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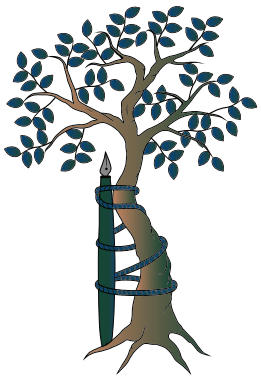

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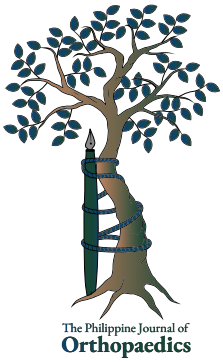
ORIGINAL ARTICLES

CASE REPORT / CASE SERIES



ABOUT THE LOGO: THE TREE OF ANDRY

Nicholas Andry coined the French term “orthopédie” which is derived from the Greek words “orthos” (correct or straight) and “paidion” (child). As implied in its etymology, “orthopédie” was first practiced treating childhood spinal and bone deformities.

The main elements of the logo are the tree of Andry; the Philippine Journal of Orthopaedics wordmark; and the fountain pen. The fountain pen, in replacement of the stake, represents how research has been the backbone of orthopaedic learning and practice.

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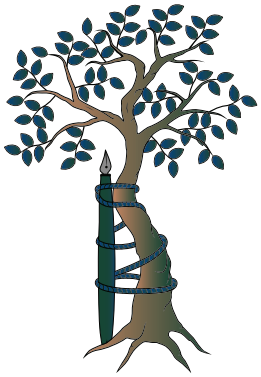

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The **Philippine Journal of Orthopaedics** shall advance the art and science of orthopaedics in the country by publishing high quality original clinical investigations, epidemiological studies, case reports, review articles, evaluations of diagnostic and surgical techniques, and the latest updates on management guidelines. The journal's target audience are local and international practitioners, clinicians, and other scientists, researchers. It shall accept manuscript submissions from consultants, fellows, residents, and other allied medical professions and specialties, not only from the Philippines but also from Asia and the rest of the world as long as these are within scope and relevant to the practice. Non-members of the Association may submit scientific manuscripts to the journal.

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Greetings!

I cannot overemphasize the importance of research in our work. Orthopaedic treatments continue to evolve thanks to technology and a better understanding of how things work and how the body responds. Research is critical in helping the orthopaedic community innovate, solve issues, and treat patients.

So, I congratulate the efforts of Dr Tammy dela Rosa and the Editorial Board of the Philippine Journal of Orthopaedics. This also serves as another venue for more orthopods to write, publish, and reach a greater audience. The Philippine Orthopaedic Association will continue supporting the Philippine Journal of Orthopaedics to uphold research in our field.

So again, congratulations to the Philippine Journal of Orthopaedics! To all our fellows and residents... keep on writing!

Mabuhay ang POA!

Melito Antonio P. Ramos, MD, FPOA
2024 President, Philippine Orthopaedic Association

The Philippine Journal of Orthopaedics

Advancing Orthopaedic Care Through Innovation and Trauma Management

The Philippine Journal of Orthopaedics remains a cornerstone in the academic and research landscape of Philippine orthopaedics. Orthopaedic surgery is continually evolving, driven by improvements in musculoskeletal and trauma care outcomes. In this issue, we focus on trauma involving the pelvis, acetabulum, tibia, spine, and hand, as well as innovations that could shape the Philippine orthopaedic landscape.

Trauma management may differ from the ideal, yet outcomes can still be optimized. Delaying surgery for acetabular fractures by two weeks has been shown to yield similar outcomes to immediate treatment. Closed management of tibial fractures may also be a viable option for patients nearing skeletal maturity.

Understanding the epidemiology of spine disorders in our population is crucial. In a tertiary hospital setting, traumatic spine disorders were the most common causes of admission (66%), while among non-traumatic causes, tuberculous infection was the most common etiology (74.7%). Surgery for patients with intermediate SINS (Spinal Instability Neoplastic Score) was found to reduce both functional decline and the risk of revision surgery compared to medical management.

Percutaneous pinning of proximal phalanges and metacarpals under conventional radiographic guidance in the emergency room resulted in 47% of patients achieving good or excellent outcomes in terms of total active motion of the fingers on follow-up. A randomized controlled study on WALANT (Wide Awake Local Anesthesia No Tourniquet) for hand surgery concluded that lower concentrations of lidocaine may be sufficient for short procedures. Another study comparing the classic Atasoy flap to the Pentagonal flap for fingertip injuries found no significant differences in terms of technique, sensation, patient satisfaction, return to work, and complications. However, the Pentagonal flap was advantageous for larger defects where tension-free closure might be challenging.

Two papers reported innovative materials research. Digital finite element analysis was used to design and simulate biomechanical testing of materials for an external fixator clamp. The resulting 3D-printed plastic resin was then used to create iFix clamp prototypes, which displayed comparable deformation under axial loading when compared with conventional Roger-Anderson clamps. Titanium nail-spanning systems have also been designed and manufactured locally for limb salvage surgery (primary knee resection-arthrodesis) in tumors around the knee, and they have proven useful when a prosthesis is not available.

I would like to congratulate the authors for their steadfast commitment to advancing Philippine orthopaedic research. As the field continues to evolve, the PJO will remain at the forefront of driving positive change, improving patient outcomes, and shaping the future of orthopaedic practice in the Philippines and beyond. As we enter our third year of publication, I wish everyone a Blessed Christmas and a Prosperous New Year on behalf of our Editor-in-Chief, Associate Editors, and dedicated editorial staff.

Mabuhay!

Emmanuel P. Estrella, MD, MSc, PhD
Associate Editor

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Sydney Declaration on Predatory or Pseudo Journals and Publishers

We, the participants in the Joint Meeting of the Asia Pacific Association of Medical Journal Editors (APAME), the Western Pacific Region Index Medicus (WPRIM), and Index Medicus of the South-East Asia Region (IMSEAR), held in Newcastle, New South Wales, Australia from August 28 to 30, 2024:

CONSIDERING

That predatory (or pseudo) journals and publishers offer open access publication in exchange for fees without robust editorial or publishing services; these include "fake" or "scam" journals or publishers who send phishing emails which promise quick review;

That the articles collected by predatory (or pseudo) journals or publishers may never be published, or often are published with poor quality or accessibility, irrespective of any attempts by authors to withdraw them, resulting in such research effectively being lost;

CONFIRM

Our commitment to uphold the quality and integrity of our individual journals and their respective submission, editing and review processes, in opposition to predatory (or pseudo) journal practices;

Our commitment to exercise vigilance and safeguard the quality and integrity of our respective publishers against predatory (or pseudo) publication processes;

Our commitment to ensure that member journals of the Asia Pacific Association of Medical Journal Editors (including those indexed in the Western Pacific Region Index Medicus and Index Medicus of the South-East Asia Region) and their publishers do not engage in predatory (or pseudo) journal or publication practices;

CALL ON

Member States of and governments in the World Health Organization (WHO) Western Pacific and South-East Asia Regions, in collaboration with stakeholders from the nongovernmental and private sectors, to formulate and implement procedures and processes for identifying and dealing with predatory (and pseudo) Sydney Declaration on Predatory or Pseudo Journals and Publishers journals and publishers, and for guiding new and existing journals away from engaging in predatory (and pseudo) journal and publisher practices;

Stakeholders from the public and private sectors, national and international organizations, universities and academic societies to support WPRIM, IMSEAR, the Global Index Medicus of WHO, in ensuring the availability of high quality health information for all that is not marred by predatory (and pseudo) journal and publication practices;

COMMIT

Ourselves and our journals not to engage in predatory (or pseudo) journal practices, by learning about and implementing best journal practices, in accordance with the recommendations and guidelines issued by such bodies as the International Committee of Medical Journal Editors (ICMJE), the Committee on Publication Ethics (COPE), and the World Association of Medical Editors (WAME);

Our organization, APAME, to building collaborative networks, convening meaningful conferences, and organising participative events to educate and empower editors, peer reviewers, authors, librarians, and publishers to recognise and avoid engaging in predatory (or pseudo) journal and publisher practices.

30 August 2024, Newcastle, NSW, Australia

This declaration was launched at the 2024 Convention of the Asia Pacific Association of Medical Journal Editors (APAME) held in New South Wales, Australia from 28 to 30 August 2024. It is concurrently published in Journals linked to APAME and listed in the Index Medicus of the South-East Asia Region (IMSEAR) and the Western Pacific Region (WPRIM).

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The Philippine Journal of Orthopaedics

ORIGINAL ARTICLE

Biomechanical Evaluation of a Locally Manufactured Modular External Fixator for Tibial Shaft Fractures*

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ABSTRACT

Background. Modular external fixations used in the Philippines are manufactured abroad, leading to high costs and limited availability, making them unaffordable for most Filipino patients. The reliability of some external fixators is limited because not all have undergone biomechanical testing.

Objective. This study aimed to determine the biomechanical stability of locally manufactured modular external fixator clamps (iFIX) versus commercially available fixators (Roger-Anderson) for tibial shaft fractures.

Methodology. The biomechanical stability (stiffness, yield, ultimate strength) under loading of the local prototypes was compared with the commercially available fixators.

Result. No slippage was observed in all rods, pins, and clamps in all groups. No bending occurred in any rods or pins in all groups. There was also no apparent deformation of the internal threading of the pins within the tibial analogs. The commercial fixator group's ultimate load to failure up was double (110.57% difference) that of the local prototype.

Conclusion. The differences in the biomechanical performance between the iFIX and Roger-Anderson clamps may be attributed to variations in clamp material composition. The iFIX fixator exhibited lower stiffness but did not display deformation under axial loading, component displaced slippage, or thread loosening, making it comparable to the commercial fixator.

Keywords. external fixator, tibia, biomechanics

INTRODUCTION

Theoretical background

Tibia fractures are the most common long bone fractures, with an incidence of 17 in 100,000 person-years. Fractures most often occur in the diaphysis and are more likely to be open fractures due to the tibia's subcutaneous location, correlating with more complications and worse outcomes.[1] In a study conducted at the Philippine General Hospital from 1999 to 2002, which included 70 patients with open tibial fractures, the infection rates were as follows: 7% for type I, 23% for type II, 33% for type IIIa, 50% for type IIIb, and 100% for type IIIc. Moreover, infection was associated with a higher incidence of non-union or delayed union.[2] Temporary stabilization with external fixators followed by conversion to definitive internal treatment is recommended for Type IIIb, IIIc, and some IIIa fractures.[1]

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**Oral presentation at the 31st Philippine Orthopaedic Association Midyear Convention. 19–21 April 2023.*

External fixation is used to stabilize fractures after trauma temporarily. It is generally favored because it does not need direct access to the fracture site, avoids infected regions, allows direct wound surveillance, minimizes further soft tissue injury, gives more freedom in wire and pin placement, and sometimes enables early mobilization.[3] External fixation allows compression, neutralization, and distraction of fracture fragments. It is also used for infected and non-infected non-unions.[4]

External fixation must adhere to several principles of frame stability. Frame stiffness is increased by using bicortical pin fixation, increasing the number of pins, increasing pin separation, increasing the distance of the most distant pins from the fracture, increasing the pin diameter (not exceeding 30% of the diaphysis), using a double stacked bar, decreasing the distance of the bar from the bone, and using a triangular or delta configuration.[1,4]

Ease of application and biomechanical properties are two important factors when choosing an external fixator. The pin-bar system is more commonly used in acute trauma cases due to its relatively simpler application. Moreover, external fixators may be applied in one, two, three, or more planes. Versatility is key in managing fractures that cannot be fixed with unilateral constructs. Most current monolateral systems can be applied in one or more planes using large multipin clamps, separate monolateral bars, Schanz pins, and other modular components.[1] These are known as modular external fixators, enabling fracture reduction and fixation primarily through highly adaptable multipin clamps. Despite its clamp complexity, the construct is relatively simple to apply and has exceptional rigidity. One example is the Hoffmann II Stryker system; both the uniplanar and biplanar structures were found to have similar application time and ease. However, the biplanar system demonstrated slightly higher biomechanical stability in torsion and bending.[5]

Burden of illness

At present, all modular external fixation systems being used in the Philippines are manufactured in other countries, most commonly in China. Because of this, they are not always readily available locally and tend to be more expensive. Most lack diversity in their designs and the construct sizes and directions for application are limited. Furthermore, not all have undergone testing for biomechanical stability. These factors have a great impact on the healthcare of our fellow Filipinos. Patients might not afford these fixators, and even when they can, may receive subpar products, causing greater morbidity.

Significance of the study

Given this background, we found that there is a role for locally manufactured external fixators. The goal is to open an avenue for self-sustaining design, biomechanical and clinical testing, production, and provision of affordable yet rigid and safe external fixators for Filipino patients.

Review of related literature

External fixation system

External fixation was first described by Hippocrates 2400 years ago, where it was characterized as a "shackle" external device for a tibial fracture, consisting of leather wraps, thick coats, and four European dogwood rods. Over the years, external fixation has evolved significantly, resulting in increasingly diverse designs and application techniques.[1]

Monolateral external fixation

Monolateral external fixators fall under two categories. The "mono-tube" type's large-diameter monotube connecting body, which is three to four times the size of monolateral bars, confers significant stability, but limits the options for pin placement, angle, and bone-bar distance, limiting its use. The "simple monolateral" system, on the other hand, is composed of individual pins placed at angles while connected to a bar. Various modifications include the double stacked bar in an anterior 4-pin frame, increasing bending and torsional stiffness,[3] and the "delta" plane, effectively allowing multiplanar constructs.[1,3,6]

Modular external fixation

The modular frame is highly versatile, making it useful for injuries that cannot be reduced and stabilized optimally with uniplanar systems. Modular systems boast improved stability,[7] speed and ease of application similar to uniplanar designs, and higher torsion and bending stiffness.[5] They allow straightforward reduction of complex fractures and possess superior biomechanical rigidity.

Role of fabrication and evaluation

In 1997, Goh et al. recognized the importance of designing a cheaper but biomechanically effective external fixator to provide medical devices for poorer countries.[8] They developed and tested the Alinoor-Goh (AG) fixator against a commercially available external fixator and found no significant difference in stiffness. Besides cutting costs, new materials and innovations must also be developed and tested.[6]

Currently, there is no available literature on the fabrication and testing of locally manufactured external fixator components (iFIX). This study aims to address this gap by describing the investigation, design, manufacture, and biomechanical testing of a locally manufactured modular external fixator.

OBJECTIVES

General objective

To describe the design, production, and biomechanical stability of a locally manufactured modular external fixator clamp (iFIX) prototype versus commercially available modular external fixators for tibial shaft fractures.

Specific objectives

1. To survey available biocompatible materials used for external fixator clamps in the market
2. To determine the most appropriate materials for manufacturing the modular external fixator clamp
3. To fabricate a modular external fixator clamp prototype
4. To establish the biomechanical properties and determine if there is a difference among the modular external fixators across different designs in terms of axial loading

METHODOLOGY

Study design

Experimental

Study venue and duration

Evaluations were conducted at the UP Diliman Mechanical Engineering Department and Philippine General Hospital. Fabrication of materials was done in cooperation with the Department of Mining, Metallurgical, and Materials Engineering and with the Advanced Manufacturing Center of the Department of Science and Technology – Philippine Council for Health Research and Development.

Patient selection

No human or animal subjects were used for this study. As such, no inclusion and exclusion criteria were stated.

Data collection procedures

Analysis and parametric study of external fixator parts and dimensions

An external fixator model was digitally designed based on previous research.[9] We applied the properties of Markforged Onyx™ to the clamps, while the remaining parts were assigned properties of 316L stainless steel. Markforged Onyx™ was chosen due to its availability, reasonable mechanical properties, and low cost. The Young's moduli and Poisson ratios of the materials were incorporated as well. Finite element analysis was then done to analyze the maximum deformation in the external fixator assembly.[10]

A parametric assessment was done to identify the most ideal parameters to increase the stiffness and stability of the design. A compressive axial stress amounting to 350 N load was applied to the proximal end of the tibia, which is 50% of the mass of a 70 kg person during the stance phase of walking.[11] Maximum stiffness was achieved in the finite element analysis when the rod-to-bone distance was decreased, the pin-to-pin distance was increased, and the pin-to-fracture gap was decreased. A modified external fixator model was then designed incorporating these parameters to achieve 51.76% of the original maximum deformation from the base design.[10]

Survey of commercially available external fixator materials and properties

Candidate materials were selected from studies focusing on inert and biocompatible materials with medical applications. Currently used external fixator materials across different suppliers and/or manufacturers in the Philippine market were documented. The simplicity of manufacturing the materials was also taken into consideration.

Material simulation testing and selection

Materials were selected using multi-criteria decision-making methods (Fuzzy Analytic Hierarchy Process (F-AHP) and Fuzzy Technique for Order Preference by Similarity to an Ideal Solution (TOPSIS).[12] The Fuzzy Analytic Hierarchy Process (F-AHP) involves breaking, grouping, and ordering solution problems into a categorized list. The method pairs criteria with a measurement scale and incorporates insights from experts. It also combines the logic of "degrees of truth" rather than "true or false" in the hierarchy.[13] Using F-AHP, weights were given to each criterion for the material needed for the external fixator parts.

Fuzzy Technique for Order Preference by Similarity to an Ideal Solution (TOPSIS), on the other hand, assesses several alternatives against chosen criteria. The alternative that is closest to the Fuzzy Positive Ideal Solution and farthest from the Fuzzy Negative Ideal Solution is chosen as the best option.[14] Fuzzy TOPSIS was used to generate a list ranking the most suitable materials for the parts. Materials were also considered for their ease of 3D printing, accessibility, and lightweight properties. The ideal materials were determined to be carbon fiber and stainless steel 304 for the rod, stainless steel for the nuts and bolts, and stereolithography-printed resin for the clamps.

Review and analysis of common clamp designs and design changes

The clamp components of several modular external fixator systems were sent to partner engineers for evaluation. Clamps from modular systems in catalogs and online sources were analyzed as well. A single-rod modular external fixator was computer-generated. The clamp was developed to have 360 degrees of movement in two planes.

Fabrication of prototype modular external fixator clamp

The finalized design was then used to initiate fabrication locally under the project "iFIX: Design and Fabrication of External Fixator," as shown in Figure 1. Like previous studies, the prototype was reverse-engineered from existing commercial external fixators and computerized models.[9] A stereolithography (SLA) 3D printer was used to fabricate the external fixator (iFIX clamp).

Figure 1. Single-rod modular external fixator prototype 3D render design.

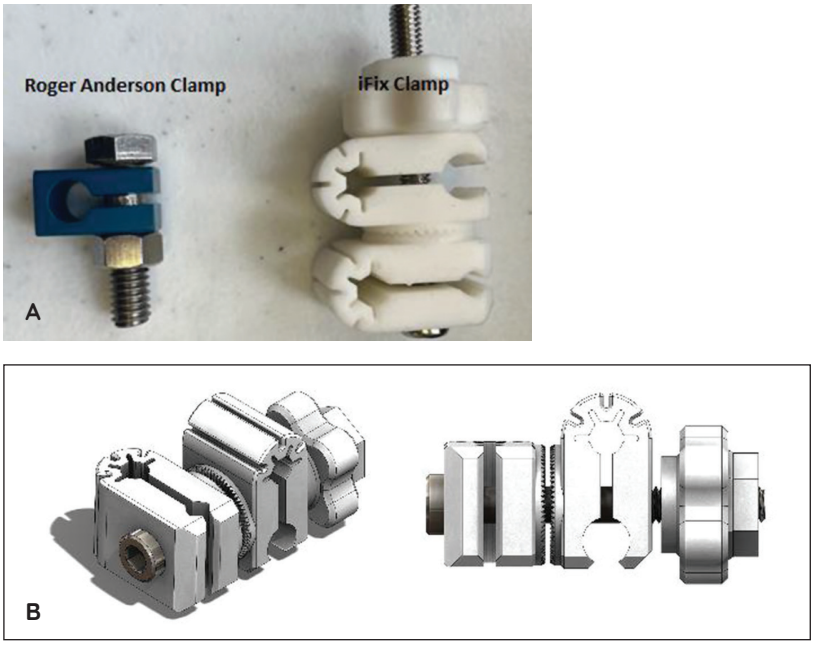

Figure 2. Standard Roger Anderson Clamp and iFIX Clamp **(A)**. Oblique and lateral 3D render views of iFIX Clamp **(B)**.

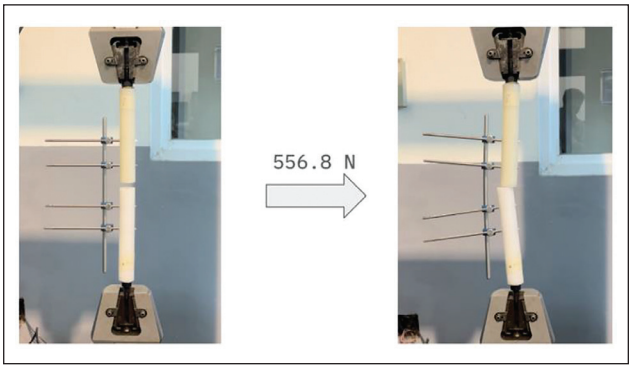

Figure 3. Roger-Anderson fixator-tibia analog setup upon failure.

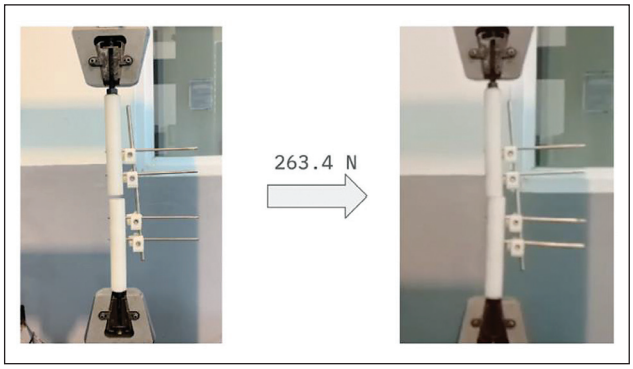

Figure 4. iFIX fixator-tibia analog setup upon failure.

Outcome assessment

The fabricated external fixator prototype was subjected to biomechanical testing following the standards set by the ASTM F1541-17 (Standard Specification and Test Methods for External Skeletal Fixation Devices). Ultra-High Molecular Weight Polyethylene (UHMWPE) cylinders (30 mm in diameter and 180 mm in length) were prepared as representatives for the tibia due to their comparable Young's modulus (YM_{UHMWPE} = 33.2 GPa) with the tibia (YM_{tibia} = 34.11 GPa). The tibial fracture was simulated by two of these cylinders with a gap in between. Each cylinder was drilled two holes transversely for 4.5 mm diameter pins 44 mm apart. At the end of one cylinder, an 11.5 mm hole was bored by 10 mm to mount the threaded rod fixture.

The Roger-Anderson external fixator (with Aluminum 6061-T4 clamps, Figure 2A) and iFIX external fixator (with stereolithography-printed resin clamps, Figure 2A, 2B) were then assembled onto the bone models. The same commercially available stainless steel pins and rods were used for both groups (Figure 3).

The bone analog and external fixator setups were independently subjected to axial compression using a Universal Testing Machine (UTM).[8,15,16]

Methods for quality control

Testing followed standards set by the ASTM F1541 (Standard Specification and Test Methods for External Fixation Devices) and ISO 10993 (Biological Evaluation of Medical Devices).

Statistical considerations

Sample size calculation

Two samples each of Roger-Anderson and iFIX external fixator were subjected to biomechanical testing.

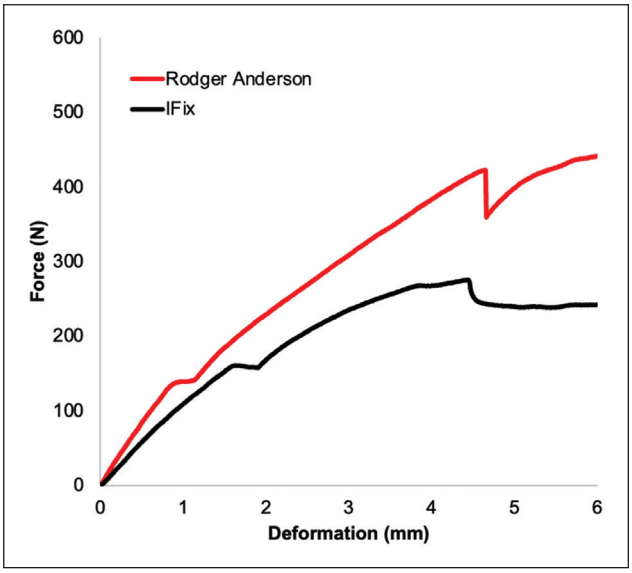

Figure 5. Force-Deformation curves of the Roger-Anderson fixator and iFIX fixator (n = 2).

Table 1. Comparison of mean axial stiffness, yield, and ultimate load to failure between commercial Roger-Anderson external fixator and locally fabricated external fixator

	Roger-Anderson (n = 2)	iFix (n = 2)	% Difference
Stiffness (N/m)	163.64	105.75	42.97%
Yield (N)	139.37	160.38	14.02%
Ultimate (N)	556.77	263.41	110.57%

Statistical methods

The stiffness coefficient for axial loading was calculated. Stiffness (k) was computed by dividing the axial load applied by the displacement of the bone model.[8,15] The Yield and Ultimate load to failure were also computed. The average values for each group are presented in Table 1. The average force deformation curves of both fixators were also plotted.

RESULTS

In both biomechanical testing setups, there was no slippage of rods, pins, and clamps. On increasing the axial load, failure eventually occurred (indicated by the closing of the gap between the two tibial fracture fragment analogs) (Figures 3 and 4). No bending occurred for all rods and pins. There was also no apparent deformation of the internal threading of the pins within the tibial analogs. The derived Force-Deformation curves from the UTM are plotted in Figure 5. Based on the curves, stiffness was then calculated (Table 1). The ultimate load to failure of the tibia-external fixator set-up was double (110.57% difference) for the control Roger-Anderson fixator as compared to the iFIX fixator.

DISCUSSION

Biomechanical properties differed between the two fixators likely due to their material composition; metals, particularly stainless steels, are generally stiffer than polymers. The effect of the material on the holding capacity of the clamps onto rods and pins could also influence stability.

Failure was defined in this research as clamp slippage. The breaking point of the external fixator was not tested. The iFIX external fixator, despite possessing lower stiffness, exhibited properties important to an external fixator. It did not display deformation under axial loading and none of the components of the fixator displaced slippage of loosening of threads onto the bone models.

This study cannot be compared to existing literature due to differences in the definition of load to failure. Landaeta et al. allowed no mode of failure, and determined only the behavior of the fixator under loading. The stiffness of their fabricated construct was 246.12 N/mm.[9] Goh et al. defined failure as touching of the bone surfaces; their fabricated fixator had a stiffness of 55.7 N/mm.[8]

CONCLUSION

The iFIX stereolithography-printed resin clamp showed potential in an external fixator construct. Its biomechanical testing showed no slippage between rods, pins, and clamps, similar to the Roger-Anderson commercial external fixator, but with a lower ultimate load to failure. Despite lower stiffness, the iFIX model exhibited relevant properties of an external fixator, being capable of resisting deformation and preventing slippage. These findings contribute to advancing the local fabrication of external fixators, potentially enhancing orthopedic care.

The AO/Synthes external fixator clamp would have been a good comparator. However, the purpose of this research is to establish a baseline comparison of the fabricated external fixator with the simplest, cheapest, and most available design in the Philippine market. In the future, we plan to compare our model with the AO/Synthes modular external fixator and test its modularity. Current testing was limited to comparison with the Roger-Anderson external fixator in one plane to be consistent with the ASTM testing standards.

The design process follows a sequence of Finite Element Analysis (FEA), biomechanical testing, design changes, the next round of FEA, the next round of biomechanical testing, and so forth. Given this sequence, axial loading was tested in this study, but additional biomechanical testing such as load to failure, bending stiffness, and cyclic loading will be facilitated once the design has matured. Further research is also recommended to explore more samples for material fretting/brittleness, corrosion analyses, and cadaveric applicability. Comparative testing and cost analysis can be done for different materials.

The main strength of this study is that it is one of the first documented studies on a fabricated modular external fixator that underwent the stages of the US Food and Drugs

Administration (FDA) design control process. This research also presents the early-stage results of an iterative design process that is guided by simulation. This early stage also presents a weakness. More design developments, comparisons, and biomechanical tests are needed before cadaveric and clinical testing can be done. The fabrication process will be optimized once the final design undergoes the full set of examinations.

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STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

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ORIGINAL ARTICLE

Functional Outcome Measures after Operative Management of Acetabular Fractures*

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ABSTRACT

Objectives. This study evaluated the functional outcome of patients with acetabular injuries using the Majeed pelvic score. The specific objectives were to assess any differences in functional outcomes among patients treated with early versus delayed surgery and those with or without concomitant injuries.

Methodology. Patients from our institution, Baguio General Hospital and Medical Center, with acetabular injuries from January 2019 to December 2022, were included. Patients with acetabular fractures with or without other injuries were included. All available data sources were reviewed, such as charts from hospital records, patient census, and electronic medical records. Patients underwent physical therapy before discharge and were followed up. The patients' outcomes after surgical intervention were assessed using Majeed's pelvic score.

Results. Thirteen patients were included in the study with follow-ups ranging from one to three years. A functional assessment using Majeed's pelvic score with a mean of 83 points (range 72–100). The majority had good functional outcomes.

Conclusions. Early surgical intervention may have no advantage over delayed surgeries regarding functional outcomes. However, concomitant injuries and complications may contribute to a poor to fair functional outcome.

Keywords. acetabular, Majeed, functional outcome, operative, multiply injured

INTRODUCTION

Acetabular fractures are rare injuries with a bimodal distribution wherein young patients sustain high-velocity trauma while elderly patients sustain low-energy fragility fractures.[1] They are potentially life-threatening and are challenging since they require unique expertise to treat.[2] Morbidity and mortality are associated with high energy transfer to soft tissue, joint, and neurovascular structures.[3] In a retrospective study conducted by Matta involving 259 patients with acetabular fractures, 50% of patients had associated injuries: 35% involving extremities, 19% involving the head, 18% involving the chest, 13% having a nerve palsy, 8% with an abdominal injury, 6% with genitourinary injury, and 4% involving the spine.[4] Hence, a multidisciplinary approach is crucial for resuscitating and managing bone injuries. The management focuses on identifying the severity of injury and other concomitant injuries, early hemodynamic stabilization, and restoration of acetabular structures with reliable and stable rigid fixation.[4,5] Recovery is sometimes slow and incomplete, resulting in long-term consequences. Therefore, functional and quality-of-life-related outcomes should also be considered.[6] There are other functional scoring systems, such as the Short Form (SF-36) survey, short musculoskeletal function assessment

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(SMFA), Iowa pelvic score (IPS), and Orlando pelvic outcome score (OPS). The SF-36 is a validated, reliable, functional questionnaire summarized into a mental component score and a physical component score. Each domain is scored up to 100 and is comparable to a standardized value for the general population. A higher score implies a high functional outcome. The SMFA is also a validated, two-part 46-item questionnaire specifically for patients with musculoskeletal injuries. It is divided into a dysfunction index and a bother index. A lower score implies a higher function.[7] The Iowa pelvic score is a pelvic-specific functional assessment tool focusing on the patient's conditions. It is divided into six items with a total score of 100. A higher score represents a decrease in disability.[8] The OPS is a pelvic-specific, 40-point tool based on clinical and radiographic findings.[9] The standards for reporting functional outcomes in patients with pelvic and acetabular fractures are still developing. The SF-36 and SMFA scores have been used, but neither has received adequate responsiveness testing.[7] For this study, we used the Majeed pelvic score (MPS), a pelvic injury-specific functional assessment divided into the following seven items: pain, work, sitting, sexual intercourse, standing, unaided gait, and walking distance.[8]

METHODOLOGY

Study design

This case series was conducted at our institution, Baguio General Hospital and Medical Center, on patients with acetabular fractures treated with open reduction and internal fixation from 2019 to 2022. All patients with acetabular fractures, with or without other injuries, were included. All available data sources were reviewed, such as charts from hospital records, patient census, and electronic medical records. The data collected were age, gender, other associated injuries, time of surgery, and intervention.

Fixation and timing of surgery

All participants underwent surgical intervention with either definitive internal fixation, definitive external fixation, or temporary external followed by definitive internal fixation. Based on the available radiographs and CT scan images, indications were limited to displaced acetabular fractures, with or without associated injuries. The majority of the procedures were performed or assisted by a trauma specialist consultant. The timing of the surgical intervention was classified as follows: immediately upon admission (i.e., external fixation application if with pelvic injury), less than a week, within two weeks, or more than two weeks. All the patients underwent rehabilitation until discharge. Rehabilitation began one to two days after surgery, starting with general body conditioning and continuing until the patient could ambulate with assistance before discharge.

Ethical approval

This was a retrospective study. The imaging and other data used in this study were approved by the Ethics Committee of our institution, Baguio General Hospital and Medical Center, per the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Data collection and functional assessment

The following parameters were collected: age, gender, other associated injuries, time of surgery, and intervention. Functional outcome using Majeed's pelvic score was measured at follow-up. They were assessed and scored for the following: pain (0–30 points), return to work (0–20 points), gait (0–12 points), use of walking aid (0–12 points), sitting tolerance (10 points), sexual intercourse (0–4 points), and performance at work (0–20 points). According to the total Majeed score, outcomes were graded as excellent (≥85), good (84 to 70), fair (69 to 55), and poor (<55). A score of 100 points was defined as the best result. Categorical data were expressed in frequency and percentage.[10]

RESULTS

A total of thirteen patients were included in the study. Patients were predominantly male (n = 11, 85%). The majority were aged 20–39 (n = 6, 46%). The average age of the patients was 38 years, with a follow-up range of one to three years (Table 1).

Most patients had a posterior wall acetabular fracture (54%) based on the Judet-Letournel classification, and two patients had a combination of pelvic and acetabular injuries (15%). More than half of the patients had other injuries (n = 8, 62%). Among these injuries, the most common was hip dislocation (n = 5, 38%), whereas sciatic nerve palsy, sacral fracture, calcaneal fracture, and clavicular fracture contributed similar percentages (n = 1, 8%). Based on the severity of fracture patterns and other associated injuries involved, surgical intervention was warranted. All acetabular fractures underwent internal fixation(n = 11, 85%). Half of those with combined pelvic and acetabular fractures were treated with external fixation alone (n = 1, 8%), while the remaining half received combined treatment (n = 1, 8%). Most participants underwent surgical intervention within one to two weeks. Using Majeed's pelvic score, we compared the functional outcome of patients with acetabular fractures associated with other injuries versus those without. Isolated acetabular injuries (83 points, range 72–100) had higher functional outcomes than those with other related injuries. Eighty percent had a good functional outcome (n = 4), and 20% showed an excellent functional outcome (n = 1). Heterotopic ossification and avascular necrosis were seen in patients with poor functional outcomes.

Four of the five patients with a two-week delay in surgery still achieved good or excellent functional outcomes. Poor functional outcomes were seen in patients with concomitant injuries and complications.

Table 1. Summary of Patient Demographics (n = 13)

Case	Age/ Sex	Fracture Classification	Associated injuries	Treatment	Timing of Surgery	Rehab*	Functional Score (Majeed's Scoring)	Follow-up (year)	Complication
1	36/M	Posterior wall	Posterior Hip dislocation	ORIF	Within 2 weeks	(+)	Excellent (100)	1	None
2	35/M	Anterior column with posterior wall	Posterior hip dislocation Sciatic nerve palsy	ORIF	Within 2 weeks	(+)	Poor (23)	1	Delayed osteosynthesis-associated infection
3	50/M	Posterior wall	(-)	ORIF	Within 2 weeks	(+)	Good (82)	1	None
4	35/M	Posterior wall	Posterior hip dislocation	ORIF	<7 days	(+)	Poor (40)	1	Heterotopic ossification, AVN
5	36/M	Posterior column with posterior wall	Distal radius fracture	ORIF	<7 days	(+)	Good (76)	1	None
6	77/F	Posterior wall	(-)	ORIF	>2 weeks	(+)	Good (81)	3	None
7	47/M	Posterior wall	Clavicular fracture	ORIF	Within 2 weeks	(+)	Good (81)	1	None
8	53/M	Both column	(-)	ORIF	<7 days	(+)	Good (80)	1	None
9	25/M	Posterior wall	Posterior hip dislocation	ORIF	<7 days	(+)	Good (76)	1	None
10	51/M	Posterior wall	Posterior hip dislocation	ORIF	Within 2 weeks	(+)	Excellent (86)	2	None
11	23/M	Both column	(-)	ORIF	<7 days	(+)	Excellent (100)	1	None
12	43/M	LC II Anterior column	Sacral fracture, Bilateral Calcaneal fracture	External Fixation	Immediate***	(-)	Poor (22)	1	Post-traumatic arthritis sec to bilateral calcaneal fractures Depression
13	62/F	LC III Posterior column with posterior wall	(-)	Combined**	Immediate***	(+)	Good (72)	3	None

* Rehabilitation initiated after surgery until discharge.
** Application of External Fixature then converted to ORIF.
*** Immediate: application of External fixature upon admission.

DISCUSSION

In our study, most patients were male patients of working age (20–39 years) who also presented with limb injuries such as hip dislocation (56%), distal radius fracture (22%), sacral, clavicular, and calcaneal fractures (11%). Singh et al. presented a similar incidence.[11] In displaced acetabular fractures, the treatment of choice is open reduction and internal fixation, as conservative management leads to a high frequency of secondary arthritis.[12,13] The anatomic restoration of the acetabulum will allow patients to achieve good functional outcomes and clinical results, enabling patients to return to work.[14] This study uses Majeed's score to assess the outcome of patients with acetabular injuries with or without other injuries. Our study demonstrated that isolated acetabular fractures may have a better clinical outcome, with a mean score of 83 points (range 72–100) versus the 63 points (range 22–100) of those with other injuries. Among the associated injuries were hip dislocation, distal radius fracture, sacral fracture, clavicular fracture, and sciatic nerve palsy.

Complications such as infection, nerve injury, heterotopic ossification, thromboembolic issues, nonunion, and malunion are common.[15] Some of our patients showed delayed osteosynthesis-related infection, heterotopic ossification, avascular necrosis, and post-traumatic arthritis.

Similarly, Borg stated that the patient's age, type of fractures, damage to the femoral head, associated injuries, quality of fracture reduction, and development of heterotopic ossifications are significant prognostic factors that correlate with poorer clinical outcomes,[16] lowering the quality of life both mentally and physically, even with good radiographic healing in two years post-surgical intervention.[17] Mbatha et al. also pointed out that chest injuries, traumatic brain injuries, and combined pelvic acetabular fractures are all linked to poor outcomes or complications.[18] Age has been correlated with an increased risk of developing complications, with patients in the fourth decade of life being more at risk. The incidence of an associated pelvic fracture ranges from 5–15%, which is similar to our incidence of 15%. These injuries have been associated with an increased mortality rate, hemodynamic instability, and a higher rate of blood transfusion.[18] The rate of heterotopic ossification was reported in up to 80% of cases treated with the posterior surgical approach.[19] A concomitant hip dislocation was present in 56% (n = 5) of our patients, which was higher as compared to the findings of Meena et al. (41%),[20] Briffa et al. (33%),[21] and Yeo et al. (20%).[22] The incidence of avascular necrosis (AVN) was 5.6%, and patients with a posterior dislocation had a higher incidence of AVN than those who did not.[15] Vasculature to the femoral head is compromised by hip dislocation, high-velocity injury, fracture comminution, articular impaction, and cartilage damage, ultimately resulting in AVN and poor outcomes.[4]

The timing of surgery may not have affected the functional outcome. Even when operated after two weeks, four of five participants still showed good and excellent scores. Historically, the timing of surgery has been referred to as either early or late. Some define "early" as the first eight or 24 hours, the first week, or even the first two to three post-injury, and the term "late" for periods two weeks to three months post-injury. Few studies compare the outcomes after early and late acetabular fixation. The operative treatment of acetabular fractures within 14 days of injury afforded good to excellent results in 80% of patients.[23] Multiple authors, like Plaisier et al., found that patients who underwent early acetabular ORIF (<24 hours) had significantly less organ dysfunction and improved functional outcomes.[24] Johnson et al. reported that delayed management of acetabular fractures (21–120 days with an average delay of 43 days) increases the difficulty of operative treatment and significantly reduces good to excellent outcomes. Furthermore, he also mentions that post-operative sciatic nerve palsy, avascular necrosis of the femoral head, and the long-term prevalence of osteoarthritis were found to be higher than for those who have earlier surgical treatments.[25] Oransky and Sanguinetti's study reported that displaced acetabular fractures operated at three weeks had a failure rate of 40% compared with 17% of fresh fractures.[26]

We treated a 43-year-old man with a combination of LC II and anterior column fractures associated with a sacral fracture (Denis Zone III) and bilateral calcaneal fractures (Sanders Type III and Type IV) (Figures 1-2). The patient was treated with external fixation and opted for conservative management for his bilateral calcaneal fractures, hence the application of bilateral short leg casts. At one year post-injury, the patient was wheelchair-ambulatory, with complaints of pain on both feet. Moreover, he was undergoing treatment for his depression. The patient presented with a Majeed score of 22, which correlates to a poor functional outcome.

Figure 1 demonstrates a 35-year-old man who sustained a posterior wall acetabular fracture with associated posterior hip dislocation from a vehicular crash. The patient underwent open reduction and internal fixation in less than a week (Figure 2). At one month postoperatively, heterotopic ossifications were visible (Figure 3). At six months postoperatively, the patient demonstrated pain and difficulty of ambulation on the operative site accompanied by limitation of movement (0–60 deg hip flexion and hip abduction could not be assessed due to pain). Avascular necrosis was more evident on radiographs at six months post-surgery (Figure 4). At one year, Majeed's pelvic score revealed a poor functional outcome score of 40. At eighteen months post ORIF, the patient underwent THA without noted complications (Figure 5).

Figure 6 represents a 50-year-old man who sustained a posterior wall acetabular fracture from a vehicular crash with no associated injuries. The patient underwent open reduction and internal fixation within two weeks (Figure 7). At one month postoperatively, the patient complained of no pain on the operative site and could ambulate toe-touch

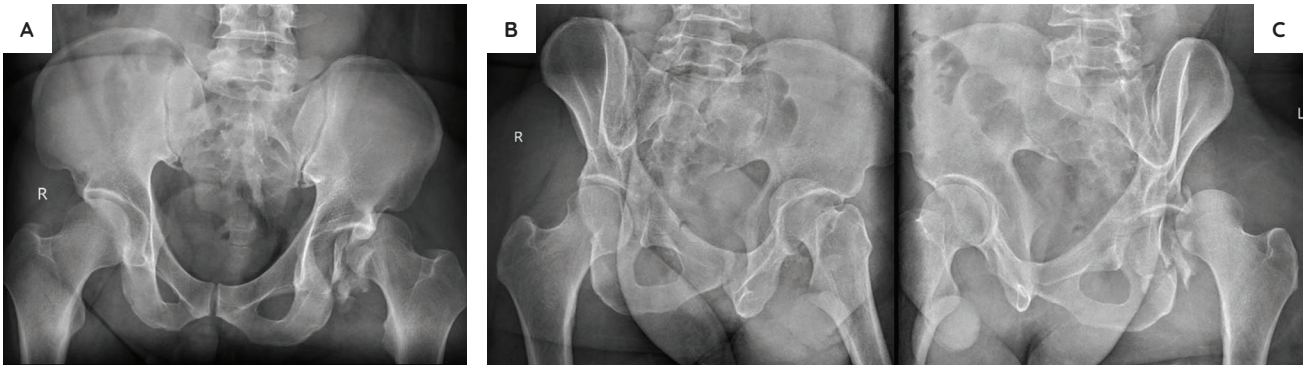

Figure 1. Injury film of 35/M, vehicular crash: posterior wall acetabulum fracture with posterior hip dislocation, left in anteroposterior (AP) **(A)** and Judet views (Internal obturator and External Iliac oblique) **(B and C)**.

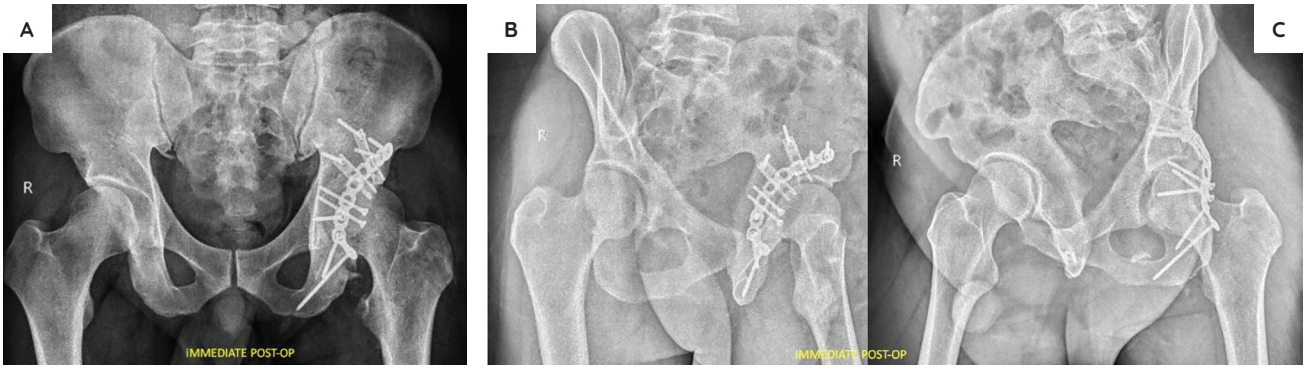

Figure 2. Immediate post-op x-ray after ORIF in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

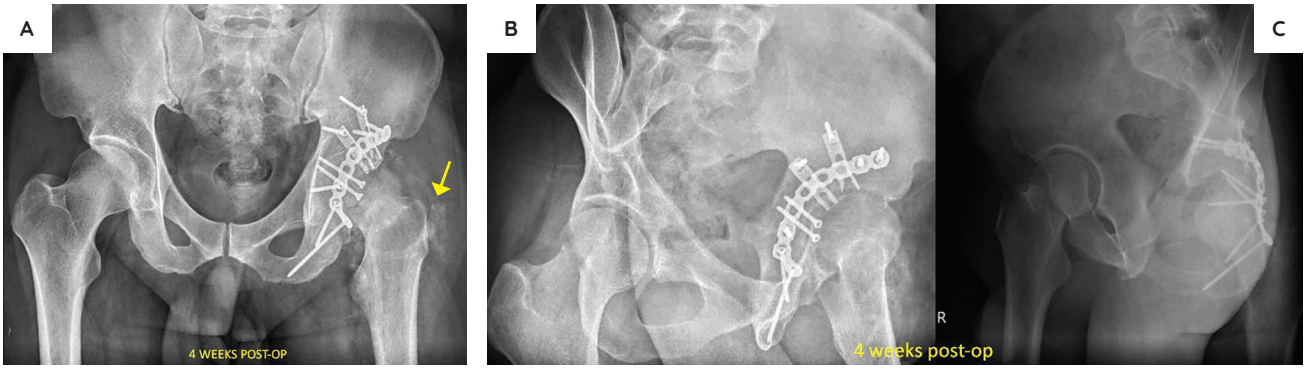

Figure 3. One month post-ORIF with visible heterotopic ossification *(arrow)* in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

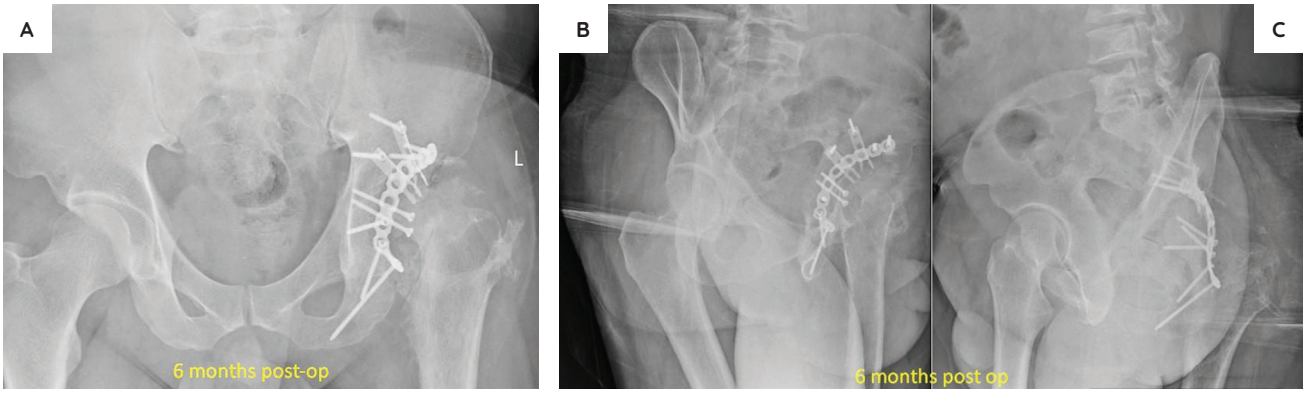

Figure 4. Six months post-op with subsequent AVN in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

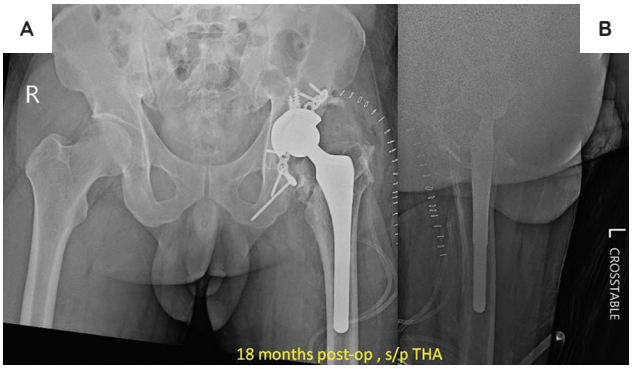

Figure 5. Eighteen months post-ORIF [hips in AP bilateral view **(A)** and crosstable left lateral view **(B)**]. The patient underwent THA.

with crutches. Fracture union was noted on radiographs at six and ten months postoperatively (Figures 8-10). He had a good functional outcome with a score of 82, was able to do full weight-bearing without assistive devices, and had a full range of motion.

The current study has limitations, such as using only one functional scoring specific for the pelvis, having a small sample size, and having no control population, making it challenging to assume that fixations may contribute to a better functional outcome. We recommend including other validated questionnaires and a larger sample size for future studies. We also recommend comparing patients treated conservatively versus surgically.

Figure 6. Injury film of a 50/M, vehicular crash. Isolated fracture of the posterior wall of the acetabulum in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

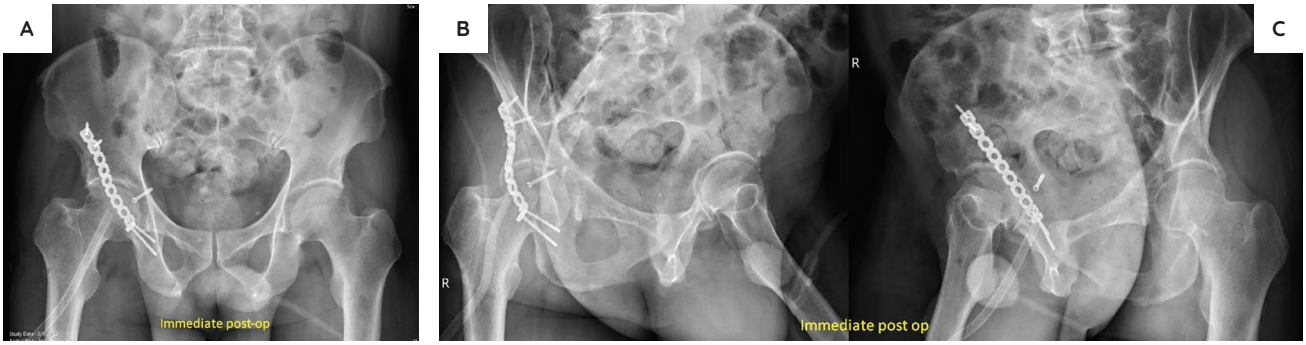

Figure 7. Immediate post-ORIF in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

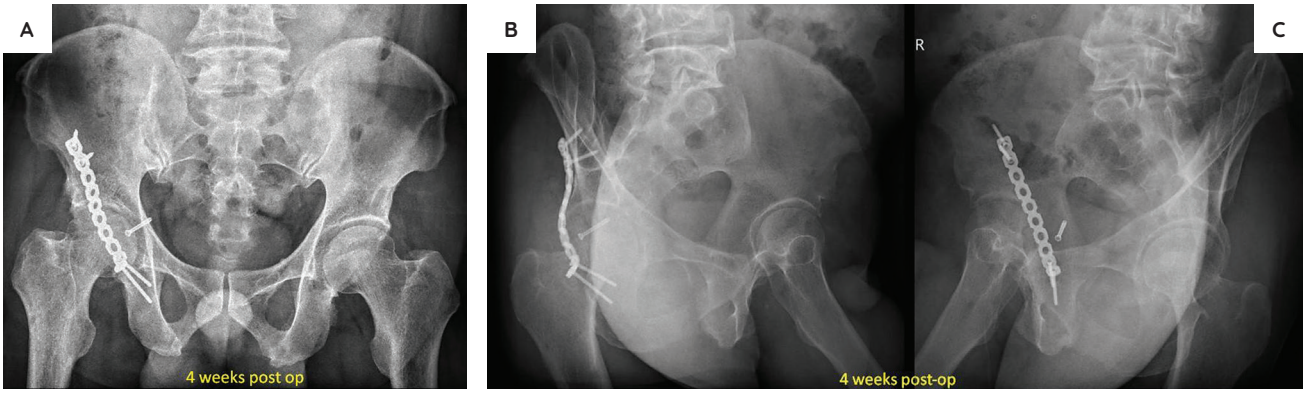

Figure 8. One month post-ORIF in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

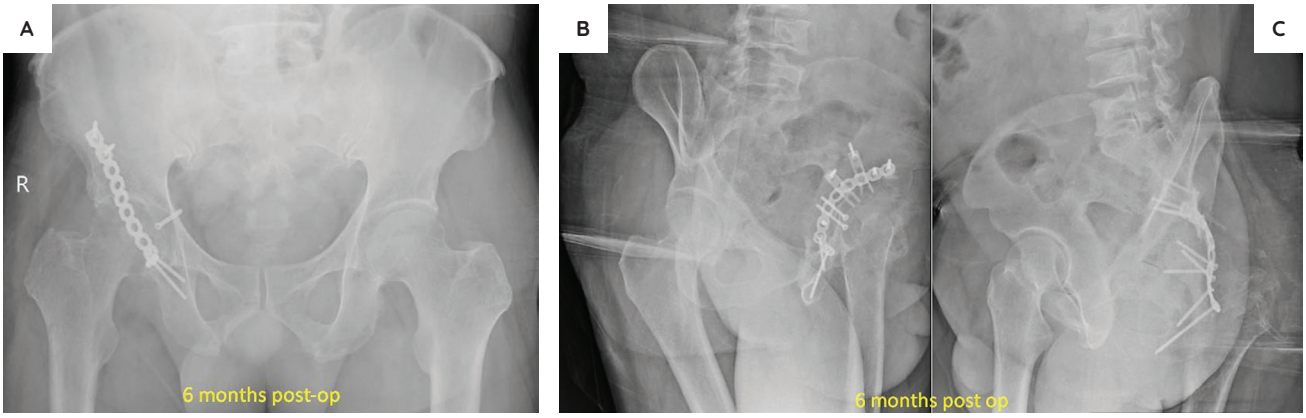

Figure 9. Six months post-ORIF in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

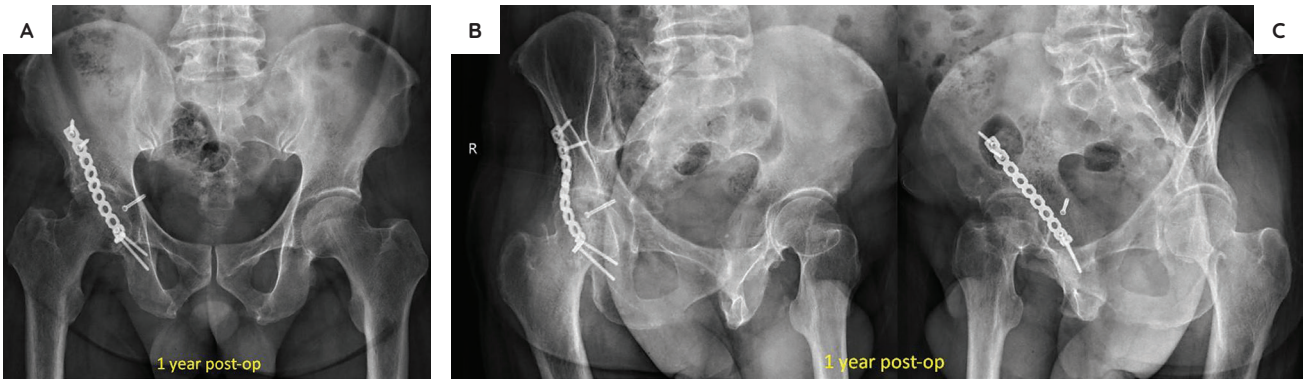

Figure 10. One year post-op in AP **(A)** and Judet views (internal obturator and external iliac oblique) **(B and C)**.

CONCLUSIONS

The findings may suggest that patients may have a good to excellent functional outcome regardless of the timing of surgery. However, concomitant injuries or complication sequelae may contribute to a poor to fair functional outcome.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

DATA AVAILABILITY STATEMENT

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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ORIGINAL ARTICLE

Residual Deformity and Outcome in Non-surgically Treated Tibial Shaft Fractures in Adolescents Nearing Skeletal Maturity: A Cross-sectional Study

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ABSTRACT

Background. Anatomic reduction is crucial to avoid malalignment in tibial shaft fractures in adolescents approaching physeal closure. While surgical treatment is becoming more common, casting and immobilization are still widely done for appropriately selected fractures. Local radiographic and clinical outcomes of non-surgical treatment need to be explored.

Objective. The primary objective of this study was to report residual lower limb deformity of tibial shaft fractures treated non-surgically in adolescents nearing skeletal maturity. The study also identified factors or fracture characteristics that may predict these deformities and reported the clinical outcomes using the Lower Extremity Functional Scale (LEFS).

Methodology. This was a cross-sectional study of 31 adolescents nearing skeletal maturity at the time of injury with acute closed tibial shaft fractures treated non-surgically at the Philippine Orthopedic Center from 2017 to 2020. Skeletal maturity and residual sagittal & coronal angulation were analyzed through radiographs. Rotational alignment and leg length discrepancies were evaluated clinically. Functional outcome was measured using the LEFS.

Results. Coronal plane angulation (r = -0.397; p = 0.05) and leg length discrepancy (r = -0.394; p = 0.05) were inversely correlated with LEFS scores. Coronal plane angulation was also correlated with ipsilateral fibular fractures (p = 0.007). LEFS scores were 79.39 on average (range 75 to 80).

Conclusion. Among adolescents nearing skeletal maturity with isolated acute tibial shaft fractures, closed reduction and casting followed by close monitoring remains useful and effective.

Keywords. Filipino, IKDC, translation, validation, PROM

INTRODUCTION

Tibial fractures comprise 15.1% of all long bone fractures in children, with 6.2% of fractures occurring at the shaft. Around 70% of these cases are isolated injuries, while ipsilateral fibular fractures occur in 30% of tibial fractures.[1]

Tibial development involves three ossification centers – one in each physis and one in the shaft. The proximal epiphyseal center unites with the shaft between 14 to 16 years of age, while the distal epiphyseal ossification center closes at around 14 to 15 years of age. On the other hand, the distal fibular physis closes at 16 years of age, while the proximal fibular physis closes between 15 and 18 years of age.[1] Linear bone growth is complete in 99% of girls at a bone age of 15 years, while boys reach this stage at a bone age of 17 years.[2] The

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Risser staging is a reliable marker of remaining skeletal growth, with a Risser stage 5 determining skeletal maturity. Menarche has also been a useful marker of skeletal maturity in females, coinciding with the end of peak height velocity and skeletal maturity in girls.[1]

Most uncomplicated tibial shaft fractures in children are treated with closed manipulation and casting. However, some surgeons prefer to manage these cases surgically to attain better alignment, especially in adolescents. Acceptable parameters vary, but the following general guidelines may be used: 1) varus and valgus angulation up to 10 degrees in children younger than eight years old, and up to five degrees in children older than eight years old; 2) at least 50% of apposition; 3) up to 10 degrees of apex anterior angulation and minimal apex posterior angulation; 4) up to 1 cm of shortening.[1] Reduction to acceptable parameters is typically followed by immobilization in a long leg cast for a period of four to six weeks, before being shifted to partial weight-bearing cast or boot for another three to five weeks. Full bony union is typically expected at around eight to 12 weeks.[3] While closed reduction and casting is effective with uncomplicated tibial shaft fractures, close monitoring is required to catch compartment syndrome or loss of reduction. Complications such as a limp with an out-toeing gait after cast removal are regularly observed. Muscle weakness, muscle atrophy, and joint stiffness are also transient but expected effects of cast immobilization.[1]

Nonoperative management necessitates a functional reduction since the tibial shaft remodels poorly. Tibial shaft fractures with associated fibular fractures may also develop valgus malignment, while 60% of tibial shaft fractures with an intact fibula will develop varus angulation in the first two weeks. Deformities in a single plane are more likely to remodel, especially apex anterior and varus angulation. On the other hand, apex posterior angulation, valgus malalignment, and multiplanar deformities have less remodeling potential. Rotational deformities do not remodel. Any symptomatic malrotational malunion greater than 10 degrees requires a derotational osteotomy.[3] A systematic review and meta-analysis by Stenroos et al. showed a malunion rate of 4% in non-surgically treated tibial shaft fractures in children.[4]

A retrospective review of 57 adolescents with displaced closed tibial shaft fractures treated with closed reduction and casting reported that failure is predicted by 20% displacement and concurrent fibular fractures. Of these cases, 40% required surgical stabilization. Patients treated with intramedullary nailing had a better final alignment (92.5% vs. 72.4%, $p = 0.10$) but had longer hospitalization (5.4 vs. 1.9 d, $p < 0.001$), and a higher incidence of anterior knee pain (20% vs. 0%, $p < 0.01$).[5]

In a large Finnish epidemiological study that involved 296 patients under 16 years old treated for tibial shaft fractures across six years, 47% of children were treated with casting at the emergency department, 22.3% underwent closed manipulation under anesthesia, and 30.4% were treated with surgery. Patients treated surgically were more likely to have a concomitant fibular fracture (46/66 vs 52/214, $p < 0.001$), were older (13.08 ± 2.4 vs 6.4 ± 3.7, $p < 0.001$), and had greater primary angulation (6.9 ± 5.8 vs 0.48 ± 3.1, $p < 0.001$). In the group who underwent casting at the emergency room, the median primary angulation of tibia fractures was 0° (range 0° to 5°). The group who underwent closed manipulation under anesthesia had a median primary angulation of 3° and a median primary displacement of 3 mm. The surgically treated group had a median primary angulation of 6.7° and a median primary displacement of 7 mm.[6] In another national database study in the United States from 2000 to 2012 covering 24,166 tibial shaft fractures, 15,621 (67.7%) were treated surgically and multivariable regression showed that increasing age was associated with an increased rate of surgical treatment ($p < 0.001$).[7]

Given the increasing trend of surgical treatment of tibial shaft fractures, especially among adolescents, this study presents the adequacy of reduction, alignment, and functional outcomes of closed tibial shaft fractures treated non-surgically in our institution.

The main objective of this study was to report residual lower limb deformity (defined as any angular deviation from the normal long bone axis) of tibial shaft fractures treated non-surgically in adolescents nearing skeletal maturity, identify factors or fracture characteristics that may predict these deformities, and report the clinical outcomes using the LEFS.

METHODOLOGY

This cross-sectional study investigated non-surgically treated tibial shaft fractures in adolescents nearing skeletal maturity at the Philippine Orthopedic Center from 2017 to 2020 through a purposive sampling method. The study included Filipino adolescents aged 11 to 16 years old with acute tibial shaft fractures treated non-surgically with closed manipulation and casting at our institution's Emergency Department [ED] and had reached skeletal maturity at the time of the investigation. Treatment was selected by the respective attending orthopaedic surgeons based on their clinical assessment. The age range was chosen to ensure that, theoretically, no more bone remodeling will likely take place after investigation and that the radiographic and clinical measurements will be carried over into adulthood. Patients nearing skeletal maturity were defined as those with Risser stages 0 to 4 on pelvis anterior-posterior (AP) radiographs taken at the initial consult and a Risser stage 5 on the day of evaluation for the study. To check for skeletal maturity, full-length radiographs of both legs were obtained and the proximal epiphysis was checked for complete closure in both lateral and anteroposterior radiographs, along with a Risser score of 5 on final pelvis AP radiographs.

Excluded from the study were patients with polytrauma, open fractures, other lower extremity injuries, neuromuscular disorders, muscular dystrophy, connective tissue disorders, metabolic conditions, and other systemic conditions that affect bone growth.

After approval was obtained from the Ethics Review Board, patients were selected based on the established inclusion and exclusion criteria and consent was obtained. Data collection was done through a retrospective chart and radiographic review, along with patient interviews.

Demographic information was collected, including age, gender, affected extremity, number of days from injury to treatment, fracture pattern (simple transverse, simple oblique, simple spiral, or multifragmentary), presence of ipsilateral fibular fracture, time to radiographic union, and time to full weight-bearing. Time to full weight-bearing was assessed from the patient's recall of the physician's instruction of full weight-bearing ambulation. For females, the age of menarche was also documented.

Radiographic measurements were taken from the most recent whole-leg radiograph accessed through our institution's PACS system. Tibial torsion or rotation was measured clinically using the tibial-foot angle, performed by the principal investigator, and compared with the contralateral lower extremity. Leg length discrepancy was measured using the standard measurement of true leg length, using the anterior superior iliac spine, patella, and medial malleolus as markers. This was compared with the contralateral lower extremity on the day of examination.

Functional outcomes of all patients were measured using the Lower Extremity Functional Scale (LEFS) administered by the principal investigator on the day of the investigation, a patient-reported outcome measure shown to be reliable, valid, and responsive in assessing patients who sustained tibial shaft fractures.[8,9]

Sample size calculation

The minimum number of patients was determined based on the reported incidence of tibial shaft fractures in children at 1.1%.[1] At a confidence level of 95% and a margin of error of 5%, the number of patients required to provide correlation was 20. This number considers a 15% allowance for anticipated dropout.

Statistical analysis

Data were encoded and tallied in SPSS version 23 for Windows. The data were analyzed through descriptive statistics using means and standard deviation to describe the demographic, radiographic, and functional outcome scores of each patient. Descriptive statistics were generated for all variables. For nominal data, frequencies and percentages were computed. For numerical data, mean ± SD was generated, as well as range. Bivariate correlation of the coronal and sagittal angulation was done using Pearson Correlation. Comparison of fracture pattern with LEFS score, coronal angulation, and sagittal angulation were analyzed using T-test. Finally, a comparison between the presence of fibular fracture coronal and sagittal angulation was done using the Mann-Whitney U test and T-test.

RESULTS

A total of 31 adolescents nearing skeletal maturity with non-surgically treated tibial shaft fractures at the Philippine Orthopedic Center from 2017 to 2020 were included in the study. Their age ranged from 11 to 16 years with a mean of 13.45 years (SD = 1.71 years) (Table 1). Time from injury to consult ranged from 0 to 6 days with a mean of 2.68 days (SD = 2.16 days). Among the 31 patients, 6 (19.4%) were females and 25 (80.6%) were males. Of the female patients, 3 (50%) had menarche at 13 years, 2 (33.3%) at 14 years, and 1 (16.7%) at 15 years, with an average age of menarche of 13.67 years old. Most cases were caused by vehicular accidents (VA) at 58.1%, followed by sports injuries and falls at 38.7% and 3.2%, respectively. Left tibia injuries were more predominant at 54.8%.

Oblique fractures were the most common fracture pattern at 64.5%, followed by spiral fractures (35.5%). There were no transverse fractures seen in the pool of patients. Fibular fractures were noted in 11 (35.5%) patients (Table 2). Weeks to cast removal ranged from 12 to 16 weeks with a mean of 13.55 weeks, while weeks to full weight bearing ranged from 12 to 24 weeks with a mean of 14.32 weeks.

The tibial-foot angles of injured extremities ranged from 8 to 20 degrees, with a mean of 12.90 degrees. The tibia-foot angles of uninjured extremities ranged from 5 to 20 degrees, with the same mean at 12.90 degrees. Three subjects (9.7%) had leg length discrepancies, two had a 1 cm shortening of the injured leg and one had a 1 cm lengthening of the injured leg. Twenty-two (71.0%) subjects had no coronal plane (i.e. varus or valgus) angulations, while 9 (29%) subjects had valgus angulations. Three (9.7%) subjects, on the other hand, had posterior angulations, with the remaining 28 (90.3%) having no sagittal plane angulation. Finally, LEFS scores ranged from 75 to 80 with a mean of 79.39 (Table 3).

LEFS was significantly correlated with coronal plane (i.e. varus or valgus) angulation and leg length discrepancy (Table 4). Significant inverse correlations were noted, which means that as coronal plane (i.e. varus or valgus) angulation (r = -0.397; p = 0.05) or leg length discrepancy (r = -0.394; p = 0.05) increases, LEFS increases, and vice versa. On the other hand, no significant correlation was noted between LEFS and sagittal plane (anterior or posterior) angulation (r = 0.056; p = 0.76) or LEFS and tibial-foot angle (injured) (r = -0.145; p = 0.44).

There was no significant difference in the LEFS of patients with oblique or spiral patterns, (p = 0.55) (Table 5). Coronal and sagittal angulation did not correlate with fracture pattern (p >0.05) (Table 6). The presence of a concurrent fibular fracture correlated with coronal angulation (p = 0.007), but not with sagittal angulation (p = 0.94) (Table 7).

Table 1. Demographic and clinical characteristics of subjects

	Frequency (%); Mean ± SD (n=31)
Age (in years)	13.45 ± 1.71
11	4 (12.9%)
12	8 (25.8%)
13	4 (12.9%)
14	5 (16.1%)
15	5 (16.1%)
16	5 (16.1%)
Sex	
Male	25 (80.6%)
Female	6 (19.4%)
Days from injury	2.68 ± 2.16
Menarche (age in years)	13.67 ± 0.82
Mechanism of action	
Fall	1 (3.2%)
Sports	12 (38.7%)
VA	18 (58.1%)
Laterality of tibia fracture	
Left	17 (54.8%)
Right	14 (45.2%)

Table 2. Fracture characteristics and clinical progress

	Frequency (%); Mean ± SD (n=31)
Fracture pattern	
Oblique	20 (64.5%)
Spiral	11 (35.5%)
Fibular fracture	
Yes	11 (35.5%)
No	20 (64.5%)
Weeks to cast removal	13.55 ± 1.84
12	17 (54.8%)
14	4 (12.9%)
16	10 (32.3%)
Weeks to full weight-bearing	14.32 ± 2.64
12	13 (41.9%)
14	5 (16.1%)
16	11 (35.5%)
18	1 (3.2%)
24	1 (3.2%)

Table 3. Clinical and functional outcomes

	Frequency (%); Mean ± SD (n=31)
Tibial-foot angle injured (degree)	12.90 ± 2.30 (8 – 20)
Tibial-foot angle uninjured (degree)	12.90 ± 2.40 (5 – 20)
Leg length injured (cm)	88.10 ± 4.04 (76 – 93)
Leg length uninjured (cm)	88.13 ± 3.93 (77 – 92)
Leg length discrepancy	
Yes	3 (9.7%)
No	28 (90.3%)
Coronal angulation (degree)	1.03 ± 1.88
0	22 (71.0%)
1 – 5	8 (25.8%)
6 – 10	1 (3.2%)
Sagittal angulation (degree)	0.26 ± 0.82
0	28 (90.3%)
1 – 5	3 (9.7%)
6 – 10	0 (0.0%)
LEFS	79.39 ± 1.38 (74 – 80)

DISCUSSION

This study showed that non-surgical management of isolated tibial shaft fractures in children nearing skeletal maturity remains effective and reliable in providing acceptable radiographic outcomes and good clinical outcomes. All 31 patients had acceptable reductions.[1] Long cast immobilization was prescribed for four to six weeks, at which point the patients were transitioned to partial weight bearing with cast boot or short leg immobilization. In this cohort, however, 14 (45.20%) of them surpassed 12 weeks,[3] probably due to the out-patient scheduling, patient logistical concerns, availability of resources, or surgeon's preference of extending immobilizations. Unfortunately, interval data showing conversion immobilization and initiation of partial weight-bearing were not readily available. This points to an opportunity to refine our protocols to maximize earlier cast removal and weight-bearing once fracture healing allows.

Clinical outcomes, based on the LEFS scores, showed excellent results. A significant inverse correlation was found between coronal angulation and LEFS score, and leg length discrepancy and LEFS score. This was supported by literature showing that varus malalignment and shortening affect clinical outcomes in tibia fractures.[10] The correlation between sagittal angulation and thigh-foot angle with LEFS, on the other hand, was shown to be non-significant. This was in contrast with evidence supporting the correlation between malrotation and poor satisfaction in pediatric tibial shaft fractures.[11] Fracture pattern was not found to correlate with LEFS score, coronal angulation, and sagittal angulation.

Finally, the presence of fibular shaft fracture showed a significant correlation with coronal angulation, typically valgus. This supports the established risk factor of valgus malalignment and eventual malunion in tibial shaft fractures with concomitant fibular shaft fracture.[10,11] The correlation

Table 4. Pearson correlation of LEFS with coronal and sagittal angulation

	Correlation coefficient	*P* value
LEFS and coronal angulation	-0.397	0.05 (S)
LEFS and sagittal angulation	0.056	0.76 (NS)
Leg length discrepancy	-0.394	0.05 (S)
Tibial foot angle (injured)	-0.145	0.44 (NS)

Table 5. Distribution of diagnoses

	n	Mean ± SD	*P* value
Fracture pattern			
Oblique	20	79.50 ± 1.36	0.55 (NS)
Spiral	11	79.18 ± 1.47	

*p >0.05 – Not significant; p ≤0.05 – Significant; T-test

Table 6. Comparison of coronal and sagittal angulation according to fracture pattern

		n	Mean ± SD	*P* value
Coronal angulation	***Fracture pattern***			
	Oblique	20	0.85 ± 2.01	0.48 (NS)
	Spiral	11	1.36 ± 1.69	
Sagittal angulation	***Fracture pattern***			
	Oblique	20	0.15 ± 0.67	0.33 (NS)
	Spiral	11	0.46 ± 1.04	

*p >0.05 – Not significant; p ≤0.05 – Significant; T-test

Table 7. Comparison of varus/valgus and anterior/posterior angulation according to fibular fracture

		n	Mean ± SD	*P* value
Varus/valgus angulation	***Fibular fracture***			
	Yes	11	2.55 ± 2.30	0.007 (S)†
	No	20	0.20 ± 0.89	
Anterior/ posterior angulation	***Fibular fracture***			
	Yes	11	0.27 ± 0.90	0.94 (NS)‡
	No	20	0.25 ± 0.78	

*p >0.05 – Not significant; p ≤0.05 – Significant; †Mann Whitney U test; ‡T- test

between fibular fracture and sagittal angulation was non-significant.

However, these results should be viewed with reservations, first, due to the small sample population of this study. Among the 112 patients identified to be within our inclusion criteria, only 31 responded. Second, there may have been selection bias in recruitment due to the purposive sampling method utilized. This meant that the patients included were already deemed to be ideal candidates for non-surgical management. Patients with more comminuted fracture patterns, those with greater initial angulations, or those who failed closed reduction at the Emergency Department and subsequently underwent surgical management were not included. There is an opportunity for a larger, randomized study to evaluate and compare different treatment options. Finally, there is a gap in information between the initial consult and the time of this study's investigation. No data regarding interval follow-ups were collected.

This study shows the good outcomes with casting and immobilization in appropriately selected tibial shaft fractures in the adolescent population. With the increase in non-surgical management of these injuries during the COVID-19 pandemic due to different government guidelines,[12] the efficacy of this treatment option remains reliable and easily applicable. A continuation of this investigation to monitor the radiographic and clinical outcomes of these patients may be warranted to further evaluate its efficacy and reliability in the background of its extended indication during these times.

CONCLUSION

The radiographic and clinical outcomes of adolescents nearing skeletal maturity with isolated acute tibial shaft fractures treated non-surgically showed that the current method of closed reduction and casting followed by close monitoring provides good clinical outcomes. This further establishes the role of non-surgical management in appropriately selected cases of tibial shaft fractures in adolescents. A larger randomized study comparing non-surgical with surgical management may provide more conclusive results.

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STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

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ORIGINAL ARTICLE

Comparison of Outcomes of V-Y Atasoy vs Pentagonal Advancement Flap in the Management of Fingertip Injuries Allen Type II and III in a Tertiary Hospital

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ABSTRACT

Background. Fingertip injuries are the most common traumatic conditions of the hand, affecting productivity and livelihood due to a decrease in manual labor capabilities. The V-Y Atasoy advancement flap is typically effective in managing dorsal or transverse fingertip Allen type II and III injuries but may result in complications like dog ears, flap necrosis, paresthesia, and hook nail deformities.

Objective. This paper aimed to describe the assessment, operative technique, and outcomes in patients with fingertip injury Allen type II and type III treated with the V-Y Atasoy advancement flap versus the pentagonal flap. We also aimed to compare the outcomes and complications associated with each technique.

Methodology. A randomized controlled trial was done among patients with fingertip injury Allen type II and III who were admitted to a tertiary hospital.

Results. There were no significant differences in the rates of immediate complications (flap necrosis, infection, dog ear deformity) or short-term outcomes (two-point discrimination, Semmes-Weinstein monofilament test) between the two groups. Most patients had excellent satisfaction and were able to return to work.

Conclusion. Patients of the two groups had good to excellent outcomes and had minimal complications, with no significant differences between the groups. The pentagonal flap can be an alternative to the V-Y Atasoy flap in managing fingertip injuries, especially those with a larger surface area of injury.

Keywords. fingertip injury Allen II and III, V-Y Atasoy flap, pentagonal flap

INTRODUCTION

The hand is one of the most important parts of the body for accomplishing tasks from typing reports in the office to manual labor in the streets. In the same vein, the hand is prone to work-related injuries which entail additional financial burden on the family. The goal of management is to preserve the length of the finger, minimize pain, maximize functionality, provide satisfaction, and hasten return to work. The V-Y advancement flap technique creates a triangular volar flap with its apex at the distal interphalangeal crease and its base at the margin of the amputation. It is advantageous in providing padding and good contour, and sensation. It is an outstanding reconstructive method in many distal fingertip injuries with bone exposure. However, its indication is limited, as this is only applicable to dorsal oblique and transverse types of fingertip injury, and complications can occur (dog ear, flap necrosis, paresthesia, and hook nail deformity). Due to this, modifications include leaving the donor site defect open to prevent flap necrosis, managing volar oblique amputations with the V-Y flap,

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modifying the dissection of the flap to prevent tension through stretching, and dividing the vertical fibrous septa proximally. Since complications can still occur even with these modifications, the researcher introduces their modification of the V-Y Atasoy flap: the Pentagonal advancement flap. Two longitudinal parallel incisions were made the same width apart as the width of the defect. These were connected proximally with a V-shaped incision with an apex >60 degrees. The nail was sutured to the distal subcuticular edge of the flap using an interrupted technique, and the donor site was left open to heal with a secondary intention of preventing flap necrosis. This shape is intended for complete coverage of the defect while avoiding dog ears from excess skin and preventing flap necrosis from a narrow proximal apex. This study is the first to present this innovation in managing fingertip injuries.

Fingertip injuries are difficult to manage due to the complex and small anatomy of the fingertip's veins and arteries.[1] Treatment must be individualized based on patient-related factors (e.g., age) and specific wound characteristics. The goal of treatment is to restore form and function. Factors such as the cost-effectiveness of the procedure, recovery duration, and the surgeon's technical skill should also be considered.[2]

Allen's classification is commonly used to describe the level of fingertip amputation.[3] Type 1 injuries involve the pulp only. Type 2 injuries include the pulp and nail bed. Type 3 injuries include partial loss of the distal phalanx plus corresponding losses of pulp and nail. Type 4 injuries involve the lunula, distal phalanx, and pulp with nail bed loss.[4] Proper classification guides the clinician on the appropriate management. Type I injury may heal through secondary intention. On the other hand, for Type II injuries, the Atasoy V-Y advancement flap is frequently used.[5] A type III injury can be managed with a composite graft, local flap, cross-finger flap, finger replantation, revision amputation, or pocket technique.[6] Type IV Allen classification would most likely need nailbed grafting, microvascular replantation, or amputation.[7] Complications can result in hook nail deformities, necrosis, or a shortened finger.[8]

This paper aimed to describe the operative technique and compare the outcomes and complication rates of patients with fingertip injury Allen type II and type III treated with the V-Y Atasoy advancement flap versus the pentagonal flap. There was no local data found on the V-Y advancement flap for fingertip injuries in the Philippines, nor any studies on the pentagonal flap.

METHODOLOGY

This was a randomized controlled trial, open-label, non-inferiority study with an experimental and a control group. The participants were randomly allocated to two groups; one group was managed with the pentagonal flap and the other group was managed using the V-Y Atasoy technique. Randomization was done through simple random sampling by generating random numbers using OpenEpi version 3.01. The researcher provided the number coding in sealed envelopes to patients who met the inclusion criteria. Ethical approval was obtained from the Ethics Review Committee, Baguio General Hospital and Medical Center, before the commencement of the study.

Inclusion criteria

1. Allen fingertip injury type II and III
2. Patients aged 19 to 60 years old
3. Intact volar skin distal to the distal digital crease
4. Transverse or dorsal oblique fingertip injury
5. Fingertip injuries in the index to small finger
6. ASA Physical Classification 1 and 2

Exclusion criteria

1. No consent
2. Volar fingertip injury
3. Multiple fractures on the same site
4. Existing infection on the same site
5. Presence of profound scarring on the fingertip
6. Preexisting nerve injury on the same hand
7. Direct-to-operating room patients with multiple injuries
8. Patients with co-morbidities (e.g., hypertension, diabetes mellitus)

The target sample size of 16 was based on the successful outcomes of previous cases using pentagonal flap and outcomes of cases treated with bilateral V-Y rotation flap[3] and computed using a 95% confidence interval, 80% power, 5% margin of error, and odds ratio of 76 via OPEN-EPI version 3.1.

Between February 2022 to September 2023, 15 patients with fingertip injury Allen type II and III who fulfilled the inclusion criteria were randomized. The ages ranged between 20 to 50 years old. There were nine men and six women included in the study.

The wounds were initially assessed, irrigated, and dressed. Anterior-posterior, oblique, and lateral X-rays were taken to document any bony involvement. Patients were screened and advised of the need for admission and surgery. After the patient consented to admission, the study was introduced by the primary researcher. The patient's case, the study, the procedure, the attending surgeon, and any risks and benefits were thoroughly explained. The patient provided the informed consent in the language or dialect they preferred. The surgical procedure was conducted by the orthopedic hand rotator during their term of rotation. The patients were blinded regarding the procedure done to them. The author also either conducted or assisted the surgery depending on her current rotation and assisted in the patients' postoperative follow-up.

Immediate operative debridement and flap reconstruction were performed on all subjects using a digital nerve block with lidocaine. For the V-Y Atasoy flap technique, the incision was a V-shape at the volar area of the finger with the width of

the distal edge equal to the nail bed and the apex not passing proximally to the distal digital crease. The incision was made through the skin continuing it out deep down to the bone dividing the periosteal attachments. The deep surface of the flap was freed completely from the underlying tendon sheath. The lateral subcutaneous tissues that contained the pedicle of the flap were spread apart with micro-scissors. The flap was advanced and closed using a monofilament 3-0 or 4-0 suture starting at the apex creating the vertical stem of the "Y" (Figure 1).

For the pentagonal flap, the shape of the flap was modified by cutting longitudinal parallel lines of the same width as the recipient site defect on the distal volar skin. The V-shaped cut with an apex >60 degrees was made connecting the longitudinal incisions proximally, forming a pentagon-shaped flap. The fibrous septa anchoring the skin to deeper structures was delicately divided. The subcutaneous tissues were detached from the periosteum and flexor tendon sheath to free the deep margin of the flap. The full-thickness skin flap was then advanced to cover the exposed bone, and the neurovascular bundles were maintained intact. The flap was carefully shaped and contoured to the fingertip by suturing with a Monocryl 3-0 suture. The flap was then sutured to the nail. The V-shaped donor site defect was left open to heal with a second intention to prevent neurovascular impingement to avoid flap necrosis (Figures 2 and 3).

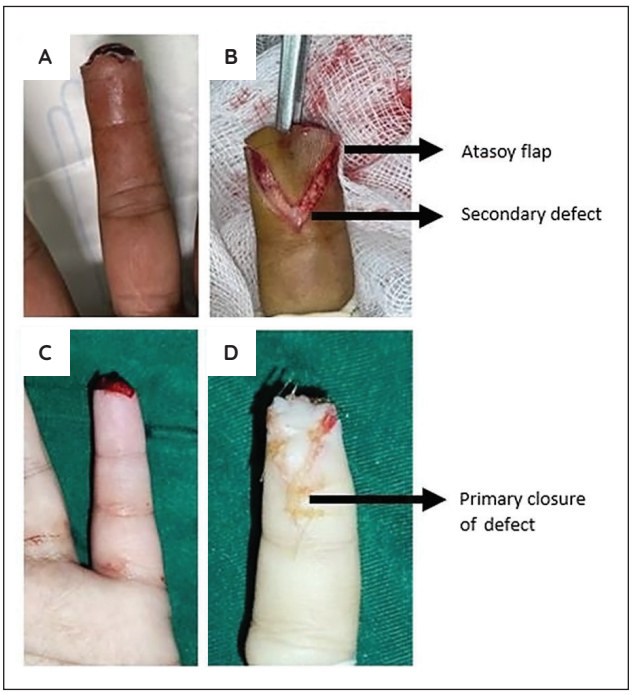

Figure 1. Intra-operative V-Y Atasoy Flap. Preoperative image **(A)**. Intraoperative image showing the flap advancement, with a secondary defect left open **(B)**. Preoperative image **(C)**. Intraoperative image showing the sutured "Y" shape after primary closure of the defect **(D)**.

Care was taken to monitor vital signs, maintain sterility, achieve hemostasis, and control pain during and after the procedure. The patient started taking antibiotics upon admission to the emergency room until seven days postoperatively to prevent infection. The open wounds were dressed with a single layer of Xeroform, followed by a layer of wet and dry dressing. Xeroform is a nonadherent fine mesh gauze that has bacteriostatic properties. It also has occlusive properties, thereby providing a moist environment conducive to healing and protecting the wound from contamination.

At the ward, patients were monitored for 24 to 48 hours and any complications (flap necrosis, infection, and dog ear deformity) were recorded as immediate outcomes. Flap viability was monitored by noting circulation on the flap through capillary refill, temperature, and color. Patients were discharged if the surgical site improved with no signs of complications.

On the first follow-up visit three to five days postoperatively, the dressing was removed but the Xeroform gauze was left intact. The patient was then asked to bathe the finger in a warm saline bath once daily for one minute then dress the digit with dry gauze. The Xeroform gauze was left covering the defect and if these instructions were carefully followed, abscess formation could be avoided.

Sensation, scar appearance, functional outcomes (via the Sollerman hand function test, Figure 6), satisfaction, and return to work were assessed at two weeks, one month, and three months post-operatively. The sensory function was

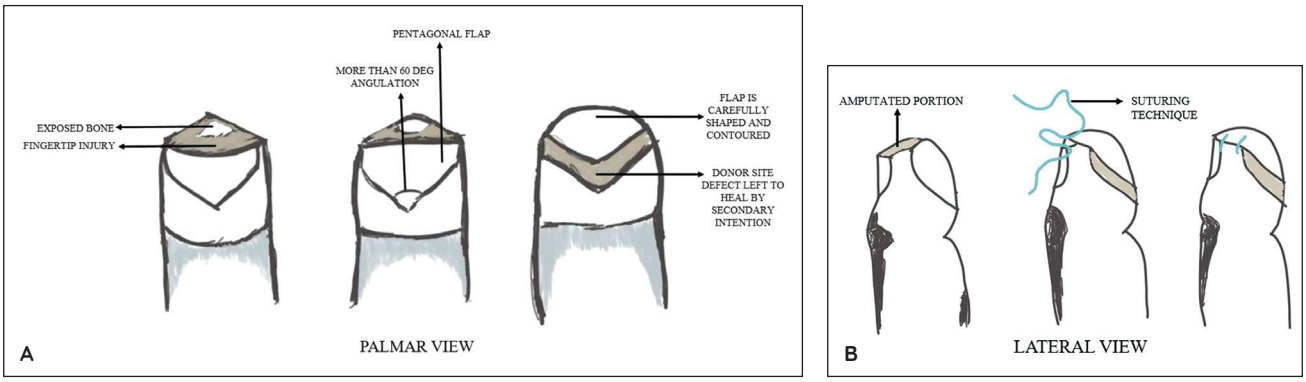

Figure 2. Pentagonal Advancement Flap Diagram. Palmar view showing the longitudinal parallel incisions and the V-shaped incision, and the advancement of the pentagonal flap **(A)**. Lateral view showing the suturing technique to the nail **(B)**.

measured using the static two-point discrimination test (Figure 6) and Semmes-Weinstein monofilaments (Figure 7). Patient satisfaction was self-reported using a questionnaire asking them to rate their experience as excellent, good, fair, or poor. These assessments were conducted by the resident and researcher during outpatient follow-ups.

Descriptive and inferential statistics were utilized for data analysis. The chi-square test of homogeneity was used to compare the values between the pentagonal flap and the V-Y Atasoy flap. A t-test was used to compare the values between sensation, functional outcome, satisfaction, and return to work. A significant *p*-value was set at ≤0.05. Data processing was done through OpenEpi Version 3.1 (Open-Source Epidemiologic Statistics for Public Health).

RESULTS

The mean age of the participants was 32 years (n = 15) (Table 1). Most patients were in the age range of 19 to 30 years (n = 8). More patients were men (n = 9) and the most common occupation was laborer (n = 6). For immediate outcomes, there was no significant difference in the rate of complications. Flap necrosis occurred in two patients from each group (p = 0.875). Minor early infections occurred in one patient from each group (p = 0.919), resolving with wound care and oral antibiotics. Dog ear deformities occurred in three patients in the Atasoy group and one patient in the Pentagonal group (p = 0.310) (Table 2).

Wounds were completely healed on peeling off the Xeroform gauze after 10 to 12 days. After two weeks, patients in the

Table 1. Clinical and demographic profile of adult patients admitted with fingertip injury

		Pentagonal (n = 7)	V-Y Atasoy (n = 8)	Total	%	*p*-value*
Age	20-30 y/o	2	6	8	53.33	0.193
	31-40 y/o	2	1	3	20	
	41-50 y/o	3	1	4	26.67	
Sex	Male	4	5	9	60	0.832
	Female	3	3	6	40	
Work	Professional	3	1	4	26.67	0.404
	Clerical	2	3	5	33.33	
	Laborer	2	4	6	40	
Handedness	Right	6	6	12	80	0.604
	Left	1	2	3	20	

*p-value as calculated by chi-square

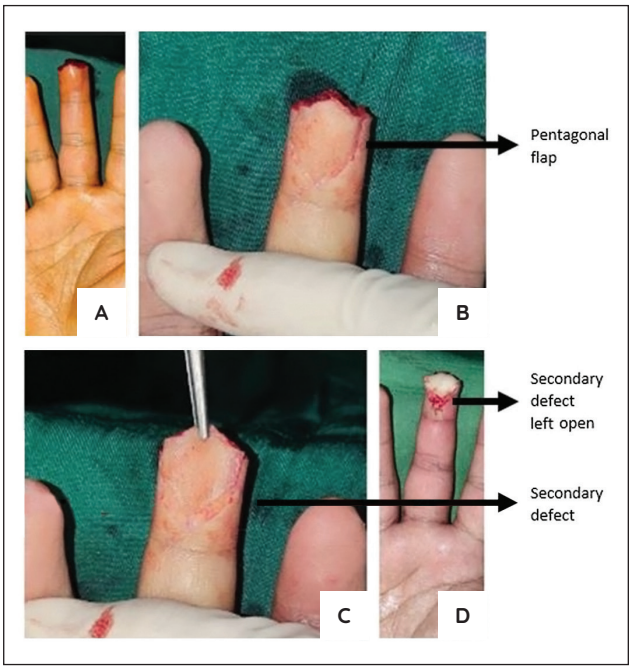

Figure 3. Intra-operative Pentagonal Advancement Flap. Preoperative image **(A)**. Incisions were made outlining the pentagonal flap **(B)**. The pentagonal flap was advanced, leaving a secondary defect **(C)**. Appearance of the pentagonal flap and secondary defect after suturing **(D)**.

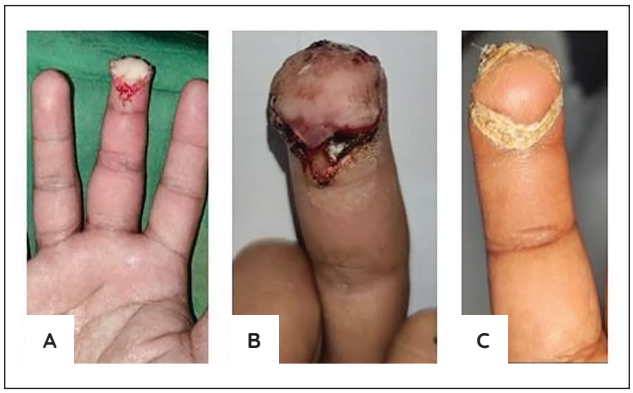

Figure 4. Outcomes of Pentagonal flap. Immediate postoperatively **(A)**; 48 hours postoperatively **(B)**; One month postoperatively **(C)**.

Table 2. Comparing the complications of V-Y Atasoy flap vs Pentagonal flap after 24–48 hours

	Pentagonal	V-Y Atasoy	*p*-value*
Flap necrosis	2	2	0.875
Early infection	1	1	0.919
Dog ear deformity	1	3	0.310

*p-value as calculated by chi-square

Pentagonal group had a non-significantly higher rate of scar tenderness compared to the Atasoy group (p = 0.184). Most patients scored a grade of 3 in 2-point discrimination, with no significant difference between the groups (p = 0.875). There was also no significant difference in the results of Semmes-Weinstein monofilament testing (p = 0.411) (Table 3).

Satisfaction rates were similar between the two groups at one month postoperatively (p = 0.408). Most patients in each group (n = 5) reported a score of 4 on the Sollerman hand function test (able to carry out tasks without any difficulty) (p = 0.403). At the end of the follow-ups, patients were able to return to their work without limitations (p = 0.385) (Table 4). At the final follow-up, one patient from each group had improvement in their two-point discrimination (p = 0.454). Likewise, one patient from each group improved by one grade when tested with the Semmes-Weinstein monofilaments (p = 0.434). There were no significant differences between the groups (Table 5).

There was no significant difference in the rates of nail deformity, insensate digit, cold intolerance/hyperesthesia, or late infection between the two groups (p = 0.310) (Table 6). The average time to re-epithelization of the Pentagonal flap was 3.7 weeks. No patient was lost to follow-up.

DISCUSSION

The classic V-Y advancement flap, also known as the Atasoy flap, is frequently used for the reconstruction of fingertip amputations with exposed bone. It is applicable in dorsal oblique and transverse amputations, supplying sensate skin and robust subcutaneous tissue thanks to the preservation of the distal branches of the digital vessels and nerves.[9]

The V-Y advancement flap was originally described by Tranquilli-Leali in 1935 but was first reported in the United States by Atasoy et al. in 1970. In the study done by Tranquilli-Leali to review the anatomy of the fingertip and compare two flap techniques, it was proven that the flap was supplied by the anastomotic connections via the fibro-osseous hiatus between the terminal branches of the dorsal nail-bed arcades and palmar digital arteries.[10]

Previous studies have reported good outcomes with the

Table 3. Comparing the sensation outcomes of V-Y Atasoy Flap vs Pentagonal Flap after two weeks

		Pentagonal	V-Y Atasoy	*p*-value
Scar tenderness		3	1	0.184
2-Point Discrimination				
Grade	Interpretation			
3	<6 mm	5	6	0.875
2	6-10 mm	2	2	
1	11-15 mm	0	0	
0	>15 mm	0	0	
Semmes-Weinstein Monofilament test				
Grade	Interpretation			
6	Normal	3	5	0.411
5	Diminished light touch	3	1	
4	Diminished protective sensation	1	2	
3	Loss of protective sensation	0	0	
2	Loss of protective sensation	0	0	
1	Deep pressure sensation only	0	0	
0	Loss of sensation	0	0	

*p-value as calculated by t-test

Table 4. Comparing the satisfaction, Sollerman hand function, and return to work of V-Y Atasoy flap vs Pentagonal flap after one month

		Pentagonal	V-Y Atasoy	*p*-value
Satisfaction	Excellent	4	4	0.408
	Good	1	2	
	Fair	1	1	
	Poor	1	1	
Sollerman hand function test	4 - the task was carried out without any difficulty	5	5	0.403
	3 - the task was completed, but with slight difficulty	2	3	
	2 - task was completed, but with great difficulty	0	0	
	1 - task was partially performed within 60 seconds	0	0	
	0 - patient could not carry out the task	0	0	
Return to work	Soft labor/office work	5	4	0.385
	Hard labor	2	4	

*p-value as calculated by t-test

Table 5. Comparing the sensation outcomes of V-Y Atasoy flap vs Pentagonal flap after three months

		Pentagonal	V-Y Atasoy	*p*-value
2-Point Discrimination				
Grade	Interpretation			
3	<6 mm	6	7	0.454
2	6-10 mm	1	1	
1	11-15 mm	0	0	
0	>15 mm	0	0	
Semmes-Weinstein Monofilament test				
Grade	Interpretation			
6	Normal	4	6	0.434
5	Diminished light touch	2	1	
4	Diminished protective sensation	1	1	
3	Loss of protective sensation	0	0	
2	Loss of protective sensation	0	0	
1	Deep pressure sensation only	0	0	
0	Loss of sensation	0	0	

*p-value as calculated by t-test

Table 6. Late complications of V-Y Atasoy flap vs Pentagonal flap

Complications	Pentagonal	V-Y Atasoy	*p*-value
Nail deformity (hooked nail)	1	1	0.310
Insensate digit and stiff fingers	0	0	
Cold intolerance/ hyperesthesia (Figure 8)	1	2	
Late infection	1	1	

technique. Viciana reported on a 12-year-old who sustained a transverse amputation of the distal third of the left ring finger distal phalanx treated with an Atasoy flap. They report good color and sensibility after seven days, and full range of motion after 14 days. Two-point discrimination was 5 mm throughout.[11] The current study found that most patients had a grade 3 two-point discrimination (<6 mm) with the rest falling under grade 2 (6 to 10 mm).

Another study done by Ozyigit et.al. presented five dorsal V-Y advancement flaps done in patients aged 25 to 46 and presented results after 12 to 24 months. All flaps survived and a full range of movement was retained in the affected digit. All patients were satisfied and used their digits without difficulty. The mean static two-point discrimination differed on both sides of the finger but was satisfactory. The fingertips looked excellent, and no patient had any pain. All patients returned to work by the 21st day. No dysesthesia or hyperesthesia was seen in any patient.[12] In this study, none of the patients developed an insensate digit; however, three patients developed cold intolerance (Pentagonal n = 1, Atasoy n = 2).

Modifications of the V-Y Atasoy advancement flap were done to improve the outcome. In a study made by Thoma, the donor site defect was left open and allowed to heal by secondary intention instead of closing the donor site in a Y pattern.[13] To cover the bone, the base of the triangle was loosely sutured to the nail bed. Small wound gaps are of no concern for this open area heals adequately by secondary intention without the burden of tight closure. Another study used the V-Y rotation advancement flap bilaterally for fingertip amputations. Rotation made this flap more mobile and easier to cover larger defects in all amputation planes. The follow-up period was 3 months to 2 years. There was neither total nor partial flap loss. Physical therapy was not indicated because the fingers had a full range of motion. No reports of cold intolerance or scar hypersensitivity. No stiffness of the PIP joint was seen. No hooked nails occurred in patients who have remaining nail matrices. Satisfactory function and sensation on the amputation stump were obtained. Most patients returned to work in about 1.5–2.5 weeks (the mean time off work was 9 days).[8]

The need for a tension-free closure is emphasized in many sources. The flap is at risk for necrosis if tension-free closure is not achieved. The problem may be because of the swelling that occurs after closure. Also, the distal nail bed may be dragged in the anterior direction, forming a hook nail deformity. The author undertook this study due to the number of cases treated with classical Atasoy flap that necrosed.

In this study, outcomes were similar between the Pentagonal flap and the V-Y Atasoy flap. There were minimal complications between the two groups. The Pentagonal flap was easier to shape to cover most of the injury and faster to close since the surgeon needed to close only the distal portion. However, during dressing changes, it was easier to change those in the Atasoy group since all the corners were closed. Most patients in this study had good wound healing and were able to return to work without limitations. The rate of flap necrosis in both

groups may be attributed to the surgeon's technique and the study's small population.

Limitations of the study include a small population, different surgeons, and anatomical variations. These may have caused varying outcomes and rates of healing among the patients.

CONCLUSION

Patients of the two groups had good to excellent outcomes and had minimal complications, with no significant differences between the groups. The pentagonal flap can be an alternative to the V-Y Atasoy flap in managing fingertip injuries, especially those with a larger surface area of injury. Further study is recommended with larger populations.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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ORIGINAL ARTICLE

Early Functional Outcome of Closed Reduction and Percutaneous Pinning of Proximal Phalangeal and Metacarpal Fractures Done Under Conventional Radiograph Guidance

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ABSTRACT

Background. Fluoroscopy is the standard intraoperative imaging in orthopaedic surgery. Real-time visualization of fracture reduction and implant placement is essential, especially during closed reduction and percutaneous pin (CRPP) fixation. In the absence of fluoroscopy, conventional radiographs are used.

Objective. This study evaluated the early functional outcomes of CRPP fixation for proximal phalangeal and metacarpal fractures done under conventional radiograph guidance.

Methodology. Fifty-four patients with 72 fractures of the metacarpal or proximal phalanx in 70 fingers underwent CRPP fixation at the emergency room. Radiographs were used to assess reduction and fixation. Primary outcome measures were Total Active Motion (TAM), and Disabilities of the Arm, Shoulder, and Hand (DASH) score, while secondary outcome measures included fracture reduction, union rate, and complications. These were all evaluated at a mean of 12 weeks after surgery.

Results. An average of 2.9 radiographs were taken for each fracture, with a mean surgical time of 40 minutes. The TAM was "excellent to good" in 47% of fingers (mean = 258°), while the rest had "fair" scores (mean = 235°). Seventy-six percent of patients had a mean DASH score of 4.9. Thirty-five percent of fractures achieved anatomic reduction and maintained until union. Short procedure time did not influence the DASH scores. Complications reported were malunion (2), stiffness (5), and extension lag (7). There was no reported nonunion.

Conclusion. Closed reduction with pinning of proximal phalangeal and metacarpal fractures guided by conventional radiograph in the absence of fluoroscopy, remains to be effective and reliable with favorable early outcomes.

Keywords. radiograph, closed reduction with percutaneous pinning, metacarpal, finger proximal phalanx, fracture

INTRODUCTION

Hand fractures are the most common injuries seen in the emergency room.[1-4] While most are treated nonsurgically using closed reduction and immobilization, fractures that are irreducible, unstable, or open with concomitant soft tissue injuries require surgical intervention.[1,4-7] Closed reduction and percutaneous pin (CRPP) fixation have remained a popular surgical intervention despite innovations in orthopaedic implants and techniques.[8,9] This method allows for early joint mobilization to avoid complications such as adhesions, stiffness, and contractures.[4,7]

The use of fluoroscopy in CRPP for hand fractures is universally accepted and has greatly improved outcomes.[1,8-11] Its use has in part led to predictable results in terms of operative time, anatomic reduction, and accuracy of pin placement.[10,11] In low-resource settings such as the Philippines however,

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many institutions continue to perform CRPP fixation using conventional biplanar radiographs in the absence of fluoroscopy. Performing this procedure in the emergency room was quicker and cheaper than open reduction with internal fixation in the operating theater. Although, compared to fluoroscopy, this practice is considered time-consuming and potentially frustrating for orthopaedic trainees.[11]

At a time when the fluoroscope at the emergency room of our institution was under repair, orthopaedic residents-in-training fixed hand fractures without real-time imaging. This study was conducted to evaluate the early functional outcomes of these CRPP fixations of phalangeal and metacarpal fractures performed under conventional radiograph guidance.

METHODOLOGY

Study design and setting

This was a single-center prospective study and was approved by the institution's Ethics Review Board.

Patients and methods

All sixty patients with closed, displaced, unstable fractures of the proximal phalanx and/or metacarpal treated at the emergency room of our institution between March to December 2016 were included. This was the period when the fluoroscope at the emergency room was not available. Six patients were lost to follow-up and dropped from the study. A total of 54 patients with 72 fractures in 70 fingers were included in the final analysis. All injuries were sustained within one week of the emergency room visit. Fracture configurations of any kind involving one or more proximal phalanx or metacarpal, in one or both hands, were included. Excluded from the study were open or severely comminuted fractures, patients less than 15 years old, and patients with concurrent limb- or life-threatening injuries. All patients were informed of the unavailability of fluoroscopic imaging upon admission to the emergency room. Informed consent was similarly secured from all patients before inclusion in the study.

The procedures were done under Wide Awake Local Anesthesia No Tourniquet (WALANT) technique using locally manufactured Kirschner wires (0.45-inch diameter). Fractures were reduced with manual traction and manipulation and verified by palpation of the dorsal cortex and inspection of the plane of the nail plate. Wires were introduced at both the radial and ulnar corners of the base of the proximal phalanx, or the medial and lateral collateral ligament recesses of the metacarpal head, as entry points. After penetrating the intramedullary canal, wires were pushed until they reached the opposite subchondral end of the bone. Surgeries were performed by orthopaedic residents-in-training going on ER duties. Conventional radiographs were done intra-operatively by a licensed radiologic technologist. Antero-posterior and lateral radiographs were taken for phalangeal fractures, with an additional oblique view for metacarpal fractures. Unacceptable reduction for metacarpal shaft fractures was defined as apex dorsal angulation of more than 30°, 20°, 10°, and 10° for the small, ring, long, and index fingers, respectively. Metacarpal shortening of more than 5mm and malrotation leading to scissoring on finger flexion were not accepted.[9] Unacceptable reduction for proximal phalangeal shaft fractures was defined as more than 10° sagittal or coronal angulation, more than 20° sagittal angulation at the metaphyseal region, and any shortening or malrotation.[12] Only anatomic reduction or precise restoration of the position of fracture fragments was acceptable for head or base fractures with intra-articular extensions. Accurate fixation was defined as visualizing radiographically both pins traversing both proximal and distal ends of the fractured bone. Five failed attempts at reduction or fixation of a fracture would warrant the exclusion of the patient from the study to avoid further trauma to the injured bone.

Once acceptable reduction and fixation were achieved, wires were bent and cut close to the bone, then buried under the skin. Wounds were dressed and no external immobilization was applied. Patients were sent home on the same day with oral analgesics and second-generation cephalosporins, prescribed for five days. Instructions for immediate interphalangeal as well as metacarpophalangeal flexion and extension exercises as tolerated were given. Follow-up was done every three weeks to record outcome measures. Telephone interviews were conducted as needed.

Outcome measure

Primary outcome measures were Total Active Motion (TAM), and Disability Assessment of the Hand and Shoulder (DASH) scores, while secondary outcome measures included maintenance of fracture reduction on radiograph, time to union, and complications.

Total active motion was measured using a metal goniometer. Measurements were classified as "excellent" (260–270°), "good" (250–259°), "fair" (200–249°), or "poor" (<200°).[8] The 30-item DASH questionnaire was made available in both English and Filipino versions. Time to union was based on radiographic evidence of callus or absence of cortical gap at the previous fracture site. Complications were monitored and reported. Malrotation was described as the presence of finger overlapping on simultaneous flexion of the metacarpophalangeal joint (MCPJ) and the interphalangeal joints (IPJs). Extensor lag was defined as the inability to fully extend the MCPJ and the IPJs. Stiffness was defined by difficulty initiating finger motion at the MCPJ or the IPJs, or both. All measurements were done by the orthopaedic resident in charge of the patient.

Statistical analysis

Test for normal distribution was done using the Shapiro-Wilk test. The correlation between the duration of surgery and the DASH score was determined through the Pearson R test. Statistical tests were performed using Stata © Statistical

Software (StataCorp 2013, College Station, TX, USA) with the level of significance set at $p < 0.05$.

RESULTS

Patient and fracture demography

Seventy-two fractures in 70 fingers from 54 patients were evaluated, mostly involving the dominant hand (55%) (Appendix). There were 38 isolated proximal phalangeal and 30 isolated metacarpal fractures recorded. Two patients sustained multiple fractures in one digit. The average follow-up duration was 12.6 weeks (range, 11–15 weeks). Most patients (94%) were male, more than half were in the second and third decades of life (54%), and half of the patients (N = 27) were involved in heavy manual labor (Table 1).

Table 1. Patient demographics (n = 54)

	Male (n = 51)	Female (n = 3)
Age (in years)		
<20	6	0
21-30	22	1
31-40	6	1
41-50	10	0
51-60	7	0
<60	0	1
Mean (SD)	33.6 (13.05)	40.6 (22.37)
Occupation		
Manual laborer*	27	
Service related**	7	
Clerical work***	10	
Unemployed****	10	

*construction, carpentry, machine operator, mechanic, etc.
**security guard, service crew, tailor, driver, etc.
***call center agents, teacher, desk officer, etc.
****student, housewife, etc.

Table 2. Fracture demographics based on AO classification

Region/Bone	Metacarpals (32)			
Finger	Index (2)	Middle (3)	Ring (4)	Small (5)
	5	7	12	8
Segment		Fracture pattern		
Proximal (1)	7	Extraarticular (A)		6
		Partial articular (B)		0
		Complete articular (C)		1
Diaphyseal (2)	20	Simple (A)		20
		Wedge (B)		0
		Comminuted (C)		0
Distal (3)	5	Extraarticular (1)		5
		Partial Articular (2)		0
		Complete Articular (3)		0
Region/ Bone	Proximal Phalanx (40)			
Finger	Index (2.1)	Middle (3.1)	Ring (4.1)	Small (5.1)
	12	9	10	9
Segment		Fracture pattern		
Proximal (1)	13	Extraarticular (A)		8
		Partial articular (B)		1
		Complete Articular (C)		4
Diaphyseal (2)	23	Simple (A)		15
		Wedge (B)		3
		Comminuted (C)		5
Distal (3)	4	Extraarticular (1)		4
		Partial Articular (2)		0
		Complete Articular (3)		0

Most patients had single bone involvement (N = 41, 76%), with phalangeal fractures (N = 40) being more common than metacarpal fractures (N = 32). The most common fracture configuration was transverse (50%) (Table 2).

Surgical procedure

The mean surgical time for all fractures was 40 minutes (range, 15–50 minutes). Transverse metacarpal and oblique proximal phalangeal fractures took the longest (75 and 78 minutes) and the most attempts at pin insertion (means, 3.4 times and 4.6 times). A total of 156 radiographs were taken for 54 patients, averaging 2.9 radiographs per patient (range = 1–6 radiographs). Anatomic reduction was achieved in 25 fractures (35%), most frequently in transverse configurations (64%). Among all cases, only two proximal phalangeal fractures developed fracture displacement on the final follow-up. Both cases led to malunion.

Outcome measures

Total active motion

The mean finger TAM was 246° (range, 205–270°). Thirty-three fingers (47%) had "excellent to good" TAM (mean = 258°) at 12 weeks; the rest of the fingers had "fair" TAM (mean = 235°). The mean TAM for isolated proximal phalangeal fractures (38 fingers in 32 patients) was 242.2°. The mean TAM for isolated metacarpal fractures (30 fingers in 21 patients) was 251° (Table 3). The mean TAM improved with time (Table 4; Figure 1).

Table 3. TAM of isolated proximal phalanx and isolated metacarpal fractures

	Proximal phalanx TAM [N = 38 fingers (in 32 patients)] Mean TAM: 242.2	Metacarpal TAM [N = 30 fingers (in 21 patients)] Mean TAM: 251
Excellent (260-270)	7 (18.4%)	9 (30%)
Good (250-259)	7 (18.4%)	8 (26.7%)
Fair (200-249)	24 (63.2%)	13 (43.3%)
Poor (<200)	0	0

Table 4. Mean Total Active Motion (TAM)*

	6th week	9th week	12th week
Index finger	178 (155-215)	219 (190-255)	246 (205-265)
Long finger	186 (150-245)	216 (190-255)	246 (230-270)
Ring finger	178 (140-250)	209 (165-255)	245 (210-270)
Small finger	179 (130-255)	214 (135-265)	245 (220-265)

*Eberlin KR et al.[7]: TAM Interpretation: Excellent: 260-270; Good: 250-259; Fair: 200-249; Poor: >200

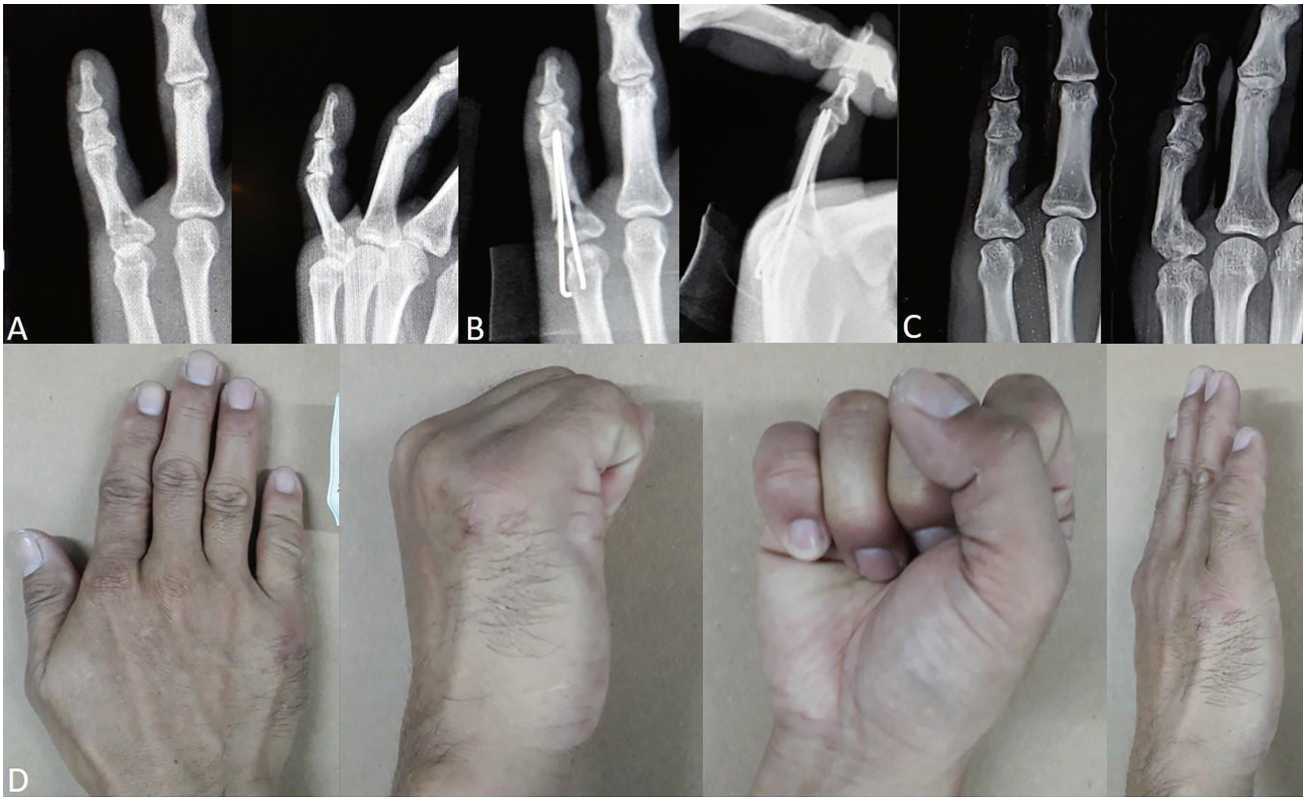

Figure 1. Patient 24 with small finger proximal phalangeal fracture. Injury radiograph **(A)**, immediate postoperative radiograph **(B)**, radiograph at 12th week follow-up **(C)**, range of motion at 12th week follow-up **(D)**.

DASH scores

Forty-one patients (76%) had DASH scores (mean score 4.9) corresponding to "no longer considering their injury a problem" at 12 weeks. Thirteen patients (24%) had scores (mean = 13.5) corresponding to "still aware of their limitations." No patient had a DASH score corresponding to "having a lot of difficulty in their daily chores."[13]

Time to union and removal of pins

The mean time to radiographic union was six and a half weeks (4–10 weeks). Pins were removed at an average of eight weeks after surgery (6–9.8 weeks). No non-union was observed.

Complications

There were 14 complications in 54 patients (26%). These were extensor lag (7), stiffness (5), and malrotation (2) (Table 5; Figure 2). Complaints of mild pains and irritation from the buried pins were immediately relieved after pin removal.

Analysis of data

Duration of surgery

There was no significant correlation between the duration of surgery (in hours) and DASH scores ($r = 0.03$; $p = 0.85$).

DISCUSSION

Roentgen's discovery of X-rays in 1895 led to the development of an objective tool for evaluating bones and fractures.[14] The use of conventional radiography allowed for a detailed assessment of skeletal injuries and treatment outcomes. Real-time visualization, known as fluoroscopy, was eventually developed for visualization of fracture reduction and fixation intraoperatively.[14] Since then, fluoroscopic imaging has been an indispensable tool in orthopaedic practice, particularly in modern hand surgery.[15,16] Conventional radiography continues to be used for skeletal evaluation but has become less popular as an intra-operative imaging tool.

Despite fluoroscopy's utility and convenience, its accuracy has been questioned. A study found that intra-articular step-off and displacement of simulated Bennett's fractures in cadavers were underestimated by fluoroscopy after CRPP.[17] Another study showed that fluoroscopy underestimates the length of smooth pins protruding from upper extremity bone models.[18] These observations are critical in closed percutaneous pinning of fractures, especially with intra-articular involvement.

Numerous studies have evaluated the functional outcomes of pinning in hand fractures. Hsu reported minimal complications with pinning of phalangeal, metacarpal, and wrist bone fractures.[19] A study by Eberlin showed good to excellent results, with only 7% developing stiffness requiring tenolysis, and only two cases of pin site infection after phalangeal

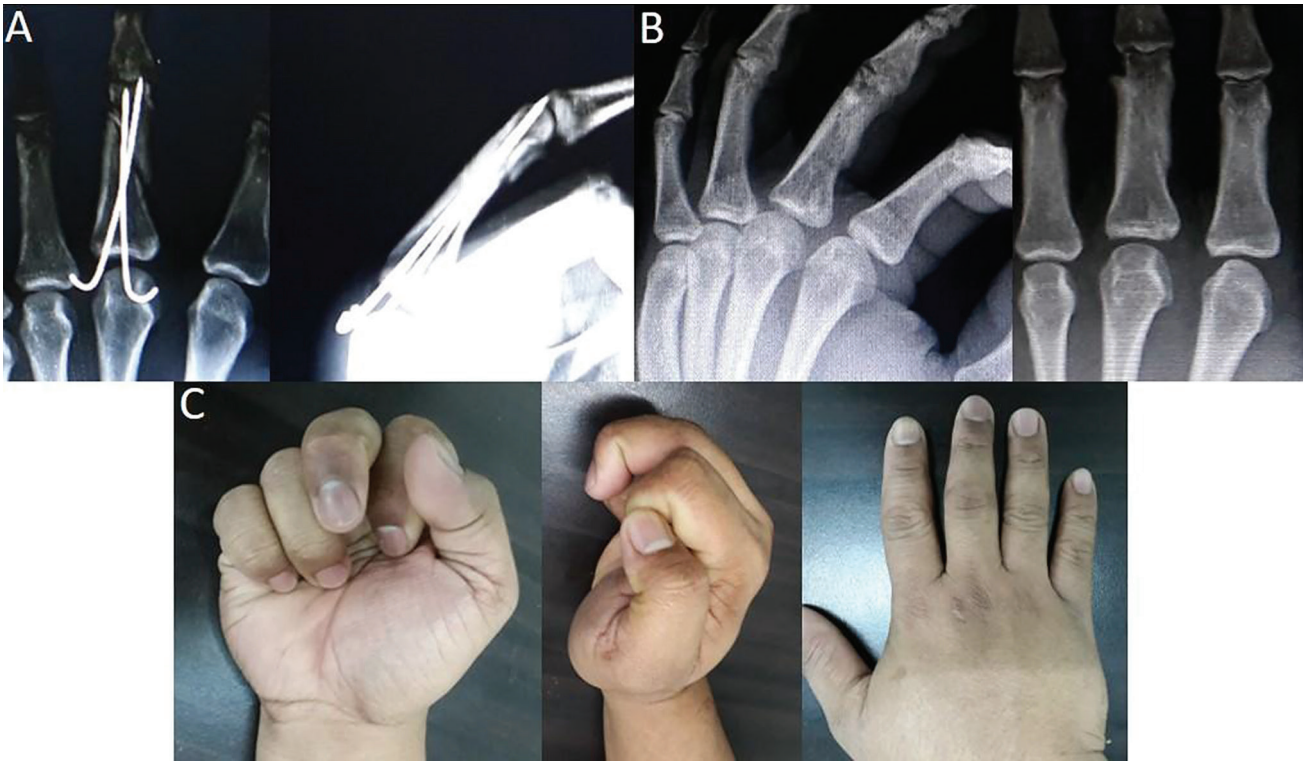

Figure 2. Patient 12 with malrotation noted at the final follow up. Immediate post-operative radiograph **(A)**, radiograph at final follow-up **(B)**, range of motion at final follow-up showing malrotation of middle finger **(C)**.

Table 5. Patients with complications

Patient number	Age/ Gender	Complication	Mechanism of injury	Fracture pattern	Days with pin	Surgical time in hours	Pinning attempts	Anatomic reduction
6	40/M	Extension lag	Industrial accident	Spiral MC	50	1	5	No
7	22/M	Extension lag	Motor vehicular accident	Transverse MC	54	1	4	No
8	48/M	Stiff finger	Fall from height	Oblique P1	54	1	4	No
9	57/M	Stiff finger	Industrial accident	Multiple P1	45	2	5	No
12	23/M	Malrotation	Motor vehicular accident	Spiral P1	58	1	4	No
22	32/M	Stiff finger	Industrial accident	Transverse P1	47	0.75	2	No
23	19/M	Extension lag	Sports injury	Transverse P1	55	0.5	2	No
27	58/M	Extension lag	Industrial accident	Mild Comminution P1	68	0.25	2	No
31	43/M	Extension lag	Industrial accident	Multiple P1	63	0.5	2	No
47	36/F	Malrotation	Sports injury	Mild Comminution P1	59	0.5	2	No
50	26/M	Stiff finger	Industrial accident	Transverse MC	52	1	4	No
51	26/M	Stiff finger	Motor Vehicular accident	Spiral P1	60	0.5	2	Yes
52	22/M	Extension lag	Fall from height	Multiple P1 MC	52	1	3	Yes
59	21/M	Extension lag	Motor vehicular accident	Oblique MC	69	0.25	1	Yes

P1 = Proximal Phalanx; MC = Metacarpal

pinning.[8] Faruqui however, found a significant decrease in TAM in almost half of the fingers treated with phalangeal trans-articular or extra-articular pin fixation.[20] Although it is now standard to do this procedure under fluoroscopy, modifications were adopted in low-resource settings. It was for the same reason that our patients agreed to proceed with the surgery despite lacking fluoroscopy. With this limitation, surgery became more difficult but functional outcome was not far behind compared to previous studies. The mean TAM score for isolated proximal phalangeal fractures was 242.2° (fair), while the score for isolated metacarpal fractures was 251° (good). Unfortunately, these previous studies lack consistency in reporting TAM for accurate comparison.[8,18,21–25]

The absence of real-time imaging during the performance of CRPP in this series was challenging. Actual restoration of length, rotation, and alignment were accomplished "blind" with just traction and palpation of these bones. The sequential radiographs confirmed the adequacy of fracture reduction and fixation. Generally, anatomic restoration of a fractured bone is desired. In the finger, however, a stable, functional reduction of shaft fractures is enough for a favorable outcome

and acceptable function.[26] In this series, less than half (35%) achieved anatomic reduction, while the rest fell within acceptable parameters. Oblique proximal phalangeal and transverse metacarpal fracture fixations were more challenging than the others as shown by more pinning attempts and longer surgical time. Still, TAM and DASH scores were good. This confirmed the observations of Baldwin, who found that radiographic findings do not always correlate with functional recovery.[5]

Early joint mobilization has been shown to improve finger motion in proximal phalangeal pinning.[23,26,27] The stable fixation achieved in this group allowed for immediate mobilization. In addition, performing the procedure under WALANT allowed the surgeons to give timely instructions, which provided patients with a better understanding of their condition and the surgery, as well as the confidence to perform early active exercises.[28] Both early mobilization and performance under the WALANT technique proved beneficial for this group.

Among the benefits of CRPP done under conventional radiography is the possibility of lower radiation exposure compared to a fluoroscopic-guided procedure.[10,29] Fluoroscopy has been found to expose both the patient and the surgeon to a greater amount of ionizing radiation,[30–32] which in turn may cause deleterious effects on the eyes, thyroid, and hands.[14,32] Despite refinements made in more compact mobile fluoroscopic devices such as the "mini C-arm", associated radiation risks have not been significantly mitigated. The mini C-arm for example, may release lower ionizing radiation, but the machine layout brings the beam source closer to the surgeon.[29,33] This, combined with a false sense of safety, can lead to longer use with direct exposure of the hand while performing surgery.[14,29,30,32]

Complications reported in this study were comparable to previous studies.[8,19,20] The two malunions were phalangeal malrotations, which may have resulted from gradual loss of reduction during active mobilization. These two patients did not achieve an anatomic reduction from the beginning of treatment and were inconsistent with follow-up. The soft tissue complications reported (five cases of stiffness and seven cases of extension lag) were considered by the patients as mild and did not cause restrictions in their daily activities. The causes were multifactorial and associated with high-impact injury, non-anatomic fracture reduction, and a longer stay of pins (Table 4).

The decision to bury Kirschner wires underneath the skin in this study stems from the anecdotal experience of the lead author in the local setting. Most patients in this study are members of the labor sector, and early return to work was key to remaining employed. Hence, buried pins prevented accidental implant pullout while working, and minimized potential areas for infection.

LIMITATIONS

The main limitation of this study was irregular patient follow-up. Over half of patients were unable to comply with scheduled consults every three weeks, and only 20% were able to follow-up beyond 12 weeks. The primary reason for this was occupation-related. For some of these patients, telephone interviews were conducted to augment actual follow-up. This was a potential source of bias.

Surgeons that performed the procedure were orthopaedic residents-in-training. The procedure's learning curve and the varying levels of skill affect the quality of reduction and fixation. The number of previous similar cases performed as well as the number of weeks spent learning in the Hand Surgery Unit may have influenced the duration and quality of the surgical intervention. Likewise, TAM measurements should have been repeated by a second investigator to eliminate bias.

This study reported short-term outcomes. Long-term follow-up, although difficult to achieve, can provide a better picture of functional outcomes and potential late complications. Similarly, another study on CRPP done under fluoroscopy in the same institution in the future may provide a more valid comparison for this study.

CONCLUSION

While we don't recommend choosing conventional radiography over fluoroscopy in performing CRPP for proximal phalangeal and metacarpal fractures, it was a good alternative. The option for open reduction with internal fixation would require more expense and preparations for the patient, and aggravate the long queue for surgery at the operating theater. This technique was reliable even in the hands of a novice orthopaedic surgeon, was useful for most fracture configurations, and was associated with favorable early outcomes.

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STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

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Appendix. Patients with demographics and injury details

Pt #	Age	Sex	Occupation	Dominant hand involvement	Mechanism of injury	Diagnosis	Complaints / Complications
1	46	M	Maintenance worker	no	Industrial accident	proximal phalanx, small finger	none
2	44	M	Businessman	no	Motor vehicle accident (MVA)	metacarpal, long finger	none
						metacarpal, ring finger	
4	28	M	Factory worker	yes	Industrial accident	proximal phalanx, index finger	none
5	21	M	Student	no	MVA	proximal phalanx, small finger	none
6	40	M	Construction worker	no	Industrial accident	metacarpal, ring finger	Extension lag
7	22	M	Call center agent	yes	MVA	metacarpal, index finger	Extension lag
8	48	M	Clothing ironing man	no	fall from height	proximal phalanx, index finger	Stiff finger
9	57	M	Factory worker	no	Industrial accident	proximal phalanx, index finger	Stiff finger
						proximal phalanx, long finger	
						proximal phalanx, ring finger	
11	25	M	Carpenter	yes	Industrial accident	proximal phalanx, index finger	none
12	23	M	Food vendor	yes	MVA	proximal phalanx, long finger	malrotation
13	29	M	Liaison officer	no	MVA	proximal phalanx, index finger	None
14	56	M	Mechanic	yes	Industrial accident	metacarpal, ring finger	None
15	44	M	Mechanic	no	Industrial accident	metacarpal, index finger	None
						metacarpal, long finger	
						metacarpal, ring finger	
17	25	M	Machine operator	yes	MVA	proximal phalanx, long finger	None
18	22	M	Construction worker	no	Industrial accident	proximal phalanx, index finger	none
19	31	M	Service Crew	no	MVA	proximal phalanx, index finger	None
20	43	M	Mechanic	no	Industrial accident	metacarpal, small finger	None
21	17	M	Student	yes	sport injury	proximal phalanx, ring finger	None
22	32	M	Factory worker	yes	Industrial accident	proximal phalanx, index finger	Stiff finger
23	19	M	Student	yes	sports injury	proximal phalanx, index finger	Extension lag
24	44	M	Book keeper	yes	MVA	proximal phalanx, small finger	None
25	18	M	Student	no	sport injury	proximal phalanx, long finger	None
						proximal phalanx, ring finger	
27	58	M	Unemployed	no	fall from height	proximal phalanx, ring finger	Extension lag
28	59	M	Driver	yes	Industrial accident	proximal phalanx, ring finger	None
29	35	M	Factory worker	yes	MVA	proximal phalanx, ring finger	None
30	30	M	Construction worker	no	Industrial accident	proximal phalanx, long finger	None
						proximal phalanx, ring finger	
31	43	M	Machine operator	yes	Industrial accident	proximal phalanx, ring finger	Extension lag
						proximal phalanx, small finger	
32	65	F	Engineer	no	Industrial accident	proximal phalanx, small finger	None
						metacarpal, small finger	
34	28	M	Barista	no	MVA	proximal phalanx, small finger	None
36	53	M	Driver	yes	MVA	metacarpal, small finger	None
37	44	M	Guard	yes	MVA	metacarpal, ring finger	None
						metacarpal, small finger	
38	28	M	Machine operator	no	Industrial accident	metacarpal, index finger	None
						metacarpal, long finger	
						metacarpal, ring finger	
39	29	M	Merchandiser	no	MVA	proximal phalanx, long finger	None
						proximal phalanx, ring finger	
						proximal phalanx, small finger	
						metacarpal, small finger	
40	24	M	Real estate agent	yes	Punched the wall	metacarpal, small finger	None
41	32	M	Teacher	yes	MVA	metacarpal, long finger	None
42	40	M	Messenger	no	MVA	metacarpal, long finger	None
43	51	M	Construction worker	yes	Industrial accident	metacarpal, ring finger	None
						metacarpal, small finger	
44	21	M	Carpenter	yes	Industrial accident	proximal phalanx, ring finger	None
45	15	M	Student	yes	Punched the wall	metacarpal, ring finger	None

Appendix. Patients with demographics and injury details *(continued)*

Pt #	Age	Sex	Occupation	Dominant hand involvement	Mechanism of injury	Diagnosis	Complaints / Complications
46	21	F	Machine operator	yes	MVA	proximal phalanx, index finger	None
						proximal phalanx, long finger	
47	36	F	Housewife	no	sports injury	proximal phalanx, ring finger	malrotation
48	29	M	Helper	no	Industrial accident	metacarpal, ring finger	None
						metacarpal, small finger	
49	23	M	Crane assistant	no	Industrial accident	proximal phalanx, index finger	None
50	26	M	Delivery Helper	yes	Industrial accident	metacarpal, small finger	Stiff finger
51	26	M	Merchandiser	yes	MVA	proximal phalanx, long finger	Stiff finger
52	22	M	Unemployed	yes	fall from height	metacarpal, index finger	Extension lag
						metacarpal, long finger	
53	42	M	Tailor	no	MVA	proximal phalanx, small finger	None
54	23	M	IT consultant	no	MVA	metacarpal, long finger	None
						metacarpal, ring finger	
55	16	M	Student	yes	sports injury	proximal phalanx, long finger	None
56	59	M	construction worker	yes	industrial injury	metacarpal, ring finger	None
57	46	M	carpenter	yes	fall from height	proximal phalanx, index finger	None
58	15	M	student	yes	sport injury	proximal phalanx, small finger	None
59	21	M	service ambassador	no	MVA	metacarpal, ring finger	Extension lag
60	26	M	elctrical technician	yes	industrial injury	metacarpal, ring finger	None

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ORIGINAL ARTICLE

Epidemiological Profile of Spine Cases in a Tertiary Care Hospital

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ABSTRACT

Introduction. The global incidence and prevalence of spine disorders are increasing with population growth. Traumatic spine injury and non-traumatic spine disorders are life-changing conditions. Despite growing literature about spine disorders, we found little published Asian epidemiological data. This study aimed to thoroughly understand the epidemiology of patients with spine disorders in our institution.

Methodology. This study utilized a descriptive retrospective cohort study design, and included patients with spine disorders admitted from January 1, 2016, to December 31, 2022. The patient records were retrieved, and data was collected according to the demographic profile, level of spinal disorders, type of management, and mortality rate.

Results. Of 474 patients with spinal disorders admitted to our institution, most were young and older adults at 31.4% and 36.3%, respectively. Most were males at 70.3%. Traumatic spinal disorders were more common at 66.2%. Infection was the most common non-traumatic disorder at 56.9%. The cervical spine was most affected by traumatic etiology (56.1%), while the thoracic spine was most affected by non-traumatic causes (57.5%). Among non-traumatic cases, infectious etiology, particularly tuberculosis, accounted for the highest number, followed by degenerative causes and tumors (74.7%, 70.0%, and 25.8%, respectively). Surgical management was primarily used for traumatic spinal disorders, while the majority of non-traumatic cases received conservative treatment (55.1% and 72.5%, respectively). There has been a steady decrease in mortality for spinal disorders for the past seven years.

Conclusion. Both traumatic and non-traumatic etiologies of spine disorders show a steady decrease in mortality rate, which may indicate an improvement in the hospital's orthopaedic spine service. The reduced mortality rates indicate improvement in spine care in the locality and can be used to advocate for public health measures.

Keywords. traumatic spine injury, non-traumatic spine injury, spine disorder epidemiology

INTRODUCTION

Spinal disorders include a heterogeneous spectrum of diseases that affect the vertebrae, intervertebral discs, facet joints, tendons, ligaments, muscles, spinal cord, and nerve roots. These conditions often lead to permanent changes in strength, sensation, and other body functions below the site of involvement. Traumatic spine injuries, especially to the cervical spine, have the worst mortality, morbidity, and disability. For a growing population of spine patients, proper treatment is crucial.[1] Traumatic spine injury remains a global health priority. It represents a burden for healthcare systems due to the expensive and complex medical support required.[2-4] In addition, this condition is a leading cause of disability due to the loss of productivity.[5,6]

The incidence of cervical, thoracic, and lumbar or sacral injuries, varies widely. In China, cervical lesions account for less

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than <5% of patients hospitalized with traumatic spine injuries, while in Turkey this percentage rises to 92%.[7] This variability may be partly explained by underreporting, the availability of treatment, and geographical and financial factors. Socio-economic disparities could play a role as indigent patients may die before receiving medical care and are therefore not detected.[8] Data are available for 41 countries, mostly European and high-income countries. Research efforts encouraged to gather information in developing and low-income countries to plan appropriate cost-effective preventive strategies.[9] Epidemiological data in China are only available for a few provinces and are mostly outdated. Updated data are needed for targeted implementation of preventive strategies.[10,11]

The incidence of non-traumatic spine disorders has increased rapidly in recent years. The incidence of non-traumatic spine disorders in Ireland was 26.9 per million per year, more than double the incidence of traumatic spine disorders (with degenerative and neoplastic conditions being the most common causes). Older females are more likely to be affected, and incomplete paraplegia is the most common neurological outcome.[12]

The incidence rates of both traumatic and non-traumatic spine disorders are higher in older individuals, particularly those in their 70s and 80s. Injuries secondary to falls and traffic accidents are the most common causes, with falls being more prevalent in older adults. Traumatic spine disorders involving the cervical spine were reportedly higher, especially in high-income countries like South Korea.[13] There is little published epidemiological data for Asia.[14] This study aimed to describe the epidemiological profile of spine disorder patients seen and managed in a tertiary government hospital in the Philippines.

METHODOLOGY

This study utilized a descriptive retrospective cohort study design and was done in Corazon Locsin Montelibano Memorial Regional Hospital (CLMMRH), a tertiary government hospital in Bacolod City, Negros Occidental. The institution's PHREB Accredited Research Ethics Review Committee approved the study. The study included all 474 admitted patients with traumatic and non-traumatic spine disorders treated by the Department of Orthopedic and Traumatology from January 1, 2016, to December 31, 2022. The study excluded patients who refused admission. Patients were screened using the hospital database. The following data was collected from the patient records: demographic profile, level of spinal disorders, management, and mortality outcomes. Statistical analysis was done using Excel and SPSS (v.26, IBM) applications. Kolmogorov-Smirnov (KS) statistic (D) was used to calculate normality, The Chi-Square Test of Independence was used to test for association among observations, and the Shapiro-Wilk statistic (W) was used to calculate normality.

RESULTS

The patients were primarily young (21 to 39 years old) and older adults (40 to 59 years old). Males were more commonly involved (70.3%). Traumatic spine disorders were more common (66.2%) than non-traumatic spinal disorders. Among non-traumatic disorders, infectious etiologies (e.g., Tuberculous infection) predominated (56.9%) (Table 1).

The cervical spine was the most affected level for traumatic spine disorders (56.1%). On the other hand, the thoracic spine was the most affected by non-traumatic etiologies (57.5%). The most common sites per non-traumatic category were the thoracic spine for infection (74.7%), the lumbar spine for degenerative (70.0%), and the thoracic spine for tumors (38.7%) (Table 2).

Traumatic cases were more likely to receive surgical management than non-traumatic spinal disorders (55.1% vs 27.5%, p <0.001) (Table 3).

Mortality for both traumatic and non-traumatic spine disorders has been decreasing for the past seven years (Figures 1 and 2). This may indicate an improvement in the hospital's orthopaedic spine service with an orthopaedic spine specialist consultant. The overall mortality rate for the past seven years was 20.7%, with no significant difference in the mortality rates between traumatic and non-traumatic cases (20.1% vs 21.9%, p = 0.1667) (Table 4).

DISCUSSION

Spine disorders and their debilitating sequelae place a considerable bio-psychological and socio-economic burden on the healthcare system, necessitating detailed epidemiologic data.[7,15] This study corroborates local and global epidemiological profiles where males and adults were the most commonly affected.[16,17] Young adults may engage in more high-risk activities, such as sports or extreme sports, which can increase their risk of fractures.[17,18] On the other hand, old

Table 1. Demographic profile of patients and test for normality

Patient characteristics	f	%	KS (D)	p
A. Age (in years)			0.155	0.338
Children (1-12)	13	2.7		
Adolescents (13-20)	53	11.2		
Young Adult (21-39)	149	31.4		
Older adult (40-59)	172	36.3		
Geriatric (60 and above)	87	18.4		
B. Sex			0.212	0.489
Male	333	70.3		
Female	141	29.7		
C. Etiology			0.174	0.730
Traumatic	314	66.2		
Non-traumatic	160	33.8		
			0.197	0.198
c1) Tumor	31	19.4		
c.2) Infectious	91	56.9		
c.3) Degenerative	30	18.8		
c.4) Deformity	8	5.0		

Note: Kolmogorov-Smirnov (KS) statistic (D) was used to calculate normality; all p-values suggest no deviation from normality.

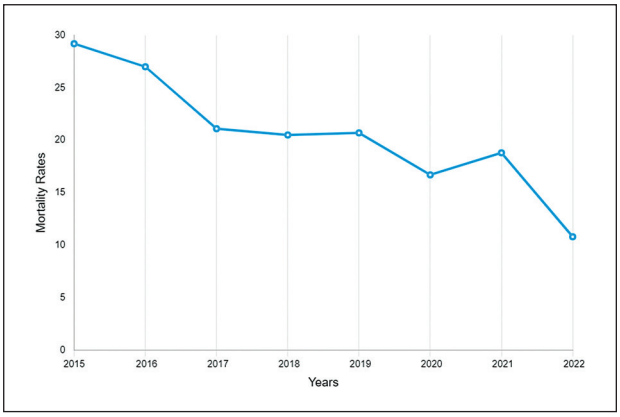

Figure 1. Mortality rates of spinal disorders for the past 7 years.

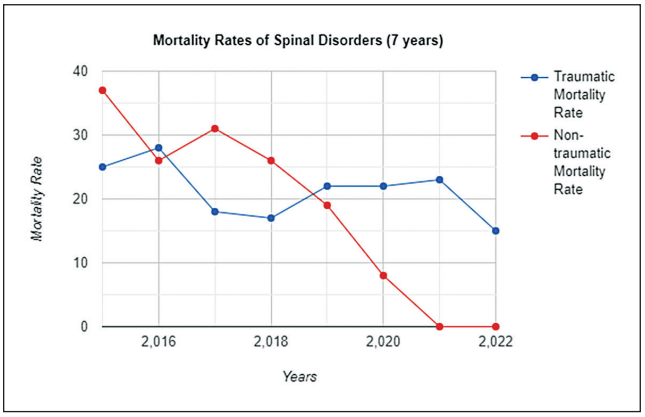

Figure 2. Mortality rates of traumatic vs non-traumatic etiologies.

Table 2. Incidence of spinal injury by spinal level according to etiology

Spinal Levels	Cervical		Thoracic		Lumbar		Sacral		N	X^2	*p*
	f	%	f	%	f	%	f	%			
Etiology										81.460	<0.001
Traumatic	176	56.1	84	26.8	51	16.2	3	0.9	314		
Non-traumatic	21	13.1	92	57.5	45	28.1	2	1.3	160		
										49.370	<0.001
c.1) Tumor	8	25.8	12	38.7	10	32.3	1	3.2	31		
c.2) Infectious	9	9.9	68	74.7	13	14.3	1	1.1	91		
c.3) Degenerative	4	13.3	5	16.7	21	70.0	0	0.0	30		
c.4) Deformity	0	0.0	7	87.5	1	12.5	0	0.0	8		

Note: The Chi-Square test of independence was used to test for association among observations.

Table 3. Management by etiology

Management	Conservative		Surgical		N	X^2	*p*
	f	%	f	%			
Etiology						32.517	<0.001
Traumatic	141	44.9	173	55.1	314		
Non-traumatic	116	72.5	44	27.5	160		
						6.6854	0.0826*
c.1) Tumor	20	64.5	11	35.5	31		
c.2) Infectious	70	76.9	21	23.1	91		
c.3) Degenerative	22	73.3	8	26.7	30		
c.4) Deformity	3	37.5	5	62.5	8		

Note: The Chi-Square test of independence was used to test for the association among observations; the asterisk (*) denotes no significant association among observations.

adults are more prone to fractures because their bones become weaker and more brittle as they age.[19,20] This is due to lower bone density, which can be caused by various factors, including hormonal changes, poor nutrition, and lack of exercise. Additionally, older adults may be more prone to falls due to balance issues or medical conditions, such as osteoporosis or arthritis.

The cervical spine was the most affected level for traumatic spine disorders while the thoracic spine was the most affected by non-traumatic etiologies such as Tuberculous infections and degenerative causes. When tuberculosis infects the lungs, it can spread to other parts of the body through the bloodstream. The proximity of the thoracic spine to the lungs makes it more susceptible to infection. In addition, the thoracic spine is surrounded by a network of blood vessels that can transport the bacterium throughout the body.[21]

Spine disorders can cause significant pain and discomfort. While there are a variety of treatment options available, surgical methods are often the most effective way to address these disorders. Surgical methods offer a more direct and targeted approach to treating spinal disorders, through decompression and stabilization with instrumentation. Surgical management of traumatic spine disorders may lead to faster and more effective relief of symptoms, as well as a reduced risk of long-term complications and mortality. Additionally, surgical methods are often necessary for severe cases.

We found few publications on non-traumatic spine disorders, but we anticipate that the incidence will increase substantially secondary to an aging population.[22] Most tumors, tuberculous infections, and degenerative disorders of the spine undergo conservative treatment, while deformities undergo surgical correction. The high incidence of non-traumatic spine disorders in older adults in other high-income countries is consistent with our findings. In Norway and Scotland, non-traumatic spine disorders were more prevalent in older adults aged 60–74 years and 66–75 years, respectively.[23-25] A prospective population-based study in Ireland found the highest incidence in adults 76 years and older.[26] Similarly, studies from Canada, Finland, and Australia found a higher incidence in adults aged 61 to 70 years.[12,27,28] These non-traumatic spine disorders can cause pain, discomfort, and limited mobility. While surgery may be necessary in some cases, conservative methods are often the preferred treatment option.

Table 4. Mortality Rates of Patients per year

Year	n of Mortality	N	Mortality rate	W	*p*
All Cases:				0.9035	0.3373
2022	4	37	10.8%		
2021	3	16	18.8%		
2020	5	30	16.7%		
2019	17	82	20.7%		
2018	23	112	20.5%		
2017	26	123	21.1%		
2016	20	74	27.0%		
Total	98	474	20.7%		
Traumatic:				0.8897	0.2503
2022	4	27	14.8%		
2021	3	13	23.1%		
2020	4	18	22.2%		
2019	11	50	22.0%		
2018	11	65	16.9%		
2017	17	94	18.1%		
2016	13	47	27.7%		
Total	63	314	20.1%		
Non-traumatic:				0.9182	0.4575
2022	0	10	0.00%		
2021	0	3	0.00%		
2020	1	12	8.33%		
2019	6	32	18.8%		
2018	12	47	25.5%		
2017	9	29	31.0%		
2016	7	27	25.9%		
Total	35	160	21.9%		

Note: Shapiro-Wilk statistic (W) was used to calculate normality; all p-values suggest no deviation from normality.

Overall, the incidence and prevalence of traumatic and non-traumatic spine disorders vary from nation to nation, and most surveys were conducted in developed regions.[2,29,30] In the last 7 years, there has been a significant reduction in the number of deaths caused by spine disorders in our locality. This reduction can be attributed to several factors, including improved spine care, available medical technology, increased awareness, and better treatment options. Regardless of the setting and anatomical level of the associated spinal cord injury, patients with traumatic etiology of spine disorders are at increased risk of premature death.[31] There are wide geographical variations in the reported incidence, prevalence, and mortality related to spine disorders. This can be partly explained by differences in the mechanism of injury, demographic characteristics of patients, and cultural and lifestyle differences.[32] The mortality rates in the first year post-injury are still generally high, and significantly higher than those observed at greater distance from the accident.[33] High cervical traumatic spine injuries such as levels C1–C4 were associated with the highest mortality rates at all time points, especially one month after the injury, as confirmed by previous studies.[6,8] Factors contributing to the reduction in deaths from traumatic spine disorders are increased awareness and public education campaigns aimed at raising awareness about the recognition of the burden, outcomes, and prevention of spine disorders. This includes the use of protective gear in motorsports, precautions in lifestyle activities, maintaining a healthy lifestyle, exercising regularly, and seeking medical attention at the first sign of symptoms.

CONCLUSION

The cervical spine was the most affected level for traumatic spine disorders while the thoracic spine was the most affected level for non-traumatic spine disorders. Decreasing mortality rates may indicate improvements in spine trauma care, prompt diagnosis, strengthening of spine rehabilitation services, and support services. Both traumatic and non-traumatic spine disorders have significant determinants that can aid clinical decision-making.

Our sample size was relatively small because we excluded outpatient cases, usually those with deformity and degenerative etiologies. This data set may be used as a baseline for future analytical and epidemiological studies focused on specific etiologies.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

Table 5. Mortality rates of non-traumatic spinal disorders

Non-traumatic Etiologies	n of Mortality	N (2022-2016)	Mortality rate	W	*P*
c.1) Tumor	9	31	29.0%	0.8711	0.1664
c.2) Infectious	19	91	20.9%	0.8804	0.2044
c.3) Degenerative	6	30	20.0%	0.8105	0.045*
c.4) Deformity	1	8	12.5%	0.4186	<0.001*

Notes: Shapiro-Wilk statistic (W) was used to calculate normality; all p-values suggest no deviation from normality; the asterisk (*) denotes significant deviation from normality. Data were reported in summary due to a lack of sample size.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

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ORIGINAL ARTICLE

Onset and Duration of Anesthesia of Varying Lidocaine and Epinephrine Concentrations Used in WALANT: A Randomized Double-Blind Comparative Study

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ABSTRACT

Background. Wide awake local anesthesia no tourniquet (WALANT) is an increasingly popular anesthetic technique used in hand surgery which uses local anesthetic and epinephrine, achieves adequate anesthesia, and eliminates the need for a tourniquet.

Objective. This study compares the onset and duration of the three most commonly used concentrations of lidocaine and epinephrine for WALANT.

Methodology. This was a randomized double-blind comparative study of 78 middle fingers subjected to either 1% lidocaine with 1:100,000 epinephrine, 0.5% lidocaine with 1:200,000 epinephrine or 0.25% lidocaine with 1:400,000 epinephrine. The pinprick test was used to measure onset time and anesthetic duration for the local effect and as a digital nerve block.

Results. The contents of each treatment arm were as follows: Arm A: 0.25% lidocaine with 1:400,000 epinephrine, Arm B: 1% lidocaine with 1:100,000 epinephrine, and Arm C: 0.5% lidocaine with 1:200,000 epinephrine. Arm B had the shortest onset time (30.77 ± 10.39 seconds for local, 2.78 ± 0.69 minutes for digital block) followed by Arm C (38 ± 17.17 seconds for local, 4.30 ± 1.62 minutes for digital block) and Arm A (55.38 ± 18.48 seconds for local, 5.18 ± 1.46 minutes for digital block, p <0.001). A longer duration of anesthesia was achieved in both local and digital blocks for Arm B (5.07 ± 0.34 hours for local, 4.26 ± 0.33 hours for digital block) followed by Arm C (4.44 ± 0.31 hours for local, 3.36 ± 0.24 hours for digital block) then Arm A (3.01 ± 0.33 hours for local, 2.29 ± 0.29 hours for digital block, p <0.001).

Conclusion. Higher concentrations of lidocaine and epinephrine provided faster onset and longer duration of anesthesia for both local block and digital nerve block. Lower concentrations in higher volumes may be sufficient for short procedures (less than three hours).

Keywords. WALANT, onset, duration, local anesthesia, digital block

INTRODUCTION

Wide-awake local anesthesia, no tourniquet (WALANT) is a technique commonly employed in hand surgery where a mixture of lidocaine and epinephrine is injected in a tumescent fashion over the surgical field.[1] Advantages of this technique include achieving hemostasis without the use of a tourniquet due to the effect of epinephrine, eliminating the need for sedation resulting in decreased operative time, and permitting intraoperative assessment leading to improved results of tendon repairs, transfers, and hand fracture fixations.[2]

Lidocaine with epinephrine is generally safe with a maximal dose of 7 mg/kg. The concentrations of lidocaine and epinephrine are adjusted based on the anticipated required

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anesthetic volume. If 50 ml or less is needed, 1% lidocaine with 1:100,000 epinephrine is used. For procedures requiring 50–100 ml, 0.5% lidocaine with 1:200,000 epinephrine is used. If 100-200 ml is needed, 0.25% lidocaine with 1:400,000 epinephrine is used.[3] It was presumed that even with varying concentrations of lidocaine and epinephrine, sufficient anesthetic effect would be achieved for common procedures lasting roughly less than two hours.

The study aimed to compare and assess the clinical utility of three different lidocaine and epinephrine concentrations commonly used in WALANT in terms of anesthetic onset time and duration.

METHODOLOGY

Thirty-nine individuals aged 18 to 60 with uninjured hands were invited to participate in this randomized double-blind comparative study upon approval from the Institutional Review Board and Ethical Review Board. The participants were informed regarding the planned interventions and gave consent. Participants were excluded from the study if they had a known allergy to local anesthesia, existing cardiovascular disease, peripheral neuropathy, liver disease, hypercoagulable state, immunocompromised state, pregnancy, chronic pain, daily sedative or analgesic use, local skin infection, and needle-phobia. After screening by the primary author, the second author randomized eligible participants using Research Randomizer (Version 4.0) [Urbaniak, G. C., & Polus, S. (2013)] to three groups. The second author prepared three different anesthetic mixtures. The three treatments—1% lidocaine with 1:100,000 epinephrine [49 ml of normal saline solution (NSS), 50 ml of 2% lidocaine, 1 ml of 1:1,000 epinephrine], 0.5% lidocaine with 1:200,000 epinephrine (74.5 ml of NSS, 25 ml of 2% lidocaine, 0.5 ml of 1:1,000 epinephrine) and 0.25% lidocaine with 1:400,000 epinephrine (86.75 ml of NSS, 12.5 ml of 2% lidocaine, 0.25 ml of 1:1,000 epinephrine)—were randomly assigned to three groups: Arm A, Arm B and Arm C. The contents of each arm were not disclosed to the primary author and the participants.

The study was done in the Emergency Room setting to manage possible adverse events. Both middle fingers of each participant were randomly assigned to an anesthetic solution for injection. For each middle finger, the anesthetic was aspirated aseptically from the previously prepared mixtures. After preparing the finger with an antiseptic solution, the volar surface of each proximal phalanx was pinched for sensory distraction. The single-injection volar subcutaneous block technique was used for each finger.[4] Using a syringe with the respective anesthetic and a 27-gauge needle, the needle was introduced perpendicularly into the subcutaneous space at midline of the proximal digital flexion crease, and 2 ml of anesthetic was injected.[4] The time of onset and duration of anesthesia for both the local effect at the injection site and digital nerve block at the finger pulp were measured using the pinprick test (using a safety pin) every 10 seconds. The onset of anesthesia was measured from the time of injection up to the disappearance of pain on the pinprick test, and the duration of anesthesia was measured from the disappearance of pain until pain sensation returned on the pinprick test every 5 minutes.

Descriptive statistics were used to summarize the demographic and clinical characteristics of the participants. Frequency and proportion were used for categorical variables and mean and SD for normally distributed continuous variables. One-way ANOVA and Fisher's exact test were used to determine the differences in mean and frequency, respectively, among the groups. Null hypotheses were rejected at 0.05 α-level of significance.

RESULTS

There were 39 participants (78 middle fingers) subjected to anesthesia in this study. The mean age was 25 years old with most being males ($n = 28$). There were no statistically significant differences in the baseline demographic data between the three groups (Table 1). The contents of each arm were as follows: Arm A: 0.25% lidocaine with 1:400,000 epinephrine, Arm B: 1% lidocaine with 1:100,000 epinephrine, and Arm C: 0.5% lidocaine with 1:200,000 epinephrine.

For the local onset of anesthesia, 1% lidocaine with 1:100,000 epinephrine had the fastest onset (30.77 $\pm$ 10.39 seconds) followed by 0.5% lidocaine with 1:200,000 epinephrine (38 $\pm$ 17.17 seconds) and 0.25% lidocaine with 1:400,000 epinephrine (55.38 $\pm$ 18.48 seconds) (Table 2). The same observation was found for the digital nerve blocks. One percent lidocaine with 1:100,000 epinephrine had the fastest onset (2.78 $\pm$ 0.69 minutes) followed by 0.5% lidocaine with 1:200,000 epinephrine (4.30 $\pm$ 1.62 minutes) and 0.25% lidocaine with 1:400,000 epinephrine (5.18 $\pm$ 1.46 minutes) (Table 2). The differences in onset times for local (p <0.001) and digital nerve block ($p < 0.001$) of the three groups were found to be statistically significant.

Statistically significant differences were also found for the duration of anesthesia of the three groups for local ($p < 0.001$) and digital blocks (p <0.001). One percent lidocaine with

Table 1. Demographic profile of participants

	Anesthetic mixtures				*P*-value
	Total (n = 78)	Arm A (n = 26)	Arm B (n = 26)	Arm C (n = 26)	
Age (Mean)	25.21 (SD 2.67)	25.23 (SD 2.80)	25.15 (SD 2.60)	25.23 (SD 2.70)	0.993
Sex (Frequency (%))					1.000
Male	56 (71.79)	18 (69.23)	19 (73.08)	19 (73.08)	
Female	22 (28.21)	8 (30.77)	7 (26.92)	7 (26.92)	

Table 2. Onset of anesthesia

	Anesthetic mixtures			*P*-value
	Arm A (n = 26)	Arm B (n = 26)	Arm C (n = 26)	
Local, seconds (Mean)	55.38 (SD 18.48, Range 32–93)	30.77 (SD 10.39, Range 15–65)	38 (SD 17.17, Range 15–92)	**<0.001***
Digital, minutes (Mean)	5.18 (SD 1.46, Range 3.24–9.12)	2.78 (SD 0.69, Range 1.12–4.22)	4.30 (SD 1.6, Range 1.8–7.97)	**<0.001***

*statistically significant

Table 3. Duration of anesthesia

	Anesthetic mixtures			*P*-value
	Arm A (n = 26)	Arm B (n = 26)	Arm C (n = 26)	
Local, hours (Mean)	3.01 (SD 0.33, Range 2.37–3.82)	5.07 (SD 0.34, Range 4.2–5.9)	4.44 (SD 0.31, Range 3.52–4.92)	**<0.001***
Digital, hours (Mean)	2.29 (SD 0.29, Range 1.82–3.1)	4.26 (SD 0.33, Range 3.48–4.95)	3.36 (SD 0.24, Range 2.7–3.77)	**<0.001***

*statistically significant

1:100,000 epinephrine had the longest local anesthetic duration (5.07 ± 0.34 hours) followed by 0.5% lidocaine with 1:200,000 epinephrine (4.44 ± 0.31 hours) and 0.25% lidocaine with 1:400,000 epinephrine (3.01 ± 0.33 hours) (Table 3). For digital nerve block, 1% lidocaine with 1:100,000 epinephrine lasted the longest (4.26 ± 0.33 hours) followed by 0.5% lidocaine with 1:200,000 epinephrine (3.36 ± 0.24 hours) and 0.25% lidocaine with 1:400,000 epinephrine (2.29 ± 0.29 hours) (Table 3). There were no adverse reactions encountered during the study.

DISCUSSION

In this study, the onset time and duration of anesthesia of three different solutions containing varying concentrations of lidocaine and epinephrine were compared. The onset time and duration of anesthesia were investigated concerning their local effect and as a digital nerve block. The results showed that higher concentrations of lidocaine and epinephrine yielded shorter onset time and longer duration of anesthesia.

The same can be concluded for brachial plexus blocks, achieving shorter onset time and longer anesthetic duration with higher concentrations of lidocaine in smaller volumes.[5]

Epinephrine enhances the duration of local anesthesia. Prasetyono and Lestari compared the anesthetic onset and duration of 2% plain lidocaine and 0.2% lidocaine with 1:1,000,000 epinephrine. Longer duration was achieved even with lower lidocaine concentration due to the pharmacologic effect of epinephrine. Onset time however was observed to be more dependent on the local anesthetic concentration to achieve a shorter onset.[6] In this study, the onset times were faster with higher concentrations of lidocaine.

The average time for simple hand procedures is around 20 minutes.[7,8] This is within the anesthetic duration of 0.25% lidocaine with 1:400,000 epinephrine solution. Even when using this lower concentration, sufficient quality of anesthesia can be achieved for simple hand surgeries. Ban et al. concluded similarly after comparing three different concentrations of lidocaine in inguinal hernia mesh repairs. The study outcome showed that effective anesthesia was achieved even at lower concentrations of lidocaine.[9] Short and effective procedural anesthesia helps reduce accidental injuries and other unrecognized complications associated with prolonged anesthesia.[10]

The use of 4% vs 2% lidocaine both with 1:100,000 epinephrine has also been previously compared. The onset was faster with the 4% group, but the duration of anesthesia did not differ significantly.[11] This may suggest that the maximum duration plateaus after a certain concentration of anesthetic.

In our study, digital nerve block had shorter durations and longer onset times compared to the local block using the same concentration. This can be attributed to substance distribution and clearance. The measuring tool used in this study was more objective compared to earlier studies, which used subjective sensory perception,[9,10,12,13] in contrast to our study which used sequential pin pricks.

Lidocaine with epinephrine has long been used and is generally safe with a maximal dose of 7 mg/kg.[3] Although rare, adverse reactions associated with WALANT include fainting secondary to vasovagal response and jitters. Seizures, altered mentation and cardiac ischemia are rare severe reactions.[14] No adverse events were recorded during this study, but it is noteworthy that we achieved similar or comparable efficacy of anesthesia with lower concentrations. This further reduces the risk of possible anesthetic toxicity. The same was also observed by Song et al. who compared three different lidocaine concentrations for tension-free inguinal hernia repair under local infiltration anesthesia and determined that even the lowest concentration provided satisfactory anesthesia and pain relief.[15]

CONCLUSION

Higher concentrations of lidocaine and epinephrine provide faster onset and longer duration of anesthesia both as a local agent and in digital nerve block. Using lower concentrations in higher volumes may be sufficient for short procedures (less than three hours). For procedures which require low volumes, using higher concentrations within the allowable dose may still be beneficial to provide longer lasting post-operative analgesia.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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ORIGINAL ARTICLE

Comparing the Effectiveness of Surgical versus Medical Approaches in Managing Patients with Indeterminate Spinal Instability Neoplastic Scores

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ABSTRACT

Background. Treating indeterminate cases of spinal metastases (those with spinal instability neoplastic score [SINS] of 7–12) remains a clinical dilemma, as there are currently no well-defined recommendations for this category. This study aimed to identify the most appropriate approach for patients with indeterminate SINS by reviewing and analyzing published evidence.

Objective. To determine the effectiveness of surgical and medical approaches in managing spinal metastasis with indeterminate SINS.

Methodology. A comparative effectiveness study was conducted using systematic review and meta-analysis. A systematic search was performed in the following databases: PubMed, Embase, Cochrane Library, and Google Scholar. Studies were selected based on inclusion and exclusion criteria comparing surgical and medical approaches for indeterminate SINS. The outcomes analyzed were patients' functional status, complications, and conversion to surgery/revision surgery. Quantitative data were analyzed using Review Manager version 5.3 software, and results were reported using a forest plot.

Results. Eight studies were included in the qualitative review, and six were included for quantitative synthesis, involving 1,312 patients. In patients with spinal metastasis with indeterminate SINS, surgery resulted in less functional decline than medical management, with a pooled odds ratio (OR) of 0.50 (95% CI: 0.31, 0.81). However, significantly more complications were associated with surgery (OR of 2.6; 95% CI: 1.66, 4.08). The authors reported a pooled result of 21.19% conversion to surgery among those initially managed with a medical approach. In the initial surgery group, there was a significant reduction in conversion to surgery or revision surgery, with an OR of 0.19 (95% CI: 0.10, 0.34).

Conclusion. This study addresses the dilemma of treating spinal metastasis with indeterminate instability, advocating for surgery as the primary intervention due to its potential to improve functional outcomes and provide a satisfactory quality of life, which may, in turn, influence overall survival. This topic can be explored further including identifying a specific SINS threshold that could serve as a criterion for recommending surgery.

Keywords. spinal metastasis, spinal instability neoplastic score, surgery, vertebrectomy, medical management cement augmentation, external beam radiation therapy, stereotactic body radiation therapy

INTRODUCTION

Spinal metastasis is the most common tumor of the spine, presenting with variable clinical manifestations. It may manifest as back pain, with or without neurological compromise due to spinal cord compression, and commonly results in spinal instability.[1] Managing patients with spinal metastasis poses a significant challenge for clinicians, as it requires a multidisciplinary approach.

Treatments for spinal metastases range from medical management to invasive surgical intervention. Medical approaches include pain relievers, bisphosphonates, corticosteroids,

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chemotherapy, radiation therapy, and conservative management. Surgical intervention, on the other hand, focuses on maintaining the integrity of the spine, decompressing the spinal cord or nerves, and performing separation surgery, with options to utilize the advancements in minimally invasive treatment modalities.[2,3] In most cases, surgical intervention is supplemented with medical management. The primary goal is generally palliative, aiming to improve the quality of remaining life by providing adequate pain control, maintaining or improving neurological function and performance status, and achieving local control of the lesion.[4,5]

Multiple decision-making systems have been established, such as prognostication models (i.e., Tomita, Takahashi and Katagiri scoring systems) and principle-based systems (i.e. NOMS and LMNOP frameworks), to help determine the most appropriate treatment option for each patient.[2,3,6-10] Among the various components assessed by each decision-making system, evaluating spinal instability is particularly important, as it serves as an independent indication to consider surgical intervention.[2,3,9-11]

Spinal instability due to cancer is defined as a "loss of spinal integrity as a result of a neoplastic process that is associated with movement-related pain, symptomatic or progressive deformity, and/or neural compromise under physiologic loads."[11] The Spine Instability Neoplastic Score (SINS), introduced by the Spinal Oncology Consortium, is the most widely used classification system. It evaluates six components to determine the instability of the affected vertebral segment(s). Table 1 shows the different factors assessed and scored in SINS. A spinal lesion can have a minimum score of zero or a maximum score of 18, categorizing it as stable (SINS score of 0–6), indeterminate (SINS score of 7–12) or unstable (SINS score of 13–18).[11] Stable spinal lesions do not require surgery and are managed medically, while unstable lesions need surgical stabilization. However, indeterminate lesions present a clinical dilemma, as patients in this category require further investigation to determine if stabilization is indicated.[2,11]

Several frameworks, such as NOMS and LMNOP, use SINS to assess mechanical instability as an indication for offering surgery.[2,9,10] The NOMS framework incorporates the neurologic, oncologic, mechanical stability, and systemic considerations to facilitate decision-making in treating patients with SM.[2] On the other hand, the LMNOP system evaluates the location and level of the spine involved, mechanical instability, neurology, oncology, patient fitness, prognosis, and prior therapy to formulate a management plan.[9,10] The therapeutic approach for indeterminate SINS is unclear and inconsistent in these frameworks. This presents a clinical dilemma, as there are currently no well-defined guidelines or recommendations for managing this patient cohort. To our knowledge, few studies have specifically addressed this clinical issue. This study aimed to identify the most appropriate approach for patients with indeterminate SINS by reviewing and analyzing published evidence.

METHODOLOGY

This was a comparative effectiveness study of two treatment approaches (surgery versus medical management) for patients with indeterminate SINS, using a systematic review and meta-analysis. We searched several electronic databases, including PubMed, Embase, Cochrane Library, and Google Scholar, using the following search terms: "Spinal Metastasis AND Spinal Instability," "Spinal Instability Neoplastic Score," OR "Indeterminate (or "intermediate") Spinal Instability Neoplastic Score," with no restrictions on language. Publications from the year 2000 to 2023 were included. The inclusion and exclusion criteria are listed in Table 2. Two authors (LW, IS) independently screened all eligible full-text studies retrieved. A third author (RT) was consulted to resolve conflicts or discrepancies. A risk of bias assessment was conducted.

The interventions compared were surgery (vertebrectomy, spinal decompression with or without instrumentation and cement augmentation) and medical management (radiotherapy, including external beam radiotherapy [EBRT] or stereotactic body radiotherapy [SBRT], and chemotherapy). The selected studies utilized various outcome measures for functional status, such as the Frankel score, Karnofsky performance scale (KPS), and ambulatory status.[12,13] Additionally, the rates of complications and conversion to surgery/revision surgery were

Table 1. Spinal instability neoplastic score[11]

Elements of SINS	Score
Location	
Junctional (occiput-C2, C7–T2, T11–L1, L5–S1)	3
Mobile spine (C3–C6, L2–L4)	2
Semi-rigid (T3–T10)	1
Rigid (S2–S5)	0
Pain relief with recumbency and/or pain with movement/loading of the spine	
Yes	3
No (occasional pain but not mechanical)	1
Pain free lesion	0
Bone lesion	
Lytic	2
Mixed (lytic/blastic)	1
Blastic	0
Radiographic spinal alignment	
Subluxation/translation present	4
De novo deformity (kyphosis/scoliosis)	2
Normal alignment	0
Vertebral body collapse	
>50% collapse	3
<50% collapse	2
No collapse with >50% body involved	1
None of the above	0
Posterolateral involvement of the spinal elements (facet, pedicle or CV joint fracture or replacement with tumor)	
Bilateral	3
Unilateral	1
None of the above	0

Table 2. Inclusion and exclusion criteria

Inclusion
• Randomized controlled trials (RCTs) and controlled clinical trials (CCTs), peer-reviewed observational studies (cohort, case-control, and cross-sectional) providing data on the effectiveness of surgical intervention and medical management among patients with Spinal metastasis with indeterminate SINS
• Studies published in English or with available English translations
• Studies published from the year 2000 until year 2023
Exclusion
• Studies involving patients with a Spinal Instability Neoplastic Score (SINS) outside the range of 7 to 12
• Studies on non-metastatic spinal diseases or primary spinal tumors
• Review articles, meta-analyses, case reports, editorials, opinion pieces, and letters that do not provide original research data
• Studies with incomplete data or insufficient detail on study design, methods, outcomes, that preclude a meaningful analysis or comparison
• Duplicate studies and data

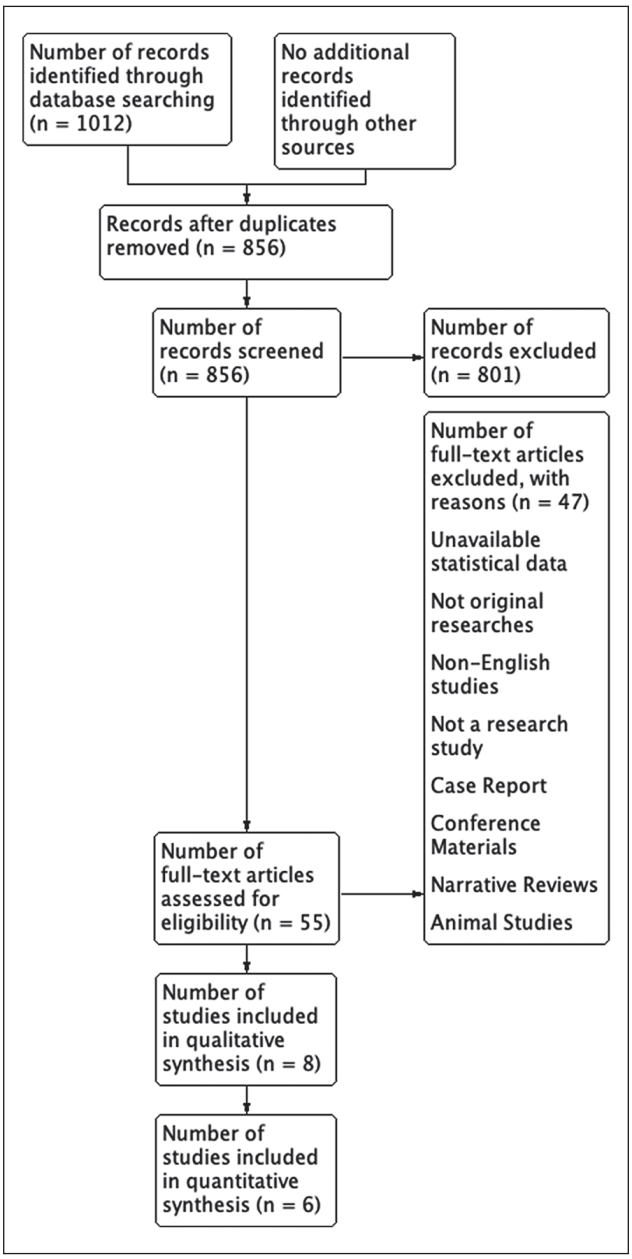

Figure 1. PRISMA Diagram of Studies Reviewed, Included and Excluded.

also measured. The studies were assessed, and the following data were extracted: research design, year of publication, location, patient population and characteristics, duration of follow-up, treatment approach, outcomes, and complications. A systematic review was conducted by obtaining data of interest, which was reported in a standardized format. For quantitative synthesis, Review Manager version 5.3 (RevMan 5.3) software was used, and results were reported using a forest plot. Heterogeneity was also assessed.

RESULTS

The search identified 1,012 articles, which were narrowed down to 55 related studies due to duplicates and exclusion criteria. The next stage involved checking for eligibility by reviewing the full-text articles of the remaining studies. The authors finally decided to include eight studies for qualitative synthesis and six studies for quantitative synthesis, involving a total of 1,312 patients with spinal metastasis classified under indeterminate SINS. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram in Figure 1 outlined the study selection process.

The overall and individual study risk of bias (Figure 2) were assessed to determine the quality and reliability of the included studies. The studies were found to have a low to moderate risk of bias. It can be assumed that the reviewed studies are reliable and have the potential to provide strong evidence for the objectives of this study.

The comparative effectiveness of surgical and medical management for spinal metastases with indeterminate SINS is summarized in Table 3. The insights were derived from seven retrospective studies and one prospective study. Zadnik et al. and Donellan et al. primarily focused on the outcomes of surgical management, while no studies specifically addressed the outcomes of medical or conservative approaches.[14,15] The remaining studies in the table compared the effectiveness and outcomes of both surgical intervention and medical management in patients with indeterminate SINS.

Zadnik et al. and Donnellan et al. presented their data on the outcomes of surgical intervention for indeterminate or impending instability, highlighting a significant difference in improved median survival days for patients undergoing surgery (435 days and 79 months, respectively).[14,15] In comparison, Dial et al. reported that surgery combined with radiotherapy offered a longer median survival (430 days vs 121 days), with statistically significant 1-year survivorship rates (59.6% vs 25.8%, with $p < 0.001$). Surgery, age, and Revised Tokuhashi score were identified as predictive factors for the length of survival in these patients. The authors emphasized how patients' performance status influenced survival among those with spinal metastasis.[16]

Regarding functional status, four studies reported on outcome measures such as the Karnofsky Performance Scale (KPS), Frankel score, and ambulation status of patients who

underwent surgery for SM with indeterminate SINS.[14,16-18] Zadnik et al. found that one month after surgery, 65% of patients with more than six months of follow-up achieved Frankel grades D or E, with 88% remaining at Frankel grade E one year after surgery, while 12% were non-ambulatory (Frankel C) at that same time.[14] Dial et al. reported that 90.4% (76 out of 84) of patients retained the ability to ambulate until their time of death.[16] Furthermore, Vargas et al. 2023 demonstrated that KPS scores improved in 60.3% of surgical patients, compared to 32.3% in those who received radiotherapy ($p < 0.001$).[17] The minority of patients experienced neurological worsening in both groups attributed to local tumor recurrence or distant tumor progression, resulting in reduced performance status and central nervous system involvement.[14,16,17] In contrast, only Lenschow et al. reported a non-significant difference in the Frankel score and ambulatory status between instrumented and non-instrumented patients.[18]

Versteeg et al. also reported a significant improvement in terms of pain control and health-related quality of life (HRQOL) among the surgical group, which was maintained up to one year after surgery. The radiotherapy-only group showed similar outcomes regarding pain and HRQOL, but these improvements were sustained only for up to 12 weeks after radiation therapy.[19] This evidence supports the improvement in the quality of life provided by surgical intervention in SM with SINS scores of 7–12.

Given the reported benefits, several authors also presented the complications associated with surgical intervention.[14,18-20] The rate of instrumentation failure after surgery was low (7.75%).[11] However, a high incidence of peri-admission complications (i.e., infection, venous thrombosis, medical-related events) was reported at about 27% to 42.3%.[18-20] Complications were also more frequent in the instrumented group (15.5%) compared to the non-instrumented group (5.1%). These complications included wound healing disorders, wound infections, material dislocation or construct failure, thrombosis, and pneumonia.[18]

Among patients initially treated with radiotherapy, vertebral compression fractures were common at the irradiated levels. The pooled conversion rate to surgery among these patients was 21.19%.[16,17,20,21] This conversion rate to surgery was significant in the first year of follow-up, with little change thereafter.[21] Surgery was indicated due to vertebral collapse, neurological deterioration, severe or intractable pain, tumor progression, and cord compression.[16,17,20,21]

Figure 3 shows the comparative outcomes between surgical and medical management across six different studies using quantitative data. The analysis was divided into three subgroups: A. Functional Status, B. Complications, and C. Conversion to Surgery/Revision Surgery. The individual study results were visually represented with squares proportional to their weight in the analysis, and horizontal lines indicate the 95% confidence intervals (CIs). The vertical line at odds ratio (OR) = 1 represents the line of no effect, where outcomes were equally likely in both groups.

Functional status

Three studies (Dial et al., Vargas et al. 2023, and Lenschow et al.,) were included in this subgroup analysis, comparing the functional status after treatment between the two interventions.[16-18] There were 360 patients in the surgical group and 252 in the medical group. The pooled odds OR was 0.50 (95% CI: 0.31, 0.81), suggesting a smaller decline in functional status favoring surgical management. A substantial heterogeneity (I^2 = 69%) indicated that the results varied significantly across the studies included.

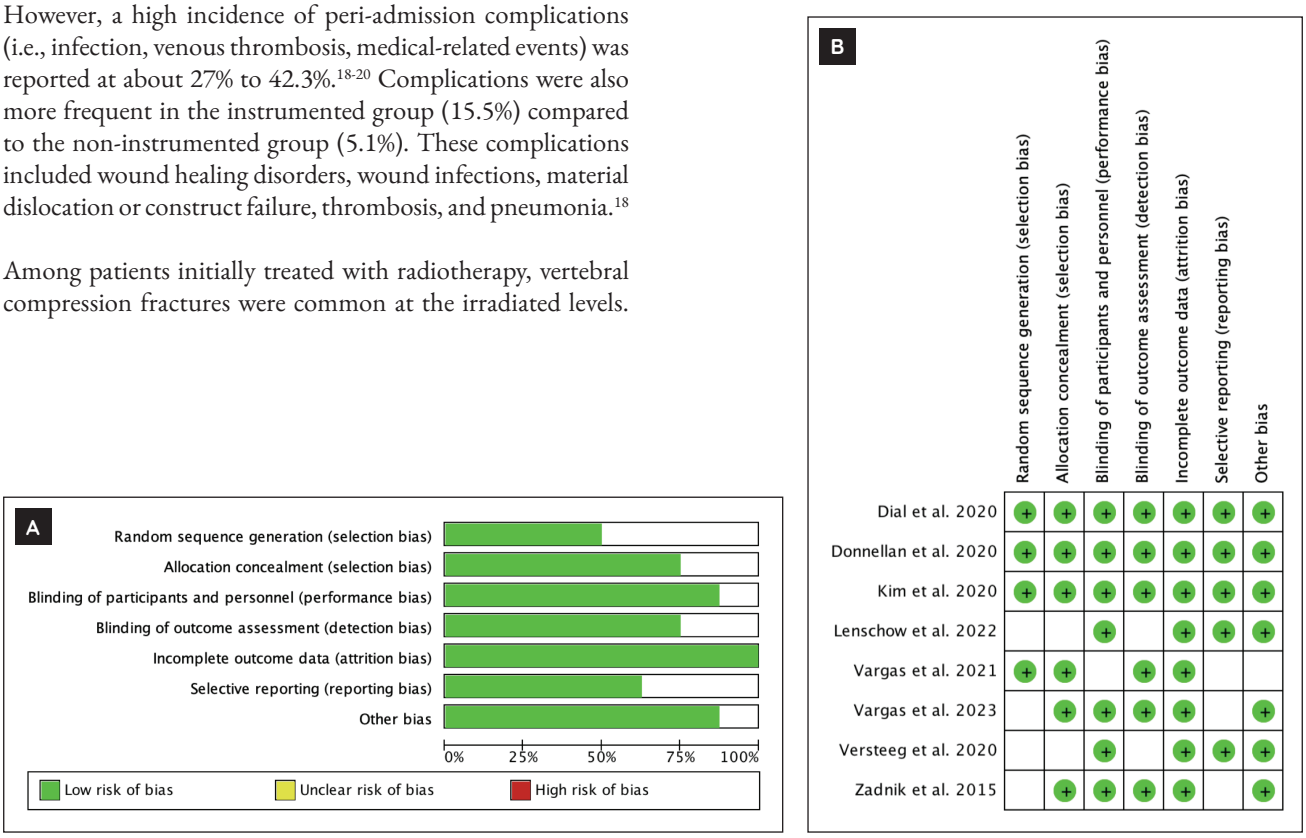

Figure 2. (A) Overall Risk of Bias Assessment. **(B)** Individual Study Risk of Bias Assessment.

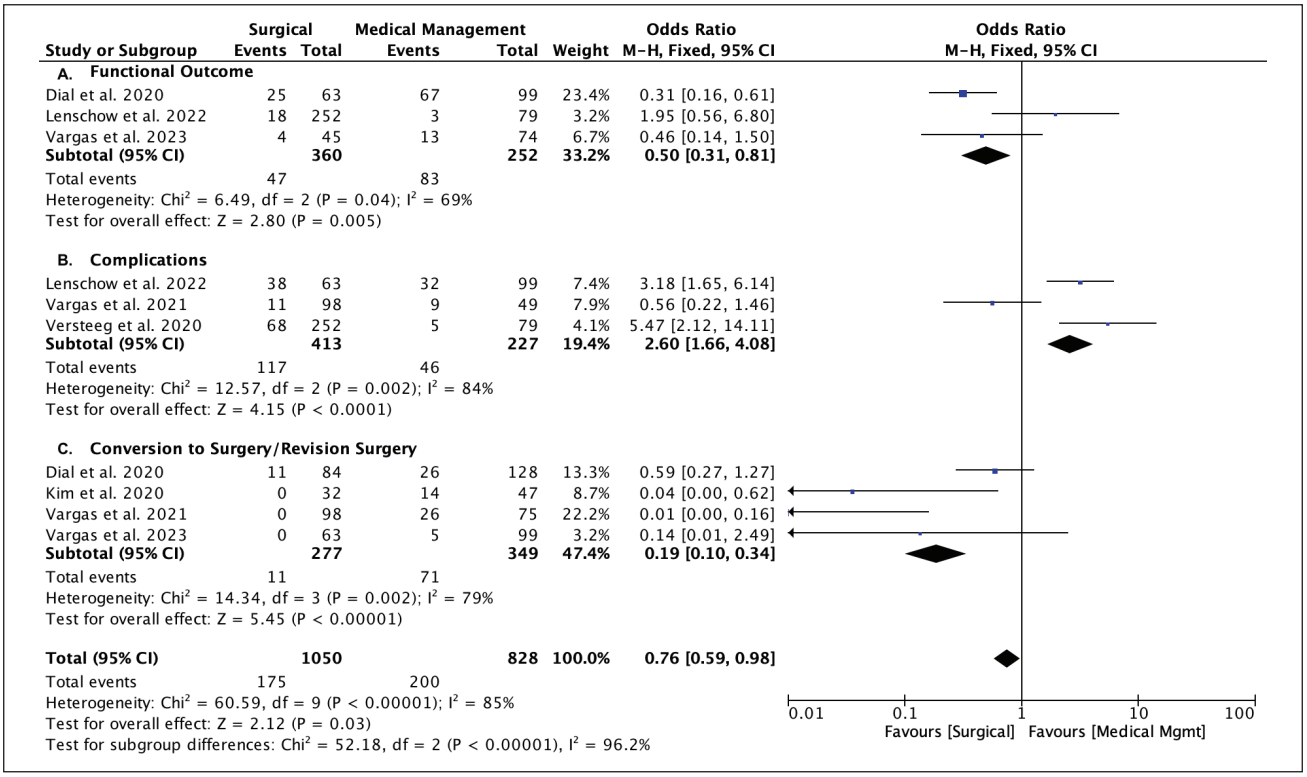

Figure 3. Effectiveness of Surgery Versus Medical Management for Spinal Metastasis with Indeterminate SINS. **(A)** Functional Outcome **(B)** Complications **(C)** Conversion to Surgery/Revision Surgery.

Table 3. Summary of the characteristics of the included studies on the effectiveness of surgery versus medical management for Spinal Metastasis with Indeterminate SINS

Author	Country	Study design	Subjects	Patient's age	Duration of treatment and follow-up	Intervention	Number of participants (n = 1,312)	Study results
Zadnik et al. 2015[14]	USA	Retrospective review	Patients with multiple myeloma with impending spinal instability	Median 58.5 years	Median follow-up 12.5 months	Surgical intervention ± chemoradiation	31 underwent surgery	Surgical intervention for multiple myeloma with impending instability resulted in improved neurological function and low rates of instrumentation failure.
Dial et al. 2020[16]	USA	Retrospective cohort study	Patients with spinal metastatic disease who were neurologically intact and had a SINS of 7 to 12	Surgery Mean Age = 59 Medical Management Mean Age = 66	The median length of follow-up for the cohort was 174 days, ranging from 4 to 2793 days	Surgery, cement augmentation and External beam radiotherapy	Surgery (84) Medical Management (128)	Patients who underwent surgery + radiation had a significantly longer length of survival and higher ability to ambulate at the time of death compared to those who received radiation alone. Ambulatory status is significantly higher among surgery and cement augmentation groups.
Donnellan et al. 2020[15]	Australia and New Zealand	Retrospective cohort study	Patients with malignancy: indeterminate stability	Mean age of 61.3 years	Covered a period of 10 years (2006-2016)	Vertebrectomy	68 underwent vertebrectomy 134 patients	The study demonstrated that SINS can be a valuable prognostic tool in predicting survival time. Patients who underwent surgery showed a statistically significant increase in survival.

Table 3. Summary of the characteristics of the included studies on the effectiveness of surgery versus medical management for Spinal Metastasis with Indeterminate SINS *(continued)*

Author	Country	Study design	Subjects	Patient's age	Duration of treatment and follow-up	Intervention	Number of participants (n = 1,312)	Study results
Kim et al. 2020[21]	South Korea	Retrospective cohort study	Patients with spinal metastasis (SINS 7-12)	Mean 61.3 years	Mean follow-up 20.9 months	Initial radiotherapy vs. surgical intervention	47 initially radiotherapy, 32 initially operative group	In patients with intermediate SINS, 33% required surgery within the first year. Tumors located in T3-T10 or with more than 50% vertebral body collapse were more likely to convert to surgery.
Versteeg et al. 2020[19]	International (multicenter)	Prospective cohort study (multi-center)	Patients with spinal metastases (SINS 7–12)	Mean: 58.9 years (SD 10.2)	Follow-up: 52 weeks	Surgery ± radiotherapy or radiotherapy alone	136 surgery ± radiation, 84 radiation only	Surgery group experienced significant improvements in pain and HRQOL; radiotherapy alone showed less sustained results.
Lenschow et al. 2022[18]	Switzerland	Retrospective observational cohort study	Patients with spinal metastases and SINS 7–12	Median: 64 years	Median follow-up: 3 months	Instrumented vs non-instrumented	252 instrumented and 79 non-instrumented patients	Non-significant difference in improvement in Frankel score (0.73) or ambulation status (0.55) in both groups.
Vargas et al. 2021[20]	USA	Retrospective cohort study	Adult patients diagnosed with metastatic spine disease (SINS 7–12) from 2005 to 2019	Mean age of 57.6 yrs in no surgery, 61.8 in surgery	At least a year of follow-up after initial treatment	Initial radiation vs upfront surgery	49 no surgery, 26 with surgery	34.7% of patients with intermediate SINS eventually required surgical stabilization. Higher SINS scores (>10) and lower Karnofsky Performance Status (KPS) were associated with an increased need for surgery.
Vargas et al. 2023[17]	USA	Retrospective Review	Patients with SINS 7–12, metastatic spinal tumors	61.8 ± 13.5 surgery; 58.8 ± 13.1 radiation	Mean follow-up 1.9 years surgery, 2 years radiation	Surgery vs. stereotactic body radiotherapy or external beam radiotherapy	63 operated patients, 99 underwent radiation	Patients undergoing surgery showed significant improvement in KPS and ECOG scores postoperatively. Radiation therapy alone had a higher incidence of vertebral compression fractures compared to the surgical group.

Complications

This subgroup included studies from Lenschow et al., Versteeg et al., and Vargas et al. 2021, determining the complications associated with each treatment group.[18-20] The pooled OR was 2.6 (95% CI: 1.66, 4.08), suggesting a significant increase in complications associated with surgery. Again, there was substantial heterogeneity (I^2 = 84%).

Conversion to surgery / Revision surgery

The studies included were Dial et al., Kim et al., Vargas et al. 2021, and Vargas et al. 2023, comparing the rates of conversion to surgery or revision surgery.[16,17,20,21] The pooled OR was 0.19 (95% CI: 0.10, 0.34), indicating a statistically significant reduction in the conversion to surgery or revision surgery among those initially treated with surgical management. The heterogeneity was substantial (I^2 = 79%), and the test for overall effect (Z = 6.17, P < 0.00001) showed vital statistical significance.

The quantitative synthesis, which involved 1,050 patients in the surgery group and 828 patients in the medical group, yielded a significant overall OR of 0.76 (95% CI: 0.59, 0.98), with substantial heterogeneity (I^2 = 85%). This suggests that surgical intervention was associated with a lower likelihood of adverse outcomes compared to medical management alone. The confidence interval indicates that this result is statistically significant, as it does not cross 1.0, reinforcing the potential benefits of surgery in this patient population.

DISCUSSION

It is difficult to determine the best approach to treating cases of spinal metastases with indeterminate SINS. This study helps address this dilemma by comparing the effectiveness of surgery versus medical management.

In our review, three studies reported that surgery provides a longer median length of survival.[14-16] A quantitative synthesis to compare the length of survival between both approaches was not feasible due to incomplete reporting of data. Nevertheless, the reported survival benefit may be attributed to improved performance status after surgery. Additionally, when controlling baseline performance status, Dea et al. found that HRQOL at six weeks after surgery was similar regardless of patient survival.[22] This indicates that even in patients with a short life expectancy of less than three months, surgery still offers significant benefits.[22,23]

Ambulatory status, Frankel grade, and KPS scores are predictors of functional outcome, quality of life, and survival.[24-27] During our literature review, no studies specified how many changes in grades or scores were considered improvements. This gap highlights the need for further research to establish specific guidelines for defining improvements in clinical settings. Nevertheless, our systematic review indicates that surgery, compared to medical management, resulted in a maintained or improved functional status as measured by ambulatory status, Frankel score, and KPS score.[16-18] Our subgroup analysis yielded a pooled OR of 0.50 (95% CI: 0.31, 0.81), indicating that surgical management was associated with better preservation of functional abilities (Figure 3A). This is important for patients with spinal metastasis, where maintaining mobility can affect their activities of daily living and quality of life. Moreover, there was a notable enhancement in HRQOL as well as pain control among those who underwent surgery.[19] These improvements underscore the importance of surgical intervention not only in improving performance status but also in enhancing the overall well-being of patients. This surgical benefit has been demonstrated in spinal metastases regardless of the SINS category.[22-26] Thus, the findings support considering surgical options as a viable approach to improve functional outcomes in patients with indeterminate SINS.

Despite the substantial benefits of restoring mobility and reducing pain after surgery, there was an increased risk of complications inherent to surgical procedures. Complication rates from other studies range from 6.5% to 66.7% after surgery.[28-31] This is comparable to our review, which found surgical complications ranging from 27% to 42.3%.[18-20] Our study reported an odds ratio of 2.6 (95% CI: 1.66, 4.08), indicating a significant increase in complications associated with surgery (Figure 3B). These findings emphasize the importance of careful patient selection, where the benefits of functional improvement must be weighed against the likelihood of postoperative risks and complications. It is also crucial to consider independent risk factors for surgical complications, which include age over 65 years, diabetes mellitus, and involvement of three or more levels.[32] In selected cases, providers can offer minimally invasive spine surgery, which has reproducible functional outcomes and pain control with fewer complications compared to traditional open spine surgery.[33-35]

Vertebral compression fractures (VCFs) are common complications associated with radiotherapy.[3,36] Stereotactic body radiotherapy (SBRT) has a five-year rate of VCFs of 22.22%, compared to a 6.67% rate following external beam radiation therapy (EBRT).[36] Our pooled result showed a 21.19% conversion rate to surgery in patients who were initially managed medically. Indications for surgery included vertebral collapse, neurological deterioration, severe or intractable pain, tumor progression, and cord compression.[16,17,20,21] Our analysis in Figure 3C showed an OR of 0.19 (95% CI: 0.10, 0.34), which indicated that patients who received surgical intervention were 81% less likely to require subsequent surgical procedures compared to those who underwent medical management. Therefore, offering surgery as the initial treatment for cases of spinal metastasis with indeterminate SINS appears beneficial. Also, recent evidence still supports the use of SBRT for spinal metastases, providing high rates of pain control and local disease control without significantly increasing the risk of VCFs.[37-39]

Overall, our findings suggest that surgery can offer favorable outcomes, including improvement in functional status and a reduced incidence of conversion or revision surgeries (Figure 3). However, it is important to note that surgery also carries a higher risk of complications. We emphasize that this study focused on treatment outcomes for patients with spinal metastasis with indeterminate SINS. As highlighted by Fisher et al., the SINS score is just one part of the evaluation process.[11] Therefore, the decision to proceed with surgical intervention should involve a multidisciplinary team that considers all aspects of the patient's health and disease status. Furthermore, the availability of spine specialists and logistical factors such as the necessary spine implants, equipment, and funding, should also be considered when creating a treatment plan.

Several limitations were considered in this study. Meta-analyses depend on the quality and rigor of the studies included. A substantial heterogeneity was observed and warrants careful interpretation of these results. Heterogeneity may arise from variations in the study design, patient populations, and methodologies. Additionally, the choice of surgical technique can be influenced by factors beyond clinical outcomes, including surgeon experience, the specific characteristics of the tumor, and patient preferences. There was also significant variability in data reporting across studies, which affected the quality of data extracted. This meta-analysis does not account for these nuanced factors; thus, clinicians should consider them when interpreting our results.

Future research could explore this topic further, as some of the studies in this review have proposed certain SINS cut-offs to determine which patients benefit from surgery versus

medical management.[20,40] Additionally, long-term follow-up studies could provide valuable insights into the durability of outcomes and potential late complications associated with each intervention. This research helps refine and expand our understanding of the effectiveness of surgical intervention and medical management for SM with indeterminate SINS.

CONCLUSION

This study addresses the dilemma in treating spinal metastasis with indeterminate instability (SINS score of 7-12), advocating for surgery as the primary intervention due to its potential to improve functional outcomes and enhance quality of life, which may, in turn, influence overall survival. However, the primary goal of surgery is palliative care rather than extending the patient's survival. The risks and benefits of both surgical and medical interventions must be thoroughly weighed in the treatment plan. Future research should explore this issue further, including the identification of a specific SINS threshold that could serve as a criterion for recommending surgery.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

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CASE REPORT / CASE SERIES

A New Modular Nail Spanning System for Cement Spacer Reconstructions after Tumor Resection of the Knee

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ABSTRACT

Limb Salvage procedure is now the management of choice for most musculoskeletal malignant tumors. Thanks to advances in imaging and adjuvant modalities, limb salvage has become an oncologically safe option.

The purpose of this paper is to demonstrate the use of a new modular titanium nail spanning system designed and developed locally in the Philippines which consists of two interchangeable end-to-end interlocked IM nails in varying sizes and a sliding nail connector that can be locked in place with two set screws. Results have shown good outcomes. Several implants have been used to augment these spacers such as Kuntscher nails, Steinmann pins, plates, and other fixed-angle devices. The challenge lies in increasing the longevity of these constructs as the durability beyond 26 months has not been well established. We present two patients who underwent a knee resection arthrodesis for distal femur osteosarcoma and reconstruction using the Tumor Nail System. The largest and longest possible diameter nails were inserted: one antegrade through the tibia and the other retrograde through the femur. Once the connector was locked, the defect was filled with antibiotic-impregnated cement. Post-operative recovery was unremarkable and patients were able to do pain-free full weight bearing on their affected lower extremity. This implant's advantages include its modularity, ease of insertion, secure and robust nail connector, and circumventing contamination of the hip unlike traditionally inserted Kuntscher nails. This system is a viable option for primary knee resection-arthrodesis procedures following tumor resection. Long-term follow-up is needed to establish implant durability. Further studies can also show the potential of this implant for use as an initial spacer even in non-oncologic cases.

Keywords. limb salvage, knee fusion, knee spacer

INTRODUCTION

The application of a cement spacer following resection arthrodesis for infected knee arthroplasties has been well-known for decades, but there are few studies on its use in primary knee resection arthrodesis in tumor patients.

Primary knee resection arthrodesis with the application of a cement spacer has been a cost-effective limb salvage alternative for resource-limited countries either as a definitive treatment or as a temporary spacer while awaiting the availability of an endoprosthesis.[1] Several implants have been used to augment these spacers such as Kuntscher nails, Steinmann pins, plates, and other fixed-angle devices. The challenge lies in increasing the longevity of these constructs as the durability beyond 26 months has not been well established.[2] The purpose of this paper was to demonstrate the use of a new modular titanium nail spanning system (Tumor Nail) as a temporary spacer in two patients undergoing knee resection arthrodesis for high-grade osteosarcoma of the distal femur.

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Implant design

The implant was designed and developed locally in the Philippines. It consisted of two interchangeable end-to-end interlocked solid intramedullary titanium nails with varying sizes and a sliding nail connector that can be locked into place with two set screws (Figure 1). Biomechanical testing has not yet been done. The materials used are identical to those used by the implant company for making titanium interlocking nails. The patients and responsible guardians were informed of these limitations.

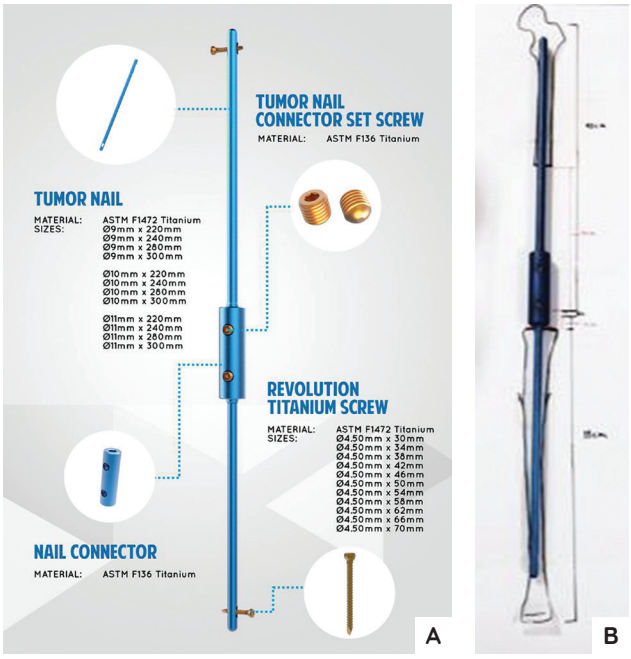

Figure 1. Implant design with the available lengths and diameters of titanium solid nails and screws **(A)**. Pre-operative templating of a tumor resection using the actual implant **(B)**.

CASE 1: EXTRA-ARTICULAR KNEE RESECTION

A 16-year-old girl presented with a three-month history of a painful left knee mass. Biopsy and curettage of the distal femur lesion were done by a private surgeon one month prior. Radiographs and MRI images are shown (Figure 2) revealing a permeative lytic lesion in the lateral aspect of the distal femur extending into the knee joint area but sparing the neurovascular bundle posteriorly. Histopathology revealed a high-grade osteosarcoma; hence, the patient underwent neoadjuvant chemotherapy with Ifosfamide, MESNA, Cisplatin, and Adriamycin for three cycles. Figure 3 shows the MRI images after neoadjuvant chemotherapy.

A direct lateral approach was done encompassing the previous biopsy site with a 2 cm margin (Figure 4). We proceeded with an extra-articular resection of the knee which involved performing a careful patellar osteotomy under fluoroscopic guidance. Femoral osteotomy was done with a 3 cm margin from the tumor while the tibial cut was positioned approximately

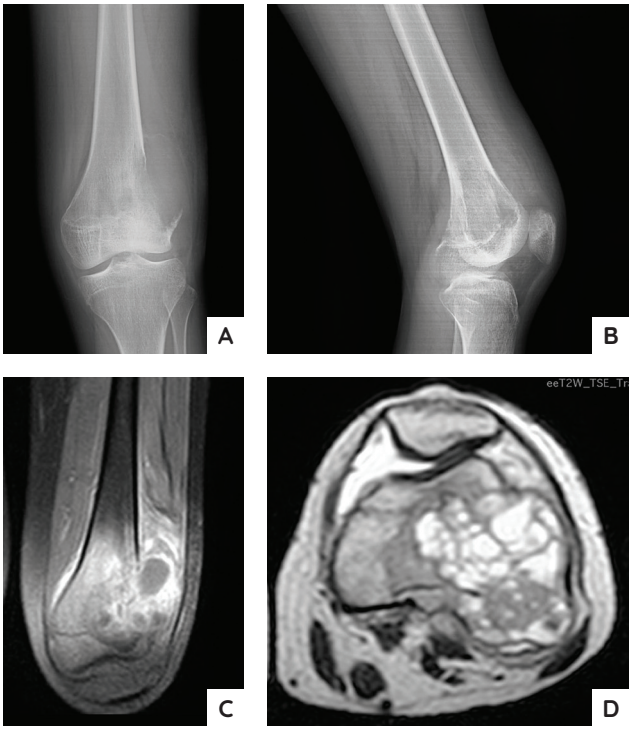

Figure 2. Initial AP **(A)** and lateral **(B)** radiographs show an aggressive lytic lesion of the distal femur with a cortical break and soft tissue mass on the lateral aspect. Initial MRI sequences before treatment. T1W FS contrast-enhanced coronal cut **(C)** and T2W TSE axial cut **(D)**.

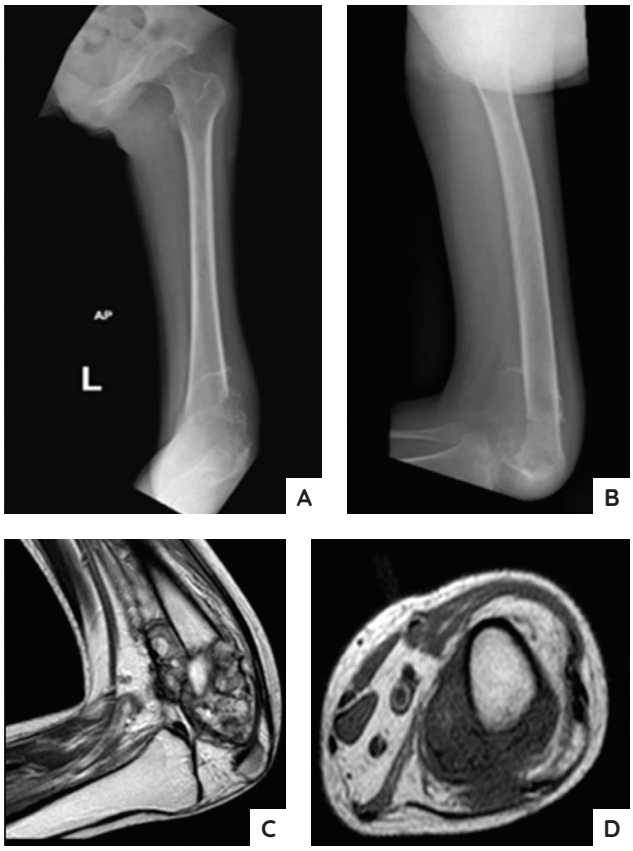

Figure 3. Imaging after neoadjuvant chemotherapy. AP **(A)** and lateral **(B)** radiographs of the femur showing radiographic response. Knee MRI sagittal **(C)** and axial **(D)** cuts show involvement of posterior femoral condyles.

12 mm below the tibial plateau thereby keeping the joint capsule intact but being proximal to the tibial tubercle to preserve the patellar tendon attachment (Figure 5).

The defect post-resection was 17 cm. Rapid frozen section for the bone osteotomy margins were negative. Reaming was done before the insertion of the nail. We planned for a 1 cm shorter lower extremity to facilitate gait clearance. Based on pre-operative templating we inserted the largest and longest possible diameter nails which was 10 x 300 mm: one antegrade through the tibia and the other retrograde through the femur. The design of the connector (8 cm in length) allowed it to slide easily between the exposed cut ends of the femur and tibia nail allowing intra-op adjustment of the modular components. Once the connector was locked into place, the defect was filled with 80 grams of antibiotic-impregnated cement molded around the implant. We were able to cover the implant using the rectus femoris together with the medial retinaculum (Figure 6). No intra-operative complications occurred. Post-operative soft tissues and radiographs are shown in Figure 7.

CASE 2: INTRA-ARTICULAR KNEE RESECTION

A 16-year-old boy presented with a six-month history of progressive pain in the left knee. Radiographs revealed an osteolytic mass at the distal femur. MRI images showed extra-articular involvement from the knee joint. A biopsy at our institution confirmed this to be a high-grade osteosarcoma hence the patient underwent neoadjuvant chemotherapy. Following a good response to the chemotherapy, the patient was then scheduled for limb salvage surgery.

A direct lateral approach to the femur was done in line with the previous biopsy site, making sure to include a 2 cm margin. An intra-articular knee resection was carried out. The femoral osteotomy was made 15 cm distal to the greater trochanter. After the removal of the tumor, a 23 cm long defect was left. We then used a 10 x 280 mm solid nail for the femur and a 9 x 300 mm solid nail for the tibia to span the defect. The defect was filled with bone cement. The construct was covered with the remaining muscle bulk (part of the rectus femoris, vastus lateralis, and part of the tensor fascia lata) (Figure 10).

Neither patient developed intra- or post-operative complications. Immediately post-operatively, no immobilizer was required for either of them. Weight bearing on the post-operative leg was delayed for two weeks for both patients to allow adequate healing of retinacular repairs. Figure 12 shows both patients doing full weight bearing on the post-operative leg after six weeks (Case 1) and two weeks (Case 2). The marked delay in ambulation of our first patient was due to prolonged room isolation after contracting a Burkholderia

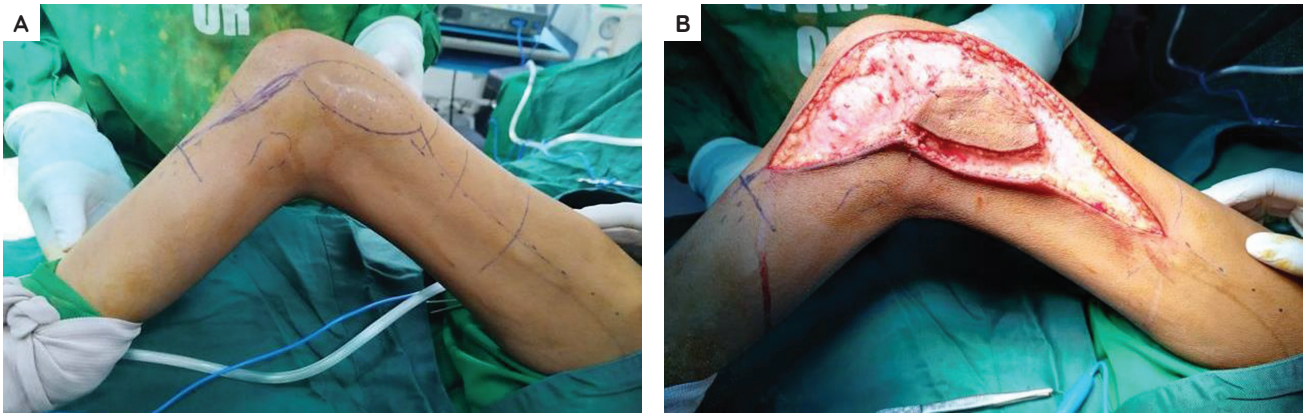

Figure 4. Incision encompassing previous biopsy site via a lateral approach **(A)**. The biopsy site was outlined and removed together with the tumor **(B)**.

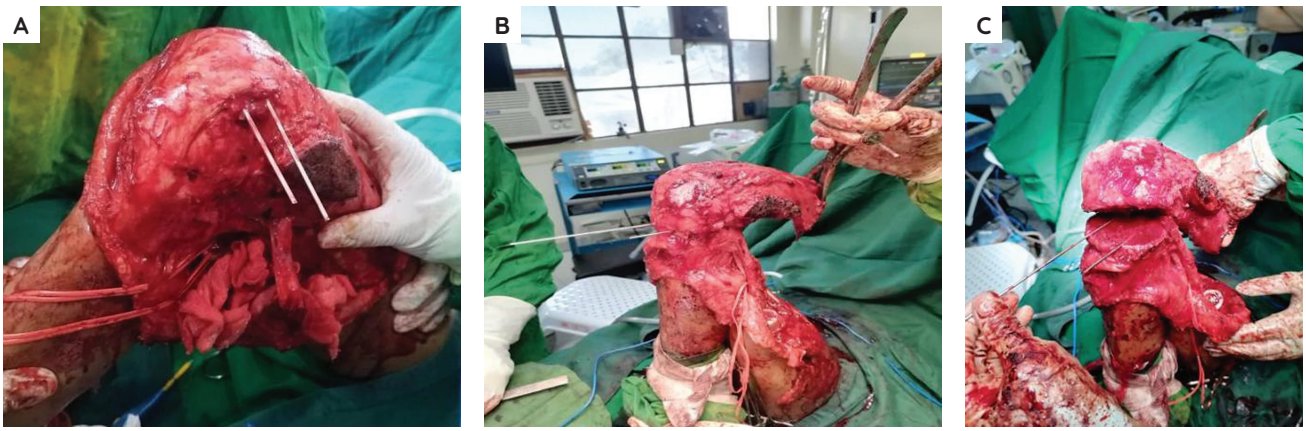

Figure 5. Extra-articular resection with patellar **(A)**, femoral **(B)**, and tibial **(C)** osteotomy.

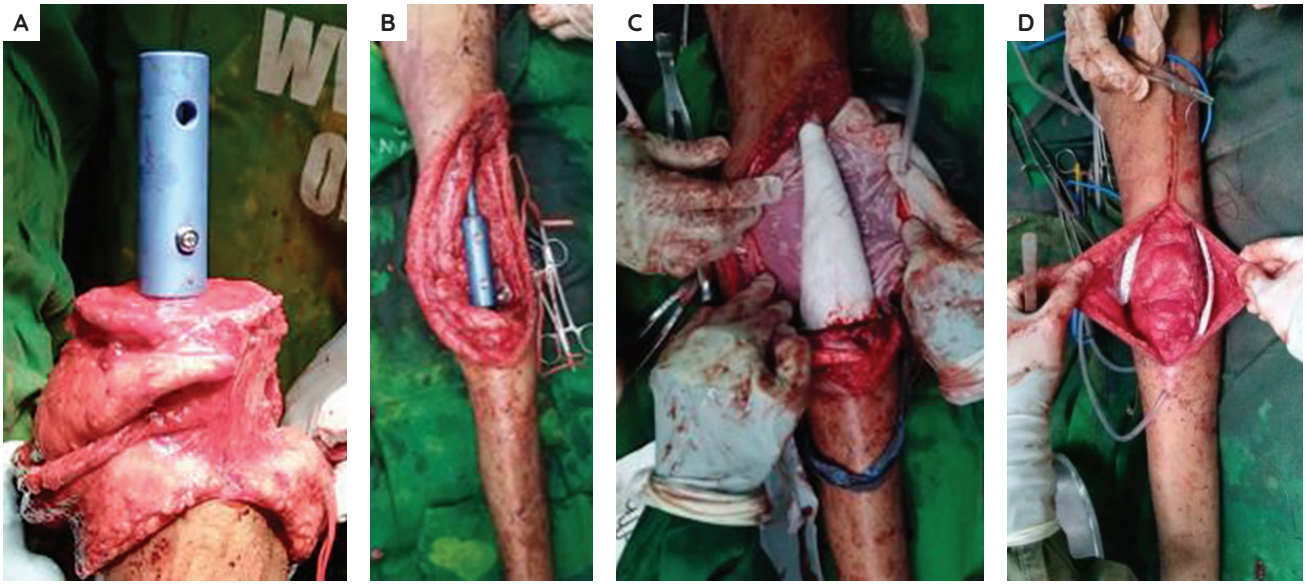

Figure 6. Intra-operative photographs. Sliding of connector through tibial nail and locking with set screw **(A)**. Defect spanned by tumor nail **(B)**. Augmentation of construct with antibiotic bone cement **(C)**. Rectus femoris with preserved medial retinaculum covering the implant **(D)**.

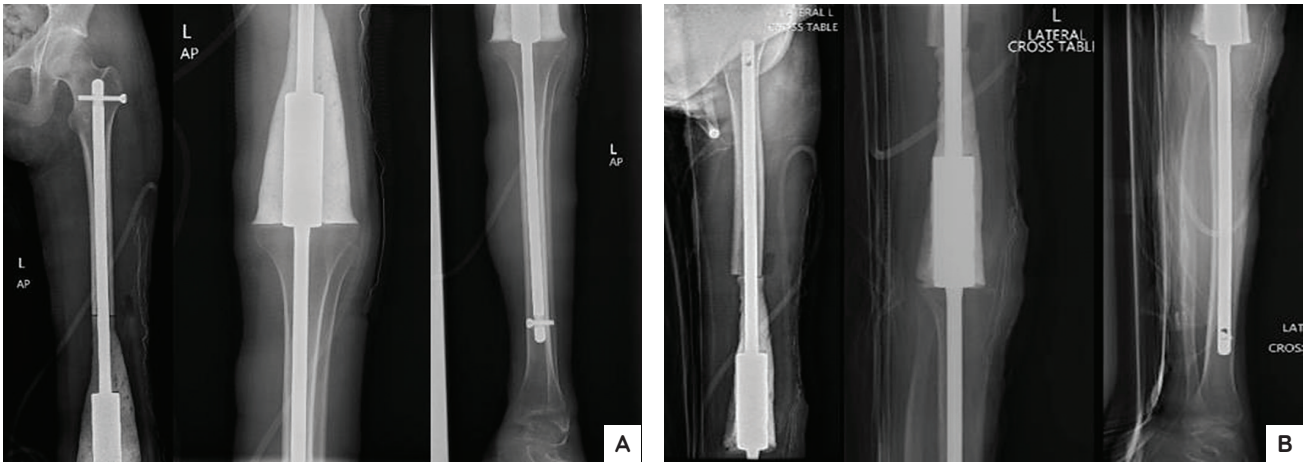

Figure 7. Post-operative AP **(A)** and lateral **(B)** radiographs of femur, knee, and leg.

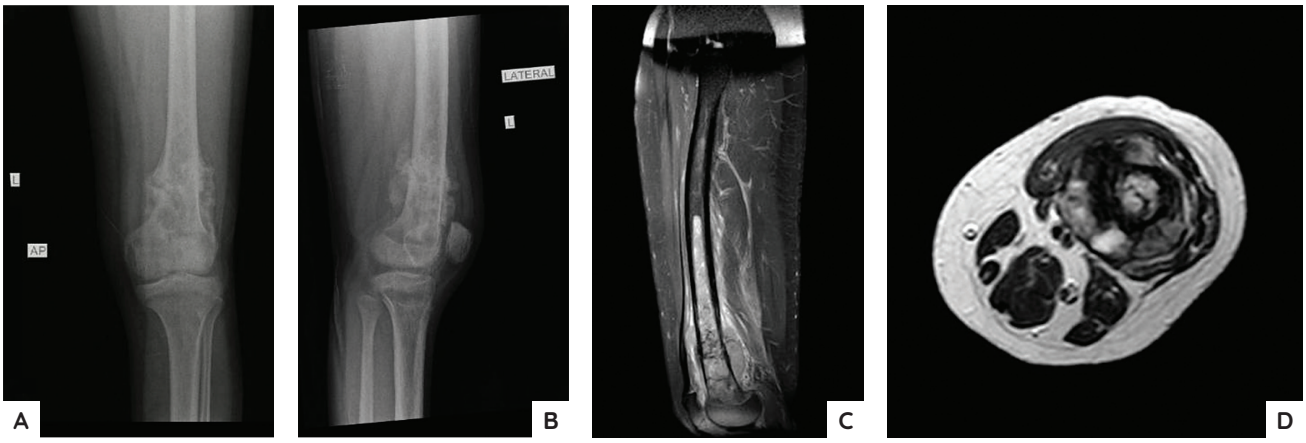

Figure 8. Initial AP **(A)** and lateral **(B)** radiographs show a lytic lesion in the distal femur with involvement of surrounding soft tissue. T1W FS contrast-enhanced sagittal cut **(C)** and T2W TSE axial cut **(D)**.

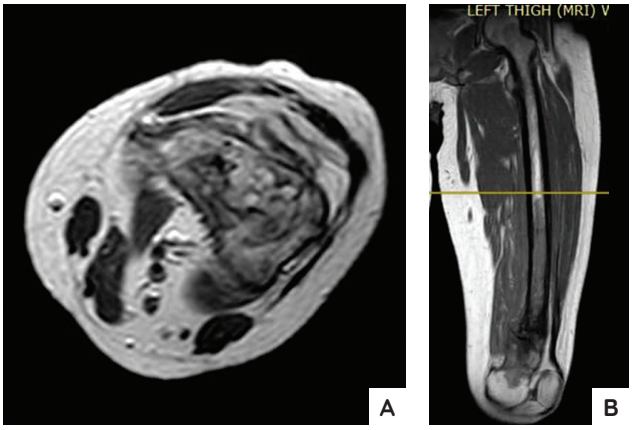

Figure 9. MRI after neoadjuvant chemotherapy. Axial cuts show no contamination of the knee joint **(A)**. Extensive intramedullary involvement proximally **(B)**.

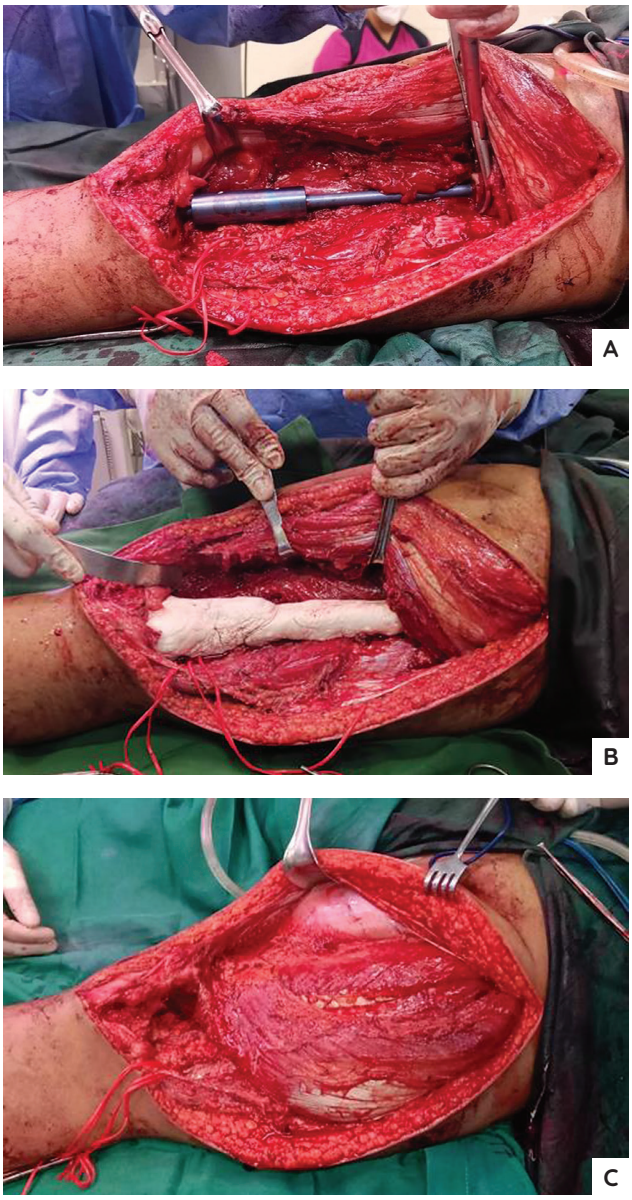

Figure 10. Intra-operative photos following placement of tumor nail to span the defect after resection **(A)**, augmentation with antibiotic-impregnated bone cement **(B)**, soft tissue coverage with remaining muscle bulk **(C)**.

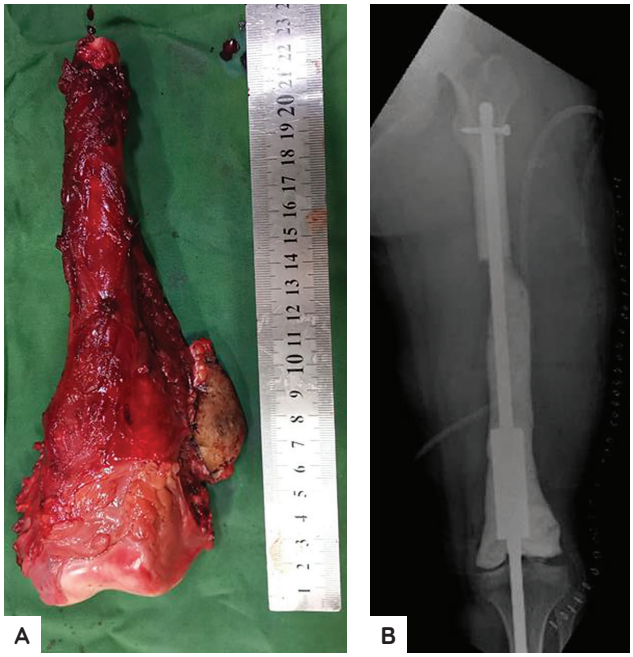

Figure 11. Twenty-three (23) cm resected distal femur with tumor and biopsy site **(A)**. Post-operative AP radiographs of the femur showing cement spacer spanning the defect **(B)**.

Figure 12. Latest clinical follow-up. Patient 1 at 12 months after surgery showing full weight bearing over left leg, side **(A)** and front **(B)** view. Patient 2 at 12 months post-surgery, side **(C)** and front **(D)** view.

infection which was not related to the operative site. Both patients were able to ambulate pain-free and independently without crutches, climb stairs, and go about their activities of daily living. Both patients also remained disease-free at seven months (Case 1) and two months (Case 2) post-operatively.

DISCUSSION

The distal femur and proximal tibia are the locations most affected by malignant bone tumors, particularly osteosarcoma.[3] The standard approach for this disease was neoadjuvant chemotherapy, surgery, which includes osteochondral allograft, allograft composite prosthesis, autograft reconstruction, and modular megaprosthesis (with the goal of a mobile knee), and then adjuvant chemotherapy.[3] However, postoperative chemotherapy was considered dangerous for wound healing and implant integration thus temporary spacers were considered to ensure completion of chemotherapy.[3] When evaluating a reconstruction technique we need to consider the ease of the procedure, its complications, functional outcome, and the durability of the construct. Besides being cost-effective compared to other grafts, cement spacers provided other advantages as well. The operating time was shorter compared to using biological constructs which require shaping to ensure optimal fit to the defect.[3] Using a cement spacer avoided donor site morbidity and graft complications from adjuvant treatment modalities.[5] The rehabilitation schedule did not depend on evidence of graft incorporation or "hypertrophy" of the graft and patients are ambulant with immediate weight bearing on a stable limb.[2]

A study by Puri et al. reported on 15 patients who underwent cement spacer constructs following tumor resection, none of whom had mechanical failures. However, the mean follow-up was only 26 months. They accepted that a longer follow-up may lead to failure of the construct in some cases which prompted them to recommend the use of stacked Kuntscher nails, or combinations of a nail and a plate with adequate intramedullary length of the nail on either side.[2] In this case, the patients could ambulate at 4 weeks with no difficulty, and follow-up radiographs did not show any signs of failure.

The use of Kuntscher nails for cement spacers in knee arthrodesis typically necessitates insertion through the hip abductors, which poses a risk of contaminating the hip with tumor cells. Hence, the Tumor Nail's modularity allowed interchangeable nail lengths and diameters, and insertion through the knee defect (avoiding hip contamination), while being a securely locked and durable construct.

CONCLUSION

We showcased several advantages of this implant design, including modularity, ease of insertion, a securely locked and robust nail connector, and protection of the proximal hip structures from contamination. This implant system is an acceptable option for primary knee resection-arthrodesis procedures following tumor resection, especially when tumor endoprostheses are not available.

Although one patient acquired a Burkholderia infection, this case was determined by Infectious Disease Unit to be a contaminant in IV fluids and antiseptic formulas, therefore, it was difficult to pinpoint the exact moment of infection, precluding the classification of the case as a post-op complication.

However, the post-operative recovery was unremarkable and both patients were able to do full weight-bearing on their affected lower extremity, long-term follow-up will be needed to establish implant durability. Further studies can also show the potential of this implant for use as an initial spacer even in Masquelet procedures and infected knee arthroplasties.

ETHICAL CONSIDERATION

Patients' consent was obtained before submission of the manuscript.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

FUNDING SOURCE

None.

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Acknowledgments

Contributors to the work who do not fulfill the authorship criteria should be acknowledged.

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COVER LETTER

(Date)

TO: **The Editor-in-Chief**
Philippine Journal of Orthopaedics

Subject: **SUBMISSION OF MANUSCRIPT FOR PUBLICATION**

We intend to publish the manuscript/, entitled "_____
_____
_____
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On behalf of all the authors, I shall act as the corresponding author with the journal from this point onward.

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COMPLETE TITLE OF MANUSCRIPT

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