Design of an Innovative Assisting Device for Knee Osteoarthritis

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Abstract. Osteoarthritis is usually found in weight-bearing joints. Since medial knee joints bear most of the loading during gait, osteoarthritis is especially common in these joints. For early osteoarthritis patients, unloading or increasing muscle strength through exercise is the most fundamental healing approach. The use of assistive devices during exercise can relieve pain and thus increase patient motivation or improve on the duration. However, long-term use of assistive devices may cause discomfort or even side effects and in turn make matters worse. Hence, the purpose of this study includes (1) Developing an innovative assistive device that reduces medial knee loading; (2) Aiming for this device to relieve knee pain caused by OA; (3) Aiming for this device to be free of knee and peripheral muscle movement restrictions and thus increase comfort.

To design an innovative assistive device, this research obtains design criterions through reviewing existing products and expert focus groups. Design concepts are generated in co-design activities following these criterions and eventually converged into one final design with morphological charts. Finally, prototypes are built according to the final design. The results of the experiments show that this innovative assistive device can significantly reduce medial knee loading on both legs, and that the satisfaction scores of design criterions are able to reach an acceptable level.

Keywords: Knee osteoarthritis · Assisting device · Design

1 Introduction

Knee osteoarthritis (KOA) is one of the crucial health issues among the elderly around the world. It is considered the leading cause of disability amongst the elderly, especially those who are above 55 years old [1]. With osteoarthritis, all tissues around the knee joints are affected [2]. Quadriceps dysfunction decreases the protection around the knee joints and periarticular tissues [3]. These local biomechanical factors are particularly important in weight-bearing knee joints and therefore are risk factors of KOA [4]. Additionally, direct injury to cartilage may cause biochemical changes and induce chondrocytes to apoptosis. Thus, previous trauma, incorrect knee movements, and overweight are also risk factors of KOA [5]. Other than that, systematic factors like gender, age, or race that predispose to KOA should also be considered.

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Using aids to decrease the intensity and frequency of impact or change knee alignments efficiently help reduce pain found in patients with mild to moderate KOA [6]. Although aids like bracing and wedged insoles can improve knee functions or reduce pain, Risberg, Holm, Steen, etc. (1999) found significant quadriceps strength decrease after long-term usage [7]. This indicates that bracing may actually improve knee biomechanics but may also limit quadriceps contractions and impedes leg movement. Additionally, other negative impacts including flexion contracture, peripheral vascular disease and intractable contact dermatitis [8]. These disadvantages are largely caused by how traditional bracing works, existing bracings are bound to fix tightly around knee in order to stabilize or realign joint.

The purpose of this research is to develop a new assisting device, which can relief painful symptom of KOA by improving knee biomechanics. By utilizing an innovative assisting approach that allows natural muscle contractions, negative impacts caused by traditional aids may be decreased. This will eventually increase the quality of life among KOA patients.

This research focuses on the design and evaluation of the prototype. Specific procedures are listed below:

(1) Investigate the relationship between knee biomechanics and painful symptoms of KOA, and establish the basic architecture of proper assisting method.
(2) Review traditional and novel aids and set further design criterions including comfort and aesthetics aspects.
(3) Develop an innovative assisting device based on proper assisting methods and design criterions.
(4) Evaluate the efficiency of final design through objective and subjective methods.

2 Methods

From literature review, we have learnt that unloading of medial knee compartment during one-legged stance is the key to relief pain and to slow progression of knee osteoarthritis. Also, correct alignment is crucial to medial to lateral load distribution. The improvement of disproportionate medial load can be achieved by several mechanisms including expending support base, realigning knee loading axis, supporting corresponding muscles, and using compensatory gaits. However, these mechanisms should not increase knee flexion moment to avoid following ascension of contact force. As for the improvement of comfort level and aesthetics in assisting devices, lightweight and material softness are possible directions for a better design.

2.1 Development of Design Criterions

In order to develop an innovative assisting device, specific design criterions such as in-depth understanding of unloading mechanisms and appropriate directions for development are necessary. These criterions are obtained through expert focus groups and reviewing of existing aids in this research.

2.2 Expert Focus Group

Four experts from KOA related fields in National Cheng Kung University are invited to attend the focus group. The professional background of these experts includes fields of biomechanics, orthopedics, engineering, and wearable device.

After an explanation of the whole process and self-introduction of participants, possible unloading mechanisms are introduced together with current research progress. These include expending support base and unload symptomatic joint, realigning maligned loading axis, supporting corresponding muscles, and the use of compensatory gaits. The discussion focused mainly on the effects of each unloading mechanism and possible directions for future development.

Besides their own viewpoints, the consensus of all experts include: Avoid prolonged use of assistive devices to prevent side effects. Assistive devices should only be used in cases of serious discomfort or in cases of large amount of activities. Additionally, assistive devices should be used with core treatments such as exercises and weight management. Improvement of medial loading can be assessed by joint space since it is defined in the criteria of severity. Also, it is unnecessary and difficult to find a new unloading mechanism. It would be more practical to improve on existing products or using existing mechanisms to create innovative applications. As for applications of assistive devices, combining sensors, big data and customization is more flexible and suitable for different user groups. Since knee joint degeneration is irreversible, the developing direction should aim towards prevention and delaying deterioration.

2.3 Review of Existing Aids

Extra in-vitro structures are necessary and will increase overall size of the product and decrease user acceptance. Being the most effective orthosis, unloading braces combine wearable design and realigning function. It should be noted that comfort is important and related to adverse effects. As for the third assisting way, protecting joints from adverse movements may be beneficial but relatively passive. Additionally, design direction should focus on the use of light and soft materials to improve comfort and aesthetics. In conclusion, direct unloading of symptomatic joint is the most effective mechanism. While in terms of structure size consideration, realigning may have a higher application potential.

2.4 Design of Assisting Device

After preliminary design criterions are confirmed, the development of design concepts can begin. The forming of final design depends on the output of concept designs and morphological charts. Ultimately, the final design transforms from detailed sketches to tangible and functional prototypes through repetitive improvement and is ready for efficacy evaluation.

Concept Design

Design is conducted according to design criterions obtained from expert focus group and review of existing aids. The aim of design is to generate as many different concepts as possible. Six graduate students from Department of Industrial Design NCKU are invited to attend the concept design procedures.

In the beginning of concept design, background information on KOA and its relationship with unloading is explained to participants. After that, existing assistive devices, unloading mechanisms, and the feedbacks from the expert focus group are introduced.

Among different unloading mechanisms, increasing loading base is the most preferred due to it is the only method that can distract loading of knee joints. Also, it is a more compatible solution and works for most of the patient cases. However, how to increase the loading base while keeping the assistive device compact and small will be a big challenge. Thus, wearable assistive device designs become the mainstream concept in order to reduce product size. After a period of development, several design concepts are generated after co-design.

The detail mechanisms of these concept designs are explained below:

(1) An exoskeleton-like device that can assist corresponding muscles according to user's gait characteristics.
(2) An innovative insole that can adjust loading axis according to plantar pressure under different situations.
(3) A wearable device which will remind users to maintain unloading gait pattern.
(4) A wearable device that shows loading distribution synchronously and allows user to compare with their subjective feeling.
(5) A wearable device that coordinates with walking aids and warns the user in cases of excessive or insufficient loading on the knee.
(6) A wearable structure that will distribute loading out of the knee.
(7) An inflatable device that will support knee joints.

Final Design

Design concepts mentioned above are then deconstructed along with existing assistive devices to set the components and parameters of morphological charts. Converged with the design criterions set up, components of the assistive device are divided into unloading mechanism, assisting basis, usage, position and material. These components are listed according to their importance in the formation of an innovative assistive device, while parameters are listed according to efficacy of existing products or ideal design directions acquired previously.

In order to limit the divergence and increase efficiency, front row parameters will be combined preferentially. Although ideal designs should be the combination of front row parameters, unreasonable results may still be produced. For example, the first row of parameters can form a plantar wearable device which can increase loading base according to knee loading. However, located at plantar is inconsistent to its function of distracting knee loading. Other contradictions include knee loading are impossible to measure directly, and soft material is ineffective in increasing the loading base.

In order to reduce the size of innovative assistive device and increase comfort, the mechanism for increasing the loading base is eventually abandoned as it requires a hard structure to achieve maximum effect. Thus, realigning loading axis, assisting during stance phase, wearable device, and soft material becomes the parameters with priority. After a variety of combination trials, these parameters are combined with full leg positioning and developed into an innovative assistive device.

2.5 Prototype

The building of prototype starts from detailed sketches, enhancing to rough models, then refined to final models. Detail sketches are used to arrange explicit structures, materials and appearances, while putting into consideration the functions, usability, and the manufacturing process.

Rough models are direct implementations of the detailed sketches. They are first built with paper templates before moving onto fabrics. They are used to verify the structures and arrangements of sketches, and determine whether a revision of the detailed sketch is required before continuing with the proofing process (Fig. 1).

Fig. 1. (A) Paper template and (B) fabric rough model

Inevitably, many errors and corrections were made during the proofing process. Versions of sketches and rough models were also developed. For example, the first rough model was designed to use elastic bands to form assistive abduction moment. Also, the elasticity of the bands prevents them from becoming loose and droopy during knee flexion. However, the elasticity turned out to offset the force yet increase the difficulty of wearing (Fig. 2).

Final model make references to popular sports leggings to avoid the stereotypical bulky and rigid appearance of aids. It uses inelastic nylon belt of a variety of lengths between flexion and extension of knee to create an assisting force. Because of this mechanism, it is able to provide dynamic assistance force only at stance phase and low flexion. Also, the adjustable nylon belt length is able to produce different assisting force magnitudes.

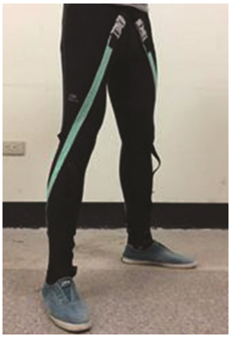

Fig. 2. Tilted views of first rough model

By moving connection points to waist and foot, no tightening is required around thigh and calf and hence will not restrict muscle contraction. Each end of the nylon belt is fixed on the waist with buckles. The belt extends across the thigh and through a ring located on the side of the knee. The ring is fixed at the end of another black nylon belt that runs across the plantar and is sewn around the calf section. Additionally, a device is screwed beside the ring and act as the conductor of assisting abduction force.

2.6 Pilot Study

Pilot study is used to objectively determine whether the final model is comparable to existing assistive device. The data is drawn by built-in serial plotter of Arduino Integrated Development Environment with vertical axis presents force (N) and horizontal axis presents time (0.1 s). The process of pilot testing includes sitting for ten seconds, walking for ten seconds, and then stand for ten seconds. The variations of force are clearly visible.

Since the adjustment of assisting force depends on the length of the belts, the data are respectively recorded at 15 and 20 cm long to present different force magnitudes. 15 cm is the minimum length to prevent the belt from becoming too loose when seated, and it provides a mean force of about 5.5 N. Additionally, the prototype can provide a mean force of about 9 N when the belt length is 20 cm. As for existing products, Rebel Reliever (Townsend, CA, USA) was chosen. It is an unloading brace with mechanism that allows a maximum angle adjustment of 18°, and the data was collected under two degree settings. At a setting of relatively small angle, this unloading brace provides a mean force of about 7 N. In sum, the result of the pilot test shows that the new design is able to provide comparable assisting force to existing unloading brace at a low to medium angle setting. This means the chosen mechanism and structure are functional and ready for evaluation experiments.

3 Results

Medial knee loading is assessed by the frontal plane lever arm variation in this research. If the lever arm is lengthened due to assisting abduction force, the medial knee loading is relatively unloaded. As for pain relief, the visual analogue scale is used to record acute pain intensity.

In the objective evaluation experiment, gait data were recorded by camera while test subjects walk on the treadmill at their own chosen speeds. Reflective markers are located at three points: most lateral superior iliac crest, medial knee joint line and medial malleolus. Gait recording were respectively conducted before and after the belts are put on, to compare the efficacy of assisting abduction force.

However, the results need to be normalized before analyzing against paired sample t-test due to offset caused by body size differences. Divided by another vector of the same test subject, frontal plane lever arm magnitudes can be converted into the same ratio. In this research, we choose thigh vector $\left|\left(\vec{AB}\right)\right|$ as comparison (Fig. 3). The recorded gait data were converted into ratio of frontal plane lever arm magnitude to thigh using equations mentioned above. The descriptive statistics are shown in Table 1.

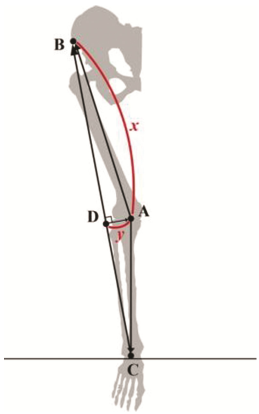

Fig. 3. Vectors and angle relationships of lower extremity markers

Table 1. Lever arm and thigh ratios before and after using innovative assistive device

		N	Mean	SD
Left leg ratio	Before	8	.084	.016
	After	8	.103	.024
Right leg ratio	Before	8	.099	.018
	After	8	.118	.024

Mean ratio of frontal plane lever arm magnitude to thigh increased after using the innovative assistive device. The variations of both legs were further analyzed with paired samples t-test (Table 2).

Table 2. Paired samples t-test results of ratio variation

	Mean	SD	95% confidence interval	T	df	p-val.
Left leg ratio variation	.019	.012	.007 to .029	4.58	7	.003*
Right leg ratio variation	.018	.013	.009 to .029	3.82	7	.006*

4 Conclusion

The purpose of this research is to develop an innovative assistive device which relieves painful symptoms of knee osteoarthritis by reducing medial knee loading. By utilizing an innovative approach with assistance that allows natural muscle contractions, we aim to reduce negative impacts caused by the use of traditional aids and increase comfort.

In order to achieve the research purpose, we first investigate the relationship between knee biomechanics to establish a thorough understanding of assistive methods. These include the importance of medial knee loading, knee alignment, and avoid the increase of overall contact force. Moreover, we reviewed traditional and novel aids to set further design criterions including comfort and aesthetics aspects. After that, innovative assistive device was developed through a co-design activity and morphological charts. Finally, objective and subjective evaluation experiments are conducted to verify whether medial knee compartment is unloaded and whether the pain is notably relieved. Current experiment result shows that the device significantly reduced medial knee loading. However, it did not reduce pain to a notable degree. Besides, overall satisfaction of the current prototype has reached an acceptable level, especially the free movement degree of the lower limbs and its appearance.

To sum up, the current prototype in this research is able to bring benefit by providing assisting abduction moment at stance phase and low leg flexion to reduce medial knee loading. It also allows natural muscle contraction and increase the comfort by utilizing soft, elastic and breathable materials and move the connection points to waist and plantar. Also, its current appearance is well accepted but closer to the preferences of young people. Thus, a customized appearance with functional inner structure may be the direction of future development. Additionally, the current assisting force adjusting mechanisms are highly affected by body sizes. Combining with sensor technology may simplify the process and standardize the assisting force among different users.

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