OUTCOMES OF NON-OPERATIVE TREATMENT VERSUS PLATE FIXATION OF DISPLACED MIDSHAFT CLAVICLE FRACTURES IN ADULT PATIENTS IN A WITS TEACHING HOSPITAL

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Declaration

I, Mluleki Tsama, do hereby declare that this report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Mluleki Tsama

Signed: …….

……day of……..2017 in ……

Dedication

This work is dedicated to my wife Belinda Mmabatho Kgokong-Tsama who has been very supportive during the preparation of this project.

Abstract

Background

The treatment of displaced midshaft clavicle fractures remains a topic of controversy. In the current literature, most authors favour plate fixation in treating these injuries while some still believe in the traditional non-operative approach.

Methods

24 adult patients with displaced midshaft clavicle fractures were randomised to either operative treatment with a precontoured plate (13 patients) or non-operative treatment (11 patients) with an arm sling. At three months follow up their DASH scores; Constant Murley shoulder scores and radiographic evidence of union were compared.

Results

There was a statistically significant difference between the two groups with the surgical group having better results evidenced by low DASH scores (p=0.008) as well as high Constant Murley shoulder scores (p=0.004) and better union rates (p=0.001) compared to the non-operative group.

Conclusion

Primary plate fixation of displaced midshaft clavicle fractures should be considered as it gives better functional and radiographic outcomes compared to non-operative treatment in adult patients.

Acknowledgements

I owe my deepest gratitude to my supervisors Professor A.A. Aden and Dr. T. Sefeane whose encouragement; guidance and support from the initial to the final stages enabled me to develop an understanding of this research topic.

I would also like to thank Professor F. Bischof, Dr. B. L. Milner, Dr. M. Jingo and Mr. A. Poopedi from the department of Orthopaedic Surgery for their input in ensuring a successful outcome for this research report.

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Lastly, I would like to thank the University of the Witwatersrand and the Helen Joseph Hospital for allowing me to conduct the research in their institutions.

Mluleki Tsama

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NOMENCLATURE

DASH Score – Disabilities of the Arm, Shoulder and Hand score

SK Test – Skewness and kurtosis test

CHAPTER ONE

1.0 Introduction and literature review

1.1 Anatomy of the clavicle

The clavicle, commonly known as the collarbone forms a connection between the trunk and the upper limb.[1] The collarbone has a poorly defined medullary cavity and it is a dense bone.[2] It is configured in an S-shape and has two curves in the horizontal plane. One curve is on its distal half and is concave anteriorly; the second curve is on its proximal end where it is convex anteriorly.[1, 3]

The collarbone has a flat distal end; this is where the articulation with the acromion of the scapula takes place at the acromioclavicular joint. The middle third is tubular, and the proximal end is triangular where the articulation with the sternal manubrium takes place.[1-3]Due to the fact that the clavicle is narrowest in its midsection, most fractures occur in this region.

One of the functions of the clavicle is to maintain the width of the shoulder by acting as a strut. In this way, it provides stability and power to the arm-trunk mechanism.[2, 3]This means that if the clavicle shortens as a result of malunion following a fracture, this will have a negative effect on shoulder function.[3] The other function of the clavicle is to protect the axillary and the subclavian neurovascular structures.[2, 3]

The motion of the clavicle takes place with abduction and elevation of the arm. It presents elevation of 11 to 15 degrees; posterior displacement of 15 to 29 degrees and posterior rotation of 15 to 31 degrees during arm elevation.[5] Clavicular rotation is limited as long as the elevation of the arm is below 90 degrees. This means that the clavicle can be rehabilitated under the plane of the shoulder with rotational forces kept to a minimum at the fracture site.[3, 5]

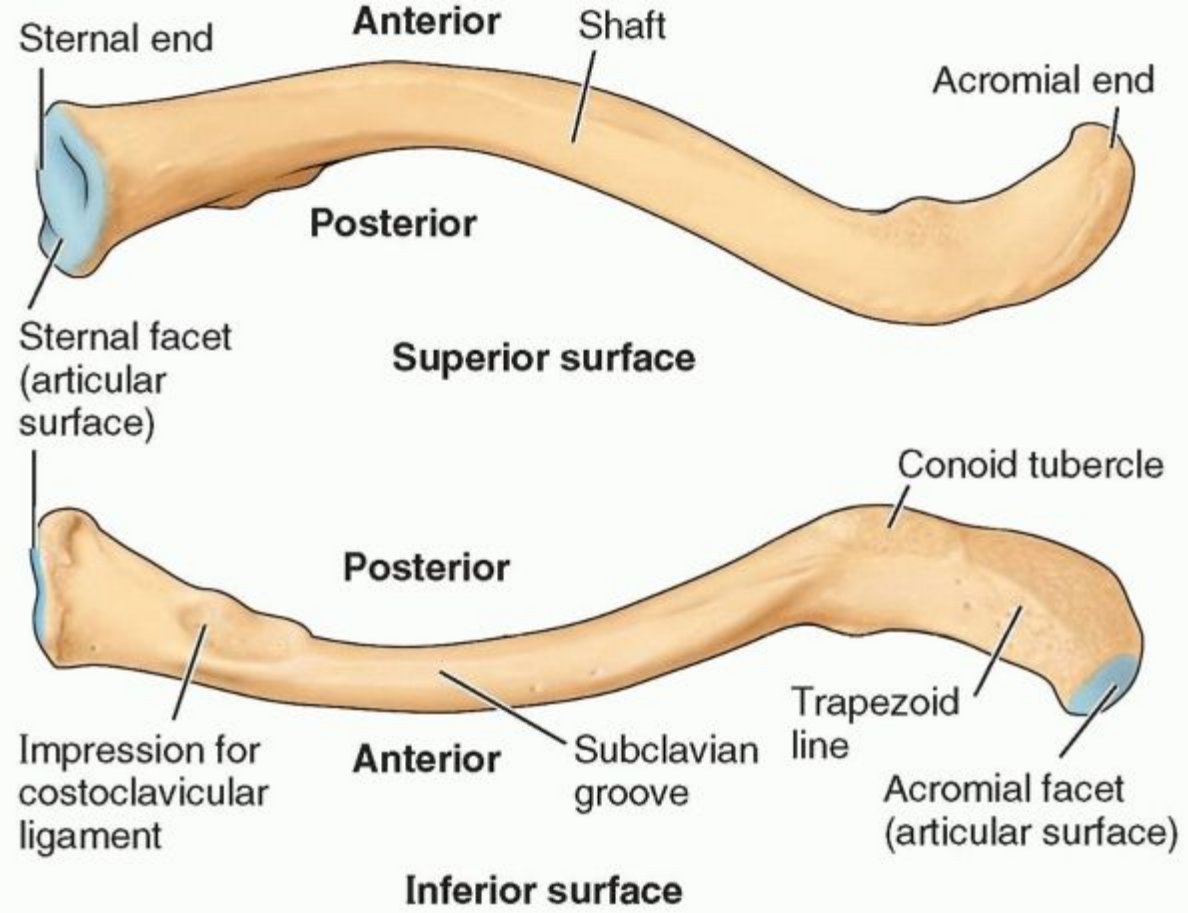


Figure. 1.1: A picture demonstrating the anatomy of the clavicle.[1]

Medial end of the clavicle	Lateral end of the clavicle

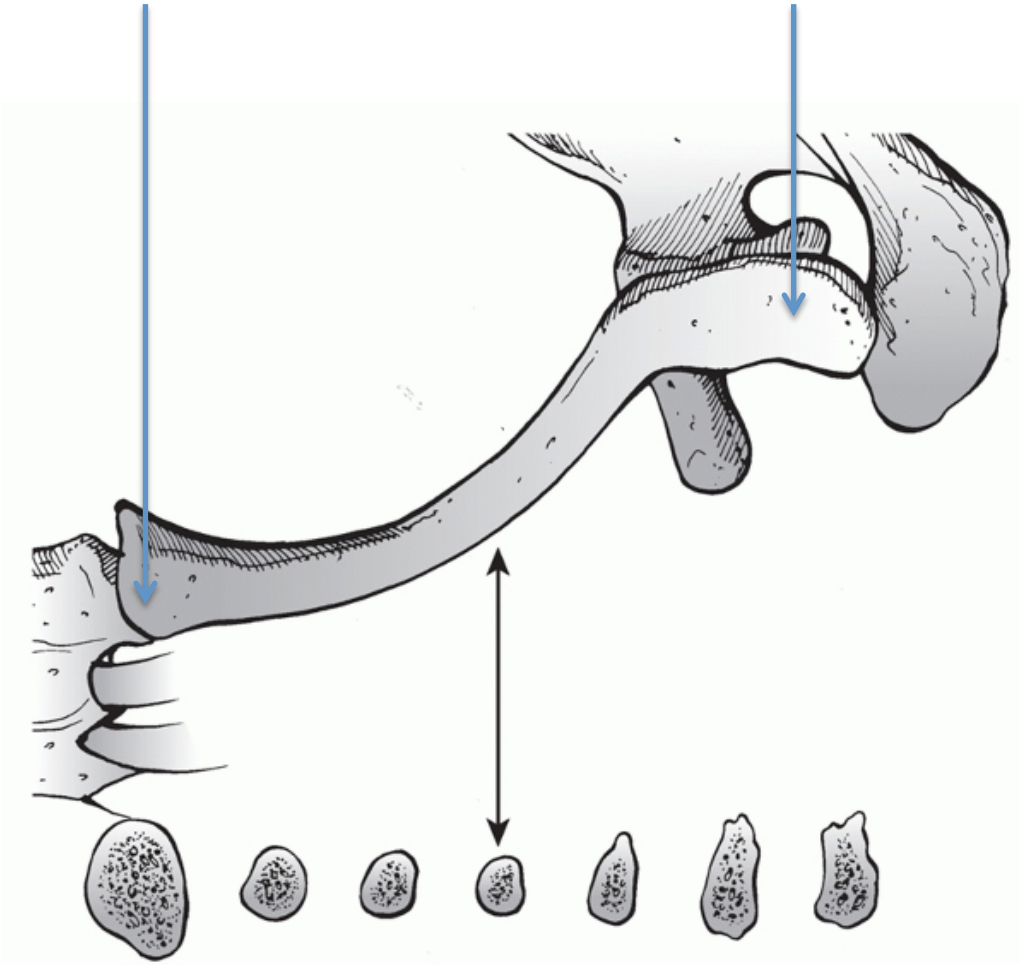


Figure 1.2: A picture demonstrating the different diameters of the clavicle at different sections, the narrowest being the middle section, this is where most fractures occur. [4]

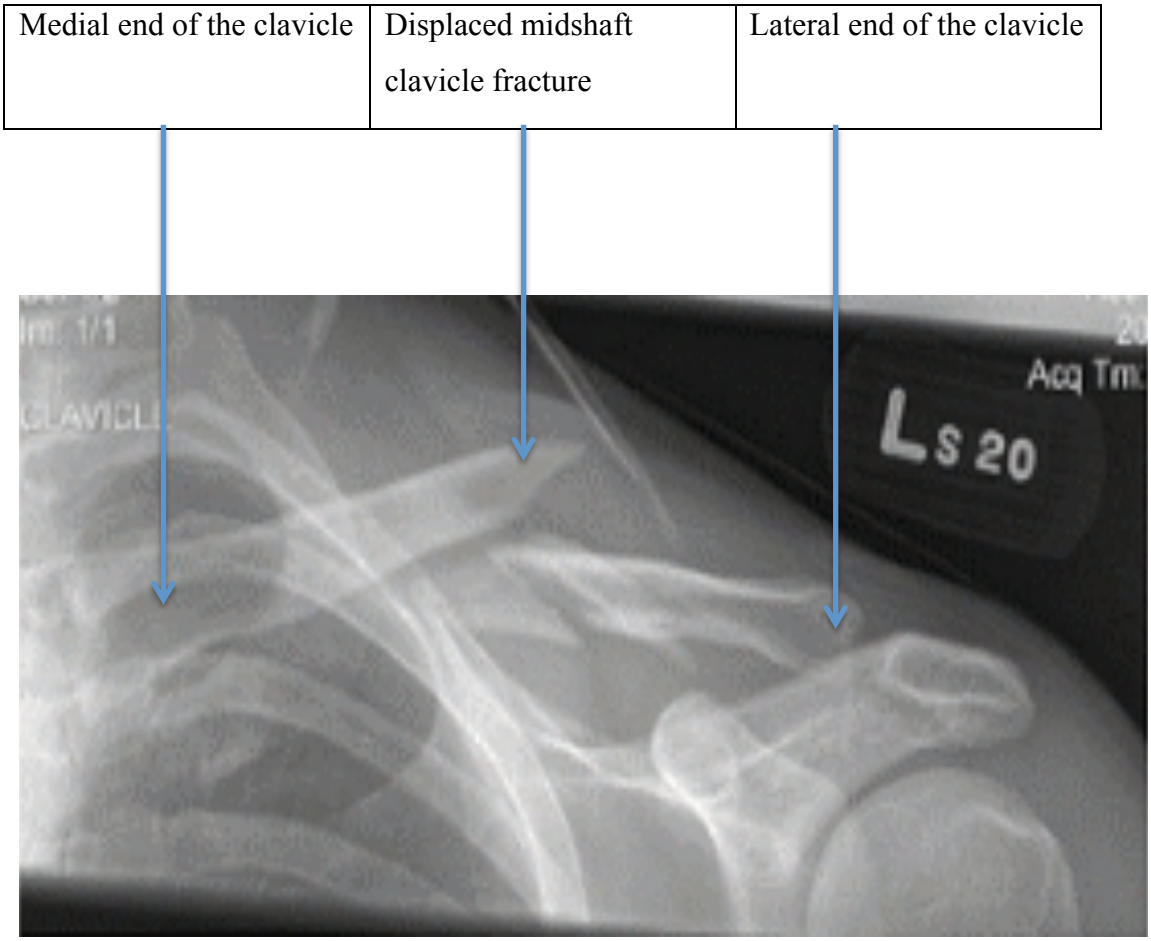


Figure 1.3: A radiograph showing a displaced midshaft clavicle fracture on the left side.[4]

1.2 Literature review

Fractures of the clavicle account for a total of 2.6% of all fractures in the body and 44% of all fractures that involve the shoulder girdle. Fractures involving the middle segment of the clavicle account for approximately 80% of all fractures of the clavicle and 50% of these fractures are displaced.[6]

The mechanism of injury commonly seen is a direct blow to the point of the shoulder rather than a fall on the outstretched arm. Injuries to the clavicle most commonly occur in young, healthy people as a result of sports injuries as well as road accidents. These young people are economically productive and a search for an ideal treatment for these injuries would help them recover sooner and return to work earlier.[3, 6]

In the olden days, these fractures were treated non-operatively even when there was a significant amount of displacement.[2, 7] This treatment approach to these fractures was based on publications that came out in the 1960s which suggested that nonunion of the clavicle was a rare occurrence and malunion was said to be of radiographic interest and had no clinical significance.[2, 7, 8]

Neer published one of these early studies in 1960.[2] He had a large group of 2235 patients treated non-operatively and only reported three (0.1%) patients with nonunion. He also reported results on 45 patients who were treated operatively and found two (4.6%) patients with nonunion. He concluded that with non-operative treatment of midshaft clavicle fractures, nonunion was a rare occurrence.[2]

Rowe published his results of a study involving 566 patients in 1968.[7] He reported a nonunion rate of 0.8% in patients treated with non-operative means and 3.7% nonunion rate in those who were treated surgically. His conclusion echoed Neer's: that nonunion of the midshaft clavicle fractures was a rare occurrence following non-operative treatment.[7]

The high rate of nonunion in the surgically treated patients was said to be related to soft tissue damage and stripping during surgery. The other contributing factors included bone loss, inadequate fixation and postoperative infection.[7]

These early studies included children who have greater healing and remodeling potential than adults and this skewed their results. The authors based their results on surgeon oriented outcomes (radiography) and not on patient based outcomes (DASH and Constant Murley shoulder scores) which assess shoulder function and patient satisfaction.[2, 7]

Recent studies suggest higher nonunion rates and poor function in patients treated non-operatively while the surgically treated groups show good union rates with low rates of nonunion and better upper limb function. This information has changed the previously favoured non-operative approach to displaced midshaft clavicle fractures.[8, 17, 18, 19, 20, 21]

The Canadian Orthopaedic Trauma Society in a multicenter randomised trial with 132 patients obtained high Constant Murley shoulder scores and low DASH scores with low nonunion rates in the operative group compared to the non-operative group, which had low Constant Murley shoulder scores and high DASH scores as well as high nonunion rates. They concluded that primary plate fixation of displaced midshaft clavicle fractures results in improved outcomes both functionally and radiographically.[8]

Kulshrestha et al. in a study involving 73 patients obtained good results in the operative group with 100% union rate. They reported a nonunion rate of 29% in the non-operative group. The malunion rate was 36% in the non-operative group versus 4% in the operative group. The operative group showed significantly better Constant Murley shoulder Scores. They concluded that primary plate fixation of displaced midshaft clavicle fractures results in better functional outcomes with low rates of nonunion and malunion in comparison to the non-operative group.[19]

Robinson et al. in a multicenter randomised trial with a total of 200 patients obtained similar results. The non-operative group showed higher nonunion rates compared to the surgical group.[20]

Mckee et al. in a systematic review of randomised clinical trials that included six studies with a total of 412 patients found higher nonunion rates in the non-operative group (29 out of 200) compared to the operative group (3 out of 212). They also reported a high malunion rate (7 out of 200) in the non-operative group compared to the operative group (0 out of 212). They concluded that operative treatment results in lower nonunion and malunion rates with early return to function compared to non-operative treatment.[21]

These current studies are in contradiction to the old literature that used to favour non-operative treatment over operative treatment of displaced midshaft clavicle fractures.

While most authors favour plate fixation of midshaft clavicle fractures over non-operative treatment in current studies, there are still some authors who still believe that non-operative treatment yields good results.[12]

Faldini et al. in a study involving 100 patients treated non-operatively reported excellent functional outcomes measured with DASH score and a union rate of 97%. The conclusion was that non-operative treatment of displaced midshaft clavicle fractures is still appropriate as it yields as good as the results obtained with operative treatment in terms of fracture healing, functional outcomes and patient satisfaction without the potential complications of surgery.[12]

It is evident that there is no agreement as to which is the best method of managing these fractures hence the continuous search for the best method of treating these injuries.

Table 1.1: Outcomes of nonsurgical, surgical and comparative studies

Nonsurgical treatment studies	**Surgical treatment studies**	**Comparative studies**	**Outcomes**
Hill et al.[10] In a study involving 42 patients.			Unsatisfactory results were obtained with nonsurgical treatment. **31% of patients with complaints including shoulder weakness, brachial plexus irritation, cosmetic deformity and residual pain. In conclusion the authors recommended surgical treatment of displaced midshaft clavicle fractures.**
Faldini et al.[12] In a study involving 100 patients.			Reported excellent functional outcomes measured with DASH score and a union rate of 97%. **The conclusion was that non-operative treatment of displaced midshaft clavicle fractures is still appropriate as it yields as good as the results obtained with surgical treatment in terms of fracture healing, functional outcomes and patient satisfaction without the potential complications of surgery.**
Lazarides et al.[13] In a study involving 132 patients.			With non-operative treatment, clavicular shortening of more than 18mm in males and 14mm in females was significantly associated with unsatisfactory results. **Complications included pain, reduced range of shoulder motion, loss of shoulder strength and thoracic outlet syndrome. They recommended surgical treatment in conclusion.**

Nonsurgical treatment studies	Surgical treatment studies	Comparative studies	Outcomes
Mckee et al.[14] In a study involving 130 patients			The strength of the involved shoulder was reduced compared to the uninjured shoulder with a mean DASH score of 24.6 points and a mean Constant Murley shoulder score of 71 points indicating **substantial residual dysfunction with nonsurgical treatment. The authors concluded that with non-operative treatment, there is a level of dysfunction that is detectable with patient based outcome scores.**
Flavin et al.[15] In a study involving 35 patients.			Isokinetic and functional assessment suggested that with non-operative treatment, patients with a high degree of shortening and malunion would benefit from restoring the clavicle to normal length, i.e. **Surgery would be needed in conclusion.**
Murray et al.[16] In a study involving 941 patients.			With nonsurgical treatment, 125 patients developed nonunion. It was found that significant displacement; overlap, fracture comminution and smoking were associated with increased risk of nonunion. **The conclusion was that the treatment of each patient must be individualized; those that are at risk of nonunion should receive surgical treatment and those with a low risk of nonunion to be treated non-surgically.**

Nonsurgical treatment studies	Surgical treatment studies	Comparative studies	Outcomes
	Wijdicks et al.[17] In a systemic review of 11 studies.		Found low rates of minor and major complications following plate fixation as well as low rates of nonunion and malunion. **The conclusion was that plate fixation is a safe treatment option for displaced midshaft clavicle fractures.**
	Campochiaro et al.[18] In a study involving 68 patients with 70 fractures.		Reported excellent results with the use of pre-contoured angular stability plates. **They obtained excellent DASH and Constant Murley shoulder scores with only 2.9% nonunion rate and in conclusion they supported the use of pre-contoured angular stability plate**.
		The Canadian Orthopaedic Trauma Society.[8] In a multicenter randomised trial with 132 patients, 67 patients in the operative group and 65 patients in the nonsurgical group.	Obtained high Constant Murley shoulder scores and low DASH scores with low nonunion rates in the operative group compared to the non-operative group, which had low Constant Murley shoulder scores and high DASH scores as well as high nonunion rates. **The results showed that operative treatment was superior to non-operative treatment at 1 year follow up and in conclusion they recommended primary plate fixation as a treatment of choice for displaced midshaft clavicle fractures.**

Nonsurgical treatment studies	Surgical treatment studies	Comparative studies	Outcomes
		Kulshrestha et al.[19] In a study involving 73 patients, 45 patients in the operative group and 28 patients in the non-operative group.	Obtained good results in the operative group with 100% union rate, they reported a nonunion rate of 29% in the nonsurgical group. The malunion rate was 36% in the non-operative group versus 4% in the surgical group. **They concluded that displaced midshaft clavicle fractures should be treated operatively with a plate.**
		Robinson et al.[20] In a multicenter, randomised, controlled trial with a total of 200 patients, 95 patients in the operative group and 105 patients in the non-operative group.	Showed higher rates of nonunion in the non-operative group compared to the operative group, however when the non-unions were excluded no difference was seen in the DASH and Constant Murley shoulder scores at one year follow up in those patients that had united in both groups. They also noticed a high cost in the treatment of patients using plate fixation. **They concluded that a policy of routine open reduction and plate fixation of these injuries could not be advocated, rather the risk factors for nonunion should be balanced with the risks of surgery.**

Nonsurgical treatment studies	Surgical treatment studies	Comparative studies	Outcomes
		Mckee et al.[21] in systematic review of randomised clinical trials which included 6 studies with a total of 412 patients, 212 patients in the surgical group and 200 patients in the nonsurgical group.	Found higher nonunion rates in the non-operative group (29 of 200) compared to the surgical group (3 of 212). They also reported a high malunion rate (7of 200) in the non-operative group compared to the surgical group (0 of 212). **They concluded that operative treatment results in lower nonunion rates as well as lower malunion rates and early return to function compared to non-operative treatment.**

CHAPTER TWO

2.0 Research aims and objectives

2.1 Motivation for the study

Based on the contradictory views of different authors (see Table 1.1), it is clear that there is no consensus as to which is the best method of treatment for displaced midshaft clavicle fractures. The best treatment method is still being investigated worldwide and this study will hopefully add value to this ongoing research.

2.2 Aim of the study

The aim of this study is to determine the differences in functional outcomes of the upper limb as well as radiological outcomes in patients treated non-operatively *versus* those treated operatively with plate fixation for displaced midshaft clavicle fractures.

2.3 Objectives of the study

2.3.1 Clinical assessment of surgical and non-operative groups of patients with displaced midshaft clavicle fractures

Assessment of functional outcomes in the two groups was effected using two clinical functional outcome scores: Disabilities of the Arm, Shoulder and Hand score (DASH) (see Appendix E) and the Constant Murley shoulder score (see Appendix F).

2.3.2 Documentation of individual groups' functional scores

Individual functional outcome scores were documented and a comparison between the two groups was made using the Mann–Whitney Ranksum test.

2.3.3 Radiographic assessment and documentation of bone union

Radiographic assessment and documentation of bone union were effected using the radiographic assessment form for fracture union (see Appendix G).

2.4 Ethics

Ethics approval was granted by the Wits Human Research Ethics Committee (Medical), University of the Witwatersrand, Johannesburg; the ethics clearance number is M140753 (see Appendix A). The title of the study was approved by the Post Graduate Committee, University of Witwatersrand, Johannesburg (see Appendix B). The hospital clearance was obtained from the superintendent of the hospital (Helen Joseph Hospital) (see Appendix C). An informed consent was obtained from each patient participating in the study (see Appendix D).

CHAPTER THREE

3.0 Methodology

3.1 Study design

The study was a prospective randomised trial aimed at comparing the functional and radiological outcomes in adult patients presenting with displaced midshaft clavicle fractures in a Wits teaching hospital (Helen Joseph Hospital).

The study involved twenty-four adult patients with displaced midshaft clavicle fractures. All fractures were closed injuries and no pathological fractures were included. There were fifteen males and nine females in the study. The dominant hand was involved in fifteen of the twenty-four patients. Our patients had sustained fractures from different mechanisms of injury. Five fractures were sustained from motorbike accidents, nine from motor vehicle accidents, seven from falls, and three from an unknown mechanism of injury. No cases of injury on duty or insurance claims were encountered in our study.

Patients were assigned to each treatment method in an alternate manner (e.g. patient one = non-operative treatment and patient two = operative treatment). This was done after giving an explanation of the study, its implications and having obtained an informed consent from each one of the patients.

The surgeries were performed randomly by the allocated unit consultant or registrar depending on the day's theatre roster. In order to limit the number of variables involved, the following were kept standard and used routinely for all patients:

- An arm sling for the nonsurgical group for six weeks.
- A pre-contoured plate for the surgical group.

Routine antibiotics were given to all patients in the surgical group according to the protocol of the treating unit. Postoperatively, the shoulders were immobilised with an arm sling for ten days after which the arm sling was removed and shoulder mobilisation was started.

3.2 Study population

Twenty-four adult patients, both male (fifteen) and female (nine) aged 18 to 65 years who presented with closed displaced midshaft clavicle fractures sustained from motor bike accidents (five patients), falls (seven patients), motor vehicle accidents (nine patients) and an unknown mechanism of injury (three patients) were recruited for the study subject to their consent.

3.3 Inclusion criteria

- Adult patients aged 18 to 65 years with displaced midshaft clavicle fractures
- Closed fractures that were transverse, oblique and comminuted

3.4 Exclusion criteria

- All other clavicle fractures
- Patients with a nonunion from a previous fracture
- Pathological fractures
- Open fractures
- Associated neurovascular injuries
- Associated fractures of the proximal humerus and the glenoid
- Neuromuscular upper limb disability
- Patients not fit for surgery

3.5 Data collection

On admission each patient had a comprehensive documentation of the assessment that included the following:

- History and full clinical examination.
- Antero-posterior X-rays views of the clavicle.

At the operation, besides the details of the patient, the following data were documented:

- The surgeon and the assistant
- The details of the surgical approach, findings and procedure as a whole
- The plate used

- Any unusual intra-operative findings
- Any intra-operative complications

Post-operatively, routine post-operative care was followed. At three months follow up the patients functional scores were assessed and documented. The same was done with the radiographic assessment.

3.6 Measurements, tests, materials and apparatus

Patients were assessed clinically and radiographically at three months. The full clinical assessment of patients was carried out and functional scores awarded according to the DASH and Constant Murley shoulder score questionnaires. The principal investigator using the assessment sheet did these. There was no language barrier encountered during the assessment and therefore no interpretation or translation was required. The results were entered into the standard assessment sheet.

With the DASH score[22], a higher score means poor functionality of the arm, shoulder and hand and a low score is the opposite. On the other hand with the Constant Murley shoulder score[23] a higher score means better shoulder functionality and a low score is the opposite.

The radiographic assessment was done by the principal investigator using the concept of fracture line disappearance and bridging callus on one cortex as shown in the assessment sheet attached in Appendix G.

3.7 Data analysis

Patients' clinical and radiographic data taken at three months follow up were captured in the Excel sheet and analysed. A comparison was made between the two groups in terms of their DASH scores and Constant Murley shoulder scores using the Mann–Whitney Ranksum test (Statistica software version 12). A *p*-value less than 0.05 was taken as significant.

A comparison of radiographic evidence of fracture union between the two groups was made using the Chi square test (Statistica software version 12). A *p*-value less than 0.05 was taken as significant.

CHAPTER FOUR

4.0 Results

This prospective randomised study looked at a total of twenty-four adult patients. There were fifteen males and nine females in the study. The surgical group had eight males and five females. The non-operative group had seven males and four females. All fractures were closed and no pathological fractures were included in the study. Five fractures were sustained from motorbike accidents, nine from motor vehicle accidents, seven from falls, and three from an unknown mechanism of injury. No cases of injury on duty or insurance claims were encountered in our study. The dominant hand was involved in fifteen of the twenty-four patients in the study.

The follow up period was for three months at which period the functional scores and radiological bone healing were assessed. The tools used were the two functional assessment questionnaires (DASH and Constant Murley shoulder scores) and X-rays images.

Using the skewness kurtosis (SK) test it was found that the data (both the DASH and Constant Murley shoulder scores) did not follow normal distribution (see Appendix K) and therefore a non-parametric test (Mann–Whitney Ranksum test) was used for data analysis.

4.1 DASH scores

A comparison of the DASH scores between the two groups was made and the *p*-value was derived using the Mann–Whitney Ranksum test. There was a statistically significant difference between the two groups with the surgical group having low DASH scores indicating less disability compared to the non-surgical group (p=0.008) (see Figure 4.1). The values for the actual DASH scores for both groups are shown in Appendix H.

4.2 Constant Murley shoulder scores

The Constant Murley shoulder scores were compared between the two groups using the Mann–Whitney Ranksum test and the surgical group had high scores indicating better shoulder function compared to the non-surgical group (p=0.004) (see Figure 4.2).
The values for the Constant Murley shoulder scores for both groups are shown in Appendix I.

4.3 Fracture union

The comparison of radiographic evidence of union between the two groups was carried out using the Chi square test. The difference between the two groups was found to be statistically significant with the surgical group having better union rates compared to the non-surgical group (p=0.001). The values for radiographic evidence of union for both groups are shown in Appendix J.

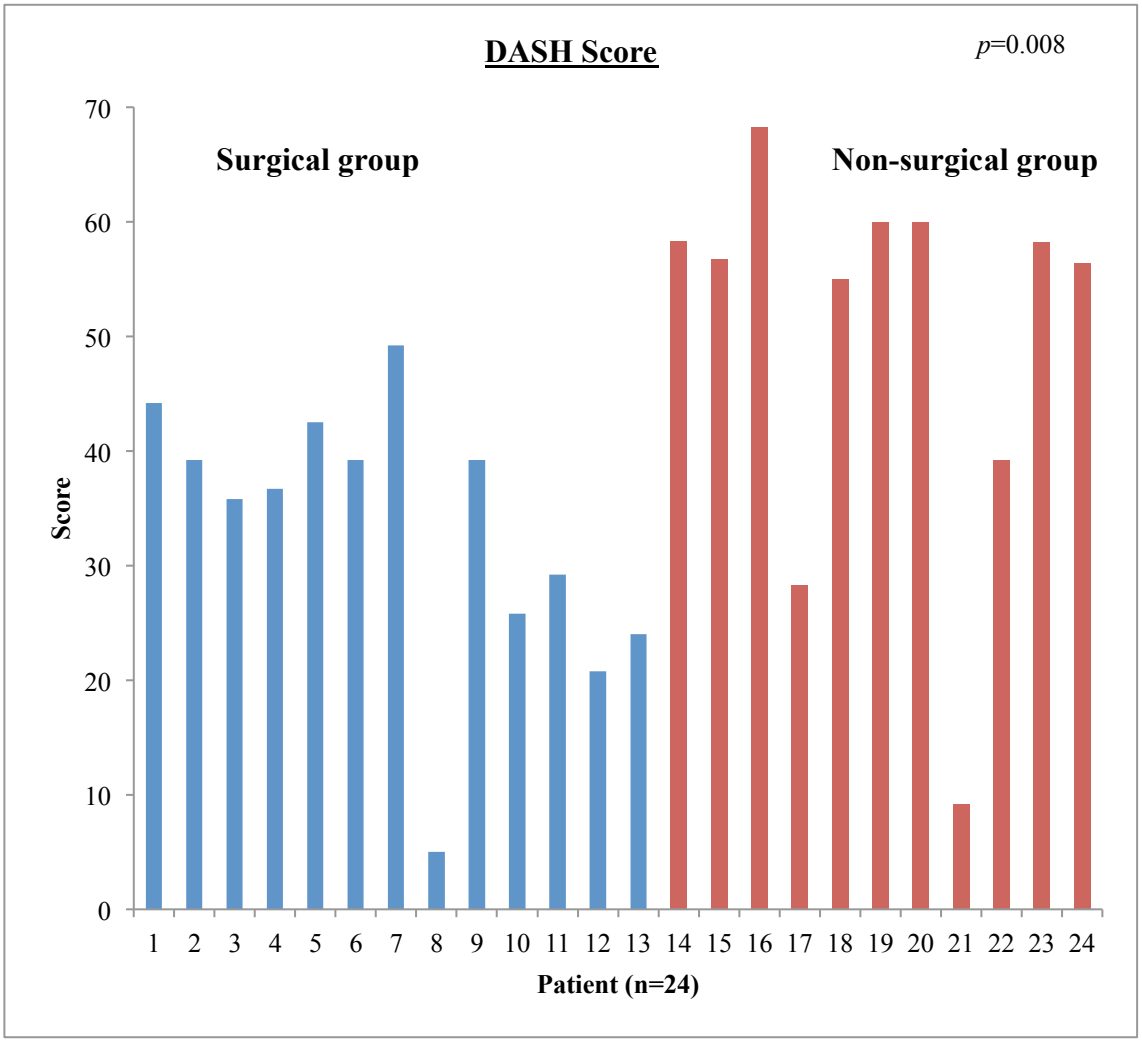


Figure 4.1: Histogram showing the differences in the DASH scores between the two groups.

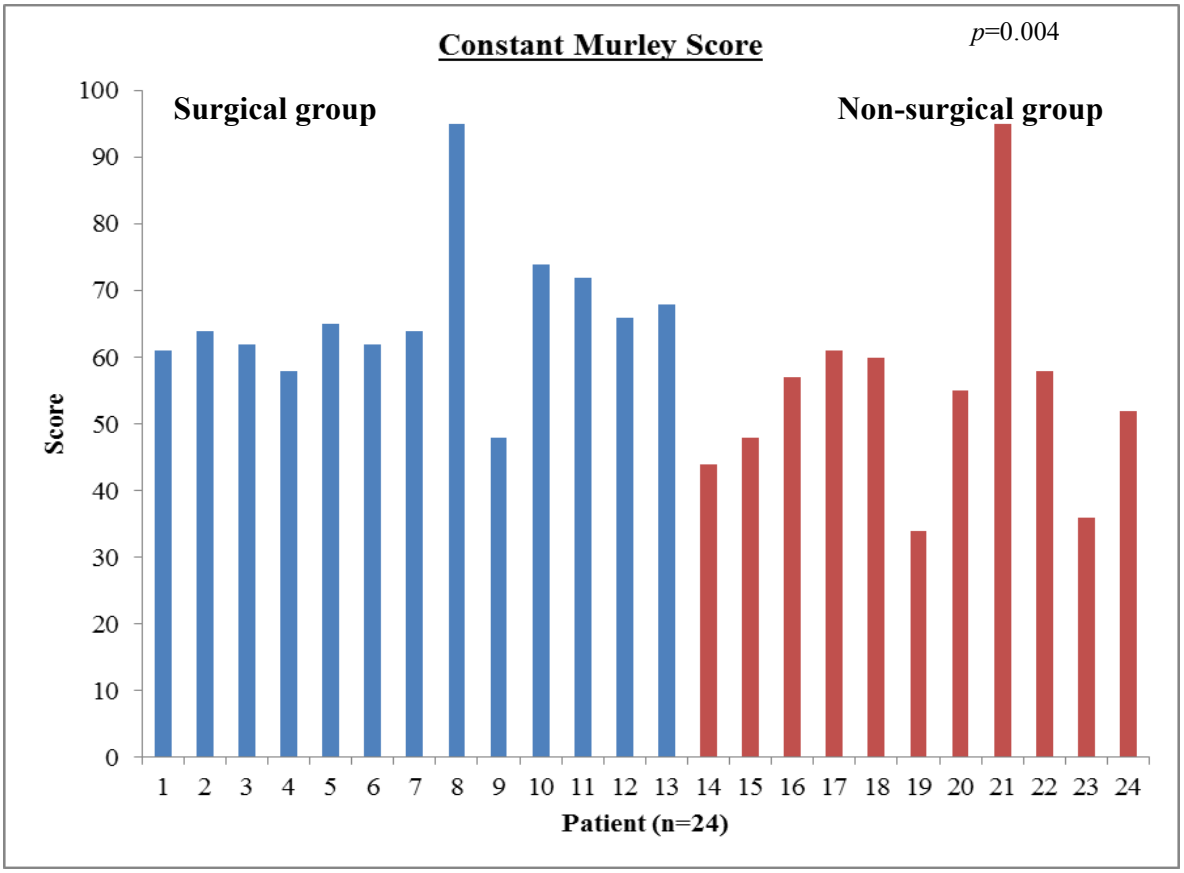


Figure 4.2: Histogram showing the differences in the Constant Murley shoulder scores between the two groups.

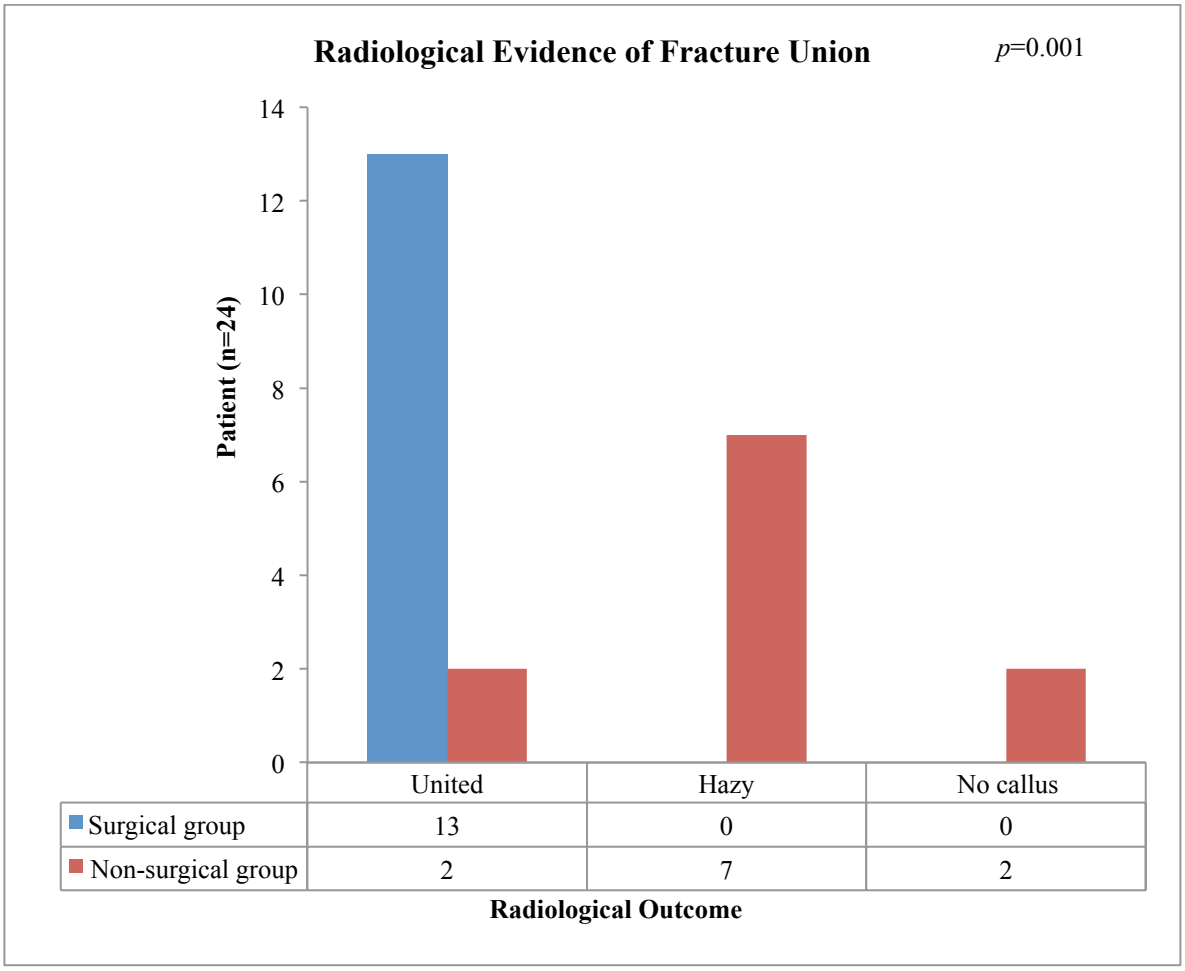


Figure 4.3: Histogram showing the differences in fracture union rates between the two groups.

CHAPTER FIVE

5.0 Discussion

The traditional approach to the treatment of displaced midshaft clavicle fractures has been non-operative treatment even when there was a significant amount of displacement. This treatment approach was based on studies that were published in the 1960s that showed high union rates and low rates of nonunion in patients treated non-operatively compared to the surgically treated patients who showed the opposite.[2, 7, 8] Based on the information gathered from these old studies, non-operative treatment became the dominant approach in the management of displaced midshaft clavicle fractures.

While malunion of the clavicle was previously thought to be of radiographic interest with no clinical significance in the 1960s, it is becoming clear in the current studies that clavicular malunion is a pronounced clinical entity with both clinical and radiographic features. Hill et al. showed this in a study that looked at functional outcomes of the upper limb following non-operative treatment of displaced midshaft clavicle fractures. They found that with malunion of the clavicle, 31% of patients were not satisfied with the results with complaints including shoulder weakness, brachial plexus irritation, cosmetic deformity and residual pain.[10]

In another study, McKee et al. looked at functional deficits following non-operative treatment in patients with displaced midshaft clavicle fractures. They found deficits, which included poor strength of the injured shoulder, high DASH scores and low Constant Murley shoulder scores. They concluded that the surgeon-based outcomes that were used in the past were insensitive in identifying loss of muscle strength in comparison to the patient based outcomes that are currently in use.[14]

The other issue that is changing with time is patient expectations. Currently, clinicians are aware of the fact that today's patient is more likely to expect a rapid return to work and a pain free function following a fracture. If this does not happen, the modern patient is more likely to question it in comparison to their 1960 counterpart.[10] These changing patient expectations and the currently used patient oriented assessment scores have brought a challenge to the previously favoured non-operative treatment approach to displaced midshaft clavicle fractures.

More recent studies have shown that the union rates in non-surgically treated patients with displaced midshaft clavicle fractures may not be as good as it was previously thought**.** These current studies suggest higher nonunion rates and poor function in patients treated non-operatively while the surgically treated groups show the opposite. The Canadian Orthopaedic Trauma Society showed this in a multicenter randomised trial where they found high Constant Murley shoulder scores and low DASH scores with low nonunion rates in the operative group compared to the non-operative group, which showed the opposite.[8]

Several prominent authors like Kulshrestha et al. Robinson et al. McKee et al. subsequently echoed this. This information has changed the previously favoured non-operative treatment approach to displaced midshaft clavicle fractures.[14, 20, 21]

Our study was a prospective randomised trial that looked at a total of twenty-four adult patients. We included fifteen males and nine females with displaced midshaft clavicle fractures. The fractures were sustained from various mechanisms of injury; five fractures were sustained from motorbike accidents, nine from motor vehicle accidents, seven from falls, and three from an unknown mechanism of injury.

The dominant hand was involved in fifteen patients. All fractures were closed and no pathological fractures were included. The patients were randomised to either non-operative treatment (eleven patients) with an arm sling or surgical treatment (thirteen patients) with plate fixation.

For the operative group, we used the pre-contoured S-shaped plates that anatomically fit the clavicle. These plates that are in current use are designed to match the shape of the clavicle and limit soft tissue irritation. These plates were not available in the 1960s instead straight plates were used and a significant bone-implant mismatch was always present resulting in soft tissue irritation. With the use of these pre-contoured S-shape plates, we did not experience any plate related complaints like plate prominence, brachial plexus irritation or wound breakdown.

At three months follow up the patients' functional scores were assessed and documented. The same was done with the radiographic assessment. As opposed to the early studies in the 1960s, in our study we used both the patient oriented outcome scores (DASH and Constant

Murley shoulder scores) that assess patient satisfaction and upper limb function as well as the surgeon-based outcomes (radiography) that assess fracture union.

We found plate fixation to be superior to non-operative treatment of displaced midshaft clavicle fractures in terms of functional outcomes and radiographic outcomes. This is contrary to the traditional approach that used to favour non-operative treatment over surgical treatment in the management of displaced midshaft clavicle fractures. Our results are consistent with what has been published in the current literature.

5.1 Limitations of the study

Results from this study should be examined in light of certain limitations.

The follow up period of three months was short compared to most studies that have follow ups of more than a year. This follow up period is not long enough to define a nonunion.

The sample size in this study was too small compared to most studies. More patient numbers and longer follow-ups would have been more ideal. The results are however in keeping with some of the prominent authors such as Mckee et al.[21]

The findings in this study are valuable and with a potential to encourage more research in the area or influence future clinical decision-making.

CHAPTER SIX

6.0 Conclusion, recommendations and future research

Ours was a short and limited study in terms of the number of research participants and the time period for follow up. However valuable information and leads for future research have been paved.

Based on the results of this research, there is a support for operative over non-operative treatment of displaced midshaft clavicle fractures in adult patients.

It will be worthwhile to look into a bigger sample study over an extended time period and with fewer variables.

In a future study it would be worthwhile to look into the influence of social habits such as smoking and alcohol consumption in the healing rates in patients with displaced midshaft clavicle fractures as we did not take this into account in our study.

APPENDIX A

Ethics Approval

R14/49 Dr Mluleki Tsama et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140753

NAME: (Principal Investigator)	Dr Mluleki Tsama et al
DEPARTMENT:	Orthopaedics Helen Joseph Hospital
PROJECT TITLE:	Outcomes of Non-Operative Treatment versus Plate Fixation of Displaced Midshaft Clavicle Fractures in Adult Patients in a Wits Teaching Hospital
DATE CONSIDERED:	27/07/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof AA Aden
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	01/10/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B

Post Graduate Approval of the Title

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

26 May 2014
Person No: 721345
PAG

Dr M Tsama
P O Box 5897
Weltevreden Park
Johannesburg
1715
South Africa

Dear Dr Tsama

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Outcomes of non-operative treatment versus plate fixation of displaced midshaft clavicle fractures in adult patients in a Wits teaching hospital* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX C

Permission for research from the Hospital Superintendent

health and social development
Department: Health and Social Development
GAUTENG PROVINCE

PERMISION FOR RESEARCH

DATE: 23/10/2013

NAME OF RESEARCH WORKER: DR. A A. ADEN

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):

(011) 489-0639 / 0636

oraden@global.co.za

TITLE OF RESEARCH PROJECT: OUTCOMES OF NON-OPERATIVE TREATMENT VS. PLATE FIXATION OF DISPLACED MIDSHAFT CLAVICLE FRACTURES IN ADULT PATIENTS @ WITS TEACHING HOSP

OBJECTIVES OF STUDY (Briefly or include a protocol): PLEASE SEE INCLUDED

METHODOLOGY (Briefly or include a protocol): INCLUDED

THE APPROVAL BY THE SUPERINTENDENT IS STRICTLY ON THE BASIS OF THE FOLLOWING:

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: YES

(ii) NO COSTS TO THE HOSPITAL: YES

(iii) APPROVAL OF HEAD OF DEPARTMENT: YES

(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: YES

SUPERINTENDENT PERMISION

Signature: _____ Date: 28/10/2013

SUBJECT TO ANY RESTRICTIONS: NO FINANCIAL IMPACT TO THE HOSPITAL.

Helen Joseph Hospital
Perth Road
Tel: 011 489 1011

Private Bag X47
Auckland Park
2006

APPENDIX D

Consent Form

Hello

I am Dr. Mluleki Tsama, a registrar from the division of Orthopaedic Surgery, University of the Witwatersrand medical school. I am investigating the Outcomes of Non-operative Treatment versus Plate Fixation of Displaced Midshaft Clavicle Fractures in Adult Patients in a Wits Teaching Hospital.

Why are we doing this? There are two ways of treating displaced midshaft clavicle fractures, i.e. operative treatment and non-operative treatment. This study is aiming to find which of the two treatment methods gives better results and lesser complications in order to inform future management decisions. We need to include you in this group of patients that we are going to use for this research and we would be grateful if you would be part of it.

What do we expect from the participants in the study? You will be randomly chosen to undergo the operation or be treated non-operatively after which you will be followed up with X-rays and clinical examination, at three months. However if there is a need for you to be seen earlier we will be able to do so. If you are chosen to be part of the non-operative group, there is still a chance that you might have to undergo the operation if need be. You however still retain the right to decide on which treatment you would prefer and declining to be part of the study will not compromise your treatment whatsoever.

Are there benefits to the participants? No

May I withdraw from the study? As already mentioned you may certainly do so at any time without having to give a reason. Remember that this study is completely voluntary and not taking part in it, or withdrawing from it, carries no penalty of any sort. Your treatment will not be compromised either currently or in future.

If you have any queries, more information may be obtained from
Dr. M. Tsama at telephone number (011) 489-0636

If you are happy to take part in the study, please read and sign the consent form below.

Thank you

Dr. M.Tsama

I agree to participate in the study "Outcomes of Non-operative Treatment versus Plate Fixation of Displaced Midshaft Clavicle Fractures in Adult Patients in a Wits Teaching Hospital" outlined above:

Patient Name_____ Signature_____

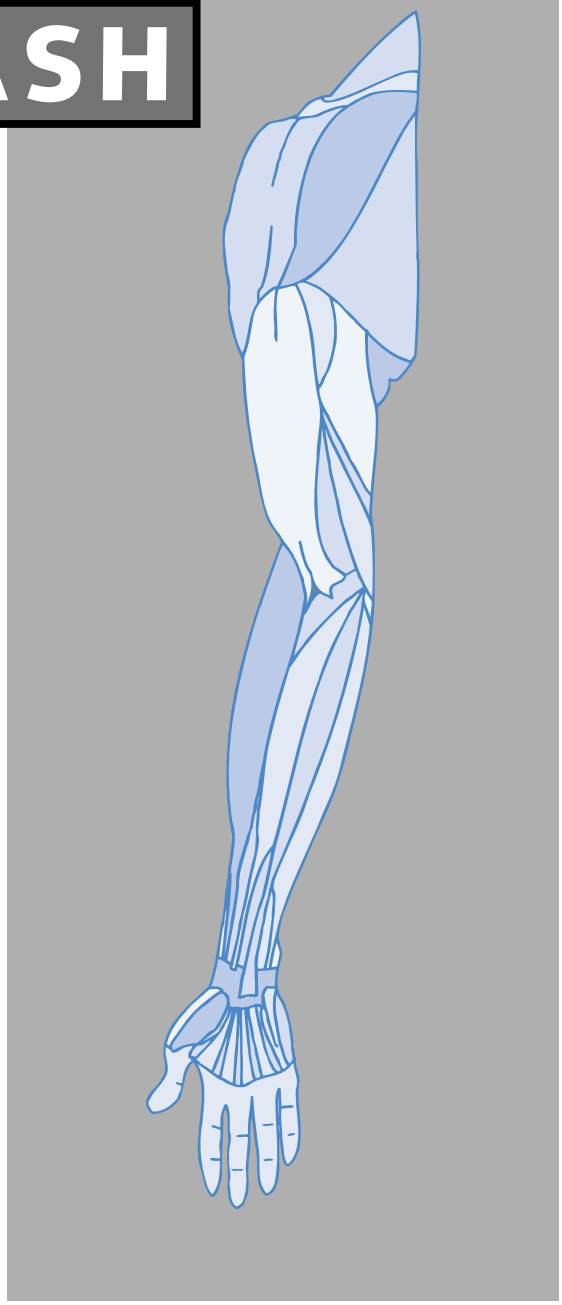
Date_____

APPENDIX E

DASH Score[22] assessment sheet

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE **DASH**



INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

Disabilities of the Arm, Shoulder and Hand

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\left[\left(\frac{\text{sum of n responses}}{n}\right) - 1\right] \times 25$, where n is equal to the number of completed responses.

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

❒ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*.
If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

❑ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may <u>not</u> be calculated if there are any missing items.

APPENDIX F

Constant Murley shoulder score[23] assessment sheet

Overview:
Constant and Murley developed a scoring system to quantitate the functionality of the shoulder. Each shoulder is evaluated separately. The score can be used to monitor a shoulder over time and to assess the effectiveness of interventions. The score was develo at Addenbrooke's Hospital at Cambridge, England.

Parameters in score (100 points maximum):
(1) pain (maximum 15 points)
(2) activities of daily living (ADL) (maximum 20 points)
- **(a) positioning of hand (maximum 10 points)**
- **(b) full work (maximum 4 points)**
- **(c) full recreation and sport (maximum 4 points)**
- **(d) sleep unaffected (maximum 2 points)**

(3) range of motion (maximum 40 points)
- **(a) flexion (elevation in frontal plane) (maximum 10 points)**
- **(b) abduction (elevation in lateral plane) (maximum 10 points)**
- **(c) internal rotation (maximum 10 points)**
- **(d) external rotation (maximum 10 points)**

(4) power (maximum 25 points)

Parameter	Finding	Points
pain	none	15
	mild	10
	moderate	5
	severe	0
positioning of hand (ADL)	above head	10
	up to top of head	8
	up to neck	6
	up to xyphoid	4
	up to waist	2
	unable to lift to waist level	0
elevation in forward plane (range)	151 – 180°	10
	121 – 150°	8
	91 – 120°	6
	61 – 90°	4
	31 – 60°	2
	0 – 30°	0
elevation in lateral plane (range)	151 – 180°	10
	121 – 150°	8
	91 – 120°	6
	61 – 90°	4

	31 – 60°	**2**
	0 – 30°	**0**
internal rotation (range)	**dorsum of hand to interscapular region**	**10**
	dorsum of hand to 12th dorsal vertebra	**8**
	dorsum of hand to waist (level of 3rd lumbar vertebra)	**6**
	dorsum of hand to lumbosacral junction	**4**
	dorsum of hand to buttock	**2**
	dorsum of hand to lateral thigh	**0**

Activity of Daily Life	**Finding**	**Points**
able to do full work (ADL)	**yes**	**4**
	no	**0**
able to do full recreation and sport (ADL)	**yes**	**4**
	no	**0**
sleep unaffected (ADL)	**yes**	**2**
	no	**0**

External Rotation	**Finding**	**Points**
hand behind head with elbow held forward	**yes**	**2**
	no	**0**
hand behind head with elbow held back	**yes**	**2**
	no	**0**
hand on top of head with elbow held forward	**yes**	**2**
	no	**0**
hand on top of head with elbow held back	**yes**	**2**
	no	**0**
full elevation from top of head	**yes**	**2**
	no	**0**

power points =
= ((pounds held at 90°, up to 25 lbs) / 25) * 25 =

= (pounds held at 90°, up to 25 lbs)

where:
- **Power is scored based on the number of pounds of pull that the patient can resist in abduction, up to a maximum of 90°.**
- **A normal shoulder in a 25 year old man can resist 25 pounds without difficulty and is awarded 25 points.**
- **The ability to lift a lesser weight is awarded proportionately fewer points.**

total score =
= SUM(points for all of the parameters)

Interpretation:
- **minimum score: 0**
- **maximum score: 100**
- **The higher the score, the better the shoulder functionality.**

References:
Constant CR, Murley AHG. A clinical method of functional assessment of the shoulder. Clin Orthopaedics Related Research. 214; 1987; 160-164.

APPENDIX G

Radiographic evaluation sheet
Clavicle Fractures

Radiographic Patterns

Last Name: _____ First **Name**: _____

Patient No.: _____ **Study ID**: _____

Date of Surgery (dd/mm/yy) : _____ / _____ / _____

Reviewer: _____

Reviewed by : **O** Operator **O** Other MD

Date of Review (dd/mm/yy) : _____ /_____/ _____

Reviewed at: **O** Day 1 **O** 5/12 **O** 6/12 **O** Other:_____ weeks

Fracture Type: **O** Transverse **O** Oblique **O** Comminuted
O Segmental **O** Closed **O** Open
Side **O** Right **O** Left **O** bilateral

Post-op

Screws: **O** in place **O** lucency around **O** pulled out: How many? _____
O Broken: How many? _____ **O** N/A
Plate: **O** N/A **O** in plate **O** bent **O** pulled off **O** broken

Fracture line: **O** visible **O** Hazy **O** Partially obliterated in one plane
O Totally obliterated in one plane

Callus: **O** Absent **O** Hazy around fracture **O** Bridging callus - one cortex
O Bridging callus – 2 cortices **O** Solid union

NOTES

_____
_____
_____
_____
_____

APPENDIX H

Table H1: DASH scores - (Results)

SURGICAL GROUP			NON-SURGICAL GROUP	
Patients	**Scores**		**Patients**	**Scores**
1	44.2		1	58.3
2	39.2		2	56.7
3	35.8		3	68.3
4	36.7		4	28.3
5	42.5		5	55.0
6	39.2		6	60.0
7	49.2		7	60.0
8	5.0		8	9.2
9	39.2		9	39.2
10	25.8		10	58.2
11	29.2		11	56.4
12	20.8			
13	24.0			

APPENDIX I

Table I1: Constant Murley shoulder scores - (Results)

SURGICAL GROUP			**NON-SURGICAL GROUP**	
Patients	**Scores**		**Patients**	**Scores**
1	61.0		1	44.0
2	64.0		2	48.0
3	62.0		3	57.0
4	58.0		4	61.0
5	65.0		5	60.0
6	62.0		6	34.0
7	64.0		7	55.0
8	95.0		8	95.0
9	48.0		9	58.0
10	74.0		10	36.0
11	72.0		11	52.0
12	66.0			
13	68.0			

APPENDIX J

Table J1: Radiographic Evidence Of Fracture Union - (Results)

SURGICAL GROUP			**NON-SURGICAL GROUP**	
Patients	**X-ray Findings**		**Patients**	**X-ray Findings**
1	Fracture united		1	Fracture site hazy
2	Fracture united		2	Fracture united
3	Fracture united		3	Fracture site hazy
4	Fracture united		4	No callus seen
5	Fracture united		5	No callus seen
6	Fracture united		6	Fracture site hazy
7	Fracture united		7	Fracture site hazy
8	Fracture united		8	Fracture site united
9	Fracture united		9	Fracture site hazy
10	Fracture united		10	Fracture site hazy
11	Fracture united		11	Fracture site hazy
12	Fracture united			
13	Fracture united			

APPENDIX K

Histograms showing abnormal distribution of DATA (DASH and Constant Murley shoulder scores)

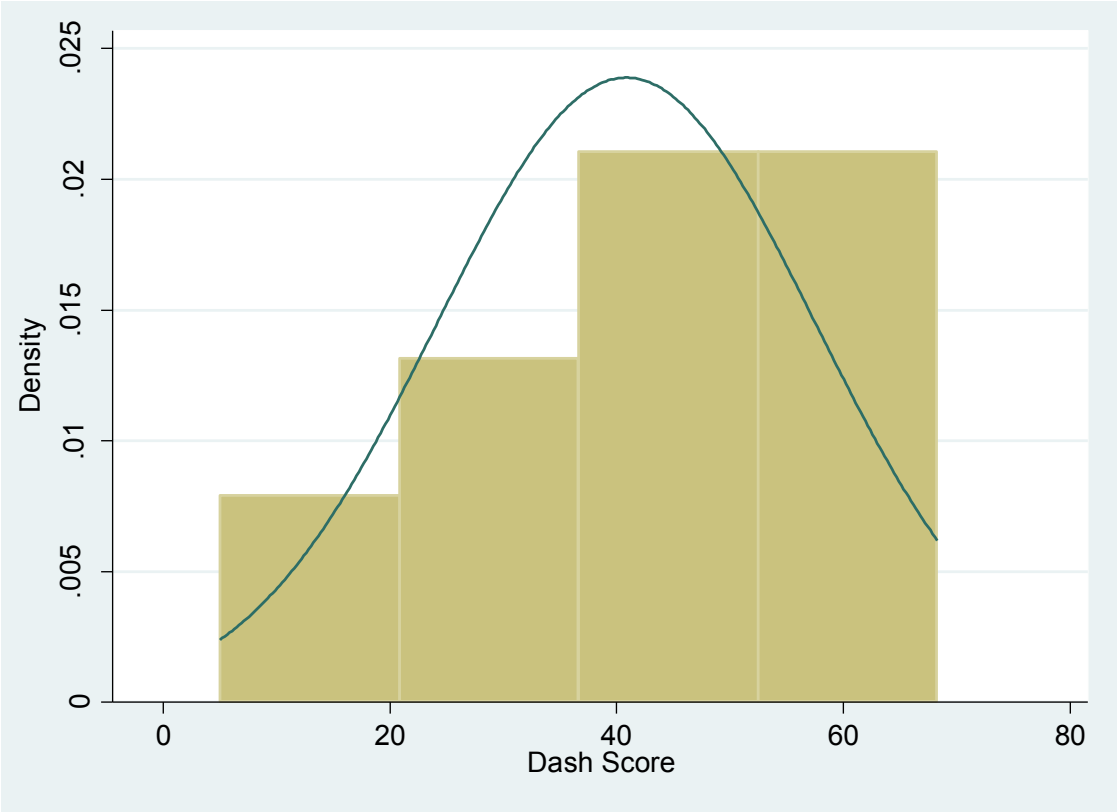


Figure K1: Histogram showing abnormal distribution of DASH scores (Statistica, version 12).

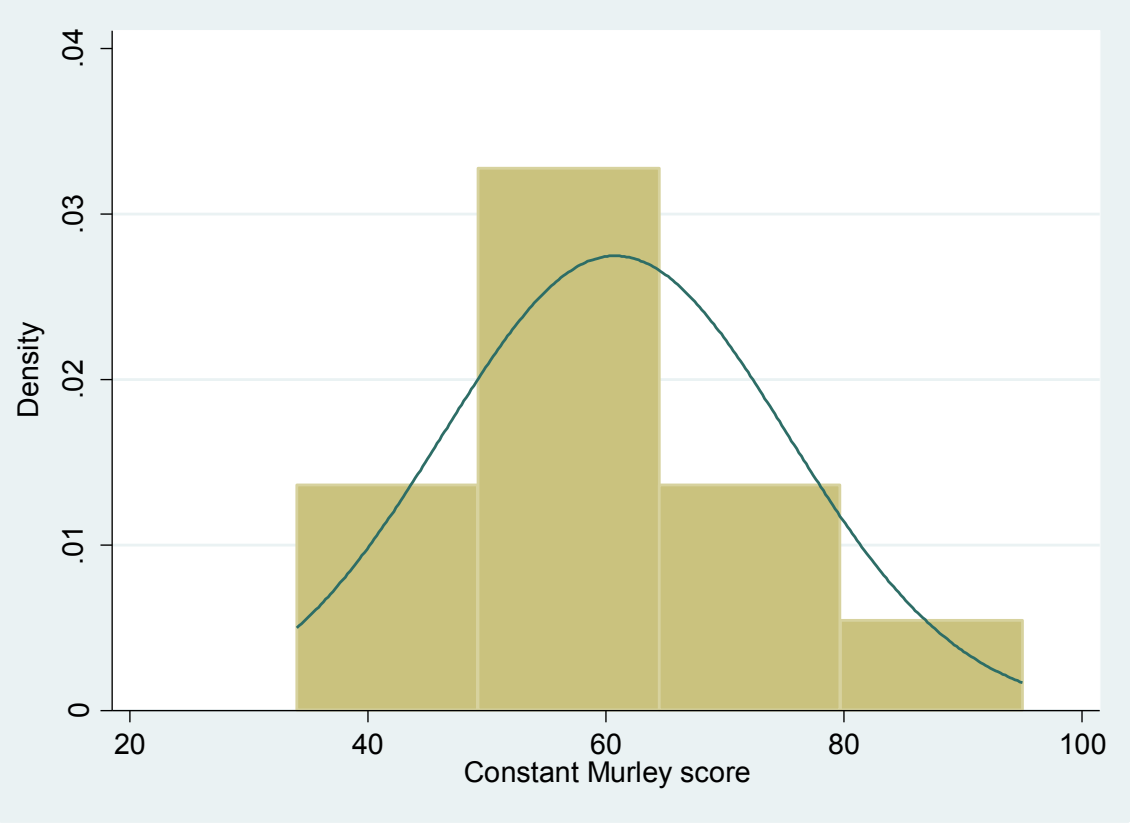


Figure K2: Histogram showing abnormal distribution of Constant Murley shoulder scores (Statistica, version 12).

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