Development and Trial of a Multipurpose Customized Orthosis for Activities of Daily Living in Patients with Spinal Cord Injury

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Abstract: People with mid-cervical spinal cord injury (SCI) often have difficulty in performing activities of daily living due to weakness or paralysis in the flexor muscles. The inability to perform activities requiring fine motor control, such as eating, brushing, writing, unlocking doors, etc., affects overall quality of life negatively. To perform such tasks, appropriate movement of the hands, specifically at the wrist, is essential. For SCI patients, wrist orthotics are considered a viable option with which to perform general tasks. Wrist orthotics, used for rehabilitating people with SCI, help to maintain proper wrist and hand positioning; however, patients must frequently change these orthotic devices as per separate activity requirements. This becomes difficult and cumbersome for such patients. In this work, a passive 3D-printed upper-extremity dynamic orthosis was developed to assist SCI patients in their activities of daily living. The orthosis works on the principle of a worm-gear-based mechanism to produce pronation/supination motions at the wrist. To test the developed multipurpose customized orthosis, ten patients with cervical SCI were recruited and prescribed the 3D-printed splint for a period of four weeks. It was assessed through the QUEST questionnaire and a task completion assessment for its performance. The developed multipurpose customized orthotic device was found to provide an appropriate range of motion, ease in performing tasks, and took less time to complete tasks compared to previous works. The results indicated satisfactory performance, thereby improving quality of life. The multipurpose customized orthotic device successfully assisted the subjects with their daily activities, thus making them more independent in their rehabilitative period.

Keywords: spinal cord injury; orthosis; activities of daily living; custom-made; cervical

1. Introduction

Spinal cord injury (SCI) is considered to be a serious injury, thereby increasing the risk of mortality and morbidity. SCI could be traumatic and non-traumatic with different etiologies; however, both of them result in analogous consequent degenerative alterations in the spinal cord [1]. The most prevalent cause of traumatic spinal cord injury is trauma, the incidence of which shows peaks in adults aged between 15 and 29 (associated with road traffic accidents) and in those over 65 years of age (primarily due to falls) [2,3].

SCI causes the subjects affected by it to be profoundly disabled, following loss of livelihood in conjunction with psychological as well as socio-economic issues. The classification of SCI is based on the motor and sensory capabilities of the affected person, as described by the ASIA (American Spinal Injury Association) [4]. A strong correlation is present between functional status and the severity as well as completeness of a spinal cord injury. In the case of complete injury at the distal stage, the loss of all sensory as well as motor capabilities is reported. On the other hand, incomplete damage refers to the partial preservation of the sensory and motor capabilities below the neurological level. Due to this...
weakness or paralysis in the flexor and extensor muscles, patients with mid-cervical spinal cord injury often have difficulty in performing the activities of daily life, which require fine motor control [5]. Performing these tasks can become difficult for such patients but can be managed through using assistance; however, it is anticipated that these patients spend more time on personal care and more time on mobility as well as transferring activities [6]. Due to the reduced function, the activities take longer to complete [7].

Orthotic devices are externally fixed splints that are used to support and immobilize limbs to accelerate healing or for rehabilitation purposes. Upper-extremity orthoses have been frequently employed for the rehabilitation of people with SCI to help them maintain proper wrist and hand positioning as well as alignment. These positions enable patients to independently perform their day-to-day activities without depending on caregivers. There are various types of upper-extremity orthoses prescribed to achieve various rehabilitative goals. These orthoses can broadly be categorized as depending upon the movement needed—static, functional, or dynamic—and depending upon the level of involvement—hand, wrist, elbow, and shoulder. SCI-affected individuals are assessed thoroughly before these orthoses are prescribed. A higher level of cervical injury leads to more joint involvement [8]. These orthoses are either fabricated through the traditional manual method or manufactured using three-dimensional (3D) printing. The traditional method usually involves the use of various types of thermoplastics and various varieties of metals incorporated together for the production of patient-specific orthotic devices. The latest evolving technology, 3D printing uses computer-aided manufacturing to create 3D orthoses. This technology is considered cost-effective, allowing for better customizable options with improved productivity [9]. Fabricating orthoses through 3D printing has been proven to be cost-efficient with faster manufacturing in comparison to the traditional production methods. These orthotic devices allow for more precise results, which can be used to rehabilitate patients using the residual muscle function as much as possible [10].

Studies from the literature prove that the application of elbow–wrist–hand orthoses, along with a rehabilitation regimen, significantly reduces motor impairment in upper extremities and increases the functional level of paralyzed patients [11,12]. Orthotic management that involves wrists, powered by either an external source or the voluntary extension of the wrist joint has always been the primary orthotic management technique for rehabilitation [12]. As stated by the International Spinal Cord Injury Upper Extremity Basic Data Set, it is essential to prescribe splinting for those with a spinal cord injury to achieve maximum upper-extremity functional strength [13]. There are plenty of orthotic devices that are currently used for the rehabilitation phase of cervical-cord-injured patients, such as a universal cuff, three-jaw chuck writing device, and low-temperature thermoplastic (LTTP) orthosis; however, each of these devices needs to be changed according to need [14,15]. Additionally, patients must change the orthotic devices as per the activity requirements. This becomes cumbersome for cervical-spine-injured patients. The individuals affected with SCI always have to depend on their caregivers to change the orthotic devices, which ultimately leads to complications throughout. Technologies that could help in the precise fabrication of orthotic devices aiming to combine multiple midline activities have been the need of the hour. To date, very few studies have been reported on orthotic devices aiming to incorporate multiple activities of daily living. Upper-extremity orthoses help in assisting patients in performing their daily activities independently. Existing braces hold the wrists at a fixed position and do not provide the freedom of holding the wrist and hand at varying angles. This was the main approach for designing the current orthosis. Therefore, this project aims to develop a technology to assist SCI patients in their day-to-day activities with the help of a multipurpose customized upper-extremity splint with the incorporation of 3D printing technology. This research hypothesizes that the use of this multipurpose wrist orthosis would reduce the time required by SCI patients to perform ADLs, such as brushing teeth, eating, combing, and writing independently, with comfort and a quick adaptation time.
2. Materials and Methods

This section describes the detailed demographics of the patients recruited, the procedure of the multipurpose customized orthosis development, and the validation as well as data analysis techniques used in the study.

2.1. Demographics

This study was conducted on subjects with cervical spinal cord injury. The subjects were recruited from Indian Spinal Injuries Center, Delhi, India. The recruitment was based on the following inclusion criteria: subjects with an incomplete cervical cord injury, both males and females, ages between 18 and 60 years, subjects that were medically stable with no contractures in their upper extremities, and subjects with both acute and chronic stages of injury. The basis for the exclusion criteria were subjects with diabetes, chronic pain, any other neurological, psychiatric, or orthopedic impairment, pregnancy, any skin problems, any skin allergy, malignancy, pacemaker use, and medical instability. The ten subjects meeting the inclusion criteria were selected and received an informed consent detailing the procedure of the study. The subjects were recruited only after they agreed to participate in the study and signed the informed consent. The patients were in the rehabilitation phase under observation in the hospital. All of the recruited volunteers were in-patients; therefore, they were under specialized supervision while performing the activities, as per ethical norms. Table 1 below describes the detailed demographics of the patients recruited in the study.

Table 1. Detailed demographics of the patients recruited in the study.

<table>
<thead>
<tr>
<th>Age</th>
<th>Vertebral Level</th>
<th>Neurological Level</th>
<th>ASIA</th>
<th>Reason of Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>C5</td>
<td>C4</td>
<td>A</td>
<td>RTA</td>
</tr>
<tr>
<td>48</td>
<td>C4–C5</td>
<td>C5</td>
<td>B</td>
<td>Fall on neck</td>
</tr>
<tr>
<td>54</td>
<td>C4–C5, C5–C6</td>
<td>C4</td>
<td>A</td>
<td>RTA</td>
</tr>
<tr>
<td>20</td>
<td>C6</td>
<td>C6</td>
<td>A</td>
<td>RTA</td>
</tr>
<tr>
<td>22</td>
<td>C5–C6</td>
<td>C5</td>
<td>A</td>
<td>diving</td>
</tr>
<tr>
<td>33</td>
<td>C6–C7</td>
<td>T1</td>
<td>A</td>
<td>RTA</td>
</tr>
<tr>
<td>56</td>
<td>Cervical spondylosis myelopathy</td>
<td>C5</td>
<td>B</td>
<td>Non-traumatic</td>
</tr>
<tr>
<td>43</td>
<td>C3–C6 lateral mass fixation</td>
<td>C6</td>
<td>C</td>
<td>RTA</td>
</tr>
<tr>
<td>28</td>
<td>C5</td>
<td>C5</td>
<td>A</td>
<td>RTA</td>
</tr>
<tr>
<td>20</td>
<td>C6</td>
<td>C6</td>
<td>A</td>
<td>Fall</td>
</tr>
</tbody>
</table>

2.2. Measurements

The design of the multipurpose customized orthosis was based on the anthropometric data of the hand and forearm reported, as per ISO 7250-1 [16,17]. Table 2 illustrates the mean anthropometric dimensions of both males and females that were used for the mean multipurpose customized orthosis dimensions. To incorporate actual hand geometry for the development of the multipurpose customized orthosis, the upper extremity of the subject was 3D-scanned via the use of a 3D scanner (Sense, 3D Systems, Rock Hill, SC, USA). The scanned surface model was smoothened, re-meshed, and converted into a solid model through using Meshmixer software (Autodesk, San Rafael, CA, USA). The model was then imported into SolidWorks 2020 (Dassault Systèmes, France) for the development of the multipurpose customized orthosis. The multipurpose customized orthosis was designed to cover the entire range of motion of 0–180 degrees, as most of the activities require a standard range of motion between 40 and 140 degrees [18].

2.3. Design

Figure 1 illustrates the developed multipurpose customized orthosis. A worm and worm wheel–gear mechanism was incorporated at the wrist to generate supination/pronation motions, as it presented several crucial benefits. A worm gear pair is self-locking and cannot be back-driven [19]. Hence, the wrist was held in a static position after setting
the desired supination/pronation angle, eliminating the use of any additional locking mechanisms that would otherwise be required if other gear arrangements were employed. It also provided an inherently high gear reduction ratio in a compact space, which resulted in sufficient torque amplification, making it an effortless task for the caregiver to position the patient’s wrist by turning a small knob. Moreover, since the torque is transmitted between non-parallel, non-intersecting, and perpendicular axes, as seen in Figure 1, the knob was inherently oriented at an ergonomic position, making the turning operation highly intuitive. The hand passes through the hollow worm wheel, aligning its rotational axis with the longitudinal axis of the arm, at the wrist. Figure 2 shows the mean dimensions considered while designing the customized multipurpose orthosis.

Table 2. Anthropomorphic dimensions of the upper extremities.

<table>
<thead>
<tr>
<th>Name of Length</th>
<th>Male (cm)</th>
<th>Female (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elbow–wrist (EW)</td>
<td>29.03</td>
<td>1.54</td>
</tr>
<tr>
<td>Forearm–hand (FH)</td>
<td>48.40</td>
<td>2.33</td>
</tr>
<tr>
<td>Wrist–center of grip (WCOG)</td>
<td>6.97</td>
<td>0.49</td>
</tr>
<tr>
<td>Elbow–center of grip (ECOG)</td>
<td>36.00</td>
<td>1.79</td>
</tr>
<tr>
<td>Hand breadth (HB)</td>
<td>9.04</td>
<td>0.42</td>
</tr>
</tbody>
</table>

In lieu of using bulky bearings between the worm wheel and the gear housing, V grooves were modeled on both the worm wheel and the gear housing, as seen in Figure 3, to achieve a low-friction, sliding contact bearing and provide an axial constraint to the worm wheel. This significantly reduced the end-point mass and overall cost of the multipurpose customized orthosis.

Figure 1. Developed multipurpose customized orthosis.
The positions of the forearm bones, i.e., the radius and ulna, overlap during the supination/pronation movement of the wrist, which make it non-ideal for any orthotic attachment. Hence, the device had an attachment that was fastened to the proximal part of the upper extremities of the patients, i.e., the biceps, and the other end of the orthosis was supported at the palmar region via the use of Velcro straps. This ensured a uniform distribution mass over the entire arm. The gear housing was connected to the stationary bicep brace assembly via the use of rigid metal tubes, as shown in Figure 1. The bicep attachment was designed with hinges along the medial–lateral direction to accommodate variations in bicep diameters. The gap in the device and the hand part was kept purposefully to accommodate all patients, and has not been observed to affect the results. The orthotic device was designed in such a way that there was no vibration transmission from the upper extremities of the patients to the orthosis. The arm was comfortably supported and rested on the palmar section of the orthotic device, thereby limiting vibration.
The palm rest and the worm wheel were coalesced into a single component to simplify the manufacturing and assembly processes (Figure 3). A slot with a screwed-in knob was provided under the palm rest to accommodate the interchangeability of different items of daily use, such as a toothbrush, comb, spoon, etc., as per an individual’s requirement.

2.4. Fabrication

The parts of the multipurpose customized orthosis were fabricated from polylactic acid (PLA) (PLA+, Esun Industrial Co., Ltd., Shenzhen, China) through the use of fused deposition manufacturing (FDM) 3D printing. PLA material was selected as it was easy to use [20,21], readily available, structurally rigid, light in weight, non-toxic, and approved by the Food and Drug Administration (FDA). The worm wheel–gear housing assembly (Figure 3) and the bicep brace assembly with hinged attachments (Figure 1) were printed in place (PIP), with a radial clearance of 0.25 mm. Certain part-specific settings were taken into account while slicing the various components of the multipurpose customized orthosis in Ultimaker Cura (Utrecht, the Netherlands). All of the parts were designed and sliced such that no support structures were needed, eliminating almost all post-processing clean up and trimming, which saved machine run time, material, and hence overall costs. All of the parts were printed with a standard 0.4 mm nozzle, 0.2 mm layer height, 0.8 mm wall and skin thickness, and with an infill density of 20%, with a tri-hexagonal infill pattern. For the PIP parts, adaptive layers with a maximum variation of 0.1 mm and a variation step size of 0.025 mm were used to print fine details, such as the V-groove in the worm wheel–gear housing assembly, and print at larger layer heights of 0.3 mm where details were coarse, such as the palm rest. A coating volume of 0.064 mm^3 was used to reduce the seam formation, which is usually profound in the fused deposition modeling (FDM) style of 3D printers and is the main cause of fused walls in PIP parts. Cura’s bridge settings were also used to achieve zero-support manufacturing.

2.5. Usage Procedure

The patients, assisted by caregivers, donned the device. After a patient had comfortably placed their hand on the palm rest, a caregiver checked the coinciding angle of the elbow joint, and the Velcro straps at the bicep brace were fastened to hold the orthosis at an appropriate position. The attachments used for a particular activity, such as a comb, spoon, or brush, were fixed in their corresponding slots and tightened using the knob on the bottom surface of the orthotic device. The wrist assembly was then angulated at the desired supination/pronation angle by turning the knobs at the wrist. After the desired placement of the hand, wrist, and activity attachment, the patient could perform their activity independently.

2.6. Validation

The fabricated multipurpose customized orthotic device was validated for the assistance provided to the subjects through the QUEST 2.0 (Quebec User Evaluation of Satisfaction with Assistive Technology) questionnaire, as illustrated in Table 3. The QUEST 2.0 questionnaire was used in line with previous reports [22,23] to effectively assess the extent of assistance provided by said device on the device and service subscales. The questionnaire is a 12-item instrumentation, which is used to assess the performance of any kind of assistive technology through several questions asked to the user about the characteristics of the multipurpose customized orthotic device applied as well as the service provided in the follow-up of the orthotic device. The scoring ranges from 1 to 5, where 1 is not satisfied at all and number 5 indicates very satisfied; however, it does not provide quantitative information. Hence, the time duration for the completion of each task was also taken into consideration to generate a more relevant result. The time taken to complete the given tasks was compared with the time taken by other means of assistance used by the patients. Another method of assessment was through the potential assessment of the multipurpose
customized orthotic device in assisting task completion [24]. This assessment only observed the completeness of the task allotted before and after the application of the multipurpose customized orthotic device. The day-to-day tasks were eating, brushing, combing, and writing. The same orthotic device was used throughout, with only the various attachments (toothbrush, comb, and spoon) being changed for each desired activity as per the need of the patient.

Table 3. QUEST 2.0 questionnaire [25].

<table>
<thead>
<tr>
<th>Scale</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Not satisfied at all</td>
<td>Not very satisfied</td>
<td>More or less satisfied</td>
<td>Quite satisfied</td>
<td>Very satisfied</td>
</tr>
</tbody>
</table>

3. Results

The results of the study were evaluated via the use of the QUEST questionnaire [23]. As per the subdivision of the QUEST scale, the results obtained for the QUEST devices score were $4.71 \pm 0.17$ and the results obtained from the QUEST services score were $4.77 \pm 0.21$. The QUEST total result obtained was $4.74 \pm 0.15$. The results obtained for the satisfactory performance of the multipurpose customized orthosis from the QUEST measure indicated its range as being between a score of 4, i.e., quite satisfactory, and a score of 5, i.e., very satisfactory. Figure 4 illustrates the QUEST scoring obtained in the study.

Figure 4. QUEST scoring of the multipurpose customized orthosis.

The multipurpose customized orthosis was further investigated in terms of its performance in assisting the individuals affected with spinal cord injury in performing their activities of daily living, such as brushing, eating, combing, etc. Figure 5 illustrates the ability of spinal-cord-injured individuals to perform their daily activities via using the assistance provided by the multipurpose customized orthosis. The individuals were able to independently complete their daily tasks without the assistance of their caregivers, which was stated to be a huge accomplishment by these individuals.
The multipurpose customized orthosis was further investigated in terms of its performance in assisting the individuals affected with spinal cord injury in performing their activities of daily living, such as brushing, eating, combing, etc. Figure 5 illustrates the ability of spinal-cord-injured individuals to perform their daily activities via using the assistance provided by the multipurpose customized orthosis. The individuals were able to independently complete their daily tasks without the assistance of their caregivers, which was stated to be a huge accomplishment by these individuals.

Figure 5. Ability to perform activities of daily living with the assistance of the multipurpose customized orthosis.

The time taken by the patients to complete the given tasks was calculated and compared to the usual time taken by the patients with the help of any other type of orthotic device [14,15]. There were various orthotic devices used by each patient in the hospital, including a universal cuff, three-jaw chuck writing device, and certain activity-specific orthotic devices, which were custom-fabricated using LTTP (low-temperature thermoplastic) material. It was observed that the time initially taken by the patients to operate the multipurpose customized orthosis was longer than the usual time taken by them; however, after an intervention time of four weeks, the patients became used to the functioning and operating procedure of the experimental multipurpose customized orthosis. A time duration assessment of the task after the application of the multipurpose customized orthotic device was taken after four weeks. A routine follow-up was also conducted at the end of each week, either through a phone call or in the hospital itself if the patient required any modifications. These follow-ups were conducted to know if the patients were comfortable with the devices and were using them for the prescribed time. For tracking the activity repetition, the patients were observed three times daily for eating, twice each day for brushing, once each day for combing their hair, and writing for half an hour each day. The data analyzed are illustrated in Table 4, which compares the time taken by the multipurpose customized orthotic device and the time taken in the conventional method of completing their day-to-day tasks.

Table 4. Time taken by the patients to perform their daily tasks with the multipurpose and conventional orthosis.

<table>
<thead>
<tr>
<th>Name of Activity</th>
<th>Repetition Each Day</th>
<th>Mean Time Taken by Conventional Method (Seconds)</th>
<th>Mean Time Taken by Multipurpose Orthosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eating</td>
<td>3</td>
<td>142 ± 13.31</td>
<td>136 ± 11.26</td>
</tr>
<tr>
<td>Brushing</td>
<td>2</td>
<td>135 ± 21.07</td>
<td>131 ± 17.45</td>
</tr>
<tr>
<td>Combing</td>
<td>1</td>
<td>143 ± 16.77</td>
<td>138 ± 13.23</td>
</tr>
<tr>
<td>Writing</td>
<td>1 (half hour)</td>
<td>156.24 ± 27.86</td>
<td>147 ± 24.33</td>
</tr>
</tbody>
</table>
The time was calculated as per the time taken by the individuals when they initiated wearing the multipurpose customized orthotic device till the time taken to perform the first step of a task, such as, while eating, the time taken in wearing the multipurpose customized orthosis and attaching the spoon; thereafter, picking the food from the bowl and the time taken for the first bite to reach their mouth. The same method was used for the calculation of the time while brushing, combing, and writing.

The subjects required assistance in wearing the multipurpose customized orthotic device and attaining the required angle for performing the desired activity. The caregivers assisted the individuals in wearing the multipurpose customized orthosis at the angle of their comfort, such that they could perform the desired activity independently without any further assistance. The brace was secured at the bicep level, and the elbow joint was free from any joint obstruction. The elbow joint was given free movement, such that the individuals could place their elbow in the required angle as per their activity.

4. Discussion

This study focused on the rehabilitation through orthotic management of individuals affected by spinal cord injury. Individuals affected with cervical injury were recruited for this study. There have been many studies reporting the application of upper-extremity splinting for rehabilitative purposes [26–28]. The target population selected for this study was cervical-cord-injured individuals who had difficulty in performing their activities of daily living, such as eating, brushing, combing, etc. [24,29]. Studies report that cervical-cord-injured individuals face difficulties in performing their day-to-day activities. Spinal-cord-injured individuals have to frequently change their orthoses or splints for performing these activities, which becomes difficult and cumbersome for them.

The multipurpose customized orthotic device aimed to incorporate assistance for all activities of daily living, for which the individuals required support from their caregivers. The multipurpose customized orthotic device was designed for and fabricated using 3D printing as it presented certain benefits. Three-dimensional printing allowed for the better customizability and precision of the orthosis [30–32]. The multipurpose customized orthotic device incorporated the manual angulation of the wrist joint for performing the activities of daily living. The multi-purpose customized orthotic device also had flexibility at the elbow joint. Therefore, the individuals could place their elbow at the desired angle without any obstruction. As nearly every component of the proposed orthosis was 3D-printed using a low-cost commercial desktop 3D printer (Ender 3, Creality, Shenzhen, China), scaling-up manufacturing would be possible on any 3D print farm. The choice of 3D printing over injection molding was based on its capability to print complete mechanisms and assemblies with the intention of interconnected motion between parts, such as the worm wheel and worm wheel housing in the aforementioned orthosis. This eliminates post-manufacturing assembly processes and eliminates bulky intermediary parts, such as bearings. The personalization of some features of the orthotic device could be possible in the future without requiring a huge initial investment, as would be the case with injection molding or other conventional manufacturing methods. It should be mentioned that the 3D-printed parts did not conform to any specific standards, as this device was intended as an initial prototype to display proof of concept. The device can be printed on an industrial printer with better materials (e.g., PEEK) when being prescribed to a larger sample size, which would then conform to certain manufacturing standards. Another major challenge that the additive manufacturing (AM) industry is currently facing is the absence of standards for quality, materials, and processes for AM, being predominantly dictated by OEMs; however, the terminology of the process for manufacturing said orthotic device conforms to ISO 52900.

The multipurpose customized orthotic device was prescribed for an intervention time of four weeks for the patients to become accustomed to it. The multipurpose customized orthotic device was then assessed using the QUEST measure and the ability of the individuals to finish their daily activities. The QUEST scoring assessed showed an inclination
towards a score of five, which indicated very satisfactory. The QUEST measure assessed the scores on the basis of subcategories, as device and service scores. The service scores assessed the need of follow-up services required for the multipurpose customized orthotic device. Both of the subscores were nearly five, as reported by the individuals wearing them for the prescribed period of time.

The ability of the individuals to complete their tasks using the multipurpose customized orthosis took less time in performing the daily activities than normal. The individuals took a few days to become accustomed to the multipurpose customized orthotic device. Initially, they took more time for their activities and needed much more assistance than usual; however, eventually, with experience and time, they were able to gradually improve the time required to perform the daily activities, such as eating, brushing, combing, and writing. The time difference between the experimental orthosis and conventional method was not highly significant; however, keeping the period of 4 weeks in mind, this time duration seemed to be significant for the patients. During the trial, the patients had to become accustomed to the device and be familiar with the methodology of its usage; therefore, the improvement in the time duration of performing the tasks when compared to before can be considered as having had a large impact. They could also perform these activities for longer durations with the assistance provided by the multipurpose customized orthosis. Since the energy expenditure spent in changing the orthosis frequently for each activity was reduced, the acceptability of the device was greater when compared to the existing designs available. The multipurpose customized orthotic device had an attachment point for the devices that were required by the individuals. The devices, such as a brush, spoon, and comb, could be easily changed by simply tightening the screw present at the palmar area of the orthotic device. Additionally, the multipurpose customized orthotic device was found to be less cumbersome, as the individuals did not change to a separate device for each activity. The orthotic device had a hinge joint at the location of the anatomical elbow joint; therefore, the vibrations created in the proximal part of the upper extremity of a patient’s bicep were not transferred to the forearm and hand parts. The device was stable enough during each activity; therefore, the results were unaffected by any adjacent vibrations. The assessment of the time taken for completion was carried out through the use of a stopwatch to compare the timings taken in each assigned task.

Future studies with a larger sample size should be performed to provide strong results of the performance of the multipurpose customized orthosis. This 3D-printed upper-extremity multipurpose customized orthosis can be modified for future studies. These modifications may include attachment points for more day-to-day activities, such as typing, holding a glass, etc. Furthermore, various types of grips can be incorporated into the orthotic device. Since the orthosis was designed to be a passive device, no active gimbal stabilization was included. This was because the end-point mass of the orthosis would increase significantly and cause premature fatigue in the bicep and shoulder of a patient, rendering them unable to use the device altogether. This would also increase the cost of the orthotic device significantly. Additionally, it should be mentioned that the patients in this study were able to complete the various individual tasks without an active gimbal stabilization mechanism. The functionality of the multipurpose customized orthotic device can be enhanced further by using electromechanical actuators [33,34] for active gimbal stabilization to achieve a higher level of control; however, future work is necessary for producing a cost-effective and low-mass gimbal stabilizer for upper-extremity orthotic devices for rehabilitation purposes. The device should also be compared with other devices to evaluate the effectiveness of this multipurpose customized orthosis as compared to those that are currently prescribed to individuals suffering from cervical spinal cord injury. These devices could be the ones that are prescribed by healthcare practitioners during the rehabilitative period of spinal-cord-injured individuals or the prefabricated orthotic options available commercially. These comparisons could help in validating the performance of the multipurpose customized orthotic device.
5. Conclusions

This study aimed at fabricating and testing a multipurpose customized orthosis to assist those that are cervical-cord-injured in allowing them to perform their activities of daily living, such as eating, brushing their teeth, combing their hair, etc. The performance of the multipurpose customized orthosis was observed to be satisfactory after assessment through the questionnaire and time taken for the completion of tasks performed by spinal-cord-injured individuals. The time taken to perform daily activities was compared to be lower with the multipurpose orthosis, such that there was an approximate reduction of 6 s in eating, 4 s in brushing, 5 s in combing, and 9 s in writing. Furthermore, there was a maximum time reduction of 20% and 27% for eating and brushing activities, respectively. Based on this study, it can be concluded that this multipurpose customized orthotic device can be prescribed to a larger sample size. This study helped in defining a new protocol for the rehabilitation of individuals affected by SCI for assistance in their daily activities. Future recommendations for healthcare providers and researchers working in rehabilitation would be the incorporation of such multipurpose splinting that makes the life of these individuals less tedious.

Author Contributions: K.C.: methodology, validation, investigation, formal analysis, writing—original draft and writing—review and editing. D.B.: design, manufacturing, methodology, and formal analysis. S.G.: methodology, data curation, formal analysis, and investigation. C.K.: data curation, investigation, and formal analysis. A.C.: conceptualization, methodology, formal analysis, supervision, and writing—review and editing. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethical Committee of the Indian Spinal Injuries Centre, New Delhi (protocol code New Delhi ISIC/RP/2022/033, and the date of approval was 10 October 2022).

Informed Consent Statement: The subjects provided signed consent forms before the study was conducted, consisting of the procedure and intervention time of the study.

Data Availability Statement: The datasets generated and/or analyzed during the current study are not publicly available due to being large datasets; however, data are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

References


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