The Fc Orth (SA) final examination

Adherence to Standard Operating Procedure for patients with Acute Cervical Spine Dislocated Injuries: A case of a teaching central referral hospital in South Africa.

By

Goud Ayik

Registrar, Department of Orthopaedic Surgery, Faculty of Health Science, University of Cape Town

AYKGOU001

This study is in partial fulfilment of the requirements for the degree Master of Medicine in Orthopaedic Surgery, University of Cape Town.

Supervisor: DR. N. Kruger

BSc MBChB FRCS(Ed) FCS Orth (SA), Consultant Orthopaedic Spinal Surgeon Head of Acute Spinal Cord Injury, UCT Student Orthopaedic Training

Co-ordinator, Groote Schuur Hospital.

August 2020

DECLARATION

I, Goud Ayik, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature:

Signed by candidate

Date: 24/08/2020

ACKNOWLEDGEMENTS AND CONTRIBUTIONS

Acknowledgements

To all the lectures of the Department of Orthopaedics at UCT for their enthusiastic approach to practice and teaching orthopaedics.

To Nick Kruger for his guidance and supervision with this project.

To my family for their support.

Format

The format is in accidence with South African Orthopaedic Journal guidelines (Page 20-33).

Contributions

The authors confirm that all authors have made a substantial contribution to this manuscript.

Goud Ayik: Primary author, Study Design, Data collection, Data analysis

Nick Kruger: Conceptualisation, study design, manuscript revision and supervision

T. Mukubeta: Data collection and analysis

C. Osborn: Data collection and analysis

G. Nyandoro: Information technology and Data analysis

GLOSSARY OF ABBREVIATIONS

MVA	Motor Vehicle Accidents
GSH	Groote Schuur Hospital
SOP	Standard Operating Procedure
ASIA	American Spinal Injury Association
ASCI	Acute Spinal Cord Injury
ER	Emergency Room
HREC	Human Research Ethics Committee
UCT	University of Cape Town
CRC	Clinical Research Centre
UFD	Unifacet Dislocation
BFD	Bifacet Dislocation

KEYWORDS

trauma, emergency care, spinal injury, cervical spine, cervical dislocation, closed reduction, neurological deficit, disability, neurological function, retrospective review

Table of Contents

Acknowledgements and Contributions i

Glossary of Abbreviations ii

1. Part A: Adherence to Standard Operating Procedure for patients with Acute Cervical Spine Dislocation Injuries: review of a tertiary, referral academic hospital in South Africa. 1

1.1 Abstract 1

1.1.1 Aims: 1

1.1.2 Patients and methods: 1-2

1.1.3 Results: 2

1.1.4 Conclusion: 2

1.2 Level of Study: 2

1.3 Introduction 3-4

1.4 Material and Methods 4-5

1.4.1 Inclusion Criteria 5

1.4.2 Exclusion Criteria 5

1.4.3 Qualitative Assessment 5-6

1.5 Statistical Analysis 6

1.6 Ethics 6

1.7 Results 6-7

1.8 Qualitative Findings 7-8

1.9 Discussion 8-9

1.9.1 Limitations 9

1.9.2 Conclusions 10

1.10 References 10-11

2. Part B: Appendices 21

2.1 Appendix A: Letter of Ethics 22-25

2.2 Appendix B: SAOJ Guidelines for Publication 26-39

2.3 Appendix C: Preliminary Reviewers Comments 40-47

2.4 Appendix D: Final Reviewers Comments 48-51

2.5 Appendix E: SAOJ Letter of Publication Acceptance 52

Adherence to a Standard Operating Procedure for Patients with acute Cervical Spine Dislocations: review of a tertiary, referral academic, hospital in South Africa

Ayik GDD[1], Mukabeta TDM[2], Nyandoro G[3], Osborne C[4], Kruger NA[5]

[1] MBBS (Sudan); Registrar, Division of Orthopaedic Surgery, University of Cape Town, Cape Town, South Africa

[2] MBChB, FC Orth (SA), Orthopaedic Specialist, Division of Orthopaedic Surgery, University of Cape Town, Cape Town, South Africa

[3] MSc Biostatistics, BSc Statistics and Biochemistry; Statistician, Department of Community Medicine, College of Health Sciences, University of Zimbabwe

[4] MBChB, MPH; Medical Doctor, NHS Lothian Edinburgh Royal Infirmary, University of Aberdeen, Edinburgh

[5] BSc, MBChB, FRCS(Ed), FC Orth (SA), Head of Acute Spine Injury Unit &Spine Consultant, Division of Orthopaedic Surgery, University of Cape Town, Cape Town, South Africa

Corresponding author: Dr Goud Ayik, Department of Orthopaedic Surgery, Groote Schuur, Observatory, Cape Town 8000; Tel: 0214045108; cell: 0617577649;

email: gooddeng_75@yahoo.com

1.1 Abstract

1.1.1 Aims: To analyse the impact that the adoption of our institutional standard operating procedure (SOP) for cervical spine dislocations had on the timing of closed reduction at our hospital.

1.1.2 Patients and methods: The study was a retrospective review of patients who presented to our institution with cervical dislocation injuries and were managed with closed reduction. The patient records of acute cervical spine dislocations from 2015 to 2018, Data from the Acute Spinal Cord Injury database along with patient's demographic information were gathered and compared. Participants within the study time frame were diagnosed with a cervical facet

dislocation based on clinical examination findings and radiological confirmation. Patients who had reduction performed at other referring hospitals were excluded from the study.

1.1.3 Results: The practice within all tertiary hospitals in the Western Cape is to perform closed reduction of cervical fracture dislocations as soon as possible after injury. In this study the time between injury and closed reduction before introducing the SOP was13 h 13 min and after introducing the SOP, the time increased to an average of 14 h 28 min. The main cause of delay was the transfer time from the site of injury to emergency ward. Other reasons for the delay include missed diagnosis, orthopaedic registrar unavailability, and incomplete reduction bed.

1.1.4 Conclusion: This study found that the time taken for orthopaedic management of cervical dislocations increased by an hour after introduction of the SOP. Additionally, the overall time to reduction also increased This was due to delays in transfer to the emergency ward and referral to Orthopaedics. We recommend that in our setting, reduction could be initiated within an hour of patient arrival, if emergency ward doctors rapidly identified the problem and commenced cervical traction when the orthopaedic team was not immediately available. Our impression was that there was poor adherence to the new SOP guidelines on time management by the trauma team, and possibly transport delays prior to hospital admission. A further study to investigate the bottlenecks of the referral system is advisable.

1.2 Level of evidence: Level 3

Keywords: acute outcomes, cervical spine, dislocation injuries

Citation: Ayik GDD, Kruger NA, Mukabeta TDM, Nyandoro G, Osborne C. Adherence to a standard operating procedure for patients with acute cervical spine dislocations: a case of a teaching central referral hospital in South Africa. *SA Orthop J* 2020;**19**(3):XX-XX. http://dx.doi.org/10.17159/2309-8309/2020/v19n4a5

Editor: Dr Johan Davis, Stellenbosch University, Cape Town, South Africa

Received: February 2019 *Accepted*: June 2020 *Published*: November 2020

Funding: None

Conflict of interests: The authors declare they have no conflicts of interest that are directly or indirectly related to the research.

1.3 Introduction

Cervical dislocations are acute, high-risk injuries associated with a range of potentially catastrophic long-term disabilities. Regional hospital data has shown that up to 60% of spinal trauma, which accounts for 3–6% of all trauma admissions, involve injury to the cervical region[1]. The most common mechanism of injury results from motor vehicle accidents (MVAs), violent assault or falls, with the typical patient being a male under the age of 30 years[2,3].

These injuries have the potential to cause a profound change in lifestyle, with the resulting neurological deficit affecting the motor, sensory and autonomic nervous system[4]. Patients require lifelong supportive care, impacting patient's quality of life, independence and psychological wellbeing[5,6]. Additionally, given the aetiology of the injury, a large proportion of those affected are earning an income with dependants reliant on them. As such, cervical spine injuries tend to have a profound effect on not only the individual patient but also on their direct family members and society.

Unless there are any contraindications, the best management for patients with cervical dislocations is early reduction, with skeletal traction to realign the vertebrae[7]. The objective of early reduction is to align the vertebral column and alleviate external pressure on the spinal cord. Successful early reduction may potentially reduce subsequent neurological deficits[7]. A key variable in this treatment method was found to be the time between the offending injury and

the intervention being performed[8]. A retrospective review of rugby players with cervical dislocations found a 63% difference in reported neurological improvement if closed reduction was performed within four hours of the injury – a larger quantified effect on patient recovery than surgical intervention[9].

All Western Cape hospitals strive to perform closed reduction of cervical dislocations within four hours of the injury[10], partly to comply with a 2015 Constitutional Court ruling but also to adhere to best medical practise[11]. This is however particularly challenging as the mean transport time between sustaining a spinal injury and receiving medical care was previously found to be three hours, which leaves little room to comply with the four-hour ruling[10]. Therefore, a new management protocol was introduced in June 2016 – the 'early reduction protocol' – requiring all closed reductions to be performed within one hour of admission.

This study aims to assess adherence and the effect of the 'early reduction SOP or protocol' on the timing of the reduction of cervical dislocations and its influence on the neurological outcomes of patients managed at our institution during the time period of the study.

1.4 Materials and methods

This was a retrospective analysis of records for patients managed at our institution from 2015 to 2018. The study compared the management of patients with low and high velocity injuries treated before the introduction of the early reduction standard operating procedure (SOP) in June 2016 against those treated after. Low velocity injuries were classified as injuries sustained during sport activities or fall from low heights where the patients sustain purely ligamentous dislocation. High velocity injuries were classified as MVA and violent assaults where the patients sustain fracture dislocations. From the Acute Spinal Cord Injury database, records and notes of patients who presented to our institution from 2015 to 2018 with acute cervical dislocation and received subsequent closed reduction management were reviewed by the principal author (the researcher). The SOP requirement for cervical reduction was set to be within 1 hour after patients arriving at the primary emergency ward (ER). Variables such as ASIA score, time to reduction, duration of hospital stay, along with patient mortality and morbidity, were retrieved. Data collected included age, sex, date, mechanism of injury, neurological examination findings and

radiological diagnoses. A qualitative interview was conducted with the emergency room personnel at GSH to complement our quantitative analysis findings

1.4.1 Inclusion Criteria

Patients who presented to our institution in a conscious state with cervical injuries within the given time frame of the study and were diagnosed with a cervical facet dislocation based on clinical examination findings with radiological confirmation (X-rays or CT scan).

1.4.2 Exclusion Criteria

All patients who were managed outside our institution with closed reduction were excluded from the study as well as patients with other injuries such as open head injuries, obtunded state or decreased level of consciousness.

1.4.3 Qualitative assessment

The qualitative assessment was conducted by the principal author between August and September 2018 on emergency personnel (ER nurses, ER doctors and orthopaedic registrars) at Groote Schuur Hospital. The participants were individually interviewed in person and asked to complete the ''yes/no'' answers in *Table I* based on their area of speciality.

Table I: The qualitative assessment questionnaire tailored to area of speciality

Questions	**ER nurses**	**ER doctors**	**Orthopaedic registrars**
1. Are you aware of the SOP for rapid reduction?	Yes/No	Yes/No	Yes/No
2. What is the four-hour rule under the Constitutional Court?	Yes/No	Yes/No	Yes/No
3. Do you know where the reduction bed and equipment are kept?	Yes/No	Yes/No	Yes/No
4. What patients require urgent neck X-rays?	Yes/No	Yes/No	---------
5. Which doctors can apply cervical traction in an emergency?	Yes/No	Yes/No	---------

6. Do you know who to refer to for neck dislocations?	---------	Yes/No	---------
7. With a cervical dislocation, do you request an MRI scan?	---------	Yes/No	---------
8. Is there always available radiography for rapid reductions?	---------	---------	Yes/No
9. List causes that delay initiating reductions.	---------	---------	Yes/No
10. If you are scrubbed in theatre and are referred a cervical dislocation, what action do you take?	---------	---------	Yes/No

1.5 Statistical analysis

Data was summarised using descriptive statistics. Continuous variables were summarised using means and standard deviations, whereas categorical or nominal variables were summarised using percentages. Matched t-tests were used to test for significance between continuous variables, while chi-squared tests were used for categorical or nominal variables. Graphical analysis was used to display the distribution of variable(s) and to illustrate findings visually.

1.6 Ethics

This study was approved by the University of Cape Town Human Ethics Committee (2018/137). Verbal consent was obtained from Doctors and Nurses that participated in the study. There was no direct involvement of patients, thus no need for verbal or oral consent. The study was comprised of patient notes and records, with each patient identified by their hospital number only. All study data storage was password protected.

1.7 Results

The study comprised 19 participants, of whom 79% were male and 21% female. The median (IQR) age of participants was 48 years (26.0–55.0); range from 20 to 80 years (*Figure 1*). There was a

pre-hospital delay between injury and arrival at the primary emergency ward (ER) of 7 hours. The mean time between injury and closed reduction before introducing the new SOP was 13 h13 min (*Table II*). After introducing the new SOP, the time to closed reduction increased significantly (P<0.0001) to a mean of 14 h28 min (*Table II*).

Other associated injuries werepelvic fractures in 26%, bilateral lamina fractures in 21% and vertebral body fracture in 11% (*Figure 2A and 2B*).

The main time delays (*Figure 3*) were between injury and arrival at the ER (7 h 43 min after the new SOP). There was minimal change between pre- and post-introduction of the new SOP, with only a 6% decrease in time taken between injury and arrival at ER.

A matched t-test was used to compare pre- and post-mean changes on the ASIA scale, pre-reduction and post-reduction (*Table III*) and no significant changes were found (pre- versus post p=0.331). Similarly, there were no significant changes between admission versus discharge for: ASIA motor score, p=0.078; ASIA light touch, p=0.454; ASIA pinprick, p=0.662.

Table IV presents the time delays in the referral system at GSH. The median time delay from injury to ER was increased by 55% (07 h 13 min) whereas the median time from ER to the orthopaedic registrar on call was increased by 12% (01 h 36 min). Times from start to completion of reduction by the orthopaedic registrar were increased by a median of 8% (01 h 00 min) and 6% (00 h 45 min), respectively.

In this study, there were equal rates of reduction success before the new SOP and after the new SOP (p=50%) (*Figure 4*).

The common injuries were sustained from MVAs (37%) and falling (37%). The most common pattern of injury was C5/C6 bifacet dislocation (32%). Common neurological deficits were C4 motor complete, sensory complete (MCSC) (26%) and C5 MCSC (21%). Most patients had a pre-reduction ASIA-A, 63% and the most common post-reduction score was ASIA A, 63% (*Table V*).

1.8 Qualitative findings

Additional in-depth qualitative interviews were used to complement evidence gathered quantitatively. *Table VI* summarises themes that emerged from in-depth interviews with five ER nurses, five ER doctors and five orthopaedic registrars. The red colour coding highlights answers

indicating poor understanding of the management of cervical dislocations while answers in green demonstrated a better knowledge of cervical dislocation management. There was no awareness of the SOP for rapid reduction among ER nurses 0% (n=5) and ER doctors 0% (n=5); the exception was the orthopaedic registrars who had 100% (n=5) level of awareness. In addition, orthopaedic registrars had 100% (n=5) level of awareness on the 'four-hour ruling under the Constitutional Court', while ER nurses had 0% (n=5) and ER doctors had 20% (n=1). Only two out five (40%) ER nurses knew 'where the reduction bed and equipment were kept'; this shows a knowledge gap since ER nurses attend most cases during admissions. Surprisingly, only one out of five (20%) orthopaedic registrars 'knew where the reduction bed and equipment are kept'.

1.9 Discussion

Cervical dislocations are serious injuries associated with a range of potentially catastrophic long-term disabilities. Previous regional hospital data has shown that up to 60% of spinal trauma, which accounts for 3–6% of all trauma admissions, is caused by injury to the cervical region[1]. The most common mechanism of injury is the result of an MVA, violent assault or fall – with the typical patient being a male under the age of 30 years[2,3]. In this study MVA and falls were the most common causes of injury: MVA 37% and falls 37%.

Previously, it had been recommended that the time between injury and closed reduction should be within four hours in order to have favourable neurological outcomes[9,12]. In this study, the mean time between injury and closed reduction before introducing the new SOP was 13 h 13 min , with median time of 9 h 19 min. After introducing the new SOP, the mean time significantly increased to 14 h 28 min and median time of 13 h 15 min. Based on the study findings, the intended potential benefits of the SOP were not achieved. There was no significant improvement in reduction times from initial injury. The main delay was from injury to arrival at the ER. In-depth study reflected the challenges of low awareness of the SOP for rapid reduction; lack of knowledge of where the reduction bed and equipment are kept; and inconsistency on preparations before surgery. Reduction beds and equipment may not be maintained and not always prepared, all of which point to low availability of adequate resources. These gaps explain why there was no significant improvement on several continuous outcomes and increased time delays along the

referral chain before actual reduction. It took 1 h 21 min to 1 h 51 min from assessment to initiating reduction, with a variety of factors causing delays including doctors needing to look for equipment. The SOP failed to improve on this time to initiate reduction. Although recent data showed that the average transport time between sustaining a spinal injury and receiving medical care was three hours, in this study the average time was 13 h 56 min after a new management protocol was introduced as of June 2016 whereby all closed reductions a should be performed within one hour of admission. This indicates a discrepancy in terms of policy availability and/or SOP adherence and implementation of guidelines regarding this issue.

The SOP was an effort to improve reduction times; however, our review found that the overall time from injury to reduction had not appreciably improved. Furthermore, the time taken for ER doctors to assess the patient and refer to Orthopaedics had increased from 1 h 56 min to 2 h 56 min. The possible reasons for this were difficulties in locating required equipment, lack of equipment, policy unavailability and very low SOP adherence. We recommend that, in our setting, reduction could be done within an hour of patient arrival if other ER doctors activate the early reduction protocol, even in the absence of an orthopaedic registrar. Furthermore, we recommend pre-hospital diagnosis by paramedics be done at the scene of the accident and in-hospital activation of the SOP by the ER staff which would then result in time saving.

In the qualitative assessment of staff, results showed only Orthopaedic Doctors were aware of the new SOP for cervical dislocation injuries and had knowledge of the 4 h constitutional rule for performing early reduction of cervical dislocation injuries. Based on these findings, we recommend that all ER staff must be educated and made aware of the SOP and the 4 h rule. The SOP should be available on large posters in ER.

1.9.1 Limitations

Firstly, the new SOP did not include the transport time (it addresses the time from arrival in ER to reduction). Secondly, most of the study patients had high energy mechanisms of injury thus other associated injuries resulted in their exclusion from having acute reduction performed. Thirdly, due to the retrospective aspect of the study selection bias and mis-classification or information bias might have been introduced.

1.9.2 Conclusions

In this study, motor vehicle accidents and falls were the most common causes of injury. The time taken from the site of injury to an assessment and complete reduction was significantly increased after introduction of the new SOP. There were no significant changes in ASIA scales post-introduction of the new SOP. The main message is that there is very poor adherence to the new SOP guidelines on time management along the emergency health referral system by healthcare workers (nurses and general doctors). Future study is needed to examine the role of patient assessment at a primary care level prior to transfer to a tertiary hospital for patients with suspected spinal injury.

1.10 References

1. Ghafoor A, Martin T, Gopalakrishnan S, Viswamitra S. Caring for the patients with cervical spine injuries: what have we learned? *J Clin Anesth*. 2005;**17**:640-49.

2. Joseph C, Delcarme A, Vlok I, Wahman K, Phillips J, Nilsson Wikmar L. Incidence and aetiology of traumatic spinal cord injury in Cape Town, South Africa: a prospective, population-based study. *Spinal Cord.* 2015;**53**:692-96.

3. Sothmann J, Stander J, Kruger N, Dunn R. Epidemiology of acute spinal cord injuries in the Groote Schuur Hospital Acute Spinal Cord Injury (GSH ASCI) Unit, Cape Town, South Africa, over the past 11 years. *S Afr Med J.* 2015;**105**:835.

4. Savic G, DeVivo M, Frankel H, Jamous M, Soni B, Charlifue S. Long-term survival after traumatic spinal cord injury: a 70-year British study. *Spinal Cord*. 2017;**55**:651-58.

5. Malhotra M, Bhatoe B, Sudambrekar S. Spinal cord injuries. *Med J. Armed Forces India.* 2010;**66**:325-8

6. Oderud T. Surviving spinal cord injury in low income countries. *Afr J Disabil.* 2014;**3**: 1-9.

7. Gelb D, Hadley M, Aarabi B, Dhall S, Hurlbert R, Rozzelle C *et al*. Initial closed reduction of cervical spinal fracture-dislocation injuries. *J Neurosurg*. 2013;**72**:73-83.

8. Storey R, Singhal R, Inglis T, Kieser D, Schouten R. Urgent closed reduction of the dislocated cervical spine in New Zealand. *ANZ J Surg*. 2017;**88**:56-61.

9. Newton D, England M, Doll H, Gardner B. The case for early treatment of dislocations of the cervical spine with cord involvement sustained playing rugby. *Bone Joint J*. 2011; **93**-B:1646-52.
10. M Potgieter, D H Badenhorst, M Mohideen, J H Davis *et al*. Closed traction reduction of cervical spine facet dislocations: Compelled by law. *S Afr Med J* .2019;**109**:854-858
11. Oppelt v Head: Health, Department of Health Provincial Administration: Western Cape (CCT185/14) [2015] ZACC 33; 2016 (1) SA 325 (CC); 2015 (12) BCLR 1471 (CC) (14 October 2015)
12.Storey RN, Singhal R, Ingli T. Urgent closed reduction of the dislocated cervical spine in New Zealand. *ANZ J Surg*. 2018;**88**:56-61.

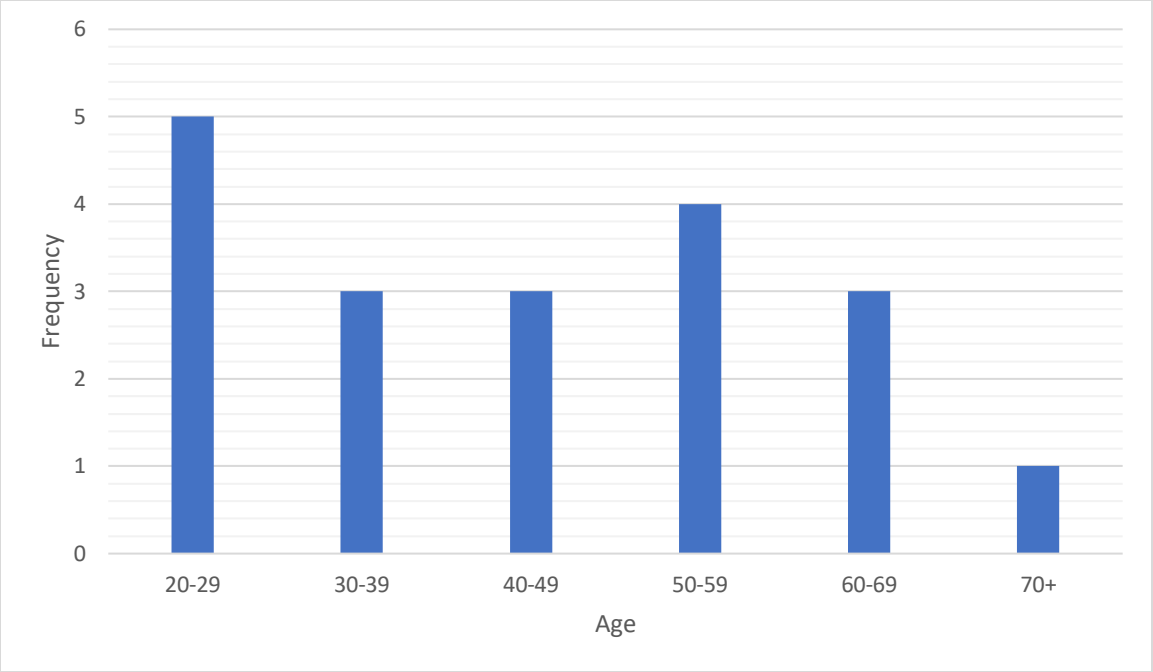

Figure 1: Distribution of patients age in the study

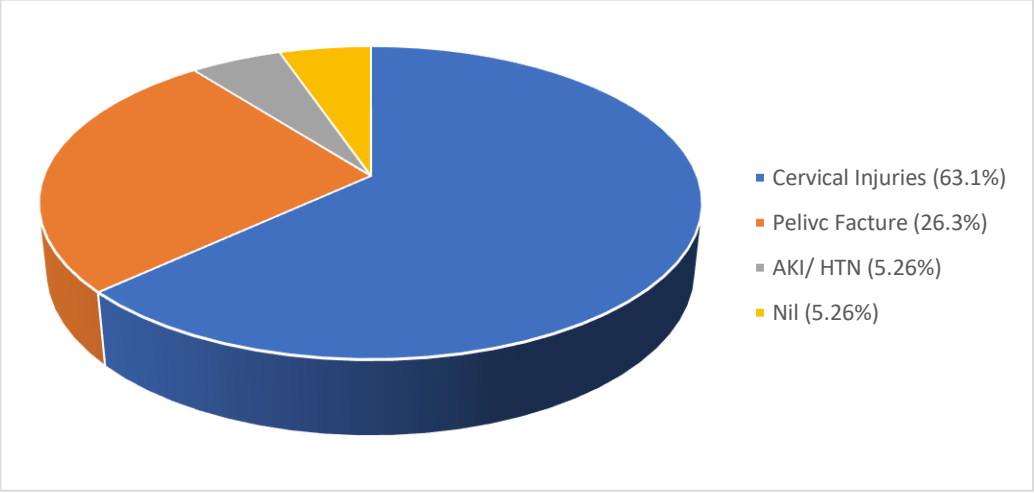

Figure 2A: Injuries and medical conditions sustained by patients in the study

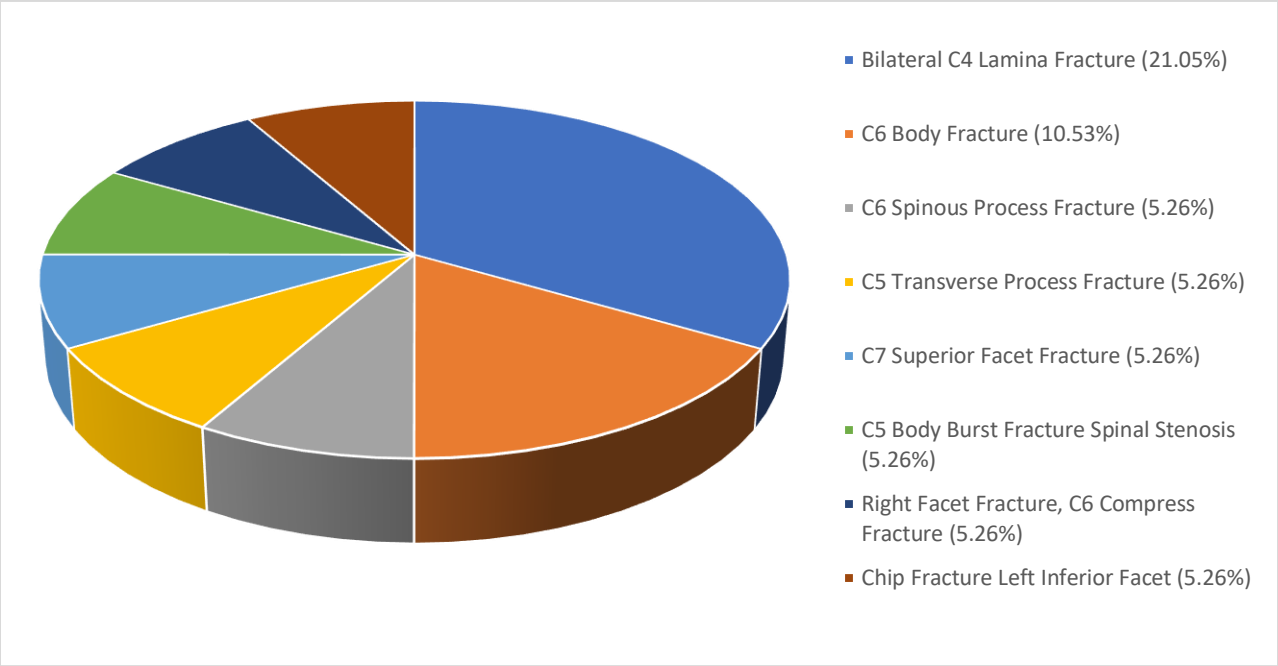

Figure 2B: Injuries and medical conditions sustained by patients in the study

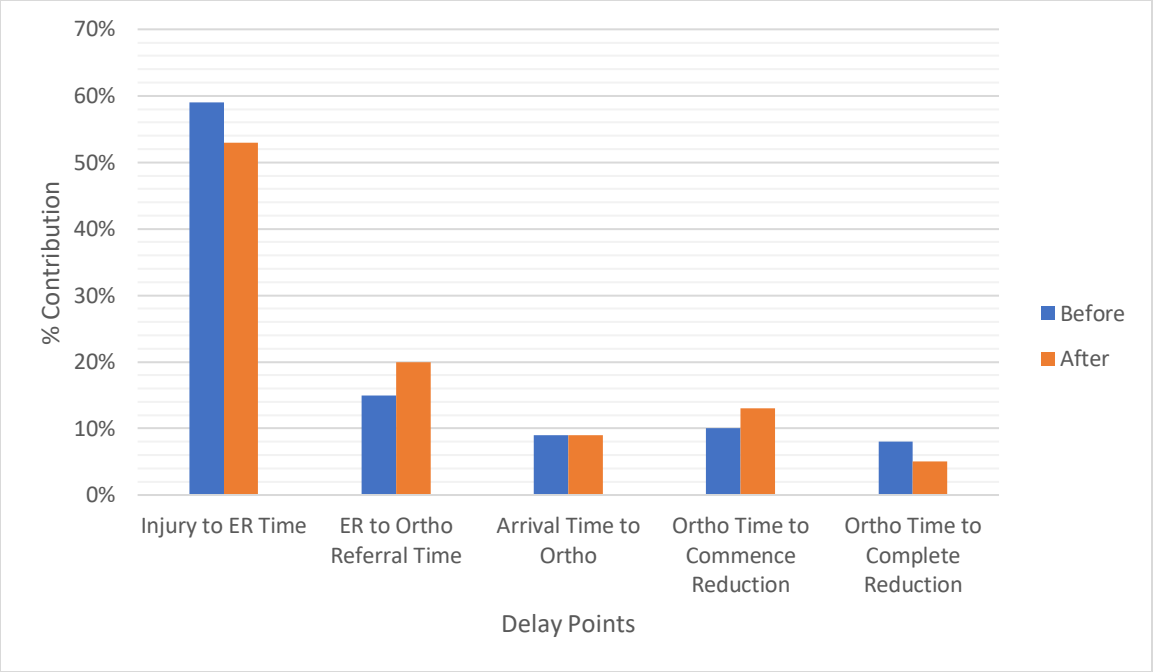

Figure3: Change in time delays in the emergency referral system; before and after new SOPs

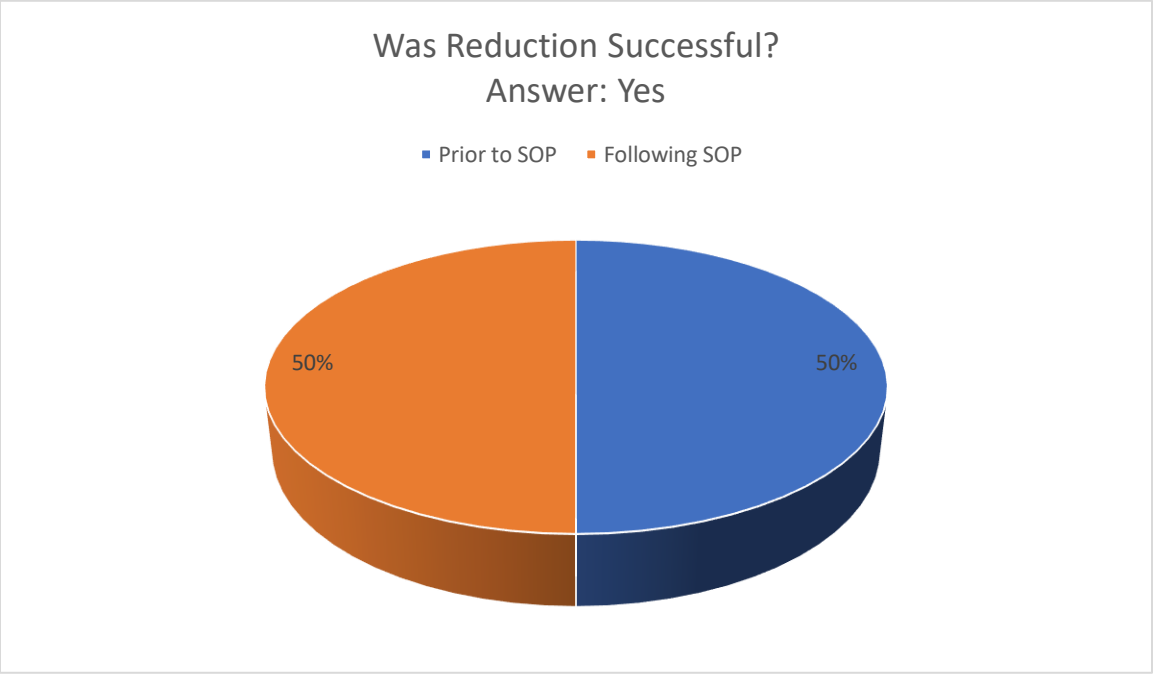

Figure 4: Percentage of successful reduction pre and post introduction of the SOP

Table II: Time delays summary

Period (time in hours:minutes)			Injury to ER	ER to ortho referral time	Ortho referral to assessment	Ortho time to start reduction	Ortho time to complete reduction	Injury to reduction total time	P Value
Before new SOP	Mean (n=8)		7:45±8:33	1:56±1:14	1:08±0:41	1:21±0:44	1:01±0:17	13:13±9:07	<0.0001
	Median (n=8)		03:17	01:40	00:57	01:07	00:54	09:19	
	Minimum		01:14	00:34	00:05	00:25	00:45	04:00	
	Maximum		24:00	04:00	02:00	02:44	01:30	05:30	
	Percentiles	25	01:30	00:51	00:40	01:00	00:46	06:50	
		75	15:13	02:57	01:55	01:57	01:15	21:56	
After new SOP	Mean (n=11)		07:43±04:39	02:50±03:24	01:14±01:10	01:51±02:48	00:47±00:34	14:28±08:53	
	Median (n=11)		08:30	01:36	01:00	00:30	00:36	13:15	
	Minimum		02:00	00:19	00:15	00:15	00:19	03:30	
	Maximum		13:56	10:15	04:19	09:00	02:20	07:15	
	Percentiles	25	02:19	00:20	00:30	00:15	00:30	04:35	
		75	12:06	04:25	01:04	03:05	00:45	22:25	

Table III: Comparison of admission versus discharge for post-reduction clinical measurements

Paired t-test (two-tailed)						
		Mean	**n**	**Std deviation**	**Std error mean**	**p-value**
Pair 1	Pre-reduction ASIA scale	2.11	19	1.629	0.374	0.331
	Post-reduction ASIA scale	2.16	19	1.642	0.377	
Pair 2	Admission ASIA motor score	25.11	19	32.493	7.454	0.078
	Discharge ASIA Motor score	29.68	19	36.917	8.469	
Pair 3	Admission ASIA Light touch	39.53	19	40.622	9.319	0.454
	Discharge ASIA Light touch	41.95	19	44.244	10.150	
Pair 4	Admission ASIA Pinprick	40.47	19	40.171	9.216	0.662
	Discharge ASIA pinprick	41.84	19	44.276	10.158	

Table IV: Time delays in the referral system post SOP

		Injury to ER	ER to ortho referral time	Ortho referral to assessment	Ortho time to start reduction	Ortho time to complete reduction	Injury to reduction total time
Mean (hours:minutes)		07:44 (56%)	02:27 (18%)	01:11 (8%)	01:39 (12%)	00:53 (6%)	13:56 (100%)
Median (hours:minutes)		07:13 (55%)	01:36 (12%)	01:00 (8%)	01:00 (8%)	00:45 (6%)	13:05 (100%)
Std deviation		06:21	02:41	00:58	02:09	00:28	08:45
Minimum		01:14	00:19	00:05	00:15	00:19	03:30
Maximum		00:00	10:15	04:19	09:00	02:20	07:15
Percentiles	25	02:00	00:34	00:40	00:25	00:34	06:45
	75	12:06	03:00	01:43	02:10	01:15	22:25

Table V: Common description of patient notes

Variable	Categories	Frequencies	%
Cause of injury	Assault	1	5
	Diving accident	1	5
	Falling	7	37
	MVA	7	37
	PVA	1	5
	Surfing accident	1	5
	Train accident	1	5
Cervical level	C4/5BFD	1	5
	C4/5UFD	1	5
	C4/C5BFD	3	16
	C4/C5UFD	1	5
	C5/C6BFD	6	32
	C5/C6UFD	2	11
	C6/7UFD	1	5
	C6/C7BFD	2	11

	C6/C7UFD	2	11
Neurological deficit	C3-4MISI	1	5
	C3-5MCSC	1	5
	C4-C5MCSC	2	11
	C4MCSC	5	26
	C4MISI	1	5
	C5MCSC	4	21
	C5MCSI	1	5
	C5MISI	2	11
	Nil	2	11
Other injury or medical conditions	AKI, hypertension	1	5
	Bilateral C4 lamina fracture	4	21
	C5 body burst fracture spinal stenosis	1	5
	C5 transverse process#	1	5
	C6 body fracture	2	11
	C6 spinous process fracture	1	5
	Nil	1	5
	Rt facet #,C6 compare #	1	5
	Scapula and pelvic fracture C7 superior facet fracture C7 transverse process	1	5
	Chip fracture left inferior facet	1	5
	Pelvic fracture	5	26
Pre-reduction ASIA scale	A	12	63
	B	1	5
	C	1	5
	D	2	11
	E	3	16
Post-reduction ASIA scale	A	12	63
	C	2	11
	D	2	11
	E	3	16

AKI, acute kidney injury; ASIA scale, American Spinal Injury Association scale; BFD, bifacet dislocation; MCSC, motor complete sensory complete; MISI, motor incomplete sensory incomplete; MVA, motor vehicle accident; PVA, pedestrian vehicle accident; UFD, unifacet dislocation

Table VI: In-depth interviews with ER nurses, ER doctors and orthopaedic registrars

ER Nurses	1. Are you aware of the SOP for rapid reduction?	2. What is the four-hour rule under the Constitutional Court?	3. Do you know where the reduction bed and equipment are kept?	4. What patients require urgent neck X-rays?	5. Which doctors can apply cervical traction in an emergency?	
1	No, I'm not aware	Observation of a patient	Yes	Patient with long bone fracture, poly trauma patient	Neurosurgeon	
2	No, I'm not aware	I don't know	No	Spine injury, MVA, neck pain, fall from height	I don't know	
3	No, I'm not aware	I don't know	Yes	Neck pain, fall from height, MVA	Orthopaedic Doctor	
4	No, I'm not aware	I don't know	No	MVA, fall from height, gunshot, knife stab	Orthopaedic Doctor, Neurosurgeon	
5	No, I'm not aware	I don't know	Yes	Neck pain	Orthopaedic Doctor, ASCI	
ER Doctors	1. Are you aware of the SOP for rapid reduction?	2. What is the four-hour rule under the Constitutional Court?	3. Do you know where the reduction bed and equipment are kept?	4. What patients require urgent neck X-rays?	5. Which doctors can apply cervical traction in an emergency?	6. Do you know who to refer to for neck dislocations?
1	No	Not sure	Yes	MVA, fall from height, neck pain	Orthopaedic, Neurosurgeon, ASCI	Orthopaedic, ASCI
2	No	Not sure	Yes	Fall from height, MVA, gunshot, knife stab	Orthopaedic	Orthopaedic, Neurosurgeon, ASCI
3	No	Not sure	Yes	Fall from height, MVA, gunshot, knife stab	Orthopaedic, ASCI, Neurosurgeon	Orthopaedic, Neurosurgeon
4	No	Not sure	Yes	Neck pain, significant tenderness, neurological fallout	Orthopaedic	Orthopaedic on call
5	No	Neck dislocation should be reduced within 4 hours	Yes	Low GCS, suspected C-Spine Injury, focal neurological deficit in polytrauma	Orthopaedic	Orthopaedic on call
Orthopaedic Registrars	1. Are you aware of the SOP for rapid reduction?	2. What is the four-hour rule under the Constitutional Court?	3. Are the reduction bed and equipment maintained and always prepared?	4. Is there always available radiographer for rapid reduction?	5.List causes that delay initiating reduction?	6. If you are scrubbed in theatre and are referred a cervical reduction, what do you do?
1	Yes	C-Spine dislocation must be reduced in 4 hours	Not always	Yes	Late referral, late presentation	Will ask someone on call to do it
2	Yes	C-Spine dislocation must be reduced in 4 hours	Not always	Yes	Late referral, late presentation	Will ask the Senior Trauma Doctor to do it
3	Yes	C-Spine dislocation must be reduced in 4 hours	Yes	Yes	Late referral, late presentation	Will ask someone on call

4	Yes	C-Spine dislocation must be reduced in 4 hours	Not always	Yes	Late referral, late presentation	Will ask to call consultant
5	Yes	C-Spine dislocation must be reduced in 4 hours	Not always	Yes	Late referral, late presentation	Ask someone in trauma to reduce it

APPENDIX A

UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH ETHICS COMMITTEE
24 JUN 2020
HEALTH SCIENCES FACULTY

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00021637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report. Approved until next renewal date		30/3/2021
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	24/6/20

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	18/06/2020		
HREC REF Number	162/2019	Current Ethics Approval was granted until	30/03/2020
Protocol title	A Review of The Updated Standard Operating Procedure for Cervical Spine Dislocations at Groote Schuur Hospital (Sub-Study Linked to R039/2013) MMed Candidate Dr. G. Ayik		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes	(X) No	
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study			
Principal Investigator	Dr. Nick A Kruger		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

APPENDIX A

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Department / Office Internal Mail Address	Nicholas.Kruger@uct.ac.za

1.1 Does this protocol receive US Federal funding?	☐ Yes	(X) No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for Full Committee review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)	☐ Yes	(X) No
If yes in 1.2 please complete section 1.3 below for invoicing purposes		
1.3 Annual Approval for full committee review	- R 3480 (inclusive of vat)	

For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

2. List of documentation for approval

3. Protocol status (tick ✓)

☐	Open to enrolment
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Number of participants enrolled to date	19
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	0

6. Cumulative summary of participants

Total number of participants who provided consent	0
Number of participants determined to be ineligible (i.e. after screening)	0
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	0
Number of participants withdrawn at participants' request, i.e. changed their mind	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	

7. Progress of study

Please provide a brief summary of the research to-date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
The Study completed, and been accepted for publication at SAOJ, however not been submitted for MMed. We would like to renew our ethics approval for period of one year to allow for MMed submission.

8. Protocol violations and exceptions (tick ✓ all that apply)

(X)	No prior violations or exceptions have occurred since the original approval

APPENDIX A

☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

(X)	No prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be bolded, italicised or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	(X) Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	(X) Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	(X) Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	(X) Not applicable

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

APPENDIX A

	DSMB report attached	☐ Yes	☐ No	(X) Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	(X) No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
(X)	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

13. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	(X) No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

14. Signature

My signature certifies that the above is complete and correct.

(Note: Please complete the Closure form (FHS013) if the study is completed within the approval period)

Signature of PI		Date	18/06/2020

APPENDIX B

INSTRUCTIONS FOR AUTHORS

- Scope and Policy
- Formatting of Submissions
- Instructions for Reviewers
- Manuscripts Submission

Scope and Policy

The scope of publication encompasses all orthopaedic surgery sub–disciplines including paediatric orthopaedics, hip, knee, tumour and sepsis, spine, shoulder and elbow, foot and ankle and hand surgery. In addition the journal addresses the subjects of orthopaedic service delivery, teaching, training and research. Publications should influence orthopaedic care on our continent.

The *South African Orthopaedic Journal* aims to advance the knowledge of all aspects of musculoskeletal medicine through publication of:

- Original research articles.
    - Clinical research
    - Basic science and theoretical research
- Review articles.
- Invited expert opinions.
    - A review of significant local or international publications journal article or cluster of articles dealing with a similar topic for the purpose of conveying a useful message.
- Editorials.
- Letters to the editor.
    - Forum to raise issues or debate aspects of previously published papers.

Criteria for publication

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented in an appropriate fashion and are supported by the data.
- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

APPENDIX B

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
- Other 'contributors' can be acknowledged at the end of the manuscript together with their contribution.
- Authors of manuscripts representing a multi–centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.
- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.

Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health–related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process–of–care changes.
- Clinical trials should be registered in a public trials registry in accordance with International Committee of Medical Journal Editors recommendations.
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design that was used (listed below):

Randomised trials	CONSORT
Observational studies	STROBE
Systematic reviews	PRISMA
Case reports	CARE
Qualitative research	SRQR
Diagnostic / prognostic studies	STARD
Quality improvement studies	SQUIRE
Economic evaluations	CHEERS
Animal pre–clinical studies	ARRIVE

APPENDIX B

Study protocols	SPIRIT

-
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Role of funding source

- Authors are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement, then this should be stated.

Formatting of Submissions

Text formatting

- Use Helvetica or Arial font, size 11.
- Use double line spacing throughout the document.
- Number the pages of the blinded manuscript consecutively.
- Use italics for emphasis.
- When referring to an article with multiple authors please use the following format: Rabinowitz *et al*. published their retrospective review.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

- Use no more than three levels of displayed headings.

Abbreviations

- Define abbreviations and acronyms at first mention and use consistently thereafter.

Units

APPENDIX B

- Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: … wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures should be understandable without the main text.
- For radiographs please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Figures should not be imbedded in the text file, but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in the text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, … high–energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table heading explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower–case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.
- Do not embed tables in the text file, but submit them as separate individual files. Each table should be a separate file, entitled Table I, Table II, etc.
- We accept a maximum of eight tables.
- Do not duplicate information given already in the text.

APPENDIX B

- Do not submit any figures, photos, tables or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.
- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
- Authors should add DOIs to all references in articles.
- Accuracy of references is the author's responsibility and the author is to verify the references against the original documents.
- Manuscripts in preparation, unpublished data (including articles submitted but not in the press) and personal communications may not be included in the reference listing. They may be listed in the text in parentheses only if absolutely necessary to the contents and meaning of the article.
- The titles of journals should be abbreviated according to the style used in Index Medicus, obtainable through the website http://www.nlm.nih.govshould
- The following format should be used for references:

Journal article:
Sidhu GS, Ghag A, Prokuski V, Vaccaro AR, Radcliff KE. Civilian gunshot injuries of the spinal cord: a systematic review of the current literature. Clin Orthop Relat Res 2013;471:3945-55.

Ideally, the names of all authors should be provided, but the usage of 'et al.' in long author lists (more than six authors) will also be accepted: Fong K, Truong V, Foote CJ, et al. Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. BMC Musculoskelet Disord 2013;14:103.

On–line journal article:
Caetano–Lopes J, Lopes A, Rodrigues A, et al. Upregulation of inflammatory genes and downregulation of sclerostin gene expression are key elements in the early phase of fragility fracture healing. PLoS One 2011;6:e16947.

Web reference (with authors):
Cierny G, DiPasquale D. Adult osteomyelitis protocol. http://www.osteomyelitis.com/pdf/treatment_protocol.pdf. (date last accessed 05 March 2013).

APPENDIX B

Web reference (no authors listed):
No authors listed. International commission on radiological protection. http://www.icrp.org (date last accessed 20 September 2009).

Chapter in a book:
Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). Spinal Trauma. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

Dissertation:
Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

Abstract:
Peterson L. Osteochondritis of the knee treated with autologous chondrocyte transplantation [abstract]. ISAKOS Congress, 2001.

Structure and content of submission

- We accept a maximum of 3500 words including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta–analysis, at the discretion of the Editor–in–Chief.
- Please follow the following structure when preparing your submission.
    - Title page (Title, authors and affiliations, corresponding author and declarations)
    - Blinded manuscript (Abstract, key words, introduction, methods, results, discussion, funding sources, conflict of interest statement, ethical statement, acknowledgements and references)
    - Tables (with headings), each as a separate file.
    - Figures (with legends), each as a separate file.

<u>Title page</u>

Title

- The title should be concise and informative.

Author names and affiliations

- Please provide the following information for each author:
    - Full names and surname, as well as title
    - Qualifications
    - Affiliation and address
    - ORCID ID (see Article Submission section)
- Please check that all names are accurately spelled.
- Indicate all affiliations with a lower–case superscript letter immediately after the author's name and in front of the appropriate affiliation details.

APPENDIX B

- Provide the full postal address of each affiliation, including the country name and, if available, the e–mail address of each author.

Corresponding author

- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post–publication.
- Ensure that the e–mail address and permanent address is given and that contact details are kept up to date by the corresponding author.
- Please note that the corresponding author's contact details will be provided in the final article.
- Provide the following information for the corresponding author:
    - Full names and title
    - Affiliation
    - Physical address
    - Postal address
    - Telephone Number
    - E–mail address

Declarations
Authors are to insert a section at the end of the title page entitled declarations. Following the declarations all authors need the to sign the document (please provide name of author, signature and date). The following statements are required under the declarations section:

a. Authorship
The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data
- The drafting the article or its critical revision for important intellectual content
- Final approval of the version to be submitted.b.Sound scientific research practice
  The authors further confirm that:
- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami–publishing').

b. Plagiarism
The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work has been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks are used for verbatim copying of material.
- Permissions have been secured for material that is copyrighted.

c. Conflict of interest statement
A conflicting interest exists when professional judgement concerning a primary interest (such as the patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It represents a situation in which financial or other personal considerations from authors, reviewers or editors have the potential to compromise or bias professional judgment and objectivity. It may arise for the authors when they have a financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. All potential conflicts of interest need to be declared. The conflict of interest statement should list each author separately by name, i.e.,

> 'John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A. Mike Schultz has received a speaker honorarium from Drug Company B and owns stock in Drug Company C.'

If multiple authors declare no conflict, this can be done in one sentence.

d. Funding sources
All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated.

e. Compliance with ethical guidelines
   - For all publications:

APPENDIX B

'The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.'

Available from:
http://publicationethics.org/resources/international-standards-for-editors-and-authors

Institutional Review Board (IRB) ethical approval must have been given if the study involves human subjects or animals. Please provide the approval number. IRB documentation should be available upon request.

'Prior to commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number'*

- For studies with human subjects include the following: 'All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.'

  'Informed written consent was or was not obtained from all patients for being included in the study.'
- For studies with animals include the following sentence: 'All institutional and national guidelines for the care and use of laboratory animals were followed.'
- For articles that do not contain studies with human or animal subjects:
  'This article does not contain any studies with human or animal subjects.'
- If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article.

  The Helsinki Declaration 2008 can be found at http://www.wma.net/en/30publications/10policies/b3/

Blinded manuscript

Abstract

- A structured abstract (maximum of 350 words), summarising the most important points in the article is required.

- The abstract consists of four paragraphs with the subheadings:
    - Aims (it is unnecessary to include an introductory section)
    - Patients and methods
    - Results
    - Conclusion
- References should be avoided. Avoid uncommon abbreviations. If essential they must be defined at their first mention in the abstract itself

Key words

- Immediately after the abstract, provide a maximum of six key words, using standard searchable terms. These key words will be used for indexing purposes.

Level of evidence

- Level 1 to 5.
- Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence–Based Medicine (OCEBM); version 2.1.
- Available from: OCEBM Levels of Evidence Working Group. 'The Oxford Levels of Evidence 2'.Oxford Centre for Evidence–Based Medicine. http://www.cebm.net/index.aspx?o=5653

Introduction

- The introduction should contextualise the study by providing the background to the research; explain the problem that is to be addressed and provide the rationale for the study.
- Briefly outline the relevance of the study with respect to the current literature. Avoid a detailed literature survey or a summary of the results.
- The last sentence should outline the research question or hypothesis.

Patients (or Materials) and methods

- State the methods, outcome measures, and selection criteria. The following aspects need to be described:
    - The study design and research methodology
    - Whether randomisation (with methods) was applied
    - If case controlled, how the controls were selected
    - The time period under review
    - Number of patients/subjects under investigation and why this number was chosen
    - Inclusion and exclusion criteria
    - Case and outcome definitions
    - A description of the procedure or intervention, including post–operative protocol
    - The outcome measures or scores used
    - The minimum follow–up period
    - Statistical analysis paragraph. This should be included at the end of this section to detail statistical tests and

package used, the reasons why these tests were used, and what p–value was considered statistically significant. A power analysis is recommended for studies comparing two or more groups.

- Provide sufficient detail so that another researcher can replicate the study.
- The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g., state of disease, choice of treatment).
- Do not describe standard procedure for common operations. Only include new procedures or adaptations to standard procedure.
- If you name any specific product, then it requires the name, city and state/country of the manufacturer.
- Present information in the narrative format and use the past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should be presented in this section.

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow–up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.
- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).
- Avoid using percentages in studies involving well under 100 subjects.
- All results must be backed up with p–values or survivorship analysis. All Kaplan–Meier data should be presented with the confidence intervals. Always present exact absolute p–values, whether significant or not, unless $p < 0.001$.
- However, p–values do not always convey the entire picture and where relevant the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

APPENDIX B

- The question or hypothesis stated at the end of the introduction should be discussed and either supported or rejected.
- The results must be interpreted clearly, and any deficiencies expressed. All possible confounding factors, sources of bias, or weaknesses in the study should be identified.
- Explore the significance of the results of the work, rather than repeating the results.
- The discussion must point out the relevance of the work described in the paper and its contribution to current knowledge.
- Explain what can be deduced from the results and how will it affect clinical practice.
- Include a review of the relevant literature, placing the results of the study in the context of previous work in this area.
- Discussion of relevant prior research and references must be concise. Avoid extensive citations and discussion of published literature but put emphasis on previous findings that agree (or disagree) with those of the present study.
- Do not repeat the introduction.
- Present the limitations of the study and suggest how the study could have been improved for a future study.
- Avoid making inferences from non–significant trends unless you believe your study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

- Provide a summary statement which conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

Conflict of interest

- 'Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z.'
- If no conflicts of interest exist, state this as follows: 'The authors declare they have no conflicts of interest that are directly or indirectly related to the research.'

Ethical statement

- For studies involving human subjects please include an ethical statement as follows: 'All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.'
- For animal studies please include the following ethical statement: 'All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.'

- If the study did not involve human or animal subjects state that: 'This article does not contain any studies with human participants or animals performed by any of the authors.'
- Please also include an informed consent statement: 'Informed consent was obtained from all individual participants included in the study.'
- Or alternatively, for retrospective studies, please add the following sentence: 'For this study formal consent was not required.'
- If identifying information about participants is available in the article, the following statement should be included: 'Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.'

Funding sources

- List all funding sources as follows: 'This work was supported by the xxxx (grant numbers xxxx, yyyy).'
- When funding is from a block grant or other resources available to a university, college or other research institution, submit the name of the institute or organisation that provided the funding.
- If no funding was received, state as follows: 'No funding was received for this study.'

Acknowledgements

- Acknowledgements should be placed at the end of the discussion and before the references.
- In this section persons who were involved but did not earn authorship can be acknowledged.
- Statements should be brief. A person can be thanked for assistance or for comments.
- Should not include contributions by editors or referees.

References

- Please refer to the section on Formatting of submissions.

Tables and figures

- Table and figures should not be imbedded in the text file, but should be submitted as separate individual files. Each table should be a separate file, entitled Table I, Figure 2, etc.
- Each table and figure should be provided with a heading or legend.
- Please refer to the 'Formatting of submission' section for further guidelines.

Article Submission

Submission declaration and verification

With the submission of an article the authors confirm that:

APPENDIX B

- The work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis or as an electronic preprint). Please see our ethics policy for more information.
- That it is not under consideration for publication elsewhere.
- The content of the article is the sole work of the author(s) and that the article has been prepared with cognisance of our plagiarism policy.
- That its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in any other language.

Prior to submission

- Please familiarize yourself with the policies of the SAOJ.
- Please read Instructions to Authors prior to submission. It will also be beneficial to familiarize yourself with the Instructions for Reviewers section.
- It is the responsibility of the authors, and not the reviewers, to ensure that the language, grammar, or spelling is acceptable for publication.
- Crosscheck all references to ensure that the bibliography is accurate.

Submission procedure

- On submission of your article the ORCID (Open Researcher and Contributor ID) identifier of all authors will be required. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and supports automated linkages between you and your professional activities ensuring that your work is recognized. To register and find more information please visit: http://orcid.org
- All correspondence will be sent by e–mail.
- Articles can be submitted be e–mail to: pat@saoj.co.za.

APPENDIX C

Response to Reviewers

Reviewer A:

Results:

Line 17: Reduction bed incomplete

Comment/suggest: Incomplete reduction bed

Comment noted and changed

Conclusion:

Line No 19: The time decreased by an hour after implementation of the SOP

Comment: The time increased by an hour.

Comment noted and changed

Results:

Lines 94 – 96: This accounted for 56% of the delay before the new SOPs, which improved after new SOPs were introduced ((6%) to 53%).

Comment: I don't understand it. Did it improve by 6% or between 6% - 53%?. Or is it 59% and it decreased by 6% to 53%?

We thank the reviewer for this comment, we change the sentence as follows: "Prior to the introduction of the new SOPs the delay was 56%, which deteriorated to 44-47%."

Line 101: 10.53% body fracture

Comment: 10.53% vertebral body fracture

Comment noted and changed

Line 123: BFD

Comment: Bi Facet Dislocation

Comment noted and changed

Discussion:

APPENDIX C

My impression is that the author has apprehension (for the lack of better word) about the decision taken by the constitutional court. The author should present his/her findings instead of constant referral to the constitutional court decision.

Comment appreciated, we have changed the discussion points and based them on our findings as per suggestion

Conclusion:

I think the conclusion, for most part, is vague, long, confusing and does not give a clear message. There is no need to repeat the figures all over again as they have been discussed already in details.

The last part of conclusion {The main message is that there is limited or very poor level of adherence to new SOP guidelines on time management along the emergency health referral system by healthcare workers (nurses, and general doctors) and possibly transport delays.} gives much better message than the whole paragraph written about it. I suggest this part of the conclusion can be a little more elaborated to wrap up the article.

Comment welcomed, the conclusion has been changed as follows “In conclusion, Motor Vehicle Accidents and falls in this study remained the most common mechanisms of injury. The time taken by the Orthopaedic doctor on call from assessment to reduction completion was significantly increased after introduction of the new SOP. There were no significant changes in ASIA scales post introduction of the new SOP. The main message is that there is limited or very poor level of adherence to new SOP guidelines on time management along the emergency health referral system by healthcare workers (nurses, and general doctors) and possibly transport delays. A further study to investigate the bottlenecks of the referral system is advisable”

General comment:

APPENDIX C

I suggest the author includes the SOP either as a table form or a picture or a small paragraph. The article is written about the implementation of the SOP but the reader is left guessing what the SOP actually is.

Noted, the SOP has been added as supplementary table

Reviewer B:

Thank you for submitting this manuscript for review. This is important work that attempts to get to the root of delays to management of very serious and debilitating injuries. This could potentially shed some light on where improvements need to be made in the South African medical system regarding the management of cervical spine injuries.

Specific comments

Title: Acceptable.

Abstract: The abstract needs to be altered following changes to the manuscript body.

Comment noted, we agree with the reviewer, after reviewing the manuscript the abstract has been changed accordingly particularly the results and conclusions

Level of evidence: Not provided in the manuscript.

Comment noted, the level of study has been added on lines 110-111

Introduction: Acceptable. Raises relevance and communicates aims clearly.

Comment appreciated

Ethics:

Line 79 only refers to the fact that patient consent was not required.

You have two groups of study participants in this manuscript - the cervical spine injury patients as well as the nurses, ER doctors and orthopaedic registrars that you interviewed - was consent obtained from these participants?

APPENDIX C

Was institutional ethics committee and hospital board approval obtained prior to commencing of this study?

This study was approved by the University of Cape Town Human Ethics Committee (2018/137). Verbal consent was obtained from Doctors and Nurses that participated in the study. There was no direct involvement of patients, thus no need for verbal or oral consent. The study was comprised of patient notes and records, with each patient identified by their hospital number only. All study data storage was password protected

Methods:

Incomplete.

Please provide a full description of the 'new SOP' as this will help the reader understand where the anticipated improvement should come from.

The main observations and findings in this paper revolves around timing of events: Injury to ER, ER to Ortho referral, Arrival time to ortho, Ortho to reduction, yet your methods section only refers to 'Time to reduction' as a measured variable. This should be explained in greater detail.

Comments appreciated, as per request from the previous reviewer, the SOP has been added as supplementary material.

No description of the qualitative interviews was provided - this should be included in the methodology.

Comment noted, clarification has been provided on lines 81-94

Please describe the statistical methods used in analysing your data.

Noted, we agree with the reviewer, hence a section describing the statistical methods has been added on lines 96-101 as follows

"Statistical Analysis

Data was summarized using descriptive statistics. Continuous variables summarized using means and standard deviations whereas categorical or nominal variables were summarized using percentages. Marched t-tests were to test for significance between continuous

variables whilst chi-squared tests were used for categorical or nominal variables. Graphical analysis was used to display distribution of variable(s) and to illustrated findings visually".

Results:

Results in Line 84 is repeated at Line 121.

Noted and changed

Results in Line 84 - 85 is repeated at Line 98 - 99.

Noted and changed

Results in Line 85 - 90 is repeated at Line 110 - 114.

Noted and changed

Line 95 - 96. you state that there was an improvement from 56% to 53% for delay between injury and arrival in ER. The median time from injury to ER actually increased from 07:13 to 08:30. As this contribution of the overall delay went DOWN, it means that the in-hospital contribution the delay increased. As your new SOP was not changing this aspect (acknowledged by you in Line 166), it is actually more accurate to state that as this percentage cause of delay went down, your in-hospital contribution to delay actually went UP (44% to 47%). So this is actually a reflection of worse performance and should not be presented as 'improved after new SOPs were introduced.

Comment appreciated, we agree with the reviewer and the sentence was revised as follows "Prior to the introduction of the new SOPs the delay was 56%, which deteriorated to 44-47%."

Line 103 - 105. Same logic as above. You refer to the Mean time of 7:43 - is this data normally distributed? Should you not rather use the Median interval to report here?

Noted, we agree with the reviewer and the time has been duly changed as follows

Discussion:

APPENDIX C

Are there any similar other / international studies that you can related your findings to? As it stands your results are presented in a vacuum that doesn't relate it to anything else. Are your efforts mirrored in other institutions, are your current time frames good or bad in terms if other literature? Some context would greatly help the reader grasp the magnitude of the findings.

Comment appreciated, in order to context to the findings the following changes and additions have been made

Lines 174-179 Previous regional hospital data has shown that up to 60% of spinal trauma, which accounts for 3-6% of all trauma admissions, is caused by injury to the cervical region (1). The most common mechanism of injury is the result of a motor vehicle accident (MVA), violent assault or fall – with the typical patient being a male under the age of 30 years old (2,3). In this study MVA and fall were the most common mechanisms of injury; MVA, 36% and fall, 36%.

Lines 180-181 Previously, it has been recommended that the time between injury and closed reduction to be within 4 hours in order to have favorable neurological outcomes

Line 164 - 165 might be misleading: 'After introduction the SOP for rapid reduction, there was little improvement in transport times….' The median time from injury to ER actually increased from 07:13 to 08:30.

Comment noted, the sentence was removed

Please provide the limitations of the study.

We agree with the reviewer, the following has been added from lines 211-216

Limitations

Firstly, the new SOP did not include the transport time (it was only about the time of arrival in ER to reduction). Secondly, most of the study patients were high energy mechanism of injury. Thirdly, the emergency health referral system did not perform to the level expected and represented an area of weakness with regards to performing closed reduction within one hour from the time of admission Lastly, the sample size of the study population was low.

APPENDIX C

Conclusion:

The conclusion should be rewritten. As it stands it repeats the main results which is not necessary. The conclusion should be a summary / interpretation of the findings and recommendation for future research or improvements.

Comment appreciated, the conclusion has been revised as per request by the previous review as follows "In conclusion, Motor Vehicle Accidents and falls in this study remained the most common mechanisms of injury. The time taken by the Orthopaedic doctor on call from assessment to reduction completion was significantly increased after introduction of the new SOP. There were no significant changes in ASIA scales post introduction of the new SOP. The main message is that there is limited or very poor level of adherence to new SOP guidelines on time management along the emergency health referral system by healthcare workers (nurses, and general doctors) and possibly transport delays. A further study to investigate the bottlenecks of the referral system is advisable"

References:

Please use journal abbreviations according to the style used in the National Library of Medicine's Journals in NCBI Databases.

Comment noted, the references have been changed accordingly

Illustrations:

Acceptable.

Thank you

Tables:

Some of the data in the tables are incorrect: For example, Median time Injury to ER is presented as 03:17 in Table II and 07:13 in Table IV. The stated Minimum Time Injury to ER (01:14) is also less than the stated Maximum Time Injury to ER (00:00). Please go over all the stated data in the tables.

Comment noted, after reviewing the 2 tables, we concluded that table 3(now table 2) was more appropriate in answering the intends and purpose of the study and therefore table 4 has been omitted

Organization:

Acceptable

Thank you

Further requirements:

Was the research question clearly elucidated in the introductory section? Yes

Thank you

Was sufficient detail provided in the methods section so that another researcher can replicate the study? No

The methods have expanded with more details

APPENDIX C

Was the statistical methodology employed sound? Yes

Thank you

Was subject recruitment procedure, inclusion and exclusion criteria accurately described?

No - recruitment of interview participants was not described

This has been described in the method section lines 81-94

Was the follow-up period adequate? Yes

Were the limitations of the study adequately explored? No

This has been addressed in the discussion on lines 211-216

Was the conclusion supported by the data presented in the study? Yes

Thank you

Were all necessary references provided? Yes

Thank you

Was the necessary ethical standard maintained? Not explicitly addressed

Further information has been added in lines 103-108

Does the article satisfy the requirements set out in the Instructions for Authors section? Partly worsened

The manuscript addresses the question regarding the new SOP's influence on time to reduction, which was shown to be worse due to lack of emergency staff adherence to the SOP

APPENDIX D

" Adherence to Standard Operating Procedure for patients with Acute Cervical Spine Dislocated Injuries: A case of a teaching central referral hospital in South Africa, Groote Schuur Hospital"

The reviewer has uploaded the review and have found that further revisions are required. Please may I ask that you revise the manuscript according to the guidelines given by the reviewer underneath, as appropriate, or give reasons where you do not make such changes.

Please make all the changes with *tracking* in WORD switched on, and upload a new version on our website.

Please compose a letter that includes the query by the reviewer, how the author has dealt with the query and please state and highlight the change in the manuscript.

We would like to receive your revised manuscript within 2 weeks of today's date, 12 June 2020.

Should you experience difficulty to upload your revised manuscript onto the website, please email the revision to Robyn Marais at robyn@jesser-point.co.za

Thank you and kind regards
Prof J Davis
Section Editor: SA Orthopaedic Journal Goud Deng Ayik, Dr, Takura Darlington Mukabeta, Dr, George Nyandoro, Mr, Charlie Osborne, Dr:

robyn@jesser-point.co.za

Reviewer B:

Most of the points raised in the first review was addressed, however, some language and logic errors still remain and these need to be corrected before this paper can be accepted for publication.

APPENDIX D

Line 15 - 17. Please rewrite this sentence: 'The main cause for delay was transfer time from site of injury to emergency ward, Other reasons for delay missed diagnosis, orthopaedic registrar unavailability, and incomplete reduction bed incomplete.'

Noted, the sentence has been edited as follows 'The main cause for delay was transfer time from site of injury to emergency ward; other reasons for the delay include missed diagnosis, orthopaedic registrar unavailability, and incomplete reduction bed'.

Line 83 - 98. A description of how, who and when the assessment was performed should be included. The qualitative assessment questions would be better represented in a separate table.

Noted and agreed, the following was added "The qualitative assessment was conducted by the principal author between August-September 2018.The study participants for the assessment were emergency personnel (ER Nurses, ER Doctors and Orthopaedic Registrars) at Groote Schuur Hospital. The participants were individually interviewed physically, and they were asked the following questions based on their area of speciality":

Line 114 - 115. Level of evidence should follow the Abstract

Noted and changed, please see lines 28-29

Line 124 - 126. 'The main delay occurred between injury and arrival in the primary emergency ward (ER). Prior to the introduction of the new SOPs the delay was 56%, which deteriorated to 44-47%.' There is a logic error in this statement - using percentages to make this point is confusing - time delay between injury and ER did increase (so yes, this deteriorated) but as a percentage of overall delay it decreased from (65% to 44%). The reader need to infer that this means that the in-hospital contribution to the overall time delay increased in percentage.

Your next sentence then refer to in-hospital delay - missed initial diagnosis in polytrauma patients, orthopaedic registrar being busy etc - yet, you have not introduced to effect of the new SOP on in-hospital delay.

Most of your Results section focusses on the pre-hospital delay which could not foreseeably be changed by the introduction of a new in-hospital SOP. I would certainly mention this, but

spend most of my time on the in-hospital reasons for delay and the effect of the new SOP in this.

I would suggest rewriting the results section using actual times and then making references to percentage contribution to overall delay.

We would like to thank the reviewer for the points raised above, to clarify we have added a sentence in the methods section regarding the expected time to perform reduction in ER (see lines 69-70). With regards to the results, we have done the following changes "There was a pre-hospital delay between injury and arrival to the primary emergency ward (ER) of 7 hours. Closed reduction of cervical dislocations should be performed as soon as possible after arrival to ER (<1 hour), in our study the in-hospital time between injury and closed reduction before introducing the new SOP was 13:13±9:07 hours on average (**Table 1**). After introducing the new SOP (**Supplementary Table 1**), the in-hospital time increased to an average of 14:28±08:53 hours (**Table 1**). Reasons for in-hospital delay included missed initial diagnosis in polytrauma patients, orthopaedic registrars being busy operating in emergency theatre at time of referral and the reduction bed not being complete (missing pulleys).''

Line 149 is a repeat of Line 124 - 125.

Noted and changed

Line 199 - 208. This represents interpretations of your results and should be moved to the discussion section.

Noted and moved to the discussion, please check lines 162-166

Line 313 - 314. 'In the present study, Motor Vehicle Accidents and falls in this study remained the most common mechanisms of injury.' Please rewrite this sentence.

Agreed, the sentence has been edited as follows 'In our setting, motor vehicle accidents and falls were the most common cause of injury'

APPENDIX D

Table 1. There is an error in the data provided in Table 1. How is the Maximum time from Injury to ER = 00:00, which is less than the minimum time of 01:14? Surely this should be at least more than 01:14.

Noted and agreed, the error has been corrected to 24:00

APPENDIX E

Dr Goud Deng Diing Ayik
University of Cape Town
H49 OMB
Groote Schuur Hospital
Observatory
Cape Town
7937

17 June 2020

Dear Dr Ayik

Title: Adherence to Standard Operating Procedure for patients with Acute Cervical Spine Dislocated Injuries: A case of a teaching central referral hospital in South Africa

The above manuscript has been accepted for publication and will be published in the South African Orthopaedic Journal.

Thank you for supporting the South African Orthopaedic Journal.

Yours sincerely

pp
Prof L Marais
Editor: South African Orthopaedic Journal