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Low-Cost/High-Utility Implants: Performance Metrics of Locally Manufactured and Reusable Orthopaedic Implants Compared with Imported Implants in Resource-Constrained Healthcare Systems

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ABSTRACT

Background: Musculoskeletal disorders and traumatic injuries represent a major global health burden, particularly in low- and middle-income countries where access to affordable orthopaedic care remains limited. The high cost of imported implants often delays treatment and increases financial hardship. Low-cost orthopaedic implants, including locally manufactured and reusable implants, have emerged as potential alternatives to improve accessibility and affordability. However, evidence regarding their clinical performance, safety, and cost-effectiveness compared with imported implants remains limited.

Aim: To evaluate the clinical performance, safety, and cost-effectiveness of low-cost orthopaedic implants (locally manufactured and/or reusable implants) compared with imported orthopaedic implants in resource-constrained healthcare systems.

Objectives

1. To compare fracture union rates, implant survival, complication rates, mechanical failure, functional outcomes, and patient satisfaction between low-cost and imported orthopaedic implants.
2. To compare implant cost, procurement efficiency, affordability, hospital stay, reoperation rates, and overall cost-effectiveness between the two groups.

Materials and Methods: A hospital-based observational comparative study was conducted in the Department of Orthopaedics of a tertiary care teaching hospital over a period of 18 months. A total of 180 patients undergoing orthopaedic surgical procedures requiring implant fixation were included. Group A consisted of 90 patients receiving low-cost orthopaedic implants (locally manufactured and/or reusable implants), while Group B consisted of 90 patients receiving imported orthopaedic implants. Clinical, radiological, implant-related, and economic data were collected using a structured case record form. Patients were followed up for 12 months. Statistical analysis was performed using SPSS version 26.0. Independent t-test, Chi-square test, Fisher's exact test, Kaplan–Meier survival analysis, and multivariable logistic regression analysis were applied. A p-value of <0.05 was considered statistically significant.

Results: The mean age of the participants was 45.5 ± 13.0 years, and 66.1% were males. Fracture union was achieved in 93.3% of patients in the low-cost implant group and 91.1% of patients in the imported implant group ($p=0.592$). Implant survival rates at 12 months were 95.6% and 97.8%, respectively (p=0.408). Mechanical failure rates were low and comparable between the groups (3.3% vs 2.2%; p=0.649). Functional outcome scores and patient satisfaction were similar in both groups (p>0.05). The low-cost implant group demonstrated significantly lower implant costs (USD 82 ± 18 vs USD 246 ± 52; p<0.001) and shorter procurement times (2.8 ± 0.9 vs 6.7 ± 1.8 days; p<0.001). Multivariable logistic regression identified open fractures, diabetes mellitus, and delayed surgery as independent predictors of fracture non-union, whereas implant type was not significantly associated with non-union.

Conclusion: Low-cost orthopaedic implants demonstrated clinical effectiveness and safety comparable to imported implants while providing substantial economic advantages. The use of locally manufactured and reusable implants can improve accessibility and affordability of orthopaedic care without compromising patient outcomes. Adoption of these implant strategies may strengthen trauma and orthopaedic services in resource-constrained healthcare settings.

Keywords*: Low-cost orthopaedic implants; locally manufactured implants; reusable implants; imported implants; fracture union; implant survival; cost-effectiveness; resource-constrained healthcare systems.*

INTRODUCTION

Musculoskeletal disorders and traumatic injuries constitute a major global public health challenge and are among the leading causes of disability, morbidity, and healthcare expenditure worldwide. According to the Global Burden of Disease (GBD) 2021 study, more than 1.7 billion people suffer from musculoskeletal conditions, making them the largest contributors to years lived with disability globally.[1] Fractures, degenerative joint diseases, spinal disorders, and traumatic musculoskeletal injuries frequently require surgical intervention using orthopaedic implants to restore anatomical alignment, achieve stable fixation, facilitate early mobilization, and improve functional recovery.[2] The widespread adoption of orthopaedic implants, including plates, screws, intramedullary nails, external fixators, prostheses, and fixation wires, has revolutionized modern orthopaedic practice and significantly improved patient outcomes.[3]

Despite remarkable advances in implant technology, access to affordable orthopaedic implants remains a substantial challenge in low- and middle-income countries (LMICs). The high cost of imported implants, dependence on international supply chains, inadequate insurance coverage, and significant out-of-pocket healthcare expenditure often delay definitive surgical management and contribute to poorer clinical outcomes.[4] The Lancet Commission on Global Surgery emphasized that access to safe, affordable, and timely surgical care is an essential component of universal health coverage and highlighted the need for cost-effective surgical technologies that can be implemented in resource-constrained settings.[5] In many LMICs, imported orthopaedic implants account for a major proportion of treatment costs, creating barriers to equitable access to trauma and reconstructive surgical care. Consequently, there has been increasing interest in the development and utilization of low-cost orthopaedic implant strategies capable of providing acceptable biomechanical performance and clinical outcomes while remaining affordable and accessible.[5]

Globally, trauma accounts for approximately 4.4 million deaths annually, and musculoskeletal injuries represent a substantial proportion of the global surgical burden. Road traffic accidents, falls, occupational injuries, and sports-related trauma continue to increase, particularly in developing countries undergoing rapid urbanization and motorization. Importantly, nearly 90% of injury-related deaths occur in LMICs despite these countries possessing limited surgical resources and infrastructure.[6] The growing demand for orthopaedic trauma services has intensified the need for affordable implant solutions that can support timely fracture fixation and reduce long-term disability. In this context, locally manufactured implants and institutionally approved reusable orthopaedic implants have emerged as promising alternatives to expensive imported devices.

Locally manufactured orthopaedic implants offer several potential advantages. Indigenous production reduces dependence on foreign manufacturers, improves supply chain resilience, shortens procurement timelines, and may substantially reduce implant costs. Government initiatives promoting domestic medical device manufacturing have further strengthened the feasibility of producing high-quality orthopaedic implants that comply with national and international standards. Additionally, local manufacturing can facilitate rapid customization of implants to meet regional clinical needs and improve the availability of essential trauma care services. However, concerns persist regarding quality control, standardization, biomechanical integrity, corrosion resistance, sterilization compatibility, and long-term durability, necessitating rigorous clinical evaluation before widespread adoption.[7]

Reusable orthopaedic implants represent another strategy for reducing treatment costs in resource-limited settings. Selected orthopaedic hardware may be safely reprocessed and reused following validated sterilization and quality assurance protocols. Reuse has the potential to significantly reduce implant expenditure, improve inventory management, and enhance healthcare sustainability. Nevertheless, concerns regarding implant fatigue, material degradation, infection transmission, mechanical failure, and regulatory oversight continue to limit widespread acceptance. Studies evaluating reprocessed orthopaedic devices have reported encouraging safety profiles when stringent sterilization procedures and quality assurance measures are followed, suggesting that carefully regulated implant reuse may represent a viable option in resource-constrained healthcare systems. [7]

India bears a particularly significant burden of musculoskeletal disorders and traumatic injuries. The India State-Level Disease Burden Initiative has demonstrated that injuries constitute a major cause of mortality and disability, particularly among economically productive age groups. Road traffic accidents alone account for more than 150,000 deaths annually, with a much larger number of survivors requiring orthopaedic intervention and rehabilitation. [6] Despite substantial improvements in healthcare infrastructure, access to affordable orthopaedic care remains uneven across the country. Many patients continue to rely on out-of-pocket expenditure for surgical treatment, making implant affordability a critical determinant of healthcare access. Recognizing this challenge, the Government of India has actively promoted indigenous medical device manufacturing through initiatives such as "Make in India" and implementation of the Medical Devices Rules, 2017, encouraging the development of domestically manufactured orthopaedic implants capable of meeting stringent quality standards. However, robust comparative evidence regarding the clinical performance, safety, and economic impact of locally manufactured and reusable implants relative to imported implants remains limited.

The evaluation of orthopaedic implants should extend beyond conventional measures of fracture healing and encompass a comprehensive assessment of implant performance metrics. These include fracture union rates, implant survival, mechanical integrity, infection rates, complication profiles, functional recovery, patient satisfaction, cost-effectiveness, procurement efficiency, and healthcare system impact. Such evidence is essential for guiding procurement decisions, informing regulatory policies, supporting indigenous manufacturing initiatives, and optimizing resource allocation in low-resource healthcare environments. Therefore, a systematic comparison of locally manufactured and reusable orthopaedic implants with imported implants is necessary to determine whether low-cost implant strategies can provide comparable clinical outcomes while improving affordability and accessibility of orthopaedic care. The findings of the present study are expected to contribute valuable evidence regarding the role of low-cost, high-utility implant systems in strengthening orthopaedic services within resource-constrained healthcare settings.

AIM

To evaluate the clinical performance, safety, and cost-effectiveness of low-cost orthopaedic implants (locally manufactured and/or reusable implants) compared with imported orthopaedic implants in resource-constrained healthcare systems.

OBJECTIVES

Primary Objective

To compare the clinical performance of low-cost orthopaedic implants and imported orthopaedic implants by assessing fracture union rates, implant survival, mechanical failure, implant-related complications, functional outcomes, and patient satisfaction.

Secondary Objective

To compare the economic and healthcare system impact of low-cost orthopaedic implants and imported orthopaedic implants by evaluating implant cost, procurement efficiency, affordability, reoperation rates, duration of hospital stay, and overall cost-effectiveness.

MATERIALS AND METHODS

Study Design

The study was conducted as a hospital-based observational comparative study.

Study Setting

The study was conducted in the Department of Orthopaedics of a tertiary care teaching hospital.

Study Duration

The study was conducted over a period of 18 months from January 2025 to June 2026.

Study Population
The study population consisted of adult patients undergoing orthopaedic surgical procedures requiring implant fixation for fractures and other musculoskeletal conditions.

Study Groups
Group A (Low-Cost Implant Group):
Patients who received:
- Locally manufactured orthopaedic implants, and/or
- Institutionally approved reusable orthopaedic implants.

Group B (Imported Implant Group):
Patients who received:
- Imported commercially available orthopaedic implants.

Inclusion Criteria
1. Patients aged 18 years and above.
2. Patients undergoing orthopaedic surgery requiring implant fixation.
3. Patients receiving either low-cost orthopaedic implants (locally manufactured/reusable) or imported orthopaedic implants.
4. Patients who provided written informed consent.
5. Patients available for follow-up for a minimum period of 12 months.

Exclusion Criteria
1. Patients with pathological fractures secondary to malignancy.
2. Patients with active infection at the surgical site.
3. Patients undergoing revision surgery for previously failed implants.
4. Patients with severe immunocompromised conditions.
5. Patients lost to follow-up before completion of the study period.

Sample Size
The sample size was calculated using the formula for comparison of two proportions.

Assuming a fracture union rate of 90% in the low-cost implant group and 80% in the imported implant group, with a confidence level of 95%, statistical power of 80%, and an anticipated attrition rate of 10%, the required sample size was estimated to be 90 patients per group.

Accordingly, a total of 180 patients were included in the study, with 90 patients in each group.

Sampling Technique
Consecutive sampling technique was employed, and all eligible patients who satisfied the inclusion criteria during the study period were recruited until the required sample size was achieved.

Study Variables
Demographic Variables
- Age
- Sex
- Occupation
- Socioeconomic status
- Residence (Urban/Rural)

Clinical Variables
- Mechanism of injury
- Fracture type
- Fracture location
- Open or closed fracture
- Comorbidities
- Time interval between injury and surgery

Implant-Related Variables

- Implant origin (Local/Imported)
- Reusability status
- Implant type
- Manufacturer details
- Number of reuse cycles
- Sterilization method
- Implant cost
- Procurement time

Outcome Measures

Primary Outcomes

- Fracture union rate
- Time to fracture union
- Implant survival
- Mechanical failure rate
- Implant-related complications

Secondary Outcomes

- Functional outcome scores
- Patient satisfaction scores
- Time to weight-bearing
- Duration of hospital stay
- Reoperation rates
- Cost-effectiveness measures
- Procurement efficiency indicators

Data Collection Procedure

Eligible patients were identified at the time of admission and enrolled after obtaining written informed consent. Baseline demographic, clinical, and implant-related details were recorded using a structured case record form.

Perioperative information including implant specifications, sterilization details, operative findings, and surgical duration was documented.

Patients were followed up at 6 weeks, 3 months, 6 months, and 12 months postoperatively. Clinical examination and radiographic assessment were performed during each follow-up visit to evaluate fracture union, implant integrity, mechanical failure, complications, and functional recovery.

Hospital procurement records, inventory databases, and sterilization logs were reviewed to assess implant availability, procurement timelines, implant costs, and reprocessing practices.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) version 26.0.

Continuous variables were expressed as mean ± standard deviation or median with interquartile range, as appropriate. Categorical variables were expressed as frequencies and percentages.

The following statistical tests were applied:

- Independent t-test or Mann–Whitney U test for continuous variables.
- Chi-square test or Fisher's exact test for categorical variables.
- Kaplan–Meier survival analysis for implant survival.
- Cox proportional hazards regression analysis for predictors of implant failure.
- Multivariable logistic regression analysis for factors associated with fracture union and complications.

Multivariable regression analysis was performed to adjust for implant reusability while assessing the effect of implant origin on clinical outcomes.

A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1. Baseline Demographic Characteristics of Study Participants

Variable	Low-Cost Implant Group (n=90)	Imported Implant Group (n=90)	p value
Age (years), Mean ± SD	44.8 ± 13.2	46.1 ± 12.8	0.502[a]
Male sex, n (%)	61 (67.8)	58 (64.4)	0.634[b]
BMI (kg/m²), Mean ± SD	24.9 ± 3.8	25.2 ± 4.1	0.617[a]
Diabetes Mellitus, n (%)	18 (20.0)	21 (23.3)	0.588[b]
Hypertension, n (%)	24 (26.7)	27 (30.0)	0.623[b]

Interpretation: Baseline demographic and comorbidity profiles were comparable between the two groups (p>0.05).

Table 2. Fracture Characteristics and Surgical Profile

Variable	Low-Cost Implant Group	Imported Implant Group	p value
Lower limb fractures, n (%)	52 (57.8)	55 (61.1)	0.648[b]
Upper limb fractures, n (%)	28 (31.1)	24 (26.7)	0.510[b]
Open fractures, n (%)	18 (20.0)	21 (23.3)	0.588[b]
Time to surgery (days), Mean ± SD	3.9 ± 1.6	4.2 ± 1.8	0.238[a]
Duration of surgery (minutes), Mean ± SD	78.4 ± 18.2	80.7 ± 19.6	0.421[a]

Table 3. Fracture Union Outcomes

Variable	Low-Cost Implant Group	Imported Implant Group	p value
Fracture union achieved, n (%)	84 (93.3)	82 (91.1)	0.592[b]
Non-union, n (%)	6 (6.7)	8 (8.9)	0.592[b]
Mean time to union (weeks)	14.2 ± 3.1	13.8 ± 3.0	0.372[a]

Interpretation: Fracture union rates and time to union were comparable between groups.

Table 4. Implant Survival Analysis at 12 Months

Variable	Low-Cost Implant Group	Imported Implant Group	p value
Implant survival, n (%)	86 (95.6)	88 (97.8)	0.408[b]
Implant failure, n (%)	4 (4.4)	2 (2.2)	0.408[b]

Interpretation: Implant survival was excellent in both groups with no statistically significant difference.

Table 5. Implant-Related Complications

Complication	Low-Cost Implant Group	Imported Implant Group	p value
Surgical site infection	5 (5.6)	4 (4.4)	0.732
Implant loosening	2 (2.2)	2 (2.2)	1.000
Mechanical failure	3 (3.3)	2 (2.2)	0.649
Reoperation required	4 (4.4)	3 (3.3)	0.701
Overall complications	11 (12.2)	9 (10.0)	0.640

Table 6. Functional Outcomes at One-Year Follow-up

Outcome	Low-Cost Implant Group	Imported Implant Group	p value
Functional score*, Mean ± SD	84.6 ± 8.5	86.1 ± 8.2	0.244[a]
Patient satisfaction score (0–10)	8.7 ± 1.1	8.9 ± 1.0	0.218[a]
Time to weight-bearing (weeks)	7.2 ± 1.8	7.0 ± 1.6	0.457[a]

*Site-specific validated functional scores used.

Table 7. Economic Comparison Between Groups

Variable	Low-Cost Implant Group	Imported Implant Group	p value
Implant cost (USD)	82 ± 18	246 ± 52	<0.001[a]
Procurement time (days)	2.8 ± 0.9	6.7 ± 1.8	<0.001[a]
Hospital stay (days)	6.8 ± 2.2	6.6 ± 2.0	0.532[a]

Interpretation: Low-cost implants demonstrated significantly lower implant costs and shorter procurement times.

Table 8. Cost-Effectiveness Analysis

Parameter	Low-Cost Implant Group	Imported Implant Group	p value
Cost per successful union (USD)	88 ± 21	270 ± 58	<0.001
Cost-effectiveness ratio	0.95	0.34	<0.001

Table 9. Multivariable Logistic Regression Analysis for Non-union

Variable	Adjusted OR (95% CI)	p value
Open fracture	3.42 (1.22–9.58)	0.019
Diabetes mellitus	2.75 (1.01–7.49)	0.048
Implant type (Low-cost vs Imported)	1.16 (0.44–3.09)	0.761
Time to surgery >7 days	2.98 (1.08–8.21)	0.035

Interpretation: Implant type was not an independent predictor of non-union after adjustment for confounding factors.

Overall Results Summary

Low-cost orthopaedic implants (locally manufactured and reusable implants) demonstrated clinical outcomes comparable to imported implants with respect to fracture union, implant survival, complication rates, functional recovery, and patient satisfaction. However, low-cost implants were associated with significantly lower implant costs, superior procurement efficiency, and improved cost-effectiveness, supporting their utility in resource-constrained healthcare systems.

DISCUSSION

The present study evaluated the clinical performance, safety, and cost-effectiveness of low-cost orthopaedic implants (locally manufactured and reusable implants) compared with imported orthopaedic implants in a resource-constrained healthcare setting. The findings demonstrated that low-cost implants achieved clinical outcomes comparable to imported implants while providing substantial economic advantages through reduced implant costs and improved procurement efficiency.

The baseline demographic and clinical characteristics were comparable between the two study groups, with no statistically significant differences in age, sex distribution, body mass index, diabetes mellitus, hypertension, fracture profile, or surgical timing. This comparability minimized the potential influence of confounding variables and strengthened the validity of the outcome comparisons. Similar observations were reported by Gupta et al., who demonstrated that baseline demographic variables did not significantly affect implant-related outcomes when standardized surgical protocols were followed. [8]

In the present study, fracture union was achieved in 93.3% of patients receiving low-cost implants and 91.1% of patients receiving imported implants, with no statistically significant difference between the groups. These findings suggest that appropriately manufactured and quality-assured low-cost implants can provide fracture healing outcomes comparable to imported devices. Agarwal et al. reported a union rate of 92.5% among patients treated with indigenous trauma implants, concluding that locally produced implants achieved clinical outcomes similar to internationally marketed devices. [9] Likewise, Chagomerana et al. demonstrated excellent fracture healing outcomes with affordable implant systems used in low-resource African settings, emphasizing that implant affordability does not necessarily compromise biological healing. [10]

The mean time to fracture union was comparable between the two groups, indicating that implant origin had minimal influence on the biological process of bone healing. Similar findings were reported by Gosselin et al., who observed no significant differences in fracture healing time between low-cost and conventional implant systems when appropriate fixation principles were followed. [11] These findings support the concept that surgical technique, fracture characteristics, and patient-related factors may be more important determinants of fracture healing than implant cost or origin.

Implant survival at one year exceeded 95% in both study groups. Mechanical failure rates remained low and were not significantly different between groups. These findings indicate satisfactory biomechanical performance of low-cost implants when used within appropriate clinical indications. Zirkle and Shearer reported comparable implant durability with the SIGN intramedullary nail system across several developing countries, demonstrating that cost-effective implants can achieve long-term structural reliability comparable to imported alternatives. [12] Similarly, Conway et al. found excellent implant retention and low failure rates with affordable fixation systems used in trauma centres serving resource-limited populations. [13]

The overall complication rates observed in the present study were low, and no statistically significant differences were identified between the low-cost and imported implant groups. Surgical site infection, implant loosening, and reoperation rates remained within acceptable ranges in both groups. Similar findings were reported by Maratt et al., who concluded that appropriately selected and quality-controlled low-cost orthopaedic devices did not demonstrate higher complication rates compared with conventional implants. [14] Furthermore, Allegranzi et al. emphasized that strict adherence to infection prevention protocols and sterilization standards plays a greater role in determining postoperative outcomes than implant source or cost. [15]

Functional outcomes at one-year follow-up were excellent in both groups, with mean functional scores exceeding 80 points and no statistically significant difference between low-cost and imported implants. These findings indicate that implant affordability did not adversely affect long-term functional recovery. Agarwal-Harding et al. similarly demonstrated that affordable orthopaedic implant systems were capable of producing favourable functional outcomes in trauma patients treated in low-resource environments. [16]

Patient satisfaction scores were high in both groups and did not differ significantly. These results suggest that patients prioritize clinical recovery, pain relief, and restoration of function rather than implant origin alone. Peters et al. reported that accessibility and affordability of treatment are major determinants of patient satisfaction in developing countries, particularly among patients who bear substantial out-of-pocket healthcare expenses. [17]

One of the most important findings of the present study was the significant economic advantage associated with low-cost implants. Implant costs were substantially lower in the low-cost implant group, while procurement times were significantly shorter. These findings highlight the potential role of indigenous manufacturing and regulated implant reuse in improving access to orthopaedic care. Shrime et al. demonstrated that surgical expenses frequently lead to catastrophic health expenditure in low-income settings and emphasized the importance of affordable surgical technologies in reducing financial hardship. [18] Similar economic benefits were reported by Mock et al., who found that cost-effective trauma interventions substantially improved access to surgical care while maintaining acceptable clinical outcomes. [19]

Cost-effectiveness analysis in the present study demonstrated a markedly lower cost per successful fracture union among recipients of low-cost implants. These findings support the integration of low-cost implant strategies into public healthcare systems and resource-constrained hospitals. Grimes et al. reported that investments in affordable surgical technologies generate substantial economic returns by reducing disability, improving productivity, and expanding access to essential surgical services. [20]

Multivariable logistic regression analysis identified open fractures, diabetes mellitus, and delayed surgical intervention as significant predictors of fracture non-union, whereas implant type was not independently associated with failure of fracture healing. These findings indicate that patient-related and injury-related factors exert a greater influence on treatment outcomes than implant origin. Similar observations have been reported in multiple orthopaedic studies, which consistently identified open injuries, metabolic disorders, and delayed fixation as major determinants of non-union and postoperative complications. [20]

Overall, the present study demonstrated that low-cost orthopaedic implants, including locally manufactured and reusable implants, achieved clinical outcomes comparable to imported implants while significantly reducing treatment costs and improving procurement efficiency. These findings support the wider adoption of low-cost implant strategies in resource-constrained healthcare systems, provided that stringent quality assurance measures, regulatory oversight, and sterilization standards are maintained.

CONCLUSION

Low-cost orthopaedic implants, including locally manufactured and reusable implants, demonstrated clinical outcomes comparable to imported implants with respect to fracture union, implant survival, complication rates, and functional recovery. Implant type was not found to be an independent predictor of fracture non-union. Low-cost implants offered significant economic advantages through reduced implant costs and improved procurement efficiency. Open fractures, diabetes mellitus, and delayed surgery were identified as important predictors of adverse outcomes. These findings support the safe and cost-effective use of low-cost orthopaedic implants in resource-constrained healthcare systems when appropriate quality assurance and sterilization protocols are maintained.

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