Product Lifecycle Management Strategy for the Definition and Design Process of Face Implants Oriented to Specific Patients

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Abstract. The main purpose of this research was oriented to generate a structured model from an organizational vision to the definition and development of precise osteosynthesis prosthesis. Implants were adapted to the Colombian population anthropometry allowing fracture reductions and craniofacial defects corrections based on technologies for specific patients. This research was developed taking into account the first three PLM stages: Imagination, definition, and realization. Procedures, stages, roles, and activities that take part in the design and pre-surgical planning were identified for the patient-specific implants PSI, carried out through a study case. It was established as a definition model for design and fabrication process of patient-specific implants (PSI). It was possible that technology included in a collaborative workflow wherein the roles which intervene in the design process and the pre-surgical planning were related. The ability to design implants for specific patients and surgical guides was obtained different pathology situations including face trauma. According to the PLM strategy for designing custom implant, it would be possible to build innovation capabilities. With those, an organization could generate a collaborative workflow integrating stages, roles, activities, applying technology and local human resource. Further work related to the subject is necessary to enhance the process by iteration and improve the clinical cases management.

Keywords: Collaborative workflow · Digital manufacturing
Patient-specific device · PLM model · Virtual surgical planning

1 Introduction

Development of new medical devices influences strongly in the surgical quality, that increases a better anatomical situation, real quantity of bone, and reconstruction demands. Therefore, functional restoration is achieved through those devices [1]. From those is obtained a surer, shorter and time predictable surgery [2].

Nowadays, plastic surgery is the health specialty with more influence in the reconstructive field for patients with osseous craniofacial defects [3, 4]. Surgeons have found complex defects that have been corrected through medical devices such as

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surgical guides and patient-specific implants (PSI). These devices, also known as patient-specific devices (PSD), are designed according to the patient osseous structure and allowing restoration of anatomical appearance looking for aesthetic and functional properties [3]. However, virtual technology and digital manufacturing make possible application, which is necessary to medical procedures, such as diagnosis, pre-surgical planning, and surgery, becoming less complex by reducing uncertainty [5].

The main four steps in PSI development are: First, making a digital reconstruction model. Second, design process and device simulation. Third, evaluate the accuracy of the PSI compared with the biological surface. Fourth, piece evaluation [2]. The development of those steps in the process of PSI device involve tools such as reverse engineering (RE), computer-aided design - manufacturing- engineering (CAx), 3D modeling, and rapid prototyping (RP) techniques [6, 7].

Although the importance of the virtual technologies to guarantee PSI development, there would be uncertainty in the development process of this product related to its application on surgery. Implant design process is complex. To achieve medical requirement it demands lots of time and effort. That is why a specialized staff is mandatory, as well a complete evaluation of skull condition, soft tissue bundle, greater accuracy, and time during trauma treatment [1, 2]. The use of specialized software allows reducing the vagueness in precision and accuracy [5]. This implies that a multidisciplinary team must articulate different profiles in the organized structured way inside a collaborative workflow, defining roles and activities atPSI development.

PLM strategy has been implemented successfully in the automotive and aerospace industry [7]. They have defined an integrative vision of PLM strategy, that led to optimizing development time and resources, reducing mistakes on design and manufacture stages, increasing productivity and change controlling [8]. Product Lifecycle Management (PLM) has been set to control RE procedures, to take geometric or organic models as input. RE is been applying in the design process due to its feature to bring human models and the instance of using CAx tools to modify components [8, 9]. PLM strategy involves product data management PDM software, an information technology resource that enables a company to structure a collaborative workflow in safety database. It is useful to planning resources and creating a communication path among different stages, like design, manufacture, sales, support, and elimination. Its value resides in control procedures and selects the accurate tools to intervene through lifecycle product [9, 10]. Quality control and traceability of the process are crucial for medical device, topics which could be covered by PLM implemented strategy [11, 12]. This research defines the application of a PLM strategy looking for improving the development process of medical devices in a public university hospital from a developing country. The main contribution of this paper is related to the proposal of a visual model for PLM strategy in a non-traditional field such as Health. This paper was structured into four parts: first, materials and methods. Second, a PLM strategies structure proposed. Third, a case report is presented. Fourth, the conclusion of PLM implementation related to study case.

2 Materials and Methods

This research was developed in the following way: The first stage was to understand the current situation. This stage was divided in two: first, an exploratory study was conducted to defining procedures for PSI development in a Public University Hospital. Field observation was executed in the subject of context through collecting data about people, artifacts, and procedures, with non-structured interviews. Data were organized according to the timeline for patient attention, specifically on maxillofacial surgery field. Second, a non-structured literature review was conducted, related with PSI for skull and face recovery cases, in order to identify software tools for imaging, virtual reconstruction, modeling and 3D printing of custom medical devices. The second stage was to propose a process line with in the public university hospital for developing a PSI, by implementing a PLM strategy to make decision process and pre-surgical planning. In order to meet this objective, current sequential flow from user perspective was first identified. Then, process areas were established according to fundamental activities from diagnosis, to design, and manufacture. Then, it was analyzed how the proposed PLM strategy could be according with a process to obtaining a PSI. Once workflow and software tools were defined, PLM strategies through project data management (PDM) were applied.

Finally, in the third stage, according to previous evaluation, a new workflow was proposed according to PLM strategies, in order to get a design process for craniofacial implants. For verification purposes, the new workflow was applied to one study case. The evaluation scope was to confirming the design solutions proposed. The accuracy of PSI was verified by physician concept. With that in mind, activities for implant development in the case study were integrated through a PDM.

3 PLM Strategy Structuration Results

A strategy based on product lifecycle was proposed to define craniofacial implants design from current workflow patient service, which showed opportunities to improve the service. Implementation of a visual model allows for controlling productivity associated with equipment, according to each stage involved in the development of the product. This model provides transparency from a Top-down approach [13].

To establish a PLM strategy visual framework, main stages were specified. From academic scope, covered lifecycle just include the initial three: imagination, definition, and realization. Then, process areas involved in main stages were identified: requirements, design, manufacturing, testing, and knowledge management. Each one has a workflow that connects among others, through every activity performed by a specific role. Thought decomposition graphics in every activity, a role is understanding, as well as its skills, tools, and input or output items [13].

3.1 Current Process Description

Through observation techniques and non-structured interviews, the process related to surgical treatment was drawn. A business process model BMP was made to get a

graphic flow that showed activities in the timeline when a patient asks for health attention. It is established that in complex craniofacial trauma cases, use of PSI implants is applied where standard implants performance would be no adequate, although in many cases the surgeon had no other choices. Figure 1 shows an opportunity to include design area in pre-surgical planning procedure. That would enhance endogenous advance of PED under a service procedure based on PLM strategy that facilitates collaboration among multidisciplinary roles.

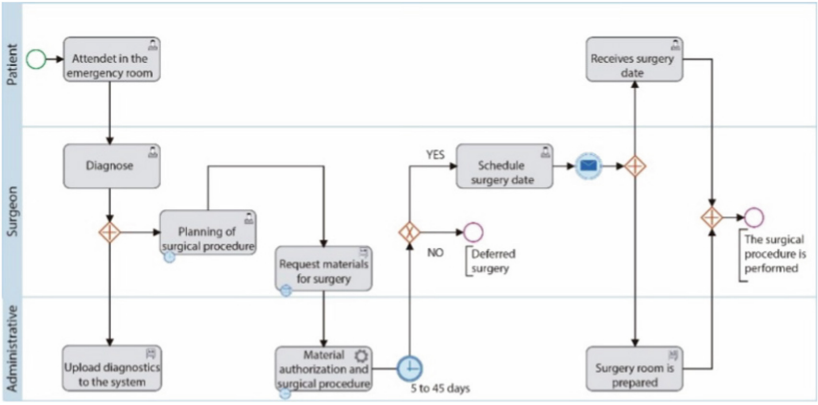

Fig. 1. Workflow in the Hospital. Sequential process observed by authors.

3.2 Building a Visual Model. Stage/Areas Description

Activities involved in the process of obtaining a PSI implant must match by correspondence. Related works in literature are focused on digital workflow in reconstructive implants [14], and how to share complex and heavy data from imaging [15, 16]. A few works presented exchange problems between roles in health [17], specifically how people must conduct a PLM implementation according to organization objectives would be a lack [18]. That gap was identified in the literature review, and next, it was proposed a PLM strategy in order to adapt it to a public university hospital.

The process areas framed in the initial three stages of the PLM approach suggested by Stark were adopted, which correspond to the stages of imagination, definition, and realization [19] as shown in Fig. 2. That also corresponds with the research scope, in order to reduce complexity on technical data management [20].

First, imagination stage. Diagnosis and analysis area has to get information about the patient situation. In this process area, a specialist identifies a defect. Specialist generates a list of requirements that a specific device must accomplish for the patient. Second, definition stage. Three process areas interact as following: first, 3D reconstruction process area, the one in charge to translate Digital Imaging and Communications in Medicine DICOM images [21] from tomography to a 3D biomodel by means of RE technologies [22]. Second, the design area, where the PSI should be virtually made following specifications is previously given by the specialist [23]. Third,

Fig. 2. The initial stage of Lifecycle and Process areas involved, proposed by authors.

knowledge management, where practices related to acquiring information for current and future products are established. Third, realization stage. Rapid prototyping processes are established, rather a biomodel, a PSI, or a surgical guide would be needed, according to any case. Validation must perform by testing quality, or metrology process area, where the evaluation, measurement, and verification of product quality are carried out. Knowledge management area acts again, to creating information manuals for the production process and user manuals for PED. See Fig. 2.

3.3 Roles and Technology Integration

Once the process area was established, roles that are involved in PSI development procedures were identified with his respective technological tools. These roles were integrated by a public access PDM. Selection from PLM services are complex and deepens of organization resources [13]. Due economic limitation, a public PDM service was selected, the GrabCAD workbench from Stratasys [24]. That tool allows interaction among different roles, being possible to visualize change estates on 3D files. Although a role could be performed at least by one person, roles definition corresponds to:

- *Surgeon specialist:* Who generates requirements from the patient about a product and asks the designer for a service according to needs. He is an expert on the surgical correction that requires repair or replaces a craniofacial bone structure.
- *Requirements analyst*: Who directs requirements process area. That role coordinates to obtaining requirements from the indirect user (the surgeon) to define product functionality. Analyst deployed activities in PDM, looking for controlling requirement to accomplishing or updating in every process areas.

- *Reverse Engineer:* Who carries out the translation from DICOM to 3D reconstruction. A trained person who domains reverse engineering techniques.
- *Designer:* The designer role is responsible for the design process according to the needs and requirements requested. He must have knowledge regarding creativity, innovation and design, computational skills in software creation PSI products.
- *Rapid Prototyping Operator:* The one who performs 3D printing according to the indications given by manufacture requirements.
- *Knowledge manager*: Consists of identifying, collecting, managing and storing the knowledge, so that this can be shared, reviewed, and modified in a safety way.
- *Metrology Engineer*: Who carries out the inspections and product verifications. He finally evaluates manufacturing costs from other areas.

3.4 Medical Prosthesis Development. A Proposed Workflow

Three study cases with craniofacial defects were done. The cases need to be attended by a physician specialist. The main target was to know the common activities to develop each case. Then, a collaborative workflow was performed where roles that intervene in a PSD design interact constantly along the whole procedure. Next, study cases related to PSD (pre-surgical planning, surgical guides, and PSI) was shown. In Fig. 3, a workflow for PSI development was suggested. Procedures were according to activities and steps in a public hospital, which was taken as reference. Those activities flow through different professionals, whom could accept or reject inputs and outputs form each activity, taking into account custom conditions for each device. Proposed workflow is described as follows:

First, the surgeon specialist SS identifies the defect that should be treated. Specialist generates a diagnosis and requests a service based on the cost analysis and justification about advantages. In this stage, procedure requested is assessed by requirements analyst, is appropriate or not for the patient. The PS probably requests the service in an iterative way until all changes suggested over the first proposal were defined, including overall schedule and a probable price.

Once the proposal is accepted, reverse engineer intervenes, getting TAC images from Hospital, traducing DICOM to a virtual 3D shape, and correcting mesh. Next, designer structures all ideas to be developed using 3D imaging as input. When the designer has already done a concept, PS intervenes again in establishing if concept accomplishes expectations or must be modified. Once SS concedes his approval, detailing design, materialization and refinement are carried out. At this point, idea evolves to the product, and designer recommends specifications for each device. It is verified whether rapid prototyping could be done or it must be configured from concept refinement again. With a final design, metrology engineer ME could evaluate the performance virtually or physically by testing. If ME approves, knowledge manager could create a product manual for the application, bringing a compact product to SS.

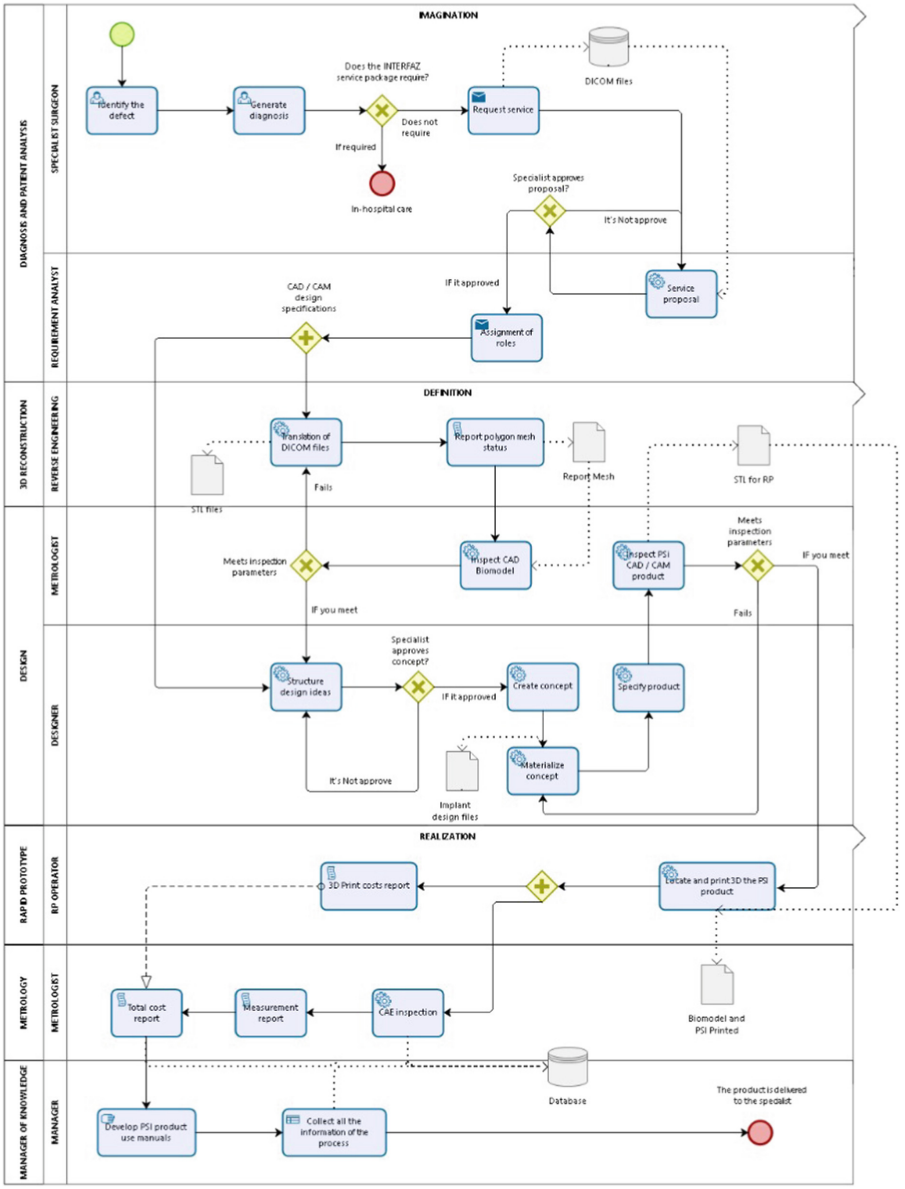

Fig. 3. Systematic Workflow proposed by authors.

4 Study Case

The collaborative workflow was proposed and implemented for a study case. The patient was diagnosed with sequels Le-fort 1 of cleft palate with retrusion of congenital type maxilla, see Fig. 4. The surgeon specialist requests the design of a cutting guide for osteosynthesis, and the pre-surgical planning to improve the patient's bite.

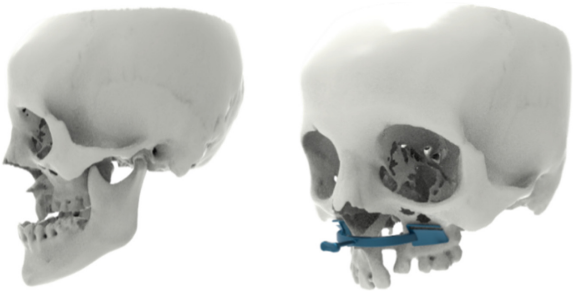

Fig. 4. Study case. Image drawn by authors.

Roles communication and technology integration were taken into account. Table 1 shows time spent in each stage according to activity. Comparing with other works [25], time reduction must be a goal for future developments.

Table 1. Time for each activity

Stage	Activities	Time (h)
Imagination	Defect identification/Diagnosis generation	8
	Requesting service	0.5
	Requirements management	3
Definition	Roles assignation	1.5
	Reverse engineering	8
	Mesh correction	8
	Ideas structuration	5
	Concept creation	14
	Concept evaluation	1
	Concept materialization	4
	Product specification	1
	Measure verification	0.5
Realization	Rapid prototyping	5.7
	Knowledge management	2
	Information manuals generation	2

Finally, a prototype was brought to surgery to check, according to surgeon specialist observation, if it fits osseous geometry or not. That cutting guide was not used along the surgical procedure. It was sterilized and its contact was less than 10 s. Integration of RE, CAx, and RP technologies was established, founding guidelines and procedures to development. Co-creation among key roles and technological tools were also defined. Technology inclusion was possible within a collaborative workflow where roles are constantly interacting. The capability to generate PED must be obtained by experience by attending different situations of pathology treatment.

5 Conclusions

Based on the PLM strategy for the design of the patient-specific implant it is possible to build capabilities to generate a collaborative workflow integrating stages, roles, activities and a workflow with technology and local human resource. PLM strategy improves the development of the case in an organized manner allowing to knowledge management. However, it is necessary to implement cost validation and control scheduling in activities, in order to measure biomodel results, starting with academic validation. Developing PDM software could be recommended to improve roles interaction and interface, easing exchange formats requested for each case. Develop the four remaining stages of the PLM strategy(commercialization, use, support, and disposal) will imply further research and effort, to develop stages which were not taken into account on this paper reducing complexity and because that would be beyond research scope.

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