Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as a reference standard by emergency centre clinicians in the Cape Town metropole

by

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This study is in partial fulfilment of the requirements for the degree Masters of Philosophy in the Faculty of Health Sciences at the University of Cape Town

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Declaration

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Abbreviations

CT – Cape Town

EC/ECs – Emergency Centre/Emergency Centres

EM – Emergency Medicine

PI – Principal Investigator

SA – South Africa

SHO – Senior House Officer/Junior doctor

USA/US– United State of America

VH – Victoria Hospital

WC – Western Cape

Part A: Literature Review

1. Objectives of literature review

This literature review has as its principal objectives:

- To describe the radiology anatomy of the forearm and wrist bones
- To describe the management of closed forearm and wrist fractures
- To describe what is known about the management of fractures in the Emergency Centre

In general, this review will serve as a basis for the following research study.

2. Literature search strategy, including inclusion and exclusion criteria and quality criteria

The relevant publications for this literature review were identified by the lead investigator and the search was done by the use of the following online databases: PubMed, Google scholar, NBCI, and Medline. The keywords used for the research included: “forearm fractures”, “wrist fractures”, “fracture management”, “Emergency department”, “Emergency Centre”, “emergency medicine”, “closed fractures”, “Emergency Physicians”, “fractures diagnosis”, “missed diagnostic fractures”, “forearm fractures X-ray” and “wrist fractures X-ray”. Only studies in English were used and all other non-English journals were excluded. More studies were found in the reference list from publications selected and were included. Preference was given to journals published after but not limited to, the year 2000, and the inclusion of other studies with content considered relevant for this study.

3. Summary or interpretation of literature

3.1. Background: summary of forearm and wrist radiology anatomy

In an Emergency Centre (EC), where the pressure is high, due mostly to the elevated influx of patients, a good knowledge of the normal anatomy of the human bones is important for a good and accurate interpretation of X-Rays by the emergency physicians.

3.1.1. The Forearm bones

The forearm is the second-longest segment of the upper limb (after the arm) and is situated between the elbow and the wrist. Its skeletal frameworks present two long bones, the radius

and the ulna [1-3] with three important parts: epiphysis (at both proximal and distal ends), a metaphysis (a transitional area that contains the epiphyseal plate in children), and a diaphysis (medial segment between the epiphysis) [4].

In a forearm postero-anterior radiological view, the ulna is positioned medially and is the larger and longer bone. Proximally, the olecranon process, a posterior bony projection bent forward articulates with the humerus forming the elbow joint. Anteriorly, the proximal end forms a protrusion, the coronoid process, which, together with the olecranon

forms the trochlear notch, a semilunar depression that receives the humeral trochlea [1-3]. Laterally to the coronoid process, is the radial notch, a depression where the head of the radius articulates.

In a lateral view, the shaft or body of the ulna is large proximally and, running distally, becomes thinner [5]. Distally, the ulnar head articulates with the radius laterally and distally with the fibrocartilage of the wrist, which allows an indirect articulation with the carpus [5]. The ulnar styloid process, which is shorter than that of the radius, is a distal conical prominence that descends onto the medial side of the bone [1-3,5].

The radius runs on the lateral side of the forearm and is the shortest of the two forearm bones [1,2,6]. It is smaller proximally and larger on its distal end [6]. At its proximal end, it has the radial head that articulates with the radial notch of the ulna and the capitulum of the distal humerus [1,2,6]. Immediately below the head it constricts forming the radius neck, and descending, on the medial aspect of the bone, is the radial tuberosity [1,2,6]. Contrary to the ulna, the radius shaft is thicker proximally and becomes larger as it runs distally. Distally, the radial styloid is larger [1,2,6] and its tip extends farther (1-1,5 mm) distally than the tip of the ulna [5]. In the case of fracture of one or both of the forearm bones, this relationship mark is clinically important [1,2,6]. Distally, the radius articulates with the scaphoid and lunate carpus forming the wrist joint and medially with the ulnar head [1,2,5,6]. Besides the proximal and distal end articulations, the radius and ulna bones are connected by an interosseous membrane that runs between their shafts (Radius medial border and ulnar lateral border).

3.1.2. The Wrist (radio-carpal joint)

The wrist, located between the forearm and the hand, is normally formed by a group of eight small carpal bones, the distal end of the radius, and the ulna (indirect articulation) and the proximal surfaces of the metacarpals [1,7,8]. The carpal bones are arranged in two rows of four carpi each. Located at the level of the distal crease, the proximal row presents, from medial to lateral, the pisiform (sesamoid bone with a pea-shape), triquetrum (pyramidal bone shape),

lunate (moon-shaped carpus), and scaphoid (lateral, larger and boat-shaped carpus) and the distal row by the hamate (a wedge-shaped form with a process that is hook-shaped on the palmar surface), the capitate (most prominent and largest of the carpal bones and its name is due to its head shaped aspect.), trapezoid (trapezoidal bone with a wedge shape) and trapezium (the most lateral bone and presents four sides) [1,7,8].

The proximal row, excluding the pisiform, articulates with the distal end of the radius and the articular disc of the distal radioulnar joint by its proximal surface and with the proximal surface of the distal row by its distal surface. The distal surface of the distal carpal row articulates with the five metacarpal bones [1,7]. In a radiological image, the joint space between the carpus should measure between 1-2 mm and the bone contours should have a smooth look with no irregularities. Any bone irregularity is suggestive of fracture and joint spaces with more than 2 mm present suspicion of traumatic injury [9].

3.1.3. Important landmarks on radiological images

When interpreting a radiological image, the alteration of the normal anatomic position of the forearm and wrist bones can be quickly accessed by useful landmarks. In the lateral view, a normal radiocapitellar line drowns from the centre of the proximal end of the radius and parallel to its long axis to the elbow joint, passing through the centre of the capitellum [10,11]. An abnormal radiocapitellar line is suggestive of the dislocation of the radius head secondary to the fracture of the ulna shaft, known as Monteggia fracture-dislocation [10,11].

The radial tilt or angle is the angle formed by two drawn lines at the wrist joint: one passing through the articular surface of the distal end of the radius and a line that is perpendicular to the radius longitudinal axis. A range of 2-20 degrees (average of 10 degrees) is considered normal [9,11,12]. Still looking at a lateral image, a normal wrist joint should show an alignment of the radius, lunate, capitate [10,12,13], and the third metacarpus [9].

A normal radius and ulna position, in a postero-anterior radiological image, is accessed by measuring the radial angle or inclination, with a range of 21-25 degrees, that is formed by a tangential line passing by the tip of the radial styloid and the base of the ulnar styloid (or distal point of the ulnar surface of the distal end of radius) and by a line that is perpendicular to the radial-longitudinal axis [11,12]. In the same view, the normal radial length is 10-13 mm and is measured by the vertical distance between the ulnar-radial rim at the distal end and the styloid process of the radius [9].

3.2. Management of forearm and wrist closed fractures

In the EC, fracture management involves multiple steps from the time that the patient arrives until he/she is discharged or transferred for follow-up. Proper management of fractures include taking a detailed history of all events associated with the injury [14-16], a good and well-documented physical examination [15,16] and, a proficient description of the abnormality from the radiological images, being the X-ray, the exam of choice in the Western Cape (WC) EC. When upper limb fractures are suspected, the X-ray should follow a set of rules, such as at least two views (posteroanterior and lateral), with additional views when suspecting wrist fractures [14,15,17], should include the joints above and below the fracture (to rule out associated injury in the joint), and both sides (right/left) of the anatomical area (is advised) for comparison purposes [10,14-16], a practice especially used in children [14] or uncertainty of the existence of an abnormality. However, in the presence of suspected radial and/or ulnar shaft fractures, some refer that if the patient is alert, responsive, and capable of communicating, a proper clinical exam can cancel the inclusion of above and below joints in the X-rays [18]. A pre- and post-reduction X-ray is another important rule since it is a reliable way to check the adequacy of the fracture reduction [14,15] and to decide the further management.

Many studies analysing fracture diagnosis errors by using X-ray interpretation agree that misinterpretations of fractures are not uncommon by EC doctors [19-26], and are one of the most common errors in the EC [27-29], accounting for 41-80% of all diagnostic errors [22-24,27]. Furthermore, 1% of patients seen in an EC present with a fracture diagnosis error [20,23], and from all fractures seen in the first visit, 3% are undiagnosed [20]. The extremities are reported to have one of the highest rates of errors in fracture diagnosis [23;24] with one study reporting 3,7% of all fractures being misdiagnosed [24]. Considering all fractures in the extremities, fractures from the forearm [19-21,23,24] and wrist [19,21,23,24,28,30-32] are commonly reported as one of the areas with frequent errors or misdiagnosis. Some publications suggest the wrist is the anatomical area with the highest [24,30] and the second-highest percentage [19,22,32] of misdiagnosis.

Misinterpretations of fractures on the radiologic image may have a serious impact on the choice of the course of action, with negative clinical outcomes for the patient, such as treatment and healing delay, resulting in poor consequences that may have a legal impact [22,27]. In a study at an acute orthopaedic clinic, with 250 patients referred from the EC, 17,2% had a wrong diagnostic and 12% the wrong treatment resulting in the admission of 6% of the patients. From all plaster splints applied in EC, the orthopaedic staff removed

49,4% and altered 25,4% [33]. Other clinically significant percentages [34-39] resulted from misinterpreting fracture X-Rays, with an impact on the management [32,34-38] were reported by others. Reasons for X-ray misdiagnoses for fractures are the following:

- fracture not perceptible in X-ray or not seen [22,24,31,40];
- requesting the wrong X-ray [22,40], the wrong view [40] or an insufficient number of X-rays [24,27,31];
- more than one fracture on the same X-ray where one is easily seen and the other(s) are missed [22,24,27,31,40];
- X-ray with poor quality [22,31];
- fracture identified but wrongly interpreted [22,40];
- poor clinical exam [22,40] and clinical history notes [40] may lead to misinterpretation of the radiologist that can help with the choice of the right anatomic position and view to capture a specific fracture in the image.

Interruptions, distractions, shift work [23,41], and no 24/7 access to specialist or senior doctors [23] – all characteristics that are well known in the WC EC work environment–are other factors that play an important role as causes of misdiagnosis of fractures in EC. One study [20] analysing the fracture diagnosis errors with 'the diurnal variation of doctors' work' showed that a significant percentage of errors were made during the evening and overnight, and most were due to misreading the X-rays. The same study also reported that 38% of all cases of misdiagnosis included a consultation of a senior doctor to read an X-ray [20]. The level of experience and training of the EC staff is another important factor related to errors in fracture management [31,37,41-43]. In a WC EC, it is common to find a mix of medical officers, EM physicians in post-graduates, and EM consultants, from different training schools and experience, all acting as first-line doctors in receiving and managing patients with fractures. McLauchlan et al. when comparing how well junior and senior doctors were able to read X-rays in an Accident and Emergency Department, showed that junior doctors misinterpreted X-rays significantly higher (68%) than senior doctors (20%), and in the junior group those with more than five months of EC experience had fewer misdiagnoses than those with less time working in the department [43]. Another study of 1,2% of misinterpretation X-rays, showed that EC consultants had fewer diagnostic misinterpretations (0,28%) than specialist registrars (0,89%) and Senior House Officers (SHO) (0,75%) [37]. In general, good clinical decision-making and reduction of diagnostic errors are closely related to training and experience [31,41,42] with

some theorists defending that “expertise in any domain requires around 10-years of experience”[41].

4. Identification of gaps or need for further research

As described, fracture management is not only the identification of the abnormality on an X-ray image but a set of interconnected procedures consisting of clinical history, evaluation of the patient, diagnostics, treatment, and proper disposition of the patient for follow-up. Regarding the evaluation of EC clinicians' knowledge in forearm and wrist fracture management, this literature review helped to identify some gaps that can be addressed in further research. Firstly, most of the literature evaluates that EC knowledge related to fractures focuses mainly on the diagnosis of all fractures in general and not specifically forearm and wrist fractures. Secondly, no specific studies in evaluating the EC staff knowledge on the course of action for fractures were identified. Thirdly, no studies were found evaluating fractures from the forearm and wrist, in particular, for diagnostic, treatment, and disposition of the patient. Fourthly, no similar studies were found regarding EC fracture management and outcomes in South Africa (SA).

In many underdeveloped countries, including in SA, where the EC is characterized by being overburdened due to the high influx of patients, studies evaluating fracture management in general, and of forearm and wrist in particular, would not only be useful as a comparison for this study but could help improve the quality of care for a trauma patient in the EC settings in Africa and SA in particular.

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Part B: Manuscript in Article Format

Title page

Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as a reference standard by emergency centre clinicians in the Cape Town metropole

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Abstract

Introduction

Reduction of forearm and wrist fractures is a common practice in the Emergency Centre (EC). EC doctors must be familiar with the appropriate management thereof. The standard treatment of a fracture involves reduction and immobilization. This study aims to describe the diagnostic and management accuracy of EC clinicians using validated vignettes (also used as the reference standard) of adult patients with closed fractures of the forearm or wrist.

Methods

This is a prospective, cross-sectional study in the form of an electronic questionnaire to address the study aim. A set of vignettes were created and then validated to serve as the control for the study participants. The study was open to emergency medicine consultants, emergency medicine trainees/registrars, medical officers, and community service medical officers employed at a secondary-level public hospital EC in the Cape Town metropole. Comparison is made by the number and proportions of correct and incorrect answers using the vignette reference standard. Data were analysed using Chi-Square (X^2).

Results

For the diagnosis of forearm and wrist fractures, EC clinicians present 86,8% (1309/1508) correct responses (p=0.68) and, for the course of action, 78% (278/354) correct responses (p=0.09). For the overall management of the fractures (diagnostic and course of action), EC clinicians answered correctly to 84,9% (1585/1866) and incorrectly to 15,1% (281/1866), although the difference by each EC clinician group.was not significant (p=0.72).

Conclusion

In Western Cape, EC doctors appear to fare better than reported in the literature. However, this can not be shown definitively with this dataset. Regular training is necessary for all clinicians working in EC to improve their skills in managing forearm and wrist fractures, including the interpretation of X-ray imaging. Clear and good notes in the patient folder, top-quality X-ray images, good EC work environment, and improvement between doctors communication are other sets of requirements important to help to avoid errors in fracture management.

Main text of the article

Introduction

Reduction of forearm and wrist fractures under procedural sedation is common practice in the Emergency Centre (EC). Around 16% of all fractures tend to be fractures of the distal radius; and around 25% of all limb fractures tend to be fractures of the wrist – with 75% of these involving the distal radius and ulna [1,2]. According to a study in the United States, 1.5% of all fractures seen in EC were hand/ forearm fractures and 44% of these were radial and/ or ulnar fractures [3].

Fracture management in the EC varies depending on the fracture, although the standard method involves a combination of traction, reduction, and immobilization. A repeat X-ray post-manipulation is required to evaluate the position of the fracture and to provide the EC doctor with the information to whether further manipulation is required. A study to assess radiographic outcomes from EC reduction of Colles-type fractures in patients between 21-85 years old showed that within the group of patients with displaced fractures, 69 of 114 (61%) either went on to require surgery or resulted in a poor radiographic outcome [4].

In African ECs, because of the resource:workload ratio (a small number of clinicians versus a high number of patients), good early management of fractures in the EC may have an impact on the number of patients that require optimization of fracture care downstream. This can have a substantial impact on cost reduction. This study aims to describe the diagnostic and management accuracy of Emergency Medicine (EM) clinicians using validated vignettes (also used as the reference standard) of adult patients with closed fractures of the forearm or wrist.

Methods

We designed a prospective, cross-sectional study design in the form of an electronic questionnaire to address the study aim. A set of vignettes were created and then validated to serve as the control (Appendix A) for the study participants.

The study was open to emergency medicine (EM) consultants, EM trainees/registrars, medical officers, and community service medical officers, to obtain a representative sample of EC clinicians employed at a secondary level public hospital EC in the Cape Town (CT) metropole. We excluded clinicians in other sectors. We expected to collect data from at least 50 clinicians; that is a 50% return from an estimated 100 EC clinicians (approximately

20 staff members per EC times five ECs). A specific sample size calculation was not performed. We felt that as the first local study into this topic, starting with a smaller, practical sample would be more appropriate. The findings from this study can then be used to formulate a better hypothesis for future local studies.

The vignettes created represented both the cases used in the questionnaire as well as the correct reference standard answers to each of the clinical questions posed in the survey. These were used to compare answers from participants. To create the vignettes, the Principal investigator (PI) collected nine cases of wrist or forearm fractures, at the fracture clinic of Victoria hospital (VH) CT that was initially managed through the EC. These included a selection of proximal (including carpals), midshaft and distal forearm fractures.

Each vignette was provided with a brief clinical history and the pre- and post-X-ray sets. The X-rays images were photographs from the original X-ray and were prepared by the principal investigator using a professional photographic machine. Vignettes were provided with a reference diagnosis, description (position, angulation, and impaction) and course of action for each X-ray set. To validate, each vignette was checked and edited by the study team and the orthopaedic lead at VH. Vignettes were then shared with two emergency physicians external to the study to comment on the context, readability, and recommended diagnosis of individual vignettes. This was an iterative process and vignettes were edited according to the suggestions made by the external emergency physicians in consultation with the orthopaedic lead from VH to produce the final vignettes used in the questionnaire.

For the questionnaire (Appendix B), participants were provided with a range of defined options to describe the diagnosis and course of action for each vignette. For example, the course of action included the following options for participants to select from: conservative management, no follow up; conservative management and follow-up; EC clinician manipulation required; further EC clinician manipulation required; and orthopaedic manipulation required (in the theatre).

Data were collected using an institutional subscription to the e-survey client, Survey Monkey. The questionnaire collected the following additional variables: the participant age, experience in years, formal qualifications, and job description. We also collected data about employment, mainly to ensure non-public sector employees could be excluded at the backend. The questionnaire then collected variables related to the nine vignettes. The e-survey client was set to collect information anonymously.

To improve data collection, the PI visited some of the included facilities such as VH and New Somerset hospital and contact the head of EC of Groote Schuur, Khayelitsha and Mitchells Plain hospitals to promote the study. The PI also promoted the study at faculty teaching and training sessions. A poster with a QR-link to the study summary protocol was placed in each facilities' clinician rest area. Email reminders were sent weekly to specialist trainees and to the EC heads of department.

All data were collected and analysed in Microsoft Excel (Microsoft Office, Redmond, USA). Data are expressed as counts and proportions for each variable and are presented in tables and figures. Comparison is made by number and proportions of correct and incorrect answers using the vignette reference standard. All diagnostic data were analysed using Chi-square (X2). A p-value of less than 0.05 was considered statistically significant.

The study protocol was approved by the Human Research Ethics Committee of the University of Cape Town (HREC REF: 537/2017).

Results

From a total of 46 survey responses submitted, 21 were excluded for being incomplete and the 25 surveys were used for analysis.

The majority of the participants were EM consultants (n=13, 52%), their age was between 30-39 years old (n=16, mean 37.8, SD 5.82), who mostly graduated between 2009-2013 (n=9, 36%) and the majority had worked in an EC department for 1 to 5 years (n=9, 36%) and 5-10 years (n=9, 36%). Most of the consultants (n=7, 53.9%) graduated between 1999-2003 and worked in the EC for more than five years (46.2% for 5-10 years and more than 10 years). Most of EM registrars (n=4, 57.1%) graduated in 2009-2013 and the Medical officers in 2009-2013 (n=2, 50%) and both worked in the department for 1-5 years (n=4, 57.1% and n=3, 75% respectively) (Table 1).

Table 1 Age, graduation date and time working in the Emergency Centre per Emergency Centre Clinicians.

Variables	**All (n=25)**	EM Registrar **(n=7)**	EM Consultants **(n=13)**	Medical Officer **(n=4)**	Unknown **(n=1)**
Age (years) Mean (±SD)					
30-50 years	37.8 (±5.82)	33.57 (±2.94)	40.77 (±4.49)	36.25 (±9.32)	35.0 (±0.0)
Graduation date n (%)					
Pre-1999	4 (16.0%)	0 (0.0%)	3 (23.1%)	1 (25.0%)	0 (0.0%)
1999-2003	8 (32.0%)	1 (14.3%)	7 (53.9%)	0 (0.0%)	0 (0.0%)
2004-2008	4 (16.0%)	2 (28.6%	1 (7.7%)	1 (25.0%)	0 (0.0%)
2009-2013	9 (36.0%)	4 (57.1%)	2 (15.4%)	2 (50.0%)	1 (100%)
2014-2018	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Time in EM n (%)					
1-4 years	9 (36.0%)	4 (57.1%)	1 (7.7%)	3 (75.0%)	1 (100%)
5-10 years	9 (36.0%)	3 (42.9%)	6 (46.2%)	0 (0.0%)	0 (0.0%)
> 10 years	7 (28.0%)	0 (0.0%)	6 (46.2%)	1 (25.0%)	0 (0.0%)

EM, emergency medicine; SD, standard deviation; n, frequency; %, percentage

From a total of 1508 overall diagnostic answers, EC clinicians responded correctly to 1309 (86.8%). From this, there was no significant difference between the responses per EC clinicians in the overall diagnostic (p=0.68).

Compared to the reference standard, the Medical officer group responded with fewer correct answers (85.7%) than the Registrars (86.7%), Consultants (86.8%), and the Unknown group (91.7%) (Table 2).

Although there were more correct diagnostic answers in the pre-manipulation X-ray responses, with 87.6% (982/1121) than in the post-manipulation X-ray, with 84.5% (327/387), this difference was not significant (p=0.12).

Table 2 Diagnostic and Course of action per Emergency Centre Clinicians against the reference standard: correct and incorrect answers for pre- and post-manipulation X-rays and the overall diagnostic and course of action (pre- plus post-manipulations X-rays)

Answers	All (n=25)	EM Consultants (n= 13)	EM Registrars (n=7)	Medical Officer (n=4)	Unknown (n=1)
Diagnostic answers					
Pre-manipulation X-ray					
Correct n (%)	982 (87.6%)	508 (87.3%)	274 (87.0%)	158 (88.3)	42 (93.3%)
Incorrect n (%)	139 (12.4%)	74 (12.7%)	41 (13.0%)	21 (11.7%)	3 (6.7%)
Post-manipulation X-ray					
Correct n (%)	327 (84.5%)	159 (85.5%)	103 (85.8%)	52 (78.8%)	13 (86.7%)
Incorrect n (%)	60 (15.5%)	27 (14.5%)	17 (14.2%)	14 (21.2%)	2 (13.3%)
Overall Diagnostic					
Correct n (%)	1309 (86.8%)	667 (86.8%)	377 (86.7%)	210 (85.7%)	55 (91.7%)
Incorrect n (%)	199 (13.2%)	101 (13.2%)	58 (13.3%)	35 (14.3%)	5 (8.3%)
Course of Action answers					
Pre-manipulation X-ray					
Correct n (%)	169 (75.1%)	88 (75.2%)	45 (71.4%)	29 (80.6%)	7 (77.8%)
Incorrect n (%)	56 (24.9%)	29 (24.8%)	18 (28.6%)	7 (19.4%)	2 (22.2%)
Post-manipulation X-ray					
Correct n (%)	107 (82.9%)	53 (85.5%)	31 (77.5%)	19 (86.4%)	4 (80.0%)
Incorrect n (%)	22 (17.1%)	9 (14.5%)	9 (22.5%)	3 (13.6%)	1 (20.0%)
Overall Course of action					
Correct n (%)	276 (78.0%)	141 (78.8%)	76 (73.8%)	48 (82.8%)	11 (78.6%)
Incorrect n (%)	78 (22.0%)	38 (21.2%)	27 (26.2%)	10 (17.2%)	3 (21.4%)

EM, emergency medicine; n, frequency; %, percentage

A significant difference is seen between the answers for each diagnostic variable ($p<0.001$) for pre-manipulation X-rays with the location of fractures having the most correct answers (99.5%) and the impaction of fractures (80.8%) and anatomic structure identification (83.6%) having the least correct answers. In post-manipulation X-rays, this difference was not significant ($p=0.66$) where the impaction of fractures was the variable with fewer correct answers (82.2%), suggesting that, from all variables used for diagnosis, doctors found difficulty in the differentiation between impacted or not/minimally impacted fractures.

From an overall of 354 responses for the course of action (table 2), EC clinicians correctly answered 276 questions (78.0%) with no significant difference ($p=0.09$) between the answers of pre- and post-manipulation X-rays with 75.1% and 82.9% respectively. Furthermore, no significant difference was again observed in the course of action between the EC professional role in both pre- ($p=0.79$) and post-manipulation X-rays ($p=0.72$) where the Medical Officers' gave more correct answers in both pre- (80.6%) and post-manipulation X-rays (86.4%) and the registrars had fewer correct answers (71.4% and 77.5% respectively). Overall, the Medical officers' group scored higher, with 82.8% (48/58), than the consultants and registrars (table 3). The differences between the EC clinicians were, however, not significant ($p=0.59$).

For the total management of the fractures (diagnostic and course of action), from a total of 1862 responses, EC clinicians answered 1584 questions correctly (85.1%), although the difference was not significant ($p=0.72$) when analysing the responses by each EC clinician group. The EM consultants, with 85.3% (808/947), presented with more correct answers than the other groups.

Analysing only the answers of the cases with forearm and wrist fractures with the indication for manipulation, from the 175 overall answers, 155 (88.6%) answers were correct, indicating that the manipulation would be done and 20 (11.4%) answers were incorrect meaning that no manipulation would be done. From this, the registrars' group indicated that they would be the group with most manipulations done, having 91.8% of correct answers Although the higher number of correct answers was provided by the registrars this difference between the EC clinicians was not significant ($p=0.43$) (Figure 1).

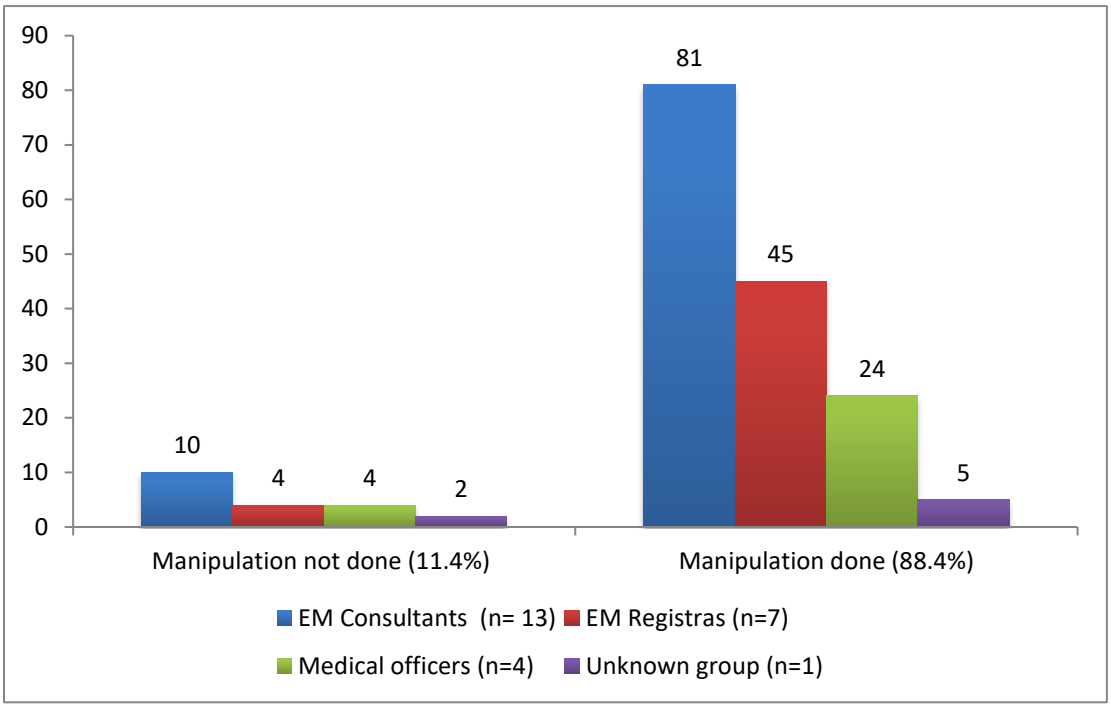

Figure 1 Forearm and wrist fractures with an indication for manipulation: fractures manipulation done versus not done (in the Emergency Centre or orthopaedic department)

Regarding the graduation date, the EC doctors who had graduated before 1999, provided less correct answers than those who graduated after 1999, however, no significant difference was found between the graduation date of EC clinicians for diagnostic (p=0.85), course of action (p=0.82) and overall management (p=0.91). Most correct answers were given by EC Doctors who graduated in 2004-2008 for diagnostic (87.8%), and in 2009/2013 for Course of action (80.6%). For the total management of fractures of forearm and wrist, most of the correct answers were presented by EC Doctors who graduated between 1999-2003 and 2004-2008 with 85.5% of responses for each group (Table 3).

Table 3 Overall diagnostic, course of action and full management (diagnostic plus course of action) against the reference standard by Clinicians graduation date

Answers overall	**All (n=25)**	**Pre-1999 (n=4)**	**1999-2003 (n=8)**	**2004-2008 (n=4)**	**2009-2013 (n=4)**
Diagnostic					
Correct (%)	1309 (86.8%)	209 (85.7%)	398 (87.5%)	216 (87.8%)	486 (86.3%)
Incorrect (%)	199 (13.2%)	35 (14.3%)	57 (12.5%)	30 (12.2%)	77 (13.7%)
Course of action					
Correct (%)	276 (78.0%)	44 (75.9%)	80 (76.9%)	44 (75.9%)	108 (80.6%)
Incorrect (%)	78 (22.0%)	14 (24.1%)	24 (23.1%)	14 (24.1%)	26 (19.4%)
Total Management					
Correct (%)	1585 (85.1%)	253 (83.8%)	478 (85.5%)	260 (85.5%)	594 (85.2%)
Incorrect (%)	277 (14.9%)	49 (16.2%)	81 (14.5%)	44 (14.5%)	103 (14.8%)

EM, emergency medicine; n, frequency; %, percentage

Evaluating the experience in effecting the management of forearm and wrist fractures in the EC, the doctors working in EC for more than 10 years had a higher percentage of correct answers (88.9%) than those with less time in EC. For the course of action, doctors with more than 10 years scored second place with 78.1% of correct answers, a slight difference from the doctors working for 1-4 years who scored first with 78.3%. As total management of forearm and wrist fractures, the doctors with more than 10 years of experience in working in EC had more correct answers (86.9%) than those with less experience. Although there is a difference in the percentage for the time in working in EC, this difference was not significant for both diagnostic (p=0.24), course of action (p=0.99), and full management of the fractures (p=0.33) (table 4).

Table 4 Overall diagnostic, course of action and full management (diagnostic plus course of action) against the reference standard by time of working in Emergency Centre

Answers	All (n=25)	1-4 years (n=9)	5-10 years (n=9)	>10 years (n=7)
Diagnostic				
Correct (%)	1309 (86.8%)	473 (86.2%)	468 (85.4%)	368 (88.9%)
Incorrect (%)	199 (13.2%)	76 (13.8%)	80 (14.6%)	43 (11.1%)
Course of action				
Correct (%)	276 (78.0%)	101 (78.3%)	100 (77.5%)	75 (78.1%)
Incorrect (%)	78 (22.0%)	28 (21.7%)	29 (22.5%)	21 (21.9%)
Total Management				
Correct (%)	1585 (85.1%)	574 (84.7%)	568 (83.9%)	443 (86.9%)
Incorrect (%)	277 (14.9%)	104 (15.3%)	109 (16.1%)	64 (13.1%)

EM, emergency medicine; n, frequency; %, percentage

Discussion

The EC can present a great burden for the health care system especially in an underdeveloped country where there is a large influx of patients and a long waiting time. Good care of fractures also contributes to improving the health system and patient satisfaction by reducing the cost, use of unnecessary resources, and time in hospital. Good management of fractures starts from the clinical history collection from the patient and ends with an ideal course of action, including the final disposition of the patient before discharge from the EC.

The findings in this study suggest that, overall, there is no significant difference in the diagnosis and course of action of the EC doctors when compared to that recommended by our reference standard. Unfortunately, there are no similar studies that focus specifically on forearm and wrist fractures, neither in SA nor globally, and no studies using different variables for the X-ray fracture interpretation. Most of the studies found focussed basically on describing the misdiagnosis of multiply fractures in general by comparing the interpretation of X-rays between EC doctors and radiologists [5-7].

Although there is no significant difference between the diagnosis answers by EC clinicians, just over a tenth of overall diagnostic answers were incorrect, suggesting that EC doctors have some difficulties in interpreting forearm and wrist fracture X-rays with respect to location, anatomic structure, position, angulation, and impaction of fractures.

Our findings of incorrect answers for diagnosing forearm and wrist fractures are different from the findings in other studies. Some found that 41-80% of all fractures are misdiagnosed in the EC [5,8-11]. This is different from our findings of just over a tenth of wrong answers in diagnoses, but we only concentrated on forearm and wrist fractures. One study found that from 250 patients referred from EC to the fracture clinic, 17.2% had a wrong diagnosis, a percentage closer to our findings, and from the total fractures with wrong diagnoses, 3.6% had the wrong treatment [12], a different result from the one found in this study with just over a fifth of overall wrong answers for the course of action. Moreover, from all forearm and wrist fractures requiring manipulations, one-ninth responded incorrectly, meaning that for every nine patients requiring a forearm or wrist fracture manipulation, one is discharged from EC without the appropriate treatment. Other studies found that 1-6% [10,13,14] of missed fractures are from the extremities. A study was done in a Paediatric EC showed that from 220 missed fractures, 7.7% were from the distal radius, and from this 76% were seen in a wrist X-ray and only 12% on a forearm X-ray [15].

Comparing data from pre- and post-manipulation X-rays, there are more correct answers in course of action in the post-X-ray than in pre-X-ray, suggesting that a post-X-ray does not only indicate the result of a fracture manipulation but it may be important for a final decision for the right course of treatment for fractures of forearm and wrist.

In this study, the Medical officer group had fewer correct answers for diagnosis of fractures than the consultants and registrar group which is consistent with the findings from other studies where SHO/junior doctors showed higher misinterpretation of X-rays than senior doctors [16,17] and specialist registrars [16].

Regarding the experience and training, our findings show that doctors who graduated after the year 1999 and doctors working in EC for more than 10 years had fewer wrong answers for diagnoses and total management of forearm and wrist fractures than the ones graduated before the year 1999 and with less time working in EC. These findings are consistent with what was previously referred by others, that the level of experience and training are important factors in preventing errors in fracture management [16-20].

Limitations

This study has many limitations. The first limitation found is concerning the sample size which is small not giving enough power to the study, and meaning that the results found cannot be generalized to all EC clinicians of WC. Secondly, the fact that most of the responses were given by the consultants' group (n=13) and that one of the EC doctors did not identify his role, might have influenced the results. Further studies with a bigger sample and with a similar group size might give different results. Thirdly, the collection of data and its transfer to an Excel sheet was done only by the primary investigator which might have introduced bias to this study. To try to avoid bias, the principal investigator doublechecked the data during the collection and transfer of data and re-checked it every time it was necessary. The use of a standard sheet for collection of data and capture on an electronic sheet for analysis, was another way to attempt to reduce the potential bias. Fourthly, the EC doctors gave their answers based on a set of X-ray images and a clinical history collected from a short and incomplete note in the patient folder. The X-ray images in the questionnaire were photographs from the original images. The quality of the X-ray image, the clinical history, and the direct examination of the patient all have an important bearing in the interpretation of X-rays [8,18,21]. The answers presented by the EC doctors might have been influenced by the quality of the X-ray images, the short clinical history available, and the lack of direct interaction with the patient.

Conclusion

Errors in diagnosing fractures lead to errors in the course of action with a delay in fracture healing with a poor impact on the outcome of patients as a final result [10,11]. In We WC ECs, 13.2% of forearm and wrist fractures are misdiagnosed and 22% have the wrong course of action. Overall, 14.9% of forearm and wrist fractures are not well managed in the EC and 11.4% with manipulation indications are discharged without being manipulated. Regular training is necessary for all clinicians working in EC to improve their skills in managing forearm and wrist fractures, including the interpretation of X-ray imaging. Notes in the patient folder providing a good quality clinical history and observation of the abnormality may direct the radiologist in helping to select the best view and position for a specific fracture.

Other sets of requirements are important to help to avoid errors in fracture management such as top-quality X-ray images and a good EC work environment. Improvement in

communication between EC doctors, radiologists, and orthopaedic surgeons 24/7 is another measure that may help decrease the number of management errors in forearm and wrist fractures and can contribute to EC clinicians' skills improvement.

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Dissemination of results

To the Department of EM of CT and the Orthopedic Surgery Department from Victoria Hospital.

Author contribution

Authors contributed to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; drafting the work or revising it critically for important intellectual content; and final approval of the version to be published: MTS contributed 80%, and PC and SRB 10% each. The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests

The authors declare no conflict of interest.

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Part C: Addenda

1. Relevant journal Instructions to Authors

The access for the African Journal of Emergency Medicine Authors instructions guidelines can be found on the following link:

https://www.elsevier.com/journals/african-journal-of-emergency-medicine/2211-419X/guide-for-authors

2. Consent forms and any related participant information sheets

Title of the research project: Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as a reference standard by emergency centre clinicians in the Cape Town metropole

You are invited to partake in a research study with the aim to describe the diagnostic and management accuracy of Emergency Centre clinicians when caring for adult patients with closed fractures of the forearm or wrist. It consists of a set of simulated case descriptions and their x-ray findings and requires you to select the most appropriate answer(s) to describe the diagnosis and management of a particular case. Continuing to the questions implies consent to participate in this study.

How long will it take?

This survey will take approximately 10 minutes to complete.

Do I have to do it?

Your participation in this study is voluntary and completion of the survey implies consent. You can decline to participate or withdraw at any stage without any penalties or consequences. You will not receive any incentives for participating.

What will happen to my data?

Safety mechanisms are in place to protect your personal details. The questionnaire will collect data anonymously and any identifiable data will be coded as soon as the data collection is completed. Data will be stored in a password-protected document on an access-controlled computer.

Has this study been formally reviewed?

This study has been approved by the Health Research Ethics Committee at the University of

Cape Town (HREC Ref: 537/2017); Tel nr. +27 21 406 6626).

Whom can I contact if I have further queries?

For any inquiries please contact Dr. Melisanda Goncalves at SCHMEL018@myuct.ac.za.

Thank you for your participation,

Melisanda Goncalves (Lead Investigator & MPhil candidate)

On behalf of Dr Flip Cloete (Principal Investigator & Co-Supervisor) and Ass/Prof Stevan Bruijns (Co-Supervisor).

3. Validation sheet / reference standard (listed as appendix A in Part B)

Title of the research project: Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as a reference standard by emergency centre clinicians in the Cape Town metropole

Case No	XRays	Questions	Reference standard Response for questionnaire validation
1	Pre manipulation	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Minimally/non-displaced
		This fracture is (impactation)	Minimally/non-angulated
		Recommended Immediate course of action to include	Impacted
		The location of the fracture is	EC clinician manipulation required
	Post manipulation	The position is now	Minimally/non-displaced
		The alignment is now	Minimally/non-angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Fracture clinic follow up

2	**Pre manipulation**	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Displaced
		This fracture is (impactation)	Angulated
		Recommended Immediate course of action to include	Impacted
		The location of the fracture is	EC clinician manipulation required
	Post manipulation	The position is now	Displaced
		The alignment is now	Angulated
		This fracture is now	Impacted
		Recommended course of action to include now	Orthopedic manipulation required
3	**Pre manipulation**	The location of the fracture is	Midshaft
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Minimally/non-displaced
		This fracture is (impactation)	Minimally/non-angulated
		Recommended Immediate course of action to include	Minimally/non-impacted

		The location of the fracture is	Conservative management and fracture clinic follow up
	Post manipulation	The position is now	Minimally/non-displaced
		The alignment is now	Minimally/non-angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Fracture clinic follow up
4	**Pre manipulation**	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Displaced
		This fracture is (impactation)	Angulated
		Recommended Immediate course of action to include	Impacted
		The location of the fracture is	EC clinician manipulation required or Orthopedic manipulation required
	Post manipulation	The position is now	Displaced
		The alignment is now	Angulated
		This fracture is now	Impacted
		Recommended course of action to include now	Orthopedic manipulation required

5	**Pre manipulation**	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Displaced
		This fracture is (impactation)	Angulated
		Recommended Immediate course of action to include	Impacted
		The location of the fracture is	EC clinician manipulation required
	Post manipulation	The position is now	Minimally/non-displaced
		The alignment is now	Minimally/non-angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Fracture clinic follow up
6	**Pre manipulation**	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius and ulna
		The position is	Fracture
		The alignment is	Displaced
		This fracture is (impactation)	Angulated
		Recommended Immediate course of action to include	Impacted

		The location of the fracture is	EC clinician manipulation required
	Post manipulation	The position is now	Minimally/non-displaced
		The alignment is now	Minimally/non-angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Fracture clinic follow up
7	**Pre manipulation**	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Displaced
		This fracture is (impactation)	Angulated
		Recommended Immediate course of action to include	impacted
		The location of the fracture is	EC clinician manipulation required
	Post manipulation	The position is now	Minimally/non-displaced
		The alignment is now	Minimally/non-angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Fracture clinic follow up
8	**Pre**	The location of the fracture is	Midshaft

	manipulation	The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Displaced
		This fracture is (impactation)	Angulated
		Recommended Immediate course of action to include	Minimally/non-impacted
		The location of the fracture is	EC clinician manipulation required or orthopedic manipulation required
	Post manipulation	The position is now	Displaced
		The alignment is now	Angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Orthopedic manipulation required
9	**Pre manipulation**	The location of the fracture is	Distal
		The following anatomical structures are involved	Radius
		The position is	Fracture
		The alignment is	Minimally/non-displaced
		This fracture is (impactation)	Minimally/non-angulated
		Recommended Immediate course of action to include	Minimally/non-impacted

		The location of the fracture is	Conservative management and fracture clinic follow up
	Post manipulation	The position is now	Minimally/non-displaced
		The alignment is now	Minimally/non-angulated
		This fracture is now	Minimally/non-impacted
		Recommended course of action to include now	Fracture clinic follow up

4. Questionnaire/ data capture instrument (listed as appendix B in Part B)

Title of the research project: Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as a reference standard by emergency centre clinicians in the Cape Town metropole

Managing fractures in the emergency centre

Basic information

Please select one of the options below:

1. Please enter your age

2. When did you graduate from your primary medical degree (MBChB, etc.)

- pre-1999
- 1999-2003
- 2004-2008
- 2009-2013
- 2014-2018

3. What is your current role

- Community service
- Medical officer
- Trainee/ registrar
- Consultant

4. What is your specialty

- Emergency medicine

- General practice
- None
- Other (please specify)

5. How long have you worked in emergency care

- less than 1 year
- 1-5 years
- 5-10 years
- More than 10 years
- I have never worked in emergency care

Managing fractures in the emergency centre

Case 1

A 46-year old female with no significant past medical history presents after falling from her chair and landing on outstretched right hand. She complains of pain in the right wrist. The right wrist appears swollen, has a limited range of movement and is tender on palpation. It is neuro-vascular intact distal to the injury and with no obvious deformity.

The image below shows her initial X-rays which demonstrate a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

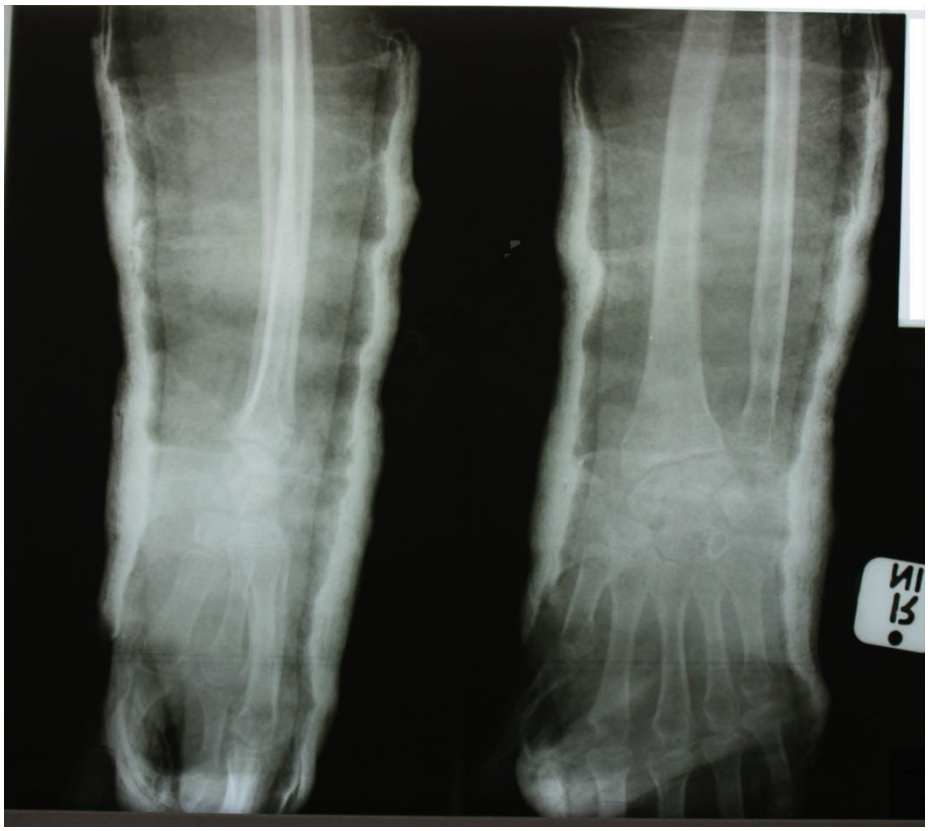
5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.



1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required

○ Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre
Case 2

A 30 year old male patient was involved in a pedestrian-vehicle accident resulting in an injured right arm. He is complaining of a painful, swollen and deformed right wrist. His right wrist has an obvious deformity, is swollen and is tender on palpation. It isneurovascularly intact distal to the injury.
The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

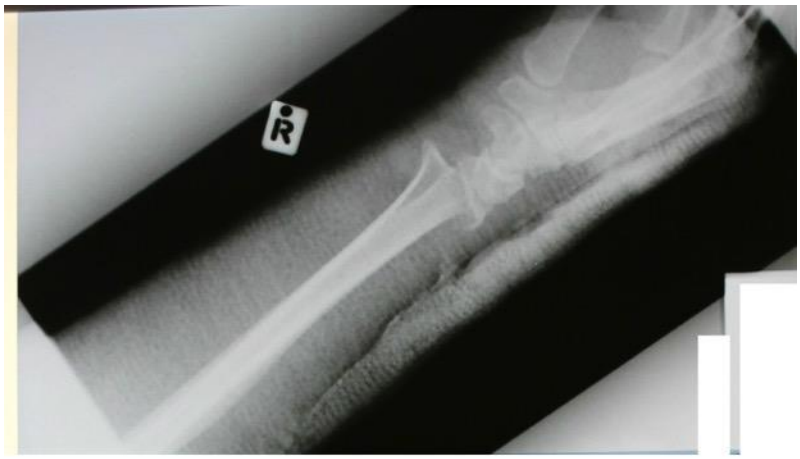
5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.



1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted

- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre
Case 3

A 28-year old male is seen in the emergency centre with a history of injuring his right arm whilst playing rugby. On examination he has a tender right forearm with presents a limit range of movement at both the elbow and wrist. It is neurovascularly intact distal to the injury.
The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.

1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre
Case 4

A 67-year old male presents to the emergency centre with a history of fallen from a “bakkie” onto an extended right hand. He is complaining of pain and difficulty in movement of the right wrist. On examination he is markedly swollen and deformed at the right wrist, tender to touch, with limited movement. It is neurovascularly intact distal to the injury.
The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.

1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted

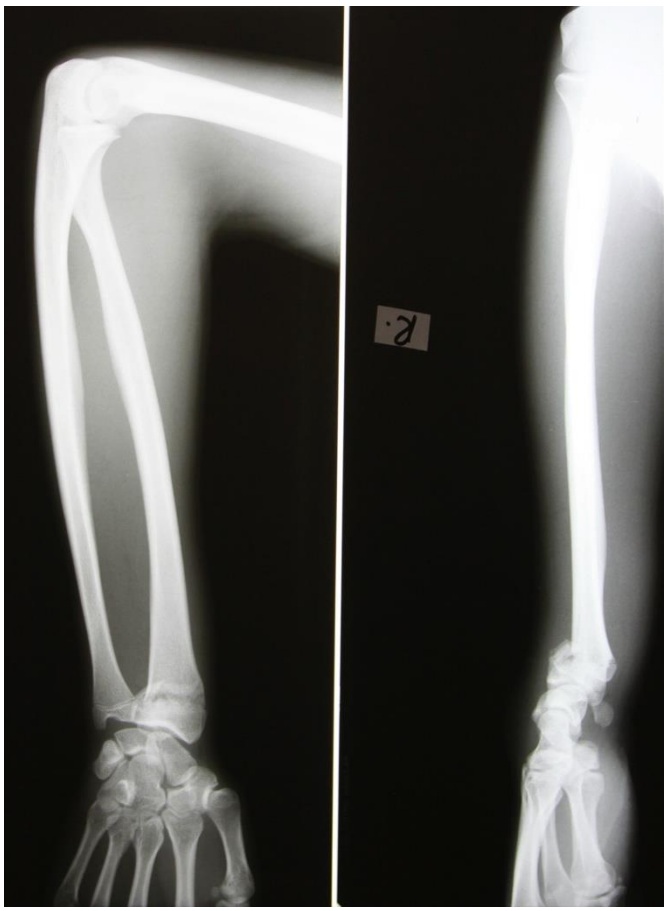
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre
Case 5

A 16-year old male presented as a victim of a pedestrian-vehicle accident, resulting in a right arm injury. He presents to the emergency centre complaining of pain to the right wrist. The right wrist is deformed with associated swelling and tenderness to touch. It is neurovascularly intact distal to the injury.
The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.



1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.

1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

Case 6

A 70-year old male is referred from the day clinic with pain of the left wrist after falling on an outstretched hand a week ago. He has an obvious swelling of the left wrist and decreased range of movement. The wrist is tender on palpation, with limited range of movement. It is neurovascularly intact distal to the injury.

The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

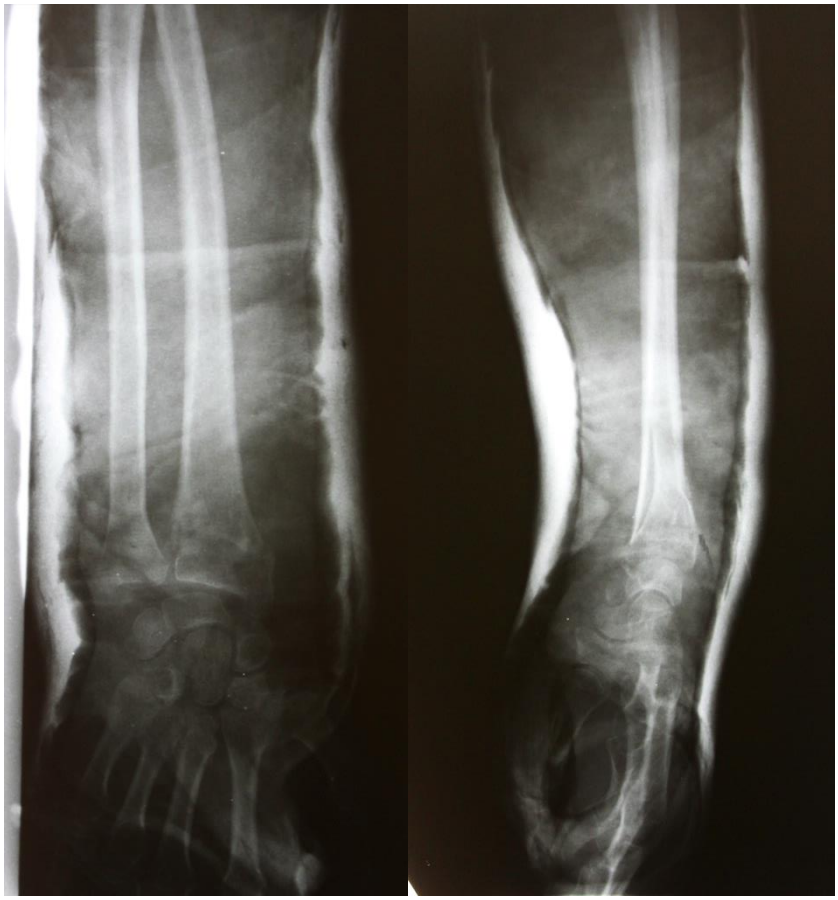
5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.



1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required

- Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre

Case 7

A 52-year old female is referred from day clinic with a history of falling on an outstretched right hand. Her right wrist has an obvious deformity and is swollen. It is neurovascularly intact distal to the injury.
The image below shows her initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.

1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

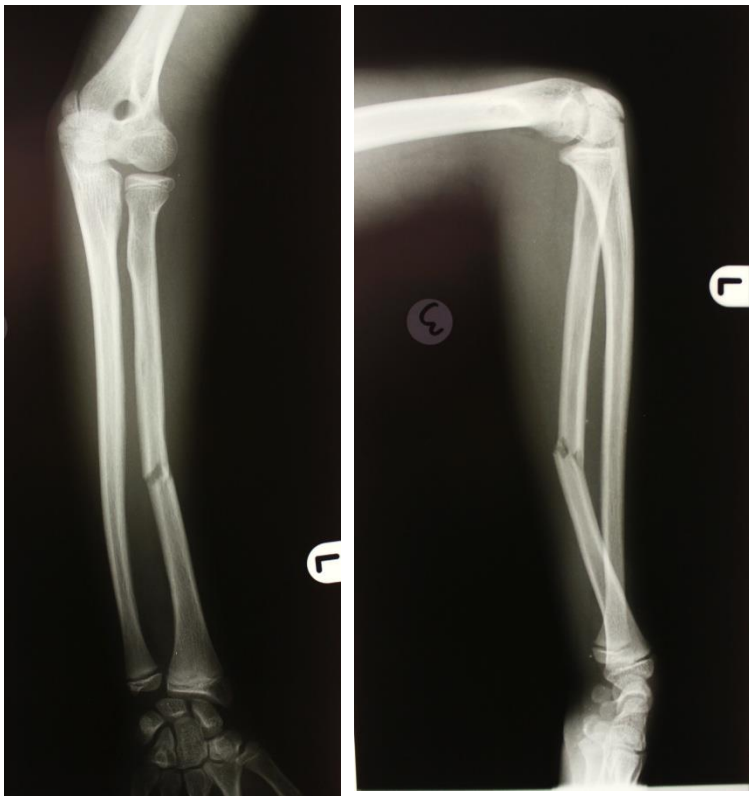
- Fracture clinic follow up
- Further EC clinician manipulation required

- Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre

Case 8

A 15-year old male patient presents with an injury of the left arm while playing soccer at school. On examination the left forearm is deformed. The patient cannot extend the wrist due to pain but can extend and flex the fingers. There is little to no swelling. It is neuro-vascularly intact distal to the injury. His past medical history includes a history of previous fractures: a left greenstick fracture and left distal radius fracture in 2012, and an injury of the right fifth finger in 2017.
The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.



1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.

1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up
- Further EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

Managing fractures in the emergency centre

Case 9

A 15-year old male is referred from day clinic with an injury of the right wrist after a fall. The patient is complaining of painful right arm. On examination he has swelling of the right wrist with pain on movement. It is neurovascularly intact distal to the injury.
The image below shows his initial x-rays which demonstrates a fracture. Please study the images and then answer the questions below.

1. The location of the fracture is:

- Distal
- Midshaft
- Proximal

2. The following anatomical structures are involved:

- Radius
- Ulna
- Radius and ulna
- Radius, ulna and scaphoid
- Other carpal

3. The position is:

- Displaced
- Minimally/ non-displaced

4. The alignment is:

- Angulated
- Minimally/ non-angulated

5. This fracture is:

- Impacted
- Minimally/ non-impacted

6. Recommended Immediate course of action to include:

- Conservative management (plaster) and primary clinic follow up
- Conservative management (plaster) and fracture clinic follow up
- EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

The image below shows the post-manipulation x-rays for the same fracture. Please study the images and then answer the questions below.

1. The position is now:

- Displaced
- Minimally/ non-displaced

2. The alignment is now:

- Angulated
- Minimally/ non-angulate

3. This fracture is now:

- Impacted
- Minimally/ non-impacted

4. Recommended course of action to include now:

- Fracture clinic follow up

- Further EC clinician manipulation required
- Orthopaedic manipulation required (in theatre)

5. Data/Responses collection sheet (appendix C)

Participant No:		**Responses**
Basic information	**Present your age**	
	When did you graduate from your primary medical degree (MBChB, etc.)	
	What is your current role	
	What is your specialty	
	How long have you worked in emergency care	

		Case 1	**Case 2**	**Case 3**	**Case 4**	**Case 5**	**Case 6**	**Case 7**	**Case 8**	**Case 9**
Part I	**The location of the fracture is:**									
	The following anatomical structures are involved									
	The position is:									
	The alignment is:									
	This fracture is (impacted):									
	Recommended Immediate course of action to include:									

		Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7	Case 8	Case 9
Part II	**The position is now:**									
	The alignment is now:									
	This fracture is now:									
	Recommended course of action to include now:									

6. Acknowledgements

Special thanks to my supervisors, Dr Phillip Cloete and Prof Stevan Bruijns, for their support and guidance throughout this entire dissertation process, as without them I would not have been able to finish and complete this work.

Thank you to all the participants for their contribution to the questionnaire.

7. Research Protocol

Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as reference standard by emergency centre clinicians in the Cape Town metropole.

Student name: **Dr. Melisanda Goncalves**

Affiliation: **University of Cape Town**

Student number: **SCHMEL018**

Supervisor:

DR Philip Cloete, MMED (EM), FCEM (SA), Victoria Hospital

Colaborator:

Dr. Stevan Bruijns, PhD, Senior lecturer, Division of Emergency Medicine, University of Cape Town

Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as reference standard by emergency centre clinicians in the Cape Town metropole.

Abstract:

Introduction: Reduction of forearm and wrist fractures under procedural sedation is a common practice in the emergency Centre (EC). The upper extremity is the most commonly injured extremity (6), therefore, early management with appropriate stabilisation and anatomic reduction is of great importance. In African ECs, because of the resource: workload ratio (a small number of clinicians versus a high number of patients), as well as the relative experience of EC clinicians, good early management of fractures in the EC may have an impact on the number of patients that require optimizing of fracture care downstream. This study will provide a first look into EC fracture care. The aim of this study is to describe the diagnostic and management accuracy of EC clinicians using validated vignettes (also used as the reference standard) of adult patients with closed fractures of the forearm or wrist.

Method: A prospective, cross-sectional study design will be used. Data will be collected in the form of an electronic survey. The vignettes will be constructed from ten cases of wrist or forearm fractures that were managed through the EC of Victoria Hospital. Each vignette will constitute a brief clinical history, and the pre- and post-x-ray sets. Each x-ray set (two per vignette) will have a set diagnosis and description (position, angulation, and impaction). Each vignette will also have a set course of action required for each x-ray set included. All EC clinicians actively employed at a secondary level public hospital EC in the Cape Town metropole will be included in the study.

Ethics: Personal information of patients and clinicians participating will not be used or exchanged; it is unlikely that the hospital services will be compromised. Data collected will be entered into a password protected electronic spreadsheet, which will only be accessible by the research team. An informed consent statement will be included in the body of the email message containing the link inviting the participants to take the survey. The informed consent statement will be in accordance with the Informed Consent Standard Operating Procedure from the Human Research Ethics Committee.

1. Project title

Evaluation of the diagnostic and management accuracy of closed fractures of forearm and wrist using validated vignettes as reference standard by emergency centre clinicians in the Cape Town metropole.

2. Background & Motivation

Reduction of forearm and wrist fractures under procedural sedation is a common practice in the emergency Centre (EC). From all skeletal fractures, 16% are fractures of the distal radius; 25% of all limb fractures are of the wrist, with 75% of these involving the distal radius and ulna (1,2). In adults, distal radial fractures are more frequently seen in patients aged 60-69 years (3). The mechanism of injury of forearm fractures, including the wrist, is variable, including direct trauma, fall from a height, road traffic accidents, and sporting injuries (4).

According to a study of hand and forearm fractures in the United States in 1988, 1.5% of all fractures seen in EC were hand/forearm fractures and 44% of these were radial and/or ulnar fractures (5). Accidental falls (47%) were the main cause, with most of the fractures occurring at home (30%) (5).

Fractures of the forearm can be classified as proximal, middle, or distal depending on the shaft segment involved, affecting one or both forearm bones, and be open or closed (6,7). Additionally, proximal forearm fractures can affect the elbow joint and distal forearm fractures can affect the wrist joint (6,7).

Because the upper extremity is the most commonly injured extremity (6), it is important that EC doctors are familiar with the appropriate management thereof (6). The standard treatment of a fracture involves reduction and immobilization. Because the radius and ulna support each other, and their importance for the normal function of the elbow and wrist joint, mal-union of these bones may result in deformity and loss of mobility of the associated joints (8,9). Therefore, early management with appropriate stabilisation and anatomic reduction is of great importance.

Fracture management in the EC varies depending on the fracture although the standard method involves a combination of traction, reduction, and immobilization. Immobilization is most commonly achieved by applying a plaster of Paris back slab, which is held in place by crepe bandages. A repeat X-ray post manipulation is required to evaluate the position of the fragment and to provide the EC doctor with the information required to decide whether

further manipulation is required before referral for inpatient or outpatient management. If further manipulation is required this is deferred to the orthopaedic team, to be performed under general anaesthesia.

A study performed in a tertiary hospital in Western Australia to assess radiographic outcomes from EC reduction of Colles-type fractures in patients between 21-85 years old showed that in the group of patients with displaced fractures, 69 of 114 (61%) either went on to require surgery or resulted in a poor radiographic outcome (8). A study performed in an EC of a level one paediatric trauma centre in the US showed that the use of a mini C-arm in EC to assist with the reduction of fractures of the forearm and wrist improved the quality of the reduction and decreased the need for repeat fracture manipulation. The study showed that only 2% of 133 fractures reduced with the assistance of imaging needed further manipulation or surgical treatment vs. 8,4% of 166 fractures reduced without imaging assistance (10).

An abbreviated literature search found no data regarding EC fracture management and outcomes in South Africa. In African ECs, because of the resource: workload ratio (a small number of clinicians versus a high number of patients), as well as the relative experience of EC clinicians, good early management of fractures in the EC may have an impact on the number of patients that require optimizing of fracture care downstream. This can have a substantial impact on cost reduction.

Presently, we do not know whether EC clinicians manage simple fractures such as those of the forearm adequately. Anecdotal evidence suggests that it is not as good as it can be. Given that forearm fractures are relatively common fracture-wise, if EC clinicians are unable to manage these adequately then this likely provides a signal that other fractures are also inadequately cared for. This will be the first study on this topic and it will provide a first look into EC fracture care. It is likely that this work will lead to further exploratory work on this potential cost-saving topic.

3. Research question

In adult patients with closed forearm or wrist fractures can EC clinicians diagnose, describe and recommend the correct course of action when using a validated set of vignettes as reference standard?

4. Aim & Objectives

The aim of this study is to describe the diagnostic and management accuracy of EC clinicians using validated vignettes (also used as the reference standard) of adult patients with closed fractures of the forearm or wrist.

- To derive and validate a set of vignettes of adult patients with closed fractures of the forearm or wrist to serve as the reference standard for this study.
- To compare the fracture diagnosis and description (position, angulation, and impaction) as described by a cohort of EC clinicians against the reference standard.
- To compare the recommended course of action as described by a cohort of EC clinicians against the reference standard

5. Study Methodology

5.1. Study design

A prospective, cross-sectional study design in the form of an electronic survey will be used. The vignettes will serve as the control for the study participants.

5.2. Study Setting, Population and sample

Te study will include all EC clinicians actively employed at a secondary level public hospital EC in the Cape Town metropole. Because the existing emergency medicine pool is relatively small, the sample will include specialists, specialist trainees, medical officers, community service medical officers, and interns to be able to obtain a convenience sample. We will exclude clinicians, not in the direct employ of the public sector. We expect to collect data from at least 50 clinicians; that is a 50% return from an estimated 100 EC clinicians (approximately 20 staff members per EC times five ECs). We appreciate that this sample size will not allow sub-group analysis, but feel that seeing that this is the first study into this topic within this setting, starting with a smaller, convenience sample would be appropriate. The findings from this study can then be used to calculate more appropriate sample sizes for future local studies.

5.3. Vignettes, data collection and management

The Vignettes

The vignettes will represent both the cases used in the survey as well as the correct reference answers to each of the clinical questions posed in the vignette. These will then be used to compare answers from the survey participants.

The lead investigator (MS) will collect, at the fracture clinic of Victoria hospital, ten cases each of wrist or forearm fractures that were managed through the EC of Victoria hospital as the basis for constructing the vignettes. These will include a selection of proximal (including carpals), midshaft and distal fractures. Each vignette will constitute a brief clinical history, and the pre- and post-x-ray sets. Each x-ray set (two per vignette) will have a set diagnosis and description (position, angulation, and impaction). The fracture description will be presented in a binary format: position- displaced or minimally/ non-displaced; alignment- angulated or minimally/ non-angulated, and impacted or minimally/ non-impacted.

Each vignette will also have a set course of action required for each x-ray set included. The course of action may include: conservative management no follow up, conservative management and follow-up, EC clinician manipulation required, further EC clinician manipulation required and orthopaedic manipulation required (in the theatre).

The draft vignettes will then be checked and edited by the study supervisors (SB and FC) and the orthopaedic lead at Victoria hospital. To validate, vignettes will be shared with two emergency physicians external to the study to comment on the context and readability of individual vignettes.

Data collection and management

Data will be collected using an institutional subscription to the e-survey client, Survey Monkey. The e-client will be used to send the vignettes for interpretation to:

- Heads of secondary level, Cape Town ECs for distribution to EC clinicians
- Emergency medicine trainees through the divisional education database

The survey will collect the following additional variables: age of the participant, experience in years, formal qualifications, and job description. We will collect data about employment (Western Cape Government employee | South African medical student| work experience) mainly to ensure non-public sector employees that may end up taking the survey can be excluded at the backend. The survey will collect the proposed variables related to the ten cases as described in Table 1; participants will have to choose between the options presented in table 1. No personal identification of EC clinicians or facilities will be required for data collection. The e-survey client will be set to collect information anonymously. This

setting allows for reminders to be sent out. At the outset, the lead researcher will visit all facilities included promoting the study. A poster with a QR-link to the study will be placed in each facility's clinician rest area to assist with promotion. The survey will remain open for four weeks, with reminders sent weekly. Should an insufficient sample be collected at this point, the survey will remain open for another two weeks and reminders will be intensified. Data will be transferred to a password-protected Microsoft Excel spreadsheet (Microsoft Office, Redmond, USA) by the lead investigator. The captured electronic data will be saved on a password-protected work computer. Only the study team will have access to the data.

Table 1. Proposed variables to be collected for each vignette
1. X-ray set 1 1.1. Diagnosis: [(distal | proximal | midshaft) (radius | ulna | scaphoid | other carpal) (fracture | greenstick | torus) 1.2. Position: [displaced | minimally/ non-displaced] 1.3. Alignment: [angulated | minimally/ non-angulated] 1.4. Impaction: [impacted | minimally/ non-impacted] 1.5. Course of action may include: conservative management no fracture clinic follow up | conservative management fracture clinic follow up | EC clinician manipulation required* | further EC clinician manipulation required | orthopaedic manipulation required (in theatre) 2. X-ray set 2 (* continue to x-ray set to if selected) 2.1. Position: [displaced | minimally/ non-displaced] 2.2. Alignment: [angulated | minimally/ non-angulated] 2.3. Impaction: [impacted | minimally/ non-impacted] 2.4. Course of action may include: Fracture clinic follow up | further EC clinician manipulation required | orthopaedic manipulation required (in theatre)

5.4. Timeframe

Planning the project	2 months
EMDRC (EM Divisions' Research Committee): submission and approval	2 months
HREC (Human Research Ethics Committee): submission and approval	2 months

WCG approval	2 months
Data collection	3 months
Analysis of data and submission.	6 months
Total (estimated) timeframe	17 months

5.5. Statistical analysis

Data will be collected using an institutional subscription to the e-survey client, Survey Monkey as described. Data analysis will be conducted using Microsoft Excel. Data will be expressed as proportions for each variable and presented in tables and figures and will mainly be descriptive. A comparison will be made using the vignette as the reference standard and the various clinicians' decisions. This will then be described in terms of accuracy (sensitivity, specificity, and likelihood ratio). We will present 95% confidence intervals of these calculations. Subgroup analysis may be attempted and if so will include similar analysis. As stated previously we are aware of the limitations related to the sample size. Inferential statistics may be included to compare categorical data using Fisher's exact or the chi-square, although this will need to be reviewed given the various sizes of the groups resulting from the data. The analysis will mainly focus on providing descriptive statistics. Data will be transferred to a password-protected Microsoft Excel spreadsheet (Microsoft Office, Redmond, USA) by the lead investigator. The captured electronic data will be saved on a password-protected work computer. Only the study team will have access to the data.

6. Proposed Budget – estimated

	Description	**Unit cost**	**Total cost**
I.	***Research travel*** *(according to AA rates, see below)*	R2,87/Km	R443,13
II.	***Supplies and Materials***		
	Paper (1 pack A4 white copy paper 500 sheets)	R47.99	R47.99
	Printer black cartridge	R250.00	R250.00
	Pens (2 x pack of 2)	R14.99	R29.98

III.	**Statistical service** – *not applicable*	0	0
IV.	**Telephone / Internet** - *estimated*		R500.00
	Total direct cost		***R1,271.10***
	Inflation (10%)		***R127.11***
	Total cost		**R1,398.21**

Travel breakdown

Travel would be required to post posters and promoting the research at ECs. This will come to 154.4 km at R2.87 per km (AA rates). Data will be required for completing work on the survey (design, etc.), although this could likely be reduced if this part of the work is completed at the Division offices, which has an eduroam hotspot.

7. Ethical considerations

7.1. Description of risks and benefits

This is a low-risk study and the participants. Personal information of patients included in the vignettes and clinicians participating will not be used or exchanged; the data collection will be completed by the research team as described. There is always a minimal risk of privacy lapse although we are confident that the methods adequately safeguard against these risks. It is unlikely that the hospital services (including the EC and the orthopaedic service) will be compromised during vignette design and completion of the survey. It would, however, be difficult to control how and when participants access the survey. Data collected will be entered into a password protected electronic spreadsheet, which will only be accessible by the research team.

It is unclear how well emergency care providers diagnose and manage simple forearm and wrist fractures. Better management at the front door of this commonly seen fracture may provide substantial downstream benefits in terms of quality, efficiency, and cost. The results of the study may be used to give feedback and recommendations to stakeholders to improve the service regarding the acute EC fracture care, however, the real value would be in using this data to plan larger future studies. We feel that the benefits of this study outweigh the low risks.

7.2. Simple consent process

Written permission will be obtained from the management of the hospital and relevant heads of departments where the information will be collected to construct the vignettes. An informed consent statement will be included in the body of the email message containing the link inviting the participants to take the survey. The informed consent statement will be in accordance with the Informed Consent Standard Operating Procedure from the Human Research Ethics Committee (Annex 1). The information will again be provided at the start of the survey and subjects will have to click to confirm they understand the content to continue to the survey. No personal identification from the participating clinicians will be collected.

7.3. Privacy and confidentiality

This is a low-risk study and is not life-threatening for any of the participants in the study. No personal identification of EC clinicians or facilities will be required for data collection. The e-survey client will be set to collect information anonymously, maintaining the confidentiality of all participants. Data will be transferred to a password-protected Microsoft Excel spreadsheet by the lead investigator. The captured electronic data will be saved on a password-protected work computer. Only the study team will have access to the data.

7.4. Reimbursement for participation

None of the participants in this study will be reimbursed.

7.5. Emergency care and insurance for research-related injury

Insurance for research-related injury is not indicated for this study.

8. Limitations

There are no other studies on this topic in South Africa or Internationally so will not be possible to make comparisons regarding EC doctors' ability to manage fractures. The study will only consider hypothetical management. Real management will have to be confirmed. The study will only consider the management of closed fractures of the forearm and wrist. Therefore further investigation will be required to evaluate the management of other fractures as well as open fractures.

In general, consultants are clinically less active than the non-consultants in the EC. However, the existing emergency medicine pool is relatively small, already requiring a convenience sample. This is the main reason why will include the consultants in this study. It should be

noted that participation is voluntary and that staff not willing to participate would not be required to do so.

The vignettes are a construction of the study team and can indeed be flawed for that reason. The derivation and validation of the vignettes are basic but should be sufficient for the purposes of the study. Care has been taken to include knowledgeable contributors to the vignettes as well as validation. Not making use of more orthopaedic surgeons may be a limitation, however, we feel that this would only apply if the study was conducted with orthopaedic staff and not emergency medicine staff as described. There would be subtle differences (eg. more detailed fracture descriptions apply for orthopaedics than are necessary for emergency medicine purposes). We therefore feel that the vignette derivation should be sufficient and indeed apply within an emergency medicine field. Naturally, vignettes can be refined in follow-up research.

Validation of Data: the validity of the data is entirely dependent on the internal validity of the vignettes. We intend to disclose the derivation process of the vignettes in any study outputs.

External validity: unlikely to be valid in the private sector or high-income settings where resources are more available. There are only ten vignettes and much more iterations of forearm or wrist fractures. May not be inclusive of the entire spectrum of disease. Using a closed-ended survey means that opinion is lost, as clinicians have to select an answer from the list of answers.

References

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8. HREC approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

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24 July 2017

HREC REF: 537/2017

Dr P Cloete
Emergency Medicine
C/O Aileen Maas
F51, OMB

Dear Dr Cloete

PROJECT TITLE: EVALUATION OF THE DIAGNOSTIC AND MANAGEMENT ACCURACY OF CLOSED FRACTURES OF FOREARM AND WRIST USING VALIDATED VIGNETTES AS REFERENCE STANDARD BY EMERGENCY CENTRE CLINICIANS IN THE CAPE TOWN METROPOLE-(MPhil-candidate-Dr M Goncalves)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

- Please change "Health Research Ethics Committee" to 'Human Research Ethics Committee' in the informed consent form.

Approval is granted for one year until the 30 July 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

The HREC acknowledge that the student, Dr Melisanda Concalves will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC 537/2017