Hand Burn Rehabilitation Device

Validation and Verification

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Group 17

Overview

- Changes to overall project
- Validation/Verification Plan
- Results of proof-of-concept testing
- Current status of project

Changes to overall project

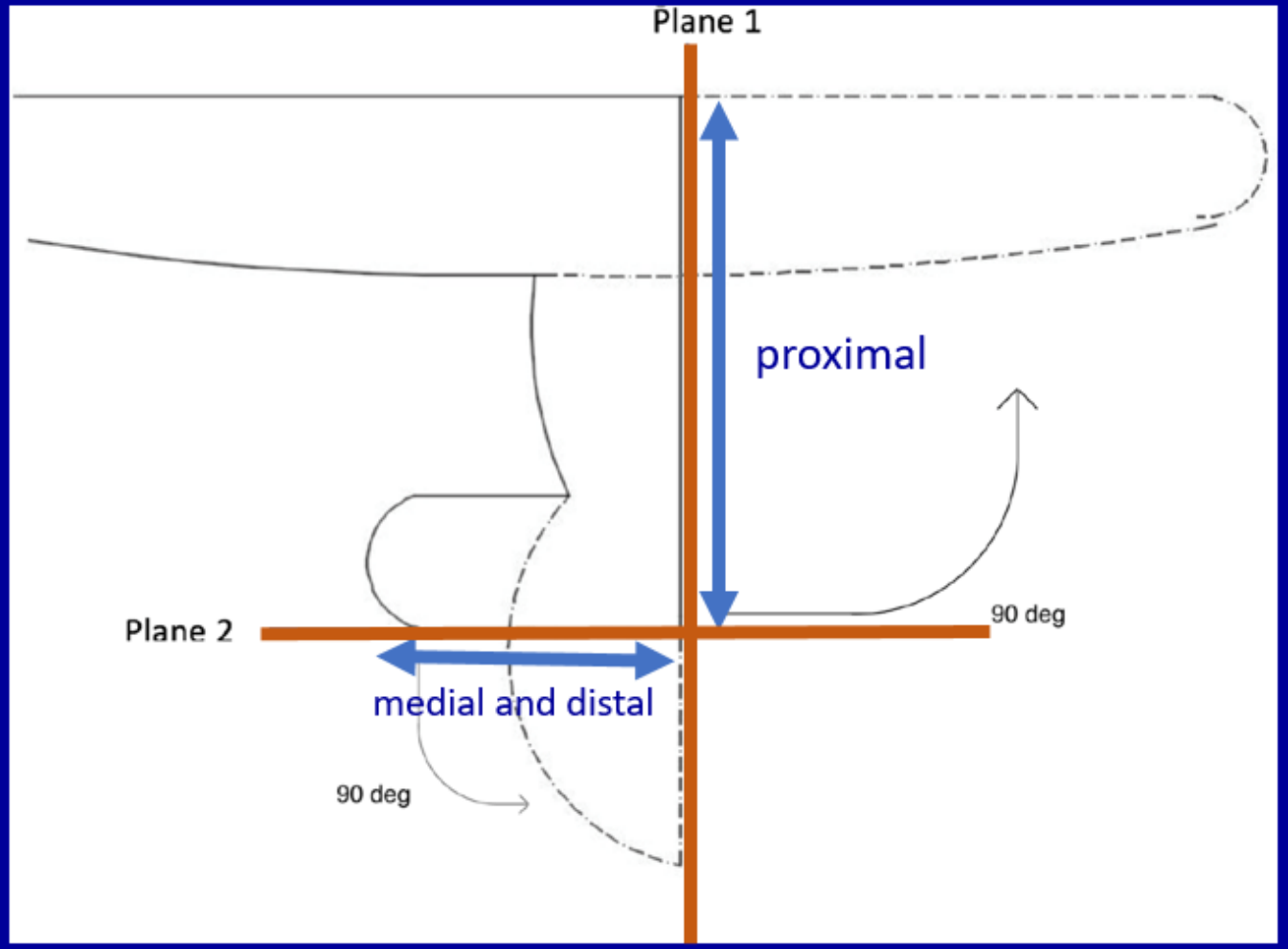
- No changes have been made to the need statement, project scope, design schedule or team responsibilities
- Two changes to design specifications

Changes to design specifications

- Waterproofness: 10 m to 1 m
- Due to feasibility of testing and after consideration of patient use

Changes to design specifications

- made the static progressive requirement more specific by adding an angular requirement
- Plane 1 along proximal phalanges will allow for 45-90 degrees of angular rotation
- Plane 2 along the medial and distal phalanges will also allow 45-90 degrees of angular movement



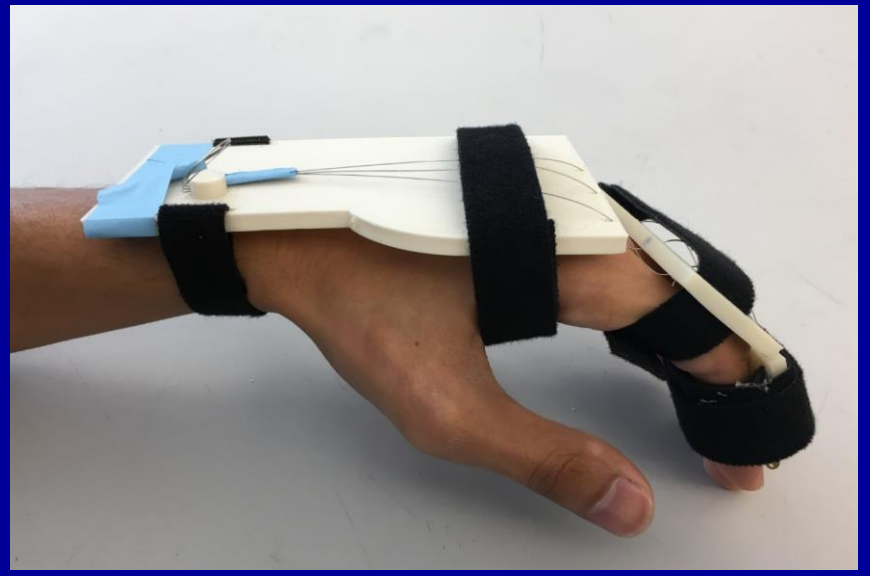
Cross section of left hand

Validation-Verification Plan

- Verification: perform tests to ensure that final prototype meets design specifications
  - Iterate through all design specifications
- Validation: ensure that client and patients are satisfied with the product

Validation-Verification Plan: Verification

- Overall effectiveness will be based on the **static progressive nature of exoskeleton**
- determined by measuring the two planar angles specified in the design specifications
- This test will be run while the splint is worn by one of our group members



Validation-Verification Plan: Verification

- Baseline angular readings of both angles will be taken by setting the splint to the lowest setting (least amount of tension)
- A second set of readings will then by taken by adjusting the splint to the highest setting
- The difference in the two angles must be greater than 45 degrees

Validation-Verification Plan: Verification

- **Waterproofness**:
- submerge device in 1 m of water for a period of 1 hour
- Perform static progressive test after to confirm device still works

Validation-Verification Plan: Verification

- **Temperature**:
- leave device in environment of 0 degrees C (freezer) for a period of an hour
- leave device in environment of 45 degrees C (warm water bath) for a period of an hour
- Perform static progressive test after both tests to confirm device still works

Validation-Verification Plan: Verification

- **Durability (drop test)**:
- Drop the device from a vertical distance of 2 m
- Perform static progressive test after to confirm device still works

Validation-Verification Plan: Verification

- **Breathability**:
- Have group member wear device while running for a distance of 400 m while outside temperature is greater than 21 degrees C
- If group member does not experience discomfort due to excessive sweating or heating caused by splint, breathability will be confirmed

Validation-Verification Plan: Verification

- **Ease-of-use:** have group member take off and put on splint without any assistance while being timed: <5 minutes is success
- **Mass** the final iteration of device will be massed: must be <0.45 kg
- **Total cost of materials** required to produce final iteration of device will be computed: <$20 dollars

Validation-Verification Plan: Verification

- **In case of failure with any test:**
- Design will be analyzed to see if any adjustments can be made to improve the effectiveness
- If requirement still cannot be met, the client will be consulted to see if the requirement can be adjusted (the requirement may not have been feasible such as in the waterproofness case)

Validation-Verification Plan: Validation

- It will not be possible to test our product in the real world since we will not have a patient population to work with
- two approaches will be taken to best validate the final device

Validation-Verification Plan: Validation

- First, the device will be presented to the client who will analyze the device to see if it matches their needs and requirements
- Critique will be used to determine the validity of the device

Validation-Verification Plan: Validation

- Second, a random participant will be chosen to wear the device over a period of 8 hours (within the same day)
- They will be presented with a questionnaire in two hour intervals (including at the beginning of the 8 hours)
- The questions will gauge their comfort level and satisfaction with the device
- the effectiveness of the splint will also be tested (using the static progressive test)

Validation-Verification Plan: Validation

- results will be analyzed to see if either the comfort or the effectiveness decreased significantly throughout the 8 hours
- a significant decrease will be described as a greater than 40 percent decrease in participant satisfaction or a failure of the static progressive test

Validation-Verification Plan: Validation

- **In case of requirements are not met:**
- Both client and participant will be asked to list their reservations about device
- These will be analyzed and appropriate modifications will be made to the device design

Proof-of-concept testing

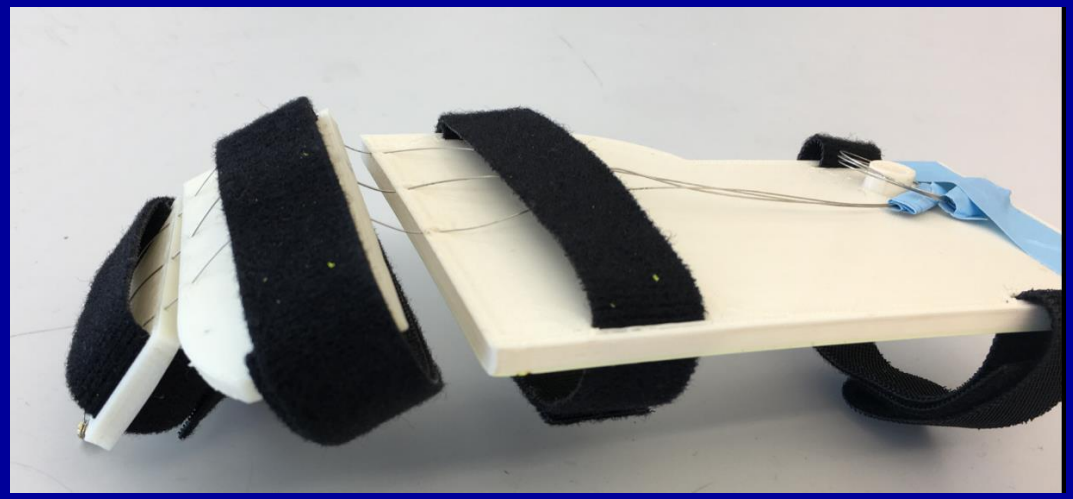
- The final prototype will compose of three unique modules: an inner lining of Hypafix, a compressive glove made from spandex, and an outer encapsulating exoskeletal splint
- Because the exoskeleton plays the largest role in the rehabilitation process, the proof-of-concept testing focused on ensuring it functioned properly

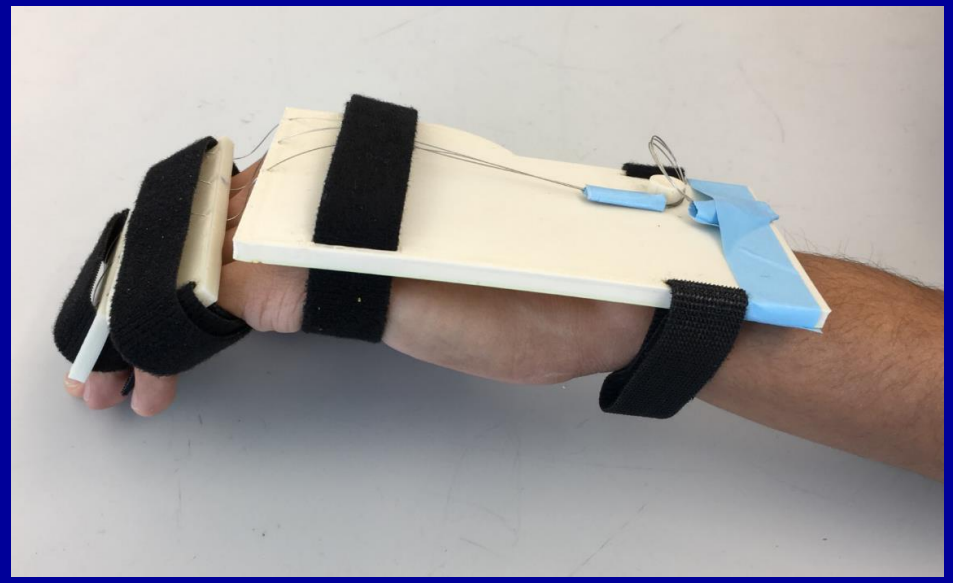
Proof-of-concept testing

- **Two properties were analyzed**
- its ability to restrict hand motion to only two degrees of freedom
- and its ability to rotate Plane 1 for a range of 45-90 degrees

Results of proof-of-concept testing

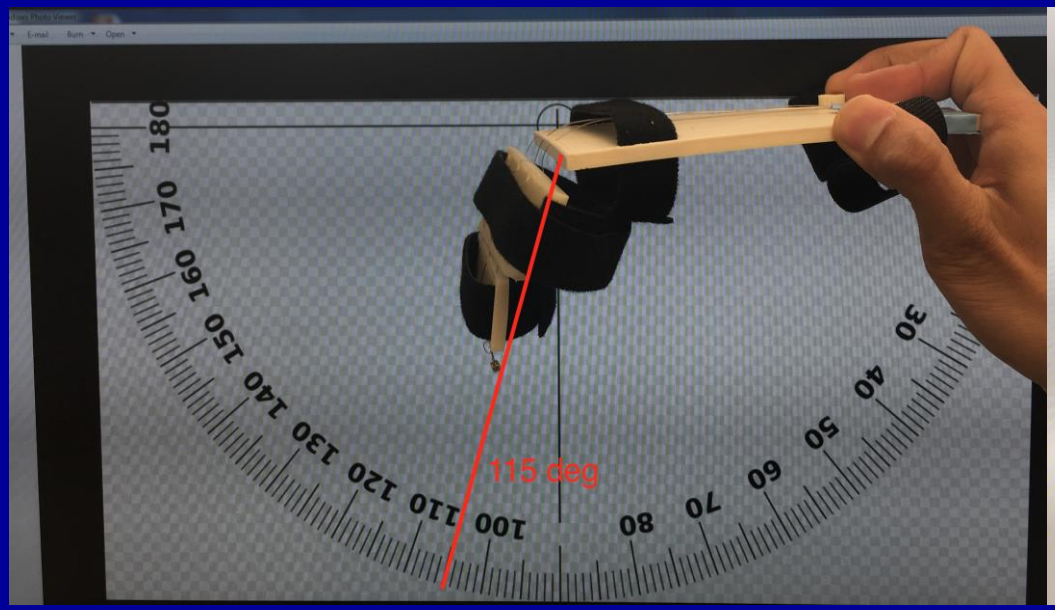
- Group member wore the device to test restriction of motion
- Device was able to restrict motion to two degrees of freedom

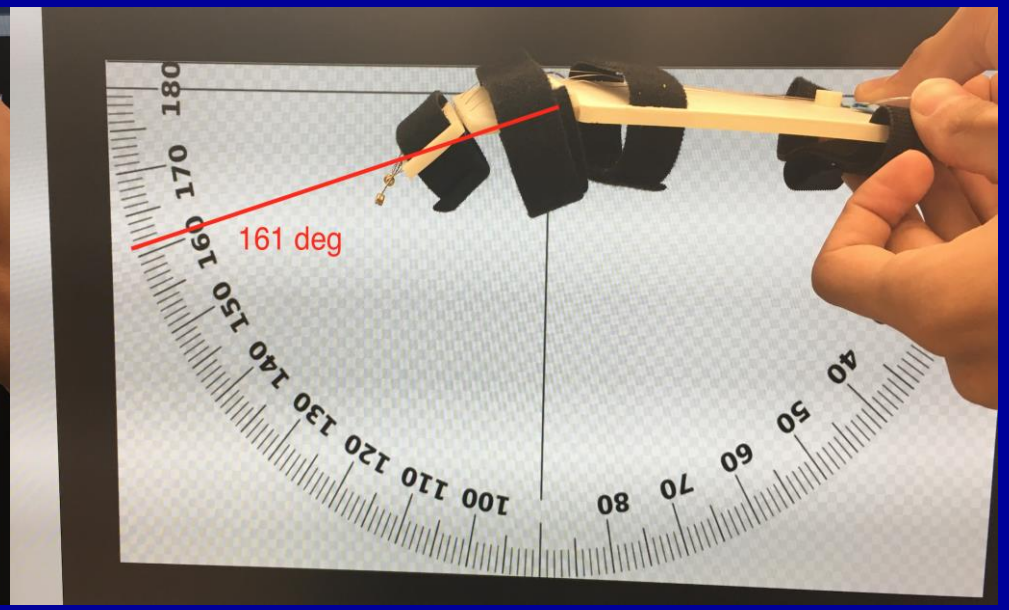




Results of proof-of-concept testing

- Adjusting the tension on the wire connection three pieces moved the splint 46 degrees along Plane 1





Results of proof-of-concept testing

- Even though device passed those two tests, it had some shortcomings
- Device was not very comfortable due to flat shape of splint components (addition of a glove layer will increase comfort)
- Tension had to be adjusted by pulling on the connecting wire (rather than through the use of a knob)

Current status of project

- Finished printing the first iteration of exoskeletal splint
- Next iteration will include a knob to adjust tension, will accommodate for the curvature of the hand, and will also take the thumb into account
- Left hand vs right hand will be taken into consideration

Current status of project

- Finished ordering materials for all three components
- Working on models for the elastic glove
- Once development of the splint is complete, the elastic glove and inner lining will be produced
- Will be taking textiles class at TechShop in order to create the elastic glove
- All three components will be put together to create final prototype

Questions?