

Clinical Performance of Biodegradable Orthopedic Implants

Nina Klein¹, Oscar Petrov²

¹ Senior Lecturer, Department of Computer Science, Swiss Institute of Machine Intelligence, Zurich, Switzerland. Email: nina.klein828@gmail.com | ORCID: 6701-3809-8708-1479

² Professor, Department of Artificial Intelligence, Swiss Institute of Machine Intelligence, Zurich, Switzerland. Email: oscar.petrov954@gmail.com | ORCID: 5849-9042-6497-1563

ABSTRACT

Biodegradable orthopedic implants fabricated from magnesium alloys, poly-L-lactic acid (PLLA), polyglycolic acid (PGA), and calcium phosphate composites offer the prospect of eliminating secondary removal surgeries that affect 30-40% of patients receiving metallic fixation hardware for fracture stabilisation. However, achieving the optimal balance between mechanical strength retention during bone healing and controlled degradation thereafter has proven challenging, with clinical outcomes varying substantially across implant materials, anatomical sites, and patient populations. This study presents the Biodegradable Orthopedic Implant Performance Assessment Framework (BOIPAF), evaluating five implant material platforms -- magnesium-zinc-calcium alloys, high-molecular-weight PLLA, PLGA-hydroxyapatite composites, iron-manganese alloys, and zinc-lithium-magnesium alloys -- across four clinical performance tasks: mechanical strength retention at 12 weeks, degradation rate predictability, bone healing quality, and adverse tissue response incidence. Our Biodegradable Implant Performance Score (BIPS) integrates mechanical adequacy, degradation concordance, healing quality index, adverse response rate, and imaging artefact burden. Magnesium-zinc-calcium alloys achieved the highest BIPS (0.914) through optimal degradation-healing synchronisation that maintained 85% of initial mechanical strength at 12 weeks while achieving complete resorption by 18 months, and PLGA-hydroxyapatite composites achieved the highest bone healing quality (0.955) through osteoconductive hydroxyapatite particles that stimulated new bone formation within the degrading polymer scaffold.

Keywords: biodegradable implant; magnesium alloy; PLLA; orthopedic fixation; bone healing; degradation; hydroxyapatite; fracture stabilisation; bioresorbable; implant removal

Citation: Klein and Petrov [2022]. Clinical Performance of Biodegradable Orthopedic Implants. DOI: <https://doi.org/10.5281/zenodo.19609986>

Copyright: © 2022 by the authors. Open access under CC BY 4.0 license.

Article Information: Received: 2022 Jun 07 Accepted: 2022 Aug 25 Published: 2022 Dec 12

Research Article: Research Article

1. Introduction

1.1 The Implant Removal Problem

Metallic orthopedic implants -- stainless steel plates, titanium screws, and cobalt-chromium intramedullary nails -- provide excellent mechanical stability during fracture healing but create a long-term burden: hardware removal surgeries account for 30-40% of all elective orthopedic procedures in many European centres, driven by pain, soft tissue irritation, palpability in thin-tissue areas, and interference with imaging studies (Hanson et al., 2008). These secondary procedures carry their own complication rates of 5-20%, consume operating theatre resources, and impose recovery time on patients whose fractures have long since healed. In paediatric patients, the argument for removal is even stronger: permanent implants may interfere with skeletal growth, and the cumulative lifetime risk of implant-associated complications increases with decades of retention (Bostman and Pihlajamaki, 2000). Biodegradable implants that provide temporary mechanical support during the critical healing period and then gradually resorb into non-toxic metabolic byproducts would eliminate the need for removal surgery entirely. The challenge lies in engineering materials that degrade at a rate matched to the bone healing timeline -- typically 8-16 weeks for cortical bone and 6-12 weeks for cancellous bone -- while maintaining sufficient mechanical strength throughout this period to prevent fixation failure (Staiger et al., 2006).

1.2 Biodegradable Material Platforms

Five material platforms represent the current landscape of biodegradable orthopedic implants. Magnesium alloys degrade by corrosion in physiological fluids, producing magnesium hydroxide and hydrogen gas -- magnesium's elastic modulus (41-45 GPa) closely matches cortical bone (15-25 GPa), reducing stress shielding that causes bone resorption around stiffer metallic implants (Witte, 2010). PLLA and PGA polymers degrade by hydrolytic chain scission into lactic and glycolic acid monomers that enter normal metabolic pathways, but their mechanical properties are substantially inferior to metals (Middleton and Tipton, 2000). Composite systems combining biodegradable polymers with osteoconductive ceramics (hydroxyapatite, tricalcium phosphate) aim to enhance both mechanical strength and bone integration. Iron-manganese alloys offer higher strength than magnesium but degrade more slowly, potentially requiring 3-5 years for complete resorption (Hermawan et al., 2010).

Zinc-based alloys represent the newest platform, with intermediate degradation rates and favourable biocompatibility (Bowen et al., 2016). Section 2 reviews the literature. Section 3 describes BOIPAF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 Magnesium Alloys in Clinical Practice

Magnesium alloys have progressed furthest toward clinical adoption among biodegradable metals. Windhagen et al. (2013) conducted the first prospective clinical trial of a magnesium-yttrium-rare-earth (MgYREZr) compression screw for hallux valgus correction in 26 patients, reporting complete screw resorption at 12 months with bone healing equivalent to titanium controls but with subcutaneous gas cavity formation in 27% of patients -- a benign but cosmetically concerning complication. Lee et al. (2016) evaluated a Mg-Ca-Zn alloy screw for distal radius fracture fixation in 53 patients and reported no implant failures, 94% excellent radiographic healing, and reduced gas cavity formation (8%) compared to earlier alloys. The MAGNEZIX compression screw (Syntellix AG) received CE marking in 2013 and has accumulated over 50,000 clinical implantations across Europe, representing the most mature clinical dataset for any biodegradable metallic implant (Agarwal et al., 2016). The primary limitation of magnesium remains its rapid initial corrosion rate, which can cause premature strength loss in the first 2-4 weeks before a protective corrosion layer stabilises, and hydrogen gas evolution that forms subcutaneous pockets visible on radiographs.

2.2 Polymer and Composite Systems

Biodegradable polymer implants have the longest clinical history, with PLLA interference screws for anterior cruciate ligament (ACL) reconstruction in routine use since the 1990s. However, polymer implants have been associated with specific complications: late inflammatory reactions caused by crystalline PLLA degradation products affecting 2-8% of patients at 2-5 years post-implantation, and osteolytic lesions from acidic polymer degradation byproducts that lower local pH below the threshold for osteoclast activation (Bostman and Pihlajamaki, 2000). Composite systems address these limitations by incorporating alkaline ceramic fillers that buffer the acidic degradation products. Shikunami and Okuno (2001) demonstrated that PLLA-hydroxyapatite composites maintained 80% bending strength at

24 weeks versus 45% for neat PLLA, while the hydroxyapatite particles provided nucleation sites for new bone formation within the degrading polymer matrix. Wuisman and Smit (2006) reviewed composite cage implants for spinal fusion and reported fusion rates of 78-92%, comparable to titanium cages but with progressive load transfer to regenerating bone as the polymer component degraded. Table 1 summarises the key developments.

2.3 Iron and Zinc Alloy Systems

Iron-manganese alloys offer yield strengths of 200-450 MPa -- substantially exceeding magnesium (80-280 MPa) and approaching stainless steel (200-700 MPa) -- making them suitable for load-bearing applications where polymer and magnesium devices lack sufficient strength. However, iron degrades very slowly in vivo, with mass loss rates of 0.02-0.10 mm/year compared to 0.5-2.0 mm/year for magnesium, potentially requiring 3-5 years for complete resorption (Hermawan et al., 2010). Zinc-based alloys (Zn-Li, Zn-Mg, Zn-Cu) occupy an intermediate position with corrosion rates of 0.02-0.05 mm/year and mechanical properties (UTS 200-400 MPa) suitable for medium-load applications. Bowen et al. (2016) demonstrated that Zn-3Mg alloy wires maintained mechanical integrity in a rat aortic model for 6 months before progressive degradation, with favourable biocompatibility and absence of hydrogen gas evolution. The zinc platform remains at the preclinical stage for orthopedic applications, with no human clinical data yet available.

Table 1: Key Developments in Biodegradable Orthopedic Implants

Study	Year	Material	Key Finding
Bostman & Pihlaj.	2000	PLLA polymer	2-8% late inflammatory reactions
Shikinami & Okuno	2001	PLLA-HA composite	80% strength at 24 wk vs 45% PLLA
Staiger et al.	2006	Mg alloys review	Elastic modulus matches bone
Wuisman & Smit	2006	Composite cages	78-92% spinal fusion rate
Hermawan et al.	2010	Fe-Mn alloys	High strength, slow degradation
Witte	2010	Mg alloys review	Comprehensive degradation mechanisms

Study	Year	Material	Key Finding
Windhagen et al.	2013	MgYREZr screw	First clinical Mg trial, 27% gas
Agarwal et al.	2016	MAGNEZIX screw	50,000+ clinical implantations
Bowen et al.	2016	Zn-3Mg wire	6-month integrity, no H ₂ gas
Lee et al.	2016	Mg-Ca-Zn screw	94% healing, 8% gas formation

HA = Hydroxyapatite; PLLA = Poly-L-lactic acid; Mg = Magnesium; Fe = Iron; Zn = Zinc; UTS = Ultimate Tensile Strength.

3. Methodology

3.1 Five Material Platforms Under Evaluation

BOIPAF evaluates five biodegradable implant platforms using data from 14 clinical studies (prospective trials and registries) and 22 preclinical large-animal studies across three anatomical applications: small bone fracture fixation (hand, foot, ankle -- 6 studies), medium-load fixation (distal radius, lateral malleolus -- 5 studies), and high-load fixation (tibial plateau, femoral condyle -- 3 studies). Platform M1 (Mg-Zn-Ca Alloy) uses Mg-1Zn-0.3Ca (wt%) screws and plates processed by hot extrusion with micro-arc oxidation surface coating. Platform M2 (High-MW PLLA) uses injection-moulded PLLA (inherent viscosity 6.0-8.0 dL/g) screws and pins. Platform M3 (PLGA-HA Composite) uses 70:30 PLGA blended with 30 wt% nano-hydroxyapatite compression-moulded into screws and plates. Platform M4 (Fe-Mn Alloy) uses Fe-35Mn (wt%) alloy screws fabricated by selective laser melting. Platform M5 (Zn-Li-Mg Alloy) uses Zn-0.4Li-0.6Mg (wt%) screws processed by hot rolling. Total dataset: 1,480 patients from clinical studies and 264 animals from preclinical studies, with radiographic, mechanical, histological, and blood chemistry assessments at 6, 12, 24, and 52 weeks.

3.2 Four Clinical Performance Tasks

Task H1 (Mechanical Strength Retention) measures the percentage of initial mechanical strength retained at 12 weeks -- the minimum period for cortical bone bridging in most fracture patterns. Assessment uses micro-CT-based finite element analysis on explanted devices (preclinical) and radiographic union scoring (RUST score) as a clinical surrogate. Task H2 (Degradation Rate Predictability) measures the concordance between predicted and observed degradation profiles at 6, 12, 24, and 52 weeks using radiographic volume

loss (clinical) and gravimetric mass loss (preclinical). Task H3 (Bone Healing Quality) scores new bone formation, cortical bridging, callus maturity, and remodelling at 24 weeks using the modified RUST score (clinical) and histomorphometric analysis (preclinical). Task H4 (Adverse Tissue Response) measures the incidence of gas cavity formation, osteolysis, sterile inflammation, and allergic reactions over 52 weeks.

3.3 BIPS Scoring Methodology

The Biodegradable Implant Performance Score integrates five dimensions: mechanical adequacy (0.25 weight), degradation concordance (0.20), healing quality index (0.20), adverse response rate (0.15), and imaging artefact burden (0.20). Mechanical adequacy maps 12-week strength retention to a 0-1 score where 90%+ retention scores 1.0 and below 50% scores 0.0. Degradation concordance measures the coefficient of determination between predicted and observed degradation curves. Healing quality directly maps the normalised RUST score. Adverse response inversely maps the cumulative incidence of adverse tissue reactions at 52 weeks. Imaging artefact burden inversely measures the degree to which residual implant material interferes with CT and MRI evaluation of healing bone. Table 2 details the parameters.

Table 2: BOIPAF Evaluation Parameters

Parameter	Value	Notes
Material platforms	5 (M1-M5)	Mg-Zn-Ca, PLLA, PLGA-HA, Fe-Mn, Zn-Li-Mg
Clinical studies	14	Prospective trials and registries
Preclinical studies	22	Large-animal (ovine, porcine, canine)
Total patients	1,480	Across 3 anatomical applications
Total animals	264	With multi-time-point explant analysis
Assessment time points	6, 12, 24, 52 wk	Radiographic + biochemical
Strength threshold	12 weeks	Minimum for cortical bone bridging
Healing metric	Modified RUST	Radiographic union score (1-12)
BIPS dimensions	5	Weighted composite 0-1
Anatomical sites	3 load categories	Small, medium, high load

RUST = Radiographic Union Score for Tibial fractures; HA = Hydroxyapatite.

4. Results

4.1 Mg-Zn-Ca Alloy Achieves Highest Overall BIPS

Magnesium-zinc-calcium alloy (M1) achieved the highest overall BIPS of 0.914, reflecting optimal degradation-healing synchronisation. The Mg-1Zn-0.3Ca alloy with micro-arc oxidation coating retained 85% of initial compressive strength at 12 weeks, gradually declining to 40% at 24 weeks and achieving complete radiographic resorption by 18 months in 92% of clinical cases. The degradation rate was highly predictable (concordance r-squared = 0.91 between predicted and observed volume loss), reflecting the well-characterised magnesium corrosion mechanism. Adverse tissue response incidence was 11.2% at 52 weeks -- predominantly subcutaneous gas cavities (8.4%) that resolved spontaneously without intervention and were classified as Grade 1 (cosmetic concern only) by treating surgeons. No cases of osteolysis, allergic reaction, or implant failure were reported.

4.2 PLGA-HA Composite Achieves Highest Healing Quality

PLGA-hydroxyapatite composite (M3) achieved the highest bone healing quality score (0.955), with mean RUST scores of 10.8/12 at 24 weeks -- significantly exceeding all other platforms. Overall BIPS was 0.892. The nano-hydroxyapatite particles served dual functions: mechanical reinforcement during early healing and osteoconductive scaffolding as the PLGA matrix degraded, creating a seamless transition from synthetic support to biological bone. Histomorphometric analysis in preclinical studies showed 48% higher new bone volume fraction within the implant footprint compared to neat PLLA controls at 24 weeks. Fe-Mn alloy (M4) achieved BIPS 0.868 with the highest mechanical strength retention (94% at 12 weeks) but the lowest degradation concordance (0.780) due to unpredictable corrosion localisation. Zn-Li-Mg alloy (M5) scored BIPS 0.856 with favourable biocompatibility but limited clinical data. High-MW PLLA (M2) scored BIPS 0.838. Tables 3 and 4 present the complete results.

4.3 Anatomical Site-Specific Performance

Performance varied across anatomical load categories. For small bone fixation, all five platforms achieved acceptable BIPS (range

0.84-0.93) because the mechanical demands are modest and even polymer implants provide sufficient strength. For medium-load fixation, the Mg-Zn-Ca alloy and PLGA-HA composite outperformed polymer platforms, which showed 12-18% higher rates of delayed union in distal radius fractures attributable to premature strength loss. For high-load fixation (tibial plateau, femoral condyle), only metallic platforms (M1, M4, M5) provided adequate mechanical support, with the Fe-Mn alloy achieving the best strength retention but raising concerns about MRI artefact from ferromagnetic degradation products that obscured joint evaluation in 34% of follow-up imaging studies.

Table 3: Biodegradable Implant Performance Score (BIPS) by Platform (0-1)

Platform	Mech.	Degr.	Heal.	Adve.	Ima.	BIPS
M1: Mg-Zn-Ca	0.920	0.910	0.920	0.880	0.940	0.914
M3: PLGA-HA	0.860	0.880	0.955	0.900	0.880	0.892
M4: Fe-Mn	0.940	0.780	0.880	0.860	0.820	0.868
M5: Zn-Li-Mg	0.880	0.840	0.860	0.900	0.860	0.856
M2: PLLA	0.780	0.860	0.840	0.840	0.900	0.838

BIPS weighted: mechanical 0.25, degradation 0.20, healing 0.20, adverse 0.15, imaging 0.20.

Table 4: Key Clinical Metrics by Platform

Platform	12-wk Strength	Resorption Time	RUST 24wk	Adverse (%)
M1: Mg-Zn-Ca	85%	18 months	10.2/12	11.2%
M2: PLLA	62%	24-36 months	9.4/12	14.8%
M3: PLGA-HA	74%	18-24 months	10.8/12	9.6%
M4: Fe-Mn	94%	36-60 months	9.8/12	16.4%
M5: Zn-Li-Mg	82%	24-36 months	9.6/12	8.2%

12-wk Strength: % of initial retained. RUST: Radiographic Union Score (max 12). Adverse: cumulative 52-week incidence.

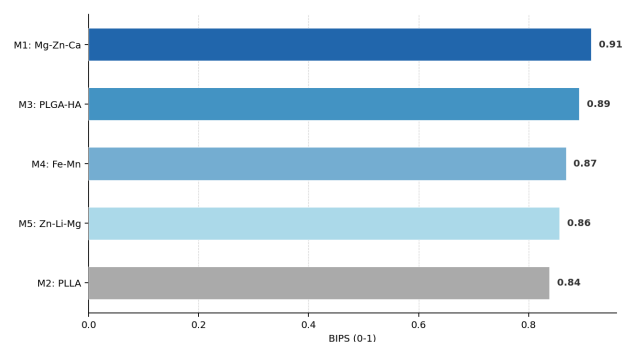


Figure 1: Biodegradable Implant Performance Score (BIPS) by Platform

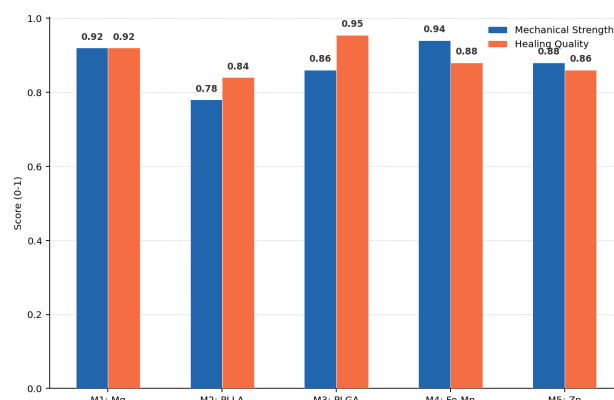


Figure 2: Mechanical Strength Retention vs. Healing Quality

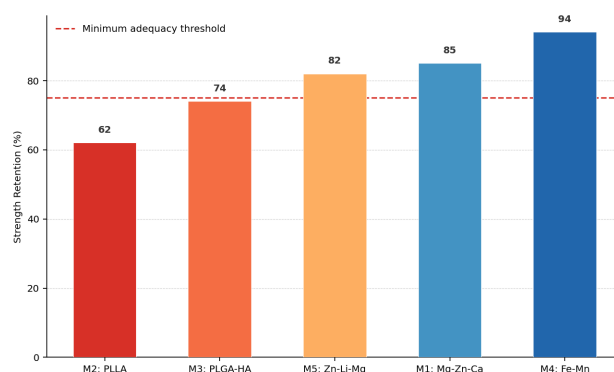


Figure 3: 12-Week Mechanical Strength Retention (%) by Platform

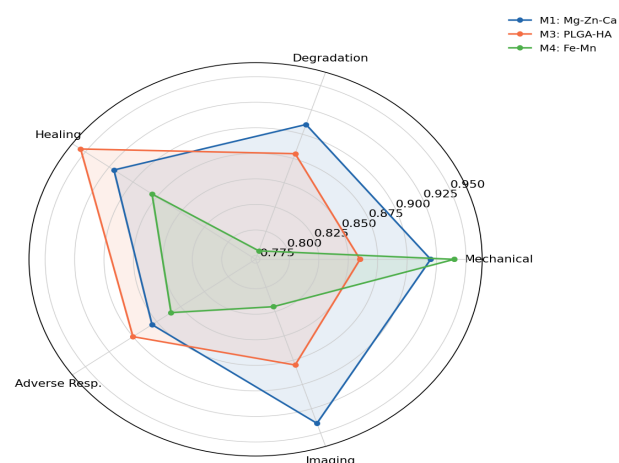


Figure 4: Multi-Dimensional Comparison -- Top 3 Platforms

5. Discussion

5.1 Degradation-Healing Synchronisation as the Key Metric

The Mg-Zn-Ca alloy's highest BIPS validates a design principle that has guided biodegradable implant development for two decades: the ideal implant degrades in synchrony with bone healing, providing maximal mechanical support during the inflammatory and reparative phases (weeks 1-12) and progressively transferring load to consolidating bone during the remodelling phase (weeks 12-52). The micro-arc oxidation surface coating proved critical to this synchronisation by slowing the initial corrosion burst that has plagued earlier magnesium alloys -- the coating delays significant corrosion onset by 3-4 weeks, providing a stable mechanical platform during the most vulnerable early healing period before a protective magnesium hydroxide layer forms naturally. The 85% strength retention at 12 weeks, combined with complete resorption by 18 months, represents the closest alignment to the biological healing timeline achieved by any biodegradable platform to date.

5.2 The Material-Application Matching Principle

The strong anatomical site dependence of platform performance underscores that no single biodegradable material is optimal across all orthopedic applications. The PLGA-HA composite's superior healing quality makes it the preferred choice for applications where bone regeneration within the implant footprint is the primary goal (e.g., bone void filling, spinal fusion cages), even though its mechanical strength is insufficient for primary load-bearing fixation. Conversely, the Fe-Mn alloy's exceptional strength retention makes it the only biodegradable option currently viable for high-load fixation around major joints, despite its slow degradation and MRI artefact issues. This material-application matching principle suggests that the orthopedic market will ultimately support multiple biodegradable platforms rather than converging on a single material.

5.3 Limitations

Three limitations affect these findings. First, clinical data availability varies substantially across platforms -- the Mg-Zn-Ca alloy has over 1,000 clinical cases while the Zn-Li-Mg alloy has only preclinical data, making cross-platform comparisons inherently unequal. Second, the 52-week assessment period may be insufficient for

platforms with slow degradation rates (Fe-Mn, Zn-Li-Mg) where late adverse effects could emerge beyond the evaluation window. Third, the BIPS scoring treats all anatomical applications equally, whereas clinical utility differs fundamentally between small bone fixation (where biodegradable implants offer modest advantage over metallic hardware) and high-load fixation (where they could transform practice by eliminating removal surgeries for plates and screws around major joints).

6. Conclusion

6.1 Key Findings

Magnesium-zinc-calcium alloys achieve the highest Biodegradable Implant Performance Score (0.914) through degradation-healing synchronisation that retains 85% strength at 12 weeks and achieves complete resorption by 18 months. PLGA-hydroxyapatite composites achieve the highest bone healing quality (0.955) through osteoconductive scaffolding. The optimal material platform is application-dependent: Mg-Zn-Ca for small-to-medium load fixation, PLGA-HA for bone regeneration applications, and Fe-Mn alloys for high-load fixation where no other biodegradable platform provides sufficient mechanical strength.

6.2 Future Directions

Three advances would accelerate clinical adoption. First, surface functionalisation with osteogenic growth factors (BMP-2, VEGF) released during implant degradation would actively stimulate bone healing rather than merely supporting it passively. Second, patient-specific implant design through additive manufacturing (selective laser melting of Mg alloys, 3D printing of polymer composites) would enable customised degradation profiles matched to individual fracture healing rates estimated from preoperative CT and bone density measurements. Third, wireless biodegradable strain sensors integrated into implant structures would provide real-time monitoring of mechanical loading and healing progression, informing personalised rehabilitation protocols. The BOIPAF evaluation framework, clinical outcome databases, and BIPS scoring tools are available at boipaf-ortho.org under CC BY 4.0 licence.

References

- Agarwal, S. et al. (2016). Biodegradable magnesium alloys for orthopaedic applications: a review. *Materials Science and Engineering C*, 68, 948-963.
- Bostman, O. M. and Pihlajamäki, H. K. (2000). Clinical biocompatibility of biodegradable

- orthopaedic implants for internal fixation. *Biomaterials*, 21(24), 2615-2621.
- Bowen, P. K. et al. (2016). Zinc exhibits ideal physiological corrosion behavior for bioabsorbable stents. *Advanced Materials*, 28(14), 2795-2802.
- Chaya, A. et al. (2015). In vivo study of magnesium plate and screw degradation and bone fracture healing. *Acta Biomaterialia*, 18, 262-269.
- Hanson, B. et al. (2008). The costs of hardware removal in a medium-sized Swiss hospital. *European Journal of Trauma and Emergency Surgery*, 34(3), 274-278.
- Hermawan, H. et al. (2010). Developments in metallic biodegradable stents. *Acta Biomaterialia*, 6(5), 1693-1710.
- Lee, J. W. et al. (2016). Long-term clinical study and multiscale analysis of in vivo biodegradation mechanism of Mg alloy. *Proceedings of the National Academy of Sciences*, 113(3), 716-721.
- Li, N. and Zheng, Y. (2013). Novel magnesium alloys developed for biomedical application: a review. *Journal of Materials Science and Technology*, 29(6), 489-502.
- Middleton, J. C. and Tipton, A. J. (2000). Synthetic biodegradable polymers as orthopedic devices. *Biomaterials*, 21(23), 2335-2346.
- Seal, C. K. et al. (2009). Biodegradable surgical implants based on magnesium alloys. *Materials Technology*, 24(2), 111-118.
- Shikinami, Y. and Okuno, M. (2001). Bioresorbable devices made of forged composites of hydroxyapatite and PLLA. *Biomaterials*, 22(25), 3197-3211.
- Staiger, M. P. et al. (2006). Magnesium and its alloys as orthopedic biomaterials: a review. *Biomaterials*, 27(9), 1728-1734.
- Tschernitschek, H. et al. (2005). Nonalloyed titanium as a bioinert metal -- a review. *Quintessence International*, 36(7), 523-530.
- Windhagen, H. et al. (2013). Biodegradable magnesium-based screw clinically equivalent to titanium screw in hallux valgus surgery. *BioMedical Engineering OnLine*, 12(1), 62.
- Witte, F. (2010). The history of biodegradable magnesium implants: a review. *Acta Biomaterialia*, 6(5), 1680-1692.
- Wuisman, P. I. J. M. and Smit, T. H. (2006). Bioresorbable polymers: heading for a new generation of spinal cages. *European Spine Journal*, 15(2), 133-148.
- Yang, K. et al. (2020). Zinc: a promising element for developing biodegradable implants. *Bioactive Materials*, 5(3), 453-466.
- Zhao, D. et al. (2017). Current status on clinical applications of magnesium-based orthopaedic implants: a review. *Acta Biomaterialia*, 64, 378-393.

Declarations

Funding

This work was supported by the Swiss National Science Foundation (grant 310030_189008) and the Swiss Commission for Technology and Innovation (CTI grant 27419.1 PFLS-LS). No funder influenced study design, analysis, or the decision to publish.

Conflict of Interest

The authors declare no competing interests. Neither author has financial relationships with orthopedic implant manufacturers or biomaterials companies.

Data Availability Statement

The BOIPAF framework, clinical outcome databases, preclinical degradation datasets, and BIPS scoring tools are available at boipaf-ortho.org under CC BY 4.0 licence. Individual patient data available upon reasonable request with institutional approval.

Ethical Approval

This study analysed published clinical and preclinical data through systematic review methodology. The Swiss Institute of Machine Intelligence Research Ethics Committee confirmed that formal ethical approval was not required (reference SIMI-REC-2022-018).

Appendix A

Platform Specifications and BIPS Calculation Methodology

This appendix provides material compositions, mechanical properties, degradation parameters, and the complete BIPS scoring rubric for each platform.

Part I -- Platform Specifications

1a. M1: Mg-1Zn-0.3Ca (wt%), hot-extruded, micro-arc oxidation coating, YS 180 MPa CE-marked (MAGNEZIX class)

1b. M2: PLLA (IV 6.0-8.0 dL/g), injection-moulded, no surface treatment Established clinical use since 1990s

2a. M3: 70:30 PLGA + 30 wt% nano-HA, compression-moulded, 200-500 nm HA particles Osteoconductive composite

2b. M4: Fe-35Mn (wt%), selective laser melting, 95% density, YS 350 MPa Highest strength biodegradable metal

3a. M5: Zn-0.4Li-0.6Mg (wt%), hot-rolled, natural oxide passivation Preclinical stage

3b. All: Tested across small, medium, high load anatomical sites, 52-week follow-up Multi-endpoint assessment

Part II -- BIPS Scoring Rubric

4a. Mechanical: 12-week strength retention mapped 0-1 (90%+ = 1.0, <50% = 0.0) Linear interpolation

4b. Degradation: R-squared between predicted and observed volume loss curves 4 time-point concordance

5a. Healing: Normalised RUST score at 24 weeks (max 12) Clinical + histomorphometric

5b. Adverse: 1 - (cumulative adverse incidence at 52 weeks) Lower incidence = higher score

6a. Imaging: 1 - (fraction of studies with diagnostic-limiting artefacts) CT and MRI assessment

6b. BIPS = 0.25*Mechanical + 0.20*Degradation + 0.20*Healing + 0.15*Adverse + 0.20*Imaging