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Full Length Article

Utilization of 3D printed orthoses for musculoskeletal conditions of the upper extremity: A systematic review

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ABSTRACT

Study Design: Systematic Review
Introduction: 3D printed orthoses are emerging as a possible option in the field of hand therapy to fabricate conventional casts and orthoses. It is unknown how this technology is currently being used to treat upper extremity musculoskeletal conditions, and if 3D orthoses are comparable to custom- made low temperature thermoplastic orthoses fabricated by hand therapists.
Purpose of the Study: The primary aim of this review was to investigate the utilization, effectiveness and feasibility of 3D printed technology to manufacture custom orthoses for musculoskeletal conditions of the upper extremity.
Methods: Studies describing 3D printed orthoses or casts used in treatment with patients were included following a comprehensive literature search using CINAHL, PubMed, Medline, ProQuest, and EBSCO databases. The selected studies had to address musculoskeletal conditions of the elbow, wrist, hand and/or digits that would typically be immobilized with a cast or brace or orthotic or orthosis.
Results: Ten studies met the inclusion criteria. Study designs included case studies, case series, and 1 randomized clinical trial. 3D printed orthoses/casts appear to be comfortable, provide adequate immobilization, and have pleasing aesthetics. However, expensive equipment, lack of appropriate software and scanning tools and lack of highly skilled clinicians are all factors preventing the implementation of 3D printed orthoses into current clinical practice.
Discussion: 3D printed orthoses appear to be effective at immobilization of a limb, aesthetically pleasing, and utilize lightweight and well -ventilated materials. However, the feasibility of implementing 3D printing technology in hand therapy settings remains challenging in part due to the resources required.
Conclusions: While 3D printing shows promise, the high cost of equipment, lack of training and skill of clinicians and the long time required for production are all factors that need to be improved to make 3D printing a viable option in the hand therapy setting.

Introduction

Orthoses are rigid or semi-rigid devices that are commonly utilized to support, restrict, mobilize and/or immobilize an injured or diseased body segment to assist in improving function and facilitating healing. These devices can be custom fabricated, prefabricated, or custom fit by a qualified clinician.[1] Hand therapy clinicians typically fabricate orthoses from low temperature thermoplastic materials (LTTP).[1] The recent 2019 Practice Analysis of Hand Therapy conducted by the Hand Therapy Certification Commission noted that orthoses are an integral part of hand rehabilitation and that these items are “highly critical to practice.”[2] The terms “splint” or “brace” refer to casts commonly used for fractures and dislocations.[3] These splints or braces, also called orthoses, can be provided as plaster or fiberglass casts, prefabricated splints/orthoses, and more recently, through utilization of 3D technology. The type of orthosis or splint prescribed depends on many factors including type of injury, practice setting, client needs, availability of materials, health care provider experience, cost, and time. Rigid cast immobilization is typically indicated for injuries and conditions where the body segment needs to be immobilized on a full-time basis without removal or movement at or near the injury

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site. Similarly, custom molded orthoses with LTTP provide rigid immobilization, but can also be removed for wound care, hygiene, and prescribed exercises and allowed movement.[2] Prefabricated orthoses, which are orthoses that require minimal self-adjustment, may be suitable for conditions requiring light support, or for situations where time, cost, and health care providers lack experience to provide a custom orthosis.[3]

The use of 3D printed technology appears to be emerging as an alternative and/or viable option for the fabrication of orthoses, splints, casts and/or braces for individuals with a variety of orthopedic conditions including fractures, sprains, and tendinopathies.[4] According to Keller et al, (2019), 3D printing technology is currently used “infrequently” or “not at all” by hand therapists, and proficiency with this skill is not seen as essential for newly certified hand therapists.[2] Collectively, it remains unknown if 3D printing technology is a feasible and viable alternative to traditional custom orthotic fabrication by hand therapists.

3D printing in general terms refers to the fabrication of 3-dimensional objects based on a computer design and built in 3 dimensions.[5] Current application of this technology in the medical field includes facial reconstruction, orthodontics, exoskeletons, and prosthetic devices.[6] There is a great deal of interest in the specific area of 3D printed orthoses for immobilization to replace plaster and/or fiberglass casts.[7,8] Reported advantages of 3D printed orthoses as compared to traditional plaster/fiberglass casts or custom-made low temperature thermoplastic orthoses, as reported in the literature, include being lighter in weight, producing less incidence of skin irritation, offering better hygiene with less odor and perspiration, appealing and custom-tailored aesthetic design, and the ability to use recycled, affordable materials.[6,8-10] A 3D printed orthosis can also be easily revised and/or modified if needed, as the 3D scanned data is saved.[7] The materials used are much less prone to mechanical failure, and the material thickness can be precisely controlled.[11] Conversely, some researchers postulate that custom orthoses made from low temperature thermoplastic materials, such as those fabricated by occupational therapists and certified hand therapists, require specialized training to fabricate, are time consuming, expensive, difficult to keep clean, are bulky and cumbersome, and are unable to tolerate moisture at high temperatures.[9,12,13] Furthermore, fabrication of these orthoses relies on clinician expertise and application of tacit knowledge that can be difficult to share and teach others.[9]

The process of creating a 3D printed orthosis proceeds in several stages. First, 3D scanning involves the collection of digital data reflecting the shape or appearance of the desired object and creating a digital model based on this object.[15] Computer aided design (CAD) software is then used to process the collected data and create the 3D printable model. The CAD software is transferred to a 3D printer for the actual fabrication process.

Specifically, the procedure of 3D printed orthoses can be described in 5 steps:

1. Scanning the patient’s affected limb with a 3D scanner.
2. Designing the orthosis model using a computer aided designing software program and exporting the data to a 3D printer.
3. Printing the physical orthosis using a 3D printer.
4. Finishing steps include grinding and removal of unnecessary parts, smoothing of edges, and attachment of fixation devices such as Velcro hook and loop.
5. Verifying and checking the fit of the orthosis, preferably by a certified hand therapist or orthotist with orthotic fabrication training.[10]

Although the above-described process may sound over simplified and direct, there are many obstacles and issues that prevent the smooth transition for 3D printed orthoses to replace custom orthotic fabrication using low temperature thermoplastic sheet materials at this time.[4] Scanning of the involved limb can be challenging; it takes time and may involve awkward and uncomfortable positioning for the patient.[14-16] The anatomy of the upper extremity is complex and scanning procedures do not always pick up all the intricate details. In order to offer the patient improved comfort in a 3D printed orthosis, particular detail must be given to accurately address the anatomical aspects of the involved limb in order to avoid pressure areas and offer adequate support and conformity.[14] Currently, there are no specific software programs in use to address upper extremity orthotic design, although many different programs are being developed.[4] Further, the computerized software models require time and skill to fix mistakes and address incomplete scans. This process requires advanced computer training and experience, which most hand therapy clinicians do not possess.[8,14,17] The printing stage can take anywhere from 6 to 10 hours to complete. Afterwards, the finished printed orthosis may require mechanical grinding to smooth edges and corners, padding for rough areas and attachment of straps.[4,15-20] In the future, it will be desirable for hand therapy clinicians with their detailed knowledge base of anatomy and clinical conditions to be involved in this process or perhaps it will be advantageous to bypass this process altogether.[4,8] Despite these factors, 3D printing of orthoses for the upper extremity remains a possible addition to the hand therapy rehabilitation process.[1,4]

The primary purpose of this systematic review is to investigate the current utilization and effectiveness of 3D printed technology to manufacture custom orthoses for musculoskeletal conditions of the upper extremity. A secondary purpose is to explore the feasibility of using this technology in hand rehabilitation settings.

Methods

Identification and selection of studies

The reporting of this systematic review was guided by the standards of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA).[21] The protocol for this systematic review is registered in the PROSPERO database (under file number #CRD42021246820).

All studies, including randomized controlled trials (RCTs), retrospective cohort studies, case series and case reports that evaluated the use of 3D printed orthoses with actual patients with musculoskeletal conditions of the elbow, wrist, hand and/or digits were included in this review. Inclusion criteria included studies published in English between the dates of 2010-2021. Studies that described 3D printed orthotic intervention were included if the clinical diagnosis were determined to be one that would typically receive a custom thermoplastic splint or orthosis or cast, the 3D printed orthoses were made for actual patients and used instead of or compared with some other type of external fixation, such as a plaster cast or physician applied splint. Clinical diagnoses were preselected as musculoskeletal conditions of the elbow, wrist, hand and/or digits.

Studies were excluded if they described 3D printing of orthoses with or for the following circumstances: neurological conditions (stroke, high tone, or spasticity), wrist driven or motorized, medical aids, assistive devices, prostheses, lower limb/foot, robotic upper limb, bone/ bony defects, internal devices, mouth, and/or exoskeleton. Studies were also excluded if they only described the methodology of 3D printing, compared methods of 3D printing, and/or described trials of 3D printed orthoses made for healthy volunteers.

Search strategy

Both authors, 2 certified hand therapists/occupational therapists, independently searched the databases using the above-described inclusion criteria to determine the studies to be reviewed. The following databases were searched: CINAHL, PubMed, Medline, ProQuest, and EBSCO. Search terms included the following: 3D printing, AND (splinting or splint or orthotics or brace or braces or bracing) AND (elbow/ wrist/ finger/ hand) AND (upper extremity or upper limb or hand or arm). A hand search was also done using reference lists of relevant scientific articles and reviews of additional articles.

Data abstraction

The reviewers organized the data extraction process using data abstraction forms (C. Brown, PhD, oral communication, June 2021). Data extracted from the studies included study design; participant demographics; the intervention and a comparison intervention (if noted); the data analysis method; the outcome measures used; the wearing schedule of the orthosis (if noted); the process of 3D printing (including scanning, software usage, 3D printing materials, cost, and finishing steps, if noted), and study limitations. Demographic data was extracted from the studies as able: number of participants, participant age, clinical diagnosis, orthosis design, and gender. A data extraction form is found in Appendix A.

Study quality and risk of bias assessment

The reviewers individually and collectively evaluated the quality of research using the Methodological Index for Non-Randomized Studies (MINORS)[22] and the level of evidence scale (LOE) of the studies.[23] The MINORS is a 12-item standardized tool used to determine the methodological quality of nonrandomized studies. Each item of this tool is given a score of 0 (“not reported”), 1 (“reported but inadequate”), or 2 (“reported and adequate”). The MINORS index has good internal consistency (a ¼ 0.73), moderate-to-good inter-reviewer agreement (k ¼ 0.61-1.00), and test-retest reliability (k ¼ 0.59-1.00).[24] The items examine the following: the aim of the study, inclusion of patients, prospective collection of data, appropriate and unbiased endpoints of the study, follow-up period, loss to follow-up, and prospective calculation of the sample size. The scores are added together, with maximum total scores reaching 16 for noncomparative studies and 24 for comparative studies. Blind scoring was conducted independently by both reviewers and discussed until a consensus was reached.

At the time of appraising the quality of each article, the Level of Evidence (LOE) of each article was ascertained. The LOE rating system spans from Level 1, which is the highest LOE, usually referring to systematic reviews, meta-analyses of studies and randomized clinical trials (RCTs), to Level 5 for clinical evidence based on expert opinion. Further divisions of the levels of evidence have been described, with the more common descriptors found at the Oxford Center for Evidence-Based Medicine. For this systematic review, only studies with Level of Evidence of 4 or higher were included.[23]

Risk of bias was also assessed by both reviewers and compared for each of the 10 studies in accordance with the 5 principal types of bias: selection, performance, attrition, detection, and reporting.[25] Risks of bias can be classified as low, high, or unclear.

Results

Our initial search for studies describing the use of 3D printed splints identified 537 articles (EBSCOhost [n = 65], PubMed [n = 31], Medline [n = 60], ProQuest [n = 370], CINAHL [n = 21]). Duplicates were removed as were all articles describing 3D printed interventions for the lower extremity, dental devices, and assistive devices as well as all exclusion criteria listed previously. Articles describing the procedures involved in producing a 3D printed orthosis but without patient applications were also not included. One of the 10 studies was a randomized clinical trial (RCT); 1 was a comparative cohort study; 4 of the 10 were case series, 1 was a retrospective study and 3 were case reports. Figure 1 outlines the PRISMA flow chart and the article selection process.[21] Ten studies are included in this review.[7,13,15,16,18-20,26-28] Key study characteristics are summarized in Table 1.

Quality of selected studies

The MINORS scale scores for the quality of the studies selected for this review ranged from 1 to 10 out of a maximum of 16 for non-comparative study designs[7,13,15,16,19,26,27] and from 10 to 18 out of 24 for comparative studies.[18,20,28] Ratings are found in Table 2. Two of the 10 studies had a score of 1[13,26]; 2 of the 10 studies had a score of 6[7,27]; 2 studies had a score of 9[15,16]; 2 had a score of 10[18,19]; and 1 study had a score of 18.[20] Sample size calculations were not done in any of the studies, most studies did not use unbiased assessments, and only 3 studies[18,20,28] utilized adequate statistical analysis.

Risk of bias

Most of the studies in this review revealed high levels of bias, as shown in Table 3. The high prevalence of risk of bias in most of the included studies was due to lack of statistical analysis in reporting results; use of convenience sampling and lack of randomization of participants; absence of blinding of both participants and assessors; and use of unvalidated assessment/outcome measures.

Subjects

A total of 145 subjects with various musculoskeletal conditions were included in the 10 studies. When the studies comprised both lower extremity orthoses as well as orthoses for the upper extremity, only the latter were included in this review.[18] When the study included patients with neurological conditions, they were also excluded from the final count.[16] Demographic and clinical characteristics of the participants are found in Table 4.

Diagnoses

The most common conditions reported in the studies that used 3D printed orthoses were fractures of the wrist and forearm, specifically distal radius fractures (n = 93)[7,15,18-20,28] and forearm fractures (n = 11).[7,15,18-20,28] Other conditions involving the wrist included wrist pain/overuse (n = 22)[28] and wrist trauma (n = 3).[16] Seven patients were diagnosed as having thumb CMC joint osteoarthritis[16,27]; 1 patient had rheumatoid arthritis[28]; 2 patients had joint hypermobility (swan neck deformity)[16]; 2 patients had peripheral neuropathies (carpal or ulnar tunnel syndrome[13]; 3 patients had hand burns[26]; and 1 patient was diagnosed with Charcot Marie Tooth disease.[16]

Orthotic designs and types

All 10 studies utilized custom 3D printed orthoses to address musculoskeletal conditions of the elbow, wrist, hand, and/or digits. One study used 3D printed orthotic intervention to fabricate an orthosis with the elbow immobilized at 90 degrees with the

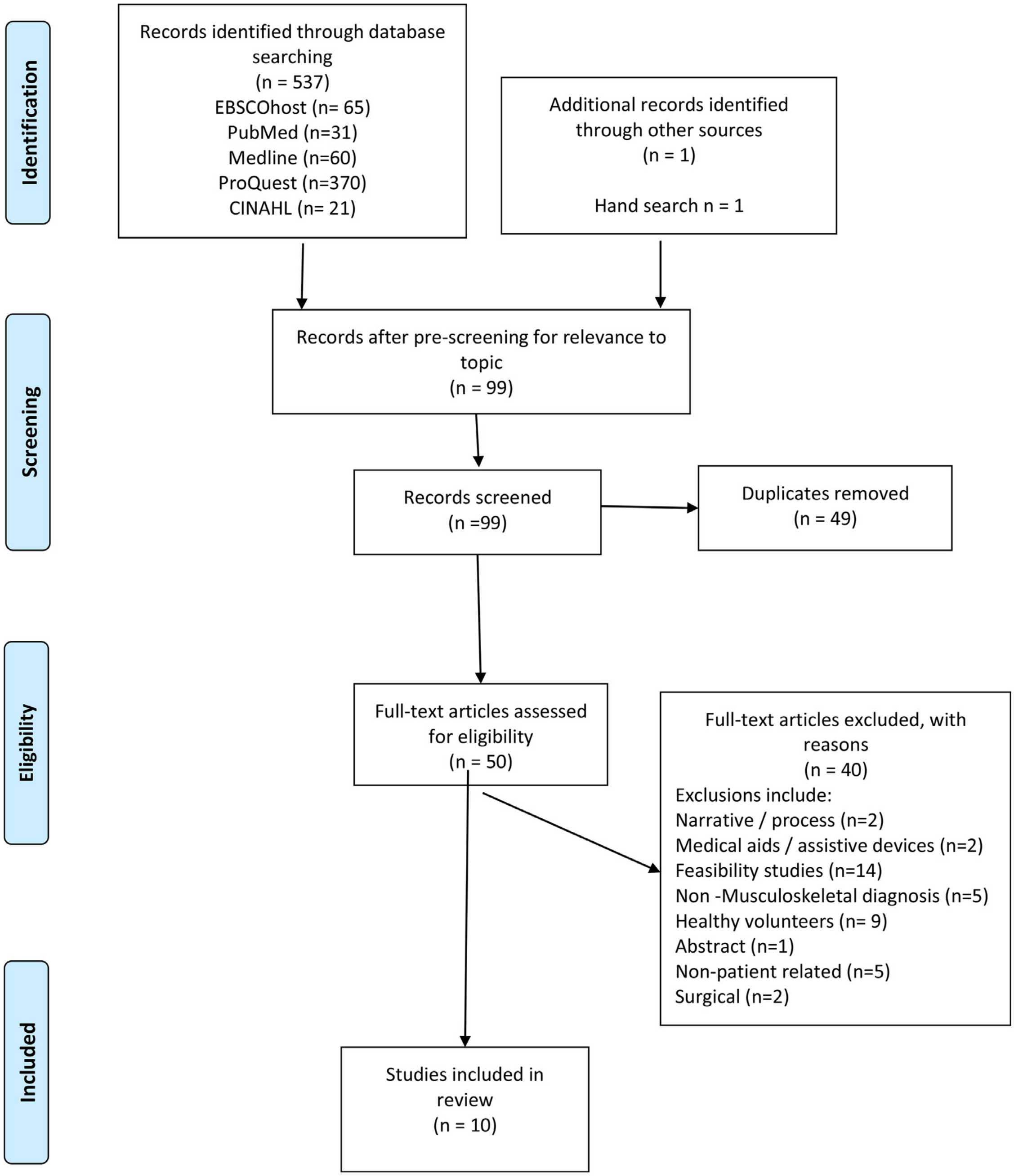

Fig. 1. PRISMA flow diagram.

wrist and hand free.[7] One study reported on utilizing 3D printed orthoses for elbow fractures ($n = 7$) but did not report on the orthosis design.[18] Studies that investigated 3D printed wrist orthoses used a variety of orthotic designs including a dorsal wrist cock up ($n = 1$)[16], a circumferential wrist orthosis ($n = 9$),[7,15,16,18-20] and/or volar wrist orthotic designs ($n = 29$).[18,28] One of the 10 studies fabricated hand-based 3D printed orthoses: 1 for carpal tunnel syndrome, and 1 for ulnar tunnel syndrome.[13] The latter 2 orthoses were categorized as hand-based orthoses as the length of both orthoses covered the forearm approximately 2 inches proximal to the wrist and thereby did not immobilize the wrist completely. In the studies that described digit-based orthoses, 1 research group replicated a PIP extension restriction orthosis used to address the swan neck deformity[16]; 1 study replicated a static PIP extension orthosis[26]; and 1 study utilized a 3D printed thumb MP extension restriction orthosis with CMC stabilization.[27]

It is important to note that the study by Oud et al (2021),[16] described orthoses made by orthotists and prosthetists in their comparison to 3D printed orthoses and utilized materials and methodology not typically used by hand therapy clinicians. The significance of this difference will be highlighted throughout our review.

Wearing schedules

Due to the differences in clinical diagnoses, there was considerable variability in reported wearing schedules between the studies. In addition, several studies did not report wearing schedules consistent with current acceptable practice. One study reported wearing times between 12 and 18 months, 24 hours per day to address

Table 1
Summary of evidence for 3d printed orthoses for patients with musculoskeletal conditions of the elbow, wrist, hand, and /or digits

Author/*Country*	Study design	Level of evidence	Intervention/comparison	Outcome measures	Conclusions/comments
Chae et al, (2020)[13] *Korea*	Case series	Level 4	3D printed orthoses- no comparison to conventional orthoses	JHFT, VAS, grip and pinch strength, QUEST, MMT (for ankle case)	No statistical analysis of results, CTS: improvements in VAS, JHFT scores, and grip and pinch strength UTS: improvement in VAS/ grip strength Improved QUEST scores
Chen L et al, (2021)[18] *China*	Retrospective comparative cohort	Level 3	3D printed cast compared to traditional plaster cast	X- rays to evaluate fracture healing and reduction; VAS pain scale, patient satisfaction, ROM, complications	Decreased complications ($P < .05$), less pain ($P < .05$), increased patient satisfaction ($P < .05$), increased ROM ($P < .05$) with 3D printed orthosis
Chen YJ et al, (2017)[15] *China*	Case series	Level 4	3D printed cast with no comparison	Clinical efficacy of treatment and patient satisfaction questionnaires, complications	Patient preference for 3D printed cast for comfort, less pressure sores, holds fracture reduction. 3D printing requires more time
Chen YJ et al, (2020)[20] *China*	Randomized Clinical trial	Level 2	3D printed cast compared to plaster cast and external splint	Clinical efficacy of treatment, patient satisfaction, wrist functional assessment (modified Green and O'Brien score) for pain, ROM, and grip strength	3D printed cast scores were higher for patient satisfaction ($P \leq .001$) and total score for clinical efficacy ($P = .005$). Green and O'Brien score was higher (80%) for 3D group. 3D printed cast took longer to create and was more expensive.
Guida et al, (2019)[19] *Italy*	Prospective clinical trial	Level 2	3D printed orthosis with no comparison	PRWE/ VAS pain/patient satisfaction	Significant differences ($P < .001$) for PRWE and VAS favoring 3D printed orthoses
Katt et al, (2021)[7] *USA*	Case reports	Level 4	3D printed casts with no comparison	Pilot study	Excellent clinical outcomes, no skin issues, no fracture displacement
Kim, et al, (2018)[28] *South Korea*	Randomized Clinical Trial	Level 2	3D printed wrist orthosis compared to commercially available wrist cock up orthosis	PRWE/ JHFT /OPUS 1 week before and 1 week after (Short time frame of use = one week)	Pain relief in both groups/high patient satisfaction, higher OPUS score (2 items) for 3D printed orthosis. No significant differences in PRWE or JHFT between groups
Marinho et al, (2020)[27] *Brazil*	Case Series	Level 3	3D printed thumb orthosis with no comparison	QUEST, dynamometer, pinch gauge, VAS	High level satisfaction with 3D orthosis, improved strength, 5 patients out of 6 noted less pain
Nam et al, (2018)[26] *Korea*	Case Series	Level 3	3 D printed orthoses with no comparison	Modified Barthel index; ROM, patient satisfaction	Improved MBI scores (dressing, bathing domains) and improved ROM and satisfaction although actual measures were not reported
Oud et al, (2021)[16] *The Netherlands*	Prospective case series	Level 3	3D printed orthoses compared to custom orthoses (leather, silicone, polypropylene, resin or silver)	Production time and fitting time for orthoses/ patient satisfaction/ function and orthosis preference/ number of visits	Mean production time of the 3D-printed orthosis was 112 (11.0) min, compared to conventional orthosis (239 [29.2] min, 95% CI 71-182 min, $P = .001$); 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, $P = .027$); Satisfaction scores were similar; no significant difference in number of visits

JHFT = Jebsen Taylor Hand Function Test; ROM = range of motion; VAS = visual analog scale; QUEST = Quebec User Evaluation of Satisfaction with Assistive Technology; Complications- infections, fragment displacement, non-union; Clinical efficacy = stability of immobilization, blood circulation, pressure pain, pressure sores; OPUS = Orthotics and Prosthetics User's Survey; PRWE = Patient Rated Wrist Evaluation; SD = standard deviation; CI = Confidence Interval.
Level of Evidence-Level I = Systematic Review, Level II = Randomized Clinical Trail, Level III = Case Series/Retrospective studies, Level IV = Case Report, Level V = Expert Opinion.

PIP flexion contractures[26] while another study reported wearing schedules between 2 and 8 weeks for median and ulnar neuropathy at the wrist.[13] Two studies had participants wear the 3D orthosis for 1 week only to treat wrist overuse injuries, distal radius malunion, partial wrist fusion, and Charcot-Marie-Tooth disease.[16,28] Studies investigating 3D orthoses to treat distal radius fractures reported wearing times between 4 and 6 weeks.[15,19,20] Two studies did not report orthosis wearing time.[18,27]

Printing: Materials, scanning, software usage, cost, and finishing steps

The materials, process, fabrication time and cost involved to create a 3D orthosis varied between studies. Relevant data can be found in Table 5. Collectively, the most reported materials used for 3D printed orthoses included thermoplastic polyurethane filament (TPF)[13,26,28] and polylactic acid (PLA).[7,26,27] Polylactic acid or PLA is very commonly used in 3D printed orthoses and incorporates both organic and inorganic components.[29] It is biodegradable and is composed of polymers and renewable agricultural raw products and is thus considered to be non-toxic. Other materials reported included silver[16] polypropylene (PP)[15] and polyamide (PA2000).[13,15,20] One study reported developing a corn starch based biodegradable material specifically for their study.[18]

The steps required to fabricate a 3D printed orthosis, as reported in the studies, include the following: scanning the body segment with a 3D scanner, CT scan or MRI; transferring the scanned data to a computer modeling software program; printing the orthosis; and finishing/adjusting the final product. The time needed to scan the affected upper limb ranged from 1 to 3 minutes. One study reported needing the assistance of a hand therapist

Table 2
Study quality assessment according to methodological index for non-randomized studies (MINORS)

Authors (year)	Clearly stated aim	Inclusion of consecutive patients	Prospective collection of data	Endpoints appropriate to aim of study	Unbiased assessment	Follow up period	Loss to follow up <5%	Prospective calculation of study size	Adequate control group	Contemporary group	Baseline equivalent group	Adequate statistical analysis	Total
Chae et al, 2020[13]	1	0	0	0	0	0	0	0	na	na	na	na	1
*Chen Lang et al, 2021[18]	2	2	0	2	0	2	0	0	0	0	0	2	10
Chen Yan Jun et al, 2017[15]	2	1	2	2	0	2	0	0	na	na	na	na	9
*Chen Yan Jun et al, 2020[20]	2	2	2	2	1	2	0	0	1	2	2	2	18
Guida et al (2019)[19]	2	1	2	2	0	2	0	0	0	0	0	1	10
Katt et al, 2021[7]	1	1	0	1	0	1	2	0	na	na	na	na	6
*Kim et al, 2018[28]	2	1	1	1	0	1	0	0	2	2	2	2	14
Marinho et al, 2020[27]	2	1	0	1	0	2	0	0	na	na	na	na	6
Nam et al, 2018[26]	1	0	0	0	0	0	0	0	na	na	na	0	1
Oud et al, 2021[16]	2	2	2	2	0	1	0	0	0	0	0	0	9

Items are scored as follows: 0 = not reported; 1 = reported but inadequate; 2 = reported and adequate; na = not applicable to a noncomparative study.
The global ideal score of 16 for non-comparative studies and 24 for comparative studies.
* Comparative studies.

Table 3
Risk of bias table

Authors (year)/risk of bias	Chae et al, 2020[13]	Chen Lang et al, 2021[18]	Chen Yan Jun et al, 2017[15]	Chen Yan Jun et al, 2020[20]	Guida et al 2019[19]	Katt et al, 2021[7]	Kim et al, 2018[28]	Marinho et al, 2020[27]	Nam et al, 2018[26]	Oud et al, 2021[16]
Random Sequence Generation	high	unknown	high	low	high	high	low	high	high	high
Allocation Concealment	high	high	high	low	high	high	low	high	high	high
Blinding of participants and personnel	high	high	high	unknown	high	high	unknown	high	high	high
Blinding of Outcome Assessment- Self reported outcomes	high	high	high	high	high	high	unknown	unknown	high	low
Blinding of Outcome Assessment objective measures	high	unknown	high	high	unknown	high	unknown	unknown	high	high
Incomplete outcome data	unknown	unknown	unknown	unknown	unknown	high	low	low	high	unknown
Selective reporting	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown	high
Other bias	high	high	high	unknown	high	high	unknown	high	high	low

Adapted from Higgins, JPT, Thomas, J, Chandler, J, Cumpson, M, Page, MJ, Welch, VA. Cochrane Handbook for Systematic Reviews of Interventions, 2nd Edition. Chichester, Wiley; 2019.

to support the limb during this process.[16] Two studies report that the scanning process can be challenging if patients have difficulty maintaining the desired joint position due to pain, discomfort, or swelling.[16,20] The time needed to modify the scanned digital file in a computer aided design software program, so it is ready for 3D printing was reported to take approximately 1 hour.[20]

Five studies reported on the time needed to produce a 3D printed orthosis. The total time ranged from 10-12 hours[26] to 3-5 days.[19] Oud et al (2021) compared 3D printed orthoses with orthoses made by certified orthotists.[16] They reported a 53% reduction in total fabrication time with a 3D printed orthosis compared with a traditional orthosis made with high temperature thermoplastic materials. Their results contrast significantly with the LTTP orthoses typically made by hand therapists and is the only study reporting on markedly less fabrication time with 3D printed orthoses. Collectively, none of the studies[7,13,15,16,18-20,26-28] compared the timing for 3D printed orthotic manufacturing to custom made low temperature thermoplastic orthoses fabricated by hand therapists.

The cost of producing a 3D printed orthosis was reported in 6 of the 10 studies.[7,15,18-20,28] Of those 6 studies, 3 reported material costs that ranged from $15 to $150 US dollars.[15,19,28] Costs of necessary equipment reported included US $500 to 5000.00 for a 3D scanner, and US $3 to $4000.00 for a 3D printer. CAD software programs are typically free and can be used with most personal computers.[3] One study reported the cost of 3D printed or-

Table 4
Participant characteristics

Study	Number of participants	Gender	Age range	Diagnosis/clinical conditions	Follow up
Chae et al, (2020)[13]	3 (2 with upper limb conditions, 1 with back condition not included)	2 M, 1 F	55-72	Carpal tunnel syndrome ($n = 1$) Ulnar tunnel syndrome ($n = 1$)	2 weeks (CTS) 8 weeks (UTS)
Lang Chen et al, (2021)[18]	27 total 14 with upper limb fractures (13 with lower limb not included)	7 M, 7 F	21-65 Mean 47.8	Wrist fracture ($n = 7$) Elbow fracture ($n = 7$)	14-19 months Mean 13.59
Chen et al, (2017)[15]	10	4 M, 6 F	5-78	Distal radius fractures ($n = 3$), distal radius and ulnar styloid fractures ($n = 6$), distal radius and ulna fractures ($n = 1$)	2 and 6 weeks
Chen et al, (2020)[20]	60: 20 3D orthosis 20 plaster cast 20 splint	24 M, 36 F	5-78	Forearm/wrist fractures: Colles - 46 Smith's - 12 Ulnoradial diaphysis – 2	6 weeks to 3 months
Guida et al, (2019)[19]	18	17 M, 1 F	11-14 Mean 11.9	Nondisplaced metaphyseal distal radius fractures	7-15-23-30/40 days
Katt et al, (2021)[7]	2	2 M	3 years old and 6 years old	Supracondylar elbow fracture ($n = 1$) Ulnar shaft fracture ($n = 1$)	4 weeks to 12 months
Kim et al, (2018)[28]	22	2 M, 20 F	19-65 Mean 31.8 $\pm$ 7.8 control group/mean 33.8 $\pm$ 8.5 experimental group	Wrist pain/overuse	1 week
Marinho et al, (2020)[27]	6	2 M, 4 F	30-69 Mean 54.3	Thumb rhizoarthrosis	Not reported
Nam et al, (2018)[26]	3	1 M, 2 F	21-39	Hand burns	12-18 months
Oud et al, (2021)[16]	10 (1 CVA not included)	1 M, 9 F	19-79 Mean 52.1	Joint hypermobility ($n = 2$) Traumatic wrist injury ($n = 2$) STT OA ($n = 1$) Distal radius malunion ($n = 1$) RA ($n = 1$) Partial wrist fusion ($n = 1$) Charcot-Marie -Tooth disease ($n = 1$)	1 week

thoses to be equivocal to traditional plaster orthoses/casts.[18] However, other researchers[18-20] report the high cost of acquisition of a 3D printer may limit widespread application of this technology in hospital and rehabilitation settings.

A variety of finishing tools were used to adjust the orthosis following 3D printing. These differ considerably from tools typically used by hand therapists. Eight of the 10 studies reported using grinders, chisels, sandpaper, and / or pinchers to optimize fit and comfort of the 3D printed orthoses.[13,15,16,18-20,26,27] Several studies mentioned the addition of Velcro hook and loop to secure the orthoses and padding materials to optimize comfort and minimize pressure areas.[13,15,16,19,20] Other studies made no mention of how the 3D printed orthoses were held on the patients' limbs.[7,18,26-28]

Outcome measures

Outcome measures reported by the 10 studies in this review included pain scales, grip and pinch strength measures, range of motion, complications, patient satisfaction measures (standardized and nonstandardized), and patient functionality.

Pain scales such as the standardized visual analog scale (VAS) and other non- standardized pain scales were often included as an outcome measure.[13,18,19,27] Both Lang Chen et al (2021),[18] and Guida et al (2019)[19] reported statistically significant differences in pain with the use of the 3D printed orthosis. Lang Chen et al (2021)[18] reported lower VAS scores in the 3D printed group compared to the plaster cast group post -surgery (64.19$\pm$5.72 vs 52.75 $\pm$6.50, P= .01). Guida et al (2019)[19] reported lower pain scores following 3D printed orthosis intervention (5.70 $\pm$ 3.20 pretreatment, 0.22 $\pm$ 0.55 post-treatment, P= <.001). Grip and pinch strength measures were included in several studies,[13,28] and range of motion measures were included by Lang Chen et al (2021)[18] (wrist or elbow range of motion) and by Nam et al (2018)[26] (digital motion).

Patient satisfaction questionnaires were included in 5 of the 10 studies.[15,18-20] Most of these were non-standardized questionnaires designed by the researchers for their specific study. Two studies included formal standardized studies such as the Quebec User Satisfaction Evaluation of Assistive Technology (QUEST)[13,27]; the Orthotic and Prosthetic User Survey (OPUS)[28]; and the Patient Rated Wrist Evaluation (PRWE).[13,28]

The QUEST is a self-report or interview-based scale designed to capture an individual's satisfaction with assistive technology devices such as comfort, weight, durability, ease of use, and time, as well as the quality of services provided (delivery, repairs and technical assistance, quality of services and follow up).[30,34] This assessment was used in 2 studies.[13,28] A total of 12 items are assessed; 8 pertain to the level of satisfaction with the orthotic or assistive device, and 4 address satisfaction with services provided. All items are rated on a 5-point scale; 1 = not at all satisfied, 5 = very satisfied. A QUEST total score is calculated by adding up scores for responses to assigned items, with scores ranging from 1.00 to 5.00.[24] Both studies using this outcome measure reported high QUEST scores ($\geq$ 4 out of 5 points) for all 3D printed devices.[13,28]

The study by Kim et al (2018)[28] utilized the OPUS as one of the outcome measures to assess participant's satisfaction with their 3D

Table 5
3D printing materials, cost, time

Study	Materials used	3D scanner	CAD program	3D printer	Finishing process	Cost/time
Chae et al, (2020)[13]	Thermoplastic Polyurethane Filament (TPF)	CT Scan	exported MIMICS Medical v17 (Materialize, Leuven, Belgium) Geomagic Freeform Software (#D System, Santa Clara, USA)	FINEBOT 2420 (TPC Mechatronics, Inc. Incheon, Korea)	Grinding machine, pinchers, Velcro straps	Not reported
Lang Chen et al, (2021)[18]	Biodegradable corn starch-based material Material 1/6 weight of traditional plaster and 20x as durable	Pylon-lex-Yacc (PLY) (produces VRML or WRL format file)	STL file	BiYing – 3D Instant printer, Wuhan Biotechnology Co, Ltd, Wuhan, China Curved surfaces rough – needed to print bigger image and grind surfaces smooth	Grinder, fastening materials not reported	Cost: not reported Time: 10 mins
Chen et al, (2017)[15]	Polyamide (PA 2200), polypropylene (PP)	CT or MRI Imaging (Aquillion CX64, Toshiba, Japan OR MR (Achieva 1.5 T, Phillips)	not reported	EOS P395 (Germany) or Stereolithography (SLA) Printer RS4500 (Union Tech, China)	Padding, grinder, Velcro straps	$150 US dollars (cost breakdown not reported)
Chen et al, (2020)[20]	Polyamide (PA 2200)	CT Scan (Aquillion 64, Toshiba, Japan) OR MR (Achieva 1.5 or 3.0 T Phillips, Netherlands)	Workbench 18.0 (ANSYS, USA)	SLS 3D Printer EOS P395 (Germany)	Padding, grinder, Velcro	Total time 3-5 days Reported “high fabrication cost of 3D cast”
Guida et al, (2019)[19]	Thermoplastic modified ABS (Z-Ultra T, Ultra T, Olsztyn, Poland with polycarbonate and FDM	Laser scanner (3D Sense, 3D Systems Inc, Rock Hill, Soth Carolina)	Polygonal STL file – Rhionoceros version 5.0 (Robert McNeel & Associates, Seattle, WA, USA)	Not reported		1 hour = design of 3D model 10-12 hours: printing
Katt et al, (2021)[7]	Poly-lactic acid (PLA)	Not reported	Not reported	Not reported		6-7 hours total
Kim et al, (2018)[28]	Thermoplastic polyurethane filament (TPC)	Arctec Eva, Arctec Group	Geomagic Touch (3D Systems Corp, Rock Hills, SC, USA) and Geomagic Freeform Software (3D Systems Corp)	Fused Filament Fabrication (FFF), FINEBOT 2420 3D Printer (TPC Mechatronics Inc, Incheon, Korea)	Grinder, pinchers	Total time 6 hours
Marinho et al. (2020)[27]	PLA	Not reported	“free software creations”	Not reported		Not reported
Nam et al, (2018)[26]	FDM with TPU or PLA	Manually measured digits	Simplify 3D (Cincinnati, OH), Rhionceros 5.0 (Robert McNeel & Associates, Seattle, WA, USA), Thingiverse (MakerBot Industries, Brooklyn NY, USA)	FlashForge Creator Pro (FlashForge, City of Industry, CA, USA)	Chisel, sandpaper	Total time: one hour, material cost: $1.00 US dollar
Oud et al, (2021)[16]	Nylon PA 12	White light scanner (Healthcare Partner 3D Scanner Creaform, Inc, Quebec, CA)	Rodin 4D software (Rodin 4D, Merignac, France Mesh mixer software (to adjust for pressure areas), 3. Fusion 360 Software (Autodesk, Inc.)	HP jet Fusion 4200, Hulotech Stadskanaal, The Netherlands	Scan time: 3D: 5.0 (3.96) Conventional: 10.3 (4.93) 95% CI 0.8-9.7 mins, $P =$ .027 Production time: 3D: 112(11.0SD) Conventional: 239(29.2 SD) 95% CI, 71-182, $P =$ .001)	

printed orthosis. The OPUS is a patient reported outcome measure including 5 modules that evaluates common goals of rehabilitation in Orthotics and Prosthetics clinical settings. The 5 modules are as follows: Lower Extremity Functional Status (LEFS), Upper Extremity Functional Status (UEFS), Client Satisfaction with Device (CSD), Client Satisfaction with Services (CSS), and Health-Related Quality of Life (HRQoL). Each of these is rated on a 4-5 Likert Scale.[31,32] Kim et al (2018)[29] found that 2 items out of 26 functional tasks scored statistically significant differences in the group that wore a 3D printed orthosis compared to a control group wearing a commercially available wrist cock up orthosis. The 2 items were “Put toothpaste on a toothbrush” and “Dial a touch tone phone.”

Two studies[13,28] utilized the PRWE to assess wrist pain and the ability to function in activities of daily living. Pain is addressed in a subscale of 5 items and function is addressed in a subscale of 10 items.[32,33] Both studies utilizing the PRWE as an outcome measure reported improved pain levels with use of the 3D printed orthoses.[13,28] However, one did not include a comparable control group,[13] and the other did not find significant differences in pain levels between the control and experimental groups.[28]

Utilization of the Jebsen-Taylor Hand Function Test (JTHF) to assess function of the injured wrist was reported by Kim et al (2018)[28] and Chae et al (2020).[13] This test, first reported in 1969, consists of 7 tasks that simulate activities of daily living.[35,36] The JTHF has been widely used in clinical settings and in research studies for a wide range of conditions.[35,36] Scores for the JTHF did not change substantially in the study by Kim et al (2018)[28] perhaps because these patients wore their 3D printed orthosis for only 1 week. Chae et al (2020)[13] reported improved JTHF test scores in each of the 2 patients in their study.

Two additional assessments used were the Modified Barthel Index and the Cooney modification of Green and O'Brien assessment.[20,26] The Modified Barthel Index measures independence in activities of daily living (ADL) with a 5-point system and is based on the original Barthel Index (which uses a 2-, 3- or 4-point scale). It was originally created to assess the ADL status of stroke patients.[37] Nam et al (2018)[26] used this scale to assess function in 3 patients with significant hand burns and found scores improved for personal hygiene and other areas in 1 of 3 patients. The Cooney modification of the Green and O'Brien score is an examiner-rated assessment of pain, functional status, range of motion, and grip strength. Each of the 4 parameters are given a weight of 25 points, and total scores are out of 100. Scores are rated as excellent from 90-100, good 80-89, fair 65-79, and poor when totals are less than 65.[38] Chen et al (2020)[20] evaluated wrist function at 3 months and found 12 of 20 patients (60%) in the 3D printed group with excellent results as compared to 7 patients in each of the other study groups.

Complications

Complications were assessed in 8 of the 10 studies. These include skin irritation, itchiness, pressure areas, pressure sores, blisters, excess perspiration, and compromised overall comfort. It should be noted that these are complications most often associated with plaster cast application following surgery. Four of the 10 studies reported no incidence of any complications following use of a 3D printed orthosis.[7,16,19,28] Two of the 10 studies did not use incidence of complications as an outcome measure.[13,27] Three of the 10 studies reported complications including: a blister on the ulnar head for 1 participant[15]; reduced compliance with the recommended wearing schedule for the 3D printed orthosis group likely because of participants being uncertain about the efficacy of and use of new technology[20]; and skin irritation under the orthosis for 1 participant with mallet injury.[26]

Comparison between 3D printed and "Traditional" orthoses

Four of the 10 studies compared use of a 3D printed orthosis with "traditional" orthoses, which hand therapists would more commonly refer to as a cast or brace.[16,18,20,28] "Traditional orthoses," as described by authors of the studies, include plaster casts, splint fixation, prefabricated wrist orthoses, or orthoses made with a variety of different materials such as leather, silicone, silver, or polypropylene. Outcome measures compared between the 3D printed orthosis and the "traditional orthosis" included pain, overall satisfaction, and function. Lang Chen et al (2021)[18] reported statistically significant differences in favor of the 3D printed orthosis group compared with traditional plaster casts for observed complications (4/13 vs 0/14, $P = .041$), pain (64.19 ± 5.72 vs 52.75 ± 6.50, $P = .018$), ROM (wrist 58.00 ± 6.76 vs 63.21 ± 5.89, $P = .042$; elbow 99.31 ± 7.03 vs 109.21 ± 11.74, $P = .014$) and overall participant satisfaction (87.13 ± 3.88 vs 91.71 ± 5.02, $P = .018$). Observed complications in this study referred to infections, non- union, and fracture displacement.[18] Similarly, the study by Chen et al (2020)[20] reported participants who wore a 3D printed orthosis, or a splint had less skin irritation, itchiness and odor as compared to a traditional plaster cast. The study by Kim et al (2018)[28] reported no statistically significant difference in the JHFT scores between the use of a wrist cock up orthosis and a 3D printed wrist orthosis. Oud et al (2021) compared conventional orthoses made by a certified orthotist with 3D printed orthoses.[16] The type and design of the orthoses varied between participants (joint hypermobility, wrist trauma, arthritis).

In the Oud et al study (2021),[16] the authors included a total of 10 participants who received both a 3D printed and a traditional orthosis; the latter was made with a variety of different materials including leather, silicone, silver, or polypropylene. Even though these are not materials with which hand therapists customarily fabricate orthoses for their clients, it is relevant to include this study in our review because the clinical conditions were comparable to those treated by hand therapists. Overall, there were no statistically significant differences between the 2 types of orthoses for functionality, satisfaction, or personal preference. However, the molding experience was reported to be better in the 3D group. There was no preference between the 2 types of orthoses among participants.[16] It is critical to understand the differences in production time, as hand therapists can fabricate custom- made orthoses from LTTP in a much shorter time period when compared to either orthotists / prosthetists or 3D printers.

Discussion

This systematic review highlights the current trends in utilization of 3D printed technology to manufacture custom orthoses and casts for musculoskeletal injuries of the elbow, wrist, hand and digits, and investigates the feasibility of including this technology in hand therapy settings. Of the 10 studies included in this review, only 1 was a randomized controlled trial, all used heterogeneous methodologies, outcome measures, orthotic designs, wearing schedules and diagnoses; collectively making recommendations to inform clinical practice very difficult. Moreover, all studies lacked comparison of 3D printed orthoses to custom low temperature thermoplastic orthoses fabricated by hand therapists in practice, further compounding the difficulty in generalizing the results. The findings of this review are important for healthcare professionals treating upper limb conditions in outlining the status of 3D printed orthoses for actual patients with orthopedic conditions and illuminate some of the key factors that require further consideration and investigation before this practice becomes widespread.

The current evidence for the future use of 3D printing technology for custom fabrication of upper extremity orthoses is promising, but much of the published literature on this topic are narratives on the 3D printing process or feasibility studies that are conducted on healthy volunteers, thereby making it difficult to determine the impact of this technology on the outcome of this intervention on clients with injuries. Additionally, these investigations do not appear to have input from the rehabilitation team, specifically hand therapists. Nonetheless, it is important to consider the initial findings of these feasibility studies as an avenue to guide future research.

Orthoses prototypes

A study done by Cazon et al (2017)[9] compared the tensile strength of materials used to fabricate a 3D printed orthosis and a custom- made low temperature thermoplastic wrist immobilization orthosis and noted that the 3D printed orthosis was more rigid when compared to the LTTP design with realistic loading of the orthosis during movement. Graham et al (2020)[10] compared 3D printed wrist orthoses with traditional plaster casts and focused on comfort and functionality. Twelve healthy participants wore both types of orthoses and completed the JHFT and the PRWE to assess dexterity and function. The JHFT scores were comparable with both orthoses; client satisfaction, overall comfort and perceived functionality was rated higher for the 3D orthosis. Additionally, skin irritation occurred in 42% of the plaster cast wearers, as compared to only 8% ($n = 1$) for the 3D orthoses wearers.

Another group of researchers compared 3D printed digit orthoses with custom made LTTP orthoses in terms of preparation time, weight, and wearer satisfaction.[11] Thirty-six occupational therapy students fabricated 2 orthoses on a rubber mannequin finger: a custom made proximal interphalangeal (PIP) joint extension restriction orthosis out of LTTP and a similar design using 3D printed technology. Overall, the 3D printed design was more favorable in terms of comfort, weight, fit, and esthetics; the LTTP design took much less time to fabricate.

Lastly, Choi et al (2019)[38] explored the use of 3D printing to manufacture mallet finger orthoses and compared these with plaster casts on healthy volunteers. The total number of participants was not reported. The QUEST was used as the primary outcome measure, and the 3D printed orthoses were rated higher on orthosis dimensions, weight, ease of use, and comfort. The authors note the small orthosis size, speed of printing, and user-friendly materials to support use of 3D printing technology for mallet finger injuries. Again, it is difficult to generalize these findings as the 3D printed orthoses were not evaluated on individuals with an actual mallet injury.

Technological skills necessary for 3D printing

Critical knowledge and experience working with specialized computer aided design (CAD) programs is an essential skill for creating 3D printed orthotic devices, along with utilization of expensive equipment such as a 3D scanner and printer. Fernandez-Vicente et al (2017)[39] aimed to design a process that utilized low-cost desktop scanning and printing to fabricate a hand-based thumb orthosis. Key to reducing costs was the use of a desktop Fused Filament Fabrication (FFF) 3D printer rather than industrialized Fused Deposition Modeling (FDM) printers that are used in industry,[31] and free CAD software. The authors were able to produce a clinically feasible orthosis but reported that more research is required to determine the efficacy and feasibility of this simpler method to treat injury or disease processes in clinical practice.

Several researchers have investigated the primary process of producing a 3D printed orthosis, or prototypes, with the intent of exploring the feasibility of widespread use in health care, and more specifically orthopedic rehabilitation.[6,14,39-41] Baronio et al (2016)[14] explored the steps involved in producing a 3D orthosis prototype to help inform rehabilitation professionals on the feasibility of using 3D printed technology to produce custom orthoses. More accurate data processing software that fully captures anatomical details, lower cost scanning devices, and CAD modeling software that can be used easily by clinicians was reported as major obstacles to widespread use at this time. In the study by Blaya et al (2018),[6] a 3D wrist orthosis prototype was developed with notable advantages including lightweight, waterproof, and recyclable materials, patient pleasing aesthetics, and well-ventilated design. However, the high cost of equipment coupled with long printing times were reported as significant drawbacks to adopting this technology in current clinical practice.

Li and Tanaka (2018)[40] explored the development of a CAD modeling software program that can potentially minimize current problems encountered during the scanning and modeling process such as unwanted movement by the patient during scanning, and lack of therapist training and experience with computer aided design software programs. The authors developed a programmable modeling tool designed to generate a 3D wrist immobilization orthosis. Components of orthosis design and fabrication including scanned body segment/anatomical details, material thickness, and overall orthosis design were programmed into the CAD software. They postulate that their proposed method reduces the overall time needed to design and produce a 3D printed orthosis and requires much less training and skill on the part of the therapist. Although the proposed program potentially reduces the duration of scanning and CAD adjustment to a few hours, the total time needed to produce a finished 3D orthosis is still more when compared to traditional orthotic fabrication, and hence is not a readily viable option to adopt in current practice.

In a small feasibility study done by Patterson et al (2020),[5] a specialized software workflow was designed to replicate the steps involved in fabricating a wrist orthosis. Ten practitioners evaluated the software, and qualitative data was collected on ease of use. Although participants reported being able to use the software easily, the authors identified several critical areas to address including creating an effective way to scan a patient's extremity to fully capture the anatomy, further development and examination of the proposed software by computer and engineering professionals and performing a cost benefit analysis before such software can be considered for use in a clinical setting.

Printing in other areas of rehabilitation

There is evidence on the use of 3D printed orthoses in other fields of rehabilitation. A small retrospective study looked at the application of 3D printed neck orthoses for the treatment of post -burn neck contractures for 6 participants.[41] The process of optical 3D scanning took 30 minutes; computer aided design (CAD) was completed in 4 hours, and total production time was 5 days. Patients reported the orthoses were comfortable and wore them for long periods during the day with 2 patients also wearing them at night. Advantages reported with use of CAD technology is the ability to modify the orthosis design easily as scar tissue characteristics change over time. This is done with a quick scan, compared to adjusting the orthosis directly on the client with traditional low temperature thermoplastic designs. Collectively however, use of 3D technology was deemed as not yet cost effective, as the production costs were higher than what is currently being used. Use of cheaper 3D scanners and free open-source CAD programs may help to reduce costs and facilitate more widespread availability and use of this technology in the future.[41]

3D printed orthoses have progressed more rapidly in the treatment of lower extremity clinical conditions. Several studies of 3D printed ankle-foot orthoses (AFO's) highlight how 3D printing has evolved in the treatment of the lower limb regarding time, cost, and treatment conditions.[42,43] AFOs support the foot, ankle and lower leg for children and adults with a wide variety of neurological disorders, including cerebral palsy, multiple sclerosis, cerebral vascular accident, and others. The fabrication process for these orthoses is labor intensive, time consuming and can be expensive. This has led to an increasing demand to prepare 3D printed AFOs which can eliminate many steps of the production process and allow for creativity in design.

Farhan et al (2021)[42] completed a systematic review comparing the speed, accuracy, and reliability of 3D scanning with traditional methods of capturing ankle and foot anatomy for fabricating orthoses for the ankle and/or foot. Overall, the quality of the evidence was low. The authors found that 3D printing took less time compared to traditional plaster molds but noted that this was evident only with those who are experienced with 3D printing. For foot orthoses, accuracy and reliability were similar between both 3D printed and traditional methods. Wojciechowski et al (2019)[43] reported on 11 studies that evaluated 3D printed AFOs. The primary condition treated was unilateral foot drop in both adults and children, but several of the studies also included healthy volunteers. The studies reported on a variety of 3D printing techniques and outcomes including walking ability and/or biomechanical function, mechanical properties, patient comfort, pain, and disability. The authors found that 3D printed AFOs are comparable to traditionally manufactured AFOs in many aspects. However, only 2 of the 11 studies reported on use with patient populations (pathologies from trauma, neuromuscular disorder, and cerebral palsy). Only 1 study reported on a patient satisfaction questionnaire while 2 other studies reported on subjective feedback regarding only comfort and fit. Lastly, the 3D printing methods varied widely (SLS, SLA, FDM) and appear to each require additional testing and finishing processes as well as lengthy time for production. The authors of this review conclude that further research is required to determine the appropriate printing method and optimal materials.[44]

Implementation of 3D printed technology: Logistical issues

The pragmatics of implementing 3D technology in a health care setting is currently being explored and the resources required for such an endeavor appear to be extensive. Keller et al (2021)[44] studied the feasibility of applying 3D printing procedures in hospitals. They report on the complex digital design software needed, the time-consuming printing process and the high cost of equipment as being factors preventing widespread use. The authors suggest that different medical specialists be involved in creating a multidisciplinary team to handle the various aspects of the 3D printing process. More specifically, they recommend the expertise of a medical engineer to program/modify the scanned image(s), as this is a highly specialized skill, the treating surgeon to scan the patient's extremity using specially designed software, and a trained hand therapist to handle the actual printing, post printing processing and fitting of each orthosis to the actual patient. The authors also suggest that multiple orthoses could be printed for each patient at the same time with slight variations in size to accommodate for changes in edema and/ or positioning.[44]

In a follow up study, Keller et al (2021)[45] also explored the practical side of implementing 3D printing into hand surgery departments and identified many applications: use of 3D printed models for surgical skills training for junior hand surgeons and patient education, preoperative planning, designing surgical implants, and fabrication of customized orthoses. They described the practical issues which include extensive staff training, safety procedures, providing adequate space for the 3D scanning and printing procedures to take place, maintaining the scanning devices and 3D printers, and regularly updating software programming. The need for individualized specialists in the process is again highlighted, with the health care team members assigned to specific roles. The authors also mention the issue of FDA approval for all medical devices in the USA. Clinical data regarding the performance and intended use of new medical devices needs to be submitted for regulatory and quality assurance control. This may be a challenge for providers initially. The authors also acknowledge the time consuming, yet importance of the post-production process: each 3D printed orthosis must be custom fit on each patient, and the issue of accommodating for changes in post-surgical edema must be addressed.

Outcome measures

Many outcome measurement tools were used across the 10 studies included in this review, making it difficult to ascertain the efficacy and clinical utility of 3D orthoses. Some of the instruments used, such as the VAS, the QUEST, the OPUS, the PRWE and the JHFT are standardized, but other patient reported outcome measures were written by the researchers themselves and are not tested for validity and/or reliability. Future studies involving 3D printed orthoses should include standardized measures that specifically address the use of orthotic designs. While the QUEST and/or OPUS address orthotic fit and comfort, newer outcome measures specifically designed to capture information relevant to 3D printing should be developed

Limitations

This systematic review has limitations. Our emphasis on studies with actual patients experiencing defined musculoskeletal conditions excluded studies on the use of 3D printed orthoses with healthy subject and/ or those with neurological conditions. This limited the number of available studies and narrowed the scope of this review. It is also possible that some articles were missed because of the keywords chosen. The 10 studies in this review scored low to moderate on the MINORS index, primarily due to the lack of prospective collection of data, control groups, blinded reviewers and patients, and small sample sizes. Additionally, the low methodological quality of most of the studies contributed to significant risk of bias. Although the first author works for an orthosis material manufacturer this was not considered a conflict of interest since the focus of the review was not which name brand of material was used, and since dual independent appraisers were used to verify results.

Five of the 10 studies were case series. Although the outcomes reported in the studies were encouraging, it is difficult to conclude that any of the reported effects are a result of clinical significance and not bias. Furthermore, only 1 study used random allocation of participants.[29] There was also lack of consistency with regards to the materials used and the equipment needed to manufacture a 3D printed orthosis between the studies. This made it difficult to compare and generalize the results.

Conclusion

This systematic review sought to gather evidence on the current utilization and effectiveness of 3D printed orthoses in the treatment of musculoskeletal conditions of the elbow, wrist, hand, and digits. Ten studies involving researchers from Korea, United States, Brazil, the Netherlands, China, and Italy were included, offering a global perspective to the topic. The included studies focused on real patients: they are mostly case studies, small case series, and/or experimental studies looking at the viability of producing 3D printed orthoses. The results appear to demonstrate the effectiveness of 3D printed orthoses in terms of adequate immobilization of the limb, patient comfort, aesthetics, and lightweight and waterproof materials with excellent ventilation. In terms of feasibility, the resources required to produce 3D printed orthoses are costly and not widely available. As Keller et al (2021) suggest, professionals with specialized skills in software design are needed and not typical members of a healthcare team.[44-45] Timing remains a concern due to the lengthy printing process and the post-production finishing demands.

While 3D printing shows promise, the high cost of equipment, lack of training and skill of clinicians and the long time required for production are all factors that need to be improved to make 3D printing a viable option in the future. It is possible to consider that training programs for this specialty will be offered, and hand therapists will gain expertise in this field. If the various aspects of scanning and computer aided design are handled by other specialists of a multi-disciplinary team, as suggested by Keller et al (2021), the process may advance more quickly than expected. More studies are needed to ascertain the benefits of 3D printed orthoses as compared to low temperature thermoplastic orthoses. Future studies should also include standardized patient reported functional scales and specific assessments of orthotic use.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jht.2021.10.005.

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Quiz: # 912

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\# 1. The study design is
  a. RCTs
  b. case series
  c. systematic review
  d. prospective cohort

\# 2. The 3D printed orthotics were an alternative for casts whose purpose was
  a. immobilization
  b. restoration of ROM
  c. esthetics
  d. protection

\# 3. The study investigates the ___________ of 3D printed orthotics in hand therapy
  a. feasibility
  b. utilization
  c. effectiveness
  d. all of the above

\# 4. How many articles were found that were RCTs
  a. 5
  b. 3
  c. 1
  d. 0

\# 5. There are significant hurdles that will need to be crossed before 3D printed orthotics become standard in hand therapy practices
  a. not true
  b. true

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