

## ORIGINAL REPORT

## PRODUCTION TIME AND USER SATISFACTION OF 3-DIMENSIONAL PRINTED ORTHOSES FOR CHRONIC HAND CONDITIONS COMPARED WITH CONVENTIONAL ORTHOSES: A PROSPECTIVE CASE SERIES

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**Objective:** Hand orthoses are often prescribed for persons with chronic hand and wrist impairments. This study assessed the feasibility, in terms of production time and user satisfaction, of 3-dimensional printed hand orthoses compared with conventional hand orthoses for this population.

**Methods:** In this prospective case series, both a conventional hand orthosis and a 3-dimensional printed hand orthosis were manufactured for 10 participants. Production time (in minutes) of each orthosis was recorded. Each orthosis was worn for one week, after which participants completed a self-designed questionnaire on satisfaction, scored on a 5-point Likert scale. Functionality and orthosis preference were also assessed.

**Results:** The mean (standard deviation (SD)) production time for the 3-dimensional printed orthoses, of 112 (11.0) min, was significantly shorter compared with 239 (29.2) min for the conventional orthoses (95% confidence interval (95% CI) 71–182 min,  $p=0.001$ ). Satisfaction scores were similar for both orthoses, except for comfort item “fitting method”, which was rated significantly higher for scanning compared with casting (median [IQR] score: 5 [0.0]; 4 [2.0],  $p=0.034$ ). Functionality and orthosis preference were rated similar for both orthoses.

**Conclusion:** As the production time was halved, user satisfaction similar, and scanning experienced as slightly more comfortable than casting, 3-dimensional printed hand orthoses seem feasible and potentially beneficial for use in people with chronic hand and wrist impairments.

**Key words:** printing; three-dimensional; orthotic device; hand; feasibility; production time; satisfaction.

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## LAY ABSTRACT

Persons with chronic hand and wrist impairments often use an orthosis to make it easier to perform daily activities. Three-dimensional scanning and printing can facilitate the manufacturing of hand orthoses. This study compared 3-dimensional printed orthoses with conventional orthoses for persons with chronic hand and wrist impairments, with regard to production time and user satisfaction. Ten participants used a 3-dimensional printed orthosis, as well as a conventional orthosis, each for one week. The results showed that production time of 3-dimensional printed orthoses was half that of conventional orthoses. Satisfaction with both orthoses was similar, except for the “fitting method”, whereby fitting by 3-dimensional scanning was perceived as slightly more comfortable compared with conventional casting. Functionality and orthosis preference were rated similar for both orthoses. In conclusion, 3-dimensional printed orthoses appear to be a potential treatment option for persons with chronic hand and wrist impairments.

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Chronic impairments of the hand and wrist can occur in a wide range of neurological, neuromuscular and musculoskeletal disorders. Common hand- and wrist-related impairments in neurological disorders (e.g. stroke) are, for example, spasticity and joint contractures (1), while in neuromuscular disorders (e.g. Charcot-Marie-Tooth disease) muscle weakness and sensory loss are often present (2). In musculoskeletal disorders (e.g. os-

teoarthritis), impairments commonly include pain, joint deformity, and loss of grip strength (3). These chronic impairments of the hand and wrist can restrict the performance of activities of daily living, such as eating, dressing and writing, as well as work-related activities (3–5).

Treatment with hand orthoses can benefit persons with chronic hand and wrist impairments by significantly reducing pain, enabling better grip and/or increasing the ability to use the hand in performing daily activities (6–8). An orthosis is a rigid or semi-rigid device used for the purpose of support, alignment, prevention or correction of joint deformity, or to improve function or restrict motion of a movable body part (9), whereby hand orthoses specifically encumber the hand and/or wrist or solely the finger(s).

In persons with chronic hand and wrist impairments, hand orthoses are almost always intended for permanent use, and should therefore be made of sustainable and hygienic material and fit well. In current orthotic practice, hand orthoses for permanent use are mostly custom-fabricated, based on a plaster hand model, and usually made out of leather, polypropylene, silicone, resin or silver (10). Despite reported benefits of these conventional customized hand orthoses (6–8), patients in our clinical practice, as well as previous studies (6, 8), also indicated a number of adverse aspects, such as the fact that the orthosis can be bulky, sweaty, not waterproof and not hygienic. In addition, the manufacturing process of conventional custom-fabricated hand orthoses is highly laborious and time-consuming (10).

In recent years, new technology, such as additive manufacturing, has emerged, enabling the use of 3-dimensional (3D) scanning and printing to manufacture hand orthoses. Use of this technology to manufacture hand orthoses is expected to reduce production time (11, 12), and possibly improve satisfaction with respect to comfort, usability and aesthetics. However, scientific evidence regarding 3D-printed hand orthoses is scarce. To our best knowledge, only a few, mostly small, studies have evaluated the effects of 3D-printed hand orthoses, including one study in persons with overuse syndrome of the wrist (12), 2 studies in distal radius fractures (11, 13), and a study in post-stroke hand spasticity (14). None of these studies evaluated the feasibility of 3D-printed orthoses compared with conventional manufactured orthoses intended for permanent use worn by persons with chronic hand and wrist impairments. Therefore, the aim of this study was to assess the feasibility of 3D-printed manufactured hand orthoses in clinical practice compared with conventionally manufactured hand orthoses, with regard to production time and user satisfaction in persons with chronic hand and wrist impairments.

## METHODS

### *Study design and participants*

This prospective case series is reported according to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (15). Between January 2018 and Sep-

tember 2018, a convenience sample of 10 consecutive patients with chronic hand and wrist impairments was recruited from our outpatient rehabilitation clinic at the Amsterdam UMC, location Academic Medical Center (AMC), the Netherlands. Participants were screened for eligibility according to the following criteria: age  $\geq 18$  years; already wearing a hand orthosis or plaster cast; indicated for a (new) hand orthosis intended for permanent use; and no difficulty in understanding and writing the Dutch language. Written informed consent was obtained from each participant. The requirement for ethics review of the study was waived under the *Medical Research Involving Human Subjects Act* in the Netherlands by the local ethics committee of the AMC.

### *Procedures*

Each participant was provided with 2 customized hand orthoses made by an experienced orthotist (OIM Orthopedie, Noordwijkerhout, The Netherlands): a conventional orthosis and a 3D-printed orthosis. Both orthoses had a similar design and closure. At least 2 visits with the participant were planned in order to manufacture the orthoses. At the first visit, data on the anatomical features of the participants' affected hand and forearm were obtained for fitting of the orthoses. During the second visit, the fitting and alignment of both orthoses were checked. If necessary and possible, the orthoses were corrected in the same visit and delivered to the participant. When further adaptations were required, additional visits were arranged until the orthoses fitted well. For both orthoses, production time was recorded, as well as the number of visits to the clinic.

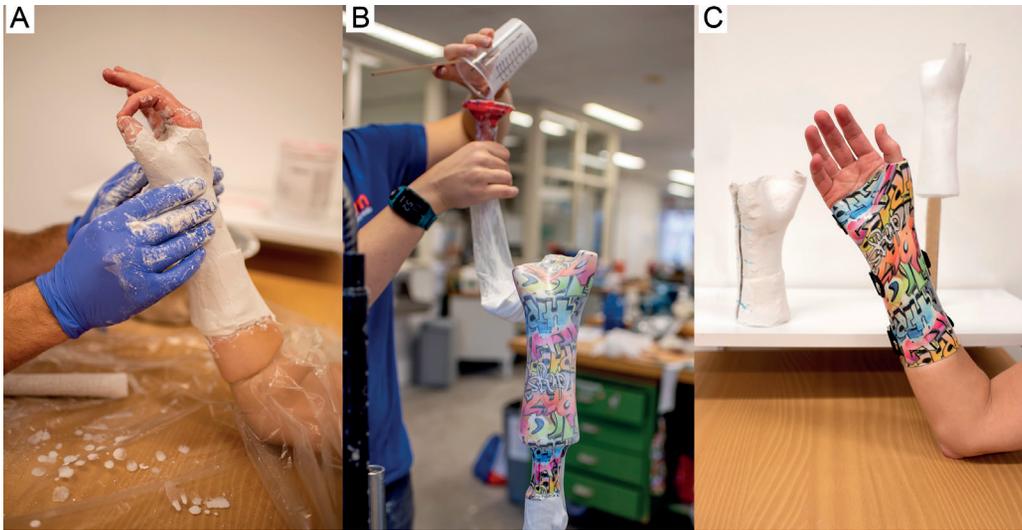
Each orthosis was worn for one week. The sequence of wearing the orthoses was determined by the sequence of completion of each respective orthosis. When both orthoses were completed at the same time, the participant could choose which orthosis to wear first.

After wearing the orthosis for one week, the participants were asked to complete an online questionnaire on user satisfaction. This questionnaire was designed in Google Forms (<https://docs.google.com/forms/u/0/>). The link to the questionnaire was sent by e-mail. If the questionnaire was not returned after one week, a reminder email with the link was sent. The questionnaire was coded with a number, so it could be returned anonymously. Participants who did not use e-mail were sent the questionnaire by post with a return envelope. This procedure was applied to both orthoses.

### *Intervention*

**Conventional orthosis.** The conventional orthoses were made of leather, silicone, polypropylene, resin or silver. For fitting of a leather, silicone, polypropylene and resin orthosis, a plaster cast of the affected hand and forearm was made (**Fig. 1A**). Next, a plaster model was made out of the plaster cast. The subsequent steps taken to manufacture the orthosis on this plaster model were dependent on the chosen material. For example, for a resin orthosis, this included vacuuming foil over the plaster model, adding layers of tricot and carbon, pulling another foil over the model, and vacuuming this whole package. Then, resin was added, divided over the model and vacuumed again (**Fig. 1B**). After hardening, the orthosis was removed from the model, trim lines were marked and the orthosis was cut out. Finally, sharp edges were smoothed (**Fig. 1C**). Silver orthoses were manufactured by an external silversmith.

**3D-printed orthosis.** For fitting the 3D-printed orthosis, the participant's affected hand and forearm were scanned by the orthotist with a white-light scanner (Health Care Partner 3D



**Fig. 1.** Production process of a conventional orthosis. (A) Casting the hand and forearm, (B) adding resin and vacuuming, and (C) the final orthosis.

Scanner, Creaform Inc., Québec, Canada) (**Fig. 2A**) using Rodin 4D software (Rodin4D, Merignac, France). Participants had to keep their arm in the correct position without moving for a maximum of 3 min. If the participant was not able to maintain this position, a hand therapist supported the arm. If needed, the 3D-scan model was post-processed for scan faults, and areas of the injured arm requiring pressure relief were adjusted (Mesh-mixer software, Autodesk Inc., San Rafael, CA, USA). Based on the 3D-scan, the orthosis was designed (**Fig. 2B**) using Fusion 360 software (Autodesk Inc.). The thickness of (specific parts of) the orthosis was set based on the required stiffness. The final model was printed out of nylon “PA 12” with a 3D printer (HP Jet Fusion 4200, Hulotech, Stadskanaal, The Netherlands) (**Fig. 2C**).

#### Measurements

*Participant characteristics.* Demographic data and clinical data (e.g. diagnosis, and reason/purpose/design of the orthosis) were obtained from the participants’ medical records.

In this study, aspects of feasibility taken into consideration were production time (i.e. orthotist’s labour time to produce the orthosis) and user satisfaction, including perceived functionality and orthosis preference.

*Production time.* For the cast-moulded conventional orthosis, production time was determined as the sum of the time needed to make the plaster cast of the affected hand (casting), create the plaster model, manufacture the orthosis on the plaster model, add strappings to the orthosis, fit the orthosis to the participant, and, if necessary, make adjustments to the orthosis.

For the 3D-printed orthosis, production time included the sum of the time required to scan the affected hand and forearm (scanning), if necessary post-process for scan faults, (computer) design the orthosis, make a print order, add strappings to the orthosis, fit the orthosis to the participant, and if necessary, make adjustments to the orthosis.

Apart from the total production time, the time needed solely for the fitting procedure (casting vs scanning) was recorded.



**Fig. 2.** Production process of the 3-dimensional (3D)-printed orthosis. (A) Scanning the hand and forearm, (B) designing the orthosis based on the digital model of the hand, and (C) the 3D-printed orthosis.

**Table I.** Demographic and clinical characteristics of the participants

No.	Sex (M/F), age (years)	Diagnosis	Reason for orthosis	Purpose of orthosis	Design of orthosis	Material of conventional orthosis
1	F: 28	Joint hypermobility	Instability	Stabilization	Anti-hyperextension MCP 4-5 orthosis	Silver
2	F: 62	Traumatic wrist injury with post-surgery complications	Pain	Immobilization	Circumferential wrist orthosis	Silicone
3	M: 19	Joint hypermobility	Pain	Stabilization	Anti-swan neck IP 1 orthosis	Silver
4	F: 62	STT-osteoarthritis	Pain	Immobilization	Circumferential wrist/thumb orthosis	Polypropylene
5	F: 51	Traumatic wrist injury	Pain	Immobilization	Circumferential wrist orthosis	Resin
6	F: 54	Stroke	Deformity	Correction	MCP anti-ulnar deviation orthosis	Silver
7	F: 79	Mal-union distal radius	Pain	Immobilization	Dorsal wrist cock-up orthosis	Resin
8	F: 65	Rheumatoid arthritis	Pain	Immobilization	Circumferential wrist orthosis	Leather
9	F: 52	Partial wrist arthrodesis	Pain	Immobilization	Circumferential wrist orthosis	Leather
10	F: 49	Charcot-Marie-Tooth disease	Muscle weakness	Support of function	Circumferential thumb orthosis	Silicone

F: female; M: male; STT: scaphotrapezotrapezoidal; MCP: metacarpophalangeal; IP: interphalangeal.

Furthermore, for each participant, the number of visits to the rehabilitation clinic until final delivery of each orthosis was counted.

**User satisfaction.** Since currently recommended questionnaires to assess satisfaction with limb orthoses do not cover all relevant items to assess feasibility, for example the fitting method, a self-designed questionnaire was used (16). Satisfaction was assessed for 10 items with regard to comfort, usability and aesthetics, all rated on a 5-point Likert scale (1=very poor; 5=excellent). Comfort was assessed with the items: fitting method (casting or scanning), fit, feeling of material, and transpiration. Usability was assessed with the items: effectiveness, donning/doffing, and use of closure. Aesthetics was assessed by the items: cleaning, appearance of the orthosis and other people's reactions to the orthosis.

**Functionality and preference.** Functionality was measured by asking the participants whether they could do less, equal or more with the 3D-printed orthosis compared with the conventional orthosis, and which orthosis they preferred to wear.

#### Statistical analysis

Demographic and clinical data, production time, number of visits, satisfaction scores, functionality and preference outcomes for both orthoses were summarized with descriptive statistics. Missing values were not imputed and individuals with missing data were not discarded. The difference in production time between the 3D-printed orthosis and the conventional orthosis, and the difference in time between the 2 fitting methods were analysed with paired *t*-tests, and 95% confidence intervals (95% CI) of the differences were calculated. Wilcoxon signed-rank tests were used to analyse differences in satisfaction-scores between the orthoses. The statistical significance level was set at  $p < 0.05$ . SPSS Statistics for Windows version 25.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

## RESULTS

### Study population

Ten participants (one male, mean (SD) age 52.1 (17.6) years) with various chronic hand and wrist impairments participated, and all returned the questionnaires. Demographic and clinical characteristics of the participants are shown in **Table I**.

For participants 1–8, the conventional orthosis was ready first, and therefore initially worn, followed by the 3D-printed orthosis. For the other 2 participants, the 3D-

printed orthosis was available first, and worn initially, followed by the conventional orthosis.

### Production time

Production time for conventional orthoses was available for 7 participants, since 3 participants received a silver orthosis made by an external company that did not record production time. Based on these 7 participants, the mean (SD) total production time of the 3D-printed orthosis was 112 (11.0) min, which was significantly shorter than that of the conventional orthosis (239 (29.2) min, 95% CI 71–182 min,  $p = 0.001$ ). The mean (SD) fitting time for 3D-scanning was 5.0 (3.96) min, vs 10.3 (4.39) min for casting (95% CI 0.8–9.7 min,  $p = 0.027$ ). There was no difference in the mean number of visits to the rehabilitation clinic between the 2 orthoses (3D-printed orthosis 3.8 times; conventional orthosis 3.7 times ( $n = 10$ )).

### User satisfaction

Satisfaction scores (based on 10 participants) were not significantly different for 3D-printed orthoses compared with conventional orthoses, except for the comfort item “fitting method” (**Table II**), which was rated significantly

**Table II.** Satisfaction scores for the conventional orthosis and 3-dimensional (3D)-printed orthosis

Satisfaction items	Conventional orthosis	3D-printed orthosis	Z	p-value
	Median [IQR]	Median [IQR]		
<b>Comfort</b>				
Casting: scanning <sup>a</sup>	4.0 [2.0]	5.0 [0.0]	-2.121	0.034*
Fit	4.0 [1.5]	3.0 [2.3]	-0.660	0.509
Material	4.0 [1.3]	3.5 [2.3]	-0.787	0.431
Transpiration	3.5 [2.5]	4.0 [0.5]	-0.284	0.776
<b>Usability</b>				
Effectiveness	3.0 [2.0]	4.0 [2.0]	-0.921	0.357
Donning/doffing	5.0 [0.3]	5.0 [1.0]	0.000	1.000
Using closure	5.0 [1.0]	5.0 [2.0]	-0.414	0.679
<b>Aesthetics</b>				
Cleaning	4.5 [1.3]	5.0 [1.0]	-1.289	0.197
Appearance	5.0 [2.0]	4.0 [1.3]	-0.173	0.862
Reactions of other people	4.0 [1.3]	4.0 [2.0]	-0.649	0.516

\* $p < 0.05$ . <sup>a</sup>Based on  $n = 7$ . IQR: interquartile range.

higher for 3D-scanning (median [interquartile range; IQR] satisfaction score: 5 [0.0]) compared with casting (median [IQR] satisfaction score: 4 [2.0],  $p=0.034$  ( $n=7$ )).

### *Functionality and preference*

Functionality of the 3D-printed orthosis compared with the conventional orthosis was experienced better by participants 1–3, equal by participants 4–8 and less by participants 9–10. Regarding preference, participants 1–5, wearing a silver ( $n=2$ ), resin ( $n=1$ ), silicon ( $n=1$ ) and polypropylene ( $n=1$ ) conventional orthosis, preferred to wear the 3D-printed orthosis. The other 5 participants preferred the conventional orthosis, which was made of silver ( $n=1$ ), resin ( $n=1$ ), silicon ( $n=1$ ) or leather ( $n=2$ ). Reasons for preference that were given for both orthoses were better fitting, more comfortable and lightweight.

## DISCUSSION

This study of the feasibility of 3D-printed hand orthoses in persons with chronic hand and wrist impairments showed that the production time for manufacturing 3D-printed orthoses intended for permanent use was 53% less than the production time for conventional orthoses. User satisfaction with comfort, usability and aesthetics after wearing the orthosis for one week was similar for both orthoses, except for the fitting method scanning, which was rated slightly more comfortable than the conventional casting method. Perceived functionality was similar for both orthoses.

To the best of our knowledge, this is the first study assessing the feasibility with regard to the time taken to manufacture 3D-printed hand orthoses, hence we cannot compare these results with other studies. The much shorter production time of 3D-printed orthoses compared with conventional orthoses in this study can be explained by the fact that more automation is used in the manufacturing process. For example, to design the orthosis, obtaining the dimensions of the hand and forearm with scanning takes less time than with conventional casting, as reported in our results, and fewer manual actions are required to manufacture the orthosis. Accordingly, this reduces the chance of making mistakes, and therefore the time needed for correction, although, in the current study, this did not lead to a lower number of visits. However, as this was our first experience with scanning and printing of hand orthoses, efficiency may be improved in the future, possibly resulting in fewer visits to the clinic needed for the patient. Although we did not measure costs, it can be expected that a reduction of production time and visits to the clinic will also result in lower costs. As no previous studies have investigated the production time and costs of manufacturing 3D-printed hand orthoses, we recommend that future research examines these aspects.

Regarding feasibility with respect to user satisfaction, we found that the median scores on comfort were good

for conventional orthoses and fair to excellent for 3D-printed orthoses. Previously, Chen et al. (13) also reported on the comfort of 3D-printed orthoses in persons with forearm fractures, and, although rated on a different scale (4-point), they found excellent scores for comfort for 3D-printed orthoses. The slightly lower comfort scores in the current study may be explained by the fact that, in Chen et al.'s study (13), persons had to wear the orthosis for only 6 weeks, with possibly fewer demands on comfort compared with an orthosis intended for permanent use, as in our study. Unlike Chen et al. (13), the current study assessed satisfaction with different aspects of comfort, and found that, to fit the orthosis, the scanning method to obtain hand and forearm dimensions was perceived as more comfortable than the conventional casting method. A possible reason for this difference may be that with scanning, as opposed to casting, there is no direct contact with the, sometimes painful or sensitive, wrist and/or hand. This benefit of scanning was also reported by Wu et al. (17). In addition, as shown in the current study, scanning takes less time than casting, which also may have positively influenced satisfaction with comfort.

Satisfaction with usability of the 3D-printed orthosis was comparable to that of the conventional orthosis, and the perceived functionality of both orthoses was equal. This could be expected, since the aim and design of the orthoses were the same. Orthosis preference was also equal, whereby half of the participants preferred the 3D-printed orthosis over the conventional one. This is much lower compared with studies in adults (13) and children with distal radius fractures (11), in which all participants preferred the 3D-printed orthosis over a conventional plaster cast. The difference between these and our results may be explained by the more negative properties of a plaster cast (bulky, sweaty, not hygienic) compared with the conventional orthoses as used in our study, which already had properties more similar to 3D-printed orthoses. This is supported by our data, showing similar reasons for preference for each orthosis, i.e. better fitting, more comfortable and lightweight. Alternatively, the conventional orthoses in the current study were made of a variety of materials, which each could have affected preference differently. For example, the 2 participants with a leather orthosis preferred this orthosis over the 3D-printed orthosis, probably because of the smoothness of the material. In addition, not all possibilities of 3D-printing have yet been explored. It is expected that in the near future, 3D-printed hand orthoses can be better designed, e.g. by using other materials, which could improve satisfaction, and therewith preference for 3D-printed orthoses.

The results showed no difference in satisfaction with respect to aesthetics between the 3D-printed orthosis and conventional orthosis, which was contrary to what we expected. It is possible that the study sample was too small to detect a difference. Furthermore, the variety of materials used for the conventional orthosis was very

large, ranging from silver and resin, which have a more refined and modern look, just like the 3D-printed orthosis, compared with silicone, polypropylene and leather, which are more bulky and have a more traditional look. Although aesthetics was analysed in other studies on hand orthoses (8, 18), we are not aware of studies that have reported specifically on the aesthetics of 3D-printed hand orthoses. Considering that patient-reported outcome measures (PROMs), such as aesthetics, are becoming increasingly important (19), that aesthetics can influence the adherence with wearing an orthosis (20), and that, with 3D-printing, there are good possibilities to personalize the orthosis, future studies should assess satisfaction with the aesthetics of 3D-printed hand orthoses in a larger population.

#### Study limitations

A limitation of this study is that a small convenience sample of 10 participants was used. Therefore, generalizability of the results to persons with chronic hand and wrist impairments in general may be compromised, although all kinds of disorders (neurological, neuromuscular and musculoskeletal) were represented. The questionnaire used was self-designed and not tested on validity. The results of the questionnaire regarding the 3D-printed orthosis may be slightly biased because of the “coolness factor” of the emerging technology of 3D-printing. Finally, the current study focused on short-term use of the orthoses, by assessing results after one week of wear, while the orthoses are intended for permanent use. Therefore, this study does not analyse the feasibility of 3D-printed orthoses in the long-term.

#### Clinical implications

In this feasibility study some clinical advantages of using 3D-scanning and 3D-printing for designing and manufacturing hand orthoses became apparent. First, scanning takes less time than casting and was experienced as slightly more comfortable by the participants. Secondly, the data of the scan and the design of the orthosis can be stored digitally, hence the orthosis can easily be reprinted when a new one is needed. Yet, manufacturing 3D-printed orthoses demands other skills of the orthotist. Instead of manufacturing the orthosis manually, the orthotist needs computer-related skills, such as scanning and digital drawing, which may require training, and related costs. Furthermore, certain investments are needed to manufacture a 3D-printed orthosis, i.e. purchasing a scanner, software and a 3D printer, although printing can also be outsourced. However, these costs may easily be amortized if 3D techniques for manufacturing hand orthoses are used on a large scale.

## CONCLUSION

The results of this study suggest that the use of 3D-scanning and 3D-printing for manufacturing hand orthoses

for persons with chronic hand and wrist impairments is feasible for use in clinical practice, considering that production time was half that of conventional orthoses, satisfaction with both orthoses was similar, and participants experienced fitting by 3D-scanning as slightly more comfortable compared with casting. Future studies should investigate the long-term effectiveness and usability of 3D-printed hand orthoses, including cost-effectiveness.

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*Author contribution.* TO, YK, PdG, and HG designed the study, TO collected and analyzed the data, TO and MB wrote the manuscript, and all authors revised and approved the final version.

*Declaration of conflicting interests.* OIM Orthopedie, the company which employs Yvette Kerkum and Peter de Groot, was included as a partner in the project and provided the 3D-printed orthoses for this study. We wish to confirm that neither the company, nor Yvette Kerkum and Peter de Groot have (financial) benefits related to this project. The authors have no other conflicts of interest to declare.

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