Fashionable 3D Printed Wrist Support for Young Adults with Rheumatoid Arthritis

Jennifer Farmerie, Marine Sanosyan, and Elise Scipioni
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Abstract

Rheumatoid Arthritis is an inflammatory, autoimmune disease affecting joints in the hands, wrists, and knees and potentially leading to joint deformity. A possible solution is surgery, which is expensive, irreversible, and not guaranteed. Another solution is a wearable assistive device, however they have been known to be uncomfortable and not visually appealing. After conducting an interview with a student with RA, we gained some insight into the limitations of her current devices. Based on her responses, we hypothesize that there is an ability to generate assistive devices using new and aesthetic fabrication methods, which will not only be more comfortable but also make a social impact. We created a 3D printed wrist brace customized to our need-knower's wrist, incorporating 2 FSR's to monitor the forces being applied on her wrist. We proposed a 3 month study to test our device against other traditional devices to prove our hypothesis. If our hypothesis is proven true, this affordable technology can be easily replicated and adapted to RA patients around the world, providing the best hope of recovery.

I. Introduction

Rheumatoid arthritis is an autoimmune disease which thickens the synovium around the joints [1]. Common symptoms of this disease are pain, swelling, stiffness, and deformity in joints, which can often lead individuals to struggle in performing daily activities. RA has a 1 percent prevalence worldwide, meaning that out of 100 people, at least 1 individual is diagnosed with RA [2]. Additionally, about 75 percent of patients with RA present hand deformity [1]. We are addressing the challenges that individuals who struggle in performing daily activities face, particularly due to the pain they experience. We want to prioritize wrist support, as this is an important feature for several individuals with RA. Our goal with this project is to provide RA patients with an assistive device that stabilizes the wrist while still allowing them to perform the daily activities they enjoy. Additionally, we want to assure that our device is aesthetically pleasing while still providing all of its functionalities. This is primarily because the results of several studies show that patients do not use their current devices because it is uncomfortable and unattractive to wear, emphasizing the need for improvement in the design and aesthetics of assistive devices [3]. We hope that RA patients around the world can confidently wear this device to prevent pain while still performing their favorite daily activities.

A. *Background*

Impacts: RA is not only difficult to diagnose, but also difficult to treat. The major symptoms individuals feel are joint pain, redness, warmth, swelling and stiffness, in addition to weakness and loss of control[4]. Patients tend to have the least range of motion and grip strength in the hand and wrist, and are unable to complete pinching exercises [5]. Individuals also experience fatigue, sleeping difficulties, and depressive symptoms as a result of RA [4]. RA is also known to be an invisible disability, meaning that it is not evident to those around you. This means that the assistive technology also plays a crucial role in how an individual is seen by others. This can have an impact their self esteem, especially for young adults, since they don't want to be viewed as different from everybody else.

Types of therapy: There is currently no known cure for RA, however there are a number of assistive devices on the market, as well as therapy exercises, which are used to treat RA. Some common devices individuals own include grab bars, orthopedic shoes, pillows, shower chairs, and electric can openers [3].

However, in a study conducted with the usage of these devices, majority complained that the devices were not comfortable or easy to use [3]. Physiotherapy is also a promising treatment for RA, as performing strengthening exercises can improve hand grip, pinch strength, and functionality. However, there is a lack of documentation on their effects[6].

Jewelry/Exoskeletons: There is a noticeable trend as well as an increased interest in the use of jewelry and exoskeletons as assistive devices for RA. For example, silver ring splints have shown to be relatively successful in increasing dexterity [7]. Not only are they a promising solution, but they are also aesthetic and don't strike individuals as a medical device. While majority of individuals in a study conducted stated that they would continue using the splint, they requested that optimal adjustment be done. We have also seen soft robotics become highly applicable and successful in the biomedical field, especially in relation to grasping and manipulation [8]. This is also a promising solution, since majority of individuals complain about the comfort of current devices, and soft robotics are commonly made of soft materials. There is a lack of scientific information about how effective these technologies are, but we believe that there is great potential in both of these fields. Our goal with our project is to create supportive jewelry that takes advantage of the accessible and personalized soft fabrication methods emerging today.

B. Overview

We hypothesize that there is an ability to generate an effective device using new fabrication methods, such as a sparse design using 3D printing of a personalized shape. We also hypothesize that device aesthetics plays a crucial role in social impact. By customizing the brace to each individuals arm and making it visually appealing, we hope to provide RA patients with a more comfortable and aesthetic assistive device. Conducting an interview with a student with RA in Section II allowed us to understand her primary needs, highlighting the importance of stabilization, comfort, and aesthetics. Section III presents our 3D printed voronoi patterned wrist brace incorporating FSR sensors, as well as our proposed study to assess the ability of our device and prove our hypothesis. If proven true, Section IV discusses how the wrist brace can be easily replicated and adapted to fit anyone with RA, and Section V discusses the broader impact this technology can have.

II. Preliminary results

To gain an in-depth understanding of the goals and requirements of our device to aid a user with RA, we conducted an interview with a student with juvenile RA. During this interview, we had the client go through her everyday life and talk about the disruptions caused by her RA, and what some limitations were of her current assistive devices. Our 90 minute interview took place in-person, with masks on, which made it difficult to gauge emotions, but the meeting was very enlightening and helped our team understand what to implement in our assistive device to help the client.

While our client was officially diagnosed with RA around the age of 15, she struggled to obtain this diagnosis for numerous years, resulting in severe inflammation and joint deformity in her wrists, and even toes. Initially she tried physical therapy, but found that she was only able to regain her strength to a certain extent. She was also given anti-inflammatory medicine, steroid injections in her wrists to control inflammation, and a splint for her finger and wrists. The medicine and injections have helped to reduce the inflammation, but she found the splints' lack of results and comfort frustrating and decided to wear them only when necessary, unfortunately still leaving her with severe wrist and joint discomfort.

During the conversation with our client, we were able to gauge key needs that she desired in order to have a more functional assistive device that she would want to wear consistently. One of the major sources of frustration for her comes from wrist pain, so providing a device that could stabilize her wrist was of utmost importance. She also talked about how her current splint was uncomfortable, broke easily, and was visually unappealing, causing our client to want to hide it from sight. This supported our idea to develop a device that was comfortable, flexible but strong, and aesthetically pleasing. Another detail disclosed by our client was that she enjoys painting and drawing and does not want to lose those fine motor skills. Thus, we hope to provide her with a solution that promotes her range of motion, while also providing support and stabilization. Below in Table 1 is a short list of the needs generated relevant to our device generation.

TABLE I
KEY CUSTOMER NEEDS

Customer Statements:	**Customer Needs:**
Typing is fine for me, but handwriting is hard and irritates my wrist	The device supports wrist motion and ability to write
I want the device to be stabilizing	The device will provide stabilization of the joint in the wrist
I hate the aesthetics of it	The device can be visually pleasing to the user's eye
It can get really hot and sweaty	The device allows for proper airflow
I want the device to be comfortable	The device is compatible with skin while doing body movements

At the conclusion of the interview, our team had generated an extensive list of needs, even more than previously mentioned, which can be referenced in Appendix B-A. While the research we had referenced prior to the interview was helpful, the interview with our client helped us generate a deeper understanding of her needs and a motivation to design and develop an assistive device that would help her and possibly other RA patients in day to day activities. We believe we can accomplish this through establishing a focus on comfort, wrist stabilization, and flexibility for a wide range of motion.

III. METHODS

A. *Device Concept:*

We have created an assistive device to test the effect of flexibility, comfort, and aesthetics on the ability to successfully stabilize the wrist, as displayed in Fig. 1. We have accomplished this by creating a 3D printed voronoi patterned wrist brace made of a bio-compatible flexible polymer. The device has a string tightening mechanism that when tightened, will increase support on the wrist, or when it is loosened, it can be easy to take on and off. The voronoi pattern established throughout the wrist brace has a higher infill density around the wrist bone, where the user needs to be stabilized, and a lower infill density around the fingers and arm, to promote full range of motion and flexibility. The pattern of the device and the polymer it is comprised of is inconspicuous to the eye, and visually appealing.

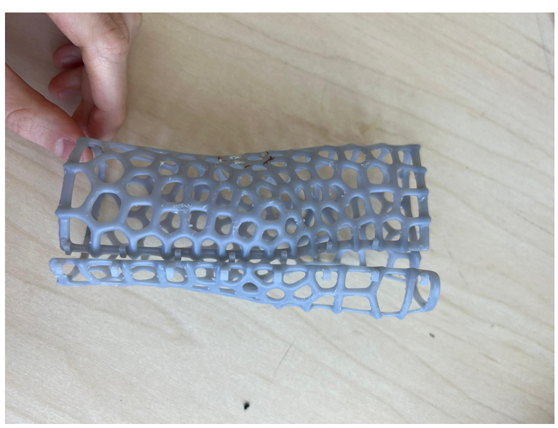

Fig. 1. 3D Printed Wrist Brace

B. Subsystem description / proof of function:

Our device is made of 4 parts: a 3D printed voronoi patterned wrist brace, a string, a string tightening wheel mechanism, and multiple FSR sensors. as displayed in Fig. 2. For the 3D printed voronoi patterned wrist brace, we decided to harness this pattern because the voronoi pattern is gaining popularity for its organic and natural spatial structures. The voronoi pattern is a form of biomimicry, where shapes are adapted to replicate cells found in nature and the human body. After analyzing this pattern, we realized that with the organic, natural pattern, it not only provides stability to our user, but also provides ample air flow throughout the device, reducing overheating and enhancing comfort. As mentioned previously, we were able to increase the infill density of this pattern around the wrist bone, providing an increased stabilizing force when the brace is tightened. Additionally, leveraging 3D printing technology allowed our team to produce a device that was strong, but still flexible and biocompatible, in a short period of time. The specific software we used to design the voronoi pattern was nTopology. We utilized the Form 3 SLA Printers located in the Jacobs Makerspace, and 3D printed using Tough 1500 resin as our material of choice. This allowed us to complete multiple iterations of our device quickly and make the desired improvements, such as a more comfortable fit or a larger gap to insert the wrist, in a short period of time.

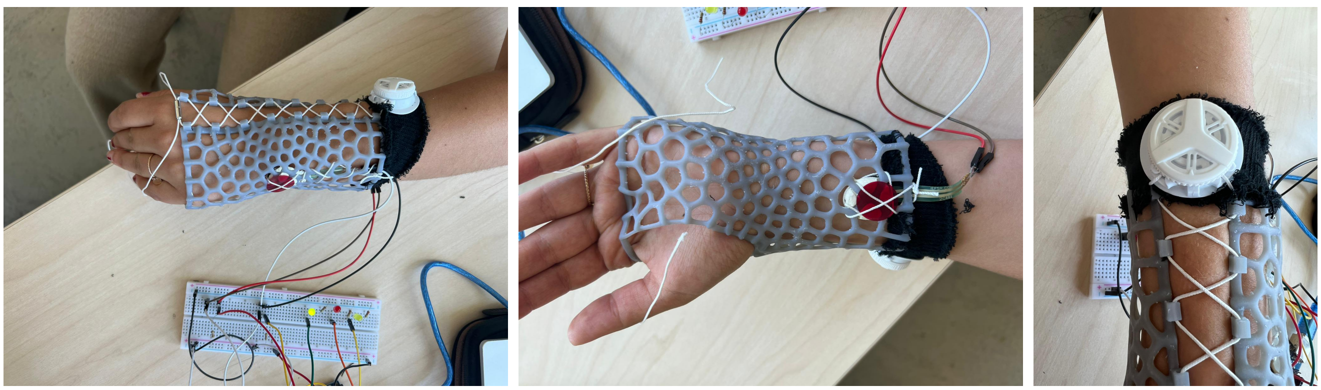

Fig. 2. Final Prototype images, showing the lacing path and tightening ratchet. The red dots indicate where pressure sensors are located within the brace.

As for the tightening mechanism, our 3D printed brace has loops designed on the edges, as displayed in Fig. 2(right), that allow us to weave a string between. This string is then connected to our wheel tightening mechanism. This mechanism is able to tighten the strings and pull the wrist brace edges closer together when turned one direction, and loosen the strings to easily allow the user to remove the brace from their wrist when the wheel is turned the other direction.

The last component in our device is the FSR sensors, which are used to monitor the efficacy of the device during the study. We have two sensors attached to our device, one spanning the metacarpals on the dorsal side of the hand, and one FSR below the proximal carpals. Putting the FSRs in these locations allow us to monitor any increase in force in our user's wrist while using the device, which would help us prove if our device is decreasing load on her wrist and increasing stabilization. THE FSR does not need to be included for day to day use of the device, merely for monitoring purposes.

C. Prototype Iterations:

We went through a few iterations of prototypes before achieving our final device. We first 3D printed our wrist brace using a flexible material on the Form 3 SLA Printers. This original prototype utilized the voronoi pattern with a low density. However, the material was not biocompatible, and the prototype did not completely cover the wrist. We were able to present this prototype who our need-knower, who provided us with some crucial feedback. She stated that although the material was flexible, she felt that it was not sturdy enough to stabilize the wrist. Additionally, she felt that the prototype should be a bit longer and cover more of the wrist to allow for more stability. With this feedback in mind, we created our next iteration of the prototype.

Our second prototype utilized tough 1500 as our biocompatible material, which was much sturdier while still allowing flexibility. Additionally, we extended the device to be longer than the previous one in order to provide better suport and unload the wrist. We also increased the density around the wrist bone to allow for more stability. Our need-knower was extremely happy with this new prototype, and strongly preferred it over the first prototype. However, a few improvement she had requested were to increase the thickness of the material between her thumb and index finger, in fear that it may break while completing daily activities. Additionally, we adjusted the pattern to sit lower on the palm of her hand to be more comfortable and allow mobility in the fingers. We also changed the hooks on the device into closed holes to prevent the strings of the tightening mechanism from falling out. Lastly, we added a wrist band to fix the closing mechanism and prevent it from moving. Images of the iterations of our prototypes can be found in Appendix C-G.

D. A proposed study:

The main purpose of conducting testing is to assess the ability of our device to systematically stabilize the wrist. This chronic disease is capable of causing joint deformity in the bone structure of the wrist. We want to help people with RA regain their strength and motor functions in their hands, no matter how impacted the bone structure is. To do so we will have to conduct testing on human subjects with RA, specifically affecting the wrist.

A pre-evaluation of patients X-rays will determine the affect of RA on a patient's wrist joint and bones. Regarding our inclusion criteria, eligible patients will have a verified diagnosis of rheumatoid arthritis that only impacts their wrist or distal part of their upper limb/proximal part of their hands and that has been treated for at least one year. Additionally, they should be able to perform a movement pattern in one hand or both hands to pick up a glass. Eligible patients will be randomly divided into 2 groups: either a test group which will benefit from the use of the device over a period of 3 months or a control group who will wear a traditional wrist bracelet commonly used in therapy.

Outcomes measured will include pain, wrist stabilization, and range of motion during daily activities as well as the frequency at which patients use the device. Active range of motion will be assessed using a goniometer, and experienced functioning in daily life using the Michigan Hand Outcome Questionnaire and Disability of Arm, Shoulder, and Hand questionnaire, found in Appendix C-A, C-B. We will also assess grip strength with a Jamar dynamometer. Measurements of such metrics will be conducted before the trial, at the halfway point of the study, and at study completion. We will gather subjects' opinions and attitudes regarding the aesthetics and social impact of the device by asking a series of survey questions at the beginning and end of the study, displayed in Appendix C-C.

The testing protocol will comprise of several steps, inspired by our user interview where our need-knower mentioned particular difficult daily tasks for wrist stability. Subjects are asked to continue their daily lives as normal and are requested to wear the device for at least 2 hours every day. They would also have to keep a journal of how long they wear it for, including if they are under the requested time.

E. Discussion of procedure / expected outcomes:

The main limitation of our study will be to avoid the placebo effect, which is when the excitement of testing a new treatment causes the patients to report significant improvements without any actual significant clinical evidence. Additionally, reasons for the lack of significant changes in ROM or strength can be due to the variation of RA and its impact on bone structure from one patient to another, leading to different effects on the wrist and interactions with the device. An idea to tackle this problem would be to develop a patient-specific mesh where the density of the pattern would be tuned according to each patient's deformities in the wrist.

Another difficulty we may encounter while assessing the effectiveness of our device is its impact on pain. It would be difficult to determine if pain is either caused by the use of the device, and thus results in a design challenge to improve its ergonomics, or if it is a flare up caused by RA. The level of pain encountered is also difficult to measure because it depends on the pain tolerance of the patient tolerance.

For now, we think this is a good procedure to assess the functionality of the device, while still analysing any risks or hazards encountered in their daily environment while using the device. Feedback from users on discomfort and aesthetics will directly lead to an improvement in the design that can be easily changed on our CAD model. We have completed CITI training for human research, however, in order to conduct such a study, we would need to receive Internal Review Board Certification prior to running the aforementioned study we outlined in our proposal.

IV. Intellectual Merit

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Through the testing of our device, we will be able to assess the impact flexibility and comfort has on wrist stability in patients with RA. While our device is custom fit to our client, the material and pattern can be easily replicated and adapted to fit anyone with RA to provide them joint support and relief, while also maintaining comfort. Hopefully, the testing of our device will signify within the academic community the need to incorporate new ideas in the form of flexible polymers and intuitive design patterns into existing technologies, such as hard plastic wrist molds. By regularly adapting and improving medical devices based on new proven successful research, engineers can provide the best hope of recovery and increased satisfaction in patients suffering from RA.

Through the testing of our device, we also want to test the aesthetic of the device and assess how easily our need-knower would adopt it for a daily use. Considering that RA is an invisible disability, we want to assure that the device blends in as jewelry and doesn't stand out as a medical device. By doing so, our need-knowers can feel more confident when wearing their device and not feel excluded from others around them. Hopefully, the testing of our device will signify the need to incorporate more fashionable designs while developing medical devices and consider the aesthetics of wearable devices as a way for subjects to be less stigmatized and more accepted in a social environment.

V. Broader Impact

RA affects the wrist in 2.5 million people in the US, and the general prevalence of wrist arthritis is 75% [9]. Treatments to ensure wrist stabilization are either irreversible and with considerable risks or they are uncomfortable, and not custom-fit. With our 3D printed device, that costs only $40, we offer a non-invasive, accessible, and custom-fit solution to stabilize and support the wrist in patients with RA. The idea will be an open source CAD model that includes a scan of the patient's wrist, and the use of the software NTopology. The model can be adapted to the patient's wrist and 3D printed. This offers an inexpensive and easy solution to manufacture this device.

The main purpose of the device is to support the wrist, while also preserving range of motion. Our bracelet may also be adapted in the sports industry to protect the wrist during workouts, such as push ups. With our device we see a future where patients with RA can have a device that fits seamlessly into their everyday life, not one where they must adapt to fit the needs of a device.

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APPENDIX A
DISCOVERY DECOMPOSITION

1) Involvement of Joints and Deformity Pattern with Seropositivity in Rheumatoid Arthritis: [1].

- Background/Hypothesis: RA is an autoimmune systemic disease that thickens the synovium around the joints causing pain and joint deformity.
- Methods: Researchers used descriptive statistics, Chi-Square tests, and Fischer's exact tests to determine the relationship between joint involvement and deformity in patients.
- Results: Hand and joint deformity had nothing to do with age and sex and was found to be 79.2 percent more common in patients that were positive with the anti-cyclic citrullinated peptide antibody and were RA positive.
- Conclusion: Patients that have hand and wrist joint deformities are likely to be positive for the anti-cyclic citrullinated peptide antibody and RA positive.
- Test Hypothesis: In the future, testing patients for the Anti-CCP antibody and RA will be a good predictor if they will have errosive RA and joint deformity.

2) Effect of Mechanical Stress on Rheumatoid Arthritis of the Temporomandibular Joint: a Morphological and Histological Evaluation: [2].

- Background/Hypothesis: Rheumatoid arthritis of the temporomandibular joint is proven to being diagnosed in patients at a much higher rate than RA, and is thought to be triggered by mechanical stress on the joint.
- Methods: The team of researchers created different groups of mice, some with RA, others without, and added mechanical stress to the TMJ to see the relationship between TMJ-RA and mechanical stress.
- Results: After mechanical stress, mice with RA revealed a decrease in the chondrocyte layer width and an increase in the number of osteoclasts in the mandibular condyle.
- Conclusion: When mechanical stress is applied, the TMJ-RA significantly worsens, wheras when RA acts on its own, the TMJ is less sensitive.
- Test Hypothesis: TMJ-RA is excacerbated by MS, and certain T cells in this joint are affected by MS. In the future, therapy targeting these specific cells may be required for TMJ-RA.

3) Assistive devices: usage in patients with rheumatoid arthritis: [3].

- Background/Hypothesis: Assistive devices have the ability to improve functional ability for individuals with rheumatoid arthritis, and as a result are commonly prescribed for patients.
- Methods: A study was conducted to study the usage of these devices, measuring the presence of an impairment/limitation as well as the usage and satisfaction of each specific device.
- Results: 89 percent of individuals in the study owned at least one assistive device, majority being grab bars, orthopedic shoes, pillows, shower chairs, and electric can openers.
- Conclusion: Certain devices were not used because they were not comfortable or easy to use. Most commonly unused device was orthopedic footwear.
- Test Hypothesis: Rheumatoid arthritis patients need a device that can enable activity they have difficulty doing.

4) Symptoms in individuals at risk of rheumatoid arthritis: [4].

- Background/Hypothesis: Identifying and understanding the symptoms of rheumatoid arthritis (RA) for individuals who may be at risk is a critical issue.
- Methods: Qualitative and quantitative research were conducted to explore the symptoms experienced by individuals. Surveys were conducted, as well as interviews and focus groups.
- Results: These symptoms carry a heavy burden on patients, which result in significant physical and psychological impact.

- Conclusion: There are 5 major themes in regards to symptoms: 1. Pain in and around the joints 2. Joint redness, warmth, swelling, and stiffness 3. Weakness and loss of motor control 4. Fatigue, sleeping difficulties and depressive symptoms 5. Pattern of symptom experience and onset.
- Test Hypothesis: The knowledge of these symptoms can help individuals seek help, get properly diagnosed, and prevent further damage.

5) Direct, quantitative clinical assessment of hand function: usefulness and reproducibility: [5].

- Background/Hypothesis:). Techniques to measure hand functions and disability are subjective and variable. Joint motion and functional strength measurements are evaulated for Rheumatoid arthritis (RA) and Osteoarthritis (OA).
- Methods: The method comprises 2 steps :
- 1. Pain chart is documented (Coachin/VAS)
- 2. The strength testing comprises 3 prehensile patterns: key grip, pinch, and power grip measured using a pinchmeter and a grip dynamometer. ROM is measured as the total range from maximal flexion to maximal extension of each joint.
- Results: There is a correlation between disability, ROM and disease duration. RA patients tend to have the least ROM and grip strength in hand and wrist and can't complete the pinch exercise. Pain is mostly located in MCP-PIP areas.
- Conclusion: It is complex to precisely assess the damage causes by RA on hand functions.
- Test Hypothesis: Because of great variability outcomes, no method of choice for hand function assessment for RA or OA is defined.

6) Strengthening exercises to improve hand strength and functionality in rheumatoid arthritis with hand deformities: a randomized, controlled trial: [6].

- Background/Hypothesis: Physiotherapy is a promising treatment for RA, but there is a lack of documentation on their effects on hand functionality. The objective of this study was to assess the effects of an exercise program.
- Methods: Before any treatments the hand grip and pinch strength of subjects are assessed using a dynamometer and pinch gauge. Exercises mainly focus on strengthening the intrinsic and extrinsic muscles of the hands.The intensity and the load of the strength exercises increase after 3 weeks.
- Results: RA patients following the exercising program show significant increase in handgrip strength and pinch strength especially the one involving the thumb and index finger for both hands after 10 sessions.
- Conclusion: The developed program is beneficial for hand grip, pinch strength and functionality.
- Test Hypothesis: The designed program showed promising outcomes on hand functionality for RA patients.

7) Silver ring splints improve dexterity in patients with rheumatoid arthritis: [7].

- Background/Hypothesis: Surgery is an invasive operation to treat RA. Silver ring splints (SRS) can be a non invasive, easy to use solution. The study aims at evaluating the effect of SRS on hand function.
- Methods: 29 patients are given proper SRS : - Dexterity is measured using a SODA score : the therapist rates the way tasks are performed and their difficulty. - Strength is measured by asking patients to squeeze a hand-pressure balloon(3 attempts). - Hand function is evaluated by asking 5 questions. - 28 joints tenderness and swelling are assessed by rheumatologist.
- Results: Dexterity (SODA dexterity score) increases significantly (+14 pts after 1 year). 11 subject out of 15 will continue to use SRS.
- Conclusion: The use of silver ring splints leads to satisfactory results. But optimal adjustment should be done.

- Test Hypothesis: Silver rings is a promising solution for RA patients who show net improvements.

8) Moving toward Soft Robotics: A Decade Review of the Design of Hand Exoskeletons: [8].

- Background/Hypothesis: Soft Robotics have become highly applicable and successful in the biomedical field in relation to grasping and manipulation.
- Methods: A review was conducted to identify the trend of soft robotics in hand exoskeletons starting from the year 2008, studying the design of different exoskeletons based on their mechanical, electrical, and functional attributes.
- Results: A tendon/cable-driven mechanism is most commonly embedded in the soft hand glove, however there has been a shift to pneumatic actuation.
- Conclusion: Pneumatic-based soft robotic hand exoskeletons have several advantages over tendon/cable-driven mechanisms.
- Test Hypothesis: There is the potential of a hybrid approach using both tendon/cable and pneumatic-based actuation to receive advantages on both sides.

Appendix B
Investigational Device Details

A. Interpret the Interview Results

TABLE II
CUSTOMER NEEDS

Customer Statements:	**Customer Needs:**
Typing is fine for me, but handwriting is hard and irritates my wrist	The device supports wrist motion and ability to write
I have limited grip and pinch strength in both hands, especially left hands, apparent when I carry bags/books/single item holds	The device assist the user in grip and pinch strength for bags/books/ other school supplies
When I wake up and it is hurting I can't make food, squeeze my toothpaste, and I can't take notes	The device enables the user to do daily activities/ simple tasks/grasps
I cant do push ups because wrist can't move 90 degrees	The device will promote full range of motion of wrist
I can't grip upper body exercise equipment at the gym due to lack of grip strength	The device will aid grip strength for gym equipment
I can't carry heavy things because of the pain	The device will support load on the wrist
I can't open tight jars because I don't have enough strength	The device will offer wrist support in torsional motions
Washing the dishes is a particular difficult task, as my hands are wet and I have to hold and manipulate carefully and precisely the dishes	The device will adapt to wet/slippery surfaces
I like how its stable and immobilizes my wrist	The device remains aligned with her hand and reduces pain
I like that it is custom fit for me	The device can comfortably fit the hand as it is custom made
Velcro is loud	The device can be quiet and not draw attention
Things stick to it	Material choice of the device promotes use in any environment
Limits the range of motion of her fingers	The device allows range of motion in her fingers
Splint is not strong and breaks often	The device can be strong and sturdy
Design it to be more heavily utilized	The device is easy to use
I want more flexibility	The device would allow range of motion in the wrist
I want improvements in wrist splint and load offsetting (deloading the wrist)	The device can transfer load to the upper arm
I want to increase grip strength	The device will offer increased grip strength
I want something that can be worn for longer periods of time and that can be still taken on and off	The device is durable and reliable
I want the device to be stabilizing	The device will provide stabilization of the joint in the wrist
I hate the aesthetics of it	The device can be visually pleasing to the user's eye
It can get really hot and sweaty	The device allows for proper airflow
I want the device to be comfortable	The device is compatible with skin while doing body movements

Ranked list of customer needs:

The device allows for hand stabilization
*The device will provide stabilization of the joint in the wrist
*The device remains aligned with the hand
*The device will support load on the wrist
**The device can transfer load to the upper arm

The device is comfortable
*The device prevents/limits pain

*The device does not irritate the user after a period of time
*The device can comfortably fit the hand as it is custom made
**The device does not get hot and sweaty after prolonged use
**The device is easy to put on and off
***The device has the right weight

The device will aid in grip strength
*The device assist the user in grip and pinch strength in daily activities such as for bags/books
**The device will help the user to hold and maintain object of different shape
***The device will enable the user to have sufficient strength in different workouts/movements of the arm/hand: supinated, pronated; neutral

The device allows for adequate movement and range of motion
*The device will give sufficient ROM of the wrist
*The device allows range of motion in the fingers
*The device will offer wrist support in torsional motions
**The device does not restrict natural movements of the hand

The device is sturdy and long-lasting
*The device survives heavy and repetitive use
**The device can resist strong load-bearing applications
***The device utilizes a strong material
**The device can be dropped from a human height without damage

The device adapts to any environment
*The device allows for proper airflow
**Material choice of the device promotes use in any environment (stick resistant)
***The device works with wet/slippery surfaces
**The device resists corrosion from environmental factors

The device is easy to set up and use
*The device maintains its shape when under load.
**The device can be put on and off easily and comfortably
***The device is easy to store and travel with

The device is safe
*The device is medically safe to use, biocompatible
***The device respects the integrity of the user mechanically and biologically
**The device remains stable

The device is aesthetically pleasing
*The device can be put on silently without drawing attention
**The device blends in and does not stand out as a medical device
***The device is visually appealing

B. Brainstorming Ideas

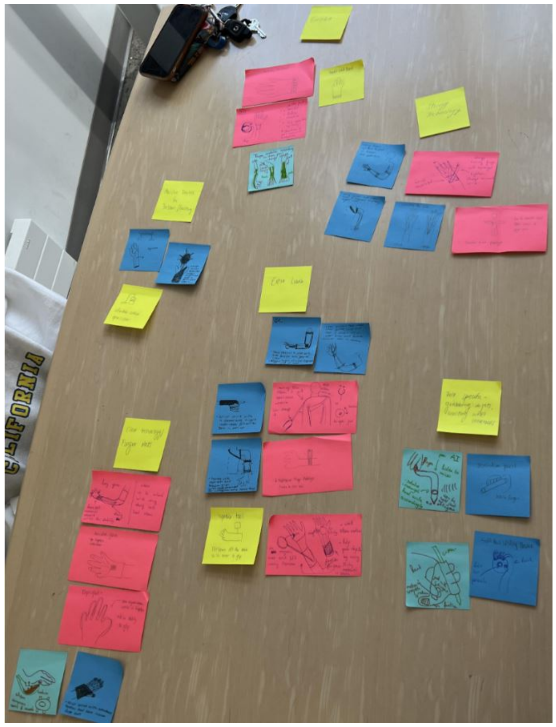

Fig. 3. Concepts generation and clustering

We divided our ideas into multiple different groups. We sorted them based on glove technology, task specific ideas, devices for torsion and twisting, extra limbs, string technology, and then bracelet technology. From here we ranked these groups with a weighted matrix.

C. Weighted Matrix

Criteria	Weight	Bracelets	Assistive Devices for Twisting	Extra Limb	String Technology	Task specific	Glove Technology/Finger Hats
Wrist Stability	3	5	2	2	4	1	4
Grip strength	2	1	4	4	3	3	2
Increase ROM	1	1	3	4	2	2	1
Comfort	2	5	2	1	3	4	4
Ease of Use	1	5	2	1	2	3	4
Aesthetics	1	5	1	1	2	3	4
Totals	10	38	24	22	30	25	33

To describe the reason for picking these criteria, we decided to mainly focus on what was said during the interview. She pointed out that the most important features for a device to help her dealing with arthritis would be first stabilizing her wrist, then increasing both grip strength and range of motion. She really wanted a device that would be easy to use and comfortable, that's why in the weighted matrix, these criteria have the higher weight. The concepts that are the highest score are first the bracelets and wrist band, then the glove technology and finally devices with string technology.

D. CAD generation

nTopology

The software of nTopology has a built in voronoi function, that allowed us to overlay this voronoi design over the stl file of our need-knowers wrist. nTopology runs on a command base system, and we have included a figure of code we created to created the wrist brace.

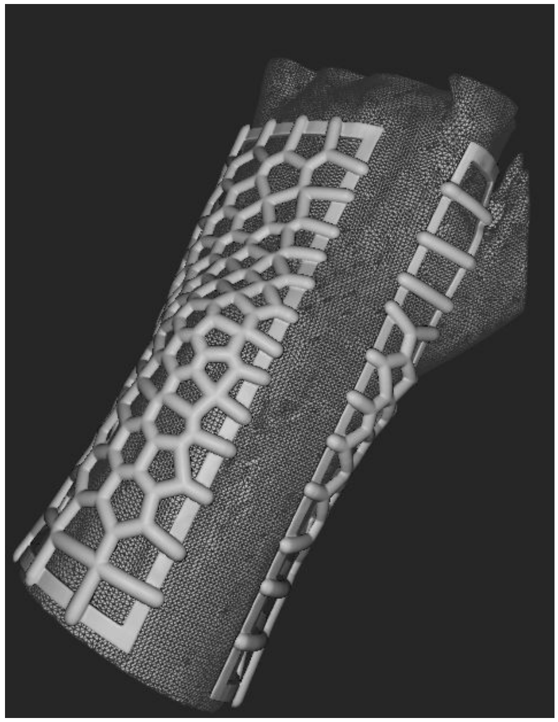

Fig. 4. NTopology software, CAD model adapted to the need knower's 3D wrist scan

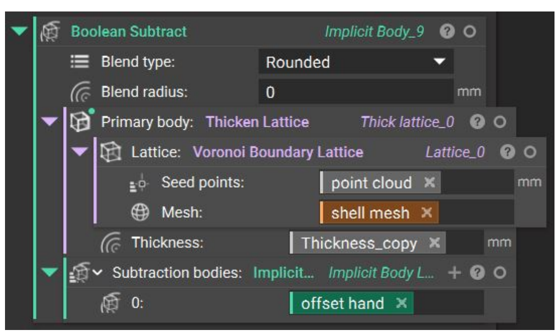

Fig. 5. Functions used in NTopology to create the voronoi pattern with different density

SolidWorks

After creating the voronoi brace in nTopology, we moved the design to SolidWorks to create hooks for our string tightening mechanism, and to create a sturdy connection over the thumb.

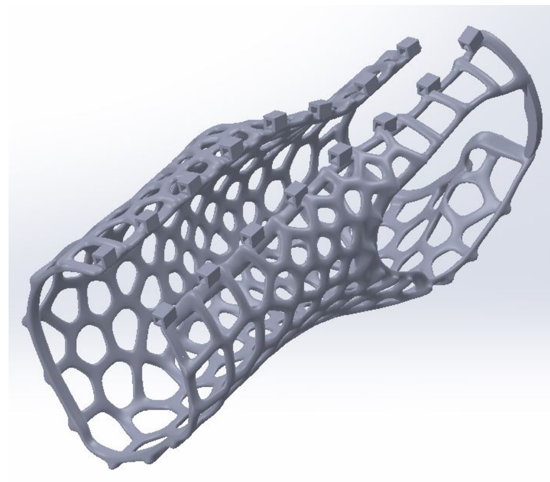

Fig. 6. Final CAD model of the device on Solidworks

E. Sensors-Mechatronics design

Arduino

For usability as well as for testing purposes we added two force sensors located on the wrist bone and in the forearm and 3 LEDs . The idea is to ensure the safety of the user by controlling the force applied by the bracelet on the wrist. Our procedure will detect non acceptable/ high force which may cause discomfort, skin injury, over constrained joint and pain. It can be used during the evaluation and testing step of the design process to calibrate the closing mechanism to control the force This procedure can also be useful during daily use in order to inform the users through visual indicators, that the bracelet may be too tightened which causes some risk for them.

For this procedure the materials we are using are Arduino cardboard Mega 2560, 2 FSR and 3 LED (green, orange and red). The procedure (code in appendix) works as followed :

Both measurements from the FSR are compared to threshold values tuned to the user sensitivity : the force applied by the bracelet to the user's wrist is considered as 'light squeeze', ' medium, acceptable', or 'high, not acceptable'. This information is displayed on the screen.

For safety considerations, visual indicators are implemented, when the squeeze is considered high, a warning message is displayed on the screen as well as the red led which turns on, and the green led turns off. If the squeeze is not considered dangerous for the user (light and medium) the green led is on.

```
#define FORCE_SENSOR_PIN_wristbone A0
#define FORCE_SENSOR_PIN_forearm A1

#define LED_G 30//32
#define LED_Y 28//32
#define LED_R 26
int thresh = 20;
char led_state;

int VCC = 5 ; // not
void setup() {
  Serial.begin(9600);
  pinMode(LED_G, OUTPUT);
  pinMode(LED_R, OUTPUT);
  pinMode(LED_Y, OUTPUT);
}

void loop() {
  int analogReading_wristbone = analogRead(FORCE_SENSOR_PIN_wristbone);
  float fsrV_wristbone = analogReading_wristbone * VCC / 1023.0;
  int analogReading_forearm = analogRead(FORCE_SENSOR_PIN_forearm);
  float fsrV_forearm = analogReading_forearm * VCC / 1023.0;

  Serial.print("The force sensor value on the wrist bone = ");
  Serial.print(analogReading_wristbone); // print the raw analog reading
  Serial.println("\t ");
  Serial.print("The force sensor value on the forearm = ");
  Serial.print(analogReading_forearm);
  Serial.println("\t ");// print


  if ((analogReading_wristbone < 500) && (analogReading_forearm < 150)) {//  both below
    led_state = 'g';
  }
  else if ((analogReading_wristbone > 500) && (analogReading_forearm < 200)) { // if wrist higher than its thresh medium
    led_state = 'w';
  }
  else if ((analogReading_forearm > 180) && (analogReading_wristbone < 500)) { // if forearm higher than its thresh medium
    led_state = 'f';
  }

   if ((analogReading_wristbone > 650 )&& (analogReading_forearm < 500)){ // if wrist higher than it thresh high
    led_state = 'W';
  }
  else if ((analogReading_forearm > 350) && (analogReading_wristbone < 650)){ // if forearm higher than it thresh high
    led_state = 'F';
  }
   else if ((analogReading_forearm > 350) && (analogReading_wristbone > 650)){ // if both forearm and wrist higher than both thresh high
    led_state = 'B';
  }


  switch (led_state) {
  case 'g':
    Serial.println(" -> light squeeze");
```

```
  switch (led_state) {
  case 'g':
    Serial.println(" -> light squeeze");

    digitalWrite(LED_G, HIGH);
    digitalWrite(LED_R, LOW);
    digitalWrite(LED_Y, LOW);
    break;

  case 'w':
    Serial.println(" -> medium squeeze on the wrist bone");
    digitalWrite(LED_G, LOW);
    digitalWrite(LED_Y, HIGH);
    digitalWrite(LED_R, LOW);
    break;

  case 'f':
    Serial.println(" -> medium squeeze on the forearm");
    digitalWrite(LED_G, LOW);
    digitalWrite(LED_Y, HIGH);
    digitalWrite(LED_R, LOW);
    break;

   case 'b':
    Serial.println(" -> medium squeeze on both the wrist and the forearm");
    digitalWrite(LED_G, LOW);
    digitalWrite(LED_Y, HIGH);
    digitalWrite(LED_R, LOW);
    break;

  case 'W':
    Serial.println(" -> big squeeze on the wrist bone, be careful, it may lead to pain!");
    digitalWrite(LED_G, LOW);
    digitalWrite(LED_Y, LOW);
    digitalWrite(LED_R, HIGH);
    break;

   case 'F':
    Serial.println(" -> big squeeze on the forearm, be careful, it may lead to pain!");
    digitalWrite(LED_G, LOW);
    digitalWrite(LED_Y, LOW);
    digitalWrite(LED_R, HIGH);
    break;

    case 'B':
    Serial.println(" -> big squeeze on both the wrist bone and forearm, be careful, it may lead to pain!");
    digitalWrite(LED_G, LOW);
    digitalWrite(LED_Y, LOW);
    digitalWrite(LED_R, HIGH);
    break;
  }
  delay(1000);
}
```

Fig. 7. Code on Arduino to collect data from force sensors and display visual information

F. Prototype Iterations

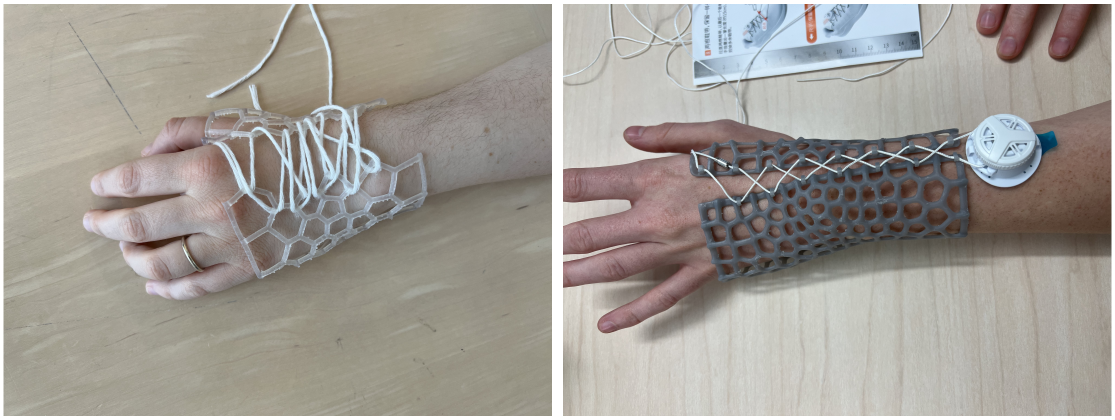

Fig. 8. Picture of the first prototype (left) and second prototype (right).

APPENDIX C
PROPOSED STUDY DOCUMENTS

A. *Michigan Hand Outcome Questionnaire*

Item	Item Statement	MNSQ Infit[a]	MNSQ Outfit[b]	Chi Square (X^2)	P-value	DOF[c]	DIF[d] or Misfit?
Function Domain							
1	How well did your hand work?	0.515	0.506	80.918	1	161	
2	How well did your fingers move?	0.612	0.619	99.074	1	161	
3	How well did your wrist move?	1.263	1.261	201.796	0.012	161	
4	How was the strength?	0.761	0.745	119.221	0.992	161	
5	How was the sensation (feeling)?	0.960	1.077	172.392	0.221	161	
Activities of Daily Living Domain							
1	How difficult was it for you to turn a door knob?	0.768	0.692	107.900	0.999	155	non-uniform DIF dominant hand
2	How difficult was it for you to pick up a coin?	0.976	0.999	155.878	0.465	155	non-uniform DIF dominant hand
3	How difficult was it for you to hold a glass of water?	1.061	1.018	158.820	0.400	155	non-uniform DIF dominant hand
4	How difficult was it for you to turn a key in a lock?	0.827	0.747	116.521	0.991	155	non-uniform DIF dominant hand
5	How difficult was it for you to hold a frying pan?	0.878	0.893	139.342	0.811	155	
6	How difficult was it for you to open a jar?	1.355	1.119	174.536	0.135	155	
7	How difficult was it for you to button a shirt/blouse?	0.952	0.882	137.615	0.839	155	
8	How difficult was it for you to eat with a knife/fork?	0.902	0.869	135.609	0.867	155	
9	How difficult was it for you to carry a grocery bag?	1.062	1.021	159.291	0.390	155	
10	How difficult was it for you to wash dishes?	1.017	0.916	142.853	0.749	155	
11	How difficult was it for you to wash your hair?	0.874	0.899	140.233	0.796	155	
12	How difficult was it for you to tie shoelaces/knots?	0.754	0.657	102.570	1.000	155	non-uniform DIF dominant hand
Work Domain							
1	Unable to work because of hand(s)/wrist(s)?	1.214	1.254	189.349	0.016	150	
2	Shorten your work day because of hand(s)/wrist(s)?	0.747	0.690	104.213	0.998	150	
3	Have to take it easy at your work because of your hand(s)/wrist(s)?	0.627	0.612	92.453	1.000	150	
4	Accomplish less in your work because of hand(s)/wrist(s)?	0.587	0.573	86.491	1.000	150	uniform DIF education level
5	Take longer to do the tasks because of hand(s)/wrist(s)?	0.830	0.782	118.123	0.974	150	
Pain Domain							
1	How often did you have pain in your hand(s)/wrist(s)?	0.785	0.744	101.209	0.987	135	
2	Please describe the pain you had in your hand(s)/wrist(s)	0.807	0.808	109.877	0.945	135	
3	How often did the pain in your hand(s)/wrist(s) interfere with your sleep?	0.625	0.657	89.284	0.999	135	
4	How often did the pain in your hand(s)/wrist(s) interfere with your daily activities (such as eating or bathing)?	0.847	0.842	114.571	0.898	135	
5	How often did the pain in your hand(s)/wrist(s) make you unhappy?	1.027	1.142	155.354	0.111	135	non-uniform DIF location
Aesthetics Domain							
1	I am satisfied with the appearance (look) of my hand.	1.234	1.178	179.069	0.059	151	
2	The appearance (look) of my hand sometimes made me uncomfortable in public.	0.714	0.666	101.215	0.999	151	
3	The appearance (look) of my hand made me depressed.	0.558	0.541	82.266	1.000	151	
4	The appearance (look) of my hand interfered with my normal social activities.	0.823	0.794	120.644	0.967	151	non-uniform DIF education level
Satisfaction Domain							
1	How satisfied are you with the overall function of your hand?	0.646	0.598	89.654	1.000	149	
2	How satisfied are you with the motion of the fingers in your hand?	0.717	0.675	101.321	0.999	149	
3	How satisfied are you with the motion of your wrist?	1.269	1.392	208.748	0.001	149	item misfit
4	How satisfied are you with the strength of your hand?	0.841	0.832	124.744	0.927	149	
5	How satisfied are you with the pain level of your hand?	0.716	0.682	102.354	0.999	149	
6	How satisfied are you with the sensation (feeling) of your hand?	0.965	0.937	140.532	0.678	149	

a. Outfit MNSQ = outlier-sensitive mean square statistic

b. Infit MNSQ = information-weighted mean square statistic

c. DOF = degrees of freedom

d. DIF = differential-item-functioning

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B. Disability of Arm, Shoulder, and Hand questionnaire

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\left[\left(\frac{\text{sum of n responses}}{n}\right) - 1\right] \times 25$, where n is equal to the number of completed responses.

A DASH score may not be calculated if there are greater than 3 missing items.

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job/work is:______________________________

❐ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:______________________________

❐ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.

An optional module score may <u>not</u> be calculated if there are any missing items.

C. Aesthetics and Social Impact of RA Wrist Brace Survey

On a scale of 1-5 with 5 being most appealing, how does the device look to you? *

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5

Is this device something you would feel confident wearing? *

- ☐ Yes
- ☐ No
- ☐ Unsure

Does the device seem fashionable to you? *

- [ ] Yes
- [ ] No
- [ ] Unsure

Is this something you would regularly wear? *

- [ ] Yes
- [ ] No
- [ ] Unsure

Is this something you would recommend to a friend? *

- [ ] Yes
- [ ] No
- [ ] Unsure

How does the device make you feel? *

Your answer

Is there any changes you wish to see made to the device in terms of aesthetics? *

Your answer