# IMPROVING PRODUCT FUNCTIONALITY FOR CONSUMERS WITH DISABILITIES:

# THE CASE OF A CUSHION TO PREVENT PRESSURE ULCERS IN WHEELCHAIR USERS WITH SPINAL CORD INJURIES

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## ABSTRACT

Patients with mobility impairments who are wheelchair-bound (users) need to avoid the incidence of pressure ulcers, for which it typically is necessary to have a special cushion. The Rehabilitation Engineering Laboratory from the Instituto Nacional de Rehabilitación (INR) has developed a prototype cushion product.

The objective of this article is to demonstrate and understand how user perceptions can help to improve functionality in the product design of a wheelchair cushion. A satisfaction assessment model is developed such that a specific and holistic perspective of user perceptions regarding the prototype wheelchair cushion is taken into account. The approach taken allows for the evaluation of satisfaction over time.

**Key words: customer satisfaction, improved product design, customer/user evaluation.**

## INTRODUCTION

Gleaning users' perceptions regarding new or upgraded products has become a requirement to allow for continuous improvement. The objective of this case study is analyze the contribution of user perception on the functionality of a wheelchair cushion product design in order to enable improvements.

When we are talking about health, any contribution to the improvement of the product should be reflected in an increased quality of life for users. As Donabedian states (1992, p. 21), the quality of health care is "the degree to which the most desirable means are used to achieve the highest possible improvements in the health of each patient-user."

Embellishing upon this definition, Ruelas-Barajas in his public health research publication "Quality, Productivity and Costs" (1993) indicates that any improvement which involves greater product quality is a concept that must be judged on two closely interrelated and interdependent dimensions:

- The first is a technical one, represented by knowledge application and techniques for solving a patient's problem, which is normally reflected by the medical team.

- The other dimension is represented by the patient-user's relationship with the product and who supplies it.

As part of health care service, the purpose of Rehabilitation is to help an individual achieve the highest level of independence and quality of life possible, after a serious injury, illness or surgery.

One branch of rehabilitation service is orthotics and prosthetics, with goals to "restore the physical functioning and improve the overall welfare of patients through the provision of a device" (Peaco 2011, p. 95). Orthotics are external devices designed to modify the neuromuscular and skeletal system. A prosthetic is a device that replaces a missing body part. The design of a wheelchair cushion falls under the rehabilitation branch of medicine.

An assistive device should compensate for decreased or lost function and ability to manage daily life, maintain and preferably increase function and ability, and prevent future loss of function and ability (Samuelsson et. al, 2008). Satisfaction in this project, therefore, is defined "as a person's critical and positive evaluation of several aspects of a device" (Demers 2002, p. 102).

Assistive devices are evaluated primarily by the medical team through technical procedures, testing devices and apparatus. The user´s participation in this evaluation is typically limited to answering questions related to their health.

Peaco et al. (2011) developed a systematic literature review about assessing satisfaction with orthotic devices and services. The computerized databases analyzed were: PubMed (1950 to January 2010), CINAHL (1982 to January 2010), and RECAL Legacy (1900 to 2007). These authors found only a small number of unique publications about formalized measures of satisfaction. Several evaluations regarded specific devices other than wheelchair cushions (e.g.: elbow-wrist-hand orthotics). Other articles reported generic evaluations to apply to all services of this branch. Notably, Peaco et al.'s comprehensive literature review did not uncover even a single specific evaluation of satisfaction vis-a-vis different types of wheelchair cushions.

Another literature review specifically conducted in advance of this study found that the Quebec User Evaluation of Satisfaction with Assistive Technology Version 2.0 (QUEST 2.0) survey developed by Demers, Weiss-Lambrou and Ska (2002) and reported by Peaco et al. (2011) has been used to evaluate wheelchair cushion satisfaction in Canada (Barlow, Liu and Sekulic 2009) and China (Chan and Chan 2006).

The QUEST 2.0 is an outcome measurement instrument to evaluate a person's satisfaction with a wide range of assistive technology (Demers 2002) which evaluates both the device and the service. The device is assessed on eight variables: comfort, weight, durability, adjustments, simplicity of use, dimensions, effectiveness, and safety. The service aspect is assessed with four variables: delivery, professional service, follow up, and repairs and servicing.

Currently, the literature does not reveal a specific instrument to measure user satisfaction of wheelchair cushions that include the factors of functionality. The application of the QUEST 2.0 to evaluate general satisfaction with a wheelchair cushion is an important advance, but it does not include the evaluation of the specific factors of the wheelchair cushion's functionality, as proposed by current models of customer satisfaction. To maximize the improvement process of this product requires more specific and precise information.

The Mexican National Rehabilitation Institute (INR in Spanish), in the Rehabilitation Engineering Laboratory under the coordination of Professor Diana Gayol, designed and developed a prototype wheelchair cushion for wheelchair-bound patient/users, specifically those with spinal cord injuries. This wheelchair cushion was designed to prevent the formation of pressure ulcers, one of the most common complications of extended wheelchair use. Researchers estimate that such patients as these develop this kind of ulcer in 50% to 80% of the cases (Brienza, D., Iñigo, R., Cheng, K., 2003).

According to Cannon and Cannon (2004, p: 64), "ulcers are an area of damage caused by constant pressure, repetitive friction, and / or interruption of blood flow in a localized area, impeding the flow of oxygen to the cells of this tissue. If the pressure isn't released, the result is likely to be necrosis."

Among the devices used to prevent pressure ulcers are pressure redistribution attachments that conform themselves to the shape of the patient and distribute pressure to a larger area (Nixon, J. *et al.*, 2006). Poveda et al. (2000) present different types of wheelchair cushions:

- Foam cushions: inexpensive and low maintenance, but they become compressed over the time.
- Air cushions: lightweight and effective support but with high costs.
- Seats of water: climate comfort, but heavy.
- Gel cushions: effective support but heavy.
- Finally, custom made cushions: help to maintain posture and redistribute pressure away from high risk areas (not commercially known in Mexico).

The last type of wheelchair cushion is the object of study for this article (i.e., the prototype developed by the Laboratory of Rehabilitation).

## RESEARCH PURPOSE

The last type of wheelchair cushion in the list presented above is the object of study for this article (i.e., the prototype developed by the Laboratory of Rehabilitation).

The goal is to identify how user perception, regarding the functionality of the wheelchair cushion in their daily life experiences, contributes to the product design by identifying improvement opportunities.

## THEORETICAL FRAMEWORK

To measure satisfaction as a perceived quality of a product, some satisfaction models are used as the cornerstones for further research. They involve the participation of the users as the main source of evaluation. The following models for the assessment of satisfaction are cornerstones for this study:

- ACSI (American Customer Satisfaction Index, University of Michigan).
- IMSU (Mexican Satisfaction Index User-Universidad Iberoamericana, Mexico City).
- Deficiencies Model from Parasuraman, Berry and Zeithaml.
- Applications in the health field, such as the model for assessing the quality of service of a Public Health Institution (PHI) which is highly complex in its user satisfaction component (Bristow, 2001) and the model which Carina Rey (2000) entitled 'The user satisfaction: a concept on the rise,' among others.

The importance of modelling user satisfaction evaluation from different points of view is to determine the common elements of input and output that must be considered in a final, single model. Thus, we have:

Inputs:

- User Expectations.
- The perceived quality of the product.
- The activities or components of the process that influence
- perceived quality.

Processing element:

- User satisfaction.

Elements of outputs:

- Confidence in the product.
- Recommendation or opinion to offer others.
- Complaints that become improvement opportunities.

We believe that all of these elements must be considered in the development of research when evaluating a product's user perception and impact on user satisfaction.

### Perception of Functioning

Very specifically and within the scope of this research, there are specialized studies in the design of seats in which the main objective is to attain good quality for spinal cord injury wheelchair users. Within these category of study, Sprigle, S., Faisant, T., K. Chung stand out, mainly because of their publication "Clinical Evaluation of Custom-Contour Cushions for the Spinal Cord Injured," in which they indicate that all seats should be functionally assessed considering the following factors:

1. Trunk control: determined by the observation of patient stability while sitting and extending forward and backward.

2. Position: estimated by palpation and observation of the symmetry of the trunk, antero-posterior tilt of the pelvis, and general appearance.

3. Transfer capacity: estimated by identifying any change in the effort or the assistance received at the moment of the evaluation.

4. Comfort: evaluated by the people at rest and during propulsion.

5. Skin reaction: estimated as redness or skin irritation in the buttocks.

6. Propulsive power: identified by changes in the stability or the skill required to navigate different slopes and soil surfaces.

7. Ability to release pressure: for laterality or weight change, estimated by the ability to (re)position on the cushion.

8. Spasticity: evaluated at each cushion.

These factors are each a benchmark for assessment of the functionality or process activities (inputs) of the wheelchair cushions developed by the Rehabilitation Engineering Laboratory within the protocol-SALUD-CONACYT 2006-01-45395.

To further understand the functional independence of a spinal cord injury patient in a wheelchair, the internationally valid independence measures scale (FIM, for its acronym in English) is

used to quantify objectively the degree of patient disability at any given time and measure changes that occur in the treatment of rehabilitation. The scale assesses a total of 18 activities, grouped in two dimensions, 13 motor items (relating to self-care, continence and ambulation) and 5 cognitive items. Each of the activities is valued from 1 to 7, where 1 indicates total dependence and 7 complete independence. The final score varies between 18 and 126 (Vilches et al. 2009).

All these references allow us to frame theoretical research through the following question: how can user perception help to improve the functionality of a product in the design stage itself?

These references form the backdrop to this research in order to help determine how the user´s perception of functioning in daily life contributes to product design and how user perception can influence the continued improvement of the cushion product.

## RESEARCH METHOD

The design of the specific model of satisfaction evaluation for the prototype seat is based on the application of the methodology of the ACSI through IMSU experience as an adaptation to the satisfaction assessment system in Mexico (Lobato *et al*. 2006).

The functionality assessment factors offered by Sprigle et al. (1990) were taken into account while determining the input elements, with spasticity removed due to the fact that the sample did not have spasticity.

To arrive at a project definition, the design (see Figure 1) considered the following features:

- *Inputs:* the functionality aspects such as control of the trunk, posture, ability to transfer, comfort, skin reaction, propulsion ability and ability to relieve pressure; all of these inputs were supplied by the user. Likewise, the users' expectations and perceptions of quality are also considered as inputs.
- *Process elements:* satisfaction determination.
- *Output elements:* complaints management, ability to make recommendations to third party and confidence level.

The proposed model is formulated based on a descriptive, longitudinal study.

### Subject Recruitment

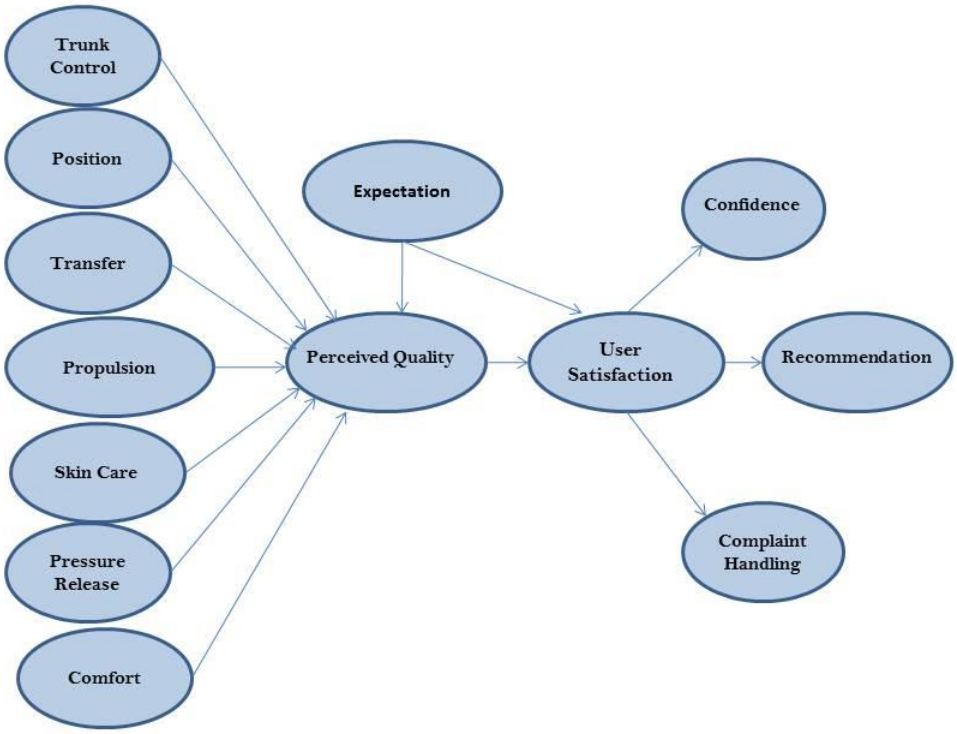
Fifteen volunteers with a spinal cord injury diagnosis were recruited, all of them beneficiaries of the INR in coordination with the Humanist Foundation to Assist the Disabled (FHADI, Fundación Humanista de Ayuda a Discapacitados, in Spanish). They all signed an informed consent document to participate in the research protocol which includes the assessment of their perception and their satisfaction. The characteristic of impaired mobility of the recruited persons complicates their transfer from their home to the INR. Also, these recruited persons needed to comply with medical and psychological criteria, factors which reduced the size of the population and resulting sample of such individuals.

Inclusion criteria were: FIM (Independence of functionality measurement) of more than 75 points, more than 2 years of evolution with the injury, not having another kind of disease, both sexes, aged between 18 and 60, having their own wheelchair and experience in using it.

The average age of the 15 users was 31.5 years ($\sigma = 7.35$) within the range of 22 to 47 years; there were eight men and seven women. The time since spinal cord injury was 8.27 years on average ($\sigma = 4.81$) with a minimum of three and a maximum of 22 years in the total sample. Even though the sample size was small, it included participants whose spinal cord injuries were situated in different levels: in two cases, it was at a cervical level (13%), in four cases it was at a high thoracic level (T1-T6) (27%), in eight cases, lower thoracic (T7-T12) (53%), and one case, lumbar (7 %).

**FIGURE 1**

**Proposed Satisfaction Assessing Model of Prototype Seat**




## Observation Times

The methodology consisted of measurements from three different points in time in order to observe the hoped-for improvement of the wheelchair cushion design. As such, this longitudinal study provided for the possibility of a continuous, modifiable process:

- Initially, "time zero", before use of prototype wheelchair cushion.
- After one month of use of the prototype wheelchair cushion, the "time one" portion of the study was conducted by the same researcher.
- After a year (12 months) of use, the "time two" portion of the study was conducted by the same researcher.

The data collected was used to design an instrument for the assessment of the wheelchair seats from the perspective of the users, and consisted of two sections (see **Appendix 1 and 2**): the first contains user expectations and perceived quality of a previous wheelchair cushion; the second section includes information after more than a month of use about perceived quality, overall satisfaction and every aspect of the aforementioned functionality of the prototype seat.

These instruments were administered in semi-structured form and were applied by only one researcher through personal interviews (face to face). We believe that this procedure led to richer, more useful user experiences and testimonies about perception of functioning.

## Assessment Procedure

### Time Zero Measurements

Step 1: At the beginning of the protocol, a technical evaluation (in order to be considered in the design of the prototypes seats) was applied to

each user by medical specialists. This evaluation included elements such as:

- The International Instrument for Functional Independence Measure (FIM, by its acronym in English).
- User propulsion angle measurements once seated in his/her wheelchair with his/her previous wheelchair cushion.
- Pressure map with the Force Sensory Array® (FSA) which verified the conditions of pressure brought by the user because of his/her wheelchair and his/her previous wheelchair cushion.

Step 2: A semi-structured interview was conducted based on an instrument previously defined for each user in order to collect information on:

- The expectations the each user had when they entered the protocol.
- The perceived quality of each user's seat cushion prior to entering the protocol.

This semi-structured interview was part of the methodology IMSU used to determine user satisfaction when there is no measuring instrument defined and validated for assessing wheelchair cushions.

We believe that it is noteworthy that, according to Woods (1987), semi-structured interviews as a qualitative methodology to identify user opinion or perception is broad in its application, and allows the gathering of more information. The study of experiential cases, the comparative description of parameters, the possibility of going into complaints in depth and identifying opportunities for improvement, are just some of the benefits of a semi-structured interview in which, face to face (Lobato et al. 2006), the interviewer and the respondent create an empathetic connection in the knowledge of the situation under study.

Besides the open-ended questions, the interviewer asked about issues that were assessed through a visual analogue scale (VAS) of 10 levels for each factor, where 10 was the maximum and 1 the minimum value (see Q's in **Appendix 1**).

Step 3: A prototype wheelchair cushion adapted to each subject's anthropometric measurements and fitted to the user's wheelchair was designed and delivered. Each prototype took into account all of the technical comments made by the physicians and engineering specialists team, as identified in step 1.

**Measurements in "time one"**

Step 4: A control evaluation for each user was carried out by the medical team after a month of use, applying again the FIM, the measurements of the propulsion angles and the map of pressures with the Force Sensory Array® (FSA). The results revealed that none had points of pressure.

Step 5: Another section of the semi-structured interview was conducted (see Q's in **Appendix 2**), using the 10 level VAS in order to assess elements of the proposed model, such as the perceived quality of the seat and the 7 factors of functionality for the inputs elements, and the general satisfaction for the processed element. The output elements were trust recommendations to third parties and complaints management.

Step 6: This step involved adjusting the seat design based on medical assessments and the feedback given by the users' perceptions and experiences (including graphs of pressure maps and photographs of design improvements in each case).

**Measurements in "time two"**

Step 7: Twelve months later, monitoring and control steps 4 and 5 were repeated.

The information gathered from the semi-structured interviews was processed in order to determine any trend in the results of the evaluation of perceived quality, satisfaction based on user perception, and every aspect of functionality of the delivered prototype wheelchair cushion.

## OUTCOMES

### Time "Zero"

Step 1: In the implementation of the medical assessment, the following results were obtained:

- The FIM average was 112.3 (on a scale from 0 to 126 points, where 126 is adequate).

- Only 13.3% of the patients presented propulsion angles of 120°. This angle of propulsion (120˚) is an average standard (which C. Brubaker (1992) considers adequate).

- 86.7% had inadequate propulsion angles (outside the range of 115° as a minimum and 130° as a maximum).

- Regarding the pressure maps, 100% of the patients had pressure areas above 70mmHg –which exceeds the maximum accepted value of pressure (H. Pain, 2002).

Step 2: The descriptive results of the semi-structured interviews (see Q's in **Appendix 1**):

Input elements:

- Regarding the expectation that users had to be invited to participate in the research protocol of INR prototype wheelchair cushions, an average score of 8.53 ($\sigma$=2.29) was calculated. The scale used was 1 to 10 points.

During the semi-structured interview, it was shown that the motivations for low expectations ratings were influenced by: unpleasant previous experiences and fears that unpleasant experiences from previous protocols would be repeated; lack of credibility of the product based on the status as a prototype rather than a commercial product; failure to assess the product due to a lack of cost to users; and lack of knowledge of the organizations that support the research and its scope.

Regarding high expectations ratings, it was found that they were influenced by: previous positive experiences with INR and their protocols; the need for a product to help them; and finally, positive interactions with previous users of the same protocol.

- As for the Perceived Quality of their previous seat, a mean of 5.80 was obtained ($\sigma$=2.21). The scale used was 1 to 10 points where 10 equated to outstanding high quality.

Step 3: Fifteen prototype wheelchair cushions were individually designed, adapted to the judged needs of each of the fifteen users, and delivered.

## Time One and Time Two

Due to the fact that the assessment procedure was exactly the same for time one (after a month of use) and for time two (after 12 months), results are reported together and in a comparative manner.

Step 4: When making medical assessments of the user sitting in his/her prototype wheelchair cushion, the following issues were observed:

- No change had taken place in the FIM (medical assessment scale) in either a month or a year compared to time Zero. Thus, we can infer that no change had taken place in the wheelchair cushion design. However, there was variation in user perception, which was taken into account in order to adjust the wheelchair cushion design (see section below pertaining to the descriptive contributions of user perceptions).

- The angle of propulsion was adjusted to 100% in the given prototype wheelchair cushion design, and all users stayed within a range from 115° to 127°. Sixty-seven percent (67%) of the users specifically got an angle of 120°, which is considered adequate.

- The pressure maps for each wheelchair cushion scored higher distributions than the initial measures related to user support area and in compliance with the appropriate reference level of 70 mmHg (see example in **Figure 2**).

There was no skin reaction, and the formation of pressure ulcers was prevented in all cases (which was the objective of the prototype wheelchair cushion).

Step 5: When applying the semi-structured interview to user perception about the proposed model and regarding the input elements in terms of the specific features of functionality, the results were as follows (see **Table 3**).

**TABLE 3**

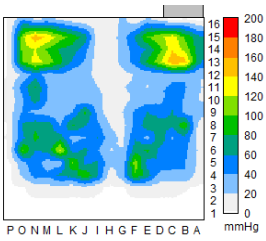
**Results of the Input Elements:**
**Functionality Factors after a Month and after a Year of Use of the Delivered Prototype Wheelchair Cushion**

| | Time One | | Time Two | |
|---|---|---|---|---|
| | **1 month** | **Standard deviation** | **12 months** | **Standard deviation** |
| **Trunk control** | 8.20 | 1.78 | 8.54 | 1.33 |
| **Position** | 9.20 | 1.61 | 9.31 | 0.95 |
| **Pressure release** | 8.80 | 1.78 | 9.46 | 0.66 |
| **Transfer** | 7.20 | 3.19 | 8.46 | 2.26 |
| **Propulsion** | 7.93 | 2.40 | 9.23 | 0.93 |
| **Skin reaction** | 8.60 | 2.64 | 9.77 | 0.60 |
| **Comfort** | 8.80 | 1.93 | 9.62 | 0.77 |

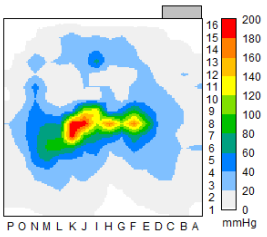
**Source:** Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR, 2009.

**FIGURE 2**
**Examples of Pressure Maps for the Same User**

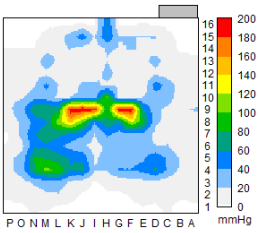
User's pressure map when sitting on previous seat



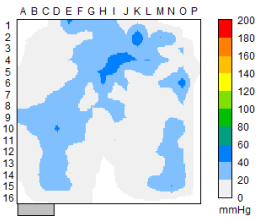

Pressure map evaluation in phase of design




Pressure map evaluation in phase of design




Final user's pressure map when sitting on prototype




- **Source**: Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR 2009.
- **Legend**: darker areas represent areas of higher pressure. Pressure less than or equal to 70 mmHg is considered appropriate.

**Note: There was no skin reaction, and the formation of pressure ulcers was prevented in all cases (which was the overriding objective of the prototype wheelchair cushion project).**

Regarding Perceived Quality, the summary data is presented in **Table 4**.

**TABLE 4**

**Results of the Input Elements:**
**Perceived Quality after a Month and a Year of Use of**
**the Delivered Prototype Wheelchair Cushion**

| | Time One | | Time Two | |
|---|---|---|---|---|
| | **1 month** | **Standard deviation** | **12 months** | **Standard deviation** |
| **Product perceived quality** | 8.80 | 1.37 | 9.23 | 0.73 |

**Source**: Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR, 2009.

**Process Element**

The user satisfaction figures obtained are listed in **Table 5.**

**TABLE 5**

**Process Element Results:**
**General Satisfaction after a Month and a Year of Use of**
**the Delivered Prototype Wheelchair Cushion**

| | Time One | | Time Two | |
|---|---|---|---|---|
| | **1 month** | **Standard deviation** | **12 months** | **Standard deviation** |
| **General Satisfaction** | 9.00 | 1.20 | 9.31 | 0.85 |

**Source**: Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR, 2009.

**Output items**

Regarding the possibility of recommending the wheelchair cushion and the confidence that, in the future, this product may benefit other users, the data obtained is shown in **Table 6**.

**Table 6**

**Results of the Output Items:**
**Recommendation to Third Parties and Confidence Level**
**after a Month and a Year of Use of Delivered Prototype Wheelchair Cushion**

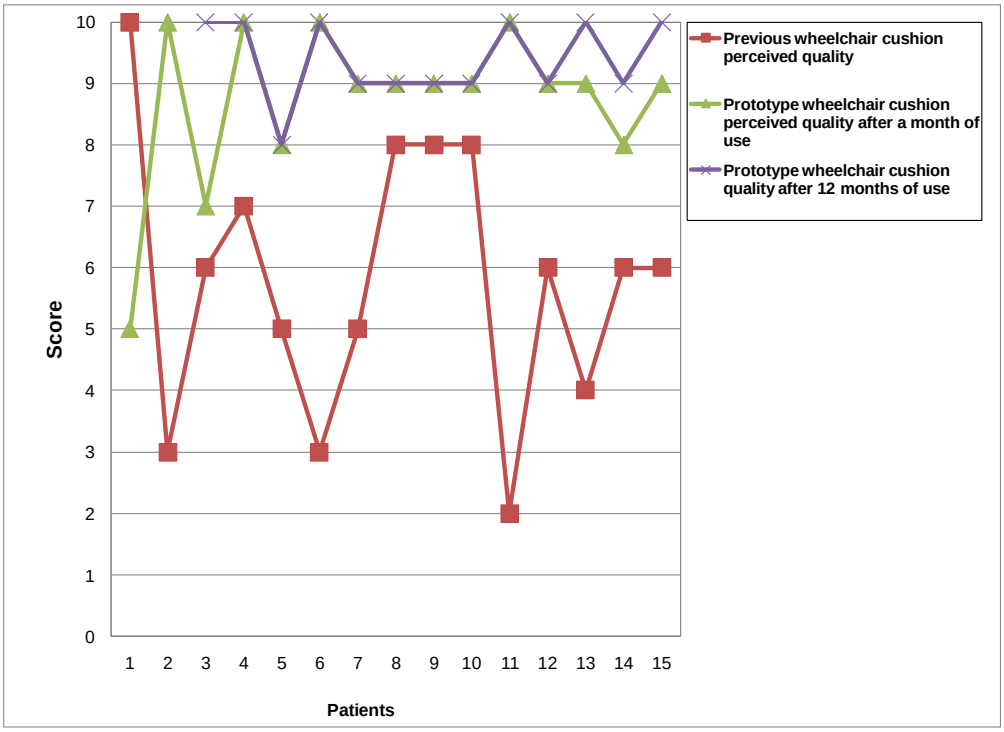
| | Time One | | Time Two | |
|---|---|---|---|---|
| | **1 month** | **Standard deviation** | **12 months** | **Standard deviation** |
| **Recommendation to third parties** | 9.67 | 0.62 | 9.92 | 0.28 |
| **Confidence Level** | 9.80 | 0.56 | 10.00 | 0.00 |

**Source**: Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR, 2009.

To present an integrated analysis of user perceptions we established a comparison between the values of the previous seat (time zero) user's perceived quality and the delivered prototype wheelchair cushion after a month and a year of use (times one and two, respectively) (**see Figure 3**).

**Figure 3**

**Results of the Input Element: Perceived Quality of Satisfaction Evaluation Model**




**Source**: Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR 2009

**Figure 3** reveals that the perceived quality of the delivered prototype wheelchair cushion was higher than that of the previous wheelchair cushion, both after a month and after a year of use. (It is important to note that for the 1-year follow-up, two of the initial 15 users were not involved in the monitoring, and they reported that they were not using the seat; so, only 13 active users remained for the complete year monitoring.)

## PROTOTYPE WHEELCHAIR CUSHION DESIGN PERCEPTION: DESCRIPTIVE CONTRIBUTION TO A CONTINUOUS IMPROVEMENT PROCESS

In the semi-structured interviews, user complaints served to identify improvement opportunities for the design of the wheelchair cushion. For example:

- 26.6% of the subjects identified problems in the transfer process, and in the height of the lateral sides of their wheelchair. This feedback led to an adjustment to the design of the wheelchair cushion without laterals in the cases where this was medically and technically possible.
- 20% of the subjects commented on the problem of instability generated by the wheelchair. This feedback led to the design of the wheelchair cushion to take into account tilt angles compared to the wheelchair, ensuring balance and the pressure release of the ischial tuberosities in order to prevent ulcers.
- 20% of the subjects commented on the poor posture they had to assume in the wheelchair with the previous wheelchair cushion. These comments led to an alteration of the wheelchair cushion height and the propulsion angle, which improved not only the users' posture but also trunk control and their ability to propel the wheelchair (see **Figure 4**).

Last, but not least, it should be noted that in 46.6% of the cases, the wheelchairs themselves were incorrectly prescribed, as was identified by the specialized physicians team.

**FIGURE 4**

**User with Prior Seat (left) and User with the Prototype Wheelchair Cushion (right)**

**Source**: Draft Protocol User CONACyT-SALUD-2006-1-45395 INR 2009

Finally, in order to understand perception during the wheelchair cushion learning-adjustment process, we compared the perceived quality, the overall satisfaction, the general functionality and each process-functionality factor after 1 month (time one) and 12 months of use (time two) (see **Table 7**).

**Table 7**

**Satisfaction and Functional Assessment of Prototype Wheelchair Cushions while Measuring Functionality and User Experience**

| | | Time One | | Time Two | |
|---|---|---|---|---|---|
| | | 1 month | Standard deviation | 12 months | Standard deviation |
| General Questions | Product perceived quality | 8.80 | 1.37 | 9.23 | 0.73 |
| | General Satisfaction | 9.00 | 1.20 | 9.31 | 0.85 |
| | General Functionality | 8.80 | 1.61 | 9.23 | 0.93 |
| Functionality features | Trunk control | 8.20 | 1.78 | 8.54 | 1.33 |
| | Position | 9.20 | 1.61 | 9.31 | 0.95 |
| | Pressure release | 8.80 | 1.78 | 9.46 | 0.66 |
| | Transfer capacity | 7.20 | 3.19 | 8.46 | 2.26 |
| | Propulsion capacity | 7.93 | 2.40 | 9.23 | 0.93 |
| | Skin reaction | 8.60 | 2.64 | 9.77 | 0.60 |
| | Comfort | 8.80 | 1.93 | 9.62 | 0.77 |

**Source**: Members of the Draft Protocol CONACyT-SALUD-2006-1-45395 INR 2009.

The results portrayed in **Table 7** support the following conclusions:

- Although the FIM scale does not show any change in its assessment, the patients do perceive the change, as evidenced by the previous wheelchair cushion perceived quality and that of the delivered prototype wheelchair cushion.

- While the user employs the prototype wheelchair cushion, an adaptation of movement is shown which favors perception in all functional aspects and of satisfaction over time. It is relevant to note that in all model elements (input, process and output), when comparing time one and time two, there is an improvement in the rating of user perceptions and their standard deviations are lower, which suggest more commonality of opinion after one year of use.

- The technical design assessments are complemented by the expression of user experience and functionality.

At this stage of the research protocol, the wheelchair cushion absorbed the weaknesses of the wheelchair itself to achieve measurable characteristics such as propulsion angles and heights needed to increase transfer capabilities.

## CONCLUSION

This study was designed to recruit only persons with significant mobility impairments and serious medical and psychological problems, which hinder their transfer to INR. These recruitment requirements were one of the reasons causing the sample size to be small. Fortunately, a variety of spinal cord injuries were represented. Another limiting factor was the dependence on grants that limited the materials and human resources the authors of this study could use. The outcomes of this study, however, proved to be very useful because the design and production processes were improved upon and the protocol implemented here will be more widely used in the future.

## Main Findings

Clinical measurements related to functionality (FIM) do not well-reflect user perceptions regarding the delivered prototype wheelchair cushions.

Users of the prototype wheelchair cushion define, according to their experiences in the activities of their daily life, the design features that must be incorporated on the prototype wheelchair cushions such as weight, width, height of the lateral sides, and support for the sacrum area, among others.

The proposed satisfaction assessment model allows, through all the defined elements, a specific and holistic perspective of user perceptions regarding the prototype wheelchair cushion, and also allows the evaluation of satisfaction longitudinally over time.

According to the bibliographical research which has been carried out, there are only studies that compare different pressure release systems, without evidence of their use in patients with neurological injuries (e. g., Phillips *et al*., 1999; Cullum *et al*., 2004; Brown, S., 2001; and Crane *et al*., 2007), although a pair of studies used a generic assistive technology instrument in order to evaluate satisfaction in wheelchair cushions. No published study was found that assessed the specific factors of wheelchair cushion functionality in daily life activities. The present study, therefore, can be viewed as ground-breaking.

Of course, a limitation of this study is the fact that the small sample size affects external validity, thus, limiting generalizability. We are hopeful that this exploratory inquiry will generate bigger grants to conduct larger scale studies using the protocol described herein. With a significantly larger sample size, it would then be possible to rigorously compare different groups of spinal cord injury patients (patients categorized as acute (e.g., less than two years of having the injury) and patients categorized as chronic (e.g., more than two years of having the spinal cord injury).

## Practical Implications of the Research Results

A strong inference gained from this study is the necessity to establish enhanced/improved clinical assessments regarding wheetchair cushion functionality that are more specific and sensitive to the perceptual needs of patients with spinal cord injuries.

It is necessary to validate the perceived quality and its impact on user satisfaction in the seats, under the condition that the wheelchair is prescribed and properly designed, since some of the complaints-improvement opportunities reflect that the prototype cushions absorb the deficiencies of wheelchairs, such as the height of the seat (which affected the propulsion angle), the width (which influenced the design of the lateral sides of the seat and did not suit itself to transfers), the height of the back (which affected the position for propulsion), among others. Addressing all of these complaints led to significantly increased user perceptions of quality and satisfaction with the finally configured prototype seat.

Facilitating the propulsion capacity and the transfer capacity when diminishing lateral sides and the weight of the seat were seen as design improvement opportunities.

It has been possible to carry out this work due to the fact that it is immersed within the monitoring phase of the research protocol of the National Rehabilitation Institute (INR), coordinated by the Rehabilitation Engineering Laboratory, along with the Neurological Rehabilitation Service of the INR, with the support of the Universidad Iberoamericana Ciudad de Mexico, and it has had the backing of the National Council of Science and Technology (CONACYT, by its Spanish acronym), under code SALUD-2006-key 1-45395.

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## APPENDIX 1

(Applied at time zero)

DATE: dd/mm/yy

| | | | | | |
|---|---|---|---|---|---|
| GENDER | FEMALE: | | MALE: | | |
| AGE (years) | | | | | |
| TYPE AND LEVEL OF INJURY | LM: COMPLETE | | INCOMPLETE | | |
| INJURY TIME | | | | | |
| THE SEAT YOU HAVE BEFORE THE PROTOCOL WAS: | SELECTED AN PURCHASED BY YOU | DONATED | CAME WITH THE WHEELCHAIR: | CUSTOM MADE | OTHER |
| SEAT TIME | | | Hours | | |
| AVERAGE DAYS PER WEEK THAT: | | | Days | | |
| DAILY ACTIVITIES | | | (Listed) | | |
| WORK | YES: | NO: | USED SEAT | YES | NO |
| STUDY | YES: | NO: | USED SEAT | YES | NO |
| SPORT | YES: | NO: | USED SEAT | YES | NO |

| Number | Description | Question |
|---|---|---|
| 1 | Expectation of the overall product quality before entering the research protocol on the prototype seat of the INR | At the moment you were invited to participate as a user in the research protocol of the seats (pressure relief systems) in the INR, probably you thought something (expectation) regarding the product you would receive. Try to remember what your thought about it was. |
| | | How this seat would contribute to you (i.e., how useful would it result)? |
| | | Please, answer on a scale from 1 to 10, where "1" means that "you thought it wasn't going to be useful" and "10" means that "you thought it would be very useful". |
| | | Before starting the protocol, what did you think about how this seat would help you? |
| 2 | **Previous Perceived Quality** | Try to remember the moment when you were delivered the prototype seat, here at the INR. Remember the seat you brought with you. |
| | | How would you describe this seat you brought? |
| | | Please, answer on a scale from 1 to 10, where "1" means "very bad" and "10" means "very good". |
| | | How would you qualify the seat you brought? |

Now, let's evaluate some functionality aspects of the delivered prototype seat on your daily activities or routine

## APPENDIX 2

(Applied at time one and time two)

We'll appreciate your honesty while answering because this will enable us to achieve continuous improvements in this prototype seat.

If possible, it is important that your answers represent the generality of ALL your activities.
If you consider that there is an important event which is worth mentioning in detail, please, let us know about it.

| Number | Description | Specific Questions |
|---|---|---|
| 3 | Regarding equilibrium and / or balance | While using the delivered prototype seat. |
| | | How much did the seat help you to keep your stability or balance? |
| | | Please, answer on a scale from 1 to 10, where "1" means "unhelpful" and "10" means "it helped a lot". |
| | | How much did the seat help you to keep your stability or balance? |

| | | |
|---|---|---|
| 4 | Regarding the position | While using the delivered prototype seat. |
| | | How useful was the seat in maintaining a proper posture? |
| | | Please, answer on a scale from 1 to 10, where "1" means "unhelpful" and "10" means "it helped a lot". |
| | | How useful was the seat in maintaining a proper posture? |
| 5 | Regarding the ability to release pressure | While using the delivered prototype seat. |
| | | How helpful was the seat in maintaining your ability to release pressure when sitting on it? (getting up, weight changes and inclinations) |
| | | Please, answer on a scale from 1 to 10, where "1" means "unhelpful" and "10" means "it helped a lot". |
| | | How helpful was the seat in maintaining your ability to release pressure when sitting on it? (getting up, weight changes and inclinations) |
| 6 | Regarding the ability to transfer | While using the delivered prototype seat. |
| | | How helpful was the seat in maintaining your ability to transfer? |
| | | Please, answer on a scale from 1 to 10, where "1" means "unhelpful" and "10" means "it helped a lot". |
| | | How helpful was the seat in maintaining your ability to transfer? |
| 7 | Regarding the effect of propulsion | While using the delivered prototype seat. |
| | | How helpful was the seat about the effect of propulsion in the different surfaces and levels? |
| | | Please, answer on a scale from 1 to 10, where "1" means "unhelpful" and "10" means "it helped a lot". |
| | | How helpful was the seat about the effect of propulsion in the different surfaces and levels? |
| 8 | Regarding the skin reaction | While using the delivered prototype seat. |
| | | How helpful were the design and materials of the seat? Did they help with your skin care and to prevent a reaction? |
| | | Please respond on a scale of 1 to 10, "1 " means "not conducive at all" and "10" means "very conducive". |
| | | How helpful were the design and materials of the seat? Did they help with your skin care and to prevent a reaction? |
| 9 | Regarding comfort | While using the delivered prototype seat. |
| | | How do you think is the comfort given by the prototype seat? |
| | | Please respond on a scale of 1 to 10, "1 " means "not comfortable at all" and "10" means "very comfortable". |
| | | How do you think is the comfort given by the prototype seat? |

| Number | Description | GENERAL QUESTIONS |
|---|---|---|
| 11 | Overall assessment of the perceived quality | In general terms, considering the product received during your stay in the research protocol of the prototype seat protocol at the INR, |
| | | How do you rate the prototype seat? |
| | | Please respond on a scale from 1 to 10, where "1" means "very bad" and "10" means "very good". |
| | | How do you rate the prototype seat? |
| 12 | General satisfaction with the INR protocol prototype seat | In general terms, how satisfied or not satisfied are you about to the prototype seat? |
| | | Please, answer on a scale from 1 to 10, where "1" means "absolutely not satisfied" and "10" means "completely satisfied". |
| | | In general, how satisfied or not satisfied are you about the prototype seat? |
| 13 | Functionality of the prototype seat | According to all your answers |
| | | In general terms, and considering all the daily life activities you carry on |
| | | How functional do you find the prototype seat? |
| | | Please, answer on a scale from 1 to 10, where "1" means "totally dysfunctional" and "10" means "completely functional". |
| | | How functional do you find the prototype seat? |

| Number | Description | Question |
|---|---|---|
| 14 | Willingness to recommend or to speak well of the prototype seat. | How willing are you to recommend or to speak well of the prototype seat? |
| | | Please, answer on a scale from 1 to 10, where "1" means "not willing" and "10" means "completely willing". |
| | | How willing are you to recommend or to speak well of the prototype seat? |
| 15 | Confidence on the fact that the prototype seat will provide a good service to protocol users in the future | In the future, how confident do you feel on the fact that the prototype seat will provide a good service to next users? |
| | | Please respond on a scale from 1 to 10, where "1" means "not, I don't trust on it" and "10" means "I really trust on it". |
| | | In the future, how confident do you feel on the fact that the prototype seat will provide a good service to next users? |