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Comparison in clinical performance of surgical guides for mandibular surgery and temporomandibular joint implants fabricated by additive manufacturing techniques

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ABSTRACT

Additive manufacturing (AM) offers great design freedom that enables objects with desired unique and complex geometry and topology to be readily and cost-effectively fabricated. The overall benefits of AM are well known, such as increased material and resource efficiency, enhanced design and production flexibility, the ability to create porous structures and on-demand manufacturing. When AM is applied to medical devices, these benefits are naturally assumed. However, hard clinical evidence collected from clinical trials and studies seems to be lacking and, as a result, systematic assessment is yet difficult. In the present work, we have reviewed 23 studies on the clinical use of AM patient-specific surgical guides (PSGs) for the mandible surgeries (n = 17) and temporomandibular joint (TMJ) patient-specific implants (PSIs) (n = 6) with respect to expected clinical outcomes. It is concluded that the data published on these AM medical devices are often lacking in comprehensive evaluation of clinical outcomes. A complete set of clinical data, including those on time management, costs, clinical outcomes, range of motion, accuracy of the placement with respect to the pre-operative planning, and extra complications, as well as manufacturing data are needed to demonstrate the real benefits gained from applying AM to these medical devices and to satisfy regulatory requirements.

1. Introduction

Additive manufacturing (AM), also widely known as 3D printing, refers to the processes of making three-dimensional (3D) objects by adding materials layer-upon-layer. The technology makes use of computational data in the form of STL-files to make 3D objects in one single manufacturing step using AM. Currently, a number of well-established AM processes are commercially available, such as powder bed fusion (PBF) processes, during which a (metal) power layer becomes melted or sintered at selected areas by high intensity energy, such as laser in selective laser melting (SLM) or electron beam in electron beam melting (EBM) (Frazier, 2014; Mirzaali et al., 2019; Putra et al., 2020). Other common AM processes include vat photopolymerization, represented by stereolithography (SLA), in which ultraviolet (UV) light is used to cure a liquid monomer (Ngo et al., 2018). Material extrusion, represented by fused deposition modeling (FDM), during which a thermoplastic polymer filament in the semi-liquid state is ejected out of a nozzle to form desired layers (Ngo et al., 2018). Material jetting (MJ) uses liquid photopolymer droplets to build objects. And finally, binder jetting (BJ), during which a liquid binder is selectively deposited on a layer of powder particles. The choice of materials depends on the process intended to use. In most cases, SLM, EBM and LENS (laser engineered net shaping – a technique under the category of directed energy deposition) use metal powder as the starting material, while FDM, SLA and MJ use thermoplastics or photopolymers. Indirect or hybrid AM processes, in which AM is applied, for example, to make a mold for casting (Zadpoor and Malda, 2017), are not included in this review paper.

The design freedom offered by AM enables objects with desired unique and complex geometry and topology to be rapidly and cost-effectively fabricated. Tailor-made designs (*e.g.*, patient-specific AM biomaterials and implants) are most suited for AM, particularly when one single design cannot meet all the requirements for individual patients. The typical example is the design of patient-specific (orthopedic) implants that can perfectly match individual's (bone) anatomies, geometries and even internal structures. In addition, the number of AM

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medical devices largely does not affect manufacturing costs (Zadpoor, 2018a). Therefore, in the last decades, AM has made inroads into the area of biomedical engineering, as an advanced fabrication technology for patient-specific medical devices.

Medical applications of AM can, in general, be classified into the following categories (Tuomi et al., 2014): (*i*) medical models, (*ii*) medical aids, supportive guides, splints and prostheses, (*iii*) medical tools and instruments, (*iv*) inert implants and (*v*) biomanufacturing. Despite the increasing use of AM in fabricating custom-made medical devices, whether custom-made designs can indeed improve the clinical performance, as compared to the designs suitable for batch-fabricated medical devices and for the conventional manufacturing methods is yet to be proven.

Among the five different categories of medical devices, in this study, we made choice of patient-specific surgical guides (PSGs) for mandibular surgery, which belong to category *iii* (Fig. 1) and patient-specific implants (PSIs) for the surgical replacement of dysfunctional temporomandibular joint (TMJ), which belong to category *iv* (Fig. 2). As TMJ is unique in every individual and is subjected to cyclic movement and loading, a perfect, customized fit is of great importance for the total joint replacement surgery and its mechanical and tribological performance is vital for its intended function and longevity. The use of patient-specific TMJ implants resulted in the improvement in the quality of life for 85% of the patients and the establishment of the four criteria accepted by orthopaedic surgeons for the development and utilization of successful TMJ reconstruction implants (Mercuri, 2012). Being very different from PSIs in requirement, PSGs assist the surgeon during a complex surgery by giving guidance on where to drill or cut (hard) tissue (*e.g.*, bone tissue) exactly during the surgery. To create AM medical devices of these two categories, non-destructive medical images, such as computed tomography (CT) and/or magnetic resonance imaging (MRI) scans, can be used as input data. CT scans are generally used for segmenting bones. However, MRI scans can have comparable accuracy with long bones (Rathnayaka et al., 2012). MRI scans can also be used as an additional tool for visualization of soft tissues, such as cartilage (White et al., 2008) and tumors (Wong et al., 2008). Based on medical images, surgical guides and implants can be designed by using computer-aided design (CAD) tools (see Fig. 1 and Fig. 3).

Both PSGs and PSIs for the mandibular joint have been fabricated by AM and the conventional manufacturing techniques in the past few decades. The first prototype of an AM PSG was built by van Brussel et al. (Van Brussel et al., 1996) in 1996, while the first AM PSI was clinically used in 2012 (Nickels, 2012), when a patient's lower jaw bone was replaced entirely by an AM mandibular implant. Although such surgical guides and implants have been successfully implemented in a clinical setting, their clinical outcomes and performances are only scarcely available in the literature. Critical clinical evidence often used in the assessment of different types of PSGs and PSIs includes operating room (OR)/treatment time, recovery time, accuracy of the 3D printed part, radiation exposure, clinical outcomes and costs (Tack et al., 2016). In addition to these, comparisons in clinical outcomes are necessary with respect to the accuracy and efficiency that different manufacturing methods are able to offer (*i.e.*, AM versus non-AM techniques) for the fabrication of PSGs for mandibular surgery and TMJ PSIs.

In 2016, Tack et al. (2016) published a systematic review on 3D printing applied in the surgery of human medicine, which included clinical trials and case studies on more than three patients. Of the 227 papers selected, 60% involved surgical guides and 12.17% custom implants. The review summed up the critical clinical evidence. It reported in how many papers the critical clinical evidence was provided and if the clinical outcomes were quantified and/or statistically analyzed, which was the case only for 20% and 7% in PSG and PSI studies, respectively.

Being different from the review mentioned above, the present review is aimed at comparing PSGs for mandibular surgery and TMJ PSIs fabricated by applying different AM techniques and the conventional manufacturing methods based on some of the relevant clinical evidence reported in the literature. In this connection, we first describe the current applications of different AM and non-AM techniques in the fabrication of these medical devices. We discuss the available regulations, as well as some of the advantages and limitations of different AM

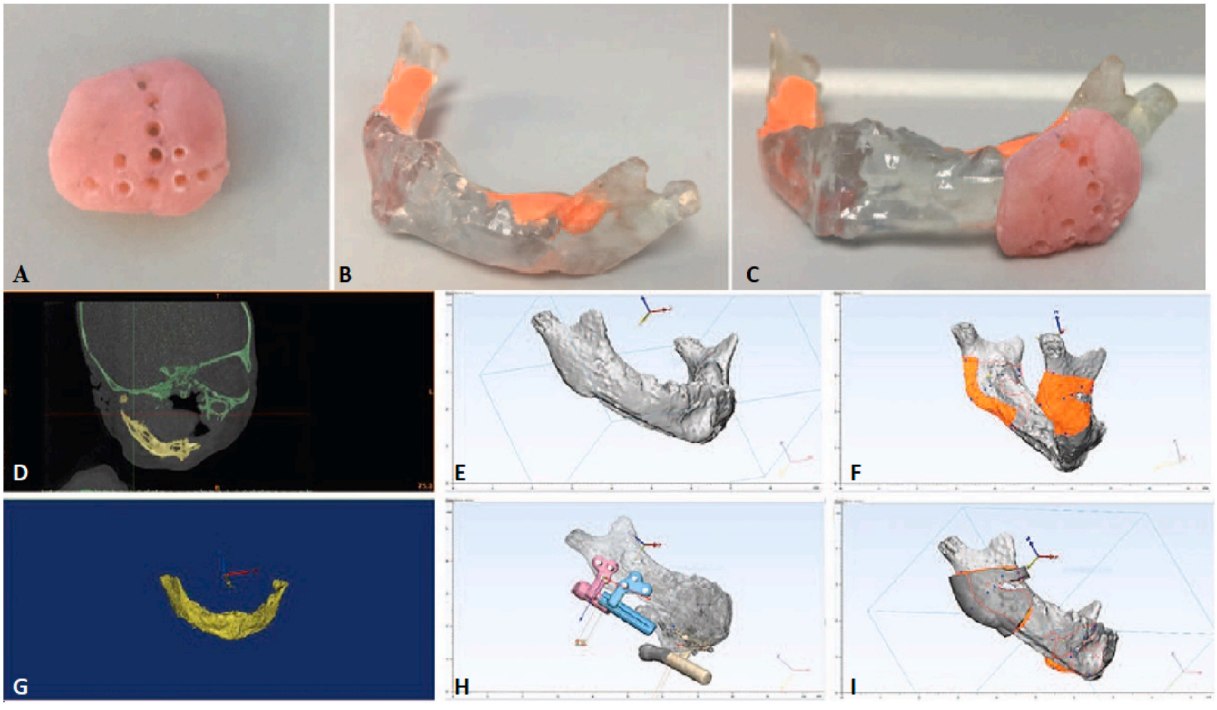

Fig. 1. Fabrication of surgical guides for mandibular distraction osteogenesis in infancy by Moa et al. (Mao et al., 2019). One surgical guide is handmade with the conventional methods (A–C), in which a 3D mandible model was used and a handmade surgical guide was fitted on this model by using wax. Another surgical guide was made with AM (D–I), in which DICOM files were used for image processing and CAD with the Mimics and 3magic software (Materialize, Leuven, Belgium). The designed surgical guide was exported for AM.

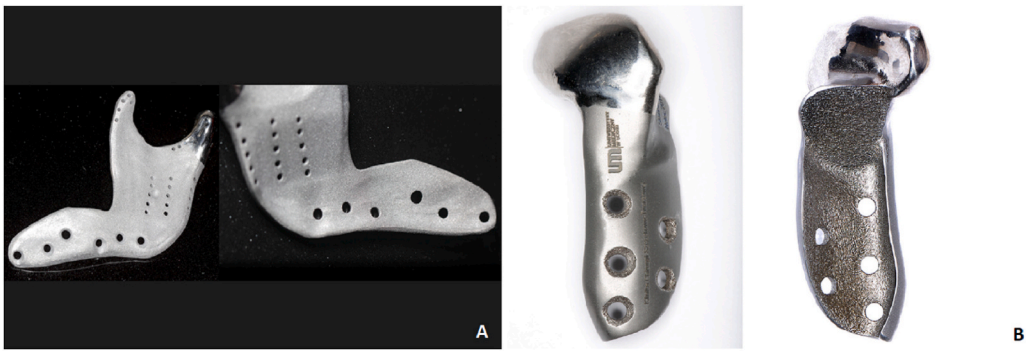

Fig. 2. Customized TMJ implants made of a titanium alloy and fabricated by using (A) CNC milling and (B) AM (DMLS) (Kozakiewicz et al., 2017).

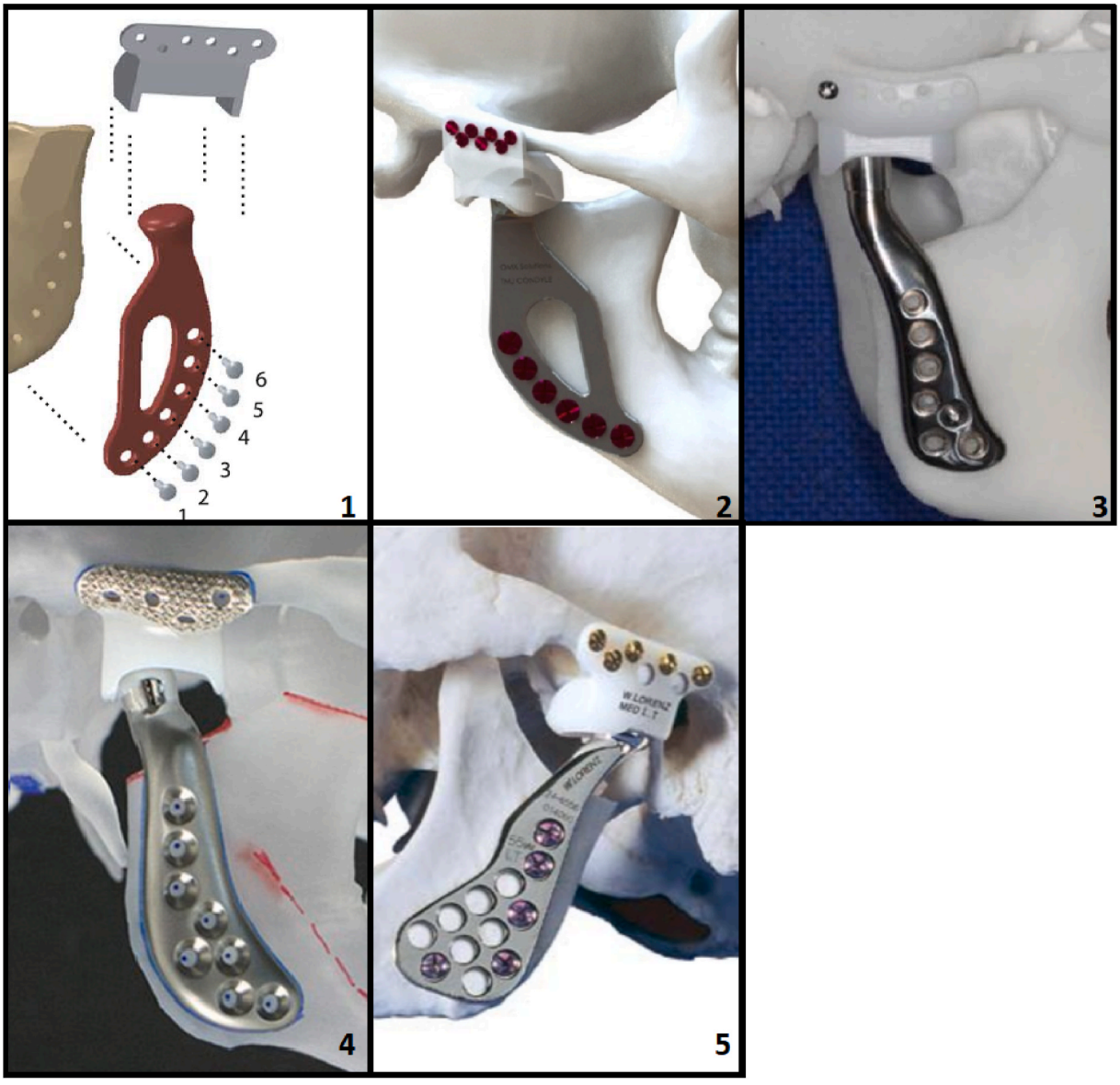

Fig. 3. Comparison between AM and conventionally manufactured TMJ implants: (1) the prosthetic TMJ developed by the researchers of the University of Melbourne and used in the study of Ackland et al. (Ackland et al., 2017), (2) the TMJ prosthetic total joint replacement system developed by OMX Solutions and used in the study of Dimitroulis et al. (Dimitroulis et al., 2018), (3) the TMJ prosthetic device used in the study of Zheng et al. (Zheng et al., 2019a), (4) the TMJ implant developed by TMJ Concepts (Concepts, 2019) and (5) the TMJ implant developed by Biomet Zimmer (Microfixation, 2007).

techniques. Then, we discuss the most well-known clinical outcome parameters that have been used for the clinical assessment of PSGs for mandibular surgery and TMJ PSIs. Based on this analysis, we indicate the strong need for data in order to validate the benefits gained from using AM PSGs for mandibular surgery and TMJ PSIs. We suggest the most important clinical parameters that need to be addressed in the future for the design and implementation of PSGs for mandibular surgery and TMJ PSIs.

2. AM techniques used in the manufacturing of PSGs for mandibular surgery

AM PSGs have been widely used in maxillofacial and orthopedic treatments. Examples include craniomaxillofacial surgery (Levine et al., 2012), mandibular reconstruction (Liu et al., 2014), dental implantation procedure (Flugge et al., 2013), spinal surgery (Lu et al., 2009), total knee arthroplasty (TKA) (Qiu et al., 2017), total hip arthroplasty (THA) (Spencer-Gardner et al., 2016), total shoulder arthroplasty (TSA) (Gauci et al., 2016) and osteotomies of the femoral neck (Schneider et al., 2018), tibia (Perez-Mananes et al., 2016), humerus (Omori et al., 2015) and distal radius (Kunz et al., 2013).

PSGs for mandibular surgery are often manufactured with thermoplastics, or photopolymers, since no high mechanical strength is needed for such assisting tools used during the surgery. The AM processes used for such PSGs include FDM, SLA, MJ and BJ. Metallic PSGs can be manufactured by using the methods involving metal sintering or even melting, such as selective laser sintering (SLS) and direct metal laser sintering (DLSM).

The main difference between these AM methods concerns the way that the layer is deposited, and each of these techniques has its own cons and pros. In the FDM technique, for example, the semi-liquid material is deposited through a moveable nozzle. Material options include thermoplastics, wax, metal-loaded filament and ceramic-loaded filament. The main advantages of this technique include the low costs in feedstock material and AM machine, a broad range of useable materials and reasonable accuracy regarding geometrical dimensions and surfaces. However, 3D printed parts usually have low mechanical properties and poor surface quality (Ngo et al., 2018).

SLA makes use of UV laser and a photosensitive monomer to create a layer in one go. By layering the build platform with a resin, a new layer is ready to be cured (Huang et al., 2013). This process is fast and can create good surface finish. However, support structures are needed and part sizes are often limited. The limitation in material choice is another disadvantage.

MJ works with a liquid ink that is forced to be ejected out of a nozzle into a chamber onto pre-programmed substrates in different layers (Huang et al., 2013). MultiJet modeling (MJM) is a variant of MJ that makes use of multiple nozzles simultaneously. Typically, acrylic photopolymers that are curable with UV light, resulting in high accuracy of small structures, are used.

BJ makes use of a liquid binder dropped on a powder layer to glue powder particles together (Wong and Hernandez, 2012). After one layer, the powder bed platform moves downwards, and another layer of powder is spread. With this method, many types of polymers or a variety of other powdered materials can be used.

The SLS and DMLS techniques involve the sintering of powder (Ngo et al., 2018) that is heated to a temperature just below the melting temperature of the powdered material by a laser with the use of mirrors (Kruth et al., 2005). Materials available for SLS include thermoplastic polymers, such as polycarbonate and several other types of polymers, wax, and ceramic/polymer composites (Gibson and Shi, 1997), while only metals are used with DMLS that in practice often involves partial melting (Khaing et al., 2001; Azarniya et al., 2019).

2.1. AM techniques used in the manufacturing of TMJ PSIs

In contrast to PSGs, PSIs are mostly fabricated with metal, since higher mechanical properties and biocompatibility are needed. The manufacturing processes involved are generally the metal powder bed (PBF) processes (*e.g.*, SLM, SLS, EBM and DMLS). PSIs can be broadly classified into two groups: load-bearing and non-load bearing implants. Load-bearing implants are the ones that are used to re-establish the quality of the load-bearing joints that are subjected to mechanical stresses, wear and cyclic loading during daily activities (Paital and Dahotre, 2008), while non-load bearing implants do not undergo mechanical loading cycles and are often merely there to support or replace bone structures. Examples of currently used AM load-bearing implants are the TKA implant (the femoral component) (Song et al., 2016), the THA implant (the acetabular cup) (Weber et al., 2018), TMJ implant (Zheng et al., 2019a) and several spinal implants, such as the interbody implant (Mobbs et al., 2019), the custom vertebral body implant (Choy et al., 2017) and the sacral implant (Kim et al., 2017). Examples of non-load-bearing implants reported in the literature are those for the reconstruction of large cranial defects (Jardini et al., 2014) or orbital wall defects (Stoor et al., 2014), and the bone plate to support the fibula free flap for mandibular reconstruction (Ciocca et al., 2012).

As mentioned earlier, the PBF techniques have mostly been used in the manufacturing of PSIs. PBF refers to the processes, in which a layer of powder is melted or sintered through an energy source, such as a laser or electron beam. These processes can create complex structures with high accuracy and porosity. However, only one single material can be used at a time. The PBF processes include SLM, where a high power-density laser melts the powdered metal, and EBM, where an electron beam is used for selective melting (Prashanth and Eckert, 2017). The main differences between the SLM and EBM techniques lie in the higher temperatures (around 650–700 °C) of the EBM technique, which makes a material with a melting point lower than 600 °C not suitable for this process. Besides that, in EBM, the built part slowly cools down to room temperature, while SLM's cooling rate ranges between 10^5 - 10^6 [K/s] (Prashanth and Eckert, 2017), often resulting in non-equilibrium microstructures and unusual mechanical properties. In addition, the sizes of powder particles used in SLM are often smaller than those used in EBM, resulting in smaller processing inconsistencies (Azarniya et al., 2019).

2.2. Regulations concerning PSGs for mandibular surgery and TMJ PSIs

Patient-specific designs can be applied in the manufacturing with either non-AM/conventional or AM processes (Figs. 1–2 and Table 1). The conventional methods for the manufacturing of customized TMJ implants include computer numerical control (CNC) machining (see an example in Fig. 2a), *e.g.,* CNC milling, and metal casting. Sometimes, stock implants manufactured to standard sizes are manually fitted, which includes bending standardized implants for a better fit to the

Table 1
Different non-AM and AM manufacturing processes used for the manufacturing of patient-specific surgical guides (PSGs) for mandibular surgery and TMJ patient-specific implants (PSIs).

	Non-AM methods	AM methods
Patient specific Surgery guides (PSG) for mandibular surgery	Casting CNC milling Manual forming	FDM SLA IJP 3DP DMSL SLM
TMJ patient-specific implants (PSI)	Casting CNC milling Manual forming	DMSL SLM SLS EBM

shape of the mandible. However, these types of implants are not custom-made, but personalized after fabrication. Additionally, manually forming implants after the manufacturing process is the least accurate approach to customizing medical devices (Kozakiewicz et al., 2017).

Since every patient-specific device is designed according to patient's anatomy, making every design unique in shape, size and sometimes making an adaption of surgical procedure are necessary. Therefore, regulations for custom-made medical devices are needed. In April 2017, the European Parliament and the Council of the European Union published the regulation (EU) 2017/745 (The European Parliment a, 2017), regarding medical devices, whose implementation was planned to be fully effective from 26 May 2020 onwards and has recently been postponed by one year to 26 May 2021[1]. All surgically invasive transient (continuous use for less than 60 min) devices (*e.g.,* PSGs for mandibular surgery) are classified as class IIa medical devices. All implantable or long-term surgically invasive devices are classified as class IIb medical devices, unless they are either a total or partial joint replacement (*e.g.*, TMJ PSIs), a spinal disc implant or the implants in contact with the spinal column, which would make them class III medical devices. Expectations are made for screws, wedges, plates or instrument components, making them not class III devices. For class IIb and III medical devices, a summary regarding its primary safety and performance, including clinical evaluation, is required to be publicly available.

Custom-made medical devices receive a special treatment and are described by the European Commission as the medical devices that are '*specifically made for the use of a particular patient exclusively to meet their individual conditions and needs*' (The European Parliment a, 2017). Exceptions are made with mass-produced medical devices that need to be altered to meet the precise requirements and made by industrial manufacturing methods (The European Parliment a, 2017). PSGs and PSIs are custom medical devices and, as such, they do not require CE marking, which is usually a very time-consuming process. However, up-to-date technical documentation is still needed and must be in accordance with the requirements specified in the regulation.

In the United States of America, the U.S. Food and Drugs Administration (FDA) has described custom-made medical devices, since 2012, as the ones that are designed to function for an individual at request of a clinician. Additionally, fabrication may not exceed a maximum of five pieces per year and needs to be annually updated on the requirements of the fabrication of these pieces to the FDA (FDA, 2014).

However, AM patient-matched devices are not always appointed customized devices, but can include apparatus that undergo modifications to a particular already approved appliance, and will need to follow the regulatory pathway for the designated device. They are allowed to have standardized characteristics, compositions and processes of already known products (FDA, 2017). Since modifications to these already known devices can cause consequences to the individual receiving the implant, it is important to classify all parameters and ranges for the design of these modified patient-specific devices (FDA, 2017).

All class II devices are generally required to undergo premarket notification (510(k) clearance) in the US, meaning that they need acceptable performance and post-market surveillance, but clinical efficiency in this stage is often not obtainable yet (Maak and Wylie, 2016). For class III devices, premarket authorization (PMA) - an approval regarding the safety and efficacy is needed. Since many of the patient-specific instrumentation will not be classified custom devices by the FDA, but rather devices with small modifications within the prior established ranges, such premarket approvals are not needed for the patient-specific TMJ implants in the U.S. Since patient-specific devices often rely on the adaptions of previously known products, it is important that all data on these products are well reported in the literature and technical documentations of each product so that the outcomes of small adaptions can be predicted.

2.3. Advantages and limitations of AM for PSGs for mandibular surgery and TMJ PSIs

In addition to the aforementioned regulations, the following engineering aspects need to be taken into account when comparing the AM processes to the conventional ones (Huang et al., 2013). First, when using AM, material efficiency is significantly improved, since no subtractive processes take place, and leftover materials can often be recycled and reused. Furthermore, resource efficiency is enhanced, as AM does not require extra recourses except the main machine used, if post-processing is not considered. Higher design flexibility is possible in AM, resulting in the ability to manufacture complex patient-specific structures for TMJ applications to fit the patient's mandible, since no tooling constraints are present. AM allows porous TMJ implants with well controlled pore sizes, porosity, and interconnectivity (Taniguchi et al., 2016) to facilitate bone ingrowth and drug delivery and to possess high permeability and diffusivity (Zadpoor and Malda, 2017). For bone tissue reconstruction, a minimum pore size in a range of a few hundred micrometers is needed (Zadpoor, 2015). On top of that, different parts with different mechanical properties can be created in one single implant, and the mechanical properties can be tailored with topological porous structures to match the mechanical properties of the bone to be replaced (Putra et al., 2020; Zadpoor, 2018b), thereby minimizing stress shielding (Zadpoor and Malda, 2017). Finally, production flexibility can be gained, since the setup costs are usually low, making AM easier to produce single part or small batches. Another benefit of AM is the on-demand manufacturing of patient-specific devices under extraordinary circumstances (*e.g.*, wars, third world countries or remote places) (Zadpoor, 2017).

On the other hand, inherent limitations of AM are easily recognizable, including limited part sizes, poor surface finish, high costs of some AM machines, the need for specific software resulting in possible extra high costs, and limited availability of starting materials. Because the TMJ implant is a relatively small implant, its size does not pose a problem. With the advantages and limitations taken into consideration, AM is often a preferred choice for single or small batch production, but not for mass production. Patient-specific designs are, therefore, particularly suitable for AM. Implants, such as TMJ implants, can be made for the reconstruction of the patient's anatomy with a precise fit assured. It is, however, important to note that these advantages and limitations only concern the manufacturing process and clinical benefits and efficacy for AM TMJ PSIs are not yet well documented in the open-access literature. The systematic review of Javaid and Haleem (2018) presents the general advantages of AM for medical devices, considering its ability to produce medical devices rapidly with complex geometries for personalized use. In addition, increased patient care, functional integration, better cost effectiveness for the hospital, and weight reduction are mentioned (Javaid and Haleem, 2018). Customized surgical guides, for example, can reduce surgery time and surgery-associated complications (*e.g.*, infections) (Zadpoor and Malda, 2017). The main advantages of AM for customized TMJ implants include a secure, comfortable fit to the shape of the mandible (Zheng et al., 2019a; Javaid and Haleem, 2019) at an acceptable price, considering its ability to create accurate implants instead of the ones with standardized sizes and its ability to convert complex designs into products within a reasonable time.

In the systematic review of Diment et al. (2017) published in 2018, of a total of 350 papers found on the clinical efficacy and effectiveness of 3D printing, only 14% clinical studies included control groups. Over 40% included individual case studies, of which 41% did not report on clinically relevant data. In total, only 12 concerned randomized trials, of

[1] Proposal for a Regulation of The European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions, European Commission, Brussels, 3 April 2020 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0144&from=EN.

Table 2
Papers on PSGs used on the mandible for mandibular reconstruction or for the distraction osteogenesis of the mandible.

Authors	Abou-ElFetouh et al. (Abou-ElFetouh et al., 2011)	Ciocca et al. (Ciocca et al., 2012)	Sun et al. (Sun et al., 2013)	Ayoub et al. (Ayoub et al., 2014)	Liu et al. (Liu et al., 2014)	Modabber et al. (Modabber et al., 2014)	Ciocca et al. (Ciocca et al., 2015)	Mottini et al. (Mottini et al., 2016)
year	2011	2012	2013	2014	2014	2014	2015	2016
# cases	2	1	6	10	15	2	5	1
# cases control	0	0	0	10	8	0	5	0
Type of surgery	Mandibular reconstruction	Mandibular resection	Distraction osteogenesis	Mandibular reconstruction	Mandibular reconstruction	Mandibular reconstruction	Mandibular reconstruction	Mandibular reconstruction
Material	Plastic (VisiJet SR 200)	Cobalt Chrome	Stereolithographic resin	–	DuraForm	Polyamide	–	Polyjet (MED610)
Printing process	MJM	DMLS	SLA	SLS	SLS	SLS	–	FDM
Follow-up	Yes, when is unknown	12 months	101 days	–	1 month	–	–	–
Complications	-	No	–	Yes	Yes	No	–	–
Clinical outcome data	Yes	Yes	–	–	Yes	–	–	–
Clinical outcome numbers/statics	No	No	–	–	Yes	–	–	–
accuracy of virtual surgery vs postoperative scan	Yes	Yes	Yes	Yes	Yes	Yes	Yes	–
OR/surgery time	Yes, reduced	Yes, reduced	–	Yes, not reduced	Yes, reduced	–	–	Yes. reduced
Radiation exposure	-	-	Yes	–	–	–	–	–
Costs	Yes	Yes	–	Yes	Yes	–	–	Yes
Blood loss	–	–	–	Yes	–	–	–	–

which only 57% included follow-ups (Diment et al., 2017). It states that in the studies that included a control group, reduced surgery time and better surgical accuracy were indeed achieved. However, an insufficient number of implants in comparison with the control group were studied to ascertain improved effectiveness in these clinical trials.

3. Clinical parameters

As mentioned earlier, PSGs are widely used and many benefits are naturally assumed. However, hard clinical evidence collected from clinical trials and studies seems to be lacking. Therefore, literature studies on the clinical use of both AM PSGs for mandibular surgery and TMJ PSIs is performed and clinical evidence reported in these papers was marked down. Information on the methodology on search and exclusion/inclusion criteria for the selection of the articles can be found in the supplementary document.

3.1. PSGs for mandibular surgery

In Table 2, we listed some of the most important clinical evidence that reported in the literature for the PSGs for mandibular surgery which can be summarized as follows: surgery time, the accuracy of the pre-operative surgery plan versus the post-operative location of the mandible, additional radiation exposure and the costs associated with the surgery.

Comparing these clinical evidence confirms that AM techniques can indeed be used for making surgical guides for mandibular surgery and good alignment can be reached (Table 2). Using AM techniques leads to reduced OR/surgery time. However, clinical outcome data, such as patients' outcomes, are often not given in detail as follow-up data. Surgical guides made by using the conventional manufacturing methods can be standardized ones or simply no surgical guides are used at all, solely relying on surgeon's experience. Comparing clinical outcomes of conventionally manufactured PSG with AM PSG can be dependent on several factors (*e.g.,* surgeon's experience, whether CT or radiographs are available, *etc.*) and therefore it is difficult. Only when more papers become available as those listed in Table 2 to provide more data, can the benefits of AM be validated. In addition, detailed description of the manufacturing process used is necessary, which can lead to enhanced reproducibility and broadened application of PSGs in the future.

3.2. Clinical outcomes of TMJ PSIs

The TMJ is one of the most used joints in the human body and temporomandibular joint diseases (TMD) are highly prevalent, especially in women aged 20–40. Using TMJ implants is the last treatment choice for the patients with TMD. AM TMJ PSIs have not been widely used yet and therefore only a number of papers on this topic have been published. Non-AM custom-made TMJ implants have already been commercially available and supplied by TMJ Concepts and Biomet Zimmer and these implants have been comprehensively discussed in (Mercuri, 2016a). A total of 27 TMJ implants existed (Elledge et al., 2019), of which 21 were custom-made. However, only 4 received regulatory approval (Elledge et al., 2019). Twelve of the 27 implants included additively manufactured parts. These customized implants for TMJ replacement were used with the following indications: incorrect fit with stock implants, or degraded anatomy of the patient due to, for example, bone tumor, unique anatomical features possibly due to having several surgeries, jaw mispositioning or demand for occlusion with jaw repositioning (Gerbino et al., 2017).

It has been reported (Zheng et al., 2019a, 2019b; Kozakiewicz et al., 2017; Ackland et al., 2017, 2018; Dimitroulis et al., 2018) that the visual analogue scales (VAS) were taken for rating pain, diet and function on a scale from 0 to 10, similar to data reporting on non-AM fabricated TMJ implants (Johnson et al., 2017). The mouth opening parameters, including the maximal interincisal opening (MIO), mouth opening deviation (MOD) to the diseased side, lateral movement to the diseased side (MDS), lateral movement to the normal side (MNS), and the mandible forward movement (MFM) (Zheng et al., 2019a) were the other clinical parameters reported in the past. To be able to compare post-operative range of motion (ROM) results with the values of healthy patients, the ROM data of the mandible were collected from several studies (Hochstedler et al., 1996; Dijkstra et al., 1998, 1999). It is however important to mention that even after an effective TMJ replacement, fully functional restoration of the TMJ is not feasible (Linsen et al., 2012). One study reported a healthy population having a mean mandibular MIO value of 54.4 mm, lateral movement to either the left or right side with a mean value of 12.2 mm and the forward movement, also called the protrusive movement with a value of 12.3 mm (Hochstedler et al., 1996). Another study reported a mean mandibular MIO value of 57.2 mm, lateral movement of either 9.9 or 9.7 mm and protrusion of 9.9 mm in people with good health (Dijkstra

Bosc et al. (Bosc et al., 2017)	Dahake et al. (Dahake et al., 2017)	Dell'Aversana et al. (Dell'AversanaOrabona et al., 2018)	Kraeima et al. (Kraeima et al., 2018)	Dupret-Bories et al. (Dupret-Bories et al., 2018)	Ren et al. (Ren et al., 2018)	Li et al. (Li et al., 2018)	Chen et al. (Chen et al., 2018)	Moa et al. (Mao et al., 2019)
2016	2017	2018	2018	2018	2018	2018	2018	2019
18	1	4	4	7	15	16	7	10
0	0	0	0	0	15	0	0	12
Mandibular reconstruction	Distraction osteogenesis	Mandibular reconstruction	Mandibular reconstruction	Mandibular reconstruction	Mandibular reconstruction	Distraction osteogenesis	Distraction osteogenesis	Distraction osteogenesis
	ABS	PLA	Polyamide	PLA polymer	Polyamide	Photo-sensitive resin	–	Bio-resin
MJM	FDM	FDM	–	FDM	SLA	–	–	–
19 months	20 days	13 months	–	–	1, 3 & 6 months	5–7 days	8 months	6 months
Yes	–	No	–	–	No	No	No	Yes
Yes	Yes	–	–	–	Yes	Yes	Yes	Yes
No	No	-	–	–	No	No	Yes	No
Yes	–	Yes	Yes		Yes	Yes	Yes	–
Yes	Yes, reduced	Yes	–	Yes, reduced	Yes, reduced	–	–	Yes, reduced
–	–	–	–	–	–	–	–	–
Yes	Yes	Yes	–	Yes	–	–	–	Yes
–	–	–	–	–	–	–	–	Yes

et al., 1998).

The ratio between the vertical and horizontal ROM (*e.g.* MIO: MFM) of the mandible was reported to be approximately 6:1 (Dijkstra et al., 1998). However, it should be taken into account that MIO is also influenced by the mandibular length and the angle of mouth opening (Dijkstra et al., 1999).

In 2017, a meta-analysis (Johnson et al., 2017) was performed on three commercially available non-AM fabricated TMJ implants, namely the patient-tailored TMJ Concepts implant, stock and customized Biomet implant and the Nexus CMF system (Table 4). However, the Nexus CMF system was removed from the market in 2019. No significant differences between the implants from these manufacturers were found in pain and diet results. Function data were only reported with the TMJ implants of Concepts. The mean MIO values post-operative were 34.55 mm, 38.33 mm and 27.57 mm for the Concepts, Biomet and Nexus implants, respectively (Johnson et al., 2017). Other ROM parameters were not given.

In comparing all clinical outcomes of AM TMJ implants made with non-AM techniques, it was noted that all the results of postoperative outcomes were within similar ranges and none of the implants were able to reach a ROM value as high as the healthy population. Based on the results obtained from the only two studies reported (Zheng et al., 2019a, 2019b) on MFM, it appears that with AM TMJ implants it is possible to attain a good ratio between vertical and horizontal mandibular ROM (Dijkstra et al., 1998), meaning that the movements in both superior-inferior and anterior-posterior directions are in proportion with each other. However, recently, the American Association of Oral and Maxillofacial Surgeons' TMJ Surgery ParCare guidelines have reported the MIO as an unrealistic goal, due to possible muscle loss. Rather, improved function, regarding mastication, deglutition, speech, and oral hygiene, is used for the evaluation of successful outcomes.

As mentioned earlier, the benefits of AM include design freedom, which is shown in (Zheng et al., 2019b) where the TMJ implant included a skull base for extensive defects of either the glenoid fossa or skull. The defects can be classified using a bipartite classification (Elledge et al., 2018), and implants can be designed and fabricated for different fossa and mandible defect sizes. A stock implant would not be sufficient here, since every patient's case is unique in relation to the severity and type of illness. The TMJ implant in this case is taken as an example to show what data have been published for one specific application so as to assess the completeness of clinical outcome data. Table 3 gathers the clinical data as the evidence reported in (Tack et al., 2016). As can be seen, none mentioned radiation exposure time or anything concerning the costs. Only one research paper reported on the surgery time (Zheng et al., 2019b). Additionally, blood loss during the surgery was only mentioned in one paper (Zheng et al., 2019b). To verify that the implant placement was in agreement with the pre-operative computational planning, and, therefore, the accuracy of the 3D printed part alignment, three papers showed post-operative radiographs (Ackland et al., 2017, 2018; Dimitroulis et al., 2018) and one showed a model made from the post-operative CT-scan (Zheng et al., 2019b). However, none of these studies gave any measurements, such as those publicated in other studies on TMJ PSI (Sembronio et al., 2019; Wolford, 2016). Due to this fact, none of the commonly expected benefits, *e.g.,* an affordable price, decreased surgery and/or production time and increased patient care (Javaid and Haleem, 2018), can be confirmed.

So far we have discussed some of the clinical outcomes mentioned in the literature. These clinical outcomes were supported by measurable data. Most importantly, only one paper (Kozakiewicz et al., 2017) used both AM and non-AM techniques to manufacture the implants, in which no statistical difference was found in MIO after surgery between these two techniques. Although the authors of all the papers mentioned the improvements in VAS and ROM measurements, thereby verifying safe and improved outcomes using the AM techniques, no conclusion can be drawn as to if AM implants indeed resulted in the better clinical outcomes than non-AM implants.

3.3. Preferred clinical outcome data

By now, AM implants and surgical guides have been used for several years, and much research has been carried out in this field, resulting in more than 270 papers on 3D printing applied to orthopedics alone (Vaishya et al., 2018), published till May 2018, with an increasing number of publications appearing every year since 2013.

In contrast to the expectations, the present literature search attempts for the published clinical data of PSGs for mandibular surgery and TMJ PSIs showed that the number of the results reported was similar to or worse than that previously mentioned (Tack et al., 2016), and much important data are still missing.

Obviously, to verify that AM is superior to the conventional methods, more clinical outcome data are needed. These data are essential for the validation to be made in further research in this regard and for the

Table 3
Papers on TMJ PSIs.

Authors	Ackland et al. (Ackland et al., 2017)	Kozakiewicz et al. (Kozakiewicz et al., 2017)	Ackland et al. (Ackland et al., 2018)	Dimitroulis et al. (Dimitroulis et al., 2018)	Zheng et al. (Zheng et al., 2019a)	Zheng et al. (Zheng et al., 2019b)
Year published	2017	2017	2018	2018	2019a	2019b
# patients	1	4 (+7 control)	1	38	12	5
# joints	1	4	1	50	12	5
Total/partial AM	Partial	Partial	Partial	Partial	Partial	Partial
Part AM	Condylar	Condylar	Condylar	Condylar	Condylar	Skull and ramus
Material AM	Ti6AL4 Alloy	Ti6Al4V alloy	Ti6AL4 Alloy	Titanium	Ti6AL4 Alloy	Ti6AL4 Alloy
Printer technique	SLS	DMSL	SLS	SLS	EBM	EBM
Follow-up	6 months	4–47 months	12 months	15.3 months	1 week, 1 month, 6 months & 12 months	Mean 13.6 months (rang 3–24)
Pain level preoperative	–	–	7.0	5.8 ± 2.5	7.17 ± 1.4	6.8 ± 1.9
Pain level postoperative	1.0	–	1.0	1.5 ± 1.8	0.67 ± 0.78	1.4 ± 0.4
Diet preoperative	–	–	–	7.4 ± 2.3	5.83 ± 1.95	7.2 ± 1.3
Diet postoperative	–	–	–	1.7 ± 1.5	1.17 ± 0.94	3.2 ± 0.8
Mandibular function preoperative	–	–	–	6.1 ± 1.7	6.0 ± 2.37	6.6 ± 2.1
Mandibular function postoperative	–	–	–	2.5 ± 1.3	1.75 ± 1.29	3.0 ± 0.7
MIO preoperative	–	18.0 ± 13.2 mm	22.0 mm	29.2 ± 8.9 mm	26.42 ± 9.30 mm	19.0 ± 9.6 mm
MIO Postoperative	40.0 mm	36.7 ± 7.4 mm	28.0 mm	38.2 ± 5.4 mm	39.25 ± 5.17 mm	28.6 ± 3.4 mm
MOD Preoperative	–	–	–	–	1.67 ± 1.37 mm	–
MOD postoperative	–	–	–	–	3.82 ± 0.98 mm	–
MDS preoperative	–	–	–	–	4.79 ± 2.17 mm	5.0 ± 2.6 mm
MDS postoperative	–	–	–	–	7.50 ± 1.54 mm	7.0 ± 1.0 mm
MNS preoperative	–	–	–	–	7.25 ± 2.21 mm	2.1 ± 1.1 mm
MNS postoperative	–	–	–	–	3.54 ± 1.10 mm	1.8 ± 0.8 mm
MFM preoperative	–	–	–	–	6.33 ± 2.14 mm	4.8 ± 2.8 mm
MFM postoperative	–	–	–	–	4.63 ± 1.75 mm	5.2 ± 0.8 mm
OR/surgery time	–	Reduced	–	–	–	4 h 45 min
Accuracy printed part	–	–	–	–	–	–
Radiation exposure	–	–	–	–	–	–
Costs	–	–	–	–	–	–
Blood loss	–	–	–	–	–	710 mL

Table 4
Meta-analysis data of Concepts, Biomet en Nexus TMJ implants (Johnson et al., 2017).

	Concepts	Biomet	Nexus
Total number of patients	$n = 312$	$n = 728$	$n = 125$
Total number of implants	505	1048	196
Mean follow-up time	6.32 years (1–21 years)	2.97 years	2.18 years
Pain difference pre- & post-operative	−5.61 (−6.43; −3.90) (*n = 274*)	−3.21 (−6.03; −0.40) (*n = 601*)	−5.05 (−5.87; −4.24) (*n = 102*)
Diet difference pre- & post-operative	−4.26 (−6.06; −2.45) (*n = 225*)	−5.51 (−6.70; −4.31) (*n = 624*)	–
Funtion difference pre- & postoperative	−3.50 (−5.07; −1.93) (*n = 189*)	–	–
MIO gain	8.99 (5.45; 12.54) mm ($n = 242$)	24.88 (2.91; 46.85) mm ($n = 601$)	9.50 (5.86; 13.14) mm ($n = 102$)
MIO post-operative	34.55 (33.29; 35.82) mm ($n = 242$)	38.33 (28,29; 48.37) mm ($n = 601$)	27.57 (24.02; 31.13) mm ($n = 102$)

validation of other patient specific medical devices. Moreover, these publicly available data are needed anyway for regulatory approval, since often small adaptions are made on previously used implants. This is important particularly for the proper selection of TMJ implants by the surgeons and patients (Elledge et al., 2019).

First of all, more data on the time management is necessary. Reduction in operation time is often mentioned as one of the benefits when PSGs are used. However, the surgery duration is rarely reported. Besides that, additional time for medical imaging, image processing and the modelling, production and delivery of patient specific medical devices are unknown in many cases. Obviously, extra time is needed for all these, incurring extra costs. Therefore, it is important to mention all additional pre-operative time and hospital stay for patients for the devices manufactured by using AM and the conventional methods.

In general, all the costs, including those for manufacturing, software, designing, material and delivering as well as those related to medical imaging and image processing, are important and need to be taken into account. The prices of AM medical devices still need to be reasonable and acceptable for their clinical applications on a daily basis. However, the costs will be different, per country, printer and sterilization option available. In any case, estimated costs for machine maintenance, man and machine hours, materials *etc.*, should be mentioned and compared to the costs of the conventional methods.

Clinical outcomes that are related to the patient experience, such as pain, restored functionality and the ability to perform daily activities, need to be mentioned. These outcomes are a decisive factor in many cases. For every application of an AM device, the patient performances pre- and postoperative need to be reported and compared to a control group to verify the assumed advantages of the AM medical device. The quality of life (QoL) can also be measured with the use of questionnaires at different follow-up times. An example of that is the modified SF36 questionnaire (Gupta et al., 2020). For the non-AM TMJ concept device, for example, it was reported that the QoL after a mean follow-up of 21 years increased in 48 patients, stayed the same in 6 patients and decreased in 2 patients (Wolford et al., 2015). Long term follow-up needs to take place to verify if the QoL develops in patients with AM TMJ PSIs.

In the case of joint replacement, ROM is an important parameter to assess. Quantified data like this can be compared in the studies where AM and the conventional methods are both used. When ROM scores are compared to patient QoL, an assumption can be made as to whether the

potential lower ROM than a healthy intact TMJ is satisfying enough for the patient. For a TMJ implant, the normal ROM value includes an MIO value of above 50 mm (Hochstedler et al., 1996; Dijkstra et al., 1998), however, a lower MIO value and no pain can still lead to a high QoL score.

To verify the preferred design, the accuracies of both the 3D printed part and pre-operative surgery planning compared to post-operative outcomes (*e.g.* the alignment) are important for engineers. The accuracy in the alignment can verify accurate placement, while extra CT-scan and associated radiation exposure are needed for this purpose.

Radiation exposure reported in (Tack et al., 2016) is barely mentioned in the literature on both AM PSGs and TMG PSIs. Additional radiation exposure needs to be mentioned and must be within reasonable quantities. Extra radiation exposure occurs due to additional medical images both pre- and post-operative.

Finally, complications, infections and possible revisions always need to be mentioned to warn other surgeons and engineers about potential hazards. These points were comprehensively discussed in other literature (Mercuri, 2016a, 2016b; Hoffman and Puig, 2014).

By now, additively manufactured TMJ implants have been clinically used for over 5 years. More long-term follow-ups should be available and need to be published to compare them with those of the previous generation of TMJ implants. Such data will be important for the approval by the EU Commission and the FDA. The outcomes regarding long-term complications, loosening of implants, bone ingrowth and possible late infections, are all meaningful to collect. The ability to compare several studies also relies on the availability of 3D printing data. The material, process and post-processing conditions and parameters are recommended to be published so that in further studies these data can be compared with each other.

4. Conclusion

AM has the ability to manufacture patient-specific surgical guides and implants at relatively low costs. This technology has been increasingly used over the last decades. However, the data published on its application to TMJ PSIs and PSGs for mandibular surgery are often incomplete in relevant clinical outcomes. This is clearly shown by the literature studies on the AM PSGs for mandibular surgery and AM TMJ PSIs. Therefore, it is obvious that more data regarding the patients' outcomes, the patient satisfaction, accuracy regarding the implant's placement, time management and the overall costs incurred in clinical trials are all needed for comparison with those achieved with the counterparts made with the conventional manufacturing methods.

In the future, more clinical outcomes and measurements should be available, including all the information mentioned above, since these data are also needed for regulatory approval. Besides that, more data and control groups will allow for more meta-analysis options, which can be used to verify the beneficial use of AM in the case of PSIs and PSGs.

Author statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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