The Emerging Roles for 3 Dimensional Printing in Orthopedics

Applications, Evidence, and Future Directions

David M. Bennett, MD[a], Romie F. Gibly, MD, PhD[b,*]

KEYWORDS

• 3D printing • Additive manufacturing • Patient-specific instrumentation • Orthopedic surgery • Cost-effectiveness

KEY POINTS

- Point-of-care 3 dimensional (3D) printing allows surgeons to create patient-specific models, guides, and splints that shorten operative time and improve precision.
- Meta-analyses show consistent reductions in blood loss and operative duration when 3 D printing is used for complex fractures.
- Hospital-based printing programs must implement quality systems and understand Food and Drug Administration/European Union (EU) exemptions before manufacturing clinical devices.
- Custom-printed metal implants are transforming revision and tumor reconstruction yet remain limited to specialized centers.
- Future advances promise greater personalization but require tempered expectations and rigorous evidence.

INTRODUCTION

The technology of additive manufacturing ("3D printing") uses digital models to construct objects layer-by-layer.[1] Within orthopedic surgery, 3 dimensional (3D) prints were initially used for surgical planning and visualization, but advancements have introduced patient-specific instruments (PSI),[2] custom implants,[3] durable medical equipment,[4] and high-fidelity teaching models[5] to enhance surgical learning.[6] An explosion of literature demonstrates both benefits and limitations; notably, 3D printing has reduced operative time,[7] blood loss,[8] and complications in complex cases.[9] Nevertheless, widespread adoption is challenged by institutional inertia, regulation, and perceived technical expertise requirements.[10–13] Upfront expenses can be offset by downstream savings from shorter surgeries and fewer complications.[14,15] Point-of-care 3D printing outside of planning and visualization needs rigorous quality control and regulatory compliance.[10,16,17] This review summarizes current orthopedic applications—including customized surgical guides, implants, bracing, and educational models—and addresses material and regulatory factors.[3]

[a] Department of Orthopaedic Surgery, Phoenix Children's Hospital / University of Arizona, Mayo Clinic, Barrow Neurological Institute, Creighton, Phoenix, AZ, USA; [b] Department of Orthopaedic Surgery, Division of Orthopaedic Surgery and Sports Medicine, Northwestern University Feinberg School of Medicine, Ann and Robert H Lurie Children's Hospital of Chicago, Chicago, IL, USA
* Corresponding author. Department of Orthopaedics, Phoenix Childrens Hospital, 1919 E. Thomas Road, Phoenix, AZ 85016.
E-mail address: rgibly@luriechildrens.org

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Abbreviations	
3D	3 dimensional
IRB	Institutional Review Board
MDR	Medical Device Regulation
PSI	patient-specific instruments
QA	quality assurance

PATIENT-SPECIFIC SURGICAL GUIDES AND INSTRUMENTATION (PATIENT-SPECIFIC INSTRUMENTS)

Beyond visualization and planning, 3D printing is increasingly used to create patient-specific surgical guides and instruments, a field experiencing rapid commercial growth.[18] These guides are custom-designed to help surgeons perform precise actions such as cutting or drilling at locations and orientations matched to the patient's unique anatomy. Common PSI examples include cutting guides for osteotomies (eg, high tibial osteotomy, double forearm osteotomies,[19] and pediatric limb deformity corrections), drill guides for challenging screw placements like the spine,[20] and tumor resection guides for accurate bone cuts with proper margins.[21] The workflow involves processing patient imaging to virtually plan cuts or drill trajectories, designing a guide that fits the bone surface and aligns the tool to the planned path, then printing the guide in biocompatible, sterilizable material.[18] In the operating room, the guide fits onto bone landmarks, allowing cuts or drilling through guide slots or sleeves, greatly improving efficiency, accuracy, and reproducibility.[7] PSI reduces alignment errors in complex osteotomies and pelvic fractures versus freehand techniques.[19,22] In pediatrics, PSI aids screw placement in narrow, hard-to-image areas such as congenital scoliosis vertebral pedicles.[7,23]

PSI also saves operative time and radiation exposure by reducing repeated measurements and fluoroscopy during surgery.[24,25] Beyond static guides, custom patient-matched reduction clamps, aiming devices, and instruments like acetabular reamers adapted to anatomy have been developed.[26] For instance, patient-specific drill guides for slipped capital femoral epiphysis can be used for precise screw placement across the femoral epiphysis in adolescents, minimizing malposition risk.[27] In reconstruction, custom cutting jigs facilitate precise cuts matching prefabricated implants or allografts.[28] Benefits are greatest where standard instrumentation fails to accommodate for anatomic variability. Improved accuracy may lead to better alignment, union, or tumor clearance depending on use. However, PSI creation demands preoperative effort and time, making it suited primarily for elective or complex cases. The significant technical and engineering skills needed mean that most PSI is produced commercially.[4]

CUSTOM IMPLANTS

A highly specialized application of 3D printing in orthopedics is producing custom implants.[29] Traditional implants like plates, rods, or prostheses come in standardized sizes, which may not fit patients with significant bony deformity, massive bone loss from trauma or tumor, or unusual anatomy. Three-dimensional printing allows creation of implants tailored to the patient rather than forcing conformity to standard shapes.[30] This is especially useful in orthopedic oncology and revision arthroplasty, where large bone defects require implants precisely fitting the defect with optimized fixation points. Patient-specific acetabular implants have been used when off-the-shelf options fail. Three-dimensional-printed reconstructions for bones like the scapula or distal femur posttumor resection achieve improved joint contour and soft tissue attachments. Custom total knee implants that minimize bone resection, talar body implants replacing necrotic talus, and patient-specific spinal cages and plates for complex cases have also been developed.[4,27] Porous lattices and biomimetic structures incorporated into titanium alloy implants facilitate bone ingrowth, soft tissue attachment, and reduce weight, surpassing traditional manufacturing capabilities.[31] Many modern implants feature 3D-printed porous surfaces for these advantages. Challenges include high costs, regulatory and logistical hurdles, and the need for industrial-grade metal printers.[32] Most patient-specific permanent implants are made by specialized companies or research laboratories rather than hospitals. Pilot projects have 3D-printed titanium spinal cages or hip implants on-site under compassionate use exemptions,[32–35] but regulatory and quality demands limit in-hospital implant fabrication. Currently, surgeons mainly use 3D printing for custom implants and guides via industry collaboration, while simpler aids like models can often be made in-house.[4,21,33,36–39] The majority of current 3D-printed implants is made from metals such as titanium, and less commonly cobalt-chrome and stainless steel. There are biodegradable metals such as magnesium and zinc alloys that can resorb over time.

These metal-based technologies require much more complex and expensive printing infrastructure. Polyetheretherketone is a biocompatible thermoplastic that can be 3D printed that is commonly seen in suture anchor implants. Other biocompatible and biodegradable plastics such as poly(lactic acid), poly(glycolic acid), and polycaprolactone, as well as other newer emerging bioplastics are being investigated and are in early use. These bioplastics offer the potential for simpler printing infrastructure and could open the door to more accessible implant printing. As printers and regulations evolve, on-demand hospital production of implants may increase.

CASTS, SPLINTS, AND ORTHOTIC DEVICES

Three-dimensional printing is increasingly used in orthopedics beyond the operating room to fabricate external devices such as casts, braces, and orthoses.[4] Traditional casts and splints can be bulky, and off-the-shelf orthotics often lack individualized fit.[40,41] Skilled orthotists may not be widely available. Using 3D scanning and printing, lightweight, ventilated casts, or braces can be tailored to a patient's limb contours.[4,42–44] Commercially, custom lattice-designed wrist and forearm casts offer lighter, breathable, water-resistant immobilization, improving comfort, especially in pediatric fracture care.[26,45] Three-dimensional-printed ankle-foot orthoses for children with cerebral palsy are digitally designed to match foot and ankle anatomy precisely and allow appealing cutouts or designs, improving acceptance compared to generic braces.[45–47] Custom insoles based on foot pressure scans better offload diabetic ulcers and pressure points than standard insoles.[48] Prosthetic sockets, crucial for amputee comfort and function, can be customized by scanning the residual limb and printing a well-fitted socket, potentially shortening fabrication and easing adjustments.[40,48] Additionally, 3D-printed scoliosis braces that are less bulky and more ventilated improve wear tolerance over traditional thoracolumbosacral orthoses.[46] Even simple devices like ergonomic grips for crutches or tools can be custom-made for patients with limb deformities or contractures.[48] The primary benefit of 3D-printed orthotics is personalization, yielding better fit, function, and comfort, alongside design innovations like lightweight lattices unavailable via traditional methods.[4]

Workflow requires 3D scanning or precise measurements and access to printers producing durable, skin-safe products.[47] Turnaround can be rapid, hours to days, benefitting acute fracture care.[26] Some hospitals and clinics already offer 3D-printed casts or braces on a limited scale.[43] Patients appreciate the modern appearance and comfort, though insurance and cost remain barriers.[3] Particularly in pediatrics, 3D printing offers colorful, lighter casts and highly customizable braces enhancing patient experience.

ECONOMIC AND REGULATORY CONSIDERATIONS

Cost-effectiveness and Economic Impact

Sustainable adoption of new medical technology requires assessing cost-effectiveness. Although 3D printing adds a step to preoperative planning, evidence suggests upfront costs are offset by downstream savings and improved efficiency. The clearest economic benefit is reducing costly operating room time and complications. A 2016 UK study estimated orthopedic operating room cost around £24.77 (~$33.50 USD) per minute, while US operating room time can reach US$750 per 15 minute block.[49] A pooled analysis found printed models and guides cut operative time by about 23 minutes, yielding savings exceeding printing costs.[50] For example, producing a 3D-printed scaphoid nonunion surgical guide costs about US$300 but saved roughly 30 minutes of surgical time (worth >US$600), outweighing the guide's cost.[51] Meta-analyses conclude 3D printing is cost-effective in fracture surgery when considering the entire care episode.[52] Patients benefit from shorter surgeries and fewer complications, resulting in reduced hospital stays and costly adverse events.[4] While initial point-of-care capital investment once exceeded US$100,000, an entry-level 3D printing setup can be started for less than US$2000. Benefits include improved preoperative planning, reduced surgical trial-and-error, enhanced precision, and lower complication rates, leading to long-term health care savings.

Beyond clinical cost savings, point-of-care manufacturing improves supply-chain efficiency.[4] Traditional supply chains require ordering standardized products from vendors and maintaining inventory. Hospital-based 3D printing enables on-demand production, such as same-day printing of custom drill guides or cast wedges, eliminating ordering, manufacturing, and shipping delays. This agility is vital in urgent cases, resource-limited settings, or supply shortages. During the early coronavirus disease 2019 pandemic, hospitals with 3D printers alleviated supply issues by locally producing personal protective equipment.[4]

Regulatory and Quality Considerations

Hospitals or surgeons producing medical devices with 3D printers must navigate complex regulatory frameworks ensuring patient safety. Any invasive item, such as instruments, cutting guides, or implants, is classified as a "medical device" and regulated by bodies like the US[4,16] FDA and European Medicines Agency. Considerations include whether devices are used within the same institution for specific patients (potentially qualifying as custom-made under health care facility exemptions) versus distribution outside, which subjects the hospital to full regulatory approval.[16,53] The EU's Medical Device Regulation (MDR 2017/745) Article 5(5) allows hospitals a "health institution exemption" to 3D-print custom devices for in-house use if they maintain a quality management system, do not transfer devices elsewhere, meet MDR safety and performance requirements, and justify why off-the-shelf alternatives fail the patient's needs.[16] The FDA expects point-of-care manufacturing to implement quality controls (eg, ISO 13485 compliance), with risk-based regulation; high-risk implants require stricter oversight than printed anatomic models for planning.

Table 1 outlines major economic and regulatory challenges in adopting 3D-printed instruments, intraoperative guides, or implants in pediatric orthopedics. It highlights financial burdens from equipment and operational costs, uncertainty in reimbursement pathways, and complexities related to intellectual property and liability. Critical regulatory needs include navigating FDA-approval processes, ensuring sterilization and quality assurance (QA), and securing institutional oversight. Successful implementation demands coordinated financial planning, regulatory compliance, and structured institutional support encompassing staffing, training, and workflow integration.

Setting up on-site point-of-care 3D printing for implants and instruments is challenging.[15] Table 1 summarizes issues, implications, and mitigation strategies. Every step, from converting imaging to printable models, printer calibration and maintenance, to postprocessing and sterilization, requires strict control to ensure accuracy and safety.[54–56] Poorly printed devices risk inaccuracy or contamination that could harm patients. Regulatory concerns also cover intellectual property and design validation.[17] New implant or instrument prototypes intended for patient use generally require institutional review board (IRB) approval and potentially FDA investigational device exemption.[57] Hospitals manufacturing 3D-printed devices face stringent sterilization and quality system standards, meticulous regulatory documentation, costly and time-sensitive Investigational Device Exemption processes, and the need to protect intellectual property and operational freedom.[10,33,57]

Hospitals adopting point-of-care 3D printing should collaborate closely with administration and regulatory bodies. This involves establishing standard operating procedures, staff training, QA testing, and securing institutional approvals for clinical use. In-house manufacture of medical devices carries responsibilities for documentation, traceability, and quality control.[17] Regulators increasingly recognize the value of 3D printing in medicine and are developing clearer guidelines, while international standards bodies create technical standards for health care additive manufacturing.[10] As regulations mature, compliance should become easier without hindering innovation. Current challenges such as acquiring expertise, ensuring quality systems, and meeting regulatory requirements are manageable with proper oversight as this technology integrates into routine care.[17]

Despite enthusiasm, clinical and institutional integration requires rigor similar to other new technologies. Cost-effectiveness analyses are limited, mostly based on single-center or short-term data. Reported efficiency gains often come from well-selected cases or experienced centers. Reliable value assessment needs large, multicenter studies analyzing direct and indirect costs, validated outcome measures including patient-reported outcomes, and long-term follow-up. Surgeons and administrators should consider 3D printing an evolving adjunct to standard practice until more robust data emerge.

EMERGING DEVELOPMENTS AND FUTURE DIRECTIONS

The role of 3D printing in orthopedics is set to expand significantly. Ongoing advances in software automation, material science, and printer reliability will simplify workflows and reduce entry costs. AI-assisted segmentation and design tools are likely to shorten preparation time and standardize model generation, helping smaller programs establish point-of-care capability. As sterilizable and bioactive materials mature, applications will broaden from planning and simulation toward in-hospital production of patient-specific devices. If regulatory challenges are overcome, a future with patient-specific

Table 1
Economic and regulatory considerations for integrating 3 dimensional printing in pediatric orthopedics

Topic	Issues	Practical Implications	Strategies for Mitigation
Capital investment	Equipment, software licenses, and training	High upfront expenses may strain budgets	Consider shared facilities, phased acquisition, or grant
Operational costs	Materials, maintenance, and staff time	Recurring expenses affect sustainability	Track cost per case; optimize print utilization
Reimbursement	Limited or absent coding	Financial returns are often uncertain	Advocate for Current Procedural Terminology code expansion; bundle costs
Intellectual property	Proprietary sharing and design ownership	Risk of disputes over intellectual property	Develop clear institutional policies and agreements
Liability and risk	Device failure and patient safety	Potential medico-legal exposure	Document quality assurance process; align with device standards
Regulatory approval	FDA pathways (IDE, 510k, and exemptions)	Complex slow implementation	Engage regulatory experts early; validated workflows
Sterilization and quality assurance	Validation of sterilization for prints	Noncompliance could bar clinical use	Establish Standard Operating Procedures with infection control and Sterile Processing Departments
Staffing and training	Expertise in segmentation, Computer-Aided Design, and printing	Lack of skills delays integration	Provide structured training, partnerships, and continuing education
Workflow integration	Data transfer, compatibility, and operating room logistics	Breakdowns increase turnaround time	Standardize Digital Imaging and Communications in Medicine pipelines; formalize hand-offs
Institutional oversight	Institutional Review Board (IRB), ethics boards, and hospital compliance	Approvals may delay patient-specific use	Early engagement of IRB and compliance committees

biodegradable implants that function during healing and then dissolve may become reality.[31,58,59] Early versions, like absorbable polymer suture anchors and magnesium screws, are already in research and limited clinical use.[31,59] Three-dimensional printing has transitioned from experimental novelty to routine orthopedic adjunct with enormous growth potential. Success will depend on collaboration between surgeons, engineers, and radiology and quality teams to maintain safety and regulatory alignment. Lessons from early institutional programs now provide a practical framework for scaling printing responsibly within routine orthopedic care. Three-dimensional printing is a growing, valuable tool enhancing the art and science of musculoskeletal treatment. When used thoughtfully, 3D printing is a valuable and growing addition to the orthopedic surgeon's toolbox, enhancing the art and science of musculoskeletal treatment.

CLINICS CARE POINTS

- Not every case needs 3D printing, prioritize its use for situations where standard instruments or implants are insufficient (complex deformities, tumors, and unique anatomy). In routine cases, the added time and cost may not provide benefit.
- Consider using commercial 3D-printed PSI or models and guides for challenging cases, and if interested in using them more often, explore the possibilities of point-of-care hospital-based printing.

- Harness a multidisciplinary team for hospital-based 3D printing. Engage regulatory officers, radiology, engineering, and sterile processing early when developing new workflows to align safety, data handling, and sterilization standards.
- For point-of-care programs, establish a quality-control checklist for each print, including verification against imaging, labeling, and basic dimensional checks while keeping centralized records of materials, printer settings, and model versions to ensure traceability and reproducibility.
- Educate patients and obtain informed consent when using 3D-printed aids in surgery. Explain how a 3D model or guide will be used to improve their care; patients are often receptive and may value the personalized approach, but they should understand it is an adjunct, not a magic solution.

DECLARATION OF ARTIFICIAL INTELLIGENCE AND ARTIFICIAL INTELLIGENCE-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this article, the authors used Gen AI. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

DISCLOSURE

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