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Application of Quality Function Deployment for the Development of a Prosthetic Knee Joint

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Abstract

The design of biomedical devices often involves consultation with patients, caregivers, clinicians, technicians, and other technical professionals. Quality Function Deployment (QFD) provides a structured approach during the design process to identify which specific design parameters (DPs) of a product or system most efficiently address the end-user's requirements. This technique was applied to the development of a new prosthetic knee joint for transfemoral amputees. Customer Requirements (CRs) and importance ratings were identified through a large-scale international survey on lower-limb prosthetics. The list of DPs and the relations to each CR were determined through consultation with a team of engineers and prosthetists familiar with prosthetic rehabilitation and design. The resulting relative importance ratings of each DP were used in a validation of the initial prototype knee and in a strategic prioritization of future work.

Keywords

Quality Function Deployment, Prosthetic Design, Knee Joint, Clinical Engineering, Needs Assessment, Rehabilitation

1 Introduction

The lack of an affordable, highly functional artificial knee joint for amputees, appropriate for the conditions faced in many countries around the world continues to be a major concern [1].

To design effective prosthetic knee joints requires a multidisciplinary process which involves balancing numerous technical and clinical specifications. Unique inputs from patients, caregivers, clinicians, physicians, technicians, manufacturers, and other technical professionals limit the range of appropriate designs. Effectively managing all the inputs of these groups in the design of new prosthetic devices can be very challenging and quickly lead to high costs and lengthy development times. This is why the Quality Function Deployment (QFD) design planning technique has proven to be particularly useful in rehabilitation engineering applications [2-3].

The QFD method, developed in Japan in the 1970s, was designed to improve product development times by employing a systematic method of relating specific design parameters (DPs) to the customer requirements (CRs) of a product. The goal of the approach is to eliminate wasted resources involved with product modifications or redesigns [3]. This is particularly beneficial in the field of prosthetic design due to the immense time and cost associated with the clinical trials and long-term field testing required for the adoption of any new technology.

Rehabilitation engineering presents a unique challenge to the conventional QFD method and as a result, designers of products and processes in rehabilitation engineering have often made minor changes to the standard QFD method [2]. A difficult aspect of applying the standard QFD method to a rehabilitation product is incorporating both the engineering and clinical perspective. Successful prosthetic rehabilitation relies on both, a well designed prosthetic technology and also appropriate clinical fitting and training. This means that the views of both prosthetic designers and clinical professionals are important in developing a new device.

In this work a novel method of efficiently integrating the subjective views of designers and clinicians together into the final analysis stage of the QFD method is presented.

This modified QFD analysis has been applied in the validation and strategic prioritization of future work on an early prosthetic knee prototype named the Rear Locking Knee (RL-Knee). The RL-Knee is an automatic, rear-locking knee joint designed to meet the requirements of a broad range of transfemoral amputees and demanding environments. This study highlights how the QFD method can be applied to both pre- and post-development phases of a medical device.

2 Methods

The basic template for the QFD design method is shown in Figure 1. The template includes a list of CRs with relative importance ratings and a list of quantifiable DPs which can be altered to affect the CRs. These two lists then form the two dimensions of the Relationship Matrix, a matrix comprising the main section of the QFD diagram which relates each DP to each CR. The Competitive Analysis section compares related, competing mechanisms. Finally, the Correlation Matrix, represented by a triangular matrix turned on its side, forms the roof of the 'house of quality' and shows how changes in one DP may affect the others.

The general method outlined in the work by Jacques et al. [3] was applied for the RL-Knee joint. The following sections describe in detail the development of each portion of the QFD diagram.

2.1 Customer input

The multidisciplinary nature of prosthetic rehabilitation means there are many groups which can be considered the 'customers' of any given prosthetic device. Therefore, the first step in the analysis was to identify the appropriate customer.

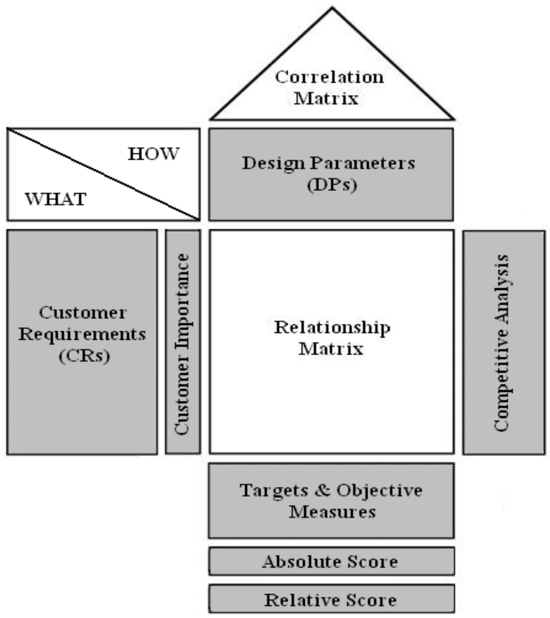

Figure 1. Quality function deployment 'House of Quality' template.

In this study it was decided that the practitioners (prosthetists, technologists and technicians) working in the field of lower-limb prosthetics with experience with different types of prosthetic knees would provide the most reliable customer requirements and importance ratings. This was because prosthetists deal closely with the amputees and often have direct contact with many of the other 'customer' groups. Also, in some cases, amputees may not be familiar enough with the technical and service related issues of their prosthesis to effectively determine a complete list of requirements. With the customer identified, a list of the primary customer requirements and the relative importance of each could be established.

A self-reporting online survey on lower-limb prosthetics was developed and sent to practitioners around the world. The survey was designed to highlight the most crucial service and technology-related needs of populations requiring lower-limb prosthetic treatment around the world. In a section of the survey designed for this study, respondents were asked to identify the five most important CRs while considering the needs of the amputee. Also, three different classes of comparable prosthetic knee mechanisms were presented and practitioners were asked to rate, on a three-point scale (1-poor, 2-acceptable, 3-good), how well each mechanism addresses each CR. The survey was translated and made available in English, French, and Spanish and then distributed using the online survey tool, Fluid Surveys. The survey was made available to contact networks of the International Committee of the Red Cross (ICRC), the International Society for Prosthetics and Orthotics (ISPO), Handicap International (HI), La Fédération Africaine des Techniciens Orthoprothésistes (FATO), the Canadian Board for Certification of Prosthetists and Orthotists (CBCPO), and certain other individuals in the field of lower-limb prosthetics. A total of 199 respondents completed the survey covering rehabilitation work conducted in 64 different countries.

The 16 most commonly listed requirements were compiled and importance ratings were generated based on the frequency with which each was selected. The data from the ratings of the three different knee mechanisms were averaged to determine the values for the competitive analysis.

2.2 Engineering and clinical input

A list of quantifiable DPs was established through a literature review and then refined by iterative amendments made by engineers, and other designers familiar with prosthetic development, until a consensus was reached. A direction of improvement for each DP was established where the objective was either to minimize, maximize or hit a target value.

With the CRs and the DPs defined, the strengths of the relationship between each DP and CR were assigned in the Relationship Matrix. Values in the Relationship Matrix were assigned as either: strong, moderate, weak, or no relationship, with weights of 9, 3, 1, and 0, respectively. Two prosthetic designers and two clinical prosthetists discussed the relationships between each CR and DP before individually assigning weightings to them. Values in the Correlation Matrix and the difficulty ratings associated with improving each DP individually were assigned by the consensus of two prosthetic designers. Correlations were assigned as either: strongly positive, positive, negative, or strongly negative and difficulty was rated on a scale of one to ten, with one being easiest and ten being hardest.

2.3 Analysis stage

To compile results from each completed Relationship Matrix the relative importance of each DP was averaged across the four experts to obtain a single value for each DP. The final stage of the procedure then involved simultaneously taking each aspect of the house of quality into consideration. The Relationship Matrix defined the relative importance of each DP, however the difficulty of improvement of each DP was also considered before making any final recommendations. The correlations between DPs were also a factor to consider for if a highly rated DP negatively affects several other significant parameters it may be wiser to focus resources on improving another aspect of the design. Finally, the competitive analysis was used in identifying specific CRs which have been neglected by competitors. The sum of this knowledge helped assess and guide the design process of a knee joint aimed at most efficiently meeting the diverse needs of a broad group of amputees living in the developing world.

3 Results

Customer requirements and relative importance ratings are shown in Table 1. The main results from each QFD diagram are summarized in Table 2. The DPs are ordered from highest to lowest, by the averaged relative weightings; the difference between the rank of the averaged weightings and the ranks from each individual analysis is also presented. Also included are the directions of improvement, the symbols ▲,▼, and **x**, indicate whether the objective is to maximize, minimize, or hit a target value, respectively.

The most influential design parameter was found to be *Ease of flexion initiation*, which represents the moment required to initiate flexion of the prosthetic joint. The next three most significant parameters were: *Range of stable positions*, *Swing-phase control response*, and *Extension assist stiffness*.

The Competitive Analysis section is shown separately in Figure 2 where three candidate technologies of prosthetic knees joints applicable for use in developing countries (single-axis manual locking, weight-activated friction locking, and four-bar polycentric) are compared. As an additional measure, the average rating for each customer requirement was multiplied by its relative importance weighting and then summed for each mechanism. The result is a single value performance score, shown in Table 3.

Table 1. Ordered customer requirements and relative weights.

Customer Requirement	Relative Weight
Sense of Stability	21.8
Comfortable/Smooth gait	15.9
Durability	11.6
Low Energy Expenditure	9.5
Variable Adjustments	8.1
Simple Maintenance	5.5
Large Range of Motion	4.5
Quiet Operation	4.2
Easy Extension	3.1
Modular Design	2.9
Voluntary Lock	2.9
Walk on Uneven Terrain	2.6
Lightweight	2.5
Corrosion Resistance	1.7
Robustness	1.6
Aesthetically Pleasing	1.5

4 Discussion

Prior to this study there was no extensive quantitative data on both the customer needs and product design parameters of a prosthetic knee joint. A study by Andrysek et al. identified six functional requirements and asked five subjects to rate the importance of each [4]. Despite the smaller sample size and scope, the overall results are consistent with the findings presented here. Work by Postema et al. on user choice and deciding factors for prosthetic feet also found users to rate stability as a top concern [5].

The results of this study have been used to validate the completed work on the knee prototype and to direct future work toward developing an optimal device for as many amputees around the world as possible. The RL-Knee prototype was designed prioritizing a secure locking mechanism for stance-phase stability control (resistance to knee flexion during weight-bearing), and a simple and durable design.

Table 2. Ordered average relative weights and comparison of design parameter rankings.

	Design Parameter	A	D1	D2	C1	C2
x	Ease of flexion initiation	**16.3**	0	0	1	2
x	Range of stable positions	**13.7**	0	0	3	-1
x	Swing-phase braking response	**12.3**	4	0	-2	-1
x	Extension assist stiffness	**8.6**	-1	1	-1	0
▲	Extension bumper hardness	**8.0**	-1	-1	-1	3
x	Meets ISO standards	**6.4**	-1	0	1	1
▼	Total weight	**5.2**	-1	1	6	-1
▼	No. of main body parts	**5.0**	5	5	-2	-3
▲	Min. ground clearance	**4.6**	-1	-2	-1	5
▼	Corrosivity of materials	**3.7**	-1	2	-1	0
▲	Extension stop moment arm	**3.3**	-2	-2	4	1
▲	Young's modulus	**2.9**	0	-1	-1	-1
▲	Alignment adjustability	**2.6**	2	4	-3	-4
x	Overall size	**2.2**	0	0	-2	-1
▲	Max. knee flexion angle	**1.7**	-4	-5	3	2
▲	Flexion stop moment arm	**1.3**	0	-1	-2	0
▲	Kneeling surface area	**1.3**	0	-1	0	-2
x	Thigh length during sitting	**0.8**	0	0	-1	-1
▲	No. available colours	**0.2**	0	0	0	0

A = Averaged Relative Weights
D1, D2 = individual designer rank differences
C1, C2 = individual clinician rank differences

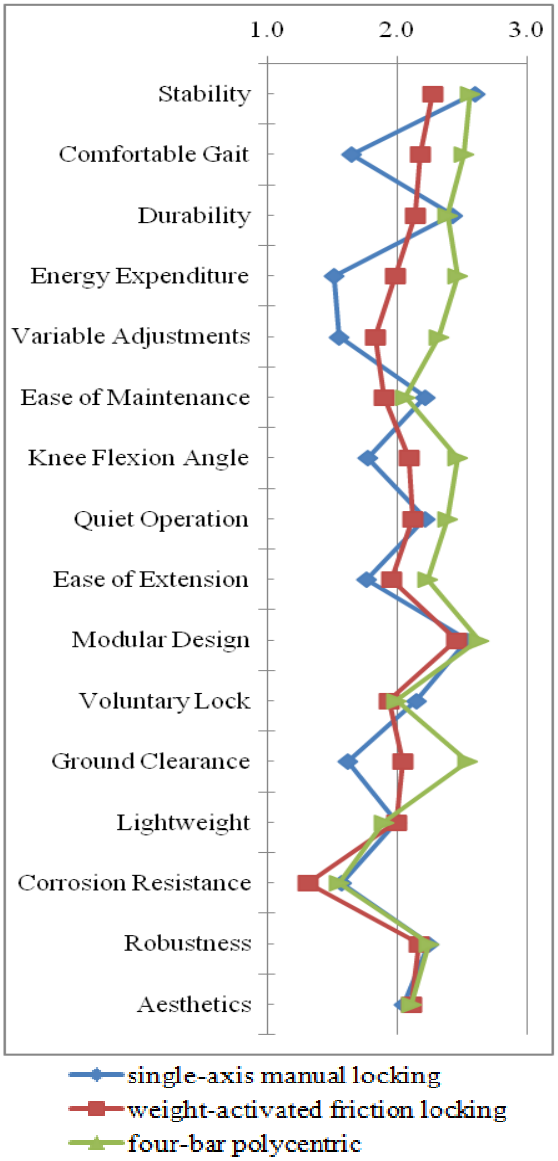

Figure 2. Competitive analysis.

Table 3. Performance scores of applicable mechanisms.

Knee Mechanism	Performance Score
Single-axis manual locking	638
Weight-activated friction locking	650
Four-bar polycentric	728

These priorities were shown to be appropriate as they address several of the highest rated customer requirements (CRs) such *Stability*, *Durability*, and *Ease of Maintenance* directly. The RL-Knee mechanism actively locks prior to loading at the beginning of stance-phase, yet allows for a natural initiation of flexion prior to toe-off during the gait cycle. This means the user is not required to voluntarily maintain an active hip moment to ensure stability. This has been shown to improve walking speeds in a similarly configured knee [6]. Addressing the other highly rated requirements, *Comfortable Gait* and *Energy Expenditure*, will involve future work on swing-phase control (controlling the duration and acceleration of the shank during limb advancement). These CRs are both current priorities for on-going work.

The two highest rated design parameters are both closely associated with the stance-phase control of the knee. The mechanism employed in the RL-Knee facilitates a simple flexion initiation and the engaged lock allows for stability under a broad range of loading conditions [7]. The next three highest design parameters (DPs) are all related primarily to the swing-phase and therefore will likely help improve the comfort and energy efficiency of gait.

The most significant correlation in this analysis is the negative correlation between *Ease of flexion initiation* and *Extension assist stiffness*. These are both highly rated DPs and a reduction in either is undesirable. However, both DPs have a target value objective, so it is possible that the correlation may allow for each target to be reached successfully. Therefore, priority should be given for *Ease of flexion initiation*, the most highly rated DP, and the *Extension assist stiffness* should be monitored carefully for any significant negative effects.

Many of the remaining correlations between DPs are related to the parameters *Overall size* and *Total weight* which are strongly positively correlated with each other. There are three DPs negatively correlated with O*verall size*, however, the positive effect of improving the O*verall size* on *Total weight* outweighs the other three since it is rated higher than any of the three parameters. Therefore, *Overall size* and *Total weight* should be given priority over the *Extension stop moment arm*, *Flexion stop moment arm*, and *Kneeling surface area*, though each of these parameters should be monitored for a major drop in performance.

The difficulty ratings can also help guide development, any DP rated as relatively easy to improve should be considered. The lowest rated DP should not necessarily be interpreted as unimportant, just as the lowest rated CR is still an important concern for at least a portion of users. However, because a lower rated DP has less influence on the customer requirements; fewer resources should be spent on addressing them and should only be considered after the more influential DPs.

4.1 Competitive analysis

The competitive analysis was found to be consistent with the existing notions of the applicability of the considered mechanisms. The manual locking mechanism received the lowest overall score and was particularly deficient in providing low *Energy expenditure*, *Comfortable gait*, *Variable adjustments*, and sufficient *Ground clearance*. These deficiencies are likely why in 2006 experts in the field of prosthetics agreed that a stiff-legged gait was unacceptable [1]. The areas in which the manual lock excels above other mechanisms are: *Stability*, *Durability*, and *Ease of maintenance*. The high stability rating is a result of the extreme unlikelihood of unintended flexion with this knee mechanism and is supported in the literature [8]. With the lock in place, there is no position which will cause the knee to flex; only a functional failure of the mechanism would cause unwanted flexion. The high durability and low maintenance resulting in longer life of the components and few failures to be repaired are attributable to the inherently simpler nature of the mechanism.

The friction locking mechanism is typically viewed as an improvement over a manual lock. The competitive analysis supports this with the particular exceptions of *Durability* and *Ease of maintenance*, likely because the friction braking mechanism introduces greater wear and requires more frequent adjustments to maintain proper function.

The four-bar polycentric knee performs better than the others in most areas, most notably in *Comfortable gait*, *Energy expenditure*, *Variable adjustments*, and *Ground clearance*. The improved ground clearance over single-axis knee is supported by other studies in the literature [4, 9]. However, the improvements in gait gained with polycentric knees do not differentiate them from manual locking knees in the areas of *Stability* or *Durability*, and the *Ease of maintenance* seems to be reduced.

In terms of the prototype RL-Knee design, the competitive analysis has allowed the designers to know which customer requirements should be focused on to meet and exceed the overall performance of the competing mechanisms. *Corrosion resistance*, for instance, is an area in which none of the competing mechanisms perform very well, by adding a small amount of focus to this customer requirement will separate the new design from competitors.

The competitive analysis also reinforces many of the choices made in designing the knee joint. The design was based on keeping the high stability and durability inherent in most single axis devices while also improving upon the associated deficiencies in gait. The automatic locking allows for an efficient and simple way to provide a comfortable gait without the reduction in durability and ease of maintenance associated with the polycentric knees.

4.2 Individual differences

Filling the relationship matrix in QFD is a very subjective and time consuming process. Generally, to counteract the effect of individual differences, a group of people is used and a consensus of the strength of each relationship is determined. In this study, the consensus score was obtained through averaging individual scores, in an attempt to reduce the time needed to complete the QFD analysis. Given the multidisciplinary nature of prosthetic rehabilitation, it was important to involve multiple people with different backgrounds so two prosthetic designers and two prosthetists composed the QFD team.

The rank differences in Table 1 indicate the level of agreement for each particular parameter. The *No. of available colours* parameter shows all zeros and was therefore determined to be the least influential DP in each individual analysis. Contrarily, *alignment adjustability* shows greater variation; much of the variability can be attributed to a difference in the views of the designers versus the prosthetists as their rankings are on opposite sides of the average. *Max. knee flexion* and *No. of main body parts* are other examples of this behavior. In a consensus focus group, there may be instances where one individual disagrees with the majority and their opinion is subsequently unfairly represented in the final result. An example of where this situation could have occurred during this study is for the *Min. ground clearance* parameter, the ranking from the C2 individual strongly opposed the others. However, by employing the averaging technique, each member of the team is assured and equal contribution to the final score.

The fact that the most influential DPs seem to have a low degree of variability suggests that consensus obtained by averaging appropriately reflects the overall views of the QFD team.

4.3 Future work

In addition to the future work on the RL-Knee prototype guided by the results of this study, it may also be interesting to conduct a full QFD analysis where the outcome of a consensus focus group and the averaging technique used in this study are compared and contrasted.

It may also be useful to gain the amputees' perspectives on customer requirements and contrast them with those of the practitioners.

5 Conclusions

In this work, a QFD analysis employing a new averaging approach in defining relationships was applied to the development of a prosthetic knee joint. Results confirmed the priority focus on stability and durability and suggested improvements in swing-phase control and extension assistance to gain a more comfortable and efficient gait.

While the prescription of a transfemoral prosthetic system is uniquely defined by the profile of each patient, some common CRs are expected to span across groups. QFD can help to identify the most impactful DPs that attend to these priority CRs. Moreover, providing adjustability and flexibility in the design to suit individual needs, can aid to extend the design functionality further. For example, for the RL-Knee a level of individualization was attained from adjustability in the stability and swing-phase control. In this way, the ability of QFD to capture the CRs of the population while identifying variances that serve individual patient needs, make it an ideal tool for use in rehabilitation engineering.

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References

[1] Rehabilitation Engineering Research Center (RERC). (2006) Chicago, USA, *State-of-the-Science on Appropriate Technology for Developing Countries*.

[2] Y.Y. Huang and K.H. Low. (2010) *In Proceedings.* Toronto, Canada, *Comprehensive planning of robotic therapy and assessment of task-oriented functions via improved QFD applicable to hand rehabilitation*. IEEE Conference on Automation Science and Engineering (CASE), pages 252–257. IEEE.

[3] G.E. Jacques, S. Ryan, S. Naumann, M. Milner, and W.L. Cleghorn. (1994) Application of quality function deployment in rehabilitation engineering, *IEEE Trans Rehabil Eng*, 2*(3)*, 158–164.

[4] J. Andrysek, S. Naumann, and W.L. Cleghorn. (2004) Design characteristics of pediatric prosthetic knees. *IEEE Trans Neural Syst Rehabil Eng*, 12,369–378.

[5] K. Postema, H.J. Hermens, J. De Vries, H.F.J.M Koopman, and W.H. Eisa (1997) Energy storage and release of prosthetic feet Part 2. *Prosthet Orthot Int*, 21, 28–34.

[6] J. Andrysek, S. Klejman, R. Torres-Moreno, W. Heim, B. Steinnagel, and S. Glasford. (2011) Mobility function of a prosthetic knee joint with an automatic stance phase lock. *Prosthet Orthot Int*, 35(2), 163–170.

[7] J. Andrysek, S. Naumann, and W.L. Cleghorn. (2005) Design and quantitative evaluation of a stance-phase controlled prosthetic knee joint for children. *IEEE Trans Neural Syst Rehabil Eng*, 13*(4)*, 437–443.

[8] M. Devlin, L.B. Sinclair, D. Colman, J. Parsons, H. Nizio, and J.E. Campbell. (2002) Patient preference and gait efficiency in a geriatric population with transfemoral amputation using a free-swinging versus a locked prosthetic knee joint. *Arch Phys Med Rehabil*, 83*(2)*, 246–249.

[9] S.A. Gard, D.S. Childress, and J.E. Uellendahl. (1996) The influence of four-bar linkage knees on prosthetic swing-phase floor clearance. *JPO: J Prosthet Orthot*, 8*(2)*, 34–41.