Systems in the Aerospace Industry – a Report on Case Study Research. *2009 International Conference on Information, Process, and Knowledge Management*, 147–152.

Colombo, G., Facoetti, G., & Rizzi, C. (2013). A digital patient for computer-aided prosthesis design. *Interface Focus*, *3*(2), 20120082.

Colombo, G., Filippi, S., Rizzi, C., & Rotini, F. (2010). A new design paradigm for the development of custom-fit soft sockets for lower limb prostheses. *Computers in Industry*, *61*(6), 513–523. https://doi.org/10.1016/j.compind.2010.03.008

Colombo, G., Rizzi, C., Regazzoni, D., & Vitali, A. (2018). 3D interactive environment for the design of medical devices. *International Journal on Interactive Design and Manufacturing*, *12*(2), 699–715. https://doi.org/10.1007/s12008-018-0458-8

Demoly, F., Yan, X. T., Eynard, B., Gomes, S., & Kiritsis, D. (2012). Integrated product relationships management: A model to enable concurrent product design and assembly sequence planning. *Journal of Engineering Design*, *23*(7), 544–561.

Dhokia, V., Bilzon, J., Seminati, E., Talamas, D. C., Young, M., & Mitchell, W. (2017). The Design

and Manufacture of a Prototype Personalized Liner for Lower Limb Amputees. *Procedia CIRP*, *60*, 476–481. https://doi.org/10.1016/j.procir.2017.02.049

Díaz Lantada, A. (2013). *Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices*. (A. Díaz Lantada, Ed.). Springer.

Doubrovski, E. L., Tsai, E. Y., Dikovsky, D., Geraedts, J. M. P., Herr, H., & Oxman, N. (2015). Voxel-based fabrication through material property mapping: A design method for bitmap printing. *CAD Computer Aided Design*, *60*, 3–13.

Garro, F. (2016). *Propuesta de implementación de sistema de gestión de ciclo de vida del producto en el desarrollo de dispositivos médicos*. Universidad Nacional de Córdoba.

Grieves, M. W., & Tanniru, M. (2008). PLM, process, practice and provenance: Knowledge provenance in support of business practices in Product Lifecycle Management. *International Journal of Product Lifecycle Management*, *3*(1), 37.

Hachani, S., Gzara, L., & Verjus, H. (2013). A service-oriented approach for flexible process support within enterprises: Application on PLM systems. *Enterprise Information Systems*, *7*(1), 79–99. https://doi.org/10.1080/17517575.2012.688221

Herramienta de Autodiagnóstico de la Gestión del Ciclo de Vida del Producto. (2010). Retrieved from http://www.prodintec.es/attachments/article/267/fichero_6_0139.pdf

Hribernik, K., Arabsolgar, D., Canepa, A., & Thoben, K.-D. (2019). Applying Product Usage Information to Optimise the Product Lifecycle in the Clothing and Textiles Industry. In *Product Lifecycle Management (Volume 4): The Case Studies* (pp. 73–95).

Hsu, L. H., Huang, G. F., Lu, C. T., Hong, D. Y., & Liu, S. H. (2010). The Development of a Rapid Prototyping Prosthetic Socket Coated with a Resin Layer for Transtibial Amputees. *Prosthetics and Orthotics International*, *34*(1), 37–45.

Machuca, J. A. (2015). *Propuesta de diseño de un socket para usuarios con amputación transfemoral, basado en la integración de técnicas de ingeniería inversa, modalidad práctica empresarial en la empresa Líneas Hospitalarias S.A.S.* Universidad Industrial de Santander.

Martínez, J. M., López, C. I., Murillo, A. P., & Garnica, I. (2019). PLM Strategy for Developing Specific Medical Devices and Lower Limb Prosthesis at Healthcare Sector: Case Reports from the Academia. In *Product Lifecycle Management (Volume 4): The Case Studies* (pp. 201–221). https://doi.org/10.1007/978-3-030-16134-7_16

Martínez, J., Sauza, J., Ricci, F., & Chiabert, P. (2014). Validation process model for product lifecycle management. *International Journal of Product Lifecycle Management*, *7*(2/3), 230.

Moreno, A. R. (2016). *Desarrollo de un socket para amputación transtibial adaptable a los cambios de volumen del muñon*. Universidad Industrial de Santander.

Murillo, A., López, Cl., & Martínez, J. (2017). Design and development of orthopedic implants through PLM strategies. *IFIP Advances in Information and Communication Technology*, *517*. https://doi.org/10.1007/978-3-319-72905-3_21

Nascimento, J., & Cessa, A. (2019). Use of Industry 4.0 Concepts to Use the "Voice of the Product" in the Product Development Process in the Automotive Industry. In *Product Lifecycle Management (Volume 4): The Case Studies* (pp. 223–232).

Ngo, T., Bernard, A., & Belkadi, F. (2017). Interest of PLM for data sharing in the patient treatment

process requiring prosthesis implantation. In *15e Colloque National AIP-Priméca* (pp. 1–6).

Pinna, C., Galati, F., Rossi, M., Saidy, C., Harik, R., & Terzi, S. (2018). Effect of product lifecycle management on new product development performances: Evidence from the food industry. *Computers in Industry*, *100*(March), 184–195.

Saverio Frillici, F., & Rotini, F. (2013). Prosthesis socket design through shape optimization. *Computer-Aided Design and Applications*, *10*(5), 863–876.

Schuh, G., Rozenfeld, H., Assmus, D., & Zancul, E. (2008). Process oriented framework to support PLM implementation. *Computers in Industry*, *59*(2–3), 210–218.

Scott, F., McDonnell, W., & Burkett, M. (2009). Designing Medical Devices To Improve Patient Outcomes. *AMR Research Custom Executive Summary in Collaboration With Siemens*, 1–9.

Sengeh, D. M., Moerman, K. M., Petron, A., & Herr, H. (2016). Multi-material 3-D viscoelastic model of a transtibial residuum from in-vivo indentation and MRI data. *Journal of the Mechanical Behavior of Biomedical Materials*, *59*, 379–392.

Solano, M., & Bravo, L. (2018). *Diseño de proceso para la obtención de socket temporal en miembro inferior por medio de manufactura digital*. Universidad Industrial de Santander.

Songkajorn, Y., & Thawesaengskulthai, N. (2014). Medical Device Innovation Development Process. *International Journal of Innovation and Technology Management*, *11*(04), 1450027. https://doi.org/10.1142/S0219877014500278

Stark, J. (2016). *Product Lifecycle Management (Volume 2)*. Cham: Springer International Publishing.

Tzeng, M.-J., Hsu, L.-H., & Chang, S.-H. (2015). Development and evaluation of a cad/3dp process for transtibial socket fabrication. *Biomedical Engineering: Applications, Basis and Communications*, *27*(05), 1550044.

Vitali, A., Rizzi, C., & Regazzoni, D. (2017). Design and Additive Manufacturing of Lower Limb prosthetic socket. *Proceedings of the ASME 2017 International Mechanical Engineering Congress and Exposition*, 1–7.