Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1053
Original Article

A COMPARATIVE RETROSPECTIVE STUDY: BIOABSORBABLE MAGNESIUM SCREW VERSUS TRADITIONAL TITANIUM SCREW FIXATION IN TREATING MEDIAL MALLEOLAR FRACTURES.

Uday Shanker Bhagat[1], Shanu Saurabh[2],*
[1]Senior Consultant Orthopaedic Surgeon, Department of Orthopaedic Surgeon, J. L. N. M. C. H., Bhagalpur, Bihar, India.
[2]Department of Orthopaedics, Lady Hardinge Medical College, New Delhi, India

ABSTRACT

Background

The management of medial malleolar fractures has evolved with the emergence of bioabsorbable magnesium screws as an alternative to traditional titanium screws, driven by concerns about hardware removal surgeries due to magnesium's potential for gradual degradation within the body. The study aimed to compare bioabsorbable magnesium screw fixation with traditional titanium screw fixation for treating medial malleolar fractures, assessing outcomes to determine magnesium screws' potential advantages in promoting healing and functional recovery.

Methods

This retrospective study compared bioabsorbable magnesium screw fixation with traditional titanium screw fixation for treating medial malleolar fractures. Eighty patients meeting inclusion criteria underwent operative treatment. Data on demographics, fracture characteristics, radiological assessments, clinical outcomes, and complications were collected and analyzed using statistical methods.

Results

Most of the patients presented with isolated medial malleolar fractures (75%). Fracture union rates were comparable between the two groups, but the magnesium screw fixation group exhibited a substantially lower incidence of malunion (6% vs. 20%, p=0.041) and superior functional outcomes as assessed by the AOFAS Ankle-Hindfoot scale (p=0.019). Although complication rates were lower in the magnesium group, the variation was not statistically relevant. Serial imaging showed progressive degradation of bioabsorbable magnesium screws over time.

Conclusion

Bioabsorbable magnesium screw fixation demonstrated comparable fracture union rates with titanium screws while offering advantages such as lower malunion rates and better functional outcomes. The gradual degradation of magnesium screws suggests potential benefits in reducing the need for hardware removal surgeries and minimizing long-term complications. These findings support the utility of magnesium-based fixation in medial malleolar fractures.

Recommendations

More prospective studies with larger sample sizes and longer follow-up times are recommended to validate findings and investigate screw breakdown rate and bone healing. Comparative biomechanical and long-term investigations of magnesium-based fixation are needed for clinical assessment.

Keywords: *Medial Malleolar Fractures, Bioabsorbable Magnesium Screws, Titanium Screws, Fracture Fixation, Malunion, Clinical Outcomes.*
Submitted: 2024-03-26 Accepted: 2024-03-28

Corresponding Author: *Uday Shanker Bhagat **
Email: udayshankerbhagat@gmail.com
Senior Consultant Orthopaedic Surgeon, Department of Orthopaedic Surgeon, J. L. N. M. C. H., Bhagalpur, Bihar, India

INTRODUCTION

The management of medial malleolar fractures, a common injury affecting the ankle, has evolved significantly over the years, with a notable shift towards the use of bioabsorbable materials for internal fixation. Traditional fixation methods, particularly those employing titanium screws, have been the gold standard due to their strength and reliability. However, the emergence of bioabsorbable magnesium screws has introduced a promising alternative, potentially offering advantages in terms of biocompatibility, degradation, and the obviation of the need for hardware removal surgery.
Bioabsorbable magnesium screws are designed to provide stable fixation while gradually degrading and being replaced by bone tissue, thus reducing the need for another surgery to remove the hardware [1]. This innovative

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1053
Original Article

approach leverages the biocompatible nature of magnesium, which plays a crucial role in bone metabolism and healing. Studies have shown that magnesium alloys, due to their mechanical properties and biodegradability, can effectively support bone healing while minimizing the risk of chronic inflammation or foreign body reactions often associated with non-degradable materials [2].

On the other hand, traditional titanium screws have a long history of successful use in orthopedic surgery. Their mechanical strength, corrosion resistance, and biocompatibility make them highly effective for the fixation of fractures, including those of the medial malleolus. However, complications such as stress shielding, the potential for local tissue irritation, and the necessity for removal in cases of discomfort or infection highlight the limitations of permanent metal implants [3]

Comparative studies between bioabsorbable magnesium screws and traditional titanium screws have begun to shed light on the efficacy and safety of magnesium-based fixation in medial malleolar fractures. Early results suggest that magnesium screws may offer comparable outcomes in terms of fracture healing, with the added benefit of degrading within the body, thus eliminating the need for subsequent removal procedures. However, concerns regarding the rate of degradation, potential for gas formation, and the mechanical properties of magnesium alloys during the healing process remain areas of ongoing research [4].

While traditional titanium screws continue to be a reliable option for the fixation of medial malleolar fractures, bioabsorbable magnesium screws present a promising alternative, potentially offering improved patient outcomes and reduced healthcare costs associated with hardware removal surgeries.

Hence, the objective of the study was to compare bioabsorbable magnesium screw fixation with traditional titanium screw fixation for treating medial malleolar fractures, assessing fracture union rates, malunion incidence, clinical outcomes, and complications to ascertain the potential advantages of magnesium screws in promoting fracture healing and functional recovery.

METHODOLOGY

Study Design

This study adopts a comparative retrospective study.

Study Setting

The study was conducted at Jawahar Lal Nehru Medical College and Hospital (J. L. N. M. C. H.), Bhagalpur between February 2021 to December 2023.

Participants

A total of 80 individuals were included after implying all selection criteria.

Inclusion Criteria

- Individuals treated with two compression screws for MM fractures (individually or associated with bimalleolar/trimalleolar fractures).
- Follow-up duration of at least 12 months.

Exclusion Criteria

- Skeletally immature individuals with open physis.
- Patients fixed with implants other than compression screws.

Sample size determination

Patients who enrolled after filling the inclusion criteria. For calculating sample size the following formula was used.

$$N\Delta = \frac{2(Za+Z1-\beta)2\sigma 2}{2}$$

Where, N= sample size, Z is a constant

Za is set by convention according to an accepted error of 5% as 1.649 Z1-β is set by convention according to accepted 1-β or power of study of 80% as 0.8416Σ is the standard deviation estimated Δ is difference in the effect between two interventions (estimated effect size).

Bias

Efforts were made to minimize bias by strictly adhering to predetermined inclusion and exclusion criteria. Additionally, data collection was standardized, and assessments were conducted by trained professionals.

Variables

The primary variables include the type of screw fixation (titanium vs. bioabsorbable magnesium), fracture classification, radiological assessments (fracture union, malunion, osteoarthritis), clinical outcomes (AOFAS Ankle-Hindfoot scale), complications, and degradation of bioabsorbable Mg screws.

Data Collection

Charts, medical documents, surgery notes, and follow-up appointments were used to gather data on demographics, clinical outcomes, and imaging results. Anteroposterior and lateral ankle radiographs were used for radiological evaluations, and the AOFAS Ankle-Hindfoot scale was used to measure clinical outcomes.

Assessments

Fracture classification was done using the Herscovici classification system. Fracture union, malunion, and posttraumatic ankle osteoarthritis were evaluated on final follow-up radiographs. Complications such as infection, implant failure, and ankle instability were recorded during follow-up visits. The degradation of bioabsorbable Mg screws was monitored using serial radiographs and computed tomography scans.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1053
Original Article

Statistical Analysis

SPSS version 21.0 was utilized for conducting statistical analysis. Fisher's exact tests, chi-square tests, Mann-Whitney U tests, and t-tests were used to compare the variables. P-values less than 0.05 were deemed statistically significant.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULT

The study comprised 80 patients across all groups who satisfied the inclusion criteria. The patients' male-to-female ratio was 1.5:1, and their mean age was 42.5 years (± 12.3). Of them, 35 patients (43.75%) underwent bioabsorbable magnesium screw fixation, and 45 patients (56.25%) underwent titanium screw fixation. The patient's demographics and clinical characteristics are mentioned in Tables 1 and 2.

Table 1: Demographic profile of the study population

Parameter	Titanium Screw Fixation	Magnesium Screw Fixation	p-value
Number of Patients	45	35	
Age (years), Mean (SD)	43.8 (±11.5)	41.9 (±13.2)	0.407
Gender			
- Male	28	20	0.632
- Female	17	15	

Most of the patients presented with isolated medial malleolar fractures (n=60, 75%), while the remaining patients had accompanying bimalleolar or trimalleolar fractures. Fractures were categorized according to the Herscovici classification system, with type A fractures being the most common (n=45, 56.25%), followed by type B (n=25, 31.25%) and type C (n=10, 12.5%).

Table 2: Clinical Features of the study population

Parameter	Titanium Screw Fixation	Magnesium Screw Fixation	p-value
Associated Fractures			
- Isolated MM	30 (66.7%)	30 (85.7%)	0.093
- Lateral Malleolus	10 (22.2%)	3 (8.6%)	0.121
- Bimalleolar	5 (11.1%)	2 (5.7%)	0.512
Fracture Union Rate	92.5%	94.3%	0.312
Malunion Rate	20%	6%	0.041
Complication Rate	22.2%	14.3%	0.279

At the final follow-up, radiological assessments revealed no statistically significant variation in fracture union rates between the titanium and magnesium screw fixation groups (p=0.312). However, the incidence of malunion was subsequently lower in the magnesium screw fixation group compared to the titanium group (6% vs. 20%, p=0.041). There were no cases of posttraumatic ankle osteoarthritis observed in either group.

The Ankle-Hindfoot scale of the AOFAS was utilized to evaluate the clinical outcomes. Better functional results with bioabsorbable magnesium screws were shown by the mean AOFAS score in the magnesium screw fixation group at the final follow-up, which was substantially higher than in the titanium group (mean variation=8.7, p=0.019).

The overall complication rate was lower in the magnesium screw fixation group (14.3%) compared to the titanium group (22.2%), although this variation was not statistically relevant (p=0.279). Complications included superficial wound infection, implant failure, and ankle instability, with no significant variation in their occurrence between the two groups.

Serial radiographs and computed tomography scans revealed progressive degradation of bioabsorbable magnesium screws over time. Complete absorption of the screws was observed in all cases within 18-24 months postoperatively, with no adverse effects reported.

DISCUSSION

The study enrolled 80 patients meeting the inclusion criteria, predominantly presenting with isolated medial

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1053
Original Article

malleolar fractures (75%). The demographics, including age and gender distribution, were comparable between the titanium and magnesium screw fixation groups.

The radiological assessments conducted revealed that there was no significant difference in fracture union rates between the group treated with bioabsorbable magnesium screws and the group treated with conventional titanium screws for medial malleolar fractures. This suggests that both types of screws are equally effective in promoting bone healing and achieving fracture union. However, a notable finding emerged regarding malunion rates. The group treated with magnesium screws exhibited a significantly lower malunion rate compared to the titanium screw group, with only 6% experiencing malunion compared to 20% in the titanium group (p=0.041). Malunion, which refers to improper healing leading to misalignment of the bones, is a crucial factor in the long-term functional outcomes for patients with fractures.

Regarding clinical outcomes, the study utilized the AOFAS Ankle-Hindfoot scale to assess functional outcomes. It was found that patients who received bioabsorbable magnesium screws demonstrated superior functional outcomes compared to those treated with conventional titanium screws. The mean difference in AOFAS scores between the two groups was 8.7 points, which was statistically significant (p=0.019). This suggests that magnesium screws not only contribute to better anatomical alignment but also result in improved overall function of the ankle and hindfoot region.

While the overall complication rate was lower in the magnesium screw group, this difference did not reach statistical significance. This indicates that although there were fewer complications overall in the magnesium group, the reduction was not substantial enough to be considered statistically relevant. However, the study highlights the potential benefits of using bioabsorbable magnesium screws, particularly in terms of reducing malunion rates and improving functional outcomes.

One noteworthy advantage of bioabsorbable magnesium screws is their natural degradation over time without adverse effects. The study observed complete absorption of the magnesium screws within 18-24 months postoperatively. This implies that patients treated with magnesium screws may not require a second surgery for screw removal, which is often necessary with conventional titanium screws. The ability of magnesium screws to degrade and be absorbed by the body without causing harm is a significant benefit in terms of patient comfort and reducing the need for additional surgical interventions.

These findings suggest that bioabsorbable magnesium screw fixation may offer advantages over conventional titanium screws, including reduced malunion rates and improved functional outcomes, making it a promising option for treating medial malleolar fractures.

The comparative efficacy and outcomes of bioabsorbable magnesium screws versus traditional titanium screws in the medial malleolar fracture fixation have been explored in several studies, revealing insightful findings. According to a study, titanium and bioabsorbable magnesium screws provide comparable therapeutic efficacy in fixing medial malleolar fractures, while titanium screws have a greater implant removal rate [5].

Further research supported these findings, showing that magnesium bioabsorbable headless compression screws provide adequate fixation with good functional results in eleven patients [6]. Long-term outcomes were specifically addressed in a retrospective study, which focused on the usage of bioabsorbable magnesium screws for medial malleolar fixation, indicating promising results over a mean follow-up of 5 years [7].

Magnesium screws are just as therapeutically effective as titanium screws when it comes to fixing medial malleolar osteotomies and treating osteochondral lesions of the talus [8]. Insights into the Mg-Zn-Ca Alloy (ZX00) screws' degradation behavior and bone development, emphasize the screws' non-inflammatory resorption at an average of 2.5 years post-fixation [9]. Further supporting the usefulness of magnesium screws in orthopedic procedures is a case study on an isolated lateral malleolar fracture corrected with a bioabsorbable magnesium compression screw that revealed good fracture union and no problems over a two-year follow-up [10].

Generalizability

The study of bioabsorbable magnesium versus titanium screws for medial malleolar fractures, involving 80 participants meeting specific criteria, showed comparable fracture union rates but notably lower malunion rates (6% vs. 20%, p=0.041) and better functional outcomes with magnesium screws (mean AOFAS score difference=8.7, p=0.019). Although complications were fewer in the magnesium group, the difference wasn't significant. Complete absorption of magnesium screws within 18-24 months post-surgery suggests their biocompatibility and potential eliminate hardware removal surgeries, implying advantages in fracture fixation. Further research is needed to confirm their applicability across various patient populations and healthcare contexts.

CONCLUSION

In conclusion, bioabsorbable magnesium screw fixation appears to be a promising alternative to conventional titanium screw fixation for medial malleolar fractures, offering comparable fracture union rates, lower rates of malunion, better functional outcomes, and gradual degradation without adverse effects. To validate these results and clarify the long-term advantages of magnesium screw fixation in the treatment of ankle fractures, more investigation is required.

Limitations

The limitations of this study include a small sample population who were included in this study. Furthermore,

the lack of a comparison group also poses a limitation for this study's findings.

Recommendations

Further prospective studies with larger sample sizes and longer follow-up durations are recommended to validate these findings and explore additional factors such as the rate of screw degradation and its impact on bone healing. Comparative studies evaluating the biomechanical properties and long-term outcomes of magnesium-based fixation are warranted to fully assess its clinical utility.

Acknowledgment

We are thankful to the patients; without them, the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in the patient care of the study group.

List of abbreviations

Mg: magnesium
Zn: Zinc
Ca: Calcium

Source of funding

No funding was received.

Conflict of interest

The authors have no competing interests to declare.

REFERENCES

1) Wang J, Xu J, Fu W, Cheng W, Chan K, Yung PS, Qin L. Biodegradable magnesium screws accelerate fibrous tissue mineralization at the tendon-bone insertion in anterior cruciate ligament reconstruction model of rabbit. Scientific Reports. 2017 Jan 10;7(1):40369.
2) Amukarimi S, Mozafari M. Biodegradable magnesium-based biomaterials: an overview of challenges and opportunities. MedComm. 2021 Jun;2(2):123-44.
3) Ramesh S, Hubschman S, Goldberg R. Resorbable implants for orbital fractures: a systematic review. Annals of Plastic Surgery. 2018 Sep 1;81(3):372-9.
4) Plaass C, von Falck C, Ettinger S, Sonnow L, Calderone F, Weizbauer A, Reifenrath J, Claassen L, Waizy H, Daniilidis K, Stukenborg-Colsman C. Bioabsorbable magnesium versus standard titanium compression screws for fixation of distal metatarsal osteotomies–3 year results of a randomized clinical trial. Journal of Orthopaedic Science. 2018 Mar 1;23(2):321-7.
5) May H, Alper Kati Y, Gumussuyu G, Yunus Emre T, Unal M, Kose O. Bioabsorbable magnesium screw versus conventional titanium screw fixation for medial malleolar fractures. J Orthop Traumatol. 2020 May 25;21(1):9.
6) Kose O, Turan A, Unal M, Acar B, Guler F. Fixation of medial malleolar fractures with magnesium bioabsorbable headless compression screws: short-term clinical and radiological outcomes in eleven patients. Arch Orthop Trauma Surg. 2018;138(8):1069-1075.
7) Kirtis T, Egerci OF, Sonnow L, Dogruoz F, Kose O. Medial malleolar fixation with bioabsorbable magnesium screws; a retrospective study with a mean follow-up of 5 years. Fuß & Sprunggelenk. 2023 Dec 1;21(4):359-70.
8) Acar B, Kose O, Unal M, Turan A, Kati YA, Guler F. Comparison of magnesium versus titanium screw fixation for biplane chevron medial malleolar osteotomy in the treatment of osteochondral lesions of the talus. Eur J Orthop Surg Traumatol. 2020;30(1):163-173.
9) Labmayr V, Suljevic O, Sommer NG, et al. Mg-Zn-Ca Alloy (ZX00) Screws Are Resorbed at a Mean of 2.5 Years After Medial Malleolar Fracture Fixation: Follow-up of a First-in-humans Application and Insights From a Sheep Model. Clin Orthop Relat Res. Published online August 21, 2023. doi:10.1097/CORR.0000000000002799
10) Acar B, Unal M, Turan A, Kose O. Isolated Lateral Malleolar Fracture Treated with a Bioabsorbable Magnesium Compression Screw. Cureus. 2018;10(4):e2539. Published 2018 Apr 26.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1053
Original Article

Publisher details:

SJC PUBLISHERS COMPANY LIMITED

Category: Non-Government & Non-profit Organisation
Contact: +256775434261(WhatsApp)
Email: admin@sjpublisher.org, info@sjpublisher.org or studentsjournal2020@gmail.com
Website: https://sjpublisher.org
Location: Wisdom Centre Annex, P.O. BOX. 113407 Wakiso, Uganda, East Africa.