THE DEVELOPMENT OF A NEW STANCE CONTROLLED ORTHOTIC KNEE JOINT

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INTRODUCTION

Individuals with severe quadriceps muscle weakness require external knee stabilization, which is typically applied using knee-ankle-foot orthoses (KAFOs). The most prevalent approach to immobilize the knee is to provide the KAFO with manually locking knee hinges. The individual will lock the knee joint during ambulation to prevent knee collapse, and unlock it for tasks such as sitting. A major limitation of this approach is that the patient walks with a stiff-legged gait. [1]

In order to address this limitation, a number of stance control orthotic knee joints (SCOKJs) have become available.[2] These SCOKJs restrict knee flexion during stance-phase, but allow swing-phase flexion, a process that is referred to as stance-phase control. In comparison to stiff-legged gait, SCOKJs have been found to increase walking speed[3,4], efficiency[5,6], and decrease compensatory gait deviations and abnormal gait patterns.[7]

Various strategies are utilized by SCOKJs to stabilize the knee or allow it to freely bend, depending on the specific events of gait.[2,7] Biomechanical signals, such as for example motion at the ankle, are used to determined whether the knee joint should be locked or unlocked. A braking or locking mechanism then provides the locking function.

The overall objective of this work was to design a SCOKJ that would by default result in a locked knee, with unlocking occurring only as a result of biomechanical signals that are unique to late stance-phase of gait. In this way, the knee would unlock specifically to allow initiation of swing-phase knee flexion, but otherwise provide stability. Secondly, the goal was to do the latter using a self contained design, meaning that all of the biomechanical signals would be ‘sensed’ at the knee joint. In contrast, many SCOKJs require signaling from other parts of the KAFO to operate, using for example cables which may require complicated integration, and may stretch overtime, consequently resulting in unreliable stance-phase control performance. Thirdly, the goal was to develop a device that would be simple, reliable and low maintenance. As such, an entirely mechanical system was developed.

METHODS

The study comprised of two parts. Part one outlines the technical aspects associated with the development of the knee joint, and part two the clinical evaluation involving quantitative gait analysis.

Part 1 – Technical development

The control strategy used in the SCOKJ was based on temporal, kinematic and kinetic biomechanical signals that are associated with various parts of the gait cycle of KAFO gait. Data were obtained using instrumented gait analysis.[8] A design was conceptualized and a mechanism was developed around the strategy. Computer-aided design software (Solidworks) was used during the design, to develop models and generate drawings for fabrication. Prototypes of the SCOKJ were then fabricated using conventional and CNC machining.

Part 2 – Clinical evaluation

The prototype was tested on a male, 29 years of age, with lower-limb muscle weakness stemming from poliomyelitis. The subject was a community ambulator, but required the assistance of a locked-knee KAFO. To test the new SCOKJ, a testing brace was fabricated for the subject that was equivalent to his conventional KAFO. The prototype SCOKJ was then applied to the KAFO. Efforts were taken to adjust alignment and knee settings to optimize stance-phase control function and gait characteristics. Moreover, the subject was provided training on how to utilize the stance control feature of the device. Once the subject felt adequately comfortable with the SCOKJ knee, instrumented gait analysis was performed. The subject was instrumented with reflective spheres, and full body motion analysis was preformed using a 7-camera VICON system. Data were collected as the subject walked along a 10-meter long runway. Data were collected for the SCOKJ knee with stance-phase control function enabled and with it disabled, thus in the latter case causing the subject to walk with a stiff-legged gait. Spatiotemporal and kinematic parameters were compared between the two conditions.

RESULTS

Technical development

A stance-phase control strategy utilizing robust biomechanical signals was determined from previously acquired gait data.[8] The strategy was based on sequenced signals that were associated with specific phases of the gait cycle. Specifically, the following sequence of biomechanical signals was used. The first signal is a flexion moment exceeding a certain (large) threshold. This large flexion moment is unique to the mid-stance phase and prepares the knee joint to unlock. Secondly, the knee joint requires that the large flexion moment is followed (within a certain amount of time) by a slight knee extension moment. The extension moment, which is typically associated with toe-loading in late stance, must occur within deciseconds of the flexion moment otherwise the knee will default to the locked state, thus ensuring safety. In the case that the extension moment follows the large flexion moment in a timely manner, the knee will remain unlocked for a brief period of time, allowing the patient to initiate swing-phase flexion. See figure 1. Within the prototype SCOKJ, both the flexion moment threshold and timing characteristics were adjustable to suit the user's needs. The prototype can be seen in figure 2.

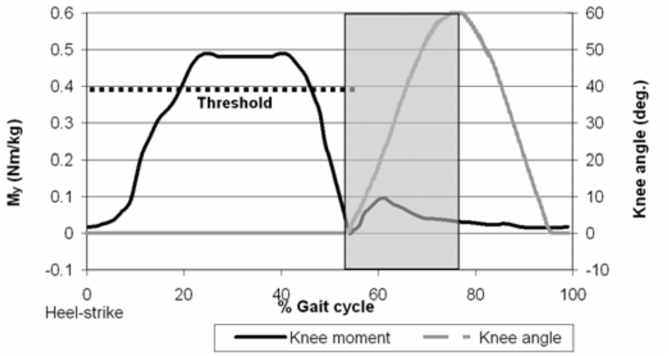

Fig. 1: Control strategy based on biomechanical signals. The timing of the knee for unlocking is shown by the shaded area.

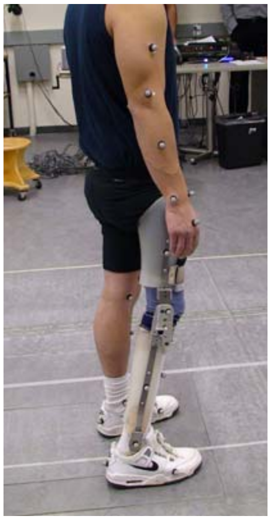

Fig. 2: Subject wearing the prototype SCOKJ.

Clinical Evaluation

The subject walked more slowly with the prototype SCOKJ in the stance-phase control mode (0.77 m/s) compared to when it was permanently locked (0.84 m/s). He also exhibited a greater reliance on the non-braced limb as is evident by the increase in percentage stance during the stance-control mode. KAFO side stance-phase as percent of gait cycle was 74.2% and 70.0% for the stance control and locked modes, respectively. These shortcomings may be at least in part due to the limited training and acclimation that was provided for the stance-phase control mode. As expected, knee joint kinematics on the braced limb greatly improved, resulting in 44 degrees of maximum knee flexion, where in the locked mode knee flexion was 0 degrees. All other spatiotemporal and kinematic gait parameters were similar between the two conditions. Subjective feedback was positive, as the subject felt that walking was more effortless with the SCOKJ, primarily due to the added knee flexion.

DISCUSSION

Gait laboratory data assisted the development of a unique new SCOKJ strategy that does not rely on remote biomechanical signaling. This approach may ultimately result in more reliable control as well as simpler implementation into a KAFO. The design of the SCOKJ was based on a purely mechanical system, capable of responding to the unique flexion moment in mid stance, and a timing element to release a locking mechanism prior to toe-off. The effectiveness of this approach was evaluated in the gait laboratory with a single subject providing preliminary but important insight into its function. The subject was able to use the prototype SCOKJ reliably to achieve more normal swing-phase knee kinematics, albeit slightly diminished spatio-temporal measures that were likely attributed to the limited accustomization period that was provided. Future work involves home trials and testing on multiple subjects.

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REFERENCES

[1] DiBello TV, Campbell JH. Knee-ankle-foot and hip-knee-ankle-foot orthoses. In: Lusardi MM, Nielsen CC, eds. Orthotics and prosthetics in rehabilitation. St. Louis: Saunders Elsevier 2007:237-62.

[2] Travolta, RL. Stance control revolutionizes knee bracing. Biomechanics 10, 2002: 53-62.

[3] Irby SE, Bernhardt KA, Kaufman KR. Gait of stance control orthosis users: the dynamic knee brace system. Prosthet Orthot Int 2005;29:269-82.

[4] McMillan AG, Kendrick K, Michael J, Aronson J, Horton G. Preliminary evidence for effectiveness of a stance control orthosis. JPO 2004;16:6-13.

[5] Kaufman KR, Irby SE, Mathewson JW, Wirta RW, Sutherland DH. Energy-efficient knee-ankle foot orthosis: a case study. JPO 1996;8:79-85.

[6] Hebert JS, Liggins AB. Gait evaluation of an automatic stance-control knee orthosis in a patient with postpoliomyelitis. Arch Phys Med Rehabil 2005;86:1676-80.

[7] Yakimovich T, Lemaire ED, Kofman J. Engineering design review of stance-control knee-ankle-foot orthoses. J Rehabil Res Dev 2009;46:257-67.

[8] Andrysek J, Redekop S, Matsui N, Kooy J, Hubbard S. A method to measure the accuracy of loads in knee-ankle-foot orthoses using conventional gait analysis applied to persons with poliomyelitis. Arch Phys Med Rehabil, 2008, 89:1372-79.