MECHATRONIC DESIGN METHOD FOR SURGERY DEVICES

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***Abstract**. Steady progress has been registered in medicine in the last years attested by the new techniques, equipments and procedures. Nowadays, the relationship between medicine and engineering occurs through casuistic situations, for instance the informal contacts between surgeons and engineers. In spite of that, many devices and automatic systems have been developed and used in medical procedures, such as surgery robots, automatic equipment for physiotherapy and others. However, there are many collaborative opportunities that could be materialized if a systematic form to drive the development process would be applied. This is the core of this paper, that addresses the importance of applying a systematic, mechatronic design process to surgery devices. The reasons for applying such method are presented, based on the results derived from a number of interviews with professional surgeons. A case study – an orthopaedic saw – is presented and analyzed for the sake of understanding the proposed procedure.*

***Keywords**: Mechatronics, bioengineering, Quality Function Deployment (QFD)*

1. Introduction

Steady progress has been registered in medicine in both, new drug conception and the development of new surgical instruments and techniques to improve the illness treatment. An important aid to this trend is the contribution of mechatronic design for the medical field.

The mechatronic devices developed to assist surgery procedures are very important because they improve the safety for the patient and surgeon during the surgery and guarantee a quicker and better patient recovery. The current problem is how to make the several professional of different areas, for example engineers and medicals to come together and develop a common project. Thus, a systematic method must be created to help and solve this knowledge interchange problem. This is the very core of this paper.

The implementation of the proposed method is based upon a well-known design tool - Quality Function Deployment (QFD) - that makes possible to map the overall the product development process. The information gathered from questionnaires filled by surgeons is the input for the first matrix of QFD. The following matrices supply the product specification, product components, process and production plan, and finally, production activities. However, only the two first QFD matrixes were found to be necessary to promote the engineering – medicine interaction, as it will become clear herein. The proposed method is applied to a case study from a mechatronic orthopaedic saw.

2. Design method: QFD

Origin of QFD: According to Hauser et *al.* (1988) the earliest use of this management technique has been traced to Kobe Shipyard, Mitsubishi, Heavy Industries Corp., Japan in 1972. In the late 70s, Toyota began to use QFD, and the results were impressive. From 1977 to 1984, Toyota Autobody introduced four new van-type vehicles. The company reported a twenty percent reduction in start-up costs (1979) which improved progressively to thirty-eight percent (1982). At the end, a sixty-one percent cost reduction, cumulative total had been archived.

Definition: QFD is a method for the development of quality design and its goal is to satisfy the customers, translating their necessities into design requirements and guaranteeing the quality to be from the conceptual stage up to up to the production stage. According to the Akao (1990), QFD allows to: give a general vision of overall design; obtain more productivity with less costs; reduce engineering changes; and execute the product development in shorter cycle reducing the time of its release to the market.

There are four stages in QFD, beginning with the customer needs until the determination of manufacture operations that makes a product that satisfies these necessities. This paper addresses only the two first matrices.

The first matrix is used to translate the customer needs into a technical language. This matrix can be used to support the decisions taken by a company. The most important results include: customer identification and requirements, determination of opportunities to improve competitiveness and establishment of functional structure of the overall product.

The second matrix is used to deploy the functional structure into a component structure of the product. This matrix relates the critical characteristics of parts for systems requirements.

QFD has a wide application field due to the very large flexibility and adaptability in different technical areas. This is the reason why QFD is brought forward to be employed within the medical field.

3. Mechatronic Design

According to the Industrial Research and Development Advisory Committee (IRDAC) mechatronics is defined as: "(…) the synergetic combination of mechanical engineering, electrical engineering, and information technology for the integrated design of intelligent systems, in particular mechanisms and machines."

The mechatronic design is more than collaboration between engineers. Mechatronics means to apply the mechanical, electrical and computational design knowledge simultaneously in the early development process. This involves intensive interdisciplinary communication of design concepts and decisions. Making better use of people is the key in using mechatronics as a strategic approach to competitiveness. This includes a closer cooperation between engineers and several disciplines from many departments.

According to Kabayama et *al.* (2003), the extra feature which can be achieved using mechatronic, is likely to include one or more of the following features: realization of new functions or behavior not feasible with traditional technologies; extension of the range of parameters used for machine control into the "intelligent functions" of man; increase of flexibility during both design and use; compensation for limitations in mechanism design through the use of electronic control.

The mechatronic product development is a complex task, particularly due to the multidisciplinary aspects. Traditional frontiers among different disciplines and the lack of common solution methods and understanding make it difficult to develop good conceptual solutions. Therefore, design teams are strictly necessary to carry out the mechatronics activities.

4. Mechatronics Design Applied to Medical Equipment

The biomedical engineering consists of several knowledge areas such as the mechanical, electronic, chemical, mathematics, computer sciences, physics, and others in order to solve biology and medicine problems. According to Vidal et *al.* (2001), in spite of the large quantity of electronic devices for diagnose employed in the medical area, the surgery procedures are still handling and using the archaic tools developed in the beginning of the last century.

Fonseca (2003) shows that the fundamental goal of mechatronics applied to medicine is to supply the medical environment with accuracy, mechanical rigidity, the state-of-the-art of technology and operational safety wherever and whenever necessary. As banks and airlines companies cannot operate without the computational support and automatic systems, medicine is finding more and more difficult to function without this technology.

The continuous concern with the patient comfort and the necessity of right and fast decisions to be taken in the surgical theater put medicine in a different position when compared with other areas that use mechatronics systems. According to Kabayama et *al.* (2003), mechatronic design methods applied to medical surgery devices have additional and specific issues due to medical requirements. Such particularities originate the biomecatronics, which is a new terminology to mechatronics related specifically to medical applications.

Biomechatronics deals with technical issues like: sensing, actuation and modeling techniques for the automated control of mechatronic tools for surgical assistance; ergonomics of surgical equipment, adaptation of surgery techniques for use with mechatronic tools and user interface design; patient restraints and tool fixation requirements and methods to achieve sterile conditions.

Due to the fact that biological and exact sciences are very different, the interaction between the professionals of these different areas can be difficult, even finding resistance and skepticism, mainly by people that are used to the traditional devices and methods. Probably this is a main reason why the development of technological applications in medicine does not follow the speed that it could be now. But the continuous release of medical devices and techniques requests the surgeons to recycle their knowledge and this is an inevitable tendency. The understanding of benefits that the current technology can bring for surgeons in potential is an important issue because this understanding can impel the development of more modern, safe and accessible devices. It is also necessary that the engineers do understand the requests and necessities of surgeons and patients in order to satisfactorily promote this development.

The base of the study is an existent questionnaire in the literature developed by Fonseca (2003). This questionnaire was elaborated to identify the medical proceedings and necessities in which the mechatronic device can be applied to improve both sides, medical work and quick patient recovery.

The answers obtained from the questionnaire show that high ability and accuracy during the surgery procedure was a common necessity for various medical fields. Consequently, the use of the mechatronic devices could be the answer to meet these requirements.

The next step was to apply the QFD method to obtain the surgery device configuration to be developed or improved.

5. Case Study: Orthopaedic saw

The application of the mechatronic design method for a surgery device is exemplified through the orthopaedic saw design for tibia osteotomy.

According to Slade et *al.* (2003), in the context of orthopaedic knee surgery, the term osteotomy is used to describe a surgical procedure that involves the cutting, realignment and subsequent stabilization of either the upper tibia or the lower femur.

This case study was conducted under the reverse engineering approach, once the mechatronic saw has already been designed.

QFD Matrix 1: Product specification

Customer needs: analyzed through the Objective Tree method, according to Cross (2004).

Objective tree: The first step is the development of a customer objective tree in order to identify the actual needs of the customers. This is shown in Figure 1.

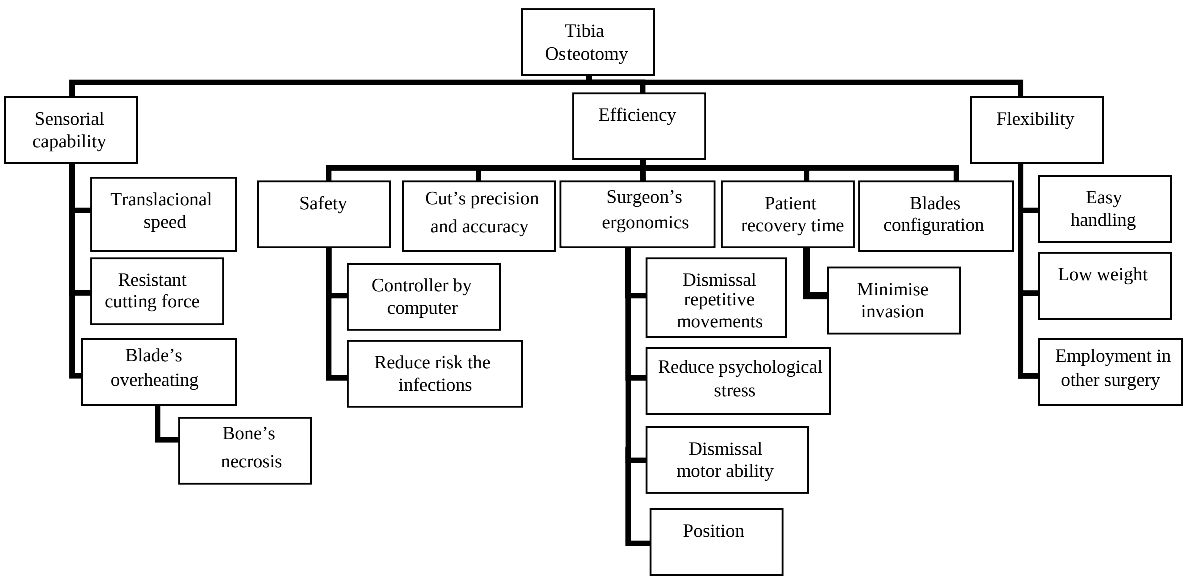

Figure 1. Objective tree

Competitive analysis: The second step is to make of a competitive analysis between the product under development and similar products commercially available. They are shown in Figure. 2.

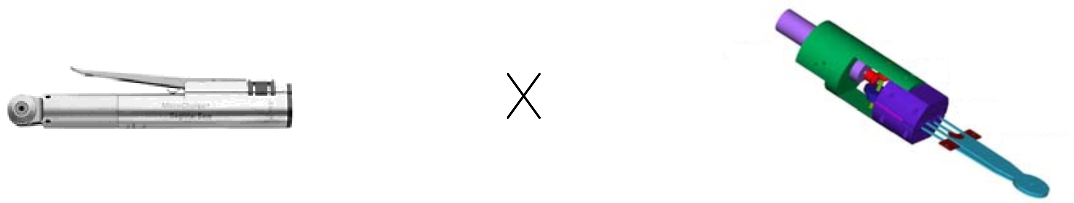

Figure 2. Linvatec Corp. saw and ITA/Dundee orthopaedic saw

Weighting the customer needs: The third step is to calculate the absolute and relative weights of each customer need. These figures show a "priority degree" of each need of the customer. Table 1 shows the customer needs described in the objective tree, the competitive analysis and the weights associated to each customer needs.

Table 1. Customer needs

				Importance Degree	Comparison with others industries		Desired Quality	Improvement ratio	Strong sales feature	Customer needs weight	
					Ours	Conc.				Absolute	Relative
Tibia Osteotomy	Flexibility	Easy handling		3	4	3	4	1.00	●	3	4.20
		Low weight		2	4	4	4	1.00	●	2	2.80
		Employment in other surgery		2	3	5	3	1.00	●	2	2.80
	Sensorial capability	Translacional speed		4	4	4	5	1.25	■	6.25	8.04
		Resistant cutting force		4	4	4	5	1.25	■	6.25	8.74
		Blade's overheating	Bone´s Necrosis	5	5	1	5	1.00	♦	7.5	10.49
	Efficiency	Cut's precision and accuracy		5	5	2	5	1.00	♦	7.5	10.49
		Blades configuration		4	5	4	5	1.00	♦	6	8.39
		Patient recovery time	Minimise invasion	4	4	3	5	1.25	♦	7.5	10.49
		Safety	Controller by computer	4	5	3	5	1.00	♦	6	8.39
			Reduce risk the infections	4	4	3	5	1.25	■	6.25	8.74
		Surgeon's ergonomics	Dismissal repetitive movements	3	5	2	5	1.00	■	3.75	5.24
			Reduce psychological stress	3	3	3	5	1.67	■	6.25	8.74
			Dismissal motor ability	3	5	2	5	1.00	■	3.75	5.24
			Position	3	5	2	5	1.00	■	3.75	5.24
										77.75	

The other parameters of Table 1 are described below:

Importance degree (id_i): it is a qualitative indication of how much given customer need influences his/her decision of purchasing the product. The grades range from 1 up to 5, where: 1 - very few importance; 2 - few importance; 3 - average importance; 4 - high importance; and 5 - very high importance.
Comparison with other industries: it is a comparison regarding quality between the saw under development and the saw of a competitor. The grades range from 1 up to 5, where: 1 - not satisfactory; 2 - satisfactory with restrictions; 3 - satisfactory; 4 - good satisfactory; and 5 - excellent satisfactory.
Desired Quality: it is the product's quality degree that the customer needs must achieve. It can assume values from 1 to 5, where: 1 - not satisfactory; 2 - satisfactory with restrictions; 3 - satisfactory; 4 - good; and 5 - excellent.
Improvement ratio (ir_i): it is desired quality and the current level ratio, as shown below.

$$ir_i = \text{desired quality/current quality}$$

The current quality is calculated based on comparisons with other industries.

Strong sales feature (ssf_i): they are identified based on competitors and the market information. The following legend is used: 1 - weak - ●; 1.25 - average - ■; and 1.5 - strong **-** ♦.

Customer needs weight: according to Carvalho (1997) they are calculated as absolute and relative, as follows:
Absolute:

$$AW_{NCi} = id_i . ir_i . ssf_i \tag{1}$$

Relative:

$$RW_{NCi} = AW_{NCi} \cdot \frac{100}{\sum_k AW_{NCk}} \tag{2}$$

System requirements: implemented through the Functional Analysis method, according to Cross (2004).

Functional analysis: Figure 3 shows a functional analysis which describes the main function of the mechatronic saw, followed by the deployment of the main function into the sub-functions.

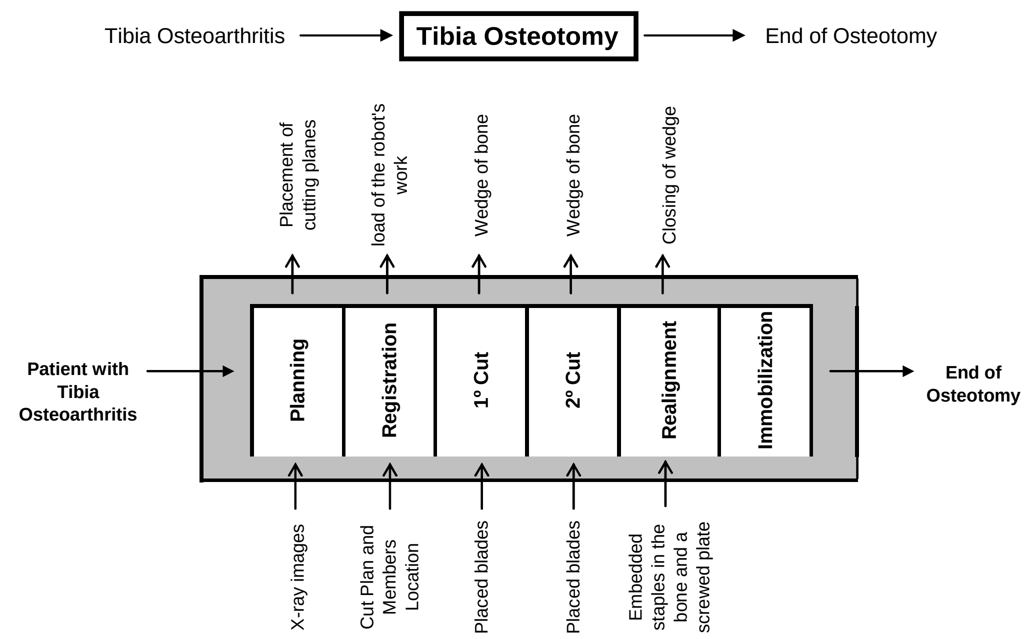

Figure 3. Functional analysis of the mechatronic saw

Relationship Matrix: The fifth step is to fill in the relationship matrix. This matrix provides a systematic procedure to identify the relationship between customer needs and system requirements. The relation matrix cell was completed with symbols according to the following: 1 – weak - ■; 3 – average - ∞; 9 – strong - ●.

Table 2. Relationship matrix

				Planning	Registration	1º Cut	2º Cut	Realignment	Immobilization
Tibia Osteotomy	Flexibility	Easy handling		■	■	■	■	■	■
		Low weight		■	■	■	■	■	■
		Employment in other surgery		■	■	■	■	■	■
	Sensorial capability	Translacional speed		■	∞	●	●	■	■
		Resistant cutting force		■	∞	●	●	■	■
		Blade's overheating	Bone´s Necrosis	■	■	●	●	■	■
	Efficiency	Cut's precision and accuracy		∞	∞	●	●	■	■
		Blades configuration		■	■	●	●	■	■
		Patient recovery time	Minimise invasion	∞	■	●	●	∞	■
		Safety	Controller by computer	●	●	●	●	∞	■
			Reduce risk the infections	■	■	∞	∞	■	■
		Surgeon's ergonomics	Dismissal repetitive movements	■	■	●	●	∞	∞
			Reduce psychological stress	■	■	∞	∞	■	■
			Dismissal motor ability	■	■	●	●	∞	∞
			Position	■	■	●	●	∞	∞

Requirements Weight: The seventh step refers to the calculation of the requirements weights. This step determines which requirements are important to satisfy the customer needs and only they are transferred to Matrix 2.

Customer needs weight: according to Carvalho (1997) they are calculated as absolute and relative, as follows:
Absolute:

$$AW_{RSj} = \sum_{i} \prod_{j} (RW_{NCi} . R_{ij}) \qquad (3)$$

Relative:

$$RW_{RSj} = AW_{RSj} \cdot \frac{100}{\sum_k AW_{RSk}} \qquad (4)$$

The results are shown in Table 3.

Table 3. Requirements weight

	Planning	Registration	1º Cut	2º Cut	Realignment	Immobilization
Absolute weight	200.32	213.18	731.51	731.51	163.67	128.94
Relative weight	9.24	9.83	33.72	33.72	7.55	5.94

Pareto Chart: This step selects the systems requirements with higher relative weight. The graph in Figure 4 helps to identify the functional requirements more strongly related with the customer's needs. The requirements - 1st and 2nd cut - are, consequently, transferred to Matrix 2.

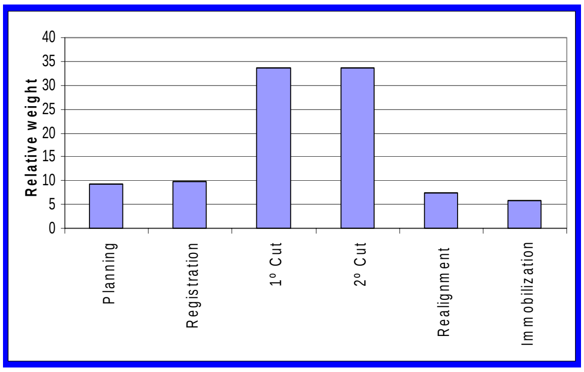

Figure 4. Pareto chart

Matrix 2 of QFD: Product structure (parts definition)

Technical degree of importance (tdi_j): The first step consists of indicating the technical importance of the part feature necessary to achieve the system's requirements. The grades ranges from 1 up to 5, where: 1 – very few importance; 2 – few importance; 3 – average importance; 4 – high importance; and 5 – very high importance. They are shown in Table 4. The overall structure of the mechatronic saw is depicted in Figure 5.

Table 4. Importance Degree

	Blades	Blades support	Removable blade holder	Pivot	Cam drive for blades	Transfer gearbox	Rolling	Cutting force sensor	Blade drive motor	Rack	Feed motion motor	Rolling	Roll motion motor	Roll motion gear train	Electromagnetic brake	Temperature sensor	Manipulator interface	Absolute requirements weight	Relative requirements weight
Planning	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	200.32	9.24
Registration	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	5	213.18	9.83
1º Cut	5	4	3	4	5	5	4	5	5	5	5	4	5	5	5	5	4	731.51	33.72
2º Cut	5	4	3	4	5	5	4	5	5	5	5	4	5	5	5	5	4	731.51	33.72
Realignment	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	163.67	7.55
Immobilization	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	128.94	5.94

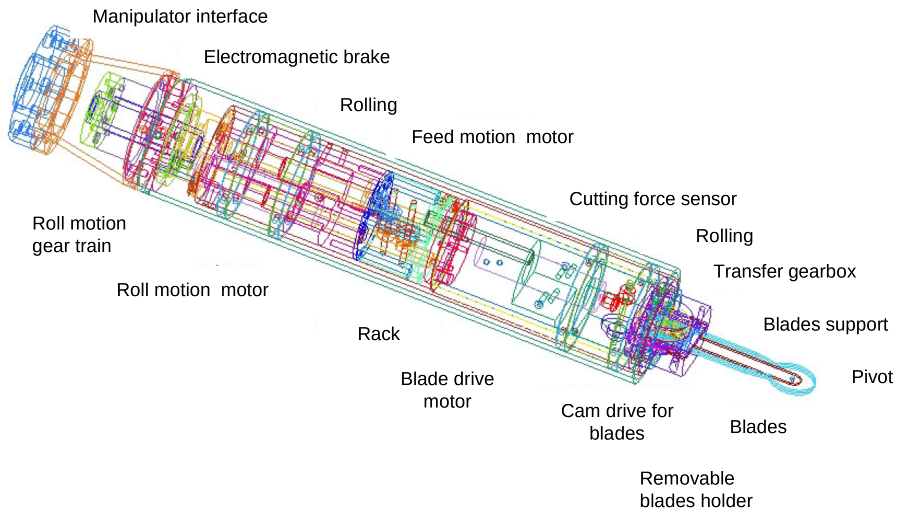

Figure 5. Parts of orthopaedic saw

Relationship Matrix: The second step is the development of the relationship matrix between the functions (inherited from matrix 1) and the physical parts of the saw. The relation matrix cells are filled with symbols according to the following: 1 – weak - ■; 3 – average - ∞; 9 – strong - ●.

Table 5. Relationship matrix

	Blades	Blades support	Removable blade holder	Pivot	Cam drive for blades	Transfer gearbox	Rolling	Cutting force sensor	Blade drive motor	Rack	Feed motion motor	Rolling	Roll motion motor	Roll motion gear train	Electromagnetic brake	Temperature sensor	Manipulator interface
Planning	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Registration	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	∞
1º Cut	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
2º Cut	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Realignment	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Immobilization	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Parts Features Weight: the last step consists in calculating the parts' features weight. This step indicates which parts satisfy the main functional requirements of the system.
Customer needs weight: according to Carvalho (1997) they are calculated as absolute and relative, as follows:
Absolute:

$$AW_{PFj} = tdi_j . \sum_i \prod_j (RW_{RSi} . R_{ij}) \tag{5}$$

Relative:

$$RW_{PFj} = AW_{PFj} \cdot \frac{100}{\sum_k AW_{PFk}} \tag{6}$$

Table 6. Parts weight

	Blades	Blades support	Removable blade holder	Pivot	Cam drive for blades	Transfer gearbox	Rolling	Cutting force sensor	Blade drive motor	Rack	Feed motion motor	Rolling	Roll motion motor	Roll motion gear train	Electromagnetic brake	Temperature sensor	Manipulator interface
Relative parts weight	3,067.36	2,460.4	1,853.44	2,460.4	3,067.36	3,067.36	2,460.4	3,067.36	3,067.36	3,067.36	3,067.36	2,460.4	3,067.36	3,067.36	3,067.36	3,067.36	2,598.02
Absolute parts weight	6.39	5.12	3.86	5.12	6.39	6.39	5.12	6.39	6.39	6.39	6.39	5.12	6.39	6.39	6.39	6.39	5.41

With the two QFD matrixes, it is possible to identify the actual medical needs regarding the osteothomy surgery device development. The parts that compose this device have been identified with the functional requirements.

Based on upon the findings from the QFD analysis, a questionnaire was sent to orthopaedics professionals in order to justify the actual need for the development of such mechatronic device. The returned answers have confirmed the necessity for the development for such an orthopaedic saw. One of the main reasons for the general positive answer is that the tibia osteothomy surgery is very difficult to carry out because the movements demand high accuracy.

6. Conclusion

The QFD method is a system to identify and prioritize customer needs obtained from every available source. By using QFD, engineers can methodically analyze the details of design and process improvement to find those needs. The charts and tables of QFD are living documents that simulate continuous improvement. The QFD process clearly builds teamwork within an organization. An outcome and significantly important benefit of a successful QFD application is communication and complete teamwork by all disciplines within an organization. QFD is a highly versatile engineering tool.

The medicine and engineering relationship has many communication problems, so it is not usual to find a research team composed by members of both areas. The QFD method and the customized questionnaire have been employed to bridge the gap between them. As a case study, a mechatronic orthopedic saw has been analyzed through reverse to prove the proposed method is effective to achieve this goal.

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