TECHNOLOGY REVIEW (MINI-HTA)

3D-PRINTING FOR ORTHOSIS, PROSTHESIS AND EXOSKELETON

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
002/2025

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Mini-HTA

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EXECUTIVE SUMMARY

BACKGROUND

Three-dimensional (3D) printing is a relatively new, rapidly expanding method of manufacturing that had numerous applications in healthcare, automotive, aerospace and defense industries and in many other industries. The 3D printing has been used in the healthcare field in order to create devices that improve patient's outcomes. In occupational therapy, this technology is being used to create splints and adaptive devices that allow patients to heal and better perform tasks in their everyday life. The 3D-printing in medicine includes customised implants, and prosthetics, medical models, and medical devices that revolutionised healthcare and may even disrupt many areas of traditional medicine.

In contrast to traditional subtractive manufacturing technologies, the 3D-printing is a technique that creates objects from 3D data, usually in layer-by-layer manner using digitally controlled and operated material laying tools. Compared to the traditional manufacturing, the 3D-printing is belief to reduce material waste, shortens the fabrication period and eliminates the need for most skill-based manual operations.

This review was request by Engineering Services Division of Ministry of Health, Malaysia to assess and analyse the benefit and issue related to 3D-printing technology for the development of prosthesis, orthosis and exoskeleton.

OBJECTIVE/ AIM

To assess the efficacy/effectiveness, safety and cost-effectiveness of 3D-printing for orthosis, prosthesis and exoskeleton.

RESULTS:

Search results

A total of **580** records were identified through the Ovid interface and PubMed. Of these, **35** relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria, **eight** systematic reviews (SRs) were included. Last search was conducted on 10 April 2025.

Efficacy/Effectiveness

Surgical planning / simulation model

In surgery, 3D-printing prosthesis became an alternative or complimentary cadaveric models for educational/training purposes among doctors. As simulation models, the 3D-printed models helped in predicting possible difficulties during the actual surgery such as reduced the risk of blood loss, to determine the best approach as well as reduced the operation time. On the other hand, the 3D-printed prosthesis improved doctor-patient communication during inform consent process.

3D-printing orthoses and exoskeleton

The 3D-printed orthosis, exoskeleton and prosthesis had various applications in orthopaedic and musculoskeletal field. The findings varied in terms of pain score, functionality and patient satisfaction when compared with conventional manufactured devices.

3D-printed custom implants / prostheses
3D-printing applications in custom implants also showed significant benefits and improved medical outcomes over conventional manufactured implants.

Safety
3D-printed orthoses, exoskeleton and prostheses had less skin irritation, itchiness and odour when compared to plaster cast (traditional orthosis). However, there were also cases of failure/malfunction and breaking prostheses were reported. Other safety concerned were risk of contamination during production process and quality assurance of the finished products.

Organisation Issues
There were several organisational issues related to 3D-printing devices such as choice of materials, quality assurance of the finish products, patient's preference, requirement for expertise and training as well as limitation in production capacity.

Economic Implication
No cost-effectiveness study retrieved. The cost depends on several factors such as the cost of materials, equipment, image scanner and the 3D-printer itself.

CONCLUSIONS

The review showed that, 3D-printing technology is used in healthcare especially in manufacturing 3D-printed orthosis, exoskeleton and prosthesis. The applications of those 3D-printed orthosis, exoskeleton and prosthesis varies either in musculoskeletal, custom 3D-printed implants and surgical planning/training. Although the 3D-printed orthosis, exoskeleton and prosthesis showed a potential in reducing operation and treatment time, had good accuracy and improved patient's outcome as well as increased their satisfaction; the outcomes were depended on patient's conditions and types of the 3D-printed devices used. In terms of safety, less complications were reported with 3D-printing manufactured devices compared to conventionally manufactured. However, there are concerns on failure/malfunction and breaking issues. Other concerns were related to organisational issues which were production time, choice of materials, patient's conditions which might affect the data collections such as image taking or molding process, expert personnel both in printing process and medical expertise, lastly the production capacity especially for mass production.

The cost-effectiveness for 3D-printed orthosis, exoskeleton and prosthesis could not be determining as it depended on types of 3D-printed device to be manufactured, the whole manufacturing process involved included the raw materials cost as well as the 3D-printer which had different price range.

METHODS

Literature search was conducted by an *Information Specialist* who searched for published articles on 3D-printed orthosis, prosthesis and exoskeleton. The following electronic databases were searched through the Ovid interface:

- MEDLINE® In-Process and Other Non-Indexed Citations and Ovid MEDLINE® 1946 to 31 March 2025

Other databases:

- PubMed
- Other websites: US FDA, INAHTA, CADTH, Google Scholar

Keywords: 3D-printing, orthosis, prosthesis and exoskeleton

General databases such as Google and Yahoo were used to search for additional web-based materials and information. Additional articles retrieved from reviewing the bibliographies of retrieved articles. The search was limited to articles on human and study years. There was no language limitation in the search. However, at the end only English and full text article were included. **Appendix 1** showed the detailed search strategies. The last search was conducted on 10 April 2025.

TABLE OF CONTENTS

ABBREVIATIONS

ROM	Room of Motion
3D-printing	3-Dimensional printing
CAD	Computer-aided design
STL	Surface tessellation language
SLA	sterolithography
SLS	Selective laser sintering
SLM	Selective laser melting
EBM	Electorn beam melting

1.0 BACKGROUND

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In contrast to traditional subtractive manufacturing technologies, the 3D-printing is a technique that creates objects from 3D data, usually in layer-by-layer manner using digitally controlled and operated material laying tools. Compared to the traditional manufacturing, the 3D-printing is belief to reduce material waste, shortens the fabrication period and eliminates the need for most skill-based manual operations.

This review was request by Engineering Services Division of Ministry of Health, Malaysia to assess and analyse the benefit and issue related to 3D-printing technology for the development of prosthesis, orthosis and exoskeleton.

2.0 OBJECTIVE / AIM

To assess the efficacy/effectiveness, safety and cost-effectiveness of 3D-printing for orthosis, prosthesis and exoskeleton.

3.0 TECHNICAL FEATURES

3.1 3D-printing applications in healthcare

3.1.1 3D-printing for Orthosis

Orthoses, also known as braces and support are rigid or semi-rigid devices used to support, restrict, mobilise and/or immobilise an injured or diseased body segment to assist in improving function and facilitating healing. It can be custom fabricated, prefabricated or custom fit by a qualified clinician. Depending on the affected portion of the body, orthoses are categorised into upper-limb orthoses, spinal orthoses and lower-limb orthoses, and being specific if involved the joints; wrist-hand orthoses, lumbar orthoses and ankle-foot orthoses.[3, 4] Figure 1 are several types of orthoses from 3D-printing manufacturing.

Figure 1.0: Orthosis[5,6,7]

3.1.2 3D-printing for prosthesis

Prostheses are used to replace missing body parts of such as upper and lower limb, ear, nose, part of skull etc. The prosthesis socket is a cup-like structure that fits around the residual limb of amputees and transfers mechanical loading from the body to the prosthesis. Figure 2 are the examples of 3D-printing prosthesis.[3]

Figure 2.0: Prosthesis[8.9]

3.1.3 3D-printing for exoskeleton

Exoskeleton is an external wearable structure that provides functional support and enable to reproduce the human movement. The exoskeleton can be divided into several categories according to the stiffness of the structure and the type of actuation. In term of stiffness, the skeletons can be defined as rigid, soft or hybrid. Meanwhile for actuation, the exoskeletons are classified as passive, and active if their mechanical assistance resorts to passive or powered solutions. However, if the mechanical assistance is achieved solely through passive elements, an external power source is used for sensing and control of the system, the exoskeletons are classified as quasi-passive (semi-passive or semi-active).[10]

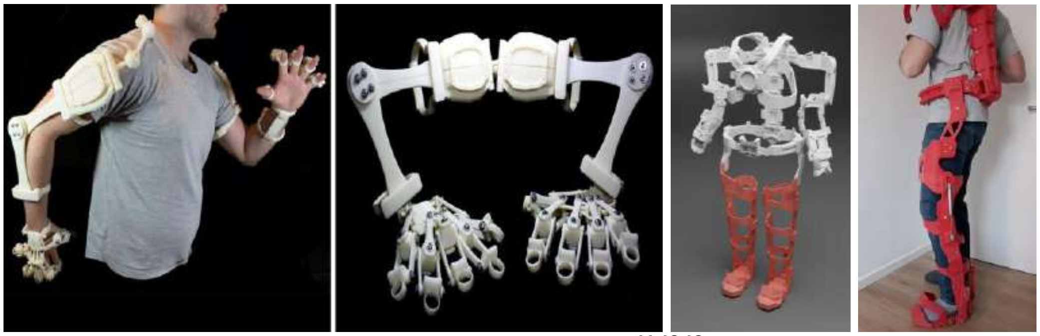


Figure 3.0: Exoskeleton[11,12,13]

3.2 Fabrication Process

3.2.1 Traditional fabrication process

During traditional fabrication, a patient requiring a prosthesis or orthosis comes to a prosthetist or othotist to take a relevant anthropometic measurements. A cast mod is batined by wrapping plaster bandages around the affected part of the body. A positive mold is then made by pouring plaster into the negative cast mold. Next, the prosthesis or orthosis is made by heating and vacuum-forming sheets of thermoplastic (commonly polypropyelene or polyethylene) onto the positive plaster mold, which are left to cool down and are then trimmed into the correctt shape. Depending on the loading on sensitive and bearing areas of the human body, modification of the plaster mold might be conducted, or an additional component might be added. Accessories and straps are then added to finalise the production. It is necessary for the patient to have a fitting visit. Further adjustments are required in most cases to ensure the comfort and functionality of the product. This procedure results in the waste of materials and has high time and labor costs. The quality of products is extremely dependent on the skill and experience of the prosthetist or orthotist ; thus, it is impractical to produce repeatable results.[14]

3.2.2 3D-printing / additive manufacturing process

The 3D-printing is possible to manufacture complex structures that has flexibility permiting customisation for special applications or consideration of individual characteristics. In addition to that, the 3D-printing permits precise replication of the exisiting products and make it possible to increase functional performance with less weight. Furthermore, the integration of functions in the 3D-printing can reduce the need for assembly procedures.[14] There are three main processes in 3D-printing, the process included[15]:

i. Image acquisition:
Quality of the printed products depends on the qualty of medical image. The images are from imaging techniques such as multidetector computed tomography (MDCT), magenetic resonance image (MRI), ultrasound (US), positron emission tomography (PET), and cone beam computed tomography (CBCT). The image data collected are usually saved in Digital Imaging and Communications in Medicine (DICOM) format.[15]

ii. Image post-processing
The DICOM image will be reconstructed with image segmentation/computer-aided design (CAD) and format conversion. The software will convert the contour of the region of

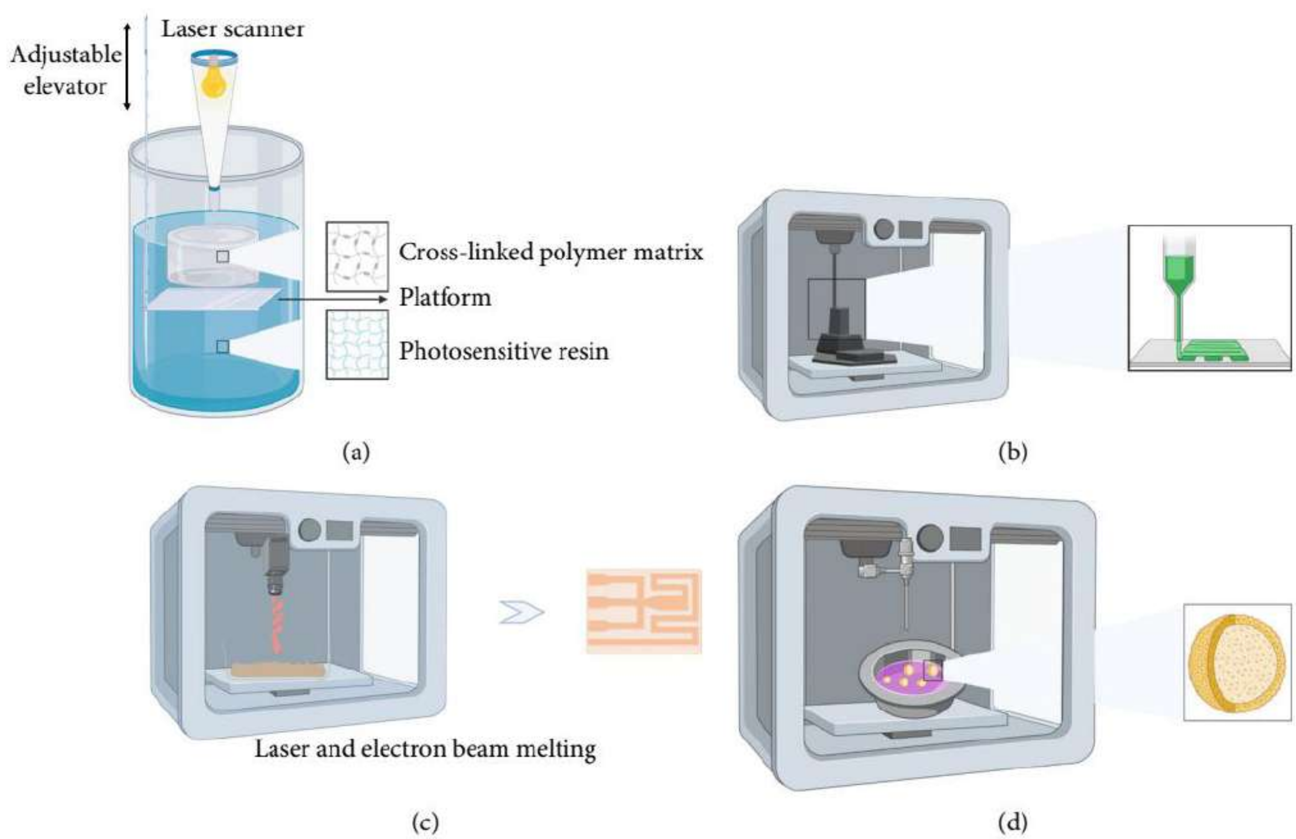
interest in the image data into a 3D-triangular mesh, that is, mesh processing. The irregular curved surfaces will appear in the meshing process and the tiny triangular plane can produce a smoother surface and shape the product. CAD information is converted into additive manufacturing file format, Surface Tesselation language (STL).[15]

iii. 3D-printing

The process of using CAD data generates a 3D-object model during 3D printing. The CAD software analyses the 3D-model that the STL file wants to make, and the slicing software slices the model into a series of thin sections. STL files are converted into G-code to control the 3D printer to create 3D products by continuously adding materials to create virtual layers.[15]

3.3 3D-printing techniques

They are several techniques in 3D-printing. The main four 3D-printing techniques as follow and was shown in Figure 4 (a, b c and, d).[15]



Source: Li B. et. al.[15]

Figure 4.0: Different types of 3D-printer with different techniques

a. Vat photopolymerisation

Vat photopolymerisaton also known as stereolithography (SLA) is the first commercial application of 3D-printing technology. The SLA starts with the solution in the vat and maps the required pattern on the surface of the solution according to the CAD file. Focusing the ultraviolet rays in a cylinder filled with photosensitive resin, using light propagation chain polymerisation, the photosensitive resin is cross-linked on the build plate to form a polymer matrix and then cured layer by layer until the digital 3D object is printed.[15]

b. Fused deposition modelling

Fused deposition modeling is the second commonly used 3D printing technology. The starting material of FDM is a polymer composed of thermoplastic materials. the polymer filaments are fed into the heated print head and nozzles and heated into a molten semisolid form. The molten filaments are rapidly cooled and solidified. The print head squeezes the material on the x-y axis plane and deposits it layer by layer along the z axis on the build plate.[15]

c. Powder Bed Fusion

Powder bed fusion is a powder-based AM technology that uses high-power laser and electron beam to melt and fix material particles on the build plate to build 3D printed objects. According to different sources of heat energy, powder bed fusion can be divided into laser- and electron beam-based powder bed fusion. The former can be divided into selective laser sintering (SLS) and selective laser melting (SLM), and the latter mainly includes electron beam melting (EBM).[15]

d. Bio-printing

Biological 3D printing is a 3D-printing technology that uses the living cells, extracellular matrix, biological factors, and biological materials as raw materials and restores its lost functions by constructing highly bionic and biologically active tissue and organ substitutes.[15]

3.4 Material for 3D-printing

There are various material used in 3D-printing. The most common materials are listed below:[15]

i. Metals and alloys
ii. Bio-ceramic materials
iii. Polymer materials
iv. Composite materials
v. Performance requirements of 3D-printing materials

4.0 METHODS

Literature search was conducted by the author and an *Information Specialist* who searched for full text articles on 3D-printing for orthosis, prosthesis and exoskeleton.

4.1 SEARCHING

The following electronic databases were searched through the Ovid interface:
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4.2 SELECTION

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria. Relevant articles were then critically appraised using *Critical Appraisal Skills Programme (CASP) checklist* for diagnostic accuracy study, JBI for cross-sectional study and ROBIS for SR. Data were extracted and summarised in evidence table as in **Appendix 2**.

The inclusion and exclusion criteria were:

Inclusion criteria:

a.	**Population**	People with physical disabilities, Orthosis, prosthesis and exoskeleton
b.	**Intervention**	3D-printing
c.	**Comparator**	i. No comparator ii. Conventional / standard method
d.	**Outcomes**	i. Efficacy and effectiveness ii. Safety

e.	**Study design**	SR, RCT, diagnostic accuracy study, cross-sectional study
f.	Full text articles published in English	

Exclusion criteria:

a.	**Study design**	Animal study

5.0 RESULTS

Search results

An overview of the search is illustrated in **Figure 9**. A total of **580** records were identified through the Ovid interface and PubMed. After removal of duplicates and irrelevant titles, **264** titles were found to be potentially relevant and were screened using the inclusion and exclusion criteria. Of these, **35** relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria, **eight** studies were included while the other **19** studies were excluded since the studies either had different objectives or narrative reviews. **Eight** systematic reviews (SRs) were finally selected for this review. One SR discussed the applications of 3D-printing in surgical, one SR on applications of 3D-printing in orthosis and exoskeleton, 2 SRs on 3D-printed orthoses and the rest of the studies on 3D-printed prosthesis.

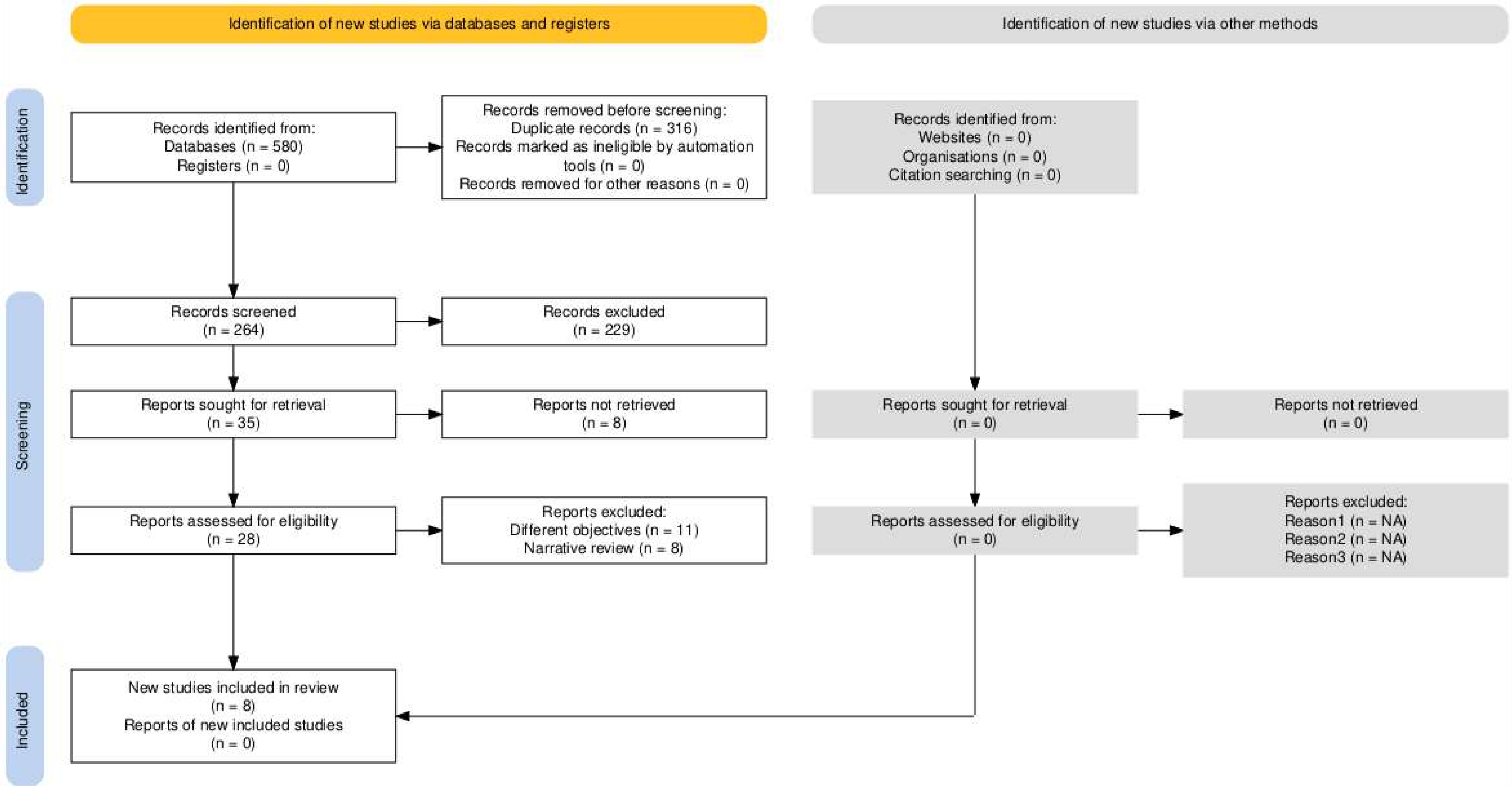

Figure 5.0: Flow chart of retrieval of articles used in the results

Quality assessment of the studies

The risk of bias (RoB) in the included studies were assessed using domain-based evaluation. Tools that are being used by MaHTAS to assess the risk of bias are adopted from ROBIS (for systematic review). This is achieved by answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias as either:

Judgement of overall risk of bias is high if any one of the domains concerned has high risk of bias. If more than two domains are judged as uncertain, it was categorised as moderate RoB. While if there is less than two domains judged as unclear than it was categorised as low RoB.

The risk of bias for the SRs were considered high because among the included studies of each SRs, there were many limitations such as variability of the sample sizes with different patient's conditions, difference types of 3D-printed devices, difference in mechanical tests conducted, and difference in type of materials used to produce the 3D-printed devices. Most of the studies included also revealed high risk of bias and low to very low quality of evidence such as case series and case reports. There were also reported of lack of randomisation and no blinding in RCTs included in the SRs. The results of the risk of bias assessment of the included studies are summarised in **Figure 6.0**

Figure 6.0: Risk of Bias of Systematic Review

5.1 EFFICACY / EFFECTIVENESS

Tack P. et. al. conducted an SR to identify domains and usages where the 3D-printing is common or has been used several times as well as to reports it potential advantages and disadvantages. The SRs included a total of 227 full text papers of controlled trials and case series of 3D-printings in surgical purposes on living humans. Based on the included studies, they found that 3D-printing applications were mostly used as surgical guides (60%) and as models for surgical planning (38.70%). Other usage was for customs implants (12.17%), mold for prosthetics (3.9%), models of implant shaping (1.74%) and models for patient selection (0.87%). On top of that, orthopaedics becomes the most specific field discussed in the included studies; 45.18%, followed by maxillofacial surgery (24.12%), cranial surgery (12.72%) and spinal surgery (7.46%). For each application, the outcomes assessed were impact on operation room (OR) time/treatment time (reductions in operating time are assessed as beneficial), accuracy of the printed, radiation exposure which were explicitly mentioned in the paper, clinical outcome, cost and cost-effectiveness (when the authors of the included studies explicitly mentioned about it). The results for those listed outcomes were shown in Table 1; from the table, more than half of the studies reported time reduction with 3D-printing during operation room/treatment time. Meanwhile, 82.2% of the included studies reported that the accuracy of the printed part with 3D-printing was good/better than other alternatives. Out of 270 usage of 3D-printed devices reported in the included studies, 222 devices showed an improvement in patient’s conditions. In term of cost, more studies reported that 3D-printing involved higher cost compared to other alternatives. However, out of 29 studies reported on the cost-effectiveness, 19 studies reported that 3D-printing was cost-effective.[16]

Table 1: Outcomes of interest reported in included studies

Number of studies	Custom implant	Model for implant shaping	Model for patient selection	Model for surgery planning	Mold for prosthetic	Surgical guides	Total
	30	**9**	**2**	**89**	**4**	**136**	**270**
OR/treatment time							
Not mentioned	11	4	2	37	3	68	125
Time reduction	17 (4)	5 (1)	0	48 (13)	1	53 (28)	123 (46)
No time difference	1 (1)	0	0	3 (2)	0	8 (1)	12 (4)
Time increase	1	0	0	2 (1)	0	7 (5)	10 (6)
Accuracy of printed part							
Not mentioned	3	1	1	4	0	16	28
Good/better accuracy	26	8	1	80 (4)	4	87 (13)	205 (17)
Average accuracy	1	0	0	6 (1)	0	23 (3)	30 (4)
Bad accuracy	0	0	0	0	0	10 (6)	10 (6)
Radiation exposure							
Not mentioned	30	7	2	77	4	121	241
Less radiation	0	0	0	8 (1)	0	9	17 (1)
equal radiation	0	0	0	1	0	2	3
Increased radiation	0	2	0	3	0	4	9
Clinical outcome							
Not mentioned	1	0	2	10	0	15	28
Improved	25 (2)	9 (2)	0	73 (8)	4	85 (15)	195 (27)
Equal	4	0	0	7 (1)	0	30 (7)	41 (8)
Negative impact	0	0	0	0	0	7 (2)	7 (2)
Cost							
Not mentioned	16	7	1	52	3	94	173
Cheaper	0	0	0	4	1	2 (1)	7 (1)
Equally expensive	0	0	0	1	0	1	2
More expensive	14 (4)	2 (2)	1	32 (21)	0	39 (19)	88 (46)
Cost effectiveness							
Cost-effective	1	0	0	8	1	10	19
Neutral	0	0	0	2	0	1	3
Not cost-effective	0	0	0	1	0	6	7

(x) **Number of studies quantifying the data with numbers/statistics**

Source: Tack P et. al.[16]

Tack P. et. al. also specifically reported on four applications of 3D-printing; first was on *custom implants*. Twenty-eight studies reported on the applications of 3D-printing for custom implants especially in cranial surgery, dentistry and maxillofacial surgery. Out of the 28 studies, 17 studies reported that the 3D-printing reduced the OR/treatment time, and 25 studies reported on good accuracy and improvement in medical outcomes. The most common material used for 3D-printing customs implants were titanium and polyether ether ketone (PEEK). Second applications were 3D-printing in *anatomical models* which were implant shaping in maxillofacial surgery (in nine studies), used in cardiovascular surgery (in two studies) and used in surgical planning (in 89 studies). Most of the studies reported that 3D-printing reduced the operation time, had good accuracy, and improved medical outcomes. However, despite the improvement in services, 3D-printing was reported to increase the costs of surgery. Third application was in *prosthetic mold* especially for cranial, maxillofacial and ear surgery. Fourth application was 3D-printing as a *surgical guide or training* (in 137 studies) in orthopaedics, neurosurgery, dental surgery, spinal surgery and maxillofacial surgery disciplines. There were 28 studies reported that 3D-printing reduced the operation time, and seven studies reported on an increased in procedural time. The surgical guides also improved clinical outcomes in 86 cases (62.31%) with 3D-printing. However, there was negative impacts reported in seven studies which were related to knee orthopaedics. In term of costs, 39 studies reported that 3D-printing for surgical guide increased the costs and no difference with standard procedure were reported in two studies. Meanwhile, in term of cost-effectiveness, ten studies found that 3D-printing in surgical guide were cost-effective, but not in another six studies. Of all the included studies, the authors concerned on an advantage of 3D-printing towards reduction in Operating Room (OR) time. There were 42 studies described the precise impact of using 3D-printing technology on OR time. Most of the studies reported that 3D-printing was time saving and the areas that benefited the most were maxillofacial surgery, models for spinal and maxillofacial surgical planning and models for shaping implants used in maxillofacial surgery.[16]

5.1.1 Orthoses and Exoskeleton

Fernandes da Silva JLG. et. al. conducted an SR to assess the current landscape in exoskeleton and orthosis developed for upper limb medical assistance which were partly or fully produced with 3D-printing technologies and contain at least the elbow or the shoulder joints. The SR included 33 papers on the applications of the 3D-printing in various types of exoskeletons and orthosis specifically involving elbow and shoulder joints. Table 2 summarised the applications of 3D-printing in exoskeleton and orthosis included the materials used and mechanical features within the design to improve patient's conditions.[10]

Table 2: Applications of 3D-printing exoskeleton and orthosis

	Degree of freedom (DoF)	Materials	Mechanical features	Others
For elbow joint support				
Ultralight soft device for rehabilitation of stroke patients	single	Acrylonitrile butadiene styrene (ABS)	Set of silicone modules that actuated pneumatically	-
Soft passive exoskeleton	Single (highly compact in shape of sleeve)	Lycra	Has elastic elastomer wave net on elbow are that stretches with forearm flexion	-
Rigid actuated exoskeleton for rehabilitation	-	Aluminium with polyamide and polylactic acid (PLA)	Shape memory alloy actuators (low cost, noiseless and lightweight)	Upgraded with high-level control algorithm for mechanical existence: used electromyography and pressure sensors and was validated with computational

	Degree of freedom (DoF)	Materials	Mechanical features	Others
				simulations and in service tests on control population
Rigid exoskeletons that articulate at user's elbow joint for patients with neuromuscular disorder	Single (minimum number of rigid parts)	-	Memory alloy wine-based actuators controlled by a set of flexor sensors	-
Rigid exoskeletons for patients with stroke and neuromuscular diseases	Single (passive and active actuators with 3 rehabilitation modes)	-	-	-
Rigid actuated for neurological disease	Single (used in seating positions)	-	2 actuations • 1st: asymmetrical approach that provides lateral supports only • 2nd: symmetrical approach that support media and lateral sides of arm	-
Elbow exoskeletons	double	Endure material	Computational model and mathematical models that described the movement of the elbow joint and the surrounding tissues resulted in development of customised joints	-
Rigid actuated that incorporated the shoulder joint in a soft sleeve and the elbow joint	single	-	Digital control system that sent data to website for further monitored by medical team	Various actuation modes to assist during different stages of rehabilitation
Elbow orthosis	single	PA 2200	Used of passive torsion springs resulted in highly compact solution	Optimised algorithm to create flexible structure or Voronoi mash to support the required loads
Rehabilitation of elbow joint	single	PLA	Equipped with sensors for patient's movements tracking Integrated with medical sensors to enhance evaluations	Connects to virtual reality environment
Orthotic for peripheral nervous system disease	single and rigid	Polyethylene terephthalate glycol	Incorporated elastic elements to provide gravity compensation and equipped with features motors to enable adjustment of the attachment position	-

	Degree of freedom (DoF)	Materials	Mechanical features	Others
			for elastic elements	
Rigid skeleton	rigid	PLA	With gravity compensation for passive or active used AI and neural networks models were used to optimise the structural design of the solution and to use as little filament as possible without compromising the function of the device	-
Semi-active spring-actuated exoskeleton for disabilities and assist workers in demanding tasks	Semi-active and rigid	nylon	With gravity compensation	-
For elbow, wrist and hand support				
Exoskeleton for neurological disease and stroke	-	-	Signals collected by the sensors, surface electromyography and inertial measurement unit (IMU)	Placed on healthy arm to move and control the impaired arm
Soft actuated exosuit for neuromuscular diseases	9 DoF	Some part made of ABS with neoprene interface	2 actuators: 1st to control elbow movement and 2nd to control hand opening and closing	Resulted in a delay of the fatigue
Rigid Exoskeleton	2 DoF	ABS	Actuated by Bowden cable transmission	Being assessed in computational simulations Focused mainly on pronation/supination movement
Semi-rigid exoskeleton to healp impaired people to have upper limb movement and assisted the rehabilitation of the arm	Semi-rigid	PLA and ABS	• Controlled with smartphone • Actuated elbow and finger to able to lift up loads up to 0.5kg	-
Orthosis for children with cerebral palsy	16 DoF Passive device with elastic along the fingers	ABS and biodegradable PLA	-	To restore upper limb function especially on elbow, wrist and finger joints
Semi-rigid actuated soft exosuit for stroke survivors	-	Rigid structure was printed in nylon plastic	• Bowden cable was used to actuate and was controlled based on data acquired • With gravity	-

	Degree of freedom (DoF)	Materials	Mechanical features	Others
			compensation, light and has an interface of soft materials	
Shoulder and joint support				
Shoulder exoskeleton	3 DoF associated with glenohumeral joint	Printed in steel	Used scissors linkage mechanism to be more compact	To simplify the design of exoskeleton joints for the support of complex anatomic joints
Shoulder and elbow joints support				
Wilmington robotic exoskeleton for children with neuromuscular diseases	4 DoF Passive rigid device	Polyetherimide combined with metal parts	Attached to vest or to wheelchair With gravity compensation	Showed improvement in arm function for ADLs
Dual-arm exoskeleton for stroke recovery patient	8 DoF Rigid, active and bulky	-	• With multi-axis force/torque for control purposes • To facilitate single-arm and dual-arm movements	-
Full upper limb support				
Exoskeleton	8 DoF Modes: passive, assistive and active-assistive actuation mode	-	Only evaluated in computational simulation	Active mode: to collect motion data and assist in rehabilitation especially in stroke patients
Compact and actuated exoskeleton for patients with motor disabilities	6 active and 2 passive DoF	Carbon fiber reinforced polymer	-	-
Ultralight semi-rigid exoskeleton for upper limb rehabilitation	4 DoF	ABS	• Soft actuators to actively assisted 2 DoF pressure sensors • With gravity compensation	-
Robotic exoskeleton	9 DoF	PLA	Controlled with mobile apps	Active device with surface electromayography and IMU sensors to evaluate the quality of the patient's motion and adapts the rehabilitation controls
Soft active exoskeleton for post-stroke complications	7 DoF	-	• Based on functional anatomy and sport biomechanics principal • Actuation principle	Increased join movement in patients with stroke that allow them to perform ADLs

	Degree of freedom (DoF)	Materials	Mechanical features	Others
			was based on the use of tension lines that are aligned with the principal muscle of the upper lib being controlled by motors • Combine with AI to allow personalised assistance and more efficient rehabilitation	
Exoskeleton in paralysis patients	3 DoF	Nylon 6850	Controlled by electroencephalograph, IMU sensors and depth/cameras to recognise the position of the objects interacted	-

Source: Fernandes da Silva JLG. et. al.[10]

5.1.3 Orthosis

Schwartz A.D. et. al. conducted an SR to investigate the utilisation, effectiveness and feasibility of 3D printed technology in customised orthoses for musculoskeletal conditions. Ten included studies consisted of one RCT, one retrospective cohort, one comparative cohort, four case series and three case reports. The studies described the 3D-printed orthoses or casts that involved elbow (elbow orthosis), wrist, hand, and/or digits that typically immobilised with a cast or brace like a fabricated hand-based orthosis for carpal and ulna tunnel syndrome, and digit-based orthosis. The studies also reported on wearing times ranging from one-week to eight-weeks. The most common material used reported were thermoplastic polyurethane filament (TPF), PLA, silver, polyprophylene (PP), polyamide (PA2000) and corn starch based. The main outcome measures assessed were pain scales, grip and pinch strength measures, range of motion and patient satisfactions and functionality. For pain scales, low Visual Analog Scale (VAS) score was recorded with 3D-printing orthosis compared to plaster cast group after surgery. The difference was statistically significant ($p = 0.01$); 64.19 ± 5.72 versus 52.75 ± 6.50, respectively. Another study compared pain score before and after treatment, the pain score was significantly lower after treatment with 3D-printer orthosis (5.70 ± 3.2 pre-treatment versus 0.22 ± 0.55 post-treatment, $p < 0.001$). For patient satisfactions and functionality assessments, the assessments were conducted based on questionnaires as follows; Quebec User Satisfaction Evaluation of Assistive Technology (QUEST), Orthotic and Prosthetic User Survey (OPUS), Patient Rated Wrist Evaluation (PRWE), Jebsen-Taylor Hand Function Test (JTHF), Modified Barthel Index, and Cooney Modification of Green and O'Brien assessment. Results for the questionnaires assessment were summarised in Table 3.[4]

Table 3: Patient' satisfaction assessment

Assessment tools	Area of assessment		Results
QUEST	Assessment on comfort, weight, durability, ease of use, time, quality of services provided	12 items in the (8 on level of satisfaction with the device and 4 on services provided)	**High score for all 3D-printed devices (≥ 4.00)** – reported in 2 studies
OPUS	Assessment on patient's satisfaction with 3D-printed orthosis	5 modules • Lower Extremity Functional Status (LEFS) • Upper Extremity Functional Status (UEFS) • Client Satisfaction with Device (CSD) • Client Satisfaction with Services (CSS) • Health-Related Quality of Life (HRQoL)	2 studies rated **4-5 Likert scale** 1 study reported that 2 items out of 26 functional tasks scored statistically significant differences in the group that core a 3D-printed orthosis compared to control group that wore a commercially available wrist cock-up orthosis
PRWE	Assessment of wrist pain	15 subscales (5 subscale for pain and 10 subscales for function)	Reported in 2 studies **Significant improvement in pain scal**e with 3D-printd orthosis in 1 study and **none in the other study**
JTHF	Assessment of function of the injured wrist	7 task that simulate activities of daily living	1 study scored **no changes** after using the 3D-printed orthosis (just 1 week) 1 study scored an **improvement** in 2 patients with 3D-printed orthosis
Modified Barthel Index	Measure independence in activities of daily living (ADL)	5-point system and based on original Barthel Index	1 study scored an **improvement in 1 of 3** patients with hand burn
Cooney modification of Green and O'Brien Assessment	Assessment of pain, functional status, range of motion and grip strength	4 parameters with given weight of 25 points each	1 study reported 12 out of 20 patients from 3D-printed group showed an **excellent result (90-100) on wrist function** after 3 months compared to 7 patients in the other group

Schwartz A.D. et. al. also reported on three studies that compared between 3D-printed orthosis and traditional orthoses. All three studies reported on different types of orthoses based on different patient's conditions. First study compared between 3D-printed orthosis and traditional plaster casts in patients with arm fracture. From the study, it showed that 3D-printed orthosis was statistically significant in reducing pain, improving room of motion (ROM) and overall patient's satisfaction compared to traditional plaster casts; reducing pain (64.19 ± 5.72 versus 52.75 ± 6.50 [p = 0.018]), ROM of wrist (58.00 ± 6.76 versus 63.21 ± 5.89, [p = 0.042]), ROM of elbow (99.31 ± 7.03 versus 109.21 ± 11.74, [p = 0.014]) and patient's satisfaction (87.13 ± 3.88 versus 91.71 ± 5.02 [p = 0.018]), respectively. Second study reported that there was no significant difference in JHFT scores between used of traditional wrist cock-up orthosis and 3D-printed wrist orthosis. Meanwhile, for the third study, 10 patients with various conditions of patient's join hypermobility, wrist trauma and arthritis were involved. Different types of 3D-printed orthosis were manufactured with 3D-printer and the traditional orthosis was conventionally made by certified orthotists. All ten patients will wear both 3D-printed and traditional orthosis after certain period. From the assessment, they found that no statistically significant differences between two types of orthoses for functionality, satisfaction and personal preference. However, molding experience was better in 3D-printed group.[4]

Another SR by Wojciechowski E. et. al. was to determine the feasibility of designing, manufacturing and delivering customised 3D-printed ankle-foot orthoses (AFO) by evaluating the biochemical outcomes, mechanical properties and fit of 3D printed compared to traditional manufactured AFOs. The SR included 11 studies which were case control, case studies, and cross-sectional study. There was variation of the type of 3D-printed AFO reported in the studies such as dynamic passive AFO and non-dynamic depending on patient's conditions. Out of 11 included studies, only four studies compared 3D-printed AFO to traditional AFO. The outcomes reported were on walking ability, patient perceived comfort, dimensional accuracy between CAD model and 3D-printed AFO, and mechanical properties. *Walking ability* was evaluated in five studies. There was one study compared selective laser sintering (SLS) AFO with traditionally manufactured AFO to barefoot walking. In terms of stride length and stance phase duration of the affected limb and ankle kinematics, both AFOS showed significant benefit when compared to barefoot walking. On the other hand, there was no statistically significant differences in temporal spatial parameters (stride duration, stride length and stance phase duration of both affected and unaffected limb), ankle plantarflexion during swing between the traditional manufactured AFOs and SLS AFOs. However, significant differences were reported in ankle range of motion over the whole gait cycle between traditional manufactured AFOs and SLS AFOs where the SLS AFOs showed smaller range of motion. Another study compared 3D-printed AFO with traditional AFO in one patient. Both AFOs improved temporal spatial parameters compared to barefoot walking. However, based on ankle kinematic data, the traditional AFO was more effective to support ankle dorsiflexion during swing compared to the 3D-printed AFO. As for *patient-perceived comfort*, three studies reported on this outcome. All patients reported that they were more satisfied with 3D-printed AFOs in terms of weight and ease of use when compared to traditional AFOs. The traditional AFO was reported as difficult to wear due to thickness. In terms of *dimensional accuracy* between CAD model of the AFO and 3D-printed AFO, two studies found that there were dimensional discrepancies about <2mm tolerances for four half-scaled AFOs. No other assessment was conducted. For *mechanical properties,* the authors reported on the stiffness (from five studies), energy dissipation (from one study) and durability testing (from one study) of the 3D-printed orthoses. The stiffness depends on the types of material used, during bending or rotational stiffness of 3D-printed AFOs, its showed that the stiffness measures of the SLS AFOs manufactured in Rilsan D80 (Nylon 11), DuraForm PA (Nylon 12) and DuraForm GF (glass-filled Nylon 12) were within in 5% of the targeted carbon fibre AFO stiffness value. Meanwhile, the FDM AFO printed in polycarbonate was strong (average 0.20 ± 0.14 Nm/deg). During measurement of energy dissipation and destructive testing performed on 3D-printed AFO, AFO fabricated with Rilsan D80 exhibited the last amount of mechanical damping and was the only material to withstand destructive testing compared to AFOs fabricated in DuraForm PA and DuraForm GF. Lastly, for durability testing, after 300,000 cycles of mechanical testing, the polyurethane 3D-printed AFO showed a damage and changes in shape and stiffness.[17]

5.1.2 Prosthesis

Zoltan J. et. al. conducted an SR to fully evaluate the advantages and shortcomings of patient-specific additively manufactured implants (customised 3D-prinintg implant). The SR included 26 studies consisted of case series and case reports of patients with total hip arthroplasty, acetabular fracture, sacrum defects and underwent oncologic reconstruction. From the included studies, significant benefits of 3D-printed implants over conventional implants for major pelvic reconstructions and clinical findings were reported as summarised in Table 4. The 3D-printing prosthesis also showed potential in improving bone ingrowth in patient with massive bone loss. For post-operative functional outcome, it was measured with standardised scoring systems; Musculoskeletal Tumours Society (MSTS) rating scale, and Harris Hip Score (HHS). One study compared 3D-printing with conventional implants showed that 3D-printing reduced incision length, blood loss and surgery duration. The MSTS functional outcome was superior in the 3D-printing group compared to the conventional implant group. Besides, customised implants production was faster with 3D-printing compared to conventional implants productions. In terms of material of choice, most of studies reported the used of titanium alloy as it had an excellent biocompatibility/biochemical property, and corrosion resistance compared to stainless steel and cobalt alloys. Three included studies also conducted Finite Element Analysis (FEA) for geometric optimisation of patient-specific implants analysis to ensure structural integrity under static and dynamic loads. The FEA simulation included the surrounding bone to evaluate the stress distribution on the bone under loading with respect to height, weight and gait. The stress analysis on the implants revealed that the implant will not fail under load and the bone stress fall within a safe region.[18]

Table 4: 3D-printing implants and the clinical benefits

Diagnosis	Anatomical site and implants	Functional scores	Miscellaneous outcome
Skeletal malignancy, total hip arthroplasty (THA) sequele	Ilium Acetabulum	Post-op MSTS (Musculoskeletal Tumor Society score): 74% (73–76%); 64.5% (57–70%)	**Higher, but non-significant incidence** of infections in patients treated with pelvic reconstructions than other sites (p = 0.2667)
		Post-op MSTS: 21/30; 20/30	5 infectious complications/29 patients
		Post-op OHS (Oxford Hip Score): 32.4	1/20 case of failure of fixation inferiorly
		Post-op HHS: 79.8 ± 8.4. Pre-op: 39.2 ± 19.1	-
		Post-op HHS: 82; Pre-op: 36	1/24 suspected aseptic loosening at follow-up
		Pain free at follow-up, walking with 1 crutch and lightly limping	-

Diagnosis	Anatomical site and implants	Functional scores	Miscellaneous outcome
Hip arthritis	Acetabulum	Post-op HHS (Harris Hip Score): 94.2 ± 4.1; Pre-op: 46.5 ± 9.3 Control-Post-op HHS: 93.3 ± 4.8 points; Pre-op: 45.7 ± 10.1	Compared to conventional cups: **increase in survival at 8 years** (p < 0.01), 3 times lower aseptic loosening of cup, 2 times lower global aseptic loosening, 2 times lower periprosthetic fracture risk
Chondrosarcoma	Pubis, ischium, acetabulum	Post-op HHS: 92	Unaided ambulation at follow-up
		Post-op MSTS: 30/35. Pre-op: 31/35	-
		Post-op MSTS: 30/35. Pre-op: 31/35	-
Chondrosarcoma recurrence		Post-op HHS: 81; Pre-op: 42	-
Skeletal tumour/malignancy	Acetabulum with pelvic extension, ilium, hemipelvis	Post-op MSTS: 83.9%	No aseptic loosening noted
		Iliac prosthesis post-op MSTS: 23/30. screw-rod prosthesis post-op MSTS: 18/30. standard prosthesis post-op MSTS: 20/30	-
		Independent gait without moderate-t-severe pain at 6 weeks	Delayed rehab in 2 patients with chemotherapy after surgery
		Post-op HHS: 58 ± 14. Pre-op: 32 ± 11; post-op MSTS: 20 ± 4/ 30	-
		Post-op HHS: 82; Pre-op: 64 Post-op MSTS: 23; Pre-op: 14	-
		Post-op MSTS: 19	-
		Post-op MSTS: 24 Conventional-Post-op MSTS: 18	Incision length (cm), duration of surgery (min), blood loss (mL): AM −10, 115, 213 Conv-20, 157, 361
		Post-op MSTS: 46.3%	-

Diagnosis	Anatomical site and implants	Functional scores	Miscellaneous outcome
Ewings sarcoma	Acetabulum, ilium	Post-op MSTS: 27.5/30	-
Acetabular metastatic malignancy	Acetabulum, ilium	Post-op HHS: 52; Pre-op: 10 Post-op MSTS: 16. Pre-op: 7	Progressive functional improvement at 1, 3, 6, 12-month follow-up
Fracture	-	-	Reduction quality % (anatomic, satisfactory, poor): AM – 67, 27, 7% Conv-51, 37, 11% (p = 0.661)
Failed reconstruction	Hemipelvis	Post-op HHS: 78. Post-op MSTS: 21	-
Developmental dysplasia of the hip	acetabulum	Post-op HHS: 92; Pre-op: 31	-

**Source: 2024 Zoltan J. et. al.*

An SR by Quinones JVM. et. al. evaluated the utility and limits and 3D-printing in spine surgery by analysing to what degree 3D-printing may improve the surgical process. The SR included 38 studies with various study designs such as SRs, comparative studies, case series and case studies. According to the included studies, 3D-printing applications in spine injuries were used in a few areas. First for *educational and training* among doctors especially as an alternative or complementary device towards cadaveric models. The 3D-printing could provide surgical experiences through simulation for developing and improving surgical knowledge as well as technical skills. Secondly, in *helping inform consent process for specific patients* where the 3D-printing able to make the patients and their family members understand their respective conditions and the necessary of certain surgical procedures required. This situation improved doctor-patient communication for certain treatment. The third application was for *pre-operative planning* where the 3D-printing models were used as surgical simulation picturing the condition more visibly before undergoing the actual surgical process. During the simulation with the 3D-printing models, surgical planning that involved complex spinal disorders will be facilitated by predicting possible difficulties and later able to determine the best approach in each case. This approach would possibly reduce both surgical time and the risk of blood loss during the actual surgery. The example of the 3D-printing models used for surgical simulation were complex en-bloc resections of primary vertebral tumours, complex cranio-cervical junction surgeries, spinal deformity correction surgeries, disc replacement surgery and fracture-dislocations of the thoracic and lumbar spine. One study reported that 3D-printing reduced instrumentation time, blood loss, and fluoroscopy exposure (number of shots) with statistically significant differences between 3D-printing model groups and free-hand technique group; 61.9 minutes ± 4.7 versus 75.5 minutes ± 11.0, $P < 0.0001$, 268.4ml ± 42.7 versus 347.8ml ± 52.2, $P < 0.0001$ and 16.3 shots ± 1.9 versus 19.7 shots ± 2.4, $P < 0.0001$, respectively. Next applications were *3D-printing customised implants and surgical tools* to match both biomechanical requirements and patient's anatomy (anatomical fit). Based on included case series, there were reports on successful used of 3D-printed patient-specific implants for spinal fusion in complex spine conditions. The included studies also reported various advantages with customised 3D-printed implants which were improved load-bearing surface, reduced rate of implant dislocation and subsidence, excellent primary stabilisation while promoting fusion due to bionic, trabecular bone tissue microporous structure, reduced surgical time, enhanced correction of deformity, reduced blood loss and reduced risk of neurovascular compromise. Lastly, the authors reported that 3D-printing enhances adjustment of prostheses during post-operative period for greater comfort and acceptance. [20]

Another SR by Abbady HEM. et. al. evaluated 3D-printing of limb prosthesis production in lower-income (LI) and lower-middle-income countries (LIM) countries. The SR included 18 studies consisted of case reports, case series, and observational studies. All the studies involved patients with upper limb prosthesis with different level of amputations such as flexy hand in those who were amputated through the carponetacarpal joint, Robohand in those with wrist disarticulation and Cyborg Beast in those with transmetacarpal amputation. From the 18 studies, 27 different 3D-printed prostheses were reported and 14 of them were body-powered which meant that the user could control the motion of the prosthesis through a harness or cable. From the assessments, one of the included study showed that 3D-printing potentially increased QoL and daily usage at low cost without loss of functionality compared to non-3D printed orthoses. Besides the 3D-printing fitting procedure did not require manufacturing site and involved simple manufacturing process as well as ability to easily repair broken parts with minimal skill required. In contrast, one study reported that fitting of 3D-printed orthoses requires sophisticated equipment and technical knowledge. On the other hand, three included studies reported that the 3D-printed prosthesis was as comparable as non-3D printed prostheses in terms of functionality, satisfaction and comfort. User satisfaction also being assessed and all patients were satisfied with 3D-printed prosthesis where an aesthetics aspects of the 3D-printed prostheses play a major role among recruited patients. However, one study reported on patient dissatisfaction towards undesirable overall size of 3D-printed prosthesis either oversized or undersize.[21]

5.2 SAFETY

The SR by Schwartz A.D. et. al. observed for any safety issues involved the use of 3D-printed orthosis. Fortunately, four studies reported no complications with used of 3D-printed orthosis. On the other hand, one study compared between 3D-printed orthosis with plaster cast (traditional orthosis), the result showed that 3D-printed orthosis was statistically significant in reducing complications ($p = 0.041$). The 3D-printed orthoses also caused less skin irritation, itchiness and odour when compared to the plaster cast. However, a study reported that there were patients who did not comply with the recommended wearing schedule of the 3D-printed orthosis as they were uncertain about the efficacy of the new technology.[4]

Quinones JVM et. al. raised a few safeties concerned regarding the 3D-printed prosthesis. First, the use of recycled substrates in manufacturing process might increase potential source of contamination. Second, bio-models must have reproducible physical characteristics and offer post-production quality assurance. Final concerned was the bio-models must be able to withstand sterilisation procedures without any alteration or defect on physical and structural characteristics of the models.[20]

Meanwhile, the SR by Abbady HEM. et. al. reported on failure/malfunctioning of the 3D-printed prosthesis within certain period of follow-up. Out of 11 3D-printed prostheses assessed, six prostheses were failed which were malfunction of the elastic components and the socket after 2- to 5-weeks of follow-up and malfunctioning and breaking of metacarpophalangeal joint of the thumb after one-month used.[21]

5.3 ORGANISATIONAL ISSUES

Wang Y. et al., in their review on the biomechanical applications of additive manufacturing/3D printing, noted that while the technology offers many benefits, its use in prosthetics and orthotics remains limited. This slow adoption is due to several challenges: limited research on product performance, lack of clear metrics to compare additive manufacturing/3D-printing with traditional methods, absence of an integrated design-to-production system, and unclear regulations for personalized products.[3]

Waqas M. et. al. conducted an SR to evaluate the designs, physical properties, accuracy and experimental outcomes of 3D-printed vascular models (prosthesis) developed to provide simulation for neuroendovascular procedures. Twenty-three studies were included which described the use of 3D-printed models and/or for cerebrovascular interventions, training or education. The 3D-printed models included were 3D-aneurysm models, arteriovenous malformation (AVM) models, stroke intervention, 3D-printed prototypes and 3D-printed prototypes for stroke or aneurysms interventions. The SR detail up the material used and the source of images used for 3D-printing of the vascular models. Most of materials used were elastomer and the sources of the images were from computed tomography angiogram (CTA), magnetic resonance angiograms (MRA), digital subtraction angiograms and rotational angiogram. Most of the studies used patients-specific models generated using a 3D-angiogram of a specific patients. Meanwhile, others were developed through population-representative vascular model based on geometric characteristics of 20 patients with normal MRA. For compliance and flow characteristics, the included studies described a tensile test that compared 3D-printed to post-mortem human middle cerebral artery values and varies alternative to adjust flow rate such as maintained by pulsatile pump, programmable piston or mixture of glycerol and water. Meanwhile for lubricity of the vascular models, coefficient of friction (COF) was measured and because of that a liquid silicone rubber coating was applied to the luminal surface to achieve a COF comparable to one observed in cadaveric blood vessels. [22]

There a were few organisational issues regarding 3D-printing orthosis highlighted in the SR by Schwartz A.D. et. al. The issues were related to manufacturing time, personnel, during manufacturing process and patient's condition. According to the SR, 3D-printing manufacturing involved scanning, data transfer, printing and finishing/adjusting processes. All over a time taken for production of one orthosis will take around 10 to 12 hours even three to five days. One study compared the production time between 3D-printed orthosis with orthosis made by certified orthosis through conventional process. The study reported that the 3D-printing reduced 53% of total fabrication time compared to the traditional orthosis made with high temperatures thermoplastic materials. During 3D-printing process, one study reported on a requirement of an assistance where in this case hand therapist to support the patient's limb during a scanning process. Another concern was a patient's condition who had difficulty to maintain a position during data collection due to pain, discomfort, and swelling of an affected area.[4]

The SR by Quinone JVM. et. al. reported on a limitation with 3D-printing prosthesis in spine surgery. In terms of education and surgical training, cadaver is still considered as a gold standard because the 3D-printing could not 100% simulated anatomy, the 3D-models could not simulate soft tissue like nerves and blood vessels, their location and texture. On the other hand, there were not many materials can be used for 3D-printing implants. Besides, 3D-printing implants tend to be used in relatively specific, highly complex cases that reduces the potential market and generalisation that limit their used. The SR also specified the limitations based on pre- and post-operative of the surgery. The pre-operative limitations included a need for a specialist with an experience in handling 3D software to segment the model for printing, more time needed to design and construct the 3D-printing model prior to surgery, as well as concerned on production cost that depends on the material used or the number of implants created to ensure the procedure is successful. Post-operative limitation was mainly on lack of long-term follow-up studies after 3D-printing implant in spine surgery to justify the positive clinical outcomes. Another concerned discussed was standardisation in terms of design of personalised medical device (such as bio-models, guides and implants), production and the usage of the 3D-printing in spine surgery. This standardisation was to ensure patient safety in accordance with FDA’s current quality assurance practices for new devices, where the personalised 3D-printed implants require the corresponding design and material certifications. Meanwhile, at hospital level, the 3D-printing units may be created for intra-hospital additive manufacturing to meet on non-industrial scale, with specific needs of patients that could not be met with other equivalent devices available in market. However, these units should comply with series of legal recommendations with a main concern on a cost as these units usually involved high cost and required qualified personnel with experience in CAD software. Such additional expenses meant that this technology might not be affordable in most of countires.[20]

In an SR by Abbady HEM et. al., the limitation was on limited production capacity of a single 3D-printer. Thus, for high production volume, there were requirement for more 3D-printers which consequently required more labour, and increased maintenance as well as repair cost. Other problems discussed were difficulty in conducting follow-up due to level of education of the patients, low availability of communication devices and language barrier.[21]

5.4 COST

Schwartz A.D. et. al. reported on production cost of 3D-printing orthosis in six studies. Out of the six studies, three studies reported that the cost of raw materials used for 3D-printing ranged from US$15 to US150. Meanwhile, one study mentioned that the costs for necessary equipment involved were US$500 to US$5000 for a 3D-scanner and US$3 to $4000 for a 3D-printer. Although CAD software programs were free and can be used with most of personal computers, the included studies found that a high cost of acquisition of a 3D-printer may limit widespread application of 3D-printed orthosis in hospital and rehabilitation settings. One study reported that cost of 3D-printed orthoses was unclear when compared to traditional orthoses or cast.[4]

The cost for 3D-printed prosthesis reported in the SR by Abbady HEM et. al. varied depending on type of the prosthesis. The cost ranged from approximately US$35 to US$1,000 for complete prosthesis. The production costs were unknown and not specified in the included studies. In the meantime, the material costs for hand prosthesis were ranged from US$10 to US$250 and from US$14 to US$980 for prosthesis of transradial amputation. [21]

5.5 LIMITATIONS

There were some limitations in this technology review and should be considered when interpreting the results. Although the search did not limit language, finally only English full text articles were included. The other important limitations need to be considered were related to the included studies as mentioned under risk of bias assessment. Most of the included studies of the included SRs have small sample size, different study design and conducted among different population.

6.0 CONCLUSION

The review showed that, 3D-printing technology is used in healthcare especially in manufacturing 3D-printed orthosis, exoskeleton and prosthesis. The applications of the 3D-printed orthosis, exoskeleton and prosthesis varies either in orthopaedic, surgical, dental, 3D-implant even as simulation 3D-model in medical training of various field. Although the 3D-printed orthosis, exoskeleton and prosthesis showed potential in reducing operation and treatment time, had good accuracy and improved patient's outcome as well as increased their satisfaction; the outcomes depended on patient's conditions and types of the 3D-printed orthosis, exoskeleton and prosthesis used. In terms of safety, less complications were reported with 3D-printed orthosis compared to traditional orthosis. However, there are concerns on failure and malfunction. Other concerns were related to organisational issues which were production time, choice of materials that had different characteristics, patient's conditions which might affect the data collections such as image taking or molding process, expert personnel both in printing process and medical expertise, lastly the production capacity especially for mass production.

The cost-effectiveness for 3D-printed orthosis, exoskeleton and prosthesis could not be determining as it depends on types of 3D-printed device to be manufactured, the whole manufacturing process involved included the raw materials cost as well as the 3D-printer which had different price range.

8.0 REFERENCES

1. Dodziuk H. Applications of 3D Printing in Healthcare. Kardiochirurgia i Torakochirurgia Polska 2016; 13 (3): 283-293. DOI: https://doi.org/10.5114/kitp.2016.62625
2. Willett, Amber K., "3D Printing and Occupational Therapy: The Process of 3D Printing Adaptive Devices" (2019). Honors Theses. 654. https://encompass.eku.edu/honors_theses/654
3. Wang Y., Tan Q., Pu F., et. al. A Review of the Application of Additive Manufacturing in Prosthetic and Orthotic Clinics from a Biomechanical Perspective. Engineering 6. 2020; 1258-1266
4. Schwartz A.D, Schofield KA., Utilisation of 3D printed orthoses for musculoskeletal conditions of the upper extremity: a systematic review. J Hand Ther. 2023; 36(1):166-178. doi: 10.1016/j.jht.2021.10.005.
5. https://all3dp.com/2/3d-printed-orthotics-most-promising-projects/
6. https://www.3dnatives.com/en/3d-printed-orthoses-110620194/#!
7. https://oncedaily.co/andiamo-custom-prints-3d-orthosis/
8. https://www.unionfab.com/blog/2024/06/3d-printed-prosthetics
9. https://www.artec3d.com/cases/thought-controlled-bionic-arm
10. Fernandes da silva JLG., Goncalves SMB., Placido da Silva HH., et. al. Three-dimensional printed exoskeletons and orthoses for the upper limb - A systematic review. Prosthet Orthot Int. 2024; 48(5): 590-602
11. https://www.igus.my/info/3d-printing-application-exoskeleton
12. https://3dprint.com/75997/3d-printed-exoskeleton-arms/
13. https://www.crealitycloud.com/model-detail/66008d5aa52087b715b65c2c
14. Wang Y., Tan Q., Boone D. et. al. A review of the application of additive manufacturing in prosthetics and orthotic clinics from a biomechanical perspective. Engineering. 2020; 6: 1258-1266
15. Li B., Zhang M., Lu Q. et. al. Application and development of modern 3D-printing technology in the field of orthopaedics. Biomed Research Int. 2022; 8759060: 1-15
16. Tack P., Victor J., Gemmel P., et. al. 3D-Printing Techniques in a Medical Setting: a Systematic Literature Review. BioMed Eng OnLine. 2016; 15:115. DOI 10.1186/s12938-016-0236-4
17. Wojciechowski E., Chang AY., Balasone D., Ford J., Cheng TG., Little D., Menezes MJ., Hogan S & Burns J. Feasibility of designing, manufacturing and delivering 3D printed ankle-foot orthoses: A Systematic Review. J Foot Ankle Res. 2019; 12:11. doi: 10.1186/s13047-019-0321-6.
18. Zoltan J., Popescu D., Sanei SYR. A systematic review of follow-up results of additively manufactured customised implants for the pelvic area. Expert Rev Med Devices. 2023 Mar;20(3):233-244. doi: 10.1080/17434440.2023.2183839.
19. Valenti C., Federici MI, Masciotti F, Marinucci L., Xhimitiku I., et al. Mechanical properties of 3D printed prosthetic materials compared with milled and conventional processing: A systematic review and meta-analysis of in vitro studies. 2024; 132(2): 381-391
20. Quinones JVM, Martinez JO, Arias DP, Lecina MB, Rossi FB, Calvo RA. Systematic review of the utility and limits of 3D printing in spine surgery. Neurocirugia. 2024; 35(1): 30-40
21. Abbady HEM, Klinkenberg ETM, de Moel L., Nicolai N., van der Stelt M., et. al. 3D-printed prostheses in developing countries: a systematic review. 2022; 46 (1): 19-30

22. Waqas M., Mokin M., Lim J., Vakharia K., Springer ME., Meess KM. et. al. Design and Physical Properties of 3-Dimensional Printed Models Used for Neuro-intervention: A Systematic Review of the Literature. Neurosurgery. 2020; 87: E445-E453
23. Revilla-Leon M, Gomez-Polo M, Barmak A, Yilmaz B, Rutkunas V, Kois JC. Influence of the manufacturing trinomial (Technology, Printer and Material) on the marginal and internal discrepancies of printed metal frameworks for the fabrication of toot-supported prostheses: a systematic review and meta-analysis. 2024; 37(7): 285-307
24. Xie L., Chen C., Zhang Y., Zheng W., Chen H., Cai L. Three dimensional printing assisted ORIF versus conventional ORIF for tibial plateau fractures: a systematic review and meta-analysis. Int J Surg. 2018; 57: 35-44
25. Diment LE., Thompson MS., Bergmann JH. Three-dimensional printed upper-limb prostheses lack randomised controlled trials: a systematic review. Prosthet Orthot Int. 2018; 42(1): 7-13

9.0 APPENDIX

APPENDIX 1: LITERATURE SEARCH STRATEGY

Database: Ovid MEDLINE(R) ALL <1946 to May 02, 2025>
Search Strategy:

1. Orthotic Devices/
2. orthos*.tw.
3. orthosis.tw.
4. orthotic device*.tw.
5. parapodium*.tw.
6. "Prostheses and Implants"/
7. artificial impant*.tw.
8. endoprosthes*.tw.
9. (implant* adj2 prosthes*).tw.
10. prosthes*.tw.
11. (prosthes* adj2 implant*).tw.
12. prosthetic implant*.tw.
13. Exoskeleton Device/
14. exoskeleton device*.tw.
15. robotic exoskeleton*.tw.
16. Printing, Three-Dimensional/
17. 3d printing.tw.
18. 3 d printing.tw.
19. 3 dimensional printing.tw.
20. 3-d printing*.tw. (389)
21. 3-dimensional printing*.tw
22. 3d printing*.tw.
23. three dimensional printing.tw.
24. three-demensional printing*.tw.
25. Traditional fabrication.mp.
26. conventional fabrication.tw.

Other Databases

EBM Reviews - Health Technology Assessment EBM Reviews - Cochrane database of systematic reviews EBM Reviews - Cochrane Central Registered of Controlled Trials EBM Reviews - Database of Abstracts of Review of Effects EBM Reviews - NHS economic evaluation database	Same MeSH, keywords, limits used as per MEDLINE search
PubMed INAHTA US FDA	Same MeSH and keywords as per MEDLINE search

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