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Original article

3D printed splint designed by 3D surface scanner for patients with hand allodynia

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ABSTRACT

Allodynia is a neuropathic pain triggered by a normally painless stimulus: for example, a slight touch on the skin or slight sensation of hot or cold is extremely painful. Rehabilitation is long and uncertain. Protecting the painful area from stimuli is a priority of care. This type of care is complex and challenging for the care team: the pain caused in manufacturing a classic molded orthosis is unbearable for the patient, and the orthosis has a limited lifetime, and experience shows that it is not possible to produce two identical splints. The present study consisted in creating protective splints by 3D printing, designed from data collected with the 3D surface scanner used in our forensic imaging and anthropology unit. The pros and cons of the 3D orthosis versus standard molded orthoses from the point of view of the patient and the practitioner are discussed, with evaluation of related indications of this technology.

Introduction

Hand injury always has significant impact on the patient's occupational activities, social relations, leisure and psychological state. Rehabilitation is complex. It must consider the type of injury, the type of surgery and its specific protocols, in a global approach. Treatment of pain by the multidisciplinary team is essential. Among pains of various origins, neuropathic pain is the most difficult for healthcare teams to manage. It requires rethinking usual treatment, in favor of long-term accompaniment both to reduce pain and also for the patient to manage and somehow accept it. Among neuropathic pains, here we focus on mechanical allodynia, a "useless" pain, as opposed to an "alarm" pain that signals the danger of acute tissue injury [1]. Static mechanical allodynia is defined as pain caused by a stimulus that normally does not cause pain [2]. It can also be described as painful hypoesthesia since it covers all or part of a hypoesthetic skin area [3]. It differs from dynamic mechanical allodynia (pain caused by a mobile stimulus) and hyperalgesia (exaggerated pain in response to a nociceptive stimulus) [4]. It may be associated with neuralgia and complex regional pain syndrome [5–7].

Allodynia develops in the territory of an injured nerve. Lesions may be consecutive to direct nerve injury, by cutting, stretching, infection or burning [8–10]. The nerve can undergo external but also internal compression, following edema or later by an adherent scar. It can extend beyond the cutaneous territory of the nerve branch [11,12], in what is called extraterritorial contamination [13]. Allodynia results from a disturbance of the peripheral and central nervous systems [14–17]. Splinting the affected limb aims to reduce nerve stimuli, and thus painful stimuli, by protecting the painful area. The present study consisted creating protective splints for allodynia patients by 3D printing, designed from data collected with a 3D surface scanner. The pros and cons of 3D printed orthoses versus standard molded orthoses are discussed from the point of view of the patient and the practitioner. Finally, we present the evaluation of a large-scale application and related indications for this technology.

Materials and methods

3D surface scanner

A 3D surface scanner emits a pulsed beam of visible light toward an object and, with 2 cameras, collects the fraction of light reflected. The software calculates 3D points on the surface. Sometimes colors are also captured. The data enable true-to-scale

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3D digital reconstruction of the surface of the object. Frequent applications can be found in industrial design (e.g., automobiles), reverse engineering, virtual reality, gesture recognition, civil engineering, cartography, medicine [18] and forensic sciences.

The hardware we used was precise enough to digitize a hand for splint design. The equipment was portable and versatile. There was no need to touch the patient. The volume acquisition process was not scary, compared to a CT or MRI scanner, in which the patient may feel uncomfortable, notably in case of claustrophobia for, and there were no contraindications or need for radiation protection. Although quick, the volume acquisition process still required minimal compliance, especially to maintain the required stillness. The technology was limited by the reflectivity or absorption of the object: areas that are too shiny or transparent limit acquisition, and sprinkling with talcum powder may be useful. Over time, high-quality surface scanners have become increasingly affordable. Similar equipment to produce 3D images has recently been on the market for $3,700. For our study, surface scans were obtained using the CREAFORM GO! Scan 50 hand-held scanner [19].

3D printing

We used stereolithography (SLA), because we have expertise in making orthodontic guides with this kind of printer and a biocompatible resin. The 3D printer used for splints was a Form2 [20]. SLA technology offers a feel-good finish. The choice of materials available for 3D printers is extraordinarily broad, and the catalog is constantly growing. We chose to use Formlabs Dental LT Clear Resin [21], which provides a good compromise in terms of weight, stiffness and heat resistance compared to conventional thermoformable plastics used in occupational therapy. This class IIa resin is generally used to manufacture orthodontic aligners. It also had the advantage of being marketed as biocompatible by the manufacturer.

Two software programs were used in the study:

Meshmixer [22] is a freeware for modifying the STL (stereolithography) file generated by the surface scanner, perfectly adapted to our need to modify the object;

Cura [23] is an open-source software provided with the Ultimaker printer, converting data into a usable file for the printer.

Procedure

Acquisitions were made in the occupational therapist’s consulting room. Average scan time was 2 min. This imaging method did not require any special means of restraint apart from practitioner’s the table, with the patient sitting on a chair. The painful area was delineated by the patient, in collaboration with the occupational therapist [24,25]. When the data of the anterior and the posterior part of a limb could be acquired in a single scan, for example with the limb leaning against a support so as not to move, it was possible to acquire the two sides independently. The VXELEMENTS software [19] allowed the fusion of two acquisitions of the same object made from two different sides (Fig. 1).

3D scanner software

The raw data were processed after the patient’s departure. We used Creaform VXELEMENTS [19], which is the propriety software, for real-time acquisition and VXModel [19] as module for data processing. Items such as the table and irrelevant body parts had to be segmented and false edge effects needed to be corrected; areas such as inter-digit spaces were hard to acquire and needed to be filled in by post-processing with an interpolation algorithm. Small movement artefacts were sometimes present but could easily be corrected in the post-processing step by smoothing the area. The average processing time of the raw data was 15 min; with practice, this time can be much shorter. The data were then exported in. stl format, which is widely used in 3D design. This file format contains only the geometry of the surface without including color or texture (Fig. 2).

Fig. 1. Surface acquisition. Surface acquisition with the surface scanner.

Fig. 2. Data processing. Last step of data processing in. stl format.

Splint design

The splint was generated from the surface scan of the finger to obtain a real-scale 3D model. The software used was Meshmixer [22], which was sufficient for the necessary manipulations, and moreover was free. For post-processing, the object was enlarged with an offset of 2 mm to match the patient's finger. 3 mm protection offset was then added, correlating with the allodynography (a photograph of the limb with a highlight of the affected area). The number of faces of the object was reduced by applying a Voronoi pattern. This pattern was then used to create holes, to keep the finger ventilated while maintaining good rigidity. The last step was to make a watertight model, which was easily done with the software. The model was then exported to the printer as an. stl file. With experience, the orthosis could be designed in 10 min (Fig. 3).

Printing time

The Formlabs Form2 printer took 3 h 45 min to print the 748 layers of the finger splint seen in Fig. 4, with 100 microns layer thickness. This step did not require human intervention. Once printed, the resin on the surface was cleaned off by soaking in an alcoholic solution of isopropanol (IPA) for 10 min. Elimination of print media by hand took 5 min. Fifteen minutes' exposure to ultraviolet (UV) light increased the strength of the model. The patient trial was performed at the next appointment (Fig. 4).

Study cases

Three volunteer patients, with long-term allodynia of the hand or finger that had proved irreversible, received 3D-printed splints after surface scanning of the affected area and virtual design. All were being followed in long-term occupational therapy and had already had a conventional splint. 3D prototypes worn permanently in place of the classic splint. The patients continued to be seen in occupational therapy (Table 1).

Patients' feedback

Being able to assess the gain obtained with the 3D printed splint was made possible by the fact that all patients had been followed for a long time in occupational therapy, and already had had several conventional splints. We asked the patients to fill out a Likert scale questionnaire, based on their perception after wearing the 3D printed splint for a couple of weeks, compared to the same questionnaire completed for their classic molded splint. The parameters evaluated were esthetics, comfort, ease of wearing in public, rigidity, bulkiness, ventilation, ease of cleaning, aging, quality of protection of affected areas, and overall satisfaction [26].

Occupational therapists' feedback

Being able to assess the gain obtained with the 3D printed splint from the occupational therapist's point of view was also crucial. It was possible in that all patients were followed for other reasons. Occupational therapists who followed patients with 3D printed splints were asked to fill out a dedicated Likert scale questionnaire to evaluate these new splints. The parameters evaluated were time-saving by 3D technology, reduction in pain, reaction to this new technology, time to get splints, hygiene, material aging, replicability of the splint, use for other fields of application, and quality of protection of the affected areas.

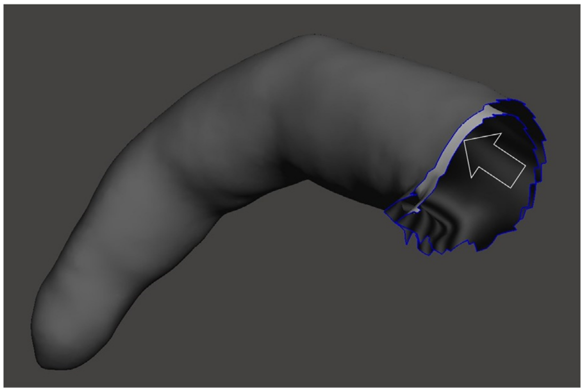

Fig. 3. Digital orthosis design. White arrow indicates the initial volume of the finger, which is enlarged by 2 mm in order to be able to fit the splint and wear it without discomfort.

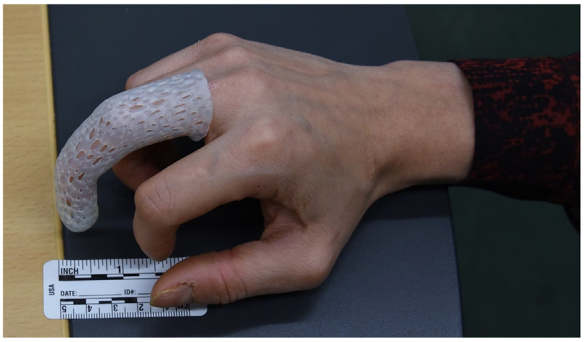

Fig. 4. Trial. Splint trial with the patient during the next appointment.

Time and money, comparative view

The last data we wanted to quantify and compare were cost and time. Working time, for a conventional splint and for the scan and virtual design of a 3D printed splint, could be considered as constant between countries. The cost of the thermoformable boards used by occupational therapists and of the filament for printers also tends to be constant between countries. Printing time, which does not require the presence of an operator, was not counted.

Table 1
Demographic data.

Patient	Gender	Age (Years)	History of allodynia	History with standard molded splint
1	Female	33	Allodynia following a metal needle prick on a finger	3 years' follow-up. Occupationally handicapped because working in contact with customers, who sometimes find the splint repulsive
2	Female	34	Allodynia following 5th metacarpal orthopedic surgery	3 years' follow-up. Child careperson
3	Male	42	Allodynia following a burn	4 years' follow-up

Results

Patients' feedback

Responses to questions were based on a 5-point Likert scale: Strongly Disagree (1); Disagree (2); Neutral (3); Agree (4); Strongly Agree (5) (Fig. 5). Our questionnaire analyzed 3 esthetic factors, 4 mechanical factors, 2 effectiveness factors and 1 general appreciation factor.

Occupational therapists' feedback

Responses to questions were based on a 5-point Likert scale: Strongly Disagree (1); Disagree (2); Neutral (3); Agree (4); Strongly Agree (5) (Fig. 6). Our questionnaire analyzed 3 patient-related factors, 3 organizational factors, 2 factors related to the goal of the splint, and 1 in relation to the development of this combination of technologies.

Time and money, comparative view

The price of materials was comparable between a classic splint and a 3D printed splint: between $1 and $5 each, varying linearly depending on the size of the splint. Producing a classic splint for a patient suffering from allodynia took between 45 min and 1 h, with the patient present. Comparatively, the presence of the patient was reduced to 5 min for surface scan; 30 min were then needed for segmentation, design of the splint and the start of printing. This second step could be carried out at any time, while printing could be done at any time, including at night. We had no printing failures, although these may occasionally occur. The time saved for the patient was therefore 40–55 min, and the time saved for the therapist was 10–25 min. The time spent on making a second splint, in case the first one was worn out, lost or broken, was 2 min, a time saving of 43–58 min.

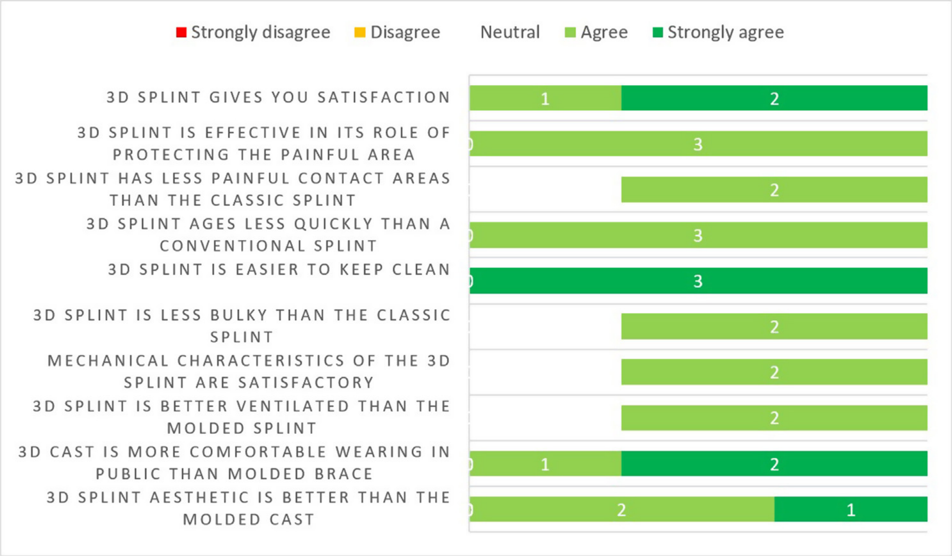

Fig. 5. Patients' questionnaire.

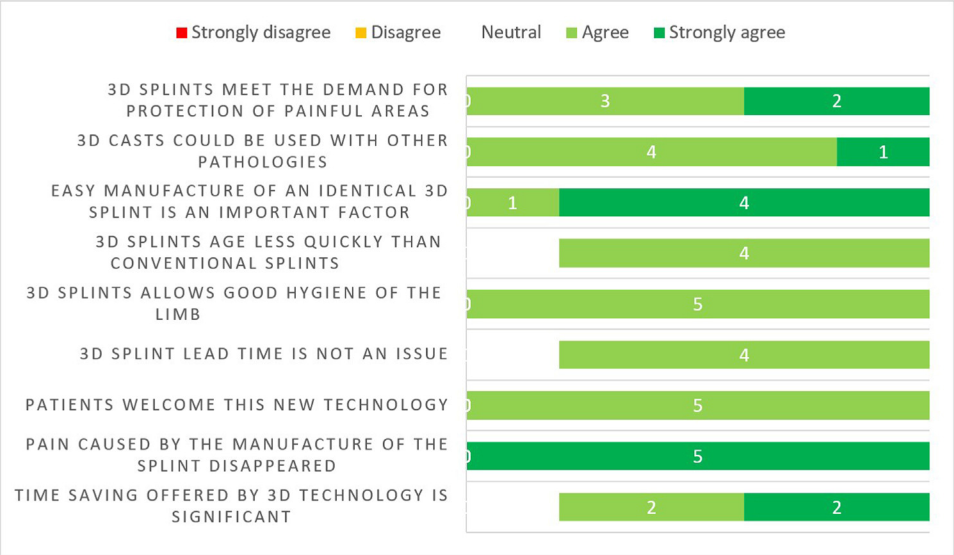

Fig. 6. Occupational therapists' questionnaire.

Discussion

For the patients, no questionnaire responses indicated that the conventional splint was preferable to the 3D printed splint. There was a strong consensus of satisfaction in terms of ventilation and ease of cleaning. Comfort in creating the splint is assured, given that there is no need to touch the painful area or to adopt a particular position; on the contrary, we seek a neutral, painless position, comfortable for the patient. The time spent by the patient in the occupational therapy department is reduced from 45 to 5 min (the time the 3D scan takes). Being able to obtain the same comfortable splint again without a new appointment is assured. Patients for whom we have designed splints are all enthusiastic about this innovative and personalized care. However, new technologies generally receive an enthusiastic reception just because of their innovative aspect, which may bias the objectivity of respondents.

On the occupational therapists' side, there was general agreement that using 3D printing for patients suffering from allodynia avoids the pain associated with contact during the manufacture of conventional splints. Secondly, there was agreement on the possibility of reprinting an identical 3D printed splint easily. All the other factors evaluated, in terms of time saving, acceptance of this new technology, hygiene, aging and the possibilities of development in other areas, received excellent ratings. However, this technology, due to the time it takes to print the splint, is not currently used in cases where the splint must be available quickly.

Regarding the institution, consumables costs are identical for conventional splints and 3D printed splints. Working time is shortened, especially after the first splint: for subsequent splints, printing takes in 2 min, without the patient being involved.

Conclusion

The technique developed in this article allows occupational therapists to design splints for their patients with allodynia in a rapid, reproducible and painless way, which is not the case with conventional molding.

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

Informed consent and patient details

The authors declare that they obtained a written informed consent from the patients and/or volunteers included in the article and that this report does not contain any personal information that could lead to their identification.

Disclosure of interest

The authors declare that they have no known competing financial or personal relationships that could be viewed as influencing the work reported in this paper.

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Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

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