The management of acute knee dislocations: A global survey of orthopaedic surgeons' strategies

by

Santa-Marié Venter

MSc Sports Medicine(UP); MBChB(UP); BA Languages and Literature(UNISA); LLB(UNISA)

VNTSAN002

This study is in partial fulfilment of the requirements for the degree

Master of Medicine in Orthopaedic Surgery

University of Cape Town

Supervisor: Prof Michael Held

December 2021

Table of Contents

Declaration

I, Santa-Marié Venter, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree at this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever. I further declare the following:

1. I know that plagiarism is a serious form of academic dishonesty.
2. I have read the document about avoiding plagiarism, am familiar with its contents and have avoided all forms of plagiarism mentioned there.
3. Where I have used the words of others, I have indicated this by the use of quotation marks.
4. I have referenced all quotations and properly acknowledged other ideas borrowed from others.
5. I have not and shall not allow others to plagiarise my work.
6. I declare that this is my own work.
7. I am attaching the summary of the Turnitin match overview.

Signature: Signed by candidate **Date: 2021-04-15**

……

ABSTRACT

Purpose: The aim of this study was to compare the management approach of acute knee dislocations (AKDs) by orthopaedic surgeons from nations with different economic status.

Methods: A survey sent to members of the Societe Internationale de Chirurgie Orthopedique et de Traumatologie (SICOT) compared different management strategies for acute multiligament knee injuries (aMLKIs). These were compared after categorising surgeons into developed economic nations (DEN) and emerging markets and developing nations (EMDN) based on the gross domestic product (GDP) per capita.

Results: 138 orthopaedic surgeons from 47 countries participated in this study. DEN surgeons had more years of experience and were older ($p<0.05$). Surgeons from EMDN preferred conservative management and delayed reconstruction with autograft ($p<0.05$) if surgery was necessary. Surgeons from DEN favoured early, single stage arthroscopic ligament reconstruction. Significantly more EMDN surgeons preferred clinical examination ($p<0.05$) and duplex doppler scanning ($p<0.05$) compared to DEN surgeons. More surgeons from EMDN did not have access to a physiotherapist for their patients.

Conclusions: Treatment of aMLKIs varied significantly based on the economic status of the country. In EMDN, aMLKIs are often treated conservatively, ligament surgery is often delayed and staged, alternative vascular assessment methods are more commonly used, and access to physiotherapy is challenging. This calls for adjusted guidelines when treating patients in areas of low resource setting.

Key words: Multiligament knee injuries; management knee dislocations

ACKNOWLEDGEMENTS, FORMAT AND CONTRIBUTIONS

I acknowledge the following co-authors and their respective contributions to this research:
Dr Roopam Dey: Statistical analysis, result generation, manuscript revision
Dr Vikas Khanduja: Conceptualisation of study, data collection
Dr Richard PB von Bormann: Conceptualisation of study, data collection
Prof Michael Held: Conceptualisation of study, data collection, editing, manuscript revision

This research study has been published on 30 March 2021 in SICOT-J and is available at:
https://doi.org/10.1051/sicotj/2021017

LIST OF FIGURES AND TABLES

ABBREVIATIONS

ACL – Anterior Cruciate Ligament

aMLKI – Acute Multiligament Knee Injuries

CTA – Computerised Tomography Angiography

DEN – Developed Economic Nations

EMDN – Emerging Markets and Developing Nations

GDP – Gross Domestic Product

RedCAP - Research Electronic Data Capture

SICOT - Societe Internationale de Chirurgie Orthopedique et de Traumatologie

SICOT-J 2021, 7, 21
The Authors, published by EDP Sciences, 2021 https://doi.org/10.1051/sicotj/2021017

SICOT-J
Available online at:
www.sicot-j.org

ORIGINAL ARTICLE OPEN ACCESS

The management of acute knee dislocations: A global survey of orthopaedic surgeons' strategies

Santa-Marie Venter[1], Roopam Dey[1,3], Vikas Khanduja[2], Richard PB von Bormann[4], and Michael Held[1,*]

[1] Department of Orthopedic Surgery, Groote Schuur Hospital, Orthopedic Research Unit, University of Cape Town, Cape Town 7925, South Africa

[2] Consultant Orthopedic Surgeon, Addenbrooke's Hospital, Cambridge, University of Cambridge, Cambridge CB2 2QQ, United Kingdom

[3] Department of Human Biology, Division of Biomedical Engineering, University of Cape Town, Cape Town 7925, South Africa

[4] Cape Town Sports and Orthopaedic Clinic, Christian Barnard Memorial Hospital, Cape Town, 8001, South Africa

Received 24 September 2020, Accepted 28 February 2021, Published online 26 March 2021

Abstract – Purpose: Great variety and controversies surround the management strategies of acute multiligament knee injuries (aMKLIs) and no established guidelines exist for resource-limited practices. The aim of this study was to compare the management approach of acute knee dislocations (AKDs) by orthopedic surgeons from nations with different economic status. Methods: This descriptive cross-sectional scenario-based survey compares different management strategies for aMLKIs of surgeons in developed economic nations (DEN) and emerging markets and developing nations (EMDN). The main areas of focus were operative versus non-operative management, timing and staging of surgery, graft choice and vascular assessment strategies. The members of the Societe Internationale de Chirurgie Orthopedique et de Traumatologie (SICOT) were approached to participate and information was collected regarding their demographics, experience, hospital setting and management strategies of aMLKIs. These were analyzed after categorizing participants into DEN and EMDN based on the gross domestic product (GDP) per capita. Results: One-hundred and thirty-eight orthopedic surgeons from 47 countries participated in this study, 67 from DEN and 71 (51.4%) from EMDN. DEN surgeons had more years of experience and were older ($p < 0.05$). Surgeons from EMDN mostly worked in public sector hospitals, were general orthopedic surgeons and treated patients from a low-income background. They preferred conservative management and delayed reconstruction with autograft ($p < 0.05$) if surgery was necessary. Surgeons from DEN favored early, single stage arthroscopic ligament reconstruction. Selective Computerized Tomography Angiography (CTA) was the most preferred choice of arterial examination for both groups. Significantly more EMDN surgeons preferred clinical examination ($p < 0.05$) and duplex doppler scanning ($p < 0.05$) compared to DEN surgeons. More surgeons from EMDN did not have access to a physiotherapist for their patients. Conclusions: Treatment of aMLKIs vary significantly based on the economic status of the country. Surgeons from DEN prefer early, single stage arthroscopic ligament reconstruction, while conservative management is favored in EMDN. Ligament surgery in EMDN is often delayed and staged. EMDN respondents utilize duplex doppler scanning and clinical examination more readily in their vascular assessment of aMLKIs. These findings highlight very distinct approaches to MLKIs in low-resource settings which are often neglected when guidelines are generated.

Key words: Multiligament knee injury, Acute knee dislocation, Management knee dislocation.

Introduction

Acute multiligament knee injuries (aMLKIs) are uncommon injuries, however, if not recognized and managed appropriately, they can have devastating consequences [1]. The popliteal artery is injured in 1.6% [2] to 40% [3] of cases and vascular assessment forms a crucial, yet controversial part of the initial assessment. Ligament reconstruction can be performed acutely (<3 weeks), delayed (>3 weeks), or it can be staged [4]. Conservative treatment with bracing is reserved for certain compromised patients and if access to surgical care is restricted [5].

The prognosis following an aMLKI depends on many factors such as the velocity of injury [6], associated neurovascular damage [7], treatment methods, rehabilitation [8], and more recently, obesity was also found to play a role [9]. The treatment of knee dislocations has been inconsistent, although surgical treatment has become the preferred option [10] and

high-volume centers in the developed world recommend early single-stage arthroscopic ligament reconstruction with

*Corresponding author: Michael.held@uct.ac.za

auto – or allografts [11]. For vascular assessment, selective angiography is regarded by many as the modality of choice [12]. Yet, for resource-constrained settings in low-income countries, there are no evidence-based guidelines that are adapted to local challenges, such as access to surgical time, sub-specialist surgeons, arthroscopic equipment, allograft, and physiotherapy.

The aim of our study was therefore to compare the management approach of aMLKIs by orthopedic surgeons from developed economic nations (DEN) and emerging markets and developing nations (EMDN), specific to resources available. Given the resource-constraints of hospitals and the socio-economic circumstances of patients in EMDN, we hypothesize that the approach of orthopedic surgeons towards aMLKIs would be different compared to surgeons from DEN.

Materials and methods

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Human Research Ethics Committee of a tertiary academic government hospital (HREC REF 050/2018). Informed consent was obtained from all surgeons participating in the survey.

This descriptive cross-sectional questionnaire-based survey was designed to assess the treatment choices made by orthopedic surgeons around the world.

Questionnaire development

The questionnaire was generated by the core research team, based on propositions made by subspecialist knee surgeons during a focus group interview of knee surgeons. This was then sent to a group of knee surgeons for feedback. After adjustments and approval by the research team, the questionnaire was finalized (Appendix). Before answering the questions, every participant provided informed consent. The questionnaire consisted of 26 questions: 12 (46.2%) multiple-choice questions, 4 binary questions, and 10 subjective questions of which 4 were optional depending on the previous response. Questionnaires took approximately 5 min to complete.

Survey population

This questionnaire was then sent to members of the Societe Internationale de Chirurgie Orthopedique et de Traumatologie (SICOT) via email with three monthly reminders from July 2019 – September 2019. All completed questionnaires were included. Excluded were double entries or incomplete submissions. Study data were anonymously collected and managed using Research Electronic Data Capture (REDCap). REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources.

Data analysis

Responses to questionnaires were analyzed with reference to the management approaches of aMLKIs, and the responder nation's socio-economic status. Participating surgeons were divided into two groups based on their country's Gross Domestic Product (GDP) per-capita: DEN and EMDN. The cut-off GDP was set equal to the average GDP of all the EMDN countries in the world, pre-COVID-19 pandemic, as reported by the International Monetary Fund ($5380) [13]. Any country below this limit was grouped as EMDN (Figure 1).

Demographic data recorded included the age, gender, years of experience, and level of specialization of the participating surgeons. The continent and country of residence, socioeconomic status of patients and sector of service were also included. This information was collected to judge the patients' access to treatment. The number of anterior cruciate ligament (ACL) injuries and MLKIs treated per year, as well as access to arthroscopy equipment, magnetic resonance imaging (MRI), and physiotherapy, were recorded.

Statistical analysis

Responses from surgeons hailing from the same country were added and reported as percentages. Mean and standard deviation was calculated for the surgeon's age and experience. The data analyses were performed in IBM SPSS Statistics v.26 (Armonk, NY: IBM Corp). Non-parametric tests for significance, the Mann-Whitney U test was used to compare the responses from the EMDN and DEN groups. The level of significance was set at $p < 0.05$.

Results

Surgeon demographics

One-hundred and thirty- eight participants, from 47 countries, submitted their responses. 32 countries (67 surgeons, 48.5%) were DEN and the remaining 15 countries (71 surgeons,

51.4%) were identified as EMDN. The surgeons' age, gender, and experience are presented in Table 1. DEN surgeons were significantly older ($p < 0.05$) and had more years of surgical experience ($p < 0.05$) compared to participating surgeons in the EMDN.

The number of surgeons working in private sectors was higher (n = 28, 41.8%, $p > 0.05$) for the DEN group, while a significantly higher number of surgeons (n = 32, 45.1%, $p < 0.05$) worked in the public sector hospitals in the EMDN group (Supplementary Fig. 1). Twenty surgeons (29.9%) who completed the questionnaire from the DEN group were subspecialized knee surgeons, compared to only 9 (12.7%)

Hospital sector and patient socioeconomic status

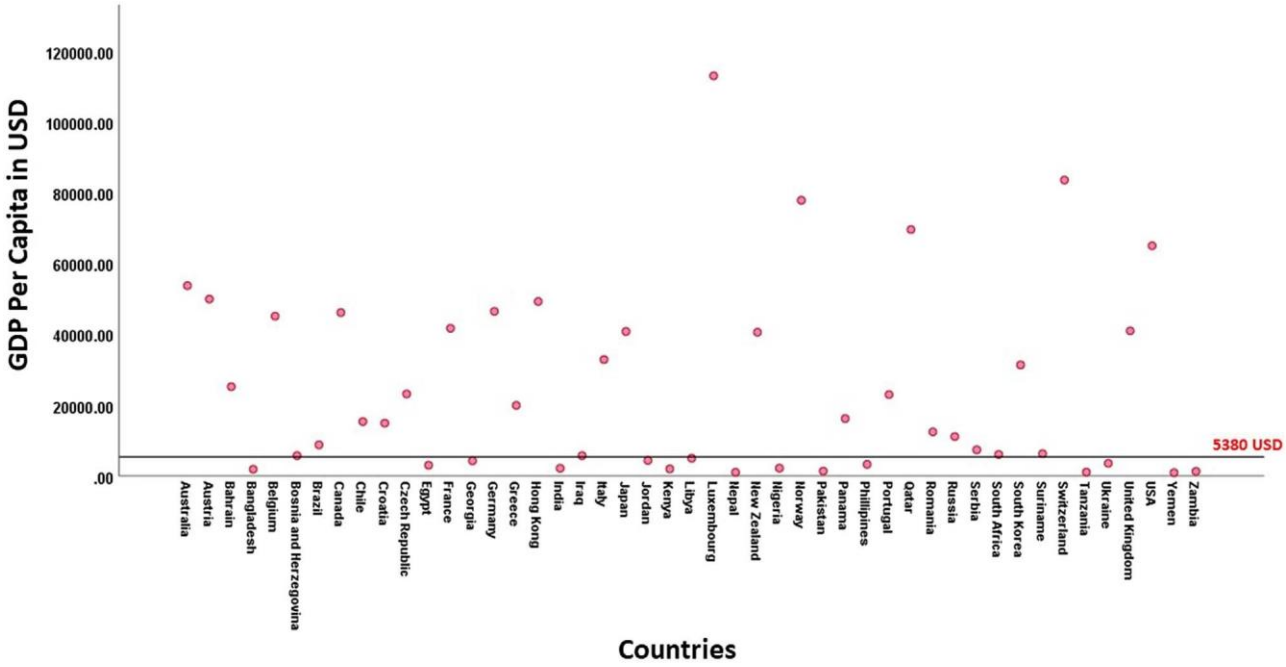

Figure 1. The gross domestic product (GDP) of the countries from which the study's surgeon population belonged. The cut-off GDP was $5380 shown by the black line.

Table 1. Demographic details of surgeons.

Groups	Average age (range) in years	Male: Female	Average experience (range) in years
Overall	47.18 (31–73)	131:7	15.02 (01–40)
DEN	50.02 (32–73)	61:6	17.53 (02–40)
EMDN	41.13 (31–67)	70:1	9.67 (01–35)

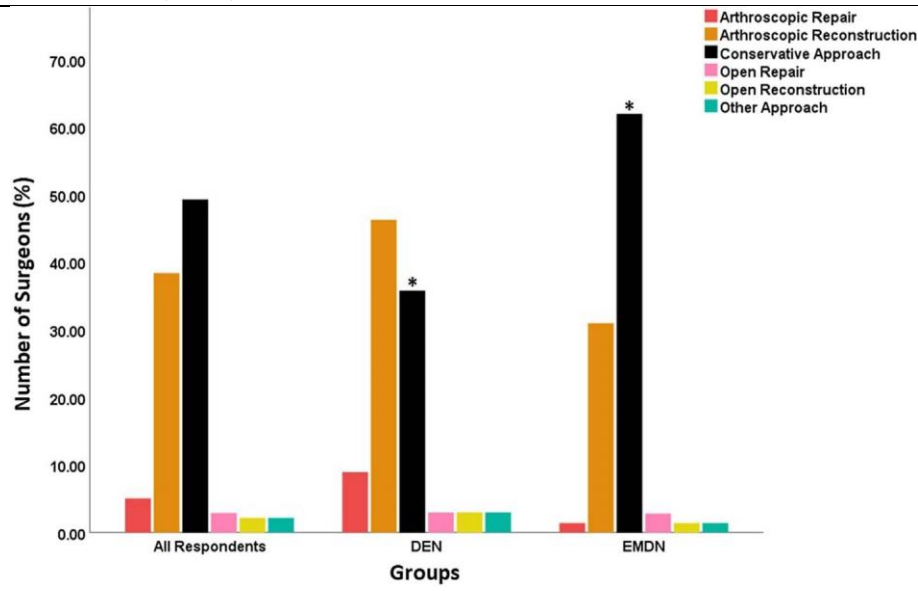

Figure 2. The different surgical approaches used by the participating surgeons to treat aMLKIs. Significant differences are denoted by *.

surgeons from the EMDN group (p > 0.05). Seventy nine of the Surgeons in the EMDN countries treated a significantly higher overall respondents (57.3%) reported that their patients belonged number of patients from the low-income bracket (n = 32, to the middle-income category (Supplementary Fig. 2). 45.1%) compared to only (n = 11, 16.4%, p < 0.05) of surgeons

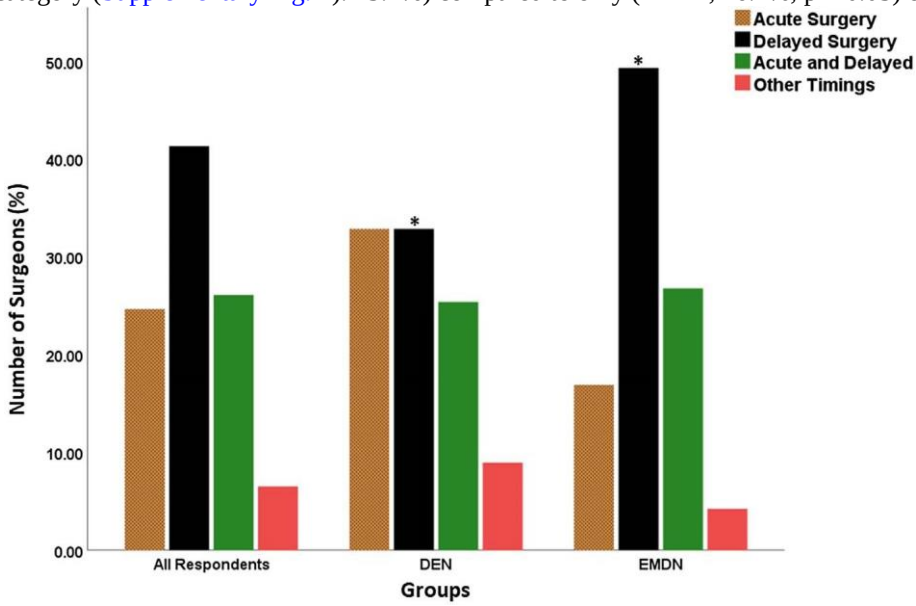

Figure 3. Timing of the aMLKI surgeries as reported by the participating surgeons. Significant differences are denoted by *.

from the DEN countries, who treated more high-income (16.4%) patients compared to surgeons in the EMDN group (1.4%, p > 0.05).

Annual surgery load

The average number of ACL surgeries performed across both the groups (DEN: 62.06; EMDN: 68.42), were consistently higher than the MLKI surgeries performed (DEN: 9.99; EMDN: 13.52). The ratio of these surgeries varied significantly between the DEN (ratio = 6.85) and EMDN (ratio = 4.15, p < 0.05) groups.

Management strategy and grafts

The acute management strategy of MLKIs varied between surgeons from DEN and EMDN countries. Arthroscopic reconstruction of cruciate ligaments was preferred by surgeons from the DEN group (n = 31, 46.3%), while EMDN participants favored conservative management (n = 44, 62%, p < 0.05) (Figure 2). DEN Surgeons preferred acute and delayed surgery equally (n = 22; 32.8%), while a significantly higher number of surgeons from EMDN preferred delayed surgery (n = 35; 49.3%; p < 0.05) (Figure 3). Autograft was preferred significantly more by the surgeons in the EMDN group (n = 56,
78.9%) compared to surgeons from the DEN group (n = 38, 56.7%, p < 0.05). More EMDN surgeons (n = 46, 64.8%) do not use allograft compared to DEN participants (n = 23, 34.3%, p < 0.05).

Vascular examination and access to physiotherapy

Selective Computed Tomography Angiography (CTA) was the preferred choice of vascular examination to exclude vascular injuries (Figure 4) for both the DEN (n = 33,

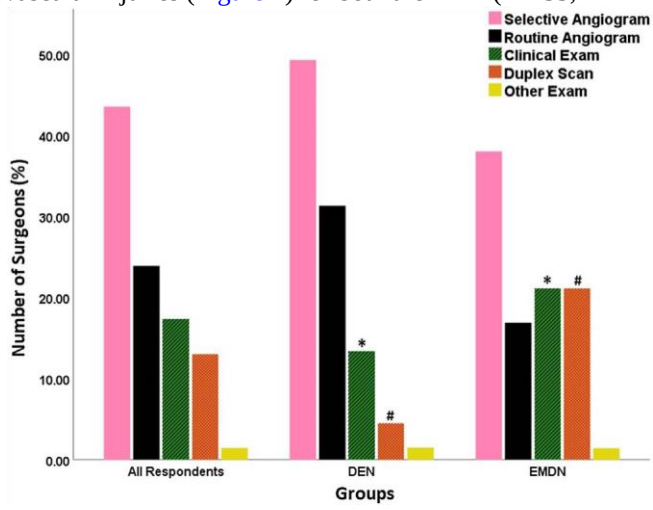

Figure 4. Various vascular examinations that were reported to be performed by the participating surgeons. Significant differences are denoted by * and #.

49.3%) and the EMDN (n = 27, 38%) groups. A significantly higher number of surgeons from the EMDN group preferred clinical examination (n = 15, 21.1%, p < 0.05) and duplex doppler scanning (n = 15, 21.1%) compared to surgeons from

DEN group (n = 9, 13.4%, p < 0.05) and (n = 3, 4.5%, p < 0.05) respectively. A significantly higher number of surgeons from the EMDN group (n = 16, 22.5%) had no access to physiotherapists compared to the surgeons from the DEN group (n = 3, 4.5%, p < 0.05) (Figure 5).

Discussion

The most important finding of the present study was the significant differences in management strategies of MLKIs when comparing DEN to EMDN. Other significant differences include the practice setting, experience, and specialization of participating surgeons.

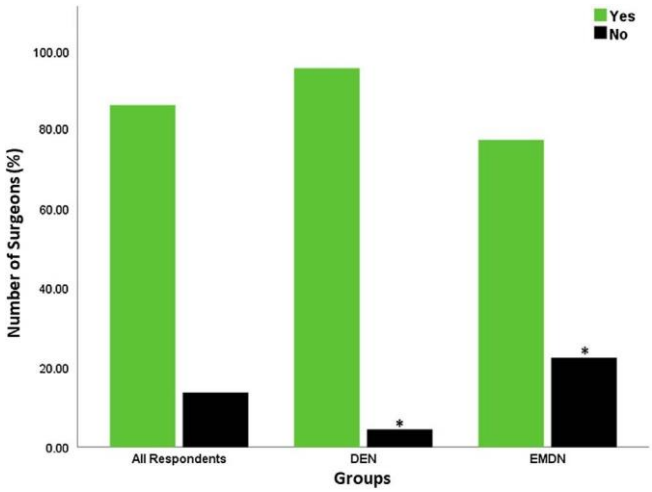

Figure 5. Access to physiotherapy plans as reported by the participating surgeons. Significant differences are denoted by *.

Participating EMDN surgeons were younger, had fewer years of experience, worked more commonly in the public sector, and had a lower proportion of subspecialists. They also reported treating a higher portion of patients from low socioeconomic backgrounds.

Limited training posts in EMDN could contribute to the lower number of qualified subspecialists. Patients from lower socio-economic backgrounds, an increased workload, and a lack of resources in EMDN result in an increased need for orthopedic surgeons to work in the public sector. Research regarding orthopedic surgeon density has revealed that in DEN there are more orthopedic surgeons available per 100,000 population [14] than in EMDN. It was also noted that the number of training posts available per 100,000 is much higher in DEN when compared to EMDN.

The differing levels of surgeon experience between the two groups could have influenced management strategies in MLKI. As such, early, single-stage arthroscopic ligament reconstruction is recommended for knee dislocations by DEN centers [15], but conservative management is favored by most surgeons in EMDN. Furthermore, in EMDN, surgery is often delayed when indicated and is more commonly staged and performed via open cruciate surgery (Figure 4).

This might be due to the lack of theater access and resources as well as an increased trauma load [16]. To date, there is no high-level evidence to promote operative over conservative management, but non-operative management is usually reserved for patients unfit for surgery or in settings with severe resource constraints. A meta-analysis of retrospective studies with low levels of evidence compared operative to conservative treatment of MLKIs in 206 patients [17]. The surgical group had 15 degrees more range of motion (ROM) when compared to the non-surgical group. There were otherwise no significant differences in stability, return to sport, or work. Functional rehabilitation was noted to be the most important prognostic factor. A recently published report of sports-related MLKIs promotes single-stage anatomic knee ligament reconstructions with immediate post-operative rehabilitation as this yielded significantly improved outcomes. This is in line with the current trend of surgical management, yet arthrofibrosis had still been developed by 9.3% of these patients, who required further surgery [15].

Furthermore, physiotherapy services were not readily accessible to 16 surgeons from the EMDN group (22.5%). This is likely due to remote and/or rural locations with rationing of services (service prioritization) [18], compounded by public transport challenges that limit patient accessibility. With limited physiotherapy services, many surgeons will also likely favor delayed or staged surgery as options for the treatment of aMLKIs in EMDN to avoid post-operative stiffness.

Our survey demonstrated that delayed and staged reconstruction of aMLKIs has important roles for all participants, especially in countries with limited resources (p = 0.03). DEN surgeons reported an equal preference for acute surgery and delayed surgery, while more surgeons from the EMDN group preferred delayed surgery (Figure 5). The reason for this could be available resources in DEN, where lack of theater access, surgeon availability, limited access to physiotherapy, and poor patient compliance are less common.

A meta-analysis by Levy et al. [19] suggested that early operative treatment of MLKIs improved functional and clinical outcomes when compared to delayed surgery with similar outcomes in knee stability, ROM, or activities of daily living. Another systematic review [20] found equivalent outcomes in terms of knee stability, but acute surgery was strongly associated with ROM deficits. Similarly, a more recent review found that acute surgery increases the risk of requiring manipulation under anesthesia or arthrolysis [21].

Regarding graft choice, surgeons from all socio-economic settings preferred autograft for surgical ligament reconstruction, although there was a higher use of allograft in DEN. Proportionally more surgeons preferred not to use allograft in the EMDN (64.79%) compared to the DEN group (34.33%, p = 0.009).

For allograft, factors such as availability, cost [22], and the potential for disease transmission can be the reasons for

the decreased use in EMDN. A recent systemic review indicates that autografts lead to better outcomes, are more cost-effective, and should be the first choice [23]. Using allograft does however save time and avoids the potential for donor site morbidity [24]. The decision of graft choice ultimately depends on the number of ligaments requiring reconstruction or augmentation, graft availability, surgeon preference, patient-specific factors, and the chosen surgical technique for reconstruction. Concomitant neurovascular injuries and choice of surgical approach should also be considered when choosing graft options.

Regarding workup for vascular compromise in MLKIs, selective CTA is the gold standard used by many centers [25, 26]. This was also reflected in our study as the preferred choice of arterial examination in both groups (DEN: 49.6%; EMDN: 38%). However, more surgeons in resource-limited settings utilized duplex doppler scanning and clinical examination than their colleagues in developed countries.

Routine CTA played a larger role for DEN (31.3%) compared to EMDN surgeons (16.9%).

The need for arteriography in MLKIs was promoted by Jones et al. [27] in 1979 who deemed clinical examination unreliable. This was disproven by a subsequent study arguing that vascular examination is acceptable to screen patients for the need of "selective" arteriography [28]. This data was utilized by Stannard et al. [29], who developed and tested a widely used protocol of selective angiography. According to our survey, EMDN surgeons also follow this philosophy, although repeated clinical examinations are time-consuming and need well-trained staff. This can be challenging in hospitals with resource restrictions and a large trauma burden. A recent systematic review illustrated the lack of consensus among practitioners regarding the diagnostic and treatment algorithm for vascular injury in MLKIs [12]. A heightened clinical suspicion of vascular injury should be had by surgeons, and they should err on the side of caution to exclude this diagnosis with the best possible means available.

Our study had some limitations. The focus group interviews for the questionnaire did not involve low-volume surgeons, which might have excluded possible treatment options. Yet, it was developed through a formal process, tested, and adjusted before its use.
Lack of funds to pay for physiotherapy was not considered- only the availability or lack of a physiotherapy service was recorded.

The questionnaire was completed by surgeons from a wide geographic footprint including Asia, Africa, and Europe. However, we realize that non-participating countries might treat MLKIs differently. We, therefore, included the DEN and EMDN categories to create applicability for non-participating countries with similar socioeconomic circumstances. Also, more options to describe patient profiles (i.e. skeletal immaturity, athletes, elderly, obese) or specific resources (i.e. frequency and extent of physiotherapy) could have provided more insight into the various treatment philosophies.

Conclusion

This study showed that surgeons from EMDN preferred to treat knee dislocations conservatively when compared to their colleagues in DEN. They also favored delayed and/or staged surgery when the decision was made to surgically intervene. EMDN surgeons also utilized clinical arterial examination and duplex doppler scanning more readily to assess vascular status in MLKIs. These findings highlight very distinct approaches to MLKIs in low-resource settings which are often neglected when guidelines are generated. Clinical studies should be pursued in order to generate more recommendations and evidence regarding the conservative, delayed, and staged surgical treatment of MLKIs in overburdened developing countries with poor resources.

Declarations

Funding

None

Ethics approval

HREC 647/2018

Conflicts of interest

Santa-Marie Venter: The author has no conflict of interests to declare.

Roopam Dey: The author has no conflict of interests to declare.

Vikas Khanduja: Educational consultant: Smith & Nephew and Arthtrex.

R von Bormann: The author has no conflict of interests to declare.

Michael Held: The author has no conflict of interests to declare.

Availability of data and material

Author's contribution

Santa-Marie Venter: Protocol writing, research and ethics approval, data analysis and interpretation, article writing, manuscript revision, final article submission.

Roopam Dey: Statistical analysis, result generation, manuscript revision.

Vikas Khanduja: Conceptualisation of study, data collection.

Richard von Bormann: Conceptualisation of study, data collection.

Michael Held: Conceptualisation of study, data collection, editing, manuscript revision.

Supplementary Material

The Supplementary material of this article is available at https://www.sicot-j.org/10.1051/sicotj/2021017/olm

Supplementary Figure 1: The clinical sectors where the responders operated. Significant differences are denoted by *.

Supplementary Figure 2: Patient's socio-economic status as reported by the participating surgeons. Significant differences are denoted by *.

References

1. Boyce RH, Singh K, Obremskey WT (2015) Acute management of traumatic knee dislocations for the generalist. J Am Acad Orthop Surg 23, 761–768.
2. Sillanpää PJ, Kannus P, Niemi ST, Rolf C, Felländer-Tsai L,Mattila VM (2014) Incidence of knee dislocation and concomitant vascular injury requiring surgery: A nationwide study. J Trauma Acute Care Surg 76, 715–719.
3. Azar FM, Brandt JC, Miller RH, Phillips BB (2011) Ultra-low velocity knee dislocations. Am J Sports Med 39, 2170–2174.
4. Samuel LT, Rabin J, Jinnah A, et al. (2019) Management of the multi-ligamentous injured knee: An evidence-based review. Ann Jt 4, 4–21.
5. Holmes CA, Bach BR (1995) Knee dislocations: Immediate and definitive care. Phys Sportsmed 23, 69–82.
6. Shelbourne K, Porter D, Clingman J, McCarroll J, Rettig A(1991) Low-velocity knee dislocation. Orthop Rev 20, 995–1004.
7. Reckling FW, Peltier LF (2004) Acute knee dislocations and their complications. Clin Orthop Relat Res 422, 135–141.
8. Windsor R, Insall J (1994) Surgery of the knee, 2nd edn.Philadelphia, WB Saunders Company.
9. Johnson JP, Kleiner J, Klinge SA, McClure PK, Hayda RA,Born CT (2018) Increased incidence of vascular injury in obese patients with knee dislocations. J Orthop Trauma 32, 82–87.
10. Burrus MT, Werner BC, Griffin JW, Gwathmey FW, Miller MD (2016) Diagnostic and management strategies for multiligament knee injuries. JBJS Rev 4, 1.
11. Khakha RS, Day AC, Gibbs J, et al. (2016) Acute surgical management of traumatic knee dislocations – Average follow-up of 10 years. Knee 23, 267–275.
12. Medina O, Bs GAA, Yeranosian MG, Petrigliano FA, McallisterDR (2014) Vascular and nerve injury after knee dislocation a systematic review. Clin Orthop Relat Res 472, 2621–2629.
13. International Monetary Fund (2019) World Economic Outlook – GDP per capita, current prices. Accessed on 15 October 2019.
14. Dell AJ, Gray S, Fraser R, Held M, Dunn R (2018) Orthopaedic surgeon density in South Africa. World J Surg 42, 3849–3855.
15. LaPrade RF, Chahla J, DePhillipo NN, et al. (2019) Single-stage multiple-ligament knee reconstructions for sports-related injuries: Outcomes in 194 patients. Am J Sports Med 47, 2563–2571.
16. Meara JG, Leather AJM, Hagander L, et al. (2015) GlobalSurgery 2030: Evidence and solutions for achieving health, welfare, and economic development. Lancet 386, 569–624.
17. Dedmond BT, Almekinders LC (2001) Operative versus nonoperative treatment of knee dislocations: A meta-analysis. Am J Knee Surg 14, 33–38.
18. Adams R, Jones A, Lefmann S, Sheppard L (2015) Rationing is a reality in rural physiotherapy: A qualitative exploration of service level decision-making. BMC Health Serv Res 15, 121.
19. Levy BA, Dajani KA, Whelan DB, et al. (2009) Decision making in the multiligament-injured knee: An evidence-based systematic review. Arthroscopy 25, 430–438.
20. Mook WR, Miller MD, Diduch DR, Hertel J, Boachie-Adjei Y,Hart JM (2009) Multiple-ligament knee injuries: A systematic review of the timing of operative intervention and postoperative rehabilitation. JBJS 91, 2946–2957.
21. Sheth U, Sniderman J, Whelan DB (2019) Early surgery of multiligament knee injuries may yield better results than delayed surgery: A systematic review. J ISAKOS Jt Disord Orthop Sport Med 4, 26–32.
22. Oro FB, Sikka RS, Wolters B, et al. (2011) Autograft versus allograft: An economic cost comparison of anterior cruciate ligament reconstruction. Arthroscopy 27, 1219–1225.
23. Mistry H, Metcalfe A, Colquitt J, et al. (2019) Autograft or allograft for reconstruction of anterior cruciate ligament: A health economics perspective. Knee Surgery Sport Traumatol Arthrosc 27, 1782–1790.
24. Shaerf DA, Pastides P, Sarraf K, Willis-Owen C (2014) Anterior cruciate ligament reconstruction best practice: A review of graft choice. World J Orthop 5, 23.
25. Levy BA, Fanelli GC, Whelan DB, et al. (2009) Controversies in the Treatment of Knee Dislocations and Multiligament Reconstruction. J Am Acad Orthop Surg 17, 197–206.
26. Hollis JD, Daley BJ (2005) 10-Year review of knee dislocations: Is arteriography always necessary? J Trauma 59, 672–676.
27. Jones R, Smith E, Bone G (1979) Vascular and orthopedic complications of knee dislocation. Surg Gynecol Obstet 149, 554–558.
28. Kendall RW, Taylor DC, Salvian AJ, O'Brien PJ (1993) The role of arteriography in assessing vascular injuries associated with dislocations of the knee. J Trauma Inj Infect Crit Care 35, 875–878.
29. Stannard JP, Sheils TN, Lopez-Ben RR (2004) Vascular injuries in knee dislocations: The role of physical examination in determining the need for arteriography. J Vasc Surg 40, 1061.

APPENDICES

APPENDIX A: Survey Questionnaire

Consent

Do you agree to anonymously participate in this survey-based analysis and grant permission that the results of this survey may be used in a scientific study?

Yes/No

Profile of Practice

Do you treat sporting injuries of the knee on a regular basis?
How many cases of ligament injuries in the knee do you see per annum?
How many multiligament knee injuries do you treat per year?
Do you have access to arthroscopic equipment? Do you have access to an MRI scan for most (80%) of your patients?

Management

How do you assess for arterial perfusion in acute multiligament knee injuries?

(a) Clinical examination only
(b) Selective angiography (only if physical exam is abnormal)
(c) Routine angiography
(d) Duplex scan
(e) Other

How do you manage multi-ligament injuries in the acute phase (up to 3 weeks)?

(a) Conservative
(b) Arthroscopic Repair & Reconstruction
(c) Open Repair & Reconstruction
(d) Other

How often do you treat multi-ligament knee injuries conservatively ONLY in your practice?

(a) Never
(b) Sometimes
(c) Often
(d) Always

For those patients who are treated surgically, do you operate acutely (within 3 weeks) or delayed (after 3 weeks)?
What is your primary choice for reconstruction of torn ligaments (including posterolateral corner) in multiligament knee injuries?

(a) Autograft
(b) Allograft
(c) ACL Repair
(d) Internal Bracing

For those patients who are managed conservatively, what do you place them in?

(a) Knee brace
(b) Cast
(c) Other

And in what position and for how long? Please describe your protocol.
Do you have access to a dedicated physiotherapy programme post-operatively?
What outcome measures do you use for assessment of multiligament injuries?
What percentage of your patients return to preinjury level of sports?

(a) 0–25%
(b) 25–50%
(c) 50–75%
(d) 75–100%

What percentage of your patients return to preinjury level of work?

(a) 0–25%
(b) 25–50%
(c) 50–75%
(d) 75–100%

What is the incidence of stiffness in your practice following conservative or surgical management of multi-ligament injuries?
What is the incidence of complications in your practice following conservative or surgical management of multiligament injuries?

APPENDIX B: Explanation of variables

Conservative management refers to any non-operative management, such as casting, splinting, bracing, pharmacological and physiotherapeutic treatment.

Acute surgery includes any ligament repair/reconstruction within 3 weeks of the initial injury.

Staged surgical repair/reconstruction involves acute repair/reconstruction of the extra-articular structures (medial and lateral structures) with a delayed reconstruction of the cruciate ligaments.

Delayed surgery refers to any ligament repair/reconstruction 3 weeks after the initial injury.

Autograft includes ipsi-or contralateral hamstring tendon graft, bone-patella tendon-bone (BPB) graft or quadriceps tendon graft.

Allograft includes Achilles tendon graft, quadriceps tendon graft, tibialis anterior graft, bone-patella tendon-bone (BPB) graft, or synthetic ligament augmentation and reconstruction systems (LARS).

Clinical vascular examination includes physical examination of pulses (including serial examinations) and measuring the ankle-brachial-pulse-index (ABPI).

Duplex doppler scanning uses ultrasound to assess blood flow and aids in the diagnosis of vascular injury.

Access to physiotherapy refers to the ease of regular access that patients have to a physiotherapist.

APPENDIX C: SICOT-J *Instructions to Authors*

Instruction for authors

Download **SICOT-J instructions for authors** in PDF format.

1 General

1.1 Conditions of acceptance

Submission of a manuscript implies that the work has not been published and is not submitted for publication anywhere else. Publication must be approved by all authors. Authors should accept publication fees. For all enquiries relevant to ethics in publishing, please consult COPE **http://publicationethics.org/**.

Authors are invited to comply with the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals", which were established and made available by the International Committee of Medical Journal Editors (ICMJE) at: **http://www.icmje.org/recommendations/**.

1.2 Authorship

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Furthermore, the ICMJE recommends that all those designated as authors meet all 4 of the aforementioned criteria for authorship; and reciprocally, all those who meet all 4 of the aforementioned criteria for authorship should be identified as authors.

The list of criteria is available at **http://www.icmje.org/recommendations/browse/roles-and-responsibilities/**. Those contributors who do not meet all of the authorship criteria shall simply be acknowledged.

1.3 Conflict of interest

Authors must disclose whether or not they have a financial relationship with the organization that sponsored the research. They should also state that they have full control of all primary data and that they agree to allow the journal to review their data if requested.

Therefore the manuscript must be accompanied by the "**Conflicts of Interest Disclosure Form**" at the initial submission.

Any additional conflict of interest, on personal or any other level must also be disclosed (please find below, in section 3.5.5, more information on how to introduce Conflict of Interest in your article).

1.4 Publication Ethics and protection of research participants

All laws and regulations should be strictly followed. Authors are requested to indicate ethical declarations issued by their institution and concerning their research, including permit numbers, in the Material and Methods section. Authors are requested to fully comply with the ICMJE recommendations in this respect, particularly with the patient's right to privacy, as well as the necessity to have the patient's written consent.

1.5 Reporting guidelines and clinical trial registration

Depending on the study design, reporting guidelines such as CONSORT, STROBE, PRISMA, STARD should be followed. For more information about these guidelines authors should visit the websites of the EQUATOR network or the corresponding sources at the NLM website. The policy for clinical trial registration by the ICMJE is given in **their recommendations**. These should be followed by the authors in this journal.

1.6 Publication fees

SICOT-J has implemented a Two-Tier APC payment system. The publication fees for articles accepted in SICOT-J are displayed **here**.

1.7 Open access

All articles published by SICOT Open Journal are made freely and permanently accessible online immediately upon publication, without subscription charges or registration barriers. Articles are available from the website of the journal (**http://www.sicot-j.org**), from PubMed Central as soon as the indexation of the journal is effective and from Europe PubMed Central, in various formats. Authors are the copyright holders of their articles. All articles bear the following mention: This is an Open Access article distributed under the terms of the **Creative Commons Attribution License 4.0**, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

1.8 Manuscript compliance with the instructions for authors

Authors are invited to carefully read the below instructions. Articles not compliant with these instructions will be immediately sent back to the author. In order to avoid these additional delays in the publication of their articles, authors should know that their articles will enter the peer review process only if they are compliant after re-submission. The most frequent reasons for sending back a manuscript are:

- No line numbering.
- Wrong reference style.

A frequent reason of immediate rejection is plagiarism. Using the Similarity Check tool allows to detect even minimal plagiarism. Thus authors are invited to read the corresponding chapter and apply the given indications in order to avoid this sanction.

1.9 Data sharing policy

Authors may be invited to share with the peer reviewers during the article evaluation process in a confidential manner the data on which the research is based. Further, as long as the

publication of data is not in opposition with patients' privacy, authors are invited to upload supplemental datasets related to their research to an online repository. Doing so makes it available for both human and machine reading in order to further aid the acceleration of scientific discovery.

Authors are invited to prepare and deposit their data according to the FAIR data principles. FAIR stands for Findable, Accessible, Interoperable and Re-usable. The principles are available here. To summarize this, the dataset should be findable through a complete set of metadata, including a license for re-use and a data identifier (DOI or other). The dataset is accessible when access is open. Interoperable means that the data can be used and combined with other datasets in a format that is sufficiently widely distributed. Re-usability is achieved when the dataset is deposited with a corresponding Creative Commons open license and is downloadable. Furthermore, re-usability implies that parameters describing how this dataset has been collected needs to be disclosed. Machine and experimental conditions must be documented.

2 Types of papers

Seven types of articles are considered:

1. Original Research articles
2. Review articles
3. Surgical Techniques
4. Case reports
5. Congress Proceedings
6. Editorials
7. Letters to the Editors

3 Presentation of manuscripts

Use Times 12 with 1.5 interline throughout the manuscript and avoid unnecessary formatting. Number pages. Use up to three subheading levels in total. Italics should be used in the text for all scientific names and other terms such as genes, mutations, genotypes and alleles. SI units should be used throughout the manuscript. The whole text should be numbered (use the appropriate option in WORD), in order to quickly identify changes proposed during the peer review process.

3.1 Limits of numbers of words, references, figures and tables

- Original Research article: not more than 2,500 words with an abstract of 250-300 words, not more than 5 figures and 3 tables, and a maximum of 25 references, 2-3 videos
- Review Article should have no more than 3,500 words and 50-70 references
- Surgical techniques: not more than 1500 words, 10 figures, 15 references and 5 videos
- Case Report: Not more than 1500 words, and 5 references
- Letter to the Editor: are limited to 500 words and 5 references

3.2 Order of parts

In accordance with the ICMJE guidelines, the instructions of authors have been updated. Your manuscript must include the following sections between the Discussion (Conclusion) and References : Conflict of Interest, Funding, Ethical approval, Informed consent, Authors contributions, Acknowledgements.

Manuscripts should be prepared according to the following order (Reviews, very long articles may use a different presentation):

- Title Page
- Abstract and 4–6 keywords
- Introduction
- Material and Methods
- Results
- Discussion
- Conflict of interest
- Funding
- Ethical approval
- Informed Consent

- Authors contributions
- Acknowledgements
- Tables
- Figure Legends
- References

3.3 First page, title

The first page should include: title of paper, list of all authors with full given and family names, addresses of all authors, and name of corresponding author with email address. The title should be short and descriptive, and less than 250 characters in length (including spaces). All individual disclosures of conflict of interest of all co-authors shall also be indicated on this page.

To keep the identity of the authors concealed to the referees, as per SICOT-J's double-blind peer review procedure, the main manuscript shall be submitted without any information regarding the authors. The text file of the manuscript shall nevertheless contain all the other elements, including Title, Abstract, Keywords and the text structured as described in the sections below.

3.4 Abstracts

The abstracts of Original articles, Systematic reviews and Meta-analyses shall be submitted with the IMRAD structure, containing: Introduction, Methods, Results And Discussion. It shall not contain more than 250-300 words.

Abstracts of articles publishing results of clinical trials shall be compliant with the CONSORT checklist regarding all items of reporting.
The registration number of the clinical trial shall be included at the end of the abstract, when available.

3.5 Main text

3.5.1 Introduction

No subsection. This section is headed "Introduction".

3.5.2 Materials and Methods

This part may be presented as several subsections (up to two levels of subheadings).

3.5.3 Results

This section may be presented as a single part or as several subsections; maximum of two subheading levels.

3.5.4 Discussion

This section may be presented as a single part or as several subsections; maximum of two subheading levels. The last subsection can be “Conclusions”. Follow instructions for citations. In certain cases, it might be appropriate to mix the results and discussion in a single section, headed “Results and discussion”.

3.5.5 Conflict of Interest

This mandatory section must be inserted before the Acknowledgements. This section shall describe whether yes or no, each individual author has to disclose any kind of **conflict of interest**.

Depending on the type of conflict, the following sentences are recommended to be added for each author (please use the authors’ initials here):

- For author AA receiving directly research funding please state:
  "AA has received funding from" and note the source.
- In case BB’s institution received any sort of support, state:
  "The institution of BB has received funding from…" and note the source.
- If CC received no financial support please state,
  "CC certifies that he or she has no financial conflict of interest (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) in connection with this article."
- If DD has received or may receive any personal payment or other benefit from a commercial entity (e.g., serve as a consultant), please note:
  "DD has or may receive payments or benefits from … (note the source) related to this work."

If you do not have any conflict of interest to declare, please include the following statement : “The authors declare that they have no relevant financial or non-financial interests to report”.

3.5.6 Funding

This mandatory field should not be left empty. All sources of funding should be indicated in this section. Authors must describe the role of the study sponsor(s), if any, in :

- the study design
- the collection, analysis and interpretation of data
- writing of the report
- and in the decision to submit the paper for publication.

For compliance purpose, funding sources should be listed as follows:

“Funding: This work was supported by the A Foundation [grant numbers xxxx, yyyy]; the B Agency [grant number zzzz];”

If no funding has been provided for the research, please include the following statement : “This research did not receive any specific funding”.>

3.5.7 Ethical Approval

This mandatory field should not be left empty.

- If your study requires ethical approval, please include the ethical protocols followed and the name of the committee, which approved the study. For example : “This study received ethical approval from the Ethics committee of X hospital under the protocol number XXXX.”
- If your study does not require ethical approval, please state that : “Ethical approval was not required.”

3.5.8 Informed Consent

In accordance with the **Helsinki Declaration as revised in 2013**, a statement confirming that informed consent was obtained must be included for experimentation involving humans.

- When informed consent has been obtained, it must be stated in the published article : “Written informed consent was obtained from all patients and/or families”.
- If not applicable, the following sentence should be used : “This article does not contain any studies involving human subjects”.

3.5.9 Authors contributions

Authors should use this section to outline their individual contributions to the article with the corresponding roles.

The following format should be used :

J. Arnaud : Conceptualization, Methodology ; T. Gaston : Writing original draft ; R. Raymond : Visualization, Investigation ; M. Leroy : Supervision ; B. Arnaud : Writing, Reviewing and Editing.

3.5.10 Acknowledgements

This section must be concise. No subdivisions. Mention here colleagues and grants. See also the above section about authorship (1.2) and mention here all those persons not meeting all the criteria necessary for authorship.

The names of the individuals who provided assistance during the research should be listed with a clear contribution statement (e.g. S. André : language editing; B. Champion : proofreading the article, etc.) Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those, whose contributions do not justify authorship, may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript"). Please ensure that all individuals have given written permission to be acknowledged.

3.5.11 References

This section should be arranged according to the precise format detailed below in Section 8. Only works cited in the text should appear here. Citation of unpublished papers and grey literature should generally be avoided. Software cited in the Material and Methods should have a citation. Papers may be cited as “in press” only when they have been accepted for publication (in this case, include the DOI).

4 Tables

Tables (numbered as Table 1, Table 2, etc.) should be presented as one per page. Avoid complex formatting and use the basic Table format in Word or Excel.

5 Figures

5.1 Figure numbers and legends

Figures should be numbered as Figure 1, Figure 2, etc. They are referred to in the text as Figure 1, Figure 2, etc. Legends are grouped on a separate page.

5.2 Technical information

All figures are published free of charge (i.e. they are included in the publication fee), including color photographs and diagrams. However, only photographs of scientific interest and pertaining to the subject of the article should be included. Color illustrations, especially diagrams, should be understandable even, if they are printed as grey levels.

Figures should be prepared to be of good quality both when they are viewed onscreen as HTML and when the PDF is printed. Figures may be arranged as “plates”, but keep in mind that PDFs are prepared to be printed on A4 pages.

The electronic submission system will accept PNG (preferred), TIFF (with compression), and EPS files, with appropriate resolution (300 dpi for colour photographs, 600 dpi for halftone work, 1200 dpi for line work). JPG format is not recommended – PNG is preferred.

Manuscripts with figures of insufficient technical quality will be immediately sent back for revision by the editorial team and will not begin the review process before correct files are uploaded. In other words, sending a manuscript with incorrect figures will gain nothing and may delay its possible publication.

6 Online material

Online material may include data too long to be included in the manuscript, additional illustrations and movies. Online material is subjected to strict refereeing. Formats accepted are: PDF, graphic formats for supplementary figures (see 5.2), MPEG for videos. Files should preferably be less than 20 Mb.

7 Mathematics, statistics and significant figures

Write mathematical equations as simply as possible. Statistical software should be clearly indicated and cited.

Figures should be indicated with a reasonable number of digits, coherent with the significance of the result. This is especially important for the abstract.

8 References

Authors are encouraged to use a reference manager software. The below given format of the references is mandatory, authors are invited to strictly follow these guidelines.

8.1 References in the text

References are numbered as [1], [2,3,7] or [5–9]. This allows copious lists of references without lengthening the text itself. The use of numbered references does not mean that author names and dates of cited papers are prohibited in the text, but this should be used only if necessary.

Example: Many studies [1–9] have addressed … (no special need to indicate authors here). In 2013, Smith [10] claimed that … but Dupont [11,12] later demonstrated that… (names of authors and dates are useful here).

8.2 Presentation of references

References are numbered and sorted in the order of appearance in the text. Words in titles are not capitalised. No journal name begins with “The”.

The common structure of each reference follows always the below example:

Journal articles

Names of authors (Year of publication) Title of publication, Journal name, Volume Number, pages.

Book chapter

Names of authors (Year of publication) Title of chapter, in: Book Title, Names of Editors, Name of Publisher.

Complete book

Names of authors (Year of publication) Book Title, Location of Publisher, Name of Publisher.

Examples:

Journal articles

1. Mella C, Villalón IE, Núñez A, Paccot D, Díaz-Ledezma C (2015) Hip arthroscopy and osteoarthritis: Where are the limits and indications?, SICOT J, 1, 27

2. Krishnan H, Krishnan SP, Blunn G, Skinner JA, Hart AJ (2013) Modular neck femoral stems, Bone Joint J, 95B, 8, 1011-1021

3. Sievänen H, Kannus P (2007) Physical Activity Reduces the Risk of Fragility Fracture. PLoS Med 4(6): e222. doi:10.1371/journal.pmed.0040222

Book chapter

4. Amendola A,. Bonasia DE (2011) The menisci: Anatomy, healing response, and biomechanics, in The Knee Joint Bonnin M, Amendola NA, Bellemans J, MacDonald SJ, Menetrey J, Editors Paris, Heidelberg, Springer.

Complete book

5. Bonnin M, Amendola NA, Bellemans J, MacDonald SJ, Menetrey J (2011), The Knee Joint. Paris, Heidelberg, Springer.

9 Electronic submission

Authors should use the electronic submission system powered by **Editorial Manager**. Before you begin submission, prepare the following:

- A list of full names of all authors and a valid email address for each of them (copy and paste from first page of manuscript);
- A Word file of the manuscript;
- A Word file of the covering letter, explaining why the manuscript is of importance and any other detail.
- The electronic files of all figures, with appropriate resolution and technical quality (see 5.2).

The submission system will produce a PDF from these elements, which will be submitted for your approval, and will eventually be sent to the referees after evaluation by the Editors.

Authors who wish to send confidential comments about their manuscript to the Editor should send a separate email.

10 Post-publication corrections

The published version of a SICOT-J article constitutes its Version-of-Record (VoR).

Should an author discover a material error or inaccuracy in their own published article, they should promptly notify the Editor(s)-in-Chief and the Publisher of the journal so that appropriate action can be taken in order to correct the issue and ensure that the VoR of their SICOT-J article remains exact, complete and authoritative.

A thorough investigation involving the Publisher, the Editor(s)-in-Chief, the author and/or the Editorial Board may be needed hence undertaken in some cases when problems affecting SICOT-J published articles are reported, and so as to assess the severity of the situation.

Depending on the circumstances and significance of a reported issue, the journal may have to publish a Correction, a **Retraction**, an **Expression of Concern** or even remove the article, in accordance with the **COPE Post-publication guidelines**

APPENDIX D: Reviewer comments and response letter

Dr S Venter
Department of Orthopedic Surgery
Groote Schuur Hospital
Cape Town, South-Africa

Dr Fatih Kucukdurmanz
Section Editor
SICOT-J

03 February 2021

Dear Dr Kucukdurmanz,

Thank you very much for the feedback regarding the reviewer's comments on our submission. We have responded to the comments and have made necessary changes to our manuscript. The changes are detailed below.

We hope that the manuscript changes are aligned with your journal publication standards.

Best Regards,

Dr Santa-Marié Venter
MSc, MBChB, BA, LLB

#1 Reviewer Comments:

1. **Firstly, I'd like to see a sample of the questionnaire in your article(Btw. In the article I got, there is mentioned the Appendix A; but I can't see there any Appendix A)**

   Response: We have attached the questionnaire as Appendix A during the revision submission.

2. **Secondly, how do you decide your cut off GDP value? Because your GDP value is lower than real development countries.**

   Response: We took into account the average GDP per capita of the Emerging Market and Developing Nation (EMDN) as reported by the International Monetary Fund, during the time this study was being performed which was before the COVID-19 pandemic. We have updated the article (line 54 - 56) and have added the reference to the website we had used for GDP per capita values.

APPENDIX E: HREC APPROVAL LETTER

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	25.02.22
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	4/3/21

Comments to PI from the HREC
Thank you for the additional document

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	26.2.21		
HREC REF Number	647/2018	Current Ethics Approval was granted until	30.10.2019
Protocol title	Managment of acute knee dislocations - a global survey of orthopaedic surgeons' strategies		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes ☐ No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Michael Held		
Department / Office Internal Mail Address	H49 OMB GSH Ortho Department		

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

1.1 Does this protocol receive US Federal funding?	☐ Yes	x No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)	☐ Yes	☐ No
If yes in 1.2 please complete section 1.3 below for invoicing purposes		
1.3 Annual Approval for **full committee** review	- R 3450 (inclusive of vat)	
For invoicing purposes, please provide:		
Sponsor's name		
Contact person		
Address		
Telephone number		
Email Address		

2. List of documentation for approval

3. Protocol status (tick ✓)

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

4. Enrolment

Number of participants enrolled to date	40
Number of participants enrolled, since last HREC Progress report (continuing review)	40

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

Additional number of participants still required	0

5. Refusals

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

6. Cumulative summary of participants

Total number of participants who provided consent	40
Number of participants determined to be ineligible (i.e. after screening)	
Number of participants currently active on the study	
Number of participants completed study (without events leading to withdrawal)	
Number of participants withdrawn at participants' request (i.e. changed their mind)	
Number of participants withdrawn by PI due to toxicity or adverse events	
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
This project was delayed due to covid restrictions and exam priorities by the student

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

☐	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved

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

x	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

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

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

10. Adverse events

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

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

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

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

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

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

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

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

12. Level of risk (tick ✓)

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

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

13. Statement of conflict of interest

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

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	26.2.21

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