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CARPOMETACARPAL THUMB BRACE

Abstract

A brace for a carpometacarpal joint of a thumb includes a body made of an elastomeric material. The body includes a wrist strap configured to surround a wrist, a dorsal projection extending from the wrist strap, a first palmar strap extending between a proximal end connected to the wrist strap and a distal end configured to removably attach to the dorsal projection, and a second palmar strap extending between a proximal end connected to the wrist strap and a distal end configured to removably attach to the dorsal projection. The brace also includes a heat-moldable insert positioned within the body. The heat-moldable insert is configured so as to be positioned over a CMC joint of the thumb.

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Background/Summary

PRIORITY APPLICATIONS [0001] This application is a continuation of U.S. application Ser. No. 18/766,222, filed Jul. 8, 2024, which is a continuation of U.S. application Ser. No. 18/069,443, filed Dec. 21, 2022, now U.S. Pat. No. 12,053,407, which is a continuation of U.S. application Ser. No. 16/477,042, filed Jul. 10, 2019, now U.S. Pat. No. 11,540,936, which is a National Phase Application of PCT Application PCT/US2018/014441, filed Jan. 19, 2018, which claims priority to U.S. Provisional Application No. 62/449,221, filed Jan. 23, 2017. Each of the aforementioned applications is incorporated by reference herein in its entirety, and each is hereby expressly made a part of this specification. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

BACKGROUND

Field

[0002] This disclosure relates to orthopedic braces. In particular, a carpometacarpal thumb brace is disclosed.

Description

[0003] The carpometacarpal (“CMC”) joint of the thumb (also referred to as the basal joint of the thumb, the first carpometacarpal joint, or the trapeziometacarpal joint) is formed between the metacarpal bone of the thumb and the trapezium bone of the wrist. The CMC joint permits a wide range of motion for the thumb.

[0004] Unfortunately, arthritis of the CMC joint is common. Arthritis can cause the CMC joint to become inflamed and can make movement of the thumb painful. In early stages, arthritic pain may occur only with motion of the CMC joint. In later stages, pain may be present even at rest. In addition to pain, sufferers of arthritis of the CMC joint often have difficulty using the thumb, for example, to grip objects.

SUMMARY

[0005] In one aspect, a brace for a carpometacarpal joint of a thumb is disclosed. The brace includes a body made of an elastomeric material. The body includes a wrist strap configured to surround a wrist, a dorsal projection extending from the wrist strap, the dorsal projection configured to extend across a portion of a dorsum of a hand, a first palmar strap extending between a proximal end connected to the wrist strap and a distal end, the first palmar strap configured to extend across a portion of a palm of the hand and over a pulcrue of the hand, the distal end configured to removably attach to the dorsal projection, and a second palmar strap extending between a proximal end connected to the wrist strap and a distal end, the second palmar strap configured to extend across a portion of the palm of the hand and over the pulcrue of the hand, the distal end configured to removably attach to the dorsal projection. The brace also includes an insert positioned within the body. The insert comprises a heat-moldable material that is pliable above a temperature and substantially stiff below the temperature, the insert positioned within the body to be positioned over a carpometacarpal joint of a thumb. In some embodiments, the elastomeric material comprises silicone. In some embodiments, the elastomeric material comprises a thermoplastic elastomer. In some embodiments, the temperature that affects the pliability (or

stiffness) of the heat-moldable material is between approximately 130° F. and approximately 250° F.

[0006] In another aspect, a brace for a carpometacarpal joint of a thumb is disclosed. The brace includes a body having a wrist strap, a dorsal projection extending from the wrist strap, a first palmar strap extending between a proximal end connected to the wrist strap and a distal end configured to removably attach to the dorsal projection, and a second palmar strap extending between a proximal end connected to the wrist strap and a distal end configured to removably attach to the dorsal projection.

[0007] In some embodiments, the body comprises an elastomeric material. In some embodiments, the elastomeric material comprises silicone. In some embodiments, the elastomeric material comprises a thermoplastic elastomer. In some embodiments, the brace further comprises an insert embedded within the body to be positioned over a CMC joint of the thumb when the brace is worn. In some embodiments, the insert comprises a stiff material. In some embodiments, the insert comprises a heat-moldable material that is pliable above a temperature and stiff below the temperature. In some embodiments, the temperature is between approximately 130° F. and approximately 250° F. In some embodiments, the wrist strap is configured in size and shape to encircle a patient's wrist when the brace is worn. In some embodiments, the first and second palmar straps are each configured in size and shape to extend across a portion of a palm of the hand and over a purlicue of the hand. In some embodiments, the dorsal projection is configured in size and shape to extend across a portion of a dorsum of the hand.

[0008] In another aspect, a brace for a carpometacarpal joint of a thumb is disclosed. The brace includes a body having a wrist strap configured to encircle a patient's wrist when the brace is worn, and a strap connected on a first end to a first location of the wrist strap and connected on a second end to a second location of the wrist strap. The strap is configured in size and shape to extend across a portion of the patient's palm, over the purlicue, and across a portion of the dorsum of the patient's hand. The brace also includes an insert comprising a heat-moldable material that is pliable above a temperature and stiff below the temperature.

[0009] In some embodiments, the temperature is between approximately 130° F. and approximately 250° F. In some embodiments, the body comprises an elastomeric material. In some embodiments, the elastomeric material comprises silicone. In some embodiments, the strap comprises a dorsal projection extending from the first location of the wrist strap, and a palmar strap extending between a proximal end connected to the second location wrist strap and a distal end configured to removably attach to the dorsal projection. In some embodiments, the dorsal projection is configured in size and shape to extend over a portion of the dorsum of the hand when the brace is worn. In some embodiments, the palmar strap is configured is size and shape to extend across a portion of the palm and over the purlicue of the hand when the brace is worn.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The features and advantages of the CMC braces and methods described herein will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. These drawings depict only several embodiments in accordance with the disclosure and are not to be considered limiting of its scope. In the drawings, similar reference numbers or symbols typically identify similar components, unless context dictates otherwise. In some instances, the drawings may not be drawn to scale.

[0011] FIG. 1 is a plan view of an exterior side of an embodiment of a CMC thumb brace, illustrated when not worn by a patient and lying flat.

[0012] FIG. 2 is a cross-sectional view of the CMC thumb brace taken along the line shown in FIG.

1.

[0013] FIG. 3 is a plan view of an insert of the CMC thumb brace of FIG. 1.

[0014] FIG. 4 is a perspective view of an embodiment of a fastener that can be used with the CMC thumb brace of FIG. 1.

[0015] FIG. 5 is a cross-sectional view of the fastener of FIG. 4, illustrated in use.

[0016] FIG. 6 is a dorsal view of a right hand wearing the CMC thumb brace of FIG. 1.

[0017] FIG. 7 is palmar view of a right hand wearing the CMC thumb brace of FIG. 1.

[0018] FIG. 8 is a perspective view of a right hand wearing the CMC thumb brace of FIG. 1.

[0019] FIG. 9 is a plan view of an exterior side of another embodiment a CMC thumb brace, illustrated when not worn by a patient and lying flat.

[0020] FIG. 10 is a cross-sectional view of a strap of the CMC thumb brace taken along the line illustrated in FIG. 9.

[0021] FIG. 11 illustrates a perspective view of an embodiment of a mold that can be used to manufacture a CMC thumb brace.

[0022] FIG. 12 is a plan view of an exterior side of another embodiment a CMC thumb brace, illustrated when not worn by a patient and lying flat, illustrating several example dimensions of the CMC thumb brace.

[0023] FIG. 13 is an end view of CMC thumb brace of FIG. 12, illustrated when not worn by a patient and lying flat and after the brace has been heat molded to conform to a wearer's anatomy.

DETAILED DESCRIPTION

[0024] The following detailed description describes embodiments of CMC thumb braces and methods, some of which are illustrated in the figures. These embodiments are not intended to be limiting, and various modifications, variations, combinations, etc., of the features of these embodiments are possible and within the scope of this disclosure.

[0025] In some embodiments, the CMC thumb braces described herein provide stabilization, support, splinting, bracing, compression, and/or pain relief for the CMC thumb joint. The CMC thumb braces may be used to treat and/or prevent arthritis of the CMC joint. The CMC thumb braces may alleviate pain associated with arthritis of the CMC joint. In some embodiments, the CMC thumb braces are configured to abduct the thumb and/or seat the CMC joint. In some embodiments, the CMC thumb braces provide stabilization, support, splinting, and/or bracing for the CMC thumb joint while still permitting movement of the thumb. That is, in some embodiments, the CMC thumb braces are non-immobilizing. In some embodiments, the CMC thumb braces partially limit motion of the thumb.

[0026] In some embodiments, the CMC thumb braces include one or more adjustable tension mechanisms that are configured to provide variable and/or changeable support. For example, in some embodiments the CMC thumb brace may include one or more fasteners that may secure to various locations of the brace to attach a strap that secures the brace to the patient's thumb/hand. The fasteners can be attached to different locations to provide various levels of tension, support, and/or immobilization.

[0027] In some embodiments, the CMC thumb braces are configured to be patient specific. For example, in some embodiments, the CMC thumb braces (or at least a portion thereof) can be custom fit or custom molded to conform to a particular patient's anatomy. For example, at least a portion of the CMC thumb braces can be heat-moldable. In some embodiments, the heat-moldable portion can be an insert. In some embodiments, the CMC thumb braces can have a low profile and/or be water resistant or water proof.

[0028] FIG. 1 is a plan view of an exterior side **104** of one embodiment of a CMC thumb brace **100** (referred to herein as the “brace **100**”), illustrated when not worn by a patient and lying flat. The brace **100** is illustrated when worn by a patient, according to an embodiment, in FIGS. 6-8. The exterior side **104** can be the side of the brace **100** that faces away from a patient when the brace **100** is worn. An interior side of the brace **100** may contact the patient when the brace **100** is worn. The

interior side is opposite the exterior side **104**.

[0029] The brace **100** includes a body **102**. In the illustrated embodiment, the body **102** includes a wrist strap **106**, a first palmar strap **108**, a second palmar strap **110**, and a dorsal projection **112**. In some embodiments, the body **102** is made from one or more elastomeric materials. In some embodiments, the elastomeric materials include a thermoplastic elastomer (TPE) or thermoplastic rubber that exhibits both thermoplastic and elastomeric properties. In some embodiments, the elastomeric materials comprise silicone. In some embodiments, the elastomeric materials are stretchable, exhibit low fatigue, are abrasion and chemical resistant, and/or are soft. In some embodiments, the one or more elastomeric materials allow the body **102** to be expandable, recoverable, and/or flexible. As used herein, “elastomeric material” refers to a material that is capable of being easily expanded (in other words, stretched) or compressed and that resumes or recovers its former shape (in other words, its pre-stretch or pre-compression shape) once released. Something that has the ability to resume its former shape after expansion or compression is referred to herein as being “recoverable.” Something that is expandable and recoverable may also be referred to herein as being “elastically stretchable.”

[0030] In some embodiments, the body **102** is flexible and is capable of conforming to the general area of the body to be supported without substantial stretching; however, it is contemplated that the body **102** of the brace **100** may need to be stretched in order to conform to the general area of the body part to be supported. In some embodiments, the body **102** may be stretched over the body part to which it is applied so as to provide a degree of compression to the body part. As used herein, “flexible” generally refers to the ability (e.g., of a material or an article) to bend freely and repeatedly without breaking and/or to conform to the shape of the body part to which the flexible material (or article) is applied.

[0031] In some embodiments, the body **102** is formed from a transparent or translucent material. This may allow for visual inspection of areas covered by the body **102** of the brace **100**.

[0032] In some embodiments, the brace **100** and the body **102** can be molded, for example, using the mold **400** shown in FIG. **11**. For example, the mold **400** may include a depression **402** shaped to form the body **102**. An elastomeric material in liquid form can be poured into the mold **400** and allowed to solidify (in some embodiments, into a solid that is expandable, recoverable, and/or flexible) to form the body **102**. Other methods for manufacturing the brace **100** and the body **102** are possible.

[0033] The wrist strap **106** extends generally in a first direction between a first edge **114** and a second edge **116**. For example, as illustrated in FIG. **1**, the wrist strap **106** extends generally in the x-direction (relative to the illustration) between the first edge **114** and the second edge **116**. Between the first edge **114** and the second edge **116**, the wrist strap **106** is partially defined by a proximal edge **118** and a distal edge **120**. Each of the proximal edge **118** and the distal edge **120** extend generally in the first-direction (for example, the x-direction). In general, a length $L_{sub.w}$ of the wrist strap **106**, measured between the first edge **114** and the second edge **116**, is configured to be sufficient to extend around and partially overlap a patient's wrist. For example, in various embodiments, the length $L_{sub.w}$ may be between approximately 4 inches and approximately 12 inches, although other lengths are also possible.

[0034] The wrist strap **106** is configured to be secured around the patient's wrist when the brace **100** is worn (see FIGS. **6-8**, for example). In some embodiments, the wrist strap **106** includes a closure system for securing a second end **124** of the wrist strap **106** to a first end **122** of the wrist strap **106**, such that the wrist strap **106** forms a closed band-shape that surrounds the patient's wrist. In some embodiments, when secured around the patient's wrist, the second edge **116** overlaps the first edge **114**, or vice versa.

[0035] In the illustrated embodiment, the closure system of the wrist strap **106** includes a plurality of apertures **126** extending through the first end of the wrist strap **106**. The plurality of apertures **126** can be aligned along an axis. For example, in the illustrated embodiment, the plurality of

apertures **126** are aligned along an axis that extends in the x-direction. In the illustrated embodiment, ten apertures **126** are shown, although other numbers of apertures (fewer and greater) are possible. In the illustrated embodiment, spacing between apertures **126** is even, although this need not be the case in all embodiments. In the illustrated embodiment, a first **126a** of the apertures **126** is positioned near the first edge **114** and each successive aperture **126** is positioned inwardly (i.e., toward the second edge **116**) from the first **126a** of the apertures **126**. The illustrated embodiment also includes an aperture **128** extending through the second end **124** of the wrist strap **106**. The aperture **126** can be positioned near the second edge **116**. The aperture **128** is configured to receive a fastener or connector therein (see, for example, fastener **200** of FIGS. 4-5). The fastener or connector is configured to secure the second end **124** to the first end **122** of the wrist strap **106**. For example, in some embodiments, the fastener extends through both the aperture **126** of the second end **124** and one or more of the apertures **126** of the first end **122**. In some embodiments the apertures **126** and the aperture **128** can be reversed. That is the aperture **128** can be positioned in proximity to the first edge **114** and the apertures **126** can be positioned in proximity to the second edge **116**.

[0036] FIG. 4 is a perspective view of an example connector or fastener **200** that can be used with the brace **100**. In the illustrated embodiment, the fastener **200** includes a base **202** and two projections **204**. The projections **204** extend perpendicularly away from a surface **206** of the base **202**. A distal end **208** (that is, the free end of the projection **204** opposite the connection to the base **202**) of each projection **204** includes prongs **210** that extend outwardly from the projection **204**. Thus, in some embodiments, each protrusion **204** is substantially T-shaped. Other embodiments of the fastener are possible. For example, the fastener may include a single projection. Alternatively, the fastener **200** can comprise a snap, button, clasp, etc.

[0037] With reference again to FIG. 1, the fastener **200** can be inserted through the aperture **128** of the second end **124** such that the projections **204** extend through the aperture **128** and the surface **206** of the base **202** of the fastener **200** may be brought into contact with the exterior surface **104** of the body **102**. To secure the second end **124** to the first end **122**, the projections **204** can then be inserted through two of the plurality of apertures **126** of the first end **122**, with each projection **204** being inserted through one of the plurality of apertures **126**. The prongs **210** then secure the fastener **200** in place.

[0038] FIG. 5 is a cross-sectional view of the fastener **200** in use securing the second end **124** to the first end **122**, according to one embodiment. As shown, the second end **124** can be positioned on top of the first end **122** such that the aperture **128** is aligned with two of the plurality of apertures **126**. The fastener **200** can then be inserted through the aperture **128** and the two of the plurality of apertures **126**. One of the projections **204** can extend through the aperture **128** and one of the apertures **126**. The other projection **204** can extend through the aperture **128** and the other of the apertures **126**. The surface **206** of the base **202** can be positioned on the exterior surface **104** of the second end **124**. The prongs **210** can be positioned on an interior side **130** of the first end **122**. The prongs **210** may prevent the fastener **200** from being inadvertently pulled back through the apertures **126**, **128**. Although one particular configuration is illustrated in FIG. 5, other configurations are possible. For example, the first end **122** can be positioned on top of the second end **124** and/or the fastener **200** can be inserted from the opposite direction (that is, such that the base **202** is located on the interior side **130** and the prongs **210** are located on the exterior side **104**).

[0039] Returning again to FIG. 1, the plurality of apertures **126** can allow the brace **100** to be used on patients with wrists of different sizes. For example, by inserting the fastener **200** through apertures **126** nearer the first edge **114**, the brace **100** can be used with larger wrists and by inserting the fastener **200** through apertures **126** nearer the second edge **116** the brace **100** can be used with smaller wrists. Similarly, the plurality of apertures **126** can allow a user to adjust the fit and/or tightness of the brace **100** around the wrist. For example, by inserting the fastener **200** through apertures **126** nearer the first edge **114**, the brace **100** can provide a looser fit and by

inserting the fastener **200** through apertures **126** nearer the second edge **116** the brace **100** can provide a tighter fit. Examples of the wrist strap **106** secured around a patient's wrist by the fastener **200** are shown in FIGS. **6-8**. Additionally or alternatively, the brace **100** can be provided in a plurality of different sizes (e.g., small, medium, large, etc.) to accommodate wrists of different sizes.

[0040] In some embodiments, other closure systems for securing the wrist strap **106** around the patient's wrist can be implemented. For example, the brace **100** can include snaps, buckles (e.g., similar to a wrist watch), or hook and loop material to secure the brace **100**. In some embodiments, the wrist strap **106** is configured as a continuous loop, such that no fastener is needed. For example, the wrist strap **106** can be configured as a continuous loop of elastic material that can be stretched to pass over the user's hand and which can then tighten (recover) around the wrist.

[0041] The first palmar strap **108**, the second palmar strap **110**, and the dorsal projection **112** may each extend generally away from the distal edge **120** of the wrist strap **106** in a second direction that is perpendicular to the first direction. For example, as illustrated in FIG. **1**, each of the first palmar strap **108**, the second palmar strap **110**, and the dorsal projection **112** extend generally away from the distal edge **120** of the wrist strap **106** in the y-direction.

[0042] The first palmar strap **108** and the second palmar strap **110** are each referred to as “palmar” because, in some embodiments, when the brace **100** is worn by the patient, the first and second palmar straps **108**, **110** extend at least partially over a palm (or inside surface) of the hand (see FIGS. **6-8**, for example). The dorsal projection **112** is referred to as “dorsal” because, in some embodiments, when the brace **100** is worn by the patient, the dorsal projection extends at least partially over a dorsum (or outside surface) of the hand (again, see FIGS. **6-8**, for example). As illustrated in FIG. **1**, the second palmar strap **110** is connected to the wrist strap **106** between the connection of the first palmar strap **108** to the wrist strap **106** and the dorsal projection **112**. In the illustrated implementation, the first palmar strap **108** and the second palmar strap **110** extend from the wrist strap **106** to a length that is longer than a length that the dorsal projection **112** extends from the wrist strap **106**. Also, in the illustrated implementation, the distal end **134** of the first palmar strap **108** extends from the wrist strap **108** farther than a distal end **159** of the second palmar strap **110** extends from the wrist strap **108**. In the example shown in FIG. **1**, the first palmar strap **108** is separated from the second palmar strap **110** by a gap that is smaller than a gap separating the second palmar strap **110** and the dorsal projection **112**.

[0043] Still referring to FIG. **1**, in the illustrated embodiment, the first palmar strap **108** extends between a proximal end **132** and a distal tip **134**. The proximal end **132** may be connected to or extend from the distal edge **120** of the wrist strap **106**. The palmar strap **108** may include a first edge **136**, a second edge **138**, and a distal edge **140**. In some embodiments, the first edge **136** and the second edge **138** are substantially parallel, extending generally in the y-direction. In some embodiments, the distance between the first edge **136** and the second edge **138** narrows along the first palmar strap **108** moving from the wrist strap **106** to the distal tip **134**. In some embodiments, the first edge **136** and the second edge **138** are substantially straight. In some embodiments, the first edge **136** and the second edge **138** may include one or more curves. In some embodiments, the first edge **136** is continuous with a portion of the distal edge **120** of the wrist strap **106**. The first edge **136** and the distal edge **120** may meet at an intersection **142**. In some embodiments, the intersection **142** may include a curve between the first edge **130** and the distal edge **120**.

[0044] At a distal end **144**, the first edge **136** and the second edge **138** are connected by the distal edge **140** of the first palmar strap **108**. The distal edge **140** may include a curve connecting the edge **136** and the second edge **138**. The curve of the distal edge **140** may define a lobe shape at the distal end **144** of the first palmar strap **108**. The distal end **144** may be curved or bent with respect to a main portion **146** (in other words, the portion between the first edge **136** and the second edge **138**) of the first palmar strap **108**. In some embodiments, the distal end **144** curves in a direction toward the second palmar strap **110** and/or the dorsal projection **112**. In some embodiments, the

main portion **146** may also curve toward the second palmar strap **110** and/or the dorsal projection **112**. In some embodiments, the first palmar strap **108** may comprise a finger-like shape.

[0045] In the illustrated embodiment, the first palmar strap **108** includes an aperture **148** in the distal end **144**. The aperture **148** may be configured in size and shape to receive a fastener **200** to connect the distal end **144** of the first palmar strap **108** to one or more of a plurality of apertures **150**, **152** on the dorsal projection (as shown, for example, in FIGS. **6-8**). In some embodiments, when the brace **100** is worn, the first palmar strap **108** extends from the wrist strap **106**, across a portion of a palm of a hand, over the pulcrum of the hand (the space or webbing connecting the thumb and index finger) and connects to the dorsal projection **112**. The connection between the first palmar strap **108** and the dorsal projection **112** can be made using the fastener **200** in a manner substantially similar to the connection between the second end **124** and the first end **122** of the wrist strap **106** described above (see, for example, FIGS. **4** and **5**). In some embodiments, other closure systems for connecting the first palmar strap **108** to the dorsal projection **112** can be implemented. For example, the brace **100** can include snaps, buckles (e.g., similar to a wrist watch), or hook and loop material for connecting the first palmar strap **108** to the dorsal projection **112**.

[0046] In some embodiments, the second palmar strap **110** is positioned substantially adjacent to the first palmar strap **110** in a direction toward the dorsal projection **112**. In some embodiments, a space **154** is formed between the first palmar strap **108** and the second palmar strap **110**. In some embodiments, a width of the space **154** increases in a direction moving away from the wrist strap **106**.

[0047] The second palmar strap **110** extends between a proximal end **156** and a distal tip **159**. The proximal end **156** may be connected to or extend from the wrist strap **106**. In the illustrated embodiment, a portion of the proximal end of the second palmar strap **110** is also connected to a portion of the proximal end **132** of the first palmar strap **108**. The second palmar strap **110** may include a first edge **158**, a second edge **160**, and a distal edge **162**. In the illustrated embodiment, the first edge **158** and the second edge **160** are generally parallel, extending generally in the y-direction and curving toward the dorsal projection **112**. In some embodiments, the distance between the first edge **158** and the second edge **160** narrows along the second palmar strap **110** moving from the wrist strap **106** toward the distal tip **159**. In some embodiments, the distance between the first edge **158** and the second edge **160** widens along the second palmar strap **110** moving from the wrist strap **106** toward the distal tip **159**. In some embodiments, the first edge **158** and the second edge **160** are substantially straight. In some embodiments, the first edge **158** and the second edge **160** may include one or more curves. In some embodiments, the first edge **158** is continuous with the second edge **138** of the first palmar strap **108**. The first edge **158** of the second palmar strap **110** and the second edge **138** of the first palmar strap **108** may meet at an intersection **164**. In some embodiments, the intersection **164** may include a curve between the first edge **158** and the second edge **138**.

[0048] At a distal end **166**, the first edge **158** and the second edge **160** are connected by the distal edge **162** of the second palmar strap **110**. The distal edge **162** may include a curve connecting the first edge **158** and the second edge **160**. The curve of the distal edge **162** may define a lobe shape at the distal end **166** of the second palmar strap **110**. The distal end **166** may be curved or bent with respect to a main portion **170** (in other words, the portion between the first edge **158** and the second edge **160**) of the second palmar strap **110**. In some embodiments, the distal end **166** curves in a direction toward the dorsal projection **112**. In some embodiments, the main portion **170** may also curve toward the dorsal projection **112**. In some embodiments, the second palmar strap **110** may comprise a finger-like shape.

[0049] In the illustrated embodiment, the second palmar strap **110** includes an aperture **172** in the distal end **166**. The aperture **172** may be configured in size and shape to receive a fastener **200** to connect the distal end **166** of the second palmar strap **110** to one or more of the plurality of

apertures **150**, **152** on the dorsal projection (as shown, for example, in FIGS. **6-8**). In some embodiments, when the brace **100** is worn, the second palmar strap **110** extends from the wrist strap **106**, across a portion of the palm of the hand, over the pulcrum of the hand and connects to the dorsal projection **112**. The connection between the second palmar strap **110** and the dorsal projection **112** can be made using the fastener **200** in a manner substantially similar to the connection between the second end **124** and the first end **122** of the wrist strap **106** described above (see, for example, FIGS. **4** and **5**). In some embodiments, other closure systems for connecting the second palmar strap **110** to the dorsal projection **112** can be implemented. For example, the brace **100** can include snaps, buckles (e.g., similar to a wrist watch), or hook and loop material for connecting the second palmar strap **110** to the dorsal projection **112**.

[0050] In the illustrated embodiment, the brace **100** includes two palmar straps (the first palmar strap **108** and the second palmar strap **110**). In some embodiments, only one of these is included (for example, either the first palmar strap **108** or the second palmar strap **110**) and the other is omitted. In some embodiments, the first palmar strap **108** and the second palmar strap **110** can be combined to form a single palmar strap. In some embodiments, more than two palmar straps (for example, three, four, or more) may be included.

[0051] As mentioned previously, the brace **100** can also include a dorsal projection **112**, for example, as illustrated in FIG. **1**. The dorsal projection **112** may extend from the wrist strap **106** from a proximal portion **180** to a distal tip **182**. The proximal portion **180** can be connected to the wrist strap **106**. In the illustrated embodiment, the dorsal projection **112** includes a first edge **174**, a second edge **176**, and a distal edge **178**. The first edge **174** can be connected to the second edge **160** of the second palmar strap **110** at an intersection **184**. The intersection **184** can include a curve. A space **186** is formed between the dorsal projection **112** and the second palmar strap **110**. When the brace **100** is worn, the thumb may extend through the space **186** (see, for example, FIGS. **6-8**). In some embodiments, a width of the space **186** increases in a direction moving away from the wrist strap **106**. In some embodiments, the second edge **176** of the dorsal projection **112** is continuous with a portion of the distal edge **120** of the wrist strap **106**. The second edge **176** and the distal edge **120** may meet at an intersection **188**. In some embodiments, the intersection **188** may include a curve between the second edge **176** and the distal edge **120**.

[0052] In the illustrated embodiment, a width of the dorsal projection **112** (measured between the first edge **174** and the second edge **176**) narrows in a direction moving away from the wrist strap **106**, such that the dorsal projection **112** has a substantially triangular shape. Other shapes for the dorsal projection **112** are also possible, as discussed below. The distal edge **178** connects the first edge **174** and the second edge **176**. The distal edge **178** may be curved.

[0053] As mentioned above, the dorsal projection **112** may include a plurality of apertures **150** and a plurality of apertures **152**. The apertures **150**, **152** can be used to connect the first and second palmar straps **108**, **110** to the dorsal projection **112**. In the illustrated embodiment, the apertures **150** are arranged along an axis. Ten apertures **150** are illustrated, although other numbers (greater than fewer) are possible. In the illustrated embodiment, the apertures **152** are also arranged along an axis. Six apertures **152** are illustrated, although other numbers (greater and fewer) are possible. In some embodiments, the axes of the first and second apertures **150**, **152** are substantially parallel. In some embodiments, the axes are straight. In some embodiments the axes are curved. In some embodiments, the axes of the first and second apertures **150**, **152** are not parallel. In some embodiments, the axes of the first and second apertures **150**, **152** extend generally in the y-direction. In some embodiments, the axes of the first and second apertures **150**, **152** are angled with respect to the axis of the apertures **126**. In some embodiments, the angle the axis of the first and/or second apertures **150**, **152** with respect to the axis of the apertures **126** is about 90 degrees, about 85 degrees, about 80 degrees, about 75 degrees, about 70 degrees, about 65 degrees, or about 60 degrees, or smaller (as well as all ranges listed between the listed angles).

[0054] The apertures **150**, **152** provide a plurality of connection points for the first and second

palmar straps **108**, **110** allowing for the fit and tightness of the brace **100** to be adjusted to fit the anatomy of a particular patient or to vary the amount of support or compression provided by the brace **100**. In some embodiments, the first palmar strap **108** is connected to the apertures **150** and the second palmar strap **110** is connected to the apertures **152**, such that the first and second palmar straps **108**, **110** run generally parallel over the purlicue of the hand. In some embodiments, the first palmar strap **108** is connected to the apertures **152** and the second palmar strap **110** is connected to the apertures **150** such that the first and second palmar straps **108**, **110** cross each other over the purlicue of the hand (either the first palmar strap **108** or the second palmar strap **110** may be on top). In some embodiments, the cross of the first and second palmar straps **108**, **110** (if present) may occur over the dorsum or the palm of the hand.

[0055] In some embodiments, the dorsal projection **112** can be omitted and the first and second palmar strap **108**, **110** can connect to the wrist strap **106**. In some embodiments, more than one dorsal projection **112** can be included, with each dorsal projection **112** configured to connect to one of the first and second palmar straps **108**, **110**.

[0056] In some embodiments, a length of the palmar straps **108**, **110** is longer than a length of the dorsal projection **112**, such that when worn, the palmar straps **108**, **110** extend over a portion of the palm, over the purlicue, and connect to the dorsal projection **112** over the dorsum of the hand. This need not be the case in all embodiments, however, and the lengths of the palmar straps **108**, **110** and dorsal projection **112** can be varied such that the connections between the palmar straps **108**, **110** and dorsal projection **112** can occur over the palm or purlicue. In some embodiments, the palmar straps **108**, **110** and dorsal projection **112** are continuously formed such that no connection between the palmar straps **108**, **110** and dorsal projection **112** is needed. That is, the palmar straps **108**, **110** and dorsal projection **112** can form one or more continuous loops or straps extending from the wrist strap **106** configured to extend across the palm, over the purlicue, and across the dorsum.

[0057] As shown in the cross-sectional view of FIG. 2, the brace **100** may have a thickness $T_{sub.1}$ as shown. In some embodiments, the thickness $T_{sub.1}$ is approximately 1 cm, 7.5 mm, 5 mm, 4 mm, 3 mm, 2 mm, or 1 mm. Other thicknesses are also possible. As shown in FIGS. 1 and 2, the body **102** may include a lip **192** formed around the edges of the body **102**. The lip **192** may be formed as a region of reduced thickness. The lip **192** may be, in some embodiments, approximately one half the thickness $T_{sub.1}$.

[0058] In the illustrated embodiment, the brace **100** also includes an insert **190**. The insert **190** is shown in greater detail in FIG. 3. The insert **190** can be configured to provide additional support for the CMC joint. In some embodiments, the insert **190** can be positioned on (or in) the brace **100** so as to be positioned over the CMC joint when the brace **100** is worn. In some embodiments, the insert **190** can be positioned on (or in) the brace **100** so as to be positioned below the CMC joint (in other words, up the arm below the CMC joint) when the brace **100** is worn.

[0059] In some embodiments, the insert **190** is made of plastic or other similar materials. In some embodiments, the insert **190** is not elastic or recoverable. In some embodiments, the insert **190** is flexible so as to conform to the shape of the patient's wrist. In some embodiments, the insert **190** is stiff or rigid. In some embodiments, the insert **190** is formed with a curved shape that wraps around the patient's wrist. As will be described below, in some embodiments, the insert **190** is made of a heat formable material. In some embodiments, the insert **190** can be omitted.

[0060] In some embodiments, the insert **190** is embedded within the body **102** of the brace **100**. FIG. 2 is a cross-sectional view of the brace **100** taken along the line shown in FIG. 1. As shown in FIG. 2, the insert **190** is included within the body **102** between the exterior surface **104** and the interior surface **130**. In some embodiments, the insert **190** may be centered between the exterior surface **104** and the interior surface **130**. In some embodiments, the insert **190** may be closer to the exterior surface **104** than the interior surface **130**. In some embodiments, the insert **190** may be closer to the interior surface **130** than the exterior surface **104**. In some embodiments, the insert **190** may be flush with the interior surface **130** or the exterior surface **104**. Although illustrated

embedded in the body **102** in FIG. 2, in some embodiments, the insert **190** can be attached (by adhesive or mechanical means) to the exterior surface **104** or interior surface **130**. The insert **190** can have a thickness $T_{sub.2}$ as shown. In some embodiments, the thickness $T_{sub.2}$ can be about 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, or 0.5 mm. Other thicknesses are possible. In some embodiments, the insert **190** is as thick as the body **102**. In some embodiments, the insert **190** is about 90%, about 80%, about 70%, about 60%, about 50%, about 40%, about 30%, about 20%, or about 10% as thick as the body **102** (as well as ranges and values between the listed percentages).

[0061] FIG. 3 is a plan view of the insert **190**. In the illustrated embodiment, the insert **190** includes a CMC portion **194**, a dorsal portion **196**, and a palmar portion **198**. When the brace **100** is worn, the CMC portion **194** can be positioned over the CMC joint, the dorsal portion **196** can wrap around a portion of the dorsum of the hand, and the palmar portion can wrap around a portion of the palm of the hand. The dorsal portion **196** and the palmar portion **198** can each be formed as lobes. In some embodiments, the lobe of the palmar portion **198** is larger than the dorsal portion **196**, as illustrated. In some embodiments, the lobe of the dorsal portion **196** can be larger than the lobe of the palmar portion **198**. In some embodiments, the lobes of the dorsal portion **196** and the palmar portion **198** can be approximately the same size.

[0062] The insert **190** includes a proximal edge **191** and an opposite distal edge **193**. On the dorsal end the proximal edge **191** is connected to the distal edge **193** by a dorsal edge **195**. On the palmar end the proximal edge **191** is connected to the distal edge **193** by a palmar edge **197**. In some embodiments, the dorsal edge **195** comprises a curve having a substantially constant radius. In some embodiments, the palmar edge **197** comprises a curve having a substantially constant radius. In some embodiments, the proximal edge **191** includes a convex curve. In some embodiments, the distal edge **193** includes a concave curve. Thus, in some embodiments, the insert **190** comprises a general C-shape. In some embodiments, one end of the C-shape curves towards the first and second palmar straps **108**, **110**, and the opposite end of the C-shape curves towards the dorsal projection **112**. Other shapes for the insert **190** are possible.

[0063] The insert **190** can be positioned within the body **102** within the wrist strap **106**, and/or the proximal portions **132**, **156**, **180** of the first and second palmar straps **108**, **110** and the dorsal projection **112**. In general, when worn, the insert **190** can be positioned over or below the CMC joint and curves around the patient's wrist or the base of the patient's thumb.

[0064] In the illustrated embodiment, the insert **190** includes holes **199** formed therethrough. Three holes **199** are illustrated, although other numbers and locations are possible. The holes **199** may be used to position the insert **190** in the mold (see FIG. 11) so that the elastomeric material of the body **102** can be poured around the insert **190**.

[0065] As mentioned above, in some embodiments, the insert **190** is made a polymer that is heat moldable. The heat-moldable polymer can have, for example, a medium to high flexural modulus and/or a medium to high elongation or tensile strength. In some embodiments, the heat-moldable polymer is heat moldable at temperatures between about 130° F., about 150° F., or about 165° F. and about 250° F. or about 275° F. but stiff at temperatures below about 130° F., about 150° F., or about 165° F. The insert **190** can thus be moldable to fit a particular patient's anatomy. In certain implementations, the insert **190** is heat formable so that it can be fit in real time to the patient, then stiffen as it cools for patient-specific fit. Examples of suitable materials for the insert **190** include thermoplastic alloys formed from one or more polymers. Suitable polymers include polyester, polyethylene, polyvinyl chloride, polyethylene terephthalate, polyamide, or PVC foam such as Sintra™ or Komatex™, or combinations thereof. An example of a suitable heat-moldable material for the insert **190** includes a thermoformable material provided by DJO Global under the trademark "Exos 40BX."

[0066] When the brace **100** includes a heat-moldable insert **190** it can be formed and custom shaped to a patient's anatomy by heating the brace **100** at a relatively low temperature (such that the heat-moldable insert **190** becomes pliable), placing the heated brace **100** on the patient, and

applying pressure to custom form the brace **100** to the patient as the brace **100** cools and the insert **190** hardens. An example process for conforming or molding the brace **100** to the specific and unique musculoskeletal shape of a patient will now be described in detail.

[0067] As an initial step, a brace **100** having a general shape is provided. The general shape may be the flat shape illustrated in FIG. **1**, for example. The general shape may be preconfigured to fit generally around the patient wrist and thumb. In some embodiments, the general shape is configured as a one-size-fits-all shape that can be molded, according the method described herein to fit a particular patient. In some embodiments, a patient or a healthcare provider may select a brace **100** having a general shape from among a limited number of size options. For example, in some embodiments, braces **100** may be provided in a first size with a general shape configured to fit adults and a second size with a general shape configured to fit children.

[0068] Next, the brace **100** can be heated in a heating/warming source to the prescribed temperature, which in some embodiments is between about 130° F., about 150° F., or about 165° F. and about 250° F. or about 275° F. As the brace **100** is heated, the insert **190** becomes pliable and moldable. The elastomeric body **102** is not substantially affected by heating, and in some embodiments, can be heated with the insert **190**. Once the desired temperature is achieved, brace **100** can be removed from the heating/warming source. In some embodiments, the heating/warming device may be portable. This may allow a healthcare provider to bring the heating/warming device to the patient. This may be advantageous because it may allow for a complete custom fitting in a single home visit. In some embodiments, however, the brace **100** can be heated in any conventional heating source capable of heating to the prescribed temperature, including a conventional home oven. This may allow a user to purchase a brace **100** and then custom fit it at home. In some embodiments, however, it is advantageous to have a healthcare provider custom fit the brace **100** a proper fitting.

[0069] Next, the heated brace **100** can be placed on the wrist (for example, as shown in FIGS. **6-8**). A medical professional may hold the wrist and thumb in a desired alignment. The medical professional can then gently mold the insert **190** to the specific shape of the patient's wrist and thumb by applying gentle pressure. In some embodiments, the medical professional may apply pressure to the brace **100** with his/her hands in order to mold the insert **190** to the specific shape of the patient. In some embodiments, the various closures systems connecting the palmar straps **108**, **110** to the dorsal projection **112** (described above) may be tightened while the brace **100** remains heated and the pressure of the closure may mold the insert **190** to the contours of a patient.

[0070] As the brace **100** cools, the insert **190** hardens in the molded configuration about the wrist and thumb, providing a stabilizing brace structure that is specific to the patient. In some embodiments, the brace **100** can be re-heated and re-shaped to adjust the configuration of the brace **100** in response to changes in the patient's anatomy such as swelling.

[0071] As shown in FIG. **13**, for example, in some embodiments, after the insert **190** has been heat molded, it may retain a curved shape. In some embodiments, the insert **190** may be manufactured to include the curved shape shown in FIG. **13**.

[0072] FIGS. **6-8** illustrate an example of the brace **100** as worn by a patient. FIG. **6** is a dorsal view of a right hand wearing the brace **100**. FIG. **7** is palmar view of the right hand wearing the brace **100**. FIG. **8** is a perspective view of a right hand wearing the brace **100**. As shown in these FIGS. **6-8**, in some embodiments, when the brace **100** is worn, the insert **190** is positioned over the CMC joint of the thumb and wraps around the patient's wrist and thumb. This can provide support and bracing for CMC joint.

[0073] As shown, the wrist strap **106** can encircle the patient's wrist and can be connected by the connector or fastener **200**. The first and second palmar straps **108**, **110** can extend across a portion of the palm, over the purlicue, and connect to the dorsal projection **112** by connectors **200**. In some embodiments, one or both of the first and second palmar straps **108**, **110** extend over a portion of the thenar eminence of the palm.

[0074] Various other features of the brace **100** are also illustrated in FIGS. **6-7** and correspond with similarly numbered features described above with reference to FIG. **1**.

[0075] FIG. **9** is a plan view of an exterior side of another embodiment a CMC thumb brace **300** (the “brace **300**”), illustrated when not worn by a patient and lying flat. In many aspects, the brace **300** is similar to the brace **100** described above. For example, the brace **300** includes a wrist strap **306**, a first palmar strap **308**, a second palmar strap **310**, and a dorsal projection **312** that are similar to corresponding features described above. The brace **300** can also include an insert **190** as described above.

[0076] As illustrated in FIG. **9**, the second dorsal strap **310** of the brace **300** includes a thinner portion **315**. FIG. **10** is a cross-sectional view of the second dorsal strap **310** of the brace **300** taken along the line illustrated in FIG. **9** and illustrates the thinner portion **315**. The thinner portion **315** may be positioned on the second dorsal strap **310** at a location that overlies the purlicue when the brace is worn. The thinner portion **315** can facilitate wrapping the second dorsal strap **310** over the purlicue. Although not illustrated, the first dorsal strap **308** can also include a similar thinner portion.

[0077] FIG. **9** also illustrates that a variety of surface textures **301, 303, 305, 307, 309** can be applied to the exterior surface of the brace **300**. In the illustrated embodiment, a first surface texture **301**, formed as a pattern of slightly indented circles is formed over a portion of the wrist strap **306**. A second surface texture **303**, also formed as a pattern of slightly indented circles, is formed over a portion of the first palmar strap **308**. A third surface texture **305**, formed as pattern of slightly indented hexagons, can be formed over a portion of the second palmar strap **310**. A fourth surface texture **307**, formed as a radial pattern of slightly indented grooves, divides the first surface texture **301**, the second surface texture **303**, and the third surface texture **305**, from a fifth surface texture **309**. The fifth surface texture **309** is formed as pattern of diagonal indented grooves over another portion of the wrist strap **306**, the dorsal projection **312**, and portions of the first and second palmar straps **308, 310**. Other surface textures and locations are possible. In some embodiments, the surface textures are omitted. In some embodiments, the textures can enhance grip and/or breathability.

[0078] FIG. **11** illustrates an embodiment of mold **400** that can be used to manufacture a CMC brace as described above. In the illustrated embodiment, the mold **400** includes a depression or recess **402** that corresponds in size and shape to the body **102** of the brace **100**. The mold includes one or more protrusions **406** that extend upwardly from the recess **402**. The protrusions **406** are configured in size, shape, and position to form the various apertures (e.g., apertures **126, 128, 148, 150, 152, 172**) of the brace **100**. The mold **400** can also include posts **408**. The posts **408** are configured to support the insert **190** within the mold. For example, as shown, the insert **190** can be placed on the posts **408**. An additional protrusion **410** can be included to form a logo into the molded brace. The mold **400** can also include various surface textures **412, 414, 416** so as to form various surface textures on the brace (see, e.g., the brace **300** of FIG. **9**).

[0079] A method of manufacturing the brace **100** can include, for example, providing the mold **400**; positioning an insert **190** onto the posts **408**; and pouring a liquid material into the mold. The liquid material can comprise, for example, an elastomeric material, such as silicone, as described above. The liquid material can fill the recess **402** of the mold **400**. The liquid material can, in some embodiments, flow below and above the insert **190** such that the insert **190** becomes embedded in the material. The method can also include allowing the material to solidify and removing the formed brace from the mold **400**. Other methods of manufacture are also possible.

[0080] FIGS. **12** and **13** illustrate example dimensions for one embodiment of a CMC thumb brace. The illustrated embodiment and dimensions are provided by way of one example only and are not intended to be limiting. FIG. **13** illustrates a side view of the CMC thumb brace that includes an insert **190** that has been heat molded to conform to a patient. The illustrated dimension is a height of a curve formed in the brace measured when the brace is lying flat. Again, the illustrated

dimensions are only examples, and other dimensions can be used in other embodiments.

[0081] In some embodiments, the braces described herein can be used post operation after basilar joint reconstruction surgery.

[0082] The foregoing description details certain embodiments of the systems, devices, and methods disclosed herein. It will be appreciated, however, that no matter how detailed the foregoing appears in text, the systems, devices, and methods can be practiced in many ways. As is also stated above, it should be noted that the use of particular terminology when describing certain features or aspects of the invention should not be taken to imply that the terminology is being re-defined herein to be restricted to including any specific characteristics of the features or aspects of the technology with which that terminology is associated.

[0083] It will be appreciated by those skilled in the art that various modifications and changes may be made without departing from the scope of the described technology. Such modifications and changes are intended to fall within the scope of the embodiments. It will also be appreciated by those of skill in the art that parts included in one embodiment are interchangeable with other embodiments; one or more parts from a depicted embodiment can be included with other depicted embodiments in any combination. For example, any of the various components described herein and/or depicted in the figures may be combined, interchanged or excluded from other embodiments.

[0084] The above description discloses several methods and materials of the present invention. This invention is susceptible to modifications in the methods and materials, as well as alterations in the fabrication methods and equipment. Such modifications will become apparent to those skilled in the art from a consideration of this disclosure or practice of the invention disclosed herein. Consequently, it is not intended that this invention be limited to the specific embodiments disclosed herein, but that it cover all modifications and alternatives coming within the true scope and spirit of the invention as embodied in the attached claims. Applicant reserves the right to submit claims directed to combinations and sub-combinations of the disclosed inventions that are believed to be novel and non-obvious. Inventions embodied in other combinations and sub-combinations of features, functions, elements and/or properties may be claimed through amendment of those claims or presentation of new claims in the present application or in a related application. Such amended or new claims, whether they are directed to the same invention or a different invention and whether they are different, broader, narrower or equal in scope to the original claims, are to be considered within the subject matter of the inventions described herein.

Claims

1. A brace for a carpometacarpal joint of a thumb, comprising: a body including a wrist strap configured to encircle a patient's wrist when the brace is worn, and a strap connected on a first end to a first location of the wrist strap and connected on a second end to a second location of the wrist strap, the strap configured in size and shape to extend across a portion of the patient's palm, over the pulicue, and across a portion of a dorsum of the patient's hand; and an insert embedded within the body, the insert comprising a heat-moldable material that is pliable above a temperature and stiff below the temperature.
2. The brace of claim 1, wherein the temperature is between approximately 130° F. and approximately 250° F.
3. The brace of claim 1, wherein the body comprises an elastomeric material.
4. The brace of claim 3, wherein the elastomeric material comprises silicone.
5. The brace of claim 1, wherein the strap comprises: a dorsal projection extending from the first location of the wrist strap; and a palmar strap extending between a proximal end connected to the second location wrist strap and a distal end configured to removable attach to the dorsal projection.
6. The brace of claim 5, wherein the dorsal projection is configured in size and shape to extend

over a portion of the dorsum of the hand when the brace is worn.

7. The brace of claim 5, wherein the palmar strap is configured in size and shape to extend across a portion of the palm and over the purlicue of the hand when the brace is worn.
