

**UNIVERSITY OF RWANDA** 

COLLEGE OF MEDICINE AND HEALTH SCIENCES

SCHOOL OF MEDICINE AND PHARMACY

**DEPARTMENT OF SURGERY** 

**ORTHOPEDIC SURGERY PROGRAM** 

# EFFECTIVENESS OF AIRCAST ANKLE BRACE COMPARED TO BACKSLAB IN THE MANAGEMENT OF ACUTE LATERAL ANKLE SPRAIN, A PROSPECTIVE COHORT STUDY.

To be submitted for the partial fulfillment of the requirements for award of Masters of Medicine in Orthopedic Surgery

**By: Dr Olivier KUBWIMANA** 

Reg. N<sup>0</sup>: 11111487

Supervisor: Prof. Jean Claude BYIRINGIRO

Co-Supervisor: Dr Emmanuel MURWANASHYAKA

Kigali, September 12<sup>th</sup>, 2022

# Declaration

The Principal investigator:

I declare this dissertation to be my own work and has not been submitted anywhere else for a University award degree.

Signature.....

Date:.....September 12<sup>th</sup>, 2022

Dr Olivier KUBWIMANA

The Supervisors:

We declare that this dissertation entitled " Effectiveness of aircast ankle brace compared to backslab in the management of acute lateral ankle sprain, a prospective cohort study" is compliant with antiplagiarism rules and submitted in accordance with our approval.

Signature ,

Date: 12/09/2022

Prof. Jean Claude BYIRINGIRO

Signature.....

Date:..... September 12<sup>th</sup>, 2022

Dr Emmanuel MURWANASHYAKA

# Dedication

To my family, my esteemed friends and entire Rwanda orthopedic fraternity.

# Acknowledgements

I acknowledge an immense contribution of everyone who helped me in different ways along this training.

I pay special tribute to my supervisors Prof. Jean Claude BYIRINGIRO and Dr Emmanuel MURWANASHYAKA for their tremendous and duly comments, inputs and advice along the way.

My gratitude also goes to Prof. John BYIMANA, Prof. Alex M. BUTERA, Dr Edmond MUKIMBILI, Dr Emmanuel NSENGIYUMVA, Dr Emmanuel BUKARA, Dr Jean de la Croix Allen INGABIRE, Dr Albert NZAYISENGA and other members of orthopedic fraternity for their very important daily academic support. My fellow resident contribution was also very valuable.

I express my esteemed gratitude to my family and friends who continuously made this journey smooth and meaningful.

God bless everyone!

Olivier KUBWIMANA, MD

# Table of Contents

Declaration	i
Dedication	ii
Acknowledgements	111
List of Abbreviations	vi
List of Figures	vii
List of tables	viii
Abstract	ix
Background	ix
Methodology	ix
Results	ix
Conclusion	ix
CHAPTER 1. INTRODUCTION AND STUDY JUSTIFICATION	1
1.1 Introduction	1
1.2 Problem statement	3
1.3 Research question	3
1.4 Research Hypothesis	3
1.5 Objectives	3
Specific Objectives	3
CHAPTER 2. LITERATURE REVIEW	4
2.1 Anatomy and biomechanics of Ankle joint	4
2.2 Epidemiology and Classification of Ankle sprain	6
2.3 Acute Lateral Ankle Sprain Diagnosis	7
2.4 Acute lateral Ankle sprain treatment modalities	10
2.5 Documented outcomes of Ankle sprain	11
2.6 Commonly encountered complications	12
CHAPTER 3. METHODOLOGY	13
3.1 STUDY AREA	13
3.2 STUDY DESIGN	13
3.3 STUDY PARTICIPANTS	13
3.3.1 Inclusion criteria	13
3.3.2 Exclusion criteria	13

3.4 PATIENTS RECRUITMENT	14
3.5 DATA COLLECTION AND VARIABLES	15
3.6 DEFINITION OF KEY CONCEPTS	16
3.7 SAMPLE SIZE CALCULATION	16
3.8 DATA ANALYSIS AND RESULTS INTERPRETATION	17
3.9 ETHICAL CONSIDERATION	17
CHAPTER 4. RESULTS	18
4.1. Patients' Demographics	18
4.2 Mechanism of injury	19
4.3 Primary outcomes	20
4.3.1 Pain at 3 and 6weeks	20
4.4 Secondary outcomes	23
4.4.1 Ankle sprain recurrence at 6 weeks post-injury	23
4.4.2 Timing of Weight bearing and activities restoration post-treatment	23
CHAPTER 5. DISCUSSION	25
5.1 Study limitations	27
CHAPTER 6. CONCLUSION AND RECOMMENDATIONS	28
REFERENCES	29
APPENDICES	33
APPENDIX 1.Informed consent (English version)	33
APPENDIX 2. Kwemera kujya mu bushakashatsi (Ubusobanuro mu Kinyarwanda)	35
Appendix 3. Data collection form	38

#### List of Abbreviations

A/E: Accident and Emergency

AFO: Ankle Foot Orthosis

CHUK: Centre Hospitalier Universitaire De Kigali

DVT: Deep Venous Thrombosis

FAOS: Foot and Ankle Outcome Score

KFH: King Faisal Hospital

LAS: Lateral Ankle Sprain

MeSH: Medical Subjects Headings

MRI: Magnetic Resonance Imaging

NSAIDs: Non-Steroid Anti-Inflammatory Drugs

RCT: Randomized Controlled Trial

**RICE:** Rest Ice Compression Elevation

**ROM: Range Of Motion** 

UK: United Kingdom

**US: United States** 

USD: United States Dollar

# List of Figures

Figure 1: Bony components of mortise joint (Anterior view)	4
Figure 2: Lateral ligament of the ankle joint (lateral view)	5
Figure 3: Medial ligament of the ankle joint (Medial view)	5
Figure 4: Anterior drawer test	8
Figure 5: Talar tilt test	8

# List of tables

Table 1: West point ankle sprain grading system	7
Table 2. Patients' Demographics	18
Table 3: Mechanism of injury	19
Table 4: Pain after treatment	20
Table 5: Swelling after treatment	21
Table 6: Pain and swelling after 3 weeks when considering West point grading	22
Table 7: Rate of ankle sprain recurrence	23
Table 8: Weight bearing and activities restoration	23

#### Abstract

#### Background

The world knows a current burden of acute ankle injuries, prevalent in professional athletes and acute lateral ankle sprain is the most common type. This high occurrence is universal but more pronounced in the western world with associated substantial economic expenditures. Disparities across the globe are notable when management is considered and this renders the choice of treatment difficult. The loco-regional literature presents paucity of data in regards to this subject.

#### **Methodology**

This was a prospective cohort study conducted at two centers. We included patients 18 years of age and above who presented for isolated grade 2 or 3 acute lateral ankle sprain treated by backslab or aircast ankle brace and followed up to six weeks from the time of injury. Results found analyzed using SPSS 28 by t-test and the study obeyed standard ethical guidelines.

#### Results

In total we recruited 90 patients divided equitably into backslab and air cast ankle brace arms, with median age being respectively 42 and 45.5. The male to female ratio was 0.87/1 for backslab and 1.04/1 air cast ankle brace group. Outcomes of two treatment arms were compared and we noted a significant improvement in pain at 3 and 6 weeks favoring aircast ankle brace with a p-value (0.04) using a t-test. Ankle instability was similar in both arms at 4.4%, degree of swelling after treatment and timing or weight bearing were also favoring ankle braces but not statistically significant.

### Conclusion

We noted occurrence of acute lateral ankle sprain in Rwanda, even in non-athletic population. Use of aircast ankle brace is superior to backslab in early pain control. The local medical bodies should avail all treatment modalities and foster related research.

Keywords (MesH): Ankle injuries, Sprains and Strains, Braces, Immobilization

#### **CHAPTER 1. INTRODUCTION AND STUDY JUSTIFICATION**

#### **1.1 Introduction**

Globally, ankle sprains rank at the top among sports-related musculoskeletal injuries and are more prevalent in professional athletes (1–4). This trend is more pronounced in the western world where quite a number of emergency departments are overcrowded with sprain injuries. For instance 3-5% of emergencies received in the UK are ankle sprain cases and majority of them being lateral ankle injuries (5). It is a fact that it remains on its peak in sports medicine and variant games have got different rates of ankle sprain. Rugby and soccer are the 2 most commonly involved games as reported by Fong et al (3). Injuries occurring during basketball games were relatively associated with significant rate of ankle sprain recurrence (6). Ankle sprain remain on the top amongst joint injuries accounting more than 10% of all traumatic joint injuries (7). Besides the clinical challenges associated with the ankle sprains, their management is associated with substantial economic expenditures (8,9) in US, around 30 millions USD per 1 million of population annually goes to ankle sprain management (8).

Foot and ankle practice has improved significantly in Africa over the past decades; however there is still a lack of enough literature about the management and outcomes of ankle sprains . A study done in South-Africa reported conservative management to be a common practice around 82% of lateral ankle sprain injuries and it is done as bracing or casting on individual choice or depending on economic factors (10). During a soccer tournament in Nairobi, Foot and ankle sprain were the commonest sustained injuries at 24%, while ankle sprain at 38% was the most frequent cause of game delay (11). In Rwanda very few data were published on foot and ankle practice; Murwanashyaka et al. were interested in the use of Ottawa ankle rules, and found it to be effective in reducing unnecessary radiography and associated expenditures (12). Another study conducted for young and young adult female professionally practicing soccer, reported lower extremities injuries to be the commonest and recurrence rate to be low when preventive measures were implemented (13).

A wide range of diagnostic modalities exists, however the physical examination remains at the top. The physical examination accuracy of detecting grade 3 ankle sprains goes beyond the standard MRI. However, the sensitivity decreases by three quarter for lower grade ankle sprain and this is more credible when the examination is performed at the  $5^{th}$  day. This highlights the need of a thorough and exhaustive physical examination in ankle injuries (2).

There is a wide range of management option for ankle sprains raising a lot of controversies in research and clinical practice (14). The hallmark in treatment of ankle sprain rely on limb rest with a time of immobilization followed by session of physical therapy and weight bearing (2). However, a lot of controversies exist in the stepwise approach for ankle sprain management. The very initial management of ankle sprain consists of reducing or limiting pain and edema; some studies advocate for the use of compressive ice with limb elevation whereas others recommend intermittent ice application, or ice in combination with physical therapy. The role of immobilization is still very debatable in different RCTs; some recommend the use 10 days cast immobilization and others recommend the immobilization with a short leg cast for up to 4 weeks, while others recommend functional therapy using rigid or semi-rigid braces and the latter seems to gain more popularity and advantageous, although not always affordable in resources limited settings (15). standard cast or semi-rigid cast is a good restraint to coronal forces hence recommended in management of ankle sprains (16), moreover the study done by Robroy L. Martin et al. through their systematic review recommended use of cast in management of grade 3 ankle sprain (6,17). Use of walking boot has well been documented to be less effective due to patients' poor compliance and it remain expensive when comparable to the backslab or aircast ankle brace, aircast ankle brace (air stirrup ankle brace) is a preferred treatment modality over the tubular bandage since there is quick restoration of ankle function (17). Among documented complications ankle sprain is associated with a high rate of chronic ankle instability resulting from suboptimal management (1,2,18), the rate of chronic ankle sprain following the first ankle sprain is reported to be nearly twice that of general population (19).

To the best of our knowledge there is local scarcity of data with regards to the best option when comparing a backslab to the use of walking boots in acute ankle sprain management. Hence we opt to conduct this study in order to reveal and raise awareness of the most effective method of treatment.

#### **1.2 Problem statement**

Acute lateral ankle sprain is a common entity received in different Accident and Emergency departments of the main referral Hospitals in Kigali. They mainly result from contact sports injuries, subtle ankle twisting, and other various mechanisms. The local practice is that medical doctors tend to use what they routinely have been using, such as a below knee backslab, walking boot and rarely the aircast ankle brace. The choice doesn't rely on scientific evidence but rather socio-economic factors since the backslab is mainly the one affordable as it is covered by the Community Health Based Insurance. Therefore, we opted to conduct this study to compare the effectiveness of aircast ankle brace (air stirrup ankle brace) and a backslab in treating grade 2 and 3 acute lateral ankle sprain, but also prevent residual complications that may be associated including recurrent ankle sprain leading to chronic ankle instability. There is no published data on management of ankle sprain in Rwanda.

### **1.3 Research question**

What is the best treatment modality for grade 2 and 3 acute lateral ankle sprain between backslab and air cast ankle brace?

### **1.4 Research Hypothesis**

A conventional backslab is as effective as an air cast ankle brace in non-operative management of grade 2 and 3 acute lateral ankle sprain

# **1.5 Objectives**

Main Objectives

• Compare the outcomes of grade 2 and 3 acute lateral ankle sprain patients managed with backslab and those with aircast ankle brace at KFH and CHUK.

# Specific Objectives

- To estimate the proportion of patients with pain/swelling in backslab and aircast ankle brace groups (Primary outcomes at 3 weeks and 6 weeks after immobilization)
- To estimate the rate of ankle sprain recurrence in aircast versus backslab groups (Secondary outcomes at 6 weeks)
- To compare the timing of return to daily activities (sport or work) in aircast ankle brace versus backslab arms.( Secondary outcomes at 6 weeks)

# **CHAPTER 2. LITERATURE REVIEW**

### 2.1 Anatomy and biomechanics of Ankle joint

The ankle joint also known as mortise joint or talocrural joint is among the very distal joint of the human body. The ankle joint bear a relatively high load and has got potential protective factors like resistance to deforming forces ensuring stability and resisting degeneration in comparison with proximal joints. It joins the leg and foot typically made of bony and complex ligamentous structures. The bony aspect is made of the tibia plafond which is the distal articular surface of the tibia, malleoli being lateral and medial and the dome shaped articular surface of the talus as seen in figure 1 Drake et al: Gray's Anatomy for Students.

The complexed 3 group of ligaments maintain ankle stability in a 3 dimension model, those are anterior, posterior tibiofibular ligaments and interosseous tibiofibular ligament which stabilizes the tibiofibular joint against diverging forces thought the gait phases. The medial aspect is under eversion and valgus forces which joint resist thanks to a fan shaped strong complex ligament known as deltoid ligament. The more vulnerable lateral collateral ligaments protect the joint from 3 deforming forces, notably inversion, varus and rotation, illustrated in figure 1, 2 and 3 (20).



Figure 1: Bony components of mortise joint (Anterior view)



Figure 2: Lateral ligament of the ankle joint (lateral view)



Figure 3: Medial ligament of the ankle joint (Medial view)

Biomechanically the ankle joint has got a great stability to deforming forces in comparison to other joints. Moreover the joint anatomically appears as a hinge. However, its function has got a wide range of motion in combination with adjacent joint such as subtalar joint. Therefore, the entire generated motion appear in 3D fashion, nevertheless the motion in sagittal plane has got a relatively wider range of motion when compared to other motions (21).

The sagittal plane range of motion vary from  $10-20^{\circ}$  for dorsiflexion (21) and  $40-55^{\circ}$  of plantar flexion, the coronal plane has got a ROM of more pronounced in inversion at  $23^{\circ}$  while the eversion goes up to  $12^{\circ}$  (21). As a very distal joint biomechanically the ankle joint bears a tremendous amount of weight, times 5 the body weight during normal stance phase and up to 13 times while running (21). The normal distribution of weight thought the mortise joint is of paramount typically in prevention or delay of degenerative arthritis with chronic pain, hence the tibio-talar joint bears a great amount of load and importantly the talar dome receive nearly 90% of total load while 10% goes to the sides of the talus (21). Ankle sprain occurrence depends on the position of the foot at the time of insult, the most common mechanism of injury occurs with a forceful plantar flexion and inversion foot increasing tensile forces in lateral collateral ligament of the ankle joint hence tear (7,22).

#### 2.2 Epidemiology and Classification of Ankle sprain

The ankle sprain present enormous occurrence among athletics mainly in the western world and more common amongst teenagers (23). The US knows around 28000 ankle sprains every single day and this reflect a significant economic burden this entity poses on health care system (22). Around 7% of patient presenting with an ankle sprain, have an associated foot and ankle fractures, whereas majority of patients with an isolated mild staged ankle sprain do not consult since they often consider it as a subtle injury (9). Referring to previously standard classification the lateral ankle sprain is very common amongst others at 85-90% of all cases (9,24,25). Ankle sprain remain at the top among joint injuries accounting for 15-21% of sport injuries, mostly reported in professionals (1,2,25).

It may vary from a very mild and bearable injury to a much severe and complex injury with inability to use the limb (1,2,22). It may be classified by severity or anatomically, the latter may be lateral ankle sprain, medial or syndesmotic injury (9,25). Whereas O'Donoghue has elaborated a useful classification according to severity which is divided into 3 types, where Type I stands for a simple sprain mainly stretched in nature, type II is incomplete tear of the ligament while type III is a complete ligamentous injury (1,2,9). In ankle sprain classification basing on timing, the acute phase mark the inflammatory period marked with clinical evidence of inflammation. The second phase is marked by proliferation of connective tissues and neovascularization (22).

The more clinically applied and comprehensive classification is the West Point Ankle Grading classification as seen in table 1 (25).

Table 1: West point ankle sprain grading system						
Criteria	Grade I	Grade II	Grade III			
Swelling/ecchymosis	Mild and localized	Moderate	Severe and diffuse			
Tenderness	Yenderness         Mild and Localized         Moderate at ATFL		Severe at ATFL, CFL,			
	at ATFL area	CFL areas	PTFL areas			
Weight bearing	Full/ partial	Crutches dependent	Impossible			
Ligament damage	Stretched	Partial tear	Complete tear			
Instability	None	None/ slight	Definite			
ATEL, Antonion talefibular ligament, CEL, Calegnoofibular ligament, DTEL, Destanion						

ATFL: Anterior talofibular ligament; CFL: Calcaneofibular ligament; PTFL: Posterior talofibular ligament.

Gerber et al.(25)

# 2.3 Acute Lateral Ankle Sprain Diagnosis

Ankle sprain typically present after a traumatic ankle insult where patients present with ankle pain which may be generalized or more less localized, depending on involved ligaments it may range from a very mild to severe unbearable pain, there is associated swelling and inability to bear weight except for very minor injuries, patients with grade III ankle sprain may present with ankle ecchymosis (5). Ecchymosis may be present in 60% of cases mainly results from injury of anterior talofibular ligament (26). Quite often because of pain, it may not be easy to perform a thorough physical examination therefore much of grading is done by observation of present symptoms (5). Anterior drawer test done after resolution of edema and pain was found to be effective in diagnosis of grade 3 ankle sprain (14). The hallmark of physical examination is based on special test, to note anterior drawer test done with the ankle in anatomical position then there is an anterior translation of the talus on tibia plafond and it evaluates the integrity of anterior talofibular ligament part of lateral collateral ligament and syndesmosis. The talar tilt done with the knee in extension, the foot in forceful inversion and instability of lateral complex appreciated mainly calcaneofibular and anterior talofibular ligaments. Illustrated in figure 4 and 5 (7)



Figure 4: Anterior drawer test



Figure 5: Talar tilt test

Different authors emphasized on clinical examination as a hallmark in diagnosis of ankle sprain mainly by palpation of bony eminences and ligaments (22,27). Bergfeld has elaborated a clinical based classification of lateral ankle sprain whereby a Grade 3 acute lateral ankle sprain is defined as the unfunctional ankle joint with diffuse swelling and ecchymosis, severe tenderness as the area underlying the lateral complex ligamentous area, positive anterior drawer and talar tilt tests (28). Delayed Physical examination suffice for diagnosis of ankle sprain for mainly type 3 ankle sprain (1,29,30), this is the physical examination done between the 3<sup>rd</sup> and 5<sup>th</sup> day from the time of injury it's accuracy results from resolution of oedema and pain at this time interval. Hence the special test such as the anterior drawer test and talar tilt become positive, it has got a high interobserver reliability with sensitivity and specificity respectively at 96% and 84% (1,29). Moreover Frey et al. reported physical examination to be effective at 100% in diagnosing grade 3 acute lateral ankle sprain the results comparable to MRI findings (31). However in case, severe pain and tenderness appreciated to the very unusual location MRI may be adjunct for diagnosis of commonly associated missed injuries such like midfoot injuries and osteochondral lesions (22,27,30). MRI may as well be obligatory in complex ankle ligamentous injuries and in chronic ankle sprains (30).

Ottawa Ankle rule present benefit in minimizing unnecessary cost and exposure to x-rays and it may be used in settings where radiography machines are not easily accessible, hence play an important role in excluding ankle fractures and diagnosing ankle sprain, it remain very useful in ankle and mid-foot trauma (9,12,32,33). The standard radiography in ankle sprain has got its room where medial or lateral mortise clear space will widens depending on injured ligament (34). The role of ultrasound in diagnosis of musculoskeletal abnormalities has long been documented with controversies. However some studies have reported its accuracy in detecting ankle pathologies including ankle sprain to be fairly near to MRI results (35).

#### 2.4 Acute lateral Ankle sprain treatment modalities

Treatment consist of RICE (rest, ice, compression and limb elevation), then immobilization followed by ROM and weight bearing (2,36). Patients with ankle sprain present with ankle pain and swelling therefore there are undoubtful in need of analgesics and the role on NSAIDs use is well documented with high level of evidence (37). Moreover the treatment of ankle sprain tends to depend on local protocol, although the general consensus remains the same. Although surrounded with controversies as discussed ahead, the short leg cast in management of ankle sprain was found advantageous compared to ankle brace in regard to early pain cessation, improving quality of life although the trend of outcomes seems to be different in early phase posttreatment and fairly the same later (5). Nevertheless both of walking boot (Bledsoe boot) or a short leg backslab were found to be so effective in treatment of highly staged ankle sprain (9). However a different study done by Hubbard et al. reported use of aircast ankle brace or a backslab to have a relatively better results when comparable to walking boot, referring to timing of symptoms resolution (38). Moreover, walking boot was less effective to backslab since it was associated with poor patients outcomes, since for it to be effective the patient has to keep it for 24 hour along the duration of treatment (17). The current management plan is full of controversies mostly in regard to grade 3 injuries on O'Donoghue classification system (14).

Use of cast immobilization was found to be so effective in treatment of ankle sprain; preferably the cast to be applied for 3 weeks, a below knee weight bearing cast is most preferred. Alternatively use of an ankle foot orthosis is a valid alternative and it is so beneficial when used over 3 weeks coupled and followed with sessions of physical therapy and AFO may be a good alternative to surgery in advanced ankle sprain (26). Physical therapy has been documented to be so efficient in enhancing healing ligament remodeling post-acute lateral ligamentous complex injury, this was reported in a high level of evidence study (4). Slimmon et al. reported the below knee backslab to be so efficient in management of severe ankle sprain over other different modalities (39).

The hallmark of ankle sprain management as discussed earlier is summarized by RICE, as the patient is received in outpatient or at A/E department an ice is applied then the area is compressed and elevated this is typically followed by immobilizing the limb depending on local protocol which maybe an AFO or an cast/slab. Crutches are typically recommended to let the ankle resting during the ligament healing phase.

In a mild disease a functional AFO is preferred over a slab since the former allow a relatively wider ROM which orient collagen fibers in their proper position while regenerating. In case of complete injury of the ligaments still the non-operative management is the best amongst other choices in most cases. Grade 3 ankle sprain after following RICE protocol a walking boot is used for 3 weeks converted into aircast ankle brace latter (4). Since a couple of decades ago braces have gained popularity over casts use in foot and ankle disorders, since the former allow users to be removed and inspect the area for local hygiene ever wound care in contrary to use of casts (16). Biomechanical principles of different foot and ankle immobilization tools differs, having main principles at the back of the mind may help to choose the right one depending on presenting condition. The convention plaster of paris is best in limiting coronal forces, typically eversion and inversion when compared to other different type of immobilization such as fiberglass cast, walking boot and other functional braces (16). Moreover Beynnon et al. through their study, reported both aircast ankle brace and use of cast to have relatively comparable longterm outcomes (28). The above management has got controversies reported in a different systematic review by Kerkhoffs et al. they reported functional treatment to be far superior to immobilization as the latter may predispose to various complications including DVT, however this is remain valuable for simple sprains (40).

#### 2.5 Documented outcomes of Ankle sprain

Patients treated for ankle sprain are expected to recover and resume their daily activities hence some parameters has to reappear including ROM, balance and strength (9). Outcomes of ankle sprain are in line with the standardized method of evaluation of Foot and ankle injury using Foot and Ankle Outcomes Score (FAOS), which is a valid tool to be used after surgical reconstruction of ankle ligaments (5)(41). The hallmark in management of ankle sprain is the proper management and outcomes are time and severity dependent. In general upon optimal treatment, in 2 weeks there an expected substantial decrease in pain and improvement of range of motion and weight bearing, although definitive outcome will depend on severity of injury where the very mild disease will recover so quickly in contrary to the more severe form of ankle sprain (6). Although no robust study confirming the fact, however some literature reports some predictive factors of poor prognosis such as being female, upper extreme of age, multiple recurrences. Moreover severity of pain and inability to bear weight alternatively predict short outcomes (36).

#### 2.6 Commonly encountered complications

Ankle sprain notably LAS as the commonest entity presents potential complications including chronic ankle instability defined as suboptimal ROM, balance and strength above 12 months since the time of injury. Osteoarthritis which may present latter and change in lifestyle mainly resulting in decreasing level of activity (9). Cooke MW et al. has classified Ankle sprain complications into early versus late , whereby among late or chronic complications we can list prolonged need of medications, long-term limitation of ROM, chronic pain and instability, recurrent ankle sprain, persistent swelling (5). Almost a third ankle sprain patients may have persisting mild symptoms at 6 months such like instability and bearable pain which doesn't interfere their activities (4,25). The time frame interval direct the healing potential of the ankle sprain, however it has to be coupled with the severity and mode of treatment for disease to predict the outcome (4).

# **CHAPTER 3. METHODOLOGY**

# **3.1 STUDY AREA**

This study was carried out in Accident and Emergency (A&E), and Orthopedic Unities of two Teaching hospitals in Kigali, namely King Faisal Hospital and the University Teaching Hospital of Kigali (CHUK). Those Hospitals serve as main teaching hospitals in terms of various specialties. More specifically for orthopedic program, a substantial number of orthopedic and trauma procedures are done there.

# **3.2 STUDY DESIGN**

This study was a prospective cohort study.

# **3.3 STUDY PARTICIPANTS**

# 3.3.1 Inclusion criteria

Patients aged 18 years and above presenting to the A&E and outpatient department of the abovementioned tertiary centers, with grade 2 and 3 acute lateral ankle sprain were included in the study.

### 3.3.2 Exclusion criteria

Patients in the following categories were excluded:

- Patients refusing to consent for the study
- Patients with open ligamentous injuries requiring surgery
- Patients with a recurrent ankle sprain
- Patients with associated major distracting injuries (eg: moderate to severe Traumatic Brain Injury)
- Incompetent patients like associated major psychiatric disorder
- Patients with ankle sprain associated with ankle fracture
- Patients not suitable to immobilization (DVT)

### **3.4 PATIENTS RECRUITMENT**

Patients recruitment started after gathering both University and sites ethical clearances. A research assistant was trained about patients' recruitment; he recruited patients both at KFH and CHUK alternating with the primary investigator.

Patients who sustained sports injuries, road traffic related injuries, assault trauma, subtle fall upon their arrival to A&E or OPD, those presenting ankle and midfoot symptoms being mild, moderate and severe in intensity were thoroughly examined at the day of injury (delayed clinical examination was not done since we were able to classify the injury initially) and more specifically the ankle examination done primarily by the principal investigator or the research assistant. The Ottawa ankle rule was used to assess the need for radiography. The West Point grading was applied to retain only grade 2 and 3 acute lateral ankle sprain. Upon confirmation of the diagnosis, patients were sent to be treated by the A/E or OPD treating medical doctor without the influence of primary investigator or research assistant. Patients immobilized with backslab or aircast ankle brace were retained to the study, after obtaining consent and signature of a consent form.



Patients' recruitment flow diagram

# **3.5 DATA COLLECTION AND VARIABLES**

Patients immobilized with backslab or aircast ankle brace were followed up with the primary investigator after 3 weeks and 6 weeks, for evaluation of the outcomes.

We used a data collection form where different types of data were recorded including demographic data such as age, gender and phone number, then clinical data such as the mechanism of injury and pain score using a numerical rating pain scale at 3 then 6-week intervals, ankle instability features, range of motion, limping, edema, and anterior drawer test and sign evaluated on arrival and in follow-up sessions. Moreover, we evaluated the timing of return to daily activities (sports/work) as part of outcomes.

The outcomes were evaluated as primary or secondary outcomes on every single patient. The proportion of patients with pain/swelling at intervals of 3 weeks and 6 weeks in backslab versus aircast ankle brace groups, were reported as primary outcomes. Moreover we evaluated activity restoration before and after the 28<sup>th</sup> day, considered as the mean timing ligament remodeling (28,42).

# **3.6 DEFINITION OF KEY CONCEPTS**

Pain grading, referring to numeric pain rating by Jensen et al. (43)

- Mild: pain from 1 to 4
- Moderate: pain from 5 to 6
- Severe: pain from 7 to 10

Ankle swelling grading by Geber et al. (25)

- Mild: swelling localized to lateral malleolus
- Moderate: swelling diffuse to lateral aspect of ankle
- Severe: diffuse swelling across the whole ankle

Chronic ankle instability: occurrence of 2 or more ankle sprain recurrence or giving away in 6 months after initial ankle sprain (19).

# **3.7 SAMPLE SIZE CALCULATION**

The sample size for this study was obtained using the formula used to estimate sample sizes in cohort studies (44). To note that the power was set at 90% and level of significance at 5%.

n: stand for sample size for each group

p1: Proportion of patients cured by treatment A(backslab) in previous study (13%), p1=0.13

p2: Proportion of patients improved by treatment B(aircast ankle brace) in previous study (43%), p2=0.43

p1 and p2 were obtained from the study done by Eiff et al.(45)

 $Z_{\alpha/2}$ =1.96, as the level of significance is 5%

 $Z_{\beta}$ = 1.28, as the power is set at 90%

p=(p1+p2)/2=(0.13+0.43)/2=0.28

$$n = \{Z_{\alpha/2} \sqrt{[2p(1-p)] + Z_{(1-\beta)}} \sqrt{[p1(1-p1) + p2(1-p2)]} \frac{2}{(p1-p2)^2}$$

$$n = \{1.96 \sqrt{[0.56(1-0.28)]} + 1.28 \sqrt{[0.13(1-0.13)+0.43(1-0.43)]} \frac{2}{(0.13-0.43)^2} = 44.9 \approx 45$$

Therefore, referring to the findings of our formula each of the two groups of our study contains 45 patients making a sum of 90 patients for the whole study.

#### **3.8 DATA ANALYSIS AND RESULTS INTERPRETATION**

Data obtained in patient's data collection form were entered in the computer by Excel and analyzed using SPSS version 28 statistical software. Data analysis started after completion of data collection from 90 participants. Patients' demographics were compared in both ankle brace and backslab groups and summarized in tables with descriptive statistics including mean, median and percentages. The mechanisms that led to ankle sprain were reported and compared in the 2 arms. The t-test was the statistical test used and represented as p-value, moreover our dichotomous and ordinal categorical data were analyzed and represented into the mean value, mode and standard deviation. Primary outcomes and secondary outcomes were presented in comparative manner aiming to identifier the statistical significance among the two treatment groups. Residual pain at 3 weeks was reported comparing two treatment arms and considering initial west point grading. Results were reported as tables, graphs and charts.

#### **3.9 ETHICAL CONSIDERATION**

There was minimal risk on retained patients since there is no new intervention adopted rather patients were treated according to the usual practice. We ensured confidentiality in patients' information storage which was only seen by the research team. Data collection sheets were enclosed in a filing cabinet only accessed by investigators. No reimbursements were expected for participants in this study since it is purely voluntary. Moreover, we sought consent from each individual participant, and a consent form was signed after obtaining consent. We obtained an initial ethical approval from CMHS IRB on 17<sup>th</sup> March 2021 with approval notice: No 095/CMHS IRB/2021, we sought amendment for study design and other changes which was issued on 8<sup>th</sup> August 2021 with approval notice No 263/CMHS IRB/2021. We proceeded and got CHUK and KFH ethical approvals before recruitment, data collection and progressing upon further steps of the study.

# **CHAPTER 4. RESULTS**

# 4.1. Patients' Demographics

Our cohort has recruited in total 90 patients as per our sample size, patients were recruited from CHUK and KFH which are tertiary health facilities in Kigali.

Table 2. Patients' Demographics						
Variables	Backslab group (BS)			Ankle brace group (AB)		
Age	Min – Max (Age	Mean age	Median	Min – Max	Mean age	Median
	in years)	(standard	age	(age in	(standard	age
		deviation)		years)	deviation)	
	19-65	35.76	42	18-73	35.18	45.5
		(10.428)			(12.721)	
		P v	alue= 0.4			I
Gender	Male	Female		Male	Female	
	21	24		23	22	
	M/F	M/F: 0.87/1		M/F: 1.04/1		
		Р	value=0.53	I		
Patients by	СНИК	KFH		CHUK	KFH	
hospital	37	8		34	11	
Side injured	Right	Left		Right	Left	
	25	20		19	26	
West point	Grade 2	Grade 3		Grade 2	Grade 3	
grading						
	36	9		36	9	

71 patients were recruited from CHUK and 19 patients form KFH over 6 months. Patients demographics are summarized in the table 2. When comparing both treatment arms, the mean age for backslab group was 35.76 while the ankle brace group was 35.18 whilst the median age was 42 and 45.5 respectively for backslab and ankle brace group. The male to female ration was 0.87 for BS versus 1.04 AB. Using the t-test and reported as p value in tables there was no difference among age distribution and male to female ratio in the 2 groups. Among patient recruited in both arms there were 36 patients grade 2 ankle sprain injuries and 9 patients as grade 3 on west point grading system. This was similar to both treatment arms.

#### 4.2 Mechanism of injury

Table 3: Mechanism of inj	ury		
Mechanism of injury	Backslab	Ankle brace	Total number (%)
Twisting & rolling ankle	30	36	66 (73.3%)
Fall from height	12	6	18 (20%)
Moto-pedestrian collision	3	1	4 (4.4%)
Moto-Moto collision	0	2	2 (2.2%)

The mechanisms of injury were summarized in table 3. The commonest mechanism was twisting & rolling ankle among 66 (73.3%) patients this represent 36 patients of ankle brace group and 30 patients of backslab group. The least reported mechanism was moto-moto collision 2.2% they were involved as passengers.

# 4.3 Primary outcomes

4.3.1 Pain at 3 and 6weeks

Table 4: Pain after treatment					
At 3 weeks	Pain ≥ moderate*				
	Ankle brace	Backslab			
	26.7%	55.5%			
At 6 weeks	Pain ≥ mild				
	Ankle brace	Backslab			
	13.3%	35.6%			
	P value=0.04				

\*patients of pain equal or greater than moderate pain, the same applies to the rest of the table. Pain grading was defined v concept section.

in definition of key concept section.

Patients with grade 2 and 3 acute lateral ankle sprain outcomes are summarized in Table 4. We identified that after 3 weeks 26.7 % of patients treated with aircast ankle brace had moderate or severe pain while 55.5% of backslab cohort had the same pain. After 6 weeks from the timing of injury a small proportion of patients treated with ankle brace were having mild to moderate pain compared to backslab cohort. We could note that given the p value calculated referring to t-test, pain improvement was statistically significant. Hence these findings favor ankle brace to be effective in early pain control.

Table 5: Swelling	after treatment				
At 3 weeks	Swelling $\geq$ moderate*				
	Ankle brace	Backslab			
	26.7%	48.8%			
At 6 weeks	6 weeks Swelling $\geq$ mild				
	Ankle brace	Backslab			
	13.3%	28.9%			
	P value= 0.0543				

\*patients of swelling equal or greater than moderate swelling, the same applies to the rest of the table. Swelling grading was defined in definition of key concept section.

Patients with grade 2 and 3 acute lateral ankle sprain outcomes are summarized in Table 5. We found moderate to severe swelling to be present at 26.7% and 48.8% respectively for ankle brace and backslab. After 6 weeks from the timing of injury a small proportion of patients treated with ankle brace were having mild to moderate swelling compared to backslab group. The difference identified was not statistically significant when swelling resolution was taken into consideration among the 2 groups.

Table 6: P	ain and swell	ing after 3 weeks when conside	ering West po	int grading	
Grading	A	Ankle brace		Backslab	
					value
Grade 2	Mild pain	Moderate to severe pain	Mild pain	Moderate to severe pain	
	72.22%	22.22%	38.88%	52.77%	-
	Mild swelling	Moderate to severe swelling	Mild swelling	Moderate to severe swelling	
	66.66%	22.22%	44.44%	44.44%	0.9
Grade 3	Mild pain	Moderate to severe pain	Mild pain	Moderate to severe pain	
	55.5%	44.44%	11.11%	66.66%	
	Mild swelling	Moderate to severe swelling	Mild swelling	Moderate to severe swelling	
	55.5%	44.44%	22.22%	66.66%	

Table 6 is comparing both treatment arms while considering the initial west point grading, we could note that a larger proportion of patients with grade 3 acute lateral ankle sprain treated with backslab were still having moderate to severe pain and swelling at 3 weeks. However those findings were not statistically significant give a p value= 0.9. Therefore the grading of injury was not identified to influence the outcome at the  $3^{rd}$  week among our findings.

# 4.4 Secondary outcomes

Table 7: Rate of ankle sprain recurrence					
Intervention	Rate (%)	West point grading			
Ankle brace group	2 (4.4%)	Grade 2 Grade 3			
		1	1		
Backslab group	2 (4.4%)	Grade 2	Grade 3		
		2	0		
		P value >0.05			

4.4.1 Ankle sprain recurrence at 6 weeks post-injury

The rate of ankle sprain recurrence was calculated referring to patients who had recurrent acute LAS. We obtained 2 patients in each group. When the treatment arms compared to the initial injury classification, we noted 2 patients with Grade 2 Acute lateral ankle sprain to have recurrence in Backslap group. However the difference noted was not statistically significant.

4.4.2	Timing of	Weight	bearing and	l activities	restoration	post-treatment
	0	0	0			1

Table 8: Weight bearing and activities restoration								
Intervention	Timing of weight bearing in days		Timing of return to daily activities					
Ankle brace	≤28 days	>28 days	≤28 days	>28 days				
	45 patients	0	43 patients	2 patients				
	(100%)		(95.5%)	(4.5%)				
Backslab	≤28 days	>28 days	≤28 days	>28 days				
	40 patients	5 patients	34	11				
	(88.9%)	(11.1 %)	(75.5 %)	(24.4%)				
	P value= 0.5							

Patients with ankle sprain were expecting to bear weight and return to their daily activities before 6 weeks the latest but most of them should resume their activity by the 4<sup>th</sup> week. Patients were immobilized by ankle brace or backslab for 21 days then physical therapy sessions initiated, initial weight bearing and timing of return to daily activities was considered as secondary outcome and was evaluated at the 28<sup>th</sup> day. Two groups were elaborated on each intervention one less or equal to 28 days another one above 28 days. 100% of patients treated with aircast ankle brace have resumed weight bearing at by 28<sup>th</sup> day from the injury day, when compared to 88.9% in the backslab group. 95.5 % could return to daily activities by 28<sup>th</sup> day in the ankle brace group when compared to 75.5% in the backslab group. Even though the ankle brace group seems to be more efficient in terms of early return to activities and weight bearing, it is not statistically significant since the p value was equal to 0.05.

#### **CHAPTER 5. DISCUSSION**

The present study aimed to assess the best treatment modality for patients consulting with grade 2 and 3 acute lateral ankle sprain between backslab and aircast ankle brace. Early pain and swelling control were primary outcomes, while recurrence rate of ankle sprain and timing of activity restoration were secondary outcomes. In total we recruited 90 patients referring to the previously calculated sample size, 45 patients were enrolled on each treatment group. Patients' characteristics reported and not statistically different in both treatment arms, as this was an observational study and the investigators did not influence similarities in patients' characteristics. Patients were recruited from CHUK which receive a large number of trauma cases and KFH which does as well receive a number of trauma and sport injury cases. An above mentioned sample size recruited in six months may show that ankle sprain is not a rare entity in our setting nor anywhere else in developed countries and this trend of increase is likely to progress.

Epidemiologically ankle sprain is not rare in our setting, since when combining CHUK and KFH findings we could estimate 1 case of ankle sprain every 2 days. Our findings are similar to those documented by other authors such as Polzer H. et al. (46) who reported the incidence of ankle sprain to be 1 per 10000 people per day. The US knows this frequency of ankle sprain emergencies as well, in a study by Prado et al. they reported daily occurrence of 27000 ankle sprains (47). The commonest cause of Acute LAS in our cohort was identified as twisting ankle and rolling as reported by patients. Biomechanically the above mechanism of injury may be justified as plantar flexed and inverted foot while landing on the ground which actually is the commonest mechanism of injury leading to acute lateral ankle sprain injury (48,49). Inversion injuries are very common and biomechanically ones leading to lateral ankle sprain grading is a scientific way of documenting and communicating about the severity of injury and to report ligaments involved, however it was not identified to affect the outcomes and this has previously been documented (50).

Using an ankle brace was advantageous in terms of primary outcomes in our study where we found lower rate of pain at 3 and 6 weeks intervals post injury following ankle sprain and this is supported by previously available literature reporting semi-rigid ankle brace to be recommended in grade 2 and 3 acute lateral ankle sprain (46). Using functional braces are not only superior to backslab but also to walking boot in early return to daily living activities and pain free weight bearing (47). The west point grading system does predict as well the estimate timing of recovery when related to the injury grade, a study by Davis H. et al. report restoration of daily activities for Grade 2 and 3 to range from the end of 2<sup>nd</sup> week to 26<sup>th</sup> week the upper limit reserved for full recovery of professional athletes (4) these findings could be related to our findings since most of our patient resumed their daily living activities by the end of the 4<sup>th</sup> week. Activity restoration is an important indicator in ankle sprain recovery, it was considered in our study and when comparing both treatment arms, 95.5% and 75.5% respectively treated by ankle sprain and backslab could return to their initial daily activities before or at the 28<sup>th</sup> day from the injury time. However, this difference is not statistically significant as p value >0.05. Moreover, in accordance with the recommendation of the above study, all our patients were sent to physical therapy in their treating hospitals for a period of 3 weeks.

The present work not only shows similarities to previous studies, however some differences were as well seen. Outcomes in the current study were identified as primary versus secondary outcomes. Primary outcomes were compared when looking at pain on the 3<sup>rd</sup> week post injury. Moderate and severe symptoms were present in the backslab group twice than the ankle brace group. At the 6<sup>th</sup> week, the ratio was almost 3 to 1. This could be explained by 2 factors; one being some free range of motion at the mortise joint while wearing an ankle brace than a backslab, another being biomechanical characteristics of an aircast ankle brace whereby there is a compressive force on the body while bearing weight relieving pain and edema. These findings reported the ankle brace to be a bit superior to the backslab group when looking at the pain, swelling and timing of weight bearing. However, in the study by Beynnon et al. this difference couldn't be identified (28). The difference in findings between two studies could be related to the study design since one is a randomized controlled trial.

The rate of ankle instability was equal and low in both groups at 4.4% each group. This low rate may be due to the shorter time of follow-up, it may also be caused by lack of professional athletes in our cohort. The current available literature presents differences among findings when considering ankle instability post-lateral ankle sprain, a study by Ferreira et al. reported the ankle instability to range from 0 to 33 %. These findings are in line with our current results (51). However, Cavazos Jr. et al. reported ankle instability to be around 40% of patients who sustained an acute lateral ankle sprain (49). There are notable differences in causes and mechanism of injuries of our population from the previously reported literature. In our study, causes were more non-athletic related injuries and road traffic related injuries. Whereas a study done by Fong et al. reported athletic injuries to lead the list of causes of acute lateral ankle sprain (3). Majority of above mentioned differences could be related to different population characteristics, lifestyle, culture and health system structure.

#### 5.1 Study limitations

Our study was done at CHUK and KFH which are amongst main referrals in Kigali, however it was an observation study therefore the principal investigator was out of control of some important factors that may have led to bias in the results. Among important aspect we were not able to control we could note, to decide whom to give ankle brace or backslab, patient who were not able to afford ankle braces were automatically treated with backslab. The primary treating doctors were not always aware of standardized treatment options for acute lateral ankle sprain. Another factor could be working in 2 hospitals with different settings, at CHUK there was tendency to give backslab while at KFH they often use functional treatment. A semi-blinded randomized controlled trial could overcome much of those challenges.

# **CHAPTER 6. CONCLUSION AND RECOMMENDATIONS**

Our study showed that ankle sprains are prevalent in our hospitals, with the trend likely to increase given local development of athletic industry. The present cohort showed that even older subject may sustain an ankle sprain. Landing on inverted and plantarflexed foot was the main mechanism identified in our study reflecting the existing findings in the current literature. The aircast ankle brace was superior to backslab on pain improvement at  $3^{rd}$  and  $6^{th}$  week interval. Swelling resolution, timing of activity restoration and recurrence rate were not statistically significant. To extend these findings to the general population we may need to look at long term outcomes.

Therefore we recommend the following:

- Implementation of Ankle sprain management protocols at CHUK and KFH
- We recommend hospitals to avail aircast ankle braces
- To retrain more physical therapist manly in district hospitals in how to rehabilitate a patient with ankle sprain
- Referrals should organize District Hospitals visit on management of acute ankle injuries
- o Ottawa ankle rule should be taught at Accident and Emergencies
- We recommend a semi-blinded randomized controlled trial

#### REFERENCES

- 1. Ivins D. Acute ankle sprain: An update. Am Fam Physician. 2006;74(10).
- Richardson DR. Sports injuries of the ankle. In: Campbell's operative orthopaedics. 13th ed. p. 4351–5.
- 3. Fong DTP, Hong Y, Chan LK, Yung PSH, Chan KM. A systematic review on ankle injury and ankle sprain in sports. Sport Med. 2007;37(1):73–94.
- 4. Davis H. The sprained ankle. Br J Sports Med. 1964;1(3–4):76–80.
- 5. Cooke MW, Marsh JL, Clark M, Nakash R, Jarvis RM, Hutton JL, et al. Treatment of severe ankle sprain: A pragmatic randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of three types of mechanical ankle support with tubular bandage. The CAST trial. Health Technol Assess (Rockv). 2009;13(13).
- Martin R, McGovern R. Managing ankle ligament sprains and tears: current opinion. Open Access J Sport Med. 2016;33.
- Al-Mohrej OA, Al-Kenani NS. Acute ankle sprain: Conservative or surgical approach? EFORT Open Rev. 2016;1(2):34–44.
- Van Den Bekerom MPJ, Struijs PAA, Blankevoort L, Welling L, Van Welling CN, Kerkhoffs GMMJ. What is the evidence for rest, ice, compression, and elevation therapy in the treatment of ankle sprains in adults? J Athl Train. 2012;47(4):435–43.
- Feger MA, Glaviano NR, Donovan L, Hart JM, Saliba SA, Park JS, et al. Current trends in the management of lateral ankle sprain in the United States. Clin J Sport Med. 2017;27(2):145–52.
- 10. Wever G, McCollum G. The management of acute lateral ankle sprains: a survey of South African surgeons and best evidence available. SA Orthop J. 2018;17(3).
- Lislevand M, Andersen TE, Junge A, Dvorak J, Steffen K. Injury surveillance during a 2day national female youth football tournament in Kenya. Br J Sports Med. 2014;48(11):924–8.
- Murwanashyaka E, Buteera AM, Byimana J, Bukara E, Nzayisenga A, Byiringiro JC. Applicability of Ottawa ankle rules in predicting the need for radiography in ankle and midfoot injuries in Rwanda. East African Orthop J. 2020;14:4–7.
- Niyonsenga J, Phillips J. Factors associated with injuries among first-division Rwandan female soccer players. Afr Heal Sci. 13(4):1021–1026.

- Avci S, Şayli U. Comparison of the results of short-term rigid and semi-rigid cast immobilization for the treatment of grade 3 inversion injuries of the ankle. Injury. 1998;29(8):581–4.
- Kerkhoffs GM, Van Den Bekerom M, Elders LAM, Van Beek PA, Hullegie WAM, Bloemers GMFM, et al. Diagnosis, treatment and prevention of ankle sprains: An evidence-based clinical guideline. Br J Sports Med. 2012;46(12):854–60.
- 16. Raikin SM, Parks BG, Noll KH, Schon LC. Biomechanical evaluation of the ability of casts and braces to immobilize the ankle and hindfoot. Foot Ankle Int. 2001;22(3):214–9.
- Lamb SE, Marsh JL, Hutton JL, Nakash R, Cooke MW. Mechanical supports for acute, severe ankle sprain: a pragmatic, multicentre, randomised controlled trial. Lancet [Internet]. 2009;373(9663):575–81. Available from: http://dx.doi.org/10.1016/S0140-6736(09)60206-3
- Mellet E, Stewart AV. The prevalence of clinical signs of ankle instability in club rugby players. South African J Sport Med. 2013;25(1):23–7.
- Lin CI, Houtenbos S, Lu YH, Mayer F, Wippert PM. The epidemiology of chronic ankle instability with perceived ankle instability- a systematic review. J Foot Ankle Res. 2021;14(1).
- Drake RL, Vogl W, Mitchell AWM. Foot. In: Gray's Anatomy for Students. 2004. p. 558–83.
- Brockett CL, Chapman GJ. Biomechanics of the ankle. Orthop Trauma [Internet].
   2016;30(3):232–8. Available from: http://dx.doi.org/10.1016/j.mporth.2016.04.015
- Kaminski TW, Hertel J, Amendola N, Docherty CL, Dolan MG, Hopkins JT, et al. National athletic trainers' association position statement: Conservative management and prevention of ankle sprains in athletes. J Athl Train. 2013;48(4):528–45.
- 23. Waterman BR, Owens BD, Davey S, Zacchilli MA, Belmont PJ. The epidemiology of ankle sprains in the United States. J Bone Jt Surg Ser A. 2010;92(13):2279–84.
- 24. Terada M, Pietrosimone BG, Gribble PA. Therapeutic interventions for increasing ankle dorsiflexion after ankle sprain: A systematic review. J Athl Train. 2013;48(5):696–709.
- Gerber JP, Williams GN, Scoville CR, Arciero RA, Taylor DC. Persistent disability associated with ankle sprains: A prospective examination of an athletic population. Foot Ankle Int. 1998;19(10):653–60.

- Lane SE. Severe ankle sprains: Treatment with an ankle-foot orthosis. Phys Sportsmed. 1990;18(11):43-44+46.
- Debieux P, Wajnsztejn A, Nacime Salomão Barbachan Mansur. Epidemiology of injuries due to ankle sprain diagnosed in an orthopedic emergency room. einstein (São Paulo). 2020;18.
- Beynnon BD, Renström PA, Haugh L, Uh BS, Barker H. A prospective, randomized clinical investigation of the treatment of first-time ankle sprains. Am J Sports Med. 2006;34(9):1401–12.
- 29. Van Dijk CN, Lim LSL, Bossuyt PMM, Marti RK. Physical examination is sufficient for the diagnosis of sprained ankles. J Bone Jt Surg Ser B. 1996;78(6):958–62.
- 30. Vuurberg G, Hoorntje A, Wink LM, Van Der Doelen BFW, Van Den Bekerom MP, Dekker R, et al. Diagnosis, treatment and prevention of ankle sprains: Update of an evidence-based clinical guideline. Br J Sports Med. 2018;52(15):956.
- 31. Frey C, Bell J, Teresi L, Kerr R, Feder K. A comparison of MRI and clinical examination of acute lateral ankle sprains. Foot Ankle Int. 1996;17(9):533–7.
- 32. Stiell I. Ottawa ankle rules. Can Fam Physician. 1996;42(MAR.):478–80.
- 33. Pires R, Pereira A, Abreu-e-Silva G, Labronici P, Figueiredo L, Godoy-Santos A, et al. Ottawa ankle rules and subjective surgeon perception to evaluate radiograph necessity following foot and ankle sprain. Ann Med Health Sci Res. 2014;4(3):432.
- Hu H. Common types and countermeasures of ankle ligament injury caused by intense basketball movement. Niger J Clin Pract. 2017;20(8):1036–9.
- 35. Bashaeb MO, Mutala TM, Muriithi IM. Pattern of ultrasonographic findings of disorders of the ankle joint complex in patients presenting with ankle pain at the department of diagnostic imaging, university of Nairobi. Pan Afr Med J. 2018;31.
- Thompson JY, Byrne C, Williams MA, Keene DJ, Schlussel MM, Lamb SE. Prognostic factors for recovery following acute lateral ankle ligament sprain: A systematic review. BMC Musculoskelet Disord. 2017;18(1):1–14.
- Doherty C, Bleakley C, Delahunt E, Holden S. Treatment and prevention of acute and recurrent ankle sprain: An overview of systematic reviews with meta-analysis. Br J Sports Med. 2017;51(2):113–25.
- 38. Tricia Hubbard T. Ankle sprain: pathophysiology, predisposing factors, and management

strategies. Open Access J Sport Med. 2010;115.

- Slimmon D, Brukner P. Sports ankle injuries: Assessment and management. Aust Fam Physician. 2010;39(1):18–22.
- 40. Rowe GMMJK· BH, · WJJA· KDK, Dijk PAAS· CN van. Immobilisation for acute ankle sprain A systematic review. Arch Orthop Trauma Surg. 2001;121 :462–4.
- 41. Hogan MC V., Mani SB, Chan JY, Do H, Deland JT, Ellis SJ. Validation of the Foot and Ankle Outcome Score for Hallux Rigidus. HSS J. 2016;12(1):44–50.
- 42. James C. Puffer. The sprained ankle. Br J Sports Med. 1964;1(3–4):76–80.
- 43. Jensen MP, Smith DG, Ehde DM, Robinsin LR. Pain site and the effects of amputation pain: Further clarification of the meaning of mild, moderate, and severe pain. Pain. 2001;91(3):317–22.
- Kasiulevičius V, Šapoka V, Filipavičiūtė R. Sample size calculation in epidemiological studies. Gerontologija. 2006;7(4):225–31.
- 45. Eiff MP, Smith AT, Smith GE. Early Mobilization Versus Immobilization in the Treatment of Lateral Ankle Sprains. Am J Sports Med. 1994;22(1):83–8.
- Polzer H, Kanz KG, Prall WC, Haasters F, Ockert B, Mutschler W, et al. Diagnosis and treatment of acute ankle injuries: development of an evidence-based algorithm. Orthop Rev (Pavia). 2011;4(1):5.
- 47. Prado MP, Mendes AAM, Amodio DT, Camanho GL, Smyth NA, Fernandes TD. A comparative, prospective, and randomized study of two conservative treatment protocols for first-episode lateral ankle ligament injuries. Foot Ankle Int. 2014;35(3):201–6.
- 48. Lynch SA. Assessment of the injured ankle in the athlete. J Athl Train. 2002;37(4):406–12.
- 49. G Javier CJ, Lawrence B H. The epidemiology, evaluation, and assessment of lateral ankle sprains in athletes. J Sport Med Ther. 2021;6(2):008–17.
- 50. Bullock SA, Allen GM, Watson MS, Wilson DJ. Predicting poor outcome from simple ankle injuries: A prospective cohort study. Br J Radiol. 2018;91(1081).
- Ferreira JN, Vide J, Mendes D, Protásio J, Viegas R, Sousa MR. Prognostic factors in ankle sprains: A review. EFORT Open Rev. 2020;5(6):334–8.

### **APPENDICES**

APPENDIX 1.Informed consent (English version) PART I: INFORMATION SHEET RESEARCH: EFFECTIVENESS OF AIRCAST ANKLE BRACE COMPARED TO BACKSLAB IN THE MANAGEMENT OF ANKLE SPRAIN, A PROSPECTIVE COHORT STUDY

Principal investigator: Dr KUBWIMANA Olivier, Resident in Orthopedic Surgery.

Given the lack of enough local data on ankle sprain I was dedicated to conduct this research in two Teaching hospitals in Kigali, notably CHUK and KFH. Hence you are warmly welcome and we thank you to participate in this research.

Details about the study are to be given below and you have a room to ask questions and I will explain it with much details.

#### •Aim of the research

The tremendous rise of sports injuries was noted over several decades ago. The ankle sprain is among the very most common amongst those injuries and they pose economic expenditures when management is concerned. However its management is full of controversies and even more in local settings, hence we aim to highlight the best immobilization option between a below knee backslab and aircast ankle brace.

### •Participant and Intervention

Eligible candidate are participant who sustained ankle injuries without fractures, we shall rely on physical examination, Ottawa ankle rule and standard radiography to rule out fractures. After full examinations patients having ankle sprain will be treated depending on treating physicians' choice, those ones immobilized with a backslab or aircast ankle brace, after signing a consent form will be enrolled to the study. Patients will be followed on phone in 3 weeks then after the immobilization removed in OPD and start physiotherapy.

# •Voluntary Participation

The participation is voluntary, and your choice won't affect the standardized way of ankle sprain management. Moreover you are free to leave research at any research step wherever the process seems inconvenient to you.

### • Risks

The current study will subject very minimal risk to participant because there is no new treatment introduced, patients will be treated with daily used treatment.

# • Reimbursements

No reimbursements expected in the current study participation because it is purely voluntary.

# • Confidentiality

We ensure confidential storage of names and other personal information they will be only seen by the principal investigator. Upon report and data analysis names will not appear instead numbers.

# • Sharing the Results

Upon completion of the study results will be published in order to highlight and let the local and international practice know the most effective treatment option.

# PART II: CERTIFICATE OF CONSENT

I have read the above information, or it has been read to me. I (or witness) have had the opportunity to ask questions and they were answered with satisfaction. Hence I voluntarily consent to participate in this research.

Name of Participant/Witness.....

Signature of Participant/Witness .....

Date ...../..... (Day/month/year)

# Statement by the researcher/person taking consent

I have read the information sheet in a detailed way to the participant and he/she was satisfied upon even answering his/her questions. The participant is aware that the process will be in a stepwise approach: signing consent form, treatment with analgesics and immobilization, on phone followup, outpatient visit after 3 weeks.

I confirm that the participant is aware of the whole research process and not coerced to consent, there was freedom to consent voluntarily.

Name of Researcher/person taking the consent...... Signature of Researcher /person taking the consent...... Date...../...... (Day/month/year) Researcher contact: Dr KUBWIMANA Olivier Tel: + 250788896431 Email: <u>oliviee3@gmail.com</u>

If you have questions about your rights in the study, contact Dr STEFAN Jansen Tel: +250784575900 Chairperson – IRB CMHS / University of Rwanda

# APPENDIX 2. Kwemera kujya mu bushakashatsi (Ubusobanuro mu Kinyarwanda) Inyito y'Ubushakashatsi: EFFECTIVENESS OF AIRCAST ANKLE BRACECOMPARED TO BACKSLAB IN THE MANAGEMENT OF ANKLE SPRAIN, A PROSPECTIVE COHORT STUDY.

Umushakashatsi: Dr KUBWIMANA Olivier, umuganga wizobereza mu gashami ko kubaga amagufa.

Ngendeye ku kuba ntamakuru ahagije dufite hano iwacu ku mvune zo guhinyagara mu kagombambari, nahisemo gukora ubu bushakashatsi mu bitaro bibiri bikuru biherereye muri Kigali, birimo KFH na CHUK. Kubwizo mpamvu nguhaye ikaze kandi ngushimiye cyane kwinjira muri ubu bushakashatsi. Ubusobanuro burambuye urabuhabwa mu bika bikurikira by'iyi nyandiko kandi urabona umwanya wo kubaza ibyo utasobanukiwe neza.

# Intumbero y'ubushakashatsi

Imyaka ishize yaranzwe no kwiyongera kudasanzwe kw'imvune z'imikino. Guhinyagara mu kagombambari ni imwe mu mvune ikunda kuboneka kandi iteza igihombo kubijyanye no kwivuza. Uburyo izimvune zivurwa ntabwo buvugwaho rumwe arinayo mpamvu twahisemo gukora ubu bushakashatsi kugirango tumenye igifitiye abarwayi akamaro kurusha ikindi hagati ya sima y'inyuma (backslab) n'urukweto rw'umwuka rufata mu kagombambari (aircast ankle brace).

### Abazitabira ubushakashatsi n'uko bizakorwa

Abemerewe kujya mu bushakashatsi ni abantu bose bavunitse mu kagombambari ariko nta mvune z'amagufa zirimo. Tuzagendera ku isuzuma rusange ry'umurwayi, Ottawa ankle rule, no guca mucyuma kugirango tumenye ko amagufa ari mazima. Nyuma y'iryo suzuma abarwayi babonyweho guhinyagara mu kagombambari babishaka bazinjizwa mu bushakashatsi hanyuma bavurwe hakurikijwe amabwiriza yo kuvura ihinyagara ryo mu kagombambari , bazavurwa hakurikijwe amahitamo ya muganga umukurikirana, abavuwe hakoreshejwe sima y'inyuma cyangwa urukweto rw'umwuka (air cast ankle brace) bazinjizwa mu bushakashatsi nyuma yo gusobanurirwa no gushyiraho umukono. Umurwayi azakurikiranwa kuri telephone mu gihe cy'ibyumweru 3 nyuma yaho urukweto cg sima bikurweho umurwayi atangire ubugororangingo.

# Kwinjira mu bushakashatsi ku bushake

Kwinjira mu bushakashatsi ni ubushake bwawe nyuma yo gusobanurirwa imiterere y'ubushakashatsi. Kutinjira mubushakashatsi ntacyo bihungabanya kuburyo bwo kuvurwa.

# Ingaruka zo kujya mu bushakashatsi

Nta bibazo bidasanzwe ubushakashatsi bwaguteza kuko dukoresha ubuvuzi busanzwe butangwa, gusa nuko ubushakashatsi aribwo buguhitiramo uko uvurwa.

# Igihembo cyo kujya mu bushakashatsi

Ntagihembo cyihariye cyagenewe uwinjiye mu bushakashatsi kuko kwinjiramo ari ubushake.

# Ibikwa ry'amakuru mw'ibanga

Amakuru yose uzatanga yaba umwirondoro cyangwa uburwayi bwawe azabikwa neza mu ibanga. Umwirondoro ntabwo uzashyirwa ahagaragara uzabonwa gusa n'umushakashatsi mukuru. Mugutangaza amakuru amazina azasimbuzwa imibare.

### Gutangaza ibizava mu bushakashatsi

Ibizava muri ubu bushakashatsi bizashyirwa ahagaragara kugirango ubuvuzi bw'inaha ndetse nahandi bumenye amahitamo meza mukuvura guhinyagara ko mukagombambari.

### Uwinjiye mu bushakashatsi

Nyuma yo gusoma cg gusomerwa ibyerekeranye nubu bushakashatsi. Nabonye(cg umpagarariye) umwanya wo kubaza ibibazo kandi nasobanuriwe bihagije.Nkabanemeye kwinjira muri ububushakashatsi.

Amazina y"umurwayi/umuhagarariye...... Umukono w"umurwayi/umuhagarariye...... Italiki ...... /..../....

### Umuganga

Nasobanuriye uwinjiye mu bushakashatsi amakuru yose ajyanye nabwo. Yanahawe umwanya wokubaza ibyo atasobanukiwe ahabwa ibisubizo bimunyuze. Akaba yasobanuriwe ko ubushakashatsi buzakorwa mu buryo bukurikira: gushyira umukono ku nyandiko imwemerera kwinjira mu bushakashatsi, kuvurwa hakoreshejwe imiti igabanya kubabara , sima y'unyuma cyangwa urukweto rw'umwuka, gukomeza kumukurikirana kuri telephone, kugaruka mw'isuzumiro nyuma y'ibyumweru 3 no gukuraho isima cyangwa urukweto, kumwohereza mu bugororangingo.

Ndahamya ko umurwayi yinjiye mu bushakashatsi ku bushake ntagahato ashyizweho.

Amazina ya muganga...... Umukono wa muganga...... Italiki ..... /..../.... Ku bindi bisobanuro wahamagara: Dr KUBWIMANA Olivier Tel: + 250788896431 Email: <u>oliviee3@gmail.com</u> Ufite ikindi kibazo kuburenganzira bwawe muri ubu bushakashatsi wabaza:

Dr STEFAN Jansen Tel: +250784575900

Chairperson - IRB CMHS / University of Rwanda

Appendix 3. Data collection form

DATA COLLECTION FORM	ANKLE SPRAIN
GRADE 2 3 ANKLE SPRAIN COHORT STUDY	STUDY NUMBER
PATIENT DEMOGRAPHY	
Date of initial visit [//] [DD/MM/YYY	Y]
Patient ID number	
Patient phone number	
Hospital: CHUK□ KFH□	
Gender: Male □ Female□	
Date of Birth [/] [DD/MM/YYYY	7]
INJURY DETAILS	
Date of Injury [//] [DD/MM/YYYY]	
Injured side: Right Left Cause of injury and mechanism of injury Pain: Mild Moderate Severe	
[Numerical rating pain scale: Mild (1-3), Moderate (4-6	), Severe (7-10)]
Anterior drawer test: Positive Negative	
(Positive test means tear of talofibular ligament)	
Talar tilt test: Positive□ Negative□	
(Positive test means tear of calcaneofibular ligament)	
Grading of ankle sprain by West point ankle sprain Gra	nding system
Grade: II□ III□	
Imaging done, if any: Ankle Radiography□ MRI□ Findings	

# **DEFINITIVE INTERVENTION**

Immobilization done : Backslab Aircast ankle brace

Date of immobilization [...../....] [DD/MM/YYYY]

Date of immobilization removal [...../....] [DD/MM/YYYY]

# **OUTCOMES AT 3 WEEKS, 6 WEEKS**

Pain: (at 3wee	Pain: (at 3weeks)		No □			
If Yes,	Mild   Modera	ite □ Sev	ere 🗆			
Swelling: (at 3	weeks)	Yes □	No □			
If Yes,	Mild D Mo	oderate 🗆	Seve	re 🗆		
Pain: (at 6 weeks)		Yes		No 🗆		
If Yes,	Mild   Modera	ite □ Sev	ere 🗆			
Swelling: (at 6	weeks)	Yes 🗆	1 I	No 🗆		
If Yes,	Mild	oderate 🗆	Seve	re 🗆		
OUTCOMES AT 6 WEEKS						
Date of return to work or sports [//] [DD/MM/YYYY Weight bearing: Yes						
If Yes, date of initial weight bearing [//] [DD/MM/YYYY]						
Recurrent ankle sprain: Yes  No  No						