DESIGN OF MEDICAL DEVICES FOR PRESSURE ULCER PREVENTION

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Abstract

This paper presents a stage-gate design methodology implemented during the design of two mechatronic medical devices for the prevention of ulcers in skin. Each product required the integration of different disciplines such as mechanics, electronics and software, and went through three stages on which technical tests were performed on each stage. Afterwards a feedback was introduced into the next stage and improvements were implemented on the design. At the end both products were tested by health-care staff members, and patent applications were issued for.

Keywords: Design Methodology, Mechatronics, Biomedical design, Pressure ulcers, Integrated Product Development

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1 INTRODUCTION

Pressure ulcers are sores produced in the skin by shear, friction and prolonged pressure without a total recovery of the tissues producing necrosis (Hagisawa, et al., 2001). The bony prominence parts of the body are in higher risk of developing pressure ulcers due to the direct contact between skin and bone. Furthermore, there are common risk factors that make people prone to suffer from pressure ulcers such as poor nutrition, moisture, skin condition, incontinence and low mobility (Stechmiller, et al., 2008). Around 412000 people are likely to have pressure ulcers in the UK every year (Bennett, et al., 2004) and the prevalence proportions obtained from a pilot study in five European countries are between 8% to 23% of hospitalized patients (Vanderwee, et al., 2007). In addition, as presented by Bennet et al. (2004), 4% of total National Health Service (NHS) expenditure in the UK is spent in the treatment of pressure ulcers. These facts make pressure ulcers one of the most common health problems with the most expensive treatments; therefore a good solution is to prevent the appearance of the pressure ulcers.

There are different methods of prevention like foam mattresses, alternating air pressure mattresses, skin protectors, preventing nursing care measures as control of nutrition, massages and patient mobilization (Shahin, et al., 2009). In the longitudinal study done by Shahin et al. (2009) it was found that a good preventing tool for pressure ulcers are the alternating air loss pressure mattresses. Moreover is established that changing position every 2h in a non-pressure reducing mattress and 4h in an alternating mattress could help with the prevention of pressure ulcers. Besides, it is remarked that with an alternating mattress the nursing time is lessened contributing with the reduction of medical costs (Defloor, et al., 2005).

On the other hand, according to the World Bank Group, Colombia has 1.5 hospital beds every 1000 people, far behind from developed countries such as Germany with an index of 8.2 (Bank, 2015). Certainly it is not a matter of getting an amount of beds into the hospitals in order to increase their availability, but a matter of who is going to take care of the patients, how are the patients going to be treated and how much time are the patients going to remain at the hospitals.

When these two facts (i) a long time prevalence disease such as pressure ulcer and (ii) a low availability of hospital beds are met, then there is a health problem bigger than the sum of the factors.

This paper describes the development performed by a multidisciplinary group of people of two medical devices for pressure ulcer prevention: (i) an alternating low air loss pressure device mattress and (ii) a multipurpose hospital bed, which can be used either independently or in combination.

2 PROJECT PLANNING

2.1 REGIONAL CONTEXT

In Colombia, specifically in the city of Medellin, the innovation roadmap is given by the CTI plan (which in Spanish states for Science, Technology and Innovation) and sets the three main fields where the research efforts should focus on: (i) Energy, (ii) Health and (iii) Information-Communication Technologies (RutaN, 2011). The project, on which this paper is based upon, was funded through the city's public call Inlab2market that took place within 15 months between the years 2013 and 2014.

2.2 PRIOR WORK

Prior to the development of this project, the same research group worked on two projects which became the inputs for this final project.

2.2.1 Project 1

This project was performed during the year 2009, and a single concept was designed that combined the action of an alternating pressure device and a multipurpose hospital bed. This medical device was granted a utility model patent in Colombia and is shown in Figure 1.

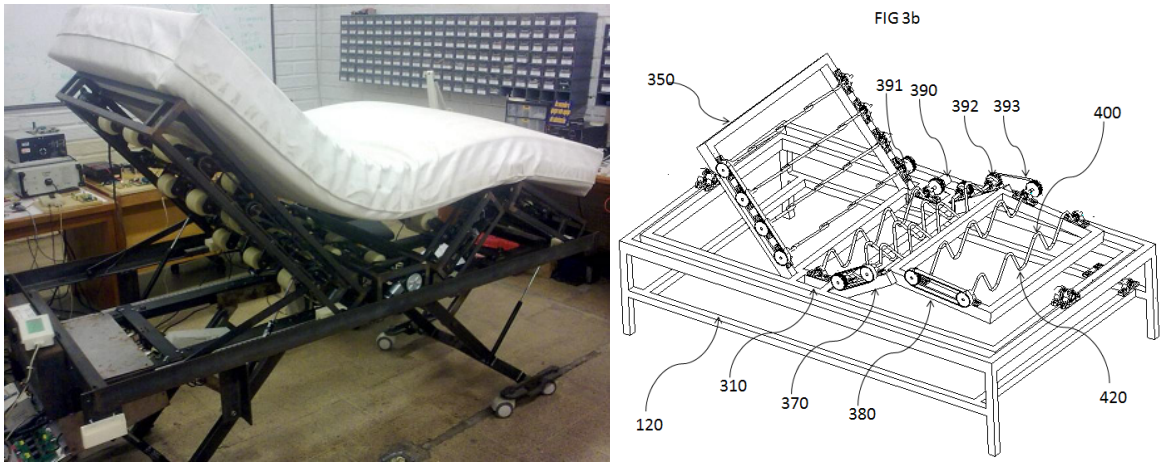

Figure 1. Prototype of Utility Model (Correa-Vélez & Velásquez-López, 2010).

Nonetheless, a hospital bed could have a more general purpose than just preventing pressure ulcers, and the development should be flexible to let the users (hospitals, care takers and patients) to either (a) buy a multipurpose bed in the case that they already had a pressure ulcer preventing mattress, (b) get a pressure ulcer preventing mattress in the case that they already had a bed or (c) buy both. For this reason, the research group decided to tackle the problem separately.

2.2.2 Project 2

This project was performed during the year 2011, and the focus was given on a pressure ulcer preventing mattress. After a creativity session based upon superheroes (Tassoul, 2006) it was concluded that a floating body would be a good concept, for which a low air loss device seem to be a solution.

2.3 DESIGN METHODOLOGY

The research project's intention was to create two products that improve low mobility rest bed patients' life. Since medical products are very strict on trials, the schedule was divided into three stages of five months each, with every stage involving design, manufacturing and testing as shown in Figure 2.

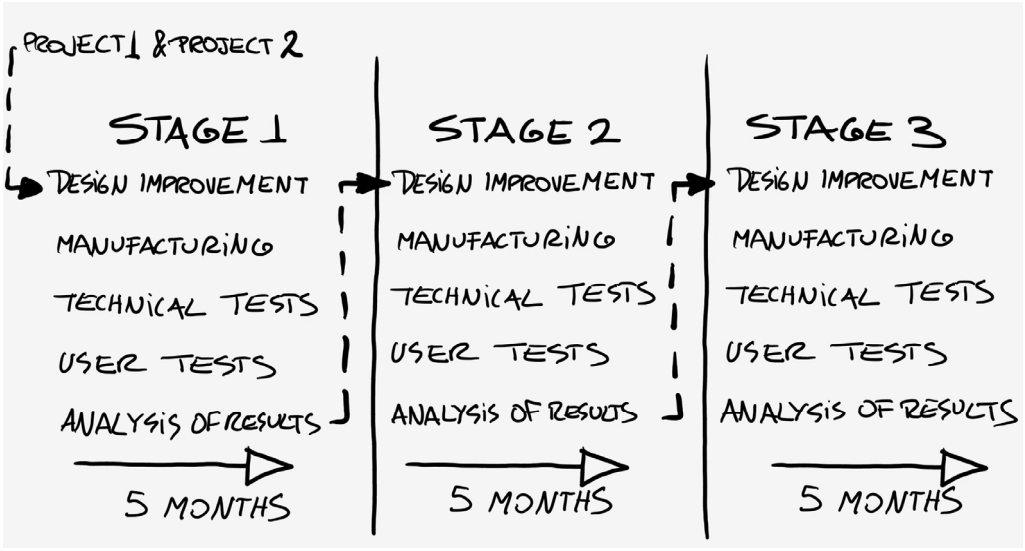

Figure 2. Stage Gate Methodology.

Each following stage started by improving the features that were noticed to have failed during the tests of the previous stage. Thus, after three iterations the results would be more robust.

As preventing pressure ulcer device, it was design an alternating air loss medical device. Yet, the hospital bed was designed with a large set of movements allowing pressure ulcer prevention by changing the angles of the back and feet part. As revealed by Defloor (2000) the 30° semi-Fowler position resulted in the lowest contact pressures. The product design specifications (PDS) for both products were established following the Colombian technical regulation INCONTEC for hospital beds NTC-IEC 60601-1, the document Assistive products for persons with disability - General requirements and test methods of The Spanish Association for Standardization and Certification (UNE-EN 12182), medical personal specifications and further requirements that the research group found valuable.

3 FUNCTIONAL AND USER´S TESTS

3.1 FUNCTIONAL TESTS

3.1.1 Alternating low air loss medical device

Mechanical and electrical testing were assessed in the first and last stage of the research project. During second stage there were some problems with the prototype that will be explained further in the paper. In the mechanical testing, six features were estimated: (i) sealing vs. pressure, (ii) material characterization, (iii) hydrophobicity / hydrophilic, (iv) material bending properties, (v) flammability and (vi) connection between air chambers. For the electrical evaluation, the system was tested by putting it in continuous activity. The electrical expend was measured at the same time. In addition, a biomedical certified technician evaluated the prototype to evaluate the functionality.

Figure 3. Assesment of alternating cell direction and cell material

3.1.2 Multipurpose hospital bed

During the first and second stage of the research, the mechanical testing was done based on the document of the Colombian Institute of Technical Standards and Certification (ICONTEC). The evaluation was realized at room temperature as specified in the document NTC-IEC 60601-1 of the INCONTEC (2013) with constant pressure and humidity. Before starting the evaluation procedure, the bed was in resting position for the last 24 hours.

In order to evaluate the operation and performance of the bed, an automatic sequence of actuators movements was programmed. First it was planned to upload two legs, then the back and foot, right transfer motion, download back and foot, left transfer function, transfer to the centre, Trendelenburg

(normal and inverted), and download two legs. This sequence was repeated until the final failure of the actuators.

3.2 USERS TESTs

In order to test the comfort and performance of the medical devices, two volunteers' testing were carried out. In both cases an informed consent form was handled to every participant.

3.2.1 Alternating low air loss medical device

A sample of 24 healthy people was part of the trial. Volunteers were 15 men and 9 women between 19 and 30 years old. The average weight was 69,9Kg and the average height 1,72m.
First there was an examination of the skin in the most likely parts of suffering from pressure ulcers of each participant like neck, shoulder blade, sacrum, elbows and ankles. It was done by evaluating the following characteristics: hydrated/dry, unharmed/harmed, soft/hard, normal color skin/redness. Also the Braden scale questionnaire was asked.
The test was effectuated on a volunteer per time for two hours in the supine position. During the evaluation time, the position, volunteers' perceptions and general comportment were taken into account. At the end of the two hours, the skin of each participant was evaluated in the same anatomical points as at the beginning of the test. The characteristics that were rated were the disappearance of redness when touch, hardening of the skin, inflammation, transpiration, pale skin, pain, heat, and tingling. In addition, other general variables where analyzed like heat, numbness, tremor, inability to relax, dizziness, light-headedness, shakiness, nervousness, sweating, itching, relaxation, sleep, comfort, serenity and comfort.

3.2.2 Multipurpose hospital bed

A sample of 23 healthy people was part of the trial. Volunteers were 14 men and 9 women between 19 and 30 years old. The average weight was (66.73 ± 15.44)Kg and the average height (1.65 ± 0.1)m. During 10 minutes the volunteers were asked to lie down on the prototype the bed in supine position while all the bed movements were programmed (Figure 4).

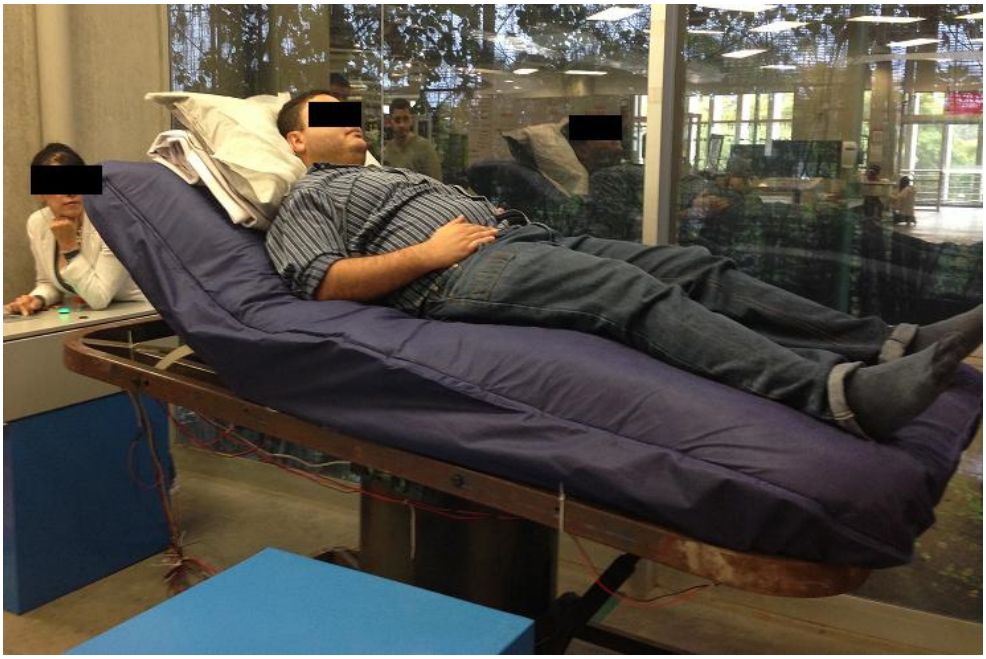

Figure 4. User tests on multipurpose hospital bed.

While the users were laying on the bed, it had the following automatic sequence: Fowler (back and knees in an upper position), Trendelenburg (head lower than the rest of the body by an angle of 12° in supine position), Trendelenburg reverse (head upper than the rest of the body by an angle of 12° in supine position), bed transfer for both sides (bed rotation to facilitate the transfer of a patient in a

supine position) and initial position (supine position with an equal body weight distribution in the lowest height of the bed).
Through the evaluation time, positioning, volunteers' perceptions and general performance were taken into account. Besides, after the test some questions were done in order to know the general experience while lying down in the hospital bed. These variables were heat, numbness, tremor, inability to relax, dizziness, light-headedness, shakiness, nervousness, sweating, itching, relaxation, sleep, comfort, serenity and comfort. In addition, a questioner was given to evaluate the product perception.

4 PRODUCT DEVELOPMENT

4.1 PRODUCT DEVELOPMENT: ALTERNATING LOW AIR LOSS MEDICAL DEVICE

4.1.1 Stage I

Eight prototypes were built based on two compound materials available in the market, flexible PVC and cotton-polyester. The design consisted in a mattress with air cells capable of alternate while releasing air. The air cells diameter were11cm and 16cm distributed horizontally or vertically depending on the prototype. Additionally, the cells length distribution through the surface was equally.
The aim of this stage was to determine the low air loss system of the device. It was needed to define the pore size and the pressure required to support a person laying down the device surface. The feature estimated was sealed vs. pressure. For this reason a pressure test was effectuated on four prototypes. The prototypes used to this test were two mattresses of flexible PVC and two mattresses of cotton-polyester. Also, there were two mattresses with cells of 11cm and the other two with 16cm. The pore size was 0.15cm of diameter in each case.
Four prototypes resisted 207KPa, pressure measure with a subject of approximately 80Kg, and the failure was only in one of them at 400KPa. It was also determined that the part of the head in the mattress should not have alternating cells in order to improve comfort.
In addition, the control system of the alternating low air loss system was developed and proved during this stage. Inflate/deflate cycles were effectuated were the prototype resisted 200 cycles without failure. Users testing resulted in comfort and air realized was refreshing. Also it was proven that the control system was working properly and volunteers did a proper feedback to improve for next stage. The most remarkable observations were the height of the cells and the velocity of the alternating pressure.

4.1.2 Stage II

During stage II there was a redesign process of the alternating low air loss device. The main idea was to improve the alternating cells design. Cells distributions were changed and replaced creating different configurations. Five prototypes were developed. Besides, each prototype had a novel design and cell distribution. In addition, the composite material was also change to enhance the fabrication process and avoid undesired wrinkles.
The novel designs were inspired by the shape of a V and the shape of an X. However, first two prototypes presented problems of wrinkles and inflation. Due to cell design the air was unable to pass through all the cells and unwanted folds were seen. For this reason improvements in the design of cells were done. The sharp angles of the borders of the air conducts were softened and another two prototypes were developed.
There were failures in the pressure testing; the material and design did not resist the air pressure. The failure was again due to the sharp angles in the borders of the air conducts. For this reason, a new design with no sharp angles was created. At this stage, the shape of the X was the one that better suited the design requirements. This shape was the one developed with the use of curves instead of severe angles.
Nonetheless, the last enhanced design of this stage, did not resist the inflate/deflate cycles. Also it did not meet the requirement specifications to go further with these designs. Consequently, there were no volunteers testing. Even so, important remarks were discussed from the prototypes resulted from this stage. As for example, it was established by the group how should be the shape of the air conducts in order to produce an adequate inflation and alternation process. Besides, the X shape could not be developed successfully.

4.1.3 Stage III

This was the last stage of the product development. The design of the alternating low air loss device was improved based on the results from previous stages. Therefore a novel design was created with wavy lines shape air conducts. Two prototypes were constructed to evaluate the design behavior. Additionally, it was also determined that the low air loss system should be separated from the alternating system, so lesser air and pressure needed.

The medical device design was finally achieved after the development of 15 prototypes throughout the stages I, II and II. For the last stage, a final design was selected and improved based on the previous results.

The alternating low air loss medical device consists of two layers, one of them are alternating cells to relieve pressure and a low air loss system that allows skin ventilation. The main purpose of the two layers is to prevent energy loss and to have a finer control system of the variables as air pressure and air released.

In Figure 5 a cross section is shown of the alternating low air loss medical device design. It is possible to observe the internal mechanism of the alternating cells and in the upper layer, the pores where the air comes out to ventilate the patient's skin.

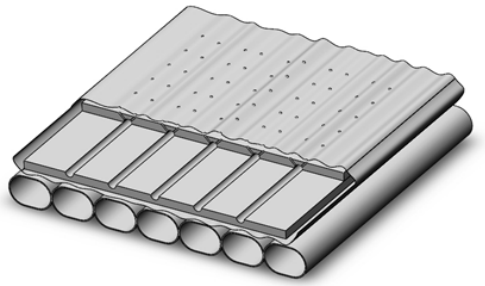

Figure 5. Cross section of the alternating low air loss medical device (Velásquez-López, et al., 2014).

The final prototype selected fulfilled the design specifications of having a novel design, suitable material for medical uses and a low air loss alternating pressure design. The mechanical and electrical testing were performed to confirm the model. In addition, a biomedical certified technician evaluated the prototype to evaluate the functionality.

An important component of the system for the alternating low air loss device is the compressor that allows the flow of air into both layers. It is a medical rated compressor which runs silently and appropriate for this purpose.

About 1918 cycles of air loss in 100 cycles of alternating cells were completed. During the cycles there were no failures in the medical device system. The control system worked as expected. However, the solenoid valves were overheated in every cycle done in the system.

The alternating low air loss medical device was tested with 24 people that volunteer to give a feedback about comfort and functionality of the prototype. There was a questionnaire of 15 questions regarding the perception of the product where was well graded.

4.2 PRODUCT DEVELOPMENT: HOSPITAL BED

The design and function specifications that were defined in the PDS were that the hospital bed could be able to have different height levels, Trendelenburg position, semifowler position, upper independent movement of the back part, specialized knee movements by changing height of the lower limbs and turn assist which allows the lateral rotation of the bed in both sides.

There were two hospital bed prototypes during the research project. The first one was developed in the stage I and the second one in stage II. For stage III, the last prototype was improved. As a result, it was obtained a functional hospital bed with a novel design.

4.2.1 Stage I

During this stage the previous bed constructed by the team in a former project was revaluated in order to improve it and to separate the pressure relieve mechanism of the main bed movements.

Consequently, a hospital bed prototype was built and tested in this stage. However, the main design of the former prototype was maintain.
It was noticed that the first design did not meet the specifications and functionality established by the group in the PDS. During the assembly of the hospital bed there were issues due to the use of non-standardized pieces e.g. own manufacture of screws. Also, from the mechanical testing was encountered that there was a failure in the actuator from the back of the bed due to radial forces. Besides, there were problems with the lineal displacement of the height system and support mechanism. These structures were not correct align with the ground.
These results were obtained from the performance evaluation of the hospital bed. It was programmed an automatic sequence of actuators movements as describe in the methods section. This sequence was repeated 1973 times until the final failure of the actuator from the back because a bending force. In between, in the cycle 763, there was a failure of the actuators of the legs due to a radial force. In this case, the actuators were replaced to continue with the mechanical testing.
Therefore, it was concluded from this stage that the design of the hospital bed needed to be change in order to have all the required movements and the adequate functionality with any structural failure.

4.2.2 Stage II

Stage II consisted of a modeling and simulation of a new structure. During this stage of the research project, there was a complete redesign of the hospital bed. There was no assembly or construction of any prototype. For this reason there is no information on mechanical testing or volunteers' perception of the product.

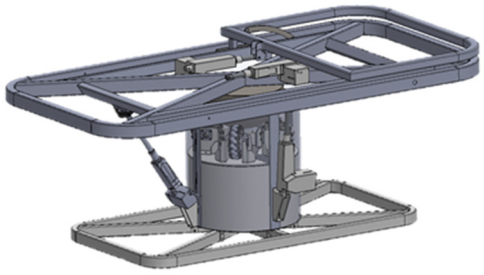

Figure 6. 3D Model of the redesign hospital bed prototype.

4.2.3 Stage III

A novel support system was created from the hospital bed re-designed in stage II. It consists of a knuckle joint and rotating mechanisms operatively arranged between a column and the support surface along with a movement mechanism operationally arranged to rotate the support surface.

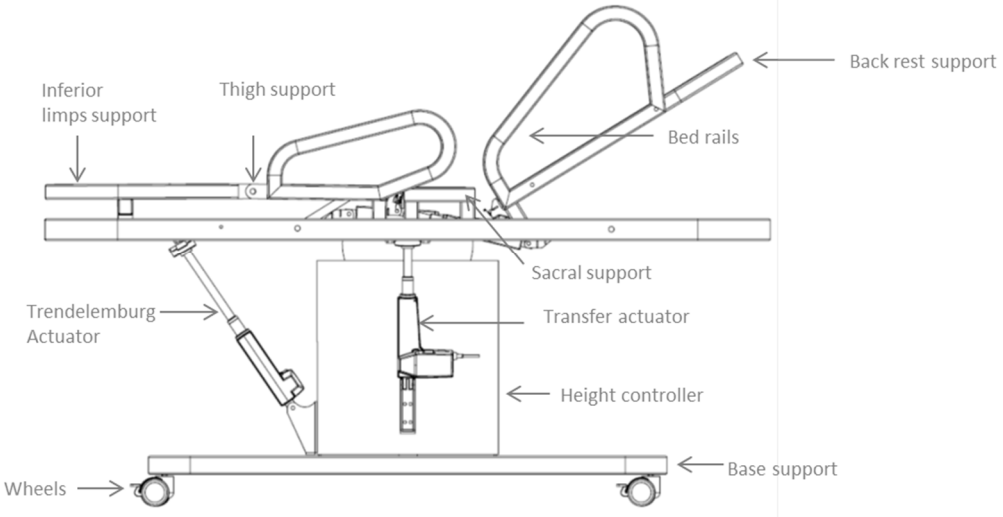

Figure 7. Hospital bed side view (Velásquez-López, et al., 2014).

As a result, it was created a hospital bed with movements in the three perpendicular axes. However, it was needed a big load to give it stability while rotating around the support column. It was also improved the design of the riels to adjust the contact with the limit sensors, they were shortened. The manufacture of the lineal actuators was modified in order to meet the design specifications. Besides, the caliber of the frame was reduced to decrease the total weight of the structure.
There are three levels in the bed structure, one above the other, with the aim of having efficient movements. The first level has the control function of the movements of the back and legs. The second level has a spherical structure to join the upper and lower segment allowing the Trendelenburg movement and the turn assist feature. The third level sustains the whole bed. It is attached to the second level and allows the change of height. Also, it has wheels letting the displacement of the bed and its control and stop system.
The construction of this prototype was complicated due to the curves of its design. Besides, it remained the problem of not having standard pieces to assemble the core of the hospital bed. In addition, there were some instability issues for loads applied in the borders higher than 150Kg. Besides, the volunteers testing of the product showed that there was a sensation of falling down of the bed. Another remark to be improved is the final weight of the bed to allow an easier displacement.

5 CONCLUSIONS

The suppliers are a key factor in the development of a research project like this one. It is the high importance to count with appropriate delivery times and suppliers. For imported items the shipping time took longer than expected. For this reason, there should be a very well defined plan scheme to avoid delays. Besides, the quality of the manufacture and assembly of the products have to be outstanding in order to avoid reprocesses and to obtain valuable products.
In addition, the manufacture process needs to be improved. There were different materials and pieces fabricated by external suppliers that took longer time in being delivered. In consequence the assembly of the prototypes was delayed. Again, the plan scheme needed to be improved taking into account the time limit and processing term.
After studying several designs and pilot prototypes it was necessary to find through analysis the appropriate materials that reached the medical specifications. This is a very critical part for a medical device to be successful. However, it increases remarkably the production costs. Moreover, further research is needed to develop an integral product. In this research project were used commercial polymeric fabrics for the construction of the alternating low air loss medical device and it was noticed that there are a lot of novel materials been developed around the world that could suit better the medical specifications.
Once the project has reached a development peak, if the technology is a novelty, it should have the correct legal protection in order to avoid plagiarism. Besides, the legal protection has to occur before any public demonstration of the products.
From this research project two patents are pending in Colombia and one in the World Intellectual Property Organization with the title ADAPTABLE BED FOR OBTAINING DIFFERENT POSITIONS, Submission Number: 065886, Application Number: PCT/IB2014/065886.
After 15 months of design and construction of many prototypes, it was possible to develop novel products that could be sell to the industry and being improved. This laboratory stage is the beginning for a commercial phase.

6 FUTURE WORK

In order to validate the developed products, clinical trials still will be performed at the Neurologic Institute of Colombia (INDEC).

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