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ENHANCING VOLUNTARY MOTION IN BROAD PATIENT POPULATIONS
WITH MODULAR POWERED ORTHOSES

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Goals and Objectives:

The overall goal of this project is to develop and validate modular, lower-limb, powered orthoses that fit to user-specific weakened joints (ankle, knee, and/or hip) and control force/torque in a manner that enhances voluntary motion in broad patient populations. Conventional orthoses tend to immobilize joints, and emerging powered orthoses constrain voluntary motion by using highly geared electric motors and/or control methods that force the user to follow a specific gait pattern. Consequently, these devices have not seen widespread success across populations with weakened voluntary control due to advanced age, musculoskeletal disorders, etc. These heterogeneous populations require partial, not full, assistance of user-specific muscle groups during daily activities. However, there is a fundamental gap in knowledge about how to design and control powered orthoses to assist the user without constraining their motion. Our central hypothesis is that high-torque, low-inertia motor systems controlled with energetic objectives will enable modular powered orthoses to partially assist various joints. High-torque electric motors combined with minimal transmissions can be freely rotated (i.e., backdriven) by human joints, allowing the use of an emerging torque control method called *energy shaping* to reduce the perceived weight/inertia of the body during any motion. By mounting these modular actuators to commercial orthoses, this technology will be easily prescribed/configured by clinicians.

In this study we will assess the *feasibility* of assisting different populations with modular powered orthoses:

Able-bodied young adults
Part A: Implement and validate task-invariant toque controllers on the powered orthosis modules
Part B: Assess muscle effort and posture during repetitive lifting, lowering, and carrying

Elderly adults
Assess mobility scores in participants during activities of daily living (e.g. stair ascent/descent, ramp traversal)

Adults with mild to moderate neurologic or orthopedic impairments (e.g. stroke, multiple sclerosis, etc.)
Assess mobility scores during activities of daily living (e.g. stair ascent/descent, ramp traversal)

Adults with hip, knee, or ankle osteoarthritis
Assess mobility scores during activities of daily living (e.g. stair ascent/descent, ramp traversal)

We expect that assistance provided by the modular powered orthoses will improve lifting and lowering in able-bodied young adults and functional outcomes in elderly adults, adults with mild to moderate impairments, and adults with hip, knee, or ankle osteoarthritis.

Background:

One in eight adults in the U.S. has a mobility disability according to the CDC [1], which limits social activity [2], economic productivity [3], and quality of life [4]. These disabilities are largely associated with advanced age, stroke, or musculoskeletal disorders [5], [6]. Most of these individuals have some voluntary control of their lower limbs, and thus require only *partial* assistance of lower-limb musculature to overcome weakness during activities of daily living. However, *no broadly applicable intervention fits this critical need* [7]. Conventional orthoses tend to immobilize rather than actively assist joints, causing side-effects including compensations [8], gait asymmetry [9], and overdependence on the brace [10]. Passive orthoses, canes, and walkers cannot provide positive mechanical work to assist the most challenging activities, such as sit-to-stand and stair ascent. Conventional devices simply cannot restore normative limb function, and the development of new mobility technologies was recently identified as a national need for the aging U.S. population [11].

Emerging *powered* orthoses have the potential to restore normative leg biomechanics [7], but these devices have not been widely adopted due to their stiffness, bulkiness, acoustic noise, cost, battery life, and/or non-intuitive control. While parallel industries such as drones are providing powerful, lightweight, and inexpensive motors with longer lasting batteries [12], [13], [14], critical barriers in powered orthosis design and control limit their applicability across patient populations. Commercial rehabilitation exoskeletons like Ekso Bionics, Indego, and ReWalk feature an integrated lower-body frame with a fixed set of actuators (motor plus transmission) targeting specific joints for a specific patient population [15], [16], [17], [18], [19], [20]. These actuators are generally designed with a highly-geared transmission that 1) *stiffens* the joint to prevent the user's weight from *backdriving* it (i.e., the load rotating the motor) and 2) enables large output torques to provide the *complete* limb function for a person with spinal cord injury [15], [16], [17], [18] or severe stroke [19], [20]. Although some devices (e.g., Indego [15]) are more backdrivable than others, actuator inertia and friction still limit a weakened user's ability to freely move their joints. Stiff actuators typically track pre-defined joint patterns [21], forcing the user to follow the exoskeleton rather than their own volition. High-ratio transmissions also have more/faster meshing parts, causing acoustic noise that makes robotic devices less desirable for everyday use.

Single-joint powered orthoses [22], [23], [24], [25], [26], [27], [28], [29], [30] and soft exosuits [31], [32], [33], [34], [35] are addressing some of these challenges but are currently limited to specific use cases by their actuation and control methods. The Honda [36] and Samsung [37], [38] hip exoskeletons for elderly assistance use a lower gear ratio to reduce actuator stiffness and noise at the cost of output torque (less than 10 Nm), demonstrating the need for *high-torque, backdrivable* actuators to provide more meaningful assistance. A couple recent designs [39], [40] (e.g., Dephy ExoBoot) approach this goal but control pre-defined torque profiles that limit volitional motion. Such profiles must be optimized for every user and activity in time-intensive sessions [41], [42], and user intent must be accurately estimated to correctly transition between activities [21]. This control limitation is shared by exosuits and orthoses actuated by Bowden cables [29], [30], [31], [32], [33], [34], [35] or pneumatic pistons [22], [23], [24], which often have offboard actuation systems that constrain users to a treadmill. Bowden cable and high-ratio transmissions [25], [26], [27], [28] (e.g., B-Temia Keeogo) also have high friction and must use force feedback from load cells [43] or series elastic elements [44] to accurately control torque, which limits actuator bandwidth and backdrivability. Finally, because these various orthoses are not designed to work together, they do not offer a reconfigurable solution that can be applied to different populations.

These limitations in design and control constitute *key roadblocks* to the widespread deployment of powered orthoses across different populations with weakened voluntary control. These different

populations require *task-invariant* torque assistance of *user-specific* joints to perform activities of daily life. For example, warehouse and assembly line workers would benefit from knee and ankle assistance [45] to maintain safe lifting form (i.e., lifting with the knees instead of the back [46], [47]), whereas elderly individuals can have generalized weakness affecting all lower-limb joints [7], [48]. The *overall goal* of this project is then to develop partial-assist powered orthoses that have modular joint configurations, low acoustic noise, high output torque, low backdrive torque, and a trajectory-free torque control strategy that enhances voluntary motion.

We will primarily study how this technology can 1) mitigate muscular fatigue that leads to risky lifting and lowering (L&L) techniques in the workplace, and 2) strengthen weakened joints to improve functional outcomes in elderly patients. The first study is inspired by a rigorous study [49] that found a (passive) postural-assist exoskeleton significantly reduced torso flexion in 10 able-bodied participants lifting a box. Our second study design is based on a rigorous study of the Samsung hip exoskeleton with 30 elderly adults [38], finding a significant increase in gait speed with the exoskeleton. Both studies used repeated-measures ANOVAs with Tukey's test for post-hoc analysis. However, the Samsung study was limited by the small amount of torque (<10 Nm) applied to only one joint for only one task (level-ground walking). *Additional joints are needed to account for the generalized weakness that is typically associated with aging* [7], [48]. Moreover, the rigid back exoskeletons in [49] did not address the underlying cause of poor L&L posture: weak/fatigued distal joint musculature [45], *which can only be addressed by actively assisting distal leg joints*. These studies motivate the proposed protocol, which will demonstrate the proposed system's modularity across these two populations. In addition, we will perform pilot studies of other mild to moderate neurological and orthopedic impairments (e.g., multiple sclerosis, transverse myelitis, stroke, osteoarthritis, etc.) to inform future studies of these patient populations.

Justification for able-bodied lifting/lowering:

L&L tasks are common in warehouse and construction settings and are highly associated with low-back pain due to their repetitive nature causing overuse injury [50]. The squat lift is recommended to prevent low-back injury, but because it involves lifting and lowering the body's center of mass, it is not as energy efficient as the stoop lift. *The knee and ankle produce significantly more torque/power for the squat lift than the stoop lift, which primarily uses the hips and puts more stress on the lower back* [45], [51]. The squat lift is more difficult to maintain due to distal muscle fatigue, causing individuals to eventually transition to the stoop lift [46], [47]. Currently there is no causal orthotic treatment that prevents poor biomechanics (stooping) due to weak/fatigued lower-limb muscles [46]. In contrast, rigid back braces reduce lumbar loading during stooping but also restrict voluntary motion [49]. Other workplace exoskeletons use a posterior elastic element in the back brace to compliantly assist lumbar extension [52], [53], [54], but this can increase the activity of trunk flexor muscles [55]. Powered workplace exoskeletons address this problem by using hip actuators to assist trunk extension [55]. While these devices can compensate for gravity at the hips [56], [57], they cannot assist the distal joints which are critically involved in squatting. Instead these designs may *encourage* stooping. We *hypothesize* that assistive torques at the *knee and/or ankle* will target the root cause of poor L&L biomechanics: weak/fatigued distal joint musculature. We expect that people will be able to lift and lower for longer periods of time using the proper technique with orthotic assistance. Moreover, our data from [58], [59] suggest the proposed orthoses will reduce muscle effort to delay fatigue, allowing proper lifting biomechanics for longer periods to prevent low-back injuries in the workplace.

Justification for elderly population:

The U.S. Census Bureau projects that the elderly population (65+ years) will grow to 95 million—a quarter of the U.S. population—by 2060 [11]. Old age is associated with an increased incidence of mobility-related

disabilities that impact functional performance and quality of life [60]. For example, sarcopenia, or age-related decrease in muscle mass and strength, is a major cause of movement disability in the elderly [61], affecting nearly 10% of the population and 50% of people aged 80+ years [62]. Treatment can help break the "vicious cycle"—inability to complete a task leads to less activity which in turn accelerates sarcopenia. Task-specific training [63] is recommended to facilitate simultaneous gains in muscle strength and motor control, but assistance is needed to complete many tasks. Powered orthoses could provide this assistance, but training requires backdrivable orthotic joints to maximize the transfer of muscular forces to joint movement. The control must facilitate such voluntary movement and be adjustable to provide just enough assistance for task completion. Recent hip exoskeletons for elderly assistance, e.g., by Samsung [37], [38] and Honda [36], are backdrivable but provide little assistance torque (<10 Nm) and cannot address the effects of sarcopenia on the knee and ankle [7], [48]. *Weakness in ankle plantarflexors and hip flexors/extensors contribute to reduced step length and gait speed in elderly adults* [64], [65], [66], [67]*, and quadriceps strength also correlates with gait speed* [68] *and stair climbing cadence* [69]. We therefore *hypothesize* that a bilateral configuration of the proposed modular system will acutely improve performance outcomes such as gait speed. *Gait speed is a key indicator of sarcopenia* [70] *and also predicts mortality in older adults* [71].

Justification for mild to moderate neurological or orthopedic impairment population:
A multitude of patient populations could benefit from modular powered orthoses, but first feasibility studies (like this one) must be conducted to see if utilizing powered orthoses will improve performance outcomes. While impairments such as stroke, multiple sclerosis, and muscular dystrophy are due to variety of causes, they often share similar outcomes like decreased walking speed, decreased maximum muscle force, and increased fall risk [7]. Powered orthoses may be able to target and improve these mobility related deficits. Thus, we expect that the use of the modular powered orthoses will improve performance outcomes such as gait speed. This work is an important *first step* towards future studies that assess use of these powered orthoses in a larger cohort of patients with these impairments.

Justification for osteoarthritis population:
*Knee OA***:** Conventional unloader braces for knee osteoarthritis (OA) adjust mediolateral alignment to offload forces in one tibiofemoral compartment but cannot address patellofemoral loads due to quadriceps action [72], [73]. This represents a critical gap in conservative care, as patellofemoral OA is highly prevalent (24% of knee OA cases are isolated, and 40–59% are multi-compartmental [74], [75], [76]). Pain worsens during weight-bearing flexion (e.g., gait) due to quadriceps-induced patellofemoral compression. While spring-based tri-compartmental unloaders can offload minimal body weight [6], they lack the ability to dynamically assist during demanding activities of daily living (ADLs) like stairs, ramps, and sit-to-stand [77], perpetuating a cycle of pain, inactivity, and OA progression [78]. This strongly justifies the need for a new class of powered knee unloaders that provide a small fraction of biological torque to reduce tendon forces [79] for pain relief across ADLs. Pilot testing of our motorized knee brace (N=4) demonstrated consistent pain reduction across ADLs compared to standard care, supporting the need for powered tri-compartmental unloading that combines mediolateral realignment with active torque assistance.

*Ankle OA***:** Ankle-foot orthoses for ankle OA redistribute load and stabilize the joint, but many immobilize the ankle to reduce plantarflexion-induced pain, leading to compensatory gait adaptations and reduced mobility [8]. Chronic pain with conservative treatments drives 10% of patients to undergo ankle fusion, which sacrifices mobility and risks secondary degeneration [80]. A new class of powered ankle unloaders (i.e., energy-assist ankle orthoses) is needed to dynamically reduce painful compressive loads from plantarflexor action, providing targeted relief to degraded cartilage and subchondral bone at the

talocrural joint while stabilizing the subtalar joint. Our preliminary powered ankle exoskeleton (N=3) reduced pain across ADLs and increased walking speed by up to 35% in low-mobility users, demonstrating the potential for dynamic load reduction while preserving subtalar stability.

Hip OA: Hip OA lacks effective conservative treatments. While unloading braces restrict frontal-plane motion to reduce joint load [81], [82], their rigid design compromises usability and fails to address sagittal-plane moments critical for locomotion [83]. Powered exoskeletons offer a promising alternative by directly reducing joint compression via external torque [84], but existing devices rely on task-specific controllers ill-suited for real-world ADLs [85]. Our energy-shaping hip exoskeleton controller [86] uses intuitive, tunable parameters (e.g., virtual springs) to provide task-agnostic assistance. Pilot testing (N=3) showed significant pain reduction during ADLs and improved hip range of motion, suggesting its potential as a non-invasive intervention.

Unmet Need: Across all three joints, existing unloader braces are limited by passive mechanics, while surgical options are invasive and irreversible. Powered orthoses can bridge this gap by dynamically modulating joint loads during ADLs. Our preliminary data (N=4 knee, N=3 ankle, N=3 hip) consistently demonstrate pain reduction and functional improvements, justifying further clinical validation of this novel therapeutic approach.

Knowledge to be gained:

Human participant data will be collected during these experiments. Ground reaction forces during contact with the stance foot will be measured by an instrumented treadmill, force plates embedded in a level walkway, force plates embedded in the steps of a staircase, and/or an instrumented insole placed inside the subject's shoe. Reflective markers will be placed on human participants in order to use a motion capture system to measure the joint angles, velocities, and torques of the ankle, knee and hip. Biological joint loading will be measured using motion capture and ground reaction force data. Electromyography (EMG) will be collected to measure muscle activation patterns. Metabolic consumption data will be collected to measure the rate of energy expenditure. The orthosis will also measure the positions of the leg, ground reaction forces, and joint angles, velocities, and torques.

The knowledge to be gained from these experiments is critically important to the technical capability and clinical practice of lower-limb orthotics. Individuals with mild to moderate mobility impairments will be able to more safely ambulate through environments structured for able-bodied individuals. The knowledge gained from these experiments will vastly enhance the adaptability and clinical viability of future powered orthoses.

RESEARCH PLAN

Secondary Data Analysis:

Part of this study will involve secondary use of a pre-existing dataset from Chapman University under 23-UFA01520. The dataset will contain stroke gait kinematics (ankle, knee, hip, thigh angles) as well as kinetic data (forces, torques). All data will be de-identified and will not contain protected health information. The UM study team will use this dataset for offline evaluation and re-optimization of control strategies for exoskeletons to assist the stroke population (part of the mild to moderate impairment group).

Participants:

These experiments will primarily involve able-bodied/young and elderly human participants performing various activities, including lifting and lowering, sit-stand, walking with variable inclines, and stair ascent/descent. The able-bodied participants will use the powered orthosis to 1) validate the design and task-invariant control system of the powered joint orthosis modules, or 2) to assess viability of this modular orthotic system for improving lifting posture. Elderly participants will use the modular orthosis system to assess clinical viability and mobility outcomes associated with this technology. Up to 40 able-bodied, young participants, 30 elderly participants, 40 participants with mild to moderate neurological or orthopedic impairments, and 48 participants with osteoarthritis are expected to be enrolled. Before participation, written informed consent will be obtained from each research participant, after a thorough explanation of the study including risks and participants rights. The study for each aim has a maximum of 5 visits, but participants may be asked to optionally return and repeat each aim a number of times for different configurations of exoskeleton joints or controller.

Study Protocols:

Before conducting experiments, participants will be fitted with the proposed orthoses by trained research staff. The fitting will include adjusting the actuator module mounting locations in the sagittal plane to align joint axes (and account for limb length differences between participants) and shimming the mounts to account for any lateral displacements between segments. If any participants encounter issues with fitting the prefabricated orthoses (e.g., due to obesity, pain, etc.), research staff will evaluate the participant for a customized orthosis. To understand overall comfort and satisfaction with the device, we may administer the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) survey. The participant will rate their perceived satisfaction with the device on a five-point scale ("not satisfied" to "very satisfied") for the following characteristics of the device: 1) Dimensions (size), 2) Weight, 3) Adjustments, 4) Safety, 5) Durability, 6) Simplicity of use, 7) Comfort, and 8) Effectiveness. Additionally, subjects may be evaluated by the researchers through the following tools: modified QUEST survey for lifting and lowering, modified QUEST survey, modified Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale, modified Ankle Osteoarthritis Scale (AOS), Mini –Mental State examination, 10-meter walk test, 6-minute walk test, Timed-Up and Go test, Manual Muscle Test, Modified Ashworth Scale, Lower-extremity Fugl-Meyer Assessment, Berg's Balance Scale. These evaluations will be administered at the first research session and may be re-administered for subsequent research sessions.

Study data will be collected in PI Gregg's and Co-I Rouse's joint laboratory in the Ford Robotics Building. Participants will perform the following activities at different stages of the project:

- Up to thirty able-bodied participants will perform level/decline/incline walking (on treadmill or over ground), stair ascent/descent, sit-stand transitions, and/or non-locomotive activities (e.g., lunges) with and without a powered orthosis module in the design/control validation study.
- Up to ten able-bodied participants will perform repetitive lifting and lowering of a weight of either 15% body weight or 10 kg (whichever is lower) and complete a circuit comprising multiple activities of daily living while carrying the same weight in pre- and post-fatigued conditions, to assess effect on lifting/lowering posture with and without the powered orthosis.
- Up to thirty elderly participants will perform a 10-meter walk test, 6-minute walk test, level/decline/incline walking (on treadmill or over ground), stair ascent/descent, and sit-stand transitions with and without the powered orthosis to assess effect on mobility scores.

- Up to forty participants with mild to moderate neurological or orthopedic impairments will perform a 10-meter walk test, 6-minute walk test, level/decline/incline walking (on treadmill or overground), stair ascent/descent, sit-stand transitions, and/or non-locomotive activities (e.g., lunges) with and without the powered orthosis to assess effect on mobility scores.
- Up to forty-eight participants with hip, knee, or ankle osteoarthritis will perform a 10-meter walk test, 6-minute walk test, level/decline/incline walking (on treadmill or overground), stair ascent/descent, and sit-stand transitions with and without the powered orthosis or with a conventional orthosis to assess effect on mobility scores.

For all experiments the participant will be given a break every 30 minutes or whenever requested. For each study, participants may be asked to return for up to five visits each lasting no longer than five hours. If optional consent is given, the participant will be photographed and videotaped for research purposes. We will attempt to exclude the participant's face from all photos and videos; any images that include the participant's face will be immediately deleted, cropped, or blurred to ensure confidentiality. De-identified photographs will be used as figures in publications, presentations, or for public dissemination of the research such as the lab website or Twitter. De-identified videos will be used as supplemental multimedia for publications, presentations, or public dissemination such as the lab website or YouTube channel. The participant may still participate in this study if he/she choose not to have photos or videos taken.

Young Adult Protocol Part A

Each joint orthosis configuration (ankle, knee, and/or hip) will be validated by up to 10 able-bodied participants (even male/female) performing activities of daily life with and without unilateral or bilateral devices. The 10 participant sample size is based on standard results in the field [73]. Before collecting data, participants will have a ~30-minute acclimation period during which the assistance torque will be set to their highest comfortable level. During data collection trials, muscle activation may be measured by surface EMG using low-profile electrodes under orthosis pads (stationary between conditions). We may also record motion capture and ground reaction force data, which may be used to measure biological joint loading.

Activities may include level, inclined, and declined walking (on a treadmill or over ground), stair climbing, sit-stand transitions, and a circuit of these tasks. The circuit includes up to 5 tasks: 1) sit-stand, 2) level walk, 3) walk up a ramp, 4) walk down a staircase, 5) stand-sit, where the circuit is completed in both directions (from activity 1 to 5 and then from 5 to 1). Walking trials on the treadmill will be done at a self-selected speed or at a pre-selected speed between 0.5 and 1.5 m/s. The laps up/down a 5-step staircase and laps around the circuit will be done at a self-selected speed. In addition to these primary activities of daily life, participants may be asked to perform non-locomotive tasks such as squats, stand-crouch transitions, lunges, and calf raises at a pace determined by a metronome. Then participants will complete at least 60 strides for each walking incline, 50 strides for each stair direction, 15 sit-stand-sit cycles, 10 squats, 10 stand-crouch-stand cycles, 10 lunges, and 10 calf raises to obtain representative samples while avoiding fatigue. To ensure data quality, the order of trials with and without orthosis will alternate, and regular breaks will prevent fatigue. One subject may validate multiple modules separately and this may occur within one experimental visit or more depending on time constraints.

EMG measurements may include the following relevant muscles: ankle plantarflexion via gastrocnemius medialis, ankle dorsiflexion via tibialis anterior, knee flexion via biceps femoris, knee extension via vastus medialis oblique, hip flexion via rectus femoris, and hip extension via gluteus maximus. For each task/condition, EMG readings will be normalized per-muscle by the peak EMG observed during the no-orthosis condition, and then averaged over the cycle and across repetitions to obtain "normalized

exertion" values. Performance will be assessed for each participant by averaging normalized exertion across tasks and relevant muscles to compute the "orthosis effect" relative to the no-orthosis condition, as a percent reduction in normalized exertion. The metric for success for each module is achieving greater than a 25% orthosis effect to outperform the Samsung hip exoskeleton [38]. [58][58]Exertion for each muscle and task and the corresponding orthosis torque commands will serve as secondary measures.

Young Adult Protocol Part B

This study will assess the feasibility of our novel orthotic intervention for mitigating the primary causes of chronic overuse injuries during repetitive lifting, lowering, and carrying. The primary inclusion criteria will be able-bodied participants aged 18-65 who can lift and lower 10kg using the neutral-spine squat technique for 25 repetitions [49], [59], [87]. We may record EMG from relevant lower limb muscles. We may also record motion capture and ground reaction force data during certain trials. Additionally, we may gather subjects' feedback on the comfort of the powered orthosis device via the QUEST 2.0 questionnaire.

The L&L experiment will consist of a series of activities which includes lifting and lowering a weight that is 10kg or 15% of the participant's body weight (whichever is less) and completing a circuit. The circuit will consist of up to five tasks that replicate activities of daily living: 1) sit-stand, 2) walk 10 m on level ground, 3) walk up a ramp, 4) walk down a staircase, 5) stand to sit. Completing the activities from 1 to 5 then in reverse from 5 to 1 will consist of one repetition of the circuit. Participants may also be asked to perform up to 10 repetitions of L&L in between tasks. Participants will perform the activities in two conditions: active (while wearing the bilateral powered orthosis) and bare (no orthosis). Participants may also be asked to perform the activities pre-fatigue and post-fatigue (i.e. they will be asked to hold up to 4 consecutive squats or perform the lifting and lowering task until failure in order to induce temporary fatigue [47]). Participants will perform up to 10 sets of L&L (up to 25 L&L repetitions in a set) and up to 10 sets of circuit repetitions (up to 10 circuit reps in a set) across all conditions (orthosis and fatigue). The order of the activities (the L&L and circuit) and conditions (active and bare) may alternate between participants in order to remove any order effect. Participants will be given breaks between activities and may request additional breaks at any time.

Using motion capture, time to completion of the circuit in both directions and the completion of the L&L reps for both conditions (bare vs active) will be the primary outcomes, measuring the extent of assistance provided by the powered orthosis for the multiple tasks. A Linear Mixed Model (LMM) will assess the effect of fixed factors—condition (bare, active) and sex—on this primary outcome. The model will include a random intercept for participant. We may also investigate secondary measures such as EMG, kinematic, and kinetic data. EMG of relevant lower-limb and low-back muscles will assess muscular effort as in our prior work [58], [59]. Using motion capture, the peak global thorax angle (with respect to vertical) will be another secondary outcome measure to study the extent of stooping (from squatting below 55 deg to stooping above 55 deg [88]). A LMM will assess the effect of fixed factors—condition (bare, active) and sex—on this outcome post-fatigue. The model will include a random intercept for participant. We used the SIMR package to calculate the sample size based on a LMM of peak thorax angles with and without bilateral knee assistance using our pilot data with three able-bodied participants. We estimate that 10 participants will provide adequate power (>80%) for detecting significant differences ($\alpha = 0.05$) between thorax angles of the two conditions. LMMs will again determine the effect of condition and sex on these secondary measures.

Elderly Protocol

This study will assess clinical feasibility for improving functional outcomes in up to thirty elderly participants. In the experiment session, participants will be given sufficient time to acclimate to the

powered orthosis before data collection. The assistance level for each joint direction will be adjusted based on the participant's deficits. Data collection will comprise eight tasks (or a subset thereof) for two conditions: baseline (no orthosis) and active (bilateral powered orthosis). If participants regularly use a walking aid (e.g., cane), they will use it during both conditions. Task 1 will be the 10-meter walk test repeated thrice per condition. Task 2 (sit-stand cycles) will be repeated up to 15 times per condition. Task 3 (ascending/descending a staircase), and Task 4 (ascending/descending a ramp with maximum 15 degrees inclination) will each have up to 10 repetitions. These tasks will also be performed in a continuous activity sequence including walking, repeated up to 15 times. Tasks 5-7 will be level, incline, and decline treadmill walking for up to 15 minutes per level. Task 8 will be a 6-minute walk test. Repetitions are limited to minimize fatigue. We may record EMG from relevant lower-limb muscles. We may also record motion capture and ground reaction force data during certain trials. Subjects may also be asked to repeat the abovementioned tasks while wearing another commercially available brace (e.g. an OA specific brace).

Outcome metrics may include gait speed, cadence, stride length, step width, single-support time, joint range of motion, peak joint angles, task-specific completion times, circuit completion times, task-specific distances travelled, rating of perceived exertion, rating of device effectiveness, EMG activation, and metabolic cost

Mild to Moderate Impairment Protocol

This study will assess *clinical feasibility* for improving functional outcomes for individuals with other mild to moderate neurological or orthopedic impairments (e.g., multiple sclerosis, transverse myelitis, stroke, osteoarthritis, etc.). The experiment procedures and outcome metrics will be identical to those in the Elderly Adult Protocol, with the exception that participants may use either a unilateral or bilateral powered orthosis based on the affected side(s) in the active condition.

Osteoarthritis Protocol

The study protocol involves two lab visits. In the first visit, we will fit unilateral or bilateral device(s) to the participant's affected side(s). Participants will then be given adequate time to acclimate to the device under different assistance/resistance levels over the primary ADLs (about 15 min per activity). Data collection will begin after the acclimation session. A joint-specific survey (e.g., modified WOMAC, modified Ankle Osteoarthritis Scale) will be used to assess perceived pain and difficulty. The first test comprises a continuous sequence of sit-to-stand, walk, stair ascent, walk, ramp descent, walk, and stand-to-sit, followed by the reverse sequence including ramp ascent and stair descent. A self-selected pace will be fixed between conditions and may be enforced by audible cues marking temporal milestones in the circuit (e.g., reaching the elevated landing, reaching the second chair, and returning to the landing). If participants regularly use a walking aid (e.g., cane), they will use it during each condition. The primary outcome will be overall pain, assessed via a joint-specific survey (e.g., modified WOMAC, modified Ankle Osteoarthritis Scale), comparing three conditions: no orthosis, conventional orthosis, and powered orthosis at the preferred assistance level. Additionally, a 10-meter walk test (repeated twice) on an overground walkway or a six-minute walk test on a treadmill to assess self-selected walking speed for the same three conditions.

In the second visit, EMG electrodes and reflective markers will be placed on the legs to measure muscle effort (average EMG) and joint moment load (average biological torque). Joint moment load will serve as a primary objective measure in addition to the subjective pain measure. Data collection will comprise five tasks (or a subset thereof) for two conditions: no orthosis and powered orthosis. Tasks 1-3 will be level, incline, and decline treadmill walking for up to 4 minutes. Task 4 will be ascending/descending a 5-

step staircase up to 20 times. Task 5 will be sitting and standing from a backless, armless stool up to 20 times. Participants will perform these isolated activities with the powered orthosis at -20%, 0%, 50%, and 100% peak motor torque (participant blinded), allowing us to understand the effect of resistance/assistance level for each activity. In particular, the resistance condition (-20%) will oppose the biological torque during stance (with zero torque during swing to avoid trips). This condition—akin to resistance training commonly used in OA therapy—may cause increased difficulty and/or discomfort, thus minimizing the placebo effect for other conditions. The order of conditions and the order of peak motor torque will be alternated between tests and participants.

Outcome metrics may include perceived pain, perceived difficulty, gait speed, cadence, stride length, step width, single-support time, joint range of motion, peak joint angles, task-specific completion times, circuit completion times, task-specific distances travelled, rating of perceived exertion, rating of device effectiveness, EMG activation, and joint moments.

Inclusion and Exclusion Criteria:

Our inclusion criteria for **able-bodied, young participants** will be:

- Aged between 18 to 65 years
- Weigh less than 250 lbs due to limitations in the design of the orthoses
- Ability to lift and lower a 10 kg weight using the neutral-spine squat technique for 25 repetitions

Our exclusion criteria for **able-bodied, young adult participants** will be:

- Pregnant (self-report)
- Any significant neuromuscular or musculoskeletal disorder that would interfere with the study
- Prior history of chronic lower-back pain
- Unable to walk for 20 minutes
- History of any cardiovascular, vestibular, or visual diseases and/or impairments that may interfere with the study
- Cognitive deficits that would impair their ability to give informed consent or impair their ability to follow simple instructions during the experiments. Cognitive deficits will be determined by a Mini-Mental State Examination (MMSE) score of <22.
- Adults with a known allergy to medical grade tape

Our inclusion criteria for **elderly participants** will be:

- Aged between 65 to 90 years
- Weigh less than 250 lbs due to limitations in the design of the orthoses
- Ability to walk 6 minutes without assistance from a person (may use walking aid)

Our exclusion criteria for **elderly participants** will be:

- Pregnant (self-report)
- Significant pain due to arthritis or other joint problems that would limit their ability to walk
- Any recent lower-extremity fracture (within 3 months)
- Significant neurological (e.g., stroke), orthopedic, or cardiovascular disorder that may affect the ability to walk
- Advised by a physician not to walk or exercise
- Uncontrolled hypertension or diabetes

- Cognitive deficits or visual impairment that would impair their ability to give informed consent or impair their ability to follow simple instructions during the experiments. Cognitive deficits will be determined by a Mini-Mental State Examination (MMSE) score of <22.
- Adults with a known allergy to medical grade tape
- Unable to complete at least two minutes of steady-state activity with a metabolic face mask

Our inclusion criteria for **individuals with neurological or orthopedic impairments** will be:

- Aged between 18 to 90 years
- Weigh less than 250 lbs due to limitations in the design of the orthoses
- Ability to walk 6 minutes without assistance from a person (may use walking aid)
- History of mild to moderate neurological or orthopedic impairment (e.g., multiple sclerosis, transverse myelitis, stroke, osteoarthritis, etc.)

Our exclusion criteria for **individuals with neurological or orthopedic impairments** will be:

- Pregnant (self-report)
- Significant pain due to arthritis or other joint problems that would limit their ability to walk
- Any recent lower-extremity fracture (within 3 months)
- History of any cardiovascular or vestibular diseases and/or impairments that may affect the ability to walk
- Advised by a physician not to walk or exercise
- Uncontrolled hypertension or diabetes
- Cognitive deficits or visual impairment that would impair their ability to give informed consent or impair their ability to follow simple instructions during the experiments. Cognitive deficits will be determined by a Mini-Mental State Examination (MMSE) score of <22.
- Adults with a known allergy to medical grade tape
- Unable to complete at least two minutes of steady-state activity with a metabolic face mask

Our inclusion criteria for **knee, hip and ankle osteoarthritis participants** will be

- Aged between 30 to 85 years
- Medical diagnosis of knee osteoarthritis, hip osteoarthritis, or ankle osteoarthritis
- Weigh less than 250 lbs due to limitations in the design of the orthoses
- Ability to walk 6 minutes without assistance from a person (may use walking aid)
- Ability to ascend/descend ramps and stairs with or without the use of handrails

Our exclusion criteria for **knee, hip and ankle osteoarthritis participants** will be:

- Pregnant (self-report)
- Any recent lower-extremity fracture (within 6 months)
- Significant limitation on hip, knee, or ankle joint range of motion
- Significant neurological (e.g., stroke) or cardiovascular disorder that may affect the ability to walk
- Advised by a physician not to walk or exercise
- Uncontrolled hypertension or diabetes
- Cognitive deficits or visual impairment that would impair their ability to give informed consent or impair their ability to follow simple instructions during the experiments. Cognitive deficits will be determined by a Mini-Mental State Examination (MMSE) score of <22.
- Adults with a known allergy to medical grade tape

Data and Specimen Banking:

No specimens will be collected. A range of biomechanical data will be collected during the study visits including motion capture data using reflective markers using a Vicon Motion Capture System, lower limb electromyography data (EMG) using a Delsys Trigno EMG system, and metabolic expenditure data using a COSMED K5 system. These systems are all commercially available and will be used as prescribed. The powered orthoses themselves will also be capturing data including joint angle, joint torque, orientation, velocity, acceleration, and ground contact pressure. Anatomical measurements such as height, weight, and leg length of each participant will be included. We may additionally collected relevant clinical surveys from participants (e.g., Manual Muscle Test, Modified Ashworth Score, and Fugl-Meyer Assessment). Not all outcome measures may be collected for all participants.

Participants will be assigned confidential codes for data collection based on order of enrollment. A paper code assignment sheet will include the participants' names, contact information, and demographic information (age, race, ethnicity, sex) as required for enrollment reporting to federal agencies. This code assignment sheet will be kept separate from research data and stored in a secure cabinet in a secure office under lock and key. This paper code key will be retained in case the participant needs to be contacted after the experiment and to ensure the same person is not enrolled twice in the study. The list will be retained for 3 years after the completion of this study. No personal information will be stored with research data. Any data, photos or video will be stored for as long as it is deemed scientifically valuable and will be stored on a secure UM ARC Turbo Research Storage drive (for sensitive data) and/or UM Dropbox.

In the event this study will be published, data may be released to report the outcomes of this study. No released data will include identifiable information. Research data may also be deposited into a repository for public use; this data will be labelled with a code and no identifiable information will be included.

Data Management:

Statistical analyses of data are described above for each study. Data will be stored under the participant's code as an identifier for reference during the study. Any data, photos or video will be stored indefinitely on a secure, password protected computer at the University of Michigan. No personal information will be stored with their data. Any hard documents will be kept in a secure and locked location in a secure office at the University of Michigan. Only authorized UM research personnel specific to this study will have access to the data.

Withdrawal of Participants:

The participants will be informed that their participation is strictly voluntary and that they can withdraw from any experiment at any time for any reason without consequence. Participants may be withdrawn from this study for missing scheduled research visits, if it is determined that they are not able to comfortably walk on the device, or if they are unable to safely perform the mobility tasks.

In the event of a participant withdrawal, participants will be compensated for their time rounded up to the nearest hour, and permitted to leave the study site. If participants are withdrawn from the study after

data has been collected, the data that was collected will be retained if it is deemed to be scientifically relevant by the researchers. If the data is not relevant, it will be discarded.

Risks to Participants:

This study is a non-invasive, minimal risk that involves no collection of specimens. Potential risks and prevention strategies are listed below:

- Fatigue, exhaustion, or discomfort (likely)

Participants will have scheduled breaks every 30 minutes and also allowed to take breaks if they become tired at any point in the study. Additionally, there are built-in breaks to the study protocol between individual trials to minimize exhaustion. Resistance conditions for the OA group may cause slight, acute discomfort due to increased muscle forces and strain on the arthritic joint; any condition can be skipped if not well tolerated.

- Other risks include skin irritation and joint or muscle strain due to use of the orthosis (unlikely). Skin irritation may occur while using any orthosis. Minor muscle strain is a common problem with a new or abnormal gait and can also be caused by forces produced by a powered orthosis.

Experienced research team members following current clinical practices will fit the orthosis to the participant. The participant will have ample opportunity to discuss the fit and comfort of the device and participants will be monitored for sign of discomfort. The power of the device can also be reduced in software if the participant feels it is too strong or jerky. If the participant expresses discomfort, the experiment will be paused for a break and/or equipment adjustment.

- Skin irritation due to sensor tape or wearing face mask for metabolic measurements (unlikely)

All sensors and markers will be affixed to participants using medical grade tape. Any redness or irritation is temporary and should go away shortly after the tape is removed making this a minor risk. Participants can remove the mask whenever they want, and they can resume the study if and when they put the mask back on. Participants who do not put their mask back on will not be withdrawn from the study. The face mask is part of the COSMED K5 system, which has been approved by FDA for metabolic rate measurement during exercises. The FDA 501k number is K162515.

- Mild claustrophobia due to the face mask (unlikely).

Participants can remove the mask whenever they want, and they can resume the study if and when they put the mask back on. Participants who do not put their mask back on will not be withdrawn from the study. The face mask is part of the COSMED K5 system, which has been approved by FDA for metabolic rate measurement during exercises. The FDA 501k number is K162515.

- Risk for falls (rare) due to impairment, use of the orthosis, or wearing face mask for metabolic measurements.

Risk of falls will be minimized by requiring that all participants have the ability to walk 6 minutes without assistance of another person(may use walking aid). Handrails will be available for a participant to grab if he/she loses balance, or a researcher will follow and hold onto the participant with a gait belt to catch a possible fall. In addition, participants may wear a harness throughout the experiment. Participants will

begin with simple activities such as level-ground walking and will only be asked to perform other activities after they become proficient users of the orthosis. The participant will be monitored throughout the study to ensure they are able to maintain balance appropriately. In the unlikely case of a system malfunction, the device will operate like a passive (unpowered device) which may be unexpected to the user and could potentially cause a loss of balance. The powered orthoses involved in this study are similar to our prior designs that have been used without incident in past IRB-approved studies (e.g., HUM00164931 and HUM00158854). In case of metabolic rate testing, participants will receive prior training on walking with the face mask until they are fully acclimated and feel confident.

The research team has completed extensive bench-top mechanical testing on the powered orthoses prior to use in this study to ensure durability, strength, and safety. The robotic orthoses have been designed by experts in the field with several safety features, both in software and hardware, to minimize the risk of joint or muscle soreness/injury. The participant will be able to disable the motors through a button on the device or in their hand (e.g., if the participant feels discomfort or loses balance). These devices are also designed so that participants can resist their joint motion, i.e., the torque generated by the orthosis motors are limited to about 1/3 of the joint's peak torque during walking. The orthotic joints have hardware or software stops so that the user's leg joints cannot exceed their normal range of motion at any time. Software will immediately disable the motors if onboard sensors measure any safety limit being exceeded.

- Breach of confidentiality (rare)

All records will be confidential, coded, and kept in a locked cabinet or on a secure network drive that only the study team has access to.

Potential Benefits to Participants:

There is no direct benefit to participants for participating in this study.

Sharing of Results with Participants:

Results will be shared with participants if they request the information, but only after data analysis is complete. Results will only be shared among qualified research staff within University of Michigan.

Setting:

Experimental visits will occur in the Rehabilitation Laboratory in the Ford Robotics Building on the University of Michigan North Campus at 2505 Hayward St, Ann Arbor MI 48109. Fitting visits may occur in the same lab or the UM Orthotics & Prosthetics Center at 2850 S Industrial Hwy STE 400, Ann Arbor, MI 48104.

Resources Available:

Principal Investigator: Robert Gregg, PhD is the director of the Locomotor Control Systems Laboratory at the University of Michigan. His expertise includes prosthetics and orthotics, human locomotion, legged and wearable robots, and control theory. He has substantial experience with human subjects research, including 18+ IRB protocols. PI Gregg will be responsible for overall project direction and IRB protocol management.

Co-Investigator: Elliott Rouse, PhD is the director of the Neurobionics Lab at the University of Michigan. His expertise includes biomechanics, prosthesis and orthosis design, mechatronics, and human performance augmentation. Prof. Rouse will co-advise one of the Graduate Research Assistants for the validation experiments.

Co-Investigator: Chandramouli Krishnan, PT, PhD is an Associate Professor in the Department of Physical Medicine & Rehabilitation, Robotics Institute, Department of Biomedical Engineering, and School of Kinesiology at U-M. Dr. Krishnan will assist in study implementation, recruitment/screening/scheduling of elderly participants, human subjects research design, statistical analysis, and dissemination efforts.

Co-Investigator: Damon Bagley-Ayres, CPO is a Certified Orthotist/Prosthetist at the U-M Orthotics & Prosthetics Center, which is part of the Department of Physical Medicine & Rehabilitation. Co-I Bagley-Ayres will assist recruiting, perform pre-experiment fittings, fabricate orthotic components, and support experiments with patient participants.

Co-Investigator: Ed Wojtys, MD is a Professor in the Department of Orthopaedic Surgery and practices medicine in the Orthopaedic Sports Medicine Program at U-M. Co-Wojtys will assist in recruitment and screening of osteoarthritic participants, design of study methods, and interpretation of results.

Recruitment Methods:

Patient participants will be recruited through a rolling referral beginning after the approval of this protocol. Recruitment will end once the appropriate number of participants has been recruited.

We will recruit patient participants from the greater Ann Arbor and Metro Detroit areas with the assistance of Co-Investigators Chandramouli Krishnan, PT, PhD and Damon Bagley-Ayres, CPO. Study participants will be primarily recruited via flyers placed in the Michigan Medicine hospital and health centers and local community centers and boards, UM Geriatrics Center, and online advertisements on the UMHealthResearch.org recruiting registry and/or the Orthotic and Prosthetic patient registry (HUM00154795). The research team will also inform clinicians at the UM Geriatrics Center that we are looking for elderly participants that meet our inclusion/exclusion criteria. Clinicians will inform patients who match these criteria about our study and provide the study poster with the PI's contact information to interested participants. The participants will contact the PI to schedule experiments. Study participants may also be recruited through MiChart. In addition, we will use word-of mouth communication and the internet (e.g., PI/Co-I's websites, social media sites like Facebook, Twitter, etc.) to further expand our reach.

Able-bodied participants will be recruited from the staff and students at UM and acquaintances from the Ann Arbor area. Study personnel will give flyers or send scripted emails (see "interview" document) to acquaintances that match the inclusion criteria. Printed flyers will also be posted on departmental message boards. In the event that a participant is a student or employee of the Principal Investigator, that participant will be consented by a study team member other than the PI.

Once a potential participant has contacted us, a member of the research team will discuss the study in more detail and answer any questions they might have. If the participant is still interested, an evaluation will be scheduled over the phone in order to ensure the participant meets the inclusion/exclusion criteria.

Patient participants (Elderly, mild to moderate impairment, and osteoarthritis) will be paid $40 per hour for study related visits and travel mileage to campus. Able-bodied participants will be $10 per hour. The reason for the discrepancy in payment amounts is due to the fact that the inconvenience and likely the distance required for travel to UM will be much larger for patient participants and is needed to secure and retain these participants. Payments will be made using a University-approved method for participant support.

Confidentiality:

All data collected from participants will be considered privileged and held in confidence: participants will be assigned confidential codes and no identifying personal data will be stored with study data. Study data will be stored in a secure UM ARC Turbo Research Storage drive (for sensitive data), UM Dropbox, or in the PI's locked filing cabinets as applicable.

Each participant will be identified with a participant code, and filenames will be labeled with the participant code instead of participant name. The participant name - participant code link will be stored in a locked file cabinet. In the case that the results of this data are published, the participants will be referenced through the participant code and the identity of the research participants will not be indicated. If a participant gives specific permission on the consent, he/she may be photographed and videotaped during the experiment for possible use in scientific presentations, publications, or public dissemination. All photographs and videos will be stored with study data in a secure UM server or UM Dropbox.

Provisions to Protect the Privacy Interests of Participants:

Any personal information collected from the participant will be held in confidence. Each participant will be assigned a code, under which all their information will be stored. The code-name key will be kept in a locked file cabinet. Only research staff involved in this study will have access to this key.

The participants will be instructed that at any point along the way, they may stop the research staff and ask any questions. If at any point, the participant does not wish to answer a question, they will be instructed that they can decline to answer at any point during the study without facing any repercussions from doing so.

Compensation for Research-Related Injury:

If a participant gets an injury or illness as a result of the study, the participant is required to promptly notify the PI of the study about the illness or injury. The University of Michigan will not pay for medical care required because of a bad outcome resulting from participation in this research study.

Economic Burden to Participants:

Patient participants (elderly, mild to moderate impairment, and osteoarthritis) will be compensated for their participation in the study. Participants will be responsible for transportation to and from the study site.

Consent Process:

Informed consent to participate in the study will be obtained per IRB protocol. The participants will be asked if they wish to participate in the study. Participants who meet the inclusion criteria will then be

asked if they understand all sections of the consent form. Ample time will be provided so that the participant can discuss the study with significant others, such as family members, employer or other member of his or her clinical team. Participants will be free to decline participation in the study. A researcher will answer any questions that arise from the informed consent sheet and witness the consent process. Participants will be provided with contact information so that they are able to obtain information and ask questions at any stage of the study. A copy of the informed consent documents will be offered to the participant. Participants will be informed that participation is strictly voluntary and they can withdraw from any experiment at any time for any reason without consequence. Consent will be performed on an ongoing basis until sufficient numbers of participants are recruited.

Devices:

All biomechanical data will be collected using commercially available devices designed for that purpose. We note that the final prototype of our device will fall into a generic category of Class I and Class II 510(k) exempt devices as defined by 21 CFR Parts 862-892 and would not require FDA review. These devices would come under one of the following categories: (1) Limb Orthosis (regulation no. 890.3475), (2) Measuring exercise equipment (regulation no. 890.5360), or (3) Powered exercise equipment (regulation no. 890.5380). Commercial sensor-controlled orthoses (e.g., Ottobock's Sensor Walk KAFO) fall under Class I limb orthoses. Similarly, many of the commercial robotic devices (Lokomat, Armeopower, Armeospring, etc.) that are powered and actuated using motors are also 510(k) exempt under regulation no. 890.1925 (Isokinetic testing and evaluation system). Devices used in this project will be stored in a locked room and will only be accessible by the PI and authorized personnel. All hardware or software limits, including torque and position, are within the range of normal human movement and that of commercially available devices. In the event of equipment malfunction the user will not experience anything other than mild discomfort associated with the device working slightly differently than expected (participant will NOT experience high torques/forces or huge variations in position). The powered orthoses involved in this study are similar to our prior designs that have been used without incident in past IRB-approved studies (e.g., HUM00164931 and HUM00158854).

M-BLUE Modular Hip/Knee/Ankle Modules: The Modular Backdrivable Lower-limb Unloading Exoskeleton (*M-BLUE*) contains powered hip, knee, and ankle orthosis modules that can be used independently or together (Figure 1). *M-BLUE* comprises conventional Breg T-Scope hip and knee braces, which have been modified by replacing the joint and uprights with aluminum pieces that mount an actuator pack in place of the joint. The actuator pack combines the Dephy FASTER driver system with the T-motor AK80-9 actuator, which together weigh 584g and produce 30 Nm peak torque. The unpowered backdrive torque is less than 0.5 Nm, allowing the user to freely control their joint kinematics. The actuators are powered by a battery pack and controlled by a Raspberry Pi microcomputer. This system has joint encoders to measure joint angles/velocity, a Microstrain IMU to measure leg orientation with respect to gravity, and an insole sensor to measure foot pressure. The Breg braces come in multiple sizes with adjustable straps to allow customization to individuals for proper fit and comfort. *M-BLUE* is also compatible with the *Dephy* ankle module described below.



Figure 1. Top: Hip+knee, hip-only, and knee-only configurations of *M-BLUE*. Middle: CAD design and assembly of *M-BLUE* ankle module. Bottom: Unloader OA brace version of knee module on a benchtop stand.

An alternative version of the M-BLUE knee module consists of a commercially available DonJoy unloader knee brace to address multicompartmental knee OA cases. Aluminum and 3d-printed components adapt the brace to connect the aforementioned actuator pack and introduces a low-ratio linkage transmission to accomodate the polycentric nature of the knee brace. While the original brace provides a passive torque in the coronal plane to offload the medial or lateral knee compartment and alleviate osteoarthritis pain, the added motor delivers active torque in the sagittal plane to assist knee flexion and extension. The goal is to reduce muscle activation and thereby lower patellofemoral joint loading. Onboard sensing and electronics remain equivalent to aformentioned M-BLUE description. The total mass of the brace, including the actuator and transmission system, is approximately 1.7 kilograms, excluding the weight of cables, sensors, and hip-mounted control and power system (battery, Raspberry Pi).

Dephy Powered Ankle Module*:* The robotic ankle exoskeleton system (*ExoBoot*) in Figure 2 is a commercially-available device designed and manufactured by Dephy, Inc. (Maynard, MA, USA). Each ExoBoot consists of four main assemblies: 1) a custom boot with an embedded rigid footplate attached to a short lever arm on the lateral side, 2) a fiberglass strut attached to the boot via the ankle hinge joint, 3) a brushless motor and associated electronics (i.e., the Dephy Actuator Package), fully encased and mounted to the strut, and 4) batteries and control electronics (i.e., a small microprocessor) contained in a pack worn around the waist. The motor provides plantarflexion torque about the ankle joint (up to 50 Nm) by spooling an inelastic cable that is rigidly attached to the boot's lever arm. The ExoBoot features several onboard sensors that measure ankle joint angle and velocity, motor angle and velocity, motor current and voltage, and the acceleration and angular velocity of the shank. The device is modular and thus can be worn as only one ExoBoot (unilateral), or as two ExoBoots on the left and right legs (bilateral). The bilateral device weighs a total of 3.97 kg (each leg: 1.35 kg; battery & control pack: 1.27 kg). The shank straps are adjustable in both circumference and height to accommodate participants of various sizes. Three different boot sizes are available (US 8M, 10M, and 12M). All the cabling routed along the posterior side of the leg is adjustable in length and has spring-like winding to ensure the cable stretches comfortably as the person walks and does not hinder their motion or become a tripping hazard. This device was previously approved under HUM00164931 and HUM00158854.

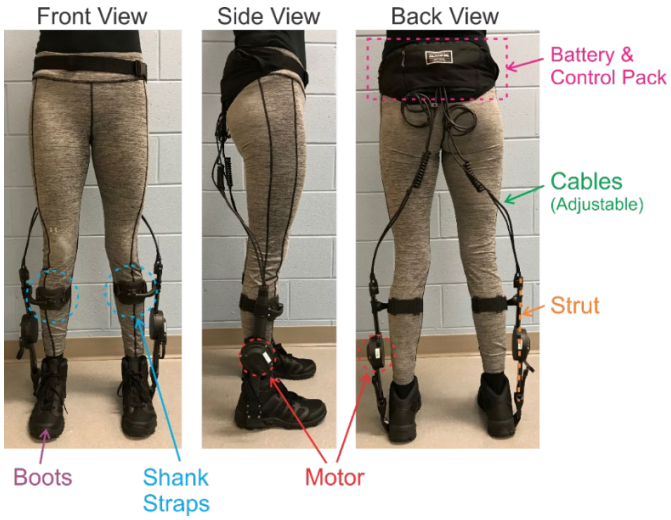


Figure 2. Bilateral Dephy ExoBoot system.


Figure 3. Rendering of the ExoBoot modification with the addition of a passive mechanism to provide dorsiflexion torque to the wearer.

The ExoBoot may additionally be modified by the addition of a custom, passive mechanism to bias the system torque (Figure 3). A cam-follower mechanism will be installed with the rotation of the cam coupled to the ExoBoot ankle rotation. Displacement of the follower bearing will compress a spring (or springs), making the ExoBoot's motor and transmission into a parallel elastic actuator. The cam profile and spring selection will be designed/chosen to produce a desired biasing torque-angle profile, augmenting the uni-directional torque of the ExoBoot to allow the device to impart mild dorsiflexion torques to the wearer.

In the event that the hip and knee modules are unavailable/inoperable, the following devices are available for use:



Figure 4. Comex2 powered knee orthosis.

Comex2 Powered Knee Orthosis: The Locomotor Control Systems Lab designed and built this partial-assist device (Figure 4) to produce 10 Nm continuous torque (20 Nm peak) at the knee using a custom frameless BLDC motor with a custom 7:1 planetary gear core inside the motor's stator. The motor is driven with sinusoidal commutation by an Elmo Gold Solo Twitter drive. The control system includes the onboard sensors and computation needed to implement current-based torque control at a sampling rate greater than 1 kHz on a Texas Instruments C2000 microcontroller. A high-resolution encoder measures the knee angle/velocity, and a 6-axis IMU measures orientation. The system is powered by an onboard Lithium-Ion battery pack. The unpowered backdrive torque is less than 2 Nm, allowing the user to control their joint kinematics. The device weighs about 2.7 kg and includes safety features such as hard stops and a current limiter. This device was previously approved under HUM00164931.

Movex Powered Hip Exoskeleton*:* The robotic hip exoskeleton system (*Movex*) in Figure 5 is a commercially-available device designed and manufactured by Enhanced Power Technology (Shenzhen, China). Two motors power both hips with up to 32 Nm of torque, which is transferred to the thighs through adjustable straps. The controller and lithium-ion battery management system (BMS) are located in a back pack, which also has adjustable straps for the waist and shoulders. The system has onboard sensors to measure joint angle, velocity, and torque as well as back orientation. The total system weighs 4.2 kg. This device was previously approved under HUM00164931.



Figure 5. Movex hip system.

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