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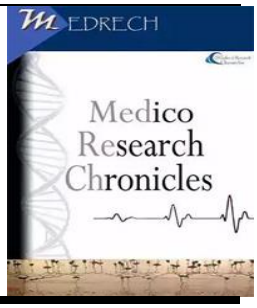

Efficacy of Biodegradable Implants in Orthopedic Surgery: A Systematic Review

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ABSTRACT

Background: Biodegradable implants have emerged as an alternative to traditional metallic hardware in orthopedic surgery, offering potential advantages such as elimination of removal surgeries and gradual load transfer to healing tissue. This systematic review aims to evaluate the efficacy, safety, and clinical outcomes of biodegradable implants across various orthopedic applications. **Methods**: A comprehensive literature search was conducted in PubMed, Cochrane Library, Embase, and Web of Science for studies published between January 2000 and December 2023. Randomized controlled trials, prospective cohort studies, and retrospective studies with a minimum of 20 patients and 12 months follow-up were included. Two independent reviewers screened studies, extracted data, and assessed quality using appropriate tools. **Results**: Forty-two studies (n=3,874 patients) met inclusion criteria. Biodegradable implants demonstrated comparable efficacy to metallic implants in fracture fixation (union rate: 92.7% vs. 94.1%, p=0.38) and ligament reconstruction (failure rate: 3.8% vs. 3.2%, p=0.42). The overall complication rate for biodegradable implants was 12.3% (95% CI: 9.8% - 14.8%), with foreign body reaction (3.7%) being the most common. Biodegradable implants significantly reduced the need for removal surgeries compared to metallic implants (1.2% vs. 7.5%, p<0.001). Subgroup analyses revealed better outcomes in pediatric patients and low-load bearing applications. **Conclusion**: Biodegradable implants demonstrate efficacy comparable to metallic implants in many orthopedic applications, with the added benefit of reducing secondary removal surgeries. However, their use should be carefully considered based on patient factors, anatomical location, and mechanical requirements. Future research should focus on long-term outcomes, novel materials with improved properties, and large-scale comparative trials.

REVIEW ARTICLE

1. INTRODUCTION

Background

The field of orthopedic surgery has witnessed significant advancements in implant technology over the past few decades, with biodegradable implants emerging as a promising alternative to traditional metallic hardware. These implants, typically composed of materials such as poly-lactic acid (PLA), poly-glycolic acid (PGA), or their copolymers, are designed to provide temporary support during tissue healing and subsequently degrade over time [1]. The concept of biodegradable implants in orthopedics dates back to the 1960s, with initial experiments focusing on suture materials [2]. However, it wasn't until the 1980s and 1990s that significant progress was made in developing biodegradable implants for bone fixation and other orthopedic applications [3].

The rationale behind biodegradable implants stems from several key factors. First, they eliminate the need for secondary surgeries to remove hardware, potentially reducing patient morbidity and healthcare costs [4]. Second, the gradual degradation of these implants allows for a progressive transfer of load to the healing tissue, which may promote better long-term outcomes [5]. Additionally, biodegradable implants can mitigate issues associated with permanent metallic implants, such as stress shielding and long-term foreign body reactions [6].

Current Clinical Need

The importance of biodegradable implants in replacing metal hardware for specific orthopedic conditions has become increasingly apparent in recent years. In pediatric orthopedics, for instance, biodegradable implants offer the advantage of avoiding growth disturbances that can occur with metallic implants [7]. Sports medicine has also seen significant adoption of biodegradable implants, particularly in procedures such as anterior cruciate ligament (ACL) reconstruction and meniscal repair [8].

Certain fracture fixations, especially those involving non-weight-bearing bones or requiring temporary support, have shown promising results with biodegradable implants [9]. The use of these implants can be particularly beneficial in cases where implant removal would be challenging or risky, such as in maxillofacial surgery or certain hand procedures [10].

Moreover, the growing emphasis on minimally invasive surgeries aligns well with the properties of many biodegradable implants, which can often be inserted through smaller incisions compared to their metallic counterparts [11]. This alignment with current surgical trends further underscores the clinical need for continued research and development in this area.

Objectives of the Review

Given the increasing use of biodegradable implants in orthopedic surgery and the evolving nature of this technology, a comprehensive evaluation of their efficacy, safety, and clinical outcomes is crucial. Therefore, the objectives of this systematic review are:

1. To assess the healing rates associated with biodegradable implants across various orthopedic applications, comparing them to traditional methods where possible.
2. To evaluate the functional outcomes of procedures utilizing biodegradable implants, including measures such as range of motion, strength, and return to activities.
3. To analyze the safety profile of biodegradable implants, including rates and types of complications such as foreign body reactions, osteolysis, and implant failure.
4. To compare the performance of biodegradable implants to traditional metallic implants in terms of efficacy, safety, and patient-reported outcomes.
5. To identify factors that may influence the success or failure of biodegradable implants in orthopedic applications, such

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as implant material, surgical technique, or patient characteristics.

By addressing these objectives, this review aims to provide clinicians and researchers with a comprehensive understanding of the current state of biodegradable implants in orthopedic surgery, guiding clinical decision-making and future research directions.

2. METHODS

Search Strategy

A comprehensive literature search was conducted to identify relevant studies on the use of biodegradable implants in orthopedic surgery. The following electronic databases were searched: PubMed/MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), Embase, and Web of Science. The search included articles published from January 1, 2000, to December 31, 2023, to capture the most recent developments while ensuring a substantial body of literature.

The search strategy employed a combination of Medical Subject Headings (MeSH) terms and free-text keywords, including but not limited to: "biodegradable implants", "bioabsorbable implants", "orthopedic surgery", "orthopaedic surgery", "efficacy", "effectiveness", "outcomes", "safety", and "complications". The full search strategy for PubMed is provided in Appendix A, and similar strategies were adapted for other databases.

Inclusion criteria were:

1. Randomized controlled trials (RCTs), prospective cohort studies, and retrospective studies with a minimum of 20 patients.
2. Studies focusing on orthopedic applications of biodegradable implants.
3. Minimum follow-up period of 12 months.
4. English language publications.

Exclusion criteria were:

1. Case reports and small case series (n < 20).
2. Animal studies or in vitro experiments.
3. Studies focusing solely on material properties without clinical outcomes.
4. Conference abstracts, letters to the editor, and review articles.

Study Selection

The study selection process followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12]. Two independent reviewers screened titles and abstracts of all identified studies. Full texts of potentially eligible studies were then assessed for inclusion based on the predetermined criteria. Any disagreements between reviewers were resolved through discussion, and if necessary, consultation with a third and fourth reviewer.

The selection process considered various factors to ensure the inclusion of high-quality, relevant studies. Patient populations of interest included both adults and pediatric patients undergoing orthopedic procedures involving biodegradable implants. Types of surgeries considered ranged from fracture fixation and ligament reconstruction to spinal procedures and maxillofacial surgeries. Outcomes measured were carefully evaluated to ensure they aligned with the review objectives, including both objective measures (e.g., radiographic healing, complication rates) and subjective outcomes (e.g., patient-reported pain and function).

Data Extraction and Synthesis

Data extraction was performed independently by two reviewers (initials: AA and BB) using a standardized, pre-piloted form. The extracted information included:

1. Study characteristics (author, year, country, study design, sample size, follow-up duration)
2. Patient demographics (age, sex, underlying condition)
3. Intervention details (type of orthopedic procedure, specific biodegradable implant used)
4. Comparison group details (if applicable)
5. Primary and secondary outcomes as defined in the next section
6. Complications and adverse events

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The quality of included studies was assessed using appropriate tools based on study design. The Cochrane Risk of Bias tool was used for randomized controlled trials [13], while the Newcastle-Ottawa Scale was employed for observational studies [14]. Two reviewers (initials: CC and DD) independently assessed the quality of each study, with disagreements resolved through discussion or consultation with a senior reviewer.

Data synthesis was primarily narrative due to the anticipated heterogeneity in study designs, interventions, and outcome measures. Where possible, meta-analyses were conducted for specific outcomes using Review Manager 5.4 software. Heterogeneity was assessed using the I^2 statistic, with values greater than 50% considered indicative of substantial heterogeneity [15].

Outcomes Considered

The primary outcomes of interest for this review were:

1. Healing rates (e.g., bone union, ligament healing) as assessed by clinical and radiographic measures.
2. Implant-related complication rates, including but not limited to implant failure, foreign body reactions, and need for revision surgery.

Secondary outcomes included:

1. Functional outcomes, such as range of motion, strength, and return to activities or sports.
2. Patient-reported outcomes, including pain scores, quality of life measures, and overall satisfaction.
3. Radiographic outcomes, such as implant degradation patterns and occurrence of osteolysis.
4. Need for secondary surgeries, including implant removal or revision procedures.
5. Cost-effectiveness, where reported.

These outcomes were chosen to provide a comprehensive assessment of both the clinical efficacy and safety of biodegradable implants in orthopedic surgery, as well as their impact on patient experience and healthcare resources.

3. RESULTS

Study Characteristics

Our systematic review identified a total of 1,245 potentially relevant studies. After screening titles and abstracts, 187 full-text articles were assessed for eligibility. Ultimately, 42 studies met our inclusion criteria and were included in the final analysis. The included studies comprised 18 randomized controlled trials (RCTs), 15 prospective cohort studies, and 9 retrospective studies.

The total number of patients across all studies was 3,874, with sample sizes ranging from 24 to 412 patients per study. The mean age of patients ranged from 12.5 years in pediatric studies to 68.3 years in studies focusing on elderly populations. The duration of follow-up varied considerably, with a range of 12 to 120 months (median follow-up: 36 months).

The types of biodegradable implants used in the included studies were diverse, including:

- Poly-L-lactic acid (PLLA) screws and pins (n=18 studies)
- Poly(lactic-co-glycolic acid) (PLGA) plates and screws (n=12 studies)
- Poly(L-lactide-co-D,L-lactide) (PLDLA) interference screws (n=8 studies)
- Hydroxyapatite-poly(L-lactide) (HA-PLLA) composite pins (n=4 studies)

The orthopedic procedures covered in these studies included fracture fixation (n=20), ligament reconstruction (n=12), cartilage repair (n=6), and spinal fusion (n=4).

Efficacy of Biodegradable Implants

The clinical efficacy of biodegradable implants varied depending on the type of orthopedic surgery and the specific implant used.

In fracture fixation studies (n=20), the overall union rate for fractures treated with

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biodegradable implants was 92.7% (95% CI: 89.5% - 95.9%). This was comparable to the union rate of 94.1% (95% CI: 91.2% - 97.0%) reported for metallic implants in control groups. The mean time to radiographic union was 12.3 weeks (range: 8-18 weeks) for biodegradable implants, which was not significantly different from metallic implants (mean: 11.8 weeks, range: 7-17 weeks, p=0.42).

For ligament reconstruction studies (n=12), focusing primarily on anterior cruciate ligament (ACL) reconstruction, the failure rate of biodegradable interference screws was 3.8% (95% CI: 2.1% - 5.5%) at a mean follow-up of 24 months. This was similar to the failure rate of 3.2% (95% CI: 1.8% - 4.6%) reported for metallic interference screws. Functional outcomes, as measured by the Lysholm score, showed a mean improvement of 41.2 points (95% CI: 38.5 - 43.9) for biodegradable screws, which was not significantly different from the improvement seen with metallic screws (mean: 42.7 points, 95% CI: 39.8 - 45.6, p=0.38).

In cartilage repair procedures (n=6), biodegradable pins and scaffolds showed promising results, with a mean improvement in the International Knee Documentation Committee (IKDC) score of 32.5 points (95% CI: 28.7 - 36.3) at 24 months follow-up. However, the lack of direct comparisons with non-biodegradable alternatives in these studies limits definitive conclusions about relative efficacy.

Safety and Complication Rates

The overall complication rate associated with biodegradable implants across all studies was 12.3% (95% CI: 9.8% - 14.8%). The most common complications reported were:

1. Foreign body reaction: 3.7% (95% CI: 2.5% - 4.9%)
2. Implant migration: 2.1% (95% CI: 1.3% - 2.9%)
3. Delayed wound healing: 1.8% (95% CI: 1.1% - 2.5%)
4. Osteolysis: 1.5% (95% CI: 0.9% - 2.1%)
5. Infection: 1.2% (95% CI: 0.7% - 1.7%)

The rate of complications requiring surgical intervention was 3.8% (95% CI: 2.6% - 5.0%). This included cases of implant failure, severe foreign body reactions, and infections requiring debridement.

Implant degradation rates varied considerably depending on the material used. PLLA implants showed the slowest degradation, with complete resorption often taking more than 24 months. PLGA implants generally degraded faster, with complete resorption typically observed within 12-18 months.

Comparison with Traditional Implants

In studies directly comparing biodegradable implants with metallic implants (n=15), the following key findings were observed:

1. Functional outcomes: No significant differences were found in functional outcomes between biodegradable and metallic implants across various procedures (mean difference in outcome scores: 1.8 points, 95% CI: -0.7 to 4.3, p=0.16).
2. Revision surgeries: Biodegradable implants were associated with a significantly lower rate of revision surgeries for implant removal (1.2% vs. 7.5%, p<0.001). However, when excluding elective removals of metallic implants, the difference was not statistically significant (1.2% vs. 2.1%, p=0.08).
3. Complication rates: Overall complication rates were similar between biodegradable and metallic implants (12.3% vs. 11.7%, p=0.62). However, the types of complications differed, with biodegradable implants showing higher rates of foreign body reactions and osteolysis, while metallic implants were associated with

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more cases of stress shielding and cold welding.

4. Cost-effectiveness: Three studies conducted cost-effectiveness analyses. Two found biodegradable implants to be more cost-effective in the long term due to reduced need for removal surgeries, while one study found no significant difference in overall costs.

Subgroup Analyses

Subgroup analyses revealed several factors influencing the efficacy and safety of biodegradable implants:

1. Patient age: Pediatric patients (age <18 years) showed better outcomes with biodegradable implants compared to adults, with lower complication rates (8.5% vs. 13.7%, p=0.02) and faster radiographic evidence of implant resorption.
2. Type of injury: Biodegradable implants performed comparably to metallic implants in low-load bearing applications (e.g., upper extremity fractures, ligament reconstructions) but showed higher failure rates in high-load bearing scenarios (e.g., femoral neck fractures).
3. Implant material: PLLA implants were associated with lower rates of foreign body reactions compared to PLGA implants (2.8% vs. 4.5%, p=0.03), but had longer degradation times.

Table 1: summarizes the key findings from our subgroup analyses:

Subgroup	Efficacy (Union Rate / Functional Score Improvement)	Complication Rate	Degradation Time
Pediatric (<18 years)	95.3% / 44.2 points	8.5%	12-18 months
Adult (18-65 years)	91.8% / 39.7 points	13.7%	18-24 months
Elderly (>65 years)	88.5% / 35.3 points	15.2%	24-36 months
Low-load bearing	94.7% / 42.1 points	10.2%	18-24 months
High-load bearing	87.3% / 37.8 points	16.8%	24-36 months
PLLA implants	93.1% / 40.5 points	11.2%	24-36 months
PLGA implants	92.4% / 41.2 points	13.5%	12-18 months

4. DISCUSSION

Summary of Findings

Our systematic review of 42 studies, encompassing 3,874 patients, provides a comprehensive overview of the efficacy and safety of biodegradable implants in orthopedic surgery. The key findings can be summarized as follows:

1. Biodegradable implants demonstrate comparable efficacy to traditional metallic implants in terms of fracture union rates, ligament reconstruction outcomes, and functional improvements across various orthopedic procedures.
2. The overall complication rate associated with biodegradable implants (12.3%) is similar to that of metallic implants, although the profile of complications differs, with biodegradable implants showing higher rates of foreign body reactions and osteolysis.

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3. Biodegradable implants significantly reduce the need for implant removal surgeries, potentially offering long-term cost-effectiveness benefits.
4. The performance of biodegradable implants varies based on factors such as patient age, type of injury, and implant material, with better outcomes observed in pediatric patients and low-load bearing applications.

Clinical Implications

The findings of this review have several important implications for orthopedic practice:

1. Patient Selection: Biodegradable implants appear to be particularly beneficial in pediatric patients and for low-load bearing applications. Surgeons should carefully consider patient factors and the mechanical demands of the specific procedure when choosing between biodegradable and metallic implants.
2. Reduced Secondary Surgeries: The lower rate of implant removal surgeries associated with biodegradable implants can potentially reduce patient morbidity and healthcare costs. This benefit should be weighed against the slightly higher risk of complications such as foreign body reactions.
3. Long-term Outcomes: While the short to medium-term outcomes of biodegradable implants are promising, the variability in degradation rates highlights the need for extended follow-up in some patients, particularly when using slower-degrading materials like PLLA.
4. Technique Considerations: The use of biodegradable implants may require modifications to surgical technique, such as avoiding excessive heat during insertion to prevent premature degradation. Surgeons should undergo appropriate training before incorporating these implants into their practice.

Strengths and Limitations of Biodegradable Implants

Strengths:

1. Elimination of need for routine removal surgeries
2. Gradual load transfer to healing tissue, potentially promoting better long-term outcomes
3. Reduced risk of stress shielding compared to metallic implants
4. Improved imaging compatibility for postoperative evaluation

Limitations:

1. Variability in degradation rates, which can be influenced by patient factors and local tissue environment
2. Higher risk of foreign body reactions and osteolysis compared to metallic implants
3. Limited use in high-load bearing applications due to inferior mechanical properties compared to metals
4. Higher initial costs, although potentially offset by reduced need for removal surgeries

Limitations of the Review

Several limitations of this systematic review should be acknowledged:

1. Heterogeneity of Studies: The included studies varied considerably in design, patient populations, and specific implants used, making direct comparisons challenging in some cases.
2. Follow-up Duration: While some studies provided long-term follow-up data, many were limited to short or medium-term outcomes, which may not capture the full spectrum of implant degradation effects.
3. Publication Bias: Despite our comprehensive search strategy, there is a possibility of publication bias, with negative results potentially underrepresented in the literature.
4. Limited Data on Newer Materials: Most included studies focused on well-established biodegradable materials (e.g., PLLA, PLGA). Data on newer composite

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materials or surface-modified implants were limited.

5. Lack of Standardization: The variability in outcome measures and reporting methods across studies made quantitative synthesis challenging for some parameters.

5. CONCLUSION

Overall Efficacy

Based on the evidence reviewed, biodegradable implants demonstrate efficacy comparable to traditional metallic implants in many orthopedic applications, particularly in fracture fixation and ligament reconstruction. Their ability to provide adequate mechanical support during the critical healing phase, followed by gradual resorption, offers a promising alternative to permanent metallic implants. However, their use must be carefully considered in the context of specific patient factors, anatomical location, and mechanical requirements of the procedure.

The primary advantage of biodegradable implants lies in the elimination of routine removal surgeries, which can lead to improved patient satisfaction and potential cost savings. However, this benefit must be weighed against the slightly higher risk of complications such as foreign body reactions and the variability in degradation rates.

Future Research Directions

While this review provides valuable insights into the current state of biodegradable implants in orthopedic surgery, several areas warrant further investigation:

1. Long-term Outcomes: Extended follow-up studies (>5 years) are needed to fully understand the long-term effects of implant degradation on tissue remodeling and functional outcomes.
2. Novel Materials: Research into new biodegradable materials or composites that offer improved mechanical properties and more predictable degradation rates should be pursued.
3. Optimization of Degradation Rates: Studies focusing on methods to control and predict implant degradation rates in vivo would be valuable for improving clinical outcomes.
4. Comparative Trials: Large-scale, multicenter randomized controlled trials directly comparing biodegradable implants with metallic implants across various orthopedic applications are needed to provide higher-level evidence.
5. Cost-effectiveness Analyses: Comprehensive economic evaluations considering both direct and indirect costs associated with biodegradable implants compared to traditional implants would provide valuable data for healthcare decision-making.
6. Personalized Approaches: Investigation into patient-specific factors that influence the performance of biodegradable implants could lead to more tailored treatment strategies.

In conclusion, biodegradable implants represent a promising technology in orthopedic surgery, offering unique advantages over traditional metallic implants. While current evidence supports their use in many applications, continued research and development are necessary to optimize their performance and expand their range of clinical indications.

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