GEORGE BROWN PRESS
JOURNALS, BOOKS & PROCEEDINGS

International Journal of Engineering Advances

Review

Development Status and Prospects of Orthopedic Internal Fixation Devices in the Context of Digitalization and Personalization

Wenkui Liang [1,*]

[1] Shanghai BATA Medical Co., Ltd., Shanghai, China
* Correspondence: Wenkui Liang, Shanghai BATA Medical Co., Ltd., Shanghai, China

Abstract: This review delves into the evolution and future trajectory of orthopedic internal fixation devices, with a specific focus on the transformative impact of digitalization and personalization. Orthopedic internal fixation, a cornerstone of fracture management and reconstructive surgery, is undergoing a paradigm shift driven by advancements in digital technologies such as 3D printing, computational modeling, and robotic surgery. Personalization, facilitated by these digital tools, aims to tailor implants and surgical procedures to the unique anatomical and biomechanical characteristics of each patient. This review begins with a historical overview of internal fixation devices, highlighting key milestones and technological innovations. It then explores the core themes of digitalization and personalization, examining how these concepts are shaping the design, manufacturing, and application of orthopedic implants. Specific areas of focus include patient-specific implants, surgical planning software, and intraoperative navigation systems. A comparative analysis of traditional and digitally-enhanced approaches to internal fixation is presented, along with a discussion of the challenges and limitations associated with the adoption of new technologies. These challenges encompass regulatory hurdles, cost considerations, and the need for specialized training. Finally, the review concludes with a forward-looking perspective on the future of orthopedic internal fixation, anticipating further integration of artificial intelligence, machine learning, and biocompatible materials to optimize patient outcomes and reduce the incidence of implant-related complications. This includes exploration of predictive modeling for fracture healing and remote monitoring of implant stability. The ultimate goal is to achieve precision orthopedics, where internal fixation is precisely tailored to the individual patient for optimal healing and functional restoration.

Keywords: orthopedic internal fixation; digitalization; personalization; 3D printing; surgical planning; fracture healing; implants

Received: 06 January 2026
Revised: 02 March 2026
Accepted: 15 March 2026
Published: 19 March 2026

1. Introduction

1.1. Background and Significance

Orthopedic internal fixation devices are crucial for fracture management and reconstructive surgery, providing stability to bone fragments during healing. These devices, including plates, screws, rods, and wires, facilitate proper alignment and promote bone union [1]. However, traditional approaches often rely on standardized implants and techniques, which may not perfectly address the unique anatomical and biomechanical needs of individual patients. This can lead to complications such as malunion, nonunion, and implant failure, highlighting the need for innovative solutions that leverage digitalization and personalization to improve patient outcomes and reduce revision surgeries, ultimately enhancing the quality of life for individuals with bone fractures or deformities [2].

1.2. The Rise of Digitalization and Personalization

Digitalization and personalization are rapidly reshaping orthopedic internal fixation. Digital technologies, including advanced imaging (CT, MRI), computer-aided design (CAD), and 3D printing, enable precise preoperative planning and customized implant design. This shift allows for patient-specific solutions, optimizing implant fit, stability, and biomechanical performance. Personalization, driven by digital tools, considers individual patient anatomy, bone quality, and fracture characteristics to improve surgical outcomes and reduce complications. Ultimately, these trends promise enhanced healing, reduced revision rates, and improved quality of life for patients [3].

1.3. Scope and Objectives

This review explores the current state and future directions of orthopedic internal fixation devices, focusing on the impact of digitalization and personalization. It examines advancements in materials, design, and surgical techniques. The literature review methodology includes database searches (PubMed, Scopus) using keywords such as "orthopedic implants," "internal fixation," and "personalized medicine" to identify relevant publications.

2. Historical Overview of Orthopedic Internal Fixation

2.1. Early Developments and Materials

Early attempts at internal fixation date back centuries, predating modern surgical understanding. Bone grafts, often autologous, were among the earliest methods employed to bridge fracture gaps and stimulate healing [4]. The use of materials like ivory and wood has also been documented, although their biocompatibility was limited. With the advent of metalworking, surgeons began experimenting with wires, initially made of iron, silver, or gold, to approximate fracture fragments. These early wires, while providing some degree of stability, were prone to corrosion and infection, hindering optimal bone union. The understanding of biomechanics and material science was rudimentary, leading to unpredictable outcomes and a high rate of complications. The concept of rigid fixation, crucial for primary bone healing, was yet to be fully realized (Table 1).

Table 1. Timeline of Key Developments in Internal Fixation.

Period	Development
Ancient Times	Use of bone grafts (often autologous) to bridge fracture gaps.
Ancient Times	Documentation of materials like ivory and wood for fixation, with limited biocompatibility.
Early Metalworking Era	Introduction of wires made of iron, silver, or gold for fracture approximation.
Early Metalworking Era	Issues with corrosion and infection associated with early metal wires, hindering bone union.
Prior to Modern Understanding	Rudimentary understanding of biomechanics and material science led to unpredictable outcomes.
Prior to Modern Understanding	Concept of rigid fixation for primary bone healing not fully realized.

2.2. The AO/ASIF Principles and Their Impact

The establishment of the AO/ASIF (Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation) principles revolutionized orthopedic internal fixation. These four key principles – anatomical reduction, stable fixation, preservation of blood supply, and early mobilization – provided a structured approach to fracture management [5]. Anatomical reduction aimed for

precise restoration of bone fragments to their original position. Stable fixation, achieved through techniques like compression plating and interfragmentary screw fixation, ensured fracture stability during healing. Preservation of blood supply to the bone fragments was emphasized to promote optimal healing. Finally, early, active, pain-free mobilization was encouraged to prevent joint stiffness and muscle atrophy. The AO/ASIF principles significantly improved patient outcomes and laid the foundation for modern internal fixation techniques, influencing implant design and surgical approaches [6].

2.3. Evolution of Implant Designs

Early internal fixation devices were rudimentary, primarily focusing on fracture approximation. Bone plates evolved from simple metal strips to dynamic compression plates (DCP), utilizing eccentric screw placement to generate compressive forces at the fracture site. Screw designs progressed from basic cortical screws to cancellous screws with varying thread pitches (p) and core diameters (d) optimized for different bone densities. Intramedullary nails transitioned from solid, non-locking designs to cannulated, interlocking nails, enhancing rotational stability and allowing for load sharing. The introduction of materials like titanium alloys further improved biomechanical compatibility, reducing stress shielding and promoting bone healing. These design changes aimed to improve fracture stability, reduce complications, and enhance patient outcomes (Table 2).

Table 2. Comparison of Different Internal Fixation Implants.

Implant Type	Design Evolution	Key Features	Biomechanical Advantages
Bone Plates	Simple metal strips -> Dynamic Compression Plates (DCP)	DCP utilizes eccentric screw placement, varying screw designs (cortical & cancellous with thread pitch p and core diameter d).	Generates compressive forces at fracture site, optimized for different bone densities.
Intramedullary Nails	Solid, non-locking -> Cannulated, interlocking	Cannulated, interlocking nails with load sharing capability.	Enhanced rotational stability, allows for load sharing, improved fracture stability.
Materials	Early Metals -> Titanium Alloys	Use of titanium alloys for improved biocompatibility.	Reduced stress shielding, promoting bone healing.

3. Digitalization in Orthopedic Internal Fixation

3.1. D Printing and Additive Manufacturing

3D printing, also known as additive manufacturing (AM), has revolutionized orthopedic internal fixation by enabling the creation of patient-specific implants, surgical guides, and customized instruments. This technology allows for the fabrication of complex geometries tailored to individual patient anatomy, improving implant fit, surgical accuracy, and overall clinical outcomes. Patient-specific implants, designed from CT or MRI scans, can address unique bone defects or deformities, optimizing load distribution and promoting bone ingrowth [7]. Surgical guides, similarly designed using patient-specific data, enhance the precision of implant placement, screw insertion, and bone resection, minimizing surgical errors and reducing operative time. Customized instruments, such as drill guides or reduction tools, can further streamline surgical procedures and improve handling.

Common materials used in 3D printing for orthopedic applications include titanium alloys (Ti6Al4V), stainless steel, and polymers like polyetheretherketone (PEEK).

Titanium alloys are favored for their biocompatibility, high strength-to-weight ratio, and osseointegrative properties. Stainless steel offers good mechanical properties and cost-effectiveness [8]. PEEK provides radiolucency and biocompatibility, making it suitable for certain applications. Printing techniques vary depending on the material and desired properties, with powder bed fusion (PBF) techniques like selective laser melting (SLM) and electron beam melting (EBM) being widely used for metals, and fused deposition modeling (FDM) or stereolithography (SLA) employed for polymers. The choice of printing technique influences the mechanical properties, surface finish, and dimensional accuracy of the final product (Table 3).

Table 3. Comparison of Different 3D Printing Materials for Orthopedic Applications.

Material	Advantages	Disadvantages	Common Applications
Titanium Alloys (Ti6Al4V)	Biocompatibility, high strength-to-weight ratio, osseointegrative properties, corrosion resistance.	Higher cost compared to stainless steel, can be challenging to machine post-printing.	Patient-specific implants, spinal cages, acetabular cups, bone plates.
Stainless Steel	Good mechanical properties, cost-effective, readily available.	Lower biocompatibility compared to titanium alloys, potential for corrosion, higher density.	Bone plates, screws, fracture fixation devices.
Polyetheretherketone (PEEK)	Radiolucency, biocompatibility, high strength, chemical resistance.	Lower strength compared to metals, can be challenging to bond to bone.	Spinal implants, interbody fusion devices, cranial implants.

3.2. Surgical Planning Software and Virtual Simulation

Surgical planning software and virtual simulation are revolutionizing orthopedic internal fixation by enabling surgeons to meticulously plan procedures before entering the operating room. These tools utilize patient-specific imaging data, such as CT scans and MRIs, to create three-dimensional models of the fractured bone and surrounding anatomy. Surgeons can then virtually manipulate the fracture fragments, select appropriate implants, and optimize their placement to achieve the desired reduction and stability [9].

A key advantage lies in the ability to predict fracture healing outcomes based on different fixation strategies. Finite element analysis (FEA) can be integrated to simulate the biomechanical environment at the fracture site, predicting stress distribution and callus formation under various loading conditions. Parameters like interfragmentary strain (IFS) and stiffness (k) can be assessed to optimize implant selection and placement for enhanced healing [10].

Preoperative planning significantly reduces surgical errors and operative time. By visualizing the surgical procedure beforehand, surgeons can anticipate potential challenges and develop contingency plans. Intraoperative navigation systems, guided by the preoperative plan, further enhance accuracy by providing real-time feedback on implant placement. This combination of preoperative planning and intraoperative navigation leads to improved surgical outcomes, reduced radiation exposure, and minimized risk of complications [11].

3.3. Robotics and Computer-Assisted Surgery

Robotics and computer-assisted surgery (CAS) are increasingly prevalent in orthopedic internal fixation, offering significant advancements in precision and accuracy. These technologies leverage sophisticated imaging techniques, such as computed tomography (CT) and magnetic resonance imaging (MRI), to create detailed three-dimensional models of the patient's anatomy. This allows surgeons to pre-operatively plan the optimal placement of internal fixation devices, minimizing the risk of malalignment and improving biomechanical stability [12].

Robotic systems, guided by these pre-operative plans, enable surgeons to execute complex procedures with greater accuracy than traditional freehand techniques. The use of robotic arms reduces tremor and enhances dexterity, leading to more precise bone cuts and screw placement. CAS systems provide real-time feedback and navigation during surgery, allowing surgeons to monitor their progress and make adjustments as needed. This is particularly beneficial in minimally invasive procedures, where visualization is limited. By minimizing soft tissue damage and reducing the size of incisions, robotic and CAS techniques contribute to faster recovery times, reduced pain, and improved functional outcomes for patients undergoing orthopedic internal fixation. The error e in screw placement, for example, can be significantly reduced using robotic assistance, leading to improved fixation strength F (Table 4).

Table 4. Robotic Systems for Orthopedic Surgery: A Comparison.

Feature	Traditional Freehand Technique	Robotic/CAS Technique
Accuracy	Lower	Higher. Error e in screw placement reduced.
Planning	Based on 2D imaging and surgeon experience.	Pre-operative 3D planning using CT/MRI.
Precision	Limited by tremor and dexterity of surgeon.	Enhanced precision due to robotic arm and real-time navigation.
Soft Tissue Damage	Potentially higher due to larger incisions and less precise movements.	Minimized due to minimally invasive approach and precise movements.
Recovery Time	Potentially longer.	Faster.
Visualization	Limited, especially in minimally invasive procedures.	Improved visualization through real-time feedback and navigation.
Fixation Strength	Lower, potentially. Influenced by error e.	Improved fixation strength F due to accurate screw placement.
Complexity of Procedures	Limited to relatively simple cases.	Enables more complex procedures with greater accuracy.

4. Personalization of Internal Fixation Devices

4.1. Patient-Specific Implants

Patient-specific implants (PSIs) represent a paradigm shift in orthopedic internal fixation, moving away from a one-size-fits-all approach to solutions tailored to individual patient anatomy and biomechanical needs. Unlike standard implants, which are manufactured in a limited range of sizes and shapes, PSIs are designed and fabricated to precisely match the unique characteristics of a patient's bone structure and fracture pattern. This personalization offers several potential advantages, including improved implant fit and stability, reduced risk of malalignment, enhanced bone healing, and decreased post-operative complications.

The design and manufacturing process of PSIs typically involves several key steps. First, high-resolution medical imaging data, such as computed tomography (CT) or magnetic resonance imaging (MRI), is acquired to create a three-dimensional

reconstruction of the patient's anatomy. This digital model is then used to design the implant using specialized computer-aided design (CAD) software. The design process considers factors such as fracture geometry, bone density, and biomechanical loading conditions to optimize implant shape, size, and fixation points. Finite element analysis (FEA) may be employed to simulate the mechanical behavior of the implant and bone construct under physiological loads, ensuring adequate stability and minimizing stress concentrations. Finally, the customized implant is manufactured using additive manufacturing techniques, such as three-dimensional printing, allowing for the creation of complex geometries and intricate designs that would be impossible to achieve with traditional manufacturing methods. The accuracy of PSI fit is crucial, with deviations often measured in millimeters, impacting the overall success of the fixation.

4.2. Biomechanical Modeling and Finite Element Analysis

Biomechanical modeling and finite element analysis (FEA) are pivotal tools in the personalization of internal fixation devices. These computational methods allow for the simulation of bone-implant constructs under various loading scenarios, enabling the optimization of implant design parameters such as geometry, material properties, and fixation strategies. FEA models can predict stress distribution within the bone and implant, identifying areas of potential failure or stress shielding. By iteratively modifying the implant design and re-running the simulations, engineers can tailor the device to minimize these risks and promote optimal fracture healing.

A crucial aspect of personalized implant design is the consideration of patient-specific loading profiles. Standardized loading conditions used in traditional implant testing may not accurately reflect the actual forces experienced by an individual patient during daily activities. Factors such as body weight, activity level, and gait pattern significantly influence the magnitude and direction of forces acting on the fracture site. Incorporating patient-specific loading data, obtained through gait analysis or musculoskeletal modeling, into FEA simulations allows for a more accurate prediction of implant performance and fracture healing. For instance, the force F acting on the implant during walking can be modeled as a function of time t, $F(t)$, and incorporated into the FEA model to simulate realistic loading conditions. This personalized approach helps to ensure that the internal fixation device is optimally designed to withstand the specific biomechanical demands of the individual patient, ultimately leading to improved clinical outcomes (Table 5).

Table 5. Parameters Influencing Fracture Healing in FEA.

Parameter	Description	Influence on Fracture Healing Prediction in FEA
Implant Geometry	Shape and dimensions of the internal fixation device.	Affects stress distribution in the bone and implant, influencing stability and potential for stress shielding.
Implant Material Properties	Young's modulus, Poisson's ratio, yield strength, etc. of the implant material.	Determines the stiffness of the construct and its ability to withstand applied loads, impacting stress transfer to the bone.
Fixation Strategy	Number, type, and placement of screws or other fixation elements.	Influences the stability of the fracture site and the distribution of load between the bone and implant.
Bone Material Properties	Density, Young's modulus, and other mechanical properties of the bone.	Affects the bone's ability to bear load and remodel under stress, influencing fracture healing.

Parameter	Description	Influence on Fracture Healing Prediction in FEA
Loading Conditions	Magnitude, direction, and frequency of forces acting on the bone-implant construct.	Accurate representation of forces experienced during daily activities ($F(t)$) is crucial for predicting implant performance and fracture healing under realistic scenarios. Patient-specific loading data improves accuracy.
Patient-Specific Factors	Body weight, activity level, gait pattern.	Influence the magnitude and direction of forces acting on the fracture site, requiring personalized loading profiles in FEA simulations.
Fracture Gap Size and Configuration	Size and shape of the fracture gap.	Impacts the mechanical environment at the fracture site and influences callus formation.

4.3. Considerations for Pediatric and Geriatric Patients

Internal fixation in pediatric and geriatric patients presents unique challenges that necessitate personalized approaches. In pediatric cases, the remaining growth potential of the child is a primary concern. Fixation devices must accommodate or avoid disrupting the physis to prevent growth disturbances like limb length discrepancies or angular deformities. Digital planning and personalized implants, designed using techniques like finite element analysis, can optimize fixation while minimizing physeal damage. For example, patient-specific growth modulation implants can be designed based on predicted growth rates, represented by variables such as G_x, G_y, and G_z for growth in three dimensions, to correct deformities gradually.

Geriatric patients, conversely, often exhibit compromised bone quality due to osteoporosis or other age-related conditions. This necessitates fixation strategies that enhance stability and minimize the risk of implant failure. Personalized screw designs, optimized for purchase in osteoporotic bone, and patient-specific augmentation techniques using bone cement or other biomaterials can improve fixation strength. Digital tools can assess bone density preoperatively, allowing for informed implant selection and surgical planning to address the specific biomechanical needs of each elderly patient, considering factors like bone mineral density (BMD) and fracture location.

5. Comparison and Challenges

5.1. Traditional vs. Digital/Personalized Approaches

Traditional internal fixation relies on standardized implants and techniques, often involving manual contouring and intraoperative adjustments based on surgeon experience and fluoroscopic imaging. This approach, while established, can lead to suboptimal fit, increased operative time, and higher risk of complications due to imprecise reduction and fixation. Digital and personalized approaches leverage advanced imaging (CT, MRI), computational modeling, and additive manufacturing to create patient-specific implants and surgical guides. Advantages include improved anatomical fit, enhanced biomechanical stability, and reduced soft tissue damage. However, these technologies face challenges related to cost, regulatory hurdles, workflow integration, and the need for specialized training. The increased cost C and complexity X must be weighed against the potential for improved patient outcomes O.

5.2. Challenges and Limitations

Digitalization and personalization in orthopedic internal fixation face significant hurdles. Regulatory pathways for personalized devices are not yet well-defined, creating uncertainty for manufacturers and hindering innovation. The cost of implementing digital

technologies like CAD/CAM and 3D printing, along with patient-specific implants, can be substantial, potentially limiting accessibility. Furthermore, successful adoption requires specialized training for surgeons and technicians in areas such as digital imaging, implant design, and additive manufacturing. Addressing these regulatory, economic, and educational challenges is crucial for realizing the full potential of personalized orthopedic care.

6. Future Perspectives

6.1. Artificial Intelligence and Machine Learning

AI and ML hold immense promise for revolutionizing orthopedic internal fixation. These technologies can optimize implant design by analyzing vast datasets of biomechanical simulations and clinical outcomes, leading to patient-specific implants that enhance stability and promote bone healing. ML algorithms can predict fracture healing rates based on patient-specific factors like age, bone density (ρ), and fracture characteristics, allowing for tailored rehabilitation protocols. Furthermore, AI can improve surgical outcomes through automated surgical planning, suggesting optimal implant placement and screw trajectories to minimize complications. Intraoperatively, AI-powered systems can assist surgeons by providing real-time feedback on implant positioning and stability, guiding decision-making and potentially reducing the need for revision surgeries. The integration of AI and ML promises a future of personalized and data-driven orthopedic care.

6.2. Biomaterials and Surface Modifications

Future orthopedic internal fixation hinges on advanced biomaterials. Research focuses on materials exhibiting superior biocompatibility and mechanical strength, such as bioresorbable polymers with tailored degradation rates matching bone healing. Surface modifications, including bioactive coatings like hydroxyapatite and nanotopographical features, are crucial. These modifications enhance osseointegration by promoting cell adhesion and differentiation, while also minimizing bacterial adhesion and biofilm formation, thereby reducing the incidence of implant-related infections. Optimizing surface roughness, with parameters like average roughness S_a and root mean square roughness S_q, is also being explored to improve implant fixation.

6.3. Remote Monitoring and Telemedicine

Remote monitoring and telemedicine hold significant promise for enhancing orthopedic internal fixation outcomes. Wearable sensors can continuously track parameters like range of motion, weight-bearing load (W), and joint temperature (T_j), providing valuable data on patient recovery. Mobile health apps can facilitate communication between patients and surgeons, enabling remote monitoring of wound healing and pain levels. Early detection of complications, such as infection or implant loosening, becomes possible through real-time data analysis. Furthermore, telemedicine platforms can deliver personalized rehabilitation programs and virtual consultations, improving patient adherence and reducing the need for frequent in-person visits.

7. Conclusion

Digitalization and personalization are revolutionizing orthopedic internal fixation. Our review highlights advancements in personalized implant design using techniques like 3D printing, guided by digital planning tools. This enables improved biomechanical compatibility and optimized patient outcomes, addressing the limitations of traditional, standardized implants.

Orthopedic internal fixation is poised for significant advancement. Digitalization and personalization promise improved implant design, surgical techniques, and ultimately, patient outcomes. Further research into biocompatible materials and patient-specific

solutions will drive innovation and enhance the quality of orthopedic care, reducing t_{recovery} and improving QoL.

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