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COLLEGE OF MEDICINE AND HEALTH SCIENCES
SCHOOL OF MEDICINE AND PHARMACY
DEPARTMENT OF SURGERY**

**PREDICTION OF PATIENT-REPORTED OUTCOME AFTER ARTHROSCOPIC
ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION**

A Cross-Section Study at King Faisal Hospital

**To be submitted for the partial fulfillment of the requirements for award of Master
of Medicine in Orthopedic Surgery.**

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Declaration

Declaration

I do hereby declare that this research entitled "Prediction of patient-reported outcome after arthroscopic anterior cruciate ligament reconstruction at King Faisal Hospital", submitted in partial fulfillment of the requirement for the Award of Master of Medicine in Orthopedic Surgery in the College of Medicine and Health Sciences, University of Rwanda is my original work and has not previously been submitted elsewhere.

Dr. BIMENYIMANA Emmanuel

Sign  Date 27/08/2021

This research has been submitted with our approval as University of Rwanda, School of Medicine and Pharmacy Supervisors.

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Co-Supervisor: Dr. Emmanuel MURWANASHYAKA Sign  Date 27/08/2021

Dedication

To almighty God

To my wife and lifetime partner Emmanuelle KWIZERA and my beloved son IMENA Liam Trevor who lifted me up when I was down.

To late Liam Jasper who we lost during the journey, you are always part of the team and this great achievement.

To my family and friends

God bless you.

Acknowledgement

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Lastly, I am thankful to my wife, my mum and my children who despite missing my home presence, have been always supportive and encouraging and have not given up till the end of this journey.

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List of abbreviations

ACL: Anterior cruciate ligament

ACL R: Anterior cruciate ligament reconstruction

AMB: Anteromedial bundle

AP: Anterolateral

BPTB: Bone-Patella-Tendon-Bone

CKRS: Cincinnati Knee Rating System

CT: Computed Tomography

EQ-5D: European Quality of life

HT: Hamstring Tendon

IKDC: International Knee Documentation Committee

IKDC-SKF: International Knee Documentation Committee Subjective Knee Form

ITB: Iliotibial Band

IRB: Institutional Review Board

KFH, K: King Faisal Hospital, Kigali

KOOS: Knee Osteoarthritis Outcome Score

KT-1000: Knee Arthrometer 1000

MOS: Medical Outcome Study

MRI: Magnetic Resonance Imaging

PLB: Posterolateral bundle

PROs: Patient-reported Outcomes

SANE: Single Assessment Numeric Evaluation

SF-36, 12: Short-Form 36, 12

VAS: Visual Analogue Scale

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KFH ethical approval

Abstract

Background

Anterior cruciate ligament tear is ranked among the most frequent sports injuries. Its reconstruction using arthroscopy is considered gold standard when surgical management is opted. PRO measures are paramount when quality of care is to be assessed. Various tools have been in place including Lysholm knee score. Some factors may impact the outcome hence our aim of assessment of predictors of PRO post arthroscopic ACLR.

Methods

This was a prospective cross sectional analytical study done at KFH, K. Patients whom ACL were arthroscopically reconstructed from June 2016 to June 2020 were interviewed through a phone call and Lysholm knee score was calculated for each participant and categorized. Demographic factors, limb dominance, smoking, level of athletic activity and injury characteristics such as nature of tear and associated injuries were evaluated. Return to preinjury level of activities, period of physiotherapy and insurance status were evaluated.

Results

A total of 136 patients participated in our study. The majority of the participants in this study were in the middle age and 84% were males. Ninety-seven percent of the participants do not smoke and 52% do their athletic activities for recreational purposes and 34% for competitive purposes. Majority had acute tear and the dominant limb was involved at 59%. Meniscal injury was associated at 53%. Majority of the participants did physiotherapy for at most 3 months at 39%. About 42% of the participants returned to their pre-injury level of activities. Using the Lysholm scoring for the ACL reconstruction recovery, 29% achieved an excellent score, good at 33%, fair at 28% and 9% had poor score.

Conclusion

Majority of participants in our study were male with M: F ratio 5:1 and were below 40 years at more than 80%. Male gender, involvement in professional and competitive sport, 6 to 9 months of physiotherapy and having a chronic tear were predictors of good outcome. Involvement of non-dominant knee, multiligamentous injury and lack of preinjury physical activities were associated with poor results and finally; age, associated meniscal tear and insurance status had showed no influence on patient-reported outcome.

Key words: patient-reported outcome, prediction, anterior cruciate ligament reconstruction, lysholm knee score.

CHAPTER I. INTRODUCTION

ACL tear is reported to be among the most common orthopedic injuries worldwide. The incidence is reported recently at around 68.6 injuries over 100,000 persons per year in the United States with over 100,000 ACL reconstructed every year(1).

Arthroscopic ACL reconstruction is believed to be the gold standard management approach for those injuries and are more commonly performed on young subjects and mostly on active patients with the aim of resuming their pre-injury level of activities by restoration of knee biomechanics(2).The outcome assessment after ACL reconstruction is the key when clinical efficacy assessment has to be undertaken and when the effectiveness of the intervention needs to be evaluated(3).

In a study conducted in Qatar by Raouf Nader Rekik et al, evaluating incidence, patterns of injury and severity of ACL rupture in Middle Eastern League performed on male soccer players revealed 0.076 injuries of 1000 hours exposure and there was 10 times increase of rupture in competitive matches than was in training with the average time lost after the injury being 225 days(4)

In Africa, especially in sub-Saharan region, literatures on outcome post ACL reconstruction are scarce. However, a study done in Kenya evaluating the result of ACL reconstruction using a quadrupled hamstring tendon repair showed good results and high rate of patient satisfaction(5).

Both subjective and objective ways to measure outcomes have been put in place. Recently, patients' centric quality measures are being promoted through surveys and various validated patient-reported outcomes (PROs) tools are in place(6) citing the Lysholm knee score, the Cincinnati knee score, the IKDC system, the Hospital for Special Surgery score, the Knee Outcome Survey and the KOOS(7).The outcomes measured include generic measures, patient satisfaction and condition-specific measures(7).

Since 2013, the arthroscopic ACL reconstruction has been introduced in Rwanda and started mainly at King Faisal Hospital, Kigali by a fellow sports orthopedic surgeon. Average of 10 to 12 cases are performed monthly and no study has been conducted for outcome assessment of patients who have undergone ACLR in our settings.

The aim of our study was to evaluate patient reported outcomes measured with Lysholm Knee Score post ACL reconstruction and to analyze factors associated with the reported outcome.

I.1. Problem statement and justification of the study

Measurement of clinical outcome after any joint procedure is important for every orthopedic surgeon as restoration of the function is among the main goals for surgery(8). However, subjective measures have gained recognition as they permit patients to express their perceptions and evaluation of their functional outcomes.

Shelbourne and Patel recommend surgery after 3 weeks to minimize incidence of arthrofibrosis and associated post-surgical knee stiffness(9) however; there was an increased rate of complications when surgery was delayed for more than a year (1). A meta-analysis study that reviewed 6 different studies showed no difference in clinical outcome regarding early vs delayed reconstruction and concluded on lack of consensus of timing of surgery worldwide(10). Different factors are implicated in outcome of patients after ACLR including patient, surgery and injury related with its associated conditions.

Rwanda, a fast-developing economy, has seen an increase in demand of sports injuries management and ACL treatment abroad has led to an increased cost to the country, a delay in management of professional players in general and also to a non-attendance of the rest of the population in need of surgery. Arthroscopic ACL reconstruction as a new intervention in our setting, results were still unknown and with lack of local data, preoperative preparation and education are also limited as most of the referenced data have been carried out in developed countries and on different population groups.

In our settings, no study has been carried out to evaluate patient reported outcome and factors that are linked to the outcome post arthroscopic ACL reconstruction and the follow up is limited at the completion of treatment and the status of patients and their appreciation to treatment post discharge were yet to be evaluated.

Hence, the aim of our study was to evaluate prediction of patient-reported outcomes post arthroscopic ACL reconstruction at KFH, Kigali.

I.2 Research question

How do patients perceive their outcomes post arthroscopic ACL reconstruction at KFH and what are the determinants of the outcomes?

I.3. General Objective

Evaluate patient-reported outcomes post arthroscopic ACL reconstruction.

I.3.1 Specific objectives

1. Determine patient reported outcomes using Lysholm knee score form.
2. Analyze factors associated with outcome

CHAPTER II. LITERATURE REVIEW

II.1 Anatomy and function of anterior cruciate ligament

ACL, posterior cruciate ligament, medial and lateral collateral ligaments are among the main and major stabilizers of the knee(11).It is found within the joint together with the posterior cruciate ligament predisposing them to poor healing potential once they get injured. It is made up with an anteromedial bundle (AMB) that lengthens during knee flexion and a posterolateral bundle (PLB) that shortens as the knee flexes(12).

It is microscopically composed with a network of collagen fibers mainly type I and a matrix composed with glycosaminoglycans, elastic network and glucoproteins conferring it a resisting ultrastructural connection to multiaxial stresses and tensile stresses(13).ACL originates from the lateral condyle of the femur on its medial side and attaches on the tibia anterior to intercondyloid eminence blending with medial meniscus mainly on its anterior horn(14).

When the knee is flexed at 30 and 90 degrees, ACL primarily prevents the anterior tibia translation at 87% with remaining provided with ITB, MCL, fibular collateral ligament, midmedial and midlateral capsules. It also intervenes at resisting of rotational loads(13)(15)(16).

Posterior articular branches of tibial nerve provides its innervation while branches of middle genicular arteries give its blood supply(13).

II.2 Epidemiology of ACL injuries

ACL injuries occur commonly in the athletes and is mostly found at higher incidence during the knee trauma. Most of non-contact tears occur in female than they occur in male population(10)(12). Incidence in developed world is reported to range from 8-52 cases per 100.000 persons per year(17). In US, over 175.000 ACL reconstructions are performed yearly(18).

In a paper published online in February 2018 evaluating epidemiology of ACL injuries at the international level, revealed incidences of 34/100.000 in Norway, 32/100.000 in Sweden and 38 per 100.000 in Denmark from National registries of these countries(19). Australia recorded the highest incidence of ACL injures of around 77.4 per 100.000(20). In a study done in Brazil from 2008 and 2014 revealed an incidence of 3.49 per

100.000 persons per year and they found dramatic increase in females by 112% compared to males with 56%(21).

In a study with telephonic interview done in Northern India evaluating the epidemiology of knee injuries ranked an ACL rupture as the most common cause of knee trauma in athletes with soccer players among the mostly affected(22).

In sub-saharian Africa, a study done in Younde, Cameroun; a prevalence of ACL injury was reported to be 45.8% and there was no difference in gender reported(23). In low and middle income countries in Africa, study done evaluating the burden and the incidence of injuries in adolescents concluded to the lack of data and highlighted the need of research in Africa(24).

II.3 Clinical assessment

Patient who sustains an ACL injury typically presents at the clinic with complaints of pain, swelling and instability of the knee immediately after traumatic events. The instability is described as a “double fist sign” by the patient and signs of instability or giving away limit their activity participation(25). Patient age, occupation and level of activities must be obtained and expectations of the patient must be put into consideration as all these factors would influence treatment options(6)(26).

Goal to physical examination is to detect instability linked to the ACL rupture and to detect other associated injuries. Range of motion both passive way and active way needs to be conducted. Pain, anxiety and muscle guarding may limit the accuracy and sensitivity of physical assessment(27).

When properly done, physical assessment may yield up to sensitivity of 82% and a specificity of 94%(25). Lachman test not forgetting anterior drawer test and also pivot shift test are all the most used tests for ACL tear assessment with variable sensitivities and specificities(25)(27).Lever sign test, a newly diagnostic test approved in mid-2010 has proved to have an improved sensitivity of around 94-100% more than other diagnostic tests(28).

II.4 Radiological evaluation

Initial evaluation of an ACL injured knee will include an AP and lateral knee radiographs. However; this modality has a low sensitivity compared to a gold standard MRI; it can still detect indirect signs that will raise suspicion to an ACL tear once they are seen on radiography(29).Those findings include; Segond fracture which is an avulsion of lateral tibia rim mostly from ilio-tibial band and some reports avulsion from biceps femoris and fibular collateral ligament to result on Segond fracture, lateral condylopatellar sulcus which is abnormally deepened (lateral femoral notch sign), radiographic anterior drawer sign consisting of

anterior tibia subluxation in ACL deficient knee, avulsion of ACL tibia attachment, increased opacity in suprapatellar pouch indicating haemarthrosis and lateral tibia plateau avulsion fracture located on posterior aspect seen on lateral radiography(29)(30).

MRI is an imaging of choice for diagnosing an ACL injury provided low accuracy of clinical assessment alone with both sensitivity and specificity exceeding more than 90% (31).

In the settings of inconclusive clinical assessment and imaging, diagnostic arthroscopy serves as the modality of choice to evaluate the ACL tear and other intra-articular pathologies and assist in the management(31).

CT arthrography yields diagnostic accuracy comparable to MRI for both ACL and meniscal injuries and may serve as alternative in the presence of contraindications to MRI. It also serves for better assessment of avulsion injuries associated to ACL rupture(30).

II.5 Management

Management approaches to an ACL tear consist of non-operative, repair or reconstruction. The choice of intervention depends on both patients' factors and injury's characteristics including age, occupation, level of activities, comorbidities, associated injuries and patient's expectations. Non-operative management is reported to result in poor outcomes in young adults and skeletally immature patients due to recurrent instability, chondral and meniscal injuries(32).

ACL repair was the first surgical approach procedure to an ACL injury described in early 1900 by Robson(32). It consists of ruptured edges approximation and repair with sutures or suture anchors. In 1903, ACL reconstruction was attempted using braided silk attached to semitendinosus by F Lange of Munich but it failed(33).

Arthroscopic ACL reconstruction started in 1970's and was popular in 1980's and since then, it has led to better outcome compared to open techniques and is now considered to be the gold standard in ACL tear management(33)(32).

Many literatures reported superior results of arthroscopic reconstruction over open surgery in terms of scar cosmesis, fewer incisions, easy rehabilitation with improved quadriceps strength and easy placement of tunnels with direct vision with arthroscopy. However in a study done by Ahmad H. S. Et al, concluded to no difference of either approaches in terms of knee functional outcomes but pointed out the longer time of surgery associated with arthroscopy(34).

Controversies exist on anterior cruciate ligament injury regarding timing for reconstruction, time to initiate rehabilitation program post reconstruction, the graft to be used with emphasis to advantages and disadvantages associated with each choices and Nikolaos K. P et al, in their work on principles of treatment, ACL reconstruction revealed no difference in functional outcome and activity level when either hamstring or bone patella tendon bone is used with excellent results in both choices(35).

In a systematic review by Hayden et al comparing bone patella tendon bone and hamstring autograft revealed better results in static knee stability with BPTB but postoperative complications were lower in HT autografts(36).

II.6 Outcome measurement

Outcome assessment post anterior cruciate ligament reconstruction is done either with objective outcome measurement independent on patient perceptions or with subjective assessment emphasizing on patient's view of the outcome(37).

Objective assessment scores include those testing strength with use of dynamometer, range of motion using goniometer, diaries of pain medication requirement and those measuring stability using KT-1000. They yield consistent and reliable results and minimize subjective biases but they overlook patient's considerations(38).

Different ways to assess subjective outcomes exist and include assessment of generic health questionnaire, anatomically-specific or disease specific(37). Broad subjective outcome measures used are SANE and VAS scores and can quickly permit the patient to rate pain, functional status or even patient satisfaction(39).

Among general health measurement scores include EQ-5D and The MOS derived SF-36, SF-12. They are limited in the way that they were originally tested on different population from those who commonly get ACL injury but they are still useful in evaluating quality of life in ACL patients(39).

Knee specific quality of life scores include ACL-QoL initiated and validated by Mohtadi et al in patients with chronic ACL tear but is widely used in all ACL aspects and quality of life portion of the KOOS-QoL(40). For the knee and disease-specific PRO measures, we include IKDC-SKF, CKRS, LKS, KOOS and Tegner activity scale(37)(40)(41).

LKS is one of the oldest knee specific PRO measures and was introduced in 1982 for ACL patients but 3 years later was modified to fit also meniscal pathologies. Its advantage is that it can be accurately evaluated on the phone and find the same results as face-to-face evaluation; hence its utility in our study(37).

CHAPTER III. METHODS

III.1 Description of the study

In our study, participants whom their ACL were arthroscopically reconstructed at KFH, Kigali and were eligible for our study, were included for participation. Patients' files were reviewed to analyze intraoperative findings in associations to ACL injury and other important information. Patient reported outcome was evaluated using LKS that was filled as part of questionnaire after being translated in Kinyarwanda and interview was completed through phone call. A score greater than 94% indicated excellent outcome, 84-94% represented good outcome, 65-83% stood for fair outcome while a score less than 65 represented patients with poor outcome.

III.2 Study design

It was a cross-sectional analytical study conducted at KFH, K and patients operated from June 2016 to June 2020 were interviewed via phone call and their statuses were recorded on questionnaire and their PROs using Lysholm knee score were calculated. The interview was conducted in the month of July 2021 after ethical approvals from both CMHS and KFH were obtained.

III.3 Study settings

This study was conducted at King Faisal Hospital, Kigali. It is a quaternary referral hospital with public-private based practice and is located in the city of Kigali, Gasabo District and Kacyiru Sector. It is a highly specialized medical center where it sometimes receives patients from other referral hospitals. It is a teaching hospital since 2005 where it has contributed to the development of health education in Rwanda and majority of its clients are using private insurances.

III.4 Study population

Patients who had undergone arthroscopic ACL reconstruction and who met inclusion criteria by the time of data collection were included in the study and had given verbal telephonic consent of participation after being explained the study.

III.5 Selection of study population

Inclusion criteria

Patients aged above 18 years

Patients who completed 1 year of treatment

Exclusion criteria

Patients who didn't consent

Patients who were out of reach

Patients whose files were incomplete

III.6 Data collection

Questionnaire was used to collect data and information was obtained verbally from patients in the study through phone interview including information contained on Lysholm knee score and others retrieved from patients' files including post-operative protocol. Age, sex, time for surgery, associated knee injuries were recorded on the data collection form.

III.7 Data analysis

Collected data were entered into Epidata version 3.1 for database creation and then exported to Stata version 13 for analysis. Descriptive data were presented using frequencies and percentages. Chi-square test and logistic regression were used to study the relationship between the outcome (Lysholm knee scoring scale) and possible predictors of good post-operative Lysholm knee score. Statistical significance for associations was taken at the level $p < 0.05$.

III.8 Sample size

136 patients operated in the timeframe of our study and meeting selection criteria constituted our sample size.

The sample size N was calculated as follow;

$$N = Z^2 * P * (1 - P) / M^2$$

Z is a Z score estimated from the confidence interval and P is the population proportion with M being margin of error and is set at 5% in our study corresponding with 0.05

We used the confidence interval of 80% corresponding to Z value of 1.28 and population proportion of 30% is estimated corresponding to P of 0.3

In our formula, we have $N = (1.28)^2 * 0.3 * (1 - 0.3) / (0.05)^2 = 138(42)$.

III.9 Ethical considerations

Participants voluntarily participated in the study and full explanations were provided to enable them to consent or to refuse the participation. Participants' privacy was respected and their identifications were kept unanimous with only participants' name initials appearing on data collection form. There was no harm to the participants and no rewards were provided for the participation.

Only those who consented, were enrolled in the study after getting ethical approvals from University of Rwanda IRB (Approval Notice: No 139/CMHS IRB/2021) and ethical committee of King Faisal Hospital, Kigali.

CHAPTER IV: RESULTS

In the timeframe of our study from June 2016 to June 2020, a number of 206 patients had their ACL arthroscopically reconstructed with the use of hamstring as a graft and the surgery was carried out by a single surgeon. From that number, we were able to find 179 files from King Faisal Hospital medical record department and 3 files among them had incomplete data including phone numbers of the patients. 35 patients had either their phones off or not responded to our calls while 5 patients responded to our calls but did not consent to the participation. We remained with a final number of 136 patients who made our sample size.

Table 1: Socio-demographic characteristics of participants

Characteristics	Frequency	Percentage
Age in years		
<20	6	4.41
20-29	48	35.29
30-39	61	44.85
40-49	17	12.5
>50	4	2.94
Gender		
Male	114	83.82
Female	22	16.18
Time of surgery		
2016	17	12.5
2017	30	22.06
2018	36	26.47
2019	29	21.32
2020	24	17.65
Insurance		
100 % insured	79	58.09
Partially insured	54	39.71
Self-pay	3	2.21
Smoking		
Yes	2	1.47
No	132	97.06
Quitted	2	1.47
Level of athletic activities		
Recreational	71	52.21
Competitive	47	34.56
Professional	7	5.15
Office work	11	8.09

Many of the participants in this study were in the middle age where 35.3% were aged between 20 and 29 years, 44.8% were aged between 30 and 39 years, and 12.5% had age ranging between 40 and 49 years. Eighty-four percent of the participants were males and there was almost equal distribution across year-period of recruitment from 2016 to 2020. Ninety-seven percent of the participants do not smoke and 52% do their athletic activities for recreational purposes and 34% for competitive purposes.

Table 2: Characteristics related to anterior cruciate ligament injury

Characteristics	Frequency	Percentage
Nature of tear		
Acute tear	109	80.15
Chronic tear	27	19.85
Involvement of dominant knee		
Yes	81	59.56
No	55	40.44
Associated injuries		
Meniscal	73	53.68
Isolated ACL	57	41.91
Posterolateral corner	4	2.94
Others	2	1.47
Period of physiotherapy in months		
0-3	54	39.71
4 to 6	46	33.82
7 to 9	18	13.24
10 to 12	7	5.15
Above 12	11	8.09
Return in pre-injury activities		
Yes	58	42.65
No	78	57.35

Eighty percent of the participants had acute tear and among the participants, 59% the tear involved the dominant knee. In 53% of the ACL injuries there was an association of meniscal injury.

Thirty-nine percent of the participants did physiotherapy for at most a 3 months' period, 34% did physiotherapy for a period between 4 and 6 months, 13% for a period of 7 to 9 months, 5% for a period ranging from 10 to 12 months and 8% of the participants did at least 1 year of physiotherapy. About 42% of the participants returned to their pre-injury activities.

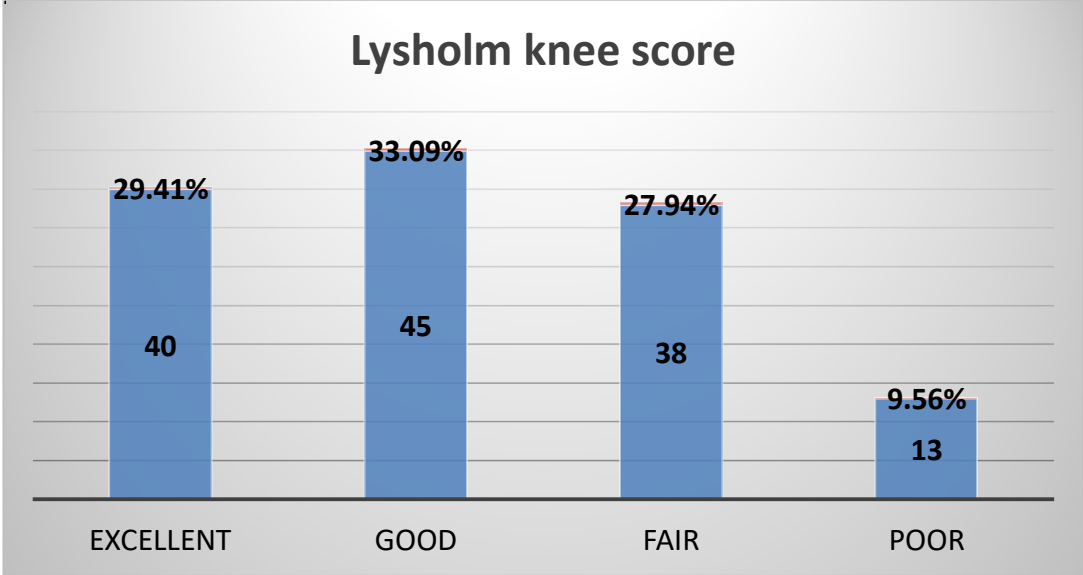


Figure 1: Anterior cruciate ligament reconstruction outcome using Lysholm score

Using the LKS for the ACLR recovery, 29% of the patients who were recruited in the study achieved an excellent Lysholm knee score, 33% had Good Lysholm score, 28% had fair Lysholm score and 9% had poor score.

Table 3: Factors associated with anterior cruciate ligament reconstruction outcome

Predictors	Lysholm score		OR (95%CI)	P value
	Fair/poor	Excellent/good		
Age				
<20	1 (16.67%)	5 (83.33%)	ref	
20-29	13 (27.08%)	35 (72.92%)	0.53 (0.05-5.05)	0.588
30-39	30 (49.18%)	31 (50.82%)	0.20 (0.02-1.87)	0.161
40-49	7 (41.18%)	10 (58.82%)	0.28 (0.02-3.00)	0.297
>50	0 (0.00%)	4 (100.00%)		
Gender				
Male	39 (34.21%)	75 (65.79%)	2.30 (0.91-5.81)	0.076
Female	12 (54.55%)	10 (45.45%)	ref	
Nature of tear				
Acute tear	44 (40.37%)	65 (59.63%)	ref	
Chronic tear	7 (25.93%)	20 (74.07%)	1.93 (0.75-4.96)	0.17
Period of physiotherapy in months				
0-3	22 (40.74%)	32 (59.26%)	ref	
4 to 6	19 (41.30%)	27 (58.70%)	0.97 (0.43-2.17)	0.954
7 to 9	3 (16.67%)	15 (83.33%)	3.43 (0.88-13.30)	0.074
10 to 12	2 (28.57%)	5 (71.43%)	1.71 (0.30-9.66)	0.539
Above 12	5 (45.45%)	6 (54.55%)	0.82 (0.22-3.04)	0.773
Level of athletic activities				
Recreational	30 (42.25%)	41 (57.75%)	ref	
Competitive	14	33 (70.21%)	1.72 (0.78-3.77)	0.172

	(29.79%)			
Professional	1 (14.29%)	6 (85.71%)	4.39 (0.50-38.40)	0.181
Office work	6 (54.55%)	5 (45.45%)	0.60 (0.17-2.18)	0.448
Involvement of dominant knee				
Yes	27 (33.33%)	54 (66.67%)	ref	
No	24 (43.64%)	31 (56.36%)	0.64 (0.31-1.30)	0.224
Associated injuries				
Meniscal	27 (36.99%)	46 (63.01%)	ref	
Isolated ACL	21 (36.84%)	36 (63.16%)	1.00 (0.49-2.06)	0.987
Posterolateral corner	2 (50.00%)	2 (50.00%)	0.58 (0.78-4.41))	0.605
Others	1 (50.00%)	1 (50.00%)	0.58 (0.03-9.77)	0.71

Male participants had 2.3 times chance of having Excellent and/or good outcome than female participants (OR=2.30, 95% CI: 0.9-5.81; p=0.076). Participants who had chronic tear of the ACL were 1.93 times more likely to have excellent and/or good outcome than those who sustained acute tear but there was no statistical significance of the difference (OR=1.93; 95% CI: 0.75-4.96; P=0.170). Participants who did physiotherapy for 7 to 9 months had 3.43 times likelihood of having excellent and/or good outcome than those who did physiotherapy for at most 3 months' period (OR=3.43; 95% CI: 0.88-13.3; p=0.074).

No difference was found for PRO using LKS to be significant statistically across age groups, involved knee, level of athletic activities and having other associated injuries.

CHAPTER V: DISCUSSION

In our study, most of our participants were male at the rate of 83.83% with male to female ratio of 5:1; this male predominance was also found in other studies. The similar male predominance was reported by Badole et al(43) in their evaluation of meniscal tear pattern in ACL injury patients and found 85.5% while M. Majewski et al(44) in their epidemiological study, found 68.1% for male and 31,6% for women. Iqbal et al (45) also found a slight increase in male to female ratio with reported 51.6% of male and 48.3% of female though the difference was not remarkable compared to our study. The considerable difference of gender found, might be attributable to the fact that men are involved in labored activities than female and are likely less tolerant to live with an ACL deficient knee but also most occupations that provide 100% coverage of insurance like competitive, professional sports and military activities are likely to have male predominance: hence a big number of male ACL surgical intervention.

A big proportion of our participants were below 40 years of age at the rate of 84.55% and the predominant age group was 30-39 year at 44.85% followed by 20-29 years' age group highlighting the high incidence of ACL tear and reconstruction in young population as it was found in the study of Iqbal et al, where they reported the mean age of 35.17 ± 18 (45).M. Majewski et al(44)reported the predominance of young adults 20-29 years of age at 43.1%. In our study, the predominant age group was 30-39 years at the rate of 44.85%. we had also around 15% who are above 40 years of age including 2.29% who are above 50 years and this also goes with the recent literature recommending the ACL reconstruction in this population group. In a study done by Mark E. Cinque et al(46) reported a similar rate of complications and outcome when younger subjects(20-30 years) were compared to older participants(50-75 years). A systematic review by Christopher A. Brown et al(47) evaluating ACLR in patients above 40 years , also concluded to the satisfactory outcomes among that age group. Similarly, the difference was not observed across the age group in our study.

We observed a high association rate of ACL tear with meniscal injury at 53.68% and isolated tear was at 41.91% while 2.94% had associated posterolateral corner injury to the ACL tear and few others at 1.47% had other issues including 1 case of loose body and 1 case of medial collateral ligament injury. The study done by Binfield et al(48) evaluating patterns of meniscal tears in ruptured ACL revealed 58.5% association and more tears were lateral at 30.25% and it also revealed 41% tears of ACL that occurred in isolation and this percentage was similar to findings in our study group.

Badole et al(43) found 38.7% association of meniscal tear with ACL tear while Shirish Pathak et al(49) in their evaluation of functional outcome when ACL reconstruction was combined with meniscal repair, found an increased rate of meniscal healing and favorable clinical and functional knee outcome and they also reported between 40 and 65% of association which matches the findings in our study. The presence of associated meniscal tear did not play any role when compared to those with injuries that happened in isolation (OR:1, CI:0.49-2.06, P:0.987). There was worse outcome when associated injuries were posterolateral corner and others.

Most patients in our study did physiotherapy in the period of at most 3 months at the rate of 39.71% followed by 4 to 6 months with the rate of 33.82%, 7 to 9 months at 13.24%, 10 to 12 months at 5.15% and 8.09% went above 1 year of physiotherapy and this correlated with most of the recommendations to perform supervised physiotherapy in the period of 2 to 3 months and the remaining sessions till return to sports be done with home based protocol or in Gymnastics settings(50)(51). Participants reported lack of time to perform the prescribed physiotherapy sessions as their work schedules were busy and had to return prematurely to their work. However; in a meta-analysis study conducted in Brazil bydo Carmo Almeida et al(52) evaluating functional rehabilitation protocol of physiotherapy post ACL reconstruction concluded on importance of its use but also highlighted mixed results for different protocols. Tolga Saka(53) in his study of principles of postoperative ACL rehabilitation emphasized on importance of techniques of physiotherapy rather than the duration of the rehabilitation protocol. In our results, no difference in outcomes with those who did physiotherapy for up to 3 months and to those who did physiotherapy up to 6 months. However, those who did physiotherapy for 7 to 9 months had 3.43 times more chance of excellent and good outcome than those reported in previous groups and we think that this difference is related to most professional players in this category. There were poor results to those who went beyond 12 months of physiotherapy (OR 0.82 CI:0.22-3.04 P: 0.773) because the results were not satisfactory even before this period and they tentatively increased the period of physiotherapy in hope to get better results.

In our study, concerning the level of athletic activities, a big proportion of participants (n=71,52.2%)were participating in recreational sport activities followed by 47 participants (34.56%)in competitive activities, 7 subjects (5.15%) were professional players and 11(8.09%) were involved in office work. There was a strong correlation of being professional and having excellent to good outcome at 4.39 times than those participating in recreational activities and also 1.72 times of having excellent to good outcomes as a competitive sport participant than as a recreational one and being physically inactive (office work) was associated with poorer outcome (OR 0.60, CI: 0.17-2.18, P:0.448). The high success rate in professionals was also reported by Lai et

al(54) in their evaluation of return to play in elite athletes and found 83% of return to the preinjury level of activities.

In the work by Kim et al(55) conducted in Korea evaluating return to preinjury level among recreational athletes, revealed a 24% return to preinjury activity level and concluded to the need of setting a realistic target before conducting surgery in that group of patients. This inferiority was also observed in our study and lack of time for adequate physiotherapy and poor preinjury muscle strengths might have been among the contributing factors and professionals had increased desire to resume their activities and their own physiotherapists in their respective teams. However, in India, C. Joseph et al(56) evaluated the rate of meniscal and cartilage damage between athletes and non-athletes and found no difference among the groups and advocated also to the early surgical intervention in the non-athlete subjects.

Regarding the return to preinjury level of activity, 58 (42.65%) participants returned to their preinjury level of activities and the remaining 78 (57.35%) participants reported to have not reached their level of activity and most of those who did not return, they reported fear of re-rupture as the limiting factor. This level of return to their activities in our study is higher than what was reported by John R et al(22) in their epidemiological study that also evaluated return to sports post knee injury and found 39.8% who resumed their athletic activities. In another study by Benedict U. Nwachukwu et al(2) evaluating psychological factors that affect lack of return to sports in patients who underwent arthroscopic ACLR, found 63.4% of return to sports but reported 36.6% who returned and were unable to perform at their preinjury level of activities. They also reported psychological factors as being the main reason of lack of return to sports at a rate of 64.7%.

We also noted involvement of dominant knee at the rate of 59.56% while the remaining was non-dominant at 40.44% and the non-dominance involvement was likely linked to poor results. Similarly, the superior good results of the dominant knee were revealed by Uzun et al(57) in the evaluation of the association of limb dominance on medium to long-term outcome post ACL reconstruction but they showed that leg dominance didn't play a role in high recovery rate achieved post arthroscopic ACL reconstruction. However, a study done in Singapore by Boo et al(58) evaluating the effect of leg dominance on early outcome and return to sports showed no association despite the theoretical differences that were reported before.

Overall, in 136 patients who were involved in our study, the outcome using Lysholm knee score was evaluated and 40 (29.41%) patients had excellent results, 45 (33.09%) patients had good outcome while 38 patients equivalent to 27.94% had fair outcome and 13 patients corresponding to 9.56% were ranked to have had poor results. Patients who were in the category of excellent, good and fair had overall good knee function while those in poor results reported the worst outcome.

Lynch AD, et al(59) evaluated consensus criteria to define successful outcome and found that 6 criteria including absence of giving way, no or minimal effusion, adequate muscle strengths, return to play, activity and participation were predictors of successful outcome.

In the study by Magnussen et al(60) evaluating patient reported outcome with their predictors in 10 years follow-up period and focused on factors like sex, meniscal status, BMI and types of graft but all failed to show the significant association with the outcome. Svantesson et al(61) studied the comparison of associated injuries on primary and revision ACL reconstruction and highlighted the negative prediction with associated posterolateral corner injuries as was also revealed in our study. The results in our study were also slightly inferior to the results by Chodavarapu LM et al(62) that analyzed clinical outcomes after quadrupled arthroscopic ACL reconstruction and found 72% excellent results with Lysholm knee score >90%, 24% good result and 4% of fair result at 65-83%. This difference in results may have been to the lack of physiotherapy plan within the participants in our study.

5.1 Study Limitations

The limitations in our study were mainly due to inadequate sample size. This was because a single surgeon was performing the procedure and the number of participants would have been bigger and the procedure was still new in our settings. It caused our observations to be statistically insignificant while the difference was observed in reality. On the other hand, failure to record the preoperative knee scores and compare with the postoperative ones, lead to lack of objective data that would have showed the improvement in the category of participants who were deemed to have fair and poor outcomes.

CHAPTER VI: CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

In our study, majority of our participants were male with male to female ratio of 5:1 and they were predominantly in their third and fourth decade in more than 80%. More than 63% had excellent to good outcome using Lysholm knee score and there was a 42.65% of return to preinjury level of activity.

Factors that were associated to good outcome included being male gender, involvement in professional and competitive sport, 6 to 9 months of physiotherapy and having a chronic tear. Involvement of non-dominant knee, multiligamentous injury and lack of preinjury physical activities were associated with poor results. Factors like age, associated meniscal tear and insurance status had showed no influence on Lysholm knee score. No conclusion on smoking as most of our participants were nonsmoker at 97.06%

6.2. Recommendation

- To increase and avail adequate number of skilled surgeons in performing arthroscopic ACL reconstruction.
- Make arthroscopic ACL reconstruction accessible to public hospital to be benefited by general population including those who use community-based health insurance.
- Extend period of physiotherapy in professional players and those involved in competitive activities and encourage gymnastics and home-based approach to physiotherapy to those in late phase of rehabilitation.
- Whenever possible, preoperative physiotherapy should be considered for quick postoperative recovery.
- Choice to perform surgery in those who are physically inactive should be made with caution and must be discussed with the patient.
- Psychological support and counselling should be considered preoperatively and patient expectations should be evaluated before surgery.

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APPENDICES

1. INFORMED CONSENT

Dear Participant,

My name is Dr Emmanuel BIMENYIMANA doing my studies in UR and pursuing Masters of Medicine in Orthopedic Surgery. I am conducting research entitled: **PREDICTION OF PATIENT REPORTED OUTCOME AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION. A cross-section study at King Faisal Hospital.** ACL is one of the commonest knee injuries and arthroscopic reconstruction is among the proven methods of treatment. Various outcome studies have been conducted for both objective and subjective means; however, subjective studies gained the recognition for that they take account to patients' perceptions and general functions. Then, we are conducting this study to know the patient reported outcome in our settings for better knowledge and for improvement where applicable.

We will ask you questions retrieved from the questionnaire and other important information will be gotten from your medical records. Your participation in this study is safe and its safety has been certified and verified by the ethic committees of both the University of Rwanda and King Faisal Hospital who would not provide us a permission to conduct the study if your life would be at risk. The interview will take around 5 to 10 minutes.

There is no obligation of participation in our study and you have the right to answer to all or to none of the questions. You have also the right to stop the participation at any time. However, we hope that you will participate in this study since your opinion is paramount. Whatever information you provide will be kept strictly confidential and no reference to your name or other family members will be made anywhere. For any query you can refer to the Chairperson of the CMHS IRB (0788 490 522) or research committee (researchcenter@ac.ur.rw) Tel +250 788563311 and also you can contact Dr. BIMENYIMANA Emmanuel on email: biemmal@gmail.com, Tel: 0783742691 as the main investigator.

Iunderstand the explanation given by
about the risks and benefits of this research on **PREDICTION OF PATIENT REPORTED OUTCOME AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION. A cross-section study at King Faisal Hospital**, I accept willingly to participate in this research.

Participant's response 1. YES, 2. NO

Researcher's signature

Date:...../...../2021

.....

2. AMASEZERANO YO KWINJIRA CG KUVA MUBUSHAKASHATSI

Nitwa BIMENYIMANA Emmanuel, umunyeshuri muri kaminuza y' u Rwanda mu ishamiry' ubuvuzi aho nakurikiranye ibijyanye no kuvura amagufa, imitsi n' inyama ziyakikije. Ndigukora ubushakashatsi bwitwa: **imimerere n' imikirire by' ivi ryabazwe hakoreshejwe camera ireba mu ivi byakorewe mu bitaro byitiriwe umwami Fayisali**. Gucika k umutsi wo mu ivi ni imwe mumvune zikunze kubaho cyane ku bantu bavunitse ivi ikaba igira uburyo butandukanye bwo kuyivura kandi ababazwe hakoreshejwe kamera bakaba bagira imikirire itandukanye. Uburyo bw' imikirire bushobora gushimwa na muganga cyangwa n' umurwayi kugiti cye ariko ubushakashatsi bwibanda uko umurwayi yiyumva nibwo buri guhabwa agaciro cyane kuko bureba ibyiyumviro bya nyirubwite. Rero, natwe dushaka kureba uko bimeze hano mu gihugu cyacu kuko ntabundi bushakashatsi busa na bwo bwakozwe mbere y, ubungubu. Bityo bikazadufasha kumenya ahari ingufu nke muri izimvune n' imivurire yazo kugirango hakorwe ubuvugizi buzafasha abandi mu bihe biri imbere.

Turababaza ibibazo mudusubize ibindi tuzabivana mu ifishi yanyu yo kwa muganga irimo amakuru yerekeranye n' ibyo dukeneye. Kuba muri ubu bushakashatsi kwanyu birizewe, bifite umutekano kandi byanasuzumwe n' inama zishinzwe imigendekere myiza y, ubushakashatsi zo muri kaminuza y' u Rwanda ndetse n' iyo mu bitaro byitiriwe umwami Fayisali ubu bushakashatsi buzaberamo. Turafata hagati y' iminota itanu n' icumi y' ikiganiro kandi tugashima umwanya muribuduhe.

Kuba muri ubu bushakashatsi ni ubushake bwanyu kandi igihe cyose mwashaka mwabuvamo nti hagire ingaruka zibabaho. Ni ubwitange bwanyu kandi kuko ntamafaranga arimo; gusa kububamo kwanyu ni iby' agaciro kuri twe no kubanyarwanda mu rirusange.

Amakuru aberekeyeho azabikwa byizewe kandi mugize ikibazo icyo aricyo cyose mwakwitabaza ikigo gishinzwe ubushakashatsi (Chairperson of the CMHS IRB (0788 490 522), research committee (researchcenter@ac.ur.rw Tel +250 788563311). Cyangwa Muganga BIMENYIMANA Emmanuel, nyiri ugutegura ubu bushakashatsi kuri Email: biemmal@gmail.com cyangwa kuri Telefone ngendanwa 0783742691.

Twizeye kumutwemereye kuduha ubufasha mu bushakashatsi bwacu.

Njyewe....., maze gusobanurirwa na Ingaruka n'inyungu kuri ubu bushakashatsi, nemeye nta gahato kubujyamo.

1. Ndabyemeye 2. Simbyemeye

Umukono w' uwafashe amakuru.

.....

Itariki...../...../2021

3. QUESTIONNAIRE

Patient initial..... **patient ID**.....

Age: 1 <20 Y, 2. 20-29, 3. 30-39, 4. 40-50, 5. >50 y

Sex: 1. Male 2. Female

Nature of tear: 1. Acute tear, 2. Chronic tear

Time for surgery. . / . . /

Period of physiotherapy in months:

1. 0-3

2. 4-6

3. 7-9

4. 10-12

5. More than 12

Insurance status: 1. 100% insured, 2. Partially insured, 3. Self-pay, 4. Workers' compensation

Smoker: 1. Yes, 2. No, 3. Quitted

Level of athletic activity: 1. Recreational, 2. Competitive, 3. Professional, 4. Office work

Types of graft: 1. Hamstring, 2. BPTB, 3. Other

Involvement of dominant knee: 1. Yes, 2. No

Return in pre-injury level of activities: 1. yes, 2. No

Associated injuries: 1. Meniscal injury, 2. Osteochondral lesion, 3. Other

PRO with lysholm score:

LYSHOLM KNEE SCORING SCALE Instructions:

Below are common complaints which people frequently have with their knee problems.

Please check the statement which best describes your condition.

I.LIMP

- _____ I have no limp when I walk. (5)
- _____ I have a slight or periodical limp when I walk. (3)
- _____ I have a severe and constant limp when I walk. (0)

II.USING CANE OR CRUTCHES

- _____ I do not use a cane or crutches. (5)
- _____ I use a cane or crutches with some weight-bearing. (2)
- _____ Putting weight on my hurt leg is impossible. (0)

III.LOCKING SENSATION IN THE KNEE

- _____ I have no locking and no catching sensations in my knee. (15)
- _____ I have catching sensation but no locking sensation in my knee. (10)
- _____ My knee locks occasionally. (6)
- _____ My knee locks frequently. (2)
- _____ My knee feels locked at this moment. (0)

IV.GIVING WAY SENSATION FROM THE KNEE

- _____ My knee never gives way. (25)
- _____ My knee rarely gives way, only during athletics or other vigorous activities. (20)
- _____ My knee frequently gives way during athletics or other vigorous activities; in turn I am unable to participate in these activities. (15)
- _____ My knee occasionally gives way during daily activities. (10)

___ My knee often gives way during daily activities. (5)

___ My knee gives way every step I take. (0)

V. PAIN

___ I have no pain in my knee. (25)

___ I have intermittent or slight pain in my knee during vigorous activities. (20)

___ I have marked pain in my knee during vigorous activities. (15)

___ I have marked pain in my knee during or after walking more than 1 mile. (10)

___ I have marked pain in my knee during or after walking less than 1 mile. (5)

___ I have constant pain in my knee. (0)

VI. SWELLING

___ I have no swelling in my knee. (10)

___ I have swelling in my knee only after vigorous activities. (6)

___ I have swelling in my knee after ordinary activities. (2)

___ I have swelling constantly in my knee. (0)

VII. CLIMBING STAIRS

___ I have no problems climbing stairs. (10)

___ I have slight problems climbing stairs. (6)

___ I can climb stairs only one at a time. (2)

___ Climbing stairs is impossible for me. (0)

VIII. SQUATTING

___ I have no problems squatting. (5)

___ I have slight problems squatting. (4)

___ I cannot squat beyond a 90degree bend in my knee. (2)

___ Squatting is impossible because of my knee. (0)

TOTAL___/100

INSTRUCTIONS: Please place an X on the line to indicate the amount of pain you have had in your knee(s) the past 24 hours.

CMHS IRB Approval



CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 28th April 2021Dr Bismarimana Emmanuel
School of Medicine and Pharmacy, CMHS, URApproval Notice No 129/CMHS IRB/2021

Your Project Title *"Patients reported outcomes after Arthroscopic anterior cruciate Ligament Reconstruction: A cross section study at King Faisal Hospital"* has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof. Kato J. Njirwa	UR-CMHS	X		
Dr. Bwafu Janson	UR-CMHS	X		
Dr. Brenda Asinywe-Katzeru	UR-CMHS	X		
Prof. Ntagwiru Joseph	UR-CMHS	X		
Dr. Tuzumire K. David	UR-CMHS	X		
Dr. Kayunga N. Egide	UR-CMHS	X		
Mr. Kanyoni Mutarica	UR-CMHS		X	
Prof. Muryambungwe Cyprien	UR-CMHS	X		
Mrs. Ruzindana Latdrine	Kicukiro district		X	
Dr. Gashema Darius	UR-CMHS	X		
Dr. Doranilla Mukamuna	UR-CMHS	X		
Prof. Kyamanywa Patrick	UR-CMHS		X	
Prof. Condo Urutesi Jeanmarie	UR-CMHS		X	
Dr. Nyiranzoye Lactitia	UR-CMHS	X		
Dr. Nkurambige Emmanuel	UR-CMHS		X	
Se. Maliboh Marie Josse	CHUK	X		
Dr. Mulege Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 23rd April 2021, Approval has been granted to your study.

Please note that approval of the protocol and consent form is valid for 12 months.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 28th April 2021

Expiration date: The 28th April 2022



Dr Stefan Jansen
Ag. Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

KFH Ethical approval



**KING FAISAL HOSPITAL, KIGALI
ETHICS RESEARCH COMMITTEE**

Patient Centered Care

18th May, 2021

ETHICAL APPROVAL

Dear Dr. Emmanuel BIMENYIMANA

We acknowledge receipt of your study protocol: **"Patient reported outcome after arthroscopic anterior cruciate ligament reconstruction: A cross section study at King Faisal Hospital, Rwanda"**

After a thorough review, the reviewers of KFH Ethics Research Committee consider this study relevant. The investigator is allowed to start data collection.

N.B.

- The investigator is requested to submit one hard copy of his final research results in the office of the Directorate of Education, Training and Research at King Faisal Hospital, Kigali

Best Regards



Dr. Dushimiyimana Jean Marie Vanhey
Consultant ENT surgeon
Chair, Ethics Research Committee
King Faisal Hospital, Rwanda.

CC:

1. Chief Executive Officer, KFH-Rwanda
2. Director of Education, Training & Research, KFH-Rwanda
3. Members of the Ethics Research Committee, KFH-Rwanda

King Faisal Hospital, Kigali will become a Centre of Excellence in health services provision and clinical education in Africa

• EMAIL: info@kfhrw.rw • WEBSITE: www.kfhrw.rw
GASABO DISTRICT, P.O. Box 2534 KIGALI, RWANDA

*Dear Medical Record
Supervisor
Please facilitate the
Ortho doctor in
his research process
with the files he may
need*

*An Amuto
Himisiyimana
[Signature]*