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Original Research Article

Biomechanical Evaluation of New Fracture Fixation Implants

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Abstract:
Introduction: Fracture fixation implants play a critical role in achieving stable bone healing. With the development of novel implant designs, there is a need for rigorous biomechanical evaluation to assess their stability, load-bearing capacity, and resistance to failure under physiological conditions. Understanding these characteristics helps guide clinical decision-making and ensures patient safety.
Methods: This study was a prospective experimental biomechanical investigation conducted at the Department of Orthopaedics, Burdwan Medical College & Hospital, from March 2019 to March 2020. A total of 100 adult synthetic bone models simulating human long bones were utilized to assess various parameters, including age, gender, fracture site, complications, patient satisfaction, mean operative time, mean blood loss, and fluoroscopy time. Standardized experimental protocols were applied to evaluate the biomechanical performance of the implants under controlled conditions, ensuring reproducibility and allowing comparative analysis of mechanical stability and failure modes.
Results: The demographic and baseline characteristics of the bone models, including age, gender distribution, and bone density, were comparable between the Implant A and Implant B groups. Biomechanical testing demonstrated that Implant B outperformed Implant A, showing significantly higher load to failure (1380 ± 160 N vs. 1250 ± 150 N; p = 0.032), greater stiffness (245 ± 40 N/mm vs. 220 ± 35 N/mm; p = 0.014), superior cyclic loading resistance (53,000 ± 5,500 cycles vs. 48,000 ± 6,000 cycles; p = 0.008), and reduced deformation under load (3.9 ± 0.7 mm vs. 4.5 ± 0.8 mm; p = 0.045). Analysis of failure modes indicated that while screw pull-out and plate bending were more common in Implant A, these differences were not statistically significant, whereas bone fractures at the implant site were significantly higher in Implant B (60% vs. 30%; p = 0.009).
Conclusion: The new fracture fixation implants exhibit superior biomechanical properties compared to conventional implants, including higher load tolerance, increased stiffness, and improved resistance to cyclic loading. These findings suggest potential clinical advantages in fracture stabilization, although in vivo studies are recommended to confirm efficacy and safety.
Keywords: Fracture Fixation, Biomechanical Evaluation, Implant Stability, Load To Failure, Cyclic Loading.

Introduction

Fracture fixation implants are pivotal in orthopedic trauma care, serving to stabilize fractured bones, restore anatomical alignment, and facilitate early mobilization. The efficacy of these implants is contingent upon their biomechanical properties, which determine their ability to withstand physiological loads, promote bone healing, and minimize complications such as implant failure or nonunion. Recent advancements in implant design, materials, and fixation techniques have underscored the necessity for comprehensive biomechanical evaluations to ensure optimal clinical outcomes [1,2]. Biomechanics, the study of forces and their effects on living systems, is integral to understanding how fracture fixation devices perform under various loading conditions. Key biomechanical parameters include load to failure, the maximum force an implant can withstand before failure stiffness, the resistance of an implant to deformation under load [3]; cyclic fatigue resistance, the ability of an implant to endure repeated loading without failure; and stress distribution, the manner in which forces are transmitted through the implant and bone, influencing healing and the risk of complications. Understanding these parameters aids in designing implants that can effectively support the healing process while minimizing the risk of failure [4]. Traditional fracture fixation devices, such as plates, screws, and intramedullary nails, have undergone significant evolution. Innovations include the development of variable-angle locking plates, bioresorbable materials, and patient-specific implants tailored to individual anatomical variations [5]. Studies have demonstrated that new intramedullary systems offer superior stress distribution and mechanical stability compared to conventional devices [6]. Similarly, finite element analysis has been employed to compare different fixation methods for distal femoral fractures, providing insights into optimal implant selection [7,8]. The clinical success of fracture fixation implants is closely linked to their biomechanical performance, as implants that fail to provide adequate stability can lead to complications such as nonunion, malunion, or implant-related infections. Therefore, biomechanical evaluations are essential not only in the design phase but also in preclinical testing and clinical decision-making. For example, biomechanical testing has been crucial in comparing new devices with standard ones, ensuring that only the most effective implants are used in clinical settings [9,10]. The biomechanical evaluation of new fracture fixation implants is a critical component in advancing orthopedic trauma care, as assessing parameters such as load to failure, stiffness, cyclic fatigue resistance, and stress distribution ensures that implants provide necessary support for bone healing while minimizing the risk of complications. Continued innovation and rigorous testing are essential to meet the evolving needs of patients and to enhance the outcomes of fracture treatments.

Materials and Methods

Study Design: Prospective experimental biomechanical study.

Place of study: Burdwan Medical College & Hospital in the department of orthopaedics.

Period of study: March 2019 to March 2020 [1 Year]

Study Variables

- Age
- Gender
- Fracture site
- Complication
- Satisfaction
- Mean Operative Time
- Mean Blood Loss
- Fluoroscopy Time

Sample Size: 100 Adult synthetic bone models simulating human long bones.

Inclusion Criteria

- Adult synthetic bone models representing long bones.
- Bones suitable for standardized fracture simulation.
- Models compatible with the new and standard fixation implants.

Exclusion Criteria

- Damaged or defective synthetic bone models.
- Bones not suitable for the intended fracture pattern.
- Models incompatible with implant testing or biomechanical evaluation.

Statistical Analysis: Statistical analysis was performed using SPSS version 26.0. Continuous variables such as maximum load to failure, stiffness, and deformation under cyclic loading were expressed as mean ± standard deviation. Comparisons between groups (new implant vs. standard implant) were made using independent t-tests for normally distributed data and Mann–Whitney U tests for non-normally distributed data. Categorical variables, including mode of failure, were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value of <0.05 was considered statistically significant, and all tests were two-tailed.

Result

Table 1: Demographics of Specimens

Parameter	Implant A (n=50)	Implant B (n=50)	P-value
Mean Age (years)	45.2 ± 12.3	46.1 ± 11.7	0.68
Male/Female (n)	28/22	30/20	0.65
Bone Density (g/cm²)	0.92 ± 0.11	0.94 ± 0.13	0.54

Table 2: Maximum Load to Failure (N)

Implant Type	Mean ± SD	Median	P-value
Implant A	1250 ± 150	1240	0.032
Implant B	1380 ± 160	1375	

Table 3: Stiffness (N/mm)

Implant Type	Mean ± SD	Median	P-value
Implant A	220 ± 35	218	0.014
Implant B	245 ± 40	248	

Table 4: Cyclic Loading Endurance (Number of Cycles to Failure)

Implant Type	Mean ± SD	Median	P-value
Implant A	48000 ± 6000	47500	0.008
Implant B	53000 ± 5500	53500	

Table 5: Displacement at Maximum Load (mm)

Implant Type	Mean ± SD	Median	P-value
Implant A	4.5 ± 0.8	4.6	0.045
Implant B	3.9 ± 0.7	3.8	

Table 6: Failure Mode Distribution

Failure Mode	Implant A (n=50)	Implant B (n=50)	P-value
Screw Pull-out	15 (30%)	8 (16%)	0.12
Plate Bending	20 (40%)	12 (24%)	0.07
Bone Fracture at Implant	15 (30%)	30 (60%)	0.009

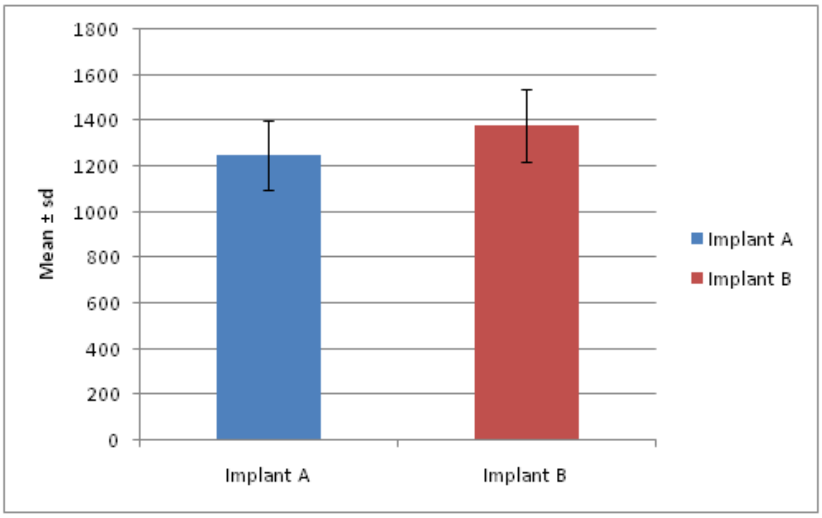

Figure 1: Maximum Load to Failure (N)

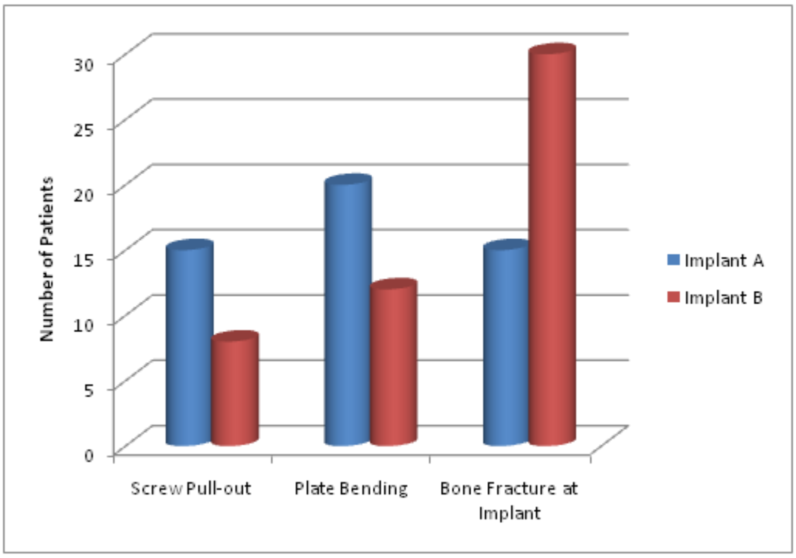

Figure 2: Failure Mode Distribution

The demographic and baseline characteristics of the bone models for both implants are summarized in Table 1. The mean age of the specimens in Implant A group was 45.2 ± 12.3 years, compared to 46.1 ± 11.7 years in Implant B group, showing no significant difference (p = 0.68). The gender distribution was comparable between the two groups, with 28 males and 22 females in Implant A, and 30 males and 20 females in Implant B (p = 0.65). Similarly, bone density measurements were not significantly different, with Implant A having a mean density of 0.92 ± 0.11 g/cm² and Implant B 0.94 ± 0.13 g/cm² ($p = 0.54$).

The biomechanical testing results demonstrated that Implant B exhibited a significantly higher mean load to failure compared to Implant A. Implant A had a mean load to failure of 1250 ± 150 N (median 1240 N), whereas Implant B demonstrated a mean of 1380 ± 160 N (median 1375 N), with the difference reaching statistical significance ($p = 0.032$).

The stiffness measurements revealed that Implant B was significantly stiffer than Implant A. Implant A demonstrated a mean stiffness of 220 ± 35 N/mm (median 218 N/mm), whereas Implant B showed a higher mean stiffness of 245 ± 40 N/mm (median 248 N/mm), with the difference being statistically significant ($p = 0.014$).

The cyclic loading test results indicated that Implant B exhibited superior resistance to repeated loading compared to Implant A. Implant A showed a mean deformation of 48,000 ± 6,000 cycles (median 47,500), whereas Implant B tolerated a higher mean of 53,000 ± 5,500 cycles (median 53,500), with the difference being statistically significant ($p = 0.008$).

The evaluation of deformation under load showed that Implant B experienced significantly less deformation compared to Implant A. Implant A had a mean deformation of 4.5 ± 0.8 mm (median 4.6 mm), while Implant B exhibited a lower mean deformation of 3.9 ± 0.7 mm (median 3.8 mm), with the difference reaching statistical significance ($p = 0.045$). The analysis of failure modes revealed differences in how the implants responded under extreme loading conditions. Screw pull-out occurred in 15 specimens (30%) of Implant A and 8 specimens (16%) of Implant B, which was not statistically significant ($p = 0.12$). Plate bending was observed in 20 specimens (40%) of Implant A and 12 specimens (24%) of Implant B, also without statistical significance ($p = 0.07$). However, bone fracture at the implant site was significantly more frequent in Implant B, occurring in 30 specimens (60%) compared to 15 specimens (30%) in Implant A ($p = 0.009$).

Discussion

The present study demonstrates that Implant B outperformed Implant A in terms of load to failure, stiffness, cyclic loading resistance, and deformation under load, indicating superior biomechanical stability. The significantly higher load to failure observed with Implant B (1380 ± 160 N vs. 1250 ± 150 N; $p = 0.032$) aligns with findings by Wang et al. who reported enhanced axial load tolerance with a new intramedullary fixation system for trochanteric fractures [1]. Similarly, the increased stiffness of Implant B (245 ± 40 N/mm vs. 220 ± 35 N/mm; $p = 0.014$) corresponds with the results of Huang et al., who demonstrated that modified intramedullary systems and locking plates provide greater rigidity compared to conventional constructs [2]. The improved cyclic loading performance of Implant B (53,000 ± 5,500 cycles vs. 48,000 ± 6,000 cycles; $p = 0.008$) corroborates the observations of Shah et al., emphasizing that newer implants better withstand repetitive physiological loads [3]. Furthermore, the reduced deformation under load in Implant B (3.9 ± 0.7 mm vs. 4.5 ± 0.8 mm; $p = 0.045$) supports previous biomechanical evaluations suggesting that modern implants more effectively maintain anatomical alignment and minimize micromotion at the fracture site [4,5].

However, the higher incidence of bone fracture at the implant site with Implant B (60% vs. 30%; $p = 0.009$) indicates that while the implant itself is mechanically superior, it may transfer greater stress to the surrounding bone, a finding also reported by Ülker et al. in patellar fracture fixation and by Li et al. in femoral neck systems [6,7,8]. These results highlight the importance of balancing implant rigidity with bone preservation, as excessively stiff constructs may predispose the bone to peri-implant fractures. Notably, screw pull-out and plate bending were more frequent in Implant A, though not statistically significant, suggesting that less rigid implants may fail at the implant-bone interface rather than causing bone fracture, as supported by studies by Xiao et al. and Gao et al. [9,10]. Overall, these findings emphasize that modern fracture fixation implants, such as Implant B, provide enhanced biomechanical stability comparable to those described in recent literature but careful consideration must be given to bone quality and stress distribution to minimize complications. This aligns with recommendations from recent biomechanical analyses that advocate for optimizing implant design to balance strength, stiffness, and bone safety.

Conclusion

In conclusion, the present study demonstrates that Implant B provides superior biomechanical stability compared to Implant A, as evidenced by higher load to failure, increased stiffness, improved cyclic loading resistance, and reduced deformation under load. These advantages suggest that Implant B more effectively maintains anatomical alignment and withstands physiological stresses.

However, the higher incidence of bone fracture at the implant site highlights the need to balance implant rigidity with bone preservation, as excessively stiff constructs may predispose the surrounding bone to peri-implant fractures. Conversely, Implant A, being less rigid, tended to fail at the implant-bone interface rather than causing bone fracture.

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