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ACHIEVING HIGH PERFORMANCE AND LOW COST: DEVELOPMENT OF A HIGH-PERFORMING PASSIVE PROSTHETIC KNEE FOR EMERGING MARKETS

Madison Reddie[1,†], Saloni Bedi[1,†], Manasi Vaidya[1,†], Amari Griffin[2,†], Nina T. Petelina[1,*]Amos G. Winter[1]

[1]Massachusetts Institute of Technology, Cambridge, MA
[2]Harvard University, Cambridge, MA

ABSTRACT

There is significant need for low-cost, high-performance prosthetic knees in low- and middle-income countries (LMICs) due to a large number of amputees and particularly challenging socioeconomic and environmental conditions. Prostheses are important for maintaining one's participation in society, culture, and the economy, but many are either prohibitively expensive or do not provide near-able-bodied kinematics. Poor performing prosthetic knees cause discomfort and draw unwanted attention to transfemoral amputees. In this study, we refine the design of a high-performing, single-axis, passive prosthetic knee developed with a focus on the Indian market in order to reduce cost, weight, and part count; enhance manufacturability; and improve aesthetics. The load paths and functional componentry were critically analyzed to identify opportunities to streamline the design while maintaining strength and the near-able-bodied kinematics offered by the original design. The part count was reduced almost four-fold, and the mass of the prosthesis was reduced three-fold. An enclosure was also designed to encase the functional componentry in an aesthetically acceptable package. The changes made to the design are believed to significantly advance the usability and commercial viability of the prosthetic knee. This study may serve as an example of how products developed for emerging markets may achieve affordability without sacrificing performance.

Keywords: prosthesis, design for manufacturing, emerging markets

1. INTRODUCTION

USAID reports that 100 million people around the world need prosthetic or orthotic devices, but only 10% actually have access to such devices, with much of the unmet need found in low- and middle-income countries (LMICs) [1, 2]. For those who need them, these devices are critical to quality of life; independence; and the ability to participate in society, culture, and the economy [1]. The intricate structure and function of the knee make knee prostheses among the most challenging assistive devices to engineer, leaving many of the estimated nine million transfemoral amputees around the world underserved [3]. India alone is home to 300,000 transfemoral amputees, representing a huge need and potential for socioeconomic impact [4].

There are generally two segments in the prosthetic knee market: knees that are affordable but have poor biomechanical performance, and knees with high biomechanical performance that are prohibitively expensive for the average Indian amputee. Cheaper knees often lack the stability, durability, and provision of natural gait that is demanded by all prosthesis users. Challenges unique to amputees in LMICs, such as chronic unemployment, lack of proximity to orthopedists, stigma, and frequent ambulation over uneven terrain, make performance on these metrics even more important [2, 5, 6]. This market gap has motivated the development of a high-performance prosthetic knee for India through a project whose progress has been reported in [2, 4, 7, 8].

This prosthetic knee is a passive, single-axis joint that has been parametrically designed drawing on both gait biomechanics and perspectives of Indian transfemoral amputees [2]. It demonstrates high biomechanical performance through modules focused on stance stability and swing damping. However, the design to date is heavy, bulky, complex, and unenclosed, making the knee expensive to manufacture, difficult to use, and aesthetically unacceptable. Thus, the objective of this study is to revise the knee design to reduce the joint weight, volume, part count, and cost and to encase the functional componentry in a cosmetically satisfactory enclosure.

In this paper, we first present the previous knee design and further specify the redesign objectives. Second, we discuss our approach to redesigning the functional componentry of the knee, part by part. Third, we present the design of an enclosure for

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[†]Joint first authors
[*]Corresponding author: petelina@mit.edu
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the knee joint. Fourth, we present the results of the mechanical redesign and enclosure design and compare the new structure to the previous knee. We discuss how our approach can be used as a model for achieving both high performance and low cost in products for emerging markets. Finally, we present limitations and future work.

2. MATERIALS AND METHODS

2.1 Previous Design

The modularly designed prosthetic knee joint (Fig. 1) provides near-able-bodied kinematics through two primary modules: one controlling knee flexion and stability and one that provides damping during leg swing. Further detail regarding gait biomechanics, stance phases, and the development of these two modules can be found in [2, 4, 7, 8]. Labeled parts and the names used to reference them appear in Fig. 2 and Table 1 (damper not pictured in Fig. 2). The flexion and stability module uses a four bar-linkage latch (parts 8 and 9 in Fig. 2) that locks the knee, preventing flexion and buckling during early and mid-stance, and is disengaged as the ground reaction force (GRF) crosses a virtual axis created by the linkages (part 9). The virtual axis was deliberately placed such that the moment on the latch generated by the GRF reverses direction in late stance, when the GRF crosses the axis. With the latch unlocked, the knee piece (part 3) can rotate about the axle (part 2), and the user can flex the knee.

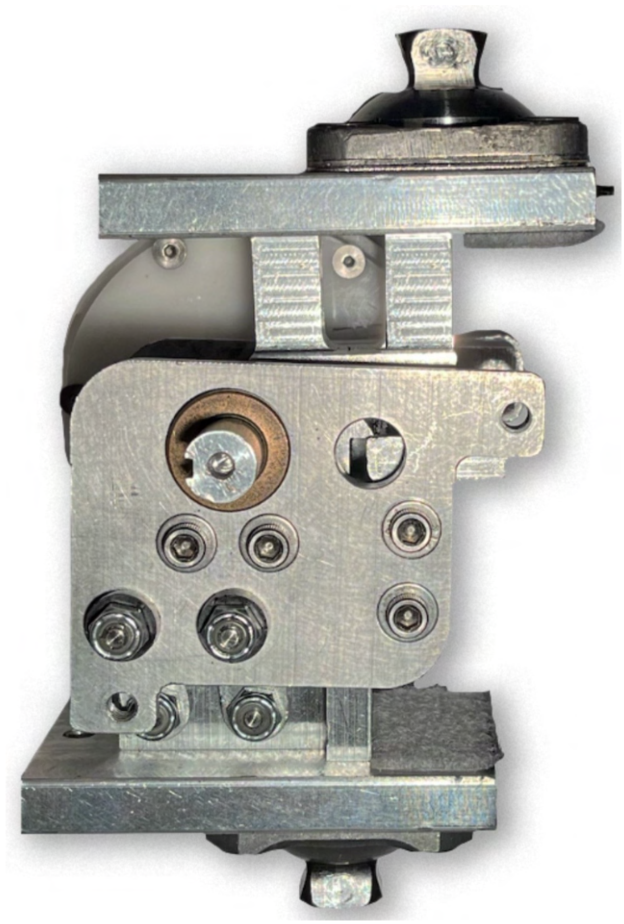

FIGURE 1: PREVIOUS KNEE PROTOTYPE

After toe-off, as the user swings the limb forward, a rotary hydraulic damper (round part in the back of Fig. 1) is engaged via a one-way roller clutch paired to the axis about which the knee rotates to prevent over-swing while facilitating ground clearance. The damper shears a viscous silicone oil between sets of concentric fixed and rotating plates, which generates a damping coefficient based on the user's body mass. A bias spring (part 7, held by part 5) restores the latch to the locked position, and a hard stop (part 6) prevents hyperextension by over-rotation of the knee piece (part 3). While the stability and damping modules together offer near-able-bodied kinematics passively, the mechanical designs of the stability module and integrated knee have yet to be optimized for weight, manufacturability, cost, and aesthetics.

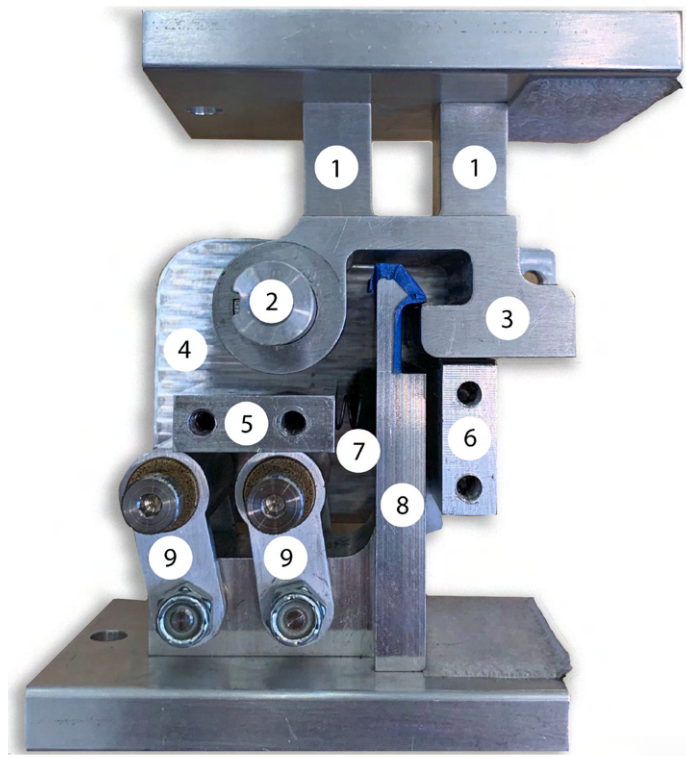

FIGURE 2: PREVIOUS KNEE DESIGN WITH ONE SIDE PLATE AND DAMPER REMOVED. PART NAMES APPEAR IN TABLE 1.

TABLE 1: FUNCTIONAL COMPONENTS IN PREVIOUS KNEE DESIGN

Part no.	Part name
1	columns
2	axle
3	knee piece
4	side plate
5	spring holder
6	hard stop
7	bias spring
8	latch
9	linkages

Most components were made from Aluminum 6061, with the latch part (8) being made from Aluminum 7075 for extra strength. The axle system (2) includes a key, two oil-infused brass bushings, two roller bearings, a clutch, and four washers. The spring holder (5) and hard stop (6) each use four screws and washers. The linkages (9) include four screws, four nuts, four oil-infused brass bushings, four ball bearings, and four washers. Finally, there are six spacers between the side plates (4) and other components. The cost of the parts for this one-off prototype reached approximately 1000USD. The prototype is shown disassembled in Fig. 3.

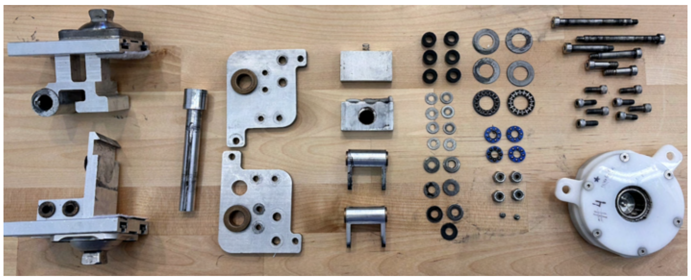

FIGURE 3: PREVIOUS KNEE PROTOTYPE DISASSEMBLED

Given prior research and interactions with Indian users in prototype tests [4], along with the specifications of knees currently popular in emerging markets [5], we sought to maintain the knee's kinematics and support users within the 95th percentile body mass in India (76 kg) [9] while reducing the weight of the knee joint to under 1 kg, reducing its manufacturing cost to less than 100 USD, and ensuring a natural and discreet appearance under pants, which entails making the joint small enough to be encased by an inconspicuous enclosure. We also assigned a minimum safety factor of 2.4 to increase the robustness of the knee. The mechanical design of the functional componentry was refined first, and an enclosure was later developed around the revised structure.

2.2 Mechanical Design

Loading. The prosthetic knee transmits the user's body mass and GRFs between the upper and lower prosthesis. The body mass load travels down the two columns (part 1 in Fig. 2) through the knee piece (part 3) to the hard stop (6) and axle (2) and then through the side plates (4). The side plates transmit the load to the linkages (9), through which the load travels to the bottom the of the latch (8) and the lower prosthesis. It is unknown how much of the load is transmitted through the hard stop (6) compared to the axle (2). During particular phases of the stance cycle, the latching mechanism (the interface of parts 3 and 8) is also loaded. To be conservative, it was assumed that each possible load path bears the maximum possible load. Peduzzi de Castro et al. [10] experimentally measured GRF in unilateral transfemoral amputees wearing passive prosthetic knees and found a maximum GRF at heel strike of 101.6 +/- 5.7% of the user's body mass. Using +2 standard deviations, 76 kg body mass produces a GRF of 840 N.

Four-bar Linkage. As the integrity of the latch is critical to preventing buckling of the knee, the latch (part 8) strength was an initial focus. Finite element analysis (FEA) in Fusion 360 was used to understand the baseline strength of the starting latch design as well as the stresses in the part generated by an 840 N upward force on the latching face. Forces were modeled as uniformly distributed over entire faces in the analyses in this study. At their originally designed widths of 38 mm in their initially specified material (Aluminum 7075), the latch lever and tip provided safety factors near seven. FEA showed a maximum stress of 61 MPa at the edge where the latch tip face meets the latch lever. As Aluminum 7075 is unnecessarily strong for this load case, we opted to use Aluminum 6061, the common aluminum alloy used in the rest of the joint, for the latch. Some engineering plastics could handle this loading, but the higher strength of aluminum allows for greater part size reduction, enabling a more compact enclosure. We assumed a yield strength of Aluminum 6061-T6 of 276 MPa. To achieve a safety factor of 2.4, maximum stress should not exceed 115 MPa, approximately double the FEA maximum stress output.

FEA demonstrated that the enlargement of the cross-section of the latch lever (part 8) below the knee piece (part 3) did not significantly affect the lever's strength or deflection under load, so the additional material (accounting for 25% of the latch's volume) was removed. The latch was further narrowed to 25mm. The latch tip, besides its width being narrowed, was left intact to maintain a substantial contact surface with the knee piece for stable latching.

The two linkages (part 9) need only move a small amount (approximately 5 mm, just enough to eliminate the interference at the latching mechanism) under a modest force from the GRF (about 27 N), making them a reasonable candidate for replacement by a compliant mechanism. The feasibility of a compliant mechanism in place of the linkages and bias spring (7) was therefore investigated. However, because the body mass and GRF loads are transmitted via the linkages between the knee piece (3)/upper prosthesis and lower prosthesis, a compliant mechanism could not satisfy the latch translation requirements while also transmitting body mass and GRF loads without buckling.

Using only a single set of linkages, as opposed to the symmetrical structure in the previous design, was also considered, but this adds manufacturing complexity to the latch (8), which could otherwise be CNC machined from a single direction. Thus, the basic structure of the original four-bar (parts 8 and 9) was retained. As the large vertical forces on the linkages (9) are balanced, making stresses in the linkages relatively small, the linkages were switched from aluminum to an engineering plastic (Nylon 6/6 or Delrin, depending on manufacturer preference). Plastic linkages allow near-frictionless rotation about their fasteners, so the fasteners, bushings, bearings, and washers were replaced with off-the-shelf press-fit steel pins, significantly reducing part count. The width of the four-bar system was reduced to match the new latch width, and the required pin size was calculated based on the Von Mises equivalent stress from shear and bending stress under the 840 N load, plus the safety factor. While the side plates (4) are intended to be in direct contact with the linkages, since friction is not a concern with plastic linkages, a conservative spacing of 1 mm between the plates (4) and linkages (9) was allowed in the pin stress calculations to account for any imperfections in manufacturing and assembly. The pin diameter was rounded up to the nearest standard size to reduce part cost and increase ease of part sourcing, and the linkages were then resized to accommodate the necessary pins with minimal material.

With smaller linkages (9), the latch lever (8) could also be shortened while maintaining clearance between the linkages and knee piece (3). The tail of the latch was also made smaller around the smaller pins.

Axle and Knee Piece. The required size of the axle (2) where it interfaces with the one-way roller clutch in the damper was determined in a prior study [8]. The cross-section of the axle decreases as it emerges from the clutch and keys into the knee piece (3). We avoided further reducing the axle cross-section as a large reduction in cross-sectional area would significantly weaken the axle.

The width of the knee piece (3) was reduced to match the new width of the latch (8) plus two linkages (9), and the depth of the latching face of the knee piece was minimized based on the latch tip geometry. The cross-sectional area of the knee piece structure surrounding the latch tip was also minimized using FEA for the maximum possible latch loading.

The set of columns (1) atop the knee piece serve to transmit load from the upper prosthesis down to the knee piece (3). Structural buckling formulae were used to determine the minimum cross-sectional dimensions for a column for this purpose at the length required by the updated latch (8) and knee piece (3) designs. This area was less than the cross-sectional area of a standard pyramid adapter (about 1 cm square). Thus, we used a single column, and since the column must lead to a male pyramid adapter for compatibility with various thigh sockets (upper prosthesis), the thickness was set to the approximate length of a pyramid adapter. The width was set to the same as the rest of the knee piece (3) so that the part forms a 2D shape that may be milled from a single direction. An adapter can also be milled into the top of the column by one additional CNC operation, in which case the column could also be narrowed to the width of the adapter.

Alternative materials for the latch (8) and knee piece (3), such as steel and titanium, were considered, but aluminum offers favorable machinability, strength-to-weight ratio, and cost and is sufficiently strong for the loads experienced by the knee. Shrinking the parts beyond the dimensions required for aluminum does not provide significant marginal benefit for compactness.

Other Components. As done with the linkage fasteners, an off-the-shelf press-fit steel pin was substituted for the hard stop (6), which previously consisted of a block of aluminum and four screws and washers. Although the knee piece (3) is intended to extend to the side plates (4), a conservative spacing between each side plate and each end of the knee piece of 1 mm was used in analysis as with the linkage (9) pins. A minimum pin diameter was then found from the analytically calculated Von Mises equivalent stress from the shear and bending loads.

The similar aluminum block and four fasteners used to place the bias spring (part 5) were another target for design simplification and part reduction. The addition of an enclosure around the knee mechanism presented an opportunity to build a feature into the inside of the enclosure to place the spring (7). To streamline this mechanism, the spring action was moved to the posterior-most surface of the latch (8), behind the linkages. A concentric cylindrical feature was then to be incorporated into the inside of the enclosure to hold the compression spring to this surface.

Based on the revised knee structure, the side plates (4) were reconfigured to join the axle (2), hard stop (6), and top linkage (9) pins with as little material as possible. They were determined to be made of 3 mm thick (half of their prior thickness) Nylon 6/6 or Delrin, as forces on the side plates are always balanced, putting them under low stress, and the vertically oriented plate shape is strong.

The new knee joint was 3D printed to ensure that the knee dynamics remain intact. The damper design was parametrically optimized in [8] and was thus not a focus of this study but will be revisited in future work given the significant changes to the rest of the mechanical design.

2.3 Enclosure Design

Enclosing the knee is important to product aesthetics and market acceptance as well as safety (preventing user exposure to pinch points and sharp edges). Previously collected user feedback emphasized the need for the prosthesis to resemble a physiological knee under clothing. Prostheses in high-income markets are often designed to appear sleek and high-tech, whereas popular prostheses in LMIC markets are more commonly designed to resemble physiological limbs [2, 5, 6]. Thus, the enclosure for this knee was designed in a horizontal cylindrical shape for discreetness under clothing. The enclosure will not be load bearing and can therefore be manufactured from a durable plastic. The enclosure details were designed specifically for ease of injection molding to lower manufacturing costs.

The enclosure consists of four parts that snap together and attach to the mechanical structure of the knee via the axle (part 2 in Fig. 2). The top and bottom sections of the enclosure are each more than half of a cylinder in order to anchor to the axle, making them challenging to eject from injection molds in single pieces. Separating the enclosure into four parts also eases assembly of the enclosed mechanical knee.

The top two parts of the enclosure rotate with the knee piece about the axle. The enclosure fits tightly around the damper for compactness, and adapters protrude through openings at the top and bottom for compatibility with existing upper and lower prostheses. Internal ribbing strengthens the parts in case of impact. Prototypes were iteratively 3D printed to test the pivoting of the parts, required spacing and tolerances, and smooth rotation. Prototypes were made with ABS and sanded smooth.

3. RESULTS

3.1 Mechanical Design

We found the four-bar latch (part 8), knee piece (3), axle (2), hard stop (6), bias spring (5 and 7), and side plate (4) systems of the knee in Figs. 1 and 2 to be over-engineered and inefficient. The improved design is pictured in Fig. 4.

Aluminum 6061-T6 was substituted for the Aluminum 7075 used in the latch (8), and the latch lever and tip were reduced from 38 mm wide and 70 mm tall to 20 mm wide and 35 mm tall. The extension of the cross-section below the latch face was

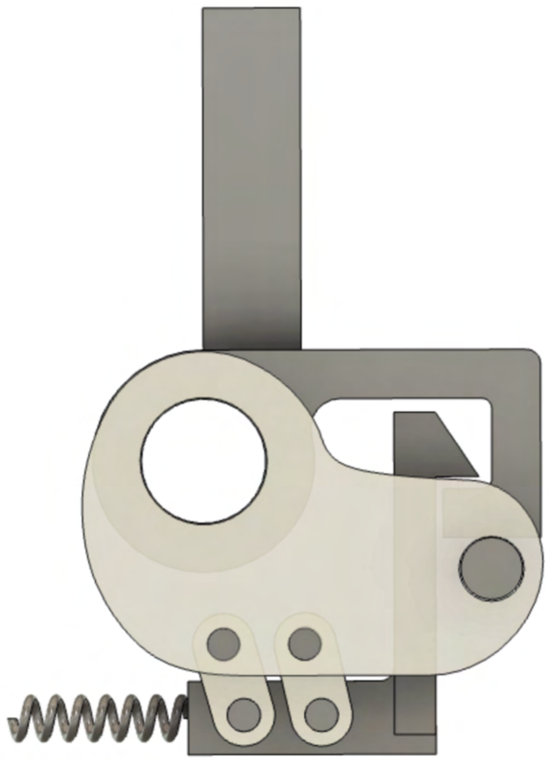

FIGURE 4: CAD MODEL OF UPDATED DESIGN OF FUNCTIONAL COMPONENTRY OF THE KNEE

also removed. The updated latch design thus reduced the volume and weight of the latch by 76% (versus the prior design). FEA demonstrated a maximum stress of 99.2MPa and corresponding minimum safety factor of 2.8 for Aluminum 6061, which exceeds the target safety factor of 2.4 (Fig. 5).

The knee piece (3) was condensed around the latch (8), with its thickness almost halved to 5 mm, while the previous axle (2) size was maintained due to requirements imposed by the damper's roller clutch. The cross-section of the knee piece was thus reduced from 38 mm wide and almost 10 mm thick to about 32 mm wide and 5 mm thick, and the two columns (1) were replaced with one, effectively reducing the part volume by 47%. FEA for the updated knee piece showed a maximum stress of 93.8MPa and minimum safety factor of 2.9 (Fig. 6). The latch and knee piece can each be CNC machined in a single operation from one side. Die casting was considered for these parts but ruled out due to the potential for material weakening from porosity.

The linkage (9) fasteners were replaced with off-the-shelf steel pins of the minimum required diameter per the loading (rounded up to the nearest standard size), and the linkages were condensed around the pins and switched to an engineering plastic. The plastic linkages can be injection molded and mitigate friction between themselves and the pins, allowing the elimination of the oil-infused brass bushings, ball bearings, and washers.

The hard stop piece (6) and the four fasteners anchoring it to the side plates (4) were likewise replaced with a simple, off-the-shelf press-fit steel pin. The aluminum block and four associated fasteners (5) used to place the bias spring (7) were replaced with

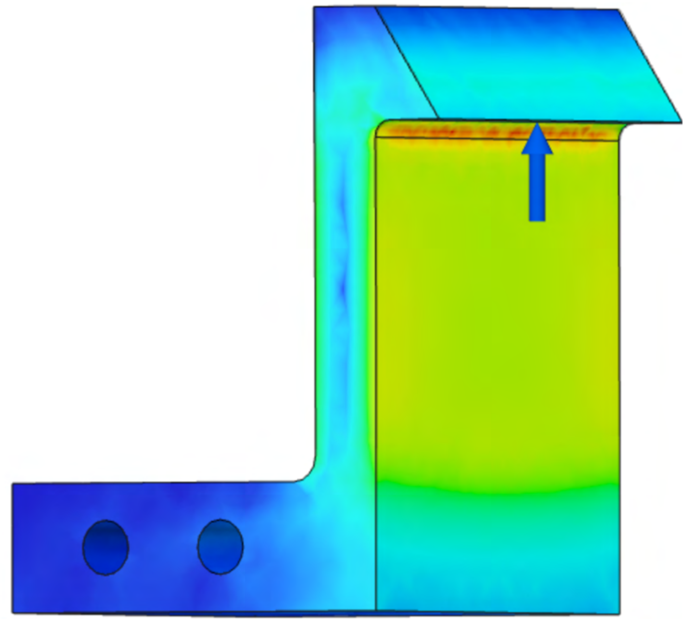

FIGURE 5: FEA-CALCULATED STRESS DISTRIBUTION IN THE UPDATED LATCH PART DESIGN

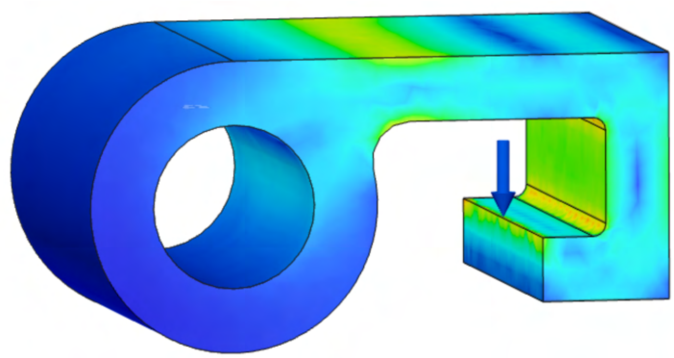

FIGURE 6: FEA-CALCULATED STRESS DISTRIBUTION IN THE UPDATED KNEE PART DESIGN

an injection molded feature on the inside of the enclosure, which adds negligible marginal cost to the enclosure. Each of these substitutions also eliminated washers from the assembly. Finally, the side plates (4) were reconfigured to transmit loads between parts using minimal material. They were also made plastic, which enables other parts to move while in direct contact with them with minimal friction. Like the linkages, they can be injection molded. These changes result in a new mechanical design with a total part volume 76% lower than that of the previous design and a mass approximately 67% lower than that of the previous design. Further comparisons are shown in Table 2. A side-by-side of to-scale prototypes of the previous and new designs is pictured in Fig. 7.

3.2 Enclosure

CAD models of the enclosure design are pictured in Figs. 9 and 10, and an exploded view of the functional componentry and enclosure is shown in Fig. 11. The enclosure is 96 mm

TABLE 2: COMPARISON OF THE PREVIOUS AND NEW MECHANICAL DESIGNS

Part(s)	Previous	New	% change
Latch (8) vol	$32.6cm^3$	$7.8cm^3$	-76%
Knee pc (3) vol	$37.8cm^3$	$20cm^3$	-47%
Linkages (9) vol	$10.6cm^3$	$0.8cm^3$	-93%
Hard stop (6) vol	$9.8cm^3$	$1.2cm^3$	-88%
Spring holder (5) vol	$9.8cm^3$	0	-100%
Side plate (4) vol	$52.1cm^3$	$5.9cm^3$	-89%
Vol of above parts	$152.7cm^3$	$35.7cm^3$	-77%
Mass of above parts	1500g	500g	-67%
# fasteners	14	0	-100%
# internal parts	64	17	-73%

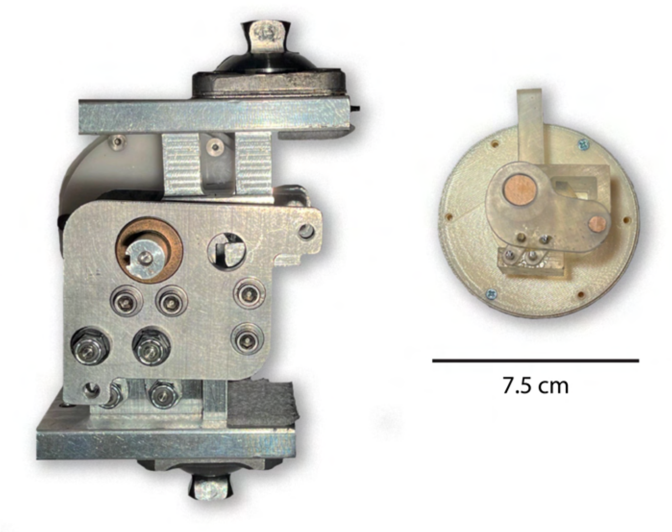

FIGURE 7: TO-SCALE PROTOTYPES OF THE PREVIOUS (LEFT, ALUMINUM) AND NEW (RIGHT, 3D PRINTED) MECHANICAL DESIGNS. FOR SCALE, THE DAMPERS BOTH HAVE A DIAMETER OF APPROXIMATELY 75 MM.

FIGURE 8: A PHYSIOLOGICAL KNEE (LEFT) UNDER PANTS, AND A PROTOTYPED PROSTHETIC KNEE ENCLOSURE (FIG. 12) UNDER THE SAME PAIR OF PANTS (RIGHT).

FIGURE 9: SIDE, ANGLED, AND SECTION VIEWS OF CAD MODEL OF THE ENCLOSURE

in diameter and approximately 85 mm wide, putting it within the range of physiological knees. The size and shape give it an appearance not unlike that of physiological knees under pants, as pictured in Fig. 8, thus satisfying the basic aesthetic requirement of discreetness.

Furthermore, the enclosure seals off pinch points and sharp edges in the functional componentry, improving safety and the user experience. Radial rib lines on the inside of the top left and bottom right parts (Fig. 9) add strength and rigidity to the parts, which makes the enclosure less likely to permanently deform or break due to impacts, such as a user falling on the knee. The four-piece structure lowers the cost of injection molding, as less-than-half cylinders are easier than more-than-half cylinders to eject from molds, and affords the assembly process greater flexibility. A 3D printed prototype (Fig. 12) attests to the ease of assembly of the snap fit enclosure.

4. DISCUSSION

In this study, we performed a design iteration on the prosthetic knee joint designed in [4, 7, 8] to provide stable, natural gait. We sought to maintain the exceptional performance achieved in stability and swing damping while reducing the size, weight, and cost of the mechanical design and enclosing it in a compact, aesthetically acceptable package. The loads on the knee were analyzed, and load-bearing components were reduced to the minimum sizes necessary to support maximum loads with a minimum safety factor of 2.4. The functionalities of each component were analyzed, and simplified or combined mechanisms were substituted where possible.

The knee was simplified from over 60 distinct components to 17 (plus four for the enclosure) and reduced from approximately 1.5 kg to 0.5 kg. The volume of the major internal componentry was reduced by 76%, largely by condensing the latching

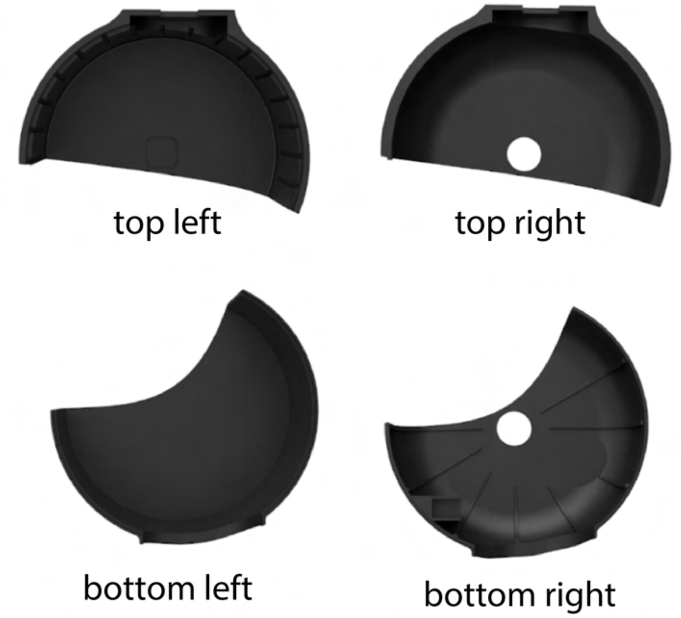

FIGURE 10: CAD MODELS OF THE FOUR PARTS OF THE ENCLOSURE

FIGURE 11: EXPLODED VIEW CAD MODEL OF THE NEW MECHANICAL AND ENCLOSURE DESIGNS

mechanism (parts 3 and 8 in Fig. 2). The hard stop (part 6) was miniaturized, and the two linkages (part 9) were condensed around pins and switched from metal to plastic. The side plates (4) were reduced in size based on this new joint structure and also switched to plastic. The spring holder and its fasteners were removed entirely. An enclosure for the knee that resembles a physiological knee under clothes was also designed. Based on prior user feedback and benchmarking of popular prosthetic knees in LMICs, we expect these changes to significantly enhance the usability and commercial viability of the knee. Importantly, a more natural appearance under clothes can reduce the discrimination experienced by prosthesis users in many cultures. Eliminating all 14 fasteners may also contribute to the longevity of the knee compared to other prosthetic knees, as a trial of the Red Cross knee in Tanzania found that loosening of fasteners was a common cause of instability [6].

Based on preliminary discussions about the design with manufacturers Alfaset and FURPO, manufacturing cost is projected to approach our cost target. The manufacturers encouraged our use of standard-sized components and a four-piece injection molded enclosure (as opposed to two pieces) for their contributions to cost reduction.

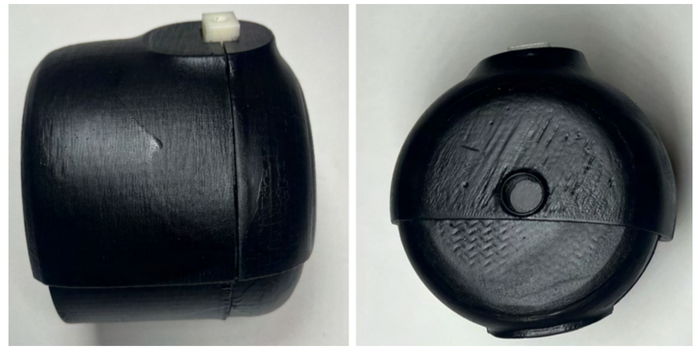

FIGURE 12: FRONT (LEFT) AND SIDE (RIGHT) VIEWS OF A PROTOTYPE OF THE ENCLOSURE

For nine million transfemoral amputees, prosthetic knees are critical to social and economic life. Unfortunately, high-performance prosthetic knee design has proved to be an engineering challenge, and most prosthetic knees tend to be either low-performance and inexpensive or high-performance and unaffordable for most users living in LMICs. The prosthetic knee market is a microcosm of a larger trend in global product development. Many projects taking aim at LMIC markets fall into the "trap" of sacrificing performance or features to reduce cost, often based on the misconception that LMIC markets do not demand performance on par with that seen in high-income markets [11]. In many cases, LMIC contexts may in fact demand higher performance. For example, a clinical study of two above-knee prostheses in Tanzania found that participants used their prostheses for a median of 14 hours per day [6], indicating that prostheses for this population should be exceptionally durable and comfortable to accommodate such heavy use. In India, a discreet appearance under clothing is more important than in the U.S. due to cultural factors.

Although earlier design iterations of this high-performance knee were expensive, in this study, we have demonstrated how thoughtful engineering analysis and design for manufacturing can be applied to to develop a simultaneously high-performance and low-cost product that meets the needs of an LMIC market. By conducting an additional design iteration, spending extra time and effort analyzing and simplifying structures and condensing functionalities, we were able to dramatically reduce the complexity of a knee prosthesis that offers near-able-bodied gait. Throughout this process, we did not strip down or sacrifice any functionality, with the exception of reducing factors of safety to no less than 2.4.

4.1 Limitations and Future Work

The structural components of the knee were redesigned to reduce part volume and weight using hand calculations and simple finite element analyses in this study. In future work, topology optimization may be utilized to further minimize the knee size and weight. While the redesigned knee has been CAD modeled and finite element analyses have been performed for all load-bearing component redesigns, a complete prototype of the updated knee has yet to be fabricated from the intended knee materials. Fatigue life has also not yet been evaluated. ISO standards require a life of

3 million cycles (approximately 3 years of use) for prostheses [12]. Load cells placed on a new, high-fidelity knee prototype may help elucidate more precisely the distribution of loads between different load paths, which will be useful for fatigue analysis. In future work, innovations on the damper described in [8] will continue.

New prototypes integrating design changes will be constructed from the selected materials in order to confirm that the knee kinematics are intact and for fatigue testing. Updated prototypes will also be tested with transfemoral amputees locally and in India, and feedback will be collected regarding the knee's appearance and usability. Of particular concern is whether the asymmetry of the enclosed knee about the upper and lower prosthesis caused by the damper is bothersome to users. Finally, FEA only accounts for predicted use cases, so longitudinal studies of prosthesis performance in real-world conditions should also be conducted. Depending on prosthetic knee user falling patterns, impact testing of the enclosed knee may be warranted. The infiltration of dust and other elements into the enclosure may affect prosthesis function and longevity and should also be studied. Seals may be added around the openings of the enclosure in future work based on the findings.

5. CONCLUSIONS

In this study, we redesigned the mechanical structure of a passive, single-axis prosthetic knee that provides near-able-bodied kinematics to increase usability and commercial viability in low- and middle-income markets. Engineering analyses facilitated the reduction of the knee's part count from over 60 components to 17, with the sum of part volumes and masses reduced by 76% and 67%, respectively. An enclosure has also been designed to encase the mechanism and create a discreet profile. This study demonstrates how engineering analysis and design for manufacturing can be employed to reduce product cost without sacrificing performance.

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