

PATIENT SPECIFIC DYNAMIC HAND SPLINTS PRODUCED THROUGH SELECTIVE LASER SINTERING

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ABSTRACT

The ability of additive manufacturing (AM) to produce on demand and patient specific medical devices has made it an attractive technology in the medical orthoses and prosthetics environment. Current available dynamic hand splints are not always cost effective and have extended manufacturing lead times due to the patient specific and complex nature of the devices. This paper highlights the use of AM to locally manufacture cost effective and accessible patient specific dynamic hand splints. AM design principles such as live hinges and in-process assembly of parts were utilized to produce a dynamic hand splint with improved functionality. This allows for hand motion in a specific direction while restricting and supporting undesired abnormal positions and movements of the fingers as a result of spasticity.

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1. INTRODUCTION

A functional hand is a prerequisite for the optimal performance of all activities of daily living that make it possible to meaningfully fulfil one's life roles and tasks. In order for the hand to be considered functional, excellent integration between a complex structural arrangement of bones and joints to provide stability, an intricate system of muscles, tendons and blood vessels to facilitate movement, and an elaborate system of nerves controlling action is required. The hand (Figure 1) consists of a stable wrist joint, the palm and five fingers. The wrist is composed of eight carpal bones that articulate with the ulna and radius on the proximal side and the five metacarpal bones on the distal side. The five metacarpals make up the palm of the hand and articulate with the phalanges. The proximal, middle and distal phalanges make up the fingers and thumb. The wrist and hand therefore consist of 21 major joints that are controlled by 28 muscles in a coordinated manner to perform multiple, complex and dexterous grasps required to facilitate both gross and fine motor task performance [1]. These movements can be either conscious or reflexive in nature and are dependent on feedback received from the multiple sensory mechanisms in the hand [2]. The proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints are found between the phalanges of the fingers, both have one degree of freedom. The metacarpophalangeal (MCP) joints, the joints between the proximal phalanx and the metacarpal bone have two degrees of freedom [1].

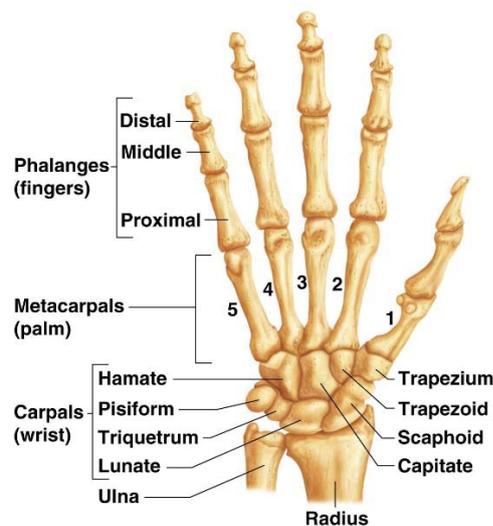


Figure 1: Skeletal features of the hand [3].

The hand is composed of extrinsic and intrinsic muscles. The extrinsic muscles - the long tendons of the wrist, thumb and fingers based in the forearm - are considered more important than the smaller, intrinsic muscles (within the hand). The flexor tendons (Figure 2) run through the carpal tunnel and the tunnel of Guyon, and their action performs wrist flexion, radial and ulnar deviation and flexion of the fingers to form a fist. The extensor tendons pass through the extensor tendon compartments and the extensor retinaculum and their actions perform dorsiflexion of the wrist and extension of the fingers to make a flat hand [2].

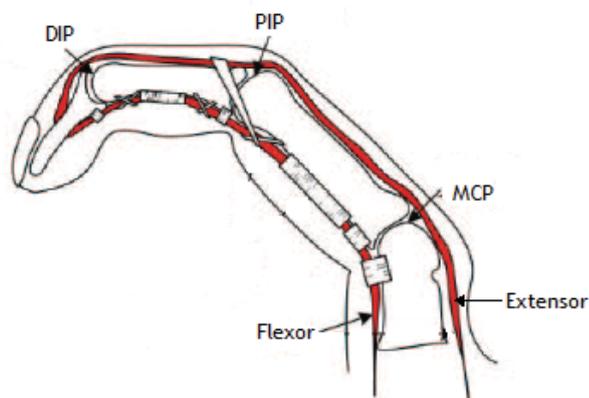


Figure 2: Joints and tendons of the finger [4].

The hand contains a high density of several specialised nerve endings in the joints, muscles and skin. A large area of the motor and sensory cortex in the brain is focused on the interpretation of sensory input received from the sensory receptors in the hand and the resultant motor response. These sensory receptors ensure that the

brain is provided with tactile (pain, temperature, light touch, deep pressure) and proprioceptive (information regarding joint angle, muscle length and muscle tension) input to guide and direct responses in order to perform movements and to protect the structures from damage [5]. Should any one of the integral aspects of hand function mentioned above be damaged either temporarily or permanently, the optimal functioning of the hand will be negatively influenced. It is therefore essential that devices be developed that assist with the compensation for impaired function whilst not inhibiting the intact function still available.

Chronic hand impairment commonly occurs following a stroke. Stroke patients often experience unusual stiffness of the hand which is referred to as spasticity. This impairment or spasticity is caused by an imbalance of signals from the brain to the muscles and can result in the development of contractures without intervention. A contracture occurs when connective tissue such as ligaments, tendons, and joint capsules become scarred, or when muscle tissue becomes shortened. This can occur at any joint. Rather than applying an unmaintained quick stretch to the connective tissue involved, which may be very painful for the patient, a low-load (75 - 300g), prolonged stretch (LLPS) evokes a plastic, more permanent and less painful, change in tissue length. Soft, static and dynamic hand splinting is widely used to stabilise, maintain, restrict and / or facilitate active use of the hand during various stages of recovery following impairment or, as an alternative to compensate for a permanent loss of one or more functional ability. Static and / or dynamic splinting is used under the guidance of qualified professionals in acute and chronic nerve and tendon injuries, acute and chronic neurological conditions, soft tissue injuries involving multiple structures, pain related conditions as well as degenerative conditions [6].

The goal of dynamic splinting is to stress scarred or shortened connective tissue with a LLPS to promote non-traumatic, more permanent tissue remodelling. The lengthened tissue can provide increased range of motion [7]. A study by Chang et al. describe that wearing a dynamic splint for 30 minutes a day for five days a week over three months has shown noticeable improvement in hand function of a patient. The authors also indicate that six months is the minimum time required for rehabilitation [8]. Jeon et al. [9] as well as Frank et al. [10] also showed that the use of dynamic hand splinting is an effective means of rehabilitating hand impairment after a stroke.

An appropriate dynamic hand splint needs to be patient specific due to the complex nature of the hand's biomechanics. Ideal biomechanical function is essential for clinical rehabilitation as secondary impairments can be established if the movement induced is incorrect. The complex biomechanics of the hand with numerous joints in a small area has traditionally led to dynamic hand splints with complex structures and mechanisms that are bulky, often ineffective and not aesthetically pleasing (Figure 3). Effectively replicating the biomechanical function of the hand will improve functionality, durability and comfort of a dynamic hand splint [11].



Figure 3: Conventionally manufactured dynamic hand splints [11].

Heo et al. [12] reviewed various exoskeleton structures that facilitate appropriate biomechanical function of the finger (Figure 4). The authors concluded that the direct matching joint center exoskeleton configuration was the most functional. This however results in the necessity for structures to be placed between the fingers which lead to restricted movement and discomfort for the patient.

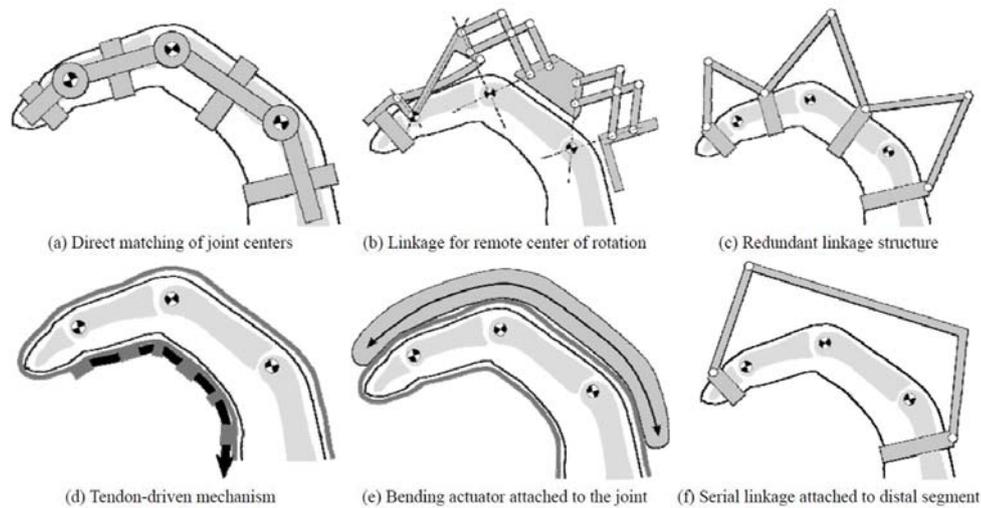


Figure 4: Mechanisms for matching finger biomechanical function [12].

Yap et al. [13] utilized a moulding process to manufacture patient specific soft pneumatic bending actuators from pour cast elastomer. The structure induced the necessary tension, stability and aesthetic appeal with a slender design. The casting process to produce the actuators was however time consuming and not cost effective.

In order to produce an exoskeleton type dynamic splint with slender finger features, the joints of the device's fingers need to be moved from the sides to the top of the fingers. Finger joints of the hand rotate through the centers of the joints (Figure 5). With the joint sections of the proposed exoskeleton however placed on top of the fingers, the structures need to lengthen in flexion and contract in extension to counteract the variation of arc length created by rotation away from the neutral axis. Insufficient variation in arc length or misaligned rotation points will cause discomfort for the patient since the joints will be put under pressure. This effect is most noticeable at the MCP joint as the link hinge point needs to be placed on the wrist splint, resulting in a greater arc length. Counteracting the variation in arc length around the finger joints has resulted in dynamic splints with complex linkages that are bulky, or soft expandable pneumatic structures that provide the correct motion but without adequate support [12].



Figure 5: Difference in arc length between center of joint on top of finger [12].

AM has widely been utilized in the physical medicine and rehabilitation sector [14] and has also been specifically useful in manufacturing patient specific foot orthoses, ankle-foot orthoses and prosthetic sockets [15]. Feasibility studies have shown that patient specific foot and ankle orthoses produced through the selective laser sintering (SLS) AM process are as / more effective than currently prescribed orthoses [16], [17]. Paterson et al. [18] investigated various AM processes to directly manufacture upper extremity static splints, concluding that SLS and PolyJet material jetting display unique advantageous characteristics when manufacturing splints, only made feasible by the manufacturing processes. Agarwal et al. [19] and Abdallah et al. [20] utilized AM to produce complex exoskeleton mechanisms that exhibit appropriate biomechanical function, however these mechanisms proved to be bulky and prone to fatigue failure. The patient specific and complex nature of dynamic hand splint manufacturing make it well suited for AM.

Considering the shortcomings of existing dynamic hand splint designs, the aim of this study was to investigate the suitability of AM to produce aesthetically pleasing low cost durable dynamic splints which could be easily customized to fit the needs of different patients and thus addressing the shortfall in delivery to low income patients.

2. METHODOLOGY

Research into various concepts of producing an appropriate dynamic hand splint through AM was performed on an EOS P385 printer using nylon PA2200 as printing material. The SLS printing process and material were selected

because of the durability of parts produced and no need for support structures during the manufacturing process. This paper documents the iterative design process followed to create an AM patient specific dynamic hand splint and the equipment and procedures used to compare different design concepts.

2.1 Exoskeleton design

Two joint concepts were investigated to produce aesthetically pleasing slender finger sections for a biomechanically functional exoskeleton type dynamic hand splint using SLS. These were conical hinge direct joint matching structures and live hinge structures.

2.1.1 Conical hinge concept

The conical hinge concept was investigated by designing in process assembled conical hinges that allow rotation but restrict axial movement (Figure 6). Literature indicates that the direct matching joint center exoskeleton configuration is not effective due to restricted movement of the hand as a result of adding structures on the sides of the fingers [12]. This concept was nonetheless investigated to determine if AM could produce a sufficiently slender structure to reduce the restrictive motion compared to traditional hinge structures. The ability of AM to produce in process assembled structures was leveraged to create a slender hinge design. Samples were produced at various thicknesses (1 mm, 1.4 mm and 1.6 mm) and build orientations (x and y directions) to test the durability and the effectiveness. Printing in the z direction was not investigated because of the excessive costs involved in printing in this direction through SLS.

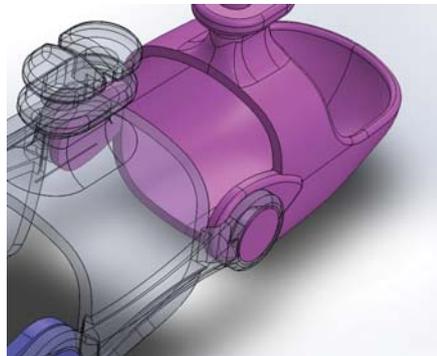


Figure 6: CAD of conical hinge joint concept.

2.1.2 Live hinge concept

The live hinge concept was investigated in an attempt to solve the MCP joint design problem and create a slender design that allows for appropriate hand motion. The use of live hinges should result in a simple joint design that should be easy to manipulate to produce patient specific finger sections. Three live hinge designs were produced (Figure 7) to investigate the concept namely solid (a), lattice (b) and geometrical wave (c) live hinges.

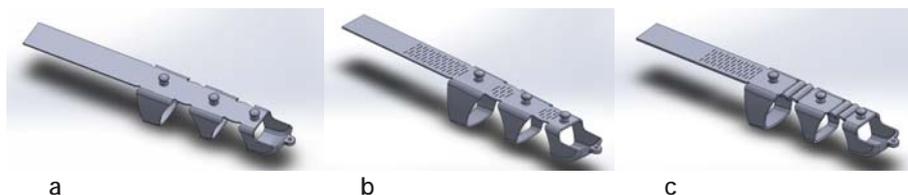


Figure 7: Solid (a), lattice (b) and geometric wave (c) live hinge structure designs.

The solid hinge was produced as a control to determine the properties of such structure without alteration. With the lattice hinge concept, the lattices weaken a section thus creating more flexibility in a required direction. The lattice structure design should also allow for some stretch to overcome the difference in arc length during extension/flexion while restricting side to side movement. The geometric wave structure was used to investigate if a flexible structure that allows extension in arc length can be produced without significantly reducing the strength of the structure. Samples were produced at different thicknesses (1 mm, 1.4 mm and 1.6 mm) and build orientations (x and y directions) to test effectiveness.

2.2 Tendon tension mechanism

Two concepts were considered to replicate the biomechanical function of the extensor tendons of the hand. First was to use a wire and guide system with two 1 mm spring steel wires mounted on top of the finger (Figure 8 a).

Second was a 99% natural rubber strip that attached to pins on top of each joint of the finger through corresponding holes in the strip (Figure 8 b).



Figure 8: (a) Steel wire and guide and (b) rubber strip concepts to replicate tendons.

The tension of the rubber tendon can be specifically tailored to each patient's needs by changing the width of the section. Patient specific rubber tendons are easily manufactured utilizing a CO₂ laser cutter.

2.3 Cyclic tester

A finger cyclic tester was designed and manufactured to determine the durability and functionality of the produced concepts (Figure 9). The tester comprised of a crank arm that was driven by a Nema 23 stepper motor. The stepper motor was controlled by a Raspberry Pi and it recorded the number of cycles performed. The result was displayed on a liquid crystal display (LCD) screen.

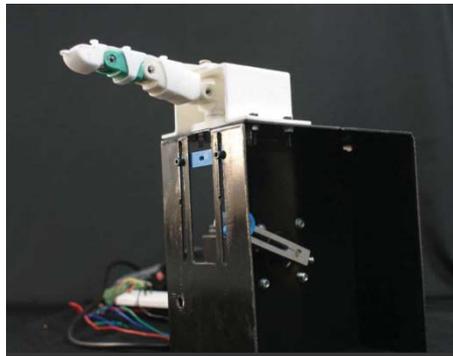


Figure 9: Finger cyclic tester.

A 1 mm stainless steel cable with clear plastic coating was used to connect the front link of the finger to the crank arm of the tester. The connecting hinge point on the crank arm was made adjustable as to vary the stroke length of the finger. A front guide determined the angle at which the cable was pulled. The tester was designed such that the joints of the finger had two ball bearings mounted in each joints to ensure smooth repetitive motion. The three links of the finger were manufactured in nylon PA2200 through SLS.

3. RESULTS AND DISCUSSION

3.1 Exoskeleton structure design

It was possible to produce both the concept conical and live hinge exoskeleton structures of a patient specific dynamic hand splint utilizing SolidWorks instant 3D features. In this software, patient specific dimension data is populated in a spreadsheet that interacts with the SolidWorks CAD file, thus presenting an effective means of producing patient specific data that can be used to manufacture parts through AM.

3.1.1 Conical hinge concept results

The conical hinge concept was produced by creating in process assembled conical hinges with thicknesses of 1, 1.4 and 1.6 mm respectively. A clearance of 0.25 mm is required between the sides of the conical wall of the hinge to allow for in process assembly and un-sintered powder to be removed. The 1.6 mm thickness hinge walls and x-axis build direction showed the most promising results amongst the three hinge thicknesses and two built orientations investigated. Even at this hinge thickness, the thin walls of the conical hinges proved to be not practical and easily broke. Adding 1.6 mm to each side of the finger exoskeleton (which had a shell thickness of 1.4 mm) also meant that 3 mm was added on both sides of each finger with resultant restriction of motion of the hand (Figure 10).



Figure 10: Dynamic splint with conical hinge joints.

A major concern of the conical hinge concept was furthermore producing an effective MCP joint. Due to the MCP joint having to be placed on the wrist splint, there was no effective way of creating a durable linkage that was not bulky.

3.1.2 Live hinge concept results

Solid, lattice and geometric wave structure concepts were considered to improve biomechanical function and durability of the dynamic hand splint finger sections. This was printed at 1, 1.2 and 1.4 mm thicknesses in the x and y print orientations (Figure 11).



Figure 11: Solid, lattice and geometric wave structure live hinge printed concepts.

All printed concepts were physically tried on a finger and it was found that the 1 mm thickness produced the desired flexibility of the joint sections while the 1.2 and 1.4 mm wall thickness proved to be excessively stiff. It was not possible to perceive any difference between concepts printed in the x and y directions. The geometric wave live hinge concept proved to be impractical since the bottom edge of the wave induce direct pressure onto the knuckles of the finger during flexion. The lattice live hinge allowed for more flexible movement compared to the solid hinge. From these observations, it was decided to produce a complete dynamic hand splint incorporating lattice joints between finger sections (Figure 12 (a) and (b)). To overcome the extensive arc length across the MCP joints, the splint design included linear slide mechanisms for each finger on top of the wrist splint.

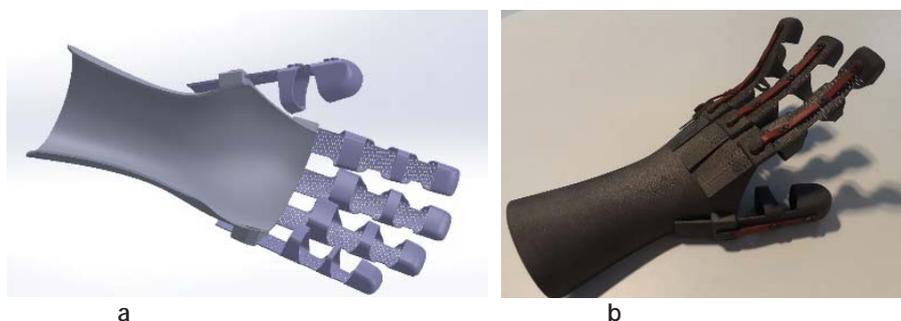


Figure 12. (a) CAD and (b) additive manufactured dynamic hand splint.

Physical testing of the dynamic splint showed that it did not exhibit appropriate biomechanical function. Although the lattice joints were flexible, they did not sufficiently compensate for the increase in arc length between

flexion and extension of the fingers. This resulted in discomfort to the knuckles of the wearer. The sliding mechanism that was incorporated into the dynamic splint design for the MCP joints however proved to be successful and it was therefore decided to also incorporate the same design into the finger joints. A test concept was printed in the x and y directions and the sliding motion of each section of the live hinge slider concept was found to allow for a more comfortable natural hand motion (Figure 13 (a) and (b)).

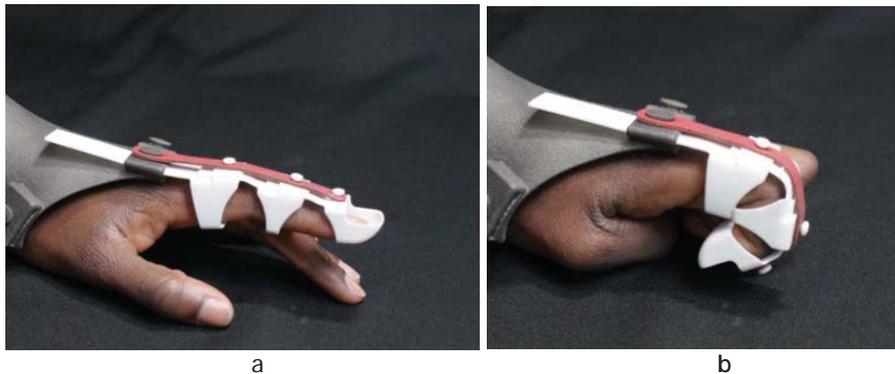


Figure 13: (a) Finger section with live sliding hinge during extension and (b) flexion.

Since the 1 mm solid joint was considered to be sufficiently flexible it was decided to move away from the lattice structures in the live hinge slider concept. Although the lattices allow more flexibility, it also results in weakness in the joint structure.

The cost of producing a patient specific dynamic hand splint through SLS in nylon such as shown in Figure 12b was R 3600. This was taking machine time for laser sintering, material cost as well as operator time into consideration. Compared to the R 8000 - R 13000 of a conventionally manufactured patient specific dynamic splint, the AM splint can be considered affordable. The cost of AM is largely dependent on the number of parts that are manufacture together in the same build. If more than one dynamic splint is produced at the same time, the cost can be reduced even further to make these devices available to low income patients at reasonable cost. The design for the additive manufactured splint can also be easily adapted to the unique dimensions of each patient using SolidWorks instant 3D features.

3.3 Tendon tension mechanism results

Prototypes finger exoskeletons were manufactured and tested for both the spring wire and rubber tendon concepts. The spring wires showed insufficient spring effect and friction between the wires and guides proved too high for this concept to be effective. The rubber tendon concept however produced the desired results. Rubber tendons with different designs were produced in an iterative process and tested on the cyclic tester with the slider live hinge joints. A first concept (Figure 14) lasted 1043 cycles while a second concept (Figure 15) lasted 2010 cycles.



Figure 14: Rubber tendon Concept 1.



Figure 15: Rubber tendon Concept 2.

The finite element analysis (FEA) module of SolidWorks was used to investigate the stresses that were induced on the second rubber tendon concept (Figure 16). The MCP joint was fixed while a 10 N load was applied to the PIP joint and 8 N to the DIP joint in the simulation. This was the same loading that the rubber tendon experienced

during cyclic testing. The maximum stress concentration indicated in the simulation corresponded well with the actual point of failure of the second concept.

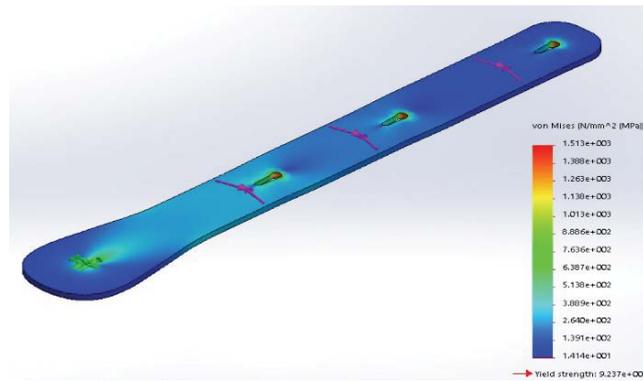


Figure 16: FEA analysis of Concept 2 rubber tendon.

Taking the stress concentrations indicated in the second concept simulation into consideration, a third concept (Figure 17) was produced.



Figure 17: Rubber tendon Concept 3.

The third rubber tendon concept was placed on the cyclic tester and at the time of writing this paper was shown to last more than 26 000 cycles without any evidence of failure of the rubber tendon or sliding joints of the finger sections. This was for finger sections printed in both the x and y printing orientations. The finger sections and rubber tendons can therefore be considered sufficiently durable for this application. Since the CAD data of each patient's dynamic splint will be available, it will also be easy to reproduce a finger section or rubber tendon should failure occur.

4. CONCLUSION

This paper investigated the suitability of AM to produce aesthetically pleasing durable dynamic splints that promotes natural hand movements while restricting / supporting undesired abnormal positions and movements of the finger caused by spasticity. Further requirements were that the device should be easily customizable to fit the needs of different patients and that it should be produced at low cost to address the shortfall in delivery to low income patients.

Different joint concepts were investigated to produce a dynamic hand splint by SLS and it was found that the live hinge structure concept showed the most promise. Physical testing of a dynamic splint incorporating these live hinge features however showed insufficient movement of the MCP joints. An improved live hinge slider mechanism was designed and incorporated into the MCP joints of the dynamic splint. The revised design demonstrated a significant improvement in biomechanical function of the MCP joints compared to the previous design. It was decided to also incorporate the live hinge slider mechanism design into the DIP and PIP joints resulting in slim aesthetically pleasing finger sections. An optimized patient specific laser cut rubber band was proven to be the most effective means of replicating tendon function. The durability of slider live hinge joints and rubber tendons were demonstrated on a cyclic testing device. A cost comparison indicated that a patient specific dynamic hand splint can be produced through SLS in nylon at a lower cost compared to conventionally manufactured patient specific dynamic splints.

Considering the above, the aim of producing aesthetically pleasing low cost durable dynamic splints through AM which can be easily customized according to patient requirements was achieved.

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