

Efficacy of Assistive Devices Produced with Additive Manufacturing

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ABSTRACT

Additive manufacturing grants the possibility to produce inexpensive, custom assistive devices. The primary objective of this research was to develop a highly flexible, parametrically-defined assistive device design which has the potential to reduce expert intervention in the fitting of devices, and would allow for fast and easy creation of assistive devices in the treatment of injury. We propose a central hypothesis that these customized assistive devices will produce similar or enhanced function when compared to traditional solutions.

Knowledge gained from this study will validate novel assistive devices which could be used in the treatment of musculoskeletal injury for astronauts' both during spaceflight and after return to Earth. These novel solutions will require less expert intervention and less on-site modifications for fitting.

Gross manual dexterity was evaluated using a standardized functional task, while satisfaction with the device was assessed via survey.

Obtained results indicate no functional difference in gross manual dexterity between types of wrist orthosis. The custom design scored better with regard to comfort, donning/doffing, and aesthetic appearance.

INTRODUCTION

Despite the frequency of musculoskeletal injuries such as sprains, broken bones and torn ligaments, [1] treatment options are often costly, time-consuming and ill-fitted. [2,3] Additive manufacturing ("3D-printing") allows for the production of highly-customized and inexpensive assistive devices, [4] which suggests potential efficacy in the prescription of splints and casts for musculoskeletal injury. [3]

Emerging studies reference the fact that additive manufacturing can produce clinical improvements in rehabilitation that are similar to traditional methods. [2] It has also been documented that the time required to produce these types of devices is significantly faster and lower cost than traditional methods. [3] To date, no studies have produced a parametric assistive device using additive manufacturing. There exists an opportunity to enhance the function and production speed of these innovative devices through the application of parametric, anthropometric-driven part design. Through this new method, the possibility exists to improve recovery time from injury, decrease risk of further injury, and better utilize materials and time.

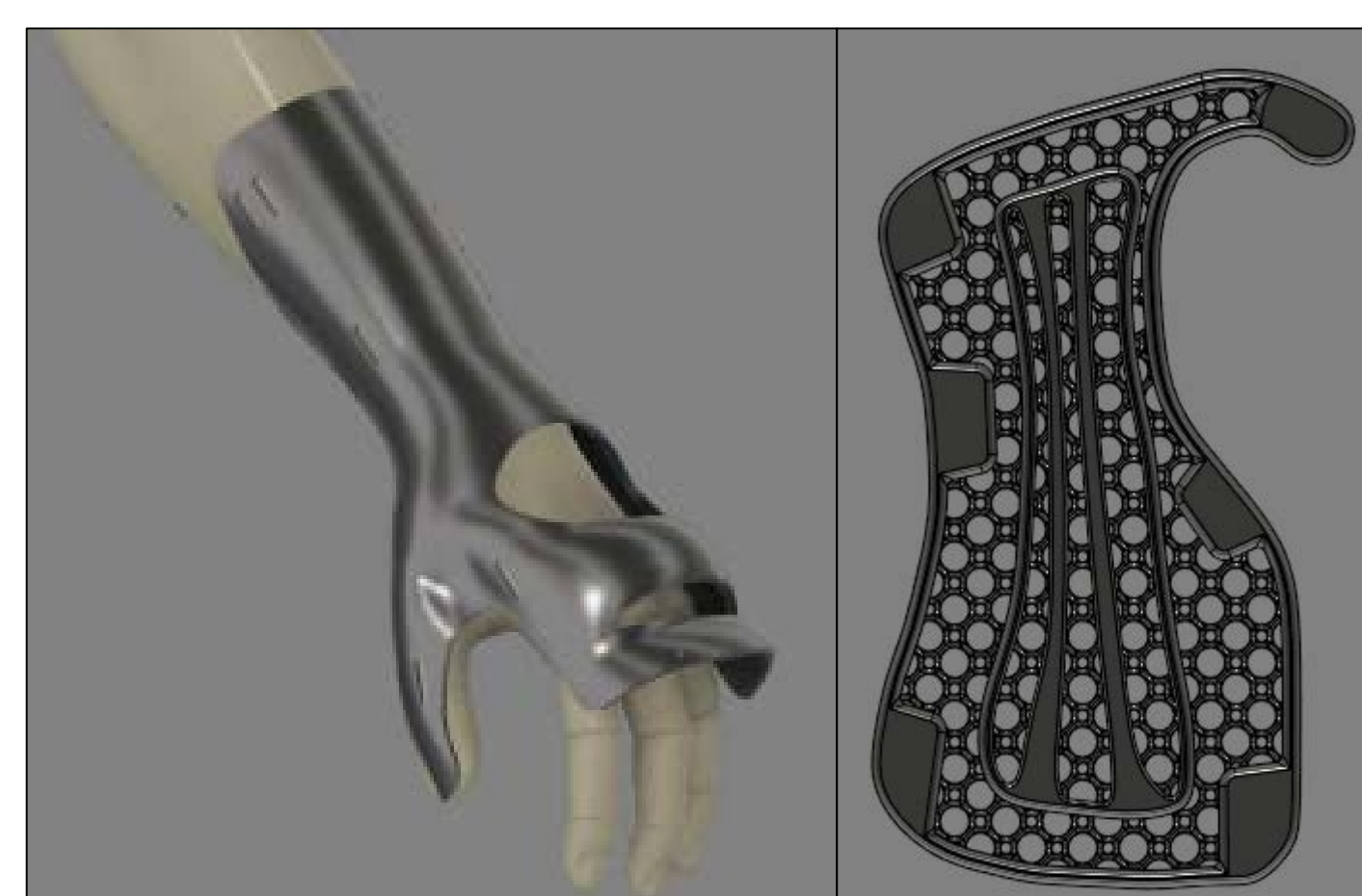


Figure 1: A) 3D model of a parametrically-defined hand exoskeleton design, scaled to fit a participant in CAD before part production. B) 3D model of a wrist orthosis, which is printed flat and thermoformed to the contours of the users' upper-limb.

METHODS

Recruitment: A single subject was used to produce the pilot data for this research study (male, age = 26 years).

Device Design: Design of the assistive devices was performed using a computer-aided design (CAD) program (Autodesk Fusion 360, Autodesk, San Rafael, CA, USA). All devices incorporated fully parametric definition; this allowed for morphological device changes to match the anthropometric measurements of participants before part fabrication.

Device Functionality Assessment: To assess the efficacy of the produced orthoses, performance quality during a standard functional task was collected using a contemporary, over-the-counter wrist splint as well as the additively manufactured prototype. The test, called the "Box and Block," utilizes a partitioned tray filled with identical blocks. The number of blocks transferred by the user in one minute is used as a measure of gross manual dexterity. Comfort, ease of donning/doffing and aesthetic appearance were also considered as factors in the efficacy of the device.



Figure 2: Traditional wrist splint used for functional comparison

MATERIALS

The low-cost 3D printers used in this study were the Ultimaker 2 Extended+ (Ultimaker B.V., Geldermalsen, The Netherlands). The material for printing the orthoses was polylactic acid (PLA), which was selected for its ease to thermoform. The only other component of the orthoses was Velcro, which was used for strapping the orthoses to users.

All parts were printed at 35%-40% infill (hexagon pattern), 60-100 mm/s print speed, 150-200 mm/s travel speed, 50°C heated bed, 0.15-.25 mm layer height, and 0.8mm shell thickness. No rafts or supports were necessary, as the orthoses were printed flat and then thermoformed to users' limbs.

The "Box and Block" was performed using a small, partitioned box filled with 120 identical blocks.



Figure 3: A) Unformed wrist splint; B) A 3D printed wrist splint, thermoformed to fit the user.

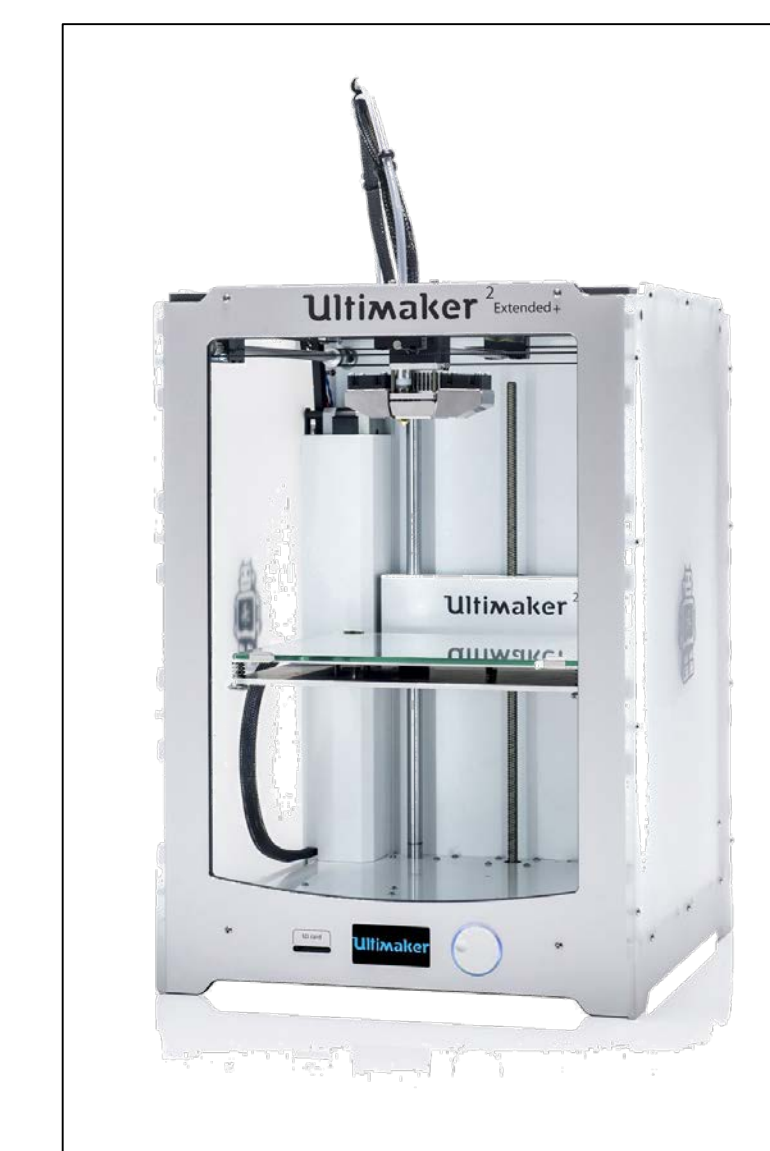


Figure 4: Low-cost 3D printer used for the production of the orthoses (Ultimaker)

RESULTS

Preliminary data from one subjects (a 26 year old male) indicates that the performance of the 3D printed wrist orthosis ($n = 56.25 \pm 0.957$ blocks) is not significantly different ($p = 0.531$) than that of the traditional, store-bought wrist orthosis ($n = 55.00 \pm 1.826$ blocks). Performance with either wrist orthosis was significantly worse ($p < 0.001$) than in the control condition ($n = 64 \pm 1.826$ blocks). (Figure 5)

It was noted during testing that the 3D printed orthosis was more comfortable than the traditional one, due to the breathability of the design compared to the fabric orthosis.

No significant differences in the difficulty of donning/doffing were noted, as both used Velcro straps.

Aesthetic appearance of the 3D printed splint was noted to be better than the traditional one; this was determined based on the decreased bulk, bright colors and geometric/organic design aspects.

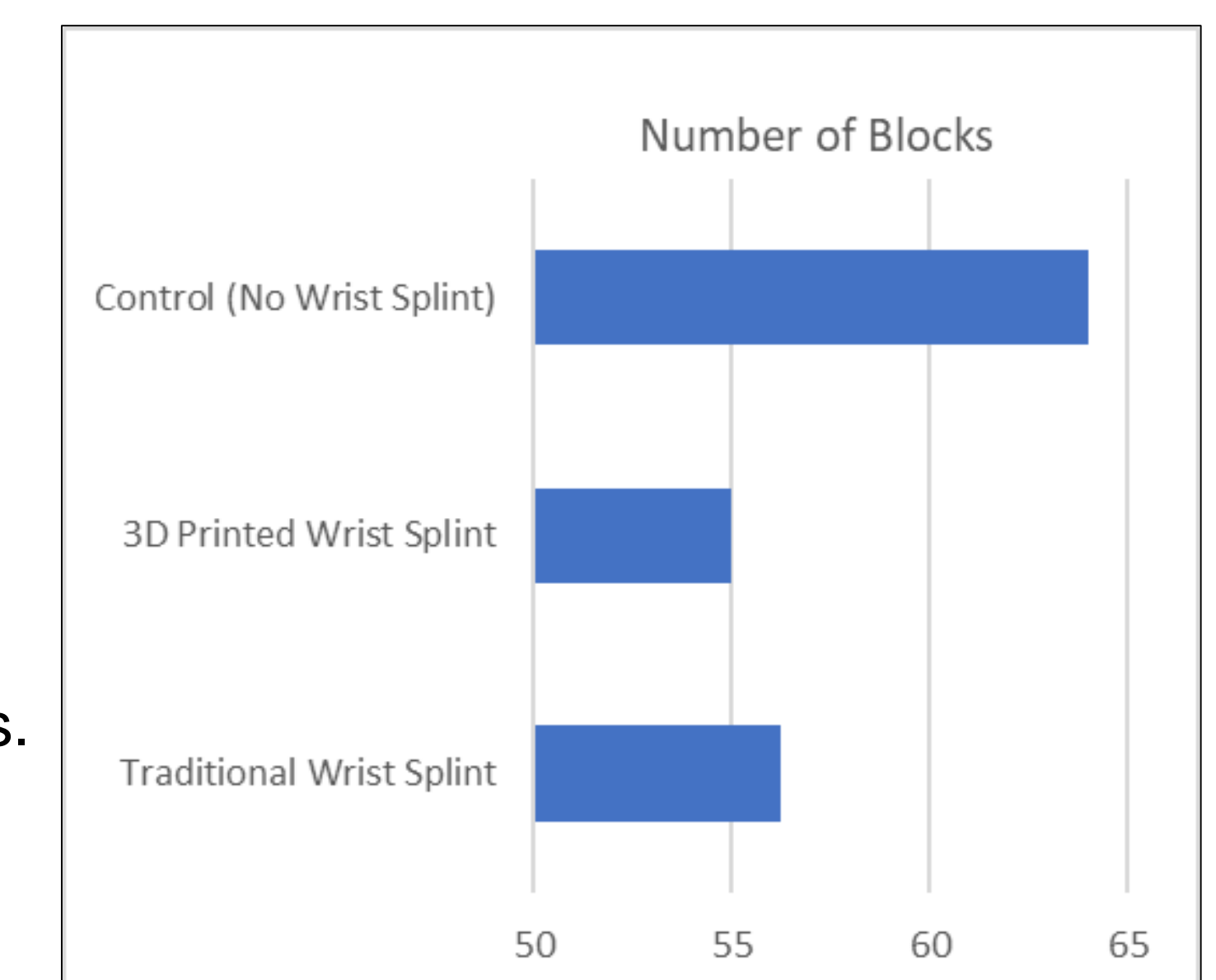


Figure 5: Functional gross manual dexterity differences between each type of wrist splint and a control (no splint) condition.

CONCLUSIONS

Full data collections will be performed for five young adults. Data analysis will be performed for gross manual dexterity and survey responses regarding comfort, ease of donning/doffing and aesthetic appearance.

Preliminary results indicate: No significant performance differences between traditional and 3D printed wrist orthoses, and worse performance with wrist orthoses in general compared to without. Full analysis of data will be available April 2019.

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