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Economic evaluation of technological developments in the Prosthetics and Orthotics Laboratory

Evaluación económica de un desarrollo tecnológico en el Laboratorio de Órtesis y Prótesis

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Palabras clave: BPM, *análisis de minimización de costos, diseño de prótesis, amputación parcial de pie, flujo de trabajo.*

Abstract

Previous economic evaluations for health care have focused mainly on the clinical and pharmacological areas. This paper presents the implementation of a methodology for economic evaluation on technological research. The case of a new prosthetics design for partial foot amputee patients was used for analysis. The aim of this work was to calculate the cost of device manufacture and to separate it from research costs. A cost-minimization analysis was done based on the economic assessment by process. A business process modeling was adapted to synthesize research results to obtain a sequence of activities required for the production area (prosthesis manufacture process) and to generate a manufacture manual. Once the activities were modeled, the cost of prosthetics manufacture process and total time of prosthesis manufacture process were calculated. These results permitted identification of critical paths to ensure quality production that could be used for cost or process optimization.

Resumen

Las evaluaciones económicas en el ámbito de la salud se han enfocado principalmente a las áreas clínicas y farmacológicas. Este trabajo presenta la implementación de una metodología para evaluación económica en el área de investigación tecnológica. Para este análisis, se utilizó el caso de un nuevo diseño protésico para amputación parcial de pie. El objetivo de este proyecto fue permitir a los investigadores conocer el costo de manufactura del dispositivo protésico y separar los costos de investigación. Para lograrlo se realizó un análisis de minimización de costos, basado en la evaluación económica por procesos, en donde el modelado de procesos de negocio fue adaptado para sintetizar los resultados de investigación y obtener una secuencia de actividades requeridas para el área de producción, las cuales fueron registradas en un manual de manufactura. Una vez realizado el modelado de las actividades, se determinó el costo y los tiempos de fabricación del nuevo diseño protésico. Estos resultados permitirán identificar rutas críticas para asegurar la calidad de producción, así mismo, podrán ser utilizados como base para la optimización de los costos y procesos de producción.

Introduction

Economic evaluation can be defined as a comparative analysis of alternative actions based in their costs and outcomes. The basic steps of any economic evaluation are to identify, quantify, evaluate and compare costs and consequences of the alternatives considered.[1]

When the cost of alternatives is required to make decisions, a cost-minimization analysis can be performed. With this information and based on measured consequences, it is possible to perform cost-effectiveness, cost-utility and cost-benefit analysis.[1]

The application of economic evaluation should be essential to plan an orderly introduction of technologies, as it is known to have impact on the macro, meso and micro decision making level.[2] Economic evaluation plays an important role in the policies of some countries to implement health care technology and health interventions.[3] In Mexico, the main initiatives to conduct economic evaluation in health care are IMSS, CENETEC and Cofepris,[4-6] which focus on drugs, clinical and surgical procedures. To our knowledge, no one has evaluated the introduction of medical devices developed by the research areas to the health care system.

Therefore, our aim was to study the experience of developing and implementing a methodology for economic evaluation of a technological research. This methodology was applied to evaluate a new design of a prosthetic device (PD) for patients with partial foot amputation.

The economic evaluation was performed in the production area, to determine manufacturing costs for the hospital. This approach allowed to differentiate between research and production costs and created a framework to compare prosthetics designs and technological alternatives.

Methodology

This methodology is based on economic process management,[7] considering section generation and evidence analysis. In this way, business process modeling[8] (BPM) was integrated to the economic evaluation. *Figure 1* describes in detail the section generation and evidence analysis.

This study comprised three steps. First, we applied generation and evidence analysis section and integrated business process modeling (BPM). Second, cost minimization analysis was developed for the modeled process. Third, the cost of manufacture process was calculated. *Figure 1* describes this workflow to obtain the cost of manufacture process.

A. Business process modeling (BPM)

Business process modeling was used to integrate the research results of the design process of a medical technology, along with the results of prototype test on research subjects and the experience of manufacture staff at the Prosthetics and Orthotics Laboratory (OPL). As a result, a new Prosthesis manufacture process was developed.

1. **Process identification (investigation results).** Manuals, research documentation and *in situ* information were obtained.[9] The manufacture process model was implemented during the production of six prosthetic devices manufactured for experimentation purposes. The manufacture facilities, tools and personal within the hospital were used to trace and observe the process.
2. **Process modeling.** In this stage, a multi-level BPM modeling was performed considering the prosthesis manufacture process workflow. This modeling was done with BizAgi Process Modeler version 2.7.0.2.[10]
3. **Modeling review.** Initial BPM modeling was reviewed and corrected.
4. **Evaluation and implementation process.** Final BPM modeling was implemented in the production area. Workflow indexes were measured and data were analyzed with descriptive statistics. Finally, the relevant cost factors were identified and procedures manuals debugged.

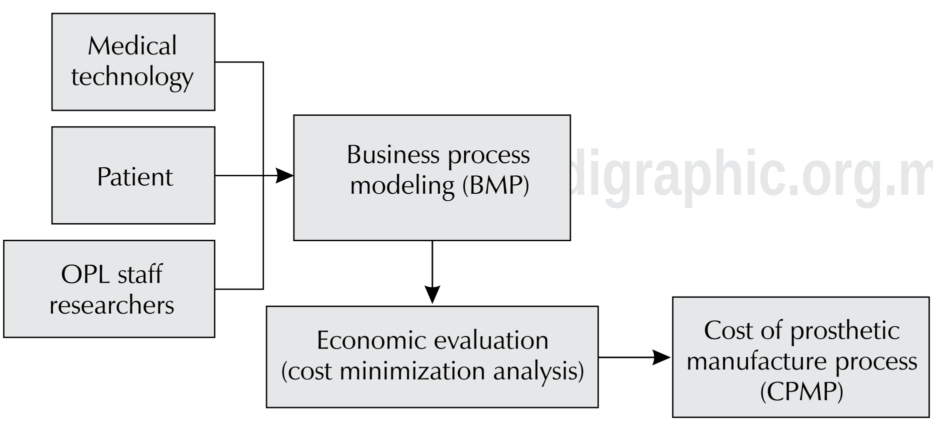


Figure 1.

Generation and evidence analysis section. OPL (Prosthetics and Orthotics Laboratory). The BPM modeling of the prosthetic manufacture process took into account the medical technology used by OPL staff involved in attention of patients, to perform the cost minimization analysis and determine of cost of prosthetic manufacture process.

4.1) Workflow indexes

A Time of prosthesis Manufacture Process (*TMP*) was identified for each activity in the business process modeling. *TMP* was defined as the time the activity finished (t_f) minus the time is started (t_i). Using this data, the Total time of prosthesis manufacture process (*TTMP*) was calculated as the summation of times of prosthesis manufacture process activities, using equation (1).

$$TTMP = \sum_{m=1}^{m=j} TMP_m \qquad (1)$$

Where:
j = Number of activities

B. Economic evaluation (cost minimization analysis)

The cost minimization analysis was done in the production area of the Prosthetics and Orthotics Laboratory, to determine the cost of prosthetics manufacture process (*CPMP*) for the hospital. A description of the analysis is as follows:

1. **Temporal horizon.** Economic data were collected during a 12 month period. An annual costs period was defined in 2014.
2. **Perspective.** Only costs pertinent to INR were included.
3. **Operational capacity.** The Prosthetics and Orthotics Laboratory manufactured 242 prosthetics systems in a year *(P)*, and only one PD was manufactured by prosthetics manufacture process.[11]
4. **Cost analysis.** *CPMP* was determined. For this purpose, relevant cost factors were analyzed under the criteria of macro-costing, production function and equivalent annual cost, these costs were classified as fixed and variable.[1]

The *CPMP* was defined as the sum of the annual costs of each relevant economic factor of the process (C_i) divided by the operational capacity (P), using equation 2.

$$CPMP = \frac{\sum_{i=1}^{n} Ci}{P} \qquad (2)$$

The Cis factors were identified and classified as fixed or variable costs.[1] Fixed costs included physical spaces[12] (e.g., infrastructure), equipment[13] (e.g., ovens, vacuum pumps, saws for cutting plaster, sander, vertical drill and sewing machine), accessories and tools[14] (e.g., surfom, vernier caliper, scissors). Variable costs included supplies[15] (e.g. traditional plaster, plaster bandages, caucasian pelite, polypropylene, acrylic resin, carbon fiber), maintenance contracts,[16] equipment's electricity consumption[17] and human resources[18,19] (prosthetists, researchers and engineers).

Finally, in order to identify which factors had more impact in cost of prosthetics manufacture process, the participation percentage of relevant economic factors (%Ci) was calculated. The percentage of relevant economic factors is defined as cost of annual relevant economic factor, divided by the sum of the annual costs of each relevant economic factor in the process by 100%, as shown in equation 3.

$$\%Ci = \frac{Ci}{\sum_{i=1}^{n} Ci} * 100\ [\%] \qquad (3)$$

Results

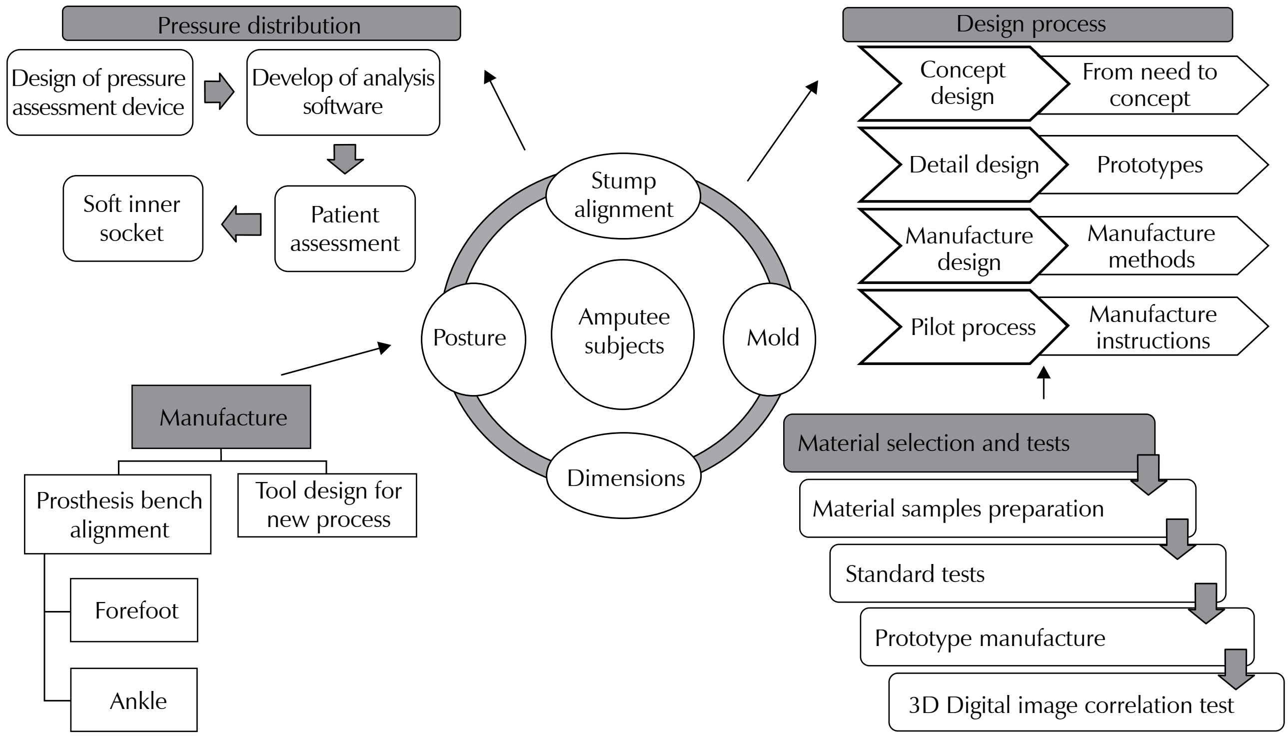
Business process modeling (BPM)

In an effort to organize all research information for the model, the research team generated a schematic representation of the five projects ongoing for the prosthetic device development *(Figure 2a)*. Despite the schematic representation, it was not possible to define the essential steps for manufacture a prosthetic device. Therefore, it was necessary to observe the fabrication of six models in the field and to attend the fitting sessions with test subjects.

The entire prosthetics manufacture processes were integrated into nine complex activities or sub-processes in a graphical model *(Figure 2b)*. This model allowed researchers the identification of activities related to manufacture and to disengage them from those required for research. In the same way, it was possible to identify critical process and check points for quality assurance. Time used was obtained from observing elements for cost analysis, such as materials, staff work time and equipment.

Evaluation and implementation process

Once the research procedures were eliminated form the process, each activity was timed. *Figure 2b* shows the time of prosthesis manufacture process activity by sub-process. The total time of prosthesis manufacture process was estimated as 4.65 days.



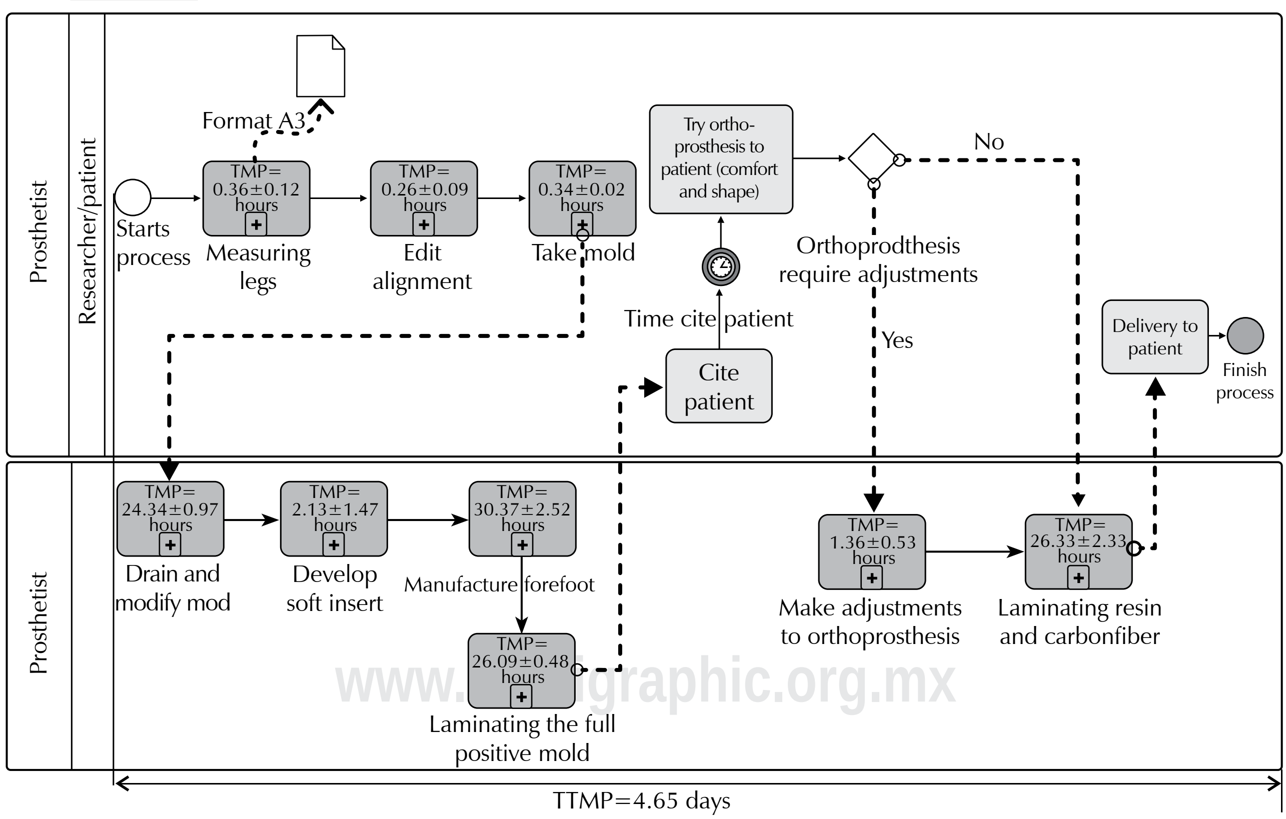


Figure 2. a) Representation of the research process to design and implement test prosthesis for partial foot amputation. b) BPM model of prosthesis manufacture process, where each sub-process shows the Time of prosthesis manufacture process activity. *TTMP* = total time of prosthesis manufacture process.

After process depuration, a procedures manual was developed with the manufacture process instructions of the prosthetic system. This way, it was possible to establish a comprehensible prosthesis manufacture process. The main result of business process modeling was to establish critical paths to identify activities that could be adapted and improved in the production area.

Economic evaluation

Figure 3 presents the percentage of relevant economic factors. Prosthetics and Orthotics Laboratory staff had the main participation in the cost with 52.5%.Electricity consumption was the second factor with 22.8%, supplies and materials followed with 20.7%. These results allowed the identification of relevant economic factors on hospital expenditure. The cost of prosthetics manufacture process in 2014 was calculated on $605.43 USD, which is approximately 20% more than the cost estimated by the hospital for a standard leather and polypropylene prosthesis.

Discussion

In this study, economic process management was adapted for a technology research field, becoming a useful tool for visualization and organization of an intricate manufacture process that tends to have redundant objectives and procedures, as well as unnecessary activities.

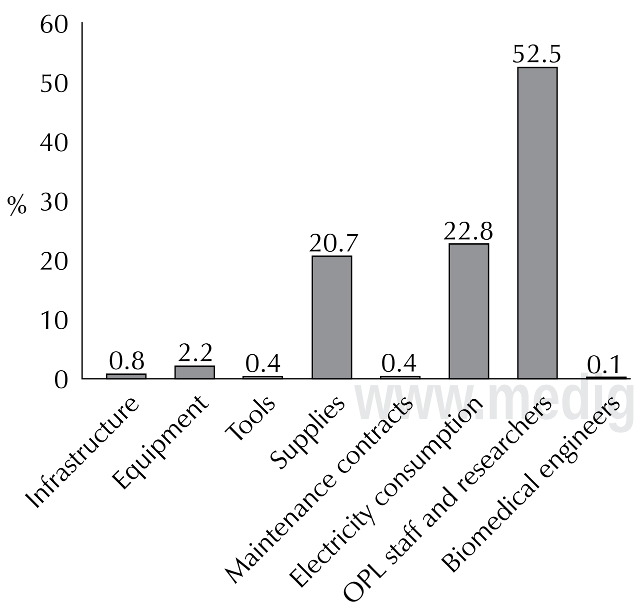


Figure 3. Percentage of relevant economic factors of *CPMP*.

Business modeling process facilitated the visualization of the prosthesis manufacture process for debugging. From the model, it was possible to observe important activities critically linked to production quality assurance. Likewise, it facilitated the identification of relevant economic factors for cost analysis. One of the most important results was the development of a concise procedure manual for prostheses manufacture, which can be used for technological transference.

Although research on prostheses implementations in the production area were observed, our study is limited to the manufacture of test devices. Certainly the process was modeled in the site where it takes place and precautions were taken to avoid possible interference, nevertheless some of the production times could be overestimated due to the lack of experience of the production staff. Furthermore, it was essential to have feedback from staff involved to reduce errors in the model.

Future research should seek the use of the business modeling process for economic evaluation in two ways: process optimization and costs reduction. The first could focus on identifying changes in the manufacturing process, to test, select and optimize processes. The second could be done though the implementation of tools like times and movement analysis, mainly because, in the hospital setting, the optimization is multifactorial.

The cost minimization analysis in this study can provide to researchers tools to conduct, in the future, complete economic evaluations, considering the impact of technology research developments on patient's health, such as cost-utility analysis or cost-effectiveness.

Conclusions

Economic assessment provided systematic, standardized and quantitative tools to determine the cost of prosthetics manufacture process and total time of prosthesis manufacture process and can be adapted in the field of technological research. Optimization of the prosthesis manufacture process impacts the cost of manufacture. The economic assessment by process generated a direct connection between research and production areas, allowing development of the expected prosthetic system and quality in the production. This experience was important for meeting goals and objectives of the technology research and development department.

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Conflict of interests

The authors declare that there is no conflict of interest.

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