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# Identification of design requirements for Stance Control Knee-Ankle-Foot orthosis without actuator using the QFD method

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**Abstract.** The starting point of this study is the emerging interest in Stance Control Knee-Ankle-Foot orthosis (SCKAFO). SCKAFO is prescribed for many diseases, such as polio, muscle weakness, spinal injury, and multiple sclerosis. There are commercial examples and numerous attempts in literature, but functional SCKAFO is still a challenging issue. Users reject orthosis due to functional, comfortable, and cosmetic issues. This study proposes a new design approach to increase the acceptance rate of the orthosis. Design requirements and qualitative data used in this research were determined using users' and practitioners' opinions and information in the relevant articles. Quality function deployment was applied, and the new design was compared with commercial examples. Since there is no standard for SCKAFO design, measurable design requirements were determined using certain fundamental research and review studies. It was determined that a reliable control system is the most critical design requirement, and other important criteria are low weight and low cost, respectively. The outcomes were also examined from the perspective of orthotist and manufacturers. According to the results, a new design approach was proposed. These outcome parameters and solutions are in line with the latest design studies. In addition, size, cost, and weight reduction were achieved. The results of this research can be used for personalized solutions that can meet the different needs of individuals or groups in need of specific solutions.

**Keywords.** Lower limb orthotics; stance control; quadriceps weakness; quality function deployment; user-driven.

## 1. Introduction

Walking is one of the most common activities in our daily life that people can do without thinking, but it is also a complex mechanism. It requires an advanced balance and coordination of the limbs. Knee-Ankle-Foot orthoses (KAFO) are often prescribed to people with stroke, spinal cord injury, and polio. The primary KAFO function in persons with flask quadriplegia is to stabilize the knee or compensate for muscle weakness, but an actuator system is mandatory in patients with high muscle weakness [1]. As a result of these functional differences, optional orthosis design can be studied depending on muscle strength.

KAFO is a lower extremity assistive device used to control the knee in the case of instabilities. It keeps the knee locked and fully extended throughout the gait cycle. Thus, knee flexion and extension are prevented during the swing and stance phase. It causes abnormal walking, and this functional shortening is compensated by the unnatural gait pattern. To provide enough toe clearance during the swing phase, particular gait compensations such as hip hiking, vaulting, and circumduction are required [2]. This unnatural gait requires excessive energy consumption and leads to premature exhaustion, limited mobility, pain, and decreased range of motion in lower limb joints during ambulation [3]. It has been reported that the ineffectiveness of the limb's complete rigidity reduces walking efficiency by 24% and increases the vertical displacement of the body's center of mass by up to 65% [4]. Therefore, more than 60% (higher in some studies) of these devices were abandoned by the intended users [5].

Stance Control KAFO (SCKAFO or SCO) is a mechanical or electromechanical device that overcomes the disadvantages of conventional KAFO by providing free knee motion in the swing phase and bearing the user's weight in the stance phase, thus providing a more natural gait than a locked KAFO. Several types of SCKAFO have been developed in this manner, and they provide motion using different systems [3]. Researchers report that SCKAFO improves gait efficiency, kinematics, and mobility compared with traditional KAFO [6, 7]. The users of SCKAFO have advantages like increased knee range of

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motion, stride, step length, and user satisfaction [5]. However, the user still faces an abnormal gait pattern problem because of the fully locked knee joint in the stance phase [8]. Thus, the main functional limitation in this type of SCKAFO is the lack of dampened knee flexion under load [9]. Tian reported other problems of SCKAFO as the need for full knee extension to engage the lock mechanism, rough switching between phases, improper functioning when used in stair ascent and descent, and stepping over something [10].

SCKAFO has many advantages over KAFO, but these are generally limited to straight walking [3]. Users manually disable SCKAFO to permanently lock the knee when there are slopes, obstacles, and stairs. This problem can be solved by an intelligent control system and stiffness-controlled lock mechanism. Dynamic KAFO (DKAFO) or microprocessor-controlled SCKAFO (M-SCKAFO) emerged to provide more natural walking ability throughout the entire gait cycle and for different daily life activities [4, 11]. They generally have a microprocessor, pressure sensors, and inertial measurement units to monitor the limb's movement. They can detect the gait phase and activate the lock system according to the control system output [12]. They increased the acceptance rate, and also users showed an increase in velocity, stride/step length, and cadence. However, these devices are generally bulky (cannot hide), heavy, high cost, lack aesthetics, fewer orthotic component choices, and a power source problem. Therefore they have minimal usage opportunities [13]. For example, poliomyelitis subjects were fitted with a powered orthosis, and no significant improvement has been reported for primary outcome measurements such as walking speed and distance walked [14]. The advantages of MSCKAFO over SCKAFO in static and dynamic balance, gait speed, and walking on uneven surfaces have been studied and showed [15]. However, the reduction of knee joint size and weight has been suggested as crucial considerations for future studies.

Although the orthotic design has improved, problems continue to arise. Braun identified five key issues for a successful orthotic device: individualization, specialized design, target group, asymmetric gait, and device acceptance [16]. The target group can be determined according to the type of disease or the degree of disease. However, this method can lead to arise of too many alternatives. A more general grouping is required. This exploratory research aims to present a new approach and recommendations for orthosis wearers, offering different design solutions according to the degree of muscle weakness. If the user has sufficient muscle strength against gravity, controlled orthosis increases mobility compared to conventional orthosis and provides many clinical benefits [17]. These patients do not require actuation force in the swing phase, but the device should allow for knee bending during stance and swing phases on different terrains. Auberger supports that different patient cases require new design requirements [18]. Braun emphasized the importance of device variability to preserve a patient's remaining abilities, and the choice of assistive devices can be decided by grouping [16]. Therefore, increasing user satisfaction is more important than improving the orthosis functions.

The flexion and extension are actively controlled in the powered orthosis, but a minimum level of residual motor function is necessary for orthosis without an actuator. An energy-efficient support orthosis that does not use power sources such as motors and batteries can be designed [19]. In this light, the orthosis should have different alternatives or be determined according to the person's condition. The new design should eliminate functional shortening of the original SCKAFO, such as the choice of different modes and the ability to flex-extension in stance. In this study, we aim to offer solutions while developing the design criteria of SCKAFO. This design should be a simple, cosmetically appealing, and affordable device for users with low degrees of muscle weakness. Thus different orthosis solutions can provide a balance between functionality and flexibility.

The organization of the paper is as follows. The next section presents the method used to evaluate orthosis's performance and design requirements. A summary of the design criteria is provided at the end of this section. In the third section, the Quality Function Deployment (QFD) method is demonstrated based on the selected design attributes and their relationship from the perspective of users, practitioners, and manufacturers. Section 4 compares QFD results with selected research studies and commercially available models. Section 5 presents results and discussions. The conclusions are provided in section 6.

## 2. Method

A user-centered approach may be the best way to improve the orthosis design. QFD is a set of method and tools used to define customer requirements and translate them into detailed engineering requirements [20, 21]. It links users, marketers, engineers, competitors, and production methods.

The first step in QFD is to identify the functional requirements of the intended users. A comprehensive search was carried out through international databases PubMed, Google Scholar, and Science Direct for the last 20 years. General keywords SCKAFO, KAFO, and related combinations such as lower limb orthosis and energy cost were also searched. 48 papers were selected based on the following criteria: design-related study, case experiments, and consumer opinions [22–24]. In addition, the literature on design, modeling, testing, and examination studies related to KAFO and SCKAFO were reviewed [8, 21–23]. The advantages and disadvantages of the studied model by researchers and suggestions for design and future studies were collected and organized. KAFO design studies were examined only for their mechanical systems. Users of commercial examples of this type of device were asked to clarify the drawbacks and benefits of their orthosis. This information was used to determine the functional requirements necessary to design a good orthosis. These data were tabulated on the left side of the QFD chart.

The qualitative data used in this study were obtained through conversations with practitioners, orthoptist, physical therapists, manufacturers, and related field experts. They were asked to clarify the main expectations and desires from a SCKAFO and rank them from the most important to the least important. Also, 5 orthotics-prosthetics application centers and orthotics in these centers were visited. The same questions were asked to them to be answered according to their perspectives. This information was also used to construct the QFD matrix. During the determination of functional requirements, the relevant persons were also asked to rate the importance of these features for themselves on a scale of 1 to 10. These ratings were grouped in a different column for each category. In the next section, the characterization of orthosis design is explained with the support of related research and the studies mentioned above.

## 3. Characterization of SCKAFO requirements

The muscle grades of the patients using SCKAFO are different from each other. According to muscle grade classification, people with grade 2 and higher disabilities have no strength even against gravity [25]. They need an actuation mechanism to flex and extend their limb, resulting in a high-power requirement and related problems such as increased device volume and weight. SCKAFO can be optionally designed according to the degree of muscle weakness. Patients with hip flexor strength less than grade 3 may be equipped with a more powerful device capable of producing high torque. In conclusion, the main functions of orthosis in individuals with high muscle weakness are activated flexion and extension in the swing phase and high stiffness in the stance, while these functions may be free movement in the swing and high stiffness in the stance in patients with low muscle degrees. Depending on this grading scale, various design solutions can be studied.

In order to fully address user desire in the design of SCKAFO, the standard design requirements of all user groups were identified. Technical attributes related to the design specification could not be implemented as there is no design standard for SCKAFO. However, the work of Yakimovich [5], Farah [26], Bernhardt [27], and Noah [28] are valuable design studies about KAFO and SCKAFO, and they were accepted as fundamental resources. Measurable objectives and technical attributes of design were determined according to these studies. Yakimowich and Noah preferred the same design methodology used in this study. Rafiaei conducted detailed research about SCKAFO, reviewed 18 SCKAFO directly related papers, and identified each method and the results of these studies [22]. They were also included in this study. Design requirements were collected under three main categories, and other requirements of the selected group were added in accordance with the purpose of the study.

### 3.1 *Functional requirements*

The most critical parameter in orthosis design is patient safety, and any functionality should not compromise it. Users should feel safe at every stage of the gait. The selected lock system must meet this requirement. A functional and practical SCKAFO should be used at all daily activities for our selected group (grade 3 and higher values). In order to provide this function, the device must apply different algorithms on even/uneven ground, stair ascent and descent, as well as descending and ascending slopes. The user can select this different mode, or the control system can detect it automatically with the help of a smart algorithm.

A flexible variable lock system has an advantage during stance, as knee flexion also occurs during limb loading and pre-swing [29]. Unlike conventional SCKAFO, the new design must allow knee extension while restricting knee flexion during the stance phase. Generally, mechanical lock systems such as ratchets and clutches generate noise. Users want the device hidden under clothing and not be noticed by sound. The new locking system should be quiet and reliable. These types of devices started to prefer by elderly persons who have sufficient muscle strength but prefer to wear orthosis to be confident. Therefore, the device needs a system that can detect falling and stumbling with a fast locking mechanism. Modern orthotic systems have electronic sensors and require a power source. A noise warning system should be integrated to inform the user in the case of a low battery or any other problem in the system.

Orthoses are also used for rehabilitation. The actuator weight is approximately half of the orthosis weight [7]. The electrical system and power source also contribute more to the weight. Powered orthoses are too bulky and heavy and cannot hide under clothing [30]. For this reason, one of the main goals of orthosis production is to reduce the total weight and volume. Our approach offers new solutions according to the user actuation need (muscle weakness grade). A lighter and simpler mechanism can be achieved by designing the orthosis without requiring an actuator and high power supply.

### 3.2 *Structural requirements*

Size and weight are critical considerations in the structural requirements of the device, as cosmetic is one of the top reasons for abandoning orthosis. The excessive weight of the device contributes to more energy demand on the weak limb. Users already suffer from muscle weakness; this extra weight causes more energy requirements and leads to abnormal gait. The effect of orthosis weight has been shown as an increase in user satisfaction with lightweight designs [12]. Even though the design fulfils all the desired functions, the users do not want to wear the device if it has a bulky structure [16]. A thin, laterally shaped, and low-weight design has general acceptance. The maximum dimensions for the device were determined by 30 mm thickness, 50 mm width, and 125 mm length, according to the previous studies.

Mechanically controlled SCKAFO changes free knee motion during the swing and has advantages such as a simple control system that does not require external power, a slim design, and a low number of parts. Thus the low weight and opportunity of hiding under trousers can be provided [13]. However, they do not allow knee extension during weight-bearing, and another problem is that a particular joint angle is required to switch between stance and swing phases. These constraints can be solved by an electromechanical design, gait phase recognition, and a variable lock system.

Researchers tried many different designs and lock systems to decrease the device weight, but the frame structure of the orthosis also affects the weight. Sidebars are generally made of stainless steel, and thigh, calf, and foot shells are manufactured from metals covered with polymer. A light, nontoxic, and formable material should be selected. The KAFO weight can be reduced by 30% using carbon fiber instead of metal. It has been reported that 70% of the polio subjects preferred composite structure, and weight optimization is advised for future studies [30]. The weight reduction of the device also significantly increases walking distance. Since carbon fiber is expensive, glass fiber can be preferred in sections that do not require high strength.

### 3.3 *Control requirements*

A mechanical control system divides the gait into two distinct phases, and there is no smooth transition between the stance and the swing. The user must reach a predetermined level of elongation and bending angle to activate the locking system. Besides, the mechanical system is generally designed for only level-walking conditions. The individual's condition may change over time and requires calibration. The system should automatically self-calibrate or be very easy to adjust.

The control system of a SCKAFO has two main tasks; (1) detection of the gait and (2) deciding the action of the locking system. The electronic control system can divide the gait into many sub-phases. Thus it can generate different lock stiffness for every case. Another benefit of the electronic system is the prevention of falls and stumble. Sensors can detect the uncontrolled movement of the knee by angle or angular velocity change and take precautions such as blocking or decreasing the speed of the moving parts, then patients take control and correct their posture. The disadvantages of electronic control are specified as power requirement and extra weight [8, 22]. However, actuation was excluded in this project, and the power consumption of sensors and circuits is very low. The battery should provide at least one day or 6000 steps of use per charge. Standard batteries or cells with standard sockets increase the attractiveness of the orthosis. Also, measured data can be stored to follow the progress of the patient's condition.

The knee angle and ground reaction force (GRF) are generally preferred parameters to control an orthosis [6]. The hip, trunk, and foot angles are also used by researchers (figure 1) [31]. The knee angle and GRF are sufficient to detect phase, but the locomotor's rotational speed can improve safety and stability. The knee angle is the difference between the shank and femur and can be calculated directly on the knee via different methods. However, measuring angle value from the difference of locomotor provides precise calculation and increases the ability to control the limb movement for any unnatural movement.

The accuracy of the sensors and the durability of the mechanic parts are vital for an orthosis. The sensors and the mechanical parts may need calibration when first installed. Service provides preventative maintenance for full calibration, cleaning, and repair if necessary. However, the time interval between services should be at least 6 months. The importance of size standardization of orthosis was specified by Spring [32]. However, there are no international or local standards for orthosis design or manufacturing techniques. According to the information outlined above, the critical parameters of the device are tabulated (table 1).

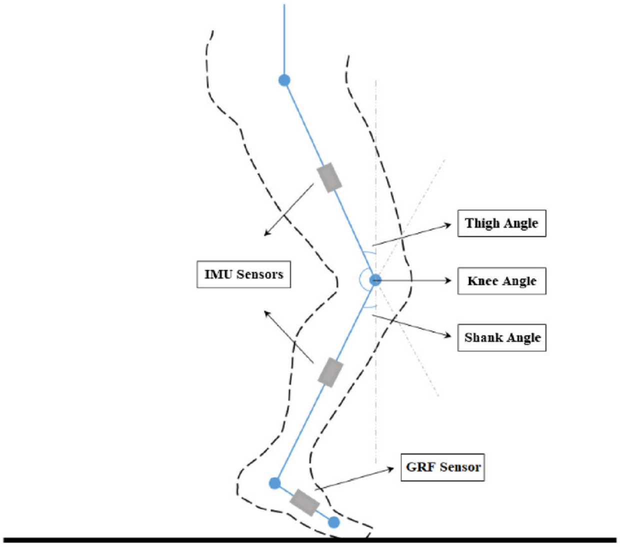


**Figure 1.** General variables that are used for controlling orthosis.

**Table 1.** The critical elements for the design.

| Design criteria | Target value |
|---|---|
| Flexion resistance | 150 Nm |
| Weight | < 2.5 kg |
| Thickness | < 50 mm |
| Width | < 75 mm |
| Length | < 200 mm |
| User weight | 100 kg |
| Power consumption | 6000 steps by one charge |
| Servicing time | 1 year |
| Sale price | < 5000 USD |

## 4. Identification of design requirements for the selected group by QFD method

A user-driven design process can improve the design of orthosis. This analysis aimed to prioritize SCKAFO design specifications based on the needs of the selected patient group. The opinion of practitioners and manufacturers was also included to improve the acceptance of the design. The house of quality chart for the SCKAFO was constructed according to the above information and presented in figure 2. The relationship strength between design requirements and engineering parameters is represented by the numbers on the middle part of the matrix. Higher values indicate that engineering parameters significantly influence the design requirements, and lower numbers have a slight effect. The triangle region at the top shows positive and negative correlations between engineering parameters. That is the improvement of one parameter increases or decreases another simultaneously. For comparison, 4 different models were selected, one commercially available. Some information for design parameters is missing or not attempted. All satisfy the primary function of SCKAFO, such as resisting knee torque, free motion in swing, and resisting flexion at any angle.

The overall results of the QFD analysis are shown bottom part of the matrix. The assigned user weights and their related engineering specifications were multiplied. The total sum was calculated separately for the user, orthoptist, and manufacturer at the bottom of each column. This information shows the ranking of engineering specifications in order of relative importance. The highest-rated engineering parameters should take special attention.

## 5. Results and discussion

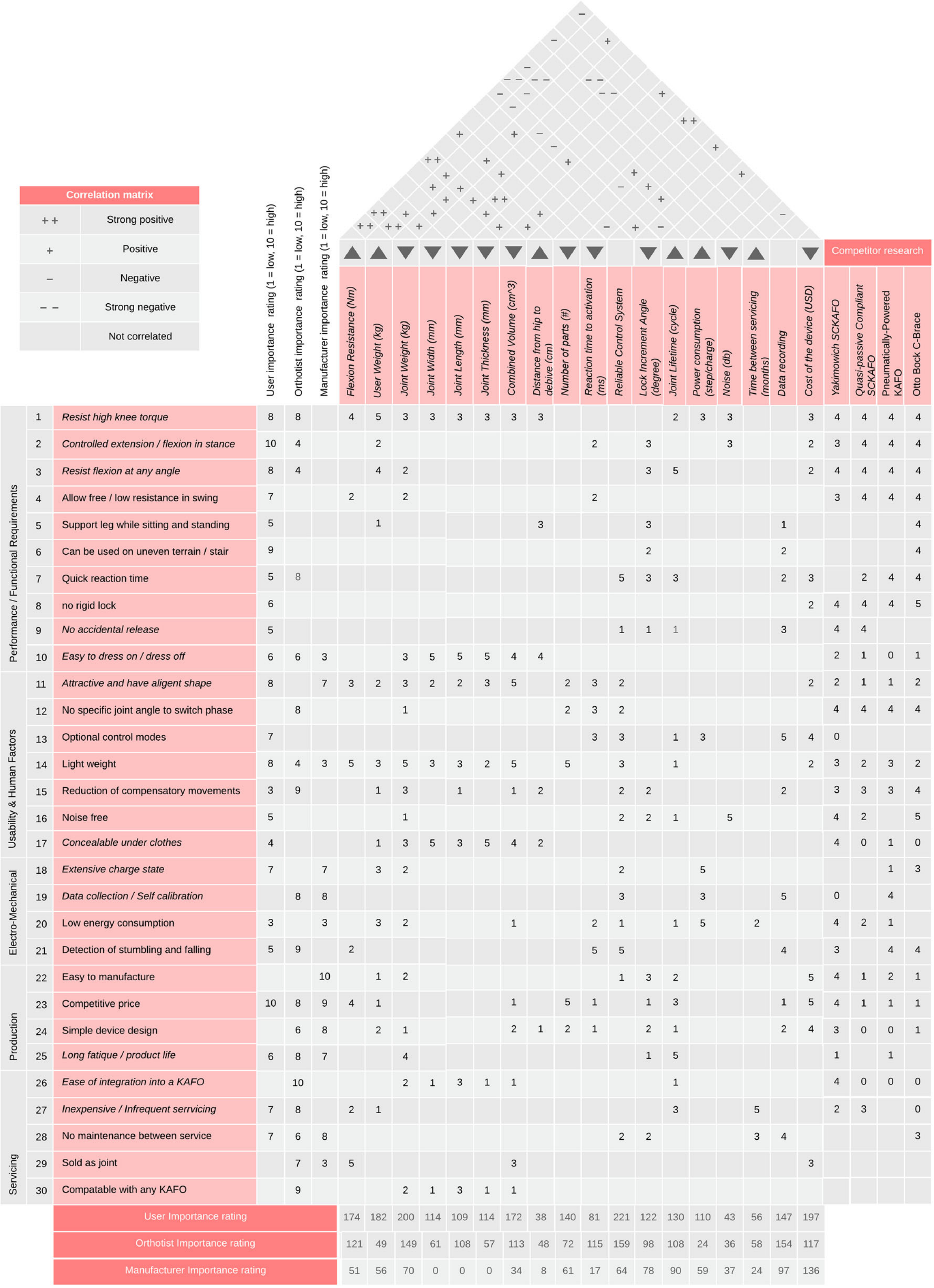
A SCKAFO is a long-leg brace and can be examined in two parts; the lock mechanism and control system. Different lock mechanisms develop day by day and perform their functions better. Therefore, recent studies are mainly about the control system [26]. This section combined the result of the QFD chart and reviewed studies to reveal new design suggestions. Finally, it was compared with existing models.

According to the results, the most important parameter is a reliable control system. Not surprisingly, most patients prefer to use the Swiss lock type knee joint embedded orthosis if they have at least grade 3 hip strength [33]. They feel confident because the lock only disengages when they pull the trigger. That proves that a fully functional and reliable control system is the most desired target requirement. The orthosis should also be used in different terrains, such as uneven ground and stairs. This is also directly related to the control system and requires an excellent gait phase detection algorithm. The other effective weighted parameters can be summarized as follows; simple design, low weight, and low cost.

Joint width, length, thickness, and combined volume approximately have the same importance (table 2). The width and thickness of the device are more important than the length. The increased width and thickness make it more difficult to hide the device under the clothes. The extended device length only gives trouble when dressing on and off the orthosis. Therefore, its tolerance is higher than other dimensions. Due to space and weight limitations, prostheses are of higher practical relevance than orthosis [16]. The knee area has higher volume due to lock placement in the orthosis. The other units, such as battery and electronic sections, can be placed in the up direction. Generally, design studies try to decrease the lock size [34]. The most crucial criterion related to the size is the use of the orthosis in such a way that it cannot be noticed under the dress. Thus a lateral placement of orthosis is recommended.

The researchers showed that the rejection rate of SCKAFO is still high despite the advent of more technological devices [12]. Therefore, a long orthosis lifetime is less critical for the user, but durability is essential during usage. The useful lifetime for a SCKAFO is generally considered 5 years [35]. The number of parts parameter has high importance because it is related to functions that orthosis can accomplish. SCKAFO should provide different stiffness values, and this requires many moving mechanisms. The high number of parts increases the device's complexity, weight, and size. Rakib examined many mechanisms and stated that a successful orthosis design is limited by weight, bulkiness, lack of enough cosmetic appeal, noise, and cost [23]. In addition, significant stress on the device while supporting the user's body weight during walking restricts its ability to create a compact and less bulky design.

The reaction time of activation is of low weighted importance, but it is essential for maintaining balance in case of stumbling and recovering gait. Quick switches between phases allow a smooth change, thus increasing the orthosis's comfort. Another reason for refusing device use is that the locking system or mechanism creates annoying and repetitive noise. A noise-free device is desirable. In the case of any need, a vibrating mechanism can be designed for warning. Noise alerts can only be preferred for emergencies.



| | | | | | | | | | | | | | | | | | | | | | | | | Competitor research | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | User importance rating (1 = low, 10 = high) | Orthotist importance rating (1 = low, 10 = high) | Manufacturer importance rating (1 = low, 10 = high) | Flexion Resistance (Nm) | User Weight (kg) | Joint Weight (kg) | Joint Width (mm) | Joint Length (mm) | Joint Thickness (mm) | Combined Volume (cm^3) | Distance from hip to debive (cm) | Number of parts (#) | Reaction time to activation (ms) | Reliable Control System | Lock Increment Angle (degree) | Joint Lifetime (cycle) | Power consumption (step/charge) | Noise (db) | Time between servicing (months) | Data recording | Cost of the device (USD) | Yakimowich SCKAFO | Quasi-passive Compliant SCKAFO | Pneumatically-Powered KAFO | Otto Bock C-Brace |
| | | | | | | ▲ | ▲ | ▼ | ▼ | ▼ | ▼ | ▼ | ▲ | ▼ | ▼ | | ▼ | ▲ | ▲ | ▼ | ▲ | | ▼ | | | | |
| Performance / Functional Requirements | 1 | *Resist high knee torque* | 8 | 8 | | 4 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | | | | | 2 | 3 | 3 | | | 3 | 4 | 4 | 4 | 4 |
| | 2 | *Controlled extension / flexion in stance* | 10 | 4 | | | 2 | | | | | | | | 2 | | 3 | | | 3 | | | 2 | 3 | 4 | 4 | 4 |
| | 3 | *Resist flexion at any angle* | 8 | 4 | | | 4 | 2 | | | | | | | | | 3 | 5 | | | | | 2 | 4 | 4 | 4 | 4 |
| | 4 | Allow free / low resistance in swing | 7 | | | 2 | | 2 | | | | | | | 2 | | | | | | | | | 3 | 4 | 4 | 4 |
| | 5 | Support leg while sitting and standing | 5 | | | | 1 | | | | | | 3 | | | | 3 | | | | | 1 | | | | | 4 |
| | 6 | Can be used on uneven terrain / stair | 9 | | | | | | | | | | | | | | 2 | | | | | 2 | | | | | 4 |
| | 7 | Quick reaction time | 5 | 8 | | | | | | | | | | | | 5 | 3 | 3 | | | | 2 | 3 | | 2 | 4 | 4 |
| | 8 | no rigid lock | 6 | | | | | | | | | | | | | | | | | | | | 2 | 4 | 4 | 4 | 5 |
| | 9 | *No accidental release* | 5 | | | | | | | | | | | | | 1 | 1 | 1 | | | | 3 | | 4 | 4 | | |
| | 10 | *Easy to dress on / dress off* | 6 | 6 | 3 | | | 3 | 5 | 5 | 5 | 4 | 4 | | | | | | | | | | | 2 | 1 | 0 | 1 |
| Usability & Human Factors | 11 | *Attractive and have aligent shape* | 8 | | 7 | 3 | 2 | 3 | 2 | 2 | 3 | 5 | | 2 | 3 | 2 | | | | | | | 2 | 2 | 1 | 1 | 2 |
| | 12 | No specific joint angle to switch phase | | 8 | | | | 1 | | | | | | 2 | 3 | 2 | | | | | | | | 4 | 4 | 4 | 4 |
| | 13 | Optional control modes | 7 | | | | | | | | | | | | 3 | 3 | | 1 | 3 | | | 5 | 4 | 0 | | | |
| | 14 | Light weight | 8 | 4 | 3 | 5 | 3 | 5 | 3 | 3 | 2 | 5 | | 5 | | 3 | | 1 | | | | | 2 | 3 | 2 | 3 | 2 |
| | 15 | Reduction of compensatory movements | 3 | 9 | | | 1 | 3 | | 1 | | 1 | 2 | | | 2 | 2 | | | | | 2 | | 3 | 3 | 3 | 4 |
| | 16 | Noise free | 5 | | | | | 1 | | | | | | | | 2 | 2 | 1 | | 5 | | | | 4 | 2 | | 5 |
| | 17 | *Concealable under clothes* | 4 | | | | 1 | 3 | 5 | 3 | 5 | 4 | 2 | | | | | | | | | | | 4 | 0 | 1 | 0 |
| Electro-Mechanical | 18 | *Extensive charge state* | 7 | | 7 | | 3 | 2 | | | | | | | | 2 | | | 5 | | | | | | | 1 | 3 |
| | 19 | *Data collection / Self calibration* | | 8 | 8 | | | | | | | | | | | 3 | | | 3 | | | 5 | | 0 | | 4 | |
| | 20 | Low energy consumption | 3 | | 3 | | 3 | 2 | | | | 1 | | | 2 | 1 | | 1 | 5 | | 2 | | | 4 | 2 | 1 | |
| | 21 | Detection of stumbling and falling | 5 | 9 | | 2 | | | | | | | | | 5 | 5 | | | | | | 4 | | 3 | | 4 | 4 |
| Production | 22 | Easy to manufacture | | | 10 | | 1 | 2 | | | | | | | | 1 | 3 | 2 | | | | | 5 | 4 | 1 | 2 | 1 |
| | 23 | Competitive price | 10 | 8 | 9 | 4 | 1 | | | | | 1 | | 5 | 1 | | 1 | 3 | | | | 1 | 5 | 4 | 1 | 1 | 1 |
| | 24 | Simple device design | | 6 | 8 | | 2 | 1 | | | | 2 | 1 | 2 | 1 | | 2 | 1 | | | | 2 | 4 | 3 | 0 | 0 | 1 |
| | 25 | *Long fatique / product life* | 6 | 8 | 7 | | | 4 | | | | | | | | | 1 | 5 | | | | | | 1 | | 1 | |
| Servicing | 26 | *Ease of integration into a KAFO* | | 10 | | | | 2 | 1 | 3 | 1 | 1 | | | | | | 1 | | | | | | 4 | 0 | 0 | 0 |
| | 27 | *Inexpensive / Infrequent servicing* | 7 | 8 | | 2 | 1 | | | | | | | | | | | 3 | | | 5 | | | 2 | 3 | | 0 |
| | 28 | No maintenance between service | 7 | 6 | 8 | | | | | | | | | | | 2 | 2 | | | | 3 | 4 | | | | | 3 |
| | 29 | Sold as joint | | 7 | 3 | 5 | | | | | | 3 | | | | | | | | | | | 3 | | | | |
| | 30 | Compatable with any KAFO | | 9 | | | | 2 | 1 | 3 | 1 | 1 | | | | | | | | | | | | | | | |
| | | User Importance rating | | | | 174 | 182 | 200 | 114 | 109 | 114 | 172 | 38 | 140 | 81 | 221 | 122 | 130 | 110 | 43 | 56 | 147 | 197 | | | | |
| | | Orthotist Importance rating | | | | 121 | 49 | 149 | 61 | 108 | 57 | 113 | 48 | 72 | 115 | 159 | 98 | 108 | 24 | 36 | 58 | 154 | 117 | | | | |
| | | Manufacturer Importance rating | | | | 51 | 56 | 70 | 0 | 0 | 0 | 34 | 8 | 61 | 17 | 64 | 78 | 90 | 59 | 37 | 24 | 97 | 136 | | | | |

**Figure 2.** Quality function deployment (QFD) results for the design of SCKAFO.

Muhammad Rakib *et al* [12] published an article on the design analysis of SCKAFO and summarized design criteria as follows; quick switch between phases, full control at different terrain, controlled knee flexion, acceptable device volume, weight, noise, and minimal cost. As a result, in accordance with the result of this study, the design

**Table 2.** Relative percentage of engineering parameters.

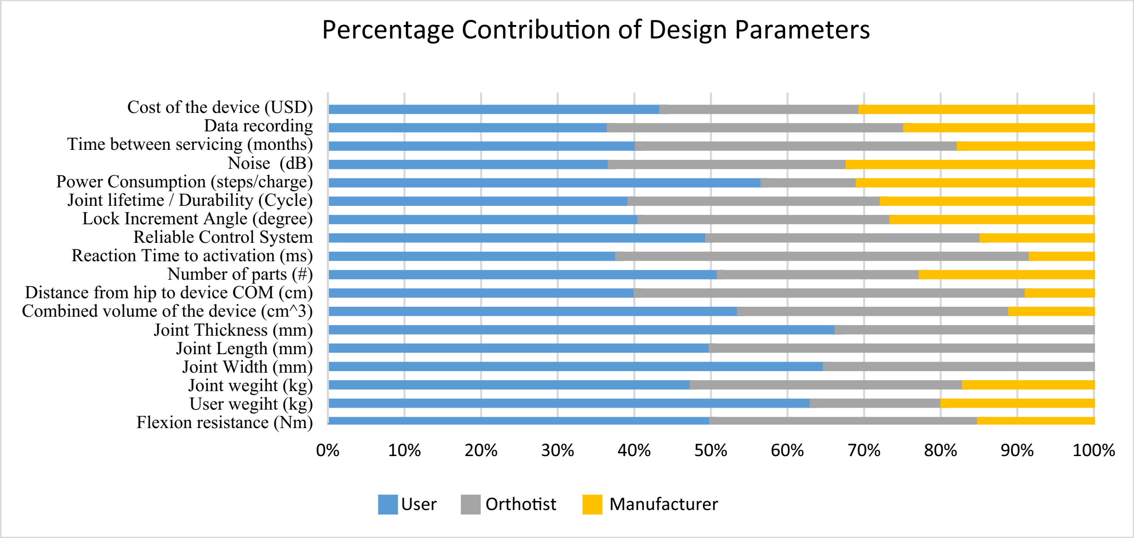


**Table 3.** The result of the weighted importance of design parameters.

| Number (user perspective) | Engineering parameters | Weighted importance | Orthotist perspective | Manufacturer perspective |
|---|---|---|---|---|
| 1 | Reliable Control System | 221 | # 1 | # 5 |
| 2 | Joint Weight | 200 | # 3 | # 4 |
| 3 | Cost of the Device | 197 | # 5 | # 1 |
| 4 | User Weight | 182 | Insignificant | Insignificant |
| 5 | Flexion Resistance | 174 | # 4 | Insignificant |

criteria can be collected as an operational control unit with an appropriate size and cost.

In this study, weighted importance was also calculated from the practitioner (orthotist) and manufacturer's perspectives (table 3). Joint weight, reliable control system, and data recording have high importance for the practitioner. Although users and orthotics attach the same importance to the reliable control system, it is the fifth important engineering parameter from the manufacturer's point of view. The orthosis weight issue is related to the ease of orthosis application for the practitioner. SCKAFO is always heavier than passive KAFO because they have a complex system. It is assumed that the greater the device's weight, the more energy is needed to move it through space during the swing phase [36]. Therefore, users need to expend more effort and energy while walking. However, the patients pointed out that the extra weight and volume may be acceptable if the orthosis provides a full-function active movement [37]. They declared that added weight is tolerated when the stance control mechanism is activated and fully functional. The second-ranked parameter for orthotist is data recording. Orthotist or physiotherapists can follow a patient's progress, and by these, different treatments and devices can be applied.

Joint price is the most weighted importance for manufacturers. Data recording is also important for manufacturers like orthotist because this output can be used to develop and improve the device. Other influential factors are joint weight, increment angle, and lifetime which have the same meaning in line with the joint price.

## 6. Conclusions

This study aims to provide insights into a new design approach according to the SCKAFO user needs and thus increase user satisfaction. Despite the many research studies associated with SCKAFO and some commercial examples, a compact, lightweight, cosmetically attractive, and low-cost design is still desired.

The research reported here investigates the most important design attributes in the design and customization of SCKAFO by collecting and examining data from users, practitioners, manufacturers, and research papers. These findings can provide a basis for a comprehensive analysis of SCKAFO design and its implications for performance characteristics. The QFD chart provides important technical information about the SCKAFO requirements and ranks these requirements according to their importance. The research identifies the design features in accordance with the weight of importance in the design and also gives a chance to customize the orthosis according to the individual muscle weakness grade. The design requirements are also evaluated in terms of practitioners and manufacturers.

According to the result of QFD and the inferences mentioned above, the design should have a noise-free, lateral shape, variable stiffness lock mechanism, and a reliable control system at an affordable price. Since the 1990s, SCKAFO development has been carried out using mechanical and powered systems. They are helpful for patients with paresis or paralysis due to neurological disorders. However, many individuals also suffer from quadriceps weakness or knee instability due to paralysis. The second group of users needs a walking assist device rather than the movement done entirely by the device. Therefore, a SCKAFO without an actuator is recommended in this study. For patients with low-grade muscle strength, excluding this system can reduce the device's weight by 50%.

The stance control knee mechanism has been developed using a variety of mechanisms and design techniques. Ratchet, pendulum mechanism, spring clutch, belt clamping, hydraulic systems, and electromechanical controlled actuation are some of these mechanisms and approaches [23]. However, they are bulky, expensive, noisy, and very complex. A piston-cylinder system with valve control can provide variable stiffness, noise-free motion, and lateral placement. Two models, scientific research and a commercial device, have very similar designs [16, 38]. Both models have the same structure (hydraulic damper) controlled by an intelligent system. The first model uses resistive sensors, as this study suggests, while the second system uses strain information on the back bar. Although they used a similar structure, model one tried to achieve better device acceptance by applying different control mechanisms. However, model two has an actuation system which makes it bulky and expensive, although it performs the desired functions. Both SCKAFOs have design criteria compatible with the results we obtained in this study.

As a result, a microprocessor-controlled sensor system with an actuatorless piston-cylinder mechanism is recommended for patients with grade 3 and above muscle weakness. This new design reduces overall orthosis weight by approximately 30%, and electronic gait control provides ambulation on uneven terrain. Optional SCKAFO designs can increase the overall satisfaction rate for the selected group. A survey was conducted about custom-made KAFO in polio survivors [39]. Effectiveness and satisfaction were important considerations when walking and standing with the orthosis. Ottobock C-Brace® is very consistent with the results obtained in this study and performs more functions than other SCKAFO devices. Increased user satisfaction provides speed-adapted control during the damped knee flexion and swing phase in stance. However, light-compact structure, hiding under clothing, and the low-cost design are still challenging problems for researchers.

The information obtained from this study helps both researcher and manufacturer by revealing the essential expected parameters and functions for users. Outcomes of this research can be translated into specific design customized solutions capable of meeting the needs of patients. In addition, it can also provide high user satisfaction, thus acceptance by proposing a new device design that changes according to patients' condition.

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