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Gait Evaluation of a New Electromechanical Stance-Control Knee-Ankle-Foot Orthosis

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Abstract— **Commercial versions of a stance-control knee-ankle-foot orthosis (SCKAFO) have emerged to improve gait over conventional knee-ankle-foot orthoses (KAFOs), which lock the knee in full extension in individuals with quadriceps muscle weakness. A new electromechanical SCKAFO was recently designed to address the functional, structural, and cost limitations of these commercial SCKAFOs. This paper presents an evaluation of the new SCKAFO conducted to determine its functional and clinical effectiveness during gait. Three healthy adults (100% male; age, 35.3 ±19.7y) and three KAFO users with knee extensor weakness in at least one limb (100% male; mean age, 56.3±4.0y) participated in the study. The SCKAFO had a minimal effect, as desired, on the kinematics of the able-bodied subjects. KAFO users had a mean increase in knee flexion of 21.1° (sd=8.2) during swing, and a greater total knee range of motion when walking with the new SCKAFO compared to their prescribed KAFO. Two KAFO users experienced a reduction in pelvic obliquity and hip abduction angle abnormalities when walking with the SCKAFO compared to their prescribed KAFO.**

I. Introduction

INDIVIDUALS with quadriceps muscle weakness due to polio, degenerative muscle disease, stroke, incomplete spinal injury, congenital defects, or aging are often prescribed a knee-ankle-foot orthosis (KAFO) that locks the knee in constant full extension. Due to the absence of knee flexion, KAFO users must adopt abnormal gait patterns that can lead to premature exhaustion while walking [1], cosmetic implications, limited mobility, and chronic hip and lower-back injury [2]. A new type of orthosis, referred to as a stance-control knee-ankle-foot orthosis (SCKAFO), has recently emerged to permit free knee motion in swing while providing knee support in stance. Preliminary clinical studies [2]-[9] have shown that some SCKAFO designs promote a more symmetric gait, improve mobility [2], improve gait kinematics [2]-[5], increase walking velocity [2], [9] and require less compensatory movements [2], [5], and less energy spent [3], by the user when used for walking than conventional KAFO technology. However, current SCKAFO knee joints either require full knee extension to engage the knee-joint lock, are excessively noisy, offer a limited number of locking positions, or are too heavy and bulky or expensive. Users wearing some SCKAFOs are limited in where they can walk since they are not given sufficient support in activities that require weight bearing with a flexed knee. Heavy and cumbersome SCKAFO designs demand excessive energy expenditure during ambulation and offer poor cosmetic appeal.

A new electromechanical SCKAFO was recently designed to address the functional, structural, and cost limitations of current commercial SCKAFOs [10]. During initial limb loading, the orthotic knee joints permit resisted knee flexion to provide energy-absorption. In stance during weight-bearing, the new orthosis provides limb support and knee extension at any knee angle. In swing, the orthosis permits free-knee motion in flexion and extension. These orthotic knee joints are also 30% thinner medio-laterally and 7% lighter than existing SCKAFO knee joints that provide similar function.

This paper presents an evaluation of the new SCKAFO conducted to determine its functional and clinical effectiveness during gait.

II. Method

A. Subjects

Three able-bodied subjects (numbered A1 to A3) (35.3 ±19.7 y, mass 78.3 ±1.5 kg) and three KAFO users (B1 to B3) (56.3±4.0 y, mass 88.3 ±12.3 kg) participated in the study. Since a single SCKAFO was constructed for the group of able-bodied subjects, a convenience sample of three able-bodied male subjects was selected based on the subjects' ability to wear the SCKAFO with minimal modifications such as in leg length and girth. KAFO users with moderate knee extensor weakness in at least one limb were recruited at The Rehabilitation Centre, Ottawa, Canada. All six recruited subjects were male.

Subject B1 had previously been prescribed a conventional KAFO that allowed up to 18° of spring-resisted knee flexion during limb loading. However, subject B1 was prone to trip, even on level ground, since he had insufficient strength to attain any knee flexion with the brace. Therefore, subject B1 rarely wore his KAFO and instead preferred to walk with a walker or cane. Subject B2 had walked with a KAFO for the past 12 years. His KAFO allowed 18° of free knee movement. Subject B2 almost always wore his KAFO when walking. Subject B3 was fitted with a Horton SCKAFO five months prior to the gait test but found the triggering mechanism problematic and only used the brace when walking in busy environments or outdoors. For the purposes of this research, subject B3 switched his SCKAFO to the fully extended, locked position for the walking trials.

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B. Interventions

A series of custom SCKAFOs were manufactured by a certified orthotist and orthotic technician over the course of clinical testing. Subjects B1, B2 and B3 made an extra visit to the orthotics service for fitting with a custom SCKAFO. The same set of SCKAFO knee joints, electronics, and foot switches were used in all four SCKAFOs. Three force-sensing-resistor (FSR) pressure sensors were adhered to the top surface of the SCKAFO footplate. The sensors were located at the heel, lateral forefoot and medial forefoot. A light emitting diode (LED) was connected in parallel to the solenoids to provide a visual signal when the solenoids were active. Activation periods were noted during image processing and applied in data analysis. The FSRs and solenoids were remotely connected to a stationary control system via a 10 m cable. Custom control software activated the solenoids based on FSR pressure levels above a predetermined threshold. Tamarack ankle joints, which allowed ankle motion with minimal resistance, were installed on some SCKAFOs.

A calibrated 4-camera, video-based motion analysis system was used to capture unilateral lower-limb kinematics. Passive reflective markers were placed on the test subjects using a modified National Institutes of Health (NIH) six degree-of-freedom marker set. To obtain unilateral observation of the test subject, pelvis markers of the original bilateral NIH marker set were positioned on the posterior side of the pelvis to ensure marker visibility. Four markers were attached each on the foot, lateral shank, lateral thigh, and posterior pelvis of each subject. Three successful trials were captured of subjects walking along an 8-m walkway at a natural cadence, wearing no brace (able-bodied subjects) or wearing their conventional KAFO (KAFO users). Subjects were then given approximately 20 minutes to practice walking with the SCKAFO. Threshold pressure levels for the three FSRs were adjusted at the beginning of the training period to accommodate the individual's gait pattern and account for the constant residual pressures applied to the FSRs due to shoe tightness. To adjust FSR threshold levels, the subject was asked to walk slowly and pause in terminal stance at the instant they wished the SCKAFO to switch to swing mode. A laboratory assistant then adjusted the individual FSR threshold pressure levels accordingly to achieve solenoid activation with this pressure profile. A similar process was used to determine the FSR pressure thresholds at the onset of limb loading for the stance phase. This method was effective in achieving a high level of control-system reliability in walking. Following the practice session, three SCKAFO trials for each subject were captured while walking at natural cadence.

Video data was processed using the Ariel Performance Analysis System to obtain synchronized three-dimensional (3D) coordinates of the tracking markers [11]-[12]. The synchronized 3D marker coordinates were exported as a C3D file to Visual3D. Visual3D was used to process the marker data for visual, graphical, and quantitative analysis. The mean stride time, stride distance, walking speed, and stance/swing duration ratio, and associated standard deviations were determined over the three trials. Ensemble averages over three walking trials of the ankle angle, knee angle, sagittal hip angle, frontal hip angle, and pelvic obliquity were calculated for each subject, with the stride time normalized to 100% of the gait cycle. Using the pre-ensembled trial data, absolute peak kinematic values for each condition (able-bodied: no orthosis, SCKAFO; orthosis user: KAFO, SCKAFO) were averaged over the subject's three trials. Joint ranges of motion and mean peak kinematic values were compared between SCKAFO and non-SCKAFO trials for each subject. These data were not ensembled over subjects since there was considerable variation in subject strength, walking ability, height, and age.

III. Results

A. Gait Kinematics

The mean peak lower-body angle values for all six subjects for both walking conditions described above are shown in Table I. Peak value labels are defined as follows: A_1, A_2: first and second ankle-angle peaks; K_1, K_2, K_3: first, second and third knee-angle peaks; SH_1: first sagittal-hip angle peak; FH_1, FH_2: first and second frontal-hip angle peaks; PO_1: first pelvic-obliquity peak. A summary of the lower-body joint ranges of motion for all six test subjects for both walking conditions is given in Table II.

The SCKAFO had no consistent effect on the knee angle, frontal-hip angle, and pelvic-obliquity patterns for able-bodied subjects. The three subjects did experience some increase in mean peak sagittal-hip angle (SH_1) when walking with the SCKAFO compared to no orthosis; however, the increase in SH_1 was quite small (A1 = 8.6°, A2 = 6.0°, A3 = 4.9° - Table I). There was an increase of 15.4° for subject A1 and 17.6° for subject A3 in sagittal hip range of motion (Table II).

At the knee, there was little flexion for able-bodied subjects A1 and A2 in stance with the SCKAFO (K_1 and K_2, Table I), but subject A3 did achieve a mean K_1 peak flexion of 7.3°. In swing, the mean knee flexion peak (K_3) decreased 18.8° for A1 and 13.7° for A2, and increased 9.0° for subject A3 when using the SCKAFO compared to the no-brace condition.

At the ankle, able-bodied subjects experienced a 24.5% average reduction in range of motion with the SCKAFO compared to non-braced gait. The reduced range of motion occurred mainly for subjects A1 and A2. (Table II).

The three KAFO users had considerable increases in mean knee flexion during swing when walking with the new SCKAFO compared to their prescribed KAFO. Peak K_3 during swing increased by 11.7° for B1, 24.7° for B2, and 26.9° for B3 (mean = 21.1°, sd = 8.2°) (Table I). This contributed to a knee range of motion increase of 13.2°, 26.7°, and 29.7° (mean = 23.2°) for subjects B1, B2 and B3, respectively. Subjects B1 and B2 experienced little knee stance-flexion with both their prescribed KAFO and the SCKAFO; however, subject B3 had an average increase of 5.6° for stance-flexion range of motion with the SCKAFO.

TABLE I
Mean Peak Values of Lower-Body Segment Angles (deg)

	Subject A1		Subject A2		Subject A3	
	No Brace	SCKAFO	No Brace	SCKAFO	No Brace	SCKAFO
A_1	-6.9	-12.3	-2.3	-3.2	-7.2	-1.1
A_2	26.9	7.3	30.1	9.4	17.6	17.5
K_1	16.6	-2.1	30.1	-0.8	1.3	7.3
K_2	1.7	-5.0	7.6	-5.1	-7.4	-4.9
K_3	66.9	48.1	78.8	65.1	45.6	54.6
SH_1	12.9	21.5	3.7	9.7	10.1	15.0
FH_1	13.6	20.7	14.0	15.2	10.9	11.6
	Subject B1		Subject B2		Subject B3	
	KAFO	SCKAFO	KAFO	SCKAFO	KAFO	SCKAFO
A_1	-7.8	-2.9	-7.5	-2.6	-6.7	-1.1
A_2	3.6	1.2	3.2	6.3	2.2	3.9
K_1	3.7	0.0	1.9	3.8	0.8	4.4
K_2	1.1	-2.7	-0.8	-2.8	-0.2	-2.2
K_3	2.8	14.5	19.6	44.3	1.4	28.3
SH_1	26.4	13.9	17.9	10.9	-1.9	8.1
FH_1	16.8	17.0	18.8	9.5	12.6	15.3
FH_2	-10.4	-4.1	-10.8	-16.9	-7.1	-8.8
PO_1	-5.3	-4.6	-5.1	-3.3	-7.8	-7.3

TABLE II
MEAN LOWER-BODY JOINT RANGES OF MOTION (DEG)

Able-bodied subjects A1 to A3, wearing no brace and wearing the Stance-Control KAFO (SC KAFO), and for KAFO-user subjects B1 to B3, wearing the KAFO and SC KAFO.

	A1		A2		A3	
	No brace	SC KAFO	No brace	SC KAFO	No brace	SC KAFO
Ankle	34.1	26.3	32.3	19.5	24.8	22.2
Knee	66.8	53.2	71.2	70.7	54.0	59.6
Sagittal Hip	39.4	54.8	37.9	37.7	23.4	41.0
Frontal Hip	36.8	46.2	29.1	32.1	33.2	30.5
Pelvic Obl.	14.3	15.8	12.6	11.3	9.6	6.6
	B1		B2		B3	
	KAFO	SC KAFO	KAFO	SC KAFO	KAFO	SC KAFO
Ankle	17.0	14.6	16.8	11.0	12.1	8.6
Knee	4.3	17.5	20.3	47.0	2.9	32.6
Sagittal Hip	48.5	36.3	39.3	37.7	19.4	23.8
Frontal Hip	27.2	21.0	29.7	26.4	19.8	24.1
Pelvis Obl.	9.4	8.5	8.2	4.2	8.6	9.6

At the hip, Subject B1 experienced 60.6% less hip abduction, from 10.4° to 4.1° (FH_2) when walking with the SCKAFO when compared with his original KAFO (Table I). The reduction in hip abduction was accompanied by a pelvic obliquity pattern that was closer to normal gait. Subject B1's pelvis returned closer to the neutral position in early swing, while walking with the SCKAFO compared to walking with the KAFO. Walking with the KAFO, subject B1's pelvis tilted upward at a greater angle on the side of the braced leg in early swing.

Subject B2 had less hip adduction when walking with the SCKAFO (9.3° less than original KAFO at peak FH_1). Walking with the fixed-knee KAFO, Subject B3 exhibited an abnormal pelvic obliquity pattern tilting his pelvis upwards on the side of the braced leg in late stance. When walking with the SCKAFO, subject B3 experienced an improved pelvic obliquity pattern dropping his pelvis on the side of the braced leg in late stance.

B. Participant Feedback

Following gait testing, a questionnaire on the user's experience walking with the SCKAFO was given to each participant. Open-ended feedback by participants on how the SCKAFO compared to their existing brace was also obtained. Subjects A1, A2 and A3 could not compare the SCKAFO performance to an existing KAFO, but did comment on the feeling of security and control issues of the SCKAFO. All six subjects found that an increased amount of mental effort was required when walking with the SCKAFO, specifically to disengage the SCKAFO knee joint for free knee motion at the end of stance to initiate swing. Subjects B1 and B3 preferred the SCKAFO over their prescribed KAFOs as they felt the new orthosis required less effort to walk. Subject B2 preferred his prescribed KAFO to the SCKAFO as he required considerable concentration to disengage the SCKAFO in walking. Subject B1 expressed a desire for audio feedback when walking with the SCKAFO to assure him that the orthosis was switched to stance support mode. Subject B3 found the SCKAFO lighter, less bulky, and easier to control than his prescribed Horton SCKAFO. All six subjects felt secure when walking with the SCKAFO.

IV. DISCUSSION

The clinical effectiveness of a new SCKAFO was evaluated using quantitative kinematic gait analysis and subjective participant feedback. The main functional objective of the new SCKAFO was to provide free knee rotation in swing while resisting knee flexion and providing support in stance at any knee or ankle angle. This study demonstrated that the newly designed SCKAFO can achieve this function. All three KAFO users achieved increased knee flexion when walking with the SCKAFO compared to their prescribed KAFO. A 488% ensemble mean increase in knee-joint range of motion with the SCKAFO demonstrated an improvement in swing-phase gait patterns over KAFOs.

By correcting the knee flexion gait pattern, motion at the pelvis also improved. The decrease in hip abduction experienced by subject B1 when walking with the SCKAFO indicated that the subject experienced less circumduction of their braced leg during swing. Past studies indicated that increased knee motion in swing leads to increased energy-efficiency during walking [2], [3]. KAFO users also experienced improved pelvic obliquity.

The SCKAFO had no consistent or considerable effect on the knee angle of the able-bodied subjects during walking. The SCKAFO did not seem to introduce substantial gait abnormalities based on its functional design. Gait deviations in able-bodied subjects could be attributed to added weight on the braced leg, a knee extension moment used to unlock the knee joint at the end of stance, and restrained ankle motion from the semi-rigid ankle joints.

The SCKAFO's ability to provide resisted knee flexion upon limb loading, allowed subjects A3 and B3 to achieve smooth knee flexion during initial stance. This demonstrates that the SCKAFO can permit a more natural knee loading response than conventional fixed-knee KAFOs. This smooth resisted knee flexion allowed by the new SCKAFO in initial stance may benefit orthosis users who would otherwise find the rigid knee-locking in current SCKAFO designs uncomfortable, especially when load transmission from the ground to the thigh-pelvis-spine aggravates pre-existing soft tissue problems.

All subjects initially found the knee extension requirement difficult to satisfy consistently; however, their experience walking with the SCKAFO increased over the short accommodation period in the laboratory and lead to an increased ability to control the SCKAFO. Because of the stationary nature of the SCKAFO's temporary control system, test subjects were only able to practice walking with the SCKAFO in the gait laboratory and were limited to approximately 20 minutes of training time with the SCKAFO. Ideally, the SCKAFO users should have several days or weeks to become accustomed to walking with the new SCKAFO to increase their ability and confidence to control the SCKAFO and improve gait performance. Further improvement in gait would be expected with the appropriate accommodation period for the newly designed SCKAFO.

Despite the short accommodation period, two out of three KAFO users still preferred walking with the SCKAFO over their prescribed KAFO. It should be noted that nearly all commercial SCKAFOs require the user to provide a knee extension moment to initiate swing. Toward further gait improvement, a design reiteration of new SCKAFO evaluated in this paper aims to minimize knee extension demands for disengaging the locking mechanism.

The solenoid reaction time was adequate throughout clinical testing. Once the threshold pressures for the FSR pressure sensors were custom set to accommodate the walking pattern of the individual test subject, the sensors and control system were reliable in activating and deactivating the solenoid at the onset of terminal stance and limb loading.

V. Conclusions

Clinical evaluation of a new SCKAFO found that the SCKAFO introduced only minor deviations in the gait patterns of the able-bodied subjects and provided improved gait kinematics for KAFO users. The SCKAFO successfully provided knee support in stance and free knee motion in swing at appropriate instants in the gait cycle for all test subjects. While gait improved, additional training and accommodation time is required before SCKAFO users can walk without consciously extending their leg to disengage the locking mechanism. Two out of the three KAFO users who participated in the study preferred walking with the SCKAFO over their prescribed KAFO. Overall, the SCKAFO provided a more natural gait for KAFO users compared to conventional KAFOs. Future clinical studies should allow the subjects a longer accommodation period with the SCKAFO.

References

[1] R. Waters, J. Campbell, L. Thomas, L. Hugos and P. Davis, "Energy cost of walking in lower extremity plaster casts," *J Bone Joint Surg*, vol. 64, pp. 896-899, 1982.

[2] A. G. McMillan, K. K. Kendrick, J. W. Michael, J. Aronson and G. W. Horton, "Preliminary evidence for effectiveness of a stance control orthosis," *J Prosthet Orthot*, vol. 16, no. 1, pp. 6-13, 2004.

[3] K. R. Kaufman, S. E. Irby, J. Mathewson, R. W. Wirta and D. H. Sutherland, "Energy-efficient knee-ankle foot orthosis: A case study," *J Prosthet Orthot*, vol. .8, no.3, pp. 79-85, 1996.

[4] S. E. Irby, K. R. Kaufman, R. W. Wirta and D. H. Sutherland, "Optimization and application of a wrap-spring clutch to a dynamic knee-ankle-foot orthosis," *IEEE Trans Rehabil Eng*, vol. 7, no. 2, pp. 130-134, 1999.

[5] J. S. Hebert and A. B. Liggins, "Gait evaluation of an automatic stance-control knee orthosis in a patient with postpoliomyelitis", *Arch. Phys. Med. Rehabil*, vol. 86, pp. 1676-80, 2005.

[6] S. E. Irby, K. R. Kaufman and D. H. Sutherland, "Electronically controlled long leg brace," *Southern Biomedical Eng Conf*, 1996, pp.427-430..

[7] Y. Tokuhara, O. Kameyama, T. Kubota, M. Matsuura and R. Ogawa, "Biomechanical study of gait using an intelligent brace," *J Orthop Sci*, vol. 5, pp. 342-348, 2000.

[8] S. E. Irby, K. R. Kaufman, J. W. Mathewson and D. H. Sutherland, "Automatic control design for a dynamic knee-brace system", *IEEE Trans Rehabil Eng*, vol. 7, no. 2, pp. 135-139, 1999.

[9] S. E. Irby, K. A. Bernhardt and K. R. Kaufman, "Gait of stance control orthosis users: The Dynamic Knee Brace System," *Prosthet Orthot Intl*, vol. 29, no. 3, pp. 269-282, 2005.

[10] T. Yakimovich, J. Kofman and E. D. Lemaire, "Design and Evaluation of a Stance-Control Knee-Ankle-Foot Orthosis Knee Joint," *IEEE Trans Neural Systems Rehabil Eng*, (in press).

[11] D. J. Wilson, B. K. Smith and J.K. Gibson, "Accuracy of reconstructed angular estimates obtained with the Ariel Performance Analysis System", *Phys Ther*, vol. 77, pp. 1741-61, 1997.

[12] P. J. Klein and J. J. DeHaven, "Accuracy of three-dimensional linear and angular estimates obtained with the Ariel Performance Analysis System", *Arch Phys Med Rehabil*, vol. 76, pp. 183-189, 1995.

[13] D. Winter The Biomechanics and Motor Control of Human Gait: Normal, Elderly and Pathological. Waterloo: Univ. Waterloo Press, 1991.