Design and Evaluation of a High-Performance, Low-Cost Prosthetic Foot for Developing Countries

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A novel, high-performance, cosmetic, rugged, appropriately costed, and mass-manufacturable prosthetic foot for use in low-income countries was designed and field tested. This ruggedized foot was created to accommodate the unique economic, environmental, and cultural requirements for users in India. A previous prototype that enabled able-bodied like gait was modified to include a durable cosmetic cover without altering the tuned stiffness of the overall foot. After undergoing mechanical benchtop testing, the foot was distributed to prosthesis users in India to for at least 5 months. Afterward, participants underwent clinical tests to evaluate walking performance, and additional benchtop testing was performed on the field-tested feet to identify changes in performance. The ruggedized foot endured 1×10^6 fatigue cycles without failure and demonstrated the desired stiffness properties. Subjects walked significantly faster (0.14 m/s) with the ruggedized foot compared to the Jaipur foot, and the feet showed no visible sign of damage after months of use. Additionally, the field-tested feet showed little difference in stiffness from a set of unused controls. Anecdotal feedback from the participants indicated that the foot improved their speed and/or walking effort, but may benefit from more degrees-of-freedom about the ankle. The results suggest that the foot fulfills its design requirements; however, further field testing is required with more participants over a longer period to make sure the foot is suitable for use in developing countries.
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Introduction

This paper describes the design and testing of a novel, cosmetic, rugged, appropriately costed, and mass-manufacturable prosthetic foot that imitates able-bodied walking motions. In India alone, 600,000 people are estimated to have lower limb amputations [1,2]. These amputations can profoundly limit a person's mobility, employment opportunities, and relationships. Over half of Indians with amputations are within their wage earning years [2,3], and most of the amputations in India are the result of trauma [2,4]. This group of young people with traumatic amputations are the most likely to achieve the highest activity levels of prosthesis users [5] and utilize high-performance prostheses that can improve their mobility and quality of life. Many of these feet have energy storage and return (ESAR) properties that allow them to store mechanical energy passively when the foot is loaded after the heel strike and then return that energy when the user is pushing off the ground with the foot. Walking with ESAR feet has been shown to be more energy efficient than with other prosthetic feet [6]. However, currently available high-performance prosthetic feet are not practical in low-income countries due to unique economic, environmental, and cultural factors, which leaves prosthesis users in these countries with few practical options except for certain low-mobility feet [7]. The lack of appropriate high-performance prostheses in low-income countries limits the capability of young, traumatic amputees in India to integrate into society.

High performance prosthetic feet cost thousands of dollars, which is prohibitively expensive in low-income countries. However, even if these feet were provided at a lower price, Indian amputees may still not adopt them due to cosmetic and durability considerations. Strong stigmas surrounding disabilities in India create demand for prostheses that mimic the appearance of the human body and enable their users to move like able-bodied people. If a prosthetic foot does not look anatomical, or makes the user walk with a limp, these stigmas contribute to the shunning of people with amputations and prevent them from finding work or forming social relationships [8]. Typical high performance ESAR prosthetic feet do not look anatomical. The feet may have a cosmetic shell, but they only cover the lower half of the prosthesis, which would not be acceptable in India.

Additionally, high performance prosthetic feet would not last long in the Indian environment. Indian users may not wear closed toe shoes that would normally protect prosthetic feet from abrasive dust and grit [8]. Since the cosmetic cover does not completely encase the foot, abrasives can easily get inside and wear away both the prosthesis and the cover. All of this wear dramatically shortens the lifespan of the prosthesis, and prosthetic feet that last for years in high-income countries fail within months in low-income countries [7,9,10].

In response to the dearth of practical prosthetic feet, low-income countries have developed their own solutions, and one of the most prominent is the Jaipur foot from India, which has been widely distributed throughout the world [10]. Made by hand from readily available materials, the Jaipur foot can be manufactured at low cost and has a rugged cosmetic shell that resists wear and can endure over 3 yr of continual use in India [9]. The Jaipur foot is flexible but it does not store and return energy like an ESAR foot, and requires more effort for walking. Additionally, the flexibility limits the support the foot can provide when the user is pushing off the ground [11], which can limit its ability to provide an able-bodied-like gait.

Neither commercially available feet nor the Jaipur foot is able to provide practical, high performance solutions for use in India. Therefore, a new design is needed that blends high performance with the cosmesis, affordability, and durability of the Jaipur foot. The overall goal of this work was to design and test a novel, high-performance, cosmetic, rugged, appropriately costed, and mass-

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manufacturable prosthetic foot for use in developing countries. The first objective in meeting this goal was to ruggedize a prototype foot from the authors' previous work, which had been optimized for a cosmetic, able-bodied gait using a novel optimization method known as the lower leg trajectory error (LLTE) design framework [12,13]. This previous prototype was modified to include a durable, over-molded cosmetic cover without changing the overall biomechanical response of the foot. The second objective of this study was to test the efficacy of this ruggedized foot in its intended environment over an extended period, and understand the effects of continued use.

Designing With the Lower Leg Trajectory Error Design Framework

The LLTE design framework facilitated the rapid design of a prosthetic foot that enables able-bodied gait. By describing how well a prosthetic foot design replicates a desired motion, the LLTE is a novel metric that links prosthesis design parameters to biomechanical performance [12]. The LLTE can be used to identify the optimal foot stiffness and geometry for replicating able-bodied gait. Since, there is a limited understanding of how the mechanical properties of a prosthetic foot affect its biomechanical performance [14], the LLTE provides useful information for guiding the rapid development of new prosthetic feet.

The LLTE design framework uses a constitutive model of a proposed prosthetic foot design to predict how the foot will deform under the expected loading condition for the desired leg motion (Fig. 1(*a*)). The trajectory of the lower leg is calculated from this predicted deformation. The calculated trajectory is then compared to the desired leg motion using Eq. (1) to determine the LLTE. In this equation, the calculated (C) lower leg trajectory is described by the horizontal knee position, the vertical knee position, and the shank orientation with respect to the vertical (x^C, y^C, and θ^C, respectively). Corresponding variables are used to describe the desired (D) lower leg trajectory (x^D, y^D, and θ^D). Each of these variables are evaluated at discrete moments in time, denoted by i, and N is the total number of time points evaluated. Lastly, the mean values of the desired lower leg trajectory ($\bar{x}$, $\bar{y}$, and $\bar{\theta}$) serve as normalization factors

$$\mathrm{LLTE} = \frac{1}{N}\sum_{i=1}^{N}\sqrt{\frac{\left[x_i^C - x_i^D\right]^2}{\bar{x}} + \frac{\left[y_i^C - y_i^D\right]^2}{\bar{y}} + \frac{\left[\theta_i^C - \theta_i^D\right]^2}{\bar{\theta}}} \tag{1}$$

The LLTE is the average normalized deviation from the desired trajectory over time caused by the mechanical properties of the foot. Foot designs with a lower LLTE replicate the desired motion better than foot designs with a higher LLTE, and a LLTE of zero indicates a perfect match between the expected and desired trajectories. As a result, the LLTE can be used as an objective function to optimize prosthetic foot designs. The LLTE design framework works by varying different design parameters and identifying the ones that yield the lowest LLTE to produce a prosthetic foot that closely replicates the desired leg motion.

In previous work, the LLTE design framework was used to create a high-performance, appropriately costed, and mass-manufacturable prototype prosthetic foot that could enable able-bodied-like gait [13]. The foot was made with an elastic material, nylon 6/6, to provide energy storage and return while walking, much like high performance ESAR feet. Nylon 6/6 has a high strain energy density (2.51 J/g), allowing it to store a great deal of energy as it deflects, and with a low cost ($4.80/kg USD), it is well-suited for this application. To reduce manufacturing costs, the foot was designed as a single piece with a simple shape that could be easily casted or injection molded.

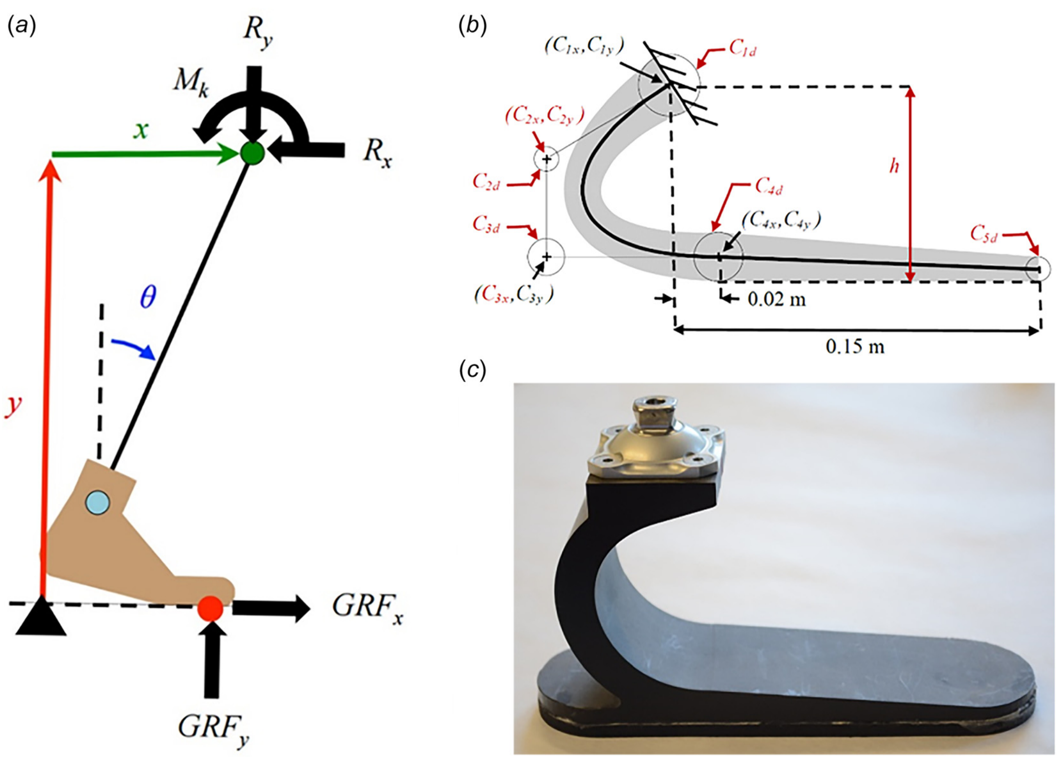

Fig. 1 The LLTE design framework. (*a*) Sample constitutive model used to calculate the LLTE. Known loads (*GRF*) cause a horizontal and vertical displacement of the knee (*x* and *y*) and angular displacement of the thigh (θ). (*b*) Diagram of wide Bèzier curve parameters that specify the shape of a prosthetic foot. The LLTE optimazes the parameters in red to enable able-bodied gait. (*c*) Photo of a previous prototype foot designed by the LLTE framework. (Color version online.)

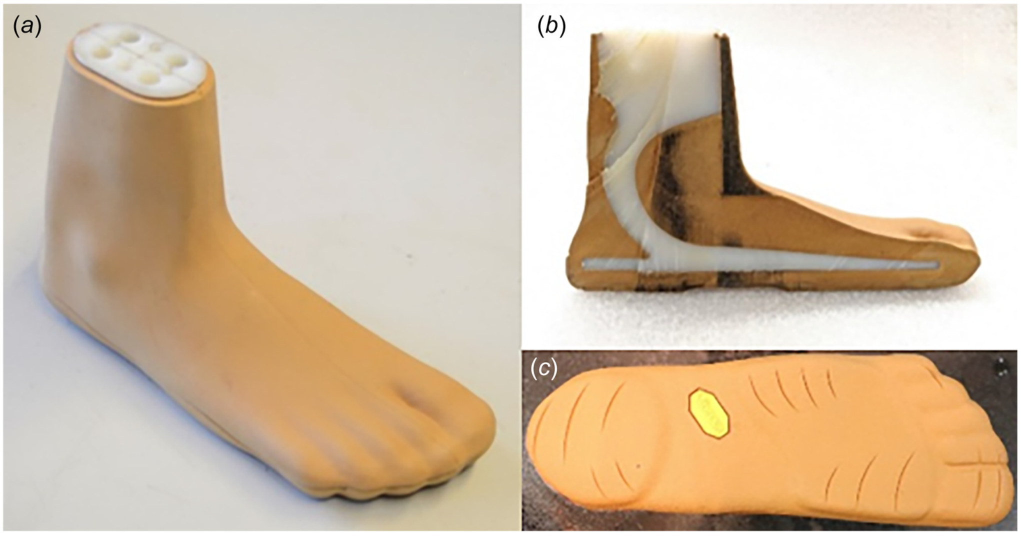

Fig. 2 Appearance and construction of the prosthetic foot: (*a*) photo of the foot with the cosmetic overmold, (*b*) cross section of the foot revealing the elastic keel surrounded by the foam cosmetic shell, and (*c*) detailed view of the rubber sole with stylized foot creases for traction

This simple shape was optimized to promote a cosmetic, able-bodied like gait using the LLTE design framework. The shape of the prototype was defined using wide Bèzier curves (Fig. 1(*b*)), where 12 different parameters described the thickness and curvature of the entire length of the prototype. A genetic search algorithm explored different combinations of these parameters to construct constitutive models of different shapes using the material properties of Nylon 6/6. The corresponding LLTE was calculated for each shape using published data of able-bodied gait [15] to define the desired lower leg motion and expected loading condition. The combination of parameters that yielded the lowest LLTE where used for the prototype.

This optimized prototype was tested with human subjects who used a lower leg prosthesis (Fig. 1(*c*)). Motion gait analyses revealed that the subjects walked with close to able-bodied gait patterns, and anecdotal feedback indicated that walking with the foot felt smooth and comfortable [13,16]. These preliminary tests suggest that the design criterion of providing an able-bodied gait could be fulfilled by using the LLTE design framework.

Incorporating a Rugged Cosmetic Cover

Although the prototype foot in Fig. 1(*c*) was shown to provide a comfortable, cosmetic walking motion, its appearance did not satisfy Indian users. In order to be accepted, the foot needed a cosmetic cover that was durable enough for use in low-income countries. Vibram, a leading boot sole manufacturer, lent its expertise in designing durable footwear in the creation of this cover. The cover was based on three-dimensional scans of the Jaipur foot, whose anatomical appearance was already accepted by Indians. To keep out water and abrasives, this cover completely encased the Nylon 6/6 prototype as an overmold, making the prototype a keel within the prosthetic foot. Polyurethane foam was chosen for the overmold based on its low cost, abrasion resistance, water resistance, compliance, light weight, and its moldability. However, other foam-covered feet have been shown to fail in India [9], due to the breakdown of the sole, which causes the keel to break through the cover. Therefore, a natural rubber sole was added to protect the bottom of the foot from rugged terrain. The sole was designed with a low profile for a more cosmetic appearance, and stylized treads that resemble wrinkles on the soles of human feet were added for traction (Fig. 2).

The resulting ruggedized foot could be efficiently manufactured on a large scale using conventional manufacturing techniques. The foam cover could be casted around the Nylon 6/6 keel by suspending the keel in a negative mold of the foot. The rubber sole would be casted in a separate mold, then glued to the bottom of the foam-covered foot.

Encasing the keel in polyurethane foam required certain modifications for functional, cosmetic, and manufacturing reasons (Fig. 3). The results from the LLTE design framework guided these changes so that the ruggedized foot would continue to enable able-bodied-like gait. The first modifications were made to mitigate the mechanical effects of the foam shell and rubber sole. Compressing the foam cover and stretching the sole can reduce the load on the keel, which would cause the foot to deform differently and alter the trajectory of the lower leg. In order to preserve able-bodied-like gait provided by the original prototype, the ruggedized foot had to deform the same as the original prototype under the same loading conditions. Therefore, the effective stiffness of the ruggedized foot must match that of the original prototype. The deformation of the foot can be described by Euler–Bernoulli beam bending theory. Equation (2) shows how the product of the beam's Young's modulus (E) and the cross-sectional second moment of area (I) dictate the beam's stiffness, relating the deformation of the beam (y) to the internal bending

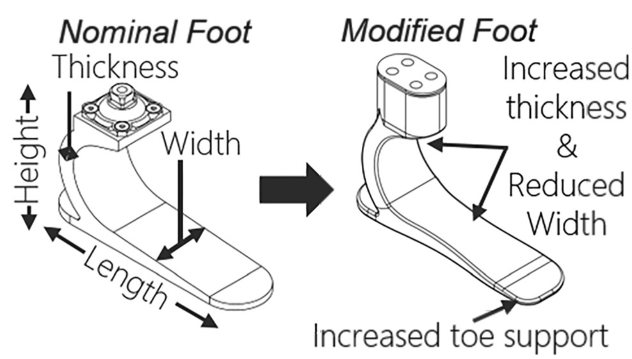

Fig. 3 Changes made to the prototype keel to improve cosmesis and enable injection molding. The ankle of the prototype keel (left panel) was tapered to fit within the volume of a human foot and the width of the keel was reduced to allow the flow of polyurethane foam around the foot. The keel's thickness was increased in these modified areas to preserve the biomechanical function of the foot.

moment caused by the external load (M). All of I, y, and M vary along the length of beam (x). The optimal stiffness profile along the length of the beam (foot) had already been calculated through the LLTE design framework for the original prototype. Matching the effective stiffness of the combined rubber sole, nylon keel, and polyurethane foam cover to that optimal stiffness profile preserved the biomechanical performance of the foot.

By modeling the rubber (r), nylon 6/6 (n), and foam (p) layers of the cosmetic foot as different layers within a composite beam (Fig. 4), the effective stiffness, $EI(x)$, can be calculated from the width of the foot (w) and the Young's modulus (E), thickness (t), and position (h) of each layer using Eq. (3). $T(x)$ represents the distance from the midline of the nylon keel to the top surface of the foot, which is constrained by the geometry of the cosmetic shell. Additionally, $t_r(x)$, $h_r(x)$, $t_P(x)$, and $h_P(x)$ were all defined by manufacturing constraints so that the rubber sole could properly adhere to the foam cover. Therefore, the thickness of the nylon keel, $t_n(x)$, is the only unknown in Eq. (3). Solving for $t_n(x)$ identified the keel thickness that preserved the biomechanical performance of the foot

$$M(x) = \mathrm{EI}(x)\frac{d^2y}{dx^2} \tag{2}$$

$$\begin{aligned}\mathrm{EI}(x) = w\Bigg(&E_n\frac{t_n^3(x)}{12} + E_r\left[\frac{t_r^3(x)}{12} + t_r h_r^2(x)\right] \\ &+ E_p\left[\frac{t_p^3(x)}{12} + t_P h_p^2(x)\right] + \cdots \\ &+ E_p\left\{\frac{\left[T(x) - \frac{t_n(x)}{2}\right]^3}{12} + \left[T(x) - \frac{t_n(x)}{2}\right]\left[\frac{T(x) + \frac{t_n(x)}{2}}{2}\right]^2\right\}\Bigg)\end{aligned} \tag{3}$$

The contribution of the foam and rubber to the overall stiffness of the ruggedized foot was found to be less than 10% of the nylon keel's contribution. The Young's modulus of the nylon keel was much larger than that of the rubber or foam, and, thus, it had a much larger effect on the total stiffness.

Other modifications were made to the keel to improve the cosmesis and facilitate manufacturing. To improve the appearance, the width of the keel near the ankle was reduced to fit within the profile of a human foot. The width of the keel near the forefoot was also reduced to improve the flow of PU foam around the keel during injection molding, so that it completely encased the keel. In all of these cases, the thickness of the keel was increased in the affected regions to counteract changes in stiffness caused by reductions in width. Since the stiffness contributions of the rubber and foam layers where negligible compared to that of the nylon keel, they were ignored for calculating these changes in keel thickness, which simplified Eq. (3) to Eq. (4). $I(x)$ must be the same as the original prototype to preserve the stiffness and biomechanical function of the foot; therefore, the second moment of area of the original prototype was substituted for $I(x)$ in terms of the original prototype's width (w_o) and thickness (t_o) to yield Eq. (5). Thus, the necessary thickness at x, $t_n(x)$, can be calculated from the desired width of the keel at point x, $w_n(x)$, in the affected regions

$$I(x) = \frac{wt_n^3(x)}{12} \tag{4}$$

$$t_n(x) = t_o\left[\frac{w_o}{w_n(x)}\right]^{\frac{1}{3}} \tag{5}$$

The rounded end of the nylon keel at the toe was flattened to provide more support to the foam toes so that they would not tear off. Through all of these changes, the uncosmetic and unprotected original prototype was transformed into a durable, cosmetic, and ruggedized foot without altering its biomechanical performance (Fig. 2).

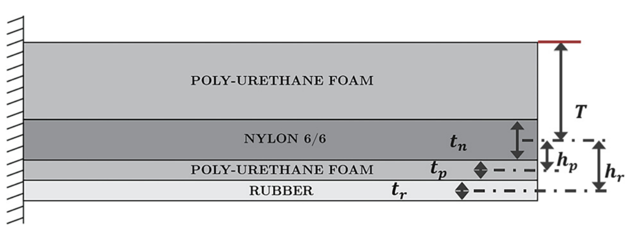

Fig. 4 Simplified diagram of the composite beam model that calculated the required nylon keel thickness (t_n) to compensate for changes in stiffness caused by the cosmetic cover

Mechanical and Performance Testing Methods

After incorporating the cosmetic overmold with the elastic keel, the resulting prototype was tested both in the lab and in the field to determine its performance and durability. Initial lab testing involved mechanical tests that measure stiffness and durability. Field testing involved human subjects wearing the foot for several months in India, and concluded with both clinical evaluations of the foot's biomechanical performance and mechanical evaluations of its stiffness and shape after prolonged use.

Lab Testing. To validate the constitutive model that guided the design, a materials testing machine (Instron, Norwood, MA), or MTM, was used to measure the foot's stiffness (Fig. 5(*a*)). The stiffness was calculated from the measured displacement of the foot under a known load. A loading platform with a roller was used to control the point of application for the load while minimizing shear at the sole of the foot [17].

The durability of the foot was assessed through mechanical fatigue testing. Under conditions similar to those described by ISO standard 10328 for prosthetic feet [18], cyclical loads typical of able-bodied gait were applied to the heel and toe; however, the loads from ISO 10328 were scaled to the average weight of an Indian male to reflect the target user demographic that the feet were optimized for [19]. The loads were applied at specific angles from the vertical to simulate the position of the foot at heel contact (15 deg) and toe off (20 deg). The fatigue testing was performed on the ruggedized foot both with and without the overmold to investigate the overmold's influence on the foot's durability. Testing stopped at 1×10^6 cycles or failure whichever occurred first. Even though ISO 10328 requires 2×10^6 cycles, testing stopped after a maximum of 1×10^6 cycles because, in our testing partner's experience, feet that endure 1×10^6 cycles are likely to fulfill ISO 10328, and they stopped at 1×10^6 to save time. After the feet underwent 1×10^6 cycles, their stiffness was measured with an MTM to investigate the effect of repeated use.

Because water absorption within the foot can contribute to foot degradation, increased weight, and user discomfort, the foot's resilience to water was tested. A foot was weighed before and after being submerged in water for 48 h, where any increases in mass was assumed to be caused by water absorption.

Field Testing. While the lab testing provided useful information, it could not account for all the different ways people would walk with the foot, nor all of the environmental factors the foot would encounter. Field testing exposed the ruggedized feet to the myriad of mechanical and environmental conditions of everyday use (Fig. 5(*b*)). Sixteen ruggedized feet were distributed to subjects with prior experience using the Jaipur foot through Bhagwan Mahaveer Viklang Sahayata Samithi (BMVSS), the Jaipur Foot Organization (Jaipur, India)[2]. Qualified subjects that wore size nine feet were recruited with approval from the MIT Committee

[2] www.jaipurfoot.org

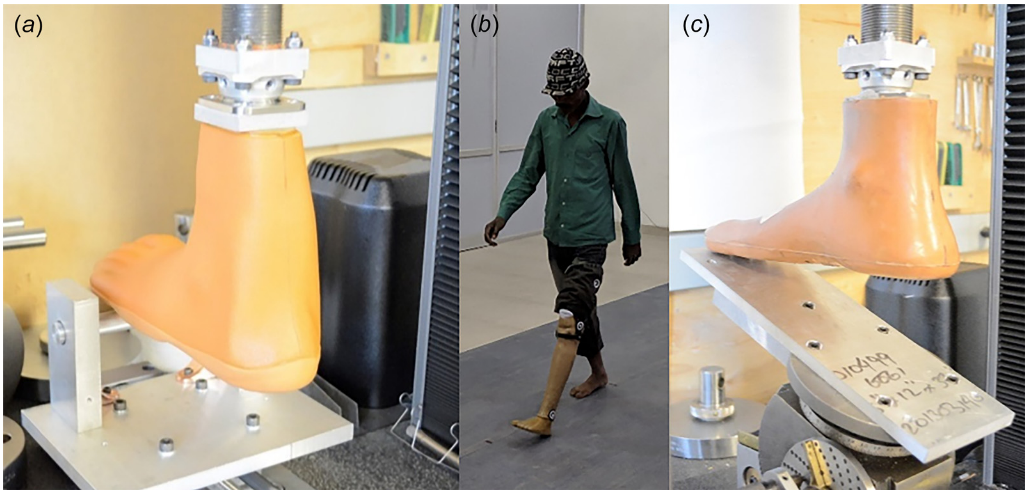

Fig. 5 Testing the prototype. (*a*) Material testing machine setup to investigate stiffness. A loading platform with a roller applies loads at the toe. (*b*) Photo of a subject walking during field testing. (*c*) Material testing set up to detect changes in stiffness after field testing.

on the Use of Humans as Experimental Subjects. Foot size was restricted because manufacturing molds for different sized feet was prohibitively costly. Size nine was chosen because that was the most common foot size in India according to anthropometric studies [19]. After obtaining the subjects' informed consent, they were fitted with the ruggedized foot by technicians at BMVSS. The foot was attached to a custom socket using wood screws, which is a conventional fitting practice at BMVSS for the Jaipur foot. The subjects were given several hours to acclimate to the foot under the supervision of clinicians, then used the foot as their main prosthesis for at least 5 months.

At the end of the trial period, the subjects were invited to return and demonstrate how they walked with the foot and share their opinion on its performance. Walking performance was measured through two clinical tests: the 6 m walk test and the L-test [20]. The 6 m walk test measures walking speed by recording the amount of time it takes to walk 6 m on level ground during steady-state walking. The L-test is a measure of maneuverability in which the subject begins seated in a chair, stands up, walks along an L-shaped path, turns around, returns to the chair along the same path, and sits down. The total time to finish all of these tasks was recorded, and each of the tests were repeated three times for each subject. Then, the subjects were fitted with a Jaipur foot, and the clinical tests were conducted again. The average completion time of the L-test was calculated for each subject under each test condition, as well as the average walking speed for the 6 m walk test. The difference in averages between the different foot conditions was calculated, and the distribution of these differences was tested for normality using the Kolgorov–Smirnoff test. If the differences were normally distributed, a paired t-test was used to determine if the difference was significant. If the distribution was not normal, the Wilcoxon signed rank test was used.

The feet from the field test were recovered and inspected to determine the effects of prolonged use in the Indian environment. The cosmetic overmold was visibly inspected for wear and tear, and one foot was randomly selected for a CT scan to observe the interior structure. An MTM machine was used to measure the stiffness profile using the AOPA dynamic keel test [21], where a foot is loaded on a 20 deg incline to better simulate the typical orientation of a prosthesis under its peak bending load 5(c). The load recommended by the dynamic keel test was scaled to 1000 N to correspond with the expected peak walking load from the average Indian male [19]. These results were compared against a control group of three unused ruggedized feet to determine if extended use altered foot stiffness while accounting for variability from manufacturing.

To identify any creep or plastic deformation in the foot, the MTM machine was also used to measure the shape of the used feet and the control group. The vertical distance between the ankle and the sole was measured at the ball of each foot and at each toe using the MTM's linear transducer. The roller from the previously mentioned loading platform (Fig. 5(*a*)) provided a point contact at each region of interest on the sole. Feet were loaded at 2 N for every measurement to ensure contact.

Results

Lab Testing. The initial stiffness tests found that the foot was within 6% of the stiffness predicted by the constitutive model. For the ISO fatigue testing, the uncovered keel failed after 369,681 cycles, while the keel with the cosmetic overmold completed at least 1×10^6 cycles. Lastly, the foot only gained 2 g of mass after remaining submerged in water for 48 h, indicating that the foot absorbed 2 mL of water.

Field Testing. Seven of the 16 feet were recovered. While six of the seven subjects who returned for the follow up wore the prosthesis for over five months, one subject erroneously returned for a follow up after only 3 months. This subject was also found to have no prior experience with the Jaipur foot. Another subject did not complete the clinical testing due to time constraints. These two subjects were excluded from the clinical test analysis, but included in the mechanical analysis. Figures 6(*a*) and 6(*b*) show the results from the remaining five subjects for the 6 m walk test and L-test, respectively. Each subject walked faster using the prototype than with the Jaipur foot during the 6 m walk test with an average increase of 0.14 m/s. The differences in walking speed between the two feet during the 6 m walk test was found to be normally distributed, and the paired t-test found the difference to be significant ($p < 0.05$). Four out of five subjects completed the L-test faster with the ruggedized foot compared to the Jaipur foot. However, the differences in average completion times was not normally distributed, and the Wilcoxon signed rank test did not detect a significant difference ($p < 0.1$). Subject 3 became tired near the end of testing and was only able to complete one L-test trial with the Jaipur foot. Subject 5 had difficulty understanding the instructions for the L-test, and upon review, two trials for the Jaipur foot and one trial for the ruggedized foot had to be eliminated because they did not successfully execute the instructions.

Visual inspection revealed no tears or abrasions on the recovered feet (Fig. 7(*a*)). However, one foot was improperly attached

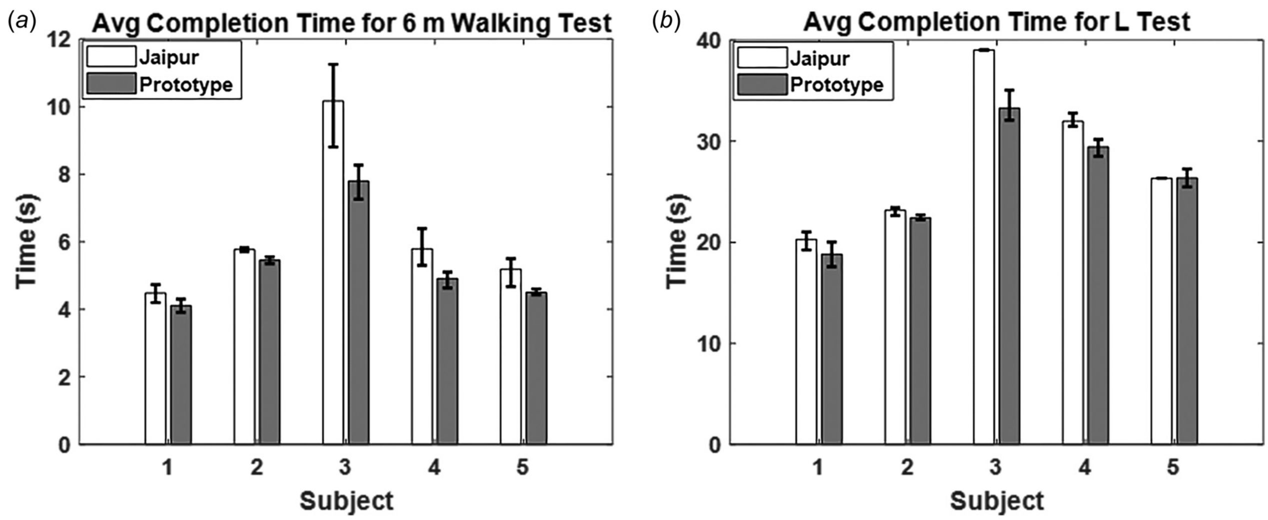

Fig. 6 Clinical test results. All subjects walked faster with the prototype (gray bar) compared to the Jaipur foot (white bar), for both (*a*) the 6 M walking test and (*b*) the L-test. Error bars indicate the range of measured times over all trials.

to the prosthetic socket, with a wood screw penetrating the flexible keel rather than the rigid attachment block. Mechanical tests were performed on this foot with the screw in place, as this best reflects the conditions of use during the trial period. The CT scan of a randomly selected foot showed no damage or wear to the keel, even after six months of use (Fig. 7(*b*)). MTM testing of the recovered feet showed that the stiffness profiles of five of the seven used feet fell within the range of the unused control group during loading (Fig. 8), but fell outside that range during unloading. One of the feet whose loading response fell outside the range was the foot with the wood screw in the keel. The foot that underwent ISO fatigue testing was shown to be stiffer than the unused feet during loading. Both the unused controls and the used feet were stiffer and showed less hysteresis than the Jaipur foot, indicating better energy storage and return. Figure 9 illustrates the differences in foot shape between the used and unused feet. The tests suggested a greater variability in shape between the recovered feet than the unused feet.

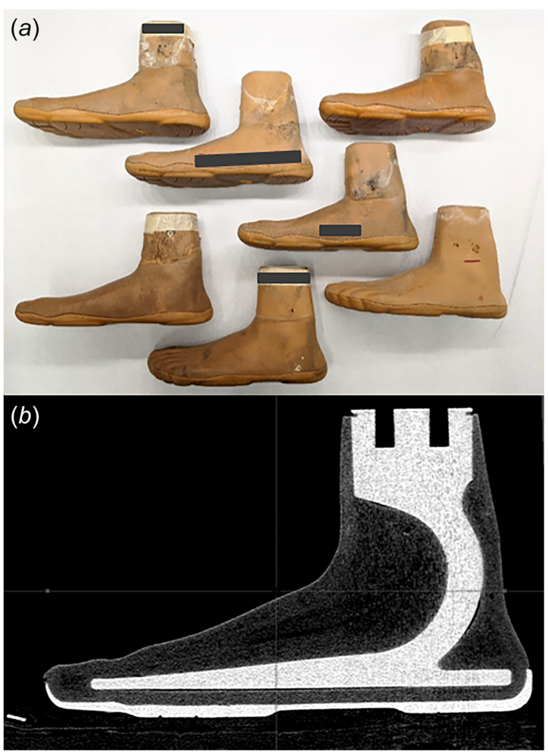

Fig. 7 The recovered feet appear to be undamaged after months of use. (*a*) Photo of the seven feet recovered from participants personal identifying participant information has been covered by spoilers. (*b*) CT scan of a randomly selected recovered foot showing no damage to the inner keel.

Discussion

The overall goal of this project was to create a high performance prosthetic foot that could operate within the economic, environmental, and cultural constraints of low-income countries. Through the LLTE design framework, an elastic keel that could store and release energy during walking much like high-performance prostheses was optimized for able-bodied gait. This keel was encased in a durable overmold to protect it from the environmental conditions found in low-income countries without altering its biomechanical performance. The overmold was given an anatomical appearance and a durable rubber sole to avoid

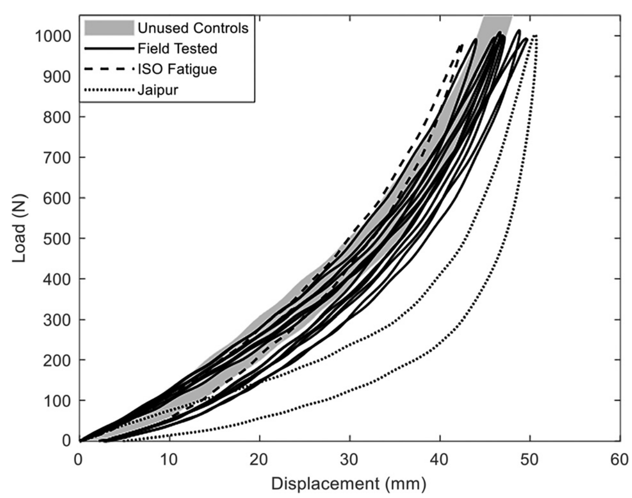

Fig. 8 Long-term use did not change prototype stiffness. The gray region shows the range of stiffness profiles within the unused control group, black lines show the profiles of each field tested foot, the dashed line is the profile for the cyclically fatigued foot, and the dotted line shows the profile for an unused Jaipur foot for reference.

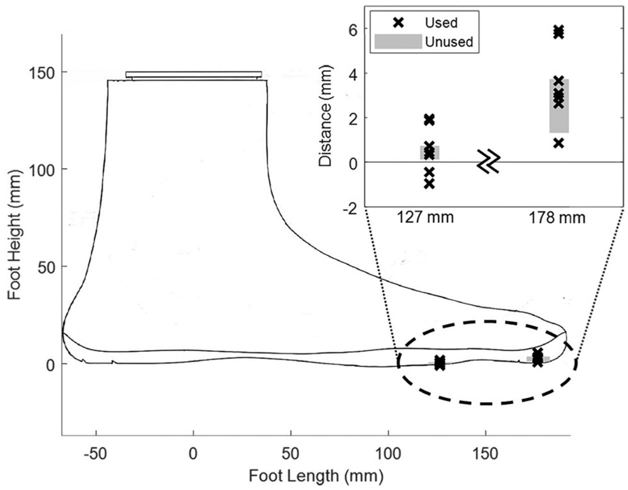

Fig. 9 Measuring plastic deformation from continual use. The measurements are plotted to scale on a profile of the ruggedized foot. Grey bars represent the range of values measured for the unused controls, while black x's denote measurements from the used feet. An exploded view shows numerical values of the measurements.

cultural stigmas around disability and accommodate the common practice of barefoot walking. The resulting ruggedized foot could be mass-manufactured at low cost with affordable materials to lower the economic barriers that limit access to the foot in low-income countries. The field tests with this novel, high-performance, cosmetic, rugged, appropriately costed, and mass-manufacturable prosthetic foot have demonstrated how it has met the overall goal.

One of the goals of the field testing was to determine how the prosthesis performed over time. Both the lab and field tests suggest that use and fatigue did not appear to change the stiffness of the foot, but did appear to diminish the amount of energy returned to the user during push off. Mechanical testing of the used feet revealed that months of use had no clear effect on the loading response the foot: the foot fatigued in the laboratory was stiffer than the controls, while two of the feet fatigued in the field were shown to be less stiff. However, an improperly mounted screw damaged one of those feet. The remaining feet had stiffnesses within the range of the control group. All field tested feet were shown to be less stiff than the controls during unloading. The resulting increase in hysteresis suggests a decrease in energy storage and return. However, all of the feet demonstrated better energy return than the Jaipur foot.

There was some evidence of small changes in foot shape as shown by the plastic deformation tests. The used feet had greater variability in their measurements and a greater median distance from the sole under the ankle compared to the unused controls. The foot was designed for level ground walking; however, subject feedback revealed that they frequently engaged in more intense activities. The comparatively larger forces from these activities may have exceeded the foot design's safety factor, and thus cause the keel of the foot to creep into dorsiflexion. Changes in foot shape can lead to the different positioning of the shank in the gait cycle and, thus alter the LLTE. A plastic deformation of 4 mm at the toe would have the same effect on the LLTE as a 3.5% change in foot stiffness. This change in stiffness has been shown to be imperceptible to prosthetic users [22]. The median of the deviation at the toe was 3.1 mm for the used feet, suggesting that the observed creep would not affect the users' perception of foot performance.

The overmold showed great resistance to water and abrasion, demonstrating its ability to protect the keel against rugged environments. Only 2 mL of water penetrated the cover after being submerged for 48 h. The ruggedized foot will not likely encounter such an extreme condition during daily use, so little if any water is expected to penetrate the cover and add weight to the foot. After at least five months of continuous use in the field, the feet showed no visible damage to the foam cover or the rubber sole. Furthermore, CT scans of a random foot revealed no damage to the keel. Unfortunately, access to the CT scanner was limited so we were only able to obtain scans for one foot. The ruggedized foot appeared to function well over the five to ten months that they were used, while commercial feet, and even some made for use in developing countries, fail within six months [9]. The fact that the ruggedized feet showed no visible wear and limited changes in mechanical behavior suggest that they could be suited for longer use in the field.

The overmold also reduced the effects of fatigue and allowed the foot to endure at least 1×10^6 cycles, which the keel could not withstand on its own. However, it is unknown if the ruggedized foot satisfies ISO 10328, which requires 2×10^6 cycles, and future work should be done to verify this.

Initial lab testing demonstrated that the cover did not diminish the biomechanical performance of the foot. MTM testing showed that the ruggedized foot was able to achieve the target stiffness profile, which suggests the keel modifications successfully offset the effects of the cosmetic cover on stiffness. Therefore, the cover did not alter the biomechanical response of the foot. The 6 m walk test showed that the subjects walked faster with the ruggedized foot than with the Jaipur foot. Four of the five subjects completed the L-test faster with the ruggedized foot, although the difference in performance was not found to be significant. Care should be taken while interpreting these results because subjects were only given a few minutes to refamiliarize themselves with the Jaipur foot after walking on another foot for over five months. This lack of accommodation time could result in slower walking speeds when using the Jaipur foot. Furthermore, the smaller number of trials for subjects 3 and 5 from the L-test complicate their comparison by giving more weight to some trials.

Even with the added complexity of the cover, the foot can still be mass-manufactured at an affordable cost. Since the keel can be injection molded or cast and the cosmetic cover can be molded over it, the ruggedized foot can be manufactured much faster than the hand-made Jaipur foot. Additionally, the manual manufacture of the Jaipur foot can lead to variable quality. One study found that 56% of Jaipur feet were inadequately manufactured [23]. Injection molding can provide a much higher and more consistent quality, reducing the cost of replacing improperly made feet. The cost of materials is low and the parts can be created with standard manufacturing techniques. There is a large capital cost in manufacturing the molds for making the feet, but if this cost is amortized among the quantity of feet expected to be distributed by the Jaipur foot organization in the next 5 yr, then the cost of each foot is expected to be equal to that of the Jaipur foot.

The large capital cost of molds encourages centralized fabrication of feet that can be distributed to low-income countries. This approach is somewhat controversial, given that guidelines from the International Society for Prosthetics and Orthotics (ISPO) recommend local manufacture of appropriate prosthetic technology for low-income countries [24]. ISPO's recommendations promote independence for low-income countries, makes them less sensitive to disruptions in distribution chains, and reduces distribution costs [24,25]. However, starting and maintaining multiple, local manufacturing sites across low-income countries is costly, and can lead to a high variability in manufacturing quality [23]. Given the mass-manufacturability of the prototype, the high capital cost, and greater quality control, central fabrication is a better option for manufacturing the ruggedized foot. This central fabrication model is not unique in providing prostheses for low-income countries and is used by the International Red Cross and the international efforts of BMVSS.

The lab and field tests suggest the prototype fulfills the requirements for a cosmetic, durable, appropriately costed, and mass-manufacturable prosthetic foot that encourages able-bodied gait.

The users also appear to like the foot. Anecdotally, subjects commented on how they could perform manual labor with the ruggedized foot, including farming and pushing a vegetable cart 7 km each day. They commented positively on how they felt a "spring" in their step, which can be attributed to the return of mechanical energy that was stored in the foot throughout early stance. Two subjects commented that they walked faster with the ruggedized foot while feeling less tired. They also enjoyed the tread on the rubber sole, saying that it gave them better traction in the shower and restrooms. One subject's gait was visibly improved and asked to keep the foot at the end of the study. However, in spite of these positive comments, two subjects still preferred the Jaipur foot to the ruggedized foot. Based on user feedback, this preference is likely due to additional degrees-of-freedom within the Jaipur foot. The ruggedized foot only bends in one of the anatomical planes, while the Jaipur foot is free to bend in all three planes. This flexibility allows the Jaipur foot to provide a broader base of support on uneven terrain. The added flexibility also facilitates squatting and sitting cross-legged, which are common positions in daily Indian activities [10]. Future designs for the ruggedized foot may feature a split keel, which would allow motion in the frontal plane and may better meet user needs and expectations.

While these results are encouraging, more work is required to verify the ruggedized foot's performance. The sample size for the field trial was small, which leads to limited statistical power. For the mechanical testing, the control group may not have been large enough to capture the full variability resulting from manufacturing tolerances, which could explain the apparent differences in variability between the used feet and unused controls. The measurements in plastic deformation are also susceptible to errors from variations in wear pattern since they are relative measurements from different parts of the sole, which may not wear at the same rate. The feet also need to be measured over a longer period; ISPO suggests that prosthetic feet should be able to last 3 yr in low-income countries [25]. A longer trial with more test subjects would provide stronger evidence for the efficacy of the ruggedized foot. Additionally, more accommodation time should be given for subjects to acclimate to each foot during testing, in order to mitigate any confounding learning effects.

The findings from this study suggest that the ruggedized foot can provide prosthesis users in low-income countries with a practical tool that can improve their daily lives. High performance prostheses can help young people with traumatic amputations live more active and fulfilling lives and open up more employment and social opportunities. This ruggedized foot will lower some of the economic, environmental, and cultural barriers that prevent people in low-income countries from having high performance prosthetic feet. By using low-cost materials and mass-manufacturing techniques to combine a durable overmold with a finely tuned elastic keel, this project has created an appropriately costed, rugged, and cosmetic prosthetic foot that enables able-bodied like gait and can be distributed to low-income countries at a large scale. This foot addresses a need that the International Society for Prosthetics and Orthotics has identified decades ago [25] by improving access to practical, high-performance prostheses for a vulnerable population.

Conclusion

Modifications were made to a tuned prosthetic foot to incorporate a durable cosmetic cover without altering the foot's biomechanical performance. Benchtop stiffness and fatigue testing and an extended field trial were used to evaluate the performance of the foot. The tests revealed that the foot could survive at least 1×10^6 loading cycles in the lab as well as endure the wear and tear of daily life in India for five or more months without altering its performance. Users were shown to walk significantly faster with the foot and many spoke favorably about the prosthesis. While more work needs to be done in evaluating the foot's efficacy, these preliminary findings suggest that the foot may be able to address the need for high performance, rugged, appropriately costed, and prosthetic feet in low-income countries.

Disclaimer

The views expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of the Air Force, or the Department of Defense, or the U.S. Government.

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Data Availability Statement

The datasets generated and supporting the findings of this article are obtainable from the corresponding author upon reasonable request.

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