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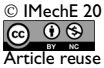

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Functional evaluation of a non-assembly 3D-printed hand prosthesis

Juan Sebastian Cuellar, Gerwin Smit, Paul Breedveld, Amir Abbas Zadpoor and Dick Plettenburg

Abstract

In developing countries, the access of amputees to prosthetic devices is very limited. In a way to increase accessibility of prosthetic hands, we have recently developed a new approach for the design and 3D printing of non-assembly active hand prostheses using inexpensive 3D printers working on the basis of material extrusion technology. This article describes the design of our novel 3D-printed hand prosthesis and also shows the mechanical and functional evaluation in view of its future use in developing countries. We have fabricated a hand prosthesis using 3D printing technology and a non-assembly design approach that reaches certain level of functionality. The mechanical resistance of critical parts, the mechanical performance, and the functionality of a non-assembly 3D-printed hand prosthesis were assessed. The mechanical configuration used in the hand prosthesis is able to withstand typical actuation forces delivered by prosthetic users. Moreover, the activation forces and the energy required for a closing cycle are considerably lower as compared to other body-powered prostheses. The non-assembly design achieved a comparable level of functionality with respect to other body-powered alternatives. We consider this prosthetic hand a valuable option for people with arm defects in developing countries.

Keywords

3D printing, limb prosthetics, biomechanical testing/analysis, mechanical design, biomedical devices

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Background

The most frequent causes of upper limb amputations are traumas, malignancy, vascular disease, congenital deformities, and infection.[1] Recent estimations by the World Health Organization (WHO)[2] indicate that out of the nearly 40 million people around the globe that require prosthetic and orthotic devices, just 5%–15% have access to them. In developing countries, reasonable healthcare services are usually merely available in a small number of big cities, while transportation from rural regions to the major healthcare hubs may be expensive and difficult. Under such circumstances, the access of amputees to prosthetic devices is very limited, and maintenance and follow-up checks are very rare.[3–5] The lack of treatment centres for amputees can be explained by a broad absence of trained workforce and materials, leading to limited availability of prosthetic workshops.[6,7] In particular, active, multi-articulated, and personalized prosthetic hands are mostly inaccessible.

Due to the rising of additive manufacturing (AM) technologies, also known as 3D printing, many research groups and non-profit institutions have already produced affordable prosthetic devices[8–10] by reducing the production costs to a few hundreds or even tens of Euros. Furthermore, according to Phillips et al.,[11] the 3D printing technology is also more suited for developing countries as compared to other manufacturing techniques because of its relatively low start-up costs and minimal skill required. Little information is however available regarding whether basic user requirements are met for short- or long-term use by prosthetic hands produced this way.[12] Moreover, additional post-printing assembly actions are yet necessary to provide functional prostheses to users. Those assembly steps

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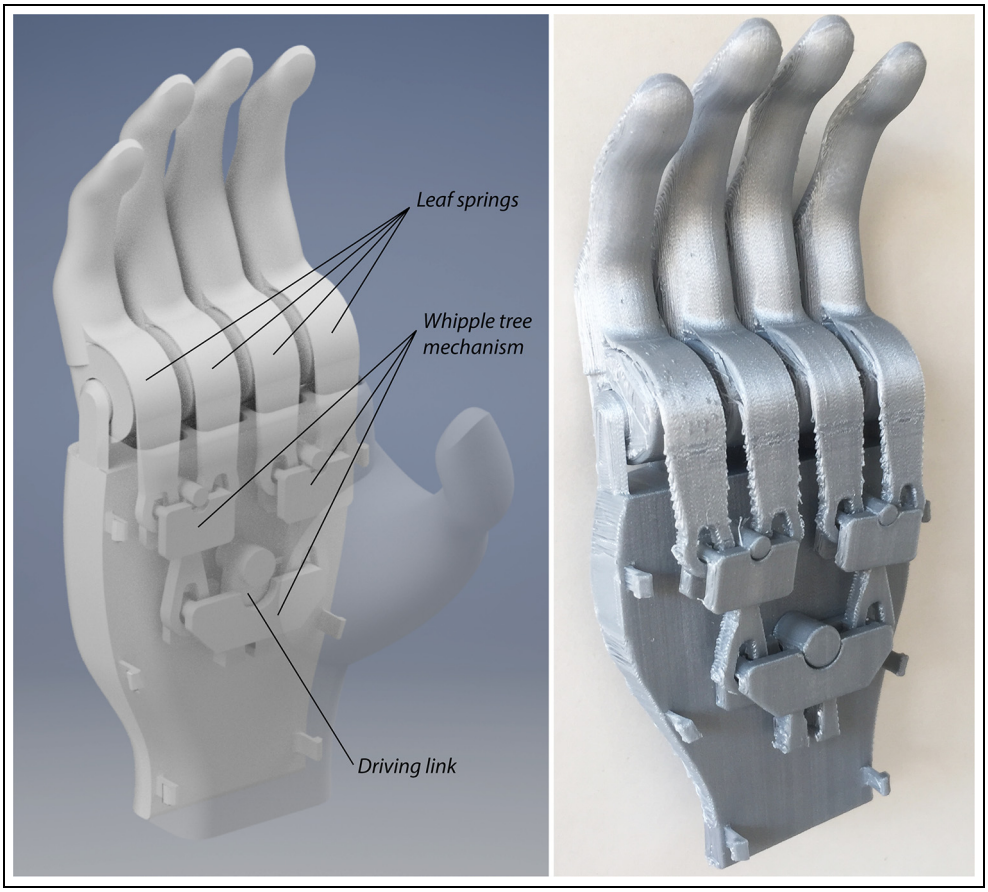

Figure 1. Design of our 3D-printed prosthetic hand. The palm in the left picture is translucent to show the inner mechanisms (from top to bottom: leaf springs, whippletree mechanisms, and driving link), and the right picture shows the 3D-printed prosthetic hand without the palm.

usually need to be performed by skilled personnel and may necessitate extra tools, thereby reducing the overall accessibility of prostheses. The design versatility offered by AM allows for production of mechanisms that do not require additional assembly steps (non-assembly mechanisms).[13–16] While a functional prosthetic device still requires an activation system and proper fitting to the residual limb, an active prosthetic hand that is printed in a fully assembled state will increase the accessibility of such prosthetic devices through elimination of a number of post-processing steps. In low resource settings, the prosthetic hand can be 3D-printed in the closest centres in large cities where reasonable technical conditions can be found and 3D printers are available. The prosthetic hand can be transported to the end user using local distribution networks.

Based on a study on 3D-printed mechanisms and joints,[17] we have recently developed a new approach for the design and 3D printing of non-assembly active hand prostheses[18] using inexpensive printers working on the basis of fused deposition modelling (FDM™; i.e. polymer extrusion).[19] This article describes the design of our novel 3D-printed hand prostheses with a focus on a mechanical and functional evaluation in view of its future use in developing countries.

The 3D-printed hand prosthesis

Our 3D-printed hand prosthesis was designed to be the first 3D-printed fully assembled prosthesis that meets the following basic (functional) requirements: body-powered (BP) control, cosmetic appearance, light weight, and water/dirt resistant (materials do not fail in contact with water and dirt).[20]

A detailed explanation of the 3D-printed prosthetic design (Figure 1) can be found in Cuellar et al.;[18] however, a brief description is given in order to contextualize this study. The design is made up of four individual fingers and a stationary thumb. All fingers are coupled to the palm through one hinged joint permitting a one-degree-of-freedom (DoF) rotating motion. The fingers are joined through a whippletree arrangement. This permits relative movement among the fingers equalizing the pinching force on each finger as they adjust to the geometry of the object being grasped (adaptive grasping).[21] All fingers in motion are activated by a force transmission scheme which is made out of a main driving link, the whippletree arrangement, and the links that connect the four fingers. The hand is actuated by a Bowden cable attached to the main driving link that is allowed to go on a linear motion following the movement of the cable. Return forces that permit hand

opening are generated by leaf springs connected on one end to the base of the fingers and on the other end to the whippletree mechanism. The leaf spring configuration is designed as a series of curved thin 3D-printed plastic sheets that allow elastic bending and work as pulling elements at the same time. When the fingers are activated, the pulling forces drive the leaf springs to unbend and deform to a straight configuration. As the leaf springs return and recover from the deformation, spring-like behaviour is provided, combining actuation and a return spring in one non-assembly 3D-printed element.

In order to achieve non-assembly fabrication of the concept, a number of design guidelines[18] were used using the advantages of 3D printing for design versatility while circumventing many of its shortcomings. The prosthetic hand was 3D-printed from polylactic acid (PLA) using an Ultimaker 3 3D printer. This machine is relatively an affordable alternative compared to other 3D printing technologies, allowing for the production of low-cost parts. A cover encasing the whippletree mechanism and forming the palm of the prosthetic hand was printed separately and was assembled using snap-fit joints. The entire mechanisms were 3D-printer-assembled so as to avoid elaborated post-assembly steps. Only one simple additional snap-fit step is needed to cover the mechanism with the prosthetic palm, which can be easily done by the user. The hand was 3D-printed with the circular cross-section area of the hinges of the fingers parallel to building plate of the 3D printer. In this way, the layers that form the leaf springs, the whippletree mechanism, and the driving link are deposited along the perpendicular direction of their moving direction during the hand prosthesis activation. To visualize the printing direction of the prosthesis, please refer to Cuellar et al.[18]

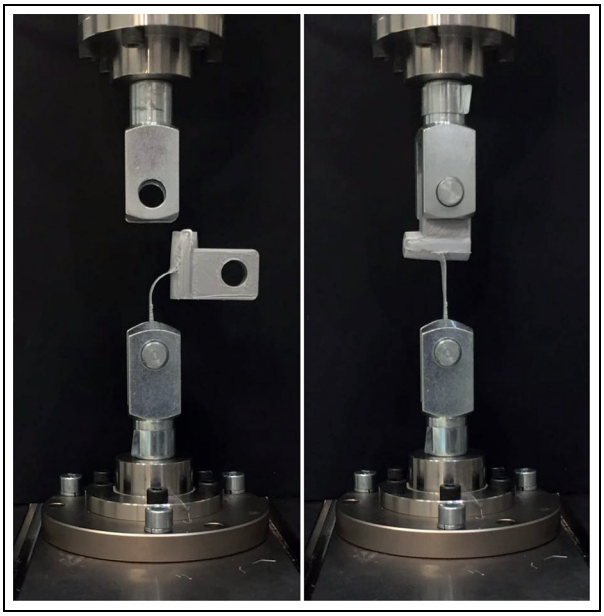

Figure 2. The experimental setup for the leaf spring ultimate strength test. The leaf spring is in its neutral configuration (left). The 3D-printed sample is under tensile and bending loading conditions during experiment. Note that the leaf spring is bent to a straight configuration, corresponding with a 90° flexion of the finger (right).

Methods

Leaf spring ultimate strength and fatigue life

In the prosthetic hand, the moving part that has the lowest cross-sectional area (most prone to failure) is the leaf spring. Furthermore, the leaf springs experience a combination of tensile and bending loads as the prosthetic hand activates. This loading condition is worrisome since it can be more critical to the structural integrity of the part than any other in the prosthetic hand. Tensile stress versus strain experiments have been conducted previously on a number of 3D-printed PLA samples.[22] However, a combination of tensile and bending loads has never been explored. It is therefore unclear whether the leaf spring configuration is able to withstand the maximum input force delivered by a regular prosthetic user via a Bowden cable. According to Hichert et al.,[23] the maximum input force registered by a prosthetic user is 538 N. Due to the distribution of the force given by the whippletree mechanism that divides the force equally over the four fingers, with this maximum input force, each leaf spring should be able to withstand a tensile load of 134.5 N (538 N/4). An experimental setup consisting of an ElectroPuls™ E10000 (Instron) electrodynamic testing machine and customized 3D-printed PLA samples designed to fit into the testing clamps were used in order to measure the failure force of a leaf spring under the corresponding loading and motion conditions. The 3D-printed samples were designed to have the same dimensions as the leaf springs in the prosthetic hand, with a bent initial shape (Figure 1 and Figure 2, left), and to fully restrict the motion at both extremes once the leaf spring has been manually uncurled to a straight configuration (Figure 2, right), equivalent to their full closing function (90° flexion) in the prosthetic hand. In the straight configuration, the sample was loaded with a strain rate of 0.01 mm/s until failure. The experiment was repeated five times using samples fabricated with the same 3D printing parameters as the prosthetic hand.

Similar to the ultimate strength, the number of cycles that the leaf spring can be used before it breaks is unknown. A similar experimental setup using the same equipment and materials as the previous experiment was used. The testing samples were modified to allow free rotation at one of the clamping ends to simulate the activation of one finger. The clamped end of the sample that is connected to the finger is able to move from the extended (0°) to the flexed position (90°). Note that the leaf spring goes from the bent (curved) configuration to the straight configuration

during one cycle. Five samples were cyclically loaded at 0.5 Hz until failure.

Pinch force and mechanical work

To study the mechanical performance of the prosthetic hand, a previously established test setup was employed.[18,24] The test setup measured the input force using a load cell (Zemic: FLB3G-C3-50 kg-6B), the pinch force of the prosthetic hand using a 11-mm-thick cover encasing a FUTEK LLB130 load cell positioned on the tip of thumb, and the actuation displacements of the driving cable using a displacement sensor (Schaevitz: LCIT 2000). The variables of interest are (1) pinch force output, delivered by the contact between the thumb and the index and middle fingers, given a driving input force and displacement and (2) the energy used to close and open the prosthesis for one cycle.

The measurements of the energy input to close the device and the energy returned to move the fingers back to the straight configuration were used to calculate the mechanical efficiency of the hand prosthesis. The energy utilized in each opening–closing cycle could be calculated as the integration of the cable loads along the measured driving cable displacements. A calculation of energy dissipation can be acquired as the subtraction of the input energy minus the returned energy. Figure 3 shows the test setup. In order to quantify the concerning variables, the subsequent procedure was used. First, a cycle of closing and opening with no pinch force measurements was repeated five times. Second, closing and holding into a pinch grasp the load cell until an activation force of 100 N was attained. The index and middle fingers pressed the load cell against the thumb as they were moved towards the thumb by activation of the prosthetic hand. Note that the ring finger and little finger moved until they met the maximum closing angle (90°), at which point the whole system was in equilibrium.

Functional testing

The prosthesis design was assessed using the Box and Blocks Test (BBT)[25] and the Southampton Hand Assessment Procedure (SHAP) test,[26] which are well-established tests for evaluating prosthetic designs with prosthetic users.[27,28] The BBT consists of 25-mm wooden square cubes and a container separated in two areas by a wall in the middle. The subject must transfer as many blocks as possible from one area into the other. The score is registered as the number of blocks the subject is able to transfer within 1 min. The SHAP test consists of a first part in which the user has to move abstract items with different shapes and weights and a second part in which some activities of daily living (ADLs) have to be completed by the user. This test measures the ability of the user to perform spherical, power, tip, tripod, lateral, and extension grasping. The times to perform all activities are measured and uploaded to the online SHAP test center[29] in order to obtain the SHAP index of function (IOF).

A total of 20 able-body and right-handed students or employees of the Delft University of Technology (8 males and 12 females; age: 22–32 years) were recruited. Of them, 10 (four males and six females; age: 27 ± 5 years) were assigned to perform both tests. During the tests, our 3D-printed prosthesis was attached to a strapped cuff that fits around the user's forearm (TRS Inc.) in order to use it as a prosthesis simulator. The fingers were driven by pulling a Bowden cable attached to a figure-of-nine shoulder harness (Figure 4). The simulator was placed at the dominant arm of the subject. The study was approved by the human research ethics committee of the Delft University of Technology. Written informed consent to participate in the study was obtained for all subjects.

The subjects were allowed to perform two practice sessions of BBT to familiarize with the test setup before being scored. Afterwards, the BBT was repeated four times followed by one implementation of the SHAP test given the inherent long testing time (45–60 min for one test of the SHAP). The first results suggested lack of friction properties over the interacting surfaces used for grasping (i.e. finger pads), as the objects tended to slip away during testing. To assess the effects of such friction properties on the performance of the prosthesis, the other 10 subjects (four males and six females; age: 27.5 ± 2.5 years) were assigned to perform the BBT with our 3D-printed hand prosthesis enhanced by sticking strips of gaffer tape over the surface of the finger pads to increase the friction to a level that objects did not slip out of the fingers anymore during the tests

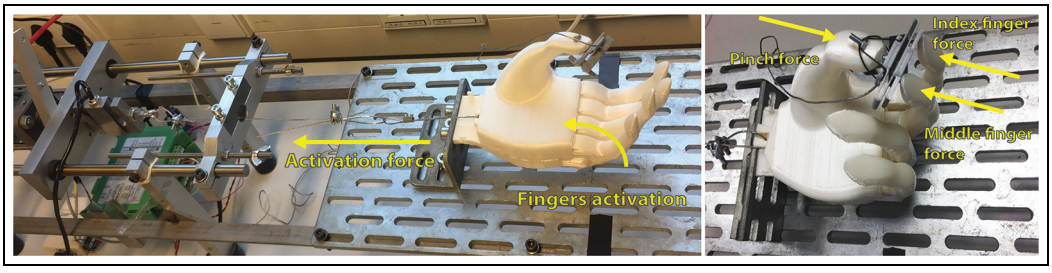

Figure 3. The experimental setup to measure the activation and pinch forces (left). The index and middle fingers push the load cell against the thumb. The ring and little fingers meet the maximum closing angle (90°) (right).

Figure 4. Our 3D-printed prosthetic hand attached to the simulator and a figure-of-nine shoulder harness. The cable tension that is delivered by the harness and activates the prosthetic hand is depicted (left).

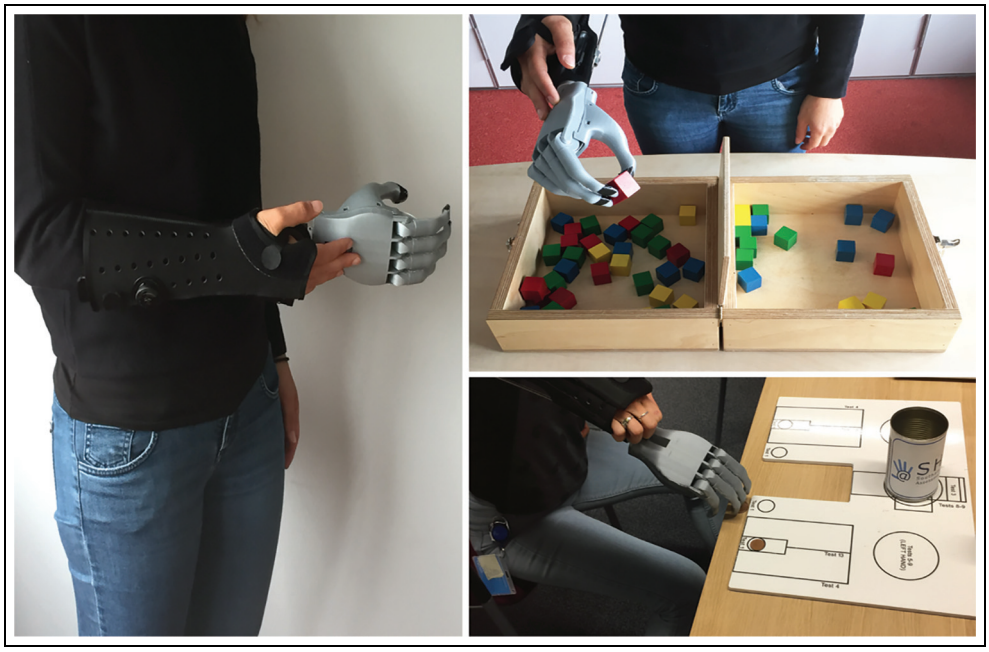

Figure 5. Our 3D-printed prosthetic hand attached to the simulator and used by the participating subjects (left) for the Box and Blocks test (top right) and the SHAP test (bottom right). Gaffer tape strips were put over the thumb, the index, and middle fingers to increase grip (right).

(Figure 5). The subjects were again allowed to perform two practice sessions of BBT, and then four sessions of BBT were performed and recorded. The median of the last trial of all subjects is calculated and used as a functional metric of the BBT to compare with other BP prostheses. The median of the last trial of all subjects is more consistent because of the effects of a learning curve. Using the average of means for all subjects would include trials where the subject is still not fully familiarized with the device and thus evidencing not low functionality of the device but rather inexperience of the subject when using it. The median is also less susceptible to the occurrence of outliers, while the average can be largely affected by them.

Results

The ultimate tensile strength of the leaf springs and fatigue life

Figure 6 shows the mechanical behaviour of the leaf spring design under tension and bending loading. The ultimate load to failure of the five tests was 316 ± 22.7 N (mean $\pm$ SD), which is significantly larger

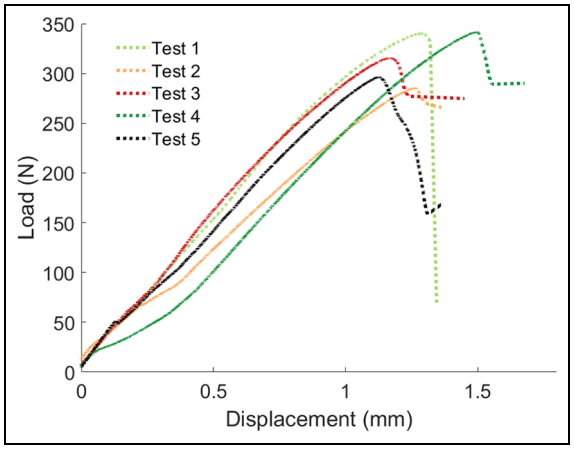

Figure 6. A load versus displacement response for five samples of the leaf spring configuration.

than the required maximum of 134.5 N. The number of cycles to failure of the five leaf spring samples was 2446 ± 499 cycles (mean ± SD).

Pinch force and mechanical work

The five closing–opening cycles are shown in Figure 7 (left). A full closing–opening cycle and the relationship between the input force and output pinch force over the index and middle fingers are shown in Figure 7 (right). The energy used to close the prosthetic hand was computed as $0.104 \pm 6 \times 10^{-3}$ Nm, and the energy dissipated for one cycle of closing and opening motion was computed as $0.048 \pm 3 \times 10^{-3}$ Nm.

Functional testing

The scores of the BBT and the IOF of the SHAP test are shown in Tables 1 and 2. For the prosthetic device without further modifications, the median score of the last trial (fourth) of the BBT among all subjects is 14 blocks, and the average IOF for the SHAP is 33.1. For the prosthetic device with enhanced friction properties, the median score of the last trial (fourth) of the BBT among all subjects is 21 blocks (Figure 8).

Data availability. The datasets generated and/or analysed during this study are available from the corresponding author on reasonable request.

Discussion

We have fabricated a prosthetic hand with reduced post-assembly requirements using 3D printing technology. Apart from the removal of support material and a single snap-fit step, the hand was successfully designed following a non-assembly approach. The hand achieves adaptive grasping even though it is made out of only two parts. We argue that such a design and fabrication approach can increase accessibility of hand prostheses since easily accessible low-cost equipment (an Ultimaker 3 3D printer) was used together with low-cost material (PLA).

The leaf spring strength requirement has been met. The measurements show a significantly larger load to failure (316 ± 22.7 N) than required (134.5 N). The thin sheet of PLA material fabricated to serve as a spring component is able to work under the static loading conditions proposed in this prosthetic design. On the contrary, the fatigue life experiments show that the leaf spring is not able to withstand cyclic loading for a prolonged period. The material used for the leaf spring is therefore not suitable to ensure long-term durability and reliability of the prosthetic hand. The use of other materials suitable for 3D printing might provide better fatigue life properties for such compliant configurations

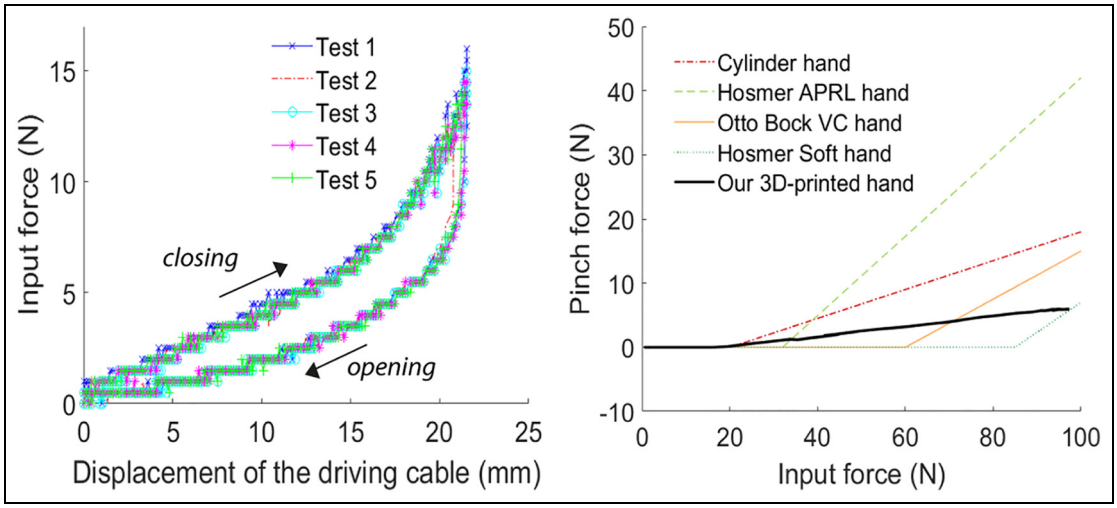

Figure 7. The results of the mechanical assessment of the prosthesis. Cable displacement versus the input force for five closing–opening cycles (left), and a representative trial of the input force versus pinch force including commercially available prostheses subjected to the same testing protocol (adapted from Smit and Plettenburg[24] and Smit et al.[21]) (right).

Table 1. Scores of the box and blocks tests and index of function (IOF) from SHAP test.

Subject	1	2	3	4	5	6	7	8	9	10
Mean # of blocks (std. deviation)	7.8 (±2.4)	11 (±2.9)	17.5 (±2.6)	11.5 (±4.9)	12.8 (±1.9)	8 (±0.8)	12 (±3.7)	15 (±1.2)	13 (±3.7)	12.3 (±1.7)
Median of the last (fourth) trial					14					
IOF	31	13	37	40	31	14	36	48	40	41
Average					33.1					

SHAP: Southampton Hand Assessment Procedure.

Table 2. Scores of the box and blocks tests for the prosthetic hand with increased friction properties over the finger pads.

Subject	1	2	3	4	5	6	7	8	9	10
Mean # of blocks (std. deviation)	26.8 (±2.2)	18.3 (±3.9)	17.8 (±1.3)	15.8 (±4.8)	13 (±5.8)	14 (±4.2)	21.5 (±2.4)	20 (±2.2)	23.5 (±1.3)	22.3 (±3.4)
Median of the last (fourth) trial					21					

like the leaf spring. Further investigations aimed to study the fatigue life of compliant mechanisms fabricated with 3D-printed polymers should be conducted.

The design choices made for the mechanisms led to a prosthetic hand that needs considerable lower energy ($0.104 \pm 6 \times 10^{-3}$ Nm) to close as compared to other BP prosthetic hands (1.1–2.3 Nm or J[24]). In addition, the activation force (16–18 N) needed for the onset of a pinch grasp on the 11-mm pinch load cell is considerably lower as compared to other alternatives[24] (Figure 7). This indicates that the user has to put less energy in order to close our hand prosthesis. The force transmission (pinch force/input force) to the fingertips is lower than other BP prosthetic hands as indicated by the slopes shown in Figure 7 (right). The pinch force achieved by the index and middle fingers given a force input of 100 N is low (6 N) in comparison to other BP prostheses (10–60 N).[24]

The results of the BBT (median: 14 blocks) and the SHAP (average overall IOF of 33.1) indicate lower functionality of the device compared to other BP alternatives (median: 17–30 blocks;[27,30] average overall IOF of 65.75–66.05[31] and 64–65[32]). This could be explained partly by the low pinch forces and the lack of friction between the fingertips (made of PLA material) and the objects involved in the test. An increase of the friction coefficient of the finger pads led to better performances of the BBT (median: 21 blocks), reaching comparable scores to that of other BP hands. This highlights the importance of friction of the fingertips for improving the performance of 3D-printed prosthetic hands and indicates that new finger designs providing high friction

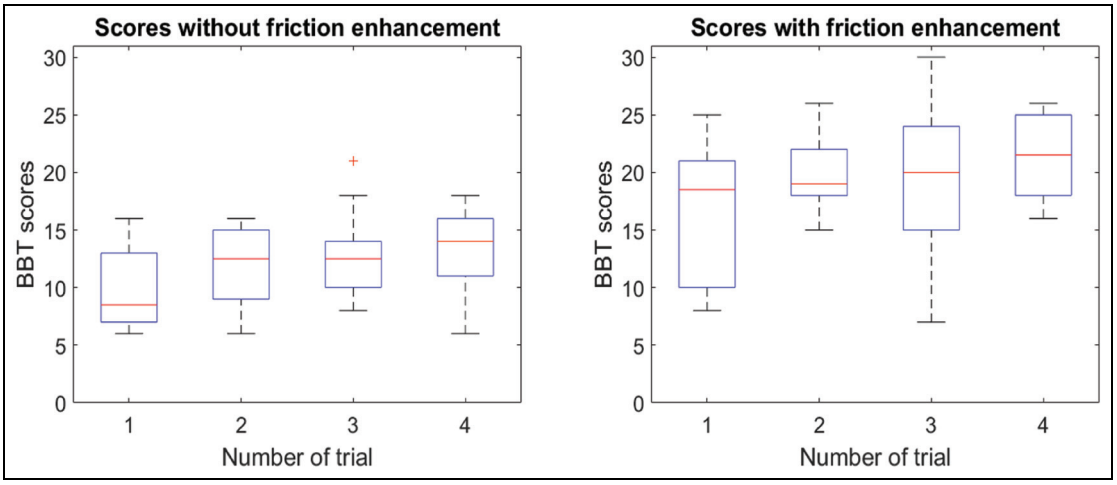

Figure 8. Scores during the BBT in four trials for the 3D-printed hand without any modifications (left) and the 3D-printed hand with friction enhancement (right).

surfaces should be developed. Moreover, a learning curve effect can be considered as the scores of the BBT tend to be higher on the fourth trial (Figure 8). It is likely, yet unproven, that scores could improve if the subjects had repeated the test more times since learning curve effects have been demonstrated in BP prosthetic users at least up to the ninth trial in BBT.[27]

Our design is one of the few entirely 3D-printed and BP hands that has been assessed by mechanical and user testing. Only one 3D-printed hand reports comparable force measurements over the fingertips (3.9–11.5 N),[33] and only one study presents results of a SHAP test on a 3D-printed hand,[34] not reporting, however, IOF scores. Just another study performs a BBT on a 3D-printed hand (Cyborg beast; 13 ± 12.7 blocks) scoring similarly to our 3D-printed non-assembly hand,[35] although our design performs better in comparison when using friction enhancements over the finger pads. Interestingly, Zuniga et al.'s[35,36] study is one of the few that provides other clinical metrics like range of motion or wrist strength. Apart from prosthesis for partial hand amputation,[37–39] little is known about the performance and reliability of most 3D-printed hand prostheses. Most studies of fully 3D-printed hand prostheses do not present any kind of evaluation on the short- or long-term use[12] or use other different metrics making a direct comparison with the prosthetic hand presented here very limited. The data acquired during this study can be used as a basis for future developments on 3D-printed prosthetic hands.

The prosthetic design assessed in this work shows functional characteristics (Box and Blocks and SHAP scores) that are not yet matching the traditional BP prosthetic devices. Nevertheless, the 3D-printed hand evaluated in this study shows a comparable performance with just a small friction enhancement on the finger pads. Yet, grasping and functionality can be improved by increasing the pinch force. Moreover, it is worth noting that most ADLs require low grip forces.[40] This suggests that with such level of functionality and considering that this hand was mainly designed to reduce manufacturing requisites to just one 3D printer and its fabrication material, we can consider the design and manufacturing strategies used for this prosthetic hand as valuable approaches that could aid in improving the access to prosthetic devices in developing countries. To finally demonstrate the usefulness of the prosthetic hand, further usability studies involving end users with arm defect should be conducted including close follow-up checks and questionnaires.

Conclusion

We have fabricated a hand prosthesis using 3D printing technology and a non-assembly design approach that reaches certain level of functionality. The mechanical resistance of critical parts (leaf spring), the mechanical performance, and the functionality of a non-assembly 3D-printed hand prosthesis were assessed. The leaf spring configuration used in the hand prosthesis is able to withstand typical actuation forces delivered by prosthetic users. Moreover, the activation forces and the energy required for a closing cycle are considerably lower as compared to other BP prostheses. Conversely, the achievable pinch force and the functionality scores are in comparison significantly lower. The results also suggest that increased friction over the finger pads is highly beneficial for the prosthesis functionality. Direct comparison with other existing 3D-printed hands was not possible given the lack of data in the literature. The results presented in this study can be used as a starting point for future developments on 3D-printed prosthetic hands.

The non-assembly design achieved a comparable level of functionality with respect to other BP alternatives. Taking into consideration that most ADLs require low gripping forces and adding an increased accessibility provided by the advantages of the non-assembly and 3D printing approach, we consider this prosthetic hand a valuable option for people with arm defects in developing countries.

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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