DEVELOPMENT OF A CUSTOM 3D-PRINTED ORTHOTIC DEVICE WITH INTEGRATED ELECTRODE INTERFACES FOR ELECTRICAL STIMULATION IN CARPAL TUNNEL SYNDROME

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Abstract

This article focuses on the design and fabrication of a customized orthotic device with the capability of applying electrical stimulation for the treatment of carpal tunnel syndrome. A 3D positive model of the affected area was obtained using a handheld optical 3D scanner. This model was used for the orthosis design in suitable CAD (Computer-Aided Design) software. Two prototypes were produced: the first by Fused Deposition Modeling (FDM) with PLA, and the second by Selective Laser Sintering (SLS) with polyamide PA2200. The FDM variant required longer time of printing and extensive post-processing, offering low cost but limited durability. In contrast, the SLS orthosis was completed in shorter time, with higher material cost but improved flexibility, comfort, and surface quality. This work demonstrates the feasibility of producing individualized orthoses that integrate dual conservative therapies using additive manufacturing. Future research should include clinical validation and testing in diverse patient populations.

Keywords

orthosis, CAD modelling, additive manufacturing, electrical stimulation

Introduction

Carpal tunnel syndrome is the most common peripheral nerve compression syndrome. According to Padua et al., it is the most frequent and most studied condition of this type. It is caused by compression of the median nerve (*nervus medianus*), which passes through a narrow canal formed by the wrist bones, the transverse carpal ligament, and the flexor tendons of the fingers [1]. Increased pressure on the nerve may be caused by hormonal changes, swelling, manual labor, or inflammation of the tendons, resulting in pain and, in more severe cases, weakness of the hand due to weakening of the muscles innervated by the median nerve [1].

Despite the high prevalence of carpal tunnel syndrome, non-occupational risk factors remain insufficiently clarified. Risk factors unrelated to occupation include diabetes mellitus, pregnancy, increased body mass index (BMI), rheumatoid arthritis, menopause, and hysterectomy [2]. Manual labor, exposure to vibrating tools, and repetitive flexion and extension are considered occupational risk factors for the development of the syndrome. Although some authors argue that the link between the use of a computer mouse and keyboard and carpal tunnel syndrome is unclear due to insufficient evidence supporting this theory, others have demonstrated increased pressure on the carpal tunnel during computer mouse use [3, 4]. Moreover, the repetitive flexion and extension typical of mouse use may also contribute to the development of the condition.

The development of symptoms [5] is divided into three stages:

1. the patient wakes up from sleep with a sensation of numbness or swelling in the hand, without any visible swelling,
2. symptoms also occur during the day, especially during repetitive movements of the hand and wrist or when the hand is kept in the same position for a prolonged period,
3. hypotrophy or atrophy of the thenar region occurs.

Since each stage of carpal tunnel syndrome is characterized by specific symptoms, it is important to identify and distinguish them early. A precise description of the disease progression allows for quick

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and effective treatment, which is key to preventing permanent muscle and nerve damage. Current treatments for carpal tunnel syndrome combine surgical and conservative methods, depending on the severity of the condition and the individual needs of the patient.

Surgical treatment options include open surgery and endoscopic surgery. Open surgery provides direct access to the wrist structures [6], while endoscopic techniques are less invasive, causing less postoperative pain and allowing for faster recovery [7, 8].

Conservative treatment aims to cure the condition without invasive interventions [9]. Non-surgical methods include pharmacological treatment such as orally or transdermally administered analgesics [10, 11], diuretics [9], corticosteroid injections [12, 13], immobilization of the affected area using splints [9, 11], and physical therapy methods including ice application, electrical stimulation, and more [9, 11]. Recently, platelet-rich plasma injections have also been investigated as an alternative to corticosteroids, showing promising long-term analgesic effectiveness [13, 14].

Wrist immobilization in a neutral position using a splint is a frequently used and cost-effective non-invasive treatment. Since carpal tunnel syndrome is associated with intense and repetitive hand and wrist movements, limiting movement can help relieve symptoms such as pain or numbness. Splint use can also be beneficial for night-time paresthesia, as it prevents prolonged extreme wrist positions in flexion or extension during sleep, which increase pressure in the carpal tunnel [15]. A study has shown that this method is effective primarily in the first stage of the disease, when symptoms occur only at night, but it may also alleviate symptoms in more advanced stages [16].

To what extent this form of treatment is generally effective remains a subject of debate, as the results of different studies are inconsistent [1, 5, 9, 11, 15, 17]. The optimal duration of splint uses and whether it is more effective when used only at night or also during the day has not been determined [17]. Despite the lack of consensus and standard treatment protocol, this method is a common part of conservative therapy.

Splints are manufactured using conventional or innovative methods. The conventional method can be divided into serial and individual production. Serial production eliminates the waiting time for devices, as patients can purchase splints directly from medical supply stores upon prescription. The disadvantage is that they are not customized to the patient's anatomy and individual needs and therefore may not be suitable and can cause discomfort during use [18].

In innovative manufacturing, a 3D positive model of the body segment is created using a 3D scanner [18, 19]. The scan is exported to CAD (Computer-Aided Design) software, where it is modified, and the splint is modeled onto this positive. Modeling in CAD software allows better adaptation to the patient's anatomy and needs compared to conventional manufacturing [18]. After creating the final 3D model of the splint, the device is converted into STL (Standard Triangle Language) format and produced using additive manufacturing [19]. After printing, the splint is sanded and smoothed if necessary and then tested on the patient [18, 19].

Electrical currents can stimulate nerve tissue and are therefore used for pain relief in electrotherapy. Transcutaneous electrical nerve stimulation (TENS) is a non-invasive and cost-effective method applied through the skin using electrodes. The most used is conventional TENS (low intensity, high frequency), which suppresses pain transmission by blocking C-fibers and activating A-fibers. It may also increase serotonin and ATP levels and reduce inflammation. Settings are adjusted to the patient's sensitivity, with the frequency usually around 100 Hz. For carpal tunnel syndrome, two electrodes are placed on the palmar side of the wrist and forearm. TENS is safe when used properly but contraindicated in pregnant women, epileptic patients, and those with pacemakers.

Interferential current stimulation (IFC) uses medium-frequency currents that intersect within the tissue to produce a therapeutic modulated frequency. It has analgesic, anti-inflammatory, and vasodilatory effects and is considered a more comfortable alternative to TENS. In treating carpal tunnel syndrome, four electrodes are used, placed so that the currents intersect in the affected area. Although the number of studies is limited, some suggest better outcomes with IFC compared to TENS, particularly in reducing pain and improving nerve function [20, 21].

The aim of this work is to design and manufacture a prototype of a customized orthotic device with the capability of applying electrical stimulation, which could be used as part of the conservative treatment for carpal tunnel syndrome.

Methods

The prototype of this orthotic device (Fig. 1) combines two types of conservative treatment: orthotic therapy and electrical stimulation. The orthosis immobilizes the affected area in a neutral position, thereby preventing excessive flexion and extension, which contributes to the development of the condition, while the electrical stimulation provides analgesic effects. This design was created for use with the OMRON E3 Intense TENS electrical stimulator (OMRON Corporation, Kyoto, Japan).

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Fig. 1: Proposal of an orthosis with integrated electrode interfaces for electrical stimulation in carpal tunnel syndrome.

Data acquisition

To create the orthosis design, a 3D positive of the area where the device would be applied had to be generated. In this case, that area was the hand and forearm. For the purposes of this research, a handheld optical 3D scanner, the Artec Eva (Artec 3D, Luxembourg, Luxembourg), was used to scan a 23-year-old female subject, with no upper limb disabilities. The scanning frequency was set to 16 frames per second (fps). The scanned subject was seated, with the upper limb positioned in abduction, 30° rotation at the shoulder joint, and 100° flexion at the elbow joint, supported on a table to ensure stability and minimize movement during scanning. The thumb was in opposition with slight flexion, the fingers were slightly flexed, and the wrist was in 10° flexion. The completed 3D positive (Fig. 2) was then exported into CAD software for further editing and CAD modeling of the orthotic device itself. Two orthosis variants were designed in Autodesk Meshmixer (Autodesk, Inc., San Rafael, CA, USA).

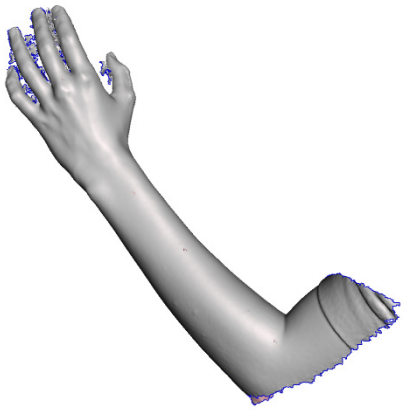

Fig. 2: 3D positive of the arm and forearm.

First variant design

On the surface of the positive, the contact area of the orthosis (Fig. 3) was marked. To allow the use of an electrical stimulator while wearing the orthosis, the contact surface was made larger than that of standard wrist orthoses. The electrode application areas (100×65 mm) were marked on the palmar side, with a minimum distance of 20 mm between them. The proximal boundary of the orthosis was defined at the proximal end of the forearm, and the distal boundary was at the level of the metacarpophalangeal (MCP) joints, also enclosing the thumb and its MCP joint. On the dorsal side, an opening was designed to simplify the application of the orthosis to the segment. From the contact surface, a shell of the orthosis was generated with a 1 mm offset, oriented perpendicularly from the surface of the positive. The wall thickness of the orthosis was then set to a constant 2 mm, and all edges of the design were smoothed. In the next step, recesses were created on the inner palmar side of the orthosis using negative 0.5 mm extrusion to allow for the application of electrodes. These cutouts help to secure the electrodes in the correct application areas. For the cable outlets connecting the electrodes to the stimulator, holes were cut at the edges of the electrode protrusions. Components of the orthosis responsible for cable routing and orthosis attachment were modeled in the parametric CAD software SolidWorks (Dassault Systemes, Waltham, USA). The designed device is to be fastened to the user's body using straps, allowing for easy donning and removal, as well as individual adjustment. Strap holders were designed with dimensions of 20×10×10 mm. The stimulator's electrodes are connected to the device via cables. To prevent the cables from sticking out during use, cable clips with dimensions 5×4×5 mm were also designed. A running armband for a mobile phone can be used to attach the stimulator to the user.

Fig. 3: CAD model of the first variant.

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First variant production using FDM technology

Before printing, the orthosis needed to be positioned in an optimal orientation for FDM printing. For this preparation, the freely available software PrusaSlicer (Prusa Research, Prague, Czech Republic) was used. The orthosis was oriented with the distal side facing the print bed and automatically generated organic support structures were applied (Fig. 4).

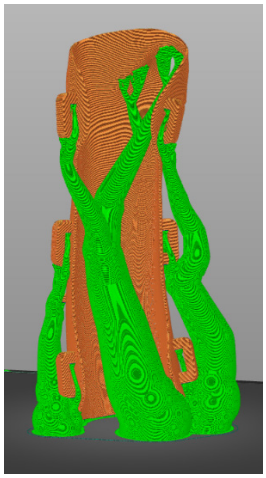

Fig. 4: Model orientation and support generation for FDM additive manufacturing.

Both the model and the support structures were printed using PLA (polylactic acid) material, using a Creality Ender-5 Plus printer (Shenzhen Creality 3D Technology Co., Ltd., Shenzhen, China). The estimated print time was 25 hours and 5 minutes. To ensure precision and strength, the number of vertical walls was set to 3, and the number of horizontal walls to 7 top layers and 5 bottom layers, to prevent deformation. The seam positions were set to nearest, with 15% mutual spacing, which contributes to a more aesthetically pleasing model by evenly distributing layer joints. The Skirt parameter (base of the build) was enabled for this print to stabilize material flow before printing the model itself. Important printing parameters are listed in Table 1.

Table 1: FDM printing parameters.

Printing parameter	Value
Shell thickness	1.60 mm
Nozzle diameter	0.40 mm
Layer height	0.12 mm
Infill	100%
Vertical walls	3
Horizontal walls (top)	7
Horizontal walls (bottom)	5
Seam spacing	15%
Perimeter loop distance	3.00 mm
Perimeter height	0.24 mm

Second variant design

In the second variant (Fig. 5), perforations were created to reduce the weight of the orthosis and to provide a breathable design that enhances comfort while also serving an aesthetic function. The strap attachments for securing the orthosis to the limb segment were replaced by holes placed around the perimeter of the orthosis model. The contact area remained the same as in the optimized model, but this modification focused on lightweighting and further design optimization. In areas outside the electrode protrusions, perforations were added, which reduce the amount of material required for fabrication and make the orthosis more breathable and comfortable for the user. Instead of external strap holders, cut-out openings were created in the areas where the orthosis is fixed to the body segment. This solution not only reduces material usage in the manufacturing process, but also offers a practical benefit, as the strap holes do not interfere with the user's comfort.

Fig. 5: CAD model of the second variant.

Second variant production using SLS technology

To produce the second orthosis variant, the SLS (Selective Laser Sintering) technology was chosen. The model was printed using an EOS P 396 printer (EOS GmbH, Krailling, Germany). Polyamide PA 2200 was used as the printing material. The printing orientation of the orthosis was again set parallel to the build platform (Fig. 6), and the printing parameters were left in their default settings, as was the material profile. The base layer thickness of the unsintered powder was 6 mm, and the layer thickness of the printed model was 0.12 mm. The chamber temperature was set to 172 °C, and other printing and material parameters are predefined by the manufacturer and cannot be modified.

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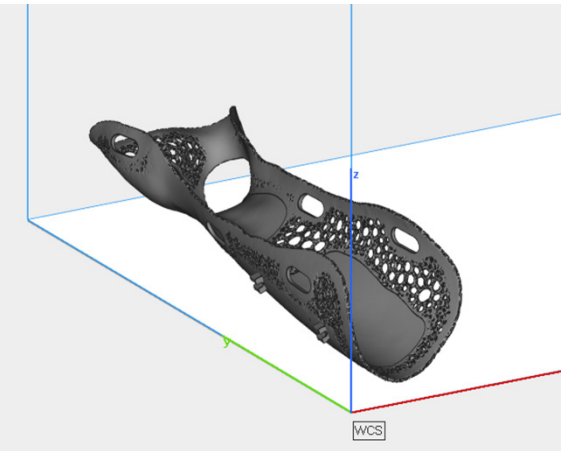

Fig. 6: Model orientation for SLS additive manufacturing.

Results

Prototype of the first variant

After the printing was completed, the support structures were removed from the orthosis. Any irregularities on the outer and inner surfaces of the orthosis were sanded down to ensure comfortable use. The dorsal opening on the printed orthosis allows easy donning and removal, even though there was low material flexibility (Fig. 7). The strap holders can be considered a drawback of this device, as they protrude from the surface and may cause discomfort to the user.

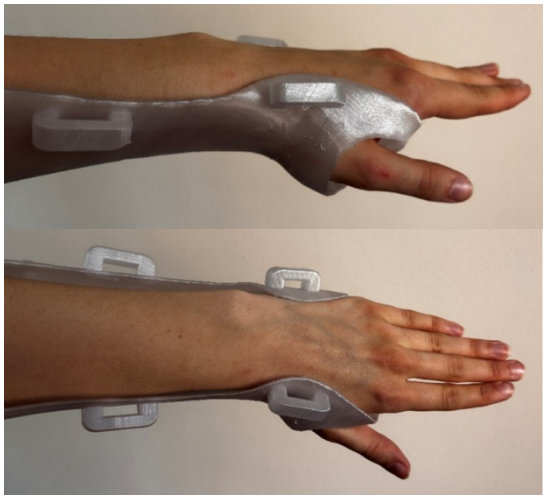

Fig. 7: Prototype of the first variant.

Prototype of the second variant

The printing process lasted approximately 5 hours in a closed chamber with a protective nitrogen atmosphere. After printing, the orthosis was cooled inside the printing chamber for 3.5 hours. Then, the printing chamber was moved to a cleaning chamber where excess material was removed manually and by blasting. The design optimization in the second variant has shown itself to be more comfortable for the user and is more flexible, so the donning and removing of the orthosis is easier than with the first variant (Fig. 8).

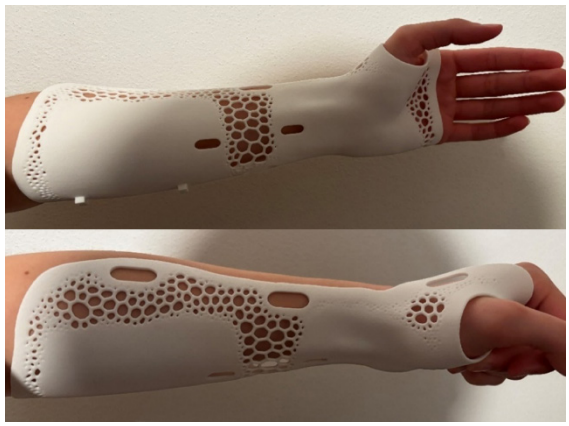

Fig. 8: Prototype of the second variant.

Table 2 compares the estimated production time, material use, and costs for the FDM and SLS orthosis variants production.

Table 2: Variants production comparison.

Variant	1st	2nd
Technology	FDM	SLS
Material	PLA	PA 2200
Manufacturing time	25 hr 5min	8.5 hr
Post-processing	30 min	1 hr
Approximately cost	15 EUR	80 EUR

Discussion

An individual aid has been designed and manufactured, which combines two methods of conservative treatment for carpal tunnel syndrome—wrist fixation in a neutral position using an orthosis and stimulation through electrodes of an electrical stimulator.

TENS can provide temporary pain relief and functional improvement in carpal tunnel syndrome by modulating pain pathways and enhancing circulation. It is safe, non-invasive, and generally well tolerated, with only minor risks such as skin irritation [9, 11]. However, its long-term effectiveness is inconsistent across studies, and further research is needed to define its clinical role [1, 5, 15, 17]. While the integration of electrode placement areas in individual orthotics is a novel feature, the device has not yet been clinically tested for therapeutic outcomes. The actual effectiveness of combining immobilization with TENS in patients with carpal tunnel syndrome remains to be validated in

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controlled clinical studies. Patient comfort, adherence, and the impact on symptoms such as pain, numbness, or grip strength were not assessed in this work.

Currently, there is only a limited number of stimulators on the market that meet functional criteria, which are portable and affordable. For comparison, a portable IFC stimulator was offered in only one model at a price of €441 according to internet sources. TENS stimulators were available in several models priced between €64.90 and €89.90. Due to lower cost, availability, and ease of use, a TENS stimulator was chosen for this work as an effective and financially accessible option for electrotherapy in carpal tunnel syndrome. Due to the limited availability of portable electrical stimulators, the orthoses were designed to be longer to allow electrode application in designated areas.

Two variants of the orthosis were designed, allowing simple application of electrical stimulation along with fixation of the affected area. The orthosis produced by FDM technology had a limited design to prevent model cracking. The second variant of the orthosis was produced using SLS technology as a functional prototype with a lightweight design featuring perforations and holes for straps, providing maximum comfort during use. This orthosis highlights the potential of additive manufacturing as a replacement for traditional.

Orthoses produced using FDM technology were printed on a Creality Ender-5 Plus printer from PLA filament. PLA material was selected for the FDM prototype due to its wide availability, ease of printing, and low cost, making it suitable for proof-of-concept prototyping. However, PLA has limited mechanical strength and durability. Other materials (e.g., ABS, PETG, TPU) were considered less suitable due to either higher warping tendencies, inferior surface quality, or reduced biocompatibility. While the raw material cost is very low, the print time exceeded 25 hours, and significant manual labor was required for post-processing (removing support structures, sanding). This makes it inexpensive but impractical for producing larger batches or clinical-grade devices. The long print time also increases the risk of print failure.

The advantage of FDM technology is relatively simple printing of models, suitable for creating low-cost prototypes. The disadvantage is the lack of an enclosed print chamber. The printing is influenced by the external environment, and it is necessary to adjust the nozzle temperature during production if the room is not air-conditioned and well insulated from the surroundings. It is also prone to random errors during the deposition of individual filament layers because it lacks automatic calibration. The material used for printing is exposed to environmental influences and thus degrades, negatively affecting print quality. It is advisable to choose a professional FDM printer with an enclosed chamber, automatic calibration, and high-quality filament with minimal diameter deviation for continuous layer printing. FDM printing also has design limitations regarding perforations. Although it would be possible to print a perforated orthosis using FDM, it would pose a risk to the user. Pressure would accumulate in the perforation areas, making them prone to cracking.

Due to these disadvantages, the orthosis with perforations and holes for straps was produced using SLS technology.

For the functional prototype, PA 2200 was selected for SLS production because of its favorable mechanical properties, flexibility, and biocompatibility [22], consistent with ISO 10993 standards for cytotoxicity and skin contact. The essence of SLS technology is joining powdered materials with a laser layer by layer to create a solid 3D model. This method allows printing of various materials, such as polymers, ceramics, or metals [23]. Printing takes place in a closed chamber to maintain a constant temperature below the material's melting point. SLS technology is used for manufacturing functional parts in various industries and is suitable for producing medical aids with complex designs that are also aesthetically pleasing in prosthetics and orthotics [22]. The advantage is that it is not necessary to generate support structures because the unsintered powder performs this function [23]. The disadvantage of SLS technology is its economic demand, associated with high costs of materials, equipment, and operation. A scanning system directs a laser beam onto the powder layer surface, selectively sintering the powder based on the CAD model. The powder is evenly distributed by a roller. After each layer is applied, a piston lowers the build platform by the thickness of one layer to allow application of a new powder layer [23].

This technology enables the production of complex-shaped models and does not require generating support structures, as this function is fulfilled by the unsintered powder. Materials used in selective laser sintering have better mechanical properties than those used in FDM, making SLS an ideal choice for manufacturing functional parts. Layering effects are also eliminated, and there is no stair-stepping effect where transitions between layers is visible. The orthosis produced using this technology was printed completely without errors, with comfortable application to the segment. The orthosis was designed with a 1.5 mm clearance, and negative extrusion was applied to form the electrode application areas. These design features allow the device to integrate wrist immobilization with electrical stimulation, effectively combining two conservative treatment methods for carpal tunnel syndrome.

Although the material and energy cost per device is substantially higher, the effective production time is shorter than using FDM technology. The absence of support structures reduces manual post-processing, and the mechanical and surface quality is superior. The large print chamber of the EOS P396 allows production of up to 30 orthoses in a single build, which could significantly reduce costs in serial production.

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The developed orthotic device falls under the scope of the EU Medical Device Regulation (MDR), as it is intended for medical use in the treatment of carpal tunnel syndrome. Accordingly, future production and clinical implementation would require compliance with MDR classification, risk management, and biocompatibility testing.

One of the limitations of this work is that the orthotic device was designed from a single hand scan, which limits generalizability. Patients with higher BMI or non-standard anatomical proportions may require additional design adaptations. Future work should include scanning of diverse patient cohorts to validate scalability across anatomical variations.

Two material and technology variants were produced (FDM-PLA and SLS-PA 2200), but their performance was only assessed in terms of manufacturability and usability. No systematic evaluation of mechanical strength, durability, or long-term wear testing was performed. PLA is known to be brittle and sensitive to humidity and temperature, which limits its clinical applicability beyond prototyping.

Conclusion

The result of this research is two variants of a hand and forearm orthosis with the possibility of applying electrodes from an electrical stimulator. The device provides dual clinical benefit of wrist immobilization in a neutral position to alleviate carpal tunnel pressure, and TENS therapy integration application for analgesic effect. This combined approach has the potential to improve patient adherence to conservative therapy, enhance symptom relief, and reduce the need for invasive interventions. In the future, it would be advisable to clinically test the functional prototype with an integrated electrical stimulation system on patients in collaboration with medical professionals.

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