SplintPal: A Monitor for Carpal Tunnel Syndrome Splints

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Background

Carpal tunnel syndrome is a neurological condition that affects the hands and the wrists. It results from the compression of the median nerve in the area known as the carpal tunnel, the space in the wrist surrounded by the bones of the wrist and the supporting ligaments. The tendons of the fingers pass through the carpal tunnel and surround the median nerve. Swelling of these tendons reduces the space in the tunnel and compresses the median nerve, which is responsible for the communication between the fingers, the hand, and the brain. Carpal tunnel syndrome can be congenital but is more commonly caused by physical stress to the wrist in the form of acute trauma, injury, and overuse. Symptoms of carpal tunnel syndrome include swelling of the wrist, numbness, a tingling sensation, acute pain, and stiffness of the fingers. There is a great deal of discomfort caused by carpal tunnel syndrome when performing everyday tasks such as typing, handling objects, turning keys, using tools, fastening buttons and doing outdoor work. It is the most common neuropathy of the body and affects 3-6% of the adult population, translating to about 3 million new cases a year (1).

Splinting is a commonly used intervention in the treatment of carpal tunnel syndrome and is generally seen as the first line of defense against mild to moderate symptoms. The majority of splints provide a comfortable base of support that immobilize the wrist in a position that minimizes the impingement of the median nerve. Clinicians have the freedom to prescribe different kinds of splints as well as different wearing regimens to best suit the needs of their patients.

The effectiveness of splinting, different styles of splints, and different wearing regimens is hard to measure, and, furthermore, studies that compare these factors are sparse and difficult to design. In fact, there have been no studies conducted on the benefits of

one specific recommended wearing regimen over another. Additionally, almost all studies fail to mention or account for wearing regimen when determining patient outcomes and the effectiveness of splints (2). For research to be conducted accurately and for methods of treating patients with carpal tunnel syndrome to be improved, proper use of splints must be adhered to and effectively monitored. Patient non compliance may be another large barrier in carpal tunnel splinting treatment and research, and it is usually not accounted for in studies. In one compliance study, researchers found that the mean compliance rate over five studies was 47.2% (3). This data was also collected via patient self-reporting and may be less accurate than reported.

Overall, very little is known about the effectiveness of splint wear and the benefits of various splint-wearing regiments. The inability to accurately quantify patient compliance or track wearing regimens may result in this lack of understanding in splinting since no effective or accurate approach to monitoring splint usage currently exists. Researchers and clinicians working to improve CTS treatment need a tool to effectively monitor splint usage in order to quantify patient compliance and evaluate the effectiveness of treatment.

Methods & Approaches

Through literature research and clinician interviews, our team found that very little consistent and reliable research exists in the context of splinting used to treat carpal tunnel syndrome. We discovered that this may be attributed to there being no effective way to monitor or account for how patients are using their splint outside of the clinic or research studies. We sought to create a device that addressed these fallbacks by identifying what we felt were important design criteria that met this need. We weighed our criteria in a design matrix based on our thoughts from a design perspective and included input obtained through clinical visits and interviews. Some important and heavily weighted criteria include the ability to determine if a patient is wearing their splint, the preservation of the biomechanics of treatment, the maintenance of patient comfort, and the ease of data acquisition. We then drafted various solution proposals,

and, after comparison of our design matrix with each proposed solution, our team decided that the solution we wanted to proceed with to prototyping was that of a sensor and battery-powered processor system that can be integrated into the splint.

To decide what sensor-processor combination would be the foundation of our design, we researched different kinds of sensors and performed a second iteration of a design matrix where we weighed factors such as sensitivity, accuracy, reliability, compatibility with splint biomechanics, and cost of these sensors. The decision to proceed with a force sensor stemmed from the consistency and reliability with which input can be received without excessive interference from external environmental factors. For example, accelerometers and thermistors can both receive information from a hot and moving car and read the data as though a splint in this car was being worn even if it was simply lying on the front seat. However, the signal detected by a force sensor can be specific to the simple contact between the splint and the patient once a predetermined threshold is reached and maintained. The remaining process of narrowing down to one processor and one kind of battery was done through a series of bench testing trials to determine the optimal combination of components that produced the most efficient system.

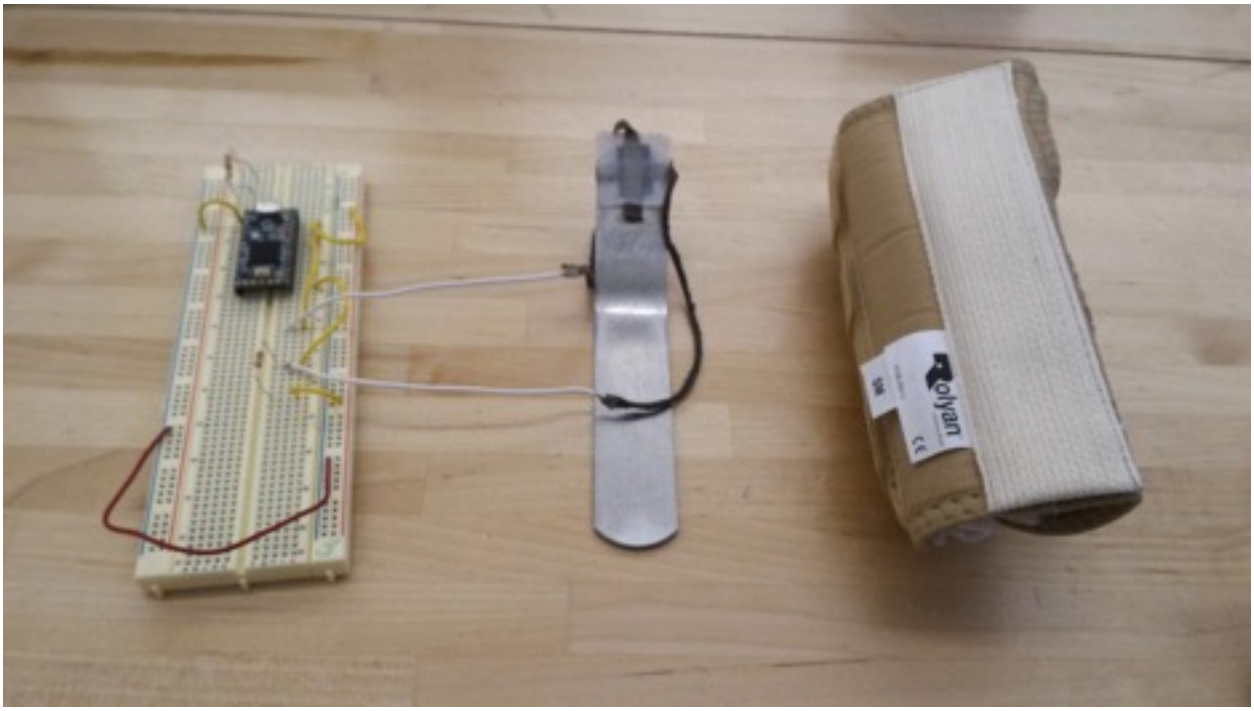
Description of Final Approach and Design

The final design of SplintPal is comprised of a textile force sensor made from conductive fabric and a Teensy 3.2 processor that is powered by a lithium battery. Most carpal tunnel splints are designed such that the stability of the splint is provided by a removable metal frame located on the volar side of the splint. This feature allows the splint to be washed when the metal frame is removed since the support and shape of the splint is regained when the frame is inserted again.

The textile sensor will be placed on the most distal part of the frame on the side that has contact with the hand. It will then be secured with an adhesive. To make insertion of the metal support with the textile sensor as smooth as possible, a flat covering made from

an appropriate material will be placed over the sensor and the accompanying circuitry. This will minimize the friction between the fabric of the sensor and the fabric of the splint to ensure proper placement of the sensor is maintained upon insertion. Additionally, this will allow the circuitry between the sensor and the processor to be protected and kept as close to the splint as possible as it exits the pocket of the metal frame and connects to the processor. The processor and power unit will be attached to the outside of the splint in the most unobtrusive location as possible. The exact location is highly dependant on the dimensions of the final design of the power unit and will be determined upon further testing.

Force readings will be taken from the sensor at an interval of 20 minutes and stored in the processor's internal memory until a clinician or researcher is able to upload the data onto a computer. The information can then be analyzed and represented graphically to quantify patient compliance and understand a patient's' splint wearing behavior between visits to the clinic.



SplintPal bench test system depicting the Teensy 3.2 processor on a breadboard and the textile force sensor placed onto the removable metal frame of the Rolyan Splint.

Outcomes

Since SplintPal is still in its developmental phase, we do not currently have any outcomes testing or user feedback. However, our primary expected outcome is to enable researchers with a reliable research tool to collect data and quantify compliance.

Cost

Our anticipated product will consist of a sensor, processor, battery, breadboard, and case. A suitably small Teensy processor for our system will be approximately $25 while a lithium battery will cost $10. We anticipate the breadboard will be $5, bringing the total cost to $40. Our sensor and case will also have minor manufacturing costs that we have not determined. However, we do not anticipate the total cost of SplintPal to exceed $50.

Significance

Our most significant predicted beneficiaries are researchers. Using SplintPal, researchers will be able to conduct studies that test the effectiveness of splinting as well as several factors of splinting treatment, such as different styles of splints and different prescribed wearing regimens. For example, a standardized wearing regimen may be tested for and developed in a research setting in order to help future patients with carpal tunnel syndrome.

We expect that clinicians and patients also benefit from SplintPal. Clinicians will be able to track patient compliance and know if splinting is truly benefitting the patient or not. There will no longer be a need to rely on patient self-reporting, which has been shown to be inaccurate and misleading. Patients will also have a greater sense of accountability due to the monitoring system, which may lead to more consistent splint use and result in greater patient compliance.

Finally, the application of SplintPal can be expanded to cases outside the context of carpal tunnel syndrome. Any disease or disorder requiring the use of a splint could also utilize SplintPal in order to track compliance and patient outcomes. For example, an app can display the data collected by SplintPal to the patient and can be customized by either the patient or their clinician to set compliance reminders, a simple notification to remind the patient to wear their splint if they are not doing so. This potential application would be revolutionary in the treatment of carpal tunnel syndrome and other medical conditions that require splinting.

Acknowledgements and References

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