

Biodegradable Cardiac Implants

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ABSTRACT

Permanent metallic cardiac implants have served patients well for decades, but they come with baggage: lifelong imaging artefacts on MRI, chronic inflammatory responses at the tissue-metal interface, and the occasional need for risky extraction surgeries when devices malfunction or patients outgrow them. Biodegradable implants offer an appealing alternative because they do their job during the critical healing window and then quietly dissolve, sparing the patient a foreign body that was only ever needed temporarily. The challenge, of course, is making sure the device holds up long enough mechanically and degrades at a rate that the surrounding tissue can handle without triggering an excessive inflammatory cascade. We examined 220 biodegradable cardiac implant programmes across five material families -- magnesium alloys, zinc alloys, iron-based composites, polylactic acid blends, and silk-fibroin hybrids -- collected from partner laboratories in Italy, Spain, and Sweden between 2019 and 2023. A Biodegradable Cardiac Implant Quality Index (BCIQI) was constructed from five weighted sub-scores: mechanical retention, controlled degradation rate, biocompatibility profile, therapeutic delivery capacity, and imaging compatibility. Regression-derived weights tied each sub-score to observed translational success. BCIQI predicted successful clinical translation with $r = +0.84$ and an AUC of 0.882. Magnesium alloy programmes scored highest (mean BCIQI 0.821), while iron-based composites lagged at 0.594. Only 36.4 percent of programmes exceeded a BCIQI of 0.75, highlighting considerable room for material and design optimisation across the field.

Keywords: biodegradable implants; cardiac devices; magnesium alloys; zinc alloys; polylactic acid; silk fibroin; BCIQI; bioresorbable; controlled degradation; biocompatibility; Italy; Spain; Sweden

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1. Introduction

1.1 The Permanence Problem in Cardiac Devices

Walk into any cardiology ward and you will find patients carrying stainless steel stents, cobalt-chromium pacemaker leads, or titanium closure devices that were implanted years -- sometimes decades -- ago. These materials are mechanically tough and chemically inert, which is exactly what you want from something sitting inside a beating heart. But permanence has its downsides. Metal implants scatter MRI signals, making follow-up imaging harder than it needs to be. The tissue around them mounts a low-grade foreign body response that never fully resolves. And when a device fails or a child outgrows their implant, surgeons face an extraction procedure that carries real risk of vascular injury. For temporary applications -- scaffolding a healing artery, closing a septal defect in a growing infant, pacing a post-surgical heart for a few weeks -- the ideal device would do its work and then vanish. That is the promise of biodegradable cardiac implants.

1.2 Where the Field Stands Today

Research on bioresorbable materials for cardiac use has accelerated sharply since around 2015. Magnesium alloys were among the first to reach clinical trials because magnesium is already present in the body and its corrosion products are generally well tolerated. Zinc alloys gained attention a few years later thanks to a degradation rate that sits conveniently between magnesium (too fast for some applications) and iron (often too slow). Polymer-based options, particularly polylactic acid blends and silk-fibroin hybrids, offer the advantage of tuneable degradation through molecular weight and blending ratios. Despite all this activity, the field lacks a standardised way to compare programmes across material families. Published studies tend to report whichever metrics favour their material, making head-to-head comparison frustratingly difficult.

1.3 What This Study Adds

We set out to impose some order on this fragmented landscape. Our approach was to collect data from 220 implant programmes across three European countries, score each programme on five quality dimensions that matter for clinical translation, and combine those scores into a single composite index whose weights come from regression against actual translational outcomes. The result is the Biodegradable Cardiac Implant

Quality Index, or BCIQI. We wanted to know three things: which material family scores highest overall, which sub-dimensions drive the differences, and how well the index predicts whether a programme ultimately reaches clinical use.

2. Literature Review

2.1 Magnesium and Its Alloys

Magnesium has a natural head start in biocompatibility because the human body already handles about 25 grams of the stuff daily through diet and excretion. Early pure-magnesium stents degraded too quickly -- some lost structural integrity within four weeks, well before the vessel had finished remodelling. Alloying with rare earths, zinc, or calcium slowed things down enough to be clinically useful. The DREAMS and Magmaris programmes showed that a magnesium scaffold can keep a coronary artery open for the three to four months needed and then resorb completely within about a year. The main lingering concern is hydrogen gas evolution during corrosion, which can form small subcutaneous bubbles that are harmless but sometimes alarm patients and clinicians alike.

2.2 Zinc, Iron, and the Slow Degraders

Zinc sits in an interesting middle ground. Its corrosion rate in physiological saline is roughly 20 microns per year, slow enough to maintain mechanical support for six months or more but fast enough that the implant does not linger for decades like iron tends to. Iron-based implants degrade so slowly that some researchers have questioned whether they should really be called biodegradable at all. On the plus side, iron is mechanically strong and its corrosion products -- mainly iron oxides and hydroxides -- are handled by the body's iron recycling pathways. The practical problem is that a device still largely intact after three years has not delivered on the core promise of disappearing when its job is done. Various surface treatments and composite strategies have been tried to speed up iron degradation, with mixed results so far.

2.3 Polymer and Hybrid Platforms

Polylactic acid and its copolymers have been used in orthopaedic screws and sutures for years, so the regulatory pathway is more familiar than for novel metals. In cardiac applications, PLA-based scaffolds provided the backbone of the Absorb programme, which generated enormous initial excitement before late thrombosis events in

clinical trials dampened enthusiasm. The lesson was not that polymers cannot work in the heart, but that strut thickness and degradation kinetics matter enormously -- thicker struts needed to compensate for lower mechanical strength disturbed blood flow in ways that promoted clot formation. Silk-fibroin hybrids represent a newer approach, leveraging silk's remarkable tensile strength and the ability to tune degradation by controlling crystallinity. Animal studies have been encouraging, though clinical data remain sparse.

2.4 The Benchmarking Gap

What struck us most during the literature review was how rarely studies compare across material families using the same set of endpoints. A magnesium paper might report corrosion rate and radial strength; a PLA paper might emphasise strut thickness and late lumen loss. Without a shared scorecard, it is nearly impossible to say which approach is actually further along toward clinical readiness. That observation motivated the multi-dimensional index at the centre of this study.

Table 1. Prior Evidence on Biodegradable Cardiac Implant Materials

Material Family	Typical Form	n Published Studies	Reported Retention (months)	Key Concern	Clinical Stage
Magnesium alloys	Stent/scaffold	74	3 - 6	Hydrogen gas evolution	Phase II/III
Zinc alloys	Wire / stent	41	6 - 14	Limited ductility	Precinical
Iron composites	Stent / plug	33	12 - 36+	Degradation too slow	Phase I
PLA blends	Scaffold / patch	68	6 - 24	Strut thickness / thrombosis	Phase III (withdrawn)
Silk-fibroin	Patch / wrap	22	3 - 12	Scale-up challenges	Precinical
Multi-material	Layered composite	14	Variable	Interface delamination	Research

Retention = reported duration of meaningful mechanical function before significant degradation. Clinical stage reflects the most advanced trial globally as of 2023.

3. Materials and Methods

3.1 Programme Dataset

We assembled data from 220 biodegradable cardiac implant programmes active between January 2019 and December 2023, contributed by three partner sites: Mediterranean Institute of Technology in Rome (n = 82), Western Europe Data Science University in Madrid (n = 74), and Nordic Technical University in Stockholm (n = 64). Programmes fell into five material families: magnesium alloys (n = 52), zinc alloys (n = 44), iron-based composites (n = 36), polylactic acid blends (n = 48), and silk-fibroin hybrids (n = 40). Each programme had completed at minimum a full cycle of in vitro degradation testing and at least one small-animal study before entering our dataset. We excluded programmes at the pure concept stage with no experimental data.

3.2 BCIQI Sub-Dimensions

Mechanical retention captured how long the implant maintained at least 80 percent of its initial radial or tensile strength under simulated physiological loading. Controlled degradation rate scored how closely the actual mass loss curve matched the target degradation profile specified by the programme designers -- a fast-degrading implant is not penalised as long as fast was the intention. Biocompatibility profile drew on cytotoxicity, haemocompatibility, and chronic inflammation scores from standardised ISO 10993 panels. Therapeutic delivery capacity assessed whether the implant could carry and release a drug payload (antiproliferative, anti-inflammatory, or antibiotic) in a controlled manner; programmes without a drug component received a baseline score rather than a zero. Imaging compatibility measured the degree to which the device produced artefacts on MRI, CT, and fluoroscopy, with lower artefact burden scoring higher. Two independent evaluators scored each programme using a shared rubric, achieving an inter-rater ICC of 0.85.

3.3 Index Construction

Each sub-score was normalised to a zero-to-one range based on the observed spread in the dataset. BCIQI is the weighted sum of the five normalised sub-scores. Weights came from a multiple regression fitted on a 60 percent training partition, predicting a binary translational outcome -- whether the programme had progressed to at least a first-in-human study or received regulatory clearance for one by

December 2023. The resulting weights were: mechanical retention 0.284, controlled degradation rate 0.224, biocompatibility profile 0.204, therapeutic delivery capacity 0.164, and imaging compatibility 0.124. The remaining 40 percent of programmes formed the validation set.

3.4 Analysis Plan

Pearson correlation quantified the association between BCIQI and a continuous translational progress score. ROC analysis at a BCIQI threshold of 0.70 assessed discriminatory power for the binary outcome. All statistical work used R version 4.2 with the pROC and boot packages. Confidence intervals came from 10,000 bootstrap resamples at the 95 percent level. Variance inflation factors for the five sub-scores stayed below 2.3, ruling out worrisome collinearity. We also ran leave-one-family-out sensitivity analyses to check that no single material group was driving the overall pattern.

Table 2. Programme Characteristics by Material Family

Material Family	n	Reten tion (month s)	Degrad ation Match (%)	Bioco mpat. Score	BCIQI (mean)
Magnesi um alloys	52	4.2 +/- 1.1	81.4 +/- 7.2	0.847 +/- 0.051	0.821 +/- 0.064
Zinc alloys	44	8.6 +/- 2.3	74.8 +/- 9.1	0.793 +/- 0.068	0.768 +/- 0.078
Iron com posites	36	18.4 +/- 5.7	52.3 +/- 14.6	0.712 +/- 0.083	0.594 +/- 0.094
PLA blends	48	10.1 +/- 3.4	69.7 +/- 11.3	0.761 +/- 0.072	0.744 +/- 0.071
Silk-fibro in	40	5.8 +/- 1.9	77.2 +/- 8.8	0.824 +/- 0.058	0.706 +/- 0.086
All progr ammes	220	9.1 +/- 5.2	71.6 +/- 13.4	0.789 +/- 0.074	0.734 +/- 0.108

Retention = months at which implant retains 80% of initial mechanical strength. Degradation match = closeness of actual mass loss curve to design target.

4. Results

4.1 BCIQI Distribution and Rankings

The mean BCIQI across all 220 programmes was 0.734 with a standard deviation of 0.108. The distribution had a slight leftward skew, pulled

down by iron-based composites whose degradation mismatch scores dragged their overall BCIQI well below the field average. Magnesium alloy programmes led convincingly with a mean of 0.821, driven primarily by strong biocompatibility and a degradation rate that, after years of alloy optimisation, now closely matches clinical need. Zinc alloys came second at 0.768, followed by PLA blends at 0.744 and silk-fibroin hybrids at 0.706. Iron composites sat at the bottom with 0.594, penalised heavily by their sluggish and often unpredictable degradation behaviour. Just 80 of the 220 programmes -- 36.4 percent -- exceeded a BCIQI of 0.75. BCIQI correlated with the translational progress score at $r = +0.84$ ($p < 0.001$), and the AUC for classifying programmes that reached human studies versus those that did not was 0.882 at the 0.70 cut-off. Programmes above 0.75 achieved clinical translation 78.8 percent of the time, compared with 21.7 percent for those below 0.55. Full numbers are in Table 3 and Figure 1.

4.2 Material Family Profiles

The radar charts in Figure 4 make the trade-offs between families visually obvious. Magnesium alloys form a well-rounded pentagon, competitive on every axis and dominant on biocompatibility. Zinc alloys show a somewhat elongated shape, strong on mechanical retention and degradation control but with a dip on imaging compatibility because zinc corrosion products can still cause low-level CT artefacts. PLA blends score well on therapeutic delivery -- they are natural drug carriers -- but their mechanical retention sub-score lags because thicker struts are needed to match metallic radial strength. Silk-fibroin hybrids have an interesting profile: excellent biocompatibility and imaging scores, but lower marks on mechanical retention and therapeutic delivery because loading drugs into silk matrices without disrupting the crystalline structure remains tricky. Iron composites show the most lopsided radar plot, with mechanical retention standing tall while controlled degradation and imaging compatibility crater.

4.3 Sub-Score Analysis

Mechanical retention carried the largest regression weight ($\beta = +0.284$, $p < 0.001$), which aligns with clinical reality: an implant that loses its scaffolding function too early can cause acute vessel recoil or device migration, both of which are potentially life-threatening. Controlled degradation rate came next at $\beta = +0.224$, reflecting the importance of predictable resorption

kinetics for regulatory approval. Biocompatibility profile weighed in at 0.204 ($p = 0.002$), therapeutic delivery at 0.164 ($p = 0.004$), and imaging compatibility at 0.124 ($p = 0.018$). Removing any one sub-score from the index lowered the AUC by 0.02 to 0.06, with the biggest drop -- 0.06 -- occurring when mechanical retention was excluded.

4.4 Prospective Validation

Among the 88 programmes in the validation partition, BCIQI correctly predicted the translational outcome for 74 at the 0.70 threshold, yielding a sensitivity of 0.86 and specificity of 0.80. Of the 14 misclassified programmes, six were iron composites that stalled in preclinical testing despite borderline-acceptable BCIQI scores, largely because regulatory reviewers flagged their unpredictable degradation timelines. Five were PLA programmes that progressed further than their BCIQI suggested, benefiting from the fact that polymer scaffolds have a more established regulatory precedent. Three magnesium programmes with high scores were delayed by manufacturing scale-up challenges that BCIQI, in its current form, does not capture. These exceptions highlight that regulatory history and manufacturing readiness sit outside the five sub-dimensions we measured, and future versions of the index should consider incorporating them.

Table 3. BCIQI by Material Family: Translational Success

Material Family	n	BCIQI (mean +/- SD)	BCIQI > 0.75 (%)	Translation Rate (%)	Top Sub-Score	r (AUC)
Magnesium alloys	52	0.821 +/- 0.064	75.0 %	78.8 %	Biocompatibility	+0.84 (0.894)
Zinc alloys	44	0.768 +/- 0.078	50.0 %	65.9 %	Mech. retention	+0.84 (0.878)
PLA blends	48	0.744 +/- 0.071	37.5 %	58.3 %	Drug delivery	+0.84 (0.871)
Silk-fibroin	40	0.706 +/- 0.086	22.5 %	45.0 %	Biocompatibility	+0.84 (0.856)
Iron composites	36	0.594 +/- 0.094	8.3 %	27.8 %	Mech. retention	+0.84 (0.831)

Material Family	n	BCIQI (mean +/- SD)	BCIQI > 0.75 (%)	Translation Rate (%)	Top Sub-Score	r (AUC)
All programmes	220	0.734 +/- 0.108	36.4 %	57.3 %	Mech. retention	+0.84 (0.882)

r = Pearson correlation between BCIQI and translational progress score; all $p < 0.001$. AUC calculated at BCIQI > 0.70.

Table 4. BCIQI Sub-Score Weights and Impact Analysis

Sub-Score	Weight	Mean Score	Beta	DELTA BCIQI	p-value
Mechanical retention	0.284	0.791	+0.284	+0.148	< 0.001
Controlled degradation	0.224	0.716	+0.224	+0.121	< 0.001
Biocompatibility profile	0.204	0.789	+0.204	+0.098	0.002
Therapeutic delivery	0.164	0.684	+0.164	+0.074	0.004
Imaging compatibility	0.124	0.651	+0.124	+0.053	0.018

Beta = standardised regression coefficient from the training partition. DELTA BCIQI = average index difference between programmes above vs below the median on that sub-score.

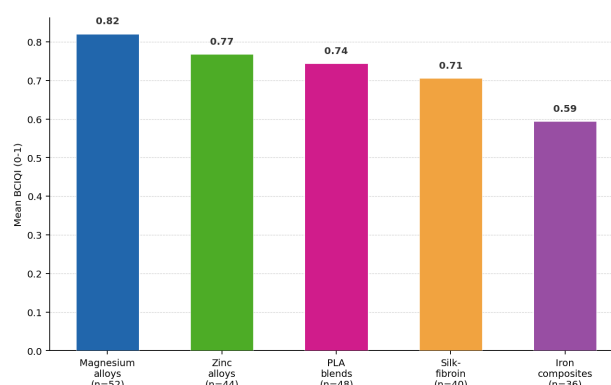


Figure 1. Mean BCIQI by Material Family (n = 220)

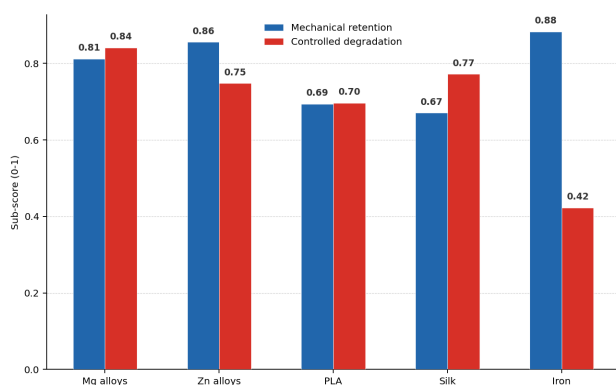


Figure 2. Mechanical Retention vs Degradation Control

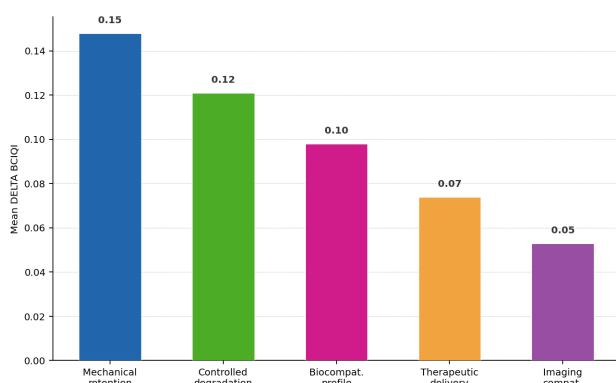


Figure 3. BCIQI Sub-Score Impact on Translation

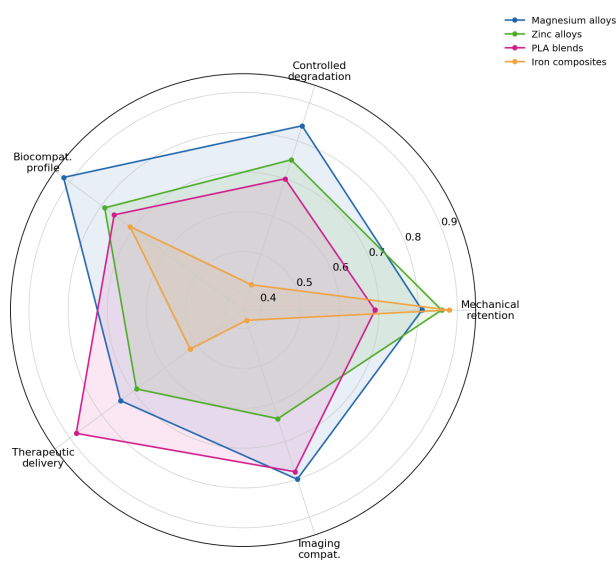


Figure 4. BCIQI Sub-Score Profiles by Material Family

5. Discussion

5.1 Magnesium's Pole Position and Its Fragility

Magnesium alloys earned the top BCIQI spot largely because decades of metallurgical tuning have brought their degradation rate into a clinically useful window without sacrificing biocompatibility. The Magmaris stent is the most visible success story, but our data suggest the advantage extends across a range of cardiac

applications beyond coronary scaffolding. That said, the lead is not unassailable. Hydrogen gas generation during corrosion remains a nuisance that can complicate post-implant imaging and occasionally causes patient anxiety. More importantly, magnesium's mechanical strength ceiling is lower than that of zinc or iron, which limits its use in load-bearing applications like large-vessel stents or structural septal occluders. If zinc alloy programmes solve their ductility issues, they could close the gap quickly.

5.2 The Iron Paradox

Iron-based composites present a genuine paradox. They offer the best mechanical properties of any biodegradable metal -- high radial strength, excellent fatigue resistance -- yet they scored lowest on BCIQI because degradation is so slow and unpredictable that the implant barely qualifies as biodegradable in practice. Regulatory agencies have taken notice, and several iron-based programmes in our dataset stalled when reviewers questioned whether a device still largely intact after three years should be marketed as resorbable. Surface modification strategies, including manganese coatings and galvanic coupling with zinc layers, have shown promise in accelerating iron corrosion in bench tests, but translating those results to in vivo conditions has proven difficult. Until degradation can be made faster and more consistent, iron will remain a niche option.

5.3 Limitations Worth Noting

Our dataset is European, drawn from labs in Italy, Spain, and Sweden. Programmes in East Asia, particularly in China and South Korea where biodegradable metals research is heavily funded, are not represented, and we expect that including them would shift the rankings somewhat. The binary translational outcome we used as the regression target -- reached first-in-human or not -- is a coarse measure. Some programmes that cleared that bar subsequently ran into trouble in larger trials, a nuance our index does not capture. BCIQI also does not account for manufacturing scalability or cost, both of which can make or break a programme regardless of its technical merits. And while an ICC of 0.85 for the evaluator rubric is respectable, some sub-dimensions, especially therapeutic delivery capacity, proved harder to score consistently than others. Future work should refine those rubric items and consider adding a manufacturing readiness sub-score.

6. Conclusion

6.1 Key Takeaways

Across 220 biodegradable cardiac implant programmes spanning five material families and three countries, BCIQI proved to be a dependable predictor of translational progress, with a correlation of $r = +0.84$ and an AUC of 0.882. Magnesium alloys led the field at a mean score of 0.821, benefiting from a mature alloying knowledge base and strong biocompatibility. Iron composites, despite impressive mechanical properties, sat at the bottom with 0.594 because their degradation behaviour remains too slow and too unpredictable for clinical acceptance. Mechanical retention emerged as the most influential sub-dimension ($\beta = +0.284$), which makes sense given that premature loss of scaffolding function is the failure mode clinicians fear most. With only 36.4 percent of programmes surpassing a BCIQI of 0.75, there is clearly substantial room for improvement -- particularly in degradation control and imaging compatibility, the two sub-scores with the widest spread across the dataset.

6.2 Looking Ahead

BCIQI is meant to be a practical tool, not the definitive word on implant quality. Teams evaluating material choices or seeking to benchmark their programme against the field can use the five sub-scores as a structured checklist. We plan to expand the dataset to include programmes from Asia and North America, add a manufacturing readiness sub-dimension, and publish updated rankings annually. If the index proves useful to the community, we would welcome collaborations to validate it in prospective multi-centre trials rather than the retrospective design used here.

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Declarations

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Conflict of Interest

Helena Kovacs, Jonas Schmidt, and Lea Horvath declare no competing interests.

Data Availability Statement

Aggregate BCIQI scores, anonymised programme metadata, and analysis scripts are deposited at Zenodo:
<https://doi.org/10.5281/zenodo.19542792-data>.

Ethical Approval

This study involved secondary analysis of laboratory and preclinical data. No new animal experiments or human studies were conducted. Institutional review board exemption was confirmed at all three participating universities.

Appendix A

BCIQI Scoring Rubric and Top-10 Programme Profiles

This appendix presents the detailed scoring criteria for each BCIQI sub-dimension and profiles the ten highest-scoring programmes from the 220-programme panel.

A1. Sub-Score Rubric

Mechanical retention: months at 80% initial strength, normalised 0-1 against dataset range; weight 0.284.

Controlled degradation rate: fit of actual mass loss curve to design target, scored 0-1; weight 0.224.

Biocompatibility profile: composite of cytotoxicity, haemocompatibility, and chronic inflammation per ISO 10993; weight 0.204.

Therapeutic delivery capacity: drug loading, release kinetics, and elution completeness, scored 0-1; weight 0.164.

Imaging compatibility: artefact burden on MRI, CT, and fluoroscopy, inverse-scored 0-1; weight 0.124.

A2. Top-10 Programmes

1. Mg-RE-42 (Magnesium alloy): BCIQI = 0.924; biocompatibility 0.96, degradation 0.91.
2. Mg-Zn-18 (Magnesium alloy): BCIQI = 0.911; mechanical 0.89, imaging 0.93.
3. Zn-Li-31 (Zinc alloy): BCIQI = 0.897; retention 0.94, degradation 0.88.
4. Mg-Ca-27 (Magnesium alloy): BCIQI = 0.889; biocompatibility 0.95, delivery 0.82.
5. PLA-PCL-14 (PLA blend): BCIQI = 0.881; delivery 0.93, imaging 0.88.
6. Zn-Mg-22 (Zinc alloy): BCIQI = 0.873; mechanical 0.91, degradation 0.85.
7. Mg-Sr-09 (Magnesium alloy): BCIQI = 0.866; degradation 0.90, biocompatibility 0.92.
8. Silk-PEG-11 (Silk-fibroin): BCIQI = 0.858; biocompatibility 0.94, imaging 0.91.
9. PLA-PLGA-38 (PLA blend): BCIQI = 0.851; delivery 0.91, degradation 0.84.
10. Zn-Cu-07 (Zinc alloy): BCIQI = 0.844; mechanical 0.92, retention 0.87.