Knee Instability Correction Device

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Abstract

Knee instability is a common condition from serious knee injuries, such as complete anterior ligament (ACL) tears, requiring extensive rehabilitation to return to daily life. Patients experience instability through the buckling of their knee under weight acceptance, with the knee primarily buckling towards the midline into abduction. Current rehabilitation procedures in ACL injury recovery utilize bracing to support the brace, and periods of free movement to encourage motor control development, but these methods result in disuse atophy and risk of re-injury. The Knee Instability Correction Device (KICD) fills this gap in treatment through cutaneous stimulation. The KICD provides vibration guidance to help the user correct their knee alignment to a stable position while standing, as it allows the knee physical freedom to gain strength while encouraging muscle development by virtually limiting dangerous movements through the use of tactile vibration cues. The device consists of a flex sensor cage around the knee, with an array of eccentric rotating mass (ERM) motors above the knee to provide haptic feedback in response to knee position. The KICD device was able to provide directional vibration feedback to users in experimental trials, with a majority of users responding to the device by correcting their knee position. In addition, perception of vibration intensity and resolution was investigated in the context of the lower limb sensation experience. Future work includes changes to the physical device to allow for more flexibility, as well as decoupling the perception of amplitude and frequency in the context of vibration.

I. Introduction

Knee instability is a common complication of knee-related injuries, resulting in unintentional buckling due to weakened ligaments and tendons from damage and disuse. Knee stability is crucial for bipedal locomotion and adaptation to uneven ground surfaces, posing its relevance to activities of daily living. Knee-related injuries are a common cause for rehabilitation and surgery, with an estimated 80,000-120,000 cases in the United States annually for anterior cruciate ligament (ACL) injuries alone. The anterior cruciate ligament is a band of tissue that connects the thigh bone to the shin bone at the knee, allowing knee alignment and rotational stability during movement [1].

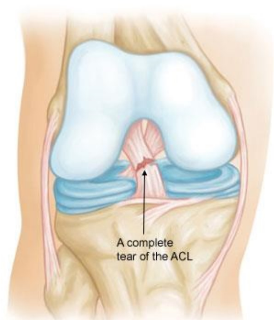

Fig. 1: Fully torn anterior cruciate ligament (ACL) [1].

The ACL can be fully torn from extreme knee inversion, often in the context of sports, shown in Figures 1 and 2. This extensive inversion to the point of injury is known as dynamic valgus, where the knee buckles towards the midline of the body when accepting weight, causing instability until it is treated [2].

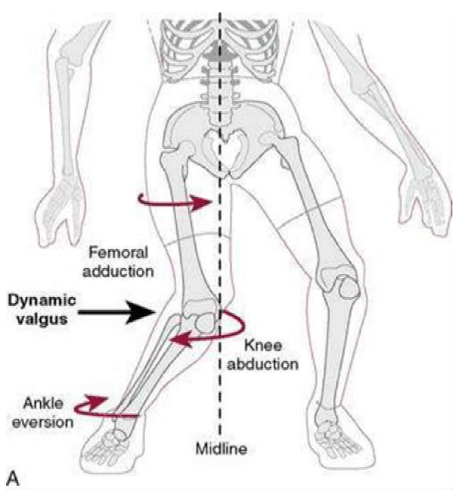

Fig. 2: Altered stance from a torn ACL, resulting in abduction and dynamic valgus at the knee [2].

ACL injury treatments, due to a tendency to completely tear the ligament, result in ligament graft surgery and post-surgery rehabilitation to stabilize the knee [3]. Current rehabilitation methods include passive bracing for up to a year to prevent imbalance by allowing limited movement while the ligament heals after surgery or injury, with daily removal of the brace for a short duration of time to promote freedom of motion [4]. Use of the brace increases the odds of disuse atrophy in the surrounding ligaments and potentially further knee instability, but the removal of the brace to prevent disuse atrophy in the surrounding muscles exposes the user to the risk of re-injury [5]. This presents a gap in the treatment of knee instability between fully constrained passive bracing and unconstrained brace removal. Haptic assistive technology could bridge these two states of treatment by selectively correcting the imbalance during moments of instability to impede disuse atrophy while reducing the risk of re-injury.

Two key aspects of active bracing suggest the benefits of bidirectional haptics as a potential solution. First, the device must be capable of detecting when a postural imbalance occurs, which can be achieved by sensing the dynamic valgus caused by the instability. Secondly, the imbalance caused by instability should be managed by retraining muscle memory and coordination when it occurs to reduce the risk of re-injury. Given that the former can be achieved through kinesthetic perception of the instability, and the latter by the user correcting for the imbalance, the gap in current rehabilitation methods can be fulfilled via a haptic guiding device.

Touch, both kinesthetic and cutaneous information, has been found to be more effective in developing motor skills than force methods, such as exoskeletons, which limit motion and whose feedback is difficult to deliver across joints. Vibration has been used a form of movement guidance throughout haptic literature, particularly in the context of upper extremities. Vibrotactile cues have been used for pose training to help users maintain a static yoga position in the arms and torso, with improvement in motor task performance by 27 % with the use of tactile feedback [6]. Recent uses of vibration include guiding weight bearing in the foot after injury [7]. Bjelland et al. developed a booted device that provided vibrotactile feedback through ERM motors in response to the amount of force applied on the bottom of the foot to communicate weight under or overloading, with both immediate correction and a post-response training loop for adjusting future cues based on patient behavior [7]. Studies have additionally proposed the efficacy of vibration to reduce spastic hypertonia by providing strong afferent input through cutaneous mechanoreceptors, with applications in training muscle contraction timing, particularly in the range of 70-90 Hz [8].

The perception of vibration in the lower extremities is not characterized and quantified to the extent of upper extremities, making detailed feedback, including perception of intensity, less understood. Despite limited characterization, vibrotactile cues have proven to be effective in correcting and training user movement. A directionalized vibrotactile haptic device with modulating intensity based on knee inversion could provide users with the tactile cues to redevelop motor coordination and strength after ACL injury.

II. Methods

A. Device Description

The Knee Instability Correction Device, which will be referred to as KICD in this paper, aims to assist in knee rehabilitation from an ACL injury by bridging a gap between fully constrained knee bracing and the re-injury risk of unconstrained brace removal. The KICD detects knee instabilities and applies directionalized vibrotactile simulation in the direction the knee should go, which prompts a reflex to move the knee back into a safe position. This cutaneous device utilizes ERM motors, which produces high frequency vibrations that stimulate the pacinian corpuscles.

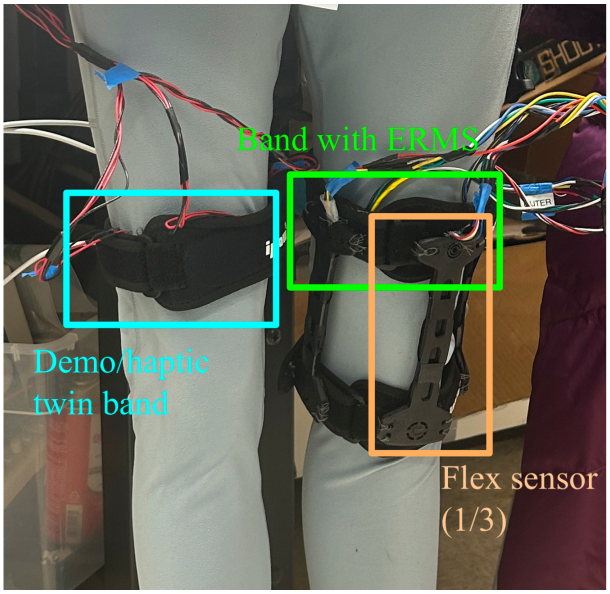

Fig. 3: Demonstration configuration of the KICD device, with electronics boards housed in an upstream backpack and not included in the figure.

The KICD Device consists of two bands worn above and below the knee, forming a soft brace base. Three one-axis flex sensors, attached to the knee bands through flexible TPU enclosures, detect the 3D knee angle, as shown in Fig. 3. Six ERM motors, which provide vibration stimulus to the front and side quadrants of the upper knee, are attached to the inside of the upper knee band, with a spacing of 40 mm, using 3D-printed PLA mounts. The motors are all controlled individually, allowing them to create patterned vibration stimulus to the user.

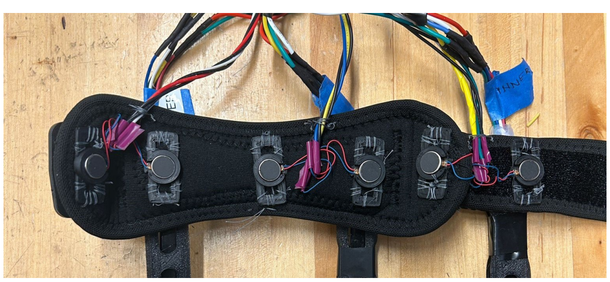

Fig. 4: Internal ERM array of the KICD device.

For ease of demonstration to uninjured patients with intact/stable knee position, a demo ERM band, controlled as a haptic twin of the KICD device, was created so that the complete device could be manipulated on a mannequin to bend into abduction (knee inwards) and adduction (knee outwards) without posing risk of injury or soreness to the user.

1) Sensors and Electronics: The primary sensors on the device are an array of 1-axis silicone elastomer flex sensors, chosen for their flexibility in movement, essential due to their mounting locations on the knee requiring multi-axis flex depending on knee movement. The flex sensors measure the absolute angle along its length, which when placed on the front and sides of the knee joint allow for estimation of knee position. Each flex sensor is connected to an ELEGOO Nano, all of which communicate to a main Arduino Mega microcontroller, which also commands all of the ERM motors.

The vibration actuators chosen were 3.3V, 80mA 1020 eccentric rotating mass (ERM) coin motors, with a peak torque of 5 gcm and peak frequency of 11,000 RPM. The low torque is sufficient for a primary purpose of cutaneous stimulation, while the high RPM allows for vibration responses from a low frequency of 79 Hz to a high peak frequency of 183 Hz determined experimentally from perceivable thresholds. The motors were driven through 2N2221A NPN transistors connected to 5V from the Arduino mega and controlled through PWM to compensate for limited current from microcontroller pins.

The overall architecture can be seen in the diagram below, with two perfboards and connectorized bundles comprising the physical harness system for serviceability, as shown by the yellow boxes in the diagram.

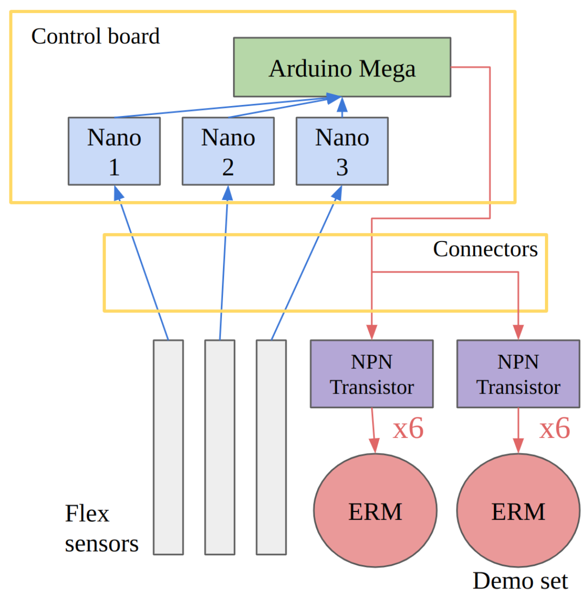

Fig. 5: Electronics architecture of the system, with physical boards represented by yellow boxes, and arrows representing signal transmission.

B. Control

The preliminary control design for the KICD device is to provide haptic feedback to help a standing user remain standing straight. As such, knee bends in any plane beyond a threshold value result in vibration feedback encouraging the user to straighten their leg.

The three flex sensors each measure a bent angle. Using these measurements, the angle at which the knee is bent most is determined, which dictates whether the knee is bending in the sagittal plane, in abduction, or in adduction. When the knee enters an unstable position, determined by crossing any of the three thresholds, the ERM motors in the direction of the instability are turned on. The vibration feedback starts in the direction of the instability and moves towards the direction of stability, creating a tracing sensation across the leg for the user to follow with their knee. The vibration motors turn on and off in a running pattern at equal intensities, beginning again at the direction of instability once the final ERM in the array has actuated, until the user's leg has returned to a neutral/stable position. The pattern/staggering of the ERM can be seen for the forward knee bend case in Fig. 6.

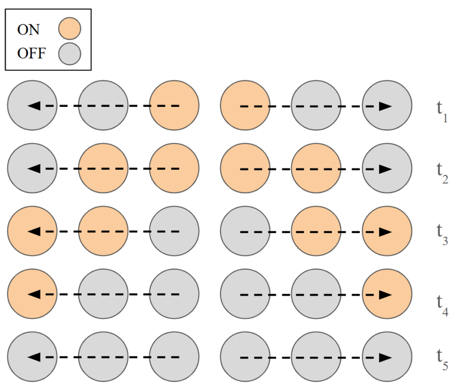

Fig. 6: ERM vibration pattern for forward knee bend, left is the outside of the knee, right is the inside of the knee.

The ERM staggering represented in the figure above is applied to sequences of ERM vibrations shown in Fig. 7 for different primary knee bend directions, as determined by the flex sensors.

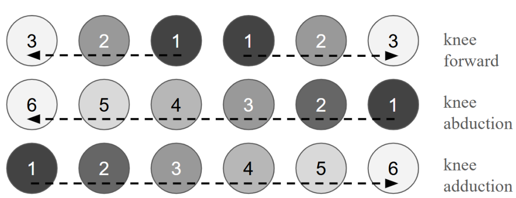

Fig. 7: ERM vibration patterns for directions of knee bend, left is the outside of the knee, right is the inside of the knee.

The overall control flow can be seen in the Figure below.

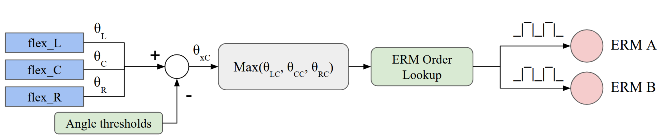

Fig. 8: Overall control architecture of the KICD device.

III. Preliminary Results

A. Perception Studies

To assist in device design, preliminary vibrotactile perception studies of the upper knee were conducted to determine discrimination thresholds, how timing between ERM motors affects sensation, and to understand the perception of intensity. First, discrimination thresholds were conducted using a procedure similar to the two-point discrimination test commonly used for contact perception on the upper extremities. Two ERM motors, clamped down to the leg using a knee band, were vibrated at full duty cycle at varying spacings from 10-60mm apart from each other across four regions of the knee. Studies were carried out in male and female participants totaling 4 subjects, testing with and without pants between the ERM and the user to check the damping effect of the clothing.

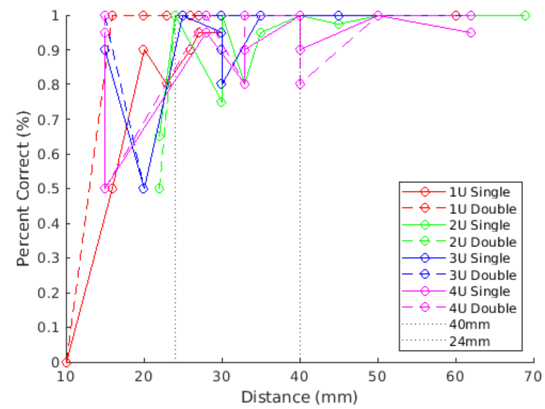

Fig. 9: 2-point Discrimination Testing Results, 1U=front, 2U=outer, 3U=back, 4U=inner regions of the upper knee.

All regions of the upper knee generally achieved ≥75% success in discrimination above 24mm, with near perfect consistency in all but one region above 40mm. Additional observations on the impact of the order and number of vibrations on perception impacted primarily the perception of one vibration motor. From the results of discrimination testing, a 40mm spacing for the ERM array was chosen to ensure all regions of cutaneous skin around the knee have accurate perception beyond the threshold. In addition, the region 3U at the back of the leg was excluded in the final design of the device to allow for better adjustability, with the additional realization of the uncomfortable sensitivity of the back knee to vibration.

In addition to discrimination thresholds, intensity perception was evaluated using a single vibrotactile object on the front of the upper knee of the subject (region 1U) due to the region's discrimination test results generally following a consistent trend. Intensity in the context of the ERM motor was modulated using pwm duty cycles. A script was written to increase the duty cycle with a button press. The subject was briefed on how to respond when asked, but was unaware of what was to happen in the test. After each button press, the subject was asked whether the vibration felt more, less, or the same, with the test administrator correlating the perceptions to a scale of +1, -1, and 0 respectively. The button was incremented until duty cycle reached its limits. Results for each person were repeated for 2-3 trials, then normalized by the maximum ”intensity” to account for variations in maximum ”intensity” numbers based on subject sensitivity and use of pants or direct skin contact. The normalized results can be in Fig. 10 below.

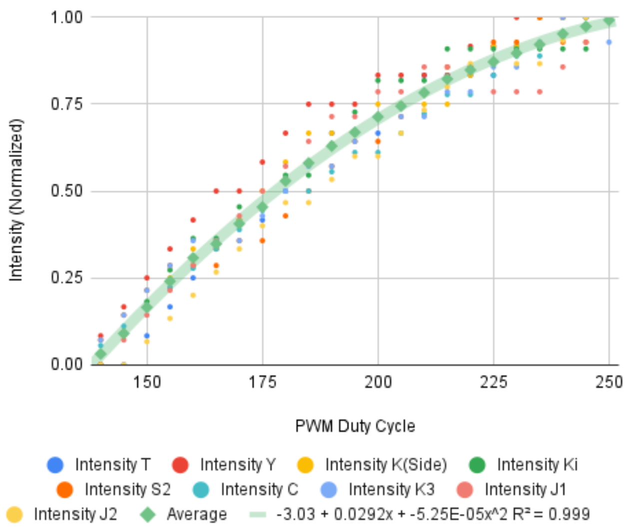

Fig. 10: Normalized intensity perceptions for 9 test subjects (M&F) through motor duty cycles of 110-255.

Although subjects had varied perceptions of quantifying maximum intensity, when normalized to their perceived maximums the subjects followed a 2nd order polynomial trend with a fit of $R^2 = 0.999$, with intensity feeling saturated near its peak from PWM cycles of 225-255 (161 to 183 Hz). This nonlinear experience of vibration intensity guides quantitatively changing intensity to ramp linearly in the context of the device requiring nonlinear adjustment of the PWM duty cycles.

B. Device Performance

Previous to demonstrations, use of the KICD device was tested on 2 individuals with uninjured knees but varying ranges of motion. Healthy subjects were capable of being their knee forward, such as in a squat, or at a compounded forward with knee abduction (towards midline) angle, with a peak knee abduction angle of $22 \pm 11°$ accounting for both test subjects. Knee adduction was unable to be replicated on healthy test subjects.

Before active usage of the device, automatic calibration of the flex sensors was completed to reset the straight angle of each of the flex sensors, as varying leg widths between upper and lower legs caused initial bend configurations for the sensors to vary based on individuals. After standing still for the calibration process of 5-10 seconds, the two center ERMs were vibrated at full intensity for 500 ms to signal to the user that calibration procedures were done.

Thresholds for unstable knee positioning was experimentally determined to be 5° for the side flex sensors and 8° for the front flex sensor, with these angles being determined relative to the initial calibration angles. Weighting of threshold was applied to the angle measurements from the three flex sensors to adjust the relative importance, though front and side scales were ultimately tuned to be equal to adjust feedback direction.

When the subject bent their knee, they were able to clearly feel the directional vibration over clothing, with the front bend triggering correctly 100% of the time, and the compounded abduction triggering in the proper direction 50% of the time due to individualized combinations of forwards and sideways bends requiring scaling adjustments to trigger proper correction more frequently. In the context of a wearable rehab device, these weights could be adjusted during an initial calibration session for the brace.

During haptic demo sessions, over 30 subjects of varying size and gender were tested with the haptic twin of the knee brace, with physical manipulation of the brace to trigger the vibration modes. Subjects were widely able to sense the directional feedback, with most subjects feeling inclined to move with the direction vector back into stability, proving the success of the haptic device. However, a minority of subjects experienced the opposing effect, moving in the opposite direction, while 6% of test subjects were unable to respond due to knismesis (tickling/itching sensation) from the combined frequency and amplitude of the actuators. Adjusting for these behaviors could be investigated in future work.

IV. Future Work

A. Future Development

Pancake ERM motors provide limited control methods for delivering vibration. Initially, it was planned for the vibration motors used to be voice coils, due to their ability to modulate both frequency and amplitude. However, struggles with resource access ultimately determined the final use of the pancake ERM motors for their accessibility and simplicity in motor control. This resulted in limited experimentation of decoupling frequency and amplitude in the context lower limb vibration perception. Future iterations of the device should explore use of voice coils in the context of both frequency and amplitude modulation.

In addition, the TPU mount design for the flex sensors limited the bending of the flex sensors to primarily be in a single axis, as the print would not allow 3D twist from compound knee bends. This resulted in the flex sensor cages bending outwards from the device, reading false high knee angles that needed to be compensated with sensor weighting. This could be mitigated by changing the flex sensor to a 2-axis version, which would provide multi axis bend readings for exclusion of irrelevant axes. To be effective, the mount would also need to be modified to bend in at least two planes of motion. This could be accomplished by changing the print quality/material, as well as the wall design from a rigid plane to an accordion shape for flexibility.

B. User Study Protocol

Characterization of vibration perception can improve the efficacy of vibration in motor learning, however this topic has limited published research in lower limb applications. The primary objective of this system performance study would be to examine the efficacy of motor learning via haptic cues to treat knee instability via the KICD. The study would consist of 4 experiments. In each experiment, a healthy participant will be asked to perform a task such as squatting while wearing the KICD. The device will detect the position of their knee, and in response will provide (a) no feedback, (b) directionalized feedback, or (c) static feedback when their knee arrives or exceeds a target posture. A pre-experiment baseline will be developed, before subjects are trained to limit their motion with haptic cues. The subjects will then be re-evaluated with no haptic feedback, before being trained to return to their baseline range of motion. The vibrotactile patterns used during each experiment trial are as follows:

- Experiment 1: Directionalized towards bend location
- Experiment 2: Directionalized away from bend location
- Experiment 3: Static Vibration
- Experiment 4: None (Control)

Success in motor learning would be proven by the initial movement limiting, then return to baseline, with the use of vibration cutaneous sensation.

C. Evaluation Metrics

Quantitative evaluation of the haptic device in the user study would primarily be through the measurement in changes in angle (normalized) and return to baseline angle during training. The following data would be taken at different stages of the experiment:

- At baseline: The user's comfortable knee bend/range will form the baseline for evaluation.
- After training phase (Evaluation Phase 1): The reduction in knee bend range (% in the context of the baseline range) will be measured. Expectation at this point is to see a reduction from baseline to training even without device due to motor learning.
- After skill washout phase (Evaluation Phase 2): knee bend range relative to baseline (% and numerical). Expectations are to return to baseline after retraining/skill washout due to motor learning.
- Between experiments: which experimental method (1,2,3,4) provides the highest percent of subject success (ie. proven limitation and then retraining to baseline), as well also how quickly they do both of the above (time).

Qualitative evaluation would primarily revolve around feedback preference, particularly in the nature of the vibration sensation. What patterns or static vibration or intensity/speed users prefer and feel is most intuitive would provide further guidance in the development of the haptic device.

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