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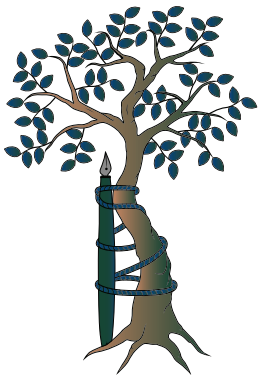

The Philippine Journal of Orthopaedics

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ORIGINAL ARTICLES

CASE REPORTS / CASE SERIES

The Philippine Journal of Orthopaedics

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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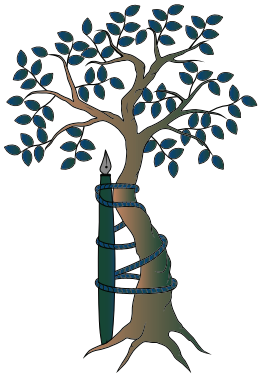

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The **Philippine Journal of Orthopaedics** shall advance the art and science of orthopaedics in the country by publishing high quality original clinical investigations, epidemiological studies, case reports, review articles, evaluations of diagnostic 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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This year's edition of the Philippine Journal of Orthopaedics marks a milestone in research history for the Philippine Orthopaedic Association. Not only has our Association's official journal been revived; it has been transformed into a peer-reviewed and indexing-ready publication, poised to join the ranks of credible orthopaedic journals in the region.

This achievement owes its realization to the generosity of our loyal and research-oriented sponsor, Uratex. But more importantly, we give credit to Dr. Tammy Dela Rosa, who graciously accepted the role of Editor-in-Chief. Under his tutelage, we expect more of our work to grace the international stage and align with global standards.

As we celebrate this achievement, let us continue producing quality research, well-grounded on the principles of ethics and integrity. Each study, innovative idea, and unique experience adds to our knowledge in Orthopaedics. With this publication, we showcase not only our clinical outcomes, but also our best scholars in the field of research.

So, as our mentors say, pass your papers now!

David L. Alagar, MD, FPOA
2023 President, Philippine Orthopaedic Association

The Philippine Journal of Orthopaedics

Philippine Orthopaedics Steps on to the World Stage

The Philippine Journal of Orthopaedics is finally online! Thirty years ago, communication and information availability underwent a sea change. The internet was invented and the world has never been the same.

Connecting to the web used to be more of a chore than a boon. Your dial-up modem would shriek and your computer would struggle to download an email, a document, a picture, or – God forbid – a song on Napster. Since then, the internet has improved by leaps and bounds. Nearly everyone I know uses the internet daily. Scientific publications also rode this wave; today, nearly everything we need to know is reachable with the tap of a button. It is about time that we hitch our proverbial wagon to the information superhighway.

This issue is the journal's first to be published both physically and electronically; a fitting transition to our full migration online starting next year. The printed copy serves as a memento of the classic format, and an homage to the people instrumental to its revival – the board of trustees of the Philippine Orthopaedic Association, with Dr. David Alagar, current president, spearheading the efforts.

Our call for submissions was met with a resounding response; we received manuscripts enough to fill more than three issues. This only reinforces the need for a journal to call our own. The editors have worked tirelessly for the past six months to bring everyone an issue that rises to the occasion. These articles represent a cross-section of our emerging economy's unique position; our country battles poverty, inequality, and injustice, while also advancing at the forefront of Orthopaedics. In this issue, you will find described the presentation and results of age-old cervical Pott's disease, economic issues inherent in the reuse of external fixator outriggers, the mental health effects of prolonged skeletal traction, and innovations that overcome logistic barriers in residents' microsurgical training. These are questions that do not concern the first world and will not find their place in other top-tier journals. Our issue also showcases advancements in Philippine Orthopaedics – the study of powered air purifiers, the use of software to measure joint positions, an investigation into the significance of plicae in the knee, and a new technique in tumor surgery.

The editors have set out a stepwise 5-year plan to get our journal onto the relevant indices. After all, what good is a journal that cannot reach its widest audience? To this end, the editors have crafted an editorial policy, ensured objective peer review, and engaged the services of a copy editor, and journal, production, and website managers. The authors will agree that the review process has polished their articles to their finest forms.

We have taken the first step on our journey: to be a locally and globally relevant indexed international journal. A steady stream of quality submissions from local and eventually international authors will help carry us along.

In this, our journal's new era, the editors make this vow – the Philippine Journal of Orthopaedics shall take its rightful place in the community of scientific journals, giving voice to our unique set of problems while joining the discussion of current and global Orthopaedic topics. *Mabuhay!*

Tammy L. Dela Rosa, MD, MSc
Editor-in-Chief

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ORIGINAL ARTICLE

The Hand Pose Estimation Model in Measuring Range of Motion

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ABSTRACT

Objective. The COVID pandemic has challenged medical practitioners to perform clinical examinations remotely, including assessing the range of motion of the finger joints. This sparked the development of the 3D (three-dimensional) Hand Pose Estimation Model, a software that can generate hand pose estimates and compute hand joint angles from a 2D (two-dimensional) image. The study aims to assess the accuracy of the 3D Hand Pose Estimation Model when compared with a goniometer and radiography.

Methodology. The 3D Hand Pose Estimation Model was developed by training a machine learning model with a parametric hand model and 2D hand images. Ten healthy participants with no history of trauma, disease, or deformity of the hand were enrolled in the study. Active flexion and extension joint angles of the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints of the fingers, excluding the thumb, were measured using the 3D Hand Pose Estimation Model, a goniometer, and radiographs.

Results. The mean joint angles derived from the 3D Hand Pose Estimation Model and goniometer were not significantly different in 18 out of 24 joint angles (75%). While measurements from both instruments differed greatly from those taken on radiographs, more goniometric measurements are within five degrees of the radiographic measurements.

Conclusion. The 3D Hand Pose Estimation Model can estimate joint angles given a 2D image. Improvements in the model can be made with the aid of the data obtained from this study.

Keywords. hand, range of motion, estimation model, machine learning

INTRODUCTION

Joint range of motion (ROM) is a quantitative measure of hand function. It is a measurement obtained to assess a patient's initial disability, therapeutic intervention outcomes, and disease progression or improvement. It can help establish goals and decide the surgical procedure for a patient. Hence, there is a need to measure ROM with accurate, repeatable, and reliable instruments.[1,2]

In clinical practice, doctors most often use a manual goniometer, given that it is accessible, inexpensive, and easy to understand.[1,3,4] Other reported methods include visual estimation, photogoniometers, digital goniometers, and motion sensors. Some of these tools can process digital data and have the advantage of faster data recording, saving, calculation, and sharing. While some offer high precision and accuracy, they are either expensive, or difficult to set up.[5,6]

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The pandemic brought about by SARS-CoV-2 has challenged physicians to perform physical examinations with limited physical contact. While the end of the pandemic is already in sight, these adaptations and tools developed are likely to last. Van Nest et al., discussed a systematic way of doing hand examinations through telemedicine, emphasizing the current demand for remote physical examinations. In terms of measuring hand range of motion, the ideal tool must be acceptably accurate, easily accessible, and convenient to use for both clinician and patient.[7]

The 3D Hand Pose Estimation Model is a software developed by computer scientists from the University of the Philippines (UP) Diliman under the UP Surgical Innovation and Biotechnology Laboratory (UP SIBOL). It generates hand pose estimates and computes hand joint angles, given 2D hand images as input. The model is based on Mesh Graphormer, a state-of-the-art computer vision model for human pose estimation. Following the U-Net architecture, we modified the Mesh Graphormer model by replacing its backbone network with a 2D hand pose estimation model. This improved the accuracy of the estimates and hand joint angles.

The objective of the study was to compare the measurements obtained with a goniometer and with the 3D Hand Pose Estimation Model of the joint angles of the metacarpophalangeal joint (MCPJ), proximal interphalangeal joint (PIPJ), and distal interphalangeal joints (DIPJ), of the index finger (IF), middle finger (MF), ring finger (RF) and small finger (SF) in extension and flexion. The accuracy of both tools was also evaluated by comparing them to radiographic measurements, considered the gold standard of ROM measurement.

METHODOLOGY

Participants and protocols

Ten healthy participants with a mean age of 27 years old (SD 1.17) were enrolled in the study. Participants with a history of trauma, disease, or deformity of the hand were excluded. The protocol was approved by the University of the Philippines Manila Research Ethics Review Boards; informed consent was obtained from all participants.

Range of motion measurement

Joint angles at active extension and flexion of the MCPJ, PIPJ, and DIPJ of the IF, MF, RF, and SF were measured using the 3D Hand Pose Estimation Model, goniometry, and radiography.

With the subject sitting, the forearm and wrist were positioned in neutral on an X-ray cassette, with the X-ray machine head and smartphone camera overhead. Extension of the MCPJs, PIPJs, and DIPJs was measured with all digits simultaneously in full extension. The patient was then asked to maximally flex the DIPJ and PIPJ while extending the MCPJ (hook fist) to measure the flexion of the DIPJ and PIPJ. The participant was then asked to make a fist with the MCPJ maximally flexed to measure MCPJ flexion. For every position, a video was taken with a smartphone camera and a radiograph was taken with a portable X-ray machine. Following this, goniometry was done by placing the goniometer at the dorsal aspect of the joint and noting the value at full extension and flexion (Figure 1).

Data processing and analysis

The mean joint angles obtained with the goniometer and with the 3D Hand Pose Estimation Model were compared using a two-tailed t-test at a 5% level of significance. The median absolute difference between measurements obtained with the 3D Hand Pose Estimation Model and radiograph and between those obtained with goniometer and radiograph were compared using paired Wilcoxon signed rank test. The number of goniometric and 3D Hand Pose Estimation Model measurements that are within five degrees of the radiographic measurement was calculated to assess for accuracy; five degrees is the reported measurement error of goniometry.[3,9]

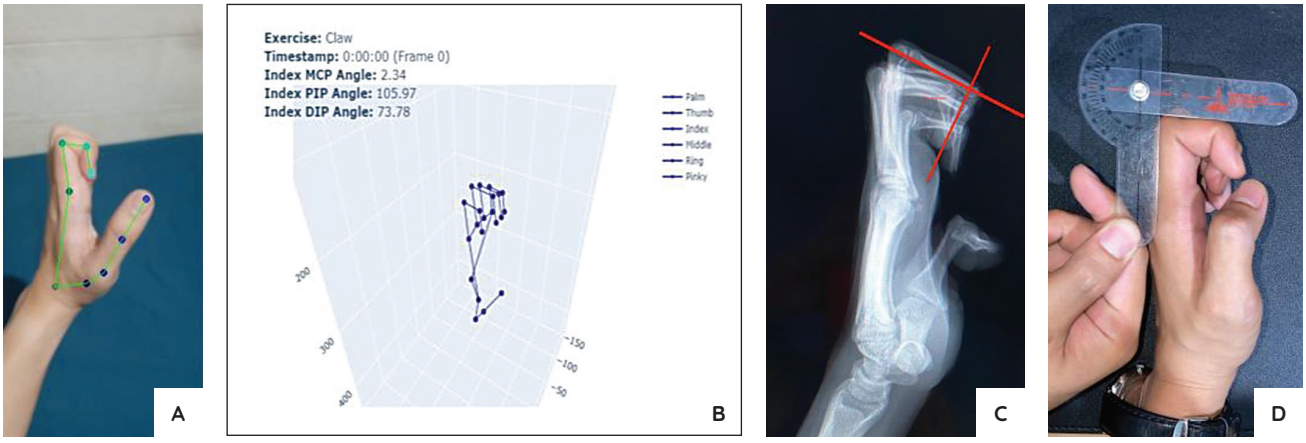

Figure 1. **(A)** Image of hand with keypoint assignments for Hand Pose estimation model; **(B)** ROM measurement by Hand Pose estimation model; **(C)** ROM measurement with radiographic image; **(D)** ROM measurement with a goniometer.

RESULTS

The mean joint angles for each joint in extension and flexion are shown in Table 1. The range of measured angle in maximum flexion and extension among healthy subjects is wider with the hand pose estimation model (SD 32 deg) compared to the goniometer (SD 15 deg). The 3D Hand Pose Estimation Model-estimated angles are on average higher than the goniometer-measured angle when the joint is in extension. The mean joint angles measured with the two methods were significantly different ($p<0.05$) for the MF MCPJ and RF PIPJ in extension, and for IF DIPJ and MCPJ, MF MCPJ, and SF MCPJ in flexion.

To assess which method most approximated radiographs, the median absolute difference was obtained (Table 2). Median differences between goniometry and radiography are smaller compared to the median difference between the 3D Hand Pose Estimation Model and radiographs. Wilcoxon signed rank test showed that most differences are statistically significant especially during flexion (10 out of 12 joints) compared to extension (5 out of 12 joints). More goniometric (15 to 70%) than 3D Hand Pose Estimation Model measurements (5 to 45%) are within five degrees of radiographic measurements.

DISCUSSION

The goniometer is the most used device to measure joint ROM. Groth found that 14 out of 16 (13%) goniometric measurements of the interphalangeal joints of the index and middle fingers were significantly different from their radiographic measurement.[1] In our study, 14 of the 24 joint angles measured with a goniometer were not significantly different from radiograph-measured angles ($p>0.05$, 58.3%). Mcveigh likewise reported that the proportion of goniometric measurements that are within 5 degrees of the radiographic measurement varies from 23 to 58%.[3]

With the advent of telemedicine, motion analysis systems are being developed for remote and dynamic evaluation of joints (e.g., while doing activities of daily living). Meals et al.,[8] compared a photogoniometer with a goniometer in measuring wrist and digit ROM. While they reported good interrater reliability (correlation coefficient ranging from 0.7–0.96) depending on the joint being measured, most of the measurements taken were not in acceptable agreement (correlation coefficient ranging from 0.06–0.86). They encountered problems with the effect of tenodesis, and occlusion of joints (i.e., the joint in study is being covered by

Table 1. Range of motion of (mean and SD) for 3D Hand Pose Estimation Model and goniometer

Digit	Joint	3D Hand Pose Estimation Model, ° mean, (SD)	Goniometer, ° mean, (SD)	*p*
Extension				
IF	DIP	-5 (11)	-3 (4)	0.517
	PIP	-8 (18)	-8 (10)	0.857
	MCP	-2 (18)	4 (14)	0.096
MF	DIP	-7 (17)	-6 (8)	0.782
	PIP	-9 (19)	-10 (11)	0.717
	MCP	-2 (18)	5 (11)	0.030*
RF	DIP	-6 (14)	-3 (9)	0.316
	PIP	-8 (17)	-16 (8)	0.016*
	MCP	-2 (20)	-2 (10)	0.209
SF	DIP	-6 (15)	-5 (7)	0.763
	PIP	-8 (16)	-10 (8)	0.476
	MCP	-2 (16)	-2 (14)	0.901
Flexion				
IF	DIP	51 (22)	71 (9)	<0.001*
	PIP	108 (23)	102 (9)	0.311
	MCP	72 (15)	82 (11)	0.004*
MF	DIP	73 (32)	81 (8)	0.303
	PIP	114 (24)	105 (8)	0.177
	MCP	84 (10)	71 (15)	<0.001*
RF	DIP	64 (28)	72 (12)	0.297
	PIP	104 (22)	104 (8)	0.949
	MCP	80 (17)	81 (10)	0.704
SF	DIP	66 (29)	73 (12)	0.312
	PIP	100 (21)	92 (11)	0.189
	MCP	62 (13)	82 (10)	<0.001*

* statistically significant at a 5% level of significance

Table 2. Comparison of 3D Hand Pose Estimation Model and goniometer with radiographs

Digit	Joint	3D Hand Pose Estimation Model measurement vs radiograph		Goniometer measurement vs radiograph		*p*
		Median (range), absolute difference	Number (%) of absolute differences ≤5 deg	Median (range), absolute difference	Number (%) of absolute differences ≤5 deg	
Extension						
IF	DIP	8 (0,33)	6 (30)	3 (0,9)	12 (60)	0.008*
	PIP	8 (0,32)	9 (45)	4 (0,14)	14 (70)	0.204
	MCP	8 (1,43)	8 (40)	11 (0,22)	4 (20)	0.478
MF	DIP	9 (1,37)	8 (40)	4 (1,18)	14 (70)	0.006*
	PIP	10 (0,34)	6 (30)	6 (0,20)	9 (45)	0.005*
	MCP	11 (0,42)	4 (20)	4 (0,23)	11 (55)	0.001*
RF	DIP	9 (0,38)	6 (30)	5 (0,14)	11 (55)	0.070
	PIP	15 (0,36)	6 (30)	7 (0,22)	7 (35)	0.009*
	MCP	13 (1,50)	6 (30)	6 (0,19)	9 (45)	0.073
SF	DIP	6 (0,36)	8 (40)	4 (0,15)	13 (65)	0.020*
	PIP	7 (1,34)	7 (35)	5 (1,26)	12 (60)	0.083
	MCP	9 (3,50)	5 (25)	9 (0,17)	9 (45)	0.145
Flexion						
IF	DIP	14 (2,81)	4 (20)	7 (0,47)	8 (40)	0.011*
	PIP	14 (0,86)	5 (25)	5 (0,32)	12 (60)	0.025*
	MCP	7 (0,33)	5 (25)	16 (3,38)	3 (15)	0.022*
MF	DIP	14 (2,51)	2 (10)	4 (1,10)	11 (55)	0.002*
	PIP	12 (3,90)	1 (5)	5 (1,21)	11 (55)	0.002*
	MCP	9 (1,21)	9 (45)	6 (0,19)	10 (50)	0.137
RF	DIP	7 (1,83)	5 (25)	5 (1,104)	11 (55)	0.036*
	PIP	14 (0,38)	4 (20)	8 (1,18)	5 (25)	0.020*
	MCP	11 (3,28)	1 (5)	4 (0,17)	13 (65)	0.006*
SF	DIP	12 (1,53)	7 (35)	5 (0,30)	11 (55)	0.005*
	PIP	12 (0,80)	5 (25)	7 (0.16)	8 (40)	0.126
	MCP	13 (3,45)	4 (20)	8 (0,21)	7 (35)	0.018*

* statistically significant at a 5% level of significance

another structure in the image), and recommend obtaining other views of the hand to increase accuracy.

Reissner[9] used a 3D motion capture system (using skin markers to identify key points) to measure the ROM of the hand and wrist and compared it to a goniometric measurement; their measurements were not significantly different. Since the true measure of a joint angle is based on the movement of the bones, the accuracy of ROM measurement using skin markers is limited by the fact that there is skin movement relative to the bone. This is also true for our 3D Hand Pose Estimation Model since assigning key points for those joints that are not occluded is based on skin landmarks like creases or bony prominences. Another limitation reported by Reissner was marker loss; in this regard, our 3D Hand Pose Estimation Model's digitally assigned key points may be advantageous.

The accuracy of 2D images to measure ROM decreases as anatomic landmarks are occluded. Lim et al.,[10] proposed a system using at least three plane mirrors and a camera. By increasing the number of mirrors, multiple simultaneous views of the hand can be obtained and processed to calculate ROM with greater accuracy. They also reported that increasing the number of views from three to five views does not affect accuracy. The 3D Hand Pose Estimation Model is trained using a series of 2D images as well as a parametric hand model; this constraint prevents the program from making estimates for occluded joints that are considered unnatural or impossible joint positions. This is postulated to contribute to the high mean difference in measurements.

Most digital tools are tested by checking for interrater reliability.[8–11] Zhao et al.,[11] reported limitations in using smartphone photography which included the high dependence on the patient taking the photo. The angle measured can be altered by the background, the angle from which the photo was taken, and the quality of the photograph. The 3D Hand Pose Estimation Model should be validated, considering factors such as video lighting, video noise, and camera angulation that can change the assignment of point

estimates. This is also to test the applicability of the 3D Hand Pose Estimation Model in a less controlled setting like telemedicine.

CONCLUSION

The goniometer is the most used instrument to measure ROM despite variable accuracy. Our findings show the feasibility of using the 3D Hand Pose Estimation Model in measuring the range of motion of digits; its measurements are comparable to those obtained by a goniometer despite the low accuracy rate when compared to radiographic measurement. This study serves to guide the development of future estimation models.

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

Aegis Mark II Study on Powered Air Purifying Innovation Respirator Efficiency Comparison: ASPIRE Study*

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ABSTRACT

Introduction. COVID-19, a respiratory droplet-transmitted disease, has claimed approximately 7 million lives worldwide, partly due to a shortage of Personal Protective Equipment (PPEs) needed for prompt patient care. This study was done to assess if the locally developed Aegis Mark II Powered Air Purifying Respirator (PAPR) can fill this need in terms of usability and filtration efficacy.

Methodology. The battery life was recorded in a controlled environment by running the PAPR continuously on low and high settings. To test usability, participants were allocated to three groups (commercial PAPR, Aegis Mark II, and Aegis Mark I), then participated in a clinical simulation while wearing the PAPR, and answered a questionnaire regarding their satisfaction with the PAPR. Filtration efficacies of the commercial PAPR and Aegis Mark II were compared in a controlled environment (acrylic box) by measuring the number of aerosolized NaCl particles inside the PAPR compared to outside the PAPR.

Results. The Aegis Mark II PAPR's 20,000mAh rechargeable Lithium battery pack lasted for a mean of 11 h and 34 min (SD 16 min), and 8 h and 34 min (SD 38 min), for low and high flow blower settings, respectively. The mean charging time was 2 h and 20 min (SD 19 min) using a Fast Cellphone Charger (2.4 Amps). Participants reported higher satisfaction with the Aegis Mark II compared to the commercial PAPR in terms of factors affecting residency and education use and communication effort (n = 30, overall mean = 7.86 ±1.81) (Table 1), comfort (n = 8.52, overall mean = 8.52 ±1.63), and PAPR care (n = 30, overall mean = 7.76 ±1.75). The mean particle counts inside the hood of the Aegis Mark II PAPR and Commercial PAPR showed that PM2.5 (5.7 and 6.2), and PM10 (6.2 and 6.6) values were within acceptable Ambient Air Quality Standards.

Conclusion. The locally developed Aegis Mark II PAPR displayed a high degree of protection comparable with commercial PAPRs. Its battery life was adequate. It was highly conducive to training and clinical work while being comfortable to use and maintain. It can provide a high degree of protection and alleviate the logistical strain during pandemics and public health emergencies.

Keywords. Aegis Mark II PAPR, filtration efficacy, user comfort and acceptance

INTRODUCTION

The COVID-19 pandemic has caused approximately 7 million reported deaths worldwide.[1] The virus is transmitted through respiratory droplets between people in proximity indoors, placing healthcare workers at risk for infection.[2,3] Personal protective equipment (PPE) were some of the most important means to protect healthcare workers. This massive demand led to a shortage of PPEs.[4,5]

Respiratory protection programs worldwide have increasingly used reusable devices. These devices include loose-fitting powered air-purifying respirators (PAPRs) and elastomeric half mask respirators. Loose-fitting PAPRs are well-accepted and more comfortable but may influence communication and mobility. They provide a high degree of protection when measured in a simulated workplace.[6]

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It is important to understand how PAPR use affects employees' physical, psychological, psychomotor, cognitive, and visual abilities. PAPRs enhance compliance and reduce heart, lung, and heat stress by delivering ambient air into the user's breathing zone as opposed to non-powered respirators that require active air intake through a resistive filter.[7] Loose-fitting facepieces do not require fit testing, and improve communication.[8]

Protection factors indicate how safe a device is. Of these, the Assigned Protection Factor (APF) is the expected value when the respirator is used in the prescribed situation by a respiratory protection program. The Program Protection Factor (PPF) is the actual measurement in the workplace or in work simulations. The value of the protection factor for each commercially available filter or device is provided by the manufacturer.[9-13]

A PAPR is a PPE in which a battery-powered blower passes positive air flow through a filter to a hood. The filters are often P100 and high-efficiency particulate air (HEPA) filters, with efficiencies of more than 99%, and are considered more protective than N95 respirators. These PPEs are used when working closely with COVID-19 patients, especially during high risk aerosol-generating procedures.[14-17] While there are several studies determining the efficiency and comfort of N95 respirators, studies on PAPR's are few.

The CDC has allowed respirator manufacturers to produce equivalent new classes of PAPR to protect the front lines as soon as possible.[18] Innovation has driven the use of 3D printed materials and arthroplasty helmets repurposed as PPEs.[19] The ultra-portable low-cost improvised powered air-purifying respirator, novel reusable respirators, Bubble-PAPR, and Novel 3D printable powered air purifying respirator were encouraged.[20-23]

The Aegis Mark II PAPR is an improvement from the Aegis Mark I prototype. The current study assessed the Aegis Mark II PAPR's battery power, user acceptance, user comfort, and filtration efficacy.

METHODOLOGY

This laboratory controlled non-interventional study was conducted at the Corazon Locsin Montelibano Memorial Regional Hospital, a Tertiary Hospital, in Lacson St., Bacolod City, Negros Occidental, Philippines, in cooperation with the Department of Science and Technology Region VI and the Western Visayas Health Research and Development Consortium. Ethics approval was granted by the Western Visayas Research and Development Consortium Research Ethics Committee.

The following parameters were tested: battery life in a controlled environment at high and low blower power settings; mechanical and material construct of hood, blower unit, strength of hose and coupling, non-collapsibility, ability of the hose to resist kinking, and detachable coupling (CFR_42 CFR Part 84);[24] filtration efficacy using NaCl particulate (CVB-APR-STP-0081-508);[25] and users' acceptance, communication and comfort (CVB-APR-STP-0089-508).[26]

Participants were surgery and anesthesia residents, scrub nurses, and nurse assists who signed the informed consent, and were completely vaccinated. The study excluded those who are non-surgical/cutting and non-anesthesia residents, and ward nurses, and those who refused consent. Participants with pulmonary disease, cardiac disease, uncontrolled hypertension, claustrophobia, and facial abnormalities that prevent good fit were excluded. The study allowed participants to opt out. Participants who experienced mechanical failures were also excluded. Participants were randomly allocated to one of three groups: commercial PAPR (COLEMATE PAPR CM-200), Aegis Mark I, and Aegis Mark II.

Clinical simulation was performed inside a surgical theater with participants wearing their assigned PAPR for at least three hours. They simulated their respective job roles during a regular operation, including but not limited to transferring the patient, operating surgical equipment, postoperative care, etc.

Participants then answered a questionnaire which measured the study variables (clinical performance, communication, comfort and PAPR care) on a 10-point Likert scale (1-2 not satisfied, 3-4 slightly satisfied, 5-6 neutral, 7-8 very satisfied, and 9-10 extremely satisfied). The parameters included were factors affecting (Appendix 1):

- residency training and education (visual field, fogging, inside lighting/less shadowing, and noise)
- clinical performance (movement restrictions, weight distribution, and ambulation)
- communication effort (voice modulation and less muffling of voice)
- comfort (ease of donning, ease of doffing, ease of operation, and ease of monitoring)
- PAPR care (ease of storage, handling, size, durability of material during cleaning, material disassembly, time required to disinfect, time required for drying)

The Aegis Mark II's filtration efficacy was compared against the commercial PAPR's in a controlled environment. An adult size mannequin wearing the PAPR was placed in an acrylic box where a 0.9 NaCl solution was aerosolized (using a nebulizer) into airborne NaCl particles. Two particle counters (Temtop M2000C Air Quality Monitor for PM2.5 PM10 Particles) (one inside the PAPR hood, the other outside the PAPR hood but inside the acrylic box) measured the number of aerosol particles. The following set-ups were tested:

A: (Aegis Mark II) Nebulizer Off/PAPR Off
B: (Commercial PAPR) Nebulizer Off/PAPR Off
C: (Aegis Mark II) Nebulizer On/PAPR Off
D: (Commercial PAPR) Nebulizer On/PAPR Off
E: (Aegis Mark II) Nebulizer On/PAPR On
F: (Commercial PAPR) Nebulizer On/PAPR On

Efficacy was measured by dividing the number of particles inside the PAPR by those outside the PAPR. The differences between these setups were then analyzed.

Aegis Mark II PAPR System

The Aegis Mark II has two main parts: the blower/power unit and the hood assembly with tubing (Figures 1-3). This system can deliver 245 liters of filtered air per minute, well above the 115-170 lpm basic requirement. The centrifugal fan is housed in an airtight container with intake and output manifolds. The two intake manifolds hold the two filters. The filters are in-line bacterial/viral breathing circuit filters used in anesthesia and ventilator machines. These filters were chosen due to the following reasons: these are already certified for medical use with an APF of 25 (as stated by the manufacturer); these can be easily and safely replaced because the filter membranes are enclosed in a plastic that prevent direct contact; and these are supplied by the hospital. The output manifold connects with the hood's tubing. The fan is supplied by a 20,000 mAh lithium-ion battery. The blower unit, battery, and charger are housed in an integrated pack with a total weight of 1.8 kg. The hood assembly is constructed from a double layer of waterproof nylon fabric. The tubing is a corrugated 40 mm plastic tube, with a maximum length of 1100 mm and a diameter of 40 mm.

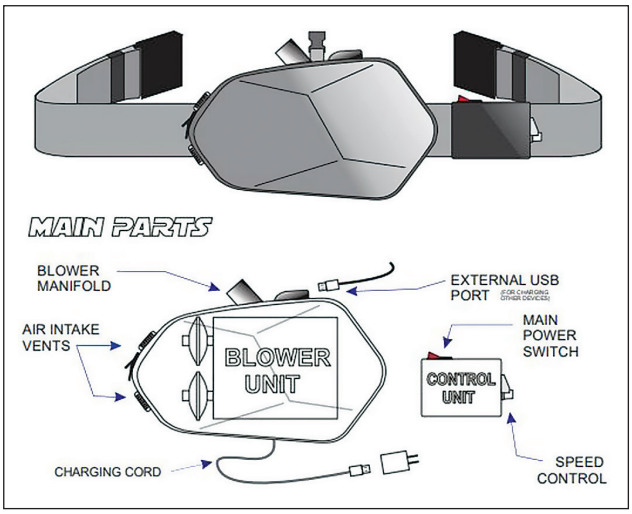

Figure 1. Blower unit.

Statistical analysis was done using Microsoft Excel and SPSS (v.26, IBM). Descriptive statistics (mean and standard deviation) were used to summarize battery power supply, filtration efficacy, and participant questionnaire answers. Kruskall-Wallis H-test was used to determine if there were significant differences in the responses among those who tested the Commercial PAPR, Aegis Mark I, and Aegis Mark II. Furthermore, Mann-Whitney U-Test was used to determine which two groups showed significant differences. Welch's One-way Analysis of Variance was used for comparing filtration efficacy for Aegis Mark II and the commercial type since the homogeneity of variances requirement for the F-test using One-way ANOVA was violated (Levene's tests for all dependent variables returned $p<0.05$). Consequently, the Games-Howell Post Hoc test was used to identify significant differences among the set-ups for each dependent variable.

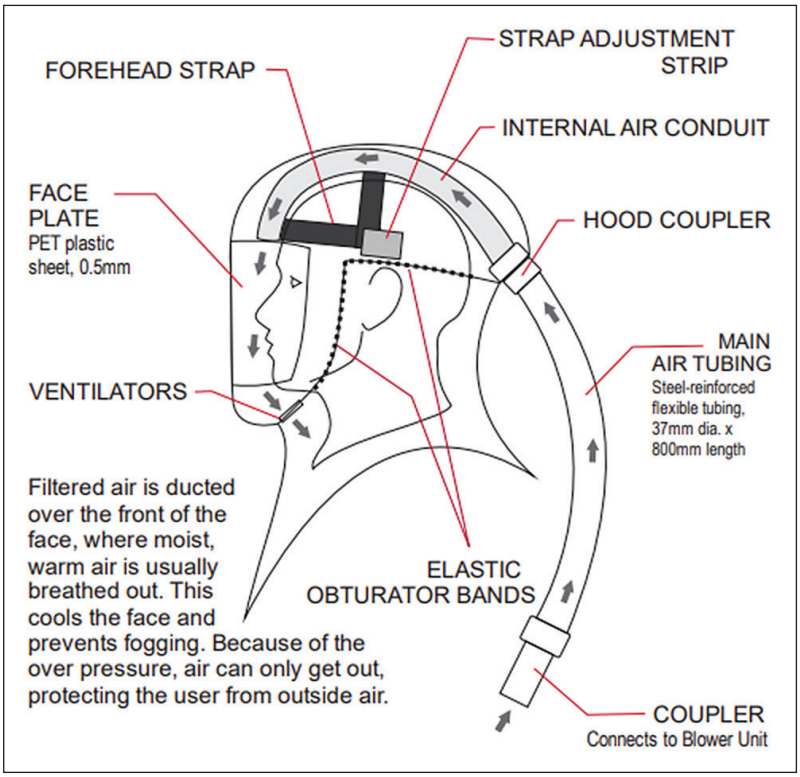

Figure 2. Surgical hood. Direction of airflow shown by the arrows.

Figure 3. Hood and blower unit when worn.

RESULTS

The Aegis Mark II PAPR rechargeable lithium battery pack required a mean total charging time of 2 h and 20 min (SD 19 min), while the mean service time was 11 h and 34 min (SD 16 min), and 8 h and 34 min (SD 38 min), in low and high flow blower setting, respectively.

Its materials and construction were durable; the hoses and coupling were non-collapsible, non-kinking, and detachable. A total of 50 participants were recruited. Ten participants were allocated to the commercial PAPR and Aegis Mark I groups, while 30 participants were allocated to the Aegis Mark II group. No participant experienced mechanical failure.

Most of the participants were very satisfied with the Aegis Mark II on factors affecting residency and education use and communication effort (n = 30, overall mean = 7.86 ± 1.81) (Table 1), comfort (n = 8.52, overall mean = 8.52 ± 1.63), and PAPR care (n = 30, overall mean = 7.76 ± 1.75) (Table 2). These all differed significantly from satisfaction with the commercial PAPR (Table 3).

The Aegis Mark II PAPR and commercial PAPR both showed significant decreases in the particle counts on PM2.5 and PM10 particle size counts when compared with environmental baseline data where the nebulizer is off (Setup E vs A, and Setup F vs B, respectively). Both PAPRs also show significant differences when compared with setups when the nebulizer is on (Setup E vs C, and Setup F vs D, respectively). The mean particle counts inside the user's breathing zone of both PAPRs (Setup E and F) showed that PM2.5 (5.7 and 6.2), and PM10 (6.2 and 6.6) values were within acceptable Ambient Air Quality Standards (Tables 4 and 5).

Table 1. Residency Training and Education, Clinical Performance and Communication

	Mean (±Std. Dev.)		
	Commercial (n = 10)	**Aegis Mark I (n = 30)**	**Aegis Mark II (n = 10)**
Residency training and education use (visual field)	7.10 (±1.29)	8.23 (±1.87)	8.80 (±0.92)
Residency training and education use (fogging)	6.40 (±1.35)	7.40 (±2.6)	9.10 (±0.57)
Residency training and education use (inside lighting / less shadow)	6.80 (±1.23)	8.40 (±1.35)	8.90 (±0.74)
Residency training and education use (PAPR noise reduction)	7.00 (±1.33)	7.13 (±1.96)	8.80 (±0.92)
Clinical performance (movement restrictions)	6.50 (±1.35)	8.40 (±1.65)	9.10 (±0.57)
Clinical performance (weight distribution)	6.10 (±2.02)	8.30 (±1.64)	8.90 (±0.74)
Clinical performance (ambulation)	6.40 (±1.78)	8.57 (±1.41)	9.20 (±0.63)
Communication effort (voice modulation)	6.80 (±1.23)	7.13 (±1.72)	9.30 (±0.67)
Communication effort (less muffling of voice)	6.80 (±1.14)	7.17 (±1.70)	8.70 (±1.16)
Overall Mean (±Std. Dev)	6.66 (±1.41)	7.86 (±1.81)	8.98 (±0.78)

Table 2. Comfort and Aegis II PAPR Care

	Mean (±Std. Dev.)		
	Commercial (n = 10)	**Aegis Mark I (n = 30)**	**Aegis Mark II (n = 10)**
Comfort			
Ease of donning	5.80 (±0.92)	8.57 (±1.63)	9.30 (±0.67)
Ease of doffing	5.80 (±0.92)	8.63 (±1.45)	9.40 (±0.52)
Ease of operation	6.60 (±1.17)	9.07 (±1.11)	9.50 (±0.53)
Ease of monitoring	6.80 (±1.03)	8.47 (±1.74)	9.20 (±0.79)
Ease of storage	6.90 (±1.20)	7.87 (±1.96)	9.20 (±0.42)
Overall Mean (±Std. Dev)	6.45 (±1.12)	8.52 (±1.63)	9.27 (±0.59)
Aegis II PAPR Care			
PAPR handling	6.80 (±1.23)	8.17 (±1.68)	9.00 (±0.82)
PAPR size/dimensions	6.70 (±1.16)	7.10 (±1.83)	8.60 (±1.43)
Ease of cleaning (durability of material)	7.10 (±1.45)	7.97 (±1.47)	9.2 (±0.63)
Ease of cleaning (material breakdown)	7.10 (±1.45)	7.90 (±1.81)	9.20 (±0.63)
Ease of disinfection (time required to disinfect)	7.40 (±1.51)	7.70 (±1.80)	9.30 (±0.48)
Ease of disinfection (time required for drying)	7.40 (±1.51)	7.70 (±1.80)	9.30 (±0.48)
Overall Mean (±Std. Dev)	7.08 (±1.36)	7.76 (±1.75)	9.10 (±0.82)

DISCUSSION

The National Institute for Occupational Safety and Health (NIOSH) suggested that the battery must operate for a minimum period of four hours. The airflow level or battery status generally should be checked prior to use, after four hours, and every two hours thereafter. The battery performance depends on the battery capacity, air-purifying components used, and the environment.[27] The average battery life of Aegis Mark II is 11 h and 34 min, (SD 16 min), and 8 h and 34 min, (SD 38 min) in low and high blower settings, respectively. providing an adequate use-time with approximately 2 h and 20 min charging time. The user can also monitor battery levels using the indicators, and extend use by connecting the charger continuously.

The study instructed the use of N95 mask inside the hood to maintain the user's protection during donning and doffing. Using an N95 mask concurrently with a loose-fitting PAPR has multiplicative protection.[28] The Program Protection Factor (PPF) provided by a loose-fitting PAPR exceeds its original Assigned Protection Factor (APF) of 25,[29] and provides 150%

Table 3. Results of the tests for significant differences in the responses to the questionnaire

	Multiple comparison			Commercial vs Aegis Mark I		Aegis Mark I vs Aegis Mark II		Commercial vs Aegis Mark II	
	Kruskal-Wallis H	df	Asymp. Sig.	Mann-Whitney U	Asymp. Sig. (2-tailed)	Mann-Whitney U	Asymp. Sig. (2-tailed)	Mann-Whitney U	Asymp. Sig. (2-tailed)
Residency Training and Education, Clinical Performance and Communication									
Residency training and education use (visual field)	8.119	2	0.017*	74.000	0.015*	131.000	0.537	15.000	0.006*
Residency training and education use (fogging)	14.432	2	0.001*	89.000	0.053	67.500	0.008*	1.000	0.000*
Residency training and education use (inside lighting/ less shadow)	12.664	2	0.002*	55.500	0.003*	120.000	0.331	7.000	0.001*
Residency training and education use (PAPR noise reduction)	8.016	2	0.018*	145.000	0.874	74.000	0.016*	12.000	0.003*
Clinical performance (movement restrictions)	13.728	2	0.001*	55.000	0.002*	124.500	0.409	1.000	0.000*
Clinical performance (weight distribution)	12.464	2	0.002*	54.500	0.002	126.500	0.448	7.000	0.001*
Clinical performance (ambulation)	16.316	2	0.000*	43.500	0.001**	113.500	0.235	1.500	0.000*
Communication effort (voice modulation)	15.708	2	0.000*	130.000	0.524	40.000	0.000*	2.000	0.000*
Communication effort (less muffling of voice)	9.162	2	0.010*	131.000	0.545	70.500	0.011*	10.500	0.002*
Comfort									
Ease of donning	18.742	2	0.000*	30.000	0.000*	122.500	0.367	0.000	0.000*
Ease of doffing	21.440	2	0.000*	24.500	0.000*	106.000	0.136	0.000	0.000*
Ease of operation	20.831	2	0.000	22.000	0.000*	125.000	0.399	0.000	0.000*
Ease of monitoring	12.796	2	0.002*	59.000	0.004*	123.000	0.379	3.000	0.000*
Aegis II PAPR Care									
Ease of storage	9.601	2	0.008*	97.000	0.092	97.000	0.089	4.000	0.000*
PAPR handling	10.557	2	0.005*	72.500	0.013*	109.500	0.193	8.000	0.001*
PAPR size/dimensions	7.833	2	0.020*	129.000	0.503	77.500	0.021*	13.500	0.004*
Ease of cleaning (durability of material)	10.823	2	0.004*	101.500	0.123	74.000	0.015*	9.000	0.001*
Ease of cleaning (material breakdown)	9.278	2	0.010*	105.000	0.152	84.000	0.035*	9.000	0.001*
Ease of disinfection (time required to disinfect)	10.299	2	0.006*	128.000	0.482	65.500	0.006*	10.500	0.001*
Ease of disinfection (time required for drying)	10.299	2	0.006*	128.000	0.482	65.500	0.006*	10.500	0.001*

* Difference is significant at $\alpha = 0.05$

more protection than just an N95 mask (APF of 10).[18] This study found that the filtration efficacy of the Aegis Mark II PAPR was comparable with the commercial PAPR, thanks to its two certified anesthesia machine breathing circuit filters with 99.99% filtration efficacy (APF of 25)[2,6,9] The mean particle counts inside the hood or the user's breathing zone between PAPRs were within acceptable Ambient Air Quality Standards. Both groups showed a significant decrease of particle counts once the PAPR was turned on. In the NIOSH standards, the filtration efficiency of the device is measured by challenging the device with sodium chloride particles having a diameter in the most penetrating particle size range for the filter media made between filters supplied by different manufacturers.[30-33] However, in the absence of any other recommendations, it may be considered appropriate to use a breathing system filter that has a filtration efficiency of at least 95% when challenged with sodium chloride particles in the most penetrating particle size range to prevent the air-borne transmission of microbes.[34-36]

Users of the Aegis Mark II were on average very satisfied with the PAPR's performance in factors affecting user training, user clinical performance, user communication, user comfort, and PAPR care variables, compared to the commercial PAPR. Since design features can affect utilization and acceptance, clinical simulation is a better measure of APF. In addition,

Table 4. PM2.5 Particle Count Assessment on the different testing set-up: differences in particles counts between two set-ups at a time

Set-up 1	Set-up 2					
	A	B	C	D	E	F
A	---	5.2667*	-22.2667*	-15.2000*	7.6000*	7.1000*
B	-5.2667*	---	-27.5333*	-20.4667*	2.3333*	1.8333
C	22.2667*	27.5333*	---	7.0667	29.8667*	29.3667*
D	15.2000*	20.4667*	-7.0667	---	22.8000*	22.3000*
E	-7.6000*	-2.3333*	-29.8667*	-22.8000*	---	-0.5000
F	-7.1000*	-1.8333	-29.3667*	-22.3000*	0.5000	---

Notes:
1) Filtration Efficacy Setup:
   A: (Aegis Mark II) Nebulizer Off/PAPR Off
   B: (Commercial PAPR) Nebulizer Off/PAPR Off
   C: (Aegis Mark II) Nebulizer On/PAPR Off
   D: (Commercial PAPR) Nebulizer On/PAPR Off
   E: (Aegis Mark II) Nebulizer On/PAPR On
   F: (Commercial PAPR) Nebulizer On/PAPR On
2) Each entry represents the difference in particle counts between Set-up 1 and Set-up 2; e.g., the difference in particle counts between A ((Aegis Mark II) Nebulizer Off/PAPR Off) and B ((Commercial PAPR) Nebulizer Off/PAPR Off), that is, A – B = 5.2667
3) Asterisk (*) means that the difference is significant at $\alpha = 0.05$
4) The comparison of the PM2.5 particle counts on the different filtration efficacy set-up showed that there is a significant decrease of the particle counts in the groups C – E (29.8667*) and groups D – F (22.3000*).

Table 5. PM10 Particle Count Assessment on the different testing set-up: differences in particles counts between two set-ups at a time

Set-up 1	Set-up 2					
	A	B	C	D	E	F
A	---	8.1333*	-35.7667*	-24.9333*	12.6667*	12.7333*
B	-8.1333*	---	-43.9000*	-33.0667*	4.5333	4.6000*
C	35.7667*	43.9000*	---	10.8333	48.4333*	48.5000*
D	24.9333*	33.0667*	-10.8333	---	37.6000*	37.6667*
E	-12.6667*	-4.5333	-48.4333*	-37.6000*	---	0.0667
F	-12.7333*	-4.6000*	-48.5000*	-37.6667*	-0.0667	---

Notes:
1) Filtration Efficacy Set-up:
   A: (Aegis Mark II) Nebulizer Off/PAPR Off
   B: (Commercial PAPR) Nebulizer Off/PAPR Off
   C: (Aegis Mark II) Nebulizer On/PAPR Off
   D: (Commercial PAPR) Nebulizer On/PAPR Off
   E: (Aegis Mark II) Nebulizer On/PAPR On
   F: (Commercial PAPR) Nebulizer On/PAPR On
2) Each entry represents the difference in particle counts between Set-up 1 and Set-up 2; e.g., the difference in particle counts between A ((Aegis Mark II) Nebulizer Off/PAPR Off) and B ((Commercial PAPR) Nebulizer Off/PAPR Off), that is, A – B = 8.1333
3) Asterisk (*) means that the difference is significant at $\alpha = 0.05$
4) The comparison of the particle counts on the PM10 different filtration efficacy set-up showed that there is a significant decrease of the particle counts in the groups C – E, (48.4333*) and groups D – F, (37.6667*).

users are diverse and have differing respiratory demands.[8] The Aegis Mark II's filters, durability, and long battery life offered reliability and inspired confidence among the users. The visual field, clinical performance, communication, and comfort were on par with the published literature.[28,37,38] In contrast, N95 respirators resist air intake and retain heat and moisture, causing heat stress; these factors can reduce focus on the critical tasks. The adequate and cooling air flow rate, wide visual field, and clear communication helps the user perform clinical duties.[39-44] PAPRs have become indispensable during infectious disease outbreaks.[40,45-48]

CONCLUSION

The locally developed Aegis Mark II PAPR displayed a high degree of protection comparable with commercial PAPRs by using 99.99% filtration efficacy bacterial and viral filters. It is highly conducive to training and clinical work while being comfortable to use and maintain. Materials are more durable and can withstand repeated use and disinfection procedures. The high level of user satisfaction and acceptance can lead to a higher user's compliance. The Aegis Mark II may prevent the spread of infection to healthcare workers, reduce physiologic stress, and reduce the healthcare sector's financial burden.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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APPENDIX

Questionnaire Form

Name of Participant: _____
Date: _____
Study Group: _____

Questionnaire: Likert scale 1-10 (1-2- not satisfied, 3-4 slightly satisfied, 5-6 neutral, 7-8 very satisfied, 9-10 extremely satisfied).
Check box according to your response.

Variables	Responses									
	1	2	3	4	5	6	7	8	9	10
Residency Training and Education										
Visual field										
Fogging										
Inside lighting/less shadow										
PAPR noise reduction										
Clinical Performance										
Movement restrictions										
Weight distribution										
Ambulation										
Communication Effort										
Voice modulation										
Less muffling of voice										
User's Comfort										
Ease of donning										
Ease of doffing										
Ease of operation										
Ease of monitoring										
Aegis II PAPR care										
Ease of storage										
PAPR handling										
PAPR size/dimensions										
Ease of cleaning (durability of material)										
Ease of cleaning (material breakdown)										
Ease of disinfection (time required to disinfect)										
Ease of disinfection (time required for drying)										

The Philippine Journal of Orthopaedics

ORIGINAL ARTICLE

Enhancing Orthopaedic Residents' Microsurgery Suturing Skills Using a Low-Fidelity Setup*

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ABSTRACT

Objective. To describe the suturing consistency of orthopaedic residents in microsurgery using a low-fidelity set-up.

Background. Residents lack the time and resources to practice microsurgical suturing under a microscope before being exposed to live surgeries. Speedy and consistent suturing are critical skills during live surgery (e.g., vessel anastomosis in free flap surgery, or critical revascularization). This study presents a budget-friendly home or office setup for microsurgery practice to improve the consistency of suture distance and interval.

Methodology. This is a cross-sectional study that measured the consistency of suture distances and intervals and time to completion of seven Orthopaedic residents using a locally available digital USB-powered microscope, a monitor, and latex sheets. Consistency was analyzed using intraclass correlation.

Results. All residents had a faster time to completion with each attempt (mean 1st attempt = 27.7 min, 2nd attempt = 20.4 min, 3rd attempt = 17 min). The third attempt showed significantly improved suture consistency in all participants (ICC = 0.50, $p<0.001$).

Conclusion. This budget-friendly home or office set-up for microsurgery practice improves time to completion and consistency in suture intervals when suturing under magnification.

Keywords. microsurgery, simulation model, microvascular surgery, surgical education, simulation

INTRODUCTION

Microsurgery is defined as any type of surgery performed with the assistance of a microscope.[1] It is a skill honed by a small subset of Orthopaedic surgeons who perform free tissue transfers, neurovascular repairs, and replantation of amputated digits.

High-fidelity training comes only with specialized workshops or access to a microscope. There are few microsurgical workshops conducted locally. Anecdotally, a resident's first encounter with a microscope is likely inside the operating room during live surgery.

Familiarity, consistency, and speed are critical to the success of any microsurgery. Variable clinical exposure, premiums on operating room efficiency, and a steep learning curve make microsurgical suturing a difficult skill to master.[2]

Significance of the study

We presented a low-fidelity set-up with a digital microscope for microsurgical suturing exercise on non-living models that can be done almost anytime and anywhere, to help residents

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**This study was presented in the following:*

1. *POA 31st Annual Mid-Year Convention, Bacolod, Negros Occidental, Philippines – April 2023, Won 2nd Place, Innovations Category Research Contest*
2. *Asia Pacific Orthopaedic Association, Hand and Upper Limb Society Meeting, Seoul, South Korea – June 2023*
3. *SICOT Young Surgeons Meeting 2023 – Chennai, India – August 2023*

develop and improve their suturing consistency under magnification.

OBJECTIVES

General objective

- Describe the suturing consistency of orthopaedic residents in microsurgery using a low-fidelity set-up

Specific objectives

- Determine how long (in minutes) each resident takes to complete the suturing exercise
- Determine if the residents improve their consistency in the suture distances and intervals
- Determine if there is a significant difference in the consistency of suture distances and intervals with each attempt

METHODOLOGY

This was a cross-sectional study done at the De La Salle University Medical Center, Dasmariñas (DLSUMC). We included all Orthopaedic surgery residents (7 residents) at DLSUMC. This study was approved by the institutional review board and was exempted from review by the ethics committee because of the non-involvement of patients and patient data.

Prior to measurement, a hand and microsurgical consultant did a microsurgical suturing demonstration using the same setup. The ideal sutures should be tightly knotted and lie 1-2 mm from the wound edge (suture distance) and with 2–3 mm in between sutures (suture interval).

The microscope used was a generic Wireless HD camera with adjustable magnification up to 1000x magnification (Figure 1). Clinically, image clarity was found to be best at around 2x to 3x magnification using fine adjustment at 12 inches working length. The setup was as follows: the participant sat with forearms flat on the table, with the microscope at 12 inches above the microsurgical field, and the laptop/screen in front of the participant at his/her most convenient position (Figure 2).

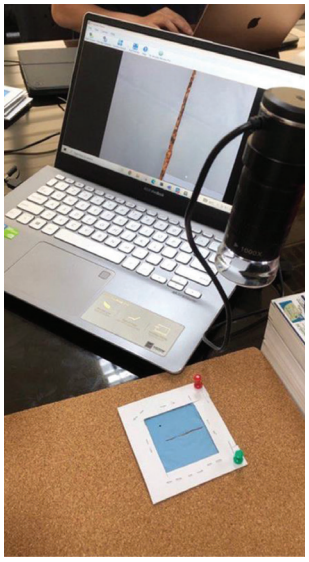

Figure 1. USB-powered digital microscope connected to a laptop.

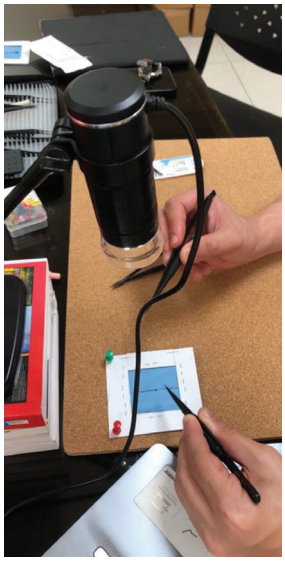

Figure 2. Participant performing microsurgical exercise.

Square latex sheets cut from surgical gloves were used to simulate transected vessels. The perimeters of these sheets were fixed by staples between an illustration board and a corkboard. A laceration was made in the middle of the latex. Nylon 7-0 sutures and microsurgical instruments were used to repair the laceration using a simple interrupted technique. A completed attempt required the completion of five sutures passed and tied tightly (Figure 3). All attempts were observed directly by the researchers. Participants were not allowed to look directly at the instrument or sutures and looked only at the laptop screen to simulate a microsurgery. All participants were given three attempts, with 10-minute intervals in between attempts. We allotted a total of two hours per participant including the rest periods to complete the activity. Up to four participants could perform the surgical exercise simultaneously.

A vernier plastic caliper (Eagle Professional tools 6" / 150 mm) was used to measure the suture distances and intervals after each attempt (Figures 4 and 5). Measurements were made by a researcher, and double-checked by the supervising hand surgeon consultant. The time to completion was recorded from the first suture bite until the completion of the final suture.

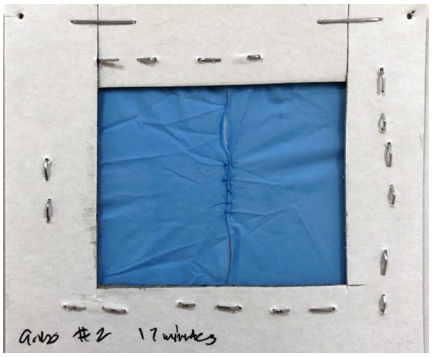

Figure 3. Example of a completed attempt.

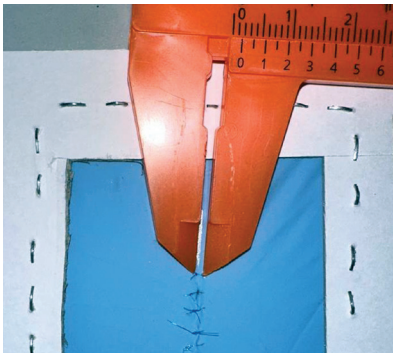

Figure 4. Measuring the suture distance.

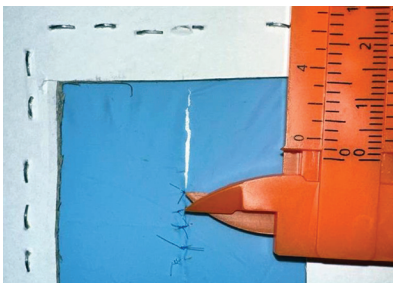

Figure 5. Measuring the suture intervals.

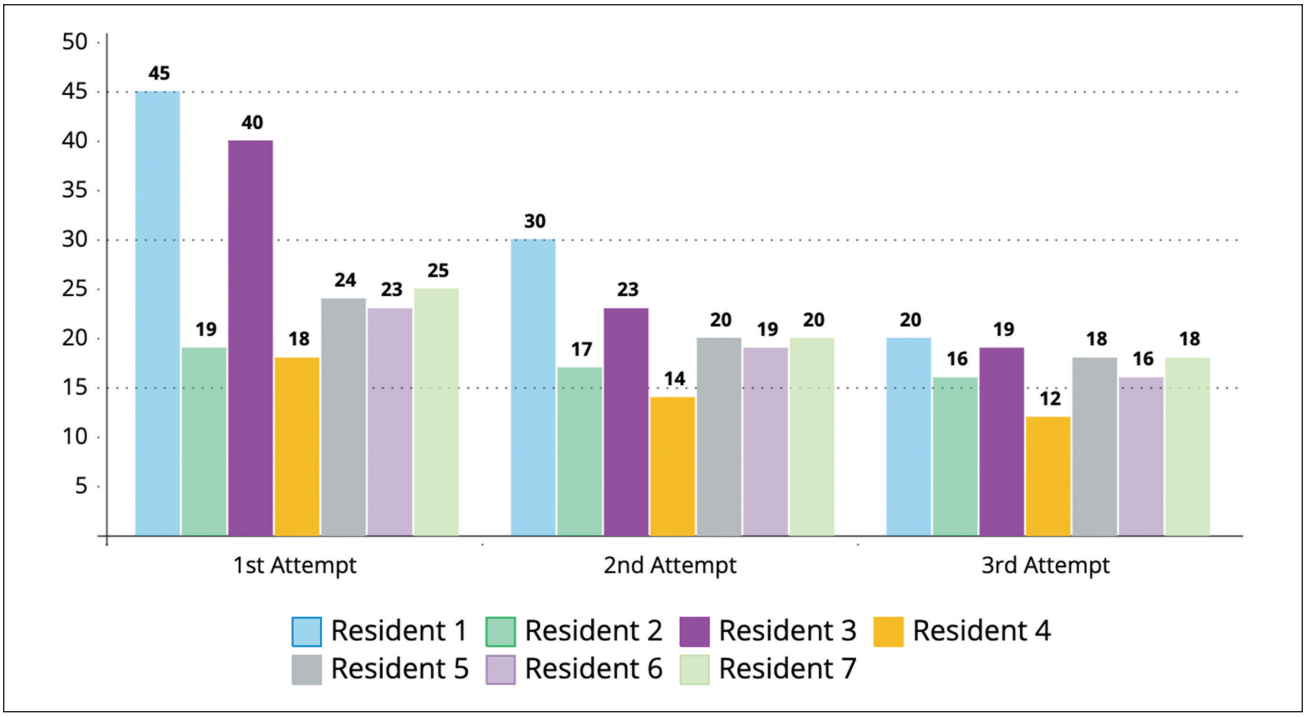

Figure 6. Time to Completion (in minutes). Each participant is represented by a vertical bar. The three groupings along the X-axis represent the three attempts. Y-axis is represented by time to completion in minutes.

Descriptive statistics (mean, standard deviation) were used to describe suture distances, suture intervals, and the time to completion was measured (Table 1). Consistency was measured using intraclass correlation. Values less than 0.5 indicated poor consistency, values of 0.5 to 0.75 indicated moderate consistency, values ranging from 0.75 to 0.9 indicated good consistency, and values greater than 0.9 indicated excellent consistency.

RESULTS

Participants were orthopaedic surgery residents (YL1-YL4), with a mean age of 32.1 (29-33 years). None of the residents did suturing under the microscope before this research was done. All of them can do simple interrupted suturing with non-microsurgical size sutures without magnification. None of them had resting tremors. No changes were made to the participants' caffeine or nicotine intake, if any.

Time to completion

All participants were faster with each attempt, with the mean time to completion of 27.7 minutes in the first attempt, 20.4 minutes on the second attempt, and 17 minutes in the final attempt. There was a 38.7% improvement in time from the first to the final attempt (Figure 6).

Table 1. Intraclass correlation of suture intervals

Suture intervals (in mm)	Ortho 1	Ortho 2	Ortho 3	Ortho 4	Ortho 5	Ortho 6	Ortho 7	ICC	*p*
Attempt 1	3.00	2.20	7.00	4.00	4.00	4.00	3.00	0.37	0.004
	2.50	2.20	3.50	6.00	3.00	5.00	2.50		
	2.00	2.00	3.00	5.00	2.00	5.00	2.50		
	3.00	2.00	3.20	5.00	3.00	4.00	2.50		
Attempt 2	3.50	3.50	3.00	5.00	3.00	4.50	4.00	0.18	0.064
	2.50	2.00	5.00	8.00	3.00	1.00	3.00		
	2.50	3.00	4.00	8.00	2.50	1.20	3.00		
	2.50	2.00	1.80	7.00	2.00	5.00	2.50		
Attempt 3	3.00	3.00	5.50	5.00	5.00	3.00	3.00	0.50	<0.001
	2.00	3.00	4.50	6.00	4.00	4.00	3.00		
	2.20	4.00	4.00	5.00	4.00	2.00	3.00		
	2.00	2.00	5.00	5.00	5.00	3.00	4.00		

ICC – Intraclass Correlation
*ICC Attempt 2 vs ICC Attempt 3 = (0.18 vs 0.50) = statistically significant improvement (p<0.001)

Table 2. Intraclass correlation of suture distances

Suture distances (in mm)	Ortho 1	Ortho 2	Ortho 3	Ortho 4	Ortho 5	Ortho 6	Ortho 7	ICC	*p*
Attempt 1	1.50	0.90	0.75	2.25	3.00	2.25	2.00	-0.030	0.541
	2.00	0.95	0.45	3.00	2.25	2.00	2.75		
	2.00	1.00	0.50	2.50	2.25	1.50	2.50		
	1.50	0.95	0.75	2.75	1.75	2.00	2.20		
	1.50	1.00	0.50	2.50	1.00	2.50	2.00		
Attempt 2	1.00	1.50	0.50	0.75	2.50	1.50	2.75	0.102	0.163
	1.65	1.00	0.65	1.00	3.00	3.50	1.50		
	1.10	0.90	0.45	0.90	2.50	1.25	2.00		
	1.75	1.00	0.50	1.00	2.75	2.50	2.25		
	1.00	1.00	0.45	0.85	2.25	2.00	1.50		
Attempt 3	1.50	0.85	1.00	1.00	3.00	2.00	2.20	-0.022	0.509
	1.00	1.10	0.90	1.00	2.00	3.00	1.50		
	1.25	1.00	1.00	1.00	2.50	3.00	2.00		
	1.75	1.25	0.90	0.85	3.00	2.50	2.50		
	1.75	1.00	0.75	1.00	2.00	2.50	2.50		

ICC – Intraclass Correlation

Suture intervals

Consistency in suture intervals was improved on the final attempt. Participants had ICC values of 0.18 on the second attempt, which improved to a value of 0.50 on the final attempt (p <0.001) (Table 2).

Suture distances

Participants' consistency in suture distances remained the same among all attempts (Table 3).

Erroneous or unacceptable sutures

There was a total of nine erroneous sutures (9/105, 8.6%) in five participants. These sutures were either loose or too tight which caused the latex rubber to tear.

DISCUSSION

A resident's clinical experience is not enough to hone his/her microsurgical skills. Microsurgical training models can be broadly classified into three groups: synthetic, non-living, and virtual reality. Synthetic and non-living models allow trainees to be introduced to the manual microsurgical skill, by high repetition at minimal cost.[3] Ko et al., described a microvascular training curriculum beginning with the use of non-living models and progressing to the use of living animal models.[4] Most recommend that a course should last at least a week or 40 hours, while others recommend at least two to three months, including a personalized one-to-one format and step-by-step teaching. Still, others recommend that microsurgery training be integrated directly into the residency training program, with proven increases in residents' performance on Global Rating Scales.[4] Despite the proven benefits, implementation remains difficult. At present, no studies described the improvement in consistency of suture distances and intervals in a low-fidelity microsurgery setup.

We found that our participants improved the consistency of their suture intervals and shortened their time to completion when suturing under magnification under a low-fidelity setup. No improvement was found in the consistency of their suture distances. Most of the suture placements were acceptable. Participants were given only three attempts, with rest periods in between, to prevent exhaustion.

The size and scarcity of typical operating microscopes present considerable barriers to effective microsurgical training.[5] In contrast, our equipment can be deployed at the office or even at home, at any convenient time. Chai et al. also used a low-cost digital microscope with a 1-600x zoom amounting to ~2100 PhP.[6] While we did not consider the cost of the microsurgery instruments, affordable practice instruments are available online. Surgeons can develop required fine motor skills, hand and eye coordination, and depth perception through increased repetition. While other studies used subjective measurements of improvement, we objectively measured participants' improvements through suture distances and intervals.

CONCLUSION

A portable setup for microsurgery practice improves time to completion and consistency in suture intervals when suturing under magnification.

LIMITATIONS AND RECOMMENDATIONS

Our study utilizes a low-fidelity setup. This will be ideal for beginners to practice microsurgery, or experienced surgeons, who want to refine microsurgery techniques at their most convenient time and place. This should not replace a high-fidelity setup to properly simulate a proper microsurgical exercise.

This study has few participants due to time and financial constraints. We also wanted to pilot test the methodology in our local setting before expanding to other hospitals. A maximum of four participants were observed simultaneously because we only had four microsurgical instrument sets and four USB microscopes. The whole activity lasts five hours. Residents from different hospitals will have varying availability in a week and protected time. We recommend to expand the use of this setup for basic microsurgery training workshops with a larger sample size.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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None.

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ORIGINAL ARTICLE

Biomechanical Stiffness and Strength of New Versus Reused Stainless Steel Uniplanar Tibial External Fixator Constructs in a Low-Resource Setting*

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ABSTRACT

Introduction. External fixation is used in the initial or definitive management of open fractures. Branded fixators are costly and often unavailable in low-resource countries. Low-cost locally available stainless steel fixators are relatively easy to procure. When these low-cost fixators are depleted in hospitals and purchase cost is prohibitive for patients, the reuse of non-implanted components (the rods and clamps, referred to as outriggers) is a frequent alternative. New Schanz pins should be implanted into bone to reduce the risk of infection. The reuse of outriggers translates to significant savings both for hospitals and patients. Knowing the stiffness and strength of reused versus new fixators will help guide their policies regarding reuse.

Objectives. The general objective of this study was to assess the biomechanical stiffness and strength of both new and previously used external fixator constructs available in our hospital. Specifically, this study compared the axial stiffness, bending stiffness, torsional stiffness, and ultimate strength of new versus previously used low-cost uniplanar tibial external fixator constructs. In addition, this study compared the axial stiffness and ultimate strength of an all-new low-cost uniplanar tibial external fixator constructs using five Schanz pins versus six Schanz pins.

Methodology. Forty-five plastic tibia were osteotomized at midshaft to create a fracture gap, simulating a comminuted diaphyseal fracture. Tibias were randomly divided into three groups of fifteen specimens. Each tibia was stabilized using five new Schanz pins in a uniplanar configuration held by one of three constructs: 1) with all-new components, 2) once-used and re-sterilized outriggers, or 3) twice-used and re-sterilized outriggers. Specimens were then biomechanically tested to determine fixation stiffness in axial compression, bending, and torsion. Static loading until failure was also performed to determine ultimate construct strength.

A fourth group of five specimens (osteotomized tibias) were stabilized using all-new components with six Schanz pins (three pins in each fracture segment). These specimens were tested to determine axial stiffness and ultimate strength. Results were then compared to the first group (5-pin all-new components).

Results. There were no significant differences among the first three groups in terms of axial stiffness, axial strength, and bending stiffness. In the torsion test, the reused fixators were even stiffer than the all-new group.

The all-new fixators using six Schanz pins were significantly stiffer and stronger versus the all-new fixators using five Schanz pins.

Conclusion. Reused, locally available stainless steel uniplanar tibial external fixators were mechanically comparable to new fixators in terms of axial stiffness, bending stiffness, and ultimate strength. Reused fixators were superior in terms of torsional stiffness versus new fixators. The reuse of non-implantable fixator components is a viable option without compromising construct mechanical strength even if the components have undergone two cycles of clinical use and reprocessing.

The study also concludes that in using new external fixators, increasing the number of pins from five Schanz pins to six Schanz pins increased the construct's axial stiffness two times and increased the construct's axial strength four times.

Keywords. external fixator, stiffness, strength, reuse

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INTRODUCTION

Increasing urbanization and motorcycle use in developing countries expose people to more high-energy trauma.[1] Road traffic accidents result in open trauma, especially fractures; the tibia is at particular risk in motorcycle crashes.[2] Pedestrians are considered one of the most vulnerable road users in less developed countries such as the Philippines.[3] The poor infrastructure and hygiene conditions in some areas make internal fixation techniques inaccessible,[4] leaving external fixation the treatment of choice.

External fixation involves pins or wires percutaneously implanted in bone and connected outside the body using clamps and rods.[5] Although traditionally used to provisionally (and sometimes definitively) treat open tibial fractures,[6] they may also be used for certain closed fractures with severe soft tissue injury.[7,8] Unfortunately, external fixation is also expensive in some areas.[9] External fixators are considered disposable devices, adding a great burden to healthcare costs, especially in developing countries.[10]

There are numerous sophisticated external fixator models available on the market, but these are too costly for routine use in developing countries.[11] Many enterprising surgeons have devised cheaper models.[12] Simplifying the design, changing the material and overall finish can reduce manufacturing costs. These fixators generally achieve the same results as those that are more expensive when used properly.[12,13] However, the efficacy and safety of low-cost external fixators should be analyzed before being deployed in clinical settings.

Low-cost, locally manufactured external fixators are typically made of stainless steel. The construct's stiffness is key, as this helps maintain bone alignment under a mechanical load. When used for fracture management, the stiffness should be sufficient to overcome the forces during patient mobilization to prevent fracture displacement, avoid nonunion,[14] and enhance callus formation.[15]

Recycling external fixator components is often economical.[16] In developing countries, even locally manufactured external fixator stocks are often depleted and many patients cannot afford commercial devices. A common practice is to reuse, with the patient's consent, the non-implantable components (outriggers) of previously used external fixators, thus greatly reducing the cost of treatment. Biomechanical studies comparing new and previously used, low-cost, locally available uniplanar tibial external fixator constructs would be necessary to justify this practice. There is also a need to standardize the method of reprocessing used fixators to minimize differences in their properties.

According to the United States Centers for Disease Control and Prevention,[17] proper disinfection and sterilization in healthcare facilities may include cleaning using water with detergents or enzymatic products, disinfection by chemical disinfectants, and sterilization. The method depends on the type of material and the manufacturer's suggestions. In general, for cleaning and reprocessing heat-stable medical equipment like stainless steel external fixators and other surgical instruments, heat sterilization (i.e., autoclave sterilization) is the method of choice.[18] All external fixator constructs undergo cleaning with water and liquid detergent, disinfection by chemical products (such as povidone-iodine solution), and sterilization by steam and pressure from an autoclave.

Many orthopedic trauma surgeons have expressed interest in the reuse of external fixator components but have reported barriers to implementation including reprocessing logistics and concerns about litigation.[9] Others believe that components should not be reused due to issues with the device response, mechanical wear and fatigue, lack of reprocessing control, liability for device failure, fiduciary consideration, and advancement of fixator technology.[5]

A single center's experience with a reuse program for external fixators in the United States concluded that the reuse of external fixator components in good repair is safe and should be supported due to its advantages in cost reduction,[19] and that reused external fixators are still mechanically sound.[20]

A randomized clinical trial in a single center, level I trauma center in the United States involving the use of new versus refurbished non-implantable external fixator components concluded that it was safe and effective with actual cost savings of 25% of the cost of all new frames. It was also found that there were no statistical differences in the incidence of pin tract infections, loss of fixation, or loosening of components.[21] A prospective randomized interventional study in a tertiary care teaching hospital in India also found no significant difference in the incidence of pin tract infection, loss of fixation, and loosening of components. The conclusion was similar, that recycling external fixator components is safe and effective, with a sizable cost saving. Due to this demonstration of safety and the cost savings in the reuse of external fixation devices, reuse appears inevitable.[22]

Assessment of external fixator reusability using load- and cycle-dependent tests on unilateral DynaFix fixators determined that it can be reused no more than three times as the device accrues fatigue damage with more loading cycles.[23]

Stainless steel continues to be a popular material for a wide range of orthopedic implants. Most medical-grade stainless steel is an alloy called 316 L.[24]

The American Society for Testing and Materials (ASTM) sets the standard for mechanical testing of stainless-steel products including external skeletal fixation devices (ASTM designation F1541-17).[25] For uniplanar external fixator constructs, the tests include the axial compression test, bend test, and torsion test, as can be expected from clinical use.

In the Philippines, the price of a new, low-cost locally available stainless steel uniplanar tibial external fixator

ranges from PhP5,000 to PhP15,000 and the price of a percutaneously implanted Schanz pin is about PhP 150 to PhP 300. Therefore, using new Schanz pins with a reused external fixator frame or outriggers results in significant cost reduction. Schanz pins should not be reused to avoid the risk of directly seeding pathogens into the patient's bone. The low-cost, locally available stainless steel uniplanar tibial external fixator constructs that are widely used in this country and other developing nations have rods and clamps that may be reused as long as they are mechanically sound in terms of axial compression, bending, and torsion. This study can be the basis for guidelines for reusing these external fixators, developing criteria for reuse, and standardizing procedures for recycling, disinfecting, and sterilizing external fixators.

We believe this study is the first of its kind in the country. The usual low-cost uniplanar tibial external fixators sold have five Schanz pins. However, increasing the number of pins increases the construct stiffness or rigidity.[26] We will also test an all-new uniplanar tibial external fixator construct using six Schanz pins.

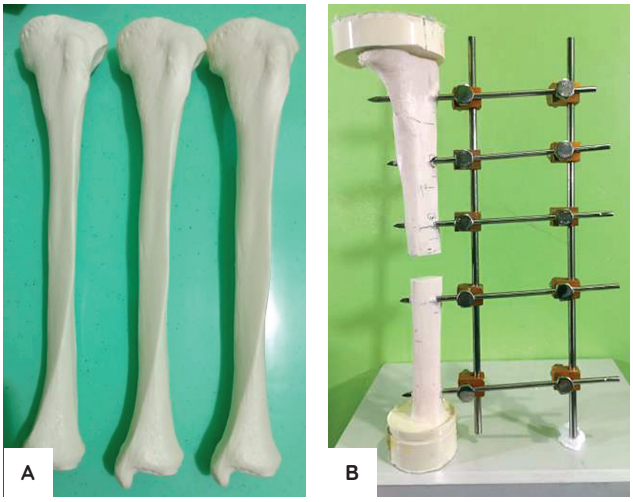

Figure 1. (A) Adult-size left tibias made of synthetic plastic polymer (polyvinylchloride) **(B)** External fixator construct attached to a plastic tibia with a fracture gap of 20 mm with bone ends potted in polyurethane.

METHODOLOGY

Type of study

This is an experimental study testing low-cost locally available uniplanar tibial external fixators. It uses non-human subjects and was given a certificate of exemption from ethics review.

External fixator selection

All stainless steel uniplanar tibial external fixators were not branded, and were made of the same type, design, and materials. All Schanz pins used were new. The three groups were as follows:

1. The all-new group includes five new Schanz pins and new outriggers.
2. The once-used group includes five new Schanz pins and outriggers that had been used and reprocessed once.
3. The twice-used group includes five new Schanz pins and outriggers that had been used and reprocessed twice.

Sample size

This study utilizes non-random sampling. A total of 45 external fixators were tested in this study, 15 in each group. From each group, 5 were tested for axial compression, 5 were tested for bending, and 5 were tested for torsion (Figure 2). Based on the guidelines from the ASTM Designation F1541-17 entitled "Standard Specification and Test Methods for External Skeletal Fixation Devices," a minimum sample size of 5 for any given load condition is considered adequate for the testing.

Preparation of external fixator

Components showing mechanical defects were discarded. Preparation of the external fixators involved inspecting, cleaning, disinfecting, and sterilizing before testing. First, these fixators were soaked in a basin with 4 liters of tap water mixed with 1 sachet or 60 mL of ready-to-use liquid detergent, then scrubbed using a sponge and plastic brush. The fixators were then rinsed under running tap water. The fixators were then soaked in 1 liter of 7.5% povidone-iodine solution before being scrubbed using a sponge and plastic brush and rinsed under running tap water. The third step was the sterilization process, performed using moist heat and pressurized steam from an autoclave. Fixators were double-wrapped with linen and then sterilized in an autoclave for 45 minutes at a temperature of 121 degrees Celsius and pressure of 15 pounds per square inch.

Bone and fracture model

Forty-five models of adult-size left tibia made of synthetic plastic polyvinyl chloride (Figure 1A) were divided into three groups. All the synthetic bones had the following measurements: 350 mm in length, 72 mm wide at the proximal tibia, 50 mm wide at the distal tibia, and 28 mm wide at the midshaft level. A fracture gap of 20 mm was created using a handle saw and measured with the aid of a Vernier caliper, to simulate a comminuted mid-shaft tibial fracture. The gap was created to ensure that there was no contact between the two ends of the fracture gap during axial loading. These were then implanted with the external fixators per group as described. All tibia were potted at each end using polyurethane (Figure 1B).

External fixator construct assembly

Each external fixator set was assembled according to the test construct configuration parameter suggested by ASTM.[25] All clamps (or pin-rod connectors) were tightened to 10 Newton-meter of torque using a torque wrench. The following were the details of the components of the external fixator: partially

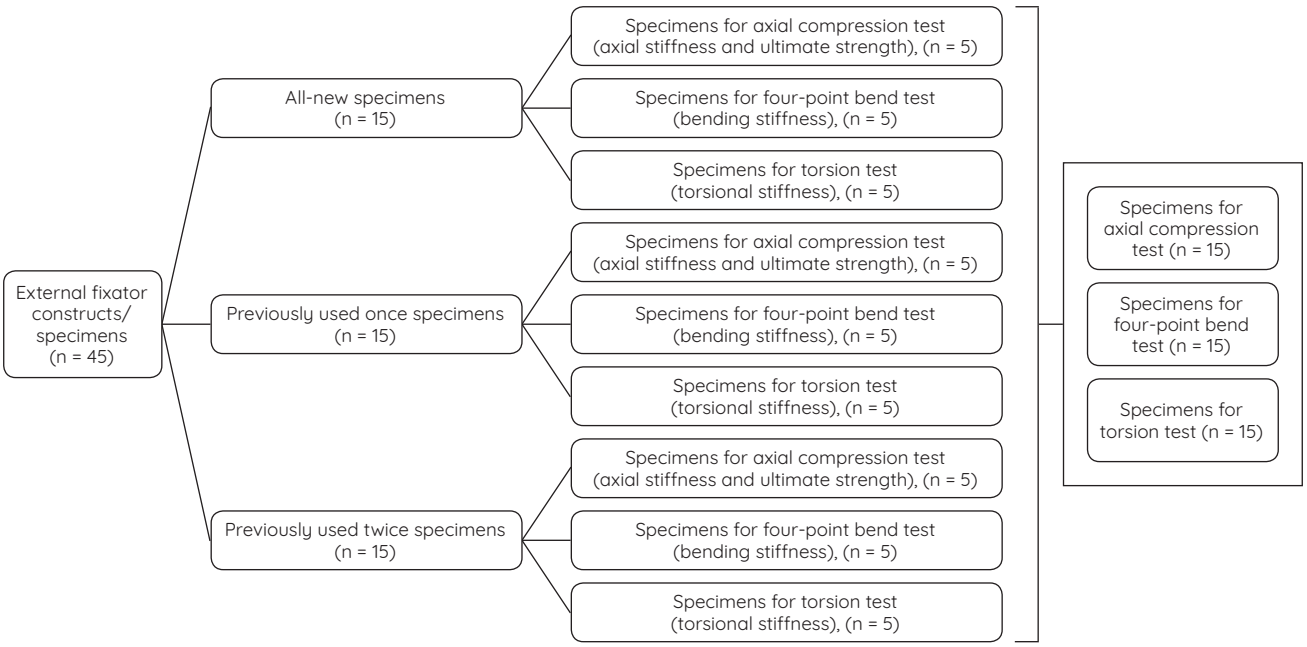

Figure 2. Schematic diagram of the distribution of the 45 external fixators.

threaded Schanz pins 4.5 mm diameter, 200 mm length, 30 mm threaded portion; pin-rod clamp or screw clamps with nuts and bolts; and longitudinal rods 6 mm diameter, 330 mm length. The following were the details of the bone-fixator assembly: fracture gap size of 20 mm; a bone-to-rod distance of 25 mm; rod-to-rod distance of 70 mm; Schanz pin-to-fracture distance of 20 mm; pin-to-pin distance in the proximal segment of 50 mm; and pin-to-pin distance at the distal segment of 80 mm.

Biomechanical testing of the external fixator construct

All constructs were tested in an accredited material testing laboratory in Cagayan de Oro City, the TestLab Engineering & Geotech Sevices. The tests included axial compression, four-point bending, and torsion testing. The experiment set-up and procedures were performed in concordance with the ASTM Designation F1541-17 entitled "Standard Specification and Test Methods for External Skeletal Fixation Devices." The results include axial stiffness (N/mm), bending stiffness (N/mm), and torsional stiffness (N•m/degrees). In the axial compression test, the specimens were also loaded to failure to determine the ultimate strength (N).

A trial run ensured that the bone analog material was sufficiently tough so that the anchorage elements (Schanz pins) remained tightly embedded in bone throughout the test.

Axial compression test

Both ends of the construct were mounted and aligned axially with the use of spacers and a setting load—about 0.1% of the expected load—to hold the specimen axially in place before starting the test (Figure 3). The axial compression was tested with a Matest Servo Controlled Universal Testing Machine of 500 kN Capacity with a Digital Touch Screen Display. The applied load was gradually increased from 0 to a maximum of 700 N (corresponding to the weight of a 70 kg person during a one-legged stance) at a deformation rate of 0.1 mm/s. The displacement was measured simultaneously with the load using Neoteck Digital Indication—Model NTK021; 0–25.4 mm. Tangent stiffness was determined by the slope of linear-most of the bone-fixator construct response curve (Figure 4). The ultimate load was determined by locating the peak point on the response curve (Figure 4). All determinations were in conformance with ASTM F1541-17 Section A7 method.

Four-point bending test

The constructs were mounted on a bending fixture with a 70 mm-loading span distance and 310 mm-support span distance (Figure 5). The four-point bend test was tested with Matest Sheartronic with a Load cell capacity of 25kN with 0.001kN readability at a rate of 1.0 mm/min. The applied loading was gradually increased until a deflection of 8–9 mm was achieved. The displacement was automatically logged by the machine using the Linear Variable Differential Transformer. Bending stiffness was determined by the slope of the curve (Figure 4). All determinations were in conformance with ASTM F1541-17 Section A7.

Torsional stiffness

The proximal end of the construct was clamped on the load cell plunger while the distal end was clamped with a C-clamp which served as its lever arm (Figure 6). The distal end is then manually twisted clockwise until the load cell reading reads approximately 326 to 330 N to produce 9–10 Nm of torque. The lever arm distance from the center of the axis

of twist is 0.18 m which serves as its lever arm for twisting. The angle of twist was manually logged corresponding to the 4-intervals within the specified max load cell reading. The machine used is the Matest Sheartronic Machine with a 5 kN capacity load cell. Torque force is the force that can cause an object to rotate about its axis and also cause an angular displacement. Thus, torque was determined by multiplying the force recorded by the load cell by the lever arm of 0.03 m. Torsional stiffness was then determined by the average slope of the reaction curve of the external fixator construct (Figure 4). All determinations were in conformance with ASTM F1541-17 Section A7 method.

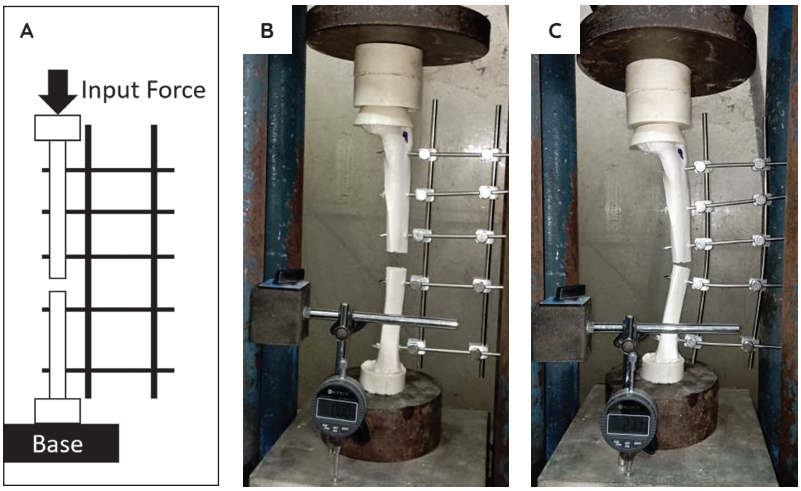

Figure 3. (A) Schematic test configuration for axial compression test of an external fixator (adapted from ASTM F1541-17). Actual axial compression before **(B)** and after **(C)** the test.

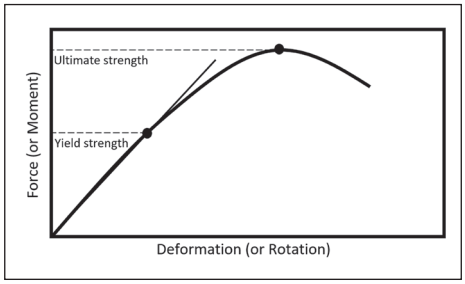

Figure 4. Typical fixator-bone construct response curve (adapted from ASTM F1541-17).

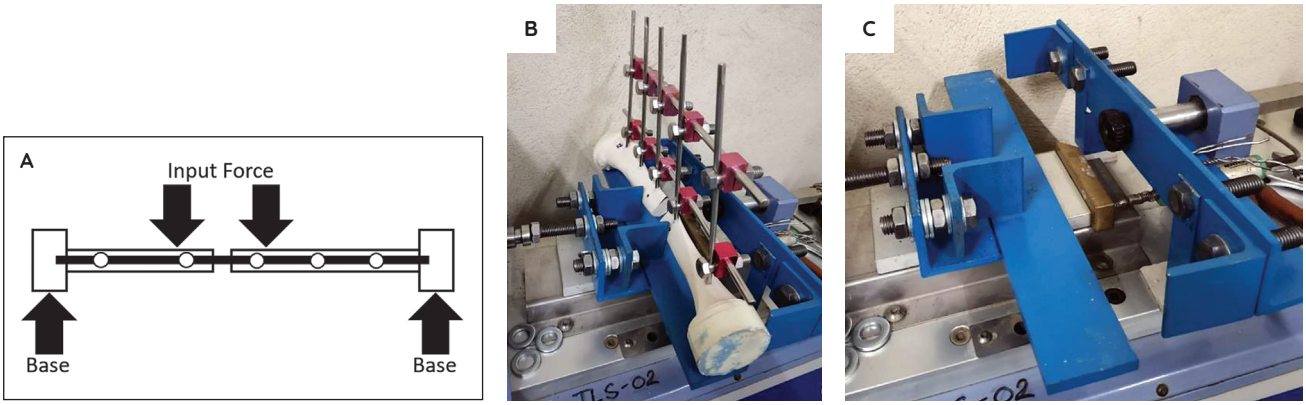

Figure 5. (A) Schematic test configuration for four-point bending test of an external fixator (adapted from ASTM F1541-17). Actual four-point bending test set-up with **(B)** and without **(C)** specimen inserted.

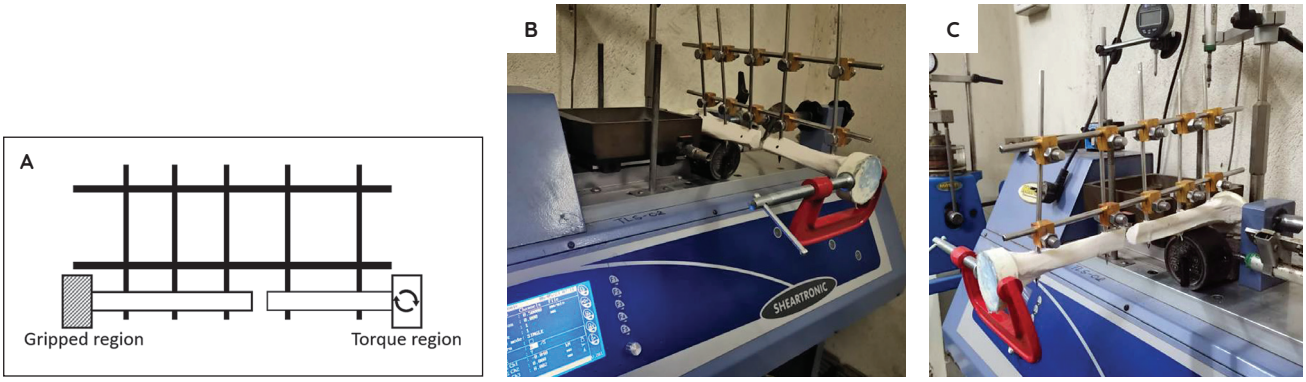

Figure 6. (A) Schematic test configuration for torsion test of an external fixator (adapted from ASTM F1541-17). Torsional stiffness test set-up **(B and C)**.

Testing an all-new fixator construct with six Schanz pins

In the external fixator assembly described above, we inserted the sixth Schanz pin in between the pins of the distal fracture fragment. The same procedure was then performed for the axial compression test as described above (Figure 7). Results include axial stiffness and ultimate strength (Figure 4).

RESULTS

The collected data (Table 1) were statistically analyzed using SPSS software. A one-way ANOVA test was chosen to determine significant differences between the means of the three independent groups. A $p<0.05$ was considered statistically significant. Post hoc testing was performed using the Tukey test, as applicable.

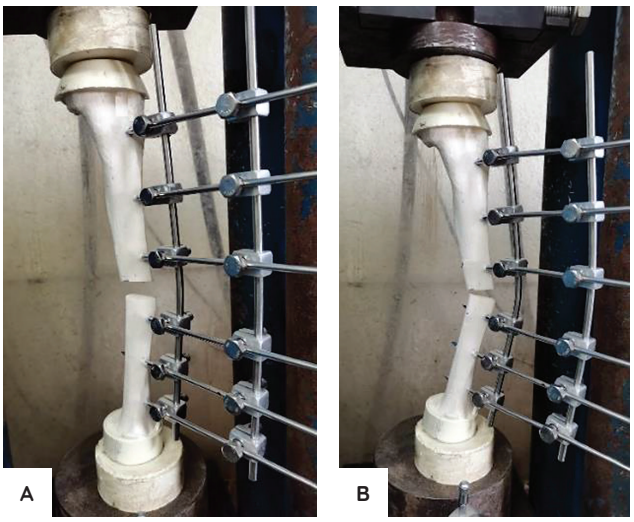

Figure 7. Axial compression test of the external fixator construct with 6 Schanz pins before **(A)** and after **(B)** the test.

The six Schanz pin construct ($n = 5$) was found to have greater stiffness ($p = 0.0028$) and strength ($p = 0.0002$) compared to its corresponding all-new five Schanz pin construct (Tables 2, 7 and 8).

DISCUSSION

The stiffness of a fixation device is a principal determinant of interfragmentary movement, which has a significant effect on the mechanism and progression of fracture healing.[27-29] Excessive interfragmentary movement results in deficient callus formation, eventually leading to delayed union or even nonunion with ultimate implant failure.[27,30-32] Meanwhile, an external fixator with high strength can contribute to durable fixation to allow progressive functional training.[27,28]

The data showed that reused external fixator constructs are comparable to the all-new fixators in terms of stiffness and strength (Tables 3-5 and Figures 8-10). In torsion testing, previously used external fixators were even significantly superior to the all-new fixators in terms of torsional stiffness (Table 6 and Figure 11). The cause of this difference is uncertain.

The mean axial stiffness was very similar for the three constructs (Table 3 and Figure 8): all-new external fixators (102.4 N/mm), once-used external fixators (92.9 N/mm), and twice-used external fixators (85.7 N/mm). One-way ANOVA testing in all three groups demonstrated no significant difference ($p = 0.545$).

The mean bending stiffness was very similar for the three constructs (Table 5 and Figure 10): all-new external fixators (19.56 N/mm), previously used once external fixators (22.3 N/mm), and previously used twice external fixators (23.32 N/mm). One-way ANOVA testing in all three groups demonstrated no significant difference ($p = 0.145$).

Table 1. Test results for axial compression, four-point bending, and torsion testing of new versus previously used fixators

Construct	Specimen	Axial stiffness (N/mm)	Bending stiffness (N/mm)	Torsional stiffness (N•m/degrees)	Ultimate strength (N)
New external fixator	1	112.1	25.5	0.829	655.4
	2	85.3	20.8	0.738	587.0
	3	144.2	15.1	0.751	736.1
	4	98.2	20.1	0.711	547.2
	5	72.3	16.3	0.658	684.6
Previously used once external fixator	1	93.5	25.5	0.969	793.6
	2	123.2	24.6	0.973	694.6
	3	75.0	20.4	0.890	694.7
	4	88.5	21.3	0.895	512.4
	5	84.1	19.7	0.835	673.9
Previously used twice external fixator	1	68.6	21.7	0.908	617.7
	2	116.3	23.0	1.019	679.2
	3	94.4	23.8	1.064	640.9
	4	56.5	24.7	1.001	584.8
	5	92.8	23.4	1.019	758.5

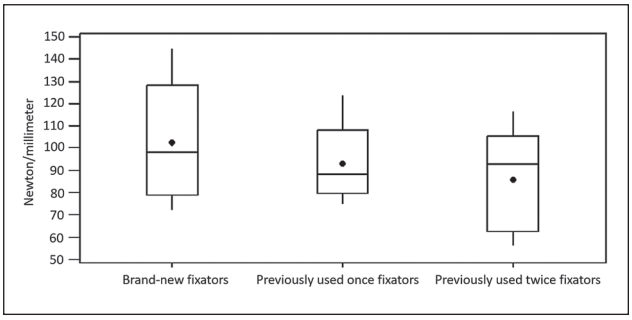

Figure 8. Box plot for axial compression stiffness (N/mm) testing showing no significant difference among the three constructs. Means are indicated by solid circles.

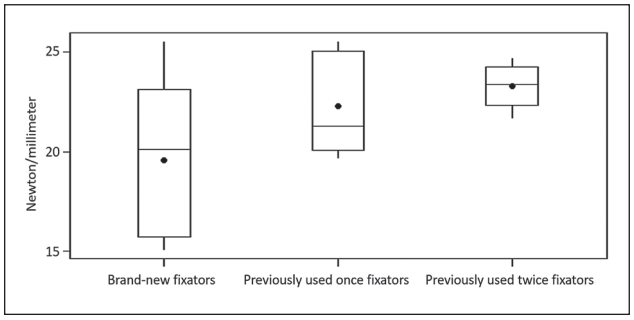

Figure 10. Box plot for four-point bend stiffness (N/mm) testing showing no significant difference among the three constructs. Means are indicated by solid circles.

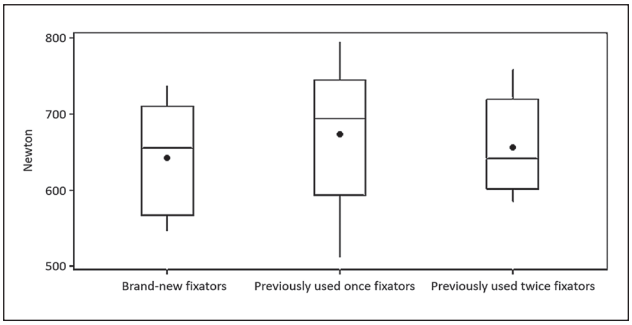

Figure 9. Box plot for axial compression strength (N) testing showing no significant difference among the three constructs. Means are indicated by solid circles.

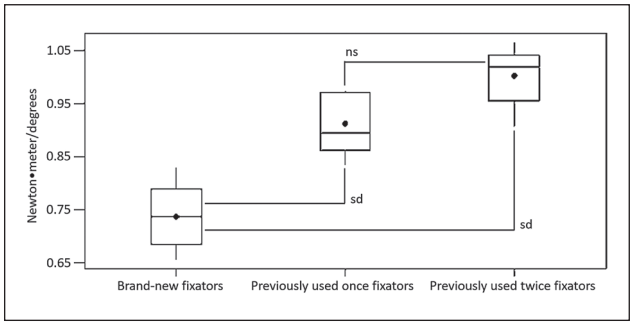

Figure 11. Box plot for torsional stiffness (N•m/deg) testing. Means are indicated by solid circles. ns indicates no significant difference. sd indicates a significant difference (p<0.0167).

There was a significant difference in mean torsional stiffness between new (0.7374 N•m/deg), previously used once (0.9124 N•m/deg), and previously used twice (1.0022 N•m/deg) fixators, as determined by one-way ANOVA. A Tukey post hoc test revealed that the torsional stiffness of the two groups of previously used external fixators were statistically higher than the new fixators (p<0.0167).

Construct stiffness

The result of our experiment showed that new and previously used external fixator constructs were not significantly different in terms of axial and bending stiffness (n = 15, p = 0.545). New external fixator constructs were significantly less stiff than once- and twice-used external fixators in terms of torsional stiffness (p<0.0167).

The average axial stiffness of branded external fixators reported were: 469–528 N/mm,[33] 1157.8–1898.8 N/mm,[27] and 35–71.8 N/mm.[34] The average bending stiffness of branded external fixators reported in previous literature ranges from 15 to 26.7 Nm/deg.[27] The average torsional stiffness results of branded external fixators reported in previous literature are the following: 0.512–0.686 Nm/deg,[33] 1.3–3.0 Nm/deg,[27] and 0.8–1.8 Nm/deg.[34]

The stiffness values of our experiment in terms of axial stiffness, four-point bending stiffness, and torsional stiffness all fall within these ranges.

Construct strength and failure mode

The ultimate strengths of all our constructs were not significantly different from each other. It ranges from a minimum of 512 N to 793 N with an average of about 650 N, comparable to a 65 kg person standing on one leg. The failure mode in our axial compression testing are the irrecoverable bending of Schanz pins, more prominent on the two distal

Table 2. Axial compression test results for 5 new external fixators using 6 Schanz pins

Construct	Specimen	Axial stiffness (N/mm)	Ultimate strength (N)
New external fixators using 6 Schanz pins	1	281.7	2460
	2	197.1	2350
	3	244.1	3020
	4	151.5	2240
	5	242.7	3260

pins, and the buckling of two longitudinal rods. All Schanz pin-bone interfaces were intact (no pin loosening) and there was no loosening of screw clamp or pin-rod connectors.

Low-cost locally available uniplanar tibial external fixators

Branded tibia external fixators are costly and often not available in our locality. This experiment showed that our low-cost external fixators are mechanically sound and within the acceptable range in terms of axial stiffness, four-point bending stiffness, and torsional stiffness as compared to high-cost branded external fixators tested from other studies.[27,33,34]

However, our locally available external fixators have low axial compression strength with an average of only about 650 N versus some studies using expensive commercial external fixators with their ultimate strength to failure that ranges from 1769 N to 2792.2 N.[27]

All-new fixators using five Schanz pins versus six Schanz pins

We also tested all-new external fixator constructs using six Schanz pins and compared them to the results from all-new external fixator constructs using five Schanz pins during axial compression testing. We copied the five Schanz pin external fixator assembly (Figure 3) and inserted the sixth Schanz pin between the pins of the distal fracture fragment (Figure 7).

After the test, careful examination of the fixators showed the same mode of failure in both constructs. The failure modes are the irrecoverable bending of Schanz pins and the buckling of two longitudinal rods or columns. There was

Table 3. One-way ANOVA (Axial compression test – tangent stiffness)

Construct	Specimen	Axial stiffness (N/mm)	Mean	Standard deviation	*p*
New external fixator	1	112.1	102.4	27.65	0.545
	2	85.3			
	3	144.2			
	4	98.2			
	5	72.3			
Previously used once external fixator	1	93.5	92.9	18.27	
	2	123.2			
	3	75.0			
	4	88.5			
	5	84.1			
Previously used twice external fixator	1	68.6	85.7	23.49	
	2	116.3			
	3	94.4			
	4	56.5			
	5	92.8			

Table 4. One-way ANOVA (Axial compression test – ultimate strength)

Construct	Specimen	Ultimate strength (N)	Mean	Standard deviation	*p*
New external fixator	1	655.4	642.06	75.60	0.833
	2	587.0			
	3	736.1			
	4	547.2			
	5	684.6			
Previously used once external fixator	1	793.6	673.84	101.58	
	2	694.6			
	3	694.7			
	4	512.4			
	5	673.9			
Previously used twice external fixator	1	617.7	656.22	66.72	
	2	679.2			
	3	640.9			
	4	584.8			
	5	758.5			

no pin-bone loosening and there was no loosening of screw clamp or pin-rod connectors. From Euler's column buckling theory, the stiffness of a component, not the strength of its materials, determines the load at which it buckles.[35] Increasing the number of Schanz pins increases construct stiffness. The critical load that causes the column to buckle is greater for the fixator with six Schanz pins versus five Schanz pins (Tables 7 and 8).

Constructs using six Schanz pins are significantly stiffer (p = 0.0028) and stronger (p = 0.0002) as compared to constructs using five Schanz pins (p<0.05) (Table 7). From the results of our study, if the average ultimate strength of constructs using five Schanz pins is about 650 N, a comparison to a 65 kg person standing on one leg, then the average ultimate strength of constructs using six Schanz pins is about 2500 N, a comparison to a 250 kg person standing on one leg. This proves our claim and the results of other studies that increasing the number of pins increases the construct stiffness and strength. In using six Schanz pins, our low-cost fixator's mean ultimate strength (2666 N) already matches that of other expensive commercial fixators with their ultimate strength to failure ranging from 1769 N to 2792.2 N.[27]

LIMITATIONS

The following are the limitations of the study. First, we used a synthetic plastic polyvinyl chloride tibia bone instead of a fresh cadaver bone or a synthetic composite bone (sawbone). Despite the use of a plastic bone, there was no pin-to-bone loosening after testing which may have affected the result of the experiment. Second, static loading was done due to equipment unavailability and not cyclic load testing which more closely simulates multifaceted bone loading

Table 5. One-way ANOVA (Four-point bend test – bending stiffness)

Construct	Specimen	Bending stiffness (N/mm)	Mean	Standard deviation	*p*
New external fixator	1	25.5	19.56	4.11	0.145
	2	20.8			
	3	15.1			
	4	20.1			
	5	16.3			
Previously used once external fixator	1	25.5	22.3	2.59	
	2	24.6			
	3	20.4			
	4	21.3			
	5	19.7			
Previously used twice external fixator	1	21.7	23.32	1.10	
	2	23.0			
	3	23.8			
	4	24.7			
	5	23.4			

Table 6. One-way ANOVA (Torsion test – torsional stiffness)

Construct	Specimen	Torsional stiffness (Nm/degrees)	Mean	Standard deviation	*p*
New external fixator	1	0.829	0.7374	0.0624	0.0000469
	2	0.738			
	3	0.751			
	4	0.711			
	5	0.658			
Previously used once external fixator	1	0.969	0.9124	0.0585	
	2	0.973			
	3	0.890			
	4	0.895			
	5	0.835			
Previously used twice external fixator	1	0.908	1.0022	0.0576	
	2	1.019			
	3	1.064			
	4	1.001			
	5	1.019			

Table 7. T-test of all-new external fixators using five versus six Schanz pins (Axial compression test – tangent stiffness)

Construct	Specimen	Axial stiffness (N/mm)	Mean	Standard deviation	*p*
New external fixator using 5 pins	1	112.1	102.42	27.65	0.0028
	2	85.3			
	3	144.2			
	4	98.2			
	5	72.3			
New external fixator using 6 pins	1	281.7	223.42	50.15	
	2	197.1			
	3	244.1			
	4	151.5			
	5	242.7			

Table 8. T-test of all-new external fixators using five versus six Schanz pins (Axial compression test – ultimate strength)

Construct	Specimen	Axial stiffness (N/mm)	Mean	Standard deviation	*p*
New external fixator using 5 pins	1	655.4	642.06	75.60	0.0002
	2	587.0			
	3	736.1			
	4	547.2			
	5	684.6			
New external fixator using 6 pins	1	2460	2666.00	447.75	
	2	2350			
	3	3020			
	4	2240			
	5	3260			

patterns in vivo. Also, material testing of the exact metallic composition of our stainless steel was not performed.

CONCLUSIONS

The study concludes that once- and twice-used low-cost, locally available uniplanar tibial external fixators have comparable mechanical strength to new fixators, in terms of axial stiffness, bending stiffness, and ultimate strength. Used fixators were superior in terms of torsional stiffness versus new fixators. Without compromising function, significant cost savings are possible when components are reused.

The study also concludes that in using new external fixators, increasing the number of pins from five Schanz pins to six Schanz pins increases the construct's axial stiffness two times and increases the construct's axial strength four times.

In low-resource countries where cost-saving is a priority, reusing non-implantable external fixator components up to two times is an acceptable option, provided no mechanical defects are seen on inspection. Since our low-cost, locally available constructs have less axial strength as compared to high-cost branded external fixators, we recommend using a total of six Schanz pins (three Schanz pins in each fracture segment) to increase construct strength and stiffness. In reusing components, processing should be standardized to include manual cleaning using liquid detergent and tap water, disinfection using liquid disinfectants such as povidone-iodine solution, and sterilization using heat and pressurized steam in an autoclave. Labeling used components (i.e., with a metal engraver) would help in tracking the number of uses.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

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ORIGINAL ARTICLE

The Correlation between Patellar Plica and Degeneration of the Femoral Condyle among Military Personnel*

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ABSTRACT

Objective. To determine if there is a correlation between patellar plica syndrome and presence of osteochondral defect among patients who underwent diagnostic arthroscopy.

Methodology. This is a single-center, retrospective cohort study involving patients who underwent diagnostic arthroscopy of the knee with or without primary ACL reconstruction, meniscectomy, and application of Hyalofast scaffold done between January 1, 2018, and December 31, 2020. A retrospective chart review was conducted. Inclusion criteria were: (1) patients aged 18 to 56 years who underwent diagnostic arthroscopy, (2) patients with nonspecific anterior and anteromedial knee pain, (3) patients who were diagnosed with degenerative osteoarthritis via physical exam/X-rays and (4) patients who had complaints of persistent knee pain with no improvement despite conservative management. The exclusion criteria were: (1) patients who have history of significant knee trauma causing fracture of the tibio-femoral and patello-femoral joint and (2) patients who were diagnosed with septic arthritis and post-traumatic arthritis. Patients' demographic data, history, physical examination findings were gathered and tabulated.

Results. There were a total of 70 patients who underwent diagnostic arthroscopy from January 2018 to December 2020. The prevalence rate of patellar plica syndrome was 10%. There were no significant differences noted in terms of age, gender, comorbidities, BMI, and length of military service. None of the patients with patellar plica syndrome had sports-related injuries (n = 0, p = 0.007), and most of these patients did not have other knee pathology (n = 6, 86%, p<0.001). The most common type of patellar plica noted intraoperatively was mediopatellar plica (71%), followed by infrapatellar plica (29%). Anterior and/or anteromedial pain was the most common symptom of patellar plica syndrome (100%), followed by pain when kneeling (71%). There were significantly fewer patients presenting with clicking or catching with patellar plica syndrome (p = 0.003), and significantly more patients who had a positive mediopatellar test on physical examination (p = 0.023). An osteochondral defect was present in 86% of the cases with patellar plica as compared to 21% of patients without patellar plica (p = 0.001).

Conclusion. Patellar plica syndrome was present in 10% of military personnel who underwent diagnostic arthroscopy. The presence of osteochondral defects were correlated with patellar plica.

Keywords. patellar plica syndrome, degeneration of the femoral condyle, military personnel, soldier/s; knee pain, degenerative osteoarthritis

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INTRODUCTION

Knee pain is a common problem with many causes, from acute injuries to complications of medical conditions. Risk factors for knee pain include biomechanics, excess weight, and overuse during repetitive motions.[1] Overuse is common in military personnel as daily jogging and exercises are needed to maintain fitness and to pass the quarterly Physical Fitness Test.

The Armed Forces of the Philippines (AFP) represent a physically active population of male and female service members with generally high occupational demands. They participate in organized physical fitness training and undergo physical fitness testing.[2] Knee pain is a common cause of consult in military treatment facilities, most commonly located anteriorly and anteromedially. The usual diagnoses are knee sprain, ligamentous knee injuries, fractures/dislocations, and osteoarthritis.

Patellar plica syndrome is a rarely diagnosed condition which is sometimes incidentally found during diagnostic arthroscopy for other conditions. Diagnosis of plica syndrome is difficult since when the symptoms occur, they are not easily distinguishable from other intra-articular conditions and knee derangements of the knee joint.[3]

Currently, there were no data gathered as to the prevalence of patellar plica syndrome among military personnel who consulted for knee pain. The purpose of this study is to determine the correlation of osteochondral defect on the medial femoral condyle and presence of patellar plica syndrome in the military population.

METHODOLOGY

Study design

This is a single-center, retrospective cohort involving patients who underwent diagnostic arthroscopy with or without primary ACL reconstruction, meniscectomy, and application of Hyalofast scaffold done between January 1, 2018, and December 31, 2020.

A retrospective chart review was conducted on all patients admitted between 2018 and 2020 who underwent diagnostic arthroscopy of the knee. All charts that satisfied the inclusion criteria were included in the study.

The following details were collected: demographic and clinical profile (age, sex, length of military service, physical fitness level, presence of comorbidities, body mass index, history of trauma to the knee, pre-existing knee conditions), signs and symptoms (anterior and/or anteriomedial pain, pain on kneeling/crouching, clicking/catching/intermittent locking, knee swelling), physical examination findings (medio-patellar plica test, Hughston plica test), types of synovial knee plica seen intraoperatively (infrapatellar, mediopatellar, suprapatellar, lateral), and other intraoperative arthroscopic findings (presence of osteochondral defect, presence of an ACL tear, presence of a meniscal tear) (Figure 1).

The surgeries were done by two consultants specializing in arthroscopy following a standard operative checklist which included the following procedures: Inspect suprapatellar pouch, Evaluate patellofemoral articulation, Evaluate patella (medial/lateral and inferior/superior), Inspect the lateral gutter, Inspect the popliteus tendon and recess, Inspect medial gutter, Inspect and probe medial femoral condyle, Inspect and probe medial tibial plateau, Inspect and probe anterior, middle and posterior medial meniscus, Inspect and probe ACL/PCL, Inspect and probe lateral femoral condyle, Inspect and probe lateral tibial plateau, Inspect and probe anterior, middle and posterior lateral meniscus, and Evaluate passive tracking of patella in trochlear groove.

Any plica seen were shaved; patients with osteochondral defect underwent application of Hyalofast scaffolding with micro fracture of the cartilage and were advised to undergo intraarticular injections of PRP and sodium hyaluronic acid post operatively (Figure 2).

Setting

The study included active military personnel in the Department of Orthopaedics and Traumatology, Armed Forces of the Philippines Health Service Command – Victoriano Luna Medical Center (VLMC).

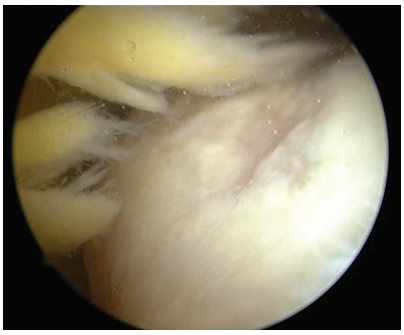

Figure 1. Intraoperative image revealing findings of patellar plica with an osteochondral defect on the femoral condyle.

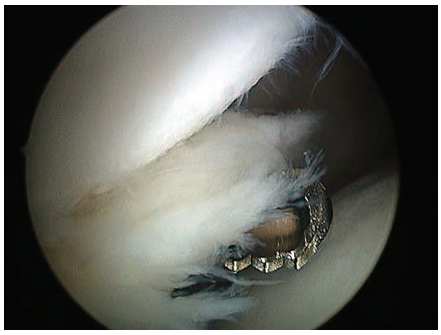

Figure 2. Intraoperative image taken during removal of the plica via arthroscopic shaving.

Table 1. Comparison of demographics between patients with and without patellar plica

Demographics	With patellar plica (N=7) n (%)	Without patellar plica (N=63) n (%)	*p*-value
Age (x ± SD)	35 ± 6.298	31.79 ± 8681	0.253
Sex			0.581
Male	7 (100%)	58 (92%)	
Female	0 (0%)	5 (8%)	
Comorbids			0.698
Hypertension	1 (14%)	6 (10%)	
Diabetes Mellitus	1 (14%)	7 (11%)	
Asthma	0 (0%)	2 (3%)	
BMI (x ± SD)	28.43 ± 3.207	26.67 ± 3.797	0.615
Length of military service (in years) (x ± SD)	7.57 ± 4.237	6.68 ± 4.428	0.213
History of trauma			
None	1 (14%)	1 (2%)	0.191
Sports-related	0 (0%)	34 (54%)	0.007*
Wear and tear	6 (82%)	43 (68%)	0.317
Motor vehicular accident	0 (0%)	5 (8%)	0.581
Fall	3 (43%)	19 (30%)	0.383
Other knee pathology			
None	6 (86%)	3 (5%)	<0.001*
Meniscal tear	1 (14%)	37 (59%)	0.032
Cruciate ligament tear	0 (0%)	52 (83%)	<0.001*

Table 2. Types of patellar plica

Type	Frequency (N=7) n (%)
Infrapatellar	2 (29%)
Mediopatellar	5 (71%)
Suprapatellar	0 (0%)
Lateral	0 (0%)

Participants

The study included patients with non-specific anterior and anteromedial knee pain who underwent diagnostic arthroscopy from 2018–2020.

The following were the inclusion criteria:
- Patients aged 18 to 56 years who underwent diagnostic arthroscopy of the knee
- Patients with nonspecific anterior and anteromedial knee pain
- Patients who were diagnosed with degenerative osteoarthritis via physical exam and x-rays
- Patients who had complaints of persistent knee pain with no improvement despite conservative management

The following are the exclusion criteria:
- Patients who have history of significant knee trauma causing fracture of the tibio-femoral and patello-femoral joint
- Patients who were diagnosed with septic arthritis and post traumatic arthritis.

Patients' demographic data, history, physical examination findings were gathered and tabulated.

This study was approved by the Bioethics Review Board of the Department of Research of the Armed Forces of the Philippines Medical Center prior to subject gathering.

RESULTS

There were a total of 70 patients who underwent diagnostic arthroscopy from January 1, 2018, to December 31, 2020. Overall, the prevalence rate of patellar plica syndrome was 10% (n = 7). There were no significant differences noted in terms of age, gender, comorbidities, BMI, and length of military service (Table 1). None of the patients with patellar plica syndrome had sports-related injuries (n = 0, p = 0.007), and most of these patients did not have other knee pathology (n = 6, 86%, p<0.001).

The most common type of patellar plica noted intraoperatively was mediopatellar plica (n = 5, 71%), followed by infrapatellar plica (n = 2, 29%) (Table 2).

Anterior and/or anteromedial pain was the most common symptom of patellar plica syndrome (n = 7, 100%), followed by pain upon kneeling (n = 5, 71%) (Table 3). There were significantly fewer patients with patellar plica syndrome who presented with clicking or catching (n = 1, 14%, p = 0.003), and significantly more patients who had a positive mediopatellar test on physical examination (n = 7, 100%, p = 0.023).

Osteochondral defects were associated with patellar plica syndrome, being present in 86% of the cases as compared to 21% of patients without patellar plica (p = 0.001) (Table 4). Post-hoc analysis shows that only osteochondral defect was directly correlated with patellar plica syndrome (Table 5). Intraoperatively, it was directly observed that the plica grinds on the area of the defect during knee flexion and extension.

Table 3. Comparison of signs and symptoms in patients with or without patellar plica

Signs and symptoms	With patellar plica (N=7) n (%)	Without patellar plica (N=63) n (%)	*p*
Anterior / Anteromedial pain	7 (100%)	52 (83%)	0.285
Pain upon kneeling or crouching	5 (71%)	47 (75%)	0.583
Clicking or catching	1 (14%)	47 (75%)	0.003*
Swelling	1 (14%)	4 (6%)	0.419
Positive Mediopatellar test	7 (100%)	35 (56%)	0.023*
Hughston plica test	7 (100%)	46 (73%)	0.129

Table 4. Comparison of arthroscopic findings in patients with or without patellar plica

Arthroscopic findings	With patellar plica (N=7) n (%)	Without patellar plica (N=63) n (%)	*p*
Osteochondral defect	6 (86%)	13 (21%)	0.001*

Table 5. Post-hoc analysis on the factors affecting patellar plica syndrome

	B	S.E.	Wald	df	Sig.	Exp(B)
Positive mediopatellar test	-18.112	7595.757	0.000	1	0.998	0.000
Osteochondral defect	-2.318	1.135	4.168	1	0.041*	0.098
Constant	-0.773	0.494	2.454	1	0.117	0.462

DISCUSSION

Plica syndrome of the knee is a constellation of signs and symptoms that occur secondary to injury or overuse. *Plica* is a Latin word meaning "fold." This term is simply descriptive; there is no empiric evidence that true folding of the synovial lining ever occurs.[3] The synovial plica of the knee is formed during the embryogenic phase of development and begins to involute during the 12th week of fetal life. This involution is incomplete in many individuals, and plica persist in 50% of the population, varying in shape and size. When the synovial plica of the knee persists, it transforms into an embryonic relic.[3] Four types of synovial plica of the knee have been described: infrapatellar, mediopatellar, suprapatellar, and lateral.[4-6] Kim and Choe found suprapatellar plica in 87%, mediopatellar plica in 72%, infrapatellar plica in 86%, and lateral plica in 1.3%, in a study of over 400 knees.[4]

In normal conditions, synovial plica are thin, pink, and flexible. Under the microscope, they are visible as a lining of single or reduplicated synovial cells lying on a stroma of connective tissue which contains numerous small blood vessels and collagen fibres, but no elastic fibres. This allows the plica to change size and shape during knee movement. When pathologic, inflammation turns the plica hypertrophic, more vascular, edematous, more hyalyinized, tight, thickened, fibrotic, and non-elastic. With overuse or trauma, these plica can become irritated and inflamed leading to the disorder or syndrome.[7]

Diagnosis of plica syndrome is made by physical examination or arthroscopy. Plica syndrome presents similarly to meniscal tears and patellar tendonitis, and is common among active individuals. Symptoms include knee pain on the inner side of the joint, tenderness directly over the medial plica, swelling and warmth around the plica, and snapping and clicking on knee flexion. In some cases, there is an associated degeneration of the femoral condyle among these population. Thus, diagnosis is difficult.[5]

There are a few physical examination maneuvers that aid in the diagnosis of patellar plica syndrome. The mediopatellar plica test is done by having the patient lie supine while the examiner flexes the affected knee to 30 degrees and presses the patella medially; this pinches the edge of the plica between the medial femoral condyle and the patellar facet. The test is positive if the patient complains of typical anteromedial pain. The Hughston plica test is done by having the patient lie supine position. The examiner grasps around the knee anterolaterally with one hand and presses the patella medially with the heel of the hand palpating the medial femoral condyle with the fingers of the same hand. The examiner then grasps the patient's heel with the other hand then internally rotates the lower leg and then repeatedly flexes and extends the knee. If a painful, audible, or palpable "popping" is noted, the test is positive suggesting a mediopatellar plica syndrome.[7]

As the symptoms experienced with pathological plica are not specific, the diagnostic procedure should keep a high level of suspicion and ideally work through exclusion, to differentiate from any other knee derangement. Physical examination does not give exclusive results due to possible tenderness of the antero-medial capsule or the area around the suprapatellar pouch on direct palpation.[6] Non-invasive modalities such as X-rays, ultrasound, computed tomography and magnetic

resonance imaging today allow precise assessment of diseased and injured structures in the knee.[5,7] X-rays of the knee are typically normal in a patient with plica syndrome.

While synovitis can be a source of possible knee pain, it is relatively uncommon and should be diagnosed only through exclusion. Diagnostic arthroscopy and surgical treatment should only be considered in exceptional cases that do not respond to conservative treatment.[3]

CONCLUSION

Ten percent of our patients with knee pain who underwent diagnostic arthroscopy had patellar plica. This may be because patellar plica syndrome presents similarly to other knee pathologies. Anterior and/anteromedial knee pain and a positive mediopatellar test were present in all our patients with patellar plica. Osteochondral defects were also seen in 86% of patients with patellar plica, as compared to 21% of patients without patellar plica ($p = 0.001$). The osteochondral defect and pain may be caused by grinding of the plica on the area of the defect during flexion and extension, as seen on diagnostic arthroscopy.

LIMITATIONS

The study was limited only to a single institution. The main investigator was not present during all the surgeries. Post-operative or long-term follow-up was not in the scope of the study.

RECOMMENDATIONS

It is recommended to perform the study including the other station hospitals/institutions which also cater to military personnel. Proper documentation of intraoperative findings (type of plica, location of osteochondral defect) as well as the history and physical exam of the patients should be done.

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

Psychosocial Impact of Prolonged Skeletal Traction of Lower Extremity Fractures in a Philippine Specialty Tertiary Government Hospital*

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ABSTRACT

Introduction. Skeletal traction for lower extremity injuries remains a preliminary treatment in managing lower extremity fractures in a Philippine tertiary orthopedic hospital. Studies have shown an increased prevalence of the development of depression and anxiety among those confined on skeletal traction before their definitive surgery.

Objective. This study associated variables present in the patient population to the development of depressive and/or anxiety symptoms while on skeletal traction before surgery for lower extremity fractures.

Methodology. Depression and anxiety symptoms were determined using the Hospital Anxiety and Depression Scale in Filipino Version (HADS-P), which is the validated Filipino language version. Clinical and social variables were gathered from patient interviews before the administration of the scoring tool. The HADS-P questionnaire was administered before skeletal traction and a day before definitive surgery.

Results. The study included fifty-four adult patients without prior psychiatric diagnoses and medications indicated for lower extremity skeletal traction before surgery. The results showed an increase in depressive and anxiety symptoms among the population. However, no significant difference was seen relative to the identified demographics. There was a minimum traction duration of 30 days and a maximum of 76 days.

Conclusion. All patients exhibited increased depressive symptoms, however, the longer the duration of traction, the more depressed they got however with less or retained anxiety symptoms. The incidence of these symptoms did not have a significant relationship to the number of days they were in traction nor with the identified patient demographics.

Keywords. skeletal traction, depression, anxiety, orthopedic surgery, days on skeletal traction

INTRODUCTION

In high-income countries, especially with socialized medical assistance, skeletal traction has been abandoned in favor of immediate surgery. Despite all the recommendations pointing to early fixation, the method is still extensively applied as a preliminary treatment in a government orthopedic specialist hospital because of logistic and economic reasons. Because of this, the patient is confined to the bed while waiting for their definitive surgery. In a descriptive study done in Malawi, Africa, patients with lower extremity fractures were primarily treated with eight to twelve weeks of skeletal traction. Aside from pin tract infection, malunion, nonunion, and mobility problems, there was a growing incidence of depression and anxiety among these patients.[1] The time confined in the hospital and the multitude of common complications of skeletal traction led to a growing functional and social handicap, especially among the productive population. Their psychiatric conditions typically outlast recovery from primary illness and hinder the patients from attaining the expected outcome and quality of life after the surgery.

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In a general hospital in Germany, 41.3% to 46.5% of in-patients suffered from a mental disorder, stemming from an organic mental illness, adjustment disorders with depressed mood, or drug dependence. While most of these needed psychiatric help, only 2.66% to 3.30% had consulted.[2] The Department of Health identified the incidence of depressive disorders in the Philippines at 5.3% each year. One in four women is likely to experience depression in her lifetime, with a 10–20% lifetime prevalence, compared to 5.0–10% for men. The average onset of the first depressive episode occurs in the mid 20's. The overall prevalence of psychiatric disorders among medically ill patients in the Philippines is higher (48%) compared to foreign literature.[3]

In 1978, 55% of patients aged 16–45 on skeletal traction for femoral shaft fractures admitted at the UCLA Orthopedic Service developed what was termed "Traction Intolerance Syndrome" after at least three weeks. This was defined as any behavioral or emotional reaction related to skeletal traction severe enough to require psychiatric consultation and/or the use of major psychiatric medication for prolonged periods in the absence of preexisting major psychiatric illness.[4]

The most common psychiatric disorders in hospitalized patients were depressive and anxiety disorders. They were common and frequently outlasted the primary illness, hampering the patients' quality of life post-intervention.[2,3,5-7]

The general objective of the study was to associate variables present in the Filipino patient population to the development of depressive and/or anxiety symptoms while on skeletal traction prior to surgery for lower extremity fractures. Specifically, the study aims to determine the prevalence of anxiety and depression using the Hospital Anxiety and Depression Scale – Pilipino (HADS-P) questionnaire, identify independent variables related to the development of depressive or anxiety symptoms, and determine the association between depression and anxiety and duration of skeletal traction.

Significance of the study

In a setting where most healthcare expenditure comes out-of-pocket, families often struggle to procure money to pay for expensive orthopedic implants. Patients in the lower economic strata frequently receive delayed treatment even in the face of devastating orthopedic trauma. In orthopedics, there is little evidence identifying the psychosocial effects of surgical interventions: specifically, prolonged immobility equated to loss of dignity, fear of permanent disability, anxiety about lacking the means to provide for their family, and regret and guilt for negatively affecting their families. We aimed to identify the deleterious psychiatric effects of delayed definitive surgery so that we can advocate for timely psychiatric referral, better support from their families and medical team, and expedited social services, ultimately leading to earlier definitive care.

METHODOLOGY

This is an institutional cross-sectional study done using non-probability sampling of patients subjected to skeletal traction as part of the management of lower extremity fractures in a specialty orthopedic hospital in the Philippines. Patient recruitment was done in 6 months from July 2021 to January 2022.

A minimum of 50 subjects was set for recruitment based on a level of significance of 5% and a confidence interval of 10%. To account for a possible non-response/patient withdrawal, an additional 20% was suggested, hence placing the minimum to 60 patients. The study was reviewed and approved by the Ethics Review Board of the institution before recruiting the participants.

The researchers were able to recruit 58 Filipino adults aged 19–86 years old who were diagnosed with lower extremity fractures in need of skeletal traction before definitive surgical fixation. The participants were not previously diagnosed with a psychiatric ailment, were not taking any psychoactive medication, and were not taking prohibited substances before engaging in the study. Informed consent was taken prior to participation in the study. We documented the following demographic variables: age, sex, civil status, educational attainment, employment status, monthly income, and the American Society of Anesthesiologists (ASA) classification. Participants were then asked to answer the 14-item validated HADS-P[8] upon admission. The HADS-P was administered again a day prior to definitive surgery; also at this time, the duration of traction was computed and added to the datasheet. Questionnaires were given only twice in the study to eliminate cognitive bias (from recall of their previous answers) and fatigue (from being asked to answer too frequently). The questionnaires were then individually analyzed and scored accordingly. Data were processed using STATA version 15.0 (StataCorp SE, College Station, TX, USA) aided by a third-party statistician. The participants were informed that they could withdraw at any time without any repercussion to their plan of care.

Descriptive statistics including mean, standard deviation, median, and lower and upper quartiles were used to summarize demographic variables. Frequency and proportion were reported for categorical variables. Shapiro-Wilk was used to determine the normality distribution of continuous variables. Continuous quantitative data that did not meet the normality assumption was described using median and range.

The prevalence of depressive and anxiety symptoms was determined by calculating the percentage of patients with a score of 8.0 points or higher on the HADS-P. Logistic regression was used to determine the association of the clinical variables with depressive and anxiety symptoms, as measured by HADS-P Crude odds ratios, and its 95% confidence intervals were reported.

The null hypothesis was rejected at 0.05α-level of significance.

The HADS-P Questionnaire

Hospital Anxiety and Depression Scale – Pilipino (HADS-P) is the validated Filipino language version of HADS.[8,9] This was validated at the University of the Philippines – Philippine General Hospital to determine the prevalence of depressive and anxiety symptoms and determine an optimal cut-off score for Filipinos using the receiver operative characteristic curve. The validity of the HADS screening test was assessed through consideration of its sensitivity and specificity compared to a formal psychiatric interview. Anxiety was defined as an unpleasant state of inner turmoil, often accompanied by nervous behavior. Depression on the other hand was defined as a state of low mood and aversion to activity.[9]

We used the recommended high-sensitivity HADS cut-off score. A HADS score >8 had a sensitivity of 91%, specificity of 59%, and a PPV of 61% for detecting anxiety or depression; while a HADS-P of >11 had a sensitivity of 75%, specificity of 70%, and PPV of 75%. De Guzman concluded that this tool could serve as a guide for clinicians toward the diagnosis of depression and anxiety.[8]

RESULTS

The study analyzed data from 54 out of 58 enrolled patients with a median age of 49 years old (range 19–86), mostly young adults (42.59%), married (51.85%), attended at least secondary education (46.30%) and unemployed (55.56%) (Table 1). There was a dropout of 1.07% since 4 patients either died, did not undergo surgery during the same hospitalization period, or were sent home for other reasons. About half (51.85%) were classified as ASA I. The median duration of traction was 52 days (range 30–76).

On admission, the prevalence of depressive symptoms was 7.41% (95% CI 2.06-17.89) and the prevalence of anxiety symptoms was 29.63% (95% CI 17.98-43.61). On the day before surgery, the prevalence of depressive symptoms increased to 16.76% (95% CI 7.92-29.29) and the prevalence of anxiety symptoms increased to 48.15% (95% CI 34.34 -62.16) (Table 2). There was a significant increase in the prevalence of depressive and anxiety symptoms pre-traction and one day prior to surgery as shown by the p values <0.0001 and 0.002 derived from the Mc Nemar test respectively (Tables 6 and 7).

There was no statistically significant association between the patient's age, sex, civil status, educational attainment, employment status, monthly income, ASA classification, and duration of traction, with the occurrence of depressive and anxiety symptoms (Table 3).

DISCUSSION

We hypothesized that patients on prolonged skeletal traction would become more anxious and/or depressed compared to the healthy population. Increased anxiety symptoms are seen in orthopedic surgical patients based on the Patient-Reported

Table 1. Demographic profile of patients (n = 54)

	Median (Range); Frequency (%)
Age, years	49 (19–86)
Young adults	23 (42.59)
Adults	15 (27.78)
Elderly	7 (12.96)
Octogenarians	9 (16.67)
Sex	
Male	29 (53.7)
Female	25 (46.3)
Civil status	
Single	16 (29.63)
Married	28 (51.85)
Divorced/Separated	5 (9.26)
Widowed	5 (9.26)
Highest education attained	
No formal education	5 (9.26)
Grade school	13 (24.07)
High school	25 (46.3)
College	10 (18.52)
Postgraduate	1 (1.85)
Employment status	
Unemployed	30 (55.56)
Employed	19 (35.19)
Self-employed	5 (9.26)
Monthly income (money at hand)	2850 (0–25000)
<5000	29 (53.70)
≥5000	25 (46.30)
ASA classification	
I	28 (51.85)
II	22 (40.74)
III	4 (7.41)
Duration of traction, days	52 (30–76)

ASA – American Society of Anesthesiologists

Table 2. HADS-P results on admission and one day prior to surgery

	n	Prevalence (95% CI)
On admission		
Depression		
Normal	41	75.93 (62.36–86.51)
Borderline abnormal (borderline case)	9	16.67 (7.92–29.29)
Abnormal (case)	4	7.41 (2.06–17.89)
Anxiety		
Normal	24	44.44 (30.92–58.60)
Borderline abnormal (borderline case)	14	25.93 (14.96–39.65)
Abnormal (case)	16	29.63 (17.98–43.61)
One day prior to surgery		
Depression		
Normal	21	38.89 (25.92–53.12)
Borderline abnormal (borderline case)	24	44.44 (30.92–58.60)
Abnormal (case)	9	16.67 (7.92–29.29)
Anxiety		
Normal	13	24.07 (13.49–37.64)
Borderline abnormal (borderline case)	15	27.78 (16.46–41.64)
Abnormal (case)	26	48.15 (34.34–62.16)

Outcomes in Surgery – Anxiety and Depression, computer adaptive tests (PROMIS – Anxiety and Depression CAT) even in first world countries.[10] We documented increasing anxiety levels that the surgeon may alleviate through reassurance and empathy. While the PROMIS CAT scoring tool has been applied in surgery, it lacks validation for a Filipino population, hence its exclusion from this study; validation and a further follow-up study using the PROMIS CAT may prove promising.

Anxiety symptoms were more prevalent than depressive symptoms before the application of skeletal traction, regardless of demographic profile. Participants were generally still conscious of their appearance, with an intact sense of humor and a generally positive outlook. During their stay, more participants developed depressive symptoms. There was still no statistically significant association with regard to the demographics and development of symptoms.

Table 3. Association of patient profile with depression and anxiety

	Borderline to case Crude OR (95% CI) and *p*			
	Depression		Anxiety	
Age	0.98 (0.96–1.01)	0.271	1.004 (0.97–1.03)	0.810
Young adults/Adults	Reference	-	Reference	-
Elderly/Octogenarians	0.931 (0.24-3.61)	0.918	0.931 (0.24-3.61)	0.918
Female sex (Reference: Male)	1.255 (0.42–3.78)	0.686	1.524 (0.43–5.45)	0.517
Civil status (Reference: Single)				
Married	0.702 (0.19–2.58)	0.595	3.373 (0.89–12.80)	0.074
Divorced/Separated	0.303 (0.04–2.42)	0.260	8.684 (0.41–183.23)	0.165
Widowed	0.682 (0.09–5.45)	0.718	2.368 (0.30–18.98)	0.417
Married civil status (Reference: Single/ Divorced/ Separated/ Widowed)	0.966 (0.32–2.89)	0.951	2.044 (0.57–7.33)	0.272
Highest education attained (Reference: No formal education)				
Grade school	5.000 (0.55–45.39)	0.153	3.667 (0.35–38.03)	0.276
High school	1.909 (0.27–13.50)	0.517	1.714 (0.23–12.55)	0.596
College/Postgraduate	2.625 (0.30–23.00)	0.383	3.000 (0.28–31.63)	0.361
Employment status (Reference: Unemployed)				
Employed	1.896 (0.57–6.32)	0.298	2.415 (0.61–9.53)	0.208
Self-employed	3.5 (0.35–35.11)	0.287	5.634 (0.28–111.9)	0.257
ASA classification (Reference: I)				
II	0.568 (0.18–1.80)	0.338	0.727 (0.20–2.67)	0.632
III	0.474 (0.06–3.92)	0.489	0.819 (0.07–9.35)	0.872
Duration of traction, days	0.993 (0.95–1.04)	0.745	1.012 (0.96–1.07)	0.633

Table 4. Hospital anxiety and depression scale item responses on hospital admission

	0	1	2	3
	Frequency (%)			
1. I feel tense or 'wound up' (A)	14 (25.93)	**32 (59.26)**	5 (9.26)	3 (5.56)
2. I feel as if I am slowed down (D)	16 (29.63)	**26 (48.15)**	6 (11.11)	6 (11.11)
3. I still enjoy the things I used to enjoy (D)	**33 (61.11)**	13 (24.07)	7 (12.96)	1 (1.85)
4. I get a sort of frightened feeling like 'butterflies' in the stomach (A)	14 (25.93)	**28 (51.85)**	10 (18.52)	2 (3.7)
5. I get a sort of frightened feeling as if something awful is about to happen (A)	15 (27.78)	**27 (50)**	11 (20.37)	1 (1.85)
6. I have lost interest in my appearance (D)	**48 (88.89)**	2 (3.7)	3 (5.56)	1 (1.85)
7. I can laugh and see the funny side of things (D)	**30 (55.56)**	9 (16.67)	15 (27.78)	0 (0)
8. I feel restless as I have to be on the move (A)	10 (18.52)	10 (18.52)	**21 (38.89)**	13 (24.07)
9. Worrying thoughts go through my mind (A)	15 (27.78)	**22 (40.74)**	11 (20.37)	6 (11.11)
10. I look forward with enjoyment to things (D)	19 (35.19)	**24 (44.44)**	6 (11.11)	5 (9.26)
11. I feel cheerful (D)	12 (22.22)	**32 (59.26)**	6 (11.11)	4 (7.41)
12. I get sudden feelings of panic (A)	19 (35.19)	**20 (37.04)**	12 (22.22)	3 (5.56)
13. I can sit at ease and feel relaxed (A)	**14 (25.93)**	12 (22.22)	19 (35.19)	9 (16.67)
14. I can enjoy a good book or radio or TV program (D)	**23 (42.59)**	17 (31.48)	12 (22.22)	2 (3.7)

*Items in bold represent responses with the highest frequency

Other studies have identified certain demographics that predispose to mood disorders: these include younger age, female gender, prolonged hospitalization, bad family relationships, low income, low educational attainment, widowed or divorced, and retired individuals.[11-13]

All the respondents had a length of traction more than the established timeframe (3 or more weeks) of the development of traction intolerance syndrome.[4] Our study design only administered the HADS-P at the start and end of their traction period. Because of this, we could not pinpoint the time when depressive and anxiety symptoms developed. However, we have concluded a definite increase in the development of these symptoms during their hospital stay of at least 30 days with a median range of 54 days. The incidence of these symptoms does not have a direct relationship to the number of days they were in traction.

In a similar study which also aimed to identify predictors of mood disorders in surgical patients, they identified that 2 weeks of hospitalization had a significant increase in depressive and anxiety symptoms.[11] Another study found that longer hospital stays conversely were not associated with the incidence of depression in young patients with aortic aneurysms or occlusive diseases.[12]

Poor postoperative outcomes and patient dissatisfaction were more likely to occur when psychiatric symptoms were present before orthopedic surgery.[6,10,11,13,14] These patients fared poorly due to poor motivation to mobilize postoperatively. Hence, proper identification of risk factors, anticipation of prolonged hospital stays, and constant patient communication can help orthopedic surgeons prepare the patient holistically for better outcomes.

Table 5. Hospital anxiety and depression scale item responses prior to definite surgery

	0	1	2	3
	Frequency (%)			
1. I feel tense or 'wound up' (A)	5 (9.26)	**28 (51.85)**	17 (31.48)	4 (7.41)
2. I feel as if I am slowed down (D)	8 (14.81)	**30 (55.56)**	13 (24.07)	3 (5.56)
3. I still enjoy the things I used to enjoy (D)	13 (24.07)	18 (33.33)	**22 (40.74)**	1 (1.85)
4. I get a sort of frightened feeling like 'butterflies' in the stomach (A)	4 (7.41)	**28 (51.85)**	20 (37.04)	2 (3.7)
5. I get a sort of frightened feeling as if something awful is about to happen (A)	6 (11.11)	21 (38.89)	**25 (46.3)**	2 (3.7)
6. I have lost interest in my appearance (D)	**18 (33.33)**	**18 (33.33)**	16 (29.63)	2 (3.7)
7. I can laugh and see the funny side of things (D)	12 (22.22)	**20 (37.04)**	**20 (37.04)**	2 (3.7)
8. I feel restless as I have to be on the move (A)	3 (5.56)	14 (25.93)	**24 (44.44)**	13 (24.07)
9. Worrying thoughts go through my mind (A)	9 (16.67)	**25 (46.3)**	16 (29.63)	4 (7.41)
10. I look forward with enjoyment to things (D)	8 (14.81)	**26 (48.15)**	17 (31.48)	3 (5.56)
11. I feel cheerful (D)	11 (20.37)	**28 (51.85)**	11 (20.37)	4 (7.41)
12. I get sudden feelings of panic (A)	9 (16.67)	**24 (44.44)**	18 (33.33)	3 (5.56)
13. I can sit at ease and feel relaxed (A)	8 (14.81)	16 (29.63)	**20 (37.04)**	10 (18.52)
14. I can enjoy a good book or radio or TV program (D)	20 (37.04)	**22 (40.74)**	10 (18.52)	2 (3.7)

*Items in bold represent responses with the highest frequency

Table 6. Comparison of the depression scores pre-traction and one day prior to surgery

Pre-traction	One day prior to surgery			Total	*p*
	Normal	Borderline	Abnormal		
Normal	20 (48.9%)	19 (46.3%)	2 (4.8%)	41	<0.0001* (S)
Borderline	1 (11.1%)	5 (55.6%)	3 (33.3%)	9	
Abnormal	0	0	4 (100%)	4	
Total	21	24	9	54	

**p*-value is significant

Table 7. Comparison of the anxiety scores pre-traction and one day prior to surgery

Pre-traction	One day prior to surgery			Total	*p*
	Normal	Borderline	Abnormal		
Normal	12 (50.0%)	9 (37.5%)	3 (12.5%)	24	0.002* (S)
Borderline	1 (7.1%)	5 (35.7%)	8 (57.1%)	14	
Abnormal	0	1 (6.2%)	15 (93.8%)	16	
Total	13	15	26	54	

**p*-value is significant

Our limitations include variables such as cultural aspects, personal experiences, and coping mechanisms which could have affected our results. Likewise, the trauma itself could have directly affected the anxiety and depression scores. As of writing, there is no objective tool to our knowledge that isolates the effects of injury on the psyche while investigating the effects of prolonged hospital stay or immobility due to skeletal traction. Our population was also relatively homogenous in terms of monthly income, educational status, and level of employment contrary to the heterogenous population in other studies.

CONCLUSION

Skeletal traction has generally fallen out of favor among orthopedic surgeons. Hospitals in low-resource settings, however, need to make do with skeletal traction as temporary stabilization before surgery. It was clear that morbidity in the form of depressive and anxiety symptoms became more prevalent in these patients.

We recommend that patients be screened on admission with the HADS-P to identify those at risk and refer them for psychosocial management to maximize recovery and satisfaction. We also recommend that patients be counseled on the benefits of expediting surgery, to hasten logistical procurement.

We encourage that this study design be repeated in a multi-center study to ensure more population variety and discuss the different social services of other government hospitals. Prolonged financial procurement forced the patients to stay in the hospital more than indicated for their injuries. This was the main reason why patients needed to undergo traction before definitive surgery. Furthermore, future research should delve into validating a Filipino translation of the PROMIS CAT so that we can use a more specific tool to identify depressive and anxiety symptoms in patients at multiple time-frames without cognitive bias.

Finally, discussions with hospital management and the country's leaders are needed to lessen the overall psychosocial impact of delays in orthopedic injury management to patients and their families.

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All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

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None.

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CASE REPORT / CASE SERIES

Treatment Outcomes among Pediatric Patients with Cervical Pott's Disease in a Tertiary Care Center: A Case Series

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ABSTRACT

Tuberculosis remains a perennial global problem despite advances in detection and treatment. Apart from the pulmonary system, it can also affect the spine of both adult and pediatric patients, with a predilection for the thoracic and lumbar spine. Rarely does spinal TB or Pott's disease affect the cervical spine and there are few high-level studies in the pediatric population.

Variations are the following: Atlantoaxial/Upper Cervical TB (AATB), Subaxial Cervical TB (SACTB), and Cervicothoracic TB (CTTB). Motor and sensory deficits are more common in CTTB and some SACTB patients while myelopathic signs predominate in AATB patients. The mainstay of treatment for pediatric cervical TB is still anti-tubercular treatment (ATT) using anti-Koch's medication depending on the level of drug resistance. For some patients, surgery may be indicated with CTTB having the lowest threshold because of its anatomic location. Most patients improve after a year of treatment with at least a 1 Frankel letter grade improvement.

Keywords. pediatric, Pott's disease, cervical spine, spinal tuberculosis

INTRODUCTION

Tuberculosis is a global concern that affects both developed and underdeveloped countries. Globally, it is the 13th leading cause of death and the second in terms of infectious disease killers behind COVID-19 despite improvements in detection and treatment. It can affect people of all age groups with most cases being adults. In addition to this, mortality rates are highest in low- and middle-income countries.[1] Unfortunately, the Philippines falls under this category as stated by the Organization for Economic Cooperation and Development (OECD). Furthermore, the Philippines is one of the high-burden countries that account for 80% of TB cases worldwide.[2]

Despite the rise in treatment rates, a fraction of the population still progresses to Extra-Pulmonary TB. This refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs. When it involves two or more non-contiguous sites it is referred to as Disseminated TB. In 2015, the Philippine General Hospital TB Directly Observed Treatment Short Course (PGH TB-DOTS) Center reported that their Disseminated TB patients had a mean age of 33.97 years old, none of whom were pediatric patients. In terms of location, the pulmonary system had the highest concentration of cases followed by the intestinal system (32%) and the spine (27%).[3]

Spinal TB or Pott's disease was discovered as early as the 1700s by Sir Percival Pott; he described a tuberculous spondylitis

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Table 1. Description, stages, and treatment for Atlantoaxial/Craniovertebral TB (AATB)[8]

Stage	Description	Recommended treatment	Additional remarks
I	• Unilateral involvement of the facet of the atlas • No destructive deformation • No neurologic deficits	Medical treatment (ATT)	May or may not involve long-term rigid orthosis application
II	• Involvement of atlantoaxial joint by destructive necrosis and inflammation • May involve parts of the axis • Presence of neck pain, neck muscle spasm, and severe restriction of neck movements • Torticollis may be present • Patient may or may not have neurologic deficits	Medical treatment (ATT) Surgical Management	Posterior approach • Preferred approach globally • Atlantoaxial fusion - Reducible AA dislocation • Occipitocervical fusion - Occipitoatlantial joint involvement - Bilateral AA joint destruction
III	• Involvement of the atlantoaxial joint as well as other bones and joints in the region • Evidence of instability noted • Patients have neurologic deficits		Combined Anterior- Posterior (Intra or Pre-Operative Halo distraction if needed) • Irreducible AA dislocation • Rotatory AA dislocation Anterior approach alone – does not provide biomechanically robust options for stabilization

ATT = anti-tubercular treatment; AA = Atlantoaxial

presenting as paraplegia in patients with kyphotic deformities.[4] It more commonly affects the thoracic and lumbar areas while rarely affecting the cervical and sacral areas. For diagnosed Category I cases, anti-tubercular treatment (ATT) lasts for 6 months while for Category IA cases (Extra-pulmonary TB of meninges, bones, or joints), treatment lasts for 1 year.[5] Although most patients can be managed medically, some will require surgical treatment on top of ATT.[4]

The Frankel Grading System is used to classify a patient's deficits. Patients are scored from A to E (with A being the worst and E the best indicating no deficits).[6,7] Cervical TB is also classified according to location: Atlantoaxial/Upper Cervical (AATB) from C1–C2, Subaxial Cervical (SACTB) from C3–C6, or Cervicothoracic (CTTB) from C7–T2.

AATB is usually treated medically only, except when there are extensive neurologic deficits and/or radiologic destruction. Patients in the 2nd or 3rd stages of AATB usually benefit from surgery (Table 1).[8]

For SACTB, a grading system helps determine whether patients need surgery on top of ATT (Table 2).[9,10] Grade 2 (5-6) patients require surgery via an anterior approach, and grade 3 (7-8) patients require surgery via a combined posterior and anterior approach. Despite this grading system, the anterior approach is preferred for SACTB. This is because of its direct approach to diseased vertebra, better disease clearance, spinal decompression, robust stabilization, ameliorated reconstruction, fusion, and better lordosis restoration. The posterior approach on the other hand is indicated for pan-vertebral disease (multi-level), posterior-only involvement, significant kyphosis/sagittal imbalance, long-segment disease needing corpectomies at more than two levels, and compression from vertebral elements lying posterior to the cord.[9] For SACTB patients with no MRI available, parameters that warrant surgery include progressive deterioration of neurologic function, serious deformity such as kyphosis at diagnosis (C2–C7 lordosis of >0 degrees or SVA >4 cm), deterioration of neurologic function after 1 week of ATT.[11]

The cervicothoracic junction represents a transitional zone between the rigid kyphotic and mobile lordotic spinal segments. These enhanced biomechanical stresses predispose it to developing progressive kyphosis and instability. Approaches to this area include Anterior only, Anterior and Posterior, or Posterior only (Table 3).[12]

While Rajasekaran's "spine at risk" signs have been used to guide the decision for surgery in pediatric patients, these were studied only in the thoracic and lumbar levels in pediatric patients 15 years old and younger.[4]

Table 2. Xiangya Institute of Medical Sciences Cervical Tuberculosis grading system[9]

Parameter	Score
Restriction of active neck movement	
No	1
Yes	2
Motor power	
No	1
Minimal (Motor power ≥4)	2
Severe (Motor power ≤3)	3
Radiologic features	
Paravertebral collection (C7 anteroposterior diameter) without evidence of bone destruction or radiological instability	1
Paravertebral collection, evidence of bone destruction (involvement of one vertebral column in the Denis System)[10], thecal sac compression without cord compression, or cord changes	2
Severe bone destruction (involvement of 1 vertebral column in the Denis system)[10] with cord compression and/or cord signal changes	3

Table 3. Surgical approaches for Cervicothoracic Spinal TB (CTTB) and indications[12]

Anterior only	• Single-segment lesion • Infection and destruction confined to anterior column with abscess/necrotic tissue compressing the front of the spinal cord • Mild kyphosis deformity less than 30 degrees
Anterior and Posterior	• Multi-segment lesions • Severe destruction • Complex kyphotic deformity greater than 50 degrees
Posterior only	• Moderate kyphotic deformity less than 50 degrees • Presence of significant vertebral collapse caused by bone destruction or multicentric TB spondylitis • One or two segment involvement with lesions accessible through a posterior approach • Spinal cord compression caused by paravertebral/epidural abscess • Severe or progressive neurological dysfunction and persistent lower neck pain unresponsive to conventional therapy • Elderly patients with complicated co-morbidities intolerant of extreme surgical intervention

Clinically, 43% of pediatric patients with TB present with neck pain and cervical involvement.[13] Their deformities, unfortunately, are worsened by the growth retardation of the anterior column and unrestricted growth of the posterior column.[14] A higher red bone marrow content and richer peripheral blood supply also hasten the spread of *Mycobacteria Tuberculosis*; there is a 66.7 % chance of consecutive vertebra involvement, 23.8% chance of single vertebra involvement, and a 9.5% chance of non-consecutive multiple vertebral body involvement.[13]

Given the increasing prevalence and disastrous consequences of pediatric cervical Pott's disease, we aimed to expand the body of knowledge in this field.

METHODOLOGY

Setting and study population

From January 2020 to January 2023, data was collected from Pediatric patients diagnosed with cervical Pott's disease (Upper Cervical/Atlantoaxial, Subaxial Cervical, Cervicothoracic) in a single institution. All included patients were histopathologically or microbiologically diagnosed with Pott's Disease. None of the patients had documented drug resistance and were compliant with ATT up to the final follow-up of at least one year. Adults and patients with T3-S5 involvement were excluded.

Types of interventions

Patients were managed medically or surgically. All patients received ATT. Medically managed patients received: 1) external immobilization, and/or 2) minimally invasive image-guided aspiration. Surgically managed patients underwent either: 1) decompression with or without instrumentation, or 2) open biopsy with or without immobilization.

Methods of instrumentation were the following: occipito-cervical fusion with screws and rods, fusion with lateral mass screws and rods, or anterior discectomy and fusion. External immobilization methods were: Halo vest for AATB, Philadelphia/Miami J collar for SACTB, and Cervico-thoracic Orthosis for CTTB.

Main and secondary outcomes

Outcomes monitored for the patients included: Frankel grade, Modified Japanese Orthopaedic Association scale (mJOA) improvement, and complications (implant failure or surgical site infections).

Frankel grade improvement was documented by assigning the following values:

- Frankel A: 1
- Frankel B: 2
- Frankel C: 3
- Frankel D: 4
- Frankel E with myelopathic signs: 5
- Frankel E without myelopathic signs: 6

The Frankel grade improvement was then calculated as the difference between the value at the last follow-up and the initial assessment.

Informed consent

Except for patient # 9 who dropped out from the study, informed consent was obtained from all patients either during the study or on the final follow-up of 1 year. The adult relative gave consent for patients below 18 years of age. Patients were updated on the progress of the manuscript as well as the intention of the authors to submit it for publication. All patients who had signs of Myelopathy were contacted at a later date from the latest follow-up to obtain final mJOA scores. Patients 6, 10, and 11 were evaluated face-to-face while patients 5 and 7 were evaluated via call.

RESULTS

Information obtained included: age, sex, area of pathology, date of first consult and Frankel grade, date of follow-up between 3 months to 1 year and Frankel grade, date of last follow-up and Frankel grade, mJOA on first consult for patients with signs of myelopathy, mJOA on last follow- up, spine diagnosis, other areas of disseminated TB, comorbids, procedure/s performed, and type of immobilization if applicable (Table 4).

Eleven pediatric patients from January 2021 to January 2023 were included with a mean age of 12. The atlantoaxial spine was the most involved cervical spine segment.

Table 4. Database of patients with cervical Pott's disease

Patient #	Age/ Sex	Levels affected	Diagnosis/ Presentation	Frankel Grade (First Consult)	Frankel Grade (3 - 6 month follow-up)	Frankel Grade (minimum 1 year follow-up)	Intervention/ Treatment
1	14/M	Subaxial (C6-C7)	Paraplegia LN C6 / Nape pain	Frankel B	Frankel C (3 months)	Frankel E	Medical CT-guided aspiration biopsy application of orthosis
2	7/M	Cervico-thoracic (T1)	Paraplegia LN T1 / Neck pain	Frankel C	Frankel E (3 months)	Frankel E	Medical
3	13/M	Subaxial (C5-C6)	Paraparesis LN C4 / Neck pain	Frankel D	Frankel E (6 months)	Frankel E	Surgical Laminectomy C4-C6, open biopsy Philadelphia collar
4	12/M	Cervico-thoracic (C7)	Paraplegia LN T2 / Neck pain	Frankel B	Frankel C (6 months)	Frankel C	Medical Refused surgical treatment during the first consult, referred back due to admission for a medical problem
5	14/M	Upper cervical (C2-C4)	Neck pain from cervical instability secondary to Pott's Disease	Frankel E Myelopathic hand signs (mJOA 15)	Frankel E (5 months)	Frankel E (mJOA 17)	Medical Application of halo vest
6	12/F	Upper cervical (C1- C2)	Neck pain from cervical instability secondary to Pott's disease	Frankel E Myelopathic hand signs (mJOA 12)	Frankel E (3 months)	Frankel E (mJOA 15)	Surgical Occipitocervical fusion
7	16/M	Upper cervical (C1- C2)	Neck pain from cervical instability (Odontoid migration) Pre-vertebral abscess	Frankel E Myelopathic hand signs (mJOA 11)	Frankel E (6 months)	Frankel E (mJOA 16)	Surgical Occipitocervical fusion
8	16/F	Subaxial (C5)	Cervical radiculopathy	Frankel D	Frankel E (5 months)	Frankel E	Surgical Anterior cervical discectomy and fusion
*9**	3/M	Cervico-thoracic (C7-T1)	Quadriparesis LN C5 Tuberculous arthritis, left hip	Frankel C	Opted to transfer back to the previous hospital	N/A	Medical Debridement, arthrotomy, left hip (Previous hospital)
10	18/F	Subaxial (C2-C3)	Cervical myelopathy	Frankel D myelopathic hand signs (mJOA 14)	Frankel E (3 months)	Frankel E (mJOA 17)	Medical Transoral drainage (ORL-HNS) orthosis application
11	9/M	Upper cervical (C2)	Cervical myelopathy	Frankel E myelopathic hand signs (mJOA 16)	Frankel E (6 months)	Frankel E (mJOA 17)	Medical

All patients received anti-tubercular treatment (ATT)
*drop-out/lost to follow-up; LN = last normal level; mJOA = Modified Japanese Orthopaedic Association scale; ORL-HNS = Otorhinolaryngology-Head and Neck Service

Four patients were managed surgically for varying indications; these were radiologic instability, progressive neurologic deficit, draining sinus, or enlarging abscess. One drop-out was noted due to their decision to transfer to their hospital of choice (#9). Four AATB patients (#5, #6, #7, #11) initially presented with Frankel E grades and myelopathic signs that improved after treatment. Despite the refusal of two patients (#1 and #2) to proceed with surgery, Frankel grade improvement was documented despite persistent deformity.

Among patients who presented with neurologic deficits, there was an improvement of at least one Frankel letter grade with a mean value of 1.8. Surgically managed patients improved by a mean Frankel grade of 1.67 while medically managed patients improved by a mean of 1.86. All myelopathic symptoms also resolved.

There was a weak negative correlation [Pearson R = -0.15)] between age and area of pathology and a positive correlation (R = 0.85) between initial Frankel grade and area of pathology. AATB patients are less likely to present with motor or sensory deficits as compared to SACTB and CTTB patients.

CASE DISCUSSION

Patient #1

A 14-year-old male with a 4-month history of nape pain [numerical rating scale score (NRS) of 6/10], weight loss, and night sweats, with neck stiffness and bilateral lower extremity weakness [Last normal level (LN) = C5], with sacral sparing.

Imaging showed a retropharyngeal abscess and gibbus deformity at the cervicothoracic junction. The retropharyngeal abscess was aspirated, and a brace was applied since he and his parent did not consent to surgery (Figure 1A and B). The focal kyphosis of 32 (Figure 1E and F) degrees could have benefitted from a posterior-only approach. Apart from this, ATT was completed. The patient recovered one year after initiation of treatment based on the Frankel grade but deformity persisted at 32 degrees (Figure 1C) with occasional pain.

Patient #2

A 7-year-old male presented with a 3-month history of neck pain (NRS 5/10) and gradual onset bilateral lower extremity weakness (Figure 2A, C, and Figure 3). Physical examination showed normal motor and sensory levels at T1. After one year of ATT, Frankel grade improvement was seen on reevaluation despite the patient having a kyphosis between 30 and 50 degrees (Figures 2B and D).

Like Patient #1, a posterior approach could have been beneficial to correct the patient's deformity but again no consent could be obtained.

Patient #3

A 13-year-old male presented with a 1-month history of dull, aching neck pain (NRS 7/10) and weakness of both upper and lower extremities, and a 2-week history of myelopathic signs. Physical examination upon admission showed weakness of both upper extremities (4/5) and lower extremities (3/5) and the presence of inverted radial reflexes and Hoffman signs.

Imaging studies showed an enlarging abscess posterior to the vertebral bodies of the subaxial cervical spine with no radiologic instability (Figure 4A-E). Open drainage of the abscess was done (Figure 4F). Subsequently, the patient underwent external immobilization and initiation of ATT. He had Frankel grade improvement upon follow-up.

This patient had a SACTB score of 5 (Grade 2) for which the anterior approach is recommended. The open biopsy and drainage were done via the posterior approach instead for the following reasons: pan-vertebral disease (multi-level), posterior-only involvement, and canal compromise due to compression from vertebral elements lying posterior to the cord.

Patient #4

A 12-year-old male presented with a 4-month history of neck pain with no associated signs and symptoms and a 3-month history of worsening neck pain and both lower extremity weakness. Physical examination showed motor and sensory deficits (LN T3) and hyperreflexia on both knee and Achilles tendon deep tendon reflexes.

Given the progression of symptoms, kyphosis of >50 degrees, and severe destruction causing lateral translation, the patient was advised to undergo surgery (Figure 5A and C). The patient and his family refused surgery but were willing to undergo ATT. The patient was initially lost to follow-up but at 1 year post-treatment, was readmitted for a different complaint by another service and was subsequently referred to Ortho. Repeat radiographs showed no improvement in the thoracic spine (Figure 5B and D) and a 1-letter Frankel grade improvement. Any further surgical interventions were still refused.

Table 5. Frankel grade improvement

Patient #	Frankel (Initial)	Frankel Grade (Latest Follow-up)	Grade Improvement
1	B	E	4
2	C	E	3
3*	D	E	2
4	B	C	1
5	E with Myelopathy	E	1
6*	E with Myelopathy	E	1
7*	E with Myelopathy	E	1
8*	D	E	2
9 **	C	THOC	N/A
10	D	E	2
11	E with Myelopathy	E	1
Mean			1.8
Mean (Surgical)	1.67	Mean (Non- Surgical)	1.86

All patients received anti-tubercular treatment (ATT)
*surgically managed; **drop-out/lost to follow-up; THOC = To Hospital Of Choice

Patient #5

A 14-year-old male presented with a 2-month history of gradual onset neck pain (highest NRS at 8/10) with associated gait difficulties and paresthesia of both upper extremities. Physical examination showed no motor and sensory deficits but with hyperreflexia on biceps and triceps deep tendon reflexes, and inverted radial reflexes. Radiographs showed involvement of the C2–C4 vertebrae (Figure 6A, C, E-H). A halo vest was applied to address the instability (Figure 6B and D).

Given the involvement from C2-C4, both the AATB classification by Goel et al. and the SACTB classification by Wang et al. can be used.[8] Since he is classified as AATB Grade I and SACTB Grade 4, while surgery is not warranted, an orthosis may be applied. The focal kyphosis resulting from

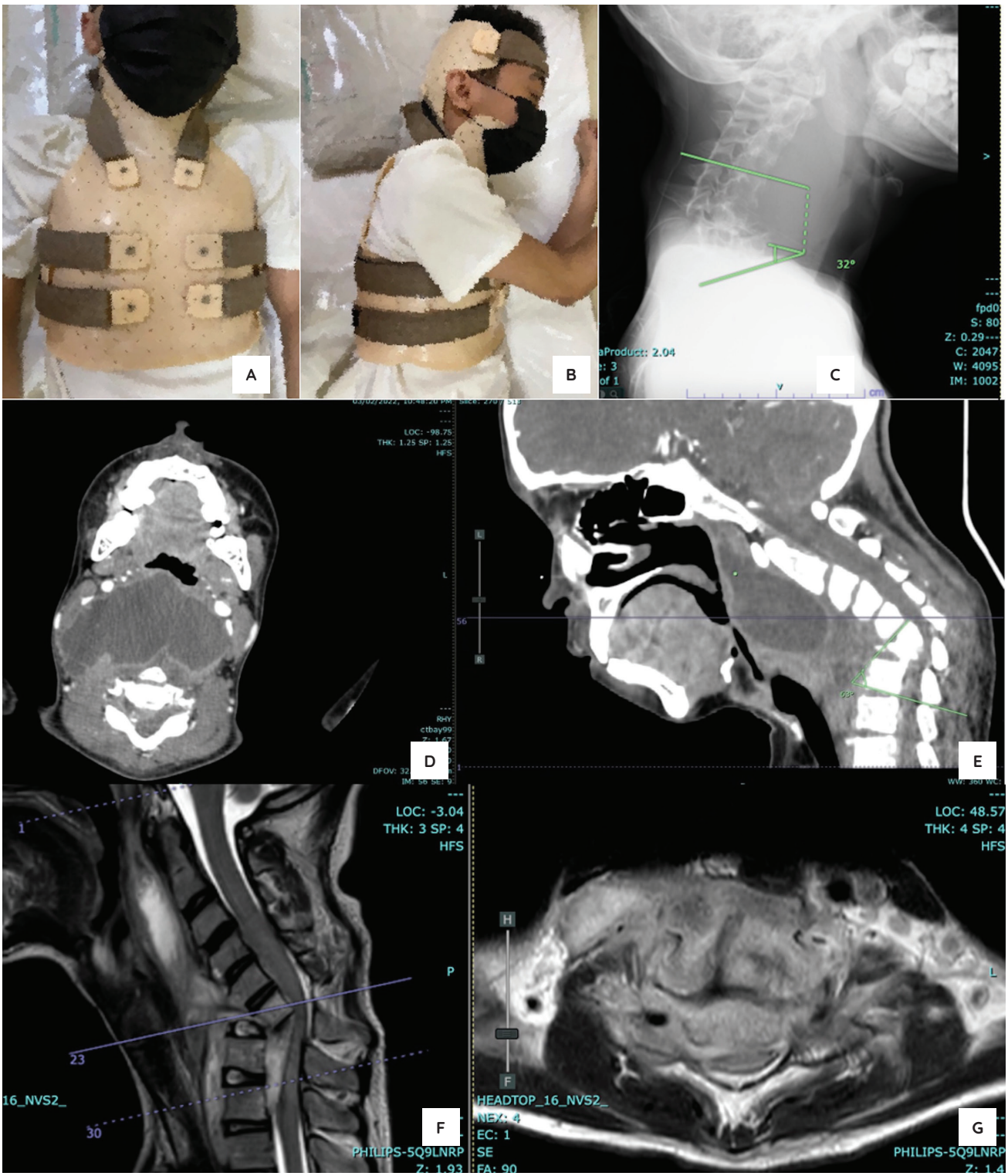

Figure 1. Patient 1 Imaging studies and clinical images. **(A and B)** Clinical pictures on follow-up. **(C)** latest radiograph on 1 year follow-up. **(D and E)** Pre- treatment CT- Scans. **(F and G)** Pre- treatment representative MRI cuts (T2- weighted sagittal and axial).

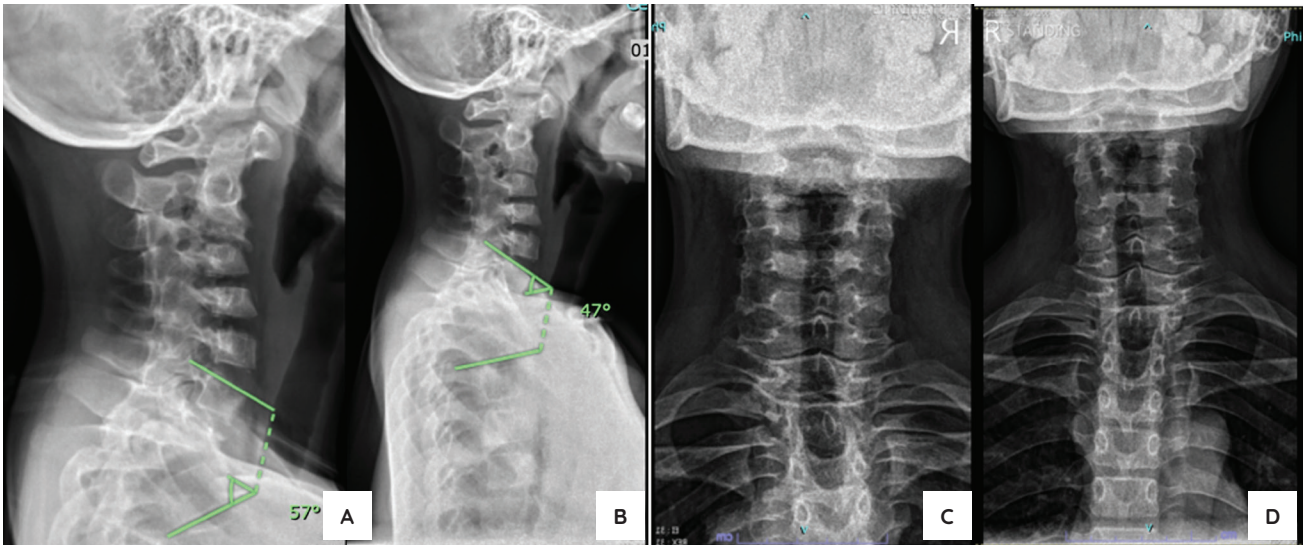

Figure 2. Patient # 2 Imaging studies. **(A and C)** Pre- treatment Cervical AP and Lateral radiographs. **(B and D)** Post- treatment (1 year): Cervical AP and Lateral radiographs.

the involvement of C2 indicated the long-term application of a halo vest.

Follow-up consultations at 5 months and 1 year post-treatment recorded complete recovery.

Patient #6

A 12-year-old female presented with a 3-month history of neck pain and paresthesias of both upper extremities. After 2 months, her pain worsened and she started having difficulty with ambulation and experiencing episodes of "clumsiness" when performing activities of daily living. Physical examination showed hyperreflexia of both upper and lower extremity deep tendon reflexes, positive clonus, and positive Hoffman signs. Imaging showed translation of C1 over C2 (Figure 7A and B).

Given the involvement of the atlantoaxial joint which was lysed on X-rays, she underwent a posterior occipitocervical fusion up to the C4 level. The final follow-up at one year showed no myelopathic signs and full neurologic recovery based on the Frankel grade (Figure 7C and D).

Patient #7

A 16-year-old male presented with a 4-month history of neck pain (NRS of 6/10) with no associated signs and symptoms. Two months later, the pain intensified (8/10) and the patient would have difficulty performing activities of daily living due to "clumsiness" and difficulty maintaining proper posture on the neck without any support. Physical examination showed hyperreflexia on both knees and Achilles deep tendon reflexes as well as inverted radial reflexes. Imaging showed desiccation of the C2 vertebral body and translation of C1 over C2 (Figure 8A). Like Patient #7, there is lysis of the C2 vertebral body extending to the atlantoaxial joint causing translation. There were no other adjacent joints involved.

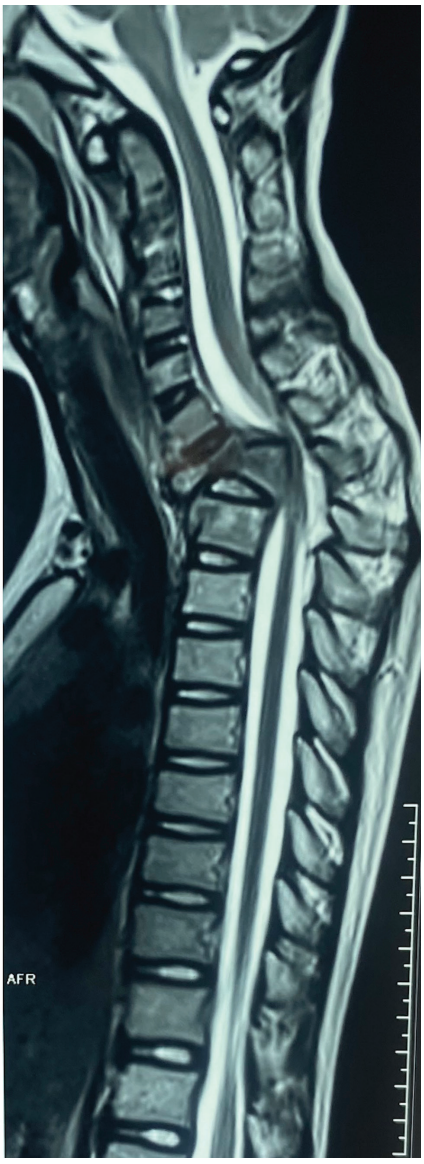

Figure 3. T2- weighted sagittal MRI Image of Patient 2.

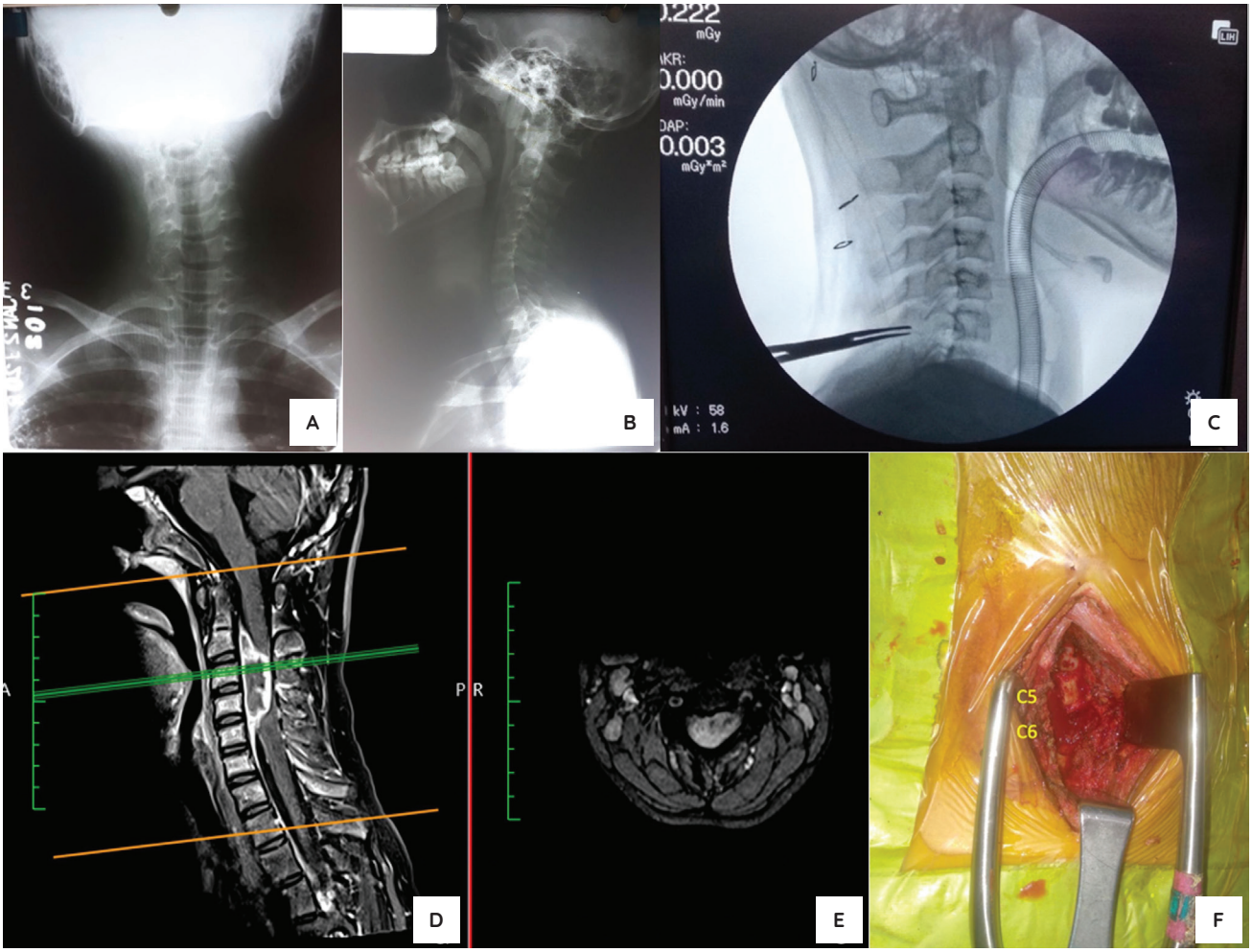

Figure 4. Patient 3 Pre-operative and Intra-operative images. **(A and B)** Pre-treatment AP and Lateral radiographs. **(C)** Intraoperative Lateral radiograph. **(D and E)** Pre-treatment T2 weighted MRI images. **(F)** Intraoperative clinical image of open drainage and biopsy.

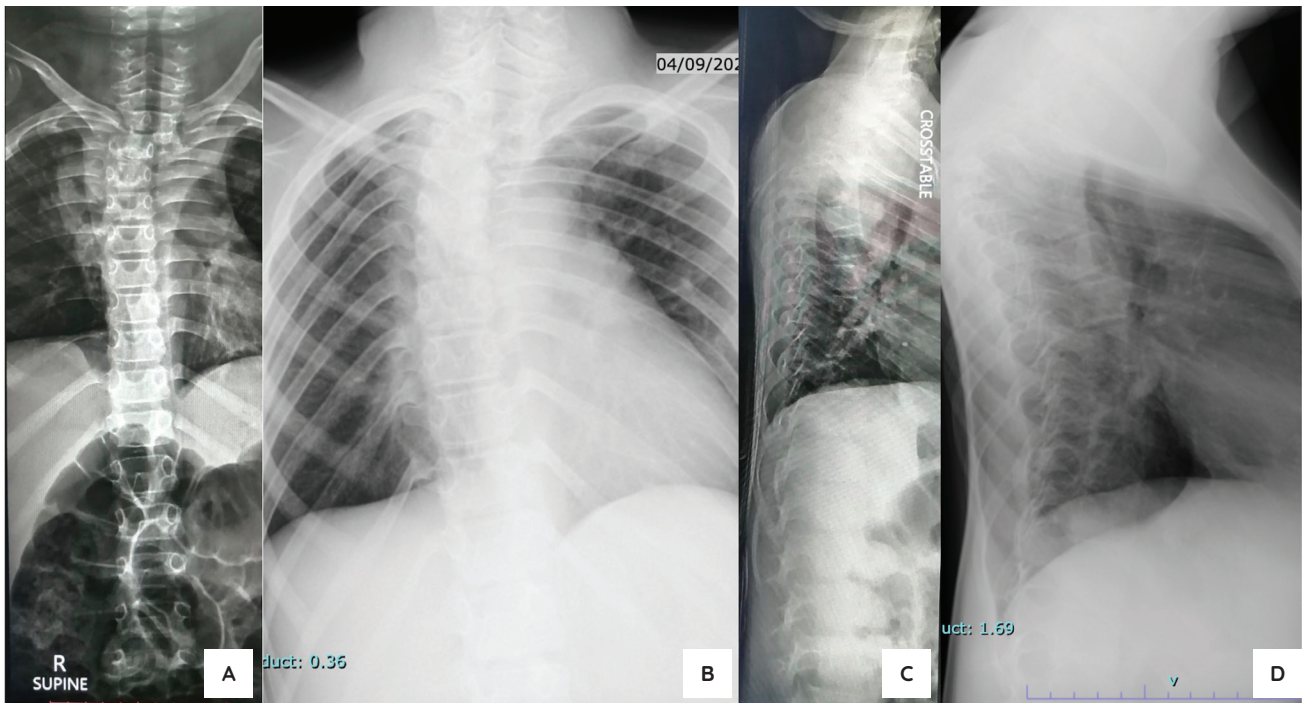

Figure 5. Patient 4 Radiographs 1 year apart. **(A and C)** AP and Lateral radiographs on initial consult. **(B and D)** AP and Lateral radiographs upon readmission for a medical problem. Patient initially refused surgery and was lost to follow-up.

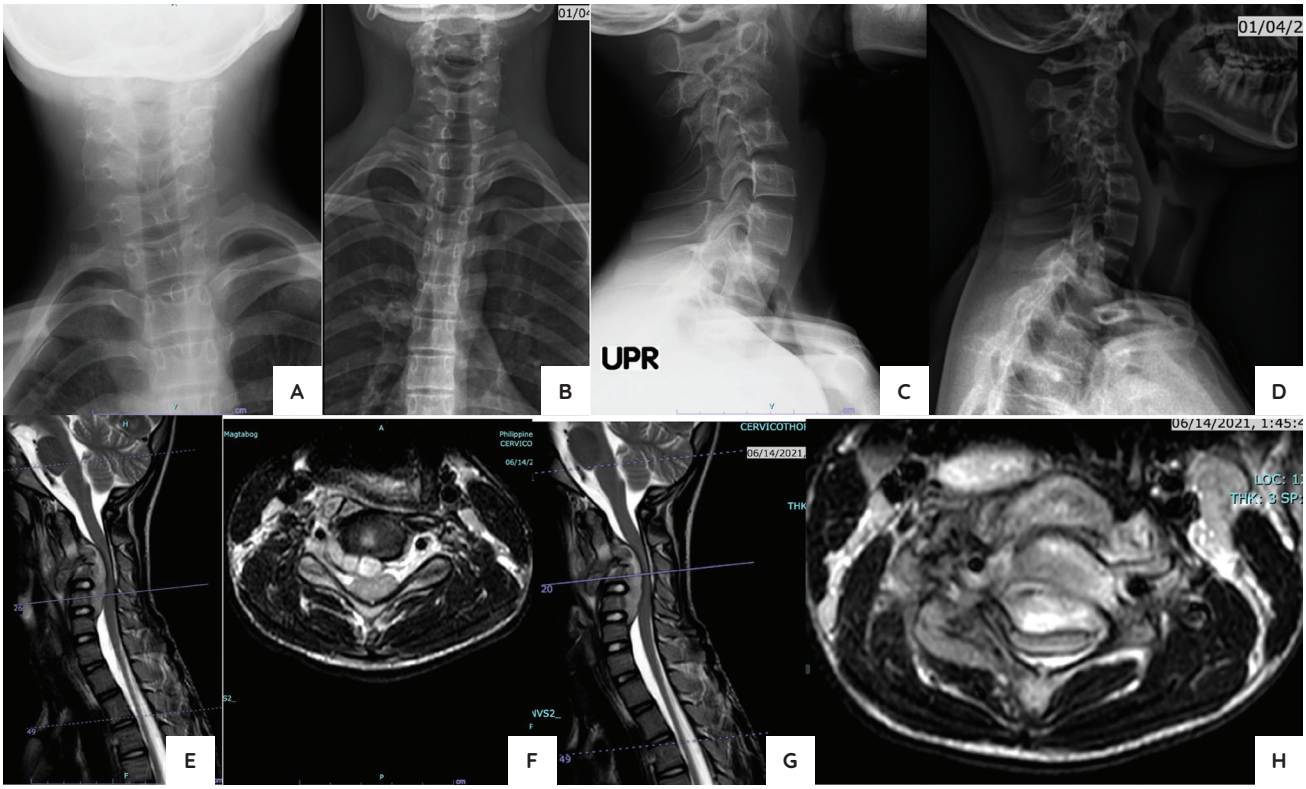

Figure 6. Patient 5 Radiographs (2 years apart) and T2- Weighted MRI. **(A and C)** AP and Lateral radiographs on initial consult. (**B and D)** AP and lateral radiographs on 2-year follow-up. **(E-H)** T2- weighted Sagittal and Axial representative images on the first consult.

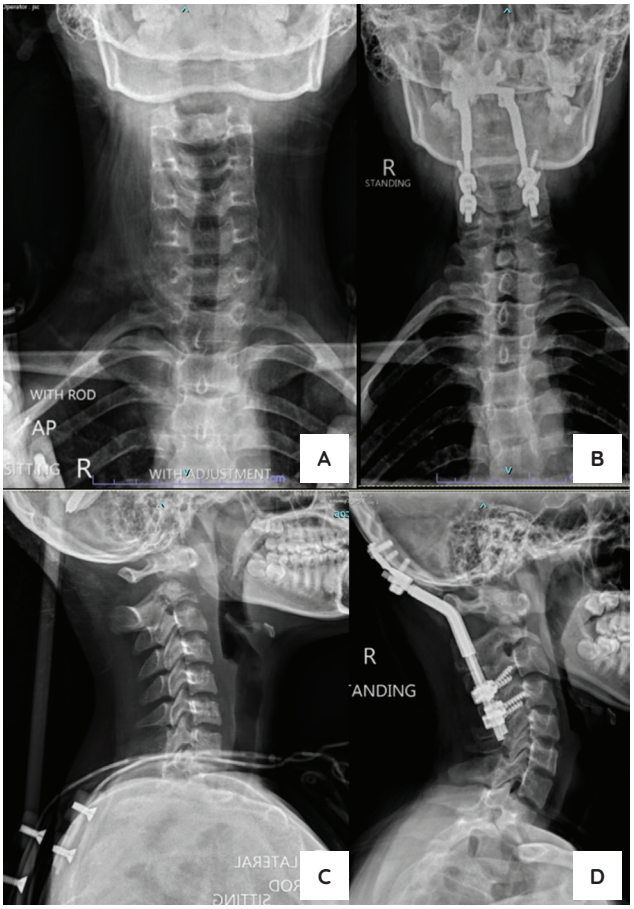

Figure 7. Patient 6 imaging studies. **(A and B)** AP and Lateral radiographs on initial consult. **(C and D)** AP and Lateral radiographs 1-year post-treatment.

This required occipito-cervical fusion. Follow-up consultations at 6 months and 1 year both showed no implant loosening and recovery of the cervical myelopathy (Figure 8B and C).

Patient #8

A 16-year-old female presented with a 5-month history of neck pain (NRS of 4/10) with limitation of movement and paresthesia on both upper extremities. Physical examination showed impaired sensation (LN C5). Imaging studies showed a 32-degree focal kyphosis on the affected level (Figure 9A and C). Given the limitation of movement, weakness, and one-column involvement, she was given a Xiangya Institute score of 6 (Grade II). The patient underwent Anterior Cervical Discectomy and Fusion. These resulted in improvement of kyphosis and functional recovery of Frankel grade at 5 months and 1 year post-operatively (Figure 9B and D).

Patient #9

A 3-year-old male presented with an 8-month history of neck pain and inability to perform range of motion of the neck and difficulty feeding. He then developed weakness in both hands and feet and was unable to ambulate independently. He also had a history of Tuberculous Arthritis on the left hip for which surgical debridement and arthrotomy were done in a previous tertiary hospital. ATT had already been initiated in the previous hospital.

The patient was in a hip spica cast upon examination. Both upper extremities and the right lower extremity did not show spontaneous movement and were hyporeflexive.

Imaging studies showed an abscess on the subaxial spine with spinal cord compression (Figure 10A-D). He was graded a Xiangya Institute score of 8 indicating surgical treatment with a posterior approach and possible anterior approach. The patient's family however preferred to return to their previous hospital and could not be followed up.

Patient #10

An 18-year-old female presented with a 6-month history of sudden-onset neck pain (NRS of 6/10), a 4-month history of increased intensity of pain (8/10) and difficulty ambulating, and a 1-month history of weakness of both upper and lower extremities. Upon examination, there were no noted motor and sensory deficits but all extremities were hyperreflexive and the patient had a wide-based gait.

Imaging showed abnormal kyphosis, sagittal-vertical angulation, a posterior abscess, and increased retropharyngeal spaces, (Figure 11A-F) all indicating spinal cord compression. The Xiangya Institute grade for this patient was 5 which

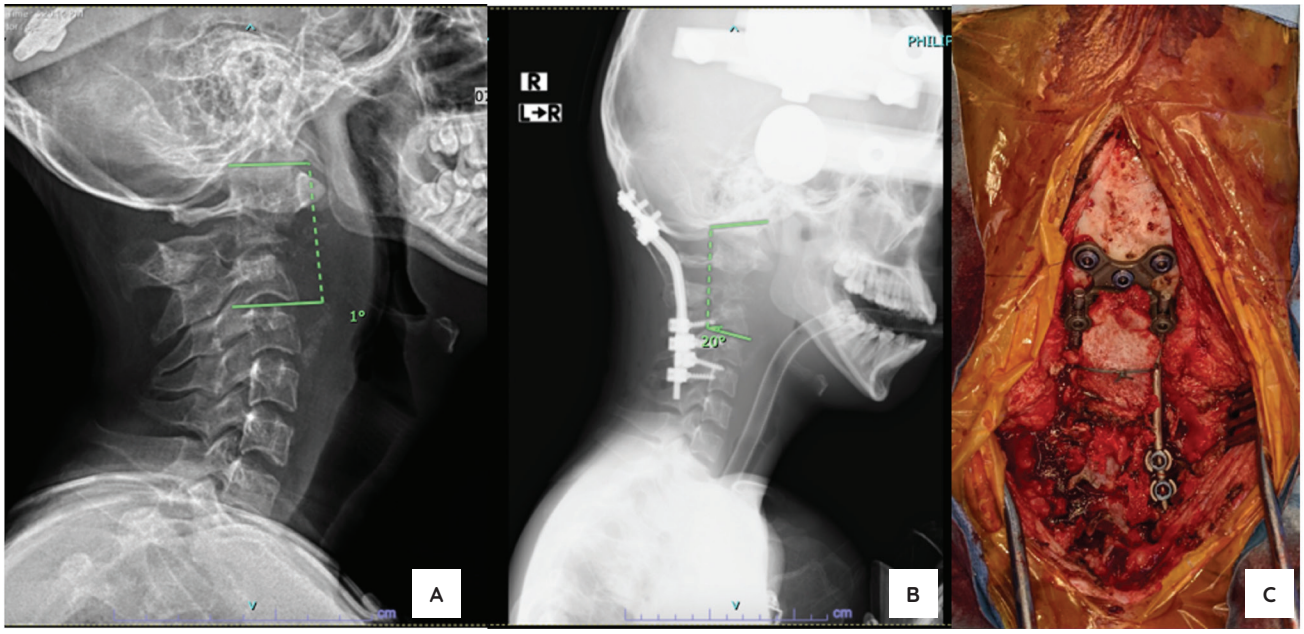

Figure 8. Patient 7 imaging and clinical pictures. **(A)** Pre-operative Lateral Radiograph. **(B)** Post-operative Lateral radiograph. **(C)** Intraoperative clinical picture.

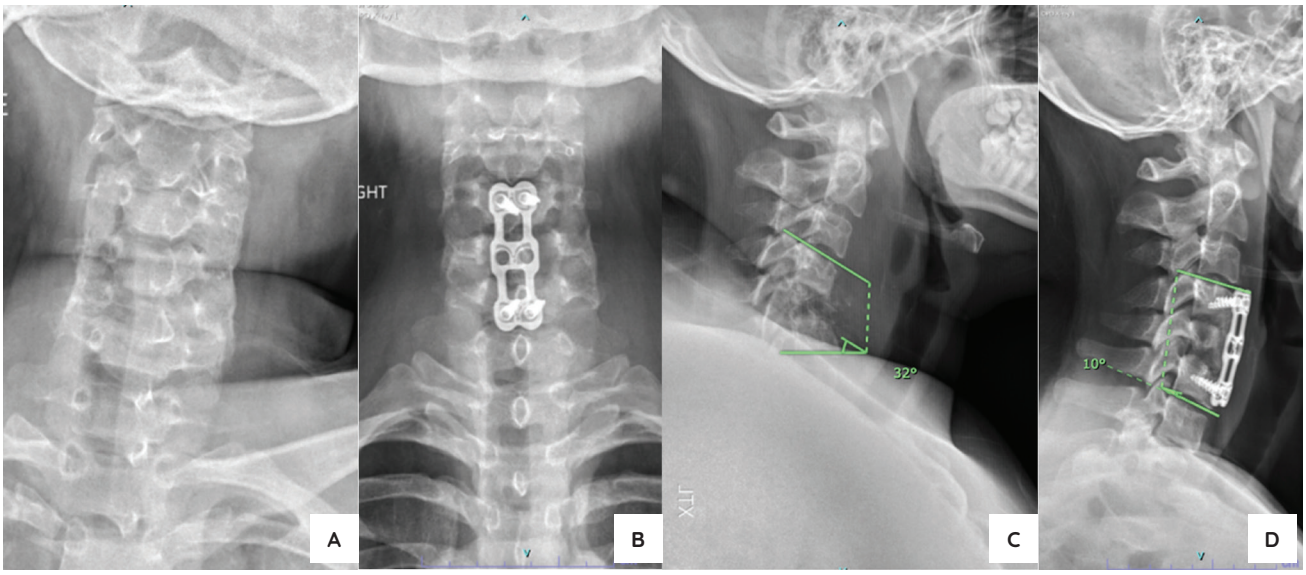

Figure 9. Patient 8 Radiographs 1 year apart. **(A and C)** AP and Lateral radiographs on initial consult. **(B and D)** AP and Lateral radiographs 1-year post-op/ initiation of ATT.

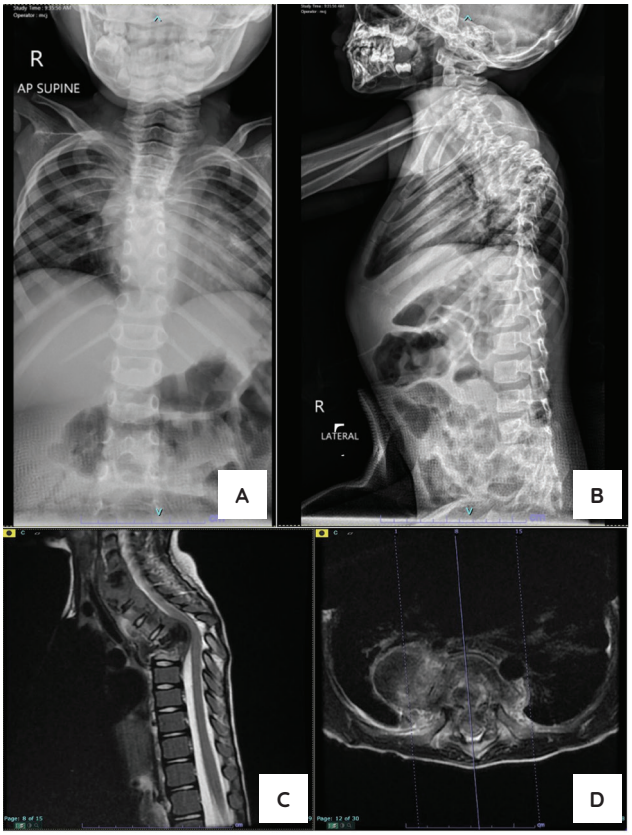

Figure 10. Patient 9 Images (Refused surgical management, continued ATT, opted transfer back to the hospital of origin). **(A and B)** AP and Lateral radiographs on initial consult. **(C and D)** T2- weighted MRI images Sagittal and Axial.

warranted an anterior surgical approach. Given the patient's complaint of dysphagia, the abscess was drained transorally. An orthosis was applied for immobilization. There were no remaining myelopathic signs at 3 months, 6 months, and 1 year follow-up.

Patient #11

A 9-year-old presented with a 1-month history of intermittent headaches and difficulty with ambulation. Examination showed a wide-based gait and no motor and sensory deficits. Imaging showed involvement of the tip and body of the C2 vertebra with decreased canal size and atlantoaxial joint lysis (AATB Grade 1) (Figure 12A-D). The patient started ATT and showed complete recovery on subsequent follow-up (6 months and 1 year).

DISCUSSION

Symptoms of cervical Pott's disease include pain, neurologic deficits, deformity, and constitutional symptoms (fever, weight loss, night sweats).[8] Pain is the most common symptom because cervical Pott's disease is a predominantly extradural pathology causing pain through dural irritation, free nerve ending irritation, endplate changes, and/or bony destruction.[15]

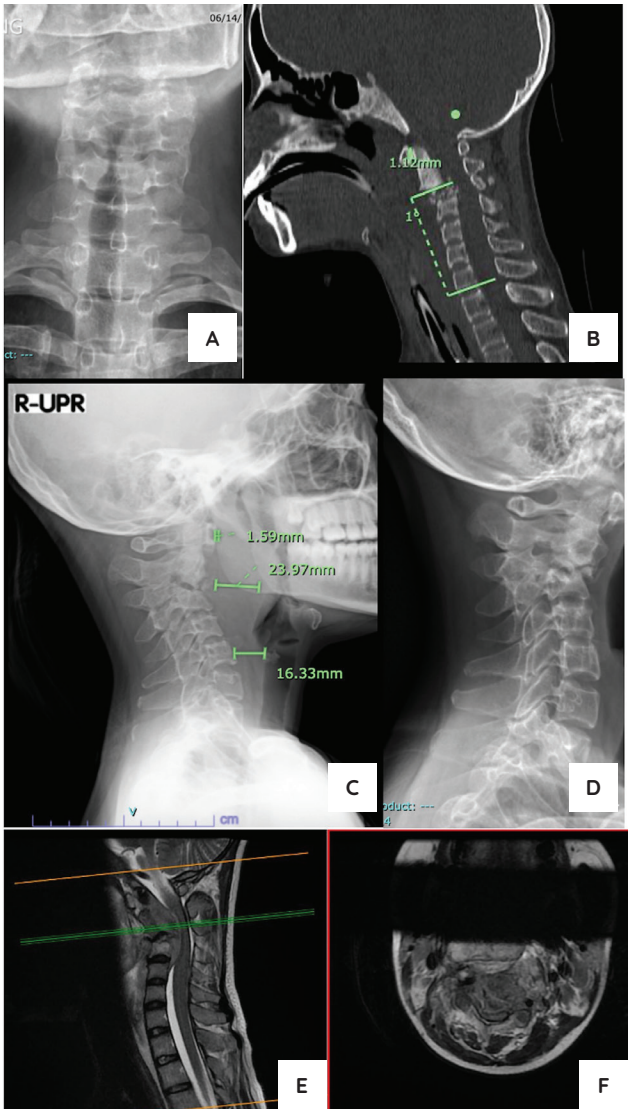

Figure 11. Patient 10. **(A-C, E-F)** Imaging studies on initial consult. **(D)** Lateral radiograph 1 year post-treatment.

Apart from pain, some patients presented with myelopathic signs graded using the mJOA score (Table 6). This is a revision of the previously published JOA score and is more applicable to cultures that do not use chopsticks regularly. The mJOA score assesses only motor dysfunction in the upper and lower extremities, sensory function in the upper extremities, and bladder function. Scores are mild if the mJOA score is 15 or larger, moderate if 12 to 14, or severe if less than 12.[16] Myelopathic signs in this study were present only in patients with AATB. These patients usually present with neck pain 50% of the time, neurologic deficits or numbness 70% of the time, and pyramidal signs 90% of the time. These include spasticity, weakness, slowing of rapid alternating movements, and hyperreflexia caused by corticospinal tract involvement.[15,17]

Clinically and radiologically, eight out of our eleven patients had a gibbus/kyphotic deformity. This is caused by the preferentially anterior osseous destruction.[18] This deformity, among other factors, caused the neurologic deficits.

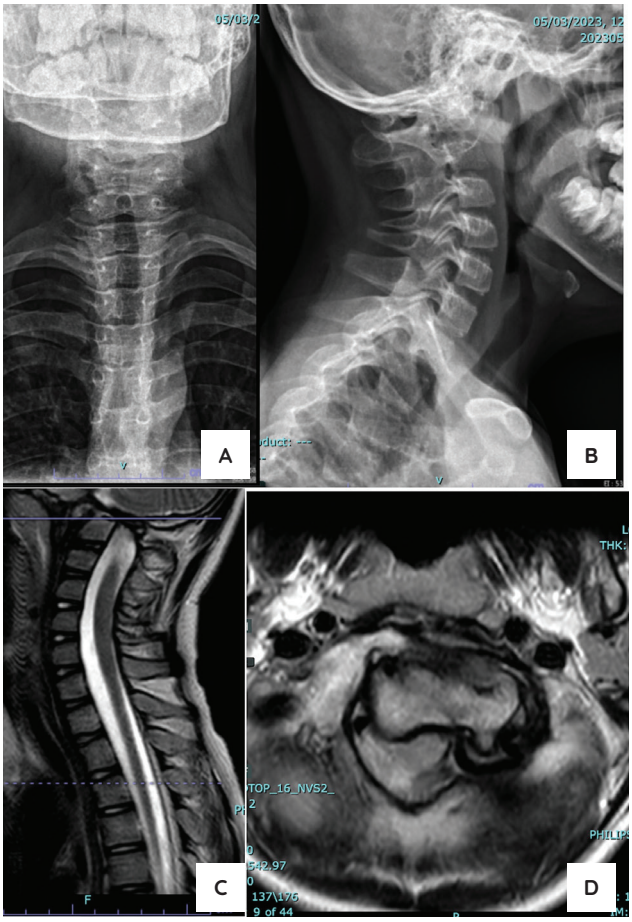

Figure 12. Patient 11 Imaging studies. **(A and B)** AP and Lateral radiographs on initial consult. **(C and D)** T2-weighted MRI images on initial consult.

With or without surgery, all patients showed at least one Frankel grade letter improvement (mean of 1.8). Myelopathic signs were also resolved post-treatment. Regardless of the type of cervical Pott's disease, surgical goals were the same: decompression for patients with progressive/severe neurologic deficits, stabilization, multilevel/pan-vertebral disease, open biopsy for patients with inadequate tissue samples or doubtful diagnosis, and debridement for patients with large/persistent abscesses.[18] The mainstay of treatment is still ATT.[19]

Although statistically not significant, younger patients presented with pathologies in the subaxial or cervicothoracic areas. All patients with SACTB were >10 years old and this is due to the vertical orientation of facet joints reducing upper cervical mobility and increasing subaxial cervical mobility.

Except for one patient who presented with myelopathic signs due to AATB (#11), all patients <10 years old presented with motor deficits resulting in worse Frankel grades because of the relatively poor muscle control, ligamentous laxity, and horizontal orientation of the facet joints causing increased mobility and compression.[20]

Patients with CTTB and SACTB presented with worse Frankel grades than patients with AATB. This is due to the relatively larger cross-sectional area of the atlantoaxial/upper cervical spinal canal.[17] For CTTB and SACTB, neurologic deficits are expected due to the mechanical effects of kyphosis, the small canal size, and the tenuous blood supply to the cord.[20]

CONCLUSION AND RECOMMENDATIONS

Cervical Pott's disease may still be seen in the pediatric population despite poor documentation. The mainstay of treatment is still anti-tubercular treatment (ATT), with surgery indicated for unstable cervical spines, depending on the location. After completing one year of treatment, an improvement of at least one letter Frankel grade is expected for patients.

ETHICAL CONSIDERATION

Patient consent forms were obtained before manuscript submission.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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CASE REPORT

The Use of Extended Curettage with Freezing Nitrogen Ethanol Composite for Giant Cell Tumor of Bone: A Case Report*

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ABSTRACT

Liquid nitrogen (LN) has been used successfully to treat benign-aggressive lesions such as the Giant Cell Tumor of bone (GCTB). However, its volatility has led to concerns regarding peri- and post-operative complications. A novel, semi-solid composite of liquid nitrogen and ethanol was developed to mitigate these risks, called freezing nitrogen ethanol composite (FNEC). We present the first application of this technique in the Philippines, for a 20-year-old male with a pathologic fracture of the proximal femur secondary to GCTB. FNEC was applied after extended curettage, followed by proximal femoral plating. At 4 years post-surgery the patient's functional status is excellent, with no evidence of local recurrence.

Keywords. FNEC, giant cell tumor of bone, liquid nitrogen

INTRODUCTION

In 1969, Marcove and Miller were the first to use liquid nitrogen as a palliative treatment for metastatic bone disease, via direct application into a bone lesion in the humeral shaft. Several authors since then have demonstrated liquid nitrogen as an effective cryogen. The minimum temperature range required for tumor cell necrosis is -50°C to -70°C. The temperature of liquid nitrogen in room air ranges from -195°C to -197°C, making it suitable for both tissue preservation and destruction.[1,2]

In the early 2000s, Tsuchiya et al., processed extremity bone sarcomas in situ via immersion in liquid nitrogen. Histology demonstrated complete tumor cell necrosis while retaining the bone's structural and osteoinductive properties, with local recurrence rates comparable to other limb salvage methods. Liquid nitrogen, however, boils at room temperature; its volatile state makes surgical handling difficult for smaller lesions. Unintended exposure increases the risk for complications such as nerve palsy, and skin and soft tissue necrosis.[3-5]

To address these risks, Wu and colleagues developed a novel material composed of liquid nitrogen and 95% ethanol and called it freezing nitrogen ethanol composite (FNEC). This composite assumes a semisolid state that aids surgical handling and accurate placement in smaller lesions, thereby minimizing complications. With a working temperature range of -114°C to -122°C, FNEC is comparable in terms of efficacy with liquid nitrogen when used to treat giant cell tumor of bone (GCTB).[5,6]

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Giant cell tumor of bone (GCTB) is a benign-aggressive lesion with a relatively high prevalence among Asians, common in young adults during the second to third decades. Most patients are diagnosed at Campanacci Stage 2 or higher, with up to 50% affecting the distal femur or tibia. This emphasizes the need for a durable surgical option that preserves joint mobility, provides oncologic control, and low re-operation rate at an economic cost. This is relevant for developing countries such as the Philippines, where close to 20% of citizens live below the poverty threshold, and the majority of health expenditures are not subsidized.[7-10]

This surgical case report aims to discuss indications and procedure-related specifics following the first application of FNEC, according to the original description by its innovators, for the biologic reconstruction of a pathologic fracture secondary to GCTB.

CASE

A 20-year-old male consulted emergently due to severe left hip pain after a basketball game. Radiographs revealed a pertrochanteric fracture through a geographic, lytic lesion in the intertrochanteric region of the left proximal femur (Figure 1). An open biopsy was performed, which confirmed a diagnosis of GCTB (Figure 2). The patient was then started on Denosumab while preparing for surgery. The standard dosing regimen for GCTB was followed, with a subcutaneous 120 mg injection of Denosumab every 4 weeks following loading doses on the day of initiation, day 8, and day 15.[10] After

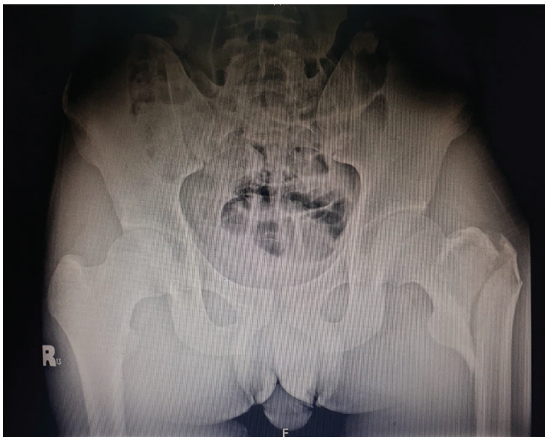

Figure 1. This antero-posterior (AP) radiograph of both hips shows a pertrochanteric fracture at the left proximal femur, through a lytic lesion at the intertrochanteric region with geographic borders, no apparent bone response, no matrix, thinned cortices, and no associated soft tissue mass. Correlation with biopsy findings are consistent with giant cell tumor of bone, Campanacci 3.

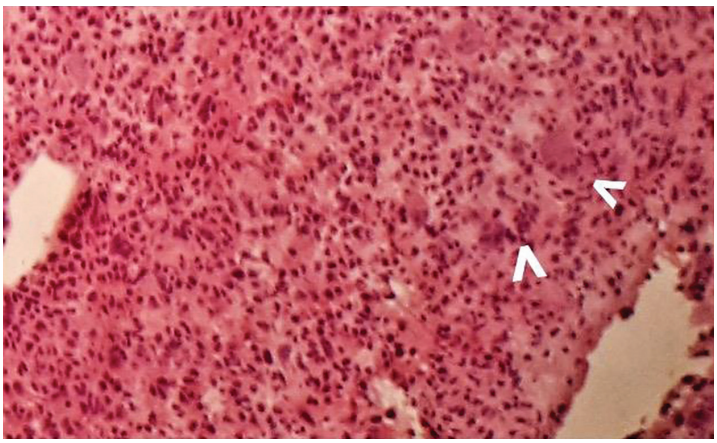

Figure 2. Histology slide on high power magnification shows layered nests of multi-nucleated giant cells *(arrowheads)* on a background of highly cellular stroma, consistent with giant cell tumor of bone.

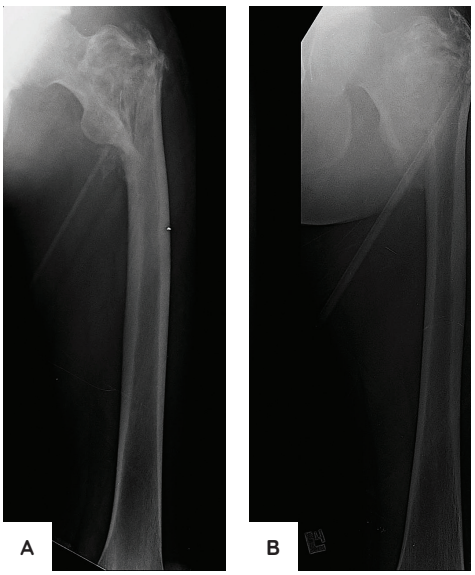

Figure 3. AP radiographs at 1 month **(A)** and 3 months **(B)** post-injury of the left hip show fracture site consolidation and development of a sclerotic rim around the lesion while on Denosumab.

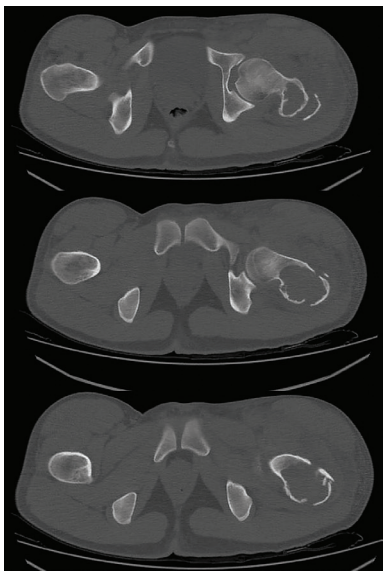

Figure 4. These representative axial cuts of computed tomography (CT) scans taken after the second month of Denosumab show an intact medial cortex.

four doses, repeat imaging showed fracture site consolidation, a sclerotic border around the lesion, and an intact medial cortex (Figures 3 and 4). The following surgical options were discussed in detail with the patient and his family: extended curettage with FNEC followed by polymethylmethacrylate (PMMA) application and plate fixation, tumor resection with subsequent hip fusion, and resection followed by reconstruction with tumor endoprosthesis. The latter constitutes the current standard of care internationally.[12] Citing a desire for a mobile joint, intention to resume high-impact activities, and monetary considerations, the family decided on extended curettage with FNEC. Government financial assistance for implants was obtained a month after the fourth dose of Denosumab.

All materials for storing, handling, and creating FNEC were provided for free by the musculoskeletal tumor service. Surgeries were performed by a team of two orthopedic oncologists and two residents in training. The patient was placed in the right lateral decubitus position and a direct lateral approach was used to expose the left proximal femur, making sure to include the previous biopsy site (Figure 5).

The team created a cortical window large enough to allow adequate curettage of all gross tumor (Figure 6). Approximately 150cc of tumor material was removed using curettes and sent for histologic confirmation. This was followed by mechanical extension of margins using a high-speed burr under fluoroscopy. The cavity was washed copiously with normal saline solution, and soft tissues were covered with gauze for protection before adjuvant application.

The liquid nitrogen-ethanol composite was prepared according to the protocol described by Wu et al.[5] A ratio of 1 part ethanol (95% formulation) was mixed with 2 parts liquid nitrogen to create a semi-crystalline solid (Figure 7A). Once the desired consistency was reached, osteotomes and forceps were used to insert FNEC into the bone cavity (Figure 7B). A total exposure time of 10 minutes was completed for 2 cycles. The residual fluid was suctioned and the cavity was washed with normal saline at room temperature.

Reconstruction was completed using PMMA and a 7-hole 4.5mm standard locking compression plate (Figure 8). Closure was performed by repairing the gluteus medius tendon and fascia proximally, and the vastus lateralis fascia distally. A surgical drain was placed to allow for the egress of excess fluid and removed on the third postoperative day. Intravenous antibiotics were continued for three days. The patient tolerated sitting up on the first day after surgery and standing bedside with a walker on the third day. He was able to do walker ambulation with partial weight-bearing on the affected side by the fifth day and was discharged from the hospital.

At two weeks post-surgery the surgical site healed without signs of infection, frostbite, or dehiscence. Physical therapy sessions were initiated three times a week for the first month,

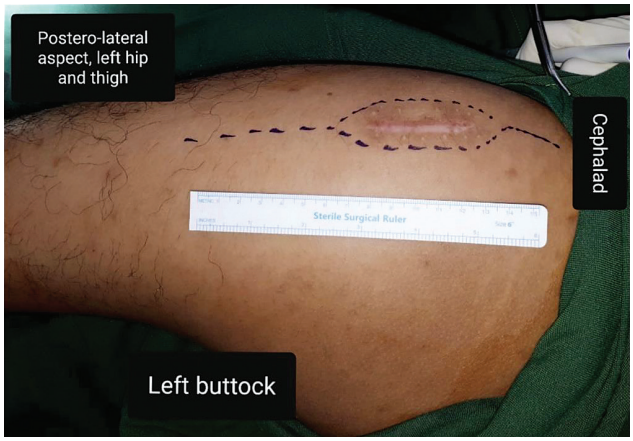

Figure 5. Image shows pre-operative markings for the surgical incision, including the previous biopsy site.

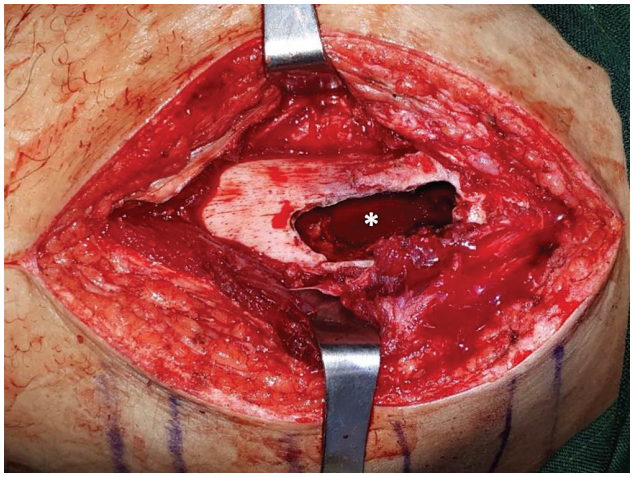

Figure 6. Image shows an ovoid cortical window on the lateral aspect of the left proximal femur, with an aperture* large enough to allow for access to entire area.

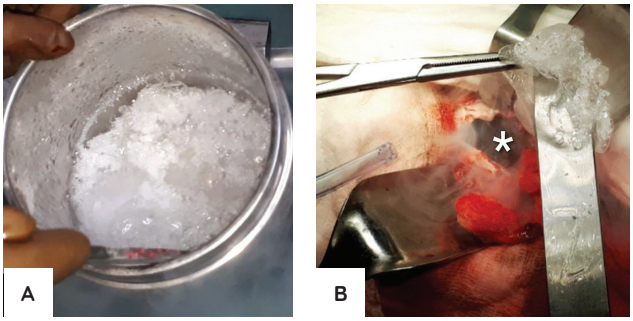

Figure 7. FNEC prepared using 1 part 95% ethanol and 2 parts liquid nitrogen, mixed to create a semi-crystalline solid **(A)** which was then placed into the tumor cavity* **(B)**.

focusing on strengthening the quadriceps and hip abductors and performing daily activities. The patient achieved full weight-bearing at two months, and had a Musculoskeletal Tumor Society Score (MSTS) of 28/30 at three months. Regular surveillance continued except for the year 2020, when COVID-19 restrictions made physical follow-up and

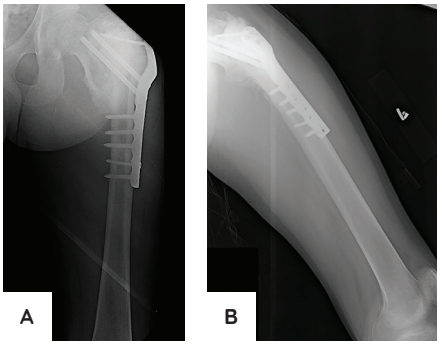

Figure 8. Femur AP **(A)** and lateral **(B)** radiographs showing PMMA and proximal femoral locking plate.

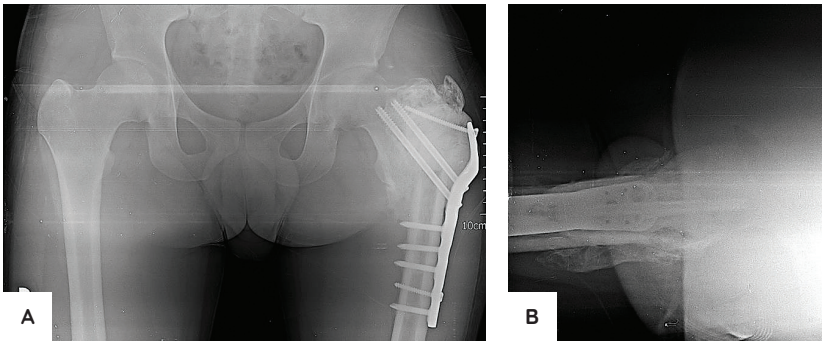

Figure 9. Bilateral hip AP **(A)** and left hip cross-table lateral **(B)** radiographs at 3 years' follow-up.

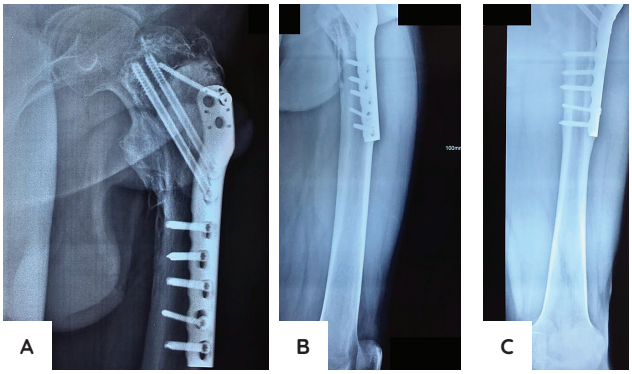

Figure 10. Left hip AP **(A)** and femur AP **(B)** and lateral **(C)** radiographs at 4 years' follow-up.

imaging inaccessible (Figure 9). At the latest follow-up at 48 months post-surgery, he has an MSTS score of 30/30 and no signs of local recurrence or distant metastases (Figure 10).

DISCUSSION

Giant cell tumor of bone is a benign-aggressive neoplasm with a predilection for the epi-metaphyseal region of long bones. Successful treatment of GCTB relies on a correct diagnosis and complete tumor removal, emphasizing the need for confirmatory biopsy and pre-operative planning. While en bloc resection has consistently produced excellent oncologic results, its higher surgical morbidity may affect long-term functional outcomes. Several authors emphasize the importance of balancing tumor eradication with joint preservation, particularly for GCTB in young, active patients. Related studies on tumor margins for GCTB over the past three decades have reported that a well-performed intralesional excision leads to comparable local recurrence rates while mitigating functional impairment.[7,8,12-17]

These findings are particularly relevant for low- and middle-income countries (LMICs) such as the Philippines, where economic considerations play a significant role in decision-making. With just six Southeast and East Asian countries achieving over 95% of healthcare coverage, surgery and implant costs remain prohibitive.[9,11,19,20] This novel procedure mitigates such limitations as it preserves bone and allows for the use of more affordable standard orthopedic implants such as plates, screws, and primary hip and knee prostheses, which are subsidized by the Philippine Charity Sweepstakes Office's Medical Access Program.[20]

Intralesional excision consists of mechanical curettage typically followed by a high-speed burr. Adequate exposure allows the surgeon to access all intraosseous crevices for complete tumor removal. Tumor seeding is minimized by avoiding contamination of surrounding soft tissues. With curettage alone, the reported local recurrence rate for extremity GCTB ranges from 25% to 54%.[7,12-14] Different adjuvants are used to extend margins and may decrease local recurrence rates, despite conflicting reports.[7,12-15,17] Chemical adjuvants such as phenol, ethanol (EtOH), and hydrogen peroxide (H_2O_2) denature proteins in GCTB stromal cells, causing tumor necrosis. Phenol has largely fallen out of favor internationally due to its systemic toxicity, difficult disposal, and carcinogenic potential. While more readily available, H_2O_2 and EtOH are seldom used alone as adjuvants due to the paucity of evidence-based publications.[5-7,10-17] One such paper has reported a local recurrence rate as high as 41% for H_2O_2 when administered as the definitive adjuvant following intralesional curettage.[18] The thermoelectric adjuvant argon beam exposure has replaced phenol due to its relative ease of application as a thermoelectric adjuvant to coagulate proteins in tumor cells. However, the equipment is expensive and not readily available in the Philippines.

Liquid nitrogen, a cryogenic adjuvant, uses ultra-low temperatures to induce intracellular crystallization in stromal cells via a process of fast-freezing and slow-thawing, causing cell membrane disruption and subsequent apoptosis. The fast-freeze phase induces the formation of ice crystals which expand intracellular volume and disrupt the cell membrane. As the cells slowly thaw, intracellular ice crystals coalesce and induce cell lysis and apoptosis.[1,5] It has a 2.3% recurrence rate among GCTB patients treated with intralesional excision. Because liquid nitrogen boils at room temperature, it releases significant amounts of vapor, which affects the visibility

of the surgical site particularly for smaller lesions. Worse, it can cause adjacent skin and soft tissue necrosis secondary to cold exposure.

FNEC has been found to have comparable local recurrence rates to phenol, argon beam, and liquid nitrogen while mitigating the risks.[5-7,10-18] Orthopedic oncologists in Taipei Veterans General Hospital developed this semi-solid composite of liquid nitrogen and 95% ethanol, with the same cryogenic action as liquid nitrogen. FNEC exists at a temperature range of -114°C to -122°C, which induces bone tumor necrosis while having fewer complications.[1,2,5,6]

The cryoablative effects on human GCTB tissue were confirmed *in vivo*, then clinically by Wu et al., in a 2017 study. Chicken chorioallantoic membrane models were used to grow primary GCT stromal cells from consenting patients, a method that has been validated for pharmacologic GCTB studies.[5,21] Following a 7-day incubation period, 15 specimens were divided into 3 groups. The first group was set aside as control, the second group was exposed to liquid nitrogen, and the third group to FNEC. Histologic analysis showed that both liquid nitrogen and FNEC significantly inhibited tumor progression and angiogenesis versus the control group, to a comparable degree. With this proof of concept, seven patients (mean age 39 years, range: 23 to 53) with non-recurrent GCTB of the distal or proximal tibia and distal femur (one patient classified as Campanacci Stage 1, four patients as Stage 2, and two as Stage 3) were treated with intralesional curettage followed by adjuvant FNEC. Within the follow-up period (mean: 24 months, range: 19 to 30 months), there were no recorded intraoperative nerve injuries, skin necrosis, fractures, infections, or local recurrences.[5]

Patient selection remains key to minimizing local recurrence following extended curettage with liquid nitrogen or FNEC. Treatment is more often successful with a minimal or absent soft tissue component, an expected subchondral bone margin of 1 cm or greater for articular areas, and/or at least 75% intact surrounding cortex beyond the cavity post-curettage. While pre-operative magnetic resonance imaging (MRI) better delineates soft tissue involvement and related bone edema, findings are non-specific and may mimic other tumors. The decision to perform a computed tomography (CT) scan instead of an MRI for this patient was influenced by the above recommendations, logistics, and socio-economic limitations. Pre-operative antibiotics, adequate exposure, and protecting the soft tissue envelope with warm saline irrigation all contribute to reducing complications post-surgery.[1,2,5,6]

CONCLUSION

Application of FNEC as an adjuvant cryogen for extended curettage of GCTB was successfully done for the first time in the Philippines, following the specifications of Wu et al. The patient has resumed all pre-morbid activities with an MSTS score of 30/30; he had no post-operative complications and no evidence of local recurrence at 4 years post-surgery. A larger sample size is recommended to determine long-term outcomes, technique modifications, and multi-center and multi-national comparisons that may improve and promote its use in the Philippine setting.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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