INTERNSHIP TRAINING

AT

ANVKA HEALTHCARE PVT LTD

(20 JAN 2026 – 10 MAY 2026)

"Patient Specific Implants in India and Developed Markets: Adoption, Barriers, And Future Prospects: A Secondary Review"

BY
SAKSHI MUGDHA
PG/24/093

Under the guidance of

DR. SHIKHA BASSI

PGDM (HOSPITAL AND HEALTH MANAGEMENT)

2024-2026

International Institute of Health Management Research New Delhi

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Annexure D: Completion of dissertation certificate

The certificate is awarded to

Name: SAKSHI MUGDHA

in recognition of having successfully completed his/her internship in the department of

Title: Patient Specific Implants in India and Developed Markets: Adoption, Barriers, and Future Prospects

and has successfully completed his/her Project on

Patient Specific Implants in India and Developed Markets: Adoption, Barriers, and Future Prospects

Date: 10th May 2026

Organization: ANVKA Healthcare Pvt Ltd

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

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Academic and Student Affairs
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The following dissertation titled **"Patient Specific Implants in India and Developed Markets: Adoption, Barriers, and Future Prospects"** at **"ANVKA Healthcare"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **PGDM (Hospital & Health Management)** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name	Signature
DR. RATHI	
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Annexure G: Certificate from Dissertation Advisory Committee

Certificate from Dissertation Advisory Committee

This is to certify that **Ms. Sakshi Mugdha,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. He/ She is submitting this dissertation titled "**Patient Specific Implants in India and Developed Markets: Adoption, Barriers, and Future Prospects**" at "ANVKA Healthcare" in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

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Annexure H: Certificate by Student

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

CERTIFICATE BY STUDENT

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Signature

FEEDBACK FORM (IIHMR Mentor)

Name of the Student: Sakshi Mugdha

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Area of Dissertation: Patient-Specific Implants (PSIs), Additive Manufacturing, and Health Management /Medical Technology

Attendance: The student maintained consistent attendance and full active engagement throughout her dissertation.

Objectives achieved: Successfully conducted a detailed secondary review comparing Patient Specific Implants against Off-The-Shelf implants across clinical, economic, and operational metrics

Deliverables: A comprehensive dissertation report titled

Strengths: Strong analytical, critical-thinking, and secondary research methodology skills.

Suggestions for Improvement: Expand experience in direct field-level business development,

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):

Signature of the Officer-in-Charge/ IIHMR Mentor

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Place: New Delhi

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ABOUT THE ORGANIZATION

ANVKA Healthcare Pvt. Ltd. is a healthcare-focused organization established in 2021 with the objective of transforming healthcare delivery through innovation, technology, and patient-centric solutions. Headquartered in New Delhi, the company operates across multiple domains of the healthcare ecosystem, aiming to improve accessibility, efficiency, and quality of care.

The organization envisions creating a comprehensive healthcare ecosystem that extends beyond hospitals and supports patients throughout their healthcare journey. ANVKA focuses on developing solutions that bridge gaps in healthcare delivery through advanced technologies, medical products, and allied healthcare services.

ANVKA Healthcare functions through various specialized business verticals, including medical implants, healthcare technology solutions, medical value travel, and patient support services. One of its key divisions, Cure with 3D, specializes in the design and development of patient-specific medical solutions using advanced 3D technologies. The division works closely with healthcare professionals to provide customized implants, anatomical models, and surgical planning solutions, contributing to improved clinical outcomes and personalized patient care.

The company is committed to fostering innovation in healthcare and actively collaborates with healthcare institutions, clinicians, researchers, and technology partners. Through its various initiatives, ANVKA aims to promote indigenous healthcare solutions and contribute to the advancement of the Indian healthcare sector.

Vision

To build an integrated healthcare ecosystem that enhances patient outcomes through innovation, technology, and accessible healthcare solutions.

Mission

- To develop innovative healthcare solutions that address emerging clinical needs.
- To improve patient care through technology-enabled services.

- To support healthcare professionals with advanced medical products and solutions.
- To contribute to a more accessible, efficient, and patient-centric healthcare system.

Major Business Divisions

- IndiaMD (Medical Value Travel
- Medical Implants
- Other allied healthcare and support service initiatives under the ANVKA ecosystem.

Cure with 3D is a specialized division of ANVKA Healthcare Pvt. Ltd. focused on the development of patient-specific medical solutions through advanced 3D technologies. The division leverages medical imaging, computer-aided design (CAD), additive manufacturing, and virtual surgical planning to provide customized solutions for complex surgical cases.

The primary objective of Cure with 3D is to enhance surgical precision and improve patient outcomes by offering personalized implants, anatomical models, and surgical guides tailored to the unique anatomy of each patient. By converting patient CT and MRI scan data into three-dimensional digital models, the division enables surgeons to visualize complex anatomical structures, plan procedures in advance, and execute surgeries with greater accuracy. This approach has been increasingly adopted in cranio-maxillofacial, neurosurgical, orthopedic, and reconstructive procedures.

The division specializes in the design and development of Patient-Specific Implants (PSIs) for cranial and cranio-maxillofacial reconstruction, along with customized

surgical guides and anatomical models used for pre-operative planning and surgical simulation. The use of personalized implants and virtual surgical planning helps reduce intraoperative challenges, improve implant fit, and support better functional and aesthetic outcomes for patients.

Cure with 3D works in close collaboration with surgeons, hospitals, and healthcare institutions to deliver innovative and patient-centric solutions. The division combines engineering expertise with clinical requirements to bridge the gap between technology and healthcare, contributing to the advancement of personalized medicine in India.

Through its commitment to innovation, quality, and precision, Cure with 3D continues to support healthcare professionals in managing complex cases and delivering improved standards of patient care.

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Abbreviations

Abbreviation	Full Form
PSI	Patient-Specific Implant
OTS	Off-the-Shelf
3D	Three-Dimensional
AM	Additive Manufacturing
CAD/CAM	Computer-Aided Design / Computer-Aided Manufacturing
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
SLM	Selective Laser Melting
EBM	Electron Beam Melting
PEEK	Polyetheretherketone
TKA	Total Knee Arthroplasty
THA	Total Hip Arthroplasty
CMF	Cranio-Maxillofacial
FDA	Food and Drug Administration (USA)
EU MDR	European Union Medical Device Regulation
CDSCO	Central Drugs Standard Control Organisation
IMDRF	International Medical Device Regulators Forum
PM-JAY	Pradhan Mantri Jan Arogya Yojana
PLI	Production-Linked Incentive
ICMR	Indian Council of Medical Research
IIT	Indian Institute of Technology
AIIMS	All India Institute of Medical Sciences
CAGR	Compound Annual Growth Rate
KSS	Knee Society Score

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Dissertation Experiences:

The completion of this dissertation during my internship at ANVKA Healthcare Pvt. Ltd. (Cure with 3D Division) has been one of the most enriching learning experiences of my PGDM programme. The internship provided me with a unique opportunity to understand the practical aspects of the healthcare and medical device industry while simultaneously conducting research on Patient-Specific Implants (PSIs), an emerging area in personalized healthcare.

At the beginning of the internship, understanding the technical concepts associated with PSIs, 3D printing technologies, surgical planning, and customized implants was both challenging and exciting. Coming from a healthcare management background, I had to familiarize myself with several clinical and technological aspects of the field. Learning how patient-specific implants are designed, manufactured, and utilized in complex surgical procedures required continuous learning and interaction with industry professionals.

One of the most valuable aspects of my internship was the exposure to real-world healthcare settings. Through hospital visits, interactions with surgeons and healthcare professionals, and observations of operative procedures, I gained insights into how advanced medical technologies are integrated into clinical practice. These experiences helped me understand the practical benefits of patient-specific implants as well as the challenges associated with their adoption.

In addition to the technical learning, I was also involved in business development and market research activities. Identifying potential hospitals and clinicians, understanding stakeholder requirements, maintaining databases, and studying market opportunities helped me appreciate the commercial and operational dimensions of the healthcare industry. This exposure enabled me to understand the gap between technological innovation and its adoption in the healthcare system, particularly in the Indian context.

Conducting this dissertation required an extensive review of scientific literature, market reports, and regulatory frameworks from India and developed countries. One of the major challenges was analyzing information from diverse sources and synthesizing it

into meaningful insights. However, this process significantly strengthened my analytical thinking, research skills, and ability to interpret healthcare market trends.

Overall, this dissertation has enhanced my understanding of healthcare innovation, medical technology adoption, and the evolving landscape of patient-specific implants. The experience has helped me develop a broader perspective on healthcare management and has strengthened my interest in the medical technology sector. I am grateful to my faculty mentor, organizational guide, and the entire team at ANVKA Healthcare for their guidance, support, and encouragement throughout this learning journey.

1. Introduction

1.1 Background and Context

The progress in surgical implant design technology during the last thirty years has been one of the most important trends in modern healthcare. The evolution from total hip arthroplasty to the present use of patient-specific implants that are developed with the help of fully digitized planning and additively manufactured technologies indicates fundamental changes in the paradigm of surgical implant design from population-average designs to patient-specific devices. Patient-specific implants (PSIs) reflect this concept most effectively as they are designed using the individual imaging of the patient. (1)

PSIs can be designed based on medical images acquired from imaging systems, such as computed

tomography (CT) scans and, more recently, magnetic resonance imaging (MRI). This data is segmented

using dedicated software to produce three-dimensional representations of the patient's anatomy.

Computer-Aided Design (CAD) is used to create the PSI design, and this is fabricated by way of

additive manufacturing (3D printing), subtractive milling, or a hybrid process. The clinically most advanced

PSIs are manufactured by way of metal additive manufacturing techniques such as Selective Laser Melting

(SLM) and Electron Beam Melting (EBM). (11)

The clinical appeal of PSIs is intuitively compelling. Standard implants are designed for a statistical average of patient anatomy, and while implant libraries typically include a range of sizes, the increments between sizes mean that many patients receive an implant that is an approximation of, rather than a precise fit for, their anatomy. In routine primary arthroplasty in patients with near-normal anatomy, this approximation is generally clinically acceptable. However, in patients with significant anatomical variation whether from congenital deformity, post-traumatic remodeling, oncological bone loss, or severe degenerative change, the limitations of standard implants become clinically significant. And it is in these cases of complexity where PSIs become justified by their

clinical advantage, which is not coincidentally where we have seen some of the first,

and strongest clinical data on the use of PSIs, being in complex reconstructions such

as limb salvage for cancer patients and cranio-maxillofacial reconstruction. (2, 12)

The level of market and clinical maturity of PSI utilization throughout the world

has reached a point where PSIs can be considered a non-experimental technology. In

the US, Stryker recently obtained FDA clearance for custom, 3D-printed titanium

knee implants in February 2024, and the first FDA clearance of a 3D-printed PEEK

cranial implant was obtained in April 2024. (20) In Europe, the Medical Device

Regulation (MDR) 2017/745 gives an established framework for custom medical device

approval. (23)

Major global manufacturers including Zimmer Biomet, Materialise, 3D Systems, and Smith and Nephew have invested heavily in PSI product lines and digital surgery platforms. The global market for 3D-printed medical implants was valued at approximately USD 2.8 billion in 2024 and is projected to reach USD 9.81 billion by 2034. (16)

India's position in this global landscape is paradoxical. By virtually every fundamental measure, India should be a significant PSI market. It is the world's most populous country, with a population of over 1.44 billion as of 2025. Its population aged 60 and above. The primary demographic for joint replacement surgery has nearly doubled as a share of total population over the past three decades and is projected to reach 20.8% by 2050. (6) India's orthopedic implant market was valued at approximately USD 2.35–2.75 billion in 2024 and is growing at 8–10% annually. (6, 7) India has a substantial 3D printing sector, including academia that includes institutions like the Indian Institutes of Technology

(IITs), which have shown great competence in innovating medical devices. (19, 30) Despite

this, the use of PSI in India continues to be restricted to some specialised tertiary

centres in the cities, mainly used for complicated oncological and anatomically rare

cases. (4, 5)

The discrepancy between the two is not just a mere coincidence but a consequence of a

number of structural limitations in the regulatory policies, reimbursement system,

manufacturing capabilities and training of clinicians that are quite different from the

circumstances under which the PSI was adopted in other parts of the world. This

identification of the exact nature of these limitations, and devising strategies to deal

with them based on scientific research forms the main goal of this thesis.

This thesis has been written in the realm of health management, and specifically from the perspective of health systems and management, rather than from the purely clinical aspect of PSI. The questions it asks about market access, regulatory barriers, reimbursement design, and institutional capacity are the questions that hospital administrators, healthcare policymakers, medical device industry strategists, and clinical educators need answered in order to make informed decisions about PSI technology in the Indian context.

1.2 Problem Statement

India faces a pronounced and widening gap between its capacity to benefit from patient-specific implant technology and its current level of adoption. This gap has multiple dimensions, each of which compounds the others.

At the clinical level, Indian patients who could benefit from PSIs, particularly those with complex anatomical presentations that standard implants cannot adequately address are either receiving suboptimal standard implants or foregoing surgery altogether due to the unavailability of patient-specific options at accessible price points. The clinical consequences include higher revision rates, poorer functional outcomes, and reduced quality of life in a patient population that is growing rapidly as India's demographic profile ages. (6, 7)

At the economic level, India's out-of-pocket health expenditure constituted approximately 54.8% of current health expenditure in 2024, one of the highest rates globally. Healthcare expenses pushed 8–9% of Indian households below the poverty line as of 2023. Within this context, the increased unit cost of PSIs compared to regular implants leads to an

important impediment to accessing care for most Indian patients. Although the program Ayushman Bharat PM JAY covers medical implants under its package benefits, the regular package does not account for the extra cost of making the implant patient-specific.

At the regulatory level, India's Central Drugs Standard Control Organization (CDSCO) which oversees medical device regulation under the Medical Devices Rules (MDR) 2017 has not published device-class-specific guidance for PSIs or additively manufactured implants. In contrast, the U.S. FDA released Technical Considerations for Additive Manufactured Medical Devices in 2017, and the MDR explicitly includes provisions for custom devices. (22, 23, 25) The lack of such a regulation in India makes investment in PSI production and clinical usage uncertain.

From the human resources perspective, the shortage of skilled specialists for PSI delivery covering all necessary stages from medical image interpretation for surgery planning, 3D CAD design for implants development, additive manufacturing process engineering to post-implantation clinical management is evident in India, which illustrates the problem of insufficient biomedical engineering education and clinical engineering training. (5)

To our knowledge, no previous comprehensive secondary research review has attempted to synthesize the identified factors contributing to the PSI adoption gap in India. This dissertation fills this gap by developing a structured evidence synthesis.

No comprehensive secondary review has previously synthesized these dimensions of the PSI adoption gap in India within a single analytical framework. This dissertation addresses that gap directly, providing a structured evidence synthesis that can inform policy, investment, and institutional decision-making.

1.3 Rationale of the Study

The motivation for conducting this research study has a clinical as well as managerial aspect to it. In the clinical aspect, better access to the PSI product can actually make a difference in surgical performance for hundreds of thousands of patients annually that have access only to standard implants that do not cater to their anatomy in the optimal way possible. The Indian market for orthopedic surgeries is growing very quickly. This growth creates both an opportunity a growing market for advanced implant technologies and an imperative to ensure that the technologies reaching Indian patients are the best available for their clinical needs. (6, 7)

Managerially, decisions about PSI technology investment, regulatory reform, and reimbursement design require synthesized evidence, not just about the clinical performance of PSIs, but about the market, regulatory, and institutional conditions that determine whether clinical evidence can be translated into adoption at scale. Hospital chief executives deciding whether to invest in PSI programmes, policymakers designing the next iteration of the National Medical Device Policy, and medical device company executives assessing the Indian market opportunity all need the kind of multi-domain evidence synthesis that this dissertation provides.

The significance of this study lies in several specific contributions. First, it provides one of the most comprehensive India-focused reviews of PSI adoption barriers available in the academic and policy literature. Second, it provides a comparative global perspective on India's PSI environment, thereby making it possible for policymakers and stakeholders within the industry to understand which strategies have proven successful in developed countries. Third, it combines information from the marketplace, regulatory environment, and clinical evidence into a cohesive analytical framework that can be utilized within healthcare management practice. Fourth, it will serve as the basis for a research project at the level of a dissertation that would provide primary data in addition to the secondary data collected in this review.

1.4 Aims and Objectives

- The overall goal of this research is to carry out a thorough secondary review of the existing literature on Patient Specific Implants, especially the current state of PSI adoption in India compared to other developed healthcare sectors, as well as finding evidence based solutions that could be used in order to increase adoption.
- Objectives of the study are:
- 1) Describe the clinical indication, manufacture, materials used and surgical applications of PSI in orthopedics, cranio maxillofacial surgery, neurosurgery and spine surgery.
- To critically evaluate and analyze the existing evidence regarding the outcomes of PSI in comparison to commercially available implants.
- To understand the current market scenario and landscape of PSI and 3D printed medical implants including the market size, market growth, key players and

geographical distribution, and commercial factors driving or hindering the market.

- To understand the current situation of PSI implementation in India with regards to organizational initiatives, domestic production capabilities, and

factors limiting wider implementation.

- To identify the regulatory framework surrounding PSIs in the US, Europe, and India, highlighting gaps and benchmarking the existing regulations.

- To understand the current reimbursement framework for PSIs in India as well as developed nations, especially PM-JAY scheme and private insurer policies.To propose a set of evidence-based, actionable recommendations for accelerating PSI adoption in India, directed at policymakers, regulatory bodies, the medical device industry, hospital administrators, and clinical educators.

1.5 Key Research Questions

This study addresses the following key research questions:

What is the current state of clinical evidence for patient-specific implants, and what do systematic reviews and meta-analyses reveal about their outcomes relative to conventional implants? • How does the global PSI and 3D-printed medical implant market landscape compare across North America, Europe, and Asia Pacific, and where does India currently sit within this landscape? • What are the primary structural barriers - regulatory, financial, infrastructural, and workforce-related that constrain PSI adoption in India? • How does India's regulatory and reimbursement framework for medical devices and PSIs compare to those of the United States and European Union, and what specific gaps exist? • What evidence-based strategic interventions would most effectively and efficiently accelerate PSI adoption in India at a health systems level?

1.6 Scope and Limitations

The present study is a secondary research involving an assessment of peer-reviewed academic literature, market research reports, regulatory literature, and industry publications. The geography involved includes India and major developed countries in the field of healthcare, including the United States, the European Union countries, and the United Kingdom. Clinical aspects include orthopedic surgery with focus on total knee arthroplasty, total hip arthroplasty, corrective osteotomy, oncological limb salvage, cranio-maxillofacial surgery, and neurosurgery. The timeline considered in this study is from 2014 to 2026 as this time frame marks the maturity of the PSI technology based on additive manufacturing. The study does not contain any primary data obtained from patients, clinicians, and healthcare organizations. Being a secondary study, its conclusions depend on the accuracy and completeness of existing literature. India specific PSI primary literature is rare in peer-reviewed databases, restricting the possibility of in-depth clinical and economic studies in regard to India. There is a lack of transparency in market research methods used.

2. Literature Review

2.1 Conceptual Framework for the Review

The literature review in question comprises five thematic clusters which jointly cover the multidimensional problem of PSI implementation: (i) the technical and clinical preconditions of PSI technology; (ii) the body of evidence for clinical effectiveness of

PSI results in different types of surgeries; (iii) the PSI and 3D-printed implants market worldwide; (iv) the regulatory and policy framework in developed countries and India; and (v) the peculiarities of PSI implementation, barriers and prospects in India. The above-listed topics are approached from a health management standpoint, which suggests that the process of disseminating innovative technologies in healthcare is not limited by their clinical efficacy alone; it also hinges upon the surrounding context of regulatory, financing, supply chain and other conditions. (1, 2).

The theoretical anchor of this review is the health technology adoption literature, which consistently identifies three categories of determinants for technology diffusion: technology-intrinsic factors (clinical performance, ease of use, cost), health system factors (regulatory approval, reimbursement coverage, procurement processes), and organizational and professional factors (clinician training, institutional culture, workforce capacity). (1) PSIs present a particularly instructive case because the technology-intrinsic evidence is broadly positive, yet adoption in India lags substantially a pattern that points to health system and organizational factors as the primary constraints and the primary leverage points for intervention.

2.2 Technical Foundations of Patient-Specific Implants

2.2.1 Definition and Classification

Patient-specific implants are a subset of customized medical devices in which the implant geometry is derived directly from individual patient imaging data, making the device anatomically unique to a single patient. This distinguishes PSIs from standard off-the-shelf (OTS) implants which are manufactured in predefined sizes and geometries and

from patient-specific instrumentation guides, which are custom jigs and cutting blocks that assist in the placement of standard implants but are not themselves implanted. (1, 9)

PSIs may be classified along several dimensions. By manufacturing process, they are categorized as additively manufactured (3D printed), subtractively manufactured (CNC machined from solid stock), or hybrid. By material, they include metallic (titanium alloys, cobalt-chromium, stainless steel), polymeric (PEEK, PMMA), ceramic, and composite devices. By anatomical application, they span load-bearing orthopedic implants, non-load-bearing cranial and facial reconstruction implants, and spinal reconstruction devices. By clinical context, they include primary implants for first-time surgical intervention and revision or reconstruction implants for complex secondary procedures. Each classification dimension has direct implications for design requirements, manufacturing process selection, regulatory pathway, and the evidence base for clinical outcomes. (11, 22)

2.2.2 The Digital Workflow: From Scan to Implant

The production of a PSI follows a structured digital-to-physical workflow comprising six principal stages, each of which introduces quality-critical steps that differentiate PSI production from standard implant manufacturing.

The first stage is medical imaging acquisition. High-resolution CT scanning with slice thicknesses of 0.5–1.0 mm is the standard for bone-focused orthopedic and CMF applications. For applications requiring soft tissue detail such as some spinal procedures MRI may supplement or replace CT. Image quality at this stage is foundational, as the anatomical model derived from imaging is the basis for all subsequent design decisions. Imaging protocol standardization is therefore a key quality system requirement for PSI

programmes, and one that is not consistently addressed in settings without dedicated PSI clinical pathways. (1, 22)

The second stage is image segmentation and three-dimensional reconstruction, using specialized software such as Materialise Mimics, Synopsys Simpleware, or the open-source 3D Slicer to identify and isolate the anatomical structures of interest. Segmentation can be manual, semi-automated, or fully automated through AI-assisted algorithms. The accuracy of segmentation directly determines the accuracy of the anatomical model and, ultimately, the fit of the manufactured implant. This is a step that requires trained medical imaging and biomedical engineering personnel a workforce category that is in short supply in India. (4, 5)

The third stage is implant design. Using CAD software, biomedical engineers and surgical planners design the implant geometry based on the three-dimensional anatomical model, surgical planning objectives (restoring alignment, joint line, offset, leg length), biomechanical requirements, and material properties. This stage typically involves virtual surgical simulation to confirm the planned implant position and predict post-operative alignment. Design review by the operating surgeon is essential at this stage, and iterative communication between the design team and the surgeon is a key quality process. (22)

The fourth stage is manufacturing. For metallic PSIs, additive manufacturing through SLM or EBM is the most common production method. SLM uses a high-power laser to fuse metal powder particles layer by layer, while EBM uses an electron beam in a vacuum environment. Both the manufacturing methods can be employed to produce complex geometries,

including controlled porosity for osseointegration, which cannot be produced using any other process. In case of PEEK implants, conventional manufacture using CNC machines starting from a solid PEEK piece is more popular than PEEK 3D printing. Post additive

machining for important surfaces, like articulation and bone contact surface, can be done to meet the dimensional requirements. (11)

The fifth step is post processing and includes stress relief treatment, surface finish (grinding, polishing, or bead blasting according to specified roughness requirements), application of bioactive coatings (e.g. Hydroxyapatite or titanium plasma spray for improvement of osseointegration), cleaning and sterilization. The sixth step is quality control and involves dimension checking with the help of design specification, material characterization tests, biocompatibility tests, sterility checks, and packaging. (22).

This full quality pipeline requires substantial infrastructure investment, and is one of the key barriers to domestic PSI manufacturing in India.

2.2.3 Key Materials and Their Properties

Titanium alloys, particularly Ti-6Al-4V ELI (Extra Low Interstitials, Grade 23), are the most widely used materials for PSIs in load-bearing orthopedic, spinal, and CMF applications. Titanium's excellent biocompatibility it is classified as a biologically inert material that does not elicit adverse tissue response combined with its corrosion resistance, high strength-to-weight ratio (comparable to stainless steel at 40% less weight), established clinical track record, and amenability to surface modification, makes it the material of choice for most metallic PSIs. The ability of SLM additive manufacturing to produce controlled porosity in titanium implants, replicating the porous architecture of trabecular bone at 60–80% porosity is a significant functional advantage, facilitating bony ingrowth and long-term biological fixation without cement. (11)

Cobalt chrome (CoCr) alloys, especially CoCrMo, are useful in applications that require extremely high hardness and wear resistance, especially in articulation surface parts like femoral heads and bearing surface components. The excellent hardness of CoCr (about 500 Hv against 320 Hv of Ti-6Al-4V) is what has made it the material of choice in articulation surfaces but concerns over the cobalt ion leaching from certain implants has seen an adoption of ceramic bearing surfaces and highly cross-linked polyethylene. (11)

Stainless steel (316L) has been used in some cheaper implant applications and in price sensitive markets like India's public sector but because of poor corrosion resistance and high density as opposed to titanium, stainless steel has become less favorable for load bearing PSI applications where performance is optimized.

PEEK (polyetheretherketone) is the key high performance polymer used in PSIs in applications of cranial, spinal and maxillofacial PSIs..

2.3 Clinical Evidence: Total Knee Arthroplasty

Total knee arthroplasty (TKA) represents both the largest application domain for PSIs and the most extensively studied. The clinical rationale rests on the hypothesis that anatomically matched implants will more faithfully restore natural knee kinematics, reduce the proportion of patients with suboptimal component positioning a known predictor of long-term revision risk and ultimately improve patient satisfaction and reduce revision rates.

Moret, Schelker, and Hirschmann (2021) conducted a systematic review of 13 comparative studies including a total of 2,127 knee implants. (9) The review compared PSI and OTS implants across multiple clinical outcome domains: range of motion, Knee Society Score (KSS), Forgotten Joint Score (FJS-12), and radiological alignment

measures. The analysis found no statistically significant differences in clinical outcome scores between PSI and OTS. However, PSI demonstrated statistically significantly fewer outliers from the neutral mechanical limb axis a radiological outcome measure associated with long-term implant survival and better overall implant fit as measured by three-dimensional geometric congruence. The authors explicitly note that whether these radiological advantages translate to clinically meaningful long-term differences in implant survival requires further study with longer follow-up.

Rudran et al. (2022) present a systematic review and meta-analysis of 22 randomised controlled trials and prospective studies comprising 2,277 TKAs- the largest and most methodologically rigorous evidence synthesis in the PSI TKA literature. (10) The pooled analysis confirms no significant functional outcome difference at 3, 6, and 12 months post-operatively. Critically, at 24 months, a statistically significant advantage for PSI was identified on the Knee Society Score (mean difference 2.37, 95% CI 0.07–4.67). While this difference did not exceed the accepted minimum clinically important difference for the KSS in this context, the emergence of a statistically significant difference at 24 months, absent at all earlier time points is one of the most important patterns in the PSI literature. It suggests that PSI's functional advantages emerge over time and that most clinical trials, by virtue of their 6–12-month follow-up periods, are systematically blind to the technology's true functional benefit.

Nugent, Kasture, and Ganapathi (2022) provide the most compelling long-term real-world evidence in the reviewed literature. (13) Their retrospective cohort study examines 298 consecutive PSI TKAs performed by a single high-volume surgeon at a minimum five-year follow-up (mean 6.8 years), representing one of the largest and longest-follow-up PSI TKA series in the literature. The Oxford Knee Score (OKS) improved from a median of 18 pre-operatively in the severe impairment range to 44 post-operatively, representing a clinically substantial improvement of 26 points. Patient satisfaction was

high: 75% of patients rated themselves as 'Very Happy' with their outcome, and only 4% as 'Never Happy'. These data derived from a real-world cohort rather than a clinical trial population make the most persuasive available case for PSI TKA in routine clinical practice.

A 2023 narrative review of patient-specific instruments and implants in arthroplasty published in the Journal of Personalized Medicine synthesizes additional evidence, noting that PSI reduces tibial rotational positioning outliers compared to conventional techniques, and that promising results are emerging particularly in revision situations where complex anatomy makes standard instruments inadequate. (MDPI, J Pers Med, 2023) The review identifies the absence of multicenter randomized controlled trials and registry data as the primary evidence gap in the PSI TKA literature.

2.4 Clinical Evidence: Total Hip Arthroplasty

The evidence base for PSI in total hip arthroplasty (THA) is less developed than for TKA, reflecting in part the already excellent clinical results achievable with standard THA in straightforward primary cases, 10-year implant survival rates exceeding 95% in well-performed primary THA reduce the clinical imperative for routine PSI use. The primary application domain for PSI in THA is therefore complex and revision cases: developmental dysplasia of the hip, post-traumatic deformity, large acetabular bone defects, and revision surgery with significant bone stock compromise. (9)

The 2023 narrative review in J Pers Med documents a systematic analysis of 634 custom-made acetabular implants from 18 studies, with a mean follow-up of 58.6 months, showing high implant survival, a particularly important finding in the revision context where standard revision implants often fail to achieve adequate fixation in large defect

scenarios. The review also references the systematic review by Constantinescu et al. (2022), which concluded that PSI is effective in improving acetabular component positioning and post-operative outcomes in THA without increasing intraoperative time or blood loss, compared to standard instrumentation. (MDPI, J Pers Med, 2023; ScienceDirect, 2022)

Zheng et al. (2023) present a randomized controlled trial comparing PSI-assisted THA (n=30) with conventional free-hand THA (n=30), finding significantly higher precision in achieving desired femoral component position, particularly femoral anteversion accuracy in the PSI group. (BMC Biomed Eng, doi:10.1186/s12938-023-01152-5) Clinical outcomes were equivalent at short-term follow-up, consistent with the broader evidence pattern of radiological superiority without short-term functional outcome difference.

2.5 Clinical Evidence: Cranio-Maxillofacial Reconstruction

The use of PSIs in cranio-maxillofacial surgeries is among the domains with strong clinical evidence for PSIs, since the unique anatomy and function of the facial and skull bones require that patient specific implants become part and parcel of high quality surgical procedures rather than merely a luxury. There is no existing standardized catalogue of implants that can cater to the geometries of a resected mandible, orbital floor defect or cranium bone defect after tumor removal.

Valls-Esteve et al. (2025) provide a scoping review, done following PRISMA-ScR guidelines, of the literature from 2015-2025 on PSIs used for intraoral and

maxillofacial reconstruction. (12) The findings of the review include: significant reductions in surgical times due to preoperative planning and patient-specific fit

that eliminate intraoperative adjustments; very high implant survival rate in both titanium and PEEK; clinical improvement in mastication and speech outcomes in

mandible reconstructions; and low complication rates. CAD/CAM and 3D printing technologies were cited by the authors as the key enablers of PSI development.

Moreover, it is noted that transition from manual to digital planning processes made the procedure more predictable and repeatable.

During 2021-2022, mucormycosis (Black Fungus) epidemic in India caused extensive bone destruction in maxillofacial area of immunocompromised post-COVID

patients. The need for patient-specific facial reconstruction in India has emerged and could not be fulfilled by regular implants. Response of Zoriox Inn

Labs and IIT Madras by developing 3D-printed titanium and PEEK facial implants for these patients demonstrates the necessity of the procedure and technical

capacity of India under the circumstances of urgency. Tino et al. (2020) contextualize this type of crisis-driven PSI innovation within the global phenomenon of additive manufacturing deployment during COVID-19, noting that disruptions to standard supply chains activated domestic manufacturing capability that had previously lacked commercial incentive to develop. (15)

2.6 Clinical Evidence: Pediatric Corrective Osteotomy

The application of PSI in pediatric orthopedic surgery, particularly corrective osteotomies of the femur and pelvis for deformity correction represents an important application

domain with specific advantages over adult arthroplasty applications. A systematic review specifically examining 3D-printed PSI in corrective osteotomies of the femur and pelvis identifies several clinically significant advantages. (14) The review finds that PSI significantly reduces the number of intraoperative fluoroscopy images required to confirm osteotomy accuracy, a particularly important benefit in younger patients where cumulative radiation exposure is a lifetime concern while simultaneously simplifying the surgical procedure and improving three-dimensional osteotomy accuracy.

2.7 Technical Literature: Manufacturing and Materials Science

Technical aspects of PSI fabrication are extensively covered in the review by Ngo et al. (2018), where different additive manufacturing materials, techniques, and applications are discussed and which serves as the most cited reference on the topic with over 6,800 citations. (11) The review outlines the whole range of AM processes: powder bed fusion (SLM, EBM), directed energy deposition, material extrusion, and vat photopolymerization along with corresponding materials, resolutions obtainable with each technology and mechanical properties. As far as metallic PSIs are concerned, the review proves that both SLM and EBM technologies produce materials with tensile strength higher than those of cast or wrought titanium alloys when the process parameters are properly adjusted and that the porous structure provided by AM is biomechanically superior to solid implants in osseointegration applications. Ventola (2014) describes additive manufacturing within the wider context of development of medical devices, highlighting the

process of evolution from rapid prototyping of anatomical models (first 3D printing application in medicine) to production of functional implants. (1) According to this review, regulatory framework, material standards and reimbursement coverage are the factors determining the speed of the technology adoption, which conforms to the current dissertation's approach to analyzing PSI adoption barriers

2.8 Global PSI Market Landscape

2.8.1 Overall Market Size and Trajectory

Various market research reports point towards the strong, consistent global growth in the PSI and market for 3D-printed medical implants. According to Precedence Research (2024), the global 3D-printed medical implants market is valued at USD 2.8 billion in 2024 and forecasted to reach USD 9.81 billion by 2034 with a compound annual growth rate (CAGR) of 15.9%. (16) The global custom medical implants market value of Custom Market Insights (2024) is estimated to be USD 1,597.6 million in 2022 reaching USD 9,099.9 million in 2032 with a CAGR of 19.2%. (17) Fairfield Market Research (2024) projects a CAGR of 12.1% through 2030. (21) The variation in the CAGR

Within this broader market, the personalized 3D-printed orthopedic implant segment is addressed specifically by Data Bridge Market Research (2023), which values this segment at USD 915.65 million in 2022 and projects growth to USD 1.78 billion by 2030 at a 17% CAGR. (18) High start-up costs and lack of standardized quality control protocols are identified as the key barriers to entry in this segment. Business Research Insights (2024) reports on the 3D-printed orthopedic implants market specifically,

documenting the two landmark FDA clearances of 2024 Stryker's custom titanium knees in February and the first 3D-printed PEEK cranial implant in April as market-validating regulatory events. (20) Fortune Business Insights (2024) addresses the patient-specific implants market with India-specific content, identifying the December 2023 IIT Madras Black Fungus facial implant initiative as the most significant recent India-specific PSI development. (19)

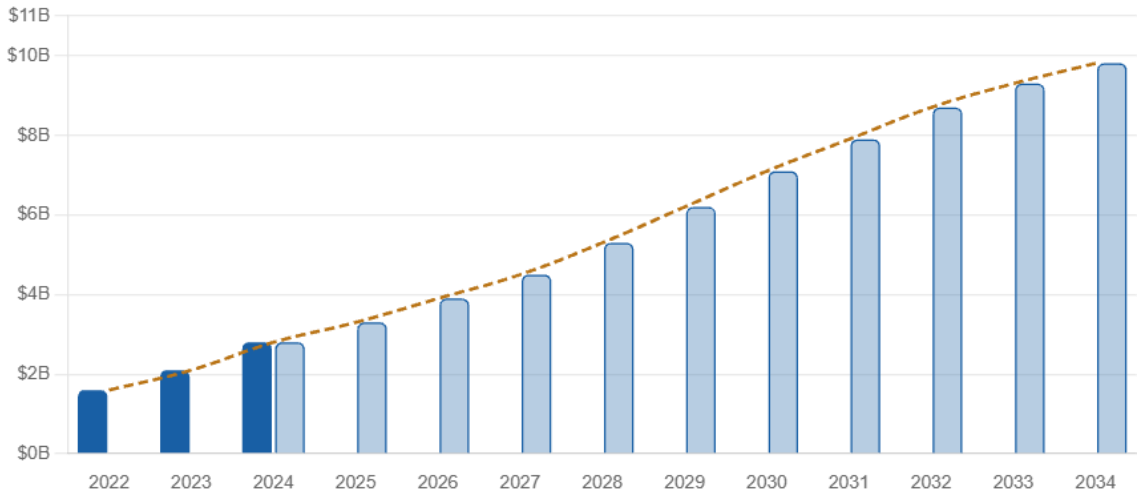


Figure 2.1: Global 3D-printed medical implant market size and projected growth (USD billion), 2022–2034

Source: Precedence Research (2024); Custom Market Insights (2024); Fairfield Market Research (2024)

2.8.2 Geographic Distribution and Competitive Landscape

North America primarily the United States is the dominant PSI market, accounting for approximately 36–40% of global market share according to multiple reports. (16, 20) The United States' dominance reflects the convergence of the world's highest arthroplasty volumes, the most developed regulatory pathway for custom devices, the most mature reimbursement framework, and the headquarters presence of the world's leading medical

device manufacturers. (22) Europe ranks as the second-biggest market, where Germany, United Kingdom, France, and

Netherlands possess the most developed clinical programs related to PSI.

Asia Pacific region represents the fastest-growing regional market. China leads in terms of the adoption rate of PSI because of the state investment in domestic 3D printing capabilities and state regulation of personalized additively manufactured medical devices. (25) In Japan, a mature market of medical devices with PSI adoption exists. India and Southeast Asian markets are younger, with high unmet demand and commercial interest, as can be seen from opening of EOS GmbH India technology center in March 2023. (21)

Market structure on the international level is characterized by dominance of large international companies such as Zimmer Biomet, Stryker, Johnson and Johnson (DePuy Synthes), Materialise, 3D Systems, and Smith and Nephew. (19, 20) These companies possess necessary financial means, regulatory expertise, and clinical contacts to maintain their market leadership. At the same time, specialized companies become more

competitive in certain applications: Conformis in personalized knee arthroplasty, KLS Martin in CMF PSI, and Adler Ortho in revision hip reconstruction. Barrier to entry for new domestic manufacturers in India is high but not impossible to overcome: it is the capital

2.8.3 Key Market Drivers and Barriers

The main commercial factors that have been identified in all three reviewed market reports regarding PSI market expansion are: demographic aging in both developed and emerging markets, resulting in increasing demand for joint replacements and reconstructive procedures; advancement in manufacturing technologies reducing production time and cost while increasing precision; creation of digital surgery ecosystem with better planning software and robotized manufacturing; development of regulatory framework reducing commercial risk; and increasing clinical adoption due to positive evidence base. (16, 17, 18)

The main commercial factors restricting PSI market expansion include the following: high infrastructure cost required for manufacturing; high unit device cost, restricting its adoption in price sensitive markets and healthcare systems with limited reimbursement; complex and highly variable regulatory environment requiring higher compliance costs; lack of standardized quality assurance program for additive manufactured devices; and longer lead times compared to off-the-shelf implants. (17, 18, 29) These barriers appear more acute in emerging markets like India, where development of capital markets for medical technology is still lacking, regulatory framework is not well developed, and financing system for healthcare is not equipped to handle price difference between custom and standard implant.

2.9 Regulatory Frameworks

2.9.1 United States: FDA Framework for Additive Manufactured Medical Devices

Among the global regulatory authorities, it is the United States Food and Drug Administration that has been the most active in formulating guidance regarding additive manufactured medical devices. In its guidance issued in 2017 titled Technical Considerations for Additive Manufactured Medical Devices, the FDA has offered guidance on various considerations related to the design and manufacturing of additive

manufactured medical devices, which include: design software validation and data flow; characterization (composition, microstructure and mechanical properties) of AM metals and polymers; build orientation and support structures; post-processing validation; physical/mechanical tests; and device testing.

2.9.2 European Union: MDR 2017/745 and Custom Device Provisions

The European Union's Medical Device Regulation (MDR) 2017/745 comprehensively overhauled the previous Medical Device Directives framework, significantly strengthening regulatory requirements for all device classes. (23) For patient-specific and custom-made devices, Article 52(8) and Annex XIII of the MDR establish specific provisions that differ materially from the standard conformity assessment pathway.

Under the MDR, a custom-made device is defined as a device specifically made in accordance with a written prescription of a qualified practitioner, giving specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet individual conditions and needs. PSIs clearly meet this definition. The Annex XIII provisions require the manufacturer to prepare a technical documentation statement covering the device design and manufacture, clinical rationale for the custom design, compliance with applicable general safety and performance requirements, and post-market follow-up plan. This documentation must be made available to the competent authority on request but does not require pre-market submission for approval.

The MDR approach contrasts with the FDA's guidance-based framework in being legally prescriptive requirements are established through regulation rather than guidance which provides certainty but reduces flexibility for evolving technologies. The increased post-market surveillance requirements under the MDR have raised compliance costs for PSI manufacturers in Europe and contributed to some supply chain consolidation toward

larger, better-resourced manufacturers. However, the fundamental regulatory certainty provided by the MDR custom device provisions remains a significant competitive advantage for the European PSI market compared to markets without equivalent clarity. (23)

2.9.3 IMDRF International Harmonization Framework

The International Medical Device Regulators Forum (IMDRF) has developed guidance on personalized medical devices that provides a harmonization framework across member jurisdictions, including the US, EU, Japan, Canada, Australia, and China. (24) The IMDRF guidance establishes a classification system for personalized devices — from mass customization (standard devices with minor patient-specific modifications) through to fully bespoke devices (completely patient-specific design) — with regulatory expectations scaled to the degree of personalization and clinical risk.

The IMDRF framework is directly relevant to India's regulatory development: India is an IMDRF affiliate member, and the IMDRF guidance on personalized devices could serve as the international reference standard against which CDSCO develops its own device-class-specific guidance. Adopting IMDRF-aligned guidance would simultaneously address India's domestic regulatory gap and position India as a harmonized regulatory environment attractive to international PSI manufacturers a dual benefit that makes IMDRF alignment the recommended approach for India's regulatory reform. (24, 25)

2.9.4 India: CDSCO Framework and Critical Gaps

India's medical device regulatory framework is governed by the Central Drugs Standard Control Organization (CDSCO) under the Medical Devices Rules (MDR) 2017 a

significant modernization from the previous regulatory approach in which medical devices were regulated under the Drugs and Cosmetics Act as Schedule M, creating a fundamentally inappropriate regulatory paradigm for complex medical devices. The MDR 2017 introduces risk-based classification (Class A through D), mandatory pre-market licensing for higher-risk devices, performance standards, and import registration requirements. (25, 26)

The National Medical Device Policy 2023 articulates an ambitious vision for India's medical device sector, targeting a 10–12% share of the global market up from approximately 1.5% in 2023 through domestic manufacturing promotion, regulatory streamlining, research and development investment, and human resource development.

2.10 Reimbursement Frameworks

2.10.1 Developed Market Reimbursement Models

The United Kingdom's NHS covers PSIs through standard tariff codes for routine cases and individual funding requests for exceptional cases a pathway that provides access but creates administrative burden that can deter clinical adoption.

2.10.2 India: Ayushman Bharat PM-JAY and the Reimbursement Gap

Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) is the world's largest health assurance scheme, providing cashless hospital coverage of up to Rs. 5 lakh per family per year for secondary and tertiary hospitalization. As of June 2025, the scheme covered approximately 12.37 crore poor and lower-income families roughly 55 crore individuals, representing approximately 40% of India's population. In October 2024, the

scheme was further expanded through Ayushman Vay Vandana to include all senior citizens above 70 years irrespective of income, a significant extension given that the over-70 population is the primary demographic for major joint replacement surgery. (Government of India, IBEF 2025)

PM-JAY's benefit package includes medical implant services as a component of its comprehensive hospitalization coverage, with approximately 1,500 health benefit packages covering 25 medical specialties. Standard total knee arthroplasty and total hip arthroplasty are included within defined packages. However, these packages are priced based on the cost of standard OTS implants, and there is no provision within the current PM-JAY framework for reimbursing the additional cost of PSI customization above the standard implant cost. A patient requiring PSI TKA under PM-JAY would therefore receive reimbursement at the standard TKA package rate, with the substantial cost differential for the custom implant either absorbed by the treating hospital, paid out-of-pocket by the patient, or most commonly leading to the substitution of a standard implant for the PSI that was clinically indicated. (29, Government of India NHA)

Private health insurance in India similarly lacks PSI-specific provisions. Most private health plans reimburse implant costs at standard rates, often defined by reference to government-notified ceiling prices for medical devices under the Drugs (Prices Control) Order. The AMRIT (Affordable Medicines and Reliable Implants for Treatment) initiative provides discounted standard implants through AMRIT pharmacies at major government hospitals a valuable initiative for standard implants but not designed to address the PSI cost differential. (IBEF 2025)

Mark Wide Research (2024) specifically identifies high cost and limited reimbursement as the primary barriers to growth in India's medical implants market, noting that the absence of PSI-specific reimbursement provisions places PSIs effectively outside the reach of the Indian public and most insured private-sector patients. (29) This

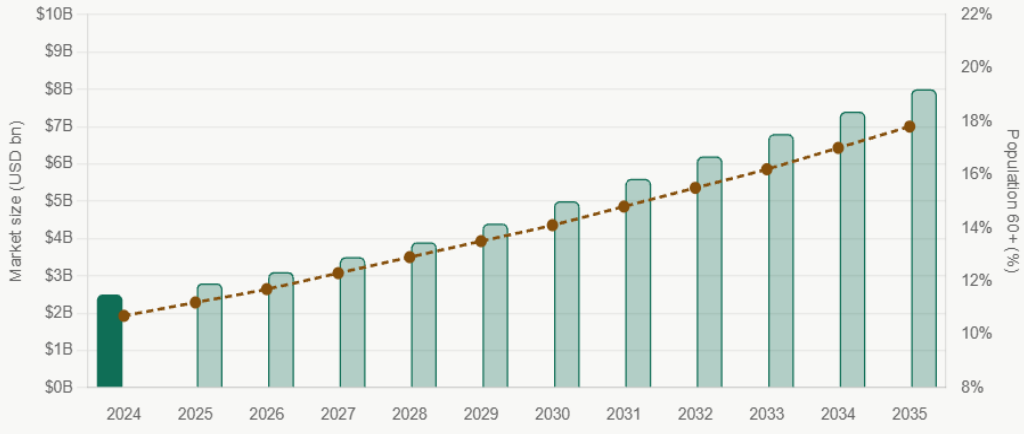
reimbursement gap is identified across multiple reviewed sources as the most immediate patient-access barrier, distinct from but reinforcing of the regulatory and manufacturing infrastructure gaps.

2.11 PSI Adoption in India: Current State

2.11.1 Market Fundamentals

India's medical device market overall was valued at USD 115.4 billion in 2024, projected to reach USD 189.6 billion by 2033 at a CAGR of 5.39%. (28) The orthopedic implants segment specifically is valued between USD 2.35 and 2.75 billion in 2024 across reviewed reports, with growth projections of 8–10% annually through 2034. (6, 7) Market Research Future (2026) places the market at USD 2.75 billion in 2024, projecting growth to USD 8.0 billion by 2035 at a CAGR of 10.19%, with the reconstructive joint implants segment leading at USD 1.1 billion. (7)

Figure 2.5: India orthopedic implants market — size and projections (USD billion), 2024–2035



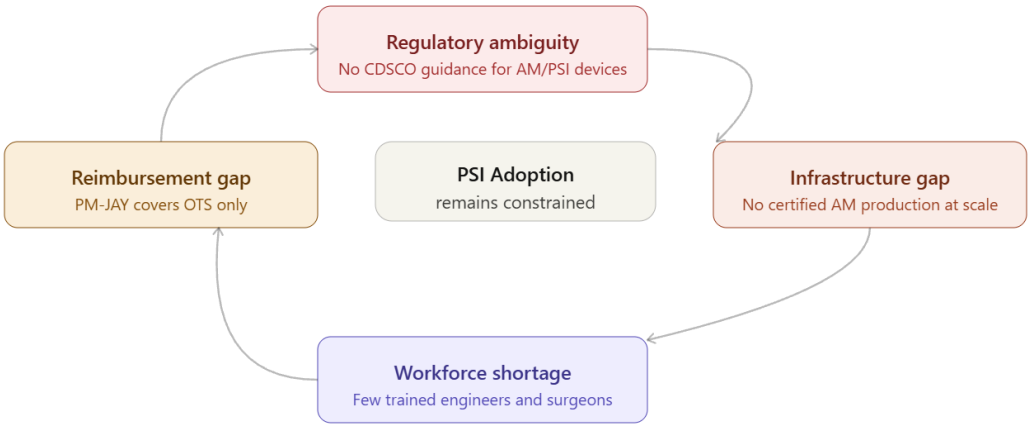
Source: Research and Markets (2025); Market Research Future (2026); IMARC Group (2024)

2.11.2 Clinical Adoption Patterns

Singh et al. (2020) survey 3D printing healthcare applications in India, documenting that PSI use is restricted to tertiary centers and identifying lack of awareness among surgeons outside major metropolitan areas as a significant adoption constraint. (4) The review finds that while 3D printing for pre-surgical anatomical models and simulation is increasingly common at major teaching hospitals including AIIMS campuses, Christian Medical College Vellore, and large private chains such as Manipal Hospitals and Apollo Hospitals the deployment of 3D-printed implants for patient use is rare and concentrated in specialist programmes.

Chaudhary (2022) provides a more granular analysis of clinical adoption barriers in India, identifying three mutually reinforcing constraints that form a structural barrier system. (5) First, limited infrastructure: the absence of certified additive manufacturing facilities with the full PSI production workflow imaging, segmentation, CAD design, manufacturing, post-processing, quality assurance, and sterile packaging at most Indian hospitals, even at the tertiary level

Figure 2.4: Structural barriers to PSI adoption in India — the vicious cycle



Source: Chaudhary (2022); Singh et al. (2020); Mark Wide Research (2024)

2.11.3 Notable Institutional and Commercial Developments

The most clinically and strategically significant India-specific PSI development in the reviewed literature is the December 2023 initiative by Zoriox Innovation Labs, in collaboration with researchers from IIT Madras, to develop and deploy 3D-printed titanium and PEEK facial implants for patients with mucormycosis-related maxillofacial bone destruction. (19) This initiative which arose from the acute and large-scale unmet clinical need created by the Black Fungus crisis demonstrates three things simultaneously: that the clinical need for patient-specific facial implants exists at significant scale in India; that domestic design and manufacturing capability at the academic-institutional level can meet that need; and that crisis conditions can activate innovation capability that normal commercial incentives have not.

Paradise 3D (2025) documents the breadth of 3D printing clinical applications at Indian institutions. (30) IIT Madras's development of a body-powered prosthetic hand at a unit cost under Rs. 8,000 demonstrates that India's additive manufacturing ecosystem can achieve patient-specific device production at dramatically lower cost than global market prices when designed for the Indian cost context. Manipal Hospitals' use of 3D-printed vascular and neurosurgical anatomical models for pre-operative planning has been associated with reduced operative times and improved surgical confidence. AIIMS Bhopal has incorporated 3D printing in complex urological surgery planning. While these applications represent planning model use rather than implant production, they demonstrate the imaging, planning, and manufacturing infrastructure components that are prerequisites for PSI implant production.

The March 2023 opening of EOS GmbH's India technology center is commercially significant. (21) EOS is the global market leader in industrial polymer and metal additive manufacturing systems, and its decision to establish dedicated India infrastructure including application support, training programmes, and technical resources for medical-grade AM signals a commercial assessment that India's industrial and healthcare AM

market has reached a critical scale. The EOS technology center will lower barriers to medical-grade AM adoption for Indian manufacturers and research institutions by providing in-country access to application expertise that previously required international engagement.

Figure 2.2: Comparative framework — PSI adoption dimensions: India vs. USA vs. EU

Dimension	USA	EU	India
Regulatory Guidance for PSIs	FDA 2017 Technical Considerations published; active clearance pipeline	EU MDR Annex XIII; legally prescriptive custom device provisions	No PSI-specific CDSCO guidance published as of 2025
Reimbursement Coverage	CMS codes for complex reconstruction; partial PSI coverage	National DRG codes for complex revision and oncological cases	PM-JAY covers standard implants only; no PSI cost-differential provision
Domestic Manufacturing	World-leading AM companies such as Stryker, 3D Systems, and Materialise	EOS GmbH, Materialise HQ in Europe; certified production pipelines	Nascent ecosystem; IIT Madras–EOS India Centre; no commercial-scale certified production
Clinical Evidence Base	Multiple RCTs, meta-analyses, and long-term cohort studies	Extensive multicentre European registries and prospective studies	Limited India-specific studies; lack of prospective data
Market Maturity	Mainstream adoption in complex arthroplasty and CMF procedures; 36–40% global market share	Established programmes at major academic centres; second-largest global market	Early-stage adoption; concentrated in tertiary metro hospitals with growing private-sector interest

Source: Shukla et al. (2023); FDA (2017); EU MDR (2017); IMARC Group (2024)

3. Methodology

3.1 Research Design and Philosophical Orientation

This study employs a secondary research design based on a narrative literature review methodology. Secondary research synthesizes, analyses, and interprets evidence from previously published sources, rather than collecting original primary data. Within secondary research, this study adopts a narrative review approach one that provides a broad, integrative synthesis of evidence across multiple domains and study types rather than a systematic review or meta-analysis, which would be appropriate for a narrower, more homogeneous clinical question amenable to statistical pooling. (1)

3.4 Data Extraction and Synthesis

Within each domain, findings were analyzed for convergence (where multiple independent sources report consistent findings), divergence (where sources report conflicting findings with analysis of possible explanations), and evidence gaps (where the literature is silent on questions relevant to the research objectives). The synthesis prioritized peer-reviewed evidence for clinical and regulatory claims, and market research evidence for commercial and market claims, with explicit acknowledgment of the limitations and methodological variability of each source type.

3.5 Quality Assessment

For peer-reviewed publications, quality was assessed based on: study design hierarchy, with systematic reviews and meta-analyses weighted most highly, followed by RCTs, prospective cohort studies, retrospective cohort studies, and narrative reviews; sample size adequacy relative to the study's statistical objectives; follow-up duration relative to PSI's expected time-to-benefit; risk of bias considerations including selection bias,

performance bias, detection bias, and reporting bias; and the credibility and impact factor of the publishing journal.

Three studies were assigned the highest evidential weight for clinical outcome claims: Moret et al. (2021) for PSI TKA outcomes, Rudran et al. (2022) for PSI TKA meta-analysis, and Valls-Esteve et al. (2025) for CMF PSI outcomes as the most methodologically rigorous and comprehensive evidence syntheses in their respective domains. (9, 10, 12) Nugent et al. (2022) was assigned high weight for long-term real-world TKA outcomes by virtue of its large sample size and exceptionally long follow-up duration. (13)

Market research reports were assessed based on the established reputation and track record of the publishing organization, the internal consistency of reported data, and consistency with estimates from other independent publishers. Where estimates diverge significantly, the range is reported and possible explanatory factors are noted. Regulatory documents from official sources were treated as authoritative for their respective jurisdictions. Industry publications were used as supporting evidence for institutional developments and are explicitly noted as such to distinguish them from peer-reviewed sources.

3.6 Ethical Considerations

This study involves no primary data collection from human participants, no use of personal data or clinical records, and no identifiable information about individuals. There are no conflicts of interest: the study is conducted as an independent academic dissertation with no commercial funding or industry affiliation of any kind.

4. Results

4.1 Overview of Sources Identified and Included

In total, 30 articles have been retrieved that fit the inclusion criteria for the current review. Breakdown by source type is: 11 peer reviewed journal articles (including 3 systematic reviews, 1 scoping review, 1 systematic review with meta-analysis, 2 retrospective cohort studies, 2 narrative reviews, 1 randomized controlled trial, 1 literature review); 10 commercial market research reports; 4 regulatory and policy documents, authored by official government or regulatory body; 3 industry/institutional publications; and 2 academic literature reviews focused on India. The publication dates range from 2014 to 2026.

Geographic focus of included sources: 10 are primarily focused on India; 12 cover global or multi-country topics; 5 primarily cover the USA or North America; 3 cover Europe or specific European countries. The clinical areas of the review include: orthopedic surgery (TKA, THA, corrective osteotomy, oncological reconstruction), cranio-maxillofacial/maxillofacial surgery, general 3D printing technology and manufacturing science, regulatory/policy analysis, medical device market analysis. The literature review matrix is provided in Appendix A.

4.3 Theme 2: The Global Market is a High-Growth Commercial Opportunity

All ten market research reports reviewed converge on a picture of rapid, sustained global market growth for PSIs and 3D-printed medical implants across segments and geographies. CAGR estimates for the broader 3D-printed medical implants market range from 12.1% (Fairfield 2024) to 19.2% (Custom Market Insights 2024), reflecting

methodological differences in segment definition rather than fundamental disagreement. (16, 17, 21) Market size estimates range from USD 1.6 billion (Custom Market Insights, 2022 base) to USD 2.8 billion (Precedence Research, 2024 base). (16, 17) Projections converge on USD 9–12 billion by 2032–2034.

North America holds 36–40% of global market share and is the most commercially mature region. (16, 20) Asia Pacific is the fastest-growing region. Key commercial players Zimmer Biomet, Stryker, Materialise, 3D Systems, Johnson and Johnson are investing in PSI product lines and digital surgery platforms. (19, 20)

4.4 Theme 3: Regulatory Framework Maturity Determines

4.5 Theme 4: India has Genuine Capability but Structural Barriers Constrain Adoption

Fortune Business Insights (2024), Fairfield Market Research (2024), and Paradise 3D (2025) document the most significant recent institutional and commercial developments. (19, 21, 30)

The convergence of India-focused sources on three primary barriers regulatory ambiguity, cost and reimbursement gaps, and trained personnel shortage across independent academic, market, and institutional sources, provides strong cross-source validation for these findings. The absence of India-specific indexed DOI publications among the academic sources on India's PSI adoption (with Singh 2020 and Chaudhary 2022 both lacking DOIs) is itself a finding: it reflects the genuine scarcity of rigorous

published primary research on PSI adoption in India, and underscores the priority for commissioned primary research.

4.6 Theme 5: Reimbursement is the Most Immediate Patient-Access Barrier

Multiple sources identify the reimbursement gap as the most immediate barrier to patient access for PSIs in India. (29, Government of India) PM-JAY's benefit package while broad in scope and recently expanded to all citizens over 70 contains no PSI-specific reimbursement provisions. (Government of India NHA) Standard arthroplasty package rates do not accommodate the cost differential of custom devices. Private insurers similarly lack PSI coverage provisions. (29) The consequence is that PSIs are economically accessible only to self-paying patients with substantial financial resources a small fraction of India's population.

Addressing the reimbursement gap requires specific policy action at the National Health Authority level to modify PM-JAY benefit packages for PSI in defined high-need indications. The evidence reviewed provides a clear basis for defining those indications oncological reconstruction, complex CMF reconstruction, and complex revision arthroplasty where PSI's clinical advantage over standard alternatives is most firmly established and most defensible from a cost-effectiveness perspective. (9, 10, 12, 13)

5. Discussion

5.2 Clinical Evidence: What It Means for India

First, the finding that PSI's functional advantages emerge at 24 months and beyond means that short-term clinical trials will systematically underestimate PSI's value. India's primary research agenda should therefore include studies with minimum 3-year follow-up to adequately capture the benefit profile that the global literature suggests. (10, 13)

Second, the strongest and most consistent evidence for PSI comes from complex reconstruction scenarios CMF, oncological limb salvage, complex revision arthroplasty, pediatric corrective osteotomy rather than routine primary arthroplasty. For India, where cost-effectiveness considerations are particularly important, this suggests that selective deployment of PSI in high-complexity, high-unmet-need scenarios represents the most defensible initial adoption strategy, building evidence and capability before expanding to broader indications. This mirrors the adoption trajectory of developed markets, where PSI penetration was initially led by complex reconstruction applications before extending to primary arthroplasty. (9, 12, 14)

Third, the clinical evidence reviewed here was generated almost entirely in developed-country populations with different anatomical characteristics, comorbidity profiles, and healthcare system contexts than India. The extrapolation of this evidence to Indian patients requires caution and ultimately requires India-specific validation. The ICMR-commissioned multicenter studies recommended in Chapter 6 would address this evidence gap directly. (4, 5)

5.3 Regulatory Reform: The Priority Intervention

The evidence from Shukla et al. (2023), Emergo by UL (2023), and Pacific Bridge Medical (2025) collectively establishes that CDSCO's absence of PSI-specific guidance is the most fundamental regulatory barrier to PSI commercial development in India. (25,

26, 27). Without regulatory clarity, manufacturers will not invest in PSI production infrastructure for the Indian market; hospitals will not develop PSI programmes without confidence in the regulatory status of the devices they would implant; and payers cannot develop reimbursement frameworks for product categories with undefined regulatory status.

The pathway for regulatory reform is well-specified by the comparative evidence. CDSCO should develop and publish a guidance document for PSIs and additive manufactured implants that addresses at minimum: design and manufacturing workflow documentation requirements; material characterization and testing requirements specific to AM materials; process validation requirements; finished device testing protocols including dimensional inspection and mechanical testing; and post-market surveillance obligations. This guidance should be aligned with the IMDRF personalized medical device framework to ensure international harmonization and facilitate market access for both domestic and international manufacturers. (24, 25)

CDSCO's institutional capacity to develop this guidance is demonstrated by its recent regulatory activity — the risk-based import surveillance programme (September 2024) and the Medical Device Software draft guidance (October 2025). (27) The PSI guidance document should be positioned as the next priority in CDSCO's device-class-specific guidance development programme, with a target publication timeline of 18–24 months.

5.7 The Hub-and-Spoke Model for Equitable Access

Given the high capital cost of establishing full PSI production workflows at every hospital and the geographic concentration of existing capability, a hub-and-spoke delivery model is the most pragmatic approach to expanding PSI access beyond metropolitan centres.

Under this model, five to six PSI hub centres at major academic teaching hospitals - AIIMS Delhi, AIIMS Bhopal, AIIMS Bhubaneswar, CMC Vellore, Tata Memorial Centre, and potentially one IIT-hospital partnership would provide integrated PSI delivery capability: advanced imaging, planning software, AM manufacturing or manufacturer partnerships, and trained surgical teams. Spoke hospitals at district and taluka levels would identify complex cases requiring PSI and refer them to hub centres, with digital telemedicine planning consultation and centralized manufacturing support enabling efficient cross-site workflow.

This model has well-established precedents in other complex surgical technology domains in India - cardiac surgery, organ transplantation, complex oncological surgery, where concentration of specialist capability at academic centers has enabled access for referred patients from wide geographic catchments. The PM-ABHIM programme's investment in critical care and emergency infrastructure at district hospitals could potentially strengthen spoke capacity over time.

5.8 Comparison with Prior Literature and Implications

The absence of India-specific primary PSI research reflected in the lack of indexed DOIs for the two India-specific academic sources in this review is a structural characteristic of the India PSI literature that this review cannot remedy but can clearly document. The recommendation for ICMR-commissioned primary research is the most direct response to this gap. Until India-specific prospective clinical studies, health economic analyses, and adoption surveys are conducted, India's PSI policy decisions will necessarily be extrapolated from global evidence rather than grounded in local empirical foundations.

6. Conclusion

6.1 Summary of Principal Findings

This dissertation has conducted a comprehensive secondary review of the literature on patient-specific implants synthesizing evidence from 30 sources across clinical, market, regulatory, institutional, and India-specific domains to characterize the global PSI landscape, map India's position within it, identify the structural barriers constraining adoption, and develop evidence-based recommendations for accelerating uptake.

6.2 Evidence-Based Recommendations

Six evidence-based recommendations are proposed; each directed at the institutional actor with the relevant decision authority:

Recommendation 1: CDSCO should develop and publish dedicated regulatory guidance for patient-specific and additively manufactured medical implants within 18–24 months, covering design validation, material characterization, process validation, device testing, and post-market surveillance requirements, aligned with the IMDRF personalized medical device framework. This is the single highest-priority intervention identified in this review, as it is the prerequisite for all other ecosystem development. (24, 25)

Recommendation 2: The National Health Authority should modify PM-JAY benefit packages to establish PSI-specific reimbursement for defined high-clinical-need indications — beginning with oncological limb salvage, complex CMF reconstruction, and complex revision arthroplasty — at rates that reflect the cost of domestic PSI production at certified facilities. (29)

Recommendation 3: The Ministry of Commerce and the PLI Scheme administration should explicitly extend PLI eligibility to certified additive manufactured medical devices

and patient-specific implants, including a capital subsidy component for metal additive manufacturing equipment, to stimulate domestic manufacturing investment. (26)

Recommendation 4: ICMR and major academic hospitals should commission multicenter prospective PSI clinical outcome studies at 5–6 academic centres, with a minimum 3-year follow-up, covering TKA, THA, and CMF reconstruction to generate the India-specific clinical and health economic evidence that is currently absent from the literature. (4, 5)

Recommendation 5: The Indian Orthopaedic Association, Association of Plastic Surgeons of India, and Neurological Society of India should develop a national PSI clinical and workflow curriculum and integrate it into postgraduate surgical training and CME requirements within 36 months. (4, 5)

Recommendation 6: The Ministry of Health and Family Welfare should pilot a hub-and-spoke PSI delivery model at one regional hub centre. For example, AIIMS Delhi or AIIMS Bhopal with three to four spoke hospitals, generating real-world access and outcomes evidence for the public sector PSI delivery context.

6.3 Contribution to Knowledge and Future Research Directions

This dissertation makes several contributions to the health management research literature. It provides one of the most comprehensive management-oriented secondary reviews of PSI adoption in India, filling a recognized gap in both the academic literature and the policy discourse.

Future primary research should address the gaps identified in this review. Priority areas include: prospective PSI clinical outcome studies at Indian academic centres with 3-year minimum follow-up; India-specific health economic analyses of PSI cost-effectiveness; qualitative and survey research on surgeon and hospital administrator awareness and

adoption intentions; and regulatory policy research on the institutional processes and timelines for CDSCO PSI guidance development. Mixed methods approach, combining quantitative outcome data with qualitative investigation of adoption barriers would provide the most complete evidence base for driving policy and institutional change.

The PSI field continues to evolve rapidly. Advances in artificial intelligence for automated image segmentation and implant design, in next-generation PEEK composites and bioactive titanium surfaces, and in high-throughput additive manufacturing are progressively reducing the cost and lead time of PSI production and expanding its indications. India's policy and regulatory frameworks need to be designed with adaptive capacity able to accommodate these technological advances without requiring fundamental revision rather than being tied to the current state of specific materials or processes.

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