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Research Article

Custom Three-Dimensional-Printed Implants for Tibial and Femoral Segmental Defects: A Systematic Review and Meta-Analysis

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Abstract

Background: Segmental bone defects of the lower extremity, particularly involving the femur and tibia, remain a major reconstructive challenge. Traditional techniques such as the Ilizarov method, Masquelet's induced membrane, and vascularized fibular grafts are effective but often associated with prolonged treatment duration and significant morbidity. Recent advances in additive manufacturing have introduced patient-specific three-dimensional (3D)-printed implants as a promising alternative.
Methods: This systematic review and meta-analysis followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was conducted to collect current knowledge on 3D-printed implants of the tibia and femur. Databases including PubMed, Scopus, Embase, and Web of Science were searched from January 2000 to April 2025 for studies reporting outcomes of treatment of tibial or femoral segmental bone defects. Primary outcomes included bone union rate and complications. Study quality was assessed using the Methodological Index for Non-Randomized Studies (MINORS) tool, and pooled data were analyzed using a random-effects model.
Results: Seventeen studies involving 174 patients were included. The mean bone defect length was 12.3 cm, and the mean follow-up was 27.2 months. The pooled union rate was 92.4% [95% confidence interval (CI): 89.0%-94.8%], with no statistically significant heterogeneity ($I^2 = 0\%$). The mean time to radiological union was 7.66 months. The pooled complication rate was 23.5% (95% CI: 15.6%-33.8%), with reoperation, deep infection, and device-related events being the most common. Assessment of publication bias revealed no statistically significant effect.
Conclusion: Custom-made 3D-printed implants represent a highly effective and safe option for the reconstruction of segmental bone defects in the lower extremity. The high union rate and acceptable complication profile support their utility in managing complex cases. Further prospective studies are needed to confirm these findings and define optimal indications.

Keywords: Three-Dimensional Printing; Tibia; Femur; Orthopedics

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Background

Segmental bone defects of the lower extremities, particularly those involving the femur and tibia, pose a formidable challenge in orthopedic surgery due to the complexity of reconstruction and the high demands for functional recovery. These defects commonly arise from high-energy trauma, chronic osteomyelitis, or nonunion following failed surgical interventions, often resulting in significant morbidity and prolonged rehabilitation periods.

Conventional treatment methods, including the Ilizarov technique, Masquelet's induced membrane, and vascularized fibular grafts, have demonstrated varying degrees of success. However, these approaches often require extended treatment durations, are technically demanding, and may lead to complications such as joint stiffness, pin tract infections, or donor site morbidity (1-5).

Recent advances in additive manufacturing and computer-aided design have enabled the clinical application of patient-specific three-dimensional (3D)-printed implants. These custom-made titanium or tantalum prostheses allow for precise anatomical matching, tailored porosity to promote osseointegration, and immediate structural support. These custom-made titanium or tantalum prostheses are preferred over traditional methods because they provide precise anatomical matching, tailored porosity to promote osseointegration, immediate structural support, and reduced donor-site morbidity, potentially leading to faster recovery and lower complication rates in complex cases. Studies have demonstrated promising outcomes in both aseptic and infectious bone defects, with union rates exceeding 90% and acceptable complication profiles (6-8).

Moreover, the integration of 3D-printed implants with staged reconstruction techniques such as the Masquelet protocol has enabled early weight-bearing, reduced reinfection risk, and enhanced mechanical stability –even in cases involving critical-sized defects larger than 10 cm (1, 9, 10).

Despite these advances, the current literature remains fragmented, with most reports consisting of small case series or retrospective analyses. There is a clear gap in synthesized evidence evaluating the overall effectiveness, safety, and comparative advantages of these implants. There remains a need to synthesize the available data to assess the efficacy and safety of these custom implants in lower limb reconstruction.

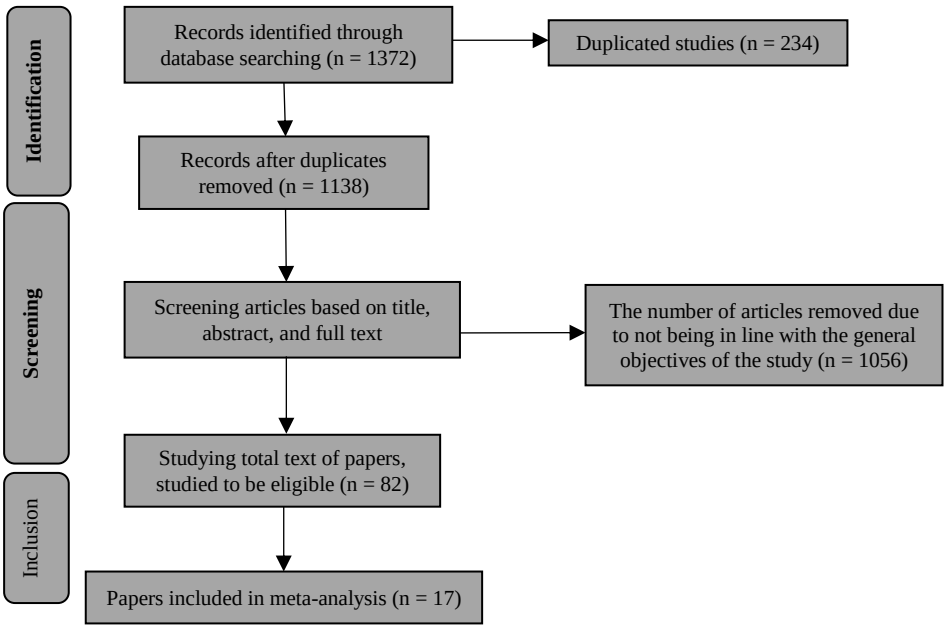

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram illustrating the selection process of studies included in the meta-analysis

Therefore, this systematic review and meta-analysis aims to evaluate the clinical outcomes, union rates, and complication profiles associated with custom-made 3D-printed implants in the treatment of segmental bone defects of the lower extremity.

Methods

Search Strategy: This systematic review and meta-analysis was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (11). A comprehensive search of PubMed, Scopus, Web of Science, and Embase databases was performed to identify relevant studies published between January 2000 and April 2025. The search strategy combined Medical Subject Headings (MeSH) terms and free-text keywords related to "custom-made 3D-printed implants", "tibia", "femur", "segmental bone defect", and "lower extremity".

Eligibility Criteria: Eligible studies were those that investigated the use of custom-made 3D-printed implants in the treatment of segmental bone defects of the tibia or femur in the lower extremities. We included studies that reported on patients with bone loss secondary to osteomyelitis, septic nonunion, aseptic nonunion, or trauma. Studies focusing on bone defects due to tumor resection or other oncological indications were excluded. Both retrospective and prospective studies were eligible, provided they reported sufficient outcome data on union rate, complications, and follow-up duration (Figure 1).

Data Extraction: Two independent reviewers screened titles and abstracts, followed by a full-text assessment. Disagreements were resolved by consensus. Extracted data included study characteristics, sample size, patient demographics, defect etiology, implant type, follow-up duration, union rate, complications, and reoperation rate. The methodological quality of non-randomized studies was evaluated using the Methodological Index for Non-Randomized Studies (MINORS) tool (Figure 2) (12).

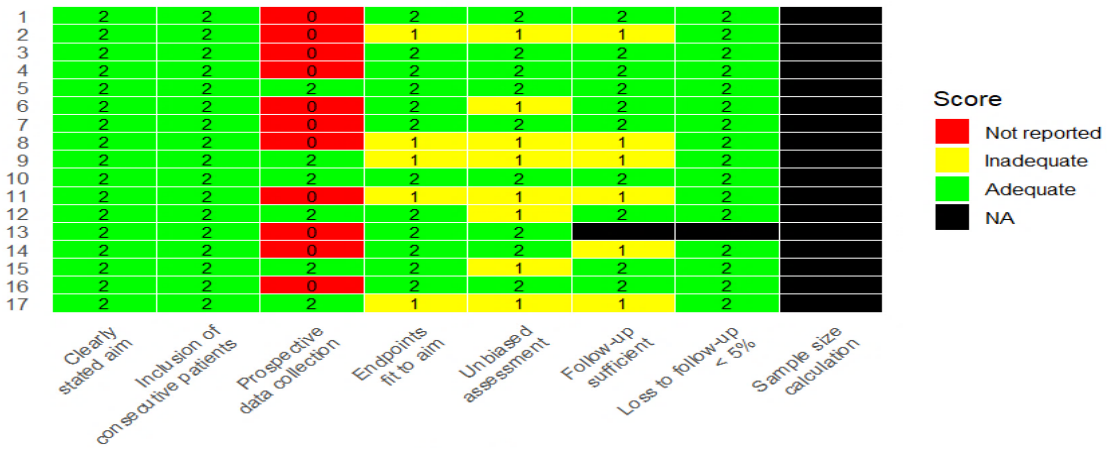

Figure 2. Methodological quality assessment of included studies using the Methodological Index for Non-Randomized Studies (MINORS) criteria

Table 1. Baseline characteristics of the included studies (the table summarizes patient demographics, defect size and location, study design, follow-up duration, and primary outcomes including union rate and time to union.)

Study	Year	Type	Number of cases	Age (year)	Sex (men/women)	Defect size (cm)	Site	Union rate (%)	Time to radiological union (month)	Time to functional union (month)	Follow-up (month)
Attias et al. (13)	2018	RS*	15	37.0	12/3	8.3	Tibia-femur	93	-	-	55.0
Gamieldien et al. (14)	2023	RS	9	35.0	7/2	9.6	Tibia-femur	100	4.9	3.1	11.3
Chen et al. (7)	2024	RS	13	48.7	12/1	14.0	Tibia	92	11.1	-	31.1
Ma et al. (15)	2023	RS	23	44.1	13/10	8.3	Femur	100	8.4	-	38.6
Gavaskar et al. (16)	2020	PC**	21	46.5	15/6	8.4	Tibia	100	5.6	1.5	27.0
Attias and Lindsey (17)	2006	RS	3	24.0	3/0	12.1	Tibia	100	-	1.5	44.3
Tetsworth et al. (10)	2019	RS	5	49.0	3/2	14.0	Femur	100	12.0	-	21.8
Wu et al. (8)	2022	RS	9	39.7	6/3	16.1	Femur	100	-	2.5	16.9
Hou et al. (1)	2020	PC	5	52.6	2/3	12.0	Femur	100	12.0	3.0	16.4
Chen et al. (2)	2024	PC	11	52.4	7/4	14.0	Femur	91	-	6.2	43.0
Lodewijks et al. (18)	2024	RS	3	43.3	3/0	11.6	Tibia	100	-	6.0	12.0
Liu et al. (19)	2022	PC	11	50.7	8/3	12.2	Tibia-femur	100	-	-	23.0
Caravelli et al. (20)	2022	RS	4	59.3	3/1	-	Tibia	100	5.0	-	
Beatti et al. (21)	2022	RS	6	30.0	5/1	12.1	Tibia-femur	100	5.0	3.0	24.0
Liu et al. (9)	2024	PC	8	56.3	5/3	14.9	Tibia-femur	75	5.0	-	24.5
Liu et al. (6)	2025	RS	14	46.0	11/3	16.9	Tibia	100	-	-	28.4
Liu et al. (22)	2022	PC	14	39.7	8/6	12.8	Tibia-femur	100	-	-	17.6
17 studies		RS	174	44.3		12.3			7.6	3.3	27.1

*Retrograde series; **Prospective clinical study

Data Analysis: Meta-analysis was performed in R (version 4.5.0) using the 'meta' and 'metafor' packages. Pooled proportions with 95% confidence intervals (CIs) were calculated using random-effects models. Statistical heterogeneity was assessed using the I^2 statistic and Cochran's Q test. Publication bias was evaluated using the Copas selection model.

Results

A total of 1372 articles were retrieved from four databases. After removing 234 duplicates, 1138 studies remained for title and abstract screening. Of these, 82 full-text articles were reviewed, and 17 studies met the inclusion criteria and were included in the meta-analysis (Figure 1) (1, 2, 6-10, 13-22).

These 17 studies included 174 patients with segmental bone defects of the lower extremity who underwent reconstruction using custom-made 3D-printed implants. The mean patient age was 44.3 years, with an average defect length of 12.3 cm and a mean follow-up duration of 27.2 months. Defects involved either the tibia or femur, and etiologies included trauma, osteomyelitis, and septic or aseptic nonunion (Table 1).

Time to union was available in 12 studies. The mean time to radiological union was 7.66 months, while the average time to functional union was 3.35 months. The union rate was reported in all studies. A total of 169 out of 174 patients achieved bone union, corresponding to a raw union rate of 97.1%. The pooled union rate estimated by a random-effects model was 92.4% (95% CI: 89.0%-94.8%). There was no statistical heterogeneity among studies ($I^2 = 0.0\%$, P = 0.987), indicating a high level of consistency (Figure 3).

Complications were reported in all studies, with a total of 34 events. The pooled complication rate was 23.5% (95% CI: 15.6%-33.8%) under a random-effects model. Statistical heterogeneity was low ($I^2 = 22.8\%$, P = 0.189) (Figure 4).

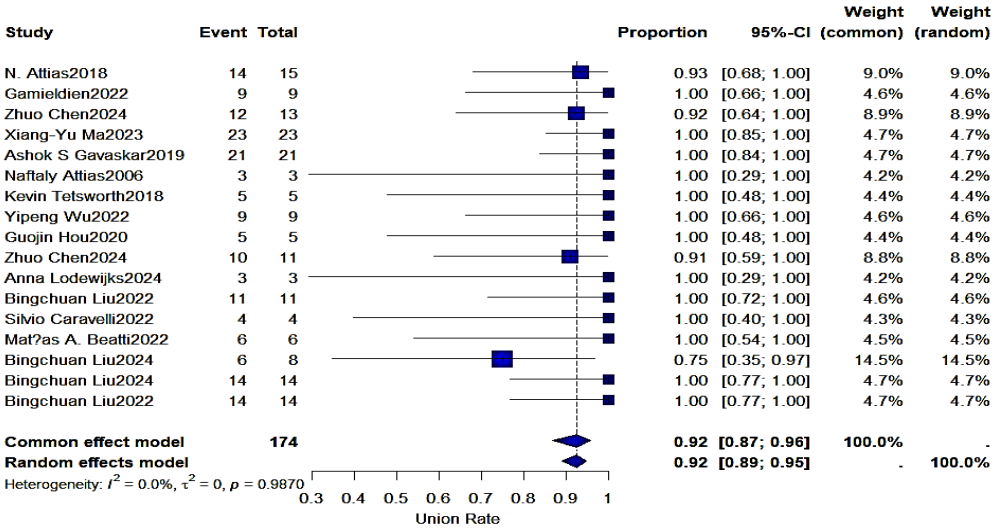

Figure 3. Forest plot showing the pooled bone union rate across included studies. The overall pooled union rate was 92.4% [95% confidence interval (CI): 89.0%-94.8%], with no statistical heterogeneity among studies ($I^2 = 0\%$). Individual study proportions and CIs are displayed, with the size of each box representing study weight in the meta-analysis.

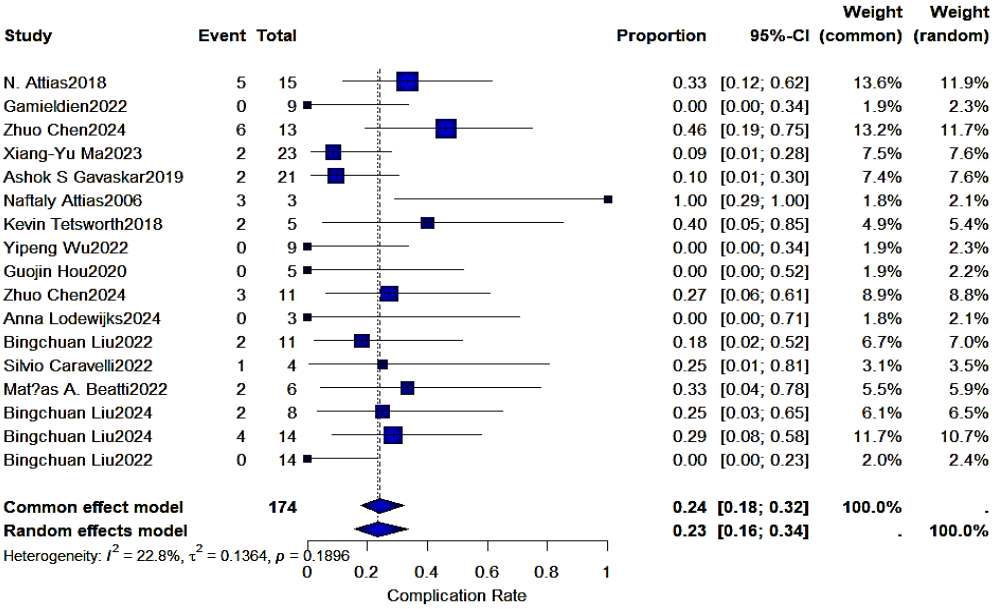

Figure 4. Forest plot showing the pooled complication rate across included studies. The overall complication rate was 23.5% [95% confidence interval (CI): 15.6%-33.8%] with low heterogeneity (I^2 = 22.8%). Each study's estimate is displayed with corresponding CIs, and box sizes reflect the relative weight of each study in the random-effects model.

The most commonly reported complications included reoperation (13.7%, 95% CI: 8.4%-21.5%), deep infection (9.2%, 95% CI: 6.3%-13.5%), device-related complications (DRCs) (13.1%, 95% CI: 8.8%-19.0%), and wound complications (13.1%, 95% CI: 6.4%-25.0%). Limb length discrepancy (LLD) (14.3%) and malalignment (8.4%) demonstrated high heterogeneity (I^2 > 80%). Less frequent complications included non-union (5.6%), joint stiffness (0.65%), and neurovascular injuries (0.66%) (Table 2).

Publication bias was assessed using the Copas selection model for both outcomes. Although the model indicated a potential for publication bias in both the union and complication analyses, the test for residual selection bias was not statistically significant (union: P = 0.341; complications: P = 0.128), suggesting that the pooled estimates remain valid despite the possible presence of unpublished data.

Discussion

This systematic review and meta-analysis demonstrates that custom-made 3D-printed implants are a promising option for the reconstruction of segmental bone defects in the lower extremity. Across 17 included studies with 174 patients, we observed a high union rate of 92.4% with a relatively low pooled complication rate of 23.5%. These findings suggest that this emerging technology may offer favorable outcomes compared to traditional reconstructive methods, particularly in complex cases involving extensive bone loss, infection, or failed prior surgeries (Tables 1 and 2) (2, 6, 9, 14).

Compared to the Ilizarov technique and other bone transport methods, which are widely regarded as gold-standard approaches for significant post-traumatic bone defects, the use of custom-made 3D-printed implants may provide several advantages (23-32). For instance, in the study by Xu et al., trifocal bone transport yielded good or excellent outcomes in 64% of cases but required external fixation durations exceeding 22 months and showed external fixation indices close to 2 months/cm, which are associated with patient discomfort and pin-site complications (9). In contrast, the 3D-printed implants analyzed in our study allowed for immediate defect filling and earlier functional recovery, with union achieved on average in less than 8 months (1, 2, 7, 13, 14, 16).

Similarly, vascularized fibular grafts and massive allografts, while biologically sound, have been associated with graft fracture, donor site morbidity, and extended healing times (33, 34). The integration of 3D-printed implants with techniques such as the Masquelet's induced membrane has shown promise in overcoming these limitations, as reported in both experimental studies and clinical case series.

The success of 3D-printed implants can be attributed to several key factors: personalized implant design tailored to the patient's anatomical and biomechanical requirements, improved stability through precise fit, and engineered porosity that promotes osseointegration.

Table 2. Summary of complications reported in the included studies

Study	Studies' number	Heterogenicities	Proportion (%)	95% CI
Reoperation	(1, 3, 5, 7, 10, 12, 13, 15, 16)	I^2 = 13.6%, P-value = 0.29	13.71	8.41-21.50
Deep infection	(1, 3, 10, 15)	I^2 = 0.0%, P-value = 0.96	9.23	6.32-13.45
DRC	(1, 3, 5, 7, 12, 13, 15, 16)	I^2 = 0.0%, P-value = 0.84	13.07	8.81-18.96
Wound complications	(1, 3, 4, 7, 10, 13, 14)	I^2 = 35.7%, P-value = 0.07	13.15	6.44-24.97
Flap complications	(1, 3, 5)	I^2 = 0.0%, P-value = 0.92	0.30	0.00-2.30
LLD	(1, 6, 7, 8, 11, 12)	I^2 = 87.1%, P-value < 0.01	14.28	0.20-37.89
Joint stiffness	(3, 7, 8, 10, 14)	I^2 = 0.0%, P-value = 0.49	0.65	0.00-4.10
Non-union	(1, 3, 10, 15)	I^2 = 0.0%, P-value = 0.99	5.60	3.79-6.72
Malalignment	(1, 7, 12)	I^2 = 81.9%, P-value < 0.01	8.40	0.00-30.40
Neurovascular complications	(1, 11)	I^2 = 36.7%, P-value = 0.07	0.66	0.00-7.06
Pooled complication rate	(1-17)	I^2 = 22.8%, P-value = 0.18	23.49	15.58-33.79

DRC: Device-related complications; LLD: Limb length discrepancy; CI: Confidence interval

In our review, the most common complications, such as reoperation and deep infection, occurred at lower rates than those reported in classical reconstruction techniques, highlighting the clinical safety of this modality (1, 6, 9, 10, 14, 19).

Our findings are further supported by multiple case reports included outside the quantitative analysis. These reports confirm the feasibility and safety of 3D-printed implants in a wide range of clinical settings –from chronic osteomyelitis to traumatic bone loss – demonstrating union even in defects exceeding 15 cm. They also emphasize the importance of accurate preoperative planning and the potential for customized solutions in managing irregular geometries, joint involvement, or LLDs (35-39).

Despite these strengths, the current evidence base has several limitations. The majority of included studies were retrospective and had small sample sizes, limiting the generalizability of their findings. Additionally, the diversity of implant designs, fixation methods, and surgical techniques may contribute to heterogeneity in outcomes. Although the Copas model identified possible publication bias in both union and complication outcomes, the P-values were not statistically significant (union: P = 0.341; complications: P = 0.128), suggesting that the pooled estimates are likely robust.

Looking ahead, high-quality prospective studies with standardized outcome reporting are needed to validate these early findings and directly compare 3D-printed implants with existing methods, such as bone transport or vascularized grafting. Additionally, cost-effectiveness analyses and long-term follow-up will be crucial in defining the role of this technology in routine clinical practice.

Conclusion

This systematic review and meta-analysis demonstrates that custom-made 3D-printed implants represent a safe and effective option for the reconstruction of segmental bone defects in the lower extremities. With a high union rate and acceptable complication profile, they offer a promising alternative to traditional techniques, particularly in complex or previously failed cases. While early results are encouraging, further high-quality prospective studies are necessary to validate these findings, compare long-term outcomes, and evaluate cost-effectiveness in broader clinical settings

Conflict of Interest

The authors declare no conflict of interest in this study.

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The Ethics Committee of Imam Khomeini Hospital Complex (Tehran, Iran) confirmed that ethical approval was not required for this systematic review. This review was not registered due to its retrospective design.

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