Design and Preliminary Evaluation of a Novel Brace for Boutonniere Deformity

Boutonniere deformities are a common injury to the extensor mechanism of the finger. The deformity results in fixed contraction in the middle finger joint and is severely debilitating to functionality. Due to the complexity of the extensor mechanism, surgical repair is difficult, which usually requires multiple procedures, and in some cases is unsuccessful. Nonsurgical treatment of the deformity has not dramatically improved in many years and usually requires long-term use of braces and physical therapy. This work is focused on design and preliminary evaluation of an improved boutonniere brace to correct the deformity with emphasis on lower costs, integrating therapeutic techniques such as heat and motion to increase blood flow and patient comfort. A review of the current state of the art is presented along with the design approach used to develop an improved device. Experimental test results are also presented. This work demonstrates a new device and approach for treatment of boutonniere deformities that may translate to treatment of other conditions such as arthritis. [DOI: 10.1115/1.4001862]

Keywords: splint, brace, boutonniere deformity, finger dislocation, therapy

1 Introduction

The boutonniere deformity (BD) is an injury to the extensor mechanism of the finger that severely hinders the afflicted digit’s functionality. Although damage to the extensor mechanism can occur from laceration, burns, or rheumatoid arthritis, many injuries that result in boutonniere deformities arise from dislocations in the finger. These dislocations can result from sudden compressive forces on the finger that cause the middle phalanx to herniate through a part of the extensor mechanism called the central slip, causing a “buttonhole,” or tear in the tendon. Damage to this tendon leads to an imbalance within the mechanism, and if left untreated, results in fixed contraction at the proximal interphalangeal joint (Fig. 1).

Permanent joint contraction is highly problematic for athletes, musicians, and professionals that rely on fine dexterity and control of their fingers. Currently, BD is often surgically treated with an invasive procedure that involves insertion of a metal pin through a part of the extensor mechanism called the central slip, as well as passing laterally to the DIP joint to attach at the base of the middle phalanx, a site over the joint and attaches at the base of the middle phalanx, a site known as the distal phalangeal joint (Fig. 2). One of these ligaments passes dorsally over the joint and attaches at the base of the middle phalanx, a site known as the distal phalangeal joint (DIP) joint (Fig. 2).

These structures are supported by a capillary network that runs along the midline of the bones along the length of the finger. Although the supply and drainage of this network is not anatomically universal, the most common route of blood flow is through the superficial arch, which supplies oxygenated blood from radial and ulnar arteries, and drains into the medial basilic vein. Innervation of the hand is complex and, while multiple nervous networks enable sensitive response throughout the hand, the ulnar nerve is responsible for the sense of touch in the fourth and fifth digits. The nervous pathway follows the midline path of the blood vessels, and similarly branches to more remote parts of the finger [1].

The extensor mechanism in the finger is composed of an intricate and complex balance of tendons and ligaments. A hood of shroud fibers, which stems from the extrinsic extensor tendon in the forearm, trifurcates at the proximal interphalangeal joint into three ligaments that connect the proximal and middle phalanges [2–5]. One of these ligaments (central tendon) passes dorsally over the joint and attaches at the base of the middle phalanx, a site known as the central slip. The lateral divisions of the extensor hood merge with part of the radial and ulnar intrinsic tendons, forming symmetric structures called lateral bands. These ligaments pass on either side of the PIP joint to converge at the central slip, as well as passing laterally to the DIP joint to attach at the
base of the distal phalanx. A triangular ligament bridges the two lateral bands across the dorsal surface of the middle phalanx, holding them in a dorsal position when the PIP joint is in flexion [2–5].

2.2 Boutonniere Deformity. Although boutonniere deformities may arise from dislocations, lacerations, or rheumatoid arthritis, damage to the central slip is common to all boutonniere deformities as shown in Fig. 2 [3–5]. Active extension is initially preserved by the lateral bands but flexion or tension in the bands eventually results in herniation through the central slip. This results in limited extension, as well as stretching or tearing of the triangular ligament that holds the lateral bands in a dorsal position. Migration of the bands to a more volar position and the damage to the central slip result in the PIP extensor mechanism being transformed into a flexor mechanism. Furthermore, additional tension in the lateral bands results in DIP hyperextension and loss of flexion [4–8]. Initially, the deformity is flexible but unless treated, imbalances within the extensor mechanism will lead to a tendency for shorter ligaments, and eventually a permanent contraction.

Surgical treatment of the deformity involves reconstruction of the central slip and later physical therapy rehabilitation. It is also reported that splinting, in combination with physical therapy, likely yields more positive results than surgery [8]. A prerequisite for many viable surgical procedures is passive extension in the PIP joint, which is only inherently possible in the first 4–6 weeks after the occurrence of the injury [7–9]. Alternatively, surgical procedures can release tension in the lateral bands or dynamic splinting may be employed to promote passivity in the joint [7–10]. Most often, extension regained from these devices is adequate for functionality and surgical procedures are discouraged. Unfortunately, available braces are cumbersome, impede blood flow, require extensive physical therapy and continual adjustment to attain any beneficial results. The goal of this project was to develop an improved splint that can be used in place of surgery, can be patient-specific, does not impede blood flow, and incorporates therapeutic treatment such as massage and heat treatment to the injury site.

2.3 Current Treatment Approaches. Surgical treatment of BD involves restoring functionality of the central slip. This is done by using neighboring tendinous tissue or by transplant and depends on a number of factors including the severity of the damage to the central slip, elapsed time from onset, and scar tissue around the PIP joint [7–11]. In one of the more commonly used approaches, the repaired tendon is kept unstressed by using a Kirshner wire and pin that are placed through the PIP joint. This immobilizes the joint for 4–6 weeks. Following the removal of the pin, 2 weeks of whole finger splinting is required, along with an additional 2 weeks’ period of only allowing PIP motion with metacarpal and DIP splints [8,9]. Finally, rehabilitation to ensure stability in the tendon involves several weeks of physical therapy and in most cases includes recovery of flexion in the PIP joint [6–9], which is largely compromised by the duration of immobilization involved in the process.

Not only are gains in active extension from surgical procedures difficult to predict but the loss of flexion in many patients limits the practicality of the surgery, as full flexion is typically more functional than full extension in the hand [12]. Furthermore, the painful nature of Kirshner wires often times necessitates the use of prescription painkillers, which adds cost and some danger to an already unpleasant process. Finally, the waitlist to schedule surgery provides the deformity more time to develop and further complicates rehabilitation. For many of these reasons, some patients are advised to try to treat the condition nonsurgically and if unsuccessful, then to consider the risks and rewards of surgery. In one study, 75% of patients achieved satisfactory results from nonsurgical treatment compared with 50% of patients that underwent surgery [13].

Research supports that massage and heat therapy may provide improved treatment outcomes. For example, researchers have found that supraphysiological temperatures increased extensibility of collagenous tissue [14]. In addition, increased capillary blood flow can result from localized heating [15], thereby, ensuring a continual supply of nutrients needed during tendon repair [16]. It has also been documented that passive motion results in superior tensile properties and functionality when compared with immobilized tendons, leading researchers to conclude that passive mobilization may enhance the healing response of repaired collagenous tissue [17,18]. Furthermore, it has been shown that vibration can increase blood flow and enhance capillary nutrient exchange [19,20]. Finally, recent studies in exercise science have shown that vibration of tendons stimulates muscle afferents [21]. As a result, vibrating the lateral bands may stimulate extensor muscles and enhance stretching. One study showed that a frequency of 250–500 Hz was most helpful in simulating blood flow [22].

The nonsurgical, physical therapy, treatment of BD focuses on several of these approaches. Using a gel to enhance reception of electrical stimulus, a penetrating heating technique is used in combination with massage and manipulation of the PIP and DIP joints in an attempt to loosen the ligaments of the finger. In particular, the lateral bands are targeted and stretched by holding the PIP joint at maximum extension while flexing the DIP joint. This exercise also prevents hyperextension in the DIP joint by using the distal phalange as the mechanism of stretching through flexion. Unfortunately, the effects from therapeutic treatment dissipate within hours, especially in cold weather as tightness and immobility return to the finger very quickly following physical therapy.
3 Improved Brace Design

3.1 Design Goals. Several key factors must be considered when designing a brace that is effective in treating a deformity in a structure as complex as the extensor mechanism. First, the application of force to the affected area is critical because tendons exhibit viscoelastic properties, thus, the most effective method of stretching is to apply a low stress load over a long period of time [24,26,27]. Second, the application of the applied force must be capable of being varied for each patient as each injury varies in severity and success in treating the condition will necessitate adjustments to the load to prevent excessive or inadequate loading of the tendon. Finally, the method by which this force is delivered must not be a hindrance to the user. Bulky or obtrusive devices not only limit functionality and freedom of the hand and finger but also can prevent the use of the hand in gripping the simplest of objects, resulting in discouraged usage of the brace.

A number of methods of applying restoring forces to the middle and distal phalanges are available. Rubber bands, springs, and magnets could each be included in a patient-specific design. However, each has drawbacks that could compromise the other goals of the splint design. To help ensure a compact splint design and allow user adjustment, springs are the leading candidate for applying force. This will allow the designed splint to apply a low load over a long period of time and individual patient-specific adjustment. In addition, the forces will need to be applied to both extend the PIP in tandem with flexion of the DIP. However, efficacy of this method is dependent on applying the delivered force correctly, and inherent difficulties in matching spring-loaded lever arms to an individual’s anatomy make properly fitting these devices a challenging process.

Patient comfort is also extremely important as obtrusive or painful braces are unlikely to be worn for long periods of time, which will ultimately allow regression and slow the treatment of the deformity [24]. Thus, the designed brace needs to avoid dorsal pressure on the PIP joint to prevent swelling, scar tissue, and skin rupture. The brace must also avoid pressure on the nervous tissue and blood vessels, be unobtrusive and have a low profile to facilitate constant use during rehabilitation. Finally, incorporation of heat and massage motions to the PIP and DIP joints may facilitate ligament stretching and mimic physical therapy. The improved boutonniere brace (IBB) design requirements include the following:

1. Restore flexion and extension to the PIP joint—A prerequisite to reconstruction of the central slip is release of tension in the lateral bands that prevent extension of the middle phalange.
2. Low load over a long period of time—Excessive load causes discomfort and short treatment duration does not permanently stretch ligaments.
3. Adjustable load—not every patient will respond in the same way or start with the same severity.
4. Treatment of the DIP joint—Effectively stretching the lateral bands requires maximum extension of the PIP joint in tandem with flexion of the DIP joint.
5. Avoiding dorsal pressure on the PIP joint—Excessive dorsal pressure on the PIP joint leads to swelling, scar tissue build up, and eventual rupture of the skin, all of which impede patient recovery.
6. Ensuring circulation to the PIP joint—Oxygen, nutrients, and warm circulating blood are required to repair ligament damage, maintain finger functionality, and facilitate ligament stretching.
7. Avoiding pressure on nervous networks—Maintaining finger sensation is essential for functionality and avoiding patient discomfort.
8. Unobtrusive mount—Maintaining a low profile without major palmar/dorsal obstruction will help ensure hand/finger functionality.

2.4 Commercial Braces and Splints. The most prevalent brace, the DeRoyal LMB spring finger extension brace [23], is a spring-loaded foam lever that applies pressure to the proximal and middle phalanges (Fig. 3(a)). Another, more bulky device is a metal splint, the Joint-Jack [24], that applies pressure to the dorsal surface of the PIP joint through tension in a strap that can be adjusted by use of a thumbscrew (Fig. 3(b)). Two other less commonly used splints are the Bunnell type splint and thermoplastic splints. The Bunnell splint is a spring-based wireframe system that contacts the finger through cotton padding. Capener splints are similarly constructed but use a coil spring instead of a torsion or “paperclip.” The DeRoyal brace is a much more common version of this spring-loaded type splint. Thermoplastic splints generally include a dorsally mounted piece of plastic that is conformed to the patient’s proximal phalange by a physical therapist and fastened to the finger by wrapping Velcro straps around the finger. Typically, two straps are used, one around the proximal phalange and one around the middle phalange. The major drawbacks are that it is a static force that is applied over blood vessels and nervous networks. In addition, in use the Velcro loses its gripping power quickly as it is the major holding force. The cost of each of these splints is: Reverse Knuckle Bunnell—$47, DeRoyal—$58, Joint-Jack—$70, and Capener Coil Spring—$71 [25].

Unfortunately, in the opinion of the authors, all of these most popular brace models are generally ineffective, difficult to use, and focus on extension of the PIP joint only. The DeRoyal brace (Fig. 3(a)) is uncomfortable and due to the palmar pressure applied by the foam frame, it also limits blood flow to the digit. These shortcomings, in the opinion of the authors, make the brace difficult to wear for extended periods of time, and as a result limit the success of the brace in preventing regression. The Joint-Jack (Fig. 3(b)) focuses pressure on the DIP joint and unless the device matches the anatomy of the patient’s finger well, a great risk for DIP hyperextension and a subsequent worsening of the condition is likely. Furthermore, in the opinion of the authors, the circumferential pressure exerted by the strap cuts off circulation to the finger, thereby, leading to nearly immediate numbness and discoloration. Finally, the palmar base size of this brace is cumbersome and can easily prevent the user from effectively using the finger and hand in most activities. Due to these shortcomings, a new device was designed, fabricated, and tested.

Fig. 3 The DeRoyal LMB spring finger extension assist [20] brace during use (top) and the Joint-Jack [19] brace during use (bottom).
9. Providing heat and motion to the PIP joint—this will facilitate ligament stretching, enhance patient comfort, and prevent ligament contraction in low temperatures.
10. Minimizing cost—keeping costs as low as possible is also important in a successful design.

Application of these requirements will ideally result in a brace that could be worn at all times and would effectively stretch the lateral bands and return them to their original positions. A design of a candidate IBB is shown in Fig. 4. This design also allows for use across all fingers. In practice, each patient would be fitted to one of a number of different cradle and palmar support options that would maximize comfort and effectiveness.

### 3.2 Candidate Design

The candidate IBB design (Fig. 5), fabricated using rapid-prototyping polymers is fully dorsal mounted with a wrist strap to maintain brace position and transfer loads to a stable support. The low-profile dorsal base houses a system of springs, cables for patient-specific adjustment, and a therapy system. Dorsal mounting allow full freedom of the finger and hand for normal activities while wearing the brace.

A Nitinol spring is used at the base of the dorsal base to hold the base tight against the proximal phalanx. A pair of Nitinol beams is extended from the base over the phalanges that pass volar to the PIP joint. Massage therapy is provided through two small pager motors mounted into the brace (20 Hz). One motor is mounted above the PIP joint in the base while the other is mounted into the cradle (Fig. 5).

#### 3.3 Therapy

The therapy system provides heat and massaging motion to the PIP joint and although the electrical system is fixed to the brace, waterproofing the design is still possible. The system’s electrical circuit consists of two 5.6 ohm resistors (R1 and R2) in series (Fig. 6). Two vibration pager motors are connected in parallel, with one with a resistance of 11 ohms (M1) and the other with a resistance value of 13 ohms (M2). The total system resistance is 17.16 ohms.

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R_{\text{total}} = R_1 + R_2 + \left( \frac{1}{R_{M1}} + \frac{1}{R_{M2}} \right)^{-1}
\]

\[
= 5.6 \, \Omega + 5.6 \, \Omega + \left( \frac{1}{11 \, \Omega} + \frac{1}{13 \, \Omega} \right)^{-1}
\]

\[
= 17.16 \, \Omega
\]

The system draws 0.52 A from a 9 V battery, dissipating at 4.72 W.

\[
I = \frac{V}{R_{\text{total}}} = \frac{9 \, V}{17.16 \, \Omega} = 0.52 \, A
\]

\[
P = VI = (9 \, V)(0.52 \, A) = 4.72 \, W
\]

The system delivers 3.08 W of thermal energy to the PIP joint. The therapy system can be engaged by the user through a switch housed in the base of the IBB. A 9 V battery can supply sufficient power for approximately 1 h of continuous use (4).

The estimated cost of the IBB at larger scale production is $60. This include $2 for molded plastic parts, $5 for vibrational motors, $1 for electronics, $2 for Nitinol springs, and $2 for assembly ($12/device with a mark-up of ×5 for sale).

### 4 Applied Forces

#### 4.1 Current Devices

The Joint-Jack (Fig. 3(b)) palm area is 0.51 in.² (3.29 cm²), PIP dorsal area is 0.72 in.² (4.65 cm²), and lateral sides of the digit prevents any dorsal pressure at the PIP joint. The distal phalanx is held by a cradle that applies flexion to the DIP joint.

Initial integrated therapy solutions included an additional “jacket” that could be worn over the brace. However, to keep the brace as unobtrusive as possible, the motion and heat therapy system was integrated into the IBB. This system provides heat to the PIP joint through a pair of laterally mounted thermal resistors housed in the cradle as shown in Fig. 5. The heat is focused primarily at the PIP joint but has been shown to dissipate slightly throughout the finger during use. This localized heat (~40°C at the resistors) concentration is focused on the lateral bands and arteries that pass volar to the PIP joint. Massage therapy is provided through two small pager motors mounted into the brace (~20 Hz). One motor is mounted above the PIP joint in the base while the other is mounted into the cradle (Fig. 5).

#### 4.2 Power Consumption

The system draws 0.52 A from a 9 V battery, dissipating at 4.72 W.

\[
P = VI = (9 \, V)(0.52 \, A) = 4.72 \, W
\]

The system delivers 3.08 W of thermal energy to the PIP joint. The therapy system can be engaged by the user through a switch housed in the base of the IBB. A 9 V battery can supply sufficient power for approximately 1 h of continuous use (4).

The estimated cost of the IBB at larger scale production is $60. This include $2 for molded plastic parts, $5 for vibrational motors, $1 for electronics, $2 for Nitinol springs, and $2 for assembly ($12/device with a mark-up of ×5 for sale).
DIP palmar area is 0.09 in.² (0.58 cm²) for a total surface area of 1.32 in.² (8.52 cm²). The Joint-Jack employs static loading over the PIP joint, and maintains position on the hand from normal forces exerted by the actuator strap. Large amounts of force can be generated by the thumb screw system as described in Sec. 2.3. The DeRoyal palm area is 0.315 in.² (2.03 cm²), PIP dorsal area is 0.72 in.² (4.65 cm²), and DIP palmar area is 0.125 in.² (0.81 cm²) for a total surface area of 1.16 in.² (7.48 cm²). According to DeRoyal specifications for the brace, load output at an angular deflection of 90 deg is approximately 4 lbf (17.79 N), and at 15 deg is 0.5 lbf (2.22 N). Using these values, and assuming a linear spring constant, an angular deflection of 60 deg results in an applied force of 2.6 lbf (11.57 N). This corresponds well to measured force, which was 2.45 lbf (10.90 N) at 60 deg of deflection. Using the data extracted from the DeRoyal specifications, the pressure exerted on the dorsal PIP joint is (2.6 lbf/0.72 in.²) 3.61 psi (24.89 kPa), the palmar pressure is (1.3 lbf/0.315 in.²) 4.13 psi (28.48 kPa), and the DIP palmar pressure is (1.3 lbf/0.125 in.²) 10.4 psi (71.71 kPa).

4.2 IBB Device. The IBB improves delivery of applied forces for several reasons. First, the amount of force applied through the Nitinol beams is controlled through a cable system that shortens the cradle cables between the Nitinol beams and the cradle (Fig. 7). An end cap, connected to both beams, ensures that both beams are deflected evenly, and enables force to be applied at a vector directly normal to the surface of the middle phalange (Fig. 8). Each half rotation of the cable screw increases the load on the middle phalange by approximately 0.25 lbf (1.11 N). The cable screw can be fully wound through 4.5 rotations. A second set of Nitinol springs are attached between the base and the palmar support to counter the beam restoring force and maintain brace contact with the dorsal side of the hand. These springs provide a torsional force that presses the palmar support upward. This helps prevent movement of the metacarpophalangeal joint (sandwiched between the base and palmar support).

In contrast to commercially available brace designs, the IBB ensures that DIP flexion is maintained as the middle phalange is pulled toward a collinear relation with the proximal phalange. This increases the effectiveness of the applied force, as the lateral bands, which migrate volar and initiate the onset and permanence of the deformity, are stretched beyond the DIP joint in the distal phalange (i.e., the desired tension in the bands can be more effectively increased by stretching them at both the DIP and PIP joints).

Finally, the IBB device is designed to prevent large forces in contact with major nerve and capillary networks so that user discomfort and poor circulation troubles are mitigated. Attachment sites are designed with contours similar to the finger’s natural shape and force is distributed through a greater surface area and latex rubber coatings on contact locations (Fig. 5). This reduces acute pressure and enhances user comfort.

Experimental tests were conducted to measure IBB applied forces during use. Weights were incrementally added to the cradle cable until the deflection of the Nitinol beams was equivalent to the deflection measured during use of the IBB. Similarly, the force applied to the metacarpophalangeal joint was measured by incrementally applying weights to the palmar support until deflection from the equilibrium position was reached. Using these measured forces and geometry taken from the brace, static calculations were made to approximate the forces applied to the finger during use.

Measured values (Fig. 8) include $F_d = 2.27$ lbf (10.10 N), $F_{1y} = 1.98$ lbf (8.81 N), $\theta = 45$ deg, $d_1 = 5.35$ in. (13.59 cm), $d_2 = 4.30$ in. (10.92 cm), $d_3 = 1.40$ in. (3.56 cm), $d_4 = 0.70$ in. (1.78 cm), and $d_5 = 0.25$ in. (0.635 cm). The cradle cable angle can be used to determine the resultant force in the cable.

$$F_1 = \frac{F_{1y}}{\cos(\theta)} = \frac{1.98 \text{ lbf}}{\cos(45 \text{ deg})} = 2.80 \text{ lbf}(12.46 \text{ N}) \quad (5)$$

Summing moments about the support spring attachment in the palmar support free-body diagram (Fig. 8) leads to a support spring torque.

$$T_1 = F_d d_1 = (2.27 \text{ lbf})(0.7 \text{ in.}) = 1.59 \text{ lbf in.}(0.18 \text{ N m}) \quad (6)$$

Summing the moments about the wrist strap ($F_3$) in the base free-body diagram leads to

$$F_2 d_2 = F_{1y} d_1 - T_1 \quad (7)$$

$$F_2 = \frac{F_{1y} d_1 - T_1}{d_2} = \frac{(1.98 \text{ lbf})(5.35 \text{ in.}) - 1.59 \text{ lbf in.}}{4.30 \text{ in.}} = 2.09 \text{ lbf}(9.30 \text{ N}) \quad (8)$$

Summing the vertical forces on the base in order to find the downward force from the wrist strap leads to

$$F_3 = F_2 - F_{1y} = 2.09 \text{ lbf} - 1.98 \text{ lbf} = 0.11 \text{ lbf}(0.49 \text{ N}) \quad (9)$$

Summing the moments about $F_3$ in the cradle free-body diagram leads to the cradle torque.

$$T_2 = F_3 d_3 = (2.80 \text{ lbf})(0.25 \text{ in.}) = 0.70 \text{ lbf in.}(0.08 \text{ N m}) \quad (10)$$

Summing forces in the cradle free-body diagram, leads to the finger normal force ($F_5$).

$$F_3 = F_4 = 2.80 \text{ lbf}(12.46 \text{ N}) \quad (11)$$

Summing the horizontal forces in the finger free-body diagram leads to

$$F_5 = F_5 \cos(\theta) = (2.80 \text{ lbf})(\cos(45 \text{ deg})) = 1.98 \text{ lbf}(8.81 \text{ N}) \quad (12)$$

Therefore, the IBB provides approximately 2.80 lbf (12.46 N) at a 45 deg angle to the DIP joint, a flexion torque of 0.70 lbf in. (0.08 N m) at the DIP joint, and a horizontal force of 1.98 lbf (8.81 N) to the finger (Fig. 8). The finger contact area at the cradle is 0.69 in.² (4.45 cm²), thus the approximate applied pressure to the finger at the DIP joint is 4.06 psi (27.99 kPa). The contact area at the metacarpophalangeal joint (where $F_2$ is applied) is 0.70 in.².
(4.52 cm²) and the contact area of the palmar support (where the force is applied) is 0.45 in² (2.90 cm²). Thus, the approximate applied pressure on the finger’s dorsal side is 2.99 psi (20.62 kPa) and palmar side is 5.04 psi (34.75 kPa).

5 Preliminary User Observations

Preliminary user observations were recorded using both the DeRoyal and Joint-Jack braces and the IBB. Co-author S. MacDonald, who suffers from BD on the left fifth phalange with a measured contracture of 45 deg at the PIP joint and 30 deg of hyperextension at the DIP joint, was the user. This evaluation focused only on observed qualitative comparisons between the different braces and, thus, has limitations. In addition, as S. MacDonald is a co-author, obviously he could not be blinded with regards to which device was being worn. Therefore the potential for bias in the observations exists.

After approval from the University of Colorado Institutional Review Board (IRB protocol No. 0109.29), he wore each device. Each device was worn independently for time periods of 15 min, 30 min, and 45 min. This testing was completed in two day increments; the first day consisted of the 15 min and 30 min sessions with 1 h recovery between testing. The second day consisted of 45 min of consecutive usage and gave insight into the viability of wearing the brace for extended periods of time. The braces were worn in a randomly assigned order with one brace worn during each day.

The DeRoyal brace was quite comfortable for the first 15 min of use and finger functionality remained high. However, at the conclusion of the 30 min test, circulation to the finger began to decrease, resulting in discoloration, numbness and a drop in external, and presumably, internal temperature. During the 45 min test, discomfort due to poor circulation increased with time, resulting in severe hindrance to the digit’s utility due to numbness after wearing the brace. The DeRoyal brace’s profile is low and fits close against the finger and although dorsal pressure on the PIP joint was uncomfortable, the device was easy to remove.

The Joint-Jack brace became uncomfortable very quickly after beginning use. One of the potential drawbacks is the hyperextension caused by distal contact of the splint at the distal phalange rather than at the DIP joint itself. This positioning was uncomfortable and possibly limiting in stretching the lateral bands. In addition, the strap passing dorsally over the PIP likely limited the sigmoid function of the lateral bands. In the conclusion of the 30 min test, discomfort due to poor circulation increased with time, resulting in discoloration, numbness and a drop in external temperature to the finger, resulting in discoloration, numbness, and temperature drop all within the first 10 min of use. The larger profile of the brace caused frequent and inadvertent contact with the environment, which in combination with poor circulation to the digit was painful. Finally, the palmar attachment and thumb-screw mount prevented flexion of the finger, and the profile of the device prevented functional use of the hand.

The IBB was quite comfortable during use. Although indentations from the cradle and base were evident on the surface of the finger after use, no discoloration or numbness occurred, and full circulation was maintained. The therapeutic aspects (heat and massage) of the brace proved useful at the first signs of discomfort, enabling enhanced comfort for the user. Finally, tension in the cables was also adjusted to relieve pressure on the finger, and retightened once discomfort had passed, thus, demonstrating the usefulness of adjusting the load. These aspects allowed the user to remain comfortable during treatment without removing the IBB and interrupting treatment. The slight high profile of the dorsal mount was the only major drawback. The IBB is currently being evaluated during long-term use. Significant finger improvements are expected to take as long as 6–12 months.

6 Discussion

This work helps demonstrate that improvements to current nonsurgical treatment of fixed finger deformities can be made. In addition, aspects of physical therapy have been considered that enhance user comfort and potential healing capability. Simple adjustments to the cradle could potentially address other finger deformities such as swan neck and hitchhikers thumb that exhibit similar disruption of the flexor and extensor mechanisms in the finger. Future work in this area includes research regarding tissue mechanics and further iteration and expansion of the current design. Research relating tendon response to mechanical loading while subjected to heat and motion would provide insight into optimization of treatment regimens.

Although this IBB is still under development and evaluation, it has been shown to apply substantial force to the lateral bands, and was comfortably worn for a period of 4 h. The palmar support has proven to be the key in preventing excessive and uncomfortable stress at the proximal phalange. The therapeutic system provides both heat and motion but may require specialized encasing that will be addressed in future iterations. Securing and attaching the brace must also be further considered to facilitate easy user entry and exit from the brace. In addition, better understanding of tendon tissue mechanics is needed to determine the appropriate level of force to be applied by the brace.

Future design work will include streamlining the dorsal mounted base to fit closer to the hand and providing an enclosure or sheath to prevent interference with clothing and grasping objects. Future user evaluation studies will include a larger cohort of subjects suffering from BD and an evaluation of long-term effectiveness.

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References