

SteadyStride
Self-Stabilizing Cane for Parkinson's Disease

Cornell DEBUT Phase 2B



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I . Abstract

Parkinson's Disease (PD) is a neurodegenerative disorder which disrupts the neural circuitry that coordinates movement and can cause uncontrolled movements, such as shaking, stiffness, and difficulty walking [1]. Parkinsonian Tremor, or uncontrollable hand oscillations, is a common symptom of PD that may worsen over time and lead to instability while using a cane, increasing the chances of a fall [2]. For PD patients, falls are a significant source of lost independence. There are pitfalls with current walking assistive devices as they do not support users both physically and emotionally. Standard rubber-tipped canes slip when placed on the ground at an abnormal angle due to hand tremors, whereas more stable walkers are emotionally demeaning and hinder a patient's quality of life.

Our device, SteadyStride, utilizes a tuned mass damper (TMD) system embedded into the cane shaft to mitigate tremors and a thermoplastic polyurethane (TPU) treaded base to further stabilize the cane. Effects from an applied tremor are primarily decreased from the TMD, and the remaining instability is mitigated by the TPU base. Using an accelerometer in a wearable glove apparatus, the tremor mitigation of SteadyStride and a standard cane were tested and compared. Based on data and testimonials obtained from patient testing at SUNY Cortland's Physiology Center, SteadyStride significantly decreased cane tremors (avg. 12.25%) and received a majority of positive user feedback (75%). Furthermore, additional video testimonials demonstrated patients were pleased with SteadyStride as they had increased confidence, better stability, and preferred it to a standard rubber-tipped cane.

II . Description of the Problem

SteadyStride is aimed to assist patients with Parkinson's Disease by counteracting the instability caused by Parkinsonian Tremor. Many with Parkinson's Disease fall as a result of this instability, with prospective studies showing that between 45% and 68% of people with PD will fall each year, with a large proportion, 50–86%, falling recurrently [3].

Currently, there is no reliable and discrete device on the market that allows patients to walk comfortably with Parkinsonian Tremor. Walkers provide full stability but limit independence by restricting mobility and decreasing the quality of life for PD patients. Through patient interviews, many reported drawing attention due to their tremors, a self-consciousness that only increased with the assistance of bulky devices. Some have noted if a day-to-day activity required the assistance of a walker, they would rather not partake in the activity than use an assistive device. Other interviewed patients noted that usage of a walker would drastically decrease their ability to participate in their hobbies or perform daily tasks, as well as increase feelings of social isolation and unwanted attention. This is corroborated by literature studies that have found PD patients more susceptible to negative socioemotional feelings such as negative stigma and dehumanization [4]. Other more discrete canes provide moderate stability but not enough to be considered a reliable source of movement for PD patients; current common canes have low-friction rubber tips that slip when used at an abnormal angle, especially in lateral movements and non-ideal environments. The issue addressed is creating a walking device that is stable, preventative against slippage, and discrete in public to reduce risks of falls and self-consciousness for Parkinson's patients, thus increasing quality of life.

III. Project Objective Statement

SteadyStride aims to mitigate the effect of Parkinsonian Tremor through the integration of novel technologies, namely the TMD and the TPU stabilizing base, into a typical cane design. This device is constructed with a soft foam grip handle with an offset curvature design to minimize the impact on the user's wrist, similar to a regular standard tip cane. Below the handle is a tuned mass damping system consisting of a square aluminum mass and four compression springs fixed on each outward face. This mechanism intends to actively dampen and counteract the angular displacement of the cane due to the hand tremor. Below the TMD is an adjustable shaft, and attached at the cane base is a 3D-printed TPU hemisphere with tread tracks, acting as an additional stabilizer. For the prototype, the technologies are augmented into the shaft and at the base of a standard cane. With the integration of the TPU base and a TMD, SteadyStride is not only functional but also discrete, providing Parkinson's patients with a sense of comfort and a higher quality of life.

Our device effectively combines the positives of the current assistive devices on the market, such as high availability and reliability, while cutting down on the bulkiness and social stigma associated with large walkers. Through the passive system of the TPU base in conjunction with the active damping provided by the tuned mass damper, our cane's technological novelty lies in the ability to dampen the hand tremors and shaking of Parkinson's patients while also preventing slippages at the ground. In doing so, SteadyStride can significantly reduce the instability that leads to falls when using a regular standard tip cane. Based on our patient data and questionnaire results, the standard cane was deemed to be unreliable and did not provide feelings of security, especially in the context of their tremors, while general feelings towards the fully assistive walker device were negative due to its size and inconvenience. In comparison, the innovative use of both a TMD system and a TPU base helps maintain stability while remaining discrete, which is not achieved with current walking-assistive devices on the market.

IV. Documentation of the Design

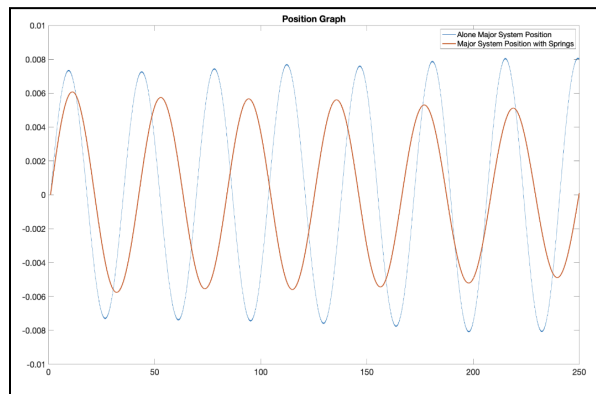
The TMD at the top of the cane reduces the amplitude of oscillation by providing a restorative force that creates an overall waveform with decreased amplitude [5]. Typically, this technology is seen in earthquake-proofing skyscrapers, and as an earthquake produces a vibration, the TMD removes the kinetic energy through a damping system. When the frequency of the earthquake matches the structural frequency of the building, resonance is achieved, causing the building to oscillate at extremely high amplitudes [5]. To stabilize the building, the TMD is "tuned" to the building's resonant frequency by adjusting the weight of the central mass, the attached supports' spring constant, and a damper fluid. When the frequency of the TMD is excited to this frequency, the TMD oscillates out of phase with the motion of the building, creates destructive interference, and removes kinetic energy in the form of heat [6].

Parkinsonian Tremor and a cane are functionally similar to an earthquake and skyscraper: both produce a vibration that causes the structure to oscillate. By tuning the parameters of a TMD to the frequency and amplitude of an average Parkinsonian tremor, the TMD can decrease the cane's oscillation amplitude, restoring it to equilibrium and making it stable. The TMD in SteadyStride consists of a central aluminum mass and four compression

springs attached to the lateral sides. When a tremor occurs, the springs oscillate due to an applied force and move the aluminum mass to recentralize the cane's center of mass, limiting the device's displacement. This design allows the system to be condensed in a small area while still producing enough restorative force.

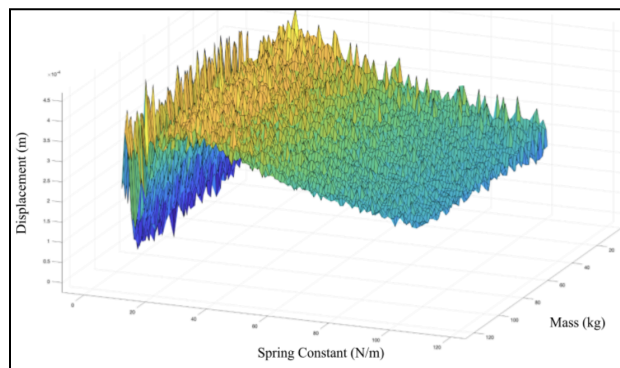
Mathematical models were created in MATLAB to predict realistic and effective mass and spring constant values for the TMD given preset cane inputs. Since Parkinsonian Tremor is bilateral, the motion of these two degrees of freedom is governed by four differential equations [6] and can be used to determine the ideal TMD parameters. First, a 2D model was scripted to determine the amplitudinal cane displacement with various mass and spring values over time (Figure 1). Second, after defining the dimensional constraints of the TMD casing, a 3D surface plot was constructed to plot the average max peak oscillation values for various potential mass and spring combinations (Figure 2). The trend of good combinations was found to be associated with higher mass and spring values, and further fine-tuning was done to determine the ideal spring constant. Based on the chart, the optimal mass and spring constant for the model are 0.45 kg and 630 N/m, respectively. By tuning the TMD to these specific values, the total oscillation of the system will inhibit the total angular displacement of the cane as a result of the PD tremor by ideally 20% (Figure 3).

Figure 1: Position Time Graph of a Close-to-Ideal Mass and Spring Constant Combination



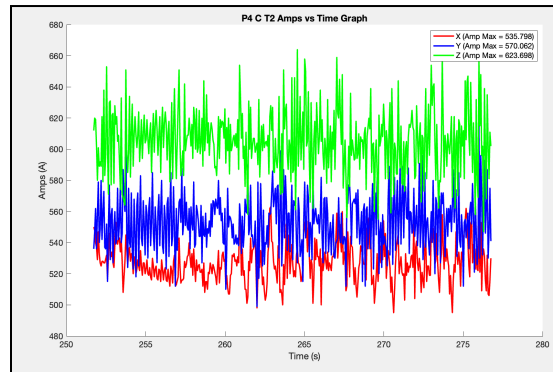
Notes. The system that contains the TMD (red) with optimal values effectively dampens the amplitude of the standard system (blue) as there is roughly a 20% decrease in amplitude.

Figure 2: 3D Surface Plot Model



Notes. This graph shows all of the possible combinations of spring constant and mass values plotted against the average max peak value of predicted tremor displacement.

Figure 3: Accelerometer Data on Participant 4 Hand Tremor Data with Control Cane



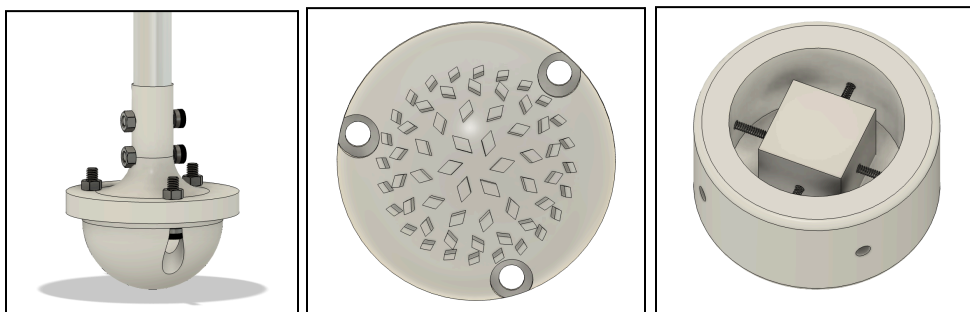
Notes. The values provide a baseline tremor value with the standard cane.

Additionally, the incorporation of the flexible, semi-spherical 3D-printed base stabilizer was inspired by the design of a pressurized bosu ball. Our design incorporates the shape of a bosu ball but is made unique with the elasticity of TPU filament, creating a shock-absorbing design perfect for various terrains. The form of the design was experimentally determined by considering variables such as pressure, indentation, degrees of freedom, and the interaction of the material with different terrains. To optimize surface contact and flexibility, an **Optimization Spreadsheet** was developed to correlate 3D-printing infill density with the applanation area of the base. With a greater applanated area, patients had further surface area for stabilization and increased mobility. Based on these qualitative results, further modifications were made to the design and measurements used for the TPU dynamic base. The TPU dynamic base was also coated with chlorinated rubber and patterned with treads to increase friction at the base.

V. Documentation of the Prototype of the Final Design

The assembly of our design began with a scaled **3D model** in Fusion360 demonstrating the integration of the dynamic TPU base and the tuned mass damping system. After creating the general form, experimental components were isolated and machined utilizing resources available in the Cornell Biomedical and Mechanical Engineering Dept.

Figures 4, 5, & 6: CAD model of the Dynamic TPU Base attachment & Inside View of the



Notes: From left to right: Assembled stabilizing base component of the device, bottom view of treads modeled on the TPU base, and top view of spring mass damper core.

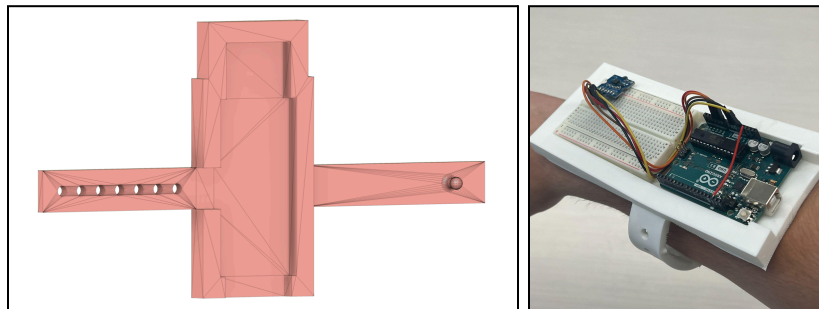
The cane's base was fabricated in-house at Cornell University, with extensive consulting to ensure proper parameters for the 3D-printed TPU base and the ABS plastic casing. The final base shape was a hollowed hemisphere to increase flexibility, and trapezoidal treads were optimized to increase contact with the ground at various angles. The TPU hemisphere is coated with Plasti-Dip, a chlorinated liquid rubber, to generate more traction with the points of contact between the device and the ground. Finally, the stabilizing base is assembled with metric, stainless-steel nuts and bolts (as shown in the 3D-model files).

The 2-degree-of-freedom tuned mass damping mechanism consists of purely a mass and spring system, removing the damper component to reduce experimental variables during the dynamic modeling process. The aluminum block mass was hand-machined with four cylindrical slots to lower spring buckling, and the compression springs were fixed with an adhesive. The cylindrical casing was also fabricated in-house with ABS and was designed with slots on the inside to set the springs in, in addition to holes to add heat-set inserts. With these inserts, the top and bottom of the TMD casing were assembled with stainless-steel panhead screws and other bolts.

Preliminary testing was conducted on an isolated, tuned mass damper **apparatus** yet results were invalidated due to issues properly simulating the driving force of typical Parkinsonian tremors. Initially, testing aimed at simulating Parkinsonian tremor through the use of a seismic shake table, however, experimental observations indicated improper engagement of the system. Due to this setback, we pivoted to testing with Parkinson's patients in a low-risk environment. After a lengthy process, our team received IRB approval to test SteadyStride on Parkinson's patients in Dr. Bauer's lab at SUNY Cortland. The testing procedure, as approved by Cornell's IRB committee, involved seven tasks designed from a thorough review of prior Parkinson's Disease mobility research. The procedure consisted of walking in a straight line, walking with a right turn, walking with a left turn, walking up/down a short staircase, sitting down in a chair, and standing up from a seat position.

A baseline tremor was taken for each participant at the beginning of each experiment to evaluate tremor propagation per trial. Tremor data was acquired through an experimental accelerometer wristband, a wearable device that streamed data through an Arduino to team members' laptops through the ArduinoIDE. **Python scripts** were additionally utilized for sampling and preliminary plotting.

Figure 7 & 8: CAD Model and Photo of Experimental Accelerometer Wristband



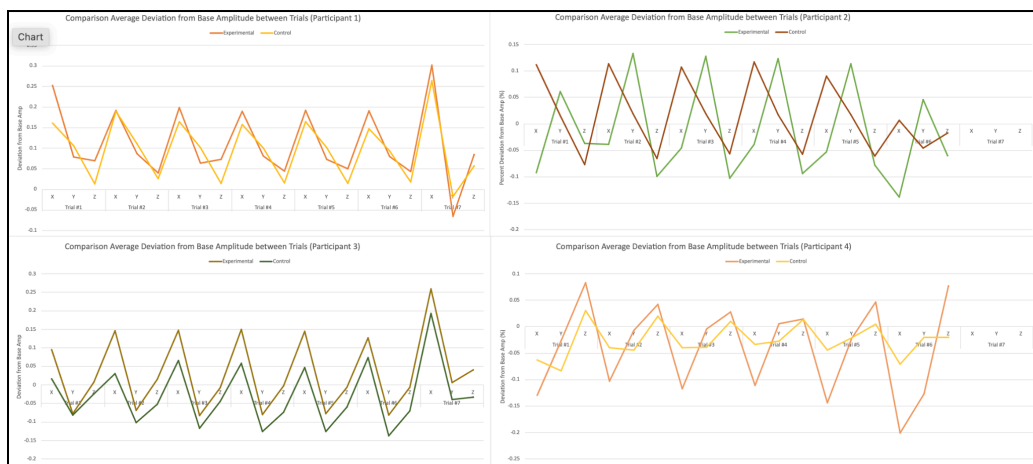
Notes: The mounting component is composed of a white TPU material to provide flexibility. Additionally, the circuit is comprised of an Arduino Uno, an accelerometer, and a small breadboard

There were a total of four patients that participated in the study. The team split into two groups to work with two patients at a time for efficient testing. One group started with the standard cane whereas the other group started with the SteadyStride cane. After the mobility tasks were completed with the initial cane, the groups swapped canes and repeated the procedure. Through questionnaires and data collection, we gathered **user feedback** on the standard and experimental cane and learned more about their experiences living with Parkinsonian Tremor. All data is protected via IRB-approved security measures on Box.

Over 80,000 data points were acquired, consisting of the x, y, and z accelerometer values from the experimental and control cane for each patient. In post-processing, the data was filtered and fitted with a spline with a **MATLAB script** that additionally averaged the max peak value of the spline. To compare the experimental to the control cane, the deviation from the base tremor recorded at the start of each experiment is computed to determine a percentage change per gait. Data acquired from participants 2 and 4 were prioritized considering the characteristics of their tremor more directly fit for the application of the device (i.e. full hand oscillations). In creating the predictive model, characteristics of typical Parkinsonian Tremor were primarily considered, meaning the SteadyStride was not suitable for those with atypical tremors such as Participants 1 and 3. Results were recorded regardless to compare usability across Parkinsonian conditions.

Participants 2 and 4 experienced the strongest tremor mitigation, with propagation in the x direction decreasing on average 12.25% with the experimental cane (15.88% for participant 2 and 8.58% for participant 4). This follows mathematical estimates across various parameters which anticipated about a 15% - 20% decrease in max amplitude for the Parkinsonian Tremor, aligning around the expected range. User testimonials noted the TPU base provided more stability in comparison to the standard tip base, but the cane's weight posed cumbersome. Overall, statistical analysis demonstrated a decrease in tremor propagation in the cane and testimonials proved an increase in patient stability. We hope to expand our model to custom user-specific parameters as an individualistic treatment option.

Figure 9: Participant Trial Results Comparing Deviation of Tremor between Control and Exp.



Notes. Deviation was formulated through the following formula: $((\text{Baseline} - \text{Tremor Gait}) / \text{Baseline})$, thus creating a ratio between the change in tremor between two motions and the baseline tremor during a trial. From here, we created a unitless comparison that measured the relative impact the cane had on a range of motions for the canes.

VI. Results of a Patent Search

Numerous patents exist for biomedical devices focused on stabilization; however, SteadyStride features a novel design that effectively mitigates the impact of hand tremors on stability.

In November 2021, a "rolling cane" was patented which is designed to transfer an individual's weight onto a supporting surface. This device targets individuals with sustained nerve damage in the lower extremities, whose pain and weakness result in difficulty moving. It uses wheels to aid mobility and reduce the overall exertion required for walking. Additionally, the device features stabilizers to prevent it from rolling backward if the user is about to fall [7].

A similar device, a cane that utilizes a robotic omnidirectional wheel for stabilization, was patented in April 2013. The cane is designed to have a grip handle with at least one wheel attached to the bottom of the cane, as well as a proximity detector and a controller module. The proximity detector is used to detect the user's relative location from the cane and provide a respective proximity signal. The controller module then receives this signal and calculates the distance between the user and the cane. Also, the controller module compares the orientation angle of the cane with the threshold angle to determine if a fall prevention signal is necessary. This data is then signaled to a motorized wheel assembly on the cane for guided movement [8].

There are few canes on the market targeted toward Parkinson's patients and none feature the same mechanisms as SteadyStride. One product currently available to Parkinson's patients is the LaserCane, which provides a safe, obstacle-free visual cue to break "freezing episodes" and increase stride length.

Unlike the mentioned patented devices, SteadyStride not only decreases the chance of injury but also intends to help the user restore stability at the onset of a fall. The aforementioned devices do not contain dynamic bases or energy-absorbing mechanisms, making SteadyStride unique and novel, while still maintaining the integrity of the original grip handles.

VII. Anticipated Regulatory Pathway

Considering the non-invasive nature of the device and its intended use, it is likely to fall into Class I, which includes devices that pose only a risk of illness or injury. Given this classification, the two primary regulatory pathways to consider are the 510(k) pathway and the De Novo pathway. The selection of the pathway depends on whether there are existing predicate devices that are substantially equivalent to SteadyStride. If predicate devices with similar intended use and design exist on the market, the 510(k) pathway becomes a viable and cost-effective option. Under the 510(k) pathway, the key requirement is to demonstrate substantial equivalence to the existing FDA-approved devices that address similar needs, through a comparison of SteadyStride's design and materials. It is important to note that the 510(k) pathway typically involves lower regulatory filing fees and often requires fewer clinical trials, making it a faster and more cost-effective option for market approval. On the other hand, if there are no predicate devices substantially similar to SteadyStride, the De Novo pathway should be considered. This pathway is particularly suitable for innovative devices that fill a unique gap in the market. However, it is essential to be prepared for more extensive clinical trials and the requirement for comprehensive proof of safety and efficacy.

SteadyStride, when used in the same way as a standard walking cane, may be eligible for submission through the 510(k) regulatory pathway. This is because SteadyStride is not a medical device subject to FDA regulation, and the combination of this product with a walking cane is unlikely to introduce significant differences from existing walking canes already on the market. However, it should be noted that there exists a potential risk that SteadyStride's incorporated technology could introduce risks of falling and discomforts not present in existing devices, potentially hindering quick approval. These risks and discomforts include the weight of the cane, the structural integrity of the dynamic TPU base, and the fear of slipping due to the device's unconventional base. With the atypical base having a rounded shape rather than a rubber stopper, it is important to note that stability on different terrains can become unpredictable and raise the risk of a potential fall. In regards to the additional weight, it is important to note that some users may have a hard time initially due to its unexpected added weight. To address these concerns, additional testing trials would be conducted to test the device's safety in a myriad of stable and unstable conditions. Should the device perform safely with little risk beyond a standard walking cane the 510(k) pathway would apply to the device, falling into a well-established product category. By leveraging the safety and effectiveness data of traditional walking canes and demonstrating the similarities with SteadyStride, the 510(k) pathway can offer an efficient route to market for this innovative mobility aid.

VIII. Reimbursement

Canes and crutches are categorized under the Durable Medical Equipment (DME) benefit category according to the Social Security Act, which is a positive indicator for potential reimbursement. Furthermore, both Medicare and Medicaid place a significant emphasis on medical necessity as a key criterion for reimbursement. If the SteadyStride is recommended by a healthcare provider as medically necessary to address the unique balance and mobility challenges faced by Parkinson's patients, it has a better chance of being considered for reimbursement. Determining medical necessity often involves detailed documentation from healthcare providers, including physicians' notes, treatment plans, and patient histories, to justify the need for a specific medical intervention. For insurance purposes, this is used to establish that a treatment or device is essential for the patient's health and well-being, rather than being optional or elective.

In the case of Medicare, coverage is likely if a Medicare-approved doctor prescribes the cane as medically necessary. However, it's important to note that Medicare typically covers 80% of the cost, leaving the patient responsible for the remaining 20%, and the Part B deductible would apply [9]. On the other hand, Medicaid policies concerning DME coverage, including canes and crutches, can vary from state to state. Some states may cover the cost fully if deemed medically necessary and cost-effective, while others might provide partial coverage or require a patient co-pay. For instance, in New York, Medicaid covers DME that is prescribed by a physician as necessary and cost-effective, but in California, the criteria for what constitutes "cost-effective" are stricter, often favoring the least expensive option available. This variability could impact the reimbursement of the Self-Stabilizing Cane for Parkinson's Disease, particularly if it is priced higher due to advanced features. To demonstrate cost-effectiveness and necessity, we could provide comparative studies showing the canes benefits over standard

canes. These studies could demonstrate reduced fall risk and improved mobility, substantiating the cane's enhanced efficacy, which could justify a potentially higher cost.

In addition to medical necessity and categorization under Durable Medical Equipment (DME), the accurate coding of our specialized Parkinson's balancing cane plays a crucial role in the reimbursement process. For our cane to be recognized and reimbursed as durable medical equipment, it must have specific HCPCS codes assigned to it, distinguishing it from standard canes and signifying its suitability for medical use. There are a few possible HCPCS codes for our specialized cane. Code E0100 encompasses canes of all materials, both adjustable and fixed, equipped with tips. Code E0105 applies to extra-wide and extra-heavy-duty canes or crutches, including those intended for obese patients. Code E0117 is associated with articulating, dynamic, or pneumatic crutches/canes that feature an adjustable length lower leg segment [10].

IX. Estimated Manufacturing Costs

The manufacturing cost of our device is estimated to be within the range of \$205.10 - \$250.67. To get this value, we added together the total costs of production of the prototype, \$227.88, and concluded that the manufacturing costs would be within 10% of the cost of production of the prototype. A **Bill of Materials** was constructed to compute the total cost.

Something that should be taken into consideration in the future is the possibility of bulk material pricing for certain components such as springs, vinyl, and rubber. This would be useful since bulk pricing would reduce the total costs of raw materials and as a result, the total manufacturing costs. Another aspect that may help reduce costs is using other framework materials for the cane; for our prototype, we augmented a cane on the market but there are alternative possibilities that may prove to be more cost-effective. With the potential decrease in material costs, the device can be more accessible, bringing in more buyers and generating higher revenues.

It is important to note that our estimated prototype costs do not encompass certain inevitable additional expenses associated with our comprehensive quality assurance procedures. These procedures involve an array of rigorous tests, including assessments for springs, TMD testing, TPU base functionality, exposure ratios of the TPU base, and rubber coating durability. While these tests play a pivotal role in guaranteeing the performance, safety, and reliability of SteadyStride, the related costs have not been integrated into our initial prototype cost estimations. Furthermore, our prototype cost estimations intentionally exclude manufacturing and labor costs. Given our current position in the prototyping phase of product development, we are unable to provide an accurate estimate for these particular costs at this time. As we progress in our development journey, we anticipate refining our cost projections to encompass the entirety of associated expenses, offering a more comprehensive financial outlook for the production of SteadyStride.

X. Potential Market and Impact

The potential market size for SteadyStride, which is designed for individuals with Parkinson's disease is substantial, with approximately 1 million people living with Parkinson's in the United States and 90,000 being diagnosed with the disease every year [11]. The severity of

Parkinson's varies across stages, with stages 1 and 2 being considered early-stage, stages 2 and 3 mid-stage, and stages 4 and 5 comprising advanced-stage Parkinson's disease. Research from the National Institutes of Health indicates that while the presentation of symptoms is similar across age groups, the severity of motor and nonmotor features tends to increase with age at onset. Hence, SteadyStride could be particularly beneficial for those with mid-stage Parkinson's. Patients between stages 2 and 4 would most likely benefit most from this cane, as patients in stage 1 (who experience mild symptoms) and stage 5 (those who are bedridden or wheelchair-bound) may not get significant use of the cane [12]. Excluding patients in stages 1 and 5, the market is still large given that patients in stages 2-4 represent 85.06% of Parkinson's patients.

Considering the progressive nature of the disease, all Parkinson's patients can potentially benefit from a cane either immediately or in the future, making the entire Parkinson's population a potential market. This amounts to 8.5 million patients worldwide. To determine a selling price, an industry-standard markup rate of 20% is assumed, reflecting the low end of pricing for medical devices, taking into account accessibility for patients. Additionally, distribution channels for the product could include big box retailers such as online platforms like Amazon, Walmart, and Target (especially useful for those with mobility issues), medical facilities like nursing homes and physician offices, as well as pharmacies. The customer base would primarily consist of direct consumers (the patients themselves), but also extend to their families, caregivers, traveling nurses, nursing homes, hospitals, and end users, collectively reaching a potential user base of 850,600 patients in the United States (the number of Parkinson's patients excluding those in Stage 1 and 5). Our impact further can extend to those with Essential Tremor or other neurological conditions that may cause involuntary hand movements and instability. The lack of electrical components to reduce the tremor indicates our design's novel ability to mechanically dampen a tremor and provide unique base stability, expanding the applicability to all individuals who seek to find a safe, stable, and reliable tool for their daily lives.

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