Check for updates

Proceedings of the 2023 Design of Medical Devices Conference
DMD2023
April 17-19, 2023, Minneapolis, MN, USA

DMD2023-4967

Downloaded from http://asmedigitalcollection.asme.org/BIOMED/proceedings-pdf/DMD2023/86731/V001T10A004/7018361/v001t10a004-dmd2023-4967.pdf by guest on 13 June 2023

DESIGN OF AN ARTICULATING NON-INVASIVE JOINT DISTRACTOR FOR METACARPOPHALANGEAL JOINT OF THE THUMB

Pardis Farjam
University of Twente
Enschede, The Netherlands

Timo Roubos
University of Twente
Enschede, The Netherlands

Edsko E.G. Hekman
University of Twente
Enschede, The Netherlands

Gijsbertus J Verkerke
University of Twente
Enschede, The Netherlands

Jeroen Rouwkema
University of Twente
Enschede, The Netherlands

ABSTRACT

There is no specific distraction device available for the metacarpophalangeal joint (MCPJ) of the thumb. Joint distraction is required to facilitate the implantation of MCPJ spacers. In addition, expanding the joint space is essential for MCPJ arthroscopy. For these reasons, a novel device has been designed to create some space in the MCPJ. This articulating joint distractor uses a finger trap to apply the distraction force to the thumb and a strap to fixate the hand. There is the possibility to flex the thumb while maintaining the distraction force. In a first cadaveric experiment, we have determined that the force required to create 2 mm of distraction is approximately 30N. A prototype of the articulating joint distractor has been built and was tested during a second cadaveric study. As a result of the second cadaveric experiment, the desired functions of the prototype have been validated. By adjusting and optimizing the design to minimize the risks found partly during the experiment, the final design of the non-invasive MCPJ distractor has been realized.

Keywords: Joint distractor, Non-invasive, Thumb, Metacarpophalangeal joint

1. INTRODUCTION

Thumb's associated injuries and osteoarthritis (OA) have serious implications for patients' well-being since the thumb supplies approximately 40% of the total hand functions [1]. The MCPJ of the thumb is formed by the metacarpal head and the phalangeal base. OA might develop in the MCPJ of the thumb as a result of a chronic trauma caused by executing repetitive heavy manual labor [2].

Expanding the MCPJ of the thumb to create some space between the phalanx and metacarpal bone is required for both diagnosis and treatment. Arthroscopy of the MCPJ has been reported to be a powerful tool to diagnose and treat intra-articular lesions [3]. To perform arthroscopy, the distraction of the MCPJ is a mandatory step. In treatment, placement of joint implants is commonly preceded by resections. However, novel thin joint implants might be correctly placed without the need for bone removal if enough space has been created between the articulating bones of MCPJ for the implantation.

There are several orthopedic joint distractors commercially available for application on different joints. However, the majority of these distractors require invasive approaches for creating the space by inserting rods (k-wires) into the bones and applying force on the rods to distract the joint. There are some approaches without drilling bones and inserting k-wires which are based on inserting two plates in between the articulating surfaces and distracting them by applying a force by a scissor-like device. That is not an appropriate solution for placing the implants, since it will hinder or prevent a proper insertion of the implant.

The common procedure for distraction of the MCPJ includes using a finger trap and a traction tower. The hand is suspended from the traction tower and is secured to the tower by adhesive tape and straps. Then, using weights, 25-45 N of traction is applied. In this procedure, the adjustment of joint angulation during the procedure is restricted and the position of the hand is

 © 2023 by ASME

not ideal. Currently, there is no specific traction device for the MCP joint and this procedure. Furthermore, there are no non-invasive traction devices that also allow for joint flexion during the surgery. Changing the angulation of the joint during the surgery can expose more surface of the joint and assist the surgeon to fix or articulate the joint.

In this paper, we report the design process of an articulating non-invasive joint distractor for the MCPJ of the thumb and demonstrate the functionality of a functional prototype during a cadaveric experiment.

2. MATERIALS AND METHODS

2.1 Design methodology

The adopted design method consists of four main phases before the use of the product, each phase with several sub-activities as depicted in Figure 1. Briefly, in the analysis phase, a complete analysis of the problem will be conducted to clarify the necessity of a new product. Based on this, the list of the product's requirements and functions will be identified. In synthesis phase one, a morphological scheme will be created based on brainstorming sessions and several pre-concepts will be developed, of which the best three will be selected. In synthesis phase two, the selected pre-concepts will be detailed to form concepts and the final concept will be selected based on its potential to meet the requirements. Then in synthesis phase three, the detailed final concept and a functional prototype will be developed and tested. This process contains several iteration loops as well. In the following, main results of the different phases will be given.

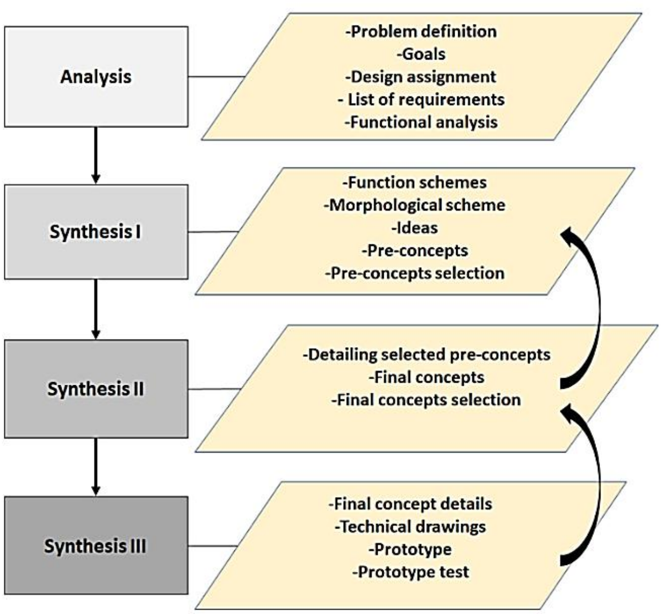

FIGURE 1: UTWENTE METHODICAL DESIGN APPROACH

3. RESULTS AND DISCUSSION

3.1 Analysis phase

A list of requirements was determined based on the various stakeholders. The Analytic Hierarchy Process (AHP) decision analysis method [4] was used to determine the weight of the most important requirements. These weighed requirements are then used in both the pre-concept and concept selection in next phases. The main requirements are reported in order of decreasing importance in Table 1.

TABLE 1: MAIN REQUIREMENTS WITH SPECIFICATIONS

Main requirements	specification
1. The product should be able to provide enough force to distract the joint	TBD in a cadaveric experiment
2. The product should leave the dorsal side of the thumb clear for medical manipulation	4 cm x thumb width
3. The product should be easy to clean	ISO14937 ISO17664-1
4. The product should be cost-effective	Increase cost of surgery by max 2%
5. The product can be used for and by various hand/thumb sizes	Hand breadth 6.6-10.6 cm [5]
6. The product should be quick in use	Increase time of surgery by max 15%
7. The size adjustment should be as simple as possible	operational by one person
8. The product should be intuitive in use	No training needed to use the device

TBD: To be determined

3.1.1 First cadaveric experiment

As part of a more elaborate cadaveric experiment, we performed an experiment to find the required force to distract the MCP joint of the thumb for 2mm. Even though the required force in live subjects is likely to differ from the cadavers, due to the lack of data and suitable data acquisition methods, measurements from a cadaver were used as a force estimation. It has been reported [6] that the architectural parameters of skeletal muscles in cadavers predominantly are between those for the relaxed and contracted muscles of live subjects. However, the exact change depends on the muscle that is assessed. A special test setup has been created to accomplish this goal. The setup is shown in Figure 2. It uses the hand plate to secure the position of the hand. A load is applied on the thumb via a finger trap. A load cell is attached to the slider mechanism to measure the traction force.

FIGURE 2: FIRST CADAVERIC EXPERIMENT SETUP

Downloaded from http://asmedigitalcollection.asme.org/BIOMED/proceedings-pdf/DMD2023/86731/V001T10A004/7018361/v001t10a004-dmd2023-4967.pdf by guest on 13 June 2023

 © 2023 by ASME

To measure when a 2 mm distraction has been reached, a set of spacers was created using 3D printing, see Figure 3. The tools have a tip of 1, 1.5, and 2 mm and can be placed within the joint cavity.

A straight skin incision starting 1 cm proximal to the MCPJ which extends approximately 1.5 cm distal of the MCPJ was made. Figure 4 shows a measuring tool in use as well as the complete force measurement setup.

FIGURE 3: MEASURING TOOLS. THE TOOLS WITH A SPECIFIC THICKNESS AT THEIR TIP HAVE BEEN 3D PRINTED TO DETERMINE THE AVAILABLE SPACE BETWEEN THE ARTICULATING SURFACE OF METACARPAL AND PROXIMAL PHALANGE OF THE THUMB.

FIGURE 4: MEASURING THE CREATED SPACE DURING THE DISTRACTION OF THE THUMB MCPJ.

The results from the experiment are shown in Table 2. The distraction is described by indicating which spacers did fit in the joint space at three different sites: the ulnar, the middle, or the radial side of the joint. Approximately 30N is needed for 2 mm distraction in the middle of the MCP joint.

TABLE 2. CREATED JOINT SPACE ACCORDING TO THE PLACEMENT OF SPACERS.

Traction Force (N)	1mm	1.5 mm	2 mm
No traction-middle	F	NF	NF
20N-middle	F	F	F
20N-ulnar	F	F	FWP
20N-radial	FWP	FWP	NF
30N-middle	F	F	F
30N-ulnar	F	F	F
30N-radial	F	F	FWP

F: Fit, NF: Not Fit, FWP: Fit with Pressure

3.2 Synthesis I

The non-invasive (without removing any tissue) articulating joint distractor must fulfill four main functions: a technique to attach to the thumb, a method to support the hand, a mechanism to create and maintain joint distraction, and a method to flex the joint. Several concepts have been created to perform the main functions, then the best three concepts which are detailed in synthesis phase II were selected based on the requirements

3.3 Synthesis II

The previously mentioned best three concepts have been detailed in synthesis phase two. The conceptual sketch and the 3D-model of concept A are shown in Figure 5 and Figure 6, respectively.

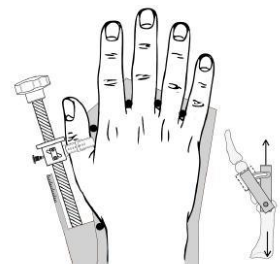

FIGURE 5: CONCEPT A, CONCEPT SKETCH.

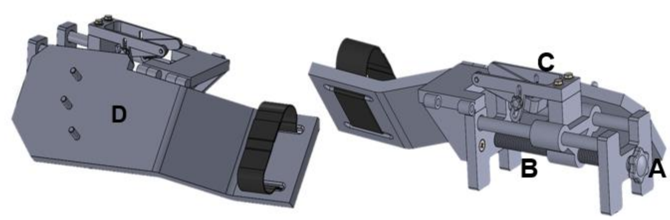

FIGURE 6: CONCEPT A, 3D MODEL. A: TURNING KNOB, B: LEAD SCREW, C: THUMB ROTATING BRACKET, D: HAND PLATE.

Concept A uses a lead screw to provide linear distraction. The chosen method for each of the main functions are listed below:

- Thumb attachment: bracket with hook and loop straps
- Hand support: rods on a hand plate and a wrist strap
- Joint distraction: lead screw
- Joint flexion: a rotating bracket around an axis collinear with the axis of rotation of the MCPJ

The knob rotates the lead screw and moves the slider.

The conceptual sketch and 3D-model of concept B is shown in Figure 7 and Figure 8, respectively.

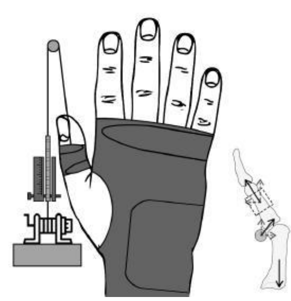

FIGURE 7: CONCEPT B, CONCEPT SKETCH.

 © 2023 by ASME

Downloaded from http://asmedigitalcollection.asme.org/BIOMED/proceedings-pdf/DMD2023/86731/V001T10A004/7018361/v001t10a004-dmd2023-4967.pdf by guest on 13 June 2023

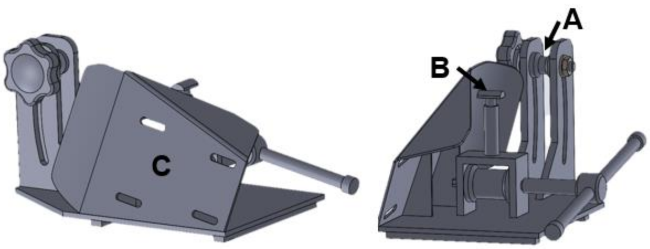

FIGURE 8: CONCEPT B, 3D MODEL. A:TOP CYLINDER, B: SADDLE, C: HAND PLATE.

Concept B is using a winch with a cable to distract the thumb. The winch can be activated by turning the arm on the side of the device. The selected mechanism for each of the main function are listed below:

- Thumb attachment: hook and loop straps
- Hand support: hand plate with hook and loop straps
- Joint distraction: winch with cable
- Joint flexion: support of a saddle and vertical movement of the top cylinder

The conceptual sketch and the 3D-model of concept C is shown in Figure 9 and Figure 10 respectively.

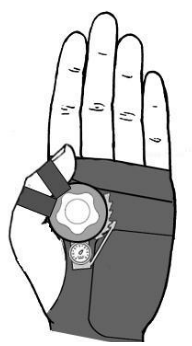

FIGURE 9: CONCEPT C, CONCEPT SKETCH

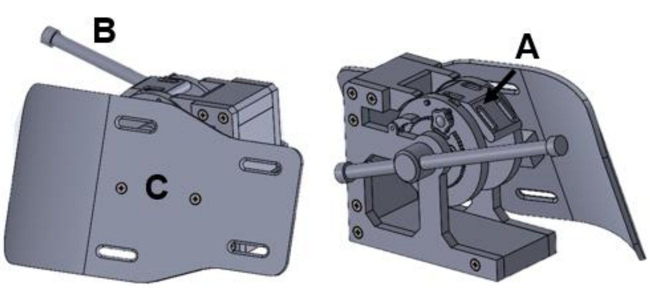

FIGURE 10: CONCEPT C, 3D MODEL. A: ANGLED PLATE, B: ARM TO TURN THE DRUM, C: HAND PLATE.

Concept C uses a rotating drum to distract the thumb. The choice of the mechanisms for the main functions are listed below:

- Thumb attachment: angled plate with hook and loop straps
- Hand support: hand plate with hook and loop straps
- Joint distraction and Joint flexion: rotating drum with a ratchet

By rotating the arm clockwise, the angled plate moves forward to create the distraction. The plate itself can also be rotated and secured using a tightening screw in order to allow flexion of the thumb.

3.4 Synthesis III

3.4.1 Final concept

The selected three concepts were detailed further to meet all the requirements. The final concept that was selected, based on the requirements, was concept C. It scored superior in fulfilling requirements 1, and 4 by containing a reliable energy storage system, and comprising one hand plate for both hands. After several design iterations for the thumb attachment and the distraction method, a prototype has been made and is presented in Figure 11. The hand can be placed on the hand plate and secured by using hook and loop straps around the fingers and the wrist. The tip of the thumb and the thumb interphalangeal (IP) joint is tightly held by a commercially available finger trap instead of a strap (compared to concept C) since finger traps showed to transfer enough force to distract the thumb according to the first cadaveric experiment. The distraction of the joint is created by turning the lead screw. The lead screw is placed inside a curved slider to allow flexion of the thumb while being distracted. A long lead screw plus a spring was integrated to allow for different hand sizes and different lengths of the finger traps. Using a lead screw instead of a lever (compared to concept C) caused a more precise, but also slower distraction. The quick-release mechanism of the device allows the user to release the tension in a single movement. This adds additional safety as distraction can be aborted fast.

3.4.2 Second cadaveric experiment

The goals for the second cadaveric experiment were finding the ideal position for hand placement, finding out if distraction is possible during flexion of the thumb MCPJ, observing the usability of the device by the surgeon, and identifying potential risks.

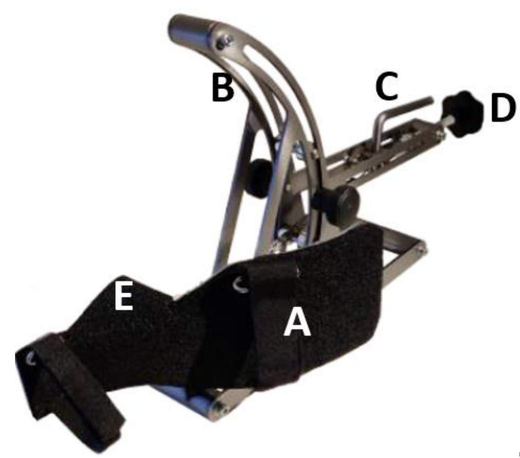

FIGURE 11: PROTOTYPE OF THE ARTICULATING JOINT DISTRACTOR THAT WAS TESTED IN THE SECOND CADAVERIC EXPERIMENT. A: HAND PLATE, B: CURVED SLOT, C: QUICK-RELEASE MECHANISM, D: LEAD SCREW, E:THUMB PLATE

Downloaded from http://asmedigitalcollection.asme.org/BIOMED/proceedings-pdf/DMD2023/86731/V001T10A004/7018361/v001t10a004-dmd2023-4967.pdf by guest on 13 June 2023

 © 2023 by ASME

The desired functions of the prototype were fixating the hand securely with optimal position for medical manipulation, generating enough force for the joint distraction, transferring the generated force to the thumb, and changing the force direction by articulating the joint. The general outcome of the experiment, see Figure 11-12, was successful. The hand could be securely fastened to the hand plate using straps. The amount of flexion and extension provided by the device was sufficient for the MCPJ to have the full range of motion (0° - 56°). The surgeon responded positively on the design and its ease of use. In addition, flexion of the joint during distraction proved to be achievable without complications.

FIGURE 12: PROTOTYPE BEING USED BY THE SURGEON DURING THE SECOND CADAVERIC STUDY

Another observation during the second cadaveric study was that the thumb plate (Figure 11E) needed to be shorter and the angle of the thumb plate did not represent the angle of flexion of the thumb during use.

3.4.3 Final design

The final design is shown in Figure 13. One of the main goals was to reduce the number of the parts in the final design to make the design more favorable in terms of design for manufacturability and ease of cleaning and sterilization.

FIGURE 13: ARTICULATING DISTRACTOR OF THE THUMB MCPJ, FINAL DESIGN.

The straps for securing the hand, shown in figure 13, have been redesigned to be more comfortable for the hand and wrist. In comparison to the straps used for the prototype of the second cadaveric experiment, extra padding is added under the metal connection point to reduce the risk of cutting the skin. The hand plate (Figure 14) of the device can be easily changed between right-hand and left-hand configuration by removing the locking pin (Figure 15), placing the other hand plate and locking it with the locking pin. The pin is attached to the cover of the hand plate with a string to avoid losing the pin in the operating room (OR) and to create a single part for packaging. To account for different hand sizes, three hand plates with different sizes have to be created. The calculation for the dimension of the hand plates is based on the range of hand sizes. The data used for these dimensions are extracted from the American National Survey (ANSUR) data [5].

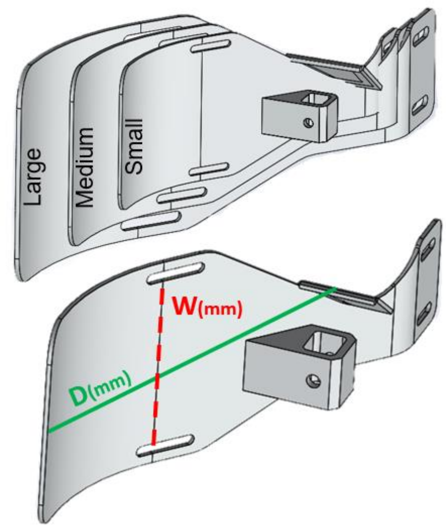

FIGURE 14: SMALL (D =129.74, W = 64.8) , MEDIUM (D =160.7, W = 81) , AND LARGE (D = 190.35, W= 97.2) HAND PLATES

FIGURE 15: LOCKING PIN FOR SECURING THE HAND PLATE

The locking system of the quick release mechanism is shown in Figure 16 and Figure 17. To reduce the risk of the mechanism being triggered by accident, two design changes have been made. First, the shape of the handle became more ergonomic to reduce the chance of trigging it accidentally. Second, the alignment of the latch mechanism is slightly offset as displayed in Figure 16 by the distance “a”. This offset creates the situation that the force of the spring is working against the trigger mechanism until the handle is moved to overcome this offset. To eliminate the risk of over-tensioning the spring, two additional plates were added to the design. These plates have a slit with length “b” (Figure 16) which is equal to the maximum

Downloaded from http://asmedigitalcollection.asme.org/BIOMED/proceedings-pdf/DMD2023/86731/V001T10A004/7018361/v001t10a004-dmd2023-4967.pdf by guest on 13 June 2023

 © 2023 by ASME

displacement the spring is rated for, therefore the spring is restricted from being over-tensioned.

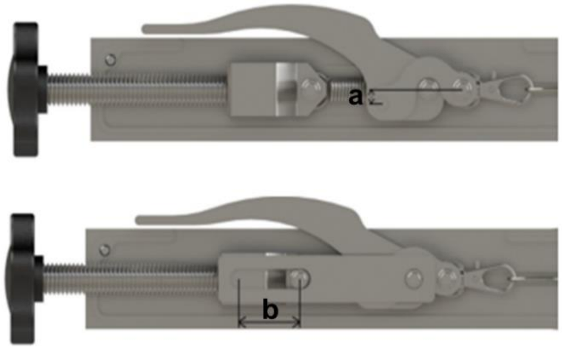

FIGURE 16: QUICK RELEASE MECHANISM, TENSIONED CONFIGURATION.

FIGURE 17: QUICK RELEASE MECHANISM, RELEASED CONFIGURATION.

The entire device can be disassembled for cleaning by removing 4 bolts and unscrewing the knobs. The cover of the hand plate, the locking pin and the straps are single-use parts which will be disposed after each surgery.

3.4.4 Materials

Mechanical properties, cleaning, sterilization, and manufacturability are important requirements that must be met by choosing appropriate materials for the device. Anodized Aluminum alloy will be used to produce the device. A series of simulations was performed using SolidWorks-2020 which showed that aluminum alloy is sufficient in terms of strength and stiffness. The hand plate will be made of 316L stainless steel to have sufficient mechanical stiffness for the fixation of the hand. The cover of the hand plate will be made from polyurethane foam which can be sterilized by either ethylene oxide gas or electron beam radiation [7]. The locking pin is a standard industrial part made from Nylon which can be sterilized using ethylene oxide gas sterilization [8]. In terms of material, three finger trap materials are commercially available, stainless steel, bamboo, and nylon. The finger traps similar to stainless steel versions have been used during the cadaveric experiments. These are durable and sterilizable. However, they might cut the skin and arose uncomfortable feelings. During the second cadaveric experiment, bamboo finger traps were supplied for testing. Since bamboo is less flexible, a tight connection which is essential for transferring the force could be difficult considering the variety in the size of the thumbs. The best option is a nylon finger trap due to its comfort and flexibility. A nylon finger trap is also autoclavable.

4. CONCLUSION

Following a stepwise design methodology we created a thumb distraction device which is capable of creating a 2 mm space between the metacarpal and proximal phalanx of the thumb. The device has been tested in a cadaveric experiment. Moreover, the flexion of the joint while it is distracted seemed to be beneficial and easily achievable by using the device.

ACKNOWLEDGEMENTS

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 863183.The authors would like to thank Prof. dr. Paul Werker, head of the department of Plastic Surgery in the University Medical Center Groningen, for performing the surgical procedures.

REFERENCES

[1] S. L. Moran and R. A. Berger, "Biomechanics and hand trauma: What you need," *Hand Clinics*, vol. 19, no. 1. pp. 17–31, 2003. doi: 10.1016/S0749-0712(02)00130-0.
[2] A. J. Berger and R. A. Meals, "Management of osteoarthrosis of the thumb joints," *Journal of Hand Surgery*, vol. 40, no. 4. W.B. Saunders, pp. 843–850, Apr. 01, 2015. doi: 10.1016/j.jhsa.2014.11.026.
[3] K.-C. Kim, Y.-E. Shin, and J.-P. Kim, "The Role of Arthroscopy of Acute and Chronic Painful Thumb Metacarpophalangeal Joint," *Journal of the Korean Society for Surgery of the Hand*, vol. 21, no. 2, p. 63, Jun. 2016, doi: 10.12790/jkssh.2016.21.2.63.
[4] Klaus D. Goepel, "AHP Online Calculator." https://bpmsg.com/ahp-online-calculator/
[5] T. M. Mclain, "The Use of Factor Analysis in the Development of Hand Sizes for The Use of Factor Analysis in the Development of Hand Sizes for Glove Design Glove Design," 2010.
[6] D. C. Martin *et al.*, "Comparing human skeletal muscle architectural parameters of cadavers with in vivo ultrasonographic measurements," 2001.
[7] L. K. Jang, L. D. Nash, G. K. Fletcher, T. Cheung, A. Soewito, and D. J. Maitland, "Enhanced x-ray visibility of shape memory polymer foam using iodine motifs and tantalum microparticles," *Journal of Composites Science*, vol. 5, no. 1, 2021, doi: 10.3390/jcs5010014.
[8] W. J. Rogers, "Sterilisation techniques for polymers," in *Sterilisation of Biomaterials and Medical Devices*, Woodhead Publishing, 2012, pp. 151–211. doi: 10.1533/9780857096265.151.

Downloaded from http://asmedigitalcollection.asme.org/BIOMED/proceedings-pdf/DMD2023/86731/V001T10A004/7018361/v001t10a004-dmd2023-4967.pdf by guest on 13 June 2023

© 2023 by ASME