Medical three-dimensional printing

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Policy contains: Additive manufacturing; craniofacial surgery; customized implant; knee surgery; maxillofacial surgery; spinal surgery; three-dimensional printing.

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Coverage policy

Three-dimensional printing (i.e., additive manufacturing) of anatomic structures for surgical planning, implant templating, procedural guidance, or customized implants is considered experimental/investigational and not clinically proven.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Medical three-dimensional printing, also called additive manufacturing, produces a three-dimensional object from a digital file of high-quality data collected from multiplanar imaging (Ballard, 2018). Most systems involve separating a digital design file into two-dimensional layers, building a three-dimensional object from raw material

one layer at a time, and joining them to the layer directly below. Three-dimensional printing adds material only where necessary (i.e., additive), unlike conventional manufacturing, which cuts and shapes an object from a solid block of material (i.e., subtractive).

A range of methods and materials can produce three-dimensional devices with potential application in patient education and medical education and training. Clinical applications that have the potential to improve patient outcomes and increase economic feasibility include surgical planning, intraoperative guidance, and individualized implants (Kim, 2016). In addition, three-dimensional printing with cells (bioprinting) may allow for regenerative scaffolds and cell-specific replacement tissue and organs.

Three-dimensional devices are classified as implantable or nonimplantable, and patient-matched (or patient-specific) or non-patient-matched (Di Prima, 2016). The term "patient-matched" is often used interchangeably with the term "custom," but, for regulatory purposes, they are not synonymous (U.S. Food and Drug Administration, 2017). Custom devices may be exempt from premarket approval requirements and review if they meet all of the following criteria:

- Are created or modified to comply with the order of an individual physician or dentist.
- Do not exceed five units per year.
- Are reported by the manufacturer to the U.S. Food and Drug Administration for devices manufactured and distributed under section 520(b) of the Food, Drug, and Cosmetic Act.

Patient-matched devices do not automatically meet all of these requirements. Patient-matched devices are typically based on an existing, standardized template model that is matched to a patient with normal bone or joint anatomy using medical imaging (U.S. Food and Drug Administration, 2017).

Findings

Guidelines

The Radiological Society of North America 3D Printing Special Interest Group guidelines recommend the use of three-dimensional printing for several specific clinical scenarios. For congenital heart disease, three-dimensional printing is highly recommended, with a rating of 7 to 9, for preoperative planning, particularly in complex cases such as septal defects and transposition of the great arteries, as it can significantly reduce operation and cardiopulmonary bypass time (Chepelev, 2018). In craniomaxillofacial pathologies, three-dimensional printing is advised for both trauma and congenital malformations, aiding in both functional and aesthetic restoration, with differentiation between simple and complex cases (Chepelev, 2018).

For musculoskeletal pathologies, three-dimensional printing is recommended for fractures, chronic osseous abnormalities, and preoperative planning, enabling the creation of custom implants and surgical guides to improve surgical outcomes and reduce operating time (Chepelev, 2018). Vascular pathologies, especially complex aortic aneurysms and dissections, benefit from three-dimensional printing for preoperative planning and simulation, aiding in device selection and understanding complex anatomy. In genitourinary pathologies, three-dimensional printing is useful for complex kidney tumors and other urological conditions, enhancing anatomical comprehension and surgical planning to improve patient outcomes (Chepelev, 2018). Lastly, for breast pathologies, three-dimensional printing aids in depicting the extent of disease and planning oncologic and reconstructive surgeries, potentially reducing operating time and improving patient outcomes (Chepelev, 2018).

Systematic reviews and meta-analyses

For this policy, we included evidence from several systematic reviews and meta-analysis, which are discussed below. The clinical applications of three-dimensional printing fall into two general categories: procedural uses and material uses. We considered the role of three-dimensional printing in surgical planning, implant templating,

procedural guidance, and customized implants. The most common clinical applications represented in the literature are craniomaxillofacial reconstruction, orthopedic repair and replacement, and spinal surgery, which are discussed below. Other emerging specialty areas include surgery for congenital heart defects (Lau, 2019), colorectal surgery (Emile, 2019), and nephrectomy (Jiang, 2020; Sun, 2018).

While the evidence from systematic reviews and meta-analysis confirms the expanding interest and role in three-dimensional printing across multiple disciplines, it also confirms the paucity of high-quality research supporting the medical necessity of three-dimensional printed materials and procedural uses at this time. Pre-surgical three-dimensional models and anatomic guides may improve intraoperative metrics and surgical outcomes by making the procedure safer and more predictable. Compared to off-the-shelf products, customized three-dimensional printed materials may offer improved fit and functional outcomes and the ability to address unique and complex anatomy.

However, the research has failed to clearly delineate a clinical advantage of three-dimensional printing relative to conventional procedures and materials, which would require higher quality comparative trials. Limitations to the research include the diversity of workflows and applications involving different materials, printers, and testing methods. In addition, the custom-made nature of implants prevents meaningful comparison of three-dimensional printed interventions to conventional interventions and off-the-shelf products.

Three-dimensional printing provides an opportunity to customize upper limb prostheses, but the evidence consists of case studies and small case series that lack external validity and avoidance of bias. The evidence fails to demonstrate statistically significant improvements in comfort, functionality, durability, and long-term effects on patient quality of life compared to conventional prostheses (Diment, 2018).

A systematic review (Francoisse, 2021) examined pediatric applications of three-dimensional printing from 139 low-quality observational studies (n = 508 total pediatric participants). Six of the studies compared three-dimensional printing to conventional methods for procedural outcomes. Three-dimensional printed contour models, guides, splints, and implants were at least equivalent to conventional methods, with shorter operating time and fluoroscopy exposure, more accurate hardware placement, and fewer complications. The results highlighted the potential of three-dimensional printing to address challenges unique to the pediatric population, such as compact anatomy, unique congenital variants, greater procedural risk, and growth over time.

Craniomaxillofacial surgery

In oral and craniomaxillofacial surgery, three-dimensional printed bone models were mainly used as training or simulation models for tumor removal, bone reconstruction, or complex deformity (Meglioli, 2020). In mandibular reconstruction, a systematic review and meta-analysis (Serrano, 2019) found that the most frequently reported clinical outcomes were a reduction in operating time (reported in 35.7% of studies) and an improvement in the final aesthetic result (28.6%).

Focusing specifically on orbital surgery, a 2024 review of 12 investigations (n = 132) demonstrated that patient-specific, three-dimensionally printed models, guides, and implants significantly improve quantitative outcomes. For fracture repairs, implants pre-contoured on printed templates reduced mean operating times by approximately 30 minutes compared to standard methods, with postoperative diplopia and enophthalmos rates below 12%. Reconstructions for tumors and congenital defects achieved near-symmetrical orbital volumes and high aesthetic satisfaction. These findings support 3D printing as a valuable adjunct for streamlining workflows and heightening surgical accuracy in orbital surgery (Michelutti, 2024). Similarly, a large 2022 meta-analysis of 906 participants found that groups using 3D-printed orbit models were less likely to have postoperative diplopia ($P < .001$) and enophthalmos ($P < .001$); however, the authors noted the contribution of 3D printing alone to these improvements remains unclear due to a lack of controlled studies (Murray-Douglas, 2022).

For nasal prostheses, evidence from three systematic reviews (Crafts, 2017; Martelli, 2016; Tack, 2016) consist of animal modeling studies, technical feasibility reports, and a low-quality retrospective case series and case reports. Currently, most otolaryngologic applications for three-dimensional printing are at preliminary stages of development, as manufacturing processes continue to be refined. Three-dimensional printing can produce accurate, patient-specific nasal prostheses, which may be particularly helpful to individuals with unique anatomies, but their superiority to conventionally manufactured prostheses has not been demonstrated. Reducing malalignment does not automatically result in improved clinical outcomes (e.g., better fit, comfort, or satisfaction), and long-term revision rates (i.e., prosthesis survival) have not been reported. Mismatched skin tone is a major limitation of three-dimensionally printed facial prostheses. Whether the additional upfront costs of three-dimensional printing result in lower overall costs of care is unclear. Beyond reconstruction, evidence also addresses the use of 3D printing for dental prosthetics, with a 2022 systematic review of 16 studies determining that additive manufacturing for implant-supported fixed prostheses demonstrates similar accuracy as conventional and computer-aided design / computer-aided manufacturing techniques in vitro (Rutkunas, 2022).

Breast Reconstruction

In the realm of soft tissue procedures, recent evidence details how 3D printing can enhance the complex planning and execution of autologous breast reconstruction. A review of 13 studies showed that patient-specific 3D models improved outcomes; for instance, vascular guides depicting deep inferior epigastric perforator anatomy increased successful flap harvests to 90% from 58.6% and reduced intramuscular dissection time. Furthermore, volumetric breast molds achieved a coefficient of determination of 0.99 between predicted and actual flap weights, helping surgeons reproduce native breast symmetry with high fidelity. With complication rates matching those of conventional imaging, these findings underscore the technology's safety and effectiveness in improving anatomical accuracy and operative efficiency, though further trials are needed to confirm patient-centered and economic benefits (Carrion, 2024).

Orthopedics

Three-dimensional (3D) printing has several clinical applications in orthopedics, including surgical planning, implant templating, and the anatomical assessment of pathologies. Increasingly, custom-made, 3D-printed, patient-specific metal implants and instruments are being studied for complex procedures such as pelvic oncologic resections and revision hip arthroplasties (Goodson, 2019).

Multiple systematic reviews and meta-analyses suggest that 3D printing-assisted preoperative planning improves intraoperative metrics when compared to conventional methods. For instance, in cases of tibial plateau fractures, a meta-analysis of 1,074 patients found that 3D-assisted surgery significantly reduced operation time, blood loss, and fluoroscopy use (Assink, 2021). Similarly, for acetabular fractures, 3D printing-assisted surgery decreased operation time by an average of 38.8 minutes and blood loss by 259.7 mL, with traditional surgery being 47% less likely to result in good to excellent hip function (Cao, 2021). This trend of improved intraoperative efficiency, including reduced operative time, blood loss, and fluoroscopy use, has also been noted in foot and ankle fracture surgeries (Wood, 2022).

Despite these intraoperative benefits, the effect of 3D printing on clinical outcomes, such as fracture healing time, postoperative joint function, and complication rates, is not yet well-defined. The variability in these results is likely influenced by factors like the location and complexity of the fracture (González-Alonso, 2020; Wang, 2020; Xie, 2018). Consequently, researchers across all analyses recommend large-sample randomized controlled trials to definitively establish the superiority of 3D printing-assisted orthopedic surgery. A health technology assessment (DEFACTUM, 2019) of six randomized controlled trials and two systematic reviews found very low-quality to low-quality evidence supporting the superiority of three-dimensional printed guides or implants over standard instrumentation with respect to malalignment and deviation in adults undergoing total

knee arthroplasty for osteoarthritis or rheumatoid arthritis. The limitations of the evidence were a high risk of bias and imprecision of the estimates in the included studies. The authors called for higher quality evidence to validate these findings. Further exploring hip surgery, a 2024 systematic review of 62 studies (n = 1,065) highlighted the potential benefits of 3D printing for surgical precision, reduced operation time, and minimized radiation exposure across various applications, including osteotomies and arthroplasties, while also emphasizing the need for more high-quality, randomized studies to conclusively establish these advantages (Aguado-Maestro, 2024).

Spinal surgery

Spinal implants fall into two categories: fusion (cages, plates with screws, rods with hooks, and pedicle screws) and non-fusion (artificial discs and expandable rods). Medical-grade titanium and polyether ether ketone are widely used for conventional off-the-shelf implants. Three-dimensional printed implants can be designed for complex tumor pathology and atypical bone defects that are considered difficult to treat or that have additional features, such as preplanned screw trajectories or conformities. In an appropriately selected patient, three-dimensional printed patient-specific spinal implants may improve outcomes in terms of surgical efficiency, stability, and potential osseointegration. Randomized controlled trials are needed to confirm these findings.

Two systematic reviews compared the safety and efficacy of three-dimensional printed patient-specific and off-the-shelf devices (Burnard, 2020; Wallace, 2020). The evidence consists of case reports and case series focused on patient-specific titanium implants for anatomically complex cases. Three-dimensional printed products appear safe with positive subjective feedback from surgeons and patients. However, the clinical and radiographic outcomes, particularly long-term data, are still uncertain.

Another systematic review of adults with spinal deformity (Lopez, 2020) compared the effects of using a three-dimensional printed drill guide template with not using such a template. The use of the template was associated with higher screw placement accuracy (96% versus 81.5%, $P < .001$, n = 22 studies), lower operative duration (272 versus 258 minutes, $P < .05$), and similar perioperative blood loss (924.6 mL versus 935.6 mL, $P = .058$). A three-dimensional printed drill guide template had a favorable deformity correction rate (n = 245 participants, 72.5%). Influential variables were the types, materials, and manufacturing costs and times of three-dimensional printed technology.

Reinforcing these findings, a large 2025 review of 105 studies (n = 2,088) confirmed the clinical utility of 3D printing in spine surgery. Patient-specific drill guides were the most common application (53%), followed by anatomical models (25%) and customized implants (16%). Shorter operative times were noted in 88% of studies, and the vast majority (102 of 105 studies) reported satisfactory or superior outcomes versus conventional techniques, especially in pedicle screw accuracy. However, the review also highlighted a significant challenge: while 52 of 60 studies that assessed costs reported higher expenditures, only 8 noted savings, indicating that while 3D printing increases surgical precision and efficiency, its cost-effectiveness remains uncertain and requires further evaluation (Hajnal, 2025).

In 2025, we revised the findings section thematically and added several new references (Carrion, 2025; Hajnal, 2025; Michelutti 2024). No policy changes were warranted.

References

On June 5, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “three dimensional," “printing,” “additive manufacturing,” and “printing, three dimensional” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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