Aspects determining adherence to wrist-hand orthoses in patients with peripheral neuropathies

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Abstract.

BACKGROUND: People with peripheral neuropathies suffer significant sensorimotor impairment. Prescribed treatment includes the use of orthosis. However, a common obstacle to treatment efficacy

is patient adherence. Given the limited information available, gathering evidence on adherence to orthotic treatment is essential.

OBJECTIVE: This study aims to identify aspects that influence adherence to orthotic treatment in patients with peripheral neuropathies.

METHODS: We applied a survey including items from the assistive device evaluation section of Quest 2.0 and self-developed questions to assess the importance and satisfaction of wrist-hand orthosis users. We used the principles of the Kano model to understand the nature of issues influencing adherence and prioritize opportunities for product improvement.

RESULTS: User satisfaction with the ease of adjustment, weight, comfort, effectiveness, durability, dimensions, and appearance of orthoses influences treatment adherence.

CONCLUSIONS: We found differences in estimating the importance of orthosis aspects from direct consultation and estimation from the satisfaction-adherence correlation. Satisfaction is an indirect measure of importance and an adequate predictor of adherence.

The application of Kano's model allows a more precise identification of the influence of orthosis attributes on adherence. This method describes relationships between aspects that are not discernible in linear models.

Keywords: hand, orthosis, adherence, satisfaction, QUEST 2.0, Kano's model.

1. Introduction

Traumatic peripheral nerve injuries cause chronic pain and significantly impair sensorimotor functions. In the long term, they can reduce patients' quality of life who acquire permanent secondary disability [1,2].

Symptomatology includes forearm and hand motor dysfunction, decreased or increased sensation, muscle tone and strength loss, pain from non-painful stimuli, numbness, tingling, and stabbing sensations [3]. Most peripheral neuropathies involve the upper limb [4], with a higher incidence in the ulnar nerve, followed by the median and radial nerve [5,6].

Despite the multiple effects, the incidence of peripheral nerve injuries remains poorly known [7]. The available statistics come from some retrospective studies in the trauma population. In 2009, a Sweden review [8] reported an incidence rate of 13.9/100,000. The same year, a study in Turkey [9] found a rate between 2% and 2.8%, and 5% if plexus and root injuries were included. In 2018, a study in Germany [10] reported that 3.3% of all upper extremity trauma patients had additional nerve injuries. A recent study in the United States (2022) [7] reported an overall incidence of 2.6%. Additionally, Huckhagel et al. [10] highlighted that patients with nerve involvement had a more extended primary hospital stay (30.6 d vs. 24.2 d) and required more subsequent hospital rehabilitation (36.0% vs. 29.2%) vs. trauma patients without nerve injuries. Portincasa et al. [11] reveal that the

incidence of neuropathic injuries has been increasing since 1993 and postulates that the decline in the number of discharges may reflect a growing subset of persons with these injuries who do not seek medical care.

Treatment of peripheral neuropathies usually involves the use of orthosis. However, effectiveness depends on adequate compliance with the therapeutic protocol [12,13]. Partial compliance (or dropout) leads to worse patient outcomes. It can reduce treatment benefits, affect recovery, increase the risk of disability, and bias the assessment of treatment efficacy [13,14]. It also contributes to increased costs to the healthcare system and decreased labor productivity [15].

The World Health Organization [16] defines adherence to treatment as "the extent to which a person's behavior - taking medication, following a diet, and executing lifestyle changes, corresponds with agreed recommendations from a health care provider." Most of the literature on adherence focuses on medication or exercise therapy. In the field of hand orthoses, almost all of the available studies on adherence rates include patients with stroke [17-19], rheumatoid arthritis [20-23], and tendon repair [24,25]. According to our review, only two studies have measured the frequency of hand orthosis use in patients with peripheral nerve injuries [26,27], and they did so through self-developed questionnaires.

Satisfaction is another variable studied in the field of orthotics. Some studies suggest a possible relationship between satisfaction and adherence [28-31]. However, we have not found any study that has measured both variables and presented evidence of their relationship. Most studies use validated tools such as the Orthotics and Prosthetics

User Survey (OPUS) [32,33] and the Quebec Assistive Technology User Satisfaction Evaluation Tool (QUEST 2.0) [31,34-36]. Although, to a lesser extent, self-developed questionnaires [30] are also used. Both instruments (OPUS and QUEST 2.0) allow determining the degree of satisfaction through a 5-point Likert scale that assesses aspects of the assistive device (e.g., weight, fit, comfort, among others) and aspects associated with the service (e.g., attention from the therapist, delivery time, follow-up, among others). Therefore, the assessment of overall satisfaction responds to the weighting of both sections. A recent systematic review [37] highlights the difficulty of measuring satisfaction with orthoses precisely because patients' ratings result from their experiences with the services and devices provided.

Additionally, these assessment methods assume that satisfaction components linearly influence overall satisfaction throughout their range of variation. For example, the study by Joseph et al. [31] measured satisfaction with orthoses using QUEST 2.0 [34]. The authors note that the aspects that users considered important (ease of use, effectiveness, and comfort) did not score highest on the satisfaction scale. Therefore, they recommend improving these attributes to increase patient satisfaction with the device and therapeutic experience. The scope of the method itself determines the scope of the recommendations. In this case, QUEST 2.0 provides an overview that does not allow them to determine precisely how much influence each aspect has on the overall assessment.

However, in product development, there are more precise methods for considering asymmetric (non-linear) relationships between attribute

performance and overall satisfaction. This type of behavior can be explained by the three-factor theory of Kano et al. [38]. This model starts from the premise that the level of fulfillment of a given requirement does not necessarily affect overall satisfaction in the same way throughout its range. Thus, Kano's model differentiates three types of requirements according to the type of response to overall satisfaction. Performance requirements have linear behavior so that a higher or lower level of compliance means a higher or lower level of satisfaction. However, the other two criteria have non-linear behavior, so they only affect the overall satisfaction in one area of their verification range. Basic quality requirements only influence (negatively) overall satisfaction when not verified, but improvements above a certain threshold do not affect overall satisfaction. Otherwise, delighter requirements only affect the overall rating when they are present, the user does not expect them, and their absence does not negatively affect the overall rating. The distinction between the three types of criteria is relevant when assessing the influence of various attributes on overall user satisfaction. Considering all requirements as linear may mask the effect of those that only act in the part of their rating range.

The three-factor theory has been applied in fields as diverse as the automotive industry [39-41], education [42-44], real estate [45], tourism [46-49], retail [50,51], delivery services [52], logistic [53] and health services [54-60].

According to our review, no study has assessed satisfaction and adherence in hand orthoses considering possible non-linear or asymmetrical effects. Consequently, the objectives of this study are:

(1) to identify the determining aspects of adherence to orthotic treatment in patients with peripheral neuropathy, (2) to establish the relationship between the aspects and adherence to orthotic treatment, and (3) to classify the aspects according to Kano's three-factor theory.

2. Materials and methods

2.1. Participants

The study targeted participants aged 18 to 65 from Colombia or Spain with ulnar, median, or radial nerve injuries who had used hand orthoses. We collected data independently through the Pollfish survey platform [61]. The Ethics Committee for Research in Medicines of the Hospital Universitario y Politécnico La Fe (CEIm La Fe) approved the study protocol. Registration number 2020-035-1.

2.2. Questionnaire

We used the items from the assistive device section of QUEST 2.0: dimensions, weight, safety, durability, comfort, effectiveness, ease of use, and ease of adjustment. Additionally, we created six screening questions on the type of injury and orthosis used, frequency of use, adverse effects, and two dichotomous questions on intention to abandon treatment and interference with daily activities. Finally, we developed an open-ended question to receive recommendations for improving orthosis design. The type of information inquired and its distribution in the survey is in Table 1. The questionnaire is available in Appendix 1.

Table 1.

Information gathered in the survey

Information requested	Question (Q)
About the pathology	1
Orthosis classification	2
Satisfaction (QUEST 2.0 items)	3
Importance (QUEST 2.0 items)	4
Adherence (Intention to abandon)	5
Frequency of use	6
Performance (Daily activities)	7
Adverse effects (physical and emotional)	8
Design criteria	9

2.3. Relationship between the aspects of orthosis and adherence to treatment

To minimize the risk of bias, we evaluated the aspects involved in adherence directly and indirectly (from the relationship between satisfaction with each aspect and adherence). In the direct inquiry, participants selected the three aspects they considered most important in the orthosis (Q4) and answered whether they intended to abandon treatment (Q5). In the indirect inquiry, the importance of each attribute is established according to its influence on adherence.

In summary, the variables used are as follows:

1. Direct importance of each aspect. The dichotomous variable takes the value zero (0) if the user has not selected the attribute in the direct question and the value one (1) if the user has selected it.

2. Indirect importance. It was quantified using the relationship between satisfaction with the aspect and adherence. We used Conditional Gamma as a parameter of importance in the cross-tabulation of each aspect with adherence.

2.4. Classification of attributes according to the Kano model

We classified the determining aspects of orthosis adherence according to Kano's model [38], which classifies the factors or attributes into

three categories, depending on how the attribute contributes to the user's overall satisfaction:

1. The basic factors are minimum requirements that cause dissatisfaction when they do not meet the customer's expectations but which go unnoticed once they reach a certain threshold. In other words, they are essential quality aspects without which customers will poorly rate the product.

2. Delighter factors do not affect overall satisfaction when they are not present, but they do increase satisfaction when they appear. These are over-quality requirements. Users do not expect them but value them positively if the product incorporates them.

3. Linear or performance factors directly correlate with overall satisfaction. The better the performance, the higher the overall satisfaction, and vice versa.

Figure 1 shows the relationship between satisfaction with an attribute (X-axis) and overall product rating or adherence in our study (Y-axis). The basic factors (shown in gray at the bottom of the graph) only influence overall satisfaction when they are poorly rated (third quadrant), but not if they are well rated. The excitatory (or over-quality) factors have a positive influence on the overall rating above a certain threshold (first quadrant) but have no effect below this threshold (gray, upper part of the graph). Finally, linear factors (in dashed black) have a monotonic relationship with overall satisfaction

throughout their rating range (positive or negative, first and third quadrants, respectively).

To quantitatively determine when an attribute is of basic, linear, or delighter quality, we use the method proposed by Llinares and Page [45] based on correlations between overall satisfaction (or adherence in our case) and the rating of each quality attribute or factor.

The users' ratings are segmented into two sections, depending on whether their rating is above the mean (positive rating or P) or below the mean (negative rating or N). Segmentation allows the calculation of two correlations for each factor or attribute with the overall rating (or adherence). We calculated the R^P correlation using the responses in section P, which corresponds to the judgments of the users who have rated this factor positively. On the other hand, we obtained the R^N correlation by using the responses of the users who rated it negatively (section N). From the comparisons between R^P and R^N, four possible combinations define the type of attribute in Kano's model (Fig. 1):

A) Basic factors. In this case, $R^N > 0$, while $R^P = 0$. This relationship indicates that the attribute affects the overall rating when it is poorly rated (zone N) but not when it is positively rated.

B) Exciting or delighter factors. Here the effect on overall satisfaction appears only in the P zone, i.e., when it is rated well. However, if it is not present or is rated poorly (zone N), it does not affect the overall rating. This implies that $R^N = 0$, while $R^P > 0$.

C) Finally, linear or performance factors have a uniform relationship with overall satisfaction ($R^N > 0$ and $R^P > 0$).

The combination of ($R^N = 0$ and $R^P = 0$) indicates that the attribute is irrelevant because it does not influence overall satisfaction.

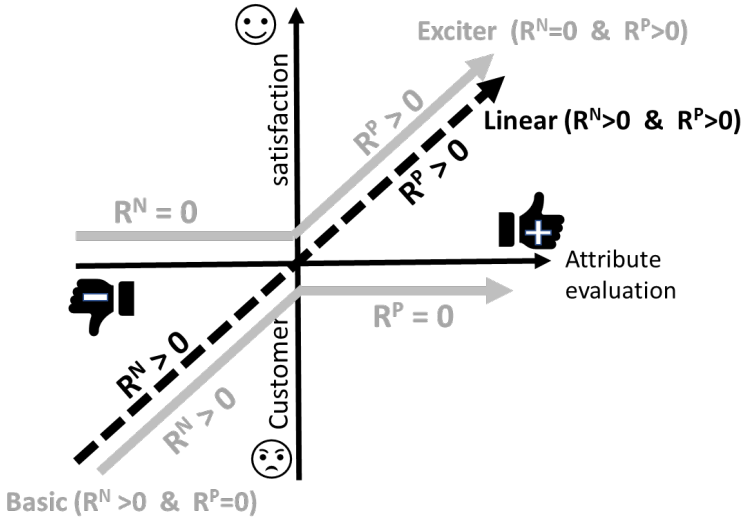

Fig. 1. Kano's model of customer satisfaction (adapted from Llinares and Page, 2011)

Our study applied this adaptation of Kano's model to contrast satisfaction with orthosis aspects and adherence. We calculated Gamma correlation coefficients between the score of each QUEST 2.0 item when satisfied and dissatisfied and the adherence variable (intention to drop out). Thus, we obtained the two correlation coefficients in the regions described by the authors as negative attribute region (R^N) and positive attribute region (R^P) (Fig. 2).

2.5. Data analysis

The relationship between the perceived importance of the aspects (direct) and adherence was quantified using Conditional Gamma in the direct importance-adherence cross-tabulation. The exact process was followed for the satisfaction-adherence relationship (indirect importance). Data were processed with the statistical package Statgraphics Centurion 19.2.02.

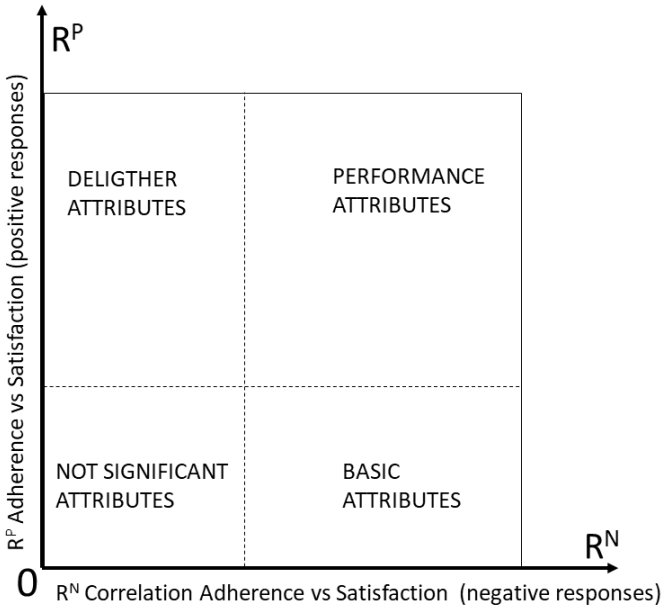

Fig. 2. Classification of attributes according to the correlation between Adherence and Satisfaction. The "negative responses" axis shows the relationship between Satisfaction and Adherence when Satisfaction is evaluated negatively. The "positive responses" axis shows the relationship between satisfaction and adherence when satisfaction is evaluated positively.

3. Results

3.1. Participants

We obtained a total of 100 responses during the one-month selection period. Among the self-reported diagnoses, there was a higher incidence of ulnar nerve injury. The most prevalent symptoms were numbness, loss of muscle tone, and sensation. The main characteristics of the participants are in Table 2.

3.2. Use, performance, and adherence of orthoses

Most respondents reported continuous use of their orthosis, 40% wore it all day and took it off to sleep, and 20% wore it during the day and at night. The remaining group reported using it less than prescribed: 18% most of the day with short breaks, 7% a few days a week, 4% only to sleep, and 11% very infrequently. Users highlighted itching and skin pain as the main adverse effects of use.

Generally, users rated the performance favorably, while adherence was slightly above average. Forty-six percent confirmed that they were considering dropping out of the orthosis. Likewise, 88% of users stated that orthosis allowed them to perform daily activities. However, among users who did perceive that the orthosis interfered with their activities, 75% intended to abandon the treatment.

We found differences according to the orthosis used. The median nerve orthosis had the highest use rate, and the median-ulnar orthosis

(claw hand) had the highest rate of dropout and perceived interference (Fig. 3).

Table 2.

Main characteristics of the participants (n = 100).

Age		Diagnostic signs self-reported (%)	
Range (%)	18 – 24 (23%)	Numbness	25%
	25 – 34 (33%)	Loss of muscle tone	15%
	35 – 44 (21%)	Loss of sensitivity	10%
	45 – 54 (16%)	Ulnar nerve injury	8%
	> 54 (7%)	Hand paralysis	7%
		Increased sensitivity	6%
Gender (%)		Brachial plexus injury	5%
Male	44%	Median nerve injury	5%
Female	56%	Radial nerve injury	5%
		Other symptoms	12%

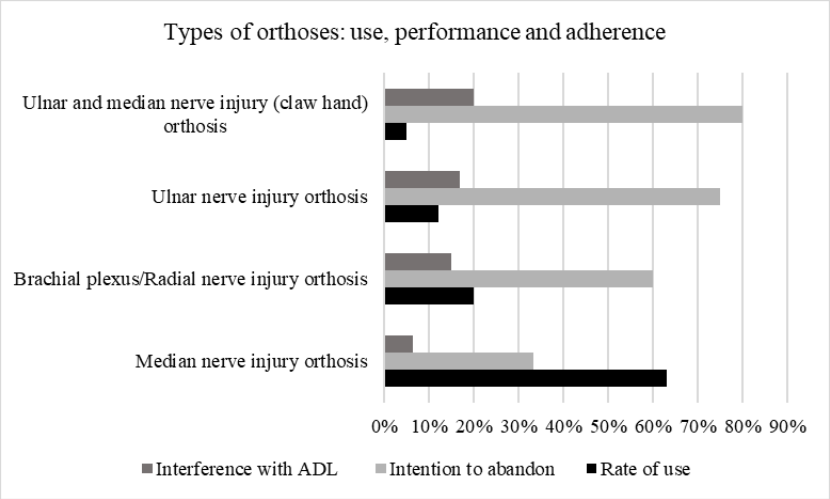

Fig. 3. Percentage of use, level of performance, and adherence according to the type of orthosis.

3.3. Design criteria

Design recommendations for improving orthoses arose from an open-ended question answered by 63% of the participants. The most frequent requests focused on changing to a lighter, more flexible, and softer material (to avoid friction on the skin). In addition, about one-third of the subjects requested adjustments in comfort and weight. Regarding appearance, some users recommended that the orthosis be less bulky and, therefore, less visible (Fig. 4).

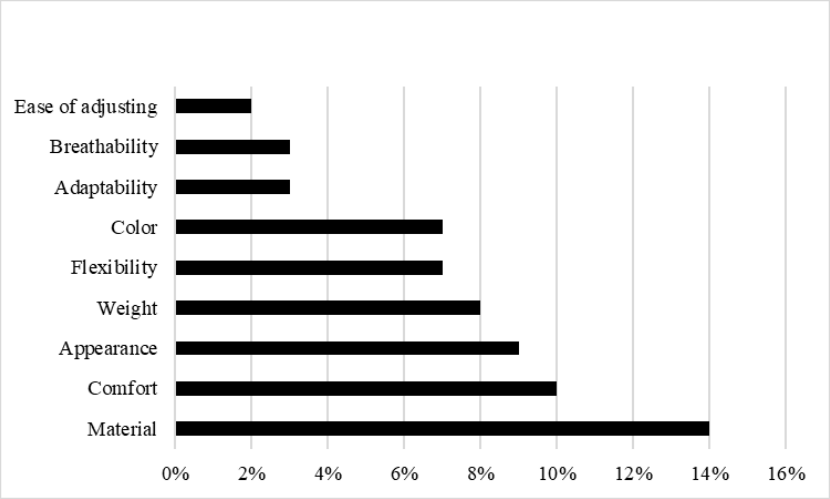

Fig. 4. Design recommendations made by users to improve orthotics. Most suggestions focused on materials, comfort, appearance, and weight changes.

3.4. Relationship between aspects of the orthosis and adherence to treatment

3.4.1 Description of the importance attributed and its influence on adherence

Table 3 shows the results of the crossover tabulation between the importance attributed (direct importance) by users to each aspect of the orthosis (Q4) and adherence (Q5). As can be seen, the safety characteristic is the only one users consider important and has a statistically significant relationship with treatment adherence. In other words, there is no consistency between direct importance and its relationship with adherence, except in the case of safety.

3.4.2 Description of satisfaction and its influence on adherence

According to the Gamma Coefficients between satisfaction with each aspect (Q3) and adherence to treatment (Q5), we found that all aspects are relevant in the decision to abandon treatment, except safety, ease of use, and ease of maintenance (Table 4). Finally, we present the relationship between dissatisfaction with each aspect (percentage of complaints) and importance in Fig. 5.

Table 3.

Relationship between the importance attributed by users to each aspect and adherence to treatment. Significant values are in bold and marked with an asterisk (p-value < 0.05).

Aspects	**% of users who consider it important**	**Conditional Gamma**	**P-value (Chi^2 test)**
Adjustment	19,33	0,056	0,7822
Weight	17,33	-0,087	0,6645
Comfort	15,33	-0,068	0,7352
Safety	13,67	0,464	**0,0168***
Effectiveness	10,67	0,159	0,4594
Ease of use	7,67	-0,373	0,1030
Durability	6	0,038	0,8837
Dimensions	7	-0,388	0,0999
Appearance	1,67	-0,289	0,5193
Maintenance	1,33	0,452	0,3897

Table 4.

Relationship between user's satisfaction with each aspect and adherence to treatment. Significant values are in bold and marked with an asterisk (p-value < 0.05).

Aspects	**% unsatisfied users**	**Conditional Gamma**	**P-value (Chi^2 test)**
Adjustment	16	0,510	**0,0463***
Weight	13	0,757	**0,0057***
Comfort	13	0,651	**0,0165***
Safety	11	0,383	0,2135
Effectiveness	9	0,647	**0,0449***
Ease of use	6	0,732	0,0584
Durability	10	0,691	**0,0230***
Dimensions	9	0,836	**0,0068***
Appearance	20	0,556	**0,0161***
Maintenance	10	0,506	0,1085

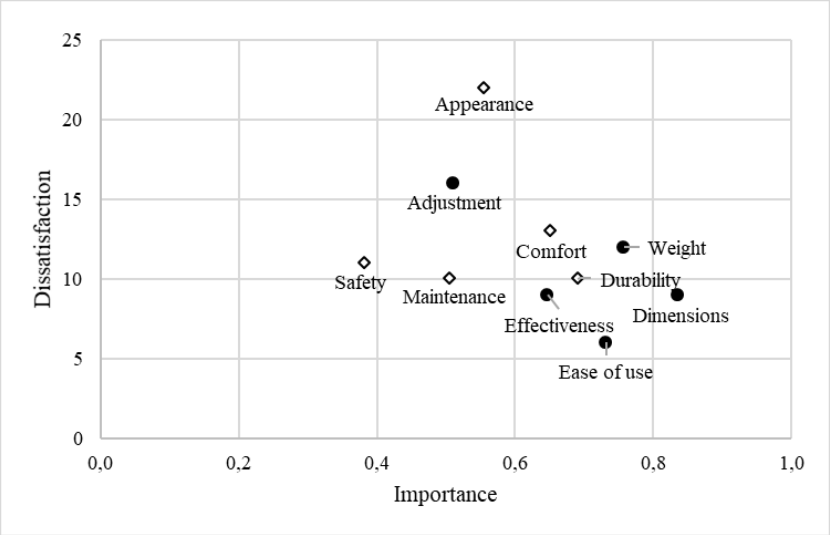

Fig. 5. Diagram of importance-frequency of dissatisfaction (percentage of complaints) versus importance. The circles correspond to the aspects with significant values (Gamma coefficient < 0.05).

3.5. Classification according to Kano's model

The overall analysis yielded a greater number of significant results. However, analyzing the relationship between positive and negative responses to adherence made it possible to identify aspects that only impact when a threshold is exceeded, either because they are not met or because the user's expectations are exceeded. This relationship is not appreciable through linear models (Table 5).

Table 5.

Classification of variables according to Kano's model categories.

Attribute		**Global**		**Negative responses**			**Positive responses**			**Category in Kano's model**
	GC*	**p-value (Chi-square)**	**n***	**R^{N*}**	**p-value (Chi-square)**	**n***	**R^{P*}**	**p-value (Chi-square)**	**n***	
Adjustment	0,510	**0,0463**	100	0,172	0,6138	39	0,495	**0,0284**	84	Delighter
Weight	0,757	**0,0057**	100	0,667	**0,0486**	40	0,267	0,2361	88	Basic
Comfort	0,651	**0,0165**	100	0,667	**0,0306**	38	-0,040	0,8683	87	Basic
Safety	0,383	0,2135	100	0,474	0,1602	37	-0,154	0,5128	89	Basic
Effectiveness	0,647	**0,0449**	100	0,495	0,2164	33	0,302	0,1920	91	Performance
Ease of use	0,732	0,0584	100	0,539	0,2834	31	0,425	**0,0539**	94	Performance
Durability	0,691	**0,0230**	100	0,707	**0,0338**	37	-0,044	0,8522	90	Basic
Dimensions	0,836	**0,0068**	100	0,787	**0,0278**	52	0,270	0,1950	91	Basic
Appearance	0,556	**0,0161**	100	0,556	**0,0375**	50	0,000	1,0000	80	Basic
Maintenance	0,506	0,1085	100	0,431	0,2362	37	0,139	0,5462	90	Basic

*GC is the global gamma coefficient. R^N and R^P are the Gamma coefficients between each aspect and adherence for each aspect with positive (N) and negative (P) values, respectively; n is the number of data used to calculate each R. Significant values are in bold.

Based on the results, we classified the aspects in terms of basic, performance, and delighter attributes (Fig. 6). We found that safety, durability, comfort, appearance, maintenance, weight, and dimensions are basic attributes (lower right area of the graph). Therefore, if there is dissatisfaction with these aspects, treatment adherence decreases, but improving these aspects may not affect adherence. On the other hand, the performance attributes are effectiveness and ease of use (upper right area of the graph). Thus, as satisfaction with these aspects increases, adherence improves, and vice versa. In addition, ease of adjusting is a delighter attribute (upper left area of the graph), so improving the orthosis adjustment mechanism would improve satisfaction and adherence.

Correlations between variables in the positive area (R^P) were only significant for ease of adjusting. Therefore, improving this aspect of orthosis could improve treatment adherence. On the other hand, correlations in the negative area (R^N) were significant for weight, comfort, durability, dimensions, and appearance, so dissatisfaction with these attributes negatively influences adherence.

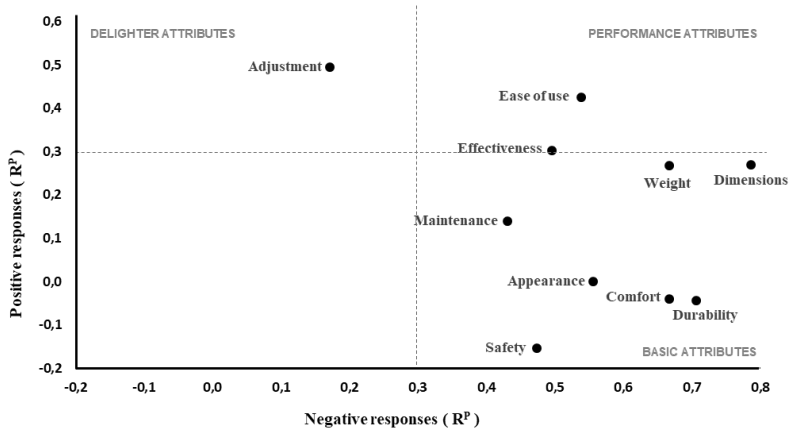

Fig. 6. Graphical representation of the pairs of values according to the type of response. The "negative responses" axis shows the relationship between satisfaction and adherence when satisfaction is rated negatively. The "positive responses" axis shows the relationship between satisfaction and adherence when satisfaction is positively assessed. The dotted lines represent the limit of significant relationships (CG > 0.3). Factors below and to the left of the dotted lines are not considered significant (lower left quadrant).

4. Discussion

4.1. Adherence assessment

The literature on adherence to orthotic treatment in peripheral neuropathies is scarce. Therefore, we compared our results with available studies and extended the review to pathologies such as rheumatoid arthritis, tendon injuries, and stroke. We inquired about the intention to abandon treatment and found an adherence rate of 54%. This rate is lower than those reported by O'Brien [13] and Safaz et al. [19] and higher than those of Walker [26] and Agnew and Maas [20]. The systematic review by O'Brien [13] evaluated therapeutic adherence in patients with acute bone, tendon, or nerve injuries. This review found higher overall rates of splint adherence in acute injuries (≥75%) versus its use to treat chronic conditions such as rheumatoid arthritis (rates of 25-65%). Walker [26] conducted a study on splints for carpal tunnel syndrome. He stated that 46% of hands reported strict compliance with specific splinting instructions, with the remainder reporting partial compliance. Agnew and Maas [20] examined self-reported compliance with working wrist splints in patients with rheumatoid arthritis. They found that 15.6% were fully compliant, and 70.3% reported wearing the splints for half or more of the prescribed time. Finally, Safaz et al. [19] examined the use of orthoses in stroke patients, 22.4% of patients wore an inhibiting hand splint, and 16.8% wore a neutral wrist splint. The dropout rates were 70.8% and 77.8%, respectively.

We inquired about the relationship between orthosis performance and treatment adherence. According to our findings, 88% of the users agreed with the orthosis performance. However, we found a 75%

intention to drop out among users who reported interference of their orthosis in daily activities. These findings are consistent with those obtained by Walker [26], Agnew and Maas [20], and Veehof et al. [23], who identified that interference with function is relevant to adherence to carpal tunnel and rheumatoid arthritis treatment.

4.2. Importance of attributes

We analyzed the relationship between direct importance and adherence. We only found a correlation for safety. This finding suggests that directly asking for the importance of aspects does not provide consistent answers, at least regarding the intention to wear or not to wear an orthosis.

In addition, we analyzed the relationship between satisfaction and adherence to obtain an indirect quantification of the importance of aspects. The results are entirely different; with that, a clear relationship between dissatisfaction and decreased adherence is evident.

Our study found a relationship between adherence to orthotic treatment and satisfaction with weight, comfort, durability, dimensions, appearance, effectiveness, and ease of adjusting. We found no relationship between satisfaction with ease of maintenance and ease of use and adherence.

Our results partially agree with Joseph et al. [31]. The authors found effectiveness, ease of use, and comfort essential for hand orthosis users. Regarding comfort, our results are consistent with some studies that identify this aspect as a cause of abandonment in patients with rheumatoid arthritis [20] and after tendon repair [24]. Likewise, Safaz

et al. [19] reported a dropout rate of 61.4% associated with discomfort in stroke patients.

Concerning ease of adjusting, we found only two studies in which this aspect had a negative impact. Safaz et al. [19] found that 27.3% of participants abandoned the orthosis because it was challenging to fit. Hannah and Hudak [29] evaluated satisfaction by comparing three orthoses: the static volar wrist splint, the dynamic tenodesis suspension splint, and the dorsal splint with finger extension. The authors reported that although the static orthosis did not statistically improve hand function, the patient preferred to use this orthosis because it was easy to fit and less visible.

In our study, appearance is a primary attribute with a significant rate of complaints. Our results disagree with Agnew and Maas [20] and Veehof et al. [23] and agree with several studies that place cosmesis as one of the leading causes of dissatisfaction and dropout. Agnew and Maas [20] and Veehof et al. [23] evaluated orthoses in patients with rheumatoid arthritis and found that appearance was considered irrelevant, whereas efficacy was identified as essential. On the other hand, Alsancak [30] evaluated the design of a dynamic orthosis for radial neuropathy. From 135 participants, 54.9% rated the appearance as “poor” and 45.1% as “fair.” These results led to the modification of the extensor springs of the orthosis. Ghoseiri and Bahramian [33] found that most patients agreed that their devices fit well. The main concerns were appearance, durability, material wear, and price. Safaz et al. [19] reported that 18.2% of stroke patients abandoned the orthosis because the appearance was “annoying.” Skogsrød [62] and Gherardini [63] emphasize that the appearance of assistive devices and

the patient's perception of external reactions influence the evaluation of the devices. Both aspects could contribute to stigmatization.

We have proposed a systematic process for defining importance. Our method differs from those applied in other studies in which the question is asked directly, thus potentially leading to biased results, as evidenced in this study.

4.3. Direct and indirect importance. Relevance of the application of Kano's method in the measurement of adherence

When analyzing the relationship between the importance attributed and adherence, we only found a relationship with safety. This finding reveals that the answers to the direct questions about the importance of the aspects are not related to the users' decisions about using or not using the orthosis.

On the contrary, there is a relationship between satisfaction with the same attributes and adherence. This relationship can effectively quantify the importance of an attribute, taking into account the effect on an objective to be met, in this case, adherence. From this perspective, almost all attributes are related to adherence, except the ease of maintenance, ease of use, and, curiously, safety.

As mentioned above, the satisfaction-adherence analysis gives a single value for indirect importance, which does not consider the effect of a negative, and a positive judgment can be different. Kano's model considers this, which makes it possible to identify three types of attributes. Basic quality attributes are weight, comfort, durability, dimensions, and appearance. In all these attributes, the effect on

adherence appears when the user expresses a negative judgment, which results in a significant decrease in adherence. Therefore, they are the most important factors, as users may drop out of treatment if these attributes are not met. Conversely, improvements in satisfaction do not influence increases in adherence.

Second, we must consider the linear or performance attributes related to adherence throughout the entire range of satisfaction scores. Here, effectiveness maintains a directly proportional relationship with adherence. Therefore, its improvement may increase the wear rate of the orthosis.

In addition, ease of adjusting is an excitatory attribute. Then, improving the fitting design could increase overall satisfaction and treatment adherence. The unexpectedness of this attribute could be a differentiating agent in the choice of one orthosis over others.

Finally, in the overall analysis, we found no relationship between adherence and satisfaction with ease of maintenance (basic attribute) and ease of use (linear attribute). However, in the segmentation by type of response of the Kano method (positive and negative), we found that satisfaction with ease of use could affect adherence only when perceived positively.

5. Conclusions

Direct importance is not related to adherence in most of the attributes analyzed. Therefore, importance is not a reliable predictor of adherence to orthotic treatment.

Satisfaction is an indirect measure of importance and an adequate predictor of adherence.

User satisfaction with the ease of adjustment, weight, comfort, effectiveness, durability, dimensions, and appearance of orthoses influences treatment adherence.

Kano's model allows more precise identification of the influence of orthosis attributes on adherence. This method describes relationships between aspects that are not discernible in linear models, as in the case of basic quality attributes, whose influence is only manifested when the judgment is negative.

From our review, classification according to Kano's model has not been previously applied to assess adherence to orthotic treatment. Therefore, we believe that the inclusion of this method in this study provides a comprehensive alternative for assessing the aspects that determine adherence and users' perception of rehabilitation products.

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Ethical considerations

Data collection was conducted through the Pollfish online survey platform (https://www.pollfish.com/). The anonymous nature of the survey ensures the respondents' confidentiality, security, and freedom of expression.

The Ethics Committee for Research in Medicines of the Hospital Universitario y Politécnico La Fe (CEIm La Fe) approved the study protocol. Registration number 2020-035-1.

Conflict of interest

The authors have no conflicts of interest to report.

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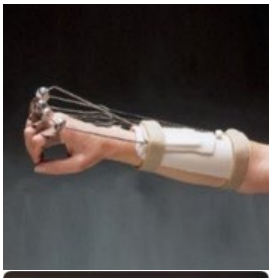
Appendixes

1. Survey: Orthosis Assessment

Q1. Select the characteristics that apply to your injury: (MultipleSelection)

- Radial nerve injury
- Ulnar nerve injury
- Median nerve injury
- Brachial plexus injury
- Partial impairment of function
- Paralysis of the hand
- Loss of sensitivity
- Increased sensitivity
- Numbness
- Loss of muscle tone
- Loss of muscle tone
- Other

Q2. Select the orthosis design most similar to the one you use or have used: (SingleSelection)

1. 
2. 
3. 
4. 
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11. 

12. 

13. 

14. 

15. 

16. 

Q3. Please indicate your level of satisfaction with the following aspects of your orthosis. (MatrixSingleSelection)

	Not satisfied at all	Not very satisfied	More or less satisfied	Quite satisfied	Very satisfied
Dimensions:					
Weight:					
Ease of putting on and taking off:					
Safety:					
Durability:					
Ease of use:					
Comfort:					
Appearance:					
Effectiveness:					
Ease of maintenance and cleaning:					

Q4. Select three aspects that you consider the most important in the orthosis. Please check the three boxes of your choice: (MultipleSelection)

- Dimensions
- Weight
- Ease of putting on and taking off
- Safety
- Durability
- Ease of use
- Comfort
- Appearance
- Effectiveness
- Ease of maintenance and cleaning

Q5. Have you ever considered discontinuing the use of your prescribed orthosis definitively? (SingleSelection)

- Yes
- No

Q6. Which frequency of use best represents your case? (SingleSelection)

- All day and to sleep
- All day long and take it off to sleep
- Most of the day with short breaks
- A few days per week
- Very few times
- Only to sleep

Q7. Does your orthosis allow you to perform daily activities properly? (SingleSelection)

- Yes
- No

Q8. Below is a list of physical and emotional conditions. If you have experienced any of them during the use of your orthosis, please select them. (MultipleSelection)

- Pain
- Itchy skin
- Burning skin
- Skin sores
- Muscle spasms or cramps
- Postural changes
- Fatigue
- Anxiety
- Depression
- Stress
- Frustration
- Fear
- Insecurity
- Other

Q9. What recommendations could you suggest to improve the design of your orthosis? (Open-ended)

Q10. Would you like to participate in design consultations for the creation of a new orthosis? If yes, please enter your e-mail address in the corresponding box. (SingleSelection)

- Yes
- No

2. Contingency tables

2.1. Satisfaction vs. Adherence

Comfort vs. Adherence

	No	Yes
Not satisfied	18	20
Satisfied	36	26

Weight vs. Adherence

	No	Yes
Not satisfied	16	24
Satisfied	38	22

Dimensions vs. Adherence

	No	Yes
Not satisfied	23	29
Satisfied	31	17

Safety vs. Adherence

	No	Yes
Not satisfied	20	17
Satisfied	34	29

Durability vs. Adherence

	No	Yes
Not satisfied	18	19
Satisfied	36	27

Ease of adjusting vs. Adherence

	No	Yes
Not satisfied	14	25
Satisfied	40	21

Effectiveness vs. Adherence

	No	Yes
Not satisfied	13	20
Satisfied	41	26

Ease of use vs. Adherence

	No	Yes
Not satisfied	11	20
Satisfied	43	26

2.2. Importance vs. Adherence

Comfort vs. Adherence

	No	Yes
Not important	30	24
Important	24	22

Weight vs. Adherence

	No	Yes
Not important	27	21
Important	27	25

Dimensions vs. Adherence

	No	Yes
Not important	46	33
Important	8	13

Safety vs. Adherence

	No	Yes
Not important	26	33
Important	28	13

Durability vs. Adherence

	No	Yes
Not important	44	38
Important	10	8

Ease of adjusting vs. Adherence

	No	Yes
Not important	22	20
Important	32	26

Effectiveness vs. Adherence

	No	Yes
Not important	35	33
Important	19	13

Ease of use vs. Adherence

	No	Yes
Not important	45	32
Important	9	14

2.3. Satisfaction vs. Importance

Comfort vs. Importance

	No	Yes
Not satisfied	16	22
Satisfied	38	24

Dimensions vs. Importance

	No	Yes
Not satisfied	38	14
Satisfied	41	7

Durability vs. Importance

	No	Yes
Not satisfied	29	8
Satisfied	53	10

Effectiveness vs. Importance

	No	Yes
Not satisfied	25	8
Satisfied	43	24

Weight vs. Importance

	No	Yes
Not satisfied	21	19
Satisfied	27	33

Safety vs. Importance

	No	Yes
Not satisfied	21	16
Satisfied	38	25

Ease of adjusting vs. Importance

	No	Yes
Not satisfied	18	21
Satisfied	24	37

Ease of use vs. Importance

	No	Yes
Not satisfied	24	7
Satisfied	53	16