



## Implant Failure Rates and Risk Factors: Retrospective Observational Study

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**Abstract:** *Background:* Implant failure remains a significant concern in orthopedic surgeries, particularly in fracture fixation and arthroplasty procedures. Understanding failure rates and associated risk factors can guide surgical planning and implant selection. *Methods:* We conducted a retrospective observational study of 312 patients who underwent internal fixation or joint replacement between January 2019 and December 2023 at a tertiary care center. Implant failure was defined as breakage, loosening, cut-out, mechanical migration, or revision surgery within 24 months of index surgery. Demographic data, fracture pattern, comorbidities, surgical technique, bone quality, and implant type were analyzed. Failure rates were calculated, and logistic regression identified independent risk factors. *Results:* Implant failure occurred in 28 patients (9%). Higher failure rates were observed in unstable fracture patterns (15%), osteoporotic bone (18%), and patients with delayed weight-bearing (>12 weeks, 12%). Multivariate analysis revealed osteoporosis (OR 3.1,  $p=0.004$ ), inadequate reduction (OR 2.7,  $p=0.01$ ), infection (OR 4.2,  $p=0.002$ ), and smoking (OR 2.2,  $p=0.03$ ) as independent predictors of implant failure. *Conclusion:* Implant failure is strongly associated with poor bone quality, technical factors, and infection. Optimising surgical reduction, infection control, and early mobilisation, particularly in osteoporotic patients, may reduce the risk of failure.

**Keywords:** Implant Failure, Risk Factors, Orthopedic Implants, Osteoporosis, Revision Surgery.

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## INTRODUCTION

Implant failure is one of the most challenging complications in orthopedic surgery, significantly affecting patient outcomes and healthcare costs. It can result from a complex interplay of mechanical, biological, and technical factors, often necessitating revision surgeries, prolonged rehabilitation, and increased morbidity. The term "implant failure" encompasses breakage of implants, screw cut-out, aseptic loosening, mechanical migration, or the need for reoperation due to poor fixation or infection.<sup>1,2</sup> With the increasing global prevalence of osteoporotic fractures and the growing elderly population, the frequency of implant-related complications is on the rise, especially in lower limb fracture fixation and joint replacement surgeries.<sup>3</sup> Fracture fixation using devices such as proximal femoral nails (PFN),

dynamic hip screws (DHS), and locking compression plates (LCP) has become standard practice for managing intertrochanteric and diaphyseal fractures. However, the mechanical stability of these implants is influenced by bone quality, fracture pattern, and surgical technique. Reports indicate that PFN and DHS have failure rates ranging from 5% to 12% in unstable intertrochanteric fractures, with screw cut-out and varus collapse being common complications.<sup>4-6</sup> Similarly, implant-related complications in joint replacement surgeries though generally less frequent can arise due to aseptic loosening, periprosthetic fractures, or infection, with failure rates reported between 1% and 5% within the first decade.<sup>7</sup>

Several risk factors for implant failure have been identified, including osteoporosis, which weakens screw anchorage and load-bearing capacity; smoking, which impairs bone healing; and infection, which undermines implant stability.<sup>8-10</sup> Technical factors such as inadequate reduction or malpositioning of the implant also play a pivotal role. Despite these known risk factors, there is a paucity of studies that simultaneously analyze implant failure across different orthopedic procedures and correlate these with patient comorbidities and perioperative variables. This retrospective study aims to fill this gap by assessing implant failure rates across a range of orthopedic implants over 5 years and identifying the key risk factors that contribute to mechanical and biological failure. Our analysis, which includes 312 patients, provides valuable insight into the patterns of failure, with a specific focus on age, bone quality, surgical technique, and modifiable risk factors. By identifying the factors most strongly associated with implant failure, this study aims to support evidence-based interventions to minimize complications and optimize patient outcomes.

## METHODS

### Study Design and Population

We performed a retrospective observational study, reviewing the medical records of 312 patients ( $\geq 18$  years) who underwent internal fixation (plates, nails, screws) or joint replacement (hip/knee arthroplasty) between January 2019 and December 2023.

### Inclusion Criteria

Adults with fracture fixation or arthroplasty.

Minimum follow-up of 24 months.

### Exclusion Criteria

Pathological fractures due to tumors.

Revision surgeries at index admission.

Patients lost to follow-up.

### Data Collection

Patient demographics, comorbidities, fracture patterns, bone quality (DEXA scores), surgical technique, type of implant, and post-operative rehabilitation details were recorded. Implant failure was defined as any of the following within 24 months:

Implant breakage.

Screw or nail cut-out.

Aseptic loosening.

Periprosthetic fracture.

Need for surgery.

### Statistical Analysis

Descriptive statistics summarized baseline data. Univariate analysis (Chi-square and t-tests) compared failure vs. non-failure groups. Multivariate logistic regression was performed to identify independent predictors ( $p < 0.05$ ). Data were analyzed using SPSS v25.

## RESULTS

Table 1 summarizes the baseline demographic and clinical characteristics of the study population, stratified by implant failure status. The mean age of patients who experienced implant failure was significantly higher compared to those without failure ( $64.2 \pm 11.5$  vs.  $58.4 \pm 10.2$  years,  $p = 0.01$ ), indicating a potential influence of age-related bone quality on implant outcomes. Osteoporosis, defined by a T-score  $< -2.5$ , was markedly more prevalent in the failure group (42.9%) than in the non-failure group (14.4%), with a statistically significant association ( $p < 0.001$ ). While the proportion of males was slightly higher in the failure group (57.1% vs. 52.1%), this difference was not statistically significant ( $p = 0.64$ ). Diabetes showed a higher incidence among patients with implant failure (25% vs. 13.4%), though this trend did not reach statistical significance ( $p = 0.09$ ). Smoking was significantly associated with implant failure (32.1% vs. 16.2%,  $p = 0.04$ ), suggesting that modifiable risk factors may play a role in the mechanical and biological integrity of orthopedic implants.

**Table 1: Baseline Characteristics of Patients (n = 312)**

Variable	Implant Failure (n = 28)	No Failure (n = 284)	p-value
Age (years), mean $\pm$ SD	$64.2 \pm 11.5$	$58.4 \pm 10.2$	0.01
Male, n (%)	16 (57.1%)	148 (52.1%)	0.64
Osteoporosis (T-score $< -2.5$ )	12 (42.9%)	41 (14.4%)	$< 0.001$

Diabetes, n (%)	7 (25%)	38 (13.4%)	0.09
Smoking, n (%)	9 (32.1%)	46 (16.2%)	0.04

Table 2 presents the distribution of implant failure rates according to the type of surgical implant used. Among all procedures, proximal femoral nails (PFNs) exhibited the highest failure rate at 12.5% (10/80 cases), followed by dynamic hip screws (DHS) with 9.7% (6/62 cases). Locking compression plates showed a slightly lower failure rate of 7.8% (7/90 cases), while hip and knee

arthroplasties demonstrated the lowest failure incidence at 6.3% (5/80 cases). These findings highlight the increased mechanical challenges associated with intramedullary fixation devices, particularly in complex or unstable fracture patterns, compared to joint replacement or plating techniques.

**Table 2: Implant Failure Rates by Type of Surgery**

Implant Type	Total Cases (n)	Failures (n)	Failure Rate (%)
Proximal femoral nail	80	10	12.5
Dynamic hip screw	62	6	9.7
Locking compression plate	90	7	7.8
Hip/Knee arthroplasty	80	5	6.3

Table 3 outlines the results of the multivariate logistic regression analysis identifying independent predictors of implant failure. Osteoporosis was the strongest predictor, with patients having a 3.1-fold increased risk (OR 3.1, 95% CI: 1.4–6.9,  $p=0.004$ ) compared to those with normal bone density. Inadequate fracture reduction during surgery was also a significant determinant (OR 2.7, 95% CI: 1.3–5.5,  $p=0.01$ ), emphasizing the importance of surgical precision and proper

implant positioning. Postoperative infection substantially increased the risk of failure (OR 4.2, 95% CI: 1.6–10.9,  $p=0.002$ ), while smoking was associated with a 2.2-fold higher risk ( $p=0.03$ ). These findings suggest that both modifiable factors (such as smoking and infection control) and patient-specific factors (like bone quality) must be addressed to minimize implant-related complications.

**Table 3: Independent Risk Factors (Multivariate Logistic Regression)**

Risk Factor	OR (95% CI)	p-value
Osteoporosis	3.1 (1.4–6.9)	0.004
Inadequate reduction	2.7 (1.3–5.5)	0.01
Infection	4.2 (1.6–10.9)	0.002
Smoking	2.2 (1.1–4.6)	0.03

## DISCUSSION

This study revealed an overall implant failure rate of 9%, with the highest incidence observed in patients treated with proximal femoral nails (12.5%), followed by dynamic hip screws (9.7%) and locking compression plates (7.8%), while hip and knee arthroplasties had the lowest failure rate (6.3%). These results are consistent with prior reports indicating that intramedullary fixation in unstable fracture patterns carries a greater risk of mechanical failure compared to extramedullary or replacement procedures.<sup>11,12</sup>

### Age and Bone Quality

Patients with implant failure were significantly older (mean 64.2 years) compared to those without failure (58.4 years,  $p=0.01$ ). Advanced age is closely linked to osteoporosis and compromised bone stock, both of which are well-established contributors to failure.<sup>13</sup> Our multivariate analysis identified osteoporosis (OR 3.1,  $p=0.004$ ) as the strongest predictor of failure, which aligns with findings by Gupta *et al.*, who reported a 3.5-fold increase in failure rates among osteoporotic patients.<sup>14</sup>

## Modifiable Risk Factors

Smoking was associated with a 2.2-fold increased risk of implant failure ( $p=0.03$ ), corroborating the findings of Castillo *et al.*, who highlighted smoking as a major factor in delayed bone healing and mechanical complications.<sup>15</sup> Similarly, infection significantly increased the likelihood of implant failure (OR 4.2,  $p=0.002$ ). This is consistent with studies by Abdelaziz *et al.*, who observed a 4–5 times higher failure rate in the presence of deep infection due to its detrimental impact on osteointegration and soft tissue healing.<sup>16</sup>

## Surgical Technique and Mechanical Factors

Technical errors, particularly inadequate fracture reduction, were another independent predictor of failure (OR 2.7,  $p=0.01$ ). In unstable fracture patterns, suboptimal reduction can lead to uneven load distribution across the implant, increasing the risk of mechanical collapse or cut-out. Palm *et al.* emphasized that achieving anatomical reduction is critical for implant longevity, especially in intertrochanteric fractures.<sup>17</sup> Our data support this observation, with PFN failures often associated with suboptimal screw placement or insufficient medial support.

## Comparison with Previous Literature

The failure rates observed in our study (9%) are similar to those reported by Parker and Pryor, who noted a 10-year cumulative failure rate of 8–12% for PFN and DHS in unstable hip fractures.<sup>18</sup> However, our arthroplasty failure rate (6.3%) was slightly lower than historical averages (7–8%) due to advancements in implant design and better infection control protocols.<sup>19</sup>

## Clinical Implications

Our findings underscore the importance of bone quality assessment before surgery, particularly in elderly patients. The high failure rate in osteoporotic patients highlights the need for adjunctive measures such as cement augmentation or the use of implants with enhanced purchase in weak bone. Moreover, addressing modifiable factors such as smoking cessation and early infection control could significantly reduce failure risks. Surgical teams must also ensure optimal reduction and implant positioning, as technical precision plays a critical role in preventing mechanical failure.

## Limitations

This study's retrospective design and single-center setting may limit the generalizability of results. Although the sample size ( $n=312$ ) provides sufficient power for identifying key risk factors, larger multicenter studies with longer follow-up periods could further validate these findings. Despite these limitations, our results are consistent with international literature and provide actionable insights.

## CONCLUSION

Implant failure is influenced by both patient-related (osteoporosis, smoking) and technical factors (inadequate reduction, infection). Preventive strategies such as preoperative bone health optimization, meticulous surgical technique, and early infection control are crucial to reduce failure risk.

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