

BUILDING INNOVATION CAPABILITIES FROM RESEARCH ADDRESSED IN AN ACADEMIC ENVIRONMENT FOR THE DEVELOPMENT OF MEDICAL DEVICES

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ABSTRACT

The main purpose of this research was to establish the level of maturity of research projects developed by INTERFAZ research group at the Industrial University of Santander, such a strategy oriented to build real capabilities to develop new technology-based products with innovative potential such as medical devices for orthopedics. This vision was carried off value creation supported by low cost for emergent economies health system such as Colombia, therefore these technologies allowed to improve the orthopedic and maxillofacial surgery practices. According to the capabilities approach, the University was defined such main stakeholder working together with its University Hospital, other research groups, and suppliers. The innovation capability was studied on 10 research projects, which were developed in collaboration with R&D stakeholders. The outputs and practices carried off in research projects were homologated in nine levels of technological readiness level TRL rubric that was created and carried out for each one. This one was made to define maturity assessment of this kind of device technologies finding that some projects reached the level of 7 over 9. The results showed the importance of collaborative teams, likely that is the incorporation of key activities; this vision was according to an organizational approach and was implemented in those practices for knowledge transfer and technological management. In this way, since building capabilities approach, this research has been a contribution to generation and development of different technologies with potential value creation and likewise the built capacities to made in the future short, medium and long-term projects.

Keywords: Technological Readiness Level; Innovation Capability; Patient-Specific Device; Digital Manufacturing.

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INTRODUCTION

In a globalized world immersed in dynamic markets, innovation constitutes a competitive advantage to generate capabilities to get solutions that contribute to society advance (Trencher, Yarime, McCormick, Doll, & Kraines, 2013). The concept of innovation from strategic management has been analyzed to understand how organizations create a competitive advantage by responding to environmental changes (Helfat & Peteraf, 2009). In emerging economies, competitiveness is oriented towards the search for effective solutions to social problems, considering costs and limited resources, maximizing the impact of their investments and promoting the development of internal engineering design capability (Schlecht & Yang, 2014); investment, skills management and applied abilities for the generation of knowledge (Martelo Landroquez & Cegarra Navarro, 2014).

The way that some organizations are competitive is due to the fact that they are backed up by their capabilities for innovation (Zawislak, Alves, Barbieux, & Reichert, 2014). The capability is built through a technological learning process, represented in management routines for technology development, manufacturing or building and commercialization of technology, creating value in the market (Zawislak, Alves, Tello-gamarra, Barbieux, & Reichert, 2012).

In the field of the health, the need to develop capabilities for innovation has also been identified, because complex problems are addressed and technologies are required to facilitate clinical practice. In this sector, human resources tend to specialize in specific areas, reorienting the service to a transversal approach where the patient is treated by a multidisciplinary team; that becomes a complex issue which consequently generates a high-cost service (Madden, 2012). In terms of innovation for VC, health organizations should have a near relationship with suppliers because there are efficient and contribute to the professional satisfaction and financial success system (Porter & Lee, 2015). In fact, kinds of innovation that contribute to the creation of value in the health sector are related new business model generation, technology and its applications for the development of new products and treatments or processes to improve health-care (Herzlinger, 2006).

Specifically, in the orthopedic field, traumatological and pathological events are aligned with the need to build capabilities to improve the diagnosis and treatment of patients. This is because of the growth in demand for products and services, caused by increasing in high-energy accident rates, as well rising at life expectancy (Struszczyk, 2012; Omachonu &

Einspruch, 2010) and population aging, increasing prevalence of low energy fractures and joint replacements (Daniachi et al., 2015); in these cases more than 70% are treated surgically (Cabalag et al., 2014; Matthiessen & Robinson, 2015). In medical field, preparing service provider organizations to offer a service based on capabilities to create value (Martelo Landroquez & Cegarra Navarro, 2014) is also relevant including specialized medical personnel to increase their performance in terms of diagnosis and surgical intervention.

However, medical devices which demanded this service are mostly imported, represent a high cost and do not fulfill the requirements of the Colombian population. The aforementioned is due to the fact that the producing companies of industrialized countries do not perceive a market opportunity to design for populations with emerging economies (Jarosławski & Saberwal, 2013). Despite that technologies that allow them to improve or perform diagnosis, and pre-planning of the surgical procedure, the conventional schemes using standard implants are still used; so the odds of orienting treatment to reduce fractures with implants that adapt to the bone of patients will continue to be low. Consequently, opportunities for appropriate technologies to improve clinical practice are reduced.

The main purpose of this full article, according to the description presented in this topic, it was to establish an approximation about how building innovation capabilities are achieved to develop a medical device to help in diagnostic and orthopedic pre-surgical planning stages. The article is structured as follows: first, a conceptual description about some topics related to this research are made; then, a conceptual framework based on TRL is proposed to related technologies, activities, and outputs made in each maturity level, specifically for medical devices. Subsequently, the methodology of this study is described and the results are presented based on the analysis of 10 case studies, where is evaluating the level of the maturity of the technology and the scope of the results related to the actors involved. Finally, the conclusions of the research are described.

THEORETICAL FRAMEWORK.

MEDICAL DEVICES

According to WHO, 80% of the world's sales revenue is led by the American and European markets. Medical devices that need to be manufactured with complex technologies are produced mainly in industrialized countries or by companies based in an industrialized country; while low-tech devices are manufactured in emerging countries (World Health Organization, 2010). In Colombia, the government created the INVIMA organization to the

regulation of drugs and device in the health care. Through Decree 4725 of 2005, it is defined as medical-surgical devices and medical equipment such as instrument, device, machine, software, biomedical equipment or another similar article (Ministerio de la Protección Social, 2005). However, despite the fact that the decree stipulates guidelines on best manufacturing practices, this regulation does not apply to custom-made devices.

CAPABILITIES AND INNOVATION CAPABILITY

Through the capabilities perspective, the aim is to improve the business models, the productivity of an organization's resources (Balslev, Haghighi, Momeni, Balslev Nielsen, & Haghighi Kafash, 2015; Teece, 2018). The capabilities correspond to the ability of the organization to integrate, build and reconfigure internal and external competencies (Bravo I., León A., & Serrano C., 2014; Teece, 2018).

The innovation capability is one of the most important capabilities in the delivery of VC (Park & Lee, 2015; Schneckenberg, Velamuri, Comberg, & Spieth, 2017). VC suggest that it is feasible to obtain new results for the organization (Leitner, K-H. Jet. al., 2012) by establishing a potential for innovation in processes (Zdravković, Trajanović, Stojković, Mišić, & Vitković, 2012), in business models (Clauss, 2017) or in product (Hagedorn, Grosse, & Krishnamurty, 2015). Under these channels, innovations impact on the social and human factor, combining as hybrid innovations (Battaglia, Landoni, & Rizzitelli, 2017).

METHODOLOGY

The investigation was structured in three stages. The first stage was defined a conceptual framework of the life cycle of development of medical device, related to the stages of the level of maturity of the technology TRL R & D + I focus on the development of personalized medical device, to establish the level of maturity of the technologies to analyze, the process of development of medical devices.

In the second stage, based on the analysis of the article of Tobergte & Curtis, (2013), a R&D framework + I defined in nine levels of technological readiness level TRL evaluation rubric was built. This instrument was created to get a better understanding of identifying the maturity level of technology. The TRL levels were defined according to the activities, outputs or evidence related to the maturity of research, with these evidences was possible to defined the innovation cycle obtained in each case how is showed in Table 1.

Table 1
Rubric to evaluate the levels of maturity of the technology

TRL. Readiness Level	Technology	Results that each level of maturity would entail	Level of development of the R + D + I scheme
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TRL 9: Successful tests in a real environment. Commercial application	TRL 9: Final reports under operating conditions or real mission.	TRL 9 and 8: INNOVATION Technological deployment, the introduction of a new product or service to the market. Real scale.
TRL 8: Validation and complete certification in a real environment. First commercial system/prototype.	TRL 8: Results of the system tests in their final configuration.	TRL 7: INNOVATION Marketable product or service Certifications specific tests homologations. Real Scale = 1
TRL 7: Validation of System / prototype validated in real environment.	TRL 7: Result of the tests at the prototype level carried out in the operating environment.	
TRL 6: Validation of validated system, subsystem or prototype in a simulated or relevant environment.	TRL 6: Results of the tests carried out at the prototype level in a relevant environment.	TRL 6 and 5: DEVELOPMENT. First Prototype / Demonstrator Technological development not marketable TRL 5 1/10 <Scale <1
TRL 5: Validation at the component level in a relevant environment. Development on a real scale.	TRL 5: Validated components in relevant environment	
TRL 4: Validation at the component level in the laboratory [approximate conditions or simulate existing ones in a real or mission environment]. Small-scale development	TRL 4: Results of laboratory tests.	TRL 4,3,2 AND 1: RESEARCH Basic TECHNOLOGY until reaching the first proof of concept. Proof of concept Industrial research. Laboratory / Bench Scale) Scale <1/10
TRL 3: Proof of concept. Applied research. Laboratory environment.	TRL 3: Measurement of parameters in the laboratory.	
TRL 2: Formulation of technology or concept in a laboratory environment.	TRL 2: Publications or references resulting from the new technology	
TRL 1: a Basic idea. Basic investigation. Laboratory environment.	TRL 1: Scientific articles published on the principles of new technology	

Font: Author adapted from Tobergte & Curtis (2013)

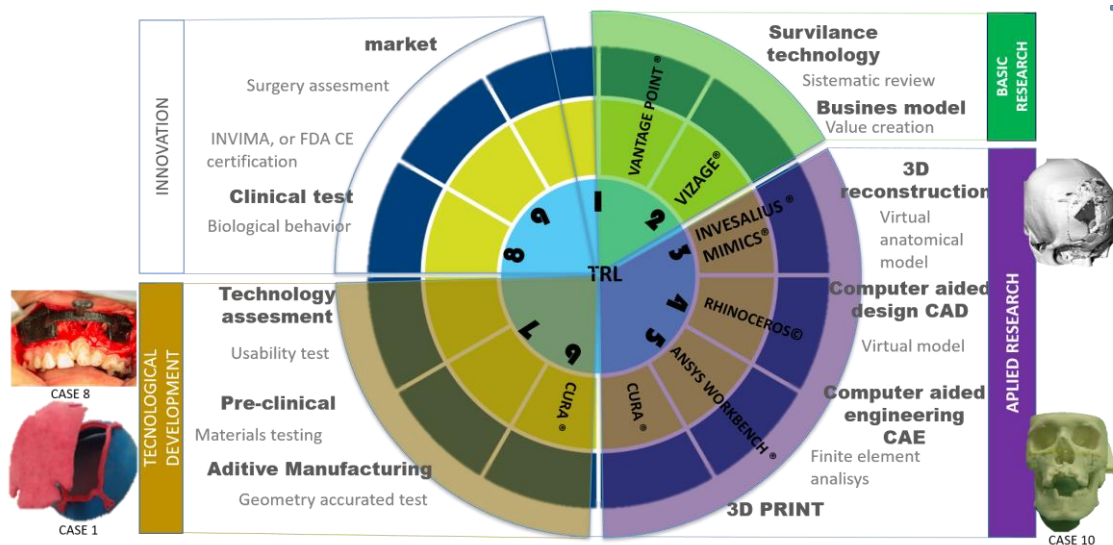
In the third stage, we preceded to the selection of the study cases under analysis. An observation window of the last 4 years was defined. We included the cases that evidenced the development of a medical device for a specific patient in the face or skull. A total of 10 cases were analyzed. The content analysis was done by identifying the main products, such as articles, prototypes, assessment, testing, and another activity that have been strengthened by the maturity of products obtained in that study. A rubric was applied through a socialization of products, workflow, the actors involved and the level of development achieved in each case, were presented in a group session composed of researchers with knowledge of the topic.

RESULTS

This section describes the main results derived from the group sessions held to identify innovative practices in the framework of collaborative work, as well as the definition of the TRL, based on the review of evidence and content analysis of the cases developed.

Figure 1 shows the conceptual framework of the life cycle of the development of a medical device for a specific patient related to the stages of the TRL R&D+I approach. The levels were grouped into basic and applied research, technological development, and innovation (Tobergte & Curtis, 2013). The stages and activities were defined according to the studies made by INTERFAZ group and other collaborators to development this type of devices (Ardila et al., 2018; González, López, & Maradei, 2018; López, Pinillos, & Moreno, 2014).

Figure 1. The conceptual framework of the life cycle of the development of a medical device for a specific patient related to the stages of the TRL R + D + I approach.



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Key stages and activities corresponding to TRL and applied software technologies were defined. Through a group of five researchers, the TRL assessment was made using the rubric on table 1. An exhaustive analysis in each case was made identifying practices, activities, products, and main results. According to that evidence was possible to identify the levels of maturity of development classified each case.

In Table 2, the case studies were documented, the type of participant actor and collaborators were identified, the knowledge area that contributed to strengthening and the products obtained from the collaborative work relationship and third-factor. Products were identified to define level I+D+i for each case.

Table 2
Analysis of case studies

Case	Actor and Collaborator	Knowledge Area	Product	Development Level I+D+i
C1	Research Group	Technology evaluation	Reference practices for implant design. Technology integration model RE CAD RP.	BASIC AND APPLIED RESEARCH. validation in laboratory environment
C2	Firm	Design for Manufacturing	Innovation in the design process for manufacturing. T Warm plate	TECHNOLOGICAL DEVELOPMENT validation in relevant environment
C3	Surgery, specialist	Clinical practice definition design process	process flow inbred capability Business model Surgical guides	APPLIED RESEARCH. validation in laboratory environment
C4	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning. Surgical guides	APPLIED RESEARCH. Proof of concept
C5	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning patient specific Implant	APPLIED RESEARCH. Proof of concept
C6	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning and Implant type PSI	APPLIED RESEARCH validation in laboratory environment
C7	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning surgical guides	APPLIED RESEARCH. validation in laboratory environment
C8	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning 3D print Surgical guides	TECHNOLOGICAL DEVELOPMENT validation in relevant environment
C9	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning Prototype: Implant type PSI	APPLIED RESEARCH. validation in laboratory environment
C10	Research Group-HUS	Clinical practice PLM Strategy	Guide: Surgical preplanning. 3D reconstructed Biomodel	TECHNOLOGICAL DEVELOPMENT validation in relevant environment

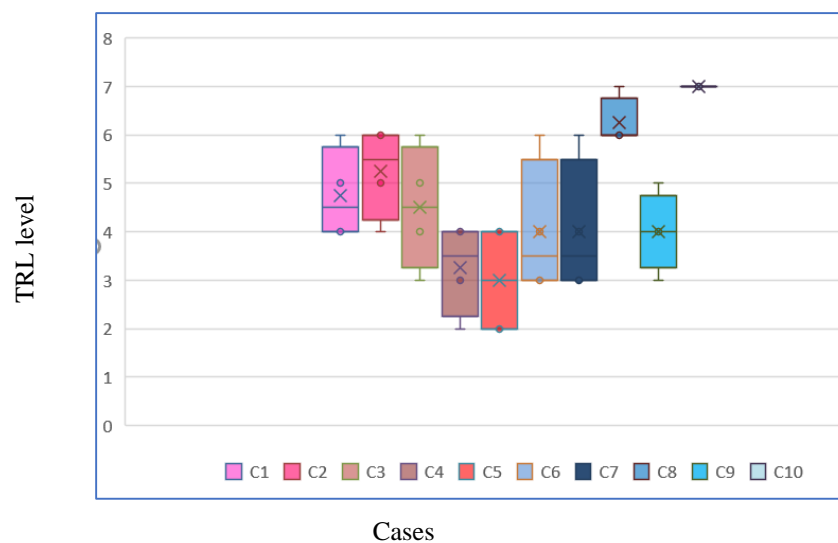
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The sample of 10 cases, in 70% of them, a contribution was generated to the area of knowledge in product development and innovation to clinical practice. However, while only 28.5% of cases have reached TRL7. Despite the limitations in the development of the cases, which only reached TRL3, based on the cases classified in TRL7, it could be affirmed that the cases classified in TRL3, when performed with the same practices, could have satisfactory results. In this way, it can be argued that under this vision the construction of capabilities for the development of technologies is sustained to obtain prototypes of the implantable medical device, surgical guide, pre-planning biomodel printed in 3D.

The projects that achieved the highest TRL may be explained because they complied with the checklist according to the technological development stage. These projects were carried out in collaboration with an external company or with another research group through

service agreement in University Hospital of Santander HUS. The scores levels were distributed since minimum value such 1 point until maximum value such 9 points. Each evaluation criterion was weighted, according to the products, practices, and evidence defined in the rubric model. The score obtained was averaged and related with the value of TRL for each case of study. In Figure 2, it can be seen that, in the boxes and whiskers chart, cases, where there was greater consensus on the TRL, were cases C7 and C10.

Figure 2. Chart of Boxes and Whiskers: distribution of values of the maturity level of each technology.



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DISCUSSION AND CONCLUSIONS

The methodology followed in this research work facilitated the analysis and classification of all cases analyzed into TRL perspective. In this case, there was no evidence of cases with TRL 8 or 9 equivalents to the innovation stage. So that these technologies, although they have not been commercialized, the address has been defined to reach this level.

Some arguments associated with a higher level in those projects, they were related to collaborative work because the profile of the collaborating actor influenced the generation of knowledge related to their abilities; on the other hand, product development strategies such as product lifecycle management PLM. According to the analysis a first case was reported with intervention by another research group, a second one was reported that was developed in collaboration with a manufacturer of orthopedic medical devices, another one case was developed in co-creation with a maxillofacial specialist; and finally seven case studies were

carried out with a GRICES a research group through agreement teaching service with the HUS, which enabled the group to conduct research and clinical practices.

The TRL score achieved in some products could be attributed to collaborative practices and activities, due to that multidisciplinary approach and shared knowledge, through these practices contributed to the advance of development of technologies. In fact, the outputs generated have been achieved mostly within the level of applied research; these outputs were derived from alliances that were created with health area and engineering research groups.

Those relationships allow the knowledge flow through co-creation practices between engineers, designers, and physicians during the development of clinical cases. The maturity accomplished was due too, an iterative, accumulative and sequential form applied to develop each project, and implementing better practices in the further projects. According to this vision and the collaborative approach, this knowledge was converted to requirements and parameters to decision making and develop of new products and define the aim, process, stages, technologies, to define the workflow and activities based on PLM perspective.

It was identified that in several cases of study the same type of project was generated to develop surgical guides, pre-planning or implants for specific-patients, applied in the different anatomical region. In these cases, they define some practices for the development of products under an organizational, coordinated scheme that allows the development of precise devices. From this perspective, it can be argued that the research group has identified the key activities for the development of the technology and already has a base product portfolio.

Considering that the collaborating actors have influenced to achieve the development of technologies with a level of maturity in basic, applied research and technology development, the inclusion of another collaborating actor that contributes to the knowledge area for marketing and application of concepts in business models in such a way that the last stages of maturity of technologies would be reached.

ACKNOWLEDGMENT

The authors want to do our acknowledgment to the researchers of GRICES research group and another participant invented in some of these projects. In an equal sense to the VIE at the University for their support in the implementation of the Cod VIE 987 project.

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